Dossier zur Nutzenbewertung gemäß § 35a SGB V

Nusinersen (Spinraza®)

Biogen GmbH

Anhang 4-G zu Modul 4 A.1

Infantile 5q-assoziierte spinale Muskelatrophie (SMA)

Stand: 01.12.2020

Anhang 4-G zu Modul 4 A.1

Primäranalyse ENDEAR ITT

Stand: 01.12.2020

```
Results for ENDEAR ITT-Population
[[1]]
[1] "Überlebensrate"

$ntab
            CTRL TRT
n_all         41  80
n_event       25  67
n_event_pct   61  84

$stats
                estimate         se    lo95ci    hi95ci      pvalue
RR_TRTvsCTRL  1.3735000 0.13429493 1.0556419 1.7870665 0.018119185
OR_TRTvsCTRL  3.2984615 0.44084969 1.3901430 7.8264238 0.006785899
ARR_TRTvsCTRL 0.2277439 0.08663093 0.0579504 0.3975374 0.008566199


\#############################################################################
[[1]]
[1] "Zeit bis zum Tod"

$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80
n_event                              16.0                13
n_event_pct                          39.0                16
time-to-event-wk-10th                 5.4                12
time-to-event-wk-25th                14.3                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           23.1                NA
time-to-event-wk-50th-hici             NA                NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.371900  0.374100  0.178700  0.774300  0.008203


\#############################################################################
[[1]]
[1] "Zeit bis zum Tod oder permanenter Beatmung (>=16 Stunden Beatmung/Tag für
>21 Tage in der Abwesenheit eines akuten reversiblen Ereignisses oder
Tracheostomie)"

$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                              28.0                31.0
n_event_pct                          68.0                39.0
time-to-event-wk-10th                 5.1                 7.9
time-to-event-wk-25th                12.1                14.4
time-to-event-wk-50th                22.6                  NA
time-to-event-wk-75th                  NA                  NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.6               36.3
time-to-event-wk-50th-hici           31.3                 NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.53070   0.26460   0.31600   0.89140   0.01664


\#############################################################################
[[1]]
[1] "Zeit bis zu permanenter Beatmung (>=16 Stunden Beatmung/Tag für >21 Tage in
der Abwesenheit eines akuten reversiblen Ereignisses oder Tracheostomie)"

$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              13.0               18.0
n_event_pct                          32.0               22.0
time-to-event-wk-10th                13.6                8.7
time-to-event-wk-25th                20.4               37.6
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6648    0.3693    0.3224    1.3710    0.2689


\#############################################################################
[[1]]
[1] "Anzahl der Stunden mit Beatmung (Std.) für Patienten die zu Baseline keine
Beatmung benötigten"

$numbers_eachgrp
           Control ISIS 396443
N      35.00000000 59.00000000
n      35.00000000 59.00000000
mean    0.31634346  0.20662790
sd      0.27786454  0.26194519
se      0.04696768  0.03410236
median  0.29304636  0.06841856
min     0.00000000  0.00000000
max     0.91495902  0.95464701
sum    11.07202097 12.19104636

$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.21     0.035         0.137         0.276
2     Control   0.32     0.046         0.225         0.407
```

```
$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   -0.109224484     0.058220812    -0.224890289     0.006441322     0.063891168

$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.4100 -0.8280  0.0160  0.0595


\#############################################################################
[[1]]
[1] "Anteil an Patienten, die keine permanente Beatmung benötigen (>=16 Stunden
Beatmung/Tag für >21 Tage in der Abwesenheit eines akuten reversiblen
Ereignisses oder Tracheostomie)"

$ntab
            CTRL TRT
n_all         41  80
n_event       28  62
n_event_pct   68  78

$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.13482143 0.12228276  0.89297696 1.4421645 0.3010026
OR_TRTvsCTRL  1.59920635 0.42932732  0.68938277 3.7097837 0.2741354
ARR_TRTvsCTRL 0.09207317 0.08637764 -0.07722389 0.2613702 0.2864519


\#############################################################################
[[1]]
[1] "Zeit bis zur Beatmung (unabhängig von der Dauer) für Patienten die zu
Baseline keine Beatmung benötigten"

$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               35.0               59.0
n_event                             30.0               38.0
n_event_pct                         86.0               64.0
time-to-event-wk-10th                1.7                1.1
time-to-event-wk-25th                5.0                4.1
time-to-event-wk-50th                9.1               15.0
time-to-event-wk-75th               15.7               44.1
time-to-event-wk-90th               27.3                 NA
time-to-event-wk-50th-loci           6.4                6.9
time-to-event-wk-50th-hici          12.9               37.3

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.61730   0.26240   0.36910   1.03300   0.06606


\#############################################################################
[[1]]
[1] "Anteil an Patienten, die keine Beatmung benötigen und zu Baseline keine
```

```
Beatmung benötigten (unabhängig von der Dauer)"

$ntab
            CTRL TRT
n_all         35  59
n_event        5  21
n_event_pct   14  36

$stats
               estimate         se     lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  2.4915254 0.44955363 1.03229680 6.0134827 0.04228847
OR_TRTvsCTRL  3.3157895 0.55431775 1.11879579 9.8270479 0.03058193
ARR_TRTvsCTRL 0.2130751 0.08593045 0.04465448 0.3814956 0.01315216


\##############################################################################
[[1]]
[1] "HINE-Responder (Subskala 2)"

$`64`
$`64`$ntab
            CTRL TRT
n_all         41  80
n_event        8  26
n_event_pct   20  32

$`64`$stats
               estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.665625 0.35576860  0.82936643 3.3450916 0.1515496
OR_TRTvsCTRL  1.986111 0.46074189  0.80504348 4.8999060 0.1364109
ARR_TRTvsCTRL 0.129878 0.08107194 -0.02902004 0.2887761 0.1091534


$`183`
$`183`$ntab
            CTRL TRT
n_all         41  80
n_event        2  30
n_event_pct    5  38

$`183`$stats
                estimate         se    lo95ci     hi95ci       pvalue
RR_TRTvsCTRL   7.6875000 0.70458718 1.9321438 30.5865730 3.794745e-03
OR_TRTvsCTRL  11.7000000 0.76090365 2.6333192 51.9838235 1.227303e-03
ARR_TRTvsCTRL  0.3262195 0.06372926 0.2013125  0.4511266 3.074296e-07


$`302`
$`302`$ntab
            CTRL TRT
n_all         41  80
n_event        0  22
n_event_pct    0  28
```

```
$`302`$stats
              estimate         se   lo95ci     hi95ci       pvalue
RR_TRTvsCTRL  23.33333 1.41714122 1.451122 375.188553 2.623589e-02
OR_TRTvsCTRL  31.92308 1.44417272 1.882880 541.236146 1.647854e-02
ARR_TRTvsCTRL  0.27500 0.04992181 0.177155   0.372845 3.616701e-08


$`394`
$`394`$ntab
            CTRL TRT
n_all         41  80
n_event        0  20
n_event_pct    0  25

$`394`$stats
              estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  21.25926 1.41867025 1.3181773 342.8644333 3.118622e-02
OR_TRTvsCTRL  28.12397 1.44547771 1.6545646 478.0457185 2.098146e-02
ARR_TRTvsCTRL  0.25000 0.04841229 0.1551137   0.3448863 2.417564e-07



\##############################################################################
[[1]]
[1] "Zeit bis zum HINE-Responder (Subskala 2)"

$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               8.0               49.0
n_event_pct                          20.0               61.0
time-to-event-wk-10th                 9.1                9.1
time-to-event-wk-25th                14.1               10.0
time-to-event-wk-50th                  NA               26.1
time-to-event-wk-75th                  NA               49.7
time-to-event-wk-90th                  NA               57.7
time-to-event-wk-50th-loci             NA               25.1
time-to-event-wk-50th-hici             NA               29.1

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 3.222000  0.388600  1.504000  6.900000  0.002605


\##############################################################################
[[1]]
[1] "Veränderung des HINE-Scores (Subskala 2) von Baseline"

$`64`
$`64`$base
          Control ISIS 396443
N      41.0000000 80.00000000
n      34.0000000 72.00000000
mean    0.7941176  0.58333333
```

```
sd      1.1488970  0.80052799
se      0.1970342  0.09434313
median  0.0000000  0.00000000
min     0.0000000  0.00000000
max     5.0000000  3.00000000
sum    27.0000000 42.00000000

$`64`$numbers_eachgrp
           Control ISIS 396443
N      41.00000000  80.0000000
n      34.00000000  72.0000000
mean    0.08823529   0.6666667
sd      0.99598123   1.3531393
se      0.17080937   0.1594690
median  0.00000000   0.0000000
min    -2.00000000  -3.0000000
max     3.00000000   6.0000000
sum     3.00000000  48.0000000

$`64`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.62     0.142         0.339         0.903
2     Control   0.18     0.210        -0.232         0.602

$`64`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     0.43599240      0.25901423     -0.07782216      0.94980695      0.09541037

$`64`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.4600 0.0460 0.8720 0.0292


$`183`
$`183`$base
          Control ISIS 396443
N      41.0000000 80.00000000
n      34.0000000 72.00000000
mean    0.7941176  0.58333333
sd      1.1488970  0.80052799
se      0.1970342  0.09434313
median  0.0000000  0.00000000
min     0.0000000  0.00000000
max     5.0000000  3.00000000
sum    27.0000000 42.00000000

$`183`$numbers_eachgrp
          Control ISIS 396443
N      41.0000000  80.0000000
n      23.0000000  59.0000000
mean   -0.1739130   1.9661017
sd      0.8868829   2.5594052
se      0.1849279   0.3332062
median  0.0000000   1.0000000
```

```
min    -2.0000000  -2.0000000
max     1.0000000  12.0000000
sum    -4.0000000 116.0000000

$`183`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.08     0.271         1.542         2.619
2     Control  -0.47     0.446        -1.355         0.421

$`183`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.547664e+00    5.351850e-01    1.481974e+00    3.613353e+00    8.883097e-06

$`183`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.9500 0.4470 1.4560 0.0002


$`302`
$`302`$base
          Control ISIS 396443
N      41.0000000 80.00000000
n      34.0000000 72.00000000
mean    0.7941176  0.58333333
sd      1.1488970  0.80052799
se      0.1970342  0.09434313
median  0.0000000  0.00000000
min     0.0000000  0.00000000
max     5.0000000  3.00000000
sum    27.0000000 42.00000000

$`302`$numbers_eachgrp
           Control ISIS 396443
N       41.0000000  80.0000000
n       16.0000000  36.0000000
mean    -0.6250000   3.5000000
sd       1.2041595   4.0035698
se       0.3010399   0.6672616
median   0.0000000   2.0000000
min     -4.0000000  -1.0000000
max      0.0000000  14.0000000
sum    -10.0000000 126.0000000

$`302`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   3.68     0.541         2.593         4.770
2     Control  -1.03     0.835        -2.713         0.647

$`302`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   4.713816e+00    1.025660e+00    2.650455e+00    6.777177e+00    3.250454e-05

$`302`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
```

```
1.1900 0.5550 1.8250 0.0002


$`394`
$`394`$base
          Control ISIS 396443
N      41.0000000 80.00000000
n      34.0000000 72.00000000
mean    0.7941176  0.58333333
sd      1.1488970  0.80052799
se      0.1970342  0.09434313
median  0.0000000  0.00000000
min     0.0000000  0.00000000
max     5.0000000  3.00000000
sum    27.0000000 42.00000000

$`394`$numbers_eachgrp
          Control ISIS 396443
N      41.0000000  80.0000000
n      11.0000000  26.0000000
mean   -0.7272727   4.4615385
sd      1.4206273   4.7009001
se      0.4283352   0.9219224
median  0.0000000   3.0000000
min    -4.0000000   0.0000000
max     0.0000000  17.0000000
sum    -8.0000000 116.0000000

$`394`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.42     0.784         2.825         6.020
2     Control  -0.63     1.241        -3.162         1.893

$`394`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    5.056759410     1.509731502     1.981536974     8.131981847     0.002086403

$`394`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.2600 0.4880 2.0220 0.0013



\#############################################################################
[[1]]
[1] "CHOP INTEND-Responder"

$`64`
$`64`$ntab
            CTRL TRT
n_all         41  80
n_event        1  41
n_event_pct    2  51
```

```
$`64`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  21.0125000 0.99373035 2.9964906 147.3474181 2.181583e-03
OR_TRTvsCTRL  42.0512821 1.03683715 5.5108915 320.8755460 3.108895e-04
ARR_TRTvsCTRL  0.4881098 0.06085574 0.3688347   0.6073848 1.110223e-15


$`183`
$`183`$ntab
            CTRL TRT
n_all         41  80
n_event        0  45
n_event_pct    0  56

$`183`$stats
                estimate         se   lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   47.18519 1.40919226 2.980568  746.985701 0.006238846
OR_TRTvsCTRL  106.38028 1.44022339 6.323256 1789.705244 0.001193271
ARR_TRTvsCTRL   0.56250 0.05546325 0.453794    0.671206 0.000000000


$`302`
$`302`$ntab
            CTRL TRT
n_all         41  80
n_event        1  28
n_event_pct    2  35

$`302`$stats
                estimate         se    lo95ci     hi95ci       pvalue
RR_TRTvsCTRL  14.3500000 0.99941185 2.0237227 101.754309 7.691565e-03
OR_TRTvsCTRL  21.5384615 1.03920405 2.8095877 165.115091 3.136532e-03
ARR_TRTvsCTRL  0.3256098 0.05851602 0.2109205   0.440299 2.629731e-08


$`394`
$`394`$ntab
            CTRL TRT
n_all         41  80
n_event        1  24
n_event_pct    2  30

$`394`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  12.3000000 1.00238537 1.7245395  87.7277684 1.229275e-02
OR_TRTvsCTRL  17.1428571 1.04140473 2.2265779 131.9861979 6.360294e-03
ARR_TRTvsCTRL  0.2756098 0.05661603 0.1646444   0.3865751 1.127038e-06



\##############################################################################
[[1]]
[1] "Zeit bis zum CHOP INTEND Responder"
```

```
$stats_num
                            TRT01P=Control TRT01P=ISIS 396443
n_all                                 41.0                80.0
n_event                                2.0                62.0
n_event_pct                            5.0                78.0
time-to-event-wk-10th                 49.1                 8.4
time-to-event-wk-25th                   NA                 9.0
time-to-event-wk-50th                   NA                11.6
time-to-event-wk-75th                   NA                26.1
time-to-event-wk-90th                   NA                43.1
time-to-event-wk-50th-loci              NA                 9.3
time-to-event-wk-50th-hici              NA                21.1

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.948e+01 7.254e-01 7.113e+00 1.222e+02 3.090e-06


\#############################################################################
[[1]]
[1] "Veränderung des CHOP INTEND von Baseline"

$`64`
$`64`$base
          Control  ISIS 396443
N       41.000000   80.0000000
n       33.000000   73.0000000
mean    29.000000   27.3424658
sd       7.881941    7.9016861
se       1.372070    0.9248224
median  29.500000   28.0000000
min     10.500000    8.0000000
max     50.500000   48.5000000
sum    957.000000 1996.0000000

$`64`$numbers_eachgrp
           Control ISIS 396443
N        41.000000  80.0000000
n        33.000000  73.0000000
mean     -3.545455   4.2054795
sd        6.352120   7.8624616
se        1.105762   0.9202315
median   -2.000000   5.0000000
min     -22.000000 -29.0000000
max       4.000000  22.5000000
sum    -117.000000 307.0000000

$`64`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   3.97     0.870         2.239         5.693
2     Control  -3.02     1.318        -5.630        -0.403

$`64`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
```

```
   6.982447e+00    1.610018e+00    3.788604e+00    1.017629e+01    3.428345e-05

$`64`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 1.040  0.601  1.471  0.000


$`183`
$`183`$base
          Control  ISIS 396443
N       41.000000   80.0000000
n       33.000000   73.0000000
mean    29.000000   27.3424658
sd       7.881941    7.9016861
se       1.372070    0.9248224
median  29.500000   28.0000000
min     10.500000    8.0000000
max     50.500000   48.5000000
sum    957.000000 1996.0000000

$`183`$numbers_eachgrp
           Control ISIS 396443
N        41.000000   80.000000
n        23.000000   59.000000
mean    -10.630435    9.050847
sd        8.139714    8.707753
se        1.697248    1.133653
median  -12.000000   10.000000
min     -23.000000  -18.000000
max       3.000000   23.500000
sum    -244.500000  534.000000

$`183`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   8.92     1.092         6.744        11.091
2     Control -10.29     1.800       -13.873        -6.704

$`183`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   1.920594e+01    2.159993e+00    1.490484e+01    2.350703e+01    1.939672e-13

$`183`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.280  1.679  2.879  0.000


$`302`
$`302`$base
          Control  ISIS 396443
N       41.000000   80.0000000
n       33.000000   73.0000000
mean    29.000000   27.3424658
sd       7.881941    7.9016861
se       1.372070    0.9248224
```

```
median  29.500000   28.0000000
min     10.500000    8.0000000
max     50.500000   48.5000000
sum    957.000000 1996.0000000

$`302`$numbers_eachgrp
           Control ISIS 396443
N        41.000000   80.000000
n        16.000000   36.000000
mean    -10.531250   11.250000
sd        9.335361    7.984360
se        2.333840    1.330727
median  -10.750000   12.000000
min     -26.000000   -5.500000
max      13.000000   31.000000
sum    -168.500000  405.000000

$`302`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  10.89     1.433         8.002        13.769
2     Control  -9.71     2.212       -14.161        -5.261

$`302`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.059619e+01    2.716687e+00    1.513092e+01    2.606145e+01    1.080623e-09

$`302`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.550  1.771  3.329  0.000


$`394`
$`394`$base
          Control  ISIS 396443
N       41.000000   80.0000000
n       33.000000   73.0000000
mean    29.000000   27.3424658
sd       7.881941    7.9016861
se       1.372070    0.9248224
median  29.500000   28.0000000
min     10.500000    8.0000000
max     50.500000   48.5000000
sum    957.000000 1996.0000000

$`394`$numbers_eachgrp
           Control ISIS 396443
N        41.000000   80.000000
n        11.000000   26.000000
mean    -11.318182   13.730769
sd        9.370893    8.004037
se        2.825431    1.569721
median  -12.000000   12.750000
min     -23.500000   -4.000000
max      11.000000   33.000000
```

```
sum    -124.500000  357.000000

$`394`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  13.55     1.592        10.311        16.797
2     Control -10.90     2.528       -16.049        -5.751

$`394`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.445388e+01    3.084192e+00    1.817159e+01    3.073618e+01    4.760956e-09

$`394`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.910  1.917  3.906  0.000



\#############################################################################
[[1]]
[1] "Veränderung des HINE-Scores (Subskala 1) von Baseline"

$`64`
$`64`$base
           Control  ISIS 396443
N        41.000000   80.0000000
n        41.000000   80.0000000
mean     37.390244   38.4062500
sd        7.326759    7.1090483
se        1.144248    0.7948158
median   37.000000   38.2500000
min      22.000000   23.0000000
max      52.000000   55.5000000
sum    1533.000000 3072.5000000

$`64`$numbers_eachgrp
       Control ISIS 396443
N         41.0          80
n          1.0           0
mean      -4.5          NA
sd          NA          NA
se          NA          NA
median    -4.5          NA
min       -4.5          NA
max       -4.5          NA
sum       -4.5          NA

$`64`$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$`64`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA
```

```
$`64`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$`183`
$`183`$base
           Control  ISIS 396443
N        41.000000   80.0000000
n        41.000000   80.0000000
mean     37.390244   38.4062500
sd        7.326759    7.1090483
se        1.144248    0.7948158
median   37.000000   38.2500000
min      22.000000   23.0000000
max      52.000000   55.5000000
sum    1533.000000 3072.5000000

$`183`$numbers_eachgrp
          Control ISIS 396443
N       41.000000   80.000000
n        4.000000    5.000000
mean    -7.000000    4.800000
sd       4.377975    6.620045
se       2.188988    2.960574
median  -6.250000    7.500000
min    -13.000000   -3.500000
max     -2.500000   11.000000
sum    -28.000000   24.000000

$`183`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.99     1.964        -0.462        10.445
2     Control  -7.24     2.201       -13.351        -1.129

$`183`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    12.23187061      2.98001932      3.95801054     20.50573067      0.01479694

$`183`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.8200 0.0910 3.5460 0.0391


$`302`
$`302`$base
           Control  ISIS 396443
N        41.000000   80.0000000
n        41.000000   80.0000000
mean     37.390244   38.4062500
sd        7.326759    7.1090483
se        1.144248    0.7948158
median   37.000000   38.2500000
```

```
min      22.000000   23.0000000
max      52.000000   55.5000000
sum    1533.000000 3072.5000000

$`302`$numbers_eachgrp
       Control ISIS 396443
N           41   80.000000
n            1    3.000000
mean        -3    7.833333
sd          NA    1.755942
se          NA    1.013794
median      -3    8.000000
min         -3    6.000000
max         -3    9.500000
sum         -3   23.500000

$`302`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$`302`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$`302`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$`394`
$`394`$base
           Control  ISIS 396443
N        41.000000   80.0000000
n        41.000000   80.0000000
mean     37.390244   38.4062500
sd        7.326759    7.1090483
se        1.144248    0.7948158
median   37.000000   38.2500000
min      22.000000   23.0000000
max      52.000000   55.5000000
sum    1533.000000 3072.5000000

$`394`$numbers_eachgrp
           Control ISIS 396443
N        41.000000   80.000000
n        11.000000   26.000000
mean     -9.818182    4.576923
sd        7.909718    9.012982
se        2.384870    1.767591
median   -6.000000    3.500000
min     -24.500000  -13.000000
max      -0.500000   24.000000
sum    -108.000000  119.000000
```

```
$`394`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.62     1.671         1.216         8.024
2     Control  -9.92     2.649       -15.317        -4.524

$`394`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   1.454082e+01    3.228724e+00    7.964125e+00    2.111751e+01    8.356109e-05

$`394`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.6200 0.8110 2.4220 0.0001



\#############################################################################
[[1]]
[1] "Veränderung des HINE-Scores (Subskala 3) von Baseline"

$`64`
$`64`$base
           Control  ISIS 396443
N       41.0000000   80.0000000
n       41.0000000   80.0000000
mean    14.3658537   13.9062500
sd       1.1780513    1.7340480
se       0.1839807    0.1938725
median  15.0000000   15.0000000
min     11.0000000    8.0000000
max     15.0000000   15.0000000
sum    589.0000000 1112.5000000

$`64`$numbers_eachgrp
       Control ISIS 396443
N           41          80
n            1           0
mean         3          NA
sd          NA          NA
se          NA          NA
median       3          NA
min          3          NA
max          3          NA
sum          3          NA

$`64`$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$`64`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA
```

```
$`64`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$`183`
$`183`$base
           Control  ISIS 396443
N       41.0000000   80.0000000
n       41.0000000   80.0000000
mean    14.3658537   13.9062500
sd       1.1780513    1.7340480
se       0.1839807    0.1938725
median  15.0000000   15.0000000
min     11.0000000    8.0000000
max     15.0000000   15.0000000
sum    589.0000000 1112.5000000

$`183`$numbers_eachgrp
          Control ISIS 396443
N      41.0000000  80.0000000
n       4.0000000   5.0000000
mean   -2.0000000   0.6000000
sd      1.8257419   1.9493589
se      0.9128709   0.8717798
median -2.0000000   0.0000000
min    -4.0000000  -2.0000000
max     0.0000000   3.0000000
sum    -8.0000000   3.0000000

$`183`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  -0.10     1.148        -3.291         3.081
2     Control  -1.12     1.341        -4.843         2.605

$`183`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      1.0141099       2.0838469      -4.7715766       6.7997963       0.6519662

$`183`$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 1.2200 -0.2960  2.7320  0.1148


$`302`
$`302`$base
           Control  ISIS 396443
N       41.0000000   80.0000000
n       41.0000000   80.0000000
mean    14.3658537   13.9062500
sd       1.1780513    1.7340480
se       0.1839807    0.1938725
median  15.0000000   15.0000000
min     11.0000000    8.0000000
```

```
max     15.0000000   15.0000000
sum    589.0000000 1112.5000000

$`302`$numbers_eachgrp
       Control ISIS 396443
N           41  80.0000000
n            1   3.0000000
mean         0  -2.0000000
sd          NA   1.0000000
se          NA   0.5773503
median       0  -2.0000000
min          0  -3.0000000
max          0  -1.0000000
sum          0  -6.0000000

$`302`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$`302`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$`302`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$`394`
$`394`$base
           Control  ISIS 396443
N       41.0000000   80.0000000
n       41.0000000   80.0000000
mean    14.3658537   13.9062500
sd       1.1780513    1.7340480
se       0.1839807    0.1938725
median  15.0000000   15.0000000
min     11.0000000    8.0000000
max     15.0000000   15.0000000
sum    589.0000000 1112.5000000

$`394`$numbers_eachgrp
          Control ISIS 396443
N       41.000000  80.0000000
n       11.000000  26.0000000
mean    -3.363636  -0.3269231
sd       3.500649   2.3872256
se       1.055485   0.4681735
median  -4.000000   0.0000000
min     -9.000000  -4.0000000
max      1.000000   7.0000000
sum    -37.000000  -8.5000000
```

```
$`394`$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  -0.36     0.444        -1.265         0.543
2     Control  -3.28     0.702        -4.713        -1.852

$`394`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    2.920960869     0.854482835     1.180436291     4.661485447     0.001735139

$`394`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.0800 0.3280 1.8310 0.0049



\#############################################################################
[[1]]
[1] "Anteil von Hospitalisierungszeiten"

$numbers_eachgrp
           Control ISIS 396443
N      41.00000000 80.00000000
n      41.00000000 80.00000000
mean    0.19929028  0.11814894
sd      0.18690606  0.13256500
se      0.02918982  0.01482122
median  0.15714286  0.08074074
min     0.00000000  0.00000000
max     0.75000000  0.56194690
sum     8.17090131  9.45191559

$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.11     0.017         0.081         0.148
2     Control   0.21     0.024         0.159         0.254

$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    -0.09258845      0.02962888     -0.15126689     -0.03391001      0.00224286

$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.5300 -0.9090 -0.1450  0.0069


\#############################################################################
[[1]]
[1] "Häufigkeit von Hospitalisierungen"

$nsubj

    Control ISIS 396443
         41          80
```

```
$numbers_eachgrp
           Control ISIS 396443
n       41.0000000  80.0000000
mean     2.9024390   3.3000000
sd       2.2891579   2.7485324
se       0.3575064   0.3072953
median   2.0000000   2.0000000
min      0.0000000   0.0000000
max     11.0000000  12.0000000
sum    119.0000000 264.0000000

$n_ptyear
    CTRL      TRT
25.38809 58.03970

$rate_unadj
    CTRL      TRT
4.687237 4.548611

$rate_adj
           CTRL      TRT
est    5.703672 4.328314
lo95ci 4.391738 3.608426
hi95ci 7.407517 5.191822

$RR_TRTvsCTRL
       est     lo95ci     hi95ci         se         pv
0.75886437 0.54807813 1.05071725 0.16602613 0.09651666


\#############################################################################
[[1]]
[1] "Zeit bis zur Hospitalisierung"

$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              39.0               72.0
n_event_pct                          95.0               90.0
time-to-event-wk-10th                 0.6                0.6
time-to-event-wk-25th                 2.1                2.0
time-to-event-wk-50th                 7.3                4.4
time-to-event-wk-75th                14.1               12.6
time-to-event-wk-90th                18.0               34.7
time-to-event-wk-50th-loci            2.9                2.6
time-to-event-wk-50th-hici           11.0                6.0

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9717    0.2023    0.6536    1.4450    0.8872


\#############################################################################
[[1]]
```

```
[1] "Häufigkeit von schwerwiegenden respiratorischen Ereignissen"

$nsubj

    Control ISIS 396443
         41          80

$numbers_eachgrp
          Control ISIS 396443
n      41.0000000  80.0000000
mean    1.9756098   1.8250000
sd      2.1964495   2.3534247
se      0.3430278   0.2631209
median  1.0000000   1.0000000
min     0.0000000   0.0000000
max     9.0000000   9.0000000
sum    81.0000000 146.0000000

$n_ptyear
    CTRL      TRT
25.38809 58.03970

$rate_unadj
    CTRL      TRT
3.190472 2.515520

$rate_adj
           CTRL      TRT
est    4.007793 2.484770
lo95ci 2.685321 1.844780
hi95ci 5.981559 3.346783

$RR_TRTvsCTRL
       est     lo95ci     hi95ci         se         pv
0.61998579 0.37363401 1.02876710 0.25838220 0.06428475


\#############################################################################
[[1]]
[1] "Zeit bis zu schwerwiegenden respiratorischen Ereignissen"

$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              30.0               48.0
n_event_pct                          73.0               60.0
time-to-event-wk-10th                 1.6                1.6
time-to-event-wk-25th                 4.0                5.4
time-to-event-wk-50th                13.9               15.7
time-to-event-wk-75th                52.6                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.1               10.0
time-to-event-wk-50th-hici           16.4               32.7
```

```
$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7564    0.2345    0.4776    1.1980    0.2339


\################################################################################
[[1]]
[1] "Patienten mit mindestens einem UE"

$ntab
            CTRL TRT
n_all         41  80
n_event       40  77
n_event_pct   98  96

$stats
                  estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.98656250 0.0331175  0.92455964 1.05272339 0.6829044
OR_TRTvsCTRL   0.64166667 1.1710339  0.06464332 6.36935308 0.7047738
ARR_TRTvsCTRL -0.01310976 0.0321177 -0.07605929 0.04983977 0.6831426


\################################################################################
[[1]]
[1] "Patienten mit mindestens einem milden UE"

$ntab
            CTRL TRT
n_all         41  80
n_event       25  54
n_event_pct   61  68

$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.1070000 0.14706555  0.8297843 1.4768284 0.4894315
OR_TRTvsCTRL  1.3292308 0.39934954  0.6076779 2.9075509 0.4760562
ARR_TRTvsCTRL 0.0652439 0.09244422 -0.1159434 0.2464312 0.4803342


\################################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten UE"

$ntab
            CTRL TRT
n_all         41  80
n_event       30  57
n_event_pct   73  71

$stats
                  estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.97375000 0.11826643  0.7722873 1.227767 0.8220402
OR_TRTvsCTRL   0.90869565 0.43042368  0.3908779 2.112495 0.8239685
ARR_TRTvsCTRL -0.01920732 0.08572419 -0.1872237 0.148809 0.8227110
```

```
\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten oder schweren UE"

$ntab
            CTRL TRT
n_all         41  80
n_event       39  65
n_event_pct   95  81

$stats
                estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.8541667 0.06430705  0.75301626  0.96890430 0.01423839
OR_TRTvsCTRL   0.2222222 0.77954622  0.04822104  1.02409072 0.05367789
ARR_TRTvsCTRL -0.1387195 0.05510016 -0.24671384 -0.03072519 0.01181614


\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem schweren UE"

$ntab
            CTRL TRT
n_all         41  80
n_event       33  45
n_event_pct   80  56

$stats
                estimate         se     lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   0.6988636 0.12504003  0.5469633  0.89294911 0.004163782
OR_TRTvsCTRL   0.3116883 0.45397872  0.1280245  0.75883597 0.010232991
ARR_TRTvsCTRL -0.2423780 0.08310622 -0.4052633 -0.07949284 0.003539998


\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs"

$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                             40.0               77.0
n_event_pct                         98.0               96.0
time-to-event-wk-10th                0.1                0.1
time-to-event-wk-25th                0.6                0.4
time-to-event-wk-50th                1.6                2.4
time-to-event-wk-75th                4.6                4.4
time-to-event-wk-90th                9.4               10.5
time-to-event-wk-50th-loci           0.9                1.3
time-to-event-wk-50th-hici           3.1                3.1

$stats_HR_TRTvsCTRL
```

```
      HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.9324    0.1968    0.6339    1.3710    0.7222


\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem schwerwiegenden UE"

$ntab
            CTRL TRT
n_all         41  80
n_event       39  61
n_event_pct   95  76

$stats
                 estimate         se     lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   0.8016026 0.07172325  0.6964792  0.92259275 0.002047373
OR_TRTvsCTRL   0.1646424 0.77114593  0.0363196  0.74634947 0.019317371
ARR_TRTvsCTRL -0.1887195 0.05827008 -0.3029268 -0.07451225 0.001200744


\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schwerwiegenden UEs"

$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              39.0               61.0
n_event_pct                          95.0               76.0
time-to-event-wk-10th                 1.0                1.1
time-to-event-wk-25th                 3.1                2.9
time-to-event-wk-50th                 8.9                8.6
time-to-event-wk-75th                15.7               32.1
time-to-event-wk-90th                26.0                 NA
time-to-event-wk-50th-loci            4.4                5.0
time-to-event-wk-50th-hici           12.7               13.0

$stats_HR_TRTvsCTRL
      HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.7429    0.2075    0.4947    1.1160    0.1521


\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines milden UEs"

$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              25.0               54.0
n_event_pct                          61.0               68.0
time-to-event-wk-10th                 0.4                0.6
time-to-event-wk-25th                 1.6                2.1
```

```
time-to-event-wk-50th                 5.1                 5.0
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            2.7                 3.1
time-to-event-wk-50th-hici           22.6                10.0

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0260    0.2421    0.6385    1.6490    0.9149


\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten UEs"

$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                80.0
n_event                             30.0                57.0
n_event_pct                         73.0                71.0
time-to-event-wk-10th                2.3                 1.2
time-to-event-wk-25th                5.3                 3.6
time-to-event-wk-50th                9.0                12.6
time-to-event-wk-75th               17.1                37.6
time-to-event-wk-90th                NA                  NA
time-to-event-wk-50th-loci           5.9                 7.7
time-to-event-wk-50th-hici          15.7                25.1

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7823    0.2313    0.4971    1.2310    0.2886


\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten oder schweren UEs"

$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                80.0
n_event                             39.0                65.0
n_event_pct                         95.0                81.0
time-to-event-wk-10th                0.9                 0.6
time-to-event-wk-25th                3.1                 3.2
time-to-event-wk-50th                7.6                 8.1
time-to-event-wk-75th               15.1                28.4
time-to-event-wk-90th               23.0                  NA
time-to-event-wk-50th-loci           4.6                 5.0
time-to-event-wk-50th-hici           9.1                12.6

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.67330   0.20940   0.44670   1.01500   0.05887
```

```
\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schweren UEs"

$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              33.0               45.0
n_event_pct                          80.0               56.0
time-to-event-wk-10th                 1.7                2.9
time-to-event-wk-25th                 4.6                7.0
time-to-event-wk-50th                11.7               23.4
time-to-event-wk-75th                23.0                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.7               11.4
time-to-event-wk-50th-hici           15.9                 NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.57390   0.23150   0.36460   0.90340   0.01645


\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem UE das zum Therapieabbruch führte"

$ntab
            CTRL TRT
n_all         41  80
n_event       16  13
n_event_pct   39  16

$stats
                 estimate         se     lo95ci     hi95ci      pvalue
RR_TRTvsCTRL   0.4164062 0.32020748  0.2223085  0.7799708 0.006218733
OR_TRTvsCTRL   0.3031716 0.44084969  0.1277723  0.7193504 0.006785899
ARR_TRTvsCTRL -0.2277439 0.08663093 -0.3975374 -0.0579504 0.008566199


\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs das zum Therapieabbruch führte"

$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                              16.0                 13
n_event_pct                          39.0                 16
time-to-event-wk-10th                 4.6                 12
time-to-event-wk-25th                14.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci           23.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.369400  0.374100  0.177500  0.769100  0.007769


\################################################################################
[[1]]
[1] "Patienten mit mindestens einem UE nach SOC, das bei mindestens 10% der
Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       13  18
n_event_pct   32  22

$`Cardiac disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.70961538 0.30917372  0.3871274 1.30074501 0.2672091
OR_TRTvsCTRL   0.62531017 0.42932732  0.2695575 1.45057295 0.2741354
ARR_TRTvsCTRL -0.09207317 0.08637764 -0.2613702 0.07722389 0.2864519


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       26  53
n_event_pct   63  66

$`Gastrointestinal disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.04471154 0.14296580  0.7894119 1.3825763 0.7596405
OR_TRTvsCTRL  1.13247863 0.40128938  0.5157650 2.4866128 0.7565439
ARR_TRTvsCTRL 0.02835366 0.09194332 -0.1518519 0.2085593 0.7577917


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         41  80
n_event       28  51
n_event_pct   68  64

$`General disorders and administration site conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93348214 0.1357641  0.7153909 1.2180598 0.6121494
OR_TRTvsCTRL   0.81650246 0.4083234  0.3667685 1.8177032 0.6195541
ARR_TRTvsCTRL -0.04542683 0.0903885 -0.2225850 0.1317314 0.6152644
```

```
$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all         41  80
n_event       31  65
n_event_pct   76  81

$`Infections and infestations`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.07459677 0.10369395  0.8769626 1.3167702 0.4877917
OR_TRTvsCTRL  1.39784946 0.46293557  0.5641686 3.4634736 0.4693713
ARR_TRTvsCTRL 0.05640244 0.08001375 -0.1004216 0.2132265 0.4808667


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         41  80
n_event       10  19
n_event_pct   24  24

$`Injury, poisoning and procedural complications`$stats
                  estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.973750000 0.3402078  0.4998758 1.896849 0.9376773
OR_TRTvsCTRL   0.965573770 0.4486458  0.4007721 2.326342 0.9377600
ARR_TRTvsCTRL -0.006402439 0.0822288 -0.1675679 0.154763 0.9379384


$Investigations
$Investigations$ntab
            CTRL TRT
n_all         41  80
n_event       14  21
n_event_pct   34  26

$Investigations$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.76875000 0.28663108  0.4383331 1.34823608 0.3588707
OR_TRTvsCTRL   0.68644068 0.41597333  0.3037567 1.55124412 0.3657461
ARR_TRTvsCTRL -0.07896341 0.08890704 -0.2532180 0.09529119 0.3744563


$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       13  14
n_event_pct   32  18

$`Metabolism and nutrition disorders`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5519231 0.33385836  0.2868784 1.06184054 0.07503738
OR_TRTvsCTRL   0.4568765 0.44633782  0.1904914 1.09577710 0.07925188
```

```
ARR_TRTvsCTRL -0.1420732 0.08417896 -0.3070609 0.02291455 0.09145892


$`Musculoskeletal and connective tissue disorders`
$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        5  11
n_event_pct   12  14

$`Musculoskeletal and connective tissue disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.12750000 0.50400282  0.4198639 3.0277815 0.8118040
OR_TRTvsCTRL  1.14782609 0.57721714  0.3702951 3.5579858 0.8112199
ARR_TRTvsCTRL 0.01554878 0.06398521 -0.1098599 0.1409575 0.8080009


$`Nervous system disorders`
$`Nervous system disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        2   9
n_event_pct    5  11

$`Nervous system disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.30625000 0.75777363  0.52226185 10.1841424 0.2701426
OR_TRTvsCTRL  2.47183099 0.80674447  0.50853006 12.0149208 0.2619721
ARR_TRTvsCTRL 0.06371951 0.04878296 -0.03189334  0.1593324 0.1914901


$`Psychiatric disorders`
$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        5   9
n_event_pct   12  11

$`Psychiatric disorders`$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.92250000 0.52366102  0.3305410 2.574586 0.8775734
OR_TRTvsCTRL   0.91267606 0.59411564  0.2848423 2.924346 0.8777684
ARR_TRTvsCTRL -0.00945122 0.06212675 -0.1312174 0.112315 0.8790860


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       36  61
n_event_pct   88  76

$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se     lo95ci     hi95ci     pvalue
```

```
RR_TRTvsCTRL   0.8684028 0.08532864  0.7346650 1.02648610 0.09820832
OR_TRTvsCTRL   0.4459064 0.54479611  0.1532895 1.29710468 0.13821418
ARR_TRTvsCTRL -0.1155488 0.06982376 -0.2524008 0.02130328 0.09795223


$`Skin and subcutaneous tissue disorders`
$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       15  23
n_event_pct   37  29

$`Skin and subcutaneous tissue disorders`$stats
                 estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.78583333 0.2706560  0.4623253 1.33571337 0.3732146
OR_TRTvsCTRL   0.69941520 0.4076154  0.3146098 1.55488380 0.3804440
ARR_TRTvsCTRL -0.07835366 0.0906598 -0.2560436 0.09933629 0.3874450



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem UE nach SOC, das bei mindestens 10 Patienten
und 1% der Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       13  18
n_event_pct   32  22

$`Cardiac disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.70961538 0.30917372  0.3871274 1.30074501 0.2672091
OR_TRTvsCTRL   0.62531017 0.42932732  0.2695575 1.45057295 0.2741354
ARR_TRTvsCTRL -0.09207317 0.08637764 -0.2613702 0.07722389 0.2864519


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       26  53
n_event_pct   63  66

$`Gastrointestinal disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.04471154 0.14296580  0.7894119 1.3825763 0.7596405
OR_TRTvsCTRL  1.13247863 0.40128938  0.5157650 2.4866128 0.7565439
ARR_TRTvsCTRL 0.02835366 0.09194332 -0.1518519 0.2085593 0.7577917


$`General disorders and administration site conditions`
```

```
$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         41  80
n_event       28  51
n_event_pct   68  64

$`General disorders and administration site conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93348214 0.1357641  0.7153909 1.2180598 0.6121494
OR_TRTvsCTRL   0.81650246 0.4083234  0.3667685 1.8177032 0.6195541
ARR_TRTvsCTRL -0.04542683 0.0903885 -0.2225850 0.1317314 0.6152644


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all         41  80
n_event       31  65
n_event_pct   76  81

$`Infections and infestations`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.07459677 0.10369395  0.8769626 1.3167702 0.4877917
OR_TRTvsCTRL  1.39784946 0.46293557  0.5641686 3.4634736 0.4693713
ARR_TRTvsCTRL 0.05640244 0.08001375 -0.1004216 0.2132265 0.4808667


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         41  80
n_event       10  19
n_event_pct   24  24

$`Injury, poisoning and procedural complications`$stats
                  estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.973750000 0.3402078  0.4998758 1.896849 0.9376773
OR_TRTvsCTRL   0.965573770 0.4486458  0.4007721 2.326342 0.9377600
ARR_TRTvsCTRL -0.006402439 0.0822288 -0.1675679 0.154763 0.9379384


$Investigations
$Investigations$ntab
            CTRL TRT
n_all         41  80
n_event       14  21
n_event_pct   34  26

$Investigations$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.76875000 0.28663108  0.4383331 1.34823608 0.3588707
OR_TRTvsCTRL   0.68644068 0.41597333  0.3037567 1.55124412 0.3657461
ARR_TRTvsCTRL -0.07896341 0.08890704 -0.2532180 0.09529119 0.3744563
```

```
$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       13  14
n_event_pct   32  18

$`Metabolism and nutrition disorders`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5519231 0.33385836  0.2868784 1.06184054 0.07503738
OR_TRTvsCTRL   0.4568765 0.44633782  0.1904914 1.09577710 0.07925188
ARR_TRTvsCTRL -0.1420732 0.08417896 -0.3070609 0.02291455 0.09145892


$`Musculoskeletal and connective tissue disorders`
$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        5  11
n_event_pct   12  14

$`Musculoskeletal and connective tissue disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.12750000 0.50400282  0.4198639 3.0277815 0.8118040
OR_TRTvsCTRL  1.14782609 0.57721714  0.3702951 3.5579858 0.8112199
ARR_TRTvsCTRL 0.01554878 0.06398521 -0.1098599 0.1409575 0.8080009


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       36  61
n_event_pct   88  76

$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.8684028 0.08532864  0.7346650 1.02648610 0.09820832
OR_TRTvsCTRL   0.4459064 0.54479611  0.1532895 1.29710468 0.13821418
ARR_TRTvsCTRL -0.1155488 0.06982376 -0.2524008 0.02130328 0.09795223


$`Skin and subcutaneous tissue disorders`
$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       15  23
n_event_pct   37  29

$`Skin and subcutaneous tissue disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.78583333 0.2706560  0.4623253 1.33571337 0.3732146
OR_TRTvsCTRL   0.69941520 0.4076154  0.3146098 1.55488380 0.3804440
```

```
ARR_TRTvsCTRL -0.07835366 0.0906598 -0.2560436 0.09933629 0.3874450



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs nach SOC, das bei mindestens 10% der
Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                             13.0               18.0
n_event_pct                         32.0               22.0
time-to-event-wk-10th                4.6                8.1
time-to-event-wk-25th               15.1               47.1
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          29.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5914    0.3647    0.2894    1.2090    0.1497


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                             26.0               53.0
n_event_pct                         63.0               66.0
time-to-event-wk-10th                2.7                1.0
time-to-event-wk-25th                5.6                4.4
time-to-event-wk-50th               15.9               13.9
time-to-event-wk-75th               39.7                 NA
time-to-event-wk-90th               43.0                 NA
time-to-event-wk-50th-loci           9.7                7.1
time-to-event-wk-50th-hici          26.1               18.7

$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0110    0.2425    0.6284    1.6260    0.9647


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                             28.0               51.0
n_event_pct                         68.0               64.0
time-to-event-wk-10th                2.1                2.5
```

```
time-to-event-wk-25th                5.1                7.6
time-to-event-wk-50th               13.4               25.1
time-to-event-wk-75th               22.7               46.7
time-to-event-wk-90th               42.6                 NA
time-to-event-wk-50th-loci           6.4               15.3
time-to-event-wk-50th-hici          18.0               36.3

$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.58680   0.24090   0.36590   0.94090   0.02691


$`Infections and infestations`
$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              31.0               65.0
n_event_pct                          76.0               81.0
time-to-event-wk-10th                 2.3                1.7
time-to-event-wk-25th                 5.3                4.0
time-to-event-wk-50th                 8.6                9.4
time-to-event-wk-75th                23.9               21.1
time-to-event-wk-90th                38.1               34.7
time-to-event-wk-50th-loci            6.1                6.7
time-to-event-wk-50th-hici           15.3               13.0

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1450    0.2220    0.7409    1.7690    0.5426


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              10.0               19.0
n_event_pct                          24.0               24.0
time-to-event-wk-10th                 7.7                5.7
time-to-event-wk-25th                34.4               43.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           34.4               51.1
time-to-event-wk-50th-hici             NA                 NA

$`Injury, poisoning and procedural complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7481    0.3948    0.3451    1.6220    0.4622


$Investigations
$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
```

```
n_event                                14.0               21.0
n_event_pct                            34.0               26.0
time-to-event-wk-10th                   6.3                5.4
time-to-event-wk-25th                  18.9               33.6
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci             27.4                 NA
time-to-event-wk-50th-hici               NA                 NA

$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6565    0.3473    0.3324    1.2970    0.2256


$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              13.0               14.0
n_event_pct                          32.0               18.0
time-to-event-wk-10th                 6.0                9.7
time-to-event-wk-25th                13.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44030   0.38730   0.20610   0.94060   0.03417


$`Musculoskeletal and connective tissue disorders`
$`Musculoskeletal and connective tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               5.0               11.0
n_event_pct                          12.0               14.0
time-to-event-wk-10th                46.9               31.9
time-to-event-wk-25th                56.4               63.0
time-to-event-wk-50th                  NA               63.0
time-to-event-wk-75th                  NA               63.0
time-to-event-wk-90th                  NA               63.0
time-to-event-wk-50th-loci           56.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Musculoskeletal and connective tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9695    0.5491    0.3305    2.8440    0.9550


$`Nervous system disorders`
```

```
$`Nervous system disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 41                 80
n_event                                2                  9
n_event_pct                            5                 11
time-to-event-wk-10th                 NA                 20
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2480    0.7834    0.4843   10.4400    0.3010


$`Psychiatric disorders`
$`Psychiatric disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              5.0                9.0
n_event_pct                         12.0               11.0
time-to-event-wk-10th               13.9               15.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8344    0.5605    0.2782    2.5030    0.7467


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                             36.0               61.0
n_event_pct                         88.0               76.0
time-to-event-wk-10th                0.6                0.6
time-to-event-wk-25th                1.1                3.1
time-to-event-wk-50th                4.6                9.1
time-to-event-wk-75th               11.0               32.1
time-to-event-wk-90th               27.0                 NA
time-to-event-wk-50th-loci           2.1                5.7
time-to-event-wk-50th-hici           7.3               15.6

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.61010   0.21670   0.39900   0.93310   0.02264
```

```
$`Skin and subcutaneous tissue disorders`
$`Skin and subcutaneous tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0              80.0
n_event                             15.0              23.0
n_event_pct                         37.0              29.0
time-to-event-wk-10th                4.3               4.4
time-to-event-wk-25th                8.1              33.9
time-to-event-wk-50th               53.9                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          20.9              49.1
time-to-event-wk-50th-hici            NA                NA

$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6660    0.3349    0.3455    1.2840    0.2248



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs nach SOC, das bei mindestens 10 Patienten
und 1% der Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0              80.0
n_event                             13.0              18.0
n_event_pct                         32.0              22.0
time-to-event-wk-10th                4.6               8.1
time-to-event-wk-25th               15.1              47.1
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          29.4                NA
time-to-event-wk-50th-hici            NA                NA

$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5914    0.3647    0.2894    1.2090    0.1497


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0              80.0
n_event                             26.0              53.0
n_event_pct                         63.0              66.0
time-to-event-wk-10th                2.7               1.0
time-to-event-wk-25th                5.6               4.4
```

```
time-to-event-wk-50th                15.9               13.9
time-to-event-wk-75th                39.7                 NA
time-to-event-wk-90th                43.0                 NA
time-to-event-wk-50th-loci            9.7                7.1
time-to-event-wk-50th-hici           26.1               18.7

$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0110    0.2425    0.6284    1.6260    0.9647


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              28.0               51.0
n_event_pct                          68.0               64.0
time-to-event-wk-10th                 2.1                2.5
time-to-event-wk-25th                 5.1                7.6
time-to-event-wk-50th                13.4               25.1
time-to-event-wk-75th                22.7               46.7
time-to-event-wk-90th                42.6                 NA
time-to-event-wk-50th-loci            6.4               15.3
time-to-event-wk-50th-hici           18.0               36.3

$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.58680   0.24090   0.36590   0.94090   0.02691


$`Infections and infestations`
$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              31.0               65.0
n_event_pct                          76.0               81.0
time-to-event-wk-10th                 2.3                1.7
time-to-event-wk-25th                 5.3                4.0
time-to-event-wk-50th                 8.6                9.4
time-to-event-wk-75th                23.9               21.1
time-to-event-wk-90th                38.1               34.7
time-to-event-wk-50th-loci            6.1                6.7
time-to-event-wk-50th-hici           15.3               13.0

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1450    0.2220    0.7409    1.7690    0.5426


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              10.0               19.0
```

```
n_event_pct                          24.0               24.0
time-to-event-wk-10th                 7.7                5.7
time-to-event-wk-25th                34.4               43.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           34.4               51.1
time-to-event-wk-50th-hici             NA                 NA

$`Injury, poisoning and procedural complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7481    0.3948    0.3451    1.6220    0.4622


$Investigations
$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              14.0               21.0
n_event_pct                          34.0               26.0
time-to-event-wk-10th                 6.3                5.4
time-to-event-wk-25th                18.9               33.6
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           27.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6565    0.3473    0.3324    1.2970    0.2256


$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              13.0               14.0
n_event_pct                          32.0               18.0
time-to-event-wk-10th                 6.0                9.7
time-to-event-wk-25th                13.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44030   0.38730   0.20610   0.94060   0.03417


$`Musculoskeletal and connective tissue disorders`
$`Musculoskeletal and connective tissue disorders`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               5.0               11.0
n_event_pct                          12.0               14.0
time-to-event-wk-10th                46.9               31.9
time-to-event-wk-25th                56.4               63.0
time-to-event-wk-50th                  NA               63.0
time-to-event-wk-75th                  NA               63.0
time-to-event-wk-90th                  NA               63.0
time-to-event-wk-50th-loci           56.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Musculoskeletal and connective tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9695    0.5491    0.3305    2.8440    0.9550


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              36.0               61.0
n_event_pct                          88.0               76.0
time-to-event-wk-10th                 0.6                0.6
time-to-event-wk-25th                 1.1                3.1
time-to-event-wk-50th                 4.6                9.1
time-to-event-wk-75th                11.0               32.1
time-to-event-wk-90th                27.0                 NA
time-to-event-wk-50th-loci            2.1                5.7
time-to-event-wk-50th-hici            7.3               15.6

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.61010   0.21670   0.39900   0.93310   0.02264


$`Skin and subcutaneous tissue disorders`
$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              15.0               23.0
n_event_pct                          37.0               29.0
time-to-event-wk-10th                 4.3                4.4
time-to-event-wk-25th                 8.1               33.9
time-to-event-wk-50th                53.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.9               49.1
time-to-event-wk-50th-hici             NA                 NA

$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6660    0.3349    0.3455    1.2840    0.2248
```

```
\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem UE nach PT, das bei mindestens 10% der
Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event       10  11
n_event_pct   24  14

$`Acute respiratory failure`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5637500 0.39245235  0.2612345 1.2165854 0.1441753
OR_TRTvsCTRL   0.4942029 0.48750375  0.1900822 1.2848997 0.1482470
ARR_TRTvsCTRL -0.1064024 0.07733256 -0.2579715 0.0451666 0.1688503


$Atelectasis
$Atelectasis$ntab
            CTRL TRT
n_all         41  80
n_event       12  18
n_event_pct   29  22

$Atelectasis$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.76875000 0.31937227  0.4110882 1.43759084 0.4102479
OR_TRTvsCTRL   0.70161290 0.43531676  0.2989202 1.64679623 0.4156113
ARR_TRTvsCTRL -0.06768293 0.08502321 -0.2343254 0.09895951 0.4260016


$`Bronchial secretion retention`
$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         41  80
n_event        7   4
n_event_pct   17   5

$`Bronchial secretion retention`$stats
                estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.2928571 0.59662962  0.09095022 0.942991702 0.03955690
OR_TRTvsCTRL   0.2556391 0.65986878  0.07013680 0.931769729 0.03872846
ARR_TRTvsCTRL -0.1207317 0.06361587 -0.24541652 0.003953109 0.05771931


$Bronchiolitis
$Bronchiolitis$ntab
            CTRL TRT
n_all         41  80
n_event        3   8
```

```
n_event_pct    7  10

$Bronchiolitis$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.36666667 0.64918648  0.38289004 4.8781049 0.6303895
OR_TRTvsCTRL  1.40740741 0.70607224  0.35270373 5.6160325 0.6283755
ARR_TRTvsCTRL 0.02682927 0.05271686 -0.07649389 0.1301524 0.6108003


$`Cardio-respiratory arrest`
$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         41  80
n_event        5   5
n_event_pct   12   6

$`Cardio-respiratory arrest`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.51250000 0.60258589  0.1573156 1.66961336 0.2672965
OR_TRTvsCTRL   0.48000000 0.66416196  0.1305887 1.76431824 0.2691138
ARR_TRTvsCTRL -0.05945122 0.05782826 -0.1727925 0.05389009 0.3039192


$Constipation
$Constipation$ntab
            CTRL TRT
n_all         41  80
n_event        9  28
n_event_pct   22  35

$Constipation$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.5944444 0.33156470  0.83249379 3.0537802 0.1594150
OR_TRTvsCTRL  1.9145299 0.44419159  0.80161455 4.5725527 0.1437017
ARR_TRTvsCTRL 0.1304878 0.08380004 -0.03375726 0.2947329 0.1194389


$Cough
$Cough$ntab
            CTRL TRT
n_all         41  80
n_event        8   9
n_event_pct   20  11

$Cough$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57656250 0.44634165  0.2403918 1.3828437 0.2172981
OR_TRTvsCTRL   0.52288732 0.52962123  0.1851798 1.4764628 0.2208576
ARR_TRTvsCTRL -0.08262195 0.07126373 -0.2222963 0.0570524 0.2463001


$Diarrhoea
$Diarrhoea$ntab
            CTRL TRT
```

```
n_all         41  80
n_event        7  11
n_event_pct   17  14

$Diarrhoea$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.80535714 0.44370710  0.3375238 1.921643 0.6256450
OR_TRTvsCTRL   0.77432712 0.52694473  0.2756692 2.175007 0.6274170
ARR_TRTvsCTRL -0.03323171 0.07025419 -0.1709274 0.104464 0.6361982


$Dysphagia
$Dysphagia$ntab
            CTRL TRT
n_all         41  80
n_event        9   9
n_event_pct   22  11

$Dysphagia$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5125000 0.43050201  0.2204194 1.19162016 0.1204870
OR_TRTvsCTRL   0.4507042 0.51725886  0.1635310 1.24217610 0.1233883
ARR_TRTvsCTRL -0.1070122 0.07366644 -0.2513958 0.03737137 0.1463185


$Dyspnoea
$Dyspnoea$ntab
            CTRL TRT
n_all         41  80
n_event        6   7
n_event_pct   15   9

$Dyspnoea$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.59791667 0.52214324  0.2148778 1.66375661 0.3246308
OR_TRTvsCTRL   0.55936073 0.59312214  0.1749144 1.78878626 0.3273350
ARR_TRTvsCTRL -0.05884146 0.06360042 -0.1834960 0.06581307 0.3548754


$`Gastrooesophageal reflux disease`
$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         41  80
n_event        8  10
n_event_pct   20  12

$`Gastrooesophageal reflux disease`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.64062500 0.4337162  0.2737940 1.49893843 0.3045459
OR_TRTvsCTRL   0.58928571 0.5192194  0.2129931 1.63037022 0.3084228
ARR_TRTvsCTRL -0.07012195 0.0720948 -0.2114252 0.07118126 0.3307346


$`Nasal congestion`
```

```
$`Nasal congestion`$ntab
            CTRL TRT
n_all         41  80
n_event        5   8
n_event_pct   12  10

$`Nasal congestion`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.82000000 0.53675856  0.2863678 2.34802962 0.7115903
OR_TRTvsCTRL   0.80000000 0.60553007  0.2441529 2.62130839 0.7124934
ARR_TRTvsCTRL -0.02195122 0.06112844 -0.1417608 0.09785832 0.7195203


$Nasopharyngitis
$Nasopharyngitis$ntab
            CTRL TRT
n_all         41  80
n_event        4  15
n_event_pct   10  19

$Nasopharyngitis$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.92187500 0.52893896  0.68154020 5.4194947 0.2167871
OR_TRTvsCTRL  2.13461538 0.59923143  0.65955788 6.9085412 0.2057166
ARR_TRTvsCTRL 0.08993902 0.06365283 -0.03481823 0.2146963 0.1576669


$`Oxygen saturation decreased`
$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         41  80
n_event       10  10
n_event_pct   24  12

$`Oxygen saturation decreased`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5125000 0.40386849  0.2322311 1.13101236 0.09789827
OR_TRTvsCTRL   0.4428571 0.49653175  0.1673459 1.17195853 0.10092313
ARR_TRTvsCTRL -0.1189024 0.07658388 -0.2690041 0.03119921 0.12052402


$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all         41  80
n_event        7  23
n_event_pct   17  29

$Pneumonia$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.6839286 0.38658138  0.78934162 3.5923805 0.1776436
OR_TRTvsCTRL  1.9598997 0.48300210  0.76050439 5.0508677 0.1635751
ARR_TRTvsCTRL 0.1167683 0.07754854 -0.03522405 0.2687606 0.1321328
```

```
$`Pneumonia aspiration`
$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         41  80
n_event        7   9
n_event_pct   17  11

$`Pneumonia aspiration`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.65892857 0.46591631  0.2643928 1.64220369 0.3706207
OR_TRTvsCTRL   0.61569416 0.54540309  0.2114059 1.79313499 0.3738636
ARR_TRTvsCTRL -0.05823171 0.06856585 -0.1926183 0.07615489 0.3957247


$Pyrexia
$Pyrexia$ntab
            CTRL TRT
n_all         41  80
n_event       24  45
n_event_pct   59  56

$Pyrexia$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.96093750 0.16431264  0.6963570 1.3260452 0.8083923
OR_TRTvsCTRL   0.91071429 0.38895224  0.4249183 1.9519060 0.8099765
ARR_TRTvsCTRL -0.02286585 0.09484721 -0.2087630 0.1630313 0.8094924


$Rash
$Rash$ntab
            CTRL TRT
n_all         41  80
n_event        4   9
n_event_pct   10  11

$Rash$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.15312500 0.56940396  0.37774512 3.5200912 0.8024180
OR_TRTvsCTRL  1.17253521 0.63421025  0.33828687 4.0641211 0.8018367
ARR_TRTvsCTRL 0.01493902 0.05827034 -0.09926875 0.1291468 0.7976618


$`Respiratory distress`
$`Respiratory distress`$ntab
            CTRL TRT
n_all         41  80
n_event       12  21
n_event_pct   29  26

$`Respiratory distress`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.89687500 0.30669551  0.4916683 1.6360313 0.7226827
OR_TRTvsCTRL   0.86016949 0.42706474  0.3724482 1.9865624 0.7243132
```

```
ARR_TRTvsCTRL -0.03018293 0.08642442 -0.1995717 0.1392058 0.7269086


$`Respiratory failure`
$`Respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event       16  20
n_event_pct   39  25

$`Respiratory failure`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6406250 0.27497228  0.3737206 1.09814759 0.1053449
OR_TRTvsCTRL   0.5208333 0.41129876  0.2325951 1.16626410 0.1127364
ARR_TRTvsCTRL -0.1402439 0.09026348 -0.3171571 0.03666927 0.1202519


$`Respiratory tract infection`
$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        2   9
n_event_pct    5  11

$`Respiratory tract infection`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.30625000 0.75777363  0.52226185 10.1841424 0.2701426
OR_TRTvsCTRL  2.47183099 0.80674447  0.50853006 12.0149208 0.2619721
ARR_TRTvsCTRL 0.06371951 0.04878296 -0.03189334  0.1593324 0.1914901


$`Rhinovirus infection`
$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         41  80
n_event        6  10
n_event_pct   15  12

$`Rhinovirus infection`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85416667 0.4793500  0.3338252 2.1855768 0.7422774
OR_TRTvsCTRL   0.83333333 0.5563486  0.2800618 2.4796111 0.7431302
ARR_TRTvsCTRL -0.02134146 0.0664391 -0.1515597 0.1088768 0.7480449


$Tachycardia
$Tachycardia$ntab
            CTRL TRT
n_all         41  80
n_event        5   7
n_event_pct   12   9

$Tachycardia$stats
                 estimate         se     lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.71750000 0.55314275  0.2426532 2.12157244 0.5483898
OR_TRTvsCTRL   0.69041096 0.61994641  0.2048370 2.32705698 0.5501195
ARR_TRTvsCTRL -0.03445122 0.06008105 -0.1522079 0.08330548 0.5663655


$Teething
$Teething$ntab
            CTRL TRT
n_all         41  80
n_event        3  14
n_event_pct    7  18

$Teething$stats
               estimate         se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  2.3916667 0.60652425  0.72849450 7.8519048 0.15052361
OR_TRTvsCTRL  2.6868687 0.66800390  0.72550514 9.9506716 0.13898087
ARR_TRTvsCTRL 0.1018293 0.05881118 -0.01343853 0.2170971 0.08336958


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        9  24
n_event_pct   22  30

$`Upper respiratory tract infection`$stats
               estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3666667 0.34042258  0.7012847 2.6633659 0.3588238
OR_TRTvsCTRL  1.5238095 0.44931606  0.6316437 3.6761160 0.3485247
ARR_TRTvsCTRL 0.0804878 0.08248453 -0.0811789 0.2421545 0.3291672


$`Viral infection`
$`Viral infection`$ntab
            CTRL TRT
n_all         41  80
n_event        3   8
n_event_pct    7  10

$`Viral infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.36666667 0.64918648  0.38289004 4.8781049 0.6303895
OR_TRTvsCTRL  1.40740741 0.70607224  0.35270373 5.6160325 0.6283755
ARR_TRTvsCTRL 0.02682927 0.05271686 -0.07649389 0.1301524 0.6108003


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        7   8
n_event_pct   17  10
```

```
$`Viral upper respiratory tract infection`$stats
                  estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.58571429 0.48059016  0.2283530 1.50232848 0.2656849
OR_TRTvsCTRL   0.53968254 0.55781520  0.1808528 1.61046587 0.2688580
ARR_TRTvsCTRL -0.07073171 0.06766261 -0.2033480 0.06188458 0.2958572


$Vomiting
$Vomiting$ntab
            CTRL TRT
n_all         41  80
n_event        8  14
n_event_pct   20  18

$Vomiting$stats
                  estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.89687500 0.3994225  0.4099613 1.962099 0.7852450
OR_TRTvsCTRL   0.87500000 0.4918161  0.3337132 2.294260 0.7860013
ARR_TRTvsCTRL -0.02012195 0.0750677 -0.1672519 0.127008 0.7886603



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem UE nach PT, das bei mindestens 10 Patienten
und 1% der Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event       10  11
n_event_pct   24  14

$`Acute respiratory failure`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5637500 0.39245235  0.2612345 1.2165854 0.1441753
OR_TRTvsCTRL   0.4942029 0.48750375  0.1900822 1.2848997 0.1482470
ARR_TRTvsCTRL -0.1064024 0.07733256 -0.2579715 0.0451666 0.1688503


$Atelectasis
$Atelectasis$ntab
            CTRL TRT
n_all         41  80
n_event       12  18
n_event_pct   29  22

$Atelectasis$stats
                  estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.76875000 0.31937227  0.4110882 1.43759084 0.4102479
OR_TRTvsCTRL   0.70161290 0.43531676  0.2989202 1.64679623 0.4156113
ARR_TRTvsCTRL -0.06768293 0.08502321 -0.2343254 0.09895951 0.4260016
```

```
$Constipation
$Constipation$ntab
            CTRL TRT
n_all         41  80
n_event        9  28
n_event_pct   22  35

$Constipation$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.5944444 0.33156470  0.83249379 3.0537802 0.1594150
OR_TRTvsCTRL  1.9145299 0.44419159  0.80161455 4.5725527 0.1437017
ARR_TRTvsCTRL 0.1304878 0.08380004 -0.03375726 0.2947329 0.1194389


$Diarrhoea
$Diarrhoea$ntab
            CTRL TRT
n_all         41  80
n_event        7  11
n_event_pct   17  14

$Diarrhoea$stats
                 estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.80535714 0.44370710  0.3375238 1.921643 0.6256450
OR_TRTvsCTRL   0.77432712 0.52694473  0.2756692 2.175007 0.6274170
ARR_TRTvsCTRL -0.03323171 0.07025419 -0.1709274 0.104464 0.6361982


$`Gastrooesophageal reflux disease`
$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         41  80
n_event        8  10
n_event_pct   20  12

$`Gastrooesophageal reflux disease`$stats
                 estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.64062500 0.4337162  0.2737940 1.49893843 0.3045459
OR_TRTvsCTRL   0.58928571 0.5192194  0.2129931 1.63037022 0.3084228
ARR_TRTvsCTRL -0.07012195 0.0720948 -0.2114252 0.07118126 0.3307346


$Nasopharyngitis
$Nasopharyngitis$ntab
            CTRL TRT
n_all         41  80
n_event        4  15
n_event_pct   10  19

$Nasopharyngitis$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.92187500 0.52893896  0.68154020 5.4194947 0.2167871
OR_TRTvsCTRL  2.13461538 0.59923143  0.65955788 6.9085412 0.2057166
```

```
ARR_TRTvsCTRL 0.08993902 0.06365283 -0.03481823 0.2146963 0.1576669


$`Oxygen saturation decreased`
$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         41  80
n_event       10  10
n_event_pct   24  12

$`Oxygen saturation decreased`$stats
                 estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5125000 0.40386849  0.2322311 1.13101236 0.09789827
OR_TRTvsCTRL   0.4428571 0.49653175  0.1673459 1.17195853 0.10092313
ARR_TRTvsCTRL -0.1189024 0.07658388 -0.2690041 0.03119921 0.12052402


$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all         41  80
n_event        7  23
n_event_pct   17  29

$Pneumonia$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.6839286 0.38658138  0.78934162 3.5923805 0.1776436
OR_TRTvsCTRL  1.9598997 0.48300210  0.76050439 5.0508677 0.1635751
ARR_TRTvsCTRL 0.1167683 0.07754854 -0.03522405 0.2687606 0.1321328


$Pyrexia
$Pyrexia$ntab
            CTRL TRT
n_all         41  80
n_event       24  45
n_event_pct   59  56

$Pyrexia$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.96093750 0.16431264  0.6963570 1.3260452 0.8083923
OR_TRTvsCTRL   0.91071429 0.38895224  0.4249183 1.9519060 0.8099765
ARR_TRTvsCTRL -0.02286585 0.09484721 -0.2087630 0.1630313 0.8094924


$`Respiratory distress`
$`Respiratory distress`$ntab
            CTRL TRT
n_all         41  80
n_event       12  21
n_event_pct   29  26

$`Respiratory distress`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.89687500 0.30669551  0.4916683 1.6360313 0.7226827
OR_TRTvsCTRL   0.86016949 0.42706474  0.3724482 1.9865624 0.7243132
ARR_TRTvsCTRL -0.03018293 0.08642442 -0.1995717 0.1392058 0.7269086


$`Respiratory failure`
$`Respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event       16  20
n_event_pct   39  25

$`Respiratory failure`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6406250 0.27497228  0.3737206 1.09814759 0.1053449
OR_TRTvsCTRL   0.5208333 0.41129876  0.2325951 1.16626410 0.1127364
ARR_TRTvsCTRL -0.1402439 0.09026348 -0.3171571 0.03666927 0.1202519


$`Rhinovirus infection`
$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         41  80
n_event        6  10
n_event_pct   15  12

$`Rhinovirus infection`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85416667 0.4793500  0.3338252 2.1855768 0.7422774
OR_TRTvsCTRL   0.83333333 0.5563486  0.2800618 2.4796111 0.7431302
ARR_TRTvsCTRL -0.02134146 0.0664391 -0.1515597 0.1088768 0.7480449


$Teething
$Teething$ntab
            CTRL TRT
n_all         41  80
n_event        3  14
n_event_pct    7  18

$Teething$stats
               estimate         se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  2.3916667 0.60652425  0.72849450 7.8519048 0.15052361
OR_TRTvsCTRL  2.6868687 0.66800390  0.72550514 9.9506716 0.13898087
ARR_TRTvsCTRL 0.1018293 0.05881118 -0.01343853 0.2170971 0.08336958


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        9  24
n_event_pct   22  30
```

```
$`Upper respiratory tract infection`$stats
               estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3666667 0.34042258  0.7012847 2.6633659 0.3588238
OR_TRTvsCTRL  1.5238095 0.44931606  0.6316437 3.6761160 0.3485247
ARR_TRTvsCTRL 0.0804878 0.08248453 -0.0811789 0.2421545 0.3291672


$Vomiting
$Vomiting$ntab
            CTRL TRT
n_all         41  80
n_event        8  14
n_event_pct   20  18

$Vomiting$stats
                  estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.89687500 0.3994225  0.4099613 1.962099 0.7852450
OR_TRTvsCTRL   0.87500000 0.4918161  0.3337132 2.294260 0.7860013
ARR_TRTvsCTRL -0.02012195 0.0750677 -0.1672519 0.127008 0.7886603



\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs nach PT, das bei mindestens 10% der
Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                              10.0                11.0
n_event_pct                          24.0                14.0
time-to-event-wk-10th                 8.6                19.9
time-to-event-wk-25th                26.0                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           52.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47740   0.43890   0.20190   1.12800   0.09205


$Atelectasis
$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                              12.0                18.0
n_event_pct                          29.0                22.0
time-to-event-wk-10th                 4.0                 9.6
time-to-event-wk-25th                17.6                44.0
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6360    0.3737    0.3058    1.3230    0.2258


$`Bronchial secretion retention`
$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               7.0                  4
n_event_pct                          17.0                  5
time-to-event-wk-10th                 6.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25730   0.62800   0.07515   0.88120   0.03067


$Bronchiolitis
$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  41                80.0
n_event                                 3                 8.0
n_event_pct                             7                10.0
time-to-event-wk-10th                  NA                32.1
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2960    0.6776    0.3433    4.8900    0.7023


$`Cardio-respiratory arrest`
$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  41                  80
n_event                                 5                   5
```

```
n_event_pct                              12                  6
time-to-event-wk-10th                    23                 NA
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               NA                 NA
time-to-event-wk-50th-hici               NA                 NA

$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4327    0.6331    0.1251    1.4970    0.1858


$Constipation
$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               9.0               28.0
n_event_pct                          22.0               35.0
time-to-event-wk-10th                15.9                6.0
time-to-event-wk-25th                40.7               18.7
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7               35.0
time-to-event-wk-50th-hici             NA                 NA

$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5280    0.3849    0.7187    3.2490    0.2705


$Cough
$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               8.0                  9
n_event_pct                          20.0                 11
time-to-event-wk-10th                 4.4                 28
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42750   0.48920   0.16390   1.11500   0.08233


$Diarrhoea
$Diarrhoea$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80
n_event                               7.0                11
n_event_pct                          17.0                14
time-to-event-wk-10th                 9.4                28
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5697    0.4926    0.2170    1.4960    0.2534


$Dysphagia
$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                               9.0                 9.0
n_event_pct                          22.0                11.0
time-to-event-wk-10th                 8.0                28.4
time-to-event-wk-25th                26.1                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           27.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40400   0.47510   0.15920   1.02500   0.05646


$Dyspnoea
$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                               6.0                 7.0
n_event_pct                          15.0                 9.0
time-to-event-wk-10th                21.3                43.1
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5108    0.5591    0.1707    1.5280    0.2296
```

```
$`Gastrooesophageal reflux disease`
$`Gastrooesophageal reflux disease`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              8.0               10.0
n_event_pct                         20.0               12.0
time-to-event-wk-10th               10.9               20.6
time-to-event-wk-25th               48.6                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          48.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5747    0.4782    0.2251    1.4670    0.2468


$`Nasal congestion`
$`Nasal congestion`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              5.0                8.0
n_event_pct                         12.0               10.0
time-to-event-wk-10th                7.9               32.1
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7152    0.5719    0.2331    2.1940    0.5578


$Nasopharyngitis
$Nasopharyngitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              4.0               15.0
n_event_pct                         10.0               19.0
time-to-event-wk-10th               28.3               11.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Nasopharyngitis$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7500    0.5630    0.5804    5.2740    0.3204


$`Oxygen saturation decreased`
$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              10.0               10.0
n_event_pct                          24.0               12.0
time-to-event-wk-10th                10.1               25.1
time-to-event-wk-25th                27.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42290   0.44910   0.17540   1.02000   0.05531


$Pneumonia
$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               7.0               23.0
n_event_pct                          17.0               29.0
time-to-event-wk-10th                11.3                8.1
time-to-event-wk-25th                  NA               25.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               43.6
time-to-event-wk-50th-hici             NA                 NA

$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5480    0.4322    0.6636    3.6110    0.3119


$`Pneumonia aspiration`
$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  41               80.0
n_event                                 7                9.0
n_event_pct                            17               11.0
time-to-event-wk-10th                   9               32.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5531    0.5056    0.2053    1.4900    0.2414


$Pyrexia
$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              24.0               45.0
n_event_pct                          59.0               56.0
time-to-event-wk-10th                 3.1                3.3
time-to-event-wk-25th                 6.4               10.3
time-to-event-wk-50th                16.0               32.1
time-to-event-wk-75th                42.6               54.3
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.4               23.4
time-to-event-wk-50th-hici           37.7               38.6

$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6877    0.2554    0.4169    1.1340    0.1426


$Rash
$Rash$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               4.0                9.0
n_event_pct                          10.0               11.0
time-to-event-wk-10th                 5.9               33.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9245    0.6033    0.2834    3.0160    0.8965


$`Respiratory distress`
$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              12.0               21.0
n_event_pct                          29.0               26.0
time-to-event-wk-10th                11.0                7.1
time-to-event-wk-25th                28.1               25.9
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           28.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7637    0.3637    0.3744    1.5580    0.4586


$`Respiratory failure`
$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                80.0
n_event                             16.0                20.0
n_event_pct                         39.0                25.0
time-to-event-wk-10th                4.6                 5.1
time-to-event-wk-25th               13.0                32.1
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci          15.7                  NA
time-to-event-wk-50th-hici            NA                  NA

$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.53990   0.33820   0.27820   1.04800   0.06841


$`Respiratory tract infection`
$`Respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41                80.0
n_event                              2                 9.0
n_event_pct                          5                11.0
time-to-event-wk-10th               NA                30.7
time-to-event-wk-25th               NA                  NA
time-to-event-wk-50th               NA                  NA
time-to-event-wk-75th               NA                  NA
time-to-event-wk-90th               NA                  NA
time-to-event-wk-50th-loci          NA                  NA
time-to-event-wk-50th-hici          NA                  NA

$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0580    0.7821    0.4443    9.5320    0.3561


$`Rhinovirus infection`
$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                 80
n_event                              6.0                 10
n_event_pct                         15.0                 12
```

```
time-to-event-wk-10th                 9.9                  18
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8173    0.5174    0.2965    2.2530    0.6966


$Tachycardia
$Tachycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               5.0                  7
n_event_pct                          12.0                  9
time-to-event-wk-10th                 4.6                 35
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6416    0.5873    0.2029    2.0280    0.4498


$Teething
$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41                80.0
n_event                               3                14.0
n_event_pct                           7                18.0
time-to-event-wk-10th                NA                 6.6
time-to-event-wk-25th                NA                  NA
time-to-event-wk-50th                NA                  NA
time-to-event-wk-75th                NA                  NA
time-to-event-wk-90th                NA                  NA
time-to-event-wk-50th-loci           NA                  NA
time-to-event-wk-50th-hici           NA                  NA

$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3560    0.6380    0.6747    8.2260    0.1792


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                41.0               80.0
n_event                               9.0               24.0
n_event_pct                          22.0               30.0
time-to-event-wk-10th                 8.7               16.3
time-to-event-wk-25th                32.6               26.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.6               35.3
time-to-event-wk-50th-hici             NA                 NA

$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2010    0.3922    0.5568    2.5900    0.6408


$`Viral infection`
$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80
n_event                               3.0                 8
n_event_pct                           7.0                10
time-to-event-wk-10th                45.7                41
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2500    0.6777    0.3311    4.7160    0.7423


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               7.0                8.0
n_event_pct                          17.0               10.0
time-to-event-wk-10th                17.6               18.9
time-to-event-wk-25th                37.3                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5092    0.5188    0.1842    1.4080    0.1933
```

```
$Vomiting
$Vomiting$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                80.0
n_event                              8.0                14.0
n_event_pct                         20.0                18.0
time-to-event-wk-10th               12.0                13.1
time-to-event-wk-25th               47.7                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci          47.7                  NA
time-to-event-wk-50th-hici            NA                  NA

$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7634    0.4441    0.3197    1.8230    0.5432



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs nach PT, das bei mindestens 10 Patienten
und 1% der Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                80.0
n_event                             10.0                11.0
n_event_pct                         24.0                14.0
time-to-event-wk-10th                8.6                19.9
time-to-event-wk-25th               26.0                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci          52.6                  NA
time-to-event-wk-50th-hici            NA                  NA

$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47740   0.43890   0.20190   1.12800   0.09205


$Atelectasis
$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                80.0
n_event                             12.0                18.0
n_event_pct                         29.0                22.0
time-to-event-wk-10th                4.0                 9.6
time-to-event-wk-25th               17.6                44.0
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           32.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6360    0.3737    0.3058    1.3230    0.2258


$Constipation
$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                               9.0                28.0
n_event_pct                          22.0                35.0
time-to-event-wk-10th                15.9                 6.0
time-to-event-wk-25th                40.7                18.7
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           40.7                35.0
time-to-event-wk-50th-hici             NA                  NA

$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5280    0.3849    0.7187    3.2490    0.2705


$Diarrhoea
$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                  80
n_event                               7.0                  11
n_event_pct                          17.0                  14
time-to-event-wk-10th                 9.4                  28
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5697    0.4926    0.2170    1.4960    0.2534


$`Gastrooesophageal reflux disease`
$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                               8.0                10.0
n_event_pct                          20.0                12.0
time-to-event-wk-10th                10.9                20.6
```

```
time-to-event-wk-25th                48.6                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           48.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5747    0.4782    0.2251    1.4670    0.2468


$Nasopharyngitis
$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               4.0               15.0
n_event_pct                          10.0               19.0
time-to-event-wk-10th                28.3               11.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7500    0.5630    0.5804    5.2740    0.3204


$`Oxygen saturation decreased`
$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              10.0               10.0
n_event_pct                          24.0               12.0
time-to-event-wk-10th                10.1               25.1
time-to-event-wk-25th                27.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42290   0.44910   0.17540   1.02000   0.05531


$Pneumonia
$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
```

```
n_event                                7.0               23.0
n_event_pct                           17.0               29.0
time-to-event-wk-10th                 11.3                8.1
time-to-event-wk-25th                   NA               25.4
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA               43.6
time-to-event-wk-50th-hici              NA                 NA

$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5480    0.4322    0.6636    3.6110    0.3119


$Pyrexia
$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              24.0               45.0
n_event_pct                          59.0               56.0
time-to-event-wk-10th                 3.1                3.3
time-to-event-wk-25th                 6.4               10.3
time-to-event-wk-50th                16.0               32.1
time-to-event-wk-75th                42.6               54.3
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.4               23.4
time-to-event-wk-50th-hici           37.7               38.6

$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6877    0.2554    0.4169    1.1340    0.1426


$`Respiratory distress`
$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              12.0               21.0
n_event_pct                          29.0               26.0
time-to-event-wk-10th                11.0                7.1
time-to-event-wk-25th                28.1               25.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7637    0.3637    0.3744    1.5580    0.4586


$`Respiratory failure`
```

```
$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                             16.0               20.0
n_event_pct                         39.0               25.0
time-to-event-wk-10th                4.6                5.1
time-to-event-wk-25th               13.0               32.1
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          15.7                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.53990   0.33820   0.27820   1.04800   0.06841


$`Rhinovirus infection`
$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                 80
n_event                              6.0                 10
n_event_pct                         15.0                 12
time-to-event-wk-10th                9.9                 18
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8173    0.5174    0.2965    2.2530    0.6966


$Teething
$Teething$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41                80.0
n_event                              3                14.0
n_event_pct                          7                18.0
time-to-event-wk-10th               NA                 6.6
time-to-event-wk-25th               NA                  NA
time-to-event-wk-50th               NA                  NA
time-to-event-wk-75th               NA                  NA
time-to-event-wk-90th               NA                  NA
time-to-event-wk-50th-loci          NA                  NA
time-to-event-wk-50th-hici          NA                  NA

$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3560    0.6380    0.6747    8.2260    0.1792
```

```
$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               9.0               24.0
n_event_pct                          22.0               30.0
time-to-event-wk-10th                 8.7               16.3
time-to-event-wk-25th                32.6               26.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.6               35.3
time-to-event-wk-50th-hici             NA                 NA

$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2010    0.3922    0.5568    2.5900    0.6408


$Vomiting
$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               8.0               14.0
n_event_pct                          20.0               18.0
time-to-event-wk-10th                12.0               13.1
time-to-event-wk-25th                47.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           47.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7634    0.4441    0.3197    1.8230    0.5432



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem milden UE nach SOC, das bei mindestens 10%
der Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        7   9
n_event_pct   17  11

$`Cardiac disorders`$stats
```

```
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.65892857 0.46591631  0.2643928 1.64220369 0.3706207
OR_TRTvsCTRL   0.61569416 0.54540309  0.2114059 1.79313499 0.3738636
ARR_TRTvsCTRL -0.05823171 0.06856585 -0.1926183 0.07615489 0.3957247


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       23  45
n_event_pct   56  56

$`Gastrointestinal disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.00271739 0.16973579  0.7189508 1.3984853 0.9872441
OR_TRTvsCTRL  1.00621118 0.38707553  0.4712050 2.1486636 0.9872369
ARR_TRTvsCTRL 0.00152439 0.09530503 -0.1852700 0.1883188 0.9872385


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         41  80
n_event       22  37
n_event_pct   54  46

$`General disorders and administration site conditions`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.86193182 0.18865664  0.5955087 1.2475494 0.4309520
OR_TRTvsCTRL   0.74312896 0.38518692  0.3492951 1.5810146 0.4408507
ARR_TRTvsCTRL -0.07408537 0.09577232 -0.2617957 0.1136249 0.4391927


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all         41  80
n_event       24  47
n_event_pct   59  59

$`Infections and infestations`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.003645833 0.16140947  0.7314565 1.3771222 0.9820121
OR_TRTvsCTRL  1.008838384 0.38996131  0.4697707 2.1664929 0.9819971
ARR_TRTvsCTRL 0.002134146 0.09459978 -0.1832780 0.1875463 0.9820015


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         41  80
n_event       10  13
n_event_pct   24  16
```

```
$`Injury, poisoning and procedural complications`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.66625000 0.37420961  0.3199701 1.38728286 0.2778354
OR_TRTvsCTRL   0.60149254 0.47339890  0.2378331 1.52120630 0.2829072
ARR_TRTvsCTRL -0.08140244 0.07873421 -0.2357186 0.07291377 0.3011880


$Investigations
$Investigations$ntab
            CTRL TRT
n_all         41  80
n_event       11  19
n_event_pct   27  24

$Investigations$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88522727 0.32657377  0.4667396 1.6789389 0.7089232
OR_TRTvsCTRL   0.84947839 0.43962194  0.3588769 2.0107552 0.7105816
ARR_TRTvsCTRL -0.03079268 0.08397477 -0.1953802 0.1337948 0.7138505


$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        7  10
n_event_pct   17  12

$`Metabolism and nutrition disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.73214286 0.45383576  0.3008085 1.78197469 0.4920904
OR_TRTvsCTRL   0.69387755 0.53530797  0.2430121 1.98124328 0.4947905
ARR_TRTvsCTRL -0.04573171 0.06942922 -0.1818105 0.09034706 0.5101006


$`Musculoskeletal and connective tissue disorders`
$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        5   9
n_event_pct   12  11

$`Musculoskeletal and connective tissue disorders`$stats
                 estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.92250000 0.52366102  0.3305410 2.574586 0.8775734
OR_TRTvsCTRL   0.91267606 0.59411564  0.2848423 2.924346 0.8777684
ARR_TRTvsCTRL -0.00945122 0.06212675 -0.1312174 0.112315 0.8790860


$`Psychiatric disorders`
$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         41  80
```

```
n_event        3   9
n_event_pct    7  11

$`Psychiatric disorders`$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.53750000 0.63839972  0.4399550 5.373063 0.5004345
OR_TRTvsCTRL  1.60563380 0.69630794  0.4101551 6.285573 0.4964779
ARR_TRTvsCTRL 0.03932927 0.05387128 -0.0662565 0.144915 0.4653535


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       23  39
n_event_pct   56  49

$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.86902174 0.17952449  0.6112503 1.2354983 0.4342179
OR_TRTvsCTRL   0.74443266 0.38608948  0.3492894 1.5865924 0.4446195
ARR_TRTvsCTRL -0.07347561 0.09555064 -0.2607514 0.1138002 0.4419109


$`Skin and subcutaneous tissue disorders`
$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       14  22
n_event_pct   34  28

$`Skin and subcutaneous tissue disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80535714 0.28283011  0.4626399 1.4019546 0.4440518
OR_TRTvsCTRL   0.73152709 0.41371673  0.3251428 1.6458367 0.4498649
ARR_TRTvsCTRL -0.06646341 0.08931253 -0.2415128 0.1085859 0.4567756



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem milden UE nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       23  45
n_event_pct   56  56

$`Gastrointestinal disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.00271739 0.16973579  0.7189508 1.3984853 0.9872441
```

```
OR_TRTvsCTRL  1.00621118 0.38707553  0.4712050 2.1486636 0.9872369
ARR_TRTvsCTRL 0.00152439 0.09530503 -0.1852700 0.1883188 0.9872385


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         41  80
n_event       22  37
n_event_pct   54  46

$`General disorders and administration site conditions`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.86193182 0.18865664  0.5955087 1.2475494 0.4309520
OR_TRTvsCTRL   0.74312896 0.38518692  0.3492951 1.5810146 0.4408507
ARR_TRTvsCTRL -0.07408537 0.09577232 -0.2617957 0.1136249 0.4391927


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all         41  80
n_event       24  47
n_event_pct   59  59

$`Infections and infestations`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.003645833 0.16140947  0.7314565 1.3771222 0.9820121
OR_TRTvsCTRL  1.008838384 0.38996131  0.4697707 2.1664929 0.9819971
ARR_TRTvsCTRL 0.002134146 0.09459978 -0.1832780 0.1875463 0.9820015


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         41  80
n_event       10  13
n_event_pct   24  16

$`Injury, poisoning and procedural complications`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.66625000 0.37420961  0.3199701 1.38728286 0.2778354
OR_TRTvsCTRL   0.60149254 0.47339890  0.2378331 1.52120630 0.2829072
ARR_TRTvsCTRL -0.08140244 0.07873421 -0.2357186 0.07291377 0.3011880


$Investigations
$Investigations$ntab
            CTRL TRT
n_all         41  80
n_event       11  19
n_event_pct   27  24

$Investigations$stats
```

```
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88522727 0.32657377  0.4667396 1.6789389 0.7089232
OR_TRTvsCTRL   0.84947839 0.43962194  0.3588769 2.0107552 0.7105816
ARR_TRTvsCTRL -0.03079268 0.08397477 -0.1953802 0.1337948 0.7138505


$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        7  10
n_event_pct   17  12

$`Metabolism and nutrition disorders`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.73214286 0.45383576  0.3008085 1.78197469 0.4920904
OR_TRTvsCTRL   0.69387755 0.53530797  0.2430121 1.98124328 0.4947905
ARR_TRTvsCTRL -0.04573171 0.06942922 -0.1818105 0.09034706 0.5101006


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       23  39
n_event_pct   56  49

$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.86902174 0.17952449  0.6112503 1.2354983 0.4342179
OR_TRTvsCTRL   0.74443266 0.38608948  0.3492894 1.5865924 0.4446195
ARR_TRTvsCTRL -0.07347561 0.09555064 -0.2607514 0.1138002 0.4419109


$`Skin and subcutaneous tissue disorders`
$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       14  22
n_event_pct   34  28

$`Skin and subcutaneous tissue disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80535714 0.28283011  0.4626399 1.4019546 0.4440518
OR_TRTvsCTRL   0.73152709 0.41371673  0.3251428 1.6458367 0.4498649
ARR_TRTvsCTRL -0.06646341 0.08931253 -0.2415128 0.1085859 0.4567756



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines milden UEs nach SOC, das bei mindestens 10% der
Patienten in einem Studienarm auftrat"
```

```
$`Cardiac disorders`
$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              7.0                9.0
n_event_pct                         17.0               11.0
time-to-event-wk-10th                4.6               22.9
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5718    0.5052    0.2124    1.5390    0.2685


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                             23.0               45.0
n_event_pct                         56.0               56.0
time-to-event-wk-10th                2.7                1.7
time-to-event-wk-25th                7.7                6.0
time-to-event-wk-50th               22.6               18.9
time-to-event-wk-75th               40.3                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          10.9               11.0
time-to-event-wk-50th-hici          39.7               35.0

$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9316    0.2577    0.5622    1.5440    0.7834


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                             22.0               37.0
n_event_pct                         54.0               46.0
time-to-event-wk-10th                3.1                3.1
time-to-event-wk-25th                6.4               12.9
time-to-event-wk-50th               22.7               38.0
time-to-event-wk-75th               43.4                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           9.4               30.6
time-to-event-wk-50th-hici          42.6                 NA

$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
  0.61660   0.27200   0.36180   1.05100   0.07546


$`Infections and infestations`
$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              24.0               47.0
n_event_pct                          59.0               59.0
time-to-event-wk-10th                 4.4                3.1
time-to-event-wk-25th                 7.4                7.7
time-to-event-wk-50th                19.7               25.6
time-to-event-wk-75th                38.1               55.0
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            9.4               13.3
time-to-event-wk-50th-hici           26.1               35.0

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8521    0.2523    0.5197    1.3970    0.5259


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              10.0               13.0
n_event_pct                          24.0               16.0
time-to-event-wk-10th                 8.7               11.4
time-to-event-wk-25th                26.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           34.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Injury, poisoning and procedural complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49540   0.42600   0.21490   1.14200   0.09919


$Investigations
$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              11.0               19.0
n_event_pct                          27.0               24.0
time-to-event-wk-10th                 6.3                5.4
time-to-event-wk-25th                27.4               36.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.4                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7601    0.3807    0.3604    1.6030    0.4712


$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80
n_event                               7.0                10
n_event_pct                          17.0                12
time-to-event-wk-10th                12.6                14
time-to-event-wk-25th                56.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           56.6                NA
time-to-event-wk-50th-hici             NA                NA

$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6289    0.4940    0.2388    1.6560    0.3478


$`Musculoskeletal and connective tissue disorders`
$`Musculoskeletal and connective tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               5.0                9.0
n_event_pct                          12.0               11.0
time-to-event-wk-10th                46.9               31.9
time-to-event-wk-25th                56.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           56.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Musculoskeletal and connective tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8605    0.5586    0.2879    2.5720    0.7880


$`Psychiatric disorders`
$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  41               80.0
n_event                                 3                9.0
n_event_pct                             7               11.0
time-to-event-wk-10th                  NA               15.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4110    0.6691    0.3801    5.2350    0.6070


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              23.0               39.0
n_event_pct                          56.0               49.0
time-to-event-wk-10th                 1.0                1.7
time-to-event-wk-25th                 4.1                8.9
time-to-event-wk-50th                11.9               32.1
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.0               21.4
time-to-event-wk-50th-hici           43.3                 NA

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6474    0.2652    0.3850    1.0890    0.1011


$`Skin and subcutaneous tissue disorders`
$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              14.0               22.0
n_event_pct                          34.0               28.0
time-to-event-wk-10th                 4.3                4.4
time-to-event-wk-25th                 8.1               33.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.9               49.9
time-to-event-wk-50th-hici             NA                 NA

$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6766    0.3450    0.3441    1.3300    0.2574



\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines milden UEs nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Gastrointestinal disorders`
```

$`Gastrointestinal disorders`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	41.0	80.0
n_event	23.0	45.0
n_event_pct	56.0	56.0
time-to-event-wk-10th	2.7	1.7
time-to-event-wk-25th	7.7	6.0
time-to-event-wk-50th	22.6	18.9
time-to-event-wk-75th	40.3	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	10.9	11.0
time-to-event-wk-50th-hici	39.7	35.0

$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.9316	0.2577	0.5622	1.5440	0.7834

$`General disorders and administration site conditions`

$`General disorders and administration site conditions`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	41.0	80.0
n_event	22.0	37.0
n_event_pct	54.0	46.0
time-to-event-wk-10th	3.1	3.1
time-to-event-wk-25th	6.4	12.9
time-to-event-wk-50th	22.7	38.0
time-to-event-wk-75th	43.4	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	9.4	30.6
time-to-event-wk-50th-hici	42.6	NA

$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.61660	0.27200	0.36180	1.05100	0.07546

$`Infections and infestations`

$`Infections and infestations`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	41.0	80.0
n_event	24.0	47.0
n_event_pct	59.0	59.0
time-to-event-wk-10th	4.4	3.1
time-to-event-wk-25th	7.4	7.7
time-to-event-wk-50th	19.7	25.6
time-to-event-wk-75th	38.1	55.0
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	9.4	13.3
time-to-event-wk-50th-hici	26.1	35.0

$`Infections and infestations`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.8521	0.2523	0.5197	1.3970	0.5259

```
$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              10.0               13.0
n_event_pct                          24.0               16.0
time-to-event-wk-10th                 8.7               11.4
time-to-event-wk-25th                26.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           34.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Injury, poisoning and procedural complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49540   0.42600   0.21490   1.14200   0.09919


$Investigations
$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              11.0               19.0
n_event_pct                          27.0               24.0
time-to-event-wk-10th                 6.3                5.4
time-to-event-wk-25th                27.4               36.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7601    0.3807    0.3604    1.6030    0.4712


$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               7.0                 10
n_event_pct                          17.0                 12
time-to-event-wk-10th                12.6                 14
time-to-event-wk-25th                56.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           56.6                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6289    0.4940    0.2388    1.6560    0.3478


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0              80.0
n_event                              23.0              39.0
n_event_pct                          56.0              49.0
time-to-event-wk-10th                 1.0               1.7
time-to-event-wk-25th                 4.1               8.9
time-to-event-wk-50th                11.9              32.1
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.0              21.4
time-to-event-wk-50th-hici           43.3                NA

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6474    0.2652    0.3850    1.0890    0.1011


$`Skin and subcutaneous tissue disorders`
$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0              80.0
n_event                              14.0              22.0
n_event_pct                          34.0              28.0
time-to-event-wk-10th                 4.3               4.4
time-to-event-wk-25th                 8.1              33.9
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           20.9              49.9
time-to-event-wk-50th-hici             NA                NA

$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6766    0.3450    0.3441    1.3300    0.2574



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem milden UE nach PT, das bei mindestens 10%
der Patienten in einem Studienarm auftrat"

$Atelectasis
$Atelectasis$ntab
           CTRL TRT
n_all        41  80
n_event       2   9
```

```
n_event_pct    5  11

$Atelectasis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.30625000 0.75777363  0.52226185 10.1841424 0.2701426
OR_TRTvsCTRL  2.47183099 0.80674447  0.50853006 12.0149208 0.2619721
ARR_TRTvsCTRL 0.06371951 0.04878296 -0.03189334  0.1593324 0.1914901


$Constipation
$Constipation$ntab
            CTRL TRT
n_all         41  80
n_event        8  25
n_event_pct   20  31

$Constipation$stats
              estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.601562 0.35792423  0.7941056 3.230052 0.1882196
OR_TRTvsCTRL  1.875000 0.46204421  0.7580686 4.637608 0.1736735
ARR_TRTvsCTRL 0.117378 0.08072186 -0.0408339 0.275590 0.1459173


$Cough
$Cough$ntab
            CTRL TRT
n_all         41  80
n_event        7   6
n_event_pct   17   8

$Cough$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.43928571 0.52214324  0.1578694 1.22235179 0.1151550
OR_TRTvsCTRL   0.39382239 0.59367423  0.1230167 1.26077279 0.1164987
ARR_TRTvsCTRL -0.09573171 0.06572988 -0.2245599 0.03309648 0.1452707


$Diarrhoea
$Diarrhoea$ntab
            CTRL TRT
n_all         41  80
n_event        7   9
n_event_pct   17  11

$Diarrhoea$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.65892857 0.46591631  0.2643928 1.64220369 0.3706207
OR_TRTvsCTRL   0.61569416 0.54540309  0.2114059 1.79313499 0.3738636
ARR_TRTvsCTRL -0.05823171 0.06856585 -0.1926183 0.07615489 0.3957247


$`Gastrooesophageal reflux disease`
$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
```

```
n_all         41  80
n_event        6   8
n_event_pct   15  10

$`Gastrooesophageal reflux disease`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.68333333 0.50475382  0.2540887 1.83772211 0.4506255
OR_TRTvsCTRL   0.64814815 0.57803718  0.2087604 2.01233567 0.4531421
ARR_TRTvsCTRL -0.04634146 0.06459076 -0.1729370 0.08025411 0.4730886


$`Nasal congestion`
$`Nasal congestion`$ntab
            CTRL TRT
n_all         41  80
n_event        5   8
n_event_pct   12  10

$`Nasal congestion`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.82000000 0.53675856  0.2863678 2.34802962 0.7115903
OR_TRTvsCTRL   0.80000000 0.60553007  0.2441529 2.62130839 0.7124934
ARR_TRTvsCTRL -0.02195122 0.06112844 -0.1417608 0.09785832 0.7195203


$Nasopharyngitis
$Nasopharyngitis$ntab
            CTRL TRT
n_all         41  80
n_event        3  12
n_event_pct    7  15

$Nasopharyngitis$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.05000000 0.61626003  0.61262170 6.8598615 0.2440867
OR_TRTvsCTRL  2.23529412 0.67652667  0.59357299 8.4177345 0.2344498
ARR_TRTvsCTRL 0.07682927 0.05698963 -0.03486835 0.1885269 0.1776175


$`Oxygen saturation decreased`
$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         41  80
n_event        5   5
n_event_pct   12   6

$`Oxygen saturation decreased`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.51250000 0.60258589  0.1573156 1.66961336 0.2672965
OR_TRTvsCTRL   0.48000000 0.66416196  0.1305887 1.76431824 0.2691138
ARR_TRTvsCTRL -0.05945122 0.05782826 -0.1727925 0.05389009 0.3039192


$Pyrexia
```

```
$Pyrexia$ntab
            CTRL TRT
n_all         41  80
n_event       19  34
n_event_pct   46  42

$Pyrexia$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.91710526 0.21249259  0.6047072 1.3908913 0.6838402
OR_TRTvsCTRL   0.85583524 0.38631208  0.4013846 1.8248182 0.6869604
ARR_TRTvsCTRL -0.03841463 0.09549661 -0.2255845 0.1487553 0.6874914


$Rash
$Rash$ntab
            CTRL TRT
n_all         41  80
n_event        4   8
n_event_pct   10  10

$Rash$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.025000000 0.58147206  0.3279246 3.2038618 0.9661275
OR_TRTvsCTRL  1.027777778 0.64491543  0.2903663 3.6379124 0.9661124
ARR_TRTvsCTRL 0.002439024 0.05720477 -0.1096803 0.1145583 0.9659911


$Tachycardia
$Tachycardia$ntab
            CTRL TRT
n_all         41  80
n_event        5   3
n_event_pct   12   4

$Tachycardia$stats
                 estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.30750000 0.70458718  0.07728575 1.22346292 0.09418605
OR_TRTvsCTRL   0.28051948 0.75769263  0.06353512 1.23854606 0.09342342
ARR_TRTvsCTRL -0.08445122 0.05534309 -0.19292168 0.02401925 0.12702038


$Teething
$Teething$ntab
            CTRL TRT
n_all         41  80
n_event        2   9
n_event_pct    5  11

$Teething$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.30625000 0.75777363  0.52226185 10.1841424 0.2701426
OR_TRTvsCTRL  2.47183099 0.80674447  0.50853006 12.0149208 0.2619721
ARR_TRTvsCTRL 0.06371951 0.04878296 -0.03189334  0.1593324 0.1914901
```

```
$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        5  12
n_event_pct   12  15

$`Upper respiratory tract infection`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.23000000 0.49643035  0.46488211 3.2543735 0.6766744
OR_TRTvsCTRL  1.27058824 0.57080381  0.41508376 3.8893221 0.6748152
ARR_TRTvsCTRL 0.02804878 0.06484933 -0.09905357 0.1551511 0.6653619


$Vomiting
$Vomiting$ntab
            CTRL TRT
n_all         41  80
n_event        6  12
n_event_pct   15  15

$Vomiting$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.025000000 0.46163812  0.4147408 2.5332086 0.9573422
OR_TRTvsCTRL  1.029411765 0.54155084  0.3561396 2.9754869 0.9573121
ARR_TRTvsCTRL 0.003658537 0.06812281 -0.1298597 0.1371768 0.9571702



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem milden UE nach PT, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Constipation
$Constipation$ntab
            CTRL TRT
n_all         41  80
n_event        8  25
n_event_pct   20  31

$Constipation$stats
              estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.601562 0.35792423  0.7941056 3.230052 0.1882196
OR_TRTvsCTRL  1.875000 0.46204421  0.7580686 4.637608 0.1736735
ARR_TRTvsCTRL 0.117378 0.08072186 -0.0408339 0.275590 0.1459173


$Nasopharyngitis
$Nasopharyngitis$ntab
            CTRL TRT
n_all         41  80
n_event        3  12
```

```
n_event_pct    7  15

$Nasopharyngitis$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.05000000 0.61626003  0.61262170 6.8598615 0.2440867
OR_TRTvsCTRL  2.23529412 0.67652667  0.59357299 8.4177345 0.2344498
ARR_TRTvsCTRL 0.07682927 0.05698963 -0.03486835 0.1885269 0.1776175


$Pyrexia
$Pyrexia$ntab
            CTRL TRT
n_all         41  80
n_event       19  34
n_event_pct   46  42

$Pyrexia$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.91710526 0.21249259  0.6047072 1.3908913 0.6838402
OR_TRTvsCTRL   0.85583524 0.38631208  0.4013846 1.8248182 0.6869604
ARR_TRTvsCTRL -0.03841463 0.09549661 -0.2255845 0.1487553 0.6874914


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        5  12
n_event_pct   12  15

$`Upper respiratory tract infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.23000000 0.49643035  0.46488211 3.2543735 0.6766744
OR_TRTvsCTRL  1.27058824 0.57080381  0.41508376 3.8893221 0.6748152
ARR_TRTvsCTRL 0.02804878 0.06484933 -0.09905357 0.1551511 0.6653619


$Vomiting
$Vomiting$ntab
            CTRL TRT
n_all         41  80
n_event        6  12
n_event_pct   15  15

$Vomiting$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.025000000 0.46163812  0.4147408 2.5332086 0.9573422
OR_TRTvsCTRL  1.029411765 0.54155084  0.3561396 2.9754869 0.9573121
ARR_TRTvsCTRL 0.003658537 0.06812281 -0.1298597 0.1371768 0.9571702



\##############################################################################
[[1]]
```

[1] "Zeit bis zum Erleiden eines milden UEs nach PT, das bei mindestens 10% der Patienten in einem Studienarm auftrat"

$Atelectasis
$Atelectasis$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	41	80
n_event	2	9
n_event_pct	5	11
time-to-event-wk-10th	NA	41
time-to-event-wk-25th	NA	NA
time-to-event-wk-50th	NA	NA
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	NA	NA
time-to-event-wk-50th-hici	NA	NA

$Atelectasis$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
2.0920	0.7824	0.4514	9.6930	0.3455

$Constipation
$Constipation$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	41.0	80.0
n_event	8.0	25.0
n_event_pct	20.0	31.0
time-to-event-wk-10th	15.9	6.0
time-to-event-wk-25th	48.6	18.9
time-to-event-wk-50th	NA	NA
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	48.6	40.9
time-to-event-wk-50th-hici	NA	NA

$Constipation$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
1.5670	0.4079	0.7045	3.4860	0.2708

$Cough
$Cough$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	41.0	80.0
n_event	7.0	6.0
n_event_pct	17.0	8.0
time-to-event-wk-10th	4.4	38.6
time-to-event-wk-25th	NA	NA
time-to-event-wk-50th	NA	NA
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	NA	NA
time-to-event-wk-50th-hici	NA	NA

```
$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33110   0.56130   0.11020   0.99480   0.04892


$Diarrhoea
$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               7.0                9.0
n_event_pct                          17.0               11.0
time-to-event-wk-10th                 9.4               43.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4490    0.5165    0.1632    1.2360    0.1211


$`Gastrooesophageal reflux disease`
$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               6.0                8.0
n_event_pct                          15.0               10.0
time-to-event-wk-10th                10.9               20.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6673    0.5433    0.2301    1.9350    0.4565


$`Nasal congestion`
$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               5.0                8.0
n_event_pct                          12.0               10.0
time-to-event-wk-10th                 7.9               32.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7152    0.5719    0.2331    2.1940    0.5578


$Nasopharyngitis
$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               3.0               12.0
n_event_pct                           7.0               15.0
time-to-event-wk-10th                42.3               24.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7960    0.6463    0.5061    6.3740    0.3649


$`Oxygen saturation decreased`
$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               5.0                  5
n_event_pct                          12.0                  6
time-to-event-wk-10th                27.4                 52
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3915    0.6357    0.1126    1.3610    0.1402


$Pyrexia
$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              19.0               34.0
n_event_pct                          46.0               42.0
time-to-event-wk-10th                 4.1                4.9
```

```
time-to-event-wk-25th                 9.4               15.6
time-to-event-wk-50th                37.7               46.7
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.7               31.7
time-to-event-wk-50th-hici             NA                 NA

$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7349    0.2874    0.4184    1.2910    0.2839


$Rash
$Rash$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              4.0                8.0
n_event_pct                         10.0               10.0
time-to-event-wk-10th                5.9               33.9
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8147    0.6149    0.2441    2.7190    0.7388


$Tachycardia
$Tachycardia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                 80
n_event                              5.0                  3
n_event_pct                         12.0                  4
time-to-event-wk-10th                4.6                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26870   0.73200   0.06401   1.12800   0.07262


$Teething
$Teething$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 41                 80
```

```
n_event                                   2                  9
n_event_pct                               5                 11
time-to-event-wk-10th                    NA                 16
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               NA                 NA
time-to-event-wk-50th-hici               NA                 NA

$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2070    0.7828    0.4759   10.2400    0.3118


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$stats_num
                            TRT01P=Control TRT01P=ISIS 396443
n_all                                 41.0               80.0
n_event                                5.0               12.0
n_event_pct                           12.0               15.0
time-to-event-wk-10th                 25.4               21.7
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0930    0.5338    0.3840    3.1130    0.8672


$Vomiting
$Vomiting$stats_num
                            TRT01P=Control TRT01P=ISIS 396443
n_all                                 41.0               80.0
n_event                                6.0               12.0
n_event_pct                           15.0               15.0
time-to-event-wk-10th                 22.6               24.1
time-to-event-wk-25th                 47.7                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            47.7                 NA
time-to-event-wk-50th-hici              NA                 NA

$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8817    0.5010    0.3303    2.3540    0.8015
```

```
\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines milden UEs nach PT, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Constipation
$Constipation$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              8.0               25.0
n_event_pct                         20.0               31.0
time-to-event-wk-10th               15.9                6.0
time-to-event-wk-25th               48.6               18.9
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          48.6               40.9
time-to-event-wk-50th-hici            NA                 NA

$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5670    0.4079    0.7045    3.4860    0.2708


$Nasopharyngitis
$Nasopharyngitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              3.0               12.0
n_event_pct                          7.0               15.0
time-to-event-wk-10th               42.3               24.1
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7960    0.6463    0.5061    6.3740    0.3649


$Pyrexia
$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                             19.0               34.0
n_event_pct                         46.0               42.0
time-to-event-wk-10th                4.1                4.9
time-to-event-wk-25th                9.4               15.6
time-to-event-wk-50th               37.7               46.7
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
```

```
time-to-event-wk-50th-loci           15.7                31.7
time-to-event-wk-50th-hici             NA                  NA

$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7349    0.2874    0.4184    1.2910    0.2839


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               5.0               12.0
n_event_pct                          12.0               15.0
time-to-event-wk-10th                25.4               21.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0930    0.5338    0.3840    3.1130    0.8672


$Vomiting
$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               6.0               12.0
n_event_pct                          15.0               15.0
time-to-event-wk-10th                22.6               24.1
time-to-event-wk-25th                47.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           47.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8817    0.5010    0.3303    2.3540    0.8015



\################################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten UE nach SOC, das bei mindestens
10% der Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$ntab
```

```
            CTRL TRT
n_all         41  80
n_event        5   9
n_event_pct   12  11

$`Cardiac disorders`$stats
                 estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.92250000 0.52366102  0.3305410 2.574586 0.8775734
OR_TRTvsCTRL   0.91267606 0.59411564  0.2848423 2.924346 0.8777684
ARR_TRTvsCTRL -0.00945122 0.06212675 -0.1312174 0.112315 0.8790860


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        9  17
n_event_pct   22  21

$`Gastrointestinal disorders`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.968055556 0.36475251  0.4736117 1.9786919 0.9290757
OR_TRTvsCTRL   0.959435626 0.46589447  0.3849867 2.3910350 0.9291750
ARR_TRTvsCTRL -0.007012195 0.07918645 -0.1622148 0.1481904 0.9294372


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         41  80
n_event       11  22
n_event_pct   27  28

$`General disorders and administration site conditions`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.025000000 0.31539403  0.5524080 1.9019003 0.9375963
OR_TRTvsCTRL  1.034482759 0.43236368  0.4432968 2.4140813 0.9375021
ARR_TRTvsCTRL 0.006707317 0.08532455 -0.1605257 0.1739404 0.9373433


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all         41  80
n_event       14  49
n_event_pct   34  61

$`Infections and infestations`$stats
               estimate         se     lo95ci    hi95ci      pvalue
RR_TRTvsCTRL  1.7937500 0.23440668 1.13301220 2.8398097 0.012677153
OR_TRTvsCTRL  3.0483871 0.40141230 1.38799322 6.6950355 0.005490917
ARR_TRTvsCTRL 0.2710366 0.09193115 0.09085483 0.4512183 0.003195722
```

```
$Investigations
$Investigations$ntab
            CTRL TRT
n_all         41  80
n_event        6   9
n_event_pct   15  11

$Investigations$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.76875000 0.49080295  0.2937737 2.01167285 0.5920725
OR_TRTvsCTRL   0.73943662 0.56606865  0.2438161 2.24253619 0.5938476
ARR_TRTvsCTRL -0.03384146 0.06553635 -0.1622904 0.09460743 0.6055912


$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        6   7
n_event_pct   15   9

$`Metabolism and nutrition disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.59791667 0.52214324  0.2148778 1.66375661 0.3246308
OR_TRTvsCTRL   0.55936073 0.59312214  0.1749144 1.78878626 0.3273350
ARR_TRTvsCTRL -0.05884146 0.06360042 -0.1834960 0.06581307 0.3548754


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       20  33
n_event_pct   49  41

$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.84562500 0.2083574  0.5621131 1.2721312 0.4209537
OR_TRTvsCTRL   0.73723404 0.3862624  0.3457946 1.5717829 0.4299776
ARR_TRTvsCTRL -0.07530488 0.0955156 -0.2625120 0.1119023 0.4304605



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten UE nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        9  17
n_event_pct   22  21
```

```
$`Gastrointestinal disorders`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.968055556 0.36475251  0.4736117 1.9786919 0.9290757
OR_TRTvsCTRL   0.959435626 0.46589447  0.3849867 2.3910350 0.9291750
ARR_TRTvsCTRL -0.007012195 0.07918645 -0.1622148 0.1481904 0.9294372


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         41  80
n_event       11  22
n_event_pct   27  28

$`General disorders and administration site conditions`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.025000000 0.31539403  0.5524080 1.9019003 0.9375963
OR_TRTvsCTRL  1.034482759 0.43236368  0.4432968 2.4140813 0.9375021
ARR_TRTvsCTRL 0.006707317 0.08532455 -0.1605257 0.1739404 0.9373433


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all         41  80
n_event       14  49
n_event_pct   34  61

$`Infections and infestations`$stats
               estimate         se     lo95ci    hi95ci      pvalue
RR_TRTvsCTRL  1.7937500 0.23440668 1.13301220 2.8398097 0.012677153
OR_TRTvsCTRL  3.0483871 0.40141230 1.38799322 6.6950355 0.005490917
ARR_TRTvsCTRL 0.2710366 0.09193115 0.09085483 0.4512183 0.003195722


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       20  33
n_event_pct   49  41

$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.84562500 0.2083574  0.5621131 1.2721312 0.4209537
OR_TRTvsCTRL   0.73723404 0.3862624  0.3457946 1.5717829 0.4299776
ARR_TRTvsCTRL -0.07530488 0.0955156 -0.2625120 0.1119023 0.4304605



\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten UEs nach SOC, das bei mindestens 10%
```

der Patienten in einem Studienarm auftrat"

```
$`Cardiac disorders`
$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              5.0                9.0
n_event_pct                         12.0               11.0
time-to-event-wk-10th               15.1               17.9
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8204    0.5596    0.2740    2.4570    0.7235


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              9.0               17.0
n_event_pct                         22.0               21.0
time-to-event-wk-10th               13.6               16.3
time-to-event-wk-25th               40.7               53.1
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          40.7                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8053    0.4145    0.3574    1.8140    0.6012


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                             11.0               22.0
n_event_pct                         27.0               28.0
time-to-event-wk-10th                7.6                8.1
time-to-event-wk-25th               16.9               38.6
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          24.3               54.3
time-to-event-wk-50th-hici            NA                 NA
```

```
$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8559    0.3717    0.4130    1.7730    0.6754


$`Infections and infestations`
$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              14.0               49.0
n_event_pct                          34.0               61.0
time-to-event-wk-10th                 6.3                3.4
time-to-event-wk-25th                17.6                9.4
time-to-event-wk-50th                33.4               25.1
time-to-event-wk-75th                  NA               51.4
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3               15.7
time-to-event-wk-50th-hici             NA               35.4

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.91600   0.30430   1.05600   3.47900   0.03255


$Investigations
$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               6.0                9.0
n_event_pct                          15.0               11.0
time-to-event-wk-10th                18.9               25.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6871    0.5286    0.2438    1.9370    0.4778


$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               6.0                7.0
n_event_pct                          15.0                9.0
time-to-event-wk-10th                 9.6               45.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5068    0.5589    0.1695    1.5160    0.2240


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              20.0               33.0
n_event_pct                          49.0               41.0
time-to-event-wk-10th                 2.9                3.6
time-to-event-wk-25th                 7.1               11.7
time-to-event-wk-50th                22.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           11.0               25.9
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7046    0.2865    0.4019    1.2360    0.2218



\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten UEs nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               9.0               17.0
n_event_pct                          22.0               21.0
time-to-event-wk-10th                13.6               16.3
time-to-event-wk-25th                40.7               53.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8053    0.4145    0.3574    1.8140    0.6012


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$stats_num
```

```
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              11.0               22.0
n_event_pct                          27.0               28.0
time-to-event-wk-10th                 7.6                8.1
time-to-event-wk-25th                16.9               38.6
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.3               54.3
time-to-event-wk-50th-hici             NA                 NA

$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8559    0.3717    0.4130    1.7730    0.6754


$`Infections and infestations`
$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              14.0               49.0
n_event_pct                          34.0               61.0
time-to-event-wk-10th                 6.3                3.4
time-to-event-wk-25th                17.6                9.4
time-to-event-wk-50th                33.4               25.1
time-to-event-wk-75th                  NA               51.4
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3               15.7
time-to-event-wk-50th-hici             NA               35.4

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.91600   0.30430   1.05600   3.47900   0.03255


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              20.0               33.0
n_event_pct                          49.0               41.0
time-to-event-wk-10th                 2.9                3.6
time-to-event-wk-25th                 7.1               11.7
time-to-event-wk-50th                22.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           11.0               25.9
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7046    0.2865    0.4019    1.2360    0.2218
```

```
\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten UE nach PT, das bei mindestens 10%
der Patienten in einem Studienarm auftrat"

$Atelectasis
$Atelectasis$ntab
            CTRL TRT
n_all         41  80
n_event        7  11
n_event_pct   17  14

$Atelectasis$stats
                 estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.80535714 0.44370710  0.3375238 1.921643 0.6256450
OR_TRTvsCTRL   0.77432712 0.52694473  0.2756692 2.175007 0.6274170
ARR_TRTvsCTRL -0.03323171 0.07025419 -0.1709274 0.104464 0.6361982


$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all         41  80
n_event        1  11
n_event_pct    2  14

$Pneumonia$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  5.6375000 1.02665420 0.75369722 42.1673389 0.09207724
OR_TRTvsCTRL  6.3768116 1.06320358 0.79360256 51.2394088 0.08141507
ARR_TRTvsCTRL 0.1131098 0.04541802 0.02409207  0.2021274 0.01275937


$`Pneumonia aspiration`
$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         41  80
n_event        5   5
n_event_pct   12   6

$`Pneumonia aspiration`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.51250000 0.60258589  0.1573156 1.66961336 0.2672965
OR_TRTvsCTRL   0.48000000 0.66416196  0.1305887 1.76431824 0.2691138
ARR_TRTvsCTRL -0.05945122 0.05782826 -0.1727925 0.05389009 0.3039192


$Pyrexia
$Pyrexia$ntab
            CTRL TRT
n_all         41  80
n_event        8  19
```

```
n_event_pct   20  24

$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.21718750 0.3751551  0.5834786 2.5391600 0.6003497
OR_TRTvsCTRL  1.28483607 0.4736328  0.5077977 3.2509082 0.5966892
ARR_TRTvsCTRL 0.04237805 0.0780650 -0.1106265 0.1953826 0.5872290


$`Respiratory distress`
$`Respiratory distress`$ntab
            CTRL TRT
n_all         41  80
n_event        5  12
n_event_pct   12  15

$`Respiratory distress`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.23000000 0.49643035  0.46488211 3.2543735 0.6766744
OR_TRTvsCTRL  1.27058824 0.57080381  0.41508376 3.8893221 0.6748152
ARR_TRTvsCTRL 0.02804878 0.06484933 -0.09905357 0.1551511 0.6653619


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        5  11
n_event_pct   12  14

$`Upper respiratory tract infection`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.12750000 0.50400282  0.4198639 3.0277815 0.8118040
OR_TRTvsCTRL  1.14782609 0.57721714  0.3702951 3.5579858 0.8112199
ARR_TRTvsCTRL 0.01554878 0.06398521 -0.1098599 0.1409575 0.8080009



\################################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten UE nach PT, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Atelectasis
$Atelectasis$ntab
            CTRL TRT
n_all         41  80
n_event        7  11
n_event_pct   17  14

$Atelectasis$stats
                 estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.80535714 0.44370710  0.3375238 1.921643 0.6256450
OR_TRTvsCTRL   0.77432712 0.52694473  0.2756692 2.175007 0.6274170
```

```
ARR_TRTvsCTRL -0.03323171 0.07025419 -0.1709274 0.104464 0.6361982


$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all         41  80
n_event        1  11
n_event_pct    2  14

$Pneumonia$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  5.6375000 1.02665420 0.75369722 42.1673389 0.09207724
OR_TRTvsCTRL  6.3768116 1.06320358 0.79360256 51.2394088 0.08141507
ARR_TRTvsCTRL 0.1131098 0.04541802 0.02409207  0.2021274 0.01275937


$Pyrexia
$Pyrexia$ntab
            CTRL TRT
n_all         41  80
n_event        8  19
n_event_pct   20  24

$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.21718750 0.3751551  0.5834786 2.5391600 0.6003497
OR_TRTvsCTRL  1.28483607 0.4736328  0.5077977 3.2509082 0.5966892
ARR_TRTvsCTRL 0.04237805 0.0780650 -0.1106265 0.1953826 0.5872290


$`Respiratory distress`
$`Respiratory distress`$ntab
            CTRL TRT
n_all         41  80
n_event        5  12
n_event_pct   12  15

$`Respiratory distress`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.23000000 0.49643035  0.46488211 3.2543735 0.6766744
OR_TRTvsCTRL  1.27058824 0.57080381  0.41508376 3.8893221 0.6748152
ARR_TRTvsCTRL 0.02804878 0.06484933 -0.09905357 0.1551511 0.6653619


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        5  11
n_event_pct   12  14

$`Upper respiratory tract infection`$stats
                estimate         se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL  1.12750000 0.50400282  0.4198639 3.0277815 0.8118040
OR_TRTvsCTRL  1.14782609 0.57721714  0.3702951 3.5579858 0.8112199
ARR_TRTvsCTRL 0.01554878 0.06398521 -0.1098599 0.1409575 0.8080009



\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten UEs nach PT, das bei mindestens 10%
der Patienten in einem Studienarm auftrat"

$Atelectasis
$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80
n_event                               7.0                11
n_event_pct                          17.0                14
time-to-event-wk-10th                 7.9                28
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6316    0.4848    0.2442    1.6330    0.3432


$Pneumonia
$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41               80.0
n_event                               1               11.0
n_event_pct                           2               14.0
time-to-event-wk-10th                NA               25.1
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   4.8290    1.0450    0.6228   37.4400    0.1319


$`Pneumonia aspiration`
$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41                80
n_event                               5                 5
```

```
n_event_pct                              12                  6
time-to-event-wk-10th                    11                 NA
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               NA                 NA
time-to-event-wk-50th-hici               NA                 NA

$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4384    0.6340    0.1266    1.5190    0.1934


$Pyrexia
$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               8.0               19.0
n_event_pct                          20.0               24.0
time-to-event-wk-10th                13.4               15.3
time-to-event-wk-25th                  NA               41.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               54.3
time-to-event-wk-50th-hici             NA                 NA

$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0590    0.4229    0.4623    2.4260    0.8921


$`Respiratory distress`
$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               5.0               12.0
n_event_pct                          12.0               15.0
time-to-event-wk-10th                20.4               19.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1370    0.5354    0.3983    3.2480    0.8099


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               5.0               11.0
n_event_pct                          12.0               14.0
time-to-event-wk-10th                28.3               25.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9495    0.5404    0.3292    2.7380    0.9236



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten UEs nach PT, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Atelectasis
$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80
n_event                               7.0                11
n_event_pct                          17.0                14
time-to-event-wk-10th                 7.9                28
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6316    0.4848    0.2442    1.6330    0.3432


$Pneumonia
$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  41               80.0
n_event                                 1               11.0
n_event_pct                             2               14.0
time-to-event-wk-10th                  NA               25.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   4.8290    1.0450    0.6228   37.4400    0.1319


$Pyrexia
$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               8.0               19.0
n_event_pct                          20.0               24.0
time-to-event-wk-10th                13.4               15.3
time-to-event-wk-25th                  NA               41.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               54.3
time-to-event-wk-50th-hici             NA                 NA

$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0590    0.4229    0.4623    2.4260    0.8921


$`Respiratory distress`
$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               5.0               12.0
n_event_pct                          12.0               15.0
time-to-event-wk-10th                20.4               19.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1370    0.5354    0.3983    3.2480    0.8099


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               5.0               11.0
n_event_pct                          12.0               14.0
time-to-event-wk-10th                28.3               25.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9495    0.5404    0.3292    2.7380    0.9236



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem schweren UE nach SOC, das bei mindestens 5%
der Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        7   7
n_event_pct   17   9

$`Cardiac disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.51250000 0.49882266  0.1927948 1.36236188 0.1802244
OR_TRTvsCTRL   0.46575342 0.57343237  0.1513734 1.43305406 0.1826958
ARR_TRTvsCTRL -0.08323171 0.06671788 -0.2139964 0.04753294 0.2122079


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        5   5
n_event_pct   12   6

$`Gastrointestinal disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.51250000 0.60258589  0.1573156 1.66961336 0.2672965
OR_TRTvsCTRL   0.48000000 0.66416196  0.1305887 1.76431824 0.2691138
ARR_TRTvsCTRL -0.05945122 0.05782826 -0.1727925 0.05389009 0.3039192


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         41  80
n_event        1   4
n_event_pct    2   5

$`General disorders and administration site conditions`$stats
                estimate        se      lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  2.05000000 1.1014126  0.23671716 17.75325461 0.5145659
```

```
OR_TRTvsCTRL  2.10526316 1.1349704  0.22762387 19.47130136 0.5118809
ARR_TRTvsCTRL 0.02560976 0.0342655 -0.04154939  0.09276891 0.4548271


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all         41  80
n_event       17  28
n_event_pct   41  35

$`Infections and infestations`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.84411765 0.24009909  0.5272666 1.3513744 0.4803087
OR_TRTvsCTRL   0.76018100 0.39425278  0.3510172 1.6462871 0.4867485
ARR_TRTvsCTRL -0.06463415 0.09361395 -0.2481141 0.1188458 0.4899220


$Investigations
$Investigations$ntab
            CTRL TRT
n_all         41  80
n_event        4   1
n_event_pct   10   1

$Investigations$stats
                 estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.12812500 1.10141262  0.01479482 1.109578413 0.06210325
OR_TRTvsCTRL   0.11708861 1.13564310  0.01264310 1.084365776 0.05893969
ARR_TRTvsCTRL -0.08506098 0.04797586 -0.17909193 0.008969979 0.07622947


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       29  39
n_event_pct   71  49

$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.6892241 0.15242552  0.5112292  0.92919170 0.01461527
OR_TRTvsCTRL   0.3936081 0.40969179  0.1763330  0.87860624 0.02285462
ARR_TRTvsCTRL -0.2198171 0.09040081 -0.3969994 -0.04263474 0.01503300



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem schweren UE nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Infections and infestations`
$`Infections and infestations`$ntab
```

```
            CTRL TRT
n_all         41  80
n_event       17  28
n_event_pct   41  35

$`Infections and infestations`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.84411765 0.24009909  0.5272666 1.3513744 0.4803087
OR_TRTvsCTRL   0.76018100 0.39425278  0.3510172 1.6462871 0.4867485
ARR_TRTvsCTRL -0.06463415 0.09361395 -0.2481141 0.1188458 0.4899220


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       29  39
n_event_pct   71  49

$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.6892241 0.15242552  0.5112292  0.92919170 0.01461527
OR_TRTvsCTRL   0.3936081 0.40969179  0.1763330  0.87860624 0.02285462
ARR_TRTvsCTRL -0.2198171 0.09040081 -0.3969994 -0.04263474 0.01503300



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schweren UEs nach SOC, das bei mindestens 5%
der Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               7.0                  7
n_event_pct                          17.0                  9
time-to-event-wk-10th                14.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4338    0.5358    0.1518    1.2400    0.1190


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                41.0                 80
n_event                               5.0                  5
n_event_pct                          12.0                  6
time-to-event-wk-10th                19.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3962    0.6362    0.1139    1.3790    0.1456


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  41                 80
n_event                                 1                  4
n_event_pct                             2                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7500    1.1190    0.1953   15.6800    0.6170


$`Infections and infestations`
$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                              17.0                28.0
n_event_pct                          41.0                35.0
time-to-event-wk-10th                 6.7                 5.0
time-to-event-wk-25th                13.9                18.4
time-to-event-wk-50th                33.4                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           17.7                32.7
time-to-event-wk-50th-hici             NA                  NA

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7399    0.3093    0.4036    1.3570    0.3301
```

```
$Investigations
$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               4.0                  1
n_event_pct                          10.0                  1
time-to-event-wk-10th                40.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.10490   1.12000   0.01169   0.94240   0.04412


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                              29.0                39.0
n_event_pct                          71.0                49.0
time-to-event-wk-10th                 1.7                 3.8
time-to-event-wk-25th                 6.1                 9.8
time-to-event-wk-50th                13.9                34.7
time-to-event-wk-75th                52.6                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            8.6                20.3
time-to-event-wk-50th-hici           18.1                  NA

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.53160   0.24740   0.32730   0.86330   0.01065



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schweren UEs nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Infections and infestations`
$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                              17.0                28.0
n_event_pct                          41.0                35.0
time-to-event-wk-10th                 6.7                 5.0
time-to-event-wk-25th                13.9                18.4
time-to-event-wk-50th                33.4                  NA
time-to-event-wk-75th                  NA                  NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.7               32.7
time-to-event-wk-50th-hici             NA                 NA

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7399    0.3093    0.4036    1.3570    0.3301


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              29.0               39.0
n_event_pct                          71.0               49.0
time-to-event-wk-10th                 1.7                3.8
time-to-event-wk-25th                 6.1                9.8
time-to-event-wk-50th                13.9               34.7
time-to-event-wk-75th                52.6                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.6               20.3
time-to-event-wk-50th-hici           18.1                 NA

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.53160   0.24740   0.32730   0.86330   0.01065



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem schweren UE nach PT, das bei mindestens 5%
der Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event        9  11
n_event_pct   22  14

$`Acute respiratory failure`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6263889 0.40636186  0.2824543 1.3891204 0.2496701
OR_TRTvsCTRL   0.5668277 0.49775793  0.2136775 1.5036383 0.2540722
ARR_TRTvsCTRL -0.0820122 0.07524041 -0.2294807 0.0654563 0.2757123


$Atelectasis
$Atelectasis$ntab
            CTRL TRT
n_all         41  80
n_event        4   6
n_event_pct   10   8
```

```
$Atelectasis$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.76875000 0.61626003  0.2297331 2.57244807 0.6695608
OR_TRTvsCTRL   0.75000000 0.67617099  0.1992982 2.82240318 0.6705031
ARR_TRTvsCTRL -0.02256098 0.05490513 -0.1301731 0.08505111 0.6811398


$`Bronchial secretion retention`
$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         41  80
n_event        5   1
n_event_pct   12   1

$`Bronchial secretion retention`$stats
                 estimate         se      lo95ci       hi95ci     pvalue
RR_TRTvsCTRL   0.10250000 1.07847566  0.01238009  0.848641009 0.03467437
OR_TRTvsCTRL   0.09113924 1.11374863  0.01027261  0.808592960 0.03149793
ARR_TRTvsCTRL -0.10945122 0.05259261 -0.21253084 -0.006371596 0.03742347


$Bronchiolitis
$Bronchiolitis$ntab
            CTRL TRT
n_all         41  80
n_event        1   4
n_event_pct    2   5

$Bronchiolitis$stats
                estimate        se      lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  2.05000000 1.1014126  0.23671716 17.75325461 0.5145659
OR_TRTvsCTRL  2.10526316 1.1349704  0.22762387 19.47130136 0.5118809
ARR_TRTvsCTRL 0.02560976 0.0342655 -0.04154939  0.09276891 0.4548271


$`Cardio-respiratory arrest`
$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         41  80
n_event        5   5
n_event_pct   12   6

$`Cardio-respiratory arrest`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.51250000 0.60258589  0.1573156 1.66961336 0.2672965
OR_TRTvsCTRL   0.48000000 0.66416196  0.1305887 1.76431824 0.2691138
ARR_TRTvsCTRL -0.05945122 0.05782826 -0.1727925 0.05389009 0.3039192


$Dysphagia
$Dysphagia$ntab
            CTRL TRT
n_all         41  80
```

```
n_event        4   4
n_event_pct   10   5

$Dysphagia$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.51250000 0.68052168  0.1350308 1.94515840 0.3259679
OR_TRTvsCTRL   0.48684211 0.73497274  0.1152864 2.05588140 0.3273937
ARR_TRTvsCTRL -0.04756098 0.05235586 -0.1501766 0.05505463 0.3636577


$`Oxygen saturation decreased`
$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         41  80
n_event        3   1
n_event_pct    7   1

$`Oxygen saturation decreased`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.17083333 1.13861455  0.01833927 1.59134035 0.1206754
OR_TRTvsCTRL   0.16033755 1.17145523  0.01613953 1.59286786 0.1181551
ARR_TRTvsCTRL -0.06067073 0.04252487 -0.14401795 0.02267648 0.1536630


$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all         41  80
n_event        5  10
n_event_pct   12  12

$Pneumonia$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.02500000 0.51294225  0.3750651 2.801181 0.9616053
OR_TRTvsCTRL  1.02857143 0.58486194  0.3268881 3.236457 0.9615834
ARR_TRTvsCTRL 0.00304878 0.06307831 -0.1205824 0.126680 0.9614506


$`Respiratory arrest`
$`Respiratory arrest`$ntab
            CTRL TRT
n_all         41  80
n_event        3   4
n_event_pct    7   5

$`Respiratory arrest`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.68333333 0.73921789  0.1604757 2.90975227 0.6064819
OR_TRTvsCTRL   0.66666667 0.78918123  0.1419569 3.13084108 0.6074062
ARR_TRTvsCTRL -0.02317073 0.04741116 -0.1160949 0.06975343 0.6250407


$`Respiratory distress`
$`Respiratory distress`$ntab
```

```
            CTRL TRT
n_all         41  80
n_event        8  12
n_event_pct   20  15

$`Respiratory distress`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.76875000 0.41405687  0.3414596 1.73073658 0.5253286
OR_TRTvsCTRL   0.72794118 0.50333115  0.2714314 1.95223699 0.5281275
ARR_TRTvsCTRL -0.04512195 0.07364932 -0.1894720 0.09922807 0.5401016


$`Respiratory failure`
$`Respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event       15  14
n_event_pct   37  18

$`Respiratory failure`$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.4783333 0.31812732  0.2564131  0.89232100 0.02044449
OR_TRTvsCTRL   0.3676768 0.43784505  0.1558733  0.86728248 0.02230277
ARR_TRTvsCTRL -0.1908537 0.08639063 -0.3601762 -0.02153114 0.02716114


$`Respiratory syncytial virus bronchiolitis`
$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         41  80
n_event        3   3
n_event_pct    7   4

$`Respiratory syncytial virus bronchiolitis`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.51250000 0.79358454  0.10819159 2.42769573 0.3996071
OR_TRTvsCTRL   0.49350649 0.84021989  0.09508158 2.56147040 0.4006185
ARR_TRTvsCTRL -0.03567073 0.04588289 -0.12559954 0.05425808 0.4369052


$`Rhinovirus infection`
$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         41  80
n_event        3   4
n_event_pct    7   5

$`Rhinovirus infection`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.68333333 0.73921789  0.1604757 2.90975227 0.6064819
OR_TRTvsCTRL   0.66666667 0.78918123  0.1419569 3.13084108 0.6074062
ARR_TRTvsCTRL -0.02317073 0.04741116 -0.1160949 0.06975343 0.6250407
```

```
$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        0   5
n_event_pct    0   6

$`Upper respiratory tract infection`$stats
              estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  5.703704 1.46480817 0.323079930 100.6940787 0.23458508
OR_TRTvsCTRL  6.046358 1.48968440 0.326191150 112.0767393 0.22706862
ARR_TRTvsCTRL 0.062500 0.02706329 0.009456919   0.1155431 0.02092134


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        5   1
n_event_pct   12   1

$`Viral upper respiratory tract infection`$stats
                 estimate         se      lo95ci       hi95ci     pvalue
RR_TRTvsCTRL   0.10250000 1.07847566  0.01238009  0.848641009 0.03467437
OR_TRTvsCTRL   0.09113924 1.11374863  0.01027261  0.808592960 0.03149793
ARR_TRTvsCTRL -0.10945122 0.05259261 -0.21253084 -0.006371596 0.03742347



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem schweren UE nach PT, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event        9  11
n_event_pct   22  14

$`Acute respiratory failure`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6263889 0.40636186  0.2824543 1.3891204 0.2496701
OR_TRTvsCTRL   0.5668277 0.49775793  0.2136775 1.5036383 0.2540722
ARR_TRTvsCTRL -0.0820122 0.07524041 -0.2294807 0.0654563 0.2757123


$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all         41  80
n_event        5  10
n_event_pct   12  12
```

```
$Pneumonia$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.02500000 0.51294225  0.3750651 2.801181 0.9616053
OR_TRTvsCTRL  1.02857143 0.58486194  0.3268881 3.236457 0.9615834
ARR_TRTvsCTRL 0.00304878 0.06307831 -0.1205824 0.126680 0.9614506


$`Respiratory distress`
$`Respiratory distress`$ntab
            CTRL TRT
n_all         41  80
n_event        8  12
n_event_pct   20  15

$`Respiratory distress`$stats
                  estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.76875000 0.41405687  0.3414596 1.73073658 0.5253286
OR_TRTvsCTRL   0.72794118 0.50333115  0.2714314 1.95223699 0.5281275
ARR_TRTvsCTRL -0.04512195 0.07364932 -0.1894720 0.09922807 0.5401016


$`Respiratory failure`
$`Respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event       15  14
n_event_pct   37  18

$`Respiratory failure`$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.4783333 0.31812732  0.2564131  0.89232100 0.02044449
OR_TRTvsCTRL   0.3676768 0.43784505  0.1558733  0.86728248 0.02230277
ARR_TRTvsCTRL -0.1908537 0.08639063 -0.3601762 -0.02153114 0.02716114



\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schweren UEs nach PT, das bei mindestens 5% der
Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               9.0               11.0
n_event_pct                          22.0               14.0
time-to-event-wk-10th                13.0               25.4
time-to-event-wk-25th                26.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.6                 NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5094    0.4522    0.2100    1.2360    0.1358


$Atelectasis
$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                  80
n_event                               4.0                   6
n_event_pct                          10.0                   8
time-to-event-wk-10th                32.9                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7006    0.6458    0.1976    2.4840    0.5816


$`Bronchial secretion retention`
$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                  80
n_event                               5.0                   1
n_event_pct                          12.0                   1
time-to-event-wk-10th                 8.6                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.08973   1.09600   0.01047   0.76930   0.02787


$Bronchiolitis
$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  41                  80
n_event                                 1                   4
n_event_pct                             2                   5
time-to-event-wk-10th                  NA                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0360    1.1190    0.2271   18.2500    0.5253


$`Cardio-respiratory arrest`
$`Cardio-respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 41                  80
n_event                                5                   5
n_event_pct                           12                   6
time-to-event-wk-10th                 23                  NA
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci            NA                  NA
time-to-event-wk-50th-hici            NA                  NA

$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4327    0.6331    0.1251    1.4970    0.1858


$Dysphagia
$Dysphagia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                  80
n_event                              4.0                   4
n_event_pct                         10.0                   5
time-to-event-wk-10th               19.9                  NA
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci            NA                  NA
time-to-event-wk-50th-hici            NA                  NA

$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4041    0.7110    0.1003    1.6280    0.2026


$`Oxygen saturation decreased`
$`Oxygen saturation decreased`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                  80
n_event                              3.0                   1
n_event_pct                          7.0                   1
```

```
time-to-event-wk-10th                40.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.14630   1.15700   0.01516   1.41200   0.09659


$Pneumonia
$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                               5.0                10.0
n_event_pct                          12.0                12.0
time-to-event-wk-10th                13.7                30.4
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9347    0.5483    0.3191    2.7380    0.9020


$`Respiratory arrest`
$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               3.0                  4
n_event_pct                           7.0                  5
time-to-event-wk-10th                20.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4944    0.7658    0.1102    2.2180    0.3577


$`Respiratory distress`
$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  41                80.0
n_event                                 8                12.0
n_event_pct                            20                15.0
time-to-event-wk-10th                  11                20.3
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6625    0.4576    0.2702    1.6240    0.3683


$`Respiratory failure`
$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                              15.0                14.0
n_event_pct                          37.0                18.0
time-to-event-wk-10th                 6.1                16.1
time-to-event-wk-25th                13.0                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           18.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.379600  0.374900  0.182000  0.791400  0.009764


$`Respiratory syncytial virus bronchiolitis`
$`Respiratory syncytial virus bronchiolitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                  80
n_event                               3.0                   3
n_event_pct                           7.0                   4
time-to-event-wk-10th                22.4                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Respiratory syncytial virus bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.37520   0.82060   0.07512   1.87400   0.23220
```

```
$`Rhinovirus infection`
$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 41                  80
n_event                                3                   4
n_event_pct                            7                   5
time-to-event-wk-10th                 NA                  NA
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci            NA                  NA
time-to-event-wk-50th-hici            NA                  NA

$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6161    0.7651    0.1375    2.7600    0.5267


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 41                80.0
n_event                                0                 5.0
n_event_pct                            0                 6.0
time-to-event-wk-10th                 NA                49.4
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci            NA                  NA
time-to-event-wk-50th-hici            NA                  NA

$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.375e+08 1.179e+04 0.000e+00       Inf 9.987e-01


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 41                  80
n_event                                5                   1
n_event_pct                           12                   1
time-to-event-wk-10th                 33.4                NA
time-to-event-wk-25th                   NA                NA
time-to-event-wk-50th                   NA                NA
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci              NA                NA
time-to-event-wk-50th-hici              NA                NA

$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
  0.08263   1.09800   0.00961   0.71040   0.02312


\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schweren UEs nach PT, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              9.0               11.0
n_event_pct                         22.0               14.0
time-to-event-wk-10th               13.0               25.4
time-to-event-wk-25th               26.0                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          52.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5094    0.4522    0.2100    1.2360    0.1358


$Pneumonia
$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              5.0               10.0
n_event_pct                         12.0               12.0
time-to-event-wk-10th               13.7               30.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9347    0.5483    0.3191    2.7380    0.9020


$`Respiratory distress`
$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41               80.0
n_event                              8               12.0
n_event_pct                         20               15.0
time-to-event-wk-10th               11               20.3
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6625    0.4576    0.2702    1.6240    0.3683


$`Respiratory failure`
$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              15.0               14.0
n_event_pct                          37.0               18.0
time-to-event-wk-10th                 6.1               16.1
time-to-event-wk-25th                13.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           18.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.379600  0.374900  0.182000  0.791400  0.009764



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten oder schweren UE nach SOC, das bei
mindestens 10% der Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        9  14
n_event_pct   22  18

$`Cardiac disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7972222 0.38164046  0.3773344 1.6843500 0.5526394
OR_TRTvsCTRL   0.7542088 0.47847800  0.2952639 1.9265167 0.5554932
ARR_TRTvsCTRL -0.0445122 0.07735234 -0.1961200 0.1070956 0.5649888


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$ntab
            CTRL TRT
```

```
n_all         41  80
n_event       11  19
n_event_pct   27  24

$`Gastrointestinal disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88522727 0.32657377  0.4667396 1.6789389 0.7089232
OR_TRTvsCTRL   0.84947839 0.43962194  0.3588769 2.0107552 0.7105816
ARR_TRTvsCTRL -0.03079268 0.08397477 -0.1953802 0.1337948 0.7138505


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         41  80
n_event       12  26
n_event_pct   29  32

$`General disorders and administration site conditions`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.11041667 0.29138399  0.6272772 1.9656784 0.7192653
OR_TRTvsCTRL  1.16358025 0.41808629  0.5127677 2.6404141 0.7170760
ARR_TRTvsCTRL 0.03231707 0.08826917 -0.1406873 0.2053215 0.7142758


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all         41  80
n_event       22  56
n_event_pct   54  70

$`Infections and infestations`$stats
               estimate         se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.3045455 0.16254675  0.94863507 1.7939869 0.10193208
OR_TRTvsCTRL  2.0151515 0.39700118  0.92550697 4.3876878 0.07756914
ARR_TRTvsCTRL 0.1634146 0.09321971 -0.01929265 0.3461219 0.07960113


$Investigations
$Investigations$ntab
            CTRL TRT
n_all         41  80
n_event       10  10
n_event_pct   24  12

$Investigations$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5125000 0.40386849  0.2322311 1.13101236 0.09789827
OR_TRTvsCTRL   0.4428571 0.49653175  0.1673459 1.17195853 0.10092313
ARR_TRTvsCTRL -0.1189024 0.07658388 -0.2690041 0.03119921 0.12052402


$`Metabolism and nutrition disorders`
```

```
$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        7   8
n_event_pct   17  10

$`Metabolism and nutrition disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.58571429 0.48059016  0.2283530 1.50232848 0.2656849
OR_TRTvsCTRL   0.53968254 0.55781520  0.1808528 1.61046587 0.2688580
ARR_TRTvsCTRL -0.07073171 0.06766261 -0.2033480 0.06188458 0.2958572


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       32  50
n_event_pct   78  62

$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.8007812 0.11983220  0.6331586 1.012780309 0.06374087
OR_TRTvsCTRL   0.4687500 0.44237365  0.1969664 1.115553524 0.08675428
ARR_TRTvsCTRL -0.1554878 0.08431124 -0.3207348 0.009759185 0.06515224



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten oder schweren UE nach SOC, das bei
mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        9  14
n_event_pct   22  18

$`Cardiac disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7972222 0.38164046  0.3773344 1.6843500 0.5526394
OR_TRTvsCTRL   0.7542088 0.47847800  0.2952639 1.9265167 0.5554932
ARR_TRTvsCTRL -0.0445122 0.07735234 -0.1961200 0.1070956 0.5649888


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       11  19
n_event_pct   27  24
```

```
$`Gastrointestinal disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88522727 0.32657377  0.4667396 1.6789389 0.7089232
OR_TRTvsCTRL   0.84947839 0.43962194  0.3588769 2.0107552 0.7105816
ARR_TRTvsCTRL -0.03079268 0.08397477 -0.1953802 0.1337948 0.7138505


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         41  80
n_event       12  26
n_event_pct   29  32

$`General disorders and administration site conditions`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.11041667 0.29138399  0.6272772 1.9656784 0.7192653
OR_TRTvsCTRL  1.16358025 0.41808629  0.5127677 2.6404141 0.7170760
ARR_TRTvsCTRL 0.03231707 0.08826917 -0.1406873 0.2053215 0.7142758


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all         41  80
n_event       22  56
n_event_pct   54  70

$`Infections and infestations`$stats
                estimate         se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.3045455 0.16254675  0.94863507 1.7939869 0.10193208
OR_TRTvsCTRL  2.0151515 0.39700118  0.92550697 4.3876878 0.07756914
ARR_TRTvsCTRL 0.1634146 0.09321971 -0.01929265 0.3461219 0.07960113


$Investigations
$Investigations$ntab
            CTRL TRT
n_all         41  80
n_event       10  10
n_event_pct   24  12

$Investigations$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5125000 0.40386849  0.2322311 1.13101236 0.09789827
OR_TRTvsCTRL   0.4428571 0.49653175  0.1673459 1.17195853 0.10092313
ARR_TRTvsCTRL -0.1189024 0.07658388 -0.2690041 0.03119921 0.12052402


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event       32  50
```

```
n_event_pct   78  62

$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.8007812 0.11983220  0.6331586 1.012780309 0.06374087
OR_TRTvsCTRL   0.4687500 0.44237365  0.1969664 1.115553524 0.08675428
ARR_TRTvsCTRL -0.1554878 0.08431124 -0.3207348 0.009759185 0.06515224



\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten oder schweren UEs nach SOC, das bei
mindestens 10% der Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               9.0               14.0
n_event_pct                          22.0               18.0
time-to-event-wk-10th                13.9                8.4
time-to-event-wk-25th                29.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6983    0.4283    0.3016    1.6170    0.4019


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              11.0               19.0
n_event_pct                          27.0               24.0
time-to-event-wk-10th                13.6                9.3
time-to-event-wk-25th                19.9               28.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7434    0.3816    0.3519    1.5710    0.4372


$`General disorders and administration site conditions`
```

$`General disorders and administration site conditions`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	41.0	80.0
n_event	12.0	26.0
n_event_pct	29.0	32.0
time-to-event-wk-10th	5.1	7.6
time-to-event-wk-25th	16.9	29.1
time-to-event-wk-50th	NA	NA
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	23.0	44.3
time-to-event-wk-50th-hici	NA	NA

$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.9335	0.3507	0.4694	1.8560	0.8444

$`Infections and infestations`
$`Infections and infestations`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	41.0	80.0
n_event	22.0	56.0
n_event_pct	54.0	70.0
time-to-event-wk-10th	5.7	2.7
time-to-event-wk-25th	8.7	6.7
time-to-event-wk-50th	22.6	15.7
time-to-event-wk-75th	NA	34.7
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	12.3	10.6
time-to-event-wk-50th-hici	33.4	25.4

$`Infections and infestations`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
1.4320	0.2537	0.8707	2.3540	0.1572

$Investigations
$Investigations$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	41.0	80.0
n_event	10.0	10.0
n_event_pct	24.0	12.0
time-to-event-wk-10th	13.9	23.3
time-to-event-wk-25th	40.7	NA
time-to-event-wk-50th	NA	NA
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	40.7	NA
time-to-event-wk-50th-hici	NA	NA

$Investigations$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.43260	0.44920	0.17940	1.04400	0.06217

```
$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0              80.0
n_event                              7.0               8.0
n_event_pct                         17.0              10.0
time-to-event-wk-10th                9.6              45.6
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4898    0.5199    0.1768    1.3570    0.1698


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0              80.0
n_event                             32.0              50.0
n_event_pct                         78.0              62.0
time-to-event-wk-10th                0.9               1.3
time-to-event-wk-25th                4.6               5.1
time-to-event-wk-50th               11.0              15.7
time-to-event-wk-75th               26.0                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           6.1              11.0
time-to-event-wk-50th-hici          15.7              32.1

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.68370   0.22910   0.43640   1.07100   0.09692



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten oder schweren UEs nach SOC, das bei
mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0              80.0
n_event                              9.0              14.0
n_event_pct                         22.0              18.0
time-to-event-wk-10th               13.9               8.4
time-to-event-wk-25th               29.4                NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6983    0.4283    0.3016    1.6170    0.4019


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              11.0               19.0
n_event_pct                          27.0               24.0
time-to-event-wk-10th                13.6                9.3
time-to-event-wk-25th                19.9               28.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7434    0.3816    0.3519    1.5710    0.4372


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              12.0               26.0
n_event_pct                          29.0               32.0
time-to-event-wk-10th                 5.1                7.6
time-to-event-wk-25th                16.9               29.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           23.0               44.3
time-to-event-wk-50th-hici             NA                 NA

$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9335    0.3507    0.4694    1.8560    0.8444


$`Infections and infestations`
$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              22.0               56.0
```

```
n_event_pct                          54.0              70.0
time-to-event-wk-10th                 5.7               2.7
time-to-event-wk-25th                 8.7               6.7
time-to-event-wk-50th                22.6              15.7
time-to-event-wk-75th                  NA              34.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           12.3              10.6
time-to-event-wk-50th-hici           33.4              25.4

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4320    0.2537    0.8707    2.3540    0.1572


$Investigations
$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0              80.0
n_event                              10.0              10.0
n_event_pct                          24.0              12.0
time-to-event-wk-10th                13.9              23.3
time-to-event-wk-25th                40.7                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
time-to-event-wk-50th-hici             NA                NA

$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.43260   0.44920   0.17940   1.04400   0.06217


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0              80.0
n_event                              32.0              50.0
n_event_pct                          78.0              62.0
time-to-event-wk-10th                 0.9               1.3
time-to-event-wk-25th                 4.6               5.1
time-to-event-wk-50th                11.0              15.7
time-to-event-wk-75th                26.0                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.1              11.0
time-to-event-wk-50th-hici           15.7              32.1

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.68370   0.22910   0.43640   1.07100   0.09692



\################################################################################
```

```
[[1]]
[1] "Patienten mit mindestens einem moderaten oder schweren UE nach PT, das bei
mindestens 10% der Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event        9  11
n_event_pct   22  14

$`Acute respiratory failure`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6263889 0.40636186  0.2824543 1.3891204 0.2496701
OR_TRTvsCTRL   0.5668277 0.49775793  0.2136775 1.5036383 0.2540722
ARR_TRTvsCTRL -0.0820122 0.07524041 -0.2294807 0.0654563 0.2757123


$Atelectasis
$Atelectasis$ntab
            CTRL TRT
n_all         41  80
n_event       10  15
n_event_pct   24  19

$Atelectasis$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.76875000 0.36024495  0.3794408 1.5574933 0.4653721
OR_TRTvsCTRL   0.71538462 0.46293557  0.2887275 1.7725197 0.4693713
ARR_TRTvsCTRL -0.05640244 0.08001375 -0.2132265 0.1004216 0.4808667


$`Bronchial secretion retention`
$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         41  80
n_event        7   3
n_event_pct   17   4

$`Bronchial secretion retention`$stats
                estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.2196429 0.66279728  0.05991603  0.80517661 0.02220154
OR_TRTvsCTRL   0.1892393 0.72013141  0.04613542  0.77622634 0.02079308
ARR_TRTvsCTRL -0.1332317 0.06248521 -0.25570046 -0.01076295 0.03298942


$`Cardio-respiratory arrest`
$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         41  80
n_event        5   5
n_event_pct   12   6

$`Cardio-respiratory arrest`$stats
```

```
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.51250000 0.60258589  0.1573156 1.66961336 0.2672965
OR_TRTvsCTRL   0.48000000 0.66416196  0.1305887 1.76431824 0.2691138
ARR_TRTvsCTRL -0.05945122 0.05782826 -0.1727925 0.05389009 0.3039192


$Dysphagia
$Dysphagia$ntab
            CTRL TRT
n_all         41  80
n_event        7   6
n_event_pct   17   8

$Dysphagia$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.43928571 0.52214324  0.1578694 1.22235179 0.1151550
OR_TRTvsCTRL   0.39382239 0.59367423  0.1230167 1.26077279 0.1164987
ARR_TRTvsCTRL -0.09573171 0.06572988 -0.2245599 0.03309648 0.1452707


$Dyspnoea
$Dyspnoea$ntab
            CTRL TRT
n_all         41  80
n_event        5   3
n_event_pct   12   4

$Dyspnoea$stats
                 estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.30750000 0.70458718  0.07728575 1.22346292 0.09418605
OR_TRTvsCTRL   0.28051948 0.75769263  0.06353512 1.23854606 0.09342342
ARR_TRTvsCTRL -0.08445122 0.05534309 -0.19292168 0.02401925 0.12702038


$`Oxygen saturation decreased`
$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         41  80
n_event        7   8
n_event_pct   17  10

$`Oxygen saturation decreased`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.58571429 0.48059016  0.2283530 1.50232848 0.2656849
OR_TRTvsCTRL   0.53968254 0.55781520  0.1808528 1.61046587 0.2688580
ARR_TRTvsCTRL -0.07073171 0.06766261 -0.2033480 0.06188458 0.2958572


$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all         41  80
n_event        6  21
n_event_pct   15  26
```

```
$Pneumonia$stats
               estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.7937500 0.42118342  0.78568767 4.0951884 0.1653498
OR_TRTvsCTRL  2.0762712 0.50971197  0.76456860 5.6383456 0.1517702
ARR_TRTvsCTRL 0.1161585 0.07393841 -0.02875809 0.2610752 0.1161786


$`Pneumonia aspiration`
$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         41  80
n_event        7   8
n_event_pct   17  10

$`Pneumonia aspiration`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.58571429 0.48059016  0.2283530 1.50232848 0.2656849
OR_TRTvsCTRL   0.53968254 0.55781520  0.1808528 1.61046587 0.2688580
ARR_TRTvsCTRL -0.07073171 0.06766261 -0.2033480 0.06188458 0.2958572


$Pyrexia
$Pyrexia$ntab
            CTRL TRT
n_all         41  80
n_event        8  21
n_event_pct   20  26

$Pyrexia$stats
               estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.34531250 0.36841390  0.6534746 2.7696039 0.4207365
OR_TRTvsCTRL  1.46822034 0.46890429  0.5856784 3.6806396 0.4127640
ARR_TRTvsCTRL 0.06737805 0.07905944 -0.0875756 0.2223317 0.3940778


$`Respiratory distress`
$`Respiratory distress`$ntab
            CTRL TRT
n_all         41  80
n_event       11  20
n_event_pct   27  25

$`Respiratory distress`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93181818 0.32251953  0.4952244 1.7533164 0.8266844
OR_TRTvsCTRL   0.90909091 0.43693145  0.3860918 2.1405434 0.8273237
ARR_TRTvsCTRL -0.01829268 0.08445023 -0.1838121 0.1472267 0.8285130


$`Respiratory failure`
$`Respiratory failure`$ntab
            CTRL TRT
n_all         41  80
```

```
n_event       16  19
n_event_pct   39  24

$`Respiratory failure`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.6085937 0.27971653  0.3517486 1.05298607 0.07583447
OR_TRTvsCTRL   0.4866803 0.41415579  0.2161293 1.09590736 0.08206413
ARR_TRTvsCTRL -0.1527439 0.08981881 -0.3287855 0.02329773 0.08902223


$`Rhinovirus infection`
$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         41  80
n_event        4  10
n_event_pct   10  12

$`Rhinovirus infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.28125000 0.55956211  0.42789159 3.8364895 0.6578302
OR_TRTvsCTRL  1.32142857 0.62554995  0.38777036 4.5031123 0.6559228
ARR_TRTvsCTRL 0.02743902 0.05928384 -0.08875517 0.1436332 0.6434779


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        5  14
n_event_pct   12  18

$`Upper respiratory tract infection`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.43500000 0.4842916  0.55542083 3.7075041 0.4558129
OR_TRTvsCTRL  1.52727273 0.5606763  0.50894178 4.5831608 0.4500638
ARR_TRTvsCTRL 0.05304878 0.0664558 -0.07720219 0.1832998 0.4247216


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        6   7
n_event_pct   15   9

$`Viral upper respiratory tract infection`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.59791667 0.52214324  0.2148778 1.66375661 0.3246308
OR_TRTvsCTRL   0.55936073 0.59312214  0.1749144 1.78878626 0.3273350
ARR_TRTvsCTRL -0.05884146 0.06360042 -0.1834960 0.06581307 0.3548754



\#############################################################################
```

```
[[1]]
[1] "Patienten mit mindestens einem moderaten oder schweren UE nach PT, das bei
mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event        9  11
n_event_pct   22  14

$`Acute respiratory failure`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6263889 0.40636186  0.2824543 1.3891204 0.2496701
OR_TRTvsCTRL   0.5668277 0.49775793  0.2136775 1.5036383 0.2540722
ARR_TRTvsCTRL -0.0820122 0.07524041 -0.2294807 0.0654563 0.2757123


$Atelectasis
$Atelectasis$ntab
            CTRL TRT
n_all         41  80
n_event       10  15
n_event_pct   24  19

$Atelectasis$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.76875000 0.36024495  0.3794408 1.5574933 0.4653721
OR_TRTvsCTRL   0.71538462 0.46293557  0.2887275 1.7725197 0.4693713
ARR_TRTvsCTRL -0.05640244 0.08001375 -0.2132265 0.1004216 0.4808667


$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all         41  80
n_event        6  21
n_event_pct   15  26

$Pneumonia$stats
               estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.7937500 0.42118342  0.78568767 4.0951884 0.1653498
OR_TRTvsCTRL  2.0762712 0.50971197  0.76456860 5.6383456 0.1517702
ARR_TRTvsCTRL 0.1161585 0.07393841 -0.02875809 0.2610752 0.1161786


$Pyrexia
$Pyrexia$ntab
            CTRL TRT
n_all         41  80
n_event        8  21
n_event_pct   20  26

$Pyrexia$stats
```

```
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.34531250 0.36841390  0.6534746 2.7696039 0.4207365
OR_TRTvsCTRL  1.46822034 0.46890429  0.5856784 3.6806396 0.4127640
ARR_TRTvsCTRL 0.06737805 0.07905944 -0.0875756 0.2223317 0.3940778


$`Respiratory distress`
$`Respiratory distress`$ntab
            CTRL TRT
n_all         41  80
n_event       11  20
n_event_pct   27  25

$`Respiratory distress`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93181818 0.32251953  0.4952244 1.7533164 0.8266844
OR_TRTvsCTRL   0.90909091 0.43693145  0.3860918 2.1405434 0.8273237
ARR_TRTvsCTRL -0.01829268 0.08445023 -0.1838121 0.1472267 0.8285130


$`Respiratory failure`
$`Respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event       16  19
n_event_pct   39  24

$`Respiratory failure`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.6085937 0.27971653  0.3517486 1.05298607 0.07583447
OR_TRTvsCTRL   0.4866803 0.41415579  0.2161293 1.09590736 0.08206413
ARR_TRTvsCTRL -0.1527439 0.08981881 -0.3287855 0.02329773 0.08902223


$`Rhinovirus infection`
$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         41  80
n_event        4  10
n_event_pct   10  12

$`Rhinovirus infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.28125000 0.55956211  0.42789159 3.8364895 0.6578302
OR_TRTvsCTRL  1.32142857 0.62554995  0.38777036 4.5031123 0.6559228
ARR_TRTvsCTRL 0.02743902 0.05928384 -0.08875517 0.1436332 0.6434779


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        5  14
n_event_pct   12  18
```

```
$`Upper respiratory tract infection`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.43500000 0.4842916  0.55542083 3.7075041 0.4558129
OR_TRTvsCTRL  1.52727273 0.5606763  0.50894178 4.5831608 0.4500638
ARR_TRTvsCTRL 0.05304878 0.0664558 -0.07720219 0.1832998 0.4247216



\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten oder schweren UEs nach PT, das bei
mindestens 10% der Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               9.0               11.0
n_event_pct                          22.0               14.0
time-to-event-wk-10th                13.0               19.9
time-to-event-wk-25th                26.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5262    0.4524    0.2168    1.2770    0.1559


$Atelectasis
$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              10.0               15.0
n_event_pct                          24.0               19.0
time-to-event-wk-10th                 4.0               14.4
time-to-event-wk-25th                32.9               44.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6433    0.4088    0.2887    1.4340    0.2805


$`Bronchial secretion retention`
$`Bronchial secretion retention`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               7.0                  3
n_event_pct                          17.0                  4
time-to-event-wk-10th                 6.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.19210   0.69110   0.04957   0.74450   0.01699


$`Cardio-respiratory arrest`
$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41                 80
n_event                               5                  5
n_event_pct                          12                  6
time-to-event-wk-10th                23                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4327    0.6331    0.1251    1.4970    0.1858


$Dysphagia
$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               7.0                  6
n_event_pct                          17.0                  8
time-to-event-wk-10th                18.7                 NA
time-to-event-wk-25th                27.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           27.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32290   0.56020   0.10770   0.96800   0.04358
```

```
$Dyspnoea
$Dyspnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                80
n_event                              5.0                 3
n_event_pct                         12.0                 4
time-to-event-wk-10th               21.3                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24660   0.73230   0.05869   1.03600   0.05587


$`Oxygen saturation decreased`
$`Oxygen saturation decreased`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                80
n_event                              7.0                 8
n_event_pct                         17.0                10
time-to-event-wk-10th               17.9                29
time-to-event-wk-25th               40.7                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5017    0.5193    0.1813    1.3880    0.1841


$Pneumonia
$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              6.0               21.0
n_event_pct                         15.0               26.0
time-to-event-wk-10th               11.9               10.6
time-to-event-wk-25th                 NA               33.1
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Pneumonia$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6000    0.4635    0.6452    3.9700    0.3102


$`Pneumonia aspiration`
$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  41                80.0
n_event                                 7                 8.0
n_event_pct                            17                10.0
time-to-event-wk-10th                   9                32.7
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4814    0.5191    0.1740    1.3310    0.1590


$Pyrexia
$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                               8.0                21.0
n_event_pct                          20.0                26.0
time-to-event-wk-10th                13.4                15.3
time-to-event-wk-25th                  NA                41.4
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                46.4
time-to-event-wk-50th-hici             NA                  NA

$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1670    0.4165    0.5160    2.6410    0.7102


$`Respiratory distress`
$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                              11.0                20.0
n_event_pct                          27.0                25.0
time-to-event-wk-10th                11.0                 7.7
time-to-event-wk-25th                28.6                35.0
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           33.1                  NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8106    0.3766    0.3875    1.6960    0.5772


$`Respiratory failure`
$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              16.0               19.0
n_event_pct                          39.0               24.0
time-to-event-wk-10th                 4.6                5.1
time-to-event-wk-25th                13.0               34.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.50600   0.34220   0.25870   0.98950   0.04651


$`Rhinovirus infection`
$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               4.0                 10
n_event_pct                          10.0                 12
time-to-event-wk-10th                18.1                 18
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2560    0.5925    0.3932    4.0110    0.7008


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               5.0               14.0
n_event_pct                          12.0               18.0
time-to-event-wk-10th                28.3               25.4
time-to-event-wk-25th                  NA               49.4
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1880    0.5218    0.4274    3.3050    0.7408


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               6.0                  7
n_event_pct                          15.0                  9
time-to-event-wk-10th                17.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5155    0.5579    0.1727    1.5380    0.2349



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten oder schweren UEs nach PT, das bei
mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                               9.0                11.0
n_event_pct                          22.0                14.0
time-to-event-wk-10th                13.0                19.9
time-to-event-wk-25th                26.0                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           52.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5262    0.4524    0.2168    1.2770    0.1559
```

```
$Atelectasis
$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                              10.0                15.0
n_event_pct                          24.0                19.0
time-to-event-wk-10th                 4.0                14.4
time-to-event-wk-25th                32.9                44.0
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           52.7                  NA
time-to-event-wk-50th-hici             NA                  NA

$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6433    0.4088    0.2887    1.4340    0.2805


$Pneumonia
$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                               6.0                21.0
n_event_pct                          15.0                26.0
time-to-event-wk-10th                11.9                10.6
time-to-event-wk-25th                  NA                33.1
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6000    0.4635    0.6452    3.9700    0.3102


$Pyrexia
$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                               8.0                21.0
n_event_pct                          20.0                26.0
time-to-event-wk-10th                13.4                15.3
time-to-event-wk-25th                  NA                41.4
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                46.4
time-to-event-wk-50th-hici             NA                  NA

$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   1.1670    0.4165    0.5160    2.6410    0.7102


$`Respiratory distress`
$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              11.0               20.0
n_event_pct                          27.0               25.0
time-to-event-wk-10th                11.0                7.7
time-to-event-wk-25th                28.6               35.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8106    0.3766    0.3875    1.6960    0.5772


$`Respiratory failure`
$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              16.0               19.0
n_event_pct                          39.0               24.0
time-to-event-wk-10th                 4.6                5.1
time-to-event-wk-25th                13.0               34.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.50600   0.34220   0.25870   0.98950   0.04651


$`Rhinovirus infection`
$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               4.0                 10
n_event_pct                          10.0                 12
time-to-event-wk-10th                18.1                 18
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2560    0.5925    0.3932    4.0110    0.7008


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               5.0               14.0
n_event_pct                          12.0               18.0
time-to-event-wk-10th                28.3               25.4
time-to-event-wk-25th                  NA               49.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1880    0.5218    0.4274    3.3050    0.7408



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem SUE nach SOC, das bei mindestens 5% der
Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        7   9
n_event_pct   17  11

$`Cardiac disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.65892857 0.46591631  0.2643928 1.64220369 0.3706207
OR_TRTvsCTRL   0.61569416 0.54540309  0.2114059 1.79313499 0.3738636
ARR_TRTvsCTRL -0.05823171 0.06856585 -0.1926183 0.07615489 0.3957247


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         41  80
n_event        5   6
n_event_pct   12   8

$`Gastrointestinal disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.61500000 0.57426163  0.1995551 1.89534164 0.3972539
OR_TRTvsCTRL   0.58378378 0.63871587  0.1669460 2.04139928 0.3994149
ARR_TRTvsCTRL -0.04695122 0.05898197 -0.1625538 0.06865133 0.4260166


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         41  80
n_event        1   7
n_event_pct    2   9

$`General disorders and administration site conditions`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.58750000 1.05164961  0.45669488 28.1810830 0.2244744
OR_TRTvsCTRL  3.83561644 1.08699392  0.45560058 32.2913402 0.2161832
ARR_TRTvsCTRL 0.06310976 0.03972935 -0.01475835  0.1409779 0.1121751


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all         41  80
n_event       19  47
n_event_pct   46  59

$`Infections and infestations`$stats
               estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2677632 0.19240044  0.86949397 1.8484584 0.2175286
OR_TRTvsCTRL  1.6491228 0.38686658  0.77259442 3.5200954 0.1959887
ARR_TRTvsCTRL 0.1240854 0.09536358 -0.06282381 0.3109945 0.1931962


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         41  80
n_event        3   3
n_event_pct    7   4

$`Injury, poisoning and procedural complications`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.51250000 0.79358454  0.10819159 2.42769573 0.3996071
OR_TRTvsCTRL   0.49350649 0.84021989  0.09508158 2.56147040 0.4006185
ARR_TRTvsCTRL -0.03567073 0.04588289 -0.12559954 0.05425808 0.4369052


$Investigations
$Investigations$ntab
            CTRL TRT
n_all         41  80
n_event        3   3
n_event_pct    7   4
```

```
$Investigations$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.51250000 0.79358454  0.10819159 2.42769573 0.3996071
OR_TRTvsCTRL   0.49350649 0.84021989  0.09508158 2.56147040 0.4006185
ARR_TRTvsCTRL -0.03567073 0.04588289 -0.12559954 0.05425808 0.4369052


$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$ntab
           CTRL TRT
n_all        41  80
n_event       5   8
n_event_pct  12  10

$`Metabolism and nutrition disorders`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.82000000 0.53675856  0.2863678 2.34802962 0.7115903
OR_TRTvsCTRL   0.80000000 0.60553007  0.2441529 2.62130839 0.7124934
ARR_TRTvsCTRL -0.02195122 0.06112844 -0.1417608 0.09785832 0.7195203


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
           CTRL TRT
n_all        41  80
n_event      30  48
n_event_pct  73  60

$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.8200000 0.13143981  0.6337706 1.06095171 0.1310884
OR_TRTvsCTRL   0.5500000 0.41991161  0.2415090 1.25254142 0.1545272
ARR_TRTvsCTRL -0.1317073 0.08825016 -0.3046745 0.04125982 0.1355861



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem SUE nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Infections and infestations`
$`Infections and infestations`$ntab
           CTRL TRT
n_all        41  80
n_event      19  47
n_event_pct  46  59

$`Infections and infestations`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2677632 0.19240044  0.86949397 1.8484584 0.2175286
OR_TRTvsCTRL  1.6491228 0.38686658  0.77259442 3.5200954 0.1959887
ARR_TRTvsCTRL 0.1240854 0.09536358 -0.06282381 0.3109945 0.1931962
```

```
$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
           CTRL TRT
n_all        41  80
n_event      30  48
n_event_pct  73  60

$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.8200000 0.13143981  0.6337706 1.06095171 0.1310884
OR_TRTvsCTRL   0.5500000 0.41991161  0.2415090 1.25254142 0.1545272
ARR_TRTvsCTRL -0.1317073 0.08825016 -0.3046745 0.04125982 0.1355861



\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines SUEs nach SOC, das bei mindestens 5% der
Patienten in einem Studienarm auftrat"

$`Cardiac disorders`
$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                              7.0                9.0
n_event_pct                         17.0               11.0
time-to-event-wk-10th               14.3               17.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5771    0.5050    0.2145    1.5530    0.2764


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                 80
n_event                              5.0                  6
n_event_pct                         12.0                  8
time-to-event-wk-10th               36.4                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA
```

```
$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5173    0.6078    0.1572    1.7030    0.2783


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 41               80.0
n_event                                1                7.0
n_event_pct                            2                9.0
time-to-event-wk-10th                 NA               46.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.1490    1.0700    0.3869   25.6200    0.2836


$`Infections and infestations`
$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0               80.0
n_event                             19.0               47.0
n_event_pct                         46.0               59.0
time-to-event-wk-10th                5.7                2.7
time-to-event-wk-25th               13.7                7.1
time-to-event-wk-50th               32.9               25.4
time-to-event-wk-75th                 NA               55.4
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          15.3               14.4
time-to-event-wk-50th-hici            NA               35.4

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3130    0.2737    0.7679    2.2450    0.3198


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                 80
n_event                              3.0                  3
n_event_pct                          7.0                  4
time-to-event-wk-10th               50.6                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
```

```
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Injury, poisoning and procedural complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44030   0.81730   0.08873   2.18500   0.31560


$Investigations
$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               3.0                  3
n_event_pct                           7.0                  4
time-to-event-wk-10th                40.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4082    0.8170    0.0823    2.0240    0.2727


$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                               5.0                 8.0
n_event_pct                          12.0                10.0
time-to-event-wk-10th                 9.6                45.6
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7385    0.5712    0.2411    2.2620    0.5957


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                              30.0                48.0
n_event_pct                          73.0                60.0
time-to-event-wk-10th                 1.6                 1.6
time-to-event-wk-25th                 4.0                 5.4
```

```
time-to-event-wk-50th                13.9                15.7
time-to-event-wk-75th                52.6                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            6.1                10.0
time-to-event-wk-50th-hici           16.4                32.7

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7564    0.2345    0.4776    1.1980    0.2339



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines SUEs nach SOC, das bei mindestens 10 Patienten
und 1% der Patienten in einem Studienarm auftrat"

$`Infections and infestations`
$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                              19.0                47.0
n_event_pct                          46.0                59.0
time-to-event-wk-10th                 5.7                 2.7
time-to-event-wk-25th                13.7                 7.1
time-to-event-wk-50th                32.9                25.4
time-to-event-wk-75th                  NA                55.4
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           15.3                14.4
time-to-event-wk-50th-hici             NA                35.4

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3130    0.2737    0.7679    2.2450    0.3198


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                              30.0                48.0
n_event_pct                          73.0                60.0
time-to-event-wk-10th                 1.6                 1.6
time-to-event-wk-25th                 4.0                 5.4
time-to-event-wk-50th                13.9                15.7
time-to-event-wk-75th                52.6                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            6.1                10.0
time-to-event-wk-50th-hici           16.4                32.7

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7564    0.2345    0.4776    1.1980    0.2339
```

```
\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem SUE nach PT, das bei mindestens 5% der
Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event        9  11
n_event_pct   22  14

$`Acute respiratory failure`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6263889 0.40636186  0.2824543 1.3891204 0.2496701
OR_TRTvsCTRL   0.5668277 0.49775793  0.2136775 1.5036383 0.2540722
ARR_TRTvsCTRL -0.0820122 0.07524041 -0.2294807 0.0654563 0.2757123


$Atelectasis
$Atelectasis$ntab
            CTRL TRT
n_all         41  80
n_event        4  14
n_event_pct   10  18

$Atelectasis$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.79375000 0.53342134  0.63054029 5.1028286 0.2733425
OR_TRTvsCTRL  1.96212121 0.60299844  0.60180062 6.3973341 0.2636563
ARR_TRTvsCTRL 0.07743902 0.06286552 -0.04577513 0.2006532 0.2180162


$`Bronchial secretion retention`
$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         41  80
n_event        5   1
n_event_pct   12   1

$`Bronchial secretion retention`$stats
                estimate         se      lo95ci       hi95ci     pvalue
RR_TRTvsCTRL   0.10250000 1.07847566  0.01238009  0.848641009 0.03467437
OR_TRTvsCTRL   0.09113924 1.11374863  0.01027261  0.808592960 0.03149793
ARR_TRTvsCTRL -0.10945122 0.05259261 -0.21253084 -0.006371596 0.03742347


$Bronchiolitis
$Bronchiolitis$ntab
            CTRL TRT
n_all         41  80
n_event        1   4
```

```
n_event_pct    2   5

$Bronchiolitis$stats
                estimate        se      lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  2.05000000 1.1014126  0.23671716 17.75325461 0.5145659
OR_TRTvsCTRL  2.10526316 1.1349704  0.22762387 19.47130136 0.5118809
ARR_TRTvsCTRL 0.02560976 0.0342655 -0.04154939  0.09276891 0.4548271


$Bronchitis
$Bronchitis$ntab
            CTRL TRT
n_all         41  80
n_event        0   4
n_event_pct    0   5

$Bronchitis$stats
              estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  4.666667 1.47853543 0.257320947 84.63274384 0.29747091
OR_TRTvsCTRL  4.882353 1.50312691 0.256545988 92.91655838 0.29147755
ARR_TRTvsCTRL 0.050000 0.02436699 0.002241585  0.09775841 0.04017387


$`Cardio-respiratory arrest`
$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         41  80
n_event        5   5
n_event_pct   12   6

$`Cardio-respiratory arrest`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.51250000 0.60258589  0.1573156 1.66961336 0.2672965
OR_TRTvsCTRL   0.48000000 0.66416196  0.1305887 1.76431824 0.2691138
ARR_TRTvsCTRL -0.05945122 0.05782826 -0.1727925 0.05389009 0.3039192


$Dyspnoea
$Dyspnoea$ntab
            CTRL TRT
n_all         41  80
n_event        2   4
n_event_pct    5   5

$Dyspnoea$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.025000000 0.8444583  0.19584825 5.36448507 0.9766726
OR_TRTvsCTRL  1.026315789 0.8881435  0.18000803 5.85153961 0.9766676
ARR_TRTvsCTRL 0.001219512 0.0415389 -0.08019524 0.08263427 0.9765788


$Hypoxia
$Hypoxia$ntab
            CTRL TRT
```

```
n_all         41  80
n_event        1   4
n_event_pct    2   5

$Hypoxia$stats
                estimate        se      lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  2.05000000 1.1014126  0.23671716 17.75325461 0.5145659
OR_TRTvsCTRL  2.10526316 1.1349704  0.22762387 19.47130136 0.5118809
ARR_TRTvsCTRL 0.02560976 0.0342655 -0.04154939  0.09276891 0.4548271


$`Lower respiratory tract infection`
$`Lower respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        0   4
n_event_pct    0   5

$`Lower respiratory tract infection`$stats
              estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  4.666667 1.47853543 0.257320947 84.63274384 0.29747091
OR_TRTvsCTRL  4.882353 1.50312691 0.256545988 92.91655838 0.29147755
ARR_TRTvsCTRL 0.050000 0.02436699 0.002241585  0.09775841 0.04017387


$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all         41  80
n_event        5  19
n_event_pct   12  24

$Pneumonia$stats
               estimate         se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.9475000 0.46447964  0.78363113 4.8399765 0.15127592
OR_TRTvsCTRL  2.2426230 0.54479611  0.77094780 6.5236034 0.13821418
ARR_TRTvsCTRL 0.1155488 0.06982376 -0.02130328 0.2524008 0.09795223


$`Pneumonia aspiration`
$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         41  80
n_event        5   8
n_event_pct   12  10

$`Pneumonia aspiration`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.82000000 0.53675856  0.2863678 2.34802962 0.7115903
OR_TRTvsCTRL   0.80000000 0.60553007  0.2441529 2.62130839 0.7124934
ARR_TRTvsCTRL -0.02195122 0.06112844 -0.1417608 0.09785832 0.7195203


$`Pneumonia viral`
```

```
$`Pneumonia viral`$ntab
            CTRL TRT
n_all         41  80
n_event        2   6
n_event_pct    5   8

$`Pneumonia viral`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.53750000 0.79358454  0.32457476 7.2830872 0.5877882
OR_TRTvsCTRL  1.58108108 0.84013166  0.30467216 8.2049418 0.5855594
ARR_TRTvsCTRL 0.02621951 0.04470926 -0.06140903 0.1138481 0.5575767


$Pyrexia
$Pyrexia$ntab
            CTRL TRT
n_all         41  80
n_event        0   4
n_event_pct    0   5

$Pyrexia$stats
              estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  4.666667 1.47853543 0.257320947 84.63274384 0.29747091
OR_TRTvsCTRL  4.882353 1.50312691 0.256545988 92.91655838 0.29147755
ARR_TRTvsCTRL 0.050000 0.02436699 0.002241585  0.09775841 0.04017387


$`Respiratory arrest`
$`Respiratory arrest`$ntab
            CTRL TRT
n_all         41  80
n_event        4   5
n_event_pct   10   6

$`Respiratory arrest`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.64062500 0.64273615  0.1817632 2.25788534 0.4884122
OR_TRTvsCTRL   0.61666667 0.70025735  0.1563113 2.43282356 0.4899705
ARR_TRTvsCTRL -0.03506098 0.05366384 -0.1402402 0.07011822 0.5135342


$`Respiratory distress`
$`Respiratory distress`$ntab
            CTRL TRT
n_all         41  80
n_event        8  21
n_event_pct   20  26

$`Respiratory distress`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.34531250 0.36841390  0.6534746 2.7696039 0.4207365
OR_TRTvsCTRL  1.46822034 0.46890429  0.5856784 3.6806396 0.4127640
ARR_TRTvsCTRL 0.06737805 0.07905944 -0.0875756 0.2223317 0.3940778
```

```
$`Respiratory failure`
$`Respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event       16  20
n_event_pct   39  25

$`Respiratory failure`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6406250 0.27497228  0.3737206 1.09814759 0.1053449
OR_TRTvsCTRL   0.5208333 0.41129876  0.2325951 1.16626410 0.1127364
ARR_TRTvsCTRL -0.1402439 0.09026348 -0.3171571 0.03666927 0.1202519


$`Respiratory syncytial virus bronchiolitis`
$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         41  80
n_event        3   4
n_event_pct    7   5

$`Respiratory syncytial virus bronchiolitis`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.68333333 0.73921789  0.1604757 2.90975227 0.6064819
OR_TRTvsCTRL   0.66666667 0.78918123  0.1419569 3.13084108 0.6074062
ARR_TRTvsCTRL -0.02317073 0.04741116 -0.1160949 0.06975343 0.6250407


$`Respiratory tract infection`
$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        1   6
n_event_pct    2   8

$`Respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.07500000 1.06290941  0.38290848 24.6942166 0.2905933
OR_TRTvsCTRL  3.24324324 1.09780699  0.37715904 27.8891015 0.2838327
ARR_TRTvsCTRL 0.05060976 0.03804684 -0.02396068  0.1251802 0.1834537


$`Rhinovirus infection`
$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         41  80
n_event        2   7
n_event_pct    5   9

$`Rhinovirus infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.79375000 0.77843876  0.39007996 8.2484090 0.4528839
OR_TRTvsCTRL  1.86986301 0.82595206  0.37047433 9.4375976 0.4486007
```

```
ARR_TRTvsCTRL 0.03871951 0.04614951 -0.05173187 0.1291709 0.4014684


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        0   4
n_event_pct    0   5

$`Upper respiratory tract infection`$stats
              estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  4.666667 1.47853543 0.257320947 84.63274384 0.29747091
OR_TRTvsCTRL  4.882353 1.50312691 0.256545988 92.91655838 0.29147755
ARR_TRTvsCTRL 0.050000 0.02436699 0.002241585  0.09775841 0.04017387


$`Viral infection`
$`Viral infection`$ntab
            CTRL TRT
n_all         41  80
n_event        1   5
n_event_pct    2   6

$`Viral infection`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.56250000 1.07847566  0.30950219 21.2160252 0.3829289
OR_TRTvsCTRL  2.66666667 1.11280427  0.30112584 23.6150810 0.3780996
ARR_TRTvsCTRL 0.03810976 0.03623253 -0.03290471  0.1091242 0.2928865


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         41  80
n_event        6   3
n_event_pct   15   4

$`Viral upper respiratory tract infection`$stats
               estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.2562500 0.68052168  0.06751539 0.972579201 0.04541173
OR_TRTvsCTRL   0.2272727 0.73590654  0.05372081 0.961506245 0.04408252
ARR_TRTvsCTRL -0.1088415 0.05914506 -0.22476366 0.007080733 0.06573214



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem SUE nach PT, das bei mindestens 10 Patienten
und 1% der Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$ntab
            CTRL TRT
```

```
n_all         41  80
n_event        9  11
n_event_pct   22  14

$`Acute respiratory failure`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6263889 0.40636186  0.2824543 1.3891204 0.2496701
OR_TRTvsCTRL   0.5668277 0.49775793  0.2136775 1.5036383 0.2540722
ARR_TRTvsCTRL -0.0820122 0.07524041 -0.2294807 0.0654563 0.2757123


$Atelectasis
$Atelectasis$ntab
            CTRL TRT
n_all         41  80
n_event        4  14
n_event_pct   10  18

$Atelectasis$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.79375000 0.53342134  0.63054029 5.1028286 0.2733425
OR_TRTvsCTRL  1.96212121 0.60299844  0.60180062 6.3973341 0.2636563
ARR_TRTvsCTRL 0.07743902 0.06286552 -0.04577513 0.2006532 0.2180162


$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all         41  80
n_event        5  19
n_event_pct   12  24

$Pneumonia$stats
                estimate         se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.9475000 0.46447964  0.78363113 4.8399765 0.15127592
OR_TRTvsCTRL  2.2426230 0.54479611  0.77094780 6.5236034 0.13821418
ARR_TRTvsCTRL 0.1155488 0.06982376 -0.02130328 0.2524008 0.09795223


$`Respiratory distress`
$`Respiratory distress`$ntab
            CTRL TRT
n_all         41  80
n_event        8  21
n_event_pct   20  26

$`Respiratory distress`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.34531250 0.36841390  0.6534746 2.7696039 0.4207365
OR_TRTvsCTRL  1.46822034 0.46890429  0.5856784 3.6806396 0.4127640
ARR_TRTvsCTRL 0.06737805 0.07905944 -0.0875756 0.2223317 0.3940778


$`Respiratory failure`
```

```
$`Respiratory failure`$ntab
            CTRL TRT
n_all         41  80
n_event       16  20
n_event_pct   39  25

$`Respiratory failure`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6406250 0.27497228  0.3737206 1.09814759 0.1053449
OR_TRTvsCTRL   0.5208333 0.41129876  0.2325951 1.16626410 0.1127364
ARR_TRTvsCTRL -0.1402439 0.09026348 -0.3171571 0.03666927 0.1202519



\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines SUEs nach PT, das bei mindestens 5% der
Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               9.0               11.0
n_event_pct                          22.0               14.0
time-to-event-wk-10th                13.0               19.9
time-to-event-wk-25th                26.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5395    0.4512    0.2228    1.3060    0.1714


$Atelectasis
$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               4.0               14.0
n_event_pct                          10.0               18.0
time-to-event-wk-10th                32.9               14.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   1.6660    0.5675    0.5478    5.0670    0.3683


$`Bronchial secretion retention`
$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                 80
n_event                               5.0                  1
n_event_pct                          12.0                  1
time-to-event-wk-10th                19.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.08595   1.09600   0.01003   0.73680   0.02519


$Bronchiolitis
$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41                 80
n_event                               1                  4
n_event_pct                           2                  5
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0360    1.1190    0.2271   18.2500    0.5253


$Bronchitis
$Bronchitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41                 80
n_event                               0                  4
n_event_pct                           0                  5
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA
```

```
$Bronchitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.282e+08 1.318e+04 0.000e+00       Inf 9.988e-01


$`Cardio-respiratory arrest`
$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  41                 80
n_event                                 5                  5
n_event_pct                            12                  6
time-to-event-wk-10th                  23                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4327    0.6331    0.1251    1.4970    0.1858


$Dyspnoea
$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  41                 80
n_event                                 2                  4
n_event_pct                             5                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8656    0.8677    0.1580    4.7410    0.8678


$Hypoxia
$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  41                 80
n_event                                 1                  4
n_event_pct                             2                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
    1.859     1.120     0.207    16.690     0.580


$`Lower respiratory tract infection`
$`Lower respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  41                  80
n_event                                 0                   4
n_event_pct                             0                   5
time-to-event-wk-10th                  NA                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Lower respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.506e+08 1.410e+04 0.000e+00       Inf 9.989e-01


$Pneumonia
$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                               5.0                19.0
n_event_pct                          12.0                24.0
time-to-event-wk-10th                13.7                 9.0
time-to-event-wk-25th                  NA                35.9
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7750    0.5030    0.6623    4.7570    0.2540


$`Pneumonia aspiration`
$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80.0
n_event                               5.0                 8.0
n_event_pct                          12.0                10.0
time-to-event-wk-10th                15.7                32.7
```

```
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7036    0.5717    0.2294    2.1580    0.5386


$`Pneumonia viral`
$`Pneumonia viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               2.0                6.0
n_event_pct                           5.0                8.0
time-to-event-wk-10th                52.6               46.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5060    0.8181    0.3030    7.4830    0.6168


$Pyrexia
$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41                 80
n_event                               0                  4
n_event_pct                           0                  5
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.210e+08 1.367e+04 0.000e+00       Inf 9.989e-01


$`Respiratory arrest`
$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0                80
```

```
n_event                                4.0                  5
n_event_pct                           10.0                  6
time-to-event-wk-10th                 20.4                 NA
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4789    0.6743    0.1277    1.7960    0.2749


$`Respiratory distress`
$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               8.0               21.0
n_event_pct                          20.0               26.0
time-to-event-wk-10th                11.0                7.7
time-to-event-wk-25th                28.6               25.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2070    0.4169    0.5330    2.7320    0.6523


$`Respiratory failure`
$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              16.0               20.0
n_event_pct                          39.0               25.0
time-to-event-wk-10th                 4.6                5.1
time-to-event-wk-25th                13.0               32.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.54050   0.33820   0.27860   1.04900   0.06891


$`Respiratory syncytial virus bronchiolitis`
```

```
$`Respiratory syncytial virus bronchiolitis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                80
n_event                              3.0                 4
n_event_pct                          7.0                 5
time-to-event-wk-10th               22.4                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$`Respiratory syncytial virus bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5195    0.7671    0.1155    2.3370    0.3933


$`Respiratory tract infection`
$`Respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                41               80.0
n_event                               1                6.0
n_event_pct                           2                8.0
time-to-event-wk-10th                NA               40.1
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.7610    1.0810    0.3321   22.9600    0.3473


$`Rhinovirus infection`
$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                41               80.0
n_event                               2                7.0
n_event_pct                           5                9.0
time-to-event-wk-10th                NA               45.3
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6970    0.8029    0.3518    8.1880    0.5100
```

```
$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 41                 80
n_event                                0                  4
n_event_pct                            0                  5
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.300e+08 1.356e+04 0.000e+00       Inf 9.988e-01


$`Viral infection`
$`Viral infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 41                 80
n_event                                1                  5
n_event_pct                            2                  6
time-to-event-wk-10th                 NA                 55
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2200    1.0960    0.2591   19.0200    0.4668


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0                 80
n_event                              6.0                  3
n_event_pct                         15.0                  4
time-to-event-wk-10th               17.6                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA
```

```
$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.20750   0.70950   0.05167   0.83370   0.02667



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines SUEs nach PT, das bei mindestens 10 Patienten
und 1% der Patienten in einem Studienarm auftrat"

$`Acute respiratory failure`
$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0              80.0
n_event                              9.0              11.0
n_event_pct                         22.0              14.0
time-to-event-wk-10th               13.0              19.9
time-to-event-wk-25th               26.0                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          52.6                NA
time-to-event-wk-50th-hici            NA                NA

$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5395    0.4512    0.2228    1.3060    0.1714


$Atelectasis
$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0              80.0
n_event                              4.0              14.0
n_event_pct                         10.0              18.0
time-to-event-wk-10th               32.9              14.4
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6660    0.5675    0.5478    5.0670    0.3683


$Pneumonia
$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               41.0              80.0
n_event                              5.0              19.0
```

```
n_event_pct                          12.0               24.0
time-to-event-wk-10th                13.7                9.0
time-to-event-wk-25th                  NA               35.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7750    0.5030    0.6623    4.7570    0.2540


$`Respiratory distress`
$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                               8.0               21.0
n_event_pct                          20.0               26.0
time-to-event-wk-10th                11.0                7.7
time-to-event-wk-25th                28.6               25.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2070    0.4169    0.5330    2.7320    0.6523


$`Respiratory failure`
$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                41.0               80.0
n_event                              16.0               20.0
n_event_pct                          39.0               25.0
time-to-event-wk-10th                 4.6                5.1
time-to-event-wk-25th                13.0               32.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.54050   0.33820   0.27860   1.04900   0.06891



\################################################################################
```

```
Results for ENDEAR ITT-Population, Subgroups
[[1]]
[1] "Überlebensrate"

$ageonset_le_12wk
$ageonset_le_12wk$ntab
            CTRL TRT
n_all         32  72
n_event       18  62
n_event_pct   56  86

$ageonset_le_12wk$stats
               estimate         se    lo95ci    hi95ci      pvalue
RR_TRTvsCTRL  1.5308642 0.16292851 1.1123761  2.106792 0.008958990
OR_TRTvsCTRL  4.8222222 0.49306507 1.8346342 12.674912 0.001419165
ARR_TRTvsCTRL 0.2986111 0.09670328 0.1090762  0.488146 0.002015688


$ageonset_gt_12wk
$ageonset_gt_12wk$ntab
            CTRL TRT
n_all          9   8
n_event        7   5
n_event_pct   78  62

$ageonset_gt_12wk$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8035714 0.3267201  0.42356476 1.5245060 0.5032740
OR_TRTvsCTRL   0.4761905 1.0845232  0.05683723 3.9895920 0.4939033
ARR_TRTvsCTRL -0.1527778 0.2202300 -0.58442070 0.2788651 0.4878584


$agetrt_lt_180d
$agetrt_lt_180d$ntab
            CTRL TRT
n_all         16  49
n_event        8  43
n_event_pct   50  88

$agetrt_lt_180d$stats
              estimate        se    lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  1.755102 0.2556319 1.0634281  2.8966539 0.027768923
OR_TRTvsCTRL  7.166667 0.6632665 1.9531865 26.2960607 0.002984741
ARR_TRTvsCTRL 0.377551 0.1334839 0.1159273  0.6391747 0.004677581


$agetrt_ge_180d
$agetrt_ge_180d$ntab
            CTRL TRT
n_all         25  31
n_event       17  24
n_event_pct   68  77

$agetrt_ge_180d$stats
```

```
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.13851992 0.1680242  0.8190646 1.5825706 0.4400636
OR_TRTvsCTRL  1.61344538 0.6069163  0.4910732 5.3010551 0.4305793
ARR_TRTvsCTRL 0.09419355 0.1197635 -0.1405385 0.3289256 0.4315766


$sex_m
$sex_m$ntab
            CTRL TRT
n_all         17  37
n_event        9  30
n_event_pct   53  81

$sex_m$stats
              estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.531532 0.2420617 0.95297742  2.4613268 0.07824015
OR_TRTvsCTRL  3.809524 0.6421071 1.08220142 13.4101392 0.03725193
ARR_TRTvsCTRL 0.281399 0.1371162 0.01265623  0.5501419 0.04014372


$sex_f
$sex_f$ntab
            CTRL TRT
n_all         24  43
n_event       16  37
n_event_pct   67  86

$sex_f$stats
               estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.2906977 0.1568584  0.94908792  1.7552647 0.10377184
OR_TRTvsCTRL  3.0833333 0.6174089  0.91935048 10.3409359 0.06818697
ARR_TRTvsCTRL 0.1937984 0.1097792 -0.02136477  0.4089617 0.07750528


$region_europe
$region_europe$ntab
            CTRL TRT
n_all         17  30
n_event       12  23
n_event_pct   71  77

$region_europe$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.08611111 0.1861578  0.7540783 1.5643433 0.6572389
OR_TRTvsCTRL  1.36904762 0.6853238  0.3573303 5.2452627 0.6467040
ARR_TRTvsCTRL 0.06078431 0.1348164 -0.2034510 0.3250196 0.6520851


$region_asiapacific
$region_asiapacific$ntab
            CTRL TRT
n_all          2  12
n_event        1  12
n_event_pct   50 100
```

```
$region_asiapacific$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   1.923077 0.5800088  0.6170100   5.993784 0.25955555
OR_TRTvsCTRL  25.000000 1.8475209  0.6688480 934.442574 0.08146162
ARR_TRTvsCTRL  0.500000 0.3535534 -0.1929519   1.192952 0.15729921


$region_northamerica
$region_northamerica$ntab
            CTRL TRT
n_all         22  38
n_event       12  32
n_event_pct   55  84

$region_northamerica$stats
               estimate        se     lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.5438596 0.2069130 1.02916056  2.315968 0.03582750
OR_TRTvsCTRL  4.4444444 0.6174545 1.32507146 14.907186 0.01570010
ARR_TRTvsCTRL 0.2966507 0.1215268 0.05846248  0.534839 0.01464542


$disdur_gt_12wk
$disdur_gt_12wk$ntab
            CTRL TRT
n_all         23  46
n_event       14  36
n_event_pct   61  78

$disdur_gt_12wk$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.285714 0.1843609  0.89581050 1.8453247 0.1728304
OR_TRTvsCTRL  2.314286 0.5570615  0.77668588 6.8958617 0.1319904
ARR_TRTvsCTRL 0.173913 0.1185513 -0.05844322 0.4062693 0.1423800


$disdur_le_12wek
$disdur_le_12wek$ntab
            CTRL TRT
n_all         18  34
n_event       11  31
n_event_pct   61  91

$disdur_le_12wek$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.4919786 0.1954478 1.01717843  2.1884068 0.04064726
OR_TRTvsCTRL  6.5757576 0.7741819 1.44198571 29.9868351 0.01498471
ARR_TRTvsCTRL 0.3006536 0.1247766 0.05609604  0.5452112 0.01597282



\##############################################################################
[[1]]
[1] "Zeit bis zum Tod"
```

```
$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                             14.0               10.0
n_event_pct                         44.0               14.0
time-to-event-wk-10th                5.1               17.4
time-to-event-wk-25th               12.6                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          13.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.261200  0.417000  0.115400  0.591600  0.001288


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              2.0                3.0
n_event_pct                         22.0               38.0
time-to-event-wk-10th               23.1                0.9
time-to-event-wk-25th               33.6                6.3
time-to-event-wk-50th                 NA               30.6
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          23.1                0.9
time-to-event-wk-50th-hici            NA                 NA

$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.2750    0.9571    0.5019   21.3700    0.2151


$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              8.0                6.0
n_event_pct                         50.0               12.0
time-to-event-wk-10th                4.4               16.3
time-to-event-wk-25th               12.2                 NA
time-to-event-wk-50th               40.3                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          11.3                 NA
time-to-event-wk-50th-hici            NA                 NA

$agetrt_lt_180d$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.167700  0.560000  0.055950  0.502600  0.001431


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               8.0                7.0
n_event_pct                          32.0               23.0
time-to-event-wk-10th                 5.4               12.0
time-to-event-wk-25th                23.1               30.6
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           23.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6667    0.5280    0.2369    1.8770    0.4426


$sex_m
$sex_m$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               8.0                7.0
n_event_pct                          47.0               19.0
time-to-event-wk-10th                 4.4                7.9
time-to-event-wk-25th                14.3                 NA
time-to-event-wk-50th                40.3                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.37800   0.52760   0.13440   1.06300   0.06519


$sex_f
$sex_f$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               8.0                6.0
n_event_pct                          33.0               14.0
time-to-event-wk-10th                 5.4               17.4
time-to-event-wk-25th                15.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.0                 NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4664    0.5551    0.1571    1.3850    0.1695


$region_europe
$region_europe$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               5.0                7.0
n_event_pct                          29.0               23.0
time-to-event-wk-10th                 5.1               11.6
time-to-event-wk-25th                13.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           12.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8028    0.5887    0.2532    2.5450    0.7091


$region_asiapacific
$region_asiapacific$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0                 12
n_event                               1.0                  0
n_event_pct                          50.0                  0
time-to-event-wk-10th                 2.9                 NA
time-to-event-wk-25th                 2.9                 NA
time-to-event-wk-50th                26.1                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            2.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.188e-28 8.557e+04 0.000e+00       Inf 9.994e-01


$region_northamerica
$region_northamerica$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              10.0                6.0
n_event_pct                          45.0               16.0
time-to-event-wk-10th                10.0               16.3
time-to-event-wk-25th                17.4                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           17.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32040   0.51890   0.11590   0.88580   0.02826


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                  46
n_event                               9.0                  10
n_event_pct                          39.0                  22
time-to-event-wk-10th                 5.1                  12
time-to-event-wk-25th                12.1                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           13.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45480   0.46190   0.18390   1.12500   0.08806


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                  34
n_event                               7.0                   3
n_event_pct                          39.0                   9
time-to-event-wk-10th                10.0                  NA
time-to-event-wk-25th                23.1                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           23.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.21910   0.69890   0.05569   0.86220   0.02985



\##############################################################################
[[1]]
[1] "Zeit bis zum Tod oder permanenter Beatmung (>=16 Stunden Beatmung/Tag für
>21 Tage in der Abwesenheit eines akuten reversiblen Ereignisses oder
Tracheostomie)"
```

```
$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                             23.0               28.0
n_event_pct                         72.0               39.0
time-to-event-wk-10th                4.4                8.3
time-to-event-wk-25th               10.6               14.4
time-to-event-wk-50th               17.1                 NA
time-to-event-wk-75th               40.3                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          12.1               36.3
time-to-event-wk-50th-hici          25.4                 NA

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49130   0.28970   0.27840   0.86690   0.01417


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              5.0                3.0
n_event_pct                         56.0               38.0
time-to-event-wk-10th                7.6                0.9
time-to-event-wk-25th               23.1                6.3
time-to-event-wk-50th               31.3               30.6
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           7.6                0.9
time-to-event-wk-50th-hici            NA                 NA

$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9089    0.7754    0.1988    4.1540    0.9019


$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                             12.0               15.0
n_event_pct                         75.0               31.0
time-to-event-wk-10th                4.4                8.3
time-to-event-wk-25th               10.6               29.0
time-to-event-wk-50th               14.6                 NA
time-to-event-wk-75th               40.3                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          10.0               39.1
time-to-event-wk-50th-hici          40.3                 NA

$agetrt_lt_180d$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
0.2635000 0.3925000 0.1221000 0.5686000 0.0006783


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              16.0               16.0
n_event_pct                          64.0               52.0
time-to-event-wk-10th                 5.1                7.9
time-to-event-wk-25th                13.6                8.7
time-to-event-wk-50th                24.3               30.6
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.1               12.0
time-to-event-wk-50th-hici             NA                 NA

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7715    0.3558    0.3841    1.5500    0.4661


$sex_m
$sex_m$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               9.0               18.0
n_event_pct                          53.0               49.0
time-to-event-wk-10th                 4.4                5.6
time-to-event-wk-25th                13.6                8.3
time-to-event-wk-50th                33.6               36.3
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.1               10.0
time-to-event-wk-50th-hici             NA                 NA

$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9781    0.4096    0.4382    2.1830    0.9568


$sex_f
$sex_f$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              19.0               13.0
n_event_pct                          79.0               30.0
time-to-event-wk-10th                 5.1               12.0
time-to-event-wk-25th                10.6               30.6
time-to-event-wk-50th                19.0                 NA
time-to-event-wk-75th                27.1                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           11.3               39.1
```

```
time-to-event-wk-50th-hici           24.3                 NA

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.305200  0.375000  0.146400  0.636600  0.001555


$region_europe
$region_europe$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                              10.0               14.0
n_event_pct                          59.0               47.0
time-to-event-wk-10th                 5.1                7.9
time-to-event-wk-25th                13.1               11.7
time-to-event-wk-50th                22.6               30.6
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           12.1               14.4
time-to-event-wk-50th-hici             NA                 NA

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0460    0.4429    0.4389    2.4910    0.9199


$region_asiapacific
$region_asiapacific$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                 12
n_event                              2.0                  1
n_event_pct                        100.0                  8
time-to-event-wk-10th                2.9                 NA
time-to-event-wk-25th                2.9                 NA
time-to-event-wk-50th                5.2                 NA
time-to-event-wk-75th                7.6                 NA
time-to-event-wk-90th                7.6                 NA
time-to-event-wk-50th-loci           2.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.303e-11 3.908e+04 0.000e+00       Inf 9.995e-01


$region_northamerica
$region_northamerica$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              16.0               16.0
n_event_pct                          73.0               42.0
time-to-event-wk-10th                 5.4                5.6
time-to-event-wk-25th                13.6               16.3
time-to-event-wk-50th                23.1                 NA
```

```
time-to-event-wk-75th                40.3                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           13.6                30.6
time-to-event-wk-50th-hici           33.6                  NA

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48530   0.35520   0.24190   0.97350   0.04181


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46.0
n_event                              16.0                25.0
n_event_pct                          70.0                54.0
time-to-event-wk-10th                 4.3                 7.9
time-to-event-wk-25th                11.3                11.0
time-to-event-wk-50th                19.1                30.6
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           12.1                12.0
time-to-event-wk-50th-hici           27.1                  NA

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8175    0.3249    0.4324    1.5450    0.5351


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                  34
n_event                              12.0                   6
n_event_pct                          67.0                  18
time-to-event-wk-10th                 6.0                  29
time-to-event-wk-25th                13.1                  NA
time-to-event-wk-50th                25.4                  NA
time-to-event-wk-75th                40.3                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           13.1                  NA
time-to-event-wk-50th-hici           40.3                  NA

$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
0.1578000 0.5253000 0.0563500 0.4417000 0.0004387



\#############################################################################
[[1]]
[1] "Zeit bis zu permanenter Beatmung (>=16 Stunden Beatmung/Tag für >21 Tage in
der Abwesenheit eines akuten reversiblen Ereignisses oder Tracheostomie)"
```

```
$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                             10.0               18.0
n_event_pct                         31.0               25.0
time-to-event-wk-10th               13.6                8.7
time-to-event-wk-25th               19.1               37.6
time-to-event-wk-50th               27.1                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          19.1                 NA
time-to-event-wk-50th-hici            NA                 NA

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7373    0.4057    0.3329    1.6330    0.4527


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                              9.0                  8
n_event                            3.0                  0
n_event_pct                       33.0                  0
time-to-event-wk-10th              7.6                 NA
time-to-event-wk-25th             31.3                 NA
time-to-event-wk-50th               NA                 NA
time-to-event-wk-75th               NA                 NA
time-to-event-wk-90th               NA                 NA
time-to-event-wk-50th-loci         7.6                 NA
time-to-event-wk-50th-hici          NA                 NA

$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.499e-10 2.385e+04 0.000e+00       Inf 9.993e-01


$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              5.0                9.0
n_event_pct                         31.0               18.0
time-to-event-wk-10th               13.6               11.4
time-to-event-wk-25th               15.0                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          13.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$agetrt_lt_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
  0.35120   0.56470   0.11610   1.06200   0.06388


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               8.0                9.0
n_event_pct                          32.0               29.0
time-to-event-wk-10th                15.1                8.0
time-to-event-wk-25th                22.6               14.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.6               37.6
time-to-event-wk-50th-hici             NA                 NA

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8295    0.4884    0.3185    2.1600    0.7020


$sex_m
$sex_m$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               2.0               11.0
n_event_pct                          12.0               30.0
time-to-event-wk-10th                25.4                7.9
time-to-event-wk-25th                  NA               11.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           25.4               29.0
time-to-event-wk-50th-hici             NA                 NA

$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.6220    0.7713    0.5782   11.8900    0.2114


$sex_f
$sex_f$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              11.0                7.0
n_event_pct                          46.0               16.0
time-to-event-wk-10th                13.6               30.6
time-to-event-wk-25th                15.1               40.3
time-to-event-wk-50th                24.3                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.1                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.233000  0.506400  0.086360  0.628700  0.004022


$region_europe
$region_europe$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               5.0                7.0
n_event_pct                          29.0               23.0
time-to-event-wk-10th                15.0                8.3
time-to-event-wk-25th                20.4               30.6
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.0               30.6
time-to-event-wk-50th-hici             NA                 NA

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9385    0.6385    0.2685    3.2810    0.9208


$region_asiapacific
$region_asiapacific$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0                 12
n_event                               1.0                  1
n_event_pct                          50.0                  8
time-to-event-wk-10th                 7.6                 NA
time-to-event-wk-25th                 7.6                 NA
time-to-event-wk-50th                 7.6                 NA
time-to-event-wk-75th                 7.6                 NA
time-to-event-wk-90th                 7.6                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.226e-11 2.785e+04 0.000e+00       Inf 9.993e-01


$region_northamerica
$region_northamerica$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               7.0               10.0
n_event_pct                          32.0               26.0
time-to-event-wk-10th                15.1                8.3
time-to-event-wk-25th                25.4               37.6
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           25.4               39.1
time-to-event-wk-50th-hici             NA                 NA

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6439    0.4973    0.2430    1.7060    0.3761


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               7.0               15.0
n_event_pct                          30.0               33.0
time-to-event-wk-10th                15.1                8.0
time-to-event-wk-25th                20.4               11.4
time-to-event-wk-50th                27.1                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.1               36.3
time-to-event-wk-50th-hici             NA                 NA

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1670    0.4631    0.4709    2.8920    0.7387


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               6.0                3.0
n_event_pct                          33.0                9.0
time-to-event-wk-10th                 7.6               39.1
time-to-event-wk-25th                15.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.12010   0.74840   0.02770   0.52080   0.00463



\#############################################################################
[[1]]
[1] "Anzahl der Stunden mit Beatmung (Std.) für Patienten die zu Baseline keine
Beatmung benötigten"

$ageonset_le_12wk
```

```
$ageonset_le_12wk$numbers_eachgrp
           Control ISIS 396443
N      28.00000000 51.00000000
n      28.00000000 51.00000000
mean    0.31298554  0.21604373
sd      0.26400489  0.26030085
se      0.04989223  0.03644941
median  0.30494564  0.07470539
min     0.00000000  0.00000000
max     0.91495902  0.95464701
sum     8.76359514 11.01823030

$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.22     0.037         0.144          0.29
2     Control   0.31     0.050         0.212          0.41

$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    -0.09406804      0.06245231     -0.21847942      0.03034335      0.13620654

$ageonset_le_12wk$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.3700 -0.8320  0.0980  0.1217


$ageonset_gt_12wk
$ageonset_gt_12wk$numbers_eachgrp
         Control ISIS 396443
N      7.0000000 8.000000000
n      7.0000000 8.000000000
mean   0.3297751 0.146602007
sd     0.3515811 0.282467051
se     0.1328852 0.099867184
median 0.1985524 0.000105753
min    0.0000000 0.000000000
max    0.8931159 0.813888889
sum    2.3084258 1.172816056

$ageonset_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.13     0.121        -0.140         0.392
2     Control   0.35     0.130         0.067         0.639

$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     -0.2263943       0.1838587      -0.6310645       0.1782759       0.2438689

$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
-0.550 -1.585  0.494  0.304


$agetrt_lt_180d
```

```
$agetrt_lt_180d$numbers_eachgrp
           Control ISIS 396443
N      15.00000000 40.00000000
n      15.00000000 40.00000000
mean    0.37563697  0.17142085
sd      0.28613922  0.22933190
se      0.07388083  0.03626056
median  0.39639037  0.06414048
min     0.00000000  0.00000000
max     0.91495902  0.95464701
sum     5.63455454  6.85683400

$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.17     0.038         0.092         0.246
2     Control   0.38     0.063         0.256         0.509

$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   -0.213566315     0.073851868    -0.361830127    -0.065302503     0.005617094

$agetrt_lt_180d$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.8200 -1.4340 -0.2050  0.0089


$agetrt_ge_180d
$agetrt_ge_180d$numbers_eachgrp
           Control ISIS 396443
N      20.00000000 19.00000000
n      20.00000000 19.00000000
mean    0.27187332  0.28074802
sd      0.27014120  0.31398791
se      0.06040541  0.07203377
median  0.15830200  0.13636364
min     0.00000000  0.00000000
max     0.89311594  0.90664557
sum     5.43746643  5.33421236

$agetrt_ge_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.26     0.067         0.126         0.399
2     Control   0.29     0.065         0.157         0.422

$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    -0.02685218      0.09511694     -0.21994984      0.16624548      0.77937086

$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 0.030 -0.598  0.658  0.926


$sex_m
```

```
$sex_m$numbers_eachgrp
           Control ISIS 396443
N      15.00000000 26.00000000
n      15.00000000 26.00000000
mean    0.29200260  0.27688628
sd      0.27182769  0.29253487
se      0.07018561  0.05737081
median  0.19855243  0.26114646
min     0.00000000  0.00000000
max     0.91495902  0.95464701
sum     4.38003895  7.19904335

$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.27     0.055         0.160         0.382
2     Control   0.30     0.072         0.156         0.449

$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    -0.03097982      0.09095762     -0.21527747      0.15331783      0.73533396

$sex_m$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.0500 -0.6880  0.5840  0.8727


$sex_f
$sex_f$numbers_eachgrp
           Control ISIS 396443
N      20.00000000 33.00000000
n      20.00000000 33.00000000
mean    0.33459910  0.15127282
sd      0.28792171  0.22436088
se      0.06438125  0.03905622
median  0.32454088  0.01466963
min     0.00000000  0.00000000
max     0.89311594  0.66909898
sum     6.69198202  4.99200301

$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.15     0.045         0.055         0.237
2     Control   0.34     0.059         0.223         0.462

$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    -0.19647917      0.07744691     -0.35211457     -0.04084377      0.01441661

$sex_f$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.7200 -1.2960 -0.1490  0.0135


$region_europe
```

```
$region_europe$numbers_eachgrp
           Control ISIS 396443
N      17.00000000 23.00000000
n      17.00000000 23.00000000
mean    0.24790796  0.17794050
sd      0.23566051  0.22947154
se      0.05715607  0.04784812
median  0.16814721  0.06042383
min     0.00000000  0.00000000
max     0.82831466  0.66909898
sum     4.21443527  4.09263159

$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.15     0.050         0.054         0.255
2     Control   0.28     0.059         0.161         0.399

$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    -0.12507041      0.08042273     -0.28817527      0.03803445      0.12865583

$region_europe$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.3000 -0.9260  0.3350  0.3584


$region_asiapacific
$region_asiapacific$numbers_eachgrp
         Control ISIS 396443
N      2.0000000 12.00000000
n      2.0000000 12.00000000
mean   0.7580163  0.04041245
sd     0.1910597  0.10967227
se     0.1350996  0.03165966
median 0.7580163  0.00000000
min    0.6229167  0.00000000
max    0.8931159  0.37355700
sum    1.5160326  0.48494941

$region_asiapacific$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.04     0.037        -0.041         0.126
2     Control   0.74     0.096         0.529         0.958

$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
  -7.010052e-01    1.048764e-01   -9.346844e-01   -4.673261e-01    5.471645e-05

$region_asiapacific$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-5.6600 -8.5560 -2.7720  0.0001


$region_northamerica
```

```
$region_northamerica$numbers_eachgrp
          Control ISIS 396443
N      16.0000000 24.00000000
n      16.0000000 24.00000000
mean    0.3338471  0.31722772
sd      0.2858144  0.29817455
se      0.0714536  0.06086462
median  0.3355185  0.32511391
min     0.0000000  0.00000000
max     0.9149590  0.95464701
sum     5.3415531  7.61346535

$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.29     0.056         0.179         0.407
2     Control   0.37     0.069         0.230         0.512

$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    -0.07799320      0.09109398     -0.26274036      0.10675396      0.39755930

$region_northamerica$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.0600 -0.6880  0.5770  0.8634


$disdur_gt_12wk
$disdur_gt_12wk$numbers_eachgrp
           Control ISIS 396443
N      19.00000000 29.00000000
n      19.00000000 29.00000000
mean    0.27727110  0.28844120
sd      0.24388777  0.30461555
se      0.05595169  0.05656569
median  0.16814721  0.22235202
min     0.00000000  0.00000000
max     0.67530225  0.95464701
sum     5.26815084  8.36479469

$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.29     0.054         0.179         0.395
2     Control   0.28     0.067         0.145         0.414

$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     0.00826747      0.08734833     -0.16777153      0.18430647      0.92502301

$disdur_gt_12wk$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.0400 -0.5400  0.6170  0.8951


$disdur_le_12wek
```

```
$disdur_le_12wek$numbers_eachgrp
           Control ISIS 396443
N      16.00000000  30.0000000
n      16.00000000  30.0000000
mean    0.36274188   0.1275417
sd      0.31527577   0.1856768
se      0.07881894   0.0338998
median  0.31592330   0.0274790
min     0.00000000   0.0000000
max     0.91495902   0.6511995
sum     5.80387013   3.8262517

$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.13     0.045         0.036         0.216
2     Control   0.37     0.062         0.242         0.490

$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   -0.240453038     0.076732436    -0.395305364    -0.085600712     0.003144394

$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
-0.970 -1.613 -0.330  0.003



\#############################################################################
[[1]]
[1] "Anteil an Patienten, die keine permanente Beatmung benötigen (>=16 Stunden
Beatmung/Tag für >21 Tage in der Abwesenheit eines akuten reversiblen
Ereignisses oder Tracheostomie)"

$ageonset_le_12wk
$ageonset_le_12wk$ntab
            CTRL TRT
n_all         32  72
n_event       22  54
n_event_pct   69  75

$ageonset_le_12wk$stats
              estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.090909 0.13723766  0.8336268 1.4275965 0.5260680
OR_TRTvsCTRL  1.363636 0.46853881  0.5443492 3.4160132 0.5079955
ARR_TRTvsCTRL 0.062500 0.09652996 -0.1266953 0.2516953 0.5173295


$ageonset_gt_12wk
$ageonset_gt_12wk$ntab
            CTRL TRT
n_all          9   8
n_event        6   8
n_event_pct   67 100
```

```
$ageonset_gt_12wk$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.4529915 0.2457277 0.89763394   2.351943 0.12838992
OR_TRTvsCTRL  9.1538462 1.5991271 0.39849617 210.272786 0.16617046
ARR_TRTvsCTRL 0.3333333 0.1571348 0.02535471   0.641312 0.03389485


$agetrt_lt_180d
$agetrt_lt_180d$ntab
            CTRL TRT
n_all         16  49
n_event       11  40
n_event_pct   69  82

$agetrt_lt_180d$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.1873840 0.1816616  0.8316883 1.6952034 0.3444273
OR_TRTvsCTRL  2.0202020 0.6534678  0.5612573 7.2715605 0.2818820
ARR_TRTvsCTRL 0.1288265 0.1284044 -0.1228414 0.3804945 0.3157221


$agetrt_ge_180d
$agetrt_ge_180d$ntab
            CTRL TRT
n_all         25  31
n_event       17  22
n_event_pct   68  71

$agetrt_ge_180d$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.04364326 0.1789414  0.7349147 1.4820649 0.8113190
OR_TRTvsCTRL  1.15032680 0.5834288  0.3666112 3.6094144 0.8102995
ARR_TRTvsCTRL 0.02967742 0.1238963 -0.2131549 0.2725098 0.8106913


$sex_m
$sex_m$ntab
            CTRL TRT
n_all         17  37
n_event       15  26
n_event_pct   88  70

$sex_m$stats
               estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.7963964 0.1388440  0.60665961 1.04547461 0.10107390
OR_TRTvsCTRL   0.3151515 0.8342885  0.06142876 1.61684004 0.16634140
ARR_TRTvsCTRL -0.1796502 0.1084090 -0.39212795 0.03282747 0.09748862


$sex_f
$sex_f$ntab
            CTRL TRT
n_all         24  43
n_event       13  36
```

```
n_event_pct   54  84

$sex_f$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.5456172 0.1994452 1.04552375  2.2849146 0.02902307
OR_TRTvsCTRL  4.3516484 0.5817792 1.39136926 13.6102212 0.01148173
ARR_TRTvsCTRL 0.2955426 0.1162491 0.06769852  0.5233867 0.01101189


$region_europe
$region_europe$ntab
            CTRL TRT
n_all         17  30
n_event       12  23
n_event_pct   71  77

$region_europe$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.08611111 0.1861578  0.7540783 1.5643433 0.6572389
OR_TRTvsCTRL  1.36904762 0.6853238  0.3573303 5.2452627 0.6467040
ARR_TRTvsCTRL 0.06078431 0.1348164 -0.2034510 0.3250196 0.6520851


$region_asiapacific
$region_asiapacific$ntab
            CTRL TRT
n_all          2  12
n_event        1  11
n_event_pct   50  92

$region_asiapacific$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   1.8333333 0.7124435  0.4537414   7.407548 0.3948891
OR_TRTvsCTRL  11.0000000 1.7580981  0.3506686 345.055171 0.1725945
ARR_TRTvsCTRL  0.4166667 0.3624441 -0.2937108   1.127044 0.2503076


$region_northamerica
$region_northamerica$ntab
            CTRL TRT
n_all         22  38
n_event       15  28
n_event_pct   68  74

$region_northamerica$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.08070175 0.1749589  0.7669739 1.5227589 0.6573366
OR_TRTvsCTRL  1.30666667 0.5875697  0.4130709 4.1333769 0.6489437
ARR_TRTvsCTRL 0.05502392 0.1223266 -0.1847318 0.2947796 0.6528462


$disdur_gt_12wk
$disdur_gt_12wk$ntab
            CTRL TRT
```

```
n_all         23  46
n_event       16  31
n_event_pct   70  67

$disdur_gt_12wk$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.96875000 0.1718740  0.6916913 1.3567853 0.8534481
OR_TRTvsCTRL   0.90416667 0.5516175  0.3066979 2.6655459 0.8550888
ARR_TRTvsCTRL -0.02173913 0.1182476 -0.2535002 0.2100219 0.8541357


$disdur_le_12wek
$disdur_le_12wek$ntab
            CTRL TRT
n_all         18  34
n_event       12  31
n_event_pct   67  91

$disdur_le_12wek$stats
              estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.367647 0.1749974 0.970545743  1.9272234 0.07359503
OR_TRTvsCTRL  5.166667 0.7845963 1.110096768 24.0469527 0.03634146
ARR_TRTvsCTRL 0.245098 0.1212924 0.007369271  0.4828268 0.04330874



\#############################################################################
[[1]]
[1] "Zeit bis zur Beatmung (unabhängig von der Dauer) für Patienten die zu
Baseline keine Beatmung benötigten"

$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                28.0               51.0
n_event                              24.0               34.0
n_event_pct                          86.0               67.0
time-to-event-wk-10th                 1.0                2.0
time-to-event-wk-25th                 5.6                4.0
time-to-event-wk-50th                 9.9               15.9
time-to-event-wk-75th                13.7               41.0
time-to-event-wk-90th                27.3                 NA
time-to-event-wk-50th-loci            6.4                6.9
time-to-event-wk-50th-hici           12.9               37.3

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.52540   0.30380   0.28970   0.95300   0.03415


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                7.0                8.0
```

```
n_event                                6.0               4.0
n_event_pct                           86.0              50.0
time-to-event-wk-10th                  1.7               0.7
time-to-event-wk-25th                  4.6               4.1
time-to-event-wk-50th                  9.1               5.3
time-to-event-wk-75th                 21.1                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci             1.7               0.7
time-to-event-wk-50th-hici            21.1                NA

$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7864    0.6527    0.2188    2.8260    0.7127


$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                15.0              40.0
n_event                              13.0              25.0
n_event_pct                          87.0              62.0
time-to-event-wk-10th                 1.0               2.0
time-to-event-wk-25th                 5.6               5.5
time-to-event-wk-50th                 8.1              31.6
time-to-event-wk-75th                12.0              41.0
time-to-event-wk-90th                13.3              45.3
time-to-event-wk-50th-loci            5.0               8.4
time-to-event-wk-50th-hici           12.0              40.4

$agetrt_lt_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.337600  0.384600  0.158900  0.717400  0.004752


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                20.0              19.0
n_event                              17.0              13.0
n_event_pct                          85.0              68.0
time-to-event-wk-10th                 2.4               0.3
time-to-event-wk-25th                 4.6               3.4
time-to-event-wk-50th                12.6               6.0
time-to-event-wk-75th                18.1                NA
time-to-event-wk-90th                39.1                NA
time-to-event-wk-50th-loci            4.6               3.4
time-to-event-wk-50th-hici           18.1               9.7

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0930    0.3751    0.5239    2.2790    0.8133


$sex_m
```

```
$sex_m$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               15.0               26.0
n_event                             13.0               20.0
n_event_pct                         87.0               77.0
time-to-event-wk-10th                1.0                1.1
time-to-event-wk-25th                5.0                3.4
time-to-event-wk-50th               12.6                6.9
time-to-event-wk-75th               13.3               18.4
time-to-event-wk-90th               39.1                 NA
time-to-event-wk-50th-loci           1.7                3.4
time-to-event-wk-50th-hici          13.3               15.0

$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9953    0.3776    0.4748    2.0860    0.9900


$sex_f
$sex_f$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               20.0               33.0
n_event                             17.0               18.0
n_event_pct                         85.0               55.0
time-to-event-wk-10th                3.1                2.4
time-to-event-wk-25th                4.6                6.0
time-to-event-wk-50th                8.1               37.3
time-to-event-wk-75th               15.7               45.3
time-to-event-wk-90th               27.3                 NA
time-to-event-wk-50th-loci           4.6                9.6
time-to-event-wk-50th-hici          15.7               45.3

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45410   0.37320   0.21850   0.94380   0.03443


$region_europe
$region_europe$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               23.0
n_event                             14.0               14.0
n_event_pct                         82.0               61.0
time-to-event-wk-10th                4.6                1.1
time-to-event-wk-25th                6.6                5.3
time-to-event-wk-50th                9.5               15.9
time-to-event-wk-75th               13.3               41.0
time-to-event-wk-90th               27.3                 NA
time-to-event-wk-50th-loci           6.4                6.0
time-to-event-wk-50th-hici          13.3               41.0

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5429    0.4381    0.2300    1.2810    0.1633
```

```
$region_asiapacific
$region_asiapacific$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0               12.0
n_event                              2.0                3.0
n_event_pct                        100.0               25.0
time-to-event-wk-10th                1.0                8.4
time-to-event-wk-25th                1.0               44.1
time-to-event-wk-50th                2.8               44.1
time-to-event-wk-75th                4.6                 NA
time-to-event-wk-90th                4.6                 NA
time-to-event-wk-50th-loci           1.0                8.4
time-to-event-wk-50th-hici            NA                 NA

$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.053830  1.246000  0.004678  0.619400  0.019060


$region_northamerica
$region_northamerica$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               24.0
n_event                             14.0               21.0
n_event_pct                         88.0               88.0
time-to-event-wk-10th                1.0                0.7
time-to-event-wk-25th                4.1                2.4
time-to-event-wk-50th               12.6                4.7
time-to-event-wk-75th               18.1               18.4
time-to-event-wk-90th               21.1               45.3
time-to-event-wk-50th-loci           3.1                2.4
time-to-event-wk-50th-hici          15.7                9.7

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1180    0.3618    0.5501    2.2710    0.7581


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               19.0               29.0
n_event                             15.0               19.0
n_event_pct                         79.0               66.0
time-to-event-wk-10th                1.0                0.7
time-to-event-wk-25th                4.6                3.9
time-to-event-wk-50th               12.6                8.4
time-to-event-wk-75th               15.9                 NA
time-to-event-wk-90th               39.1                 NA
time-to-event-wk-50th-loci           4.6                4.0
time-to-event-wk-50th-hici          15.9               44.1
```

```
$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0930    0.3719    0.5271    2.2650    0.8119


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               30.0
n_event                              15.0               19.0
n_event_pct                          94.0               63.0
time-to-event-wk-10th                 1.7                1.1
time-to-event-wk-25th                 5.0                4.7
time-to-event-wk-50th                 8.1               31.6
time-to-event-wk-75th                12.9               41.0
time-to-event-wk-90th                18.1               45.3
time-to-event-wk-50th-loci            5.0                7.6
time-to-event-wk-50th-hici           12.0               40.4

$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.300400  0.417100  0.132600  0.680300  0.003935



\#############################################################################
[[1]]
[1] "Anteil an Patienten, die keine Beatmung benötigen und zu Baseline keine
Beatmung benötigten (unabhängig von der Dauer)"

$ageonset_le_12wk
$ageonset_le_12wk$ntab
            CTRL TRT
n_all         28  51
n_event        4  17
n_event_pct   14  33

$ageonset_le_12wk$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.3333333 0.50348923 0.869773115  6.2596145 0.09240374
OR_TRTvsCTRL  3.0000000 0.61636187 0.896340615 10.0408258 0.07468168
ARR_TRTvsCTRL 0.1904762 0.09343702 0.007343001  0.3736094 0.04149479


$ageonset_gt_12wk
$ageonset_gt_12wk$ntab
            CTRL TRT
n_all          7   8
n_event        1   4
n_event_pct   14  50

$ageonset_gt_12wk$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.5000000 0.9910312  0.50176545 24.4137975 0.2061940
```

```
OR_TRTvsCTRL  6.0000000 1.2909944  0.47780950 75.3438342 0.1651703
ARR_TRTvsCTRL 0.3571429 0.2207775 -0.07557312  0.7898588 0.1057360


$agetrt_lt_180d
$agetrt_lt_180d$ntab
            CTRL TRT
n_all         15  40
n_event        2  15
n_event_pct   13  38

$agetrt_lt_180d$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.8125000 0.6892024 0.72852147 10.8578218 0.13351291
OR_TRTvsCTRL  3.9000000 0.8267949 0.77142826 19.7166746 0.09974578
ARR_TRTvsCTRL 0.2416667 0.1164606 0.01340802  0.4699253 0.03797790


$agetrt_ge_180d
$agetrt_ge_180d$ntab
            CTRL TRT
n_all         20  19
n_event        3   6
n_event_pct   15  32

$agetrt_ge_180d$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.1052632 0.6303717  0.61197413  7.2423534 0.2376207
OR_TRTvsCTRL  2.6153846 0.7973372  0.54807616 12.4804492 0.2279033
ARR_TRTvsCTRL 0.1657895 0.1332176 -0.09531216  0.4268911 0.2133150


$sex_m
$sex_m$ntab
            CTRL TRT
n_all         15  26
n_event        2   6
n_event_pct   13  23

$sex_m$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.7307692 0.7493587  0.3984592  7.5178637 0.4641397
OR_TRTvsCTRL  1.9500000 0.8908365  0.3402148 11.1767632 0.4534562
ARR_TRTvsCTRL 0.0974359 0.1205454 -0.1388288  0.3337006 0.4189225


$sex_f
$sex_f$ntab
            CTRL TRT
n_all         20  33
n_event        3  15
n_event_pct   15  45

$sex_f$stats
```

```
               estimate        se     lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  3.0303030 0.5654175 1.00046476  9.1784707 0.049904018
OR_TRTvsCTRL  4.7222222 0.7172023 1.15787786 19.2588386 0.030437201
ARR_TRTvsCTRL 0.3045455 0.1178480 0.07356764  0.5355233 0.009759872


$region_europe
$region_europe$ntab
            CTRL TRT
n_all         17  23
n_event        3   9
n_event_pct   18  39

$region_europe$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2173913 0.5849296  0.70461089  6.9780701 0.1733829
OR_TRTvsCTRL  3.0000000 0.7663560  0.66803283 13.4723917 0.1516998
ARR_TRTvsCTRL 0.2148338 0.1374941 -0.05464973  0.4843173 0.1181716


$region_asiapacific
$region_asiapacific$ntab
            CTRL TRT
n_all          2  12
n_event        0   9
n_event_pct    0  75

$region_asiapacific$stats
               estimate       se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL   4.384615 1.301924 0.3417681  56.2511535 2.562409e-01
OR_TRTvsCTRL  13.571429 1.670622 0.5135582 358.6422760 1.185060e-01
ARR_TRTvsCTRL  0.750000 0.125000 0.5050045   0.9949955 1.973175e-09


$region_northamerica
$region_northamerica$ntab
            CTRL TRT
n_all         16  24
n_event        2   3
n_event_pct   12  12

$region_northamerica$stats
              estimate        se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.8539126  0.1875635 5.3315280      1
OR_TRTvsCTRL         1 0.9759001  0.1476768 6.7715431      1
ARR_TRTvsCTRL        0 0.1067391 -0.2092047 0.2092047      1


$disdur_gt_12wk
$disdur_gt_12wk$ntab
            CTRL TRT
n_all         19  29
n_event        4  10
n_event_pct   21  34
```

```
$disdur_gt_12wk$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.6379310 0.5127238  0.5996038 4.4743183 0.3358600
OR_TRTvsCTRL  1.9736842 0.6850535  0.5154174 7.5578145 0.3209634
ARR_TRTvsCTRL 0.1343013 0.1286003 -0.1177506 0.3863532 0.2963322


$disdur_le_12wek
$disdur_le_12wek$ntab
            CTRL TRT
n_all         16  30
n_event        1  11
n_event_pct    6  37

$disdur_le_12wek$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  5.8666667 0.9975348 0.83040168 41.4471439 0.07611958
OR_TRTvsCTRL  8.6842105 1.1000942 1.00537580 75.0122613 0.04943304
ARR_TRTvsCTRL 0.3041667 0.1067841 0.09487362  0.5134597 0.00439361



\#############################################################################
[[1]]
[1] "HINE-Responder (Subskala 2)"

$ageonset_le_12wk
$ageonset_le_12wk$`64`
$ageonset_le_12wk$`64`$ntab
            CTRL TRT
n_all         32  72
n_event        8  24
n_event_pct   25  33

$ageonset_le_12wk$`64`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.33333333 0.34860834  0.6732909 2.6404302 0.4092410
OR_TRTvsCTRL  1.50000000 0.47871355  0.5869614 3.8333015 0.3970013
ARR_TRTvsCTRL 0.08333333 0.09458221 -0.1020444 0.2687111 0.3782812


$ageonset_le_12wk$`183`
$ageonset_le_12wk$`183`$ntab
            CTRL TRT
n_all         32  72
n_event        2  26
n_event_pct    6  36

$ageonset_le_12wk$`183`$stats
               estimate         se    lo95ci     hi95ci       pvalue
RR_TRTvsCTRL  5.7777778 0.70236931 1.4584884 22.8885708 1.251469e-02
OR_TRTvsCTRL  8.4782609 0.77041158 1.8729718 38.3779967 5.528698e-03
ARR_TRTvsCTRL 0.2986111 0.07096026 0.1595316  0.4376907 2.574749e-05
```

```
$ageonset_le_12wk$`302`
$ageonset_le_12wk$`302`$ntab
            CTRL TRT
n_all         32  72
n_event        0  20
n_event_pct    0  28

$ageonset_le_12wk$`302`$stats
                estimate        se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  18.5342466 1.4159021 1.1554652 297.2987001 3.920572e-02
OR_TRTvsCTRL  25.3809524 1.4486536 1.4839242 434.1143271 2.558742e-02
ARR_TRTvsCTRL  0.2777778 0.0527859 0.1743193   0.3812362 1.422271e-07


$ageonset_le_12wk$`394`
$ageonset_le_12wk$`394`$ntab
            CTRL TRT
n_all         32  72
n_event        0  19
n_event_pct    0  26

$ageonset_le_12wk$`394`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  17.6301370 1.41678523 1.0972003 283.2862281 4.282247e-02
OR_TRTvsCTRL  23.6915888 1.44939397 1.3831453 405.8079653 2.898032e-02
ARR_TRTvsCTRL  0.2638889 0.05194168 0.1620851   0.3656927 3.764738e-07



$ageonset_gt_12wk
$ageonset_gt_12wk$`64`
$ageonset_gt_12wk$`64`$ntab
            CTRL TRT
n_all          9   8
n_event        0   2
n_event_pct    0  25

$ageonset_gt_12wk$`64`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  5.555556 1.4794894  0.30576223 100.941826 0.2464368
OR_TRTvsCTRL  7.307692 1.6306776  0.29905082 178.572883 0.2225809
ARR_TRTvsCTRL 0.250000 0.1530931 -0.05005698   0.550057 0.1024704


$ageonset_gt_12wk$`183`
$ageonset_gt_12wk$`183`$ntab
            CTRL TRT
n_all          9   8
n_event        0   4
n_event_pct    0  50

$ageonset_gt_12wk$`183`$stats
```

```
              estimate        se    lo95ci     hi95ci      pvalue
RR_TRTvsCTRL      10.0 1.4181365 0.6206975 161.109063 0.104446345
OR_TRTvsCTRL      19.0 1.5967804 0.8309438 434.445727 0.065185336
ARR_TRTvsCTRL      0.5 0.1767767 0.1535240   0.846476 0.004677735


$ageonset_gt_12wk$`302`
$ageonset_gt_12wk$`302`$ntab
            CTRL TRT
n_all          9   8
n_event        0   2
n_event_pct    0  25

$ageonset_gt_12wk$`302`$stats
              estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  5.555556 1.4794894  0.30576223 100.941826 0.2464368
OR_TRTvsCTRL  7.307692 1.6306776  0.29905082 178.572883 0.2225809
ARR_TRTvsCTRL 0.250000 0.1530931 -0.05005698   0.550057 0.1024704


$ageonset_gt_12wk$`394`
$ageonset_gt_12wk$`394`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$ageonset_gt_12wk$`394`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494



$agetrt_lt_180d
$agetrt_lt_180d$`64`
$agetrt_lt_180d$`64`$ntab
            CTRL TRT
n_all         16  49
n_event        3  21
n_event_pct   19  43

$agetrt_lt_180d$`64`$stats
               estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.2857143 0.5459343 0.784010460  6.6638011 0.12996355
OR_TRTvsCTRL  3.2500000 0.7025594 0.820094115 12.8796193 0.09341373
ARR_TRTvsCTRL 0.2410714 0.1204965 0.004902666  0.4772402 0.04542999


$agetrt_lt_180d$`183`
$agetrt_lt_180d$`183`$ntab
            CTRL TRT
n_all         16  49
```

```
n_event        0  24
n_event_pct    0  49

$agetrt_lt_180d$`183`$stats
                estimate        se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  16.6600000 1.4007115 1.0700084 259.3957254 4.461433e-02
OR_TRTvsCTRL  31.7058824 1.4630920 1.8019955 557.8609668 1.815390e-02
ARR_TRTvsCTRL  0.4897959 0.0714137 0.3498276   0.6297642 6.955325e-12


$agetrt_lt_180d$`302`
$agetrt_lt_180d$`302`$ntab
           CTRL TRT
n_all        16  49
n_event       0  14
n_event_pct   0  29

$agetrt_lt_180d$`302`$stats
                estimate         se    lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   9.8600000 1.41072392 0.6209642 156.5623370 1.04759e-01
OR_TRTvsCTRL  13.4788732 1.46892498 0.7573600 239.8859418 7.65995e-02
ARR_TRTvsCTRL  0.2857143 0.06453628 0.1592255   0.4122031 9.54692e-06


$agetrt_lt_180d$`394`
$agetrt_lt_180d$`394`$ntab
           CTRL TRT
n_all        16  49
n_event       0  12
n_event_pct   0  24

$agetrt_lt_180d$`394`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL   8.500000 1.41462945 0.5312319 136.0046301 1.303278e-01
OR_TRTvsCTRL  11.000000 1.47216600 0.6141617 197.0165251 1.033509e-01
ARR_TRTvsCTRL  0.244898 0.06143238 0.1244927   0.3653032 6.706542e-05



$agetrt_ge_180d
$agetrt_ge_180d$`64`
$agetrt_ge_180d$`64`$ntab
           CTRL TRT
n_all        25  31
n_event       5   5
n_event_pct  20  16

$agetrt_ge_180d$`64`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80645161 0.5724875  0.2625887 2.4767408 0.7071038
OR_TRTvsCTRL   0.76923077 0.6989002  0.1955022 3.0266458 0.7073661
ARR_TRTvsCTRL -0.03870968 0.1037484 -0.2420528 0.1646335 0.7090658
```

```
$agetrt_ge_180d$`183`
$agetrt_ge_180d$`183`$ntab
            CTRL TRT
n_all         25  31
n_event        2   6
n_event_pct    8  19

$agetrt_ge_180d$`183`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.4193548 0.77097899  0.53387682 10.9637235 0.2518172
OR_TRTvsCTRL  2.7600000 0.86610907  0.50544709 15.0710136 0.2411271
ARR_TRTvsCTRL 0.1135484 0.08932568 -0.06152674  0.2886235 0.2036671


$agetrt_ge_180d$`302`
$agetrt_ge_180d$`302`$ntab
            CTRL TRT
n_all         25  31
n_event        0   8
n_event_pct    0  26

$agetrt_ge_180d$`302`$stats
                estimate         se    lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  13.8125000 1.43106098 0.8358936 228.2409694 0.066549489
OR_TRTvsCTRL  18.4468085 1.48304280 1.0082145 337.5122628 0.049358676
ARR_TRTvsCTRL  0.2580645 0.07858983 0.1040313   0.4120978 0.001024582


$agetrt_ge_180d$`394`
$agetrt_ge_180d$`394`$ntab
            CTRL TRT
n_all         25  31
n_event        0   8
n_event_pct    0  26

$agetrt_ge_180d$`394`$stats
                estimate         se    lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  13.8125000 1.43106098 0.8358936 228.2409694 0.066549489
OR_TRTvsCTRL  18.4468085 1.48304280 1.0082145 337.5122628 0.049358676
ARR_TRTvsCTRL  0.2580645 0.07858983 0.1040313   0.4120978 0.001024582



$sex_m
$sex_m$`64`
$sex_m$`64`$ntab
            CTRL TRT
n_all         17  37
n_event        4   9
n_event_pct   24  24

$sex_m$`64`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.033783784 0.5246528  0.3696957 2.8907796 0.9495047
```

```
OR_TRTvsCTRL  1.044642857 0.6882939  0.2710760 4.0257301 0.9494049
ARR_TRTvsCTRL 0.007949126 0.1247365 -0.2365299 0.2524281 0.9491873


$sex_m$`183`
$sex_m$`183`$ntab
            CTRL TRT
n_all         17  37
n_event        2   9
n_event_pct   12  24

$sex_m$`183`$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.0675676 0.7247486  0.49951964  8.557893 0.3162272
OR_TRTvsCTRL  2.4107143 0.8446846  0.46041441 12.622418 0.2975425
ARR_TRTvsCTRL 0.1255962 0.1052676 -0.08072459  0.331917 0.2328251


$sex_m$`302`
$sex_m$`302`$ntab
            CTRL TRT
n_all         17  37
n_event        0   7
n_event_pct    0  19

$sex_m$`302`$stats
               estimate         se     lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  7.1052632 1.43229256 0.42895381 117.692776 0.170993321
OR_TRTvsCTRL  8.6065574 1.49106106 0.46305864 159.964253 0.148846116
ARR_TRTvsCTRL 0.1891892 0.06438832 0.06299041   0.315388 0.003300671


$sex_m$`394`
$sex_m$`394`$ntab
            CTRL TRT
n_all         17  37
n_event        0   4
n_event_pct    0  11

$sex_m$`394`$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.2631579 1.46299381 0.242342081 74.9952925 0.32162440
OR_TRTvsCTRL  4.7014925 1.51961042 0.239188898 92.4124501 0.30839139
ARR_TRTvsCTRL 0.1081081 0.05104866 0.008054565  0.2081617 0.03419658



$sex_f
$sex_f$`64`
$sex_f$`64`$ntab
            CTRL TRT
n_all         24  43
n_event        4  17
n_event_pct   17  40
```

```
$sex_f$`64`$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.3720930 0.4938634 0.90106150  6.2446629 0.08028905
OR_TRTvsCTRL  3.2692308 0.6303055 0.95044838 11.2450819 0.06019888
ARR_TRTvsCTRL 0.2286822 0.1065190 0.01990878  0.4374556 0.03180383


$sex_f$`183`
$sex_f$`183`$ntab
            CTRL TRT
n_all         24  43
n_event        0  21
n_event_pct    0  49

$sex_f$`183`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  24.4318182 1.40846880 1.5454856 386.2305320 2.326528e-02
OR_TRTvsCTRL  46.8222222 1.46005904 2.6769947 818.9483825 8.428980e-03
ARR_TRTvsCTRL  0.4883721 0.07622866 0.3389667   0.6377775 1.487297e-10


$sex_f$`302`
$sex_f$`302`$ntab
            CTRL TRT
n_all         24  43
n_event        0  15
n_event_pct    0  35

$sex_f$`302`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  17.6136364 1.41484588 1.1003479 281.9473520 4.260601e-02
OR_TRTvsCTRL  26.6491228 1.46301749 1.5148170 468.8194954 2.484362e-02
ARR_TRTvsCTRL  0.3488372 0.07268118 0.2063847   0.4912897 1.590197e-06


$sex_f$`394`
$sex_f$`394`$ntab
            CTRL TRT
n_all         24  43
n_event        0  16
n_event_pct    0  37

$sex_f$`394`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  18.750000 1.41346340 1.1745163 299.3253513 3.810096e-02
OR_TRTvsCTRL  29.400000 1.46211697 1.6741375 516.3016923 2.075582e-02
ARR_TRTvsCTRL  0.372093 0.07371217 0.2276198   0.5165662 4.466495e-07



$region_europe
$region_europe$`64`
$region_europe$`64`$ntab
```

```
            CTRL TRT
n_all         17  30
n_event        5   8
n_event_pct   29  27

$region_europe$`64`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90666667 0.4825382  0.3521360 2.3344519 0.8390943
OR_TRTvsCTRL   0.87272727 0.6736378  0.2330650 3.2679852 0.8398502
ARR_TRTvsCTRL -0.02745098 0.1368613 -0.2956942 0.2407922 0.8410308


$region_europe$`183`
$region_europe$`183`$ntab
            CTRL TRT
n_all         17  30
n_event        1  10
n_event_pct    6  33

$region_europe$`183`$stats
               estimate       se    lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  5.6666667 1.003914 0.7921266 40.5378523 0.084017191
OR_TRTvsCTRL  8.0000000 1.101136 0.9242757 69.2434120 0.058965359
ARR_TRTvsCTRL 0.2745098 0.103267 0.0721102  0.4769094 0.007854693


$region_europe$`302`
$region_europe$`302`$ntab
            CTRL TRT
n_all         17  30
n_event        0  10
n_event_pct    0  33

$region_europe$`302`$stats
                estimate        se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  12.1935484 1.4168361 0.7587821 195.9490504 0.0775410751
OR_TRTvsCTRL  17.9268293 1.4836312 0.9786656 328.3769172 0.0517234212
ARR_TRTvsCTRL  0.3333333 0.0860663 0.1646465   0.5020202 0.0001075112


$region_europe$`394`
$region_europe$`394`$ntab
            CTRL TRT
n_all         17  30
n_event        0   6
n_event_pct    0  20

$region_europe$`394`$stats
              estimate         se     lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  7.548387 1.43737001 0.45119325 126.2832443 0.159643223
OR_TRTvsCTRL  9.285714 1.50060166 0.49034400 175.8448948 0.137529057
ARR_TRTvsCTRL 0.200000 0.07302967 0.05686447   0.3431355 0.006169899
```

```
$region_asiapacific
$region_asiapacific$`64`
$region_asiapacific$`64`$ntab
           CTRL TRT
n_all         2  12
n_event       0   5
n_event_pct   0  42

$region_asiapacific$`64`$stats
               estimate        se    lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  2.5384615 1.3310003 0.1869051 34.4762553 0.483993933
OR_TRTvsCTRL  3.6666667 1.6477717 0.1451061 92.6525185 0.430398971
ARR_TRTvsCTRL 0.4166667 0.1423188 0.1377270  0.6956063 0.003414791


$region_asiapacific$`183`
$region_asiapacific$`183`$ntab
           CTRL TRT
n_all         2  12
n_event       0   7
n_event_pct   0  58

$region_asiapacific$`183`$stats
               estimate        se    lo95ci     hi95ci       pvalue
RR_TRTvsCTRL  3.4615385 1.3126602 0.2641987  45.353164 0.3441732453
OR_TRTvsCTRL  6.8181818 1.6477717 0.2698254 172.287741 0.2440340195
ARR_TRTvsCTRL 0.5833333 0.1423188 0.3043937   0.862273 0.0000415333


$region_asiapacific$`302`
$region_asiapacific$`302`$ntab
           CTRL TRT
n_all         2  12
n_event       0   1
n_event_pct   0   8

$region_asiapacific$`302`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$region_asiapacific$`394`
$region_asiapacific$`394`$ntab
           CTRL TRT
n_all         2  12
n_event       0   2
n_event_pct   0  17

$region_asiapacific$`394`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
```

```
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353



$region_northamerica
$region_northamerica$`64`
$region_northamerica$`64`$ntab
            CTRL TRT
n_all         22  38
n_event        3  13
n_event_pct   14  34

$region_northamerica$`64`$stats
               estimate        se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.5087719 0.5817956  0.802113641  7.8466894 0.11388803
OR_TRTvsCTRL  3.2933333 0.7091460  0.820369596 13.2209244 0.09281062
ARR_TRTvsCTRL 0.2057416 0.1061885 -0.002383967  0.4138672 0.05268259


$region_northamerica$`183`
$region_northamerica$`183`$ntab
            CTRL TRT
n_all         22  38
n_event        1  13
n_event_pct    5  34

$region_northamerica$`183`$stats
               estimate         se    lo95ci     hi95ci       pvalue
RR_TRTvsCTRL   7.5263158 1.00257306 1.0548500 53.6999861 0.0440909118
OR_TRTvsCTRL  10.9200000 1.07913953 1.3172172 90.5290309 0.0267408674
ARR_TRTvsCTRL  0.2966507 0.08885424 0.1224996  0.4708018 0.0008419509


$region_northamerica$`302`
$region_northamerica$`302`$ntab
            CTRL TRT
n_all         22  38
n_event        0  11
n_event_pct    0  29

$region_northamerica$`302`$stats
               estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  13.5641026 1.42050598 0.8380196 219.5472220 6.642246e-02
OR_TRTvsCTRL  18.8181818 1.47233305 1.0503293 337.1551691 4.622697e-02
ARR_TRTvsCTRL  0.2894737 0.07357035 0.1452784   0.4336689 8.331754e-05


$region_northamerica$`394`
$region_northamerica$`394`$ntab
            CTRL TRT
n_all         22  38
n_event        0  12
n_event_pct    0  32
```

```
$region_northamerica$`394`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  14.7435897 1.41805526 0.9152767 237.4947760 5.775747e-02
OR_TRTvsCTRL  21.2264151 1.47043541 1.1891586 378.8903485 3.772931e-02
ARR_TRTvsCTRL  0.3157895 0.07540531 0.1679978   0.4635812 2.815542e-05



$disdur_gt_12wk
$disdur_gt_12wk$`64`
$disdur_gt_12wk$`64`$ntab
            CTRL TRT
n_all         23  46
n_event        6  12
n_event_pct   26  26

$disdur_gt_12wk$`64`$stats
              estimate        se     lo95ci   hi95ci pvalue
RR_TRTvsCTRL         1 0.4298635  0.4306253 2.322204      1
OR_TRTvsCTRL         1 0.5815800  0.3198587 3.126380      1
ARR_TRTvsCTRL        0 0.1121383 -0.2197870 0.219787      1


$disdur_gt_12wk$`183`
$disdur_gt_12wk$`183`$ntab
            CTRL TRT
n_all         23  46
n_event        2   9
n_event_pct    9  20

$disdur_gt_12wk$`183`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2500000 0.73884621  0.52878057  9.5739146 0.2723954
OR_TRTvsCTRL  2.5540541 0.82810457  0.50390213 12.9453553 0.2574986
ARR_TRTvsCTRL 0.1086957 0.08290416 -0.05379351  0.2711848 0.1898239


$disdur_gt_12wk$`302`
$disdur_gt_12wk$`302`$ntab
            CTRL TRT
n_all         23  46
n_event        0  10
n_event_pct    0  22

$disdur_gt_12wk$`302`$stats
                estimate         se     lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  10.7234043 1.42558579 0.65595169 175.3046756 0.0960768401
OR_TRTvsCTRL  13.5205479 1.47145797 0.75593943 241.8252160 0.0767577131
ARR_TRTvsCTRL  0.2173913 0.06081553 0.09819505   0.3365876 0.0003507614


$disdur_gt_12wk$`394`
$disdur_gt_12wk$`394`$ntab
```

```
            CTRL TRT
n_all         23  46
n_event        0  10
n_event_pct    0  22

$disdur_gt_12wk$`394`$stats
                estimate         se     lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  10.7234043 1.42558579 0.65595169 175.3046756 0.0960768401
OR_TRTvsCTRL  13.5205479 1.47145797 0.75593943 241.8252160 0.0767577131
ARR_TRTvsCTRL  0.2173913 0.06081553 0.09819505   0.3365876 0.0003507614



$disdur_le_12wek
$disdur_le_12wek$`64`
$disdur_le_12wek$`64`$ntab
            CTRL TRT
n_all         18  34
n_event        2  14
n_event_pct   11  41

$disdur_le_12wek$`64`$stats
               estimate        se     lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  3.7058824 0.6974677 0.94450880 14.5404299 0.060366071
OR_TRTvsCTRL  5.6000000 0.8269997 1.10724715 28.3224933 0.037237323
ARR_TRTvsCTRL 0.3006536 0.1122984 0.08055282  0.5207544 0.007422377


$disdur_le_12wek$`183`
$disdur_le_12wek$`183`$ntab
            CTRL TRT
n_all         18  34
n_event        0  21
n_event_pct    0  62

$disdur_le_12wek$`183`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  23.3428571 1.40189465 1.4957504  364.291388 2.462937e-02
OR_TRTvsCTRL  58.9259259 1.47466598 3.2739230 1060.582299 5.706143e-03
ARR_TRTvsCTRL  0.6176471 0.08334181 0.4543001    0.780994 1.252332e-13


$disdur_le_12wek$`302`
$disdur_le_12wek$`302`$ntab
            CTRL TRT
n_all         18  34
n_event        0  12
n_event_pct    0  35

$disdur_le_12wek$`302`$stats
                estimate         se    lo95ci     hi95ci       pvalue
RR_TRTvsCTRL  13.5714286 1.41378817 0.8495851 216.792492 6.508616e-02
OR_TRTvsCTRL  20.5555556 1.47597375 1.1391426 370.920084 4.053763e-02
ARR_TRTvsCTRL  0.3529412 0.08195653 0.1923093   0.513573 1.659004e-05
```

```
$disdur_le_12wek$`394`
$disdur_le_12wek$`394`$ntab
           CTRL TRT
n_all        18  34
n_event       0  10
n_event_pct   0  29

$disdur_le_12wek$`394`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  11.4000000 1.41916704 0.7061674 184.0356782 0.0863785783
OR_TRTvsCTRL  15.8571429 1.47990151 0.8720281 288.3496223 0.0618408492
ARR_TRTvsCTRL  0.2941176 0.07814249 0.1409612   0.4472741 0.0001673084




\###############################################################################
[[1]]
[1] "Zeit bis zum HINE-Responder (Subskala 2)"

$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              8.0              45.0
n_event_pct                         25.0              62.0
time-to-event-wk-10th                9.1               9.1
time-to-event-wk-25th               10.1              10.0
time-to-event-wk-50th                 NA              26.1
time-to-event-wk-75th                 NA              57.1
time-to-event-wk-90th                 NA              57.7
time-to-event-wk-50th-loci          10.1              25.1
time-to-event-wk-50th-hici            NA              39.0

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.8830    0.3911    0.8749    4.0530    0.1056


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9                 8.0
n_event                              0                 4.0
n_event_pct                          0                50.0
time-to-event-wk-10th               NA                 9.0
time-to-event-wk-25th               NA                 9.6
time-to-event-wk-50th               NA                18.2
time-to-event-wk-75th               NA                26.6
time-to-event-wk-90th               NA                27.0
time-to-event-wk-50th-loci          NA                 9.0
time-to-event-wk-50th-hici          NA                  NA
```

```
$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.628e+10 3.033e+04 0.000e+00       Inf 9.994e-01


$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               3.0               35.0
n_event_pct                          19.0               71.0
time-to-event-wk-10th                 9.1                9.1
time-to-event-wk-25th                14.1                9.6
time-to-event-wk-50th                  NA               25.1
time-to-event-wk-75th                  NA               32.1
time-to-event-wk-90th                  NA               57.7
time-to-event-wk-50th-loci            9.1               10.3
time-to-event-wk-50th-hici             NA               26.3

$agetrt_lt_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  3.49700   0.62130   1.03500  11.82000   0.04391


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               5.0               14.0
n_event_pct                          20.0               45.0
time-to-event-wk-10th                 9.3                9.1
time-to-event-wk-25th                12.0               26.1
time-to-event-wk-50th                  NA               44.1
time-to-event-wk-75th                  NA               57.1
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           12.0               26.3
time-to-event-wk-50th-hici             NA               57.1

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  2.69900   0.56460   0.89260   8.16200   0.07863


$sex_m
$sex_m$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               4.0               18.0
n_event_pct                          24.0               49.0
time-to-event-wk-10th                 9.1                9.3
time-to-event-wk-25th                 9.3               14.0
time-to-event-wk-50th                  NA               26.1
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            9.1               25.1
time-to-event-wk-50th-hici             NA                 NA

$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.8740    0.6027    0.5751    6.1080    0.2973


$sex_f
$sex_f$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                              4.0               31.0
n_event_pct                         17.0               72.0
time-to-event-wk-10th               10.1                9.1
time-to-event-wk-25th                 NA                9.3
time-to-event-wk-50th                 NA               26.3
time-to-event-wk-75th                 NA               39.0
time-to-event-wk-90th                 NA               57.1
time-to-event-wk-50th-loci          14.1               10.1
time-to-event-wk-50th-hici            NA               27.1

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 4.742000  0.539700  1.646000 13.660000  0.003932


$region_europe
$region_europe$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                              5.0               19.0
n_event_pct                         29.0               63.0
time-to-event-wk-10th                9.3                9.3
time-to-event-wk-25th               12.0               11.3
time-to-event-wk-50th                 NA               27.1
time-to-event-wk-75th                 NA               43.1
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          10.1               12.1
time-to-event-wk-50th-hici            NA               39.0

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7750    0.5076    0.6564    4.8010    0.2582


$region_asiapacific
$region_asiapacific$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2               12.0
n_event                              0                8.0
n_event_pct                          0               67.0
time-to-event-wk-10th               NA                9.1
```

```
time-to-event-wk-25th                  NA                9.3
time-to-event-wk-50th                  NA               25.1
time-to-event-wk-75th                  NA               57.1
time-to-event-wk-90th                  NA               57.1
time-to-event-wk-50th-loci             NA                9.1
time-to-event-wk-50th-hici             NA                 NA

$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.556e+08 1.534e+04 0.000e+00       Inf 9.990e-01


$region_northamerica
$region_northamerica$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               3.0               22.0
n_event_pct                          14.0               58.0
time-to-event-wk-10th                 9.1                8.4
time-to-event-wk-25th                  NA                9.1
time-to-event-wk-50th                  NA               26.1
time-to-event-wk-75th                  NA               57.7
time-to-event-wk-90th                  NA               57.7
time-to-event-wk-50th-loci             NA               10.1
time-to-event-wk-50th-hici             NA               49.7

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 5.857000  0.652600  1.630000 21.050000  0.006761


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               6.0               22.0
n_event_pct                          26.0               48.0
time-to-event-wk-10th                 9.1                9.1
time-to-event-wk-25th                12.0                9.6
time-to-event-wk-50th                  NA               43.1
time-to-event-wk-75th                  NA               57.1
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           10.1               25.1
time-to-event-wk-50th-hici             NA               57.1

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5250    0.4628    0.6156    3.7770    0.3620


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
```

```
n_event                                2.0              27.0
n_event_pct                           11.0              79.0
time-to-event-wk-10th                  9.1               8.4
time-to-event-wk-25th                   NA              10.0
time-to-event-wk-50th                   NA              25.3
time-to-event-wk-75th                   NA              27.1
time-to-event-wk-90th                   NA              57.7
time-to-event-wk-50th-loci              NA              10.1
time-to-event-wk-50th-hici              NA              27.0

$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 9.026000  0.747200  2.087000 39.040000  0.003235



\#############################################################################
[[1]]
[1] "Veränderung des HINE-Scores (Subskala 2) von Baseline"

$CHG_TOTSCRVG_64
$CHG_TOTSCRVG_64$ageonset_le_12wk
$CHG_TOTSCRVG_64$ageonset_le_12wk$base
          Control ISIS 396443
N      32.0000000 72.00000000
n      25.0000000 67.00000000
mean    0.7200000  0.47761194
sd      1.1372481  0.70406200
se      0.2274496  0.08601486
median  0.0000000  0.00000000
min     0.0000000  0.00000000
max     5.0000000  3.00000000
sum    18.0000000 32.00000000

$CHG_TOTSCRVG_64$ageonset_le_12wk$numbers_eachgrp
          Control ISIS 396443
N      32.0000000  72.0000000
n      25.0000000  67.0000000
mean    0.2000000   0.7014925
sd      1.1180340   1.3818622
se      0.2236068   0.1688213
median  0.0000000   0.0000000
min    -2.0000000  -3.0000000
max     3.0000000   6.0000000
sum     5.0000000  47.0000000

$CHG_TOTSCRVG_64$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.66     0.152         0.358         0.962
2     Control   0.31     0.251        -0.189         0.811

$CHG_TOTSCRVG_64$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      0.3491201       0.2964132      -0.2400333       0.9382735       0.2420820
```

```
$CHG_TOTSCRVG_64$ageonset_le_12wk$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.3800 -0.0850  0.8400  0.1096


$CHG_TOTSCRVG_64$ageonset_gt_12wk
$CHG_TOTSCRVG_64$ageonset_gt_12wk$base
         Control ISIS 396443
N      9.0000000   8.0000000
n      9.0000000   5.0000000
mean   1.0000000   2.0000000
sd     1.2247449   0.7071068
se     0.4082483   0.3162278
median 1.0000000   2.0000000
min    0.0000000   1.0000000
max    3.0000000   3.0000000
sum    9.0000000  10.0000000

$CHG_TOTSCRVG_64$ageonset_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N       9.0000000   8.0000000
n       9.0000000   5.0000000
mean   -0.2222222   0.2000000
sd      0.4409586   0.8366600
se      0.1469862   0.3741657
median  0.0000000   0.0000000
min    -1.0000000  -1.0000000
max     0.0000000   1.0000000
sum    -2.0000000   1.0000000

$CHG_TOTSCRVG_64$ageonset_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.11     0.322        -0.624         0.835
2     Control  -0.17     0.227        -0.683         0.343

$CHG_TOTSCRVG_64$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      0.2757393       0.4291158      -0.6949882       1.2464667       0.5365236

$CHG_TOTSCRVG_64$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.6600 -0.4740  1.7860  0.2552


$CHG_TOTSCRVG_64$agetrt_lt_180d
$CHG_TOTSCRVG_64$agetrt_lt_180d$base
          Control ISIS 396443
N      16.0000000  49.0000000
n      12.0000000  45.0000000
mean    0.4166667   0.6000000
sd      0.6685579   0.7804428
se      0.1929960   0.1163415
median  0.0000000   0.0000000
```

```
min     0.0000000   0.0000000
max     2.0000000   3.0000000
sum     5.0000000  27.0000000

$CHG_TOTSCRVG_64$agetrt_lt_180d$numbers_eachgrp
          Control ISIS 396443
N      16.0000000  49.0000000
n      12.0000000  45.0000000
mean    0.3333333   0.8666667
sd      0.7784989   1.1984839
se      0.2247333   0.1786594
median  0.0000000   1.0000000
min    -1.0000000  -1.0000000
max     2.0000000   5.0000000
sum     4.0000000  39.0000000

$CHG_TOTSCRVG_64$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.87     0.166         0.537         1.205
2     Control   0.32     0.324        -0.333         0.966

$CHG_TOTSCRVG_64$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      0.5540748       0.3649494      -0.1782497       1.2863993       0.1350149

$CHG_TOTSCRVG_64$agetrt_lt_180d$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.4700 -0.1760  1.1100  0.1548


$CHG_TOTSCRVG_64$agetrt_ge_180d
$CHG_TOTSCRVG_64$agetrt_ge_180d$base
          Control ISIS 396443
N      25.0000000  31.0000000
n      22.0000000  27.0000000
mean    1.0000000   0.5555556
sd      1.3093073   0.8473185
se      0.2791453   0.1630665
median  1.0000000   0.0000000
min     0.0000000   0.0000000
max     5.0000000   3.0000000
sum    22.0000000  15.0000000

$CHG_TOTSCRVG_64$agetrt_ge_180d$numbers_eachgrp
           Control ISIS 396443
N      25.00000000  31.0000000
n      22.00000000  27.0000000
mean   -0.04545455   0.3333333
sd      1.09009710   1.5442200
se      0.23240948   0.2971853
median  0.00000000   0.0000000
min    -2.00000000  -3.0000000
max     3.00000000   6.0000000
sum    -1.00000000   9.0000000
```

```
$CHG_TOTSCRVG_64$agetrt_ge_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.26     0.255        -0.253         0.774
2     Control   0.04     0.285        -0.530         0.618

$CHG_TOTSCRVG_64$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      0.2169219       0.3978110      -0.5848134       1.0186573       0.5883085

$CHG_TOTSCRVG_64$agetrt_ge_180d$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.2700 -0.2920  0.8400  0.3425


$CHG_TOTSCRVG_64$sex_m
$CHG_TOTSCRVG_64$sex_m$base
         Control ISIS 396443
N      17.000000  37.0000000
n      14.000000  32.0000000
mean    1.000000   0.4687500
sd      1.519109   0.8025916
se      0.405999   0.1418795
median  0.000000   0.0000000
min     0.000000   0.0000000
max     5.000000   3.0000000
sum    14.000000  15.0000000

$CHG_TOTSCRVG_64$sex_m$numbers_eachgrp
           Control ISIS 396443
N      17.00000000  37.0000000
n      14.00000000  32.0000000
mean    0.07142857   0.4687500
sd      1.20666646   1.0155048
se      0.32249518   0.1795176
median  0.00000000   0.0000000
min    -2.00000000  -1.0000000
max     3.00000000   3.0000000
sum     1.00000000  15.0000000

$CHG_TOTSCRVG_64$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.43     0.180         0.066         0.792
2     Control   0.16     0.276        -0.395         0.721

$CHG_TOTSCRVG_64$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      0.2657810       0.3353600      -0.4114922       0.9430541       0.4326170

$CHG_TOTSCRVG_64$sex_m$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.3600 -0.2700  0.9960  0.2608
```

```
$CHG_TOTSCRVG_64$sex_f
$CHG_TOTSCRVG_64$sex_f$base
          Control ISIS 396443
N      24.0000000  43.0000000
n      20.0000000  40.0000000
mean    0.6500000   0.6750000
sd      0.8127277   0.7970297
se      0.1817314   0.1260215
median  0.5000000   0.5000000
min     0.0000000   0.0000000
max     3.0000000   3.0000000
sum    13.0000000  27.0000000

$CHG_TOTSCRVG_64$sex_f$numbers_eachgrp
          Control ISIS 396443
N      24.0000000  43.0000000
n      20.0000000  40.0000000
mean    0.1000000   0.8250000
sd      0.8522416   1.5670894
se      0.1905670   0.2477786
median  0.0000000   1.0000000
min    -1.0000000  -3.0000000
max     2.0000000   6.0000000
sum     2.0000000  33.0000000

$CHG_TOTSCRVG_64$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.74     0.219         0.305         1.182
2     Control   0.26     0.322        -0.382         0.908

$CHG_TOTSCRVG_64$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      0.4805087       0.4085587      -0.3382612       1.2992787       0.2446178

$CHG_TOTSCRVG_64$sex_f$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.5200 -0.0250  1.0660  0.0613


$CHG_TOTSCRVG_64$region_europe
$CHG_TOTSCRVG_64$region_europe$base
          Control ISIS 396443
N      17.0000000  30.0000000
n      15.0000000  27.0000000
mean    0.4000000   0.4074074
sd      0.6324555   0.6938887
se      0.1632993   0.1335389
median  0.0000000   0.0000000
min     0.0000000   0.0000000
max     2.0000000   3.0000000
sum     6.0000000  11.0000000

$CHG_TOTSCRVG_64$region_europe$numbers_eachgrp
          Control ISIS 396443
```

```
N      17.0000000  30.0000000
n      15.0000000  27.0000000
mean    0.4000000   0.5555556
sd      0.9102590   1.2810252
se      0.2350279   0.2465334
median  0.0000000   0.0000000
min    -1.0000000  -1.0000000
max     2.0000000   6.0000000
sum     6.0000000  15.0000000

$CHG_TOTSCRVG_64$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.54     0.230         0.072         1.006
2     Control   0.43     0.311        -0.201         1.060

$CHG_TOTSCRVG_64$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      0.1098113       0.3917803      -0.6840110       0.9036335       0.7808178

$CHG_TOTSCRVG_64$region_europe$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.1300 -0.5010  0.7630  0.6844


$CHG_TOTSCRVG_64$region_asiapacific
$CHG_TOTSCRVG_64$region_asiapacific$base
       Control ISIS 396443
N            2  12.0000000
n            1  11.0000000
mean         0   0.5454545
sd          NA   1.0357255
se          NA   0.3122830
median       0   0.0000000
min          0   0.0000000
max          0   3.0000000
sum          0   6.0000000

$CHG_TOTSCRVG_64$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2  12.0000000
n            1  11.0000000
mean         0   0.9090909
sd          NA   2.0225996
se          NA   0.6098367
median       0   1.0000000
min          0  -3.0000000
max          0   5.0000000
sum          0  10.0000000

$CHG_TOTSCRVG_64$region_asiapacific$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.96     0.639        -0.547         2.477
2     Control  -0.61     2.773        -7.168         5.946
```

```
$CHG_TOTSCRVG_64$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
       1.575431        2.955915       -5.414196        8.565059        0.610545

$CHG_TOTSCRVG_64$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_TOTSCRVG_64$region_northamerica
$CHG_TOTSCRVG_64$region_northamerica$base
          Control ISIS 396443
N      22.0000000  38.0000000
n      18.0000000  34.0000000
mean    1.1666667   0.7352941
sd      1.3826658   0.7904285
se      0.3258975   0.1355574
median  1.0000000   1.0000000
min     0.0000000   0.0000000
max     5.0000000   2.0000000
sum    21.0000000  25.0000000

$CHG_TOTSCRVG_64$region_northamerica$numbers_eachgrp
          Control ISIS 396443
N      22.0000000  38.0000000
n      18.0000000  34.0000000
mean   -0.1666667   0.6764706
sd      1.0431852   1.1734587
se      0.2458811   0.2012465
median  0.0000000   0.0000000
min    -2.0000000  -1.0000000
max     3.0000000   3.0000000
sum    -3.0000000  23.0000000

$CHG_TOTSCRVG_64$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.65     0.187         0.269         1.022
2     Control  -0.11     0.263        -0.637         0.421

$CHG_TOTSCRVG_64$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     0.75369539      0.33323287      0.08331732      1.42407346      0.02837818

$CHG_TOTSCRVG_64$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.7300 0.1440 1.3240 0.0147


$CHG_TOTSCRVG_64$disdur_gt_12wk
$CHG_TOTSCRVG_64$disdur_gt_12wk$base
          Control ISIS 396443
N      23.0000000  46.0000000
n      19.0000000  41.0000000
mean    1.0000000   0.5365854
```

```
sd      1.2909944   0.8092454
se      0.2961744   0.1263829
median  1.0000000   0.0000000
min     0.0000000   0.0000000
max     5.0000000   3.0000000
sum    19.0000000  22.0000000

$CHG_TOTSCRVG_64$disdur_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N      23.0000000  46.0000000
n      19.0000000  41.0000000
mean    0.1052632   0.4634146
sd      1.2425215   1.4508198
se      0.2850540   0.2265800
median  0.0000000   0.0000000
min    -2.0000000  -3.0000000
max     3.0000000   6.0000000
sum     2.0000000  19.0000000

$CHG_TOTSCRVG_64$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.37     0.199        -0.026         0.771
2     Control   0.30     0.300        -0.301         0.903

$CHG_TOTSCRVG_64$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     0.07111638      0.37181670     -0.67402093      0.81625369      0.84902052

$CHG_TOTSCRVG_64$disdur_gt_12wk$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.2500 -0.2920  0.8000  0.3611


$CHG_TOTSCRVG_64$disdur_le_12wek
$CHG_TOTSCRVG_64$disdur_le_12wek$base
          Control ISIS 396443
N      18.0000000  34.0000000
n      15.0000000  31.0000000
mean    0.5333333   0.6451613
sd      0.9154754   0.7978466
se      0.2363747   0.1432975
median  0.0000000   0.0000000
min     0.0000000   0.0000000
max     3.0000000   3.0000000
sum     8.0000000  20.0000000

$CHG_TOTSCRVG_64$disdur_le_12wek$numbers_eachgrp
           Control ISIS 396443
N      18.00000000  34.0000000
n      15.00000000  31.0000000
mean    0.06666667   0.9354839
sd      0.59361684   1.1813970
se      0.15327121   0.2121852
median  0.00000000   1.0000000
```

```
min    -1.00000000  -1.0000000
max     1.00000000   5.0000000
sum     1.00000000  29.0000000

$CHG_TOTSCRVG_64$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.85     0.185         0.480         1.227
2     Control   0.24     0.272        -0.312         0.785

$CHG_TOTSCRVG_64$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     0.61696170      0.33727977     -0.06418861      1.29811200      0.07464466

$CHG_TOTSCRVG_64$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.8300 0.1870 1.4690 0.0114



$CHG_TOTSCRVG_183
$CHG_TOTSCRVG_183$ageonset_le_12wk
$CHG_TOTSCRVG_183$ageonset_le_12wk$base
          Control ISIS 396443
N      32.0000000 72.00000000
n      25.0000000 67.00000000
mean    0.7200000  0.47761194
sd      1.1372481  0.70406200
se      0.2274496  0.08601486
median  0.0000000  0.00000000
min     0.0000000  0.00000000
max     5.0000000  3.00000000
sum    18.0000000 32.00000000

$CHG_TOTSCRVG_183$ageonset_le_12wk$numbers_eachgrp
          Control ISIS 396443
N      32.0000000  72.0000000
n      16.0000000  55.0000000
mean   -0.0625000   1.8363636
sd      0.8539126   2.5731062
se      0.2134781   0.3469576
median  0.0000000   1.0000000
min    -2.0000000  -2.0000000
max     1.0000000  12.0000000
sum    -1.0000000 101.0000000

$CHG_TOTSCRVG_183$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   1.89     0.281         1.325         2.447
2     Control  -0.23     0.528        -1.287         0.821

$CHG_TOTSCRVG_183$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.1187695224    0.6028987015    0.9150434268    3.3224956181    0.0008017712
```

```
$CHG_TOTSCRVG_183$ageonset_le_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.8100 0.2390 1.3860 0.0055


$CHG_TOTSCRVG_183$ageonset_gt_12wk
$CHG_TOTSCRVG_183$ageonset_gt_12wk$base
         Control ISIS 396443
N      9.0000000   8.0000000
n      9.0000000   5.0000000
mean   1.0000000   2.0000000
sd     1.2247449   0.7071068
se     0.4082483   0.3162278
median 1.0000000   2.0000000
min    0.0000000   1.0000000
max    3.0000000   3.0000000
sum    9.0000000  10.0000000

$CHG_TOTSCRVG_183$ageonset_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N       9.0000000   8.0000000
n       7.0000000   4.0000000
mean   -0.4285714   3.7500000
sd      0.9759001   1.7078251
se      0.3688556   0.8539126
median  0.0000000   3.5000000
min    -2.0000000   2.0000000
max     1.0000000   6.0000000
sum    -3.0000000  15.0000000

$CHG_TOTSCRVG_183$ageonset_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   3.11     0.760         1.255         4.973
2     Control  -0.07     0.505        -1.301         1.170

$CHG_TOTSCRVG_183$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     3.17978636      1.08681869      0.52043683      5.83913589      0.02643194

$CHG_TOTSCRVG_183$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
3.0100 1.0190 5.0090 0.0031


$CHG_TOTSCRVG_183$agetrt_lt_180d
$CHG_TOTSCRVG_183$agetrt_lt_180d$base
          Control ISIS 396443
N      16.0000000  49.0000000
n      12.0000000  45.0000000
mean    0.4166667   0.6000000
sd      0.6685579   0.7804428
se      0.1929960   0.1163415
median  0.0000000   0.0000000
min     0.0000000   0.0000000
```

```
max     2.0000000   3.0000000
sum     5.0000000  27.0000000

$CHG_TOTSCRVG_183$agetrt_lt_180d$numbers_eachgrp
          Control ISIS 396443
N      16.0000000   49.000000
n       8.0000000   38.000000
mean   -0.3750000    2.342105
sd      0.7440238    2.316525
se      0.2630521    0.375790
median  0.0000000    2.000000
min    -2.0000000   -1.000000
max     0.0000000    8.000000
sum    -3.0000000   89.000000

$CHG_TOTSCRVG_183$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.40     0.314         1.766         3.035
2     Control  -0.65     0.690        -2.045         0.740

$CHG_TOTSCRVG_183$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   3.0531016913    0.7601125990    1.5180231554    4.5881802271    0.0002457641

$CHG_TOTSCRVG_183$agetrt_lt_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.2500 0.4380 2.0530 0.0025


$CHG_TOTSCRVG_183$agetrt_ge_180d
$CHG_TOTSCRVG_183$agetrt_ge_180d$base
          Control ISIS 396443
N      25.0000000  31.0000000
n      22.0000000  27.0000000
mean    1.0000000   0.5555556
sd      1.3093073   0.8473185
se      0.2791453   0.1630665
median  1.0000000   0.0000000
min     0.0000000   0.0000000
max     5.0000000   3.0000000
sum    22.0000000  15.0000000

$CHG_TOTSCRVG_183$agetrt_ge_180d$numbers_eachgrp
           Control ISIS 396443
N      25.00000000  31.0000000
n      15.00000000  21.0000000
mean   -0.06666667   1.2857143
sd      0.96115010   2.8834503
se      0.24816789   0.6292204
median  0.00000000   0.0000000
min    -2.00000000  -2.0000000
max     1.00000000  12.0000000
sum    -1.00000000  27.0000000
```

```
$CHG_TOTSCRVG_183$agetrt_ge_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   1.44     0.502         0.418         2.467
2     Control  -0.29     0.607        -1.524         0.951

$CHG_TOTSCRVG_183$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     1.72862435      0.83330519      0.02908721      3.42816149      0.04643250

$CHG_TOTSCRVG_183$agetrt_ge_180d$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.5800 -0.1010  1.2530  0.0956


$CHG_TOTSCRVG_183$sex_m
$CHG_TOTSCRVG_183$sex_m$base
         Control ISIS 396443
N      17.000000  37.0000000
n      14.000000  32.0000000
mean    1.000000   0.4687500
sd      1.519109   0.8025916
se      0.405999   0.1418795
median  0.000000   0.0000000
min     0.000000   0.0000000
max     5.000000   3.0000000
sum    14.000000  15.0000000

$CHG_TOTSCRVG_183$sex_m$numbers_eachgrp
          Control ISIS 396443
N      17.0000000  37.0000000
n       9.0000000  26.0000000
mean    0.0000000   1.2692308
sd      1.0000000   1.9505423
se      0.3333333   0.3825328
median  0.0000000   1.0000000
min    -2.0000000  -1.0000000
max     1.0000000   7.0000000
sum     0.0000000  33.0000000

$CHG_TOTSCRVG_183$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   1.46     0.308         0.825         2.085
2     Control  -0.54     0.540        -1.639         0.565

$CHG_TOTSCRVG_183$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    1.992293878     0.635521840     0.694385129     3.290202626     0.003827875

$CHG_TOTSCRVG_183$sex_m$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.7000 -0.0760  1.4790  0.0771


$CHG_TOTSCRVG_183$sex_f
```

```
$CHG_TOTSCRVG_183$sex_f$base
          Control ISIS 396443
N      24.0000000  43.0000000
n      20.0000000  40.0000000
mean    0.6500000   0.6750000
sd      0.8127277   0.7970297
se      0.1817314   0.1260215
median  0.5000000   0.5000000
min     0.0000000   0.0000000
max     3.0000000   3.0000000
sum    13.0000000  27.0000000

$CHG_TOTSCRVG_183$sex_f$numbers_eachgrp
          Control ISIS 396443
N      24.0000000  43.0000000
n      14.0000000  33.0000000
mean   -0.2857143   2.5151515
sd      0.8254203   2.8627043
se      0.2206029   0.4983328
median  0.0000000   2.0000000
min    -2.0000000  -2.0000000
max     1.0000000  12.0000000
sum    -4.0000000  83.0000000

$CHG_TOTSCRVG_183$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.60     0.416         1.764         3.443
2     Control  -0.49     0.672        -1.851         0.862

$CHG_TOTSCRVG_183$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   3.0977431715    0.8307074025    1.4213077621    4.7741785808    0.0005694835

$CHG_TOTSCRVG_183$sex_f$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 1.120  0.453  1.791  0.001


$CHG_TOTSCRVG_183$region_europe
$CHG_TOTSCRVG_183$region_europe$base
          Control ISIS 396443
N      17.0000000  30.0000000
n      15.0000000  27.0000000
mean    0.4000000   0.4074074
sd      0.6324555   0.6938887
se      0.1632993   0.1335389
median  0.0000000   0.0000000
min     0.0000000   0.0000000
max     2.0000000   3.0000000
sum     6.0000000  11.0000000

$CHG_TOTSCRVG_183$region_europe$numbers_eachgrp
          Control ISIS 396443
N      17.0000000  30.0000000
```

```
n      10.0000000  21.0000000
mean   -0.1000000   2.3809524
sd      0.8755950   3.1221177
se      0.2768875   0.6813019
median  0.0000000   1.0000000
min    -2.0000000   0.0000000
max     1.0000000  12.0000000
sum    -1.0000000  50.0000000

$CHG_TOTSCRVG_183$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.54     0.561         1.386         3.691
2     Control  -0.43     0.823        -2.122         1.261

$CHG_TOTSCRVG_183$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    2.968914222     1.011232029     0.890297017     5.047531428     0.006871879

$CHG_TOTSCRVG_183$region_europe$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.9200 0.1240 1.7070 0.0234


$CHG_TOTSCRVG_183$region_asiapacific
$CHG_TOTSCRVG_183$region_asiapacific$base
       Control ISIS 396443
N            2  12.0000000
n            1  11.0000000
mean         0   0.5454545
sd          NA   1.0357255
se          NA   0.3122830
median       0   0.0000000
min          0   0.0000000
max          0   3.0000000
sum          0   6.0000000

$CHG_TOTSCRVG_183$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2  12.0000000
n            1  10.0000000
mean         1   2.3000000
sd          NA   2.1108187
se          NA   0.6674995
median       1   2.5000000
min          1  -2.0000000
max          1   6.0000000
sum          1  23.0000000

$CHG_TOTSCRVG_183$region_asiapacific$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.55     0.682         0.883         4.222
2     Control  -1.52     3.210        -9.378         6.330

$CHG_TOTSCRVG_183$region_asiapacific$diffgrp_TRTvsCTRL
```

```
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      4.0765438       3.4675180      -4.4081672      12.5612547       0.2842722

$CHG_TOTSCRVG_183$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_TOTSCRVG_183$region_northamerica
$CHG_TOTSCRVG_183$region_northamerica$base
          Control ISIS 396443
N      22.0000000  38.0000000
n      18.0000000  34.0000000
mean    1.1666667   0.7352941
sd      1.3826658   0.7904285
se      0.3258975   0.1355574
median  1.0000000   1.0000000
min     0.0000000   0.0000000
max     5.0000000   2.0000000
sum    21.0000000  25.0000000

$CHG_TOTSCRVG_183$region_northamerica$numbers_eachgrp
          Control ISIS 396443
N      22.0000000  38.0000000
n      12.0000000  28.0000000
mean   -0.3333333   1.5357143
sd      0.8876254   2.2357722
se      0.2562354   0.4225212
median  0.0000000   1.0000000
min    -2.0000000  -1.0000000
max     1.0000000   7.0000000
sum    -4.0000000  43.0000000

$CHG_TOTSCRVG_183$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   1.64     0.331         0.967         2.313
2     Control  -0.58     0.525        -1.643         0.490

$CHG_TOTSCRVG_183$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     2.21675161      0.64414386      0.90907006      3.52443317      0.00151534

$CHG_TOTSCRVG_183$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.9400 0.2320 1.6530 0.0093


$CHG_TOTSCRVG_183$disdur_gt_12wk
$CHG_TOTSCRVG_183$disdur_gt_12wk$base
          Control ISIS 396443
N      23.0000000  46.0000000
n      19.0000000  41.0000000
mean    1.0000000   0.5365854
sd      1.2909944   0.8092454
```

```
se      0.2961744   0.1263829
median  1.0000000   0.0000000
min     0.0000000   0.0000000
max     5.0000000   3.0000000
sum    19.0000000  22.0000000

$CHG_TOTSCRVG_183$disdur_gt_12wk$numbers_eachgrp
           Control ISIS 396443
N      23.00000000  46.0000000
n      12.00000000  30.0000000
mean   -0.08333333   1.1333333
sd      0.99620492   2.5289133
se      0.28757959   0.4617143
median  0.00000000   0.0000000
min    -2.00000000  -2.0000000
max     1.00000000  12.0000000
sum    -1.00000000  34.0000000

$CHG_TOTSCRVG_183$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   1.23     0.388         0.442         2.014
2     Control  -0.32     0.647        -1.631         0.992

$CHG_TOTSCRVG_183$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     1.54685671      0.79142592     -0.05672453      3.15043795      0.05822815

$CHG_TOTSCRVG_183$disdur_gt_12wk$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.5400 -0.1420  1.2190  0.1206


$CHG_TOTSCRVG_183$disdur_le_12wek
$CHG_TOTSCRVG_183$disdur_le_12wek$base
          Control ISIS 396443
N      18.0000000  34.0000000
n      15.0000000  31.0000000
mean    0.5333333   0.6451613
sd      0.9154754   0.7978466
se      0.2363747   0.1432975
median  0.0000000   0.0000000
min     0.0000000   0.0000000
max     3.0000000   3.0000000
sum     8.0000000  20.0000000

$CHG_TOTSCRVG_183$disdur_le_12wek$numbers_eachgrp
          Control ISIS 396443
N      18.0000000  34.0000000
n      11.0000000  29.0000000
mean   -0.2727273   2.8275862
sd      0.7862454   2.3309864
se      0.2370619   0.4328533
median  0.0000000   2.0000000
min    -2.0000000  -1.0000000
```

```
max     1.0000000   8.0000000
sum    -3.0000000  82.0000000

$CHG_TOTSCRVG_183$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.87     0.380         2.099         3.641
2     Control  -0.38     0.636        -1.675         0.907

$CHG_TOTSCRVG_183$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   3.2539817922    0.7602503220    1.7105915860    4.7973719985    0.0001378064

$CHG_TOTSCRVG_183$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.4900 0.7140 2.2630 0.0002



$CHG_TOTSCRVG_302
$CHG_TOTSCRVG_302$ageonset_le_12wk
$CHG_TOTSCRVG_302$ageonset_le_12wk$base
          Control ISIS 396443
N      32.0000000 72.00000000
n      25.0000000 67.00000000
mean    0.7200000  0.47761194
sd      1.1372481  0.70406200
se      0.2274496  0.08601486
median  0.0000000  0.00000000
min     0.0000000  0.00000000
max     5.0000000  3.00000000
sum    18.0000000 32.00000000

$CHG_TOTSCRVG_302$ageonset_le_12wk$numbers_eachgrp
          Control ISIS 396443
N      32.0000000  72.0000000
n      11.0000000  34.0000000
mean   -0.5454545   3.3235294
sd      1.2135598   4.0505936
se      0.3659020   0.6946711
median  0.0000000   2.0000000
min    -4.0000000  -1.0000000
max     0.0000000  14.0000000
sum    -6.0000000 113.0000000

$CHG_TOTSCRVG_302$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   3.35     0.570         2.198          4.50
2     Control  -0.63     1.012        -2.671          1.42

$CHG_TOTSCRVG_302$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    3.974435815     1.170294271     1.609182864     6.339688765     0.001556168

$CHG_TOTSCRVG_302$ageonset_le_12wk$Hedgesg_TRTvsCTRL
```

```
   est lo95ci hi95ci     pv
1.0600 0.3400 1.7740 0.0039


$CHG_TOTSCRVG_302$ageonset_gt_12wk
$CHG_TOTSCRVG_302$ageonset_gt_12wk$base
         Control ISIS 396443
N      9.0000000   8.0000000
n      9.0000000   5.0000000
mean   1.0000000   2.0000000
sd     1.2247449   0.7071068
se     0.4082483   0.3162278
median 1.0000000   2.0000000
min    0.0000000   1.0000000
max    3.0000000   3.0000000
sum    9.0000000  10.0000000

$CHG_TOTSCRVG_302$ageonset_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N       9.0000000   8.0000000
n       5.0000000   2.0000000
mean   -0.8000000   6.5000000
sd      1.3038405   0.7071068
se      0.5830952   0.5000000
median  0.0000000   6.5000000
min    -3.0000000   6.0000000
max     0.0000000   7.0000000
sum    -4.0000000  13.0000000

$CHG_TOTSCRVG_302$ageonset_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   7.14     0.624         4.454         9.823
2     Control  -1.06     0.335        -2.498         0.387

$CHG_TOTSCRVG_302$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    8.194169748     0.803885586     4.735329239    11.653010257     0.009487754

$CHG_TOTSCRVG_302$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
5.0900 0.7360 9.4390 0.0219


$CHG_TOTSCRVG_302$agetrt_lt_180d
$CHG_TOTSCRVG_302$agetrt_lt_180d$base
          Control ISIS 396443
N      16.0000000  49.0000000
n      12.0000000  45.0000000
mean    0.4166667   0.6000000
sd      0.6685579   0.7804428
se      0.1929960   0.1163415
median  0.0000000   0.0000000
min     0.0000000   0.0000000
max     2.0000000   3.0000000
```

```
sum     5.0000000  27.0000000

$CHG_TOTSCRVG_302$agetrt_lt_180d$numbers_eachgrp
       Control ISIS 396443
N        16.00  49.0000000
n         4.00  21.0000000
mean     -0.25   4.3809524
sd        0.50   4.1288762
se        0.25   0.9009947
median    0.00   4.0000000
min      -1.00  -1.0000000
max       0.00  12.0000000
sum      -1.00  92.0000000

$CHG_TOTSCRVG_302$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.41     0.841         2.658         6.166
2     Control  -0.41     1.998        -4.583         3.754

$CHG_TOTSCRVG_302$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     4.82684491      2.19812902      0.24162813      9.41206169      0.04006276

$CHG_TOTSCRVG_302$agetrt_lt_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 1.160  0.037  2.287  0.043


$CHG_TOTSCRVG_302$agetrt_ge_180d
$CHG_TOTSCRVG_302$agetrt_ge_180d$base
          Control ISIS 396443
N      25.0000000  31.0000000
n      22.0000000  27.0000000
mean    1.0000000   0.5555556
sd      1.3093073   0.8473185
se      0.2791453   0.1630665
median  1.0000000   0.0000000
min     0.0000000   0.0000000
max     5.0000000   3.0000000
sum    22.0000000  15.0000000

$CHG_TOTSCRVG_302$agetrt_ge_180d$numbers_eachgrp
          Control ISIS 396443
N      25.0000000  31.0000000
n      12.0000000  15.0000000
mean   -0.7500000   2.2666667
sd      1.3568011   3.5949700
se      0.3916747   0.9282173
median  0.0000000   1.0000000
min    -4.0000000   0.0000000
max     0.0000000  14.0000000
sum    -9.0000000  34.0000000

$CHG_TOTSCRVG_302$agetrt_ge_180d$ls_mw
```

```
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.63     0.736         1.106         4.158
2     Control  -1.21     0.837        -2.942         0.529

$CHG_TOTSCRVG_302$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    3.838634333     1.195020437     1.360313632     6.316955034     0.004015036

$CHG_TOTSCRVG_302$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.0300 0.2160 1.8470 0.0132


$CHG_TOTSCRVG_302$sex_m
$CHG_TOTSCRVG_302$sex_m$base
         Control ISIS 396443
N      17.000000  37.0000000
n      14.000000  32.0000000
mean    1.000000   0.4687500
sd      1.519109   0.8025916
se      0.405999   0.1418795
median  0.000000   0.0000000
min     0.000000   0.0000000
max     5.000000   3.0000000
sum    14.000000  15.0000000

$CHG_TOTSCRVG_302$sex_m$numbers_eachgrp
         Control ISIS 396443
N      17.000000  37.0000000
n       5.000000  15.0000000
mean   -0.800000   2.4000000
sd      1.788854   2.9471536
se      0.800000   0.7609518
median  0.000000   1.0000000
min    -4.000000  -1.0000000
max     0.000000   8.0000000
sum    -4.000000  36.0000000

$CHG_TOTSCRVG_302$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.46     0.533         1.320         3.593
2     Control  -0.97     0.939        -2.973         1.031

$CHG_TOTSCRVG_302$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     3.42784540      1.09344976      1.09721240      5.75847840      0.00681366

$CHG_TOTSCRVG_302$sex_m$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.1200 0.0380 2.2050 0.0425


$CHG_TOTSCRVG_302$sex_f
$CHG_TOTSCRVG_302$sex_f$base
```

```
          Control ISIS 396443
N      24.0000000  43.0000000
n      20.0000000  40.0000000
mean    0.6500000   0.6750000
sd      0.8127277   0.7970297
se      0.1817314   0.1260215
median  0.5000000   0.5000000
min     0.0000000   0.0000000
max     3.0000000   3.0000000
sum    13.0000000  27.0000000

$CHG_TOTSCRVG_302$sex_f$numbers_eachgrp
          Control ISIS 396443
N      24.0000000  43.0000000
n      11.0000000  21.0000000
mean   -0.5454545   4.2857143
sd      0.9341987   4.5182171
se      0.2816715   0.9859558
median  0.0000000   3.0000000
min    -3.0000000   0.0000000
max     0.0000000  14.0000000
sum    -6.0000000  90.0000000

$CHG_TOTSCRVG_302$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.50     0.871         2.709         6.281
2     Control  -0.95     1.265        -3.542         1.651

$CHG_TOTSCRVG_302$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    5.440419869     1.642982527     2.069298182     8.811541555     0.002643956

$CHG_TOTSCRVG_302$sex_f$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 1.260  0.462  2.064  0.002


$CHG_TOTSCRVG_302$region_europe
$CHG_TOTSCRVG_302$region_europe$base
          Control ISIS 396443
N      17.0000000  30.0000000
n      15.0000000  27.0000000
mean    0.4000000   0.4074074
sd      0.6324555   0.6938887
se      0.1632993   0.1335389
median  0.0000000   0.0000000
min     0.0000000   0.0000000
max     2.0000000   3.0000000
sum     6.0000000  11.0000000

$CHG_TOTSCRVG_302$region_europe$numbers_eachgrp
          Control ISIS 396443
N      17.0000000   30.000000
n       5.0000000   14.000000
```

```
mean   -0.2000000    3.714286
sd      0.4472136    3.891382
se      0.2000000    1.040016
median  0.0000000    2.500000
min    -1.0000000    0.000000
max     0.0000000   14.000000
sum    -1.0000000   52.000000

$CHG_TOTSCRVG_302$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   3.93     0.887         2.028         5.833
2     Control  -0.81     1.536        -4.100         2.489

$CHG_TOTSCRVG_302$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     4.73571006      1.82208001      0.82773712      8.64368301      0.02101541

$CHG_TOTSCRVG_302$region_europe$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.1000 0.0030 2.1900 0.0494


$CHG_TOTSCRVG_302$region_asiapacific
$CHG_TOTSCRVG_302$region_asiapacific$base
       Control ISIS 396443
N            2  12.0000000
n            1  11.0000000
mean         0   0.5454545
sd          NA   1.0357255
se          NA   0.3122830
median       0   0.0000000
min          0   0.0000000
max          0   3.0000000
sum          0   6.0000000

$CHG_TOTSCRVG_302$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2   12.000000
n            1    2.000000
mean         0    6.000000
sd          NA    8.485281
se          NA    6.000000
median       0    6.000000
min          0    0.000000
max          0   12.000000
sum          0   12.000000

$CHG_TOTSCRVG_302$region_asiapacific$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_TOTSCRVG_302$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
```

```
            NA              NA              NA              NA              NA

$CHG_TOTSCRVG_302$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_TOTSCRVG_302$region_northamerica
$CHG_TOTSCRVG_302$region_northamerica$base
          Control ISIS 396443
N      22.0000000  38.0000000
n      18.0000000  34.0000000
mean    1.1666667   0.7352941
sd      1.3826658   0.7904285
se      0.3258975   0.1355574
median  1.0000000   1.0000000
min     0.0000000   0.0000000
max     5.0000000   2.0000000
sum    21.0000000  25.0000000

$CHG_TOTSCRVG_302$region_northamerica$numbers_eachgrp
          Control ISIS 396443
N      22.0000000  38.0000000
n      10.0000000  20.0000000
mean   -0.9000000   3.1000000
sd      1.4491377   3.8099592
se      0.4582576   0.8519328
median  0.0000000   1.5000000
min    -4.0000000  -1.0000000
max     0.0000000  12.0000000
sum    -9.0000000  62.0000000

$CHG_TOTSCRVG_302$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   3.19     0.697         1.753         4.625
2     Control  -1.08     1.016        -3.171         1.016

$CHG_TOTSCRVG_302$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    4.266256883     1.281176622     1.627624236     6.904889529     0.002697673

$CHG_TOTSCRVG_302$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.2000 0.3740 2.0260 0.0044


$CHG_TOTSCRVG_302$disdur_gt_12wk
$CHG_TOTSCRVG_302$disdur_gt_12wk$base
          Control ISIS 396443
N      23.0000000  46.0000000
n      19.0000000  41.0000000
mean    1.0000000   0.5365854
sd      1.2909944   0.8092454
se      0.2961744   0.1263829
```

```
median  1.0000000   0.0000000
min     0.0000000   0.0000000
max     5.0000000   3.0000000
sum    19.0000000  22.0000000

$CHG_TOTSCRVG_302$disdur_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N      23.0000000  46.0000000
n      10.0000000  20.0000000
mean   -0.9000000   2.5000000
sd      1.4491377   3.9934156
se      0.4582576   0.8929549
median  0.0000000   1.0000000
min    -4.0000000  -1.0000000
max     0.0000000  14.0000000
sum    -9.0000000  50.0000000

$CHG_TOTSCRVG_302$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.56     0.717         1.087         4.040
2     Control  -1.03     1.069        -3.229         1.175

$CHG_TOTSCRVG_302$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     3.59042654      1.37338013      0.76189723      6.41895586      0.01492974

$CHG_TOTSCRVG_302$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.9800 0.1720 1.7800 0.0174


$CHG_TOTSCRVG_302$disdur_le_12wek
$CHG_TOTSCRVG_302$disdur_le_12wek$base
          Control ISIS 396443
N      18.0000000  34.0000000
n      15.0000000  31.0000000
mean    0.5333333   0.6451613
sd      0.9154754   0.7978466
se      0.2363747   0.1432975
median  0.0000000   0.0000000
min     0.0000000   0.0000000
max     3.0000000   3.0000000
sum     8.0000000  20.0000000

$CHG_TOTSCRVG_302$disdur_le_12wek$numbers_eachgrp
          Control ISIS 396443
N      18.0000000  34.0000000
n       6.0000000  16.0000000
mean   -0.1666667   4.7500000
sd      0.4082483   3.7682887
se      0.1666667   0.9420722
median  0.0000000   4.0000000
min    -1.0000000   0.0000000
max     0.0000000  12.0000000
```

```
sum    -1.0000000  76.0000000

$CHG_TOTSCRVG_302$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.69     0.881         2.835         6.553
2     Control  -0.02     1.521        -3.226         3.192

$CHG_TOTSCRVG_302$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     4.71105029      1.83914759      0.83078806      8.59131252      0.02022355

$CHG_TOTSCRVG_302$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.4500 0.3960 2.4970 0.0069



$CHG_TOTSCRVG_394
$CHG_TOTSCRVG_394$ageonset_le_12wk
$CHG_TOTSCRVG_394$ageonset_le_12wk$base
          Control ISIS 396443
N      32.0000000 72.00000000
n      25.0000000 67.00000000
mean    0.7200000  0.47761194
sd      1.1372481  0.70406200
se      0.2274496  0.08601486
median  0.0000000  0.00000000
min     0.0000000  0.00000000
max     5.0000000  3.00000000
sum    18.0000000 32.00000000

$CHG_TOTSCRVG_394$ageonset_le_12wk$numbers_eachgrp
          Control ISIS 396443
N      32.0000000   72.000000
n       8.0000000   25.000000
mean   -0.6250000    4.520000
sd      1.4078860    4.788180
se      0.4977629    0.957636
median  0.0000000    3.000000
min    -4.0000000    0.000000
max     0.0000000   17.000000
sum    -5.0000000  113.000000

$CHG_TOTSCRVG_394$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.41     0.816         2.741         6.083
2     Control  -0.29     1.462        -3.282         2.709

$CHG_TOTSCRVG_394$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    4.698633439     1.690885272     1.235011973     8.162254905     0.009634098

$CHG_TOTSCRVG_394$ageonset_le_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
```

```
1.1800 0.3250 2.0280 0.0068


$CHG_TOTSCRVG_394$ageonset_gt_12wk
$CHG_TOTSCRVG_394$ageonset_gt_12wk$base
         Control ISIS 396443
N      9.0000000   8.0000000
n      9.0000000   5.0000000
mean   1.0000000   2.0000000
sd     1.2247449   0.7071068
se     0.4082483   0.3162278
median 1.0000000   2.0000000
min    0.0000000   1.0000000
max    3.0000000   3.0000000
sum    9.0000000  10.0000000

$CHG_TOTSCRVG_394$ageonset_gt_12wk$numbers_eachgrp
         Control ISIS 396443
N       9.000000           8
n       3.000000           1
mean   -1.000000           3
sd      1.732051          NA
se      1.000000          NA
median  0.000000           3
min    -3.000000           3
max     0.000000           3
sum    -3.000000           3

$CHG_TOTSCRVG_394$ageonset_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   3.77       NaN           NaN           NaN
2     Control  -1.26       NaN           NaN           NaN

$CHG_TOTSCRVG_394$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_TOTSCRVG_394$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_TOTSCRVG_394$agetrt_lt_180d
$CHG_TOTSCRVG_394$agetrt_lt_180d$base
          Control ISIS 396443
N      16.0000000  49.0000000
n      12.0000000  45.0000000
mean    0.4166667   0.6000000
sd      0.6685579   0.7804428
se      0.1929960   0.1163415
median  0.0000000   0.0000000
min     0.0000000   0.0000000
max     2.0000000   3.0000000
sum     5.0000000  27.0000000
```

```
$CHG_TOTSCRVG_394$agetrt_lt_180d$numbers_eachgrp
       Control ISIS 396443
N           16   49.000000
n            2   14.000000
mean         0    6.071429
sd           0    4.178043
se           0    1.116629
median       0    6.000000
min          0    0.000000
max          0   13.000000
sum          0   85.000000

$CHG_TOTSCRVG_394$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   5.90     1.175         3.318         8.490
2     Control   1.17     3.385        -6.278         8.623

$CHG_TOTSCRVG_394$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      4.7315267       3.6659564      -3.3371889      12.8002424       0.2232873

$CHG_TOTSCRVG_394$agetrt_lt_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_TOTSCRVG_394$agetrt_ge_180d
$CHG_TOTSCRVG_394$agetrt_ge_180d$base
          Control ISIS 396443
N      25.0000000  31.0000000
n      22.0000000  27.0000000
mean    1.0000000   0.5555556
sd      1.3093073   0.8473185
se      0.2791453   0.1630665
median  1.0000000   0.0000000
min     0.0000000   0.0000000
max     5.0000000   3.0000000
sum    22.0000000  15.0000000

$CHG_TOTSCRVG_394$agetrt_ge_180d$numbers_eachgrp
          Control ISIS 396443
N      25.0000000   31.000000
n       9.0000000   12.000000
mean   -0.8888889    2.583333
sd      1.5365907    4.737823
se      0.5121969    1.367692
median  0.0000000    1.500000
min    -4.0000000    0.000000
max     0.0000000   17.000000
sum    -8.0000000   31.000000

$CHG_TOTSCRVG_394$agetrt_ge_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
```

```
1 ISIS 396443   2.76     1.114         0.396         5.121
2     Control  -1.12     1.307        -3.894         1.649

$CHG_TOTSCRVG_394$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     3.88087008      1.80848821      0.04704634      7.71469382      0.04756419

$CHG_TOTSCRVG_394$agetrt_ge_180d$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.8900 -0.0230  1.8060  0.0561


$CHG_TOTSCRVG_394$sex_m
$CHG_TOTSCRVG_394$sex_m$base
         Control ISIS 396443
N      17.000000  37.0000000
n      14.000000  32.0000000
mean    1.000000   0.4687500
sd      1.519109   0.8025916
se      0.405999   0.1418795
median  0.000000   0.0000000
min     0.000000   0.0000000
max     5.000000   3.0000000
sum    14.000000  15.0000000

$CHG_TOTSCRVG_394$sex_m$numbers_eachgrp
         Control ISIS 396443
N      17.000000   37.000000
n       5.000000    8.000000
mean   -0.800000    2.625000
sd      1.788854    3.204350
se      0.800000    1.132909
median  0.000000    1.000000
min    -4.000000    0.000000
max     0.000000    7.000000
sum    -4.000000   21.000000

$CHG_TOTSCRVG_394$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.53     0.757         0.782         4.273
2     Control  -0.64     0.977        -2.897         1.610

$CHG_TOTSCRVG_394$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     3.17122339      1.28669905      0.20409005      6.13835672      0.03903657

$CHG_TOTSCRVG_394$sex_m$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 1.1500 -0.0880  2.3840  0.0686


$CHG_TOTSCRVG_394$sex_f
$CHG_TOTSCRVG_394$sex_f$base
          Control ISIS 396443
```

```
N      24.0000000  43.0000000
n      20.0000000  40.0000000
mean    0.6500000   0.6750000
sd      0.8127277   0.7970297
se      0.1817314   0.1260215
median  0.5000000   0.5000000
min     0.0000000   0.0000000
max     3.0000000   3.0000000
sum    13.0000000  27.0000000

$CHG_TOTSCRVG_394$sex_f$numbers_eachgrp
          Control ISIS 396443
N      24.0000000   43.000000
n       6.0000000   18.000000
mean   -0.6666667    5.277778
sd      1.2110601    5.096776
se      0.4944132    1.201322
median  0.0000000    3.500000
min    -3.0000000    0.000000
max     0.0000000   17.000000
sum    -4.0000000   95.000000

$CHG_TOTSCRVG_394$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   5.30     1.127         2.946         7.662
2     Control  -0.74     2.147        -5.238         3.748

$CHG_TOTSCRVG_394$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     6.04865332      2.58388516      0.64051953     11.45678711      0.03029436

$CHG_TOTSCRVG_394$sex_f$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.2700 0.2660 2.2750 0.0131


$CHG_TOTSCRVG_394$region_europe
$CHG_TOTSCRVG_394$region_europe$base
          Control ISIS 396443
N      17.0000000  30.0000000
n      15.0000000  27.0000000
mean    0.4000000   0.4074074
sd      0.6324555   0.6938887
se      0.1632993   0.1335389
median  0.0000000   0.0000000
min     0.0000000   0.0000000
max     2.0000000   3.0000000
sum     6.0000000  11.0000000

$CHG_TOTSCRVG_394$region_europe$numbers_eachgrp
       Control ISIS 396443
N           17   30.000000
n            3    8.000000
mean         0    4.500000
```

```
sd           0    5.554921
se           0    1.963961
median       0    3.000000
min          0    0.000000
max          0   17.000000
sum          0   36.000000

$CHG_TOTSCRVG_394$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.54     2.038        -0.441         9.530
2     Control  -0.12     3.610        -8.952         8.716

$CHG_TOTSCRVG_394$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      4.6620836       4.4206378      -6.1548274      15.4789945       0.3322045

$CHG_TOTSCRVG_394$region_europe$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_TOTSCRVG_394$region_asiapacific
$CHG_TOTSCRVG_394$region_asiapacific$base
       Control ISIS 396443
N            2  12.0000000
n            1  11.0000000
mean         0   0.5454545
sd          NA   1.0357255
se          NA   0.3122830
median       0   0.0000000
min          0   0.0000000
max          0   3.0000000
sum          0   6.0000000

$CHG_TOTSCRVG_394$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2   12.000000
n            0    2.000000
mean        NA    6.500000
sd          NA    9.192388
se          NA    6.500000
median      NA    6.500000
min         NA    0.000000
max         NA   13.000000
sum         NA   13.000000

$CHG_TOTSCRVG_394$region_asiapacific$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_TOTSCRVG_394$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA
```

```
$CHG_TOTSCRVG_394$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_TOTSCRVG_394$region_northamerica
$CHG_TOTSCRVG_394$region_northamerica$base
          Control ISIS 396443
N      22.0000000  38.0000000
n      18.0000000  34.0000000
mean    1.1666667   0.7352941
sd      1.3826658   0.7904285
se      0.3258975   0.1355574
median  1.0000000   1.0000000
min     0.0000000   0.0000000
max     5.0000000   2.0000000
sum    21.0000000  25.0000000

$CHG_TOTSCRVG_394$region_northamerica$numbers_eachgrp
          Control ISIS 396443
N      22.0000000   38.000000
n       8.0000000   16.000000
mean   -1.0000000    4.187500
sd      1.6035675    4.020261
se      0.5669467    1.005065
median  0.0000000    3.000000
min    -4.0000000    0.000000
max     0.0000000   13.000000
sum    -8.0000000   67.000000

$CHG_TOTSCRVG_394$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.09     0.872         2.259         5.911
2     Control  -0.80     1.269        -3.452         1.861

$CHG_TOTSCRVG_394$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    4.880833310     1.596998223     1.538277614     8.223389006     0.006498003

$CHG_TOTSCRVG_394$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 1.460  0.495  2.417  0.003


$CHG_TOTSCRVG_394$disdur_gt_12wk
$CHG_TOTSCRVG_394$disdur_gt_12wk$base
          Control ISIS 396443
N      23.0000000  46.0000000
n      19.0000000  41.0000000
mean    1.0000000   0.5365854
sd      1.2909944   0.8092454
se      0.2961744   0.1263829
median  1.0000000   0.0000000
```

```
min     0.0000000   0.0000000
max     5.0000000   3.0000000
sum    19.0000000  22.0000000

$CHG_TOTSCRVG_394$disdur_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N      23.0000000   46.000000
n       8.0000000   15.000000
mean   -1.0000000    3.333333
sd      1.6035675    5.108350
se      0.5669467    1.318970
median  0.0000000    2.000000
min    -4.0000000    0.000000
max     0.0000000   17.000000
sum    -8.0000000   50.000000

$CHG_TOTSCRVG_394$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   3.03     1.085         0.754         5.314
2     Control  -0.44     1.540        -3.674         2.796

$CHG_TOTSCRVG_394$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     3.47253824      1.97981714     -0.68690322      7.63197970      0.09644581

$CHG_TOTSCRVG_394$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.9800 0.0650 1.8900 0.0357


$CHG_TOTSCRVG_394$disdur_le_12wek
$CHG_TOTSCRVG_394$disdur_le_12wek$base
          Control ISIS 396443
N      18.0000000  34.0000000
n      15.0000000  31.0000000
mean    0.5333333   0.6451613
sd      0.9154754   0.7978466
se      0.2363747   0.1432975
median  0.0000000   0.0000000
min     0.0000000   0.0000000
max     3.0000000   3.0000000
sum     8.0000000  20.0000000

$CHG_TOTSCRVG_394$disdur_le_12wek$numbers_eachgrp
       Control ISIS 396443
N           18   34.000000
n            3   11.000000
mean         0    6.000000
sd           0    3.768289
se           0    1.136182
median       0    6.000000
min          0    1.000000
max          0   13.000000
sum          0   66.000000
```

```
$CHG_TOTSCRVG_394$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   5.87     1.184         3.196         8.551
2     Control   0.46     2.491        -5.171         6.101

$CHG_TOTSCRVG_394$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     5.40820927      2.90027884     -1.15267728     11.96909582      0.09509552

$CHG_TOTSCRVG_394$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA




\#############################################################################
[[1]]
[1] "CHOP INTEND-Responder"

$ageonset_le_12wk
$ageonset_le_12wk$`64`
$ageonset_le_12wk$`64`$ntab
            CTRL TRT
n_all         32  72
n_event        1  39
n_event_pct    3  54

$ageonset_le_12wk$`64`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  17.3333333 0.99020308 2.4889702 120.7103412 3.965981e-03
OR_TRTvsCTRL  36.6363636 1.04316927 4.7420384 283.0477137 5.564063e-04
ARR_TRTvsCTRL  0.5104167 0.06628842 0.3804938   0.6403396 1.354472e-14


$ageonset_le_12wk$`183`
$ageonset_le_12wk$`183`$ntab
            CTRL TRT
n_all         32  72
n_event        0  42
n_event_pct    0  58

$ageonset_le_12wk$`183`$stats
                estimate         se    lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  38.4246575 1.40695691 2.4378451  605.63909 0.009505234
OR_TRTvsCTRL  90.5737705 1.44467489 5.3369478 1537.13475 0.001813706
ARR_TRTvsCTRL  0.5833333 0.05810139 0.4694567    0.69721 0.000000000


$ageonset_le_12wk$`302`
$ageonset_le_12wk$`302`$ntab
            CTRL TRT
n_all         32  72
```

```
n_event        1  28
n_event_pct    3  39

$ageonset_le_12wk$`302`$stats
                estimate         se   lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  12.4444444 0.99527654 1.769272  87.5299020 1.130136e-02
OR_TRTvsCTRL  19.7272727 1.04436566 2.547425 152.7681103 4.299298e-03
ARR_TRTvsCTRL  0.3576389 0.06516747 0.229913   0.4853648 4.065170e-08


$ageonset_le_12wk$`394`
$ageonset_le_12wk$`394`$ntab
            CTRL TRT
n_all         32  72
n_event        1  23
n_event_pct    3  32

$ageonset_le_12wk$`394`$stats
                estimate        se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  10.2222222 0.9991693 1.4422842  72.4502357 1.999208e-02
OR_TRTvsCTRL  14.5510204 1.0469692 1.8694405 113.2596569 1.054167e-02
ARR_TRTvsCTRL  0.2881944 0.0629721 0.1647714   0.4116175 4.727250e-06



$ageonset_gt_12wk
$ageonset_gt_12wk$`64`
$ageonset_gt_12wk$`64`$ntab
            CTRL TRT
n_all          9   8
n_event        0   2
n_event_pct    0  25

$ageonset_gt_12wk$`64`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  5.555556 1.4794894  0.30576223 100.941826 0.2464368
OR_TRTvsCTRL  7.307692 1.6306776  0.29905082 178.572883 0.2225809
ARR_TRTvsCTRL 0.250000 0.1530931 -0.05005698   0.550057 0.1024704


$ageonset_gt_12wk$`183`
$ageonset_gt_12wk$`183`$ntab
            CTRL TRT
n_all          9   8
n_event        0   3
n_event_pct    0  38

$ageonset_gt_12wk$`183`$stats
                estimate        se    lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   7.777778 1.4403483 0.4621988 130.8826897 0.15440332
OR_TRTvsCTRL  12.090909 1.6039936 0.5213593 280.4018179 0.12020706
ARR_TRTvsCTRL  0.375000 0.1711633 0.0395261   0.7104739 0.02845974
```

```
$ageonset_gt_12wk$`302`
$ageonset_gt_12wk$`302`$ntab
            CTRL TRT
n_all          9   8
n_event        0   0
n_event_pct    0   0

$ageonset_gt_12wk$`302`$stats
              estimate       se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.111111 1.946507 0.02448431 50.42282 0.9568332
OR_TRTvsCTRL  1.117647 2.054972 0.01991174 62.73358 0.9568355
ARR_TRTvsCTRL 0.000000 0.000000 0.00000000  0.00000       NaN


$ageonset_gt_12wk$`394`
$ageonset_gt_12wk$`394`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$ageonset_gt_12wk$`394`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494



$agetrt_lt_180d
$agetrt_lt_180d$`64`
$agetrt_lt_180d$`64`$ntab
            CTRL TRT
n_all         16  49
n_event        1  28
n_event_pct    6  57

$agetrt_lt_180d$`64`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL   9.1428571 0.97611788 1.3496119  61.9376870 2.338311e-02
OR_TRTvsCTRL  20.0000000 1.07238053 2.4446576 163.6220981 5.213543e-03
ARR_TRTvsCTRL  0.5089286 0.09305927 0.3265358   0.6913214 4.529262e-08


$agetrt_lt_180d$`183`
$agetrt_lt_180d$`183`$ntab
            CTRL TRT
n_all         16  49
n_event        0  30
n_event_pct    0  61

$agetrt_lt_180d$`183`$stats
                estimate         se    lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  20.7400000 1.39784239 1.3395630 321.1103872 0.030074861
```

```
OR_TRTvsCTRL  51.6153846 1.46447089 2.9256292 910.6239161 0.007081232
ARR_TRTvsCTRL  0.6122449 0.06960546 0.4758207   0.7486691 0.000000000


$agetrt_lt_180d$`302`
$agetrt_lt_180d$`302`$ntab
            CTRL TRT
n_all         16  49
n_event        0  17
n_event_pct    0  35

$agetrt_lt_180d$`302`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  11.9000000 1.40652740 0.7556291 187.4067612 7.828129e-02
OR_TRTvsCTRL  17.7692308 1.46578244 1.0045981 314.3003747 4.963528e-02
ARR_TRTvsCTRL  0.3469388 0.06799944 0.2136623   0.4802152 3.359355e-07


$agetrt_lt_180d$`394`
$agetrt_lt_180d$`394`$ntab
            CTRL TRT
n_all         16  49
n_event        0  14
n_event_pct    0  29

$agetrt_lt_180d$`394`$stats
                estimate         se    lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   9.8600000 1.41072392 0.6209642 156.5623370 1.04759e-01
OR_TRTvsCTRL  13.4788732 1.46892498 0.7573600 239.8859418 7.65995e-02
ARR_TRTvsCTRL  0.2857143 0.06453628 0.1592255   0.4122031 9.54692e-06



$agetrt_ge_180d
$agetrt_ge_180d$`64`
$agetrt_ge_180d$`64`$ntab
            CTRL TRT
n_all         25  31
n_event        0  13
n_event_pct    0  42

$agetrt_ge_180d$`64`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  21.9375000 1.41575511 1.3680255 351.7872293 2.916067e-02
OR_TRTvsCTRL  37.2162162 1.47219014 2.0777902 666.5960518 1.402157e-02
ARR_TRTvsCTRL  0.4193548 0.08862687 0.2456494   0.5930603 2.226584e-06


$agetrt_ge_180d$`183`
$agetrt_ge_180d$`183`$ntab
            CTRL TRT
n_all         25  31
n_event        0  15
n_event_pct    0  48
```

```
$agetrt_ge_180d$`183`$stats
               estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  25.187500 1.41237551 1.5811346 401.2372822 2.235148e-02
OR_TRTvsCTRL  47.909091 1.47116888 2.6801352 856.4049163 8.536249e-03
ARR_TRTvsCTRL  0.483871 0.08975592 0.3079526   0.6597893 7.008046e-08


$agetrt_ge_180d$`302`
$agetrt_ge_180d$`302`$ntab
            CTRL TRT
n_all         25  31
n_event        1  11
n_event_pct    4  35

$agetrt_ge_180d$`302`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL   8.8709677 1.00928243 1.2270669  64.1318493 0.0305635917
OR_TRTvsCTRL  13.2000000 1.08746299 1.5664760 111.2305559 0.0176588906
ARR_TRTvsCTRL  0.3148387 0.09444988 0.1297203   0.4999571 0.0008579325


$agetrt_ge_180d$`394`
$agetrt_ge_180d$`394`$ntab
            CTRL TRT
n_all         25  31
n_event        1  10
n_event_pct    4  32

$agetrt_ge_180d$`394`$stats
                estimate         se    lo95ci     hi95ci      pvalue
RR_TRTvsCTRL   8.0645161 1.01377608 1.1057337 58.8174344 0.039483961
OR_TRTvsCTRL  11.4285714 1.09054377 1.3480916 96.8867721 0.025492625
ARR_TRTvsCTRL  0.2825806 0.09265586 0.1009785  0.4641828 0.002290037



$sex_m
$sex_m$`64`
$sex_m$`64`$ntab
            CTRL TRT
n_all         17  37
n_event        0  15
n_event_pct    0  41

$sex_m$`64`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  14.6842105 1.40806420 0.9296173 231.9514117 5.637412e-02
OR_TRTvsCTRL  24.1111111 1.47176881 1.3472412 431.5082535 3.058108e-02
ARR_TRTvsCTRL  0.4054054 0.08071502 0.2472069   0.5636039 5.095650e-07


$sex_m$`183`
$sex_m$`183`$ntab
```

```
           CTRL TRT
n_all        17  37
n_event       0  16
n_event_pct   0  43

$sex_m$`183`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  15.6315789 1.40667506 0.9922906 246.2446636 5.064659e-02
OR_TRTvsCTRL  26.8604651 1.47114260 1.5027083 480.1228539 2.529925e-02
ARR_TRTvsCTRL  0.4324324 0.08144549 0.2728022   0.5920627 1.099442e-07


$sex_m$`302`
$sex_m$`302`$ntab
           CTRL TRT
n_all        17  37
n_event       0  10
n_event_pct   0  27

$sex_m$`302`$stats
                estimate         se    lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   9.9473684 1.41893155 0.6164693 160.5110480 0.105438491
OR_TRTvsCTRL  13.3636364 1.47944063 0.7355674 242.7877666 0.079709053
ARR_TRTvsCTRL  0.2702703 0.07300949 0.1271743   0.4133662 0.000214032


$sex_m$`394`
$sex_m$`394`$ntab
           CTRL TRT
n_all        17  37
n_event       0   6
n_event_pct   0  16

$sex_m$`394`$stats
               estimate         se     lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  6.1578947 1.43943559 0.36659156 103.4384618 0.206657145
OR_TRTvsCTRL  7.2222222 1.49757639 0.38364674 135.9596948 0.186754357
ARR_TRTvsCTRL 0.1621622 0.06059739 0.04339347   0.2809309 0.007449359



$sex_f
$sex_f$`64`
$sex_f$`64`$ntab
           CTRL TRT
n_all        24  43
n_event       1  26
n_event_pct   4  60

$sex_f$`64`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  14.5116279 0.98668083 2.0982242 100.3645584 6.706863e-03
OR_TRTvsCTRL  35.1764706 1.06806523 4.3362418 285.3586436 8.576587e-04
ARR_TRTvsCTRL  0.5629845 0.08498842 0.3964102   0.7295587 3.490186e-11
```

```
$sex_f$`183`
$sex_f$`183`$ntab
            CTRL TRT
n_all         24  43
n_event        0  29
n_event_pct    0  67

$sex_f$`183`$stats
                estimate         se    lo95ci       hi95ci      pvalue
RR_TRTvsCTRL  33.5227273 1.40398399 2.1392720  525.3063845 0.012362922
OR_TRTvsCTRL  99.6896552 1.46413119 5.6543067 1757.6031582 0.001671098
ARR_TRTvsCTRL  0.6744186 0.07145956 0.5343604    0.8144768 0.000000000


$sex_f$`302`
$sex_f$`302`$ntab
            CTRL TRT
n_all         24  43
n_event        1  18
n_event_pct    4  42

$sex_f$`302`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  10.046512 0.99530552 1.4282680  70.6676882 2.044346e-02
OR_TRTvsCTRL  16.560000 1.06725527 2.0446124 134.1249791 8.535927e-03
ARR_TRTvsCTRL  0.376938 0.08557834 0.2092075   0.5446684 1.059814e-05


$sex_f$`394`
$sex_f$`394`$ntab
            CTRL TRT
n_all         24  43
n_event        1  18
n_event_pct    4  42

$sex_f$`394`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  10.046512 0.99530552 1.4282680  70.6676882 2.044346e-02
OR_TRTvsCTRL  16.560000 1.06725527 2.0446124 134.1249791 8.535927e-03
ARR_TRTvsCTRL  0.376938 0.08557834 0.2092075   0.5446684 1.059814e-05



$region_europe
$region_europe$`64`
$region_europe$`64`$ntab
            CTRL TRT
n_all         17  30
n_event        1  15
n_event_pct    6  50

$region_europe$`64`$stats
```

```
               estimate        se    lo95ci    hi95ci       pvalue
RR_TRTvsCTRL   8.5000000 0.9871726 1.2278238  58.84395 3.016825e-02
OR_TRTvsCTRL  16.0000000 1.0935416 1.8762713 136.44082 1.123122e-02
ARR_TRTvsCTRL  0.4411765 0.1076569 0.2301729   0.65218 4.167577e-05


$region_europe$`183`
$region_europe$`183`$ntab
            CTRL TRT
n_all         17  30
n_event        0  14
n_event_pct    0  47

$region_europe$`183`$stats
               estimate         se    lo95ci     hi95ci       pvalue
RR_TRTvsCTRL  16.8387097 1.40753398 1.0671211 265.707555 4.484357e-02
OR_TRTvsCTRL  30.7575758 1.47875435 1.6952514 558.046115 2.050880e-02
ARR_TRTvsCTRL  0.4666667 0.09108401 0.2881453   0.645188 2.999548e-07


$region_europe$`302`
$region_europe$`302`$ntab
            CTRL TRT
n_all         17  30
n_event        0  10
n_event_pct    0  33

$region_europe$`302`$stats
               estimate        se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  12.1935484 1.4168361 0.7587821 195.9490504 0.0775410751
OR_TRTvsCTRL  17.9268293 1.4836312 0.9786656 328.3769172 0.0517234212
ARR_TRTvsCTRL  0.3333333 0.0860663 0.1646465   0.5020202 0.0001075112


$region_europe$`394`
$region_europe$`394`$ntab
            CTRL TRT
n_all         17  30
n_event        0   7
n_event_pct    0  23

$region_europe$`394`$stats
               estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   8.7096774 1.43021667 0.52795807 143.6827740 0.13018787
OR_TRTvsCTRL  11.1702128 1.49433242 0.59714993 208.9486202 0.10632464
ARR_TRTvsCTRL  0.2333333 0.07722022 0.08198448   0.3846822 0.00251392



$region_asiapacific
$region_asiapacific$`64`
$region_asiapacific$`64`$ntab
            CTRL TRT
n_all          2  12
```

```
n_event        0   9
n_event_pct    0  75

$region_asiapacific$`64`$stats
               estimate       se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL   4.384615 1.301924 0.3417681  56.2511535 2.562409e-01
OR_TRTvsCTRL  13.571429 1.670622 0.5135582 358.6422760 1.185060e-01
ARR_TRTvsCTRL  0.750000 0.125000 0.5050045   0.9949955 1.973175e-09


$region_asiapacific$`183`
$region_asiapacific$`183`$ntab
            CTRL TRT
n_all          2  12
n_event        0   9
n_event_pct    0  75

$region_asiapacific$`183`$stats
               estimate       se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL   4.384615 1.301924 0.3417681  56.2511535 2.562409e-01
OR_TRTvsCTRL  13.571429 1.670622 0.5135582 358.6422760 1.185060e-01
ARR_TRTvsCTRL  0.750000 0.125000 0.5050045   0.9949955 1.973175e-09


$region_asiapacific$`302`
$region_asiapacific$`302`$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$region_asiapacific$`302`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353


$region_asiapacific$`394`
$region_asiapacific$`394`$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$region_asiapacific$`394`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353



$region_northamerica
```

```
$region_northamerica$`64`
$region_northamerica$`64`$ntab
            CTRL TRT
n_all         22  38
n_event        0  17
n_event_pct    0  45

$region_northamerica$`64`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  20.6410256 1.40997290 1.3018477 327.2671235 3.178940e-02
OR_TRTvsCTRL  36.6279070 1.46563943 2.0713694 647.6891837 1.401734e-02
ARR_TRTvsCTRL  0.4473684 0.08066009 0.2892775   0.6054593 2.917087e-08


$region_northamerica$`183`
$region_northamerica$`183`$ntab
            CTRL TRT
n_all         22  38
n_event        0  22
n_event_pct    0  58

$region_northamerica$`183`$stats
                estimate         se    lo95ci       hi95ci       pvalue
RR_TRTvsCTRL  26.5384615 1.40546261 1.6886661  417.0687864 1.966119e-02
OR_TRTvsCTRL  61.3636364 1.46611560 3.4669791 1086.1028368 4.985394e-03
ARR_TRTvsCTRL  0.5789474 0.08009325 0.4219675    0.7359273 4.887202e-13


$region_northamerica$`302`
$region_northamerica$`302`$ntab
            CTRL TRT
n_all         22  38
n_event        1  16
n_event_pct    5  42

$region_northamerica$`302`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL   9.2631579 0.99535404 1.3167768  65.1637339 2.532326e-02
OR_TRTvsCTRL  15.2727273 1.07497609 1.8573566 125.5850385 1.121478e-02
ARR_TRTvsCTRL  0.3755981 0.09158128 0.1961021   0.5550941 4.109172e-05


$region_northamerica$`394`
$region_northamerica$`394`$ntab
            CTRL TRT
n_all         22  38
n_event        1  15
n_event_pct    5  39

$region_northamerica$`394`$stats
                estimate         se    lo95ci     hi95ci       pvalue
RR_TRTvsCTRL   8.6842105 0.99744490 1.2294297  61.341866 0.0302315371
OR_TRTvsCTRL  13.6956522 1.07599441 1.6622434 112.842012 0.0150056923
ARR_TRTvsCTRL  0.3492823 0.09088213 0.1711566   0.527408 0.0001214181
```

```
$disdur_gt_12wk
$disdur_gt_12wk$`64`
$disdur_gt_12wk$`64`$ntab
            CTRL TRT
n_all         23  46
n_event        0  18
n_event_pct    0  39

$disdur_gt_12wk$`64`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  18.8936170 1.41106725 1.1890839 300.2048684 3.727894e-02
OR_TRTvsCTRL  30.5087719 1.46003252 1.7443868 533.5887470 1.922941e-02
ARR_TRTvsCTRL  0.3913043 0.07195791 0.2502694   0.5323393 5.389352e-08


$disdur_gt_12wk$`183`
$disdur_gt_12wk$`183`$ntab
            CTRL TRT
n_all         23  46
n_event        0  21
n_event_pct    0  46

$disdur_gt_12wk$`183`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  21.9574468 1.40839212 1.3891729 347.0622563 2.828169e-02
OR_TRTvsCTRL  39.6274510 1.45886274 2.2709623 691.4843516 1.166283e-02
ARR_TRTvsCTRL  0.4565217 0.07344173 0.3125786   0.6004649 5.096370e-10


$disdur_gt_12wk$`302`
$disdur_gt_12wk$`302`$ntab
            CTRL TRT
n_all         23  46
n_event        1  15
n_event_pct    4  33

$disdur_gt_12wk$`302`$stats
                estimate        se    lo95ci     hi95ci       pvalue
RR_TRTvsCTRL   7.5000000 1.0007244 1.0549773 53.3186808 0.0440678849
OR_TRTvsCTRL  10.6451613 1.0697566 1.3078976 86.6424555 0.0270440262
ARR_TRTvsCTRL  0.2826087 0.0811507 0.1235562  0.4416611 0.0004967236


$disdur_gt_12wk$`394`
$disdur_gt_12wk$`394`$ntab
            CTRL TRT
n_all         23  46
n_event        1  13
n_event_pct    4  28

$disdur_gt_12wk$`394`$stats
```

```
               estimate         se     lo95ci    hi95ci      pvalue
RR_TRTvsCTRL  6.5000000 1.00583581 0.90519961 46.674788 0.062752359
OR_TRTvsCTRL  8.6666667 1.07362966 1.05676122 71.076710 0.044284644
ARR_TRTvsCTRL 0.2391304 0.07883897 0.08460889  0.393652 0.002420151



$disdur_le_12wek
$disdur_le_12wek$`64`
$disdur_le_12wek$`64`$ntab
            CTRL TRT
n_all         18  34
n_event        1  23
n_event_pct    6  68

$disdur_le_12wek$`64`$stats
               estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  12.176471 0.97903572 1.7871652  82.9617949 1.067910e-02
OR_TRTvsCTRL  35.545455 1.09234193 4.1781203 302.4037724 1.079470e-03
ARR_TRTvsCTRL  0.620915 0.09670551 0.4313757   0.8104544 1.356679e-10


$disdur_le_12wek$`183`
$disdur_le_12wek$`183`$ntab
            CTRL TRT
n_all         18  34
n_event        0  24
n_event_pct    0  71

$disdur_le_12wek$`183`$stats
                estimate         se    lo95ci       hi95ci      pvalue
RR_TRTvsCTRL  26.6000000 1.39986189 1.7112641  413.4721288 0.019091515
OR_TRTvsCTRL  86.3333333 1.47990151 4.7477087 1569.9034992 0.002590982
ARR_TRTvsCTRL  0.7058824 0.07814249 0.5527259    0.8590388 0.000000000


$disdur_le_12wek$`302`
$disdur_le_12wek$`302`$ntab
            CTRL TRT
n_all         18  34
n_event        0  13
n_event_pct    0  38

$disdur_le_12wek$`302`$stats
               estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  14.6571429 1.41169085 0.9213314 233.1754127 5.718118e-02
OR_TRTvsCTRL  23.2325581 1.47466598 1.2908003 418.1527830 3.291960e-02
ARR_TRTvsCTRL  0.3823529 0.08334181 0.2190060   0.5456999 4.480092e-06


$disdur_le_12wek$`394`
$disdur_le_12wek$`394`$ntab
            CTRL TRT
n_all         18  34
```

```
n_event        0  11
n_event_pct    0  32

$disdur_le_12wek$`394`$stats
                estimate         se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  12.4857143 1.41624628 0.7778617 200.4123167 7.465322e-02
OR_TRTvsCTRL  18.1063830 1.47768866 1.0000480 327.8253756 4.999620e-02
ARR_TRTvsCTRL  0.3235294 0.08023094 0.1662797   0.4807792 5.519205e-05




\#############################################################################
[[1]]
[1] "Zeit bis zum CHOP INTEND Responder"

$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               2.0               58.0
n_event_pct                           6.0               81.0
time-to-event-wk-10th                49.1                8.4
time-to-event-wk-25th                  NA                9.0
time-to-event-wk-50th                  NA               10.1
time-to-event-wk-75th                  NA               26.0
time-to-event-wk-90th                  NA               42.0
time-to-event-wk-50th-loci           49.1                9.3
time-to-event-wk-50th-hici             NA               20.1

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.128e+01 7.275e-01 5.114e+00 8.856e+01 2.628e-05


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9                8.0
n_event                               0                4.0
n_event_pct                           0               50.0
time-to-event-wk-10th                NA                8.3
time-to-event-wk-25th                NA                8.4
time-to-event-wk-50th                NA               26.3
time-to-event-wk-75th                NA               27.0
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                8.3
time-to-event-wk-50th-hici           NA                 NA

$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.542e+10 2.241e+04 0.000e+00       Inf 9.992e-01
```

```
$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 16                49.0
n_event                                1                39.0
n_event_pct                            6                80.0
time-to-event-wk-10th                 NA                 8.4
time-to-event-wk-25th                 NA                 9.1
time-to-event-wk-50th                 NA                11.6
time-to-event-wk-75th                 NA                26.0
time-to-event-wk-90th                 NA                55.3
time-to-event-wk-50th-loci            NA                 9.6
time-to-event-wk-50th-hici            NA                25.1

$agetrt_lt_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.789e+01 1.023e+00 2.407e+00 1.330e+02 4.829e-03


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0                31.0
n_event                              1.0                23.0
n_event_pct                          4.0                74.0
time-to-event-wk-10th                 NA                 8.3
time-to-event-wk-25th                 NA                 9.0
time-to-event-wk-50th                 NA                 9.3
time-to-event-wk-75th                 NA                26.3
time-to-event-wk-90th                 NA                42.0
time-to-event-wk-50th-loci          49.1                 9.0
time-to-event-wk-50th-hici            NA                26.1

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.186e+01 1.070e+00 7.598e+00 5.037e+02 1.156e-04


$sex_m
$sex_m$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                37.0
n_event                                0                27.0
n_event_pct                            0                73.0
time-to-event-wk-10th                 NA                 9.0
time-to-event-wk-25th                 NA                 9.5
time-to-event-wk-50th                 NA                21.1
time-to-event-wk-75th                 NA                36.9
time-to-event-wk-90th                 NA                55.3
time-to-event-wk-50th-loci            NA                10.0
time-to-event-wk-50th-hici            NA                26.0

$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
1.621e+09 8.041e+03 0.000e+00       Inf 9.979e-01


$sex_f
$sex_f$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               2.0               35.0
n_event_pct                           8.0               81.0
time-to-event-wk-10th                49.1                8.3
time-to-event-wk-25th                  NA                9.0
time-to-event-wk-50th                  NA                9.3
time-to-event-wk-75th                  NA               25.4
time-to-event-wk-90th                  NA               26.3
time-to-event-wk-50th-loci           49.1                9.0
time-to-event-wk-50th-hici             NA               12.1

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.120e+01 7.572e-01 4.805e+00 9.350e+01 5.510e-05


$region_europe
$region_europe$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17               30.0
n_event                               1               20.0
n_event_pct                           6               67.0
time-to-event-wk-10th                NA                8.9
time-to-event-wk-25th                NA                9.1
time-to-event-wk-50th                NA               10.1
time-to-event-wk-75th                NA               36.9
time-to-event-wk-90th                NA               55.3
time-to-event-wk-50th-loci           NA                9.1
time-to-event-wk-50th-hici           NA               27.0

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.500e+01 1.030e+00 1.992e+00 1.130e+02 8.559e-03


$region_asiapacific
$region_asiapacific$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2               12.0
n_event                               0               10.0
n_event_pct                           0               83.0
time-to-event-wk-10th                NA                8.4
time-to-event-wk-25th                NA                8.4
time-to-event-wk-50th                NA                9.1
time-to-event-wk-75th                NA               18.1
time-to-event-wk-90th                NA               25.1
time-to-event-wk-50th-loci           NA                8.4
time-to-event-wk-50th-hici           NA               18.1
```

```
$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.552e+08 1.130e+04 0.000e+00       Inf 9.986e-01


$region_northamerica
$region_northamerica$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               1.0               32.0
n_event_pct                           5.0               84.0
time-to-event-wk-10th                49.1                8.3
time-to-event-wk-25th                  NA                9.1
time-to-event-wk-50th                  NA               20.0
time-to-event-wk-75th                  NA               26.1
time-to-event-wk-90th                  NA               41.3
time-to-event-wk-50th-loci           49.1                9.1
time-to-event-wk-50th-hici             NA               25.7

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.055e+01 1.032e+00 5.366e+00 3.064e+02 3.331e-04


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               1.0               32.0
n_event_pct                           4.0               70.0
time-to-event-wk-10th                49.1                8.4
time-to-event-wk-25th                  NA                9.0
time-to-event-wk-50th                  NA               20.1
time-to-event-wk-75th                  NA               26.3
time-to-event-wk-90th                  NA               55.3
time-to-event-wk-50th-loci           49.1                9.1
time-to-event-wk-50th-hici             NA               26.0

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.326e+01 1.029e+00 4.427e+00 2.499e+02 6.593e-04


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18               34.0
n_event                               1               30.0
n_event_pct                           6               88.0
time-to-event-wk-10th                 NA                8.4
time-to-event-wk-25th                 NA                9.0
time-to-event-wk-50th                 NA               10.0
time-to-event-wk-75th                 NA               25.4
```

```
time-to-event-wk-90th                  NA               36.9
time-to-event-wk-50th-loci             NA                9.1
time-to-event-wk-50th-hici             NA               12.1

$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.412e+01 1.021e+00 3.263e+00 1.783e+02 1.817e-03



\#############################################################################
[[1]]
[1] "Veränderung des CHOP INTEND von Baseline"

$CHG_TOTSCORE_64
$CHG_TOTSCORE_64$ageonset_le_12wk
$CHG_TOTSCORE_64$ageonset_le_12wk$base
          Control  ISIS 396443
N       32.000000   72.0000000
n       24.000000   68.0000000
mean    29.208333   26.5882353
sd       8.147975    7.3929884
se       1.663198    0.8965315
median  29.500000   27.7500000
min     14.000000    8.0000000
max     50.500000   42.5000000
sum    701.000000 1808.0000000

$CHG_TOTSCORE_64$ageonset_le_12wk$numbers_eachgrp
          Control ISIS 396443
N       32.000000   72.000000
n       24.000000   68.000000
mean    -2.000000    4.235294
sd       5.069088    8.076810
se       1.034723    0.979457
median  -0.750000    5.000000
min    -14.500000  -29.000000
max      4.000000   22.500000
sum    -48.000000  288.000000

$CHG_TOTSCORE_64$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.07     0.881         2.317         5.819
2     Control  -1.53     1.497        -4.502         1.450

$CHG_TOTSCORE_64$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    5.594131581     1.751103738     2.113623289     9.074639873     0.001950724

$CHG_TOTSCORE_64$ageonset_le_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.8300 0.3510 1.3140 0.0007
```

```
$CHG_TOTSCORE_64$ageonset_gt_12wk
$CHG_TOTSCORE_64$ageonset_gt_12wk$base
          Control ISIS 396443
N        9.000000    8.000000
n        9.000000    5.000000
mean    28.444444   37.600000
sd       7.559946    8.196036
se       2.519982    3.665379
median  29.000000   40.000000
min     10.500000   28.000000
max     38.000000   48.500000
sum    256.000000  188.000000

$CHG_TOTSCORE_64$ageonset_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N        9.000000    8.000000
n        9.000000    5.000000
mean    -7.666667    3.800000
sd       7.826238    4.452527
se       2.608746    1.991231
median  -5.500000    3.000000
min    -22.000000   -0.500000
max      1.500000   10.000000
sum    -69.000000   19.000000

$CHG_TOTSCORE_64$ageonset_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   6.21     3.503        -1.714        14.133
2     Control  -9.01     2.450       -14.549        -3.462

$CHG_TOTSCORE_64$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    15.21456010      4.68215828      4.62278221     25.80633799      0.01000576

$CHG_TOTSCORE_64$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.5600 0.2710 2.8460 0.0177


$CHG_TOTSCORE_64$agetrt_lt_180d
$CHG_TOTSCORE_64$agetrt_lt_180d$base
          Control ISIS 396443
N       16.000000   49.000000
n       12.000000   46.000000
mean    25.958333   27.391304
sd       5.902458    7.585009
se       1.703893    1.118349
median  26.750000   28.250000
min     14.000000    9.000000
max     33.000000   48.500000
sum    311.500000 1260.000000

$CHG_TOTSCORE_64$agetrt_lt_180d$numbers_eachgrp
          Control ISIS 396443
```

```
N       16.000000   49.000000
n       12.000000   46.000000
mean    -3.291667    5.347826
sd       5.520451    7.836432
se       1.593617    1.155419
median  -2.000000    5.500000
min    -14.500000  -11.500000
max      4.000000   22.500000
sum    -39.500000  246.000000

$CHG_TOTSCORE_64$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   5.46     1.064         3.327         7.597
2     Control  -3.73     2.094        -7.929         0.471

$CHG_TOTSCORE_64$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   9.190532e+00    2.355188e+00    4.466623e+00    1.391444e+01    2.707718e-04

$CHG_TOTSCORE_64$agetrt_lt_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.1500 0.4750 1.8170 0.0008


$CHG_TOTSCORE_64$agetrt_ge_180d
$CHG_TOTSCORE_64$agetrt_ge_180d$base
          Control ISIS 396443
N       25.000000   31.000000
n       21.000000   27.000000
mean    30.738095   27.259259
sd       8.456682    8.562407
se       1.845399    1.647836
median  30.000000   28.000000
min     10.500000    8.000000
max     50.500000   42.500000
sum    645.500000  736.000000

$CHG_TOTSCORE_64$agetrt_ge_180d$numbers_eachgrp
          Control ISIS 396443
N       25.000000   31.000000
n       21.000000   27.000000
mean    -3.690476    2.259259
sd       6.909190    7.659045
se       1.507709    1.473984
median  -3.000000    3.000000
min    -22.000000  -29.000000
max      3.500000   10.000000
sum    -77.500000   61.000000

$CHG_TOTSCORE_64$agetrt_ge_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.18     1.517        -0.881         5.237
2     Control  -3.59     1.738        -7.091        -0.081
```

```
$CHG_TOTSCORE_64$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     5.76378447      2.39985756      0.92401045     10.60355848      0.02071148

$CHG_TOTSCORE_64$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.8000 0.2030 1.3910 0.0085


$CHG_TOTSCORE_64$sex_m
$CHG_TOTSCORE_64$sex_m$base
          Control ISIS 396443
N       17.000000   37.000000
n       14.000000   32.000000
mean    30.785714   26.203125
sd       8.706130    8.648941
se       2.326811    1.528931
median  31.000000   28.000000
min     14.000000    8.000000
max     50.500000   48.500000
sum    431.000000  838.500000

$CHG_TOTSCORE_64$sex_m$numbers_eachgrp
          Control ISIS 396443
N       17.000000   37.000000
n       14.000000   32.000000
mean    -4.285714    3.640625
sd       5.902132    8.764145
se       1.577411    1.549297
median  -3.500000    3.000000
min    -19.500000  -29.000000
max      3.500000   22.500000
sum    -60.000000  116.500000

$CHG_TOTSCORE_64$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   3.69     1.376         0.908         6.464
2     Control  -4.39     2.115        -8.660        -0.119

$CHG_TOTSCORE_64$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    8.075052489     2.567360746     2.890162276    13.259942702     0.003084802

$CHG_TOTSCORE_64$sex_m$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 0.970  0.309  1.632  0.004


$CHG_TOTSCORE_64$sex_f
$CHG_TOTSCORE_64$sex_f$base
          Control ISIS 396443
N       24.000000   43.000000
n       19.000000   41.000000
mean    27.684211   28.231707
```

```
sd       7.169012    7.250084
se       1.644684    1.132273
median  29.000000   28.500000
min     10.500000   15.000000
max     41.000000   42.500000
sum    526.000000 1157.500000

$CHG_TOTSCORE_64$sex_f$numbers_eachgrp
          Control ISIS 396443
N       24.000000   43.000000
n       19.000000   41.000000
mean    -3.000000    4.646341
sd       6.770032    7.161742
se       1.553152    1.118476
median  -1.000000    5.000000
min    -22.000000  -11.500000
max      4.000000   20.000000
sum    -57.000000  190.500000

$CHG_TOTSCORE_64$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.45     1.163         2.118         6.777
2     Control  -2.57     1.778        -6.134         0.991

$CHG_TOTSCORE_64$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    7.018895204     2.221064131     2.567783218    11.470007191     0.002563501

$CHG_TOTSCORE_64$sex_f$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.0700 0.4930 1.6510 0.0003


$CHG_TOTSCORE_64$region_europe
$CHG_TOTSCORE_64$region_europe$base
          Control ISIS 396443
N       17.000000   30.000000
n       14.000000   27.000000
mean    29.500000   26.351852
sd       6.201737    8.446454
se       1.657484    1.625521
median  29.500000   28.000000
min     19.500000    9.000000
max     41.000000   48.500000
sum    413.000000  711.500000

$CHG_TOTSCORE_64$region_europe$numbers_eachgrp
          Control ISIS 396443
N       17.000000   30.000000
n       14.000000   27.000000
mean    -3.500000    3.648148
sd       6.063764    8.581974
se       1.620609    1.651602
median  -2.250000    5.000000
```

```
min    -14.500000  -29.000000
max      4.000000   19.000000
sum    -49.000000   98.500000

$CHG_TOTSCORE_64$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   3.53     1.480         0.533         6.535
2     Control  -3.28     2.073        -7.485         0.925

$CHG_TOTSCORE_64$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     6.81419381      2.57910680      1.58352279     12.04486483      0.01211774

$CHG_TOTSCORE_64$region_europe$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.8900 0.2180 1.5720 0.0096


$CHG_TOTSCORE_64$region_asiapacific
$CHG_TOTSCORE_64$region_asiapacific$base
       Control ISIS 396443
N            2   12.000000
n            1   12.000000
mean        29   27.250000
sd          NA    6.733566
se          NA    1.943813
median      29   26.250000
min         29   18.000000
max         29   40.500000
sum         29  327.000000

$CHG_TOTSCORE_64$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2   12.000000
n            1   12.000000
mean       -22    6.333333
sd          NA    9.420320
se          NA    2.719412
median     -22    6.500000
min        -22   -9.500000
max        -22   22.500000
sum        -22   76.000000

$CHG_TOTSCORE_64$region_asiapacific$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   6.00     2.381         0.509        11.489
2     Control -17.99    10.437       -42.055         6.080

$CHG_TOTSCORE_64$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    23.98668900     11.04681478     -1.48731157     49.46068956      0.06168696

$CHG_TOTSCORE_64$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
```

```
    NA     NA     NA     NA


$CHG_TOTSCORE_64$region_northamerica
$CHG_TOTSCORE_64$region_northamerica$base
          Control ISIS 396443
N       22.000000   38.000000
n       18.000000   34.000000
mean    28.611111   28.161765
sd       9.336134    7.962717
se       2.200548    1.365595
median  29.500000   28.750000
min     10.500000    8.000000
max     50.500000   40.000000
sum    515.000000  957.500000

$CHG_TOTSCORE_64$region_northamerica$numbers_eachgrp
          Control ISIS 396443
N       22.000000   38.000000
n       18.000000   34.000000
mean    -2.555556    3.897059
sd       5.173146    6.728253
se       1.219322    1.153886
median  -2.000000    3.500000
min    -19.500000  -11.500000
max      3.500000   20.000000
sum    -46.000000  132.500000

$CHG_TOTSCORE_64$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   3.51     1.098         1.298         5.716
2     Control  -1.82     1.541        -4.920         1.282

$CHG_TOTSCORE_64$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    5.326436999     1.950008102     1.403526698     9.249347300     0.008851552

$CHG_TOTSCORE_64$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 1.020  0.411  1.624  0.001


$CHG_TOTSCORE_64$disdur_gt_12wk
$CHG_TOTSCORE_64$disdur_gt_12wk$base
          Control ISIS 396443
N       23.000000   46.000000
n       18.000000   42.000000
mean    30.805556   26.821429
sd       8.719719    7.571466
se       2.055257    1.168302
median  29.750000   28.000000
min     14.000000    8.000000
max     50.500000   42.500000
sum    554.500000 1126.500000
```

```
$CHG_TOTSCORE_64$disdur_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N       23.000000   46.000000
n       18.000000   42.000000
mean    -2.194444    1.845238
sd       4.926336    7.596122
se       1.161149    1.172107
median  -1.250000    2.500000
min    -14.500000  -29.000000
max      3.500000   12.500000
sum    -39.500000   77.500000

$CHG_TOTSCORE_64$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   1.91     1.118        -0.328         4.153
2     Control  -2.35     1.758        -5.875         1.173

$CHG_TOTSCORE_64$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     4.26338687      2.14606831     -0.03743014      8.56420388      0.05195753

$CHG_TOTSCORE_64$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.5800 0.0140 1.1380 0.0447


$CHG_TOTSCORE_64$disdur_le_12wek
$CHG_TOTSCORE_64$disdur_le_12wek$base
          Control ISIS 396443
N       18.000000   34.000000
n       15.000000   31.000000
mean    26.833333   28.048387
sd       6.360219    8.402733
se       1.642201    1.509175
median  28.500000   29.000000
min     10.500000    9.000000
max     33.500000   48.500000
sum    402.500000  869.500000

$CHG_TOTSCORE_64$disdur_le_12wek$numbers_eachgrp
          Control ISIS 396443
N       18.000000   34.000000
n       15.000000   31.000000
mean    -5.166667    7.403226
sd       7.589153    7.151246
se       1.959511    1.284402
median  -3.500000    7.000000
min    -22.000000  -11.500000
max      4.000000   22.500000
sum    -77.500000  229.500000

$CHG_TOTSCORE_64$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
```

```
1 ISIS 396443   7.16     1.286         4.563         9.756
2     Control  -4.66     1.887        -8.474        -0.852

$CHG_TOTSCORE_64$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   1.182294e+01    2.342409e+00    7.092350e+00    1.655353e+01    9.630340e-06

$CHG_TOTSCORE_64$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 1.690  0.979  2.409  0.000



$CHG_TOTSCORE_183
$CHG_TOTSCORE_183$ageonset_le_12wk
$CHG_TOTSCORE_183$ageonset_le_12wk$base
          Control  ISIS 396443
N       32.000000   72.0000000
n       24.000000   68.0000000
mean    29.208333   26.5882353
sd       8.147975    7.3929884
se       1.663198    0.8965315
median  29.500000   27.7500000
min     14.000000    8.0000000
max     50.500000   42.5000000
sum    701.000000 1808.0000000

$CHG_TOTSCORE_183$ageonset_le_12wk$numbers_eachgrp
           Control ISIS 396443
N        32.000000   72.000000
n        16.000000   55.000000
mean     -9.093750    9.036364
sd        8.359064    8.888640
se        2.089766    1.198544
median  -10.750000   10.000000
min     -22.500000  -18.000000
max       3.000000   23.500000
sum    -145.500000  497.000000

$CHG_TOTSCORE_183$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   8.87     1.116         6.643        11.101
2     Control  -8.53     2.114       -12.750        -4.308

$CHG_TOTSCORE_183$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   1.740134e+01    2.422431e+00    1.256480e+01    2.223788e+01    7.636477e-10

$CHG_TOTSCORE_183$ageonset_le_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.040  1.388  2.699  0.000


$CHG_TOTSCORE_183$ageonset_gt_12wk
```

```
$CHG_TOTSCORE_183$ageonset_gt_12wk$base
          Control ISIS 396443
N        9.000000    8.000000
n        9.000000    5.000000
mean    28.444444   37.600000
sd       7.559946    8.196036
se       2.519982    3.665379
median  29.000000   40.000000
min     10.500000   28.000000
max     38.000000   48.500000
sum    256.000000  188.000000

$CHG_TOTSCORE_183$ageonset_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N        9.000000    8.000000
n        7.000000    4.000000
mean   -14.142857    9.250000
sd       6.896341    6.614378
se       2.606572    3.307189
median -14.500000   10.250000
min    -23.000000    1.500000
max     -3.000000   15.000000
sum    -99.000000   37.000000

$CHG_TOTSCORE_183$ageonset_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  14.84     5.542         1.280        28.404
2     Control -17.34     3.618       -26.191        -8.486

$CHG_TOTSCORE_183$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   32.180481834     8.039775163    12.507860706    51.853102961     0.007097449

$CHG_TOTSCORE_183$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
3.1400 1.0950 5.1920 0.0026


$CHG_TOTSCORE_183$agetrt_lt_180d
$CHG_TOTSCORE_183$agetrt_lt_180d$base
          Control ISIS 396443
N       16.000000   49.000000
n       12.000000   46.000000
mean    25.958333   27.391304
sd       5.902458    7.585009
se       1.703893    1.118349
median  26.750000   28.250000
min     14.000000    9.000000
max     33.000000   48.500000
sum    311.500000 1260.000000

$CHG_TOTSCORE_183$agetrt_lt_180d$numbers_eachgrp
           Control ISIS 396443
N        16.000000   49.000000
```

```
n         8.000000   38.000000
mean    -12.875000   10.605263
sd        6.854352    8.359456
se        2.423379    1.356083
median  -12.750000   13.500000
min     -21.500000  -12.500000
max       1.000000   23.500000
sum    -103.000000  403.000000

$CHG_TOTSCORE_183$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  10.77     1.173         8.397        13.134
2     Control -13.64     2.573       -18.833        -8.441

$CHG_TOTSCORE_183$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.440256e+01    2.835678e+00    1.867579e+01    3.012932e+01    9.922443e-11

$CHG_TOTSCORE_183$agetrt_lt_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.840  1.862  3.809  0.000


$CHG_TOTSCORE_183$agetrt_ge_180d
$CHG_TOTSCORE_183$agetrt_ge_180d$base
          Control ISIS 396443
N       25.000000   31.000000
n       21.000000   27.000000
mean    30.738095   27.259259
sd       8.456682    8.562407
se       1.845399    1.647836
median  30.000000   28.000000
min     10.500000    8.000000
max     50.500000   42.500000
sum    645.500000  736.000000

$CHG_TOTSCORE_183$agetrt_ge_180d$numbers_eachgrp
           Control ISIS 396443
N        25.000000   31.000000
n        15.000000   21.000000
mean     -9.433333    6.238095
sd        8.729807    8.815638
se        2.254026    1.923730
median   -7.500000    6.500000
min     -23.000000  -18.000000
max       3.000000   20.500000
sum    -141.500000  131.000000

$CHG_TOTSCORE_183$agetrt_ge_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   6.60     2.102         2.316        10.889
2     Control  -9.94     2.541       -15.127        -4.761

$CHG_TOTSCORE_183$agetrt_ge_180d$diffgrp_TRTvsCTRL
```

```
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   1.654655e+01    3.498865e+00    9.410570e+00    2.368253e+01    4.661944e-05

$CHG_TOTSCORE_183$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 1.750  0.957  2.534  0.000


$CHG_TOTSCORE_183$sex_m
$CHG_TOTSCORE_183$sex_m$base
          Control ISIS 396443
N       17.000000   37.000000
n       14.000000   32.000000
mean    30.785714   26.203125
sd       8.706130    8.648941
se       2.326811    1.528931
median  31.000000   28.000000
min     14.000000    8.000000
max     50.500000   48.500000
sum    431.000000  838.500000

$CHG_TOTSCORE_183$sex_m$numbers_eachgrp
           Control ISIS 396443
N        17.000000   37.000000
n         9.000000   26.000000
mean    -12.888889    6.615385
sd        7.109755    9.901826
se        2.369918    1.941908
median  -12.000000    7.000000
min     -22.500000  -18.000000
max      -2.500000   23.500000
sum    -116.000000  172.000000

$CHG_TOTSCORE_183$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   6.65     1.745         3.090        10.217
2     Control -13.00     3.116       -19.362        -6.636

$CHG_TOTSCORE_183$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   1.965267e+01    3.703830e+00    1.208844e+01    2.721690e+01    9.815692e-06

$CHG_TOTSCORE_183$sex_m$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.050  1.135  2.962  0.000


$CHG_TOTSCORE_183$sex_f
$CHG_TOTSCORE_183$sex_f$base
          Control ISIS 396443
N       24.000000   43.000000
n       19.000000   41.000000
mean    27.684211   28.231707
sd       7.169012    7.250084
```

```
se       1.644684    1.132273
median  29.000000   28.500000
min     10.500000   15.000000
max     41.000000   42.500000
sum    526.000000 1157.500000

$CHG_TOTSCORE_183$sex_f$numbers_eachgrp
           Control ISIS 396443
N        24.000000   43.000000
n        14.000000   33.000000
mean     -9.178571   10.969697
sd        8.672696    7.226189
se        2.317876    1.257918
median  -10.000000   14.000000
min     -23.000000   -8.500000
max       3.000000   21.000000
sum    -128.500000  362.000000

$CHG_TOTSCORE_183$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  10.99     1.373         8.218        13.760
2     Control  -9.22     2.221       -13.706        -4.742

$CHG_TOTSCORE_183$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.021319e+01    2.745490e+00    1.467256e+01    2.575381e+01    4.427489e-09

$CHG_TOTSCORE_183$sex_f$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.580  1.753  3.412  0.000


$CHG_TOTSCORE_183$region_europe
$CHG_TOTSCORE_183$region_europe$base
          Control ISIS 396443
N       17.000000   30.000000
n       14.000000   27.000000
mean    29.500000   26.351852
sd       6.201737    8.446454
se       1.657484    1.625521
median  29.500000   28.000000
min     19.500000    9.000000
max     41.000000   48.500000
sum    413.000000  711.500000

$CHG_TOTSCORE_183$region_europe$numbers_eachgrp
           Control ISIS 396443
N        17.000000   30.000000
n        10.000000   21.000000
mean    -14.450000    9.047619
sd        7.783351   10.497505
se        2.461312    2.290743
median  -17.500000   14.000000
min     -22.500000  -18.000000
```

```
max       1.000000   22.000000
sum    -144.500000  190.000000

$CHG_TOTSCORE_183$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   9.02     2.030         4.845        13.189
2     Control -14.39     2.981       -20.513        -8.258

$CHG_TOTSCORE_183$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.340210e+01    3.665296e+00    1.586797e+01    3.093622e+01    9.193419e-07

$CHG_TOTSCORE_183$region_europe$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.350  1.371  3.330  0.000


$CHG_TOTSCORE_183$region_asiapacific
$CHG_TOTSCORE_183$region_asiapacific$base
       Control ISIS 396443
N            2   12.000000
n            1   12.000000
mean        29   27.250000
sd          NA    6.733566
se          NA    1.943813
median      29   26.250000
min         29   18.000000
max         29   40.500000
sum         29  327.000000

$CHG_TOTSCORE_183$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2   12.000000
n            1   10.000000
mean       -23   12.850000
sd          NA    8.246380
se          NA    2.607734
median     -23   15.000000
min        -23   -3.500000
max        -23   23.500000
sum        -23  128.500000

$CHG_TOTSCORE_183$region_asiapacific$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  13.11     2.453         7.103        19.110
2     Control -25.57    12.213       -55.452         4.318

$CHG_TOTSCORE_183$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    38.67332514     13.22721320      6.30750041     71.03914987      0.02650097

$CHG_TOTSCORE_183$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA
```

```
$CHG_TOTSCORE_183$region_northamerica
$CHG_TOTSCORE_183$region_northamerica$base
          Control ISIS 396443
N       22.000000   38.000000
n       18.000000   34.000000
mean    28.611111   28.161765
sd       9.336134    7.962717
se       2.200548    1.365595
median  29.500000   28.750000
min     10.500000    8.000000
max     50.500000   40.000000
sum    515.000000  957.500000

$CHG_TOTSCORE_183$region_northamerica$numbers_eachgrp
          Control ISIS 396443
N       22.000000   38.000000
n       12.000000   28.000000
mean    -6.416667    7.696429
sd       6.033367    7.165167
se       1.741683    1.354089
median  -6.250000    7.500000
min    -14.500000   -8.500000
max      3.000000   21.000000
sum    -77.000000  215.500000

$CHG_TOTSCORE_183$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   7.44     1.338         4.721        10.156
2     Control  -5.81     2.121       -10.121        -1.508

$CHG_TOTSCORE_183$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   1.325320e+01    2.602403e+00    7.970045e+00    1.853636e+01    1.212279e-05

$CHG_TOTSCORE_183$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.020  1.196  2.838  0.000


$CHG_TOTSCORE_183$disdur_gt_12wk
$CHG_TOTSCORE_183$disdur_gt_12wk$base
          Control ISIS 396443
N       23.000000   46.000000
n       18.000000   42.000000
mean    30.805556   26.821429
sd       8.719719    7.571466
se       2.055257    1.168302
median  29.750000   28.000000
min     14.000000    8.000000
max     50.500000   42.500000
sum    554.500000 1126.500000
```

```
$CHG_TOTSCORE_183$disdur_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N       23.000000   46.000000
n       12.000000   30.000000
mean    -7.666667    5.450000
sd       8.307536    8.575577
se       2.398179    1.565679
median  -4.250000    6.500000
min    -22.500000  -18.000000
max      3.000000   20.500000
sum    -92.000000  163.500000

$CHG_TOTSCORE_183$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   5.65     1.638         2.331         8.968
2     Control  -8.17     2.758       -13.754        -2.577

$CHG_TOTSCORE_183$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   1.381440e+01    3.389941e+00    6.945724e+00    2.068307e+01    2.335964e-04

$CHG_TOTSCORE_183$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.5100 0.7630 2.2640 0.0001


$CHG_TOTSCORE_183$disdur_le_12wek
$CHG_TOTSCORE_183$disdur_le_12wek$base
          Control ISIS 396443
N       18.000000   34.000000
n       15.000000   31.000000
mean    26.833333   28.048387
sd       6.360219    8.402733
se       1.642201    1.509175
median  28.500000   29.000000
min     10.500000    9.000000
max     33.500000   48.500000
sum    402.500000  869.500000

$CHG_TOTSCORE_183$disdur_le_12wek$numbers_eachgrp
           Control ISIS 396443
N        18.000000   34.000000
n        11.000000   29.000000
mean    -13.863636   12.775862
sd        6.914083    7.255031
se        2.084674    1.347225
median  -14.500000   15.000000
min     -23.000000   -8.500000
max       1.000000   23.500000
sum    -152.500000  370.500000

$CHG_TOTSCORE_183$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  12.79     1.174        10.403        15.169
```

```
2     Control -13.89     1.950       -17.848        -9.932

$CHG_TOTSCORE_183$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.667590e+01    2.320401e+00    2.196523e+01    3.138656e+01    1.954213e-13

$CHG_TOTSCORE_183$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 3.640  2.553  4.733  0.000



$CHG_TOTSCORE_302
$CHG_TOTSCORE_302$ageonset_le_12wk
$CHG_TOTSCORE_302$ageonset_le_12wk$base
          Control  ISIS 396443
N       32.000000   72.0000000
n       24.000000   68.0000000
mean    29.208333   26.5882353
sd       8.147975    7.3929884
se       1.663198    0.8965315
median  29.500000   27.7500000
min     14.000000    8.0000000
max     50.500000   42.5000000
sum    701.000000 1808.0000000

$CHG_TOTSCORE_302$ageonset_le_12wk$numbers_eachgrp
          Control ISIS 396443
N       32.000000   72.000000
n       11.000000   34.000000
mean    -8.090909   11.926471
sd       9.361672    7.647670
se       2.822650    1.311565
median  -9.500000   12.000000
min    -19.500000   -5.500000
max     13.000000   31.000000
sum    -89.000000  405.500000

$CHG_TOTSCORE_302$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  11.89     1.389         9.081        14.696
2     Control  -7.97     2.478       -12.982        -2.965

$CHG_TOTSCORE_302$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   1.986215e+01    2.870473e+00    1.406070e+01    2.566359e+01    2.428262e-08

$CHG_TOTSCORE_302$ageonset_le_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.430  1.574  3.294  0.000


$CHG_TOTSCORE_302$ageonset_gt_12wk
$CHG_TOTSCORE_302$ageonset_gt_12wk$base
```

```
          Control ISIS 396443
N        9.000000    8.000000
n        9.000000    5.000000
mean    28.444444   37.600000
sd       7.559946    8.196036
se       2.519982    3.665379
median  29.000000   40.000000
min     10.500000   28.000000
max     38.000000   48.500000
sum    256.000000  188.000000

$CHG_TOTSCORE_302$ageonset_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N        9.000000    8.000000
n        5.000000    2.000000
mean   -15.900000   -0.250000
sd       7.436397    4.596194
se       3.325658    3.250000
median -14.000000   -0.250000
min    -26.000000   -3.500000
max     -8.500000    3.000000
sum    -79.500000   -0.500000

$CHG_TOTSCORE_302$ageonset_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  -7.63    17.224       -81.741        66.473
2     Control -12.95     7.313       -44.411        18.519

$CHG_TOTSCORE_302$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      5.3121006      23.8202608     -97.1782098     107.8024109       0.8442345

$CHG_TOTSCORE_302$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 1.890 -0.329  4.115  0.095


$CHG_TOTSCORE_302$agetrt_lt_180d
$CHG_TOTSCORE_302$agetrt_lt_180d$base
          Control ISIS 396443
N       16.000000   49.000000
n       12.000000   46.000000
mean    25.958333   27.391304
sd       5.902458    7.585009
se       1.703893    1.118349
median  26.750000   28.250000
min     14.000000    9.000000
max     33.000000   48.500000
sum    311.500000 1260.000000

$CHG_TOTSCORE_302$agetrt_lt_180d$numbers_eachgrp
          Control ISIS 396443
N       16.000000   49.000000
n        4.000000   21.000000
```

```
mean   -13.500000   12.380952
sd       7.359801    9.031756
se       3.679900    1.970891
median -15.750000   13.000000
min    -19.500000   -5.500000
max     -3.000000   31.000000
sum    -54.000000  260.000000

$CHG_TOTSCORE_302$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  13.05     1.792         9.313        16.789
2     Control -17.02     4.310       -26.007        -8.024

$CHG_TOTSCORE_302$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   3.006651e+01    4.754063e+00    2.014971e+01    3.998332e+01    3.577557e-06

$CHG_TOTSCORE_302$agetrt_lt_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
2.8300 1.4640 4.2030 0.0001


$CHG_TOTSCORE_302$agetrt_ge_180d
$CHG_TOTSCORE_302$agetrt_ge_180d$base
          Control ISIS 396443
N       25.000000   31.000000
n       21.000000   27.000000
mean    30.738095   27.259259
sd       8.456682    8.562407
se       1.845399    1.647836
median  30.000000   28.000000
min     10.500000    8.000000
max     50.500000   42.500000
sum    645.500000  736.000000

$CHG_TOTSCORE_302$agetrt_ge_180d$numbers_eachgrp
           Control ISIS 396443
N        25.000000   31.000000
n        12.000000   15.000000
mean     -9.541667    9.666667
sd        9.989673    6.183696
se        2.883770    1.596623
median   -9.750000   10.500000
min     -26.000000   -3.000000
max      13.000000   17.000000
sum    -114.500000  145.000000

$CHG_TOTSCORE_302$agetrt_ge_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   9.08     2.327         4.251        13.904
2     Control  -8.81     2.651       -14.303        -3.308

$CHG_TOTSCORE_302$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
```

```
   1.788325e+01    3.807515e+00    9.986946e+00    2.577955e+01    1.100441e-04

$CHG_TOTSCORE_302$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.300  1.295  3.314  0.000


$CHG_TOTSCORE_302$sex_m
$CHG_TOTSCORE_302$sex_m$base
          Control ISIS 396443
N       17.000000   37.000000
n       14.000000   32.000000
mean    30.785714   26.203125
sd       8.706130    8.648941
se       2.326811    1.528931
median  31.000000   28.000000
min     14.000000    8.000000
max     50.500000   48.500000
sum    431.000000  838.500000

$CHG_TOTSCORE_302$sex_m$numbers_eachgrp
          Control ISIS 396443
N       17.000000   37.000000
n        5.000000   15.000000
mean   -14.000000    9.000000
sd       3.840573    9.104551
se       1.717556    2.350785
median -14.000000   10.000000
min    -19.500000   -4.000000
max     -9.500000   31.000000
sum    -70.000000  135.000000

$CHG_TOTSCORE_302$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   8.36     2.233         3.604        13.125
2     Control -12.09     4.181       -21.005        -3.181

$CHG_TOTSCORE_302$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.045720e+01    4.998981e+00    9.802128e+00    3.111228e+01    9.611972e-04

$CHG_TOTSCORE_302$sex_m$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
2.6800 1.3050 4.0480 0.0001


$CHG_TOTSCORE_302$sex_f
$CHG_TOTSCORE_302$sex_f$base
          Control ISIS 396443
N       24.000000   43.000000
n       19.000000   41.000000
mean    27.684211   28.231707
sd       7.169012    7.250084
se       1.644684    1.132273
```

```
median  29.000000   28.500000
min     10.500000   15.000000
max     41.000000   42.500000
sum    526.000000 1157.500000

$CHG_TOTSCORE_302$sex_f$numbers_eachgrp
          Control ISIS 396443
N       24.000000   43.000000
n       11.000000   21.000000
mean    -8.954545   12.857143
sd      10.773705    6.857738
se       3.248394    1.496481
median  -8.500000   13.000000
min    -26.000000   -5.500000
max     13.000000   24.000000
sum    -98.500000  270.000000

$CHG_TOTSCORE_302$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  11.92     1.821         8.189        15.661
2     Control  -7.17     2.670       -12.653        -1.697

$CHG_TOTSCORE_302$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   1.909989e+01    3.492879e+00    1.193310e+01    2.626669e+01    8.679998e-06

$CHG_TOTSCORE_302$sex_f$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.540  1.554  3.527  0.000


$CHG_TOTSCORE_302$region_europe
$CHG_TOTSCORE_302$region_europe$base
          Control ISIS 396443
N       17.000000   30.000000
n       14.000000   27.000000
mean    29.500000   26.351852
sd       6.201737    8.446454
se       1.657484    1.625521
median  29.500000   28.000000
min     19.500000    9.000000
max     41.000000   48.500000
sum    413.000000  711.500000

$CHG_TOTSCORE_302$region_europe$numbers_eachgrp
          Control ISIS 396443
N       17.000000   30.000000
n        5.000000   14.000000
mean   -12.600000   11.321429
sd       6.976747   10.052950
se       3.120096    2.686764
median -11.500000   11.250000
min    -21.000000   -4.000000
max     -3.000000   31.000000
```

```
sum    -63.000000  158.500000

$CHG_TOTSCORE_302$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  11.04     2.604         5.459        16.630
2     Control -11.82     4.458       -21.386        -2.263

$CHG_TOTSCORE_302$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   22.869312570     5.257102226    11.593949698    34.144675442     0.000665768

$CHG_TOTSCORE_302$region_europe$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
2.4300 1.0870 3.7650 0.0004


$CHG_TOTSCORE_302$region_asiapacific
$CHG_TOTSCORE_302$region_asiapacific$base
       Control ISIS 396443
N            2   12.000000
n            1   12.000000
mean        29   27.250000
sd          NA    6.733566
se          NA    1.943813
median      29   26.250000
min         29   18.000000
max         29   40.500000
sum         29  327.000000

$CHG_TOTSCORE_302$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2   12.000000
n            1    2.000000
mean       -26   11.750000
sd          NA    4.596194
se          NA    3.250000
median     -26   11.750000
min        -26    8.500000
max        -26   15.000000
sum        -26   23.500000

$CHG_TOTSCORE_302$region_asiapacific$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_TOTSCORE_302$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_TOTSCORE_302$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA
```

```
$CHG_TOTSCORE_302$region_northamerica
$CHG_TOTSCORE_302$region_northamerica$base
          Control ISIS 396443
N       22.000000   38.000000
n       18.000000   34.000000
mean    28.611111   28.161765
sd       9.336134    7.962717
se       2.200548    1.365595
median  29.500000   28.750000
min     10.500000    8.000000
max     50.500000   40.000000
sum    515.000000  957.500000

$CHG_TOTSCORE_302$region_northamerica$numbers_eachgrp
          Control ISIS 396443
N       22.000000   38.000000
n       10.000000   20.000000
mean    -7.950000   11.150000
sd       9.340622    6.865436
se       2.953764    1.535158
median  -9.000000   12.000000
min    -19.500000   -5.500000
max     13.000000   23.000000
sum    -79.500000  223.000000

$CHG_TOTSCORE_302$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  10.95     1.872         7.095        14.805
2     Control  -7.55     2.727       -13.166        -1.934

$CHG_TOTSCORE_302$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   1.850046e+01    3.434858e+00    1.142624e+01    2.557468e+01    1.377062e-05

$CHG_TOTSCORE_302$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.400  1.398  3.399  0.000


$CHG_TOTSCORE_302$disdur_gt_12wk
$CHG_TOTSCORE_302$disdur_gt_12wk$base
          Control ISIS 396443
N       23.000000   46.000000
n       18.000000   42.000000
mean    30.805556   26.821429
sd       8.719719    7.571466
se       2.055257    1.168302
median  29.750000   28.000000
min     14.000000    8.000000
max     50.500000   42.500000
sum    554.500000 1126.500000

$CHG_TOTSCORE_302$disdur_gt_12wk$numbers_eachgrp
```

```
          Control ISIS 396443
N       23.000000   46.000000
n       10.000000   20.000000
mean    -8.000000    9.400000
sd       9.439868    6.709381
se       2.985148    1.500263
median  -9.750000    9.750000
min    -21.000000   -4.000000
max     13.000000   21.000000
sum    -80.000000  188.000000

$CHG_TOTSCORE_302$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   9.25     1.950         5.238        13.271
2     Control  -7.71     2.933       -13.750        -1.669

$CHG_TOTSCORE_302$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   1.696407e+01    3.793963e+00    9.150260e+00    2.477789e+01    1.466938e-04

$CHG_TOTSCORE_302$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.200  1.235  3.167  0.000


$CHG_TOTSCORE_302$disdur_le_12wek
$CHG_TOTSCORE_302$disdur_le_12wek$base
          Control ISIS 396443
N       18.000000   34.000000
n       15.000000   31.000000
mean    26.833333   28.048387
sd       6.360219    8.402733
se       1.642201    1.509175
median  28.500000   29.000000
min     10.500000    9.000000
max     33.500000   48.500000
sum    402.500000  869.500000

$CHG_TOTSCORE_302$disdur_le_12wek$numbers_eachgrp
          Control ISIS 396443
N       18.000000   34.000000
n        6.000000   16.000000
mean   -14.750000   13.562500
sd       8.177714    9.025658
se       3.338538    2.256414
median -15.750000   13.000000
min    -26.000000   -5.500000
max     -3.000000   31.000000
sum    -88.500000  217.000000

$CHG_TOTSCORE_302$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  14.59     1.579        11.262        17.923
2     Control -17.50     2.755       -23.309       -11.685
```

```
$CHG_TOTSCORE_302$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   3.208929e+01    3.348571e+00    2.502442e+01    3.915416e+01    2.880066e-08

$CHG_TOTSCORE_302$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 3.090  1.711  4.464  0.000



$CHG_TOTSCORE_394
$CHG_TOTSCORE_394$ageonset_le_12wk
$CHG_TOTSCORE_394$ageonset_le_12wk$base
          Control  ISIS 396443
N       32.000000   72.0000000
n       24.000000   68.0000000
mean    29.208333   26.5882353
sd       8.147975    7.3929884
se       1.663198    0.8965315
median  29.500000   27.7500000
min     14.000000    8.0000000
max     50.500000   42.5000000
sum    701.000000 1808.0000000

$CHG_TOTSCORE_394$ageonset_le_12wk$numbers_eachgrp
          Control ISIS 396443
N       32.000000   72.000000
n        8.000000   25.000000
mean   -11.250000   13.840000
sd      10.477868    8.149284
se       3.704486    1.629857
median -12.500000   13.500000
min    -23.500000   -4.000000
max     11.000000   33.000000
sum    -90.000000  346.000000

$CHG_TOTSCORE_394$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  13.15     1.590         9.890        16.403
2     Control  -9.08     2.915       -15.055        -3.111

$CHG_TOTSCORE_394$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.222980e+01    3.404633e+00    1.525572e+01    2.920387e+01    4.459519e-07

$CHG_TOTSCORE_394$ageonset_le_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.800  1.730  3.878  0.000


$CHG_TOTSCORE_394$ageonset_gt_12wk
$CHG_TOTSCORE_394$ageonset_gt_12wk$base
          Control ISIS 396443
```

```
N        9.000000    8.000000
n        9.000000    5.000000
mean    28.444444   37.600000
sd       7.559946    8.196036
se       2.519982    3.665379
median  29.000000   40.000000
min     10.500000   28.000000
max     38.000000   48.500000
sum    256.000000  188.000000

$CHG_TOTSCORE_394$ageonset_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N        9.000000           8
n        3.000000           1
mean   -11.500000          11
sd       7.399324          NA
se       4.272002          NA
median  -8.000000          11
min    -20.000000          11
max     -6.500000          11
sum    -34.500000          11

$CHG_TOTSCORE_394$ageonset_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_TOTSCORE_394$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_TOTSCORE_394$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_TOTSCORE_394$agetrt_lt_180d
$CHG_TOTSCORE_394$agetrt_lt_180d$base
          Control ISIS 396443
N       16.000000   49.000000
n       12.000000   46.000000
mean    25.958333   27.391304
sd       5.902458    7.585009
se       1.703893    1.118349
median  26.750000   28.250000
min     14.000000    9.000000
max     33.000000   48.500000
sum    311.500000 1260.000000

$CHG_TOTSCORE_394$agetrt_lt_180d$numbers_eachgrp
          Control ISIS 396443
N       16.000000   49.000000
n        2.000000   14.000000
mean   -15.750000   16.607143
```

```
sd       3.889087    8.065068
se       2.750000    2.155480
median -15.750000   15.750000
min    -18.500000    6.000000
max    -13.000000   33.000000
sum    -31.500000  232.500000

$CHG_TOTSCORE_394$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  16.67     1.883        12.523        20.810
2     Control -16.16     5.238       -27.693        -4.637

$CHG_TOTSCORE_394$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   3.283123e+01    5.643704e+00    2.040953e+01    4.525294e+01    1.163057e-04

$CHG_TOTSCORE_394$agetrt_lt_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
3.9000 1.7520 6.0510 0.0004


$CHG_TOTSCORE_394$agetrt_ge_180d
$CHG_TOTSCORE_394$agetrt_ge_180d$base
          Control ISIS 396443
N       25.000000   31.000000
n       21.000000   27.000000
mean    30.738095   27.259259
sd       8.456682    8.562407
se       1.845399    1.647836
median  30.000000   28.000000
min     10.500000    8.000000
max     50.500000   42.500000
sum    645.500000  736.000000

$CHG_TOTSCORE_394$agetrt_ge_180d$numbers_eachgrp
          Control ISIS 396443
N       25.000000   31.000000
n        9.000000   12.000000
mean   -10.333333   10.375000
sd      10.093315    6.776044
se       3.364438    1.956075
median -10.500000   11.250000
min    -23.500000   -4.000000
max     11.000000   20.500000
sum    -93.000000  124.500000

$CHG_TOTSCORE_394$agetrt_ge_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  10.79     2.571         5.336        16.235
2     Control -10.88     3.025       -17.294        -4.468

$CHG_TOTSCORE_394$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.166669e+01    4.219446e+00    1.272187e+01    3.061152e+01    9.978643e-05
```

```
$CHG_TOTSCORE_394$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
2.3900 1.2070 3.5630 0.0001


$CHG_TOTSCORE_394$sex_m
$CHG_TOTSCORE_394$sex_m$base
          Control ISIS 396443
N       17.000000   37.000000
n       14.000000   32.000000
mean    30.785714   26.203125
sd       8.706130    8.648941
se       2.326811    1.528931
median  31.000000   28.000000
min     14.000000    8.000000
max     50.500000   48.500000
sum    431.000000  838.500000

$CHG_TOTSCORE_394$sex_m$numbers_eachgrp
          Control ISIS 396443
N       17.000000   37.000000
n        5.000000    8.000000
mean   -16.600000   11.750000
sd       5.054701   12.142017
se       2.260531    4.292851
median -17.500000   10.750000
min    -23.500000   -4.000000
max    -10.500000   33.000000
sum    -83.000000   94.000000

$CHG_TOTSCORE_394$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  10.01     2.535         4.160        15.851
2     Control -13.81     3.397       -21.643        -5.974

$CHG_TOTSCORE_394$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.381365e+01    4.708407e+00    1.295604e+01    3.467126e+01    9.798565e-04

$CHG_TOTSCORE_394$sex_m$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
2.6000 0.9610 4.2340 0.0019


$CHG_TOTSCORE_394$sex_f
$CHG_TOTSCORE_394$sex_f$base
          Control ISIS 396443
N       24.000000   43.000000
n       19.000000   41.000000
mean    27.684211   28.231707
sd       7.169012    7.250084
se       1.644684    1.132273
median  29.000000   28.500000
```

```
min     10.500000   15.000000
max     41.000000   42.500000
sum    526.000000 1157.500000

$CHG_TOTSCORE_394$sex_f$numbers_eachgrp
          Control ISIS 396443
N       24.000000   43.000000
n        6.000000   18.000000
mean    -6.916667   14.611111
sd      10.200082    5.553366
se       4.164166    1.308941
median  -7.250000   13.750000
min    -20.000000    8.500000
max     11.000000   30.000000
sum    -41.500000  263.000000

$CHG_TOTSCORE_394$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  14.26     1.701        10.698        17.820
2     Control  -5.86     3.243       -12.647         0.929

$CHG_TOTSCORE_394$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.011798e+01    3.904625e+00    1.194551e+01    2.829046e+01    5.663580e-05

$CHG_TOTSCORE_394$sex_f$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 3.020  1.703  4.330  0.000


$CHG_TOTSCORE_394$region_europe
$CHG_TOTSCORE_394$region_europe$base
          Control ISIS 396443
N       17.000000   30.000000
n       14.000000   27.000000
mean    29.500000   26.351852
sd       6.201737    8.446454
se       1.657484    1.625521
median  29.500000   28.000000
min     19.500000    9.000000
max     41.000000   48.500000
sum    413.000000  711.500000

$CHG_TOTSCORE_394$region_europe$numbers_eachgrp
          Control ISIS 396443
N       17.000000   30.000000
n        3.000000    8.000000
mean   -14.500000   14.500000
sd       8.046738   11.253571
se       4.645787    3.978738
median -12.000000   13.750000
min    -23.500000   -4.000000
max     -8.000000   33.000000
sum    -43.500000  116.000000
```

```
$CHG_TOTSCORE_394$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  12.66     2.873         5.630        19.690
2     Control  -9.59     4.949       -21.704         2.516

$CHG_TOTSCORE_394$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   22.253870514     5.977198117     7.628193606    36.879547422     0.009816021

$CHG_TOTSCORE_394$region_europe$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
2.5000 0.6370 4.3540 0.0085


$CHG_TOTSCORE_394$region_asiapacific
$CHG_TOTSCORE_394$region_asiapacific$base
       Control ISIS 396443
N            2   12.000000
n            1   12.000000
mean        29   27.250000
sd          NA    6.733566
se          NA    1.943813
median      29   26.250000
min         29   18.000000
max         29   40.500000
sum         29  327.000000

$CHG_TOTSCORE_394$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2  12.0000000
n            0   2.0000000
mean        NA  14.2500000
sd          NA   0.3535534
se          NA   0.2500000
median      NA  14.2500000
min         NA  14.0000000
max         NA  14.5000000
sum         NA  28.5000000

$CHG_TOTSCORE_394$region_asiapacific$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_TOTSCORE_394$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_TOTSCORE_394$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA
```

```
$CHG_TOTSCORE_394$region_northamerica
$CHG_TOTSCORE_394$region_northamerica$base
          Control ISIS 396443
N       22.000000   38.000000
n       18.000000   34.000000
mean    28.611111   28.161765
sd       9.336134    7.962717
se       2.200548    1.365595
median  29.500000   28.750000
min     10.500000    8.000000
max     50.500000   40.000000
sum    515.000000  957.500000

$CHG_TOTSCORE_394$region_northamerica$numbers_eachgrp
          Control ISIS 396443
N       22.000000   38.000000
n        8.000000   16.000000
mean   -10.125000   13.281250
sd      10.048987    6.862868
se       3.552853    1.715717
median -11.750000   11.750000
min    -20.000000   -1.500000
max     11.000000   30.000000
sum    -81.000000  212.500000

$CHG_TOTSCORE_394$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  13.36     2.169         8.826        17.904
2     Control -10.29     3.155       -16.896        -3.688

$CHG_TOTSCORE_394$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.365640e+01    3.969701e+00    1.534772e+01    3.196508e+01    9.791808e-06

$CHG_TOTSCORE_394$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.820  1.602  4.037  0.000


$CHG_TOTSCORE_394$disdur_gt_12wk
$CHG_TOTSCORE_394$disdur_gt_12wk$base
          Control ISIS 396443
N       23.000000   46.000000
n       18.000000   42.000000
mean    30.805556   26.821429
sd       8.719719    7.571466
se       2.055257    1.168302
median  29.750000   28.000000
min     14.000000    8.000000
max     50.500000   42.500000
sum    554.500000 1126.500000

$CHG_TOTSCORE_394$disdur_gt_12wk$numbers_eachgrp
          Control ISIS 396443
```

```
N       23.000000   46.000000
n        8.000000   15.000000
mean   -10.812500   10.933333
sd      10.680214    6.605914
se       3.776026    1.705640
median -11.250000   11.500000
min    -23.500000   -4.000000
max     11.000000   20.500000
sum    -86.500000  164.000000

$CHG_TOTSCORE_394$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  10.58     2.240         5.878        15.291
2     Control -10.16     3.224       -16.931        -3.385

$CHG_TOTSCORE_394$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   2.074285e+01    4.201997e+00    1.191478e+01    2.957092e+01    1.065568e-04

$CHG_TOTSCORE_394$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 2.560  1.377  3.740  0.000


$CHG_TOTSCORE_394$disdur_le_12wek
$CHG_TOTSCORE_394$disdur_le_12wek$base
          Control ISIS 396443
N       18.000000   34.000000
n       15.000000   31.000000
mean    26.833333   28.048387
sd       6.360219    8.402733
se       1.642201    1.509175
median  28.500000   29.000000
min     10.500000    9.000000
max     33.500000   48.500000
sum    402.500000  869.500000

$CHG_TOTSCORE_394$disdur_le_12wek$numbers_eachgrp
          Control ISIS 396443
N       18.000000   34.000000
n        3.000000   11.000000
mean   -12.666667   17.545455
sd       6.006940    8.445278
se       3.468109    2.546347
median -13.000000   17.000000
min    -18.500000    8.500000
max     -6.500000   33.000000
sum    -38.000000  193.000000

$CHG_TOTSCORE_394$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  18.59      1.24        15.783        21.394
2     Control -16.49      2.54       -22.238       -10.745
```

```
$CHG_TOTSCORE_394$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   3.507997e+01    2.932669e+00    2.844581e+01    4.171413e+01    7.911902e-07

$CHG_TOTSCORE_394$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
3.5000 1.5050 5.4870 0.0006




\##############################################################################
[[1]]
[1] "Veränderung des HINE-Scores (Subskala 1) von Baseline"

$CHG_HINE1_64
$CHG_HINE1_64$ageonset_le_12wk
$CHG_HINE1_64$ageonset_le_12wk$base
           Control  ISIS 396443
N        32.000000   72.0000000
n        32.000000   72.0000000
mean     37.078125   38.4305556
sd        7.647590    7.1484784
se        1.351916    0.8424563
median   37.000000   38.2500000
min      22.000000   24.0000000
max      52.000000   55.5000000
sum    1186.500000 2767.0000000

$CHG_HINE1_64$ageonset_le_12wk$numbers_eachgrp
       Control ISIS 396443
N         32.0          72
n          1.0           0
mean      -4.5          NA
sd          NA          NA
se          NA          NA
median    -4.5          NA
min       -4.5          NA
max       -4.5          NA
sum       -4.5          NA

$CHG_HINE1_64$ageonset_le_12wk$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_64$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_64$ageonset_le_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA
```

```
$CHG_HINE1_64$ageonset_gt_12wk
$CHG_HINE1_64$ageonset_gt_12wk$base
          Control ISIS 396443
N        9.000000    8.000000
n        9.000000    8.000000
mean    38.500000   38.187500
sd       6.324555    7.210793
se       2.108185    2.549400
median  41.000000   38.500000
min     27.000000   23.000000
max     47.000000   46.000000
sum    346.500000  305.500000

$CHG_HINE1_64$ageonset_gt_12wk$numbers_eachgrp
       Control ISIS 396443
N            9           8
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE1_64$ageonset_gt_12wk$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_64$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_64$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_64$agetrt_lt_180d
$CHG_HINE1_64$agetrt_lt_180d$base
          Control ISIS 396443
N       16.000000   49.000000
n       16.000000   49.000000
mean    34.687500   39.408163
sd       7.173737    7.544088
se       1.793434    1.077727
median  33.250000   40.000000
min     22.000000   26.000000
max     50.000000   55.500000
sum    555.000000 1931.000000

$CHG_HINE1_64$agetrt_lt_180d$numbers_eachgrp
```

```
       Control ISIS 396443
N           16          49
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE1_64$agetrt_lt_180d$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_64$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_64$agetrt_lt_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_64$agetrt_ge_180d
$CHG_HINE1_64$agetrt_ge_180d$base
          Control ISIS 396443
N       25.000000   31.000000
n       25.000000   31.000000
mean    39.120000   36.822581
sd       7.022701    6.147558
se       1.404540    1.104134
median  40.500000   37.000000
min     27.000000   23.000000
max     52.000000   48.000000
sum    978.000000 1141.500000

$CHG_HINE1_64$agetrt_ge_180d$numbers_eachgrp
       Control ISIS 396443
N         25.0          31
n          1.0           0
mean      -4.5          NA
sd          NA          NA
se          NA          NA
median    -4.5          NA
min       -4.5          NA
max       -4.5          NA
sum       -4.5          NA

$CHG_HINE1_64$agetrt_ge_180d$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA
```

```
$CHG_HINE1_64$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_64$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_64$sex_m
$CHG_HINE1_64$sex_m$base
          Control ISIS 396443
N       17.000000   37.000000
n       17.000000   37.000000
mean    38.294118   38.432432
sd       7.897901    6.764041
se       1.915522    1.112002
median  38.000000   39.000000
min     26.500000   23.000000
max     52.000000   49.000000
sum    651.000000 1422.000000

$CHG_HINE1_64$sex_m$numbers_eachgrp
       Control ISIS 396443
N         17.0          37
n          1.0           0
mean      -4.5          NA
sd          NA          NA
se          NA          NA
median    -4.5          NA
min       -4.5          NA
max       -4.5          NA
sum       -4.5          NA

$CHG_HINE1_64$sex_m$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA             NA             NA
[2,]        NA     NA        NA             NA             NA

$CHG_HINE1_64$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_64$sex_m$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_64$sex_f
$CHG_HINE1_64$sex_f$base
          Control ISIS 396443
N       24.000000   43.000000
n       24.000000   43.000000
```

```
mean    36.750000   38.383721
sd       6.995340    7.472837
se       1.427918    1.139597
median  36.500000   37.500000
min     22.000000   24.000000
max     49.000000   55.500000
sum    882.000000 1650.500000

$CHG_HINE1_64$sex_f$numbers_eachgrp
       Control ISIS 396443
N           24          43
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE1_64$sex_f$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_64$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_64$sex_f$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_64$region_europe
$CHG_HINE1_64$region_europe$base
          Control ISIS 396443
N       17.000000   30.000000
n       17.000000   30.000000
mean    37.970588   38.066667
sd       6.328187    6.155644
se       1.534811    1.123862
median  37.000000   39.000000
min     29.000000   26.000000
max     50.000000   48.000000
sum    645.500000 1142.000000

$CHG_HINE1_64$region_europe$numbers_eachgrp
       Control ISIS 396443
N           17          30
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
```

```
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE1_64$region_europe$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_64$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_64$region_europe$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_64$region_asiapacific
$CHG_HINE1_64$region_asiapacific$base
         Control ISIS 396443
N       2.000000   12.000000
n       2.000000   12.000000
mean   33.000000   36.458333
sd      4.242641    6.080738
se      3.000000    1.755358
median 33.000000   34.000000
min    30.000000   27.000000
max    36.000000   49.000000
sum    66.000000  437.500000

$CHG_HINE1_64$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2          12
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE1_64$region_asiapacific$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_64$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_64$region_asiapacific$Hedgesg_TRTvsCTRL
```

```
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_64$region_northamerica
$CHG_HINE1_64$region_northamerica$base
          Control ISIS 396443
N       22.000000   38.000000
n       22.000000   38.000000
mean    37.340909   39.289474
sd       8.292834    8.067814
se       1.768038    1.308772
median  39.000000   38.500000
min     22.000000   23.000000
max     52.000000   55.500000
sum    821.500000 1493.000000

$CHG_HINE1_64$region_northamerica$numbers_eachgrp
       Control ISIS 396443
N         22.0          38
n          1.0           0
mean      -4.5          NA
sd          NA          NA
se          NA          NA
median    -4.5          NA
min       -4.5          NA
max       -4.5          NA
sum       -4.5          NA

$CHG_HINE1_64$region_northamerica$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_64$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_64$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_64$disdur_gt_12wk
$CHG_HINE1_64$disdur_gt_12wk$base
          Control ISIS 396443
N       23.000000   46.000000
n       23.000000   46.000000
mean    38.347826   38.076087
sd       7.367673    6.153560
se       1.536266    0.907293
median  38.500000   37.750000
min     29.000000   24.000000
max     52.000000   48.500000
```

```
sum    882.000000 1751.500000

$CHG_HINE1_64$disdur_gt_12wk$numbers_eachgrp
       Control ISIS 396443
N         23.0          46
n          1.0           0
mean      -4.5          NA
sd          NA          NA
se          NA          NA
median    -4.5          NA
min       -4.5          NA
max       -4.5          NA
sum       -4.5          NA

$CHG_HINE1_64$disdur_gt_12wk$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_64$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_64$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_64$disdur_le_12wek
$CHG_HINE1_64$disdur_le_12wek$base
          Control ISIS 396443
N       18.000000   34.000000
n       18.000000   34.000000
mean    36.166667   38.852941
sd       7.296252    8.306195
se       1.719743    1.424501
median  36.500000   39.000000
min     22.000000   23.000000
max     50.000000   55.500000
sum    651.000000 1321.000000

$CHG_HINE1_64$disdur_le_12wek$numbers_eachgrp
       Control ISIS 396443
N           18          34
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE1_64$disdur_le_12wek$ls_mw
```

```
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_64$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_64$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA



$CHG_HINE1_183
$CHG_HINE1_183$ageonset_le_12wk
$CHG_HINE1_183$ageonset_le_12wk$base
           Control  ISIS 396443
N        32.000000   72.0000000
n        32.000000   72.0000000
mean     37.078125   38.4305556
sd        7.647590    7.1484784
se        1.351916    0.8424563
median   37.000000   38.2500000
min      22.000000   24.0000000
max      52.000000   55.5000000
sum    1186.500000 2767.0000000

$CHG_HINE1_183$ageonset_le_12wk$numbers_eachgrp
          Control ISIS 396443
N       32.000000   72.000000
n        4.000000    4.000000
mean    -7.000000    4.125000
sd       4.377975    7.442838
se       2.188988    3.721419
median  -6.250000    4.500000
min    -13.000000   -3.500000
max     -2.500000   11.000000
sum    -28.000000   16.500000

$CHG_HINE1_183$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   5.75     1.591         0.686        10.814
2     Control  -8.63     1.591       -13.689        -3.561

$CHG_HINE1_183$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   14.375460146     2.319089087     6.995083650    21.755836642     0.008458526

$CHG_HINE1_183$ageonset_le_12wk$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 1.5800 -0.1790  3.3470  0.0782
```

```
$CHG_HINE1_183$ageonset_gt_12wk
$CHG_HINE1_183$ageonset_gt_12wk$base
          Control ISIS 396443
N        9.000000    8.000000
n        9.000000    8.000000
mean    38.500000   38.187500
sd       6.324555    7.210793
se       2.108185    2.549400
median  41.000000   38.500000
min     27.000000   23.000000
max     47.000000   46.000000
sum    346.500000  305.500000

$CHG_HINE1_183$ageonset_gt_12wk$numbers_eachgrp
       Control ISIS 396443
N            9         8.0
n            0         1.0
mean        NA         7.5
sd          NA          NA
se          NA          NA
median      NA         7.5
min         NA         7.5
max         NA         7.5
sum         NA         7.5

$CHG_HINE1_183$ageonset_gt_12wk$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_183$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_183$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_183$agetrt_lt_180d
$CHG_HINE1_183$agetrt_lt_180d$base
          Control ISIS 396443
N       16.000000   49.000000
n       16.000000   49.000000
mean    34.687500   39.408163
sd       7.173737    7.544088
se       1.793434    1.077727
median  33.250000   40.000000
min     22.000000   26.000000
max     50.000000   55.500000
sum    555.000000 1931.000000

$CHG_HINE1_183$agetrt_lt_180d$numbers_eachgrp
          Control ISIS 396443
```

```
N       16.000000  49.0000000
n        3.000000   2.0000000
mean    -7.333333  10.5000000
sd       5.299371   0.7071068
se       3.059593   0.5000000
median  -6.500000  10.5000000
min    -13.000000  10.0000000
max     -2.500000  11.0000000
sum    -22.000000  21.0000000

$CHG_HINE1_183$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   9.90       NaN           NaN           NaN
2     Control  -6.93       NaN           NaN           NaN

$CHG_HINE1_183$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
       16.82756             NaN             NaN             NaN             NaN

$CHG_HINE1_183$agetrt_lt_180d$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 2.9800 -1.4130  7.3820  0.1835


$CHG_HINE1_183$agetrt_ge_180d
$CHG_HINE1_183$agetrt_ge_180d$base
          Control ISIS 396443
N       25.000000   31.000000
n       25.000000   31.000000
mean    39.120000   36.822581
sd       7.022701    6.147558
se       1.404540    1.104134
median  40.500000   37.000000
min     27.000000   23.000000
max     52.000000   48.000000
sum    978.000000 1141.500000

$CHG_HINE1_183$agetrt_ge_180d$numbers_eachgrp
       Control ISIS 396443
N           25   31.000000
n            1    3.000000
mean        -6    1.000000
sd          NA    5.766281
se          NA    3.329164
median      -6   -1.000000
min         -6   -3.500000
max         -6    7.500000
sum         -6    3.000000

$CHG_HINE1_183$agetrt_ge_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.41       NaN           NaN           NaN
2     Control  -4.23       NaN           NaN           NaN
```

```
$CHG_HINE1_183$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_183$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_183$sex_m
$CHG_HINE1_183$sex_m$base
          Control ISIS 396443
N       17.000000   37.000000
n       17.000000   37.000000
mean    38.294118   38.432432
sd       7.897901    6.764041
se       1.915522    1.112002
median  38.000000   39.000000
min     26.500000   23.000000
max     52.000000   49.000000
sum    651.000000 1422.000000

$CHG_HINE1_183$sex_m$numbers_eachgrp
          Control ISIS 396443
N       17.000000          37
n        2.000000           1
mean    -9.750000          11
sd       4.596194          NA
se       3.250000          NA
median  -9.750000          11
min    -13.000000          11
max     -6.500000          11
sum    -19.500000          11

$CHG_HINE1_183$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_HINE1_183$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_183$sex_m$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_183$sex_f
$CHG_HINE1_183$sex_f$base
          Control ISIS 396443
N       24.000000   43.000000
n       24.000000   43.000000
mean    36.750000   38.383721
```

```
sd       6.995340    7.472837
se       1.427918    1.139597
median  36.500000   37.500000
min     22.000000   24.000000
max     49.000000   55.500000
sum    882.000000 1650.500000

$CHG_HINE1_183$sex_f$numbers_eachgrp
         Control ISIS 396443
N      24.000000   43.000000
n       2.000000    4.000000
mean   -4.250000    3.250000
sd      2.474874    6.512808
se      1.750000    3.256404
median -4.250000    3.250000
min    -6.000000   -3.500000
max    -2.500000   10.000000
sum    -8.500000   13.000000

$CHG_HINE1_183$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.09     1.345       -14.997        19.173
2     Control  -1.93     2.311       -31.287        27.434

$CHG_HINE1_183$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      4.0150358       3.2549034     -37.3424326      45.3725042       0.4336771

$CHG_HINE1_183$sex_f$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 1.0400 -0.9330  3.0110  0.3017


$CHG_HINE1_183$region_europe
$CHG_HINE1_183$region_europe$base
          Control ISIS 396443
N       17.000000   30.000000
n       17.000000   30.000000
mean    37.970588   38.066667
sd       6.328187    6.155644
se       1.534811    1.123862
median  37.000000   39.000000
min     29.000000   26.000000
max     50.000000   48.000000
sum    645.500000 1142.000000

$CHG_HINE1_183$region_europe$numbers_eachgrp
          Control ISIS 396443
N       17.000000   30.000000
n        3.000000    2.000000
mean    -7.166667    8.750000
sd       5.346338    1.767767
se       3.086710    1.250000
median  -6.000000    8.750000
```

```
min    -13.000000    7.500000
max     -2.500000   10.000000
sum    -21.500000   17.500000

$CHG_HINE1_183$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  10.27       NaN           NaN           NaN
2     Control  -8.18       NaN           NaN           NaN

$CHG_HINE1_183$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
       18.45361             NaN             NaN             NaN             NaN

$CHG_HINE1_183$region_europe$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 2.5800 -1.3270  6.4910  0.1955


$CHG_HINE1_183$region_asiapacific
$CHG_HINE1_183$region_asiapacific$base
         Control ISIS 396443
N       2.000000   12.000000
n       2.000000   12.000000
mean   33.000000   36.458333
sd      4.242641    6.080738
se      3.000000    1.755358
median 33.000000   34.000000
min    30.000000   27.000000
max    36.000000   49.000000
sum    66.000000  437.500000

$CHG_HINE1_183$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2          12
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE1_183$region_asiapacific$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_183$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_183$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
```

```
    NA     NA     NA     NA


$CHG_HINE1_183$region_northamerica
$CHG_HINE1_183$region_northamerica$base
          Control ISIS 396443
N       22.000000   38.000000
n       22.000000   38.000000
mean    37.340909   39.289474
sd       8.292834    8.067814
se       1.768038    1.308772
median  39.000000   38.500000
min     22.000000   23.000000
max     52.000000   55.500000
sum    821.500000 1493.000000

$CHG_HINE1_183$region_northamerica$numbers_eachgrp
       Control ISIS 396443
N         22.0   38.000000
n          1.0    3.000000
mean      -6.5    2.166667
sd          NA    7.751344
se          NA    4.475241
median    -6.5   -1.000000
min       -6.5   -3.500000
max       -6.5   11.000000
sum       -6.5    6.500000

$CHG_HINE1_183$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_HINE1_183$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_183$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_183$disdur_gt_12wk
$CHG_HINE1_183$disdur_gt_12wk$base
          Control ISIS 396443
N       23.000000   46.000000
n       23.000000   46.000000
mean    38.347826   38.076087
sd       7.367673    6.153560
se       1.536266    0.907293
median  38.500000   37.750000
min     29.000000   24.000000
max     52.000000   48.500000
sum    882.000000 1751.500000
```

```
$CHG_HINE1_183$disdur_gt_12wk$numbers_eachgrp
       Control ISIS 396443
N           23   46.000000
n            1    2.000000
mean        -6   -2.250000
sd          NA    1.767767
se          NA    1.250000
median      -6   -2.250000
min         -6   -3.500000
max         -6   -1.000000
sum         -6   -4.500000

$CHG_HINE1_183$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_HINE1_183$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_183$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_183$disdur_le_12wek
$CHG_HINE1_183$disdur_le_12wek$base
          Control ISIS 396443
N       18.000000   34.000000
n       18.000000   34.000000
mean    36.166667   38.852941
sd       7.296252    8.306195
se       1.719743    1.424501
median  36.500000   39.000000
min     22.000000   23.000000
max     50.000000   55.500000
sum    651.000000 1321.000000

$CHG_HINE1_183$disdur_le_12wek$numbers_eachgrp
          Control ISIS 396443
N       18.000000   34.000000
n        3.000000    3.000000
mean    -7.333333    9.500000
sd       5.299371    1.802776
se       3.059593    1.040833
median  -6.500000   10.000000
min    -13.000000    7.500000
max     -2.500000   11.000000
sum    -22.000000   28.500000

$CHG_HINE1_183$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
```

```
1 ISIS 396443  10.02     2.918       -27.063        47.102
2     Control  -7.85     2.918       -44.936        29.230

$CHG_HINE1_183$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      17.872673        4.625688      -40.902267       76.647613        0.161228

$CHG_HINE1_183$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 3.400 -0.252  7.057  0.068



$CHG_HINE1_302
$CHG_HINE1_302$ageonset_le_12wk
$CHG_HINE1_302$ageonset_le_12wk$base
           Control  ISIS 396443
N        32.000000   72.0000000
n        32.000000   72.0000000
mean     37.078125   38.4305556
sd        7.647590    7.1484784
se        1.351916    0.8424563
median   37.000000   38.2500000
min      22.000000   24.0000000
max      52.000000   55.5000000
sum    1186.500000 2767.0000000

$CHG_HINE1_302$ageonset_le_12wk$numbers_eachgrp
       Control ISIS 396443
N           32   72.000000
n            1    2.000000
mean        -3    7.000000
sd          NA    1.414214
se          NA    1.000000
median      -3    7.000000
min         -3    6.000000
max         -3    8.000000
sum         -3   14.000000

$CHG_HINE1_302$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_HINE1_302$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_302$ageonset_le_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_302$ageonset_gt_12wk
```

```
$CHG_HINE1_302$ageonset_gt_12wk$base
          Control ISIS 396443
N        9.000000    8.000000
n        9.000000    8.000000
mean    38.500000   38.187500
sd       6.324555    7.210793
se       2.108185    2.549400
median  41.000000   38.500000
min     27.000000   23.000000
max     47.000000   46.000000
sum    346.500000  305.500000

$CHG_HINE1_302$ageonset_gt_12wk$numbers_eachgrp
       Control ISIS 396443
N            9         8.0
n            0         1.0
mean        NA         9.5
sd          NA          NA
se          NA          NA
median      NA         9.5
min         NA         9.5
max         NA         9.5
sum         NA         9.5

$CHG_HINE1_302$ageonset_gt_12wk$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_302$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_302$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_302$agetrt_lt_180d
$CHG_HINE1_302$agetrt_lt_180d$base
          Control ISIS 396443
N       16.000000   49.000000
n       16.000000   49.000000
mean    34.687500   39.408163
sd       7.173737    7.544088
se       1.793434    1.077727
median  33.250000   40.000000
min     22.000000   26.000000
max     50.000000   55.500000
sum    555.000000 1931.000000

$CHG_HINE1_302$agetrt_lt_180d$numbers_eachgrp
       Control ISIS 396443
N           16   49.000000
```

```
n            1    3.000000
mean        -3    7.833333
sd          NA    1.755942
se          NA    1.013794
median      -3    8.000000
min         -3    6.000000
max         -3    9.500000
sum         -3   23.500000

$CHG_HINE1_302$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_HINE1_302$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_302$agetrt_lt_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_302$agetrt_ge_180d
$CHG_HINE1_302$agetrt_ge_180d$base
          Control ISIS 396443
N       25.000000   31.000000
n       25.000000   31.000000
mean    39.120000   36.822581
sd       7.022701    6.147558
se       1.404540    1.104134
median  40.500000   37.000000
min     27.000000   23.000000
max     52.000000   48.000000
sum    978.000000 1141.500000

$CHG_HINE1_302$agetrt_ge_180d$numbers_eachgrp
       Control ISIS 396443
N           25          31
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE1_302$agetrt_ge_180d$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_302$agetrt_ge_180d$diffgrp_TRTvsCTRL
```

```
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_302$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_302$sex_m
$CHG_HINE1_302$sex_m$base
          Control ISIS 396443
N       17.000000   37.000000
n       17.000000   37.000000
mean    38.294118   38.432432
sd       7.897901    6.764041
se       1.915522    1.112002
median  38.000000   39.000000
min     26.500000   23.000000
max     52.000000   49.000000
sum    651.000000 1422.000000

$CHG_HINE1_302$sex_m$numbers_eachgrp
       Control ISIS 396443
N           17   37.000000
n            0    3.000000
mean        NA    7.833333
sd          NA    1.755942
se          NA    1.013794
median      NA    8.000000
min         NA    6.000000
max         NA    9.500000
sum         NA   23.500000

$CHG_HINE1_302$sex_m$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA             NA             NA
[2,]        NA     NA        NA             NA             NA

$CHG_HINE1_302$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_302$sex_m$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_302$sex_f
$CHG_HINE1_302$sex_f$base
          Control ISIS 396443
N       24.000000   43.000000
n       24.000000   43.000000
mean    36.750000   38.383721
sd       6.995340    7.472837
```

```
se       1.427918    1.139597
median  36.500000   37.500000
min     22.000000   24.000000
max     49.000000   55.500000
sum    882.000000 1650.500000

$CHG_HINE1_302$sex_f$numbers_eachgrp
       Control ISIS 396443
N           24          43
n            1           0
mean        -3          NA
sd          NA          NA
se          NA          NA
median      -3          NA
min         -3          NA
max         -3          NA
sum         -3          NA

$CHG_HINE1_302$sex_f$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_302$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_302$sex_f$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_302$region_europe
$CHG_HINE1_302$region_europe$base
          Control ISIS 396443
N       17.000000   30.000000
n       17.000000   30.000000
mean    37.970588   38.066667
sd       6.328187    6.155644
se       1.534811    1.123862
median  37.000000   39.000000
min     29.000000   26.000000
max     50.000000   48.000000
sum    645.500000 1142.000000

$CHG_HINE1_302$region_europe$numbers_eachgrp
       Control ISIS 396443
N           17   30.000000
n            0    3.000000
mean        NA    7.833333
sd          NA    1.755942
se          NA    1.013794
median      NA    8.000000
min         NA    6.000000
```

```
max         NA    9.500000
sum         NA   23.500000

$CHG_HINE1_302$region_europe$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_302$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_302$region_europe$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_302$region_asiapacific
$CHG_HINE1_302$region_asiapacific$base
         Control ISIS 396443
N       2.000000   12.000000
n       2.000000   12.000000
mean   33.000000   36.458333
sd      4.242641    6.080738
se      3.000000    1.755358
median 33.000000   34.000000
min    30.000000   27.000000
max    36.000000   49.000000
sum    66.000000  437.500000

$CHG_HINE1_302$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2          12
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE1_302$region_asiapacific$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_302$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_302$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA
```

```
$CHG_HINE1_302$region_northamerica
$CHG_HINE1_302$region_northamerica$base
          Control ISIS 396443
N       22.000000   38.000000
n       22.000000   38.000000
mean    37.340909   39.289474
sd       8.292834    8.067814
se       1.768038    1.308772
median  39.000000   38.500000
min     22.000000   23.000000
max     52.000000   55.500000
sum    821.500000 1493.000000

$CHG_HINE1_302$region_northamerica$numbers_eachgrp
       Control ISIS 396443
N           22          38
n            1           0
mean        -3          NA
sd          NA          NA
se          NA          NA
median      -3          NA
min         -3          NA
max         -3          NA
sum         -3          NA

$CHG_HINE1_302$region_northamerica$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_302$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_302$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_302$disdur_gt_12wk
$CHG_HINE1_302$disdur_gt_12wk$base
          Control ISIS 396443
N       23.000000   46.000000
n       23.000000   46.000000
mean    38.347826   38.076087
sd       7.367673    6.153560
se       1.536266    0.907293
median  38.500000   37.750000
min     29.000000   24.000000
max     52.000000   48.500000
sum    882.000000 1751.500000
```

```
$CHG_HINE1_302$disdur_gt_12wk$numbers_eachgrp
       Control ISIS 396443
N           23          46
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE1_302$disdur_gt_12wk$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_302$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_302$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_302$disdur_le_12wek
$CHG_HINE1_302$disdur_le_12wek$base
          Control ISIS 396443
N       18.000000   34.000000
n       18.000000   34.000000
mean    36.166667   38.852941
sd       7.296252    8.306195
se       1.719743    1.424501
median  36.500000   39.000000
min     22.000000   23.000000
max     50.000000   55.500000
sum    651.000000 1321.000000

$CHG_HINE1_302$disdur_le_12wek$numbers_eachgrp
       Control ISIS 396443
N           18   34.000000
n            1    3.000000
mean        -3    7.833333
sd          NA    1.755942
se          NA    1.013794
median      -3    8.000000
min         -3    6.000000
max         -3    9.500000
sum         -3   23.500000

$CHG_HINE1_302$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
```

```
2     Control     NA        NA             NA             NA

$CHG_HINE1_302$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_302$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA



$CHG_HINE1_394
$CHG_HINE1_394$ageonset_le_12wk
$CHG_HINE1_394$ageonset_le_12wk$base
           Control  ISIS 396443
N        32.000000   72.0000000
n        32.000000   72.0000000
mean     37.078125   38.4305556
sd        7.647590    7.1484784
se        1.351916    0.8424563
median   37.000000   38.2500000
min      22.000000   24.0000000
max      52.000000   55.5000000
sum    1186.500000 2767.0000000

$CHG_HINE1_394$ageonset_le_12wk$numbers_eachgrp
          Control ISIS 396443
N       32.000000   72.000000
n        8.000000   25.000000
mean    -8.812500    4.400000
sd       6.755619    9.152641
se       2.388472    1.830528
median  -6.000000    3.000000
min    -21.000000  -13.000000
max     -0.500000   24.000000
sum    -70.500000  110.000000

$CHG_HINE1_394$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.37     1.625         1.042         7.701
2     Control  -8.72     2.917       -14.698        -2.749

$CHG_HINE1_394$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   1.309491e+01    3.374398e+00    6.182767e+00    2.000705e+01    5.781352e-04

$CHG_HINE1_394$ageonset_le_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 1.490  0.604  2.370  0.001


$CHG_HINE1_394$ageonset_gt_12wk
$CHG_HINE1_394$ageonset_gt_12wk$base
```

```
          Control ISIS 396443
N        9.000000    8.000000
n        9.000000    8.000000
mean    38.500000   38.187500
sd       6.324555    7.210793
se       2.108185    2.549400
median  41.000000   38.500000
min     27.000000   23.000000
max     47.000000   46.000000
sum    346.500000  305.500000

$CHG_HINE1_394$ageonset_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N        9.000000           8
n        3.000000           1
mean   -12.500000           9
sd      11.757976          NA
se       6.788471          NA
median -12.000000           9
min    -24.500000           9
max     -1.000000           9
sum    -37.500000           9

$CHG_HINE1_394$ageonset_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_HINE1_394$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_394$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE1_394$agetrt_lt_180d
$CHG_HINE1_394$agetrt_lt_180d$base
          Control ISIS 396443
N       16.000000   49.000000
n       16.000000   49.000000
mean    34.687500   39.408163
sd       7.173737    7.544088
se       1.793434    1.077727
median  33.250000   40.000000
min     22.000000   26.000000
max     50.000000   55.500000
sum    555.000000 1931.000000

$CHG_HINE1_394$agetrt_lt_180d$numbers_eachgrp
         Control ISIS 396443
N      16.000000   49.000000
n       2.000000   14.000000
```

```
mean   -3.000000    7.035714
sd      3.535534    9.845859
se      2.500000    2.631416
median -3.000000    5.500000
min    -5.500000  -13.000000
max    -0.500000   24.000000
sum    -6.000000   98.500000

$CHG_HINE1_394$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   7.48     2.573         1.813        13.137
2     Control  -6.08     7.810       -23.266        11.115

$CHG_HINE1_394$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     13.5507417       8.5154210      -5.1915736      32.2930570       0.1398453

$CHG_HINE1_394$agetrt_lt_180d$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 1.0000 -0.5390  2.5290  0.2035


$CHG_HINE1_394$agetrt_ge_180d
$CHG_HINE1_394$agetrt_ge_180d$base
          Control ISIS 396443
N       25.000000   31.000000
n       25.000000   31.000000
mean    39.120000   36.822581
sd       7.022701    6.147558
se       1.404540    1.104134
median  40.500000   37.000000
min     27.000000   23.000000
max     52.000000   48.000000
sum    978.000000 1141.500000

$CHG_HINE1_394$agetrt_ge_180d$numbers_eachgrp
           Control ISIS 396443
N        25.000000   31.000000
n         9.000000   12.000000
mean    -11.333333    1.708333
sd        7.901740    7.306468
se        2.633913    2.109196
median  -11.000000    1.500000
min     -24.500000   -9.500000
max      -1.000000   15.000000
sum    -102.000000   20.500000

$CHG_HINE1_394$agetrt_ge_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.14     2.437        -3.023         7.308
2     Control -11.91     2.860       -17.975        -5.850

$CHG_HINE1_394$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
```

```
    14.05516977      3.96109084      5.65803230     22.45230723      0.00267606

$CHG_HINE1_394$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.6600 0.6280 2.6830 0.0016


$CHG_HINE1_394$sex_m
$CHG_HINE1_394$sex_m$base
          Control ISIS 396443
N       17.000000   37.000000
n       17.000000   37.000000
mean    38.294118   38.432432
sd       7.897901    6.764041
se       1.915522    1.112002
median  38.000000   39.000000
min     26.500000   23.000000
max     52.000000   49.000000
sum    651.000000 1422.000000

$CHG_HINE1_394$sex_m$numbers_eachgrp
          Control ISIS 396443
N       17.000000   37.000000
n        5.000000    8.000000
mean    -9.800000    4.625000
sd       8.415759   12.043819
se       3.763642    4.258133
median  -6.000000    1.000000
min    -21.000000   -9.500000
max     -0.500000   24.000000
sum    -49.000000   37.000000

$CHG_HINE1_394$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   5.26     2.793        -1.182        11.698
2     Control -10.81     3.643       -19.215        -2.411

$CHG_HINE1_394$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    16.07098374      4.87110488      4.83819574     27.30377175      0.01087103

$CHG_HINE1_394$sex_m$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 1.2300 -0.0190  2.4890  0.0535


$CHG_HINE1_394$sex_f
$CHG_HINE1_394$sex_f$base
          Control ISIS 396443
N       24.000000   43.000000
n       24.000000   43.000000
mean    36.750000   38.383721
sd       6.995340    7.472837
se       1.427918    1.139597
```

```
median  36.500000   37.500000
min     22.000000   24.000000
max     49.000000   55.500000
sum    882.000000 1650.500000

$CHG_HINE1_394$sex_f$numbers_eachgrp
          Control ISIS 396443
N       24.000000   43.000000
n        6.000000   18.000000
mean    -9.833333    4.555556
sd       8.274459    7.728650
se       3.378034    1.821660
median  -8.500000    4.500000
min    -24.500000  -13.000000
max     -1.000000   19.000000
sum    -59.000000   82.000000

$CHG_HINE1_394$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.94     2.098         0.547         9.329
2     Control -10.98     4.039       -19.433        -2.526

$CHG_HINE1_394$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   15.917613009     4.880882159     5.701809244    26.133416774     0.004108799

$CHG_HINE1_394$sex_f$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.7700 0.6950 2.8420 0.0012


$CHG_HINE1_394$region_europe
$CHG_HINE1_394$region_europe$base
          Control ISIS 396443
N       17.000000   30.000000
n       17.000000   30.000000
mean    37.970588   38.066667
sd       6.328187    6.155644
se       1.534811    1.123862
median  37.000000   39.000000
min     29.000000   26.000000
max     50.000000   48.000000
sum    645.500000 1142.000000

$CHG_HINE1_394$region_europe$numbers_eachgrp
          Control ISIS 396443
N       17.000000   30.000000
n        3.000000    8.000000
mean    -7.166667    5.125000
sd       7.847505    7.679983
se       4.530759    2.715284
median  -4.500000    2.000000
min    -16.000000   -3.000000
max     -1.000000   19.000000
```

```
sum    -21.500000   41.000000

$CHG_HINE1_394$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   4.64     2.380        -1.188        10.459
2     Control  -5.86     4.095       -15.881         4.158

$CHG_HINE1_394$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    10.49712661      4.94252262     -1.59679057     22.59104379      0.07786921

$CHG_HINE1_394$region_europe$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 1.4600 -0.0730  2.9850  0.0619


$CHG_HINE1_394$region_asiapacific
$CHG_HINE1_394$region_asiapacific$base
         Control ISIS 396443
N       2.000000   12.000000
n       2.000000   12.000000
mean   33.000000   36.458333
sd      4.242641    6.080738
se      3.000000    1.755358
median 33.000000   34.000000
min    30.000000   27.000000
max    36.000000   49.000000
sum    66.000000  437.500000

$CHG_HINE1_394$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2   12.000000
n            0    2.000000
mean        NA   14.500000
sd          NA    6.363961
se          NA    4.500000
median      NA   14.500000
min         NA   10.000000
max         NA   19.000000
sum         NA   29.000000

$CHG_HINE1_394$region_asiapacific$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE1_394$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE1_394$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA
```

```
$CHG_HINE1_394$region_northamerica
$CHG_HINE1_394$region_northamerica$base
          Control ISIS 396443
N       22.000000   38.000000
n       22.000000   38.000000
mean    37.340909   39.289474
sd       8.292834    8.067814
se       1.768038    1.308772
median  39.000000   38.500000
min     22.000000   23.000000
max     52.000000   55.500000
sum    821.500000 1493.000000

$CHG_HINE1_394$region_northamerica$numbers_eachgrp
          Control ISIS 396443
N       22.000000   38.000000
n        8.000000   16.000000
mean   -10.812500    3.062500
sd       8.224256    9.456700
se       2.907714    2.364175
median  -8.500000    4.000000
min    -24.500000  -13.000000
max     -0.500000   24.000000
sum    -86.500000   49.000000

$CHG_HINE1_394$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   3.11     2.175        -1.438         7.667
2     Control -10.92     3.179       -17.570        -4.262

$CHG_HINE1_394$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   14.030497910     4.016154245     5.624590469    22.436405351     0.002430851

$CHG_HINE1_394$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.4700 0.5110 2.4390 0.0027


$CHG_HINE1_394$disdur_gt_12wk
$CHG_HINE1_394$disdur_gt_12wk$base
          Control ISIS 396443
N       23.000000   46.000000
n       23.000000   46.000000
mean    38.347826   38.076087
sd       7.367673    6.153560
se       1.536266    0.907293
median  38.500000   37.750000
min     29.000000   24.000000
max     52.000000   48.500000
sum    882.000000 1751.500000

$CHG_HINE1_394$disdur_gt_12wk$numbers_eachgrp
```

```
          Control ISIS 396443
N       23.000000   46.000000
n        8.000000   15.000000
mean   -11.250000    3.200000
sd       8.443087    8.327665
se       2.985082    2.150194
median  -8.500000    2.000000
min    -24.500000   -9.500000
max     -1.000000   19.000000
sum    -90.000000   48.000000

$CHG_HINE1_394$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   2.60     2.274        -2.174         7.382
2     Control -10.13     3.239       -16.938        -3.327

$CHG_HINE1_394$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   12.736561363     4.181330142     3.951912709    21.521210017     0.006952006

$CHG_HINE1_394$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.6600 0.6570 2.6720 0.0012


$CHG_HINE1_394$disdur_le_12wek
$CHG_HINE1_394$disdur_le_12wek$base
          Control ISIS 396443
N       18.000000   34.000000
n       18.000000   34.000000
mean    36.166667   38.852941
sd       7.296252    8.306195
se       1.719743    1.424501
median  36.500000   39.000000
min     22.000000   23.000000
max     50.000000   55.500000
sum    651.000000 1321.000000

$CHG_HINE1_394$disdur_le_12wek$numbers_eachgrp
          Control ISIS 396443
N       18.000000   34.000000
n        3.000000   11.000000
mean    -6.000000    6.454545
sd       5.766281    9.963570
se       3.329164    3.004129
median  -5.500000    5.500000
min    -12.000000  -13.000000
max     -0.500000   24.000000
sum    -18.000000   71.000000

$CHG_HINE1_394$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   7.82     3.094         0.820        14.820
2     Control -11.01     6.707       -26.178         4.165
```

```
$CHG_HINE1_394$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    18.82664053      7.87112697      1.02091428     36.63236678      0.04043385

$CHG_HINE1_394$disdur_le_12wek$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 1.2400 -0.1460  2.6280  0.0795




\##############################################################################
[[1]]
[1] "Veränderung des HINE-Scores (Subskala 3) von Baseline"

$CHG_HINE3_64
$CHG_HINE3_64$ageonset_le_12wk
$CHG_HINE3_64$ageonset_le_12wk$base
           Control ISIS 396443
N       32.0000000   72.000000
n       32.0000000   72.000000
mean    14.3750000   13.854167
sd       1.2115040    1.767144
se       0.2141657    0.208260
median  15.0000000   15.000000
min     11.0000000    8.000000
max     15.0000000   15.000000
sum    460.0000000  997.500000

$CHG_HINE3_64$ageonset_le_12wk$numbers_eachgrp
       Control ISIS 396443
N           32          72
n            1           0
mean         3          NA
sd          NA          NA
se          NA          NA
median       3          NA
min          3          NA
max          3          NA
sum          3          NA

$CHG_HINE3_64$ageonset_le_12wk$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_64$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_64$ageonset_le_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA
```

```
$CHG_HINE3_64$ageonset_gt_12wk
$CHG_HINE3_64$ageonset_gt_12wk$base
          Control ISIS 396443
N        9.000000   8.0000000
n        9.000000   8.0000000
mean    14.333333  14.3750000
sd       1.118034   1.4078860
se       0.372678   0.4977629
median  15.000000  15.0000000
min     12.000000  11.0000000
max     15.000000  15.0000000
sum    129.000000 115.0000000

$CHG_HINE3_64$ageonset_gt_12wk$numbers_eachgrp
       Control ISIS 396443
N            9           8
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE3_64$ageonset_gt_12wk$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_64$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_64$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_64$agetrt_lt_180d
$CHG_HINE3_64$agetrt_lt_180d$base
           Control ISIS 396443
N       16.0000000  49.0000000
n       16.0000000  49.0000000
mean    14.3125000  14.0408163
sd       1.4008926   1.6827456
se       0.3502231   0.2403922
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    229.0000000 688.0000000
```

```
$CHG_HINE3_64$agetrt_lt_180d$numbers_eachgrp
       Control ISIS 396443
N           16          49
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE3_64$agetrt_lt_180d$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_64$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_64$agetrt_lt_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_64$agetrt_ge_180d
$CHG_HINE3_64$agetrt_ge_180d$base
           Control ISIS 396443
N       25.0000000  31.0000000
n       25.0000000  31.0000000
mean    14.4000000  13.6935484
sd       1.0408330   1.8196951
se       0.2081666   0.3268269
median  15.0000000  14.5000000
min     12.0000000   8.0000000
max     15.0000000  15.0000000
sum    360.0000000 424.5000000

$CHG_HINE3_64$agetrt_ge_180d$numbers_eachgrp
       Control ISIS 396443
N           25          31
n            1           0
mean         3          NA
sd          NA          NA
se          NA          NA
median       3          NA
min          3          NA
max          3          NA
sum          3          NA

$CHG_HINE3_64$agetrt_ge_180d$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
```

```
[2,]        NA     NA        NA             NA             NA

$CHG_HINE3_64$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_64$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_64$sex_m
$CHG_HINE3_64$sex_m$base
           Control ISIS 396443
N       17.0000000  37.0000000
n       17.0000000  37.0000000
mean    14.3529412  13.6891892
sd       1.2217394   1.8156394
se       0.2963153   0.2984893
median  15.0000000  14.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    244.0000000 506.5000000

$CHG_HINE3_64$sex_m$numbers_eachgrp
       Control ISIS 396443
N           17          37
n            1           0
mean         3          NA
sd          NA          NA
se          NA          NA
median       3          NA
min          3          NA
max          3          NA
sum          3          NA

$CHG_HINE3_64$sex_m$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA             NA             NA
[2,]        NA     NA        NA             NA             NA

$CHG_HINE3_64$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_64$sex_m$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_64$sex_f
$CHG_HINE3_64$sex_f$base
           Control ISIS 396443
N       24.0000000  43.0000000
```

```
n       24.0000000  43.0000000
mean    14.3750000  14.0930233
sd       1.1726039   1.6592304
se       0.2393568   0.2530303
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    345.0000000 606.0000000

$CHG_HINE3_64$sex_f$numbers_eachgrp
       Control ISIS 396443
N           24          43
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE3_64$sex_f$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_64$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_64$sex_f$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_64$region_europe
$CHG_HINE3_64$region_europe$base
           Control ISIS 396443
N       17.0000000  30.0000000
n       17.0000000  30.0000000
mean    14.5882353  14.1166667
sd       1.0036697   1.4484435
se       0.2434257   0.2644484
median  15.0000000  15.0000000
min     11.0000000   9.0000000
max     15.0000000  15.0000000
sum    248.0000000 423.5000000

$CHG_HINE3_64$region_europe$numbers_eachgrp
       Control ISIS 396443
N           17          30
n            0           0
mean        NA          NA
sd          NA          NA
```

```
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE3_64$region_europe$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_64$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_64$region_europe$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_64$region_asiapacific
$CHG_HINE3_64$region_asiapacific$base
         Control ISIS 396443
N       2.000000  12.0000000
n       2.000000  12.0000000
mean   14.000000  13.5833333
sd      1.414214   2.3915888
se      1.000000   0.6903922
median 14.000000  15.0000000
min    13.000000   8.0000000
max    15.000000  15.0000000
sum    28.000000 163.0000000

$CHG_HINE3_64$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2          12
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE3_64$region_asiapacific$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_64$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA
```

```
$CHG_HINE3_64$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_64$region_northamerica
$CHG_HINE3_64$region_northamerica$base
           Control ISIS 396443
N       22.0000000  38.0000000
n       22.0000000  38.0000000
mean    14.2272727  13.8421053
sd       1.3068252   1.7324614
se       0.2786161   0.2810423
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    313.0000000 526.0000000

$CHG_HINE3_64$region_northamerica$numbers_eachgrp
       Control ISIS 396443
N           22          38
n            1           0
mean         3          NA
sd          NA          NA
se          NA          NA
median       3          NA
min          3          NA
max          3          NA
sum          3          NA

$CHG_HINE3_64$region_northamerica$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_64$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_64$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_64$disdur_gt_12wk
$CHG_HINE3_64$disdur_gt_12wk$base
           Control ISIS 396443
N       23.0000000  46.0000000
n       23.0000000  46.0000000
mean    14.4347826  13.9021739
sd       1.1609591   1.5972879
se       0.2420767   0.2355072
median  15.0000000  15.0000000
min     11.0000000   8.0000000
```

```
max     15.0000000  15.0000000
sum    332.0000000 639.5000000

$CHG_HINE3_64$disdur_gt_12wk$numbers_eachgrp
       Control ISIS 396443
N           23          46
n            1           0
mean         3          NA
sd          NA          NA
se          NA          NA
median       3          NA
min          3          NA
max          3          NA
sum          3          NA

$CHG_HINE3_64$disdur_gt_12wk$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_64$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_64$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_64$disdur_le_12wek
$CHG_HINE3_64$disdur_le_12wek$base
          Control ISIS 396443
N       18.0000000  34.0000000
n       18.0000000  34.0000000
mean    14.2777778  13.9117647
sd       1.2274103   1.9285361
se       0.2893034   0.3307412
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    257.0000000 473.0000000

$CHG_HINE3_64$disdur_le_12wek$numbers_eachgrp
       Control ISIS 396443
N           18          34
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA
```

```
$CHG_HINE3_64$disdur_le_12wek$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_64$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_64$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA



$CHG_HINE3_183
$CHG_HINE3_183$ageonset_le_12wk
$CHG_HINE3_183$ageonset_le_12wk$base
           Control ISIS 396443
N       32.0000000   72.000000
n       32.0000000   72.000000
mean    14.3750000   13.854167
sd       1.2115040    1.767144
se       0.2141657    0.208260
median  15.0000000   15.000000
min     11.0000000    8.000000
max     15.0000000   15.000000
sum    460.0000000  997.500000

$CHG_HINE3_183$ageonset_le_12wk$numbers_eachgrp
          Control ISIS 396443
N      32.0000000   72.000000
n       4.0000000    4.000000
mean   -2.0000000    0.750000
sd      1.8257419    2.217356
se      0.9128709    1.108678
median -2.0000000    1.000000
min    -4.0000000   -2.000000
max     0.0000000    3.000000
sum    -8.0000000    3.000000

$CHG_HINE3_183$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  -0.12     1.465        -4.778         4.547
2     Control  -1.13     1.465        -5.797         3.528

$CHG_HINE3_183$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      1.0185603       2.4151044      -6.6673798       8.7045004       0.7016078

$CHG_HINE3_183$ageonset_le_12wk$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 1.1800 -0.4280  2.7830  0.1505
```

```
$CHG_HINE3_183$ageonset_gt_12wk
$CHG_HINE3_183$ageonset_gt_12wk$base
          Control ISIS 396443
N        9.000000   8.0000000
n        9.000000   8.0000000
mean    14.333333  14.3750000
sd       1.118034   1.4078860
se       0.372678   0.4977629
median  15.000000  15.0000000
min     12.000000  11.0000000
max     15.000000  15.0000000
sum    129.000000 115.0000000

$CHG_HINE3_183$ageonset_gt_12wk$numbers_eachgrp
       Control ISIS 396443
N            9           8
n            0           1
mean        NA           0
sd          NA          NA
se          NA          NA
median      NA           0
min         NA           0
max         NA           0
sum         NA           0

$CHG_HINE3_183$ageonset_gt_12wk$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_183$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_183$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_183$agetrt_lt_180d
$CHG_HINE3_183$agetrt_lt_180d$base
           Control ISIS 396443
N       16.0000000  49.0000000
n       16.0000000  49.0000000
mean    14.3125000  14.0408163
sd       1.4008926   1.6827456
se       0.3502231   0.2403922
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    229.0000000 688.0000000

$CHG_HINE3_183$agetrt_lt_180d$numbers_eachgrp
```

```
          Control ISIS 396443
N      16.0000000    49.00000
n       3.0000000     2.00000
mean   -2.6666667     1.50000
sd      1.5275252     2.12132
se      0.8819171     1.50000
median -3.0000000     1.50000
min    -4.0000000     0.00000
max    -1.0000000     3.00000
sum    -8.0000000     3.00000

$CHG_HINE3_183$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.95       NaN           NaN           NaN
2     Control  -2.30       NaN           NaN           NaN

$CHG_HINE3_183$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
       3.257757             NaN             NaN             NaN             NaN

$CHG_HINE3_183$agetrt_lt_180d$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 1.7300 -1.2070  4.6740  0.2479


$CHG_HINE3_183$agetrt_ge_180d
$CHG_HINE3_183$agetrt_ge_180d$base
          Control ISIS 396443
N       25.0000000  31.0000000
n       25.0000000  31.0000000
mean    14.4000000  13.6935484
sd       1.0408330   1.8196951
se       0.2081666   0.3268269
median  15.0000000  14.5000000
min     12.0000000   8.0000000
max     15.0000000  15.0000000
sum    360.0000000 424.5000000

$CHG_HINE3_183$agetrt_ge_180d$numbers_eachgrp
       Control ISIS 396443
N           25   31.000000
n            1    3.000000
mean         0    0.000000
sd          NA    2.000000
se          NA    1.154701
median       0    0.000000
min          0   -2.000000
max          0    2.000000
sum          0    0.000000

$CHG_HINE3_183$agetrt_ge_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  -0.42       NaN           NaN           NaN
2     Control     NA        NA            NA            NA
```

```
$CHG_HINE3_183$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_183$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_183$sex_m
$CHG_HINE3_183$sex_m$base
           Control ISIS 396443
N       17.0000000  37.0000000
n       17.0000000  37.0000000
mean    14.3529412  13.6891892
sd       1.2217394   1.8156394
se       0.2963153   0.2984893
median  15.0000000  14.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    244.0000000 506.5000000

$CHG_HINE3_183$sex_m$numbers_eachgrp
        Control ISIS 396443
N      17.00000          37
n       2.00000           1
mean   -2.50000           3
sd      2.12132          NA
se      1.50000          NA
median -2.50000           3
min    -4.00000           3
max    -1.00000           3
sum    -5.00000           3

$CHG_HINE3_183$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA             NA             NA
2     Control     NA        NA             NA             NA

$CHG_HINE3_183$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_183$sex_m$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_183$sex_f
$CHG_HINE3_183$sex_f$base
           Control ISIS 396443
N       24.0000000  43.0000000
n       24.0000000  43.0000000
```

```
mean    14.3750000  14.0930233
sd       1.1726039   1.6592304
se       0.2393568   0.2530303
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    345.0000000 606.0000000

$CHG_HINE3_183$sex_f$numbers_eachgrp
        Control ISIS 396443
N      24.00000  43.0000000
n       2.00000   4.0000000
mean   -1.50000   0.0000000
sd      2.12132   1.6329932
se      1.50000   0.8164966
median -1.50000   0.0000000
min    -3.00000  -2.0000000
max     0.00000   2.0000000
sum    -3.00000   0.0000000

$CHG_HINE3_183$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  -0.31     1.826       -23.507        22.895
2     Control  -0.89     2.839       -36.962        35.187

$CHG_HINE3_183$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      0.5815779       3.7656168     -47.2651197      48.4282755       0.9024485

$CHG_HINE3_183$sex_f$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.6800 -1.1410  2.4980  0.4647


$CHG_HINE3_183$region_europe
$CHG_HINE3_183$region_europe$base
           Control ISIS 396443
N       17.0000000  30.0000000
n       17.0000000  30.0000000
mean    14.5882353  14.1166667
sd       1.0036697   1.4484435
se       0.2434257   0.2644484
median  15.0000000  15.0000000
min     11.0000000   9.0000000
max     15.0000000  15.0000000
sum    248.0000000 423.5000000

$CHG_HINE3_183$region_europe$numbers_eachgrp
         Control ISIS 396443
N      17.000000          30
n       3.000000           2
mean   -2.333333           0
sd      2.081666           0
se      1.201850           0
```

```
median -3.000000           0
min    -4.000000           0
max     0.000000           0
sum    -7.000000           0

$CHG_HINE3_183$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.49     0.652        -7.792         8.778
2     Control  -2.66     0.500        -9.010         3.687

$CHG_HINE3_183$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      3.1545073       0.9368379      -8.7491468      15.0581613       0.1837841

$CHG_HINE3_183$region_europe$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_183$region_asiapacific
$CHG_HINE3_183$region_asiapacific$base
         Control ISIS 396443
N       2.000000  12.0000000
n       2.000000  12.0000000
mean   14.000000  13.5833333
sd      1.414214   2.3915888
se      1.000000   0.6903922
median 14.000000  15.0000000
min    13.000000   8.0000000
max    15.000000  15.0000000
sum    28.000000 163.0000000

$CHG_HINE3_183$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2          12
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE3_183$region_asiapacific$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_183$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_183$region_asiapacific$Hedgesg_TRTvsCTRL
```

```
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_183$region_northamerica
$CHG_HINE3_183$region_northamerica$base
           Control ISIS 396443
N       22.0000000  38.0000000
n       22.0000000  38.0000000
mean    14.2272727  13.8421053
sd       1.3068252   1.7324614
se       0.2786161   0.2810423
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    313.0000000 526.0000000

$CHG_HINE3_183$region_northamerica$numbers_eachgrp
       Control ISIS 396443
N           22   38.000000
n            1    3.000000
mean        -1    1.000000
sd          NA    2.645751
se          NA    1.527525
median      -1    2.000000
min         -1   -2.000000
max         -1    3.000000
sum         -1    3.000000

$CHG_HINE3_183$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_HINE3_183$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_183$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_183$disdur_gt_12wk
$CHG_HINE3_183$disdur_gt_12wk$base
           Control ISIS 396443
N       23.0000000  46.0000000
n       23.0000000  46.0000000
mean    14.4347826  13.9021739
sd       1.1609591   1.5972879
se       0.2420767   0.2355072
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
```

```
sum    332.0000000 639.5000000

$CHG_HINE3_183$disdur_gt_12wk$numbers_eachgrp
       Control ISIS 396443
N           23   46.000000
n            1    2.000000
mean         0    0.000000
sd          NA    2.828427
se          NA    2.000000
median       0    0.000000
min          0   -2.000000
max          0    2.000000
sum          0    0.000000

$CHG_HINE3_183$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_HINE3_183$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_183$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_183$disdur_le_12wek
$CHG_HINE3_183$disdur_le_12wek$base
           Control ISIS 396443
N       18.0000000  34.0000000
n       18.0000000  34.0000000
mean    14.2777778  13.9117647
sd       1.2274103   1.9285361
se       0.2893034   0.3307412
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    257.0000000 473.0000000

$CHG_HINE3_183$disdur_le_12wek$numbers_eachgrp
          Control ISIS 396443
N      18.0000000   34.000000
n       3.0000000    3.000000
mean   -2.6666667    1.000000
sd      1.5275252    1.732051
se      0.8819171    1.000000
median -3.0000000    0.000000
min    -4.0000000    0.000000
max    -1.0000000    3.000000
sum    -8.0000000    3.000000

$CHG_HINE3_183$disdur_le_12wek$ls_mw
```

```
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.74     0.207        -1.883         3.371
2     Control  -2.41     0.207        -5.038         0.216

$CHG_HINE3_183$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     3.15493504      0.34399313     -1.21591208      7.52578216      0.06913966

$CHG_HINE3_183$disdur_le_12wek$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 1.8000 -0.5640  4.1560  0.1357



$CHG_HINE3_302
$CHG_HINE3_302$ageonset_le_12wk
$CHG_HINE3_302$ageonset_le_12wk$base
           Control ISIS 396443
N       32.0000000   72.000000
n       32.0000000   72.000000
mean    14.3750000   13.854167
sd       1.2115040    1.767144
se       0.2141657    0.208260
median  15.0000000   15.000000
min     11.0000000    8.000000
max     15.0000000   15.000000
sum    460.0000000  997.500000

$CHG_HINE3_302$ageonset_le_12wk$numbers_eachgrp
       Control ISIS 396443
N           32   72.000000
n            1    2.000000
mean         0   -2.000000
sd          NA    1.414214
se          NA    1.000000
median       0   -2.000000
min          0   -3.000000
max          0   -1.000000
sum          0   -4.000000

$CHG_HINE3_302$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_HINE3_302$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_302$ageonset_le_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA
```

```
$CHG_HINE3_302$ageonset_gt_12wk
$CHG_HINE3_302$ageonset_gt_12wk$base
          Control ISIS 396443
N        9.000000   8.0000000
n        9.000000   8.0000000
mean    14.333333  14.3750000
sd       1.118034   1.4078860
se       0.372678   0.4977629
median  15.000000  15.0000000
min     12.000000  11.0000000
max     15.000000  15.0000000
sum    129.000000 115.0000000

$CHG_HINE3_302$ageonset_gt_12wk$numbers_eachgrp
       Control ISIS 396443
N            9           8
n            0           1
mean        NA          -2
sd          NA          NA
se          NA          NA
median      NA          -2
min         NA          -2
max         NA          -2
sum         NA          -2

$CHG_HINE3_302$ageonset_gt_12wk$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_302$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_302$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_302$agetrt_lt_180d
$CHG_HINE3_302$agetrt_lt_180d$base
          Control ISIS 396443
N       16.0000000  49.0000000
n       16.0000000  49.0000000
mean    14.3125000  14.0408163
sd       1.4008926   1.6827456
se       0.3502231   0.2403922
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    229.0000000 688.0000000

$CHG_HINE3_302$agetrt_lt_180d$numbers_eachgrp
       Control ISIS 396443
```

```
N           16  49.0000000
n            1   3.0000000
mean         0  -2.0000000
sd          NA   1.0000000
se          NA   0.5773503
median       0  -2.0000000
min          0  -3.0000000
max          0  -1.0000000
sum          0  -6.0000000

$CHG_HINE3_302$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_HINE3_302$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_302$agetrt_lt_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_302$agetrt_ge_180d
$CHG_HINE3_302$agetrt_ge_180d$base
          Control ISIS 396443
N       25.0000000  31.0000000
n       25.0000000  31.0000000
mean    14.4000000  13.6935484
sd       1.0408330   1.8196951
se       0.2081666   0.3268269
median  15.0000000  14.5000000
min     12.0000000   8.0000000
max     15.0000000  15.0000000
sum    360.0000000 424.5000000

$CHG_HINE3_302$agetrt_ge_180d$numbers_eachgrp
       Control ISIS 396443
N           25          31
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE3_302$agetrt_ge_180d$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA
```

```
$CHG_HINE3_302$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_302$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_302$sex_m
$CHG_HINE3_302$sex_m$base
           Control ISIS 396443
N       17.0000000  37.0000000
n       17.0000000  37.0000000
mean    14.3529412  13.6891892
sd       1.2217394   1.8156394
se       0.2963153   0.2984893
median  15.0000000  14.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    244.0000000 506.5000000

$CHG_HINE3_302$sex_m$numbers_eachgrp
       Control ISIS 396443
N           17  37.0000000
n            0   3.0000000
mean        NA  -2.0000000
sd          NA   1.0000000
se          NA   0.5773503
median      NA  -2.0000000
min         NA  -3.0000000
max         NA  -1.0000000
sum         NA  -6.0000000

$CHG_HINE3_302$sex_m$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA             NA             NA
[2,]        NA     NA        NA             NA             NA

$CHG_HINE3_302$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_302$sex_m$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_302$sex_f
$CHG_HINE3_302$sex_f$base
           Control ISIS 396443
N       24.0000000  43.0000000
n       24.0000000  43.0000000
mean    14.3750000  14.0930233
```

```
sd       1.1726039   1.6592304
se       0.2393568   0.2530303
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    345.0000000 606.0000000

$CHG_HINE3_302$sex_f$numbers_eachgrp
       Control ISIS 396443
N           24          43
n            1           0
mean         0          NA
sd          NA          NA
se          NA          NA
median       0          NA
min          0          NA
max          0          NA
sum          0          NA

$CHG_HINE3_302$sex_f$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_302$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_302$sex_f$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_302$region_europe
$CHG_HINE3_302$region_europe$base
          Control ISIS 396443
N       17.0000000  30.0000000
n       17.0000000  30.0000000
mean    14.5882353  14.1166667
sd       1.0036697   1.4484435
se       0.2434257   0.2644484
median  15.0000000  15.0000000
min     11.0000000   9.0000000
max     15.0000000  15.0000000
sum    248.0000000 423.5000000

$CHG_HINE3_302$region_europe$numbers_eachgrp
       Control ISIS 396443
N           17  30.0000000
n            0   3.0000000
mean        NA  -2.0000000
sd          NA   1.0000000
se          NA   0.5773503
median      NA  -2.0000000
```

```
min         NA  -3.0000000
max         NA  -1.0000000
sum         NA  -6.0000000

$CHG_HINE3_302$region_europe$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_302$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_302$region_europe$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_302$region_asiapacific
$CHG_HINE3_302$region_asiapacific$base
         Control ISIS 396443
N       2.000000  12.0000000
n       2.000000  12.0000000
mean   14.000000  13.5833333
sd      1.414214   2.3915888
se      1.000000   0.6903922
median 14.000000  15.0000000
min    13.000000   8.0000000
max    15.000000  15.0000000
sum    28.000000 163.0000000

$CHG_HINE3_302$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2          12
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE3_302$region_asiapacific$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_302$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_302$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
```

```
    NA     NA     NA     NA


$CHG_HINE3_302$region_northamerica
$CHG_HINE3_302$region_northamerica$base
           Control ISIS 396443
N       22.0000000  38.0000000
n       22.0000000  38.0000000
mean    14.2272727  13.8421053
sd       1.3068252   1.7324614
se       0.2786161   0.2810423
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    313.0000000 526.0000000

$CHG_HINE3_302$region_northamerica$numbers_eachgrp
       Control ISIS 396443
N           22          38
n            1           0
mean         0          NA
sd          NA          NA
se          NA          NA
median       0          NA
min          0          NA
max          0          NA
sum          0          NA

$CHG_HINE3_302$region_northamerica$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_302$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_302$region_northamerica$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_302$disdur_gt_12wk
$CHG_HINE3_302$disdur_gt_12wk$base
           Control ISIS 396443
N       23.0000000  46.0000000
n       23.0000000  46.0000000
mean    14.4347826  13.9021739
sd       1.1609591   1.5972879
se       0.2420767   0.2355072
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    332.0000000 639.5000000
```

```
$CHG_HINE3_302$disdur_gt_12wk$numbers_eachgrp
       Control ISIS 396443
N           23          46
n            0           0
mean        NA          NA
sd          NA          NA
se          NA          NA
median      NA          NA
min         NA          NA
max         NA          NA
sum         NA          NA

$CHG_HINE3_302$disdur_gt_12wk$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_302$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_302$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_302$disdur_le_12wek
$CHG_HINE3_302$disdur_le_12wek$base
           Control ISIS 396443
N       18.0000000  34.0000000
n       18.0000000  34.0000000
mean    14.2777778  13.9117647
sd       1.2274103   1.9285361
se       0.2893034   0.3307412
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    257.0000000 473.0000000

$CHG_HINE3_302$disdur_le_12wek$numbers_eachgrp
       Control ISIS 396443
N           18  34.0000000
n            1   3.0000000
mean         0  -2.0000000
sd          NA   1.0000000
se          NA   0.5773503
median       0  -2.0000000
min          0  -3.0000000
max          0  -1.0000000
sum          0  -6.0000000

$CHG_HINE3_302$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
```

```
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_HINE3_302$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_302$disdur_le_12wek$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA



$CHG_HINE3_394
$CHG_HINE3_394$ageonset_le_12wk
$CHG_HINE3_394$ageonset_le_12wk$base
           Control ISIS 396443
N       32.0000000   72.000000
n       32.0000000   72.000000
mean    14.3750000   13.854167
sd       1.2115040    1.767144
se       0.2141657    0.208260
median  15.0000000   15.000000
min     11.0000000    8.000000
max     15.0000000   15.000000
sum    460.0000000  997.500000

$CHG_HINE3_394$ageonset_le_12wk$numbers_eachgrp
          Control ISIS 396443
N       32.000000  72.0000000
n        8.000000  25.0000000
mean    -2.625000  -0.5000000
sd       3.662064   2.2638463
se       1.294735   0.4527693
median  -2.000000   0.0000000
min     -9.000000  -4.0000000
max      1.000000   7.0000000
sum    -21.000000 -12.5000000

$CHG_HINE3_394$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  -0.48     0.429        -1.357         0.400
2     Control  -2.69     0.767        -4.264        -1.122

$CHG_HINE3_394$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      2.2148864       0.8856796       0.4006540       4.0291188       0.0185179

$CHG_HINE3_394$ageonset_le_12wk$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.7800 -0.0370  1.6050  0.0614


$CHG_HINE3_394$ageonset_gt_12wk
```

```
$CHG_HINE3_394$ageonset_gt_12wk$base
          Control ISIS 396443
N        9.000000   8.0000000
n        9.000000   8.0000000
mean    14.333333  14.3750000
sd       1.118034   1.4078860
se       0.372678   0.4977629
median  15.000000  15.0000000
min     12.000000  11.0000000
max     15.000000  15.0000000
sum    129.000000 115.0000000

$CHG_HINE3_394$ageonset_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N        9.000000           8
n        3.000000           1
mean    -5.333333           4
sd       2.516611          NA
se       1.452966          NA
median  -5.000000           4
min     -8.000000           4
max     -3.000000           4
sum    -16.000000           4

$CHG_HINE3_394$ageonset_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443     NA        NA            NA            NA
2     Control     NA        NA            NA            NA

$CHG_HINE3_394$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_394$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_394$agetrt_lt_180d
$CHG_HINE3_394$agetrt_lt_180d$base
          Control ISIS 396443
N       16.0000000  49.0000000
n       16.0000000  49.0000000
mean    14.3125000  14.0408163
sd       1.4008926   1.6827456
se       0.3502231   0.2403922
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    229.0000000 688.0000000

$CHG_HINE3_394$agetrt_lt_180d$numbers_eachgrp
         Control ISIS 396443
N      16.000000  49.0000000
```

```
n       2.000000  14.0000000
mean   -4.000000  -0.1428571
sd      7.071068   2.2138426
se      5.000000   0.5916743
median -4.000000   0.0000000
min    -9.000000  -2.0000000
max     1.000000   7.0000000
sum    -8.000000  -2.0000000

$CHG_HINE3_394$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.07     0.520        -1.077         1.213
2     Control  -5.48     1.451        -8.669        -2.284

$CHG_HINE3_394$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    5.544357496     1.563419548     2.103294272     8.985420721     0.004581722

$CHG_HINE3_394$agetrt_lt_180d$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 1.2800 -0.2880  2.8470  0.1095


$CHG_HINE3_394$agetrt_ge_180d
$CHG_HINE3_394$agetrt_ge_180d$base
           Control ISIS 396443
N       25.0000000  31.0000000
n       25.0000000  31.0000000
mean    14.4000000  13.6935484
sd       1.0408330   1.8196951
se       0.2081666   0.3268269
median  15.0000000  14.5000000
min     12.0000000   8.0000000
max     15.0000000  15.0000000
sum    360.0000000 424.5000000

$CHG_HINE3_394$agetrt_ge_180d$numbers_eachgrp
           Control ISIS 396443
N       25.0000000  31.0000000
n        9.0000000  12.0000000
mean    -3.2222222  -0.5416667
sd       2.9907264   2.6582490
se       0.9969088   0.7673704
median  -4.0000000   0.0000000
min     -8.0000000  -4.0000000
max      1.0000000   4.0000000
sum    -29.0000000  -6.5000000

$CHG_HINE3_394$agetrt_ge_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  -0.65     0.750        -2.236         0.942
2     Control  -3.08     0.885        -4.958        -1.206

$CHG_HINE3_394$agetrt_ge_180d$diffgrp_TRTvsCTRL
```

```
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     2.43491145      1.24457794     -0.20347592      5.07329882      0.06810376

$CHG_HINE3_394$agetrt_ge_180d$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.9200 0.0010 1.8360 0.0499


$CHG_HINE3_394$sex_m
$CHG_HINE3_394$sex_m$base
           Control ISIS 396443
N       17.0000000  37.0000000
n       17.0000000  37.0000000
mean    14.3529412  13.6891892
sd       1.2217394   1.8156394
se       0.2963153   0.2984893
median  15.0000000  14.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    244.0000000 506.5000000

$CHG_HINE3_394$sex_m$numbers_eachgrp
          Control ISIS 396443
N       17.000000   37.000000
n        5.000000    8.000000
mean    -3.400000   -0.375000
sd       4.037326    3.335416
se       1.805547    1.179248
median  -4.000000   -0.500000
min     -9.000000   -4.000000
max      1.000000    7.000000
sum    -17.000000   -3.000000

$CHG_HINE3_394$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  -0.63     0.997        -2.933         1.665
2     Control  -2.99     1.273        -5.922        -0.050

$CHG_HINE3_394$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      2.3519543       1.6481550      -1.4486979       6.1526064       0.1914157

$CHG_HINE3_394$sex_m$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.7800 -0.3930  1.9540  0.1926


$CHG_HINE3_394$sex_f
$CHG_HINE3_394$sex_f$base
           Control ISIS 396443
N       24.0000000  43.0000000
n       24.0000000  43.0000000
mean    14.3750000  14.0930233
sd       1.1726039   1.6592304
```

```
se       0.2393568   0.2530303
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    345.0000000 606.0000000

$CHG_HINE3_394$sex_f$numbers_eachgrp
          Control ISIS 396443
N       24.000000  43.0000000
n        6.000000  18.0000000
mean    -3.333333  -0.3055556
sd       3.386247   1.9488978
se       1.382429   0.4593596
median  -4.000000   0.0000000
min     -8.000000  -4.0000000
max      1.000000   4.0000000
sum    -20.000000  -5.5000000

$CHG_HINE3_394$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  -0.35     0.513        -1.429         0.719
2     Control  -3.19     0.989        -5.255        -1.116

$CHG_HINE3_394$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     2.83022667      1.19520740      0.32862883      5.33182451      0.02864669

$CHG_HINE3_394$sex_f$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 1.240  0.241  2.243  0.015


$CHG_HINE3_394$region_europe
$CHG_HINE3_394$region_europe$base
           Control ISIS 396443
N       17.0000000  30.0000000
n       17.0000000  30.0000000
mean    14.5882353  14.1166667
sd       1.0036697   1.4484435
se       0.2434257   0.2644484
median  15.0000000  15.0000000
min     11.0000000   9.0000000
max     15.0000000  15.0000000
sum    248.0000000 423.5000000

$CHG_HINE3_394$region_europe$numbers_eachgrp
       Control ISIS 396443
N           17  30.0000000
n            3   8.0000000
mean        -5   0.1875000
sd           0   1.1319231
se           0   0.4001953
median      -5   0.0000000
min         -5  -1.0000000
```

```
max         -5   2.5000000
sum        -15   1.5000000

$CHG_HINE3_394$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.18     0.199        -0.311         0.665
2     Control  -4.97     0.356        -5.843        -4.101

$CHG_HINE3_394$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   5.148584e+00    4.375399e-01    4.077963e+00    6.219206e+00    2.274561e-05

$CHG_HINE3_394$region_europe$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA


$CHG_HINE3_394$region_asiapacific
$CHG_HINE3_394$region_asiapacific$base
         Control ISIS 396443
N       2.000000  12.0000000
n       2.000000  12.0000000
mean   14.000000  13.5833333
sd      1.414214   2.3915888
se      1.000000   0.6903922
median 14.000000  15.0000000
min    13.000000   8.0000000
max    15.000000  15.0000000
sum    28.000000 163.0000000

$CHG_HINE3_394$region_asiapacific$numbers_eachgrp
       Control ISIS 396443
N            2          12
n            0           2
mean        NA           0
sd          NA           0
se          NA           0
median      NA           0
min         NA           0
max         NA           0
sum         NA           0

$CHG_HINE3_394$region_asiapacific$ls_mw
     TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
[1,]        NA     NA        NA            NA            NA
[2,]        NA     NA        NA            NA            NA

$CHG_HINE3_394$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
             NA              NA              NA              NA              NA

$CHG_HINE3_394$region_asiapacific$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
    NA     NA     NA     NA
```

```
$CHG_HINE3_394$region_northamerica
$CHG_HINE3_394$region_northamerica$base
           Control ISIS 396443
N       22.0000000  38.0000000
n       22.0000000  38.0000000
mean    14.2272727  13.8421053
sd       1.3068252   1.7324614
se       0.2786161   0.2810423
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    313.0000000 526.0000000

$CHG_HINE3_394$region_northamerica$numbers_eachgrp
          Control ISIS 396443
N       22.000000  38.0000000
n        8.000000  16.0000000
mean    -2.750000  -0.6250000
sd       3.991061   2.9410882
se       1.411053   0.7352721
median  -1.500000  -0.5000000
min     -9.000000  -4.0000000
max      1.000000   7.0000000
sum    -22.000000 -10.0000000

$CHG_HINE3_394$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  -0.69     0.684        -2.126         0.739
2     Control  -2.61     0.994        -4.694        -0.531

$CHG_HINE3_394$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      1.9192055       1.2494981      -0.6960241       4.5344352       0.1410287

$CHG_HINE3_394$region_northamerica$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.6200 -0.2500  1.4900  0.1628


$CHG_HINE3_394$disdur_gt_12wk
$CHG_HINE3_394$disdur_gt_12wk$base
           Control ISIS 396443
N       23.0000000  46.0000000
n       23.0000000  46.0000000
mean    14.4347826  13.9021739
sd       1.1609591   1.5972879
se       0.2420767   0.2355072
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    332.0000000 639.5000000
```

```
$CHG_HINE3_394$disdur_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N       23.000000  46.0000000
n        8.000000  15.0000000
mean    -3.250000  -0.5000000
sd       3.195980   2.3679406
se       1.129949   0.6113996
median  -4.500000   0.0000000
min     -8.000000  -4.0000000
max      1.000000   4.0000000
sum    -26.000000  -7.5000000

$CHG_HINE3_394$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443  -0.78     0.644        -2.137         0.570
2     Control  -2.72     0.930        -4.672        -0.764

$CHG_HINE3_394$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
      1.9340004       1.2159146      -0.6205414       4.4885423       0.1291152

$CHG_HINE3_394$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
0.9900 0.0780 1.9060 0.0334


$CHG_HINE3_394$disdur_le_12wek
$CHG_HINE3_394$disdur_le_12wek$base
           Control ISIS 396443
N       18.0000000  34.0000000
n       18.0000000  34.0000000
mean    14.2777778  13.9117647
sd       1.2274103   1.9285361
se       0.2893034   0.3307412
median  15.0000000  15.0000000
min     11.0000000   8.0000000
max     15.0000000  15.0000000
sum    257.0000000 473.0000000

$CHG_HINE3_394$disdur_le_12wek$numbers_eachgrp
          Control ISIS 396443
N       18.000000 34.00000000
n        3.000000 11.00000000
mean    -3.666667 -0.09090909
sd       5.033223  2.50816847
se       2.905933  0.75624125
median  -3.000000  0.00000000
min     -9.000000 -2.00000000
max      1.000000  7.00000000
sum    -11.000000 -1.00000000

$CHG_HINE3_394$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.17     0.644        -1.282         1.631
```

```
2     Control  -4.64     1.290        -7.557        -1.722

$CHG_HINE3_394$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    4.813816905     1.478631547     1.468919961     8.158713849     0.009908382

$CHG_HINE3_394$disdur_le_12wek$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 1.0900 -0.2740  2.4500  0.1175



\#############################################################################
[[1]]
[1] "Anteil von Hospitalisierungszeiten"

$ageonset_le_12wk
$ageonset_le_12wk$numbers_eachgrp
           Control ISIS 396443
N      32.00000000 72.00000000
n      32.00000000 72.00000000
mean    0.22579770  0.11465493
sd      0.19773328  0.12562599
se      0.03495464  0.01480516
median  0.17823529  0.08074074
min     0.00000000  0.00000000
max     0.75000000  0.56194690
sum     7.22552640  8.25515493

$ageonset_le_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.11     0.018         0.078         0.148
2     Control   0.23     0.027         0.177         0.282

$ageonset_le_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
  -0.1162727549    0.0319559220   -0.1796723940   -0.0528731158    0.0004359077

$ageonset_le_12wk$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.7300 -1.1580 -0.3010  0.0008


$ageonset_gt_12wk
$ageonset_gt_12wk$numbers_eachgrp
          Control ISIS 396443
N      9.00000000  8.00000000
n      9.00000000  8.00000000
mean   0.10504166  0.14959508
sd     0.10177992  0.19235417
se     0.03392664  0.06800747
median 0.07857143  0.06027427
min    0.01234568  0.00000000
```

```
max    0.34741784  0.50000000
sum    0.94537491  1.19676065

$ageonset_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.16     0.056         0.035         0.278
2     Control   0.10     0.053        -0.016         0.213

$ageonset_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
     0.05841247      0.07989110     -0.11418175      0.23100669      0.47765935

$ageonset_gt_12wk$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.2800 -0.6780  1.2390  0.5668


$agetrt_lt_180d
$agetrt_lt_180d$numbers_eachgrp
           Control ISIS 396443
N      16.00000000 49.00000000
n      16.00000000 49.00000000
mean    0.24522988  0.11732238
sd      0.23109995  0.13719268
se      0.05777499  0.01959895
median  0.15878533  0.07017544
min     0.00000000  0.00000000
max     0.75000000  0.56194690
sum     3.92367810  5.74879668

$agetrt_lt_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.12     0.023         0.069         0.162
2     Control   0.25     0.041         0.171         0.334

$agetrt_lt_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   -0.137111065     0.047053143    -0.231199640    -0.043022490     0.004982739

$agetrt_lt_180d$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.7700 -1.3490 -0.1880  0.0095


$agetrt_ge_180d
$agetrt_ge_180d$numbers_eachgrp
           Control ISIS 396443
N      25.00000000 31.00000000
n      25.00000000 31.00000000
mean    0.16988893  0.11945545
sd      0.15012065  0.12711813
se      0.03002413  0.02283109
median  0.11304348  0.08860759
min     0.00000000  0.00000000
```

```
max     0.57547170  0.50000000
sum     4.24722321  3.70311890

$agetrt_ge_180d$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.11     0.025         0.065         0.165
2     Control   0.18     0.028         0.120         0.231

$agetrt_ge_180d$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    -0.06044716      0.03744420     -0.13558445      0.01469013      0.11250920

$agetrt_ge_180d$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.3600 -0.8920  0.1710  0.1832


$sex_m
$sex_m$numbers_eachgrp
           Control ISIS 396443
N      17.00000000 37.00000000
n      17.00000000 37.00000000
mean    0.19995025  0.14083847
sd      0.22644075  0.15370454
se      0.05491995  0.02526887
median  0.07808564  0.08750000
min     0.00000000  0.00000000
max     0.75000000  0.56194690
sum     3.39915431  5.21102333

$sex_m$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.14     0.030          0.08         0.201
2     Control   0.20     0.045          0.11         0.290

$sex_m$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    -0.05880234      0.05427419     -0.16781526      0.05021059      0.28381426

$sex_m$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.3200 -0.9030  0.2530  0.2703


$sex_f
$sex_f$numbers_eachgrp
           Control ISIS 396443
N      24.00000000 43.00000000
n      24.00000000 43.00000000
mean    0.19882279  0.09862540
sd      0.15837980  0.10936650
se      0.03232914  0.01667823
median  0.17009927  0.06483791
min     0.00000000  0.00000000
```

```
max     0.57547170  0.43290043
sum     4.77174700  4.24089226

$sex_f$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.09     0.018         0.052         0.126
2     Control   0.22     0.025         0.165         0.266

$sex_f$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
  -0.1267714076    0.0324010104   -0.1915196603   -0.0620231549    0.0002265118

$sex_f$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.7700 -1.2860 -0.2510  0.0036


$region_europe
$region_europe$numbers_eachgrp
           Control ISIS 396443
N      17.00000000 30.00000000
n      17.00000000 30.00000000
mean    0.19760249  0.13021475
sd      0.15768499  0.15104512
se      0.03824423  0.02757694
median  0.16372796  0.09023241
min     0.00000000  0.00000000
max     0.56962025  0.56194690
sum     3.35924235  3.90644247

$region_europe$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.12     0.028         0.068         0.181
2     Control   0.21     0.037         0.133         0.283

$region_europe$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    -0.08313747      0.04708285     -0.17808910      0.01181415      0.08453435

$region_europe$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.4300 -1.0340  0.1700  0.1597


$region_asiapacific
$region_asiapacific$numbers_eachgrp
         Control ISIS 396443
N      2.0000000 12.00000000
n      2.0000000 12.00000000
mean   0.4315217  0.10610799
sd     0.4503963  0.13281702
se     0.3184783  0.03834097
median 0.4315217  0.05801802
min    0.1130435  0.00000000
```

```
max    0.7500000  0.43290043
sum    0.8630435  1.27329589

$region_asiapacific$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.09     0.044         -0.01         0.188
2     Control   0.53     0.114          0.28         0.787

$region_asiapacific$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    -0.44406645      0.12412532     -0.72063491     -0.16749799      0.00503203

$region_asiapacific$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-1.6800 -3.3410 -0.0090  0.0488


$region_northamerica
$region_northamerica$numbers_eachgrp
          Control ISIS 396443
N      22.0000000 38.00000000
n      22.0000000 38.00000000
mean    0.1794825  0.11242572
sd      0.1799633  0.11915066
se      0.0383683  0.01932879
median  0.1098551  0.06750667
min     0.0000000  0.00500000
max     0.6557377  0.50000000
sum     3.9486155  4.27217722

$region_northamerica$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.11     0.023         0.061         0.155
2     Control   0.19     0.031         0.125         0.250

$region_northamerica$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
  -0.0798780314    0.0394975683   -0.1590011685   -0.0007548943    0.0479260646

$region_northamerica$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.4600 -0.9910  0.0730  0.0907


$disdur_gt_12wk
$disdur_gt_12wk$numbers_eachgrp
           Control ISIS 396443
N      23.00000000 46.00000000
n      23.00000000 46.00000000
mean    0.22491793  0.11834681
sd      0.20188970  0.11893208
se      0.04209691  0.01753558
median  0.18000000  0.08805380
min     0.00000000  0.00000000
```

```
max     0.75000000  0.43290043
sum     5.17311237  5.44395342

$disdur_gt_12wk$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.11     0.022         0.068         0.156
2     Control   0.24     0.032         0.174         0.300

$disdur_gt_12wk$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
   -0.125362150     0.038990315    -0.203231186    -0.047493114     0.002031477

$disdur_gt_12wk$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
-0.700 -1.211 -0.182  0.008


$disdur_le_12wek
$disdur_le_12wek$numbers_eachgrp
           Control ISIS 396443
N      18.00000000 34.00000000
n      18.00000000 34.00000000
mean    0.16654383  0.11788124
sd      0.16560749  0.15093474
se      0.03903406  0.02588509
median  0.10561735  0.05531972
min     0.00000000  0.00000000
max     0.65573770  0.56194690
sum     2.99778894  4.00796217

$disdur_le_12wek$ls_mw
    TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1 ISIS 396443   0.11     0.027         0.061         0.169
2     Control   0.17     0.037         0.097         0.247

$disdur_le_12wek$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv
    -0.05720275      0.04658303     -0.15086421      0.03645871      0.22544440

$disdur_le_12wek$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.3100 -0.8820  0.2680  0.2949



\#############################################################################
[[1]]
[1] "Häufigkeit von Hospitalisierungen"

$ageonset_le_12wk
$ageonset_le_12wk$nsubj

    Control ISIS 396443
         32          72
```

```
$ageonset_le_12wk$numbers_eachgrp
         Control ISIS 396443
n      32.000000  72.0000000
mean    2.906250   3.5555556
sd      2.387594   2.7725459
se      0.422071   0.3267477
median  2.000000   3.0000000
min     0.000000   0.0000000
max    11.000000  12.0000000
sum    93.000000 256.0000000

$ageonset_le_12wk$n_ptyear
    CTRL      TRT
18.00958 54.24504

$ageonset_le_12wk$rate_unadj
    CTRL      TRT
5.163918 4.719326

$ageonset_le_12wk$rate_adj
           CTRL      TRT
est    6.173250 4.741430
lo95ci 4.565101 3.946415
hi95ci 8.347903 5.696602

$ageonset_le_12wk$RR_TRTvsCTRL
      est    lo95ci    hi95ci        se        pv
0.7680604 0.5388880 1.0946927 0.1807995 0.1444123


$ageonset_gt_12wk
$ageonset_gt_12wk$nsubj

    Control ISIS 396443
          9           8

$ageonset_gt_12wk$numbers_eachgrp
          Control ISIS 396443
n       9.0000000   8.0000000
mean    2.8888889   1.0000000
sd      2.0275875   0.7559289
se      0.6758625   0.2672612
median  2.0000000   1.0000000
min     1.0000000   0.0000000
max     6.0000000   2.0000000
sum    26.0000000   8.0000000

$ageonset_gt_12wk$n_ptyear
    CTRL      TRT
7.378508 3.794661

$ageonset_gt_12wk$rate_unadj
    CTRL      TRT
```

```
3.523748 2.108225

$ageonset_gt_12wk$rate_adj
       CTRL TRT
est      NA  NA
lo95ci   NA  NA
hi95ci   NA  NA

$ageonset_gt_12wk$RR_TRTvsCTRL
   est lo95ci hi95ci     se     pv
    NA     NA     NA     NA     NA


$agetrt_lt_180d
$agetrt_lt_180d$nsubj

    Control ISIS 396443
         16          49

$agetrt_lt_180d$numbers_eachgrp
          Control ISIS 396443
n      16.0000000  49.0000000
mean    3.3125000   3.4489796
sd      2.6512576   2.7314619
se      0.6628144   0.3902088
median  3.5000000   2.0000000
min     0.0000000   0.0000000
max    11.0000000  10.0000000
sum    53.0000000 169.0000000

$agetrt_lt_180d$n_ptyear
     CTRL       TRT
 8.303901 35.994524

$agetrt_lt_180d$rate_unadj
    CTRL      TRT
6.382542 4.695159

$agetrt_lt_180d$rate_adj
            CTRL      TRT
est     7.151316 4.622535
lo95ci  4.809728 3.716791
hi95ci 10.632892 5.749001

$agetrt_lt_180d$RR_TRTvsCTRL
       est     lo95ci     hi95ci         se         pv
0.64639087 0.41032847 1.01826019 0.23186466 0.05984678


$agetrt_ge_180d
$agetrt_ge_180d$nsubj

    Control ISIS 396443
         25          31
```

```
$agetrt_ge_180d$numbers_eachgrp
          Control ISIS 396443
n      25.0000000  31.0000000
mean    2.6400000   3.0645161
sd      2.0387905   2.8039910
se      0.4077581   0.5036117
median  2.0000000   2.0000000
min     0.0000000   0.0000000
max     7.0000000  12.0000000
sum    66.0000000  95.0000000

$agetrt_ge_180d$n_ptyear
    CTRL      TRT
17.08419 22.04517

$agetrt_ge_180d$rate_unadj
    CTRL      TRT
3.863221 4.309333

$agetrt_ge_180d$rate_adj
           CTRL      TRT
est    4.517408 4.165529
lo95ci 3.193563 3.074425
hi95ci 6.390032 5.643862

$agetrt_ge_180d$RR_TRTvsCTRL
      est    lo95ci    hi95ci        se        pv
0.9221330 0.5752041 1.4783089 0.2408027 0.7363821


$sex_m
$sex_m$nsubj

    Control ISIS 396443
         17          37

$sex_m$numbers_eachgrp
          Control ISIS 396443
n      17.0000000  37.0000000
mean    2.3529412   3.0000000
sd      1.4975470   2.3570226
se      0.3632085   0.3874921
median  2.0000000   2.0000000
min     0.0000000   0.0000000
max     5.0000000   9.0000000
sum    40.0000000 111.0000000

$sex_m$n_ptyear
    CTRL      TRT
10.00684 25.54415

$sex_m$rate_unadj
    CTRL      TRT
```

```
3.997264 4.345418

$sex_m$rate_adj
           CTRL      TRT
est    4.285558 4.270055
lo95ci 2.951130 3.382054
hi95ci 6.223381 5.391212

$sex_m$RR_TRTvsCTRL
      est    lo95ci    hi95ci        se        pv
0.9963827 0.6424625 1.5452705 0.2238933 0.9870862


$sex_f
$sex_f$nsubj

    Control ISIS 396443
         24          43

$sex_f$numbers_eachgrp
          Control ISIS 396443
n      24.0000000  43.0000000
mean    3.2916667   3.5581395
sd      2.6780779   3.0496083
se      0.5466604   0.4650609
median  2.0000000   3.0000000
min     0.0000000   0.0000000
max    11.0000000  12.0000000
sum    79.0000000 153.0000000

$sex_f$n_ptyear
    CTRL      TRT
15.38125 32.49555

$sex_f$rate_unadj
    CTRL      TRT
5.136125 4.708337

$sex_f$rate_adj
            CTRL      TRT
est     7.184850 4.142878
lo95ci  5.014169 3.182946
hi95ci 10.295239 5.392313

$sex_f$RR_TRTvsCTRL
       est     lo95ci     hi95ci         se         pv
0.57661322 0.35982332 0.92401685 0.24059554 0.02211309


$region_europe
$region_europe$nsubj

    Control ISIS 396443
         17          30
```

```
$region_europe$numbers_eachgrp
          Control ISIS 396443
n      17.0000000  30.0000000
mean    3.0588235   3.3333333
sd      2.7034836   3.1876197
se      0.6556911   0.5819771
median  2.0000000   2.0000000
min     0.0000000   0.0000000
max    11.0000000  10.0000000
sum    52.0000000 100.0000000

$region_europe$n_ptyear
     CTRL       TRT
 9.850787 21.075975

$region_europe$rate_unadj
    CTRL      TRT
5.278766 4.744739

$region_europe$rate_adj
            CTRL      TRT
est     6.531649 4.188686
lo95ci  4.258325 3.018920
hi95ci 10.018598 5.811711

$region_europe$RR_TRTvsCTRL
      est    lo95ci    hi95ci        se        pv
0.6412880 0.3732835 1.1017104 0.2760972 0.1075876


$region_asiapacific
$region_asiapacific$nsubj

    Control ISIS 396443
          2          12

$region_asiapacific$numbers_eachgrp
        Control ISIS 396443
n      2.000000  12.0000000
mean   3.500000   3.9166667
sd     3.535534   2.7455198
se     2.500000   0.7925633
median 3.500000   4.5000000
min    1.000000   0.0000000
max    6.000000   8.0000000
sum    7.000000  47.0000000

$region_asiapacific$n_ptyear
     CTRL       TRT
0.9993155 7.7864476

$region_asiapacific$rate_unadj
    CTRL      TRT
```

```
7.004795 6.036129

$region_asiapacific$rate_adj
           CTRL      TRT
est    21.99931 4.879756
lo95ci  7.20082 3.350950
hi95ci 67.21038 7.106051

$region_asiapacific$RR_TRTvsCTRL
       est     lo95ci     hi95ci         se         pv
0.22181397 0.06025842 0.81650732 0.66490856 0.02352206


$region_northamerica
$region_northamerica$nsubj

    Control ISIS 396443
         22          38

$region_northamerica$numbers_eachgrp
          Control ISIS 396443
n      22.0000000  38.0000000
mean    2.7272727   3.0789474
sd      1.9317354   2.3979899
se      0.4118474   0.3890053
median  2.5000000   2.0000000
min     0.0000000   1.0000000
max     7.0000000  12.0000000
sum    60.0000000 117.0000000

$region_northamerica$n_ptyear
    CTRL      TRT
14.53799 29.17728

$region_northamerica$rate_unadj
    CTRL      TRT
4.127119 4.009970

$region_northamerica$rate_adj
           CTRL      TRT
est    4.342329 3.991481
lo95ci 3.196800 3.186820
hi95ci 5.898343 4.999317

$region_northamerica$RR_TRTvsCTRL
      est    lo95ci    hi95ci        se        pv
0.9192028 0.6216407 1.3591994 0.1995671 0.6729109


$disdur_gt_12wk
$disdur_gt_12wk$nsubj

    Control ISIS 396443
         23          46
```

```
$disdur_gt_12wk$numbers_eachgrp
          Control ISIS 396443
n      23.0000000  46.0000000
mean    2.6521739   3.3478261
sd      2.0362331   2.7504940
se      0.4245839   0.4055382
median  2.0000000   2.0000000
min     0.0000000   0.0000000
max     7.0000000  12.0000000
sum    61.0000000 154.0000000

$disdur_gt_12wk$n_ptyear
    CTRL      TRT
14.31622 32.61054

$disdur_gt_12wk$rate_unadj
    CTRL      TRT
4.260901 4.722399

$disdur_gt_12wk$rate_adj
           CTRL      TRT
est    5.723403 4.820684
lo95ci 3.855069 3.732281
hi95ci 8.497213 6.226485

$disdur_gt_12wk$RR_TRTvsCTRL
      est    lo95ci    hi95ci        se        pv
0.8422758 0.5226811 1.3572875 0.2434412 0.4807547


$disdur_le_12wek
$disdur_le_12wek$nsubj

    Control ISIS 396443
         18          34

$disdur_le_12wek$numbers_eachgrp
          Control ISIS 396443
n      18.0000000  34.0000000
mean    3.2222222   3.2352941
sd      2.6021610   2.7858824
se      0.6133352   0.4777749
median  3.0000000   2.0000000
min     0.0000000   0.0000000
max    11.0000000  10.0000000
sum    58.0000000 110.0000000

$disdur_le_12wek$n_ptyear
    CTRL      TRT
11.07187 25.42916

$disdur_le_12wek$rate_unadj
    CTRL      TRT
```

```
5.238501 4.325743

$disdur_le_12wek$rate_adj
           CTRL      TRT
est    5.721223 3.817469
lo95ci 4.113062 2.973116
hi95ci 7.958155 4.901614

$disdur_le_12wek$RR_TRTvsCTRL
       est     lo95ci     hi95ci         se         pv
0.66724691 0.43737593 1.01793080 0.21549736 0.06045034



\##############################################################################
[[1]]
[1] "Zeit bis zur Hospitalisierung"

$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                             30.0               66.0
n_event_pct                         94.0               92.0
time-to-event-wk-10th                0.1                0.7
time-to-event-wk-25th                1.2                2.0
time-to-event-wk-50th                6.1                4.4
time-to-event-wk-75th               11.4               11.9
time-to-event-wk-90th               15.7               34.7
time-to-event-wk-50th-loci           2.3                2.4
time-to-event-wk-50th-hici           9.4                6.0

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9752    0.2254    0.6270    1.5170    0.9113


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               9.0                8.0
n_event                             9.0                6.0
n_event_pct                       100.0               75.0
time-to-event-wk-10th               1.7                0.6
time-to-event-wk-25th               2.3                1.8
time-to-event-wk-50th              15.3                4.2
time-to-event-wk-75th              16.4               26.8
time-to-event-wk-90th              23.0                 NA
time-to-event-wk-50th-loci          1.7                0.6
time-to-event-wk-50th-hici         18.0                 NA

$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7059    0.5730    0.2296    2.1700    0.5434
```

```
$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                              15.0               44.0
n_event_pct                          94.0               90.0
time-to-event-wk-10th                 0.1                1.0
time-to-event-wk-25th                 1.9                2.0
time-to-event-wk-50th                 7.3                4.1
time-to-event-wk-75th                 9.4               16.1
time-to-event-wk-90th                12.7               34.7
time-to-event-wk-50th-loci            0.9                2.4
time-to-event-wk-50th-hici            9.4                8.9

$agetrt_lt_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7260    0.3159    0.3909    1.3480    0.3108


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              24.0               28.0
n_event_pct                          96.0               90.0
time-to-event-wk-10th                 0.6                0.6
time-to-event-wk-25th                 2.1                1.4
time-to-event-wk-50th                 5.7                5.0
time-to-event-wk-75th                15.7               11.0
time-to-event-wk-90th                23.0               30.9
time-to-event-wk-50th-loci            2.3                2.0
time-to-event-wk-50th-hici           15.3                6.9

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0760    0.2837    0.6173    1.8770    0.7952


$sex_m
$sex_m$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                              16.0               35.0
n_event_pct                          94.0               95.0
time-to-event-wk-10th                 0.6                0.6
time-to-event-wk-25th                 1.7                1.9
time-to-event-wk-50th                 9.6                3.0
time-to-event-wk-75th                15.7                9.0
time-to-event-wk-90th                18.0               30.9
time-to-event-wk-50th-loci            0.9                2.0
time-to-event-wk-50th-hici           14.1                5.7
```

```
$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3700    0.3133    0.7412    2.5310    0.3153


$sex_f
$sex_f$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                             23.0               37.0
n_event_pct                         96.0               86.0
time-to-event-wk-10th                0.1                1.1
time-to-event-wk-25th                2.2                2.1
time-to-event-wk-50th                4.9                5.0
time-to-event-wk-75th               12.4               25.4
time-to-event-wk-90th               15.9               34.7
time-to-event-wk-50th-loci           2.3                2.9
time-to-event-wk-50th-hici           9.0               10.7

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7555    0.2820    0.4347    1.3130    0.3202


$region_europe
$region_europe$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                             16.0               24.0
n_event_pct                         94.0               80.0
time-to-event-wk-10th                0.1                0.9
time-to-event-wk-25th                2.3                2.0
time-to-event-wk-50th                6.1                5.4
time-to-event-wk-75th               12.7               11.6
time-to-event-wk-90th               16.4                 NA
time-to-event-wk-50th-loci           0.6                2.6
time-to-event-wk-50th-hici          12.7               10.7

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8919    0.3322    0.4651    1.7100    0.7304


$region_asiapacific
$region_asiapacific$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0               12.0
n_event                              2.0               10.0
n_event_pct                        100.0               83.0
time-to-event-wk-10th                0.9                0.6
time-to-event-wk-25th                0.9                2.0
time-to-event-wk-50th                1.6                2.1
time-to-event-wk-75th                2.3               27.9
time-to-event-wk-90th                2.3               43.6
```

```
time-to-event-wk-50th-loci            0.9                0.6
time-to-event-wk-50th-hici             NA                 NA

$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6308    0.7970    0.1323    3.0080    0.5632


$region_northamerica
$region_northamerica$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              21.0               38.0
n_event_pct                          95.0              100.0
time-to-event-wk-10th                 0.7                0.6
time-to-event-wk-25th                 2.1                2.0
time-to-event-wk-50th                 8.6                4.9
time-to-event-wk-75th                15.7               13.0
time-to-event-wk-90th                18.0               30.9
time-to-event-wk-50th-loci            2.1                2.4
time-to-event-wk-50th-hici           13.7                6.9

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2190    0.2805    0.7033    2.1120    0.4807


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              22.0               43.0
n_event_pct                          96.0               93.0
time-to-event-wk-10th                 0.1                0.6
time-to-event-wk-25th                 0.9                2.0
time-to-event-wk-50th                 4.0                5.2
time-to-event-wk-75th                13.7               11.0
time-to-event-wk-90th                15.7               25.4
time-to-event-wk-50th-loci            1.6                2.1
time-to-event-wk-50th-hici           11.0                8.3

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0850    0.2706    0.6383    1.8440    0.7636


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                              17.0               29.0
n_event_pct                          94.0               85.0
time-to-event-wk-10th                 0.7                0.7
time-to-event-wk-25th                 3.0                2.0
```

```
time-to-event-wk-50th                 8.7                3.1
time-to-event-wk-75th                15.7               31.6
time-to-event-wk-90th                18.0               40.4
time-to-event-wk-50th-loci            3.0                2.1
time-to-event-wk-50th-hici           15.7               10.7

$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8442    0.3238    0.4475    1.5920    0.6008



\#############################################################################
[[1]]
[1] "Häufigkeit von schwerwiegenden respiratorischen Ereignissen"

$ageonset_le_12wk
$ageonset_le_12wk$nsubj

    Control ISIS 396443
         32          72

$ageonset_le_12wk$numbers_eachgrp
          Control ISIS 396443
n      32.0000000   72.000000
mean    2.2187500    1.944444
sd      2.3242671    2.437321
se      0.4108763    0.287241
median  2.0000000    1.000000
min     0.0000000    0.000000
max     9.0000000    9.000000
sum    71.0000000  140.000000

$ageonset_le_12wk$n_ptyear
    CTRL      TRT
18.00958 54.24504

$ageonset_le_12wk$rate_unadj
    CTRL      TRT
3.942346 2.580881

$ageonset_le_12wk$rate_adj
           CTRL      TRT
est    4.787783 2.588529
lo95ci 3.101646 1.944780
hi95ci 7.390548 3.445368

$ageonset_le_12wk$RR_TRTvsCTRL
       est     lo95ci     hi95ci         se         pv
0.54065239 0.32042562 0.91223982 0.26690611 0.02121696


$ageonset_gt_12wk
$ageonset_gt_12wk$nsubj
```

```
    Control ISIS 396443
          9           8

$ageonset_gt_12wk$numbers_eachgrp
          Control ISIS 396443
n       9.0000000   8.0000000
mean    1.1111111   0.7500000
sd      1.4529663   0.8864053
se      0.4843221   0.3133916
median  1.0000000   0.5000000
min     0.0000000   0.0000000
max     4.0000000   2.0000000
sum    10.0000000   6.0000000

$ageonset_gt_12wk$n_ptyear
    CTRL      TRT
7.378508 3.794661

$ageonset_gt_12wk$rate_unadj
    CTRL      TRT
1.355288 1.581169

$ageonset_gt_12wk$rate_adj
            CTRL        TRT
est    1.4172962  3.6676753
lo95ci 0.4053249  0.7559341
hi95ci 4.9558477 17.7949922

$ageonset_gt_12wk$RR_TRTvsCTRL
       est     lo95ci     hi95ci          se          pv
 2.5878027  0.3579594 18.7080529  1.0092762  0.3461566


$agetrt_lt_180d
$agetrt_lt_180d$nsubj

    Control ISIS 396443
         16          49

$agetrt_lt_180d$numbers_eachgrp
          Control ISIS 396443
n      16.0000000  49.0000000
mean    2.8750000   1.8775510
sd      2.7049338   2.4378325
se      0.6762334   0.3482618
median  2.0000000   1.0000000
min     0.0000000   0.0000000
max     9.0000000   9.0000000
sum    46.0000000  92.0000000

$agetrt_lt_180d$n_ptyear
     CTRL       TRT
 8.303901 35.994524
```

```
$agetrt_lt_180d$rate_unadj
    CTRL      TRT
5.539565 2.555944

$agetrt_lt_180d$rate_adj
            CTRL      TRT
est     5.883801 2.384003
lo95ci  3.403995 1.708623
hi95ci 10.170143 3.326345

$agetrt_lt_180d$RR_TRTvsCTRL
       est     lo95ci     hi95ci         se         pv
0.40518062 0.21214036 0.77388073 0.33015138 0.00621177


$agetrt_ge_180d
$agetrt_ge_180d$nsubj

    Control ISIS 396443
         25          31

$agetrt_ge_180d$numbers_eachgrp
         Control ISIS 396443
n      25.000000  31.0000000
mean    1.400000   1.7419355
sd      1.607275   2.2504480
se      0.321455   0.4041924
median  1.000000   1.0000000
min     0.000000   0.0000000
max     7.000000   9.0000000
sum    35.000000  54.0000000

$agetrt_ge_180d$n_ptyear
    CTRL      TRT
17.08419 22.04517

$agetrt_ge_180d$rate_unadj
    CTRL      TRT
2.048678 2.449516

$agetrt_ge_180d$rate_adj
           CTRL      TRT
est    2.747403 2.847379
lo95ci 1.530795 1.700588
hi95ci 4.930918 4.767509

$agetrt_ge_180d$RR_TRTvsCTRL
      est    lo95ci    hi95ci        se        pv
1.0363912 0.4717428 2.2768906 0.4015717 0.9290725


$sex_m
$sex_m$nsubj
```

```
    Control ISIS 396443
         17          37

$sex_m$numbers_eachgrp
         Control ISIS 396443
n      17.000000  37.0000000
mean    1.882353   1.6216216
sd      2.315231   2.0863492
se      0.561526   0.3429937
median  1.000000   1.0000000
min     0.000000   0.0000000
max     9.000000   7.0000000
sum    32.000000  60.0000000

$sex_m$n_ptyear
    CTRL      TRT
10.00684 25.54415

$sex_m$rate_unadj
    CTRL      TRT
3.197811 2.348875

$sex_m$rate_adj
           CTRL      TRT
est    3.596641 2.921925
lo95ci 1.852842 1.809909
hi95ci 6.981614 4.717168

$sex_m$RR_TRTvsCTRL
      est    lo95ci    hi95ci        se        pv
0.8124062 0.3558459 1.8547463 0.4211826 0.6218251


$sex_f
$sex_f$nsubj

    Control ISIS 396443
         24          43

$sex_f$numbers_eachgrp
          Control ISIS 396443
n      24.0000000  43.0000000
mean    2.0416667   2.0000000
sd      2.1564699   2.5727510
se      0.4401876   0.3923408
median  1.5000000   1.0000000
min     0.0000000   0.0000000
max     7.0000000   9.0000000
sum    49.0000000  86.0000000

$sex_f$n_ptyear
    CTRL      TRT
15.38125 32.49555
```

```
$sex_f$rate_unadj
    CTRL      TRT
3.185698 2.646516

$sex_f$rate_adj
           CTRL      TRT
est    4.471242 2.104413
lo95ci 2.741830 1.443656
hi95ci 7.291483 3.067596

$sex_f$RR_TRTvsCTRL
       est     lo95ci     hi95ci         se         pv
0.47066463 0.24635579 0.89920841 0.33029639 0.02251203


$region_europe
$region_europe$nsubj

    Control ISIS 396443
         17          30

$region_europe$numbers_eachgrp
          Control ISIS 396443
n      17.0000000  30.0000000
mean    1.5882353   1.8000000
sd      2.0633354   2.2803509
se      0.5004323   0.4163332
median  1.0000000   1.0000000
min     0.0000000   0.0000000
max     7.0000000   7.0000000
sum    27.0000000  54.0000000

$region_europe$n_ptyear
     CTRL       TRT
 9.850787 21.075975

$region_europe$rate_unadj
    CTRL      TRT
2.740898 2.562159

$region_europe$rate_adj
           CTRL      TRT
est    3.686339 2.627477
lo95ci 1.866076 1.584813
hi95ci 7.282179 4.356119

$region_europe$RR_TRTvsCTRL
      est    lo95ci    hi95ci        se        pv
0.7127601 0.3055281 1.6627829 0.4322034 0.4333620


$region_asiapacific
$region_asiapacific$nsubj
```

```
    Control ISIS 396443
          2          12

$region_asiapacific$numbers_eachgrp
         Control ISIS 396443
n      2.0000000  12.0000000
mean   0.5000000   0.3333333
sd     0.7071068   0.8876254
se     0.5000000   0.2562354
median 0.5000000   0.0000000
min    0.0000000   0.0000000
max    1.0000000   3.0000000
sum    1.0000000   4.0000000

$region_asiapacific$n_ptyear
     CTRL       TRT
0.9993155 7.7864476

$region_asiapacific$rate_unadj
     CTRL       TRT
1.0006849 0.5137131

$region_asiapacific$rate_adj
               CTRL        TRT
est      3.45819055 0.30787761
lo95ci   0.09599037 0.03608627
hi95ci 124.58626378 2.62672282

$region_asiapacific$RR_TRTvsCTRL
        est      lo95ci      hi95ci          se          pv
0.089030571 0.001814637 4.368058870 1.986309047 0.223329011


$region_northamerica
$region_northamerica$nsubj

    Control ISIS 396443
         22          38

$region_northamerica$numbers_eachgrp
          Control ISIS 396443
n      22.0000000  38.0000000
mean    2.4090909   2.3157895
sd      2.3229515   2.5585602
se      0.4952549   0.4150533
median  2.0000000   1.5000000
min     0.0000000   0.0000000
max     9.0000000   9.0000000
sum    53.0000000  88.0000000

$region_northamerica$n_ptyear
    CTRL      TRT
14.53799 29.17728
```

```
$region_northamerica$rate_unadj
    CTRL      TRT
3.645621 3.016046

$region_northamerica$rate_adj
           CTRL      TRT
est    4.139087 2.947148
lo95ci 2.672246 2.063099
hi95ci 6.411101 4.210017

$region_northamerica$RR_TRTvsCTRL
      est    lo95ci    hi95ci        se        pv
0.7120299 0.3977193 1.2747348 0.2971348 0.2530243


$disdur_gt_12wk
$disdur_gt_12wk$nsubj

    Control ISIS 396443
         23          46

$disdur_gt_12wk$numbers_eachgrp
          Control ISIS 396443
n      23.0000000  46.0000000
mean    1.5217391   1.7173913
sd      1.8057878   2.1360716
se      0.3765328   0.3149466
median  1.0000000   1.0000000
min     0.0000000   0.0000000
max     7.0000000   9.0000000
sum    35.0000000  79.0000000

$disdur_gt_12wk$n_ptyear
    CTRL      TRT
14.31622 32.61054

$disdur_gt_12wk$rate_unadj
    CTRL      TRT
2.444779 2.422530

$disdur_gt_12wk$rate_adj
           CTRL      TRT
est    3.683030 2.763321
lo95ci 1.973909 1.818957
hi95ci 6.872002 4.197980

$disdur_gt_12wk$RR_TRTvsCTRL
      est    lo95ci    hi95ci        se        pv
0.7502847 0.3540688 1.5898808 0.3831507 0.4533497


$disdur_le_12wek
$disdur_le_12wek$nsubj
```

```
    Control ISIS 396443
         18          34

$disdur_le_12wek$numbers_eachgrp
          Control ISIS 396443
n      18.0000000  34.0000000
mean    2.5555556   1.9705882
sd      2.5488688   2.6455829
se      0.6007741   0.4537137
median  2.0000000   1.0000000
min     0.0000000   0.0000000
max     9.0000000   9.0000000
sum    46.0000000  67.0000000

$disdur_le_12wek$n_ptyear
    CTRL      TRT
11.07187 25.42916

$disdur_le_12wek$rate_unadj
    CTRL      TRT
4.154674 2.634771

$disdur_le_12wek$rate_adj
           CTRL      TRT
est    4.105627 2.053948
lo95ci 2.618171 1.418158
hi95ci 6.438147 2.974774

$disdur_le_12wek$RR_TRTvsCTRL
       est     lo95ci     hi95ci         se         pv
0.50027631 0.27702212 0.90345271 0.30156840 0.02163919



\#############################################################################
[[1]]
[1] "Zeit bis zu schwerwiegenden respiratorischen Ereignissen"

$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              25.0               44.0
n_event_pct                          78.0               61.0
time-to-event-wk-10th                 1.0                1.7
time-to-event-wk-25th                 3.3                5.7
time-to-event-wk-50th                 9.0               15.6
time-to-event-wk-75th                22.4                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            4.0               10.0
time-to-event-wk-50th-hici           15.7               32.7

$ageonset_le_12wk$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.63630   0.25520   0.38580   1.04900   0.07652


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               5.0                4.0
n_event_pct                          56.0               50.0
time-to-event-wk-10th                 1.7                0.6
time-to-event-wk-25th                16.4                2.9
time-to-event-wk-50th                26.0               41.3
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.7                0.6
time-to-event-wk-50th-hici             NA                 NA

$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2390    0.7083    0.3093    4.9670    0.7619


$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                              13.0               27.0
n_event_pct                          81.0               55.0
time-to-event-wk-10th                 0.9                1.7
time-to-event-wk-25th                 4.7                5.0
time-to-event-wk-50th                 8.6               32.1
time-to-event-wk-75th                15.7                 NA
time-to-event-wk-90th                22.4                 NA
time-to-event-wk-50th-loci            3.4               10.0
time-to-event-wk-50th-hici           15.7                 NA

$agetrt_lt_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.396800  0.356000  0.197500  0.797300  0.009423


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              17.0               21.0
n_event_pct                          68.0               68.0
time-to-event-wk-10th                 1.7                0.6
time-to-event-wk-25th                 4.0                5.7
time-to-event-wk-50th                15.9               11.6
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            4.6                7.1
```

```
time-to-event-wk-50th-hici           52.6                26.9

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9772    0.3297    0.5120    1.8650    0.9442


$sex_m
$sex_m$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                              12.0               24.0
n_event_pct                          71.0               65.0
time-to-event-wk-10th                 0.7                0.7
time-to-event-wk-25th                 1.7                4.1
time-to-event-wk-50th                16.4               11.3
time-to-event-wk-75th                52.6                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.0                5.7
time-to-event-wk-50th-hici           52.6               26.9

$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9298    0.3600    0.4592    1.8830    0.8398


$sex_f
$sex_f$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              18.0               24.0
n_event_pct                          75.0               56.0
time-to-event-wk-10th                 2.9                3.6
time-to-event-wk-25th                 4.3                8.6
time-to-event-wk-50th                11.4               32.1
time-to-event-wk-75th                26.0                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            4.6               11.4
time-to-event-wk-50th-hici           15.9                 NA

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7173    0.3254    0.3790    1.3570    0.3072


$region_europe
$region_europe$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                              11.0               19.0
n_event_pct                          65.0               63.0
time-to-event-wk-10th                 3.4                0.9
time-to-event-wk-25th                 6.1                5.7
time-to-event-wk-50th                13.0               11.5
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            6.0                 8.6
time-to-event-wk-50th-hici             NA                  NA

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1780    0.3991    0.5389    2.5760    0.6812


$region_asiapacific
$region_asiapacific$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                12.0
n_event                              1.0                 2.0
n_event_pct                         50.0                17.0
time-to-event-wk-10th                0.9                12.3
time-to-event-wk-25th                0.9                  NA
time-to-event-wk-50th               25.1                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci           0.9                12.3
time-to-event-wk-50th-hici            NA                  NA

$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.125100  1.466000  0.007071  2.215000  0.156300


$region_northamerica
$region_northamerica$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38.0
n_event                             18.0                27.0
n_event_pct                         82.0                71.0
time-to-event-wk-10th                1.0                 1.6
time-to-event-wk-25th                2.9                 4.1
time-to-event-wk-50th               13.9                14.6
time-to-event-wk-75th               22.4                43.4
time-to-event-wk-90th               52.6                  NA
time-to-event-wk-50th-loci           2.9                 5.0
time-to-event-wk-50th-hici          17.9                32.1

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6579    0.3088    0.3592    1.2050    0.1752


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0                46.0
n_event                             16.0                29.0
n_event_pct                         70.0                63.0
```

```
time-to-event-wk-10th                1.6               1.7
time-to-event-wk-25th                3.1               5.7
time-to-event-wk-50th               13.9              11.9
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           3.4               8.6
time-to-event-wk-50th-hici          52.6              26.9

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8991    0.3156    0.4843    1.6690    0.7362


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                              14.0               19.0
n_event_pct                          78.0               56.0
time-to-event-wk-10th                 1.0                1.0
time-to-event-wk-25th                 6.3                4.7
time-to-event-wk-50th                13.0               32.1
time-to-event-wk-75th                17.9                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            6.3                8.6
time-to-event-wk-50th-hici           17.9                 NA

$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6401    0.3661    0.3124    1.3120    0.2230



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem UE"

$ageonset_le_12wk
$ageonset_le_12wk$ntab
            CTRL TRT
n_all         32  72
n_event       31  69
n_event_pct   97  96

$ageonset_le_12wk$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.98924731 0.04014884  0.91438717 1.0702362 0.7877212
OR_TRTvsCTRL   0.74193548 1.17476983  0.07419938 7.4187722 0.7994288
ARR_TRTvsCTRL -0.01041667 0.03873804 -0.08634184 0.0655085 0.7880065


$ageonset_gt_12wk
$ageonset_gt_12wk$ntab
            CTRL TRT
```

```
n_all          9   8
n_event        9   8
n_event_pct  100 100

$ageonset_gt_12wk$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  0.9941520 0.1086237 0.80351162  1.230024 0.9569393
OR_TRTvsCTRL  0.8947368 2.0549721 0.01594043 50.221620 0.9568355
ARR_TRTvsCTRL 0.0000000 0.0000000 0.00000000  0.000000       NaN


$agetrt_lt_180d
$agetrt_lt_180d$ntab
            CTRL TRT
n_all         16  49
n_event       16  46
n_event_pct  100  94

$agetrt_lt_180d$stats
                 estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.95818182 0.05734028  0.85632730 1.072151257 0.45627992
OR_TRTvsCTRL   0.40259740 1.53877410  0.01972714 8.216329642 0.55434508
ARR_TRTvsCTRL -0.06122449 0.03424881 -0.12835091 0.005901935 0.07383432


$agetrt_ge_180d
$agetrt_ge_180d$ntab
            CTRL TRT
n_all         25  31
n_event       24  31
n_event_pct   96 100

$agetrt_ge_180d$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.044643 0.05339307  0.94084824  1.1598881 0.4133622
OR_TRTvsCTRL  3.857143 1.65506164  0.15047859 98.8682266 0.4147087
ARR_TRTvsCTRL 0.040000 0.03919184 -0.03681459  0.1168146 0.3074342


$sex_m
$sex_m$ntab
            CTRL TRT
n_all         17  37
n_event       17  35
n_event_pct  100  95

$sex_m$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.96090226 0.05865600  0.85654688 1.07797153 0.4965422
OR_TRTvsCTRL   0.40571429 1.57648719  0.01846341 8.91514953 0.5671692
ARR_TRTvsCTRL -0.05405405 0.03717461 -0.12691495 0.01880684 0.1459301


$sex_f
```

```
$sex_f$ntab
            CTRL TRT
n_all         24  43
n_event       23  42
n_event_pct   96  98

$sex_f$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.01921132 0.04863439  0.92654512  1.1211453 0.6955986
OR_TRTvsCTRL  1.82608696 1.43780659  0.10905819 30.5762796 0.6753511
ARR_TRTvsCTRL 0.01841085 0.04681910 -0.07335291  0.1101746 0.6941468


$region_europe
$region_europe$ntab
            CTRL TRT
n_all         17  30
n_event       16  27
n_event_pct   94  90

$region_europe$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.95625000 0.08590794  0.80806533 1.1316091 0.6025463
OR_TRTvsCTRL   0.56250000 1.19702563  0.05385332 5.8753345 0.6307571
ARR_TRTvsCTRL -0.04117647 0.07909909 -0.19620784 0.1138549 0.6026676


$region_asiapacific
$region_asiapacific$ntab
            CTRL TRT
n_all          2  12
n_event        2  12
n_event_pct  100 100

$region_asiapacific$stats
              estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.153846 0.2640901 0.68762870   1.936163 0.5879124
OR_TRTvsCTRL  5.000000 2.1166010 0.07894342 316.682514 0.4470227
ARR_TRTvsCTRL 0.000000 0.0000000 0.00000000   0.000000       NaN


$region_northamerica
$region_northamerica$ntab
            CTRL TRT
n_all         22  38
n_event       22  38
n_event_pct  100 100

$region_northamerica$stats
              estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.009117 0.03604419 0.94028729  1.082985 0.8012048
OR_TRTvsCTRL  1.711111 2.01752781 0.03280616 89.248515 0.7900558
ARR_TRTvsCTRL 0.000000 0.00000000 0.00000000  0.000000       NaN
```

```
$disdur_gt_12wk
$disdur_gt_12wk$ntab
            CTRL TRT
n_all         23  46
n_event       22  46
n_event_pct   96 100

$disdur_gt_12wk$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.05531915 0.05483209  0.94778680   1.175052 0.3261168
OR_TRTvsCTRL  6.20000000 1.65306276  0.24282988 158.300126 0.2697065
ARR_TRTvsCTRL 0.04347826 0.04252258 -0.03986446   0.126821 0.3065563


$disdur_le_12wek
$disdur_le_12wek$ntab
            CTRL TRT
n_all         18  34
n_event       18  31
n_event_pct  100  91

$disdur_le_12wek$stats
                  estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.92432432 0.06780176  0.80930351 1.055692272 0.24579531
OR_TRTvsCTRL   0.24324324 1.53997220  0.01189088 4.975852489 0.35861925
ARR_TRTvsCTRL -0.08823529 0.04864331 -0.18357443 0.007103837 0.06968933



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem milden UE"

$ageonset_le_12wk
$ageonset_le_12wk$ntab
            CTRL TRT
n_all         32  72
n_event       20  48
n_event_pct   62  67

$ageonset_le_12wk$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.06666667 0.1602949  0.7790862 1.4604005 0.6872250
OR_TRTvsCTRL  1.20000000 0.4425306  0.5040789 2.8566957 0.6803412
ARR_TRTvsCTRL 0.04166667 0.1020325 -0.1583134 0.2416468 0.6830046


$ageonset_gt_12wk
$ageonset_gt_12wk$ntab
            CTRL TRT
n_all          9   8
n_event        5   6
n_event_pct   56  75
```

```
$ageonset_gt_12wk$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.3500000 0.3613247  0.6649264  2.7409047 0.4062180
OR_TRTvsCTRL  2.4000000 1.0567245  0.3025002 19.0413075 0.4074021
ARR_TRTvsCTRL 0.1944444 0.2255490 -0.2476234  0.6365123 0.3886357


$agetrt_lt_180d
$agetrt_lt_180d$ntab
            CTRL TRT
n_all         16  49
n_event        9  34
n_event_pct   56  69

$agetrt_lt_180d$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2335601 0.2400306  0.7706299 1.9745802 0.3818515
OR_TRTvsCTRL  1.7629630 0.5916474  0.5528814 5.6215282 0.3378943
ARR_TRTvsCTRL 0.1313776 0.1404129 -0.1438267 0.4065818 0.3494527


$agetrt_ge_180d
$agetrt_ge_180d$ntab
            CTRL TRT
n_all         25  31
n_event       16  20
n_event_pct   64  65

$agetrt_ge_180d$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.00806452 0.2006039  0.6803525 1.4936289 0.9680613
OR_TRTvsCTRL  1.02272727 0.5608210  0.3407125 3.0699517 0.9680362
ARR_TRTvsCTRL 0.00516129 0.1288440 -0.2473683 0.2576909 0.9680465


$sex_m
$sex_m$ntab
            CTRL TRT
n_all         17  37
n_event       11  23
n_event_pct   65  62

$sex_m$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.9606880 0.2203107  0.6238118 1.4794869 0.8555504
OR_TRTvsCTRL   0.8961039 0.6103135  0.2709309 2.9638633 0.8573552
ARR_TRTvsCTRL -0.0254372 0.1406795 -0.3011640 0.2502896 0.8565115


$sex_f
$sex_f$ntab
            CTRL TRT
n_all         24  43
```

```
n_event       14  31
n_event_pct   58  72

$sex_f$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2358804 0.1968861  0.8402077 1.8178843 0.2820770
OR_TRTvsCTRL  1.8452381 0.5357424  0.6456953 5.2732360 0.2528413
ARR_TRTvsCTRL 0.1375969 0.1216805 -0.1008925 0.3760863 0.2581373


$region_europe
$region_europe$ntab
            CTRL TRT
n_all         17  30
n_event       12  16
n_event_pct   71  53

$region_europe$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7555556 0.2316818  0.4797980 1.1898010 0.2263336
OR_TRTvsCTRL   0.4761905 0.6459581  0.1342580 1.6889674 0.2507274
ARR_TRTvsCTRL -0.1725490 0.1432089 -0.4532333 0.1081353 0.2282511


$region_asiapacific
$region_asiapacific$ntab
            CTRL TRT
n_all          2  12
n_event        1  11
n_event_pct   50  92

$region_asiapacific$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   1.8333333 0.7124435  0.4537414   7.407548 0.3948891
OR_TRTvsCTRL  11.0000000 1.7580981  0.3506686 345.055171 0.1725945
ARR_TRTvsCTRL  0.4166667 0.3624441 -0.2937108   1.127044 0.2503076


$region_northamerica
$region_northamerica$ntab
            CTRL TRT
n_all         22  38
n_event       12  27
n_event_pct   55  71

$region_northamerica$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3026316 0.2204542  0.84561112 2.0066541 0.2304187
OR_TRTvsCTRL  2.0454545 0.5579242  0.68530493 6.1051426 0.1996157
ARR_TRTvsCTRL 0.1650718 0.1291601 -0.08807728 0.4182208 0.2012352


$disdur_gt_12wk
$disdur_gt_12wk$ntab
```

```
            CTRL TRT
n_all         23  46
n_event       14  30
n_event_pct   61  65

$disdur_gt_12wk$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.07142857 0.1988580  0.7255961 1.5820911 0.7286324
OR_TRTvsCTRL  1.20535714 0.5276107  0.4285611 3.3901488 0.7233364
ARR_TRTvsCTRL 0.04347826 0.1236416 -0.1988549 0.2858114 0.7251027


$disdur_le_12wek
$disdur_le_12wek$ntab
            CTRL TRT
n_all         18  34
n_event       11  24
n_event_pct   61  71

$disdur_le_12wek$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.15508021 0.2181936  0.7531569 1.7714906 0.5087774
OR_TRTvsCTRL  1.52727273 0.6127258  0.4595825 5.0753937 0.4894731
ARR_TRTvsCTRL 0.09477124 0.1389578 -0.1775810 0.3671235 0.4952297



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten UE"

$ageonset_le_12wk
$ageonset_le_12wk$ntab
            CTRL TRT
n_all         32  72
n_event       24  53
n_event_pct   75  74

$ageonset_le_12wk$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.98148148 0.12407942  0.7696008 1.251696 0.8802546
OR_TRTvsCTRL   0.92982456 0.48802271  0.3572690 2.419952 0.8814825
ARR_TRTvsCTRL -0.01388889 0.09250575 -0.1951968 0.167419 0.8806535


$ageonset_gt_12wk
$ageonset_gt_12wk$ntab
            CTRL TRT
n_all          9   8
n_event        6   4
n_event_pct   67  50

$ageonset_gt_12wk$stats
                estimate        se      lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.7500000 0.4249183  0.32611454 1.7248541 0.4983875
OR_TRTvsCTRL   0.5000000 1.0000000  0.07043175 3.5495357 0.4882172
ARR_TRTvsCTRL -0.1666667 0.2365193 -0.63023589 0.2969026 0.4810192


$agetrt_lt_180d
$agetrt_lt_180d$ntab
            CTRL TRT
n_all         16  49
n_event       13  36
n_event_pct   81  73

$agetrt_lt_180d$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90423862 0.1476235  0.6770578 1.2076480 0.4953127
OR_TRTvsCTRL   0.63905325 0.7176052  0.1565707 2.6083372 0.5326442
ARR_TRTvsCTRL -0.07780612 0.1161870 -0.3055285 0.1499162 0.5030727


$agetrt_ge_180d
$agetrt_ge_180d$ntab
            CTRL TRT
n_all         25  31
n_event       17  21
n_event_pct   68  68

$agetrt_ge_180d$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.996204934 0.1848905  0.6933772 1.4312905 0.9835926
OR_TRTvsCTRL   0.988235294 0.5757105  0.3197531 3.0542601 0.9835996
ARR_TRTvsCTRL -0.002580645 0.1255114 -0.2485784 0.2434172 0.9835958


$sex_m
$sex_m$ntab
            CTRL TRT
n_all         17  37
n_event       10  26
n_event_pct   59  70

$sex_m$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.1945946 0.2293708  0.7620434 1.8726705 0.4382251
OR_TRTvsCTRL  1.6545455 0.6101047  0.5004453 5.4701695 0.4091949
ARR_TRTvsCTRL 0.1144674 0.1410467 -0.1619791 0.3909139 0.4170460


$sex_f
$sex_f$ntab
            CTRL TRT
n_all         24  43
n_event       20  31
n_event_pct   83  72
```

```
$sex_f$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.8651163 0.1316647  0.6683459 1.11981853 0.2711329
OR_TRTvsCTRL   0.5166667 0.6446638  0.1460399 1.82788662 0.3056729
ARR_TRTvsCTRL -0.1124031 0.1023028 -0.3129130 0.08810677 0.2718863


$region_europe
$region_europe$ntab
            CTRL TRT
n_all         17  30
n_event       12  19
n_event_pct   71  63

$region_europe$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.89722222 0.2093037  0.5953061 1.3522584 0.6043503
OR_TRTvsCTRL   0.71969697 0.6533560  0.1999917 2.5899255 0.6146555
ARR_TRTvsCTRL -0.07254902 0.1412559 -0.3494056 0.2043075 0.6075318


$region_asiapacific
$region_asiapacific$ntab
            CTRL TRT
n_all          2  12
n_event        1   8
n_event_pct   50  67

$region_asiapacific$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.3333333 0.7359801  0.31511666  5.6416496 0.6958837
OR_TRTvsCTRL  2.0000000 1.5411035  0.09755293 41.0033815 0.6528739
ARR_TRTvsCTRL 0.1666667 0.3788384 -0.57584292  0.9091762 0.6599796


$region_northamerica
$region_northamerica$ntab
            CTRL TRT
n_all         22  38
n_event       17  30
n_event_pct   77  79

$region_northamerica$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.02167183 0.1427814  0.7722816 1.3515968 0.8806369
OR_TRTvsCTRL  1.10294118 0.6458768  0.3110148 3.9113231 0.8794225
ARR_TRTvsCTRL 0.01674641 0.1111600 -0.2011231 0.2346159 0.8802506


$disdur_gt_12wk
$disdur_gt_12wk$ntab
            CTRL TRT
n_all         23  46
n_event       16  34
```

```
n_event_pct   70  74

$disdur_gt_12wk$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.06250000 0.1633841  0.7713582 1.4635304 0.7105960
OR_TRTvsCTRL  1.23958333 0.5640055  0.4103868 3.7441920 0.7033490
ARR_TRTvsCTRL 0.04347826 0.1157449 -0.1833777 0.2703342 0.7071857


$disdur_le_12wek
$disdur_le_12wek$ntab
            CTRL TRT
n_all         18  34
n_event       14  23
n_event_pct   78  68

$disdur_le_12wek$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8697479 0.1730304  0.6195975 1.2208916 0.4199450
OR_TRTvsCTRL   0.5974026 0.6751414  0.1590691 2.2436159 0.4454359
ARR_TRTvsCTRL -0.1013072 0.1266460 -0.3495287 0.1469143 0.4237546



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten oder schweren UE"

$ageonset_le_12wk
$ageonset_le_12wk$ntab
            CTRL TRT
n_all         32  72
n_event       30  59
n_event_pct   94  82

$ageonset_le_12wk$stats
                estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.8740741 0.07171887  0.75945321 1.005994151 0.06056813
OR_TRTvsCTRL   0.3025641 0.79196311  0.06407626 1.428688731 0.13117305
ARR_TRTvsCTRL -0.1180556 0.06233770 -0.24023520 0.004124089 0.05825066


$ageonset_gt_12wk
$ageonset_gt_12wk$ntab
            CTRL TRT
n_all          9   8
n_event        9   6
n_event_pct  100  75

$ageonset_gt_12wk$stats
                estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7602339 0.2190849  0.494836610 1.16797262 0.2108448
OR_TRTvsCTRL   0.1368421 1.6306776  0.005599954 3.34391327 0.2225809
ARR_TRTvsCTRL -0.2500000 0.1530931 -0.550056980 0.05005698 0.1024704
```

```
$agetrt_lt_180d
$agetrt_lt_180d$ntab
            CTRL TRT
n_all         16  49
n_event       16  39
n_event_pct  100  80

$agetrt_lt_180d$stats
                estimate         se      lo95ci      hi95ci       pvalue
RR_TRTvsCTRL   0.8139394 0.08425549  0.69003905  0.96008673 0.0145498326
OR_TRTvsCTRL   0.1139971 1.47687529  0.00630631  2.06068865 0.1414562508
ARR_TRTvsCTRL -0.2040816 0.05757556 -0.31692766 -0.09123561 0.0003932275


$agetrt_ge_180d
$agetrt_ge_180d$ntab
            CTRL TRT
n_all         25  31
n_event       23  26
n_event_pct   92  84

$agetrt_ge_180d$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.91164095 0.09839581  0.75174260 1.10555026 0.3471290
OR_TRTvsCTRL   0.45217391 0.88427360  0.07991171 2.55858916 0.3694203
ARR_TRTvsCTRL -0.08129032 0.08548529 -0.24883840 0.08625776 0.3416411


$sex_m
$sex_m$ntab
            CTRL TRT
n_all         17  37
n_event       16  30
n_event_pct   94  81

$sex_m$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.8614865 0.09991385  0.7082746 1.04784077 0.1356350
OR_TRTvsCTRL   0.2678571 1.11296472  0.0302375 2.37279666 0.2365727
ARR_TRTvsCTRL -0.1303657 0.08603791 -0.2989969 0.03826554 0.1297187


$sex_f
$sex_f$ntab
            CTRL TRT
n_all         24  43
n_event       23  35
n_event_pct   96  81

$sex_f$stats
                estimate         se      lo95ci       hi95ci     pvalue
RR_TRTvsCTRL   0.8493428 0.08442280  0.71981713  1.002175567 0.05308583
```

```
OR_TRTvsCTRL   0.1902174 1.09409766  0.02228192  1.623857210 0.12930325
ARR_TRTvsCTRL -0.1443798 0.07201025 -0.28551734 -0.003242355 0.04496409


$region_europe
$region_europe$ntab
            CTRL TRT
n_all         17  30
n_event       15  23
n_event_pct   88  77

$region_europe$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8688889 0.1341196  0.6680384 1.1301265 0.2946981
OR_TRTvsCTRL   0.4380952 0.8677569  0.0799710 2.3999631 0.3415563
ARR_TRTvsCTRL -0.1156863 0.1098600 -0.3310078 0.0996353 0.2923254


$region_asiapacific
$region_asiapacific$ntab
            CTRL TRT
n_all          2  12
n_event        2   9
n_event_pct  100  75

$region_asiapacific$stats
                estimate        se      lo95ci       hi95ci     pvalue
RR_TRTvsCTRL   0.8769231 0.3082316  0.47928545  1.604459473 0.67003853
OR_TRTvsCTRL   0.5428571 1.6706219  0.02054233 14.345691040 0.71460562
ARR_TRTvsCTRL -0.2500000 0.1250000 -0.49499550 -0.005004502 0.04550026


$region_northamerica
$region_northamerica$ntab
            CTRL TRT
n_all         22  38
n_event       22  33
n_event_pct  100  87

$region_northamerica$stats
                estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.8780627 0.07194376  0.762582581  1.01103026 0.07068661
OR_TRTvsCTRL   0.1353535 1.50203641  0.007127445  2.57042723 0.18304564
ARR_TRTvsCTRL -0.1315789 0.05483610 -0.239055733 -0.02410216 0.01641771


$disdur_gt_12wk
$disdur_gt_12wk$ntab
            CTRL TRT
n_all         23  46
n_event       21  39
n_event_pct   91  85

$disdur_gt_12wk$stats
```

```
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.92857143 0.08968100  0.7788946 1.10701097 0.4086051
OR_TRTvsCTRL   0.53061224 0.84623709  0.1010320 2.78673445 0.4539340
ARR_TRTvsCTRL -0.06521739 0.07909916 -0.2202489 0.08981412 0.4096546


$disdur_le_12wek
$disdur_le_12wek$ntab
            CTRL TRT
n_all         18  34
n_event       18  26
n_event_pct  100  76

$disdur_le_12wek$stats
                estimate        se       lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   0.77760618 0.1028926  0.635590397  0.95135384 0.014499830
OR_TRTvsCTRL   0.08426073 1.4864175  0.004574929  1.55190841 0.096053203
ARR_TRTvsCTRL -0.23529412 0.0727467 -0.377875028 -0.09271321 0.001218857



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem schweren UE"

$ageonset_le_12wk
$ageonset_le_12wk$ntab
            CTRL TRT
n_all         32  72
n_event       26  41
n_event_pct   81  57

$ageonset_le_12wk$stats
                estimate         se     lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   0.7008547 0.13308979  0.5399353  0.90973359 0.007567332
OR_TRTvsCTRL   0.3052109 0.51164100  0.1119671  0.83197385 0.020367845
ARR_TRTvsCTRL -0.2430556 0.09036584 -0.4201693 -0.06594177 0.007151970


$ageonset_gt_12wk
$ageonset_gt_12wk$ntab
            CTRL TRT
n_all          9   8
n_event        7   4
n_event_pct   78  50

$ageonset_gt_12wk$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6428571 0.3959116  0.29587881 1.3967384 0.2644272
OR_TRTvsCTRL   0.2857143 1.0690450  0.03515274 2.3222271 0.2412563
ARR_TRTvsCTRL -0.2777778 0.2246205 -0.71802596 0.1624704 0.2162158


$agetrt_lt_180d
```

```
$agetrt_lt_180d$ntab
            CTRL TRT
n_all         16  49
n_event       15  27
n_event_pct   94  55

$agetrt_lt_180d$stats
                 estimate         se      lo95ci     hi95ci       pvalue
RR_TRTvsCTRL   0.58775510 0.14420659  0.44304469  0.7797319 2.284311e-04
OR_TRTvsCTRL   0.08181818 1.07198799  0.01000857  0.6688483 1.953544e-02
ARR_TRTvsCTRL -0.38647959 0.09333288 -0.56940867 -0.2035505 3.459865e-05


$agetrt_ge_180d
$agetrt_ge_180d$ntab
            CTRL TRT
n_all         25  31
n_event       18  18
n_event_pct   72  58

$agetrt_ge_180d$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8064516 0.1971118  0.5480201 1.1867525 0.2751335
OR_TRTvsCTRL   0.5384615 0.5752315  0.1743880 1.6626187 0.2818572
ARR_TRTvsCTRL -0.1393548 0.1261694 -0.3866423 0.1079327 0.2693738


$sex_m
$sex_m$ntab
            CTRL TRT
n_all         17  37
n_event       14  21
n_event_pct   82  57

$sex_m$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.6891892 0.1822006  0.48222422  0.98498110 0.04105048
OR_TRTvsCTRL   0.2812500 0.7175521  0.06891458  1.14782042 0.07708903
ARR_TRTvsCTRL -0.2559618 0.1232157 -0.49746024 -0.01446345 0.03776953


$sex_f
$sex_f$ntab
            CTRL TRT
n_all         24  43
n_event       19  24
n_event_pct   79  56

$sex_f$stats
                estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.7050184 0.1713936  0.5038601  0.98648599 0.04141517
OR_TRTvsCTRL   0.3324100 0.5890075  0.1047876  1.05447947 0.06149744
ARR_TRTvsCTRL -0.2335271 0.1122829 -0.4535976 -0.01345668 0.03754294
```

```
$region_europe
$region_europe$ntab
            CTRL TRT
n_all         17  30
n_event       11  16
n_event_pct   65  53

$region_europe$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.8242424 0.2474919  0.5074456 1.338815 0.4348038
OR_TRTvsCTRL   0.6233766 0.6257031  0.1828736 2.124956 0.4500586
ARR_TRTvsCTRL -0.1137255 0.1474111 -0.4026460 0.175195 0.4404195


$region_asiapacific
$region_asiapacific$ntab
            CTRL TRT
n_all          2  12
n_event        1   3
n_event_pct   50  25

$region_asiapacific$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5000000 0.8660254  0.09158152 2.7298084 0.4234922
OR_TRTvsCTRL   0.3333333 1.5634719  0.01556141 7.1401684 0.4822584
ARR_TRTvsCTRL -0.2500000 0.3750000 -0.98498649 0.4849865 0.5049851


$region_northamerica
$region_northamerica$ntab
            CTRL TRT
n_all         22  38
n_event       21  26
n_event_pct   95  68

$region_northamerica$stats
                estimate         se      lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   0.7167920 0.11962546  0.56698003  0.90618843 0.005378677
OR_TRTvsCTRL   0.1031746 1.08139443  0.01239048  0.85912710 0.035695971
ARR_TRTvsCTRL -0.2703349 0.08751092 -0.44185318 -0.09881667 0.002007257


$disdur_gt_12wk
$disdur_gt_12wk$ntab
            CTRL TRT
n_all         23  46
n_event       17  27
n_event_pct   74  59

$disdur_gt_12wk$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7941176 0.1750519  0.5634824 1.11915261 0.1878764
OR_TRTvsCTRL   0.5015480 0.5613901  0.1669000 1.50719202 0.2190000
```

```
ARR_TRTvsCTRL -0.1521739 0.1168492 -0.3811941 0.07684631 0.1928103


$disdur_le_12wek
$disdur_le_12wek$ntab
            CTRL TRT
n_all         18  34
n_event       16  18
n_event_pct   89  53

$disdur_le_12wek$stats
                estimate        se      lo95ci     hi95ci      pvalue
RR_TRTvsCTRL   0.5955882 0.1819017  0.41697603  0.8507092 0.004388134
OR_TRTvsCTRL   0.1406250 0.8249579  0.02791625  0.7083828 0.017412057
ARR_TRTvsCTRL -0.3594771 0.1132010 -0.58134701 -0.1376072 0.001495451



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs"

$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              31.0               69.0
n_event_pct                          97.0               96.0
time-to-event-wk-10th                 0.1                0.1
time-to-event-wk-25th                 0.4                0.4
time-to-event-wk-50th                 1.8                2.4
time-to-event-wk-75th                 4.9                4.3
time-to-event-wk-90th                 9.4               11.0
time-to-event-wk-50th-loci            0.6                1.3
time-to-event-wk-50th-hici            3.1                3.1

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9213    0.2194    0.5993    1.4160    0.7086


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              9.0                8.0
n_event_pct                        100.0              100.0
time-to-event-wk-10th                0.4                0.4
time-to-event-wk-25th                1.0                1.1
time-to-event-wk-50th                1.4                2.9
time-to-event-wk-75th                4.1                4.8
time-to-event-wk-90th               23.0                9.7
time-to-event-wk-50th-loci           0.4                0.4
time-to-event-wk-50th-hici           5.7                5.1
```

```
$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1460    0.5117    0.4204    3.1240    0.7900


$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                              16.0               46.0
n_event_pct                         100.0               94.0
time-to-event-wk-10th                 0.1                0.1
time-to-event-wk-25th                 0.3                0.9
time-to-event-wk-50th                 2.5                2.4
time-to-event-wk-75th                 6.2                4.3
time-to-event-wk-90th                 9.4               21.7
time-to-event-wk-50th-loci            0.1                1.3
time-to-event-wk-50th-hici            5.1                3.4

$agetrt_lt_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9121    0.2977    0.5090    1.6350    0.7573


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              24.0               31.0
n_event_pct                          96.0              100.0
time-to-event-wk-10th                 0.1                0.1
time-to-event-wk-25th                 0.6                0.4
time-to-event-wk-50th                 1.4                2.6
time-to-event-wk-75th                 3.6                4.4
time-to-event-wk-90th                22.6                8.1
time-to-event-wk-50th-loci            1.0                0.4
time-to-event-wk-50th-hici            3.1                3.6

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0730    0.2811    0.6187    1.8620    0.8009


$sex_m
$sex_m$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                              17.0               35.0
n_event_pct                         100.0               95.0
time-to-event-wk-10th                 0.1                0.1
time-to-event-wk-25th                 0.4                0.4
time-to-event-wk-50th                 1.4                2.4
time-to-event-wk-75th                 5.1                4.1
```

```
time-to-event-wk-90th                15.1                10.0
time-to-event-wk-50th-loci            0.3                 1.0
time-to-event-wk-50th-hici            5.1                 3.4

$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0740    0.3042    0.5915    1.9490    0.8152


$sex_f
$sex_f$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0                43.0
n_event                             23.0                42.0
n_event_pct                         96.0                98.0
time-to-event-wk-10th                0.1                 0.1
time-to-event-wk-25th                0.7                 0.7
time-to-event-wk-50th                1.8                 2.6
time-to-event-wk-75th                3.6                 4.4
time-to-event-wk-90th                7.3                11.0
time-to-event-wk-50th-loci           0.9                 1.1
time-to-event-wk-50th-hici           3.1                 4.1

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8893    0.2718    0.5220    1.5150    0.6660


$region_europe
$region_europe$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                30.0
n_event                             16.0                27.0
n_event_pct                         94.0                90.0
time-to-event-wk-10th                0.1                 0.1
time-to-event-wk-25th                0.4                 0.7
time-to-event-wk-50th                2.1                 2.5
time-to-event-wk-75th                4.6                 9.7
time-to-event-wk-90th               22.6                42.1
time-to-event-wk-50th-loci           0.1                 0.9
time-to-event-wk-50th-hici           4.6                 5.1

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7094    0.3369    0.3665    1.3730    0.3081


$region_asiapacific
$region_asiapacific$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                12.0
n_event                              2.0                12.0
n_event_pct                        100.0               100.0
time-to-event-wk-10th                0.9                 0.1
```

```
time-to-event-wk-25th                 0.9                0.7
time-to-event-wk-50th                 3.3                3.6
time-to-event-wk-75th                 5.7                4.4
time-to-event-wk-90th                 5.7               21.7
time-to-event-wk-50th-loci            0.9                0.1
time-to-event-wk-50th-hici             NA                4.4

$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9281    0.7997    0.1936    4.4500    0.9257


$region_northamerica
$region_northamerica$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              22.0               38.0
n_event_pct                         100.0              100.0
time-to-event-wk-10th                0.1                0.1
time-to-event-wk-25th                0.6                0.4
time-to-event-wk-50th                1.3                2.1
time-to-event-wk-75th                4.3                3.6
time-to-event-wk-90th                7.4                6.6
time-to-event-wk-50th-loci           0.6                1.0
time-to-event-wk-50th-hici           3.6                2.7

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1460    0.2866    0.6534    2.0100    0.6347


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              22.0               46.0
n_event_pct                          96.0              100.0
time-to-event-wk-10th                0.1                0.1
time-to-event-wk-25th                0.3                0.3
time-to-event-wk-50th                1.3                2.4
time-to-event-wk-75th                3.1                4.1
time-to-event-wk-90th                7.4               10.0
time-to-event-wk-50th-loci           0.4                1.0
time-to-event-wk-50th-hici           2.1                3.4

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8696    0.2749    0.5073    1.4900    0.6112


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
```

```
n_event                              18.0              31.0
n_event_pct                         100.0              91.0
time-to-event-wk-10th                 0.1               0.1
time-to-event-wk-25th                 1.0               0.9
time-to-event-wk-50th                 3.1               2.4
time-to-event-wk-75th                 5.7               4.4
time-to-event-wk-90th                15.1              24.1
time-to-event-wk-50th-loci            1.0               1.0
time-to-event-wk-50th-hici            5.1               4.1

$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9427    0.3012    0.5223    1.7010    0.8446



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem schwerwiegenden UE"

$ageonset_le_12wk
$ageonset_le_12wk$ntab
            CTRL TRT
n_all         32  72
n_event       31  56
n_event_pct   97  78

$ageonset_le_12wk$stats
                estimate         se      lo95ci      hi95ci       pvalue
RR_TRTvsCTRL   0.8028674 0.07054303  0.69919366  0.92191344 0.0018550500
OR_TRTvsCTRL   0.1129032 1.05480577  0.01428414  0.89239812 0.0386501952
ARR_TRTvsCTRL -0.1909722 0.05784975 -0.30435565 -0.07758879 0.0009628038


$ageonset_gt_12wk
$ageonset_gt_12wk$ntab
            CTRL TRT
n_all          9   8
n_event        8   5
n_event_pct   89  62

$ageonset_gt_12wk$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7031250 0.2981424  0.39197040 1.2612809 0.2374503
OR_TRTvsCTRL   0.2083333 1.2877629  0.01669602 2.5995881 0.2231884
ARR_TRTvsCTRL -0.2638889 0.2006759 -0.65720640 0.1294286 0.1885097


$agetrt_lt_180d
$agetrt_lt_180d$ntab
            CTRL TRT
n_all         16  49
n_event       16  38
n_event_pct  100  78
```

```
$agetrt_lt_180d$stats
                estimate         se       lo95ci     hi95ci       pvalue
RR_TRTvsCTRL   0.7933333 0.08807132  0.667558392  0.9428056 0.0085715584
OR_TRTvsCTRL   0.1014493 1.47429190  0.005640653  1.8246034 0.1206467532
ARR_TRTvsCTRL -0.2244898 0.05960655 -0.341316497 -0.1076631 0.0001657556


$agetrt_ge_180d
$agetrt_ge_180d$ntab
            CTRL TRT
n_all         25  31
n_event       23  23
n_event_pct   92  74

$agetrt_ge_180d$stats
                estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.8064516 0.12123719  0.63588858 1.022764397 0.07601323
OR_TRTvsCTRL   0.2500000 0.84377516  0.04783186 1.306660394 0.10038986
ARR_TRTvsCTRL -0.1780645 0.09550059 -0.36524223 0.009113194 0.06224613


$sex_m
$sex_m$ntab
            CTRL TRT
n_all         17  37
n_event       17  28
n_event_pct  100  76

$sex_m$stats
                 estimate         se       lo95ci     hi95ci       pvalue
RR_TRTvsCTRL   0.77142857 0.10178031  0.631917181  0.9417406 0.0107809756
OR_TRTvsCTRL   0.08571429 1.48239459  0.004690689  1.5662814 0.0974638524
ARR_TRTvsCTRL -0.24324324 0.07053387 -0.381487079 -0.1049994 0.0005634962


$sex_f
$sex_f$ntab
            CTRL TRT
n_all         24  43
n_event       22  33
n_event_pct   92  77

$sex_f$stats
                estimate         se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.8372093 0.10409176  0.68270169 1.0266848 0.08782823
OR_TRTvsCTRL   0.3000000 0.82204475  0.05989568 1.5026126 0.14302807
ARR_TRTvsCTRL -0.1492248 0.08563556 -0.31706741 0.0186178 0.08141109


$region_europe
$region_europe$ntab
            CTRL TRT
n_all         17  30
```

```
n_event       16  23
n_event_pct   94  77

$region_europe$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.8145833 0.1175644  0.64694072 1.02566741 0.08109065
OR_TRTvsCTRL   0.2053571 1.1175130  0.02297635 1.83543344 0.15661675
ARR_TRTvsCTRL -0.1745098 0.0960189 -0.36270339 0.01368378 0.06914783


$region_asiapacific
$region_asiapacific$ntab
            CTRL TRT
n_all          2  12
n_event        1   8
n_event_pct   50  67

$region_asiapacific$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.3333333 0.7359801  0.31511666  5.6416496 0.6958837
OR_TRTvsCTRL  2.0000000 1.5411035  0.09755293 41.0033815 0.6528739
ARR_TRTvsCTRL 0.1666667 0.3788384 -0.57584292  0.9091762 0.6599796


$region_northamerica
$region_northamerica$ntab
            CTRL TRT
n_all         22  38
n_event       22  30
n_event_pct  100  79

$region_northamerica$stats
                 estimate         se       lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   0.79943020 0.09006688  0.670062759  0.95377431 0.012939049
OR_TRTvsCTRL   0.07973856 1.48151220  0.004371223  1.45456746 0.087814444
ARR_TRTvsCTRL -0.21052632 0.06613483 -0.340148196 -0.08090444 0.001456118


$disdur_gt_12wk
$disdur_gt_12wk$ntab
            CTRL TRT
n_all         23  46
n_event       22  36
n_event_pct   96  78

$disdur_gt_12wk$stats
                estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.8181818 0.08952615  0.68650709  0.97511227 0.02499528
OR_TRTvsCTRL   0.1636364 1.08315849  0.01958365  1.36730689 0.09469419
ARR_TRTvsCTRL -0.1739130 0.07420713 -0.31935635 -0.02846974 0.01909781


$disdur_le_12wek
$disdur_le_12wek$ntab
```

```
           CTRL TRT
n_all        18  34
n_event      17  25
n_event_pct  94  74

$disdur_le_12wek$stats
                estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.7785467 0.11771240  0.61814121  0.98057689 0.03345397
OR_TRTvsCTRL   0.1633987 1.09997029  0.01892135  1.41105839 0.09957467
ARR_TRTvsCTRL -0.2091503 0.09294923 -0.39132748 -0.02697318 0.02443901



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schwerwiegenden UEs"

$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              31.0               56.0
n_event_pct                          97.0               78.0
time-to-event-wk-10th                 0.9                1.3
time-to-event-wk-25th                 2.9                3.0
time-to-event-wk-50th                 7.4                8.6
time-to-event-wk-75th                12.2               32.1
time-to-event-wk-90th                17.6                 NA
time-to-event-wk-50th-loci            3.1                5.0
time-to-event-wk-50th-hici            9.6               12.3

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.66260   0.22980   0.42240   1.04000   0.07329


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              8.0                5.0
n_event_pct                         89.0               62.0
time-to-event-wk-10th                1.7                0.6
time-to-event-wk-25th               15.3                1.8
time-to-event-wk-50th               16.4               10.9
time-to-event-wk-75th               23.0                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           1.7                0.6
time-to-event-wk-50th-hici          26.0                 NA

$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9101    0.5861    0.2885    2.8710    0.8723
```

```
$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                             16.0               38.0
n_event_pct                        100.0               78.0
time-to-event-wk-10th                0.9                1.6
time-to-event-wk-25th                3.2                3.0
time-to-event-wk-50th                7.4                9.0
time-to-event-wk-75th                9.5               34.7
time-to-event-wk-90th               12.7                 NA
time-to-event-wk-50th-loci           3.0                4.3
time-to-event-wk-50th-hici           9.4               16.1

$agetrt_lt_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.46390   0.32010   0.24770   0.86870   0.01641


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0               31.0
n_event                             23.0               23.0
n_event_pct                         92.0               74.0
time-to-event-wk-10th                1.6                0.6
time-to-event-wk-25th                3.1                2.0
time-to-event-wk-50th               13.7                6.9
time-to-event-wk-75th               17.9               30.9
time-to-event-wk-90th               40.3                 NA
time-to-event-wk-50th-loci           4.0                3.6
time-to-event-wk-50th-hici          17.6               12.3

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8211    0.2975    0.4583    1.4710    0.5076


$sex_m
$sex_m$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               37.0
n_event                             17.0               28.0
n_event_pct                        100.0               76.0
time-to-event-wk-10th                0.7                0.7
time-to-event-wk-25th                1.7                2.4
time-to-event-wk-50th                9.6                5.1
time-to-event-wk-75th               16.4               30.9
time-to-event-wk-90th               40.3                 NA
time-to-event-wk-50th-loci           1.0                3.4
time-to-event-wk-50th-hici          16.4               11.6

$sex_m$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8297    0.3123    0.4499    1.5300    0.5500


$sex_f
$sex_f$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              22.0               33.0
n_event_pct                          92.0               77.0
time-to-event-wk-10th                 2.3                1.6
time-to-event-wk-25th                 3.3                3.6
time-to-event-wk-50th                 8.6               11.0
time-to-event-wk-75th                15.5               34.7
time-to-event-wk-90th                26.0                 NA
time-to-event-wk-50th-loci            3.4                5.7
time-to-event-wk-50th-hici           13.7               25.4

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7400    0.2877    0.4211    1.3000    0.2953


$region_europe
$region_europe$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                              16.0               23.0
n_event_pct                          94.0               77.0
time-to-event-wk-10th                 2.3                0.9
time-to-event-wk-25th                 4.6                2.9
time-to-event-wk-50th                 8.9                5.7
time-to-event-wk-75th                12.7               35.4
time-to-event-wk-90th                40.3                 NA
time-to-event-wk-50th-loci            3.4                3.4
time-to-event-wk-50th-hici           12.7               11.0

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8909    0.3351    0.4620    1.7180    0.7303


$region_asiapacific
$region_asiapacific$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0               12.0
n_event                               1.0                8.0
n_event_pct                          50.0               67.0
time-to-event-wk-10th                 0.9                4.3
time-to-event-wk-25th                 0.9               10.4
time-to-event-wk-50th                25.1               25.3
time-to-event-wk-75th                  NA               43.6
time-to-event-wk-90th                  NA               43.6
time-to-event-wk-50th-loci            0.9                4.3
```

```
time-to-event-wk-50th-hici             NA                  NA

$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2420    1.1270    0.1363   11.3100    0.8475


$region_northamerica
$region_northamerica$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              22.0               30.0
n_event_pct                         100.0               79.0
time-to-event-wk-10th                1.0                1.3
time-to-event-wk-25th                2.9                2.4
time-to-event-wk-50th                9.1                7.5
time-to-event-wk-75th               15.9               30.9
time-to-event-wk-90th               23.0                 NA
time-to-event-wk-50th-loci           2.9                3.6
time-to-event-wk-50th-hici          15.7               16.1

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6867    0.2839    0.3936    1.1980    0.1855


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              22.0               36.0
n_event_pct                          96.0               78.0
time-to-event-wk-10th                0.9                1.3
time-to-event-wk-25th                2.9                3.4
time-to-event-wk-50th                6.0                8.9
time-to-event-wk-75th               15.7               25.4
time-to-event-wk-90th               40.3                 NA
time-to-event-wk-50th-loci           3.1                5.0
time-to-event-wk-50th-hici          13.7               13.0

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7841    0.2769    0.4557    1.3490    0.3798


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                              17.0               25.0
n_event_pct                          94.0               74.0
time-to-event-wk-10th                1.0                1.0
time-to-event-wk-25th                4.4                2.7
time-to-event-wk-50th                9.2                5.9
```

```
time-to-event-wk-75th                15.9                34.7
time-to-event-wk-90th                23.0                  NA
time-to-event-wk-50th-loci            4.4                 3.0
time-to-event-wk-50th-hici           15.7                32.1

$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7736    0.3289    0.4060    1.4740    0.4351



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines milden UEs"

$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              20.0               48.0
n_event_pct                          62.0               67.0
time-to-event-wk-10th                 0.3                0.7
time-to-event-wk-25th                 1.4                2.1
time-to-event-wk-50th                 5.1                5.3
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            2.0                3.4
time-to-event-wk-50th-hici           22.6               11.4

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9013    0.2671    0.5340    1.5210    0.6972


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               5.0                6.0
n_event_pct                          56.0               75.0
time-to-event-wk-10th                 0.4                0.4
time-to-event-wk-25th                 3.6                1.9
time-to-event-wk-50th                 5.7                3.6
time-to-event-wk-75th                  NA                9.7
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            0.4                0.4
time-to-event-wk-50th-hici             NA                 NA

$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7530    0.6275    0.5124    5.9970    0.3710


$agetrt_lt_180d
```

```
$agetrt_lt_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               9.0               34.0
n_event_pct                          56.0               69.0
time-to-event-wk-10th                 0.1                0.1
time-to-event-wk-25th                 2.5                2.1
time-to-event-wk-50th                 5.1                4.4
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            2.3                2.9
time-to-event-wk-50th-hici             NA               11.4

$agetrt_lt_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2950    0.3765    0.6193    2.7090    0.4920


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              16.0               20.0
n_event_pct                          64.0               65.0
time-to-event-wk-10th                 0.4                0.7
time-to-event-wk-25th                 1.4                2.6
time-to-event-wk-50th                 4.1                6.6
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.6                2.7
time-to-event-wk-50th-hici             NA               35.0

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8644    0.3440    0.4404    1.6960    0.6719


$sex_m
$sex_m$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                              11.0               23.0
n_event_pct                          65.0               62.0
time-to-event-wk-10th                 0.1                0.4
time-to-event-wk-25th                 3.6                2.1
time-to-event-wk-50th                 5.1                5.6
time-to-event-wk-75th                22.6                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.4                2.7
time-to-event-wk-50th-hici             NA                 NA

$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9657    0.3727    0.4651    2.0050    0.9254
```

```
$sex_f
$sex_f$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                             14.0               31.0
n_event_pct                         58.0               72.0
time-to-event-wk-10th                0.6                0.7
time-to-event-wk-25th                1.4                1.7
time-to-event-wk-50th                3.1                4.4
time-to-event-wk-75th                 NA               35.0
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           1.6                2.9
time-to-event-wk-50th-hici            NA               13.3

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0220    0.3262    0.5389    1.9360    0.9480


$region_europe
$region_europe$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                             12.0               16.0
n_event_pct                         71.0               53.0
time-to-event-wk-10th                0.1                0.7
time-to-event-wk-25th                1.4                2.6
time-to-event-wk-50th                3.0               10.0
time-to-event-wk-75th               22.6                 NA
time-to-event-wk-90th               22.6                 NA
time-to-event-wk-50th-loci           0.6                3.1
time-to-event-wk-50th-hici            NA                 NA

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47310   0.41640   0.20920   1.07000   0.07226


$region_asiapacific
$region_asiapacific$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0               12.0
n_event                              1.0               11.0
n_event_pct                         50.0               92.0
time-to-event-wk-10th                5.7                0.1
time-to-event-wk-25th                5.7                2.0
time-to-event-wk-50th                5.7                4.4
time-to-event-wk-75th                5.7               21.7
time-to-event-wk-90th                5.7               35.0
time-to-event-wk-50th-loci            NA                0.1
time-to-event-wk-50th-hici            NA               21.7
```

```
$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2780    1.0710    0.1567   10.4200    0.8190


$region_northamerica
$region_northamerica$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38.0
n_event                              12.0                27.0
n_event_pct                          55.0                71.0
time-to-event-wk-10th                 0.9                 0.4
time-to-event-wk-25th                 1.6                 2.1
time-to-event-wk-50th                10.8                 4.1
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            1.6                 2.4
time-to-event-wk-50th-hici             NA                 7.3

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7060    0.3622    0.8390    3.4700    0.1401


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46.0
n_event                              14.0                30.0
n_event_pct                          61.0                65.0
time-to-event-wk-10th                 0.3                 1.0
time-to-event-wk-25th                 1.1                 2.7
time-to-event-wk-50th                 4.1                 6.1
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            1.3                 3.0
time-to-event-wk-50th-hici             NA                21.7

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7847    0.3270    0.4134    1.4890    0.4584


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
n_event                              11.0                24.0
n_event_pct                          61.0                71.0
time-to-event-wk-10th                 0.9                 0.1
time-to-event-wk-25th                 2.7                 1.1
time-to-event-wk-50th                 5.4                 4.3
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
```

```
time-to-event-wk-50th-loci            2.7                2.1
time-to-event-wk-50th-hici             NA                9.7

$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2520    0.3684    0.6081    2.5770    0.5420



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten UEs"

$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              24.0               53.0
n_event_pct                          75.0               74.0
time-to-event-wk-10th                 2.1                1.7
time-to-event-wk-25th                 5.3                3.9
time-to-event-wk-50th                 9.0               11.6
time-to-event-wk-75th                15.7               37.6
time-to-event-wk-90th                27.0                 NA
time-to-event-wk-50th-loci            5.9                7.6
time-to-event-wk-50th-hici           15.4               25.1

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6819    0.2577    0.4115    1.1300    0.1375


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              6.0                4.0
n_event_pct                         67.0               50.0
time-to-event-wk-10th                2.3                0.4
time-to-event-wk-25th                5.1                3.3
time-to-event-wk-50th               15.1               16.7
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           2.3                0.4
time-to-event-wk-50th-hici            NA                 NA

$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0720    0.6968    0.2735    4.1990    0.9209


$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                16.0               49.0
n_event                              13.0               36.0
n_event_pct                          81.0               73.0
time-to-event-wk-10th                 2.1                2.0
time-to-event-wk-25th                 5.3                4.1
time-to-event-wk-50th                 8.6               15.0
time-to-event-wk-75th                15.1               43.6
time-to-event-wk-90th                15.4                 NA
time-to-event-wk-50th-loci            5.3                7.7
time-to-event-wk-50th-hici           15.1               25.7

$agetrt_lt_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48540   0.34740   0.24570   0.95890   0.03747


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              17.0               21.0
n_event_pct                          68.0               68.0
time-to-event-wk-10th                 2.3                0.3
time-to-event-wk-25th                 5.1                3.6
time-to-event-wk-50th                15.1                9.4
time-to-event-wk-75th                27.0               30.7
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.6                5.3
time-to-event-wk-50th-hici           23.0               26.1

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0300    0.3270    0.5423    1.9540    0.9291


$sex_m
$sex_m$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                              10.0               26.0
n_event_pct                          59.0               70.0
time-to-event-wk-10th                 2.3                0.4
time-to-event-wk-25th                 5.9                4.3
time-to-event-wk-50th                 9.6               11.6
time-to-event-wk-75th                  NA               37.6
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.9                5.7
time-to-event-wk-50th-hici             NA               18.1

$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2500    0.3799    0.5938    2.6330    0.5565
```

```
$sex_f
$sex_f$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                             20.0               31.0
n_event_pct                         83.0               72.0
time-to-event-wk-10th                2.1                2.0
time-to-event-wk-25th                4.6                3.6
time-to-event-wk-50th                9.0               15.4
time-to-event-wk-75th               15.7               43.6
time-to-event-wk-90th               23.0               52.7
time-to-event-wk-50th-loci           5.1                6.9
time-to-event-wk-50th-hici          15.7               31.1

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7242    0.3135    0.3918    1.3390    0.3032


$region_europe
$region_europe$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                             12.0               19.0
n_event_pct                         71.0               63.0
time-to-event-wk-10th                2.1                0.5
time-to-event-wk-25th                5.1                2.9
time-to-event-wk-50th               15.1               10.9
time-to-event-wk-75th               16.9                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           2.6                5.7
time-to-event-wk-50th-hici          16.9               35.4

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8183    0.3892    0.3816    1.7550    0.6064


$region_asiapacific
$region_asiapacific$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0               12.0
n_event                              1.0                8.0
n_event_pct                         50.0               67.0
time-to-event-wk-10th                7.6                4.1
time-to-event-wk-25th                7.6                6.2
time-to-event-wk-50th                7.6               28.1
time-to-event-wk-75th                7.6               43.6
time-to-event-wk-90th                7.6               43.6
time-to-event-wk-50th-loci            NA                4.1
time-to-event-wk-50th-hici            NA                 NA

$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
  0.27420   1.19600   0.02628   2.86100   0.27950


$region_northamerica
$region_northamerica$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              17.0               30.0
n_event_pct                          77.0               79.0
time-to-event-wk-10th                 2.4                2.0
time-to-event-wk-25th                 5.3                3.4
time-to-event-wk-50th                 9.0               14.4
time-to-event-wk-75th                17.1               30.7
time-to-event-wk-90th                27.0                 NA
time-to-event-wk-50th-loci            5.3                5.3
time-to-event-wk-50th-hici           17.1               25.4

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8094    0.3098    0.4410    1.4860    0.4950


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              16.0               34.0
n_event_pct                          70.0               74.0
time-to-event-wk-10th                 2.1                0.3
time-to-event-wk-25th                 5.1                3.3
time-to-event-wk-50th                15.1                9.4
time-to-event-wk-75th                16.9               37.6
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.6                5.3
time-to-event-wk-50th-hici           16.9               18.1

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9480    0.3095    0.5168    1.7390    0.8631


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                              14.0               23.0
n_event_pct                          78.0               68.0
time-to-event-wk-10th                 2.3                2.9
time-to-event-wk-25th                 5.3                5.7
time-to-event-wk-50th                 7.7               15.0
time-to-event-wk-75th                17.1               44.0
time-to-event-wk-90th                  NA               52.7
time-to-event-wk-50th-loci            5.3                7.6
time-to-event-wk-50th-hici           17.1               35.4
```

```
$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5301    0.3698    0.2568    1.0940    0.0861



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten oder schweren UEs"

$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              30.0               59.0
n_event_pct                          94.0               82.0
time-to-event-wk-10th                 0.7                1.0
time-to-event-wk-25th                 2.5                3.3
time-to-event-wk-50th                 6.8                8.1
time-to-event-wk-75th                 9.5               28.4
time-to-event-wk-90th                16.9                 NA
time-to-event-wk-50th-loci            3.1                5.0
time-to-event-wk-50th-hici            9.0               11.7

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6284    0.2339    0.3973    0.9939    0.0470


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              9.0                6.0
n_event_pct                        100.0               75.0
time-to-event-wk-10th                 1.7                0.4
time-to-event-wk-25th                 5.1                1.9
time-to-event-wk-50th                15.1               10.1
time-to-event-wk-75th                17.9               22.4
time-to-event-wk-90th                26.0                 NA
time-to-event-wk-50th-loci            1.7                0.4
time-to-event-wk-50th-hici           23.0                 NA

$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1180    0.5915    0.3508    3.5650    0.8500


$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                              16.0               39.0
```

```
n_event_pct                          100.0               80.0
time-to-event-wk-10th                  0.7                1.6
time-to-event-wk-25th                  2.4                3.1
time-to-event-wk-50th                  7.0               10.7
time-to-event-wk-75th                  9.1               31.1
time-to-event-wk-90th                  9.6                 NA
time-to-event-wk-50th-loci             2.1                4.7
time-to-event-wk-50th-hici             9.0               15.4

$agetrt_lt_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44800   0.32140   0.23860   0.84120   0.01248


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              23.0               26.0
n_event_pct                          92.0               84.0
time-to-event-wk-10th                 1.7                0.3
time-to-event-wk-25th                 4.0                3.3
time-to-event-wk-50th                 7.6                5.7
time-to-event-wk-75th                16.9               16.7
time-to-event-wk-90th                26.5                 NA
time-to-event-wk-50th-loci            4.6                3.6
time-to-event-wk-50th-hici           16.4               11.0

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9367    0.2884    0.5322    1.6490    0.8207


$sex_m
$sex_m$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                              16.0               30.0
n_event_pct                          94.0               81.0
time-to-event-wk-10th                 0.6                0.4
time-to-event-wk-25th                 1.7                2.4
time-to-event-wk-50th                 7.3                5.7
time-to-event-wk-75th                15.1               26.1
time-to-event-wk-90th                27.0                 NA
time-to-event-wk-50th-loci            0.9                4.3
time-to-event-wk-50th-hici           15.1               15.0

$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8754    0.3186    0.4688    1.6350    0.6763


$sex_f
$sex_f$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              23.0               35.0
n_event_pct                          96.0               81.0
time-to-event-wk-10th                 2.1                1.7
time-to-event-wk-25th                 3.6                3.4
time-to-event-wk-50th                 8.1                9.4
time-to-event-wk-75th                15.4               28.4
time-to-event-wk-90th                23.0               43.6
time-to-event-wk-50th-loci            4.0                5.0
time-to-event-wk-50th-hici            9.1               15.4

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7047    0.2999    0.3914    1.2690    0.2432


$region_europe
$region_europe$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                              15.0               23.0
n_event_pct                          88.0               77.0
time-to-event-wk-10th                 2.1                0.5
time-to-event-wk-25th                 4.6                2.4
time-to-event-wk-50th                 9.0                5.7
time-to-event-wk-75th                15.7               35.4
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            2.6                3.4
time-to-event-wk-50th-hici           15.7               11.7

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8900    0.3533    0.4454    1.7790    0.7416


$region_asiapacific
$region_asiapacific$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0               12.0
n_event                               2.0                9.0
n_event_pct                         100.0               75.0
time-to-event-wk-10th                 0.9                4.1
time-to-event-wk-25th                 0.9                6.2
time-to-event-wk-50th                 4.2               18.0
time-to-event-wk-75th                 7.6               43.6
time-to-event-wk-90th                 7.6               43.6
time-to-event-wk-50th-loci            0.9                4.1
time-to-event-wk-50th-hici             NA                 NA

$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.12620   0.99350   0.01800   0.88460   0.03722
```

```
$region_northamerica
$region_northamerica$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0               38.0
n_event                             22.0               33.0
n_event_pct                        100.0               87.0
time-to-event-wk-10th                0.7                0.6
time-to-event-wk-25th                3.1                3.1
time-to-event-wk-50th                7.5                7.9
time-to-event-wk-75th               15.1               25.7
time-to-event-wk-90th               23.0                 NA
time-to-event-wk-50th-loci           3.1                3.6
time-to-event-wk-50th-hici           9.6               15.4

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6518    0.2861    0.3720    1.1420    0.1347


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0               46.0
n_event                             21.0               39.0
n_event_pct                         91.0               85.0
time-to-event-wk-10th                0.9                0.3
time-to-event-wk-25th                2.4                3.3
time-to-event-wk-50th                7.3                8.1
time-to-event-wk-75th               15.7               25.4
time-to-event-wk-90th               27.0                 NA
time-to-event-wk-50th-loci           3.1                4.7
time-to-event-wk-50th-hici          15.1               11.7

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7905    0.2787    0.4578    1.3650    0.3989


$disdur_le_12wek
$disdur_le_12wek$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0               34.0
n_event                             18.0               26.0
n_event_pct                        100.0               76.0
time-to-event-wk-10th                0.7                1.0
time-to-event-wk-25th                4.4                3.1
time-to-event-wk-50th                7.6                9.1
time-to-event-wk-75th                9.4               31.1
time-to-event-wk-90th               17.9                 NA
time-to-event-wk-50th-loci           4.4                4.1
time-to-event-wk-50th-hici           9.0               25.7

$disdur_le_12wek$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.50970   0.33640   0.26360   0.98570   0.04519



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schweren UEs"

$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                             26.0               41.0
n_event_pct                         81.0               57.0
time-to-event-wk-10th                0.9                3.4
time-to-event-wk-25th                4.2                7.6
time-to-event-wk-50th                8.9               19.9
time-to-event-wk-75th               16.9                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           4.6               11.4
time-to-event-wk-50th-hici          13.7                 NA

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.50710   0.25630   0.30680   0.83810   0.00807


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              7.0                4.0
n_event_pct                         78.0               50.0
time-to-event-wk-10th                1.7                0.6
time-to-event-wk-25th               15.9                2.9
time-to-event-wk-50th               17.9               41.3
time-to-event-wk-75th               26.0                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           1.7                0.6
time-to-event-wk-50th-hici            NA                 NA

$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8083    0.6594    0.2220    2.9430    0.7468


$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                             15.0               27.0
n_event_pct                         94.0               55.0
time-to-event-wk-10th                0.7                1.9
```

```
time-to-event-wk-25th                 5.3                5.7
time-to-event-wk-50th                 8.6               23.4
time-to-event-wk-75th                11.8                 NA
time-to-event-wk-90th                15.7                 NA
time-to-event-wk-50th-loci            4.4               10.6
time-to-event-wk-50th-hici           11.7                 NA

$agetrt_lt_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.330700  0.339200  0.170100  0.643000  0.001106


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              18.0               18.0
n_event_pct                          72.0               58.0
time-to-event-wk-10th                 2.3                4.7
time-to-event-wk-25th                 4.6                7.1
time-to-event-wk-50th                16.4               25.4
time-to-event-wk-75th                52.6                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.6                9.6
time-to-event-wk-50th-hici           26.0                 NA

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7136    0.3376    0.3682    1.3830    0.3175


$sex_m
$sex_m$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                              14.0               21.0
n_event_pct                          82.0               57.0
time-to-event-wk-10th                 0.6                0.7
time-to-event-wk-25th                 1.7                4.1
time-to-event-wk-50th                11.7               15.6
time-to-event-wk-75th                17.9                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            0.9                5.1
time-to-event-wk-50th-hici           17.9                 NA

$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6327    0.3480    0.3199    1.2510    0.1884


$sex_f
$sex_f$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
```

```
n_event                              19.0               24.0
n_event_pct                          79.0               56.0
time-to-event-wk-10th                 3.1                5.0
time-to-event-wk-25th                 6.5               10.0
time-to-event-wk-50th                11.4               28.4
time-to-event-wk-75th                23.0                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.7               11.7
time-to-event-wk-50th-hici           18.1                 NA

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.56000   0.31820   0.30010   1.04500   0.06849


$region_europe
$region_europe$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                              11.0               16.0
n_event_pct                          65.0               53.0
time-to-event-wk-10th                 4.6                3.4
time-to-event-wk-25th                 6.7                5.7
time-to-event-wk-50th                11.9               20.1
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.3               10.6
time-to-event-wk-50th-hici             NA                 NA

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7993    0.4052    0.3612    1.7690    0.5805


$region_asiapacific
$region_asiapacific$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0               12.0
n_event                               1.0                3.0
n_event_pct                          50.0               25.0
time-to-event-wk-10th                 0.9               10.9
time-to-event-wk-25th                 0.9               29.6
time-to-event-wk-50th                25.1                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            0.9               10.9
time-to-event-wk-50th-hici             NA                 NA

$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13270   1.50200   0.00698   2.52200   0.17880


$region_northamerica
```

```
$region_northamerica$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              21.0               26.0
n_event_pct                          95.0               68.0
time-to-event-wk-10th                 0.7                1.6
time-to-event-wk-25th                 3.1                5.0
time-to-event-wk-50th                10.2               14.6
time-to-event-wk-75th                17.9                 NA
time-to-event-wk-90th                26.0                 NA
time-to-event-wk-50th-loci            3.1                7.1
time-to-event-wk-50th-hici           15.9               32.1

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.56110   0.29690   0.31350   1.00400   0.05161


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              17.0               27.0
n_event_pct                          74.0               59.0
time-to-event-wk-10th                 2.3                4.1
time-to-event-wk-25th                 4.0                8.4
time-to-event-wk-50th                13.7               17.4
time-to-event-wk-75th                52.6                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            4.6               10.9
time-to-event-wk-50th-hici           26.0                 NA

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6819    0.3122    0.3698    1.2570    0.2201


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                              16.0               18.0
n_event_pct                          89.0               53.0
time-to-event-wk-10th                 0.7                1.6
time-to-event-wk-25th                 6.1                4.7
time-to-event-wk-50th                10.6               28.4
time-to-event-wk-75th                16.4                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.1                5.7
time-to-event-wk-50th-hici           15.9                 NA

$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5477    0.3664    0.2671    1.1230    0.1004
```

```
\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem UE das zum Therapieabbruch führte"

$ageonset_le_12wk
$ageonset_le_12wk$ntab
            CTRL TRT
n_all         32  72
n_event       14  10
n_event_pct   44  14

$ageonset_le_12wk$stats
                estimate         se      lo95ci     hi95ci      pvalue
RR_TRTvsCTRL   0.3174603 0.35537260  0.15819609  0.6370641 0.001243409
OR_TRTvsCTRL   0.2073733 0.49306507  0.07889601  0.5450678 0.001419165
ARR_TRTvsCTRL -0.2986111 0.09670328 -0.48814605 -0.1090762 0.002015688


$ageonset_gt_12wk
$ageonset_gt_12wk$ntab
            CTRL TRT
n_all          9   8
n_event        2   3
n_event_pct   22  38

$ageonset_gt_12wk$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.6875000 0.7728015  0.3710513  7.6745628 0.4983555
OR_TRTvsCTRL  2.1000000 1.0845232  0.2506522 17.5941009 0.4939033
ARR_TRTvsCTRL 0.1527778 0.2202300 -0.2788651  0.5844207 0.4878584


$agetrt_lt_180d
$agetrt_lt_180d$ntab
            CTRL TRT
n_all         16  49
n_event        8   6
n_event_pct   50  12

$agetrt_lt_180d$stats
                estimate        se      lo95ci     hi95ci      pvalue
RR_TRTvsCTRL   0.2448980 0.4569010  0.10001620  0.5996530 0.002075205
OR_TRTvsCTRL   0.1395349 0.6632665  0.03802851  0.5119839 0.002984741
ARR_TRTvsCTRL -0.3775510 0.1334839 -0.63917475 -0.1159273 0.004677581


$agetrt_ge_180d
$agetrt_ge_180d$ntab
            CTRL TRT
n_all         25  31
n_event        8   7
```

```
n_event_pct   32  23

$agetrt_ge_180d$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.70564516 0.4422658  0.2965712 1.6789731 0.4305152
OR_TRTvsCTRL   0.61979167 0.6069163  0.1886417 2.0363564 0.4305793
ARR_TRTvsCTRL -0.09419355 0.1197635 -0.3289256 0.1405385 0.4315766


$sex_m
$sex_m$ntab
            CTRL TRT
n_all         17  37
n_event        8   7
n_event_pct   47  19

$sex_m$stats
               estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.402027 0.4266223  0.17422629  0.92767704 0.03268501
OR_TRTvsCTRL   0.262500 0.6421071  0.07457044  0.92404240 0.03725193
ARR_TRTvsCTRL -0.281399 0.1371162 -0.55014186 -0.01265623 0.04014372


$sex_f
$sex_f$ntab
            CTRL TRT
n_all         24  43
n_event        8   6
n_event_pct   33  14

$sex_f$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.4186047 0.4761766  0.16461968 1.06445262 0.06743067
OR_TRTvsCTRL   0.3243243 0.6174089  0.09670305 1.08772445 0.06818697
ARR_TRTvsCTRL -0.1937984 0.1097792 -0.40896167 0.02136477 0.07750528


$region_europe
$region_europe$ntab
            CTRL TRT
n_all         17  30
n_event        5   7
n_event_pct   29  23

$region_europe$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.79333333 0.5006998  0.2973441 2.116665 0.6438114
OR_TRTvsCTRL   0.73043478 0.6853238  0.1906482 2.798531 0.6467040
ARR_TRTvsCTRL -0.06078431 0.1348164 -0.3250196 0.203451 0.6520851


$region_asiapacific
$region_asiapacific$ntab
            CTRL TRT
```

```
n_all          2  12
n_event        1   0
n_event_pct   50   0

$region_asiapacific$stats
                estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$region_northamerica
$region_northamerica$ntab
            CTRL TRT
n_all         22  38
n_event       10   6
n_event_pct   45  16

$region_northamerica$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.3473684 0.4414706  0.14622103  0.82522206 0.01661553
OR_TRTvsCTRL   0.2250000 0.6174545  0.06708174  0.75467628 0.01570010
ARR_TRTvsCTRL -0.2966507 0.1215268 -0.53483896 -0.05846248 0.01464542


$disdur_gt_12wk
$disdur_gt_12wk$ntab
            CTRL TRT
n_all         23  46
n_event        9  10
n_event_pct   39  22

$disdur_gt_12wk$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5555556 0.3819604  0.2627860 1.17449926 0.1238365
OR_TRTvsCTRL   0.4320988 0.5570615  0.1450145 1.28752180 0.1319904
ARR_TRTvsCTRL -0.1739130 0.1185513 -0.4062693 0.05844322 0.1423800


$disdur_le_12wek
$disdur_le_12wek$ntab
            CTRL TRT
n_all         18  34
n_event        7   3
n_event_pct   39   9

$disdur_le_12wek$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.2268908 0.6254783  0.06658995  0.77308088 0.01771875
OR_TRTvsCTRL   0.1520737 0.7741819  0.03334797  0.69348815 0.01498471
ARR_TRTvsCTRL -0.3006536 0.1247766 -0.54521115 -0.05609604 0.01597282
```

```
\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs das zum Therapieabbruch führte"

$ageonset_le_12wk
$ageonset_le_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                             14.0               10.0
n_event_pct                         44.0               14.0
time-to-event-wk-10th                4.4               17.4
time-to-event-wk-25th               12.0                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          13.1                 NA
time-to-event-wk-50th-hici            NA                 NA

$ageonset_le_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.258100  0.417100  0.114000  0.584600  0.001166


$ageonset_gt_12wk
$ageonset_gt_12wk$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              2.0                3.0
n_event_pct                         22.0               38.0
time-to-event-wk-10th               23.0                0.6
time-to-event-wk-25th               33.6                5.1
time-to-event-wk-50th                 NA               30.4
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          23.0                0.6
time-to-event-wk-50th-hici            NA                 NA

$ageonset_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.3860    0.9573    0.5187   22.1100    0.2026


$agetrt_lt_180d
$agetrt_lt_180d$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              8.0                6.0
n_event_pct                         50.0               12.0
time-to-event-wk-10th                4.4               16.1
time-to-event-wk-25th               11.6                 NA
time-to-event-wk-50th               40.3                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          10.1                 NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$agetrt_lt_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.167700  0.558600  0.056100  0.501100  0.001389


$agetrt_ge_180d
$agetrt_ge_180d$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               8.0                7.0
n_event_pct                          32.0               23.0
time-to-event-wk-10th                 4.6               12.0
time-to-event-wk-25th                23.0               30.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           23.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$agetrt_ge_180d$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6680    0.5276    0.2375    1.8790    0.4445


$sex_m
$sex_m$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               8.0                7.0
n_event_pct                          47.0               19.0
time-to-event-wk-10th                 4.4                6.9
time-to-event-wk-25th                14.0                 NA
time-to-event-wk-50th                40.3                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$sex_m$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.38150   0.52700   0.13580   1.07200   0.06742


$sex_f
$sex_f$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               8.0                6.0
n_event_pct                          33.0               14.0
time-to-event-wk-10th                 4.6               17.4
time-to-event-wk-25th                14.6                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           18.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$sex_f$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4619    0.5557    0.1554    1.3730    0.1646


$region_europe
$region_europe$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                30.0
n_event                              5.0                 7.0
n_event_pct                         29.0                23.0
time-to-event-wk-10th                4.6                11.5
time-to-event-wk-25th               13.0                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci          11.0                  NA
time-to-event-wk-50th-hici            NA                  NA

$region_europe$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7745    0.5885    0.2444    2.4540    0.6641


$region_asiapacific
$region_asiapacific$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                  12
n_event                              1.0                   0
n_event_pct                         50.0                   0
time-to-event-wk-10th                0.9                  NA
time-to-event-wk-25th                0.9                  NA
time-to-event-wk-50th               25.1                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci           0.9                  NA
time-to-event-wk-50th-hici            NA                  NA

$region_asiapacific$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.188e-28 8.557e+04 0.000e+00       Inf 9.994e-01


$region_northamerica
$region_northamerica$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38.0
n_event                             10.0                 6.0
n_event_pct                         45.0                16.0
```

```
time-to-event-wk-10th                 8.6                16.1
time-to-event-wk-25th                14.3                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           14.3                  NA
time-to-event-wk-50th-hici             NA                  NA

$region_northamerica$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31650   0.51870   0.11450   0.87460   0.02654


$disdur_gt_12wk
$disdur_gt_12wk$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                 46
n_event                               9.0                 10
n_event_pct                          39.0                 22
time-to-event-wk-10th                 3.1                 12
time-to-event-wk-25th                11.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$disdur_gt_12wk$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44880   0.46210   0.18140   1.11000   0.08293


$disdur_le_12wek
$disdur_le_12wek$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               7.0                  3
n_event_pct                          39.0                  9
time-to-event-wk-10th                 8.6                 NA
time-to-event-wk-25th                23.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           23.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$disdur_le_12wek$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.21910   0.69890   0.05569   0.86220   0.02985



\##############################################################################
[[1]]
```

```
[1] "Patienten mit mindestens einem UE nach SOC, das bei mindestens 10% der
Patienten in einem Studienarm auftrat"

$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Blood and lymphatic system disorders`
$Ageonset_greater_12wk$`Blood and lymphatic system disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Blood and lymphatic system disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Cardiac disorders`
$Ageonset_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        2   3
n_event_pct   22  38

$Ageonset_greater_12wk$`Cardiac disorders`$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.6875000 0.7728015  0.3710513  7.6745628 0.4983555
OR_TRTvsCTRL  2.1000000 1.0845232  0.2506522 17.5941009 0.4939033
ARR_TRTvsCTRL 0.1527778 0.2202300 -0.2788651  0.5844207 0.4878584


$Ageonset_greater_12wk$`Eye disorders`
$Ageonset_greater_12wk$`Eye disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Eye disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Gastrointestinal disorders`
$Ageonset_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        7   4
n_event_pct   78  50

$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats
```

```
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6428571 0.3959116  0.29587881 1.3967384 0.2644272
OR_TRTvsCTRL   0.2857143 1.0690450  0.03515274 2.3222271 0.2412563
ARR_TRTvsCTRL -0.2777778 0.2246205 -0.71802596 0.1624704 0.2162158


$Ageonset_greater_12wk$`General disorders and administration site conditions`
$Ageonset_greater_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all          9   8
n_event        7   5
n_event_pct   78  62

$Ageonset_greater_12wk$`General disorders and administration site
conditions`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8035714 0.3267201  0.42356476 1.5245060 0.5032740
OR_TRTvsCTRL   0.4761905 1.0845232  0.05683723 3.9895920 0.4939033
ARR_TRTvsCTRL -0.1527778 0.2202300 -0.58442070 0.2788651 0.4878584


$Ageonset_greater_12wk$`Immune system disorders`
$Ageonset_greater_12wk$`Immune system disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Immune system disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Infections and infestations`
$Ageonset_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all          9   8
n_event        7   4
n_event_pct   78  50

$Ageonset_greater_12wk$`Infections and infestations`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6428571 0.3959116  0.29587881 1.3967384 0.2644272
OR_TRTvsCTRL   0.2857143 1.0690450  0.03515274 2.3222271 0.2412563
ARR_TRTvsCTRL -0.2777778 0.2246205 -0.71802596 0.1624704 0.2162158


$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`
$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all          9   8
```

```
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$Investigations
$Ageonset_greater_12wk$Investigations$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Investigations$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Metabolism and nutrition disorders`
$Ageonset_greater_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Metabolism and nutrition disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Musculoskeletal and connective tissue disorders`
$Ageonset_greater_12wk$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Musculoskeletal and connective tissue disorders`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Nervous system disorders`
$Ageonset_greater_12wk$`Nervous system disorders`$ntab
```

```
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Nervous system disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Psychiatric disorders`
$Ageonset_greater_12wk$`Psychiatric disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$`Psychiatric disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031


$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        8   5
n_event_pct   89  62

$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7031250 0.2981424  0.39197040 1.2612809 0.2374503
OR_TRTvsCTRL   0.2083333 1.2877629  0.01669602 2.5995881 0.2231884
ARR_TRTvsCTRL -0.2638889 0.2006759 -0.65720640 0.1294286 0.1885097


$Ageonset_greater_12wk$`Skin and subcutaneous tissue disorders`
$Ageonset_greater_12wk$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        3   0
n_event_pct   33   0

$Ageonset_greater_12wk$`Skin and subcutaneous tissue disorders`$stats
                estimate        se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.1587302 1.4403483  0.009432629  2.67107530 0.20130218
OR_TRTvsCTRL   0.1092437 1.5991271  0.004755727  2.50943442 0.16617046
ARR_TRTvsCTRL -0.3333333 0.1571348 -0.641311961 -0.02535471 0.03389485
```

```
$Ageonset_greater_12wk$`Vascular disorders`
$Ageonset_greater_12wk$`Vascular disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Vascular disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444



$Agetrt_less_180d
$Agetrt_less_180d$`Blood and lymphatic system disorders`
$Agetrt_less_180d$`Blood and lymphatic system disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$`Blood and lymphatic system disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156


$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        7  11
n_event_pct   44  22

$Agetrt_less_180d$`Cardiac disorders`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5131195 0.3884045  0.2396669 1.09857339 0.08581188
OR_TRTvsCTRL   0.3721805 0.6092562  0.1127597 1.22843841 0.10474612
ARR_TRTvsCTRL -0.2130102 0.1376001 -0.4827015 0.05668113 0.12161324


$Agetrt_less_180d$`Congenital, familial and genetic disorders`
$Agetrt_less_180d$`Congenital, familial and genetic disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        3   3
n_event_pct   19   6

$Agetrt_less_180d$`Congenital, familial and genetic disorders`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3265306 0.7640409  0.07304174 1.4597440 0.1429525
```

```
OR_TRTvsCTRL   0.2826087 0.8748308  0.05087779 1.5697946 0.1485987
ARR_TRTvsCTRL -0.1262755 0.1034140 -0.32896332 0.0764123 0.2220605


$Agetrt_less_180d$`Eye disorders`
$Agetrt_less_180d$`Eye disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        2   2
n_event_pct   12   4

$Agetrt_less_180d$`Eye disorders`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 0.95764912  0.04997715 2.13341975 0.2425131
OR_TRTvsCTRL   0.29787234 1.04532539  0.03839261 2.31106820 0.2466285
ARR_TRTvsCTRL -0.08418367 0.08737805 -0.25544151 0.08707417 0.3353258


$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event       11  32
n_event_pct   69  65

$Agetrt_less_180d$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.94990724 0.1981185  0.6442322 1.400619 0.7953305
OR_TRTvsCTRL   0.85561497 0.6172379  0.2552023 2.868615 0.8005517
ARR_TRTvsCTRL -0.03443878 0.1343565 -0.2977726 0.228895 0.7977007


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         16  49
n_event       11  31
n_event_pct   69  63

$Agetrt_less_180d$`General disorders and administration site conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92022263 0.2006464  0.6210154 1.3635889 0.6786113
OR_TRTvsCTRL   0.78282828 0.6154045  0.2343329 2.6151691 0.6907369
ARR_TRTvsCTRL -0.05484694 0.1347986 -0.3190473 0.2093534 0.6840956


$Agetrt_less_180d$`Immune system disorders`
$Agetrt_less_180d$`Immune system disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        2   5
n_event_pct   12  10

$Agetrt_less_180d$`Immune system disorders`$stats
```

```
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.81632653 0.78555193  0.1750656 3.8065096 0.7961432
OR_TRTvsCTRL   0.79545455 0.89115422  0.1386959 4.5621254 0.7973391
ARR_TRTvsCTRL -0.02295918 0.09330545 -0.2058345 0.1599161 0.8056321


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         16  49
n_event       13  42
n_event_pct   81  86

$Agetrt_less_180d$`Infections and infestations`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.05494505 0.1335082  0.8120588 1.370478 0.6886854
OR_TRTvsCTRL  1.38461538 0.7595545  0.3124605 6.135686 0.6683319
ARR_TRTvsCTRL 0.04464286 0.1096378 -0.1702432 0.259529 0.6838721


$Agetrt_less_180d$`Injury, poisoning and procedural complications`
$Agetrt_less_180d$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         16  49
n_event        4   9
n_event_pct   25  18

$Agetrt_less_180d$`Injury, poisoning and procedural complications`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.73469388 0.5274495  0.2613007 2.0657237 0.5588749
OR_TRTvsCTRL   0.67500000 0.6851602  0.1762359 2.5853132 0.5662042
ARR_TRTvsCTRL -0.06632653 0.1215677 -0.3045948 0.1719417 0.5853454


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$ntab
            CTRL TRT
n_all         16  49
n_event        7  14
n_event_pct   44  29

$Agetrt_less_180d$Investigations$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6530612 0.3624604  0.3209424 1.3288647 0.2397813
OR_TRTvsCTRL   0.5142857 0.5949523  0.1602434 1.6505504 0.2636965
ARR_TRTvsCTRL -0.1517857 0.1398063 -0.4258010 0.1222295 0.2776179


$Agetrt_less_180d$`Metabolism and nutrition disorders`
$Agetrt_less_180d$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        7  12
n_event_pct   44  24
```

```
$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5597668 0.3785265  0.2665660 1.17546432 0.1253058
OR_TRTvsCTRL   0.4169884 0.6035964  0.1277444 1.36115060 0.1472980
ARR_TRTvsCTRL -0.1926020 0.1384009 -0.4638627 0.07865865 0.1640361


$Agetrt_less_180d$`Musculoskeletal and connective tissue disorders`
$Agetrt_less_180d$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        2   8
n_event_pct   12  16

$Agetrt_less_180d$`Musculoskeletal and connective tissue disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.30612245 0.73626886  0.3085110 5.5296429 0.7168107
OR_TRTvsCTRL  1.36585366 0.84901049  0.2586575 7.2124566 0.7134497
ARR_TRTvsCTRL 0.03826531 0.09810143 -0.1540100 0.2305406 0.6964932


$Agetrt_less_180d$`Psychiatric disorders`
$Agetrt_less_180d$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        3   6
n_event_pct   19  12

$Agetrt_less_180d$`Psychiatric disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 0.6458265  0.1841728 2.3157005 0.5094139
OR_TRTvsCTRL   0.60465116 0.7747121  0.1324551 2.7602032 0.5160753
ARR_TRTvsCTRL -0.06505102 0.1082333 -0.2771844 0.1470824 0.5478227


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event       15  35
n_event_pct   94  71

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.7619048 0.11104023  0.61289076  0.94714899 0.01432671
OR_TRTvsCTRL   0.1666667 1.08012345  0.02006532  1.38436782 0.09714664
ARR_TRTvsCTRL -0.2232143 0.08847056 -0.39661340 -0.04981517 0.01163470


$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         16  49
```

```
n_event        6  13
n_event_pct   38  27

$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.7074830 0.4008511  0.3224861 1.552105 0.3879904
OR_TRTvsCTRL   0.6018519 0.6093993  0.1822921 1.987061 0.4047389
ARR_TRTvsCTRL -0.1096939 0.1364785 -0.3771868 0.157799 0.4215443



$Gender_Male
$Gender_Male$`Blood and lymphatic system disorders`
$Gender_Male$`Blood and lymphatic system disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$`Blood and lymphatic system disorders`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$`Cardiac disorders`
$Gender_Male$`Cardiac disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        8   9
n_event_pct   47  24

$Gender_Male$`Cardiac disorders`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5168919 0.3876346  0.2417935 1.10498112 0.08867439
OR_TRTvsCTRL   0.3616071 0.6188186  0.1075221 1.21611986 0.10022326
ARR_TRTvsCTRL -0.2273450 0.1401072 -0.5019500 0.04726004 0.10466414


$Gender_Male$`Congenital, familial and genetic disorders`
$Gender_Male$`Congenital, familial and genetic disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        3   3
n_event_pct   18   8

$Gender_Male$`Congenital, familial and genetic disorders`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.45945946 0.7621129  0.10316574 2.0462510 0.3075111
OR_TRTvsCTRL   0.41176471 0.8760748  0.07394911 2.2927955 0.3111477
ARR_TRTvsCTRL -0.09538951 0.1027738 -0.29682241 0.1060434 0.3533296
```

```
$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event       10  23
n_event_pct   59  62

$Gender_Male$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.05675676 0.2400577  0.6601423 1.6916578 0.8181200
OR_TRTvsCTRL  1.15000000 0.5981337  0.3560947 3.7139000 0.8152463
ARR_TRTvsCTRL 0.03338633 0.1435440 -0.2479548 0.3147275 0.8160829


$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  37
n_event       11  24
n_event_pct   65  65

$Gender_Male$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.002457002 0.2161601  0.6562509 1.5313046 0.9909421
OR_TRTvsCTRL  1.006993007 0.6133233  0.3026667 3.3503349 0.9909345
ARR_TRTvsCTRL 0.001589825 0.1399761 -0.2727583 0.2759379 0.9909380


$Gender_Male$`Immune system disorders`
$Gender_Male$`Immune system disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$`Immune system disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  37
n_event       14  29
n_event_pct   82  78

$Gender_Male$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.95173745 0.1416361  0.7210350 1.2562555 0.7269034
OR_TRTvsCTRL   0.77678571 0.7511622  0.1782013 3.3860367 0.7366698
ARR_TRTvsCTRL -0.03974563 0.1145815 -0.2643213 0.1848301 0.7286842
```

```
$Gender_Male$`Injury, poisoning and procedural complications`
$Gender_Male$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         17  37
n_event        4   9
n_event_pct   24  24

$Gender_Male$`Injury, poisoning and procedural complications`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.033783784 0.5246528  0.3696957 2.8907796 0.9495047
OR_TRTvsCTRL  1.044642857 0.6882939  0.2710760 4.0257301 0.9494049
ARR_TRTvsCTRL 0.007949126 0.1247365 -0.2365299 0.2524281 0.9491873


$Gender_Male$Investigations
$Gender_Male$Investigations$ntab
            CTRL TRT
n_all         17  37
n_event        6  10
n_event_pct   35  27

$Gender_Male$Investigations$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.76576577 0.4252248  0.3327698 1.7621705 0.5302539
OR_TRTvsCTRL   0.67901235 0.6281821  0.1982294 2.3258798 0.5377309
ARR_TRTvsCTRL -0.08267091 0.1369822 -0.3511512 0.1858093 0.5461658


$Gender_Male$`Metabolism and nutrition disorders`
$Gender_Male$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        7   6
n_event_pct   41  16

$Gender_Male$`Metabolism and nutrition disorders`$stats
                 estimate        se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.3938224 0.4729411  0.15585913 0.9951042 0.04879928
OR_TRTvsCTRL   0.2764977 0.6646667  0.07514951 1.0173183 0.05309698
ARR_TRTvsCTRL -0.2496025 0.1338654 -0.51197399 0.0127689 0.06224060


$Gender_Male$`Musculoskeletal and connective tissue disorders`
$Gender_Male$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        3   4
n_event_pct   18  11

$Gender_Male$`Musculoskeletal and connective tissue disorders`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.61261261 0.7053246  0.1537491 2.4409524 0.4872136
```

```
OR_TRTvsCTRL   0.56565657 0.8276865  0.1116927 2.8647113 0.4912095
ARR_TRTvsCTRL -0.06836248 0.1056159 -0.2753658 0.1386408 0.5174542


$Gender_Male$`Nervous system disorders`
$Gender_Male$`Nervous system disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        1   4
n_event_pct    6  11

$Gender_Male$`Nervous system disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.83783784 1.07895757  0.2217670 15.2306185 0.5727177
OR_TRTvsCTRL  1.93939394 1.15879378  0.2001239 18.7946001 0.5675877
ARR_TRTvsCTRL 0.04928458 0.07656783 -0.1007856  0.1993548 0.5197880


$Gender_Male$`Psychiatric disorders`
$Gender_Male$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        1   4
n_event_pct    6  11

$Gender_Male$`Psychiatric disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.83783784 1.07895757  0.2217670 15.2306185 0.5727177
OR_TRTvsCTRL  1.93939394 1.15879378  0.2001239 18.7946001 0.5675877
ARR_TRTvsCTRL 0.04928458 0.07656783 -0.1007856  0.1993548 0.5197880


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event       15  30
n_event_pct   88  81

$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.91891892 0.1189514  0.7278226 1.1601892 0.4771732
OR_TRTvsCTRL   0.57142857 0.8618916  0.1055160 3.0946064 0.5161523
ARR_TRTvsCTRL -0.07154213 0.1012527 -0.2699937 0.1269095 0.4798336


$Gender_Male$`Skin and subcutaneous tissue disorders`
$Gender_Male$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        8  11
n_event_pct   47  30

$Gender_Male$`Skin and subcutaneous tissue disorders`$stats
```

```
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6317568 0.3606363  0.3115844 1.2809261 0.2028598
OR_TRTvsCTRL   0.4759615 0.6045509  0.1455383 1.5565622 0.2194285
ARR_TRTvsCTRL -0.1732909 0.1424825 -0.4525515 0.1059696 0.2238987



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Blood and lymphatic system disorders`
$Disdur_less_equal_12wk$`Blood and lymphatic system disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Blood and lymphatic system disorders`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Cardiac disorders`
$Disdur_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        7   5
n_event_pct   39  15

$Disdur_less_equal_12wk$`Cardiac disorders`$stats
               estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3781513 0.5078285  0.13976587 1.02312804 0.05550020
OR_TRTvsCTRL   0.2709360 0.6842872  0.07085986 1.03593614 0.05634349
ARR_TRTvsCTRL -0.2418301 0.1299700 -0.49656665 0.01290652 0.06279218


$Disdur_less_equal_12wk$`Congenital, familial and genetic disorders`
$Disdur_less_equal_12wk$`Congenital, familial and genetic disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        3   2
n_event_pct   17   6

$Disdur_less_equal_12wk$`Congenital, familial and genetic disorders`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3529412 0.86508151  0.06476548 1.92336205 0.2286362
OR_TRTvsCTRL   0.3125000 0.96501295  0.04714433 2.07143131 0.2280792
ARR_TRTvsCTRL -0.1078431 0.09666635 -0.29730569 0.08161942 0.2645838


$Disdur_less_equal_12wk$`Eye disorders`
$Disdur_less_equal_12wk$`Eye disorders`$ntab
            CTRL TRT
n_all         18  34
```

```
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Eye disorders`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event       12  21
n_event_pct   67  62

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92647059 0.2144413  0.6085537 1.4104717 0.7217292
OR_TRTvsCTRL   0.80769231 0.6119985  0.2433951 2.6802789 0.7271057
ARR_TRTvsCTRL -0.04901961 0.1388940 -0.3212468 0.2232076 0.7241422


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         18  34
n_event       13  21
n_event_pct   72  62

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8552036 0.1989342  0.5790772 1.2629978 0.4317102
OR_TRTvsCTRL   0.6213018 0.6336128  0.1794611 2.1509722 0.4525623
ARR_TRTvsCTRL -0.1045752 0.1345038 -0.3681977 0.1590474 0.4368705


$Disdur_less_equal_12wk$`Immune system disorders`
$Disdur_less_equal_12wk$`Immune system disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   4
n_event_pct   11  12

$Disdur_less_equal_12wk$`Immune system disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 0.81549536  0.2141276 5.2356968 0.9441217
OR_TRTvsCTRL  1.066666667 0.91969198  0.1758675 6.4695184 0.9440551
ARR_TRTvsCTRL 0.006535948 0.09241262 -0.1745895 0.1876614 0.9436161
```

```
$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         18  34
n_event       14  25
n_event_pct   78  74

$Disdur_less_equal_12wk$`Infections and infestations`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94537815 0.1626691  0.6872921 1.3003785 0.7298660
OR_TRTvsCTRL   0.79365079 0.6874152  0.2063006 3.0532218 0.7367171
ARR_TRTvsCTRL -0.04248366 0.1238015 -0.2851301 0.2001628 0.7314784


$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`
$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         18  34
n_event        6   6
n_event_pct   33  18

$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5294118 0.4983633  0.1993361 1.40605150 0.2019008
OR_TRTvsCTRL   0.4285714 0.6725927  0.1146862 1.60153033 0.2077600
ARR_TRTvsCTRL -0.1568627 0.1289188 -0.4095389 0.09581343 0.2236969


$Disdur_less_equal_12wk$Investigations
$Disdur_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         18  34
n_event        7   7
n_event_pct   39  21

$Disdur_less_equal_12wk$Investigations$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5294118 0.4480479  0.2199958 1.27400958 0.1557632
OR_TRTvsCTRL   0.4074074 0.6431644  0.1154959 1.43711469 0.1626751
ARR_TRTvsCTRL -0.1830065 0.1342076 -0.4460487 0.08003559 0.1726911


$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`
$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        6   7
n_event_pct   33  21

$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6176471 0.4738739  0.2439935 1.5635169 0.3092455
OR_TRTvsCTRL   0.5185185 0.6556632  0.1434375 1.8744151 0.3164872
ARR_TRTvsCTRL -0.1274510 0.1309746 -0.3841565 0.1292545 0.3305052
```

```
$Disdur_less_equal_12wk$`Musculoskeletal and connective tissue disorders`
$Disdur_less_equal_12wk$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   7
n_event_pct   11  21

$Disdur_less_equal_12wk$`Musculoskeletal and connective tissue disorders`$stats
                 estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.85294118 0.7469202  0.4286294  8.0101617 0.4089423
OR_TRTvsCTRL  2.07407407 0.8616230  0.3831858 11.2263631 0.3971762
ARR_TRTvsCTRL 0.09477124 0.1014674 -0.1041013  0.2936437 0.3503005


$Disdur_less_equal_12wk$`Nervous system disorders`
$Disdur_less_equal_12wk$`Nervous system disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   3
n_event_pct   11   9

$Disdur_less_equal_12wk$`Nervous system disorders`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.86508151  0.1457223 4.3275646 0.7898725
OR_TRTvsCTRL   0.77419355 0.96337500  0.1171718 5.1153557 0.7904985
ARR_TRTvsCTRL -0.02287582 0.08861794 -0.1965638 0.1508122 0.7962990


$Disdur_less_equal_12wk$`Psychiatric disorders`
$Disdur_less_equal_12wk$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   4
n_event_pct   11  12

$Disdur_less_equal_12wk$`Psychiatric disorders`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 0.81549536  0.2141276 5.2356968 0.9441217
OR_TRTvsCTRL  1.066666667 0.91969198  0.1758675 6.4695184 0.9440551
ARR_TRTvsCTRL 0.006535948 0.09241262 -0.1745895 0.1876614 0.9436161


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event       16  25
n_event_pct   89  74

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.8272059 0.1324110  0.63812410 1.07231427 0.1519514
```

```
OR_TRTvsCTRL   0.3472222 0.8447551  0.06630568 1.81829491 0.2105022
ARR_TRTvsCTRL -0.1535948 0.1058847 -0.36112503 0.05393549 0.1468955


$Disdur_less_equal_12wk$`Skin and subcutaneous tissue disorders`
$Disdur_less_equal_12wk$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        8   8
n_event_pct   44  24

$Disdur_less_equal_12wk$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5294118 0.4062421  0.2387809 1.17378222 0.1174561
OR_TRTvsCTRL   0.3846154 0.6232668  0.1133707 1.30482521 0.1252587
ARR_TRTvsCTRL -0.2091503 0.1378750 -0.4793803 0.06107962 0.1292776



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       11  15
n_event_pct   34  21

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6060606 0.33531607  0.3141192 1.16933141 0.1353214
OR_TRTvsCTRL   0.5023923 0.47195197  0.1992126 1.26697855 0.1446841
ARR_TRTvsCTRL -0.1354167 0.09664503 -0.3248375 0.05400412 0.1611616


$Ageonset_less_equal_12wk$`Congenital, familial and genetic disorders`
$Ageonset_less_equal_12wk$`Congenital, familial and genetic disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        4   4
n_event_pct   12   6

$Ageonset_less_equal_12wk$`Congenital, familial and genetic disorders`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.44444444 0.67443392  0.11850544 1.6668506 0.2292138
OR_TRTvsCTRL   0.41176471 0.74190307  0.09619225 1.7626178 0.2317033
ARR_TRTvsCTRL -0.06944444 0.06439493 -0.19565618 0.0567673 0.2808487


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       19  49
n_event_pct   59  68
```

```
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14619883 0.1670355  0.8261884 1.5901600 0.4139862
OR_TRTvsCTRL  1.45766590 0.4398194  0.6155780 3.4516991 0.3915564
ARR_TRTvsCTRL 0.08680556 0.1027486 -0.1145781 0.2881892 0.3982034


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         32  72
n_event       21  46
n_event_pct   66  64

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.97354497 0.1556255  0.7176082 1.3207623 0.8632169
OR_TRTvsCTRL   0.92673993 0.4457901  0.3868126 2.2203175 0.8644845
ARR_TRTvsCTRL -0.01736111 0.1012614 -0.2158297 0.1811075 0.8638711


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         32  72
n_event       24  61
n_event_pct   75  85

$Ageonset_less_equal_12wk$`Infections and infestations`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.12962963 0.1136715  0.90402133 1.4115409 0.2835860
OR_TRTvsCTRL  1.84848485 0.5234207  0.66264269 5.1564686 0.2404942
ARR_TRTvsCTRL 0.09722222 0.0875049 -0.07428423 0.2687287 0.2665473


$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`
$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         32  72
n_event        8  18
n_event_pct   25  25

$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`$stats
             estimate         se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.36799004  0.4861455 2.0569971      1
OR_TRTvsCTRL         1 0.49065338  0.3822567 2.6160432      1
ARR_TRTvsCTRL        0 0.09199751 -0.1803118 0.1803118      1


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$ntab
```

```
            CTRL TRT
n_all         32  72
n_event       13  21
n_event_pct   41  29

$Ageonset_less_equal_12wk$Investigations$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7179487 0.2817858  0.4132729 1.24723971 0.2396274
OR_TRTvsCTRL   0.6018100 0.4436007  0.2522701 1.43566441 0.2523111
ARR_TRTvsCTRL -0.1145833 0.1020159 -0.3145309 0.08536419 0.2613565


$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       12  14
n_event_pct   38  19

$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5185185 0.33109367  0.2709797 0.99218284 0.04729299
OR_TRTvsCTRL   0.4022989 0.47117224  0.1597667 1.01300440 0.05329267
ARR_TRTvsCTRL -0.1805556 0.09746649 -0.3715864 0.01047525 0.06395569


$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue disorders`
$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        5  10
n_event_pct   16  14

$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue
disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.50483771  0.3304676 2.3909259 0.8155217
OR_TRTvsCTRL   0.87096774 0.59427777  0.2717390 2.7915938 0.8161748
ARR_TRTvsCTRL -0.01736111 0.07603267 -0.1663824 0.1316602 0.8193839


$Ageonset_less_equal_12wk$`Nervous system disorders`
$Ageonset_less_equal_12wk$`Nervous system disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        1   9
n_event_pct    3  12

$Ageonset_less_equal_12wk$`Nervous system disorders`$stats
              estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.000000 1.0324593  0.5287240 30.2615346 0.17936561
OR_TRTvsCTRL  4.428571 1.0766811  0.5367735 36.5372846 0.16694211
ARR_TRTvsCTRL 0.093750 0.0496502 -0.0035626  0.1910626 0.05899776
```

```
$Ageonset_less_equal_12wk$`Psychiatric disorders`
$Ageonset_less_equal_12wk$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        4   8
n_event_pct   12  11

$Ageonset_less_equal_12wk$`Psychiatric disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.57433536  0.2883848 2.7398238 0.8375119
OR_TRTvsCTRL   0.87500000 0.65294662  0.2433430 3.1462789 0.8379582
ARR_TRTvsCTRL -0.01388889 0.06920774 -0.1495336 0.1217558 0.8409456


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       28  56
n_event_pct   88  78

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.09182886  0.7424763 1.06417327 0.1996195
OR_TRTvsCTRL   0.50000000 0.60503837  0.1527427 1.63673963 0.2519503
ARR_TRTvsCTRL -0.09722222 0.07627921 -0.2467267 0.05228228 0.2024660


$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`
$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       12  23
n_event_pct   38  32

$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85185185 0.2857844  0.4865237 1.4915031 0.5747555
OR_TRTvsCTRL   0.78231293 0.4440943  0.3276172 1.8680748 0.5803925
ARR_TRTvsCTRL -0.05555556 0.1017038 -0.2548913 0.1437802 0.5848950



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Cardiac disorders`
$Agetrt_greater_equal_180d$`Cardiac disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        6   7
n_event_pct   24  23

$Agetrt_greater_equal_180d$`Cardiac disorders`$stats
```

```
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94086022 0.4870993  0.3621641 2.4442453 0.9004044
OR_TRTvsCTRL   0.92361111 0.6354699  0.2658130 3.2092397 0.9004856
ARR_TRTvsCTRL -0.01419355 0.1137334 -0.2371069 0.2087198 0.9006845


$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       15  21
n_event_pct   60  68

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.12903226 0.2050065  0.7554479 1.6873616 0.5538603
OR_TRTvsCTRL  1.40000000 0.5606119  0.4665888 4.2007009 0.5483813
ARR_TRTvsCTRL 0.07741935 0.1290314 -0.1754776 0.3303163 0.5485037


$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         25  31
n_event       17  20
n_event_pct   68  65

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94876660 0.1912210  0.6522165 1.3801522 0.7832894
OR_TRTvsCTRL   0.85561497 0.5698532  0.2800390 2.6141967 0.7843610
ARR_TRTvsCTRL -0.03483871 0.1268416 -0.2834436 0.2137662 0.7835750


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         25  31
n_event       18  23
n_event_pct   72  74

$Agetrt_greater_equal_180d$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.03046595 0.1636330  0.7477372 1.4200979 0.8544804
OR_TRTvsCTRL  1.11805556 0.6057152  0.3410968 3.6647904 0.8538328
ARR_TRTvsCTRL 0.02193548 0.1193330 -0.2119529 0.2558238 0.8541567


$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`
$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
```

```
n_all         25  31
n_event        6  10
n_event_pct   24  32

$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.34408602 0.4409179  0.5663919 3.1896062 0.5024252
OR_TRTvsCTRL  1.50793651 0.6057370  0.4600222 4.9429624 0.4977168
ARR_TRTvsCTRL 0.08258065 0.1197711 -0.1521663 0.3173276 0.4905166


$Agetrt_greater_equal_180d$Investigations
$Agetrt_greater_equal_180d$Investigations$ntab
            CTRL TRT
n_all         25  31
n_event        7   7
n_event_pct   28  23

$Agetrt_greater_equal_180d$Investigations$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80645161 0.4620132  0.3260708 1.9945489 0.6415049
OR_TRTvsCTRL   0.75000000 0.6188186  0.2230087 2.5223227 0.6420108
ARR_TRTvsCTRL -0.05419355 0.1170610 -0.2836290 0.1752419 0.6433993


$Agetrt_greater_equal_180d$`Metabolism and nutrition disorders`
$Agetrt_greater_equal_180d$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        6   2
n_event_pct   24   6

$Agetrt_greater_equal_180d$`Metabolism and nutrition disorders`$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2688172 0.77097899  0.05931965 1.21819150 0.08838703
OR_TRTvsCTRL   0.2183908 0.86820562  0.03983056 1.19743601 0.07969998
ARR_TRTvsCTRL -0.1754839 0.09613998 -0.36391478 0.01294704 0.06795647


$Agetrt_greater_equal_180d$`Musculoskeletal and connective tissue disorders`
$Agetrt_greater_equal_180d$`Musculoskeletal and connective tissue
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        3   3
n_event_pct   12  10

$Agetrt_greater_equal_180d$`Musculoskeletal and connective tissue
disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80645161 0.77097899  0.1779589 3.6545745 0.7802366
OR_TRTvsCTRL   0.78571429 0.86477482  0.1442670 4.2791973 0.7803425
ARR_TRTvsCTRL -0.02322581 0.08392642 -0.1877186 0.1412669 0.7819797
```

```
$Agetrt_greater_equal_180d$`Nervous system disorders`
$Agetrt_greater_equal_180d$`Nervous system disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        1   5
n_event_pct    4  16

$Agetrt_greater_equal_180d$`Nervous system disorders`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  4.0322581 1.06195195  0.50305235 32.3209007 0.1891881
OR_TRTvsCTRL  4.6153846 1.13142751  0.50249883 42.3916908 0.1764587
ARR_TRTvsCTRL 0.1212903 0.07680973 -0.02925397  0.2718346 0.1143129


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       21  26
n_event_pct   84  84

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.998463902 0.11756922  0.7929709 1.2572090 0.9895675
OR_TRTvsCTRL   0.990476190 0.73217524  0.2358388 4.1598027 0.9895720
ARR_TRTvsCTRL -0.001290323 0.09869009 -0.1947193 0.1921387 0.9895684


$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        9  10
n_event_pct   36  32

$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.89605735 0.3726299  0.4316708 1.8600257 0.7683526
OR_TRTvsCTRL   0.84656085 0.5667717  0.2787541 2.5709588 0.7688357
ARR_TRTvsCTRL -0.03741935 0.1275347 -0.2873828 0.2125441 0.7692124



$Gender_Female
$Gender_Female$`Cardiac disorders`
$Gender_Female$`Cardiac disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        5   9
n_event_pct   21  21
```

```
$Gender_Female$`Cardiac disorders`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.0046511628 0.4961740  0.3799017 2.6568030 0.9925380
OR_TRTvsCTRL  1.0058823529 0.6270203  0.2943246 3.4376989 0.9925367
ARR_TRTvsCTRL 0.0009689922 0.1035414 -0.2019684 0.2039064 0.9925331


$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       16  30
n_event_pct   67  70

$Gender_Female$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.04651163 0.1758148  0.7414642 1.4770592 0.7959585
OR_TRTvsCTRL  1.15384615 0.5456706  0.3959791 3.3622002 0.7931305
ARR_TRTvsCTRL 0.03100775 0.1190147 -0.2022567 0.2642722 0.7944494


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         24  43
n_event       17  27
n_event_pct   71  63

$Gender_Female$`General disorders and administration site conditions`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88645691 0.1758923  0.6279685 1.2513459 0.4932127
OR_TRTvsCTRL   0.69485294 0.5488330  0.2369875 2.0373256 0.5071220
ARR_TRTvsCTRL -0.08042636 0.1184977 -0.3126776 0.1518248 0.4973174


$Gender_Female$`Immune system disorders`
$Gender_Female$`Immune system disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        2   6
n_event_pct    8  14

$Gender_Female$`Immune system disorders`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.67441860 0.77572172  0.36607369 7.6587795 0.5063712
OR_TRTvsCTRL  1.78378378 0.85973731  0.33077486 9.6194875 0.5008484
ARR_TRTvsCTRL 0.05620155 0.07729862 -0.09530097 0.2077041 0.4671828


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$ntab
            CTRL TRT
n_all         24  43
```

```
n_event       17  36
n_event_pct   71  84

$Gender_Female$`Infections and infestations`$stats
              estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.181943 0.1472373  0.88566144 1.5773388 0.2562474
OR_TRTvsCTRL  2.117647 0.6101767  0.64042789 7.0022388 0.2188271
ARR_TRTvsCTRL 0.128876 0.1085253 -0.08382979 0.3415817 0.2350227


$Gender_Female$`Injury, poisoning and procedural complications`
$Gender_Female$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         24  43
n_event        6  10
n_event_pct   25  23

$Gender_Female$`Injury, poisoning and procedural complications`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93023256 0.4491594  0.3857148 2.2434517 0.8720829
OR_TRTvsCTRL   0.90909091 0.5937384  0.2839333 2.9107059 0.8724671
ARR_TRTvsCTRL -0.01744186 0.1093759 -0.2318146 0.1969309 0.8733008


$Gender_Female$Investigations
$Gender_Female$Investigations$ntab
            CTRL TRT
n_all         24  43
n_event        8  11
n_event_pct   33  26

$Gender_Female$Investigations$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.76744186 0.3885700  0.3583391 1.6436026 0.4957471
OR_TRTvsCTRL   0.68750000 0.5564702  0.2309960 2.0461666 0.5007312
ARR_TRTvsCTRL -0.07751938 0.1169895 -0.3068146 0.1517758 0.5075751


$Gender_Female$`Metabolism and nutrition disorders`
$Gender_Female$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        6   8
n_event_pct   25  19

$Gender_Female$`Metabolism and nutrition disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.74418605 0.4761766  0.2926572 1.8923602 0.5349333
OR_TRTvsCTRL   0.68571429 0.6130201  0.2062242 2.2800631 0.5382457
ARR_TRTvsCTRL -0.06395349 0.1064622 -0.2726156 0.1447086 0.5480296


$Gender_Female$`Musculoskeletal and connective tissue disorders`
$Gender_Female$`Musculoskeletal and connective tissue disorders`$ntab
```

```
            CTRL TRT
n_all         24  43
n_event        2   7
n_event_pct    8  16

$Gender_Female$`Musculoskeletal and connective tissue disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.95348837 0.76022014  0.44026106  8.6678500 0.3784156
OR_TRTvsCTRL  2.13888889 0.84622070  0.40727135 11.2329179 0.3689460
ARR_TRTvsCTRL 0.07945736 0.07970196 -0.07675561  0.2356703 0.3187980


$Gender_Female$`Nervous system disorders`
$Gender_Female$`Nervous system disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        1   5
n_event_pct    4  12

$Gender_Female$`Nervous system disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.7906977 1.0654002  0.34581396 22.5207608 0.3354009
OR_TRTvsCTRL  3.0263158 1.1268514  0.33245786 27.5481148 0.3257599
ARR_TRTvsCTRL 0.0746124 0.0636671 -0.05017282  0.1993976 0.2412314


$Gender_Female$`Psychiatric disorders`
$Gender_Female$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        4   5
n_event_pct   17  12

$Gender_Female$`Psychiatric disorders`$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.6976744 0.62054615  0.2067488 2.354305 0.5618212
OR_TRTvsCTRL   0.6578947 0.72547625  0.1587194 2.726986 0.5638365
ARR_TRTvsCTRL -0.0503876 0.09042546 -0.2276182 0.126843 0.5773717


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       21  31
n_event_pct   88  72

$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8239203 0.12228913  0.64832458 1.0470752 0.1132393
OR_TRTvsCTRL   0.3690476 0.70465863  0.09274188 1.4685506 0.1571777
ARR_TRTvsCTRL -0.1540698 0.09610476 -0.34243164 0.0342921 0.1089029
```

```
$Gender_Female$`Skin and subcutaneous tissue disorders`
$Gender_Female$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        7  12
n_event_pct   29  28

$Gender_Female$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.9568106 0.4015819  0.4355108 2.1020987 0.9124572
OR_TRTvsCTRL   0.9400922 0.5632691  0.3116843 2.8354759 0.9126660
ARR_TRTvsCTRL -0.0125969 0.1152695 -0.2385209 0.2133271 0.9129787



$Region_Europe
$Region_Europe$`Cardiac disorders`
$Region_Europe$`Cardiac disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        2   5
n_event_pct   12  17

$Region_Europe$`Cardiac disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.41666667 0.7796430  0.3073508 6.5298163 0.6550545
OR_TRTvsCTRL  1.50000000 0.8981462  0.2579810 8.7215711 0.6516677
ARR_TRTvsCTRL 0.04901961 0.1036141 -0.1540603 0.2520995 0.6361433


$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        9  14
n_event_pct   53  47

$Region_Europe$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8814815 0.3006374  0.4890015 1.5889717 0.6747683
OR_TRTvsCTRL   0.7777778 0.6083089  0.2360816 2.5624121 0.6795068
ARR_TRTvsCTRL -0.0627451 0.1514968 -0.3596735 0.2341833 0.6787513


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  30
n_event       12  20
n_event_pct   71  67

$Region_Europe$`General disorders and administration site conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94444444 0.2029199  0.6345279 1.4057307 0.7781891
```

```
OR_TRTvsCTRL   0.83333333 0.6582806  0.2293450 3.0279466 0.7818060
ARR_TRTvsCTRL -0.03921569 0.1400711 -0.3137499 0.2353186 0.7795006


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  30
n_event       11  22
n_event_pct   65  73

$Region_Europe$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.13333333 0.2102541  0.7505663 1.7113004 0.5516465
OR_TRTvsCTRL  1.50000000 0.6542402  0.4161031 5.4073137 0.5354227
ARR_TRTvsCTRL 0.08627451 0.1412525 -0.1905753 0.3631243 0.5413438


$Region_Europe$`Injury, poisoning and procedural complications`
$Region_Europe$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         17  30
n_event        2   5
n_event_pct   12  17

$Region_Europe$`Injury, poisoning and procedural complications`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.41666667 0.7796430  0.3073508 6.5298163 0.6550545
OR_TRTvsCTRL  1.50000000 0.8981462  0.2579810 8.7215711 0.6516677
ARR_TRTvsCTRL 0.04901961 0.1036141 -0.1540603 0.2520995 0.6361433


$Region_Europe$Investigations
$Region_Europe$Investigations$ntab
            CTRL TRT
n_all         17  30
n_event        4  11
n_event_pct   24  37

$Region_Europe$Investigations$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.5583333 0.4987507  0.5863042 4.1418818 0.3737580
OR_TRTvsCTRL  1.8815789 0.6859036  0.4905466 7.2171320 0.3567505
ARR_TRTvsCTRL 0.1313725 0.1353695 -0.1339468 0.3966919 0.3318104


$Region_Europe$`Metabolism and nutrition disorders`
$Region_Europe$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        4   6
n_event_pct   24  20

$Region_Europe$`Metabolism and nutrition disorders`$stats
```

```
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.5696576  0.2783079 2.5960459 0.7754202
OR_TRTvsCTRL   0.81250000 0.7316122  0.1936752 3.4085746 0.7765555
ARR_TRTvsCTRL -0.03529412 0.1261646 -0.2825721 0.2119839 0.7796719


$Region_Europe$`Psychiatric disorders`
$Region_Europe$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        3   2
n_event_pct   18   7

$Region_Europe$`Psychiatric disorders`$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3777778 0.8609161  0.06989133 2.04197063 0.2581758
OR_TRTvsCTRL   0.3333333 0.9697815  0.04981948 2.23027424 0.2572793
ARR_TRTvsCTRL -0.1098039 0.1030671 -0.31181168 0.09220384 0.2867114


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event       14  22
n_event_pct   82  73

$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.89047619 0.1572458  0.6542962 1.2119096 0.4607020
OR_TRTvsCTRL   0.58928571 0.7584303  0.1332751 2.6055710 0.4856227
ARR_TRTvsCTRL -0.09019608 0.1227488 -0.3307793 0.1503871 0.4624600


$Region_Europe$`Vascular disorders`
$Region_Europe$`Vascular disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        1   3
n_event_pct    6  10

$Region_Europe$`Vascular disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 1.11408100  0.1914880 15.0923333 0.6338661
OR_TRTvsCTRL  1.77777778 1.19702563  0.1702031 18.5689583 0.6307571
ARR_TRTvsCTRL 0.04117647 0.07909909 -0.1138549  0.1962078 0.6026676



$Region_Asia_Pacific
$Region_Asia_Pacific$`Cardiac disorders`
$Region_Asia_Pacific$`Cardiac disorders`$ntab
            CTRL TRT
n_all          2  12
```

```
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$`Cardiac disorders`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353


$Region_Asia_Pacific$`Eye disorders`
$Region_Asia_Pacific$`Eye disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Eye disorders`$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$`Gastrointestinal disorders`
$Region_Asia_Pacific$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        1   7
n_event_pct   50  58

$Region_Asia_Pacific$`Gastrointestinal disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.16666667 0.7480132  0.26930025  5.0542511 0.8367283
OR_TRTvsCTRL  1.40000000 1.5306395  0.06970202 28.1197013 0.8260077
ARR_TRTvsCTRL 0.08333333 0.3811229 -0.66365373  0.8303204 0.8269210


$Region_Asia_Pacific$`General disorders and administration site conditions`
$Region_Asia_Pacific$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all          2  12
n_event        1   4
n_event_pct   50  33

$Region_Asia_Pacific$`General disorders and administration site
conditions`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6666667 0.8164966  0.13455678  3.3030252 0.6194773
OR_TRTvsCTRL   0.5000000 1.5411035  0.02438823 10.2508454 0.6528739
ARR_TRTvsCTRL -0.1666667 0.3788384 -0.90917625  0.5758429 0.6599796


$Region_Asia_Pacific$`Infections and infestations`
```

```
$Region_Asia_Pacific$`Infections and infestations`$ntab
            CTRL TRT
n_all          2  12
n_event        0   9
n_event_pct    0  75

$Region_Asia_Pacific$`Infections and infestations`$stats
               estimate       se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL   4.384615 1.301924 0.3417681  56.2511535 2.562409e-01
OR_TRTvsCTRL  13.571429 1.670622 0.5135582 358.6422760 1.185060e-01
ARR_TRTvsCTRL  0.750000 0.125000 0.5050045   0.9949955 1.973175e-09


$Region_Asia_Pacific$`Injury, poisoning and procedural complications`
$Region_Asia_Pacific$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Injury, poisoning and procedural complications`$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$`Nervous system disorders`
$Region_Asia_Pacific$`Nervous system disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Nervous system disorders`$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`
$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        1   4
n_event_pct   50  33

$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6666667 0.8164966  0.13455678  3.3030252 0.6194773
OR_TRTvsCTRL   0.5000000 1.5411035  0.02438823 10.2508454 0.6528739
ARR_TRTvsCTRL -0.1666667 0.3788384 -0.90917625  0.5758429 0.6599796
```

```
$Region_Asia_Pacific$`Skin and subcutaneous tissue disorders`
$Region_Asia_Pacific$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        1   2
n_event_pct   50  17

$Region_Asia_Pacific$`Skin and subcutaneous tissue disorders`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3333333 0.9574271  0.051040546 2.1769185 0.2511903
OR_TRTvsCTRL   0.2000000 1.6124515  0.008482205 4.7157551 0.3182158
ARR_TRTvsCTRL -0.3333333 0.3695593 -1.057656246 0.3909896 0.3670700



$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       11  11
n_event_pct   50  29

$Region_Northamerica$`Cardiac disorders`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5789474 0.3317346  0.3021803 1.10920569 0.09944854
OR_TRTvsCTRL   0.4074074 0.5565647  0.1368611 1.21276788 0.10666542
ARR_TRTvsCTRL -0.2105263 0.1295231 -0.4643869 0.04333429 0.10407822


$Region_Northamerica$`Congenital, familial and genetic disorders`
$Region_Northamerica$`Congenital, familial and genetic disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        4   3
n_event_pct   18   8

$Region_Northamerica$`Congenital, familial and genetic disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4342105 0.71523632  0.10687843 1.76404886 0.2434674
OR_TRTvsCTRL   0.3857143 0.81698245  0.07777661 1.91285673 0.2435863
ARR_TRTvsCTRL -0.1028708 0.09314171 -0.28542520 0.07968358 0.2693959


$Region_Northamerica$`Eye disorders`
$Region_Northamerica$`Eye disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        1   4
n_event_pct    5  11

$Region_Northamerica$`Eye disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL  2.31578947 1.08546288  0.27589981 19.4377841 0.4391474
OR_TRTvsCTRL  2.47058824 1.15196823  0.25837068 23.6242216 0.4323715
ARR_TRTvsCTRL 0.05980861 0.06671354 -0.07094753  0.1905648 0.3699864


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       16  32
n_event_pct   73  84

$Region_Northamerica$`Gastrointestinal disorders`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.1578947 0.1482554  0.8659122 1.5483328 0.3227328
OR_TRTvsCTRL  2.0000000 0.6535161  0.5555921 7.1995265 0.2888523
ARR_TRTvsCTRL 0.1148325 0.1118697 -0.1044280 0.3340931 0.3046632


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         22  38
n_event       15  27
n_event_pct   68  71

$Region_Northamerica$`General disorders and administration site
conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.04210526 0.1786991  0.7341802 1.4791783 0.8174736
OR_TRTvsCTRL  1.14545455 0.5809216  0.3668567 3.5765084 0.8151642
ARR_TRTvsCTRL 0.02870813 0.1235864 -0.2135168 0.2709331 0.8163112


$Region_Northamerica$`Immune system disorders`
$Region_Northamerica$`Immune system disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        4   5
n_event_pct   18  13

$Region_Northamerica$`Immune system disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.72368421 0.6150038  0.2167988 2.4156904 0.5989920
OR_TRTvsCTRL   0.68181818 0.7320236  0.1623936 2.8626498 0.6008375
ARR_TRTvsCTRL -0.05023923 0.0988374 -0.2439570 0.1434785 0.6112417


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$ntab
            CTRL TRT
n_all         22  38
n_event       20  34
n_event_pct   91  89
```

```
$Region_Northamerica$`Infections and infestations`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.98421053 0.08741527  0.8292395 1.1681430 0.8555300
OR_TRTvsCTRL   0.85000000 0.91072046  0.1426305 5.0655382 0.8583688
ARR_TRTvsCTRL -0.01435407 0.07896246 -0.1691176 0.1404095 0.8557527


$Region_Northamerica$`Injury, poisoning and procedural complications`
$Region_Northamerica$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         22  38
n_event        7  14
n_event_pct   32  37

$Region_Northamerica$`Injury, poisoning and procedural complications`$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.15789474 0.3775121  0.5524974 2.426655 0.6977636
OR_TRTvsCTRL  1.25000000 0.5679956  0.4106116 3.805299 0.6944219
ARR_TRTvsCTRL 0.05023923 0.1264292 -0.1975575 0.298036 0.6910943


$Region_Northamerica$Investigations
$Region_Northamerica$Investigations$ntab
            CTRL TRT
n_all         22  38
n_event       10   9
n_event_pct   45  24

$Region_Northamerica$Investigations$stats
                 estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5210526 0.3732838  0.2506928 1.08298220 0.08074080
OR_TRTvsCTRL   0.3724138 0.5735218  0.1210161 1.14606265 0.08502366
ARR_TRTvsCTRL -0.2177033 0.1265948 -0.4658246 0.03041792 0.08548950


$Region_Northamerica$`Metabolism and nutrition disorders`
$Region_Northamerica$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        9   7
n_event_pct   41  18

$Region_Northamerica$`Metabolism and nutrition disorders`$stats
                 estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.4502924 0.4268465  0.1950573 1.03950600 0.06159607
OR_TRTvsCTRL   0.3261649 0.6026188  0.1001122 1.06264261 0.06300739
ARR_TRTvsCTRL -0.2248804 0.1222401 -0.4644665 0.01470577 0.06581793


$Region_Northamerica$`Musculoskeletal and connective tissue disorders`
$Region_Northamerica$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         22  38
```

```
n_event        5   9
n_event_pct   23  24

$Region_Northamerica$`Musculoskeletal and connective tissue disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.042105263 0.4892247  0.3994687 2.7185691 0.9328158
OR_TRTvsCTRL  1.055172414 0.6359382  0.3033974 3.6697376 0.9326997
ARR_TRTvsCTRL 0.009569378 0.1128683 -0.2116483 0.2307871 0.9324334


$Region_Northamerica$`Nervous system disorders`
$Region_Northamerica$`Nervous system disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        1   7
n_event_pct    5  18

$Region_Northamerica$`Nervous system disorders`$stats
              estimate        se     lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  4.052632 1.0349332  0.5330898 30.808737 0.17633306
OR_TRTvsCTRL  4.741935 1.1057731  0.5429000 41.418222 0.15926051
ARR_TRTvsCTRL 0.138756 0.0769861 -0.0121340  0.289646 0.07149018


$Region_Northamerica$`Psychiatric disorders`
$Region_Northamerica$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        2   6
n_event_pct    9  16

$Region_Northamerica$`Psychiatric disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.73684211 0.77129523  0.38302988  7.8756794 0.4741345
OR_TRTvsCTRL  1.87500000 0.86482175  0.34424184 10.2126602 0.4673087
ARR_TRTvsCTRL 0.06698565 0.08517996 -0.09996402  0.2339353 0.4316323


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       21  35
n_event_pct   95  92

$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se      lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.96491228 0.06648414  0.84702539 1.099206 0.5911004
OR_TRTvsCTRL   0.55555556 1.18723368  0.05421911 5.692495 0.6205371
ARR_TRTvsCTRL -0.03349282 0.06233575 -0.15566865 0.088683 0.5910623


$Region_Northamerica$`Skin and subcutaneous tissue disorders`
$Region_Northamerica$`Skin and subcutaneous tissue disorders`$ntab
```

```
            CTRL TRT
n_all         22  38
n_event       13  19
n_event_pct   59  50

$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.84615385 0.2403837  0.5282437 1.3553901 0.4870881
OR_TRTvsCTRL   0.69230769 0.5415693  0.2395050 2.0011692 0.4971388
ARR_TRTvsCTRL -0.09090909 0.1325403 -0.3506833 0.1688651 0.4927775



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        6  13
n_event_pct   26  28

$Disdur_greater_12wk$`Cardiac disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.08333333 0.4223415  0.4734394 2.4789048 0.8496843
OR_TRTvsCTRL  1.11616162 0.5768157  0.3603634 3.4571121 0.8489007
ARR_TRTvsCTRL 0.02173913 0.1130962 -0.1999253 0.2434036 0.8475714


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       14  32
n_event_pct   61  70

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14285714 0.1935489  0.7820649 1.6700946 0.4902506
OR_TRTvsCTRL  1.46938776 0.5340583  0.5158758 4.1853102 0.4711517
ARR_TRTvsCTRL 0.08695652 0.1223049 -0.1527567 0.3266698 0.4770958


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         23  46
n_event       15  30
n_event_pct   65  65

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats
              estimate        se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.1865010  0.6938252 1.4412851      1
OR_TRTvsCTRL         1 0.5361903  0.3496182 2.8602631      1
```

```
ARR_TRTvsCTRL        0 0.1216311 -0.2383925 0.2383925      1


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         23  46
n_event       17  40
n_event_pct   74  87

$Disdur_greater_12wk$`Infections and infestations`$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.1764706 0.1364043  0.90047883 1.5370523 0.2334770
OR_TRTvsCTRL  2.3529412 0.6458768  0.66349817 8.3441560 0.1852331
ARR_TRTvsCTRL 0.1304348 0.1041586 -0.07371236 0.3345819 0.2104713


$Disdur_greater_12wk$`Injury, poisoning and procedural complications`
$Disdur_greater_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         23  46
n_event        4  13
n_event_pct   17  28

$Disdur_greater_12wk$`Injury, poisoning and procedural complications`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.6250000 0.5115718  0.5962147 4.4289834 0.3425946
OR_TRTvsCTRL  1.8712121 0.6402013  0.5335593 6.5624098 0.3277117
ARR_TRTvsCTRL 0.1086957 0.1032173 -0.0936066 0.3109979 0.2923064


$Disdur_greater_12wk$Investigations
$Disdur_greater_12wk$Investigations$ntab
            CTRL TRT
n_all         23  46
n_event        7  14
n_event_pct   30  30

$Disdur_greater_12wk$Investigations$stats
              estimate        se     lo95ci   hi95ci pvalue
RR_TRTvsCTRL         1 0.3860937  0.4691983 2.131295      1
OR_TRTvsCTRL         1 0.5550097  0.3369573 2.967735      1
ARR_TRTvsCTRL        0 0.1175068 -0.2303090 0.230309      1


$Disdur_greater_12wk$`Metabolism and nutrition disorders`
$Disdur_greater_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        7   7
n_event_pct   30  15

$Disdur_greater_12wk$`Metabolism and nutrition disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.5000000 0.4695710  0.1991913 1.25507459 0.1399093
OR_TRTvsCTRL   0.4102564 0.6114371  0.1237654 1.35991438 0.1450671
ARR_TRTvsCTRL -0.1521739 0.1095899 -0.3669662 0.06261833 0.1649617


$Disdur_greater_12wk$`Musculoskeletal and connective tissue disorders`
$Disdur_greater_12wk$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        3   4
n_event_pct   13   9

$Disdur_greater_12wk$`Musculoskeletal and connective tissue disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.66666667 0.7198027  0.1626341 2.7327879 0.5732304
OR_TRTvsCTRL   0.63492063 0.8106435  0.1296279 3.1098570 0.5752313
ARR_TRTvsCTRL -0.04347826 0.0815926 -0.2033968 0.1164403 0.5941235


$Disdur_greater_12wk$`Nervous system disorders`
$Disdur_greater_12wk$`Nervous system disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        0   6
n_event_pct    0  13

$Disdur_greater_12wk$`Nervous system disorders`$stats
                estimate         se     lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  6.6382979 1.44599547 0.39014241 112.9510596 0.190523219
OR_TRTvsCTRL  7.5432099 1.49033241 0.40642736 140.0004533 0.175151041
ARR_TRTvsCTRL 0.1304348 0.04965567 0.03311145   0.2277581 0.008619575


$Disdur_greater_12wk$`Psychiatric disorders`
$Disdur_greater_12wk$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        3   5
n_event_pct   13  11

$Disdur_greater_12wk$`Psychiatric disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83333333 0.68418999  0.2179893 3.1856813 0.7898711
OR_TRTvsCTRL   0.81300813 0.77956628  0.1764115 3.7468206 0.7905855
ARR_TRTvsCTRL -0.02173913 0.08388968 -0.1861599 0.1426816 0.7955276


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       20  36
n_event_pct   87  78
```

```
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.90000000 0.11207313  0.7225130 1.12108704 0.3471637
OR_TRTvsCTRL   0.54000000 0.71492035  0.1330002 2.19247711 0.3887454
ARR_TRTvsCTRL -0.08695652 0.09289726 -0.2690318 0.09511876 0.3492472


$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`
$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        7  15
n_event_pct   30  33

$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.07142857 0.3798768  0.5088754 2.2558747 0.8558817
OR_TRTvsCTRL  1.10599078 0.5516175  0.3751577 3.2605374 0.8550888
ARR_TRTvsCTRL 0.02173913 0.1182476 -0.2100219 0.2535002 0.8541357




\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem UE nach SOC, das bei mindestens 10 Patienten
und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       11  15
n_event_pct   34  21

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6060606 0.33531607  0.3141192 1.16933141 0.1353214
OR_TRTvsCTRL   0.5023923 0.47195197  0.1992126 1.26697855 0.1446841
ARR_TRTvsCTRL -0.1354167 0.09664503 -0.3248375 0.05400412 0.1611616


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       19  49
n_event_pct   59  68

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14619883 0.1670355  0.8261884 1.5901600 0.4139862
OR_TRTvsCTRL  1.45766590 0.4398194  0.6155780 3.4516991 0.3915564
```

```
ARR_TRTvsCTRL 0.08680556 0.1027486 -0.1145781 0.2881892 0.3982034


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         32  72
n_event       21  46
n_event_pct   66  64

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.97354497 0.1556255  0.7176082 1.3207623 0.8632169
OR_TRTvsCTRL   0.92673993 0.4457901  0.3868126 2.2203175 0.8644845
ARR_TRTvsCTRL -0.01736111 0.1012614 -0.2158297 0.1811075 0.8638711


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         32  72
n_event       24  61
n_event_pct   75  85

$Ageonset_less_equal_12wk$`Infections and infestations`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.12962963 0.1136715  0.90402133 1.4115409 0.2835860
OR_TRTvsCTRL  1.84848485 0.5234207  0.66264269 5.1564686 0.2404942
ARR_TRTvsCTRL 0.09722222 0.0875049 -0.07428423 0.2687287 0.2665473


$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`
$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         32  72
n_event        8  18
n_event_pct   25  25

$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`$stats
              estimate         se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.36799004  0.4861455 2.0569971      1
OR_TRTvsCTRL         1 0.49065338  0.3822567 2.6160432      1
ARR_TRTvsCTRL        0 0.09199751 -0.1803118 0.1803118      1


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         32  72
n_event       13  21
n_event_pct   41  29
```

```
$Ageonset_less_equal_12wk$Investigations$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7179487 0.2817858  0.4132729 1.24723971 0.2396274
OR_TRTvsCTRL   0.6018100 0.4436007  0.2522701 1.43566441 0.2523111
ARR_TRTvsCTRL -0.1145833 0.1020159 -0.3145309 0.08536419 0.2613565


$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       12  14
n_event_pct   38  19

$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5185185 0.33109367  0.2709797 0.99218284 0.04729299
OR_TRTvsCTRL   0.4022989 0.47117224  0.1597667 1.01300440 0.05329267
ARR_TRTvsCTRL -0.1805556 0.09746649 -0.3715864 0.01047525 0.06395569


$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue disorders`
$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        5  10
n_event_pct   16  14

$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue
disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.50483771  0.3304676 2.3909259 0.8155217
OR_TRTvsCTRL   0.87096774 0.59427777  0.2717390 2.7915938 0.8161748
ARR_TRTvsCTRL -0.01736111 0.07603267 -0.1663824 0.1316602 0.8193839


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       28  56
n_event_pct   88  78

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.09182886  0.7424763 1.06417327 0.1996195
OR_TRTvsCTRL   0.50000000 0.60503837  0.1527427 1.63673963 0.2519503
ARR_TRTvsCTRL -0.09722222 0.07627921 -0.2467267 0.05228228 0.2024660


$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`
$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
```

```
n_all         32  72
n_event       12  23
n_event_pct   38  32

$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85185185 0.2857844  0.4865237 1.4915031 0.5747555
OR_TRTvsCTRL   0.78231293 0.4440943  0.3276172 1.8680748 0.5803925
ARR_TRTvsCTRL -0.05555556 0.1017038 -0.2548913 0.1437802 0.5848950



$Agetrt_less_180d
$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        7  11
n_event_pct   44  22

$Agetrt_less_180d$`Cardiac disorders`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5131195 0.3884045  0.2396669 1.09857339 0.08581188
OR_TRTvsCTRL   0.3721805 0.6092562  0.1127597 1.22843841 0.10474612
ARR_TRTvsCTRL -0.2130102 0.1376001 -0.4827015 0.05668113 0.12161324


$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event       11  32
n_event_pct   69  65

$Agetrt_less_180d$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.94990724 0.1981185  0.6442322 1.400619 0.7953305
OR_TRTvsCTRL   0.85561497 0.6172379  0.2552023 2.868615 0.8005517
ARR_TRTvsCTRL -0.03443878 0.1343565 -0.2977726 0.228895 0.7977007


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         16  49
n_event       11  31
n_event_pct   69  63

$Agetrt_less_180d$`General disorders and administration site conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92022263 0.2006464  0.6210154 1.3635889 0.6786113
OR_TRTvsCTRL   0.78282828 0.6154045  0.2343329 2.6151691 0.6907369
ARR_TRTvsCTRL -0.05484694 0.1347986 -0.3190473 0.2093534 0.6840956
```

```
$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         16  49
n_event       13  42
n_event_pct   81  86

$Agetrt_less_180d$`Infections and infestations`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.05494505 0.1335082  0.8120588 1.370478 0.6886854
OR_TRTvsCTRL  1.38461538 0.7595545  0.3124605 6.135686 0.6683319
ARR_TRTvsCTRL 0.04464286 0.1096378 -0.1702432 0.259529 0.6838721


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$ntab
            CTRL TRT
n_all         16  49
n_event        7  14
n_event_pct   44  29

$Agetrt_less_180d$Investigations$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6530612 0.3624604  0.3209424 1.3288647 0.2397813
OR_TRTvsCTRL   0.5142857 0.5949523  0.1602434 1.6505504 0.2636965
ARR_TRTvsCTRL -0.1517857 0.1398063 -0.4258010 0.1222295 0.2776179


$Agetrt_less_180d$`Metabolism and nutrition disorders`
$Agetrt_less_180d$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        7  12
n_event_pct   44  24

$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5597668 0.3785265  0.2665660 1.17546432 0.1253058
OR_TRTvsCTRL   0.4169884 0.6035964  0.1277444 1.36115060 0.1472980
ARR_TRTvsCTRL -0.1926020 0.1384009 -0.4638627 0.07865865 0.1640361


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event       15  35
n_event_pct   94  71

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.7619048 0.11104023  0.61289076  0.94714899 0.01432671
OR_TRTvsCTRL   0.1666667 1.08012345  0.02006532  1.38436782 0.09714664
```

```
ARR_TRTvsCTRL -0.2232143 0.08847056 -0.39661340 -0.04981517 0.01163470


$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        6  13
n_event_pct   38  27

$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.7074830 0.4008511  0.3224861 1.552105 0.3879904
OR_TRTvsCTRL   0.6018519 0.6093993  0.1822921 1.987061 0.4047389
ARR_TRTvsCTRL -0.1096939 0.1364785 -0.3771868 0.157799 0.4215443



$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       11  11
n_event_pct   50  29

$Region_Northamerica$`Cardiac disorders`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5789474 0.3317346  0.3021803 1.10920569 0.09944854
OR_TRTvsCTRL   0.4074074 0.5565647  0.1368611 1.21276788 0.10666542
ARR_TRTvsCTRL -0.2105263 0.1295231 -0.4643869 0.04333429 0.10407822


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       16  32
n_event_pct   73  84

$Region_Northamerica$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.1578947 0.1482554  0.8659122 1.5483328 0.3227328
OR_TRTvsCTRL  2.0000000 0.6535161  0.5555921 7.1995265 0.2888523
ARR_TRTvsCTRL 0.1148325 0.1118697 -0.1044280 0.3340931 0.3046632


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         22  38
n_event       15  27
n_event_pct   68  71
```

```
$Region_Northamerica$`General disorders and administration site
conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.04210526 0.1786991  0.7341802 1.4791783 0.8174736
OR_TRTvsCTRL  1.14545455 0.5809216  0.3668567 3.5765084 0.8151642
ARR_TRTvsCTRL 0.02870813 0.1235864 -0.2135168 0.2709331 0.8163112


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$ntab
            CTRL TRT
n_all         22  38
n_event       20  34
n_event_pct   91  89

$Region_Northamerica$`Infections and infestations`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.98421053 0.08741527  0.8292395 1.1681430 0.8555300
OR_TRTvsCTRL   0.85000000 0.91072046  0.1426305 5.0655382 0.8583688
ARR_TRTvsCTRL -0.01435407 0.07896246 -0.1691176 0.1404095 0.8557527


$Region_Northamerica$`Injury, poisoning and procedural complications`
$Region_Northamerica$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         22  38
n_event        7  14
n_event_pct   32  37

$Region_Northamerica$`Injury, poisoning and procedural complications`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.15789474 0.3775121  0.5524974 2.426655 0.6977636
OR_TRTvsCTRL  1.25000000 0.5679956  0.4106116 3.805299 0.6944219
ARR_TRTvsCTRL 0.05023923 0.1264292 -0.1975575 0.298036 0.6910943


$Region_Northamerica$Investigations
$Region_Northamerica$Investigations$ntab
            CTRL TRT
n_all         22  38
n_event       10   9
n_event_pct   45  24

$Region_Northamerica$Investigations$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.5210526 0.3732838  0.2506928 1.08298220 0.08074080
OR_TRTvsCTRL   0.3724138 0.5735218  0.1210161 1.14606265 0.08502366
ARR_TRTvsCTRL -0.2177033 0.1265948 -0.4658246 0.03041792 0.08548950


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         22  38
```

```
n_event       21  35
n_event_pct   95  92

$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate         se      lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.96491228 0.06648414  0.84702539 1.099206 0.5911004
OR_TRTvsCTRL   0.55555556 1.18723368  0.05421911 5.692495 0.6205371
ARR_TRTvsCTRL -0.03349282 0.06233575 -0.15566865 0.088683 0.5910623


$Region_Northamerica$`Skin and subcutaneous tissue disorders`
$Region_Northamerica$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       13  19
n_event_pct   59  50

$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.84615385 0.2403837  0.5282437 1.3553901 0.4870881
OR_TRTvsCTRL   0.69230769 0.5415693  0.2395050 2.0011692 0.4971388
ARR_TRTvsCTRL -0.09090909 0.1325403 -0.3506833 0.1688651 0.4927775



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        6  13
n_event_pct   26  28

$Disdur_greater_12wk$`Cardiac disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.08333333 0.4223415  0.4734394 2.4789048 0.8496843
OR_TRTvsCTRL  1.11616162 0.5768157  0.3603634 3.4571121 0.8489007
ARR_TRTvsCTRL 0.02173913 0.1130962 -0.1999253 0.2434036 0.8475714


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       14  32
n_event_pct   61  70

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14285714 0.1935489  0.7820649 1.6700946 0.4902506
OR_TRTvsCTRL  1.46938776 0.5340583  0.5158758 4.1853102 0.4711517
ARR_TRTvsCTRL 0.08695652 0.1223049 -0.1527567 0.3266698 0.4770958
```

```
$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         23  46
n_event       15  30
n_event_pct   65  65

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats
              estimate        se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.1865010  0.6938252 1.4412851      1
OR_TRTvsCTRL         1 0.5361903  0.3496182 2.8602631      1
ARR_TRTvsCTRL        0 0.1216311 -0.2383925 0.2383925      1


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         23  46
n_event       17  40
n_event_pct   74  87

$Disdur_greater_12wk$`Infections and infestations`$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.1764706 0.1364043  0.90047883 1.5370523 0.2334770
OR_TRTvsCTRL  2.3529412 0.6458768  0.66349817 8.3441560 0.1852331
ARR_TRTvsCTRL 0.1304348 0.1041586 -0.07371236 0.3345819 0.2104713


$Disdur_greater_12wk$`Injury, poisoning and procedural complications`
$Disdur_greater_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         23  46
n_event        4  13
n_event_pct   17  28

$Disdur_greater_12wk$`Injury, poisoning and procedural complications`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.6250000 0.5115718  0.5962147 4.4289834 0.3425946
OR_TRTvsCTRL  1.8712121 0.6402013  0.5335593 6.5624098 0.3277117
ARR_TRTvsCTRL 0.1086957 0.1032173 -0.0936066 0.3109979 0.2923064


$Disdur_greater_12wk$Investigations
$Disdur_greater_12wk$Investigations$ntab
            CTRL TRT
n_all         23  46
n_event        7  14
n_event_pct   30  30

$Disdur_greater_12wk$Investigations$stats
              estimate        se     lo95ci   hi95ci pvalue
RR_TRTvsCTRL         1 0.3860937  0.4691983 2.131295      1
OR_TRTvsCTRL         1 0.5550097  0.3369573 2.967735      1
```

```
ARR_TRTvsCTRL        0 0.1175068 -0.2303090 0.230309      1


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       20  36
n_event_pct   87  78

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.90000000 0.11207313  0.7225130 1.12108704 0.3471637
OR_TRTvsCTRL   0.54000000 0.71492035  0.1330002 2.19247711 0.3887454
ARR_TRTvsCTRL -0.08695652 0.09289726 -0.2690318 0.09511876 0.3492472


$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`
$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        7  15
n_event_pct   30  33

$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.07142857 0.3798768  0.5088754 2.2558747 0.8558817
OR_TRTvsCTRL  1.10599078 0.5516175  0.3751577 3.2605374 0.8550888
ARR_TRTvsCTRL 0.02173913 0.1182476 -0.2100219 0.2535002 0.8541357



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       15  21
n_event_pct   60  68

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.12903226 0.2050065  0.7554479 1.6873616 0.5538603
OR_TRTvsCTRL  1.40000000 0.5606119  0.4665888 4.2007009 0.5483813
ARR_TRTvsCTRL 0.07741935 0.1290314 -0.1754776 0.3303163 0.5485037


$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         25  31
n_event       17  20
```

```
n_event_pct   68  65

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94876660 0.1912210  0.6522165 1.3801522 0.7832894
OR_TRTvsCTRL   0.85561497 0.5698532  0.2800390 2.6141967 0.7843610
ARR_TRTvsCTRL -0.03483871 0.1268416 -0.2834436 0.2137662 0.7835750


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         25  31
n_event       18  23
n_event_pct   72  74

$Agetrt_greater_equal_180d$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.03046595 0.1636330  0.7477372 1.4200979 0.8544804
OR_TRTvsCTRL  1.11805556 0.6057152  0.3410968 3.6647904 0.8538328
ARR_TRTvsCTRL 0.02193548 0.1193330 -0.2119529 0.2558238 0.8541567


$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`
$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         25  31
n_event        6  10
n_event_pct   24  32

$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.34408602 0.4409179  0.5663919 3.1896062 0.5024252
OR_TRTvsCTRL  1.50793651 0.6057370  0.4600222 4.9429624 0.4977168
ARR_TRTvsCTRL 0.08258065 0.1197711 -0.1521663 0.3173276 0.4905166


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       21  26
n_event_pct   84  84

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.998463902 0.11756922  0.7929709 1.2572090 0.9895675
OR_TRTvsCTRL   0.990476190 0.73217524  0.2358388 4.1598027 0.9895720
ARR_TRTvsCTRL -0.001290323 0.09869009 -0.1947193 0.1921387 0.9895684
```

```
$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        9  10
n_event_pct   36  32

$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.89605735 0.3726299  0.4316708 1.8600257 0.7683526
OR_TRTvsCTRL   0.84656085 0.5667717  0.2787541 2.5709588 0.7688357
ARR_TRTvsCTRL -0.03741935 0.1275347 -0.2873828 0.2125441 0.7692124



$Gender_Male
$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event       10  23
n_event_pct   59  62

$Gender_Male$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.05675676 0.2400577  0.6601423 1.6916578 0.8181200
OR_TRTvsCTRL  1.15000000 0.5981337  0.3560947 3.7139000 0.8152463
ARR_TRTvsCTRL 0.03338633 0.1435440 -0.2479548 0.3147275 0.8160829


$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  37
n_event       11  24
n_event_pct   65  65

$Gender_Male$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.002457002 0.2161601  0.6562509 1.5313046 0.9909421
OR_TRTvsCTRL  1.006993007 0.6133233  0.3026667 3.3503349 0.9909345
ARR_TRTvsCTRL 0.001589825 0.1399761 -0.2727583 0.2759379 0.9909380


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  37
n_event       14  29
n_event_pct   82  78

$Gender_Male$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.95173745 0.1416361  0.7210350 1.2562555 0.7269034
OR_TRTvsCTRL   0.77678571 0.7511622  0.1782013 3.3860367 0.7366698
ARR_TRTvsCTRL -0.03974563 0.1145815 -0.2643213 0.1848301 0.7286842


$Gender_Male$Investigations
$Gender_Male$Investigations$ntab
            CTRL TRT
n_all         17  37
n_event        6  10
n_event_pct   35  27

$Gender_Male$Investigations$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.76576577 0.4252248  0.3327698 1.7621705 0.5302539
OR_TRTvsCTRL   0.67901235 0.6281821  0.1982294 2.3258798 0.5377309
ARR_TRTvsCTRL -0.08267091 0.1369822 -0.3511512 0.1858093 0.5461658


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event       15  30
n_event_pct   88  81

$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.91891892 0.1189514  0.7278226 1.1601892 0.4771732
OR_TRTvsCTRL   0.57142857 0.8618916  0.1055160 3.0946064 0.5161523
ARR_TRTvsCTRL -0.07154213 0.1012527 -0.2699937 0.1269095 0.4798336


$Gender_Male$`Skin and subcutaneous tissue disorders`
$Gender_Male$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        8  11
n_event_pct   47  30

$Gender_Male$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6317568 0.3606363  0.3115844 1.2809261 0.2028598
OR_TRTvsCTRL   0.4759615 0.6045509  0.1455383 1.5565622 0.2194285
ARR_TRTvsCTRL -0.1732909 0.1424825 -0.4525515 0.1059696 0.2238987



$Gender_Female
$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       16  30
```

```
n_event_pct   67  70

$Gender_Female$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.04651163 0.1758148  0.7414642 1.4770592 0.7959585
OR_TRTvsCTRL  1.15384615 0.5456706  0.3959791 3.3622002 0.7931305
ARR_TRTvsCTRL 0.03100775 0.1190147 -0.2022567 0.2642722 0.7944494


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         24  43
n_event       17  27
n_event_pct   71  63

$Gender_Female$`General disorders and administration site conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88645691 0.1758923  0.6279685 1.2513459 0.4932127
OR_TRTvsCTRL   0.69485294 0.5488330  0.2369875 2.0373256 0.5071220
ARR_TRTvsCTRL -0.08042636 0.1184977 -0.3126776 0.1518248 0.4973174


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$ntab
            CTRL TRT
n_all         24  43
n_event       17  36
n_event_pct   71  84

$Gender_Female$`Infections and infestations`$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.181943 0.1472373  0.88566144 1.5773388 0.2562474
OR_TRTvsCTRL  2.117647 0.6101767  0.64042789 7.0022388 0.2188271
ARR_TRTvsCTRL 0.128876 0.1085253 -0.08382979 0.3415817 0.2350227


$Gender_Female$`Injury, poisoning and procedural complications`
$Gender_Female$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         24  43
n_event        6  10
n_event_pct   25  23

$Gender_Female$`Injury, poisoning and procedural complications`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93023256 0.4491594  0.3857148 2.2434517 0.8720829
OR_TRTvsCTRL   0.90909091 0.5937384  0.2839333 2.9107059 0.8724671
ARR_TRTvsCTRL -0.01744186 0.1093759 -0.2318146 0.1969309 0.8733008


$Gender_Female$Investigations
$Gender_Female$Investigations$ntab
            CTRL TRT
```

```
n_all         24  43
n_event        8  11
n_event_pct   33  26

$Gender_Female$Investigations$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.76744186 0.3885700  0.3583391 1.6436026 0.4957471
OR_TRTvsCTRL   0.68750000 0.5564702  0.2309960 2.0461666 0.5007312
ARR_TRTvsCTRL -0.07751938 0.1169895 -0.3068146 0.1517758 0.5075751


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       21  31
n_event_pct   88  72

$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8239203 0.12228913  0.64832458 1.0470752 0.1132393
OR_TRTvsCTRL   0.3690476 0.70465863  0.09274188 1.4685506 0.1571777
ARR_TRTvsCTRL -0.1540698 0.09610476 -0.34243164 0.0342921 0.1089029


$Gender_Female$`Skin and subcutaneous tissue disorders`
$Gender_Female$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        7  12
n_event_pct   29  28

$Gender_Female$`Skin and subcutaneous tissue disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.9568106 0.4015819  0.4355108 2.1020987 0.9124572
OR_TRTvsCTRL   0.9400922 0.5632691  0.3116843 2.8354759 0.9126660
ARR_TRTvsCTRL -0.0125969 0.1152695 -0.2385209 0.2133271 0.9129787



$Region_Europe
$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        9  14
n_event_pct   53  47

$Region_Europe$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8814815 0.3006374  0.4890015 1.5889717 0.6747683
OR_TRTvsCTRL   0.7777778 0.6083089  0.2360816 2.5624121 0.6795068
ARR_TRTvsCTRL -0.0627451 0.1514968 -0.3596735 0.2341833 0.6787513
```

```
$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  30
n_event       12  20
n_event_pct   71  67

$Region_Europe$`General disorders and administration site conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94444444 0.2029199  0.6345279 1.4057307 0.7781891
OR_TRTvsCTRL   0.83333333 0.6582806  0.2293450 3.0279466 0.7818060
ARR_TRTvsCTRL -0.03921569 0.1400711 -0.3137499 0.2353186 0.7795006


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  30
n_event       11  22
n_event_pct   65  73

$Region_Europe$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.13333333 0.2102541  0.7505663 1.7113004 0.5516465
OR_TRTvsCTRL  1.50000000 0.6542402  0.4161031 5.4073137 0.5354227
ARR_TRTvsCTRL 0.08627451 0.1412525 -0.1905753 0.3631243 0.5413438


$Region_Europe$Investigations
$Region_Europe$Investigations$ntab
            CTRL TRT
n_all         17  30
n_event        4  11
n_event_pct   24  37

$Region_Europe$Investigations$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.5583333 0.4987507  0.5863042 4.1418818 0.3737580
OR_TRTvsCTRL  1.8815789 0.6859036  0.4905466 7.2171320 0.3567505
ARR_TRTvsCTRL 0.1313725 0.1353695 -0.1339468 0.3966919 0.3318104


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event       14  22
n_event_pct   82  73

$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.89047619 0.1572458  0.6542962 1.2119096 0.4607020
OR_TRTvsCTRL   0.58928571 0.7584303  0.1332751 2.6055710 0.4856227
```

```
ARR_TRTvsCTRL -0.09019608 0.1227488 -0.3307793 0.1503871 0.4624600



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event       12  21
n_event_pct   67  62

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92647059 0.2144413  0.6085537 1.4104717 0.7217292
OR_TRTvsCTRL   0.80769231 0.6119985  0.2433951 2.6802789 0.7271057
ARR_TRTvsCTRL -0.04901961 0.1388940 -0.3212468 0.2232076 0.7241422


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         18  34
n_event       13  21
n_event_pct   72  62

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8552036 0.1989342  0.5790772 1.2629978 0.4317102
OR_TRTvsCTRL   0.6213018 0.6336128  0.1794611 2.1509722 0.4525623
ARR_TRTvsCTRL -0.1045752 0.1345038 -0.3681977 0.1590474 0.4368705


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         18  34
n_event       14  25
n_event_pct   78  74

$Disdur_less_equal_12wk$`Infections and infestations`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94537815 0.1626691  0.6872921 1.3003785 0.7298660
OR_TRTvsCTRL   0.79365079 0.6874152  0.2063006 3.0532218 0.7367171
ARR_TRTvsCTRL -0.04248366 0.1238015 -0.2851301 0.2001628 0.7314784


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event       16  25
```

```
n_event_pct   89  74

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.8272059 0.1324110  0.63812410 1.07231427 0.1519514
OR_TRTvsCTRL   0.3472222 0.8447551  0.06630568 1.81829491 0.2105022
ARR_TRTvsCTRL -0.1535948 0.1058847 -0.36112503 0.05393549 0.1468955




\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs nach SOC, das bei mindestens 10% der
Patienten in einem Studienarm auftrat"

$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Blood and lymphatic system disorders`
$Ageonset_greater_12wk$`Blood and lymphatic system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                43.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           43.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Blood and lymphatic system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.245e-09 4.596e+04 0.000e+00       Inf 9.997e-01


$Ageonset_greater_12wk$`Cardiac disorders`
$Ageonset_greater_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               2.0                3.0
n_event_pct                          22.0               38.0
time-to-event-wk-10th                23.0                2.1
time-to-event-wk-25th                33.6               17.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           23.0                2.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  8.67900   1.19500   0.83460  90.27000   0.07051
```

```
$Ageonset_greater_12wk$`Eye disorders`
$Ageonset_greater_12wk$`Eye disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               29.3                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          29.3                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Eye disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.113e-17 4.635e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$`Gastrointestinal disorders`
$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              7.0                4.0
n_event_pct                         78.0               50.0
time-to-event-wk-10th                0.0                0.0
time-to-event-wk-25th                7.7                1.7
time-to-event-wk-50th               26.1                4.4
time-to-event-wk-75th               39.7                 NA
time-to-event-wk-90th               43.0                 NA
time-to-event-wk-50th-loci           0.0                0.0
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9490    0.7546    0.4441    8.5510    0.3766


$Ageonset_greater_12wk$`General disorders and administration site conditions`
$Ageonset_greater_12wk$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              7.0                5.0
n_event_pct                         78.0               62.0
time-to-event-wk-10th                1.3                0.4
time-to-event-wk-25th                5.1                5.9
time-to-event-wk-50th               15.1               12.7
time-to-event-wk-75th               42.6                 NA
time-to-event-wk-90th               42.6                 NA
time-to-event-wk-50th-loci           1.3                0.4
time-to-event-wk-50th-hici            NA                 NA
```

```
$Ageonset_greater_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1240    0.6108    0.3395    3.7210    0.8482


$Ageonset_greater_12wk$`Immune system disorders`
$Ageonset_greater_12wk$`Immune system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8
n_event                               1.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                17.7                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.7                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_greater_12wk$`Immune system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.900e+05 4.748e+04 0.000e+00       Inf 9.998e-01


$Ageonset_greater_12wk$`Infections and infestations`
$Ageonset_greater_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8.0
n_event                               7.0                 4.0
n_event_pct                          78.0                50.0
time-to-event-wk-10th                 1.4                 3.0
time-to-event-wk-25th                 4.4                 4.0
time-to-event-wk-50th                10.4                17.1
time-to-event-wk-75th                38.1                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            1.4                 3.0
time-to-event-wk-50th-hici           38.1                  NA

$Ageonset_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7761    0.6557    0.2147    2.8060    0.6991


$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`
$Ageonset_greater_12wk$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8.0
n_event                               2.0                 1.0
n_event_pct                          22.0                12.0
time-to-event-wk-10th                 8.7                 3.3
time-to-event-wk-25th                37.3                  NA
time-to-event-wk-50th                  NA                  NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            8.7                 3.3
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.72250   1.36400   0.04984  10.47000   0.81170


$Ageonset_greater_12wk$Investigations
$Ageonset_greater_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                15.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Metabolism and nutrition disorders`
$Ageonset_greater_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 6.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.345e-25 4.674e+04 0.000e+00       Inf 9.990e-01


$Ageonset_greater_12wk$`Musculoskeletal and connective tissue disorders`
$Ageonset_greater_12wk$`Musculoskeletal and connective tissue
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
```

```
n_event                                  0               1.0
n_event_pct                              0              12.0
time-to-event-wk-10th                   NA              31.9
time-to-event-wk-25th                   NA              31.9
time-to-event-wk-50th                   NA              37.8
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci              NA              31.9
time-to-event-wk-50th-hici              NA                NA

$Ageonset_greater_12wk$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.917e+13 5.755e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Nervous system disorders`
$Ageonset_greater_12wk$`Nervous system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                 8
n_event                                 1                 0
n_event_pct                            11                 0
time-to-event-wk-10th                  25                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             25                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_greater_12wk$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.718e-22 4.401e+04 0.000e+00       Inf 9.991e-01


$Ageonset_greater_12wk$`Psychiatric disorders`
$Ageonset_greater_12wk$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0               8.0
n_event                               1.0               1.0
n_event_pct                          11.0              12.0
time-to-event-wk-10th                50.4               2.1
time-to-event-wk-25th                53.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           50.4               2.1
time-to-event-wk-50th-hici             NA                NA

$Ageonset_greater_12wk$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.6770    1.5250    0.1348   53.1800    0.5184
```

```
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0               8.0
n_event                              8.0               5.0
n_event_pct                         89.0              62.0
time-to-event-wk-10th                0.0               0.4
time-to-event-wk-25th                1.0               2.9
time-to-event-wk-50th                2.1              18.7
time-to-event-wk-75th                4.1                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           0.0               0.4
time-to-event-wk-50th-hici          16.4                NA

$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4231    0.5960    0.1316    1.3610    0.1489


$Ageonset_greater_12wk$`Skin and subcutaneous tissue disorders`
$Ageonset_greater_12wk$`Skin and subcutaneous tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                 8
n_event                              3.0                 0
n_event_pct                         33.0                 0
time-to-event-wk-10th                0.0                NA
time-to-event-wk-25th                7.9                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           0.0                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_greater_12wk$`Skin and subcutaneous tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.851e-10 2.360e+04 0.000e+00       Inf 9.993e-01


$Ageonset_greater_12wk$`Vascular disorders`
$Ageonset_greater_12wk$`Vascular disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                 8
n_event                              1.0                 0
n_event_pct                         11.0                 0
time-to-event-wk-10th               30.4                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          30.4                NA
time-to-event-wk-50th-hici            NA                NA
```

```
$Ageonset_greater_12wk$`Vascular disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.187e-09 4.506e+04 0.000e+00       Inf 9.996e-01



$Agetrt_less_180d
$Agetrt_less_180d$`Blood and lymphatic system disorders`
$Agetrt_less_180d$`Blood and lymphatic system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 1
n_event_pct                          12.0                 2
time-to-event-wk-10th                16.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           16.4                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Blood and lymphatic system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.060140  1.468000  0.003386  1.068000  0.055480


$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               7.0              11.0
n_event_pct                          44.0              22.0
time-to-event-wk-10th                 2.6               8.1
time-to-event-wk-25th                 9.4              47.1
time-to-event-wk-50th                29.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            9.4                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31160   0.50460   0.11590   0.83790   0.02086


$Agetrt_less_180d$`Congenital, familial and genetic disorders`
$Agetrt_less_180d$`Congenital, familial and genetic disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               3.0                 3
n_event_pct                          19.0                 6
time-to-event-wk-10th                16.7                NA
time-to-event-wk-25th                49.4                NA
```

```
time-to-event-wk-50th                49.4                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Congenital, familial and genetic
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.22090   0.88410   0.03906   1.25000   0.08770


$Agetrt_less_180d$`Eye disorders`
$Agetrt_less_180d$`Eye disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  2
n_event_pct                          12.0                  4
time-to-event-wk-10th                11.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Eye disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25730   1.01600   0.03513   1.88500   0.18160


$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49.0
n_event                              11.0                32.0
n_event_pct                          69.0                65.0
time-to-event-wk-10th                 2.7                 0.3
time-to-event-wk-25th                 5.1                 5.0
time-to-event-wk-50th                10.9                14.1
time-to-event-wk-75th                22.6                  NA
time-to-event-wk-90th                36.4                  NA
time-to-event-wk-50th-loci            5.1                 7.1
time-to-event-wk-50th-hici           22.6                21.4

$Agetrt_less_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7184    0.3536    0.3592    1.4360    0.3495


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                16.0               49.0
n_event                              11.0               31.0
n_event_pct                          69.0               63.0
time-to-event-wk-10th                 0.4                3.0
time-to-event-wk-25th                 4.4               10.0
time-to-event-wk-50th                 9.1               25.1
time-to-event-wk-75th                22.7               41.4
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            4.4               15.0
time-to-event-wk-50th-hici           22.7               37.6

$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45620   0.36630   0.22250   0.93530   0.03215


$Agetrt_less_180d$`Immune system disorders`
$Agetrt_less_180d$`Immune system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0                5.0
n_event_pct                          12.0               10.0
time-to-event-wk-10th                24.4               34.1
time-to-event-wk-25th                41.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Immune system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7598    0.9070    0.1284    4.4950    0.7620


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                              13.0               42.0
n_event_pct                          81.0               86.0
time-to-event-wk-10th                 5.3                1.7
time-to-event-wk-25th                 6.3                3.4
time-to-event-wk-50th                 8.6                9.0
time-to-event-wk-75th                14.1               21.1
time-to-event-wk-90th                24.0               34.7
time-to-event-wk-50th-loci            6.0                5.0
time-to-event-wk-50th-hici           14.1               13.3

$Agetrt_less_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8995    0.3213    0.4792    1.6880    0.7416
```

```
$Agetrt_less_180d$`Injury, poisoning and procedural complications`
$Agetrt_less_180d$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               4.0                9.0
n_event_pct                          25.0               18.0
time-to-event-wk-10th                16.3                5.9
time-to-event-wk-25th                26.4                 NA
time-to-event-wk-50th                34.4                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4642    0.6265    0.1360    1.5850    0.2207


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               7.0               14.0
n_event_pct                          44.0               29.0
time-to-event-wk-10th                 0.1                5.4
time-to-event-wk-25th                 6.3               33.6
time-to-event-wk-50th                27.4                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.3               52.0
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39270   0.47870   0.15370   1.00400   0.05087


$Agetrt_less_180d$`Metabolism and nutrition disorders`
$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               7.0                 12
n_event_pct                          44.0                 24
time-to-event-wk-10th                 2.6                  6
time-to-event-wk-25th                 6.0                 32
time-to-event-wk-50th                22.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.0                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39800   0.48540   0.15370   1.03100   0.05771


$Agetrt_less_180d$`Musculoskeletal and connective tissue disorders`
$Agetrt_less_180d$`Musculoskeletal and connective tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              2.0               8.0
n_event_pct                         12.0              16.0
time-to-event-wk-10th               26.1               9.1
time-to-event-wk-25th               56.4              54.4
time-to-event-wk-50th               56.4                NA
time-to-event-wk-75th               56.4                NA
time-to-event-wk-90th               56.4                NA
time-to-event-wk-50th-loci          26.1              54.4
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5140    0.8280    0.2988    7.6730    0.6163


$Agetrt_less_180d$`Psychiatric disorders`
$Agetrt_less_180d$`Psychiatric disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              3.0               6.0
n_event_pct                         19.0              12.0
time-to-event-wk-10th                7.7              15.7
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           9.1                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5487    0.7139    0.1354    2.2230    0.4005


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                             15.0              35.0
n_event_pct                         94.0              71.0
time-to-event-wk-10th                0.7               1.0
time-to-event-wk-25th                1.5               3.3
time-to-event-wk-50th                6.0              11.7
time-to-event-wk-75th                8.4              32.7
```

```
time-to-event-wk-90th               13.0                NA
time-to-event-wk-50th-loci           0.9               4.3
time-to-event-wk-50th-hici           8.4              30.7

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.377000  0.332700  0.196400  0.723600  0.003363


$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              6.0              13.0
n_event_pct                         38.0              27.0
time-to-event-wk-10th                4.3               5.6
time-to-event-wk-25th                5.9              33.9
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           5.9              49.1
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5340    0.5066    0.1978    1.4420    0.2157



$Gender_Male
$Gender_Male$`Blood and lymphatic system disorders`
$Gender_Male$`Blood and lymphatic system disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                37
n_event                              2.0                 1
n_event_pct                         12.0                 3
time-to-event-wk-10th               16.4                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Blood and lymphatic system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.1928    1.2510    0.0166    2.2380    0.1882


$Gender_Male$`Cardiac disorders`
$Gender_Male$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              37.0
```

```
n_event                              8.0               9.0
n_event_pct                         47.0              24.0
time-to-event-wk-10th                2.6               6.6
time-to-event-wk-25th                9.4              25.4
time-to-event-wk-50th               33.6                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           9.4              47.1
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4667    0.4941    0.1772    1.2290    0.1230


$Gender_Male$`Congenital, familial and genetic disorders`
$Gender_Male$`Congenital, familial and genetic disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               3.0                 3
n_event_pct                          18.0                 8
time-to-event-wk-10th                16.7                NA
time-to-event-wk-25th                49.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           49.4                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Congenital, familial and genetic disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5356    0.8333    0.1046    2.7420    0.4537


$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                              10.0              23.0
n_event_pct                          59.0              62.0
time-to-event-wk-10th                 5.1               0.3
time-to-event-wk-25th                 9.7               4.0
time-to-event-wk-50th                12.7              16.3
time-to-event-wk-75th                40.3                NA
time-to-event-wk-90th                40.3                NA
time-to-event-wk-50th-loci            9.7               6.3
time-to-event-wk-50th-hici             NA              21.4

$Gender_Male$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1030    0.3812    0.5226    2.3290    0.7968


$Gender_Male$`General disorders and administration site conditions`
```

$Gender_Male$`General disorders and administration site conditions`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	17.0	37.0
n_event	11.0	24.0
n_event_pct	65.0	65.0
time-to-event-wk-10th	0.4	2.1
time-to-event-wk-25th	5.1	6.9
time-to-event-wk-50th	13.4	25.1
time-to-event-wk-75th	22.7	41.4
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	4.4	8.1
time-to-event-wk-50th-hici	22.7	37.6

$Gender_Male$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.6741	0.3750	0.3232	1.4060	0.2929

$Gender_Male$`Immune system disorders`

$Gender_Male$`Immune system disorders`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	17	37
n_event	2	1
n_event_pct	12	3
time-to-event-wk-10th	41	NA
time-to-event-wk-25th	41	NA
time-to-event-wk-50th	NA	NA
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	41	NA
time-to-event-wk-50th-hici	NA	NA

$Gender_Male$`Immune system disorders`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.21750	1.26100	0.01838	2.57500	0.22630

$Gender_Male$`Infections and infestations`

$Gender_Male$`Infections and infestations`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	17.0	37.0
n_event	14.0	29.0
n_event_pct	82.0	78.0
time-to-event-wk-10th	1.4	2.4
time-to-event-wk-25th	4.4	4.0
time-to-event-wk-50th	7.4	9.9
time-to-event-wk-75th	23.9	16.7
time-to-event-wk-90th	24.0	49.0
time-to-event-wk-50th-loci	2.3	4.3
time-to-event-wk-50th-hici	22.6	15.7

$Gender_Male$`Infections and infestations`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value

```
   0.9179    0.3302    0.4806    1.7530    0.7953


$Gender_Male$`Injury, poisoning and procedural complications`
$Gender_Male$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               4.0               9.0
n_event_pct                          24.0              24.0
time-to-event-wk-10th                 7.7              11.4
time-to-event-wk-25th                26.4              42.1
time-to-event-wk-50th                34.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           26.4              47.3
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Injury, poisoning and procedural complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6944    0.6161    0.2076    2.3230    0.5539


$Gender_Male$Investigations
$Gender_Male$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               6.0              10.0
n_event_pct                          35.0              27.0
time-to-event-wk-10th                 2.0               5.0
time-to-event-wk-25th                20.3              33.6
time-to-event-wk-50th                43.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           20.3              36.9
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6521    0.5232    0.2339    1.8180    0.4138


$Gender_Male$`Metabolism and nutrition disorders`
$Gender_Male$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               7.0               6.0
n_event_pct                          41.0              16.0
time-to-event-wk-10th                 5.9              11.1
time-to-event-wk-25th                 9.6                NA
time-to-event-wk-50th                56.6                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            9.6                NA
time-to-event-wk-50th-hici             NA                NA
```

```
$Gender_Male$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4016    0.5656    0.1326    1.2170    0.1067


$Gender_Male$`Musculoskeletal and connective tissue disorders`
$Gender_Male$`Musculoskeletal and connective tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               3.0               4.0
n_event_pct                          18.0              11.0
time-to-event-wk-10th                26.1              43.1
time-to-event-wk-25th                56.4              63.0
time-to-event-wk-50th                56.4              63.0
time-to-event-wk-75th                  NA              63.0
time-to-event-wk-90th                  NA              63.0
time-to-event-wk-50th-loci           26.1                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5844    0.8864    0.1029    3.3200    0.5444


$Gender_Male$`Nervous system disorders`
$Gender_Male$`Nervous system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               1.0                 4
n_event_pct                           6.0                11
time-to-event-wk-10th                  NA                 6
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           21.6                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6780    1.1280    0.1837   15.3200    0.6466


$Gender_Male$`Psychiatric disorders`
$Gender_Male$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17              37.0
n_event                                 1               4.0
n_event_pct                             6              11.0
time-to-event-wk-10th                  NA              29.7
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9090    1.1260    0.2101   17.3500    0.5657


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                              15.0               30.0
n_event_pct                          88.0               81.0
time-to-event-wk-10th                 0.6                0.6
time-to-event-wk-25th                 1.7                2.4
time-to-event-wk-50th                 6.1                6.9
time-to-event-wk-75th                15.7               25.4
time-to-event-wk-90th                27.0                 NA
time-to-event-wk-50th-loci            0.9                3.4
time-to-event-wk-50th-hici           13.0               12.4

$Gender_Male$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7607    0.3180    0.4079    1.4190    0.3896


$Gender_Male$`Skin and subcutaneous tissue disorders`
$Gender_Male$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               8.0               11.0
n_event_pct                          47.0               30.0
time-to-event-wk-10th                 4.0                2.1
time-to-event-wk-25th                 5.9               16.1
time-to-event-wk-50th                40.7                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.7               26.0
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5145    0.4745    0.2030    1.3040    0.1613



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Blood and lymphatic system disorders`
$Disdur_less_equal_12wk$`Blood and lymphatic system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                16.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Blood and lymphatic system
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.552e-10 1.977e+04 0.000e+00       Inf 9.991e-01


$Disdur_less_equal_12wk$`Cardiac disorders`
$Disdur_less_equal_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               7.0                 5
n_event_pct                          39.0                15
time-to-event-wk-10th                 2.6                16
time-to-event-wk-25th                23.0                NA
time-to-event-wk-50th                33.6                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.1                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32750   0.59860   0.10130   1.05900   0.06219


$Disdur_less_equal_12wk$`Congenital, familial and genetic disorders`
$Disdur_less_equal_12wk$`Congenital, familial and genetic disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               3.0                 2
n_event_pct                          17.0                 6
time-to-event-wk-10th                16.7                NA
time-to-event-wk-25th                49.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           49.4                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Congenital, familial and genetic
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.27360   0.92470   0.04466   1.67600   0.16100
```

```
$Disdur_less_equal_12wk$`Eye disorders`
$Disdur_less_equal_12wk$`Eye disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 2
n_event_pct                         11.0                 6
time-to-event-wk-10th               29.3                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          29.3                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Eye disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5210    1.0390    0.0680    3.9920    0.5303


$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34.0
n_event                             12.0                21.0
n_event_pct                         67.0                62.0
time-to-event-wk-10th                1.0                 0.3
time-to-event-wk-25th                5.1                 4.4
time-to-event-wk-50th               12.7                18.9
time-to-event-wk-75th               36.4                  NA
time-to-event-wk-90th               43.0                  NA
time-to-event-wk-50th-loci           5.1                 7.1
time-to-event-wk-50th-hici          36.4                26.6

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7998    0.3718    0.3860    1.6580    0.5480


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34.0
n_event                             13.0                21.0
n_event_pct                         72.0                62.0
time-to-event-wk-10th                0.4                 1.1
time-to-event-wk-25th                5.1                10.0
time-to-event-wk-50th               11.7                24.3
time-to-event-wk-75th               23.0                41.4
time-to-event-wk-90th               42.6                  NA
time-to-event-wk-50th-loci           5.1                13.4
time-to-event-wk-50th-hici          23.0                41.4
```

```
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6780    0.3688    0.3291    1.3970    0.2921


$Disdur_less_equal_12wk$`Immune system disorders`
$Disdur_less_equal_12wk$`Immune system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 2                4.0
n_event_pct                            11               12.0
time-to-event-wk-10th                  41               31.7
time-to-event-wk-25th                  41                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             41                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Immune system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9671    0.9006    0.1655    5.6490    0.9703


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                              14.0               25.0
n_event_pct                          78.0               74.0
time-to-event-wk-10th                 1.4                2.4
time-to-event-wk-25th                 5.3                4.3
time-to-event-wk-50th                 9.4               10.7
time-to-event-wk-75th                24.0               31.1
time-to-event-wk-90th                32.6               34.7
time-to-event-wk-50th-loci            5.3                6.1
time-to-event-wk-50th-hici           24.0               16.7

$Disdur_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9789    0.3491    0.4939    1.9400    0.9513


$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`
$Disdur_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               6.0                  6
n_event_pct                          33.0                 18
time-to-event-wk-10th                 8.7                  4
time-to-event-wk-25th                26.4                 NA
```

```
time-to-event-wk-50th                34.4                 NA
time-to-event-wk-75th                37.3                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31490   0.62860   0.09186   1.08000   0.06608


$Disdur_less_equal_12wk$Investigations
$Disdur_less_equal_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               7.0                7.0
n_event_pct                          39.0               21.0
time-to-event-wk-10th                 2.3                6.7
time-to-event-wk-25th                15.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           10.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4390    0.5421    0.1517    1.2700    0.1289


$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`
$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               6.0                7.0
n_event_pct                          33.0               21.0
time-to-event-wk-10th                 2.6               11.1
time-to-event-wk-25th                17.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4663    0.5612    0.1552    1.4010    0.1740


$Disdur_less_equal_12wk$`Musculoskeletal and connective tissue disorders`
$Disdur_less_equal_12wk$`Musculoskeletal and connective tissue
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                18.0               34.0
n_event                               2.0                7.0
n_event_pct                          11.0               21.0
time-to-event-wk-10th                56.4                9.1
time-to-event-wk-25th                56.4               54.4
time-to-event-wk-50th                56.4                 NA
time-to-event-wk-75th                56.4                 NA
time-to-event-wk-90th                56.4                 NA
time-to-event-wk-50th-loci             NA               54.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.8010    0.8121    0.3666    8.8450    0.4689


$Disdur_less_equal_12wk$`Nervous system disorders`
$Disdur_less_equal_12wk$`Nervous system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 2                3.0
n_event_pct                            11                9.0
time-to-event-wk-10th                  25               49.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             25                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6545    0.9207    0.1077    3.9780    0.6452


$Disdur_less_equal_12wk$`Psychiatric disorders`
$Disdur_less_equal_12wk$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               2.0                4.0
n_event_pct                          11.0               12.0
time-to-event-wk-10th                 9.1               15.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8657    0.8877    0.1520    4.9320    0.8710
```

```
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0              34.0
n_event                             16.0              25.0
n_event_pct                         89.0              74.0
time-to-event-wk-10th                0.6               1.0
time-to-event-wk-25th                1.0               3.3
time-to-event-wk-50th                5.1              11.9
time-to-event-wk-75th                9.0              32.7
time-to-event-wk-90th               16.4                NA
time-to-event-wk-50th-loci           1.0               4.1
time-to-event-wk-50th-hici           9.0              26.6

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5242    0.3401    0.2691    1.0210    0.0576


$Disdur_less_equal_12wk$`Skin and subcutaneous tissue disorders`
$Disdur_less_equal_12wk$`Skin and subcutaneous tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0              34.0
n_event                              8.0               8.0
n_event_pct                         44.0              24.0
time-to-event-wk-10th                4.3               9.0
time-to-event-wk-25th                7.6              40.4
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           7.6              40.4
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Skin and subcutaneous tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.35670   0.51030   0.13120   0.96980   0.04337



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                             11.0              15.0
n_event_pct                         34.0              21.0
time-to-event-wk-10th                4.3               8.4
time-to-event-wk-25th               13.9                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           14.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4355    0.4006    0.1986    0.9550    0.0380


$Ageonset_less_equal_12wk$`Congenital, familial and genetic disorders`
$Ageonset_less_equal_12wk$`Congenital, familial and genetic disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               4.0                  4
n_event_pct                          12.0                  6
time-to-event-wk-10th                16.7                 NA
time-to-event-wk-25th                49.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           49.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Congenital, familial and genetic
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33390   0.70990   0.08305   1.34300   0.12240


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72.0
n_event                              19.0                49.0
n_event_pct                          59.0                68.0
time-to-event-wk-10th                 4.4                 1.3
time-to-event-wk-25th                 5.6                 5.0
time-to-event-wk-50th                15.9                14.1
time-to-event-wk-75th                36.4                  NA
time-to-event-wk-90th                40.3                  NA
time-to-event-wk-50th-loci            9.7                 8.4
time-to-event-wk-50th-hici           22.6                18.9

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9751    0.2793    0.5640    1.6860    0.9282


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72.0
n_event                              21.0                46.0
```

```
n_event_pct                          66.0              64.0
time-to-event-wk-10th                 2.1               2.7
time-to-event-wk-25th                 4.4               7.6
time-to-event-wk-50th                11.7              28.6
time-to-event-wk-75th                20.6              46.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.4              15.6
time-to-event-wk-50th-hici           18.0              37.6

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.54300   0.27420   0.31720   0.92930   0.02592


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              24.0              61.0
n_event_pct                          75.0              85.0
time-to-event-wk-10th                 2.4               1.7
time-to-event-wk-25th                 6.0               3.9
time-to-event-wk-50th                 8.6               9.0
time-to-event-wk-75th                22.6              21.1
time-to-event-wk-90th                32.6              34.7
time-to-event-wk-50th-loci            6.1               6.1
time-to-event-wk-50th-hici           17.6              13.0

$Ageonset_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1030    0.2452    0.6822    1.7840    0.6891


$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`
$Ageonset_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               8.0              18.0
n_event_pct                          25.0              25.0
time-to-event-wk-10th                 4.6               5.9
time-to-event-wk-25th                26.4              42.1
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           26.4              51.1
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6551    0.4363    0.2786    1.5400    0.3322
```

```
$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                             13.0              21.0
n_event_pct                         41.0              29.0
time-to-event-wk-10th                2.3               5.4
time-to-event-wk-25th               13.9              26.4
time-to-event-wk-50th               37.4                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          18.9              52.0
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5189    0.3596    0.2564    1.0500    0.0681


$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                             12.0              14.0
n_event_pct                         38.0              19.0
time-to-event-wk-10th                5.9               9.7
time-to-event-wk-25th               12.6                NA
time-to-event-wk-50th               56.6                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          13.0                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Metabolism and nutrition
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.340100  0.399600  0.155400  0.744300  0.006954


$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue disorders`
$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              5.0              10.0
n_event_pct                         16.0              14.0
time-to-event-wk-10th               26.1              43.1
time-to-event-wk-25th               46.9              63.0
time-to-event-wk-50th               56.4              63.0
time-to-event-wk-75th                 NA              63.0
time-to-event-wk-90th                 NA              63.0
time-to-event-wk-50th-loci          46.9                NA
time-to-event-wk-50th-hici            NA                NA
```

```
$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6566    0.5622    0.2181    1.9760    0.4543


$Ageonset_less_equal_12wk$`Nervous system disorders`
$Ageonset_less_equal_12wk$`Nervous system disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 32                72
n_event                                1                 9
n_event_pct                            3                12
time-to-event-wk-10th                 NA                20
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.8780    1.0580    0.4872   30.8700    0.2003


$Ageonset_less_equal_12wk$`Psychiatric disorders`
$Ageonset_less_equal_12wk$`Psychiatric disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              4.0               8.0
n_event_pct                         12.0              11.0
time-to-event-wk-10th                9.1              29.7
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7085    0.6183    0.2109    2.3800    0.5773


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                             28.0              56.0
n_event_pct                         88.0              78.0
time-to-event-wk-10th                0.6               1.0
time-to-event-wk-25th                1.4               3.1
```

```
time-to-event-wk-50th                 5.6                8.8
time-to-event-wk-75th                11.0               32.1
time-to-event-wk-90th                27.0                 NA
time-to-event-wk-50th-loci            2.1                5.7
time-to-event-wk-50th-hici            7.9               12.4

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.64890   0.24210   0.40380   1.04300   0.07404


$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`
$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              12.0               23.0
n_event_pct                          38.0               32.0
time-to-event-wk-10th                 5.7                4.4
time-to-event-wk-25th                19.0               26.0
time-to-event-wk-50th                53.6                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.0               49.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6577    0.3625    0.3232    1.3380    0.2477



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Cardiac disorders`
$Agetrt_greater_equal_180d$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               6.0                7.0
n_event_pct                          24.0               23.0
time-to-event-wk-10th                 5.1                7.3
time-to-event-wk-25th                33.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8200    0.5730    0.2668    2.5210    0.7291


$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
```

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	25.0	31.0
n_event	15.0	21.0
n_event_pct	60.0	68.0
time-to-event-wk-10th	1.4	1.3
time-to-event-wk-25th	7.7	4.3
time-to-event-wk-50th	19.9	9.3
time-to-event-wk-75th	40.3	40.9
time-to-event-wk-90th	43.0	NA
time-to-event-wk-50th-loci	8.1	5.0
time-to-event-wk-50th-hici	40.3	27.9

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
1.3040	0.3406	0.6688	2.5420	0.4361

$Agetrt_greater_equal_180d$`General disorders and administration site conditions`

$Agetrt_greater_equal_180d$`General disorders and administration site conditions`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	25.0	31.0
n_event	17.0	20.0
n_event_pct	68.0	65.0
time-to-event-wk-10th	2.1	2.4
time-to-event-wk-25th	5.1	3.4
time-to-event-wk-50th	15.1	23.6
time-to-event-wk-75th	23.0	46.7
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	5.1	6.9
time-to-event-wk-50th-hici	23.0	46.4

$Agetrt_greater_equal_180d$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.6897	0.3433	0.3519	1.3520	0.2791

$Agetrt_greater_equal_180d$`Infections and infestations`

$Agetrt_greater_equal_180d$`Infections and infestations`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	25.0	31.0
n_event	18.0	23.0
n_event_pct	72.0	74.0
time-to-event-wk-10th	2.1	2.0
time-to-event-wk-25th	3.1	4.1
time-to-event-wk-50th	10.4	10.0
time-to-event-wk-75th	23.9	21.9
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	3.1	4.9
time-to-event-wk-50th-hici	23.9	17.1

```
$Agetrt_greater_equal_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1000    0.3210    0.5866    2.0650    0.7655


$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`
$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               6.0               10.0
n_event_pct                          24.0               32.0
time-to-event-wk-10th                 2.1                5.7
time-to-event-wk-25th                37.3               41.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.3               42.1
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1560    0.5359    0.4043    3.3040    0.7870


$Agetrt_greater_equal_180d$Investigations
$Agetrt_greater_equal_180d$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               7.0                7.0
n_event_pct                          28.0               23.0
time-to-event-wk-10th                13.9                7.3
time-to-event-wk-25th                37.4               26.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7757    0.5406    0.2689    2.2380    0.6385


$Agetrt_greater_equal_180d$`Metabolism and nutrition disorders`
$Agetrt_greater_equal_180d$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               6.0                2.0
n_event_pct                          24.0                6.0
time-to-event-wk-10th                12.6               45.6
time-to-event-wk-25th                56.6                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Metabolism and nutrition
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.23360   0.83370   0.04559   1.19700   0.08117


$Agetrt_greater_equal_180d$`Musculoskeletal and connective tissue disorders`
$Agetrt_greater_equal_180d$`Musculoskeletal and connective tissue
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0               31.0
n_event                              3.0                3.0
n_event_pct                         12.0               10.0
time-to-event-wk-10th               46.9               31.9
time-to-event-wk-25th                 NA               63.0
time-to-event-wk-50th                 NA               63.0
time-to-event-wk-75th                 NA               63.0
time-to-event-wk-90th                 NA               63.0
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.53540   0.93190   0.08618   3.32600   0.50260


$Agetrt_greater_equal_180d$`Nervous system disorders`
$Agetrt_greater_equal_180d$`Nervous system disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25                31.0
n_event                              1                 5.0
n_event_pct                          4                16.0
time-to-event-wk-10th               NA                 2.3
time-to-event-wk-25th               NA                  NA
time-to-event-wk-50th               NA                  NA
time-to-event-wk-75th               NA                  NA
time-to-event-wk-90th               NA                  NA
time-to-event-wk-50th-loci          NA                  NA
time-to-event-wk-50th-hici          NA                  NA

$Agetrt_greater_equal_180d$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   4.0540    1.0980    0.4711   34.9000    0.2025


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              21.0               26.0
n_event_pct                          84.0               84.0
time-to-event-wk-10th                 0.1                0.3
time-to-event-wk-25th                 1.1                2.7
time-to-event-wk-50th                 3.6                7.0
time-to-event-wk-75th                15.7               16.7
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.6                5.0
time-to-event-wk-50th-hici           11.0               12.0

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8243    0.2954    0.4620    1.4710    0.5131


$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               9.0               10.0
n_event_pct                          36.0               32.0
time-to-event-wk-10th                 6.6                3.3
time-to-event-wk-25th                 8.1               20.1
time-to-event-wk-50th                53.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7               45.1
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8365    0.4617    0.3384    2.0680    0.6990



$Gender_Female
$Gender_Female$`Cardiac disorders`
$Gender_Female$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               5.0                9.0
n_event_pct                          21.0               21.0
time-to-event-wk-10th                 4.6                9.3
time-to-event-wk-25th                23.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           23.0                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Gender_Female$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9978    0.5678    0.3279    3.0370    0.9969


$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              16.0              30.0
n_event_pct                          67.0              70.0
time-to-event-wk-10th                 1.4               2.4
time-to-event-wk-25th                 5.0               4.4
time-to-event-wk-50th                16.9              12.7
time-to-event-wk-75th                36.4              40.9
time-to-event-wk-90th                43.0                NA
time-to-event-wk-50th-loci            5.6               6.6
time-to-event-wk-50th-hici           36.4              19.0

$Gender_Female$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9400    0.3217    0.5004    1.7660    0.8474


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              17.0              27.0
n_event_pct                          71.0              63.0
time-to-event-wk-10th                 2.1               2.7
time-to-event-wk-25th                 4.1               8.1
time-to-event-wk-50th                15.1              20.7
time-to-event-wk-75th                23.0              54.3
time-to-event-wk-90th                42.6                NA
time-to-event-wk-50th-loci            5.1              12.7
time-to-event-wk-50th-hici           18.0              38.0

$Gender_Female$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.53030   0.32570   0.28010   1.00400   0.05141


$Gender_Female$`Immune system disorders`
$Gender_Female$`Immune system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                               2.0               6.0
n_event_pct                           8.0              14.0
time-to-event-wk-10th                24.4              34.1
time-to-event-wk-25th                  NA              54.7
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$`Immune system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1270    0.8287    0.2222    5.7210    0.8849


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              17.0               36.0
n_event_pct                          71.0               84.0
time-to-event-wk-10th                 3.0                1.3
time-to-event-wk-25th                 6.0                3.7
time-to-event-wk-50th                10.4                9.3
time-to-event-wk-75th                38.1               21.9
time-to-event-wk-90th                  NA               31.1
time-to-event-wk-50th-loci            6.1                5.7
time-to-event-wk-50th-hici           15.3               13.3

$Gender_Female$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3520    0.3124    0.7330    2.4940    0.3343


$Gender_Female$`Injury, poisoning and procedural complications`
$Gender_Female$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               6.0               10.0
n_event_pct                          25.0               23.0
time-to-event-wk-10th                 4.6                5.7
time-to-event-wk-25th                37.3               43.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7977    0.5261    0.2845    2.2370    0.6674


$Gender_Female$Investigations
$Gender_Female$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               8.0               11.0
n_event_pct                          33.0               26.0
```

```
time-to-event-wk-10th                6.3               8.1
time-to-event-wk-25th               15.9              26.4
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          15.9              52.0
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6275    0.4835    0.2432    1.6190    0.3352


$Gender_Female$`Metabolism and nutrition disorders`
$Gender_Female$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                               6.0               8.0
n_event_pct                          25.0              19.0
time-to-event-wk-10th                 8.9               9.7
time-to-event-wk-25th                13.0                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           13.0                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5876    0.5573    0.1971    1.7520    0.3401


$Gender_Female$`Musculoskeletal and connective tissue disorders`
$Gender_Female$`Musculoskeletal and connective tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43
n_event                               2.0                 7
n_event_pct                           8.0                16
time-to-event-wk-10th                46.9                12
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           46.9                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7140    0.8133    0.3481    8.4380    0.5077


$Gender_Female$`Nervous system disorders`
$Gender_Female$`Nervous system disorders`$stats_num
```

```
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 24               43.0
n_event                                1                5.0
n_event_pct                            4               12.0
time-to-event-wk-10th                 NA               49.6
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.8160    1.1130    0.3179   24.9600    0.3522


$Gender_Female$`Psychiatric disorders`
$Gender_Female$`Psychiatric disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                              4.0                5.0
n_event_pct                         17.0               12.0
time-to-event-wk-10th               13.9                8.1
time-to-event-wk-25th               50.4                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          50.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6114    0.6902    0.1580    2.3650    0.4759


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                             21.0               31.0
n_event_pct                         88.0               72.0
time-to-event-wk-10th                0.1                1.0
time-to-event-wk-25th                1.1                4.1
time-to-event-wk-50th                3.6               12.0
time-to-event-wk-75th                8.7               32.7
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           1.1                5.0
time-to-event-wk-50th-hici           6.3               30.7

$Gender_Female$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.54000   0.30420   0.29750   0.98020   0.04279
```

```
$Gender_Female$`Skin and subcutaneous tissue disorders`
$Gender_Female$`Skin and subcutaneous tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0              43.0
n_event                              7.0              12.0
n_event_pct                         29.0              28.0
time-to-event-wk-10th                7.6               5.6
time-to-event-wk-25th               53.6              40.4
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          53.6              49.1
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8954    0.4900    0.3428    2.3390    0.8217



$Region_Europe
$Region_Europe$`Cardiac disorders`
$Region_Europe$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                30
n_event                              2.0                 5
n_event_pct                         12.0                17
time-to-event-wk-10th                9.4                12
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2370    0.8461    0.2355    6.4930    0.8018


$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              30.0
n_event                              9.0              14.0
n_event_pct                         53.0              47.0
time-to-event-wk-10th                2.7               0.4
time-to-event-wk-25th               12.7               6.3
time-to-event-wk-50th               26.1              40.9
time-to-event-wk-75th               40.3                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           5.0               8.4
```

```
time-to-event-wk-50th-hici          40.3                NA

$Region_Europe$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7121    0.4481    0.2959    1.7140    0.4485


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                              12.0              20.0
n_event_pct                          71.0              67.0
time-to-event-wk-10th                 2.0               1.9
time-to-event-wk-25th                 4.1               6.4
time-to-event-wk-50th                 7.9              15.6
time-to-event-wk-75th                16.9              46.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            2.3               6.9
time-to-event-wk-50th-hici           16.9              36.3

$Region_Europe$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48760   0.40000   0.22270   1.06800   0.07259


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                              11.0              22.0
n_event_pct                          65.0              73.0
time-to-event-wk-10th                 3.0               1.6
time-to-event-wk-25th                 5.7               3.4
time-to-event-wk-50th                11.9               7.0
time-to-event-wk-75th                22.6              49.0
time-to-event-wk-90th                  NA              49.0
time-to-event-wk-50th-loci            5.7               4.7
time-to-event-wk-50th-hici           22.6              14.4

$Region_Europe$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2180    0.3873    0.5702    2.6020    0.6104


$Region_Europe$`Injury, poisoning and procedural complications`
$Region_Europe$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               2.0               5.0
n_event_pct                          12.0              17.0
time-to-event-wk-10th                16.3              20.9
time-to-event-wk-25th                  NA              47.3
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               47.3
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0890    0.8465    0.2073    5.7240    0.9196


$Region_Europe$Investigations
$Region_Europe$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               4.0               11.0
n_event_pct                          24.0               37.0
time-to-event-wk-10th                 2.3                5.2
time-to-event-wk-25th                37.4               15.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.4               19.3
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4380    0.5945    0.4486    4.6130    0.5408


$Region_Europe$`Metabolism and nutrition disorders`
$Region_Europe$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               4.0                6.0
n_event_pct                          24.0               20.0
time-to-event-wk-10th                 5.9                3.9
time-to-event-wk-25th                 8.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6483    0.6643    0.1763    2.3840    0.5142


$Region_Europe$`Psychiatric disorders`
$Region_Europe$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
```

```
n_event                              3.0                 2
n_event_pct                         18.0                 7
time-to-event-wk-10th                9.1                NA
time-to-event-wk-25th               50.4                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          50.4                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29160   0.93470   0.04668   1.82100   0.18730


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                              14.0              22.0
n_event_pct                          82.0              73.0
time-to-event-wk-10th                 0.4               0.5
time-to-event-wk-25th                 4.1               3.0
time-to-event-wk-50th                 6.3               8.8
time-to-event-wk-75th                15.7                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            3.1               4.3
time-to-event-wk-50th-hici           15.7              12.0

$Region_Europe$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8134    0.3625    0.3997    1.6550    0.5689


$Region_Europe$`Vascular disorders`
$Region_Europe$`Vascular disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               1.0               3.0
n_event_pct                           6.0              10.0
time-to-event-wk-10th                30.4              42.1
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           30.4                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Vascular disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1620    1.1630    0.1190   11.3400    0.8973
```

```
$Region_Asia_Pacific
$Region_Asia_Pacific$`Cardiac disorders`
$Region_Asia_Pacific$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  2              12.0
n_event                                0               2.0
n_event_pct                            0              17.0
time-to-event-wk-10th                 NA               8.4
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA               8.4
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.343e+07 2.340e+04 0.000e+00       Inf 9.994e-01


$Region_Asia_Pacific$`Eye disorders`
$Region_Asia_Pacific$`Eye disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                12
n_event                              1.0                 0
n_event_pct                         50.0                 0
time-to-event-wk-10th               29.3                NA
time-to-event-wk-25th               29.3                NA
time-to-event-wk-50th               29.3                NA
time-to-event-wk-75th               29.3                NA
time-to-event-wk-90th               29.3                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Eye disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.873e-12 2.762e+05 0.000e+00       Inf 9.999e-01


$Region_Asia_Pacific$`Gastrointestinal disorders`
$Region_Asia_Pacific$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  2              12.0
n_event                                1               7.0
n_event_pct                           50              58.0
time-to-event-wk-10th                 43               4.1
time-to-event-wk-25th                 43               4.4
time-to-event-wk-50th                 43              21.4
time-to-event-wk-75th                 43                NA
time-to-event-wk-90th                 43                NA
time-to-event-wk-50th-loci            NA               4.1
time-to-event-wk-50th-hici            NA                NA
```

```
$Region_Asia_Pacific$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3540    1.1460    0.1432   12.8100    0.7914


$Region_Asia_Pacific$`General disorders and administration site conditions`
$Region_Asia_Pacific$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0               12.0
n_event                               1.0                4.0
n_event_pct                          50.0               33.0
time-to-event-wk-10th                 5.7                3.0
time-to-event-wk-25th                 5.7               23.1
time-to-event-wk-50th                 5.7               38.0
time-to-event-wk-75th                 5.7                 NA
time-to-event-wk-90th                 5.7                 NA
time-to-event-wk-50th-loci             NA                3.0
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.039e-04 6.537e+00 2.831e-10 3.811e+01 1.606e-01


$Region_Asia_Pacific$`Infections and infestations`
$Region_Asia_Pacific$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
n_event                                 0                9.0
n_event_pct                             0               75.0
time-to-event-wk-10th                  NA                1.3
time-to-event-wk-25th                  NA                3.5
time-to-event-wk-50th                  NA               15.5
time-to-event-wk-75th                  NA               31.1
time-to-event-wk-90th                  NA               31.1
time-to-event-wk-50th-loci             NA                1.3
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.237e+08 1.128e+04 0.000e+00       Inf 9.986e-01


$Region_Asia_Pacific$`Injury, poisoning and procedural complications`
$Region_Asia_Pacific$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0                 12
n_event                               1.0                  0
n_event_pct                          50.0                  0
time-to-event-wk-10th                 8.7                 NA
time-to-event-wk-25th                 8.7                 NA
time-to-event-wk-50th                 8.7                 NA
```

```
time-to-event-wk-75th                 8.7                 NA
time-to-event-wk-90th                 8.7                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.266e-14 2.565e+06 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$`Nervous system disorders`
$Region_Asia_Pacific$`Nervous system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2                 12
n_event                                 1                  0
n_event_pct                            50                  0
time-to-event-wk-10th                  25                 NA
time-to-event-wk-25th                  25                 NA
time-to-event-wk-50th                  25                 NA
time-to-event-wk-75th                  25                 NA
time-to-event-wk-90th                  25                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.442e-14 1.625e+06 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`
$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0                12.0
n_event                               1.0                 4.0
n_event_pct                          50.0                33.0
time-to-event-wk-10th                 0.9                12.3
time-to-event-wk-25th                 0.9                30.7
time-to-event-wk-50th                25.1                43.1
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            0.9                12.3
time-to-event-wk-50th-hici             NA                  NA

$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.68060   1.21700   0.06269   7.38800   0.75180


$Region_Asia_Pacific$`Skin and subcutaneous tissue disorders`
$Region_Asia_Pacific$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0                12.0
```

```
n_event                              1.0               2.0
n_event_pct                         50.0              17.0
time-to-event-wk-10th                7.6              22.9
time-to-event-wk-25th                7.6                NA
time-to-event-wk-50th                7.6                NA
time-to-event-wk-75th                7.6                NA
time-to-event-wk-90th                7.6                NA
time-to-event-wk-50th-loci            NA              22.9
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.054e-10 2.848e+04 0.000e+00       Inf 9.994e-01



$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              11.0               11.0
n_event_pct                          50.0               29.0
time-to-event-wk-10th                 2.6                7.3
time-to-event-wk-25th                13.9               22.9
time-to-event-wk-50th                29.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.9               47.1
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42470   0.43410   0.18140   0.99450   0.04853


$Region_Northamerica$`Congenital, familial and genetic disorders`
$Region_Northamerica$`Congenital, familial and genetic disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               4.0                3.0
n_event_pct                          18.0                8.0
time-to-event-wk-10th                14.0               43.3
time-to-event-wk-25th                49.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           49.4                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Congenital, familial and genetic
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40640   0.77420   0.08911   1.85300   0.24470
```

```
$Region_Northamerica$`Eye disorders`
$Region_Northamerica$`Eye disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 22               38.0
n_event                                1                4.0
n_event_pct                            5               11.0
time-to-event-wk-10th                 NA               27.1
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$`Eye disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0470    1.1220    0.2271   18.4500    0.5231


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0               38.0
n_event                             16.0               32.0
n_event_pct                         73.0               84.0
time-to-event-wk-10th                1.4                1.3
time-to-event-wk-25th                5.6                4.0
time-to-event-wk-50th               10.9               10.1
time-to-event-wk-75th               19.9               16.4
time-to-event-wk-90th               36.4               27.9
time-to-event-wk-50th-loci           5.6                5.0
time-to-event-wk-50th-hici          19.9               14.1

$Region_Northamerica$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1700    0.3082    0.6394    2.1400    0.6108


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0               38.0
n_event                             15.0               27.0
n_event_pct                         68.0               71.0
time-to-event-wk-10th                3.1                2.4
time-to-event-wk-25th                7.7               10.0
time-to-event-wk-50th               18.0               28.6
time-to-event-wk-75th               23.0               41.4
time-to-event-wk-90th               42.6                 NA
time-to-event-wk-50th-loci           7.7               13.4
time-to-event-wk-50th-hici          23.0               36.0
```

```
$Region_Northamerica$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6084    0.3438    0.3101    1.1940    0.1484


$Region_Northamerica$`Immune system disorders`
$Region_Northamerica$`Immune system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               4.0               5.0
n_event_pct                          18.0              13.0
time-to-event-wk-10th                17.7              31.7
time-to-event-wk-25th                41.0                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           24.4                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Immune system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6974    0.6882    0.1810    2.6870    0.6005


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              20.0              34.0
n_event_pct                          91.0              89.0
time-to-event-wk-10th                 2.1               2.0
time-to-event-wk-25th                 3.1               4.0
time-to-event-wk-50th                 7.4               9.9
time-to-event-wk-75th                17.6              16.7
time-to-event-wk-90th                32.6              25.6
time-to-event-wk-50th-loci            3.1               5.0
time-to-event-wk-50th-hici           12.3              14.4

$Region_Northamerica$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0030    0.2904    0.5678    1.7720    0.9914


$Region_Northamerica$`Injury, poisoning and procedural complications`
$Region_Northamerica$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               7.0              14.0
n_event_pct                          32.0              37.0
time-to-event-wk-10th                 4.6               2.4
time-to-event-wk-25th                26.4              26.7
time-to-event-wk-50th                37.3                NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.4               41.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8750    0.4703    0.3481    2.1990    0.7765


$Region_Northamerica$Investigations
$Region_Northamerica$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              10.0                9.0
n_event_pct                          45.0               24.0
time-to-event-wk-10th                 6.3                7.3
time-to-event-wk-25th                15.9               52.0
time-to-event-wk-50th                27.4                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9               52.0
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40680   0.46480   0.16360   1.01200   0.05298


$Region_Northamerica$`Metabolism and nutrition disorders`
$Region_Northamerica$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               9.0                7.0
n_event_pct                          41.0               18.0
time-to-event-wk-10th                 9.6               13.9
time-to-event-wk-25th                13.0                 NA
time-to-event-wk-50th                56.6                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.37420   0.50610   0.13880   1.00900   0.05209


$Region_Northamerica$`Musculoskeletal and connective tissue disorders`
$Region_Northamerica$`Musculoskeletal and connective tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               5.0                9.0
```

```
n_event_pct                          23.0              24.0
time-to-event-wk-10th                26.1               9.1
time-to-event-wk-25th                46.9              43.1
time-to-event-wk-50th                56.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           46.9              54.4
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1100    0.5688    0.3641    3.3850    0.8542


$Region_Northamerica$`Nervous system disorders`
$Region_Northamerica$`Nervous system disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 22              38.0
n_event                                1               7.0
n_event_pct                            5              18.0
time-to-event-wk-10th                 NA               4.7
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.8590    1.0700    0.4735   31.4500    0.2071


$Region_Northamerica$`Psychiatric disorders`
$Region_Northamerica$`Psychiatric disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 22              38.0
n_event                                2               6.0
n_event_pct                            9              16.0
time-to-event-wk-10th                 13.9               7.1
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.8040    0.8185    0.3627    8.9720    0.4711


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
```

```
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              21.0              35.0
n_event_pct                          95.0              92.0
time-to-event-wk-10th                 0.6               0.4
time-to-event-wk-25th                 0.9               2.4
time-to-event-wk-50th                 2.5               5.8
time-to-event-wk-75th                 7.3              21.4
time-to-event-wk-90th                15.7              32.6
time-to-event-wk-50th-loci            0.9               3.3
time-to-event-wk-50th-hici            5.6              12.4

$Region_Northamerica$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.50640   0.28730   0.28840   0.88920   0.01785


$Region_Northamerica$`Skin and subcutaneous tissue disorders`
$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              13.0              19.0
n_event_pct                          59.0              50.0
time-to-event-wk-10th                 4.3               2.0
time-to-event-wk-25th                 6.6               9.1
time-to-event-wk-50th                20.9              40.4
time-to-event-wk-75th                53.9                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.6              16.1
time-to-event-wk-50th-hici           53.9                NA

$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7786    0.3627    0.3824    1.5850    0.4903



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               6.0              13.0
n_event_pct                          26.0              28.0
time-to-event-wk-10th                 4.6               8.1
time-to-event-wk-25th                14.3              22.9
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           14.3              47.1
time-to-event-wk-50th-hici             NA                NA
```

```
$Disdur_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8543    0.4942    0.3243    2.2510    0.7500


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0              46.0
n_event                             14.0              32.0
n_event_pct                         61.0              70.0
time-to-event-wk-10th                5.0               1.3
time-to-event-wk-25th                9.7               4.3
time-to-event-wk-50th               16.9              10.1
time-to-event-wk-75th               39.7              40.9
time-to-event-wk-90th               40.3                NA
time-to-event-wk-50th-loci           9.7               6.3
time-to-event-wk-50th-hici          39.7              16.3

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2220    0.3285    0.6418    2.3270    0.5417


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0              46.0
n_event                             15.0              30.0
n_event_pct                         65.0              65.0
time-to-event-wk-10th                2.1               2.6
time-to-event-wk-25th                4.1               6.4
time-to-event-wk-50th               13.4              25.1
time-to-event-wk-75th               16.9              46.7
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           4.1               8.1
time-to-event-wk-50th-hici          16.9              37.6

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5251    0.3394    0.2699    1.0210    0.0577


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0              46.0
n_event                             17.0              40.0
n_event_pct                         74.0              87.0
time-to-event-wk-10th                2.4               1.7
time-to-event-wk-25th                5.7               4.0
time-to-event-wk-50th                7.4               9.0
```

```
time-to-event-wk-75th                22.6               18.0
time-to-event-wk-90th                38.1               25.6
time-to-event-wk-50th-loci            5.7                4.7
time-to-event-wk-50th-hici           22.6               13.0

$Disdur_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2130    0.2960    0.6793    2.1680    0.5133


$Disdur_greater_12wk$`Injury, poisoning and procedural complications`
$Disdur_greater_12wk$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               4.0               13.0
n_event_pct                          17.0               28.0
time-to-event-wk-10th                 2.1                5.9
time-to-event-wk-25th                  NA               42.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               43.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3370    0.5741    0.4339    4.1190    0.6130


$Disdur_greater_12wk$Investigations
$Disdur_greater_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               7.0               14.0
n_event_pct                          30.0               30.0
time-to-event-wk-10th                 9.1                5.4
time-to-event-wk-25th                18.9               26.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           18.9               36.9
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9371    0.4643    0.3772    2.3280    0.8886


$Disdur_greater_12wk$`Metabolism and nutrition disorders`
$Disdur_greater_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               7.0                7.0
```

```
n_event_pct                          30.0              15.0
time-to-event-wk-10th                 8.9               8.9
time-to-event-wk-25th                13.0                NA
time-to-event-wk-50th                56.6                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.0                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40750   0.53900   0.14170   1.17200   0.09581


$Disdur_greater_12wk$`Musculoskeletal and connective tissue disorders`
$Disdur_greater_12wk$`Musculoskeletal and connective tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0                46
n_event                              3.0                 4
n_event_pct                         13.0                 9
time-to-event-wk-10th               46.9                63
time-to-event-wk-25th                 NA                63
time-to-event-wk-50th                 NA                63
time-to-event-wk-75th                 NA                63
time-to-event-wk-90th                 NA                63
time-to-event-wk-50th-loci          46.9                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_greater_12wk$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42830   0.81850   0.08611   2.13000   0.30020


$Disdur_greater_12wk$`Nervous system disorders`
$Disdur_greater_12wk$`Nervous system disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                23                46
n_event                               0                 6
n_event_pct                           0                13
time-to-event-wk-10th                NA                 6
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Disdur_greater_12wk$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.283e+08 1.092e+04 0.000e+00       Inf 9.985e-01


$Disdur_greater_12wk$`Psychiatric disorders`
```

```
$Disdur_greater_12wk$`Psychiatric disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0              46.0
n_event                              3.0               5.0
n_event_pct                         13.0              11.0
time-to-event-wk-10th               13.9              29.7
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          50.4                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_greater_12wk$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7616    0.7327    0.1812    3.2020    0.7101


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0              46.0
n_event                             20.0              36.0
n_event_pct                         87.0              78.0
time-to-event-wk-10th                0.4               0.3
time-to-event-wk-25th                1.1               2.7
time-to-event-wk-50th                4.1               8.5
time-to-event-wk-75th               11.0              32.1
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           1.6               5.0
time-to-event-wk-50th-hici           7.3              12.4

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6990    0.2967    0.3908    1.2500    0.2274


$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`
$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0              46.0
n_event                              7.0              15.0
n_event_pct                         30.0              33.0
time-to-event-wk-10th                6.6               2.1
time-to-event-wk-25th               40.7              20.1
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          40.7              45.1
time-to-event-wk-50th-hici            NA                NA

$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   1.0680    0.4616    0.4320    2.6380    0.8874



\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs nach SOC, das bei mindestens 10 Patienten
und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              11.0              15.0
n_event_pct                          34.0              21.0
time-to-event-wk-10th                 4.3               8.4
time-to-event-wk-25th                13.9                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           14.3                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4355    0.4006    0.1986    0.9550    0.0380


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              19.0              49.0
n_event_pct                          59.0              68.0
time-to-event-wk-10th                 4.4               1.3
time-to-event-wk-25th                 5.6               5.0
time-to-event-wk-50th                15.9              14.1
time-to-event-wk-75th                36.4                NA
time-to-event-wk-90th                40.3                NA
time-to-event-wk-50th-loci            9.7               8.4
time-to-event-wk-50th-hici           22.6              18.9

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9751    0.2793    0.5640    1.6860    0.9282


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
```

```
n_event                              21.0              46.0
n_event_pct                          66.0              64.0
time-to-event-wk-10th                 2.1               2.7
time-to-event-wk-25th                 4.4               7.6
time-to-event-wk-50th                11.7              28.6
time-to-event-wk-75th                20.6              46.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.4              15.6
time-to-event-wk-50th-hici           18.0              37.6

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.54300   0.27420   0.31720   0.92930   0.02592


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              24.0              61.0
n_event_pct                          75.0              85.0
time-to-event-wk-10th                 2.4               1.7
time-to-event-wk-25th                 6.0               3.9
time-to-event-wk-50th                 8.6               9.0
time-to-event-wk-75th                22.6              21.1
time-to-event-wk-90th                32.6              34.7
time-to-event-wk-50th-loci            6.1               6.1
time-to-event-wk-50th-hici           17.6              13.0

$Ageonset_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1030    0.2452    0.6822    1.7840    0.6891


$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`
$Ageonset_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               8.0              18.0
n_event_pct                          25.0              25.0
time-to-event-wk-10th                 4.6               5.9
time-to-event-wk-25th                26.4              42.1
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           26.4              51.1
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6551    0.4363    0.2786    1.5400    0.3322
```

```
$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              13.0              21.0
n_event_pct                          41.0              29.0
time-to-event-wk-10th                 2.3               5.4
time-to-event-wk-25th                13.9              26.4
time-to-event-wk-50th                37.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           18.9              52.0
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5189    0.3596    0.2564    1.0500    0.0681


$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              12.0              14.0
n_event_pct                          38.0              19.0
time-to-event-wk-10th                 5.9               9.7
time-to-event-wk-25th                12.6                NA
time-to-event-wk-50th                56.6                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.0                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Metabolism and nutrition
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.340100  0.399600  0.155400  0.744300  0.006954


$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue disorders`
$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               5.0              10.0
n_event_pct                          16.0              14.0
time-to-event-wk-10th                26.1              43.1
time-to-event-wk-25th                46.9              63.0
time-to-event-wk-50th                56.4              63.0
time-to-event-wk-75th                  NA              63.0
time-to-event-wk-90th                  NA              63.0
time-to-event-wk-50th-loci           46.9                NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6566    0.5622    0.2181    1.9760    0.4543


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              28.0               56.0
n_event_pct                          88.0               78.0
time-to-event-wk-10th                 0.6                1.0
time-to-event-wk-25th                 1.4                3.1
time-to-event-wk-50th                 5.6                8.8
time-to-event-wk-75th                11.0               32.1
time-to-event-wk-90th                27.0                 NA
time-to-event-wk-50th-loci            2.1                5.7
time-to-event-wk-50th-hici            7.9               12.4

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.64890   0.24210   0.40380   1.04300   0.07404


$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`
$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              12.0               23.0
n_event_pct                          38.0               32.0
time-to-event-wk-10th                 5.7                4.4
time-to-event-wk-25th                19.0               26.0
time-to-event-wk-50th                53.6                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.0               49.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6577    0.3625    0.3232    1.3380    0.2477



$Agetrt_less_180d
$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                16.0              49.0
n_event                               7.0              11.0
n_event_pct                          44.0              22.0
time-to-event-wk-10th                 2.6               8.1
time-to-event-wk-25th                 9.4              47.1
time-to-event-wk-50th                29.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            9.4                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31160   0.50460   0.11590   0.83790   0.02086


$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                              11.0              32.0
n_event_pct                          69.0              65.0
time-to-event-wk-10th                 2.7               0.3
time-to-event-wk-25th                 5.1               5.0
time-to-event-wk-50th                10.9              14.1
time-to-event-wk-75th                22.6                NA
time-to-event-wk-90th                36.4                NA
time-to-event-wk-50th-loci            5.1               7.1
time-to-event-wk-50th-hici           22.6              21.4

$Agetrt_less_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7184    0.3536    0.3592    1.4360    0.3495


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                              11.0              31.0
n_event_pct                          69.0              63.0
time-to-event-wk-10th                 0.4               3.0
time-to-event-wk-25th                 4.4              10.0
time-to-event-wk-50th                 9.1              25.1
time-to-event-wk-75th                22.7              41.4
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            4.4              15.0
time-to-event-wk-50th-hici           22.7              37.6

$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45620   0.36630   0.22250   0.93530   0.03215
```

```
$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                             13.0              42.0
n_event_pct                         81.0              86.0
time-to-event-wk-10th                5.3               1.7
time-to-event-wk-25th                6.3               3.4
time-to-event-wk-50th                8.6               9.0
time-to-event-wk-75th               14.1              21.1
time-to-event-wk-90th               24.0              34.7
time-to-event-wk-50th-loci           6.0               5.0
time-to-event-wk-50th-hici          14.1              13.3

$Agetrt_less_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8995    0.3213    0.4792    1.6880    0.7416


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              7.0              14.0
n_event_pct                         44.0              29.0
time-to-event-wk-10th                0.1               5.4
time-to-event-wk-25th                6.3              33.6
time-to-event-wk-50th               27.4                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           6.3              52.0
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39270   0.47870   0.15370   1.00400   0.05087


$Agetrt_less_180d$`Metabolism and nutrition disorders`
$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              7.0                12
n_event_pct                         44.0                24
time-to-event-wk-10th                2.6                 6
time-to-event-wk-25th                6.0                32
time-to-event-wk-50th               22.9                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           6.0                NA
time-to-event-wk-50th-hici            NA                NA
```

$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39800   0.48540   0.15370   1.03100   0.05771

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all   16.0   49.0
n_event   15.0   35.0
n_event_pct   94.0   71.0
time-to-event-wk-10th   0.7   1.0
time-to-event-wk-25th   1.5   3.3
time-to-event-wk-50th   6.0   11.7
time-to-event-wk-75th   8.4   32.7
time-to-event-wk-90th   13.0   NA
time-to-event-wk-50th-loci   0.9   4.3
time-to-event-wk-50th-hici   8.4   30.7

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.377000 0.332700 0.196400 0.723600 0.003363

$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all   16.0   49.0
n_event   6.0   13.0
n_event_pct   38.0   27.0
time-to-event-wk-10th   4.3   5.6
time-to-event-wk-25th   5.9   33.9
time-to-event-wk-50th   NA   NA
time-to-event-wk-75th   NA   NA
time-to-event-wk-90th   NA   NA
time-to-event-wk-50th-loci   5.9   49.1
time-to-event-wk-50th-hici   NA   NA

$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5340   0.5066   0.1978   1.4420   0.2157

$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all   22.0   38.0
n_event   11.0   11.0
n_event_pct   50.0   29.0
time-to-event-wk-10th   2.6   7.3
time-to-event-wk-25th   13.9   22.9

```
time-to-event-wk-50th                29.4                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.9               47.1
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42470   0.43410   0.18140   0.99450   0.04853


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              16.0              32.0
n_event_pct                          73.0              84.0
time-to-event-wk-10th                 1.4               1.3
time-to-event-wk-25th                 5.6               4.0
time-to-event-wk-50th                10.9              10.1
time-to-event-wk-75th                19.9              16.4
time-to-event-wk-90th                36.4              27.9
time-to-event-wk-50th-loci            5.6               5.0
time-to-event-wk-50th-hici           19.9              14.1

$Region_Northamerica$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1700    0.3082    0.6394    2.1400    0.6108


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              15.0              27.0
n_event_pct                          68.0              71.0
time-to-event-wk-10th                 3.1               2.4
time-to-event-wk-25th                 7.7              10.0
time-to-event-wk-50th                18.0              28.6
time-to-event-wk-75th                23.0              41.4
time-to-event-wk-90th                42.6                NA
time-to-event-wk-50th-loci            7.7              13.4
time-to-event-wk-50th-hici           23.0              36.0

$Region_Northamerica$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6084    0.3438    0.3101    1.1940    0.1484


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                22.0               38.0
n_event                              20.0               34.0
n_event_pct                          91.0               89.0
time-to-event-wk-10th                 2.1                2.0
time-to-event-wk-25th                 3.1                4.0
time-to-event-wk-50th                 7.4                9.9
time-to-event-wk-75th                17.6               16.7
time-to-event-wk-90th                32.6               25.6
time-to-event-wk-50th-loci            3.1                5.0
time-to-event-wk-50th-hici           12.3               14.4

$Region_Northamerica$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0030    0.2904    0.5678    1.7720    0.9914


$Region_Northamerica$`Injury, poisoning and procedural complications`
$Region_Northamerica$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               7.0               14.0
n_event_pct                          32.0               37.0
time-to-event-wk-10th                 4.6                2.4
time-to-event-wk-25th                26.4               26.7
time-to-event-wk-50th                37.3                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.4               41.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8750    0.4703    0.3481    2.1990    0.7765


$Region_Northamerica$Investigations
$Region_Northamerica$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              10.0                9.0
n_event_pct                          45.0               24.0
time-to-event-wk-10th                 6.3                7.3
time-to-event-wk-25th                15.9               52.0
time-to-event-wk-50th                27.4                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9               52.0
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40680   0.46480   0.16360   1.01200   0.05298
```

```
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                             21.0              35.0
n_event_pct                         95.0              92.0
time-to-event-wk-10th                0.6               0.4
time-to-event-wk-25th                0.9               2.4
time-to-event-wk-50th                2.5               5.8
time-to-event-wk-75th                7.3              21.4
time-to-event-wk-90th               15.7              32.6
time-to-event-wk-50th-loci           0.9               3.3
time-to-event-wk-50th-hici           5.6              12.4

$Region_Northamerica$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.50640   0.28730   0.28840   0.88920   0.01785


$Region_Northamerica$`Skin and subcutaneous tissue disorders`
$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                             13.0              19.0
n_event_pct                         59.0              50.0
time-to-event-wk-10th                4.3               2.0
time-to-event-wk-25th                6.6               9.1
time-to-event-wk-50th               20.9              40.4
time-to-event-wk-75th               53.9                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           6.6              16.1
time-to-event-wk-50th-hici          53.9                NA

$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7786    0.3627    0.3824    1.5850    0.4903



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0              46.0
n_event                              6.0              13.0
n_event_pct                         26.0              28.0
time-to-event-wk-10th                4.6               8.1
time-to-event-wk-25th               14.3              22.9
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          14.3              47.1
```

```
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8543    0.4942    0.3243    2.2510    0.7500


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                              14.0              32.0
n_event_pct                          61.0              70.0
time-to-event-wk-10th                 5.0               1.3
time-to-event-wk-25th                 9.7               4.3
time-to-event-wk-50th                16.9              10.1
time-to-event-wk-75th                39.7              40.9
time-to-event-wk-90th                40.3                NA
time-to-event-wk-50th-loci            9.7               6.3
time-to-event-wk-50th-hici           39.7              16.3

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2220    0.3285    0.6418    2.3270    0.5417


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                              15.0              30.0
n_event_pct                          65.0              65.0
time-to-event-wk-10th                 2.1               2.6
time-to-event-wk-25th                 4.1               6.4
time-to-event-wk-50th                13.4              25.1
time-to-event-wk-75th                16.9              46.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            4.1               8.1
time-to-event-wk-50th-hici           16.9              37.6

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5251    0.3394    0.2699    1.0210    0.0577


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                              17.0              40.0
n_event_pct                          74.0              87.0
time-to-event-wk-10th                 2.4               1.7
```

```
time-to-event-wk-25th                 5.7                4.0
time-to-event-wk-50th                 7.4                9.0
time-to-event-wk-75th                22.6               18.0
time-to-event-wk-90th                38.1               25.6
time-to-event-wk-50th-loci            5.7                4.7
time-to-event-wk-50th-hici           22.6               13.0

$Disdur_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2130    0.2960    0.6793    2.1680    0.5133


$Disdur_greater_12wk$`Injury, poisoning and procedural complications`
$Disdur_greater_12wk$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               4.0               13.0
n_event_pct                          17.0               28.0
time-to-event-wk-10th                 2.1                5.9
time-to-event-wk-25th                  NA               42.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               43.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3370    0.5741    0.4339    4.1190    0.6130


$Disdur_greater_12wk$Investigations
$Disdur_greater_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               7.0               14.0
n_event_pct                          30.0               30.0
time-to-event-wk-10th                 9.1                5.4
time-to-event-wk-25th                18.9               26.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           18.9               36.9
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9371    0.4643    0.3772    2.3280    0.8886


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                23.0              46.0
n_event                              20.0              36.0
n_event_pct                          87.0              78.0
time-to-event-wk-10th                 0.4               0.3
time-to-event-wk-25th                 1.1               2.7
time-to-event-wk-50th                 4.1               8.5
time-to-event-wk-75th                11.0              32.1
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            1.6               5.0
time-to-event-wk-50th-hici            7.3              12.4

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6990    0.2967    0.3908    1.2500    0.2274


$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`
$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               7.0              15.0
n_event_pct                          30.0              33.0
time-to-event-wk-10th                 6.6               2.1
time-to-event-wk-25th                40.7              20.1
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7              45.1
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0680    0.4616    0.4320    2.6380    0.8874



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0              31.0
n_event                              15.0              21.0
n_event_pct                          60.0              68.0
time-to-event-wk-10th                 1.4               1.3
time-to-event-wk-25th                 7.7               4.3
time-to-event-wk-50th                19.9               9.3
time-to-event-wk-75th                40.3              40.9
time-to-event-wk-90th                43.0                NA
time-to-event-wk-50th-loci            8.1               5.0
time-to-event-wk-50th-hici           40.3              27.9

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   1.3040    0.3406    0.6688    2.5420    0.4361


$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                             17.0              20.0
n_event_pct                         68.0              65.0
time-to-event-wk-10th                2.1               2.4
time-to-event-wk-25th                5.1               3.4
time-to-event-wk-50th               15.1              23.6
time-to-event-wk-75th               23.0              46.7
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           5.1               6.9
time-to-event-wk-50th-hici          23.0              46.4

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6897    0.3433    0.3519    1.3520    0.2791


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                             18.0              23.0
n_event_pct                         72.0              74.0
time-to-event-wk-10th                2.1               2.0
time-to-event-wk-25th                3.1               4.1
time-to-event-wk-50th               10.4              10.0
time-to-event-wk-75th               23.9              21.9
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           3.1               4.9
time-to-event-wk-50th-hici          23.9              17.1

$Agetrt_greater_equal_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1000    0.3210    0.5866    2.0650    0.7655


$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`
$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                              6.0              10.0
n_event_pct                         24.0              32.0
time-to-event-wk-10th                2.1               5.7
time-to-event-wk-25th               37.3              41.4
time-to-event-wk-50th                 NA                NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.3               42.1
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1560    0.5359    0.4043    3.3040    0.7870


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              21.0               26.0
n_event_pct                          84.0               84.0
time-to-event-wk-10th                 0.1                0.3
time-to-event-wk-25th                 1.1                2.7
time-to-event-wk-50th                 3.6                7.0
time-to-event-wk-75th                15.7               16.7
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.6                5.0
time-to-event-wk-50th-hici           11.0               12.0

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8243    0.2954    0.4620    1.4710    0.5131


$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               9.0               10.0
n_event_pct                          36.0               32.0
time-to-event-wk-10th                 6.6                3.3
time-to-event-wk-25th                 8.1               20.1
time-to-event-wk-50th                53.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7               45.1
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8365    0.4617    0.3384    2.0680    0.6990



$Gender_Male
```

```
$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                              10.0              23.0
n_event_pct                          59.0              62.0
time-to-event-wk-10th                 5.1               0.3
time-to-event-wk-25th                 9.7               4.0
time-to-event-wk-50th                12.7              16.3
time-to-event-wk-75th                40.3                NA
time-to-event-wk-90th                40.3                NA
time-to-event-wk-50th-loci            9.7               6.3
time-to-event-wk-50th-hici             NA              21.4

$Gender_Male$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1030    0.3812    0.5226    2.3290    0.7968


$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                              11.0              24.0
n_event_pct                          65.0              65.0
time-to-event-wk-10th                 0.4               2.1
time-to-event-wk-25th                 5.1               6.9
time-to-event-wk-50th                13.4              25.1
time-to-event-wk-75th                22.7              41.4
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            4.4               8.1
time-to-event-wk-50th-hici           22.7              37.6

$Gender_Male$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6741    0.3750    0.3232    1.4060    0.2929


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                              14.0              29.0
n_event_pct                          82.0              78.0
time-to-event-wk-10th                 1.4               2.4
time-to-event-wk-25th                 4.4               4.0
time-to-event-wk-50th                 7.4               9.9
time-to-event-wk-75th                23.9              16.7
time-to-event-wk-90th                24.0              49.0
time-to-event-wk-50th-loci            2.3               4.3
time-to-event-wk-50th-hici           22.6              15.7

$Gender_Male$`Infections and infestations`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9179    0.3302    0.4806    1.7530    0.7953


$Gender_Male$Investigations
$Gender_Male$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               6.0               10.0
n_event_pct                          35.0               27.0
time-to-event-wk-10th                 2.0                5.0
time-to-event-wk-25th                20.3               33.6
time-to-event-wk-50th                43.4                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.3               36.9
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6521    0.5232    0.2339    1.8180    0.4138


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                              15.0               30.0
n_event_pct                          88.0               81.0
time-to-event-wk-10th                 0.6                0.6
time-to-event-wk-25th                 1.7                2.4
time-to-event-wk-50th                 6.1                6.9
time-to-event-wk-75th                15.7               25.4
time-to-event-wk-90th                27.0                 NA
time-to-event-wk-50th-loci            0.9                3.4
time-to-event-wk-50th-hici           13.0               12.4

$Gender_Male$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7607    0.3180    0.4079    1.4190    0.3896


$Gender_Male$`Skin and subcutaneous tissue disorders`
$Gender_Male$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               8.0               11.0
n_event_pct                          47.0               30.0
time-to-event-wk-10th                 4.0                2.1
time-to-event-wk-25th                 5.9               16.1
time-to-event-wk-50th                40.7                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci            5.7               26.0
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5145    0.4745    0.2030    1.3040    0.1613



$Gender_Female
$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              16.0              30.0
n_event_pct                          67.0              70.0
time-to-event-wk-10th                 1.4               2.4
time-to-event-wk-25th                 5.0               4.4
time-to-event-wk-50th                16.9              12.7
time-to-event-wk-75th                36.4              40.9
time-to-event-wk-90th                43.0                NA
time-to-event-wk-50th-loci            5.6               6.6
time-to-event-wk-50th-hici           36.4              19.0

$Gender_Female$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9400    0.3217    0.5004    1.7660    0.8474


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              17.0              27.0
n_event_pct                          71.0              63.0
time-to-event-wk-10th                 2.1               2.7
time-to-event-wk-25th                 4.1               8.1
time-to-event-wk-50th                15.1              20.7
time-to-event-wk-75th                23.0              54.3
time-to-event-wk-90th                42.6                NA
time-to-event-wk-50th-loci            5.1              12.7
time-to-event-wk-50th-hici           18.0              38.0

$Gender_Female$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.53030   0.32570   0.28010   1.00400   0.05141


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              17.0              36.0
```

```
n_event_pct                          71.0              84.0
time-to-event-wk-10th                 3.0               1.3
time-to-event-wk-25th                 6.0               3.7
time-to-event-wk-50th                10.4               9.3
time-to-event-wk-75th                38.1              21.9
time-to-event-wk-90th                  NA              31.1
time-to-event-wk-50th-loci            6.1               5.7
time-to-event-wk-50th-hici           15.3              13.3

$Gender_Female$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3520    0.3124    0.7330    2.4940    0.3343


$Gender_Female$`Injury, poisoning and procedural complications`
$Gender_Female$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                               6.0              10.0
n_event_pct                          25.0              23.0
time-to-event-wk-10th                 4.6               5.7
time-to-event-wk-25th                37.3              43.4
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           37.3                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7977    0.5261    0.2845    2.2370    0.6674


$Gender_Female$Investigations
$Gender_Female$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                               8.0              11.0
n_event_pct                          33.0              26.0
time-to-event-wk-10th                 6.3               8.1
time-to-event-wk-25th                15.9              26.4
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.9              52.0
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6275    0.4835    0.2432    1.6190    0.3352


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
```

```
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              21.0              31.0
n_event_pct                          88.0              72.0
time-to-event-wk-10th                 0.1               1.0
time-to-event-wk-25th                 1.1               4.1
time-to-event-wk-50th                 3.6              12.0
time-to-event-wk-75th                 8.7              32.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            1.1               5.0
time-to-event-wk-50th-hici            6.3              30.7

$Gender_Female$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.54000   0.30420   0.29750   0.98020   0.04279


$Gender_Female$`Skin and subcutaneous tissue disorders`
$Gender_Female$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                               7.0              12.0
n_event_pct                          29.0              28.0
time-to-event-wk-10th                 7.6               5.6
time-to-event-wk-25th                53.6              40.4
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           53.6              49.1
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8954    0.4900    0.3428    2.3390    0.8217



$Region_Europe
$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               9.0              14.0
n_event_pct                          53.0              47.0
time-to-event-wk-10th                 2.7               0.4
time-to-event-wk-25th                12.7               6.3
time-to-event-wk-50th                26.1              40.9
time-to-event-wk-75th                40.3                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            5.0               8.4
time-to-event-wk-50th-hici           40.3                NA
```

```
$Region_Europe$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7121    0.4481    0.2959    1.7140    0.4485


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                              12.0              20.0
n_event_pct                          71.0              67.0
time-to-event-wk-10th                 2.0               1.9
time-to-event-wk-25th                 4.1               6.4
time-to-event-wk-50th                 7.9              15.6
time-to-event-wk-75th                16.9              46.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            2.3               6.9
time-to-event-wk-50th-hici           16.9              36.3

$Region_Europe$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48760   0.40000   0.22270   1.06800   0.07259


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                              11.0              22.0
n_event_pct                          65.0              73.0
time-to-event-wk-10th                 3.0               1.6
time-to-event-wk-25th                 5.7               3.4
time-to-event-wk-50th                11.9               7.0
time-to-event-wk-75th                22.6              49.0
time-to-event-wk-90th                  NA              49.0
time-to-event-wk-50th-loci            5.7               4.7
time-to-event-wk-50th-hici           22.6              14.4

$Region_Europe$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2180    0.3873    0.5702    2.6020    0.6104


$Region_Europe$Investigations
$Region_Europe$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               4.0              11.0
n_event_pct                          24.0              37.0
time-to-event-wk-10th                 2.3               5.2
time-to-event-wk-25th                37.4              15.1
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.4               19.3
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4380    0.5945    0.4486    4.6130    0.5408


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                              14.0               22.0
n_event_pct                          82.0               73.0
time-to-event-wk-10th                 0.4                0.5
time-to-event-wk-25th                 4.1                3.0
time-to-event-wk-50th                 6.3                8.8
time-to-event-wk-75th                15.7                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            3.1                4.3
time-to-event-wk-50th-hici           15.7               12.0

$Region_Europe$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8134    0.3625    0.3997    1.6550    0.5689



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                              12.0               21.0
n_event_pct                          67.0               62.0
time-to-event-wk-10th                 1.0                0.3
time-to-event-wk-25th                 5.1                4.4
time-to-event-wk-50th                12.7               18.9
time-to-event-wk-75th                36.4                 NA
time-to-event-wk-90th                43.0                 NA
time-to-event-wk-50th-loci            5.1                7.1
time-to-event-wk-50th-hici           36.4               26.6

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7998    0.3718    0.3860    1.6580    0.5480


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                18.0              34.0
n_event                              13.0              21.0
n_event_pct                          72.0              62.0
time-to-event-wk-10th                 0.4               1.1
time-to-event-wk-25th                 5.1              10.0
time-to-event-wk-50th                11.7              24.3
time-to-event-wk-75th                23.0              41.4
time-to-event-wk-90th                42.6                NA
time-to-event-wk-50th-loci            5.1              13.4
time-to-event-wk-50th-hici           23.0              41.4

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6780    0.3688    0.3291    1.3970    0.2921


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                              14.0              25.0
n_event_pct                          78.0              74.0
time-to-event-wk-10th                 1.4               2.4
time-to-event-wk-25th                 5.3               4.3
time-to-event-wk-50th                 9.4              10.7
time-to-event-wk-75th                24.0              31.1
time-to-event-wk-90th                32.6              34.7
time-to-event-wk-50th-loci            5.3               6.1
time-to-event-wk-50th-hici           24.0              16.7

$Disdur_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9789    0.3491    0.4939    1.9400    0.9513


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                              16.0              25.0
n_event_pct                          89.0              74.0
time-to-event-wk-10th                 0.6               1.0
time-to-event-wk-25th                 1.0               3.3
time-to-event-wk-50th                 5.1              11.9
time-to-event-wk-75th                 9.0              32.7
time-to-event-wk-90th                16.4                NA
time-to-event-wk-50th-loci            1.0               4.1
time-to-event-wk-50th-hici            9.0              26.6

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.5242    0.3401    0.2691    1.0210    0.0576



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem UE nach PT, das bei mindestens 10% der
Patienten in einem Studienarm auftrat"

$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Abdominal pain upper`
$Ageonset_greater_12wk$`Abdominal pain upper`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Abdominal pain upper`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Acute respiratory failure`
$Ageonset_greater_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Acute respiratory failure`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$Amblyopia
$Ageonset_greater_12wk$Amblyopia$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Amblyopia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Anxiety
```

```
$Ageonset_greater_12wk$Anxiety$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Anxiety$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$Atelectasis
$Ageonset_greater_12wk$Atelectasis$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Atelectasis$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Bone marrow disorder`
$Ageonset_greater_12wk$`Bone marrow disorder`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Bone marrow disorder`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Bradycardia
$Ageonset_greater_12wk$Bradycardia$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Bradycardia$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494
```

```
$Ageonset_greater_12wk$`Bronchial secretion retention`
$Ageonset_greater_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Bronchial secretion retention`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Candida sepsis`
$Ageonset_greater_12wk$`Candida sepsis`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Candida sepsis`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Cardio-respiratory arrest`
$Ageonset_greater_12wk$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Cardio-respiratory arrest`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$Catarrh
$Ageonset_greater_12wk$Catarrh$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Catarrh$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
```

```
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Constipation
$Ageonset_greater_12wk$Constipation$ntab
            CTRL TRT
n_all          9   8
n_event        1   3
n_event_pct   11  38

$Ageonset_greater_12wk$Constipation$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.3750000 1.0474838  0.4331656 26.2962347 0.2455384
OR_TRTvsCTRL  4.8000000 1.2877629  0.3846763 59.8945106 0.2231884
ARR_TRTvsCTRL 0.2638889 0.2006759 -0.1294286  0.6572064 0.1885097


$Ageonset_greater_12wk$Cough
$Ageonset_greater_12wk$Cough$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$Cough$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$Cyanosis
$Ageonset_greater_12wk$Cyanosis$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Cyanosis$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Dermatitis contact`
$Ageonset_greater_12wk$`Dermatitis contact`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Dermatitis contact`$stats
                estimate        se      lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Dermatitis diaper`
$Ageonset_greater_12wk$`Dermatitis diaper`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Dermatitis diaper`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Diarrhoea
$Ageonset_greater_12wk$Diarrhoea$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$Diarrhoea$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031


$Ageonset_greater_12wk$`Diarrhoea haemorrhagic`
$Ageonset_greater_12wk$`Diarrhoea haemorrhagic`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Diarrhoea haemorrhagic`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Drug hypersensitivity`
$Ageonset_greater_12wk$`Drug hypersensitivity`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0
```

```
$Ageonset_greater_12wk$`Drug hypersensitivity`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Dysphagia
$Ageonset_greater_12wk$Dysphagia$ntab
            CTRL TRT
n_all          9   8
n_event        3   1
n_event_pct   33  12

$Ageonset_greater_12wk$Dysphagia$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3750000 1.0474838  0.04812951 2.9218039 0.3490842
OR_TRTvsCTRL   0.2857143 1.2817399  0.02316930 3.5233106 0.3283749
ARR_TRTvsCTRL -0.2083333 0.1958653 -0.59222235 0.1755557 0.2874846


$Ageonset_greater_12wk$Dyspnoea
$Ageonset_greater_12wk$Dyspnoea$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Dyspnoea$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Erythema
$Ageonset_greater_12wk$Erythema$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0

$Ageonset_greater_12wk$Erythema$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$`Failure to thrive`
$Ageonset_greater_12wk$`Failure to thrive`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
```

```
n_event_pct   11   0

$Ageonset_greater_12wk$`Failure to thrive`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Femur fracture`
$Ageonset_greater_12wk$`Femur fracture`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Femur fracture`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Fungal infection`
$Ageonset_greater_12wk$`Fungal infection`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Fungal infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Fungal skin infection`
$Ageonset_greater_12wk$`Fungal skin infection`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Fungal skin infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Gastroenteritis viral`
$Ageonset_greater_12wk$`Gastroenteritis viral`$ntab
            CTRL TRT
```

```
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Gastroenteritis viral`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`
$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all          9   8
n_event        3   0
n_event_pct   33   0

$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$stats
                estimate        se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.1587302 1.4403483  0.009432629  2.67107530 0.20130218
OR_TRTvsCTRL   0.1092437 1.5991271  0.004755727  2.50943442 0.16617046
ARR_TRTvsCTRL -0.3333333 0.1571348 -0.641311961 -0.02535471 0.03389485


$Ageonset_greater_12wk$Hyperaemia
$Ageonset_greater_12wk$Hyperaemia$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Hyperaemia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Increased upper airway secretion`
$Ageonset_greater_12wk$`Increased upper airway secretion`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Increased upper airway secretion`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Infusion site bruising`
```

```
$Ageonset_greater_12wk$`Infusion site bruising`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Infusion site bruising`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Nasal congestion`
$Ageonset_greater_12wk$`Nasal congestion`$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0

$Ageonset_greater_12wk$`Nasal congestion`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$Nasopharyngitis
$Ageonset_greater_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all          9   8
n_event        3   1
n_event_pct   33  12

$Ageonset_greater_12wk$Nasopharyngitis$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3750000 1.0474838  0.04812951 2.9218039 0.3490842
OR_TRTvsCTRL   0.2857143 1.2817399  0.02316930 3.5233106 0.3283749
ARR_TRTvsCTRL -0.2083333 0.1958653 -0.59222235 0.1755557 0.2874846


$Ageonset_greater_12wk$Nystagmus
$Ageonset_greater_12wk$Nystagmus$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Nystagmus$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444
```

```
$Ageonset_greater_12wk$Oedema
$Ageonset_greater_12wk$Oedema$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Oedema$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Oral candidiasis`
$Ageonset_greater_12wk$`Oral candidiasis`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Oral candidiasis`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Oropharyngeal pain`
$Ageonset_greater_12wk$`Oropharyngeal pain`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Oropharyngeal pain`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Otitis media`
$Ageonset_greater_12wk$`Otitis media`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Otitis media`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
```

```
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Pain
$Ageonset_greater_12wk$Pain$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Pain$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$Pneumonia
$Ageonset_greater_12wk$Pneumonia$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$Pneumonia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031


$Ageonset_greater_12wk$`Pneumonia aspiration`
$Ageonset_greater_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0

$Ageonset_greater_12wk$`Pneumonia aspiration`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`
$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$stats
                estimate        se      lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Pneumonia pseudomonal`
$Ageonset_greater_12wk$`Pneumonia pseudomonal`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Pneumonia pseudomonal`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Procedural pain`
$Ageonset_greater_12wk$`Procedural pain`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Procedural pain`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Pseudomonas infection`
$Ageonset_greater_12wk$`Pseudomonas infection`$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0

$Ageonset_greater_12wk$`Pseudomonas infection`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$Pyrexia
$Ageonset_greater_12wk$Pyrexia$ntab
            CTRL TRT
n_all          9   8
n_event        6   4
n_event_pct   67  50
```

```
$Ageonset_greater_12wk$Pyrexia$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7500000 0.4249183  0.32611454 1.7248541 0.4983875
OR_TRTvsCTRL   0.5000000 1.0000000  0.07043175 3.5495357 0.4882172
ARR_TRTvsCTRL -0.1666667 0.2365193 -0.63023589 0.2969026 0.4810192


$Ageonset_greater_12wk$`Respiratory arrest`
$Ageonset_greater_12wk$`Respiratory arrest`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Respiratory arrest`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Respiratory distress`
$Ageonset_greater_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Respiratory distress`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$`Respiratory failure`
$Ageonset_greater_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all          9   8
n_event        1   2
n_event_pct   11  25

$Ageonset_greater_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2500000 1.1242281  0.2484493 20.3763897 0.4707116
OR_TRTvsCTRL  2.6666667 1.3385315  0.1934678 36.7560505 0.4637017
ARR_TRTvsCTRL 0.1388889 0.1855032 -0.2246907  0.5024685 0.4540295


$Ageonset_greater_12wk$`Respiratory tract infection`
$Ageonset_greater_12wk$`Respiratory tract infection`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
```

```
n_event_pct    0  12

$Ageonset_greater_12wk$`Respiratory tract infection`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Respirovirus test positive`
$Ageonset_greater_12wk$`Respirovirus test positive`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Respirovirus test positive`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Restlessness
$Ageonset_greater_12wk$Restlessness$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Restlessness$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Rhinovirus infection`
$Ageonset_greater_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Rhinovirus infection`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Salivary hypersecretion`
$Ageonset_greater_12wk$`Salivary hypersecretion`$ntab
            CTRL TRT
```

```
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Salivary hypersecretion`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Scoliosis
$Ageonset_greater_12wk$Scoliosis$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Scoliosis$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Seasonal allergy`
$Ageonset_greater_12wk$`Seasonal allergy`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Seasonal allergy`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Sinusitis
$Ageonset_greater_12wk$Sinusitis$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Sinusitis$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Sleep disorder`
```

```
$Ageonset_greater_12wk$`Sleep disorder`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Sleep disorder`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Staphylococcal infection`
$Ageonset_greater_12wk$`Staphylococcal infection`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Staphylococcal infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Stoma complication`
$Ageonset_greater_12wk$`Stoma complication`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Stoma complication`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Stoma site erythema`
$Ageonset_greater_12wk$`Stoma site erythema`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Stoma site erythema`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444
```

```
$Ageonset_greater_12wk$`Stoma site infection`
$Ageonset_greater_12wk$`Stoma site infection`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Stoma site infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Stoma site inflammation`
$Ageonset_greater_12wk$`Stoma site inflammation`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Stoma site inflammation`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Strabismus
$Ageonset_greater_12wk$Strabismus$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Strabismus$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Tachycardia
$Ageonset_greater_12wk$Tachycardia$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Tachycardia$stats
               estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
```

```
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$Teething
$Ageonset_greater_12wk$Teething$ntab
            CTRL TRT
n_all          9   8
n_event        1   2
n_event_pct   11  25

$Ageonset_greater_12wk$Teething$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2500000 1.1242281  0.2484493 20.3763897 0.4707116
OR_TRTvsCTRL  2.6666667 1.3385315  0.1934678 36.7560505 0.4637017
ARR_TRTvsCTRL 0.1388889 0.1855032 -0.2246907  0.5024685 0.4540295


$Ageonset_greater_12wk$`Upper respiratory tract congestion`
$Ageonset_greater_12wk$`Upper respiratory tract congestion`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Upper respiratory tract congestion`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Upper respiratory tract infection`
$Ageonset_greater_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Upper respiratory tract infection`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$`Upper respiratory tract inflammation`
$Ageonset_greater_12wk$`Upper respiratory tract inflammation`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Upper respiratory tract inflammation`$stats
                estimate        se      lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Use of accessory respiratory muscles`
$Ageonset_greater_12wk$`Use of accessory respiratory muscles`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Use of accessory respiratory muscles`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Viral infection`
$Ageonset_greater_12wk$`Viral infection`$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0

$Ageonset_greater_12wk$`Viral infection`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$`Viral upper respiratory tract infection`
$Ageonset_greater_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Viral upper respiratory tract infection`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$Vomiting
$Ageonset_greater_12wk$Vomiting$ntab
            CTRL TRT
n_all          9   8
n_event        2   2
n_event_pct   22  25
```

```
$Ageonset_greater_12wk$Vomiting$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 0.8740074  0.2028598  6.2389133 0.8928000
OR_TRTvsCTRL  1.16666667 1.1443443  0.1238452 10.9904228 0.8928439
ARR_TRTvsCTRL 0.02777778 0.2064991 -0.3769531  0.4325086 0.8929933



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event        8  10
n_event_pct   25  14

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5555556 0.42410035  0.2419539 1.27562309 0.1657587
OR_TRTvsCTRL   0.4838710 0.53178539  0.1706369 1.37210109 0.1722235
ARR_TRTvsCTRL -0.1111111 0.08672064 -0.2810804 0.05885822 0.2001047


$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         32  72
n_event       11  18
n_event_pct   34  25

$Ageonset_less_equal_12wk$Atelectasis$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7272727 0.31831707  0.3897134 1.35721698 0.3171028
OR_TRTvsCTRL   0.6363636 0.46108807  0.2577665 1.57102912 0.3269589
ARR_TRTvsCTRL -0.0937500 0.09825338 -0.2863231 0.09882309 0.3399998


$Ageonset_less_equal_12wk$`Bacterial tracheitis`
$Ageonset_less_equal_12wk$`Bacterial tracheitis`$ntab
            CTRL TRT
n_all         32  72
n_event        4   1
n_event_pct   12   1

$Ageonset_less_equal_12wk$`Bacterial tracheitis`$stats
                estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.11111111 1.09766166  0.01292487 0.955187842 0.04531355
OR_TRTvsCTRL   0.09859155 1.14008719  0.01055348 0.921050969 0.04214366
ARR_TRTvsCTRL -0.11111111 0.06006822 -0.22884265 0.006620433 0.06434977


$Ageonset_less_equal_12wk$`Bronchial secretion retention`
$Ageonset_less_equal_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
```

```
n_all         32  72
n_event        6   4
n_event_pct   19   6

$Ageonset_less_equal_12wk$`Bronchial secretion retention`$stats
                estimate         se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.2962963 0.60953078  0.08972071 0.9784976 0.04597468
OR_TRTvsCTRL   0.2549020 0.68544445  0.06651534 0.9768425 0.04613611
ARR_TRTvsCTRL -0.1319444 0.07409103 -0.27716019 0.0132713 0.07493819


$Ageonset_less_equal_12wk$Bronchiolitis
$Ageonset_less_equal_12wk$Bronchiolitis$ntab
            CTRL TRT
n_all         32  72
n_event        3   8
n_event_pct    9  11

$Ageonset_less_equal_12wk$Bronchiolitis$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.18518519 0.64280203  0.3362267 4.1777292 0.7915410
OR_TRTvsCTRL  1.20833333 0.71305055  0.2987012 4.8880595 0.7907031
ARR_TRTvsCTRL 0.01736111 0.06345685 -0.1070120 0.1417342 0.7844003


$Ageonset_less_equal_12wk$Constipation
$Ageonset_less_equal_12wk$Constipation$ntab
            CTRL TRT
n_all         32  72
n_event        8  25
n_event_pct   25  35

$Ageonset_less_equal_12wk$Constipation$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.38888889 0.34620963  0.70464979 2.7375476 0.3426924
OR_TRTvsCTRL  1.59574468 0.47743404  0.62599493 4.0677663 0.3276498
ARR_TRTvsCTRL 0.09722222 0.09490741 -0.08879288 0.2832373 0.3056510


$Ageonset_less_equal_12wk$Cough
$Ageonset_less_equal_12wk$Cough$ntab
            CTRL TRT
n_all         32  72
n_event        6   8
n_event_pct   19  11

$Ageonset_less_equal_12wk$Cough$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.59259259 0.49651564  0.2239347 1.56816261 0.2919561
OR_TRTvsCTRL   0.54166667 0.58800783  0.1710878 1.71492559 0.2970962
ARR_TRTvsCTRL -0.07638889 0.07831018 -0.2298740 0.07709624 0.3293293


$Ageonset_less_equal_12wk$Diarrhoea
```

```
$Ageonset_less_equal_12wk$Diarrhoea$ntab
            CTRL TRT
n_all         32  72
n_event        6  10
n_event_pct   19  14

$Ageonset_less_equal_12wk$Diarrhoea$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.74074074 0.47066737  0.2944648 1.8633697 0.5237243
OR_TRTvsCTRL   0.69892473 0.56679559  0.2301299 2.1226954 0.5273899
ARR_TRTvsCTRL -0.04861111 0.08013636 -0.2056755 0.1084533 0.5441131


$Ageonset_less_equal_12wk$Dysphagia
$Ageonset_less_equal_12wk$Dysphagia$ntab
            CTRL TRT
n_all         32  72
n_event        6   8
n_event_pct   19  11

$Ageonset_less_equal_12wk$Dysphagia$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.59259259 0.49651564  0.2239347 1.56816261 0.2919561
OR_TRTvsCTRL   0.54166667 0.58800783  0.1710878 1.71492559 0.2970962
ARR_TRTvsCTRL -0.07638889 0.07831018 -0.2298740 0.07709624 0.3293293


$Ageonset_less_equal_12wk$Dyspnoea
$Ageonset_less_equal_12wk$Dyspnoea$ntab
            CTRL TRT
n_all         32  72
n_event        5   7
n_event_pct   16  10

$Ageonset_less_equal_12wk$Dyspnoea$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.62222222 0.54563564  0.2135500 1.81297334 0.3845459
OR_TRTvsCTRL   0.58153846 0.62871201  0.1695969 1.99406394 0.3885751
ARR_TRTvsCTRL -0.05902778 0.07306779 -0.2022380 0.08418246 0.4191772


$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`
$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         32  72
n_event        5  10
n_event_pct   16  14

$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.50483771  0.3304676 2.3909259 0.8155217
OR_TRTvsCTRL   0.87096774 0.59427777  0.2717390 2.7915938 0.8161748
ARR_TRTvsCTRL -0.01736111 0.07603267 -0.1663824 0.1316602 0.8193839
```

```
$Ageonset_less_equal_12wk$`Nasal congestion`
$Ageonset_less_equal_12wk$`Nasal congestion`$ntab
            CTRL TRT
n_all         32  72
n_event        3   8
n_event_pct    9  11

$Ageonset_less_equal_12wk$`Nasal congestion`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.18518519 0.64280203  0.3362267 4.1777292 0.7915410
OR_TRTvsCTRL  1.20833333 0.71305055  0.2987012 4.8880595 0.7907031
ARR_TRTvsCTRL 0.01736111 0.06345685 -0.1070120 0.1417342 0.7844003


$Ageonset_less_equal_12wk$Nasopharyngitis
$Ageonset_less_equal_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all         32  72
n_event        1  14
n_event_pct    3  19

$Ageonset_less_equal_12wk$Nasopharyngitis$stats
                estimate         se     lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  6.2222222 1.01305957 0.85433393 45.3172328 0.071143509
OR_TRTvsCTRL  7.4827586 1.05873888 0.93942382 59.6021470 0.057309570
ARR_TRTvsCTRL 0.1631944 0.05587076 0.05368976  0.2726991 0.003489911


$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         32  72
n_event       10  10
n_event_pct   31  14

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.4444444 0.39352397  0.2055177 0.961137868 0.03933279
OR_TRTvsCTRL   0.3548387 0.51145242  0.1302213 0.966896705 0.04278696
ARR_TRTvsCTRL -0.1736111 0.09151481 -0.3529769 0.005754628 0.05781711


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$ntab
            CTRL TRT
n_all         32  72
n_event        6  22
n_event_pct   19  31

$Ageonset_less_equal_12wk$Pneumonia$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.6296296 0.40863471  0.73157427 3.6301068 0.2320542
OR_TRTvsCTRL  1.9066667 0.52017569  0.68786058 5.2850503 0.2147347
```

```
ARR_TRTvsCTRL 0.1180556 0.08779433 -0.05401817 0.2901293 0.1787276


$Ageonset_less_equal_12wk$`Pneumonia aspiration`
$Ageonset_less_equal_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         32  72
n_event        5   9
n_event_pct   16  12

$Ageonset_less_equal_12wk$`Pneumonia aspiration`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8000000 0.51572495  0.2911415 2.1982438 0.6652477
OR_TRTvsCTRL   0.7714286 0.60334166  0.2364451 2.5168717 0.6671061
ARR_TRTvsCTRL -0.0312500 0.07509308 -0.1784297 0.1159297 0.6773001


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         32  72
n_event       18  41
n_event_pct   56  57

$Ageonset_less_equal_12wk$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.012345679 0.1865661  0.7023013 1.4592651 0.9475625
OR_TRTvsCTRL  1.028673835 0.4285236  0.4441378 2.3825257 0.9474003
ARR_TRTvsCTRL 0.006944444 0.1053360 -0.1995103 0.2133992 0.9474363


$Ageonset_less_equal_12wk$Rash
$Ageonset_less_equal_12wk$Rash$ntab
            CTRL TRT
n_all         32  72
n_event        4   9
n_event_pct   12  12

$Ageonset_less_equal_12wk$Rash$stats
              estimate         se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.56211407  0.3322979 3.0093476      1
OR_TRTvsCTRL         1 0.64241607  0.2839059 3.5222936      1
ARR_TRTvsCTRL        0 0.07026426 -0.1377154 0.1377154      1


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         32  72
n_event       10  20
n_event_pct   31  28

$Ageonset_less_equal_12wk$`Respiratory distress`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.88888889 0.32382265  0.4712042 1.6768176 0.7160619
OR_TRTvsCTRL   0.84615385 0.46334147  0.3412341 2.0981972 0.7184418
ARR_TRTvsCTRL -0.03472222 0.09746906 -0.2257581 0.1563136 0.7216620


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event       15  18
n_event_pct   47  25

$Ageonset_less_equal_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.5333333 0.2776389  0.3095082  0.91902082 0.02356652
OR_TRTvsCTRL   0.3777778 0.4467262  0.1573919  0.90675595 0.02932621
ARR_TRTvsCTRL -0.2187500 0.1019125 -0.4184947 -0.01900525 0.03183709


$Ageonset_less_equal_12wk$`Respiratory tract infection`
$Ageonset_less_equal_12wk$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        2   8
n_event_pct    6  11

$Ageonset_less_equal_12wk$`Respiratory tract infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.77777778 0.76148612  0.39966794 7.9077992 0.4499007
OR_TRTvsCTRL  1.87500000 0.82094965  0.37515234 9.3711930 0.4438494
ARR_TRTvsCTRL 0.04861111 0.05659326 -0.06230964 0.1595319 0.3903649


$Ageonset_less_equal_12wk$`Rhinovirus infection`
$Ageonset_less_equal_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         32  72
n_event        6   9
n_event_pct   19  12

$Ageonset_less_equal_12wk$`Rhinovirus infection`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6666667 0.48232654  0.2590309 1.7157967 0.4005472
OR_TRTvsCTRL   0.6190476 0.57629188  0.2000707 1.9154226 0.4053127
ARR_TRTvsCTRL -0.0625000 0.07924544 -0.2178182 0.0928182 0.4302938


$Ageonset_less_equal_12wk$`Sleep apnoea syndrome`
$Ageonset_less_equal_12wk$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all         32  72
n_event        4   0
n_event_pct   12   0
```

```
$Ageonset_less_equal_12wk$`Sleep apnoea syndrome`$stats
                estimate        se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.05022831 1.4758796  0.002784054  0.90619060 0.04269232
OR_TRTvsCTRL   0.04367816 1.5070179  0.002277657  0.83760707 0.03775071
ARR_TRTvsCTRL -0.12500000 0.0584634 -0.239586152 -0.01041385 0.03250944


$Ageonset_less_equal_12wk$Tachycardia
$Ageonset_less_equal_12wk$Tachycardia$ntab
            CTRL TRT
n_all         32  72
n_event        5   6
n_event_pct   16   8

$Ageonset_less_equal_12wk$Tachycardia$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.53333333 0.56703419  0.1755247 1.62053759 0.2676069
OR_TRTvsCTRL   0.49090909 0.64719025  0.1380739 1.74538168 0.2716102
ARR_TRTvsCTRL -0.07291667 0.07197798 -0.2139909 0.06815758 0.3110404


$Ageonset_less_equal_12wk$Teething
$Ageonset_less_equal_12wk$Teething$ntab
            CTRL TRT
n_all         32  72
n_event        2  12
n_event_pct    6  17

$Ageonset_less_equal_12wk$Teething$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.6666667 0.73361737  0.63315858 11.2311692 0.18123028
OR_TRTvsCTRL  3.0000000 0.79582243  0.63054484 14.2733703 0.16744070
ARR_TRTvsCTRL 0.1041667 0.06131939 -0.01601712  0.2243505 0.08936519


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        7  23
n_event_pct   22  32

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats
               estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.4603175 0.37576125  0.69919566 3.0499719 0.3135995
OR_TRTvsCTRL  1.6763848 0.49673289  0.63321897 4.4380637 0.2983049
ARR_TRTvsCTRL 0.1006944 0.09143312 -0.07851119 0.2799001 0.2707702


$Ageonset_less_equal_12wk$`Viral infection`
$Ageonset_less_equal_12wk$`Viral infection`$ntab
            CTRL TRT
n_all         32  72
n_event        1   8
```

```
n_event_pct    3  11

$Ageonset_less_equal_12wk$`Viral infection`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.55555556 1.0391637  0.46384167 27.2549368 0.22219808
OR_TRTvsCTRL  3.87500000 1.0829973  0.46389829 32.3683563 0.21103014
ARR_TRTvsCTRL 0.07986111 0.0481434 -0.01449822  0.1742204 0.09715259


$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        7   7
n_event_pct   22  10

$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.4444444 0.49048486  0.1699480 1.16230191 0.09826501
OR_TRTvsCTRL   0.3846154 0.58403673  0.1224316 1.20825783 0.10182978
ARR_TRTvsCTRL -0.1215278 0.08099139 -0.2802680 0.03721242 0.13348429


$Ageonset_less_equal_12wk$Vomiting
$Ageonset_less_equal_12wk$Vomiting$ntab
            CTRL TRT
n_all         32  72
n_event        6  12
n_event_pct   19  17

$Ageonset_less_equal_12wk$Vomiting$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.45261585  0.3660835 2.1583148 0.7946884
OR_TRTvsCTRL   0.86666667 0.55238411  0.2935363 2.5588351 0.7955886
ARR_TRTvsCTRL -0.02083333 0.08179092 -0.1811406 0.1394739 0.7989436



$Agetrt_less_180d
$Agetrt_less_180d$`Acute respiratory failure`
$Agetrt_less_180d$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         16  49
n_event        4   7
n_event_pct   25  14

$Agetrt_less_180d$`Acute respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5714286 0.5567306  0.1918987 1.7015782 0.3148091
OR_TRTvsCTRL   0.5000000 0.7071068  0.1250488 1.9992191 0.3269587
ARR_TRTvsCTRL -0.1071429 0.1192380 -0.3408451 0.1265594 0.3688856


$Agetrt_less_180d$Apnoea
```

```
$Agetrt_less_180d$Apnoea$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$Apnoea$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718


$Agetrt_less_180d$Aspiration
$Agetrt_less_180d$Aspiration$ntab
            CTRL TRT
n_all         16  49
n_event        2   5
n_event_pct   12  10

$Agetrt_less_180d$Aspiration$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.81632653 0.78555193  0.1750656 3.8065096 0.7961432
OR_TRTvsCTRL   0.79545455 0.89115422  0.1386959 4.5621254 0.7973391
ARR_TRTvsCTRL -0.02295918 0.09330545 -0.2058345 0.1599161 0.8056321


$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$ntab
            CTRL TRT
n_all         16  49
n_event        5  13
n_event_pct   31  27

$Agetrt_less_180d$Atelectasis$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.84897959 0.4404712  0.3580696 2.0129225 0.7101213
OR_TRTvsCTRL   0.79444444 0.6289753  0.2315681 2.7255132 0.7144751
ARR_TRTvsCTRL -0.04719388 0.1319305 -0.3057730 0.2113852 0.7205547


$Agetrt_less_180d$`Bacterial tracheitis`
$Agetrt_less_180d$`Bacterial tracheitis`$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$`Bacterial tracheitis`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156
```

```
$Agetrt_less_180d$`Bronchial secretion retention`
$Agetrt_less_180d$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         16  49
n_event        3   3
n_event_pct   19   6

$Agetrt_less_180d$`Bronchial secretion retention`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3265306 0.7640409  0.07304174 1.4597440 0.1429525
OR_TRTvsCTRL   0.2826087 0.8748308  0.05087779 1.5697946 0.1485987
ARR_TRTvsCTRL -0.1262755 0.1034140 -0.32896332 0.0764123 0.2220605


$Agetrt_less_180d$Bronchiolitis
$Agetrt_less_180d$Bronchiolitis$ntab
            CTRL TRT
n_all         16  49
n_event        1   7
n_event_pct    6  14

$Agetrt_less_180d$Bronchiolitis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.28571429 1.02953824  0.30386271 17.1935865 0.4219975
OR_TRTvsCTRL  2.50000000 1.11055542  0.28355253 22.0417714 0.4093294
ARR_TRTvsCTRL 0.08035714 0.07849247 -0.07348528  0.2341996 0.3059505


$Agetrt_less_180d$Bronchitis
$Agetrt_less_180d$Bronchitis$ntab
            CTRL TRT
n_all         16  49
n_event        1   6
n_event_pct    6  12

$Agetrt_less_180d$Bronchitis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.95918367 1.04103722  0.25464940 15.0732758 0.5182683
OR_TRTvsCTRL  2.09302326 1.12097687  0.23259309 18.8343786 0.5099612
ARR_TRTvsCTRL 0.05994898 0.07651845 -0.09002443  0.2099224 0.4333583


$Agetrt_less_180d$`Bronchitis viral`
$Agetrt_less_180d$`Bronchitis viral`$ntab
            CTRL TRT
n_all         16  49
n_event        0   5
n_event_pct    0  10

$Agetrt_less_180d$`Bronchitis viral`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.7400000 1.45017056 0.21801390 64.1592119 0.36302969
OR_TRTvsCTRL  4.0786517 1.50495719 0.21354762 77.9001876 0.35025713
```

```
ARR_TRTvsCTRL 0.1020408 0.04324314 0.01728582  0.1867958 0.01828974


$Agetrt_less_180d$`Candida infection`
$Agetrt_less_180d$`Candida infection`$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$`Candida infection`$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$`Cardio-respiratory arrest`
$Agetrt_less_180d$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$`Cardio-respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156


$Agetrt_less_180d$Conjunctivitis
$Agetrt_less_180d$Conjunctivitis$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$Conjunctivitis$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718


$Agetrt_less_180d$Constipation
$Agetrt_less_180d$Constipation$ntab
            CTRL TRT
n_all         16  49
n_event        5  14
n_event_pct   31  29

$Agetrt_less_180d$Constipation$stats
                 estimate        se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.91428571 0.4341894  0.3903905 2.1412363 0.8364866
OR_TRTvsCTRL   0.88000000 0.6252272  0.2583975 2.9969332 0.8379948
ARR_TRTvsCTRL -0.02678571 0.1326373 -0.2867501 0.2331787 0.8399582


$Agetrt_less_180d$`Corona virus infection`
$Agetrt_less_180d$`Corona virus infection`$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$`Corona virus infection`$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$Cough
$Agetrt_less_180d$Cough$ntab
            CTRL TRT
n_all         16  49
n_event        3   6
n_event_pct   19  12

$Agetrt_less_180d$Cough$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 0.6458265  0.1841728 2.3157005 0.5094139
OR_TRTvsCTRL   0.60465116 0.7747121  0.1324551 2.7602032 0.5160753
ARR_TRTvsCTRL -0.06505102 0.1082333 -0.2771844 0.1470824 0.5478227


$Agetrt_less_180d$Cyanosis
$Agetrt_less_180d$Cyanosis$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$Cyanosis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156


$Agetrt_less_180d$`Decubitus ulcer`
$Agetrt_less_180d$`Decubitus ulcer`$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0
```

```
$Agetrt_less_180d$`Decubitus ulcer`$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$`Dermatitis contact`
$Agetrt_less_180d$`Dermatitis contact`$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$`Dermatitis contact`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156


$Agetrt_less_180d$Diarrhoea
$Agetrt_less_180d$Diarrhoea$ntab
            CTRL TRT
n_all         16  49
n_event        4   6
n_event_pct   25  12

$Agetrt_less_180d$Diarrhoea$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4897959 0.5777184  0.1578557 1.5197422 0.2166474
OR_TRTvsCTRL   0.4186047 0.7233642  0.1014087 1.7279565 0.2286442
ARR_TRTvsCTRL -0.1275510 0.1179479 -0.3587247 0.1036227 0.2795112


$Agetrt_less_180d$Dysphagia
$Agetrt_less_180d$Dysphagia$ntab
            CTRL TRT
n_all         16  49
n_event        2   5
n_event_pct   12  10

$Agetrt_less_180d$Dysphagia$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.81632653 0.78555193  0.1750656 3.8065096 0.7961432
OR_TRTvsCTRL   0.79545455 0.89115422  0.1386959 4.5621254 0.7973391
ARR_TRTvsCTRL -0.02295918 0.09330545 -0.2058345 0.1599161 0.8056321


$Agetrt_less_180d$Dyspnoea
$Agetrt_less_180d$Dyspnoea$ntab
            CTRL TRT
n_all         16  49
n_event        3   2
```

```
n_event_pct   19   4

$Agetrt_less_180d$Dyspnoea$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2176871 0.8662708  0.03985305 1.18905986 0.07839606
OR_TRTvsCTRL   0.1843972 0.9651596  0.02781051 1.22264269 0.07982660
ARR_TRTvsCTRL -0.1466837 0.1015897 -0.34579587 0.05242852 0.14877188


$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`
$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718


$Agetrt_less_180d$`Gastrooesophageal reflux disease`
$Agetrt_less_180d$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         16  49
n_event        4   3
n_event_pct   25   6

$Agetrt_less_180d$`Gastrooesophageal reflux disease`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2448980 0.7074074  0.06121233 0.97978639 0.04671987
OR_TRTvsCTRL   0.1956522 0.8297022  0.03848051 0.99478333 0.04926768
ARR_TRTvsCTRL -0.1887755 0.1135418 -0.41131327 0.03376224 0.09639079


$Agetrt_less_180d$Hypokalaemia
$Agetrt_less_180d$Hypokalaemia$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$Hypokalaemia$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$Hypoxia
$Agetrt_less_180d$Hypoxia$ntab
            CTRL TRT
```

```
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$Hypoxia$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718


$Agetrt_less_180d$Influenza
$Agetrt_less_180d$Influenza$ntab
            CTRL TRT
n_all         16  49
n_event        0   5
n_event_pct    0  10

$Agetrt_less_180d$Influenza$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.7400000 1.45017056 0.21801390 64.1592119 0.36302969
OR_TRTvsCTRL  4.0786517 1.50495719 0.21354762 77.9001876 0.35025713
ARR_TRTvsCTRL 0.1020408 0.04324314 0.01728582  0.1867958 0.01828974


$Agetrt_less_180d$`Nasal congestion`
$Agetrt_less_180d$`Nasal congestion`$ntab
            CTRL TRT
n_all         16  49
n_event        2   6
n_event_pct   12  12

$Agetrt_less_180d$`Nasal congestion`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.97959184 0.76404090  0.2191252 4.3792320 0.9784700
OR_TRTvsCTRL   0.97674419 0.87255433  0.1766287 5.4013264 0.9784858
ARR_TRTvsCTRL -0.00255102 0.09502053 -0.1887878 0.1836858 0.9785817


$Agetrt_less_180d$Nasopharyngitis
$Agetrt_less_180d$Nasopharyngitis$ntab
            CTRL TRT
n_all         16  49
n_event        1  13
n_event_pct    6  27

$Agetrt_less_180d$Nasopharyngitis$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.2448980 0.99700297 0.60147391 29.9583381 0.14704076
OR_TRTvsCTRL  5.4166667 1.08229734 0.64935016 45.1840621 0.11852059
ARR_TRTvsCTRL 0.2028061 0.08740734 0.03149088  0.3741214 0.02032783


$Agetrt_less_180d$`Oral candidiasis`
```

```
$Agetrt_less_180d$`Oral candidiasis`$ntab
            CTRL TRT
n_all         16  49
n_event        2   5
n_event_pct   12  10

$Agetrt_less_180d$`Oral candidiasis`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.81632653 0.78555193  0.1750656 3.8065096 0.7961432
OR_TRTvsCTRL   0.79545455 0.89115422  0.1386959 4.5621254 0.7973391
ARR_TRTvsCTRL -0.02295918 0.09330545 -0.2058345 0.1599161 0.8056321


$Agetrt_less_180d$`Oxygen saturation decreased`
$Agetrt_less_180d$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         16  49
n_event        6   6
n_event_pct   38  12

$Agetrt_less_180d$`Oxygen saturation decreased`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.3265306 0.5004250  0.12245073 0.870735851 0.02531497
OR_TRTvsCTRL   0.2325581 0.6757138  0.06185331 0.874379926 0.03087901
ARR_TRTvsCTRL -0.2525510 0.1297744 -0.50690422 0.001802178 0.05164549


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$ntab
            CTRL TRT
n_all         16  49
n_event        3  15
n_event_pct   19  31

$Agetrt_less_180d$Pneumonia$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.6326531 0.5631091  0.5414702 4.9228117 0.3840079
OR_TRTvsCTRL  1.9117647 0.7115721  0.4739616 7.7112663 0.3624549
ARR_TRTvsCTRL 0.1186224 0.1177133 -0.1120913 0.3493362 0.3135871


$Agetrt_less_180d$`Pneumonia aspiration`
$Agetrt_less_180d$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         16  49
n_event        2   6
n_event_pct   12  12

$Agetrt_less_180d$`Pneumonia aspiration`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.97959184 0.76404090  0.2191252 4.3792320 0.9784700
OR_TRTvsCTRL   0.97674419 0.87255433  0.1766287 5.4013264 0.9784858
ARR_TRTvsCTRL -0.00255102 0.09502053 -0.1887878 0.1836858 0.9785817
```

```
$Agetrt_less_180d$`Pneumonia bacterial`
$Agetrt_less_180d$`Pneumonia bacterial`$ntab
           CTRL TRT
n_all        16  49
n_event       2   2
n_event_pct  12   4

$Agetrt_less_180d$`Pneumonia bacterial`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 0.95764912  0.04997715 2.13341975 0.2425131
OR_TRTvsCTRL   0.29787234 1.04532539  0.03839261 2.31106820 0.2466285
ARR_TRTvsCTRL -0.08418367 0.08737805 -0.25544151 0.08707417 0.3353258


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$ntab
           CTRL TRT
n_all        16  49
n_event       8  28
n_event_pct  50  57

$Agetrt_less_180d$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14285714 0.2789375  0.6615458 1.9743492 0.6321418
OR_TRTvsCTRL  1.33333333 0.5773503  0.4300286 4.1340924 0.6182867
ARR_TRTvsCTRL 0.07142857 0.1436068 -0.2100356 0.3528928 0.6189142


$Agetrt_less_180d$Rash
$Agetrt_less_180d$Rash$ntab
           CTRL TRT
n_all        16  49
n_event       3   6
n_event_pct  19  12

$Agetrt_less_180d$Rash$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 0.6458265  0.1841728 2.3157005 0.5094139
OR_TRTvsCTRL   0.60465116 0.7747121  0.1324551 2.7602032 0.5160753
ARR_TRTvsCTRL -0.06505102 0.1082333 -0.2771844 0.1470824 0.5478227


$Agetrt_less_180d$`Respiratory arrest`
$Agetrt_less_180d$`Respiratory arrest`$ntab
           CTRL TRT
n_all        16  49
n_event       2   2
n_event_pct  12   4

$Agetrt_less_180d$`Respiratory arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 0.95764912  0.04997715 2.13341975 0.2425131
OR_TRTvsCTRL   0.29787234 1.04532539  0.03839261 2.31106820 0.2466285
```

```
ARR_TRTvsCTRL -0.08418367 0.08737805 -0.25544151 0.08707417 0.3353258


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$ntab
            CTRL TRT
n_all         16  49
n_event        4  14
n_event_pct   25  29

$Agetrt_less_180d$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14285714 0.4883855  0.4388109 2.9765038 0.7845351
OR_TRTvsCTRL  1.20000000 0.6582806  0.3302568 4.3602431 0.7818060
ARR_TRTvsCTRL 0.03571429 0.1260305 -0.2113009 0.2827295 0.7768870


$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$ntab
            CTRL TRT
n_all         16  49
n_event        9  12
n_event_pct   56  24

$Agetrt_less_180d$`Respiratory failure`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.4353741 0.3339705  0.22624889  0.83779705 0.01277829
OR_TRTvsCTRL   0.2522523 0.6035964  0.07727746  0.82341209 0.02249729
ARR_TRTvsCTRL -0.3176020 0.1384009 -0.58886274 -0.04634135 0.02174469


$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`
$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718


$Agetrt_less_180d$`Respiratory tract infection`
$Agetrt_less_180d$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         16  49
n_event        2   6
n_event_pct   12  12

$Agetrt_less_180d$`Respiratory tract infection`$stats
                estimate         se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.97959184 0.76404090  0.2191252 4.3792320 0.9784700
OR_TRTvsCTRL   0.97674419 0.87255433  0.1766287 5.4013264 0.9784858
ARR_TRTvsCTRL -0.00255102 0.09502053 -0.1887878 0.1836858 0.9785817


$Agetrt_less_180d$Rhinorrhoea
$Agetrt_less_180d$Rhinorrhoea$ntab
            CTRL TRT
n_all         16  49
n_event        1   5
n_event_pct    6  10

$Agetrt_less_180d$Rhinorrhoea$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.63265306 1.05692565  0.2057014 12.9583783 0.6427882
OR_TRTvsCTRL  1.70454545 1.13551483  0.1841012 15.7819465 0.6386026
ARR_TRTvsCTRL 0.03954082 0.07437794 -0.1062373  0.1853189 0.5949891


$Agetrt_less_180d$`Rhinovirus infection`
$Agetrt_less_180d$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         16  49
n_event        3   4
n_event_pct   19   8

$Agetrt_less_180d$`Rhinovirus infection`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4353741 0.7074074  0.10882193 1.7418425 0.2397992
OR_TRTvsCTRL   0.3851852 0.8261226  0.07629089 1.9447620 0.2481601
ARR_TRTvsCTRL -0.1058673 0.1051259 -0.31191036 0.1001757 0.3139094


$Agetrt_less_180d$`Sleep apnoea syndrome`
$Agetrt_less_180d$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all         16  49
n_event        3   0
n_event_pct   19   0

$Agetrt_less_180d$`Sleep apnoea syndrome`$stats
                estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.04857143 1.48556075  0.002641613 0.893084360 0.04174237
OR_TRTvsCTRL   0.03896104 1.54272174  0.001894364 0.801304643 0.03541767
ARR_TRTvsCTRL -0.18750000 0.09757809 -0.378749549 0.003749549 0.05466394


$Agetrt_less_180d$Tachycardia
$Agetrt_less_180d$Tachycardia$ntab
            CTRL TRT
n_all         16  49
n_event        3   4
n_event_pct   19   8
```

```
$Agetrt_less_180d$Tachycardia$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4353741 0.7074074  0.10882193 1.7418425 0.2397992
OR_TRTvsCTRL   0.3851852 0.8261226  0.07629089 1.9447620 0.2481601
ARR_TRTvsCTRL -0.1058673 0.1051259 -0.31191036 0.1001757 0.3139094


$Agetrt_less_180d$Teething
$Agetrt_less_180d$Teething$ntab
            CTRL TRT
n_all         16  49
n_event        1   9
n_event_pct    6  18

$Agetrt_less_180d$Teething$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.9387755 1.01400343  0.40275889 21.4431060 0.2877339
OR_TRTvsCTRL  3.3750000 1.09671226  0.39332415 28.9598924 0.2673746
ARR_TRTvsCTRL 0.1211735 0.08198816 -0.03952038  0.2818673 0.1394242


$Agetrt_less_180d$`Upper respiratory tract congestion`
$Agetrt_less_180d$`Upper respiratory tract congestion`$ntab
            CTRL TRT
n_all         16  49
n_event        0   5
n_event_pct    0  10

$Agetrt_less_180d$`Upper respiratory tract congestion`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.7400000 1.45017056 0.21801390 64.1592119 0.36302969
OR_TRTvsCTRL  4.0786517 1.50495719 0.21354762 77.9001876 0.35025713
ARR_TRTvsCTRL 0.1020408 0.04324314 0.01728582  0.1867958 0.01828974


$Agetrt_less_180d$`Upper respiratory tract infection`
$Agetrt_less_180d$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         16  49
n_event        4  13
n_event_pct   25  27

$Agetrt_less_180d$`Upper respiratory tract infection`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.06122449 0.4939787  0.4030249 2.794362 0.9042491
OR_TRTvsCTRL  1.08333333 0.6618415  0.2960749 3.963899 0.9037390
ARR_TRTvsCTRL 0.01530612 0.1252864 -0.2302507 0.260863 0.9027651


$Agetrt_less_180d$`Viral infection`
$Agetrt_less_180d$`Viral infection`$ntab
            CTRL TRT
n_all         16  49
n_event        0   6
```

```
n_event_pct    0  12

$Agetrt_less_180d$`Viral infection`$stats
              estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.420000 1.44049388 0.26258605 74.3999913 0.30221848
OR_TRTvsCTRL  4.931034 1.49580771 0.26284771 92.5064202 0.28611617
ARR_TRTvsCTRL 0.122449 0.04682909 0.03066565  0.2142323 0.00892782


$Agetrt_less_180d$`Viral upper respiratory tract infection`
$Agetrt_less_180d$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         16  49
n_event        2   5
n_event_pct   12  10

$Agetrt_less_180d$`Viral upper respiratory tract infection`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.81632653 0.78555193  0.1750656 3.8065096 0.7961432
OR_TRTvsCTRL   0.79545455 0.89115422  0.1386959 4.5621254 0.7973391
ARR_TRTvsCTRL -0.02295918 0.09330545 -0.2058345 0.1599161 0.8056321


$Agetrt_less_180d$Vomiting
$Agetrt_less_180d$Vomiting$ntab
            CTRL TRT
n_all         16  49
n_event        3   8
n_event_pct   19  16

$Agetrt_less_180d$Vomiting$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.87074830 0.6127195  0.2620263 2.8936127 0.8212932
OR_TRTvsCTRL   0.84552846 0.7480954  0.1951409 3.6636008 0.8225284
ARR_TRTvsCTRL -0.02423469 0.1109479 -0.2416886 0.1932192 0.8270917


$Agetrt_less_180d$`Weight gain poor`
$Agetrt_less_180d$`Weight gain poor`$ntab
            CTRL TRT
n_all         16  49
n_event        2   5
n_event_pct   12  10

$Agetrt_less_180d$`Weight gain poor`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.81632653 0.78555193  0.1750656 3.8065096 0.7961432
OR_TRTvsCTRL   0.79545455 0.89115422  0.1386959 4.5621254 0.7973391
ARR_TRTvsCTRL -0.02295918 0.09330545 -0.2058345 0.1599161 0.8056321



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Acute respiratory failure`
```

```
$Agetrt_greater_equal_180d$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         25  31
n_event        6   4
n_event_pct   24  13

$Agetrt_greater_equal_180d$`Acute respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5376344 0.5868634  0.1701955 1.69834553 0.2903080
OR_TRTvsCTRL   0.4691358 0.7115724  0.1163073 1.89230050 0.2874879
ARR_TRTvsCTRL -0.1109677 0.1045048 -0.3157934 0.09385793 0.2883068


$Agetrt_greater_equal_180d$Atelectasis
$Agetrt_greater_equal_180d$Atelectasis$ntab
            CTRL TRT
n_all         25  31
n_event        7   5
n_event_pct   28  16

$Agetrt_greater_equal_180d$Atelectasis$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5760369 0.5201914  0.2078081 1.59675392 0.2889866
OR_TRTvsCTRL   0.4945055 0.6609646  0.1353808 1.80628066 0.2866913
ARR_TRTvsCTRL -0.1187097 0.1114797 -0.3372060 0.09978661 0.2869419


$Agetrt_greater_equal_180d$Bradycardia
$Agetrt_greater_equal_180d$Bradycardia$ntab
            CTRL TRT
n_all         25  31
n_event        3   2
n_event_pct   12   6

$Agetrt_greater_equal_180d$Bradycardia$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.53763441 0.87239628  0.09725277 2.97215952 0.4768692
OR_TRTvsCTRL   0.50574713 0.95565194  0.07771073 3.29143917 0.4756265
ARR_TRTvsCTRL -0.05548387 0.07855506 -0.20944895 0.09848121 0.4799981


$Agetrt_greater_equal_180d$`Bronchial secretion retention`
$Agetrt_greater_equal_180d$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         25  31
n_event        4   1
n_event_pct   16   3

$Agetrt_greater_equal_180d$`Bronchial secretion retention`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.2016129 1.08523819  0.02403045 1.69151070 0.1400443
OR_TRTvsCTRL   0.1750000 1.15366910  0.01824035 1.67897010 0.1308381
ARR_TRTvsCTRL -0.1277419 0.07989378 -0.28433086 0.02884699 0.1098434
```

```
$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`
$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         25  31
n_event        3   4
n_event_pct   12  13

$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.075268817 0.71489529  0.2648482 4.3655304 0.9191438
OR_TRTvsCTRL  1.086419753 0.81598095  0.2194994 5.3772707 0.9190897
ARR_TRTvsCTRL 0.009032258 0.08859603 -0.1646128 0.1826773 0.9187973


$Agetrt_greater_equal_180d$Constipation
$Agetrt_greater_equal_180d$Constipation$ntab
            CTRL TRT
n_all         25  31
n_event        4  14
n_event_pct   16  45

$Agetrt_greater_equal_180d$Constipation$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.8225806 0.4991698 1.06109004  7.5082803 0.03763991
OR_TRTvsCTRL  4.3235294 0.6541186 1.19964197 15.5820712 0.02520564
ARR_TRTvsCTRL 0.2916129 0.1156070 0.06502725  0.5181986 0.01165408


$Agetrt_greater_equal_180d$Cough
$Agetrt_greater_equal_180d$Cough$ntab
            CTRL TRT
n_all         25  31
n_event        5   3
n_event_pct   20  10

$Agetrt_greater_equal_180d$Cough$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4838710 0.67902523  0.12786222 1.83112036 0.2850305
OR_TRTvsCTRL   0.4285714 0.78679579  0.09168566 2.00329546 0.2815264
ARR_TRTvsCTRL -0.1032258 0.09601897 -0.29141954 0.08496793 0.2823495


$Agetrt_greater_equal_180d$`Dermatitis diaper`
$Agetrt_greater_equal_180d$`Dermatitis diaper`$ntab
            CTRL TRT
n_all         25  31
n_event        3   3
n_event_pct   12  10

$Agetrt_greater_equal_180d$`Dermatitis diaper`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80645161 0.77097899  0.1779589 3.6545745 0.7802366
OR_TRTvsCTRL   0.78571429 0.86477482  0.1442670 4.2791973 0.7803425
```

```
ARR_TRTvsCTRL -0.02322581 0.08392642 -0.1877186 0.1412669 0.7819797


$Agetrt_greater_equal_180d$Diarrhoea
$Agetrt_greater_equal_180d$Diarrhoea$ntab
            CTRL TRT
n_all         25  31
n_event        3   5
n_event_pct   12  16

$Agetrt_greater_equal_180d$Diarrhoea$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.34408602 0.67902523  0.3551728 5.0864455 0.6632009
OR_TRTvsCTRL  1.41025641 0.78565222  0.3023777 6.5772821 0.6617038
ARR_TRTvsCTRL 0.04129032 0.09267003 -0.1403396 0.2229202 0.6559130


$Agetrt_greater_equal_180d$Dysphagia
$Agetrt_greater_equal_180d$Dysphagia$ntab
            CTRL TRT
n_all         25  31
n_event        7   4
n_event_pct   28  13

$Agetrt_greater_equal_180d$Dysphagia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4608295 0.5662147  0.15190688 1.39798685 0.1712317
OR_TRTvsCTRL   0.3809524 0.6967422  0.09723052 1.49258390 0.1660117
ARR_TRTvsCTRL -0.1509677 0.1081169 -0.36287290 0.06093741 0.1626126


$Agetrt_greater_equal_180d$Dyspnoea
$Agetrt_greater_equal_180d$Dyspnoea$ntab
            CTRL TRT
n_all         25  31
n_event        3   5
n_event_pct   12  16

$Agetrt_greater_equal_180d$Dyspnoea$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.34408602 0.67902523  0.3551728 5.0864455 0.6632009
OR_TRTvsCTRL  1.41025641 0.78565222  0.3023777 6.5772821 0.6617038
ARR_TRTvsCTRL 0.04129032 0.09267003 -0.1403396 0.2229202 0.6559130


$Agetrt_greater_equal_180d$`Gastrooesophageal reflux disease`
$Agetrt_greater_equal_180d$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         25  31
n_event        4   7
n_event_pct   16  23

$Agetrt_greater_equal_180d$`Gastrooesophageal reflux disease`$stats
                estimate        se     lo95ci   hi95ci    pvalue
```

```
RR_TRTvsCTRL  1.41129032 0.5662147  0.4652148 4.281335 0.5428995
OR_TRTvsCTRL  1.53125000 0.6943651  0.3926463 5.971600 0.5394588
ARR_TRTvsCTRL 0.06580645 0.1049537 -0.1398991 0.271512 0.5306564


$Agetrt_greater_equal_180d$Hypoxia
$Agetrt_greater_equal_180d$Hypoxia$ntab
            CTRL TRT
n_all         25  31
n_event        0   4
n_event_pct    0  13

$Agetrt_greater_equal_180d$Hypoxia$stats
               estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  7.3125000 1.4671437 0.41231666 129.6883230 0.17506917
OR_TRTvsCTRL  8.3454545 1.5158501 0.42771654 162.8335705 0.16160680
ARR_TRTvsCTRL 0.1290323 0.0602101 0.01102263   0.2470419 0.03211041


$Agetrt_greater_equal_180d$`Lower respiratory tract infection`
$Agetrt_greater_equal_180d$`Lower respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        1   4
n_event_pct    4  13

$Agetrt_greater_equal_180d$`Lower respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.22580645 1.08523819  0.38448720 27.0641711 0.2805011
OR_TRTvsCTRL  3.55555556 1.15269411  0.37130643 34.0472838 0.2711251
ARR_TRTvsCTRL 0.08903226 0.07184188 -0.05177524  0.2298398 0.2152416


$Agetrt_greater_equal_180d$`Nasal congestion`
$Agetrt_greater_equal_180d$`Nasal congestion`$ntab
            CTRL TRT
n_all         25  31
n_event        3   2
n_event_pct   12   6

$Agetrt_greater_equal_180d$`Nasal congestion`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.53763441 0.87239628  0.09725277 2.97215952 0.4768692
OR_TRTvsCTRL   0.50574713 0.95565194  0.07771073 3.29143917 0.4756265
ARR_TRTvsCTRL -0.05548387 0.07855506 -0.20944895 0.09848121 0.4799981


$Agetrt_greater_equal_180d$Nasopharyngitis
$Agetrt_greater_equal_180d$Nasopharyngitis$ntab
            CTRL TRT
n_all         25  31
n_event        3   2
n_event_pct   12   6
```

```
$Agetrt_greater_equal_180d$Nasopharyngitis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.53763441 0.87239628  0.09725277 2.97215952 0.4768692
OR_TRTvsCTRL   0.50574713 0.95565194  0.07771073 3.29143917 0.4756265
ARR_TRTvsCTRL -0.05548387 0.07855506 -0.20944895 0.09848121 0.4799981


$Agetrt_greater_equal_180d$`Oxygen saturation decreased`
$Agetrt_greater_equal_180d$`Oxygen saturation decreased`$ntab
           CTRL TRT
n_all        25  31
n_event       4   4
n_event_pct  16  13

$Agetrt_greater_equal_180d$`Oxygen saturation decreased`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80645161 0.65401983  0.2238080 2.9059023 0.7422264
OR_TRTvsCTRL   0.77777778 0.76462807  0.1737813 3.4810329 0.7424011
ARR_TRTvsCTRL -0.03096774 0.09487495 -0.2169192 0.1549837 0.7441173


$Agetrt_greater_equal_180d$Pneumonia
$Agetrt_greater_equal_180d$Pneumonia$ntab
           CTRL TRT
n_all        25  31
n_event       4   8
n_event_pct  16  26

$Agetrt_greater_equal_180d$Pneumonia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.61290323 0.5502199  0.5486057 4.7419431 0.3849518
OR_TRTvsCTRL  1.82608696 0.6827132  0.4790655 6.9606209 0.3777591
ARR_TRTvsCTRL 0.09806452 0.1074819 -0.1125962 0.3087252 0.3615679


$Agetrt_greater_equal_180d$`Pneumonia aspiration`
$Agetrt_greater_equal_180d$`Pneumonia aspiration`$ntab
           CTRL TRT
n_all        25  31
n_event       5   3
n_event_pct  20  10

$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4838710 0.67902523  0.12786222 1.83112036 0.2850305
OR_TRTvsCTRL   0.4285714 0.78679579  0.09168566 2.00329546 0.2815264
ARR_TRTvsCTRL -0.1032258 0.09601897 -0.29141954 0.08496793 0.2823495


$Agetrt_greater_equal_180d$`Pneumonia viral`
$Agetrt_greater_equal_180d$`Pneumonia viral`$ntab
           CTRL TRT
n_all        25  31
n_event       2   4
```

```
n_event_pct    8  13

$Agetrt_greater_equal_180d$`Pneumonia viral`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.61290323 0.82325083  0.3212595  8.0976815 0.5614639
OR_TRTvsCTRL  1.70370370 0.91132612  0.2855432 10.1652080 0.5587848
ARR_TRTvsCTRL 0.04903226 0.08105095 -0.1098247  0.2078892 0.5452082


$Agetrt_greater_equal_180d$Pyrexia
$Agetrt_greater_equal_180d$Pyrexia$ntab
            CTRL TRT
n_all         25  31
n_event       16  17
n_event_pct   64  55

$Agetrt_greater_equal_180d$Pyrexia$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8568548 0.2215073  0.5550856 1.3226793 0.4855310
OR_TRTvsCTRL   0.6830357 0.5512379  0.2318616 2.0121389 0.4892205
ARR_TRTvsCTRL -0.0916129 0.1311678 -0.3486971 0.1654712 0.4849017


$Agetrt_greater_equal_180d$`Respiratory distress`
$Agetrt_greater_equal_180d$`Respiratory distress`$ntab
            CTRL TRT
n_all         25  31
n_event        8   7
n_event_pct   32  23

$Agetrt_greater_equal_180d$`Respiratory distress`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.70564516 0.4422658  0.2965712 1.6789731 0.4305152
OR_TRTvsCTRL   0.61979167 0.6069163  0.1886417 2.0363564 0.4305793
ARR_TRTvsCTRL -0.09419355 0.1197635 -0.3289256 0.1405385 0.4315766


$Agetrt_greater_equal_180d$`Respiratory failure`
$Agetrt_greater_equal_180d$`Respiratory failure`$ntab
            CTRL TRT
n_all         25  31
n_event        7   8
n_event_pct   28  26

$Agetrt_greater_equal_180d$`Respiratory failure`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92165899 0.4422658  0.3873583 2.1929445 0.8536533
OR_TRTvsCTRL   0.89440994 0.6057152  0.2728669 2.9317192 0.8538328
ARR_TRTvsCTRL -0.02193548 0.1193330 -0.2558238 0.2119529 0.8541567


$Agetrt_greater_equal_180d$`Rhinovirus infection`
$Agetrt_greater_equal_180d$`Rhinovirus infection`$ntab
            CTRL TRT
```

```
n_all         25  31
n_event        3   6
n_event_pct   12  19

$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.61290323 0.6540198  0.4476160 5.8118045 0.4648284
OR_TRTvsCTRL  1.76000000 0.7651500  0.3928401 7.8851424 0.4600118
ARR_TRTvsCTRL 0.07354839 0.0962241 -0.1150474 0.2621442 0.4446618


$Agetrt_greater_equal_180d$Teething
$Agetrt_greater_equal_180d$Teething$ntab
            CTRL TRT
n_all         25  31
n_event        2   5
n_event_pct    8  16

$Agetrt_greater_equal_180d$Teething$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.01612903 0.79230167  0.42668750  9.5263542 0.3761618
OR_TRTvsCTRL  2.21153846 0.88427360  0.39084040 12.5138098 0.3694203
ARR_TRTvsCTRL 0.08129032 0.08548529 -0.08625776  0.2488384 0.3416411


$Agetrt_greater_equal_180d$`Upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        5  11
n_event_pct   20  35

$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.7741935 0.4676014  0.70954183 4.4363315 0.2201450
OR_TRTvsCTRL  2.2000000 0.6252272  0.64599372 7.4923329 0.2072824
ARR_TRTvsCTRL 0.1548387 0.1174086 -0.07527793 0.3849553 0.1872353


$Agetrt_greater_equal_180d$`Urinary tract infection`
$Agetrt_greater_equal_180d$`Urinary tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        0   4
n_event_pct    0  13

$Agetrt_greater_equal_180d$`Urinary tract infection`$stats
               estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  7.3125000 1.4671437 0.41231666 129.6883230 0.17506917
OR_TRTvsCTRL  8.3454545 1.5158501 0.42771654 162.8335705 0.16160680
ARR_TRTvsCTRL 0.1290323 0.0602101 0.01102263   0.2470419 0.03211041


$Agetrt_greater_equal_180d$`Viral infection`
```

```
$Agetrt_greater_equal_180d$`Viral infection`$ntab
            CTRL TRT
n_all         25  31
n_event        3   2
n_event_pct   12   6

$Agetrt_greater_equal_180d$`Viral infection`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.53763441 0.87239628  0.09725277 2.97215952 0.4768692
OR_TRTvsCTRL   0.50574713 0.95565194  0.07771073 3.29143917 0.4756265
ARR_TRTvsCTRL -0.05548387 0.07855506 -0.20944895 0.09848121 0.4799981


$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        5   3
n_event_pct   20  10

$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4838710 0.67902523  0.12786222 1.83112036 0.2850305
OR_TRTvsCTRL   0.4285714 0.78679579  0.09168566 2.00329546 0.2815264
ARR_TRTvsCTRL -0.1032258 0.09601897 -0.29141954 0.08496793 0.2823495


$Agetrt_greater_equal_180d$Vomiting
$Agetrt_greater_equal_180d$Vomiting$ntab
            CTRL TRT
n_all         25  31
n_event        5   6
n_event_pct   20  19

$Agetrt_greater_equal_180d$Vomiting$stats
                  estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.967741935 0.5425943  0.3341200 2.802959 0.9518119
OR_TRTvsCTRL   0.960000000 0.6757712  0.2553017 3.609846 0.9518307
ARR_TRTvsCTRL -0.006451613 0.1069349 -0.2160402 0.203137 0.9518911



$Gender_Male
$Gender_Male$`Acute respiratory failure`
$Gender_Male$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         17  37
n_event        4   5
n_event_pct   24  14

$Gender_Male$`Acute respiratory failure`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5743243 0.6034480  0.1759954 1.8741875 0.3581022
OR_TRTvsCTRL   0.5078125 0.7471098  0.1174255 2.1960611 0.3643966
```

```
ARR_TRTvsCTRL -0.1001590 0.1172302 -0.3299259 0.1296079 0.3928951


$Gender_Male$Aspiration
$Gender_Male$Aspiration$ntab
            CTRL TRT
n_all         17  37
n_event        3   2
n_event_pct   18   5

$Gender_Male$Aspiration$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3063063 0.8645709  0.05626417 1.66755432 0.1711540
OR_TRTvsCTRL   0.2666667 0.9660918  0.04014486 1.77136292 0.1712660
ARR_TRTvsCTRL -0.1224165 0.0996529 -0.31773262 0.07289956 0.2192859


$Gender_Male$Atelectasis
$Gender_Male$Atelectasis$ntab
            CTRL TRT
n_all         17  37
n_event        5   5
n_event_pct   29  14

$Gender_Male$Atelectasis$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.5604904  0.15316408 1.37828001 0.1652762
OR_TRTvsCTRL   0.3750000 0.7173446  0.09192347 1.52980520 0.1715296
ARR_TRTvsCTRL -0.1589825 0.1239808 -0.40198046 0.08401543 0.1997320


$Gender_Male$`Bacterial tracheitis`
$Gender_Male$`Bacterial tracheitis`$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$`Bacterial tracheitis`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$`Bronchial secretion retention`
$Gender_Male$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         17  37
n_event        4   4
n_event_pct   24  11

$Gender_Male$`Bronchial secretion retention`$stats
                estimate        se      lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.4594595 0.6435444  0.13015510 1.62193414 0.2268663
OR_TRTvsCTRL   0.3939394 0.7792471  0.08553287 1.81436969 0.2319076
ARR_TRTvsCTRL -0.1271860 0.1148483 -0.35228453 0.09791251 0.2681097


$Gender_Male$`Cardio-respiratory arrest`
$Gender_Male$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         17  37
n_event        3   2
n_event_pct   18   5

$Gender_Male$`Cardio-respiratory arrest`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3063063 0.8645709  0.05626417 1.66755432 0.1711540
OR_TRTvsCTRL   0.2666667 0.9660918  0.04014486 1.77136292 0.1712660
ARR_TRTvsCTRL -0.1224165 0.0996529 -0.31773262 0.07289956 0.2192859


$Gender_Male$Constipation
$Gender_Male$Constipation$ntab
            CTRL TRT
n_all         17  37
n_event        2  11
n_event_pct   12  30

$Gender_Male$Constipation$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.5270270 0.7106747  0.62759935 10.1750673 0.19207832
OR_TRTvsCTRL  3.1730769 0.8342885  0.61849037 16.2790200 0.16634140
ARR_TRTvsCTRL 0.1796502 0.1084090 -0.03282747  0.3921279 0.09748862


$Gender_Male$Cough
$Gender_Male$Cough$ntab
            CTRL TRT
n_all         17  37
n_event        2   4
n_event_pct   12  11

$Gender_Male$Cough$stats
                   estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.918918919 0.81495365  0.1860319 4.5390712 0.9173620
OR_TRTvsCTRL   0.909090909 0.92030957  0.1497057 5.5204723 0.9175160
ARR_TRTvsCTRL -0.009538951 0.09333925 -0.1924805 0.1734026 0.9186007


$Gender_Male$Cyanosis
$Gender_Male$Cyanosis$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0
```

```
$Gender_Male$Cyanosis$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$`Decubitus ulcer`
$Gender_Male$`Decubitus ulcer`$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$`Decubitus ulcer`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$`Dermatitis contact`
$Gender_Male$`Dermatitis contact`$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$`Dermatitis contact`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$Diarrhoea
$Gender_Male$Diarrhoea$ntab
            CTRL TRT
n_all         17  37
n_event        3   4
n_event_pct   18  11

$Gender_Male$Diarrhoea$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.61261261 0.7053246  0.1537491 2.4409524 0.4872136
OR_TRTvsCTRL   0.56565657 0.8276865  0.1116927 2.8647113 0.4912095
ARR_TRTvsCTRL -0.06836248 0.1056159 -0.2753658 0.1386408 0.5174542


$Gender_Male$Dysphagia
$Gender_Male$Dysphagia$ntab
            CTRL TRT
n_all         17  37
n_event        4   4
```

```
n_event_pct   24  11

$Gender_Male$Dysphagia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.6435444  0.13015510 1.62193414 0.2268663
OR_TRTvsCTRL   0.3939394 0.7792471  0.08553287 1.81436969 0.2319076
ARR_TRTvsCTRL -0.1271860 0.1148483 -0.35228453 0.09791251 0.2681097


$Gender_Male$Dyspnoea
$Gender_Male$Dyspnoea$ntab
            CTRL TRT
n_all         17  37
n_event        2   3
n_event_pct   12   8

$Gender_Male$Dyspnoea$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.86457086  0.1265944 3.7519972 0.6667969
OR_TRTvsCTRL   0.66176471 0.96406004  0.1000217 4.3783754 0.6684793
ARR_TRTvsCTRL -0.03656598 0.09011076 -0.2131798 0.1400479 0.6848975


$Gender_Male$Eczema
$Gender_Male$Eczema$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$Eczema$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$Erythema
$Gender_Male$Erythema$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$Erythema$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$`Failure to thrive`
$Gender_Male$`Failure to thrive`$ntab
            CTRL TRT
```

```
n_all         17  37
n_event        2   2
n_event_pct   12   5

$Gender_Male$`Failure to thrive`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.95611163  0.07053481 2.9928909 0.4159867
OR_TRTvsCTRL   0.4285714 1.04653624  0.05510740 3.3330089 0.4181580
ARR_TRTvsCTRL -0.0635930 0.08653439 -0.23319729 0.1060113 0.4624083


$Gender_Male$`Feeding tube complication`
$Gender_Male$`Feeding tube complication`$ntab
            CTRL TRT
n_all         17  37
n_event        2   2
n_event_pct   12   5

$Gender_Male$`Feeding tube complication`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.95611163  0.07053481 2.9928909 0.4159867
OR_TRTvsCTRL   0.4285714 1.04653624  0.05510740 3.3330089 0.4181580
ARR_TRTvsCTRL -0.0635930 0.08653439 -0.23319729 0.1060113 0.4624083


$Gender_Male$`Gastrooesophageal reflux disease`
$Gender_Male$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         17  37
n_event        2   3
n_event_pct   12   8

$Gender_Male$`Gastrooesophageal reflux disease`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.86457086  0.1265944 3.7519972 0.6667969
OR_TRTvsCTRL   0.66176471 0.96406004  0.1000217 4.3783754 0.6684793
ARR_TRTvsCTRL -0.03656598 0.09011076 -0.2131798 0.1400479 0.6848975


$Gender_Male$Hypersensitivity
$Gender_Male$Hypersensitivity$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$Hypersensitivity$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$Hypokalaemia
```

```
$Gender_Male$Hypokalaemia$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$Hypokalaemia$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$Hypoxia
$Gender_Male$Hypoxia$ntab
            CTRL TRT
n_all         17  37
n_event        2   4
n_event_pct   12  11

$Gender_Male$Hypoxia$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.918918919 0.81495365  0.1860319 4.5390712 0.9173620
OR_TRTvsCTRL   0.909090909 0.92030957  0.1497057 5.5204723 0.9175160
ARR_TRTvsCTRL -0.009538951 0.09333925 -0.1924805 0.1734026 0.9186007


$Gender_Male$`Joint contracture`
$Gender_Male$`Joint contracture`$ntab
            CTRL TRT
n_all         17  37
n_event        2   2
n_event_pct   12   5

$Gender_Male$`Joint contracture`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.95611163  0.07053481 2.9928909 0.4159867
OR_TRTvsCTRL   0.4285714 1.04653624  0.05510740 3.3330089 0.4181580
ARR_TRTvsCTRL -0.0635930 0.08653439 -0.23319729 0.1060113 0.4624083


$Gender_Male$`Nasal congestion`
$Gender_Male$`Nasal congestion`$ntab
            CTRL TRT
n_all         17  37
n_event        3   3
n_event_pct   18   8

$Gender_Male$`Nasal congestion`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.45945946 0.7621129  0.10316574 2.0462510 0.3075111
OR_TRTvsCTRL   0.41176471 0.8760748  0.07394911 2.2927955 0.3111477
ARR_TRTvsCTRL -0.09538951 0.1027738 -0.29682241 0.1060434 0.3533296
```

```
$Gender_Male$Nasopharyngitis
$Gender_Male$Nasopharyngitis$ntab
            CTRL TRT
n_all         17  37
n_event        2   9
n_event_pct   12  24

$Gender_Male$Nasopharyngitis$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.0675676 0.7247486  0.49951964  8.557893 0.3162272
OR_TRTvsCTRL  2.4107143 0.8446846  0.46041441 12.622418 0.2975425
ARR_TRTvsCTRL 0.1255962 0.1052676 -0.08072459  0.331917 0.2328251


$Gender_Male$Oedema
$Gender_Male$Oedema$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$Oedema$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$`Oral candidiasis`
$Gender_Male$`Oral candidiasis`$ntab
            CTRL TRT
n_all         17  37
n_event        2   3
n_event_pct   12   8

$Gender_Male$`Oral candidiasis`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.86457086  0.1265944 3.7519972 0.6667969
OR_TRTvsCTRL   0.66176471 0.96406004  0.1000217 4.3783754 0.6684793
ARR_TRTvsCTRL -0.03656598 0.09011076 -0.2131798 0.1400479 0.6848975


$Gender_Male$`Oxygen saturation decreased`
$Gender_Male$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         17  37
n_event        5   5
n_event_pct   29  14

$Gender_Male$`Oxygen saturation decreased`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.5604904  0.15316408 1.37828001 0.1652762
OR_TRTvsCTRL   0.3750000 0.7173446  0.09192347 1.52980520 0.1715296
```

```
ARR_TRTvsCTRL -0.1589825 0.1239808 -0.40198046 0.08401543 0.1997320


$Gender_Male$Pneumonia
$Gender_Male$Pneumonia$ntab
            CTRL TRT
n_all         17  37
n_event        3   8
n_event_pct   18  22

$Gender_Male$Pneumonia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.22522523 0.6103137  0.3704384 4.0524332 0.7392701
OR_TRTvsCTRL  1.28735632 0.7511622  0.2953305 5.6116322 0.7366698
ARR_TRTvsCTRL 0.03974563 0.1145815 -0.1848301 0.2643213 0.7286842


$Gender_Male$`Pneumonia aspiration`
$Gender_Male$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         17  37
n_event        3   2
n_event_pct   18   5

$Gender_Male$`Pneumonia aspiration`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3063063 0.8645709  0.05626417 1.66755432 0.1711540
OR_TRTvsCTRL   0.2666667 0.9660918  0.04014486 1.77136292 0.1712660
ARR_TRTvsCTRL -0.1224165 0.0996529 -0.31773262 0.07289956 0.2192859


$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$ntab
            CTRL TRT
n_all         17  37
n_event        9  20
n_event_pct   53  54

$Gender_Male$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.02102102 0.2743366  0.5963744 1.7480361 0.9395538
OR_TRTvsCTRL  1.04575163 0.5873114  0.3307564 3.3063505 0.9392833
ARR_TRTvsCTRL 0.01112878 0.1461757 -0.2753703 0.2976279 0.9393134


$Gender_Male$Rash
$Gender_Male$Rash$ntab
            CTRL TRT
n_all         17  37
n_event        3   4
n_event_pct   18  11

$Gender_Male$Rash$stats
                estimate        se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.61261261 0.7053246  0.1537491 2.4409524 0.4872136
OR_TRTvsCTRL   0.56565657 0.8276865  0.1116927 2.8647113 0.4912095
ARR_TRTvsCTRL -0.06836248 0.1056159 -0.2753658 0.1386408 0.5174542


$Gender_Male$`Respiratory arrest`
$Gender_Male$`Respiratory arrest`$ntab
            CTRL TRT
n_all         17  37
n_event        2   3
n_event_pct   12   8

$Gender_Male$`Respiratory arrest`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.86457086  0.1265944 3.7519972 0.6667969
OR_TRTvsCTRL   0.66176471 0.96406004  0.1000217 4.3783754 0.6684793
ARR_TRTvsCTRL -0.03656598 0.09011076 -0.2131798 0.1400479 0.6848975


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$ntab
            CTRL TRT
n_all         17  37
n_event        5  10
n_event_pct   29  27

$Gender_Male$`Respiratory distress`$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.91891892 0.4627628  0.3709990 2.276049 0.8550154
OR_TRTvsCTRL   0.88888889 0.6483598  0.2494380 3.167614 0.8558471
ARR_TRTvsCTRL -0.02384738 0.1324495 -0.2834437 0.235749 0.8571143


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$ntab
            CTRL TRT
n_all         17  37
n_event        7  11
n_event_pct   41  30

$Gender_Male$`Respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7220077 0.3845981  0.3397593 1.5343072 0.3970460
OR_TRTvsCTRL   0.6043956 0.6101047  0.1828097 1.9982204 0.4091949
ARR_TRTvsCTRL -0.1144674 0.1410467 -0.3909139 0.1619791 0.4170460


$Gender_Male$`Respiratory tract infection`
$Gender_Male$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         17  37
n_event        0   4
n_event_pct    0  11
```

```
$Gender_Male$`Respiratory tract infection`$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.2631579 1.46299381 0.242342081 74.9952925 0.32162440
OR_TRTvsCTRL  4.7014925 1.51961042 0.239188898 92.4124501 0.30839139
ARR_TRTvsCTRL 0.1081081 0.05104866 0.008054565  0.2081617 0.03419658


$Gender_Male$`Rhinovirus infection`
$Gender_Male$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         17  37
n_event        2   7
n_event_pct   12  19

$Gender_Male$`Rhinovirus infection`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.60810811 0.7463287  0.3724252 6.9437075 0.5244330
OR_TRTvsCTRL  1.75000000 0.8618916  0.3231429 9.4772321 0.5161523
ARR_TRTvsCTRL 0.07154213 0.1012527 -0.1269095 0.2699937 0.4798336


$Gender_Male$`Sleep apnoea syndrome`
$Gender_Male$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all         17  37
n_event        3   0
n_event_pct   18   0

$Gender_Male$`Sleep apnoea syndrome`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.06766917 1.48453459  0.003687676 1.241735222 0.06965918
OR_TRTvsCTRL   0.05523810 1.54316119  0.002683475 1.137050842 0.06055462
ARR_TRTvsCTRL -0.17647059 0.09245944 -0.357687763 0.004746586 0.05631022


$Gender_Male$`Stoma site infection`
$Gender_Male$`Stoma site infection`$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$`Stoma site infection`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$Tachycardia
$Gender_Male$Tachycardia$ntab
            CTRL TRT
n_all         17  37
n_event        2   5
```

```
n_event_pct   12  14

$Gender_Male$Tachycardia$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14864865 0.78367687  0.2472409 5.3364712 0.8596333
OR_TRTvsCTRL  1.17187500 0.89326181  0.2034864 6.7488088 0.8590708
ARR_TRTvsCTRL 0.01748808 0.09625485 -0.1711680 0.2061441 0.8558298


$Gender_Male$Tachypnoea
$Gender_Male$Tachypnoea$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$Tachypnoea$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$Teething
$Gender_Male$Teething$ntab
            CTRL TRT
n_all         17  37
n_event        2   8
n_event_pct   12  22

$Gender_Male$Teething$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.83783784 0.7342680  0.4358100  7.7502768 0.4071956
OR_TRTvsCTRL  2.06896552 0.8521440  0.3894099 10.9925780 0.3935488
ARR_TRTvsCTRL 0.09856916 0.1033752 -0.1040425  0.3011808 0.3403324


$Gender_Male$`Upper respiratory tract infection`
$Gender_Male$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         17  37
n_event        4  10
n_event_pct   24  27

$Gender_Male$`Upper respiratory tract infection`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14864865 0.5139547  0.4194770 3.1453302 0.7874321
OR_TRTvsCTRL  1.20370370 0.6811462  0.3167575 4.5741697 0.7854736
ARR_TRTvsCTRL 0.03497615 0.1261529 -0.2122790 0.2822313 0.7815865


$Gender_Male$`Viral infection`
$Gender_Male$`Viral infection`$ntab
            CTRL TRT
```

```
n_all         17  37
n_event        1   4
n_event_pct    6  11

$Gender_Male$`Viral infection`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.83783784 1.07895757  0.2217670 15.2306185 0.5727177
OR_TRTvsCTRL  1.93939394 1.15879378  0.2001239 18.7946001 0.5675877
ARR_TRTvsCTRL 0.04928458 0.07656783 -0.1007856  0.1993548 0.5197880


$Gender_Male$`Viral upper respiratory tract infection`
$Gender_Male$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         17  37
n_event        4   3
n_event_pct   24   8

$Gender_Male$`Viral upper respiratory tract infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3445946 0.7053246  0.08648386 1.37303573 0.1309181
OR_TRTvsCTRL   0.2867647 0.8304626  0.05631637 1.46021488 0.1325574
ARR_TRTvsCTRL -0.1542130 0.1122402 -0.37419981 0.06577374 0.1694556


$Gender_Male$Vomiting
$Gender_Male$Vomiting$ntab
            CTRL TRT
n_all         17  37
n_event        4   5
n_event_pct   24  14

$Gender_Male$Vomiting$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5743243 0.6034480  0.1759954 1.8741875 0.3581022
OR_TRTvsCTRL   0.5078125 0.7471098  0.1174255 2.1960611 0.3643966
ARR_TRTvsCTRL -0.1001590 0.1172302 -0.3299259 0.1296079 0.3928951



$Gender_Female
$Gender_Female$`Acute respiratory failure`
$Gender_Female$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         24  43
n_event        6   6
n_event_pct   25  14

$Gender_Female$`Acute respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5581395 0.5180838  0.2021850 1.54076548 0.2603421
OR_TRTvsCTRL   0.4864865 0.6449154  0.1374415 1.72196291 0.2638779
ARR_TRTvsCTRL -0.1104651 0.1029792 -0.3123006 0.09137032 0.2834085
```

```
$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$ntab
            CTRL TRT
n_all         24  43
n_event        7  13
n_event_pct   29  30

$Gender_Female$Atelectasis$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.03654485 0.3935197  0.4793178 2.2415718 0.9273257
OR_TRTvsCTRL  1.05238095 0.5585133  0.3521808 3.1447081 0.9271647
ARR_TRTvsCTRL 0.01065891 0.1162473 -0.2171817 0.2384995 0.9269430


$Gender_Female$`Bronchial secretion retention`
$Gender_Female$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         24  43
n_event        3   0
n_event_pct   12   0

$Gender_Female$`Bronchial secretion retention`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08116883 1.49096848  0.004367919 1.508356380 0.09212555
OR_TRTvsCTRL   0.07060755 1.53467079  0.003487683 1.429437936 0.08413938
ARR_TRTvsCTRL -0.12500000 0.06750772 -0.257312691 0.007312691 0.06407751


$Gender_Female$Bronchiolitis
$Gender_Female$Bronchiolitis$ntab
            CTRL TRT
n_all         24  43
n_event        2   5
n_event_pct    8  12

$Gender_Female$Bronchiolitis$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39534884 0.79691751  0.2926479 6.6530412 0.6759169
OR_TRTvsCTRL  1.44736842 0.87850460  0.2586989 8.0977351 0.6738410
ARR_TRTvsCTRL 0.03294574 0.07464983 -0.1133652 0.1792567 0.6589690


$Gender_Female$`Candida infection`
$Gender_Female$`Candida infection`$ntab
            CTRL TRT
n_all         24  43
n_event        3   0
n_event_pct   12   0

$Gender_Female$`Candida infection`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08116883 1.49096848  0.004367919 1.508356380 0.09212555
OR_TRTvsCTRL   0.07060755 1.53467079  0.003487683 1.429437936 0.08413938
```

```
ARR_TRTvsCTRL -0.12500000 0.06750772 -0.257312691 0.007312691 0.06407751


$Gender_Female$Constipation
$Gender_Female$Constipation$ntab
            CTRL TRT
n_all         24  43
n_event        7  17
n_event_pct   29  40

$Gender_Female$Constipation$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3554817 0.3698083  0.6566172 2.7981763 0.4108084
OR_TRTvsCTRL  1.5879121 0.5467776  0.5437616 4.6370779 0.3977097
ARR_TRTvsCTRL 0.1036822 0.1190272 -0.1296069 0.3369712 0.3837107


$Gender_Female$Cough
$Gender_Female$Cough$ntab
            CTRL TRT
n_all         24  43
n_event        6   5
n_event_pct   25  12

$Gender_Female$Cough$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4651163 0.5493125  0.1584842 1.36501417 0.1634681
OR_TRTvsCTRL   0.3947368 0.6697298  0.1062264 1.46683987 0.1651593
ARR_TRTvsCTRL -0.1337209 0.1010061 -0.3316892 0.06424733 0.1855396


$Gender_Female$`Dermatitis diaper`
$Gender_Female$`Dermatitis diaper`$ntab
            CTRL TRT
n_all         24  43
n_event        3   4
n_event_pct   12   9

$Gender_Female$`Dermatitis diaper`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.74418605 0.7200075  0.1814722 3.051779 0.6815399
OR_TRTvsCTRL   0.71794872 0.8103045  0.1466766 3.514195 0.6825917
ARR_TRTvsCTRL -0.03197674 0.0807427 -0.1902295 0.126276 0.6920809


$Gender_Female$Diarrhoea
$Gender_Female$Diarrhoea$ntab
            CTRL TRT
n_all         24  43
n_event        4   7
n_event_pct   17  16

$Gender_Female$Diarrhoea$stats
                 estimate         se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.976744186 0.57265580  0.3179328 3.0007259 0.9672240
OR_TRTvsCTRL   0.972222222 0.68602837  0.2534061 3.7300439 0.9672451
ARR_TRTvsCTRL -0.003875969 0.09463915 -0.1893653 0.1816134 0.9673316


$Gender_Female$Dysphagia
$Gender_Female$Dysphagia$ntab
            CTRL TRT
n_all         24  43
n_event        5   5
n_event_pct   21  12

$Gender_Female$Dysphagia$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.57885881  0.1794805 1.73567455 0.3137393
OR_TRTvsCTRL   0.50000000 0.69206023  0.1287915 1.94112161 0.3165510
ARR_TRTvsCTRL -0.09205426 0.09623842 -0.2806781 0.09656957 0.3388081


$Gender_Female$Dyspnoea
$Gender_Female$Dyspnoea$ntab
            CTRL TRT
n_all         24  43
n_event        4   4
n_event_pct   17   9

$Gender_Female$Dyspnoea$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.65960406  0.1532099 2.03328746 0.3766501
OR_TRTvsCTRL   0.51282051 0.75871011  0.1159178 2.26871845 0.3787419
ARR_TRTvsCTRL -0.07364341 0.08802913 -0.2461773 0.09889052 0.4028287


$Gender_Female$`Gastrooesophageal reflux disease`
$Gender_Female$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         24  43
n_event        6   7
n_event_pct   25  16

$Gender_Female$`Gastrooesophageal reflux disease`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6511628 0.4945719  0.2470070 1.7166032 0.3857185
OR_TRTvsCTRL   0.5833333 0.6267832  0.1707647 1.9926710 0.3898216
ARR_TRTvsCTRL -0.0872093 0.1047952 -0.2926041 0.1181855 0.4053028


$Gender_Female$`Nasal congestion`
$Gender_Female$`Nasal congestion`$ntab
            CTRL TRT
n_all         24  43
n_event        2   5
n_event_pct    8  12
```

```
$Gender_Female$`Nasal congestion`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39534884 0.79691751  0.2926479 6.6530412 0.6759169
OR_TRTvsCTRL  1.44736842 0.87850460  0.2586989 8.0977351 0.6738410
ARR_TRTvsCTRL 0.03294574 0.07464983 -0.1133652 0.1792567 0.6589690


$Gender_Female$Nasopharyngitis
$Gender_Female$Nasopharyngitis$ntab
            CTRL TRT
n_all         24  43
n_event        2   6
n_event_pct    8  14

$Gender_Female$Nasopharyngitis$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.67441860 0.77572172  0.36607369 7.6587795 0.5063712
OR_TRTvsCTRL  1.78378378 0.85973731  0.33077486 9.6194875 0.5008484
ARR_TRTvsCTRL 0.05620155 0.07729862 -0.09530097 0.2077041 0.4671828


$Gender_Female$`Oxygen saturation decreased`
$Gender_Female$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         24  43
n_event        5   5
n_event_pct   21  12

$Gender_Female$`Oxygen saturation decreased`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.57885881  0.1794805 1.73567455 0.3137393
OR_TRTvsCTRL   0.50000000 0.69206023  0.1287915 1.94112161 0.3165510
ARR_TRTvsCTRL -0.09205426 0.09623842 -0.2806781 0.09656957 0.3388081


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$ntab
            CTRL TRT
n_all         24  43
n_event        4  15
n_event_pct   17  35

$Gender_Female$Pneumonia$stats
               estimate        se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  2.0930233 0.5017412  0.78287281 5.5957319 0.14099581
OR_TRTvsCTRL  2.6785714 0.6343350  0.77260277 9.2864602 0.12036241
ARR_TRTvsCTRL 0.1821705 0.1052121 -0.02404143 0.3883825 0.08336982


$Gender_Female$`Pneumonia aspiration`
$Gender_Female$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         24  43
n_event        4   7
```

```
n_event_pct   17  16

$Gender_Female$`Pneumonia aspiration`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.976744186 0.57265580  0.3179328 3.0007259 0.9672240
OR_TRTvsCTRL   0.972222222 0.68602837  0.2534061 3.7300439 0.9672451
ARR_TRTvsCTRL -0.003875969 0.09463915 -0.1893653 0.1816134 0.9673316


$Gender_Female$`Pneumonia bacterial`
$Gender_Female$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         24  43
n_event        3   2
n_event_pct   12   5

$Gender_Female$`Pneumonia bacterial`$stats
                  estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.37209302 0.87659047  0.06675693 2.07399014 0.2594079
OR_TRTvsCTRL   0.34146341 0.95149494  0.05289690 2.20423626 0.2587751
ARR_TRTvsCTRL -0.07848837 0.07475726 -0.22500990 0.06803316 0.2937596


$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$ntab
            CTRL TRT
n_all         24  43
n_event       15  25
n_event_pct   62  58

$Gender_Female$Pyrexia$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93023256 0.2043139  0.6232743 1.3883657 0.7233626
OR_TRTvsCTRL   0.83333333 0.5228129  0.2990884 2.3218700 0.7272906
ARR_TRTvsCTRL -0.04360465 0.1241995 -0.2870311 0.1998218 0.7255241


$Gender_Female$Rash
$Gender_Female$Rash$ntab
            CTRL TRT
n_all         24  43
n_event        1   5
n_event_pct    4  12

$Gender_Female$Rash$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.7906977 1.0654002  0.34581396 22.5207608 0.3354009
OR_TRTvsCTRL  3.0263158 1.1268514  0.33245786 27.5481148 0.3257599
ARR_TRTvsCTRL 0.0746124 0.0636671 -0.05017282  0.1993976 0.2412314


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$ntab
            CTRL TRT
```

```
n_all         24  43
n_event        7  11
n_event_pct   29  26

$Gender_Female$`Respiratory distress`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.87707641 0.4109060  0.3919887 1.9624620 0.7495749
OR_TRTvsCTRL   0.83482143 0.5690692  0.2736535 2.5467492 0.7510536
ARR_TRTvsCTRL -0.03585271 0.1141731 -0.2596279 0.1879225 0.7535054


$Gender_Female$`Respiratory failure`
$Gender_Female$`Respiratory failure`$ntab
            CTRL TRT
n_all         24  43
n_event        9   9
n_event_pct   38  21

$Gender_Female$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5581395 0.3966103  0.2565355 1.21433384 0.1414736
OR_TRTvsCTRL   0.4411765 0.5641814  0.1460092 1.33304381 0.1469363
ARR_TRTvsCTRL -0.1656977 0.1166805 -0.3943873 0.06299193 0.1555794


$Gender_Female$`Respiratory tract congestion`
$Gender_Female$`Respiratory tract congestion`$ntab
            CTRL TRT
n_all         24  43
n_event        3   0
n_event_pct   12   0

$Gender_Female$`Respiratory tract congestion`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08116883 1.49096848  0.004367919 1.508356380 0.09212555
OR_TRTvsCTRL   0.07060755 1.53467079  0.003487683 1.429437936 0.08413938
ARR_TRTvsCTRL -0.12500000 0.06750772 -0.257312691 0.007312691 0.06407751


$Gender_Female$`Respiratory tract infection`
$Gender_Female$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        2   5
n_event_pct    8  12

$Gender_Female$`Respiratory tract infection`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39534884 0.79691751  0.2926479 6.6530412 0.6759169
OR_TRTvsCTRL  1.44736842 0.87850460  0.2586989 8.0977351 0.6738410
ARR_TRTvsCTRL 0.03294574 0.07464983 -0.1133652 0.1792567 0.6589690


$Gender_Female$Rhinorrhoea
```

```
$Gender_Female$Rhinorrhoea$ntab
            CTRL TRT
n_all         24  43
n_event        2   6
n_event_pct    8  14

$Gender_Female$Rhinorrhoea$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.67441860 0.77572172  0.36607369 7.6587795 0.5063712
OR_TRTvsCTRL  1.78378378 0.85973731  0.33077486 9.6194875 0.5008484
ARR_TRTvsCTRL 0.05620155 0.07729862 -0.09530097 0.2077041 0.4671828


$Gender_Female$`Rhinovirus infection`
$Gender_Female$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         24  43
n_event        4   3
n_event_pct   17   7

$Gender_Female$`Rhinovirus infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.41860465 0.72000754  0.10207809 1.71662556 0.2264819
OR_TRTvsCTRL   0.37500000 0.81137743  0.07645142 1.83940341 0.2267225
ARR_TRTvsCTRL -0.09689922 0.08541861 -0.26431661 0.07051816 0.2566250


$Gender_Female$Tachycardia
$Gender_Female$Tachycardia$ntab
            CTRL TRT
n_all         24  43
n_event        3   2
n_event_pct   12   5

$Gender_Female$Tachycardia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.37209302 0.87659047  0.06675693 2.07399014 0.2594079
OR_TRTvsCTRL   0.34146341 0.95149494  0.05289690 2.20423626 0.2587751
ARR_TRTvsCTRL -0.07848837 0.07475726 -0.22500990 0.06803316 0.2937596


$Gender_Female$Teething
$Gender_Female$Teething$ntab
            CTRL TRT
n_all         24  43
n_event        1   6
n_event_pct    4  14

$Gender_Female$Teething$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.34883721 1.04964003  0.42799513 26.2028932 0.2495451
OR_TRTvsCTRL  3.72972973 1.11228232  0.42160032 32.9954296 0.2366290
ARR_TRTvsCTRL 0.09786822 0.06675313 -0.03296551  0.2287019 0.1426151
```

```
$Gender_Female$`Upper respiratory tract infection`
$Gender_Female$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        5  14
n_event_pct   21  33

$Gender_Female$`Upper respiratory tract infection`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.5627907 0.4544294  0.64134218 3.8081306 0.3258577
OR_TRTvsCTRL  1.8344828 0.5987845  0.56731899 5.9319837 0.3109056
ARR_TRTvsCTRL 0.1172481 0.1094467 -0.09726348 0.3317596 0.2840434


$Gender_Female$`Urinary tract infection`
$Gender_Female$`Urinary tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        0   6
n_event_pct    0  14

$Gender_Female$`Urinary tract infection`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  7.3863636 1.44607015 0.43404378 125.697844 0.16672413
OR_TRTvsCTRL  8.4933333 1.49041241 0.45754817 157.659270 0.15118393
ARR_TRTvsCTRL 0.1395349 0.05284134 0.03596776   0.243102 0.00827499


$Gender_Female$`Viral upper respiratory tract infection`
$Gender_Female$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        3   5
n_event_pct   12  12

$Gender_Female$`Viral upper respiratory tract infection`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93023256 0.68440547  0.2432341 3.5576116 0.9158447
OR_TRTvsCTRL   0.92105263 0.77927413  0.1999701 4.2423236 0.9159539
ARR_TRTvsCTRL -0.00872093 0.08334878 -0.1720815 0.1546397 0.9166680


$Gender_Female$Vomiting
$Gender_Female$Vomiting$ntab
            CTRL TRT
n_all         24  43
n_event        4   9
n_event_pct   17  21

$Gender_Female$Vomiting$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.25581395 0.54423215  0.4321893 3.6490226 0.6755510
OR_TRTvsCTRL  1.32352941 0.66371897  0.3603919 4.8606261 0.6727913
```

```
ARR_TRTvsCTRL 0.04263566 0.09816188 -0.1497581 0.2350294 0.6640414



$Region_Europe
$Region_Europe$`Acute respiratory failure`
$Region_Europe$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         17  30
n_event        2   0
n_event_pct   12   0

$Region_Europe$`Acute respiratory failure`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1161290 1.52058751  0.005896772 2.28700568 0.1567945
OR_TRTvsCTRL   0.1016393 1.58028574  0.004591136 2.25010878 0.1479588
ARR_TRTvsCTRL -0.1176471 0.07814249 -0.270803525 0.03550941 0.1321839


$Region_Europe$Atelectasis
$Region_Europe$Atelectasis$ntab
            CTRL TRT
n_all         17  30
n_event        3   8
n_event_pct   18  27

$Region_Europe$Atelectasis$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.51111111 0.6051252  0.4615438 4.9474325 0.4950824
OR_TRTvsCTRL  1.69696970 0.7584303  0.3837930 7.5032789 0.4856227
ARR_TRTvsCTRL 0.09019608 0.1227488 -0.1503871 0.3307793 0.4624600


$Region_Europe$`Bronchial secretion retention`
$Region_Europe$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         17  30
n_event        3   2
n_event_pct   18   7

$Region_Europe$`Bronchial secretion retention`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3777778 0.8609161  0.06989133 2.04197063 0.2581758
OR_TRTvsCTRL   0.3333333 0.9697815  0.04981948 2.23027424 0.2572793
ARR_TRTvsCTRL -0.1098039 0.1030671 -0.31181168 0.09220384 0.2867114


$Region_Europe$Bronchitis
$Region_Europe$Bronchitis$ntab
            CTRL TRT
n_all         17  30
n_event        1   5
n_event_pct    6  17
```

```
$Region_Europe$Bronchitis$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.8333333 1.05254128  0.36005837 22.2957676 0.3224352
OR_TRTvsCTRL  3.2000000 1.14127122  0.34174184 29.9641390 0.3081217
ARR_TRTvsCTRL 0.1078431 0.08880482 -0.06621111  0.2818974 0.2246012


$Region_Europe$`Bronchitis viral`
$Region_Europe$`Bronchitis viral`$ntab
            CTRL TRT
n_all         17  30
n_event        0   3
n_event_pct    0  10

$Region_Europe$`Bronchitis viral`$stats
              estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.064516 1.48253184  0.222369622 74.2920332 0.34421066
OR_TRTvsCTRL  4.454545 1.54247229  0.216694854 91.5710496 0.33278158
ARR_TRTvsCTRL 0.100000 0.05477226 -0.007351649  0.2073516 0.06788915


$Region_Europe$Constipation
$Region_Europe$Constipation$ntab
            CTRL TRT
n_all         17  30
n_event        4   6
n_event_pct   24  20

$Region_Europe$Constipation$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.5696576  0.2783079 2.5960459 0.7754202
OR_TRTvsCTRL   0.81250000 0.7316122  0.1936752 3.4085746 0.7765555
ARR_TRTvsCTRL -0.03529412 0.1261646 -0.2825721 0.2119839 0.7796719


$Region_Europe$Dysphagia
$Region_Europe$Dysphagia$ntab
            CTRL TRT
n_all         17  30
n_event        2   0
n_event_pct   12   0

$Region_Europe$Dysphagia$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1161290 1.52058751  0.005896772 2.28700568 0.1567945
OR_TRTvsCTRL   0.1016393 1.58028574  0.004591136 2.25010878 0.1479588
ARR_TRTvsCTRL -0.1176471 0.07814249 -0.270803525 0.03550941 0.1321839


$Region_Europe$`Feeding disorder of infancy or early childhood`
$Region_Europe$`Feeding disorder of infancy or early childhood`$ntab
            CTRL TRT
n_all         17  30
n_event        3   2
```

```
n_event_pct   18   7

$Region_Europe$`Feeding disorder of infancy or early childhood`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3777778 0.8609161  0.06989133 2.04197063 0.2581758
OR_TRTvsCTRL   0.3333333 0.9697815  0.04981948 2.23027424 0.2572793
ARR_TRTvsCTRL -0.1098039 0.1030671 -0.31181168 0.09220384 0.2867114


$Region_Europe$`Gastrooesophageal reflux disease`
$Region_Europe$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         17  30
n_event        3   3
n_event_pct   18  10

$Region_Europe$`Gastrooesophageal reflux disease`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56666667 0.7579642  0.12827657 2.5032718 0.4536435
OR_TRTvsCTRL   0.51851852 0.8804160  0.09233213 2.9118949 0.4556748
ARR_TRTvsCTRL -0.07647059 0.1074651 -0.28709832 0.1341571 0.4767216


$Region_Europe$Nasopharyngitis
$Region_Europe$Nasopharyngitis$ntab
            CTRL TRT
n_all         17  30
n_event        0   7
n_event_pct    0  23

$Region_Europe$Nasopharyngitis$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   8.7096774 1.43021667 0.52795807 143.6827740 0.13018787
OR_TRTvsCTRL  11.1702128 1.49433242 0.59714993 208.9486202 0.10632464
ARR_TRTvsCTRL  0.2333333 0.07722022 0.08198448   0.3846822 0.00251392


$Region_Europe$`Oral candidiasis`
$Region_Europe$`Oral candidiasis`$ntab
            CTRL TRT
n_all         17  30
n_event        2   3
n_event_pct   12  10

$Region_Europe$`Oral candidiasis`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.86091606  0.1572555 4.5944339 0.8502696
OR_TRTvsCTRL   0.83333333 0.96800673  0.1249827 5.5563242 0.8506043
ARR_TRTvsCTRL -0.01764706 0.09542667 -0.2046799 0.1693858 0.8532855


$Region_Europe$`Oxygen saturation decreased`
$Region_Europe$`Oxygen saturation decreased`$ntab
            CTRL TRT
```

```
n_all         17  30
n_event        3   1
n_event_pct   18   3

$Region_Europe$`Oxygen saturation decreased`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1888889 1.11408100  0.02127644 1.67692592 0.1346698
OR_TRTvsCTRL   0.1609195 1.19968524  0.01532621 1.68959535 0.1278150
ARR_TRTvsCTRL -0.1431373 0.09809599 -0.33540185 0.04912734 0.1445224


$Region_Europe$Pain
$Region_Europe$Pain$ntab
            CTRL TRT
n_all         17  30
n_event        2   0
n_event_pct   12   0

$Region_Europe$Pain$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1161290 1.52058751  0.005896772 2.28700568 0.1567945
OR_TRTvsCTRL   0.1016393 1.58028574  0.004591136 2.25010878 0.1479588
ARR_TRTvsCTRL -0.1176471 0.07814249 -0.270803525 0.03550941 0.1321839


$Region_Europe$Pneumonia
$Region_Europe$Pneumonia$ntab
            CTRL TRT
n_all         17  30
n_event        3   7
n_event_pct   18  23

$Region_Europe$Pneumonia$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.32222222 0.6197045  0.3924742 4.454488 0.6521906
OR_TRTvsCTRL  1.42028986 0.7688285  0.3147378 6.409218 0.6481326
ARR_TRTvsCTRL 0.05686275 0.1204646 -0.1792435 0.292969 0.6369062


$Region_Europe$`Pneumonia aspiration`
$Region_Europe$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         17  30
n_event        2   3
n_event_pct   12  10

$Region_Europe$`Pneumonia aspiration`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.86091606  0.1572555 4.5944339 0.8502696
OR_TRTvsCTRL   0.83333333 0.96800673  0.1249827 5.5563242 0.8506043
ARR_TRTvsCTRL -0.01764706 0.09542667 -0.2046799 0.1693858 0.8532855


$Region_Europe$Pyrexia
```

```
$Region_Europe$Pyrexia$ntab
            CTRL TRT
n_all         17  30
n_event       10  16
n_event_pct   59  53

$Region_Europe$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90666667 0.2652228  0.5391251 1.5247748 0.7118096
OR_TRTvsCTRL   0.80000000 0.6138287  0.2402138 2.6642928 0.7162110
ARR_TRTvsCTRL -0.05490196 0.1501473 -0.3491853 0.2393813 0.7146233


$Region_Europe$`Respiratory arrest`
$Region_Europe$`Respiratory arrest`$ntab
            CTRL TRT
n_all         17  30
n_event        0   4
n_event_pct    0  13

$Region_Europe$`Respiratory arrest`$stats
               estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  5.2258065 1.46096153 0.29825011  91.5642690 0.25769180
OR_TRTvsCTRL  5.9433962 1.52220266 0.30083851 117.4183396 0.24165650
ARR_TRTvsCTRL 0.1333333 0.06206329 0.01169152   0.2549751 0.03168639


$Region_Europe$`Respiratory distress`
$Region_Europe$`Respiratory distress`$ntab
            CTRL TRT
n_all         17  30
n_event        2   8
n_event_pct   12  27

$Region_Europe$`Respiratory distress`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2666667 0.7299611  0.54205541  9.4783258 0.2622739
OR_TRTvsCTRL  2.7272727 0.8585576  0.50690081 14.6735148 0.2425687
ARR_TRTvsCTRL 0.1490196 0.1123600 -0.07120192  0.3692411 0.1847505


$Region_Europe$`Respiratory failure`
$Region_Europe$`Respiratory failure`$ntab
            CTRL TRT
n_all         17  30
n_event        8   9
n_event_pct   47  30

$Region_Europe$`Respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6375000 0.3794130  0.3030562 1.3410258 0.2353964
OR_TRTvsCTRL   0.4821429 0.6283640  0.1407056 1.6521144 0.2456521
ARR_TRTvsCTRL -0.1705882 0.1471564 -0.4590094 0.1178329 0.2463620
```

```
$Region_Europe$`Respiratory tract infection`
$Region_Europe$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         17  30
n_event        2   8
n_event_pct   12  27

$Region_Europe$`Respiratory tract infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2666667 0.7299611  0.54205541  9.4783258 0.2622739
OR_TRTvsCTRL  2.7272727 0.8585576  0.50690081 14.6735148 0.2425687
ARR_TRTvsCTRL 0.1490196 0.1123600 -0.07120192  0.3692411 0.1847505


$Region_Europe$Rhinitis
$Region_Europe$Rhinitis$ntab
            CTRL TRT
n_all         17  30
n_event        3   2
n_event_pct   18   7

$Region_Europe$Rhinitis$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3777778 0.8609161  0.06989133 2.04197063 0.2581758
OR_TRTvsCTRL   0.3333333 0.9697815  0.04981948 2.23027424 0.2572793
ARR_TRTvsCTRL -0.1098039 0.1030671 -0.31181168 0.09220384 0.2867114


$Region_Europe$`Rhinovirus infection`
$Region_Europe$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         17  30
n_event        1   3
n_event_pct    6  10

$Region_Europe$`Rhinovirus infection`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 1.11408100  0.1914880 15.0923333 0.6338661
OR_TRTvsCTRL  1.77777778 1.19702563  0.1702031 18.5689583 0.6307571
ARR_TRTvsCTRL 0.04117647 0.07909909 -0.1138549  0.1962078 0.6026676


$Region_Europe$`Salivary hypersecretion`
$Region_Europe$`Salivary hypersecretion`$ntab
            CTRL TRT
n_all         17  30
n_event        2   0
n_event_pct   12   0

$Region_Europe$`Salivary hypersecretion`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1161290 1.52058751  0.005896772 2.28700568 0.1567945
OR_TRTvsCTRL   0.1016393 1.58028574  0.004591136 2.25010878 0.1479588
```

```
ARR_TRTvsCTRL -0.1176471 0.07814249 -0.270803525 0.03550941 0.1321839


$Region_Europe$Teething
$Region_Europe$Teething$ntab
            CTRL TRT
n_all         17  30
n_event        1   3
n_event_pct    6  10

$Region_Europe$Teething$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 1.11408100  0.1914880 15.0923333 0.6338661
OR_TRTvsCTRL  1.77777778 1.19702563  0.1702031 18.5689583 0.6307571
ARR_TRTvsCTRL 0.04117647 0.07909909 -0.1138549  0.1962078 0.6026676


$Region_Europe$`Upper respiratory tract infection`
$Region_Europe$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         17  30
n_event        4   1
n_event_pct   24   3

$Region_Europe$`Upper respiratory tract infection`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.1416667 1.0760312  0.01719287 1.167312378 0.06934105
OR_TRTvsCTRL   0.1120690 1.1667930  0.01138438 1.103218002 0.06068621
ARR_TRTvsCTRL -0.2019608 0.1079733 -0.41358461 0.009663041 0.06141868


$Region_Europe$`Upper respiratory tract inflammation`
$Region_Europe$`Upper respiratory tract inflammation`$ntab
            CTRL TRT
n_all         17  30
n_event        2   0
n_event_pct   12   0

$Region_Europe$`Upper respiratory tract inflammation`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1161290 1.52058751  0.005896772 2.28700568 0.1567945
OR_TRTvsCTRL   0.1016393 1.58028574  0.004591136 2.25010878 0.1479588
ARR_TRTvsCTRL -0.1176471 0.07814249 -0.270803525 0.03550941 0.1321839


$Region_Europe$`Viral infection`
$Region_Europe$`Viral infection`$ntab
            CTRL TRT
n_all         17  30
n_event        0   5
n_event_pct    0  17

$Region_Europe$`Viral infection`$stats
               estimate         se     lo95ci      hi95ci     pvalue
```

```
RR_TRTvsCTRL  6.3870968 1.44706757 0.37459101 108.9054585 0.20005140
OR_TRTvsCTRL  7.5490196 1.50936302 0.39184871 145.4329070 0.18048859
ARR_TRTvsCTRL 0.1666667 0.06804138 0.03330801   0.3000253 0.01430588


$Region_Europe$Vomiting
$Region_Europe$Vomiting$ntab
            CTRL TRT
n_all         17  30
n_event        2   5
n_event_pct   12  17

$Region_Europe$Vomiting$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.41666667 0.7796430  0.3073508 6.5298163 0.6550545
OR_TRTvsCTRL  1.50000000 0.8981462  0.2579810 8.7215711 0.6516677
ARR_TRTvsCTRL 0.04901961 0.1036141 -0.1540603 0.2520995 0.6361433


$Region_Europe$`Weight decreased`
$Region_Europe$`Weight decreased`$ntab
            CTRL TRT
n_all         17  30
n_event        1   4
n_event_pct    6  13

$Region_Europe$`Weight decreased`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2666667 1.07603120  0.27508584 18.6769981 0.4469621
OR_TRTvsCTRL  2.4615385 1.16230871  0.25225957 24.0195902 0.4383410
ARR_TRTvsCTRL 0.0745098 0.08431203 -0.09073873  0.2397583 0.3768373


$Region_Europe$`Weight gain poor`
$Region_Europe$`Weight gain poor`$ntab
            CTRL TRT
n_all         17  30
n_event        1   4
n_event_pct    6  13

$Region_Europe$`Weight gain poor`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2666667 1.07603120  0.27508584 18.6769981 0.4469621
OR_TRTvsCTRL  2.4615385 1.16230871  0.25225957 24.0195902 0.4383410
ARR_TRTvsCTRL 0.0745098 0.08431203 -0.09073873  0.2397583 0.3768373



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        8  11
```

```
n_event_pct   36  29

$Region_Northamerica$`Acute respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79605263 0.3796561  0.3782491 1.6753504 0.5479862
OR_TRTvsCTRL   0.71296296 0.5695390  0.2334933 2.1770052 0.5524891
ARR_TRTvsCTRL -0.07416268 0.1262181 -0.3215456 0.1732202 0.5568171


$Region_Northamerica$Aspiration
$Region_Northamerica$Aspiration$ntab
            CTRL TRT
n_all         22  38
n_event        3   5
n_event_pct   14  13

$Region_Northamerica$Aspiration$stats
                  estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.964912281 0.67938428  0.2547973 3.654103 0.9580712
OR_TRTvsCTRL   0.959595960 0.78502735  0.2060022 4.469973 0.9581008
ARR_TRTvsCTRL -0.004784689 0.09143367 -0.1839914 0.174422 0.9582661


$Region_Northamerica$Atelectasis
$Region_Northamerica$Atelectasis$ntab
            CTRL TRT
n_all         22  38
n_event        9   9
n_event_pct   41  24

$Region_Northamerica$Atelectasis$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5789474 0.3878813  0.2706911 1.2382383 0.1588207
OR_TRTvsCTRL   0.4482759 0.5776055  0.1445063 1.3906057 0.1648051
ARR_TRTvsCTRL -0.1722488 0.1254771 -0.4181794 0.0736818 0.1698298


$Region_Northamerica$`Bacterial tracheitis`
$Region_Northamerica$`Bacterial tracheitis`$ntab
            CTRL TRT
n_all         22  38
n_event        4   1
n_event_pct   18   3

$Region_Northamerica$`Bacterial tracheitis`$stats
                estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.1447368 1.085463  0.01724374 1.21486151 0.07496835
OR_TRTvsCTRL   0.1216216 1.154375  0.01265915 1.16846826 0.06798725
ARR_TRTvsCTRL -0.1555024 0.086233 -0.32451596 0.01351118 0.07134397


$Region_Northamerica$Bradycardia
$Region_Northamerica$Bradycardia$ntab
            CTRL TRT
```

```
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$Bradycardia$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$`Bronchial secretion retention`
$Region_Northamerica$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         22  38
n_event        4   2
n_event_pct   18   5

$Region_Northamerica$`Bronchial secretion retention`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.2894737 0.82354700  0.05762416 1.45416460 0.1322452
OR_TRTvsCTRL   0.2500000 0.91287093  0.04177369 1.49615694 0.1288608
ARR_TRTvsCTRL -0.1291866 0.08985532 -0.30529979 0.04692658 0.1505141


$Region_Northamerica$Bronchiolitis
$Region_Northamerica$Bronchiolitis$ntab
            CTRL TRT
n_all         22  38
n_event        2   4
n_event_pct    9  11

$Region_Northamerica$Bronchiolitis$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.15789474 0.82354700  0.2304966 5.8166584 0.8587114
OR_TRTvsCTRL  1.17647059 0.91072046  0.1974124 7.0111255 0.8583688
ARR_TRTvsCTRL 0.01435407 0.07896246 -0.1404095 0.1691176 0.8557527


$Region_Northamerica$`Cardio-respiratory arrest`
$Region_Northamerica$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         22  38
n_event        4   3
n_event_pct   18   8

$Region_Northamerica$`Cardio-respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4342105 0.71523632  0.10687843 1.76404886 0.2434674
OR_TRTvsCTRL   0.3857143 0.81698245  0.07777661 1.91285673 0.2435863
ARR_TRTvsCTRL -0.1028708 0.09314171 -0.28542520 0.07968358 0.2693959


$Region_Northamerica$Constipation
```

```
$Region_Northamerica$Constipation$ntab
            CTRL TRT
n_all         22  38
n_event        5  17
n_event_pct   23  45

$Region_Northamerica$Constipation$stats
               estimate        se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.9684211 0.4324965  0.84328882 4.5947265 0.11737988
OR_TRTvsCTRL  2.7523810 0.6043725  0.84191015 8.9981109 0.09388801
ARR_TRTvsCTRL 0.2200957 0.1203693 -0.01582381 0.4560152 0.06747403


$Region_Northamerica$Cough
$Region_Northamerica$Cough$ntab
            CTRL TRT
n_all         22  38
n_event        7   7
n_event_pct   32  18

$Region_Northamerica$Cough$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5789474 0.4625408  0.2338426 1.43335739 0.2373597
OR_TRTvsCTRL   0.4838710 0.6201927  0.1434896 1.63169345 0.2417989
ARR_TRTvsCTRL -0.1339713 0.1175401 -0.3643456 0.09640299 0.2543727


$Region_Northamerica$`Decubitus ulcer`
$Region_Northamerica$`Decubitus ulcer`$ntab
            CTRL TRT
n_all         22  38
n_event        3   0
n_event_pct   14   0

$Region_Northamerica$`Decubitus ulcer`$stats
                estimate       se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08424908 1.488823  0.004552778 1.559028057 0.09657297
OR_TRTvsCTRL   0.07235622 1.537196  0.003556416 1.472106135 0.08756107
ARR_TRTvsCTRL -0.13636364 0.073165 -0.279764411 0.007037138 0.06235229


$Region_Northamerica$`Dermatitis contact`
$Region_Northamerica$`Dermatitis contact`$ntab
            CTRL TRT
n_all         22  38
n_event        3   2
n_event_pct   14   5

$Region_Northamerica$`Dermatitis contact`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.38596491 0.87267577  0.06977902 2.13486682 0.2753134
OR_TRTvsCTRL   0.35185185 0.95589889  0.05403775 2.29098609 0.2745098
ARR_TRTvsCTRL -0.08373206 0.08164106 -0.24374559 0.07628148 0.3050745
```

```
$Region_Northamerica$`Dermatitis diaper`
$Region_Northamerica$`Dermatitis diaper`$ntab
            CTRL TRT
n_all         22  38
n_event        4   5
n_event_pct   18  13

$Region_Northamerica$`Dermatitis diaper`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.72368421 0.6150038  0.2167988 2.4156904 0.5989920
OR_TRTvsCTRL   0.68181818 0.7320236  0.1623936 2.8626498 0.6008375
ARR_TRTvsCTRL -0.05023923 0.0988374 -0.2439570 0.1434785 0.6112417


$Region_Northamerica$Diarrhoea
$Region_Northamerica$Diarrhoea$ntab
            CTRL TRT
n_all         22  38
n_event        6   8
n_event_pct   27  21

$Region_Northamerica$Diarrhoea$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.77192982 0.4689311  0.3079094 1.9352303 0.5809313
OR_TRTvsCTRL   0.71111111 0.6224950  0.2099272 2.4088300 0.5839133
ARR_TRTvsCTRL -0.06220096 0.1157134 -0.2889951 0.1645932 0.5908924


$Region_Northamerica$Dysphagia
$Region_Northamerica$Dysphagia$ntab
            CTRL TRT
n_all         22  38
n_event        7   9
n_event_pct   32  24

$Region_Northamerica$Dysphagia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.74436090 0.4268465  0.3224417 1.7183671 0.4891558
OR_TRTvsCTRL   0.66502463 0.5959175  0.2068197 2.1383739 0.4936323
ARR_TRTvsCTRL -0.08133971 0.1209030 -0.3183052 0.1556258 0.5010946


$Region_Northamerica$Dyspnoea
$Region_Northamerica$Dyspnoea$ntab
            CTRL TRT
n_all         22  38
n_event        5   3
n_event_pct   23   8

$Region_Northamerica$Dyspnoea$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3473684 0.67938428  0.09172704 1.3154771 0.1196215
OR_TRTvsCTRL   0.2914286 0.78786312  0.06221596 1.3650936 0.1175964
```

```
ARR_TRTvsCTRL -0.1483254 0.09947997 -0.34330251 0.0466518 0.1359596


$Region_Northamerica$`Feeding tube complication`
$Region_Northamerica$`Feeding tube complication`$ntab
            CTRL TRT
n_all         22  38
n_event        3   1
n_event_pct   14   3

$Region_Northamerica$`Feeding tube complication`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1929825 1.12319322  0.02135276 1.74414115 0.1429992
OR_TRTvsCTRL   0.1711712 1.18869337  0.01665762 1.75892879 0.1375702
ARR_TRTvsCTRL -0.1100478 0.07763643 -0.26221244 0.04211675 0.1563435


$Region_Northamerica$Flatulence
$Region_Northamerica$Flatulence$ntab
            CTRL TRT
n_all         22  38
n_event        1   4
n_event_pct    5  11

$Region_Northamerica$Flatulence$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.31578947 1.08546288  0.27589981 19.4377841 0.4391474
OR_TRTvsCTRL  2.47058824 1.15196823  0.25837068 23.6242216 0.4323715
ARR_TRTvsCTRL 0.05980861 0.06671354 -0.07094753  0.1905648 0.3699864


$Region_Northamerica$`Gastrooesophageal reflux disease`
$Region_Northamerica$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         22  38
n_event        4   7
n_event_pct   18  18

$Region_Northamerica$`Gastrooesophageal reflux disease`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.013157895 0.5666452  0.3336936 3.0761423 0.9815950
OR_TRTvsCTRL  1.016129032 0.6933042  0.2611002 3.9544901 0.9815877
ARR_TRTvsCTRL 0.002392344 0.1035205 -0.2005041 0.2052888 0.9815626


$Region_Northamerica$Hypokalaemia
$Region_Northamerica$Hypokalaemia$ntab
            CTRL TRT
n_all         22  38
n_event        3   0
n_event_pct   14   0

$Region_Northamerica$Hypokalaemia$stats
                estimate       se       lo95ci      hi95ci     pvalue
```

```
RR_TRTvsCTRL   0.08424908 1.488823  0.004552778 1.559028057 0.09657297
OR_TRTvsCTRL   0.07235622 1.537196  0.003556416 1.472106135 0.08756107
ARR_TRTvsCTRL -0.13636364 0.073165 -0.279764411 0.007037138 0.06235229


$Region_Northamerica$Hypoxia
$Region_Northamerica$Hypoxia$ntab
            CTRL TRT
n_all         22  38
n_event        2   7
n_event_pct    9  18

$Region_Northamerica$Hypoxia$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.02631579 0.75570286  0.4607355  8.911741 0.3500358
OR_TRTvsCTRL  2.25806452 0.85153697  0.4255071 11.983010 0.3388120
ARR_TRTvsCTRL 0.09330144 0.08781362 -0.0788101  0.265413 0.2880115


$Region_Northamerica$`Nasal congestion`
$Region_Northamerica$`Nasal congestion`$ntab
            CTRL TRT
n_all         22  38
n_event        5   8
n_event_pct   23  21

$Region_Northamerica$`Nasal congestion`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92631579 0.5032193  0.3454761 2.4837056 0.8791074
OR_TRTvsCTRL   0.90666667 0.6458768  0.2556680 3.2152814 0.8794225
ARR_TRTvsCTRL -0.01674641 0.1111600 -0.2346159 0.2011231 0.8802506


$Region_Northamerica$Nasopharyngitis
$Region_Northamerica$Nasopharyngitis$ntab
            CTRL TRT
n_all         22  38
n_event        4   6
n_event_pct   18  16

$Region_Northamerica$Nasopharyngitis$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.86842105 0.5872788  0.2746868 2.7455093 0.8101564
OR_TRTvsCTRL   0.84375000 0.7095578  0.2100086 3.3899278 0.8107617
ARR_TRTvsCTRL -0.02392344 0.1012960 -0.2224600 0.1746131 0.8132980


$Region_Northamerica$`Oral candidiasis`
$Region_Northamerica$`Oral candidiasis`$ntab
            CTRL TRT
n_all         22  38
n_event        1   4
n_event_pct    5  11
```

```
$Region_Northamerica$`Oral candidiasis`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.31578947 1.08546288  0.27589981 19.4377841 0.4391474
OR_TRTvsCTRL  2.47058824 1.15196823  0.25837068 23.6242216 0.4323715
ARR_TRTvsCTRL 0.05980861 0.06671354 -0.07094753  0.1905648 0.3699864


$Region_Northamerica$`Oxygen saturation decreased`
$Region_Northamerica$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         22  38
n_event        7   8
n_event_pct   32  21

$Region_Northamerica$`Oxygen saturation decreased`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6616541 0.4428169  0.2777823 1.5760045 0.3509784
OR_TRTvsCTRL   0.5714286 0.6065123  0.1740595 1.8759711 0.3561748
ARR_TRTvsCTRL -0.1076555 0.1193098 -0.3414984 0.1261874 0.3668873


$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$ntab
            CTRL TRT
n_all         22  38
n_event        4  11
n_event_pct   18  29

$Region_Northamerica$Pneumonia$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.5921053 0.5187858  0.5759443 4.4011188 0.3700211
OR_TRTvsCTRL  1.8333333 0.6584084  0.5044326 6.6631520 0.3572553
ARR_TRTvsCTRL 0.1076555 0.1103378 -0.1086026 0.3239136 0.3292180


$Region_Northamerica$`Pneumonia aspiration`
$Region_Northamerica$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         22  38
n_event        5   6
n_event_pct   23  16

$Region_Northamerica$`Pneumonia aspiration`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.69473684 0.5430436  0.2396519 2.0140018 0.5024084
OR_TRTvsCTRL   0.63750000 0.6758256  0.1695182 2.3974191 0.5053154
ARR_TRTvsCTRL -0.06937799 0.1071530 -0.2793941 0.1406381 0.5173301


$Region_Northamerica$`Pneumonia bacterial`
$Region_Northamerica$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         22  38
n_event        3   3
```

```
n_event_pct   14   8

$Region_Northamerica$`Pneumonia bacterial`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$`Pneumonia viral`
$Region_Northamerica$`Pneumonia viral`$ntab
            CTRL TRT
n_all         22  38
n_event        2   6
n_event_pct    9  16

$Region_Northamerica$`Pneumonia viral`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.73684211 0.77129523  0.38302988  7.8756794 0.4741345
OR_TRTvsCTRL  1.87500000 0.86482175  0.34424184 10.2126602 0.4673087
ARR_TRTvsCTRL 0.06698565 0.08517996 -0.09996402  0.2339353 0.4316323


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$ntab
            CTRL TRT
n_all         22  38
n_event       13  25
n_event_pct   59  66

$Region_Northamerica$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.11336032 0.2124917  0.7341122 1.6885310 0.6133128
OR_TRTvsCTRL  1.33136095 0.5522294  0.4510631 3.9296538 0.6042727
ARR_TRTvsCTRL 0.06698565 0.1300417 -0.1878915 0.3218628 0.6064770


$Region_Northamerica$Rash
$Region_Northamerica$Rash$ntab
            CTRL TRT
n_all         22  38
n_event        3   8
n_event_pct   14  21

$Region_Northamerica$Rash$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.54385965 0.62174191  0.4564363 5.2219834 0.4848657
OR_TRTvsCTRL  1.68888889 0.73776571  0.3977533 7.1711431 0.4774880
ARR_TRTvsCTRL 0.07416268 0.09862522 -0.1191392 0.2674646 0.4520723


$Region_Northamerica$`Respiratory arrest`
$Region_Northamerica$`Respiratory arrest`$ntab
            CTRL TRT
```

```
n_all         22  38
n_event        4   1
n_event_pct   18   3

$Region_Northamerica$`Respiratory arrest`$stats
                estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.1447368 1.085463  0.01724374 1.21486151 0.07496835
OR_TRTvsCTRL   0.1216216 1.154375  0.01265915 1.16846826 0.06798725
ARR_TRTvsCTRL -0.1555024 0.086233 -0.32451596 0.01351118 0.07134397


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$ntab
            CTRL TRT
n_all         22  38
n_event       10  12
n_event_pct   45  32

$Region_Northamerica$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6947368 0.3340105  0.3610024 1.3369974 0.2755144
OR_TRTvsCTRL   0.5538462 0.5523841  0.1875854 1.6352319 0.2847682
ARR_TRTvsCTRL -0.1387560 0.1302140 -0.3939707 0.1164587 0.2866046


$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        7  11
n_event_pct   32  29

$Region_Northamerica$`Respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90977444 0.4024871  0.4133672 2.0023104 0.8142587
OR_TRTvsCTRL   0.87301587 0.5809216  0.2796023 2.7258599 0.8151642
ARR_TRTvsCTRL -0.02870813 0.1235864 -0.2709331 0.2135168 0.8163112


$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`
$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$Rhinorrhoea
```

```
$Region_Northamerica$Rhinorrhoea$ntab
            CTRL TRT
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$Rhinorrhoea$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$`Rhinovirus infection`
$Region_Northamerica$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         22  38
n_event        5   7
n_event_pct   23  18

$Region_Northamerica$`Rhinovirus infection`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8105263 0.5206600  0.2921330 2.2488148 0.6866014
OR_TRTvsCTRL   0.7677419 0.6587403  0.2111031 2.7921323 0.6882561
ARR_TRTvsCTRL -0.0430622 0.1092583 -0.2572045 0.1710801 0.6934835


$Region_Northamerica$`Salivary hypersecretion`
$Region_Northamerica$`Salivary hypersecretion`$ntab
            CTRL TRT
n_all         22  38
n_event        0   6
n_event_pct    0  16

$Region_Northamerica$`Salivary hypersecretion`$stats
               estimate         se    lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  7.6666667 1.44385833 0.4524725 129.9035492 0.158326761
OR_TRTvsCTRL  9.0000000 1.49300363 0.4823869 167.9150026 0.141107130
ARR_TRTvsCTRL 0.1578947 0.05915279 0.0419574   0.2738321 0.007601641


$Region_Northamerica$`Sleep apnoea syndrome`
$Region_Northamerica$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all         22  38
n_event        4   0
n_event_pct   18   0

$Region_Northamerica$`Sleep apnoea syndrome`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.06552707 1.46734554  0.003693294  1.16259248 0.06326934
OR_TRTvsCTRL   0.05339105 1.51731681  0.002728513  1.04474644 0.05346893
ARR_TRTvsCTRL -0.18181818 0.08223037 -0.342986739 -0.02064962 0.02703008
```

```
$Region_Northamerica$`Stoma site infection`
$Region_Northamerica$`Stoma site infection`$ntab
            CTRL TRT
n_all         22  38
n_event        3   0
n_event_pct   14   0

$Region_Northamerica$`Stoma site infection`$stats
                 estimate       se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08424908 1.488823  0.004552778 1.559028057 0.09657297
OR_TRTvsCTRL   0.07235622 1.537196  0.003556416 1.472106135 0.08756107
ARR_TRTvsCTRL -0.13636364 0.073165 -0.279764411 0.007037138 0.06235229


$Region_Northamerica$Tachycardia
$Region_Northamerica$Tachycardia$ntab
            CTRL TRT
n_all         22  38
n_event        4   5
n_event_pct   18  13

$Region_Northamerica$Tachycardia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.72368421 0.6150038  0.2167988 2.4156904 0.5989920
OR_TRTvsCTRL   0.68181818 0.7320236  0.1623936 2.8626498 0.6008375
ARR_TRTvsCTRL -0.05023923 0.0988374 -0.2439570 0.1434785 0.6112417


$Region_Northamerica$Teething
$Region_Northamerica$Teething$ntab
            CTRL TRT
n_all         22  38
n_event        2   8
n_event_pct    9  21

$Region_Northamerica$Teething$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.3157895 0.74379410  0.53898960  9.9498782 0.2588938
OR_TRTvsCTRL  2.6666667 0.84162541  0.51236079 13.8791088 0.2438576
ARR_TRTvsCTRL 0.1196172 0.09016867 -0.05711012  0.2963446 0.1846430


$Region_Northamerica$`Upper respiratory tract congestion`
$Region_Northamerica$`Upper respiratory tract congestion`$ntab
            CTRL TRT
n_all         22  38
n_event        1   5
n_event_pct    5  13

$Region_Northamerica$`Upper respiratory tract congestion`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.8947368 1.06218156  0.3609761 23.2134490 0.3169859
OR_TRTvsCTRL  3.1818182 1.13045216  0.3470825 29.1687608 0.3058897
```

```
ARR_TRTvsCTRL 0.0861244 0.07056344 -0.0521774  0.2244262 0.2222662


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        5  20
n_event_pct   23  53

$Region_Northamerica$`Upper respiratory tract infection`$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.3157895 0.4221726 1.01238371  5.2972809 0.04668828
OR_TRTvsCTRL  3.7777778 0.6036382 1.15722720 12.3325868 0.02767413
ARR_TRTvsCTRL 0.2990431 0.1205962 0.06267886  0.5354073 0.01314909


$Region_Northamerica$`Urinary tract infection`
$Region_Northamerica$`Urinary tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        0   4
n_event_pct    0  11

$Region_Northamerica$`Urinary tract infection`$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  5.3076923 1.46734554 0.299156849  94.169991 0.25531463
OR_TRTvsCTRL  5.8695652 1.51514097 0.301242051 114.365825 0.24278123
ARR_TRTvsCTRL 0.1052632 0.04978449 0.007687351   0.202839 0.03448312


$Region_Northamerica$`Viral infection`
$Region_Northamerica$`Viral infection`$ntab
            CTRL TRT
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$`Viral infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$`Viral upper respiratory tract infection`
$Region_Northamerica$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        7   8
n_event_pct   32  21

$Region_Northamerica$`Viral upper respiratory tract infection`$stats
                estimate        se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.6616541 0.4428169  0.2777823 1.5760045 0.3509784
OR_TRTvsCTRL   0.5714286 0.6065123  0.1740595 1.8759711 0.3561748
ARR_TRTvsCTRL -0.1076555 0.1193098 -0.3414984 0.1261874 0.3668873


$Region_Northamerica$Vomiting
$Region_Northamerica$Vomiting$ntab
            CTRL TRT
n_all         22  38
n_event        6   8
n_event_pct   27  21

$Region_Northamerica$Vomiting$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.77192982 0.4689311  0.3079094 1.9352303 0.5809313
OR_TRTvsCTRL   0.71111111 0.6224950  0.2099272 2.4088300 0.5839133
ARR_TRTvsCTRL -0.06220096 0.1157134 -0.2889951 0.1645932 0.5908924



$Disdur_greater_12wk
$Disdur_greater_12wk$`Acute respiratory failure`
$Disdur_greater_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         23  46
n_event        5   7
n_event_pct   22  15

$Disdur_greater_12wk$`Acute respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.70000000 0.5269153  0.2492223 1.9661162 0.4984622
OR_TRTvsCTRL   0.64615385 0.6511941  0.1803178 2.3154390 0.5024491
ARR_TRTvsCTRL -0.06521739 0.1010038 -0.2631813 0.1327465 0.5184787


$Disdur_greater_12wk$Atelectasis
$Disdur_greater_12wk$Atelectasis$ntab
            CTRL TRT
n_all         23  46
n_event        7   8
n_event_pct   30  17

$Disdur_greater_12wk$Atelectasis$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5714286 0.4501553  0.2364771 1.3808128 0.2138082
OR_TRTvsCTRL   0.4812030 0.5972210  0.1492701 1.5512571 0.2206571
ARR_TRTvsCTRL -0.1304348 0.1110335 -0.3480564 0.0871868 0.2401011


$Disdur_greater_12wk$Bradycardia
$Disdur_greater_12wk$Bradycardia$ntab
            CTRL TRT
n_all         23  46
n_event        3   3
```

```
n_event_pct   13   7

$Disdur_greater_12wk$Bradycardia$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 0.77553161  0.10935441 2.28614465 0.3714448
OR_TRTvsCTRL   0.46511628 0.86018747  0.08617249 2.51046656 0.3735277
ARR_TRTvsCTRL -0.06521739 0.07909916 -0.22024891 0.08981412 0.4096546


$Disdur_greater_12wk$`Bronchial secretion retention`
$Disdur_greater_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         23  46
n_event        3   2
n_event_pct   13   4

$Disdur_greater_12wk$`Bronchial secretion retention`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.33333333 0.87642224  0.05982281 1.85733699 0.2100167
OR_TRTvsCTRL   0.30303030 0.95187216  0.04690844 1.95758717 0.2097371
ARR_TRTvsCTRL -0.08695652 0.07639016 -0.23667848 0.06276544 0.2549865


$Disdur_greater_12wk$Bronchiolitis
$Disdur_greater_12wk$Bronchiolitis$ntab
            CTRL TRT
n_all         23  46
n_event        2   5
n_event_pct    9  11

$Disdur_greater_12wk$Bronchiolitis$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.25000000 0.79673246  0.2622588 5.9578547 0.7794212
OR_TRTvsCTRL  1.28048780 0.87864059  0.2288101 7.1659814 0.7784109
ARR_TRTvsCTRL 0.02173913 0.07455244 -0.1243810 0.1678592 0.7705962


$Disdur_greater_12wk$Constipation
$Disdur_greater_12wk$Constipation$ntab
            CTRL TRT
n_all         23  46
n_event        6  19
n_event_pct   26  41

$Disdur_greater_12wk$Constipation$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.5833333 0.3925313  0.73358268 3.4173986 0.2417236
OR_TRTvsCTRL  1.9938272 0.5613901  0.66348546 5.9916109 0.2190000
ARR_TRTvsCTRL 0.1521739 0.1168492 -0.07684631 0.3811941 0.1928103


$Disdur_greater_12wk$Cough
$Disdur_greater_12wk$Cough$ntab
            CTRL TRT
```

```
n_all         23  46
n_event        4   4
n_event_pct   17   9

$Disdur_greater_12wk$Cough$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 0.65938047  0.1373107 1.82068863 0.2931623
OR_TRTvsCTRL   0.45238095 0.75923718  0.1021505 2.00340233 0.2961278
ARR_TRTvsCTRL -0.08695652 0.08928821 -0.2619582 0.08804515 0.3301132


$Disdur_greater_12wk$Diarrhoea
$Disdur_greater_12wk$Diarrhoea$ntab
            CTRL TRT
n_all         23  46
n_event        2   7
n_event_pct    9  15

$Disdur_greater_12wk$Diarrhoea$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.75000000 0.76002615  0.39455052 7.7619972 0.4615413
OR_TRTvsCTRL  1.88461538 0.84623709  0.35884295 9.8978542 0.4539340
ARR_TRTvsCTRL 0.06521739 0.07909916 -0.08981412 0.2202489 0.4096546


$Disdur_greater_12wk$Dysphagia
$Disdur_greater_12wk$Dysphagia$ntab
            CTRL TRT
n_all         23  46
n_event        6   6
n_event_pct   26  13

$Disdur_greater_12wk$Dysphagia$stats
                 estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5000000 0.5177991  0.1812252 1.37949911 0.1806876
OR_TRTvsCTRL   0.4250000 0.6458768  0.1198444 1.50716317 0.1852331
ARR_TRTvsCTRL -0.1304348 0.1041586 -0.3345819 0.07371236 0.2104713


$Disdur_greater_12wk$Dyspnoea
$Disdur_greater_12wk$Dyspnoea$ntab
            CTRL TRT
n_all         23  46
n_event        2   7
n_event_pct    9  15

$Disdur_greater_12wk$Dyspnoea$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.75000000 0.76002615  0.39455052 7.7619972 0.4615413
OR_TRTvsCTRL  1.88461538 0.84623709  0.35884295 9.8978542 0.4539340
ARR_TRTvsCTRL 0.06521739 0.07909916 -0.08981412 0.2202489 0.4096546


$Disdur_greater_12wk$`Gastrooesophageal reflux disease`
```

```
$Disdur_greater_12wk$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         23  46
n_event        4   8
n_event_pct   17  17

$Disdur_greater_12wk$`Gastrooesophageal reflux disease`$stats
              estimate         se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.55658118  0.3359211 2.9768898      1
OR_TRTvsCTRL         1 0.67375616  0.2669917 3.7454352      1
ARR_TRTvsCTRL        0 0.09679673 -0.1897181 0.1897181      1


$Disdur_greater_12wk$Hypoxia
$Disdur_greater_12wk$Hypoxia$ntab
            CTRL TRT
n_all         23  46
n_event        0   6
n_event_pct    0  13

$Disdur_greater_12wk$Hypoxia$stats
               estimate         se     lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  6.6382979 1.44599547 0.39014241 112.9510596 0.190523219
OR_TRTvsCTRL  7.5432099 1.49033241 0.40642736 140.0004533 0.175151041
ARR_TRTvsCTRL 0.1304348 0.04965567 0.03311145   0.2277581 0.008619575


$Disdur_greater_12wk$Nasopharyngitis
$Disdur_greater_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all         23  46
n_event        2   6
n_event_pct    9  13

$Disdur_greater_12wk$Nasopharyngitis$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.50000000 0.77553161  0.3280632 6.8584340 0.6010980
OR_TRTvsCTRL  1.57500000 0.85981726  0.2920134 8.4949012 0.5972800
ARR_TRTvsCTRL 0.04347826 0.07692624 -0.1072944 0.1942509 0.5719417


$Disdur_greater_12wk$`Oral candidiasis`
$Disdur_greater_12wk$`Oral candidiasis`$ntab
            CTRL TRT
n_all         23  46
n_event        1   6
n_event_pct    4  13

$Disdur_greater_12wk$`Oral candidiasis`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.00000000 1.04949954  0.3835179 23.4669625 0.2951935
OR_TRTvsCTRL  3.30000000 1.11225951  0.3730413 29.1924772 0.2830824
ARR_TRTvsCTRL 0.08695652 0.06537473 -0.0411756  0.2150886 0.1834773
```

```
$Disdur_greater_12wk$`Oxygen saturation decreased`
$Disdur_greater_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         23  46
n_event        5   7
n_event_pct   22  15

$Disdur_greater_12wk$`Oxygen saturation decreased`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.70000000 0.5269153  0.2492223 1.9661162 0.4984622
OR_TRTvsCTRL   0.64615385 0.6511941  0.1803178 2.3154390 0.5024491
ARR_TRTvsCTRL -0.06521739 0.1010038 -0.2631813 0.1327465 0.5184787


$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$ntab
            CTRL TRT
n_all         23  46
n_event        4  14
n_event_pct   17  30

$Disdur_greater_12wk$Pneumonia$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.7500000 0.5061731  0.64890743 4.7194713 0.2689075
OR_TRTvsCTRL  2.0781250 0.6366397  0.59670949 7.2373636 0.2505774
ARR_TRTvsCTRL 0.1304348 0.1041586 -0.07371236 0.3345819 0.2104713


$Disdur_greater_12wk$`Pneumonia aspiration`
$Disdur_greater_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         23  46
n_event        3   5
n_event_pct   13  11

$Disdur_greater_12wk$`Pneumonia aspiration`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83333333 0.68418999  0.2179893 3.1856813 0.7898711
OR_TRTvsCTRL   0.81300813 0.77956628  0.1764115 3.7468206 0.7905855
ARR_TRTvsCTRL -0.02173913 0.08388968 -0.1861599 0.1426816 0.7955276


$Disdur_greater_12wk$`Pneumonia viral`
$Disdur_greater_12wk$`Pneumonia viral`$ntab
            CTRL TRT
n_all         23  46
n_event        2   6
n_event_pct    9  13

$Disdur_greater_12wk$`Pneumonia viral`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.50000000 0.77553161  0.3280632 6.8584340 0.6010980
OR_TRTvsCTRL  1.57500000 0.85981726  0.2920134 8.4949012 0.5972800
```

```
ARR_TRTvsCTRL 0.04347826 0.07692624 -0.1072944 0.1942509 0.5719417


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$ntab
            CTRL TRT
n_all         23  46
n_event       15  25
n_event_pct   65  54

$Disdur_greater_12wk$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8333333 0.2035910  0.5591416 1.2419831 0.3705045
OR_TRTvsCTRL   0.6349206 0.5284749  0.2253621 1.7887848 0.3900323
ARR_TRTvsCTRL -0.1086957 0.1235169 -0.3507844 0.1333931 0.3788560


$Disdur_greater_12wk$Rash
$Disdur_greater_12wk$Rash$ntab
            CTRL TRT
n_all         23  46
n_event        2   6
n_event_pct    9  13

$Disdur_greater_12wk$Rash$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.50000000 0.77553161  0.3280632 6.8584340 0.6010980
OR_TRTvsCTRL  1.57500000 0.85981726  0.2920134 8.4949012 0.5972800
ARR_TRTvsCTRL 0.04347826 0.07692624 -0.1072944 0.1942509 0.5719417


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         23  46
n_event        7  13
n_event_pct   30  28

$Disdur_greater_12wk$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92857143 0.3931448  0.4297045 2.0065998 0.8504844
OR_TRTvsCTRL   0.90043290 0.5590915  0.3009898 2.6937101 0.8511985
ARR_TRTvsCTRL -0.02173913 0.1166732 -0.2504144 0.2069362 0.8521900


$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         23  46
n_event        9  11
n_event_pct   39  24

$Disdur_greater_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.6111111 0.3698686  0.2959971 1.26169080 0.1830278
OR_TRTvsCTRL   0.4888889 0.5495636  0.1665025 1.43548808 0.1928615
ARR_TRTvsCTRL -0.1521739 0.1196296 -0.3866437 0.08229588 0.2033583


$Disdur_greater_12wk$`Respiratory tract congestion`
$Disdur_greater_12wk$`Respiratory tract congestion`$ntab
            CTRL TRT
n_all         23  46
n_event        3   1
n_event_pct   13   2

$Disdur_greater_12wk$`Respiratory tract congestion`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1666667 1.12610654  0.01833602 1.5149293 0.1115848
OR_TRTvsCTRL   0.1481481 1.18556128  0.01450590 1.5130310 0.1072527
ARR_TRTvsCTRL -0.1086957 0.07344173 -0.25263880 0.0352475 0.1388664


$Disdur_greater_12wk$Rhinitis
$Disdur_greater_12wk$Rhinitis$ntab
            CTRL TRT
n_all         23  46
n_event        3   0
n_event_pct   13   0

$Disdur_greater_12wk$Rhinitis$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.07294833 1.49089605  0.003926109 1.355402742 0.07908950
OR_TRTvsCTRL   0.06298003 1.53492676  0.003109359 1.275659867 0.07164801
ARR_TRTvsCTRL -0.13043478 0.07022373 -0.268070757 0.007201192 0.06325177


$Disdur_greater_12wk$`Rhinovirus infection`
$Disdur_greater_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         23  46
n_event        4   8
n_event_pct   17  17

$Disdur_greater_12wk$`Rhinovirus infection`$stats
              estimate         se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.55658118  0.3359211 2.9768898      1
OR_TRTvsCTRL         1 0.67375616  0.2669917 3.7454352      1
ARR_TRTvsCTRL        0 0.09679673 -0.1897181 0.1897181      1


$Disdur_greater_12wk$Tachycardia
$Disdur_greater_12wk$Tachycardia$ntab
            CTRL TRT
n_all         23  46
n_event        3   5
n_event_pct   13  11
```

```
$Disdur_greater_12wk$Tachycardia$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83333333 0.68418999  0.2179893 3.1856813 0.7898711
OR_TRTvsCTRL   0.81300813 0.77956628  0.1764115 3.7468206 0.7905855
ARR_TRTvsCTRL -0.02173913 0.08388968 -0.1861599 0.1426816 0.7955276


$Disdur_greater_12wk$Teething
$Disdur_greater_12wk$Teething$ntab
            CTRL TRT
n_all         23  46
n_event        1   9
n_event_pct    4  20

$Disdur_greater_12wk$Teething$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.5000000 1.02268945 0.60631411 33.3985302 0.14137015
OR_TRTvsCTRL  5.3513514 1.08793046 0.63447627 45.1348031 0.12312713
ARR_TRTvsCTRL 0.1521739 0.07231396 0.01044116  0.2939067 0.03534789


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         23  46
n_event        3  17
n_event_pct   13  37

$Disdur_greater_12wk$`Upper respiratory tract infection`$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.8333333 0.57178621 0.92383065  8.6896638 0.06854542
OR_TRTvsCTRL  3.9080460 0.69039092 1.00994529 15.1224264 0.04834785
ARR_TRTvsCTRL 0.2391304 0.09998151 0.04317028  0.4350906 0.01676841


$Disdur_greater_12wk$`Urinary tract infection`
$Disdur_greater_12wk$`Urinary tract infection`$ntab
            CTRL TRT
n_all         23  46
n_event        0   6
n_event_pct    0  13

$Disdur_greater_12wk$`Urinary tract infection`$stats
               estimate         se     lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  6.6382979 1.44599547 0.39014241 112.9510596 0.190523219
OR_TRTvsCTRL  7.5432099 1.49033241 0.40642736 140.0004533 0.175151041
ARR_TRTvsCTRL 0.1304348 0.04965567 0.03311145   0.2277581 0.008619575


$Disdur_greater_12wk$`Viral upper respiratory tract infection`
$Disdur_greater_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         23  46
n_event        5   4
```

```
n_event_pct   22   9

$Disdur_greater_12wk$`Viral upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4000000 0.62030848  0.11859120 1.34917264 0.1396345
OR_TRTvsCTRL   0.3428571 0.72757479  0.08237595 1.42700662 0.1412246
ARR_TRTvsCTRL -0.1304348 0.09551459 -0.31763995 0.05677038 0.1720644


$Disdur_greater_12wk$Vomiting
$Disdur_greater_12wk$Vomiting$ntab
            CTRL TRT
n_all         23  46
n_event        4   8
n_event_pct   17  17

$Disdur_greater_12wk$Vomiting$stats
              estimate         se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.55658118  0.3359211 2.9768898      1
OR_TRTvsCTRL         1 0.67375616  0.2669917 3.7454352      1
ARR_TRTvsCTRL        0 0.09679673 -0.1897181 0.1897181      1



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Acute respiratory failure`
$Disdur_less_equal_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         18  34
n_event        5   4
n_event_pct   28  12

$Disdur_less_equal_12wk$`Acute respiratory failure`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4235294 0.6041793  0.12960005 1.38408246 0.1550314
OR_TRTvsCTRL   0.3466667 0.7485028  0.07994391 1.50327628 0.1569666
ARR_TRTvsCTRL -0.1601307 0.1191576 -0.39367529 0.07341385 0.1789947


$Disdur_less_equal_12wk$Apnoea
$Disdur_less_equal_12wk$Apnoea$ntab
            CTRL TRT
n_all         18  34
n_event        2   3
n_event_pct   11   9

$Disdur_less_equal_12wk$Apnoea$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.86508151  0.1457223 4.3275646 0.7898725
OR_TRTvsCTRL   0.77419355 0.96337500  0.1171718 5.1153557 0.7904985
ARR_TRTvsCTRL -0.02287582 0.08861794 -0.1965638 0.1508122 0.7962990


$Disdur_less_equal_12wk$Aspiration
```

```
$Disdur_less_equal_12wk$Aspiration$ntab
            CTRL TRT
n_all         18  34
n_event        2   3
n_event_pct   11   9

$Disdur_less_equal_12wk$Aspiration$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.86508151  0.1457223 4.3275646 0.7898725
OR_TRTvsCTRL   0.77419355 0.96337500  0.1171718 5.1153557 0.7904985
ARR_TRTvsCTRL -0.02287582 0.08861794 -0.1965638 0.1508122 0.7962990


$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         18  34
n_event        5  10
n_event_pct   28  29

$Disdur_less_equal_12wk$Atelectasis$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.05882353 0.4637162  0.4266853 2.6274805 0.9018999
OR_TRTvsCTRL  1.08333333 0.6469851  0.3048227 3.8501428 0.9015398
ARR_TRTvsCTRL 0.01633987 0.1313455 -0.2410927 0.2737724 0.9009957


$Disdur_less_equal_12wk$`Bacterial tracheitis`
$Disdur_less_equal_12wk$`Bacterial tracheitis`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Bacterial tracheitis`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Bronchial secretion retention`
$Disdur_less_equal_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         18  34
n_event        4   2
n_event_pct   22   6

$Disdur_less_equal_12wk$`Bronchial secretion retention`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2647059 0.8154954  0.05353190 1.30892421 0.10313299
OR_TRTvsCTRL   0.2187500 0.9234060  0.03580498 1.33644977 0.09978616
ARR_TRTvsCTRL -0.1633987 0.1059742 -0.37110428 0.04430689 0.12310455
```

```
$Disdur_less_equal_12wk$Bronchitis
$Disdur_less_equal_12wk$Bronchitis$ntab
            CTRL TRT
n_all         18  34
n_event        1   6
n_event_pct    6  18

$Disdur_less_equal_12wk$Bronchitis$stats
              estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.176471 1.04004776  0.41367053 24.3913084 0.2664535
OR_TRTvsCTRL  3.642857 1.12303361  0.40319413 32.9131978 0.2496749
ARR_TRTvsCTRL 0.120915 0.08478989 -0.04527011  0.2871002 0.1538525


$Disdur_less_equal_12wk$`Bronchitis viral`
$Disdur_less_equal_12wk$`Bronchitis viral`$ntab
            CTRL TRT
n_all         18  34
n_event        0   4
n_event_pct    0  12

$Disdur_less_equal_12wk$`Bronchitis viral`$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.8857143 1.46322220 0.277607419  85.985469 0.27830946
OR_TRTvsCTRL  5.4590164 1.51956019 0.277755343 107.291761 0.26401687
ARR_TRTvsCTRL 0.1176471 0.05525508 0.009349083   0.225945 0.03324081


$Disdur_less_equal_12wk$`Candida infection`
$Disdur_less_equal_12wk$`Candida infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Candida infection`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Cardio-respiratory arrest`
$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         18  34
n_event        3   1
n_event_pct   17   3

$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1764706 1.1173030  0.01975251 1.5766031 0.1205452
OR_TRTvsCTRL   0.1515152 1.1959528  0.01453648 1.5792574 0.1145932
```

```
ARR_TRTvsCTRL -0.1372549 0.0924968 -0.31854530 0.0440355 0.1378386


$Disdur_less_equal_12wk$Constipation
$Disdur_less_equal_12wk$Constipation$ntab
            CTRL TRT
n_all         18  34
n_event        3   9
n_event_pct   17  26

$Disdur_less_equal_12wk$Constipation$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.58823529 0.5995641  0.4904164 5.1435710 0.4403515
OR_TRTvsCTRL  1.80000000 0.7423686  0.4201141 7.7121912 0.4284936
ARR_TRTvsCTRL 0.09803922 0.1159338 -0.1291870 0.3252654 0.3977492


$Disdur_less_equal_12wk$`Corona virus infection`
$Disdur_less_equal_12wk$`Corona virus infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Corona virus infection`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$Cough
$Disdur_less_equal_12wk$Cough$ntab
            CTRL TRT
n_all         18  34
n_event        4   5
n_event_pct   22  15

$Disdur_less_equal_12wk$Cough$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6617647 0.6041793  0.2025001 2.1626288 0.4944074
OR_TRTvsCTRL   0.6034483 0.7455946  0.1399551 2.6019044 0.4981274
ARR_TRTvsCTRL -0.0751634 0.1152883 -0.3011243 0.1507975 0.5144267


$Disdur_less_equal_12wk$Cyanosis
$Disdur_less_equal_12wk$Cyanosis$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$Cyanosis$stats
                 estimate         se       lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Decubitus ulcer`
$Disdur_less_equal_12wk$`Decubitus ulcer`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Decubitus ulcer`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Dermatitis contact`
$Disdur_less_equal_12wk$`Dermatitis contact`$ntab
            CTRL TRT
n_all         18  34
n_event        3   1
n_event_pct   17   3

$Disdur_less_equal_12wk$`Dermatitis contact`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1764706 1.1173030  0.01975251 1.5766031 0.1205452
OR_TRTvsCTRL   0.1515152 1.1959528  0.01453648 1.5792574 0.1145932
ARR_TRTvsCTRL -0.1372549 0.0924968 -0.31854530 0.0440355 0.1378386


$Disdur_less_equal_12wk$`Dermatitis diaper`
$Disdur_less_equal_12wk$`Dermatitis diaper`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Dermatitis diaper`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$Diarrhoea
$Disdur_less_equal_12wk$Diarrhoea$ntab
            CTRL TRT
n_all         18  34
n_event        5   4
n_event_pct   28  12
```

```
$Disdur_less_equal_12wk$Diarrhoea$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4235294 0.6041793  0.12960005 1.38408246 0.1550314
OR_TRTvsCTRL   0.3466667 0.7485028  0.07994391 1.50327628 0.1569666
ARR_TRTvsCTRL -0.1601307 0.1191576 -0.39367529 0.07341385 0.1789947


$Disdur_less_equal_12wk$Dysphagia
$Disdur_less_equal_12wk$Dysphagia$ntab
            CTRL TRT
n_all         18  34
n_event        3   3
n_event_pct   17   9

$Disdur_less_equal_12wk$Dysphagia$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.7626922  0.11873776 2.3604692 0.4043523
OR_TRTvsCTRL   0.48387097 0.8749808  0.08708524 2.6885280 0.4067308
ARR_TRTvsCTRL -0.07843137 0.1004103 -0.27523187 0.1183691 0.4347383


$Disdur_less_equal_12wk$Dyspnoea
$Disdur_less_equal_12wk$Dyspnoea$ntab
            CTRL TRT
n_all         18  34
n_event        4   0
n_event_pct   22   0

$Disdur_less_equal_12wk$Dyspnoea$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06031746 1.46322220  0.003427252  1.0615490 0.05496615
OR_TRTvsCTRL   0.04669887 1.52321149  0.002359100  0.9244137 0.04426607
ARR_TRTvsCTRL -0.22222222 0.09799079 -0.414280640 -0.0301638 0.02334220


$Disdur_less_equal_12wk$Erythema
$Disdur_less_equal_12wk$Erythema$ntab
            CTRL TRT
n_all         18  34
n_event        3   1
n_event_pct   17   3

$Disdur_less_equal_12wk$Erythema$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1764706 1.1173030  0.01975251 1.5766031 0.1205452
OR_TRTvsCTRL   0.1515152 1.1959528  0.01453648 1.5792574 0.1145932
ARR_TRTvsCTRL -0.1372549 0.0924968 -0.31854530 0.0440355 0.1378386


$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`
$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
```

```
n_event_pct   11   6

$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$`Gastrooesophageal reflux disease`
$Disdur_less_equal_12wk$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         18  34
n_event        4   2
n_event_pct   22   6

$Disdur_less_equal_12wk$`Gastrooesophageal reflux disease`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2647059 0.8154954  0.05353190 1.30892421 0.10313299
OR_TRTvsCTRL   0.2187500 0.9234060  0.03580498 1.33644977 0.09978616
ARR_TRTvsCTRL -0.1633987 0.1059742 -0.37110428 0.04430689 0.12310455


$Disdur_less_equal_12wk$Hypokalaemia
$Disdur_less_equal_12wk$Hypokalaemia$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$Hypokalaemia$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$Hypoxia
$Disdur_less_equal_12wk$Hypoxia$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3

$Disdur_less_equal_12wk$Hypoxia$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495


$Disdur_less_equal_12wk$`Nasal congestion`
$Disdur_less_equal_12wk$`Nasal congestion`$ntab
            CTRL TRT
```

```
n_all         18  34
n_event        3   4
n_event_pct   17  12

$Disdur_less_equal_12wk$`Nasal congestion`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.70588235 0.7059504  0.1769401 2.8160374 0.6217392
OR_TRTvsCTRL   0.66666667 0.8266398  0.1319082 3.3693475 0.6237816
ARR_TRTvsCTRL -0.04901961 0.1037746 -0.2524141 0.1543749 0.6366656


$Disdur_less_equal_12wk$Nasopharyngitis
$Disdur_less_equal_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all         18  34
n_event        2   9
n_event_pct   11  26

$Disdur_less_equal_12wk$Nasopharyngitis$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.3823529 0.7253577  0.57488438  9.872603 0.2313950
OR_TRTvsCTRL  2.8800000 0.8447551  0.54996579 15.081665 0.2105022
ARR_TRTvsCTRL 0.1535948 0.1058847 -0.05393549  0.361125 0.1468955


$Disdur_less_equal_12wk$Oedema
$Disdur_less_equal_12wk$Oedema$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$Oedema$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Oral candidiasis`
$Disdur_less_equal_12wk$`Oral candidiasis`$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3

$Disdur_less_equal_12wk$`Oral candidiasis`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495


$Disdur_less_equal_12wk$`Oxygen saturation decreased`
```

```
$Disdur_less_equal_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         18  34
n_event        5   3
n_event_pct   28   9

$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3176471 0.6696014  0.08550256 1.18007761 0.08677102
OR_TRTvsCTRL   0.2516129 0.8015700  0.05229200 1.21068325 0.08516902
ARR_TRTvsCTRL -0.1895425 0.1162393 -0.41736734 0.03828237 0.10296989


$Disdur_less_equal_12wk$Pneumonia
$Disdur_less_equal_12wk$Pneumonia$ntab
            CTRL TRT
n_all         18  34
n_event        3   9
n_event_pct   17  26

$Disdur_less_equal_12wk$Pneumonia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.58823529 0.5995641  0.4904164 5.1435710 0.4403515
OR_TRTvsCTRL  1.80000000 0.7423686  0.4201141 7.7121912 0.4284936
ARR_TRTvsCTRL 0.09803922 0.1159338 -0.1291870 0.3252654 0.3977492


$Disdur_less_equal_12wk$`Pneumonia aspiration`
$Disdur_less_equal_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         18  34
n_event        4   4
n_event_pct   22  12

$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5294118 0.6442303  0.1497696 1.8713862 0.3235411
OR_TRTvsCTRL   0.4666667 0.7776644  0.1016384 2.1426731 0.3270677
ARR_TRTvsCTRL -0.1045752 0.1124959 -0.3250630 0.1159127 0.3525828


$Disdur_less_equal_12wk$`Pneumonia bacterial`
$Disdur_less_equal_12wk$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Pneumonia bacterial`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422
```

```
$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         18  34
n_event        9  20
n_event_pct   50  59

$Disdur_less_equal_12wk$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.17647059 0.2759416  0.6850135 2.0205194 0.5558873
OR_TRTvsCTRL  1.42857143 0.5862174  0.4528067 4.5070366 0.5428992
ARR_TRTvsCTRL 0.08823529 0.1449581 -0.1958773 0.3723479 0.5427265


$Disdur_less_equal_12wk$Rash
$Disdur_less_equal_12wk$Rash$ntab
            CTRL TRT
n_all         18  34
n_event        2   3
n_event_pct   11   9

$Disdur_less_equal_12wk$Rash$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.86508151  0.1457223 4.3275646 0.7898725
OR_TRTvsCTRL   0.77419355 0.96337500  0.1171718 5.1153557 0.7904985
ARR_TRTvsCTRL -0.02287582 0.08861794 -0.1965638 0.1508122 0.7962990


$Disdur_less_equal_12wk$`Respiratory arrest`
$Disdur_less_equal_12wk$`Respiratory arrest`$ntab
            CTRL TRT
n_all         18  34
n_event        3   2
n_event_pct   17   6

$Disdur_less_equal_12wk$`Respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3529412 0.86508151  0.06476548 1.92336205 0.2286362
OR_TRTvsCTRL   0.3125000 0.96501295  0.04714433 2.07143131 0.2280792
ARR_TRTvsCTRL -0.1078431 0.09666635 -0.29730569 0.08161942 0.2645838


$Disdur_less_equal_12wk$`Respiratory distress`
$Disdur_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         18  34
n_event        5   8
n_event_pct   28  24

$Disdur_less_equal_12wk$`Respiratory distress`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.84705882 0.4899313  0.3242525 2.2128086 0.7347659
OR_TRTvsCTRL   0.80000000 0.6636148  0.2178813 2.9373787 0.7366789
```

```
ARR_TRTvsCTRL -0.04248366 0.1282088 -0.2937682 0.2088009 0.7403702


$Disdur_less_equal_12wk$`Respiratory failure`
$Disdur_less_equal_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         18  34
n_event        7   9
n_event_pct   39  26

$Disdur_less_equal_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6806723 0.4110972  0.3040965 1.5235779 0.3494143
OR_TRTvsCTRL   0.5657143 0.6203848  0.1676967 1.9084012 0.3584899
ARR_TRTvsCTRL -0.1241830 0.1375777 -0.3938304 0.1454643 0.3667175


$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`
$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$`Respiratory tract infection`
$Disdur_less_equal_12wk$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         18  34
n_event        1   5
n_event_pct    6  15

$Disdur_less_equal_12wk$`Respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.64705882 1.05595108  0.33414611 20.9696306 0.3565966
OR_TRTvsCTRL  2.93103448 1.13723625  0.31550313 27.2294067 0.3443595
ARR_TRTvsCTRL 0.09150327 0.08126588 -0.06777494  0.2507815 0.2601765


$Disdur_less_equal_12wk$`Rhinovirus infection`
$Disdur_less_equal_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Rhinovirus infection`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$`Sleep apnoea syndrome`
$Disdur_less_equal_12wk$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all         18  34
n_event        3   0
n_event_pct   17   0

$Disdur_less_equal_12wk$`Sleep apnoea syndrome`$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.07755102 1.48475967  0.004224330 1.42369592 0.08506182
OR_TRTvsCTRL   0.06418219 1.54247072  0.003122203 1.31937430 0.07503018
ARR_TRTvsCTRL -0.16666667 0.08784105 -0.338831953 0.00549862 0.05777957


$Disdur_less_equal_12wk$`Staphylococcal infection`
$Disdur_less_equal_12wk$`Staphylococcal infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Staphylococcal infection`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Stoma site erythema`
$Disdur_less_equal_12wk$`Stoma site erythema`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Stoma site erythema`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Stoma site infection`
$Disdur_less_equal_12wk$`Stoma site infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0
```

```
$Disdur_less_equal_12wk$`Stoma site infection`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$Tachycardia
$Disdur_less_equal_12wk$Tachycardia$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$Tachycardia$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$Teething
$Disdur_less_equal_12wk$Teething$ntab
            CTRL TRT
n_all         18  34
n_event        2   5
n_event_pct   11  15

$Disdur_less_equal_12wk$Teething$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.32352941 0.78424019  0.2845687 6.1557370 0.7207785
OR_TRTvsCTRL  1.37931034 0.89273891  0.2397515 7.9352887 0.7186816
ARR_TRTvsCTRL 0.03594771 0.09579228 -0.1518017 0.2236971 0.7074617


$Disdur_less_equal_12wk$`Upper respiratory tract congestion`
$Disdur_less_equal_12wk$`Upper respiratory tract congestion`$ntab
            CTRL TRT
n_all         18  34
n_event        1   4
n_event_pct    6  12

$Disdur_less_equal_12wk$`Upper respiratory tract congestion`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.1176471 1.07936680  0.25532592 17.5635484 0.4869707
OR_TRTvsCTRL  2.2666667 1.15851494  0.23402268 21.9541871 0.4799741
ARR_TRTvsCTRL 0.0620915 0.07725333 -0.08932223  0.2135052 0.4215478


$Disdur_less_equal_12wk$`Upper respiratory tract infection`
$Disdur_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         18  34
n_event        6   7
```

```
n_event_pct   33  21

$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6176471 0.4738739  0.2439935 1.5635169 0.3092455
OR_TRTvsCTRL   0.5185185 0.6556632  0.1434375 1.8744151 0.3164872
ARR_TRTvsCTRL -0.1274510 0.1309746 -0.3841565 0.1292545 0.3305052


$Disdur_less_equal_12wk$`Viral infection`
$Disdur_less_equal_12wk$`Viral infection`$ntab
            CTRL TRT
n_all         18  34
n_event        1   5
n_event_pct    6  15

$Disdur_less_equal_12wk$`Viral infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.64705882 1.05595108  0.33414611 20.9696306 0.3565966
OR_TRTvsCTRL  2.93103448 1.13723625  0.31550313 27.2294067 0.3443595
ARR_TRTvsCTRL 0.09150327 0.08126588 -0.06777494  0.2507815 0.2601765


$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`
$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   4
n_event_pct   11  12

$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 0.81549536  0.2141276 5.2356968 0.9441217
OR_TRTvsCTRL  1.066666667 0.91969198  0.1758675 6.4695184 0.9440551
ARR_TRTvsCTRL 0.006535948 0.09241262 -0.1745895 0.1876614 0.9436161


$Disdur_less_equal_12wk$Vomiting
$Disdur_less_equal_12wk$Vomiting$ntab
            CTRL TRT
n_all         18  34
n_event        4   6
n_event_pct   22  18

$Disdur_less_equal_12wk$Vomiting$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.5759335  0.2568322 2.4553889 0.6889643
OR_TRTvsCTRL   0.75000000 0.7237469  0.1815544 3.0982447 0.6910062
ARR_TRTvsCTRL -0.04575163 0.1177988 -0.2766331 0.1851299 0.6977291



$Region_Asia_Pacific
$Region_Asia_Pacific$Amblyopia
```

```
$Region_Asia_Pacific$Amblyopia$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$Amblyopia$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$Bronchiolitis
$Region_Asia_Pacific$Bronchiolitis$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$Bronchiolitis$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353


$Region_Asia_Pacific$Conjunctivitis
$Region_Asia_Pacific$Conjunctivitis$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$Conjunctivitis$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353


$Region_Asia_Pacific$Constipation
$Region_Asia_Pacific$Constipation$ntab
            CTRL TRT
n_all          2  12
n_event        0   5
n_event_pct    0  42

$Region_Asia_Pacific$Constipation$stats
               estimate        se    lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  2.5384615 1.3310003 0.1869051 34.4762553 0.483993933
OR_TRTvsCTRL  3.6666667 1.6477717 0.1451061 92.6525185 0.430398971
ARR_TRTvsCTRL 0.4166667 0.1423188 0.1377270  0.6956063 0.003414791
```

```
$Region_Asia_Pacific$Dyspnoea
$Region_Asia_Pacific$Dyspnoea$ntab
            CTRL TRT
n_all          2  12
n_event        0   3
n_event_pct    0  25

$Region_Asia_Pacific$Dyspnoea$stats
              estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.615385 1.369474 0.110300612 23.6577786 0.72619768
OR_TRTvsCTRL  1.842105 1.670622 0.069707343 48.6799765 0.71460562
ARR_TRTvsCTRL 0.250000 0.125000 0.005004502  0.4949955 0.04550026


$Region_Asia_Pacific$Erythema
$Region_Asia_Pacific$Erythema$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$Erythema$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$`Gastrooesophageal reflux disease`
$Region_Asia_Pacific$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Gastrooesophageal reflux disease`$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$Influenza
$Region_Asia_Pacific$Influenza$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$Influenza$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
```

```
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353


$Region_Asia_Pacific$Nasopharyngitis
$Region_Asia_Pacific$Nasopharyngitis$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$Nasopharyngitis$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353


$Region_Asia_Pacific$Nystagmus
$Region_Asia_Pacific$Nystagmus$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$Nystagmus$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$Oedema
$Region_Asia_Pacific$Oedema$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$Oedema$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$Pneumonia
$Region_Asia_Pacific$Pneumonia$ntab
            CTRL TRT
n_all          2  12
n_event        0   5
n_event_pct    0  42

$Region_Asia_Pacific$Pneumonia$stats
               estimate        se    lo95ci     hi95ci      pvalue
```

```
RR_TRTvsCTRL  2.5384615 1.3310003 0.1869051 34.4762553 0.483993933
OR_TRTvsCTRL  3.6666667 1.6477717 0.1451061 92.6525185 0.430398971
ARR_TRTvsCTRL 0.4166667 0.1423188 0.1377270  0.6956063 0.003414791


$Region_Asia_Pacific$Pyrexia
$Region_Asia_Pacific$Pyrexia$ntab
            CTRL TRT
n_all          2  12
n_event        1   4
n_event_pct   50  33

$Region_Asia_Pacific$Pyrexia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6666667 0.8164966  0.13455678  3.3030252 0.6194773
OR_TRTvsCTRL   0.5000000 1.5411035  0.02438823 10.2508454 0.6528739
ARR_TRTvsCTRL -0.1666667 0.3788384 -0.90917625  0.5758429 0.6599796


$Region_Asia_Pacific$`Respiratory failure`
$Region_Asia_Pacific$`Respiratory failure`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Respiratory failure`$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$`Stoma site erythema`
$Region_Asia_Pacific$`Stoma site erythema`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Stoma site erythema`$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$Strabismus
$Region_Asia_Pacific$Strabismus$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0
```

```
$Region_Asia_Pacific$Strabismus$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$Teething
$Region_Asia_Pacific$Teething$ntab
            CTRL TRT
n_all          2  12
n_event        0   3
n_event_pct    0  25

$Region_Asia_Pacific$Teething$stats
              estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.615385 1.369474 0.110300612 23.6577786 0.72619768
OR_TRTvsCTRL  1.842105 1.670622 0.069707343 48.6799765 0.71460562
ARR_TRTvsCTRL 0.250000 0.125000 0.005004502  0.4949955 0.04550026


$Region_Asia_Pacific$`Upper respiratory tract infection`
$Region_Asia_Pacific$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all          2  12
n_event        0   3
n_event_pct    0  25

$Region_Asia_Pacific$`Upper respiratory tract infection`$stats
              estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.615385 1.369474 0.110300612 23.6577786 0.72619768
OR_TRTvsCTRL  1.842105 1.670622 0.069707343 48.6799765 0.71460562
ARR_TRTvsCTRL 0.250000 0.125000 0.005004502  0.4949955 0.04550026


$Region_Asia_Pacific$`Urinary tract infection`
$Region_Asia_Pacific$`Urinary tract infection`$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$`Urinary tract infection`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem UE nach PT, das bei mindestens 10 Patienten
```

```
und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event        8  10
n_event_pct   25  14

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5555556 0.42410035  0.2419539 1.27562309 0.1657587
OR_TRTvsCTRL   0.4838710 0.53178539  0.1706369 1.37210109 0.1722235
ARR_TRTvsCTRL -0.1111111 0.08672064 -0.2810804 0.05885822 0.2001047


$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         32  72
n_event       11  18
n_event_pct   34  25

$Ageonset_less_equal_12wk$Atelectasis$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7272727 0.31831707  0.3897134 1.35721698 0.3171028
OR_TRTvsCTRL   0.6363636 0.46108807  0.2577665 1.57102912 0.3269589
ARR_TRTvsCTRL -0.0937500 0.09825338 -0.2863231 0.09882309 0.3399998


$Ageonset_less_equal_12wk$Constipation
$Ageonset_less_equal_12wk$Constipation$ntab
            CTRL TRT
n_all         32  72
n_event        8  25
n_event_pct   25  35

$Ageonset_less_equal_12wk$Constipation$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.38888889 0.34620963  0.70464979 2.7375476 0.3426924
OR_TRTvsCTRL  1.59574468 0.47743404  0.62599493 4.0677663 0.3276498
ARR_TRTvsCTRL 0.09722222 0.09490741 -0.08879288 0.2832373 0.3056510


$Ageonset_less_equal_12wk$Diarrhoea
$Ageonset_less_equal_12wk$Diarrhoea$ntab
            CTRL TRT
n_all         32  72
n_event        6  10
n_event_pct   19  14

$Ageonset_less_equal_12wk$Diarrhoea$stats
                estimate         se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.74074074 0.47066737  0.2944648 1.8633697 0.5237243
OR_TRTvsCTRL   0.69892473 0.56679559  0.2301299 2.1226954 0.5273899
ARR_TRTvsCTRL -0.04861111 0.08013636 -0.2056755 0.1084533 0.5441131


$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`
$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         32  72
n_event        5  10
n_event_pct   16  14

$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.50483771  0.3304676 2.3909259 0.8155217
OR_TRTvsCTRL   0.87096774 0.59427777  0.2717390 2.7915938 0.8161748
ARR_TRTvsCTRL -0.01736111 0.07603267 -0.1663824 0.1316602 0.8193839


$Ageonset_less_equal_12wk$Nasopharyngitis
$Ageonset_less_equal_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all         32  72
n_event        1  14
n_event_pct    3  19

$Ageonset_less_equal_12wk$Nasopharyngitis$stats
                estimate         se     lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  6.2222222 1.01305957 0.85433393 45.3172328 0.071143509
OR_TRTvsCTRL  7.4827586 1.05873888 0.93942382 59.6021470 0.057309570
ARR_TRTvsCTRL 0.1631944 0.05587076 0.05368976  0.2726991 0.003489911


$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         32  72
n_event       10  10
n_event_pct   31  14

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats
                 estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.4444444 0.39352397  0.2055177 0.961137868 0.03933279
OR_TRTvsCTRL   0.3548387 0.51145242  0.1302213 0.966896705 0.04278696
ARR_TRTvsCTRL -0.1736111 0.09151481 -0.3529769 0.005754628 0.05781711


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$ntab
            CTRL TRT
n_all         32  72
n_event        6  22
n_event_pct   19  31
```

```
$Ageonset_less_equal_12wk$Pneumonia$stats
               estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.6296296 0.40863471  0.73157427 3.6301068 0.2320542
OR_TRTvsCTRL  1.9066667 0.52017569  0.68786058 5.2850503 0.2147347
ARR_TRTvsCTRL 0.1180556 0.08779433 -0.05401817 0.2901293 0.1787276


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         32  72
n_event       18  41
n_event_pct   56  57

$Ageonset_less_equal_12wk$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.012345679 0.1865661  0.7023013 1.4592651 0.9475625
OR_TRTvsCTRL  1.028673835 0.4285236  0.4441378 2.3825257 0.9474003
ARR_TRTvsCTRL 0.006944444 0.1053360 -0.1995103 0.2133992 0.9474363


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         32  72
n_event       10  20
n_event_pct   31  28

$Ageonset_less_equal_12wk$`Respiratory distress`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.32382265  0.4712042 1.6768176 0.7160619
OR_TRTvsCTRL   0.84615385 0.46334147  0.3412341 2.0981972 0.7184418
ARR_TRTvsCTRL -0.03472222 0.09746906 -0.2257581 0.1563136 0.7216620


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event       15  18
n_event_pct   47  25

$Ageonset_less_equal_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.5333333 0.2776389  0.3095082  0.91902082 0.02356652
OR_TRTvsCTRL   0.3777778 0.4467262  0.1573919  0.90675595 0.02932621
ARR_TRTvsCTRL -0.2187500 0.1019125 -0.4184947 -0.01900525 0.03183709


$Ageonset_less_equal_12wk$Teething
$Ageonset_less_equal_12wk$Teething$ntab
            CTRL TRT
n_all         32  72
n_event        2  12
```

```
n_event_pct    6  17

$Ageonset_less_equal_12wk$Teething$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.6666667 0.73361737  0.63315858 11.2311692 0.18123028
OR_TRTvsCTRL  3.0000000 0.79582243  0.63054484 14.2733703 0.16744070
ARR_TRTvsCTRL 0.1041667 0.06131939 -0.01601712  0.2243505 0.08936519


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        7  23
n_event_pct   22  32

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats
               estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.4603175 0.37576125  0.69919566 3.0499719 0.3135995
OR_TRTvsCTRL  1.6763848 0.49673289  0.63321897 4.4380637 0.2983049
ARR_TRTvsCTRL 0.1006944 0.09143312 -0.07851119 0.2799001 0.2707702


$Ageonset_less_equal_12wk$Vomiting
$Ageonset_less_equal_12wk$Vomiting$ntab
            CTRL TRT
n_all         32  72
n_event        6  12
n_event_pct   19  17

$Ageonset_less_equal_12wk$Vomiting$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.45261585  0.3660835 2.1583148 0.7946884
OR_TRTvsCTRL   0.86666667 0.55238411  0.2935363 2.5588351 0.7955886
ARR_TRTvsCTRL -0.02083333 0.08179092 -0.1811406 0.1394739 0.7989436



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        8  11
n_event_pct   36  29

$Region_Northamerica$`Acute respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79605263 0.3796561  0.3782491 1.6753504 0.5479862
OR_TRTvsCTRL   0.71296296 0.5695390  0.2334933 2.1770052 0.5524891
ARR_TRTvsCTRL -0.07416268 0.1262181 -0.3215456 0.1732202 0.5568171


$Region_Northamerica$Constipation
```

```
$Region_Northamerica$Constipation$ntab
            CTRL TRT
n_all         22  38
n_event        5  17
n_event_pct   23  45

$Region_Northamerica$Constipation$stats
               estimate        se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.9684211 0.4324965  0.84328882 4.5947265 0.11737988
OR_TRTvsCTRL  2.7523810 0.6043725  0.84191015 8.9981109 0.09388801
ARR_TRTvsCTRL 0.2200957 0.1203693 -0.01582381 0.4560152 0.06747403


$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$ntab
            CTRL TRT
n_all         22  38
n_event        4  11
n_event_pct   18  29

$Region_Northamerica$Pneumonia$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.5921053 0.5187858  0.5759443 4.4011188 0.3700211
OR_TRTvsCTRL  1.8333333 0.6584084  0.5044326 6.6631520 0.3572553
ARR_TRTvsCTRL 0.1076555 0.1103378 -0.1086026 0.3239136 0.3292180


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$ntab
            CTRL TRT
n_all         22  38
n_event       13  25
n_event_pct   59  66

$Region_Northamerica$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.11336032 0.2124917  0.7341122 1.6885310 0.6133128
OR_TRTvsCTRL  1.33136095 0.5522294  0.4510631 3.9296538 0.6042727
ARR_TRTvsCTRL 0.06698565 0.1300417 -0.1878915 0.3218628 0.6064770


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$ntab
            CTRL TRT
n_all         22  38
n_event       10  12
n_event_pct   45  32

$Region_Northamerica$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6947368 0.3340105  0.3610024 1.3369974 0.2755144
OR_TRTvsCTRL   0.5538462 0.5523841  0.1875854 1.6352319 0.2847682
ARR_TRTvsCTRL -0.1387560 0.1302140 -0.3939707 0.1164587 0.2866046
```

```
$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        7  11
n_event_pct   32  29

$Region_Northamerica$`Respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90977444 0.4024871  0.4133672 2.0023104 0.8142587
OR_TRTvsCTRL   0.87301587 0.5809216  0.2796023 2.7258599 0.8151642
ARR_TRTvsCTRL -0.02870813 0.1235864 -0.2709331 0.2135168 0.8163112


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        5  20
n_event_pct   23  53

$Region_Northamerica$`Upper respiratory tract infection`$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.3157895 0.4221726 1.01238371  5.2972809 0.04668828
OR_TRTvsCTRL  3.7777778 0.6036382 1.15722720 12.3325868 0.02767413
ARR_TRTvsCTRL 0.2990431 0.1205962 0.06267886  0.5354073 0.01314909



$Agetrt_less_180d
$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$ntab
            CTRL TRT
n_all         16  49
n_event        5  13
n_event_pct   31  27

$Agetrt_less_180d$Atelectasis$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.84897959 0.4404712  0.3580696 2.0129225 0.7101213
OR_TRTvsCTRL   0.79444444 0.6289753  0.2315681 2.7255132 0.7144751
ARR_TRTvsCTRL -0.04719388 0.1319305 -0.3057730 0.2113852 0.7205547


$Agetrt_less_180d$Constipation
$Agetrt_less_180d$Constipation$ntab
            CTRL TRT
n_all         16  49
n_event        5  14
n_event_pct   31  29

$Agetrt_less_180d$Constipation$stats
                 estimate        se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.91428571 0.4341894  0.3903905 2.1412363 0.8364866
OR_TRTvsCTRL   0.88000000 0.6252272  0.2583975 2.9969332 0.8379948
ARR_TRTvsCTRL -0.02678571 0.1326373 -0.2867501 0.2331787 0.8399582


$Agetrt_less_180d$Nasopharyngitis
$Agetrt_less_180d$Nasopharyngitis$ntab
            CTRL TRT
n_all         16  49
n_event        1  13
n_event_pct    6  27

$Agetrt_less_180d$Nasopharyngitis$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.2448980 0.99700297 0.60147391 29.9583381 0.14704076
OR_TRTvsCTRL  5.4166667 1.08229734 0.64935016 45.1840621 0.11852059
ARR_TRTvsCTRL 0.2028061 0.08740734 0.03149088  0.3741214 0.02032783


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$ntab
            CTRL TRT
n_all         16  49
n_event        3  15
n_event_pct   19  31

$Agetrt_less_180d$Pneumonia$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.6326531 0.5631091  0.5414702 4.9228117 0.3840079
OR_TRTvsCTRL  1.9117647 0.7115721  0.4739616 7.7112663 0.3624549
ARR_TRTvsCTRL 0.1186224 0.1177133 -0.1120913 0.3493362 0.3135871


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$ntab
            CTRL TRT
n_all         16  49
n_event        8  28
n_event_pct   50  57

$Agetrt_less_180d$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14285714 0.2789375  0.6615458 1.9743492 0.6321418
OR_TRTvsCTRL  1.33333333 0.5773503  0.4300286 4.1340924 0.6182867
ARR_TRTvsCTRL 0.07142857 0.1436068 -0.2100356 0.3528928 0.6189142


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$ntab
            CTRL TRT
n_all         16  49
n_event        4  14
n_event_pct   25  29
```

```
$Agetrt_less_180d$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14285714 0.4883855  0.4388109 2.9765038 0.7845351
OR_TRTvsCTRL  1.20000000 0.6582806  0.3302568 4.3602431 0.7818060
ARR_TRTvsCTRL 0.03571429 0.1260305 -0.2113009 0.2827295 0.7768870


$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$ntab
            CTRL TRT
n_all         16  49
n_event        9  12
n_event_pct   56  24

$Agetrt_less_180d$`Respiratory failure`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.4353741 0.3339705  0.22624889  0.83779705 0.01277829
OR_TRTvsCTRL   0.2522523 0.6035964  0.07727746  0.82341209 0.02249729
ARR_TRTvsCTRL -0.3176020 0.1384009 -0.58886274 -0.04634135 0.02174469


$Agetrt_less_180d$`Upper respiratory tract infection`
$Agetrt_less_180d$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         16  49
n_event        4  13
n_event_pct   25  27

$Agetrt_less_180d$`Upper respiratory tract infection`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.06122449 0.4939787  0.4030249 2.794362 0.9042491
OR_TRTvsCTRL  1.08333333 0.6618415  0.2960749 3.963899 0.9037390
ARR_TRTvsCTRL 0.01530612 0.1252864 -0.2302507 0.260863 0.9027651



$Gender_Female
$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$ntab
            CTRL TRT
n_all         24  43
n_event        7  13
n_event_pct   29  30

$Gender_Female$Atelectasis$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.03654485 0.3935197  0.4793178 2.2415718 0.9273257
OR_TRTvsCTRL  1.05238095 0.5585133  0.3521808 3.1447081 0.9271647
ARR_TRTvsCTRL 0.01065891 0.1162473 -0.2171817 0.2384995 0.9269430


$Gender_Female$Constipation
$Gender_Female$Constipation$ntab
            CTRL TRT
```

```
n_all         24  43
n_event        7  17
n_event_pct   29  40

$Gender_Female$Constipation$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3554817 0.3698083  0.6566172 2.7981763 0.4108084
OR_TRTvsCTRL  1.5879121 0.5467776  0.5437616 4.6370779 0.3977097
ARR_TRTvsCTRL 0.1036822 0.1190272 -0.1296069 0.3369712 0.3837107


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$ntab
            CTRL TRT
n_all         24  43
n_event        4  15
n_event_pct   17  35

$Gender_Female$Pneumonia$stats
               estimate        se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  2.0930233 0.5017412  0.78287281 5.5957319 0.14099581
OR_TRTvsCTRL  2.6785714 0.6343350  0.77260277 9.2864602 0.12036241
ARR_TRTvsCTRL 0.1821705 0.1052121 -0.02404143 0.3883825 0.08336982


$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$ntab
            CTRL TRT
n_all         24  43
n_event       15  25
n_event_pct   62  58

$Gender_Female$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93023256 0.2043139  0.6232743 1.3883657 0.7233626
OR_TRTvsCTRL   0.83333333 0.5228129  0.2990884 2.3218700 0.7272906
ARR_TRTvsCTRL -0.04360465 0.1241995 -0.2870311 0.1998218 0.7255241


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$ntab
            CTRL TRT
n_all         24  43
n_event        7  11
n_event_pct   29  26

$Gender_Female$`Respiratory distress`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.87707641 0.4109060  0.3919887 1.9624620 0.7495749
OR_TRTvsCTRL   0.83482143 0.5690692  0.2736535 2.5467492 0.7510536
ARR_TRTvsCTRL -0.03585271 0.1141731 -0.2596279 0.1879225 0.7535054


$Gender_Female$`Upper respiratory tract infection`
```

```
$Gender_Female$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        5  14
n_event_pct   21  33

$Gender_Female$`Upper respiratory tract infection`$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.5627907 0.4544294  0.64134218 3.8081306 0.3258577
OR_TRTvsCTRL  1.8344828 0.5987845  0.56731899 5.9319837 0.3109056
ARR_TRTvsCTRL 0.1172481 0.1094467 -0.09726348 0.3317596 0.2840434



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         18  34
n_event        5  10
n_event_pct   28  29

$Disdur_less_equal_12wk$Atelectasis$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.05882353 0.4637162  0.4266853 2.6274805 0.9018999
OR_TRTvsCTRL  1.08333333 0.6469851  0.3048227 3.8501428 0.9015398
ARR_TRTvsCTRL 0.01633987 0.1313455 -0.2410927 0.2737724 0.9009957


$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         18  34
n_event        9  20
n_event_pct   50  59

$Disdur_less_equal_12wk$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.17647059 0.2759416  0.6850135 2.0205194 0.5558873
OR_TRTvsCTRL  1.42857143 0.5862174  0.4528067 4.5070366 0.5428992
ARR_TRTvsCTRL 0.08823529 0.1449581 -0.1958773 0.3723479 0.5427265



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$Constipation
$Agetrt_greater_equal_180d$Constipation$ntab
            CTRL TRT
n_all         25  31
n_event        4  14
n_event_pct   16  45

$Agetrt_greater_equal_180d$Constipation$stats
               estimate        se     lo95ci     hi95ci     pvalue
```

```
RR_TRTvsCTRL  2.8225806 0.4991698 1.06109004  7.5082803 0.03763991
OR_TRTvsCTRL  4.3235294 0.6541186 1.19964197 15.5820712 0.02520564
ARR_TRTvsCTRL 0.2916129 0.1156070 0.06502725  0.5181986 0.01165408


$Agetrt_greater_equal_180d$Pyrexia
$Agetrt_greater_equal_180d$Pyrexia$ntab
            CTRL TRT
n_all         25  31
n_event       16  17
n_event_pct   64  55

$Agetrt_greater_equal_180d$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8568548 0.2215073  0.5550856 1.3226793 0.4855310
OR_TRTvsCTRL   0.6830357 0.5512379  0.2318616 2.0121389 0.4892205
ARR_TRTvsCTRL -0.0916129 0.1311678 -0.3486971 0.1654712 0.4849017


$Agetrt_greater_equal_180d$`Upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        5  11
n_event_pct   20  35

$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.7741935 0.4676014  0.70954183 4.4363315 0.2201450
OR_TRTvsCTRL  2.2000000 0.6252272  0.64599372 7.4923329 0.2072824
ARR_TRTvsCTRL 0.1548387 0.1174086 -0.07527793 0.3849553 0.1872353



$Gender_Male
$Gender_Male$Constipation
$Gender_Male$Constipation$ntab
            CTRL TRT
n_all         17  37
n_event        2  11
n_event_pct   12  30

$Gender_Male$Constipation$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.5270270 0.7106747  0.62759935 10.1750673 0.19207832
OR_TRTvsCTRL  3.1730769 0.8342885  0.61849037 16.2790200 0.16634140
ARR_TRTvsCTRL 0.1796502 0.1084090 -0.03282747  0.3921279 0.09748862


$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$ntab
            CTRL TRT
n_all         17  37
n_event        9  20
```

```
n_event_pct   53  54

$Gender_Male$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.02102102 0.2743366  0.5963744 1.7480361 0.9395538
OR_TRTvsCTRL  1.04575163 0.5873114  0.3307564 3.3063505 0.9392833
ARR_TRTvsCTRL 0.01112878 0.1461757 -0.2753703 0.2976279 0.9393134


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$ntab
            CTRL TRT
n_all         17  37
n_event        5  10
n_event_pct   29  27

$Gender_Male$`Respiratory distress`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.91891892 0.4627628  0.3709990 2.276049 0.8550154
OR_TRTvsCTRL   0.88888889 0.6483598  0.2494380 3.167614 0.8558471
ARR_TRTvsCTRL -0.02384738 0.1324495 -0.2834437 0.235749 0.8571143


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$ntab
            CTRL TRT
n_all         17  37
n_event        7  11
n_event_pct   41  30

$Gender_Male$`Respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7220077 0.3845981  0.3397593 1.5343072 0.3970460
OR_TRTvsCTRL   0.6043956 0.6101047  0.1828097 1.9982204 0.4091949
ARR_TRTvsCTRL -0.1144674 0.1410467 -0.3909139 0.1619791 0.4170460


$Gender_Male$`Upper respiratory tract infection`
$Gender_Male$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         17  37
n_event        4  10
n_event_pct   24  27

$Gender_Male$`Upper respiratory tract infection`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14864865 0.5139547  0.4194770 3.1453302 0.7874321
OR_TRTvsCTRL  1.20370370 0.6811462  0.3167575 4.5741697 0.7854736
ARR_TRTvsCTRL 0.03497615 0.1261529 -0.2122790 0.2822313 0.7815865



$Disdur_greater_12wk
$Disdur_greater_12wk$Constipation
```

```
$Disdur_greater_12wk$Constipation$ntab
            CTRL TRT
n_all         23  46
n_event        6  19
n_event_pct   26  41

$Disdur_greater_12wk$Constipation$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.5833333 0.3925313  0.73358268 3.4173986 0.2417236
OR_TRTvsCTRL  1.9938272 0.5613901  0.66348546 5.9916109 0.2190000
ARR_TRTvsCTRL 0.1521739 0.1168492 -0.07684631 0.3811941 0.1928103


$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$ntab
            CTRL TRT
n_all         23  46
n_event        4  14
n_event_pct   17  30

$Disdur_greater_12wk$Pneumonia$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.7500000 0.5061731  0.64890743 4.7194713 0.2689075
OR_TRTvsCTRL  2.0781250 0.6366397  0.59670949 7.2373636 0.2505774
ARR_TRTvsCTRL 0.1304348 0.1041586 -0.07371236 0.3345819 0.2104713


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$ntab
            CTRL TRT
n_all         23  46
n_event       15  25
n_event_pct   65  54

$Disdur_greater_12wk$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8333333 0.2035910  0.5591416 1.2419831 0.3705045
OR_TRTvsCTRL   0.6349206 0.5284749  0.2253621 1.7887848 0.3900323
ARR_TRTvsCTRL -0.1086957 0.1235169 -0.3507844 0.1333931 0.3788560


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         23  46
n_event        7  13
n_event_pct   30  28

$Disdur_greater_12wk$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92857143 0.3931448  0.4297045 2.0065998 0.8504844
OR_TRTvsCTRL   0.90043290 0.5590915  0.3009898 2.6937101 0.8511985
ARR_TRTvsCTRL -0.02173913 0.1166732 -0.2504144 0.2069362 0.8521900
```

```
$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         23  46
n_event        9  11
n_event_pct   39  24

$Disdur_greater_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6111111 0.3698686  0.2959971 1.26169080 0.1830278
OR_TRTvsCTRL   0.4888889 0.5495636  0.1665025 1.43548808 0.1928615
ARR_TRTvsCTRL -0.1521739 0.1196296 -0.3866437 0.08229588 0.2033583


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         23  46
n_event        3  17
n_event_pct   13  37

$Disdur_greater_12wk$`Upper respiratory tract infection`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.8333333 0.57178621 0.92383065  8.6896638 0.06854542
OR_TRTvsCTRL  3.9080460 0.69039092 1.00994529 15.1224264 0.04834785
ARR_TRTvsCTRL 0.2391304 0.09998151 0.04317028  0.4350906 0.01676841



$Region_Europe
$Region_Europe$Pyrexia
$Region_Europe$Pyrexia$ntab
            CTRL TRT
n_all         17  30
n_event       10  16
n_event_pct   59  53

$Region_Europe$Pyrexia$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90666667 0.2652228  0.5391251 1.5247748 0.7118096
OR_TRTvsCTRL   0.80000000 0.6138287  0.2402138 2.6642928 0.7162110
ARR_TRTvsCTRL -0.05490196 0.1501473 -0.3491853 0.2393813 0.7146233




\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs nach PT, das bei mindestens 10% der
Patienten in einem Studienarm auftrat"

$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Abdominal pain upper`
```

```
$Ageonset_greater_12wk$`Abdominal pain upper`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th                7.7                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           7.7                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Abdominal pain upper`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.900e+05 4.748e+04 0.000e+00       Inf 9.998e-01


$Ageonset_greater_12wk$`Acute respiratory failure`
$Ageonset_greater_12wk$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              2.0                1.0
n_event_pct                         22.0               12.0
time-to-event-wk-10th               16.4               25.4
time-to-event-wk-25th               26.0                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          16.4               25.4
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9680    1.4020    0.1262   30.7000    0.6290


$Ageonset_greater_12wk$Amblyopia
$Ageonset_greater_12wk$Amblyopia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               29.3                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          29.3                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$Amblyopia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.113e-17 4.635e+04 0.000e+00       Inf 9.994e-01
```

```
$Ageonset_greater_12wk$Anxiety
$Ageonset_greater_12wk$Anxiety$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA                2.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                2.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Anxiety$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$Atelectasis
$Ageonset_greater_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                15.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Bone marrow disorder`
$Ageonset_greater_12wk$`Bone marrow disorder`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                43.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           43.1                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Ageonset_greater_12wk$`Bone marrow disorder`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.245e-09 4.596e+04 0.000e+00       Inf 9.997e-01


$Ageonset_greater_12wk$Bradycardia
$Ageonset_greater_12wk$Bradycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA                2.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                2.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Bradycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$`Bronchial secretion retention`
$Ageonset_greater_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8
n_event                               1.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                19.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           19.9                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_greater_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.140e-10 4.262e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Candida sepsis`
$Ageonset_greater_12wk$`Candida sepsis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8
n_event                               1.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                22.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
```

```
time-to-event-wk-50th-loci           22.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Candida sepsis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.017e-09 4.176e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Cardio-respiratory arrest`
$Ageonset_greater_12wk$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               2.0                1.0
n_event_pct                          22.0               12.0
time-to-event-wk-10th                23.0               25.4
time-to-event-wk-25th                33.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           23.0               25.4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.07200   1.31900   0.08084  14.22000   0.95780


$Ageonset_greater_12wk$Catarrh
$Ageonset_greater_12wk$Catarrh$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                30.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           30.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Catarrh$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.380e-09 4.512e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Constipation
$Ageonset_greater_12wk$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                3.0
n_event_pct                          11.0               38.0
time-to-event-wk-10th                16.3                2.0
time-to-event-wk-25th                  NA                4.4
```

```
time-to-event-wk-50th                  NA                25.9
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           16.3                 2.0
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 10.99000   1.24100   0.96580 125.10000   0.05337


$Ageonset_greater_12wk$Cough
$Ageonset_greater_12wk$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               2.0                  1
n_event_pct                          22.0                 12
time-to-event-wk-10th                 0.4                 12
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            0.4                 12
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.41000   1.29800   0.03222   5.21700   0.49210


$Ageonset_greater_12wk$Cyanosis
$Ageonset_greater_12wk$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA               17.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               17.9
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.612e+50 3.859e+04 0.000e+00       Inf 9.976e-01


$Ageonset_greater_12wk$`Dermatitis contact`
$Ageonset_greater_12wk$`Dermatitis contact`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
```

```
n_event_pct                           11.0                  0
time-to-event-wk-10th                 29.4                 NA
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            29.4                 NA
time-to-event-wk-50th-hici              NA                 NA

$Ageonset_greater_12wk$`Dermatitis contact`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.720e-10 4.298e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Dermatitis diaper`
$Ageonset_greater_12wk$`Dermatitis diaper`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 7.9                 NA
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            7.9                 NA
time-to-event-wk-50th-hici              NA                 NA

$Ageonset_greater_12wk$`Dermatitis diaper`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Diarrhoea
$Ageonset_greater_12wk$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                1.0
n_event_pct                          11.0               12.0
time-to-event-wk-10th                 8.1               28.0
time-to-event-wk-25th                   NA               35.9
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            8.1               28.0
time-to-event-wk-50th-hici              NA                 NA

$Ageonset_greater_12wk$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.70100   1.50800   0.08852  32.70000   0.72460


$Ageonset_greater_12wk$`Diarrhoea haemorrhagic`
$Ageonset_greater_12wk$`Diarrhoea haemorrhagic`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                34.6                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           34.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Diarrhoea haemorrhagic`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.338e-10 4.693e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Drug hypersensitivity`
$Ageonset_greater_12wk$`Drug hypersensitivity`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                46.7                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           46.7                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Drug hypersensitivity`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.970e+04 9.953e+04 0.000e+00       Inf 9.999e-01


$Ageonset_greater_12wk$Dysphagia
$Ageonset_greater_12wk$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8.0
n_event                               3.0                 1.0
n_event_pct                          33.0                12.0
time-to-event-wk-10th                 0.0                 1.7
time-to-event-wk-25th                26.1                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            0.0                 1.7
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.85140   1.25500   0.07276   9.96300   0.89800
```

```
$Ageonset_greater_12wk$Dyspnoea
$Ageonset_greater_12wk$Dyspnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  9                   8
n_event                                1                   0
n_event_pct                           11                   0
time-to-event-wk-10th                  0                  NA
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci             0                  NA
time-to-event-wk-50th-hici            NA                  NA

$Ageonset_greater_12wk$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.943e-10 4.030e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Erythema
$Ageonset_greater_12wk$Erythema$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  9                   8
n_event                                2                   0
n_event_pct                           22                   0
time-to-event-wk-10th                  0                  NA
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci             0                  NA
time-to-event-wk-50th-hici            NA                  NA

$Ageonset_greater_12wk$Erythema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.776e-10 2.882e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$`Failure to thrive`
$Ageonset_greater_12wk$`Failure to thrive`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                   8
n_event                              1.0                   0
n_event_pct                         11.0                   0
time-to-event-wk-10th                6.4                  NA
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci           6.4                  NA
time-to-event-wk-50th-hici            NA                  NA

$Ageonset_greater_12wk$`Failure to thrive`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.345e-25 4.674e+04 0.000e+00       Inf 9.990e-01


$Ageonset_greater_12wk$`Femur fracture`
$Ageonset_greater_12wk$`Femur fracture`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                50.6                 NA
time-to-event-wk-25th                55.5                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           50.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Femur fracture`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.522e-01 1.273e+05 0.000e+00       Inf 1.000e+00


$Ageonset_greater_12wk$`Fungal infection`
$Ageonset_greater_12wk$`Fungal infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                26.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Fungal infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.256e-09 4.032e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Fungal skin infection`
$Ageonset_greater_12wk$`Fungal skin infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                10.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           10.4                 NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Fungal skin infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Gastroenteritis viral`
$Ageonset_greater_12wk$`Gastroenteritis viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                38.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           38.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Gastroenteritis viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.095e+05 5.137e+04 0.000e+00       Inf 9.998e-01


$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`
$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               3.0                  0
n_event_pct                          33.0                  0
time-to-event-wk-10th                 0.0                 NA
time-to-event-wk-25th                43.0                 NA
time-to-event-wk-50th                48.6                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            0.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.634e-10 2.508e+04 0.000e+00       Inf 9.993e-01


$Ageonset_greater_12wk$Hyperaemia
$Ageonset_greater_12wk$Hyperaemia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                30.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           30.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Hyperaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.187e-09 4.506e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Increased upper airway secretion`
$Ageonset_greater_12wk$`Increased upper airway secretion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                  8
n_event                                 1                  0
n_event_pct                            11                  0
time-to-event-wk-10th                   0                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci              0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Increased upper airway secretion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.423e-10 3.890e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Infusion site bruising`
$Ageonset_greater_12wk$`Infusion site bruising`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                  8
n_event                                 1                  0
n_event_pct                            11                  0
time-to-event-wk-10th                  23                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             23                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Infusion site bruising`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.685e-10 4.172e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Nasal congestion`
$Ageonset_greater_12wk$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                  8
n_event                                 2                  0
n_event_pct                            22                  0
```

```
time-to-event-wk-10th                  1                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci             1                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.872e-10 2.680e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$Nasopharyngitis
$Ageonset_greater_12wk$Nasopharyngitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              3.0                1.0
n_event_pct                         33.0               12.0
time-to-event-wk-10th               10.6               15.7
time-to-event-wk-25th               28.3                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          10.6               15.7
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6931    1.1940    0.0668    7.1910    0.7587


$Ageonset_greater_12wk$Nystagmus
$Ageonset_greater_12wk$Nystagmus$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9                  8
n_event                              1                  0
n_event_pct                         11                  0
time-to-event-wk-10th               25                 NA
time-to-event-wk-25th               NA                 NA
time-to-event-wk-50th               NA                 NA
time-to-event-wk-75th               NA                 NA
time-to-event-wk-90th               NA                 NA
time-to-event-wk-50th-loci          25                 NA
time-to-event-wk-50th-hici          NA                 NA

$Ageonset_greater_12wk$Nystagmus$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.718e-22 4.401e+04 0.000e+00       Inf 9.991e-01


$Ageonset_greater_12wk$Oedema
$Ageonset_greater_12wk$Oedema$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th                7.6                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           7.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$Oedema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.253e-10 4.403e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Oral candidiasis`
$Ageonset_greater_12wk$`Oral candidiasis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th                1.4                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           1.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Oral candidiasis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.166e-10 4.053e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Oropharyngeal pain`
$Ageonset_greater_12wk$`Oropharyngeal pain`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th                4.1                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           4.1                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Oropharyngeal pain`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.999e-10 4.033e+04 0.000e+00       Inf 9.996e-01
```

```
$Ageonset_greater_12wk$`Otitis media`
$Ageonset_greater_12wk$`Otitis media`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th                4.4                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           4.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Otitis media`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.948e-25 4.113e+04 0.000e+00       Inf 9.989e-01


$Ageonset_greater_12wk$Pain
$Ageonset_greater_12wk$Pain$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 9                8.0
n_event                               0                1.0
n_event_pct                           0               12.0
time-to-event-wk-10th                NA                2.1
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                2.1
time-to-event-wk-50th-hici           NA                 NA

$Ageonset_greater_12wk$Pain$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$Pneumonia
$Ageonset_greater_12wk$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              1.0                1.0
n_event_pct                         11.0               12.0
time-to-event-wk-10th                5.7               30.4
time-to-event-wk-25th                 NA               30.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           5.7               30.4
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   2.1810    1.4550    0.1259   37.7800    0.5920


$Ageonset_greater_12wk$`Pneumonia aspiration`
$Ageonset_greater_12wk$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               2.0                  0
n_event_pct                          22.0                  0
time-to-event-wk-10th                 1.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.616e-10 2.873e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`
$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                19.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Pneumonia pseudomonal`
$Ageonset_greater_12wk$`Pneumonia pseudomonal`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                15.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.3                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Ageonset_greater_12wk$`Pneumonia pseudomonal`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.446e-09 4.265e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Procedural pain`
$Ageonset_greater_12wk$`Procedural pain`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA                3.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                3.3
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Procedural pain`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.483e+09 4.134e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Pseudomonas infection`
$Ageonset_greater_12wk$`Pseudomonas infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               2.0                  0
n_event_pct                          22.0                  0
time-to-event-wk-10th                17.7                 NA
time-to-event-wk-25th                52.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Pseudomonas infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.348e-10 3.222e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$Pyrexia
$Ageonset_greater_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               6.0                4.0
n_event_pct                          67.0               50.0
time-to-event-wk-10th                 1.3                0.4
time-to-event-wk-25th                 5.1                9.7
time-to-event-wk-50th                15.1               15.0
time-to-event-wk-75th                42.6                 NA
```

```
time-to-event-wk-90th                42.6                  NA
time-to-event-wk-50th-loci            1.3                 0.4
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0580    0.6778    0.2804    3.9950    0.9333


$Ageonset_greater_12wk$`Respiratory arrest`
$Ageonset_greater_12wk$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                19.9                  NA
time-to-event-wk-25th                 NA                   NA
time-to-event-wk-50th                 NA                   NA
time-to-event-wk-75th                 NA                   NA
time-to-event-wk-90th                 NA                   NA
time-to-event-wk-50th-loci           19.9                  NA
time-to-event-wk-50th-hici            NA                   NA

$Ageonset_greater_12wk$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.140e-10 4.262e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Respiratory distress`
$Ageonset_greater_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8.0
n_event                               2.0                 1.0
n_event_pct                          22.0                12.0
time-to-event-wk-10th                 2.3                 0.4
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci            2.3                 0.4
time-to-event-wk-50th-hici            NA                  NA

$Ageonset_greater_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.72320   1.24700   0.06275   8.33600   0.79500


$Ageonset_greater_12wk$`Respiratory failure`
$Ageonset_greater_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8.0
n_event                               1.0                 2.0
n_event_pct                          11.0                25.0
time-to-event-wk-10th                19.3                 0.6
```

```
time-to-event-wk-25th                  NA                5.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.3                0.6
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.3050    1.2530    0.2834   38.5400    0.3402


$Ageonset_greater_12wk$`Respiratory tract infection`
$Ageonset_greater_12wk$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                   8
n_event                                 0                   1
n_event_pct                             0                  12
time-to-event-wk-10th                  NA                   3
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                   3
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.316e+09 4.526e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Respirovirus test positive`
$Ageonset_greater_12wk$`Respirovirus test positive`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                15.9                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           15.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Respirovirus test positive`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Restlessness
$Ageonset_greater_12wk$Restlessness$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                 8.0
```

```
n_event                                  0                1.0
n_event_pct                              0               12.0
time-to-event-wk-10th                   NA                2.3
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                2.3
time-to-event-wk-50th-hici              NA                 NA

$Ageonset_greater_12wk$Restlessness$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$`Rhinovirus infection`
$Ageonset_greater_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                  8
n_event                                 0                  1
n_event_pct                             0                 12
time-to-event-wk-10th                  NA                  4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                  4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$`Salivary hypersecretion`
$Ageonset_greater_12wk$`Salivary hypersecretion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                43.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           43.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Salivary hypersecretion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.245e-09 4.596e+04 0.000e+00       Inf 9.997e-01


$Ageonset_greater_12wk$Scoliosis
```

```
$Ageonset_greater_12wk$Scoliosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA               31.9
time-to-event-wk-25th                  NA               31.9
time-to-event-wk-50th                  NA               37.8
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               31.9
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Scoliosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.917e+13 5.755e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Seasonal allergy`
$Ageonset_greater_12wk$`Seasonal allergy`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                17.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Seasonal allergy`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.900e+05 4.748e+04 0.000e+00       Inf 9.998e-01


$Ageonset_greater_12wk$Sinusitis
$Ageonset_greater_12wk$Sinusitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                14.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           14.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Sinusitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.345e-25 4.674e+04 0.000e+00       Inf 9.990e-01
```

```
$Ageonset_greater_12wk$`Sleep disorder`
$Ageonset_greater_12wk$`Sleep disorder`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                50.4                  NA
time-to-event-wk-25th                53.6                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           50.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Sleep disorder`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.437e-09 5.275e+04 0.000e+00       Inf 9.997e-01


$Ageonset_greater_12wk$`Staphylococcal infection`
$Ageonset_greater_12wk$`Staphylococcal infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                 2.3                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            2.3                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Staphylococcal infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.594e-10 4.064e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Stoma complication`
$Ageonset_greater_12wk$`Stoma complication`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                   8
n_event                                 1                   0
n_event_pct                            11                   0
time-to-event-wk-10th                  38                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             38                  NA
time-to-event-wk-50th-hici             NA                  NA
```

```
$Ageonset_greater_12wk$`Stoma complication`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.338e-10 4.693e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Stoma site erythema`
$Ageonset_greater_12wk$`Stoma site erythema`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 8.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Stoma site erythema`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.253e-10 4.403e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Stoma site infection`
$Ageonset_greater_12wk$`Stoma site infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  9                  8
n_event                                1                  0
n_event_pct                           11                  0
time-to-event-wk-10th                 32                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            32                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Stoma site infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.114e-10 4.782e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Stoma site inflammation`
$Ageonset_greater_12wk$`Stoma site inflammation`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                37.3                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
```

```
time-to-event-wk-50th-loci           37.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Stoma site inflammation`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.338e-10 4.693e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Strabismus
$Ageonset_greater_12wk$Strabismus$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                29.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           29.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Strabismus$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.113e-17 4.635e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$Tachycardia
$Ageonset_greater_12wk$Tachycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA                2.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                2.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$Teething
$Ageonset_greater_12wk$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  2
n_event_pct                          11.0                 25
time-to-event-wk-10th                 4.4                  0
time-to-event-wk-25th                  NA                 16
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            4.4                  0
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.0160    1.2420    0.2645   34.3900    0.3739


$Ageonset_greater_12wk$`Upper respiratory tract congestion`
$Ageonset_greater_12wk$`Upper respiratory tract congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 5.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Upper respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.520e-10 4.008e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Upper respiratory tract infection`
$Ageonset_greater_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               2.0                1.0
n_event_pct                          22.0               12.0
time-to-event-wk-10th                 2.7               17.1
time-to-event-wk-25th                28.3                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            2.7               17.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.94820   1.27300   0.07819  11.50000   0.96660


$Ageonset_greater_12wk$`Upper respiratory tract inflammation`
$Ageonset_greater_12wk$`Upper respiratory tract inflammation`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                  8
n_event                                 1                  0
```

```
n_event_pct                              11                  0
time-to-event-wk-10th                    33                 NA
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               33                 NA
time-to-event-wk-50th-hici               NA                 NA

$Ageonset_greater_12wk$`Upper respiratory tract inflammation`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.569e-09 4.770e+04 0.000e+00       Inf 9.997e-01


$Ageonset_greater_12wk$`Use of accessory respiratory muscles`
$Ageonset_greater_12wk$`Use of accessory respiratory muscles`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 2.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            2.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Use of accessory respiratory muscles`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.246e-02 4.449e+04 0.000e+00       Inf 1.000e+00


$Ageonset_greater_12wk$`Viral infection`
$Ageonset_greater_12wk$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               2.0                  0
n_event_pct                          22.0                  0
time-to-event-wk-10th                11.3                 NA
time-to-event-wk-25th                45.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           11.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.141e-09 3.399e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$`Viral upper respiratory tract infection`
$Ageonset_greater_12wk$`Viral upper respiratory tract infection`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA               16.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               16.7
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.069e+10 4.364e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Vomiting
$Ageonset_greater_12wk$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               2.0                2.0
n_event_pct                          22.0               25.0
time-to-event-wk-10th                 1.0                2.7
time-to-event-wk-25th                39.7               13.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.0                2.7
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.9520    1.1800    0.2920   29.8400    0.3591



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               8.0                10
n_event_pct                          25.0                14
time-to-event-wk-10th                 6.3                13
time-to-event-wk-25th                22.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.4                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.41920   0.48110   0.16330   1.07600   0.07075


$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              11.0               18.0
n_event_pct                          34.0               25.0
time-to-event-wk-10th                 4.0                9.6
time-to-event-wk-25th                14.1               36.0
time-to-event-wk-50th                52.7                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49610   0.38730   0.23220   1.06000   0.07029


$Ageonset_less_equal_12wk$`Bacterial tracheitis`
$Ageonset_less_equal_12wk$`Bacterial tracheitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               4.0                 1
n_event_pct                          12.0                 1
time-to-event-wk-10th                19.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Bacterial tracheitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.075280  1.120000  0.008378  0.676400  0.020950


$Ageonset_less_equal_12wk$`Bronchial secretion retention`
$Ageonset_less_equal_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               6.0                 4
n_event_pct                          19.0                 6
time-to-event-wk-10th                 6.1                NA
time-to-event-wk-25th                40.7                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24250   0.65150   0.06763   0.86950   0.02967


$Ageonset_less_equal_12wk$Bronchiolitis
$Ageonset_less_equal_12wk$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               3.0                8.0
n_event_pct                           9.0               11.0
time-to-event-wk-10th                 9.1               32.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0240    0.6800    0.2699    3.8810    0.9727


$Ageonset_less_equal_12wk$Constipation
$Ageonset_less_equal_12wk$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               8.0               25.0
n_event_pct                          25.0               35.0
time-to-event-wk-10th                11.3                7.9
time-to-event-wk-25th                20.0               18.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.0               38.4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1280    0.4124    0.5028    2.5320    0.7695


$Ageonset_less_equal_12wk$Cough
$Ageonset_less_equal_12wk$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               6.0                  8
n_event_pct                          19.0                 11
time-to-event-wk-10th                 5.1                 28
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_less_equal_12wk$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.38020   0.54860   0.12970   1.11400   0.07794


$Ageonset_less_equal_12wk$Diarrhoea
$Ageonset_less_equal_12wk$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               6.0               10.0
n_event_pct                          19.0               14.0
time-to-event-wk-10th                 9.4               18.3
time-to-event-wk-25th                31.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           31.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40740   0.53930   0.14160   1.17200   0.09593


$Ageonset_less_equal_12wk$Dysphagia
$Ageonset_less_equal_12wk$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               6.0                8.0
n_event_pct                          19.0               11.0
time-to-event-wk-10th                12.7               28.4
time-to-event-wk-25th                27.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           27.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39410   0.55240   0.13350   1.16400   0.09186


$Ageonset_less_equal_12wk$Dyspnoea
$Ageonset_less_equal_12wk$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               5.0                7.0
n_event_pct                          16.0               10.0
```

```
time-to-event-wk-10th                21.3               43.1
time-to-event-wk-25th                26.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4780    0.5960    0.1487    1.5370    0.2156


$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`
$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               5.0               10.0
n_event_pct                          16.0               14.0
time-to-event-wk-10th                10.9               20.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8246    0.5573    0.2766    2.4580    0.7293


$Ageonset_less_equal_12wk$`Nasal congestion`
$Ageonset_less_equal_12wk$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               3.0                8.0
n_event_pct                           9.0               11.0
time-to-event-wk-10th                37.4               18.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9823    0.6800    0.2591    3.7240    0.9790


$Ageonset_less_equal_12wk$Nasopharyngitis
$Ageonset_less_equal_12wk$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  32               72.0
n_event                                 1               14.0
n_event_pct                             3               19.0
time-to-event-wk-10th                  NA               11.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   5.1320    1.0360    0.6742   39.0700    0.1143


$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              10.0               10.0
n_event_pct                          31.0               14.0
time-to-event-wk-10th                10.1               18.3
time-to-event-wk-25th                20.3                 NA
time-to-event-wk-50th                40.7                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.301800  0.454400  0.123900  0.735400  0.008382


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               6.0               22.0
n_event_pct                          19.0               31.0
time-to-event-wk-10th                11.3                8.1
time-to-event-wk-25th                46.6               25.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           46.6               43.6
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3590    0.4622    0.5492    3.3620    0.5071
```

```
$Ageonset_less_equal_12wk$`Pneumonia aspiration`
$Ageonset_less_equal_12wk$`Pneumonia aspiration`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 32               72.0
n_event                                5                9.0
n_event_pct                           16               12.0
time-to-event-wk-10th                  9               32.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6058    0.5623    0.2012    1.8240    0.3727


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                             18.0               41.0
n_event_pct                         56.0               57.0
time-to-event-wk-10th                3.1                3.4
time-to-event-wk-25th                7.9               10.3
time-to-event-wk-50th               16.0               32.1
time-to-event-wk-75th               52.6               54.3
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          13.4               24.3
time-to-event-wk-50th-hici          37.7               41.4

$Ageonset_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6797    0.2862    0.3879    1.1910    0.1772


$Ageonset_less_equal_12wk$Rash
$Ageonset_less_equal_12wk$Rash$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              4.0                9.0
n_event_pct                         12.0               12.0
time-to-event-wk-10th                5.9               33.9
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.6726    0.6067    0.2048    2.2090    0.5133


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              10.0              20.0
n_event_pct                          31.0              28.0
time-to-event-wk-10th                11.0               8.9
time-to-event-wk-25th                28.1              25.9
time-to-event-wk-50th                33.9                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           28.1                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6757    0.3924    0.3131    1.4580    0.3179


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              15.0              18.0
n_event_pct                          47.0              25.0
time-to-event-wk-10th                 2.1              10.0
time-to-event-wk-25th                 9.1              32.1
time-to-event-wk-50th                21.9                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.0                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.378600  0.357500  0.187900  0.762900  0.006588


$Ageonset_less_equal_12wk$`Respiratory tract infection`
$Ageonset_less_equal_12wk$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               2.0               8.0
n_event_pct                           6.0              11.0
time-to-event-wk-10th                32.9              35.4
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA
```

```
$Ageonset_less_equal_12wk$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3280    0.7921    0.2812    6.2720    0.7203


$Ageonset_less_equal_12wk$`Rhinovirus infection`
$Ageonset_less_equal_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               6.0                 9
n_event_pct                          19.0                12
time-to-event-wk-10th                 8.7                18
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5980    0.5332    0.2103    1.7000    0.3349


$Ageonset_less_equal_12wk$`Sleep apnoea syndrome`
$Ageonset_less_equal_12wk$`Sleep apnoea syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               4.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                 7.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.665e-10 1.757e+04 0.000e+00       Inf 9.990e-01


$Ageonset_less_equal_12wk$Tachycardia
$Ageonset_less_equal_12wk$Tachycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               5.0                 6
n_event_pct                          16.0                 8
time-to-event-wk-10th                 4.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4204    0.6111    0.1269    1.3930    0.1562


$Ageonset_less_equal_12wk$Teething
$Ageonset_less_equal_12wk$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32               72.0
n_event                                 2               12.0
n_event_pct                             6               17.0
time-to-event-wk-10th                  NA                9.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.5520    0.7694    0.5649   11.5300    0.2233


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               7.0               23.0
n_event_pct                          22.0               32.0
time-to-event-wk-10th                 8.7               15.4
time-to-event-wk-25th                32.6               26.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.6               34.7
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1070    0.4352    0.4716    2.5960    0.8161


$Ageonset_less_equal_12wk$`Viral infection`
$Ageonset_less_equal_12wk$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               1.0                  8
n_event_pct                           3.0                 11
time-to-event-wk-10th                  NA                 41
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           44.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.7490    1.0610    0.3434   22.0000    0.3407


$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               7.0                7.0
n_event_pct                          22.0               10.0
time-to-event-wk-10th                11.7               18.9
time-to-event-wk-25th                33.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32880   0.54050   0.11400   0.94820   0.03956


$Ageonset_less_equal_12wk$Vomiting
$Ageonset_less_equal_12wk$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               6.0               12.0
n_event_pct                          19.0               17.0
time-to-event-wk-10th                12.0               24.1
time-to-event-wk-25th                47.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           47.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6455    0.5026    0.2411    1.7290    0.3838



$Agetrt_less_180d
$Agetrt_less_180d$`Acute respiratory failure`
```

```
$Agetrt_less_180d$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              4.0                 7
n_event_pct                         25.0                14
time-to-event-wk-10th                6.3                13
time-to-event-wk-25th               22.4                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           8.6                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4188    0.6314    0.1215    1.4440    0.1680


$Agetrt_less_180d$Apnoea
$Agetrt_less_180d$Apnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              2.0                 3
n_event_pct                         12.0                 6
time-to-event-wk-10th                6.3                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$Apnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39290   0.93040   0.06344   2.43300   0.31530


$Agetrt_less_180d$Aspiration
$Agetrt_less_180d$Aspiration$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              2.0                5.0
n_event_pct                         12.0               10.0
time-to-event-wk-10th               19.4               32.6
time-to-event-wk-25th               40.3                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          19.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6069    0.8425    0.1164    3.1640    0.5534
```

```
$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              5.0              13.0
n_event_pct                         31.0              27.0
time-to-event-wk-10th                7.9               8.1
time-to-event-wk-25th               22.9              32.1
time-to-event-wk-50th               32.9                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          17.6              44.0
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5421    0.5480    0.1852    1.5870    0.2638


$Agetrt_less_180d$`Bacterial tracheitis`
$Agetrt_less_180d$`Bacterial tracheitis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              2.0                 1
n_event_pct                         12.0                 2
time-to-event-wk-10th               20.8                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          16.1                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Bacterial tracheitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.11970   1.24100   0.01052   1.36300   0.08720


$Agetrt_less_180d$`Bronchial secretion retention`
$Agetrt_less_180d$`Bronchial secretion retention`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              3.0                 3
n_event_pct                         19.0                 6
time-to-event-wk-10th                6.1                NA
time-to-event-wk-25th               40.7                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          40.7                NA
time-to-event-wk-50th-hici            NA                NA
```

```
$Agetrt_less_180d$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.22580   0.85460   0.04230   1.20600   0.08168


$Agetrt_less_180d$Bronchiolitis
$Agetrt_less_180d$Bronchiolitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 16               49.0
n_event                                1                7.0
n_event_pct                            6               14.0
time-to-event-wk-10th                 NA               25.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5160    1.0840    0.1812   12.6900    0.7009


$Agetrt_less_180d$Bronchitis
$Agetrt_less_180d$Bronchitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 16                 49
n_event                                1                  6
n_event_pct                            6                 12
time-to-event-wk-10th                 NA                 40
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            16                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Bronchitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7070    1.0920    0.2009   14.5100    0.6241


$Agetrt_less_180d$`Bronchitis viral`
$Agetrt_less_180d$`Bronchitis viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 16               49.0
n_event                                0                5.0
n_event_pct                            0               10.0
time-to-event-wk-10th                 NA               35.3
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
```

```
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Bronchitis viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.509e+08 1.325e+04 0.000e+00       Inf 9.988e-01


$Agetrt_less_180d$`Candida infection`
$Agetrt_less_180d$`Candida infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                15.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.4                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Candida infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.677e-10 2.208e+04 0.000e+00       Inf 9.992e-01


$Agetrt_less_180d$`Cardio-respiratory arrest`
$Agetrt_less_180d$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 1
n_event_pct                          12.0                 2
time-to-event-wk-10th                14.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.115400  1.256000  0.009854  1.352000  0.085530


$Agetrt_less_180d$Conjunctivitis
$Agetrt_less_180d$Conjunctivitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                49
n_event                                 2                 3
n_event_pct                            12                 6
time-to-event-wk-10th                  29                NA
time-to-event-wk-25th                  29                NA
```

```
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             29                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$Conjunctivitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25220   0.96250   0.03824   1.66400   0.15240


$Agetrt_less_180d$Constipation
$Agetrt_less_180d$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               5.0               14.0
n_event_pct                          31.0               29.0
time-to-event-wk-10th                 0.0               11.9
time-to-event-wk-25th                15.9               19.7
time-to-event-wk-50th                40.7                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           11.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6205    0.5287    0.2201    1.7490    0.3667


$Agetrt_less_180d$`Corona virus infection`
$Agetrt_less_180d$`Corona virus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16                 49
n_event                               2                  0
n_event_pct                          12                  0
time-to-event-wk-10th                34                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           34                 NA
time-to-event-wk-50th-hici           NA                 NA

$Agetrt_less_180d$`Corona virus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.382e-10 3.930e+04 0.000e+00       Inf 9.995e-01


$Agetrt_less_180d$Cough
$Agetrt_less_180d$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               3.0                 6
```

```
n_event_pct                          19.0                12
time-to-event-wk-10th                 5.1                28
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            8.4                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4172    0.7145    0.1028    1.6920    0.2211


$Agetrt_less_180d$Cyanosis
$Agetrt_less_180d$Cyanosis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              2.0                 1
n_event_pct                         12.0                 2
time-to-event-wk-10th               15.1                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          15.1                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.070220  1.412000  0.004408  1.119000  0.060040


$Agetrt_less_180d$`Decubitus ulcer`
$Agetrt_less_180d$`Decubitus ulcer`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              2.0                 0
n_event_pct                         12.0                 0
time-to-event-wk-10th               20.9                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          20.9                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Decubitus ulcer`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.964e-10 2.040e+04 0.000e+00       Inf 9.991e-01


$Agetrt_less_180d$`Dermatitis contact`
$Agetrt_less_180d$`Dermatitis contact`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 1
n_event_pct                          12.0                 2
time-to-event-wk-10th                20.3                NA
time-to-event-wk-25th                51.0                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           20.3                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Dermatitis contact`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.17660   1.26800   0.01471   2.11900   0.17140


$Agetrt_less_180d$Diarrhoea
$Agetrt_less_180d$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49.0
n_event                               4.0                 6.0
n_event_pct                          25.0                12.0
time-to-event-wk-10th                 5.4                43.4
time-to-event-wk-25th                10.6                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            9.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.23280   0.71380   0.05746   0.94310   0.04115


$Agetrt_less_180d$Dysphagia
$Agetrt_less_180d$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49.0
n_event                               2.0                 5.0
n_event_pct                          12.0                10.0
time-to-event-wk-10th                12.7                28.4
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6263    0.8460    0.1193    3.2870    0.5801
```

```
$Agetrt_less_180d$Dyspnoea
$Agetrt_less_180d$Dyspnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              3.0                 2
n_event_pct                         19.0                 4
time-to-event-wk-10th               24.4                NA
time-to-event-wk-25th               26.1                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          24.4                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.076530  1.093000  0.008976  0.652400  0.018740


$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`
$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              2.0                 3
n_event_pct                         12.0                 6
time-to-event-wk-10th                5.9                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45430   0.91690   0.07532   2.74100   0.38960


$Agetrt_less_180d$`Gastrooesophageal reflux disease`
$Agetrt_less_180d$`Gastrooesophageal reflux disease`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              4.0                3.0
n_event_pct                         25.0                6.0
time-to-event-wk-10th                2.7               53.1
time-to-event-wk-25th               10.9                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          10.9                 NA
time-to-event-wk-50th-hici            NA                 NA
```

```
$Agetrt_less_180d$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.14060   0.84310   0.02694   0.73410   0.01999


$Agetrt_less_180d$Hypokalaemia
$Agetrt_less_180d$Hypokalaemia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                22.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.9                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Hypokalaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.361e-10 2.707e+04 0.000e+00       Inf 9.993e-01


$Agetrt_less_180d$Hypoxia
$Agetrt_less_180d$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 3
n_event_pct                          12.0                 6
time-to-event-wk-10th                33.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.4                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25610   0.96830   0.03838   1.70800   0.15950


$Agetrt_less_180d$Influenza
$Agetrt_less_180d$Influenza$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                49.0
n_event                                 0                 5.0
n_event_pct                             0                10.0
time-to-event-wk-10th                  NA                31.1
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
```

```
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Influenza$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.397e+08 1.487e+04 0.000e+00       Inf 9.990e-01


$Agetrt_less_180d$`Nasal congestion`
$Agetrt_less_180d$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0                6.0
n_event_pct                          12.0               12.0
time-to-event-wk-10th                 7.9               18.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7686    0.8244    0.1528    3.8680    0.7496


$Agetrt_less_180d$Nasopharyngitis
$Agetrt_less_180d$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16               49.0
n_event                                 1               13.0
n_event_pct                             6               27.0
time-to-event-wk-10th                  NA                7.7
time-to-event-wk-25th                  NA               27.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.5570    1.0430    0.4606   27.4800    0.2237


$Agetrt_less_180d$`Oral candidiasis`
$Agetrt_less_180d$`Oral candidiasis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0                5.0
n_event_pct                          12.0               10.0
time-to-event-wk-10th                15.3               45.4
time-to-event-wk-25th                  NA                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Oral candidiasis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45400   0.87970   0.08095   2.54600   0.36930


$Agetrt_less_180d$`Oxygen saturation decreased`
$Agetrt_less_180d$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               6.0                6.0
n_event_pct                          38.0               12.0
time-to-event-wk-10th                 2.1               36.9
time-to-event-wk-25th                20.3                 NA
time-to-event-wk-50th                40.7                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           10.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.15700   0.62810   0.04583   0.53760   0.00320


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               3.0               15.0
n_event_pct                          19.0               31.0
time-to-event-wk-10th                 5.3                5.0
time-to-event-wk-25th                  NA               25.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           11.9               42.4
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2890    0.6399    0.3679    4.5190    0.6912


$Agetrt_less_180d$`Pneumonia aspiration`
$Agetrt_less_180d$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16               49.0
n_event                                 2                6.0
```

```
n_event_pct                              12               12.0
time-to-event-wk-10th                     9               32.7
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               NA                 NA
time-to-event-wk-50th-hici               NA                 NA

$Agetrt_less_180d$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6608    0.8334    0.1290    3.3840    0.6191


$Agetrt_less_180d$`Pneumonia bacterial`
$Agetrt_less_180d$`Pneumonia bacterial`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 2
n_event_pct                          12.0                 4
time-to-event-wk-10th                36.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           36.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24730   1.03400   0.03261   1.87500   0.17640


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               8.0               28.0
n_event_pct                          50.0               57.0
time-to-event-wk-10th                 2.3                5.4
time-to-event-wk-25th                 6.4               13.4
time-to-event-wk-50th                20.6               31.7
time-to-event-wk-75th                52.6               54.3
time-to-event-wk-90th                52.6                 NA
time-to-event-wk-50th-loci            6.4               20.7
time-to-event-wk-50th-hici             NA               38.0

$Agetrt_less_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6902    0.4267    0.2990    1.5930    0.3849


$Agetrt_less_180d$Rash
$Agetrt_less_180d$Rash$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               3.0                6.0
n_event_pct                          19.0               12.0
time-to-event-wk-10th                 0.1               33.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5080    0.7156    0.1250    2.0650    0.3439


$Agetrt_less_180d$`Respiratory arrest`
$Agetrt_less_180d$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  2
n_event_pct                          12.0                  4
time-to-event-wk-10th                18.2                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.14930   1.05800   0.01878   1.18800   0.07225


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               4.0               14.0
n_event_pct                          25.0               29.0
time-to-event-wk-10th                15.4                8.9
time-to-event-wk-25th                28.1               35.0
time-to-event-wk-50th                33.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.4               43.4
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5961    0.5922    0.1867    1.9030    0.3824
```

```
$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              9.0              12.0
n_event_pct                         56.0              24.0
time-to-event-wk-10th                1.0               4.1
time-to-event-wk-25th                6.1              32.1
time-to-event-wk-50th               13.0                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           6.1                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.227600  0.477900  0.089210  0.580800  0.001956


$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`
$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              2.0                 3
n_event_pct                         12.0                 6
time-to-event-wk-10th               22.4                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          22.4                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.35970   0.92480   0.05872   2.20300   0.26880


$Agetrt_less_180d$`Respiratory tract infection`
$Agetrt_less_180d$`Respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              2.0               6.0
n_event_pct                         12.0              12.0
time-to-event-wk-10th               32.9              35.4
time-to-event-wk-25th               32.9                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          32.9                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Respiratory tract infection`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7821    0.8332    0.1528    4.0040    0.7680


$Agetrt_less_180d$Rhinorrhoea
$Agetrt_less_180d$Rhinorrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               1.0                5.0
n_event_pct                           6.0               10.0
time-to-event-wk-10th                26.4               45.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Rhinorrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9715    1.1260    0.1069    8.8270    0.9795


$Agetrt_less_180d$`Rhinovirus infection`
$Agetrt_less_180d$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               3.0                4.0
n_event_pct                          19.0                8.0
time-to-event-wk-10th                 8.7               45.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            9.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26780   0.79180   0.05673   1.26400   0.09609


$Agetrt_less_180d$`Sleep apnoea syndrome`
$Agetrt_less_180d$`Sleep apnoea syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               3.0                  0
n_event_pct                          19.0                  0
time-to-event-wk-10th                 5.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           21.1                 NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.090e-10 1.622e+04 0.000e+00       Inf 9.989e-01


$Agetrt_less_180d$Tachycardia
$Agetrt_less_180d$Tachycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               3.0                  4
n_event_pct                          19.0                  8
time-to-event-wk-10th                 4.3                 35
time-to-event-wk-25th                29.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           29.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33060   0.77290   0.07267   1.50400   0.15210


$Agetrt_less_180d$Teething
$Agetrt_less_180d$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16               49.0
n_event                               1                9.0
n_event_pct                           6               18.0
time-to-event-wk-10th                NA                4.1
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Agetrt_less_180d$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.4950    1.0590    0.3129   19.8900    0.3881


$Agetrt_less_180d$`Upper respiratory tract congestion`
$Agetrt_less_180d$`Upper respiratory tract congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16               49.0
n_event                               0                5.0
n_event_pct                           0               10.0
time-to-event-wk-10th                NA               36.4
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Upper respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.471e+08 1.454e+04 0.000e+00       Inf 9.989e-01


$Agetrt_less_180d$`Upper respiratory tract infection`
$Agetrt_less_180d$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               4.0               13.0
n_event_pct                          25.0               27.0
time-to-event-wk-10th                25.4               21.6
time-to-event-wk-25th                32.6               29.7
time-to-event-wk-50th                32.6                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           25.4               35.3
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6527    0.5801    0.2094    2.0350    0.4621


$Agetrt_less_180d$`Viral infection`
$Agetrt_less_180d$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16               49.0
n_event                               0                6.0
n_event_pct                           0               12.0
time-to-event-wk-10th                NA               31.9
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Agetrt_less_180d$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.861e+08 1.316e+04 0.000e+00       Inf 9.988e-01


$Agetrt_less_180d$`Viral upper respiratory tract infection`
$Agetrt_less_180d$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0                5.0
n_event_pct                          12.0               10.0
```

```
time-to-event-wk-10th                33.4               18.9
time-to-event-wk-25th                33.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6139    0.8406    0.1182    3.1890    0.5616


$Agetrt_less_180d$Vomiting
$Agetrt_less_180d$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               3.0                8.0
n_event_pct                          19.0               16.0
time-to-event-wk-10th                13.6               13.7
time-to-event-wk-25th                22.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7533    0.6955    0.1927    2.9440    0.6838


$Agetrt_less_180d$`Weight gain poor`
$Agetrt_less_180d$`Weight gain poor`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0                5.0
n_event_pct                          12.0               10.0
time-to-event-wk-10th                17.9               13.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Weight gain poor`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6455    0.8529    0.1213    3.4350    0.6078



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Acute respiratory failure`
```

```
$Agetrt_greater_equal_180d$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               6.0                4.0
n_event_pct                          24.0               13.0
time-to-event-wk-10th                13.9               19.9
time-to-event-wk-25th                26.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4615    0.6596    0.1267    1.6810    0.2410


$Agetrt_greater_equal_180d$Atelectasis
$Agetrt_greater_equal_180d$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               7.0                5.0
n_event_pct                          28.0               16.0
time-to-event-wk-10th                 4.0               11.4
time-to-event-wk-25th                15.3                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4665    0.5934    0.1458    1.4930    0.1988


$Agetrt_greater_equal_180d$Bradycardia
$Agetrt_greater_equal_180d$Bradycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                 31
n_event                               3.0                  2
n_event_pct                          12.0                  6
time-to-event-wk-10th                13.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Bradycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44540   0.92000   0.07339   2.70300   0.37930
```

```
$Agetrt_greater_equal_180d$`Bronchial secretion retention`
$Agetrt_greater_equal_180d$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               4.0                 1
n_event_pct                          16.0                 3
time-to-event-wk-10th                 8.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13720   1.13300   0.01491   1.26300   0.07946


$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`
$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 25               31.0
n_event                                3                4.0
n_event_pct                           12               13.0
time-to-event-wk-10th                 23               17.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9800    0.7888    0.2088    4.5990    0.9795


$Agetrt_greater_equal_180d$Constipation
$Agetrt_greater_equal_180d$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               4.0               14.0
n_event_pct                          16.0               45.0
time-to-event-wk-10th                17.6                4.4
time-to-event-wk-25th                48.6                7.9
time-to-event-wk-50th                  NA               35.0
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           48.6               18.0
time-to-event-wk-50th-hici             NA                 NA
```

```
$Agetrt_greater_equal_180d$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  3.56500   0.57900   1.14600  11.09000   0.02811


$Agetrt_greater_equal_180d$Cough
$Agetrt_greater_equal_180d$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               5.0                3.0
n_event_pct                          20.0               10.0
time-to-event-wk-10th                 1.1               38.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4473    0.7431    0.1042    1.9190    0.2790


$Agetrt_greater_equal_180d$`Dermatitis diaper`
$Agetrt_greater_equal_180d$`Dermatitis diaper`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               3.0                3.0
n_event_pct                          12.0               10.0
time-to-event-wk-10th                53.9               21.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           53.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Dermatitis diaper`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7823    0.8259    0.1550    3.9480    0.7662


$Agetrt_greater_equal_180d$Diarrhoea
$Agetrt_greater_equal_180d$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               3.0                5.0
n_event_pct                          12.0               16.0
time-to-event-wk-10th                31.9               16.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4620    0.7516    0.3350    6.3770    0.6135


$Agetrt_greater_equal_180d$Dysphagia
$Agetrt_greater_equal_180d$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               7.0                4.0
n_event_pct                          28.0               13.0
time-to-event-wk-10th                 8.0               18.9
time-to-event-wk-25th                26.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4028    0.6440    0.1140    1.4230    0.1580


$Agetrt_greater_equal_180d$Dyspnoea
$Agetrt_greater_equal_180d$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               3.0                5.0
n_event_pct                          12.0               16.0
time-to-event-wk-10th                21.3               12.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1200    0.7403    0.2626    4.7800    0.8780


$Agetrt_greater_equal_180d$`Gastrooesophageal reflux disease`
$Agetrt_greater_equal_180d$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               4.0                7.0
n_event_pct                          16.0               23.0
time-to-event-wk-10th                43.0                5.0
time-to-event-wk-25th                48.6               45.6
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           43.0               45.6
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3100    0.6336    0.3785    4.5360    0.6698


$Agetrt_greater_equal_180d$Hypoxia
$Agetrt_greater_equal_180d$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25               31.0
n_event                                 0                4.0
n_event_pct                             0               13.0
time-to-event-wk-10th                  NA               12.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.033e+08 1.213e+04 0.000e+00       Inf 9.987e-01


$Agetrt_greater_equal_180d$`Lower respiratory tract infection`
$Agetrt_greater_equal_180d$`Lower respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                 31
n_event                                 1                  4
n_event_pct                             4                 13
time-to-event-wk-10th                  NA                 35
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Lower respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.8660    1.1330    0.3109   26.4200    0.3529


$Agetrt_greater_equal_180d$`Nasal congestion`
$Agetrt_greater_equal_180d$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                 31
```

```
n_event                                3.0                  2
n_event_pct                           12.0                  6
time-to-event-wk-10th                 37.4                 NA
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Agetrt_greater_equal_180d$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6874    0.9254    0.1121    4.2160    0.6855


$Agetrt_greater_equal_180d$Nasopharyngitis
$Agetrt_greater_equal_180d$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                 31
n_event                               3.0                  2
n_event_pct                          12.0                  6
time-to-event-wk-10th                28.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           42.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7570    0.9491    0.1178    4.8630    0.7693


$Agetrt_greater_equal_180d$`Oxygen saturation decreased`
$Agetrt_greater_equal_180d$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31.0
n_event                               4.0                 4.0
n_event_pct                          16.0                13.0
time-to-event-wk-10th                18.9                 8.1
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           37.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_greater_equal_180d$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6912    0.7155    0.1700    2.8100    0.6057


$Agetrt_greater_equal_180d$Pneumonia
```

```
$Agetrt_greater_equal_180d$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0               31.0
n_event                              4.0                8.0
n_event_pct                         16.0               26.0
time-to-event-wk-10th               13.7               15.4
time-to-event-wk-25th                 NA               30.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          46.6               30.4
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3920    0.6255    0.4084    4.7420    0.5972


$Agetrt_greater_equal_180d$`Pneumonia aspiration`
$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                25               31.0
n_event                               5                3.0
n_event_pct                          20               10.0
time-to-event-wk-10th                11               37.7
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4709    0.7465    0.1090    2.0340    0.3131


$Agetrt_greater_equal_180d$`Pneumonia viral`
$Agetrt_greater_equal_180d$`Pneumonia viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0               31.0
n_event                              2.0                4.0
n_event_pct                          8.0               13.0
time-to-event-wk-10th               52.6               34.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          52.6               46.7
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4620    0.8940    0.2535    8.4340    0.6708
```

```
$Agetrt_greater_equal_180d$Pyrexia
$Agetrt_greater_equal_180d$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              16.0               17.0
n_event_pct                          64.0               55.0
time-to-event-wk-10th                 3.1                3.0
time-to-event-wk-25th                 5.7                8.1
time-to-event-wk-50th                16.0               36.0
time-to-event-wk-75th                37.7                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.7               12.7
time-to-event-wk-50th-hici           37.7               46.7

$Agetrt_greater_equal_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6375    0.3629    0.3130    1.2980    0.2147


$Agetrt_greater_equal_180d$`Respiratory distress`
$Agetrt_greater_equal_180d$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               8.0                7.0
n_event_pct                          32.0               23.0
time-to-event-wk-10th                 2.9                7.1
time-to-event-wk-25th                15.9               25.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6190    0.5234    0.2219    1.7270    0.3594


$Agetrt_greater_equal_180d$`Respiratory failure`
$Agetrt_greater_equal_180d$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                 31
n_event                               7.0                  8
n_event_pct                          28.0                 26
time-to-event-wk-10th                13.1                 10
time-to-event-wk-25th                19.3                 27
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           21.9                 34
time-to-event-wk-50th-hici             NA                 NA
```

```
$Agetrt_greater_equal_180d$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8191    0.5225    0.2941    2.2810    0.7026


$Agetrt_greater_equal_180d$`Rhinovirus infection`
$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                              3.0               6.0
n_event_pct                         12.0              19.0
time-to-event-wk-10th               18.1               6.6
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3400    0.7127    0.3316    5.4190    0.6810


$Agetrt_greater_equal_180d$Teething
$Agetrt_greater_equal_180d$Teething$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                25              31.0
n_event                               2               5.0
n_event_pct                           8              16.0
time-to-event-wk-10th                NA               9.3
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Agetrt_greater_equal_180d$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9660    0.8394    0.3793   10.1900    0.4208


$Agetrt_greater_equal_180d$`Upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                              5.0              11.0
n_event_pct                         20.0              35.0
time-to-event-wk-10th                8.7               5.7
time-to-event-wk-25th                 NA              17.1
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
```

```
time-to-event-wk-50th-loci           28.3               21.9
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9040    0.5539    0.6428    5.6370    0.2452


$Agetrt_greater_equal_180d$`Urinary tract infection`
$Agetrt_greater_equal_180d$`Urinary tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 25               31.0
n_event                                0                4.0
n_event_pct                            0               13.0
time-to-event-wk-10th                 NA               46.6
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA               52.6
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$`Urinary tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.186e+09 2.011e+04 0.000e+00       Inf 9.992e-01


$Agetrt_greater_equal_180d$`Viral infection`
$Agetrt_greater_equal_180d$`Viral infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0                31
n_event                              3.0                 2
n_event_pct                         12.0                 6
time-to-event-wk-10th               44.1                41
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          45.7                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_greater_equal_180d$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8571    0.9794    0.1257    5.8440    0.8749


$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0               31.0
n_event                              5.0                3.0
n_event_pct                         20.0               10.0
time-to-event-wk-10th               17.6               16.7
```

```
time-to-event-wk-25th                37.3                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4476    0.7478    0.1034    1.9380    0.2824


$Agetrt_greater_equal_180d$Vomiting
$Agetrt_greater_equal_180d$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               5.0                6.0
n_event_pct                          20.0               19.0
time-to-event-wk-10th                12.0               13.1
time-to-event-wk-25th                47.7               51.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           39.7               51.0
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9841    0.6245    0.2894    3.3470    0.9795



$Gender_Male
$Gender_Male$`Acute respiratory failure`
$Gender_Male$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               4.0                5.0
n_event_pct                          24.0               14.0
time-to-event-wk-10th                16.4               25.4
time-to-event-wk-25th                22.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5031    0.6776    0.1333    1.8990    0.3106


$Gender_Male$Aspiration
```

```
$Gender_Male$Aspiration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               3.0                  2
n_event_pct                          18.0                  5
time-to-event-wk-10th                40.3                 NA
time-to-event-wk-25th                40.3                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24020   0.95180   0.03719   1.55200   0.13410


$Gender_Male$Atelectasis
$Gender_Male$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37.0
n_event                               5.0                 5.0
n_event_pct                          29.0                14.0
time-to-event-wk-10th                 3.1                15.7
time-to-event-wk-25th                22.9                  NA
time-to-event-wk-50th                52.7                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           22.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4081    0.6445    0.1154    1.4440    0.1644


$Gender_Male$`Bacterial tracheitis`
$Gender_Male$`Bacterial tracheitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  1
n_event_pct                          12.0                  3
time-to-event-wk-10th                25.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           25.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Bacterial tracheitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24050   1.24900   0.02078   2.78400   0.25410
```

```
$Gender_Male$`Bronchial secretion retention`
$Gender_Male$`Bronchial secretion retention`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              37.0
n_event                              4.0               4.0
n_event_pct                         24.0              11.0
time-to-event-wk-10th                4.3              33.4
time-to-event-wk-25th               19.9                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          19.9                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.34500   0.72710   0.08296   1.43500   0.14330


$Gender_Male$`Cardio-respiratory arrest`
$Gender_Male$`Cardio-respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                37
n_event                              3.0                 2
n_event_pct                         18.0                 5
time-to-event-wk-10th               14.3                NA
time-to-event-wk-25th               33.6                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          33.6                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29500   0.93520   0.04719   1.84500   0.19180


$Gender_Male$Constipation
$Gender_Male$Constipation$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              37.0
n_event                              2.0              11.0
n_event_pct                         12.0              30.0
time-to-event-wk-10th               40.7              11.9
time-to-event-wk-25th               40.7              21.4
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          40.7              27.9
time-to-event-wk-50th-hici            NA                NA
```

```
$Gender_Male$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2540    0.7763    0.4921   10.3200    0.2952


$Gender_Male$Cough
$Gender_Male$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 4
n_event_pct                          12.0                11
time-to-event-wk-10th                 5.1                28
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7157    0.8761    0.1285    3.9850    0.7026


$Gender_Male$Cyanosis
$Gender_Male$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                15.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.116e-10 2.171e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$`Decubitus ulcer`
$Gender_Male$`Decubitus ulcer`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                20.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
```

```
time-to-event-wk-50th-loci           20.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Decubitus ulcer`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.845e-10 2.193e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$`Dermatitis contact`
$Gender_Male$`Dermatitis contact`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  1
n_event_pct                          12.0                  3
time-to-event-wk-10th                35.6                 NA
time-to-event-wk-25th                51.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Dermatitis contact`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.41630   1.31600   0.03159   5.48600   0.50540


$Gender_Male$Diarrhoea
$Gender_Male$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37.0
n_event                               3.0                 4.0
n_event_pct                          18.0                11.0
time-to-event-wk-10th                 9.4                18.3
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           10.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5450    0.7684    0.1209    2.4570    0.4296


$Gender_Male$Dysphagia
$Gender_Male$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               4.0                  4
n_event_pct                          24.0                 11
time-to-event-wk-10th                12.7                 13
time-to-event-wk-25th                27.9                 NA
```

```
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           17.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4376    0.7127    0.1082    1.7690    0.2461


$Gender_Male$Dyspnoea
$Gender_Male$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  3
n_event_pct                          12.0                  8
time-to-event-wk-10th                24.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.38630   0.94900   0.06014   2.48200   0.31630


$Gender_Male$Eczema
$Gender_Male$Eczema$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  1
n_event_pct                          12.0                  3
time-to-event-wk-10th                40.7                 NA
time-to-event-wk-25th                40.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Eczema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.21600   1.25300   0.01854   2.51800   0.22130


$Gender_Male$Erythema
$Gender_Male$Erythema$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 2                  1
```

```
n_event_pct                              12                  3
time-to-event-wk-10th                    19                 NA
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               19                 NA
time-to-event-wk-50th-hici               NA                 NA

$Gender_Male$Erythema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24920   1.24400   0.02176   2.85300   0.26390


$Gender_Male$`Failure to thrive`
$Gender_Male$`Failure to thrive`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  2
n_event_pct                          12.0                  5
time-to-event-wk-10th                 9.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Failure to thrive`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44900   1.01400   0.06149   3.27800   0.42990


$Gender_Male$`Feeding tube complication`
$Gender_Male$`Feeding tube complication`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  2
n_event_pct                          12.0                  5
time-to-event-wk-10th                26.4                 NA
time-to-event-wk-25th                53.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Feeding tube complication`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.30450   1.02000   0.04127   2.24700   0.24360


$Gender_Male$`Gastrooesophageal reflux disease`
$Gender_Male$`Gastrooesophageal reflux disease`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 3
n_event_pct                          12.0                 8
time-to-event-wk-10th                10.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.53560   0.93530   0.08565   3.35000   0.50450


$Gender_Male$Hypersensitivity
$Gender_Male$Hypersensitivity$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17                37
n_event                               2                 1
n_event_pct                          12                 3
time-to-event-wk-10th                41                NA
time-to-event-wk-25th                41                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           41                NA
time-to-event-wk-50th-hici           NA                NA

$Gender_Male$Hypersensitivity$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.21750   1.26100   0.01838   2.57500   0.22630


$Gender_Male$Hypokalaemia
$Gender_Male$Hypokalaemia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                22.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.9                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$Hypokalaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.402e-10 3.970e+04 0.000e+00       Inf 9.996e-01
```

```
$Gender_Male$Hypoxia
$Gender_Male$Hypoxia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               37.0
n_event                              2.0                4.0
n_event_pct                         12.0               11.0
time-to-event-wk-10th               33.4               26.1
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          33.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7152    0.8823    0.1269    4.0310    0.7039


$Gender_Male$`Joint contracture`
$Gender_Male$`Joint contracture`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                 37
n_event                              2.0                  2
n_event_pct                         12.0                  5
time-to-event-wk-10th               43.4                 63
time-to-event-wk-25th               43.4                 63
time-to-event-wk-50th                 NA                 63
time-to-event-wk-75th                 NA                 63
time-to-event-wk-90th                 NA                 63
time-to-event-wk-50th-loci          43.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Joint contracture`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.19190   1.25000   0.01655   2.22600   0.18680


$Gender_Male$`Nasal congestion`
$Gender_Male$`Nasal congestion`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                 37
n_event                              3.0                  3
n_event_pct                         18.0                  8
time-to-event-wk-10th                7.9                 NA
time-to-event-wk-25th               37.4                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          37.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Nasal congestion`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.46000   0.82870   0.09065   2.33400   0.34870


$Gender_Male$Nasopharyngitis
$Gender_Male$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               2.0                9.0
n_event_pct                          12.0               24.0
time-to-event-wk-10th                28.3               14.4
time-to-event-wk-25th                  NA               28.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3               29.7
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2430    0.7976    0.4697   10.7100    0.3113


$Gender_Male$Oedema
$Gender_Male$Oedema$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                43.4                 NA
time-to-event-wk-25th                43.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           43.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Oedema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.430e-10 2.204e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$`Oral candidiasis`
$Gender_Male$`Oral candidiasis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               2.0                3.0
n_event_pct                          12.0                8.0
time-to-event-wk-10th                 7.4               34.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Oral candidiasis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.50210   0.93310   0.08064   3.12600   0.46030


$Gender_Male$`Oxygen saturation decreased`
$Gender_Male$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               5.0                5.0
n_event_pct                          29.0               14.0
time-to-event-wk-10th                 2.0               25.1
time-to-event-wk-25th                20.3                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3647    0.6448    0.1031    1.2910    0.1177


$Gender_Male$Pneumonia
$Gender_Male$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               3.0                8.0
n_event_pct                          18.0               22.0
time-to-event-wk-10th                 5.3               10.6
time-to-event-wk-25th                  NA               35.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           11.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0460    0.6859    0.2726    4.0120    0.9480


$Gender_Male$`Pneumonia aspiration`
$Gender_Male$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               3.0                  2
n_event_pct                          18.0                  5
time-to-event-wk-10th                 1.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           17.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.28320   0.92860   0.04588   1.74800   0.17420


$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               37.0
n_event                              9.0               20.0
n_event_pct                         53.0               54.0
time-to-event-wk-10th                4.1                2.6
time-to-event-wk-25th                7.7                8.1
time-to-event-wk-50th               20.6               36.0
time-to-event-wk-75th               52.6                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           7.7               15.0
time-to-event-wk-50th-hici            NA               46.7

$Gender_Male$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8268    0.4197    0.3632    1.8820    0.6504


$Gender_Male$Rash
$Gender_Male$Rash$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                17               37.0
n_event                               3                4.0
n_event_pct                          18               11.0
time-to-event-wk-10th                 4               35.3
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Gender_Male$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44500   0.78050   0.09638   2.05500   0.29960


$Gender_Male$`Respiratory arrest`
$Gender_Male$`Respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               37.0
n_event                              2.0                3.0
n_event_pct                         12.0                8.0
```

```
time-to-event-wk-10th                19.9               40.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.52250   0.94830   0.08145   3.35200   0.49370


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               5.0               10.0
n_event_pct                          29.0               27.0
time-to-event-wk-10th                 2.3                3.4
time-to-event-wk-25th                33.1               19.3
time-to-event-wk-50th                33.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.1               35.0
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7316    0.5557    0.2462    2.1740    0.5738


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               7.0               11.0
n_event_pct                          41.0               30.0
time-to-event-wk-10th                 1.0                1.7
time-to-event-wk-25th                13.0               27.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.4               31.9
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6666    0.4951    0.2526    1.7590    0.4127


$Gender_Male$`Respiratory tract infection`
$Gender_Male$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  17               37.0
n_event                                 0                4.0
n_event_pct                             0               11.0
time-to-event-wk-10th                  NA               30.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.686e+08 1.381e+04 0.000e+00       Inf 9.989e-01


$Gender_Male$`Rhinovirus infection`
$Gender_Male$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 7
n_event_pct                          12.0                19
time-to-event-wk-10th                 5.3                 9
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1170    0.8287    0.2202    5.6700    0.8935


$Gender_Male$`Sleep apnoea syndrome`
$Gender_Male$`Sleep apnoea syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               3.0                 0
n_event_pct                          18.0                 0
time-to-event-wk-10th                 5.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.823e-10 1.745e+04 0.000e+00       Inf 9.990e-01
```

```
$Gender_Male$`Stoma site infection`
$Gender_Male$`Stoma site infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                  37
n_event                                2                   1
n_event_pct                           12                   3
time-to-event-wk-10th                 24                  NA
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci            24                  NA
time-to-event-wk-50th-hici            NA                  NA

$Gender_Male$`Stoma site infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.112200  1.277000  0.009192  1.371000  0.086720


$Gender_Male$Tachycardia
$Gender_Male$Tachycardia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                37.0
n_event                              2.0                 5.0
n_event_pct                         12.0                14.0
time-to-event-wk-10th               29.4                10.1
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci          29.4                  NA
time-to-event-wk-50th-hici            NA                  NA

$Gender_Male$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2160    0.8451    0.2321    6.3730    0.8168


$Gender_Male$Tachypnoea
$Gender_Male$Tachypnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                  37
n_event                              2.0                   0
n_event_pct                         12.0                   0
time-to-event-wk-10th               43.4                  NA
time-to-event-wk-25th               43.4                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci          43.4                  NA
time-to-event-wk-50th-hici            NA                  NA

$Gender_Male$Tachypnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
3.542e-11 3.119e+04 0.000e+00       Inf 9.994e-01


$Gender_Male$Teething
$Gender_Male$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 8
n_event_pct                          12.0                22
time-to-event-wk-10th                 9.7                 0
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6530    0.8017    0.3434    7.9550    0.5308


$Gender_Male$`Upper respiratory tract infection`
$Gender_Male$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               4.0              10.0
n_event_pct                          24.0              27.0
time-to-event-wk-10th                 6.3              15.4
time-to-event-wk-25th                32.6              26.4
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           32.6              30.7
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9636    0.5980    0.2984    3.1110    0.9506


$Gender_Male$`Viral infection`
$Gender_Male$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17              37.0
n_event                                 1               4.0
n_event_pct                             6              11.0
time-to-event-wk-10th                  NA              31.9
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA
```

```
$Gender_Male$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0970    1.1430    0.2233   19.6900    0.5171


$Gender_Male$`Viral upper respiratory tract infection`
$Gender_Male$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               4.0                 3
n_event_pct                          24.0                 8
time-to-event-wk-10th                17.6                NA
time-to-event-wk-25th                23.9                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.6                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.27120   0.77470   0.05941   1.23800   0.09212


$Gender_Male$Vomiting
$Gender_Male$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               4.0               5.0
n_event_pct                          24.0              14.0
time-to-event-wk-10th                12.0               6.3
time-to-event-wk-25th                22.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.6                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4585    0.6894    0.1187    1.7710    0.2580



$Gender_Female
$Gender_Female$`Acute respiratory failure`
$Gender_Female$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                               6.0               6.0
n_event_pct                          25.0              14.0
time-to-event-wk-10th                 8.6              19.9
time-to-event-wk-25th                26.0                NA
```

```
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           26.0                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4832    0.5965    0.1501    1.5550    0.2227


$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               7.0               13.0
n_event_pct                          29.0               30.0
time-to-event-wk-10th                11.0                9.6
time-to-event-wk-25th                17.6               32.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.3               36.0
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8857    0.4758    0.3486    2.2510    0.7986


$Gender_Female$`Bronchial secretion retention`
$Gender_Female$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               3.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                40.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.890e-10 1.581e+04 0.000e+00       Inf 9.989e-01


$Gender_Female$Bronchiolitis
$Gender_Female$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24               43.0
n_event                                 2                5.0
```

```
n_event_pct                               8               12.0
time-to-event-wk-10th                    NA               32.1
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               NA                 NA
time-to-event-wk-50th-hici               NA                 NA

$Gender_Female$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0370    0.8563    0.1937    5.5570    0.9658


$Gender_Female$`Candida infection`
$Gender_Female$`Candida infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               3.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                15.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Candida infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.202e-10 1.686e+04 0.000e+00       Inf 9.990e-01


$Gender_Female$Constipation
$Gender_Female$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               7.0               17.0
n_event_pct                          29.0               40.0
time-to-event-wk-10th                11.3                4.4
time-to-event-wk-25th                17.6               17.7
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.3               19.7
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2450    0.4687    0.4969    3.1210    0.6397


$Gender_Female$Cough
$Gender_Female$Cough$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               6.0                5.0
n_event_pct                          25.0               12.0
time-to-event-wk-10th                 1.0               25.9
time-to-event-wk-25th                 8.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33380   0.62190   0.09866   1.12900   0.07768


$Gender_Female$`Dermatitis diaper`
$Gender_Female$`Dermatitis diaper`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               3.0                4.0
n_event_pct                          12.0                9.0
time-to-event-wk-10th                53.9               49.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           53.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Dermatitis diaper`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5882    0.7904    0.1250    2.7690    0.5019


$Gender_Female$Diarrhoea
$Gender_Female$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               4.0                7.0
n_event_pct                          17.0               16.0
time-to-event-wk-10th                16.9               28.0
time-to-event-wk-25th                  NA               43.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           31.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7295    0.6582    0.2008    2.6500    0.6318
```

```
$Gender_Female$Dysphagia
$Gender_Female$Dysphagia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                              5.0                5.0
n_event_pct                         21.0               12.0
time-to-event-wk-10th                8.0               28.4
time-to-event-wk-25th               26.1                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          26.1                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4430    0.6470    0.1246    1.5750    0.2083


$Gender_Female$Dyspnoea
$Gender_Female$Dyspnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                              4.0                4.0
n_event_pct                         17.0                9.0
time-to-event-wk-10th               11.9               43.1
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4329    0.7313    0.1033    1.8150    0.2523


$Gender_Female$`Gastrooesophageal reflux disease`
$Gender_Female$`Gastrooesophageal reflux disease`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                              6.0                7.0
n_event_pct                         25.0               16.0
time-to-event-wk-10th                4.4                7.6
time-to-event-wk-25th               43.0                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          43.0                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5895    0.5869    0.1866    1.8620    0.3679


$Gender_Female$`Nasal congestion`
$Gender_Female$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24               43.0
n_event                                 2                5.0
n_event_pct                             8               12.0
time-to-event-wk-10th                  NA               18.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0720    0.8666    0.1961    5.8580    0.9363


$Gender_Female$Nasopharyngitis
$Gender_Female$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 24.0               43.0
n_event                                2.0                6.0
n_event_pct                            8.0               14.0
time-to-event-wk-10th                 42.3               11.4
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            42.3                 NA
time-to-event-wk-50th-hici              NA                 NA

$Gender_Female$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2510    0.8344    0.2437    6.4180    0.7886


$Gender_Female$`Oxygen saturation decreased`
$Gender_Female$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 24.0                 43
n_event                                5.0                  5
n_event_pct                           21.0                 12
time-to-event-wk-10th                 18.9                 52
time-to-event-wk-25th                 40.7                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            37.4                 NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4830    0.6437    0.1368    1.7060    0.2582


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               4.0               15.0
n_event_pct                          17.0               35.0
time-to-event-wk-10th                11.9                6.9
time-to-event-wk-25th                46.6               25.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           46.6               33.1
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9640    0.5702    0.6424    6.0050    0.2364


$Gender_Female$`Pneumonia aspiration`
$Gender_Female$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24               43.0
n_event                                 4                7.0
n_event_pct                            17               16.0
time-to-event-wk-10th                  11               28.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9684    0.6421    0.2751    3.4090    0.9601


$Gender_Female$`Pneumonia bacterial`
$Gender_Female$`Pneumonia bacterial`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               3.0                  2
n_event_pct                          12.0                  5
time-to-event-wk-10th                17.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.28270   0.93310   0.04539   1.76000   0.17570


$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                             15.0               25.0
n_event_pct                         62.0               58.0
time-to-event-wk-10th                2.3                4.9
time-to-event-wk-25th                5.7               12.7
time-to-event-wk-50th               16.0               31.7
time-to-event-wk-75th               42.6               54.3
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           6.4               15.6
time-to-event-wk-50th-hici          37.7               46.4

$Gender_Female$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6543    0.3358    0.3388    1.2640    0.2065


$Gender_Female$Rash
$Gender_Female$Rash$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                24               43.0
n_event                               1                5.0
n_event_pct                           4               12.0
time-to-event-wk-10th                NA               29.3
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Gender_Female$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.4240    1.1110    0.2745   21.4000    0.4257


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                              7.0               11.0
n_event_pct                         29.0               26.0
```

```
time-to-event-wk-10th                11.0                20.3
time-to-event-wk-25th                15.9                43.4
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           15.9                45.3
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7045    0.4966    0.2662    1.8650    0.4806


$Gender_Female$`Respiratory failure`
$Gender_Female$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43.0
n_event                               9.0                 9.0
n_event_pct                          38.0                21.0
time-to-event-wk-10th                 4.6                16.1
time-to-event-wk-25th                15.7                43.4
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           15.7                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5154    0.4917    0.1966    1.3510    0.1776


$Gender_Female$`Respiratory tract congestion`
$Gender_Female$`Respiratory tract congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                  43
n_event                               3.0                   0
n_event_pct                          12.0                   0
time-to-event-wk-10th                12.6                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$`Respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.400e-10 1.658e+04 0.000e+00       Inf 9.990e-01


$Gender_Female$`Respiratory tract infection`
$Gender_Female$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                24.0               43.0
n_event                               2.0                5.0
n_event_pct                           8.0               12.0
time-to-event-wk-10th                32.9               35.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0200    0.8580    0.1898    5.4840    0.9813


$Gender_Female$Rhinorrhoea
$Gender_Female$Rhinorrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               2.0                6.0
n_event_pct                           8.0               14.0
time-to-event-wk-10th                52.1               30.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Rhinorrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4640    0.8278    0.2890    7.4140    0.6454


$Gender_Female$`Rhinovirus infection`
$Gender_Female$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               4.0                  3
n_event_pct                          17.0                  7
time-to-event-wk-10th                15.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40480   0.78870   0.08628   1.89900   0.25150
```

```
$Gender_Female$Tachycardia
$Gender_Female$Tachycardia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0                 43
n_event                              3.0                  2
n_event_pct                         12.0                  5
time-to-event-wk-10th                4.6                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39230   0.93540   0.06271   2.45400   0.31710


$Gender_Female$Teething
$Gender_Female$Teething$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                24               43.0
n_event                               1                6.0
n_event_pct                           4               14.0
time-to-event-wk-10th                NA               22.7
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Gender_Female$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.7080    1.0990    0.3144   23.3300    0.3645


$Gender_Female$`Upper respiratory tract infection`
$Gender_Female$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                              5.0               14.0
n_event_pct                         21.0               33.0
time-to-event-wk-10th               12.3               17.1
time-to-event-wk-25th               28.3               26.0
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          28.3               28.9
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   1.5800    0.5370    0.5517    4.5270    0.3940


$Gender_Female$`Urinary tract infection`
$Gender_Female$`Urinary tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24               43.0
n_event                                 0                6.0
n_event_pct                             0               14.0
time-to-event-wk-10th                  NA               26.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Urinary tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.429e+08 1.109e+04 0.000e+00       Inf 9.986e-01


$Gender_Female$`Viral upper respiratory tract infection`
$Gender_Female$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               3.0                5.0
n_event_pct                          12.0               12.0
time-to-event-wk-10th                37.3               18.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9855    0.7465    0.2282    4.2570    0.9844


$Gender_Female$Vomiting
$Gender_Female$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               4.0                9.0
n_event_pct                          17.0               21.0
time-to-event-wk-10th                39.7               13.7
time-to-event-wk-25th                47.7               51.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           39.7                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Gender_Female$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8133    0.6145    0.2439    2.7120    0.7367



$Region_Europe
$Region_Europe$`Acute respiratory failure`
$Region_Europe$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                16.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.963e-11 3.130e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$Atelectasis
$Region_Europe$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               3.0                8.0
n_event_pct                          18.0               27.0
time-to-event-wk-10th                17.6                4.2
time-to-event-wk-25th                32.9               18.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5220    0.6851    0.3974    5.8280    0.5398


$Region_Europe$`Bronchial secretion retention`
$Region_Europe$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               3.0                2.0
n_event_pct                          18.0                7.0
time-to-event-wk-10th                 6.1               45.7
time-to-event-wk-25th                40.7                 NA
```

```
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           40.7                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29680   0.93200   0.04778   1.84400   0.19250


$Region_Europe$Bronchitis
$Region_Europe$Bronchitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               30.0
n_event                                 1                5.0
n_event_pct                             6               17.0
time-to-event-wk-10th                  NA                9.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Bronchitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2280    1.1050    0.2554   19.4300    0.4685


$Region_Europe$`Bronchitis viral`
$Region_Europe$`Bronchitis viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               30.0
n_event                                 0                3.0
n_event_pct                             0               10.0
time-to-event-wk-10th                  NA               37.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Bronchitis viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.428e+08 2.489e+04 0.000e+00       Inf 9.993e-01


$Region_Europe$Constipation
$Region_Europe$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               4.0                6.0
```

```
n_event_pct                          24.0               20.0
time-to-event-wk-10th                11.3                7.4
time-to-event-wk-25th                17.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9525    0.6673    0.2575    3.5230    0.9419


$Region_Europe$Dysphagia
$Region_Europe$Dysphagia$stats_num
                         TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                26.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           26.1                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.536e-10 3.299e+04 0.000e+00       Inf 9.995e-01


$Region_Europe$`Feeding disorder of infancy or early childhood`
$Region_Europe$`Feeding disorder of infancy or early childhood`$stats_num
                         TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               3.0                 2
n_event_pct                          18.0                 7
time-to-event-wk-10th                 5.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.21840   0.96030   0.03325   1.43500   0.11310


$Region_Europe$`Gastrooesophageal reflux disease`
```

```
$Region_Europe$`Gastrooesophageal reflux disease`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                              3.0                3.0
n_event_pct                         18.0               10.0
time-to-event-wk-10th                4.4                7.1
time-to-event-wk-25th               48.6                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          48.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.43530   0.84310   0.08341   2.27200   0.32390


$Region_Europe$Nasopharyngitis
$Region_Europe$Nasopharyngitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                17               30.0
n_event                               0                7.0
n_event_pct                           0               23.0
time-to-event-wk-10th                NA                6.3
time-to-event-wk-25th                NA               29.7
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA               29.7
time-to-event-wk-50th-hici           NA                 NA

$Region_Europe$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.197e+08 9.843e+03 0.000e+00       Inf 9.984e-01


$Region_Europe$`Oral candidiasis`
$Region_Europe$`Oral candidiasis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                              2.0                3.0
n_event_pct                         12.0               10.0
time-to-event-wk-10th               15.3               45.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Oral candidiasis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.55920   0.94630   0.08752   3.57300   0.53910
```

```
$Region_Europe$`Oxygen saturation decreased`
$Region_Europe$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               3.0                 1
n_event_pct                          18.0                 3
time-to-event-wk-10th                37.4                NA
time-to-event-wk-25th                40.7                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           37.4                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13410   1.16400   0.01368   1.31300   0.08438


$Region_Europe$Pain
$Region_Europe$Pain$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17                30
n_event                               2                 0
n_event_pct                          12                 0
time-to-event-wk-10th                 2                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Region_Europe$Pain$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.678e-10 1.887e+04 0.000e+00       Inf 9.991e-01


$Region_Europe$Pneumonia
$Region_Europe$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               3.0               7.0
n_event_pct                          18.0              23.0
time-to-event-wk-10th                 5.7              10.6
time-to-event-wk-25th                  NA              42.4
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           11.9              42.4
time-to-event-wk-50th-hici             NA                NA
```

```
$Region_Europe$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0590    0.7006    0.2683    4.1820    0.9345


$Region_Europe$`Pneumonia aspiration`
$Region_Europe$`Pneumonia aspiration`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17               30.0
n_event                                2                3.0
n_event_pct                           12               10.0
time-to-event-wk-10th                 11               27.9
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8150    0.9252    0.1329    4.9970    0.8250


$Region_Europe$Pyrexia
$Region_Europe$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                             10.0               16.0
n_event_pct                         59.0               53.0
time-to-event-wk-10th                2.3                1.9
time-to-event-wk-25th                5.1                8.1
time-to-event-wk-50th               15.1               23.4
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           5.1                8.1
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7017    0.4081    0.3153    1.5610    0.3853


$Region_Europe$`Respiratory arrest`
$Region_Europe$`Respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17               30.0
n_event                                0                4.0
n_event_pct                            0               13.0
time-to-event-wk-10th                 NA               27.3
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
```

```
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.115e+08 1.390e+04 0.000e+00       Inf 9.989e-01


$Region_Europe$`Respiratory distress`
$Region_Europe$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               2.0                8.0
n_event_pct                          12.0               27.0
time-to-event-wk-10th                15.4               10.6
time-to-event-wk-25th                  NA               24.3
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               25.9
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.5270    0.8001    0.5268   12.1300    0.2465


$Region_Europe$`Respiratory failure`
$Region_Europe$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               8.0                9.0
n_event_pct                          47.0               30.0
time-to-event-wk-10th                 2.1                5.1
time-to-event-wk-25th                 9.1               27.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.1               31.9
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4932    0.5010    0.1848    1.3170    0.1583


$Region_Europe$`Respiratory tract infection`
$Region_Europe$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               2.0                8.0
n_event_pct                          12.0               27.0
time-to-event-wk-10th                32.9                9.3
time-to-event-wk-25th                32.9               35.4
```

```
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           32.9                35.4
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6470    0.8044    0.3405    7.9710    0.5349


$Region_Europe$Rhinitis
$Region_Europe$Rhinitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               3.0                 2
n_event_pct                          18.0                 7
time-to-event-wk-10th                15.1                52
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.6                52
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$Rhinitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29890   0.92100   0.04915   1.81700   0.18980


$Region_Europe$`Rhinovirus infection`
$Region_Europe$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17                  30
n_event                               1                   3
n_event_pct                           6                  10
time-to-event-wk-10th                NA                  18
time-to-event-wk-25th                NA                  NA
time-to-event-wk-50th                NA                  NA
time-to-event-wk-75th                NA                  NA
time-to-event-wk-90th                NA                  NA
time-to-event-wk-50th-loci           NA                  NA
time-to-event-wk-50th-hici           NA                  NA

$Region_Europe$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7870    1.1580    0.1849   17.2800    0.6159


$Region_Europe$`Salivary hypersecretion`
$Region_Europe$`Salivary hypersecretion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               2.0                 0
```

```
n_event_pct                          12.0                  0
time-to-event-wk-10th                40.3                 NA
time-to-event-wk-25th                43.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Salivary hypersecretion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.215e-10 2.734e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$Teething
$Region_Europe$Teething$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 30
n_event                                1                  3
n_event_pct                            6                 10
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6970    1.1720    0.1707   16.8600    0.6518


$Region_Europe$`Upper respiratory tract infection`
$Region_Europe$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 30
n_event                                4                  1
n_event_pct                           24                  3
time-to-event-wk-10th                  6.3                NA
time-to-event-wk-25th                 25.4                NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            25.4                NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.09384   1.13600   0.01012   0.86990   0.03729


$Region_Europe$`Upper respiratory tract inflammation`
$Region_Europe$`Upper respiratory tract inflammation`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 30
n_event                                 2                  0
n_event_pct                            12                  0
time-to-event-wk-10th                  33                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             33                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Upper respiratory tract inflammation`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.295e-10 3.537e+04 0.000e+00       Inf 9.995e-01


$Region_Europe$`Viral infection`
$Region_Europe$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               30.0
n_event                                 0                5.0
n_event_pct                             0               17.0
time-to-event-wk-10th                  NA               20.6
time-to-event-wk-25th                  NA               41.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               41.0
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.156e+08 1.181e+04 0.000e+00       Inf 9.987e-01


$Region_Europe$Vomiting
$Region_Europe$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               2.0                5.0
n_event_pct                          12.0               17.0
time-to-event-wk-10th                39.7               11.7
time-to-event-wk-25th                39.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           39.7               51.0
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9835    0.8638    0.1809    5.3460    0.9846
```

```
$Region_Europe$`Weight decreased`
$Region_Europe$`Weight decreased`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17               30.0
n_event                                1                4.0
n_event_pct                            6               13.0
time-to-event-wk-10th                 NA               19.3
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Weight decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0210    1.1270    0.2221   18.4000    0.5323


$Region_Europe$`Weight gain poor`
$Region_Europe$`Weight gain poor`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17               30.0
n_event                                1                4.0
n_event_pct                            6               13.0
time-to-event-wk-10th                 NA                7.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Weight gain poor`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9040    1.1290    0.2084   17.4000    0.5683



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0               38.0
n_event                              8.0               11.0
n_event_pct                         36.0               29.0
time-to-event-wk-10th                8.6                9.0
time-to-event-wk-25th               22.4               25.4
time-to-event-wk-50th               52.6                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          22.4               28.0
time-to-event-wk-50th-hici            NA                 NA
```

```
$Region_Northamerica$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7386    0.4663    0.2961    1.8420    0.5158


$Region_Northamerica$Aspiration
$Region_Northamerica$Aspiration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               3.0                5.0
n_event_pct                          14.0               13.0
time-to-event-wk-10th                40.3               21.9
time-to-event-wk-25th                56.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7878    0.7439    0.1833    3.3860    0.7485


$Region_Northamerica$Atelectasis
$Region_Northamerica$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               9.0                9.0
n_event_pct                          41.0               24.0
time-to-event-wk-10th                 3.1                9.6
time-to-event-wk-25th                14.1               44.0
time-to-event-wk-50th                52.7                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           14.1               44.0
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4136    0.4794    0.1616    1.0580    0.0655


$Region_Northamerica$`Bacterial tracheitis`
$Region_Northamerica$`Bacterial tracheitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               4.0                  1
n_event_pct                          18.0                  3
time-to-event-wk-10th                16.7                 NA
time-to-event-wk-25th                25.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           25.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$`Bacterial tracheitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.11420   1.12500   0.01259   1.03500   0.05369


$Region_Northamerica$Bradycardia
$Region_Northamerica$Bradycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               3.0                  3
n_event_pct                          14.0                  8
time-to-event-wk-10th                11.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Bradycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4999    0.8188    0.1004    2.4880    0.3971


$Region_Northamerica$`Bronchial secretion retention`
$Region_Northamerica$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               4.0                  2
n_event_pct                          18.0                  5
time-to-event-wk-10th                 8.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24580   0.86990   0.04468   1.35200   0.10670


$Region_Northamerica$Bronchiolitis
$Region_Northamerica$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                38.0
n_event                                 2                 4.0
n_event_pct                             9                11.0
time-to-event-wk-10th                  NA                32.1
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0660    0.8667    0.1950    5.8280    0.9412


$Region_Northamerica$`Cardio-respiratory arrest`
$Region_Northamerica$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               4.0                 3
n_event_pct                          18.0                 8
time-to-event-wk-10th                17.6                NA
time-to-event-wk-25th                33.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.6                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31570   0.77270   0.06945   1.43600   0.13570


$Region_Northamerica$Constipation
$Region_Northamerica$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               5.0              17.0
n_event_pct                          23.0              45.0
time-to-event-wk-10th                16.3               4.3
time-to-event-wk-25th                40.7              13.9
time-to-event-wk-50th                  NA              38.4
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7              18.7
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0970    0.5107    0.7706    5.7040    0.1472


$Region_Northamerica$Cough
$Region_Northamerica$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
```

```
n_event                                7.0                7.0
n_event_pct                           32.0               18.0
time-to-event-wk-10th                  1.1               25.9
time-to-event-wk-25th                  5.6                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci             5.6                 NA
time-to-event-wk-50th-hici              NA                 NA

$Region_Northamerica$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4174    0.5385    0.1453    1.1990    0.1047


$Region_Northamerica$`Decubitus ulcer`
$Region_Northamerica$`Decubitus ulcer`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               3.0                 0
n_event_pct                          14.0                 0
time-to-event-wk-10th                14.9                NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$`Decubitus ulcer`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.744e-10 1.577e+04 0.000e+00       Inf 9.989e-01


$Region_Northamerica$`Dermatitis contact`
$Region_Northamerica$`Dermatitis contact`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               3.0                 2
n_event_pct                          14.0                 5
time-to-event-wk-10th                29.4                NA
time-to-event-wk-25th                51.0                NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           29.4                NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$`Dermatitis contact`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.35780   0.92450   0.05845   2.19100   0.26630


$Region_Northamerica$`Dermatitis diaper`
```

```
$Region_Northamerica$`Dermatitis diaper`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               4.0                5.0
n_event_pct                          18.0               13.0
time-to-event-wk-10th                29.5               49.1
time-to-event-wk-25th                53.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           50.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Dermatitis diaper`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6083    0.6751    0.1620    2.2840    0.4616


$Region_Northamerica$Diarrhoea
$Region_Northamerica$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               6.0                8.0
n_event_pct                          27.0               21.0
time-to-event-wk-10th                 9.4               16.3
time-to-event-wk-25th                16.9               43.7
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5756    0.5487    0.1963    1.6870    0.3141


$Region_Northamerica$Dysphagia
$Region_Northamerica$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               7.0                9.0
n_event_pct                          32.0               24.0
time-to-event-wk-10th                 5.1                9.0
time-to-event-wk-25th                17.1               30.3
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5970    0.5083    0.2205    1.6160    0.3101
```

```
$Region_Northamerica$Dyspnoea
$Region_Northamerica$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               5.0                  3
n_event_pct                          23.0                  8
time-to-event-wk-10th                21.3                 NA
time-to-event-wk-25th                24.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24800   0.73900   0.05826   1.05600   0.05919


$Region_Northamerica$`Feeding tube complication`
$Region_Northamerica$`Feeding tube complication`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               3.0                  1
n_event_pct                          14.0                  3
time-to-event-wk-10th                26.4                 NA
time-to-event-wk-25th                53.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           53.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Feeding tube complication`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13860   1.15800   0.01432   1.34100   0.08790


$Region_Northamerica$Flatulence
$Region_Northamerica$Flatulence$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                38.0
n_event                                 1                 4.0
n_event_pct                             5                11.0
time-to-event-wk-10th                  NA                28.3
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA
```

```
$Region_Northamerica$Flatulence$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6980    1.1280    0.1862   15.4800    0.6387


$Region_Northamerica$`Gastrooesophageal reflux disease`
$Region_Northamerica$`Gastrooesophageal reflux disease`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                              4.0               7.0
n_event_pct                         18.0              18.0
time-to-event-wk-10th               10.9               7.6
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8350    0.6307    0.2426    2.8740    0.7750


$Region_Northamerica$Hypokalaemia
$Region_Northamerica$Hypokalaemia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22                38
n_event                              3                 0
n_event_pct                         14                 0
time-to-event-wk-10th               14                NA
time-to-event-wk-25th               NA                NA
time-to-event-wk-50th               NA                NA
time-to-event-wk-75th               NA                NA
time-to-event-wk-90th               NA                NA
time-to-event-wk-50th-loci          NA                NA
time-to-event-wk-50th-hici          NA                NA

$Region_Northamerica$Hypokalaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.034e-10 1.626e+04 0.000e+00       Inf 9.990e-01


$Region_Northamerica$Hypoxia
$Region_Northamerica$Hypoxia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                              2.0               7.0
n_event_pct                          9.0              18.0
time-to-event-wk-10th               33.4              12.4
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
```

```
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9170    0.8020    0.3980    9.2320    0.4172


$Region_Northamerica$`Nasal congestion`
$Region_Northamerica$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               5.0                8.0
n_event_pct                          23.0               21.0
time-to-event-wk-10th                 3.6                3.4
time-to-event-wk-25th                37.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9002    0.5714    0.2938    2.7590    0.8540


$Region_Northamerica$Nasopharyngitis
$Region_Northamerica$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               4.0                6.0
n_event_pct                          18.0               16.0
time-to-event-wk-10th                28.3               20.7
time-to-event-wk-25th                42.3                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           42.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7640    0.6473    0.2149    2.7170    0.6775


$Region_Northamerica$`Oral candidiasis`
$Region_Northamerica$`Oral candidiasis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22               38.0
n_event                                 1                4.0
n_event_pct                             5               11.0
time-to-event-wk-10th                  NA               34.9
time-to-event-wk-25th                  NA                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Oral candidiasis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.1300    1.1180    0.2380   19.0600    0.4989


$Region_Northamerica$`Oxygen saturation decreased`
$Region_Northamerica$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               7.0                8.0
n_event_pct                          32.0               21.0
time-to-event-wk-10th                10.1                8.1
time-to-event-wk-25th                18.9               52.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           18.9               52.0
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5456    0.5208    0.1966    1.5140    0.2447


$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               4.0               11.0
n_event_pct                          18.0               29.0
time-to-event-wk-10th                11.3                6.9
time-to-event-wk-25th                46.6               19.3
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           46.6               33.1
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6390    0.5875    0.5183    5.1860    0.4001


$Region_Northamerica$`Pneumonia aspiration`
$Region_Northamerica$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               5.0                6.0
```

```
n_event_pct                          23.0              16.0
time-to-event-wk-10th                 4.0              32.7
time-to-event-wk-25th                17.9                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.9                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5637    0.6091    0.1708    1.8600    0.3467


$Region_Northamerica$`Pneumonia bacterial`
$Region_Northamerica$`Pneumonia bacterial`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               3.0               3.0
n_event_pct                          14.0               8.0
time-to-event-wk-10th                17.7              45.3
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           36.6                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5074    0.8212    0.1015    2.5370    0.4087


$Region_Northamerica$`Pneumonia viral`
$Region_Northamerica$`Pneumonia viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               2.0               6.0
n_event_pct                           9.0              16.0
time-to-event-wk-10th                52.6              27.6
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           52.6                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.8030    0.8330    0.3523    9.2290    0.4791


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              13.0               25.0
n_event_pct                          59.0               66.0
time-to-event-wk-10th                 3.1                5.4
time-to-event-wk-25th                13.7               13.4
time-to-event-wk-50th                20.6               31.7
time-to-event-wk-75th                42.6               46.4
time-to-event-wk-90th                52.6                 NA
time-to-event-wk-50th-loci           13.7               20.7
time-to-event-wk-50th-hici           42.6               38.6

$Region_Northamerica$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7003    0.3599    0.3459    1.4180    0.3222


$Region_Northamerica$Rash
$Region_Northamerica$Rash$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               3.0                8.0
n_event_pct                          14.0               21.0
time-to-event-wk-10th                 5.9               23.0
time-to-event-wk-25th                  NA               38.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               38.1
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4420    0.6798    0.3804    5.4640    0.5905


$Region_Northamerica$`Respiratory arrest`
$Region_Northamerica$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               4.0                  1
n_event_pct                          18.0                  3
time-to-event-wk-10th                19.9                 NA
time-to-event-wk-25th                20.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.10570   1.12500   0.01166   0.95780   0.04568
```

```
$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                             10.0              12.0
n_event_pct                         45.0              32.0
time-to-event-wk-10th                2.9               5.0
time-to-event-wk-25th               15.9              21.9
time-to-event-wk-50th               33.1                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          15.9              43.4
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5257    0.4342    0.2245    1.2310    0.1386


$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                              7.0              11.0
n_event_pct                         32.0              29.0
time-to-event-wk-10th               13.1               4.1
time-to-event-wk-25th               18.1              32.1
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          18.1              43.4
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8025    0.4849    0.3102    2.0760    0.6501


$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`
$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38
n_event                              3.0                 3
n_event_pct                         14.0                 8
time-to-event-wk-10th               17.7                34
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          22.4                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Respiratory syncytial virus
```

```
bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42960   0.82440   0.08537   2.16200   0.30540


$Region_Northamerica$Rhinorrhoea
$Region_Northamerica$Rhinorrhoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38
n_event                              3.0                 3
n_event_pct                         14.0                 8
time-to-event-wk-10th               26.4                NA
time-to-event-wk-25th               52.1                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          52.1                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$Rhinorrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39280   0.82780   0.07754   1.99000   0.25890


$Region_Northamerica$`Rhinovirus infection`
$Region_Northamerica$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38
n_event                              5.0                 7
n_event_pct                         23.0                18
time-to-event-wk-10th                8.7                 9
time-to-event-wk-25th               18.1                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          18.1                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6985    0.5870    0.2210    2.2070    0.5410


$Region_Northamerica$`Salivary hypersecretion`
$Region_Northamerica$`Salivary hypersecretion`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22                38.0
n_event                              0                 6.0
n_event_pct                          0                16.0
time-to-event-wk-10th               NA                12.3
time-to-event-wk-25th               NA                  NA
time-to-event-wk-50th               NA                  NA
time-to-event-wk-75th               NA                  NA
time-to-event-wk-90th               NA                  NA
```

```
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$`Salivary hypersecretion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.790e+08 1.047e+04 0.000e+00       Inf 9.985e-01


$Region_Northamerica$`Sleep apnoea syndrome`
$Region_Northamerica$`Sleep apnoea syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               4.0                  0
n_event_pct                          18.0                  0
time-to-event-wk-10th                 7.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           21.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.819e-10 1.396e+04 0.000e+00       Inf 9.988e-01


$Region_Northamerica$`Stoma site infection`
$Region_Northamerica$`Stoma site infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                 38
n_event                                 3                  0
n_event_pct                            14                  0
time-to-event-wk-10th                  24                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             32                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Stoma site infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.704e-10 1.754e+04 0.000e+00       Inf 9.990e-01


$Region_Northamerica$Tachycardia
$Region_Northamerica$Tachycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               4.0                5.0
n_event_pct                          18.0               13.0
time-to-event-wk-10th                 4.6               12.9
time-to-event-wk-25th                  NA                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           29.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6493    0.6750    0.1729    2.4380    0.5223


$Region_Northamerica$Teething
$Region_Northamerica$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22               38.0
n_event                                 2                8.0
n_event_pct                             9               21.0
time-to-event-wk-10th                  NA                6.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2930    0.7935    0.4843   10.8600    0.2955


$Region_Northamerica$`Upper respiratory tract congestion`
$Region_Northamerica$`Upper respiratory tract congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22               38.0
n_event                                 1                5.0
n_event_pct                             5               13.0
time-to-event-wk-10th                  NA               36.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Upper respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.8290    1.1010    0.3270   24.4800    0.3449


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               5.0               20.0
```

```
n_event_pct                          23.0              53.0
time-to-event-wk-10th                28.3              15.4
time-to-event-wk-25th                32.6              21.6
time-to-event-wk-50th                  NA              29.7
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           28.3              25.4
time-to-event-wk-50th-hici             NA              43.4

$Region_Northamerica$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.4540    0.5024    0.9169    6.5710    0.0739


$Region_Northamerica$`Urinary tract infection`
$Region_Northamerica$`Urinary tract infection`$stats_num
                         TRT01P=Control TRT01P=ISIS 396443
n_all                                22              38.0
n_event                               0               4.0
n_event_pct                           0              11.0
time-to-event-wk-10th                NA              46.6
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Region_Northamerica$`Urinary tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.349e+08 1.301e+04 0.000e+00       Inf 9.988e-01


$Region_Northamerica$`Viral infection`
$Region_Northamerica$`Viral infection`$stats_num
                         TRT01P=Control TRT01P=ISIS 396443
n_all                             22.0                38
n_event                            3.0                 3
n_event_pct                       14.0                 8
time-to-event-wk-10th             44.1                55
time-to-event-wk-25th             45.7                NA
time-to-event-wk-50th               NA                NA
time-to-event-wk-75th               NA                NA
time-to-event-wk-90th               NA                NA
time-to-event-wk-50th-loci        44.1                NA
time-to-event-wk-50th-hici          NA                NA

$Region_Northamerica$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48840   0.82090   0.09774   2.44100   0.38270


$Region_Northamerica$`Viral upper respiratory tract infection`
$Region_Northamerica$`Viral upper respiratory tract infection`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               7.0                8.0
n_event_pct                          32.0               21.0
time-to-event-wk-10th                11.7               11.4
time-to-event-wk-25th                23.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           23.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6079    0.5200    0.2194    1.6840    0.3384


$Region_Northamerica$Vomiting
$Region_Northamerica$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               6.0                8.0
n_event_pct                          27.0               21.0
time-to-event-wk-10th                12.0               13.1
time-to-event-wk-25th                22.6               44.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7103    0.5494    0.2420    2.0850    0.5335



$Disdur_greater_12wk
$Disdur_greater_12wk$`Acute respiratory failure`
$Disdur_greater_12wk$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 5                7.0
n_event_pct                            22               15.0
time-to-event-wk-10th                  13               19.9
time-to-event-wk-25th                  26                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             26                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6034    0.5875    0.1908    1.9080    0.3898


$Disdur_greater_12wk$Atelectasis
$Disdur_greater_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               7.0                8.0
n_event_pct                          30.0               17.0
time-to-event-wk-10th                 4.0               18.0
time-to-event-wk-25th                17.6               44.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           14.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4694    0.5205    0.1692    1.3020    0.1462


$Disdur_greater_12wk$Bradycardia
$Disdur_greater_12wk$Bradycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                 46
n_event                               3.0                  3
n_event_pct                          13.0                  7
time-to-event-wk-10th                11.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Bradycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.43040   0.82270   0.08582   2.15900   0.30550


$Disdur_greater_12wk$`Bronchial secretion retention`
$Disdur_greater_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                 46
n_event                               3.0                  2
n_event_pct                          13.0                  4
time-to-event-wk-10th                 8.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$Disdur_greater_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33870   0.91760   0.05608   2.04600   0.23810


$Disdur_greater_12wk$Bronchiolitis
$Disdur_greater_12wk$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 2                5.0
n_event_pct                             9               11.0
time-to-event-wk-10th                  NA               44.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1560    0.8398    0.2229    5.9960    0.8628


$Disdur_greater_12wk$Constipation
$Disdur_greater_12wk$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               6.0               19.0
n_event_pct                          26.0               41.0
time-to-event-wk-10th                15.9                5.7
time-to-event-wk-25th                20.0               14.1
time-to-event-wk-50th                  NA               40.9
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.6               25.9
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5890    0.4732    0.6286    4.0180    0.3276


$Disdur_greater_12wk$Cough
$Disdur_greater_12wk$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               4.0                4.0
n_event_pct                          17.0                9.0
time-to-event-wk-10th                 1.1               38.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_greater_12wk$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.37600   0.71420   0.09273   1.52400   0.17080


$Disdur_greater_12wk$Diarrhoea
$Disdur_greater_12wk$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                 46
n_event                               2.0                  7
n_event_pct                           9.0                 15
time-to-event-wk-10th                31.9                 28
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5340    0.8033    0.3178    7.4070    0.5941


$Disdur_greater_12wk$Dysphagia
$Disdur_greater_12wk$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46.0
n_event                               6.0                 6.0
n_event_pct                          26.0                13.0
time-to-event-wk-10th                17.1                18.9
time-to-event-wk-25th                19.9                  NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3529    0.5837    0.1124    1.1080    0.0744


$Disdur_greater_12wk$Dyspnoea
$Disdur_greater_12wk$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46.0
n_event                               2.0                 7.0
n_event_pct                           9.0                15.0
```

```
time-to-event-wk-10th                21.3               19.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5640    0.8043    0.3234    7.5670    0.5780


$Disdur_greater_12wk$`Gastrooesophageal reflux disease`
$Disdur_greater_12wk$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               4.0                8.0
n_event_pct                          17.0               17.0
time-to-event-wk-10th                18.9                7.1
time-to-event-wk-25th                48.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           48.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9682    0.6164    0.2893    3.2400    0.9582


$Disdur_greater_12wk$Hypoxia
$Disdur_greater_12wk$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 0                6.0
n_event_pct                             0               13.0
time-to-event-wk-10th                  NA               18.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.718e+08 1.111e+04 0.000e+00       Inf 9.986e-01


$Disdur_greater_12wk$Nasopharyngitis
$Disdur_greater_12wk$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                23.0               46.0
n_event                               2.0                6.0
n_event_pct                           9.0               13.0
time-to-event-wk-10th                42.3               27.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2630    0.8196    0.2534    6.2960    0.7757


$Disdur_greater_12wk$`Oral candidiasis`
$Disdur_greater_12wk$`Oral candidiasis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 1                6.0
n_event_pct                             4               13.0
time-to-event-wk-10th                  NA               12.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Oral candidiasis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.7690    1.0830    0.3318   23.1100    0.3468


$Disdur_greater_12wk$`Oxygen saturation decreased`
$Disdur_greater_12wk$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               5.0                7.0
n_event_pct                          22.0               15.0
time-to-event-wk-10th                13.9               25.1
time-to-event-wk-25th                37.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6354    0.5871    0.2011    2.0080    0.4398
```

```
$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0               46.0
n_event                              4.0               14.0
n_event_pct                         17.0               30.0
time-to-event-wk-10th               11.3               10.6
time-to-event-wk-25th               46.6               25.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          46.6               35.9
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4010    0.5693    0.4591    4.2770    0.5535


$Disdur_greater_12wk$`Pneumonia aspiration`
$Disdur_greater_12wk$`Pneumonia aspiration`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                23               46.0
n_event                               3                5.0
n_event_pct                          13               11.0
time-to-event-wk-10th                11               28.7
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Disdur_greater_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7273    0.7333    0.1728    3.0620    0.6642


$Disdur_greater_12wk$`Pneumonia viral`
$Disdur_greater_12wk$`Pneumonia viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0               46.0
n_event                              2.0                6.0
n_event_pct                          9.0               13.0
time-to-event-wk-10th               52.6               27.6
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          52.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   1.5060    0.8191    0.3025    7.5000    0.6171


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              15.0               25.0
n_event_pct                          65.0               54.0
time-to-event-wk-10th                 2.3                4.9
time-to-event-wk-25th                 7.7               12.7
time-to-event-wk-50th                15.1               36.0
time-to-event-wk-75th                18.0                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.7               25.1
time-to-event-wk-50th-hici           18.0               46.4

$Disdur_greater_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.378600  0.359300  0.187200  0.765500  0.006855


$Disdur_greater_12wk$Rash
$Disdur_greater_12wk$Rash$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23               46.0
n_event                               2                6.0
n_event_pct                           9               13.0
time-to-event-wk-10th                NA               29.3
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Disdur_greater_12wk$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1150    0.8215    0.2228    5.5770    0.8948


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               7.0               13.0
n_event_pct                          30.0               28.0
time-to-event-wk-10th                 3.1                7.1
time-to-event-wk-25th                28.6               23.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.4               35.0
time-to-event-wk-50th-hici             NA                 NA
```

```
$Disdur_greater_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8080    0.4718    0.3205    2.0370    0.6513


$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               9.0                11
n_event_pct                          39.0                24
time-to-event-wk-10th                 2.1                10
time-to-event-wk-25th                13.1                34
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.1                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5414    0.4563    0.2214    1.3240    0.1788


$Disdur_greater_12wk$`Respiratory tract congestion`
$Disdur_greater_12wk$`Respiratory tract congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23                46
n_event                               3                 1
n_event_pct                          13                 2
time-to-event-wk-10th                 6                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Disdur_greater_12wk$`Respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13770   1.16700   0.01398   1.35500   0.08923


$Disdur_greater_12wk$Rhinitis
$Disdur_greater_12wk$Rhinitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               3.0                 0
n_event_pct                          13.0                 0
time-to-event-wk-10th                15.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Rhinitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.544e-10 1.852e+04 0.000e+00       Inf 9.991e-01


$Disdur_greater_12wk$`Rhinovirus infection`
$Disdur_greater_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               4.0                8.0
n_event_pct                          17.0               17.0
time-to-event-wk-10th                15.7                9.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           18.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9471    0.6158    0.2833    3.1660    0.9296


$Disdur_greater_12wk$Tachycardia
$Disdur_greater_12wk$Tachycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               3.0                5.0
n_event_pct                          13.0               11.0
time-to-event-wk-10th                 4.6               22.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7372    0.7352    0.1745    3.1150    0.6784


$Disdur_greater_12wk$Teething
$Disdur_greater_12wk$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 1                9.0
n_event_pct                             4               20.0
time-to-event-wk-10th                  NA                9.3
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   4.5220    1.0610    0.5655   36.1600    0.1549


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               3.0               17.0
n_event_pct                          13.0               37.0
time-to-event-wk-10th                12.3                9.9
time-to-event-wk-25th                  NA               21.9
time-to-event-wk-50th                  NA               34.7
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               25.6
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.7230    0.6281    0.7951    9.3260    0.1107


$Disdur_greater_12wk$`Urinary tract infection`
$Disdur_greater_12wk$`Urinary tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 0                6.0
n_event_pct                             0               13.0
time-to-event-wk-10th                  NA               21.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Urinary tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.389e+08 1.100e+04 0.000e+00       Inf 9.986e-01


$Disdur_greater_12wk$`Viral upper respiratory tract infection`
$Disdur_greater_12wk$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                 46
```

```
n_event                                5.0                  4
n_event_pct                           22.0                  9
time-to-event-wk-10th                 11.7                 NA
time-to-event-wk-25th                 23.9                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            23.9                 NA
time-to-event-wk-50th-hici              NA                 NA

$Disdur_greater_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33220   0.67350   0.08872   1.24400   0.10180


$Disdur_greater_12wk$Vomiting
$Disdur_greater_12wk$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46.0
n_event                               4.0                 8.0
n_event_pct                          17.0                17.0
time-to-event-wk-10th                12.0                11.7
time-to-event-wk-25th                47.7                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           39.7                  NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_greater_12wk$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8410    0.6137    0.2526    2.8000    0.7778



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Acute respiratory failure`
$Disdur_less_equal_12wk$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
n_event                               5.0                 4.0
n_event_pct                          28.0                12.0
time-to-event-wk-10th                 6.3                32.7
time-to-event-wk-25th                22.4                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           16.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_less_equal_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33930   0.68500   0.08862   1.29900   0.11460
```

```
$Disdur_less_equal_12wk$Apnoea
$Disdur_less_equal_12wk$Apnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  3
n_event_pct                          11.0                  9
time-to-event-wk-10th                 6.3                 35
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Apnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6982    0.9288    0.1131    4.3110    0.6990


$Disdur_less_equal_12wk$Aspiration
$Disdur_less_equal_12wk$Aspiration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  3
n_event_pct                          11.0                  9
time-to-event-wk-10th                40.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.55680   0.92660   0.09057   3.42300   0.52740


$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
n_event                               5.0                10.0
n_event_pct                          28.0                29.0
time-to-event-wk-10th                 7.9                 4.6
time-to-event-wk-25th                22.9                32.1
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           22.9                32.1
time-to-event-wk-50th-hici             NA                  NA
```

```
$Disdur_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9730    0.5614    0.3238    2.9240    0.9611


$Disdur_less_equal_12wk$`Bacterial tracheitis`
$Disdur_less_equal_12wk$`Bacterial tracheitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                25.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Bacterial tracheitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.173e-09 1.382e+04 0.000e+00       Inf 9.988e-01


$Disdur_less_equal_12wk$`Bronchial secretion retention`
$Disdur_less_equal_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               4.0                 2
n_event_pct                          22.0                 6
time-to-event-wk-10th                 6.1                NA
time-to-event-wk-25th                40.7                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.21470   0.88140   0.03816   1.20800   0.08092


$Disdur_less_equal_12wk$Bronchitis
$Disdur_less_equal_12wk$Bronchitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                34.0
n_event                                 1                 6.0
n_event_pct                             6                18.0
time-to-event-wk-10th                  NA                11.7
time-to-event-wk-25th                  NA                51.9
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
```

```
time-to-event-wk-50th-loci             NA               51.9
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Bronchitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.9200    1.1010    0.4533   33.9100    0.2146


$Disdur_less_equal_12wk$`Bronchitis viral`
$Disdur_less_equal_12wk$`Bronchitis viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 0                4.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA               34.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Bronchitis viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.198e+08 1.825e+04 0.000e+00       Inf 9.991e-01


$Disdur_less_equal_12wk$`Candida infection`
$Disdur_less_equal_12wk$`Candida infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                15.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Candida infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.782e-10 1.986e+04 0.000e+00       Inf 9.991e-01


$Disdur_less_equal_12wk$`Cardio-respiratory arrest`
$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               3.0                 1
n_event_pct                          17.0                 3
time-to-event-wk-10th                23.0                NA
time-to-event-wk-25th                  NA                NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci          33.6                  NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.19180   1.18800   0.01868   1.97000   0.16470


$Disdur_less_equal_12wk$Constipation
$Disdur_less_equal_12wk$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               3.0                9.0
n_event_pct                          17.0               26.0
time-to-event-wk-10th                11.3               18.7
time-to-event-wk-25th                40.7               21.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3510    0.6698    0.3634    5.0200    0.6537


$Disdur_less_equal_12wk$`Corona virus infection`
$Disdur_less_equal_12wk$`Corona virus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 18                 34
n_event                                2                  0
n_event_pct                           11                  0
time-to-event-wk-10th                 34                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            34                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Corona virus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.131e-10 2.534e+04 0.000e+00       Inf 9.993e-01


$Disdur_less_equal_12wk$Cough
$Disdur_less_equal_12wk$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               4.0                5.0
```

```
n_event_pct                          22.0               15.0
time-to-event-wk-10th                 4.4               23.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4674    0.6999    0.1186    1.8430    0.2772


$Disdur_less_equal_12wk$Cyanosis
$Disdur_less_equal_12wk$Cyanosis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 0
n_event_pct                         11.0                 0
time-to-event-wk-10th               15.1                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.838e-10 2.907e+04 0.000e+00       Inf 9.994e-01


$Disdur_less_equal_12wk$`Decubitus ulcer`
$Disdur_less_equal_12wk$`Decubitus ulcer`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 0
n_event_pct                         11.0                 0
time-to-event-wk-10th               20.9                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Decubitus ulcer`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.645e-10 1.985e+04 0.000e+00       Inf 9.992e-01


$Disdur_less_equal_12wk$`Dermatitis contact`
$Disdur_less_equal_12wk$`Dermatitis contact`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               3.0                 1
n_event_pct                          17.0                 3
time-to-event-wk-10th                29.4                NA
time-to-event-wk-25th                51.0                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           29.4                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Dermatitis contact`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13530   1.16200   0.01387   1.32000   0.08519


$Disdur_less_equal_12wk$`Dermatitis diaper`
$Disdur_less_equal_12wk$`Dermatitis diaper`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               2.0                2.0
n_event_pct                          11.0                6.0
time-to-event-wk-10th                50.9               52.6
time-to-event-wk-25th                50.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           50.9               52.6
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Dermatitis diaper`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31170   1.13200   0.03389   2.86700   0.30320


$Disdur_less_equal_12wk$Diarrhoea
$Disdur_less_equal_12wk$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               5.0                4.0
n_event_pct                          28.0               12.0
time-to-event-wk-10th                 5.4               43.9
time-to-event-wk-25th                10.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            9.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25620   0.71300   0.06335   1.03600   0.05617
```

```
$Disdur_less_equal_12wk$Dysphagia
$Disdur_less_equal_12wk$Dysphagia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0               34.0
n_event                              3.0                3.0
n_event_pct                         17.0                9.0
time-to-event-wk-10th                5.1               28.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32290   0.85460   0.06048   1.72400   0.18590


$Disdur_less_equal_12wk$Dyspnoea
$Disdur_less_equal_12wk$Dyspnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              4.0                 0
n_event_pct                         22.0                 0
time-to-event-wk-10th                7.1                NA
time-to-event-wk-25th               26.1                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          24.4                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.077e-10 1.545e+04 0.000e+00       Inf 9.989e-01


$Disdur_less_equal_12wk$Erythema
$Disdur_less_equal_12wk$Erythema$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              3.0                 1
n_event_pct                         17.0                 3
time-to-event-wk-10th                7.6                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$Erythema$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.1689    1.1660    0.0172    1.6590    0.1271


$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`
$Disdur_less_equal_12wk$`Feeding disorder of infancy or early
childhood`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 2
n_event_pct                          11.0                 6
time-to-event-wk-10th                 5.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48910   1.01100   0.06736   3.55000   0.47940


$Disdur_less_equal_12wk$`Gastrooesophageal reflux disease`
$Disdur_less_equal_12wk$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               4.0                2.0
n_event_pct                          22.0                6.0
time-to-event-wk-10th                 2.7               53.1
time-to-event-wk-25th                43.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           43.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.16760   0.91560   0.02785   1.00800   0.05106


$Disdur_less_equal_12wk$Hypokalaemia
$Disdur_less_equal_12wk$Hypokalaemia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                22.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_less_equal_12wk$Hypokalaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.141e-09 1.398e+04 0.000e+00       Inf 9.988e-01


$Disdur_less_equal_12wk$Hypoxia
$Disdur_less_equal_12wk$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  1
n_event_pct                          11.0                  3
time-to-event-wk-10th                33.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.22240   1.25600   0.01897   2.60700   0.23130


$Disdur_less_equal_12wk$`Nasal congestion`
$Disdur_less_equal_12wk$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                34.0
n_event                                 3                 4.0
n_event_pct                            17                12.0
time-to-event-wk-10th                   1                18.7
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_less_equal_12wk$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6415    0.7778    0.1397    2.9460    0.5681


$Disdur_less_equal_12wk$Nasopharyngitis
$Disdur_less_equal_12wk$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
n_event                               2.0                 9.0
n_event_pct                          11.0                26.0
time-to-event-wk-10th                28.3                 7.7
```

```
time-to-event-wk-25th                  NA               27.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3               29.7
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.5520    0.7934    0.5390   12.0900    0.2376


$Disdur_less_equal_12wk$Oedema
$Disdur_less_equal_12wk$Oedema$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                11.7                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Oedema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.083e-10 1.959e+04 0.000e+00       Inf 9.991e-01


$Disdur_less_equal_12wk$`Oral candidiasis`
$Disdur_less_equal_12wk$`Oral candidiasis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 1
n_event_pct                          11.0                 3
time-to-event-wk-10th                15.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Oral candidiasis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.20980   1.23400   0.01869   2.35500   0.20560


$Disdur_less_equal_12wk$`Oxygen saturation decreased`
$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
```

```
n_event                                5.0                  3
n_event_pct                           28.0                  9
time-to-event-wk-10th                 10.1                 NA
time-to-event-wk-25th                 27.4                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            27.4                 NA
time-to-event-wk-50th-hici              NA                 NA

$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.23970   0.73570   0.05669   1.01400   0.05223


$Disdur_less_equal_12wk$Pneumonia
$Disdur_less_equal_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
n_event                               3.0                 9.0
n_event_pct                          17.0                26.0
time-to-event-wk-10th                 5.3                 5.0
time-to-event-wk-25th                  NA                33.1
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                42.4
time-to-event-wk-50th-hici             NA                  NA

$Disdur_less_equal_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0340    0.6880    0.5282    7.8360    0.3020


$Disdur_less_equal_12wk$`Pneumonia aspiration`
$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
n_event                               4.0                 4.0
n_event_pct                          22.0                12.0
time-to-event-wk-10th                 1.7                32.7
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            17.9                 NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4739    0.7221    0.1151    1.9510    0.3010


$Disdur_less_equal_12wk$`Pneumonia bacterial`
```

```
$Disdur_less_equal_12wk$`Pneumonia bacterial`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0               34.0
n_event                              2.0                2.0
n_event_pct                         11.0                6.0
time-to-event-wk-10th               36.6               45.3
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          36.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47650   1.01600   0.06511   3.48700   0.46540


$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0               34.0
n_event                              9.0               20.0
n_event_pct                         50.0               59.0
time-to-event-wk-10th                4.1                1.1
time-to-event-wk-25th                6.4               10.3
time-to-event-wk-50th               42.6               24.3
time-to-event-wk-75th               52.6               54.3
time-to-event-wk-90th               52.6                 NA
time-to-event-wk-50th-loci           5.7               15.0
time-to-event-wk-50th-hici            NA               54.3

$Disdur_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1760    0.4120    0.5246    2.6380    0.6933


$Disdur_less_equal_12wk$Rash
$Disdur_less_equal_12wk$Rash$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0               34.0
n_event                              2.0                3.0
n_event_pct                         11.0                9.0
time-to-event-wk-10th                5.9               33.9
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.59080   0.92210   0.09695   3.60000   0.56810
```

```
$Disdur_less_equal_12wk$`Respiratory arrest`
$Disdur_less_equal_12wk$`Respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              3.0                 2
n_event_pct                         17.0                 6
time-to-event-wk-10th               19.9                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          20.4                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26230   0.94900   0.04083   1.68500   0.15850


$Disdur_less_equal_12wk$`Respiratory distress`
$Disdur_less_equal_12wk$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34.0
n_event                              5.0                 8.0
n_event_pct                         28.0                24.0
time-to-event-wk-10th               11.7                15.6
time-to-event-wk-25th               28.1                43.4
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci          28.1                43.4
time-to-event-wk-50th-hici            NA                  NA

$Disdur_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6632    0.5840    0.2112    2.0830    0.4819


$Disdur_less_equal_12wk$`Respiratory failure`
$Disdur_less_equal_12wk$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34.0
n_event                              7.0                 9.0
n_event_pct                         39.0                26.0
time-to-event-wk-10th                6.1                 3.1
time-to-event-wk-25th               13.0                32.1
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci          10.6                43.4
time-to-event-wk-50th-hici            NA                  NA
```

```
$Disdur_less_equal_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5422    0.5181    0.1964    1.4970    0.2375


$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`
$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 2
n_event_pct                          11.0                 6
time-to-event-wk-10th                22.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Respiratory syncytial virus
bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4430    1.0060    0.0617    3.1810    0.4182


$Disdur_less_equal_12wk$`Respiratory tract infection`
$Disdur_less_equal_12wk$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               1.0                5.0
n_event_pct                           6.0               15.0
time-to-event-wk-10th                32.9               35.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3140    1.0970    0.2695   19.8700    0.4443


$Disdur_less_equal_12wk$`Rhinovirus infection`
$Disdur_less_equal_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               2.0                2.0
n_event_pct                          11.0                6.0
time-to-event-wk-10th                 8.7               45.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49910   1.01100   0.06888   3.61700   0.49170


$Disdur_less_equal_12wk$`Sleep apnoea syndrome`
$Disdur_less_equal_12wk$`Sleep apnoea syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               3.0                 0
n_event_pct                          17.0                 0
time-to-event-wk-10th                 5.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.597e-10 1.637e+04 0.000e+00       Inf 9.990e-01


$Disdur_less_equal_12wk$`Staphylococcal infection`
$Disdur_less_equal_12wk$`Staphylococcal infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                16.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Staphylococcal infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.256e-10 1.965e+04 0.000e+00       Inf 9.991e-01


$Disdur_less_equal_12wk$`Stoma site erythema`
$Disdur_less_equal_12wk$`Stoma site erythema`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                34.4                NA
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           34.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Stoma site erythema`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.369e-10 2.194e+04 0.000e+00       Inf 9.992e-01


$Disdur_less_equal_12wk$`Stoma site infection`
$Disdur_less_equal_12wk$`Stoma site infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 2                  0
n_event_pct                            11                  0
time-to-event-wk-10th                  32                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             32                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Stoma site infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.204e-10 2.576e+04 0.000e+00       Inf 9.993e-01


$Disdur_less_equal_12wk$Tachycardia
$Disdur_less_equal_12wk$Tachycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  2
n_event_pct                          11.0                  6
time-to-event-wk-10th                29.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           29.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3800    1.0090    0.0526    2.7460    0.3376


$Disdur_less_equal_12wk$Teething
$Disdur_less_equal_12wk$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
```

```
n_event                                2.0               5.0
n_event_pct                           11.0              15.0
time-to-event-wk-10th                  5.9               6.6
time-to-event-wk-25th                   NA                NA
time-to-event-wk-50th                   NA                NA
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci              NA                NA
time-to-event-wk-50th-hici              NA                NA

$Disdur_less_equal_12wk$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3040    0.8448    0.2490    6.8300    0.7533


$Disdur_less_equal_12wk$`Upper respiratory tract congestion`
$Disdur_less_equal_12wk$`Upper respiratory tract congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18              34.0
n_event                                 1               4.0
n_event_pct                             6              12.0
time-to-event-wk-10th                  NA              36.4
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Upper respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9130    1.1440    0.2033   18.0000    0.5706


$Disdur_less_equal_12wk$`Upper respiratory tract infection`
$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 18.0              34.0
n_event                                6.0               7.0
n_event_pct                           33.0              21.0
time-to-event-wk-10th                  6.3              21.6
time-to-event-wk-25th                 28.3              43.4
time-to-event-wk-50th                 32.6                NA
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci            25.4              43.4
time-to-event-wk-50th-hici              NA                NA

$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.36570   0.56870   0.12000   1.11500   0.07688


$Disdur_less_equal_12wk$`Viral infection`
```

```
$Disdur_less_equal_12wk$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 1                5.0
n_event_pct                             6               15.0
time-to-event-wk-10th                  NA               31.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               55.0
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3040    1.1020    0.2658   19.9700    0.4489


$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`
$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               2.0                4.0
n_event_pct                          11.0               12.0
time-to-event-wk-10th                33.4               18.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9603    0.8956    0.1660    5.5560    0.9640


$Disdur_less_equal_12wk$Vomiting
$Disdur_less_equal_12wk$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               4.0                6.0
n_event_pct                          22.0               18.0
time-to-event-wk-10th                 5.4               24.1
time-to-event-wk-25th                22.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.6215    0.6488    0.1743    2.2170    0.4635


$Region_Asia_Pacific
$Region_Asia_Pacific$Amblyopia
$Region_Asia_Pacific$Amblyopia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                12
n_event                              1.0                 0
n_event_pct                         50.0                 0
time-to-event-wk-10th               29.3                NA
time-to-event-wk-25th               29.3                NA
time-to-event-wk-50th               29.3                NA
time-to-event-wk-75th               29.3                NA
time-to-event-wk-90th               29.3                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$Amblyopia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.873e-12 2.762e+05 0.000e+00       Inf 9.999e-01


$Region_Asia_Pacific$Bronchiolitis
$Region_Asia_Pacific$Bronchiolitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 2               12.0
n_event                               0                2.0
n_event_pct                           0               17.0
time-to-event-wk-10th                NA                2.7
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                2.7
time-to-event-wk-50th-hici           NA                 NA

$Region_Asia_Pacific$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.337e+08 2.601e+04 0.000e+00       Inf 9.994e-01


$Region_Asia_Pacific$Conjunctivitis
$Region_Asia_Pacific$Conjunctivitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 2               12.0
n_event                               0                2.0
n_event_pct                           0               17.0
time-to-event-wk-10th                NA               29.6
time-to-event-wk-25th                NA               29.6
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
```

```
time-to-event-wk-50th-loci             NA               29.6
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Conjunctivitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.793e+08 3.168e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$Constipation
$Region_Asia_Pacific$Constipation$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  2               12.0
n_event                                0                5.0
n_event_pct                            0               42.0
time-to-event-wk-10th                 NA               17.7
time-to-event-wk-25th                 NA               18.7
time-to-event-wk-50th                 NA               35.0
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA               17.7
time-to-event-wk-50th-hici            NA                 NA

$Region_Asia_Pacific$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.356e+08 1.773e+04 0.000e+00       Inf 9.991e-01


$Region_Asia_Pacific$Dyspnoea
$Region_Asia_Pacific$Dyspnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  2               12.0
n_event                                0                3.0
n_event_pct                            0               25.0
time-to-event-wk-10th                 NA               12.3
time-to-event-wk-25th                 NA               43.1
time-to-event-wk-50th                 NA               43.1
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA               12.3
time-to-event-wk-50th-hici            NA                 NA

$Region_Asia_Pacific$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.349e+08 2.103e+04 0.000e+00       Inf 9.993e-01


$Region_Asia_Pacific$Erythema
$Region_Asia_Pacific$Erythema$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                12
n_event                              1.0                 0
n_event_pct                         50.0                 0
time-to-event-wk-10th                7.6                NA
time-to-event-wk-25th                7.6                NA
```

```
time-to-event-wk-50th                 7.6                 NA
time-to-event-wk-75th                 7.6                 NA
time-to-event-wk-90th                 7.6                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Erythema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.266e-14 2.565e+06 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$`Gastrooesophageal reflux disease`
$Region_Asia_Pacific$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2                 12
n_event                                 1                  0
n_event_pct                            50                  0
time-to-event-wk-10th                  43                 NA
time-to-event-wk-25th                  43                 NA
time-to-event-wk-50th                  43                 NA
time-to-event-wk-75th                  43                 NA
time-to-event-wk-90th                  43                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.398e-10 4.566e+04 0.000e+00       Inf 9.996e-01


$Region_Asia_Pacific$Influenza
$Region_Asia_Pacific$Influenza$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
n_event                                 0                2.0
n_event_pct                             0               17.0
time-to-event-wk-10th                  NA               29.6
time-to-event-wk-25th                  NA               31.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               28.1
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Influenza$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.930e+08 3.515e+04 0.000e+00       Inf 9.996e-01


$Region_Asia_Pacific$Nasopharyngitis
$Region_Asia_Pacific$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
n_event                                 0                2.0
```

```
n_event_pct                              0               17.0
time-to-event-wk-10th                   NA                9.3
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                9.3
time-to-event-wk-50th-hici              NA                 NA

$Region_Asia_Pacific$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.023e+08 2.565e+04 0.000e+00       Inf 9.994e-01


$Region_Asia_Pacific$Nystagmus
$Region_Asia_Pacific$Nystagmus$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  2                12
n_event                                1                 0
n_event_pct                           50                 0
time-to-event-wk-10th                 25                NA
time-to-event-wk-25th                 25                NA
time-to-event-wk-50th                 25                NA
time-to-event-wk-75th                 25                NA
time-to-event-wk-90th                 25                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$Nystagmus$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.442e-14 1.625e+06 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$Oedema
$Region_Asia_Pacific$Oedema$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                12
n_event                              1.0                 0
n_event_pct                         50.0                 0
time-to-event-wk-10th                7.6                NA
time-to-event-wk-25th                7.6                NA
time-to-event-wk-50th                7.6                NA
time-to-event-wk-75th                7.6                NA
time-to-event-wk-90th                7.6                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$Oedema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.266e-14 2.565e+06 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$Pneumonia
$Region_Asia_Pacific$Pneumonia$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2                12.0
n_event                                 0                 5.0
n_event_pct                             0                42.0
time-to-event-wk-10th                  NA                20.0
time-to-event-wk-25th                  NA                25.1
time-to-event-wk-50th                  NA                43.6
time-to-event-wk-75th                  NA                43.6
time-to-event-wk-90th                  NA                43.6
time-to-event-wk-50th-loci             NA                20.0
time-to-event-wk-50th-hici             NA                  NA

$Region_Asia_Pacific$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.083e+08 1.813e+04 0.000e+00       Inf 9.992e-01


$Region_Asia_Pacific$Pyrexia
$Region_Asia_Pacific$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0                12.0
n_event                               1.0                 4.0
n_event_pct                          50.0                33.0
time-to-event-wk-10th                 5.7                 3.0
time-to-event-wk-25th                 5.7                23.1
time-to-event-wk-50th                 5.7                38.0
time-to-event-wk-75th                 5.7                  NA
time-to-event-wk-90th                 5.7                  NA
time-to-event-wk-50th-loci             NA                 3.0
time-to-event-wk-50th-hici             NA                  NA

$Region_Asia_Pacific$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.039e-04 6.537e+00 2.831e-10 3.811e+01 1.606e-01


$Region_Asia_Pacific$`Respiratory failure`
$Region_Asia_Pacific$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0                  12
n_event                               1.0                   0
n_event_pct                          50.0                   0
time-to-event-wk-10th                 0.9                  NA
time-to-event-wk-25th                 0.9                  NA
time-to-event-wk-50th                25.1                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            0.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Asia_Pacific$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.188e-28 8.557e+04 0.000e+00       Inf 9.994e-01
```

```
$Region_Asia_Pacific$`Stoma site erythema`
$Region_Asia_Pacific$`Stoma site erythema`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                12
n_event                              1.0                 0
n_event_pct                         50.0                 0
time-to-event-wk-10th                8.7                NA
time-to-event-wk-25th                8.7                NA
time-to-event-wk-50th                8.7                NA
time-to-event-wk-75th                8.7                NA
time-to-event-wk-90th                8.7                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Stoma site erythema`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.266e-14 2.565e+06 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$Strabismus
$Region_Asia_Pacific$Strabismus$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                12
n_event                              1.0                 0
n_event_pct                         50.0                 0
time-to-event-wk-10th               29.3                NA
time-to-event-wk-25th               29.3                NA
time-to-event-wk-50th               29.3                NA
time-to-event-wk-75th               29.3                NA
time-to-event-wk-90th               29.3                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$Strabismus$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.873e-12 2.762e+05 0.000e+00       Inf 9.999e-01


$Region_Asia_Pacific$Teething
$Region_Asia_Pacific$Teething$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 2               12.0
n_event                               0                3.0
n_event_pct                           0               25.0
time-to-event-wk-10th                NA                9.3
time-to-event-wk-25th                NA               39.8
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                9.3
time-to-event-wk-50th-hici           NA                 NA

$Region_Asia_Pacific$Teething$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.972e+07 2.715e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$`Upper respiratory tract infection`
$Region_Asia_Pacific$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2              12.0
n_event                                 0               3.0
n_event_pct                             0              25.0
time-to-event-wk-10th                  NA               8.1
time-to-event-wk-25th                  NA              21.7
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA               8.1
time-to-event-wk-50th-hici             NA                NA

$Region_Asia_Pacific$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.057e+07 2.635e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$`Urinary tract infection`
$Region_Asia_Pacific$`Urinary tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2              12.0
n_event                                 0               2.0
n_event_pct                             0              17.0
time-to-event-wk-10th                  NA              26.9
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA              26.9
time-to-event-wk-50th-hici             NA                NA

$Region_Asia_Pacific$`Urinary tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.423e+07 2.038e+04 0.000e+00       Inf 9.993e-01




\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs nach PT, das bei mindestens 10 Patienten
und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
```

```
n_event                                8.0                 10
n_event_pct                           25.0                 14
time-to-event-wk-10th                  6.3                 13
time-to-event-wk-25th                 22.4                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            22.4                 NA
time-to-event-wk-50th-hici              NA                 NA

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.41920   0.48110   0.16330   1.07600   0.07075


$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              11.0               18.0
n_event_pct                          34.0               25.0
time-to-event-wk-10th                 4.0                9.6
time-to-event-wk-25th                14.1               36.0
time-to-event-wk-50th                52.7                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49610   0.38730   0.23220   1.06000   0.07029


$Ageonset_less_equal_12wk$Constipation
$Ageonset_less_equal_12wk$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               8.0               25.0
n_event_pct                          25.0               35.0
time-to-event-wk-10th                11.3                7.9
time-to-event-wk-25th                20.0               18.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.0               38.4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1280    0.4124    0.5028    2.5320    0.7695


$Ageonset_less_equal_12wk$Diarrhoea
```

```
$Ageonset_less_equal_12wk$Diarrhoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              6.0               10.0
n_event_pct                         19.0               14.0
time-to-event-wk-10th                9.4               18.3
time-to-event-wk-25th               31.9                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          31.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40740   0.53930   0.14160   1.17200   0.09593


$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`
$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              5.0               10.0
n_event_pct                         16.0               14.0
time-to-event-wk-10th               10.9               20.6
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8246    0.5573    0.2766    2.4580    0.7293


$Ageonset_less_equal_12wk$Nasopharyngitis
$Ageonset_less_equal_12wk$Nasopharyngitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 32               72.0
n_event                                1               14.0
n_event_pct                            3               19.0
time-to-event-wk-10th                 NA               11.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   5.1320    1.0360    0.6742   39.0700    0.1143
```

```
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              10.0               10.0
n_event_pct                          31.0               14.0
time-to-event-wk-10th                10.1               18.3
time-to-event-wk-25th                20.3                 NA
time-to-event-wk-50th                40.7                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.301800  0.454400  0.123900  0.735400  0.008382


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               6.0               22.0
n_event_pct                          19.0               31.0
time-to-event-wk-10th                11.3                8.1
time-to-event-wk-25th                46.6               25.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           46.6               43.6
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3590    0.4622    0.5492    3.3620    0.5071


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              18.0               41.0
n_event_pct                          56.0               57.0
time-to-event-wk-10th                 3.1                3.4
time-to-event-wk-25th                 7.9               10.3
time-to-event-wk-50th                16.0               32.1
time-to-event-wk-75th                52.6               54.3
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.4               24.3
time-to-event-wk-50th-hici           37.7               41.4
```

```
$Ageonset_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6797    0.2862    0.3879    1.1910    0.1772


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              10.0               20.0
n_event_pct                          31.0               28.0
time-to-event-wk-10th                11.0                8.9
time-to-event-wk-25th                28.1               25.9
time-to-event-wk-50th                33.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6757    0.3924    0.3131    1.4580    0.3179


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              15.0               18.0
n_event_pct                          47.0               25.0
time-to-event-wk-10th                 2.1               10.0
time-to-event-wk-25th                 9.1               32.1
time-to-event-wk-50th                21.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.378600  0.357500  0.187900  0.762900  0.006588


$Ageonset_less_equal_12wk$Teething
$Ageonset_less_equal_12wk$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32               72.0
n_event                               2               12.0
n_event_pct                           6               17.0
time-to-event-wk-10th                NA                9.3
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
```

```
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.5520    0.7694    0.5649   11.5300    0.2233


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               7.0               23.0
n_event_pct                          22.0               32.0
time-to-event-wk-10th                 8.7               15.4
time-to-event-wk-25th                32.6               26.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.6               34.7
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1070    0.4352    0.4716    2.5960    0.8161


$Ageonset_less_equal_12wk$Vomiting
$Ageonset_less_equal_12wk$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               6.0               12.0
n_event_pct                          19.0               17.0
time-to-event-wk-10th                12.0               24.1
time-to-event-wk-25th                47.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           47.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6455    0.5026    0.2411    1.7290    0.3838



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               8.0               11.0
n_event_pct                          36.0               29.0
```

```
time-to-event-wk-10th                 8.6                 9.0
time-to-event-wk-25th                22.4                25.4
time-to-event-wk-50th                52.6                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           22.4                28.0
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7386    0.4663    0.2961    1.8420    0.5158


$Region_Northamerica$Constipation
$Region_Northamerica$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38.0
n_event                               5.0                17.0
n_event_pct                          23.0                45.0
time-to-event-wk-10th                16.3                 4.3
time-to-event-wk-25th                40.7                13.9
time-to-event-wk-50th                  NA                38.4
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           40.7                18.7
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0970    0.5107    0.7706    5.7040    0.1472


$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38.0
n_event                               4.0                11.0
n_event_pct                          18.0                29.0
time-to-event-wk-10th                11.3                 6.9
time-to-event-wk-25th                46.6                19.3
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           46.6                33.1
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6390    0.5875    0.5183    5.1860    0.4001


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                22.0              38.0
n_event                              13.0              25.0
n_event_pct                          59.0              66.0
time-to-event-wk-10th                 3.1               5.4
time-to-event-wk-25th                13.7              13.4
time-to-event-wk-50th                20.6              31.7
time-to-event-wk-75th                42.6              46.4
time-to-event-wk-90th                52.6                NA
time-to-event-wk-50th-loci           13.7              20.7
time-to-event-wk-50th-hici           42.6              38.6

$Region_Northamerica$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7003    0.3599    0.3459    1.4180    0.3222


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              10.0              12.0
n_event_pct                          45.0              32.0
time-to-event-wk-10th                 2.9               5.0
time-to-event-wk-25th                15.9              21.9
time-to-event-wk-50th                33.1                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.9              43.4
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5257    0.4342    0.2245    1.2310    0.1386


$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               7.0              11.0
n_event_pct                          32.0              29.0
time-to-event-wk-10th                13.1               4.1
time-to-event-wk-25th                18.1              32.1
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           18.1              43.4
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8025    0.4849    0.3102    2.0760    0.6501
```

```
$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 22.0               38.0
n_event                                5.0               20.0
n_event_pct                           23.0               53.0
time-to-event-wk-10th                 28.3               15.4
time-to-event-wk-25th                 32.6               21.6
time-to-event-wk-50th                   NA               29.7
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            28.3               25.4
time-to-event-wk-50th-hici              NA               43.4

$Region_Northamerica$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.4540    0.5024    0.9169    6.5710    0.0739



$Agetrt_less_180d
$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 16.0               49.0
n_event                                5.0               13.0
n_event_pct                           31.0               27.0
time-to-event-wk-10th                  7.9                8.1
time-to-event-wk-25th                 22.9               32.1
time-to-event-wk-50th                 32.9                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            17.6               44.0
time-to-event-wk-50th-hici              NA                 NA

$Agetrt_less_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5421    0.5480    0.1852    1.5870    0.2638


$Agetrt_less_180d$Constipation
$Agetrt_less_180d$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 16.0               49.0
n_event                                5.0               14.0
n_event_pct                           31.0               29.0
time-to-event-wk-10th                  0.0               11.9
time-to-event-wk-25th                 15.9               19.7
time-to-event-wk-50th                 40.7                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            11.3                 NA
time-to-event-wk-50th-hici              NA                 NA
```

```
$Agetrt_less_180d$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6205    0.5287    0.2201    1.7490    0.3667


$Agetrt_less_180d$Nasopharyngitis
$Agetrt_less_180d$Nasopharyngitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 16               49.0
n_event                                1               13.0
n_event_pct                            6               27.0
time-to-event-wk-10th                 NA                7.7
time-to-event-wk-25th                 NA               27.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.5570    1.0430    0.4606   27.4800    0.2237


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              3.0               15.0
n_event_pct                         19.0               31.0
time-to-event-wk-10th                5.3                5.0
time-to-event-wk-25th                 NA               25.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          11.9               42.4
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2890    0.6399    0.3679    4.5190    0.6912


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              8.0               28.0
n_event_pct                         50.0               57.0
time-to-event-wk-10th                2.3                5.4
time-to-event-wk-25th                6.4               13.4
time-to-event-wk-50th               20.6               31.7
time-to-event-wk-75th               52.6               54.3
time-to-event-wk-90th               52.6                 NA
```

```
time-to-event-wk-50th-loci            6.4               20.7
time-to-event-wk-50th-hici             NA               38.0

$Agetrt_less_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6902    0.4267    0.2990    1.5930    0.3849


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               4.0               14.0
n_event_pct                          25.0               29.0
time-to-event-wk-10th                15.4                8.9
time-to-event-wk-25th                28.1               35.0
time-to-event-wk-50th                33.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.4               43.4
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5961    0.5922    0.1867    1.9030    0.3824


$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               9.0               12.0
n_event_pct                          56.0               24.0
time-to-event-wk-10th                 1.0                4.1
time-to-event-wk-25th                 6.1               32.1
time-to-event-wk-50th                13.0                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.227600  0.477900  0.089210  0.580800  0.001956


$Agetrt_less_180d$`Upper respiratory tract infection`
$Agetrt_less_180d$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               4.0               13.0
n_event_pct                          25.0               27.0
time-to-event-wk-10th                25.4               21.6
time-to-event-wk-25th                32.6               29.7
```

```
time-to-event-wk-50th                32.6                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           25.4                35.3
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6527    0.5801    0.2094    2.0350    0.4621



$Gender_Female
$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               7.0               13.0
n_event_pct                          29.0               30.0
time-to-event-wk-10th                11.0                9.6
time-to-event-wk-25th                17.6               32.1
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           15.3               36.0
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8857    0.4758    0.3486    2.2510    0.7986


$Gender_Female$Constipation
$Gender_Female$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               7.0               17.0
n_event_pct                          29.0               40.0
time-to-event-wk-10th                11.3                4.4
time-to-event-wk-25th                17.6               17.7
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           16.3               19.7
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2450    0.4687    0.4969    3.1210    0.6397


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                24.0               43.0
n_event                               4.0               15.0
n_event_pct                          17.0               35.0
time-to-event-wk-10th                11.9                6.9
time-to-event-wk-25th                46.6               25.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           46.6               33.1
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9640    0.5702    0.6424    6.0050    0.2364


$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              15.0               25.0
n_event_pct                          62.0               58.0
time-to-event-wk-10th                 2.3                4.9
time-to-event-wk-25th                 5.7               12.7
time-to-event-wk-50th                16.0               31.7
time-to-event-wk-75th                42.6               54.3
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.4               15.6
time-to-event-wk-50th-hici           37.7               46.4

$Gender_Female$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6543    0.3358    0.3388    1.2640    0.2065


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               7.0               11.0
n_event_pct                          29.0               26.0
time-to-event-wk-10th                11.0               20.3
time-to-event-wk-25th                15.9               43.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9               45.3
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7045    0.4966    0.2662    1.8650    0.4806
```

```
$Gender_Female$`Upper respiratory tract infection`
$Gender_Female$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               5.0               14.0
n_event_pct                          21.0               33.0
time-to-event-wk-10th                12.3               17.1
time-to-event-wk-25th                28.3               26.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3               28.9
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5800    0.5370    0.5517    4.5270    0.3940



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               5.0               10.0
n_event_pct                          28.0               29.0
time-to-event-wk-10th                 7.9                4.6
time-to-event-wk-25th                22.9               32.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.9               32.1
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9730    0.5614    0.3238    2.9240    0.9611


$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               9.0               20.0
n_event_pct                          50.0               59.0
time-to-event-wk-10th                 4.1                1.1
time-to-event-wk-25th                 6.4               10.3
time-to-event-wk-50th                42.6               24.3
time-to-event-wk-75th                52.6               54.3
time-to-event-wk-90th                52.6                 NA
time-to-event-wk-50th-loci            5.7               15.0
time-to-event-wk-50th-hici             NA               54.3
```

$Disdur_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
1.1760	0.4120	0.5246	2.6380	0.6933

$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$Constipation
$Agetrt_greater_equal_180d$Constipation$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	25.0	31.0
n_event	4.0	14.0
n_event_pct	16.0	45.0
time-to-event-wk-10th	17.6	4.4
time-to-event-wk-25th	48.6	7.9
time-to-event-wk-50th	NA	35.0
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	48.6	18.0
time-to-event-wk-50th-hici	NA	NA

$Agetrt_greater_equal_180d$Constipation$stats_HR_TRTvsCTRL
HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
3.56500	0.57900	1.14600	11.09000	0.02811

$Agetrt_greater_equal_180d$Pyrexia
$Agetrt_greater_equal_180d$Pyrexia$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	25.0	31.0
n_event	16.0	17.0
n_event_pct	64.0	55.0
time-to-event-wk-10th	3.1	3.0
time-to-event-wk-25th	5.7	8.1
time-to-event-wk-50th	16.0	36.0
time-to-event-wk-75th	37.7	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	7.7	12.7
time-to-event-wk-50th-hici	37.7	46.7

$Agetrt_greater_equal_180d$Pyrexia$stats_HR_TRTvsCTRL
HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.6375	0.3629	0.3130	1.2980	0.2147

$Agetrt_greater_equal_180d$`Upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	25.0	31.0
n_event	5.0	11.0
n_event_pct	20.0	35.0
time-to-event-wk-10th	8.7	5.7
time-to-event-wk-25th	NA	17.1
time-to-event-wk-50th	NA	NA

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3               21.9
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9040    0.5539    0.6428    5.6370    0.2452



$Gender_Male
$Gender_Male$Constipation
$Gender_Male$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               2.0               11.0
n_event_pct                          12.0               30.0
time-to-event-wk-10th                40.7               11.9
time-to-event-wk-25th                40.7               21.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7               27.9
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2540    0.7763    0.4921   10.3200    0.2952


$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               9.0               20.0
n_event_pct                          53.0               54.0
time-to-event-wk-10th                 4.1                2.6
time-to-event-wk-25th                 7.7                8.1
time-to-event-wk-50th                20.6               36.0
time-to-event-wk-75th                52.6                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.7               15.0
time-to-event-wk-50th-hici             NA               46.7

$Gender_Male$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8268    0.4197    0.3632    1.8820    0.6504


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                17.0               37.0
n_event                               5.0               10.0
n_event_pct                          29.0               27.0
time-to-event-wk-10th                 2.3                3.4
time-to-event-wk-25th                33.1               19.3
time-to-event-wk-50th                33.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.1               35.0
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7316    0.5557    0.2462    2.1740    0.5738


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               7.0               11.0
n_event_pct                          41.0               30.0
time-to-event-wk-10th                 1.0                1.7
time-to-event-wk-25th                13.0               27.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.4               31.9
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6666    0.4951    0.2526    1.7590    0.4127


$Gender_Male$`Upper respiratory tract infection`
$Gender_Male$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               4.0               10.0
n_event_pct                          24.0               27.0
time-to-event-wk-10th                 6.3               15.4
time-to-event-wk-25th                32.6               26.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.6               30.7
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9636    0.5980    0.2984    3.1110    0.9506
```

```
$Disdur_greater_12wk
$Disdur_greater_12wk$Constipation
$Disdur_greater_12wk$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               6.0               19.0
n_event_pct                          26.0               41.0
time-to-event-wk-10th                15.9                5.7
time-to-event-wk-25th                20.0               14.1
time-to-event-wk-50th                  NA               40.9
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.6               25.9
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5890    0.4732    0.6286    4.0180    0.3276


$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               4.0               14.0
n_event_pct                          17.0               30.0
time-to-event-wk-10th                11.3               10.6
time-to-event-wk-25th                46.6               25.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           46.6               35.9
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4010    0.5693    0.4591    4.2770    0.5535


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              15.0               25.0
n_event_pct                          65.0               54.0
time-to-event-wk-10th                 2.3                4.9
time-to-event-wk-25th                 7.7               12.7
time-to-event-wk-50th                15.1               36.0
time-to-event-wk-75th                18.0                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.7               25.1
time-to-event-wk-50th-hici           18.0               46.4
```

```
$Disdur_greater_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.378600  0.359300  0.187200  0.765500  0.006855


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               7.0               13.0
n_event_pct                          30.0               28.0
time-to-event-wk-10th                 3.1                7.1
time-to-event-wk-25th                28.6               23.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.4               35.0
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8080    0.4718    0.3205    2.0370    0.6513


$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                 46
n_event                               9.0                 11
n_event_pct                          39.0                 24
time-to-event-wk-10th                 2.1                 10
time-to-event-wk-25th                13.1                 34
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5414    0.4563    0.2214    1.3240    0.1788


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               3.0               17.0
n_event_pct                          13.0               37.0
time-to-event-wk-10th                12.3                9.9
time-to-event-wk-25th                  NA               21.9
time-to-event-wk-50th                  NA               34.7
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci             NA               25.6
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.7230    0.6281    0.7951    9.3260    0.1107



$Region_Europe
$Region_Europe$Pyrexia
$Region_Europe$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              30.0
n_event                             10.0              16.0
n_event_pct                         59.0              53.0
time-to-event-wk-10th                2.3               1.9
time-to-event-wk-25th                5.1               8.1
time-to-event-wk-50th               15.1              23.4
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           5.1               8.1
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7017    0.4081    0.3153    1.5610    0.3853



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem milden UE nach SOC, das bei mindestens 10%
der Patienten in einem Studienarm auftrat"

$Agetrt_less_180d
$Agetrt_less_180d$`Blood and lymphatic system disorders`
$Agetrt_less_180d$`Blood and lymphatic system disorders`$ntab
           CTRL TRT
n_all        16  49
n_event       2   0
n_event_pct  12   0

$Agetrt_less_180d$`Blood and lymphatic system disorders`$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$ntab
           CTRL TRT
```

```
n_all         16  49
n_event        4   7
n_event_pct   25  14

$Agetrt_less_180d$`Cardiac disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5714286 0.5567306  0.1918987 1.7015782 0.3148091
OR_TRTvsCTRL   0.5000000 0.7071068  0.1250488 1.9992191 0.3269587
ARR_TRTvsCTRL -0.1071429 0.1192380 -0.3408451 0.1265594 0.3688856


$Agetrt_less_180d$`Congenital, familial and genetic disorders`
$Agetrt_less_180d$`Congenital, familial and genetic disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        3   2
n_event_pct   19   4

$Agetrt_less_180d$`Congenital, familial and genetic disorders`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2176871 0.8662708  0.03985305 1.18905986 0.07839606
OR_TRTvsCTRL   0.1843972 0.9651596  0.02781051 1.22264269 0.07982660
ARR_TRTvsCTRL -0.1466837 0.1015897 -0.34579587 0.05242852 0.14877188


$Agetrt_less_180d$`Eye disorders`
$Agetrt_less_180d$`Eye disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        2   2
n_event_pct   12   4

$Agetrt_less_180d$`Eye disorders`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 0.95764912  0.04997715 2.13341975 0.2425131
OR_TRTvsCTRL   0.29787234 1.04532539  0.03839261 2.31106820 0.2466285
ARR_TRTvsCTRL -0.08418367 0.08737805 -0.25544151 0.08707417 0.3353258


$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event       10  26
n_event_pct   62  53

$Agetrt_less_180d$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.84897959 0.2356976  0.5348981 1.3474835 0.4872939
OR_TRTvsCTRL   0.67826087 0.5904291  0.2132174 2.1575997 0.5108418
ARR_TRTvsCTRL -0.09438776 0.1404683 -0.3697006 0.1809251 0.5016153


$Agetrt_less_180d$`General disorders and administration site conditions`
```

```
$Agetrt_less_180d$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         16  49
n_event        9  21
n_event_pct   56  43

$Agetrt_less_180d$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7619048 0.2753579  0.4441356 1.3070307 0.3233660
OR_TRTvsCTRL   0.5833333 0.5807767  0.1868783 1.8208527 0.3533757
ARR_TRTvsCTRL -0.1339286 0.1427543 -0.4137218 0.1458646 0.3481541


$Agetrt_less_180d$`Immune system disorders`
$Agetrt_less_180d$`Immune system disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        2   4
n_event_pct   12   8

$Agetrt_less_180d$`Immune system disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 0.81675690  0.1317435 3.2372678 0.6018943
OR_TRTvsCTRL   0.62222222 0.91850465  0.1028284 3.7651137 0.6054670
ARR_TRTvsCTRL -0.04336735 0.09146536 -0.2226362 0.1359015 0.6354004


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         16  49
n_event        9  34
n_event_pct   56  69

$Agetrt_less_180d$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2335601 0.2400306  0.7706299 1.9745802 0.3818515
OR_TRTvsCTRL  1.7629630 0.5916474  0.5528814 5.6215282 0.3378943
ARR_TRTvsCTRL 0.1313776 0.1404129 -0.1438267 0.4065818 0.3494527


$Agetrt_less_180d$`Injury, poisoning and procedural complications`
$Agetrt_less_180d$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         16  49
n_event        4   7
n_event_pct   25  14

$Agetrt_less_180d$`Injury, poisoning and procedural complications`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5714286 0.5567306  0.1918987 1.7015782 0.3148091
OR_TRTvsCTRL   0.5000000 0.7071068  0.1250488 1.9992191 0.3269587
ARR_TRTvsCTRL -0.1071429 0.1192380 -0.3408451 0.1265594 0.3688856
```

```
$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$ntab
            CTRL TRT
n_all         16  49
n_event        6  13
n_event_pct   38  27

$Agetrt_less_180d$Investigations$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.7074830 0.4008511  0.3224861 1.552105 0.3879904
OR_TRTvsCTRL   0.6018519 0.6093993  0.1822921 1.987061 0.4047389
ARR_TRTvsCTRL -0.1096939 0.1364785 -0.3771868 0.157799 0.4215443


$Agetrt_less_180d$`Metabolism and nutrition disorders`
$Agetrt_less_180d$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        2   9
n_event_pct   12  18

$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.46938776 0.72677572  0.3535931 6.1061720 0.5964414
OR_TRTvsCTRL  1.57500000 0.84115378  0.3028929 8.1897747 0.5891706
ARR_TRTvsCTRL 0.05867347 0.09947807 -0.1363000 0.2536469 0.5553160


$Agetrt_less_180d$`Musculoskeletal and connective tissue disorders`
$Agetrt_less_180d$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        2   7
n_event_pct   12  14

$Agetrt_less_180d$`Musculoskeletal and connective tissue disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14285714 0.74829739  0.2636575 4.9538612 0.8583720
OR_TRTvsCTRL  1.16666667 0.85912469  0.2166000 6.2839838 0.8576020
ARR_TRTvsCTRL 0.01785714 0.09661727 -0.1715092 0.2072235 0.8533675


$Agetrt_less_180d$`Psychiatric disorders`
$Agetrt_less_180d$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        2   6
n_event_pct   12  12

$Agetrt_less_180d$`Psychiatric disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.97959184 0.76404090  0.2191252 4.3792320 0.9784700
OR_TRTvsCTRL   0.97674419 0.87255433  0.1766287 5.4013264 0.9784858
```

```
ARR_TRTvsCTRL -0.00255102 0.09502053 -0.1887878 0.1836858 0.9785817


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event       10  27
n_event_pct   62  55

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.88163265 0.2326561  0.5587923 1.390993 0.5881733
OR_TRTvsCTRL   0.73636364 0.5908961  0.2312707 2.344575 0.6045208
ARR_TRTvsCTRL -0.07397959 0.1403473 -0.3490552 0.201096 0.5981115


$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        6  12
n_event_pct   38  24

$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.6530612 0.4087687  0.2930956 1.455119 0.2972445
OR_TRTvsCTRL   0.5405405 0.6140253  0.1622441 1.800891 0.3163968
ARR_TRTvsCTRL -0.1301020 0.1357291 -0.3961261 0.135922 0.3377894



$Gender_Male
$Gender_Male$`Blood and lymphatic system disorders`
$Gender_Male$`Blood and lymphatic system disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$`Blood and lymphatic system disorders`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$`Cardiac disorders`
$Gender_Male$`Cardiac disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        4   6
n_event_pct   24  16
```

```
$Gender_Male$`Cardiac disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.5751662  0.2232318 2.1277509 0.5175116
OR_TRTvsCTRL   0.62903226 0.7251536  0.1518522 2.6057024 0.5226439
ARR_TRTvsCTRL -0.07313196 0.1193994 -0.3071504 0.1608865 0.5402078


$Gender_Male$`Congenital, familial and genetic disorders`
$Gender_Male$`Congenital, familial and genetic disorders`$ntab
           CTRL TRT
n_all        17  37
n_event       3   2
n_event_pct  18   5

$Gender_Male$`Congenital, familial and genetic disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3063063 0.8645709  0.05626417 1.66755432 0.1711540
OR_TRTvsCTRL   0.2666667 0.9660918  0.04014486 1.77136292 0.1712660
ARR_TRTvsCTRL -0.1224165 0.0996529 -0.31773262 0.07289956 0.2192859


$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$ntab
           CTRL TRT
n_all        17  37
n_event       8  17
n_event_pct  47  46

$Gender_Male$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.97635135 0.3130063  0.5286578 1.8031739 0.9390524
OR_TRTvsCTRL   0.95625000 0.5873114  0.3024483 3.0233734 0.9392833
ARR_TRTvsCTRL -0.01112878 0.1461757 -0.2976279 0.2753703 0.9393134


$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$ntab
           CTRL TRT
n_all        17  37
n_event       9  15
n_event_pct  53  41

$Gender_Male$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7657658 0.3031950  0.4226841 1.3873180 0.3787390
OR_TRTvsCTRL   0.6060606 0.5901121  0.1906390 1.9267280 0.3960981
ARR_TRTvsCTRL -0.1240064 0.1454988 -0.4091788 0.1611661 0.3940564


$Gender_Male$`Immune system disorders`
$Gender_Male$`Immune system disorders`$ntab
           CTRL TRT
n_all        17  37
n_event       2   1
```

```
n_event_pct   12   3

$Gender_Male$`Immune system disorders`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  37
n_event       12  21
n_event_pct   71  57

$Gender_Male$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8040541 0.2123719  0.5302906 1.2191483 0.3044585
OR_TRTvsCTRL   0.5468750 0.6272578  0.1599430 1.8698678 0.3359591
ARR_TRTvsCTRL -0.1383148 0.1372802 -0.4073791 0.1307496 0.3136773


$Gender_Male$`Injury, poisoning and procedural complications`
$Gender_Male$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         17  37
n_event        4   6
n_event_pct   24  16

$Gender_Male$`Injury, poisoning and procedural complications`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.5751662  0.2232318 2.1277509 0.5175116
OR_TRTvsCTRL   0.62903226 0.7251536  0.1518522 2.6057024 0.5226439
ARR_TRTvsCTRL -0.07313196 0.1193994 -0.3071504 0.1608865 0.5402078


$Gender_Male$Investigations
$Gender_Male$Investigations$ntab
            CTRL TRT
n_all         17  37
n_event        4  10
n_event_pct   24  27

$Gender_Male$Investigations$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14864865 0.5139547  0.4194770 3.1453302 0.7874321
OR_TRTvsCTRL  1.20370370 0.6811462  0.3167575 4.5741697 0.7854736
ARR_TRTvsCTRL 0.03497615 0.1261529 -0.2122790 0.2822313 0.7815865


$Gender_Male$`Metabolism and nutrition disorders`
$Gender_Male$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
```

```
n_all         17  37
n_event        2   3
n_event_pct   12   8

$Gender_Male$`Metabolism and nutrition disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.86457086  0.1265944 3.7519972 0.6667969
OR_TRTvsCTRL   0.66176471 0.96406004  0.1000217 4.3783754 0.6684793
ARR_TRTvsCTRL -0.03656598 0.09011076 -0.2131798 0.1400479 0.6848975


$Gender_Male$`Musculoskeletal and connective tissue disorders`
$Gender_Male$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        3   2
n_event_pct   18   5

$Gender_Male$`Musculoskeletal and connective tissue disorders`$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3063063 0.8645709  0.05626417 1.66755432 0.1711540
OR_TRTvsCTRL   0.2666667 0.9660918  0.04014486 1.77136292 0.1712660
ARR_TRTvsCTRL -0.1224165 0.0996529 -0.31773262 0.07289956 0.2192859


$Gender_Male$`Psychiatric disorders`
$Gender_Male$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        1   4
n_event_pct    6  11

$Gender_Male$`Psychiatric disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.83783784 1.07895757  0.2217670 15.2306185 0.5727177
OR_TRTvsCTRL  1.93939394 1.15879378  0.2001239 18.7946001 0.5675877
ARR_TRTvsCTRL 0.04928458 0.07656783 -0.1007856  0.1993548 0.5197880


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        7  16
n_event_pct   41  43

$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.05019305 0.3456972  0.5333485 2.0678887 0.8873428
OR_TRTvsCTRL  1.08843537 0.5941180  0.3396945 3.4875208 0.8865795
ARR_TRTvsCTRL 0.02066773 0.1445036 -0.2625541 0.3038895 0.8862699


$Gender_Male$`Skin and subcutaneous tissue disorders`
```

```
$Gender_Male$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        8  11
n_event_pct   47  30

$Gender_Male$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6317568 0.3606363  0.3115844 1.2809261 0.2028598
OR_TRTvsCTRL   0.4759615 0.6045509  0.1455383 1.5565622 0.2194285
ARR_TRTvsCTRL -0.1732909 0.1424825 -0.4525515 0.1059696 0.2238987



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Blood and lymphatic system disorders`
$Disdur_less_equal_12wk$`Blood and lymphatic system disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Blood and lymphatic system disorders`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Cardiac disorders`
$Disdur_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        3   2
n_event_pct   17   6

$Disdur_less_equal_12wk$`Cardiac disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3529412 0.86508151  0.06476548 1.92336205 0.2286362
OR_TRTvsCTRL   0.3125000 0.96501295  0.04714433 2.07143131 0.2280792
ARR_TRTvsCTRL -0.1078431 0.09666635 -0.29730569 0.08161942 0.2645838


$Disdur_less_equal_12wk$`Congenital, familial and genetic disorders`
$Disdur_less_equal_12wk$`Congenital, familial and genetic disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        3   1
n_event_pct   17   3

$Disdur_less_equal_12wk$`Congenital, familial and genetic disorders`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1764706 1.1173030  0.01975251 1.5766031 0.1205452
OR_TRTvsCTRL   0.1515152 1.1959528  0.01453648 1.5792574 0.1145932
```

```
ARR_TRTvsCTRL -0.1372549 0.0924968 -0.31854530 0.0440355 0.1378386


$Disdur_less_equal_12wk$`Eye disorders`
$Disdur_less_equal_12wk$`Eye disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Eye disorders`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event       11  18
n_event_pct   61  53

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.86631016 0.2479865  0.5328278 1.4085100 0.5627849
OR_TRTvsCTRL   0.71590909 0.5931457  0.2238574 2.2895197 0.5731352
ARR_TRTvsCTRL -0.08169935 0.1432847 -0.3625323 0.1991336 0.5685497


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         18  34
n_event       10  14
n_event_pct   56  41

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7411765 0.2940429  0.4165161 1.3188987 0.3083858
OR_TRTvsCTRL   0.5600000 0.5885818  0.1766795 1.7749650 0.3245695
ARR_TRTvsCTRL -0.1437908 0.1443654 -0.4267419 0.1391602 0.3192405


$Disdur_less_equal_12wk$`Immune system disorders`
$Disdur_less_equal_12wk$`Immune system disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   3
n_event_pct   11   9
```

```
$Disdur_less_equal_12wk$`Immune system disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.86508151  0.1457223 4.3275646 0.7898725
OR_TRTvsCTRL   0.77419355 0.96337500  0.1171718 5.1153557 0.7904985
ARR_TRTvsCTRL -0.02287582 0.08861794 -0.1965638 0.1508122 0.7962990


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         18  34
n_event       11  17
n_event_pct   61  50

$Disdur_less_equal_12wk$`Infections and infestations`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8181818 0.2544903  0.4968523 1.3473249 0.4303925
OR_TRTvsCTRL   0.6363636 0.5928012  0.1991187 2.0337552 0.4457876
ARR_TRTvsCTRL -0.1111111 0.1433735 -0.3921180 0.1698958 0.4383535


$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`
$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         18  34
n_event        6   4
n_event_pct   33  12

$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`$stats
                 estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3529412 0.5759335  0.11414763 1.09128397 0.07056160
OR_TRTvsCTRL   0.2666667 0.7302967  0.06372928 1.11583106 0.07031305
ARR_TRTvsCTRL -0.2156863 0.1240919 -0.45890196 0.02752941 0.08219019


$Disdur_less_equal_12wk$Investigations
$Disdur_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         18  34
n_event        5   6
n_event_pct   28  18

$Disdur_less_equal_12wk$Investigations$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6352941 0.5307536  0.2244898 1.7978485 0.3926837
OR_TRTvsCTRL   0.5571429 0.6923179  0.1434381 2.1640565 0.3981713
ARR_TRTvsCTRL -0.1013072 0.1241764 -0.3446885 0.1420741 0.4145957


$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`
$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   6
```

```
n_event_pct   11  18

$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.58823529 0.76269217  0.3562133 7.081408 0.5441386
OR_TRTvsCTRL  1.71428571 0.87457473  0.3087762 9.517493 0.5376995
ARR_TRTvsCTRL 0.06535948 0.09879951 -0.1282840 0.259003 0.5082683


$Disdur_less_equal_12wk$`Musculoskeletal and connective tissue disorders`
$Disdur_less_equal_12wk$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   6
n_event_pct   11  18

$Disdur_less_equal_12wk$`Musculoskeletal and connective tissue disorders`$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.58823529 0.76269217  0.3562133 7.081408 0.5441386
OR_TRTvsCTRL  1.71428571 0.87457473  0.3087762 9.517493 0.5376995
ARR_TRTvsCTRL 0.06535948 0.09879951 -0.1282840 0.259003 0.5082683


$Disdur_less_equal_12wk$`Nervous system disorders`
$Disdur_less_equal_12wk$`Nervous system disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Nervous system disorders`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$`Psychiatric disorders`
$Disdur_less_equal_12wk$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   4
n_event_pct   11  12

$Disdur_less_equal_12wk$`Psychiatric disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 0.81549536  0.2141276 5.2356968 0.9441217
OR_TRTvsCTRL  1.066666667 0.91969198  0.1758675 6.4695184 0.9440551
ARR_TRTvsCTRL 0.006535948 0.09241262 -0.1745895 0.1876614 0.9436161


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
```

```
n_all         18  34
n_event       10  19
n_event_pct   56  56

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.005882353 0.2601235  0.6041289 1.6748069 0.9820113
OR_TRTvsCTRL  1.013333333 0.5867693  0.3208436 3.2004518 0.9819908
ARR_TRTvsCTRL 0.003267974 0.1448054 -0.2805453 0.2870813 0.9819948


$Disdur_less_equal_12wk$`Skin and subcutaneous tissue disorders`
$Disdur_less_equal_12wk$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        8   7
n_event_pct   44  21

$Disdur_less_equal_12wk$`Skin and subcutaneous tissue disorders`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.4632353 0.4276562  0.20034570 1.07108332 0.07195706
OR_TRTvsCTRL   0.3240741 0.6363130  0.09311373 1.12791107 0.07659392
ARR_TRTvsCTRL -0.2385621 0.1361106 -0.50533394 0.02820976 0.07965217



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        7   8
n_event_pct   22  11

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5079365 0.47193035  0.2014195 1.28090603 0.1511792
OR_TRTvsCTRL   0.4464286 0.56875491  0.1464289 1.36105926 0.1562003
ARR_TRTvsCTRL -0.1076389 0.08192874 -0.2682163 0.05293849 0.1889098


$Ageonset_less_equal_12wk$`Congenital, familial and genetic disorders`
$Ageonset_less_equal_12wk$`Congenital, familial and genetic disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        4   2
n_event_pct   12   3

$Ageonset_less_equal_12wk$`Congenital, familial and genetic disorders`$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.22222222 0.83956007  0.04286992 1.15191999 0.07321204
OR_TRTvsCTRL   0.20000000 0.89442719  0.03464912 1.15443052 0.07195444
ARR_TRTvsCTRL -0.09722222 0.06158778 -0.21793205 0.02348761 0.11442875
```

```
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       17  41
n_event_pct   53  57

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.07189542 0.1951279  0.7312389 1.5712510 0.7219826
OR_TRTvsCTRL  1.16698292 0.4267769  0.5055817 2.6936281 0.7174772
ARR_TRTvsCTRL 0.03819444 0.1057697 -0.1691103 0.2454992 0.7180175


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         32  72
n_event       18  34
n_event_pct   56  47

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83950617 0.1995706  0.5677395 1.2413628 0.3807098
OR_TRTvsCTRL   0.69590643 0.4274479  0.3010971 1.6084040 0.3963542
ARR_TRTvsCTRL -0.09027778 0.1056027 -0.2972553 0.1166998 0.3926169


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         32  72
n_event       18  45
n_event_pct   56  62

$Ageonset_less_equal_12wk$`Infections and infestations`$stats
              estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.111111 0.1806624  0.7797895 1.5832065 0.5597653
OR_TRTvsCTRL  1.296296 0.4315592  0.5563657 3.0202868 0.5476176
ARR_TRTvsCTRL 0.062500 0.1046214 -0.1425542 0.2675542 0.5502456


$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`
$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         32  72
n_event        8  13
n_event_pct   25  18

$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.72222222 0.3959598  0.3323757 1.5693235 0.4111582
OR_TRTvsCTRL   0.66101695 0.5104301  0.2430713 1.7975935 0.4173466
ARR_TRTvsCTRL -0.06944444 0.0889624 -0.2438075 0.1049187 0.4350352


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         32  72
n_event       11  19
n_event_pct   34  26

$Ageonset_less_equal_12wk$Investigations$stats
                 estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.76767677 0.31369058  0.4151112 1.419686 0.3993259
OR_TRTvsCTRL   0.68439108 0.45828773  0.2787463 1.680349 0.4079628
ARR_TRTvsCTRL -0.07986111 0.09872942 -0.2733672 0.113645 0.4185792


$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        6  10
n_event_pct   19  14

$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.74074074 0.47066737  0.2944648 1.8633697 0.5237243
OR_TRTvsCTRL   0.69892473 0.56679559  0.2301299 2.1226954 0.5273899
ARR_TRTvsCTRL -0.04861111 0.08013636 -0.2056755 0.1084533 0.5441131


$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue disorders`
$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        5   8
n_event_pct   16  11

$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue
disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.71111111 0.52901901  0.2521365 2.0055766 0.5192833
OR_TRTvsCTRL   0.67500000 0.61454214  0.2023972 2.2511425 0.5224523
ARR_TRTvsCTRL -0.04513889 0.07410543 -0.1903829 0.1001051 0.5424468


$Ageonset_less_equal_12wk$`Psychiatric disorders`
$Ageonset_less_equal_12wk$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        3   8
n_event_pct    9  11
```

```
$Ageonset_less_equal_12wk$`Psychiatric disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.18518519 0.64280203  0.3362267 4.1777292 0.7915410
OR_TRTvsCTRL  1.20833333 0.71305055  0.2987012 4.8880595 0.7907031
ARR_TRTvsCTRL 0.01736111 0.06345685 -0.1070120 0.1417342 0.7844003


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       17  38
n_event_pct   53  53

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.993464052 0.2000011  0.6712912 1.4702574 0.9738446
OR_TRTvsCTRL   0.986159170 0.4256968  0.4281473 2.2714374 0.9738816
ARR_TRTvsCTRL -0.003472222 0.1060353 -0.2112976 0.2043532 0.9738772


$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`
$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       11  22
n_event_pct   34  31

$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.30203435  0.4917625 1.6067177 0.6965619
OR_TRTvsCTRL   0.84000000 0.45164442  0.3466082 2.0357278 0.6994661
ARR_TRTvsCTRL -0.03819444 0.09998331 -0.2341581 0.1577692 0.7024553



$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Cardiac disorders`
$Ageonset_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Cardiac disorders`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Eye disorders`
```

```
$Ageonset_greater_12wk$`Eye disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Eye disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Gastrointestinal disorders`
$Ageonset_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        6   4
n_event_pct   67  50

$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7500000 0.4249183  0.32611454 1.7248541 0.4983875
OR_TRTvsCTRL   0.5000000 1.0000000  0.07043175 3.5495357 0.4882172
ARR_TRTvsCTRL -0.1666667 0.2365193 -0.63023589 0.2969026 0.4810192


$Ageonset_greater_12wk$`General disorders and administration site conditions`
$Ageonset_greater_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all          9   8
n_event        4   3
n_event_pct   44  38

$Ageonset_greater_12wk$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.84375000 0.5892557  0.2658511 2.677868 0.7730955
OR_TRTvsCTRL   0.75000000 0.9916317  0.1073947 5.237688 0.7717322
ARR_TRTvsCTRL -0.06944444 0.2381842 -0.5362769 0.397388 0.7706248


$Ageonset_greater_12wk$`Immune system disorders`
$Ageonset_greater_12wk$`Immune system disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Immune system disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
```

```
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Infections and infestations`
$Ageonset_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all          9   8
n_event        6   2
n_event_pct   67  25

$Ageonset_greater_12wk$`Infections and infestations`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3750000 0.6561673  0.10363361 1.35694394 0.13497049
OR_TRTvsCTRL   0.1666667 1.0801234  0.02006532 1.38436782 0.09714664
ARR_TRTvsCTRL -0.4166667 0.2193829 -0.84664925 0.01331592 0.05752940


$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`
$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0

$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$`Metabolism and nutrition disorders`
$Ageonset_greater_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Metabolism and nutrition disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Musculoskeletal and connective tissue disorders`
$Ageonset_greater_12wk$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Musculoskeletal and connective tissue disorders`$stats
              estimate        se     lo95ci      hi95ci    pvalue
```

```
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Nervous system disorders`
$Ageonset_greater_12wk$`Nervous system disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Nervous system disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Psychiatric disorders`
$Ageonset_greater_12wk$`Psychiatric disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Psychiatric disorders`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        6   1
n_event_pct   67  12

$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se       lo95ci     hi95ci      pvalue
RR_TRTvsCTRL   0.18750000 0.9646531  0.028306559  1.2419824 0.082685121
OR_TRTvsCTRL   0.07142857 1.2817399  0.005792326  0.8808276 0.039497609
ARR_TRTvsCTRL -0.54166667 0.1958653 -0.925555687 -0.1577776 0.005683466


$Ageonset_greater_12wk$`Skin and subcutaneous tissue disorders`
$Ageonset_greater_12wk$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        3   0
n_event_pct   33   0
```

```
$Ageonset_greater_12wk$`Skin and subcutaneous tissue disorders`$stats
                estimate        se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.1587302 1.4403483  0.009432629  2.67107530 0.20130218
OR_TRTvsCTRL   0.1092437 1.5991271  0.004755727  2.50943442 0.16617046
ARR_TRTvsCTRL -0.3333333 0.1571348 -0.641311961 -0.02535471 0.03389485


$Ageonset_greater_12wk$`Vascular disorders`
$Ageonset_greater_12wk$`Vascular disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Vascular disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Cardiac disorders`
$Agetrt_greater_equal_180d$`Cardiac disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        3   2
n_event_pct   12   6

$Agetrt_greater_equal_180d$`Cardiac disorders`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.53763441 0.87239628  0.09725277 2.97215952 0.4768692
OR_TRTvsCTRL   0.50574713 0.95565194  0.07771073 3.29143917 0.4756265
ARR_TRTvsCTRL -0.05548387 0.07855506 -0.20944895 0.09848121 0.4799981


$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       13  19
n_event_pct   52  61

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.17866005 0.2393671  0.7372910 1.8842485 0.4922589
OR_TRTvsCTRL  1.46153846 0.5442622  0.5029600 4.2470469 0.4856431
ARR_TRTvsCTRL 0.09290323 0.1328056 -0.1673909 0.3531974 0.4842126


$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
```

```
conditions`$ntab
            CTRL TRT
n_all         25  31
n_event       13  16
n_event_pct   52  52

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.992555831 0.2591621  0.5972494 1.6495070 0.9769990
OR_TRTvsCTRL   0.984615385 0.5379806  0.3430337 2.8261584 0.9770088
ARR_TRTvsCTRL -0.003870968 0.1343135 -0.2671206 0.2593787 0.9770078


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         25  31
n_event       15  13
n_event_pct   60  42

$Agetrt_greater_equal_180d$`Infections and infestations`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6989247 0.2670799  0.4140870 1.17969365 0.1798499
OR_TRTvsCTRL   0.4814815 0.5469418  0.1648246 1.40649200 0.1814457
ARR_TRTvsCTRL -0.1806452 0.1321163 -0.4395884 0.07829806 0.1715253


$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`
$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         25  31
n_event        6   6
n_event_pct   24  19

$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80645161 0.5109553  0.2962459 2.1953522 0.6737562
OR_TRTvsCTRL   0.76000000 0.6526599  0.2114796 2.7312326 0.6741277
ARR_TRTvsCTRL -0.04645161 0.1110454 -0.2640966 0.1711933 0.6757190


$Agetrt_greater_equal_180d$Investigations
$Agetrt_greater_equal_180d$Investigations$ntab
            CTRL TRT
n_all         25  31
n_event        5   6
n_event_pct   20  19

$Agetrt_greater_equal_180d$Investigations$stats
                  estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.967741935 0.5425943  0.3341200 2.802959 0.9518119
OR_TRTvsCTRL   0.960000000 0.6757712  0.2553017 3.609846 0.9518307
```

```
ARR_TRTvsCTRL -0.006451613 0.1069349 -0.2160402 0.203137 0.9518911


$Agetrt_greater_equal_180d$`Metabolism and nutrition disorders`
$Agetrt_greater_equal_180d$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        5   1
n_event_pct   20   3

$Agetrt_greater_equal_180d$`Metabolism and nutrition disorders`$stats
                estimate         se      lo95ci       hi95ci     pvalue
RR_TRTvsCTRL   0.1612903 1.06195195  0.02012209 1.2928360263 0.08577672
OR_TRTvsCTRL   0.1333333 1.13284303  0.01447641 1.2280511976 0.07530125
ARR_TRTvsCTRL -0.1677419 0.08606402 -0.33642432 0.0009404441 0.05129104


$Agetrt_greater_equal_180d$`Musculoskeletal and connective tissue disorders`
$Agetrt_greater_equal_180d$`Musculoskeletal and connective tissue
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        3   2
n_event_pct   12   6

$Agetrt_greater_equal_180d$`Musculoskeletal and connective tissue
disorders`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.53763441 0.87239628  0.09725277 2.97215952 0.4768692
OR_TRTvsCTRL   0.50574713 0.95565194  0.07771073 3.29143917 0.4756265
ARR_TRTvsCTRL -0.05548387 0.07855506 -0.20944895 0.09848121 0.4799981


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       13  12
n_event_pct   52  39

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7444169 0.2966452  0.4162089 1.3314382 0.3197491
OR_TRTvsCTRL   0.5829960 0.5442622  0.2006267 1.6941129 0.3214961
ARR_TRTvsCTRL -0.1329032 0.1328056 -0.3931974 0.1273909 0.3169548


$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        8  10
```

```
n_event_pct   32  32

$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.008064516 0.3908221  0.4686190 2.1684865 0.9836030
OR_TRTvsCTRL  1.011904762 0.5757105  0.3274115 3.1274135 0.9835996
ARR_TRTvsCTRL 0.002580645 0.1255114 -0.2434172 0.2485784 0.9835958



$Gender_Female
$Gender_Female$`Cardiac disorders`
$Gender_Female$`Cardiac disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        3   3
n_event_pct   12   7

$Gender_Female$`Cardiac disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.77572172  0.1220246 2.55292650 0.4522034
OR_TRTvsCTRL   0.52500000 0.85981726  0.0973378 2.83163374 0.4536092
ARR_TRTvsCTRL -0.05523256 0.07788834 -0.2078909 0.09742577 0.4782470


$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       15  28
n_event_pct   62  65

$Gender_Female$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.04186047 0.1935419  0.7129620 1.5224840 0.8321992
OR_TRTvsCTRL  1.12000000 0.5293002  0.3968961 3.1605247 0.8304610
ARR_TRTvsCTRL 0.02616279 0.1226710 -0.2142680 0.2665936 0.8311117


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         24  43
n_event       13  22
n_event_pct   54  51

$Gender_Female$`General disorders and administration site conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94454383 0.2396980  0.5904604 1.5109616 0.8118647
OR_TRTvsCTRL   0.88644689 0.5107894  0.3257377 2.4123338 0.8134512
ARR_TRTvsCTRL -0.03003876 0.1271029 -0.2791558 0.2190783 0.8131733


$Gender_Female$`Immune system disorders`
```

```
$Gender_Female$`Immune system disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        2   5
n_event_pct    8  12

$Gender_Female$`Immune system disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39534884 0.79691751  0.2926479 6.6530412 0.6759169
OR_TRTvsCTRL  1.44736842 0.87850460  0.2586989 8.0977351 0.6738410
ARR_TRTvsCTRL 0.03294574 0.07464983 -0.1133652 0.1792567 0.6589690


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$ntab
            CTRL TRT
n_all         24  43
n_event       12  26
n_event_pct   50  60

$Gender_Female$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2093023 0.2384793  0.7577761 1.9298736 0.4255105
OR_TRTvsCTRL  1.5294118 0.5137623  0.5587392 4.1863903 0.4082351
ARR_TRTvsCTRL 0.1046512 0.1263959 -0.1430803 0.3523826 0.4076913


$Gender_Female$`Injury, poisoning and procedural complications`
$Gender_Female$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         24  43
n_event        6   7
n_event_pct   25  16

$Gender_Female$`Injury, poisoning and procedural complications`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6511628 0.4945719  0.2470070 1.7166032 0.3857185
OR_TRTvsCTRL   0.5833333 0.6267832  0.1707647 1.9926710 0.3898216
ARR_TRTvsCTRL -0.0872093 0.1047952 -0.2926041 0.1181855 0.4053028


$Gender_Female$Investigations
$Gender_Female$Investigations$ntab
            CTRL TRT
n_all         24  43
n_event        7   9
n_event_pct   29  21

$Gender_Female$Investigations$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.71760797 0.4347939  0.3060483 1.6826141 0.4453481
OR_TRTvsCTRL   0.64285714 0.5849817  0.2042571 2.0232603 0.4500730
ARR_TRTvsCTRL -0.08236434 0.1116106 -0.3011172 0.1363885 0.4605379
```

```
$Gender_Female$`Metabolism and nutrition disorders`
$Gender_Female$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        5   7
n_event_pct   21  16

$Gender_Female$`Metabolism and nutrition disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.78139535 0.5271951  0.2780491 2.1959381 0.6398568
OR_TRTvsCTRL   0.73888889 0.6505893  0.2064412 2.6446110 0.6418394
ARR_TRTvsCTRL -0.04554264 0.1002080 -0.2419467 0.1508614 0.6494826


$Gender_Female$`Musculoskeletal and connective tissue disorders`
$Gender_Female$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        2   7
n_event_pct    8  16

$Gender_Female$`Musculoskeletal and connective tissue disorders`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.95348837 0.76022014  0.44026106  8.6678500 0.3784156
OR_TRTvsCTRL  2.13888889 0.84622070  0.40727135 11.2329179 0.3689460
ARR_TRTvsCTRL 0.07945736 0.07970196 -0.07675561  0.2356703 0.3187980


$Gender_Female$`Psychiatric disorders`
$Gender_Female$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        2   5
n_event_pct    8  12

$Gender_Female$`Psychiatric disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39534884 0.79691751  0.2926479 6.6530412 0.6759169
OR_TRTvsCTRL  1.44736842 0.87850460  0.2586989 8.0977351 0.6738410
ARR_TRTvsCTRL 0.03294574 0.07464983 -0.1133652 0.1792567 0.6589690


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       16  23
n_event_pct   67  53

$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8023256 0.2026223  0.5393594 1.1935016 0.2770578
OR_TRTvsCTRL   0.5750000 0.5300738  0.2034549 1.6250529 0.2964957
```

```
ARR_TRTvsCTRL -0.1317829 0.1226577 -0.3721876 0.1086217 0.2826453


$Gender_Female$`Skin and subcutaneous tissue disorders`
$Gender_Female$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        6  11
n_event_pct   25  26

$Gender_Female$`Skin and subcutaneous tissue disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.023255814 0.4389229  0.4328849 2.4187781 0.9582282
OR_TRTvsCTRL  1.031250000 0.5868401  0.3264711 3.2574906 0.9581811
ARR_TRTvsCTRL 0.005813953 0.1106336 -0.2110238 0.2226517 0.9580893



$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        6   7
n_event_pct   27  18

$Region_Northamerica$`Cardiac disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.67543860 0.4875997  0.2597408 1.7564326 0.4209673
OR_TRTvsCTRL   0.60215054 0.6358316  0.1731746 2.0937554 0.4250036
ARR_TRTvsCTRL -0.08851675 0.1138878 -0.3117328 0.1346993 0.4370246


$Region_Northamerica$`Congenital, familial and genetic disorders`
$Region_Northamerica$`Congenital, familial and genetic disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        4   1
n_event_pct   18   3

$Region_Northamerica$`Congenital, familial and genetic disorders`$stats
                estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.1447368 1.085463  0.01724374 1.21486151 0.07496835
OR_TRTvsCTRL   0.1216216 1.154375  0.01265915 1.16846826 0.06798725
ARR_TRTvsCTRL -0.1555024 0.086233 -0.32451596 0.01351118 0.07134397


$Region_Northamerica$`Eye disorders`
$Region_Northamerica$`Eye disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        1   4
n_event_pct    5  11
```

```
$Region_Northamerica$`Eye disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.31578947 1.08546288  0.27589981 19.4377841 0.4391474
OR_TRTvsCTRL  2.47058824 1.15196823  0.25837068 23.6242216 0.4323715
ARR_TRTvsCTRL 0.05980861 0.06671354 -0.07094753  0.1905648 0.3699864


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       15  25
n_event_pct   68  66

$Region_Northamerica$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.96491228 0.1868056  0.6690809 1.3915443 0.8483653
OR_TRTvsCTRL   0.89743590 0.5713553  0.2928633 2.7500587 0.8497808
ARR_TRTvsCTRL -0.02392344 0.1256339 -0.2701614 0.2223145 0.8489786


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         22  38
n_event       12  20
n_event_pct   55  53

$Region_Northamerica$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.96491228 0.2481189  0.5933195 1.5692316 0.8855356
OR_TRTvsCTRL   0.92592593 0.5374838  0.3229008 2.6551149 0.8861420
ARR_TRTvsCTRL -0.01913876 0.1335307 -0.2808541 0.2425766 0.8860307


$Region_Northamerica$`Immune system disorders`
$Region_Northamerica$`Immune system disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        4   4
n_event_pct   18  11

$Region_Northamerica$`Immune system disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.65439259  0.1605532 2.0876566 0.4036094
OR_TRTvsCTRL   0.52941176 0.76483156  0.1182409 2.3703878 0.4056681
ARR_TRTvsCTRL -0.07655502 0.09612663 -0.2649598 0.1118497 0.4258009


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$ntab
            CTRL TRT
n_all         22  38
```

```
n_event       16  21
n_event_pct   73  55

$Region_Northamerica$`Infections and infestations`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7598684 0.1958283  0.5176653 1.11539251 0.1608257
OR_TRTvsCTRL   0.4632353 0.5793179  0.1488282 1.44184290 0.1840721
ARR_TRTvsCTRL -0.1746411 0.1245866 -0.4188265 0.06954416 0.1609855


$Region_Northamerica$`Injury, poisoning and procedural complications`
$Region_Northamerica$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         22  38
n_event        7  10
n_event_pct   32  26

$Region_Northamerica$`Injury, poisoning and procedural complications`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.82706767 0.4136264  0.3676729 1.8604606 0.6462094
OR_TRTvsCTRL   0.76530612 0.5875697  0.2419329 2.4208918 0.6489437
ARR_TRTvsCTRL -0.05502392 0.1223266 -0.2947796 0.1847318 0.6528462


$Region_Northamerica$Investigations
$Region_Northamerica$Investigations$ntab
            CTRL TRT
n_all         22  38
n_event        7   9
n_event_pct   32  24

$Region_Northamerica$Investigations$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.74436090 0.4268465  0.3224417 1.7183671 0.4891558
OR_TRTvsCTRL   0.66502463 0.5959175  0.2068197 2.1383739 0.4936323
ARR_TRTvsCTRL -0.08133971 0.1209030 -0.3183052 0.1556258 0.5010946


$Region_Northamerica$`Metabolism and nutrition disorders`
$Region_Northamerica$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        4   5
n_event_pct   18  13

$Region_Northamerica$`Metabolism and nutrition disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.72368421 0.6150038  0.2167988 2.4156904 0.5989920
OR_TRTvsCTRL   0.68181818 0.7320236  0.1623936 2.8626498 0.6008375
ARR_TRTvsCTRL -0.05023923 0.0988374 -0.2439570 0.1434785 0.6112417


$Region_Northamerica$`Musculoskeletal and connective tissue disorders`
$Region_Northamerica$`Musculoskeletal and connective tissue disorders`$ntab
```

```
            CTRL TRT
n_all         22  38
n_event        5   8
n_event_pct   23  21

$Region_Northamerica$`Musculoskeletal and connective tissue disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92631579 0.5032193  0.3454761 2.4837056 0.8791074
OR_TRTvsCTRL   0.90666667 0.6458768  0.2556680 3.2152814 0.8794225
ARR_TRTvsCTRL -0.01674641 0.1111600 -0.2346159 0.2011231 0.8802506


$Region_Northamerica$`Nervous system disorders`
$Region_Northamerica$`Nervous system disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        1   4
n_event_pct    5  11

$Region_Northamerica$`Nervous system disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.31578947 1.08546288  0.27589981 19.4377841 0.4391474
OR_TRTvsCTRL  2.47058824 1.15196823  0.25837068 23.6242216 0.4323715
ARR_TRTvsCTRL 0.05980861 0.06671354 -0.07094753  0.1905648 0.3699864


$Region_Northamerica$`Psychiatric disorders`
$Region_Northamerica$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        2   6
n_event_pct    9  16

$Region_Northamerica$`Psychiatric disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.73684211 0.77129523  0.38302988  7.8756794 0.4741345
OR_TRTvsCTRL  1.87500000 0.86482175  0.34424184 10.2126602 0.4673087
ARR_TRTvsCTRL 0.06698565 0.08517996 -0.09996402  0.2339353 0.4316323


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       16  22
n_event_pct   73  58

$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7960526 0.1902215  0.5483085 1.15573588 0.2304985
OR_TRTvsCTRL   0.5156250 0.5806214  0.1652373 1.60901391 0.2539513
ARR_TRTvsCTRL -0.1483254 0.1242204 -0.3917929 0.09514214 0.2324584
```

```
$Region_Northamerica$`Skin and subcutaneous tissue disorders`
$Region_Northamerica$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       12  18
n_event_pct   55  47

$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.86842105 0.2590725  0.5226458 1.442957 0.5860613
OR_TRTvsCTRL   0.75000000 0.5374838  0.2615497 2.150643 0.5924849
ARR_TRTvsCTRL -0.07177033 0.1335307 -0.3334857 0.189945 0.5909348



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        4   7
n_event_pct   17  15

$Disdur_greater_12wk$`Cardiac disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.87500000 0.57239825  0.2849586 2.6867937 0.8155408
OR_TRTvsCTRL   0.85256410 0.68638892  0.2220607 3.2732739 0.8162386
ARR_TRTvsCTRL -0.02173913 0.09513738 -0.2082050 0.1647267 0.8192556


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       12  27
n_event_pct   52  59

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 0.2348467  0.7099874 1.7826021 0.6159971
OR_TRTvsCTRL  1.30263158 0.5137227  0.4759267 3.5653583 0.6067988
ARR_TRTvsCTRL 0.06521739 0.1269623 -0.1836241 0.3140589 0.6074790


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         23  46
n_event       12  23
n_event_pct   52  50

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.95833333 0.2481818  0.5892015 1.5587244 0.8638419
OR_TRTvsCTRL   0.91666667 0.5110763  0.3366530 2.4959756 0.8648125
ARR_TRTvsCTRL -0.02173913 0.1276080 -0.2718462 0.2283679 0.8647281


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         23  46
n_event       13  30
n_event_pct   57  65

$Disdur_greater_12wk$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.15384615 0.2122240  0.7612066 1.7490140 0.5001260
OR_TRTvsCTRL  1.44230769 0.5222609  0.5182134 4.0142755 0.4831363
ARR_TRTvsCTRL 0.08695652 0.1249640 -0.1579685 0.3318815 0.4865213


$Disdur_greater_12wk$`Injury, poisoning and procedural complications`
$Disdur_greater_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         23  46
n_event        4   9
n_event_pct   17  20

$Disdur_greater_12wk$`Injury, poisoning and procedural complications`$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 0.54396114  0.3873753 3.267180 0.8285759
OR_TRTvsCTRL  1.15540541 0.66390490  0.3144977 4.244742 0.8277577
ARR_TRTvsCTRL 0.02173913 0.09832367 -0.1709717 0.214450 0.8250164


$Disdur_greater_12wk$Investigations
$Disdur_greater_12wk$Investigations$ntab
            CTRL TRT
n_all         23  46
n_event        6  13
n_event_pct   26  28

$Disdur_greater_12wk$Investigations$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.08333333 0.4223415  0.4734394 2.4789048 0.8496843
OR_TRTvsCTRL  1.11616162 0.5768157  0.3603634 3.4571121 0.8489007
ARR_TRTvsCTRL 0.02173913 0.1130962 -0.1999253 0.2434036 0.8475714


$Disdur_greater_12wk$`Metabolism and nutrition disorders`
$Disdur_greater_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        5   4
n_event_pct   22   9
```

```
$Disdur_greater_12wk$`Metabolism and nutrition disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4000000 0.62030848  0.11859120 1.34917264 0.1396345
OR_TRTvsCTRL   0.3428571 0.72757479  0.08237595 1.42700662 0.1412246
ARR_TRTvsCTRL -0.1304348 0.09551459 -0.31763995 0.05677038 0.1720644


$Disdur_greater_12wk$`Musculoskeletal and connective tissue disorders`
$Disdur_greater_12wk$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        3   3
n_event_pct   13   7

$Disdur_greater_12wk$`Musculoskeletal and connective tissue disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 0.77553161  0.10935441 2.28614465 0.3714448
OR_TRTvsCTRL   0.46511628 0.86018747  0.08617249 2.51046656 0.3735277
ARR_TRTvsCTRL -0.06521739 0.07909916 -0.22024891 0.08981412 0.4096546


$Disdur_greater_12wk$`Psychiatric disorders`
$Disdur_greater_12wk$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        1   5
n_event_pct    4  11

$Disdur_greater_12wk$`Psychiatric disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.50000000 1.06526176  0.30987573 20.1693759 0.3897033
OR_TRTvsCTRL  2.68292683 1.12687390  0.29472164 24.4233724 0.3811426
ARR_TRTvsCTRL 0.06521739 0.06256418 -0.05740614  0.1878409 0.2972226


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       13  20
n_event_pct   57  43

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.7692308 0.2484063  0.4727296 1.251701 0.2908814
OR_TRTvsCTRL   0.5917160 0.5151549  0.2155821 1.624105 0.3084006
ARR_TRTvsCTRL -0.1304348 0.1265976 -0.3785616 0.117692 0.3028646


$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`
$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        6  15
```

```
n_event_pct   26  33

$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.25000000 0.4100194  0.5596298 2.7920243 0.5862854
OR_TRTvsCTRL  1.37096774 0.5695743  0.4489569 4.1864874 0.5796117
ARR_TRTvsCTRL 0.06521739 0.1147197 -0.1596290 0.2900638 0.5696998



$Region_Asia_Pacific
$Region_Asia_Pacific$`Eye disorders`
$Region_Asia_Pacific$`Eye disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Eye disorders`$stats
                  estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$`Gastrointestinal disorders`
$Region_Asia_Pacific$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        1   6
n_event_pct   50  50

$Region_Asia_Pacific$`Gastrointestinal disorders`$stats
               estimate        se      lo95ci     hi95ci pvalue
RR_TRTvsCTRL          1 0.7637626  0.22381237  4.4680283      1
OR_TRTvsCTRL          1 1.5275252  0.05009198 19.9632771      1
ARR_TRTvsCTRL         0 0.3818813 -0.74847361  0.7484736      1


$Region_Asia_Pacific$`General disorders and administration site conditions`
$Region_Asia_Pacific$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all          2  12
n_event        1   3
n_event_pct   50  25

$Region_Asia_Pacific$`General disorders and administration site
conditions`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5000000 0.8660254  0.09158152 2.7298084 0.4234922
OR_TRTvsCTRL   0.3333333 1.5634719  0.01556141 7.1401684 0.4822584
ARR_TRTvsCTRL -0.2500000 0.3750000 -0.98498649 0.4849865 0.5049851
```

```
$Region_Asia_Pacific$`Infections and infestations`
$Region_Asia_Pacific$`Infections and infestations`$ntab
            CTRL TRT
n_all          2  12
n_event        0   6
n_event_pct    0  50

$Region_Asia_Pacific$`Infections and infestations`$stats
              estimate        se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL       3.0 1.3204506 0.2255027  39.9108364 0.4054100546
OR_TRTvsCTRL       5.0 1.6455067 0.1987523 125.7847088 0.3280345432
ARR_TRTvsCTRL      0.5 0.1443376 0.2171036   0.7828964 0.0005320055


$Region_Asia_Pacific$`Injury, poisoning and procedural complications`
$Region_Asia_Pacific$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Injury, poisoning and procedural complications`$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$`Nervous system disorders`
$Region_Asia_Pacific$`Nervous system disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Nervous system disorders`$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`
$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        0   3
n_event_pct    0  25

$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$stats
              estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.615385 1.369474 0.110300612 23.6577786 0.72619768
OR_TRTvsCTRL  1.842105 1.670622 0.069707343 48.6799765 0.71460562
ARR_TRTvsCTRL 0.250000 0.125000 0.005004502  0.4949955 0.04550026
```

```
$Region_Asia_Pacific$`Skin and subcutaneous tissue disorders`
$Region_Asia_Pacific$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        1   2
n_event_pct   50  17

$Region_Asia_Pacific$`Skin and subcutaneous tissue disorders`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3333333 0.9574271  0.051040546 2.1769185 0.2511903
OR_TRTvsCTRL   0.2000000 1.6124515  0.008482205 4.7157551 0.3182158
ARR_TRTvsCTRL -0.3333333 0.3695593 -1.057656246 0.3909896 0.3670700



$Region_Europe
$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        7  14
n_event_pct   41  47

$Region_Europe$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.13333333 0.3494694  0.5713323 2.2481565 0.7202296
OR_TRTvsCTRL  1.25000000 0.6138287  0.3753341 4.1629575 0.7162110
ARR_TRTvsCTRL 0.05490196 0.1501473 -0.2393813 0.3491853 0.7146233


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  30
n_event        9  14
n_event_pct   53  47

$Region_Europe$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8814815 0.3006374  0.4890015 1.5889717 0.6747683
OR_TRTvsCTRL   0.7777778 0.6083089  0.2360816 2.5624121 0.6795068
ARR_TRTvsCTRL -0.0627451 0.1514968 -0.3596735 0.2341833 0.6787513


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  30
n_event        8  20
n_event_pct   47  67

$Region_Europe$`Infections and infestations`$stats
```

```
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.4166667 0.2878248  0.80588065 2.4903743 0.2262274
OR_TRTvsCTRL  2.2500000 0.6213784  0.66567810 7.6050271 0.1918756
ARR_TRTvsCTRL 0.1960784 0.1485342 -0.09504322 0.4872001 0.1868051


$Region_Europe$`Injury, poisoning and procedural complications`
$Region_Europe$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         17  30
n_event        2   3
n_event_pct   12  10

$Region_Europe$`Injury, poisoning and procedural complications`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.86091606  0.1572555 4.5944339 0.8502696
OR_TRTvsCTRL   0.83333333 0.96800673  0.1249827 5.5563242 0.8506043
ARR_TRTvsCTRL -0.01764706 0.09542667 -0.2046799 0.1693858 0.8532855


$Region_Europe$Investigations
$Region_Europe$Investigations$ntab
            CTRL TRT
n_all         17  30
n_event        4  10
n_event_pct   24  33

$Region_Europe$Investigations$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.41666667 0.5077826  0.5236515 3.8325955 0.4927530
OR_TRTvsCTRL  1.62500000 0.6905962  0.4197753 6.2905685 0.4820389
ARR_TRTvsCTRL 0.09803922 0.1341327 -0.1648560 0.3609344 0.4648327


$Region_Europe$`Metabolism and nutrition disorders`
$Region_Europe$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        3   4
n_event_pct   18  13

$Region_Europe$`Metabolism and nutrition disorders`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.75555556 0.7008398  0.1912980 2.9841617 0.6891922
OR_TRTvsCTRL   0.71794872 0.8326004  0.1404050 3.6711673 0.6906460
ARR_TRTvsCTRL -0.04313725 0.1113580 -0.2613949 0.1751204 0.6984789


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        7  14
n_event_pct   41  47
```

```
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.13333333 0.3494694  0.5713323 2.2481565 0.7202296
OR_TRTvsCTRL  1.25000000 0.6138287  0.3753341 4.1629575 0.7162110
ARR_TRTvsCTRL 0.05490196 0.1501473 -0.2393813 0.3491853 0.7146233




\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem milden UE nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       17  41
n_event_pct   53  57

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.07189542 0.1951279  0.7312389 1.5712510 0.7219826
OR_TRTvsCTRL  1.16698292 0.4267769  0.5055817 2.6936281 0.7174772
ARR_TRTvsCTRL 0.03819444 0.1057697 -0.1691103 0.2454992 0.7180175


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         32  72
n_event       18  34
n_event_pct   56  47

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83950617 0.1995706  0.5677395 1.2413628 0.3807098
OR_TRTvsCTRL   0.69590643 0.4274479  0.3010971 1.6084040 0.3963542
ARR_TRTvsCTRL -0.09027778 0.1056027 -0.2972553 0.1166998 0.3926169


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         32  72
n_event       18  45
n_event_pct   56  62

$Ageonset_less_equal_12wk$`Infections and infestations`$stats
```

```
              estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.111111 0.1806624  0.7797895 1.5832065 0.5597653
OR_TRTvsCTRL  1.296296 0.4315592  0.5563657 3.0202868 0.5476176
ARR_TRTvsCTRL 0.062500 0.1046214 -0.1425542 0.2675542 0.5502456


$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`
$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         32  72
n_event        8  13
n_event_pct   25  18

$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.72222222 0.3959598  0.3323757 1.5693235 0.4111582
OR_TRTvsCTRL   0.66101695 0.5104301  0.2430713 1.7975935 0.4173466
ARR_TRTvsCTRL -0.06944444 0.0889624 -0.2438075 0.1049187 0.4350352


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         32  72
n_event       11  19
n_event_pct   34  26

$Ageonset_less_equal_12wk$Investigations$stats
                 estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.76767677 0.31369058  0.4151112 1.419686 0.3993259
OR_TRTvsCTRL   0.68439108 0.45828773  0.2787463 1.680349 0.4079628
ARR_TRTvsCTRL -0.07986111 0.09872942 -0.2733672 0.113645 0.4185792


$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        6  10
n_event_pct   19  14

$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.74074074 0.47066737  0.2944648 1.8633697 0.5237243
OR_TRTvsCTRL   0.69892473 0.56679559  0.2301299 2.1226954 0.5273899
ARR_TRTvsCTRL -0.04861111 0.08013636 -0.2056755 0.1084533 0.5441131


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       17  38
n_event_pct   53  53
```

```
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.993464052 0.2000011  0.6712912 1.4702574 0.9738446
OR_TRTvsCTRL   0.986159170 0.4256968  0.4281473 2.2714374 0.9738816
ARR_TRTvsCTRL -0.003472222 0.1060353 -0.2112976 0.2043532 0.9738772


$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`
$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`$ntab
           CTRL TRT
n_all        32  72
n_event      11  22
n_event_pct  34  31

$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.30203435  0.4917625 1.6067177 0.6965619
OR_TRTvsCTRL   0.84000000 0.45164442  0.3466082 2.0357278 0.6994661
ARR_TRTvsCTRL -0.03819444 0.09998331 -0.2341581 0.1577692 0.7024553



$Agetrt_less_180d
$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$ntab
           CTRL TRT
n_all        16  49
n_event      10  26
n_event_pct  62  53

$Agetrt_less_180d$`Gastrointestinal disorders`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.84897959 0.2356976  0.5348981 1.3474835 0.4872939
OR_TRTvsCTRL   0.67826087 0.5904291  0.2132174 2.1575997 0.5108418
ARR_TRTvsCTRL -0.09438776 0.1404683 -0.3697006 0.1809251 0.5016153


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site conditions`$ntab
           CTRL TRT
n_all        16  49
n_event       9  21
n_event_pct  56  43

$Agetrt_less_180d$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7619048 0.2753579  0.4441356 1.3070307 0.3233660
OR_TRTvsCTRL   0.5833333 0.5807767  0.1868783 1.8208527 0.3533757
ARR_TRTvsCTRL -0.1339286 0.1427543 -0.4137218 0.1458646 0.3481541


$Agetrt_less_180d$`Infections and infestations`
```

```
$Agetrt_less_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         16  49
n_event        9  34
n_event_pct   56  69

$Agetrt_less_180d$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2335601 0.2400306  0.7706299 1.9745802 0.3818515
OR_TRTvsCTRL  1.7629630 0.5916474  0.5528814 5.6215282 0.3378943
ARR_TRTvsCTRL 0.1313776 0.1404129 -0.1438267 0.4065818 0.3494527


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$ntab
            CTRL TRT
n_all         16  49
n_event        6  13
n_event_pct   38  27

$Agetrt_less_180d$Investigations$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.7074830 0.4008511  0.3224861 1.552105 0.3879904
OR_TRTvsCTRL   0.6018519 0.6093993  0.1822921 1.987061 0.4047389
ARR_TRTvsCTRL -0.1096939 0.1364785 -0.3771868 0.157799 0.4215443


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event       10  27
n_event_pct   62  55

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.88163265 0.2326561  0.5587923 1.390993 0.5881733
OR_TRTvsCTRL   0.73636364 0.5908961  0.2312707 2.344575 0.6045208
ARR_TRTvsCTRL -0.07397959 0.1403473 -0.3490552 0.201096 0.5981115


$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        6  12
n_event_pct   38  24

$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.6530612 0.4087687  0.2930956 1.455119 0.2972445
OR_TRTvsCTRL   0.5405405 0.6140253  0.1622441 1.800891 0.3163968
ARR_TRTvsCTRL -0.1301020 0.1357291 -0.3961261 0.135922 0.3377894
```

```
$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       13  19
n_event_pct   52  61

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.17866005 0.2393671  0.7372910 1.8842485 0.4922589
OR_TRTvsCTRL  1.46153846 0.5442622  0.5029600 4.2470469 0.4856431
ARR_TRTvsCTRL 0.09290323 0.1328056 -0.1673909 0.3531974 0.4842126


$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         25  31
n_event       13  16
n_event_pct   52  52

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.992555831 0.2591621  0.5972494 1.6495070 0.9769990
OR_TRTvsCTRL   0.984615385 0.5379806  0.3430337 2.8261584 0.9770088
ARR_TRTvsCTRL -0.003870968 0.1343135 -0.2671206 0.2593787 0.9770078


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         25  31
n_event       15  13
n_event_pct   60  42

$Agetrt_greater_equal_180d$`Infections and infestations`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6989247 0.2670799  0.4140870 1.17969365 0.1798499
OR_TRTvsCTRL   0.4814815 0.5469418  0.1648246 1.40649200 0.1814457
ARR_TRTvsCTRL -0.1806452 0.1321163 -0.4395884 0.07829806 0.1715253


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       13  12
```

```
n_event_pct   52  39

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7444169 0.2966452  0.4162089 1.3314382 0.3197491
OR_TRTvsCTRL   0.5829960 0.5442622  0.2006267 1.6941129 0.3214961
ARR_TRTvsCTRL -0.1329032 0.1328056 -0.3931974 0.1273909 0.3169548


$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        8  10
n_event_pct   32  32

$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.008064516 0.3908221  0.4686190 2.1684865 0.9836030
OR_TRTvsCTRL  1.011904762 0.5757105  0.3274115 3.1274135 0.9835996
ARR_TRTvsCTRL 0.002580645 0.1255114 -0.2434172 0.2485784 0.9835958



$Gender_Male
$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        8  17
n_event_pct   47  46

$Gender_Male$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.97635135 0.3130063  0.5286578 1.8031739 0.9390524
OR_TRTvsCTRL   0.95625000 0.5873114  0.3024483 3.0233734 0.9392833
ARR_TRTvsCTRL -0.01112878 0.1461757 -0.2976279 0.2753703 0.9393134


$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  37
n_event        9  15
n_event_pct   53  41

$Gender_Male$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7657658 0.3031950  0.4226841 1.3873180 0.3787390
OR_TRTvsCTRL   0.6060606 0.5901121  0.1906390 1.9267280 0.3960981
ARR_TRTvsCTRL -0.1240064 0.1454988 -0.4091788 0.1611661 0.3940564
```

```
$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  37
n_event       12  21
n_event_pct   71  57

$Gender_Male$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8040541 0.2123719  0.5302906 1.2191483 0.3044585
OR_TRTvsCTRL   0.5468750 0.6272578  0.1599430 1.8698678 0.3359591
ARR_TRTvsCTRL -0.1383148 0.1372802 -0.4073791 0.1307496 0.3136773


$Gender_Male$Investigations
$Gender_Male$Investigations$ntab
            CTRL TRT
n_all         17  37
n_event        4  10
n_event_pct   24  27

$Gender_Male$Investigations$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14864865 0.5139547  0.4194770 3.1453302 0.7874321
OR_TRTvsCTRL  1.20370370 0.6811462  0.3167575 4.5741697 0.7854736
ARR_TRTvsCTRL 0.03497615 0.1261529 -0.2122790 0.2822313 0.7815865


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        7  16
n_event_pct   41  43

$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.05019305 0.3456972  0.5333485 2.0678887 0.8873428
OR_TRTvsCTRL  1.08843537 0.5941180  0.3396945 3.4875208 0.8865795
ARR_TRTvsCTRL 0.02066773 0.1445036 -0.2625541 0.3038895 0.8862699


$Gender_Male$`Skin and subcutaneous tissue disorders`
$Gender_Male$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        8  11
n_event_pct   47  30

$Gender_Male$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6317568 0.3606363  0.3115844 1.2809261 0.2028598
OR_TRTvsCTRL   0.4759615 0.6045509  0.1455383 1.5565622 0.2194285
ARR_TRTvsCTRL -0.1732909 0.1424825 -0.4525515 0.1059696 0.2238987
```

```
$Gender_Female
$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       15  28
n_event_pct   62  65

$Gender_Female$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.04186047 0.1935419  0.7129620 1.5224840 0.8321992
OR_TRTvsCTRL  1.12000000 0.5293002  0.3968961 3.1605247 0.8304610
ARR_TRTvsCTRL 0.02616279 0.1226710 -0.2142680 0.2665936 0.8311117


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         24  43
n_event       13  22
n_event_pct   54  51

$Gender_Female$`General disorders and administration site conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94454383 0.2396980  0.5904604 1.5109616 0.8118647
OR_TRTvsCTRL   0.88644689 0.5107894  0.3257377 2.4123338 0.8134512
ARR_TRTvsCTRL -0.03003876 0.1271029 -0.2791558 0.2190783 0.8131733


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$ntab
            CTRL TRT
n_all         24  43
n_event       12  26
n_event_pct   50  60

$Gender_Female$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2093023 0.2384793  0.7577761 1.9298736 0.4255105
OR_TRTvsCTRL  1.5294118 0.5137623  0.5587392 4.1863903 0.4082351
ARR_TRTvsCTRL 0.1046512 0.1263959 -0.1430803 0.3523826 0.4076913


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       16  23
n_event_pct   67  53

$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats
```

```
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8023256 0.2026223  0.5393594 1.1935016 0.2770578
OR_TRTvsCTRL   0.5750000 0.5300738  0.2034549 1.6250529 0.2964957
ARR_TRTvsCTRL -0.1317829 0.1226577 -0.3721876 0.1086217 0.2826453


$Gender_Female$`Skin and subcutaneous tissue disorders`
$Gender_Female$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        6  11
n_event_pct   25  26

$Gender_Female$`Skin and subcutaneous tissue disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.023255814 0.4389229  0.4328849 2.4187781 0.9582282
OR_TRTvsCTRL  1.031250000 0.5868401  0.3264711 3.2574906 0.9581811
ARR_TRTvsCTRL 0.005813953 0.1106336 -0.2110238 0.2226517 0.9580893



$Region_Europe
$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        7  14
n_event_pct   41  47

$Region_Europe$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.13333333 0.3494694  0.5713323 2.2481565 0.7202296
OR_TRTvsCTRL  1.25000000 0.6138287  0.3753341 4.1629575 0.7162110
ARR_TRTvsCTRL 0.05490196 0.1501473 -0.2393813 0.3491853 0.7146233


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  30
n_event        9  14
n_event_pct   53  47

$Region_Europe$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8814815 0.3006374  0.4890015 1.5889717 0.6747683
OR_TRTvsCTRL   0.7777778 0.6083089  0.2360816 2.5624121 0.6795068
ARR_TRTvsCTRL -0.0627451 0.1514968 -0.3596735 0.2341833 0.6787513


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  30
```

```
n_event        8  20
n_event_pct   47  67

$Region_Europe$`Infections and infestations`$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.4166667 0.2878248  0.80588065 2.4903743 0.2262274
OR_TRTvsCTRL  2.2500000 0.6213784  0.66567810 7.6050271 0.1918756
ARR_TRTvsCTRL 0.1960784 0.1485342 -0.09504322 0.4872001 0.1868051


$Region_Europe$Investigations
$Region_Europe$Investigations$ntab
            CTRL TRT
n_all         17  30
n_event        4  10
n_event_pct   24  33

$Region_Europe$Investigations$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.41666667 0.5077826  0.5236515 3.8325955 0.4927530
OR_TRTvsCTRL  1.62500000 0.6905962  0.4197753 6.2905685 0.4820389
ARR_TRTvsCTRL 0.09803922 0.1341327 -0.1648560 0.3609344 0.4648327


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        7  14
n_event_pct   41  47

$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.13333333 0.3494694  0.5713323 2.2481565 0.7202296
OR_TRTvsCTRL  1.25000000 0.6138287  0.3753341 4.1629575 0.7162110
ARR_TRTvsCTRL 0.05490196 0.1501473 -0.2393813 0.3491853 0.7146233



$Region_Northamerica
$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       15  25
n_event_pct   68  66

$Region_Northamerica$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.96491228 0.1868056  0.6690809 1.3915443 0.8483653
OR_TRTvsCTRL   0.89743590 0.5713553  0.2928633 2.7500587 0.8497808
ARR_TRTvsCTRL -0.02392344 0.1256339 -0.2701614 0.2223145 0.8489786
```

```
$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         22  38
n_event       12  20
n_event_pct   55  53

$Region_Northamerica$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.96491228 0.2481189  0.5933195 1.5692316 0.8855356
OR_TRTvsCTRL   0.92592593 0.5374838  0.3229008 2.6551149 0.8861420
ARR_TRTvsCTRL -0.01913876 0.1335307 -0.2808541 0.2425766 0.8860307


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$ntab
            CTRL TRT
n_all         22  38
n_event       16  21
n_event_pct   73  55

$Region_Northamerica$`Infections and infestations`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7598684 0.1958283  0.5176653 1.11539251 0.1608257
OR_TRTvsCTRL   0.4632353 0.5793179  0.1488282 1.44184290 0.1840721
ARR_TRTvsCTRL -0.1746411 0.1245866 -0.4188265 0.06954416 0.1609855


$Region_Northamerica$`Injury, poisoning and procedural complications`
$Region_Northamerica$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         22  38
n_event        7  10
n_event_pct   32  26

$Region_Northamerica$`Injury, poisoning and procedural complications`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.82706767 0.4136264  0.3676729 1.8604606 0.6462094
OR_TRTvsCTRL   0.76530612 0.5875697  0.2419329 2.4208918 0.6489437
ARR_TRTvsCTRL -0.05502392 0.1223266 -0.2947796 0.1847318 0.6528462


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       16  22
n_event_pct   73  58

$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7960526 0.1902215  0.5483085 1.15573588 0.2304985
OR_TRTvsCTRL   0.5156250 0.5806214  0.1652373 1.60901391 0.2539513
```

```
ARR_TRTvsCTRL -0.1483254 0.1242204 -0.3917929 0.09514214 0.2324584


$Region_Northamerica$`Skin and subcutaneous tissue disorders`
$Region_Northamerica$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       12  18
n_event_pct   55  47

$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.86842105 0.2590725  0.5226458 1.442957 0.5860613
OR_TRTvsCTRL   0.75000000 0.5374838  0.2615497 2.150643 0.5924849
ARR_TRTvsCTRL -0.07177033 0.1335307 -0.3334857 0.189945 0.5909348



$Disdur_greater_12wk
$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       12  27
n_event_pct   52  59

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 0.2348467  0.7099874 1.7826021 0.6159971
OR_TRTvsCTRL  1.30263158 0.5137227  0.4759267 3.5653583 0.6067988
ARR_TRTvsCTRL 0.06521739 0.1269623 -0.1836241 0.3140589 0.6074790


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         23  46
n_event       12  23
n_event_pct   52  50

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.95833333 0.2481818  0.5892015 1.5587244 0.8638419
OR_TRTvsCTRL   0.91666667 0.5110763  0.3366530 2.4959756 0.8648125
ARR_TRTvsCTRL -0.02173913 0.1276080 -0.2718462 0.2283679 0.8647281


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         23  46
n_event       13  30
n_event_pct   57  65
```

```
$Disdur_greater_12wk$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.15384615 0.2122240  0.7612066 1.7490140 0.5001260
OR_TRTvsCTRL  1.44230769 0.5222609  0.5182134 4.0142755 0.4831363
ARR_TRTvsCTRL 0.08695652 0.1249640 -0.1579685 0.3318815 0.4865213


$Disdur_greater_12wk$Investigations
$Disdur_greater_12wk$Investigations$ntab
            CTRL TRT
n_all         23  46
n_event        6  13
n_event_pct   26  28

$Disdur_greater_12wk$Investigations$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.08333333 0.4223415  0.4734394 2.4789048 0.8496843
OR_TRTvsCTRL  1.11616162 0.5768157  0.3603634 3.4571121 0.8489007
ARR_TRTvsCTRL 0.02173913 0.1130962 -0.1999253 0.2434036 0.8475714


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       13  20
n_event_pct   57  43

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.7692308 0.2484063  0.4727296 1.251701 0.2908814
OR_TRTvsCTRL   0.5917160 0.5151549  0.2155821 1.624105 0.3084006
ARR_TRTvsCTRL -0.1304348 0.1265976 -0.3785616 0.117692 0.3028646


$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`
$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        6  15
n_event_pct   26  33

$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.25000000 0.4100194  0.5596298 2.7920243 0.5862854
OR_TRTvsCTRL  1.37096774 0.5695743  0.4489569 4.1864874 0.5796117
ARR_TRTvsCTRL 0.06521739 0.1147197 -0.1596290 0.2900638 0.5696998



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$ntab
```

```
            CTRL TRT
n_all         18  34
n_event       11  18
n_event_pct   61  53

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.86631016 0.2479865  0.5328278 1.4085100 0.5627849
OR_TRTvsCTRL   0.71590909 0.5931457  0.2238574 2.2895197 0.5731352
ARR_TRTvsCTRL -0.08169935 0.1432847 -0.3625323 0.1991336 0.5685497


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         18  34
n_event       10  14
n_event_pct   56  41

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7411765 0.2940429  0.4165161 1.3188987 0.3083858
OR_TRTvsCTRL   0.5600000 0.5885818  0.1766795 1.7749650 0.3245695
ARR_TRTvsCTRL -0.1437908 0.1443654 -0.4267419 0.1391602 0.3192405


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         18  34
n_event       11  17
n_event_pct   61  50

$Disdur_less_equal_12wk$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8181818 0.2544903  0.4968523 1.3473249 0.4303925
OR_TRTvsCTRL   0.6363636 0.5928012  0.1991187 2.0337552 0.4457876
ARR_TRTvsCTRL -0.1111111 0.1433735 -0.3921180 0.1698958 0.4383535


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event       10  19
n_event_pct   56  56

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.005882353 0.2601235  0.6041289 1.6748069 0.9820113
OR_TRTvsCTRL  1.013333333 0.5867693  0.3208436 3.2004518 0.9819908
ARR_TRTvsCTRL 0.003267974 0.1448054 -0.2805453 0.2870813 0.9819948
```

```
\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines milden UEs nach SOC, das bei mindestens 10% der
Patienten in einem Studienarm auftrat"

$Agetrt_less_180d
$Agetrt_less_180d$`Blood and lymphatic system disorders`
$Agetrt_less_180d$`Blood and lymphatic system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                16.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Blood and lymphatic system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.523e-10 2.173e+04 0.000e+00       Inf 9.992e-01


$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49.0
n_event                               4.0                 7.0
n_event_pct                          25.0                14.0
time-to-event-wk-10th                 4.3                15.4
time-to-event-wk-25th                40.7                  NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           10.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31330   0.66610   0.08492   1.15600   0.08143


$Agetrt_less_180d$`Congenital, familial and genetic disorders`
$Agetrt_less_180d$`Congenital, familial and genetic disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               3.0                  2
n_event_pct                          19.0                  4
```

```
time-to-event-wk-10th                16.7                 NA
time-to-event-wk-25th                49.4                 NA
time-to-event-wk-50th                49.4                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Congenital, familial and genetic
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.17010   0.95710   0.02606   1.11000   0.06422


$Agetrt_less_180d$`Eye disorders`
$Agetrt_less_180d$`Eye disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                 49
n_event                              2.0                  2
n_event_pct                         12.0                  4
time-to-event-wk-10th               11.1                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$`Eye disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25730   1.01600   0.03513   1.88500   0.18160


$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49.0
n_event                             10.0                26.0
n_event_pct                         62.0                53.0
time-to-event-wk-10th                2.7                 0.3
time-to-event-wk-25th                5.1                 6.6
time-to-event-wk-50th               10.9                18.9
time-to-event-wk-75th               36.4                  NA
time-to-event-wk-90th               36.4                  NA
time-to-event-wk-50th-loci           5.1                 9.6
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6529    0.3780    0.3112    1.3700    0.2594


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site
```

```
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               9.0               21.0
n_event_pct                          56.0               43.0
time-to-event-wk-10th                 0.4                5.4
time-to-event-wk-25th                 6.4               15.6
time-to-event-wk-50th                20.6               38.0
time-to-event-wk-75th                23.3                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.4               30.6
time-to-event-wk-50th-hici           23.3                 NA

$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.34270   0.42500   0.14900   0.78830   0.01174


$Agetrt_less_180d$`Immune system disorders`
$Agetrt_less_180d$`Immune system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0                4.0
n_event_pct                          12.0                8.0
time-to-event-wk-10th                24.4               43.1
time-to-event-wk-25th                41.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Immune system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5691    0.9270    0.0925    3.5010    0.5431


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               9.0               34.0
n_event_pct                          56.0               69.0
time-to-event-wk-10th                 6.0                2.7
time-to-event-wk-25th                 7.4                7.7
time-to-event-wk-50th                14.1               21.1
time-to-event-wk-75th                32.6               49.0
time-to-event-wk-90th                32.6                 NA
time-to-event-wk-50th-loci            7.3                9.9
time-to-event-wk-50th-hici             NA               32.1

$Agetrt_less_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.7561    0.3866    0.3544    1.6130    0.4697


$Agetrt_less_180d$`Injury, poisoning and procedural complications`
$Agetrt_less_180d$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               4.0               7.0
n_event_pct                          25.0              14.0
time-to-event-wk-10th                15.9              11.4
time-to-event-wk-25th                26.4                NA
time-to-event-wk-50th                34.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.4                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.34580   0.65800   0.09524   1.25600   0.10660


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               6.0              13.0
n_event_pct                          38.0              27.0
time-to-event-wk-10th                 1.0               5.4
time-to-event-wk-25th                 6.3              33.6
time-to-event-wk-50th                27.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.3              52.0
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4467    0.5074    0.1652    1.2070    0.1122


$Agetrt_less_180d$`Metabolism and nutrition disorders`
$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               2.0               9.0
n_event_pct                          12.0              18.0
time-to-event-wk-10th                14.3              10.7
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           14.3                NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2490    0.7887    0.2662    5.8580    0.7782


$Agetrt_less_180d$`Musculoskeletal and connective tissue disorders`
$Agetrt_less_180d$`Musculoskeletal and connective tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               2.0               7.0
n_event_pct                          12.0              14.0
time-to-event-wk-10th                26.1               9.1
time-to-event-wk-25th                56.4                NA
time-to-event-wk-50th                56.4                NA
time-to-event-wk-75th                56.4                NA
time-to-event-wk-90th                56.4                NA
time-to-event-wk-50th-loci           26.1                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2990    0.8337    0.2536    6.6570    0.7535


$Agetrt_less_180d$`Psychiatric disorders`
$Agetrt_less_180d$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               2.0               6.0
n_event_pct                          12.0              12.0
time-to-event-wk-10th                 9.1              15.7
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8398    0.8243    0.1669    4.2250    0.8323


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                              10.0              27.0
n_event_pct                          62.0              55.0
time-to-event-wk-10th                 3.1               2.1
time-to-event-wk-25th                 5.9               9.3
```

```
time-to-event-wk-50th                10.1               32.1
time-to-event-wk-75th                43.3                 NA
time-to-event-wk-90th                43.3                 NA
time-to-event-wk-50th-loci            5.1               21.3
time-to-event-wk-50th-hici             NA               43.1

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5878    0.3769    0.2808    1.2300    0.1586


$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               6.0               12.0
n_event_pct                          38.0               24.0
time-to-event-wk-10th                 0.1                5.6
time-to-event-wk-25th                 5.9               33.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4875    0.5102    0.1794    1.3250    0.1591



$Gender_Male
$Gender_Male$`Blood and lymphatic system disorders`
$Gender_Male$`Blood and lymphatic system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                16.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Blood and lymphatic system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.645e-10 2.216e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$`Cardiac disorders`
$Gender_Male$`Cardiac disorders`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               4.0                6.0
n_event_pct                          24.0               16.0
time-to-event-wk-10th                 5.1               15.4
time-to-event-wk-25th                40.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5991    0.6547    0.1661    2.1610    0.4339


$Gender_Male$`Congenital, familial and genetic disorders`
$Gender_Male$`Congenital, familial and genetic disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               3.0                  2
n_event_pct                          18.0                  5
time-to-event-wk-10th                16.7                 NA
time-to-event-wk-25th                49.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           49.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Congenital, familial and genetic disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.38540   0.93590   0.06156   2.41300   0.30830


$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               8.0               17.0
n_event_pct                          47.0               46.0
time-to-event-wk-10th                 5.1                0.3
time-to-event-wk-25th                10.6                6.3
time-to-event-wk-50th                22.6               27.9
time-to-event-wk-75th                40.3                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           10.6                9.0
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9689    0.4333    0.4144    2.2650    0.9419
```

```
$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              37.0
n_event                              9.0              15.0
n_event_pct                         53.0              41.0
time-to-event-wk-10th                0.4               3.4
time-to-event-wk-25th                7.7              23.6
time-to-event-wk-50th               20.6              46.7
time-to-event-wk-75th               43.4                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           5.1              30.6
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47880   0.42890   0.20660   1.11000   0.08595


$Gender_Male$`Immune system disorders`
$Gender_Male$`Immune system disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                17                37
n_event                               2                 1
n_event_pct                          12                 3
time-to-event-wk-10th                41                NA
time-to-event-wk-25th                41                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           41                NA
time-to-event-wk-50th-hici           NA                NA

$Gender_Male$`Immune system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.21750   1.26100   0.01838   2.57500   0.22630


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              37.0
n_event                             12.0              21.0
n_event_pct                         71.0              57.0
time-to-event-wk-10th                2.3               3.6
time-to-event-wk-25th                7.4               8.1
time-to-event-wk-50th                9.4              26.4
time-to-event-wk-75th               24.0              49.0
time-to-event-wk-90th               32.6                NA
time-to-event-wk-50th-loci           5.3              10.0
time-to-event-wk-50th-hici          24.0              45.7
```

```
$Gender_Male$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6085    0.3676    0.2960    1.2510    0.1767


$Gender_Male$`Injury, poisoning and procedural complications`
$Gender_Male$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               4.0               6.0
n_event_pct                          24.0              16.0
time-to-event-wk-10th                15.4              19.0
time-to-event-wk-25th                26.4              47.3
time-to-event-wk-50th                34.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           26.4              47.3
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Injury, poisoning and procedural complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4482    0.6623    0.1224    1.6410    0.2256


$Gender_Male$Investigations
$Gender_Male$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               4.0              10.0
n_event_pct                          24.0              27.0
time-to-event-wk-10th                10.1               5.0
time-to-event-wk-25th                27.4              33.6
time-to-event-wk-50th                43.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           27.4              36.9
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0760    0.5969    0.3341    3.4670    0.9021


$Gender_Male$`Metabolism and nutrition disorders`
$Gender_Male$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 3
n_event_pct                          12.0                 8
time-to-event-wk-10th                56.6                32
time-to-event-wk-25th                56.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
```

```
time-to-event-wk-50th-loci           56.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7536    0.9190    0.1244    4.5640    0.7582


$Gender_Male$`Musculoskeletal and connective tissue disorders`
$Gender_Male$`Musculoskeletal and connective tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               3.0                  2
n_event_pct                          18.0                  5
time-to-event-wk-10th                26.1                 NA
time-to-event-wk-25th                56.4                 NA
time-to-event-wk-50th                56.4                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.37950   0.96240   0.05754   2.50300   0.31400


$Gender_Male$`Psychiatric disorders`
$Gender_Male$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                37.0
n_event                                 1                 4.0
n_event_pct                             6                11.0
time-to-event-wk-10th                  NA                29.7
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9090    1.1260    0.2101   17.3500    0.5657


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37.0
n_event                               7.0                16.0
n_event_pct                          41.0                43.0
time-to-event-wk-10th                 3.6                 2.7
```

```
time-to-event-wk-25th                 7.9              11.6
time-to-event-wk-50th                37.4              38.9
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            7.9              22.0
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9197    0.4559    0.3764    2.2480    0.8544


$Gender_Male$`Skin and subcutaneous tissue disorders`
$Gender_Male$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               8.0              11.0
n_event_pct                          47.0              30.0
time-to-event-wk-10th                 0.0               2.1
time-to-event-wk-25th                 5.9              16.1
time-to-event-wk-50th                40.7                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            4.3              26.0
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4995    0.4733    0.1975    1.2630    0.1425



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Blood and lymphatic system disorders`
$Disdur_less_equal_12wk$`Blood and lymphatic system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                16.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Blood and lymphatic system
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.552e-10 1.977e+04 0.000e+00       Inf 9.991e-01
```

```
$Disdur_less_equal_12wk$`Cardiac disorders`
$Disdur_less_equal_12wk$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              3.0                 2
n_event_pct                         17.0                 6
time-to-event-wk-10th               10.0                NA
time-to-event-wk-25th               40.7                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          40.7                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.30740   0.91740   0.05091   1.85600   0.19850


$Disdur_less_equal_12wk$`Congenital, familial and genetic disorders`
$Disdur_less_equal_12wk$`Congenital, familial and genetic disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              3.0                 1
n_event_pct                         17.0                 3
time-to-event-wk-10th               16.7                NA
time-to-event-wk-25th               49.4                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          49.4                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Congenital, familial and genetic
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.14820   1.15900   0.01528   1.43700   0.09955


$Disdur_less_equal_12wk$`Eye disorders`
$Disdur_less_equal_12wk$`Eye disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 2
n_event_pct                         11.0                 6
time-to-event-wk-10th               29.3                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          29.3                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Eye disorders`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5210    1.0390    0.0680    3.9920    0.5303


$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                              11.0               18.0
n_event_pct                          61.0               53.0
time-to-event-wk-10th                 1.0                0.3
time-to-event-wk-25th                 5.1                4.4
time-to-event-wk-50th                22.6               24.1
time-to-event-wk-75th                36.4                 NA
time-to-event-wk-90th                43.0                 NA
time-to-event-wk-50th-loci            5.1                7.1
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7678    0.3908    0.3569    1.6520    0.4989


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                              10.0               14.0
n_event_pct                          56.0               41.0
time-to-event-wk-10th                 0.4                3.1
time-to-event-wk-25th                 5.7               15.6
time-to-event-wk-50th                22.7               46.7
time-to-event-wk-75th                42.6                 NA
time-to-event-wk-90th                42.6                 NA
time-to-event-wk-50th-loci            5.7               24.3
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5032    0.4317    0.2159    1.1730    0.1116


$Disdur_less_equal_12wk$`Immune system disorders`
$Disdur_less_equal_12wk$`Immune system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 2                3.0
n_event_pct                            11                9.0
time-to-event-wk-10th                  41               31.7
time-to-event-wk-25th                  41                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             41                  NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_less_equal_12wk$`Immune system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7031    0.9393    0.1116    4.4310    0.7076


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                              11.0               17.0
n_event_pct                          61.0               50.0
time-to-event-wk-10th                 2.3                3.0
time-to-event-wk-25th                 7.3                9.3
time-to-event-wk-50th                14.1               35.0
time-to-event-wk-75th                32.6                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.3               10.0
time-to-event-wk-50th-hici           32.6                 NA

$Disdur_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5953    0.4074    0.2679    1.3230    0.2030


$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`
$Disdur_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               6.0                4.0
n_event_pct                          33.0               12.0
time-to-event-wk-10th                15.4               26.7
time-to-event-wk-25th                26.4                 NA
time-to-event-wk-50th                34.4                 NA
time-to-event-wk-75th                37.3                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.18860   0.70230   0.04762   0.74700   0.01753


$Disdur_less_equal_12wk$Investigations
$Disdur_less_equal_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               5.0                6.0
```

```
n_event_pct                          28.0              18.0
time-to-event-wk-10th                 2.3               6.7
time-to-event-wk-25th                27.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           10.1                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5304    0.6120    0.1598    1.7600    0.3001


$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`
$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 6
n_event_pct                          11.0                18
time-to-event-wk-10th                14.3                14
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3770    0.8187    0.2768    6.8520    0.6959


$Disdur_less_equal_12wk$`Musculoskeletal and connective tissue disorders`
$Disdur_less_equal_12wk$`Musculoskeletal and connective tissue
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                               2.0               6.0
n_event_pct                          11.0              18.0
time-to-event-wk-10th                56.4               9.1
time-to-event-wk-25th                56.4              54.4
time-to-event-wk-50th                56.4                NA
time-to-event-wk-75th                56.4                NA
time-to-event-wk-90th                56.4                NA
time-to-event-wk-50th-loci             NA              54.4
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5260    0.8234    0.3039    7.6640    0.6077
```

```
$Disdur_less_equal_12wk$`Nervous system disorders`
$Disdur_less_equal_12wk$`Nervous system disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0              34.0
n_event                              2.0               2.0
n_event_pct                         11.0               6.0
time-to-event-wk-10th               29.1              49.6
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          29.1                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.43710   1.02800   0.05825   3.28000   0.42090


$Disdur_less_equal_12wk$`Psychiatric disorders`
$Disdur_less_equal_12wk$`Psychiatric disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0              34.0
n_event                              2.0               4.0
n_event_pct                         11.0              12.0
time-to-event-wk-10th                9.1              15.7
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8657    0.8877    0.1520    4.9320    0.8710


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0              34.0
n_event                             10.0              19.0
n_event_pct                         56.0              56.0
time-to-event-wk-10th                0.9               3.3
time-to-event-wk-25th                3.6               9.3
time-to-event-wk-50th               26.4              26.6
time-to-event-wk-75th               43.3                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           3.6              18.7
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
```

```
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7749    0.4013    0.3529    1.7010    0.5250


$Disdur_less_equal_12wk$`Skin and subcutaneous tissue disorders`
$Disdur_less_equal_12wk$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               8.0                7.0
n_event_pct                          44.0               21.0
time-to-event-wk-10th                 0.0                9.0
time-to-event-wk-25th                 7.6               40.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.6               40.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Skin and subcutaneous tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31150   0.52810   0.11060   0.87700   0.02722



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               7.0                8.0
n_event_pct                          22.0               11.0
time-to-event-wk-10th                 4.6               22.9
time-to-event-wk-25th                40.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.37890   0.52270   0.13600   1.05500   0.06333


$Ageonset_less_equal_12wk$`Congenital, familial and genetic disorders`
$Ageonset_less_equal_12wk$`Congenital, familial and genetic disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               4.0                  2
n_event_pct                          12.0                  3
time-to-event-wk-10th                16.7                 NA
time-to-event-wk-25th                49.4                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           49.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Congenital, familial and genetic
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.16830   0.86850   0.03068   0.92340   0.04020


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              17.0              41.0
n_event_pct                          53.0              57.0
time-to-event-wk-10th                 4.4               2.4
time-to-event-wk-25th                10.6               6.3
time-to-event-wk-50th                16.9              20.6
time-to-event-wk-75th                40.3                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           10.9              12.6
time-to-event-wk-50th-hici           36.4              40.9

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8737    0.2938    0.4912    1.5540    0.6457


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              18.0              34.0
n_event_pct                          56.0              47.0
time-to-event-wk-10th                 3.1               3.1
time-to-event-wk-25th                 7.7              13.4
time-to-event-wk-50th                18.0              38.0
time-to-event-wk-75th                40.0                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            7.9              30.6
time-to-event-wk-50th-hici           40.0                NA

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49240   0.30140   0.27270   0.88910   0.01877


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$stats_num
```

```
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              18.0               45.0
n_event_pct                          56.0               62.0
time-to-event-wk-10th                 6.0                3.6
time-to-event-wk-25th                 8.3                7.7
time-to-event-wk-50th                19.7               25.6
time-to-event-wk-75th                32.6               55.0
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.7               11.4
time-to-event-wk-50th-hici           24.0               35.0

$Ageonset_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8316    0.2838    0.4768    1.4500    0.5159


$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`
$Ageonset_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               8.0               13.0
n_event_pct                          25.0               18.0
time-to-event-wk-10th                 4.6               11.4
time-to-event-wk-25th                26.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4756    0.4616    0.1925    1.1750    0.1074


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              11.0               19.0
n_event_pct                          34.0               26.0
time-to-event-wk-10th                 2.3                5.4
time-to-event-wk-25th                19.1               36.9
time-to-event-wk-50th                43.4                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.1               52.0
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.5365    0.3873    0.2511    1.1460    0.1079


$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               6.0                10
n_event_pct                          19.0                14
time-to-event-wk-10th                12.6                14
time-to-event-wk-25th                56.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           28.4                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Metabolism and nutrition
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5615    0.5196    0.2028    1.5550    0.2667


$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue disorders`
$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               5.0                8.0
n_event_pct                          16.0               11.0
time-to-event-wk-10th                26.1               54.4
time-to-event-wk-25th                46.9                 NA
time-to-event-wk-50th                56.4                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           46.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5820    0.5738    0.1890    1.7920    0.3454


$Ageonset_less_equal_12wk$`Psychiatric disorders`
$Ageonset_less_equal_12wk$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               3.0                8.0
n_event_pct                           9.0               11.0
time-to-event-wk-10th                13.9               29.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9426    0.6836    0.2468    3.5990    0.9310


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                             17.0               38.0
n_event_pct                         53.0               53.0
time-to-event-wk-10th                1.6                1.7
time-to-event-wk-25th                6.0                6.9
time-to-event-wk-50th               26.4               30.7
time-to-event-wk-75th               43.3                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           6.4               21.3
time-to-event-wk-50th-hici          43.3               43.1

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7332    0.2959    0.4105    1.3100    0.2943


$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`
$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                             11.0               22.0
n_event_pct                         34.0               31.0
time-to-event-wk-10th                4.3                4.4
time-to-event-wk-25th               19.0               26.0
time-to-event-wk-50th               53.6                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          19.0               49.9
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6923    0.3753    0.3318    1.4450    0.3271



$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Cardiac disorders`
$Ageonset_greater_12wk$`Cardiac disorders`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA                2.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                2.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$`Eye disorders`
$Ageonset_greater_12wk$`Eye disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8
n_event                               1.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                29.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           29.3                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_greater_12wk$`Eye disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.113e-17 4.635e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$`Gastrointestinal disorders`
$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               6.0                4.0
n_event_pct                          67.0               50.0
time-to-event-wk-10th                 0.0                0.0
time-to-event-wk-25th                 7.7                1.7
time-to-event-wk-50th                39.7                4.4
time-to-event-wk-75th                43.0                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            0.0                0.0
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9620    0.7594    0.4429    8.6900    0.3749
```

```
$Ageonset_greater_12wk$`General disorders and administration site conditions`
$Ageonset_greater_12wk$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              4.0                3.0
n_event_pct                         44.0               38.0
time-to-event-wk-10th                1.3                0.4
time-to-event-wk-25th                5.7                9.7
time-to-event-wk-50th               42.6                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           1.3                0.4
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0420    0.7867    0.2230    4.8720    0.9579


$Ageonset_greater_12wk$`Immune system disorders`
$Ageonset_greater_12wk$`Immune system disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               17.7                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          17.7                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Immune system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.900e+05 4.748e+04 0.000e+00       Inf 9.998e-01


$Ageonset_greater_12wk$`Infections and infestations`
$Ageonset_greater_12wk$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              6.0                2.0
n_event_pct                         67.0               25.0
time-to-event-wk-10th                1.4                3.0
time-to-event-wk-25th                4.4               17.1
time-to-event-wk-50th               26.1                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           1.4                3.0
time-to-event-wk-50th-hici            NA                 NA
```

```
$Ageonset_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48310   0.85250   0.09085   2.56900   0.39340


$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`
$Ageonset_greater_12wk$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               2.0                  0
n_event_pct                          22.0                  0
time-to-event-wk-10th                 8.7                 NA
time-to-event-wk-25th                37.3                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.005e-10 3.095e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$`Metabolism and nutrition disorders`
$Ageonset_greater_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 6.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.345e-25 4.674e+04 0.000e+00       Inf 9.990e-01


$Ageonset_greater_12wk$`Musculoskeletal and connective tissue disorders`
$Ageonset_greater_12wk$`Musculoskeletal and connective tissue
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA               31.9
```

```
time-to-event-wk-25th                  NA               31.9
time-to-event-wk-50th                  NA               37.8
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               31.9
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.917e+13 5.755e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Nervous system disorders`
$Ageonset_greater_12wk$`Nervous system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                  8
n_event                                 1                  0
n_event_pct                            11                  0
time-to-event-wk-10th                  25                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             25                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.718e-22 4.401e+04 0.000e+00       Inf 9.991e-01


$Ageonset_greater_12wk$`Psychiatric disorders`
$Ageonset_greater_12wk$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA                2.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                2.3
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               6.0                  1
n_event_pct                          67.0                 12
time-to-event-wk-10th                 0.0                 12
time-to-event-wk-25th                 1.0                 NA
time-to-event-wk-50th                 3.6                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            0.0                 12
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13300   1.08600   0.01584   1.11600   0.06308


$Ageonset_greater_12wk$`Skin and subcutaneous tissue disorders`
$Ageonset_greater_12wk$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               3.0                  0
n_event_pct                          33.0                  0
time-to-event-wk-10th                 0.0                 NA
time-to-event-wk-25th                 7.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            0.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Skin and subcutaneous tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.851e-10 2.360e+04 0.000e+00       Inf 9.993e-01


$Ageonset_greater_12wk$`Vascular disorders`
$Ageonset_greater_12wk$`Vascular disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                30.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           30.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Vascular disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
1.187e-09 4.506e+04 0.000e+00       Inf 9.996e-01



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Cardiac disorders`
$Agetrt_greater_equal_180d$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               3.0                 2
n_event_pct                          12.0                 6
time-to-event-wk-10th                 5.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.51500   0.91710   0.08534   3.10800   0.46930


$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              13.0               19.0
n_event_pct                          52.0               61.0
time-to-event-wk-10th                 1.4                2.4
time-to-event-wk-25th                 8.1                5.0
time-to-event-wk-50th                39.7               20.6
time-to-event-wk-75th                  NA               40.9
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           11.7                6.0
time-to-event-wk-50th-hici           43.0               35.0

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3560    0.3656    0.6622    2.7750    0.4053


$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              13.0               16.0
n_event_pct                          52.0               52.0
time-to-event-wk-10th                 3.1                2.7
time-to-event-wk-25th                 5.7                9.7
time-to-event-wk-50th                40.0               36.3
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.7               12.7
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8226    0.3837    0.3877    1.7450    0.6107


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0              31.0
n_event                              15.0              13.0
n_event_pct                          60.0              42.0
time-to-event-wk-10th                 2.3               4.9
time-to-event-wk-25th                 8.7              10.0
time-to-event-wk-50th                22.6              45.7
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            8.7              11.4
time-to-event-wk-50th-hici           38.1                NA

$Agetrt_greater_equal_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6247    0.3862    0.2930    1.3320    0.2232


$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`
$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0              31.0
n_event                               6.0               6.0
n_event_pct                          24.0              19.0
time-to-event-wk-10th                 2.1               8.4
time-to-event-wk-25th                37.3              47.3
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           37.3                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6323    0.5958    0.1967    2.0330    0.4417


$Agetrt_greater_equal_180d$Investigations
$Agetrt_greater_equal_180d$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                25.0               31.0
n_event                               5.0                6.0
n_event_pct                          20.0               19.0
time-to-event-wk-10th                19.1                7.3
time-to-event-wk-25th                43.4               45.6
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.4               45.6
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7957    0.6157    0.2381    2.6600    0.7105


$Agetrt_greater_equal_180d$`Metabolism and nutrition disorders`
$Agetrt_greater_equal_180d$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               5.0                 1
n_event_pct                          20.0                 3
time-to-event-wk-10th                12.6                NA
time-to-event-wk-25th                56.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           56.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Metabolism and nutrition
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.16210   1.10900   0.01845   1.42400   0.10070


$Agetrt_greater_equal_180d$`Musculoskeletal and connective tissue disorders`
$Agetrt_greater_equal_180d$`Musculoskeletal and connective tissue
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               3.0                2.0
n_event_pct                          12.0                6.0
time-to-event-wk-10th                46.9               31.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
  0.53540   0.93190   0.08618   3.32600   0.50260


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0              31.0
n_event                              13.0              12.0
n_event_pct                          52.0              39.0
time-to-event-wk-10th                 0.4               0.6
time-to-event-wk-25th                 2.1               6.9
time-to-event-wk-50th                27.1                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            3.6               7.0
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6489    0.4019    0.2952    1.4270    0.2819


$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0              31.0
n_event                               8.0              10.0
n_event_pct                          32.0              32.0
time-to-event-wk-10th                 6.6               3.3
time-to-event-wk-25th                 8.1              20.1
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7              45.1
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9481    0.4768    0.3724    2.4140    0.9110



$Gender_Female
$Gender_Female$`Cardiac disorders`
$Gender_Female$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43
n_event                               3.0                 3
n_event_pct                          12.0                 7
time-to-event-wk-10th                 4.6                NA
time-to-event-wk-25th                  NA                NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5625    0.8347    0.1096    2.8880    0.4906


$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              15.0              28.0
n_event_pct                          62.0              65.0
time-to-event-wk-10th                 1.4               2.4
time-to-event-wk-25th                 5.0               5.0
time-to-event-wk-50th                16.9              15.3
time-to-event-wk-75th                39.7                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            7.7               7.1
time-to-event-wk-50th-hici           39.7              35.0

$Gender_Female$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9342    0.3314    0.4879    1.7890    0.8373


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              13.0              22.0
n_event_pct                          54.0              51.0
time-to-event-wk-10th                 3.1               3.0
time-to-event-wk-25th                 6.4              12.7
time-to-event-wk-50th                23.3              34.7
time-to-event-wk-75th                42.6                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.4              15.6
time-to-event-wk-50th-hici           42.6                NA

$Gender_Female$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7235    0.3550    0.3608    1.4510    0.3620


$Gender_Female$`Immune system disorders`
$Gender_Female$`Immune system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
```

```
n_event                              2.0               5.0
n_event_pct                          8.0              12.0
time-to-event-wk-10th               24.4              43.1
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$`Immune system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8865    0.8531    0.1665    4.7190    0.8877


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              12.0              26.0
n_event_pct                          50.0              60.0
time-to-event-wk-10th                 6.0               2.7
time-to-event-wk-25th                10.4               7.7
time-to-event-wk-50th                19.7              21.9
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           10.4              11.4
time-to-event-wk-50th-hici            NA                55.0

$Gender_Female$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0810    0.3564    0.5377    2.1740    0.8266


$Gender_Female$`Injury, poisoning and procedural complications`
$Gender_Female$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                               6.0               7.0
n_event_pct                          25.0              16.0
time-to-event-wk-10th                 4.6               8.4
time-to-event-wk-25th                37.3                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           37.3                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5172    0.5694    0.1694    1.5790    0.2470
```

```
$Gender_Female$Investigations
$Gender_Female$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                              7.0                9.0
n_event_pct                         29.0               21.0
time-to-event-wk-10th                2.3               19.3
time-to-event-wk-25th               19.1               52.0
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          19.1               52.0
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6001    0.5167    0.2180    1.6520    0.3230


$Gender_Female$`Metabolism and nutrition disorders`
$Gender_Female$`Metabolism and nutrition disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                              5.0                7.0
n_event_pct                         21.0               16.0
time-to-event-wk-10th               12.6               10.7
time-to-event-wk-25th               28.4                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          28.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5867    0.6008    0.1807    1.9050    0.3748


$Gender_Female$`Musculoskeletal and connective tissue disorders`
$Gender_Female$`Musculoskeletal and connective tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0                 43
n_event                              2.0                  7
n_event_pct                          8.0                 16
time-to-event-wk-10th               46.9                 12
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          46.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7140    0.8133    0.3481    8.4380    0.5077


$Gender_Female$`Psychiatric disorders`
$Gender_Female$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               2.0                5.0
n_event_pct                           8.0               12.0
time-to-event-wk-10th                13.9                8.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2950    0.8559    0.2419    6.9280    0.7630


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              16.0               23.0
n_event_pct                          67.0               53.0
time-to-event-wk-10th                 0.4                1.0
time-to-event-wk-25th                 1.4                4.3
time-to-event-wk-50th                 6.4               30.7
time-to-event-wk-75th                43.3                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.6               12.0
time-to-event-wk-50th-hici           43.3                 NA

$Gender_Female$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.51750   0.33820   0.26670   1.00400   0.05142


$Gender_Female$`Skin and subcutaneous tissue disorders`
$Gender_Female$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               6.0               11.0
n_event_pct                          25.0               26.0
time-to-event-wk-10th                 7.6                5.6
time-to-event-wk-25th                53.6               40.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci           53.6               49.9
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9602    0.5238    0.3439    2.6810    0.9382



$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0               38.0
n_event                              6.0                7.0
n_event_pct                         27.0               18.0
time-to-event-wk-10th                4.6                9.3
time-to-event-wk-25th               40.7                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          40.7                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5802    0.5615    0.1930    1.7440    0.3322


$Region_Northamerica$`Congenital, familial and genetic disorders`
$Region_Northamerica$`Congenital, familial and genetic disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                 38
n_event                              4.0                  1
n_event_pct                         18.0                  3
time-to-event-wk-10th               14.0                 NA
time-to-event-wk-25th               49.4                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          49.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$`Congenital, familial and genetic
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13770   1.13000   0.01504   1.26000   0.07916


$Region_Northamerica$`Eye disorders`
$Region_Northamerica$`Eye disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22               38.0
n_event                              1                4.0
```

```
n_event_pct                              5               11.0
time-to-event-wk-10th                   NA               27.1
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Region_Northamerica$`Eye disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0470    1.1220    0.2271   18.4500    0.5231


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              15.0               25.0
n_event_pct                          68.0               66.0
time-to-event-wk-10th                 1.4                2.1
time-to-event-wk-25th                 7.7                5.0
time-to-event-wk-50th                11.7               12.7
time-to-event-wk-75th                31.9                 NA
time-to-event-wk-90th                36.4                 NA
time-to-event-wk-50th-loci            7.7                6.6
time-to-event-wk-50th-hici           31.9               20.9

$Region_Northamerica$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8860    0.3288    0.4651    1.6880    0.7129


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              12.0               20.0
n_event_pct                          55.0               53.0
time-to-event-wk-10th                 3.1                3.4
time-to-event-wk-25th                 9.4               13.4
time-to-event-wk-50th                20.6               36.0
time-to-event-wk-75th                42.6                 NA
time-to-event-wk-90th                43.4                 NA
time-to-event-wk-50th-loci            9.4               20.7
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49430   0.39360   0.22850   1.06900   0.07338
```

```
$Region_Northamerica$`Immune system disorders`
$Region_Northamerica$`Immune system disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                              4.0               4.0
n_event_pct                         18.0              11.0
time-to-event-wk-10th               17.7              31.7
time-to-event-wk-25th               41.0                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          24.4                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Immune system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5300    0.7213    0.1289    2.1790    0.3787


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                             16.0              21.0
n_event_pct                         73.0              55.0
time-to-event-wk-10th                4.4               5.6
time-to-event-wk-25th                7.4              11.4
time-to-event-wk-50th               13.7              27.4
time-to-event-wk-75th               24.0                NA
time-to-event-wk-90th               38.1                NA
time-to-event-wk-50th-loci           7.4              17.1
time-to-event-wk-50th-hici          24.0              55.0

$Region_Northamerica$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48600   0.33600   0.25150   0.93890   0.03174


$Region_Northamerica$`Injury, poisoning and procedural complications`
$Region_Northamerica$`Injury, poisoning and procedural complications`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                              7.0              10.0
n_event_pct                         32.0              26.0
time-to-event-wk-10th                4.6               4.0
time-to-event-wk-25th               26.4              42.1
time-to-event-wk-50th               37.3                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          26.4              43.4
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5998    0.5014    0.2245    1.6020    0.3080


$Region_Northamerica$Investigations
$Region_Northamerica$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               7.0                9.0
n_event_pct                          32.0               24.0
time-to-event-wk-10th                 6.3                7.3
time-to-event-wk-25th                19.1               45.6
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.1               52.0
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5881    0.5084    0.2171    1.5930    0.2964


$Region_Northamerica$`Metabolism and nutrition disorders`
$Region_Northamerica$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               4.0                5.0
n_event_pct                          18.0               13.0
time-to-event-wk-10th                12.6               20.1
time-to-event-wk-25th                56.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           56.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6924    0.6730    0.1851    2.5900    0.5850


$Region_Northamerica$`Musculoskeletal and connective tissue disorders`
$Region_Northamerica$`Musculoskeletal and connective tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               5.0                8.0
n_event_pct                          23.0               21.0
time-to-event-wk-10th                26.1                9.1
time-to-event-wk-25th                46.9               54.4
time-to-event-wk-50th                56.4                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           46.9               54.4
```

```
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9567    0.5810    0.3064    2.9870    0.9392


$Region_Northamerica$`Nervous system disorders`
$Region_Northamerica$`Nervous system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22               38.0
n_event                                 1                4.0
n_event_pct                             5               11.0
time-to-event-wk-10th                  NA               49.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0110    1.1210    0.2237   18.0800    0.5329


$Region_Northamerica$`Psychiatric disorders`
$Region_Northamerica$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               2.0                6.0
n_event_pct                           9.0               16.0
time-to-event-wk-10th                13.9                7.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.8040    0.8185    0.3627    8.9720    0.4711


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              16.0               22.0
n_event_pct                          73.0               58.0
time-to-event-wk-10th                 0.9                1.0
time-to-event-wk-25th                 1.6                6.9
```

```
time-to-event-wk-50th                 7.9               21.1
time-to-event-wk-75th                27.1                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.6                8.9
time-to-event-wk-50th-hici           27.1               32.6

$Region_Northamerica$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5830    0.3310    0.3047    1.1150    0.1031


$Region_Northamerica$`Skin and subcutaneous tissue disorders`
$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              12.0               18.0
n_event_pct                          55.0               47.0
time-to-event-wk-10th                 4.0                2.0
time-to-event-wk-25th                 6.6                9.1
time-to-event-wk-50th                20.9               40.4
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.6               16.1
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7893    0.3748    0.3786    1.6450    0.5278



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               4.0                7.0
n_event_pct                          17.0               15.0
time-to-event-wk-10th                 4.6               15.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6927    0.6294    0.2017    2.3790    0.5597


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_num
```

```
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              12.0               27.0
n_event_pct                          52.0               59.0
time-to-event-wk-10th                 5.0                2.4
time-to-event-wk-25th                11.7                6.3
time-to-event-wk-50th                31.9               15.3
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           11.7                9.0
time-to-event-wk-50th-hici           40.3               40.9

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1120    0.3493    0.5607    2.2050    0.7615


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              12.0               23.0
n_event_pct                          52.0               50.0
time-to-event-wk-10th                 3.1                3.0
time-to-event-wk-25th                 7.9               12.7
time-to-event-wk-50th                18.0               37.6
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.9               20.7
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7236    0.3587    0.3582    1.4620    0.3671


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              13.0               30.0
n_event_pct                          57.0               65.0
time-to-event-wk-10th                 6.0                3.6
time-to-event-wk-25th                 8.7                7.1
time-to-event-wk-50th                22.6               21.1
time-to-event-wk-75th                38.1               45.7
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.4               10.0
time-to-event-wk-50th-hici           38.1               27.4

$Disdur_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   1.1490    0.3336    0.5975    2.2090    0.6772


$Disdur_greater_12wk$`Injury, poisoning and procedural complications`
$Disdur_greater_12wk$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               4.0               9.0
n_event_pct                          17.0              20.0
time-to-event-wk-10th                 2.1              11.4
time-to-event-wk-25th                  NA              47.3
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9155    0.6064    0.2789    3.0050    0.8843


$Disdur_greater_12wk$Investigations
$Disdur_greater_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               6.0              13.0
n_event_pct                          26.0              28.0
time-to-event-wk-10th                 9.1               5.4
time-to-event-wk-25th                37.4              33.6
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           37.4              45.6
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9733    0.4947    0.3691    2.5670    0.9564


$Disdur_greater_12wk$`Metabolism and nutrition disorders`
$Disdur_greater_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               5.0                 4
n_event_pct                          22.0                 9
time-to-event-wk-10th                 8.9                NA
time-to-event-wk-25th                56.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           28.4                NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33030   0.67620   0.08777   1.24300   0.10140


$Disdur_greater_12wk$`Musculoskeletal and connective tissue disorders`
$Disdur_greater_12wk$`Musculoskeletal and connective tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               3.0                 3
n_event_pct                          13.0                 7
time-to-event-wk-10th                46.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           46.9                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42830   0.81850   0.08611   2.13000   0.30020


$Disdur_greater_12wk$`Psychiatric disorders`
$Disdur_greater_12wk$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 1                5.0
n_event_pct                             4               11.0
time-to-event-wk-10th                  NA               29.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3370    1.0980    0.2715   20.1200    0.4395


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              13.0               20.0
n_event_pct                          57.0               43.0
time-to-event-wk-10th                 1.1                1.0
time-to-event-wk-25th                 4.1                7.0
```

```
time-to-event-wk-50th                11.9               33.0
time-to-event-wk-75th                37.4                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            4.1               16.7
time-to-event-wk-50th-hici           37.4                 NA

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.50720   0.37280   0.24430   1.05300   0.06862


$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`
$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               6.0               15.0
n_event_pct                          26.0               33.0
time-to-event-wk-10th                 6.6                2.1
time-to-event-wk-25th                40.7               20.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7               45.1
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2250    0.4870    0.4716    3.1820    0.6770



$Region_Asia_Pacific
$Region_Asia_Pacific$`Eye disorders`
$Region_Asia_Pacific$`Eye disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0                 12
n_event                               1.0                  0
n_event_pct                          50.0                  0
time-to-event-wk-10th                29.3                 NA
time-to-event-wk-25th                29.3                 NA
time-to-event-wk-50th                29.3                 NA
time-to-event-wk-75th                29.3                 NA
time-to-event-wk-90th                29.3                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`Eye disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.873e-12 2.762e+05 0.000e+00       Inf 9.999e-01


$Region_Asia_Pacific$`Gastrointestinal disorders`
$Region_Asia_Pacific$`Gastrointestinal disorders`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2                12.0
n_event                                 1                 6.0
n_event_pct                            50                50.0
time-to-event-wk-10th                  43                 4.4
time-to-event-wk-25th                  43                11.6
time-to-event-wk-50th                  43                35.0
time-to-event-wk-75th                  43                  NA
time-to-event-wk-90th                  43                  NA
time-to-event-wk-50th-loci             NA                 4.4
time-to-event-wk-50th-hici             NA                  NA

$Region_Asia_Pacific$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6860    1.1800    0.1669   17.0300    0.6580


$Region_Asia_Pacific$`General disorders and administration site conditions`
$Region_Asia_Pacific$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0                12.0
n_event                               1.0                 3.0
n_event_pct                          50.0                25.0
time-to-event-wk-10th                 5.7                 9.6
time-to-event-wk-25th                 5.7                38.0
time-to-event-wk-50th                 5.7                  NA
time-to-event-wk-75th                 5.7                  NA
time-to-event-wk-90th                 5.7                  NA
time-to-event-wk-50th-loci             NA                 9.6
time-to-event-wk-50th-hici             NA                  NA

$Region_Asia_Pacific$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.066160  1.492000  0.003557  1.231000  0.068650


$Region_Asia_Pacific$`Infections and infestations`
$Region_Asia_Pacific$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2                12.0
n_event                                 0                 6.0
n_event_pct                             0                50.0
time-to-event-wk-10th                  NA                 2.7
time-to-event-wk-25th                  NA                 8.7
time-to-event-wk-50th                  NA                21.7
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                 2.7
time-to-event-wk-50th-hici             NA                  NA

$Region_Asia_Pacific$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
2.343e+08 1.630e+04 0.000e+00       Inf 9.991e-01


$Region_Asia_Pacific$`Injury, poisoning and procedural complications`
$Region_Asia_Pacific$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0                12
n_event                               1.0                 0
n_event_pct                          50.0                 0
time-to-event-wk-10th                 8.7                NA
time-to-event-wk-25th                 8.7                NA
time-to-event-wk-50th                 8.7                NA
time-to-event-wk-75th                 8.7                NA
time-to-event-wk-90th                 8.7                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Asia_Pacific$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.266e-14 2.565e+06 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$`Nervous system disorders`
$Region_Asia_Pacific$`Nervous system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  2                12
n_event                                1                 0
n_event_pct                           50                 0
time-to-event-wk-10th                 25                NA
time-to-event-wk-25th                 25                NA
time-to-event-wk-50th                 25                NA
time-to-event-wk-75th                 25                NA
time-to-event-wk-90th                 25                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.442e-14 1.625e+06 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`
$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  2              12.0
n_event                                0               3.0
n_event_pct                            0              25.0
time-to-event-wk-10th                 NA              30.7
time-to-event-wk-25th                 NA              33.0
time-to-event-wk-50th                 NA              43.1
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA              30.7
```

```
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.373e+09 3.138e+04 0.000e+00       Inf 9.994e-01


$Region_Asia_Pacific$`Skin and subcutaneous tissue disorders`
$Region_Asia_Pacific$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0              12.0
n_event                               1.0               2.0
n_event_pct                          50.0              17.0
time-to-event-wk-10th                 7.6              22.9
time-to-event-wk-25th                 7.6                NA
time-to-event-wk-50th                 7.6                NA
time-to-event-wk-75th                 7.6                NA
time-to-event-wk-90th                 7.6                NA
time-to-event-wk-50th-loci             NA              22.9
time-to-event-wk-50th-hici             NA                NA

$Region_Asia_Pacific$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.054e-10 2.848e+04 0.000e+00       Inf 9.994e-01



$Region_Europe
$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               7.0              14.0
n_event_pct                          41.0              47.0
time-to-event-wk-10th                 2.7               0.4
time-to-event-wk-25th                15.9               6.3
time-to-event-wk-50th                40.3              40.9
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            5.0               8.4
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0480    0.4752    0.4130    2.6600    0.9212


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               9.0              14.0
n_event_pct                          53.0              47.0
```

```
time-to-event-wk-10th                2.0               2.6
time-to-event-wk-25th                6.4               8.1
time-to-event-wk-50th               23.3              36.3
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           5.1               9.7
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6707    0.4450    0.2804    1.6050    0.3695


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              30.0
n_event                              8.0              20.0
n_event_pct                         47.0              67.0
time-to-event-wk-10th                3.0               1.9
time-to-event-wk-25th                6.0               4.9
time-to-event-wk-50th               22.6              13.3
time-to-event-wk-75th                 NA              45.7
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           6.0               6.1
time-to-event-wk-50th-hici            NA              45.7

$Region_Europe$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4270    0.4261    0.6190    3.2890    0.4041


$Region_Europe$`Injury, poisoning and procedural complications`
$Region_Europe$`Injury, poisoning and procedural complications`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              30.0
n_event                              2.0               3.0
n_event_pct                         12.0              10.0
time-to-event-wk-10th               16.3              47.3
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6665    0.9237    0.1090    4.0740    0.6605


$Region_Europe$Investigations
```

```
$Region_Europe$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               4.0               10.0
n_event_pct                          24.0               33.0
time-to-event-wk-10th                 2.3                5.2
time-to-event-wk-25th                37.4               19.3
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.4               26.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3260    0.6028    0.4069    4.3230    0.6395


$Region_Europe$`Metabolism and nutrition disorders`
$Region_Europe$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               3.0                4.0
n_event_pct                          18.0               13.0
time-to-event-wk-10th                 8.9               10.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           14.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6271    0.7712    0.1383    2.8430    0.5451


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               7.0               14.0
n_event_pct                          41.0               47.0
time-to-event-wk-10th                 3.1                1.4
time-to-event-wk-25th                 5.9                4.3
time-to-event-wk-50th                43.3               29.7
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.9               12.0
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.8992    0.4723    0.3563    2.2690    0.8220



\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines milden UEs nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              17.0              41.0
n_event_pct                          53.0              57.0
time-to-event-wk-10th                 4.4               2.4
time-to-event-wk-25th                10.6               6.3
time-to-event-wk-50th                16.9              20.6
time-to-event-wk-75th                40.3                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           10.9              12.6
time-to-event-wk-50th-hici           36.4              40.9

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8737    0.2938    0.4912    1.5540    0.6457


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              18.0              34.0
n_event_pct                          56.0              47.0
time-to-event-wk-10th                 3.1               3.1
time-to-event-wk-25th                 7.7              13.4
time-to-event-wk-50th                18.0              38.0
time-to-event-wk-75th                40.0                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            7.9              30.6
time-to-event-wk-50th-hici           40.0                NA

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49240   0.30140   0.27270   0.88910   0.01877


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                32.0              72.0
n_event                              18.0              45.0
n_event_pct                          56.0              62.0
time-to-event-wk-10th                 6.0               3.6
time-to-event-wk-25th                 8.3               7.7
time-to-event-wk-50th                19.7              25.6
time-to-event-wk-75th                32.6              55.0
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            8.7              11.4
time-to-event-wk-50th-hici           24.0              35.0

$Ageonset_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8316    0.2838    0.4768    1.4500    0.5159


$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`
$Ageonset_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               8.0              13.0
n_event_pct                          25.0              18.0
time-to-event-wk-10th                 4.6              11.4
time-to-event-wk-25th                26.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           26.4                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4756    0.4616    0.1925    1.1750    0.1074


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              11.0              19.0
n_event_pct                          34.0              26.0
time-to-event-wk-10th                 2.3               5.4
time-to-event-wk-25th                19.1              36.9
time-to-event-wk-50th                43.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           19.1              52.0
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5365    0.3873    0.2511    1.1460    0.1079
```

```
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0                72
n_event                              6.0                10
n_event_pct                         19.0                14
time-to-event-wk-10th               12.6                14
time-to-event-wk-25th               56.6                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          28.4                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Metabolism and nutrition
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5615    0.5196    0.2028    1.5550    0.2667


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                             17.0               38.0
n_event_pct                         53.0               53.0
time-to-event-wk-10th                1.6                1.7
time-to-event-wk-25th                6.0                6.9
time-to-event-wk-50th               26.4               30.7
time-to-event-wk-75th               43.3                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           6.4               21.3
time-to-event-wk-50th-hici          43.3               43.1

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7332    0.2959    0.4105    1.3100    0.2943


$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`
$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                             11.0               22.0
n_event_pct                         34.0               31.0
time-to-event-wk-10th                4.3                4.4
time-to-event-wk-25th               19.0               26.0
time-to-event-wk-50th               53.6                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
```

```
time-to-event-wk-50th-loci           19.0               49.9
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Skin and subcutaneous tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6923    0.3753    0.3318    1.4450    0.3271



$Agetrt_less_180d
$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                              10.0               26.0
n_event_pct                          62.0               53.0
time-to-event-wk-10th                 2.7                0.3
time-to-event-wk-25th                 5.1                6.6
time-to-event-wk-50th                10.9               18.9
time-to-event-wk-75th                36.4                 NA
time-to-event-wk-90th                36.4                 NA
time-to-event-wk-50th-loci            5.1                9.6
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6529    0.3780    0.3112    1.3700    0.2594


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               9.0               21.0
n_event_pct                          56.0               43.0
time-to-event-wk-10th                 0.4                5.4
time-to-event-wk-25th                 6.4               15.6
time-to-event-wk-50th                20.6               38.0
time-to-event-wk-75th                23.3                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.4               30.6
time-to-event-wk-50th-hici           23.3                 NA

$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.34270   0.42500   0.14900   0.78830   0.01174


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                16.0              49.0
n_event                               9.0              34.0
n_event_pct                          56.0              69.0
time-to-event-wk-10th                 6.0               2.7
time-to-event-wk-25th                 7.4               7.7
time-to-event-wk-50th                14.1              21.1
time-to-event-wk-75th                32.6              49.0
time-to-event-wk-90th                32.6                NA
time-to-event-wk-50th-loci            7.3               9.9
time-to-event-wk-50th-hici             NA              32.1

$Agetrt_less_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7561    0.3866    0.3544    1.6130    0.4697


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               6.0              13.0
n_event_pct                          38.0              27.0
time-to-event-wk-10th                 1.0               5.4
time-to-event-wk-25th                 6.3              33.6
time-to-event-wk-50th                27.4                NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            6.3              52.0
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4467    0.5074    0.1652    1.2070    0.1122


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                              10.0              27.0
n_event_pct                          62.0              55.0
time-to-event-wk-10th                 3.1               2.1
time-to-event-wk-25th                 5.9               9.3
time-to-event-wk-50th                10.1              32.1
time-to-event-wk-75th                43.3                NA
time-to-event-wk-90th                43.3                NA
time-to-event-wk-50th-loci            5.1              21.3
time-to-event-wk-50th-hici             NA              43.1

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5878    0.3769    0.2808    1.2300    0.1586
```

```
$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              6.0              12.0
n_event_pct                         38.0              24.0
time-to-event-wk-10th                0.1               5.6
time-to-event-wk-25th                5.9              33.9
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           5.9                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4875    0.5102    0.1794    1.3250    0.1591



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                             13.0              19.0
n_event_pct                         52.0              61.0
time-to-event-wk-10th                1.4               2.4
time-to-event-wk-25th                8.1               5.0
time-to-event-wk-50th               39.7              20.6
time-to-event-wk-75th                 NA              40.9
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          11.7               6.0
time-to-event-wk-50th-hici          43.0              35.0

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3560    0.3656    0.6622    2.7750    0.4053


$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                             13.0              16.0
n_event_pct                         52.0              52.0
time-to-event-wk-10th                3.1               2.7
time-to-event-wk-25th                5.7               9.7
time-to-event-wk-50th               40.0              36.3
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
```

```
time-to-event-wk-50th-loci            7.7               12.7
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8226    0.3837    0.3877    1.7450    0.6107


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                             15.0              13.0
n_event_pct                         60.0              42.0
time-to-event-wk-10th                2.3               4.9
time-to-event-wk-25th                8.7              10.0
time-to-event-wk-50th               22.6              45.7
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           8.7              11.4
time-to-event-wk-50th-hici          38.1                NA

$Agetrt_greater_equal_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6247    0.3862    0.2930    1.3320    0.2232


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                             13.0              12.0
n_event_pct                         52.0              39.0
time-to-event-wk-10th                0.4               0.6
time-to-event-wk-25th                2.1               6.9
time-to-event-wk-50th               27.1                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           3.6               7.0
time-to-event-wk-50th-hici            NA                NA

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6489    0.4019    0.2952    1.4270    0.2819


$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`
$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                              8.0              10.0
```

```
n_event_pct                          32.0              32.0
time-to-event-wk-10th                 6.6               3.3
time-to-event-wk-25th                 8.1              20.1
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7              45.1
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Skin and subcutaneous tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9481    0.4768    0.3724    2.4140    0.9110



$Gender_Male
$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               8.0              17.0
n_event_pct                          47.0              46.0
time-to-event-wk-10th                 5.1               0.3
time-to-event-wk-25th                10.6               6.3
time-to-event-wk-50th                22.6              27.9
time-to-event-wk-75th                40.3                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           10.6               9.0
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9689    0.4333    0.4144    2.2650    0.9419


$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               9.0              15.0
n_event_pct                          53.0              41.0
time-to-event-wk-10th                 0.4               3.4
time-to-event-wk-25th                 7.7              23.6
time-to-event-wk-50th                20.6              46.7
time-to-event-wk-75th                43.4                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            5.1              30.6
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47880   0.42890   0.20660   1.11000   0.08595
```

```
$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              37.0
n_event                             12.0              21.0
n_event_pct                         71.0              57.0
time-to-event-wk-10th                2.3               3.6
time-to-event-wk-25th                7.4               8.1
time-to-event-wk-50th                9.4              26.4
time-to-event-wk-75th               24.0              49.0
time-to-event-wk-90th               32.6                NA
time-to-event-wk-50th-loci           5.3              10.0
time-to-event-wk-50th-hici          24.0              45.7

$Gender_Male$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6085    0.3676    0.2960    1.2510    0.1767


$Gender_Male$Investigations
$Gender_Male$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              37.0
n_event                              4.0              10.0
n_event_pct                         24.0              27.0
time-to-event-wk-10th               10.1               5.0
time-to-event-wk-25th               27.4              33.6
time-to-event-wk-50th               43.4                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          27.4              36.9
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0760    0.5969    0.3341    3.4670    0.9021


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              37.0
n_event                              7.0              16.0
n_event_pct                         41.0              43.0
time-to-event-wk-10th                3.6               2.7
time-to-event-wk-25th                7.9              11.6
time-to-event-wk-50th               37.4              38.9
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           7.9              22.0
time-to-event-wk-50th-hici            NA                NA
```

```
$Gender_Male$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9197    0.4559    0.3764    2.2480    0.8544


$Gender_Male$`Skin and subcutaneous tissue disorders`
$Gender_Male$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               8.0              11.0
n_event_pct                          47.0              30.0
time-to-event-wk-10th                 0.0               2.1
time-to-event-wk-25th                 5.9              16.1
time-to-event-wk-50th                40.7                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            4.3              26.0
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4995    0.4733    0.1975    1.2630    0.1425



$Gender_Female
$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              15.0              28.0
n_event_pct                          62.0              65.0
time-to-event-wk-10th                 1.4               2.4
time-to-event-wk-25th                 5.0               5.0
time-to-event-wk-50th                16.9              15.3
time-to-event-wk-75th                39.7                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            7.7               7.1
time-to-event-wk-50th-hici           39.7              35.0

$Gender_Female$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9342    0.3314    0.4879    1.7890    0.8373


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              13.0              22.0
n_event_pct                          54.0              51.0
time-to-event-wk-10th                 3.1               3.0
time-to-event-wk-25th                 6.4              12.7
```

```
time-to-event-wk-50th                23.3               34.7
time-to-event-wk-75th                42.6                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.4               15.6
time-to-event-wk-50th-hici           42.6                 NA

$Gender_Female$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7235    0.3550    0.3608    1.4510    0.3620


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              12.0               26.0
n_event_pct                          50.0               60.0
time-to-event-wk-10th                 6.0                2.7
time-to-event-wk-25th                10.4                7.7
time-to-event-wk-50th                19.7               21.9
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           10.4               11.4
time-to-event-wk-50th-hici             NA               55.0

$Gender_Female$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0810    0.3564    0.5377    2.1740    0.8266


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              16.0               23.0
n_event_pct                          67.0               53.0
time-to-event-wk-10th                 0.4                1.0
time-to-event-wk-25th                 1.4                4.3
time-to-event-wk-50th                 6.4               30.7
time-to-event-wk-75th                43.3                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.6               12.0
time-to-event-wk-50th-hici           43.3                 NA

$Gender_Female$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.51750   0.33820   0.26670   1.00400   0.05142


$Gender_Female$`Skin and subcutaneous tissue disorders`
$Gender_Female$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                24.0              43.0
n_event                               6.0              11.0
n_event_pct                          25.0              26.0
time-to-event-wk-10th                 7.6               5.6
time-to-event-wk-25th                53.6              40.4
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           53.6              49.9
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9602    0.5238    0.3439    2.6810    0.9382



$Region_Europe
$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               7.0              14.0
n_event_pct                          41.0              47.0
time-to-event-wk-10th                 2.7               0.4
time-to-event-wk-25th                15.9               6.3
time-to-event-wk-50th                40.3              40.9
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            5.0               8.4
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0480    0.4752    0.4130    2.6600    0.9212


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               9.0              14.0
n_event_pct                          53.0              47.0
time-to-event-wk-10th                 2.0               2.6
time-to-event-wk-25th                 6.4               8.1
time-to-event-wk-50th                23.3              36.3
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            5.1               9.7
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.6707    0.4450    0.2804    1.6050    0.3695


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               8.0              20.0
n_event_pct                          47.0              67.0
time-to-event-wk-10th                 3.0               1.9
time-to-event-wk-25th                 6.0               4.9
time-to-event-wk-50th                22.6              13.3
time-to-event-wk-75th                  NA              45.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.0               6.1
time-to-event-wk-50th-hici             NA              45.7

$Region_Europe$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4270    0.4261    0.6190    3.2890    0.4041


$Region_Europe$Investigations
$Region_Europe$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               4.0              10.0
n_event_pct                          24.0              33.0
time-to-event-wk-10th                 2.3               5.2
time-to-event-wk-25th                37.4              19.3
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           37.4              26.4
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3260    0.6028    0.4069    4.3230    0.6395


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               7.0              14.0
n_event_pct                          41.0              47.0
time-to-event-wk-10th                 3.1               1.4
time-to-event-wk-25th                 5.9               4.3
time-to-event-wk-50th                43.3              29.7
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            5.9              12.0
time-to-event-wk-50th-hici             NA                NA
```

```
$Region_Europe$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8992    0.4723    0.3563    2.2690    0.8220



$Region_Northamerica
$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                             15.0              25.0
n_event_pct                         68.0              66.0
time-to-event-wk-10th                1.4               2.1
time-to-event-wk-25th                7.7               5.0
time-to-event-wk-50th               11.7              12.7
time-to-event-wk-75th               31.9                NA
time-to-event-wk-90th               36.4                NA
time-to-event-wk-50th-loci           7.7               6.6
time-to-event-wk-50th-hici          31.9              20.9

$Region_Northamerica$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8860    0.3288    0.4651    1.6880    0.7129


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                             12.0              20.0
n_event_pct                         55.0              53.0
time-to-event-wk-10th                3.1               3.4
time-to-event-wk-25th                9.4              13.4
time-to-event-wk-50th               20.6              36.0
time-to-event-wk-75th               42.6                NA
time-to-event-wk-90th               43.4                NA
time-to-event-wk-50th-loci           9.4              20.7
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49430   0.39360   0.22850   1.06900   0.07338


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                             16.0              21.0
```

```
n_event_pct                          73.0              55.0
time-to-event-wk-10th                 4.4               5.6
time-to-event-wk-25th                 7.4              11.4
time-to-event-wk-50th                13.7              27.4
time-to-event-wk-75th                24.0                NA
time-to-event-wk-90th                38.1                NA
time-to-event-wk-50th-loci            7.4              17.1
time-to-event-wk-50th-hici           24.0              55.0

$Region_Northamerica$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48600   0.33600   0.25150   0.93890   0.03174


$Region_Northamerica$`Injury, poisoning and procedural complications`
$Region_Northamerica$`Injury, poisoning and procedural complications`$stats_num
                         TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               7.0              10.0
n_event_pct                          32.0              26.0
time-to-event-wk-10th                 4.6               4.0
time-to-event-wk-25th                26.4              42.1
time-to-event-wk-50th                37.3                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           26.4              43.4
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5998    0.5014    0.2245    1.6020    0.3080


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats_num
                         TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              16.0              22.0
n_event_pct                          73.0              58.0
time-to-event-wk-10th                 0.9               1.0
time-to-event-wk-25th                 1.6               6.9
time-to-event-wk-50th                 7.9              21.1
time-to-event-wk-75th                27.1                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            1.6               8.9
time-to-event-wk-50th-hici           27.1              32.6

$Region_Northamerica$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5830    0.3310    0.3047    1.1150    0.1031
```

```
$Region_Northamerica$`Skin and subcutaneous tissue disorders`
$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              12.0              18.0
n_event_pct                          55.0              47.0
time-to-event-wk-10th                 4.0               2.0
time-to-event-wk-25th                 6.6               9.1
time-to-event-wk-50th                20.9              40.4
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.6              16.1
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7893    0.3748    0.3786    1.6450    0.5278



$Disdur_greater_12wk
$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                              12.0              27.0
n_event_pct                          52.0              59.0
time-to-event-wk-10th                 5.0               2.4
time-to-event-wk-25th                11.7               6.3
time-to-event-wk-50th                31.9              15.3
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           11.7               9.0
time-to-event-wk-50th-hici           40.3              40.9

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1120    0.3493    0.5607    2.2050    0.7615


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                              12.0              23.0
n_event_pct                          52.0              50.0
time-to-event-wk-10th                 3.1               3.0
time-to-event-wk-25th                 7.9              12.7
time-to-event-wk-50th                18.0              37.6
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            7.9              20.7
time-to-event-wk-50th-hici             NA                NA
```

```
$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7236    0.3587    0.3582    1.4620    0.3671


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                              13.0              30.0
n_event_pct                          57.0              65.0
time-to-event-wk-10th                 6.0               3.6
time-to-event-wk-25th                 8.7               7.1
time-to-event-wk-50th                22.6              21.1
time-to-event-wk-75th                38.1              45.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            7.4              10.0
time-to-event-wk-50th-hici           38.1              27.4

$Disdur_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1490    0.3336    0.5975    2.2090    0.6772


$Disdur_greater_12wk$Investigations
$Disdur_greater_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               6.0              13.0
n_event_pct                          26.0              28.0
time-to-event-wk-10th                 9.1               5.4
time-to-event-wk-25th                37.4              33.6
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           37.4              45.6
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9733    0.4947    0.3691    2.5670    0.9564


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                              13.0              20.0
n_event_pct                          57.0              43.0
time-to-event-wk-10th                 1.1               1.0
time-to-event-wk-25th                 4.1               7.0
time-to-event-wk-50th                11.9              33.0
```

```
time-to-event-wk-75th                37.4                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            4.1               16.7
time-to-event-wk-50th-hici           37.4                 NA

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.50720   0.37280   0.24430   1.05300   0.06862


$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`
$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               6.0              15.0
n_event_pct                          26.0              33.0
time-to-event-wk-10th                 6.6               2.1
time-to-event-wk-25th                40.7              20.1
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7              45.1
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2250    0.4870    0.4716    3.1820    0.6770



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                              11.0              18.0
n_event_pct                          61.0              53.0
time-to-event-wk-10th                 1.0               0.3
time-to-event-wk-25th                 5.1               4.4
time-to-event-wk-50th                22.6              24.1
time-to-event-wk-75th                36.4                NA
time-to-event-wk-90th                43.0                NA
time-to-event-wk-50th-loci            5.1               7.1
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7678    0.3908    0.3569    1.6520    0.4989


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
```

```
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0              34.0
n_event                             10.0              14.0
n_event_pct                         56.0              41.0
time-to-event-wk-10th                0.4               3.1
time-to-event-wk-25th                5.7              15.6
time-to-event-wk-50th               22.7              46.7
time-to-event-wk-75th               42.6                NA
time-to-event-wk-90th               42.6                NA
time-to-event-wk-50th-loci           5.7              24.3
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5032    0.4317    0.2159    1.1730    0.1116


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0              34.0
n_event                             11.0              17.0
n_event_pct                         61.0              50.0
time-to-event-wk-10th                2.3               3.0
time-to-event-wk-25th                7.3               9.3
time-to-event-wk-50th               14.1              35.0
time-to-event-wk-75th               32.6                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           7.3              10.0
time-to-event-wk-50th-hici          32.6                NA

$Disdur_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5953    0.4074    0.2679    1.3230    0.2030


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0              34.0
n_event                             10.0              19.0
n_event_pct                         56.0              56.0
time-to-event-wk-10th                0.9               3.3
time-to-event-wk-25th                3.6               9.3
time-to-event-wk-50th               26.4              26.6
time-to-event-wk-75th               43.3                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           3.6              18.7
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
```

```
      HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.7749    0.4013    0.3529    1.7010    0.5250



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem milden UE nach PT, das bei mindestens 10%
der Patienten in einem Studienarm auftrat"

$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Abdominal pain upper`
$Ageonset_greater_12wk$`Abdominal pain upper`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Abdominal pain upper`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Amblyopia
$Ageonset_greater_12wk$Amblyopia$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Amblyopia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Atelectasis
$Ageonset_greater_12wk$Atelectasis$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Atelectasis$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444
```

```
$Ageonset_greater_12wk$Bradycardia
$Ageonset_greater_12wk$Bradycardia$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Bradycardia$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$Constipation
$Ageonset_greater_12wk$Constipation$ntab
            CTRL TRT
n_all          9   8
n_event        1   3
n_event_pct   11  38

$Ageonset_greater_12wk$Constipation$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.3750000 1.0474838  0.4331656 26.2962347 0.2455384
OR_TRTvsCTRL  4.8000000 1.2877629  0.3846763 59.8945106 0.2231884
ARR_TRTvsCTRL 0.2638889 0.2006759 -0.1294286  0.6572064 0.1885097


$Ageonset_greater_12wk$Cough
$Ageonset_greater_12wk$Cough$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$Cough$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$`Dermatitis contact`
$Ageonset_greater_12wk$`Dermatitis contact`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Dermatitis contact`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444
```

```
$Ageonset_greater_12wk$`Dermatitis diaper`
$Ageonset_greater_12wk$`Dermatitis diaper`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Dermatitis diaper`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Diarrhoea
$Ageonset_greater_12wk$Diarrhoea$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$Diarrhoea$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031


$Ageonset_greater_12wk$`Diarrhoea haemorrhagic`
$Ageonset_greater_12wk$`Diarrhoea haemorrhagic`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Diarrhoea haemorrhagic`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Drug hypersensitivity`
$Ageonset_greater_12wk$`Drug hypersensitivity`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Drug hypersensitivity`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
```

```
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Dysphagia
$Ageonset_greater_12wk$Dysphagia$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$Dysphagia$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$Dyspnoea
$Ageonset_greater_12wk$Dyspnoea$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Dyspnoea$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Erythema
$Ageonset_greater_12wk$Erythema$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0

$Ageonset_greater_12wk$Erythema$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$`Failure to thrive`
$Ageonset_greater_12wk$`Failure to thrive`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Failure to thrive`$stats
```

```
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Fungal infection`
$Ageonset_greater_12wk$`Fungal infection`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Fungal infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Fungal skin infection`
$Ageonset_greater_12wk$`Fungal skin infection`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Fungal skin infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Gastroenteritis viral`
$Ageonset_greater_12wk$`Gastroenteritis viral`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Gastroenteritis viral`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`
$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0
```

```
$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$Hyperaemia
$Ageonset_greater_12wk$Hyperaemia$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Hyperaemia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Increased upper airway secretion`
$Ageonset_greater_12wk$`Increased upper airway secretion`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Increased upper airway secretion`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Nasal congestion`
$Ageonset_greater_12wk$`Nasal congestion`$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0

$Ageonset_greater_12wk$`Nasal congestion`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$Nasopharyngitis
$Ageonset_greater_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all          9   8
```

```
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$Nasopharyngitis$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$Nystagmus
$Ageonset_greater_12wk$Nystagmus$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Nystagmus$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Oral candidiasis`
$Ageonset_greater_12wk$`Oral candidiasis`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Oral candidiasis`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Oropharyngeal pain`
$Ageonset_greater_12wk$`Oropharyngeal pain`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Oropharyngeal pain`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Otitis media`
$Ageonset_greater_12wk$`Otitis media`$ntab
```

```
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Otitis media`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Pseudomonas infection`
$Ageonset_greater_12wk$`Pseudomonas infection`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Pseudomonas infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Pyrexia
$Ageonset_greater_12wk$Pyrexia$ntab
            CTRL TRT
n_all          9   8
n_event        4   3
n_event_pct   44  38

$Ageonset_greater_12wk$Pyrexia$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.84375000 0.5892557  0.2658511 2.677868 0.7730955
OR_TRTvsCTRL   0.75000000 0.9916317  0.1073947 5.237688 0.7717322
ARR_TRTvsCTRL -0.06944444 0.2381842 -0.5362769 0.397388 0.7706248


$Ageonset_greater_12wk$`Respiratory tract infection`
$Ageonset_greater_12wk$`Respiratory tract infection`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Respiratory tract infection`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494
```

```
$Ageonset_greater_12wk$Restlessness
$Ageonset_greater_12wk$Restlessness$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Restlessness$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$Scoliosis
$Ageonset_greater_12wk$Scoliosis$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Scoliosis$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Seasonal allergy`
$Ageonset_greater_12wk$`Seasonal allergy`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Seasonal allergy`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Sinusitis
$Ageonset_greater_12wk$Sinusitis$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Sinusitis$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444
```

```
$Ageonset_greater_12wk$`Staphylococcal infection`
$Ageonset_greater_12wk$`Staphylococcal infection`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Staphylococcal infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Stoma complication`
$Ageonset_greater_12wk$`Stoma complication`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Stoma complication`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Stoma site erythema`
$Ageonset_greater_12wk$`Stoma site erythema`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Stoma site erythema`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Stoma site infection`
$Ageonset_greater_12wk$`Stoma site infection`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Stoma site infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
```

```
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Stoma site inflammation`
$Ageonset_greater_12wk$`Stoma site inflammation`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Stoma site inflammation`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Strabismus
$Ageonset_greater_12wk$Strabismus$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Strabismus$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Teething
$Ageonset_greater_12wk$Teething$ntab
            CTRL TRT
n_all          9   8
n_event        1   2
n_event_pct   11  25

$Ageonset_greater_12wk$Teething$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2500000 1.1242281  0.2484493 20.3763897 0.4707116
OR_TRTvsCTRL  2.6666667 1.3385315  0.1934678 36.7560505 0.4637017
ARR_TRTvsCTRL 0.1388889 0.1855032 -0.2246907  0.5024685 0.4540295


$Ageonset_greater_12wk$`Upper respiratory tract infection`
$Ageonset_greater_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$`Upper respiratory tract infection`$stats
```

```
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031


$Ageonset_greater_12wk$`Upper respiratory tract inflammation`
$Ageonset_greater_12wk$`Upper respiratory tract inflammation`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Upper respiratory tract inflammation`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Use of accessory respiratory muscles`
$Ageonset_greater_12wk$`Use of accessory respiratory muscles`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Use of accessory respiratory muscles`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Viral infection`
$Ageonset_greater_12wk$`Viral infection`$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0

$Ageonset_greater_12wk$`Viral infection`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$Vomiting
$Ageonset_greater_12wk$Vomiting$ntab
            CTRL TRT
n_all          9   8
n_event        2   2
n_event_pct   22  25
```

$Ageonset_greater_12wk$Vomiting$stats
                estimate   se   lo95ci   hi95ci   pvalue
RR_TRTvsCTRL 1.12500000 0.8740074 0.2028598 6.2389133 0.8928000
OR_TRTvsCTRL 1.16666667 1.1443443 0.1238452 10.9904228 0.8928439
ARR_TRTvsCTRL 0.02777778 0.2064991 -0.3769531 0.4325086 0.8929933

$Region_Asia_Pacific
$Region_Asia_Pacific$Amblyopia
$Region_Asia_Pacific$Amblyopia$ntab
            CTRL TRT
n_all   2 12
n_event   1   0
n_event_pct   50   0

$Region_Asia_Pacific$Amblyopia$stats
                 estimate   se   lo95ci   hi95ci   pvalue
RR_TRTvsCTRL   0.07692308 1.5021352 0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209 0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921

$Region_Asia_Pacific$Bronchiolitis
$Region_Asia_Pacific$Bronchiolitis$ntab
            CTRL TRT
n_all   2 12
n_event   0   2
n_event_pct   0 17

$Region_Asia_Pacific$Bronchiolitis$stats
                estimate   se   lo95ci   hi95ci   pvalue
RR_TRTvsCTRL 1.1538462 1.4105827 0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL 1.1904762 1.7015399 0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189 0.3775252 0.1213353

$Region_Asia_Pacific$Constipation
$Region_Asia_Pacific$Constipation$ntab
            CTRL TRT
n_all   2 12
n_event   0   5
n_event_pct   0 42

$Region_Asia_Pacific$Constipation$stats
                estimate   se   lo95ci   hi95ci   pvalue
RR_TRTvsCTRL 2.5384615 1.3310003 0.1869051 34.4762553 0.483993933
OR_TRTvsCTRL 3.6666667 1.6477717 0.1451061 92.6525185 0.430398971
ARR_TRTvsCTRL 0.4166667 0.1423188 0.1377270 0.6956063 0.003414791

$Region_Asia_Pacific$Erythema
$Region_Asia_Pacific$Erythema$ntab

```
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$Erythema$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$`Gastrooesophageal reflux disease`
$Region_Asia_Pacific$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Gastrooesophageal reflux disease`$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$Nystagmus
$Region_Asia_Pacific$Nystagmus$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$Nystagmus$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$Pyrexia
$Region_Asia_Pacific$Pyrexia$ntab
            CTRL TRT
n_all          2  12
n_event        1   3
n_event_pct   50  25

$Region_Asia_Pacific$Pyrexia$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5000000 0.8660254  0.09158152 2.7298084 0.4234922
OR_TRTvsCTRL   0.3333333 1.5634719  0.01556141 7.1401684 0.4822584
ARR_TRTvsCTRL -0.2500000 0.3750000 -0.98498649 0.4849865 0.5049851
```

```
$Region_Asia_Pacific$`Stoma site erythema`
$Region_Asia_Pacific$`Stoma site erythema`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Stoma site erythema`$stats
                estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$Strabismus
$Region_Asia_Pacific$Strabismus$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$Strabismus$stats
                estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$`Upper respiratory tract infection`
$Region_Asia_Pacific$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$`Upper respiratory tract infection`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         32  72
n_event        1   9
n_event_pct    3  12

$Ageonset_less_equal_12wk$Atelectasis$stats
              estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.000000 1.0324593  0.5287240 30.2615346 0.17936561
```

```
OR_TRTvsCTRL  4.428571 1.0766811  0.5367735 36.5372846 0.16694211
ARR_TRTvsCTRL 0.093750 0.0496502 -0.0035626  0.1910626 0.05899776


$Ageonset_less_equal_12wk$Constipation
$Ageonset_less_equal_12wk$Constipation$ntab
            CTRL TRT
n_all         32  72
n_event        7  22
n_event_pct   22  31

$Ageonset_less_equal_12wk$Constipation$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39682540 0.37838182  0.66536957 2.9323872 0.3771064
OR_TRTvsCTRL  1.57142857 0.49830883  0.59174337 4.1730721 0.3643866
ARR_TRTvsCTRL 0.08680556 0.09103669 -0.09162307 0.2652342 0.3403253


$Ageonset_less_equal_12wk$Cough
$Ageonset_less_equal_12wk$Cough$ntab
            CTRL TRT
n_all         32  72
n_event        5   5
n_event_pct   16   7

$Ageonset_less_equal_12wk$Cough$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.44444444 0.59570220  0.1382786 1.42849957 0.1734185
OR_TRTvsCTRL   0.40298507 0.67228150  0.1079051 1.50499830 0.1764081
ARR_TRTvsCTRL -0.08680556 0.07083361 -0.2256369 0.05202576 0.2203924


$Ageonset_less_equal_12wk$Diarrhoea
$Ageonset_less_equal_12wk$Diarrhoea$ntab
            CTRL TRT
n_all         32  72
n_event        6   8
n_event_pct   19  11

$Ageonset_less_equal_12wk$Diarrhoea$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.59259259 0.49651564  0.2239347 1.56816261 0.2919561
OR_TRTvsCTRL   0.54166667 0.58800783  0.1710878 1.71492559 0.2970962
ARR_TRTvsCTRL -0.07638889 0.07831018 -0.2298740 0.07709624 0.3293293


$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`
$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         32  72
n_event        4   8
n_event_pct   12  11

$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`$stats
```

```
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.57433536  0.2883848 2.7398238 0.8375119
OR_TRTvsCTRL   0.87500000 0.65294662  0.2433430 3.1462789 0.8379582
ARR_TRTvsCTRL -0.01388889 0.06920774 -0.1495336 0.1217558 0.8409456


$Ageonset_less_equal_12wk$`Nasal congestion`
$Ageonset_less_equal_12wk$`Nasal congestion`$ntab
            CTRL TRT
n_all         32  72
n_event        3   8
n_event_pct    9  11

$Ageonset_less_equal_12wk$`Nasal congestion`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.18518519 0.64280203  0.3362267 4.1777292 0.7915410
OR_TRTvsCTRL  1.20833333 0.71305055  0.2987012 4.8880595 0.7907031
ARR_TRTvsCTRL 0.01736111 0.06345685 -0.1070120 0.1417342 0.7844003


$Ageonset_less_equal_12wk$Nasopharyngitis
$Ageonset_less_equal_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all         32  72
n_event        1  11
n_event_pct    3  15

$Ageonset_less_equal_12wk$Nasopharyngitis$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.8888889 1.02262906 0.65878959 36.2805285 0.12069855
OR_TRTvsCTRL  5.5901639 1.06750204 0.68986667 45.2985108 0.10692213
ARR_TRTvsCTRL 0.1215278 0.05238108 0.01886275  0.2241928 0.02033708


$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         32  72
n_event        5   5
n_event_pct   16   7

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.44444444 0.59570220  0.1382786 1.42849957 0.1734185
OR_TRTvsCTRL   0.40298507 0.67228150  0.1079051 1.50499830 0.1764081
ARR_TRTvsCTRL -0.08680556 0.07083361 -0.2256369 0.05202576 0.2203924


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         32  72
n_event       15  31
n_event_pct   47  43
```

```
$Ageonset_less_equal_12wk$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.91851852 0.2319177  0.5830143 1.4470937 0.7140069
OR_TRTvsCTRL   0.85691057 0.4267769  0.3712465 1.9779196 0.7174772
ARR_TRTvsCTRL -0.03819444 0.1057697 -0.2454992 0.1691103 0.7180175


$Ageonset_less_equal_12wk$Rash
$Ageonset_less_equal_12wk$Rash$ntab
            CTRL TRT
n_all         32  72
n_event        4   8
n_event_pct   12  11

$Ageonset_less_equal_12wk$Rash$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88888889 0.57433536  0.2883848 2.7398238 0.8375119
OR_TRTvsCTRL   0.87500000 0.65294662  0.2433430 3.1462789 0.8379582
ARR_TRTvsCTRL -0.01388889 0.06920774 -0.1495336 0.1217558 0.8409456


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         32  72
n_event        4   3
n_event_pct   12   4

$Ageonset_less_equal_12wk$`Respiratory distress`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.33333333 0.73361737  0.07914482 1.40389615 0.1342560
OR_TRTvsCTRL   0.30434783 0.79595249  0.06395201 1.44839226 0.1350341
ARR_TRTvsCTRL -0.08333333 0.06302825 -0.20686643 0.04019976 0.1861154


$Ageonset_less_equal_12wk$Tachycardia
$Ageonset_less_equal_12wk$Tachycardia$ntab
            CTRL TRT
n_all         32  72
n_event        5   3
n_event_pct   16   4

$Ageonset_less_equal_12wk$Tachycardia$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2666667 0.69870913  0.06779949 1.04884429 0.05852948
OR_TRTvsCTRL   0.2347826 0.76476344  0.05244428 1.05107510 0.05811518
ARR_TRTvsCTRL -0.1145833 0.06837005 -0.24858617 0.01941951 0.09375216


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
```

```
n_event        4  11
n_event_pct   12  15

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.22222222 0.54384759  0.4209459 3.548739 0.7121401
OR_TRTvsCTRL  1.26229508 0.62691054  0.3694313 4.313086 0.7102244
ARR_TRTvsCTRL 0.02777778 0.07221981 -0.1137705 0.169326 0.7005129


$Ageonset_less_equal_12wk$Vomiting
$Ageonset_less_equal_12wk$Vomiting$ntab
            CTRL TRT
n_all         32  72
n_event        4  10
n_event_pct   12  14

$Ageonset_less_equal_12wk$Vomiting$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.11111111 0.55214229  0.3765071 3.2790034 0.8486656
OR_TRTvsCTRL  1.12903226 0.63391113  0.3259269 3.9110420 0.8481748
ARR_TRTvsCTRL 0.01388889 0.07126754 -0.1257929 0.1535707 0.8454839



$Agetrt_less_180d
$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$ntab
            CTRL TRT
n_all         16  49
n_event        1   8
n_event_pct    6  16

$Agetrt_less_180d$Atelectasis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.6122449 1.02082899  0.35325041 19.3172413 0.3469007
OR_TRTvsCTRL  2.9268293 1.10274970  0.33708167 25.4132167 0.3301279
ARR_TRTvsCTRL 0.1007653 0.08031229 -0.05664388  0.2581745 0.2095991


$Agetrt_less_180d$`Candida infection`
$Agetrt_less_180d$`Candida infection`$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$`Candida infection`$stats
                  estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002
```

```
$Agetrt_less_180d$Conjunctivitis
$Agetrt_less_180d$Conjunctivitis$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$Conjunctivitis$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718


$Agetrt_less_180d$Constipation
$Agetrt_less_180d$Constipation$ntab
            CTRL TRT
n_all         16  49
n_event        4  12
n_event_pct   25  24

$Agetrt_less_180d$Constipation$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.979591837 0.5004250  0.3673522 2.6122076 0.9671336
OR_TRTvsCTRL   0.972972973 0.6661034  0.2637015 3.5899549 0.9671897
ARR_TRTvsCTRL -0.005102041 0.1244696 -0.2490580 0.2388539 0.9673037


$Agetrt_less_180d$Cough
$Agetrt_less_180d$Cough$ntab
            CTRL TRT
n_all         16  49
n_event        3   4
n_event_pct   19   8

$Agetrt_less_180d$Cough$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4353741 0.7074074  0.10882193 1.7418425 0.2397992
OR_TRTvsCTRL   0.3851852 0.8261226  0.07629089 1.9447620 0.2481601
ARR_TRTvsCTRL -0.1058673 0.1051259 -0.31191036 0.1001757 0.3139094


$Agetrt_less_180d$`Dermatitis contact`
$Agetrt_less_180d$`Dermatitis contact`$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$`Dermatitis contact`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156
```

```
$Agetrt_less_180d$Diarrhoea
$Agetrt_less_180d$Diarrhoea$ntab
            CTRL TRT
n_all         16  49
n_event        4   6
n_event_pct   25  12

$Agetrt_less_180d$Diarrhoea$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4897959 0.5777184  0.1578557 1.5197422 0.2166474
OR_TRTvsCTRL   0.4186047 0.7233642  0.1014087 1.7279565 0.2286442
ARR_TRTvsCTRL -0.1275510 0.1179479 -0.3587247 0.1036227 0.2795112


$Agetrt_less_180d$`Gastrooesophageal reflux disease`
$Agetrt_less_180d$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         16  49
n_event        4   2
n_event_pct   25   4

$Agetrt_less_180d$`Gastrooesophageal reflux disease`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.1632653 0.8167569  0.03293587 0.80931696 0.02648713
OR_TRTvsCTRL   0.1276596 0.9244512  0.02085255 0.78153357 0.02597364
ARR_TRTvsCTRL -0.2091837 0.1118827 -0.42846972 0.01010237 0.06152971


$Agetrt_less_180d$`Nasal congestion`
$Agetrt_less_180d$`Nasal congestion`$ntab
            CTRL TRT
n_all         16  49
n_event        2   6
n_event_pct   12  12

$Agetrt_less_180d$`Nasal congestion`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.97959184 0.76404090  0.2191252 4.3792320 0.9784700
OR_TRTvsCTRL   0.97674419 0.87255433  0.1766287 5.4013264 0.9784858
ARR_TRTvsCTRL -0.00255102 0.09502053 -0.1887878 0.1836858 0.9785817


$Agetrt_less_180d$Nasopharyngitis
$Agetrt_less_180d$Nasopharyngitis$ntab
            CTRL TRT
n_all         16  49
n_event        1  10
n_event_pct    6  20

$Agetrt_less_180d$Nasopharyngitis$stats
                estimate         se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  3.2653061 1.00850971  0.45235446 23.570507 0.24064807
```

```
OR_TRTvsCTRL  3.8461538 1.09192843  0.45245510 32.694735 0.21732784
ARR_TRTvsCTRL 0.1415816 0.08352877 -0.02213174  0.305295 0.09007457


$Agetrt_less_180d$`Oral candidiasis`
$Agetrt_less_180d$`Oral candidiasis`$ntab
            CTRL TRT
n_all         16  49
n_event        2   5
n_event_pct   12  10

$Agetrt_less_180d$`Oral candidiasis`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.81632653 0.78555193  0.1750656 3.8065096 0.7961432
OR_TRTvsCTRL   0.79545455 0.89115422  0.1386959 4.5621254 0.7973391
ARR_TRTvsCTRL -0.02295918 0.09330545 -0.2058345 0.1599161 0.8056321


$Agetrt_less_180d$`Oxygen saturation decreased`
$Agetrt_less_180d$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         16  49
n_event        3   5
n_event_pct   19  10

$Agetrt_less_180d$`Oxygen saturation decreased`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.54421769 0.6711372  0.1460493 2.0278961 0.3646555
OR_TRTvsCTRL   0.49242424 0.7956027  0.1035431 2.3418425 0.3732444
ARR_TRTvsCTRL -0.08545918 0.1067308 -0.2946476 0.1237292 0.4233060


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$ntab
            CTRL TRT
n_all         16  49
n_event        7  21
n_event_pct   44  43

$Agetrt_less_180d$Pyrexia$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.979591837 0.3279757  0.5150765 1.8630244 0.9498713
OR_TRTvsCTRL   0.964285714 0.5807767  0.3089212 3.0099811 0.9500699
ARR_TRTvsCTRL -0.008928571 0.1427543 -0.2887218 0.2708646 0.9501288


$Agetrt_less_180d$Rash
$Agetrt_less_180d$Rash$ntab
            CTRL TRT
n_all         16  49
n_event        3   6
n_event_pct   19  12

$Agetrt_less_180d$Rash$stats
```

```
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 0.6458265  0.1841728 2.3157005 0.5094139
OR_TRTvsCTRL   0.60465116 0.7747121  0.1324551 2.7602032 0.5160753
ARR_TRTvsCTRL -0.06505102 0.1082333 -0.2771844 0.1470824 0.5478227


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$`Respiratory distress`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718


$Agetrt_less_180d$Rhinorrhoea
$Agetrt_less_180d$Rhinorrhoea$ntab
            CTRL TRT
n_all         16  49
n_event        1   5
n_event_pct    6  10

$Agetrt_less_180d$Rhinorrhoea$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.63265306 1.05692565  0.2057014 12.9583783 0.6427882
OR_TRTvsCTRL  1.70454545 1.13551483  0.1841012 15.7819465 0.6386026
ARR_TRTvsCTRL 0.03954082 0.07437794 -0.1062373  0.1853189 0.5949891


$Agetrt_less_180d$Tachycardia
$Agetrt_less_180d$Tachycardia$ntab
            CTRL TRT
n_all         16  49
n_event        3   2
n_event_pct   19   4

$Agetrt_less_180d$Tachycardia$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2176871 0.8662708  0.03985305 1.18905986 0.07839606
OR_TRTvsCTRL   0.1843972 0.9651596  0.02781051 1.22264269 0.07982660
ARR_TRTvsCTRL -0.1466837 0.1015897 -0.34579587 0.05242852 0.14877188


$Agetrt_less_180d$Teething
$Agetrt_less_180d$Teething$ntab
            CTRL TRT
n_all         16  49
n_event        1   6
n_event_pct    6  12
```

```
$Agetrt_less_180d$Teething$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.95918367 1.04103722  0.25464940 15.0732758 0.5182683
OR_TRTvsCTRL  2.09302326 1.12097687  0.23259309 18.8343786 0.5099612
ARR_TRTvsCTRL 0.05994898 0.07651845 -0.09002443  0.2099224 0.4333583


$Agetrt_less_180d$`Upper respiratory tract congestion`
$Agetrt_less_180d$`Upper respiratory tract congestion`$ntab
            CTRL TRT
n_all         16  49
n_event        0   5
n_event_pct    0  10

$Agetrt_less_180d$`Upper respiratory tract congestion`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.7400000 1.45017056 0.21801390 64.1592119 0.36302969
OR_TRTvsCTRL  4.0786517 1.50495719 0.21354762 77.9001876 0.35025713
ARR_TRTvsCTRL 0.1020408 0.04324314 0.01728582  0.1867958 0.01828974


$Agetrt_less_180d$`Upper respiratory tract infection`
$Agetrt_less_180d$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         16  49
n_event        3   7
n_event_pct   19  14

$Agetrt_less_180d$`Upper respiratory tract infection`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.76190476 0.6271222  0.2228914 2.6044026 0.6645633
OR_TRTvsCTRL   0.72222222 0.7595545  0.1629810 3.2004042 0.6683319
ARR_TRTvsCTRL -0.04464286 0.1096378 -0.2595290 0.1702432 0.6838721


$Agetrt_less_180d$Vomiting
$Agetrt_less_180d$Vomiting$ntab
            CTRL TRT
n_all         16  49
n_event        2   7
n_event_pct   12  14

$Agetrt_less_180d$Vomiting$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14285714 0.74829739  0.2636575 4.9538612 0.8583720
OR_TRTvsCTRL  1.16666667 0.85912469  0.2166000 6.2839838 0.8576020
ARR_TRTvsCTRL 0.01785714 0.09661727 -0.1715092 0.2072235 0.8533675



$Gender_Female
$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$ntab
```

```
            CTRL TRT
n_all         24  43
n_event        2   6
n_event_pct    8  14

$Gender_Female$Atelectasis$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.67441860 0.77572172  0.36607369 7.6587795 0.5063712
OR_TRTvsCTRL  1.78378378 0.85973731  0.33077486 9.6194875 0.5008484
ARR_TRTvsCTRL 0.05620155 0.07729862 -0.09530097 0.2077041 0.4671828


$Gender_Female$`Candida infection`
$Gender_Female$`Candida infection`$ntab
            CTRL TRT
n_all         24  43
n_event        3   0
n_event_pct   12   0

$Gender_Female$`Candida infection`$stats
                estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08116883 1.49096848  0.004367919 1.508356380 0.09212555
OR_TRTvsCTRL   0.07060755 1.53467079  0.003487683 1.429437936 0.08413938
ARR_TRTvsCTRL -0.12500000 0.06750772 -0.257312691 0.007312691 0.06407751


$Gender_Female$Constipation
$Gender_Female$Constipation$ntab
            CTRL TRT
n_all         24  43
n_event        7  17
n_event_pct   29  40

$Gender_Female$Constipation$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3554817 0.3698083  0.6566172 2.7981763 0.4108084
OR_TRTvsCTRL  1.5879121 0.5467776  0.5437616 4.6370779 0.3977097
ARR_TRTvsCTRL 0.1036822 0.1190272 -0.1296069 0.3369712 0.3837107


$Gender_Female$Cough
$Gender_Female$Cough$ntab
            CTRL TRT
n_all         24  43
n_event        5   4
n_event_pct   21   9

$Gender_Female$Cough$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4465116 0.62054615  0.1323192 1.50675489 0.1938331
OR_TRTvsCTRL   0.3897436 0.72682364  0.0937790 1.61976640 0.1948320
ARR_TRTvsCTRL -0.1153101 0.09399041 -0.2995279 0.06890775 0.2198872
```

```
$Gender_Female$Diarrhoea
$Gender_Female$Diarrhoea$ntab
            CTRL TRT
n_all         24  43
n_event        4   7
n_event_pct   17  16

$Gender_Female$Diarrhoea$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.976744186 0.57265580  0.3179328 3.0007259 0.9672240
OR_TRTvsCTRL   0.972222222 0.68602837  0.2534061 3.7300439 0.9672451
ARR_TRTvsCTRL -0.003875969 0.09463915 -0.1893653 0.1816134 0.9673316


$Gender_Female$Dysphagia
$Gender_Female$Dysphagia$ntab
            CTRL TRT
n_all         24  43
n_event        3   4
n_event_pct   12   9

$Gender_Female$Dysphagia$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.74418605 0.7200075  0.1814722 3.051779 0.6815399
OR_TRTvsCTRL   0.71794872 0.8103045  0.1466766 3.514195 0.6825917
ARR_TRTvsCTRL -0.03197674 0.0807427 -0.1902295 0.126276 0.6920809


$Gender_Female$`Gastrooesophageal reflux disease`
$Gender_Female$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         24  43
n_event        4   5
n_event_pct   17  12

$Gender_Female$`Gastrooesophageal reflux disease`$stats
                 estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.6976744 0.62054615  0.2067488 2.354305 0.5618212
OR_TRTvsCTRL   0.6578947 0.72547625  0.1587194 2.726986 0.5638365
ARR_TRTvsCTRL -0.0503876 0.09042546 -0.2276182 0.126843 0.5773717


$Gender_Female$`Nasal congestion`
$Gender_Female$`Nasal congestion`$ntab
            CTRL TRT
n_all         24  43
n_event        2   5
n_event_pct    8  12

$Gender_Female$`Nasal congestion`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39534884 0.79691751  0.2926479 6.6530412 0.6759169
OR_TRTvsCTRL  1.44736842 0.87850460  0.2586989 8.0977351 0.6738410
ARR_TRTvsCTRL 0.03294574 0.07464983 -0.1133652 0.1792567 0.6589690
```

```
$Gender_Female$Nasopharyngitis
$Gender_Female$Nasopharyngitis$ntab
            CTRL TRT
n_all         24  43
n_event        2   5
n_event_pct    8  12

$Gender_Female$Nasopharyngitis$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39534884 0.79691751  0.2926479 6.6530412 0.6759169
OR_TRTvsCTRL  1.44736842 0.87850460  0.2586989 8.0977351 0.6738410
ARR_TRTvsCTRL 0.03294574 0.07464983 -0.1133652 0.1792567 0.6589690


$Gender_Female$`Oxygen saturation decreased`
$Gender_Female$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         24  43
n_event        3   2
n_event_pct   12   5

$Gender_Female$`Oxygen saturation decreased`$stats
                  estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.37209302 0.87659047  0.06675693 2.07399014 0.2594079
OR_TRTvsCTRL   0.34146341 0.95149494  0.05289690 2.20423626 0.2587751
ARR_TRTvsCTRL -0.07848837 0.07475726 -0.22500990 0.06803316 0.2937596


$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$ntab
            CTRL TRT
n_all         24  43
n_event       12  21
n_event_pct   50  49

$Gender_Female$Pyrexia$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.97674419 0.2569628  0.5902740 1.6162480 0.9270384
OR_TRTvsCTRL   0.95454545 0.5096472  0.3515476 2.5918454 0.9272710
ARR_TRTvsCTRL -0.01162791 0.1273871 -0.2613021 0.2380462 0.9272700


$Gender_Female$Rash
$Gender_Female$Rash$ntab
            CTRL TRT
n_all         24  43
n_event        1   5
n_event_pct    4  12

$Gender_Female$Rash$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.7906977 1.0654002  0.34581396 22.5207608 0.3354009
```

```
OR_TRTvsCTRL  3.0263158 1.1268514  0.33245786 27.5481148 0.3257599
ARR_TRTvsCTRL 0.0746124 0.0636671 -0.05017282  0.1993976 0.2412314


$Gender_Female$`Respiratory tract congestion`
$Gender_Female$`Respiratory tract congestion`$ntab
            CTRL TRT
n_all         24  43
n_event        3   0
n_event_pct   12   0

$Gender_Female$`Respiratory tract congestion`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08116883 1.49096848  0.004367919 1.508356380 0.09212555
OR_TRTvsCTRL   0.07060755 1.53467079  0.003487683 1.429437936 0.08413938
ARR_TRTvsCTRL -0.12500000 0.06750772 -0.257312691 0.007312691 0.06407751


$Gender_Female$Rhinorrhoea
$Gender_Female$Rhinorrhoea$ntab
            CTRL TRT
n_all         24  43
n_event        2   6
n_event_pct    8  14

$Gender_Female$Rhinorrhoea$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.67441860 0.77572172  0.36607369 7.6587795 0.5063712
OR_TRTvsCTRL  1.78378378 0.85973731  0.33077486 9.6194875 0.5008484
ARR_TRTvsCTRL 0.05620155 0.07729862 -0.09530097 0.2077041 0.4671828


$Gender_Female$Tachycardia
$Gender_Female$Tachycardia$ntab
            CTRL TRT
n_all         24  43
n_event        3   0
n_event_pct   12   0

$Gender_Female$Tachycardia$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08116883 1.49096848  0.004367919 1.508356380 0.09212555
OR_TRTvsCTRL   0.07060755 1.53467079  0.003487683 1.429437936 0.08413938
ARR_TRTvsCTRL -0.12500000 0.06750772 -0.257312691 0.007312691 0.06407751


$Gender_Female$`Upper respiratory tract infection`
$Gender_Female$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        2   6
n_event_pct    8  14

$Gender_Female$`Upper respiratory tract infection`$stats
```

```
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.67441860 0.77572172  0.36607369 7.6587795 0.5063712
OR_TRTvsCTRL  1.78378378 0.85973731  0.33077486 9.6194875 0.5008484
ARR_TRTvsCTRL 0.05620155 0.07729862 -0.09530097 0.2077041 0.4671828


$Gender_Female$Vomiting
$Gender_Female$Vomiting$ntab
            CTRL TRT
n_all         24  43
n_event        3   8
n_event_pct   12  19

$Gender_Female$Vomiting$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.48837209 0.62722472  0.4353283 5.0886921 0.5260574
OR_TRTvsCTRL  1.60000000 0.73111135  0.3817657 6.7056842 0.5203137
ARR_TRTvsCTRL 0.06104651 0.08988323 -0.1151214 0.2372144 0.4970265



$Region_Europe
$Region_Europe$Atelectasis
$Region_Europe$Atelectasis$ntab
            CTRL TRT
n_all         17  30
n_event        1   6
n_event_pct    6  20

$Region_Europe$Atelectasis$stats
               estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.4000000 1.03658565  0.4457954 25.9311764 0.2377684
OR_TRTvsCTRL  4.0000000 1.12731244  0.4390257 36.4443391 0.2187968
ARR_TRTvsCTRL 0.1411765 0.09268225 -0.0404774  0.3228303 0.1277009


$Region_Europe$Bronchitis
$Region_Europe$Bronchitis$ntab
            CTRL TRT
n_all         17  30
n_event        1   3
n_event_pct    6  10

$Region_Europe$Bronchitis$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 1.11408100  0.1914880 15.0923333 0.6338661
OR_TRTvsCTRL  1.77777778 1.19702563  0.1702031 18.5689583 0.6307571
ARR_TRTvsCTRL 0.04117647 0.07909909 -0.1138549  0.1962078 0.6026676


$Region_Europe$Constipation
$Region_Europe$Constipation$ntab
            CTRL TRT
n_all         17  30
```

```
n_event        4   6
n_event_pct   24  20

$Region_Europe$Constipation$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.5696576  0.2783079 2.5960459 0.7754202
OR_TRTvsCTRL   0.81250000 0.7316122  0.1936752 3.4085746 0.7765555
ARR_TRTvsCTRL -0.03529412 0.1261646 -0.2825721 0.2119839 0.7796719


$Region_Europe$`Gastrooesophageal reflux disease`
$Region_Europe$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         17  30
n_event        2   3
n_event_pct   12  10

$Region_Europe$`Gastrooesophageal reflux disease`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.86091606  0.1572555 4.5944339 0.8502696
OR_TRTvsCTRL   0.83333333 0.96800673  0.1249827 5.5563242 0.8506043
ARR_TRTvsCTRL -0.01764706 0.09542667 -0.2046799 0.1693858 0.8532855


$Region_Europe$Nasopharyngitis
$Region_Europe$Nasopharyngitis$ntab
            CTRL TRT
n_all         17  30
n_event        0   7
n_event_pct    0  23

$Region_Europe$Nasopharyngitis$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   8.7096774 1.43021667 0.52795807 143.6827740 0.13018787
OR_TRTvsCTRL  11.1702128 1.49433242 0.59714993 208.9486202 0.10632464
ARR_TRTvsCTRL  0.2333333 0.07722022 0.08198448   0.3846822 0.00251392


$Region_Europe$`Oral candidiasis`
$Region_Europe$`Oral candidiasis`$ntab
            CTRL TRT
n_all         17  30
n_event        2   3
n_event_pct   12  10

$Region_Europe$`Oral candidiasis`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.86091606  0.1572555 4.5944339 0.8502696
OR_TRTvsCTRL   0.83333333 0.96800673  0.1249827 5.5563242 0.8506043
ARR_TRTvsCTRL -0.01764706 0.09542667 -0.2046799 0.1693858 0.8532855


$Region_Europe$`Oxygen saturation decreased`
$Region_Europe$`Oxygen saturation decreased`$ntab
```

```
            CTRL TRT
n_all         17  30
n_event        2   0
n_event_pct   12   0

$Region_Europe$`Oxygen saturation decreased`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1161290 1.52058751  0.005896772 2.28700568 0.1567945
OR_TRTvsCTRL   0.1016393 1.58028574  0.004591136 2.25010878 0.1479588
ARR_TRTvsCTRL -0.1176471 0.07814249 -0.270803525 0.03550941 0.1321839


$Region_Europe$Pain
$Region_Europe$Pain$ntab
            CTRL TRT
n_all         17  30
n_event        2   0
n_event_pct   12   0

$Region_Europe$Pain$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1161290 1.52058751  0.005896772 2.28700568 0.1567945
OR_TRTvsCTRL   0.1016393 1.58028574  0.004591136 2.25010878 0.1479588
ARR_TRTvsCTRL -0.1176471 0.07814249 -0.270803525 0.03550941 0.1321839


$Region_Europe$Pyrexia
$Region_Europe$Pyrexia$ntab
            CTRL TRT
n_all         17  30
n_event        7  13
n_event_pct   41  43

$Region_Europe$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.05238095 0.3572441  0.5224999 2.1196284 0.8863581
OR_TRTvsCTRL  1.09243697 0.6153078  0.3270735 3.6487775 0.8857486
ARR_TRTvsCTRL 0.02156863 0.1497768 -0.2719886 0.3151258 0.8854964


$Region_Europe$`Respiratory tract infection`
$Region_Europe$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         17  30
n_event        1   4
n_event_pct    6  13

$Region_Europe$`Respiratory tract infection`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2666667 1.07603120  0.27508584 18.6769981 0.4469621
OR_TRTvsCTRL  2.4615385 1.16230871  0.25225957 24.0195902 0.4383410
ARR_TRTvsCTRL 0.0745098 0.08431203 -0.09073873  0.2397583 0.3768373
```

```
$Region_Europe$Rhinitis
$Region_Europe$Rhinitis$ntab
            CTRL TRT
n_all         17  30
n_event        3   2
n_event_pct   18   7

$Region_Europe$Rhinitis$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3777778 0.8609161  0.06989133 2.04197063 0.2581758
OR_TRTvsCTRL   0.3333333 0.9697815  0.04981948 2.23027424 0.2572793
ARR_TRTvsCTRL -0.1098039 0.1030671 -0.31181168 0.09220384 0.2867114


$Region_Europe$Teething
$Region_Europe$Teething$ntab
            CTRL TRT
n_all         17  30
n_event        1   3
n_event_pct    6  10

$Region_Europe$Teething$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 1.11408100  0.1914880 15.0923333 0.6338661
OR_TRTvsCTRL  1.77777778 1.19702563  0.1702031 18.5689583 0.6307571
ARR_TRTvsCTRL 0.04117647 0.07909909 -0.1138549  0.1962078 0.6026676


$Region_Europe$`Upper respiratory tract infection`
$Region_Europe$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         17  30
n_event        4   1
n_event_pct   24   3

$Region_Europe$`Upper respiratory tract infection`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.1416667 1.0760312  0.01719287 1.167312378 0.06934105
OR_TRTvsCTRL   0.1120690 1.1667930  0.01138438 1.103218002 0.06068621
ARR_TRTvsCTRL -0.2019608 0.1079733 -0.41358461 0.009663041 0.06141868


$Region_Europe$`Upper respiratory tract inflammation`
$Region_Europe$`Upper respiratory tract inflammation`$ntab
            CTRL TRT
n_all         17  30
n_event        2   0
n_event_pct   12   0

$Region_Europe$`Upper respiratory tract inflammation`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1161290 1.52058751  0.005896772 2.28700568 0.1567945
OR_TRTvsCTRL   0.1016393 1.58028574  0.004591136 2.25010878 0.1479588
ARR_TRTvsCTRL -0.1176471 0.07814249 -0.270803525 0.03550941 0.1321839
```

```
$Region_Europe$Vomiting
$Region_Europe$Vomiting$ntab
            CTRL TRT
n_all         17  30
n_event        2   4
n_event_pct   12  13

$Region_Europe$Vomiting$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.13333333 0.81107530  0.2311900 5.5557949 0.8773594
OR_TRTvsCTRL  1.15384615 0.92473142  0.1883715 7.0677425 0.8770196
ARR_TRTvsCTRL 0.01568627 0.09979028 -0.1798991 0.2112716 0.8750932


$Region_Europe$`Weight decreased`
$Region_Europe$`Weight decreased`$ntab
            CTRL TRT
n_all         17  30
n_event        1   3
n_event_pct    6  10

$Region_Europe$`Weight decreased`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 1.11408100  0.1914880 15.0923333 0.6338661
OR_TRTvsCTRL  1.77777778 1.19702563  0.1702031 18.5689583 0.6307571
ARR_TRTvsCTRL 0.04117647 0.07909909 -0.1138549  0.1962078 0.6026676



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         18  34
n_event        1   6
n_event_pct    6  18

$Disdur_less_equal_12wk$Atelectasis$stats
              estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.176471 1.04004776  0.41367053 24.3913084 0.2664535
OR_TRTvsCTRL  3.642857 1.12303361  0.40319413 32.9131978 0.2496749
ARR_TRTvsCTRL 0.120915 0.08478989 -0.04527011  0.2871002 0.1538525


$Disdur_less_equal_12wk$`Candida infection`
$Disdur_less_equal_12wk$`Candida infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Candida infection`$stats
```

```
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$Constipation
$Disdur_less_equal_12wk$Constipation$ntab
            CTRL TRT
n_all         18  34
n_event        2   7
n_event_pct   11  21

$Disdur_less_equal_12wk$Constipation$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.85294118 0.7469202  0.4286294  8.0101617 0.4089423
OR_TRTvsCTRL  2.07407407 0.8616230  0.3831858 11.2263631 0.3971762
ARR_TRTvsCTRL 0.09477124 0.1014674 -0.1041013  0.2936437 0.3503005


$Disdur_less_equal_12wk$Cough
$Disdur_less_equal_12wk$Cough$ntab
            CTRL TRT
n_all         18  34
n_event        4   3
n_event_pct   22   9

$Disdur_less_equal_12wk$Cough$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3970588 0.7059504  0.09952880 1.58402105 0.1907351
OR_TRTvsCTRL   0.3387097 0.8288667  0.06672599 1.71933380 0.1915066
ARR_TRTvsCTRL -0.1339869 0.1094000 -0.34840704 0.08043319 0.2206720


$Disdur_less_equal_12wk$`Dermatitis contact`
$Disdur_less_equal_12wk$`Dermatitis contact`$ntab
            CTRL TRT
n_all         18  34
n_event        3   1
n_event_pct   17   3

$Disdur_less_equal_12wk$`Dermatitis contact`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1764706 1.1173030  0.01975251 1.5766031 0.1205452
OR_TRTvsCTRL   0.1515152 1.1959528  0.01453648 1.5792574 0.1145932
ARR_TRTvsCTRL -0.1372549 0.0924968 -0.31854530 0.0440355 0.1378386


$Disdur_less_equal_12wk$`Dermatitis diaper`
$Disdur_less_equal_12wk$`Dermatitis diaper`$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3
```

```
$Disdur_less_equal_12wk$`Dermatitis diaper`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495


$Disdur_less_equal_12wk$Diarrhoea
$Disdur_less_equal_12wk$Diarrhoea$ntab
            CTRL TRT
n_all         18  34
n_event        5   4
n_event_pct   28  12

$Disdur_less_equal_12wk$Diarrhoea$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4235294 0.6041793  0.12960005 1.38408246 0.1550314
OR_TRTvsCTRL   0.3466667 0.7485028  0.07994391 1.50327628 0.1569666
ARR_TRTvsCTRL -0.1601307 0.1191576 -0.39367529 0.07341385 0.1789947


$Disdur_less_equal_12wk$Dysphagia
$Disdur_less_equal_12wk$Dysphagia$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$Dysphagia$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$Erythema
$Disdur_less_equal_12wk$Erythema$ntab
            CTRL TRT
n_all         18  34
n_event        3   1
n_event_pct   17   3

$Disdur_less_equal_12wk$Erythema$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1764706 1.1173030  0.01975251 1.5766031 0.1205452
OR_TRTvsCTRL   0.1515152 1.1959528  0.01453648 1.5792574 0.1145932
ARR_TRTvsCTRL -0.1372549 0.0924968 -0.31854530 0.0440355 0.1378386


$Disdur_less_equal_12wk$`Gastrooesophageal reflux disease`
$Disdur_less_equal_12wk$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         18  34
```

```
n_event        4   1
n_event_pct   22   3

$Disdur_less_equal_12wk$`Gastrooesophageal reflux disease`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.1323529 1.0793668  0.01595787 1.097721774 0.06098794
OR_TRTvsCTRL   0.1060606 1.1626399  0.01086209 1.035607067 0.05362288
ARR_TRTvsCTRL -0.1928105 0.1021851 -0.39308966 0.007468748 0.05917732


$Disdur_less_equal_12wk$`Nasal congestion`
$Disdur_less_equal_12wk$`Nasal congestion`$ntab
            CTRL TRT
n_all         18  34
n_event        3   4
n_event_pct   17  12

$Disdur_less_equal_12wk$`Nasal congestion`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.70588235 0.7059504  0.1769401 2.8160374 0.6217392
OR_TRTvsCTRL   0.66666667 0.8266398  0.1319082 3.3693475 0.6237816
ARR_TRTvsCTRL -0.04901961 0.1037746 -0.2524141 0.1543749 0.6366656


$Disdur_less_equal_12wk$Nasopharyngitis
$Disdur_less_equal_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all         18  34
n_event        1   6
n_event_pct    6  18

$Disdur_less_equal_12wk$Nasopharyngitis$stats
              estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.176471 1.04004776  0.41367053 24.3913084 0.2664535
OR_TRTvsCTRL  3.642857 1.12303361  0.40319413 32.9131978 0.2496749
ARR_TRTvsCTRL 0.120915 0.08478989 -0.04527011  0.2871002 0.1538525


$Disdur_less_equal_12wk$`Oral candidiasis`
$Disdur_less_equal_12wk$`Oral candidiasis`$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3

$Disdur_less_equal_12wk$`Oral candidiasis`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495


$Disdur_less_equal_12wk$`Oxygen saturation decreased`
$Disdur_less_equal_12wk$`Oxygen saturation decreased`$ntab
```

```
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         18  34
n_event        8  14
n_event_pct   44  41

$Disdur_less_equal_12wk$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92647059 0.3338581  0.4815607 1.7824288 0.8190564
OR_TRTvsCTRL   0.87500000 0.5885818  0.2760618 2.7733828 0.8205251
ARR_TRTvsCTRL -0.03267974 0.1443654 -0.3156308 0.2502713 0.8209151


$Disdur_less_equal_12wk$Rash
$Disdur_less_equal_12wk$Rash$ntab
            CTRL TRT
n_all         18  34
n_event        2   3
n_event_pct   11   9

$Disdur_less_equal_12wk$Rash$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.86508151  0.1457223 4.3275646 0.7898725
OR_TRTvsCTRL   0.77419355 0.96337500  0.1171718 5.1153557 0.7904985
ARR_TRTvsCTRL -0.02287582 0.08861794 -0.1965638 0.1508122 0.7962990


$Disdur_less_equal_12wk$`Respiratory distress`
$Disdur_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3

$Disdur_less_equal_12wk$`Respiratory distress`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495
```

```
$Disdur_less_equal_12wk$`Staphylococcal infection`
$Disdur_less_equal_12wk$`Staphylococcal infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Staphylococcal infection`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Stoma site erythema`
$Disdur_less_equal_12wk$`Stoma site erythema`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Stoma site erythema`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Stoma site infection`
$Disdur_less_equal_12wk$`Stoma site infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Stoma site infection`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$Tachycardia
$Disdur_less_equal_12wk$Tachycardia$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3

$Disdur_less_equal_12wk$Tachycardia$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495
```

```
$Disdur_less_equal_12wk$Teething
$Disdur_less_equal_12wk$Teething$ntab
            CTRL TRT
n_all         18  34
n_event        2   5
n_event_pct   11  15

$Disdur_less_equal_12wk$Teething$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.32352941 0.78424019  0.2845687 6.1557370 0.7207785
OR_TRTvsCTRL  1.37931034 0.89273891  0.2397515 7.9352887 0.7186816
ARR_TRTvsCTRL 0.03594771 0.09579228 -0.1518017 0.2236971 0.7074617


$Disdur_less_equal_12wk$`Upper respiratory tract congestion`
$Disdur_less_equal_12wk$`Upper respiratory tract congestion`$ntab
            CTRL TRT
n_all         18  34
n_event        0   4
n_event_pct    0  12

$Disdur_less_equal_12wk$`Upper respiratory tract congestion`$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.8857143 1.46322220 0.277607419  85.985469 0.27830946
OR_TRTvsCTRL  5.4590164 1.51956019 0.277755343 107.291761 0.26401687
ARR_TRTvsCTRL 0.1176471 0.05525508 0.009349083   0.225945 0.03324081


$Disdur_less_equal_12wk$`Upper respiratory tract infection`
$Disdur_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         18  34
n_event        4   2
n_event_pct   22   6

$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2647059 0.8154954  0.05353190 1.30892421 0.10313299
OR_TRTvsCTRL   0.2187500 0.9234060  0.03580498 1.33644977 0.09978616
ARR_TRTvsCTRL -0.1633987 0.1059742 -0.37110428 0.04430689 0.12310455


$Disdur_less_equal_12wk$Vomiting
$Disdur_less_equal_12wk$Vomiting$ntab
            CTRL TRT
n_all         18  34
n_event        3   6
n_event_pct   17  18

$Disdur_less_equal_12wk$Vomiting$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 0.6442303  0.2995393 3.7427723 0.9293016
```

```
OR_TRTvsCTRL  1.071428571 0.7761320  0.2340553 4.9046500 0.9291668
ARR_TRTvsCTRL 0.009803922 0.1095008 -0.2048137 0.2244215 0.9286584



$Region_Northamerica
$Region_Northamerica$`Bacterial tracheitis`
$Region_Northamerica$`Bacterial tracheitis`$ntab
            CTRL TRT
n_all         22  38
n_event        3   0
n_event_pct   14   0

$Region_Northamerica$`Bacterial tracheitis`$stats
                  estimate       se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08424908 1.488823  0.004552778 1.559028057 0.09657297
OR_TRTvsCTRL   0.07235622 1.537196  0.003556416 1.472106135 0.08756107
ARR_TRTvsCTRL -0.13636364 0.073165 -0.279764411 0.007037138 0.06235229


$Region_Northamerica$Constipation
$Region_Northamerica$Constipation$ntab
            CTRL TRT
n_all         22  38
n_event        4  14
n_event_pct   18  37

$Region_Northamerica$Constipation$stats
               estimate        se      lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  2.0263158 0.4996581  0.76102227 5.395316 0.1575367
OR_TRTvsCTRL  2.6250000 0.6470323  0.73854067 9.330055 0.1358172
ARR_TRTvsCTRL 0.1866029 0.1135129 -0.03587829 0.409084 0.1001986


$Region_Northamerica$Cough
$Region_Northamerica$Cough$ntab
            CTRL TRT
n_all         22  38
n_event        6   5
n_event_pct   27  13

$Region_Northamerica$Cough$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4824561 0.5430436  0.1664249 1.39861240 0.1795358
OR_TRTvsCTRL   0.4040404 0.6778419  0.1070150 1.52547433 0.1812391
ARR_TRTvsCTRL -0.1411483 0.1096484 -0.3560553 0.07375863 0.1979964


$Region_Northamerica$`Dermatitis contact`
$Region_Northamerica$`Dermatitis contact`$ntab
            CTRL TRT
n_all         22  38
n_event        3   2
n_event_pct   14   5
```

```
$Region_Northamerica$`Dermatitis contact`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.38596491 0.87267577  0.06977902 2.13486682 0.2753134
OR_TRTvsCTRL   0.35185185 0.95589889  0.05403775 2.29098609 0.2745098
ARR_TRTvsCTRL -0.08373206 0.08164106 -0.24374559 0.07628148 0.3050745


$Region_Northamerica$`Dermatitis diaper`
$Region_Northamerica$`Dermatitis diaper`$ntab
            CTRL TRT
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$`Dermatitis diaper`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$Diarrhoea
$Region_Northamerica$Diarrhoea$ntab
            CTRL TRT
n_all         22  38
n_event        6   6
n_event_pct   27  16

$Region_Northamerica$Diarrhoea$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.5789474 0.5114323  0.2124746 1.577506 0.2852260
OR_TRTvsCTRL   0.5000000 0.6535161  0.1388980 1.799882 0.2888523
ARR_TRTvsCTRL -0.1148325 0.1118697 -0.3340931 0.104428 0.3046632


$Region_Northamerica$Dysphagia
$Region_Northamerica$Dysphagia$ntab
            CTRL TRT
n_all         22  38
n_event        4   6
n_event_pct   18  16

$Region_Northamerica$Dysphagia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.86842105 0.5872788  0.2746868 2.7455093 0.8101564
OR_TRTvsCTRL   0.84375000 0.7095578  0.2100086 3.3899278 0.8107617
ARR_TRTvsCTRL -0.02392344 0.1012960 -0.2224600 0.1746131 0.8132980


$Region_Northamerica$`Feeding tube complication`
$Region_Northamerica$`Feeding tube complication`$ntab
            CTRL TRT
n_all         22  38
```

```
n_event        3   1
n_event_pct   14   3

$Region_Northamerica$`Feeding tube complication`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1929825 1.12319322  0.02135276 1.74414115 0.1429992
OR_TRTvsCTRL   0.1711712 1.18869337  0.01665762 1.75892879 0.1375702
ARR_TRTvsCTRL -0.1100478 0.07763643 -0.26221244 0.04211675 0.1563435


$Region_Northamerica$`Gastrooesophageal reflux disease`
$Region_Northamerica$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         22  38
n_event        3   5
n_event_pct   14  13

$Region_Northamerica$`Gastrooesophageal reflux disease`$stats
                  estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.964912281 0.67938428  0.2547973 3.654103 0.9580712
OR_TRTvsCTRL   0.959595960 0.78502735  0.2060022 4.469973 0.9581008
ARR_TRTvsCTRL -0.004784689 0.09143367 -0.1839914 0.174422 0.9582661


$Region_Northamerica$`Nasal congestion`
$Region_Northamerica$`Nasal congestion`$ntab
            CTRL TRT
n_all         22  38
n_event        5   8
n_event_pct   23  21

$Region_Northamerica$`Nasal congestion`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92631579 0.5032193  0.3454761 2.4837056 0.8791074
OR_TRTvsCTRL   0.90666667 0.6458768  0.2556680 3.2152814 0.8794225
ARR_TRTvsCTRL -0.01674641 0.1111600 -0.2346159 0.2011231 0.8802506


$Region_Northamerica$Nasopharyngitis
$Region_Northamerica$Nasopharyngitis$ntab
            CTRL TRT
n_all         22  38
n_event        3   4
n_event_pct   14  11

$Region_Northamerica$Nasopharyngitis$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.77192982 0.7152363  0.1900061 3.1360869 0.7174084
OR_TRTvsCTRL   0.74509804 0.8157062  0.1506201 3.6859024 0.7183107
ARR_TRTvsCTRL -0.03110048 0.0884964 -0.2045502 0.1423493 0.7252642


$Region_Northamerica$`Oxygen saturation decreased`
$Region_Northamerica$`Oxygen saturation decreased`$ntab
```

```
            CTRL TRT
n_all         22  38
n_event        3   5
n_event_pct   14  13

$Region_Northamerica$`Oxygen saturation decreased`$stats
                  estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.964912281 0.67938428  0.2547973 3.654103 0.9580712
OR_TRTvsCTRL   0.959595960 0.78502735  0.2060022 4.469973 0.9581008
ARR_TRTvsCTRL -0.004784689 0.09143367 -0.1839914 0.174422 0.9582661


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$ntab
            CTRL TRT
n_all         22  38
n_event       11  18
n_event_pct   50  47

$Region_Northamerica$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94736842 0.2733026  0.5544767 1.6186558 0.8431787
OR_TRTvsCTRL   0.90000000 0.5360725  0.3147290 2.5736427 0.8441863
ARR_TRTvsCTRL -0.02631579 0.1338819 -0.2887195 0.2360879 0.8441721


$Region_Northamerica$Rash
$Region_Northamerica$Rash$ntab
            CTRL TRT
n_all         22  38
n_event        3   7
n_event_pct   14  18

$Region_Northamerica$Rash$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.35087719 0.63594036  0.3884208 4.698176 0.6362644
OR_TRTvsCTRL  1.43010753 0.74905281  0.3294381 6.208170 0.6329330
ARR_TRTvsCTRL 0.04784689 0.09647682 -0.1412442 0.236938 0.6199354


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$ntab
            CTRL TRT
n_all         22  38
n_event        4   2
n_event_pct   18   5

$Region_Northamerica$`Respiratory distress`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.2894737 0.82354700  0.05762416 1.45416460 0.1322452
OR_TRTvsCTRL   0.2500000 0.91287093  0.04177369 1.49615694 0.1288608
ARR_TRTvsCTRL -0.1291866 0.08985532 -0.30529979 0.04692658 0.1505141
```

```
$Region_Northamerica$Rhinorrhoea
$Region_Northamerica$Rhinorrhoea$ntab
            CTRL TRT
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$Rhinorrhoea$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$`Salivary hypersecretion`
$Region_Northamerica$`Salivary hypersecretion`$ntab
            CTRL TRT
n_all         22  38
n_event        0   4
n_event_pct    0  11

$Region_Northamerica$`Salivary hypersecretion`$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  5.3076923 1.46734554 0.299156849  94.169991 0.25531463
OR_TRTvsCTRL  5.8695652 1.51514097 0.301242051 114.365825 0.24278123
ARR_TRTvsCTRL 0.1052632 0.04978449 0.007687351   0.202839 0.03448312


$Region_Northamerica$Tachycardia
$Region_Northamerica$Tachycardia$ntab
            CTRL TRT
n_all         22  38
n_event        4   3
n_event_pct   18   8

$Region_Northamerica$Tachycardia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4342105 0.71523632  0.10687843 1.76404886 0.2434674
OR_TRTvsCTRL   0.3857143 0.81698245  0.07777661 1.91285673 0.2435863
ARR_TRTvsCTRL -0.1028708 0.09314171 -0.28542520 0.07968358 0.2693959


$Region_Northamerica$Teething
$Region_Northamerica$Teething$ntab
            CTRL TRT
n_all         22  38
n_event        1   6
n_event_pct    5  16

$Region_Northamerica$Teething$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.4736842 1.04637294  0.44680299 27.0062695 0.2340344
OR_TRTvsCTRL  3.9375000 1.11603571  0.44182394 35.0906884 0.2194288
ARR_TRTvsCTRL 0.1124402 0.07396792 -0.03253427  0.2574147 0.1284806
```

```
$Region_Northamerica$`Upper respiratory tract congestion`
$Region_Northamerica$`Upper respiratory tract congestion`$ntab
            CTRL TRT
n_all         22  38
n_event        0   5
n_event_pct    0  13

$Region_Northamerica$`Upper respiratory tract congestion`$stats
               estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  6.4871795 1.4535126 0.37568490 112.0180704 0.19829648
OR_TRTvsCTRL  7.3880597 1.5020364 0.38904039 140.3027247 0.18304564
ARR_TRTvsCTRL 0.1315789 0.0548361 0.02410216   0.2390557 0.01641771


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        1   9
n_event_pct    5  24

$Region_Northamerica$`Upper respiratory tract infection`$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  5.2105263 1.01948064 0.70647712 38.4295313 0.10541736
OR_TRTvsCTRL  6.5172414 1.09234286 0.76605487 55.4456823 0.08616358
ARR_TRTvsCTRL 0.1913876 0.08202881 0.03061405  0.3521611 0.01963897


$Region_Northamerica$Vomiting
$Region_Northamerica$Vomiting$ntab
            CTRL TRT
n_all         22  38
n_event        4   7
n_event_pct   18  18

$Region_Northamerica$Vomiting$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.013157895 0.5666452  0.3336936 3.0761423 0.9815950
OR_TRTvsCTRL  1.016129032 0.6933042  0.2611002 3.9544901 0.9815877
ARR_TRTvsCTRL 0.002392344 0.1035205 -0.2005041 0.2052888 0.9815626



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$Constipation
$Agetrt_greater_equal_180d$Constipation$ntab
            CTRL TRT
n_all         25  31
n_event        4  13
n_event_pct   16  42

$Agetrt_greater_equal_180d$Constipation$stats
```

```
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.6209677 0.5046435 0.97478400  7.0471734 0.05621628
OR_TRTvsCTRL  3.7916667 0.6558183 1.04856795 13.7108293 0.04212544
ARR_TRTvsCTRL 0.2593548 0.1150249 0.03391023  0.4847994 0.02414766


$Agetrt_greater_equal_180d$Cough
$Agetrt_greater_equal_180d$Cough$ntab
            CTRL TRT
n_all         25  31
n_event        4   2
n_event_pct   16   6

$Agetrt_greater_equal_180d$Cough$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.40322581 0.82325083  0.08031487 2.02442037 0.2699149
OR_TRTvsCTRL   0.36206897 0.91219614  0.06057990 2.16398411 0.2654043
ARR_TRTvsCTRL -0.09548387 0.08557393 -0.26320568 0.07223794 0.2645053


$Agetrt_greater_equal_180d$Diarrhoea
$Agetrt_greater_equal_180d$Diarrhoea$ntab
            CTRL TRT
n_all         25  31
n_event        3   3
n_event_pct   12  10

$Agetrt_greater_equal_180d$Diarrhoea$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80645161 0.77097899  0.1779589 3.6545745 0.7802366
OR_TRTvsCTRL   0.78571429 0.86477482  0.1442670 4.2791973 0.7803425
ARR_TRTvsCTRL -0.02322581 0.08392642 -0.1877186 0.1412669 0.7819797


$Agetrt_greater_equal_180d$Dysphagia
$Agetrt_greater_equal_180d$Dysphagia$ntab
            CTRL TRT
n_all         25  31
n_event        3   4
n_event_pct   12  13

$Agetrt_greater_equal_180d$Dysphagia$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.075268817 0.71489529  0.2648482 4.3655304 0.9191438
OR_TRTvsCTRL  1.086419753 0.81598095  0.2194994 5.3772707 0.9190897
ARR_TRTvsCTRL 0.009032258 0.08859603 -0.1646128 0.1826773 0.9187973


$Agetrt_greater_equal_180d$`Gastrooesophageal reflux disease`
$Agetrt_greater_equal_180d$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         25  31
n_event        2   6
n_event_pct    8  19
```

```
$Agetrt_greater_equal_180d$`Gastrooesophageal reflux disease`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.4193548 0.77097899  0.53387682 10.9637235 0.2518172
OR_TRTvsCTRL  2.7600000 0.86610907  0.50544709 15.0710136 0.2411271
ARR_TRTvsCTRL 0.1135484 0.08932568 -0.06152674  0.2886235 0.2036671


$Agetrt_greater_equal_180d$`Nasal congestion`
$Agetrt_greater_equal_180d$`Nasal congestion`$ntab
            CTRL TRT
n_all         25  31
n_event        3   2
n_event_pct   12   6

$Agetrt_greater_equal_180d$`Nasal congestion`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.53763441 0.87239628  0.09725277 2.97215952 0.4768692
OR_TRTvsCTRL   0.50574713 0.95565194  0.07771073 3.29143917 0.4756265
ARR_TRTvsCTRL -0.05548387 0.07855506 -0.20944895 0.09848121 0.4799981


$Agetrt_greater_equal_180d$Pyrexia
$Agetrt_greater_equal_180d$Pyrexia$ntab
            CTRL TRT
n_all         25  31
n_event       12  13
n_event_pct   48  42

$Agetrt_greater_equal_180d$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.87365591 0.2966452  0.4884674 1.5625907 0.6488786
OR_TRTvsCTRL   0.78240741 0.5410499  0.2709508 2.2593083 0.6501707
ARR_TRTvsCTRL -0.06064516 0.1335617 -0.3224212 0.2011309 0.6497849


$Agetrt_greater_equal_180d$`Upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        2   5
n_event_pct    8  16

$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.01612903 0.79230167  0.42668750  9.5263542 0.3761618
OR_TRTvsCTRL  2.21153846 0.88427360  0.39084040 12.5138098 0.3694203
ARR_TRTvsCTRL 0.08129032 0.08548529 -0.08625776  0.2488384 0.3416411


$Agetrt_greater_equal_180d$Vomiting
$Agetrt_greater_equal_180d$Vomiting$ntab
            CTRL TRT
n_all         25  31
```

```
n_event        4   5
n_event_pct   16  16

$Agetrt_greater_equal_180d$Vomiting$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.008064516 0.61460714  0.3022274 3.3623496 0.9895729
OR_TRTvsCTRL  1.009615385 0.73217524  0.2403960 4.2401835 0.9895720
ARR_TRTvsCTRL 0.001290323 0.09869009 -0.1921387 0.1947193 0.9895684



$Gender_Male
$Gender_Male$Constipation
$Gender_Male$Constipation$ntab
            CTRL TRT
n_all         17  37
n_event        1   8
n_event_pct    6  22

$Gender_Male$Constipation$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.6756757 1.01938680  0.49846374 27.1044625 0.20160916
OR_TRTvsCTRL  4.4137931 1.10543329  0.50566797 38.5264057 0.17923169
ARR_TRTvsCTRL 0.1573927 0.08852598 -0.01611504  0.3309004 0.07541592


$Gender_Male$Cough
$Gender_Male$Cough$ntab
            CTRL TRT
n_all         17  37
n_event        2   2
n_event_pct   12   5

$Gender_Male$Cough$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.95611163  0.07053481 2.9928909 0.4159867
OR_TRTvsCTRL   0.4285714 1.04653624  0.05510740 3.3330089 0.4181580
ARR_TRTvsCTRL -0.0635930 0.08653439 -0.23319729 0.1060113 0.4624083


$Gender_Male$`Dermatitis contact`
$Gender_Male$`Dermatitis contact`$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$`Dermatitis contact`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963
```

```
$Gender_Male$Diarrhoea
$Gender_Male$Diarrhoea$ntab
            CTRL TRT
n_all         17  37
n_event        3   2
n_event_pct   18   5

$Gender_Male$Diarrhoea$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3063063 0.8645709  0.05626417 1.66755432 0.1711540
OR_TRTvsCTRL   0.2666667 0.9660918  0.04014486 1.77136292 0.1712660
ARR_TRTvsCTRL -0.1224165 0.0996529 -0.31773262 0.07289956 0.2192859


$Gender_Male$Erythema
$Gender_Male$Erythema$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$Erythema$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$`Feeding tube complication`
$Gender_Male$`Feeding tube complication`$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$`Feeding tube complication`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$`Gastrooesophageal reflux disease`
$Gender_Male$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         17  37
n_event        2   3
n_event_pct   12   8

$Gender_Male$`Gastrooesophageal reflux disease`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.86457086  0.1265944 3.7519972 0.6667969
OR_TRTvsCTRL   0.66176471 0.96406004  0.1000217 4.3783754 0.6684793
ARR_TRTvsCTRL -0.03656598 0.09011076 -0.2131798 0.1400479 0.6848975
```

```
$Gender_Male$Hypersensitivity
$Gender_Male$Hypersensitivity$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$Hypersensitivity$stats
                  estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$`Nasal congestion`
$Gender_Male$`Nasal congestion`$ntab
            CTRL TRT
n_all         17  37
n_event        3   3
n_event_pct   18   8

$Gender_Male$`Nasal congestion`$stats
                  estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.45945946 0.7621129  0.10316574 2.0462510 0.3075111
OR_TRTvsCTRL   0.41176471 0.8760748  0.07394911 2.2927955 0.3111477
ARR_TRTvsCTRL -0.09538951 0.1027738 -0.29682241 0.1060434 0.3533296


$Gender_Male$Nasopharyngitis
$Gender_Male$Nasopharyngitis$ntab
            CTRL TRT
n_all         17  37
n_event        1   7
n_event_pct    6  19

$Gender_Male$Nasopharyngitis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.2162162 1.02810826  0.42876359 24.1252916 0.2558448
OR_TRTvsCTRL  3.7333333 1.11296472  0.42144361 33.0715126 0.2365727
ARR_TRTvsCTRL 0.1303657 0.08603791 -0.03826554  0.2989969 0.1297187


$Gender_Male$`Oral candidiasis`
$Gender_Male$`Oral candidiasis`$ntab
            CTRL TRT
n_all         17  37
n_event        2   2
n_event_pct   12   5

$Gender_Male$`Oral candidiasis`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.95611163  0.07053481 2.9928909 0.4159867
```

```
OR_TRTvsCTRL   0.4285714 1.04653624  0.05510740 3.3330089 0.4181580
ARR_TRTvsCTRL -0.0635930 0.08653439 -0.23319729 0.1060113 0.4624083


$Gender_Male$`Oxygen saturation decreased`
$Gender_Male$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         17  37
n_event        2   3
n_event_pct   12   8

$Gender_Male$`Oxygen saturation decreased`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.86457086  0.1265944 3.7519972 0.6667969
OR_TRTvsCTRL   0.66176471 0.96406004  0.1000217 4.3783754 0.6684793
ARR_TRTvsCTRL -0.03656598 0.09011076 -0.2131798 0.1400479 0.6848975


$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$ntab
            CTRL TRT
n_all         17  37
n_event        7  13
n_event_pct   41  35

$Gender_Male$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85328185 0.3659640  0.4164697 1.7482424 0.6646120
OR_TRTvsCTRL   0.77380952 0.6012045  0.2381704 2.5140870 0.6697244
ARR_TRTvsCTRL -0.06041335 0.1428547 -0.3404035 0.2195767 0.6723677


$Gender_Male$Rash
$Gender_Male$Rash$ntab
            CTRL TRT
n_all         17  37
n_event        3   3
n_event_pct   18   8

$Gender_Male$Rash$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.45945946 0.7621129  0.10316574 2.0462510 0.3075111
OR_TRTvsCTRL   0.41176471 0.8760748  0.07394911 2.2927955 0.3111477
ARR_TRTvsCTRL -0.09538951 0.1027738 -0.29682241 0.1060434 0.3533296


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$`Respiratory distress`$stats
```

```
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$Tachycardia
$Gender_Male$Tachycardia$ntab
            CTRL TRT
n_all         17  37
n_event        2   3
n_event_pct   12   8

$Gender_Male$Tachycardia$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.86457086  0.1265944 3.7519972 0.6667969
OR_TRTvsCTRL   0.66176471 0.96406004  0.1000217 4.3783754 0.6684793
ARR_TRTvsCTRL -0.03656598 0.09011076 -0.2131798 0.1400479 0.6848975


$Gender_Male$Tachypnoea
$Gender_Male$Tachypnoea$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$Tachypnoea$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$Teething
$Gender_Male$Teething$ntab
            CTRL TRT
n_all         17  37
n_event        1   7
n_event_pct    6  19

$Gender_Male$Teething$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.2162162 1.02810826  0.42876359 24.1252916 0.2558448
OR_TRTvsCTRL  3.7333333 1.11296472  0.42144361 33.0715126 0.2365727
ARR_TRTvsCTRL 0.1303657 0.08603791 -0.03826554  0.2989969 0.1297187


$Gender_Male$`Upper respiratory tract infection`
$Gender_Male$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         17  37
n_event        3   6
n_event_pct   18  16
```

```
$Gender_Male$`Upper respiratory tract infection`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.91891892 0.6435444  0.2603102 3.2438683 0.8954642
OR_TRTvsCTRL   0.90322581 0.7769727  0.1969863 4.1414911 0.8957761
ARR_TRTvsCTRL -0.01430843 0.1105477 -0.2309779 0.2023611 0.8970157


$Gender_Male$Vomiting
$Gender_Male$Vomiting$ntab
            CTRL TRT
n_all         17  37
n_event        3   4
n_event_pct   18  11

$Gender_Male$Vomiting$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.61261261 0.7053246  0.1537491 2.4409524 0.4872136
OR_TRTvsCTRL   0.56565657 0.8276865  0.1116927 2.8647113 0.4912095
ARR_TRTvsCTRL -0.06836248 0.1056159 -0.2753658 0.1386408 0.5174542



$Disdur_greater_12wk
$Disdur_greater_12wk$Constipation
$Disdur_greater_12wk$Constipation$ntab
            CTRL TRT
n_all         23  46
n_event        6  18
n_event_pct   26  39

$Disdur_greater_12wk$Constipation$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.5000000 0.3962384  0.68994197 3.2611438 0.3061727
OR_TRTvsCTRL  1.8214286 0.5628144  0.60442674 5.4888406 0.2866960
ARR_TRTvsCTRL 0.1304348 0.1164529 -0.09780866 0.3586782 0.2626861


$Disdur_greater_12wk$Cough
$Disdur_greater_12wk$Cough$ntab
            CTRL TRT
n_all         23  46
n_event        3   3
n_event_pct   13   7

$Disdur_greater_12wk$Cough$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 0.77553161  0.10935441 2.28614465 0.3714448
OR_TRTvsCTRL   0.46511628 0.86018747  0.08617249 2.51046656 0.3735277
ARR_TRTvsCTRL -0.06521739 0.07909916 -0.22024891 0.08981412 0.4096546


$Disdur_greater_12wk$Diarrhoea
$Disdur_greater_12wk$Diarrhoea$ntab
```

```
            CTRL TRT
n_all         23  46
n_event        2   5
n_event_pct    9  11

$Disdur_greater_12wk$Diarrhoea$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.25000000 0.79673246  0.2622588 5.9578547 0.7794212
OR_TRTvsCTRL  1.28048780 0.87864059  0.2288101 7.1659814 0.7784109
ARR_TRTvsCTRL 0.02173913 0.07455244 -0.1243810 0.1678592 0.7705962


$Disdur_greater_12wk$`Gastrooesophageal reflux disease`
$Disdur_greater_12wk$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all         23  46
n_event        2   7
n_event_pct    9  15

$Disdur_greater_12wk$`Gastrooesophageal reflux disease`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.75000000 0.76002615  0.39455052 7.7619972 0.4615413
OR_TRTvsCTRL  1.88461538 0.84623709  0.35884295 9.8978542 0.4539340
ARR_TRTvsCTRL 0.06521739 0.07909916 -0.08981412 0.2202489 0.4096546


$Disdur_greater_12wk$Nasopharyngitis
$Disdur_greater_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all         23  46
n_event        2   6
n_event_pct    9  13

$Disdur_greater_12wk$Nasopharyngitis$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.50000000 0.77553161  0.3280632 6.8584340 0.6010980
OR_TRTvsCTRL  1.57500000 0.85981726  0.2920134 8.4949012 0.5972800
ARR_TRTvsCTRL 0.04347826 0.07692624 -0.1072944 0.1942509 0.5719417


$Disdur_greater_12wk$`Oral candidiasis`
$Disdur_greater_12wk$`Oral candidiasis`$ntab
            CTRL TRT
n_all         23  46
n_event        1   5
n_event_pct    4  11

$Disdur_greater_12wk$`Oral candidiasis`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.50000000 1.06526176  0.30987573 20.1693759 0.3897033
OR_TRTvsCTRL  2.68292683 1.12687390  0.29472164 24.4233724 0.3811426
ARR_TRTvsCTRL 0.06521739 0.06256418 -0.05740614  0.1878409 0.2972226
```

```
$Disdur_greater_12wk$`Oxygen saturation decreased`
$Disdur_greater_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         23  46
n_event        3   3
n_event_pct   13   7

$Disdur_greater_12wk$`Oxygen saturation decreased`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 0.77553161  0.10935441 2.28614465 0.3714448
OR_TRTvsCTRL   0.46511628 0.86018747  0.08617249 2.51046656 0.3735277
ARR_TRTvsCTRL -0.06521739 0.07909916 -0.22024891 0.08981412 0.4096546


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$ntab
            CTRL TRT
n_all         23  46
n_event       11  20
n_event_pct   48  43

$Disdur_greater_12wk$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90909091 0.2751212  0.5301804 1.5588020 0.7290198
OR_TRTvsCTRL   0.83916084 0.5125465  0.3073016 2.2915304 0.7322599
ARR_TRTvsCTRL -0.04347826 0.1272452 -0.2928742 0.2059177 0.7325851


$Disdur_greater_12wk$Rash
$Disdur_greater_12wk$Rash$ntab
            CTRL TRT
n_all         23  46
n_event        2   5
n_event_pct    9  11

$Disdur_greater_12wk$Rash$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.25000000 0.79673246  0.2622588 5.9578547 0.7794212
OR_TRTvsCTRL  1.28048780 0.87864059  0.2288101 7.1659814 0.7784109
ARR_TRTvsCTRL 0.02173913 0.07455244 -0.1243810 0.1678592 0.7705962


$Disdur_greater_12wk$`Respiratory tract congestion`
$Disdur_greater_12wk$`Respiratory tract congestion`$ntab
            CTRL TRT
n_all         23  46
n_event        3   0
n_event_pct   13   0

$Disdur_greater_12wk$`Respiratory tract congestion`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.07294833 1.49089605  0.003926109 1.355402742 0.07908950
OR_TRTvsCTRL   0.06298003 1.53492676  0.003109359 1.275659867 0.07164801
ARR_TRTvsCTRL -0.13043478 0.07022373 -0.268070757 0.007201192 0.06325177
```

```
$Disdur_greater_12wk$Rhinitis
$Disdur_greater_12wk$Rhinitis$ntab
            CTRL TRT
n_all         23  46
n_event        3   0
n_event_pct   13   0

$Disdur_greater_12wk$Rhinitis$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.07294833 1.49089605  0.003926109 1.355402742 0.07908950
OR_TRTvsCTRL   0.06298003 1.53492676  0.003109359 1.275659867 0.07164801
ARR_TRTvsCTRL -0.13043478 0.07022373 -0.268070757 0.007201192 0.06325177


$Disdur_greater_12wk$Tachycardia
$Disdur_greater_12wk$Tachycardia$ntab
            CTRL TRT
n_all         23  46
n_event        3   2
n_event_pct   13   4

$Disdur_greater_12wk$Tachycardia$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.33333333 0.87642224  0.05982281 1.85733699 0.2100167
OR_TRTvsCTRL   0.30303030 0.95187216  0.04690844 1.95758717 0.2097371
ARR_TRTvsCTRL -0.08695652 0.07639016 -0.23667848 0.06276544 0.2549865


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         23  46
n_event        1  10
n_event_pct    4  22

$Disdur_greater_12wk$`Upper respiratory tract infection`$stats
              estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  5.000000 1.01724265 0.68091279 36.7154214 0.11361366
OR_TRTvsCTRL  6.111111 1.08315849 0.73136471 51.0630042 0.09469419
ARR_TRTvsCTRL 0.173913 0.07420713 0.02846974  0.3193563 0.01909781


$Disdur_greater_12wk$Vomiting
$Disdur_greater_12wk$Vomiting$ntab
            CTRL TRT
n_all         23  46
n_event        3   6
n_event_pct   13  13

$Disdur_greater_12wk$Vomiting$stats
              estimate         se     lo95ci   hi95ci pvalue
RR_TRTvsCTRL         1 0.65938047  0.2746214 3.641377      1
```

```
OR_TRTvsCTRL         1 0.75828754  0.2262270 4.420339      1
ARR_TRTvsCTRL        0 0.08600615 -0.1685690 0.168569      1



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem milden UE nach PT, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$Constipation
$Ageonset_less_equal_12wk$Constipation$ntab
            CTRL TRT
n_all         32  72
n_event        7  22
n_event_pct   22  31

$Ageonset_less_equal_12wk$Constipation$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39682540 0.37838182  0.66536957 2.9323872 0.3771064
OR_TRTvsCTRL  1.57142857 0.49830883  0.59174337 4.1730721 0.3643866
ARR_TRTvsCTRL 0.08680556 0.09103669 -0.09162307 0.2652342 0.3403253


$Ageonset_less_equal_12wk$Nasopharyngitis
$Ageonset_less_equal_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all         32  72
n_event        1  11
n_event_pct    3  15

$Ageonset_less_equal_12wk$Nasopharyngitis$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.8888889 1.02262906 0.65878959 36.2805285 0.12069855
OR_TRTvsCTRL  5.5901639 1.06750204 0.68986667 45.2985108 0.10692213
ARR_TRTvsCTRL 0.1215278 0.05238108 0.01886275  0.2241928 0.02033708


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         32  72
n_event       15  31
n_event_pct   47  43

$Ageonset_less_equal_12wk$Pyrexia$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.91851852 0.2319177  0.5830143 1.4470937 0.7140069
OR_TRTvsCTRL   0.85691057 0.4267769  0.3712465 1.9779196 0.7174772
ARR_TRTvsCTRL -0.03819444 0.1057697 -0.2454992 0.1691103 0.7180175
```

```
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        4  11
n_event_pct   12  15

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.22222222 0.54384759  0.4209459 3.548739 0.7121401
OR_TRTvsCTRL  1.26229508 0.62691054  0.3694313 4.313086 0.7102244
ARR_TRTvsCTRL 0.02777778 0.07221981 -0.1137705 0.169326 0.7005129


$Ageonset_less_equal_12wk$Vomiting
$Ageonset_less_equal_12wk$Vomiting$ntab
            CTRL TRT
n_all         32  72
n_event        4  10
n_event_pct   12  14

$Ageonset_less_equal_12wk$Vomiting$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.11111111 0.55214229  0.3765071 3.2790034 0.8486656
OR_TRTvsCTRL  1.12903226 0.63391113  0.3259269 3.9110420 0.8481748
ARR_TRTvsCTRL 0.01388889 0.07126754 -0.1257929 0.1535707 0.8454839



$Agetrt_less_180d
$Agetrt_less_180d$Constipation
$Agetrt_less_180d$Constipation$ntab
            CTRL TRT
n_all         16  49
n_event        4  12
n_event_pct   25  24

$Agetrt_less_180d$Constipation$stats
                   estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.979591837 0.5004250  0.3673522 2.6122076 0.9671336
OR_TRTvsCTRL   0.972972973 0.6661034  0.2637015 3.5899549 0.9671897
ARR_TRTvsCTRL -0.005102041 0.1244696 -0.2490580 0.2388539 0.9673037


$Agetrt_less_180d$Nasopharyngitis
$Agetrt_less_180d$Nasopharyngitis$ntab
            CTRL TRT
n_all         16  49
n_event        1  10
n_event_pct    6  20

$Agetrt_less_180d$Nasopharyngitis$stats
                estimate         se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  3.2653061 1.00850971  0.45235446 23.570507 0.24064807
```

```
OR_TRTvsCTRL  3.8461538 1.09192843  0.45245510 32.694735 0.21732784
ARR_TRTvsCTRL 0.1415816 0.08352877 -0.02213174  0.305295 0.09007457


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$ntab
            CTRL TRT
n_all         16  49
n_event        7  21
n_event_pct   44  43

$Agetrt_less_180d$Pyrexia$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.979591837 0.3279757  0.5150765 1.8630244 0.9498713
OR_TRTvsCTRL   0.964285714 0.5807767  0.3089212 3.0099811 0.9500699
ARR_TRTvsCTRL -0.008928571 0.1427543 -0.2887218 0.2708646 0.9501288



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$Constipation
$Agetrt_greater_equal_180d$Constipation$ntab
            CTRL TRT
n_all         25  31
n_event        4  13
n_event_pct   16  42

$Agetrt_greater_equal_180d$Constipation$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.6209677 0.5046435 0.97478400  7.0471734 0.05621628
OR_TRTvsCTRL  3.7916667 0.6558183 1.04856795 13.7108293 0.04212544
ARR_TRTvsCTRL 0.2593548 0.1150249 0.03391023  0.4847994 0.02414766


$Agetrt_greater_equal_180d$Pyrexia
$Agetrt_greater_equal_180d$Pyrexia$ntab
            CTRL TRT
n_all         25  31
n_event       12  13
n_event_pct   48  42

$Agetrt_greater_equal_180d$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.87365591 0.2966452  0.4884674 1.5625907 0.6488786
OR_TRTvsCTRL   0.78240741 0.5410499  0.2709508 2.2593083 0.6501707
ARR_TRTvsCTRL -0.06064516 0.1335617 -0.3224212 0.2011309 0.6497849



$Gender_Female
$Gender_Female$Constipation
$Gender_Female$Constipation$ntab
            CTRL TRT
n_all         24  43
```

```
n_event        7  17
n_event_pct   29  40

$Gender_Female$Constipation$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3554817 0.3698083  0.6566172 2.7981763 0.4108084
OR_TRTvsCTRL  1.5879121 0.5467776  0.5437616 4.6370779 0.3977097
ARR_TRTvsCTRL 0.1036822 0.1190272 -0.1296069 0.3369712 0.3837107


$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$ntab
            CTRL TRT
n_all         24  43
n_event       12  21
n_event_pct   50  49

$Gender_Female$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.97674419 0.2569628  0.5902740 1.6162480 0.9270384
OR_TRTvsCTRL   0.95454545 0.5096472  0.3515476 2.5918454 0.9272710
ARR_TRTvsCTRL -0.01162791 0.1273871 -0.2613021 0.2380462 0.9272700



$Region_Northamerica
$Region_Northamerica$Constipation
$Region_Northamerica$Constipation$ntab
            CTRL TRT
n_all         22  38
n_event        4  14
n_event_pct   18  37

$Region_Northamerica$Constipation$stats
               estimate        se      lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  2.0263158 0.4996581  0.76102227 5.395316 0.1575367
OR_TRTvsCTRL  2.6250000 0.6470323  0.73854067 9.330055 0.1358172
ARR_TRTvsCTRL 0.1866029 0.1135129 -0.03587829 0.409084 0.1001986


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$ntab
            CTRL TRT
n_all         22  38
n_event       11  18
n_event_pct   50  47

$Region_Northamerica$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94736842 0.2733026  0.5544767 1.6186558 0.8431787
OR_TRTvsCTRL   0.90000000 0.5360725  0.3147290 2.5736427 0.8441863
ARR_TRTvsCTRL -0.02631579 0.1338819 -0.2887195 0.2360879 0.8441721
```

```
$Disdur_greater_12wk
$Disdur_greater_12wk$Constipation
$Disdur_greater_12wk$Constipation$ntab
            CTRL TRT
n_all         23  46
n_event        6  18
n_event_pct   26  39

$Disdur_greater_12wk$Constipation$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.5000000 0.3962384  0.68994197 3.2611438 0.3061727
OR_TRTvsCTRL  1.8214286 0.5628144  0.60442674 5.4888406 0.2866960
ARR_TRTvsCTRL 0.1304348 0.1164529 -0.09780866 0.3586782 0.2626861


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$ntab
            CTRL TRT
n_all         23  46
n_event       11  20
n_event_pct   48  43

$Disdur_greater_12wk$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90909091 0.2751212  0.5301804 1.5588020 0.7290198
OR_TRTvsCTRL   0.83916084 0.5125465  0.3073016 2.2915304 0.7322599
ARR_TRTvsCTRL -0.04347826 0.1272452 -0.2928742 0.2059177 0.7325851


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         23  46
n_event        1  10
n_event_pct    4  22

$Disdur_greater_12wk$`Upper respiratory tract infection`$stats
              estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  5.000000 1.01724265 0.68091279 36.7154214 0.11361366
OR_TRTvsCTRL  6.111111 1.08315849 0.73136471 51.0630042 0.09469419
ARR_TRTvsCTRL 0.173913 0.07420713 0.02846974  0.3193563 0.01909781



$Gender_Male
$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$ntab
            CTRL TRT
n_all         17  37
n_event        7  13
n_event_pct   41  35

$Gender_Male$Pyrexia$stats
```

```
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85328185 0.3659640  0.4164697 1.7482424 0.6646120
OR_TRTvsCTRL   0.77380952 0.6012045  0.2381704 2.5140870 0.6697244
ARR_TRTvsCTRL -0.06041335 0.1428547 -0.3404035 0.2195767 0.6723677



$Region_Europe
$Region_Europe$Pyrexia
$Region_Europe$Pyrexia$ntab
            CTRL TRT
n_all         17  30
n_event        7  13
n_event_pct   41  43

$Region_Europe$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.05238095 0.3572441  0.5224999 2.1196284 0.8863581
OR_TRTvsCTRL  1.09243697 0.6153078  0.3270735 3.6487775 0.8857486
ARR_TRTvsCTRL 0.02156863 0.1497768 -0.2719886 0.3151258 0.8854964



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         18  34
n_event        8  14
n_event_pct   44  41

$Disdur_less_equal_12wk$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92647059 0.3338581  0.4815607 1.7824288 0.8190564
OR_TRTvsCTRL   0.87500000 0.5885818  0.2760618 2.7733828 0.8205251
ARR_TRTvsCTRL -0.03267974 0.1443654 -0.3156308 0.2502713 0.8209151



\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines milden UEs nach PT, das bei mindestens 10% der
Patienten in einem Studienarm auftrat"

$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Abdominal pain upper`
$Ageonset_greater_12wk$`Abdominal pain upper`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th                7.7                 NA
time-to-event-wk-25th                 NA                 NA
```

```
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            7.7                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Abdominal pain upper`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.900e+05 4.748e+04 0.000e+00       Inf 9.998e-01


$Ageonset_greater_12wk$Amblyopia
$Ageonset_greater_12wk$Amblyopia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                29.3                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           29.3                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Amblyopia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.113e-17 4.635e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$Atelectasis
$Ageonset_greater_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                15.3                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           15.3                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Bradycardia
$Ageonset_greater_12wk$Bradycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                 8.0
n_event                                 0                 1.0
```

```
n_event_pct                              0               12.0
time-to-event-wk-10th                   NA                2.1
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                2.1
time-to-event-wk-50th-hici              NA                 NA

$Ageonset_greater_12wk$Bradycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$Constipation
$Ageonset_greater_12wk$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                3.0
n_event_pct                          11.0               38.0
time-to-event-wk-10th                16.3                2.0
time-to-event-wk-25th                  NA                4.4
time-to-event-wk-50th                  NA               25.9
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.3                2.0
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 10.99000   1.24100   0.96580 125.10000   0.05337


$Ageonset_greater_12wk$Cough
$Ageonset_greater_12wk$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               2.0                  1
n_event_pct                          22.0                 12
time-to-event-wk-10th                 0.4                 12
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            0.4                 12
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.41000   1.29800   0.03222   5.21700   0.49210


$Ageonset_greater_12wk$`Dermatitis contact`
$Ageonset_greater_12wk$`Dermatitis contact`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                29.4                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           29.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Dermatitis contact`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.720e-10 4.298e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Dermatitis diaper`
$Ageonset_greater_12wk$`Dermatitis diaper`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                 7.9                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            7.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Dermatitis diaper`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Diarrhoea
$Ageonset_greater_12wk$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8.0
n_event                               1.0                 1.0
n_event_pct                          11.0                12.0
time-to-event-wk-10th                 8.1                28.0
time-to-event-wk-25th                  NA                35.9
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            8.1                28.0
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.70100   1.50800   0.08852  32.70000   0.72460
```

```
$Ageonset_greater_12wk$`Diarrhoea haemorrhagic`
$Ageonset_greater_12wk$`Diarrhoea haemorrhagic`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               9.0                  8
n_event                             1.0                  0
n_event_pct                        11.0                  0
time-to-event-wk-10th              34.6                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci         34.6                 NA
time-to-event-wk-50th-hici           NA                 NA

$Ageonset_greater_12wk$`Diarrhoea haemorrhagic`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.338e-10 4.693e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Drug hypersensitivity`
$Ageonset_greater_12wk$`Drug hypersensitivity`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               9.0                  8
n_event                             1.0                  0
n_event_pct                        11.0                  0
time-to-event-wk-10th              46.7                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci         46.7                 NA
time-to-event-wk-50th-hici           NA                 NA

$Ageonset_greater_12wk$`Drug hypersensitivity`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.970e+04 9.953e+04 0.000e+00       Inf 9.999e-01


$Ageonset_greater_12wk$Dysphagia
$Ageonset_greater_12wk$Dysphagia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               9                  8.0
n_event                             2                  1.0
n_event_pct                        22                 12.0
time-to-event-wk-10th               0                  1.7
time-to-event-wk-25th              NA                   NA
time-to-event-wk-50th              NA                   NA
time-to-event-wk-75th              NA                   NA
time-to-event-wk-90th              NA                   NA
time-to-event-wk-50th-loci          0                  1.7
time-to-event-wk-50th-hici         NA                   NA

$Ageonset_greater_12wk$Dysphagia$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9998    1.3130    0.0762   13.1200    0.9999


$Ageonset_greater_12wk$Dyspnoea
$Ageonset_greater_12wk$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                   8
n_event                                 1                   0
n_event_pct                            11                   0
time-to-event-wk-10th                   0                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci              0                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.943e-10 4.030e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Erythema
$Ageonset_greater_12wk$Erythema$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                   8
n_event                                 2                   0
n_event_pct                            22                   0
time-to-event-wk-10th                   0                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci              0                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Erythema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.776e-10 2.882e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$`Failure to thrive`
$Ageonset_greater_12wk$`Failure to thrive`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                 6.4                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            6.4                  NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Failure to thrive`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.345e-25 4.674e+04 0.000e+00       Inf 9.990e-01


$Ageonset_greater_12wk$`Fungal infection`
$Ageonset_greater_12wk$`Fungal infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                26.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Fungal infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.256e-09 4.032e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Fungal skin infection`
$Ageonset_greater_12wk$`Fungal skin infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                10.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           10.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Fungal skin infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Gastroenteritis viral`
$Ageonset_greater_12wk$`Gastroenteritis viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                38.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           38.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Gastroenteritis viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.095e+05 5.137e+04 0.000e+00       Inf 9.998e-01


$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`
$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                  8
n_event                                 2                  0
n_event_pct                            22                  0
time-to-event-wk-10th                   0                 NA
time-to-event-wk-25th                  43                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci              0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.901e-10 2.931e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$Hyperaemia
$Ageonset_greater_12wk$Hyperaemia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                30.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           30.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Hyperaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.187e-09 4.506e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Increased upper airway secretion`
$Ageonset_greater_12wk$`Increased upper airway secretion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                  8
n_event                                 1                  0
n_event_pct                            11                  0
```

```
time-to-event-wk-10th                   0                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci              0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Increased upper airway secretion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.423e-10 3.890e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Nasal congestion`
$Ageonset_greater_12wk$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                   8
n_event                                 2                   0
n_event_pct                            22                   0
time-to-event-wk-10th                   1                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci              1                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.872e-10 2.680e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$Nasopharyngitis
$Ageonset_greater_12wk$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8.0
n_event                               2.0                 1.0
n_event_pct                          22.0                12.0
time-to-event-wk-10th                10.6                24.1
time-to-event-wk-25th                42.3                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           10.6                24.1
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8139    1.3190    0.0614   10.7900    0.8759


$Ageonset_greater_12wk$Nystagmus
$Ageonset_greater_12wk$Nystagmus$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  9                  8
n_event                                1                  0
n_event_pct                           11                  0
time-to-event-wk-10th                 25                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            25                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$Nystagmus$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.718e-22 4.401e+04 0.000e+00       Inf 9.991e-01


$Ageonset_greater_12wk$`Oral candidiasis`
$Ageonset_greater_12wk$`Oral candidiasis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 1.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Oral candidiasis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.166e-10 4.053e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Oropharyngeal pain`
$Ageonset_greater_12wk$`Oropharyngeal pain`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 4.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            4.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Oropharyngeal pain`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.999e-10 4.033e+04 0.000e+00       Inf 9.996e-01
```

```
$Ageonset_greater_12wk$`Otitis media`
$Ageonset_greater_12wk$`Otitis media`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th                4.4                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           4.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Otitis media`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.948e-25 4.113e+04 0.000e+00       Inf 9.989e-01


$Ageonset_greater_12wk$`Pseudomonas infection`
$Ageonset_greater_12wk$`Pseudomonas infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               52.9                 NA
time-to-event-wk-25th               56.6                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          52.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Pseudomonas infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.522e-01 1.273e+05 0.000e+00       Inf 1.000e+00


$Ageonset_greater_12wk$Pyrexia
$Ageonset_greater_12wk$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              4.0                3.0
n_event_pct                         44.0               38.0
time-to-event-wk-10th                1.3                0.4
time-to-event-wk-25th                5.7                9.7
time-to-event-wk-50th               42.6                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           1.3                0.4
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   1.0420    0.7867    0.2230    4.8720    0.9579


$Ageonset_greater_12wk$`Respiratory tract infection`
$Ageonset_greater_12wk$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                   8
n_event                                 0                   1
n_event_pct                             0                  12
time-to-event-wk-10th                  NA                   3
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                   3
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.316e+09 4.526e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Restlessness
$Ageonset_greater_12wk$Restlessness$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                 8.0
n_event                                 0                 1.0
n_event_pct                             0                12.0
time-to-event-wk-10th                  NA                 2.3
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                 2.3
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Restlessness$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$Scoliosis
$Ageonset_greater_12wk$Scoliosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                 8.0
n_event                                 0                 1.0
n_event_pct                             0                12.0
time-to-event-wk-10th                  NA                31.9
time-to-event-wk-25th                  NA                31.9
time-to-event-wk-50th                  NA                37.8
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                31.9
time-to-event-wk-50th-hici             NA                  NA
```

```
$Ageonset_greater_12wk$Scoliosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.917e+13 5.755e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Seasonal allergy`
$Ageonset_greater_12wk$`Seasonal allergy`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                17.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Seasonal allergy`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.900e+05 4.748e+04 0.000e+00       Inf 9.998e-01


$Ageonset_greater_12wk$Sinusitis
$Ageonset_greater_12wk$Sinusitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                14.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           14.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Sinusitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.345e-25 4.674e+04 0.000e+00       Inf 9.990e-01


$Ageonset_greater_12wk$`Staphylococcal infection`
$Ageonset_greater_12wk$`Staphylococcal infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 2.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            2.3                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Staphylococcal infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.594e-10 4.064e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Stoma complication`
$Ageonset_greater_12wk$`Stoma complication`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                  8
n_event                                 1                  0
n_event_pct                            11                  0
time-to-event-wk-10th                  38                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             38                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Stoma complication`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.338e-10 4.693e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Stoma site erythema`
$Ageonset_greater_12wk$`Stoma site erythema`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 8.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Stoma site erythema`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.253e-10 4.403e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Stoma site infection`
$Ageonset_greater_12wk$`Stoma site infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                  8
n_event                                 1                  0
n_event_pct                            11                  0
time-to-event-wk-10th                  32                 NA
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             32                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Stoma site infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.114e-10 4.782e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Stoma site inflammation`
$Ageonset_greater_12wk$`Stoma site inflammation`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                37.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Stoma site inflammation`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.338e-10 4.693e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Strabismus
$Ageonset_greater_12wk$Strabismus$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                29.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           29.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Strabismus$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.113e-17 4.635e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$Teething
$Ageonset_greater_12wk$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
```

```
n_event                              1.0                 2
n_event_pct                         11.0                25
time-to-event-wk-10th                4.4                 0
time-to-event-wk-25th                 NA                16
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           4.4                 0
time-to-event-wk-50th-hici            NA                NA

$Ageonset_greater_12wk$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.0160    1.2420    0.2645   34.3900    0.3739


$Ageonset_greater_12wk$`Upper respiratory tract infection`
$Ageonset_greater_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                1.0
n_event_pct                          11.0               12.0
time-to-event-wk-10th                 2.7               17.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            2.7               17.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.8570    1.4640    0.1054   32.7400    0.6724


$Ageonset_greater_12wk$`Upper respiratory tract inflammation`
$Ageonset_greater_12wk$`Upper respiratory tract inflammation`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                  8
n_event                                 1                  0
n_event_pct                            11                  0
time-to-event-wk-10th                  33                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             33                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Upper respiratory tract inflammation`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.569e-09 4.770e+04 0.000e+00       Inf 9.997e-01


$Ageonset_greater_12wk$`Use of accessory respiratory muscles`
```

```
$Ageonset_greater_12wk$`Use of accessory respiratory muscles`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 2.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            2.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Use of accessory respiratory muscles`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.246e-02 4.449e+04 0.000e+00       Inf 1.000e+00


$Ageonset_greater_12wk$`Viral infection`
$Ageonset_greater_12wk$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               2.0                  0
n_event_pct                          22.0                  0
time-to-event-wk-10th                11.3                 NA
time-to-event-wk-25th                45.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           11.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.141e-09 3.399e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$Vomiting
$Ageonset_greater_12wk$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               2.0                2.0
n_event_pct                          22.0               25.0
time-to-event-wk-10th                 1.0                2.7
time-to-event-wk-25th                39.7               13.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.0                2.7
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.9520    1.1800    0.2920   29.8400    0.3591
```

```
$Region_Asia_Pacific
$Region_Asia_Pacific$Amblyopia
$Region_Asia_Pacific$Amblyopia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                12
n_event                              1.0                 0
n_event_pct                         50.0                 0
time-to-event-wk-10th               29.3                NA
time-to-event-wk-25th               29.3                NA
time-to-event-wk-50th               29.3                NA
time-to-event-wk-75th               29.3                NA
time-to-event-wk-90th               29.3                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$Amblyopia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.873e-12 2.762e+05 0.000e+00       Inf 9.999e-01


$Region_Asia_Pacific$Bronchiolitis
$Region_Asia_Pacific$Bronchiolitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 2               12.0
n_event                               0                2.0
n_event_pct                           0               17.0
time-to-event-wk-10th                NA                2.7
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                2.7
time-to-event-wk-50th-hici           NA                 NA

$Region_Asia_Pacific$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.337e+08 2.601e+04 0.000e+00       Inf 9.994e-01


$Region_Asia_Pacific$Constipation
$Region_Asia_Pacific$Constipation$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 2               12.0
n_event                               0                5.0
n_event_pct                           0               42.0
time-to-event-wk-10th                NA               17.7
time-to-event-wk-25th                NA               18.7
time-to-event-wk-50th                NA               35.0
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA               17.7
```

```
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.356e+08 1.773e+04 0.000e+00       Inf 9.991e-01


$Region_Asia_Pacific$Erythema
$Region_Asia_Pacific$Erythema$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0                12
n_event                               1.0                 0
n_event_pct                          50.0                 0
time-to-event-wk-10th                 7.6                NA
time-to-event-wk-25th                 7.6                NA
time-to-event-wk-50th                 7.6                NA
time-to-event-wk-75th                 7.6                NA
time-to-event-wk-90th                 7.6                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Asia_Pacific$Erythema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.266e-14 2.565e+06 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$`Gastrooesophageal reflux disease`
$Region_Asia_Pacific$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  2                12
n_event                                1                 0
n_event_pct                           50                 0
time-to-event-wk-10th                 43                NA
time-to-event-wk-25th                 43                NA
time-to-event-wk-50th                 43                NA
time-to-event-wk-75th                 43                NA
time-to-event-wk-90th                 43                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.398e-10 4.566e+04 0.000e+00       Inf 9.996e-01


$Region_Asia_Pacific$Nystagmus
$Region_Asia_Pacific$Nystagmus$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  2                12
n_event                                1                 0
n_event_pct                           50                 0
time-to-event-wk-10th                 25                NA
time-to-event-wk-25th                 25                NA
time-to-event-wk-50th                 25                NA
```

```
time-to-event-wk-75th                  25                 NA
time-to-event-wk-90th                  25                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Nystagmus$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.442e-14 1.625e+06 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$Pyrexia
$Region_Asia_Pacific$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0               12.0
n_event                              1.0                3.0
n_event_pct                         50.0               25.0
time-to-event-wk-10th                5.7                9.6
time-to-event-wk-25th                5.7               38.0
time-to-event-wk-50th                5.7                 NA
time-to-event-wk-75th                5.7                 NA
time-to-event-wk-90th                5.7                 NA
time-to-event-wk-50th-loci            NA                9.6
time-to-event-wk-50th-hici            NA                 NA

$Region_Asia_Pacific$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.066160  1.492000  0.003557  1.231000  0.068650


$Region_Asia_Pacific$`Stoma site erythema`
$Region_Asia_Pacific$`Stoma site erythema`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                12
n_event                              1.0                 0
n_event_pct                         50.0                 0
time-to-event-wk-10th                8.7                NA
time-to-event-wk-25th                8.7                NA
time-to-event-wk-50th                8.7                NA
time-to-event-wk-75th                8.7                NA
time-to-event-wk-90th                8.7                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Stoma site erythema`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.266e-14 2.565e+06 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$Strabismus
$Region_Asia_Pacific$Strabismus$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                12
n_event                              1.0                 0
n_event_pct                         50.0                 0
```

```
time-to-event-wk-10th                29.3                 NA
time-to-event-wk-25th                29.3                 NA
time-to-event-wk-50th                29.3                 NA
time-to-event-wk-75th                29.3                 NA
time-to-event-wk-90th                29.3                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Strabismus$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.873e-12 2.762e+05 0.000e+00       Inf 9.999e-01


$Region_Asia_Pacific$`Upper respiratory tract infection`
$Region_Asia_Pacific$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
n_event                                 0                2.0
n_event_pct                             0               17.0
time-to-event-wk-10th                  NA               21.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               21.7
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.767e+07 2.378e+04 0.000e+00       Inf 9.994e-01



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32               72.0
n_event                                 1                9.0
n_event_pct                             3               12.0
time-to-event-wk-10th                  NA               24.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.3610    1.0550    0.4253   26.5600    0.2504


$Ageonset_less_equal_12wk$Constipation
```

```
$Ageonset_less_equal_12wk$Constipation$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              7.0               22.0
n_event_pct                         22.0               31.0
time-to-event-wk-10th               11.3                7.9
time-to-event-wk-25th               20.0               19.7
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          20.0                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2120    0.4409    0.5109    2.8770    0.6621


$Ageonset_less_equal_12wk$Cough
$Ageonset_less_equal_12wk$Cough$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              5.0                5.0
n_event_pct                         16.0                7.0
time-to-event-wk-10th                5.1               38.6
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29510   0.64450   0.08344   1.04400   0.05831


$Ageonset_less_equal_12wk$Diarrhoea
$Ageonset_less_equal_12wk$Diarrhoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              6.0                8.0
n_event_pct                         19.0               11.0
time-to-event-wk-10th                9.4               43.4
time-to-event-wk-25th               31.9                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          31.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.30720   0.57070   0.10040   0.94020   0.03863
```

```
$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`
$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              4.0               8.0
n_event_pct                         12.0              11.0
time-to-event-wk-10th               10.9              20.6
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8967    0.6206    0.2657    3.0260    0.8605


$Ageonset_less_equal_12wk$`Nasal congestion`
$Ageonset_less_equal_12wk$`Nasal congestion`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              3.0               8.0
n_event_pct                          9.0              11.0
time-to-event-wk-10th               37.4              18.7
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9823    0.6800    0.2591    3.7240    0.9790


$Ageonset_less_equal_12wk$Nasopharyngitis
$Ageonset_less_equal_12wk$Nasopharyngitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32              72.0
n_event                              1              11.0
n_event_pct                          3              15.0
time-to-event-wk-10th               NA              20.7
time-to-event-wk-25th               NA                NA
time-to-event-wk-50th               NA                NA
time-to-event-wk-75th               NA                NA
time-to-event-wk-90th               NA                NA
time-to-event-wk-50th-loci          NA                NA
time-to-event-wk-50th-hici          NA                NA
```

```
$Ageonset_less_equal_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.9000    1.0460    0.5018   30.3100    0.1933


$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               5.0                 5
n_event_pct                          16.0                 7
time-to-event-wk-10th                10.1                52
time-to-event-wk-25th                37.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           37.4                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.27340   0.64340   0.07748   0.96510   0.04388


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              15.0               31.0
n_event_pct                          47.0               43.0
time-to-event-wk-10th                 6.4                5.4
time-to-event-wk-25th                13.7               18.0
time-to-event-wk-50th                20.6               46.7
time-to-event-wk-75th                52.6                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.7               31.7
time-to-event-wk-50th-hici           52.6                 NA

$Ageonset_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6516    0.3171    0.3500    1.2130    0.1769


$Ageonset_less_equal_12wk$Rash
$Ageonset_less_equal_12wk$Rash$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               4.0                8.0
n_event_pct                          12.0               11.0
time-to-event-wk-10th                 5.9               33.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5980    0.6181    0.1781    2.0080    0.4055


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               4.0                 3
n_event_pct                          12.0                 4
time-to-event-wk-10th                28.9                NA
time-to-event-wk-25th                36.1                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.9                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.21150   0.77610   0.04619   0.96790   0.04529


$Ageonset_less_equal_12wk$Tachycardia
$Ageonset_less_equal_12wk$Tachycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               5.0                 3
n_event_pct                          16.0                 4
time-to-event-wk-10th                 4.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.20840   0.73480   0.04936   0.87950   0.03279


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               4.0               11.0
n_event_pct                          12.0               15.0
time-to-event-wk-10th                25.4               21.9
time-to-event-wk-25th                  NA                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9672    0.5886    0.3052    3.0660    0.9548


$Ageonset_less_equal_12wk$Vomiting
$Ageonset_less_equal_12wk$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               4.0                10
n_event_pct                          12.0                14
time-to-event-wk-10th                22.6                25
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           47.7                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8130    0.5945    0.2536    2.6070    0.7277



$Agetrt_less_180d
$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49.0
n_event                               1.0                 8.0
n_event_pct                           6.0                16.0
time-to-event-wk-10th                17.6                11.6
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           17.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.1320    1.0710    0.2612   17.4000    0.4798


$Agetrt_less_180d$`Candida infection`
$Agetrt_less_180d$`Candida infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                16.0                 49
n_event                               2.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                15.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Candida infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.677e-10 2.208e+04 0.000e+00       Inf 9.992e-01


$Agetrt_less_180d$Conjunctivitis
$Agetrt_less_180d$Conjunctivitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16                 49
n_event                               2                  3
n_event_pct                          12                  6
time-to-event-wk-10th                29                 NA
time-to-event-wk-25th                29                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           29                 NA
time-to-event-wk-50th-hici           NA                 NA

$Agetrt_less_180d$Conjunctivitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25220   0.96250   0.03824   1.66400   0.15240


$Agetrt_less_180d$Constipation
$Agetrt_less_180d$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               4.0               12.0
n_event_pct                          25.0               24.0
time-to-event-wk-10th                 0.0               11.9
time-to-event-wk-25th                15.9               24.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           11.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6402    0.5859    0.2030    2.0180    0.4465
```

```
$Agetrt_less_180d$Cough
$Agetrt_less_180d$Cough$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              3.0                4.0
n_event_pct                         19.0                8.0
time-to-event-wk-10th                5.1               38.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           8.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.2844    0.7748    0.0623    1.2990    0.1047


$Agetrt_less_180d$`Dermatitis contact`
$Agetrt_less_180d$`Dermatitis contact`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                 49
n_event                              2.0                  1
n_event_pct                         12.0                  2
time-to-event-wk-10th               20.3                 NA
time-to-event-wk-25th               51.0                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          20.3                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$`Dermatitis contact`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.17660   1.26800   0.01471   2.11900   0.17140


$Agetrt_less_180d$Diarrhoea
$Agetrt_less_180d$Diarrhoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              4.0                6.0
n_event_pct                         25.0               12.0
time-to-event-wk-10th                5.4               43.4
time-to-event-wk-25th               10.6                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           9.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
  0.23280   0.71380   0.05746   0.94310   0.04115


$Agetrt_less_180d$`Gastrooesophageal reflux disease`
$Agetrt_less_180d$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               4.0                 2
n_event_pct                          25.0                 4
time-to-event-wk-10th                 2.7                NA
time-to-event-wk-25th                10.9                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           10.9                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.12180   0.88540   0.02147   0.69060   0.01740


$Agetrt_less_180d$`Nasal congestion`
$Agetrt_less_180d$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0                6.0
n_event_pct                          12.0               12.0
time-to-event-wk-10th                 7.9               18.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7686    0.8244    0.1528    3.8680    0.7496


$Agetrt_less_180d$Nasopharyngitis
$Agetrt_less_180d$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16               49.0
n_event                                 1               10.0
n_event_pct                             6               20.0
time-to-event-wk-10th                  NA               11.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Agetrt_less_180d$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3840    1.0570    0.3004   18.9100    0.4111


$Agetrt_less_180d$`Oral candidiasis`
$Agetrt_less_180d$`Oral candidiasis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0                5.0
n_event_pct                          12.0               10.0
time-to-event-wk-10th                15.3               45.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Oral candidiasis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45400   0.87970   0.08095   2.54600   0.36930


$Agetrt_less_180d$`Oxygen saturation decreased`
$Agetrt_less_180d$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               3.0                5.0
n_event_pct                          19.0               10.0
time-to-event-wk-10th                10.1               36.9
time-to-event-wk-25th                27.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           27.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26820   0.78360   0.05774   1.24600   0.09309


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               7.0               21.0
n_event_pct                          44.0               43.0
time-to-event-wk-10th                 5.1                6.4
time-to-event-wk-25th                 7.9               18.9
time-to-event-wk-50th                52.6               38.0
time-to-event-wk-75th                52.6                 NA
```

```
time-to-event-wk-90th                52.6                 NA
time-to-event-wk-50th-loci            6.4               30.6
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5009    0.4679    0.2002    1.2530    0.1395


$Agetrt_less_180d$Rash
$Agetrt_less_180d$Rash$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               3.0                6.0
n_event_pct                          19.0               12.0
time-to-event-wk-10th                 0.1               33.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5080    0.7156    0.1250    2.0650    0.3439


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  3
n_event_pct                          12.0                  6
time-to-event-wk-10th                28.1                 NA
time-to-event-wk-25th                33.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32450   0.92820   0.05263   2.00100   0.22530


$Agetrt_less_180d$Rhinorrhoea
$Agetrt_less_180d$Rhinorrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               1.0                5.0
n_event_pct                           6.0               10.0
time-to-event-wk-10th                26.4               45.6
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Rhinorrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9715    1.1260    0.1069    8.8270    0.9795


$Agetrt_less_180d$Tachycardia
$Agetrt_less_180d$Tachycardia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                 49
n_event                              3.0                  2
n_event_pct                         19.0                  4
time-to-event-wk-10th                4.3                 NA
time-to-event-wk-25th               40.7                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          40.7                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.16440   0.93410   0.02636   1.02600   0.05328


$Agetrt_less_180d$Teething
$Agetrt_less_180d$Teething$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                16               49.0
n_event                               1                6.0
n_event_pct                           6               12.0
time-to-event-wk-10th                NA                6.6
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Agetrt_less_180d$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0090    1.0840    0.2401   16.8200    0.5198


$Agetrt_less_180d$`Upper respiratory tract congestion`
$Agetrt_less_180d$`Upper respiratory tract congestion`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                16               49.0
```

```
n_event                                  0                5.0
n_event_pct                              0               10.0
time-to-event-wk-10th                   NA               36.4
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Agetrt_less_180d$`Upper respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.471e+08 1.454e+04 0.000e+00       Inf 9.989e-01


$Agetrt_less_180d$`Upper respiratory tract infection`
$Agetrt_less_180d$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               3.0                7.0
n_event_pct                          19.0               14.0
time-to-event-wk-10th                25.4               26.4
time-to-event-wk-25th                32.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           25.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4329    0.7065    0.1084    1.7290    0.2360


$Agetrt_less_180d$Vomiting
$Agetrt_less_180d$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0                7.0
n_event_pct                          12.0               14.0
time-to-event-wk-10th                22.6               24.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1260    0.8326    0.2201    5.7560    0.8870
```

```
$Gender_Female
$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                              2.0                6.0
n_event_pct                          8.0               14.0
time-to-event-wk-10th               17.6               24.3
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2370    0.8366    0.2400    6.3760    0.7993


$Gender_Female$`Candida infection`
$Gender_Female$`Candida infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0                43
n_event                              3.0                 0
n_event_pct                         12.0                 0
time-to-event-wk-10th               13.7                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$`Candida infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.680e-10 1.716e+04 0.000e+00       Inf 9.990e-01


$Gender_Female$Constipation
$Gender_Female$Constipation$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                              7.0               17.0
n_event_pct                         29.0               40.0
time-to-event-wk-10th               11.3                4.4
time-to-event-wk-25th               17.6               17.7
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          16.3               19.7
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$Constipation$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2450    0.4687    0.4969    3.1210    0.6397


$Gender_Female$Cough
$Gender_Female$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24                43.0
n_event                                 5                 4.0
n_event_pct                            21                 9.0
time-to-event-wk-10th                   1                38.4
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29200   0.69190   0.07522   1.13300   0.07519


$Gender_Female$Diarrhoea
$Gender_Female$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43.0
n_event                               4.0                 7.0
n_event_pct                          17.0                16.0
time-to-event-wk-10th                16.9                28.0
time-to-event-wk-25th                  NA                43.9
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           31.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7497    0.6584    0.2063    2.7250    0.6617


$Gender_Female$Dysphagia
$Gender_Female$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24                  43
n_event                                 3                   4
n_event_pct                            12                   9
time-to-event-wk-10th                   8                  36
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6718    0.7817    0.1451    3.1090    0.6109


$Gender_Female$`Gastrooesophageal reflux disease`
$Gender_Female$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               4.0                5.0
n_event_pct                          17.0               12.0
time-to-event-wk-10th                 4.4                7.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           43.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7060    0.6997    0.1792    2.7820    0.6187


$Gender_Female$`Nasal congestion`
$Gender_Female$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 24               43.0
n_event                                2                5.0
n_event_pct                            8               12.0
time-to-event-wk-10th                 NA               18.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0720    0.8666    0.1961    5.8580    0.9363


$Gender_Female$Nasopharyngitis
$Gender_Female$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               2.0                5.0
n_event_pct                           8.0               12.0
time-to-event-wk-10th                42.3               27.1
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           42.3                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9887    0.8571    0.1843    5.3040    0.9894


$Gender_Female$`Oxygen saturation decreased`
$Gender_Female$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               3.0                  2
n_event_pct                          12.0                  5
time-to-event-wk-10th                37.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32360   0.93470   0.05181   2.02100   0.22740


$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43.0
n_event                              12.0                21.0
n_event_pct                          50.0                49.0
time-to-event-wk-10th                 5.7                 8.1
time-to-event-wk-25th                 9.4                13.4
time-to-event-wk-50th                37.7                34.7
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            9.4                18.9
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8159    0.3661    0.3981    1.6720    0.5784


$Gender_Female$Rash
$Gender_Female$Rash$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24                43.0
n_event                                 1                 5.0
n_event_pct                             4                12.0
```

```
time-to-event-wk-10th                  NA               29.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.4240    1.1110    0.2745   21.4000    0.4257


$Gender_Female$`Respiratory tract congestion`
$Gender_Female$`Respiratory tract congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43
n_event                               3.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                12.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.400e-10 1.658e+04 0.000e+00       Inf 9.990e-01


$Gender_Female$Rhinorrhoea
$Gender_Female$Rhinorrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               2.0                6.0
n_event_pct                           8.0               14.0
time-to-event-wk-10th                52.1               30.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Rhinorrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4640    0.8278    0.2890    7.4140    0.6454


$Gender_Female$Tachycardia
$Gender_Female$Tachycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                24.0                43
n_event                               3.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                 4.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.477e-10 1.575e+04 0.000e+00       Inf 9.989e-01


$Gender_Female$`Upper respiratory tract infection`
$Gender_Female$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               2.0                6.0
n_event_pct                           8.0               14.0
time-to-event-wk-10th                25.4               21.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6210    0.8320    0.3174    8.2790    0.5615


$Gender_Female$Vomiting
$Gender_Female$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               3.0                8.0
n_event_pct                          12.0               19.0
time-to-event-wk-10th                39.7               24.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           47.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8497    0.6998    0.2156    3.3490    0.8160
```

```
$Region_Europe
$Region_Europe$Atelectasis
$Region_Europe$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17               30.0
n_event                                1                6.0
n_event_pct                            6               20.0
time-to-event-wk-10th                 NA                4.2
time-to-event-wk-25th                 NA               41.0
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA               41.0
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.8180    1.0880    0.3342   23.7600    0.3409


$Region_Europe$Bronchitis
$Region_Europe$Bronchitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17               30.0
n_event                                1                3.0
n_event_pct                            6               10.0
time-to-event-wk-10th                 NA                9.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$Bronchitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3720    1.1710    0.1381   13.6300    0.7871


$Region_Europe$Constipation
$Region_Europe$Constipation$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                              4.0                6.0
n_event_pct                         24.0               20.0
time-to-event-wk-10th               11.3                7.4
time-to-event-wk-25th               17.6                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          15.9                 NA
time-to-event-wk-50th-hici            NA                 NA
```

```
$Region_Europe$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9525    0.6673    0.2575    3.5230    0.9419


$Region_Europe$`Gastrooesophageal reflux disease`
$Region_Europe$`Gastrooesophageal reflux disease`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                              2.0                3.0
n_event_pct                         12.0               10.0
time-to-event-wk-10th                4.4                7.1
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7167    0.9354    0.1146    4.4830    0.7218


$Region_Europe$Nasopharyngitis
$Region_Europe$Nasopharyngitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                17               30.0
n_event                               0                7.0
n_event_pct                           0               23.0
time-to-event-wk-10th                NA                6.3
time-to-event-wk-25th                NA               29.7
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA               29.7
time-to-event-wk-50th-hici           NA                 NA

$Region_Europe$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.210e+08 9.831e+03 0.000e+00       Inf 9.984e-01


$Region_Europe$`Oral candidiasis`
$Region_Europe$`Oral candidiasis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                              2.0                3.0
n_event_pct                         12.0               10.0
time-to-event-wk-10th               15.3               45.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
```

```
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$`Oral candidiasis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.55920   0.94630   0.08752   3.57300   0.53910


$Region_Europe$`Oxygen saturation decreased`
$Region_Europe$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               2.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                37.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.800e-10 3.196e+04 0.000e+00       Inf 9.995e-01


$Region_Europe$Pain
$Region_Europe$Pain$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17                 30
n_event                               2                  0
n_event_pct                          12                  0
time-to-event-wk-10th                 2                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Region_Europe$Pain$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.678e-10 1.887e+04 0.000e+00       Inf 9.991e-01


$Region_Europe$Pyrexia
$Region_Europe$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30.0
n_event                               7.0                13.0
n_event_pct                          41.0                43.0
time-to-event-wk-10th                 5.1                 2.9
time-to-event-wk-25th                 7.9                 8.1
```

```
time-to-event-wk-50th                40.0                46.7
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            7.9                 9.7
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9951    0.4757    0.3917    2.5280    0.9918


$Region_Europe$`Respiratory tract infection`
$Region_Europe$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               30.0
n_event                                 1                4.0
n_event_pct                             6               13.0
time-to-event-wk-10th                  NA               11.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9980    1.1260    0.2199   18.1400    0.5388


$Region_Europe$Rhinitis
$Region_Europe$Rhinitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               3.0                 2
n_event_pct                          18.0                 7
time-to-event-wk-10th                15.1                52
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.6                52
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$Rhinitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29890   0.92100   0.04915   1.81700   0.18980


$Region_Europe$Teething
$Region_Europe$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                30
n_event                                 1                 3
```

```
n_event_pct                              6                 10
time-to-event-wk-10th                   NA                 NA
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Region_Europe$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6970    1.1720    0.1707   16.8600    0.6518


$Region_Europe$`Upper respiratory tract infection`
$Region_Europe$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                 30
n_event                              4.0                  1
n_event_pct                         24.0                  3
time-to-event-wk-10th                8.3                 NA
time-to-event-wk-25th               25.4                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          25.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.09496   1.13700   0.01023   0.88160   0.03838


$Region_Europe$`Upper respiratory tract inflammation`
$Region_Europe$`Upper respiratory tract inflammation`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 30
n_event                                2                  0
n_event_pct                           12                  0
time-to-event-wk-10th                 33                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            33                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Upper respiratory tract inflammation`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.295e-10 3.537e+04 0.000e+00       Inf 9.995e-01


$Region_Europe$Vomiting
$Region_Europe$Vomiting$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               2.0                 4
n_event_pct                          12.0                13
time-to-event-wk-10th                39.7                25
time-to-event-wk-25th                39.7                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           39.7                51
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7055    0.9040    0.1199    4.1500    0.6996


$Region_Europe$`Weight decreased`
$Region_Europe$`Weight decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17                30.0
n_event                               1                 3.0
n_event_pct                           6                10.0
time-to-event-wk-10th                NA                19.3
time-to-event-wk-25th                NA                  NA
time-to-event-wk-50th                NA                  NA
time-to-event-wk-75th                NA                  NA
time-to-event-wk-90th                NA                  NA
time-to-event-wk-50th-loci           NA                  NA
time-to-event-wk-50th-hici           NA                  NA

$Region_Europe$`Weight decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3780    1.1670    0.1400   13.5800    0.7833



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18                34.0
n_event                               1                 6.0
n_event_pct                           6                18.0
time-to-event-wk-10th                NA                 4.6
time-to-event-wk-25th                NA                  NA
time-to-event-wk-50th                NA                  NA
time-to-event-wk-75th                NA                  NA
time-to-event-wk-90th                NA                  NA
time-to-event-wk-50th-loci           NA                  NA
time-to-event-wk-50th-hici           NA                  NA

$Disdur_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   3.4040    1.0930    0.3997   28.9900    0.2624


$Disdur_less_equal_12wk$`Candida infection`
$Disdur_less_equal_12wk$`Candida infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                15.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Candida infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.782e-10 1.986e+04 0.000e+00       Inf 9.991e-01


$Disdur_less_equal_12wk$Constipation
$Disdur_less_equal_12wk$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
n_event                               2.0                 7.0
n_event_pct                          11.0                21.0
time-to-event-wk-10th                11.3                18.7
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_less_equal_12wk$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5310    0.8049    0.3161    7.4160    0.5967


$Disdur_less_equal_12wk$Cough
$Disdur_less_equal_12wk$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
n_event                               4.0                 3.0
n_event_pct                          22.0                 9.0
time-to-event-wk-10th                 4.4                38.4
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            8.4                  NA
time-to-event-wk-50th-hici             NA                  NA
```

```
$Disdur_less_equal_12wk$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26490   0.79260   0.05603   1.25200   0.09371


$Disdur_less_equal_12wk$`Dermatitis contact`
$Disdur_less_equal_12wk$`Dermatitis contact`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               3.0                 1
n_event_pct                          17.0                 3
time-to-event-wk-10th                29.4                NA
time-to-event-wk-25th                51.0                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           29.4                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Dermatitis contact`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13530   1.16200   0.01387   1.32000   0.08519


$Disdur_less_equal_12wk$`Dermatitis diaper`
$Disdur_less_equal_12wk$`Dermatitis diaper`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 1
n_event_pct                          11.0                 3
time-to-event-wk-10th                50.9                NA
time-to-event-wk-25th                50.9                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           50.9                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Dermatitis diaper`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.061390  1.828000  0.001706  2.209000  0.126900


$Disdur_less_equal_12wk$Diarrhoea
$Disdur_less_equal_12wk$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               5.0                4.0
n_event_pct                          28.0               12.0
time-to-event-wk-10th                 5.4               43.9
time-to-event-wk-25th                10.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            9.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_less_equal_12wk$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25620   0.71300   0.06335   1.03600   0.05617


$Disdur_less_equal_12wk$Dysphagia
$Disdur_less_equal_12wk$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  2
n_event_pct                          11.0                  6
time-to-event-wk-10th                 5.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.37530   1.01900   0.05094   2.76600   0.33620


$Disdur_less_equal_12wk$Erythema
$Disdur_less_equal_12wk$Erythema$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               3.0                  1
n_event_pct                          17.0                  3
time-to-event-wk-10th                 7.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Erythema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.1689    1.1660    0.0172    1.6590    0.1271


$Disdur_less_equal_12wk$`Gastrooesophageal reflux disease`
$Disdur_less_equal_12wk$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               4.0                  1
n_event_pct                          22.0                  3
time-to-event-wk-10th                 2.7                 NA
```

```
time-to-event-wk-25th                43.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           43.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.10160   1.15200   0.01062   0.97190   0.04718


$Disdur_less_equal_12wk$`Nasal congestion`
$Disdur_less_equal_12wk$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 3                4.0
n_event_pct                            17               12.0
time-to-event-wk-10th                   1               18.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6415    0.7778    0.1397    2.9460    0.5681


$Disdur_less_equal_12wk$Nasopharyngitis
$Disdur_less_equal_12wk$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 1                6.0
n_event_pct                             6               18.0
time-to-event-wk-10th                  NA               24.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.9340    1.0900    0.3462   24.8600    0.3235


$Disdur_less_equal_12wk$`Oral candidiasis`
$Disdur_less_equal_12wk$`Oral candidiasis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
```

```
n_event                                2.0                  1
n_event_pct                           11.0                  3
time-to-event-wk-10th                 15.3                 NA
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Disdur_less_equal_12wk$`Oral candidiasis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.20980   1.23400   0.01869   2.35500   0.20560


$Disdur_less_equal_12wk$`Oxygen saturation decreased`
$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  2
n_event_pct                          11.0                  6
time-to-event-wk-10th                27.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           27.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4074    1.0050    0.0568    2.9230    0.3718


$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
n_event                               8.0                14.0
n_event_pct                          44.0                41.0
time-to-event-wk-10th                 4.1                 3.1
time-to-event-wk-25th                 6.4                15.6
time-to-event-wk-50th                42.6                46.7
time-to-event-wk-75th                52.6                  NA
time-to-event-wk-90th                52.6                  NA
time-to-event-wk-50th-loci            5.7                24.3
time-to-event-wk-50th-hici              NA                  NA

$Disdur_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7530    0.4504    0.3115    1.8200    0.5287


$Disdur_less_equal_12wk$Rash
```

```
$Disdur_less_equal_12wk$Rash$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0               34.0
n_event                              2.0                3.0
n_event_pct                         11.0                9.0
time-to-event-wk-10th                5.9               33.9
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.59080   0.92210   0.09695   3.60000   0.56810


$Disdur_less_equal_12wk$`Respiratory distress`
$Disdur_less_equal_12wk$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 1
n_event_pct                         11.0                 3
time-to-event-wk-10th               28.1                NA
time-to-event-wk-25th               33.9                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          28.1                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.17460   1.23700   0.01547   1.97000   0.15810


$Disdur_less_equal_12wk$`Staphylococcal infection`
$Disdur_less_equal_12wk$`Staphylococcal infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 0
n_event_pct                         11.0                 0
time-to-event-wk-10th               16.3                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Staphylococcal infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.256e-10 1.965e+04 0.000e+00       Inf 9.991e-01
```

```
$Disdur_less_equal_12wk$`Stoma site erythema`
$Disdur_less_equal_12wk$`Stoma site erythema`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 0
n_event_pct                         11.0                 0
time-to-event-wk-10th               34.4                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          34.4                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Stoma site erythema`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.369e-10 2.194e+04 0.000e+00       Inf 9.992e-01


$Disdur_less_equal_12wk$`Stoma site infection`
$Disdur_less_equal_12wk$`Stoma site infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                18                34
n_event                               2                 0
n_event_pct                          11                 0
time-to-event-wk-10th                32                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           32                NA
time-to-event-wk-50th-hici           NA                NA

$Disdur_less_equal_12wk$`Stoma site infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.204e-10 2.576e+04 0.000e+00       Inf 9.993e-01


$Disdur_less_equal_12wk$Tachycardia
$Disdur_less_equal_12wk$Tachycardia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 1
n_event_pct                         11.0                 3
time-to-event-wk-10th               40.7                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          40.7                NA
time-to-event-wk-50th-hici            NA                NA
```

```
$Disdur_less_equal_12wk$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.23080   1.22900   0.02077   2.56500   0.23270


$Disdur_less_equal_12wk$Teething
$Disdur_less_equal_12wk$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               2.0                5.0
n_event_pct                          11.0               15.0
time-to-event-wk-10th                 5.9                6.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3040    0.8448    0.2490    6.8300    0.7533


$Disdur_less_equal_12wk$`Upper respiratory tract congestion`
$Disdur_less_equal_12wk$`Upper respiratory tract congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 0                4.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA               36.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Upper respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.690e+08 1.337e+04 0.000e+00       Inf 9.988e-01


$Disdur_less_equal_12wk$`Upper respiratory tract infection`
$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               4.0                  2
n_event_pct                          22.0                  6
time-to-event-wk-10th                 8.3                 NA
time-to-event-wk-25th                32.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci           25.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.20400   0.88550   0.03596   1.15700   0.07258


$Disdur_less_equal_12wk$Vomiting
$Disdur_less_equal_12wk$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               3.0                6.0
n_event_pct                          17.0               18.0
time-to-event-wk-10th                 5.4               24.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8372    0.7109    0.2078    3.3720    0.8026



$Region_Northamerica
$Region_Northamerica$`Bacterial tracheitis`
$Region_Northamerica$`Bacterial tracheitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               3.0                  0
n_event_pct                          14.0                  0
time-to-event-wk-10th                25.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           36.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Bacterial tracheitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.661e-10 1.744e+04 0.000e+00       Inf 9.990e-01


$Region_Northamerica$Constipation
$Region_Northamerica$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               4.0               14.0
n_event_pct                          18.0               37.0
```

```
time-to-event-wk-10th                16.3                4.3
time-to-event-wk-25th                48.6               13.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           48.6               19.7
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0360    0.5686    0.6681    6.2070    0.2111


$Region_Northamerica$Cough
$Region_Northamerica$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               6.0                5.0
n_event_pct                          27.0               13.0
time-to-event-wk-10th                 1.1               38.4
time-to-event-wk-25th                 8.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3748    0.6105    0.1133    1.2400    0.1080


$Region_Northamerica$`Dermatitis contact`
$Region_Northamerica$`Dermatitis contact`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               3.0                  2
n_event_pct                          14.0                  5
time-to-event-wk-10th                29.4                 NA
time-to-event-wk-25th                51.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           29.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Dermatitis contact`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.35780   0.92450   0.05845   2.19100   0.26630


$Region_Northamerica$`Dermatitis diaper`
$Region_Northamerica$`Dermatitis diaper`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                22.0                38.0
n_event                               3.0                 3.0
n_event_pct                          14.0                 8.0
time-to-event-wk-10th                29.5                52.6
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           50.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$`Dermatitis diaper`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5067    0.8279    0.1000    2.5670    0.4116


$Region_Northamerica$Diarrhoea
$Region_Northamerica$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               6.0                 6
n_event_pct                          27.0                16
time-to-event-wk-10th                 9.4                28
time-to-event-wk-25th                16.9                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           16.9                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4248    0.5936    0.1327    1.3600    0.1492


$Region_Northamerica$Dysphagia
$Region_Northamerica$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38.0
n_event                               4.0                 6.0
n_event_pct                          18.0                16.0
time-to-event-wk-10th                 5.1                18.9
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7768    0.6489    0.2178    2.7710    0.6972
```

```
$Region_Northamerica$`Feeding tube complication`
$Region_Northamerica$`Feeding tube complication`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38
n_event                              3.0                 1
n_event_pct                         14.0                 3
time-to-event-wk-10th               26.4                NA
time-to-event-wk-25th               53.1                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          53.1                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Feeding tube complication`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13860   1.15800   0.01432   1.34100   0.08790


$Region_Northamerica$`Gastrooesophageal reflux disease`
$Region_Northamerica$`Gastrooesophageal reflux disease`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0               38.0
n_event                              3.0                5.0
n_event_pct                         14.0               13.0
time-to-event-wk-10th               10.9                7.6
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8846    0.7331    0.2102    3.7220    0.8672


$Region_Northamerica$`Nasal congestion`
$Region_Northamerica$`Nasal congestion`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0               38.0
n_event                              5.0                8.0
n_event_pct                         23.0               21.0
time-to-event-wk-10th                3.6                3.4
time-to-event-wk-25th               37.4                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          37.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.9002    0.5714    0.2938    2.7590    0.8540


$Region_Northamerica$Nasopharyngitis
$Region_Northamerica$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               3.0                4.0
n_event_pct                          14.0               11.0
time-to-event-wk-10th                42.3               28.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           42.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6266    0.7649    0.1399    2.8060    0.5411


$Region_Northamerica$`Oxygen saturation decreased`
$Region_Northamerica$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               3.0                5.0
n_event_pct                          14.0               13.0
time-to-event-wk-10th                27.4               36.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           27.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7618    0.7394    0.1789    3.2450    0.7129


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                              11.0                 18
n_event_pct                          50.0                 47
time-to-event-wk-10th                 3.1                 10
time-to-event-wk-25th                15.7                 18
time-to-event-wk-50th                37.7                 36
time-to-event-wk-75th                52.6                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.7                 26
time-to-event-wk-50th-hici           52.6                 NA
```

```
$Region_Northamerica$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6167    0.3960    0.2838    1.3400    0.2222


$Region_Northamerica$Rash
$Region_Northamerica$Rash$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               3.0                 7
n_event_pct                          14.0                18
time-to-event-wk-10th                 5.9                23
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2930    0.6943    0.3316    5.0420    0.7113


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               4.0                 2
n_event_pct                          18.0                 5
time-to-event-wk-10th                28.9                NA
time-to-event-wk-25th                33.9                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           28.9                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.23240   0.87130   0.04212   1.28200   0.09395


$Region_Northamerica$Rhinorrhoea
$Region_Northamerica$Rhinorrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               3.0                 3
n_event_pct                          14.0                 8
time-to-event-wk-10th                26.4                NA
time-to-event-wk-25th                52.1                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           52.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$Rhinorrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39280   0.82780   0.07754   1.99000   0.25890


$Region_Northamerica$`Salivary hypersecretion`
$Region_Northamerica$`Salivary hypersecretion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                38.0
n_event                                 0                 4.0
n_event_pct                             0                11.0
time-to-event-wk-10th                  NA                38.6
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$`Salivary hypersecretion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.795e+08 1.299e+04 0.000e+00       Inf 9.988e-01


$Region_Northamerica$Tachycardia
$Region_Northamerica$Tachycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               4.0                 3
n_event_pct                          18.0                 8
time-to-event-wk-10th                 4.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39290   0.76910   0.08702   1.77400   0.22450


$Region_Northamerica$Teething
$Region_Northamerica$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                38.0
n_event                                 1                 6.0
n_event_pct                             5                16.0
time-to-event-wk-10th                  NA                 6.6
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.8530    1.0830    0.4610   32.2000    0.2131


$Region_Northamerica$`Upper respiratory tract congestion`
$Region_Northamerica$`Upper respiratory tract congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22               38.0
n_event                                 0                5.0
n_event_pct                             0               13.0
time-to-event-wk-10th                  NA               36.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Upper respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.894e+08 1.154e+04 0.000e+00       Inf 9.986e-01


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22               38.0
n_event                                 1                9.0
n_event_pct                             5               24.0
time-to-event-wk-10th                  NA               20.9
time-to-event-wk-25th                  NA               34.7
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               35.3
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   5.1150    1.0550    0.6467   40.4600    0.1219


$Region_Northamerica$Vomiting
$Region_Northamerica$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
```

```
n_event                                4.0                7.0
n_event_pct                           18.0               18.0
time-to-event-wk-10th                 22.6               13.7
time-to-event-wk-25th                 47.7                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            47.7                 NA
time-to-event-wk-50th-hici              NA                 NA

$Region_Northamerica$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0250    0.6393    0.2929    3.5900    0.9687



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$Constipation
$Agetrt_greater_equal_180d$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               4.0               13.0
n_event_pct                          16.0               42.0
time-to-event-wk-10th                17.6                4.4
time-to-event-wk-25th                48.6                7.9
time-to-event-wk-50th                  NA               35.0
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           48.6               18.0
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  3.19000   0.58380   1.01600  10.01000   0.04694


$Agetrt_greater_equal_180d$Cough
$Agetrt_greater_equal_180d$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               4.0                2.0
n_event_pct                          16.0                6.0
time-to-event-wk-10th                 1.1               38.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.43750   0.88070   0.07787   2.45800   0.34790
```

```
$Agetrt_greater_equal_180d$Diarrhoea
$Agetrt_greater_equal_180d$Diarrhoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0               31.0
n_event                              3.0                3.0
n_event_pct                         12.0               10.0
time-to-event-wk-10th               31.9               43.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9240    0.8444    0.1766    4.8360    0.9254


$Agetrt_greater_equal_180d$Dysphagia
$Agetrt_greater_equal_180d$Dysphagia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25               31.0
n_event                              3                4.0
n_event_pct                         12               13.0
time-to-event-wk-10th                8               18.9
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Agetrt_greater_equal_180d$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0820    0.7817    0.2338    5.0070    0.9198


$Agetrt_greater_equal_180d$`Gastrooesophageal reflux disease`
$Agetrt_greater_equal_180d$`Gastrooesophageal reflux disease`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25                 31
n_event                              2                  6
n_event_pct                          8                 19
time-to-event-wk-10th               43                  5
time-to-event-wk-25th               NA                 NA
time-to-event-wk-50th               NA                 NA
time-to-event-wk-75th               NA                 NA
time-to-event-wk-90th               NA                 NA
time-to-event-wk-50th-loci          NA                 NA
time-to-event-wk-50th-hici          NA                 NA

$Agetrt_greater_equal_180d$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3770    0.8202    0.4763   11.8600    0.2911


$Agetrt_greater_equal_180d$`Nasal congestion`
$Agetrt_greater_equal_180d$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               3.0                 2
n_event_pct                          12.0                 6
time-to-event-wk-10th                37.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6874    0.9254    0.1121    4.2160    0.6855


$Agetrt_greater_equal_180d$Pyrexia
$Agetrt_greater_equal_180d$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31.0
n_event                              12.0                13.0
n_event_pct                          48.0                42.0
time-to-event-wk-10th                 4.1                 3.4
time-to-event-wk-25th                13.7                12.7
time-to-event-wk-50th                37.7                46.7
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           15.7                12.9
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_greater_equal_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8133    0.4131    0.3619    1.8280    0.6169


$Agetrt_greater_equal_180d$`Upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                31.0
n_event                                 2                 5.0
n_event_pct                             8                16.0
time-to-event-wk-10th                  NA                17.1
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_greater_equal_180d$`Upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.1270    0.8482    0.4033   11.2100    0.3737


$Agetrt_greater_equal_180d$Vomiting
$Agetrt_greater_equal_180d$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               4.0                5.0
n_event_pct                          16.0               16.0
time-to-event-wk-10th                39.7               13.1
time-to-event-wk-25th                47.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           47.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2160    0.7020    0.3071    4.8130    0.7809



$Gender_Male
$Gender_Male$Constipation
$Gender_Male$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17                37.0
n_event                               1                 8.0
n_event_pct                           6                22.0
time-to-event-wk-10th                NA                11.9
time-to-event-wk-25th                NA                27.9
time-to-event-wk-50th                NA                  NA
time-to-event-wk-75th                NA                  NA
time-to-event-wk-90th                NA                  NA
time-to-event-wk-50th-loci           NA                  NA
time-to-event-wk-50th-hici           NA                  NA

$Gender_Male$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.6490    1.0730    0.3232   21.7200    0.3641


$Gender_Male$Cough
$Gender_Male$Cough$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  2
n_event_pct                          12.0                  5
```

```
time-to-event-wk-10th                 5.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.35850   1.01600   0.04892   2.62800   0.31280


$Gender_Male$`Dermatitis contact`
$Gender_Male$`Dermatitis contact`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  1
n_event_pct                          12.0                  3
time-to-event-wk-10th                35.6                 NA
time-to-event-wk-25th                51.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Dermatitis contact`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.41630   1.31600   0.03159   5.48600   0.50540


$Gender_Male$Diarrhoea
$Gender_Male$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               3.0                  2
n_event_pct                          18.0                  5
time-to-event-wk-10th                 9.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           10.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.30350   0.92460   0.04956   1.85800   0.19710


$Gender_Male$Erythema
$Gender_Male$Erythema$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  17                  37
n_event                                 2                   1
n_event_pct                            12                   3
time-to-event-wk-10th                  19                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             19                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Erythema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24920   1.24400   0.02176   2.85300   0.26390


$Gender_Male$`Feeding tube complication`
$Gender_Male$`Feeding tube complication`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                  37
n_event                               2.0                   1
n_event_pct                          12.0                   3
time-to-event-wk-10th                26.4                  NA
time-to-event-wk-25th                53.1                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           26.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Feeding tube complication`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.14330   1.26000   0.01214   1.69300   0.12300


$Gender_Male$`Gastrooesophageal reflux disease`
$Gender_Male$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                  37
n_event                               2.0                   3
n_event_pct                          12.0                   8
time-to-event-wk-10th                10.9                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.53560   0.93530   0.08565   3.35000   0.50450
```

```
$Gender_Male$Hypersensitivity
$Gender_Male$Hypersensitivity$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 37
n_event                                2                  1
n_event_pct                           12                  3
time-to-event-wk-10th                 41                 NA
time-to-event-wk-25th                 41                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            41                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$Hypersensitivity$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.21750   1.26100   0.01838   2.57500   0.22630


$Gender_Male$`Nasal congestion`
$Gender_Male$`Nasal congestion`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                 37
n_event                              3.0                  3
n_event_pct                         18.0                  8
time-to-event-wk-10th                7.9                 NA
time-to-event-wk-25th               37.4                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          37.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.46000   0.82870   0.09065   2.33400   0.34870


$Gender_Male$Nasopharyngitis
$Gender_Male$Nasopharyngitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                37.0
n_event                                1                 7.0
n_event_pct                            6                19.0
time-to-event-wk-10th                 NA                24.1
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci            NA                  NA
time-to-event-wk-50th-hici            NA                  NA

$Gender_Male$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   2.8570    1.0780    0.3453   23.6400    0.3302


$Gender_Male$`Oral candidiasis`
$Gender_Male$`Oral candidiasis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 2
n_event_pct                          12.0                 5
time-to-event-wk-10th                 7.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Oral candidiasis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.36500   1.02400   0.04902   2.71700   0.32510


$Gender_Male$`Oxygen saturation decreased`
$Gender_Male$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               2.0                3.0
n_event_pct                          12.0                8.0
time-to-event-wk-10th                27.4               36.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           27.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.61940   0.94950   0.09633   3.98300   0.61390


$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               7.0               13.0
n_event_pct                          41.0               35.0
time-to-event-wk-10th                 4.1                3.4
time-to-event-wk-25th                 7.7               24.3
time-to-event-wk-50th                52.6                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.7               36.0
time-to-event-wk-50th-hici             NA                 NA
```

```
$Gender_Male$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6712    0.4825    0.2607    1.7280    0.4086


$Gender_Male$Rash
$Gender_Male$Rash$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               37.0
n_event                                 3                3.0
n_event_pct                            18                8.0
time-to-event-wk-10th                   4               38.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.37380   0.83460   0.07282   1.91900   0.23840


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 1
n_event_pct                          12.0                 3
time-to-event-wk-10th                28.1                NA
time-to-event-wk-25th                33.9                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           28.1                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.122300  1.296000  0.009643  1.551000  0.104900


$Gender_Male$Tachycardia
$Gender_Male$Tachycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 3
n_event_pct                          12.0                 8
time-to-event-wk-10th                40.7                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           40.7                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7554    0.9335    0.1212    4.7080    0.7638


$Gender_Male$Tachypnoea
$Gender_Male$Tachypnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                  37
n_event                               2.0                   0
n_event_pct                          12.0                   0
time-to-event-wk-10th                43.4                  NA
time-to-event-wk-25th                43.4                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           43.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Tachypnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.542e-11 3.119e+04 0.000e+00       Inf 9.994e-01


$Gender_Male$Teething
$Gender_Male$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                  37
n_event                                 1                   7
n_event_pct                             6                  19
time-to-event-wk-10th                  NA                   0
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.1360    1.0780    0.3792   25.9400    0.2889


$Gender_Male$`Upper respiratory tract infection`
$Gender_Male$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37.0
n_event                               3.0                 6.0
n_event_pct                          18.0                16.0
time-to-event-wk-10th                 8.3                25.6
```

```
time-to-event-wk-25th                32.6                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           32.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7156    0.7166    0.1757    2.9150    0.6405


$Gender_Male$Vomiting
$Gender_Male$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               3.0                4.0
n_event_pct                          18.0               11.0
time-to-event-wk-10th                12.0               44.4
time-to-event-wk-25th                22.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4726    0.7885    0.1008    2.2160    0.3418



$Disdur_greater_12wk
$Disdur_greater_12wk$Constipation
$Disdur_greater_12wk$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               6.0               18.0
n_event_pct                          26.0               39.0
time-to-event-wk-10th                15.9                5.7
time-to-event-wk-25th                20.0               14.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.6               25.9
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4640    0.4759    0.5758    3.7200    0.4236


$Disdur_greater_12wk$Cough
$Disdur_greater_12wk$Cough$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               3.0                3.0
n_event_pct                          13.0                7.0
time-to-event-wk-10th                 1.1               38.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.38640   0.82500   0.07669   1.94600   0.24900


$Disdur_greater_12wk$Diarrhoea
$Disdur_greater_12wk$Diarrhoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               2.0                5.0
n_event_pct                           9.0               11.0
time-to-event-wk-10th                31.9               43.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1500    0.8384    0.2224    5.9500    0.8673


$Disdur_greater_12wk$`Gastrooesophageal reflux disease`
$Disdur_greater_12wk$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 2                7.0
n_event_pct                             9               15.0
time-to-event-wk-10th                  NA                7.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.8420    0.8070    0.3788    8.9600    0.4490
```

```
$Disdur_greater_12wk$Nasopharyngitis
$Disdur_greater_12wk$Nasopharyngitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0               46.0
n_event                              2.0                6.0
n_event_pct                          9.0               13.0
time-to-event-wk-10th               42.3               27.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2630    0.8196    0.2534    6.2960    0.7757


$Disdur_greater_12wk$`Oral candidiasis`
$Disdur_greater_12wk$`Oral candidiasis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                23               46.0
n_event                               1                5.0
n_event_pct                           4               11.0
time-to-event-wk-10th                NA               12.1
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Disdur_greater_12wk$`Oral candidiasis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2040    1.1000    0.2554   19.0200    0.4722


$Disdur_greater_12wk$`Oxygen saturation decreased`
$Disdur_greater_12wk$`Oxygen saturation decreased`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0                 46
n_event                              3.0                  3
n_event_pct                         13.0                  7
time-to-event-wk-10th               37.4                 52
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45100   0.81880   0.09062   2.24500   0.33080


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              11.0               20.0
n_event_pct                          48.0               43.0
time-to-event-wk-10th                 7.7                5.4
time-to-event-wk-25th                 9.4               12.9
time-to-event-wk-50th                18.0               38.0
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            9.4               26.0
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6878    0.3774    0.3282    1.4410    0.3213


$Disdur_greater_12wk$Rash
$Disdur_greater_12wk$Rash$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23               46.0
n_event                               2                5.0
n_event_pct                           9               11.0
time-to-event-wk-10th                NA               29.3
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Disdur_greater_12wk$Rash$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8733    0.8421    0.1676    4.5490    0.8722


$Disdur_greater_12wk$`Respiratory tract congestion`
$Disdur_greater_12wk$`Respiratory tract congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23                 46
n_event                               3                  0
n_event_pct                          13                  0
time-to-event-wk-10th                 6                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.945e-10 1.774e+04 0.000e+00       Inf 9.990e-01


$Disdur_greater_12wk$Rhinitis
$Disdur_greater_12wk$Rhinitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               3.0                 0
n_event_pct                          13.0                 0
time-to-event-wk-10th                15.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.6                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$Rhinitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.544e-10 1.852e+04 0.000e+00       Inf 9.991e-01


$Disdur_greater_12wk$Tachycardia
$Disdur_greater_12wk$Tachycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               3.0                 2
n_event_pct                          13.0                 4
time-to-event-wk-10th                 4.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.28610   0.91980   0.04716   1.73500   0.17360


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 1               10.0
n_event_pct                             4               22.0
time-to-event-wk-10th                  NA               17.1
time-to-event-wk-25th                  NA               26.4
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                34.7
time-to-event-wk-50th-hici             NA                  NA

$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   4.8170    1.0510    0.6142   37.7800    0.1346


$Disdur_greater_12wk$Vomiting
$Disdur_greater_12wk$Vomiting$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0               46.0
n_event                              3.0                6.0
n_event_pct                         13.0               13.0
time-to-event-wk-10th               39.7               44.4
time-to-event-wk-25th               47.7                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          39.7                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8311    0.7078    0.2076    3.3280    0.7938




\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines milden UEs nach PT, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$Constipation
$Ageonset_less_equal_12wk$Constipation$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              7.0               22.0
n_event_pct                         22.0               31.0
time-to-event-wk-10th               11.3                7.9
time-to-event-wk-25th               20.0               19.7
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          20.0                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2120    0.4409    0.5109    2.8770    0.6621
```

```
$Ageonset_less_equal_12wk$Nasopharyngitis
$Ageonset_less_equal_12wk$Nasopharyngitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 32              72.0
n_event                                1              11.0
n_event_pct                            3              15.0
time-to-event-wk-10th                 NA              20.7
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.9000    1.0460    0.5018   30.3100    0.1933


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                             15.0              31.0
n_event_pct                         47.0              43.0
time-to-event-wk-10th                6.4               5.4
time-to-event-wk-25th               13.7              18.0
time-to-event-wk-50th               20.6              46.7
time-to-event-wk-75th               52.6                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          13.7              31.7
time-to-event-wk-50th-hici          52.6                NA

$Ageonset_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6516    0.3171    0.3500    1.2130    0.1769


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              4.0              11.0
n_event_pct                         12.0              15.0
time-to-event-wk-10th               25.4              21.9
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA
```

```
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9672    0.5886    0.3052    3.0660    0.9548


$Ageonset_less_equal_12wk$Vomiting
$Ageonset_less_equal_12wk$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               4.0                10
n_event_pct                          12.0                14
time-to-event-wk-10th                22.6                25
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           47.7                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8130    0.5945    0.2536    2.6070    0.7277



$Agetrt_less_180d
$Agetrt_less_180d$Constipation
$Agetrt_less_180d$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49.0
n_event                               4.0                12.0
n_event_pct                          25.0                24.0
time-to-event-wk-10th                 0.0                11.9
time-to-event-wk-25th                15.9                24.1
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           11.3                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6402    0.5859    0.2030    2.0180    0.4465


$Agetrt_less_180d$Nasopharyngitis
$Agetrt_less_180d$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                49.0
n_event                                 1                10.0
n_event_pct                             6                20.0
time-to-event-wk-10th                  NA                11.4
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3840    1.0570    0.3004   18.9100    0.4111


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               7.0               21.0
n_event_pct                          44.0               43.0
time-to-event-wk-10th                 5.1                6.4
time-to-event-wk-25th                 7.9               18.9
time-to-event-wk-50th                52.6               38.0
time-to-event-wk-75th                52.6                 NA
time-to-event-wk-90th                52.6                 NA
time-to-event-wk-50th-loci            6.4               30.6
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5009    0.4679    0.2002    1.2530    0.1395



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$Constipation
$Agetrt_greater_equal_180d$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               4.0               13.0
n_event_pct                          16.0               42.0
time-to-event-wk-10th                17.6                4.4
time-to-event-wk-25th                48.6                7.9
time-to-event-wk-50th                  NA               35.0
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           48.6               18.0
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  3.19000   0.58380   1.01600  10.01000   0.04694


$Agetrt_greater_equal_180d$Pyrexia
$Agetrt_greater_equal_180d$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
```

```
n_event                              12.0              13.0
n_event_pct                          48.0              42.0
time-to-event-wk-10th                 4.1               3.4
time-to-event-wk-25th                13.7              12.7
time-to-event-wk-50th                37.7              46.7
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.7              12.9
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8133    0.4131    0.3619    1.8280    0.6169



$Gender_Female
$Gender_Female$Constipation
$Gender_Female$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                               7.0              17.0
n_event_pct                          29.0              40.0
time-to-event-wk-10th                11.3               4.4
time-to-event-wk-25th                17.6              17.7
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           16.3              19.7
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2450    0.4687    0.4969    3.1210    0.6397


$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              12.0              21.0
n_event_pct                          50.0              49.0
time-to-event-wk-10th                 5.7               8.1
time-to-event-wk-25th                 9.4              13.4
time-to-event-wk-50th                37.7              34.7
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            9.4              18.9
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8159    0.3661    0.3981    1.6720    0.5784
```

```
$Region_Northamerica
$Region_Northamerica$Constipation
$Region_Northamerica$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               4.0               14.0
n_event_pct                          18.0               37.0
time-to-event-wk-10th                16.3                4.3
time-to-event-wk-25th                48.6               13.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           48.6               19.7
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0360    0.5686    0.6681    6.2070    0.2111


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                              11.0                 18
n_event_pct                          50.0                 47
time-to-event-wk-10th                 3.1                 10
time-to-event-wk-25th                15.7                 18
time-to-event-wk-50th                37.7                 36
time-to-event-wk-75th                52.6                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.7                 26
time-to-event-wk-50th-hici           52.6                 NA

$Region_Northamerica$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6167    0.3960    0.2838    1.3400    0.2222



$Disdur_greater_12wk
$Disdur_greater_12wk$Constipation
$Disdur_greater_12wk$Constipation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               6.0               18.0
n_event_pct                          26.0               39.0
time-to-event-wk-10th                15.9                5.7
time-to-event-wk-25th                20.0               14.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci           17.6               25.9
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Constipation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4640    0.4759    0.5758    3.7200    0.4236


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              11.0               20.0
n_event_pct                          48.0               43.0
time-to-event-wk-10th                 7.7                5.4
time-to-event-wk-25th                 9.4               12.9
time-to-event-wk-50th                18.0               38.0
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            9.4               26.0
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6878    0.3774    0.3282    1.4410    0.3213


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 1               10.0
n_event_pct                             4               22.0
time-to-event-wk-10th                  NA               17.1
time-to-event-wk-25th                  NA               26.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               34.7
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   4.8170    1.0510    0.6142   37.7800    0.1346



$Gender_Male
$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               7.0               13.0
n_event_pct                          41.0               35.0
```

```
time-to-event-wk-10th                 4.1                3.4
time-to-event-wk-25th                 7.7               24.3
time-to-event-wk-50th                52.6                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.7               36.0
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6712    0.4825    0.2607    1.7280    0.4086



$Region_Europe
$Region_Europe$Pyrexia
$Region_Europe$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               7.0               13.0
n_event_pct                          41.0               43.0
time-to-event-wk-10th                 5.1                2.9
time-to-event-wk-25th                 7.9                8.1
time-to-event-wk-50th                40.0               46.7
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.9                9.7
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9951    0.4757    0.3917    2.5280    0.9918



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               8.0               14.0
n_event_pct                          44.0               41.0
time-to-event-wk-10th                 4.1                3.1
time-to-event-wk-25th                 6.4               15.6
time-to-event-wk-50th                42.6               46.7
time-to-event-wk-75th                52.6                 NA
time-to-event-wk-90th                52.6                 NA
time-to-event-wk-50th-loci            5.7               24.3
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7530    0.4504    0.3115    1.8200    0.5287
```

```
\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten UE nach SOC, das bei mindestens
10% der Patienten in einem Studienarm auftrat"

$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Blood and lymphatic system disorders`
$Ageonset_greater_12wk$`Blood and lymphatic system disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Blood and lymphatic system disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Cardiac disorders`
$Ageonset_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        0   2
n_event_pct    0  25

$Ageonset_greater_12wk$`Cardiac disorders`$stats
              estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  5.555556 1.4794894  0.30576223 100.941826 0.2464368
OR_TRTvsCTRL  7.307692 1.6306776  0.29905082 178.572883 0.2225809
ARR_TRTvsCTRL 0.250000 0.1530931 -0.05005698   0.550057 0.1024704


$Ageonset_greater_12wk$`Gastrointestinal disorders`
$Ageonset_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`General disorders and administration site conditions`
$Ageonset_greater_12wk$`General disorders and administration site
conditions`$ntab
```

```
            CTRL TRT
n_all          9   8
n_event        4   2
n_event_pct   44  25

$Ageonset_greater_12wk$`General disorders and administration site
conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5625000 0.7168604  0.1380161 2.2925311 0.4221963
OR_TRTvsCTRL   0.4166667 1.0567245  0.0525174 3.3057825 0.4074021
ARR_TRTvsCTRL -0.1944444 0.2255490 -0.6365123 0.2476234 0.3886357


$Ageonset_greater_12wk$`Infections and infestations`
$Ageonset_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all          9   8
n_event        3   3
n_event_pct   33  38

$Ageonset_greater_12wk$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 0.6561673  0.3109008 4.0708318 0.8575439
OR_TRTvsCTRL  1.20000000 1.0165300  0.1636475 8.7994026 0.8576576
ARR_TRTvsCTRL 0.04166667 0.2323537 -0.4137382 0.4970715 0.8576830


$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`
$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Psychiatric disorders`
$Ageonset_greater_12wk$`Psychiatric disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$`Psychiatric disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031
```

```
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        3   1
n_event_pct   33  12

$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3750000 1.0474838  0.04812951 2.9218039 0.3490842
OR_TRTvsCTRL   0.2857143 1.2817399  0.02316930 3.5233106 0.3283749
ARR_TRTvsCTRL -0.2083333 0.1958653 -0.59222235 0.1755557 0.2874846



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        5   7
n_event_pct   16  10

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.62222222 0.54563564  0.2135500 1.81297334 0.3845459
OR_TRTvsCTRL   0.58153846 0.62871201  0.1695969 1.99406394 0.3885751
ARR_TRTvsCTRL -0.05902778 0.07306779 -0.2022380 0.08418246 0.4191772


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        8  17
n_event_pct   25  24

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94444444 0.37240387  0.4551826 1.9595988 0.8780158
OR_TRTvsCTRL   0.92727273 0.49363146  0.3523933 2.4399861 0.8784271
ARR_TRTvsCTRL -0.01388889 0.09145716 -0.1931416 0.1653638 0.8792956


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         32  72
n_event        7  20
n_event_pct   22  28

$Ageonset_less_equal_12wk$`General disorders and administration site
```

```
conditions`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.26984127 0.38434132  0.5978573 2.6971268 0.5342300
OR_TRTvsCTRL  1.37362637 0.50208357  0.5134455 3.6748780 0.5272081
ARR_TRTvsCTRL 0.05902778 0.09014947 -0.1176619 0.2357175 0.5126115


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         32  72
n_event       11  46
n_event_pct   34  64

$Ageonset_less_equal_12wk$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci      pvalue
RR_TRTvsCTRL  1.8585859 0.2598256 1.11691132 3.0927624 0.017055568
OR_TRTvsCTRL  3.3776224 0.4457901 1.40978822 8.0922317 0.006326322
ARR_TRTvsCTRL 0.2951389 0.1012614 0.09667026 0.4936075 0.003561164


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         32  72
n_event        6   9
n_event_pct   19  12

$Ageonset_less_equal_12wk$Investigations$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6666667 0.48232654  0.2590309 1.7157967 0.4005472
OR_TRTvsCTRL   0.6190476 0.57629188  0.2000707 1.9154226 0.4053127
ARR_TRTvsCTRL -0.0625000 0.07924544 -0.2178182 0.0928182 0.4302938


$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        6   7
n_event_pct   19  10

$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.51851852 0.51418374  0.1892737 1.42049028 0.2014877
OR_TRTvsCTRL   0.46666667 0.60280176  0.1431861 1.52094171 0.2061118
ARR_TRTvsCTRL -0.09027778 0.07732898 -0.2418398 0.06128423 0.2430284


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       17  32
```

```
n_event_pct   53  44

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83660131 0.2119779  0.5521825 1.2675190 0.3999933
OR_TRTvsCTRL   0.70588235 0.4263100  0.3060953 1.6278262 0.4139131
ARR_TRTvsCTRL -0.08680556 0.1058836 -0.2943336 0.1207225 0.4123184



$Agetrt_less_180d
$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        3   5
n_event_pct   19  10

$Agetrt_less_180d$`Cardiac disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.54421769 0.6711372  0.1460493 2.0278961 0.3646555
OR_TRTvsCTRL   0.49242424 0.7956027  0.1035431 2.3418425 0.3732444
ARR_TRTvsCTRL -0.08545918 0.1067308 -0.2946476 0.1237292 0.4233060


$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        4   9
n_event_pct   25  18

$Agetrt_less_180d$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.73469388 0.5274495  0.2613007 2.0657237 0.5588749
OR_TRTvsCTRL   0.67500000 0.6851602  0.1762359 2.5853132 0.5662042
ARR_TRTvsCTRL -0.06632653 0.1215677 -0.3045948 0.1719417 0.5853454


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         16  49
n_event        3  12
n_event_pct   19  24

$Agetrt_less_180d$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.30612245 0.5777184  0.4209487 4.0526458 0.6438866
OR_TRTvsCTRL  1.40540541 0.7215378  0.3416863 5.7806369 0.6371643
ARR_TRTvsCTRL 0.05739796 0.1153058 -0.1685972 0.2833931 0.6186327
```

```
$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         16  49
n_event        6  31
n_event_pct   38  63

$Agetrt_less_180d$`Infections and infestations`$stats
               estimate        se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.6870748 0.3406120  0.86537600 3.2889998 0.12467089
OR_TRTvsCTRL  2.8703704 0.5953825  0.89360885 9.2199468 0.07655547
ARR_TRTvsCTRL 0.2576531 0.1392529 -0.01527753 0.5305837 0.06427705


$Agetrt_less_180d$`Injury, poisoning and procedural complications`
$Agetrt_less_180d$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         16  49
n_event        2   2
n_event_pct   12   4

$Agetrt_less_180d$`Injury, poisoning and procedural complications`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 0.95764912  0.04997715 2.13341975 0.2425131
OR_TRTvsCTRL   0.29787234 1.04532539  0.03839261 2.31106820 0.2466285
ARR_TRTvsCTRL -0.08418367 0.08737805 -0.25544151 0.08707417 0.3353258


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$ntab
            CTRL TRT
n_all         16  49
n_event        3   5
n_event_pct   19  10

$Agetrt_less_180d$Investigations$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.54421769 0.6711372  0.1460493 2.0278961 0.3646555
OR_TRTvsCTRL   0.49242424 0.7956027  0.1035431 2.3418425 0.3732444
ARR_TRTvsCTRL -0.08545918 0.1067308 -0.2946476 0.1237292 0.4233060


$Agetrt_less_180d$`Metabolism and nutrition disorders`
$Agetrt_less_180d$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        5   6
n_event_pct   31  12

$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3918367 0.5326899  0.13793634 1.11309336 0.07860668
OR_TRTvsCTRL   0.3069767 0.6934202  0.07886152 1.19493923 0.08854414
ARR_TRTvsCTRL -0.1900510 0.1249828 -0.43501279 0.05491075 0.12835585
```

```
$Agetrt_less_180d$`Psychiatric disorders`
$Agetrt_less_180d$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$`Psychiatric disorders`$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        8  18
n_event_pct   50  37

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7346939 0.3124858  0.3982154 1.3554854 0.3238343
OR_TRTvsCTRL   0.5806452 0.5812174  0.1858565 1.8140277 0.3496312
ARR_TRTvsCTRL -0.1326531 0.1427162 -0.4123717 0.1470656 0.3526361



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Cardiac disorders`
$Agetrt_greater_equal_180d$`Cardiac disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        2   4
n_event_pct    8  13

$Agetrt_greater_equal_180d$`Cardiac disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.61290323 0.82325083  0.3212595  8.0976815 0.5614639
OR_TRTvsCTRL  1.70370370 0.91132612  0.2855432 10.1652080 0.5587848
ARR_TRTvsCTRL 0.04903226 0.08105095 -0.1098247  0.2078892 0.5452082


$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        5   8
n_event_pct   20  26

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats
```

```
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.29032258 0.5027345  0.4816926 3.4564211 0.6121466
OR_TRTvsCTRL  1.39130435 0.6468990  0.3915442 4.9438301 0.6097015
ARR_TRTvsCTRL 0.05806452 0.1121444 -0.1617344 0.2778635 0.6046217


$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         25  31
n_event        8  10
n_event_pct   32  32

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.008064516 0.3908221  0.4686190 2.1684865 0.9836030
OR_TRTvsCTRL  1.011904762 0.5757105  0.3274115 3.1274135 0.9835996
ARR_TRTvsCTRL 0.002580645 0.1255114 -0.2434172 0.2485784 0.9835958


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         25  31
n_event        8  18
n_event_pct   32  58

$Agetrt_greater_equal_180d$`Infections and infestations`$stats
               estimate        se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.8145161 0.3290858 0.952012075 3.4584317 0.07021408
OR_TRTvsCTRL  2.9423077 0.5624075 0.977160676 8.8595200 0.05499913
ARR_TRTvsCTRL 0.2606452 0.1286807 0.008435634 0.5128547 0.04281412


$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`
$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         25  31
n_event        0   4
n_event_pct    0  13

$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats
               estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  7.3125000 1.4671437 0.41231666 129.6883230 0.17506917
OR_TRTvsCTRL  8.3454545 1.5158501 0.42771654 162.8335705 0.16160680
ARR_TRTvsCTRL 0.1290323 0.0602101 0.01102263   0.2470419 0.03211041


$Agetrt_greater_equal_180d$Investigations
$Agetrt_greater_equal_180d$Investigations$ntab
```

```
            CTRL TRT
n_all         25  31
n_event        3   4
n_event_pct   12  13

$Agetrt_greater_equal_180d$Investigations$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.075268817 0.71489529  0.2648482 4.3655304 0.9191438
OR_TRTvsCTRL  1.086419753 0.81598095  0.2194994 5.3772707 0.9190897
ARR_TRTvsCTRL 0.009032258 0.08859603 -0.1646128 0.1826773 0.9187973


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       12  15
n_event_pct   48  48

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.008064516 0.2788224  0.5836524 1.7410947 0.9770181
OR_TRTvsCTRL  1.015625000 0.5379806  0.3538372 2.9151658 0.9770088
ARR_TRTvsCTRL 0.003870968 0.1343135 -0.2593787 0.2671206 0.9770078



$Gender_Male
$Gender_Male$`Cardiac disorders`
$Gender_Male$`Cardiac disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        3   3
n_event_pct   18   8

$Gender_Male$`Cardiac disorders`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.45945946 0.7621129  0.10316574 2.0462510 0.3075111
OR_TRTvsCTRL   0.41176471 0.8760748  0.07394911 2.2927955 0.3111477
ARR_TRTvsCTRL -0.09538951 0.1027738 -0.29682241 0.1060434 0.3533296


$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        5   7
n_event_pct   29  19

$Gender_Male$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6432432 0.5069582  0.2381506 1.7373960 0.3841078
```

```
OR_TRTvsCTRL   0.5600000 0.6778819  0.1483112 2.1144728 0.3923637
ARR_TRTvsCTRL -0.1049285 0.1278998 -0.3556074 0.1457505 0.4119904


$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  37
n_event        2  11
n_event_pct   12  30

$Gender_Male$`General disorders and administration site conditions`$stats
               estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.5270270 0.7106747  0.62759935 10.1750673 0.19207832
OR_TRTvsCTRL  3.1730769 0.8342885  0.61849037 16.2790200 0.16634140
ARR_TRTvsCTRL 0.1796502 0.1084090 -0.03282747  0.3921279 0.09748862


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  37
n_event        6  24
n_event_pct   35  65

$Gender_Male$`Infections and infestations`$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.8378378 0.3499754 0.92556643  3.6492766 0.08204352
OR_TRTvsCTRL  3.3846154 0.6133233 1.01729653 11.2608477 0.04682007
ARR_TRTvsCTRL 0.2957075 0.1399761 0.02135939  0.5700556 0.03463869


$Gender_Male$Investigations
$Gender_Male$Investigations$ntab
            CTRL TRT
n_all         17  37
n_event        3   5
n_event_pct   18  14

$Gender_Male$Investigations$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.76576577 0.6689415  0.2063915 2.841188 0.6899248
OR_TRTvsCTRL   0.72916667 0.7975035  0.1527533 3.480672 0.6920666
ARR_TRTvsCTRL -0.04133545 0.1082012 -0.2534059 0.170735 0.7024435


$Gender_Male$`Metabolism and nutrition disorders`
$Gender_Male$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        4   3
n_event_pct   24   8

$Gender_Male$`Metabolism and nutrition disorders`$stats
```

```
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3445946 0.7053246  0.08648386 1.37303573 0.1309181
OR_TRTvsCTRL   0.2867647 0.8304626  0.05631637 1.46021488 0.1325574
ARR_TRTvsCTRL -0.1542130 0.1122402 -0.37419981 0.06577374 0.1694556


$Gender_Male$`Musculoskeletal and connective tissue disorders`
$Gender_Male$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        2   2
n_event_pct   12   5

$Gender_Male$`Musculoskeletal and connective tissue disorders`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.95611163  0.07053481 2.9928909 0.4159867
OR_TRTvsCTRL   0.4285714 1.04653624  0.05510740 3.3330089 0.4181580
ARR_TRTvsCTRL -0.0635930 0.08653439 -0.23319729 0.1060113 0.4624083


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        6  17
n_event_pct   35  46

$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3018018 0.3736839  0.6258418 2.7078535 0.4803072
OR_TRTvsCTRL  1.5583333 0.6053092  0.4757954 5.1038809 0.4636338
ARR_TRTvsCTRL 0.1065183 0.1419369 -0.1716729 0.3847095 0.4529764



$Gender_Female
$Gender_Female$`Cardiac disorders`
$Gender_Female$`Cardiac disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        2   6
n_event_pct    8  14

$Gender_Female$`Cardiac disorders`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.67441860 0.77572172  0.36607369 7.6587795 0.5063712
OR_TRTvsCTRL  1.78378378 0.85973731  0.33077486 9.6194875 0.5008484
ARR_TRTvsCTRL 0.05620155 0.07729862 -0.09530097 0.2077041 0.4671828


$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         24  43
```

```
n_event        4  10
n_event_pct   17  23

$Gender_Female$`Gastrointestinal disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39534884 0.53392651  0.4900086 3.9733961 0.5326592
OR_TRTvsCTRL  1.51515152 0.65597487  0.4188796 5.4805341 0.5264516
ARR_TRTvsCTRL 0.06589147 0.09968759 -0.1294926 0.2612756 0.5086253


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         24  43
n_event        9  11
n_event_pct   38  26

$Gender_Female$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6821705 0.3702671  0.3301574 1.4094994 0.3016169
OR_TRTvsCTRL   0.5729167 0.5476649  0.1958476 1.6759640 0.3091189
ARR_TRTvsCTRL -0.1191860 0.1191340 -0.3526844 0.1143123 0.3170991


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$ntab
            CTRL TRT
n_all         24  43
n_event        8  25
n_event_pct   33  58

$Gender_Female$`Infections and infestations`$stats
              estimate        se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.744186 0.3163503 0.938242140 3.2424305 0.07867001
OR_TRTvsCTRL  2.777778 0.5320297 0.979113491 7.8806486 0.05482127
ARR_TRTvsCTRL 0.248062 0.1221439 0.008664323 0.4874597 0.04226521


$Gender_Female$Investigations
$Gender_Female$Investigations$ntab
            CTRL TRT
n_all         24  43
n_event        3   4
n_event_pct   12   9

$Gender_Female$Investigations$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.74418605 0.7200075  0.1814722 3.051779 0.6815399
OR_TRTvsCTRL   0.71794872 0.8103045  0.1466766 3.514195 0.6825917
ARR_TRTvsCTRL -0.03197674 0.0807427 -0.1902295 0.126276 0.6920809


$Gender_Female$`Psychiatric disorders`
$Gender_Female$`Psychiatric disorders`$ntab
```

```
            CTRL TRT
n_all         24  43
n_event        3   0
n_event_pct   12   0

$Gender_Female$`Psychiatric disorders`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08116883 1.49096848  0.004367919 1.508356380 0.09212555
OR_TRTvsCTRL   0.07060755 1.53467079  0.003487683 1.429437936 0.08413938
ARR_TRTvsCTRL -0.12500000 0.06750772 -0.257312691 0.007312691 0.06407751


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       14  16
n_event_pct   58  37

$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.6378738 0.2626901  0.3811821 1.06742398 0.08697426
OR_TRTvsCTRL   0.4232804 0.5205436  0.1525951 1.17412862 0.09861980
ARR_TRTvsCTRL -0.2112403 0.1247429 -0.4557320 0.03325134 0.09037839



$Region_Asia_Pacific
$Region_Asia_Pacific$`Cardiac disorders`
$Region_Asia_Pacific$`Cardiac disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$`Cardiac disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353


$Region_Asia_Pacific$`Gastrointestinal disorders`
$Region_Asia_Pacific$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        0   3
n_event_pct    0  25

$Region_Asia_Pacific$`Gastrointestinal disorders`$stats
              estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.615385 1.369474 0.110300612 23.6577786 0.72619768
OR_TRTvsCTRL  1.842105 1.670622 0.069707343 48.6799765 0.71460562
ARR_TRTvsCTRL 0.250000 0.125000 0.005004502  0.4949955 0.04550026
```

```
$Region_Asia_Pacific$`General disorders and administration site conditions`
$Region_Asia_Pacific$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all          2  12
n_event        1   2
n_event_pct   50  17

$Region_Asia_Pacific$`General disorders and administration site
conditions`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3333333 0.9574271  0.051040546 2.1769185 0.2511903
OR_TRTvsCTRL   0.2000000 1.6124515  0.008482205 4.7157551 0.3182158
ARR_TRTvsCTRL -0.3333333 0.3695593 -1.057656246 0.3909896 0.3670700


$Region_Asia_Pacific$`Infections and infestations`
$Region_Asia_Pacific$`Infections and infestations`$ntab
            CTRL TRT
n_all          2  12
n_event        0   7
n_event_pct    0  58

$Region_Asia_Pacific$`Infections and infestations`$stats
               estimate        se    lo95ci     hi95ci       pvalue
RR_TRTvsCTRL  3.4615385 1.3126602 0.2641987  45.353164 0.3441732453
OR_TRTvsCTRL  6.8181818 1.6477717 0.2698254 172.287741 0.2440340195
ARR_TRTvsCTRL 0.5833333 0.1423188 0.3043937   0.862273 0.0000415333



$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        5   5
n_event_pct   23  13

$Region_Northamerica$`Cardiac disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.5729133  0.1883538 1.7795237 0.3400974
OR_TRTvsCTRL   0.51515152 0.6993758  0.1308053 2.0288259 0.3429214
ARR_TRTvsCTRL -0.09569378 0.1048319 -0.3011604 0.1097729 0.3613314


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        6  13
n_event_pct   27  34
```

```
$Region_Northamerica$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.25438596 0.4145110  0.5566712 2.8265953 0.5845302
OR_TRTvsCTRL  1.38666667 0.5882939  0.4377391 4.3926720 0.5784301
ARR_TRTvsCTRL 0.06937799 0.1222238 -0.1701762 0.3089322 0.5702856


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         22  38
n_event        3  14
n_event_pct   14  37

$Region_Northamerica$`General disorders and administration site
conditions`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.7017544 0.5770542 0.87187942  8.3721173 0.08500237
OR_TRTvsCTRL  3.6944444 0.7064419 0.92517675 14.7527700 0.06433137
ARR_TRTvsCTRL 0.2320574 0.1071282 0.02208993  0.4420249 0.03029860


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$ntab
            CTRL TRT
n_all         22  38
n_event       11  26
n_event_pct   50  68

$Region_Northamerica$`Infections and infestations`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3684211 0.2400006  0.85493059 2.1903254 0.1912456
OR_TRTvsCTRL  2.1666667 0.5510109  0.73581857 6.3798940 0.1605511
ARR_TRTvsCTRL 0.1842105 0.1305741 -0.07171001 0.4401311 0.1583113


$Region_Northamerica$`Injury, poisoning and procedural complications`
$Region_Northamerica$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         22  38
n_event        1   5
n_event_pct    5  13

$Region_Northamerica$`Injury, poisoning and procedural complications`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.8947368 1.06218156  0.3609761 23.2134490 0.3169859
OR_TRTvsCTRL  3.1818182 1.13045216  0.3470825 29.1687608 0.3058897
ARR_TRTvsCTRL 0.0861244 0.07056344 -0.0521774  0.2244262 0.2222662


$Region_Northamerica$Investigations
$Region_Northamerica$Investigations$ntab
            CTRL TRT
n_all         22  38
```

```
n_event        5   6
n_event_pct   23  16

$Region_Northamerica$Investigations$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.69473684 0.5430436  0.2396519 2.0140018 0.5024084
OR_TRTvsCTRL   0.63750000 0.6758256  0.1695182 2.3974191 0.5053154
ARR_TRTvsCTRL -0.06937799 0.1071530 -0.2793941 0.1406381 0.5173301


$Region_Northamerica$`Metabolism and nutrition disorders`
$Region_Northamerica$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        4   2
n_event_pct   18   5

$Region_Northamerica$`Metabolism and nutrition disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.2894737 0.82354700  0.05762416 1.45416460 0.1322452
OR_TRTvsCTRL   0.2500000 0.91287093  0.04177369 1.49615694 0.1288608
ARR_TRTvsCTRL -0.1291866 0.08985532 -0.30529979 0.04692658 0.1505141


$Region_Northamerica$`Musculoskeletal and connective tissue disorders`
$Region_Northamerica$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$`Musculoskeletal and connective tissue disorders`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       12  20
n_event_pct   55  53

$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.96491228 0.2481189  0.5933195 1.5692316 0.8855356
OR_TRTvsCTRL   0.92592593 0.5374838  0.3229008 2.6551149 0.8861420
ARR_TRTvsCTRL -0.01913876 0.1335307 -0.2808541 0.2425766 0.8860307


$Region_Northamerica$`Skin and subcutaneous tissue disorders`
$Region_Northamerica$`Skin and subcutaneous tissue disorders`$ntab
```

```
            CTRL TRT
n_all         22  38
n_event        3   2
n_event_pct   14   5

$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.38596491 0.87267577  0.06977902 2.13486682 0.2753134
OR_TRTvsCTRL   0.35185185 0.95589889  0.05403775 2.29098609 0.2745098
ARR_TRTvsCTRL -0.08373206 0.08164106 -0.24374559 0.07628148 0.3050745



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        2   7
n_event_pct    9  15

$Disdur_greater_12wk$`Cardiac disorders`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.75000000 0.76002615  0.39455052 7.7619972 0.4615413
OR_TRTvsCTRL  1.88461538 0.84623709  0.35884295 9.8978542 0.4539340
ARR_TRTvsCTRL 0.06521739 0.07909916 -0.08981412 0.2202489 0.4096546


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        5  12
n_event_pct   22  26

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.20000000 0.4670288  0.4804471 2.9972083 0.6962511
OR_TRTvsCTRL  1.27058824 0.6068778  0.3867493 4.1742662 0.6931308
ARR_TRTvsCTRL 0.04347826 0.1076509 -0.1675137 0.2544702 0.6862996


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         23  46
n_event        7  13
n_event_pct   30  28

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92857143 0.3931448  0.4297045 2.0065998 0.8504844
OR_TRTvsCTRL   0.90043290 0.5590915  0.3009898 2.6937101 0.8511985
```

```
ARR_TRTvsCTRL -0.02173913 0.1166732 -0.2504144 0.2069362 0.8521900


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         23  46
n_event        6  30
n_event_pct   26  65

$Disdur_greater_12wk$`Infections and infestations`$stats
               estimate        se    lo95ci     hi95ci       pvalue
RR_TRTvsCTRL  2.5000000 0.3671275 1.2174202  5.1338067 0.0125660032
OR_TRTvsCTRL  5.3125000 0.5668541 1.7490084 16.1363757 0.0032170965
ARR_TRTvsCTRL 0.3913043 0.1153894 0.1651454  0.6174633 0.0006959619


$Disdur_greater_12wk$Investigations
$Disdur_greater_12wk$Investigations$ntab
            CTRL TRT
n_all         23  46
n_event        4   5
n_event_pct   17  11

$Disdur_greater_12wk$Investigations$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.62500000 0.62030848  0.1852987 2.1080823 0.4486346
OR_TRTvsCTRL   0.57926829 0.72596269  0.1396173 2.4033682 0.4519967
ARR_TRTvsCTRL -0.06521739 0.09139207 -0.2443426 0.1139078 0.4754745


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       12  20
n_event_pct   52  43

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83333333 0.2609903  0.4996471 1.3898698 0.4848171
OR_TRTvsCTRL   0.70512821 0.5125465  0.2582187 1.9255221 0.4954624
ARR_TRTvsCTRL -0.08695652 0.1272452 -0.3363525 0.1624395 0.4943682



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Cardiac disorders`
$Disdur_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        3   2
n_event_pct   17   6
```

```
$Disdur_less_equal_12wk$`Cardiac disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3529412 0.86508151  0.06476548 1.92336205 0.2286362
OR_TRTvsCTRL   0.3125000 0.96501295  0.04714433 2.07143131 0.2280792
ARR_TRTvsCTRL -0.1078431 0.09666635 -0.29730569 0.08161942 0.2645838


$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        4   5
n_event_pct   22  15

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6617647 0.6041793  0.2025001 2.1626288 0.4944074
OR_TRTvsCTRL   0.6034483 0.7455946  0.1399551 2.6019044 0.4981274
ARR_TRTvsCTRL -0.0751634 0.1152883 -0.3011243 0.1507975 0.5144267


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         18  34
n_event        4   9
n_event_pct   22  26

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.19117647 0.5254939  0.4252800 3.3363936 0.7392032
OR_TRTvsCTRL  1.26000000 0.6874152  0.3275229 4.8472949 0.7367171
ARR_TRTvsCTRL 0.04248366 0.1238015 -0.2001628 0.2851301 0.7314784


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         18  34
n_event        8  19
n_event_pct   44  56

$Disdur_less_equal_12wk$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2573529 0.3044080  0.6923801 2.2833359 0.4518657
OR_TRTvsCTRL  1.5833333 0.5867693  0.5013181 5.0007059 0.4335351
ARR_TRTvsCTRL 0.1143791 0.1448054 -0.1694342 0.3981924 0.4295969


$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`
$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
```

```
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$Investigations
$Disdur_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         18  34
n_event        2   4
n_event_pct   11  12

$Disdur_less_equal_12wk$Investigations$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 0.81549536  0.2141276 5.2356968 0.9441217
OR_TRTvsCTRL  1.066666667 0.91969198  0.1758675 6.4695184 0.9440551
ARR_TRTvsCTRL 0.006535948 0.09241262 -0.1745895 0.1876614 0.9436161


$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`
$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        4   3
n_event_pct   22   9

$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3970588 0.7059504  0.09952880 1.58402105 0.1907351
OR_TRTvsCTRL   0.3387097 0.8288667  0.06672599 1.71933380 0.1915066
ARR_TRTvsCTRL -0.1339869 0.1094000 -0.34840704 0.08043319 0.2206720


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        8  13
n_event_pct   44  38

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.8602941 0.3419879  0.4400948 1.681697 0.6599239
OR_TRTvsCTRL   0.7738095 0.5912209  0.2428768 2.465370 0.6644854
ARR_TRTvsCTRL -0.0620915 0.1437473 -0.3438310 0.219648 0.6657784
```

```
$Region_Europe
$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        3   1
n_event_pct   18   3

$Region_Europe$`Gastrointestinal disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1888889 1.11408100  0.02127644 1.67692592 0.1346698
OR_TRTvsCTRL   0.1609195 1.19968524  0.01532621 1.68959535 0.1278150
ARR_TRTvsCTRL -0.1431373 0.09809599 -0.33540185 0.04912734 0.1445224


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  30
n_event        7   6
n_event_pct   41  20

$Region_Europe$`General disorders and administration site conditions`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4857143 0.4662263  0.19477282 1.21124894 0.1214074
OR_TRTvsCTRL   0.3571429 0.6717071  0.09573788 1.33229414 0.1253153
ARR_TRTvsCTRL -0.2117647 0.1399330 -0.48602836 0.06249895 0.1301961


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  30
n_event        3  16
n_event_pct   18  53

$Region_Europe$`Infections and infestations`$stats
               estimate        se   lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  3.0222222 0.5510685 1.026257  8.9001379 0.044750058
OR_TRTvsCTRL  5.3333333 0.7339554 1.265479 22.4772236 0.022562620
ARR_TRTvsCTRL 0.3568627 0.1297885 0.102482  0.6112435 0.005967311


$Region_Europe$Investigations
$Region_Europe$Investigations$ntab
            CTRL TRT
n_all         17  30
n_event        1   3
n_event_pct    6  10

$Region_Europe$Investigations$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 1.11408100  0.1914880 15.0923333 0.6338661
OR_TRTvsCTRL  1.77777778 1.19702563  0.1702031 18.5689583 0.6307571
```

```
ARR_TRTvsCTRL 0.04117647 0.07909909 -0.1138549  0.1962078 0.6026676


$Region_Europe$`Metabolism and nutrition disorders`
$Region_Europe$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        2   5
n_event_pct   12  17

$Region_Europe$`Metabolism and nutrition disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.41666667 0.7796430  0.3073508 6.5298163 0.6550545
OR_TRTvsCTRL  1.50000000 0.8981462  0.2579810 8.7215711 0.6516677
ARR_TRTvsCTRL 0.04901961 0.1036141 -0.1540603 0.2520995 0.6361433


$Region_Europe$`Psychiatric disorders`
$Region_Europe$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        3   0
n_event_pct   18   0

$Region_Europe$`Psychiatric disorders`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08294931 1.48253184  0.004538156 1.516163942 0.09310543
OR_TRTvsCTRL   0.06791569 1.54514293  0.003286564 1.403453970 0.08175231
ARR_TRTvsCTRL -0.17647059 0.09245944 -0.357687763 0.004746586 0.05631022


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        8  12
n_event_pct   47  40

$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.3408467  0.4358025 1.6578612 0.6334978
OR_TRTvsCTRL   0.75000000 0.6123724  0.2258442 2.4906553 0.6385102
ARR_TRTvsCTRL -0.07058824 0.1505158 -0.3655937 0.2244173 0.6390870




\################################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten UE nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
```

```
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        8  17
n_event_pct   25  24

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94444444 0.37240387  0.4551826 1.9595988 0.8780158
OR_TRTvsCTRL   0.92727273 0.49363146  0.3523933 2.4399861 0.8784271
ARR_TRTvsCTRL -0.01388889 0.09145716 -0.1931416 0.1653638 0.8792956


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         32  72
n_event        7  20
n_event_pct   22  28

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.26984127 0.38434132  0.5978573 2.6971268 0.5342300
OR_TRTvsCTRL  1.37362637 0.50208357  0.5134455 3.6748780 0.5272081
ARR_TRTvsCTRL 0.05902778 0.09014947 -0.1176619 0.2357175 0.5126115


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         32  72
n_event       11  46
n_event_pct   34  64

$Ageonset_less_equal_12wk$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci      pvalue
RR_TRTvsCTRL  1.8585859 0.2598256 1.11691132 3.0927624 0.017055568
OR_TRTvsCTRL  3.3776224 0.4457901 1.40978822 8.0922317 0.006326322
ARR_TRTvsCTRL 0.2951389 0.1012614 0.09667026 0.4936075 0.003561164


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       17  32
n_event_pct   53  44

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83660131 0.2119779  0.5521825 1.2675190 0.3999933
```

```
OR_TRTvsCTRL   0.70588235 0.4263100  0.3060953 1.6278262 0.4139131
ARR_TRTvsCTRL -0.08680556 0.1058836 -0.2943336 0.1207225 0.4123184



$Gender_Female
$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        4  10
n_event_pct   17  23

$Gender_Female$`Gastrointestinal disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39534884 0.53392651  0.4900086 3.9733961 0.5326592
OR_TRTvsCTRL  1.51515152 0.65597487  0.4188796 5.4805341 0.5264516
ARR_TRTvsCTRL 0.06589147 0.09968759 -0.1294926 0.2612756 0.5086253


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         24  43
n_event        9  11
n_event_pct   38  26

$Gender_Female$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6821705 0.3702671  0.3301574 1.4094994 0.3016169
OR_TRTvsCTRL   0.5729167 0.5476649  0.1958476 1.6759640 0.3091189
ARR_TRTvsCTRL -0.1191860 0.1191340 -0.3526844 0.1143123 0.3170991


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$ntab
            CTRL TRT
n_all         24  43
n_event        8  25
n_event_pct   33  58

$Gender_Female$`Infections and infestations`$stats
              estimate        se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.744186 0.3163503 0.938242140 3.2424305 0.07867001
OR_TRTvsCTRL  2.777778 0.5320297 0.979113491 7.8806486 0.05482127
ARR_TRTvsCTRL 0.248062 0.1221439 0.008664323 0.4874597 0.04226521


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       14  16
n_event_pct   58  37
```

```
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.6378738 0.2626901  0.3811821 1.06742398 0.08697426
OR_TRTvsCTRL   0.4232804 0.5205436  0.1525951 1.17412862 0.09861980
ARR_TRTvsCTRL -0.2112403 0.1247429 -0.4557320 0.03325134 0.09037839



$Region_Northamerica
$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        6  13
n_event_pct   27  34

$Region_Northamerica$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.25438596 0.4145110  0.5566712 2.8265953 0.5845302
OR_TRTvsCTRL  1.38666667 0.5882939  0.4377391 4.3926720 0.5784301
ARR_TRTvsCTRL 0.06937799 0.1222238 -0.1701762 0.3089322 0.5702856


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         22  38
n_event        3  14
n_event_pct   14  37

$Region_Northamerica$`General disorders and administration site
conditions`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.7017544 0.5770542 0.87187942  8.3721173 0.08500237
OR_TRTvsCTRL  3.6944444 0.7064419 0.92517675 14.7527700 0.06433137
ARR_TRTvsCTRL 0.2320574 0.1071282 0.02208993  0.4420249 0.03029860


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$ntab
            CTRL TRT
n_all         22  38
n_event       11  26
n_event_pct   50  68

$Region_Northamerica$`Infections and infestations`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3684211 0.2400006  0.85493059 2.1903254 0.1912456
OR_TRTvsCTRL  2.1666667 0.5510109  0.73581857 6.3798940 0.1605511
ARR_TRTvsCTRL 0.1842105 0.1305741 -0.07171001 0.4401311 0.1583113


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
```

```
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       12  20
n_event_pct   55  53

$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.96491228 0.2481189  0.5933195 1.5692316 0.8855356
OR_TRTvsCTRL   0.92592593 0.5374838  0.3229008 2.6551149 0.8861420
ARR_TRTvsCTRL -0.01913876 0.1335307 -0.2808541 0.2425766 0.8860307



$Disdur_greater_12wk
$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        5  12
n_event_pct   22  26

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.20000000 0.4670288  0.4804471 2.9972083 0.6962511
OR_TRTvsCTRL  1.27058824 0.6068778  0.3867493 4.1742662 0.6931308
ARR_TRTvsCTRL 0.04347826 0.1076509 -0.1675137 0.2544702 0.6862996


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         23  46
n_event        7  13
n_event_pct   30  28

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92857143 0.3931448  0.4297045 2.0065998 0.8504844
OR_TRTvsCTRL   0.90043290 0.5590915  0.3009898 2.6937101 0.8511985
ARR_TRTvsCTRL -0.02173913 0.1166732 -0.2504144 0.2069362 0.8521900


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         23  46
n_event        6  30
n_event_pct   26  65

$Disdur_greater_12wk$`Infections and infestations`$stats
                estimate        se    lo95ci     hi95ci       pvalue
RR_TRTvsCTRL  2.5000000 0.3671275 1.2174202  5.1338067 0.0125660032
```

```
OR_TRTvsCTRL  5.3125000 0.5668541 1.7490084 16.1363757 0.0032170965
ARR_TRTvsCTRL 0.3913043 0.1153894 0.1651454  0.6174633 0.0006959619


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       12  20
n_event_pct   52  43

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83333333 0.2609903  0.4996471 1.3898698 0.4848171
OR_TRTvsCTRL   0.70512821 0.5125465  0.2582187 1.9255221 0.4954624
ARR_TRTvsCTRL -0.08695652 0.1272452 -0.3363525 0.1624395 0.4943682



$Agetrt_less_180d
$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         16  49
n_event        3  12
n_event_pct   19  24

$Agetrt_less_180d$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.30612245 0.5777184  0.4209487 4.0526458 0.6438866
OR_TRTvsCTRL  1.40540541 0.7215378  0.3416863 5.7806369 0.6371643
ARR_TRTvsCTRL 0.05739796 0.1153058 -0.1685972 0.2833931 0.6186327


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         16  49
n_event        6  31
n_event_pct   38  63

$Agetrt_less_180d$`Infections and infestations`$stats
               estimate        se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.6870748 0.3406120  0.86537600 3.2889998 0.12467089
OR_TRTvsCTRL  2.8703704 0.5953825  0.89360885 9.2199468 0.07655547
ARR_TRTvsCTRL 0.2576531 0.1392529 -0.01527753 0.5305837 0.06427705


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        8  18
n_event_pct   50  37
```

```
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7346939 0.3124858  0.3982154 1.3554854 0.3238343
OR_TRTvsCTRL   0.5806452 0.5812174  0.1858565 1.8140277 0.3496312
ARR_TRTvsCTRL -0.1326531 0.1427162 -0.4123717 0.1470656 0.3526361



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         25  31
n_event        8  10
n_event_pct   32  32

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.008064516 0.3908221  0.4686190 2.1684865 0.9836030
OR_TRTvsCTRL  1.011904762 0.5757105  0.3274115 3.1274135 0.9835996
ARR_TRTvsCTRL 0.002580645 0.1255114 -0.2434172 0.2485784 0.9835958


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         25  31
n_event        8  18
n_event_pct   32  58

$Agetrt_greater_equal_180d$`Infections and infestations`$stats
                estimate        se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.8145161 0.3290858 0.952012075 3.4584317 0.07021408
OR_TRTvsCTRL  2.9423077 0.5624075 0.977160676 8.8595200 0.05499913
ARR_TRTvsCTRL 0.2606452 0.1286807 0.008435634 0.5128547 0.04281412


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       12  15
n_event_pct   48  48

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.008064516 0.2788224  0.5836524 1.7410947 0.9770181
OR_TRTvsCTRL  1.015625000 0.5379806  0.3538372 2.9151658 0.9770088
```

```
ARR_TRTvsCTRL 0.003870968 0.1343135 -0.2593787 0.2671206 0.9770078



$Gender_Male
$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  37
n_event        2  11
n_event_pct   12  30

$Gender_Male$`General disorders and administration site conditions`$stats
               estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.5270270 0.7106747  0.62759935 10.1750673 0.19207832
OR_TRTvsCTRL  3.1730769 0.8342885  0.61849037 16.2790200 0.16634140
ARR_TRTvsCTRL 0.1796502 0.1084090 -0.03282747  0.3921279 0.09748862


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  37
n_event        6  24
n_event_pct   35  65

$Gender_Male$`Infections and infestations`$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.8378378 0.3499754 0.92556643  3.6492766 0.08204352
OR_TRTvsCTRL  3.3846154 0.6133233 1.01729653 11.2608477 0.04682007
ARR_TRTvsCTRL 0.2957075 0.1399761 0.02135939  0.5700556 0.03463869


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        6  17
n_event_pct   35  46

$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3018018 0.3736839  0.6258418 2.7078535 0.4803072
OR_TRTvsCTRL  1.5583333 0.6053092  0.4757954 5.1038809 0.4636338
ARR_TRTvsCTRL 0.1065183 0.1419369 -0.1716729 0.3847095 0.4529764



$Region_Europe
$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  30
n_event        3  16
```

```
n_event_pct   18  53

$Region_Europe$`Infections and infestations`$stats
               estimate        se   lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  3.0222222 0.5510685 1.026257  8.9001379 0.044750058
OR_TRTvsCTRL  5.3333333 0.7339554 1.265479 22.4772236 0.022562620
ARR_TRTvsCTRL 0.3568627 0.1297885 0.102482  0.6112435 0.005967311


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        8  12
n_event_pct   47  40

$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.3408467  0.4358025 1.6578612 0.6334978
OR_TRTvsCTRL   0.75000000 0.6123724  0.2258442 2.4906553 0.6385102
ARR_TRTvsCTRL -0.07058824 0.1505158 -0.3655937 0.2244173 0.6390870



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         18  34
n_event        8  19
n_event_pct   44  56

$Disdur_less_equal_12wk$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2573529 0.3044080  0.6923801 2.2833359 0.4518657
OR_TRTvsCTRL  1.5833333 0.5867693  0.5013181 5.0007059 0.4335351
ARR_TRTvsCTRL 0.1143791 0.1448054 -0.1694342 0.3981924 0.4295969


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        8  13
n_event_pct   44  38

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.8602941 0.3419879  0.4400948 1.681697 0.6599239
OR_TRTvsCTRL   0.7738095 0.5912209  0.2428768 2.465370 0.6644854
ARR_TRTvsCTRL -0.0620915 0.1437473 -0.3438310 0.219648 0.6657784
```

```
\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten UEs nach SOC, das bei mindestens 10%
der Patienten in einem Studienarm auftrat"

$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Blood and lymphatic system disorders`
$Ageonset_greater_12wk$`Blood and lymphatic system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                43.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           43.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Blood and lymphatic system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.245e-09 4.596e+04 0.000e+00       Inf 9.997e-01


$Ageonset_greater_12wk$`Cardiac disorders`
$Ageonset_greater_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  9                8.0
n_event                                0                2.0
n_event_pct                            0               25.0
time-to-event-wk-10th                 NA                2.1
time-to-event-wk-25th                 NA               17.9
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                2.1
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.364e+11 2.586e+04 0.000e+00       Inf 9.992e-01


$Ageonset_greater_12wk$`Gastrointestinal disorders`
$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                48.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           48.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.714e-09 3.573e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`General disorders and administration site conditions`
$Ageonset_greater_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               4.0                2.0
n_event_pct                          44.0               25.0
time-to-event-wk-10th                 5.1                2.1
time-to-event-wk-25th                15.1               15.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.1                2.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7580    0.8904    0.1324    4.3410    0.7557


$Ageonset_greater_12wk$`Infections and infestations`
$Ageonset_greater_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               3.0                3.0
n_event_pct                          33.0               38.0
time-to-event-wk-10th                 5.7                4.0
time-to-event-wk-25th                28.3               15.7
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.7                4.0
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3530    0.8555    0.4399   12.5800    0.3173


$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`
$Ageonset_greater_12wk$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  9                8.0
n_event                                0                1.0
n_event_pct                            0               12.0
time-to-event-wk-10th                 NA                3.3
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                3.3
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.483e+09 4.134e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Psychiatric disorders`
$Ageonset_greater_12wk$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                1.0
n_event_pct                          11.0               12.0
time-to-event-wk-10th                50.4                2.1
time-to-event-wk-25th                53.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           50.4                2.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.6770    1.5250    0.1348   53.1800    0.5184


$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               3.0                1.0
n_event_pct                          33.0               12.0
time-to-event-wk-10th                 2.3                0.4
time-to-event-wk-25th                30.3                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            2.3                0.4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
  0.48150   1.17200   0.04845   4.78600   0.53280


$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0                72
n_event                              5.0                 7
n_event_pct                         16.0                10
time-to-event-wk-10th               13.9                35
time-to-event-wk-25th               29.4                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          29.4                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4857    0.5920    0.1522    1.5500    0.2226


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              8.0              17.0
n_event_pct                         25.0              24.0
time-to-event-wk-10th               12.7              16.3
time-to-event-wk-25th               18.9              52.7
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          18.9                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6529    0.4366    0.2775    1.5360    0.3289


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              7.0              20.0
n_event_pct                         22.0              28.0
time-to-event-wk-10th               10.4              10.9
time-to-event-wk-25th               24.3              38.6
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.3               54.3
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0310    0.4443    0.4315    2.4620    0.9458


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              11.0               46.0
n_event_pct                          34.0               64.0
time-to-event-wk-10th                 6.7                3.4
time-to-event-wk-25th                17.1                9.3
time-to-event-wk-50th                33.4               25.1
time-to-event-wk-75th                  NA               51.4
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.6               15.7
time-to-event-wk-50th-hici             NA               31.1

$Ageonset_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7370    0.3388    0.8939    3.3740    0.1033


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               6.0                9.0
n_event_pct                          19.0               12.0
time-to-event-wk-10th                13.9               23.3
time-to-event-wk-25th                46.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           46.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5205    0.5330    0.1831    1.4790    0.2205


$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               6.0                7.0
n_event_pct                          19.0               10.0
```

```
time-to-event-wk-10th                 7.7               45.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Metabolism and nutrition
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.37870   0.56290   0.12560   1.14100   0.08452


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                             17.0               32.0
n_event_pct                         53.0               44.0
time-to-event-wk-10th                2.9                5.0
time-to-event-wk-25th                7.1               11.6
time-to-event-wk-50th               15.7               44.0
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           7.3               21.9
time-to-event-wk-50th-hici          27.0                 NA

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.59880   0.30860   0.32700   1.09600   0.09648



$Agetrt_less_180d
$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                 49
n_event                              3.0                  5
n_event_pct                         19.0                 10
time-to-event-wk-10th               15.1                 35
time-to-event-wk-25th               29.4                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          15.1                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.38920   0.75430   0.08874   1.70700   0.21080
```

```
$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              4.0               9.0
n_event_pct                         25.0              18.0
time-to-event-wk-10th               13.6              19.0
time-to-event-wk-25th               15.3              53.1
time-to-event-wk-50th               40.7                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          13.6              53.1
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4254    0.6117    0.1283    1.4110    0.1623


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              3.0              12.0
n_event_pct                         19.0              24.0
time-to-event-wk-10th                9.1              15.0
time-to-event-wk-25th                 NA              41.4
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          11.7              54.3
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9543    0.6550    0.2643    3.4450    0.9431


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              6.0              31.0
n_event_pct                         38.0              63.0
time-to-event-wk-10th                6.3               3.4
time-to-event-wk-25th               17.1              14.4
time-to-event-wk-50th               33.4              25.4
time-to-event-wk-75th                 NA              51.4
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           8.6              15.7
```

```
time-to-event-wk-50th-hici             NA               37.6

$Agetrt_less_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5900    0.4466    0.6626    3.8160    0.2990


$Agetrt_less_180d$`Injury, poisoning and procedural complications`
$Agetrt_less_180d$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 2
n_event_pct                          12.0                 4
time-to-event-wk-10th                47.1                NA
time-to-event-wk-25th                47.1                NA
time-to-event-wk-50th                47.1                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           47.1                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24360   1.03600   0.03199   1.85500   0.17270


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               3.0                 5
n_event_pct                          19.0                10
time-to-event-wk-10th                10.1                29
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           20.3                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.35260   0.74700   0.08155   1.52400   0.16290


$Agetrt_less_180d$`Metabolism and nutrition disorders`
$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               5.0                 6
n_event_pct                          31.0                12
time-to-event-wk-10th                 2.6                 6
time-to-event-wk-25th                 9.6                NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            9.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33460   0.61050   0.10110   1.10700   0.07292


$Agetrt_less_180d$`Psychiatric disorders`
$Agetrt_less_180d$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                11.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.167e-10 1.899e+04 0.000e+00       Inf 9.991e-01


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               8.0               18.0
n_event_pct                          50.0               37.0
time-to-event-wk-10th                 2.1                5.7
time-to-event-wk-25th                 7.1               15.7
time-to-event-wk-50th                20.4                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.1               23.1
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42630   0.44280   0.17900   1.01500   0.05417



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Cardiac disorders`
$Agetrt_greater_equal_180d$`Cardiac disorders`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25               31.0
n_event                                 2                4.0
n_event_pct                             8               13.0
time-to-event-wk-10th                  NA               12.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4170    0.8780    0.2535    7.9190    0.6914


$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               5.0                8.0
n_event_pct                          20.0               26.0
time-to-event-wk-10th                18.9                6.9
time-to-event-wk-25th                48.6               20.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           27.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1360    0.5793    0.3650    3.5360    0.8257


$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               8.0               10.0
n_event_pct                          32.0               32.0
time-to-event-wk-10th                 7.6                6.9
time-to-event-wk-25th                16.9               36.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.9               36.0
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8788    0.4784    0.3440    2.2440    0.7871


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0              31.0
n_event                               8.0              18.0
n_event_pct                          32.0              58.0
time-to-event-wk-10th                 7.1               3.7
time-to-event-wk-25th                28.3               9.3
time-to-event-wk-50th                  NA              20.6
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           28.3               9.4
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9360    0.4301    0.8335    4.4980    0.1244


$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`
$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25              31.0
n_event                               0               4.0
n_event_pct                           0              13.0
time-to-event-wk-10th                 NA              41.4
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA              51.1
time-to-event-wk-50th-hici            NA                NA

$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.780e+09 1.997e+04 0.000e+00       Inf 9.991e-01


$Agetrt_greater_equal_180d$Investigations
$Agetrt_greater_equal_180d$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0              31.0
n_event                               3.0               4.0
n_event_pct                          12.0              13.0
time-to-event-wk-10th                18.9               8.1
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           46.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9695    0.7692    0.2147    4.3780    0.9679


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0               31.0
n_event                             12.0               15.0
n_event_pct                         48.0               48.0
time-to-event-wk-10th                2.9                0.4
time-to-event-wk-25th                7.3                7.9
time-to-event-wk-50th               27.0               26.1
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           7.3               10.0
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9757    0.3889    0.4553    2.0910    0.9496



$Gender_Male
$Gender_Male$`Cardiac disorders`
$Gender_Male$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                 37
n_event                              3.0                  3
n_event_pct                         18.0                  8
time-to-event-wk-10th               15.1                 NA
time-to-event-wk-25th               29.4                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          29.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49220   0.83400   0.09601   2.52400   0.39540


$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                17.0              37.0
n_event                               5.0               7.0
n_event_pct                          29.0              19.0
time-to-event-wk-10th                12.7              16.4
time-to-event-wk-25th                27.9                NA
time-to-event-wk-50th                40.7                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.6                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5142    0.5962    0.1598    1.6540    0.2645


$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               2.0              11.0
n_event_pct                          12.0              30.0
time-to-event-wk-10th                13.4               7.6
time-to-event-wk-25th                  NA              38.6
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA              38.6
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.5230    0.7770    0.5501   11.5700    0.2337


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               6.0              24.0
n_event_pct                          35.0              65.0
time-to-event-wk-10th                 6.3               2.4
time-to-event-wk-25th                28.3               6.7
time-to-event-wk-50th                32.6              16.7
time-to-event-wk-75th                  NA              37.6
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.6              10.1
time-to-event-wk-50th-hici             NA              30.7

$Gender_Male$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  2.21500   0.46120   0.89720   5.46900   0.08459
```

```
$Gender_Male$Investigations
$Gender_Male$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              37.0
n_event                              3.0               5.0
n_event_pct                         18.0              14.0
time-to-event-wk-10th               20.3              23.3
time-to-event-wk-25th               46.6                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          20.3                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6359    0.7408    0.1489    2.7160    0.5411


$Gender_Male$`Metabolism and nutrition disorders`
$Gender_Male$`Metabolism and nutrition disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                37
n_event                              4.0                 3
n_event_pct                         24.0                 8
time-to-event-wk-10th                5.9                NA
time-to-event-wk-25th               22.9                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          22.9                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39290   0.77600   0.08585   1.79800   0.22860


$Gender_Male$`Musculoskeletal and connective tissue disorders`
$Gender_Male$`Musculoskeletal and connective tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                37
n_event                              2.0                 2
n_event_pct                         12.0                 5
time-to-event-wk-10th               43.4                63
time-to-event-wk-25th               43.4                63
time-to-event-wk-50th                 NA                63
time-to-event-wk-75th                 NA                63
time-to-event-wk-90th                 NA                63
time-to-event-wk-50th-loci          43.4                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Musculoskeletal and connective tissue
```

```
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.20040   1.27200   0.01656   2.42400   0.20630


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               6.0              17.0
n_event_pct                          35.0              46.0
time-to-event-wk-10th                 2.3               1.7
time-to-event-wk-25th                 7.3               8.6
time-to-event-wk-50th                27.0              35.0
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            7.3              11.7
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2110    0.4803    0.4723    3.1040    0.6905



$Gender_Female
$Gender_Female$`Cardiac disorders`
$Gender_Female$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                               2.0               6.0
n_event_pct                           8.0              14.0
time-to-event-wk-10th                13.9              17.9
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.8740    0.8323    0.3668    9.5780    0.4504


$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                               4.0              10.0
n_event_pct                          17.0              23.0
time-to-event-wk-10th                15.3              11.7
time-to-event-wk-25th                48.6              52.7
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           48.6               53.1
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2710    0.6054    0.3878    4.1630    0.6924


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               9.0               11.0
n_event_pct                          38.0               26.0
time-to-event-wk-10th                 5.1               15.3
time-to-event-wk-25th                15.1               44.3
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.1               46.4
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5376    0.4746    0.2120    1.3630    0.1910


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               8.0               25.0
n_event_pct                          33.0               58.0
time-to-event-wk-10th                 7.1                3.7
time-to-event-wk-25th                17.1               13.0
time-to-event-wk-50th                  NA               25.7
time-to-event-wk-75th                  NA               55.0
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.1               18.4
time-to-event-wk-50th-hici             NA               51.4

$Gender_Female$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7120    0.4180    0.7544    3.8830    0.1986


$Gender_Female$Investigations
$Gender_Female$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
```

```
n_event                               3.0                4.0
n_event_pct                          12.0                9.0
time-to-event-wk-10th                13.9               25.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6380    0.7816    0.1379    2.9520    0.5653


$Gender_Female$`Psychiatric disorders`
$Gender_Female$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43
n_event                               3.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                50.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           50.4                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.754e-10 1.650e+04 0.000e+00       Inf 9.989e-01


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              14.0               16.0
n_event_pct                          58.0               37.0
time-to-event-wk-10th                 2.9                5.0
time-to-event-wk-25th                 5.6               14.4
time-to-event-wk-50th                15.7                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.1               25.9
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5594    0.3854    0.2628    1.1910    0.1317
```

```
$Region_Asia_Pacific
$Region_Asia_Pacific$`Cardiac disorders`
$Region_Asia_Pacific$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  2              12.0
n_event                                0               2.0
n_event_pct                            0              17.0
time-to-event-wk-10th                 NA               8.4
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA               8.4
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.343e+07 2.340e+04 0.000e+00       Inf 9.994e-01


$Region_Asia_Pacific$`Gastrointestinal disorders`
$Region_Asia_Pacific$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  2              12.0
n_event                                0               3.0
n_event_pct                            0              25.0
time-to-event-wk-10th                 NA               9.3
time-to-event-wk-25th                 NA              39.8
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA               9.3
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.972e+07 2.715e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$`General disorders and administration site conditions`
$Region_Asia_Pacific$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0              12.0
n_event                              1.0               2.0
n_event_pct                         50.0              17.0
time-to-event-wk-10th                7.6               8.1
time-to-event-wk-25th                7.6                NA
time-to-event-wk-50th                7.6                NA
time-to-event-wk-75th                7.6                NA
time-to-event-wk-90th                7.6                NA
time-to-event-wk-50th-loci            NA               8.1
time-to-event-wk-50th-hici            NA                NA
```

```
$Region_Asia_Pacific$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.224e-08 1.320e+01 7.079e-20 2.116e+03 1.676e-01


$Region_Asia_Pacific$`Infections and infestations`
$Region_Asia_Pacific$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  2               12.0
n_event                                0                7.0
n_event_pct                            0               58.0
time-to-event-wk-10th                 NA                4.3
time-to-event-wk-25th                 NA               18.4
time-to-event-wk-50th                 NA               31.1
time-to-event-wk-75th                 NA               43.6
time-to-event-wk-90th                 NA               43.6
time-to-event-wk-50th-loci            NA                4.3
time-to-event-wk-50th-hici            NA                 NA

$Region_Asia_Pacific$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.835e+08 1.328e+04 0.000e+00       Inf 9.988e-01



$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0               38.0
n_event                              5.0                5.0
n_event_pct                         23.0               13.0
time-to-event-wk-10th               11.1               12.9
time-to-event-wk-25th               29.4                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          29.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4905    0.6409    0.1397    1.7230    0.2664


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0               38.0
n_event                              6.0               13.0
n_event_pct                         27.0               34.0
time-to-event-wk-10th               11.6                7.0
```

```
time-to-event-wk-25th                27.9               19.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           27.9               21.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0270    0.4968    0.3878    2.7180    0.9577


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               3.0               14.0
n_event_pct                          14.0               37.0
time-to-event-wk-10th                13.4                7.6
time-to-event-wk-25th                  NA               38.6
time-to-event-wk-50th                  NA               55.0
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               41.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.5370    0.6372    0.7278    8.8460    0.1439


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              11.0               26.0
n_event_pct                          50.0               68.0
time-to-event-wk-10th                 7.1                3.1
time-to-event-wk-25th                17.1                9.0
time-to-event-wk-50th                28.3               16.7
time-to-event-wk-75th                  NA               55.0
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.1               10.1
time-to-event-wk-50th-hici             NA               37.6

$Region_Northamerica$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3050    0.3631    0.6404    2.6580    0.4639


$Region_Northamerica$`Injury, poisoning and procedural complications`
$Region_Northamerica$`Injury, poisoning and procedural complications`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22               38.0
n_event                                 1                5.0
n_event_pct                             5               13.0
time-to-event-wk-10th                  NA               41.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.7240    1.1010    0.3148   23.5800    0.3627


$Region_Northamerica$Investigations
$Region_Northamerica$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               5.0                6.0
n_event_pct                          23.0               16.0
time-to-event-wk-10th                13.9               18.3
time-to-event-wk-25th                46.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5692    0.6095    0.1724    1.8800    0.3552


$Region_Northamerica$`Metabolism and nutrition disorders`
$Region_Northamerica$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                 38
n_event                                 4                  2
n_event_pct                            18                  5
time-to-event-wk-10th                  13                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24730   0.87130   0.04482   1.36400   0.10880
```

```
$Region_Northamerica$`Musculoskeletal and connective tissue disorders`
$Region_Northamerica$`Musculoskeletal and connective tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                              3.0               3.0
n_event_pct                         14.0               8.0
time-to-event-wk-10th               43.4              43.1
time-to-event-wk-25th               46.9                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          43.4                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47040   0.81720   0.09481   2.33300   0.35600


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                             12.0              20.0
n_event_pct                         55.0              53.0
time-to-event-wk-10th                2.9               1.7
time-to-event-wk-25th                5.3               7.9
time-to-event-wk-50th               20.4              35.0
time-to-event-wk-75th               27.0                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           5.3              10.0
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7009    0.3728    0.3375    1.4550    0.3404


$Region_Northamerica$`Skin and subcutaneous tissue disorders`
$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38
n_event                              3.0                 2
n_event_pct                         14.0                 5
time-to-event-wk-10th               31.4                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          53.9                NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.34450   0.91820   0.05696   2.08300   0.24580



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0               46.0
n_event                              2.0                7.0
n_event_pct                          9.0               15.0
time-to-event-wk-10th               13.9                8.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5320    0.8043    0.3166    7.4090    0.5961


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0               46.0
n_event                              5.0               12.0
n_event_pct                         22.0               26.0
time-to-event-wk-10th                9.7                7.0
time-to-event-wk-25th               27.9               20.1
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          27.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0710    0.5351    0.3754    3.0580    0.8975


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0               46.0
n_event                              7.0               13.0
n_event_pct                         30.0               28.0
```

```
time-to-event-wk-10th                 5.1                6.9
time-to-event-wk-25th                15.1               36.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.1               46.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7984    0.4769    0.3135    2.0330    0.6368


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0               46.0
n_event                              6.0               30.0
n_event_pct                         26.0               65.0
time-to-event-wk-10th                7.1                2.0
time-to-event-wk-25th               17.6                9.0
time-to-event-wk-50th                 NA               18.4
time-to-event-wk-75th                 NA               37.6
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          17.6               10.1
time-to-event-wk-50th-hici            NA               30.7

$Disdur_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  2.64900   0.45090   1.09500   6.41000   0.03073


$Disdur_greater_12wk$Investigations
$Disdur_greater_12wk$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0                 46
n_event                              4.0                  5
n_event_pct                         17.0                 11
time-to-event-wk-10th               13.9                 29
time-to-event-wk-25th               46.6                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          46.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6026    0.6751    0.1605    2.2630    0.4531


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              12.0               20.0
n_event_pct                          52.0               43.0
time-to-event-wk-10th                 2.9                1.7
time-to-event-wk-25th                 7.3                8.4
time-to-event-wk-50th                15.7               36.0
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.3               12.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7843    0.3714    0.3787    1.6240    0.5129



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Cardiac disorders`
$Disdur_less_equal_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               3.0                 2
n_event_pct                          17.0                 6
time-to-event-wk-10th                15.1                NA
time-to-event-wk-25th                29.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           29.4                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25900   0.93120   0.04175   1.60700   0.14690


$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               4.0                5.0
n_event_pct                          22.0               15.0
time-to-event-wk-10th                13.6               52.7
time-to-event-wk-25th                40.7               53.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7               52.7
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.38340   0.68710   0.09972   1.47400   0.16300


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0               34.0
n_event                              4.0                9.0
n_event_pct                         22.0               26.0
time-to-event-wk-10th                9.1               15.3
time-to-event-wk-25th               23.0               41.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          23.0               44.3
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9417    0.6068    0.2867    3.0930    0.9212


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0               34.0
n_event                              8.0               19.0
n_event_pct                         44.0               56.0
time-to-event-wk-10th                6.3                4.3
time-to-event-wk-25th               28.3               14.4
time-to-event-wk-50th               32.6               31.1
time-to-event-wk-75th                 NA               55.0
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          17.1               15.7
time-to-event-wk-50th-hici            NA               55.0

$Disdur_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2110    0.4278    0.5238    2.8010    0.6541


$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`
$Disdur_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                 34
n_event                              2.0                  2
n_event_pct                         11.0                  6
time-to-event-wk-10th               47.1                 NA
time-to-event-wk-25th               47.1                 NA
time-to-event-wk-50th                 NA                 NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           47.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33760   1.03800   0.04419   2.58000   0.29530


$Disdur_less_equal_12wk$Investigations
$Disdur_less_equal_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               2.0                4.0
n_event_pct                          11.0               12.0
time-to-event-wk-10th                20.3               25.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9645    0.8844    0.1704    5.4590    0.9674


$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`
$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               4.0                  3
n_event_pct                          22.0                  9
time-to-event-wk-10th                 2.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31290   0.76570   0.06976   1.40300   0.12910


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
```

```
n_event                                8.0              13.0
n_event_pct                           44.0              38.0
time-to-event-wk-10th                  2.3               8.1
time-to-event-wk-25th                  7.1              15.7
time-to-event-wk-50th                 22.9                NA
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci             5.3              17.3
time-to-event-wk-50th-hici              NA                NA

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6368    0.4557    0.2607    1.5560    0.3221



$Region_Europe
$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               3.0                 1
n_event_pct                          18.0                 3
time-to-event-wk-10th                15.3                NA
time-to-event-wk-25th                48.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.3                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.092580  1.237000  0.008202  1.045000  0.054300


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               7.0               6.0
n_event_pct                          41.0              20.0
time-to-event-wk-10th                 2.3              10.9
time-to-event-wk-25th                15.1              29.1
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            9.1                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
  0.38750   0.57090   0.12660   1.18700   0.09685


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               3.0               16.0
n_event_pct                          18.0               53.0
time-to-event-wk-10th                 6.3                5.1
time-to-event-wk-25th                33.4               10.7
time-to-event-wk-50th                  NA               20.6
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.4               14.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  3.42900   0.64180   0.97460  12.06000   0.05487


$Region_Europe$Investigations
$Region_Europe$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 17               30.0
n_event                                1                3.0
n_event_pct                            6               10.0
time-to-event-wk-10th                 NA               25.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6310    1.1640    0.1664   15.9800    0.6745


$Region_Europe$`Metabolism and nutrition disorders`
$Region_Europe$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               2.0                5.0
n_event_pct                          12.0               17.0
time-to-event-wk-10th                 5.9                4.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Region_Europe$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9520    0.8642    0.1750    5.1800    0.9546


$Region_Europe$`Psychiatric disorders`
$Region_Europe$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               3.0                 0
n_event_pct                          18.0                 0
time-to-event-wk-10th                11.1                NA
time-to-event-wk-25th                50.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           50.4                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.610e-10 2.592e+04 0.000e+00       Inf 9.993e-01


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               8.0               12.0
n_event_pct                          47.0               40.0
time-to-event-wk-10th                 2.1                5.7
time-to-event-wk-25th                11.0               14.4
time-to-event-wk-50th                30.3                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            9.0               15.7
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7807    0.4673    0.3124    1.9510    0.5964




\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten UEs nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
```

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	32.0	72.0
n_event	8.0	17.0
n_event_pct	25.0	24.0
time-to-event-wk-10th	12.7	16.3
time-to-event-wk-25th	18.9	52.7
time-to-event-wk-50th	NA	NA
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	18.9	NA
time-to-event-wk-50th-hici	NA	NA

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.6529	0.4366	0.2775	1.5360	0.3289

$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site conditions`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	32.0	72.0
n_event	7.0	20.0
n_event_pct	22.0	28.0
time-to-event-wk-10th	10.4	10.9
time-to-event-wk-25th	24.3	38.6
time-to-event-wk-50th	NA	NA
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	24.3	54.3
time-to-event-wk-50th-hici	NA	NA

$Ageonset_less_equal_12wk$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
1.0310	0.4443	0.4315	2.4620	0.9458

$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	32.0	72.0
n_event	11.0	46.0
n_event_pct	34.0	64.0
time-to-event-wk-10th	6.7	3.4
time-to-event-wk-25th	17.1	9.3
time-to-event-wk-50th	33.4	25.1
time-to-event-wk-75th	NA	51.4
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	17.6	15.7
time-to-event-wk-50th-hici	NA	31.1

$Ageonset_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7370    0.3388    0.8939    3.3740    0.1033


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                             17.0              32.0
n_event_pct                         53.0              44.0
time-to-event-wk-10th                2.9               5.0
time-to-event-wk-25th                7.1              11.6
time-to-event-wk-50th               15.7              44.0
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           7.3              21.9
time-to-event-wk-50th-hici          27.0                NA

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.59880   0.30860   0.32700   1.09600   0.09648



$Gender_Female
$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0              43.0
n_event                              4.0              10.0
n_event_pct                         17.0              23.0
time-to-event-wk-10th               15.3              11.7
time-to-event-wk-25th               48.6              52.7
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          48.6              53.1
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2710    0.6054    0.3878    4.1630    0.6924


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0              43.0
n_event                              9.0              11.0
n_event_pct                         38.0              26.0
time-to-event-wk-10th                5.1              15.3
time-to-event-wk-25th               15.1              44.3
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.1               46.4
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5376    0.4746    0.2120    1.3630    0.1910


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               8.0               25.0
n_event_pct                          33.0               58.0
time-to-event-wk-10th                 7.1                3.7
time-to-event-wk-25th                17.1               13.0
time-to-event-wk-50th                  NA               25.7
time-to-event-wk-75th                  NA               55.0
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.1               18.4
time-to-event-wk-50th-hici             NA               51.4

$Gender_Female$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7120    0.4180    0.7544    3.8830    0.1986


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              14.0               16.0
n_event_pct                          58.0               37.0
time-to-event-wk-10th                 2.9                5.0
time-to-event-wk-25th                 5.6               14.4
time-to-event-wk-50th                15.7                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.1               25.9
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5594    0.3854    0.2628    1.1910    0.1317



$Region_Northamerica
$Region_Northamerica$`Gastrointestinal disorders`
```

```
$Region_Northamerica$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               6.0              13.0
n_event_pct                          27.0              34.0
time-to-event-wk-10th                11.6               7.0
time-to-event-wk-25th                27.9              19.0
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           27.9              21.4
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0270    0.4968    0.3878    2.7180    0.9577


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               3.0              14.0
n_event_pct                          14.0              37.0
time-to-event-wk-10th                13.4               7.6
time-to-event-wk-25th                  NA              38.6
time-to-event-wk-50th                  NA              55.0
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA              41.4
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.5370    0.6372    0.7278    8.8460    0.1439


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              11.0              26.0
n_event_pct                          50.0              68.0
time-to-event-wk-10th                 7.1               3.1
time-to-event-wk-25th                17.1               9.0
time-to-event-wk-50th                28.3              16.7
time-to-event-wk-75th                  NA              55.0
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.1              10.1
time-to-event-wk-50th-hici             NA              37.6

$Region_Northamerica$`Infections and infestations`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3050    0.3631    0.6404    2.6580    0.4639


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              12.0              20.0
n_event_pct                          55.0              53.0
time-to-event-wk-10th                 2.9               1.7
time-to-event-wk-25th                 5.3               7.9
time-to-event-wk-50th                20.4              35.0
time-to-event-wk-75th                27.0                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            5.3              10.0
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7009    0.3728    0.3375    1.4550    0.3404



$Disdur_greater_12wk
$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               5.0              12.0
n_event_pct                          22.0              26.0
time-to-event-wk-10th                 9.7               7.0
time-to-event-wk-25th                27.9              20.1
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           27.9                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0710    0.5351    0.3754    3.0580    0.8975


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               7.0              13.0
n_event_pct                          30.0              28.0
time-to-event-wk-10th                 5.1               6.9
time-to-event-wk-25th                15.1              36.0
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.1               46.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7984    0.4769    0.3135    2.0330    0.6368


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               6.0               30.0
n_event_pct                          26.0               65.0
time-to-event-wk-10th                 7.1                2.0
time-to-event-wk-25th                17.6                9.0
time-to-event-wk-50th                  NA               18.4
time-to-event-wk-75th                  NA               37.6
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.6               10.1
time-to-event-wk-50th-hici             NA               30.7

$Disdur_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  2.64900   0.45090   1.09500   6.41000   0.03073


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              12.0               20.0
n_event_pct                          52.0               43.0
time-to-event-wk-10th                 2.9                1.7
time-to-event-wk-25th                 7.3                8.4
time-to-event-wk-50th                15.7               36.0
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.3               12.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7843    0.3714    0.3787    1.6240    0.5129



$Agetrt_less_180d
$Agetrt_less_180d$`General disorders and administration site conditions`
```

```
$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              3.0              12.0
n_event_pct                         19.0              24.0
time-to-event-wk-10th                9.1              15.0
time-to-event-wk-25th                 NA              41.4
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          11.7              54.3
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9543    0.6550    0.2643    3.4450    0.9431


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              6.0              31.0
n_event_pct                         38.0              63.0
time-to-event-wk-10th                6.3               3.4
time-to-event-wk-25th               17.1              14.4
time-to-event-wk-50th               33.4              25.4
time-to-event-wk-75th                 NA              51.4
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           8.6              15.7
time-to-event-wk-50th-hici            NA              37.6

$Agetrt_less_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5900    0.4466    0.6626    3.8160    0.2990


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              8.0              18.0
n_event_pct                         50.0              37.0
time-to-event-wk-10th                2.1               5.7
time-to-event-wk-25th                7.1              15.7
time-to-event-wk-50th               20.4                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           7.1              23.1
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal
```

```
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42630   0.44280   0.17900   1.01500   0.05417



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                              8.0              10.0
n_event_pct                         32.0              32.0
time-to-event-wk-10th                7.6               6.9
time-to-event-wk-25th               16.9              36.0
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          16.9              36.0
time-to-event-wk-50th-hici            NA                NA

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8788    0.4784    0.3440    2.2440    0.7871


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                              8.0              18.0
n_event_pct                         32.0              58.0
time-to-event-wk-10th                7.1               3.7
time-to-event-wk-25th               28.3               9.3
time-to-event-wk-50th                 NA              20.6
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          28.3               9.4
time-to-event-wk-50th-hici            NA                NA

$Agetrt_greater_equal_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9360    0.4301    0.8335    4.4980    0.1244


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                             12.0              15.0
```

```
n_event_pct                          48.0              48.0
time-to-event-wk-10th                 2.9               0.4
time-to-event-wk-25th                 7.3               7.9
time-to-event-wk-50th                27.0              26.1
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            7.3              10.0
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9757    0.3889    0.4553    2.0910    0.9496



$Gender_Male
$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               2.0              11.0
n_event_pct                          12.0              30.0
time-to-event-wk-10th                13.4               7.6
time-to-event-wk-25th                  NA              38.6
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA              38.6
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.5230    0.7770    0.5501   11.5700    0.2337


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               6.0              24.0
n_event_pct                          35.0              65.0
time-to-event-wk-10th                 6.3               2.4
time-to-event-wk-25th                28.3               6.7
time-to-event-wk-50th                32.6              16.7
time-to-event-wk-75th                  NA              37.6
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.6              10.1
time-to-event-wk-50th-hici             NA              30.7

$Gender_Male$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  2.21500   0.46120   0.89720   5.46900   0.08459
```

```
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               6.0              17.0
n_event_pct                          35.0              46.0
time-to-event-wk-10th                 2.3               1.7
time-to-event-wk-25th                 7.3               8.6
time-to-event-wk-50th                27.0              35.0
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            7.3              11.7
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2110    0.4803    0.4723    3.1040    0.6905



$Region_Europe
$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               3.0              16.0
n_event_pct                          18.0              53.0
time-to-event-wk-10th                 6.3               5.1
time-to-event-wk-25th                33.4              10.7
time-to-event-wk-50th                  NA              20.6
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.4              14.4
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  3.42900   0.64180   0.97460  12.06000   0.05487


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               8.0              12.0
n_event_pct                          47.0              40.0
time-to-event-wk-10th                 2.1               5.7
time-to-event-wk-25th                11.0              14.4
time-to-event-wk-50th                30.3                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
```

```
time-to-event-wk-50th-loci            9.0               15.7
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7807    0.4673    0.3124    1.9510    0.5964



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                               8.0              19.0
n_event_pct                          44.0              56.0
time-to-event-wk-10th                 6.3               4.3
time-to-event-wk-25th                28.3              14.4
time-to-event-wk-50th                32.6              31.1
time-to-event-wk-75th                  NA              55.0
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.1              15.7
time-to-event-wk-50th-hici             NA              55.0

$Disdur_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2110    0.4278    0.5238    2.8010    0.6541


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                               8.0              13.0
n_event_pct                          44.0              38.0
time-to-event-wk-10th                 2.3               8.1
time-to-event-wk-25th                 7.1              15.7
time-to-event-wk-50th                22.9                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            5.3              17.3
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6368    0.4557    0.2607    1.5560    0.3221



\#############################################################################
```

```
[[1]]
[1] "Patienten mit mindestens einem moderaten UE nach PT, das bei mindestens 10%
der Patienten in einem Studienarm auftrat"

$Ageonset_greater_12wk
$Ageonset_greater_12wk$Anxiety
$Ageonset_greater_12wk$Anxiety$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Anxiety$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Bone marrow disorder`
$Ageonset_greater_12wk$`Bone marrow disorder`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Bone marrow disorder`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Bronchial secretion retention`
$Ageonset_greater_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Bronchial secretion retention`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Catarrh
$Ageonset_greater_12wk$Catarrh$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0
```

```
$Ageonset_greater_12wk$Catarrh$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Cyanosis
$Ageonset_greater_12wk$Cyanosis$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Cyanosis$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`
$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Infusion site bruising`
$Ageonset_greater_12wk$`Infusion site bruising`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Infusion site bruising`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Nasal congestion`
$Ageonset_greater_12wk$`Nasal congestion`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
```

```
n_event_pct   11   0

$Ageonset_greater_12wk$`Nasal congestion`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Nasopharyngitis
$Ageonset_greater_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$Nasopharyngitis$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031


$Ageonset_greater_12wk$Oedema
$Ageonset_greater_12wk$Oedema$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Oedema$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Pain
$Ageonset_greater_12wk$Pain$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Pain$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$Pneumonia
$Ageonset_greater_12wk$Pneumonia$ntab
            CTRL TRT
```

```
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Pneumonia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Procedural pain`
$Ageonset_greater_12wk$`Procedural pain`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Procedural pain`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Pseudomonas infection`
$Ageonset_greater_12wk$`Pseudomonas infection`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Pseudomonas infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Pyrexia
$Ageonset_greater_12wk$Pyrexia$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$Pyrexia$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$`Respiratory arrest`
```

```
$Ageonset_greater_12wk$`Respiratory arrest`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Respiratory arrest`$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Respiratory distress`
$Ageonset_greater_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$`Respiratory distress`$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031


$Ageonset_greater_12wk$`Rhinovirus infection`
$Ageonset_greater_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Rhinovirus infection`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Sleep disorder`
$Ageonset_greater_12wk$`Sleep disorder`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Sleep disorder`$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444
```

```
$Ageonset_greater_12wk$Tachycardia
$Ageonset_greater_12wk$Tachycardia$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Tachycardia$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Upper respiratory tract congestion`
$Ageonset_greater_12wk$`Upper respiratory tract congestion`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Upper respiratory tract congestion`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Upper respiratory tract infection`
$Ageonset_greater_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Upper respiratory tract infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Viral upper respiratory tract infection`
$Ageonset_greater_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Viral upper respiratory tract infection`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
```

```
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         32  72
n_event        7  11
n_event_pct   22  15

$Ageonset_less_equal_12wk$Atelectasis$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.69841270 0.43431250  0.2981430 1.63606139 0.4085390
OR_TRTvsCTRL   0.64402810 0.53866472  0.2240746 1.85104534 0.4140092
ARR_TRTvsCTRL -0.06597222 0.08448851 -0.2315667 0.09962222 0.4348951


$Ageonset_less_equal_12wk$Dyspnoea
$Ageonset_less_equal_12wk$Dyspnoea$ntab
            CTRL TRT
n_all         32  72
n_event        4   1
n_event_pct   12   1

$Ageonset_less_equal_12wk$Dyspnoea$stats
                 estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.11111111 1.09766166  0.01292487 0.955187842 0.04531355
OR_TRTvsCTRL   0.09859155 1.14008719  0.01055348 0.921050969 0.04214366
ARR_TRTvsCTRL -0.11111111 0.06006822 -0.22884265 0.006620433 0.06434977


$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         32  72
n_event        4   7
n_event_pct   12  10

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.77777778 0.5896764  0.2448624 2.470524 0.6699691
OR_TRTvsCTRL   0.75384615 0.6663003  0.2042335 2.782522 0.6715049
ARR_TRTvsCTRL -0.02777778 0.0680955 -0.1612425 0.105687 0.6833296


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$ntab
            CTRL TRT
n_all         32  72
n_event        0  11
n_event_pct    0  15
```

```
$Ageonset_less_equal_12wk$Pneumonia$stats
                estimate         se     lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  10.3972603 1.42931972 0.63136393 171.2214092 0.1013754902
OR_TRTvsCTRL  12.1544715 1.46081687 0.69388342 212.9048975 0.0873038186
ARR_TRTvsCTRL  0.1527778 0.04239967 0.06967594   0.2358796 0.0003142301


$Ageonset_less_equal_12wk$`Pneumonia aspiration`
$Ageonset_less_equal_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         32  72
n_event        5   5
n_event_pct   16   7

$Ageonset_less_equal_12wk$`Pneumonia aspiration`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.44444444 0.59570220  0.1382786 1.42849957 0.1734185
OR_TRTvsCTRL   0.40298507 0.67228150  0.1079051 1.50499830 0.1764081
ARR_TRTvsCTRL -0.08680556 0.07083361 -0.2256369 0.05202576 0.2203924


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         32  72
n_event        6  18
n_event_pct   19  25

$Ageonset_less_equal_12wk$Pyrexia$stats
              estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.333333 0.42081271  0.5844432 3.0418316 0.4942060
OR_TRTvsCTRL  1.444444 0.52839595  0.5127780 4.0688557 0.4864748
ARR_TRTvsCTRL 0.062500 0.08581905 -0.1057022 0.2307022 0.4664443


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         32  72
n_event        4  11
n_event_pct   12  15

$Ageonset_less_equal_12wk$`Respiratory distress`$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.22222222 0.54384759  0.4209459 3.548739 0.7121401
OR_TRTvsCTRL  1.26229508 0.62691054  0.3694313 4.313086 0.7102244
ARR_TRTvsCTRL 0.02777778 0.07221981 -0.1137705 0.169326 0.7005129


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        4  11
```

```
n_event_pct   12  15

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.22222222 0.54384759  0.4209459 3.548739 0.7121401
OR_TRTvsCTRL  1.26229508 0.62691054  0.3694313 4.313086 0.7102244
ARR_TRTvsCTRL 0.02777778 0.07221981 -0.1137705 0.169326 0.7005129



$Agetrt_less_180d
$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$ntab
            CTRL TRT
n_all         16  49
n_event        3   7
n_event_pct   19  14

$Agetrt_less_180d$Atelectasis$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.76190476 0.6271222  0.2228914 2.6044026 0.6645633
OR_TRTvsCTRL   0.72222222 0.7595545  0.1629810 3.2004042 0.6683319
ARR_TRTvsCTRL -0.04464286 0.1096378 -0.2595290 0.1702432 0.6838721


$Agetrt_less_180d$Cyanosis
$Agetrt_less_180d$Cyanosis$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$Cyanosis$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$Dyspnoea
$Agetrt_less_180d$Dyspnoea$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$Dyspnoea$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156


$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`
```

```
$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`$stats
                  estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718


$Agetrt_less_180d$Hypokalaemia
$Agetrt_less_180d$Hypokalaemia$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$Hypokalaemia$stats
                  estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$Hypoxia
$Agetrt_less_180d$Hypoxia$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$Hypoxia$stats
                  estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$Nasopharyngitis
$Agetrt_less_180d$Nasopharyngitis$ntab
            CTRL TRT
n_all         16  49
n_event        0   5
n_event_pct    0  10

$Agetrt_less_180d$Nasopharyngitis$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.7400000 1.45017056 0.21801390 64.1592119 0.36302969
OR_TRTvsCTRL  4.0786517 1.50495719 0.21354762 77.9001876 0.35025713
ARR_TRTvsCTRL 0.1020408 0.04324314 0.01728582  0.1867958 0.01828974
```

```
$Agetrt_less_180d$`Oxygen saturation decreased`
$Agetrt_less_180d$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         16  49
n_event        2   4
n_event_pct   12   8

$Agetrt_less_180d$`Oxygen saturation decreased`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 0.81675690  0.1317435 3.2372678 0.6018943
OR_TRTvsCTRL   0.62222222 0.91850465  0.1028284 3.7651137 0.6054670
ARR_TRTvsCTRL -0.04336735 0.09146536 -0.2226362 0.1359015 0.6354004


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$ntab
            CTRL TRT
n_all         16  49
n_event        0   5
n_event_pct    0  10

$Agetrt_less_180d$Pneumonia$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.7400000 1.45017056 0.21801390 64.1592119 0.36302969
OR_TRTvsCTRL  4.0786517 1.50495719 0.21354762 77.9001876 0.35025713
ARR_TRTvsCTRL 0.1020408 0.04324314 0.01728582  0.1867958 0.01828974


$Agetrt_less_180d$`Pneumonia aspiration`
$Agetrt_less_180d$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$`Pneumonia aspiration`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718


$Agetrt_less_180d$`Pneumonia bacterial`
$Agetrt_less_180d$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$`Pneumonia bacterial`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
```

```
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$ntab
            CTRL TRT
n_all         16  49
n_event        2  11
n_event_pct   12  22

$Agetrt_less_180d$Pyrexia$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.7959184 0.7127418  0.4442216  7.2606173 0.4113622
OR_TRTvsCTRL  2.0263158 0.8298515  0.3984156 10.3057114 0.3947589
ARR_TRTvsCTRL 0.0994898 0.1019258 -0.1002812  0.2992608 0.3290150


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$ntab
            CTRL TRT
n_all         16  49
n_event        3   5
n_event_pct   19  10

$Agetrt_less_180d$`Respiratory distress`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.54421769 0.6711372  0.1460493 2.0278961 0.3646555
OR_TRTvsCTRL   0.49242424 0.7956027  0.1035431 2.3418425 0.3732444
ARR_TRTvsCTRL -0.08545918 0.1067308 -0.2946476 0.1237292 0.4233060


$Agetrt_less_180d$`Rhinovirus infection`
$Agetrt_less_180d$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$`Rhinovirus infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156


$Agetrt_less_180d$`Upper respiratory tract infection`
$Agetrt_less_180d$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         16  49
n_event        2   4
n_event_pct   12   8

$Agetrt_less_180d$`Upper respiratory tract infection`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.65306122 0.81675690  0.1317435 3.2372678 0.6018943
OR_TRTvsCTRL   0.62222222 0.91850465  0.1028284 3.7651137 0.6054670
ARR_TRTvsCTRL -0.04336735 0.09146536 -0.2226362 0.1359015 0.6354004



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$Atelectasis
$Agetrt_greater_equal_180d$Atelectasis$ntab
            CTRL TRT
n_all         25  31
n_event        4   4
n_event_pct   16  13

$Agetrt_greater_equal_180d$Atelectasis$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80645161 0.65401983  0.2238080 2.9059023 0.7422264
OR_TRTvsCTRL   0.77777778 0.76462807  0.1737813 3.4810329 0.7424011
ARR_TRTvsCTRL -0.03096774 0.09487495 -0.2169192 0.1549837 0.7441173


$Agetrt_greater_equal_180d$Pneumonia
$Agetrt_greater_equal_180d$Pneumonia$ntab
            CTRL TRT
n_all         25  31
n_event        1   6
n_event_pct    4  19

$Agetrt_greater_equal_180d$Pneumonia$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.8387097 1.04613986  0.622663923 37.6015222 0.13178240
OR_TRTvsCTRL  5.7600000 1.11728838  0.644740403 51.4588505 0.11708403
ARR_TRTvsCTRL 0.1535484 0.08106218 -0.005330574  0.3124273 0.05819782


$Agetrt_greater_equal_180d$`Pneumonia aspiration`
$Agetrt_greater_equal_180d$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         25  31
n_event        3   2
n_event_pct   12   6

$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.53763441 0.87239628  0.09725277 2.97215952 0.4768692
OR_TRTvsCTRL   0.50574713 0.95565194  0.07771073 3.29143917 0.4756265
ARR_TRTvsCTRL -0.05548387 0.07855506 -0.20944895 0.09848121 0.4799981


$Agetrt_greater_equal_180d$Pyrexia
$Agetrt_greater_equal_180d$Pyrexia$ntab
            CTRL TRT
n_all         25  31
n_event        6   8
```

```
n_event_pct   24  26

$Agetrt_greater_equal_180d$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.07526882 0.4684107  0.4293437 2.6929543 0.8768768
OR_TRTvsCTRL  1.10144928 0.6227170  0.3250175 3.7326924 0.8766875
ARR_TRTvsCTRL 0.01806452 0.1160705 -0.2094295 0.2455585 0.8763215


$Agetrt_greater_equal_180d$`Respiratory distress`
$Agetrt_greater_equal_180d$`Respiratory distress`$ntab
            CTRL TRT
n_all         25  31
n_event        2   7
n_event_pct    8  23

$Agetrt_greater_equal_180d$`Respiratory distress`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.8225806 0.75538009  0.64219314 12.4058652 0.1695406
OR_TRTvsCTRL  3.3541667 0.85323037  0.62996095 17.8589388 0.1560804
ARR_TRTvsCTRL 0.1458065 0.09264603 -0.03577643  0.3273893 0.1155334


$Agetrt_greater_equal_180d$`Rhinovirus infection`
$Agetrt_greater_equal_180d$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         25  31
n_event        0   5
n_event_pct    0  16

$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   8.9375000 1.45330886 0.51779435 154.2676271 0.13178959
OR_TRTvsCTRL  10.5849057 1.50292040 0.55641500 201.3609040 0.11643927
ARR_TRTvsCTRL  0.1612903 0.06605857 0.03181791   0.2907627 0.01462128


$Agetrt_greater_equal_180d$`Upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        3   7
n_event_pct   12  23

$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$stats
               estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.8817204 0.63555677  0.54146226 6.5394618 0.3198836
OR_TRTvsCTRL  2.1388889 0.75054093  0.49127722 9.3121470 0.3110675
ARR_TRTvsCTRL 0.1058065 0.09931408 -0.08884557 0.3004585 0.2867076



$Gender_Male
$Gender_Male$Atelectasis
```

```
$Gender_Male$Atelectasis$ntab
            CTRL TRT
n_all         17  37
n_event        3   4
n_event_pct   18  11

$Gender_Male$Atelectasis$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.61261261 0.7053246  0.1537491 2.4409524 0.4872136
OR_TRTvsCTRL   0.56565657 0.8276865  0.1116927 2.8647113 0.4912095
ARR_TRTvsCTRL -0.06836248 0.1056159 -0.2753658 0.1386408 0.5174542


$Gender_Male$Cyanosis
$Gender_Male$Cyanosis$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$Cyanosis$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$Dysphagia
$Gender_Male$Dysphagia$ntab
            CTRL TRT
n_all         17  37
n_event        3   0
n_event_pct   18   0

$Gender_Male$Dysphagia$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.06766917 1.48453459  0.003687676 1.241735222 0.06965918
OR_TRTvsCTRL   0.05523810 1.54316119  0.002683475 1.137050842 0.06055462
ARR_TRTvsCTRL -0.17647059 0.09245944 -0.357687763 0.004746586 0.05631022


$Gender_Male$Hypokalaemia
$Gender_Male$Hypokalaemia$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$Hypokalaemia$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839
```

```
$Gender_Male$Hypoxia
$Gender_Male$Hypoxia$ntab
            CTRL TRT
n_all         17  37
n_event        2   2
n_event_pct   12   5

$Gender_Male$Hypoxia$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.95611163  0.07053481 2.9928909 0.4159867
OR_TRTvsCTRL   0.4285714 1.04653624  0.05510740 3.3330089 0.4181580
ARR_TRTvsCTRL -0.0635930 0.08653439 -0.23319729 0.1060113 0.4624083


$Gender_Male$`Joint contracture`
$Gender_Male$`Joint contracture`$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$`Joint contracture`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$Nasopharyngitis
$Gender_Male$Nasopharyngitis$ntab
            CTRL TRT
n_all         17  37
n_event        1   4
n_event_pct    6  11

$Gender_Male$Nasopharyngitis$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.83783784 1.07895757  0.2217670 15.2306185 0.5727177
OR_TRTvsCTRL  1.93939394 1.15879378  0.2001239 18.7946001 0.5675877
ARR_TRTvsCTRL 0.04928458 0.07656783 -0.1007856  0.1993548 0.5197880


$Gender_Male$`Oxygen saturation decreased`
$Gender_Male$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         17  37
n_event        2   4
n_event_pct   12  11

$Gender_Male$`Oxygen saturation decreased`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.918918919 0.81495365  0.1860319 4.5390712 0.9173620
OR_TRTvsCTRL   0.909090909 0.92030957  0.1497057 5.5204723 0.9175160
```

```
ARR_TRTvsCTRL -0.009538951 0.09333925 -0.1924805 0.1734026 0.9186007


$Gender_Male$Pneumonia
$Gender_Male$Pneumonia$ntab
            CTRL TRT
n_all         17  37
n_event        0   4
n_event_pct    0  11

$Gender_Male$Pneumonia$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.2631579 1.46299381 0.242342081 74.9952925 0.32162440
OR_TRTvsCTRL  4.7014925 1.51961042 0.239188898 92.4124501 0.30839139
ARR_TRTvsCTRL 0.1081081 0.05104866 0.008054565  0.2081617 0.03419658


$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$ntab
            CTRL TRT
n_all         17  37
n_event        2   9
n_event_pct   12  24

$Gender_Male$Pyrexia$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.0675676 0.7247486  0.49951964  8.557893 0.3162272
OR_TRTvsCTRL  2.4107143 0.8446846  0.46041441 12.622418 0.2975425
ARR_TRTvsCTRL 0.1255962 0.1052676 -0.08072459  0.331917 0.2328251


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$ntab
            CTRL TRT
n_all         17  37
n_event        3   7
n_event_pct   18  19

$Gender_Male$`Respiratory distress`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.0720721 0.6247719  0.3150773 3.6477980 0.9113072
OR_TRTvsCTRL  1.0888889 0.7622023  0.2444532 4.8503308 0.9110407
ARR_TRTvsCTRL 0.0127186 0.1126703 -0.2081112 0.2335484 0.9101231


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$ntab
            CTRL TRT
n_all         17  37
n_event        0   4
n_event_pct    0  11

$Gender_Male$`Respiratory failure`$stats
               estimate         se      lo95ci     hi95ci     pvalue
```

```
RR_TRTvsCTRL  4.2631579 1.46299381 0.242342081 74.9952925 0.32162440
OR_TRTvsCTRL  4.7014925 1.51961042 0.239188898 92.4124501 0.30839139
ARR_TRTvsCTRL 0.1081081 0.05104866 0.008054565  0.2081617 0.03419658


$Gender_Male$`Rhinovirus infection`
$Gender_Male$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         17  37
n_event        1   5
n_event_pct    6  14

$Gender_Male$`Rhinovirus infection`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.29729730 1.05553278  0.2902325 18.1839543 0.4307114
OR_TRTvsCTRL  2.50000000 1.13743132  0.2690027 23.2339634 0.4204857
ARR_TRTvsCTRL 0.07631161 0.08009627 -0.0806742  0.2332974 0.3407175


$Gender_Male$`Sleep apnoea syndrome`
$Gender_Male$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$`Sleep apnoea syndrome`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$`Upper respiratory tract infection`
$Gender_Male$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         17  37
n_event        2   5
n_event_pct   12  14

$Gender_Male$`Upper respiratory tract infection`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14864865 0.78367687  0.2472409 5.3364712 0.8596333
OR_TRTvsCTRL  1.17187500 0.89326181  0.2034864 6.7488088 0.8590708
ARR_TRTvsCTRL 0.01748808 0.09625485 -0.1711680 0.2061441 0.8558298



$Gender_Female
$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$ntab
            CTRL TRT
n_all         24  43
n_event        4   7
```

```
n_event_pct   17  16

$Gender_Female$Atelectasis$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.976744186 0.57265580  0.3179328 3.0007259 0.9672240
OR_TRTvsCTRL   0.972222222 0.68602837  0.2534061 3.7300439 0.9672451
ARR_TRTvsCTRL -0.003875969 0.09463915 -0.1893653 0.1816134 0.9673316


$Gender_Female$Dyspnoea
$Gender_Female$Dyspnoea$ntab
            CTRL TRT
n_all         24  43
n_event        3   1
n_event_pct   12   2

$Gender_Female$Dyspnoea$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1860465 1.12623748  0.02046287 1.69151794 0.1353707
OR_TRTvsCTRL   0.1666667 1.18522652  0.01632985 1.70104339 0.1305989
ARR_TRTvsCTRL -0.1017442 0.07131302 -0.24151514 0.03802677 0.1536587


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$ntab
            CTRL TRT
n_all         24  43
n_event        1   7
n_event_pct    4  16

$Gender_Female$Pneumonia$stats
              estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.906977 1.03823632  0.51061370 29.8943549 0.18932593
OR_TRTvsCTRL  4.472222 1.10186804  0.51595473 38.7645862 0.17401814
ARR_TRTvsCTRL 0.121124 0.06952198 -0.01513654  0.2573846 0.08146631


$Gender_Female$`Pneumonia aspiration`
$Gender_Female$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         24  43
n_event        4   3
n_event_pct   17   7

$Gender_Female$`Pneumonia aspiration`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.41860465 0.72000754  0.10207809 1.71662556 0.2264819
OR_TRTvsCTRL   0.37500000 0.81137743  0.07645142 1.83940341 0.2267225
ARR_TRTvsCTRL -0.09689922 0.08541861 -0.26431661 0.07051816 0.2566250


$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$ntab
            CTRL TRT
```

```
n_all         24  43
n_event        6  10
n_event_pct   25  23

$Gender_Female$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93023256 0.4491594  0.3857148 2.2434517 0.8720829
OR_TRTvsCTRL   0.90909091 0.5937384  0.2839333 2.9107059 0.8724671
ARR_TRTvsCTRL -0.01744186 0.1093759 -0.2318146 0.1969309 0.8733008


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$ntab
            CTRL TRT
n_all         24  43
n_event        2   5
n_event_pct    8  12

$Gender_Female$`Respiratory distress`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39534884 0.79691751  0.2926479 6.6530412 0.6759169
OR_TRTvsCTRL  1.44736842 0.87850460  0.2586989 8.0977351 0.6738410
ARR_TRTvsCTRL 0.03294574 0.07464983 -0.1133652 0.1792567 0.6589690


$Gender_Female$`Respiratory failure`
$Gender_Female$`Respiratory failure`$ntab
            CTRL TRT
n_all         24  43
n_event        3   1
n_event_pct   12   2

$Gender_Female$`Respiratory failure`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1860465 1.12623748  0.02046287 1.69151794 0.1353707
OR_TRTvsCTRL   0.1666667 1.18522652  0.01632985 1.70104339 0.1305989
ARR_TRTvsCTRL -0.1017442 0.07131302 -0.24151514 0.03802677 0.1536587


$Gender_Female$`Upper respiratory tract infection`
$Gender_Female$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        3   6
n_event_pct   12  14

$Gender_Female$`Upper respiratory tract infection`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.11627907 0.65960406  0.3064198 4.0665749 0.8675525
OR_TRTvsCTRL  1.13513514 0.75805414  0.2569157 5.0153866 0.8672074
ARR_TRTvsCTRL 0.01453488 0.08572922 -0.1534913 0.1825611 0.8653687


$Gender_Female$`Viral upper respiratory tract infection`
```

```
$Gender_Female$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        0   5
n_event_pct    0  12

$Gender_Female$`Viral upper respiratory tract infection`$stats
               estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  6.2500000 1.45570976 0.36039406 108.3883020 0.20806932
OR_TRTvsCTRL  7.0000000 1.49953611 0.37041673 132.2834424 0.19439912
ARR_TRTvsCTRL 0.1162791 0.04888483 0.02046656   0.2120916 0.01737697



$Region_Europe
$Region_Europe$Atelectasis
$Region_Europe$Atelectasis$ntab
            CTRL TRT
n_all         17  30
n_event        1   6
n_event_pct    6  20

$Region_Europe$Atelectasis$stats
               estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.4000000 1.03658565  0.4457954 25.9311764 0.2377684
OR_TRTvsCTRL  4.0000000 1.12731244  0.4390257 36.4443391 0.2187968
ARR_TRTvsCTRL 0.1411765 0.09268225 -0.0404774  0.3228303 0.1277009


$Region_Europe$`Feeding disorder of infancy or early childhood`
$Region_Europe$`Feeding disorder of infancy or early childhood`$ntab
            CTRL TRT
n_all         17  30
n_event        2   2
n_event_pct   12   7

$Region_Europe$`Feeding disorder of infancy or early childhood`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56666667 0.95280803  0.08755803 3.6674089 0.5510978
OR_TRTvsCTRL   0.53571429 1.04994331  0.06842580 4.1941754 0.5522013
ARR_TRTvsCTRL -0.05098039 0.09044514 -0.22824960 0.1262888 0.5729849


$Region_Europe$Pneumonia
$Region_Europe$Pneumonia$ntab
            CTRL TRT
n_all         17  30
n_event        1   3
n_event_pct    6  10

$Region_Europe$Pneumonia$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 1.11408100  0.1914880 15.0923333 0.6338661
OR_TRTvsCTRL  1.77777778 1.19702563  0.1702031 18.5689583 0.6307571
```

```
ARR_TRTvsCTRL 0.04117647 0.07909909 -0.1138549  0.1962078 0.6026676


$Region_Europe$`Pneumonia aspiration`
$Region_Europe$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         17  30
n_event        2   2
n_event_pct   12   7

$Region_Europe$`Pneumonia aspiration`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56666667 0.95280803  0.08755803 3.6674089 0.5510978
OR_TRTvsCTRL   0.53571429 1.04994331  0.06842580 4.1941754 0.5522013
ARR_TRTvsCTRL -0.05098039 0.09044514 -0.22824960 0.1262888 0.5729849


$Region_Europe$Pyrexia
$Region_Europe$Pyrexia$ntab
            CTRL TRT
n_all         17  30
n_event        6   5
n_event_pct   35  17

$Region_Europe$Pyrexia$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4722222 0.5239368  0.16911050 1.31862790 0.1521285
OR_TRTvsCTRL   0.3666667 0.7053905  0.09201147 1.46117056 0.1549288
ARR_TRTvsCTRL -0.1862745 0.1344001 -0.44969379 0.07714477 0.1657559


$Region_Europe$`Respiratory distress`
$Region_Europe$`Respiratory distress`$ntab
            CTRL TRT
n_all         17  30
n_event        1   5
n_event_pct    6  17

$Region_Europe$`Respiratory distress`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.8333333 1.05254128  0.36005837 22.2957676 0.3224352
OR_TRTvsCTRL  3.2000000 1.14127122  0.34174184 29.9641390 0.3081217
ARR_TRTvsCTRL 0.1078431 0.08880482 -0.06621111  0.2818974 0.2246012


$Region_Europe$`Respiratory failure`
$Region_Europe$`Respiratory failure`$ntab
            CTRL TRT
n_all         17  30
n_event        3   3
n_event_pct   18  10

$Region_Europe$`Respiratory failure`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.56666667 0.7579642  0.12827657 2.5032718 0.4536435
OR_TRTvsCTRL   0.51851852 0.8804160  0.09233213 2.9118949 0.4556748
ARR_TRTvsCTRL -0.07647059 0.1074651 -0.28709832 0.1341571 0.4767216


$Region_Europe$`Respiratory tract infection`
$Region_Europe$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         17  30
n_event        1   5
n_event_pct    6  17

$Region_Europe$`Respiratory tract infection`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.8333333 1.05254128  0.36005837 22.2957676 0.3224352
OR_TRTvsCTRL  3.2000000 1.14127122  0.34174184 29.9641390 0.3081217
ARR_TRTvsCTRL 0.1078431 0.08880482 -0.06621111  0.2818974 0.2246012


$Region_Europe$`Rhinovirus infection`
$Region_Europe$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         17  30
n_event        0   3
n_event_pct    0  10

$Region_Europe$`Rhinovirus infection`$stats
               estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.064516 1.48253184  0.222369622 74.2920332 0.34421066
OR_TRTvsCTRL  4.454545 1.54247229  0.216694854 91.5710496 0.33278158
ARR_TRTvsCTRL 0.100000 0.05477226 -0.007351649  0.2073516 0.06788915


$Region_Europe$`Viral infection`
$Region_Europe$`Viral infection`$ntab
            CTRL TRT
n_all         17  30
n_event        0   4
n_event_pct    0  13

$Region_Europe$`Viral infection`$stats
               estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  5.2258065 1.46096153 0.29825011  91.5642690 0.25769180
OR_TRTvsCTRL  5.9433962 1.52220266 0.30083851 117.4183396 0.24165650
ARR_TRTvsCTRL 0.1333333 0.06206329 0.01169152   0.2549751 0.03168639



$Region_Northamerica
$Region_Northamerica$Atelectasis
$Region_Northamerica$Atelectasis$ntab
            CTRL TRT
n_all         22  38
n_event        6   4
```

```
n_event_pct   27  11

$Region_Northamerica$Atelectasis$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3859649 0.5872788  0.12208301 1.22022637 0.1050067
OR_TRTvsCTRL   0.3137255 0.7131469  0.07753863 1.26935035 0.1040511
ARR_TRTvsCTRL -0.1674641 0.1072113 -0.37759449 0.04266626 0.1182880


$Region_Northamerica$Dyspnoea
$Region_Northamerica$Dyspnoea$ntab
            CTRL TRT
n_all         22  38
n_event        3   0
n_event_pct   14   0

$Region_Northamerica$Dyspnoea$stats
                estimate       se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08424908 1.488823  0.004552778 1.559028057 0.09657297
OR_TRTvsCTRL   0.07235622 1.537196  0.003556416 1.472106135 0.08756107
ARR_TRTvsCTRL -0.13636364 0.073165 -0.279764411 0.007037138 0.06235229


$Region_Northamerica$Hypokalaemia
$Region_Northamerica$Hypokalaemia$ntab
            CTRL TRT
n_all         22  38
n_event        3   0
n_event_pct   14   0

$Region_Northamerica$Hypokalaemia$stats
                estimate       se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08424908 1.488823  0.004552778 1.559028057 0.09657297
OR_TRTvsCTRL   0.07235622 1.537196  0.003556416 1.472106135 0.08756107
ARR_TRTvsCTRL -0.13636364 0.073165 -0.279764411 0.007037138 0.06235229


$Region_Northamerica$`Oxygen saturation decreased`
$Region_Northamerica$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         22  38
n_event        4   6
n_event_pct   18  16

$Region_Northamerica$`Oxygen saturation decreased`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.86842105 0.5872788  0.2746868 2.7455093 0.8101564
OR_TRTvsCTRL   0.84375000 0.7095578  0.2100086 3.3899278 0.8107617
ARR_TRTvsCTRL -0.02392344 0.1012960 -0.2224600 0.1746131 0.8132980


$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$ntab
            CTRL TRT
```

```
n_all         22  38
n_event        0   4
n_event_pct    0  11

$Region_Northamerica$Pneumonia$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  5.3076923 1.46734554 0.299156849  94.169991 0.25531463
OR_TRTvsCTRL  5.8695652 1.51514097 0.301242051 114.365825 0.24278123
ARR_TRTvsCTRL 0.1052632 0.04978449 0.007687351   0.202839 0.03448312


$Region_Northamerica$`Pneumonia aspiration`
$Region_Northamerica$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$`Pneumonia aspiration`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$`Pneumonia viral`
$Region_Northamerica$`Pneumonia viral`$ntab
            CTRL TRT
n_all         22  38
n_event        0   4
n_event_pct    0  11

$Region_Northamerica$`Pneumonia viral`$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  5.3076923 1.46734554 0.299156849  94.169991 0.25531463
OR_TRTvsCTRL  5.8695652 1.51514097 0.301242051 114.365825 0.24278123
ARR_TRTvsCTRL 0.1052632 0.04978449 0.007687351   0.202839 0.03448312


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$ntab
            CTRL TRT
n_all         22  38
n_event        2  12
n_event_pct    9  32

$Region_Northamerica$Pyrexia$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.4736842 0.7152363 0.85502748 14.1123909 0.08168620
OR_TRTvsCTRL  4.6153846 0.8196309 0.92584179 23.0080078 0.06204753
ARR_TRTvsCTRL 0.2248804 0.0971727 0.03442539  0.4153354 0.02065488


$Region_Northamerica$`Respiratory distress`
```

```
$Region_Northamerica$`Respiratory distress`$ntab
            CTRL TRT
n_all         22  38
n_event        4   7
n_event_pct   18  18

$Region_Northamerica$`Respiratory distress`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.013157895 0.5666452  0.3336936 3.0761423 0.9815950
OR_TRTvsCTRL  1.016129032 0.6933042  0.2611002 3.9544901 0.9815877
ARR_TRTvsCTRL 0.002392344 0.1035205 -0.2005041 0.2052888 0.9815626


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        4  10
n_event_pct   18  26

$Region_Northamerica$`Upper respiratory tract infection`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.44736842 0.5274748  0.5147445 4.0697381 0.4833182
OR_TRTvsCTRL  1.60714286 0.6642814  0.4371365 5.9086991 0.4750773
ARR_TRTvsCTRL 0.08133971 0.1089248 -0.1321490 0.2948285 0.4552139


$Region_Northamerica$`Viral upper respiratory tract infection`
$Region_Northamerica$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        1   7
n_event_pct    5  18

$Region_Northamerica$`Viral upper respiratory tract infection`$stats
              estimate        se     lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  4.052632 1.0349332  0.5330898 30.808737 0.17633306
OR_TRTvsCTRL  4.741935 1.1057731  0.5429000 41.418222 0.15926051
ARR_TRTvsCTRL 0.138756 0.0769861 -0.0121340  0.289646 0.07149018



$Disdur_greater_12wk
$Disdur_greater_12wk$Atelectasis
$Disdur_greater_12wk$Atelectasis$ntab
            CTRL TRT
n_all         23  46
n_event        4   6
n_event_pct   17  13

$Disdur_greater_12wk$Atelectasis$stats
                 estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.75000000 0.59283157  0.2346616 2.397068 0.6274864
OR_TRTvsCTRL   0.71250000 0.70306347  0.1796123 2.826400 0.6297061
```

```
ARR_TRTvsCTRL -0.04347826 0.09333858 -0.2264185 0.139462 0.6413498


$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$ntab
            CTRL TRT
n_all         23  46
n_event        1   9
n_event_pct    4  20

$Disdur_greater_12wk$Pneumonia$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.5000000 1.02268945 0.60631411 33.3985302 0.14137015
OR_TRTvsCTRL  5.3513514 1.08793046 0.63447627 45.1348031 0.12312713
ARR_TRTvsCTRL 0.1521739 0.07231396 0.01044116  0.2939067 0.03534789


$Disdur_greater_12wk$`Pneumonia aspiration`
$Disdur_greater_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         23  46
n_event        3   3
n_event_pct   13   7

$Disdur_greater_12wk$`Pneumonia aspiration`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 0.77553161  0.10935441 2.28614465 0.3714448
OR_TRTvsCTRL   0.46511628 0.86018747  0.08617249 2.51046656 0.3735277
ARR_TRTvsCTRL -0.06521739 0.07909916 -0.22024891 0.08981412 0.4096546


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$ntab
            CTRL TRT
n_all         23  46
n_event        7  10
n_event_pct   30  22

$Disdur_greater_12wk$Pyrexia$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.71428571 0.4214733  0.3126895 1.631664 0.4246825
OR_TRTvsCTRL   0.63492063 0.5771784  0.2048445 1.967952 0.4312658
ARR_TRTvsCTRL -0.08695652 0.1135947 -0.3095980 0.135685 0.4439750


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         23  46
n_event        2   9
n_event_pct    9  20

$Disdur_greater_12wk$`Respiratory distress`$stats
               estimate         se      lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL  2.2500000 0.73884621  0.52878057  9.5739146 0.2723954
OR_TRTvsCTRL  2.5540541 0.82810457  0.50390213 12.9453553 0.2574986
ARR_TRTvsCTRL 0.1086957 0.08290416 -0.05379351  0.2711848 0.1898239


$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         23  46
n_event        3   3
n_event_pct   13   7

$Disdur_greater_12wk$`Respiratory failure`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 0.77553161  0.10935441 2.28614465 0.3714448
OR_TRTvsCTRL   0.46511628 0.86018747  0.08617249 2.51046656 0.3735277
ARR_TRTvsCTRL -0.06521739 0.07909916 -0.22024891 0.08981412 0.4096546


$Disdur_greater_12wk$`Rhinovirus infection`
$Disdur_greater_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         23  46
n_event        0   5
n_event_pct    0  11

$Disdur_greater_12wk$`Rhinovirus infection`$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  5.6170213 1.45563557 0.32394167  97.396940 0.23578031
OR_TRTvsCTRL  6.2289157 1.49948917 0.32964384 117.700943 0.22250900
ARR_TRTvsCTRL 0.1086957 0.04589234 0.01874832   0.198643 0.01786075


$Disdur_greater_12wk$Teething
$Disdur_greater_12wk$Teething$ntab
            CTRL TRT
n_all         23  46
n_event        1   5
n_event_pct    4  11

$Disdur_greater_12wk$Teething$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.50000000 1.06526176  0.30987573 20.1693759 0.3897033
OR_TRTvsCTRL  2.68292683 1.12687390  0.29472164 24.4233724 0.3811426
ARR_TRTvsCTRL 0.06521739 0.06256418 -0.05740614  0.1878409 0.2972226


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         23  46
n_event        2   8
n_event_pct    9  17
```

```
$Disdur_greater_12wk$`Upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.00000000 0.74818621  0.46150110  8.6673684 0.3542191
OR_TRTvsCTRL  2.21052632 0.83602323  0.42940928 11.3794154 0.3427152
ARR_TRTvsCTRL 0.08695652 0.08108737 -0.07197181  0.2458849 0.2835491



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         18  34
n_event        3   5
n_event_pct   17  15

$Disdur_less_equal_12wk$Atelectasis$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.88235294 0.6696014  0.2375071 3.2779934 0.8517219
OR_TRTvsCTRL   0.86206897 0.7965443  0.1809349 4.1073500 0.8521861
ARR_TRTvsCTRL -0.01960784 0.1067953 -0.2289228 0.1897071 0.8543256


$Disdur_less_equal_12wk$Cyanosis
$Disdur_less_equal_12wk$Cyanosis$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$Cyanosis$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$Dyspnoea
$Disdur_less_equal_12wk$Dyspnoea$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$Dyspnoea$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`
$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`$ntab
            CTRL TRT
```

```
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$Hypokalaemia
$Disdur_less_equal_12wk$Hypokalaemia$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$Hypokalaemia$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$Hypoxia
$Disdur_less_equal_12wk$Hypoxia$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$Hypoxia$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$Nasopharyngitis
$Disdur_less_equal_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all         18  34
n_event        1   4
n_event_pct    6  12

$Disdur_less_equal_12wk$Nasopharyngitis$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.1176471 1.07936680  0.25532592 17.5635484 0.4869707
OR_TRTvsCTRL  2.2666667 1.15851494  0.23402268 21.9541871 0.4799741
ARR_TRTvsCTRL 0.0620915 0.07725333 -0.08932223  0.2135052 0.4215478


$Disdur_less_equal_12wk$Oedema
```

```
$Disdur_less_equal_12wk$Oedema$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$Oedema$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Oxygen saturation decreased`
$Disdur_less_equal_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         18  34
n_event        2   3
n_event_pct   11   9

$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.86508151  0.1457223 4.3275646 0.7898725
OR_TRTvsCTRL   0.77419355 0.96337500  0.1171718 5.1153557 0.7904985
ARR_TRTvsCTRL -0.02287582 0.08861794 -0.1965638 0.1508122 0.7962990


$Disdur_less_equal_12wk$`Pneumonia aspiration`
$Disdur_less_equal_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$`Pneumonia bacterial`
$Disdur_less_equal_12wk$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3

$Disdur_less_equal_12wk$`Pneumonia bacterial`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495
```

```
$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         18  34
n_event        1   9
n_event_pct    6  26

$Disdur_less_equal_12wk$Pyrexia$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.7647059 1.01298756 0.65430393 34.6970594 0.12326346
OR_TRTvsCTRL  6.1200000 1.09997029 0.70868789 52.8503455 0.09957467
ARR_TRTvsCTRL 0.2091503 0.09294923 0.02697318  0.3913275 0.02443901


$Disdur_less_equal_12wk$`Respiratory distress`
$Disdur_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         18  34
n_event        3   3
n_event_pct   17   9

$Disdur_less_equal_12wk$`Respiratory distress`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.7626922  0.11873776 2.3604692 0.4043523
OR_TRTvsCTRL   0.48387097 0.8749808  0.08708524 2.6885280 0.4067308
ARR_TRTvsCTRL -0.07843137 0.1004103 -0.27523187 0.1183691 0.4347383


$Disdur_less_equal_12wk$`Rhinovirus infection`
$Disdur_less_equal_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3

$Disdur_less_equal_12wk$`Rhinovirus infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495


$Disdur_less_equal_12wk$`Upper respiratory tract infection`
$Disdur_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         18  34
n_event        3   3
n_event_pct   17   9

$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.7626922  0.11873776 2.3604692 0.4043523
OR_TRTvsCTRL   0.48387097 0.8749808  0.08708524 2.6885280 0.4067308
```

```
ARR_TRTvsCTRL -0.07843137 0.1004103 -0.27523187 0.1183691 0.4347383


$Disdur_less_equal_12wk$`Viral infection`
$Disdur_less_equal_12wk$`Viral infection`$ntab
            CTRL TRT
n_all         18  34
n_event        0   4
n_event_pct    0  12

$Disdur_less_equal_12wk$`Viral infection`$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.8857143 1.46322220 0.277607419  85.985469 0.27830946
OR_TRTvsCTRL  5.4590164 1.51956019 0.277755343 107.291761 0.26401687
ARR_TRTvsCTRL 0.1176471 0.05525508 0.009349083   0.225945 0.03324081



$Region_Asia_Pacific
$Region_Asia_Pacific$Oedema
$Region_Asia_Pacific$Oedema$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$Oedema$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$Pneumonia
$Region_Asia_Pacific$Pneumonia$ntab
            CTRL TRT
n_all          2  12
n_event        0   4
n_event_pct    0  33

$Region_Asia_Pacific$Pneumonia$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.0769231 1.3460928 0.14846502 29.0547188 0.58715071
OR_TRTvsCTRL  2.6470588 1.6552551 0.10323048 67.8764696 0.55646775
ARR_TRTvsCTRL 0.3333333 0.1360828 0.06661602  0.6000506 0.01430588


$Region_Asia_Pacific$Pyrexia
$Region_Asia_Pacific$Pyrexia$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17
```

```
$Region_Asia_Pacific$Pyrexia$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353


$Region_Asia_Pacific$Teething
$Region_Asia_Pacific$Teething$ntab
            CTRL TRT
n_all          2  12
n_event        0   3
n_event_pct    0  25

$Region_Asia_Pacific$Teething$stats
              estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.615385 1.369474 0.110300612 23.6577786 0.72619768
OR_TRTvsCTRL  1.842105 1.670622 0.069707343 48.6799765 0.71460562
ARR_TRTvsCTRL 0.250000 0.125000 0.005004502  0.4949955 0.04550026


$Region_Asia_Pacific$`Urinary tract infection`
$Region_Asia_Pacific$`Urinary tract infection`$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$`Urinary tract infection`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353




\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten UE nach PT, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         32  72
n_event        7  11
n_event_pct   22  15

$Ageonset_less_equal_12wk$Atelectasis$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.69841270 0.43431250  0.2981430 1.63606139 0.4085390
OR_TRTvsCTRL   0.64402810 0.53866472  0.2240746 1.85104534 0.4140092
```

```
ARR_TRTvsCTRL -0.06597222 0.08448851 -0.2315667 0.09962222 0.4348951


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$ntab
            CTRL TRT
n_all         32  72
n_event        0  11
n_event_pct    0  15

$Ageonset_less_equal_12wk$Pneumonia$stats
                estimate         se     lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  10.3972603 1.42931972 0.63136393 171.2214092 0.1013754902
OR_TRTvsCTRL  12.1544715 1.46081687 0.69388342 212.9048975 0.0873038186
ARR_TRTvsCTRL  0.1527778 0.04239967 0.06967594   0.2358796 0.0003142301


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         32  72
n_event        6  18
n_event_pct   19  25

$Ageonset_less_equal_12wk$Pyrexia$stats
              estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.333333 0.42081271  0.5844432 3.0418316 0.4942060
OR_TRTvsCTRL  1.444444 0.52839595  0.5127780 4.0688557 0.4864748
ARR_TRTvsCTRL 0.062500 0.08581905 -0.1057022 0.2307022 0.4664443


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         32  72
n_event        4  11
n_event_pct   12  15

$Ageonset_less_equal_12wk$`Respiratory distress`$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.22222222 0.54384759  0.4209459 3.548739 0.7121401
OR_TRTvsCTRL  1.26229508 0.62691054  0.3694313 4.313086 0.7102244
ARR_TRTvsCTRL 0.02777778 0.07221981 -0.1137705 0.169326 0.7005129


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        4  11
n_event_pct   12  15

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats
                estimate         se     lo95ci   hi95ci    pvalue
```

```
RR_TRTvsCTRL  1.22222222 0.54384759  0.4209459 3.548739 0.7121401
OR_TRTvsCTRL  1.26229508 0.62691054  0.3694313 4.313086 0.7102244
ARR_TRTvsCTRL 0.02777778 0.07221981 -0.1137705 0.169326 0.7005129



$Agetrt_less_180d
$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$ntab
            CTRL TRT
n_all         16  49
n_event        2  11
n_event_pct   12  22

$Agetrt_less_180d$Pyrexia$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.7959184 0.7127418  0.4442216  7.2606173 0.4113622
OR_TRTvsCTRL  2.0263158 0.8298515  0.3984156 10.3057114 0.3947589
ARR_TRTvsCTRL 0.0994898 0.1019258 -0.1002812  0.2992608 0.3290150



$Gender_Female
$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$ntab
            CTRL TRT
n_all         24  43
n_event        6  10
n_event_pct   25  23

$Gender_Female$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93023256 0.4491594  0.3857148 2.2434517 0.8720829
OR_TRTvsCTRL   0.90909091 0.5937384  0.2839333 2.9107059 0.8724671
ARR_TRTvsCTRL -0.01744186 0.1093759 -0.2318146 0.1969309 0.8733008



$Region_Northamerica
$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$ntab
            CTRL TRT
n_all         22  38
n_event        2  12
n_event_pct    9  32

$Region_Northamerica$Pyrexia$stats
               estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.4736842 0.7152363 0.85502748 14.1123909 0.08168620
OR_TRTvsCTRL  4.6153846 0.8196309 0.92584179 23.0080078 0.06204753
ARR_TRTvsCTRL 0.2248804 0.0971727 0.03442539  0.4153354 0.02065488


$Region_Northamerica$`Upper respiratory tract infection`
```

```
$Region_Northamerica$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        4  10
n_event_pct   18  26

$Region_Northamerica$`Upper respiratory tract infection`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.44736842 0.5274748  0.5147445 4.0697381 0.4833182
OR_TRTvsCTRL  1.60714286 0.6642814  0.4371365 5.9086991 0.4750773
ARR_TRTvsCTRL 0.08133971 0.1089248 -0.1321490 0.2948285 0.4552139



$Disdur_greater_12wk
$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$ntab
            CTRL TRT
n_all         23  46
n_event        7  10
n_event_pct   30  22

$Disdur_greater_12wk$Pyrexia$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.71428571 0.4214733  0.3126895 1.631664 0.4246825
OR_TRTvsCTRL   0.63492063 0.5771784  0.2048445 1.967952 0.4312658
ARR_TRTvsCTRL -0.08695652 0.1135947 -0.3095980 0.135685 0.4439750



\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten UEs nach PT, das bei mindestens 10%
der Patienten in einem Studienarm auftrat"

$Ageonset_greater_12wk
$Ageonset_greater_12wk$Anxiety
$Ageonset_greater_12wk$Anxiety$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  9                8.0
n_event                                0                1.0
n_event_pct                            0               12.0
time-to-event-wk-10th                 NA                2.1
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                2.1
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$Anxiety$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01
```

```
$Ageonset_greater_12wk$`Bone marrow disorder`
$Ageonset_greater_12wk$`Bone marrow disorder`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                43.1                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           43.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Bone marrow disorder`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.245e-09 4.596e+04 0.000e+00       Inf 9.997e-01


$Ageonset_greater_12wk$`Bronchial secretion retention`
$Ageonset_greater_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                19.9                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           19.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.140e-10 4.262e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Catarrh
$Ageonset_greater_12wk$Catarrh$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                30.3                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           30.3                  NA
time-to-event-wk-50th-hici             NA                  NA
```

```
$Ageonset_greater_12wk$Catarrh$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.380e-09 4.512e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Cyanosis
$Ageonset_greater_12wk$Cyanosis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  9                8.0
n_event                                0                1.0
n_event_pct                            0               12.0
time-to-event-wk-10th                 NA               17.9
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA               17.9
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.612e+50 3.859e+04 0.000e+00       Inf 9.976e-01


$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`
$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               48.6                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          48.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.714e-09 3.573e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Infusion site bruising`
$Ageonset_greater_12wk$`Infusion site bruising`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9                  8
n_event                              1                  0
n_event_pct                         11                  0
time-to-event-wk-10th               23                 NA
time-to-event-wk-25th               NA                 NA
time-to-event-wk-50th               NA                 NA
time-to-event-wk-75th               NA                 NA
time-to-event-wk-90th               NA                 NA
```

```
time-to-event-wk-50th-loci             23                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Infusion site bruising`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.685e-10 4.172e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Nasal congestion`
$Ageonset_greater_12wk$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                 7.1                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            7.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Nasopharyngitis
$Ageonset_greater_12wk$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8.0
n_event                               1.0                 1.0
n_event_pct                          11.0                12.0
time-to-event-wk-10th                28.3                15.7
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           28.3                15.7
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.7060    1.6690    0.1027   71.2600    0.5509


$Ageonset_greater_12wk$Oedema
$Ageonset_greater_12wk$Oedema$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                 7.6                  NA
time-to-event-wk-25th                  NA                  NA
```

```
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            7.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Oedema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.253e-10 4.403e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Pain
$Ageonset_greater_12wk$Pain$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA                2.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                2.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Pain$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$Pneumonia
$Ageonset_greater_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 5.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.101e-09 4.081e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Procedural pain`
$Ageonset_greater_12wk$`Procedural pain`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
```

```
n_event_pct                               0               12.0
time-to-event-wk-10th                    NA                3.3
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               NA                3.3
time-to-event-wk-50th-hici               NA                 NA

$Ageonset_greater_12wk$`Procedural pain`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.483e+09 4.134e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Pseudomonas infection`
$Ageonset_greater_12wk$`Pseudomonas infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               17.7                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          17.7                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Pseudomonas infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.528e-09 4.251e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Pyrexia
$Ageonset_greater_12wk$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              2.0                  1
n_event_pct                         22.0                 12
time-to-event-wk-10th                5.1                 15
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           5.1                 15
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.92650   1.25000   0.07988  10.75000   0.95130


$Ageonset_greater_12wk$`Respiratory arrest`
$Ageonset_greater_12wk$`Respiratory arrest`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                19.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.140e-10 4.262e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Respiratory distress`
$Ageonset_greater_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                1.0
n_event_pct                          11.0               12.0
time-to-event-wk-10th                 2.3                0.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            2.3                0.4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.47300   1.43100   0.08921  24.33000   0.78660


$Ageonset_greater_12wk$`Rhinovirus infection`
$Ageonset_greater_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                  8
n_event                                 0                  1
n_event_pct                             0                 12
time-to-event-wk-10th                  NA                  4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                  4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01
```

```
$Ageonset_greater_12wk$`Sleep disorder`
$Ageonset_greater_12wk$`Sleep disorder`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               50.4                 NA
time-to-event-wk-25th               53.6                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          50.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Sleep disorder`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.437e-09 5.275e+04 0.000e+00       Inf 9.997e-01


$Ageonset_greater_12wk$Tachycardia
$Ageonset_greater_12wk$Tachycardia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9                8.0
n_event                              0                1.0
n_event_pct                          0               12.0
time-to-event-wk-10th               NA                2.1
time-to-event-wk-25th               NA                 NA
time-to-event-wk-50th               NA                 NA
time-to-event-wk-75th               NA                 NA
time-to-event-wk-90th               NA                 NA
time-to-event-wk-50th-loci          NA                2.1
time-to-event-wk-50th-hici          NA                 NA

$Ageonset_greater_12wk$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$`Upper respiratory tract congestion`
$Ageonset_greater_12wk$`Upper respiratory tract congestion`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th                5.1                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           5.1                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Upper respiratory tract congestion`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.520e-10 4.008e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Upper respiratory tract infection`
$Ageonset_greater_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                28.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.720e-10 4.298e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Viral upper respiratory tract infection`
$Ageonset_greater_12wk$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA               16.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               16.7
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.069e+10 4.364e+04 0.000e+00       Inf 9.996e-01



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               7.0                 11
n_event_pct                          22.0                 15
time-to-event-wk-10th                 7.9                 28
time-to-event-wk-25th                22.9                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           22.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.43910   0.48950   0.16820   1.14600   0.09271


$Ageonset_less_equal_12wk$Dyspnoea
$Ageonset_less_equal_12wk$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               4.0                  1
n_event_pct                          12.0                  1
time-to-event-wk-10th                21.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.077740  1.123000  0.008613  0.701700  0.022880


$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               4.0                  7
n_event_pct                          12.0                 10
time-to-event-wk-10th                18.9                 29
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5923    0.6332    0.1712    2.0490    0.4081


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32                72.0
n_event                                 0                11.0
n_event_pct                             0                15.0
```

```
time-to-event-wk-10th                  NA               24.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.027e+08 8.786e+03 0.000e+00       Inf 9.982e-01


$Ageonset_less_equal_12wk$`Pneumonia aspiration`
$Ageonset_less_equal_12wk$`Pneumonia aspiration`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 32                 72
n_event                                5                  5
n_event_pct                           16                  7
time-to-event-wk-10th                  9                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33340   0.63800   0.09548   1.16400   0.08511


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              6.0               18.0
n_event_pct                         19.0               25.0
time-to-event-wk-10th               13.4               15.3
time-to-event-wk-25th               24.3               41.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA               54.3
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0970    0.4755    0.4321    2.7860    0.8453


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                32.0              72.0
n_event                               4.0              11.0
n_event_pct                          12.0              15.0
time-to-event-wk-10th                20.4              19.3
time-to-event-wk-25th                44.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           44.6                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0340    0.5935    0.3231    3.3080    0.9553


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               4.0              11.0
n_event_pct                          12.0              15.0
time-to-event-wk-10th                12.3              21.6
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9137    0.5880    0.2886    2.8930    0.8781



$Agetrt_less_180d
$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               3.0                 7
n_event_pct                          19.0                14
time-to-event-wk-10th                 7.9                28
time-to-event-wk-25th                22.9                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.9                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4783    0.7070    0.1196    1.9120    0.2969
```

```
$Agetrt_less_180d$Cyanosis
$Agetrt_less_180d$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                15.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.1                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.143e-11 3.274e+04 0.000e+00       Inf 9.994e-01


$Agetrt_less_180d$Dyspnoea
$Agetrt_less_180d$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 1
n_event_pct                          12.0                 2
time-to-event-wk-10th                26.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           26.1                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.12070   1.24000   0.01063   1.37000   0.08803


$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`
$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 3
n_event_pct                          12.0                 6
time-to-event-wk-10th                 5.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA
```

```
$Agetrt_less_180d$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44140   0.91920   0.07285   2.67500   0.37370


$Agetrt_less_180d$Hypokalaemia
$Agetrt_less_180d$Hypokalaemia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                22.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.9                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Hypokalaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.361e-10 2.707e+04 0.000e+00       Inf 9.993e-01


$Agetrt_less_180d$Hypoxia
$Agetrt_less_180d$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                33.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.4                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.578e-10 2.104e+04 0.000e+00       Inf 9.992e-01


$Agetrt_less_180d$Nasopharyngitis
$Agetrt_less_180d$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                49.0
n_event                                 0                 5.0
n_event_pct                             0                10.0
time-to-event-wk-10th                  NA                37.6
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.948e+08 1.394e+04 0.000e+00       Inf 9.989e-01


$Agetrt_less_180d$`Oxygen saturation decreased`
$Agetrt_less_180d$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 4
n_event_pct                          12.0                 8
time-to-event-wk-10th                20.3                29
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           20.3                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44420   0.88430   0.07849   2.51300   0.35870


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16               49.0
n_event                                 0                5.0
n_event_pct                             0               10.0
time-to-event-wk-10th                  NA               43.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.445e+08 1.482e+04 0.000e+00       Inf 9.990e-01


$Agetrt_less_180d$`Pneumonia aspiration`
$Agetrt_less_180d$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                49
n_event                                 2                 3
n_event_pct                            12                 6
time-to-event-wk-10th                   9                NA
```

```
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3494    0.9296    0.0565    2.1600    0.2579


$Agetrt_less_180d$`Pneumonia bacterial`
$Agetrt_less_180d$`Pneumonia bacterial`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                 49
n_event                              2.0                  1
n_event_pct                         12.0                  2
time-to-event-wk-10th               36.6                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          36.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.112000  1.274000  0.009223  1.360000  0.085710


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16                49.0
n_event                              2                11.0
n_event_pct                         12                22.0
time-to-event-wk-10th               14                15.3
time-to-event-wk-25th               NA                44.3
time-to-event-wk-50th               NA                  NA
time-to-event-wk-75th               NA                  NA
time-to-event-wk-90th               NA                  NA
time-to-event-wk-50th-loci          NA                54.3
time-to-event-wk-50th-hici          NA                  NA

$Agetrt_less_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3910    0.7787    0.3022    6.3990    0.6719


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49.0
```

```
n_event                                3.0                5.0
n_event_pct                           19.0               10.0
time-to-event-wk-10th                 18.9               32.7
time-to-event-wk-25th                 44.6                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            17.4                 NA
time-to-event-wk-50th-hici              NA                 NA

$Agetrt_less_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.20310   0.79200   0.04300   0.95900   0.04413


$Agetrt_less_180d$`Rhinovirus infection`
$Agetrt_less_180d$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 1
n_event_pct                          12.0                 2
time-to-event-wk-10th                17.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.1                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13630   1.23400   0.01213   1.53100   0.10640


$Agetrt_less_180d$`Upper respiratory tract infection`
$Agetrt_less_180d$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0                4.0
n_event_pct                          12.0                8.0
time-to-event-wk-10th                32.6               29.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.56600   0.89150   0.09862   3.24900   0.52330
```

```
$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$Atelectasis
$Agetrt_greater_equal_180d$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 25                 31
n_event                                4                  4
n_event_pct                           16                 13
time-to-event-wk-10th                 11                 36
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6014    0.7160    0.1478    2.4470    0.4776


$Agetrt_greater_equal_180d$Pneumonia
$Agetrt_greater_equal_180d$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 25               31.0
n_event                                1                6.0
n_event_pct                            4               19.0
time-to-event-wk-10th                 NA               18.4
time-to-event-wk-25th                 NA               35.9
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA               35.9
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   4.2690    1.0920    0.5018   36.3200    0.1839


$Agetrt_greater_equal_180d$`Pneumonia aspiration`
$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0                 31
n_event                              3.0                  2
n_event_pct                         12.0                  6
time-to-event-wk-10th               15.7                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45750   0.92690   0.07436   2.81400   0.39880


$Agetrt_greater_equal_180d$Pyrexia
$Agetrt_greater_equal_180d$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               6.0                8.0
n_event_pct                          24.0               26.0
time-to-event-wk-10th                13.4               10.9
time-to-event-wk-25th                24.3               38.6
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.3               38.6
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9106    0.5447    0.3131    2.6490    0.8635


$Agetrt_greater_equal_180d$`Respiratory distress`
$Agetrt_greater_equal_180d$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               2.0                7.0
n_event_pct                           8.0               23.0
time-to-event-wk-10th                33.1               14.4
time-to-event-wk-25th                  NA               25.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.7710    0.8082    0.5685   13.5100    0.2072


$Agetrt_greater_equal_180d$`Rhinovirus infection`
$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25               31.0
n_event                                 0                5.0
n_event_pct                             0               16.0
time-to-event-wk-10th                  NA                6.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.587e+08 1.092e+04 0.000e+00       Inf 9.985e-01


$Agetrt_greater_equal_180d$`Upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0              31.0
n_event                               3.0               7.0
n_event_pct                          12.0              23.0
time-to-event-wk-10th                28.3              10.1
time-to-event-wk-25th                  NA              30.7
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA              30.7
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7770    0.7042    0.4468    7.0630    0.4145



$Gender_Male
$Gender_Male$Atelectasis
$Gender_Male$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               3.0               4.0
n_event_pct                          18.0              11.0
time-to-event-wk-10th                 7.9              39.9
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.9                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5382    0.7775    0.1173    2.4710    0.4256


$Gender_Male$Cyanosis
$Gender_Male$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 0
n_event_pct                          12.0                 0
```

```
time-to-event-wk-10th                15.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.140e-10 2.177e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$Dysphagia
$Gender_Male$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               3.0                 0
n_event_pct                          18.0                 0
time-to-event-wk-10th                17.1                NA
time-to-event-wk-25th                27.9                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           27.9                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.998e-10 1.920e+04 0.000e+00       Inf 9.991e-01


$Gender_Male$Hypokalaemia
$Gender_Male$Hypokalaemia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                22.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.9                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$Hypokalaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.402e-10 3.970e+04 0.000e+00       Inf 9.996e-01


$Gender_Male$Hypoxia
$Gender_Male$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                17.0                 37
n_event                               2.0                  2
n_event_pct                          12.0                  5
time-to-event-wk-10th                33.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.34890   1.02100   0.04712   2.58300   0.30260


$Gender_Male$`Joint contracture`
$Gender_Male$`Joint contracture`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  1
n_event_pct                          12.0                  3
time-to-event-wk-10th                43.4                 63
time-to-event-wk-25th                56.6                 63
time-to-event-wk-50th                56.6                 63
time-to-event-wk-75th                  NA                 63
time-to-event-wk-90th                  NA                 63
time-to-event-wk-50th-loci           43.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Joint contracture`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.221e-10 3.888e+04 0.000e+00       Inf 9.995e-01


$Gender_Male$Nasopharyngitis
$Gender_Male$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37.0
n_event                               1.0                 4.0
n_event_pct                           6.0                11.0
time-to-event-wk-10th                28.3                37.6
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           28.3                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.7160    1.1730    0.2724   27.0900    0.3945
```

```
$Gender_Male$`Oxygen saturation decreased`
$Gender_Male$`Oxygen saturation decreased`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                 37
n_event                              2.0                  4
n_event_pct                         12.0                 11
time-to-event-wk-10th               20.3                 29
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          20.3                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7541    0.8784    0.1348    4.2180    0.7479


$Gender_Male$Pneumonia
$Gender_Male$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                37.0
n_event                                0                 4.0
n_event_pct                            0                11.0
time-to-event-wk-10th                 NA                35.9
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci            NA                  NA
time-to-event-wk-50th-hici            NA                  NA

$Gender_Male$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.445e+08 1.437e+04 0.000e+00       Inf 9.989e-01


$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                37.0
n_event                                2                 9.0
n_event_pct                           12                24.0
time-to-event-wk-10th                 14                15.0
time-to-event-wk-25th                 NA                38.6
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci            NA                41.4
time-to-event-wk-50th-hici            NA                  NA

$Gender_Male$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   1.9860    0.7930    0.4198    9.4000    0.3868


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               3.0                7.0
n_event_pct                          18.0               19.0
time-to-event-wk-10th                33.1               14.6
time-to-event-wk-25th                44.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7701    0.6969    0.1965    3.0180    0.7077


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               37.0
n_event                                 0                4.0
n_event_pct                             0               11.0
time-to-event-wk-10th                  NA               31.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.106e+08 1.382e+04 0.000e+00       Inf 9.989e-01


$Gender_Male$`Rhinovirus infection`
$Gender_Male$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               37.0
n_event                                 1                5.0
n_event_pct                             6               14.0
time-to-event-wk-10th                  NA                9.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Gender_Male$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9420    1.1080    0.2216   17.0300    0.5489


$Gender_Male$`Sleep apnoea syndrome`
$Gender_Male$`Sleep apnoea syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                 7.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.544e-10 2.103e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$`Upper respiratory tract infection`
$Gender_Male$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               2.0               5.0
n_event_pct                          12.0              14.0
time-to-event-wk-10th                32.6              16.3
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           32.6                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0480    0.8477    0.1991    5.5220    0.9555



$Gender_Female
$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24                43
n_event                               4                 7
n_event_pct                          17                16
time-to-event-wk-10th                11                28
time-to-event-wk-25th                NA                44
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8780    0.6374    0.2517    3.0620    0.8383


$Gender_Female$Dyspnoea
$Gender_Female$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43
n_event                               3.0                 1
n_event_pct                          12.0                 2
time-to-event-wk-10th                13.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.14240   1.18300   0.01401   1.44800   0.09954


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24               43.0
n_event                               1                7.0
n_event_pct                           4               16.0
time-to-event-wk-10th                NA               25.1
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Gender_Female$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.4410    1.0830    0.4116   28.7700    0.2540


$Gender_Female$`Pneumonia aspiration`
$Gender_Female$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24                43
n_event                               4                 3
```

```
n_event_pct                              17                  7
time-to-event-wk-10th                    11                 NA
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               NA                 NA
time-to-event-wk-50th-hici               NA                 NA

$Gender_Female$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.38690   0.78220   0.08353   1.79300   0.22480


$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               6.0               10.0
n_event_pct                          25.0               23.0
time-to-event-wk-10th                 5.1               28.6
time-to-event-wk-25th                24.3               44.3
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.3               46.4
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9167    0.5341    0.3218    2.6110    0.8706


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               2.0                5.0
n_event_pct                           8.0               12.0
time-to-event-wk-10th                20.4               24.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2070    0.8572    0.2249    6.4760    0.8263


$Gender_Female$`Respiratory failure`
$Gender_Female$`Respiratory failure`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43
n_event                               3.0                 1
n_event_pct                          12.0                 2
time-to-event-wk-10th                15.7                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24200   1.18700   0.02362   2.47900   0.23200


$Gender_Female$`Upper respiratory tract infection`
$Gender_Female$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               3.0                6.0
n_event_pct                          12.0               14.0
time-to-event-wk-10th                28.3               25.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1160    0.7269    0.2684    4.6380    0.8802


$Gender_Female$`Viral upper respiratory tract infection`
$Gender_Female$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24               43.0
n_event                                 0                5.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA               18.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.593e+08 1.184e+04 0.000e+00       Inf 9.987e-01
```

```
$Region_Europe
$Region_Europe$Atelectasis
$Region_Europe$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               30.0
n_event                                 1                6.0
n_event_pct                             6               20.0
time-to-event-wk-10th                  NA               15.7
time-to-event-wk-25th                  NA               44.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               44.0
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.7470    1.0850    0.4465   31.4500    0.2236


$Region_Europe$`Feeding disorder of infancy or early childhood`
$Region_Europe$`Feeding disorder of infancy or early childhood`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               2.0                 2
n_event_pct                          12.0                 7
time-to-event-wk-10th                 5.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24440   1.09200   0.02873   2.08000   0.19710


$Region_Europe$Pneumonia
$Region_Europe$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               30.0
n_event                                 1                3.0
n_event_pct                             6               10.0
time-to-event-wk-10th                  NA               35.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3630    1.1660    0.1387   13.3900    0.7906


$Region_Europe$`Pneumonia aspiration`
$Region_Europe$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                  30
n_event                                 2                   2
n_event_pct                            12                   7
time-to-event-wk-10th                  11                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5012    1.0120    0.0689    3.6450    0.4950


$Region_Europe$Pyrexia
$Region_Europe$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                  30
n_event                               6.0                   5
n_event_pct                          35.0                  17
time-to-event-wk-10th                 2.3                  15
time-to-event-wk-25th                15.1                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           15.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4022    0.6154    0.1204    1.3440    0.1389


$Region_Europe$`Respiratory distress`
$Region_Europe$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                30.0
n_event                                 1                 5.0
n_event_pct                             6                17.0
time-to-event-wk-10th                  NA                24.3
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.7720    1.1110    0.3141   24.4700    0.3588


$Region_Europe$`Respiratory failure`
$Region_Europe$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               3.0                3.0
n_event_pct                          18.0               10.0
time-to-event-wk-10th                 2.1               31.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5300    0.8319    0.1038    2.7060    0.4454


$Region_Europe$`Respiratory tract infection`
$Region_Europe$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               1.0                5.0
n_event_pct                           6.0               17.0
time-to-event-wk-10th                33.4               29.6
time-to-event-wk-25th                  NA               40.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.4               40.1
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6220    1.1190    0.1808   14.5500    0.6658


$Region_Europe$`Rhinovirus infection`
$Region_Europe$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 30
n_event                                 0                  3
n_event_pct                             0                 10
```

```
time-to-event-wk-10th                  NA                  18
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.465e+08 1.560e+04 0.000e+00       Inf 9.990e-01


$Region_Europe$`Viral infection`
$Region_Europe$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               30.0
n_event                                 0                4.0
n_event_pct                             0               13.0
time-to-event-wk-10th                  NA               31.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.084e+08 1.348e+04 0.000e+00       Inf 9.988e-01



$Region_Northamerica
$Region_Northamerica$Atelectasis
$Region_Northamerica$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               6.0                4.0
n_event_pct                          27.0               11.0
time-to-event-wk-10th                 4.1               39.9
time-to-event-wk-25th                22.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26810   0.65760   0.07389   0.97300   0.04533


$Region_Northamerica$Dyspnoea
```

```
$Region_Northamerica$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               3.0                  0
n_event_pct                          14.0                  0
time-to-event-wk-10th                21.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.795e-10 1.685e+04 0.000e+00       Inf 9.990e-01


$Region_Northamerica$Hypokalaemia
$Region_Northamerica$Hypokalaemia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                 38
n_event                                 3                  0
n_event_pct                            14                  0
time-to-event-wk-10th                  14                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Hypokalaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.034e-10 1.626e+04 0.000e+00       Inf 9.990e-01


$Region_Northamerica$`Oxygen saturation decreased`
$Region_Northamerica$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               4.0                6.0
n_event_pct                          18.0               16.0
time-to-event-wk-10th                13.9               18.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7192    0.6498    0.2012    2.5700    0.6120
```

```
$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 22               38.0
n_event                                0                4.0
n_event_pct                            0               11.0
time-to-event-wk-10th                 NA               19.3
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.206e+08 1.301e+04 0.000e+00       Inf 9.988e-01


$Region_Northamerica$`Pneumonia aspiration`
$Region_Northamerica$`Pneumonia aspiration`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0               38.0
n_event                              3.0                3.0
n_event_pct                         14.0                8.0
time-to-event-wk-10th               15.7               37.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47680   0.82230   0.09515   2.39000   0.36780


$Region_Northamerica$`Pneumonia viral`
$Region_Northamerica$`Pneumonia viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 22               38.0
n_event                                0                4.0
n_event_pct                            0               11.0
time-to-event-wk-10th                 NA               34.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA
```

```
$Region_Northamerica$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.353e+08 1.263e+04 0.000e+00       Inf 9.988e-01


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 22               38.0
n_event                                2               12.0
n_event_pct                            9               32.0
time-to-event-wk-10th                 14               25.1
time-to-event-wk-25th                 NA               41.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA               41.4
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.2500    0.7647    0.7261   14.5500    0.1232


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0               38.0
n_event                              4.0                7.0
n_event_pct                         18.0               18.0
time-to-event-wk-10th               20.4               14.4
time-to-event-wk-25th               44.6                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          33.1                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9035    0.6272    0.2643    3.0890    0.8714


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0               38.0
n_event                              4.0               10.0
n_event_pct                         18.0               26.0
time-to-event-wk-10th               28.3               16.3
time-to-event-wk-25th               32.6               28.9
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
```

```
time-to-event-wk-50th-loci           28.3                30.7
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2130    0.5974    0.3763    3.9130    0.7461


$Region_Northamerica$`Viral upper respiratory tract infection`
$Region_Northamerica$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                38.0
n_event                                 1                 7.0
n_event_pct                             5                18.0
time-to-event-wk-10th                  NA                14.6
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.9970    1.0720    0.4891   32.6700    0.1961



$Disdur_greater_12wk
$Disdur_greater_12wk$Atelectasis
$Disdur_greater_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23                  46
n_event                                 4                   6
n_event_pct                            17                  13
time-to-event-wk-10th                  11                  36
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_greater_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6005    0.6495    0.1681    2.1450    0.4324


$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23                46.0
n_event                                 1                 9.0
```

```
n_event_pct                              4               20.0
time-to-event-wk-10th                   NA               19.3
time-to-event-wk-25th                   NA               43.6
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Disdur_greater_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.5900    1.0580    0.4518   28.5300    0.2268


$Disdur_greater_12wk$`Pneumonia aspiration`
$Disdur_greater_12wk$`Pneumonia aspiration`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 23                 46
n_event                                3                  3
n_event_pct                           13                  7
time-to-event-wk-10th                 11                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42220   0.82020   0.08459   2.10700   0.29310


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0               46.0
n_event                              7.0               10.0
n_event_pct                         30.0               22.0
time-to-event-wk-10th                5.1               25.1
time-to-event-wk-25th               15.1               46.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          15.1               46.4
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6063    0.5019    0.2267    1.6220    0.3189


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               2.0                9.0
n_event_pct                           9.0               20.0
time-to-event-wk-10th                33.1               14.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2110    0.7886    0.4713   10.3700    0.3144


$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                 46
n_event                               3.0                  3
n_event_pct                          13.0                  7
time-to-event-wk-10th                15.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5254    0.8199    0.1053    2.6210    0.4324


$Disdur_greater_12wk$`Rhinovirus infection`
$Disdur_greater_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23                 46
n_event                                 0                  5
n_event_pct                             0                 11
time-to-event-wk-10th                  NA                 18
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.865e+08 1.219e+04 0.000e+00       Inf 9.987e-01
```

```
$Disdur_greater_12wk$Teething
$Disdur_greater_12wk$Teething$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 23               46.0
n_event                                1                5.0
n_event_pct                            4               11.0
time-to-event-wk-10th                 NA               22.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0590    1.1010    0.2381   17.8000    0.5118


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0               46.0
n_event                              2.0                8.0
n_event_pct                          9.0               17.0
time-to-event-wk-10th               12.3               16.6
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7390    0.7930    0.3676    8.2290    0.4853



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0               34.0
n_event                              3.0                5.0
n_event_pct                         17.0               15.0
time-to-event-wk-10th                7.9               15.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA
```

```
$Disdur_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7106    0.7363    0.1678    3.0080    0.6426


$Disdur_less_equal_12wk$Cyanosis
$Disdur_less_equal_12wk$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                15.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.769e-10 2.874e+04 0.000e+00       Inf 9.994e-01


$Disdur_less_equal_12wk$Dyspnoea
$Disdur_less_equal_12wk$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                26.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           26.1                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.821e-10 2.093e+04 0.000e+00       Inf 9.992e-01


$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`
$Disdur_less_equal_12wk$`Feeding disorder of infancy or early
childhood`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 2
n_event_pct                          11.0                 6
time-to-event-wk-10th                 5.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_less_equal_12wk$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48100   1.01100   0.06626   3.49200   0.46940


$Disdur_less_equal_12wk$Hypokalaemia
$Disdur_less_equal_12wk$Hypokalaemia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                22.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Hypokalaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.141e-09 1.398e+04 0.000e+00       Inf 9.988e-01


$Disdur_less_equal_12wk$Hypoxia
$Disdur_less_equal_12wk$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                33.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.4                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.930e-10 2.031e+04 0.000e+00       Inf 9.992e-01


$Disdur_less_equal_12wk$Nasopharyngitis
$Disdur_less_equal_12wk$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
n_event                               1.0                 4.0
```

```
n_event_pct                             6.0               12.0
time-to-event-wk-10th                  28.3               15.7
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci             28.3                 NA
time-to-event-wk-50th-hici               NA                 NA

$Disdur_less_equal_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2450    1.1350    0.2426   20.7700    0.4762


$Disdur_less_equal_12wk$Oedema
$Disdur_less_equal_12wk$Oedema$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 0
n_event_pct                         11.0                 0
time-to-event-wk-10th               11.7                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$Oedema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.083e-10 1.959e+04 0.000e+00       Inf 9.991e-01


$Disdur_less_equal_12wk$`Oxygen saturation decreased`
$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 3
n_event_pct                         11.0                 9
time-to-event-wk-10th               20.3                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7215    0.9316    0.1162    4.4790    0.7260


$Disdur_less_equal_12wk$`Pneumonia aspiration`
$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 2                  2
n_event_pct                            11                  6
time-to-event-wk-10th                   9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49050   1.02300   0.06602   3.64400   0.48630


$Disdur_less_equal_12wk$`Pneumonia bacterial`
$Disdur_less_equal_12wk$`Pneumonia bacterial`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  1
n_event_pct                          11.0                  3
time-to-event-wk-10th                36.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           36.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.20790   1.23100   0.01861   2.32200   0.20210


$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                34.0
n_event                                 1                 9.0
n_event_pct                             6                26.0
time-to-event-wk-10th                  NA                15.3
time-to-event-wk-25th                  NA                41.4
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                44.3
time-to-event-wk-50th-hici             NA                  NA

$Disdur_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   4.2730    1.0550    0.5402   33.8000    0.1687
```

```
$Disdur_less_equal_12wk$`Respiratory distress`
$Disdur_less_equal_12wk$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               3.0                3.0
n_event_pct                          17.0                9.0
time-to-event-wk-10th                20.4               32.7
time-to-event-wk-25th                44.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           44.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.46130   0.83200   0.09032   2.35600   0.35240


$Disdur_less_equal_12wk$`Rhinovirus infection`
$Disdur_less_equal_12wk$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  1
n_event_pct                          11.0                  3
time-to-event-wk-10th                17.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24870   1.24100   0.02186   2.82900   0.26200


$Disdur_less_equal_12wk$`Upper respiratory tract infection`
$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               3.0                3.0
n_event_pct                          17.0                9.0
time-to-event-wk-10th                28.3               29.7
time-to-event-wk-25th                32.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.41020   0.81810   0.08254   2.03900   0.27600


$Disdur_less_equal_12wk$`Viral infection`
$Disdur_less_equal_12wk$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 0                4.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA               31.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.177e+08 1.384e+04 0.000e+00       Inf 9.989e-01



$Region_Asia_Pacific
$Region_Asia_Pacific$Oedema
$Region_Asia_Pacific$Oedema$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0                12
n_event                               1.0                 0
n_event_pct                          50.0                 0
time-to-event-wk-10th                 7.6                NA
time-to-event-wk-25th                 7.6                NA
time-to-event-wk-50th                 7.6                NA
time-to-event-wk-75th                 7.6                NA
time-to-event-wk-90th                 7.6                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Asia_Pacific$Oedema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.266e-14 2.565e+06 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$Pneumonia
$Region_Asia_Pacific$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  2               12.0
n_event                                0                4.0
n_event_pct                            0               33.0
time-to-event-wk-10th                 NA               25.1
time-to-event-wk-25th                 NA               25.4
time-to-event-wk-50th                 NA               43.6
time-to-event-wk-75th                 NA               43.6
```

```
time-to-event-wk-90th                  NA               43.6
time-to-event-wk-50th-loci             NA               25.1
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.170e+08 1.904e+04 0.000e+00       Inf 9.992e-01


$Region_Asia_Pacific$Pyrexia
$Region_Asia_Pacific$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
n_event                                 0                2.0
n_event_pct                             0               17.0
time-to-event-wk-10th                  NA                8.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                8.1
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.759e+06 5.673e+04 0.000e+00       Inf 9.998e-01


$Region_Asia_Pacific$Teething
$Region_Asia_Pacific$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
n_event                                 0                3.0
n_event_pct                             0               25.0
time-to-event-wk-10th                  NA                9.3
time-to-event-wk-25th                  NA               39.8
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                9.3
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.972e+07 2.715e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$`Urinary tract infection`
$Region_Asia_Pacific$`Urinary tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
n_event                                 0                2.0
n_event_pct                             0               17.0
time-to-event-wk-10th                  NA               26.9
```

```
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                26.9
time-to-event-wk-50th-hici             NA                  NA

$Region_Asia_Pacific$`Urinary tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.284e+07 1.991e+04 0.000e+00       Inf 9.993e-01




\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten UEs nach PT, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               7.0                11
n_event_pct                          22.0                15
time-to-event-wk-10th                 7.9                28
time-to-event-wk-25th                22.9                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.9                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.43910   0.48950   0.16820   1.14600   0.09271


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32               72.0
n_event                               0               11.0
n_event_pct                           0               15.0
time-to-event-wk-10th                NA               24.7
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Ageonset_less_equal_12wk$Pneumonia$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.027e+08 8.786e+03 0.000e+00       Inf 9.982e-01


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               6.0               18.0
n_event_pct                          19.0               25.0
time-to-event-wk-10th                13.4               15.3
time-to-event-wk-25th                24.3               41.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               54.3
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0970    0.4755    0.4321    2.7860    0.8453


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               4.0               11.0
n_event_pct                          12.0               15.0
time-to-event-wk-10th                20.4               19.3
time-to-event-wk-25th                44.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           44.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0340    0.5935    0.3231    3.3080    0.9553


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               4.0               11.0
n_event_pct                          12.0               15.0
time-to-event-wk-10th                12.3               21.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9137    0.5880    0.2886    2.8930    0.8781



$Agetrt_less_180d
$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16               49.0
n_event                                 2               11.0
n_event_pct                            12               22.0
time-to-event-wk-10th                  14               15.3
time-to-event-wk-25th                  NA               44.3
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               54.3
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3910    0.7787    0.3022    6.3990    0.6719



$Gender_Female
$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               6.0               10.0
n_event_pct                          25.0               23.0
time-to-event-wk-10th                 5.1               28.6
time-to-event-wk-25th                24.3               44.3
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.3               46.4
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9167    0.5341    0.3218    2.6110    0.8706



$Region_Northamerica
$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  22               38.0
n_event                                 2               12.0
n_event_pct                             9               32.0
time-to-event-wk-10th                  14               25.1
time-to-event-wk-25th                  NA               41.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               41.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.2500    0.7647    0.7261   14.5500    0.1232


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               4.0               10.0
n_event_pct                          18.0               26.0
time-to-event-wk-10th                28.3               16.3
time-to-event-wk-25th                32.6               28.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3               30.7
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2130    0.5974    0.3763    3.9130    0.7461



$Disdur_greater_12wk
$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               7.0               10.0
n_event_pct                          30.0               22.0
time-to-event-wk-10th                 5.1               25.1
time-to-event-wk-25th                15.1               46.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.1               46.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6063    0.5019    0.2267    1.6220    0.3189
```

```
\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem schweren UE nach SOC, das bei mindestens 5%
der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        5   6
n_event_pct   16   8

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.53333333 0.56703419  0.1755247 1.62053759 0.2676069
OR_TRTvsCTRL   0.49090909 0.64719025  0.1380739 1.74538168 0.2716102
ARR_TRTvsCTRL -0.07291667 0.07197798 -0.2139909 0.06815758 0.3110404


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        4   5
n_event_pct   12   7

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55555556 0.63628697  0.1596317 1.93346337 0.3556029
OR_TRTvsCTRL   0.52238806 0.70755894  0.1305323 2.09058826 0.3587628
ARR_TRTvsCTRL -0.05555556 0.06569243 -0.1843104 0.07319924 0.3977246


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         32  72
n_event        1   4
n_event_pct    3   6

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.77777778 1.09766166  0.20679793 15.2830055 0.6001585
OR_TRTvsCTRL  1.82352941 1.13884325  0.19567153 16.9940896 0.5978257
ARR_TRTvsCTRL 0.02430556 0.04092411 -0.05590423  0.1045153 0.5525671
```

```
$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         32  72
n_event       14  27
n_event_pct   44  38

$Ageonset_less_equal_12wk$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8571429 0.2516480  0.5234197 1.4036421 0.5401642
OR_TRTvsCTRL   0.7714286 0.4315592  0.3310944 1.7973788 0.5476176
ARR_TRTvsCTRL -0.0625000 0.1046214 -0.2675542 0.1425542 0.5502456


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         32  72
n_event        3   1
n_event_pct    9   1

$Ageonset_less_equal_12wk$Investigations$stats
                 estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.14814815 1.1349865  0.01601747 1.37024593 0.09248428
OR_TRTvsCTRL   0.13615023 1.1755427  0.01359548 1.36345918 0.08984143
ARR_TRTvsCTRL -0.07986111 0.0533409 -0.18440735 0.02468513 0.13434552


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       24  35
n_event_pct   75  49

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats
                estimate         se     lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   0.6481481 0.15842729  0.4751391  0.88415384 0.006197792
OR_TRTvsCTRL   0.3153153 0.47145002  0.1251544  0.79440881 0.014359037
ARR_TRTvsCTRL -0.2638889 0.09658632 -0.4531946 -0.07458317 0.006292137



$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Cardiac disorders`
$Ageonset_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Cardiac disorders`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$`Gastrointestinal disorders`
$Ageonset_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Infections and infestations`
$Ageonset_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all          9   8
n_event        3   1
n_event_pct   33  12

$Ageonset_greater_12wk$`Infections and infestations`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3750000 1.0474838  0.04812951 2.9218039 0.3490842
OR_TRTvsCTRL   0.2857143 1.2817399  0.02316930 3.5233106 0.3283749
ARR_TRTvsCTRL -0.2083333 0.1958653 -0.59222235 0.1755557 0.2874846


$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`
$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Investigations
$Ageonset_greater_12wk$Investigations$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0
```

```
$Ageonset_greater_12wk$Investigations$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        5   4
n_event_pct   56  50

$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90000000 0.4624812  0.3635614 2.2279593 0.8197895
OR_TRTvsCTRL   0.80000000 0.9746794  0.1184244 5.4042898 0.8189152
ARR_TRTvsCTRL -0.05555556 0.2422495 -0.5303559 0.4192448 0.8186109



$Agetrt_less_180d
$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        3   2
n_event_pct   19   4

$Agetrt_less_180d$`Cardiac disorders`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2176871 0.8662708  0.03985305 1.18905986 0.07839606
OR_TRTvsCTRL   0.1843972 0.9651596  0.02781051 1.22264269 0.07982660
ARR_TRTvsCTRL -0.1466837 0.1015897 -0.34579587 0.05242852 0.14877188


$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        2   5
n_event_pct   12  10

$Agetrt_less_180d$`Gastrointestinal disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.81632653 0.78555193  0.1750656 3.8065096 0.7961432
OR_TRTvsCTRL   0.79545455 0.89115422  0.1386959 4.5621254 0.7973391
ARR_TRTvsCTRL -0.02295918 0.09330545 -0.2058345 0.1599161 0.8056321


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site conditions`$ntab
            CTRL TRT
```

```
n_all         16  49
n_event        1   4
n_event_pct    6   8

$Agetrt_less_180d$`General disorders and administration site conditions`$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.30612245 1.08032025  0.1571859 10.85311 0.8047480
OR_TRTvsCTRL  1.33333333 1.15710366  0.1380417 12.87856 0.8036528
ARR_TRTvsCTRL 0.01913265 0.07205612 -0.1220947  0.16036 0.7906056


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         16  49
n_event        8  19
n_event_pct   50  39

$Agetrt_less_180d$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7755102 0.3077717  0.4242402 1.4176312 0.4087770
OR_TRTvsCTRL   0.6333333 0.5796248  0.2033550 1.9724676 0.4306825
ARR_TRTvsCTRL -0.1122449 0.1430731 -0.3926631 0.1681733 0.4327303


$Agetrt_less_180d$`Injury, poisoning and procedural complications`
$Agetrt_less_180d$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         16  49
n_event        1   1
n_event_pct    6   2

$Agetrt_less_180d$`Injury, poisoning and procedural complications`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 1.38459086  0.02164502 4.92594746 0.4188901
OR_TRTvsCTRL   0.31250000 1.44481833  0.01840850 5.30495387 0.4207909
ARR_TRTvsCTRL -0.04209184 0.06379736 -0.16713236 0.08294868 0.5093989


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$Investigations$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$`Metabolism and nutrition disorders`
```

```
$Agetrt_less_180d$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        1   1
n_event_pct    6   2

$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats
                  estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 1.38459086  0.02164502 4.92594746 0.4188901
OR_TRTvsCTRL   0.31250000 1.44481833  0.01840850 5.30495387 0.4207909
ARR_TRTvsCTRL -0.04209184 0.06379736 -0.16713236 0.08294868 0.5093989


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event       13  23
n_event_pct   81  47

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci     hi95ci      pvalue
RR_TRTvsCTRL   0.5777080 0.1936315  0.39526551  0.8443604 0.004601770
OR_TRTvsCTRL   0.2041420 0.7015670  0.05161281  0.8074345 0.023522284
ARR_TRTvsCTRL -0.3431122 0.1208487 -0.57997128 -0.1062532 0.004522832



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Cardiac disorders`
$Agetrt_greater_equal_180d$`Cardiac disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        4   5
n_event_pct   16  16

$Agetrt_greater_equal_180d$`Cardiac disorders`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.008064516 0.61460714  0.3022274 3.3623496 0.9895729
OR_TRTvsCTRL  1.009615385 0.73217524  0.2403960 4.2401835 0.9895720
ARR_TRTvsCTRL 0.001290323 0.09869009 -0.1921387 0.1947193 0.9895684


$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        3   0
n_event_pct   12   0

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats
                estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.1160714 1.48862445  0.006274887 2.147062848 0.14798915
OR_TRTvsCTRL   0.1020408 1.53684897  0.005018867 2.074637104 0.13751596
```

```
ARR_TRTvsCTRL -0.1200000 0.06499231 -0.247382581 0.007382581 0.06483816


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         25  31
n_event        9   9
n_event_pct   36  29

$Agetrt_greater_equal_180d$`Infections and infestations`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80645161 0.3872521  0.3775276 1.7226929 0.5785653
OR_TRTvsCTRL   0.72727273 0.5746101  0.2358242 2.2428814 0.5794362
ARR_TRTvsCTRL -0.06967742 0.1259456 -0.3165263 0.1771715 0.5801031


$Agetrt_greater_equal_180d$Investigations
$Agetrt_greater_equal_180d$Investigations$ntab
            CTRL TRT
n_all         25  31
n_event        2   1
n_event_pct    8   3

$Agetrt_greater_equal_180d$Investigations$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.40322581 1.1948816  0.03876710 4.19404750 0.4471803
OR_TRTvsCTRL   0.38333333 1.2557116  0.03271244 4.49200497 0.4451109
ARR_TRTvsCTRL -0.04774194 0.0628571 -0.17093960 0.07545572 0.4475348


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       16  16
n_event_pct   64  52

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8064516 0.2296561  0.5141557 1.2649168 0.3489297
OR_TRTvsCTRL   0.6000000 0.5502525  0.2040683 1.7641154 0.3532272
ARR_TRTvsCTRL -0.1238710 0.1314235 -0.3814562 0.1337143 0.3459197



$Gender_Male
$Gender_Male$`Cardiac disorders`
$Gender_Male$`Cardiac disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        4   4
```

```
n_event_pct   24  11

$Gender_Male$`Cardiac disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.6435444  0.13015510 1.62193414 0.2268663
OR_TRTvsCTRL   0.3939394 0.7792471  0.08553287 1.81436969 0.2319076
ARR_TRTvsCTRL -0.1271860 0.1148483 -0.35228453 0.09791251 0.2681097


$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        2   3
n_event_pct   12   8

$Gender_Male$`Gastrointestinal disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.86457086  0.1265944 3.7519972 0.6667969
OR_TRTvsCTRL   0.66176471 0.96406004  0.1000217 4.3783754 0.6684793
ARR_TRTvsCTRL -0.03656598 0.09011076 -0.2131798 0.1400479 0.6848975


$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  37
n_event        1   2
n_event_pct    6   5

$Gender_Male$`General disorders and administration site conditions`$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.918918919 1.1891802  0.08933985  9.4516836 0.9433137
OR_TRTvsCTRL   0.914285714 1.2613768  0.07716068 10.8334757 0.9433634
ARR_TRTvsCTRL -0.004769475 0.0681074 -0.13825752  0.1287186 0.9441708


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  37
n_event        7  11
n_event_pct   41  30

$Gender_Male$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7220077 0.3845981  0.3397593 1.5343072 0.3970460
OR_TRTvsCTRL   0.6043956 0.6101047  0.1828097 1.9982204 0.4091949
ARR_TRTvsCTRL -0.1144674 0.1410467 -0.3909139 0.1619791 0.4170460


$Gender_Male$Investigations
$Gender_Male$Investigations$ntab
            CTRL TRT
```

```
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$Investigations$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$`Metabolism and nutrition disorders`
$Gender_Male$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        1   1
n_event_pct    6   3

$Gender_Male$`Metabolism and nutrition disorders`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 1.38352790  0.03052011 6.91684875 0.5740363
OR_TRTvsCTRL   0.4444444 1.44577930  0.02613171 7.55904710 0.5748692
ARR_TRTvsCTRL -0.0317965 0.06298717 -0.15524909 0.09165609 0.6136929


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event       12  19
n_event_pct   71  51

$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7274775 0.2238624  0.4691023 1.12816218 0.1552339
OR_TRTvsCTRL   0.4398148 0.6257160  0.1290207 1.49927137 0.1892710
ARR_TRTvsCTRL -0.1923688 0.1377110 -0.4622774 0.07753975 0.1624429



$Gender_Female
$Gender_Female$`Cardiac disorders`
$Gender_Female$`Cardiac disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        3   3
n_event_pct   12   7

$Gender_Female$`Cardiac disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.77572172  0.1220246 2.55292650 0.4522034
OR_TRTvsCTRL   0.52500000 0.85981726  0.0973378 2.83163374 0.4536092
ARR_TRTvsCTRL -0.05523256 0.07788834 -0.2078909 0.09742577 0.4782470
```

```
$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        3   2
n_event_pct   12   5

$Gender_Female$`Gastrointestinal disorders`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.37209302 0.87659047  0.06675693 2.07399014 0.2594079
OR_TRTvsCTRL   0.34146341 0.95149494  0.05289690 2.20423626 0.2587751
ARR_TRTvsCTRL -0.07848837 0.07475726 -0.22500990 0.06803316 0.2937596


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$ntab
            CTRL TRT
n_all         24  43
n_event       10  17
n_event_pct   42  40

$Gender_Female$`Infections and infestations`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94883721 0.3064328  0.5204220 1.7299269 0.8639209
OR_TRTvsCTRL   0.91538462 0.5183760  0.3314066 2.5284014 0.8645747
ARR_TRTvsCTRL -0.02131783 0.1252461 -0.2667956 0.2241599 0.8648469


$Gender_Female$`Injury, poisoning and procedural complications`
$Gender_Female$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         24  43
n_event        2   0
n_event_pct    8   0

$Gender_Female$`Injury, poisoning and procedural complications`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.11363636 1.52881416  0.005677908 2.27429239 0.1548786
OR_TRTvsCTRL   0.10344828 1.57080646  0.004760476 2.24799916 0.1486604
ARR_TRTvsCTRL -0.08333333 0.05641693 -0.193908491 0.02724182 0.1396494


$Gender_Female$Investigations
$Gender_Female$Investigations$ntab
            CTRL TRT
n_all         24  43
n_event        2   1
n_event_pct    8   2

$Gender_Female$Investigations$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.27906977 1.19794721  0.02666971 2.92016442 0.2866948
OR_TRTvsCTRL   0.26190476 1.25270271  0.02248231 3.05102574 0.2848413
```

```
ARR_TRTvsCTRL -0.06007752 0.06091901 -0.17947658 0.05932155 0.3240415


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       17  20
n_event_pct   71  47

$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci       hi95ci     pvalue
RR_TRTvsCTRL   0.6566347 0.2095258  0.4354870  0.990085090 0.04469423
OR_TRTvsCTRL   0.3580563 0.5432853  0.1234542  1.038476269 0.05869499
ARR_TRTvsCTRL -0.2432171 0.1199745 -0.4783627 -0.008071428 0.04263785



$Region_Europe
$Region_Europe$`Cardiac disorders`
$Region_Europe$`Cardiac disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        1   3
n_event_pct    6  10

$Region_Europe$`Cardiac disorders`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 1.11408100  0.1914880 15.0923333 0.6338661
OR_TRTvsCTRL  1.77777778 1.19702563  0.1702031 18.5689583 0.6307571
ARR_TRTvsCTRL 0.04117647 0.07909909 -0.1138549  0.1962078 0.6026676


$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Gastrointestinal disorders`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  30
n_event        0   3
n_event_pct    0  10
```

```
$Region_Europe$`General disorders and administration site conditions`$stats
              estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.064516 1.48253184  0.222369622 74.2920332 0.34421066
OR_TRTvsCTRL  4.454545 1.54247229  0.216694854 91.5710496 0.33278158
ARR_TRTvsCTRL 0.100000 0.05477226 -0.007351649  0.2073516 0.06788915


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  30
n_event        6   9
n_event_pct   35  30

$Region_Europe$`Infections and infestations`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.4308375  0.3653334 1.9776455 0.7060128
OR_TRTvsCTRL   0.78571429 0.6452177  0.2218474 2.7827550 0.7085766
ARR_TRTvsCTRL -0.05294118 0.1429467 -0.3331115 0.2272291 0.7111171


$Region_Europe$`Injury, poisoning and procedural complications`
$Region_Europe$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         17  30
n_event        1   1
n_event_pct    6   3

$Region_Europe$`Injury, poisoning and procedural complications`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5666667 1.38124695  0.03781013 8.4927277 0.6809178
OR_TRTvsCTRL   0.5517241 1.44809625  0.03229239 9.4263541 0.6813057
ARR_TRTvsCTRL -0.0254902 0.06580836 -0.15447221 0.1034918 0.6985047


$Region_Europe$Investigations
$Region_Europe$Investigations$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$Investigations$stats
                  estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event       10  13
```

```
n_event_pct   59  43

$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7366667 0.2911464  0.4163387 1.3034527 0.2938507
OR_TRTvsCTRL   0.5352941 0.6153078  0.1602660 1.7879010 0.3097949
ARR_TRTvsCTRL -0.1549020 0.1497768 -0.4484592 0.1386552 0.3010341



$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        6   4
n_event_pct   27  11

$Region_Northamerica$`Cardiac disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3859649 0.5872788  0.12208301 1.22022637 0.1050067
OR_TRTvsCTRL   0.3137255 0.7131469  0.07753863 1.26935035 0.1040511
ARR_TRTvsCTRL -0.1674641 0.1072113 -0.37759449 0.04266626 0.1182880


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        4   5
n_event_pct   18  13

$Region_Northamerica$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.72368421 0.6150038  0.2167988 2.4156904 0.5989920
OR_TRTvsCTRL   0.68181818 0.7320236  0.1623936 2.8626498 0.6008375
ARR_TRTvsCTRL -0.05023923 0.0988374 -0.2439570 0.1434785 0.6112417


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$ntab
            CTRL TRT
n_all         22  38
n_event       11  17
n_event_pct   50  45

$Region_Northamerica$`Infections and infestations`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.89473684 0.2792173  0.5176368 1.5465554 0.6903737
OR_TRTvsCTRL   0.80952381 0.5368992  0.2826313 2.3186706 0.6938962
ARR_TRTvsCTRL -0.05263158 0.1336775 -0.3146348 0.2093716 0.6937875


$Region_Northamerica$Investigations
```

```
$Region_Northamerica$Investigations$ntab
            CTRL TRT
n_all         22  38
n_event        3   0
n_event_pct   14   0

$Region_Northamerica$Investigations$stats
                 estimate       se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08424908 1.488823  0.004552778 1.559028057 0.09657297
OR_TRTvsCTRL   0.07235622 1.537196  0.003556416 1.472106135 0.08756107
ARR_TRTvsCTRL -0.13636364 0.073165 -0.279764411 0.007037138 0.06235229


$Region_Northamerica$`Nervous system disorders`
$Region_Northamerica$`Nervous system disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        0   2
n_event_pct    0   5

$Region_Northamerica$`Nervous system disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.94871795 1.52672221  0.14793977 58.7734976 0.4787618
OR_TRTvsCTRL  3.08219178 1.57220918  0.14144669 67.1624512 0.4740152
ARR_TRTvsCTRL 0.05263158 0.03622354 -0.01836525  0.1236284 0.1462331


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       18  24
n_event_pct   82  63

$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7719298 0.1595365  0.5646510 1.05529897 0.1046780
OR_TRTvsCTRL   0.3809524 0.6470323  0.1071805 1.35402157 0.1358172
ARR_TRTvsCTRL -0.1866029 0.1135129 -0.4090840 0.03587829 0.1001986


$Region_Northamerica$`Vascular disorders`
$Region_Northamerica$`Vascular disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        0   2
n_event_pct    0   5

$Region_Northamerica$`Vascular disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.94871795 1.52672221  0.14793977 58.7734976 0.4787618
OR_TRTvsCTRL  3.08219178 1.57220918  0.14144669 67.1624512 0.4740152
ARR_TRTvsCTRL 0.05263158 0.03622354 -0.01836525  0.1236284 0.1462331
```

```
$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        3   5
n_event_pct   13  11

$Disdur_greater_12wk$`Cardiac disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83333333 0.68418999  0.2179893 3.1856813 0.7898711
OR_TRTvsCTRL   0.81300813 0.77956628  0.1764115 3.7468206 0.7905855
ARR_TRTvsCTRL -0.02173913 0.08388968 -0.1861599 0.1426816 0.7955276


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        3   2
n_event_pct   13   4

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.33333333 0.87642224  0.05982281 1.85733699 0.2100167
OR_TRTvsCTRL   0.30303030 0.95187216  0.04690844 1.95758717 0.2097371
ARR_TRTvsCTRL -0.08695652 0.07639016 -0.23667848 0.06276544 0.2549865


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         23  46
n_event        8  16
n_event_pct   35  35

$Disdur_greater_12wk$`Infections and infestations`$stats
              estimate        se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.3496893  0.5038995 1.9845227      1
OR_TRTvsCTRL         1 0.5361903  0.3496182 2.8602631      1
ARR_TRTvsCTRL        0 0.1216311 -0.2383925 0.2383925      1


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       15  23
n_event_pct   65  50

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.7666667 0.2119612  0.5060401 1.16152418 0.2100069
OR_TRTvsCTRL   0.5333333 0.5278477  0.1895370 1.50073323 0.2336967
ARR_TRTvsCTRL -0.1521739 0.1236832 -0.3945885 0.09024064 0.2185651



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Cardiac disorders`
$Disdur_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        4   2
n_event_pct   22   6

$Disdur_less_equal_12wk$`Cardiac disorders`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2647059 0.8154954  0.05353190 1.30892421 0.10313299
OR_TRTvsCTRL   0.2187500 0.9234060  0.03580498 1.33644977 0.09978616
ARR_TRTvsCTRL -0.1633987 0.1059742 -0.37110428 0.04430689 0.12310455


$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   3
n_event_pct   11   9

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.86508151  0.1457223 4.3275646 0.7898725
OR_TRTvsCTRL   0.77419355 0.96337500  0.1171718 5.1153557 0.7904985
ARR_TRTvsCTRL -0.02287582 0.08861794 -0.1965638 0.1508122 0.7962990


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         18  34
n_event        1   3
n_event_pct    6   9

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.58823529 1.11730301  0.1777726 14.1894280 0.6788347
OR_TRTvsCTRL  1.64516129 1.19348855  0.1586022 17.0650585 0.6765842
ARR_TRTvsCTRL 0.03267974 0.07267134 -0.1097535  0.1751129 0.6529323


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
```

```
n_all         18  34
n_event        9  12
n_event_pct   50  35

$Disdur_less_equal_12wk$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7058824 0.3308733  0.3690562 1.3501194 0.2924835
OR_TRTvsCTRL   0.5454545 0.5924611  0.1707870 1.7420569 0.3062694
ARR_TRTvsCTRL -0.1470588 0.1435471 -0.4284059 0.1342883 0.3056161


$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`
$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3

$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495


$Disdur_less_equal_12wk$Investigations
$Disdur_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         18  34
n_event        3   0
n_event_pct   17   0

$Disdur_less_equal_12wk$Investigations$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.07755102 1.48475967  0.004224330 1.42369592 0.08506182
OR_TRTvsCTRL   0.06418219 1.54247072  0.003122203 1.31937430 0.07503018
ARR_TRTvsCTRL -0.16666667 0.08784105 -0.338831953 0.00549862 0.05777957


$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`
$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats
                estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
```

```
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event       14  16
n_event_pct   78  47

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.6050420 0.2212719  0.39213766  0.93353910 0.02316096
OR_TRTvsCTRL   0.2539683 0.6629360  0.06926077  0.93126133 0.03869759
ARR_TRTvsCTRL -0.3071895 0.1301142 -0.56220860 -0.05217049 0.01822950


$Disdur_less_equal_12wk$`Vascular disorders`
$Disdur_less_equal_12wk$`Vascular disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        0   2
n_event_pct    0   6

$Disdur_less_equal_12wk$`Vascular disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.71428571 1.52275966  0.13723983 53.6822779 0.5119938
OR_TRTvsCTRL  2.84615385 1.57633223  0.12956328 62.5222782 0.5069811
ARR_TRTvsCTRL 0.05882353 0.04035261 -0.02026613  0.1379132 0.1449128



$Region_Asia_Pacific
$Region_Asia_Pacific$`Infections and infestations`
$Region_Asia_Pacific$`Infections and infestations`$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$`Infections and infestations`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353


$Region_Asia_Pacific$Investigations
$Region_Asia_Pacific$Investigations$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$Investigations$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
```

```
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`
$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        1   2
n_event_pct   50  17

$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3333333 0.9574271  0.051040546 2.1769185 0.2511903
OR_TRTvsCTRL   0.2000000 1.6124515  0.008482205 4.7157551 0.3182158
ARR_TRTvsCTRL -0.3333333 0.3695593 -1.057656246 0.3909896 0.3670700




\################################################################################
[[1]]
[1] "Patienten mit mindestens einem schweren UE nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         32  72
n_event       14  27
n_event_pct   44  38

$Ageonset_less_equal_12wk$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8571429 0.2516480  0.5234197 1.4036421 0.5401642
OR_TRTvsCTRL   0.7714286 0.4315592  0.3310944 1.7973788 0.5476176
ARR_TRTvsCTRL -0.0625000 0.1046214 -0.2675542 0.1425542 0.5502456


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       24  35
n_event_pct   75  49

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats
                estimate         se     lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   0.6481481 0.15842729  0.4751391  0.88415384 0.006197792
OR_TRTvsCTRL   0.3153153 0.47145002  0.1251544  0.79440881 0.014359037
ARR_TRTvsCTRL -0.2638889 0.09658632 -0.4531946 -0.07458317 0.006292137
```

```
$Agetrt_less_180d
$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         16  49
n_event        8  19
n_event_pct   50  39

$Agetrt_less_180d$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7755102 0.3077717  0.4242402 1.4176312 0.4087770
OR_TRTvsCTRL   0.6333333 0.5796248  0.2033550 1.9724676 0.4306825
ARR_TRTvsCTRL -0.1122449 0.1430731 -0.3926631 0.1681733 0.4327303


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event       13  23
n_event_pct   81  47

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci     hi95ci      pvalue
RR_TRTvsCTRL   0.5777080 0.1936315  0.39526551  0.8443604 0.004601770
OR_TRTvsCTRL   0.2041420 0.7015670  0.05161281  0.8074345 0.023522284
ARR_TRTvsCTRL -0.3431122 0.1208487 -0.57997128 -0.1062532 0.004522832



$Gender_Male
$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  37
n_event        7  11
n_event_pct   41  30

$Gender_Male$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7220077 0.3845981  0.3397593 1.5343072 0.3970460
OR_TRTvsCTRL   0.6043956 0.6101047  0.1828097 1.9982204 0.4091949
ARR_TRTvsCTRL -0.1144674 0.1410467 -0.3909139 0.1619791 0.4170460


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event       12  19
n_event_pct   71  51

$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats
```

```
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7274775 0.2238624  0.4691023 1.12816218 0.1552339
OR_TRTvsCTRL   0.4398148 0.6257160  0.1290207 1.49927137 0.1892710
ARR_TRTvsCTRL -0.1923688 0.1377110 -0.4622774 0.07753975 0.1624429



$Gender_Female
$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$ntab
            CTRL TRT
n_all         24  43
n_event       10  17
n_event_pct   42  40

$Gender_Female$`Infections and infestations`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94883721 0.3064328  0.5204220 1.7299269 0.8639209
OR_TRTvsCTRL   0.91538462 0.5183760  0.3314066 2.5284014 0.8645747
ARR_TRTvsCTRL -0.02131783 0.1252461 -0.2667956 0.2241599 0.8648469


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       17  20
n_event_pct   71  47

$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci       hi95ci     pvalue
RR_TRTvsCTRL   0.6566347 0.2095258  0.4354870  0.990085090 0.04469423
OR_TRTvsCTRL   0.3580563 0.5432853  0.1234542  1.038476269 0.05869499
ARR_TRTvsCTRL -0.2432171 0.1199745 -0.4783627 -0.008071428 0.04263785



$Region_Northamerica
$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$ntab
            CTRL TRT
n_all         22  38
n_event       11  17
n_event_pct   50  45

$Region_Northamerica$`Infections and infestations`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.89473684 0.2792173  0.5176368 1.5465554 0.6903737
OR_TRTvsCTRL   0.80952381 0.5368992  0.2826313 2.3186706 0.6938962
ARR_TRTvsCTRL -0.05263158 0.1336775 -0.3146348 0.2093716 0.6937875


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$ntab
```

```
            CTRL TRT
n_all         22  38
n_event       18  24
n_event_pct   82  63

$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7719298 0.1595365  0.5646510 1.05529897 0.1046780
OR_TRTvsCTRL   0.3809524 0.6470323  0.1071805 1.35402157 0.1358172
ARR_TRTvsCTRL -0.1866029 0.1135129 -0.4090840 0.03587829 0.1001986



$Disdur_greater_12wk
$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         23  46
n_event        8  16
n_event_pct   35  35

$Disdur_greater_12wk$`Infections and infestations`$stats
              estimate        se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.3496893  0.5038995 1.9845227      1
OR_TRTvsCTRL         1 0.5361903  0.3496182 2.8602631      1
ARR_TRTvsCTRL        0 0.1216311 -0.2383925 0.2383925      1


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       15  23
n_event_pct   65  50

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7666667 0.2119612  0.5060401 1.16152418 0.2100069
OR_TRTvsCTRL   0.5333333 0.5278477  0.1895370 1.50073323 0.2336967
ARR_TRTvsCTRL -0.1521739 0.1236832 -0.3945885 0.09024064 0.2185651



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         18  34
n_event        9  12
n_event_pct   50  35

$Disdur_less_equal_12wk$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7058824 0.3308733  0.3690562 1.3501194 0.2924835
```

```
OR_TRTvsCTRL   0.5454545 0.5924611  0.1707870 1.7420569 0.3062694
ARR_TRTvsCTRL -0.1470588 0.1435471 -0.4284059 0.1342883 0.3056161


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event       14  16
n_event_pct   78  47

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.6050420 0.2212719  0.39213766  0.93353910 0.02316096
OR_TRTvsCTRL   0.2539683 0.6629360  0.06926077  0.93126133 0.03869759
ARR_TRTvsCTRL -0.3071895 0.1301142 -0.56220860 -0.05217049 0.01822950



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       16  16
n_event_pct   64  52

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8064516 0.2296561  0.5141557 1.2649168 0.3489297
OR_TRTvsCTRL   0.6000000 0.5502525  0.2040683 1.7641154 0.3532272
ARR_TRTvsCTRL -0.1238710 0.1314235 -0.3814562 0.1337143 0.3459197



$Region_Europe
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event       10  13
n_event_pct   59  43

$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7366667 0.2911464  0.4163387 1.3034527 0.2938507
OR_TRTvsCTRL   0.5352941 0.6153078  0.1602660 1.7879010 0.3097949
ARR_TRTvsCTRL -0.1549020 0.1497768 -0.4484592 0.1386552 0.3010341
```

```
\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schweren UEs nach SOC, das bei mindestens 5%
der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               5.0                 6
n_event_pct                          16.0                 8
time-to-event-wk-10th                12.7                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4461    0.6112    0.1346    1.4780    0.1865


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               4.0                 5
n_event_pct                          12.0                 7
time-to-event-wk-10th                19.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.35100   0.67900   0.09275   1.32800   0.12310


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32                  72
n_event                               1                   4
n_event_pct                           3                   6
time-to-event-wk-10th                NA                  NA
time-to-event-wk-25th                NA                  NA
time-to-event-wk-50th                NA                  NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3780    1.1190    0.1537   12.3400    0.7746


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              14.0              27.0
n_event_pct                          44.0              38.0
time-to-event-wk-10th                 5.3               5.0
time-to-event-wk-25th                11.9              16.9
time-to-event-wk-50th                33.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.7              32.7
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6642    0.3343    0.3449    1.2790    0.2209


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               3.0                 1
n_event_pct                           9.0                 1
time-to-event-wk-10th                40.7                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.10930   1.16000   0.01124   1.06200   0.05639


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
```

```
n_event                              24.0              35.0
n_event_pct                          75.0              49.0
time-to-event-wk-10th                 0.9               4.1
time-to-event-wk-25th                 4.3              10.5
time-to-event-wk-50th                11.0              34.7
time-to-event-wk-75th                22.4                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.1              19.9
time-to-event-wk-50th-hici           15.7                NA

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.428600  0.270800  0.252100  0.728700  0.001755



$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Cardiac disorders`
$Ageonset_greater_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0               8.0
n_event                               2.0               1.0
n_event_pct                          22.0              12.0
time-to-event-wk-10th                23.0              25.4
time-to-event-wk-25th                33.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           23.0              25.4
time-to-event-wk-50th-hici             NA                NA

$Ageonset_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.07200   1.31900   0.08084  14.22000   0.95780


$Ageonset_greater_12wk$`Gastrointestinal disorders`
$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8
n_event                               1.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                26.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           26.1                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.256e-09 4.032e+04 0.000e+00       Inf 9.996e-01
```

```
$Ageonset_greater_12wk$`Infections and infestations`
$Ageonset_greater_12wk$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                8.0
n_event                              3.0                1.0
n_event_pct                         33.0               12.0
time-to-event-wk-10th               15.3               30.4
time-to-event-wk-25th               22.6               30.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          15.3               30.4
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.59230   1.20000   0.05642   6.21700   0.66240


$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`
$Ageonset_greater_12wk$`Injury, poisoning and procedural
complications`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               50.6                 NA
time-to-event-wk-25th               55.5                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          50.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.522e-01 1.273e+05 0.000e+00       Inf 1.000e+00


$Ageonset_greater_12wk$Investigations
$Ageonset_greater_12wk$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               15.9                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          15.9                 NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               5.0                4.0
n_event_pct                          56.0               50.0
time-to-event-wk-10th                 1.7                0.6
time-to-event-wk-25th                16.4                2.9
time-to-event-wk-50th                26.0               41.3
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.7                0.6
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2390    0.7083    0.3093    4.9670    0.7619



$Agetrt_less_180d
$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               3.0                 2
n_event_pct                          19.0                 4
time-to-event-wk-10th                 9.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           14.3                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.16120   0.93540   0.02577   1.00900   0.05108


$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0                5.0
```

```
n_event_pct                          12.0              10.0
time-to-event-wk-10th                18.7              45.9
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           18.7                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6225    0.8468    0.1184    3.2730    0.5756


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 16                49
n_event                                1                 4
n_event_pct                            6                 8
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1090    1.1250    0.1222   10.0600    0.9266


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              8.0              19.0
n_event_pct                         50.0              39.0
time-to-event-wk-10th                6.7               4.1
time-to-event-wk-25th               11.7              13.0
time-to-event-wk-50th               32.9                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           8.7              25.1
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5979    0.4244    0.2602    1.3740    0.2255
```

```
$Agetrt_less_180d$`Injury, poisoning and procedural complications`
$Agetrt_less_180d$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               1.0                 1
n_event_pct                           6.0                 2
time-to-event-wk-10th                47.6                NA
time-to-event-wk-25th                47.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           47.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.23490   1.52200   0.01189   4.64300   0.34140


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                17.9                NA
time-to-event-wk-25th                40.7                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.9                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.567e-11 2.758e+04 0.000e+00       Inf 9.993e-01


$Agetrt_less_180d$`Metabolism and nutrition disorders`
$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               1.0                 1
n_event_pct                           6.0                 2
time-to-event-wk-10th                17.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.9                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.161800  1.528000  0.008094  3.236000  0.233400


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                              13.0              23.0
n_event_pct                          81.0              47.0
time-to-event-wk-10th                 0.7               2.4
time-to-event-wk-25th                 6.1              10.0
time-to-event-wk-50th                10.1              43.4
time-to-event-wk-75th                15.7                NA
time-to-event-wk-90th                22.4                NA
time-to-event-wk-50th-loci            6.1              16.1
time-to-event-wk-50th-hici           15.7                NA

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
0.2774000 0.3789000 0.1320000 0.5830000 0.0007143



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Cardiac disorders`
$Agetrt_greater_equal_180d$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               4.0                 5
n_event_pct                          16.0                16
time-to-event-wk-10th                17.6                12
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8610    0.6916    0.2220    3.3400    0.8286


$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               3.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                19.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.515e-10 1.486e+04 0.000e+00       Inf 9.989e-01


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               9.0                9.0
n_event_pct                          36.0               29.0
time-to-event-wk-10th                11.7                8.1
time-to-event-wk-25th                17.7               29.6
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.7               30.4
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6689    0.4823    0.2599    1.7220    0.4045


$Agetrt_greater_equal_180d$Investigations
$Agetrt_greater_equal_180d$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25                 31
n_event                               2                  1
n_event_pct                           8                  3
time-to-event-wk-10th                NA                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Agetrt_greater_equal_180d$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.46010   1.24800   0.03985   5.31300   0.53400


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              16.0               16.0
```

```
n_event_pct                          64.0              52.0
time-to-event-wk-10th                 2.3               5.1
time-to-event-wk-25th                 4.6               9.6
time-to-event-wk-50th                17.9              27.0
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            8.6              11.4
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6769    0.3589    0.3350    1.3680    0.2769



$Gender_Male
$Gender_Male$`Cardiac disorders`
$Gender_Male$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               4.0               4.0
n_event_pct                          24.0              11.0
time-to-event-wk-10th                 9.4              25.4
time-to-event-wk-25th                33.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           14.3                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4291    0.7232    0.1040    1.7710    0.2420


$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               2.0                 3
n_event_pct                          12.0                 8
time-to-event-wk-10th                18.7                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8048    0.9223    0.1320    4.9070    0.8139
```

```
$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 37
n_event                                1                  2
n_event_pct                            6                  5
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.10900   1.25200   0.09536  12.89000   0.93420


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               37.0
n_event                              7.0               11.0
n_event_pct                         41.0               30.0
time-to-event-wk-10th                5.3                4.7
time-to-event-wk-25th               13.9               25.1
time-to-event-wk-50th               52.6                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          13.9               30.4
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6844    0.4867    0.2637    1.7760    0.4359


$Gender_Male$Investigations
$Gender_Male$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                 37
n_event                              2.0                  0
n_event_pct                         12.0                  0
time-to-event-wk-10th               17.9                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA
```

```
$Gender_Male$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.563e-10 2.080e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$`Metabolism and nutrition disorders`
$Gender_Male$`Metabolism and nutrition disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                37
n_event                                1                 1
n_event_pct                            6                 3
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39970   1.45000   0.02329   6.86000   0.52720


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              37.0
n_event                             12.0              19.0
n_event_pct                         71.0              51.0
time-to-event-wk-10th                0.6               1.0
time-to-event-wk-25th                1.7               5.1
time-to-event-wk-50th               16.4              27.0
time-to-event-wk-75th               52.6                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           0.9               9.0
time-to-event-wk-50th-hici          52.6                NA

$Gender_Male$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6140    0.3751    0.2943    1.2810    0.1934



$Gender_Female
$Gender_Female$`Cardiac disorders`
$Gender_Female$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0                43
n_event                              3.0                 3
n_event_pct                         12.0                 7
time-to-event-wk-10th               17.6                NA
time-to-event-wk-25th                 NA                NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7735    0.8579    0.1439    4.1570    0.7647


$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43
n_event                               3.0                 2
n_event_pct                          12.0                 5
time-to-event-wk-10th                19.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           26.1                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.23520   0.92260   0.03856   1.43500   0.11670


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43.0
n_event                              10.0                17.0
n_event_pct                          42.0                40.0
time-to-event-wk-10th                 8.7                 8.1
time-to-event-wk-25th                13.7                18.4
time-to-event-wk-50th                32.9                46.7
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           13.7                29.6
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7851    0.4063    0.3541    1.7410    0.5514


$Gender_Female$`Injury, poisoning and procedural complications`
$Gender_Female$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43
n_event                               2.0                 0
```

```
n_event_pct                              8.0                  0
time-to-event-wk-10th                   49.1                 NA
time-to-event-wk-25th                     NA                 NA
time-to-event-wk-50th                     NA                 NA
time-to-event-wk-75th                     NA                 NA
time-to-event-wk-90th                     NA                 NA
time-to-event-wk-50th-loci              47.6                 NA
time-to-event-wk-50th-hici                NA                 NA

$Gender_Female$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.921e-37 2.445e+04 0.000e+00       Inf 9.973e-01


$Gender_Female$Investigations
$Gender_Female$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               2.0                  1
n_event_pct                           8.0                  2
time-to-event-wk-10th                40.7                 NA
time-to-event-wk-25th                 NA                   NA
time-to-event-wk-50th                 NA                   NA
time-to-event-wk-75th                 NA                   NA
time-to-event-wk-90th                 NA                   NA
time-to-event-wk-50th-loci           40.7                  NA
time-to-event-wk-50th-hici            NA                   NA

$Gender_Female$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.14550   1.28500   0.01172   1.80500   0.13350


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43.0
n_event                              17.0                 20.0
n_event_pct                          71.0                 47.0
time-to-event-wk-10th                 3.1                  8.6
time-to-event-wk-25th                 7.4                 13.0
time-to-event-wk-50th                11.8                 34.7
time-to-event-wk-75th                 NA                   NA
time-to-event-wk-90th                 NA                   NA
time-to-event-wk-50th-loci            8.6                 19.9
time-to-event-wk-50th-hici           26.0                  NA

$Gender_Female$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.50110   0.34160   0.25660   0.97890   0.04312
```

```
$Region_Europe
$Region_Europe$`Cardiac disorders`
$Region_Europe$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                30
n_event                                1                 3
n_event_pct                            6                10
time-to-event-wk-10th                 NA                16
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4880    1.1640    0.1519   14.5700    0.7329


$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                30
n_event                              1.0                 0
n_event_pct                          6.0                 0
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          26.1                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.943e-10 2.831e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17              30.0
n_event                                0               3.0
n_event_pct                            0              10.0
time-to-event-wk-10th                 NA              23.4
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA
```

```
$Region_Europe$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.310e+08 1.523e+04 0.000e+00       Inf 9.990e-01


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               6.0                9.0
n_event_pct                          35.0               30.0
time-to-event-wk-10th                11.9                4.4
time-to-event-wk-25th                15.3               25.1
time-to-event-wk-50th                32.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.9               25.1
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7867    0.5392    0.2734    2.2640    0.6564


$Region_Europe$`Injury, poisoning and procedural complications`
$Region_Europe$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               1.0                  1
n_event_pct                           6.0                  3
time-to-event-wk-10th                47.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           47.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49570   1.55800   0.02341  10.50000   0.65230


$Region_Europe$Investigations
$Region_Europe$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                40.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.405e-09 7.179e+04 0.000e+00       Inf 9.998e-01


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                              10.0               13.0
n_event_pct                          59.0               43.0
time-to-event-wk-10th                 4.6                4.3
time-to-event-wk-25th                 9.1               11.0
time-to-event-wk-50th                13.0                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.3               11.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6861    0.4328    0.2938    1.6030    0.3842



$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               6.0                4.0
n_event_pct                          27.0               11.0
time-to-event-wk-10th                14.3               25.4
time-to-event-wk-25th                23.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           23.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26260   0.65790   0.07231   0.95340   0.04210


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                22.0               38.0
n_event                               4.0                5.0
n_event_pct                          18.0               13.0
time-to-event-wk-10th                18.7               28.4
time-to-event-wk-25th                19.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6369    0.6769    0.1690    2.4000    0.5051


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              11.0               17.0
n_event_pct                          50.0               45.0
time-to-event-wk-10th                 5.3                5.0
time-to-event-wk-25th                11.7               13.0
time-to-event-wk-50th                33.4               34.7
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           11.7               27.6
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7822    0.3901    0.3641    1.6800    0.5288


$Region_Northamerica$Investigations
$Region_Northamerica$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               3.0                  0
n_event_pct                          14.0                  0
time-to-event-wk-10th                15.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.175e-10 1.605e+04 0.000e+00       Inf 9.989e-01
```

```
$Region_Northamerica$`Nervous system disorders`
$Region_Northamerica$`Nervous system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                 38
n_event                                 0                  2
n_event_pct                             0                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.069e+08 1.811e+04 0.000e+00       Inf 9.991e-01


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              18.0               24.0
n_event_pct                          82.0               63.0
time-to-event-wk-10th                 0.7                1.9
time-to-event-wk-25th                 3.1                6.9
time-to-event-wk-50th                13.9               25.4
time-to-event-wk-75th                22.4                 NA
time-to-event-wk-90th                52.6                 NA
time-to-event-wk-50th-loci            3.1                9.6
time-to-event-wk-50th-hici           18.1               34.7

$Region_Northamerica$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.53560   0.31800   0.28720   0.99880   0.04956


$Region_Northamerica$`Vascular disorders`
$Region_Northamerica$`Vascular disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                 38
n_event                                 0                  2
n_event_pct                             0                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Vascular disorders`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.525e+08 1.862e+04 0.000e+00       Inf 9.992e-01



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               3.0                5.0
n_event_pct                          13.0               11.0
time-to-event-wk-10th                14.3               25.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7013    0.7333    0.1666    2.9520    0.6284


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                 46
n_event                               3.0                  2
n_event_pct                          13.0                  4
time-to-event-wk-10th                19.9                 NA
time-to-event-wk-25th                43.3                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25820   0.91610   0.04287   1.55500   0.13940


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               8.0               16.0
n_event_pct                          35.0               35.0
time-to-event-wk-10th                 6.7                8.1
time-to-event-wk-25th                15.3               16.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.3               30.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8779    0.4358    0.3737    2.0620    0.7650


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              15.0               23.0
n_event_pct                          65.0               50.0
time-to-event-wk-10th                 2.3                5.1
time-to-event-wk-25th                 4.0               11.3
time-to-event-wk-50th                13.9               28.0
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            4.6               19.1
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6134    0.3335    0.3191    1.1790    0.1428



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Cardiac disorders`
$Disdur_less_equal_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               4.0                  2
n_event_pct                          22.0                  6
time-to-event-wk-10th                 9.4                 NA
time-to-event-wk-25th                33.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.28680   0.88600   0.05051   1.62800   0.15860


$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
```

```
n_event                              2.0               3.0
n_event_pct                         11.0               9.0
time-to-event-wk-10th               18.7              45.9
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.51290   0.92950   0.08295   3.17200   0.47260


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                34
n_event                                 1                 3
n_event_pct                             6                 9
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6150    1.1750    0.1616   16.1400    0.6831


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                               9.0              12.0
n_event_pct                          50.0              35.0
time-to-event-wk-10th                 8.7               4.1
time-to-event-wk-25th                13.9              25.1
time-to-event-wk-50th                32.9                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           11.9              32.1
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7670    0.4776    0.3008    1.9560    0.5785
```

```
$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`
$Disdur_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 1
n_event_pct                         11.0                 3
time-to-event-wk-10th               47.6                NA
time-to-event-wk-25th               50.6                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          47.6                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.16280   1.23100   0.01457   1.81800   0.14030


$Disdur_less_equal_12wk$Investigations
$Disdur_less_equal_12wk$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              3.0                 0
n_event_pct                         17.0                 0
time-to-event-wk-10th               17.9                NA
time-to-event-wk-25th               40.7                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          40.7                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.153e-10 1.868e+04 0.000e+00       Inf 9.991e-01


$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`
$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18                34
n_event                              1                 0
n_event_pct                          6                 0
time-to-event-wk-10th               NA                NA
time-to-event-wk-25th               NA                NA
time-to-event-wk-50th               NA                NA
time-to-event-wk-75th               NA                NA
time-to-event-wk-90th               NA                NA
time-to-event-wk-50th-loci          NA                NA
time-to-event-wk-50th-hici          NA                NA
```

```
$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.029e-10 4.564e+04 0.000e+00       Inf 9.996e-01


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                              14.0               16.0
n_event_pct                          78.0               47.0
time-to-event-wk-10th                 0.7                1.6
time-to-event-wk-25th                 6.3                5.7
time-to-event-wk-50th                13.0               43.4
time-to-event-wk-75th                17.9                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.3               10.0
time-to-event-wk-50th-hici           17.9                 NA

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5229    0.3866    0.2451    1.1160    0.0936


$Disdur_less_equal_12wk$`Vascular disorders`
$Disdur_less_equal_12wk$`Vascular disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 0                2.0
n_event_pct                             0                6.0
time-to-event-wk-10th                  NA               47.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Vascular disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.961e+08 1.974e+04 0.000e+00       Inf 9.992e-01



$Region_Asia_Pacific
$Region_Asia_Pacific$`Infections and infestations`
$Region_Asia_Pacific$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
n_event                                 0                2.0
n_event_pct                             0               17.0
```

```
time-to-event-wk-10th                  NA               29.6
time-to-event-wk-25th                  NA               29.6
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               29.6
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.007e+07 2.744e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$Investigations
$Region_Asia_Pacific$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2                 12
n_event                                 0                  1
n_event_pct                             0                  8
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.811e+07 3.548e+04 0.000e+00       Inf 9.996e-01


$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`
$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0               12.0
n_event                               1.0                2.0
n_event_pct                          50.0               17.0
time-to-event-wk-10th                 0.9               23.9
time-to-event-wk-25th                 0.9                 NA
time-to-event-wk-50th                25.1                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            0.9               23.9
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.130500  1.452000  0.007575  2.248000  0.160900
```

```
\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schweren UEs nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              14.0              27.0
n_event_pct                          44.0              38.0
time-to-event-wk-10th                 5.3               5.0
time-to-event-wk-25th                11.9              16.9
time-to-event-wk-50th                33.4                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.7              32.7
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6642    0.3343    0.3449    1.2790    0.2209


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              24.0              35.0
n_event_pct                          75.0              49.0
time-to-event-wk-10th                 0.9               4.1
time-to-event-wk-25th                 4.3              10.5
time-to-event-wk-50th                11.0              34.7
time-to-event-wk-75th                22.4                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.1              19.9
time-to-event-wk-50th-hici           15.7                NA

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.428600  0.270800  0.252100  0.728700  0.001755



$Agetrt_less_180d
$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               8.0              19.0
n_event_pct                          50.0              39.0
```

```
time-to-event-wk-10th                6.7               4.1
time-to-event-wk-25th               11.7              13.0
time-to-event-wk-50th               32.9                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           8.7              25.1
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5979    0.4244    0.2602    1.3740    0.2255


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                              13.0              23.0
n_event_pct                          81.0              47.0
time-to-event-wk-10th                 0.7               2.4
time-to-event-wk-25th                 6.1              10.0
time-to-event-wk-50th                10.1              43.4
time-to-event-wk-75th                15.7                NA
time-to-event-wk-90th                22.4                NA
time-to-event-wk-50th-loci            6.1              16.1
time-to-event-wk-50th-hici           15.7                NA

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
0.2774000 0.3789000 0.1320000 0.5830000 0.0007143



$Gender_Male
$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               7.0              11.0
n_event_pct                          41.0              30.0
time-to-event-wk-10th                 5.3               4.7
time-to-event-wk-25th                13.9              25.1
time-to-event-wk-50th                52.6                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.9              30.4
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6844    0.4867    0.2637    1.7760    0.4359
```

```
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                              12.0              19.0
n_event_pct                          71.0              51.0
time-to-event-wk-10th                 0.6               1.0
time-to-event-wk-25th                 1.7               5.1
time-to-event-wk-50th                16.4              27.0
time-to-event-wk-75th                52.6                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            0.9               9.0
time-to-event-wk-50th-hici           52.6                NA

$Gender_Male$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6140    0.3751    0.2943    1.2810    0.1934



$Gender_Female
$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              10.0              17.0
n_event_pct                          42.0              40.0
time-to-event-wk-10th                 8.7               8.1
time-to-event-wk-25th                13.7              18.4
time-to-event-wk-50th                32.9              46.7
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.7              29.6
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7851    0.4063    0.3541    1.7410    0.5514


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              17.0              20.0
n_event_pct                          71.0              47.0
time-to-event-wk-10th                 3.1               8.6
time-to-event-wk-25th                 7.4              13.0
time-to-event-wk-50th                11.8              34.7
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            8.6              19.9
time-to-event-wk-50th-hici           26.0                NA
```

```
$Gender_Female$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.50110   0.34160   0.25660   0.97890   0.04312



$Region_Northamerica
$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                             11.0              17.0
n_event_pct                         50.0              45.0
time-to-event-wk-10th                5.3               5.0
time-to-event-wk-25th               11.7              13.0
time-to-event-wk-50th               33.4              34.7
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          11.7              27.6
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7822    0.3901    0.3641    1.6800    0.5288


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                             18.0              24.0
n_event_pct                         82.0              63.0
time-to-event-wk-10th                0.7               1.9
time-to-event-wk-25th                3.1               6.9
time-to-event-wk-50th               13.9              25.4
time-to-event-wk-75th               22.4                NA
time-to-event-wk-90th               52.6                NA
time-to-event-wk-50th-loci           3.1               9.6
time-to-event-wk-50th-hici          18.1              34.7

$Region_Northamerica$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.53560   0.31800   0.28720   0.99880   0.04956



$Disdur_greater_12wk
$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0              46.0
```

```
n_event                                8.0              16.0
n_event_pct                           35.0              35.0
time-to-event-wk-10th                  6.7               8.1
time-to-event-wk-25th                 15.3              16.9
time-to-event-wk-50th                   NA                NA
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci            15.3              30.4
time-to-event-wk-50th-hici              NA                NA

$Disdur_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8779    0.4358    0.3737    2.0620    0.7650


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                              15.0              23.0
n_event_pct                          65.0              50.0
time-to-event-wk-10th                 2.3               5.1
time-to-event-wk-25th                 4.0              11.3
time-to-event-wk-50th                13.9              28.0
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            4.6              19.1
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6134    0.3335    0.3191    1.1790    0.1428



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                               9.0              12.0
n_event_pct                          50.0              35.0
time-to-event-wk-10th                 8.7               4.1
time-to-event-wk-25th                13.9              25.1
time-to-event-wk-50th                32.9                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           11.9              32.1
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7670    0.4776    0.3008    1.9560    0.5785
```

```
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                              14.0              16.0
n_event_pct                          78.0              47.0
time-to-event-wk-10th                 0.7               1.6
time-to-event-wk-25th                 6.3               5.7
time-to-event-wk-50th                13.0              43.4
time-to-event-wk-75th                17.9                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.3              10.0
time-to-event-wk-50th-hici           17.9                NA

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5229    0.3866    0.2451    1.1160    0.0936



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0              31.0
n_event                              16.0              16.0
n_event_pct                          64.0              52.0
time-to-event-wk-10th                 2.3               5.1
time-to-event-wk-25th                 4.6               9.6
time-to-event-wk-50th                17.9              27.0
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            8.6              11.4
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6769    0.3589    0.3350    1.3680    0.2769



$Region_Europe
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                              10.0              13.0
n_event_pct                          59.0              43.0
```

```
time-to-event-wk-10th                 4.6                4.3
time-to-event-wk-25th                 9.1               11.0
time-to-event-wk-50th                13.0                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.3               11.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6861    0.4328    0.2938    1.6030    0.3842




\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem schweren UE nach PT, das bei mindestens 5%
der Patienten in einem Studienarm auftrat"

$Agetrt_less_180d
$Agetrt_less_180d$`Acute respiratory distress syndrome`
$Agetrt_less_180d$`Acute respiratory distress syndrome`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$`Acute respiratory distress syndrome`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Acute respiratory failure`
$Agetrt_less_180d$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         16  49
n_event        4   7
n_event_pct   25  14

$Agetrt_less_180d$`Acute respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5714286 0.5567306  0.1918987 1.7015782 0.3148091
OR_TRTvsCTRL   0.5000000 0.7071068  0.1250488 1.9992191 0.3269587
ARR_TRTvsCTRL -0.1071429 0.1192380 -0.3408451 0.1265594 0.3688856


$Agetrt_less_180d$Apnoea
$Agetrt_less_180d$Apnoea$ntab
            CTRL TRT
n_all         16  49
```

```
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$Apnoea$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$Aspiration
$Agetrt_less_180d$Aspiration$ntab
            CTRL TRT
n_all         16  49
n_event        1   2
n_event_pct    6   4

$Agetrt_less_180d$Aspiration$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 1.19041667  0.06333874 6.7334618 0.7203966
OR_TRTvsCTRL   0.63829787 1.26013621  0.05399997 7.5448964 0.7216375
ARR_TRTvsCTRL -0.02168367 0.06679144 -0.15259249 0.1092251 0.7454479


$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$ntab
            CTRL TRT
n_all         16  49
n_event        1   4
n_event_pct    6   8

$Agetrt_less_180d$Atelectasis$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.30612245 1.08032025  0.1571859 10.85311 0.8047480
OR_TRTvsCTRL  1.33333333 1.15710366  0.1380417 12.87856 0.8036528
ARR_TRTvsCTRL 0.01913265 0.07205612 -0.1220947  0.16036 0.7906056


$Agetrt_less_180d$`Bronchial secretion retention`
$Agetrt_less_180d$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         16  49
n_event        3   1
n_event_pct   19   2

$Agetrt_less_180d$`Bronchial secretion retention`$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.10884354 1.11822411  0.012160979 0.97417446 0.04732694
OR_TRTvsCTRL   0.09027778 1.19628163  0.008655738 0.94158088 0.04440131
ARR_TRTvsCTRL -0.16709184 0.09964676 -0.362395906 0.02821223 0.09357347


$Agetrt_less_180d$Bronchiolitis
$Agetrt_less_180d$Bronchiolitis$ntab
```

```
            CTRL TRT
n_all         16  49
n_event        0   3
n_event_pct    0   6

$Agetrt_less_180d$Bronchiolitis$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.38000000 1.48556075  0.129439060 43.7611337 0.55943183
OR_TRTvsCTRL  2.48387097 1.53877410  0.121708846 50.6915905 0.55434508
ARR_TRTvsCTRL 0.06122449 0.03424881 -0.005901935  0.1283509 0.07383432


$Agetrt_less_180d$`Bronchitis viral`
$Agetrt_less_180d$`Bronchitis viral`$ntab
            CTRL TRT
n_all         16  49
n_event        0   3
n_event_pct    0   6

$Agetrt_less_180d$`Bronchitis viral`$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.38000000 1.48556075  0.129439060 43.7611337 0.55943183
OR_TRTvsCTRL  2.48387097 1.53877410  0.121708846 50.6915905 0.55434508
ARR_TRTvsCTRL 0.06122449 0.03424881 -0.005901935  0.1283509 0.07383432


$Agetrt_less_180d$`Cardiac arrest`
$Agetrt_less_180d$`Cardiac arrest`$ntab
            CTRL TRT
n_all         16  49
n_event        1   1
n_event_pct    6   2

$Agetrt_less_180d$`Cardiac arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 1.38459086  0.02164502 4.92594746 0.4188901
OR_TRTvsCTRL   0.31250000 1.44481833  0.01840850 5.30495387 0.4207909
ARR_TRTvsCTRL -0.04209184 0.06379736 -0.16713236 0.08294868 0.5093989


$Agetrt_less_180d$`Cardio-respiratory arrest`
$Agetrt_less_180d$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$`Cardio-respiratory arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156
```

```
$Agetrt_less_180d$`Corona virus infection`
$Agetrt_less_180d$`Corona virus infection`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$`Corona virus infection`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$Cyanosis
$Agetrt_less_180d$Cyanosis$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$Cyanosis$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$Death
$Agetrt_less_180d$Death$ntab
            CTRL TRT
n_all         16  49
n_event        1   1
n_event_pct    6   2

$Agetrt_less_180d$Death$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 1.38459086  0.02164502 4.92594746 0.4188901
OR_TRTvsCTRL   0.31250000 1.44481833  0.01840850 5.30495387 0.4207909
ARR_TRTvsCTRL -0.04209184 0.06379736 -0.16713236 0.08294868 0.5093989


$Agetrt_less_180d$Dysphagia
$Agetrt_less_180d$Dysphagia$ntab
            CTRL TRT
n_all         16  49
n_event        1   4
n_event_pct    6   8

$Agetrt_less_180d$Dysphagia$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.30612245 1.08032025  0.1571859 10.85311 0.8047480
OR_TRTvsCTRL  1.33333333 1.15710366  0.1380417 12.87856 0.8036528
ARR_TRTvsCTRL 0.01913265 0.07205612 -0.1220947  0.16036 0.7906056
```

```
$Agetrt_less_180d$Dyspnoea
$Agetrt_less_180d$Dyspnoea$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$Dyspnoea$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Heart rate decreased`
$Agetrt_less_180d$`Heart rate decreased`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$`Heart rate decreased`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$Hypoxia
$Agetrt_less_180d$Hypoxia$ntab
            CTRL TRT
n_all         16  49
n_event        1   2
n_event_pct    6   4

$Agetrt_less_180d$Hypoxia$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 1.19041667  0.06333874 6.7334618 0.7203966
OR_TRTvsCTRL   0.63829787 1.26013621  0.05399997 7.5448964 0.7216375
ARR_TRTvsCTRL -0.02168367 0.06679144 -0.15259249 0.1092251 0.7454479


$Agetrt_less_180d$`Oxygen saturation decreased`
$Agetrt_less_180d$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$`Oxygen saturation decreased`$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
```

```
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$ntab
            CTRL TRT
n_all         16  49
n_event        3   8
n_event_pct   19  16

$Agetrt_less_180d$Pneumonia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.87074830 0.6127195  0.2620263 2.8936127 0.8212932
OR_TRTvsCTRL   0.84552846 0.7480954  0.1951409 3.6636008 0.8225284
ARR_TRTvsCTRL -0.02423469 0.1109479 -0.2416886 0.1932192 0.8270917


$Agetrt_less_180d$`Respiratory arrest`
$Agetrt_less_180d$`Respiratory arrest`$ntab
            CTRL TRT
n_all         16  49
n_event        2   2
n_event_pct   12   4

$Agetrt_less_180d$`Respiratory arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 0.95764912  0.04997715 2.13341975 0.2425131
OR_TRTvsCTRL   0.29787234 1.04532539  0.03839261 2.31106820 0.2466285
ARR_TRTvsCTRL -0.08418367 0.08737805 -0.25544151 0.08707417 0.3353258


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$ntab
            CTRL TRT
n_all         16  49
n_event        2  10
n_event_pct   12  20

$Agetrt_less_180d$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.63265306 0.7190910  0.3988435 6.6832123 0.4954269
OR_TRTvsCTRL  1.79487179 0.8349069  0.3494293 9.2195030 0.4835543
ARR_TRTvsCTRL 0.07908163 0.1007516 -0.1183879 0.2765511 0.4325023


$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$ntab
            CTRL TRT
n_all         16  49
n_event        9   8
n_event_pct   56  16

$Agetrt_less_180d$`Respiratory failure`$stats
```

```
                estimate        se      lo95ci     hi95ci      pvalue
RR_TRTvsCTRL   0.2902494 0.3914115  0.13477251  0.6250884 0.001575558
OR_TRTvsCTRL   0.1517615 0.6351051  0.04370783  0.5269436 0.002990495
ARR_TRTvsCTRL -0.3992347 0.1347917 -0.66342165 -0.1350477 0.003057836


$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`
$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         16  49
n_event        2   2
n_event_pct   12   4

$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 0.95764912  0.04997715 2.13341975 0.2425131
OR_TRTvsCTRL   0.29787234 1.04532539  0.03839261 2.31106820 0.2466285
ARR_TRTvsCTRL -0.08418367 0.08737805 -0.25544151 0.08707417 0.3353258


$Agetrt_less_180d$`Respiratory tract infection`
$Agetrt_less_180d$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         16  49
n_event        1   3
n_event_pct    6   6

$Agetrt_less_180d$`Respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.97959184 1.11822411  0.10944882  8.7675701 0.9852884
OR_TRTvsCTRL   0.97826087 1.19236703  0.09451702 10.1251004 0.9852934
ARR_TRTvsCTRL -0.00127551 0.06953481 -0.13756124  0.1350102 0.9853648


$Agetrt_less_180d$`Respiratory tract infection viral`
$Agetrt_less_180d$`Respiratory tract infection viral`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$`Respiratory tract infection viral`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Rhinovirus infection`
$Agetrt_less_180d$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         16  49
n_event        1   3
n_event_pct    6   6
```

```
$Agetrt_less_180d$`Rhinovirus infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.97959184 1.11822411  0.10944882  8.7675701 0.9852884
OR_TRTvsCTRL   0.97826087 1.19236703  0.09451702 10.1251004 0.9852934
ARR_TRTvsCTRL -0.00127551 0.06953481 -0.13756124  0.1350102 0.9853648


$Agetrt_less_180d$`Sleep apnoea syndrome`
$Agetrt_less_180d$`Sleep apnoea syndrome`$ntab
           CTRL TRT
n_all        16  49
n_event       1   0
n_event_pct   6   0

$Agetrt_less_180d$`Sleep apnoea syndrome`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Tracheal haemorrhage`
$Agetrt_less_180d$`Tracheal haemorrhage`$ntab
           CTRL TRT
n_all        16  49
n_event       1   0
n_event_pct   6   0

$Agetrt_less_180d$`Tracheal haemorrhage`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Tracheal obstruction`
$Agetrt_less_180d$`Tracheal obstruction`$ntab
           CTRL TRT
n_all        16  49
n_event       1   0
n_event_pct   6   0

$Agetrt_less_180d$`Tracheal obstruction`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Upper respiratory tract infection`
$Agetrt_less_180d$`Upper respiratory tract infection`$ntab
           CTRL TRT
n_all        16  49
```

```
n_event        0   4
n_event_pct    0   8

$Agetrt_less_180d$`Upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.06000000 1.46403507 0.173593122 53.9399251 0.44491116
OR_TRTvsCTRL  3.26373626 1.51815885 0.166515972 63.9696856 0.43589168
ARR_TRTvsCTRL 0.08163265 0.03911489 0.004968874  0.1582964 0.03688843


$Agetrt_less_180d$`Viral upper respiratory tract infection`
$Agetrt_less_180d$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$`Viral upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156


$Agetrt_less_180d$Vomiting
$Agetrt_less_180d$Vomiting$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$Vomiting$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Weight gain poor`
$Agetrt_less_180d$`Weight gain poor`$ntab
            CTRL TRT
n_all         16  49
n_event        1   1
n_event_pct    6   2

$Agetrt_less_180d$`Weight gain poor`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 1.38459086  0.02164502 4.92594746 0.4188901
OR_TRTvsCTRL   0.31250000 1.44481833  0.01840850 5.30495387 0.4207909
ARR_TRTvsCTRL -0.04209184 0.06379736 -0.16713236 0.08294868 0.5093989



$Region_Europe
```

```
$Region_Europe$`Acute respiratory distress syndrome`
$Region_Europe$`Acute respiratory distress syndrome`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Acute respiratory distress syndrome`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Acute respiratory failure`
$Region_Europe$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         17  30
n_event        2   0
n_event_pct   12   0

$Region_Europe$`Acute respiratory failure`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1161290 1.52058751  0.005896772 2.28700568 0.1567945
OR_TRTvsCTRL   0.1016393 1.58028574  0.004591136 2.25010878 0.1479588
ARR_TRTvsCTRL -0.1176471 0.07814249 -0.270803525 0.03550941 0.1321839


$Region_Europe$Apnoea
$Region_Europe$Apnoea$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$Apnoea$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$Atelectasis
$Region_Europe$Atelectasis$ntab
            CTRL TRT
n_all         17  30
n_event        1   1
n_event_pct    6   3

$Region_Europe$Atelectasis$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5666667 1.38124695  0.03781013 8.4927277 0.6809178
OR_TRTvsCTRL   0.5517241 1.44809625  0.03229239 9.4263541 0.6813057
ARR_TRTvsCTRL -0.0254902 0.06580836 -0.15447221 0.1034918 0.6985047
```

```
$Region_Europe$`Bronchial secretion retention`
$Region_Europe$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         17  30
n_event        2   1
n_event_pct   12   3

$Region_Europe$`Bronchial secretion retention`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.28333333 1.18652566  0.02769014 2.89914637 0.2878376
OR_TRTvsCTRL   0.25862069 1.26536533  0.02165620 3.08847571 0.2851704
ARR_TRTvsCTRL -0.08431373 0.08473679 -0.25039477 0.08176732 0.3197327


$Region_Europe$`Candida sepsis`
$Region_Europe$`Candida sepsis`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Candida sepsis`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Cardio-respiratory arrest`
$Region_Europe$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         17  30
n_event        1   2
n_event_pct    6   7

$Region_Europe$`Cardio-respiratory arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.133333333 1.18652566  0.11076057 11.5965855 0.9159893
OR_TRTvsCTRL  1.142857143 1.26420500  0.09591769 13.6171178 0.9158801
ARR_TRTvsCTRL 0.007843137 0.07301192 -0.13525759  0.1509439 0.9144536


$Region_Europe$Dysphagia
$Region_Europe$Dysphagia$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$Dysphagia$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
```

```
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Heart rate decreased`
$Region_Europe$`Heart rate decreased`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Heart rate decreased`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Lower respiratory tract infection`
$Region_Europe$`Lower respiratory tract infection`$ntab
            CTRL TRT
n_all         17  30
n_event        0   2
n_event_pct    0   7

$Region_Europe$`Lower respiratory tract infection`$stats
                estimate       se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.90322581 1.520588  0.14741931 57.1751420 0.4833479
OR_TRTvsCTRL  3.07017544 1.578680  0.13911960 67.7544859 0.4773617
ARR_TRTvsCTRL 0.06666667 0.045542 -0.02259402  0.1559274 0.1432349


$Region_Europe$`Oxygen saturation decreased`
$Region_Europe$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Oxygen saturation decreased`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$Pneumonia
$Region_Europe$Pneumonia$ntab
            CTRL TRT
n_all         17  30
n_event        2   3
n_event_pct   12  10

$Region_Europe$Pneumonia$stats
```

```
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.86091606  0.1572555 4.5944339 0.8502696
OR_TRTvsCTRL   0.83333333 0.96800673  0.1249827 5.5563242 0.8506043
ARR_TRTvsCTRL -0.01764706 0.09542667 -0.2046799 0.1693858 0.8532855


$Region_Europe$`Pneumonia pseudomonal`
$Region_Europe$`Pneumonia pseudomonal`$ntab
           CTRL TRT
n_all        17  30
n_event       1   0
n_event_pct   6   0

$Region_Europe$`Pneumonia pseudomonal`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Respiratory arrest`
$Region_Europe$`Respiratory arrest`$ntab
           CTRL TRT
n_all        17  30
n_event       0   4
n_event_pct   0  13

$Region_Europe$`Respiratory arrest`$stats
               estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  5.2258065 1.46096153 0.29825011  91.5642690 0.25769180
OR_TRTvsCTRL  5.9433962 1.52220266 0.30083851 117.4183396 0.24165650
ARR_TRTvsCTRL 0.1333333 0.06206329 0.01169152   0.2549751 0.03168639


$Region_Europe$`Respiratory distress`
$Region_Europe$`Respiratory distress`$ntab
           CTRL TRT
n_all        17  30
n_event       2   4
n_event_pct  12  13

$Region_Europe$`Respiratory distress`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.13333333 0.81107530  0.2311900 5.5557949 0.8773594
OR_TRTvsCTRL  1.15384615 0.92473142  0.1883715 7.0677425 0.8770196
ARR_TRTvsCTRL 0.01568627 0.09979028 -0.1798991 0.2112716 0.8750932


$Region_Europe$`Respiratory failure`
$Region_Europe$`Respiratory failure`$ntab
           CTRL TRT
n_all        17  30
n_event       7   5
n_event_pct  41  17
```

```
$Region_Europe$`Respiratory failure`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.4047619 0.5006998  0.15170615 1.07993114 0.07085832
OR_TRTvsCTRL   0.2857143 0.6948792  0.07318965 1.11535785 0.07141179
ARR_TRTvsCTRL -0.2450980 0.1373956 -0.51438841 0.02419233 0.07444219


$Region_Europe$`Respiratory tract infection`
$Region_Europe$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         17  30
n_event        1   3
n_event_pct    6  10

$Region_Europe$`Respiratory tract infection`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 1.11408100  0.1914880 15.0923333 0.6338661
OR_TRTvsCTRL  1.77777778 1.19702563  0.1702031 18.5689583 0.6307571
ARR_TRTvsCTRL 0.04117647 0.07909909 -0.1138549  0.1962078 0.6026676


$Region_Europe$`Respiratory tract infection viral`
$Region_Europe$`Respiratory tract infection viral`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Respiratory tract infection viral`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Salivary hypersecretion`
$Region_Europe$`Salivary hypersecretion`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Salivary hypersecretion`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Tracheal haemorrhage`
$Region_Europe$`Tracheal haemorrhage`$ntab
            CTRL TRT
n_all         17  30
```

```
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Tracheal haemorrhage`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Tracheal obstruction`
$Region_Europe$`Tracheal obstruction`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Tracheal obstruction`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Acute respiratory distress syndrome`
$Disdur_less_equal_12wk$`Acute respiratory distress syndrome`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Acute respiratory distress syndrome`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Acute respiratory failure`
$Disdur_less_equal_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         18  34
n_event        5   4
n_event_pct   28  12

$Disdur_less_equal_12wk$`Acute respiratory failure`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4235294 0.6041793  0.12960005 1.38408246 0.1550314
OR_TRTvsCTRL   0.3466667 0.7485028  0.07994391 1.50327628 0.1569666
ARR_TRTvsCTRL -0.1601307 0.1191576 -0.39367529 0.07341385 0.1789947
```

```
$Disdur_less_equal_12wk$Apnoea
$Disdur_less_equal_12wk$Apnoea$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$Apnoea$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$Aspiration
$Disdur_less_equal_12wk$Aspiration$ntab
            CTRL TRT
n_all         18  34
n_event        1   2
n_event_pct    6   6

$Disdur_less_equal_12wk$Aspiration$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 1.18955146  0.10286687 10.8986228 0.9616761
OR_TRTvsCTRL  1.062500000 1.26098118  0.08973871 12.5799253 0.9616546
ARR_TRTvsCTRL 0.003267974 0.06740389 -0.12884123  0.1353772 0.9613309


$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         18  34
n_event        1   3
n_event_pct    6   9

$Disdur_less_equal_12wk$Atelectasis$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.58823529 1.11730301  0.1777726 14.1894280 0.6788347
OR_TRTvsCTRL  1.64516129 1.19348855  0.1586022 17.0650585 0.6765842
ARR_TRTvsCTRL 0.03267974 0.07267134 -0.1097535  0.1751129 0.6529323


$Disdur_less_equal_12wk$`Bronchial secretion retention`
$Disdur_less_equal_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         18  34
n_event        3   1
n_event_pct   17   3

$Disdur_less_equal_12wk$`Bronchial secretion retention`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1764706 1.1173030  0.01975251 1.5766031 0.1205452
OR_TRTvsCTRL   0.1515152 1.1959528  0.01453648 1.5792574 0.1145932
ARR_TRTvsCTRL -0.1372549 0.0924968 -0.31854530 0.0440355 0.1378386
```

```
$Disdur_less_equal_12wk$`Bronchitis viral`
$Disdur_less_equal_12wk$`Bronchitis viral`$ntab
           CTRL TRT
n_all        18  34
n_event       0   2
n_event_pct   0   6

$Disdur_less_equal_12wk$`Bronchitis viral`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.71428571 1.52275966  0.13723983 53.6822779 0.5119938
OR_TRTvsCTRL  2.84615385 1.57633223  0.12956328 62.5222782 0.5069811
ARR_TRTvsCTRL 0.05882353 0.04035261 -0.02026613  0.1379132 0.1449128


$Disdur_less_equal_12wk$`Candida sepsis`
$Disdur_less_equal_12wk$`Candida sepsis`$ntab
           CTRL TRT
n_all        18  34
n_event       1   0
n_event_pct   6   0

$Disdur_less_equal_12wk$`Candida sepsis`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Cardiac arrest`
$Disdur_less_equal_12wk$`Cardiac arrest`$ntab
           CTRL TRT
n_all        18  34
n_event       1   1
n_event_pct   6   3

$Disdur_less_equal_12wk$`Cardiac arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 1.38384706  0.03514478 7.97492008 0.6458175
OR_TRTvsCTRL   0.51515152 1.44538111  0.03031268 8.75478761 0.6463016
ARR_TRTvsCTRL -0.02614379 0.06127447 -0.14623955 0.09395197 0.6696220


$Disdur_less_equal_12wk$`Cardio-respiratory arrest`
$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$ntab
           CTRL TRT
n_all        18  34
n_event       3   1
n_event_pct  17   3

$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1764706 1.1173030  0.01975251 1.5766031 0.1205452
```

```
OR_TRTvsCTRL   0.1515152 1.1959528  0.01453648 1.5792574 0.1145932
ARR_TRTvsCTRL -0.1372549 0.0924968 -0.31854530 0.0440355 0.1378386


$Disdur_less_equal_12wk$`Corona virus infection`
$Disdur_less_equal_12wk$`Corona virus infection`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Corona virus infection`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$Cyanosis
$Disdur_less_equal_12wk$Cyanosis$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$Cyanosis$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$Death
$Disdur_less_equal_12wk$Death$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$Death$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$Dysphagia
$Disdur_less_equal_12wk$Dysphagia$ntab
            CTRL TRT
n_all         18  34
n_event        1   2
n_event_pct    6   6

$Disdur_less_equal_12wk$Dysphagia$stats
```

```
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 1.18955146  0.10286687 10.8986228 0.9616761
OR_TRTvsCTRL  1.062500000 1.26098118  0.08973871 12.5799253 0.9616546
ARR_TRTvsCTRL 0.003267974 0.06740389 -0.12884123  0.1353772 0.9613309


$Disdur_less_equal_12wk$Dyspnoea
$Disdur_less_equal_12wk$Dyspnoea$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$Dyspnoea$stats
                estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Femur fracture`
$Disdur_less_equal_12wk$`Femur fracture`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Femur fracture`$stats
                estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Heart rate decreased`
$Disdur_less_equal_12wk$`Heart rate decreased`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Heart rate decreased`$stats
                estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$Hypoxia
$Disdur_less_equal_12wk$Hypoxia$ntab
            CTRL TRT
n_all         18  34
n_event        1   1
n_event_pct    6   3
```

```
$Disdur_less_equal_12wk$Hypoxia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 1.38384706  0.03514478 7.97492008 0.6458175
OR_TRTvsCTRL   0.51515152 1.44538111  0.03031268 8.75478761 0.6463016
ARR_TRTvsCTRL -0.02614379 0.06127447 -0.14623955 0.09395197 0.6696220


$Disdur_less_equal_12wk$`Oxygen saturation decreased`
$Disdur_less_equal_12wk$`Oxygen saturation decreased`$ntab
           CTRL TRT
n_all        18  34
n_event       2   0
n_event_pct  11   0

$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$Pneumonia
$Disdur_less_equal_12wk$Pneumonia$ntab
           CTRL TRT
n_all        18  34
n_event       3   6
n_event_pct  17  18

$Disdur_less_equal_12wk$Pneumonia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 0.6442303  0.2995393 3.7427723 0.9293016
OR_TRTvsCTRL  1.071428571 0.7761320  0.2340553 4.9046500 0.9291668
ARR_TRTvsCTRL 0.009803922 0.1095008 -0.2048137 0.2244215 0.9286584


$Disdur_less_equal_12wk$`Pneumonia aspiration`
$Disdur_less_equal_12wk$`Pneumonia aspiration`$ntab
           CTRL TRT
n_all        18  34
n_event       2   2
n_event_pct  11   6

$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$`Pneumonia parainfluenzae viral`
$Disdur_less_equal_12wk$`Pneumonia parainfluenzae viral`$ntab
           CTRL TRT
n_all        18  34
```

```
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Pneumonia parainfluenzae viral`$stats
                estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         18  34
n_event        0   2
n_event_pct    0   6

$Disdur_less_equal_12wk$Pyrexia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.71428571 1.52275966  0.13723983 53.6822779 0.5119938
OR_TRTvsCTRL  2.84615385 1.57633223  0.12956328 62.5222782 0.5069811
ARR_TRTvsCTRL 0.05882353 0.04035261 -0.02026613  0.1379132 0.1449128


$Disdur_less_equal_12wk$`Respiratory arrest`
$Disdur_less_equal_12wk$`Respiratory arrest`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Respiratory arrest`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$`Respiratory distress`
$Disdur_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         18  34
n_event        2   7
n_event_pct   11  21

$Disdur_less_equal_12wk$`Respiratory distress`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.85294118 0.7469202  0.4286294  8.0101617 0.4089423
OR_TRTvsCTRL  2.07407407 0.8616230  0.3831858 11.2263631 0.3971762
ARR_TRTvsCTRL 0.09477124 0.1014674 -0.1041013  0.2936437 0.3503005


$Disdur_less_equal_12wk$`Respiratory failure`
$Disdur_less_equal_12wk$`Respiratory failure`$ntab
```

```
            CTRL TRT
n_all         18  34
n_event        7   7
n_event_pct   39  21

$Disdur_less_equal_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5294118 0.4480479  0.2199958 1.27400958 0.1557632
OR_TRTvsCTRL   0.4074074 0.6431644  0.1154959 1.43711469 0.1626751
ARR_TRTvsCTRL -0.1830065 0.1342076 -0.4460487 0.08003559 0.1726911


$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`
$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3

$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495


$Disdur_less_equal_12wk$`Respiratory tract infection`
$Disdur_less_equal_12wk$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         18  34
n_event        1   2
n_event_pct    6   6

$Disdur_less_equal_12wk$`Respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 1.18955146  0.10286687 10.8986228 0.9616761
OR_TRTvsCTRL  1.062500000 1.26098118  0.08973871 12.5799253 0.9616546
ARR_TRTvsCTRL 0.003267974 0.06740389 -0.12884123  0.1353772 0.9613309


$Disdur_less_equal_12wk$`Respirovirus test positive`
$Disdur_less_equal_12wk$`Respirovirus test positive`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Respirovirus test positive`$stats
                estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837
```

```
$Disdur_less_equal_12wk$`Rhinovirus infection`
$Disdur_less_equal_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         18  34
n_event        1   1
n_event_pct    6   3

$Disdur_less_equal_12wk$`Rhinovirus infection`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 1.38384706  0.03514478 7.97492008 0.6458175
OR_TRTvsCTRL   0.51515152 1.44538111  0.03031268 8.75478761 0.6463016
ARR_TRTvsCTRL -0.02614379 0.06127447 -0.14623955 0.09395197 0.6696220


$Disdur_less_equal_12wk$`Sleep apnoea syndrome`
$Disdur_less_equal_12wk$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Sleep apnoea syndrome`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Tracheal haemorrhage`
$Disdur_less_equal_12wk$`Tracheal haemorrhage`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Tracheal haemorrhage`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Tracheal obstruction`
$Disdur_less_equal_12wk$`Tracheal obstruction`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Tracheal obstruction`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837
```

```
$Disdur_less_equal_12wk$`Upper respiratory tract infection`
$Disdur_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         18  34
n_event        0   4
n_event_pct    0  12

$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.8857143 1.46322220 0.277607419  85.985469 0.27830946
OR_TRTvsCTRL  5.4590164 1.51956019 0.277755343 107.291761 0.26401687
ARR_TRTvsCTRL 0.1176471 0.05525508 0.009349083   0.225945 0.03324081


$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`
$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3

$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495


$Disdur_less_equal_12wk$Vomiting
$Disdur_less_equal_12wk$Vomiting$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$Vomiting$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Weight gain poor`
$Disdur_less_equal_12wk$`Weight gain poor`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Weight gain poor`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
```

```
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event        7  10
n_event_pct   22  14

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.63492063 0.44465521  0.2656001 1.5177863 0.3069750
OR_TRTvsCTRL   0.57603687 0.54679628  0.1972497 1.6822251 0.3130920
ARR_TRTvsCTRL -0.07986111 0.08367598 -0.2438630 0.0841408 0.3398767


$Ageonset_less_equal_12wk$Apnoea
$Ageonset_less_equal_12wk$Apnoea$ntab
            CTRL TRT
n_all         32  72
n_event        2   1
n_event_pct    6   1

$Ageonset_less_equal_12wk$Apnoea$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22222222 1.20617624  0.02089722 2.36312426 0.2124049
OR_TRTvsCTRL   0.21126761 1.24395251  0.01844925 2.41928596 0.2113909
ARR_TRTvsCTRL -0.04861111 0.04495861 -0.13672837 0.03950615 0.2795898


$Ageonset_less_equal_12wk$`Apparent life threatening event`
$Ageonset_less_equal_12wk$`Apparent life threatening event`$ntab
            CTRL TRT
n_all         32  72
n_event        2   0
n_event_pct    6   0

$Ageonset_less_equal_12wk$`Apparent life threatening event`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09041096 1.53492617  0.004463644 1.83127092 0.1173951
OR_TRTvsCTRL   0.08413793 1.56415472  0.003922662 1.80469053 0.1135321
ARR_TRTvsCTRL -0.06250000 0.04279082 -0.146368475 0.02136848 0.1441270


$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         32  72
n_event        4   6
n_event_pct   12   8
```

```
$Ageonset_less_equal_12wk$Atelectasis$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.66666667 0.60953078  0.2018716 2.20161961 0.5059171
OR_TRTvsCTRL   0.63636364 0.68376346  0.1666038 2.43066925 0.5085959
ARR_TRTvsCTRL -0.04166667 0.06692478 -0.1728368 0.08950348 0.5335543


$Ageonset_less_equal_12wk$`Bronchial secretion retention`
$Ageonset_less_equal_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         32  72
n_event        5   1
n_event_pct   16   1

$Ageonset_less_equal_12wk$`Bronchial secretion retention`$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.08888889 1.07464464  0.010817037  0.7304435 0.02430649
OR_TRTvsCTRL   0.07605634 1.11853545  0.008492515  0.6811371 0.02126407
ARR_TRTvsCTRL -0.14236111 0.06565131 -0.271035323 -0.0136869 0.03012502


$Ageonset_less_equal_12wk$Bronchiolitis
$Ageonset_less_equal_12wk$Bronchiolitis$ntab
            CTRL TRT
n_all         32  72
n_event        1   4
n_event_pct    3   6

$Ageonset_less_equal_12wk$Bronchiolitis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.77777778 1.09766166  0.20679793 15.2830055 0.6001585
OR_TRTvsCTRL  1.82352941 1.13884325  0.19567153 16.9940896 0.5978257
ARR_TRTvsCTRL 0.02430556 0.04092411 -0.05590423  0.1045153 0.5525671


$Ageonset_less_equal_12wk$`Cardiac arrest`
$Ageonset_less_equal_12wk$`Cardiac arrest`$ntab
            CTRL TRT
n_all         32  72
n_event        2   2
n_event_pct    6   3

$Ageonset_less_equal_12wk$`Cardiac arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.44444444 0.97716995  0.06547099 3.01707462 0.4066087
OR_TRTvsCTRL   0.42857143 1.02353263  0.05764885 3.18607335 0.4077741
ARR_TRTvsCTRL -0.03472222 0.04696957 -0.12678089 0.05733644 0.4597556


$Ageonset_less_equal_12wk$`Cardio-respiratory arrest`
$Ageonset_less_equal_12wk$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         32  72
```

```
n_event        3   4
n_event_pct    9   6

$Ageonset_less_equal_12wk$`Cardio-respiratory arrest`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.59259259 0.73361737  0.1407019 2.49581537 0.4756948
OR_TRTvsCTRL   0.56862745 0.79531250  0.1196345 2.70270752 0.4778149
ARR_TRTvsCTRL -0.03819444 0.05817016 -0.1522059 0.07581697 0.5114390


$Ageonset_less_equal_12wk$Dysphagia
$Ageonset_less_equal_12wk$Dysphagia$ntab
            CTRL TRT
n_all         32  72
n_event        3   4
n_event_pct    9   6

$Ageonset_less_equal_12wk$Dysphagia$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.59259259 0.73361737  0.1407019 2.49581537 0.4756948
OR_TRTvsCTRL   0.56862745 0.79531250  0.1196345 2.70270752 0.4778149
ARR_TRTvsCTRL -0.03819444 0.05817016 -0.1522059 0.07581697 0.5114390


$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         32  72
n_event        3   1
n_event_pct    9   1

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.14814815 1.1349865  0.01601747 1.37024593 0.09248428
OR_TRTvsCTRL   0.13615023 1.1755427  0.01359548 1.36345918 0.08984143
ARR_TRTvsCTRL -0.07986111 0.0533409 -0.18440735 0.02468513 0.13434552


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$ntab
            CTRL TRT
n_all         32  72
n_event        5   9
n_event_pct   16  12

$Ageonset_less_equal_12wk$Pneumonia$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8000000 0.51572495  0.2911415 2.1982438 0.6652477
OR_TRTvsCTRL   0.7714286 0.60334166  0.2364451 2.5168717 0.6671061
ARR_TRTvsCTRL -0.0312500 0.07509308 -0.1784297 0.1159297 0.6773001


$Ageonset_less_equal_12wk$`Pneumonia viral`
$Ageonset_less_equal_12wk$`Pneumonia viral`$ntab
```

```
            CTRL TRT
n_all         32  72
n_event        2   2
n_event_pct    6   3

$Ageonset_less_equal_12wk$`Pneumonia viral`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.44444444 0.97716995  0.06547099 3.01707462 0.4066087
OR_TRTvsCTRL   0.42857143 1.02353263  0.05764885 3.18607335 0.4077741
ARR_TRTvsCTRL -0.03472222 0.04696957 -0.12678089 0.05733644 0.4597556


$Ageonset_less_equal_12wk$`Respiratory arrest`
$Ageonset_less_equal_12wk$`Respiratory arrest`$ntab
            CTRL TRT
n_all         32  72
n_event        3   4
n_event_pct    9   6

$Ageonset_less_equal_12wk$`Respiratory arrest`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.59259259 0.73361737  0.1407019 2.49581537 0.4756948
OR_TRTvsCTRL   0.56862745 0.79531250  0.1196345 2.70270752 0.4778149
ARR_TRTvsCTRL -0.03819444 0.05817016 -0.1522059 0.07581697 0.5114390


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         32  72
n_event        7  11
n_event_pct   22  15

$Ageonset_less_equal_12wk$`Respiratory distress`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.69841270 0.43431250  0.2981430 1.63606139 0.4085390
OR_TRTvsCTRL   0.64402810 0.53866472  0.2240746 1.85104534 0.4140092
ARR_TRTvsCTRL -0.06597222 0.08448851 -0.2315667 0.09962222 0.4348951


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event       14  12
n_event_pct   44  17

$Ageonset_less_equal_12wk$`Respiratory failure`$stats
                estimate         se     lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   0.3809524 0.33109367  0.1990872  0.72895066 0.003558853
OR_TRTvsCTRL   0.2571429 0.47642851  0.1010736  0.65420092 0.004363211
ARR_TRTvsCTRL -0.2708333 0.09807875 -0.4630642 -0.07860251 0.005755654
```

```
$Ageonset_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`
$Ageonset_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         32  72
n_event        3   3
n_event_pct    9   4

$Ageonset_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.44444444 0.78837033  0.09478845 2.08391271 0.3036602
OR_TRTvsCTRL   0.42028986 0.84595637  0.08006995 2.20611564 0.3055275
ARR_TRTvsCTRL -0.05208333 0.05665351 -0.16312218 0.05895551 0.3579224


$Ageonset_less_equal_12wk$`Rhinovirus infection`
$Ageonset_less_equal_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         32  72
n_event        3   4
n_event_pct    9   6

$Ageonset_less_equal_12wk$`Rhinovirus infection`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.59259259 0.73361737  0.1407019 2.49581537 0.4756948
OR_TRTvsCTRL   0.56862745 0.79531250  0.1196345 2.70270752 0.4778149
ARR_TRTvsCTRL -0.03819444 0.05817016 -0.1522059 0.07581697 0.5114390


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        0   5
n_event_pct    0   7

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  4.97260274 1.46212740 0.28315137 87.3270643 0.2726445
OR_TRTvsCTRL  5.29629630 1.49244840 0.28418287 98.7067050 0.2640107
ARR_TRTvsCTRL 0.06944444 0.02995875 0.01072638  0.1281625 0.0204492


$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        5   1
n_event_pct   16   1

$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.08888889 1.07464464  0.010817037  0.7304435 0.02430649
OR_TRTvsCTRL   0.07605634 1.11853545  0.008492515  0.6811371 0.02126407
ARR_TRTvsCTRL -0.14236111 0.06565131 -0.271035323 -0.0136869 0.03012502
```

```
$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Acute respiratory failure`
$Ageonset_greater_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Acute respiratory failure`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$`Candida sepsis`
$Ageonset_greater_12wk$`Candida sepsis`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Candida sepsis`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Cardio-respiratory arrest`
$Ageonset_greater_12wk$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Cardio-respiratory arrest`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$Dysphagia
$Ageonset_greater_12wk$Dysphagia$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Dysphagia$stats
```

```
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Femur fracture`
$Ageonset_greater_12wk$`Femur fracture`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Femur fracture`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Pneumonia
$Ageonset_greater_12wk$Pneumonia$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Pneumonia$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Pneumonia aspiration`
$Ageonset_greater_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0

$Ageonset_greater_12wk$`Pneumonia aspiration`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`
$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0
```

```
$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Pneumonia pseudomonal`
$Ageonset_greater_12wk$`Pneumonia pseudomonal`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Pneumonia pseudomonal`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Respiratory distress`
$Ageonset_greater_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$`Respiratory distress`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031


$Ageonset_greater_12wk$`Respiratory failure`
$Ageonset_greater_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all          9   8
n_event        1   2
n_event_pct   11  25

$Ageonset_greater_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2500000 1.1242281  0.2484493 20.3763897 0.4707116
OR_TRTvsCTRL  2.6666667 1.3385315  0.1934678 36.7560505 0.4637017
ARR_TRTvsCTRL 0.1388889 0.1855032 -0.2246907  0.5024685 0.4540295


$Ageonset_greater_12wk$`Respirovirus test positive`
$Ageonset_greater_12wk$`Respirovirus test positive`$ntab
            CTRL TRT
n_all          9   8
```

```
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Respirovirus test positive`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Salivary hypersecretion`
$Ageonset_greater_12wk$`Salivary hypersecretion`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Salivary hypersecretion`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Acute respiratory failure`
$Agetrt_greater_equal_180d$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         25  31
n_event        5   4
n_event_pct   20  13

$Agetrt_greater_equal_180d$`Acute respiratory failure`$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.64516129 0.6146071  0.1934255 2.151904 0.4758054
OR_TRTvsCTRL   0.59259259 0.7328281  0.1409197 2.491958 0.4752197
ARR_TRTvsCTRL -0.07096774 0.1001262 -0.2672115 0.125276 0.4784592


$Agetrt_greater_equal_180d$`Apparent life threatening event`
$Agetrt_greater_equal_180d$`Apparent life threatening event`$ntab
            CTRL TRT
n_all         25  31
n_event        2   0
n_event_pct    8   0

$Agetrt_greater_equal_180d$`Apparent life threatening event`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1625000 1.52652824  0.008155868 3.23769964 0.2339154
OR_TRTvsCTRL   0.1492063 1.57299054  0.006836839 3.25626150 0.2264969
ARR_TRTvsCTRL -0.0800000 0.05425864 -0.186344980 0.02634498 0.1403687
```

```
$Agetrt_greater_equal_180d$Atelectasis
$Agetrt_greater_equal_180d$Atelectasis$ntab
            CTRL TRT
n_all         25  31
n_event        3   2
n_event_pct   12   6

$Agetrt_greater_equal_180d$Atelectasis$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.53763441 0.87239628  0.09725277 2.97215952 0.4768692
OR_TRTvsCTRL   0.50574713 0.95565194  0.07771073 3.29143917 0.4756265
ARR_TRTvsCTRL -0.05548387 0.07855506 -0.20944895 0.09848121 0.4799981


$Agetrt_greater_equal_180d$`Bronchial secretion retention`
$Agetrt_greater_equal_180d$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         25  31
n_event        2   0
n_event_pct    8   0

$Agetrt_greater_equal_180d$`Bronchial secretion retention`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1625000 1.52652824  0.008155868 3.23769964 0.2339154
OR_TRTvsCTRL   0.1492063 1.57299054  0.006836839 3.25626150 0.2264969
ARR_TRTvsCTRL -0.0800000 0.05425864 -0.186344980 0.02634498 0.1403687


$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`
$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         25  31
n_event        3   4
n_event_pct   12  13

$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.075268817 0.71489529  0.2648482 4.3655304 0.9191438
OR_TRTvsCTRL  1.086419753 0.81598095  0.2194994 5.3772707 0.9190897
ARR_TRTvsCTRL 0.009032258 0.08859603 -0.1646128 0.1826773 0.9187973


$Agetrt_greater_equal_180d$Dysphagia
$Agetrt_greater_equal_180d$Dysphagia$ntab
            CTRL TRT
n_all         25  31
n_event        3   0
n_event_pct   12   0

$Agetrt_greater_equal_180d$Dysphagia$stats
                estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.1160714 1.48862445  0.006274887 2.147062848 0.14798915
OR_TRTvsCTRL   0.1020408 1.53684897  0.005018867 2.074637104 0.13751596
ARR_TRTvsCTRL -0.1200000 0.06499231 -0.247382581 0.007382581 0.06483816
```

```
$Agetrt_greater_equal_180d$Dyspnoea
$Agetrt_greater_equal_180d$Dyspnoea$ntab
            CTRL TRT
n_all         25  31
n_event        0   2
n_event_pct    0   6

$Agetrt_greater_equal_180d$Dyspnoea$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  4.06250000 1.52652824  0.20389669 80.9424911 0.3584661
OR_TRTvsCTRL  4.32203390 1.57261375  0.19818780 94.2539187 0.3519777
ARR_TRTvsCTRL 0.06451613 0.04412365 -0.02196464  0.1509969 0.1436956


$Agetrt_greater_equal_180d$`Lower respiratory tract infection`
$Agetrt_greater_equal_180d$`Lower respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        0   2
n_event_pct    0   6

$Agetrt_greater_equal_180d$`Lower respiratory tract infection`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  4.06250000 1.52652824  0.20389669 80.9424911 0.3584661
OR_TRTvsCTRL  4.32203390 1.57261375  0.19818780 94.2539187 0.3519777
ARR_TRTvsCTRL 0.06451613 0.04412365 -0.02196464  0.1509969 0.1436956


$Agetrt_greater_equal_180d$Pneumonia
$Agetrt_greater_equal_180d$Pneumonia$ntab
            CTRL TRT
n_all         25  31
n_event        2   2
n_event_pct    8   6

$Agetrt_greater_equal_180d$Pneumonia$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80645161 0.96319361  0.1220974 5.3266015 0.8232776
OR_TRTvsCTRL   0.79310345 1.03824902  0.1036503 6.0686068 0.8233316
ARR_TRTvsCTRL -0.01548387 0.06993495 -0.1525538 0.1215861 0.8247779


$Agetrt_greater_equal_180d$`Pneumonia aspiration`
$Agetrt_greater_equal_180d$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         25  31
n_event        2   1
n_event_pct    8   3

$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats
                  estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.40322581 1.1948816  0.03876710 4.19404750 0.4471803
```

```
OR_TRTvsCTRL   0.38333333 1.2557116  0.03271244 4.49200497 0.4451109
ARR_TRTvsCTRL -0.04774194 0.0628571 -0.17093960 0.07545572 0.4475348


$Agetrt_greater_equal_180d$`Pneumonia viral`
$Agetrt_greater_equal_180d$`Pneumonia viral`$ntab
            CTRL TRT
n_all         25  31
n_event        2   2
n_event_pct    8   6

$Agetrt_greater_equal_180d$`Pneumonia viral`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80645161 0.96319361  0.1220974 5.3266015 0.8232776
OR_TRTvsCTRL   0.79310345 1.03824902  0.1036503 6.0686068 0.8233316
ARR_TRTvsCTRL -0.01548387 0.06993495 -0.1525538 0.1215861 0.8247779


$Agetrt_greater_equal_180d$`Respiratory arrest`
$Agetrt_greater_equal_180d$`Respiratory arrest`$ntab
            CTRL TRT
n_all         25  31
n_event        1   2
n_event_pct    4   6

$Agetrt_greater_equal_180d$`Respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.61290323 1.19488156  0.15506839 16.7761900 0.6891052
OR_TRTvsCTRL  1.65517241 1.25544790  0.14132014 19.3857420 0.6881442
ARR_TRTvsCTRL 0.02451613 0.05901607 -0.09115325  0.1401855 0.6778385


$Agetrt_greater_equal_180d$`Respiratory distress`
$Agetrt_greater_equal_180d$`Respiratory distress`$ntab
            CTRL TRT
n_all         25  31
n_event        6   2
n_event_pct   24   6

$Agetrt_greater_equal_180d$`Respiratory distress`$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2688172 0.77097899  0.05931965 1.21819150 0.08838703
OR_TRTvsCTRL   0.2183908 0.86820562  0.03983056 1.19743601 0.07969998
ARR_TRTvsCTRL -0.1754839 0.09613998 -0.36391478 0.01294704 0.06795647


$Agetrt_greater_equal_180d$`Respiratory failure`
$Agetrt_greater_equal_180d$`Respiratory failure`$ntab
            CTRL TRT
n_all         25  31
n_event        6   6
n_event_pct   24  19

$Agetrt_greater_equal_180d$`Respiratory failure`$stats
```

```
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80645161 0.5109553  0.2962459 2.1953522 0.6737562
OR_TRTvsCTRL   0.76000000 0.6526599  0.2114796 2.7312326 0.6741277
ARR_TRTvsCTRL -0.04645161 0.1110454 -0.2640966 0.1711933 0.6757190


$Agetrt_greater_equal_180d$`Rhinovirus infection`
$Agetrt_greater_equal_180d$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         25  31
n_event        2   1
n_event_pct    8   3

$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.40322581 1.1948816  0.03876710 4.19404750 0.4471803
OR_TRTvsCTRL   0.38333333 1.2557116  0.03271244 4.49200497 0.4451109
ARR_TRTvsCTRL -0.04774194 0.0628571 -0.17093960 0.07545572 0.4475348


$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        3   0
n_event_pct   12   0

$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`$stats
                estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.1160714 1.48862445  0.006274887 2.147062848 0.14798915
OR_TRTvsCTRL   0.1020408 1.53684897  0.005018867 2.074637104 0.13751596
ARR_TRTvsCTRL -0.1200000 0.06499231 -0.247382581 0.007382581 0.06483816



$Gender_Male
$Gender_Male$`Acute respiratory failure`
$Gender_Male$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         17  37
n_event        4   5
n_event_pct   24  14

$Gender_Male$`Acute respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5743243 0.6034480  0.1759954 1.8741875 0.3581022
OR_TRTvsCTRL   0.5078125 0.7471098  0.1174255 2.1960611 0.3643966
ARR_TRTvsCTRL -0.1001590 0.1172302 -0.3299259 0.1296079 0.3928951


$Gender_Male$Apnoea
$Gender_Male$Apnoea$ntab
            CTRL TRT
n_all         17  37
```

```
n_event        1   0
n_event_pct    6   0

$Gender_Male$Apnoea$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$`Apparent life threatening event`
$Gender_Male$`Apparent life threatening event`$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$`Apparent life threatening event`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$Aspiration
$Gender_Male$Aspiration$ntab
            CTRL TRT
n_all         17  37
n_event        1   1
n_event_pct    6   3

$Gender_Male$Aspiration$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 1.38352790  0.03052011 6.91684875 0.5740363
OR_TRTvsCTRL   0.4444444 1.44577930  0.02613171 7.55904710 0.5748692
ARR_TRTvsCTRL -0.0317965 0.06298717 -0.15524909 0.09165609 0.6136929


$Gender_Male$Atelectasis
$Gender_Male$Atelectasis$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$Atelectasis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$`Bronchial secretion retention`
$Gender_Male$`Bronchial secretion retention`$ntab
```

```
            CTRL TRT
n_all         17  37
n_event        3   1
n_event_pct   18   3

$Gender_Male$`Bronchial secretion retention`$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.1531532 1.11690769  0.01715586 1.36722342 0.09297266
OR_TRTvsCTRL   0.1296296 1.19688750  0.01241400 1.35362001 0.08782408
ARR_TRTvsCTRL -0.1494436 0.09622612 -0.33804329 0.03915617 0.12041222


$Gender_Male$Bronchiolitis
$Gender_Male$Bronchiolitis$ntab
            CTRL TRT
n_all         17  37
n_event        1   3
n_event_pct    6   8

$Gender_Male$Bronchiolitis$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.37837838 1.11690769  0.1544027 12.3050107 0.7738688
OR_TRTvsCTRL  1.41176471 1.19383629  0.1360088 14.6540482 0.7726956
ARR_TRTvsCTRL 0.02225755 0.07259729 -0.1200305  0.1645456 0.7591560


$Gender_Male$`Bronchitis viral`
$Gender_Male$`Bronchitis viral`$ntab
            CTRL TRT
n_all         17  37
n_event        0   2
n_event_pct    0   5

$Gender_Male$`Bronchitis viral`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.36842105 1.52254020  0.11980373 46.821732 0.5711858
OR_TRTvsCTRL  2.46478873 1.57648719  0.11216862 54.161169 0.5671692
ARR_TRTvsCTRL 0.05405405 0.03717461 -0.01880684  0.126915 0.1459301


$Gender_Male$`Candida sepsis`
$Gender_Male$`Candida sepsis`$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$`Candida sepsis`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457
```

```
$Gender_Male$`Cardiac arrest`
$Gender_Male$`Cardiac arrest`$ntab
            CTRL TRT
n_all         17  37
n_event        1   2
n_event_pct    6   5

$Gender_Male$`Cardiac arrest`$stats
                  estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.918918919 1.1891802  0.08933985  9.4516836 0.9433137
OR_TRTvsCTRL   0.914285714 1.2613768  0.07716068 10.8334757 0.9433634
ARR_TRTvsCTRL -0.004769475 0.0681074 -0.13825752  0.1287186 0.9441708


$Gender_Male$`Cardio-respiratory arrest`
$Gender_Male$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         17  37
n_event        3   2
n_event_pct   18   5

$Gender_Male$`Cardio-respiratory arrest`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3063063 0.8645709  0.05626417 1.66755432 0.1711540
OR_TRTvsCTRL   0.2666667 0.9660918  0.04014486 1.77136292 0.1712660
ARR_TRTvsCTRL -0.1224165 0.0996529 -0.31773262 0.07289956 0.2192859


$Gender_Male$`Corona virus infection`
$Gender_Male$`Corona virus infection`$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$`Corona virus infection`$stats
                  estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$Cyanosis
$Gender_Male$Cyanosis$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$Cyanosis$stats
                  estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457
```

```
$Gender_Male$Death
$Gender_Male$Death$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$Death$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$Dysphagia
$Gender_Male$Dysphagia$ntab
            CTRL TRT
n_all         17  37
n_event        1   3
n_event_pct    6   8

$Gender_Male$Dysphagia$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.37837838 1.11690769  0.1544027 12.3050107 0.7738688
OR_TRTvsCTRL  1.41176471 1.19383629  0.1360088 14.6540482 0.7726956
ARR_TRTvsCTRL 0.02225755 0.07259729 -0.1200305  0.1645456 0.7591560


$Gender_Male$Dyspnoea
$Gender_Male$Dyspnoea$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$Dyspnoea$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$Hypoxia
$Gender_Male$Hypoxia$ntab
            CTRL TRT
n_all         17  37
n_event        1   1
n_event_pct    6   3

$Gender_Male$Hypoxia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 1.38352790  0.03052011 6.91684875 0.5740363
```

```
OR_TRTvsCTRL   0.4444444 1.44577930  0.02613171 7.55904710 0.5748692
ARR_TRTvsCTRL -0.0317965 0.06298717 -0.15524909 0.09165609 0.6136929


$Gender_Male$`Oxygen saturation decreased`
$Gender_Male$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$`Oxygen saturation decreased`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$Pneumonia
$Gender_Male$Pneumonia$ntab
            CTRL TRT
n_all         17  37
n_event        3   3
n_event_pct   18   8

$Gender_Male$Pneumonia$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.45945946 0.7621129  0.10316574 2.0462510 0.3075111
OR_TRTvsCTRL   0.41176471 0.8760748  0.07394911 2.2927955 0.3111477
ARR_TRTvsCTRL -0.09538951 0.1027738 -0.29682241 0.1060434 0.3533296


$Gender_Male$`Pneumonia aspiration`
$Gender_Male$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$`Pneumonia aspiration`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$`Pneumonia viral`
$Gender_Male$`Pneumonia viral`$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$`Pneumonia viral`$stats
```

```
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$`Respiratory arrest`
$Gender_Male$`Respiratory arrest`$ntab
            CTRL TRT
n_all         17  37
n_event        1   3
n_event_pct    6   8

$Gender_Male$`Respiratory arrest`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.37837838 1.11690769  0.1544027 12.3050107 0.7738688
OR_TRTvsCTRL  1.41176471 1.19383629  0.1360088 14.6540482 0.7726956
ARR_TRTvsCTRL 0.02225755 0.07259729 -0.1200305  0.1645456 0.7591560


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$ntab
            CTRL TRT
n_all         17  37
n_event        1   6
n_event_pct    6  16

$Gender_Male$`Respiratory distress`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.7567568 1.03962306  0.35931032 21.1508197 0.3293588
OR_TRTvsCTRL  3.0967742 1.12313166  0.34268740 27.9847186 0.3142055
ARR_TRTvsCTRL 0.1033386 0.08323887 -0.05980655  0.2664838 0.2144318


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$ntab
            CTRL TRT
n_all         17  37
n_event        7   7
n_event_pct   41  19

$Gender_Male$`Respiratory failure`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.4594595 0.4470612  0.19129693 1.10353571 0.08193051
OR_TRTvsCTRL   0.3333333 0.6473389  0.09372661 1.18548099 0.08967382
ARR_TRTvsCTRL -0.2225755 0.1356236 -0.48839295 0.04324191 0.10077118


$Gender_Male$`Respiratory syncytial virus bronchiolitis`
$Gender_Male$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         17  37
n_event        1   1
n_event_pct    6   3
```

```
$Gender_Male$`Respiratory syncytial virus bronchiolitis`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 1.38352790  0.03052011 6.91684875 0.5740363
OR_TRTvsCTRL   0.4444444 1.44577930  0.02613171 7.55904710 0.5748692
ARR_TRTvsCTRL -0.0317965 0.06298717 -0.15524909 0.09165609 0.6136929


$Gender_Male$`Rhinovirus infection`
$Gender_Male$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         17  37
n_event        1   2
n_event_pct    6   5

$Gender_Male$`Rhinovirus infection`$stats
                   estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.918918919 1.1891802  0.08933985  9.4516836 0.9433137
OR_TRTvsCTRL   0.914285714 1.2613768  0.07716068 10.8334757 0.9433634
ARR_TRTvsCTRL -0.004769475 0.0681074 -0.13825752  0.1287186 0.9441708


$Gender_Male$Sepsis
$Gender_Male$Sepsis$ntab
            CTRL TRT
n_all         17  37
n_event        0   2
n_event_pct    0   5

$Gender_Male$Sepsis$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.36842105 1.52254020  0.11980373 46.821732 0.5711858
OR_TRTvsCTRL  2.46478873 1.57648719  0.11216862 54.161169 0.5671692
ARR_TRTvsCTRL 0.05405405 0.03717461 -0.01880684  0.126915 0.1459301


$Gender_Male$`Sleep apnoea syndrome`
$Gender_Male$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$`Sleep apnoea syndrome`$stats
                  estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$`Viral upper respiratory tract infection`
$Gender_Male$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         17  37
```

```
n_event        2   0
n_event_pct   12   0

$Gender_Male$`Viral upper respiratory tract infection`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$Vomiting
$Gender_Male$Vomiting$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$Vomiting$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$`Weight gain poor`
$Gender_Male$`Weight gain poor`$ntab
            CTRL TRT
n_all         17  37
n_event        1   1
n_event_pct    6   3

$Gender_Male$`Weight gain poor`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 1.38352790  0.03052011 6.91684875 0.5740363
OR_TRTvsCTRL   0.4444444 1.44577930  0.02613171 7.55904710 0.5748692
ARR_TRTvsCTRL -0.0317965 0.06298717 -0.15524909 0.09165609 0.6136929



$Gender_Female
$Gender_Female$`Acute respiratory failure`
$Gender_Female$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         24  43
n_event        5   6
n_event_pct   21  14

$Gender_Female$`Acute respiratory failure`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.66976744 0.54931247  0.2282172 1.9656204 0.4655831
OR_TRTvsCTRL   0.61621622 0.66807580  0.1663665 2.2824448 0.4686335
ARR_TRTvsCTRL -0.06879845 0.09830724 -0.2614771 0.1238802 0.4840329
```

```
$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$ntab
            CTRL TRT
n_all         24  43
n_event        2   5
n_event_pct    8  12

$Gender_Female$Atelectasis$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39534884 0.79691751  0.2926479 6.6530412 0.6759169
OR_TRTvsCTRL  1.44736842 0.87850460  0.2586989 8.0977351 0.6738410
ARR_TRTvsCTRL 0.03294574 0.07464983 -0.1133652 0.1792567 0.6589690


$Gender_Female$`Bronchial secretion retention`
$Gender_Female$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         24  43
n_event        2   0
n_event_pct    8   0

$Gender_Female$`Bronchial secretion retention`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.11363636 1.52881416  0.005677908 2.27429239 0.1548786
OR_TRTvsCTRL   0.10344828 1.57080646  0.004760476 2.24799916 0.1486604
ARR_TRTvsCTRL -0.08333333 0.05641693 -0.193908491 0.02724182 0.1396494


$Gender_Female$`Cardio-respiratory arrest`
$Gender_Female$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         24  43
n_event        2   3
n_event_pct    8   7

$Gender_Female$`Cardio-respiratory arrest`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83720930 0.87659047  0.1502031 4.6664778 0.8393728
OR_TRTvsCTRL   0.82500000 0.95067759  0.1280076 5.3170676 0.8396412
ARR_TRTvsCTRL -0.01356589 0.06849943 -0.1478223 0.1206905 0.8430107


$Gender_Female$Dysphagia
$Gender_Female$Dysphagia$ntab
            CTRL TRT
n_all         24  43
n_event        3   1
n_event_pct   12   2

$Gender_Female$Dysphagia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1860465 1.12623748  0.02046287 1.69151794 0.1353707
OR_TRTvsCTRL   0.1666667 1.18522652  0.01632985 1.70104339 0.1305989
ARR_TRTvsCTRL -0.1017442 0.07131302 -0.24151514 0.03802677 0.1536587
```

```
$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$ntab
            CTRL TRT
n_all         24  43
n_event        2   7
n_event_pct    8  16

$Gender_Female$Pneumonia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.95348837 0.76022014  0.44026106  8.6678500 0.3784156
OR_TRTvsCTRL  2.13888889 0.84622070  0.40727135 11.2329179 0.3689460
ARR_TRTvsCTRL 0.07945736 0.07970196 -0.07675561  0.2356703 0.3187980


$Gender_Female$`Pneumonia aspiration`
$Gender_Female$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         24  43
n_event        0   3
n_event_pct    0   7

$Gender_Female$`Pneumonia aspiration`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.97727273 1.49096848  0.214028053 73.9094626 0.3544601
OR_TRTvsCTRL  4.23456790 1.53336948  0.209702028 85.5097371 0.3465777
ARR_TRTvsCTRL 0.06976744 0.03884972 -0.006376618  0.1459115 0.0725218


$Gender_Female$`Respiratory arrest`
$Gender_Female$`Respiratory arrest`$ntab
            CTRL TRT
n_all         24  43
n_event        2   1
n_event_pct    8   2

$Gender_Female$`Respiratory arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.27906977 1.19794721  0.02666971 2.92016442 0.2866948
OR_TRTvsCTRL   0.26190476 1.25270271  0.02248231 3.05102574 0.2848413
ARR_TRTvsCTRL -0.06007752 0.06091901 -0.17947658 0.05932155 0.3240415


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$ntab
            CTRL TRT
n_all         24  43
n_event        7   6
n_event_pct   29  14

$Gender_Female$`Respiratory distress`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.4784053 0.4945719  0.1814745 1.261178 0.1360197
```

```
OR_TRTvsCTRL   0.3938224 0.6287880  0.1148352 1.350597 0.1383439
ARR_TRTvsCTRL -0.1521318 0.1067728 -0.3614026 0.057139 0.1542098


$Gender_Female$`Respiratory failure`
$Gender_Female$`Respiratory failure`$ntab
            CTRL TRT
n_all         24  43
n_event        8   7
n_event_pct   33  16

$Gender_Female$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4883721 0.4504827  0.2019758 1.18087087 0.1116297
OR_TRTvsCTRL   0.3888889 0.5984437  0.1203453 1.25667153 0.1145206
ARR_TRTvsCTRL -0.1705426 0.1114845 -0.3890482 0.04796295 0.1260803


$Gender_Female$`Respiratory syncytial virus bronchiolitis`
$Gender_Female$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         24  43
n_event        2   2
n_event_pct    8   5

$Gender_Female$`Respiratory syncytial virus bronchiolitis`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.96699406  0.08387566 3.71406607 0.5464751
OR_TRTvsCTRL   0.53658537 1.03433302  0.07066640 4.07440958 0.5472635
ARR_TRTvsCTRL -0.03682171 0.06491707 -0.16405683 0.09041342 0.5705705


$Gender_Female$`Rhinovirus infection`
$Gender_Female$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         24  43
n_event        2   2
n_event_pct    8   5

$Gender_Female$`Rhinovirus infection`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.96699406  0.08387566 3.71406607 0.5464751
OR_TRTvsCTRL   0.53658537 1.03433302  0.07066640 4.07440958 0.5472635
ARR_TRTvsCTRL -0.03682171 0.06491707 -0.16405683 0.09041342 0.5705705


$Gender_Female$`Upper respiratory tract infection`
$Gender_Female$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        0   5
n_event_pct    0  12

$Gender_Female$`Upper respiratory tract infection`$stats
```

```
               estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  6.2500000 1.45570976 0.36039406 108.3883020 0.20806932
OR_TRTvsCTRL  7.0000000 1.49953611 0.37041673 132.2834424 0.19439912
ARR_TRTvsCTRL 0.1162791 0.04888483 0.02046656   0.2120916 0.01737697


$Gender_Female$`Viral upper respiratory tract infection`
$Gender_Female$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        3   1
n_event_pct   12   2

$Gender_Female$`Viral upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1860465 1.12623748  0.02046287 1.69151794 0.1353707
OR_TRTvsCTRL   0.1666667 1.18522652  0.01632985 1.70104339 0.1305989
ARR_TRTvsCTRL -0.1017442 0.07131302 -0.24151514 0.03802677 0.1536587



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        7  11
n_event_pct   32  29

$Region_Northamerica$`Acute respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90977444 0.4024871  0.4133672 2.0023104 0.8142587
OR_TRTvsCTRL   0.87301587 0.5809216  0.2796023 2.7258599 0.8151642
ARR_TRTvsCTRL -0.02870813 0.1235864 -0.2709331 0.2135168 0.8163112


$Region_Northamerica$`Apparent life threatening event`
$Region_Northamerica$`Apparent life threatening event`$ntab
            CTRL TRT
n_all         22  38
n_event        2   0
n_event_pct    9   0

$Region_Northamerica$`Apparent life threatening event`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.11794872 1.5267222  0.005917591 2.35093991 0.1614948
OR_TRTvsCTRL   0.10649351 1.5731352  0.004878294 2.32476083 0.1545336
ARR_TRTvsCTRL -0.09090909 0.0612909 -0.211037041 0.02921886 0.1380107


$Region_Northamerica$Aspiration
$Region_Northamerica$Aspiration$ntab
            CTRL TRT
n_all         22  38
```

```
n_event        1   2
n_event_pct    5   5

$Region_Northamerica$Aspiration$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.157894737 1.19508563  0.11127827 12.048357 0.9023669
OR_TRTvsCTRL  1.166666667 1.25514813  0.09966961 13.656230 0.9022538
ARR_TRTvsCTRL 0.007177033 0.05730921 -0.10514696  0.119501 0.9003387


$Region_Northamerica$Atelectasis
$Region_Northamerica$Atelectasis$ntab
            CTRL TRT
n_all         22  38
n_event        3   5
n_event_pct   14  13

$Region_Northamerica$Atelectasis$stats
                  estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.964912281 0.67938428  0.2547973 3.654103 0.9580712
OR_TRTvsCTRL   0.959595960 0.78502735  0.2060022 4.469973 0.9581008
ARR_TRTvsCTRL -0.004784689 0.09143367 -0.1839914 0.174422 0.9582661


$Region_Northamerica$`Bronchial secretion retention`
$Region_Northamerica$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         22  38
n_event        3   0
n_event_pct   14   0

$Region_Northamerica$`Bronchial secretion retention`$stats
                 estimate       se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08424908 1.488823  0.004552778 1.559028057 0.09657297
OR_TRTvsCTRL   0.07235622 1.537196  0.003556416 1.472106135 0.08756107
ARR_TRTvsCTRL -0.13636364 0.073165 -0.279764411 0.007037138 0.06235229


$Region_Northamerica$Bronchiolitis
$Region_Northamerica$Bronchiolitis$ntab
            CTRL TRT
n_all         22  38
n_event        1   3
n_event_pct    5   8

$Region_Northamerica$Bronchiolitis$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.73684211 1.12319322  0.1921748 15.6972703 0.6230608
OR_TRTvsCTRL  1.80000000 1.18723368  0.1756699 18.4436828 0.6205371
ARR_TRTvsCTRL 0.03349282 0.06233575 -0.0886830  0.1556686 0.5910623


$Region_Northamerica$`Bronchitis viral`
$Region_Northamerica$`Bronchitis viral`$ntab
```

```
            CTRL TRT
n_all         22  38
n_event        0   2
n_event_pct    0   5

$Region_Northamerica$`Bronchitis viral`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.94871795 1.52672221  0.14793977 58.7734976 0.4787618
OR_TRTvsCTRL  3.08219178 1.57220918  0.14144669 67.1624512 0.4740152
ARR_TRTvsCTRL 0.05263158 0.03622354 -0.01836525  0.1236284 0.1462331


$Region_Northamerica$`Cardiac arrest`
$Region_Northamerica$`Cardiac arrest`$ntab
            CTRL TRT
n_all         22  38
n_event        2   1
n_event_pct    9   3

$Region_Northamerica$`Cardiac arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.2894737 1.19508563  0.02781957 3.01208915 0.2995849
OR_TRTvsCTRL   0.2702703 1.25579737  0.02306012 3.16763354 0.2974885
ARR_TRTvsCTRL -0.0645933 0.06656478 -0.19505788 0.06587128 0.3318559


$Region_Northamerica$`Cardio-respiratory arrest`
$Region_Northamerica$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         22  38
n_event        4   3
n_event_pct   18   8

$Region_Northamerica$`Cardio-respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4342105 0.71523632  0.10687843 1.76404886 0.2434674
OR_TRTvsCTRL   0.3857143 0.81698245  0.07777661 1.91285673 0.2435863
ARR_TRTvsCTRL -0.1028708 0.09314171 -0.28542520 0.07968358 0.2693959


$Region_Northamerica$Dysphagia
$Region_Northamerica$Dysphagia$ntab
            CTRL TRT
n_all         22  38
n_event        3   4
n_event_pct   14  11

$Region_Northamerica$Dysphagia$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.77192982 0.7152363  0.1900061 3.1360869 0.7174084
OR_TRTvsCTRL   0.74509804 0.8157062  0.1506201 3.6859024 0.7183107
ARR_TRTvsCTRL -0.03110048 0.0884964 -0.2045502 0.1423493 0.7252642
```

```
$Region_Northamerica$Hypoxia
$Region_Northamerica$Hypoxia$ntab
            CTRL TRT
n_all         22  38
n_event        1   3
n_event_pct    5   8

$Region_Northamerica$Hypoxia$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.73684211 1.12319322  0.1921748 15.6972703 0.6230608
OR_TRTvsCTRL  1.80000000 1.18723368  0.1756699 18.4436828 0.6205371
ARR_TRTvsCTRL 0.03349282 0.06233575 -0.0886830  0.1556686 0.5910623


$Region_Northamerica$`Oxygen saturation decreased`
$Region_Northamerica$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         22  38
n_event        2   0
n_event_pct    9   0

$Region_Northamerica$`Oxygen saturation decreased`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.11794872 1.5267222  0.005917591 2.35093991 0.1614948
OR_TRTvsCTRL   0.10649351 1.5731352  0.004878294 2.32476083 0.1545336
ARR_TRTvsCTRL -0.09090909 0.0612909 -0.211037041 0.02921886 0.1380107


$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$ntab
            CTRL TRT
n_all         22  38
n_event        3   6
n_event_pct   14  16

$Region_Northamerica$Pneumonia$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.1578947 0.65439259  0.3211065 4.1753133 0.8227341
OR_TRTvsCTRL  1.1875000 0.76412144  0.2655903 5.3095164 0.8220577
ARR_TRTvsCTRL 0.0215311 0.09408597 -0.1628740 0.2059362 0.8189894


$Region_Northamerica$`Pneumonia aspiration`
$Region_Northamerica$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         22  38
n_event        2   3
n_event_pct    9   8

$Region_Northamerica$`Pneumonia aspiration`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.86842105 0.87267577  0.1570028 4.8034503 0.8715720
OR_TRTvsCTRL   0.85714286 0.95493705  0.1318892 5.5705374 0.8717587
ARR_TRTvsCTRL -0.01196172 0.07530019 -0.1595474 0.1356239 0.8737840
```

```
$Region_Northamerica$`Pneumonia bacterial`
$Region_Northamerica$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         22  38
n_event        1   2
n_event_pct    5   5

$Region_Northamerica$`Pneumonia bacterial`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.157894737 1.19508563  0.11127827 12.048357 0.9023669
OR_TRTvsCTRL  1.166666667 1.25514813  0.09966961 13.656230 0.9022538
ARR_TRTvsCTRL 0.007177033 0.05730921 -0.10514696  0.119501 0.9003387


$Region_Northamerica$`Pneumonia viral`
$Region_Northamerica$`Pneumonia viral`$ntab
            CTRL TRT
n_all         22  38
n_event        2   2
n_event_pct    9   5

$Region_Northamerica$`Pneumonia viral`$stats
                 estimate         se      lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.96344676  0.08760960 3.825837 0.5705242
OR_TRTvsCTRL   0.55555556 1.03816077  0.07261786 4.250221 0.5712709
ARR_TRTvsCTRL -0.03827751 0.07119493 -0.17781702 0.101262 0.5908230


$Region_Northamerica$`Respiratory arrest`
$Region_Northamerica$`Respiratory arrest`$ntab
            CTRL TRT
n_all         22  38
n_event        3   0
n_event_pct   14   0

$Region_Northamerica$`Respiratory arrest`$stats
                 estimate       se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08424908 1.488823  0.004552778 1.559028057 0.09657297
OR_TRTvsCTRL   0.07235622 1.537196  0.003556416 1.472106135 0.08756107
ARR_TRTvsCTRL -0.13636364 0.073165 -0.279764411 0.007037138 0.06235229


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$ntab
            CTRL TRT
n_all         22  38
n_event        6   7
n_event_pct   27  18

$Region_Northamerica$`Respiratory distress`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.67543860 0.4875997  0.2597408 1.7564326 0.4209673
```

```
OR_TRTvsCTRL   0.60215054 0.6358316  0.1731746 2.0937554 0.4250036
ARR_TRTvsCTRL -0.08851675 0.1138878 -0.3117328 0.1346993 0.4370246


$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        7   9
n_event_pct   32  24

$Region_Northamerica$`Respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.74436090 0.4268465  0.3224417 1.7183671 0.4891558
OR_TRTvsCTRL   0.66502463 0.5959175  0.2068197 2.1383739 0.4936323
ARR_TRTvsCTRL -0.08133971 0.1209030 -0.3183052 0.1556258 0.5010946


$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`
$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$`Rhinovirus infection`
$Region_Northamerica$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         22  38
n_event        3   4
n_event_pct   14  11

$Region_Northamerica$`Rhinovirus infection`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.77192982 0.7152363  0.1900061 3.1360869 0.7174084
OR_TRTvsCTRL   0.74509804 0.8157062  0.1506201 3.6859024 0.7183107
ARR_TRTvsCTRL -0.03110048 0.0884964 -0.2045502 0.1423493 0.7252642


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        0   4
n_event_pct    0  11

$Region_Northamerica$`Upper respiratory tract infection`$stats
```

```
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  5.3076923 1.46734554 0.299156849  94.169991 0.25531463
OR_TRTvsCTRL  5.8695652 1.51514097 0.301242051 114.365825 0.24278123
ARR_TRTvsCTRL 0.1052632 0.04978449 0.007687351   0.202839 0.03448312


$Region_Northamerica$`Viral upper respiratory tract infection`
$Region_Northamerica$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        5   1
n_event_pct   23   3

$Region_Northamerica$`Viral upper respiratory tract infection`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.11578947 1.06218156  0.014439046  0.92853796 0.04238018
OR_TRTvsCTRL   0.09189189 1.13395351  0.009955297  0.84820371 0.03527823
ARR_TRTvsCTRL -0.20095694 0.09304309 -0.383318040 -0.01859584 0.03078610



$Disdur_greater_12wk
$Disdur_greater_12wk$`Acute respiratory failure`
$Disdur_greater_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         23  46
n_event        4   7
n_event_pct   17  15

$Disdur_greater_12wk$`Acute respiratory failure`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.87500000 0.57239825  0.2849586 2.6867937 0.8155408
OR_TRTvsCTRL   0.85256410 0.68638892  0.2220607 3.2732739 0.8162386
ARR_TRTvsCTRL -0.02173913 0.09513738 -0.2082050 0.1647267 0.8192556


$Disdur_greater_12wk$`Apparent life threatening event`
$Disdur_greater_12wk$`Apparent life threatening event`$ntab
            CTRL TRT
n_all         23  46
n_event        2   0
n_event_pct    9   0

$Disdur_greater_12wk$`Apparent life threatening event`$stats
                 estimate         se       lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.10212766 1.52874352  0.005103575 2.043677 0.1355883
OR_TRTvsCTRL   0.09247312 1.57099236  0.004253872 2.010234 0.1296461
ARR_TRTvsCTRL -0.08695652 0.05875338 -0.202111040 0.028198 0.1388664


$Disdur_greater_12wk$Atelectasis
$Disdur_greater_12wk$Atelectasis$ntab
            CTRL TRT
n_all         23  46
```

```
n_event        3   3
n_event_pct   13   7

$Disdur_greater_12wk$Atelectasis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 0.77553161  0.10935441 2.28614465 0.3714448
OR_TRTvsCTRL   0.46511628 0.86018747  0.08617249 2.51046656 0.3735277
ARR_TRTvsCTRL -0.06521739 0.07909916 -0.22024891 0.08981412 0.4096546


$Disdur_greater_12wk$`Bronchial secretion retention`
$Disdur_greater_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         23  46
n_event        2   0
n_event_pct    9   0

$Disdur_greater_12wk$`Bronchial secretion retention`$stats
                estimate         se       lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.10212766 1.52874352  0.005103575 2.043677 0.1355883
OR_TRTvsCTRL   0.09247312 1.57099236  0.004253872 2.010234 0.1296461
ARR_TRTvsCTRL -0.08695652 0.05875338 -0.202111040 0.028198 0.1388664


$Disdur_greater_12wk$Bronchiolitis
$Disdur_greater_12wk$Bronchiolitis$ntab
            CTRL TRT
n_all         23  46
n_event        1   3
n_event_pct    4   7

$Disdur_greater_12wk$Bronchiolitis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.50000000 1.12610654  0.16502420 13.6343640 0.7188028
OR_TRTvsCTRL  1.53488372 1.18407926  0.15072503 15.6302373 0.7174669
ARR_TRTvsCTRL 0.02173913 0.05597746 -0.08797467  0.1314529 0.6977533


$Disdur_greater_12wk$`Cardio-respiratory arrest`
$Disdur_greater_12wk$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         23  46
n_event        2   4
n_event_pct    9   9

$Disdur_greater_12wk$`Cardio-respiratory arrest`$stats
              estimate         se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.82751593  0.1975228 5.0627075      1
OR_TRTvsCTRL         1 0.90632697  0.1692517 5.9083595      1
ARR_TRTvsCTRL        0 0.07195791 -0.1410349 0.1410349      1


$Disdur_greater_12wk$Dysphagia
$Disdur_greater_12wk$Dysphagia$ntab
```

```
            CTRL TRT
n_all         23  46
n_event        3   2
n_event_pct   13   4

$Disdur_greater_12wk$Dysphagia$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.33333333 0.87642224  0.05982281 1.85733699 0.2100167
OR_TRTvsCTRL   0.30303030 0.95187216  0.04690844 1.95758717 0.2097371
ARR_TRTvsCTRL -0.08695652 0.07639016 -0.23667848 0.06276544 0.2549865


$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$ntab
            CTRL TRT
n_all         23  46
n_event        2   4
n_event_pct    9   9

$Disdur_greater_12wk$Pneumonia$stats
              estimate         se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.82751593  0.1975228 5.0627075      1
OR_TRTvsCTRL         1 0.90632697  0.1692517 5.9083595      1
ARR_TRTvsCTRL        0 0.07195791 -0.1410349 0.1410349      1


$Disdur_greater_12wk$`Pneumonia viral`
$Disdur_greater_12wk$`Pneumonia viral`$ntab
            CTRL TRT
n_all         23  46
n_event        2   2
n_event_pct    9   4

$Disdur_greater_12wk$`Pneumonia viral`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 0.96684156  0.07516107 3.32618986 0.4734240
OR_TRTvsCTRL   0.47727273 1.03457543  0.06282528 3.62575806 0.4746414
ARR_TRTvsCTRL -0.04347826 0.06600034 -0.17283655 0.08588003 0.5100511


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         23  46
n_event        6   5
n_event_pct   26  11

$Disdur_greater_12wk$`Respiratory distress`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4166667 0.5490440  0.14205015 1.2221818 0.1108167
OR_TRTvsCTRL   0.3455285 0.6707313  0.09280178 1.2865045 0.1131117
ARR_TRTvsCTRL -0.1521739 0.1024180 -0.35290943 0.0485616 0.1373287
```

```
$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         23  46
n_event        8   7
n_event_pct   35  15

$Disdur_greater_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.4375000 0.4501553  0.1810528 1.05718478 0.06629410
OR_TRTvsCTRL   0.3365385 0.6001373  0.1037999 1.09112006 0.06957679
ARR_TRTvsCTRL -0.1956522 0.1125498 -0.4162458 0.02494141 0.08214728


$Disdur_greater_12wk$`Rhinovirus infection`
$Disdur_greater_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         23  46
n_event        2   3
n_event_pct    9   7

$Disdur_greater_12wk$`Rhinovirus infection`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.75000000 0.87642224  0.1346013 4.1790082 0.7427257
OR_TRTvsCTRL   0.73255814 0.95089862  0.1136150 4.7233320 0.7434542
ARR_TRTvsCTRL -0.02173913 0.06911777 -0.1572075 0.1137292 0.7531238


$Disdur_greater_12wk$`Viral upper respiratory tract infection`
$Disdur_greater_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         23  46
n_event        3   0
n_event_pct   13   0

$Disdur_greater_12wk$`Viral upper respiratory tract infection`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.07294833 1.49089605  0.003926109 1.355402742 0.07908950
OR_TRTvsCTRL   0.06298003 1.53492676  0.003109359 1.275659867 0.07164801
ARR_TRTvsCTRL -0.13043478 0.07022373 -0.268070757 0.007201192 0.06325177



$Region_Asia_Pacific
$Region_Asia_Pacific$Dyspnoea
$Region_Asia_Pacific$Dyspnoea$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$Dyspnoea$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
```

```
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$`Lung infection`
$Region_Asia_Pacific$`Lung infection`$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$`Lung infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$`Oxygen saturation decreased`
$Region_Asia_Pacific$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$`Oxygen saturation decreased`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$Pneumonia
$Region_Asia_Pacific$Pneumonia$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$Pneumonia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$`Respiratory distress`
$Region_Asia_Pacific$`Respiratory distress`$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$`Respiratory distress`$stats
```

```
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$`Respiratory failure`
$Region_Asia_Pacific$`Respiratory failure`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Respiratory failure`$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$`Upper respiratory tract infection`
$Region_Asia_Pacific$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$`Upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699




\###############################################################################
[[1]]
[1] "Patienten mit mindestens einem schweren UE nach PT, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event        7  10
n_event_pct   22  14

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.63492063 0.44465521  0.2656001 1.5177863 0.3069750
OR_TRTvsCTRL   0.57603687 0.54679628  0.1972497 1.6822251 0.3130920
ARR_TRTvsCTRL -0.07986111 0.08367598 -0.2438630 0.0841408 0.3398767
```

```
$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         32  72
n_event        7  11
n_event_pct   22  15

$Ageonset_less_equal_12wk$`Respiratory distress`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.69841270 0.43431250  0.2981430 1.63606139 0.4085390
OR_TRTvsCTRL   0.64402810 0.53866472  0.2240746 1.85104534 0.4140092
ARR_TRTvsCTRL -0.06597222 0.08448851 -0.2315667 0.09962222 0.4348951


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event       14  12
n_event_pct   44  17

$Ageonset_less_equal_12wk$`Respiratory failure`$stats
                estimate         se     lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   0.3809524 0.33109367  0.1990872  0.72895066 0.003558853
OR_TRTvsCTRL   0.2571429 0.47642851  0.1010736  0.65420092 0.004363211
ARR_TRTvsCTRL -0.2708333 0.09807875 -0.4630642 -0.07860251 0.005755654



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        7  11
n_event_pct   32  29

$Region_Northamerica$`Acute respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90977444 0.4024871  0.4133672 2.0023104 0.8142587
OR_TRTvsCTRL   0.87301587 0.5809216  0.2796023 2.7258599 0.8151642
ARR_TRTvsCTRL -0.02870813 0.1235864 -0.2709331 0.2135168 0.8163112



$Agetrt_less_180d
$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$ntab
            CTRL TRT
n_all         16  49
n_event        2  10
n_event_pct   12  20
```

```
$Agetrt_less_180d$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.63265306 0.7190910  0.3988435 6.6832123 0.4954269
OR_TRTvsCTRL  1.79487179 0.8349069  0.3494293 9.2195030 0.4835543
ARR_TRTvsCTRL 0.07908163 0.1007516 -0.1183879 0.2765511 0.4325023




\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schweren UEs nach PT, das bei mindestens 5% der
Patienten in einem Studienarm auftrat"

$Agetrt_less_180d
$Agetrt_less_180d$`Acute respiratory distress syndrome`
$Agetrt_less_180d$`Acute respiratory distress syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                49
n_event                                 1                 0
n_event_pct                             6                 0
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Acute respiratory distress syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.753e-11 4.354e+04 0.000e+00       Inf 9.996e-01


$Agetrt_less_180d$`Acute respiratory failure`
$Agetrt_less_180d$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               4.0                 7
n_event_pct                          25.0                14
time-to-event-wk-10th                 6.3                13
time-to-event-wk-25th                22.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            8.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4188    0.6314    0.1215    1.4440    0.1680
```

```
$Agetrt_less_180d$Apnoea
$Agetrt_less_180d$Apnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                 49
n_event                              2.0                  0
n_event_pct                         12.0                  0
time-to-event-wk-10th                6.3                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Apnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.877e-10 2.854e+04 0.000e+00       Inf 9.994e-01


$Agetrt_less_180d$Aspiration
$Agetrt_less_180d$Aspiration$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                 49
n_event                              1.0                  2
n_event_pct                          6.0                  4
time-to-event-wk-10th               40.3                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          40.3                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.59190   1.24100   0.05194   6.74600   0.67270


$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                 49
n_event                              1.0                  4
n_event_pct                          6.0                  8
time-to-event-wk-10th               32.9                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          32.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   1.0720    1.1280    0.1174    9.7810    0.9512


$Agetrt_less_180d$`Bronchial secretion retention`
$Agetrt_less_180d$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               3.0                 1
n_event_pct                          19.0                 2
time-to-event-wk-10th                 6.1                NA
time-to-event-wk-25th                40.7                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.073250  1.215000  0.006768  0.792800  0.031480


$Agetrt_less_180d$Bronchiolitis
$Agetrt_less_180d$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16                49
n_event                               0                 3
n_event_pct                           0                 6
time-to-event-wk-10th                NA                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Agetrt_less_180d$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.007e+08 2.253e+04 0.000e+00       Inf 9.993e-01


$Agetrt_less_180d$`Bronchitis viral`
$Agetrt_less_180d$`Bronchitis viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16                49
n_event                               0                 3
n_event_pct                           0                 6
time-to-event-wk-10th                NA                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA
```

```
$Agetrt_less_180d$`Bronchitis viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.185e+08 1.800e+04 0.000e+00       Inf 9.991e-01


$Agetrt_less_180d$`Cardiac arrest`
$Agetrt_less_180d$`Cardiac arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                 49
n_event                                 1                  1
n_event_pct                             6                  2
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Cardiac arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29550   1.42800   0.01801   4.84900   0.39310


$Agetrt_less_180d$`Cardio-respiratory arrest`
$Agetrt_less_180d$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  1
n_event_pct                          12.0                  2
time-to-event-wk-10th                14.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.115400  1.256000  0.009854  1.352000  0.085530


$Agetrt_less_180d$`Corona virus infection`
$Agetrt_less_180d$`Corona virus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                 49
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  34                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             34                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$`Corona virus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.651e-10 1.441e+05 0.000e+00       Inf 9.999e-01


$Agetrt_less_180d$Cyanosis
$Agetrt_less_180d$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                  49
n_event                                 1                   0
n_event_pct                             6                   0
time-to-event-wk-10th                  NA                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.736e-10 3.532e+04 0.000e+00       Inf 9.995e-01


$Agetrt_less_180d$Death
$Agetrt_less_180d$Death$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                  49
n_event                                 1                   1
n_event_pct                             6                   2
time-to-event-wk-10th                  NA                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$Death$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.2854    1.4300    0.0173    4.7070    0.3806


$Agetrt_less_180d$Dysphagia
$Agetrt_less_180d$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                  49
n_event                               1.0                   4
n_event_pct                           6.0                   8
time-to-event-wk-10th                18.7                  NA
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           18.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0630    1.1260    0.1169    9.6620    0.9570


$Agetrt_less_180d$Dyspnoea
$Agetrt_less_180d$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                24.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.943e-11 3.497e+04 0.000e+00       Inf 9.995e-01


$Agetrt_less_180d$`Heart rate decreased`
$Agetrt_less_180d$`Heart rate decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                49.6                 NA
time-to-event-wk-25th                49.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           49.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Heart rate decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.074e-11 5.821e+04 0.000e+00       Inf 9.997e-01


$Agetrt_less_180d$Hypoxia
$Agetrt_less_180d$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                 49
```

```
n_event                                  1                  2
n_event_pct                              6                  4
time-to-event-wk-10th                   NA                 NA
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Agetrt_less_180d$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39520   1.27700   0.03232   4.83300   0.46740


$Agetrt_less_180d$`Oxygen saturation decreased`
$Agetrt_less_180d$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                17.9                NA
time-to-event-wk-25th                40.7                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.9                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.567e-11 2.758e+04 0.000e+00       Inf 9.993e-01


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               3.0                8.0
n_event_pct                          19.0               16.0
time-to-event-wk-10th                11.9               10.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6947    0.6880    0.1804    2.6760    0.5965


$Agetrt_less_180d$`Respiratory arrest`
```

```
$Agetrt_less_180d$`Respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              2.0                 2
n_event_pct                         12.0                 4
time-to-event-wk-10th               18.2                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          16.0                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.14930   1.05800   0.01878   1.18800   0.07225


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              2.0               10.0
n_event_pct                         12.0               20.0
time-to-event-wk-10th               15.4               15.6
time-to-event-wk-25th                 NA               45.3
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          15.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0980    0.7909    0.2329    5.1720    0.9063


$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              9.0                8.0
n_event_pct                         56.0               16.0
time-to-event-wk-10th                1.0               16.1
time-to-event-wk-25th                7.4                 NA
time-to-event-wk-50th               13.0                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           7.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
0.1382000 0.5327000 0.0486400 0.3925000 0.0002029
```

```
$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`
$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              2.0                 2
n_event_pct                         12.0                 4
time-to-event-wk-10th               22.4                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          22.4                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.21730   1.01500   0.02974   1.58800   0.13260


$Agetrt_less_180d$`Respiratory tract infection`
$Agetrt_less_180d$`Respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              1.0                 3
n_event_pct                          6.0                 6
time-to-event-wk-10th               32.9                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          32.9                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.73360   1.17400   0.07348   7.32400   0.79190


$Agetrt_less_180d$`Respiratory tract infection viral`
$Agetrt_less_180d$`Respiratory tract infection viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                16                49
n_event                               1                 0
n_event_pct                           6                 0
time-to-event-wk-10th                NA                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA
```

```
$Agetrt_less_180d$`Respiratory tract infection viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.756e-42 4.036e+04 0.000e+00       Inf 9.981e-01


$Agetrt_less_180d$`Rhinovirus infection`
$Agetrt_less_180d$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 16                49
n_event                                1                 3
n_event_pct                            6                 6
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42900   1.22900   0.03857   4.77100   0.49110


$Agetrt_less_180d$`Sleep apnoea syndrome`
$Agetrt_less_180d$`Sleep apnoea syndrome`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 16                49
n_event                                1                 0
n_event_pct                            6                 0
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.705e-10 3.646e+04 0.000e+00       Inf 9.995e-01


$Agetrt_less_180d$`Tracheal haemorrhage`
$Agetrt_less_180d$`Tracheal haemorrhage`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              1.0                 0
n_event_pct                          6.0                 0
time-to-event-wk-10th               47.6                NA
time-to-event-wk-25th               47.6                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
```

```
time-to-event-wk-50th-loci           47.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Tracheal haemorrhage`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.920e-11 4.048e+04 0.000e+00       Inf 9.995e-01


$Agetrt_less_180d$`Tracheal obstruction`
$Agetrt_less_180d$`Tracheal obstruction`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                48.4                 NA
time-to-event-wk-25th                48.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           48.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Tracheal obstruction`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.074e-11 5.821e+04 0.000e+00       Inf 9.997e-01


$Agetrt_less_180d$`Upper respiratory tract infection`
$Agetrt_less_180d$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16               49.0
n_event                                 0                4.0
n_event_pct                             0                8.0
time-to-event-wk-10th                  NA               43.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.968e+08 1.633e+04 0.000e+00       Inf 9.990e-01


$Agetrt_less_180d$`Viral upper respiratory tract infection`
$Agetrt_less_180d$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  1
n_event_pct                          12.0                  2
time-to-event-wk-10th                33.4                 NA
time-to-event-wk-25th                33.4                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.092380  1.261000  0.007799  1.094000  0.058960


$Agetrt_less_180d$Vomiting
$Agetrt_less_180d$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                 49
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.754e-10 3.144e+04 0.000e+00       Inf 9.994e-01


$Agetrt_less_180d$`Weight gain poor`
$Agetrt_less_180d$`Weight gain poor`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               1.0                  1
n_event_pct                           6.0                  2
time-to-event-wk-10th                17.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Weight gain poor`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.161800  1.528000  0.008094  3.236000  0.233400



$Region_Europe
$Region_Europe$`Acute respiratory distress syndrome`
$Region_Europe$`Acute respiratory distress syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  17                 30
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Acute respiratory distress syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.263e-10 2.667e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$`Acute respiratory failure`
$Region_Europe$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               2.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                16.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.963e-11 3.130e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$Apnoea
$Region_Europe$Apnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 30
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Apnoea$stats_HR_TRTvsCTRL
        HR   SE_logHR  HR.lo95ci  HR.hi95ci    p.value
5.856e-171  2.063e+03  0.000e+00        Inf  8.493e-01
```

```
$Region_Europe$Atelectasis
$Region_Europe$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               1.0                  1
n_event_pct                           6.0                  3
time-to-event-wk-10th                32.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39190   1.43500   0.02355   6.52400   0.51390


$Region_Europe$`Bronchial secretion retention`
$Region_Europe$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               2.0                  1
n_event_pct                          12.0                  3
time-to-event-wk-10th                40.7                 NA
time-to-event-wk-25th                40.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.1532    1.2510    0.0132    1.7770    0.1335


$Region_Europe$`Candida sepsis`
$Region_Europe$`Candida sepsis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Candida sepsis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
5.599e-10 2.836e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$`Cardio-respiratory arrest`
$Region_Europe$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 30
n_event                                 1                  2
n_event_pct                             6                  7
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.01600   1.23600   0.09009  11.47000   0.98950


$Region_Europe$Dysphagia
$Region_Europe$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.943e-10 2.831e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$`Heart rate decreased`
$Region_Europe$`Heart rate decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                49.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           49.6                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Region_Europe$`Heart rate decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.959e-08 5.023e+04 0.000e+00       Inf 9.997e-01


$Region_Europe$`Lower respiratory tract infection`
$Region_Europe$`Lower respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                30
n_event                                 0                 2
n_event_pct                             0                 7
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Lower respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.117e+08 2.034e+04 0.000e+00       Inf 9.992e-01


$Region_Europe$`Oxygen saturation decreased`
$Region_Europe$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               1.0                 0
n_event_pct                           6.0                 0
time-to-event-wk-10th                40.7                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.405e-09 7.179e+04 0.000e+00       Inf 9.998e-01


$Region_Europe$Pneumonia
$Region_Europe$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               2.0               3.0
n_event_pct                          12.0              10.0
time-to-event-wk-10th                13.9              42.4
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6524    0.9277    0.1059    4.0200    0.6452


$Region_Europe$`Pneumonia pseudomonal`
$Region_Europe$`Pneumonia pseudomonal`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                  30
n_event                                 1                   0
n_event_pct                             6                   0
time-to-event-wk-10th                  NA                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$`Pneumonia pseudomonal`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.889e-10 2.821e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$`Respiratory arrest`
$Region_Europe$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                30.0
n_event                                 0                 4.0
n_event_pct                             0                13.0
time-to-event-wk-10th                  NA                27.3
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.115e+08 1.390e+04 0.000e+00       Inf 9.989e-01


$Region_Europe$`Respiratory distress`
$Region_Europe$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30.0
n_event                               2.0                 4.0
n_event_pct                          12.0                13.0
time-to-event-wk-10th                15.4                15.6
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0570    0.8754    0.1901    5.8760    0.9497


$Region_Europe$`Respiratory failure`
$Region_Europe$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               7.0                5.0
n_event_pct                          41.0               17.0
time-to-event-wk-10th                 4.6               11.3
time-to-event-wk-25th                10.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            9.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.30620   0.60470   0.09361   1.00200   0.05031


$Region_Europe$`Respiratory tract infection`
$Region_Europe$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               1.0                3.0
n_event_pct                           6.0               10.0
time-to-event-wk-10th                32.9               32.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0940    1.1630    0.1119   10.6900    0.9386


$Region_Europe$`Respiratory tract infection viral`
$Region_Europe$`Respiratory tract infection viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 30
```

```
n_event                                1                 0
n_event_pct                            6                 0
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Respiratory tract infection viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.360e-10 2.728e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$`Salivary hypersecretion`
$Region_Europe$`Salivary hypersecretion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               1.0                 0
n_event_pct                           6.0                 0
time-to-event-wk-10th                43.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           43.1                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Salivary hypersecretion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.885e-10 3.406e+04 0.000e+00       Inf 9.995e-01


$Region_Europe$`Tracheal haemorrhage`
$Region_Europe$`Tracheal haemorrhage`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               1.0                 0
n_event_pct                           6.0                 0
time-to-event-wk-10th                47.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           47.6                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Tracheal haemorrhage`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.823e-09 5.157e+04 0.000e+00       Inf 9.997e-01


$Region_Europe$`Tracheal obstruction`
```

```
$Region_Europe$`Tracheal obstruction`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                30
n_event                              1.0                 0
n_event_pct                          6.0                 0
time-to-event-wk-10th               48.4                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          48.4                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Tracheal obstruction`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.959e-08 5.023e+04 0.000e+00       Inf 9.997e-01



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Acute respiratory distress syndrome`
$Disdur_less_equal_12wk$`Acute respiratory distress syndrome`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                18                34
n_event                               1                 0
n_event_pct                           6                 0
time-to-event-wk-10th                NA                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Disdur_less_equal_12wk$`Acute respiratory distress syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.509e-10 4.336e+04 0.000e+00       Inf 9.996e-01


$Disdur_less_equal_12wk$`Acute respiratory failure`
$Disdur_less_equal_12wk$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0              34.0
n_event                              5.0               4.0
n_event_pct                         28.0              12.0
time-to-event-wk-10th                6.3              32.7
time-to-event-wk-25th               22.4                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          16.4                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33930   0.68500   0.08862   1.29900   0.11460


$Disdur_less_equal_12wk$Apnoea
$Disdur_less_equal_12wk$Apnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                 6.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Apnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.951e-10 1.935e+04 0.000e+00       Inf 9.991e-01


$Disdur_less_equal_12wk$Aspiration
$Disdur_less_equal_12wk$Aspiration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               1.0                 2
n_event_pct                           6.0                 6
time-to-event-wk-10th                40.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.3                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.97550   1.23200   0.08723  10.91000   0.98400


$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               1.0                3.0
n_event_pct                           6.0                9.0
time-to-event-wk-10th                32.9               32.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9                 NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5340    1.1720    0.1542   15.2700    0.7151


$Disdur_less_equal_12wk$`Bronchial secretion retention`
$Disdur_less_equal_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               3.0                  1
n_event_pct                          17.0                  3
time-to-event-wk-10th                 6.1                 NA
time-to-event-wk-25th                40.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.14930   1.17100   0.01504   1.48100   0.10430


$Disdur_less_equal_12wk$`Bronchitis viral`
$Disdur_less_equal_12wk$`Bronchitis viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 0                  2
n_event_pct                             0                  6
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Bronchitis viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.089e+08 2.344e+04 0.000e+00       Inf 9.993e-01


$Disdur_less_equal_12wk$`Candida sepsis`
$Disdur_less_equal_12wk$`Candida sepsis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Candida sepsis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.819e-10 3.829e+04 0.000e+00       Inf 9.996e-01


$Disdur_less_equal_12wk$`Cardiac arrest`
$Disdur_less_equal_12wk$`Cardiac arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 18                 34
n_event                                1                  1
n_event_pct                            6                  3
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Cardiac arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.73930   1.44900   0.04319  12.66000   0.83490


$Disdur_less_equal_12wk$`Cardio-respiratory arrest`
$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                 34
n_event                              3.0                  1
n_event_pct                         17.0                  3
time-to-event-wk-10th               23.0                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          33.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.19180   1.18800   0.01868   1.97000   0.16470


$Disdur_less_equal_12wk$`Corona virus infection`
$Disdur_less_equal_12wk$`Corona virus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 18                 34
n_event                                1                  0
n_event_pct                            6                  0
```

```
time-to-event-wk-10th                  34                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             34                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Corona virus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.013e-09 1.003e+05 0.000e+00       Inf 9.998e-01


$Disdur_less_equal_12wk$Cyanosis
$Disdur_less_equal_12wk$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.380e-10 3.878e+04 0.000e+00       Inf 9.996e-01


$Disdur_less_equal_12wk$Death
$Disdur_less_equal_12wk$Death$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Death$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.645e-10 2.901e+04 0.000e+00       Inf 9.994e-01


$Disdur_less_equal_12wk$Dysphagia
$Disdur_less_equal_12wk$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  18                 34
n_event                                 1                  2
n_event_pct                             6                  6
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.60500   1.28000   0.04925   7.43200   0.69460


$Disdur_less_equal_12wk$Dyspnoea
$Disdur_less_equal_12wk$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.513e-10 3.365e+04 0.000e+00       Inf 9.995e-01


$Disdur_less_equal_12wk$`Femur fracture`
$Disdur_less_equal_12wk$`Femur fracture`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 18.0                 34
n_event                                1.0                  0
n_event_pct                            6.0                  0
time-to-event-wk-10th                 50.6                 NA
time-to-event-wk-25th                 53.6                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            50.6                 NA
time-to-event-wk-50th-hici              NA                 NA

$Disdur_less_equal_12wk$`Femur fracture`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.556e-11 6.214e+04 0.000e+00       Inf 9.997e-01
```

```
$Disdur_less_equal_12wk$`Heart rate decreased`
$Disdur_less_equal_12wk$`Heart rate decreased`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              1.0                 0
n_event_pct                          6.0                 0
time-to-event-wk-10th               49.6                NA
time-to-event-wk-25th               53.1                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          49.6                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Heart rate decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.634e-10 3.667e+04 0.000e+00       Inf 9.995e-01


$Disdur_less_equal_12wk$Hypoxia
$Disdur_less_equal_12wk$Hypoxia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                18                34
n_event                               1                 1
n_event_pct                           6                 3
time-to-event-wk-10th                NA                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Disdur_less_equal_12wk$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45590   1.44400   0.02689   7.73100   0.58660


$Disdur_less_equal_12wk$`Oxygen saturation decreased`
$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 0
n_event_pct                         11.0                 0
time-to-event-wk-10th               40.7                NA
time-to-event-wk-25th               40.7                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          40.7                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
3.176e-10 2.327e+04 0.000e+00       Inf 9.993e-01


$Disdur_less_equal_12wk$Pneumonia
$Disdur_less_equal_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               3.0                6.0
n_event_pct                          17.0               18.0
time-to-event-wk-10th                11.9                5.0
time-to-event-wk-25th                  NA               42.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               42.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5740    0.7378    0.3708    6.6860    0.5384


$Disdur_less_equal_12wk$`Pneumonia aspiration`
$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               2.0                2.0
n_event_pct                          11.0                6.0
time-to-event-wk-10th                17.9               43.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48370   1.02800   0.06446   3.63000   0.48000


$Disdur_less_equal_12wk$`Pneumonia parainfluenzae viral`
$Disdur_less_equal_12wk$`Pneumonia parainfluenzae viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Disdur_less_equal_12wk$`Pneumonia parainfluenzae viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.602e-10 2.909e+04 0.000e+00       Inf 9.994e-01


$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 0                2.0
n_event_pct                             0                6.0
time-to-event-wk-10th                  NA               44.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.097e+08 1.965e+04 0.000e+00       Inf 9.992e-01


$Disdur_less_equal_12wk$`Respiratory arrest`
$Disdur_less_equal_12wk$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 2
n_event_pct                          11.0                 6
time-to-event-wk-10th                20.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.38340   1.03300   0.05065   2.90200   0.35320


$Disdur_less_equal_12wk$`Respiratory distress`
$Disdur_less_equal_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               2.0                7.0
n_event_pct                          11.0               21.0
time-to-event-wk-10th                15.9               15.6
time-to-event-wk-25th                  NA               45.3
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               45.3
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9760    0.8172    0.3983    9.8020    0.4047


$Disdur_less_equal_12wk$`Respiratory failure`
$Disdur_less_equal_12wk$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0               34.0
n_event                              7.0                7.0
n_event_pct                         39.0               21.0
time-to-event-wk-10th                6.1                4.1
time-to-event-wk-25th               13.0               43.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          10.6               43.4
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4626    0.5640    0.1531    1.3970    0.1716


$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`
$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                 34
n_event                              2.0                  1
n_event_pct                         11.0                  3
time-to-event-wk-10th               22.4                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Respiratory syncytial virus
bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.20800   1.22700   0.01878   2.30300   0.20050


$Disdur_less_equal_12wk$`Respiratory tract infection`
$Disdur_less_equal_12wk$`Respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                 34
n_event                              1.0                  2
n_event_pct                          6.0                  6
```

```
time-to-event-wk-10th                32.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.89360   1.22600   0.08077   9.88700   0.92690


$Disdur_less_equal_12wk$`Respirovirus test positive`
$Disdur_less_equal_12wk$`Respirovirus test positive`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respirovirus test positive`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.514e-10 2.812e+04 0.000e+00       Inf 9.994e-01


$Disdur_less_equal_12wk$`Rhinovirus infection`
$Disdur_less_equal_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 1                  1
n_event_pct                             6                  3
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.50630   1.45100   0.02946   8.70200   0.63910


$Disdur_less_equal_12wk$`Sleep apnoea syndrome`
$Disdur_less_equal_12wk$`Sleep apnoea syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  18                 34
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.626e-10 2.723e+04 0.000e+00       Inf 9.994e-01


$Disdur_less_equal_12wk$`Tracheal haemorrhage`
$Disdur_less_equal_12wk$`Tracheal haemorrhage`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                47.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           47.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Tracheal haemorrhage`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.778e-10 3.319e+04 0.000e+00       Inf 9.995e-01


$Disdur_less_equal_12wk$`Tracheal obstruction`
$Disdur_less_equal_12wk$`Tracheal obstruction`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                48.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           48.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Tracheal obstruction`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.705e-10 5.157e+04 0.000e+00       Inf 9.997e-01
```

```
$Disdur_less_equal_12wk$`Upper respiratory tract infection`
$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 18               34.0
n_event                                0                4.0
n_event_pct                            0               12.0
time-to-event-wk-10th                 NA               43.6
time-to-event-wk-25th                 NA               49.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA               49.4
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.228e+08 1.317e+04 0.000e+00       Inf 9.988e-01


$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`
$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 1
n_event_pct                         11.0                 3
time-to-event-wk-10th               33.4                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          33.4                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13900   1.29300   0.01103   1.75200   0.12700


$Disdur_less_equal_12wk$Vomiting
$Disdur_less_equal_12wk$Vomiting$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 18                34
n_event                                1                 0
n_event_pct                            6                 0
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$Vomiting$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.196e-10 2.887e+04 0.000e+00       Inf 9.994e-01


$Disdur_less_equal_12wk$`Weight gain poor`
$Disdur_less_equal_12wk$`Weight gain poor`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Weight gain poor`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.029e-10 4.564e+04 0.000e+00       Inf 9.996e-01



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               7.0               10.0
n_event_pct                          22.0               14.0
time-to-event-wk-10th                 8.6               19.9
time-to-event-wk-25th                22.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4466    0.5010    0.1673    1.1920    0.1076


$Ageonset_less_equal_12wk$Apnoea
$Ageonset_less_equal_12wk$Apnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32                 72
n_event                                 2                  1
n_event_pct                             6                  1
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Apnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.18380   1.22900   0.01654   2.04300   0.16800


$Ageonset_less_equal_12wk$`Apparent life threatening event`
$Ageonset_less_equal_12wk$`Apparent life threatening event`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32                 72
n_event                                 2                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Apparent life threatening event`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.809e-10 2.221e+04 0.000e+00       Inf 9.992e-01


$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               4.0                  6
n_event_pct                          12.0                  8
time-to-event-wk-10th                32.9                 NA
time-to-event-wk-25th                52.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5371    0.6483    0.1507    1.9130    0.3376


$Ageonset_less_equal_12wk$`Bronchial secretion retention`
$Ageonset_less_equal_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               5.0                  1
n_event_pct                          16.0                  1
time-to-event-wk-10th                 6.1                 NA
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.069840  1.098000  0.008114  0.601200  0.015380


$Ageonset_less_equal_12wk$Bronchiolitis
$Ageonset_less_equal_12wk$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32                 72
n_event                                 1                  4
n_event_pct                             3                  6
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7780    1.1240    0.1964   16.1100    0.6086


$Ageonset_less_equal_12wk$`Cardiac arrest`
$Ageonset_less_equal_12wk$`Cardiac arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32                 72
n_event                                 2                  2
n_event_pct                             6                  3
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Cardiac arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3928    1.0050    0.0548    2.8150    0.3524


$Ageonset_less_equal_12wk$`Cardio-respiratory arrest`
$Ageonset_less_equal_12wk$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
```

```
n_event                              3.0                 4
n_event_pct                          9.0                 6
time-to-event-wk-10th               17.6                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5019    0.7693    0.1111    2.2670    0.3702


$Ageonset_less_equal_12wk$Dysphagia
$Ageonset_less_equal_12wk$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               3.0                 4
n_event_pct                           9.0                 6
time-to-event-wk-10th                19.1                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39200   0.77340   0.08611   1.78500   0.22600


$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               3.0                 1
n_event_pct                           9.0                 1
time-to-event-wk-10th                40.7                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.10930   1.16000   0.01124   1.06200   0.05639


$Ageonset_less_equal_12wk$Pneumonia
```

```
$Ageonset_less_equal_12wk$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0                72
n_event                              5.0                 9
n_event_pct                         16.0                12
time-to-event-wk-10th               11.9                20
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6459    0.5600    0.2155    1.9360    0.4351


$Ageonset_less_equal_12wk$`Pneumonia viral`
$Ageonset_less_equal_12wk$`Pneumonia viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0                72
n_event                              2.0                 2
n_event_pct                          6.0                 3
time-to-event-wk-10th               52.6                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          52.6                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.34900   1.00100   0.04902   2.48500   0.29320


$Ageonset_less_equal_12wk$`Respiratory arrest`
$Ageonset_less_equal_12wk$`Respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0                72
n_event                              3.0                 4
n_event_pct                          9.0                 6
time-to-event-wk-10th               19.9                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33910   0.76900   0.07511   1.53100   0.15970
```

```
$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               7.0              11.0
n_event_pct                          22.0              15.0
time-to-event-wk-10th                11.0              20.3
time-to-event-wk-25th                28.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           28.6                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5310    0.4865    0.2046    1.3780    0.1933


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              14.0              12.0
n_event_pct                          44.0              17.0
time-to-event-wk-10th                 4.6              21.3
time-to-event-wk-25th                10.1                NA
time-to-event-wk-50th                21.9                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.0                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
0.2494000 0.4017000 0.1135000 0.5480000 0.0005451


$Ageonset_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`
$Ageonset_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               3.0                 3
n_event_pct                           9.0                 4
time-to-event-wk-10th                22.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA
```

```
$Ageonset_less_equal_12wk$`Respiratory syncytial virus
bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26070   0.82330   0.05192   1.30900   0.10250


$Ageonset_less_equal_12wk$`Rhinovirus infection`
$Ageonset_less_equal_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               3.0                 4
n_event_pct                           9.0                 6
time-to-event-wk-10th                18.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4992    0.7710    0.1102    2.2620    0.3675


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32               72.0
n_event                               0                5.0
n_event_pct                           0                7.0
time-to-event-wk-10th                NA               43.7
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.822e+08 1.242e+04 0.000e+00       Inf 9.988e-01


$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               5.0                 1
n_event_pct                          16.0                 1
time-to-event-wk-10th                11.7                NA
time-to-event-wk-25th                37.3                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.058030  1.103000  0.006684  0.503900  0.009839



$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Acute respiratory failure`
$Ageonset_greater_12wk$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               2.0                1.0
n_event_pct                          22.0               12.0
time-to-event-wk-10th                16.4               25.4
time-to-event-wk-25th                26.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.4               25.4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9680    1.4020    0.1262   30.7000    0.6290


$Ageonset_greater_12wk$`Candida sepsis`
$Ageonset_greater_12wk$`Candida sepsis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                22.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Candida sepsis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.017e-09 4.176e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Cardio-respiratory arrest`
$Ageonset_greater_12wk$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
```

```
n_event                              2.0               1.0
n_event_pct                         22.0              12.0
time-to-event-wk-10th               23.0              25.4
time-to-event-wk-25th               33.6                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          23.0              25.4
time-to-event-wk-50th-hici            NA                NA

$Ageonset_greater_12wk$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.07200   1.31900   0.08084  14.22000   0.95780


$Ageonset_greater_12wk$Dysphagia
$Ageonset_greater_12wk$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8
n_event                               1.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                26.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           26.1                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_greater_12wk$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.256e-09 4.032e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Femur fracture`
$Ageonset_greater_12wk$`Femur fracture`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8
n_event                               1.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                50.6                NA
time-to-event-wk-25th                55.5                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           50.6                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_greater_12wk$`Femur fracture`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.522e-01 1.273e+05 0.000e+00       Inf 1.000e+00


$Ageonset_greater_12wk$Pneumonia
```

```
$Ageonset_greater_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA               30.4
time-to-event-wk-25th                  NA               30.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               30.4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.958e+09 4.873e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Pneumonia aspiration`
$Ageonset_greater_12wk$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               2.0                  0
n_event_pct                          22.0                  0
time-to-event-wk-10th                 1.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.616e-10 2.873e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`
$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                19.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01
```

```
$Ageonset_greater_12wk$`Pneumonia pseudomonal`
$Ageonset_greater_12wk$`Pneumonia pseudomonal`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                15.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Pneumonia pseudomonal`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.446e-09 4.265e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Respiratory distress`
$Ageonset_greater_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                1.0
n_event_pct                          11.0               12.0
time-to-event-wk-10th                15.9                0.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9                0.6
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5620    1.4570    0.0899   27.1500    0.7594


$Ageonset_greater_12wk$`Respiratory failure`
$Ageonset_greater_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                2.0
n_event_pct                          11.0               25.0
time-to-event-wk-10th                19.3                0.6
time-to-event-wk-25th                  NA                5.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.3                0.6
time-to-event-wk-50th-hici             NA                 NA
```

```
$Ageonset_greater_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.3050    1.2530    0.2834   38.5400    0.3402


$Ageonset_greater_12wk$`Respirovirus test positive`
$Ageonset_greater_12wk$`Respirovirus test positive`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                15.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respirovirus test positive`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Salivary hypersecretion`
$Ageonset_greater_12wk$`Salivary hypersecretion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                43.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           43.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Salivary hypersecretion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.245e-09 4.596e+04 0.000e+00       Inf 9.997e-01



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Acute respiratory failure`
$Agetrt_greater_equal_180d$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31.0
n_event                               5.0                 4.0
n_event_pct                          20.0                13.0
time-to-event-wk-10th                16.4                25.4
time-to-event-wk-25th                52.6                  NA
time-to-event-wk-50th                  NA                  NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5656    0.6924    0.1456    2.1970    0.4105


$Agetrt_greater_equal_180d$`Apparent life threatening event`
$Agetrt_greater_equal_180d$`Apparent life threatening event`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                 31
n_event                                 2                  0
n_event_pct                             8                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Apparent life threatening event`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.108e-09 1.770e+04 0.000e+00       Inf 9.991e-01


$Agetrt_greater_equal_180d$Atelectasis
$Agetrt_greater_equal_180d$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 25                 31
n_event                                3                  2
n_event_pct                           12                  6
time-to-event-wk-10th                 52.7               NA
time-to-event-wk-25th                   NA               NA
time-to-event-wk-50th                   NA               NA
time-to-event-wk-75th                   NA               NA
time-to-event-wk-90th                   NA               NA
time-to-event-wk-50th-loci            52.7               NA
time-to-event-wk-50th-hici              NA               NA

$Agetrt_greater_equal_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45920   0.92320   0.07519   2.80500   0.39930


$Agetrt_greater_equal_180d$`Bronchial secretion retention`
$Agetrt_greater_equal_180d$`Bronchial secretion retention`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                 31
n_event                                 2                  0
n_event_pct                             8                  0
```

```
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.287e-10 3.014e+04 0.000e+00       Inf 9.994e-01


$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`
$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25               31.0
n_event                                 3                4.0
n_event_pct                            12               13.0
time-to-event-wk-10th                  23               17.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9800    0.7888    0.2088    4.5990    0.9795


$Agetrt_greater_equal_180d$Dysphagia
$Agetrt_greater_equal_180d$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               3.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                19.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.515e-10 1.486e+04 0.000e+00       Inf 9.989e-01


$Agetrt_greater_equal_180d$Dyspnoea
$Agetrt_greater_equal_180d$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  25                 31
n_event                                 0                  2
n_event_pct                             0                  6
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.977e+08 1.748e+04 0.000e+00       Inf 9.991e-01


$Agetrt_greater_equal_180d$`Lower respiratory tract infection`
$Agetrt_greater_equal_180d$`Lower respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                 31
n_event                                 0                  2
n_event_pct                             0                  6
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Lower respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.866e+08 1.745e+04 0.000e+00       Inf 9.991e-01


$Agetrt_greater_equal_180d$Pneumonia
$Agetrt_greater_equal_180d$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                 31
n_event                                 2                  2
n_event_pct                             8                  6
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.68320   1.02000   0.09246   5.04900   0.70890
```

```
$Agetrt_greater_equal_180d$`Pneumonia aspiration`
$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 25                 31
n_event                                2                  1
n_event_pct                            8                  3
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.57790   1.26300   0.04862   6.87000   0.66420


$Agetrt_greater_equal_180d$`Pneumonia viral`
$Agetrt_greater_equal_180d$`Pneumonia viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0               31.0
n_event                              2.0                2.0
n_event_pct                          8.0                6.0
time-to-event-wk-10th               52.6               46.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          52.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.59000   1.03600   0.07747   4.49300   0.61050


$Agetrt_greater_equal_180d$`Respiratory arrest`
$Agetrt_greater_equal_180d$`Respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 25                 31
n_event                                1                  2
n_event_pct                            4                  6
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$`Respiratory arrest`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4690    1.2610    0.1240   17.4000    0.7604


$Agetrt_greater_equal_180d$`Respiratory distress`
$Agetrt_greater_equal_180d$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               6.0                 2
n_event_pct                          24.0                 6
time-to-event-wk-10th                 3.1                NA
time-to-event-wk-25th                28.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           28.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24280   0.82720   0.04800   1.22900   0.08705


$Agetrt_greater_equal_180d$`Respiratory failure`
$Agetrt_greater_equal_180d$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31.0
n_event                               6.0                 6.0
n_event_pct                          24.0                19.0
time-to-event-wk-10th                13.1                21.3
time-to-event-wk-25th                21.9                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           21.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_greater_equal_180d$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7259    0.5861    0.2301    2.2900    0.5847


$Agetrt_greater_equal_180d$`Rhinovirus infection`
$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                  31
n_event                                 2                   1
n_event_pct                             8                   3
time-to-event-wk-10th                  NA                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25620   1.25500   0.02191   2.99700   0.27780


$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               3.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                37.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.549e-10 1.464e+04 0.000e+00       Inf 9.989e-01



$Gender_Male
$Gender_Male$`Acute respiratory failure`
$Gender_Male$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37.0
n_event                               4.0                 5.0
n_event_pct                          24.0                14.0
time-to-event-wk-10th                16.4                25.4
time-to-event-wk-25th                22.4                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           22.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5031    0.6776    0.1333    1.8990    0.3106


$Gender_Male$Apnoea
$Gender_Male$Apnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                  37
n_event                                 1                   0
n_event_pct                             6                   0
```

```
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Apnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.378e-10 2.881e+04 0.000e+00       Inf 9.994e-01


$Gender_Male$`Apparent life threatening event`
$Gender_Male$`Apparent life threatening event`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Apparent life threatening event`$stats_HR_TRTvsCTRL
        HR   SE_logHR  HR.lo95ci  HR.hi95ci    p.value
2.877e-134  1.689e+03  0.000e+00        Inf  8.555e-01


$Gender_Male$Aspiration
$Gender_Male$Aspiration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               1.0                  1
n_event_pct                           6.0                  3
time-to-event-wk-10th                40.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.56770   1.47600   0.03144  10.25000   0.70130


$Gender_Male$Atelectasis
$Gender_Male$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                17.0                 37
n_event                               2.0                  1
n_event_pct                          12.0                  3
time-to-event-wk-10th                52.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13420   1.31400   0.01021   1.76400   0.12640


$Gender_Male$`Bronchial secretion retention`
$Gender_Male$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               3.0                  1
n_event_pct                          18.0                  3
time-to-event-wk-10th                 4.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.12350   1.18200   0.01217   1.25200   0.07680


$Gender_Male$Bronchiolitis
$Gender_Male$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 1                  3
n_event_pct                             6                  8
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.61070   1.23800   0.05393   6.91500   0.69040
```

```
$Gender_Male$`Bronchitis viral`
$Gender_Male$`Bronchitis viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 37
n_event                                0                  2
n_event_pct                            0                  5
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Bronchitis viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.656e+08 2.064e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$`Candida sepsis`
$Gender_Male$`Candida sepsis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                 37
n_event                              1.0                  0
n_event_pct                          6.0                  0
time-to-event-wk-10th               22.6                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          22.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Candida sepsis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.502e-10 3.607e+04 0.000e+00       Inf 9.995e-01


$Gender_Male$`Cardiac arrest`
$Gender_Male$`Cardiac arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 37
n_event                                1                  2
n_event_pct                            6                  5
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Cardiac arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
  0.94300   1.24300   0.08254  10.77000   0.96240


$Gender_Male$`Cardio-respiratory arrest`
$Gender_Male$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               3.0                  2
n_event_pct                          18.0                  5
time-to-event-wk-10th                14.3                 NA
time-to-event-wk-25th                33.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29500   0.93520   0.04719   1.84500   0.19180


$Gender_Male$`Corona virus infection`
$Gender_Male$`Corona virus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  34                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             34                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Corona virus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.616e-06 1.471e+05 0.000e+00       Inf 9.999e-01


$Gender_Male$Cyanosis
$Gender_Male$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Gender_Male$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.675e-10 2.842e+04 0.000e+00       Inf 9.994e-01


$Gender_Male$Death
$Gender_Male$Death$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Death$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.124e-10 2.810e+04 0.000e+00       Inf 9.994e-01


$Gender_Male$Dysphagia
$Gender_Male$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 1                  3
n_event_pct                             6                  8
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5510    1.1650    0.1581   15.2200    0.7062


$Gender_Male$Dyspnoea
$Gender_Male$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                24.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           24.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.610e-10 3.607e+04 0.000e+00       Inf 9.995e-01


$Gender_Male$Hypoxia
$Gender_Male$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                  37
n_event                                 1                   1
n_event_pct                             6                   3
time-to-event-wk-10th                  NA                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45140   1.44000   0.02685   7.58700   0.58060


$Gender_Male$`Oxygen saturation decreased`
$Gender_Male$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                  37
n_event                               2.0                   0
n_event_pct                          12.0                   0
time-to-event-wk-10th                17.9                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.563e-10 2.080e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$Pneumonia
$Gender_Male$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                  37
n_event                               3.0                   3
n_event_pct                          18.0                   8
time-to-event-wk-10th                11.3                  NA
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42860   0.83040   0.08418   2.18200   0.30760


$Gender_Male$`Pneumonia aspiration`
$Gender_Male$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                17.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.345e-10 2.236e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$`Pneumonia viral`
$Gender_Male$`Pneumonia viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                52.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.298e-10 4.533e+04 0.000e+00       Inf 9.996e-01


$Gender_Male$`Respiratory arrest`
$Gender_Male$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                37.0
```

```
n_event                                  1                3.0
n_event_pct                              6                8.0
time-to-event-wk-10th                   NA               40.6
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Gender_Male$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1380    1.1920    0.1099   11.7800    0.9139


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               37.0
n_event                                 1                6.0
n_event_pct                             6               16.0
time-to-event-wk-10th                  NA                3.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.6930    1.0930    0.3161   22.9400    0.3648


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               7.0                7.0
n_event_pct                          41.0               19.0
time-to-event-wk-10th                 1.0                5.1
time-to-event-wk-25th                13.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4121    0.5447    0.1417    1.1980    0.1036


$Gender_Male$`Respiratory syncytial virus bronchiolitis`
```

```
$Gender_Male$`Respiratory syncytial virus bronchiolitis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                37
n_event                              1.0                 1
n_event_pct                          6.0                 3
time-to-event-wk-10th               22.4                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          22.4                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Respiratory syncytial virus bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3398    1.6610    0.0131    8.8160    0.5158


$Gender_Male$`Rhinovirus infection`
$Gender_Male$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                17                37
n_event                               1                 2
n_event_pct                           6                 5
time-to-event-wk-10th                NA                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Gender_Male$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44990   1.32100   0.03378   5.99200   0.54540


$Gender_Male$Sepsis
$Gender_Male$Sepsis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                17                37
n_event                               0                 2
n_event_pct                           0                 5
time-to-event-wk-10th                NA                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Gender_Male$Sepsis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.864e+08 1.974e+04 0.000e+00       Inf 9.992e-01
```

```
$Gender_Male$`Sleep apnoea syndrome`
$Gender_Male$`Sleep apnoea syndrome`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                37
n_event                                1                 0
n_event_pct                            6                 0
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.255e-10 2.839e+04 0.000e+00       Inf 9.994e-01


$Gender_Male$`Viral upper respiratory tract infection`
$Gender_Male$`Viral upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                37
n_event                              2.0                 0
n_event_pct                         12.0                 0
time-to-event-wk-10th               33.4                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          33.4                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.589e-11 2.951e+04 0.000e+00       Inf 9.993e-01


$Gender_Male$Vomiting
$Gender_Male$Vomiting$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                37
n_event                                1                 0
n_event_pct                            6                 0
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA
```

```
$Gender_Male$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.937e-10 2.868e+04 0.000e+00       Inf 9.994e-01


$Gender_Male$`Weight gain poor`
$Gender_Male$`Weight gain poor`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                37
n_event                                1                 1
n_event_pct                            6                 3
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Weight gain poor`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39970   1.45000   0.02329   6.86000   0.52720



$Gender_Female
$Gender_Female$`Acute respiratory failure`
$Gender_Female$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 24              43.0
n_event                                5               6.0
n_event_pct                           21              14.0
time-to-event-wk-10th                 13              19.9
time-to-event-wk-25th                 26                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            26                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5214    0.6254    0.1530    1.7760    0.2977


$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0              43.0
n_event                              2.0               5.0
n_event_pct                          8.0              12.0
time-to-event-wk-10th               32.9              32.1
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2080    0.8530    0.2269    6.4270    0.8249


$Gender_Female$`Bronchial secretion retention`
$Gender_Female$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               2.0                  0
n_event_pct                           8.0                  0
time-to-event-wk-10th                40.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.353e-10 1.968e+04 0.000e+00       Inf 9.991e-01


$Gender_Female$`Cardio-respiratory arrest`
$Gender_Female$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24                 43
n_event                                 2                  3
n_event_pct                             8                  7
time-to-event-wk-10th                  23                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2170    0.9525    0.1881    7.8690    0.8369


$Gender_Female$Dysphagia
$Gender_Female$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               3.0                  1
n_event_pct                          12.0                  2
```

```
time-to-event-wk-10th                19.9                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           26.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.12350   1.16800   0.01251   1.22000   0.07350


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               2.0                  7
n_event_pct                           8.0                 16
time-to-event-wk-10th                13.7                 20
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7190    0.8117    0.3502    8.4360    0.5046


$Gender_Female$`Pneumonia aspiration`
$Gender_Female$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24                43.0
n_event                                 0                 3.0
n_event_pct                             0                 7.0
time-to-event-wk-10th                  NA                43.9
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.917e+08 1.521e+04 0.000e+00       Inf 9.990e-01


$Gender_Female$`Respiratory arrest`
$Gender_Female$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                24.0                 43
n_event                               2.0                  1
n_event_pct                           8.0                  2
time-to-event-wk-10th                20.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.23490   1.24800   0.02035   2.71000   0.24560


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43.0
n_event                               7.0                 6.0
n_event_pct                          29.0                14.0
time-to-event-wk-10th                11.0                23.9
time-to-event-wk-25th                15.9                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           15.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32270   0.56950   0.10570   0.98550   0.04707


$Gender_Female$`Respiratory failure`
$Gender_Female$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43.0
n_event                               8.0                 7.0
n_event_pct                          33.0                16.0
time-to-event-wk-10th                 9.1                21.3
time-to-event-wk-25th                18.1                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           18.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4115    0.5402    0.1427    1.1860    0.1002
```

```
$Gender_Female$`Respiratory syncytial virus bronchiolitis`
$Gender_Female$`Respiratory syncytial virus bronchiolitis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0                43
n_event                              2.0                 2
n_event_pct                          8.0                 5
time-to-event-wk-10th               17.7                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$`Respiratory syncytial virus bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44790   1.03000   0.05954   3.36900   0.43530


$Gender_Female$`Rhinovirus infection`
$Gender_Female$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0                43
n_event                              2.0                 2
n_event_pct                          8.0                 5
time-to-event-wk-10th               18.1                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48090   1.02200   0.06492   3.56200   0.47360


$Gender_Female$`Upper respiratory tract infection`
$Gender_Female$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 24               43.0
n_event                                0                5.0
n_event_pct                            0               12.0
time-to-event-wk-10th                 NA               43.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
2.858e+08 1.166e+04 0.000e+00       Inf 9.987e-01


$Gender_Female$`Viral upper respiratory tract infection`
$Gender_Female$`Viral upper respiratory tract infection`$stats_num
                            TRT01P=Control TRT01P=ISIS 396443
n_all                                 24.0                43
n_event                                3.0                 1
n_event_pct                           12.0                 2
time-to-event-wk-10th                 37.3                NA
time-to-event-wk-25th                   NA                NA
time-to-event-wk-50th                   NA                NA
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci              NA                NA
time-to-event-wk-50th-hici              NA                NA

$Gender_Female$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.18830   1.17200   0.01894   1.87200   0.15420



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$stats_num
                            TRT01P=Control TRT01P=ISIS 396443
n_all                                 22.0              38.0
n_event                                7.0              11.0
n_event_pct                           32.0              29.0
time-to-event-wk-10th                 13.0               9.6
time-to-event-wk-25th                 22.4              28.0
time-to-event-wk-50th                   NA                NA
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci            22.4              32.7
time-to-event-wk-50th-hici              NA                NA

$Region_Northamerica$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8393    0.4847    0.3246    2.1700    0.7178


$Region_Northamerica$`Apparent life threatening event`
$Region_Northamerica$`Apparent life threatening event`$stats_num
                            TRT01P=Control TRT01P=ISIS 396443
n_all                                   22                38
n_event                                  2                 0
n_event_pct                              9                 0
time-to-event-wk-10th                   NA                NA
time-to-event-wk-25th                   NA                NA
time-to-event-wk-50th                   NA                NA
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
```

```
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Apparent life threatening event`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.542e-10 1.953e+04 0.000e+00       Inf 9.991e-01


$Region_Northamerica$Aspiration
$Region_Northamerica$Aspiration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                 38
n_event                                 1                  2
n_event_pct                             5                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2880    1.2320    0.1151   14.4000    0.8374


$Region_Northamerica$Atelectasis
$Region_Northamerica$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               3.0                5.0
n_event_pct                          14.0               13.0
time-to-event-wk-10th                52.7               13.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8828    0.7341    0.2094    3.7220    0.8651


$Region_Northamerica$`Bronchial secretion retention`
$Region_Northamerica$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               3.0                  0
n_event_pct                          14.0                  0
time-to-event-wk-10th                 8.6                 NA
time-to-event-wk-25th                  NA                 NA
```

```
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.431e-10 1.599e+04 0.000e+00       Inf 9.989e-01


$Region_Northamerica$Bronchiolitis
$Region_Northamerica$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22               38.0
n_event                                 1                3.0
n_event_pct                             5                8.0
time-to-event-wk-10th                  NA               32.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5720    1.1550    0.1633   15.1200    0.6956


$Region_Northamerica$`Bronchitis viral`
$Region_Northamerica$`Bronchitis viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                 38
n_event                                 0                  2
n_event_pct                             0                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Bronchitis viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.402e+09 2.553e+04 0.000e+00       Inf 9.993e-01


$Region_Northamerica$`Cardiac arrest`
$Region_Northamerica$`Cardiac arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               2.0                  1
```

```
n_event_pct                              9.0                  3
time-to-event-wk-10th                   12.7                 NA
time-to-event-wk-25th                     NA                 NA
time-to-event-wk-50th                     NA                 NA
time-to-event-wk-75th                     NA                 NA
time-to-event-wk-90th                     NA                 NA
time-to-event-wk-50th-loci                NA                 NA
time-to-event-wk-50th-hici                NA                 NA

$Region_Northamerica$`Cardiac arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26720   1.22500   0.02421   2.94800   0.28130


$Region_Northamerica$`Cardio-respiratory arrest`
$Region_Northamerica$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               4.0                  3
n_event_pct                          18.0                  8
time-to-event-wk-10th                17.6                 NA
time-to-event-wk-25th                33.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31570   0.77270   0.06945   1.43600   0.13570


$Region_Northamerica$Dysphagia
$Region_Northamerica$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38.0
n_event                               3.0                 4.0
n_event_pct                          14.0                11.0
time-to-event-wk-10th                19.1                28.4
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           19.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6927    0.7678    0.1538    3.1200    0.6326


$Region_Northamerica$Hypoxia
$Region_Northamerica$Hypoxia$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                 38
n_event                                 1                  3
n_event_pct                             5                  8
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6600    1.1570    0.1721   16.0200    0.6611


$Region_Northamerica$`Oxygen saturation decreased`
$Region_Northamerica$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               2.0                  0
n_event_pct                           9.0                  0
time-to-event-wk-10th                17.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.362e-10 1.927e+04 0.000e+00       Inf 9.991e-01


$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               3.0                6.0
n_event_pct                          14.0               16.0
time-to-event-wk-10th                11.3                8.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2040    0.7114    0.2986    4.8560    0.7940
```

```
$Region_Northamerica$`Pneumonia aspiration`
$Region_Northamerica$`Pneumonia aspiration`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0               38.0
n_event                              2.0                3.0
n_event_pct                          9.0                8.0
time-to-event-wk-10th               17.9               43.9
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7418    0.9159    0.1232    4.4660    0.7443


$Region_Northamerica$`Pneumonia bacterial`
$Region_Northamerica$`Pneumonia bacterial`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                22                 38
n_event                               1                  2
n_event_pct                           5                  5
time-to-event-wk-10th                NA                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Region_Northamerica$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.92420   1.23100   0.08275  10.32000   0.94900


$Region_Northamerica$`Pneumonia viral`
$Region_Northamerica$`Pneumonia viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                 38
n_event                              2.0                  2
n_event_pct                          9.0                  5
time-to-event-wk-10th               52.6                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          52.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Northamerica$`Pneumonia viral`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39500   1.01900   0.05358   2.91300   0.36220


$Region_Northamerica$`Respiratory arrest`
$Region_Northamerica$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               3.0                 0
n_event_pct                          14.0                 0
time-to-event-wk-10th                19.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           20.4                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.389e-10 1.768e+04 0.000e+00       Inf 9.990e-01


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38.0
n_event                               6.0                 7.0
n_event_pct                          27.0                18.0
time-to-event-wk-10th                 3.1                10.4
time-to-event-wk-25th                28.6                45.3
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           28.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5914    0.5634    0.1960    1.7840    0.3512


$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38.0
n_event                               7.0                 9.0
n_event_pct                          32.0                24.0
time-to-event-wk-10th                13.1                 5.0
time-to-event-wk-25th                18.1                43.4
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           18.1                43.4
```

```
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6165    0.5072    0.2281    1.6660    0.3402


$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`
$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               3.0                 3
n_event_pct                          14.0                 8
time-to-event-wk-10th                17.7                34
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.4                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Respiratory syncytial virus
bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42960   0.82440   0.08537   2.16200   0.30540


$Region_Northamerica$`Rhinovirus infection`
$Region_Northamerica$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               3.0                4.0
n_event_pct                          14.0               11.0
time-to-event-wk-10th                18.1               45.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6089    0.7669    0.1355    2.7370    0.5177


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22               38.0
n_event                                 0                4.0
n_event_pct                             0               11.0
time-to-event-wk-10th                  NA               43.7
time-to-event-wk-25th                  NA                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.343e+09 1.831e+04 0.000e+00       Inf 9.991e-01


$Region_Northamerica$`Viral upper respiratory tract infection`
$Region_Northamerica$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               5.0                 1
n_event_pct                          23.0                 3
time-to-event-wk-10th                11.7                NA
time-to-event-wk-25th                37.3                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.4                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.09417   1.09900   0.01093   0.81110   0.03151



$Disdur_greater_12wk
$Disdur_greater_12wk$`Acute respiratory failure`
$Disdur_greater_12wk$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               4.0                7.0
n_event_pct                          17.0               15.0
time-to-event-wk-10th                13.9               25.4
time-to-event-wk-25th                52.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7232    0.6284    0.2111    2.4780    0.6061


$Disdur_greater_12wk$`Apparent life threatening event`
$Disdur_greater_12wk$`Apparent life threatening event`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23                 46
n_event                                 2                  0
n_event_pct                             9                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Apparent life threatening event`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.790e-10 2.045e+04 0.000e+00       Inf 9.992e-01


$Disdur_greater_12wk$Atelectasis
$Disdur_greater_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                 46
n_event                               3.0                  3
n_event_pct                          13.0                  7
time-to-event-wk-10th                52.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.43960   0.81990   0.08814   2.19200   0.31610


$Disdur_greater_12wk$`Bronchial secretion retention`
$Disdur_greater_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                 46
n_event                               2.0                  0
n_event_pct                           9.0                  0
time-to-event-wk-10th                 8.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.955e-10 3.147e+04 0.000e+00       Inf 9.994e-01
```

```
$Disdur_greater_12wk$Bronchiolitis
$Disdur_greater_12wk$Bronchiolitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 23                 46
n_event                                1                  3
n_event_pct                            4                  7
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5500    1.1580    0.1603   14.9900    0.7049


$Disdur_greater_12wk$`Cardio-respiratory arrest`
$Disdur_greater_12wk$`Cardio-respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0               46.0
n_event                              2.0                4.0
n_event_pct                          9.0                9.0
time-to-event-wk-10th               17.6               25.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8262    0.8684    0.1506    4.5320    0.8260


$Disdur_greater_12wk$Dysphagia
$Disdur_greater_12wk$Dysphagia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0                 46
n_event                              3.0                  2
n_event_pct                         13.0                  4
time-to-event-wk-10th               19.9                 NA
time-to-event-wk-25th               43.3                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          19.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$Dysphagia$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25820   0.91610   0.04287   1.55500   0.13940


$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               2.0                4.0
n_event_pct                           9.0                9.0
time-to-event-wk-10th                13.7               30.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7982    0.8683    0.1455    4.3770    0.7951


$Disdur_greater_12wk$`Pneumonia viral`
$Disdur_greater_12wk$`Pneumonia viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               2.0                 2
n_event_pct                           9.0                 4
time-to-event-wk-10th                52.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           52.6                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4268    1.0060    0.0594    3.0670    0.3974


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               6.0                5.0
n_event_pct                          26.0               11.0
time-to-event-wk-10th                 3.1               23.9
time-to-event-wk-25th                28.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.4                 NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32890   0.60840   0.09980   1.08400   0.06759


$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               8.0                7.0
n_event_pct                          35.0               15.0
time-to-event-wk-10th                 4.6               21.3
time-to-event-wk-25th                13.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.34780   0.52300   0.12480   0.96940   0.04344


$Disdur_greater_12wk$`Rhinovirus infection`
$Disdur_greater_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                 46
n_event                               2.0                  3
n_event_pct                           9.0                  7
time-to-event-wk-10th                18.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6795    0.9169    0.1127    4.0980    0.6734


$Disdur_greater_12wk$`Viral upper respiratory tract infection`
$Disdur_greater_12wk$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                 46
n_event                               3.0                  0
n_event_pct                          13.0                  0
time-to-event-wk-10th                11.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.271e-10 1.695e+04 0.000e+00       Inf 9.990e-01



$Region_Asia_Pacific
$Region_Asia_Pacific$Dyspnoea
$Region_Asia_Pacific$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2                 12
n_event                                 0                  1
n_event_pct                             0                  8
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.811e+07 3.548e+04 0.000e+00       Inf 9.996e-01


$Region_Asia_Pacific$`Lung infection`
$Region_Asia_Pacific$`Lung infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2                 12
n_event                                 0                  1
n_event_pct                             0                  8
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`Lung infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.385e+07 3.163e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$`Oxygen saturation decreased`
$Region_Asia_Pacific$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  2                 12
n_event                                0                  1
n_event_pct                            0                  8
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Asia_Pacific$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.811e+07 3.548e+04 0.000e+00       Inf 9.996e-01


$Region_Asia_Pacific$Pneumonia
$Region_Asia_Pacific$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  2                 12
n_event                                0                  1
n_event_pct                            0                  8
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Asia_Pacific$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.732e+07 3.123e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$`Respiratory distress`
$Region_Asia_Pacific$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  2                 12
n_event                                0                  1
n_event_pct                            0                  8
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Asia_Pacific$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.732e+07 3.123e+04 0.000e+00       Inf 9.995e-01
```

```
$Region_Asia_Pacific$`Respiratory failure`
$Region_Asia_Pacific$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                12
n_event                              1.0                 0
n_event_pct                         50.0                 0
time-to-event-wk-10th                0.9                NA
time-to-event-wk-25th                0.9                NA
time-to-event-wk-50th               25.1                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           0.9                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.188e-28 8.557e+04 0.000e+00       Inf 9.994e-01


$Region_Asia_Pacific$`Upper respiratory tract infection`
$Region_Asia_Pacific$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 2               12.0
n_event                               0                1.0
n_event_pct                           0                8.0
time-to-event-wk-10th                NA               29.6
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA               29.6
time-to-event-wk-50th-hici           NA                 NA

$Region_Asia_Pacific$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.164e-05 1.849e+05 0.000e+00       Inf 1.000e+00




\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schweren UEs nach PT, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              7.0               10.0
n_event_pct                         22.0               14.0
time-to-event-wk-10th                8.6               19.9
time-to-event-wk-25th               22.4                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4466    0.5010    0.1673    1.1920    0.1076


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               7.0              11.0
n_event_pct                          22.0              15.0
time-to-event-wk-10th                11.0              20.3
time-to-event-wk-25th                28.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           28.6                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5310    0.4865    0.2046    1.3780    0.1933


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              14.0              12.0
n_event_pct                          44.0              17.0
time-to-event-wk-10th                 4.6              21.3
time-to-event-wk-25th                10.1                NA
time-to-event-wk-50th                21.9                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.0                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
0.2494000 0.4017000 0.1135000 0.5480000 0.0005451



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                22.0              38.0
n_event                               7.0              11.0
n_event_pct                          32.0              29.0
time-to-event-wk-10th                13.0               9.6
time-to-event-wk-25th                22.4              28.0
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.4              32.7
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8393    0.4847    0.3246    2.1700    0.7178



$Agetrt_less_180d
$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               2.0              10.0
n_event_pct                          12.0              20.0
time-to-event-wk-10th                15.4              15.6
time-to-event-wk-25th                  NA              45.3
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.4                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0980    0.7909    0.2329    5.1720    0.9063




\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten oder schweren UE nach SOC, das bei
mindestens 10% der Patienten in einem Studienarm auftrat"

$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Blood and lymphatic system disorders`
$Ageonset_greater_12wk$`Blood and lymphatic system disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Blood and lymphatic system disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Cardiac disorders`
$Ageonset_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        2   3
n_event_pct   22  38

$Ageonset_greater_12wk$`Cardiac disorders`$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.6875000 0.7728015  0.3710513  7.6745628 0.4983555
OR_TRTvsCTRL  2.1000000 1.0845232  0.2506522 17.5941009 0.4939033
ARR_TRTvsCTRL 0.1527778 0.2202300 -0.2788651  0.5844207 0.4878584


$Ageonset_greater_12wk$`Gastrointestinal disorders`
$Ageonset_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0

$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$`General disorders and administration site conditions`
$Ageonset_greater_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all          9   8
n_event        4   2
n_event_pct   44  25

$Ageonset_greater_12wk$`General disorders and administration site
conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5625000 0.7168604  0.1380161 2.2925311 0.4221963
OR_TRTvsCTRL   0.4166667 1.0567245  0.0525174 3.3057825 0.4074021
ARR_TRTvsCTRL -0.1944444 0.2255490 -0.6365123 0.2476234 0.3886357


$Ageonset_greater_12wk$`Infections and infestations`
$Ageonset_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all          9   8
n_event        5   3
```

```
n_event_pct   56  38

$Ageonset_greater_12wk$`Infections and infestations`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6750000 0.5451809  0.23187020 1.9650002 0.4709466
OR_TRTvsCTRL   0.4800000 0.9916317  0.06873261 3.3521206 0.4592010
ARR_TRTvsCTRL -0.1805556 0.2381842 -0.64738803 0.2862769 0.4484210


$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`
$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031


$Ageonset_greater_12wk$Investigations
$Ageonset_greater_12wk$Investigations$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Investigations$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Psychiatric disorders`
$Ageonset_greater_12wk$`Psychiatric disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$`Psychiatric disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031


$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
```

```
n_all          9   8
n_event        6   4
n_event_pct   67  50

$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7500000 0.4249183  0.32611454 1.7248541 0.4983875
OR_TRTvsCTRL   0.5000000 1.0000000  0.07043175 3.5495357 0.4882172
ARR_TRTvsCTRL -0.1666667 0.2365193 -0.63023589 0.2969026 0.4810192



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        7  11
n_event_pct   22  15

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.69841270 0.43431250  0.2981430 1.63606139 0.4085390
OR_TRTvsCTRL   0.64402810 0.53866472  0.2240746 1.85104534 0.4140092
ARR_TRTvsCTRL -0.06597222 0.08448851 -0.2315667 0.09962222 0.4348951


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        9  19
n_event_pct   28  26

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93827160 0.34438903  0.4777317 1.8427781 0.8532203
OR_TRTvsCTRL   0.91614256 0.47548804  0.3607671 2.3264794 0.8538592
ARR_TRTvsCTRL -0.01736111 0.09494776 -0.2034553 0.1687331 0.8549164


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         32  72
n_event        8  24
n_event_pct   25  33

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.33333333 0.34860834  0.6732909 2.6404302 0.4092410
OR_TRTvsCTRL  1.50000000 0.47871355  0.5869614 3.8333015 0.3970013
```

```
ARR_TRTvsCTRL 0.08333333 0.09458221 -0.1020444 0.2687111 0.3782812


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         32  72
n_event       17  53
n_event_pct   53  74

$Ageonset_less_equal_12wk$`Infections and infestations`$stats
               estimate        se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.3856209 0.1804233 0.972899194 1.9734268 0.07065565
OR_TRTvsCTRL  2.4613003 0.4438352 1.031267627 5.8743231 0.04242431
ARR_TRTvsCTRL 0.2048611 0.1023715 0.004216691 0.4055055 0.04537579


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         32  72
n_event        9  10
n_event_pct   28  14

$Ageonset_less_equal_12wk$Investigations$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.4938272 0.40739689  0.2222277 1.09736683 0.08329179
OR_TRTvsCTRL   0.4121864 0.52030607  0.1486649 1.14282298 0.08849673
ARR_TRTvsCTRL -0.1423611 0.08932095 -0.3174270 0.03270474 0.11097739


$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        7   8
n_event_pct   22  11

$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5079365 0.47193035  0.2014195 1.28090603 0.1511792
OR_TRTvsCTRL   0.4464286 0.56875491  0.1464289 1.36105926 0.1562003
ARR_TRTvsCTRL -0.1076389 0.08192874 -0.2682163 0.05293849 0.1889098


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       26  46
n_event_pct   81  64

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats
```

```
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.7863248 0.12272644  0.6182114 1.000154064 0.05014691
OR_TRTvsCTRL   0.4082840 0.51510084  0.1487674 1.120513298 0.08202389
ARR_TRTvsCTRL -0.1736111 0.08924711 -0.3485322 0.001310003 0.05174061



$Agetrt_less_180d
$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        5   7
n_event_pct   31  14

$Agetrt_less_180d$`Cardiac disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4571429 0.5098519  0.16829267 1.24176290 0.1247180
OR_TRTvsCTRL   0.3666667 0.6764435  0.09738268 1.38057864 0.1380208
ARR_TRTvsCTRL -0.1696429 0.1262010 -0.41699228 0.07770656 0.1788748


$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        4  11
n_event_pct   25  22

$Agetrt_less_180d$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8979592 0.5079379  0.3318173 2.4300440 0.8321872
OR_TRTvsCTRL   0.8684211 0.6712363  0.2330091 3.2365904 0.8335293
ARR_TRTvsCTRL -0.0255102 0.1235787 -0.2677200 0.2166996 0.8364559


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         16  49
n_event        4  16
n_event_pct   25  33

$Agetrt_less_180d$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.30612245 0.4791574  0.5106512 3.3407458 0.5772821
OR_TRTvsCTRL  1.45454545 0.6527912  0.4046415 5.2285851 0.5659768
ARR_TRTvsCTRL 0.07653061 0.1273054 -0.1729835 0.3260447 0.5477351


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         16  49
```

```
n_event       10  36
n_event_pct   62  73

$Agetrt_less_180d$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.1755102 0.2118245  0.7761061 1.7804580 0.4452377
OR_TRTvsCTRL  1.6615385 0.6093993  0.5032558 5.4856997 0.4047389
ARR_TRTvsCTRL 0.1096939 0.1364785 -0.1577990 0.3771868 0.4215443


$Agetrt_less_180d$`Injury, poisoning and procedural complications`
$Agetrt_less_180d$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$`Injury, poisoning and procedural complications`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$ntab
            CTRL TRT
n_all         16  49
n_event        5   5
n_event_pct   31  10

$Agetrt_less_180d$Investigations$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3265306 0.5631091  0.10829405 0.98456234 0.04685674
OR_TRTvsCTRL   0.2500000 0.7166843  0.06136168 1.01855100 0.05307420
ARR_TRTvsCTRL -0.2104592 0.1236839 -0.45287514 0.03195678 0.08883237


$Agetrt_less_180d$`Metabolism and nutrition disorders`
$Agetrt_less_180d$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        6   7
n_event_pct   38  14

$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3809524 0.4760416  0.14985226 0.96845194 0.04263138
OR_TRTvsCTRL   0.2777778 0.6582806  0.07644834 1.00931552 0.05166937
ARR_TRTvsCTRL -0.2321429 0.1309481 -0.48879635 0.02451064 0.07626423


$Agetrt_less_180d$`Psychiatric disorders`
$Agetrt_less_180d$`Psychiatric disorders`$ntab
```

```
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$`Psychiatric disorders`$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event       13  28
n_event_pct   81  57

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci       hi95ci     pvalue
RR_TRTvsCTRL   0.7032967 0.1724216  0.50161795  0.986061703 0.04121395
OR_TRTvsCTRL   0.3076923 0.7025594  0.07764205  1.219372242 0.09341373
ARR_TRTvsCTRL -0.2410714 0.1204965 -0.47724019 -0.004902666 0.04542999



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Cardiac disorders`
$Agetrt_greater_equal_180d$`Cardiac disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        4   7
n_event_pct   16  23

$Agetrt_greater_equal_180d$`Cardiac disorders`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.41129032 0.5662147  0.4652148 4.281335 0.5428995
OR_TRTvsCTRL  1.53125000 0.6943651  0.3926463 5.971600 0.5394588
ARR_TRTvsCTRL 0.06580645 0.1049537 -0.1398991 0.271512 0.5306564


$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        7   8
n_event_pct   28  26

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92165899 0.4422658  0.3873583 2.1929445 0.8536533
OR_TRTvsCTRL   0.89440994 0.6057152  0.2728669 2.9317192 0.8538328
ARR_TRTvsCTRL -0.02193548 0.1193330 -0.2558238 0.2119529 0.8541567
```

```
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         25  31
n_event        8  10
n_event_pct   32  32

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.008064516 0.3908221  0.4686190 2.1684865 0.9836030
OR_TRTvsCTRL  1.011904762 0.5757105  0.3274115 3.1274135 0.9835996
ARR_TRTvsCTRL 0.002580645 0.1255114 -0.2434172 0.2485784 0.9835958


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         25  31
n_event       12  20
n_event_pct   48  65

$Agetrt_greater_equal_180d$`Infections and infestations`$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3440860 0.2471341  0.82806824 2.1816647 0.2314727
OR_TRTvsCTRL  1.9696970 0.5487855  0.67185008 5.7746606 0.2167426
ARR_TRTvsCTRL 0.1651613 0.1317907 -0.09314368 0.4234663 0.2101296


$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`
$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         25  31
n_event        1   4
n_event_pct    4  13

$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.22580645 1.08523819  0.38448720 27.0641711 0.2805011
OR_TRTvsCTRL  3.55555556 1.15269411  0.37130643 34.0472838 0.2711251
ARR_TRTvsCTRL 0.08903226 0.07184188 -0.05177524  0.2298398 0.2152416


$Agetrt_greater_equal_180d$Investigations
$Agetrt_greater_equal_180d$Investigations$ntab
            CTRL TRT
n_all         25  31
n_event        5   5
n_event_pct   20  16
```

```
$Agetrt_greater_equal_180d$Investigations$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80645161 0.5724875  0.2625887 2.4767408 0.7071038
OR_TRTvsCTRL   0.76923077 0.6989002  0.1955022 3.0266458 0.7073661
ARR_TRTvsCTRL -0.03870968 0.1037484 -0.2420528 0.1646335 0.7090658


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       19  22
n_event_pct   76  71

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93378608 0.1607111  0.6814749 1.2795137 0.6699039
OR_TRTvsCTRL   0.77192982 0.6130774  0.2321269 2.5670259 0.6728548
ARR_TRTvsCTRL -0.05032258 0.1180775 -0.2817503 0.1811051 0.6699748



$Gender_Male
$Gender_Male$`Cardiac disorders`
$Gender_Male$`Cardiac disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        6   7
n_event_pct   35  19

$Gender_Male$`Cardiac disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5360360 0.4729411  0.2121416 1.3544474 0.1873497
OR_TRTvsCTRL   0.4277778 0.6586093  0.1176546 1.5553477 0.1972904
ARR_TRTvsCTRL -0.1637520 0.1325881 -0.4236199 0.0961159 0.2168145


$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        5   9
n_event_pct   29  24

$Gender_Male$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8270270 0.4746162  0.3262313 2.0965912 0.6890457
OR_TRTvsCTRL   0.7714286 0.6558649  0.2133156 2.7897733 0.6923427
ARR_TRTvsCTRL -0.0508744 0.1311012 -0.3078280 0.2060792 0.6979757
```

```
$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  37
n_event        3  13
n_event_pct   18  35

$Gender_Male$`General disorders and administration site conditions`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.9909910 0.5695664  0.65200889  6.0797409 0.2266448
OR_TRTvsCTRL  2.5277778 0.7234305  0.61228519 10.4357586 0.1998898
ARR_TRTvsCTRL 0.1748808 0.1212778 -0.06281935  0.4125809 0.1493066


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  37
n_event       10  27
n_event_pct   59  73

$Gender_Male$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2405405 0.2262443  0.7962170 1.9328157 0.3407325
OR_TRTvsCTRL  1.8900000 0.6163556  0.5647016 6.3256420 0.3016939
ARR_TRTvsCTRL 0.1414944 0.1399225 -0.1327486 0.4157374 0.3119042


$Gender_Male$`Injury, poisoning and procedural complications`
$Gender_Male$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         17  37
n_event        1   4
n_event_pct    6  11

$Gender_Male$`Injury, poisoning and procedural complications`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.83783784 1.07895757  0.2217670 15.2306185 0.5727177
OR_TRTvsCTRL  1.93939394 1.15879378  0.2001239 18.7946001 0.5675877
ARR_TRTvsCTRL 0.04928458 0.07656783 -0.1007856  0.1993548 0.5197880


$Gender_Male$Investigations
$Gender_Male$Investigations$ntab
            CTRL TRT
n_all         17  37
n_event        5   5
n_event_pct   29  14

$Gender_Male$Investigations$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.5604904  0.15316408 1.37828001 0.1652762
OR_TRTvsCTRL   0.3750000 0.7173446  0.09192347 1.52980520 0.1715296
ARR_TRTvsCTRL -0.1589825 0.1239808 -0.40198046 0.08401543 0.1997320
```

```
$Gender_Male$`Metabolism and nutrition disorders`
$Gender_Male$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        5   4
n_event_pct   29  11

$Gender_Male$`Metabolism and nutrition disorders`$stats
                 estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3675676 0.6034480  0.11263707 1.19948003 0.09720667
OR_TRTvsCTRL   0.2909091 0.7507572  0.06679003 1.26707690 0.10003881
ARR_TRTvsCTRL -0.1860095 0.1217311 -0.42459813 0.05257906 0.12650356


$Gender_Male$`Musculoskeletal and connective tissue disorders`
$Gender_Male$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        2   2
n_event_pct   12   5

$Gender_Male$`Musculoskeletal and connective tissue disorders`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.95611163  0.07053481 2.9928909 0.4159867
OR_TRTvsCTRL   0.4285714 1.04653624  0.05510740 3.3330089 0.4181580
ARR_TRTvsCTRL -0.0635930 0.08653439 -0.23319729 0.1060113 0.4624083


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event       13  26
n_event_pct   76  70

$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.91891892 0.1718548  0.6561364 1.2869457 0.6226994
OR_TRTvsCTRL   0.72727273 0.6754952  0.1935151 2.7332529 0.6373284
ARR_TRTvsCTRL -0.06200318 0.1273987 -0.3117000 0.1876936 0.6264807



$Gender_Female
$Gender_Female$`Cardiac disorders`
$Gender_Female$`Cardiac disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        3   7
n_event_pct   12  16

$Gender_Female$`Cardiac disorders`$stats
```

```
               estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3023256 0.64130180  0.3705463 4.5771659 0.6804134
OR_TRTvsCTRL  1.3611111 0.74268924  0.3174793 5.8354158 0.6780578
ARR_TRTvsCTRL 0.0377907 0.08790235 -0.1344948 0.2100761 0.6672562


$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        6  10
n_event_pct   25  23

$Gender_Female$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93023256 0.4491594  0.3857148 2.2434517 0.8720829
OR_TRTvsCTRL   0.90909091 0.5937384  0.2839333 2.9107059 0.8724671
ARR_TRTvsCTRL -0.01744186 0.1093759 -0.2318146 0.1969309 0.8733008


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         24  43
n_event        9  13
n_event_pct   38  30

$Gender_Female$`General disorders and administration site conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80620155 0.3508728  0.4053033 1.6036407 0.5392424
OR_TRTvsCTRL   0.72222222 0.5366882  0.2522557 2.0677624 0.5442805
ARR_TRTvsCTRL -0.07267442 0.1211233 -0.3100717 0.1647229 0.5485038


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$ntab
            CTRL TRT
n_all         24  43
n_event       12  29
n_event_pct   50  67

$Gender_Female$`Infections and infestations`$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3488372 0.2299861  0.85939932 2.1170157 0.1932124
OR_TRTvsCTRL  2.0714286 0.5220900  0.74450244 5.7633341 0.1630604
ARR_TRTvsCTRL 0.1744186 0.1245919 -0.06977698 0.4186142 0.1615374


$Gender_Female$Investigations
$Gender_Female$Investigations$ntab
            CTRL TRT
n_all         24  43
n_event        5   5
n_event_pct   21  12
```

```
$Gender_Female$Investigations$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.57885881  0.1794805 1.73567455 0.3137393
OR_TRTvsCTRL   0.50000000 0.69206023  0.1287915 1.94112161 0.3165510
ARR_TRTvsCTRL -0.09205426 0.09623842 -0.2806781 0.09656957 0.3388081


$Gender_Female$`Psychiatric disorders`
$Gender_Female$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        3   0
n_event_pct   12   0

$Gender_Female$`Psychiatric disorders`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08116883 1.49096848  0.004367919 1.508356380 0.09212555
OR_TRTvsCTRL   0.07060755 1.53467079  0.003487683 1.429437936 0.08413938
ARR_TRTvsCTRL -0.12500000 0.06750772 -0.257312691 0.007312691 0.06407751


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       19  24
n_event_pct   79  56

$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.7050184 0.1713936  0.5038601  0.98648599 0.04141517
OR_TRTvsCTRL   0.3324100 0.5890075  0.1047876  1.05447947 0.06149744
ARR_TRTvsCTRL -0.2335271 0.1122829 -0.4535976 -0.01345668 0.03754294



$Region_Europe
$Region_Europe$`Cardiac disorders`
$Region_Europe$`Cardiac disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        1   5
n_event_pct    6  17

$Region_Europe$`Cardiac disorders`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.8333333 1.05254128  0.36005837 22.2957676 0.3224352
OR_TRTvsCTRL  3.2000000 1.14127122  0.34174184 29.9641390 0.3081217
ARR_TRTvsCTRL 0.1078431 0.08880482 -0.06621111  0.2818974 0.2246012


$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$ntab
```

```
            CTRL TRT
n_all         17  30
n_event        4   1
n_event_pct   24   3

$Region_Europe$`Gastrointestinal disorders`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.1416667 1.0760312  0.01719287 1.167312378 0.06934105
OR_TRTvsCTRL   0.1120690 1.1667930  0.01138438 1.103218002 0.06068621
ARR_TRTvsCTRL -0.2019608 0.1079733 -0.41358461 0.009663041 0.06141868


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  30
n_event        7   9
n_event_pct   41  30

$Region_Europe$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7285714 0.4022579  0.3311842 1.6027827 0.4311470
OR_TRTvsCTRL   0.6122449 0.6337092  0.1768117 2.1200172 0.4388076
ARR_TRTvsCTRL -0.1117647 0.1457666 -0.3974621 0.1739327 0.4432378


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  30
n_event        8  19
n_event_pct   47  63

$Region_Europe$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3458333 0.2923606  0.7588108 2.3869816 0.3096700
OR_TRTvsCTRL  1.9431818 0.6161589  0.5808153 6.5011298 0.2809559
ARR_TRTvsCTRL 0.1627451 0.1496521 -0.1305675 0.4560577 0.2768204


$Region_Europe$Investigations
$Region_Europe$Investigations$ntab
            CTRL TRT
n_all         17  30
n_event        2   3
n_event_pct   12  10

$Region_Europe$Investigations$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.86091606  0.1572555 4.5944339 0.8502696
OR_TRTvsCTRL   0.83333333 0.96800673  0.1249827 5.5563242 0.8506043
ARR_TRTvsCTRL -0.01764706 0.09542667 -0.2046799 0.1693858 0.8532855
```

```
$Region_Europe$`Metabolism and nutrition disorders`
$Region_Europe$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        2   5
n_event_pct   12  17

$Region_Europe$`Metabolism and nutrition disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.41666667 0.7796430  0.3073508 6.5298163 0.6550545
OR_TRTvsCTRL  1.50000000 0.8981462  0.2579810 8.7215711 0.6516677
ARR_TRTvsCTRL 0.04901961 0.1036141 -0.1540603 0.2520995 0.6361433


$Region_Europe$`Psychiatric disorders`
$Region_Europe$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        3   0
n_event_pct   18   0

$Region_Europe$`Psychiatric disorders`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08294931 1.48253184  0.004538156 1.516163942 0.09310543
OR_TRTvsCTRL   0.06791569 1.54514293  0.003286564 1.403453970 0.08175231
ARR_TRTvsCTRL -0.17647059 0.09245944 -0.357687763 0.004746586 0.05631022


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event       12  19
n_event_pct   71  63

$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.89722222 0.2093037  0.5953061 1.3522584 0.6043503
OR_TRTvsCTRL   0.71969697 0.6533560  0.1999917 2.5899255 0.6146555
ARR_TRTvsCTRL -0.07254902 0.1412559 -0.3494056 0.2043075 0.6075318



$Region_Asia_Pacific
$Region_Asia_Pacific$`Cardiac disorders`
$Region_Asia_Pacific$`Cardiac disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$`Cardiac disorders`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
```

```
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353


$Region_Asia_Pacific$`Gastrointestinal disorders`
$Region_Asia_Pacific$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        0   3
n_event_pct    0  25

$Region_Asia_Pacific$`Gastrointestinal disorders`$stats
              estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.615385 1.369474 0.110300612 23.6577786 0.72619768
OR_TRTvsCTRL  1.842105 1.670622 0.069707343 48.6799765 0.71460562
ARR_TRTvsCTRL 0.250000 0.125000 0.005004502  0.4949955 0.04550026


$Region_Asia_Pacific$`General disorders and administration site conditions`
$Region_Asia_Pacific$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all          2  12
n_event        1   2
n_event_pct   50  17

$Region_Asia_Pacific$`General disorders and administration site
conditions`$stats
               estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3333333 0.9574271  0.051040546 2.1769185 0.2511903
OR_TRTvsCTRL   0.2000000 1.6124515  0.008482205 4.7157551 0.3182158
ARR_TRTvsCTRL -0.3333333 0.3695593 -1.057656246 0.3909896 0.3670700


$Region_Asia_Pacific$`Infections and infestations`
$Region_Asia_Pacific$`Infections and infestations`$ntab
            CTRL TRT
n_all          2  12
n_event        0   7
n_event_pct    0  58

$Region_Asia_Pacific$`Infections and infestations`$stats
              estimate        se    lo95ci     hi95ci       pvalue
RR_TRTvsCTRL  3.4615385 1.3126602 0.2641987  45.353164 0.3441732453
OR_TRTvsCTRL  6.8181818 1.6477717 0.2698254 172.287741 0.2440340195
ARR_TRTvsCTRL 0.5833333 0.1423188 0.3043937   0.862273 0.0000415333


$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`
$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        1   2
n_event_pct   50  17
```

```
$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3333333 0.9574271  0.051040546 2.1769185 0.2511903
OR_TRTvsCTRL   0.2000000 1.6124515  0.008482205 4.7157551 0.3182158
ARR_TRTvsCTRL -0.3333333 0.3695593 -1.057656246 0.3909896 0.3670700



$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        8   7
n_event_pct   36  18

$Region_Northamerica$`Cardiac disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5065789 0.4428169  0.2126771 1.20662847 0.1245892
OR_TRTvsCTRL   0.3951613 0.6095439  0.1196547 1.30502584 0.1277070
ARR_TRTvsCTRL -0.1794258 0.1203041 -0.4152174 0.05636578 0.1358470


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        7  15
n_event_pct   32  39

$Region_Northamerica$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.24060150 0.3711516  0.5993873 2.5677757 0.5613180
OR_TRTvsCTRL  1.39751553 0.5653926  0.4614170 4.2327211 0.5538700
ARR_TRTvsCTRL 0.07655502 0.1270762 -0.1725098 0.3256198 0.5468854


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         22  38
n_event        4  15
n_event_pct   18  39

$Region_Northamerica$`General disorders and administration site
conditions`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.1710526 0.4948700  0.82306897  5.7267005 0.11723243
OR_TRTvsCTRL  2.9347826 0.6447484  0.82940207 10.3845279 0.09494896
ARR_TRTvsCTRL 0.2129187 0.1142331 -0.01097403  0.4368114 0.06233618


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$ntab
```

```
            CTRL TRT
n_all         22  38
n_event       14  30
n_event_pct   64  79

$Region_Northamerica$`Infections and infestations`$stats
              estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.240602 0.1816358  0.8690077 1.7710915 0.2352393
OR_TRTvsCTRL  2.142857 0.5956189  0.6668090 6.8862846 0.2006941
ARR_TRTvsCTRL 0.153110 0.1220337 -0.0860716 0.3922917 0.2096044


$Region_Northamerica$`Injury, poisoning and procedural complications`
$Region_Northamerica$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         22  38
n_event        2   5
n_event_pct    9  13

$Region_Northamerica$`Injury, poisoning and procedural complications`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.44736842 0.79260940  0.3061320 6.8430457 0.6408624
OR_TRTvsCTRL  1.51515152 0.88334763  0.2682558 8.5578157 0.6380784
ARR_TRTvsCTRL 0.04066986 0.08224094 -0.1205194 0.2018591 0.6209384


$Region_Northamerica$Investigations
$Region_Northamerica$Investigations$ntab
            CTRL TRT
n_all         22  38
n_event        8   6
n_event_pct   36  16

$Region_Northamerica$Investigations$stats
                estimate        se     lo95ci   hi95ci     pvalue
RR_TRTvsCTRL   0.4342105 0.4689311  0.1731991 1.088567 0.07524066
OR_TRTvsCTRL   0.3281250 0.6279691  0.0958321 1.123486 0.07597274
ARR_TRTvsCTRL -0.2057416 0.1183954 -0.4377923 0.026309 0.08225472


$Region_Northamerica$`Metabolism and nutrition disorders`
$Region_Northamerica$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        5   3
n_event_pct   23   8

$Region_Northamerica$`Metabolism and nutrition disorders`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3473684 0.67938428  0.09172704 1.3154771 0.1196215
OR_TRTvsCTRL   0.2914286 0.78786312  0.06221596 1.3650936 0.1175964
ARR_TRTvsCTRL -0.1483254 0.09947997 -0.34330251 0.0466518 0.1359596
```

```
$Region_Northamerica$`Musculoskeletal and connective tissue disorders`
$Region_Northamerica$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$`Musculoskeletal and connective tissue disorders`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       19  29
n_event_pct   86  76

$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.8836565 0.1238709  0.6931774 1.12647768 0.3180301
OR_TRTvsCTRL   0.5087719 0.7290808  0.1218789 2.12382059 0.3539995
ARR_TRTvsCTRL -0.1004785 0.1005467 -0.2975464 0.09658947 0.3176391


$Region_Northamerica$`Skin and subcutaneous tissue disorders`
$Region_Northamerica$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        3  10
n_event_pct   13  22

$Disdur_greater_12wk$`Cardiac disorders`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.66666667 0.60672559  0.50746137 5.4738704 0.3998224
```

```
OR_TRTvsCTRL  1.85185185 0.71492035  0.45610510 7.5187829 0.3887454
ARR_TRTvsCTRL 0.08695652 0.09289726 -0.09511876 0.2690318 0.3492472


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        7  13
n_event_pct   30  28

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92857143 0.3931448  0.4297045 2.0065998 0.8504844
OR_TRTvsCTRL   0.90043290 0.5590915  0.3009898 2.6937101 0.8511985
ARR_TRTvsCTRL -0.02173913 0.1166732 -0.2504144 0.2069362 0.8521900


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         23  46
n_event        7  14
n_event_pct   30  30

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats
              estimate        se     lo95ci   hi95ci pvalue
RR_TRTvsCTRL         1 0.3860937  0.4691983 2.131295      1
OR_TRTvsCTRL         1 0.5550097  0.3369573 2.967735      1
ARR_TRTvsCTRL        0 0.1175068 -0.2303090 0.230309      1


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         23  46
n_event       10  33
n_event_pct   43  72

$Disdur_greater_12wk$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.6500000 0.2551189 1.00075177 2.7204548 0.04965668
OR_TRTvsCTRL  3.3000000 0.5330565 1.16084828 9.3810709 0.02510603
ARR_TRTvsCTRL 0.2826087 0.1228497 0.04182768 0.5233897 0.02142317


$Disdur_greater_12wk$Investigations
$Disdur_greater_12wk$Investigations$ntab
            CTRL TRT
n_all         23  46
n_event        5   6
n_event_pct   22  13
```

```
$Disdur_greater_12wk$Investigations$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.60000000 0.54904396  0.2045522 1.7599419 0.3521686
OR_TRTvsCTRL   0.54000000 0.66874675  0.1455980 2.0027744 0.3568394
ARR_TRTvsCTRL -0.08695652 0.09931135 -0.2816032 0.1076901 0.3812502


$Disdur_greater_12wk$`Metabolism and nutrition disorders`
$Disdur_greater_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        2   5
n_event_pct    9  11

$Disdur_greater_12wk$`Metabolism and nutrition disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.25000000 0.79673246  0.2622588 5.9578547 0.7794212
OR_TRTvsCTRL  1.28048780 0.87864059  0.2288101 7.1659814 0.7784109
ARR_TRTvsCTRL 0.02173913 0.07455244 -0.1243810 0.1678592 0.7705962


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       18  30
n_event_pct   78  65

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8333333 0.1538554  0.6163917 1.1266285 0.2360101
OR_TRTvsCTRL   0.5208333 0.5927806  0.1629757 1.6644646 0.2711363
ARR_TRTvsCTRL -0.1304348 0.1110335 -0.3480564 0.0871868 0.2401011



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Cardiac disorders`
$Disdur_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        6   4
n_event_pct   33  12

$Disdur_less_equal_12wk$`Cardiac disorders`$stats
                 estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3529412 0.5759335  0.11414763 1.09128397 0.07056160
OR_TRTvsCTRL   0.2666667 0.7302967  0.06372928 1.11583106 0.07031305
ARR_TRTvsCTRL -0.2156863 0.1240919 -0.45890196 0.02752941 0.08219019


$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
```

```
n_all         18  34
n_event        4   6
n_event_pct   22  18

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.5759335  0.2568322 2.4553889 0.6889643
OR_TRTvsCTRL   0.75000000 0.7237469  0.1815544 3.0982447 0.6910062
ARR_TRTvsCTRL -0.04575163 0.1177988 -0.2766331 0.1851299 0.6977291


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         18  34
n_event        5  12
n_event_pct   28  35

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats
               estimate        se     lo95ci    hi95ci   pvalue
RR_TRTvsCTRL  1.2705882 0.4453830  0.5307551 3.0416940 0.590788
OR_TRTvsCTRL  1.4181818 0.6369544  0.4069634 4.9420657 0.583342
ARR_TRTvsCTRL 0.0751634 0.1336498 -0.1867855 0.3371123 0.573850


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         18  34
n_event       12  23
n_event_pct   67  68

$Disdur_less_equal_12wk$`Infections and infestations`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.014705882 0.2045587  0.6795470 1.5151683 0.9431055
OR_TRTvsCTRL  1.045454545 0.6199898  0.3101479 3.5240449 0.9428426
ARR_TRTvsCTRL 0.009803922 0.1370499 -0.2588090 0.2784168 0.9429717


$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`
$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         18  34
n_event        3   3
n_event_pct   17   9

$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.7626922  0.11873776 2.3604692 0.4043523
OR_TRTvsCTRL   0.48387097 0.8749808  0.08708524 2.6885280 0.4067308
ARR_TRTvsCTRL -0.07843137 0.1004103 -0.27523187 0.1183691 0.4347383
```

```
$Disdur_less_equal_12wk$Investigations
$Disdur_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         18  34
n_event        5   4
n_event_pct   28  12

$Disdur_less_equal_12wk$Investigations$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4235294 0.6041793  0.12960005 1.38408246 0.1550314
OR_TRTvsCTRL   0.3466667 0.7485028  0.07994391 1.50327628 0.1569666
ARR_TRTvsCTRL -0.1601307 0.1191576 -0.39367529 0.07341385 0.1789947


$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`
$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        5   3
n_event_pct   28   9

$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3176471 0.6696014  0.08550256 1.18007761 0.08677102
OR_TRTvsCTRL   0.2516129 0.8015700  0.05229200 1.21068325 0.08516902
ARR_TRTvsCTRL -0.1895425 0.1162393 -0.41736734 0.03828237 0.10296989


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event       14  20
n_event_pct   78  59

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7563025 0.1909483  0.5201877 1.09959063 0.1435298
OR_TRTvsCTRL   0.4081633 0.6654751  0.1107594 1.50413691 0.1781288
ARR_TRTvsCTRL -0.1895425 0.1293296 -0.4430239 0.06393892 0.1427636




\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten oder schweren UE nach SOC, das bei
mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
```

```
n_all         32  72
n_event        7  11
n_event_pct   22  15

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.69841270 0.43431250  0.2981430 1.63606139 0.4085390
OR_TRTvsCTRL   0.64402810 0.53866472  0.2240746 1.85104534 0.4140092
ARR_TRTvsCTRL -0.06597222 0.08448851 -0.2315667 0.09962222 0.4348951


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        9  19
n_event_pct   28  26

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93827160 0.34438903  0.4777317 1.8427781 0.8532203
OR_TRTvsCTRL   0.91614256 0.47548804  0.3607671 2.3264794 0.8538592
ARR_TRTvsCTRL -0.01736111 0.09494776 -0.2034553 0.1687331 0.8549164


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         32  72
n_event        8  24
n_event_pct   25  33

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.33333333 0.34860834  0.6732909 2.6404302 0.4092410
OR_TRTvsCTRL  1.50000000 0.47871355  0.5869614 3.8333015 0.3970013
ARR_TRTvsCTRL 0.08333333 0.09458221 -0.1020444 0.2687111 0.3782812


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         32  72
n_event       17  53
n_event_pct   53  74

$Ageonset_less_equal_12wk$`Infections and infestations`$stats
               estimate        se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.3856209 0.1804233 0.972899194 1.9734268 0.07065565
OR_TRTvsCTRL  2.4613003 0.4438352 1.031267627 5.8743231 0.04242431
ARR_TRTvsCTRL 0.2048611 0.1023715 0.004216691 0.4055055 0.04537579
```

```
$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         32  72
n_event        9  10
n_event_pct   28  14

$Ageonset_less_equal_12wk$Investigations$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.4938272 0.40739689  0.2222277 1.09736683 0.08329179
OR_TRTvsCTRL   0.4121864 0.52030607  0.1486649 1.14282298 0.08849673
ARR_TRTvsCTRL -0.1423611 0.08932095 -0.3174270 0.03270474 0.11097739


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       26  46
n_event_pct   81  64

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.7863248 0.12272644  0.6182114 1.000154064 0.05014691
OR_TRTvsCTRL   0.4082840 0.51510084  0.1487674 1.120513298 0.08202389
ARR_TRTvsCTRL -0.1736111 0.08924711 -0.3485322 0.001310003 0.05174061



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        3  10
n_event_pct   13  22

$Disdur_greater_12wk$`Cardiac disorders`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.66666667 0.60672559  0.50746137 5.4738704 0.3998224
OR_TRTvsCTRL  1.85185185 0.71492035  0.45610510 7.5187829 0.3887454
ARR_TRTvsCTRL 0.08695652 0.09289726 -0.09511876 0.2690318 0.3492472


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        7  13
n_event_pct   30  28

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats
```

```
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92857143 0.3931448  0.4297045 2.0065998 0.8504844
OR_TRTvsCTRL   0.90043290 0.5590915  0.3009898 2.6937101 0.8511985
ARR_TRTvsCTRL -0.02173913 0.1166732 -0.2504144 0.2069362 0.8521900


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         23  46
n_event        7  14
n_event_pct   30  30

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats
              estimate        se     lo95ci   hi95ci pvalue
RR_TRTvsCTRL         1 0.3860937  0.4691983 2.131295      1
OR_TRTvsCTRL         1 0.5550097  0.3369573 2.967735      1
ARR_TRTvsCTRL        0 0.1175068 -0.2303090 0.230309      1


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         23  46
n_event       10  33
n_event_pct   43  72

$Disdur_greater_12wk$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  1.6500000 0.2551189 1.00075177 2.7204548 0.04965668
OR_TRTvsCTRL  3.3000000 0.5330565 1.16084828 9.3810709 0.02510603
ARR_TRTvsCTRL 0.2826087 0.1228497 0.04182768 0.5233897 0.02142317


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       18  30
n_event_pct   78  65

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8333333 0.1538554  0.6163917 1.1266285 0.2360101
OR_TRTvsCTRL   0.5208333 0.5927806  0.1629757 1.6644646 0.2711363
ARR_TRTvsCTRL -0.1304348 0.1110335 -0.3480564 0.0871868 0.2401011



$Agetrt_less_180d
$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
```

```
n_all         16  49
n_event        4  11
n_event_pct   25  22

$Agetrt_less_180d$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8979592 0.5079379  0.3318173 2.4300440 0.8321872
OR_TRTvsCTRL   0.8684211 0.6712363  0.2330091 3.2365904 0.8335293
ARR_TRTvsCTRL -0.0255102 0.1235787 -0.2677200 0.2166996 0.8364559


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         16  49
n_event        4  16
n_event_pct   25  33

$Agetrt_less_180d$`General disorders and administration site conditions`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.30612245 0.4791574  0.5106512 3.3407458 0.5772821
OR_TRTvsCTRL  1.45454545 0.6527912  0.4046415 5.2285851 0.5659768
ARR_TRTvsCTRL 0.07653061 0.1273054 -0.1729835 0.3260447 0.5477351


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         16  49
n_event       10  36
n_event_pct   62  73

$Agetrt_less_180d$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.1755102 0.2118245  0.7761061 1.7804580 0.4452377
OR_TRTvsCTRL  1.6615385 0.6093993  0.5032558 5.4856997 0.4047389
ARR_TRTvsCTRL 0.1096939 0.1364785 -0.1577990 0.3771868 0.4215443


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event       13  28
n_event_pct   81  57

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci       hi95ci     pvalue
RR_TRTvsCTRL   0.7032967 0.1724216  0.50161795  0.986061703 0.04121395
OR_TRTvsCTRL   0.3076923 0.7025594  0.07764205  1.219372242 0.09341373
ARR_TRTvsCTRL -0.2410714 0.1204965 -0.47724019 -0.004902666 0.04542999
```

```
$Gender_Female
$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        6  10
n_event_pct   25  23

$Gender_Female$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93023256 0.4491594  0.3857148 2.2434517 0.8720829
OR_TRTvsCTRL   0.90909091 0.5937384  0.2839333 2.9107059 0.8724671
ARR_TRTvsCTRL -0.01744186 0.1093759 -0.2318146 0.1969309 0.8733008


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         24  43
n_event        9  13
n_event_pct   38  30

$Gender_Female$`General disorders and administration site conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.80620155 0.3508728  0.4053033 1.6036407 0.5392424
OR_TRTvsCTRL   0.72222222 0.5366882  0.2522557 2.0677624 0.5442805
ARR_TRTvsCTRL -0.07267442 0.1211233 -0.3100717 0.1647229 0.5485038


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$ntab
            CTRL TRT
n_all         24  43
n_event       12  29
n_event_pct   50  67

$Gender_Female$`Infections and infestations`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3488372 0.2299861  0.85939932 2.1170157 0.1932124
OR_TRTvsCTRL  2.0714286 0.5220900  0.74450244 5.7633341 0.1630604
ARR_TRTvsCTRL 0.1744186 0.1245919 -0.06977698 0.4186142 0.1615374


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       19  24
n_event_pct   79  56

$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.7050184 0.1713936  0.5038601  0.98648599 0.04141517
OR_TRTvsCTRL   0.3324100 0.5890075  0.1047876  1.05447947 0.06149744
```

```
ARR_TRTvsCTRL -0.2335271 0.1122829 -0.4535976 -0.01345668 0.03754294



$Region_Northamerica
$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        7  15
n_event_pct   32  39

$Region_Northamerica$`Gastrointestinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.24060150 0.3711516  0.5993873 2.5677757 0.5613180
OR_TRTvsCTRL  1.39751553 0.5653926  0.4614170 4.2327211 0.5538700
ARR_TRTvsCTRL 0.07655502 0.1270762 -0.1725098 0.3256198 0.5468854


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         22  38
n_event        4  15
n_event_pct   18  39

$Region_Northamerica$`General disorders and administration site
conditions`$stats
               estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.1710526 0.4948700  0.82306897  5.7267005 0.11723243
OR_TRTvsCTRL  2.9347826 0.6447484  0.82940207 10.3845279 0.09494896
ARR_TRTvsCTRL 0.2129187 0.1142331 -0.01097403  0.4368114 0.06233618


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$ntab
            CTRL TRT
n_all         22  38
n_event       14  30
n_event_pct   64  79

$Region_Northamerica$`Infections and infestations`$stats
              estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.240602 0.1816358  0.8690077 1.7710915 0.2352393
OR_TRTvsCTRL  2.142857 0.5956189  0.6668090 6.8862846 0.2006941
ARR_TRTvsCTRL 0.153110 0.1220337 -0.0860716 0.3922917 0.2096044


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       19  29
n_event_pct   86  76
```

```
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.8836565 0.1238709  0.6931774 1.12647768 0.3180301
OR_TRTvsCTRL   0.5087719 0.7290808  0.1218789 2.12382059 0.3539995
ARR_TRTvsCTRL -0.1004785 0.1005467 -0.2975464 0.09658947 0.3176391



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         25  31
n_event        8  10
n_event_pct   32  32

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.008064516 0.3908221  0.4686190 2.1684865 0.9836030
OR_TRTvsCTRL  1.011904762 0.5757105  0.3274115 3.1274135 0.9835996
ARR_TRTvsCTRL 0.002580645 0.1255114 -0.2434172 0.2485784 0.9835958


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         25  31
n_event       12  20
n_event_pct   48  65

$Agetrt_greater_equal_180d$`Infections and infestations`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3440860 0.2471341  0.82806824 2.1816647 0.2314727
OR_TRTvsCTRL  1.9696970 0.5487855  0.67185008 5.7746606 0.2167426
ARR_TRTvsCTRL 0.1651613 0.1317907 -0.09314368 0.4234663 0.2101296


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       19  22
n_event_pct   76  71

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93378608 0.1607111  0.6814749 1.2795137 0.6699039
OR_TRTvsCTRL   0.77192982 0.6130774  0.2321269 2.5670259 0.6728548
```

```
ARR_TRTvsCTRL -0.05032258 0.1180775 -0.2817503 0.1811051 0.6699748



$Gender_Male
$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  37
n_event        3  13
n_event_pct   18  35

$Gender_Male$`General disorders and administration site conditions`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.9909910 0.5695664  0.65200889  6.0797409 0.2266448
OR_TRTvsCTRL  2.5277778 0.7234305  0.61228519 10.4357586 0.1998898
ARR_TRTvsCTRL 0.1748808 0.1212778 -0.06281935  0.4125809 0.1493066


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  37
n_event       10  27
n_event_pct   59  73

$Gender_Male$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2405405 0.2262443  0.7962170 1.9328157 0.3407325
OR_TRTvsCTRL  1.8900000 0.6163556  0.5647016 6.3256420 0.3016939
ARR_TRTvsCTRL 0.1414944 0.1399225 -0.1327486 0.4157374 0.3119042


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event       13  26
n_event_pct   76  70

$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats
                   estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.91891892 0.1718548  0.6561364 1.2869457 0.6226994
OR_TRTvsCTRL   0.72727273 0.6754952  0.1935151 2.7332529 0.6373284
ARR_TRTvsCTRL -0.06200318 0.1273987 -0.3117000 0.1876936 0.6264807



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         18  34
```

```
n_event        5  12
n_event_pct   28  35

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats
               estimate        se     lo95ci    hi95ci   pvalue
RR_TRTvsCTRL  1.2705882 0.4453830  0.5307551 3.0416940 0.590788
OR_TRTvsCTRL  1.4181818 0.6369544  0.4069634 4.9420657 0.583342
ARR_TRTvsCTRL 0.0751634 0.1336498 -0.1867855 0.3371123 0.573850


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         18  34
n_event       12  23
n_event_pct   67  68

$Disdur_less_equal_12wk$`Infections and infestations`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.014705882 0.2045587  0.6795470 1.5151683 0.9431055
OR_TRTvsCTRL  1.045454545 0.6199898  0.3101479 3.5240449 0.9428426
ARR_TRTvsCTRL 0.009803922 0.1370499 -0.2588090 0.2784168 0.9429717


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event       14  20
n_event_pct   78  59

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.7563025 0.1909483  0.5201877 1.09959063 0.1435298
OR_TRTvsCTRL   0.4081633 0.6654751  0.1107594 1.50413691 0.1781288
ARR_TRTvsCTRL -0.1895425 0.1293296 -0.4430239 0.06393892 0.1427636



$Region_Europe
$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  30
n_event        8  19
n_event_pct   47  63

$Region_Europe$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.3458333 0.2923606  0.7588108 2.3869816 0.3096700
OR_TRTvsCTRL  1.9431818 0.6161589  0.5808153 6.5011298 0.2809559
ARR_TRTvsCTRL 0.1627451 0.1496521 -0.1305675 0.4560577 0.2768204
```

```
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event       12  19
n_event_pct   71  63

$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.89722222 0.2093037  0.5953061 1.3522584 0.6043503
OR_TRTvsCTRL   0.71969697 0.6533560  0.1999917 2.5899255 0.6146555
ARR_TRTvsCTRL -0.07254902 0.1412559 -0.3494056 0.2043075 0.6075318




\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten oder schweren UEs nach SOC, das bei
mindestens 10% der Patienten in einem Studienarm auftrat"

$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Blood and lymphatic system disorders`
$Ageonset_greater_12wk$`Blood and lymphatic system disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                 8
n_event                              1.0                 0
n_event_pct                         11.0                 0
time-to-event-wk-10th               43.1                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          43.1                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_greater_12wk$`Blood and lymphatic system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.245e-09 4.596e+04 0.000e+00       Inf 9.997e-01


$Ageonset_greater_12wk$`Cardiac disorders`
$Ageonset_greater_12wk$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                 8.0
n_event                              2.0                 3.0
n_event_pct                         22.0                38.0
time-to-event-wk-10th               23.0                 2.1
time-to-event-wk-25th               33.6                17.9
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci          23.0                 2.1
```

```
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  8.67900   1.19500   0.83460  90.27000   0.07051


$Ageonset_greater_12wk$`Gastrointestinal disorders`
$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               2.0                  0
n_event_pct                          22.0                  0
time-to-event-wk-10th                26.1                 NA
time-to-event-wk-25th                48.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.294e-09 3.381e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$`General disorders and administration site conditions`
$Ageonset_greater_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               4.0                2.0
n_event_pct                          44.0               25.0
time-to-event-wk-10th                 5.1                2.1
time-to-event-wk-25th                15.1               15.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.1                2.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7580    0.8904    0.1324    4.3410    0.7557


$Ageonset_greater_12wk$`Infections and infestations`
$Ageonset_greater_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               5.0                3.0
n_event_pct                          56.0               38.0
time-to-event-wk-10th                 5.7                4.0
```

```
time-to-event-wk-25th                19.3               15.7
time-to-event-wk-50th                28.3                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.7                4.0
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1470    0.7453    0.2663    4.9450    0.8536


$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`
$Ageonset_greater_12wk$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                1.0
n_event_pct                          11.0               12.0
time-to-event-wk-10th                50.6                3.3
time-to-event-wk-25th                55.5                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           50.6                3.3
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.442e+08 2.494e+04 0.000e+00       Inf 9.993e-01


$Ageonset_greater_12wk$Investigations
$Ageonset_greater_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                15.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Psychiatric disorders`
$Ageonset_greater_12wk$`Psychiatric disorders`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                1.0
n_event_pct                          11.0               12.0
time-to-event-wk-10th                50.4                2.1
time-to-event-wk-25th                53.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           50.4                2.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.6770    1.5250    0.1348   53.1800    0.5184


$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               6.0                4.0
n_event_pct                          67.0               50.0
time-to-event-wk-10th                 1.7                0.4
time-to-event-wk-25th                16.4                2.9
time-to-event-wk-50th                26.0               41.3
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.7                0.4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0350    0.6790    0.2735    3.9160    0.9598



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               7.0                11
n_event_pct                          22.0                15
time-to-event-wk-10th                11.1                12
time-to-event-wk-25th                29.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           29.4                NA
time-to-event-wk-50th-hici             NA                NA
```

```
$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5528    0.4875    0.2126    1.4370    0.2240


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              9.0              19.0
n_event_pct                         28.0              26.0
time-to-event-wk-10th               12.7               9.3
time-to-event-wk-25th               18.7              22.7
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          18.7                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6586    0.4146    0.2922    1.4840    0.3138


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              8.0              24.0
n_event_pct                         25.0              33.0
time-to-event-wk-10th                9.1               8.1
time-to-event-wk-25th               16.9              29.1
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          24.3              44.3
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0710    0.4115    0.4779    2.3980    0.8684


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                             17.0              53.0
n_event_pct                         53.0              74.0
time-to-event-wk-10th                3.1               2.7
time-to-event-wk-25th                8.6               5.9
time-to-event-wk-50th               17.6              15.4
```

```
time-to-event-wk-75th                  NA               34.7
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.7                9.4
time-to-event-wk-50th-hici           33.4               25.4

$Ageonset_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3780    0.2834    0.7907    2.4010    0.2580


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               9.0               10.0
n_event_pct                          28.0               14.0
time-to-event-wk-10th                10.1               18.3
time-to-event-wk-25th                20.3                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.36520   0.46540   0.14670   0.90920   0.03042


$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               7.0                8.0
n_event_pct                          22.0               11.0
time-to-event-wk-10th                 7.7               45.6
time-to-event-wk-25th                22.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Metabolism and nutrition
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.35970   0.52350   0.12890   1.00300   0.05077


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
```

```
n_event                              26.0              46.0
n_event_pct                          81.0              64.0
time-to-event-wk-10th                 0.7               1.7
time-to-event-wk-25th                 3.6               5.4
time-to-event-wk-50th                 8.6              15.6
time-to-event-wk-75th                15.7                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            4.6              11.0
time-to-event-wk-50th-hici           13.0              32.1

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.58680   0.25190   0.35820   0.96140   0.03432



$Agetrt_less_180d
$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               5.0               7.0
n_event_pct                          31.0              14.0
time-to-event-wk-10th                 9.4               8.4
time-to-event-wk-25th                15.1                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           14.3                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33130   0.60280   0.10170   1.08000   0.06686


$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               4.0              11.0
n_event_pct                          25.0              22.0
time-to-event-wk-10th                13.6              13.0
time-to-event-wk-25th                15.3              45.9
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5857    0.5923    0.1834    1.8700    0.3664
```

```
$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               4.0              16.0
n_event_pct                          25.0              33.0
time-to-event-wk-10th                 4.4               8.1
time-to-event-wk-25th                11.7              25.9
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           11.7              41.4
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0130    0.5654    0.3346    3.0700    0.9811


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                              10.0              36.0
n_event_pct                          62.0              73.0
time-to-event-wk-10th                 6.3               2.7
time-to-event-wk-25th                 8.6               6.7
time-to-event-wk-50th                13.9              15.7
time-to-event-wk-75th                33.4              34.7
time-to-event-wk-90th                  NA              43.6
time-to-event-wk-50th-loci            6.7               9.3
time-to-event-wk-50th-hici           33.4              25.4

$Agetrt_less_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1200    0.3613    0.5514    2.2730    0.7545


$Agetrt_less_180d$`Injury, poisoning and procedural complications`
$Agetrt_less_180d$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 3
n_event_pct                          12.0                 6
time-to-event-wk-10th                47.1                NA
time-to-event-wk-25th                47.1                NA
time-to-event-wk-50th                47.1                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           47.1                NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33990   0.94170   0.05367   2.15200   0.25180


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               5.0                 5
n_event_pct                          31.0                10
time-to-event-wk-10th                10.1                29
time-to-event-wk-25th                20.3                NA
time-to-event-wk-50th                40.7                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.9                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.179400  0.663400  0.048870  0.658300  0.009595


$Agetrt_less_180d$`Metabolism and nutrition disorders`
$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               6.0                 7
n_event_pct                          38.0                14
time-to-event-wk-10th                 2.6                 6
time-to-event-wk-25th                 9.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            9.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29690   0.56340   0.09839   0.89570   0.03112


$Agetrt_less_180d$`Psychiatric disorders`
$Agetrt_less_180d$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                11.1                NA
time-to-event-wk-25th                  NA                NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.167e-10 1.899e+04 0.000e+00       Inf 9.991e-01


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                              13.0              28.0
n_event_pct                          81.0              57.0
time-to-event-wk-10th                 0.7               1.7
time-to-event-wk-25th                 4.1               5.0
time-to-event-wk-50th                 9.0              23.1
time-to-event-wk-75th                15.7                NA
time-to-event-wk-90th                22.4                NA
time-to-event-wk-50th-loci            2.1              11.3
time-to-event-wk-50th-hici           15.7                NA

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39420   0.35650   0.19600   0.79280   0.00902



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Cardiac disorders`
$Agetrt_greater_equal_180d$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0              31.0
n_event                               4.0               7.0
n_event_pct                          16.0              23.0
time-to-event-wk-10th                23.0               7.3
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4100    0.6454    0.3979    4.9940    0.5946


$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               7.0                8.0
n_event_pct                          28.0               26.0
time-to-event-wk-10th                18.9                6.9
time-to-event-wk-25th                26.1               20.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7751    0.5282    0.2752    2.1830    0.6296


$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               8.0               10.0
n_event_pct                          32.0               32.0
time-to-event-wk-10th                 7.6                6.9
time-to-event-wk-25th                16.9               36.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.9               36.0
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8788    0.4784    0.3440    2.2440    0.7871


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              12.0               20.0
n_event_pct                          48.0               65.0
time-to-event-wk-10th                 3.1                3.4
time-to-event-wk-25th                12.3                6.9
time-to-event-wk-50th                28.3               16.3
time-to-event-wk-75th                  NA               35.9
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.3                7.0
time-to-event-wk-50th-hici             NA               30.7

$Agetrt_greater_equal_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4690    0.3675    0.7149    3.0190    0.2952


$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`
$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                              1.0               4.0
n_event_pct                          4.0              13.0
time-to-event-wk-10th                 NA              41.4
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          50.6              51.1
time-to-event-wk-50th-hici            NA                NA

$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   5.3950    1.1720    0.5425   53.6500    0.1504


$Agetrt_greater_equal_180d$Investigations
$Agetrt_greater_equal_180d$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                              5.0               5.0
n_event_pct                         20.0              16.0
time-to-event-wk-10th               15.9               8.1
time-to-event-wk-25th               46.6                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          46.6                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_greater_equal_180d$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7809    0.6387    0.2233    2.7310    0.6986


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                             19.0              22.0
n_event_pct                         76.0              71.0
time-to-event-wk-10th                1.7               0.4
time-to-event-wk-25th                4.6               5.1
time-to-event-wk-50th               15.7              11.6
```

```
time-to-event-wk-75th                30.3                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.1                6.9
time-to-event-wk-50th-hici           26.0               25.4

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8961    0.3147    0.4837    1.6600    0.7275



$Gender_Male
$Gender_Male$`Cardiac disorders`
$Gender_Male$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               6.0                7.0
n_event_pct                          35.0               19.0
time-to-event-wk-10th                 9.4                6.6
time-to-event-wk-25th                15.1                 NA
time-to-event-wk-50th                33.6                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           14.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5364    0.5690    0.1759    1.6360    0.2736


$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               5.0                9.0
n_event_pct                          29.0               24.0
time-to-event-wk-10th                12.7                8.1
time-to-event-wk-25th                18.7               21.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7711    0.5627    0.2559    2.3230    0.6442


$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                17.0              37.0
n_event                               3.0              13.0
n_event_pct                          18.0              35.0
time-to-event-wk-10th                11.7               6.9
time-to-event-wk-25th                  NA              25.1
time-to-event-wk-50th                  NA              55.0
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA              25.9
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.1280    0.6496    0.5958    7.6020    0.2450


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                              10.0              27.0
n_event_pct                          59.0              73.0
time-to-event-wk-10th                 2.1               1.7
time-to-event-wk-25th                11.7               4.7
time-to-event-wk-50th                22.6              15.7
time-to-event-wk-75th                33.4              30.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           11.7               6.7
time-to-event-wk-50th-hici           33.4              18.0

$Gender_Male$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4750    0.3721    0.7113    3.0580    0.2963


$Gender_Male$`Injury, poisoning and procedural complications`
$Gender_Male$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                37
n_event                                 1                 4
n_event_pct                             6                11
time-to-event-wk-10th                  NA                36
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Injury, poisoning and procedural complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6020    1.1390    0.1719   14.9400    0.6790
```

```
$Gender_Male$Investigations
$Gender_Male$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              37.0
n_event                              5.0               5.0
n_event_pct                         29.0              14.0
time-to-event-wk-10th                2.0              23.3
time-to-event-wk-25th               20.3                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          17.9                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.34390   0.64340   0.09745   1.21400   0.09710


$Gender_Male$`Metabolism and nutrition disorders`
$Gender_Male$`Metabolism and nutrition disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              37.0
n_event                              5.0               4.0
n_event_pct                         29.0              11.0
time-to-event-wk-10th                5.9              13.9
time-to-event-wk-25th               17.9                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          17.9                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3871    0.6823    0.1017    1.4740    0.1643


$Gender_Male$`Musculoskeletal and connective tissue disorders`
$Gender_Male$`Musculoskeletal and connective tissue disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                37
n_event                              2.0                 2
n_event_pct                         12.0                 5
time-to-event-wk-10th               43.4                63
time-to-event-wk-25th               43.4                63
time-to-event-wk-50th                 NA                63
time-to-event-wk-75th                 NA                63
time-to-event-wk-90th                 NA                63
time-to-event-wk-50th-loci          43.4                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Musculoskeletal and connective tissue
```

```
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.20040   1.27200   0.01656   2.42400   0.20630


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                              13.0              26.0
n_event_pct                          76.0              70.0
time-to-event-wk-10th                 0.6               0.6
time-to-event-wk-25th                 1.7               2.7
time-to-event-wk-50th                15.7              11.3
time-to-event-wk-75th                22.4                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            0.9               4.7
time-to-event-wk-50th-hici           22.4              23.1

$Gender_Male$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8699    0.3443    0.4430    1.7080    0.6857



$Gender_Female
$Gender_Female$`Cardiac disorders`
$Gender_Female$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                               3.0               7.0
n_event_pct                          12.0              16.0
time-to-event-wk-10th                13.9              12.9
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4070    0.7030    0.3547    5.5810    0.6272


$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                               6.0              10.0
n_event_pct                          25.0              23.0
time-to-event-wk-10th                15.3              11.7
time-to-event-wk-25th                26.1              45.9
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8015    0.5292    0.2841    2.2610    0.6759


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               9.0               13.0
n_event_pct                          38.0               30.0
time-to-event-wk-10th                 5.1               10.4
time-to-event-wk-25th                15.1               36.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.1               44.3
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6289    0.4568    0.2569    1.5390    0.3099


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              12.0               29.0
n_event_pct                          50.0               67.0
time-to-event-wk-10th                 5.7                3.4
time-to-event-wk-25th                 8.6                8.1
time-to-event-wk-50th                19.3               25.1
time-to-event-wk-75th                  NA               34.7
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.6               10.7
time-to-event-wk-50th-hici             NA               31.1

$Gender_Female$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3870    0.3559    0.6906    2.7870    0.3576


$Gender_Female$Investigations
$Gender_Female$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
```

```
n_event                                5.0                5.0
n_event_pct                           21.0               12.0
time-to-event-wk-10th                 13.9               25.4
time-to-event-wk-25th                 40.7                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            40.7                 NA
time-to-event-wk-50th-hici              NA                 NA

$Gender_Female$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4176    0.6488    0.1171    1.4890    0.1783


$Gender_Female$`Psychiatric disorders`
$Gender_Female$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43
n_event                               3.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                50.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           50.4                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.754e-10 1.650e+04 0.000e+00       Inf 9.989e-01


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              19.0               24.0
n_event_pct                          79.0               56.0
time-to-event-wk-10th                 2.9                4.1
time-to-event-wk-25th                 4.9                9.6
time-to-event-wk-50th                 9.1               20.3
time-to-event-wk-75th                26.0                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.1               12.3
time-to-event-wk-50th-hici           15.7                 NA

$Gender_Female$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6073    0.3229    0.3225    1.1440    0.1225
```

```
$Region_Europe
$Region_Europe$`Cardiac disorders`
$Region_Europe$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                30
n_event                                1                 5
n_event_pct                            6                17
time-to-event-wk-10th                 NA                12
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.4700    1.1040    0.2837   21.5100    0.4128


$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                30
n_event                              4.0                 1
n_event_pct                         24.0                 3
time-to-event-wk-10th               15.3                NA
time-to-event-wk-25th               26.1                NA
time-to-event-wk-50th               48.6                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          15.3                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.057610  1.207000  0.005407  0.613800  0.018060


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                              7.0                9.0
n_event_pct                         41.0               30.0
time-to-event-wk-10th                2.3                6.9
time-to-event-wk-25th               15.1               23.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           9.1               25.9
time-to-event-wk-50th-hici            NA                 NA
```

```
$Region_Europe$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5749    0.5148    0.2096    1.5770    0.2823


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               8.0              19.0
n_event_pct                          47.0              63.0
time-to-event-wk-10th                 6.3               2.9
time-to-event-wk-25th                11.9               6.7
time-to-event-wk-50th                22.6              15.7
time-to-event-wk-75th                  NA              35.9
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.7               7.0
time-to-event-wk-50th-hici             NA              35.9

$Region_Europe$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5440    0.4409    0.6505    3.6630    0.3248


$Region_Europe$Investigations
$Region_Europe$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               2.0               3.0
n_event_pct                          12.0              10.0
time-to-event-wk-10th                40.7              25.4
time-to-event-wk-25th                40.7                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6961    0.9245    0.1137    4.2620    0.6952


$Region_Europe$`Metabolism and nutrition disorders`
$Region_Europe$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               2.0               5.0
n_event_pct                          12.0              17.0
time-to-event-wk-10th                 5.9               4.4
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9520    0.8642    0.1750    5.1800    0.9546


$Region_Europe$`Psychiatric disorders`
$Region_Europe$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               3.0                 0
n_event_pct                          18.0                 0
time-to-event-wk-10th                11.1                NA
time-to-event-wk-25th                50.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           50.4                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.610e-10 2.592e+04 0.000e+00       Inf 9.993e-01


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                              12.0               19.0
n_event_pct                          71.0               63.0
time-to-event-wk-10th                 2.1                0.9
time-to-event-wk-25th                 6.3                5.7
time-to-event-wk-50th                13.0               11.6
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.1                8.6
time-to-event-wk-50th-hici           30.3                 NA

$Region_Europe$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0110    0.3891    0.4715    2.1670    0.9778



$Region_Asia_Pacific
$Region_Asia_Pacific$`Cardiac disorders`
$Region_Asia_Pacific$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
```

```
n_event                                0               2.0
n_event_pct                            0              17.0
time-to-event-wk-10th                 NA               8.4
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA               8.4
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.343e+07 2.340e+04 0.000e+00       Inf 9.994e-01


$Region_Asia_Pacific$`Gastrointestinal disorders`
$Region_Asia_Pacific$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  2              12.0
n_event                                0               3.0
n_event_pct                            0              25.0
time-to-event-wk-10th                 NA               9.3
time-to-event-wk-25th                 NA              39.8
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA               9.3
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.972e+07 2.715e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$`General disorders and administration site conditions`
$Region_Asia_Pacific$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0              12.0
n_event                              1.0               2.0
n_event_pct                         50.0              17.0
time-to-event-wk-10th                7.6               8.1
time-to-event-wk-25th                7.6                NA
time-to-event-wk-50th                7.6                NA
time-to-event-wk-75th                7.6                NA
time-to-event-wk-90th                7.6                NA
time-to-event-wk-50th-loci            NA               8.1
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.224e-08 1.320e+01 7.079e-20 2.116e+03 1.676e-01
```

```
$Region_Asia_Pacific$`Infections and infestations`
$Region_Asia_Pacific$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  2              12.0
n_event                                0               7.0
n_event_pct                            0              58.0
time-to-event-wk-10th                 NA               4.3
time-to-event-wk-25th                 NA              16.8
time-to-event-wk-50th                 NA              31.1
time-to-event-wk-75th                 NA              43.6
time-to-event-wk-90th                 NA              43.6
time-to-event-wk-50th-loci            NA               4.3
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.853e+08 1.327e+04 0.000e+00       Inf 9.988e-01


$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`
$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0              12.0
n_event                              1.0               2.0
n_event_pct                         50.0              17.0
time-to-event-wk-10th                0.9              12.3
time-to-event-wk-25th                0.9                NA
time-to-event-wk-50th               25.1                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           0.9              12.3
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.125100  1.466000  0.007071  2.215000  0.156300



$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 22              38.0
n_event                                8               7.0
n_event_pct                           36              18.0
time-to-event-wk-10th                 13.9             7.3
time-to-event-wk-25th                 15.1              NA
time-to-event-wk-50th                 33.6              NA
time-to-event-wk-75th                   NA              NA
time-to-event-wk-90th                   NA              NA
time-to-event-wk-50th-loci            15.1              NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40340   0.52490   0.14420   1.12900   0.08371


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               7.0              15.0
n_event_pct                          32.0              39.0
time-to-event-wk-10th                11.6               6.9
time-to-event-wk-25th                18.9              16.4
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           18.9              20.1
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0750    0.4616    0.4351    2.6580    0.8749


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               4.0              15.0
n_event_pct                          18.0              39.0
time-to-event-wk-10th                13.4               7.6
time-to-event-wk-25th                  NA              36.0
time-to-event-wk-50th                  NA              54.3
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA              38.6
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.1670    0.5641    0.7173    6.5470    0.1704


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              14.0              30.0
n_event_pct                          64.0              79.0
time-to-event-wk-10th                 2.4               2.7
```

```
time-to-event-wk-25th                 8.6                5.0
time-to-event-wk-50th                19.3               14.4
time-to-event-wk-75th                33.4               28.3
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           8.6                7.1
time-to-event-wk-50th-hici           33.4               25.4

$Region_Northamerica$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2730    0.3255    0.6726    2.4090    0.4584


$Region_Northamerica$`Injury, poisoning and procedural complications`
$Region_Northamerica$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               2.0                5.0
n_event_pct                           9.0               13.0
time-to-event-wk-10th                50.6               41.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           50.6                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2240    0.8507    0.2309    6.4830    0.8125


$Region_Northamerica$Investigations
$Region_Northamerica$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               8.0                6.0
n_event_pct                          36.0               16.0
time-to-event-wk-10th                13.9               18.3
time-to-event-wk-25th                17.9                 NA
time-to-event-wk-50th                46.6                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32510   0.54490   0.11170   0.94600   0.03922


$Region_Northamerica$`Metabolism and nutrition disorders`
$Region_Northamerica$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                22.0              38.0
n_event                               5.0               3.0
n_event_pct                          23.0               8.0
time-to-event-wk-10th                13.0              45.6
time-to-event-wk-25th                22.9                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.9                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29560   0.73410   0.07011   1.24600   0.09690


$Region_Northamerica$`Musculoskeletal and connective tissue disorders`
$Region_Northamerica$`Musculoskeletal and connective tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               3.0               3.0
n_event_pct                          14.0               8.0
time-to-event-wk-10th                43.4              43.1
time-to-event-wk-25th                46.9                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           43.4                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Musculoskeletal and connective tissue
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47040   0.81720   0.09481   2.33300   0.35600


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              19.0              29.0
n_event_pct                          86.0              76.0
time-to-event-wk-10th                 0.7               0.6
time-to-event-wk-25th                 3.1               3.6
time-to-event-wk-50th                 8.6              12.5
time-to-event-wk-75th                17.9              32.7
time-to-event-wk-90th                26.0                NA
time-to-event-wk-50th-loci            3.1               4.7
time-to-event-wk-50th-hici           15.7              25.4

$Region_Northamerica$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.58890   0.30830   0.32180   1.07800   0.08593
```

```
$Region_Northamerica$`Skin and subcutaneous tissue disorders`
$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               3.0               3.0
n_event_pct                          14.0               8.0
time-to-event-wk-10th                31.4              49.1
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           53.9                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5222    0.8194    0.1048    2.6020    0.4279



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               3.0              10.0
n_event_pct                          13.0              22.0
time-to-event-wk-10th                13.9               8.1
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4630    0.6596    0.4015    5.3280    0.5644


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               7.0              13.0
n_event_pct                          30.0              28.0
time-to-event-wk-10th                 9.7               6.9
time-to-event-wk-25th                19.9              16.4
time-to-event-wk-50th                48.6                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           19.9                NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7917    0.4734    0.3130    2.0020    0.6217


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               7.0              14.0
n_event_pct                          30.0              30.0
time-to-event-wk-10th                 5.1               6.9
time-to-event-wk-25th                15.1              36.0
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.1              38.6
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8479    0.4711    0.3368    2.1350    0.7262


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                              10.0              33.0
n_event_pct                          43.0              72.0
time-to-event-wk-10th                 3.1               2.0
time-to-event-wk-25th                 7.1               6.9
time-to-event-wk-50th                28.3              15.4
time-to-event-wk-75th                  NA              35.9
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            7.1               9.0
time-to-event-wk-50th-hici             NA              25.4

$Disdur_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7470    0.3673    0.8504    3.5890    0.1288


$Disdur_greater_12wk$Investigations
$Disdur_greater_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               5.0               6.0
n_event_pct                          22.0              13.0
time-to-event-wk-10th                13.9              13.4
```

```
time-to-event-wk-25th                46.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           18.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5740    0.6094    0.1739    1.8950    0.3624


$Disdur_greater_12wk$`Metabolism and nutrition disorders`
$Disdur_greater_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 2                5.0
n_event_pct                             9               11.0
time-to-event-wk-10th                  13               45.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0840    0.8397    0.2091    5.6210    0.9233


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              18.0               30.0
n_event_pct                          78.0               65.0
time-to-event-wk-10th                 0.9                1.7
time-to-event-wk-25th                 3.1                5.1
time-to-event-wk-50th                 9.1               12.3
time-to-event-wk-75th                27.0                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            4.0                8.6
time-to-event-wk-50th-hici           26.0               25.4

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7848    0.3037    0.4328    1.4230    0.4250



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Cardiac disorders`
```

```
$Disdur_less_equal_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               6.0                 4
n_event_pct                          33.0                12
time-to-event-wk-10th                 9.4                35
time-to-event-wk-25th                23.0                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           23.0                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.28690   0.65820   0.07897   1.04200   0.05785


$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               4.0                6.0
n_event_pct                          22.0               18.0
time-to-event-wk-10th                13.6               21.4
time-to-event-wk-25th                18.7               45.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           18.7               45.9
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4128    0.6685    0.1113    1.5300    0.1856


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               5.0               12.0
n_event_pct                          28.0               35.0
time-to-event-wk-10th                 7.6               10.4
time-to-event-wk-25th                23.0               25.9
time-to-event-wk-50th                  NA               54.3
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           23.0               41.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1170    0.5401    0.3877    3.2210    0.8372


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                              12.0              23.0
n_event_pct                          67.0              68.0
time-to-event-wk-10th                 6.3               3.1
time-to-event-wk-25th                11.7               6.7
time-to-event-wk-50th                22.6              15.7
time-to-event-wk-75th                33.4              34.7
time-to-event-wk-90th                  NA              35.4
time-to-event-wk-50th-loci            8.7              10.7
time-to-event-wk-50th-hici           33.4              31.1

$Disdur_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2700    0.3816    0.6011    2.6830    0.5313


$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`
$Disdur_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               3.0                 3
n_event_pct                          17.0                 9
time-to-event-wk-10th                47.1                36
time-to-event-wk-25th                47.1                NA
time-to-event-wk-50th                50.6                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           47.1                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.2767    0.8770    0.0496    1.5430    0.1429


$Disdur_less_equal_12wk$Investigations
$Disdur_less_equal_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                               5.0               4.0
n_event_pct                          28.0              12.0
time-to-event-wk-10th                15.9              25.4
time-to-event-wk-25th                20.3                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32740   0.68040   0.08627   1.24200   0.10080


$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`
$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               5.0                  3
n_event_pct                          28.0                  9
time-to-event-wk-10th                 2.6                 NA
time-to-event-wk-25th                22.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24930   0.73370   0.05920   1.05000   0.05834


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
n_event                              14.0                20.0
n_event_pct                          78.0                59.0
time-to-event-wk-10th                 0.7                 1.0
time-to-event-wk-25th                 6.1                 4.7
time-to-event-wk-50th                11.7                23.1
time-to-event-wk-75th                17.9                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            6.1                 8.6
time-to-event-wk-50th-hici           17.9                  NA

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6296    0.3623    0.3095    1.2810    0.2016




\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten oder schweren UEs nach SOC, das bei
```

```
mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               7.0                11
n_event_pct                          22.0                15
time-to-event-wk-10th                11.1                12
time-to-event-wk-25th                29.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           29.4                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5528    0.4875    0.2126    1.4370    0.2240


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               9.0              19.0
n_event_pct                          28.0              26.0
time-to-event-wk-10th                12.7               9.3
time-to-event-wk-25th                18.7              22.7
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           18.7                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6586    0.4146    0.2922    1.4840    0.3138


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               8.0              24.0
n_event_pct                          25.0              33.0
time-to-event-wk-10th                 9.1               8.1
time-to-event-wk-25th                16.9              29.1
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           24.3              44.3
```

```
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0710    0.4115    0.4779    2.3980    0.8684


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              17.0              53.0
n_event_pct                          53.0              74.0
time-to-event-wk-10th                 3.1               2.7
time-to-event-wk-25th                 8.6               5.9
time-to-event-wk-50th                17.6              15.4
time-to-event-wk-75th                  NA              34.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            8.7               9.4
time-to-event-wk-50th-hici           33.4              25.4

$Ageonset_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3780    0.2834    0.7907    2.4010    0.2580


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               9.0              10.0
n_event_pct                          28.0              14.0
time-to-event-wk-10th                10.1              18.3
time-to-event-wk-25th                20.3                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           20.3                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.36520   0.46540   0.14670   0.90920   0.03042


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              26.0              46.0
n_event_pct                          81.0              64.0
time-to-event-wk-10th                 0.7               1.7
```

```
time-to-event-wk-25th                3.6               5.4
time-to-event-wk-50th                8.6              15.6
time-to-event-wk-75th               15.7                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           4.6              11.0
time-to-event-wk-50th-hici          13.0              32.1

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.58680   0.25190   0.35820   0.96140   0.03432



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               3.0              10.0
n_event_pct                          13.0              22.0
time-to-event-wk-10th                13.9               8.1
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4630    0.6596    0.4015    5.3280    0.5644


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               7.0              13.0
n_event_pct                          30.0              28.0
time-to-event-wk-10th                 9.7               6.9
time-to-event-wk-25th                19.9              16.4
time-to-event-wk-50th                48.6                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           19.9                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7917    0.4734    0.3130    2.0020    0.6217


$Disdur_greater_12wk$`General disorders and administration site conditions`
```

$Disdur_greater_12wk$`General disorders and administration site conditions`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	23.0	46.0
n_event	7.0	14.0
n_event_pct	30.0	30.0
time-to-event-wk-10th	5.1	6.9
time-to-event-wk-25th	15.1	36.0
time-to-event-wk-50th	NA	NA
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	15.1	38.6
time-to-event-wk-50th-hici	NA	NA

$Disdur_greater_12wk$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.8479	0.4711	0.3368	2.1350	0.7262

$Disdur_greater_12wk$`Infections and infestations`

$Disdur_greater_12wk$`Infections and infestations`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	23.0	46.0
n_event	10.0	33.0
n_event_pct	43.0	72.0
time-to-event-wk-10th	3.1	2.0
time-to-event-wk-25th	7.1	6.9
time-to-event-wk-50th	28.3	15.4
time-to-event-wk-75th	NA	35.9
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	7.1	9.0
time-to-event-wk-50th-hici	NA	25.4

$Disdur_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
1.7470	0.3673	0.8504	3.5890	0.1288

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	23.0	46.0
n_event	18.0	30.0
n_event_pct	78.0	65.0
time-to-event-wk-10th	0.9	1.7
time-to-event-wk-25th	3.1	5.1
time-to-event-wk-50th	9.1	12.3
time-to-event-wk-75th	27.0	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	4.0	8.6
time-to-event-wk-50th-hici	26.0	25.4

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal

```
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7848    0.3037    0.4328    1.4230    0.4250



$Agetrt_less_180d
$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               4.0              11.0
n_event_pct                          25.0              22.0
time-to-event-wk-10th                13.6              13.0
time-to-event-wk-25th                15.3              45.9
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5857    0.5923    0.1834    1.8700    0.3664


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               4.0              16.0
n_event_pct                          25.0              33.0
time-to-event-wk-10th                 4.4               8.1
time-to-event-wk-25th                11.7              25.9
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           11.7              41.4
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0130    0.5654    0.3346    3.0700    0.9811


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                              10.0              36.0
n_event_pct                          62.0              73.0
time-to-event-wk-10th                 6.3               2.7
```

```
time-to-event-wk-25th                 8.6                6.7
time-to-event-wk-50th                13.9               15.7
time-to-event-wk-75th                33.4               34.7
time-to-event-wk-90th                  NA               43.6
time-to-event-wk-50th-loci            6.7                9.3
time-to-event-wk-50th-hici           33.4               25.4

$Agetrt_less_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1200    0.3613    0.5514    2.2730    0.7545


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                              13.0               28.0
n_event_pct                          81.0               57.0
time-to-event-wk-10th                 0.7                1.7
time-to-event-wk-25th                 4.1                5.0
time-to-event-wk-50th                 9.0               23.1
time-to-event-wk-75th                15.7                 NA
time-to-event-wk-90th                22.4                 NA
time-to-event-wk-50th-loci            2.1               11.3
time-to-event-wk-50th-hici           15.7                 NA

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39420   0.35650   0.19600   0.79280   0.00902



$Gender_Female
$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               6.0               10.0
n_event_pct                          25.0               23.0
time-to-event-wk-10th                15.3               11.7
time-to-event-wk-25th                26.1               45.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8015    0.5292    0.2841    2.2610    0.6759


$Gender_Female$`General disorders and administration site conditions`
```

```
$Gender_Female$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                               9.0              13.0
n_event_pct                          38.0              30.0
time-to-event-wk-10th                 5.1              10.4
time-to-event-wk-25th                15.1              36.0
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.1              44.3
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6289    0.4568    0.2569    1.5390    0.3099


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              12.0              29.0
n_event_pct                          50.0              67.0
time-to-event-wk-10th                 5.7               3.4
time-to-event-wk-25th                 8.6               8.1
time-to-event-wk-50th                19.3              25.1
time-to-event-wk-75th                  NA              34.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            8.6              10.7
time-to-event-wk-50th-hici             NA              31.1

$Gender_Female$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3870    0.3559    0.6906    2.7870    0.3576


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              19.0              24.0
n_event_pct                          79.0              56.0
time-to-event-wk-10th                 2.9               4.1
time-to-event-wk-25th                 4.9               9.6
time-to-event-wk-50th                 9.1              20.3
time-to-event-wk-75th                26.0                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            5.1              12.3
time-to-event-wk-50th-hici           15.7                NA

$Gender_Female$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6073    0.3229    0.3225    1.1440    0.1225



$Region_Northamerica
$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               7.0              15.0
n_event_pct                          32.0              39.0
time-to-event-wk-10th                11.6               6.9
time-to-event-wk-25th                18.9              16.4
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           18.9              20.1
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0750    0.4616    0.4351    2.6580    0.8749


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               4.0              15.0
n_event_pct                          18.0              39.0
time-to-event-wk-10th                13.4               7.6
time-to-event-wk-25th                  NA              36.0
time-to-event-wk-50th                  NA              54.3
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA              38.6
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.1670    0.5641    0.7173    6.5470    0.1704


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              14.0              30.0
n_event_pct                          64.0              79.0
time-to-event-wk-10th                 2.4               2.7
time-to-event-wk-25th                 8.6               5.0
```

```
time-to-event-wk-50th                19.3               14.4
time-to-event-wk-75th                33.4               28.3
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.6                7.1
time-to-event-wk-50th-hici           33.4               25.4

$Region_Northamerica$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2730    0.3255    0.6726    2.4090    0.4584


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              19.0               29.0
n_event_pct                          86.0               76.0
time-to-event-wk-10th                 0.7                0.6
time-to-event-wk-25th                 3.1                3.6
time-to-event-wk-50th                 8.6               12.5
time-to-event-wk-75th                17.9               32.7
time-to-event-wk-90th                26.0                 NA
time-to-event-wk-50th-loci            3.1                4.7
time-to-event-wk-50th-hici           15.7               25.4

$Region_Northamerica$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.58890   0.30830   0.32180   1.07800   0.08593



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               8.0               10.0
n_event_pct                          32.0               32.0
time-to-event-wk-10th                 7.6                6.9
time-to-event-wk-25th                16.9               36.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.9               36.0
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8788    0.4784    0.3440    2.2440    0.7871
```

```
$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0              31.0
n_event                              12.0              20.0
n_event_pct                          48.0              65.0
time-to-event-wk-10th                 3.1               3.4
time-to-event-wk-25th                12.3               6.9
time-to-event-wk-50th                28.3              16.3
time-to-event-wk-75th                  NA              35.9
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.3               7.0
time-to-event-wk-50th-hici             NA              30.7

$Agetrt_greater_equal_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4690    0.3675    0.7149    3.0190    0.2952


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0              31.0
n_event                              19.0              22.0
n_event_pct                          76.0              71.0
time-to-event-wk-10th                 1.7               0.4
time-to-event-wk-25th                 4.6               5.1
time-to-event-wk-50th                15.7              11.6
time-to-event-wk-75th                30.3                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            5.1               6.9
time-to-event-wk-50th-hici           26.0              25.4

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8961    0.3147    0.4837    1.6600    0.7275



$Gender_Male
$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                               3.0              13.0
n_event_pct                          18.0              35.0
time-to-event-wk-10th                11.7               6.9
time-to-event-wk-25th                  NA              25.1
time-to-event-wk-50th                  NA              55.0
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
```

```
time-to-event-wk-50th-loci             NA               25.9
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.1280    0.6496    0.5958    7.6020    0.2450


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                              10.0              27.0
n_event_pct                          59.0              73.0
time-to-event-wk-10th                 2.1               1.7
time-to-event-wk-25th                11.7               4.7
time-to-event-wk-50th                22.6              15.7
time-to-event-wk-75th                33.4              30.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           11.7               6.7
time-to-event-wk-50th-hici           33.4              18.0

$Gender_Male$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4750    0.3721    0.7113    3.0580    0.2963


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                              13.0              26.0
n_event_pct                          76.0              70.0
time-to-event-wk-10th                 0.6               0.6
time-to-event-wk-25th                 1.7               2.7
time-to-event-wk-50th                15.7              11.3
time-to-event-wk-75th                22.4                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            0.9               4.7
time-to-event-wk-50th-hici           22.4              23.1

$Gender_Male$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8699    0.3443    0.4430    1.7080    0.6857



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                18.0              34.0
n_event                               5.0              12.0
n_event_pct                          28.0              35.0
time-to-event-wk-10th                 7.6              10.4
time-to-event-wk-25th                23.0              25.9
time-to-event-wk-50th                  NA              54.3
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           23.0              41.4
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1170    0.5401    0.3877    3.2210    0.8372


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                              12.0              23.0
n_event_pct                          67.0              68.0
time-to-event-wk-10th                 6.3               3.1
time-to-event-wk-25th                11.7               6.7
time-to-event-wk-50th                22.6              15.7
time-to-event-wk-75th                33.4              34.7
time-to-event-wk-90th                  NA              35.4
time-to-event-wk-50th-loci            8.7              10.7
time-to-event-wk-50th-hici           33.4              31.1

$Disdur_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2700    0.3816    0.6011    2.6830    0.5313


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                              14.0              20.0
n_event_pct                          78.0              59.0
time-to-event-wk-10th                 0.7               1.0
time-to-event-wk-25th                 6.1               4.7
time-to-event-wk-50th                11.7              23.1
time-to-event-wk-75th                17.9                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.1               8.6
time-to-event-wk-50th-hici           17.9                NA

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.6296    0.3623    0.3095    1.2810    0.2016


$Region_Europe
$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              30.0
n_event                              8.0              19.0
n_event_pct                         47.0              63.0
time-to-event-wk-10th                6.3               2.9
time-to-event-wk-25th               11.9               6.7
time-to-event-wk-50th               22.6              15.7
time-to-event-wk-75th                 NA              35.9
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           6.7               7.0
time-to-event-wk-50th-hici            NA              35.9

$Region_Europe$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5440    0.4409    0.6505    3.6630    0.3248


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              30.0
n_event                             12.0              19.0
n_event_pct                         71.0              63.0
time-to-event-wk-10th                2.1               0.9
time-to-event-wk-25th                6.3               5.7
time-to-event-wk-50th               13.0              11.6
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           6.1               8.6
time-to-event-wk-50th-hici          30.3                NA

$Region_Europe$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0110    0.3891    0.4715    2.1670    0.9778




\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten oder schweren UE nach PT, das bei
mindestens 10% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$ntab
```

```
            CTRL TRT
n_all         32  72
n_event        7  10
n_event_pct   22  14

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.63492063 0.44465521  0.2656001 1.5177863 0.3069750
OR_TRTvsCTRL   0.57603687 0.54679628  0.1972497 1.6822251 0.3130920
ARR_TRTvsCTRL -0.07986111 0.08367598 -0.2438630 0.0841408 0.3398767


$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         32  72
n_event       10  15
n_event_pct   31  21

$Ageonset_less_equal_12wk$Atelectasis$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6666667 0.34860834  0.3366455 1.32021512 0.2447904
OR_TRTvsCTRL   0.5789474 0.47923384  0.2263156 1.48102936 0.2540976
ARR_TRTvsCTRL -0.1041667 0.09489241 -0.2901524 0.08181904 0.2723205


$Ageonset_less_equal_12wk$`Bronchial secretion retention`
$Ageonset_less_equal_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         32  72
n_event        6   3
n_event_pct   19   4

$Ageonset_less_equal_12wk$`Bronchial secretion retention`$stats
                estimate         se      lo95ci       hi95ci     pvalue
RR_TRTvsCTRL   0.2222222 0.67443392  0.05925272  0.833425298 0.02573861
OR_TRTvsCTRL   0.1884058 0.74360896  0.04386652  0.809199042 0.02478929
ARR_TRTvsCTRL -0.1458333 0.07290633 -0.28872712 -0.002939548 0.04546966


$Ageonset_less_equal_12wk$Dysphagia
$Ageonset_less_equal_12wk$Dysphagia$ntab
            CTRL TRT
n_all         32  72
n_event        6   6
n_event_pct   19   8

$Ageonset_less_equal_12wk$Dysphagia$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4444444 0.53683745  0.1551889 1.2728416 0.1308982
OR_TRTvsCTRL   0.3939394 0.62205015  0.1163964 1.3332741 0.1342473
ARR_TRTvsCTRL -0.1041667 0.07630006 -0.2537120 0.0453787 0.1721827
```

```
$Ageonset_less_equal_12wk$Dyspnoea
$Ageonset_less_equal_12wk$Dyspnoea$ntab
            CTRL TRT
n_all         32  72
n_event        5   3
n_event_pct   16   4

$Ageonset_less_equal_12wk$Dyspnoea$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2666667 0.69870913  0.06779949 1.04884429 0.05852948
OR_TRTvsCTRL   0.2347826 0.76476344  0.05244428 1.05107510 0.05811518
ARR_TRTvsCTRL -0.1145833 0.06837005 -0.24858617 0.01941951 0.09375216


$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         32  72
n_event        7   8
n_event_pct   22  11

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5079365 0.47193035  0.2014195 1.28090603 0.1511792
OR_TRTvsCTRL   0.4464286 0.56875491  0.1464289 1.36105926 0.1562003
ARR_TRTvsCTRL -0.1076389 0.08192874 -0.2682163 0.05293849 0.1889098


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$ntab
            CTRL TRT
n_all         32  72
n_event        5  20
n_event_pct   16  28

$Ageonset_less_equal_12wk$Pneumonia$stats
                estimate        se      lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.7777778 0.4526159  0.73216702 4.316630 0.2036584
OR_TRTvsCTRL  2.0769231 0.5534147  0.70202566 6.144518 0.1866058
ARR_TRTvsCTRL 0.1215278 0.0831037 -0.04135247 0.284408 0.1436417


$Ageonset_less_equal_12wk$`Pneumonia aspiration`
$Ageonset_less_equal_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         32  72
n_event        5   8
n_event_pct   16  11

$Ageonset_less_equal_12wk$`Pneumonia aspiration`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.71111111 0.52901901  0.2521365 2.0055766 0.5192833
OR_TRTvsCTRL   0.67500000 0.61454214  0.2023972 2.2511425 0.5224523
ARR_TRTvsCTRL -0.04513889 0.07410543 -0.1903829 0.1001051 0.5424468
```

```
$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         32  72
n_event        6  20
n_event_pct   19  28

$Ageonset_less_equal_12wk$Pyrexia$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.48148148 0.41415912  0.65790524 3.3360236 0.3426138
OR_TRTvsCTRL  1.66666667 0.52379287  0.59702903 4.6526679 0.3294395
ARR_TRTvsCTRL 0.09027778 0.08687401 -0.07999215 0.2605477 0.2987208


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         32  72
n_event        9  19
n_event_pct   28  26

$Ageonset_less_equal_12wk$`Respiratory distress`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93827160 0.34438903  0.4777317 1.8427781 0.8532203
OR_TRTvsCTRL   0.91614256 0.47548804  0.3607671 2.3264794 0.8538592
ARR_TRTvsCTRL -0.01736111 0.09494776 -0.2034553 0.1687331 0.8549164


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event       15  17
n_event_pct   47  24

$Ageonset_less_equal_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.5037037 0.2834631  0.2889954  0.87792889 0.01555269
OR_TRTvsCTRL   0.3503030 0.4499950  0.1450132  0.84621433 0.01975122
ARR_TRTvsCTRL -0.2326389 0.1014249 -0.4314281 -0.03384965 0.02180746


$Ageonset_less_equal_12wk$`Rhinovirus infection`
$Ageonset_less_equal_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         32  72
n_event        4   9
n_event_pct   12  12

$Ageonset_less_equal_12wk$`Rhinovirus infection`$stats
              estimate         se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.56211407  0.3322979 3.0093476      1
```

```
OR_TRTvsCTRL         1 0.64241607  0.2839059 3.5222936      1
ARR_TRTvsCTRL        0 0.07026426 -0.1377154 0.1377154      1


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        4  14
n_event_pct   12  19

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.55555556 0.52563265  0.55522141 4.3581768 0.4005870
OR_TRTvsCTRL  1.68965517 0.61186946  0.50930021 5.6056027 0.3913073
ARR_TRTvsCTRL 0.06944444 0.07478948 -0.07714024 0.2160291 0.3531315


$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        6   6
n_event_pct   19   8

$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4444444 0.53683745  0.1551889 1.2728416 0.1308982
OR_TRTvsCTRL   0.3939394 0.62205015  0.1163964 1.3332741 0.1342473
ARR_TRTvsCTRL -0.1041667 0.07630006 -0.2537120 0.0453787 0.1721827



$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Acute respiratory failure`
$Ageonset_greater_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Acute respiratory failure`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$Anxiety
$Ageonset_greater_12wk$Anxiety$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12
```

```
$Ageonset_greater_12wk$Anxiety$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Bone marrow disorder`
$Ageonset_greater_12wk$`Bone marrow disorder`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Bone marrow disorder`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Bronchial secretion retention`
$Ageonset_greater_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Bronchial secretion retention`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Candida sepsis`
$Ageonset_greater_12wk$`Candida sepsis`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Candida sepsis`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Cardio-respiratory arrest`
$Ageonset_greater_12wk$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all          9   8
```

```
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Cardio-respiratory arrest`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$Catarrh
$Ageonset_greater_12wk$Catarrh$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Catarrh$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Cyanosis
$Ageonset_greater_12wk$Cyanosis$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Cyanosis$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$Dysphagia
$Ageonset_greater_12wk$Dysphagia$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Dysphagia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Femur fracture`
$Ageonset_greater_12wk$`Femur fracture`$ntab
```

```
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Femur fracture`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`
$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Infusion site bruising`
$Ageonset_greater_12wk$`Infusion site bruising`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Infusion site bruising`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Nasal congestion`
$Ageonset_greater_12wk$`Nasal congestion`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Nasal congestion`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444
```

```
$Ageonset_greater_12wk$Nasopharyngitis
$Ageonset_greater_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$Nasopharyngitis$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031


$Ageonset_greater_12wk$Oedema
$Ageonset_greater_12wk$Oedema$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$Oedema$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Pain
$Ageonset_greater_12wk$Pain$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Pain$stats
               estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$Pneumonia
$Ageonset_greater_12wk$Pneumonia$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$Pneumonia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031
```

```
$Ageonset_greater_12wk$`Pneumonia aspiration`
$Ageonset_greater_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0

$Ageonset_greater_12wk$`Pneumonia aspiration`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`
$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Pneumonia pseudomonal`
$Ageonset_greater_12wk$`Pneumonia pseudomonal`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Pneumonia pseudomonal`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Procedural pain`
$Ageonset_greater_12wk$`Procedural pain`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Procedural pain`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
```

```
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Pseudomonas infection`
$Ageonset_greater_12wk$`Pseudomonas infection`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Pseudomonas infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Pyrexia
$Ageonset_greater_12wk$Pyrexia$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$Pyrexia$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$`Respiratory arrest`
$Ageonset_greater_12wk$`Respiratory arrest`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Respiratory arrest`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Respiratory distress`
$Ageonset_greater_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Respiratory distress`$stats
```

```
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$`Respiratory failure`
$Ageonset_greater_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all          9   8
n_event        1   2
n_event_pct   11  25

$Ageonset_greater_12wk$`Respiratory failure`$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2500000 1.1242281  0.2484493 20.3763897 0.4707116
OR_TRTvsCTRL  2.6666667 1.3385315  0.1934678 36.7560505 0.4637017
ARR_TRTvsCTRL 0.1388889 0.1855032 -0.2246907  0.5024685 0.4540295


$Ageonset_greater_12wk$`Respirovirus test positive`
$Ageonset_greater_12wk$`Respirovirus test positive`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Respirovirus test positive`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Rhinovirus infection`
$Ageonset_greater_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Rhinovirus infection`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Salivary hypersecretion`
$Ageonset_greater_12wk$`Salivary hypersecretion`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0
```

```
$Ageonset_greater_12wk$`Salivary hypersecretion`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Sleep disorder`
$Ageonset_greater_12wk$`Sleep disorder`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Sleep disorder`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Tachycardia
$Ageonset_greater_12wk$Tachycardia$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$Tachycardia$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Upper respiratory tract congestion`
$Ageonset_greater_12wk$`Upper respiratory tract congestion`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Upper respiratory tract congestion`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Upper respiratory tract infection`
$Ageonset_greater_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all          9   8
```

```
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Upper respiratory tract infection`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Viral upper respiratory tract infection`
$Ageonset_greater_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Viral upper respiratory tract infection`$stats
               estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494



$Agetrt_less_180d
$Agetrt_less_180d$`Acute respiratory failure`
$Agetrt_less_180d$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         16  49
n_event        4   7
n_event_pct   25  14

$Agetrt_less_180d$`Acute respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5714286 0.5567306  0.1918987 1.7015782 0.3148091
OR_TRTvsCTRL   0.5000000 0.7071068  0.1250488 1.9992191 0.3269587
ARR_TRTvsCTRL -0.1071429 0.1192380 -0.3408451 0.1265594 0.3688856


$Agetrt_less_180d$Apnoea
$Agetrt_less_180d$Apnoea$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$Apnoea$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718
```

```
$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$ntab
            CTRL TRT
n_all         16  49
n_event        4  10
n_event_pct   25  20

$Agetrt_less_180d$Atelectasis$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.81632653 0.5168093  0.2964525 2.2478782 0.6945556
OR_TRTvsCTRL   0.76923077 0.6774765  0.2038861 2.9021888 0.6985586
ARR_TRTvsCTRL -0.04591837 0.1226120 -0.2862334 0.1943967 0.7080312


$Agetrt_less_180d$`Bronchial secretion retention`
$Agetrt_less_180d$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         16  49
n_event        3   3
n_event_pct   19   6

$Agetrt_less_180d$`Bronchial secretion retention`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3265306 0.7640409  0.07304174 1.4597440 0.1429525
OR_TRTvsCTRL   0.2826087 0.8748308  0.05087779 1.5697946 0.1485987
ARR_TRTvsCTRL -0.1262755 0.1034140 -0.32896332 0.0764123 0.2220605


$Agetrt_less_180d$`Cardio-respiratory arrest`
$Agetrt_less_180d$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$`Cardio-respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156


$Agetrt_less_180d$`Corona virus infection`
$Agetrt_less_180d$`Corona virus infection`$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$`Corona virus infection`$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002
```

```
$Agetrt_less_180d$Cyanosis
$Agetrt_less_180d$Cyanosis$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$Cyanosis$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$Dysphagia
$Agetrt_less_180d$Dysphagia$ntab
            CTRL TRT
n_all         16  49
n_event        2   5
n_event_pct   12  10

$Agetrt_less_180d$Dysphagia$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.81632653 0.78555193  0.1750656 3.8065096 0.7961432
OR_TRTvsCTRL   0.79545455 0.89115422  0.1386959 4.5621254 0.7973391
ARR_TRTvsCTRL -0.02295918 0.09330545 -0.2058345 0.1599161 0.8056321


$Agetrt_less_180d$Dyspnoea
$Agetrt_less_180d$Dyspnoea$ntab
            CTRL TRT
n_all         16  49
n_event        3   1
n_event_pct   19   2

$Agetrt_less_180d$Dyspnoea$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.10884354 1.11822411  0.012160979 0.97417446 0.04732694
OR_TRTvsCTRL   0.09027778 1.19628163  0.008655738 0.94158088 0.04440131
ARR_TRTvsCTRL -0.16709184 0.09964676 -0.362395906 0.02821223 0.09357347


$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`
$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
```

```
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718


$Agetrt_less_180d$Hypokalaemia
$Agetrt_less_180d$Hypokalaemia$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$Hypokalaemia$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$Hypoxia
$Agetrt_less_180d$Hypoxia$ntab
            CTRL TRT
n_all         16  49
n_event        2   2
n_event_pct   12   4

$Agetrt_less_180d$Hypoxia$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 0.95764912  0.04997715 2.13341975 0.2425131
OR_TRTvsCTRL   0.29787234 1.04532539  0.03839261 2.31106820 0.2466285
ARR_TRTvsCTRL -0.08418367 0.08737805 -0.25544151 0.08707417 0.3353258


$Agetrt_less_180d$Nasopharyngitis
$Agetrt_less_180d$Nasopharyngitis$ntab
            CTRL TRT
n_all         16  49
n_event        0   5
n_event_pct    0  10

$Agetrt_less_180d$Nasopharyngitis$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.7400000 1.45017056 0.21801390 64.1592119 0.36302969
OR_TRTvsCTRL  4.0786517 1.50495719 0.21354762 77.9001876 0.35025713
ARR_TRTvsCTRL 0.1020408 0.04324314 0.01728582  0.1867958 0.01828974


$Agetrt_less_180d$`Oxygen saturation decreased`
$Agetrt_less_180d$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         16  49
n_event        4   4
n_event_pct   25   8

$Agetrt_less_180d$`Oxygen saturation decreased`$stats
```

```
               estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3265306 0.6458265  0.09208638 1.15785025 0.08309174
OR_TRTvsCTRL   0.2666667 0.7781745  0.05802102 1.22560936 0.08940702
ARR_TRTvsCTRL -0.1683673 0.1151031 -0.39396529 0.05723059 0.14353513


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$ntab
            CTRL TRT
n_all         16  49
n_event        3  13
n_event_pct   19  27

$Agetrt_less_180d$Pneumonia$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.41496599 0.5721436  0.4610378 4.3426565 0.5440663
OR_TRTvsCTRL  1.56481481 0.7176052  0.3833860 6.3868928 0.5326442
ARR_TRTvsCTRL 0.07780612 0.1161870 -0.1499162 0.3055285 0.5030727


$Agetrt_less_180d$`Pneumonia aspiration`
$Agetrt_less_180d$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         16  49
n_event        2   5
n_event_pct   12  10

$Agetrt_less_180d$`Pneumonia aspiration`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.81632653 0.78555193  0.1750656 3.8065096 0.7961432
OR_TRTvsCTRL   0.79545455 0.89115422  0.1386959 4.5621254 0.7973391
ARR_TRTvsCTRL -0.02295918 0.09330545 -0.2058345 0.1599161 0.8056321


$Agetrt_less_180d$`Pneumonia bacterial`
$Agetrt_less_180d$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         16  49
n_event        2   2
n_event_pct   12   4

$Agetrt_less_180d$`Pneumonia bacterial`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 0.95764912  0.04997715 2.13341975 0.2425131
OR_TRTvsCTRL   0.29787234 1.04532539  0.03839261 2.31106820 0.2466285
ARR_TRTvsCTRL -0.08418367 0.08737805 -0.25544151 0.08707417 0.3353258


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$ntab
            CTRL TRT
n_all         16  49
n_event        2  13
n_event_pct   12  27
```

```
$Agetrt_less_180d$Pyrexia$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.1224490 0.7028619  0.53525420  8.4161687 0.2842939
OR_TRTvsCTRL  2.5277778 0.8222709  0.50445292 12.6665152 0.2594129
ARR_TRTvsCTRL 0.1403061 0.1039898 -0.06351008  0.3441223 0.1772631


$Agetrt_less_180d$`Respiratory arrest`
$Agetrt_less_180d$`Respiratory arrest`$ntab
            CTRL TRT
n_all         16  49
n_event        2   2
n_event_pct   12   4

$Agetrt_less_180d$`Respiratory arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 0.95764912  0.04997715 2.13341975 0.2425131
OR_TRTvsCTRL   0.29787234 1.04532539  0.03839261 2.31106820 0.2466285
ARR_TRTvsCTRL -0.08418367 0.08737805 -0.25544151 0.08707417 0.3353258


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$ntab
            CTRL TRT
n_all         16  49
n_event        3  13
n_event_pct   19  27

$Agetrt_less_180d$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.41496599 0.5721436  0.4610378 4.3426565 0.5440663
OR_TRTvsCTRL  1.56481481 0.7176052  0.3833860 6.3868928 0.5326442
ARR_TRTvsCTRL 0.07780612 0.1161870 -0.1499162 0.3055285 0.5030727


$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$ntab
            CTRL TRT
n_all         16  49
n_event        9  11
n_event_pct   56  22

$Agetrt_less_180d$`Respiratory failure`$stats
                estimate        se      lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   0.3990930 0.3451261  0.20290941  0.78495718 0.007778818
OR_TRTvsCTRL   0.2251462 0.6092562  0.06821263  0.74312941 0.014394896
ARR_TRTvsCTRL -0.3380102 0.1376001 -0.60770154 -0.06831887 0.014031074


$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`
$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         16  49
```

```
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718


$Agetrt_less_180d$`Respiratory tract infection`
$Agetrt_less_180d$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         16  49
n_event        1   5
n_event_pct    6  10

$Agetrt_less_180d$`Respiratory tract infection`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.63265306 1.05692565  0.2057014 12.9583783 0.6427882
OR_TRTvsCTRL  1.70454545 1.13551483  0.1841012 15.7819465 0.6386026
ARR_TRTvsCTRL 0.03954082 0.07437794 -0.1062373  0.1853189 0.5949891


$Agetrt_less_180d$`Rhinovirus infection`
$Agetrt_less_180d$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         16  49
n_event        2   4
n_event_pct   12   8

$Agetrt_less_180d$`Rhinovirus infection`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 0.81675690  0.1317435 3.2372678 0.6018943
OR_TRTvsCTRL   0.62222222 0.91850465  0.1028284 3.7651137 0.6054670
ARR_TRTvsCTRL -0.04336735 0.09146536 -0.2226362 0.1359015 0.6354004


$Agetrt_less_180d$`Sleep apnoea syndrome`
$Agetrt_less_180d$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all         16  49
n_event        2   0
n_event_pct   12   0

$Agetrt_less_180d$`Sleep apnoea syndrome`$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.06800000 1.52354077  0.003432959 1.34694284 0.07765226
OR_TRTvsCTRL   0.05858586 1.57770959  0.002659769 1.29045134 0.07212278
ARR_TRTvsCTRL -0.12500000 0.08267973 -0.287049290 0.03704929 0.13057002


$Agetrt_less_180d$`Upper respiratory tract infection`
$Agetrt_less_180d$`Upper respiratory tract infection`$ntab
```

```
            CTRL TRT
n_all         16  49
n_event        2   7
n_event_pct   12  14

$Agetrt_less_180d$`Upper respiratory tract infection`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14285714 0.74829739  0.2636575 4.9538612 0.8583720
OR_TRTvsCTRL  1.16666667 0.85912469  0.2166000 6.2839838 0.8576020
ARR_TRTvsCTRL 0.01785714 0.09661727 -0.1715092 0.2072235 0.8533675


$Agetrt_less_180d$`Viral upper respiratory tract infection`
$Agetrt_less_180d$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         16  49
n_event        2   4
n_event_pct   12   8

$Agetrt_less_180d$`Viral upper respiratory tract infection`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 0.81675690  0.1317435 3.2372678 0.6018943
OR_TRTvsCTRL   0.62222222 0.91850465  0.1028284 3.7651137 0.6054670
ARR_TRTvsCTRL -0.04336735 0.09146536 -0.2226362 0.1359015 0.6354004



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Acute respiratory failure`
$Agetrt_greater_equal_180d$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         25  31
n_event        5   4
n_event_pct   20  13

$Agetrt_greater_equal_180d$`Acute respiratory failure`$stats
                  estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.64516129 0.6146071  0.1934255 2.151904 0.4758054
OR_TRTvsCTRL   0.59259259 0.7328281  0.1409197 2.491958 0.4752197
ARR_TRTvsCTRL -0.07096774 0.1001262 -0.2672115 0.125276 0.4784592


$Agetrt_greater_equal_180d$Atelectasis
$Agetrt_greater_equal_180d$Atelectasis$ntab
            CTRL TRT
n_all         25  31
n_event        6   5
n_event_pct   24  16

$Agetrt_greater_equal_180d$Atelectasis$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.67204301 0.5425943  0.2320278 1.9464990 0.4638830
OR_TRTvsCTRL   0.60897436 0.6765795  0.1616939 2.2935304 0.4635166
ARR_TRTvsCTRL -0.07870968 0.1079802 -0.2903471 0.1329277 0.4660466
```

```
$Agetrt_greater_equal_180d$`Bronchial secretion retention`
$Agetrt_greater_equal_180d$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         25  31
n_event        4   0
n_event_pct   16   0

$Agetrt_greater_equal_180d$`Bronchial secretion retention`$stats
                  estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.09027778 1.46714372  0.005090329  1.60109041 0.10118269
OR_TRTvsCTRL   0.07583774 1.51673329  0.003880071  1.48228296 0.08904259
ARR_TRTvsCTRL -0.16000000 0.07332121 -0.303706933 -0.01629307 0.02909633


$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`
$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         25  31
n_event        3   4
n_event_pct   12  13

$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.075268817 0.71489529  0.2648482 4.3655304 0.9191438
OR_TRTvsCTRL  1.086419753 0.81598095  0.2194994 5.3772707 0.9190897
ARR_TRTvsCTRL 0.009032258 0.08859603 -0.1646128 0.1826773 0.9187973


$Agetrt_greater_equal_180d$Dysphagia
$Agetrt_greater_equal_180d$Dysphagia$ntab
            CTRL TRT
n_all         25  31
n_event        5   1
n_event_pct   20   3

$Agetrt_greater_equal_180d$Dysphagia$stats
                 estimate         se      lo95ci       hi95ci     pvalue
RR_TRTvsCTRL   0.1612903 1.06195195  0.02012209 1.2928360263 0.08577672
OR_TRTvsCTRL   0.1333333 1.13284303  0.01447641 1.2280511976 0.07530125
ARR_TRTvsCTRL -0.1677419 0.08606402 -0.33642432 0.0009404441 0.05129104


$Agetrt_greater_equal_180d$`Lower respiratory tract infection`
$Agetrt_greater_equal_180d$`Lower respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        0   4
n_event_pct    0  13

$Agetrt_greater_equal_180d$`Lower respiratory tract infection`$stats
               estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  7.3125000 1.4671437 0.41231666 129.6883230 0.17506917
```

```
OR_TRTvsCTRL  8.3454545 1.5158501 0.42771654 162.8335705 0.16160680
ARR_TRTvsCTRL 0.1290323 0.0602101 0.01102263   0.2470419 0.03211041


$Agetrt_greater_equal_180d$`Oxygen saturation decreased`
$Agetrt_greater_equal_180d$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         25  31
n_event        3   4
n_event_pct   12  13

$Agetrt_greater_equal_180d$`Oxygen saturation decreased`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.075268817 0.71489529  0.2648482 4.3655304 0.9191438
OR_TRTvsCTRL  1.086419753 0.81598095  0.2194994 5.3772707 0.9190897
ARR_TRTvsCTRL 0.009032258 0.08859603 -0.1646128 0.1826773 0.9187973


$Agetrt_greater_equal_180d$Pneumonia
$Agetrt_greater_equal_180d$Pneumonia$ntab
            CTRL TRT
n_all         25  31
n_event        3   8
n_event_pct   12  26

$Agetrt_greater_equal_180d$Pneumonia$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.1505376 0.6213496  0.63628744  7.2684323 0.2178197
OR_TRTvsCTRL  2.5507246 0.7397744  0.59836541 10.8732826 0.2055987
ARR_TRTvsCTRL 0.1380645 0.1019822 -0.06181685  0.3379459 0.1757969


$Agetrt_greater_equal_180d$`Pneumonia aspiration`
$Agetrt_greater_equal_180d$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         25  31
n_event        5   3
n_event_pct   20  10

$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4838710 0.67902523  0.12786222 1.83112036 0.2850305
OR_TRTvsCTRL   0.4285714 0.78679579  0.09168566 2.00329546 0.2815264
ARR_TRTvsCTRL -0.1032258 0.09601897 -0.29141954 0.08496793 0.2823495


$Agetrt_greater_equal_180d$`Pneumonia viral`
$Agetrt_greater_equal_180d$`Pneumonia viral`$ntab
            CTRL TRT
n_all         25  31
n_event        2   4
n_event_pct    8  13

$Agetrt_greater_equal_180d$`Pneumonia viral`$stats
```

```
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.61290323 0.82325083  0.3212595  8.0976815 0.5614639
OR_TRTvsCTRL  1.70370370 0.91132612  0.2855432 10.1652080 0.5587848
ARR_TRTvsCTRL 0.04903226 0.08105095 -0.1098247  0.2078892 0.5452082


$Agetrt_greater_equal_180d$Pyrexia
$Agetrt_greater_equal_180d$Pyrexia$ntab
            CTRL TRT
n_all         25  31
n_event        6   8
n_event_pct   24  26

$Agetrt_greater_equal_180d$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.07526882 0.4684107  0.4293437 2.6929543 0.8768768
OR_TRTvsCTRL  1.10144928 0.6227170  0.3250175 3.7326924 0.8766875
ARR_TRTvsCTRL 0.01806452 0.1160705 -0.2094295 0.2455585 0.8763215


$Agetrt_greater_equal_180d$`Respiratory distress`
$Agetrt_greater_equal_180d$`Respiratory distress`$ntab
            CTRL TRT
n_all         25  31
n_event        8   7
n_event_pct   32  23

$Agetrt_greater_equal_180d$`Respiratory distress`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.70564516 0.4422658  0.2965712 1.6789731 0.4305152
OR_TRTvsCTRL   0.61979167 0.6069163  0.1886417 2.0363564 0.4305793
ARR_TRTvsCTRL -0.09419355 0.1197635 -0.3289256 0.1405385 0.4315766


$Agetrt_greater_equal_180d$`Respiratory failure`
$Agetrt_greater_equal_180d$`Respiratory failure`$ntab
            CTRL TRT
n_all         25  31
n_event        7   8
n_event_pct   28  26

$Agetrt_greater_equal_180d$`Respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92165899 0.4422658  0.3873583 2.1929445 0.8536533
OR_TRTvsCTRL   0.89440994 0.6057152  0.2728669 2.9317192 0.8538328
ARR_TRTvsCTRL -0.02193548 0.1193330 -0.2558238 0.2119529 0.8541567


$Agetrt_greater_equal_180d$`Rhinovirus infection`
$Agetrt_greater_equal_180d$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         25  31
n_event        2   6
n_event_pct    8  19
```

```
$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.4193548 0.77097899  0.53387682 10.9637235 0.2518172
OR_TRTvsCTRL  2.7600000 0.86610907  0.50544709 15.0710136 0.2411271
ARR_TRTvsCTRL 0.1135484 0.08932568 -0.06152674  0.2886235 0.2036671


$Agetrt_greater_equal_180d$`Upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        3   7
n_event_pct   12  23

$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$stats
               estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.8817204 0.63555677  0.54146226 6.5394618 0.3198836
OR_TRTvsCTRL  2.1388889 0.75054093  0.49127722 9.3121470 0.3110675
ARR_TRTvsCTRL 0.1058065 0.09931408 -0.08884557 0.3004585 0.2867076


$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        4   3
n_event_pct   16  10

$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.60483871 0.71489529  0.1489771 2.4556109 0.4818622
OR_TRTvsCTRL   0.56250000 0.81649658  0.1135323 2.7869275 0.4810130
ARR_TRTvsCTRL -0.06322581 0.09052979 -0.2406609 0.1142093 0.4849285



$Gender_Male
$Gender_Male$`Acute respiratory failure`
$Gender_Male$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         17  37
n_event        4   5
n_event_pct   24  14

$Gender_Male$`Acute respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5743243 0.6034480  0.1759954 1.8741875 0.3581022
OR_TRTvsCTRL   0.5078125 0.7471098  0.1174255 2.1960611 0.3643966
ARR_TRTvsCTRL -0.1001590 0.1172302 -0.3299259 0.1296079 0.3928951


$Gender_Male$Aspiration
$Gender_Male$Aspiration$ntab
```

```
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$Aspiration$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$Atelectasis
$Gender_Male$Atelectasis$ntab
            CTRL TRT
n_all         17  37
n_event        5   4
n_event_pct   29  11

$Gender_Male$Atelectasis$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3675676 0.6034480  0.11263707 1.19948003 0.09720667
OR_TRTvsCTRL   0.2909091 0.7507572  0.06679003 1.26707690 0.10003881
ARR_TRTvsCTRL -0.1860095 0.1217311 -0.42459813 0.05257906 0.12650356


$Gender_Male$`Bronchial secretion retention`
$Gender_Male$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         17  37
n_event        4   3
n_event_pct   24   8

$Gender_Male$`Bronchial secretion retention`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3445946 0.7053246  0.08648386 1.37303573 0.1309181
OR_TRTvsCTRL   0.2867647 0.8304626  0.05631637 1.46021488 0.1325574
ARR_TRTvsCTRL -0.1542130 0.1122402 -0.37419981 0.06577374 0.1694556


$Gender_Male$`Cardio-respiratory arrest`
$Gender_Male$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         17  37
n_event        3   2
n_event_pct   18   5

$Gender_Male$`Cardio-respiratory arrest`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3063063 0.8645709  0.05626417 1.66755432 0.1711540
OR_TRTvsCTRL   0.2666667 0.9660918  0.04014486 1.77136292 0.1712660
ARR_TRTvsCTRL -0.1224165 0.0996529 -0.31773262 0.07289956 0.2192859
```

```
$Gender_Male$Cyanosis
$Gender_Male$Cyanosis$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$Cyanosis$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$Dysphagia
$Gender_Male$Dysphagia$ntab
            CTRL TRT
n_all         17  37
n_event        4   3
n_event_pct   24   8

$Gender_Male$Dysphagia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3445946 0.7053246  0.08648386 1.37303573 0.1309181
OR_TRTvsCTRL   0.2867647 0.8304626  0.05631637 1.46021488 0.1325574
ARR_TRTvsCTRL -0.1542130 0.1122402 -0.37419981 0.06577374 0.1694556


$Gender_Male$Dyspnoea
$Gender_Male$Dyspnoea$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$Dyspnoea$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839


$Gender_Male$Hypokalaemia
$Gender_Male$Hypokalaemia$ntab
            CTRL TRT
n_all         17  37
n_event        2   0
n_event_pct   12   0

$Gender_Male$Hypokalaemia$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09473684 1.52254020  0.004792149 1.87286930 0.1216602
OR_TRTvsCTRL   0.08266667 1.57834812  0.003748332 1.82315160 0.1142304
ARR_TRTvsCTRL -0.11764706 0.07814249 -0.270803525 0.03550941 0.1321839
```

```
$Gender_Male$Hypoxia
$Gender_Male$Hypoxia$ntab
            CTRL TRT
n_all         17  37
n_event        2   3
n_event_pct   12   8

$Gender_Male$Hypoxia$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.86457086  0.1265944 3.7519972 0.6667969
OR_TRTvsCTRL   0.66176471 0.96406004  0.1000217 4.3783754 0.6684793
ARR_TRTvsCTRL -0.03656598 0.09011076 -0.2131798 0.1400479 0.6848975


$Gender_Male$`Joint contracture`
$Gender_Male$`Joint contracture`$ntab
            CTRL TRT
n_all         17  37
n_event        2   1
n_event_pct   12   3

$Gender_Male$`Joint contracture`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22972973 1.18918016  0.02233496 2.36292091 0.2161383
OR_TRTvsCTRL   0.20833333 1.26271313  0.01753620 2.47503945 0.2141413
ARR_TRTvsCTRL -0.09062003 0.08256492 -0.25244431 0.07120425 0.2723963


$Gender_Male$Nasopharyngitis
$Gender_Male$Nasopharyngitis$ntab
            CTRL TRT
n_all         17  37
n_event        1   4
n_event_pct    6  11

$Gender_Male$Nasopharyngitis$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.83783784 1.07895757  0.2217670 15.2306185 0.5727177
OR_TRTvsCTRL  1.93939394 1.15879378  0.2001239 18.7946001 0.5675877
ARR_TRTvsCTRL 0.04928458 0.07656783 -0.1007856  0.1993548 0.5197880


$Gender_Male$`Oxygen saturation decreased`
$Gender_Male$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         17  37
n_event        4   4
n_event_pct   24  11

$Gender_Male$`Oxygen saturation decreased`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.6435444  0.13015510 1.62193414 0.2268663
```

```
OR_TRTvsCTRL   0.3939394 0.7792471  0.08553287 1.81436969 0.2319076
ARR_TRTvsCTRL -0.1271860 0.1148483 -0.35228453 0.09791251 0.2681097


$Gender_Male$Pneumonia
$Gender_Male$Pneumonia$ntab
            CTRL TRT
n_all         17  37
n_event        3   7
n_event_pct   18  19

$Gender_Male$Pneumonia$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.0720721 0.6247719  0.3150773 3.6477980 0.9113072
OR_TRTvsCTRL  1.0888889 0.7622023  0.2444532 4.8503308 0.9110407
ARR_TRTvsCTRL 0.0127186 0.1126703 -0.2081112 0.2335484 0.9101231


$Gender_Male$`Pneumonia aspiration`
$Gender_Male$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         17  37
n_event        3   2
n_event_pct   18   5

$Gender_Male$`Pneumonia aspiration`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3063063 0.8645709  0.05626417 1.66755432 0.1711540
OR_TRTvsCTRL   0.2666667 0.9660918  0.04014486 1.77136292 0.1712660
ARR_TRTvsCTRL -0.1224165 0.0996529 -0.31773262 0.07289956 0.2192859


$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$ntab
            CTRL TRT
n_all         17  37
n_event        2  10
n_event_pct   12  27

$Gender_Male$Pyrexia$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2972973 0.7170421  0.56346873  9.3662250 0.2460690
OR_TRTvsCTRL  2.7777778 0.8388705  0.53659873 14.3795521 0.2232661
ARR_TRTvsCTRL 0.1526232 0.1069422 -0.05697965  0.3622261 0.1535349


$Gender_Male$`Respiratory arrest`
$Gender_Male$`Respiratory arrest`$ntab
            CTRL TRT
n_all         17  37
n_event        2   3
n_event_pct   12   8

$Gender_Male$`Respiratory arrest`$stats
```

```
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.86457086  0.1265944 3.7519972 0.6667969
OR_TRTvsCTRL   0.66176471 0.96406004  0.1000217 4.3783754 0.6684793
ARR_TRTvsCTRL -0.03656598 0.09011076 -0.2131798 0.1400479 0.6848975


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$ntab
            CTRL TRT
n_all         17  37
n_event        4  10
n_event_pct   24  27

$Gender_Male$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14864865 0.5139547  0.4194770 3.1453302 0.7874321
OR_TRTvsCTRL  1.20370370 0.6811462  0.3167575 4.5741697 0.7854736
ARR_TRTvsCTRL 0.03497615 0.1261529 -0.2122790 0.2822313 0.7815865


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$ntab
            CTRL TRT
n_all         17  37
n_event        7  11
n_event_pct   41  30

$Gender_Male$`Respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7220077 0.3845981  0.3397593 1.5343072 0.3970460
OR_TRTvsCTRL   0.6043956 0.6101047  0.1828097 1.9982204 0.4091949
ARR_TRTvsCTRL -0.1144674 0.1410467 -0.3909139 0.1619791 0.4170460


$Gender_Male$`Rhinovirus infection`
$Gender_Male$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         17  37
n_event        2   7
n_event_pct   12  19

$Gender_Male$`Rhinovirus infection`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.60810811 0.7463287  0.3724252 6.9437075 0.5244330
OR_TRTvsCTRL  1.75000000 0.8618916  0.3231429 9.4772321 0.5161523
ARR_TRTvsCTRL 0.07154213 0.1012527 -0.1269095 0.2699937 0.4798336


$Gender_Male$`Sleep apnoea syndrome`
$Gender_Male$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all         17  37
n_event        3   0
n_event_pct   18   0
```

```
$Gender_Male$`Sleep apnoea syndrome`$stats
                 estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.06766917 1.48453459  0.003687676 1.241735222 0.06965918
OR_TRTvsCTRL   0.05523810 1.54316119  0.002683475 1.137050842 0.06055462
ARR_TRTvsCTRL -0.17647059 0.09245944 -0.357687763 0.004746586 0.05631022


$Gender_Male$`Upper respiratory tract infection`
$Gender_Male$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         17  37
n_event        2   5
n_event_pct   12  14

$Gender_Male$`Upper respiratory tract infection`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14864865 0.78367687  0.2472409 5.3364712 0.8596333
OR_TRTvsCTRL  1.17187500 0.89326181  0.2034864 6.7488088 0.8590708
ARR_TRTvsCTRL 0.01748808 0.09625485 -0.1711680 0.2061441 0.8558298


$Gender_Male$`Viral upper respiratory tract infection`
$Gender_Male$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         17  37
n_event        3   2
n_event_pct   18   5

$Gender_Male$`Viral upper respiratory tract infection`$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3063063 0.8645709  0.05626417 1.66755432 0.1711540
OR_TRTvsCTRL   0.2666667 0.9660918  0.04014486 1.77136292 0.1712660
ARR_TRTvsCTRL -0.1224165 0.0996529 -0.31773262 0.07289956 0.2192859



$Gender_Female
$Gender_Female$`Acute respiratory failure`
$Gender_Female$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         24  43
n_event        5   6
n_event_pct   21  14

$Gender_Female$`Acute respiratory failure`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.66976744 0.54931247  0.2282172 1.9656204 0.4655831
OR_TRTvsCTRL   0.61621622 0.66807580  0.1663665 2.2824448 0.4686335
ARR_TRTvsCTRL -0.06879845 0.09830724 -0.2614771 0.1238802 0.4840329


$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$ntab
```

```
            CTRL TRT
n_all         24  43
n_event        5  11
n_event_pct   21  26

$Gender_Female$Atelectasis$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.22790698 0.4753805  0.4836385 3.117526 0.6658229
OR_TRTvsCTRL  1.30625000 0.6122015  0.3934771 4.336438 0.6625516
ARR_TRTvsCTRL 0.04748062 0.1062986 -0.1608608 0.255822 0.6551118


$Gender_Female$`Bronchial secretion retention`
$Gender_Female$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         24  43
n_event        3   0
n_event_pct   12   0

$Gender_Female$`Bronchial secretion retention`$stats
                estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08116883 1.49096848  0.004367919 1.508356380 0.09212555
OR_TRTvsCTRL   0.07060755 1.53467079  0.003487683 1.429437936 0.08413938
ARR_TRTvsCTRL -0.12500000 0.06750772 -0.257312691 0.007312691 0.06407751


$Gender_Female$Dysphagia
$Gender_Female$Dysphagia$ntab
            CTRL TRT
n_all         24  43
n_event        3   3
n_event_pct   12   7

$Gender_Female$Dysphagia$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.77572172  0.1220246 2.55292650 0.4522034
OR_TRTvsCTRL   0.52500000 0.85981726  0.0973378 2.83163374 0.4536092
ARR_TRTvsCTRL -0.05523256 0.07788834 -0.2078909 0.09742577 0.4782470


$Gender_Female$Dyspnoea
$Gender_Female$Dyspnoea$ntab
            CTRL TRT
n_all         24  43
n_event        3   3
n_event_pct   12   7

$Gender_Female$Dyspnoea$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.77572172  0.1220246 2.55292650 0.4522034
OR_TRTvsCTRL   0.52500000 0.85981726  0.0973378 2.83163374 0.4536092
ARR_TRTvsCTRL -0.05523256 0.07788834 -0.2078909 0.09742577 0.4782470
```

```
$Gender_Female$`Oxygen saturation decreased`
$Gender_Female$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         24  43
n_event        3   4
n_event_pct   12   9

$Gender_Female$`Oxygen saturation decreased`$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.74418605 0.7200075  0.1814722 3.051779 0.6815399
OR_TRTvsCTRL   0.71794872 0.8103045  0.1466766 3.514195 0.6825917
ARR_TRTvsCTRL -0.03197674 0.0807427 -0.1902295 0.126276 0.6920809


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$ntab
            CTRL TRT
n_all         24  43
n_event        3  14
n_event_pct   12  33

$Gender_Female$Pneumonia$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.6046512 0.58295748 0.83087417  8.1651445 0.10056065
OR_TRTvsCTRL  3.3793103 0.69775620 0.86078943 13.2665876 0.08096315
ARR_TRTvsCTRL 0.2005814 0.09830443 0.00790826  0.3932545 0.04130945


$Gender_Female$`Pneumonia aspiration`
$Gender_Female$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         24  43
n_event        4   6
n_event_pct   17  14

$Gender_Female$`Pneumonia aspiration`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83720930 0.59308025  0.2618202 2.6771017 0.7644896
OR_TRTvsCTRL   0.81081081 0.70263340  0.2045676 3.2136766 0.7653385
ARR_TRTvsCTRL -0.02713178 0.09262421 -0.2086719 0.1544083 0.7695808


$Gender_Female$`Pneumonia bacterial`
$Gender_Female$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         24  43
n_event        3   2
n_event_pct   12   5

$Gender_Female$`Pneumonia bacterial`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.37209302 0.87659047  0.06675693 2.07399014 0.2594079
OR_TRTvsCTRL   0.34146341 0.95149494  0.05289690 2.20423626 0.2587751
ARR_TRTvsCTRL -0.07848837 0.07475726 -0.22500990 0.06803316 0.2937596
```

```
$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$ntab
            CTRL TRT
n_all         24  43
n_event        6  11
n_event_pct   25  26

$Gender_Female$Pyrexia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.023255814 0.4389229  0.4328849 2.4187781 0.9582282
OR_TRTvsCTRL  1.031250000 0.5868401  0.3264711 3.2574906 0.9581811
ARR_TRTvsCTRL 0.005813953 0.1106336 -0.2110238 0.2226517 0.9580893


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$ntab
            CTRL TRT
n_all         24  43
n_event        7  10
n_event_pct   29  23

$Gender_Female$`Respiratory distress`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79734219 0.4218230  0.3488095 1.8226411 0.5913456
OR_TRTvsCTRL   0.73593074 0.5761803  0.2378983 2.2765777 0.5946162
ARR_TRTvsCTRL -0.05910853 0.1129548 -0.2804959 0.1622789 0.6007701


$Gender_Female$`Respiratory failure`
$Gender_Female$`Respiratory failure`$ntab
            CTRL TRT
n_all         24  43
n_event        9   8
n_event_pct   38  19

$Gender_Female$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.4961240 0.4137495  0.2204987 1.11628338 0.09024797
OR_TRTvsCTRL   0.3809524 0.5756294  0.1232804 1.17719206 0.09362731
ARR_TRTvsCTRL -0.1889535 0.1152707 -0.4148799 0.03697287 0.10116835


$Gender_Female$`Respiratory tract infection`
$Gender_Female$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        1   5
n_event_pct    4  12

$Gender_Female$`Respiratory tract infection`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.7906977 1.0654002  0.34581396 22.5207608 0.3354009
```

```
OR_TRTvsCTRL  3.0263158 1.1268514  0.33245786 27.5481148 0.3257599
ARR_TRTvsCTRL 0.0746124 0.0636671 -0.05017282  0.1993976 0.2412314


$Gender_Female$`Upper respiratory tract infection`
$Gender_Female$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        3   9
n_event_pct   12  21

$Gender_Female$`Upper respiratory tract infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.67441860 0.61605354  0.50058556 5.6007961 0.4027484
OR_TRTvsCTRL  1.85294118 0.72213244  0.44996775 7.6303046 0.3930489
ARR_TRTvsCTRL 0.08430233 0.09168429 -0.09539558 0.2640002 0.3578420


$Gender_Female$`Viral upper respiratory tract infection`
$Gender_Female$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        3   5
n_event_pct   12  12

$Gender_Female$`Viral upper respiratory tract infection`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93023256 0.68440547  0.2432341 3.5576116 0.9158447
OR_TRTvsCTRL   0.92105263 0.77927413  0.1999701 4.2423236 0.9159539
ARR_TRTvsCTRL -0.00872093 0.08334878 -0.1720815 0.1546397 0.9166680



$Region_Europe
$Region_Europe$`Acute respiratory failure`
$Region_Europe$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         17  30
n_event        2   0
n_event_pct   12   0

$Region_Europe$`Acute respiratory failure`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1161290 1.52058751  0.005896772 2.28700568 0.1567945
OR_TRTvsCTRL   0.1016393 1.58028574  0.004591136 2.25010878 0.1479588
ARR_TRTvsCTRL -0.1176471 0.07814249 -0.270803525 0.03550941 0.1321839


$Region_Europe$Atelectasis
$Region_Europe$Atelectasis$ntab
            CTRL TRT
n_all         17  30
n_event        2   6
n_event_pct   12  20
```

```
$Region_Europe$Atelectasis$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 0.7579642  0.3848297  7.5098154 0.4838834
OR_TRTvsCTRL  1.87500000 0.8803408  0.3339287 10.5280698 0.4751954
ARR_TRTvsCTRL 0.08235294 0.1069560 -0.1272769  0.2919828 0.4413174


$Region_Europe$`Bronchial secretion retention`
$Region_Europe$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         17  30
n_event        3   1
n_event_pct   18   3

$Region_Europe$`Bronchial secretion retention`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1888889 1.11408100  0.02127644 1.67692592 0.1346698
OR_TRTvsCTRL   0.1609195 1.19968524  0.01532621 1.68959535 0.1278150
ARR_TRTvsCTRL -0.1431373 0.09809599 -0.33540185 0.04912734 0.1445224


$Region_Europe$Dysphagia
$Region_Europe$Dysphagia$ntab
            CTRL TRT
n_all         17  30
n_event        2   0
n_event_pct   12   0

$Region_Europe$Dysphagia$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1161290 1.52058751  0.005896772 2.28700568 0.1567945
OR_TRTvsCTRL   0.1016393 1.58028574  0.004591136 2.25010878 0.1479588
ARR_TRTvsCTRL -0.1176471 0.07814249 -0.270803525 0.03550941 0.1321839


$Region_Europe$`Feeding disorder of infancy or early childhood`
$Region_Europe$`Feeding disorder of infancy or early childhood`$ntab
            CTRL TRT
n_all         17  30
n_event        2   2
n_event_pct   12   7

$Region_Europe$`Feeding disorder of infancy or early childhood`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56666667 0.95280803  0.08755803 3.6674089 0.5510978
OR_TRTvsCTRL   0.53571429 1.04994331  0.06842580 4.1941754 0.5522013
ARR_TRTvsCTRL -0.05098039 0.09044514 -0.22824960 0.1262888 0.5729849


$Region_Europe$Pneumonia
$Region_Europe$Pneumonia$ntab
            CTRL TRT
n_all         17  30
```

```
n_event        3   6
n_event_pct   18  20

$Region_Europe$Pneumonia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.13333333 0.6386260  0.3241591 3.9623887 0.8446194
OR_TRTvsCTRL  1.16666667 0.7830040  0.2514506 5.4130369 0.8439286
ARR_TRTvsCTRL 0.02352941 0.1178222 -0.2073979 0.2544568 0.8417132


$Region_Europe$`Pneumonia aspiration`
$Region_Europe$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         17  30
n_event        2   2
n_event_pct   12   7

$Region_Europe$`Pneumonia aspiration`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56666667 0.95280803  0.08755803 3.6674089 0.5510978
OR_TRTvsCTRL   0.53571429 1.04994331  0.06842580 4.1941754 0.5522013
ARR_TRTvsCTRL -0.05098039 0.09044514 -0.22824960 0.1262888 0.5729849


$Region_Europe$Pyrexia
$Region_Europe$Pyrexia$ntab
            CTRL TRT
n_all         17  30
n_event        6   6
n_event_pct   35  20

$Region_Europe$Pyrexia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5666667 0.4910972  0.2164238 1.4837146 0.2474516
OR_TRTvsCTRL   0.4583333 0.6825753  0.1202741 1.7465886 0.2530538
ARR_TRTvsCTRL -0.1529412 0.1369930 -0.4214425 0.1155602 0.2642441


$Region_Europe$`Respiratory arrest`
$Region_Europe$`Respiratory arrest`$ntab
            CTRL TRT
n_all         17  30
n_event        0   4
n_event_pct    0  13

$Region_Europe$`Respiratory arrest`$stats
               estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  5.2258065 1.46096153 0.29825011  91.5642690 0.25769180
OR_TRTvsCTRL  5.9433962 1.52220266 0.30083851 117.4183396 0.24165650
ARR_TRTvsCTRL 0.1333333 0.06206329 0.01169152   0.2549751 0.03168639


$Region_Europe$`Respiratory distress`
$Region_Europe$`Respiratory distress`$ntab
```

```
            CTRL TRT
n_all         17  30
n_event        2   8
n_event_pct   12  27

$Region_Europe$`Respiratory distress`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2666667 0.7299611  0.54205541  9.4783258 0.2622739
OR_TRTvsCTRL  2.7272727 0.8585576  0.50690081 14.6735148 0.2425687
ARR_TRTvsCTRL 0.1490196 0.1123600 -0.07120192  0.3692411 0.1847505


$Region_Europe$`Respiratory failure`
$Region_Europe$`Respiratory failure`$ntab
            CTRL TRT
n_all         17  30
n_event        8   8
n_event_pct   47  27

$Region_Europe$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5666667 0.3972948  0.2601056 1.23454121 0.1528236
OR_TRTvsCTRL   0.4090909 0.6376250  0.1172391 1.42747077 0.1609773
ARR_TRTvsCTRL -0.2039216 0.1455112 -0.4891183 0.08127518 0.1610901


$Region_Europe$`Respiratory tract infection`
$Region_Europe$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         17  30
n_event        1   6
n_event_pct    6  20

$Region_Europe$`Respiratory tract infection`$stats
               estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.4000000 1.03658565  0.4457954 25.9311764 0.2377684
OR_TRTvsCTRL  4.0000000 1.12731244  0.4390257 36.4443391 0.2187968
ARR_TRTvsCTRL 0.1411765 0.09268225 -0.0404774  0.3228303 0.1277009


$Region_Europe$`Rhinovirus infection`
$Region_Europe$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         17  30
n_event        0   3
n_event_pct    0  10

$Region_Europe$`Rhinovirus infection`$stats
              estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.064516 1.48253184  0.222369622 74.2920332 0.34421066
OR_TRTvsCTRL  4.454545 1.54247229  0.216694854 91.5710496 0.33278158
ARR_TRTvsCTRL 0.100000 0.05477226 -0.007351649  0.2073516 0.06788915
```

```
$Region_Europe$`Viral infection`
$Region_Europe$`Viral infection`$ntab
            CTRL TRT
n_all         17  30
n_event        0   4
n_event_pct    0  13

$Region_Europe$`Viral infection`$stats
               estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  5.2258065 1.46096153 0.29825011  91.5642690 0.25769180
OR_TRTvsCTRL  5.9433962 1.52220266 0.30083851 117.4183396 0.24165650
ARR_TRTvsCTRL 0.1333333 0.06206329 0.01169152   0.2549751 0.03168639



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        7  11
n_event_pct   32  29

$Region_Northamerica$`Acute respiratory failure`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90977444 0.4024871  0.4133672 2.0023104 0.8142587
OR_TRTvsCTRL   0.87301587 0.5809216  0.2796023 2.7258599 0.8151642
ARR_TRTvsCTRL -0.02870813 0.1235864 -0.2709331 0.2135168 0.8163112


$Region_Northamerica$Aspiration
$Region_Northamerica$Aspiration$ntab
            CTRL TRT
n_all         22  38
n_event        2   4
n_event_pct    9  11

$Region_Northamerica$Aspiration$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.15789474 0.82354700  0.2304966 5.8166584 0.8587114
OR_TRTvsCTRL  1.17647059 0.91072046  0.1974124 7.0111255 0.8583688
ARR_TRTvsCTRL 0.01435407 0.07896246 -0.1404095 0.1691176 0.8557527


$Region_Northamerica$Atelectasis
$Region_Northamerica$Atelectasis$ntab
            CTRL TRT
n_all         22  38
n_event        8   8
n_event_pct   36  21

$Region_Northamerica$Atelectasis$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5789474 0.4221726  0.2530959 1.3243202 0.1954590
```

```
OR_TRTvsCTRL   0.4666667 0.5956189  0.1452162 1.4996798 0.2006941
ARR_TRTvsCTRL -0.1531100 0.1220337 -0.3922917 0.0860716 0.2096044


$Region_Northamerica$`Bronchial secretion retention`
$Region_Northamerica$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         22  38
n_event        4   2
n_event_pct   18   5

$Region_Northamerica$`Bronchial secretion retention`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.2894737 0.82354700  0.05762416 1.45416460 0.1322452
OR_TRTvsCTRL   0.2500000 0.91287093  0.04177369 1.49615694 0.1288608
ARR_TRTvsCTRL -0.1291866 0.08985532 -0.30529979 0.04692658 0.1505141


$Region_Northamerica$`Cardio-respiratory arrest`
$Region_Northamerica$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         22  38
n_event        4   3
n_event_pct   18   8

$Region_Northamerica$`Cardio-respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4342105 0.71523632  0.10687843 1.76404886 0.2434674
OR_TRTvsCTRL   0.3857143 0.81698245  0.07777661 1.91285673 0.2435863
ARR_TRTvsCTRL -0.1028708 0.09314171 -0.28542520 0.07968358 0.2693959


$Region_Northamerica$Dysphagia
$Region_Northamerica$Dysphagia$ntab
            CTRL TRT
n_all         22  38
n_event        5   6
n_event_pct   23  16

$Region_Northamerica$Dysphagia$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.69473684 0.5430436  0.2396519 2.0140018 0.5024084
OR_TRTvsCTRL   0.63750000 0.6758256  0.1695182 2.3974191 0.5053154
ARR_TRTvsCTRL -0.06937799 0.1071530 -0.2793941 0.1406381 0.5173301


$Region_Northamerica$Dyspnoea
$Region_Northamerica$Dyspnoea$ntab
            CTRL TRT
n_all         22  38
n_event        4   1
n_event_pct   18   3

$Region_Northamerica$Dyspnoea$stats
```

```
                estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.1447368 1.085463  0.01724374 1.21486151 0.07496835
OR_TRTvsCTRL   0.1216216 1.154375  0.01265915 1.16846826 0.06798725
ARR_TRTvsCTRL -0.1555024 0.086233 -0.32451596 0.01351118 0.07134397


$Region_Northamerica$Hypokalaemia
$Region_Northamerica$Hypokalaemia$ntab
            CTRL TRT
n_all         22  38
n_event        3   0
n_event_pct   14   0

$Region_Northamerica$Hypokalaemia$stats
                 estimate       se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08424908 1.488823  0.004552778 1.559028057 0.09657297
OR_TRTvsCTRL   0.07235622 1.537196  0.003556416 1.472106135 0.08756107
ARR_TRTvsCTRL -0.13636364 0.073165 -0.279764411 0.007037138 0.06235229


$Region_Northamerica$Hypoxia
$Region_Northamerica$Hypoxia$ntab
            CTRL TRT
n_all         22  38
n_event        2   5
n_event_pct    9  13

$Region_Northamerica$Hypoxia$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.44736842 0.79260940  0.3061320 6.8430457 0.6408624
OR_TRTvsCTRL  1.51515152 0.88334763  0.2682558 8.5578157 0.6380784
ARR_TRTvsCTRL 0.04066986 0.08224094 -0.1205194 0.2018591 0.6209384


$Region_Northamerica$`Oxygen saturation decreased`
$Region_Northamerica$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         22  38
n_event        6   6
n_event_pct   27  16

$Region_Northamerica$`Oxygen saturation decreased`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.5789474 0.5114323  0.2124746 1.577506 0.2852260
OR_TRTvsCTRL   0.5000000 0.6535161  0.1388980 1.799882 0.2888523
ARR_TRTvsCTRL -0.1148325 0.1118697 -0.3340931 0.104428 0.3046632


$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$ntab
            CTRL TRT
n_all         22  38
n_event        3  10
n_event_pct   14  26
```

```
$Region_Northamerica$Pneumonia$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.9298246 0.6013011  0.59386730 6.2711363 0.2742427
OR_TRTvsCTRL  2.2619048 0.7222736  0.54912838 9.3169710 0.2584540
ARR_TRTvsCTRL 0.1267943 0.1022541 -0.07362011 0.3272086 0.2149784


$Region_Northamerica$`Pneumonia aspiration`
$Region_Northamerica$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         22  38
n_event        5   6
n_event_pct   23  16

$Region_Northamerica$`Pneumonia aspiration`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.69473684 0.5430436  0.2396519 2.0140018 0.5024084
OR_TRTvsCTRL   0.63750000 0.6758256  0.1695182 2.3974191 0.5053154
ARR_TRTvsCTRL -0.06937799 0.1071530 -0.2793941 0.1406381 0.5173301


$Region_Northamerica$`Pneumonia bacterial`
$Region_Northamerica$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$`Pneumonia bacterial`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$`Pneumonia viral`
$Region_Northamerica$`Pneumonia viral`$ntab
            CTRL TRT
n_all         22  38
n_event        2   6
n_event_pct    9  16

$Region_Northamerica$`Pneumonia viral`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.73684211 0.77129523  0.38302988  7.8756794 0.4741345
OR_TRTvsCTRL  1.87500000 0.86482175  0.34424184 10.2126602 0.4673087
ARR_TRTvsCTRL 0.06698565 0.08517996 -0.09996402  0.2339353 0.4316323


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$ntab
            CTRL TRT
n_all         22  38
```

```
n_event        2  13
n_event_pct    9  34

$Region_Northamerica$Pyrexia$stats
               estimate         se    lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.7631579 0.71074098 0.9344770 15.1543133 0.06223535
OR_TRTvsCTRL  5.2000000 0.81665358 1.0492200 25.7715260 0.04350822
ARR_TRTvsCTRL 0.2511962 0.09838419 0.0583667  0.4440256 0.01067330


$Region_Northamerica$`Respiratory arrest`
$Region_Northamerica$`Respiratory arrest`$ntab
            CTRL TRT
n_all         22  38
n_event        4   1
n_event_pct   18   3

$Region_Northamerica$`Respiratory arrest`$stats
                estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.1447368 1.085463  0.01724374 1.21486151 0.07496835
OR_TRTvsCTRL   0.1216216 1.154375  0.01265915 1.16846826 0.06798725
ARR_TRTvsCTRL -0.1555024 0.086233 -0.32451596 0.01351118 0.07134397


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$ntab
            CTRL TRT
n_all         22  38
n_event        9  11
n_event_pct   41  29

$Region_Northamerica$`Respiratory distress`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.7076023 0.3609015  0.3488104 1.435454 0.3378820
OR_TRTvsCTRL   0.5884774 0.5621213  0.1955471 1.770958 0.3455567
ARR_TRTvsCTRL -0.1196172 0.1280647 -0.3706195 0.131385 0.3502847


$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        7  11
n_event_pct   32  29

$Region_Northamerica$`Respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90977444 0.4024871  0.4133672 2.0023104 0.8142587
OR_TRTvsCTRL   0.87301587 0.5809216  0.2796023 2.7258599 0.8151642
ARR_TRTvsCTRL -0.02870813 0.1235864 -0.2709331 0.2135168 0.8163112


$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`
$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`$ntab
```

```
            CTRL TRT
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$`Rhinovirus infection`
$Region_Northamerica$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         22  38
n_event        4   7
n_event_pct   18  18

$Region_Northamerica$`Rhinovirus infection`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.013157895 0.5666452  0.3336936 3.0761423 0.9815950
OR_TRTvsCTRL  1.016129032 0.6933042  0.2611002 3.9544901 0.9815877
ARR_TRTvsCTRL 0.002392344 0.1035205 -0.2005041 0.2052888 0.9815626


$Region_Northamerica$`Sleep apnoea syndrome`
$Region_Northamerica$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all         22  38
n_event        3   0
n_event_pct   14   0

$Region_Northamerica$`Sleep apnoea syndrome`$stats
                 estimate       se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08424908 1.488823  0.004552778 1.559028057 0.09657297
OR_TRTvsCTRL   0.07235622 1.537196  0.003556416 1.472106135 0.08756107
ARR_TRTvsCTRL -0.13636364 0.073165 -0.279764411 0.007037138 0.06235229


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        4  13
n_event_pct   18  34

$Region_Northamerica$`Upper respiratory tract infection`$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.8815789 0.5051265  0.69913013 5.0639204 0.2107914
OR_TRTvsCTRL  2.3400000 0.6499836  0.65455907 8.3653260 0.1908877
ARR_TRTvsCTRL 0.1602871 0.1126264 -0.06045663 0.3810308 0.1546855
```

```
$Region_Northamerica$`Viral upper respiratory tract infection`
$Region_Northamerica$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        6   7
n_event_pct   27  18

$Region_Northamerica$`Viral upper respiratory tract infection`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.67543860 0.4875997  0.2597408 1.7564326 0.4209673
OR_TRTvsCTRL   0.60215054 0.6358316  0.1731746 2.0937554 0.4250036
ARR_TRTvsCTRL -0.08851675 0.1138878 -0.3117328 0.1346993 0.4370246



$Disdur_greater_12wk
$Disdur_greater_12wk$`Acute respiratory failure`
$Disdur_greater_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         23  46
n_event        4   7
n_event_pct   17  15

$Disdur_greater_12wk$`Acute respiratory failure`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.87500000 0.57239825  0.2849586 2.6867937 0.8155408
OR_TRTvsCTRL   0.85256410 0.68638892  0.2220607 3.2732739 0.8162386
ARR_TRTvsCTRL -0.02173913 0.09513738 -0.2082050 0.1647267 0.8192556


$Disdur_greater_12wk$Atelectasis
$Disdur_greater_12wk$Atelectasis$ntab
            CTRL TRT
n_all         23  46
n_event        6   7
n_event_pct   26  15

$Disdur_greater_12wk$Atelectasis$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5833333 0.4942736  0.2214065 1.53689171 0.2755009
OR_TRTvsCTRL   0.5085470 0.6276849  0.1486089 1.74027339 0.2813515
ARR_TRTvsCTRL -0.1086957 0.1057736 -0.3160081 0.09861675 0.3041259


$Disdur_greater_12wk$`Bronchial secretion retention`
$Disdur_greater_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         23  46
n_event        3   1
n_event_pct   13   2

$Disdur_greater_12wk$`Bronchial secretion retention`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1666667 1.12610654  0.01833602 1.5149293 0.1115848
```

```
OR_TRTvsCTRL   0.1481481 1.18556128  0.01450590 1.5130310 0.1072527
ARR_TRTvsCTRL -0.1086957 0.07344173 -0.25263880 0.0352475 0.1388664


$Disdur_greater_12wk$Dysphagia
$Disdur_greater_12wk$Dysphagia$ntab
            CTRL TRT
n_all         23  46
n_event        5   3
n_event_pct   22   7

$Disdur_greater_12wk$Dysphagia$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3000000 0.6841900  0.07847615 1.14684528 0.07845777
OR_TRTvsCTRL   0.2511628 0.7823968  0.05419734 1.16394548 0.07740844
ARR_TRTvsCTRL -0.1521739 0.0933936 -0.33522200 0.03087417 0.10323202


$Disdur_greater_12wk$`Oxygen saturation decreased`
$Disdur_greater_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         23  46
n_event        3   5
n_event_pct   13  11

$Disdur_greater_12wk$`Oxygen saturation decreased`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83333333 0.68418999  0.2179893 3.1856813 0.7898711
OR_TRTvsCTRL   0.81300813 0.77956628  0.1764115 3.7468206 0.7905855
ARR_TRTvsCTRL -0.02173913 0.08388968 -0.1861599 0.1426816 0.7955276


$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$ntab
            CTRL TRT
n_all         23  46
n_event        3  13
n_event_pct   13  28

$Disdur_greater_12wk$Pneumonia$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.1666667 0.58740022  0.68516651  6.8515381 0.1880762
OR_TRTvsCTRL  2.6262626 0.70039949  0.66551375 10.3638061 0.1680221
ARR_TRTvsCTRL 0.1521739 0.09663739 -0.03723189  0.3415797 0.1153281


$Disdur_greater_12wk$`Pneumonia aspiration`
$Disdur_greater_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         23  46
n_event        3   4
n_event_pct   13   9

$Disdur_greater_12wk$`Pneumonia aspiration`$stats
```

```
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.66666667 0.7198027  0.1626341 2.7327879 0.5732304
OR_TRTvsCTRL   0.63492063 0.8106435  0.1296279 3.1098570 0.5752313
ARR_TRTvsCTRL -0.04347826 0.0815926 -0.2033968 0.1164403 0.5941235


$Disdur_greater_12wk$`Pneumonia viral`
$Disdur_greater_12wk$`Pneumonia viral`$ntab
            CTRL TRT
n_all         23  46
n_event        2   6
n_event_pct    9  13

$Disdur_greater_12wk$`Pneumonia viral`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.50000000 0.77553161  0.3280632 6.8584340 0.6010980
OR_TRTvsCTRL  1.57500000 0.85981726  0.2920134 8.4949012 0.5972800
ARR_TRTvsCTRL 0.04347826 0.07692624 -0.1072944 0.1942509 0.5719417


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$ntab
            CTRL TRT
n_all         23  46
n_event        7  10
n_event_pct   30  22

$Disdur_greater_12wk$Pyrexia$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.71428571 0.4214733  0.3126895 1.631664 0.4246825
OR_TRTvsCTRL   0.63492063 0.5771784  0.2048445 1.967952 0.4312658
ARR_TRTvsCTRL -0.08695652 0.1135947 -0.3095980 0.135685 0.4439750


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         23  46
n_event        7  12
n_event_pct   30  26

$Disdur_greater_12wk$`Respiratory distress`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85714286 0.4012145  0.3904261 1.8817747 0.7008227
OR_TRTvsCTRL   0.80672269 0.5640055  0.2670803 2.4367257 0.7033490
ARR_TRTvsCTRL -0.04347826 0.1157449 -0.2703342 0.1833777 0.7071857


$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         23  46
n_event        9  10
n_event_pct   39  22
```

```
$Disdur_greater_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5555556 0.3819604  0.2627860 1.17449926 0.1238365
OR_TRTvsCTRL   0.4320988 0.5570615  0.1450145 1.28752180 0.1319904
ARR_TRTvsCTRL -0.1739130 0.1185513 -0.4062693 0.05844322 0.1423800


$Disdur_greater_12wk$`Rhinovirus infection`
$Disdur_greater_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         23  46
n_event        2   8
n_event_pct    9  17

$Disdur_greater_12wk$`Rhinovirus infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.00000000 0.74818621  0.46150110  8.6673684 0.3542191
OR_TRTvsCTRL  2.21052632 0.83602323  0.42940928 11.3794154 0.3427152
ARR_TRTvsCTRL 0.08695652 0.08108737 -0.07197181  0.2458849 0.2835491


$Disdur_greater_12wk$Teething
$Disdur_greater_12wk$Teething$ntab
            CTRL TRT
n_all         23  46
n_event        1   5
n_event_pct    4  11

$Disdur_greater_12wk$Teething$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.50000000 1.06526176  0.30987573 20.1693759 0.3897033
OR_TRTvsCTRL  2.68292683 1.12687390  0.29472164 24.4233724 0.3811426
ARR_TRTvsCTRL 0.06521739 0.06256418 -0.05740614  0.1878409 0.2972226


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         23  46
n_event        2   8
n_event_pct    9  17

$Disdur_greater_12wk$`Upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.00000000 0.74818621  0.46150110  8.6673684 0.3542191
OR_TRTvsCTRL  2.21052632 0.83602323  0.42940928 11.3794154 0.3427152
ARR_TRTvsCTRL 0.08695652 0.08108737 -0.07197181  0.2458849 0.2835491


$Disdur_greater_12wk$`Viral upper respiratory tract infection`
$Disdur_greater_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         23  46
```

```
n_event        4   4
n_event_pct   17   9

$Disdur_greater_12wk$`Viral upper respiratory tract infection`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 0.65938047  0.1373107 1.82068863 0.2931623
OR_TRTvsCTRL   0.45238095 0.75923718  0.1021505 2.00340233 0.2961278
ARR_TRTvsCTRL -0.08695652 0.08928821 -0.2619582 0.08804515 0.3301132



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Acute respiratory failure`
$Disdur_less_equal_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         18  34
n_event        5   4
n_event_pct   28  12

$Disdur_less_equal_12wk$`Acute respiratory failure`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4235294 0.6041793  0.12960005 1.38408246 0.1550314
OR_TRTvsCTRL   0.3466667 0.7485028  0.07994391 1.50327628 0.1569666
ARR_TRTvsCTRL -0.1601307 0.1191576 -0.39367529 0.07341385 0.1789947


$Disdur_less_equal_12wk$Apnoea
$Disdur_less_equal_12wk$Apnoea$ntab
            CTRL TRT
n_all         18  34
n_event        2   3
n_event_pct   11   9

$Disdur_less_equal_12wk$Apnoea$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.86508151  0.1457223 4.3275646 0.7898725
OR_TRTvsCTRL   0.77419355 0.96337500  0.1171718 5.1153557 0.7904985
ARR_TRTvsCTRL -0.02287582 0.08861794 -0.1965638 0.1508122 0.7962990


$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         18  34
n_event        4   8
n_event_pct   22  24

$Disdur_less_equal_12wk$Atelectasis$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.0588235 0.5385468  0.3684781 3.042534 0.9154756
OR_TRTvsCTRL  1.0769231 0.6963405  0.2750797 4.216099 0.9152452
ARR_TRTvsCTRL 0.0130719 0.1220421 -0.2261262 0.252270 0.9147019
```

```
$Disdur_less_equal_12wk$`Bronchial secretion retention`
$Disdur_less_equal_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         18  34
n_event        4   2
n_event_pct   22   6

$Disdur_less_equal_12wk$`Bronchial secretion retention`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2647059 0.8154954  0.05353190 1.30892421 0.10313299
OR_TRTvsCTRL   0.2187500 0.9234060  0.03580498 1.33644977 0.09978616
ARR_TRTvsCTRL -0.1633987 0.1059742 -0.37110428 0.04430689 0.12310455


$Disdur_less_equal_12wk$`Cardio-respiratory arrest`
$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         18  34
n_event        3   1
n_event_pct   17   3

$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1764706 1.1173030  0.01975251 1.5766031 0.1205452
OR_TRTvsCTRL   0.1515152 1.1959528  0.01453648 1.5792574 0.1145932
ARR_TRTvsCTRL -0.1372549 0.0924968 -0.31854530 0.0440355 0.1378386


$Disdur_less_equal_12wk$`Corona virus infection`
$Disdur_less_equal_12wk$`Corona virus infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Corona virus infection`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$Cyanosis
$Disdur_less_equal_12wk$Cyanosis$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$Cyanosis$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144
```

```
$Disdur_less_equal_12wk$Dysphagia
$Disdur_less_equal_12wk$Dysphagia$ntab
            CTRL TRT
n_all         18  34
n_event        2   3
n_event_pct   11   9

$Disdur_less_equal_12wk$Dysphagia$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.86508151  0.1457223 4.3275646 0.7898725
OR_TRTvsCTRL   0.77419355 0.96337500  0.1171718 5.1153557 0.7904985
ARR_TRTvsCTRL -0.02287582 0.08861794 -0.1965638 0.1508122 0.7962990


$Disdur_less_equal_12wk$Dyspnoea
$Disdur_less_equal_12wk$Dyspnoea$ntab
            CTRL TRT
n_all         18  34
n_event        3   0
n_event_pct   17   0

$Disdur_less_equal_12wk$Dyspnoea$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.07755102 1.48475967  0.004224330 1.42369592 0.08506182
OR_TRTvsCTRL   0.06418219 1.54247072  0.003122203 1.31937430 0.07503018
ARR_TRTvsCTRL -0.16666667 0.08784105 -0.338831953 0.00549862 0.05777957


$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`
$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$Hypokalaemia
$Disdur_less_equal_12wk$Hypokalaemia$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$Hypokalaemia$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
```

```
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$Hypoxia
$Disdur_less_equal_12wk$Hypoxia$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3

$Disdur_less_equal_12wk$Hypoxia$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495


$Disdur_less_equal_12wk$Nasopharyngitis
$Disdur_less_equal_12wk$Nasopharyngitis$ntab
            CTRL TRT
n_all         18  34
n_event        1   4
n_event_pct    6  12

$Disdur_less_equal_12wk$Nasopharyngitis$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.1176471 1.07936680  0.25532592 17.5635484 0.4869707
OR_TRTvsCTRL  2.2666667 1.15851494  0.23402268 21.9541871 0.4799741
ARR_TRTvsCTRL 0.0620915 0.07725333 -0.08932223  0.2135052 0.4215478


$Disdur_less_equal_12wk$Oedema
$Disdur_less_equal_12wk$Oedema$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$Oedema$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Oxygen saturation decreased`
$Disdur_less_equal_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         18  34
n_event        4   3
n_event_pct   22   9

$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats
```

```
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3970588 0.7059504  0.09952880 1.58402105 0.1907351
OR_TRTvsCTRL   0.3387097 0.8288667  0.06672599 1.71933380 0.1915066
ARR_TRTvsCTRL -0.1339869 0.1094000 -0.34840704 0.08043319 0.2206720


$Disdur_less_equal_12wk$Pneumonia
$Disdur_less_equal_12wk$Pneumonia$ntab
            CTRL TRT
n_all         18  34
n_event        3   8
n_event_pct   17  24

$Disdur_less_equal_12wk$Pneumonia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.41176471 0.6110368  0.4262328 4.6760357 0.5725139
OR_TRTvsCTRL  1.53846154 0.7506408  0.3532971 6.6993584 0.5660443
ARR_TRTvsCTRL 0.06862745 0.1140532 -0.1549127 0.2921676 0.5473643


$Disdur_less_equal_12wk$`Pneumonia aspiration`
$Disdur_less_equal_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         18  34
n_event        4   4
n_event_pct   22  12

$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5294118 0.6442303  0.1497696 1.8713862 0.3235411
OR_TRTvsCTRL   0.4666667 0.7776644  0.1016384 2.1426731 0.3270677
ARR_TRTvsCTRL -0.1045752 0.1124959 -0.3250630 0.1159127 0.3525828


$Disdur_less_equal_12wk$`Pneumonia bacterial`
$Disdur_less_equal_12wk$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Pneumonia bacterial`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         18  34
n_event        1  11
n_event_pct    6  32
```

```
$Disdur_less_equal_12wk$Pyrexia$stats
               estimate         se     lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  5.8235294 1.00296649 0.81556702 41.5827199 0.078969760
OR_TRTvsCTRL  8.1304348 1.09234193 0.95567591 69.1698610 0.055052696
ARR_TRTvsCTRL 0.2679739 0.09670551 0.07843454  0.4575132 0.005587931


$Disdur_less_equal_12wk$`Respiratory arrest`
$Disdur_less_equal_12wk$`Respiratory arrest`$ntab
            CTRL TRT
n_all         18  34
n_event        3   2
n_event_pct   17   6

$Disdur_less_equal_12wk$`Respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3529412 0.86508151  0.06476548 1.92336205 0.2286362
OR_TRTvsCTRL   0.3125000 0.96501295  0.04714433 2.07143131 0.2280792
ARR_TRTvsCTRL -0.1078431 0.09666635 -0.29730569 0.08161942 0.2645838


$Disdur_less_equal_12wk$`Respiratory distress`
$Disdur_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         18  34
n_event        4   8
n_event_pct   22  24

$Disdur_less_equal_12wk$`Respiratory distress`$stats
               estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.0588235 0.5385468  0.3684781 3.042534 0.9154756
OR_TRTvsCTRL  1.0769231 0.6963405  0.2750797 4.216099 0.9152452
ARR_TRTvsCTRL 0.0130719 0.1220421 -0.2261262 0.252270 0.9147019


$Disdur_less_equal_12wk$`Respiratory failure`
$Disdur_less_equal_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         18  34
n_event        7   9
n_event_pct   39  26

$Disdur_less_equal_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6806723 0.4110972  0.3040965 1.5235779 0.3494143
OR_TRTvsCTRL   0.5657143 0.6203848  0.1676967 1.9084012 0.3584899
ARR_TRTvsCTRL -0.1241830 0.1375777 -0.3938304 0.1454643 0.3667175


$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`
$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         18  34
```

```
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$`Respiratory tract infection`
$Disdur_less_equal_12wk$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         18  34
n_event        1   4
n_event_pct    6  12

$Disdur_less_equal_12wk$`Respiratory tract infection`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.1176471 1.07936680  0.25532592 17.5635484 0.4869707
OR_TRTvsCTRL  2.2666667 1.15851494  0.23402268 21.9541871 0.4799741
ARR_TRTvsCTRL 0.0620915 0.07725333 -0.08932223  0.2135052 0.4215478


$Disdur_less_equal_12wk$`Rhinovirus infection`
$Disdur_less_equal_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Rhinovirus infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$`Sleep apnoea syndrome`
$Disdur_less_equal_12wk$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$`Sleep apnoea syndrome`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Upper respiratory tract infection`
$Disdur_less_equal_12wk$`Upper respiratory tract infection`$ntab
```

```
            CTRL TRT
n_all         18  34
n_event        3   6
n_event_pct   17  18

$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 0.6442303  0.2995393 3.7427723 0.9293016
OR_TRTvsCTRL  1.071428571 0.7761320  0.2340553 4.9046500 0.9291668
ARR_TRTvsCTRL 0.009803922 0.1095008 -0.2048137 0.2244215 0.9286584


$Disdur_less_equal_12wk$`Viral infection`
$Disdur_less_equal_12wk$`Viral infection`$ntab
            CTRL TRT
n_all         18  34
n_event        0   4
n_event_pct    0  12

$Disdur_less_equal_12wk$`Viral infection`$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.8857143 1.46322220 0.277607419  85.985469 0.27830946
OR_TRTvsCTRL  5.4590164 1.51956019 0.277755343 107.291761 0.26401687
ARR_TRTvsCTRL 0.1176471 0.05525508 0.009349083   0.225945 0.03324081


$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`
$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   3
n_event_pct   11   9

$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.86508151  0.1457223 4.3275646 0.7898725
OR_TRTvsCTRL   0.77419355 0.96337500  0.1171718 5.1153557 0.7904985
ARR_TRTvsCTRL -0.02287582 0.08861794 -0.1965638 0.1508122 0.7962990



$Region_Asia_Pacific
$Region_Asia_Pacific$Dyspnoea
$Region_Asia_Pacific$Dyspnoea$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$Dyspnoea$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353
```

```
$Region_Asia_Pacific$Oedema
$Region_Asia_Pacific$Oedema$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$Oedema$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$Pneumonia
$Region_Asia_Pacific$Pneumonia$ntab
            CTRL TRT
n_all          2  12
n_event        0   5
n_event_pct    0  42

$Region_Asia_Pacific$Pneumonia$stats
               estimate        se    lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  2.5384615 1.3310003 0.1869051 34.4762553 0.483993933
OR_TRTvsCTRL  3.6666667 1.6477717 0.1451061 92.6525185 0.430398971
ARR_TRTvsCTRL 0.4166667 0.1423188 0.1377270  0.6956063 0.003414791


$Region_Asia_Pacific$Pyrexia
$Region_Asia_Pacific$Pyrexia$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$Pyrexia$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353


$Region_Asia_Pacific$`Respiratory failure`
$Region_Asia_Pacific$`Respiratory failure`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Respiratory failure`$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
```

```
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$Teething
$Region_Asia_Pacific$Teething$ntab
            CTRL TRT
n_all          2  12
n_event        0   3
n_event_pct    0  25

$Region_Asia_Pacific$Teething$stats
              estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  1.615385 1.369474 0.110300612 23.6577786 0.72619768
OR_TRTvsCTRL  1.842105 1.670622 0.069707343 48.6799765 0.71460562
ARR_TRTvsCTRL 0.250000 0.125000 0.005004502  0.4949955 0.04550026


$Region_Asia_Pacific$`Urinary tract infection`
$Region_Asia_Pacific$`Urinary tract infection`$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$`Urinary tract infection`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353




\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten oder schweren UE nach PT, das bei
mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event        7  10
n_event_pct   22  14

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.63492063 0.44465521  0.2656001 1.5177863 0.3069750
OR_TRTvsCTRL   0.57603687 0.54679628  0.1972497 1.6822251 0.3130920
ARR_TRTvsCTRL -0.07986111 0.08367598 -0.2438630 0.0841408 0.3398767
```

```
$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         32  72
n_event       10  15
n_event_pct   31  21

$Ageonset_less_equal_12wk$Atelectasis$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6666667 0.34860834  0.3366455 1.32021512 0.2447904
OR_TRTvsCTRL   0.5789474 0.47923384  0.2263156 1.48102936 0.2540976
ARR_TRTvsCTRL -0.1041667 0.09489241 -0.2901524 0.08181904 0.2723205


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$ntab
            CTRL TRT
n_all         32  72
n_event        5  20
n_event_pct   16  28

$Ageonset_less_equal_12wk$Pneumonia$stats
               estimate        se      lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.7777778 0.4526159  0.73216702 4.316630 0.2036584
OR_TRTvsCTRL  2.0769231 0.5534147  0.70202566 6.144518 0.1866058
ARR_TRTvsCTRL 0.1215278 0.0831037 -0.04135247 0.284408 0.1436417


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         32  72
n_event        6  20
n_event_pct   19  28

$Ageonset_less_equal_12wk$Pyrexia$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.48148148 0.41415912  0.65790524 3.3360236 0.3426138
OR_TRTvsCTRL  1.66666667 0.52379287  0.59702903 4.6526679 0.3294395
ARR_TRTvsCTRL 0.09027778 0.08687401 -0.07999215 0.2605477 0.2987208


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         32  72
n_event        9  19
n_event_pct   28  26

$Ageonset_less_equal_12wk$`Respiratory distress`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93827160 0.34438903  0.4777317 1.8427781 0.8532203
OR_TRTvsCTRL   0.91614256 0.47548804  0.3607671 2.3264794 0.8538592
ARR_TRTvsCTRL -0.01736111 0.09494776 -0.2034553 0.1687331 0.8549164
```

```
$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event       15  17
n_event_pct   47  24

$Ageonset_less_equal_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.5037037 0.2834631  0.2889954  0.87792889 0.01555269
OR_TRTvsCTRL   0.3503030 0.4499950  0.1450132  0.84621433 0.01975122
ARR_TRTvsCTRL -0.2326389 0.1014249 -0.4314281 -0.03384965 0.02180746


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        4  14
n_event_pct   12  19

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.55555556 0.52563265  0.55522141 4.3581768 0.4005870
OR_TRTvsCTRL  1.68965517 0.61186946  0.50930021 5.6056027 0.3913073
ARR_TRTvsCTRL 0.06944444 0.07478948 -0.07714024 0.2160291 0.3531315



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        7  11
n_event_pct   32  29

$Region_Northamerica$`Acute respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90977444 0.4024871  0.4133672 2.0023104 0.8142587
OR_TRTvsCTRL   0.87301587 0.5809216  0.2796023 2.7258599 0.8151642
ARR_TRTvsCTRL -0.02870813 0.1235864 -0.2709331 0.2135168 0.8163112


$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$ntab
            CTRL TRT
n_all         22  38
n_event        3  10
n_event_pct   14  26

$Region_Northamerica$Pneumonia$stats
```

```
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.9298246 0.6013011  0.59386730 6.2711363 0.2742427
OR_TRTvsCTRL  2.2619048 0.7222736  0.54912838 9.3169710 0.2584540
ARR_TRTvsCTRL 0.1267943 0.1022541 -0.07362011 0.3272086 0.2149784


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$ntab
            CTRL TRT
n_all         22  38
n_event        2  13
n_event_pct    9  34

$Region_Northamerica$Pyrexia$stats
               estimate         se    lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.7631579 0.71074098 0.9344770 15.1543133 0.06223535
OR_TRTvsCTRL  5.2000000 0.81665358 1.0492200 25.7715260 0.04350822
ARR_TRTvsCTRL 0.2511962 0.09838419 0.0583667  0.4440256 0.01067330


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$ntab
            CTRL TRT
n_all         22  38
n_event        9  11
n_event_pct   41  29

$Region_Northamerica$`Respiratory distress`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.7076023 0.3609015  0.3488104 1.435454 0.3378820
OR_TRTvsCTRL   0.5884774 0.5621213  0.1955471 1.770958 0.3455567
ARR_TRTvsCTRL -0.1196172 0.1280647 -0.3706195 0.131385 0.3502847


$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        7  11
n_event_pct   32  29

$Region_Northamerica$`Respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90977444 0.4024871  0.4133672 2.0023104 0.8142587
OR_TRTvsCTRL   0.87301587 0.5809216  0.2796023 2.7258599 0.8151642
ARR_TRTvsCTRL -0.02870813 0.1235864 -0.2709331 0.2135168 0.8163112


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        4  13
n_event_pct   18  34
```

```
$Region_Northamerica$`Upper respiratory tract infection`$stats
               estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.8815789 0.5051265  0.69913013 5.0639204 0.2107914
OR_TRTvsCTRL  2.3400000 0.6499836  0.65455907 8.3653260 0.1908877
ARR_TRTvsCTRL 0.1602871 0.1126264 -0.06045663 0.3810308 0.1546855



$Agetrt_less_180d
$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$ntab
            CTRL TRT
n_all         16  49
n_event        4  10
n_event_pct   25  20

$Agetrt_less_180d$Atelectasis$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.81632653 0.5168093  0.2964525 2.2478782 0.6945556
OR_TRTvsCTRL   0.76923077 0.6774765  0.2038861 2.9021888 0.6985586
ARR_TRTvsCTRL -0.04591837 0.1226120 -0.2862334 0.1943967 0.7080312


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$ntab
            CTRL TRT
n_all         16  49
n_event        3  13
n_event_pct   19  27

$Agetrt_less_180d$Pneumonia$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.41496599 0.5721436  0.4610378 4.3426565 0.5440663
OR_TRTvsCTRL  1.56481481 0.7176052  0.3833860 6.3868928 0.5326442
ARR_TRTvsCTRL 0.07780612 0.1161870 -0.1499162 0.3055285 0.5030727


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$ntab
            CTRL TRT
n_all         16  49
n_event        2  13
n_event_pct   12  27

$Agetrt_less_180d$Pyrexia$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.1224490 0.7028619  0.53525420  8.4161687 0.2842939
OR_TRTvsCTRL  2.5277778 0.8222709  0.50445292 12.6665152 0.2594129
ARR_TRTvsCTRL 0.1403061 0.1039898 -0.06351008  0.3441223 0.1772631


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$ntab
```

```
            CTRL TRT
n_all         16  49
n_event        3  13
n_event_pct   19  27

$Agetrt_less_180d$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.41496599 0.5721436  0.4610378 4.3426565 0.5440663
OR_TRTvsCTRL  1.56481481 0.7176052  0.3833860 6.3868928 0.5326442
ARR_TRTvsCTRL 0.07780612 0.1161870 -0.1499162 0.3055285 0.5030727


$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$ntab
            CTRL TRT
n_all         16  49
n_event        9  11
n_event_pct   56  22

$Agetrt_less_180d$`Respiratory failure`$stats
                estimate        se      lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   0.3990930 0.3451261  0.20290941  0.78495718 0.007778818
OR_TRTvsCTRL   0.2251462 0.6092562  0.06821263  0.74312941 0.014394896
ARR_TRTvsCTRL -0.3380102 0.1376001 -0.60770154 -0.06831887 0.014031074



$Gender_Female
$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$ntab
            CTRL TRT
n_all         24  43
n_event        5  11
n_event_pct   21  26

$Gender_Female$Atelectasis$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.22790698 0.4753805  0.4836385 3.117526 0.6658229
OR_TRTvsCTRL  1.30625000 0.6122015  0.3934771 4.336438 0.6625516
ARR_TRTvsCTRL 0.04748062 0.1062986 -0.1608608 0.255822 0.6551118


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$ntab
            CTRL TRT
n_all         24  43
n_event        3  14
n_event_pct   12  33

$Gender_Female$Pneumonia$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.6046512 0.58295748 0.83087417  8.1651445 0.10056065
OR_TRTvsCTRL  3.3793103 0.69775620 0.86078943 13.2665876 0.08096315
ARR_TRTvsCTRL 0.2005814 0.09830443 0.00790826  0.3932545 0.04130945
```

```
$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$ntab
            CTRL TRT
n_all         24  43
n_event        6  11
n_event_pct   25  26

$Gender_Female$Pyrexia$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.023255814 0.4389229  0.4328849 2.4187781 0.9582282
OR_TRTvsCTRL  1.031250000 0.5868401  0.3264711 3.2574906 0.9581811
ARR_TRTvsCTRL 0.005813953 0.1106336 -0.2110238 0.2226517 0.9580893


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$ntab
            CTRL TRT
n_all         24  43
n_event        7  10
n_event_pct   29  23

$Gender_Female$`Respiratory distress`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79734219 0.4218230  0.3488095 1.8226411 0.5913456
OR_TRTvsCTRL   0.73593074 0.5761803  0.2378983 2.2765777 0.5946162
ARR_TRTvsCTRL -0.05910853 0.1129548 -0.2804959 0.1622789 0.6007701



$Disdur_greater_12wk
$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$ntab
            CTRL TRT
n_all         23  46
n_event        3  13
n_event_pct   13  28

$Disdur_greater_12wk$Pneumonia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.1666667 0.58740022  0.68516651  6.8515381 0.1880762
OR_TRTvsCTRL  2.6262626 0.70039949  0.66551375 10.3638061 0.1680221
ARR_TRTvsCTRL 0.1521739 0.09663739 -0.03723189  0.3415797 0.1153281


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$ntab
            CTRL TRT
n_all         23  46
n_event        7  10
n_event_pct   30  22

$Disdur_greater_12wk$Pyrexia$stats
```

```
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.71428571 0.4214733  0.3126895 1.631664 0.4246825
OR_TRTvsCTRL   0.63492063 0.5771784  0.2048445 1.967952 0.4312658
ARR_TRTvsCTRL -0.08695652 0.1135947 -0.3095980 0.135685 0.4439750


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         23  46
n_event        7  12
n_event_pct   30  26

$Disdur_greater_12wk$`Respiratory distress`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85714286 0.4012145  0.3904261 1.8817747 0.7008227
OR_TRTvsCTRL   0.80672269 0.5640055  0.2670803 2.4367257 0.7033490
ARR_TRTvsCTRL -0.04347826 0.1157449 -0.2703342 0.1833777 0.7071857


$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         23  46
n_event        9  10
n_event_pct   39  22

$Disdur_greater_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5555556 0.3819604  0.2627860 1.17449926 0.1238365
OR_TRTvsCTRL   0.4320988 0.5570615  0.1450145 1.28752180 0.1319904
ARR_TRTvsCTRL -0.1739130 0.1185513 -0.4062693 0.05844322 0.1423800



$Gender_Male
$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$ntab
            CTRL TRT
n_all         17  37
n_event        2  10
n_event_pct   12  27

$Gender_Male$Pyrexia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2972973 0.7170421  0.56346873  9.3662250 0.2460690
OR_TRTvsCTRL  2.7777778 0.8388705  0.53659873 14.3795521 0.2232661
ARR_TRTvsCTRL 0.1526232 0.1069422 -0.05697965  0.3622261 0.1535349


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$ntab
            CTRL TRT
n_all         17  37
```

```
n_event        4  10
n_event_pct   24  27

$Gender_Male$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.14864865 0.5139547  0.4194770 3.1453302 0.7874321
OR_TRTvsCTRL  1.20370370 0.6811462  0.3167575 4.5741697 0.7854736
ARR_TRTvsCTRL 0.03497615 0.1261529 -0.2122790 0.2822313 0.7815865


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$ntab
            CTRL TRT
n_all         17  37
n_event        7  11
n_event_pct   41  30

$Gender_Male$`Respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7220077 0.3845981  0.3397593 1.5343072 0.3970460
OR_TRTvsCTRL   0.6043956 0.6101047  0.1828097 1.9982204 0.4091949
ARR_TRTvsCTRL -0.1144674 0.1410467 -0.3909139 0.1619791 0.4170460



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         18  34
n_event        1  11
n_event_pct    6  32

$Disdur_less_equal_12wk$Pyrexia$stats
                estimate         se     lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  5.8235294 1.00296649 0.81556702 41.5827199 0.078969760
OR_TRTvsCTRL  8.1304348 1.09234193 0.95567591 69.1698610 0.055052696
ARR_TRTvsCTRL 0.2679739 0.09670551 0.07843454  0.4575132 0.005587931




\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten oder schweren UEs nach PT, das bei
mindestens 10% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               7.0                10
n_event_pct                          22.0                14
```

```
time-to-event-wk-10th                8.6                 13
time-to-event-wk-25th               22.4                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          52.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4690    0.5010    0.1757    1.2520    0.1307


$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              10.0              15.0
n_event_pct                          31.0              21.0
time-to-event-wk-10th                 4.0              13.1
time-to-event-wk-25th                14.1              44.0
time-to-event-wk-50th                52.7                NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          22.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4491    0.4124    0.2001    1.0080    0.0522


$Ageonset_less_equal_12wk$`Bronchial secretion retention`
$Ageonset_less_equal_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               6.0                 3
n_event_pct                          19.0                 4
time-to-event-wk-10th                 6.1                NA
time-to-event-wk-25th                40.7                NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          40.7                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.18180   0.71070   0.04514   0.73200   0.01644


$Ageonset_less_equal_12wk$Dysphagia
$Ageonset_less_equal_12wk$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                32.0                 72
n_event                               6.0                  6
n_event_pct                          19.0                  8
time-to-event-wk-10th                18.7                 36
time-to-event-wk-25th                19.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25940   0.58810   0.08191   0.82120   0.02174


$Ageonset_less_equal_12wk$Dyspnoea
$Ageonset_less_equal_12wk$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               5.0                  3
n_event_pct                          16.0                  4
time-to-event-wk-10th                21.3                 NA
time-to-event-wk-25th                26.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.18180   0.73620   0.04296   0.76970   0.02059


$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72.0
n_event                               7.0                 8.0
n_event_pct                          22.0                11.0
time-to-event-wk-10th                13.9                23.3
time-to-event-wk-25th                20.3                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           20.3                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.37360   0.52350   0.13390   1.04200   0.06003
```

```
$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              5.0               20.0
n_event_pct                         16.0               28.0
time-to-event-wk-10th               11.9               10.6
time-to-event-wk-25th                 NA               33.1
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4330    0.5019    0.5359    3.8330    0.4732


$Ageonset_less_equal_12wk$`Pneumonia aspiration`
$Ageonset_less_equal_12wk$`Pneumonia aspiration`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                32               72.0
n_event                               5                8.0
n_event_pct                          16               11.0
time-to-event-wk-10th                 9               32.7
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Ageonset_less_equal_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5203    0.5743    0.1688    1.6040    0.2553


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              6.0               20.0
n_event_pct                         19.0               28.0
time-to-event-wk-10th               13.4               15.3
time-to-event-wk-25th               24.3               41.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA               46.4
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   1.2010    0.4684    0.4796    3.0080    0.6957


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               9.0              19.0
n_event_pct                          28.0              26.0
time-to-event-wk-10th                11.0              14.6
time-to-event-wk-25th                28.6              35.0
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           28.6                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7425    0.4083    0.3335    1.6530    0.4659


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              15.0              17.0
n_event_pct                          47.0              24.0
time-to-event-wk-10th                 2.1              11.3
time-to-event-wk-25th                 9.1              34.0
time-to-event-wk-50th                21.9                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.0                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.350400  0.362300  0.172300  0.712900  0.003802


$Ageonset_less_equal_12wk$`Rhinovirus infection`
$Ageonset_less_equal_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               4.0                 9
n_event_pct                          12.0                12
time-to-event-wk-10th                 8.7                18
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA
```

```
$Ageonset_less_equal_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9365    0.6064    0.2853    3.0740    0.9138


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               4.0              14.0
n_event_pct                          12.0              19.0
time-to-event-wk-10th                12.3              21.6
time-to-event-wk-25th                  NA              49.4
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1020    0.5694    0.3610    3.3650    0.8644


$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               6.0                 6
n_event_pct                          19.0                 8
time-to-event-wk-10th                11.7                NA
time-to-event-wk-25th                37.3                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.4                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32760   0.58420   0.10420   1.03000   0.05612



$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Acute respiratory failure`
$Ageonset_greater_12wk$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0               8.0
n_event                               2.0               1.0
n_event_pct                          22.0              12.0
time-to-event-wk-10th                16.4              25.4
```

```
time-to-event-wk-25th                26.0                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           16.4                25.4
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9680    1.4020    0.1262   30.7000    0.6290


$Ageonset_greater_12wk$Anxiety
$Ageonset_greater_12wk$Anxiety$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                 8.0
n_event                                 0                 1.0
n_event_pct                             0                12.0
time-to-event-wk-10th                  NA                 2.1
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                 2.1
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Anxiety$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$`Bone marrow disorder`
$Ageonset_greater_12wk$`Bone marrow disorder`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                43.1                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           43.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Bone marrow disorder`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.245e-09 4.596e+04 0.000e+00       Inf 9.997e-01


$Ageonset_greater_12wk$`Bronchial secretion retention`
$Ageonset_greater_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
```

```
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               19.9                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          19.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.140e-10 4.262e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Candida sepsis`
$Ageonset_greater_12wk$`Candida sepsis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                22.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Candida sepsis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.017e-09 4.176e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Cardio-respiratory arrest`
$Ageonset_greater_12wk$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               2.0                1.0
n_event_pct                          22.0               12.0
time-to-event-wk-10th                23.0               25.4
time-to-event-wk-25th                33.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           23.0               25.4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.07200   1.31900   0.08084  14.22000   0.95780


$Ageonset_greater_12wk$Catarrh
```

```
$Ageonset_greater_12wk$Catarrh$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                30.3                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           30.3                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Catarrh$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.380e-09 4.512e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Cyanosis
$Ageonset_greater_12wk$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                 8.0
n_event                                 0                 1.0
n_event_pct                             0                12.0
time-to-event-wk-10th                  NA                17.9
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                17.9
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.612e+50 3.859e+04 0.000e+00       Inf 9.976e-01


$Ageonset_greater_12wk$Dysphagia
$Ageonset_greater_12wk$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                26.1                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           26.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.256e-09 4.032e+04 0.000e+00       Inf 9.996e-01
```

```
$Ageonset_greater_12wk$`Femur fracture`
$Ageonset_greater_12wk$`Femur fracture`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                50.6                  NA
time-to-event-wk-25th                55.5                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           50.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Femur fracture`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.522e-01 1.273e+05 0.000e+00       Inf 1.000e+00


$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`
$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                48.6                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           48.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Gastrooesophageal reflux disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.714e-09 3.573e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Infusion site bruising`
$Ageonset_greater_12wk$`Infusion site bruising`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                   8
n_event                                 1                   0
n_event_pct                            11                   0
time-to-event-wk-10th                  23                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             23                  NA
time-to-event-wk-50th-hici             NA                  NA
```

```
$Ageonset_greater_12wk$`Infusion site bruising`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.685e-10 4.172e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Nasal congestion`
$Ageonset_greater_12wk$`Nasal congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 7.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Nasopharyngitis
$Ageonset_greater_12wk$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                1.0
n_event_pct                          11.0               12.0
time-to-event-wk-10th                28.3               15.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3               15.7
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.7060    1.6690    0.1027   71.2600    0.5509


$Ageonset_greater_12wk$Oedema
$Ageonset_greater_12wk$Oedema$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 7.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci            7.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Oedema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.253e-10 4.403e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Pain
$Ageonset_greater_12wk$Pain$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA                2.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                2.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Pain$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$Pneumonia
$Ageonset_greater_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                1.0
n_event_pct                          11.0               12.0
time-to-event-wk-10th                 5.7               30.4
time-to-event-wk-25th                  NA               30.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.7               30.4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.1810    1.4550    0.1259   37.7800    0.5920


$Ageonset_greater_12wk$`Pneumonia aspiration`
$Ageonset_greater_12wk$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               2.0                  0
n_event_pct                          22.0                  0
time-to-event-wk-10th                 1.7                 NA
time-to-event-wk-25th                  NA                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.616e-10 2.873e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`
$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                19.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Pneumonia pseudomonal`
$Ageonset_greater_12wk$`Pneumonia pseudomonal`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                15.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Pneumonia pseudomonal`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.446e-09 4.265e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Procedural pain`
$Ageonset_greater_12wk$`Procedural pain`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
```

```
n_event_pct                               0               12.0
time-to-event-wk-10th                    NA                3.3
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               NA                3.3
time-to-event-wk-50th-hici               NA                 NA

$Ageonset_greater_12wk$`Procedural pain`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.483e+09 4.134e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Pseudomonas infection`
$Ageonset_greater_12wk$`Pseudomonas infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               17.7                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          17.7                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Pseudomonas infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.528e-09 4.251e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$Pyrexia
$Ageonset_greater_12wk$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              2.0                  1
n_event_pct                         22.0                 12
time-to-event-wk-10th                5.1                 15
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           5.1                 15
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.92650   1.25000   0.07988  10.75000   0.95130


$Ageonset_greater_12wk$`Respiratory arrest`
$Ageonset_greater_12wk$`Respiratory arrest`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                19.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.140e-10 4.262e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Respiratory distress`
$Ageonset_greater_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               2.0                1.0
n_event_pct                          22.0               12.0
time-to-event-wk-10th                 2.3                0.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            2.3                0.4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.72320   1.24700   0.06275   8.33600   0.79500


$Ageonset_greater_12wk$`Respiratory failure`
$Ageonset_greater_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                2.0
n_event_pct                          11.0               25.0
time-to-event-wk-10th                19.3                0.6
time-to-event-wk-25th                  NA                5.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.3                0.6
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.3050    1.2530    0.2834   38.5400    0.3402
```

```
$Ageonset_greater_12wk$`Respirovirus test positive`
$Ageonset_greater_12wk$`Respirovirus test positive`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               15.9                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          15.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Respirovirus test positive`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Rhinovirus infection`
$Ageonset_greater_12wk$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9                    8
n_event                              0                    1
n_event_pct                          0                   12
time-to-event-wk-10th               NA                    4
time-to-event-wk-25th               NA                   NA
time-to-event-wk-50th               NA                   NA
time-to-event-wk-75th               NA                   NA
time-to-event-wk-90th               NA                   NA
time-to-event-wk-50th-loci          NA                    4
time-to-event-wk-50th-hici          NA                   NA

$Ageonset_greater_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$`Salivary hypersecretion`
$Ageonset_greater_12wk$`Salivary hypersecretion`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                  8
n_event                              1.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               43.1                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          43.1                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Salivary hypersecretion`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.245e-09 4.596e+04 0.000e+00       Inf 9.997e-01


$Ageonset_greater_12wk$`Sleep disorder`
$Ageonset_greater_12wk$`Sleep disorder`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                50.4                 NA
time-to-event-wk-25th                53.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           50.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Sleep disorder`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.437e-09 5.275e+04 0.000e+00       Inf 9.997e-01


$Ageonset_greater_12wk$Tachycardia
$Ageonset_greater_12wk$Tachycardia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA                2.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                2.1
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.512e+09 3.863e+04 0.000e+00       Inf 9.995e-01


$Ageonset_greater_12wk$`Upper respiratory tract congestion`
$Ageonset_greater_12wk$`Upper respiratory tract congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 5.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            5.1                 NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Upper respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.520e-10 4.008e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Upper respiratory tract infection`
$Ageonset_greater_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                28.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.720e-10 4.298e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Viral upper respiratory tract infection`
$Ageonset_greater_12wk$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                8.0
n_event                                 0                1.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA               16.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               16.7
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.069e+10 4.364e+04 0.000e+00       Inf 9.996e-01



$Agetrt_less_180d
$Agetrt_less_180d$`Acute respiratory failure`
$Agetrt_less_180d$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               4.0                  7
n_event_pct                          25.0                 14
```

```
time-to-event-wk-10th                 6.3                 13
time-to-event-wk-25th                22.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4188    0.6314    0.1215    1.4440    0.1680


$Agetrt_less_180d$Apnoea
$Agetrt_less_180d$Apnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                 49
n_event                              2.0                  3
n_event_pct                         12.0                  6
time-to-event-wk-10th                6.3                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Apnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39290   0.93040   0.06344   2.43300   0.31530


$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              4.0               10.0
n_event_pct                         25.0               20.0
time-to-event-wk-10th                7.9               14.4
time-to-event-wk-25th               22.9               44.0
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          22.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5376    0.6071    0.1636    1.7670    0.3066


$Agetrt_less_180d$`Bronchial secretion retention`
$Agetrt_less_180d$`Bronchial secretion retention`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                16.0                 49
n_event                               3.0                  3
n_event_pct                          19.0                  6
time-to-event-wk-10th                 6.1                 NA
time-to-event-wk-25th                40.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.22580   0.85460   0.04230   1.20600   0.08168


$Agetrt_less_180d$`Cardio-respiratory arrest`
$Agetrt_less_180d$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  1
n_event_pct                          12.0                  2
time-to-event-wk-10th                14.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.115400  1.256000  0.009854  1.352000  0.085530


$Agetrt_less_180d$`Corona virus infection`
$Agetrt_less_180d$`Corona virus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                 49
n_event                                 2                  0
n_event_pct                            12                  0
time-to-event-wk-10th                  34                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             34                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Corona virus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.382e-10 3.930e+04 0.000e+00       Inf 9.995e-01
```

```
$Agetrt_less_180d$Cyanosis
$Agetrt_less_180d$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                15.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.855e-11 3.030e+04 0.000e+00       Inf 9.994e-01


$Agetrt_less_180d$Dysphagia
$Agetrt_less_180d$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49.0
n_event                               2.0                 5.0
n_event_pct                          12.0                10.0
time-to-event-wk-10th                18.7                28.4
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           18.7                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6122    0.8442    0.1170    3.2020    0.5610


$Agetrt_less_180d$Dyspnoea
$Agetrt_less_180d$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               3.0                  1
n_event_pct                          19.0                  2
time-to-event-wk-10th                24.4                 NA
time-to-event-wk-25th                26.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
 0.068150  1.175000  0.006809  0.682100  0.022290


$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`
$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 3
n_event_pct                          12.0                 6
time-to-event-wk-10th                 5.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44140   0.91920   0.07285   2.67500   0.37370


$Agetrt_less_180d$Hypokalaemia
$Agetrt_less_180d$Hypokalaemia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 0
n_event_pct                          12.0                 0
time-to-event-wk-10th                22.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.9                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Hypokalaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.361e-10 2.707e+04 0.000e+00       Inf 9.993e-01


$Agetrt_less_180d$Hypoxia
$Agetrt_less_180d$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 2
n_event_pct                          12.0                 4
time-to-event-wk-10th                33.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.4                NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.17280   1.06700   0.02135   1.39900   0.09992


$Agetrt_less_180d$Nasopharyngitis
$Agetrt_less_180d$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16               49.0
n_event                                 0                5.0
n_event_pct                             0               10.0
time-to-event-wk-10th                  NA               37.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.948e+08 1.394e+04 0.000e+00       Inf 9.989e-01


$Agetrt_less_180d$`Oxygen saturation decreased`
$Agetrt_less_180d$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               4.0                 4
n_event_pct                          25.0                 8
time-to-event-wk-10th                17.9                29
time-to-event-wk-25th                20.3                NA
time-to-event-wk-50th                40.7                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.9                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.18550   0.74150   0.04337   0.79340   0.02308


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               3.0               13.0
n_event_pct                          19.0               27.0
time-to-event-wk-10th                11.9                9.0
time-to-event-wk-25th                  NA               33.1
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           13.9                43.6
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0960    0.6496    0.3067    3.9140    0.8882


$Agetrt_less_180d$`Pneumonia aspiration`
$Agetrt_less_180d$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                49.0
n_event                                 2                 5.0
n_event_pct                            12                10.0
time-to-event-wk-10th                   9                32.7
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5510    0.8554    0.1030    2.9460    0.4859


$Agetrt_less_180d$`Pneumonia bacterial`
$Agetrt_less_180d$`Pneumonia bacterial`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 2
n_event_pct                          12.0                 4
time-to-event-wk-10th                36.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           36.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24730   1.03400   0.03261   1.87500   0.17640


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                49.0
n_event                                 2                13.0
n_event_pct                            12                27.0
```

```
time-to-event-wk-10th                  14               15.3
time-to-event-wk-25th                  NA               41.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               44.3
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6890    0.7694    0.3738    7.6290    0.4958


$Agetrt_less_180d$`Respiratory arrest`
$Agetrt_less_180d$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  2
n_event_pct                          12.0                  4
time-to-event-wk-10th                18.2                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.14930   1.05800   0.01878   1.18800   0.07225


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               3.0               13.0
n_event_pct                          19.0               27.0
time-to-event-wk-10th                15.4               14.6
time-to-event-wk-25th                44.6               35.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.4               43.4
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7422    0.6655    0.2014    2.7350    0.6541


$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                16.0              49.0
n_event                               9.0              11.0
n_event_pct                          56.0              22.0
time-to-event-wk-10th                 1.0               4.1
time-to-event-wk-25th                 6.1              43.4
time-to-event-wk-50th                13.0                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.1                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.206100  0.489400  0.078980  0.537900  0.001251


$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`
$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 3
n_event_pct                          12.0                 6
time-to-event-wk-10th                22.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.4                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.35970   0.92480   0.05872   2.20300   0.26880


$Agetrt_less_180d$`Respiratory tract infection`
$Agetrt_less_180d$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               1.0               5.0
n_event_pct                           6.0              10.0
time-to-event-wk-10th                32.9              40.1
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           32.9                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3150    1.1100    0.1493   11.5900    0.8050
```

```
$Agetrt_less_180d$`Rhinovirus infection`
$Agetrt_less_180d$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              2.0               4.0
n_event_pct                         12.0               8.0
time-to-event-wk-10th                8.7              45.3
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.41710   0.89080   0.07277   2.39000   0.32620


$Agetrt_less_180d$`Sleep apnoea syndrome`
$Agetrt_less_180d$`Sleep apnoea syndrome`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              2.0                 0
n_event_pct                         12.0                 0
time-to-event-wk-10th                5.3                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.805e-10 2.855e+04 0.000e+00       Inf 9.994e-01


$Agetrt_less_180d$`Upper respiratory tract infection`
$Agetrt_less_180d$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0              49.0
n_event                              2.0               7.0
n_event_pct                         12.0              14.0
time-to-event-wk-10th               32.6              26.0
time-to-event-wk-25th                 NA              49.4
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          32.6              49.4
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   1.0280    0.8296    0.2022    5.2250    0.9736


$Agetrt_less_180d$`Viral upper respiratory tract infection`
$Agetrt_less_180d$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               2.0                 4
n_event_pct                          12.0                 8
time-to-event-wk-10th                33.4                NA
time-to-event-wk-25th                33.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.4                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4922    0.8714    0.0892    2.7160    0.4160



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Acute respiratory failure`
$Agetrt_greater_equal_180d$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31.0
n_event                               5.0                 4.0
n_event_pct                          20.0                13.0
time-to-event-wk-10th                16.4                19.9
time-to-event-wk-25th                52.6                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           52.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_greater_equal_180d$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5938    0.6863    0.1547    2.2800    0.4476


$Agetrt_greater_equal_180d$Atelectasis
$Agetrt_greater_equal_180d$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31.0
n_event                               6.0                 5.0
n_event_pct                          24.0                16.0
time-to-event-wk-10th                 4.0                11.4
time-to-event-wk-25th                52.7                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
```

```
time-to-event-wk-50th-loci           52.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5309    0.6122    0.1599    1.7620    0.3010


$Agetrt_greater_equal_180d$`Bronchial secretion retention`
$Agetrt_greater_equal_180d$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                 31
n_event                               4.0                  0
n_event_pct                          16.0                  0
time-to-event-wk-10th                 8.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.614e-10 1.264e+04 0.000e+00       Inf 9.987e-01


$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`
$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25               31.0
n_event                                 3                4.0
n_event_pct                            12               13.0
time-to-event-wk-10th                  23               17.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9800    0.7888    0.2088    4.5990    0.9795


$Agetrt_greater_equal_180d$Dysphagia
$Agetrt_greater_equal_180d$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                 31
n_event                               5.0                  1
n_event_pct                          20.0                  3
time-to-event-wk-10th                19.1                 NA
time-to-event-wk-25th                27.9                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.10260   1.11400   0.01155   0.91130   0.04102


$Agetrt_greater_equal_180d$`Lower respiratory tract infection`
$Agetrt_greater_equal_180d$`Lower respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                 31
n_event                                 0                  4
n_event_pct                             0                 13
time-to-event-wk-10th                  NA                 35
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Lower respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.175e+09 2.018e+04 0.000e+00       Inf 9.992e-01


$Agetrt_greater_equal_180d$`Oxygen saturation decreased`
$Agetrt_greater_equal_180d$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               3.0                4.0
n_event_pct                          12.0               13.0
time-to-event-wk-10th                18.9                8.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9922    0.7698    0.2194    4.4860    0.9918


$Agetrt_greater_equal_180d$Pneumonia
$Agetrt_greater_equal_180d$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
```

```
n_event                                3.0               8.0
n_event_pct                           12.0              26.0
time-to-event-wk-10th                 13.7              15.4
time-to-event-wk-25th                   NA              30.4
time-to-event-wk-50th                   NA                NA
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci              NA              30.4
time-to-event-wk-50th-hici              NA                NA

$Agetrt_greater_equal_180d$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.8250    0.6890    0.4730    7.0450    0.3825


$Agetrt_greater_equal_180d$`Pneumonia aspiration`
$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25              31.0
n_event                                 5               3.0
n_event_pct                            20              10.0
time-to-event-wk-10th                  11              37.7
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4709    0.7465    0.1090    2.0340    0.3131


$Agetrt_greater_equal_180d$`Pneumonia viral`
$Agetrt_greater_equal_180d$`Pneumonia viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0              31.0
n_event                               2.0               4.0
n_event_pct                           8.0              13.0
time-to-event-wk-10th                52.6              34.7
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           52.6              46.7
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4620    0.8940    0.2535    8.4340    0.6708


$Agetrt_greater_equal_180d$Pyrexia
```

```
$Agetrt_greater_equal_180d$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               6.0                8.0
n_event_pct                          24.0               26.0
time-to-event-wk-10th                13.4               10.9
time-to-event-wk-25th                24.3               38.6
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.3               38.6
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9106    0.5447    0.3131    2.6490    0.8635


$Agetrt_greater_equal_180d$`Respiratory distress`
$Agetrt_greater_equal_180d$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               8.0                7.0
n_event_pct                          32.0               23.0
time-to-event-wk-10th                 2.9                7.1
time-to-event-wk-25th                15.9               25.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6190    0.5234    0.2219    1.7270    0.3594


$Agetrt_greater_equal_180d$`Respiratory failure`
$Agetrt_greater_equal_180d$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                 31
n_event                               7.0                  8
n_event_pct                          28.0                 26
time-to-event-wk-10th                13.1                 10
time-to-event-wk-25th                19.3                 27
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           21.9                 34
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8191    0.5225    0.2941    2.2810    0.7026
```

```
$Agetrt_greater_equal_180d$`Rhinovirus infection`
$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 25              31.0
n_event                                2               6.0
n_event_pct                            8              19.0
time-to-event-wk-10th                 NA               6.6
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0880    0.8212    0.4176   10.4400    0.3699


$Agetrt_greater_equal_180d$`Upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                              3.0               7.0
n_event_pct                         12.0              23.0
time-to-event-wk-10th               28.3              10.1
time-to-event-wk-25th                 NA              30.7
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA              30.7
time-to-event-wk-50th-hici            NA                NA

$Agetrt_greater_equal_180d$`Upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7770    0.7042    0.4468    7.0630    0.4145


$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0              31.0
n_event                              4.0               3.0
n_event_pct                         16.0              10.0
time-to-event-wk-10th               17.6              24.3
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          37.3                NA
time-to-event-wk-50th-hici            NA                NA
```

```
$Agetrt_greater_equal_180d$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5594    0.7840    0.1203    2.6010    0.4588



$Gender_Male
$Gender_Male$`Acute respiratory failure`
$Gender_Male$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               4.0                5.0
n_event_pct                          24.0               14.0
time-to-event-wk-10th                16.4               25.4
time-to-event-wk-25th                22.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5031    0.6776    0.1333    1.8990    0.3106


$Gender_Male$Aspiration
$Gender_Male$Aspiration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  1
n_event_pct                          12.0                  3
time-to-event-wk-10th                40.3                 NA
time-to-event-wk-25th                56.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.27090   1.26400   0.02276   3.22500   0.30140


$Gender_Male$Atelectasis
$Gender_Male$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               5.0                  4
n_event_pct                          29.0                 11
time-to-event-wk-10th                 3.1                 18
```

```
time-to-event-wk-25th                22.9                 NA
time-to-event-wk-50th                52.7                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31420   0.68390   0.08222   1.20000   0.09046


$Gender_Male$`Bronchial secretion retention`
$Gender_Male$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               4.0                3.0
n_event_pct                          24.0                8.0
time-to-event-wk-10th                 4.3               33.4
time-to-event-wk-25th                19.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.28400   0.78400   0.06109   1.32000   0.10830


$Gender_Male$`Cardio-respiratory arrest`
$Gender_Male$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               3.0                  2
n_event_pct                          18.0                  5
time-to-event-wk-10th                14.3                 NA
time-to-event-wk-25th                33.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29500   0.93520   0.04719   1.84500   0.19180


$Gender_Male$Cyanosis
$Gender_Male$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
```

```
n_event                                2.0                  0
n_event_pct                           12.0                  0
time-to-event-wk-10th                 15.1                 NA
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Gender_Male$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.116e-10 2.171e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$Dysphagia
$Gender_Male$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               4.0                  3
n_event_pct                          24.0                  8
time-to-event-wk-10th                17.1                 NA
time-to-event-wk-25th                27.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           18.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32110   0.77530   0.07026   1.46800   0.14290


$Gender_Male$Dyspnoea
$Gender_Male$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                24.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.291e-10 2.648e+04 0.000e+00       Inf 9.993e-01


$Gender_Male$Hypokalaemia
```

```
$Gender_Male$Hypokalaemia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                22.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Hypokalaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.402e-10 3.970e+04 0.000e+00       Inf 9.996e-01


$Gender_Male$Hypoxia
$Gender_Male$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  3
n_event_pct                          12.0                  8
time-to-event-wk-10th                33.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5237    0.9319    0.0843    3.2530    0.4876


$Gender_Male$`Joint contracture`
$Gender_Male$`Joint contracture`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  1
n_event_pct                          12.0                  3
time-to-event-wk-10th                43.4                 63
time-to-event-wk-25th                56.6                 63
time-to-event-wk-50th                56.6                 63
time-to-event-wk-75th                  NA                 63
time-to-event-wk-90th                  NA                 63
time-to-event-wk-50th-loci           43.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Joint contracture`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.221e-10 3.888e+04 0.000e+00       Inf 9.995e-01
```

```
$Gender_Male$Nasopharyngitis
$Gender_Male$Nasopharyngitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               37.0
n_event                              1.0                4.0
n_event_pct                          6.0               11.0
time-to-event-wk-10th               28.3               37.6
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          28.3                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.7160    1.1730    0.2724   27.0900    0.3945


$Gender_Male$`Oxygen saturation decreased`
$Gender_Male$`Oxygen saturation decreased`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                 37
n_event                              4.0                  4
n_event_pct                         24.0                 11
time-to-event-wk-10th                2.0                 29
time-to-event-wk-25th               20.3                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          17.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.34320   0.72110   0.08352   1.41100   0.13810


$Gender_Male$Pneumonia
$Gender_Male$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               37.0
n_event                              3.0                7.0
n_event_pct                         18.0               19.0
time-to-event-wk-10th               11.3               19.3
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          13.9                 NA
time-to-event-wk-50th-hici            NA                 NA
```

```
$Gender_Male$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8816    0.7018    0.2228    3.4890    0.8575


$Gender_Male$`Pneumonia aspiration`
$Gender_Male$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               3.0                 2
n_event_pct                          18.0                 5
time-to-event-wk-10th                 1.7                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           17.9                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.28320   0.92860   0.04588   1.74800   0.17420


$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               37.0
n_event                                 2               10.0
n_event_pct                            12               27.0
time-to-event-wk-10th                  14               15.0
time-to-event-wk-25th                  NA               38.6
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               38.6
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3090    0.7872    0.4935   10.8000    0.2879


$Gender_Male$`Respiratory arrest`
$Gender_Male$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               2.0                3.0
n_event_pct                          12.0                8.0
time-to-event-wk-10th                19.9               40.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.52250   0.94830   0.08145   3.35200   0.49370


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               4.0               10.0
n_event_pct                          24.0               27.0
time-to-event-wk-10th                 2.3                3.4
time-to-event-wk-25th                33.1               19.3
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.1               35.0
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9180    0.6035    0.2813    2.9960    0.8872


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               7.0               11.0
n_event_pct                          41.0               30.0
time-to-event-wk-10th                 1.0                1.7
time-to-event-wk-25th                13.0               27.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.4               31.9
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6666    0.4951    0.2526    1.7590    0.4127


$Gender_Male$`Rhinovirus infection`
$Gender_Male$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  7
n_event_pct                          12.0                 19
time-to-event-wk-10th                 5.3                  9
time-to-event-wk-25th                  NA                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1170    0.8287    0.2202    5.6700    0.8935


$Gender_Male$`Sleep apnoea syndrome`
$Gender_Male$`Sleep apnoea syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               3.0                 0
n_event_pct                          18.0                 0
time-to-event-wk-10th                 5.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.823e-10 1.745e+04 0.000e+00       Inf 9.990e-01


$Gender_Male$`Upper respiratory tract infection`
$Gender_Male$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               2.0                5.0
n_event_pct                          12.0               14.0
time-to-event-wk-10th                32.6               16.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0480    0.8477    0.1991    5.5220    0.9555


$Gender_Male$`Viral upper respiratory tract infection`
$Gender_Male$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               3.0                 2
```

```
n_event_pct                          18.0                  5
time-to-event-wk-10th                17.6                 NA
time-to-event-wk-25th                33.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25300   0.92400   0.04137   1.54800   0.13690



$Gender_Female
$Gender_Female$`Acute respiratory failure`
$Gender_Female$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24               43.0
n_event                                 5                6.0
n_event_pct                            21               14.0
time-to-event-wk-10th                  13               19.9
time-to-event-wk-25th                  26                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             26                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5442    0.6306    0.1581    1.8730    0.3347


$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24               43.0
n_event                                 5               11.0
n_event_pct                            21               26.0
time-to-event-wk-10th                  11               13.1
time-to-event-wk-25th                  32.9             32.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             32.9             36.0
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1390    0.5468    0.3900    3.3260    0.8119
```

```
$Gender_Female$`Bronchial secretion retention`
$Gender_Female$`Bronchial secretion retention`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0                43
n_event                              3.0                 0
n_event_pct                         12.0                 0
time-to-event-wk-10th               40.7                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.890e-10 1.581e+04 0.000e+00       Inf 9.989e-01


$Gender_Female$Dysphagia
$Gender_Female$Dysphagia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0                43
n_event                              3.0                 3
n_event_pct                         12.0                 7
time-to-event-wk-10th               19.9                36
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          26.1                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42320   0.82540   0.08395   2.13400   0.29750


$Gender_Female$Dyspnoea
$Gender_Female$Dyspnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0                43
n_event                              3.0                 3
n_event_pct                         12.0                 7
time-to-event-wk-10th               13.6                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Female$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
  0.49920   0.83960   0.09629   2.58800   0.40790


$Gender_Female$`Oxygen saturation decreased`
$Gender_Female$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43
n_event                               3.0                 4
n_event_pct                          12.0                 9
time-to-event-wk-10th                18.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6252    0.7792    0.1357    2.8800    0.5467


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               3.0               14.0
n_event_pct                          12.0               33.0
time-to-event-wk-10th                11.9                8.1
time-to-event-wk-25th                  NA               25.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               33.1
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3130    0.6438    0.6550    8.1710    0.1927


$Gender_Female$`Pneumonia aspiration`
$Gender_Female$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24               43.0
n_event                                 4                6.0
n_event_pct                            17               14.0
time-to-event-wk-10th                  11               32.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Gender_Female$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7957    0.6610    0.2178    2.9070    0.7295


$Gender_Female$`Pneumonia bacterial`
$Gender_Female$`Pneumonia bacterial`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43
n_event                               3.0                 2
n_event_pct                          12.0                 5
time-to-event-wk-10th                17.7                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.28270   0.93310   0.04539   1.76000   0.17570


$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43.0
n_event                               6.0                11.0
n_event_pct                          25.0                26.0
time-to-event-wk-10th                 5.1                28.6
time-to-event-wk-25th                24.3                44.3
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           24.3                44.7
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9823    0.5231    0.3524    2.7380    0.9727


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43.0
n_event                               7.0                10.0
n_event_pct                          29.0                23.0
time-to-event-wk-10th                11.0                20.3
time-to-event-wk-25th                15.9                43.4
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9               45.3
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6131    0.5059    0.2275    1.6530    0.3336


$Gender_Female$`Respiratory failure`
$Gender_Female$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                              9.0                8.0
n_event_pct                         38.0               19.0
time-to-event-wk-10th                4.6               21.3
time-to-event-wk-25th               15.7               43.4
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          15.7                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4432    0.5072    0.1640    1.1980    0.1087


$Gender_Female$`Respiratory tract infection`
$Gender_Female$`Respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 24               43.0
n_event                                1                5.0
n_event_pct                            4               12.0
time-to-event-wk-10th                 NA               35.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2030    1.1130    0.2487   19.5200    0.4779


$Gender_Female$`Upper respiratory tract infection`
$Gender_Female$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               24.0               43.0
n_event                              3.0                9.0
n_event_pct                         12.0               21.0
time-to-event-wk-10th               28.3               25.4
```

```
time-to-event-wk-25th                  NA               43.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3               43.4
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3900    0.6785    0.3678    5.2560    0.6272


$Gender_Female$`Viral upper respiratory tract infection`
$Gender_Female$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               3.0                5.0
n_event_pct                          12.0               12.0
time-to-event-wk-10th                37.3               18.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9623    0.7447    0.2236    4.1420    0.9589



$Region_Europe
$Region_Europe$`Acute respiratory failure`
$Region_Europe$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               2.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                16.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.963e-11 3.130e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$Atelectasis
$Region_Europe$Atelectasis$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               2.0                6.0
n_event_pct                          12.0               20.0
time-to-event-wk-10th                32.9               14.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7470    0.8255    0.3464    8.8100    0.4992


$Region_Europe$`Bronchial secretion retention`
$Region_Europe$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               3.0                  1
n_event_pct                          18.0                  3
time-to-event-wk-10th                 6.1                 NA
time-to-event-wk-25th                40.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13220   1.17000   0.01334   1.30900   0.08370


$Region_Europe$Dysphagia
$Region_Europe$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               2.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                26.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.536e-10 3.299e+04 0.000e+00       Inf 9.995e-01
```

```
$Region_Europe$`Feeding disorder of infancy or early childhood`
$Region_Europe$`Feeding disorder of infancy or early childhood`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               2.0                 2
n_event_pct                          12.0                 7
time-to-event-wk-10th                 5.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24440   1.09200   0.02873   2.08000   0.19710


$Region_Europe$Pneumonia
$Region_Europe$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               3.0                6.0
n_event_pct                          18.0               20.0
time-to-event-wk-10th                11.9               14.4
time-to-event-wk-25th                  NA               42.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.9               42.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8553    0.7176    0.2096    3.4910    0.8276


$Region_Europe$`Pneumonia aspiration`
$Region_Europe$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                30
n_event                                 2                 2
n_event_pct                            12                 7
time-to-event-wk-10th                  11                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA
```

```
$Region_Europe$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5012    1.0120    0.0689    3.6450    0.4950


$Region_Europe$Pyrexia
$Region_Europe$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                              6.0                6.0
n_event_pct                         35.0               20.0
time-to-event-wk-10th                2.3               15.0
time-to-event-wk-25th               15.1               29.1
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          15.1               29.1
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4737    0.5847    0.1506    1.4900    0.2013


$Region_Europe$`Respiratory arrest`
$Region_Europe$`Respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17               30.0
n_event                                0                4.0
n_event_pct                            0               13.0
time-to-event-wk-10th                 NA               27.3
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.115e+08 1.390e+04 0.000e+00       Inf 9.989e-01


$Region_Europe$`Respiratory distress`
$Region_Europe$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                              2.0                8.0
n_event_pct                         12.0               27.0
time-to-event-wk-10th               15.4               10.6
time-to-event-wk-25th                 NA               24.3
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
```

```
time-to-event-wk-50th-loci             NA               25.9
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.5270    0.8001    0.5268   12.1300    0.2465


$Region_Europe$`Respiratory failure`
$Region_Europe$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               8.0                8.0
n_event_pct                          47.0               27.0
time-to-event-wk-10th                 2.1                8.2
time-to-event-wk-25th                 9.1               27.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.1               31.9
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.41700   0.51660   0.15150   1.14800   0.09039


$Region_Europe$`Respiratory tract infection`
$Region_Europe$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               1.0                6.0
n_event_pct                           6.0               20.0
time-to-event-wk-10th                32.9               15.7
time-to-event-wk-25th                  NA               40.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9               40.1
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.1430    1.0980    0.2493   18.4200    0.4874


$Region_Europe$`Rhinovirus infection`
$Region_Europe$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 30
n_event                                 0                  3
n_event_pct                             0                 10
time-to-event-wk-10th                  NA                 18
time-to-event-wk-25th                  NA                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.465e+08 1.560e+04 0.000e+00       Inf 9.990e-01


$Region_Europe$`Viral infection`
$Region_Europe$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               30.0
n_event                                 0                4.0
n_event_pct                             0               13.0
time-to-event-wk-10th                  NA               31.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.084e+08 1.348e+04 0.000e+00       Inf 9.988e-01



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               7.0               11.0
n_event_pct                          32.0               29.0
time-to-event-wk-10th                13.0                9.0
time-to-event-wk-25th                22.4               25.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.4               28.0
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8784    0.4845    0.3399    2.2700    0.7890


$Region_Northamerica$Aspiration
$Region_Northamerica$Aspiration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                22.0               38.0
n_event                               2.0                4.0
n_event_pct                           9.0               11.0
time-to-event-wk-10th                56.1               21.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           56.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1490    0.8702    0.2088    6.3270    0.8728


$Region_Northamerica$Atelectasis
$Region_Northamerica$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               8.0                 8
n_event_pct                          36.0                21
time-to-event-wk-10th                 3.1                10
time-to-event-wk-25th                14.1                44
time-to-event-wk-50th                52.7                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           14.1                44
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4471    0.5063    0.1657    1.2060    0.1119


$Region_Northamerica$`Bronchial secretion retention`
$Region_Northamerica$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               4.0                 2
n_event_pct                          18.0                 5
time-to-event-wk-10th                 8.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24580   0.86990   0.04468   1.35200   0.10670
```

```
$Region_Northamerica$`Cardio-respiratory arrest`
$Region_Northamerica$`Cardio-respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38
n_event                              4.0                 3
n_event_pct                         18.0                 8
time-to-event-wk-10th               17.6                NA
time-to-event-wk-25th               33.6                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          33.6                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31570   0.77270   0.06945   1.43600   0.13570


$Region_Northamerica$Dysphagia
$Region_Northamerica$Dysphagia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38
n_event                              5.0                 6
n_event_pct                         23.0                16
time-to-event-wk-10th               18.7                19
time-to-event-wk-25th               19.9                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          19.1                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5497    0.6106    0.1661    1.8190    0.3270


$Region_Northamerica$Dyspnoea
$Region_Northamerica$Dyspnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38
n_event                              4.0                 1
n_event_pct                         18.0                 3
time-to-event-wk-10th               21.3                NA
time-to-event-wk-25th               26.1                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          24.4                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
 0.078330  1.140000  0.008382  0.732000  0.025510


$Region_Northamerica$Hypokalaemia
$Region_Northamerica$Hypokalaemia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                 38
n_event                                 3                  0
n_event_pct                            14                  0
time-to-event-wk-10th                  14                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Hypokalaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.034e-10 1.626e+04 0.000e+00       Inf 9.990e-01


$Region_Northamerica$Hypoxia
$Region_Northamerica$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               2.0                5.0
n_event_pct                           9.0               13.0
time-to-event-wk-10th                33.4               26.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3190    0.8372    0.2556    6.8060    0.7409


$Region_Northamerica$`Oxygen saturation decreased`
$Region_Northamerica$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               6.0                6.0
n_event_pct                          27.0               16.0
time-to-event-wk-10th                13.9               18.3
time-to-event-wk-25th                18.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           18.9                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Region_Northamerica$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4601    0.5822    0.1470    1.4400    0.1824


$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               3.0               10.0
n_event_pct                          14.0               26.0
time-to-event-wk-10th                11.3                6.9
time-to-event-wk-25th                  NA               30.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9460    0.6619    0.5317    7.1220    0.3145


$Region_Northamerica$`Pneumonia aspiration`
$Region_Northamerica$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               5.0                6.0
n_event_pct                          23.0               16.0
time-to-event-wk-10th                 4.0               32.7
time-to-event-wk-25th                17.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5637    0.6091    0.1708    1.8600    0.3467


$Region_Northamerica$`Pneumonia bacterial`
$Region_Northamerica$`Pneumonia bacterial`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               3.0                3.0
n_event_pct                          14.0                8.0
time-to-event-wk-10th                17.7               45.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           36.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5074    0.8212    0.1015    2.5370    0.4087


$Region_Northamerica$`Pneumonia viral`
$Region_Northamerica$`Pneumonia viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38.0
n_event                               2.0                 6.0
n_event_pct                           9.0                16.0
time-to-event-wk-10th                52.6                27.6
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           52.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.8030    0.8330    0.3523    9.2290    0.4791


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                38.0
n_event                                 2                13.0
n_event_pct                             9                34.0
time-to-event-wk-10th                  14                25.1
time-to-event-wk-25th                  NA                41.4
time-to-event-wk-50th                  NA                55.0
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                41.4
time-to-event-wk-50th-hici             NA                  NA

$Region_Northamerica$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  3.61300   0.76080   0.81350  16.05000   0.09129


$Region_Northamerica$`Respiratory arrest`
$Region_Northamerica$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                  38
n_event                               4.0                   1
n_event_pct                          18.0                   3
time-to-event-wk-10th                19.9                  NA
```

```
time-to-event-wk-25th                20.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.10570   1.12500   0.01166   0.95780   0.04568


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               9.0               11.0
n_event_pct                          41.0               29.0
time-to-event-wk-10th                 2.9                7.1
time-to-event-wk-25th                15.9               35.0
time-to-event-wk-50th                44.6                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9               43.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5433    0.4535    0.2234    1.3220    0.1785


$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               7.0               11.0
n_event_pct                          32.0               29.0
time-to-event-wk-10th                13.1                4.1
time-to-event-wk-25th                18.1               32.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           18.1               43.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8025    0.4849    0.3102    2.0760    0.6501


$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`
$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
```

```
n_event                                3.0                  3
n_event_pct                           14.0                  8
time-to-event-wk-10th                 17.7                 34
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            22.4                 NA
time-to-event-wk-50th-hici              NA                 NA

$Region_Northamerica$`Respiratory syncytial virus
bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42960   0.82440   0.08537   2.16200   0.30540


$Region_Northamerica$`Rhinovirus infection`
$Region_Northamerica$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               4.0                  7
n_event_pct                          18.0                 18
time-to-event-wk-10th                 8.7                  9
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Region_Northamerica$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8991    0.6280    0.2626    3.0790    0.8655


$Region_Northamerica$`Sleep apnoea syndrome`
$Region_Northamerica$`Sleep apnoea syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               3.0                  0
n_event_pct                          14.0                  0
time-to-event-wk-10th                 7.3                 NA
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Region_Northamerica$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.293e-10 1.549e+04 0.000e+00       Inf 9.989e-01
```

```
$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                              4.0              13.0
n_event_pct                         18.0              34.0
time-to-event-wk-10th               28.3              16.3
time-to-event-wk-25th               32.6              26.0
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          28.3              29.7
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6830    0.5754    0.5449    5.1980    0.3656


$Region_Northamerica$`Viral upper respiratory tract infection`
$Region_Northamerica$`Viral upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                              6.0               7.0
n_event_pct                         27.0              18.0
time-to-event-wk-10th               11.7              14.6
time-to-event-wk-25th               33.4                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          33.4                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6047    0.5586    0.2023    1.8070    0.3678



$Disdur_greater_12wk
$Disdur_greater_12wk$`Acute respiratory failure`
$Disdur_greater_12wk$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0              46.0
n_event                              4.0               7.0
n_event_pct                         17.0              15.0
time-to-event-wk-10th               13.9              19.9
time-to-event-wk-25th               52.6                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          26.0                NA
time-to-event-wk-50th-hici            NA                NA
```

```
$Disdur_greater_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7567    0.6289    0.2206    2.5960    0.6575


$Disdur_greater_12wk$Atelectasis
$Disdur_greater_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               6.0                 7
n_event_pct                          26.0                15
time-to-event-wk-10th                 4.0                18
time-to-event-wk-25th                52.7                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           14.1                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5039    0.5590    0.1685    1.5070    0.2202


$Disdur_greater_12wk$`Bronchial secretion retention`
$Disdur_greater_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               3.0                 1
n_event_pct                          13.0                 2
time-to-event-wk-10th                 8.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.17580   1.15800   0.01817   1.70200   0.13340


$Disdur_greater_12wk$Dysphagia
$Disdur_greater_12wk$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               5.0                 3
n_event_pct                          22.0                 7
time-to-event-wk-10th                19.1                NA
time-to-event-wk-25th                26.1                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.20200   0.73460   0.04787   0.85250   0.02946


$Disdur_greater_12wk$`Oxygen saturation decreased`
$Disdur_greater_12wk$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                 46
n_event                               3.0                  5
n_event_pct                          13.0                 11
time-to-event-wk-10th                13.9                 29
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7984    0.7350    0.1891    3.3710    0.7593


$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               3.0               13.0
n_event_pct                          13.0               28.0
time-to-event-wk-10th                11.3               15.4
time-to-event-wk-25th                  NA               25.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               35.9
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6710    0.6429    0.4739    5.8910    0.4246


$Disdur_greater_12wk$`Pneumonia aspiration`
$Disdur_greater_12wk$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 3                4.0
n_event_pct                            13                9.0
time-to-event-wk-10th                  11               37.7
```

```
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_greater_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5651    0.7666    0.1258    2.5390    0.4565


$Disdur_greater_12wk$`Pneumonia viral`
$Disdur_greater_12wk$`Pneumonia viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               2.0                6.0
n_event_pct                           9.0               13.0
time-to-event-wk-10th                52.6               27.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5060    0.8191    0.3025    7.5000    0.6171


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               7.0               10.0
n_event_pct                          30.0               22.0
time-to-event-wk-10th                 5.1               25.1
time-to-event-wk-25th                15.1               46.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.1               46.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6063    0.5019    0.2267    1.6220    0.3189


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
```

```
n_event                                7.0               12.0
n_event_pct                           30.0               26.0
time-to-event-wk-10th                  3.1                7.1
time-to-event-wk-25th                 28.6               25.9
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            15.4               35.0
time-to-event-wk-50th-hici              NA                 NA

$Disdur_greater_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7423    0.4789    0.2904    1.8980    0.5338


$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               9.0               10.0
n_event_pct                          39.0               22.0
time-to-event-wk-10th                 2.1               11.3
time-to-event-wk-25th                13.1               34.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4901    0.4669    0.1963    1.2240    0.1267


$Disdur_greater_12wk$`Rhinovirus infection`
$Disdur_greater_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               2.0                8.0
n_event_pct                           9.0               17.0
time-to-event-wk-10th                18.1                9.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0300    0.7924    0.4295    9.5910    0.3717


$Disdur_greater_12wk$Teething
```

```
$Disdur_greater_12wk$Teething$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 23               46.0
n_event                                1                5.0
n_event_pct                            4               11.0
time-to-event-wk-10th                 NA               22.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0590    1.1010    0.2381   17.8000    0.5118


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               2.0                8.0
n_event_pct                           9.0               17.0
time-to-event-wk-10th                12.3               16.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7390    0.7930    0.3676    8.2290    0.4853


$Disdur_greater_12wk$`Viral upper respiratory tract infection`
$Disdur_greater_12wk$`Viral upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               4.0                4.0
n_event_pct                          17.0                9.0
time-to-event-wk-10th                11.7               24.3
time-to-event-wk-25th                37.3                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           37.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.4121    0.7101    0.1025    1.6570    0.2119


$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Acute respiratory failure`
$Disdur_less_equal_12wk$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               5.0                4.0
n_event_pct                          28.0               12.0
time-to-event-wk-10th                 6.3               32.7
time-to-event-wk-25th                22.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           16.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.33930   0.68500   0.08862   1.29900   0.11460


$Disdur_less_equal_12wk$Apnoea
$Disdur_less_equal_12wk$Apnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 3
n_event_pct                          11.0                 9
time-to-event-wk-10th                 6.3                35
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Apnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6982    0.9288    0.1131    4.3110    0.6990


$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               4.0                8.0
n_event_pct                          22.0               24.0
time-to-event-wk-10th                 7.9               14.4
time-to-event-wk-25th                32.9               44.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci           32.9               44.0
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8912    0.6232    0.2627    3.0230    0.8533


$Disdur_less_equal_12wk$`Bronchial secretion retention`
$Disdur_less_equal_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               4.0                 2
n_event_pct                          22.0                 6
time-to-event-wk-10th                 6.1                NA
time-to-event-wk-25th                40.7                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.21470   0.88140   0.03816   1.20800   0.08092


$Disdur_less_equal_12wk$`Cardio-respiratory arrest`
$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               3.0                 1
n_event_pct                          17.0                 3
time-to-event-wk-10th                23.0                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.6                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.19180   1.18800   0.01868   1.97000   0.16470


$Disdur_less_equal_12wk$`Corona virus infection`
$Disdur_less_equal_12wk$`Corona virus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                34
n_event                                 2                 0
n_event_pct                            11                 0
time-to-event-wk-10th                  34                NA
time-to-event-wk-25th                  NA                NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             34                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Corona virus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.131e-10 2.534e+04 0.000e+00       Inf 9.993e-01


$Disdur_less_equal_12wk$Cyanosis
$Disdur_less_equal_12wk$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                15.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.838e-10 2.907e+04 0.000e+00       Inf 9.994e-01


$Disdur_less_equal_12wk$Dysphagia
$Disdur_less_equal_12wk$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
n_event                               2.0                 3.0
n_event_pct                          11.0                 9.0
time-to-event-wk-10th                18.7                28.4
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_less_equal_12wk$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45040   0.94440   0.07076   2.86700   0.39840


$Disdur_less_equal_12wk$Dyspnoea
$Disdur_less_equal_12wk$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               3.0                 0
```

```
n_event_pct                          17.0                  0
time-to-event-wk-10th                24.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.046e-10 1.846e+04 0.000e+00       Inf 9.991e-01


$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`
$Disdur_less_equal_12wk$`Feeding disorder of infancy or early
childhood`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 2
n_event_pct                         11.0                 6
time-to-event-wk-10th                5.9                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48100   1.01100   0.06626   3.49200   0.46940


$Disdur_less_equal_12wk$Hypokalaemia
$Disdur_less_equal_12wk$Hypokalaemia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              2.0                 0
n_event_pct                         11.0                 0
time-to-event-wk-10th               22.9                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$Hypokalaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.141e-09 1.398e+04 0.000e+00       Inf 9.988e-01
```

```
$Disdur_less_equal_12wk$Hypoxia
$Disdur_less_equal_12wk$Hypoxia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                 34
n_event                              2.0                  1
n_event_pct                         11.0                  3
time-to-event-wk-10th               33.4                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          33.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.22240   1.25600   0.01897   2.60700   0.23130


$Disdur_less_equal_12wk$Nasopharyngitis
$Disdur_less_equal_12wk$Nasopharyngitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34.0
n_event                              1.0                 4.0
n_event_pct                          6.0                12.0
time-to-event-wk-10th               28.3                15.7
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci          28.3                  NA
time-to-event-wk-50th-hici            NA                  NA

$Disdur_less_equal_12wk$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2450    1.1350    0.2426   20.7700    0.4762


$Disdur_less_equal_12wk$Oedema
$Disdur_less_equal_12wk$Oedema$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                 34
n_event                              2.0                  0
n_event_pct                         11.0                  0
time-to-event-wk-10th               11.7                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$Oedema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
6.083e-10 1.959e+04 0.000e+00       Inf 9.991e-01


$Disdur_less_equal_12wk$`Oxygen saturation decreased`
$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               4.0                 3
n_event_pct                          22.0                 9
time-to-event-wk-10th                17.9                NA
time-to-event-wk-25th                40.7                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.32870   0.77160   0.07244   1.49100   0.14930


$Disdur_less_equal_12wk$Pneumonia
$Disdur_less_equal_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               3.0                8.0
n_event_pct                          17.0               24.0
time-to-event-wk-10th                11.9                5.0
time-to-event-wk-25th                  NA               42.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               42.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6670    0.6967    0.4255    6.5310    0.4633


$Disdur_less_equal_12wk$`Pneumonia aspiration`
$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               4.0                4.0
n_event_pct                          22.0               12.0
time-to-event-wk-10th                 1.7               32.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.9                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4739    0.7221    0.1151    1.9510    0.3010


$Disdur_less_equal_12wk$`Pneumonia bacterial`
$Disdur_less_equal_12wk$`Pneumonia bacterial`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               2.0                2.0
n_event_pct                          11.0                6.0
time-to-event-wk-10th                36.6               45.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           36.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47650   1.01600   0.06511   3.48700   0.46540


$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 1               11.0
n_event_pct                             6               32.0
time-to-event-wk-10th                  NA               15.3
time-to-event-wk-25th                  NA               41.4
time-to-event-wk-50th                  NA               54.3
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               41.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   5.5070    1.0460    0.7090   42.7700    0.1029


$Disdur_less_equal_12wk$`Respiratory arrest`
$Disdur_less_equal_12wk$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               3.0                  2
n_event_pct                          17.0                  6
time-to-event-wk-10th                19.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26230   0.94900   0.04083   1.68500   0.15850


$Disdur_less_equal_12wk$`Respiratory distress`
$Disdur_less_equal_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               4.0                8.0
n_event_pct                          22.0               24.0
time-to-event-wk-10th                11.7               15.6
time-to-event-wk-25th                44.6               43.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           44.6               43.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0250    0.6245    0.3014    3.4860    0.9685


$Disdur_less_equal_12wk$`Respiratory failure`
$Disdur_less_equal_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               7.0                9.0
n_event_pct                          39.0               26.0
time-to-event-wk-10th                 6.1                3.1
time-to-event-wk-25th                13.0               32.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           10.6               43.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5422    0.5181    0.1964    1.4970    0.2375


$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`
$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  2
n_event_pct                          11.0                  6
time-to-event-wk-10th                22.4                 NA
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respiratory syncytial virus
bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4430    1.0060    0.0617    3.1810    0.4182


$Disdur_less_equal_12wk$`Respiratory tract infection`
$Disdur_less_equal_12wk$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               1.0                4.0
n_event_pct                           6.0               12.0
time-to-event-wk-10th                32.9               35.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7190    1.1200    0.1914   15.4300    0.6287


$Disdur_less_equal_12wk$`Rhinovirus infection`
$Disdur_less_equal_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               2.0                2.0
n_event_pct                          11.0                6.0
time-to-event-wk-10th                 8.7               45.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49910   1.01100   0.06888   3.61700   0.49170


$Disdur_less_equal_12wk$`Sleep apnoea syndrome`
$Disdur_less_equal_12wk$`Sleep apnoea syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                18.0                 34
n_event                               2.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                 5.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.472e-10 1.937e+04 0.000e+00       Inf 9.991e-01


$Disdur_less_equal_12wk$`Upper respiratory tract infection`
$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               3.0                6.0
n_event_pct                          17.0               18.0
time-to-event-wk-10th                28.3               26.0
time-to-event-wk-25th                32.6               49.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.3               49.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7699    0.7136    0.1901    3.1180    0.7140


$Disdur_less_equal_12wk$`Viral infection`
$Disdur_less_equal_12wk$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 0                4.0
n_event_pct                             0               12.0
time-to-event-wk-10th                  NA               31.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.177e+08 1.384e+04 0.000e+00       Inf 9.989e-01
```

```
$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`
$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                 34
n_event                              2.0                  3
n_event_pct                         11.0                  9
time-to-event-wk-10th               33.4                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          33.4                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6664    0.9439    0.1048    4.2390    0.6673



$Region_Asia_Pacific
$Region_Asia_Pacific$Dyspnoea
$Region_Asia_Pacific$Dyspnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 2                12.0
n_event                               0                 2.0
n_event_pct                           0                17.0
time-to-event-wk-10th                NA                12.3
time-to-event-wk-25th                NA                  NA
time-to-event-wk-50th                NA                  NA
time-to-event-wk-75th                NA                  NA
time-to-event-wk-90th                NA                  NA
time-to-event-wk-50th-loci           NA                12.3
time-to-event-wk-50th-hici           NA                  NA

$Region_Asia_Pacific$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.266e+07 2.318e+04 0.000e+00       Inf 9.994e-01


$Region_Asia_Pacific$Oedema
$Region_Asia_Pacific$Oedema$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               2.0                 12
n_event                             1.0                  0
n_event_pct                        50.0                  0
time-to-event-wk-10th               7.6                 NA
time-to-event-wk-25th               7.6                 NA
time-to-event-wk-50th               7.6                 NA
time-to-event-wk-75th               7.6                 NA
time-to-event-wk-90th               7.6                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA
```

```
$Region_Asia_Pacific$Oedema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.266e-14 2.565e+06 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$Pneumonia
$Region_Asia_Pacific$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
n_event                                 0                5.0
n_event_pct                             0               42.0
time-to-event-wk-10th                  NA               20.0
time-to-event-wk-25th                  NA               25.1
time-to-event-wk-50th                  NA               43.6
time-to-event-wk-75th                  NA               43.6
time-to-event-wk-90th                  NA               43.6
time-to-event-wk-50th-loci             NA               20.0
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.083e+08 1.813e+04 0.000e+00       Inf 9.992e-01


$Region_Asia_Pacific$Pyrexia
$Region_Asia_Pacific$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
n_event                                 0                2.0
n_event_pct                             0               17.0
time-to-event-wk-10th                  NA                8.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                8.1
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.759e+06 5.673e+04 0.000e+00       Inf 9.998e-01


$Region_Asia_Pacific$`Respiratory failure`
$Region_Asia_Pacific$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0                12
n_event                               1.0                 0
n_event_pct                          50.0                 0
time-to-event-wk-10th                 0.9                NA
time-to-event-wk-25th                 0.9                NA
time-to-event-wk-50th                25.1                NA
time-to-event-wk-75th                  NA                NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            0.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.188e-28 8.557e+04 0.000e+00       Inf 9.994e-01


$Region_Asia_Pacific$Teething
$Region_Asia_Pacific$Teething$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
n_event                                 0                3.0
n_event_pct                             0               25.0
time-to-event-wk-10th                  NA                9.3
time-to-event-wk-25th                  NA               39.8
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                9.3
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.972e+07 2.715e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$`Urinary tract infection`
$Region_Asia_Pacific$`Urinary tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
n_event                                 0                2.0
n_event_pct                             0               17.0
time-to-event-wk-10th                  NA               26.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               26.9
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`Urinary tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.284e+07 1.991e+04 0.000e+00       Inf 9.993e-01




\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten oder schweren UEs nach PT, das bei
mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat"
```

```
$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0                72
n_event                              7.0                10
n_event_pct                         22.0                14
time-to-event-wk-10th                8.6                13
time-to-event-wk-25th               22.4                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          52.6                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4690    0.5010    0.1757    1.2520    0.1307


$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                             10.0               15.0
n_event_pct                         31.0               21.0
time-to-event-wk-10th                4.0               13.1
time-to-event-wk-25th               14.1               44.0
time-to-event-wk-50th               52.7                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          22.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4491    0.4124    0.2001    1.0080    0.0522


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              5.0               20.0
n_event_pct                         16.0               28.0
time-to-event-wk-10th               11.9               10.6
time-to-event-wk-25th                 NA               33.1
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Pneumonia$stats_HR_TRTvsCTRL
```

```
      HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.4330    0.5019    0.5359    3.8330    0.4732


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              6.0              20.0
n_event_pct                         19.0              28.0
time-to-event-wk-10th               13.4              15.3
time-to-event-wk-25th               24.3              41.4
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA              46.4
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
      HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.2010    0.4684    0.4796    3.0080    0.6957


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              9.0              19.0
n_event_pct                         28.0              26.0
time-to-event-wk-10th               11.0              14.6
time-to-event-wk-25th               28.6              35.0
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          28.6                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
      HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.7425    0.4083    0.3335    1.6530    0.4659


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                             15.0              17.0
n_event_pct                         47.0              24.0
time-to-event-wk-10th                2.1              11.3
time-to-event-wk-25th                9.1              34.0
time-to-event-wk-50th               21.9                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          13.0                NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.350400  0.362300  0.172300  0.712900  0.003802


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                               4.0              14.0
n_event_pct                          12.0              19.0
time-to-event-wk-10th                12.3              21.6
time-to-event-wk-25th                  NA              49.4
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1020    0.5694    0.3610    3.3650    0.8644



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               7.0              11.0
n_event_pct                          32.0              29.0
time-to-event-wk-10th                13.0               9.0
time-to-event-wk-25th                22.4              25.4
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.4              28.0
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8784    0.4845    0.3399    2.2700    0.7890


$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               3.0              10.0
n_event_pct                          14.0              26.0
time-to-event-wk-10th                11.3               6.9
```

```
time-to-event-wk-25th                  NA               30.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9460    0.6619    0.5317    7.1220    0.3145


$Region_Northamerica$Pyrexia
$Region_Northamerica$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22               38.0
n_event                                 2               13.0
n_event_pct                             9               34.0
time-to-event-wk-10th                  14               25.1
time-to-event-wk-25th                  NA               41.4
time-to-event-wk-50th                  NA               55.0
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               41.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  3.61300   0.76080   0.81350  16.05000   0.09129


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               9.0               11.0
n_event_pct                          41.0               29.0
time-to-event-wk-10th                 2.9                7.1
time-to-event-wk-25th                15.9               35.0
time-to-event-wk-50th                44.6                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9               43.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5433    0.4535    0.2234    1.3220    0.1785


$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
```

```
n_event                              7.0              11.0
n_event_pct                         32.0              29.0
time-to-event-wk-10th               13.1               4.1
time-to-event-wk-25th               18.1              32.1
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          18.1              43.4
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8025    0.4849    0.3102    2.0760    0.6501


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               4.0              13.0
n_event_pct                          18.0              34.0
time-to-event-wk-10th                28.3              16.3
time-to-event-wk-25th                32.6              26.0
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           28.3              29.7
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6830    0.5754    0.5449    5.1980    0.3656



$Agetrt_less_180d
$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               4.0              10.0
n_event_pct                          25.0              20.0
time-to-event-wk-10th                 7.9              14.4
time-to-event-wk-25th                22.9              44.0
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           22.9                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5376    0.6071    0.1636    1.7670    0.3066
```

```
$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              3.0               13.0
n_event_pct                         19.0               27.0
time-to-event-wk-10th               11.9                9.0
time-to-event-wk-25th                 NA               33.1
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          13.9               43.6
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0960    0.6496    0.3067    3.9140    0.8882


$Agetrt_less_180d$Pyrexia
$Agetrt_less_180d$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16               49.0
n_event                              2               13.0
n_event_pct                         12               27.0
time-to-event-wk-10th               14               15.3
time-to-event-wk-25th               NA               41.4
time-to-event-wk-50th               NA                 NA
time-to-event-wk-75th               NA                 NA
time-to-event-wk-90th               NA                 NA
time-to-event-wk-50th-loci          NA               44.3
time-to-event-wk-50th-hici          NA                 NA

$Agetrt_less_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6890    0.7694    0.3738    7.6290    0.4958


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              3.0               13.0
n_event_pct                         19.0               27.0
time-to-event-wk-10th               15.4               14.6
time-to-event-wk-25th               44.6               35.0
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          15.4               43.4
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7422    0.6655    0.2014    2.7350    0.6541


$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               9.0               11.0
n_event_pct                          56.0               22.0
time-to-event-wk-10th                 1.0                4.1
time-to-event-wk-25th                 6.1               43.4
time-to-event-wk-50th                13.0                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.206100  0.489400  0.078980  0.537900  0.001251



$Gender_Female
$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               5.0               11.0
n_event_pct                          21.0               26.0
time-to-event-wk-10th                11.0               13.1
time-to-event-wk-25th                32.9               32.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9               36.0
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1390    0.5468    0.3900    3.3260    0.8119


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               3.0               14.0
n_event_pct                          12.0               33.0
time-to-event-wk-10th                11.9                8.1
time-to-event-wk-25th                  NA               25.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               33.1
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3130    0.6438    0.6550    8.1710    0.1927


$Gender_Female$Pyrexia
$Gender_Female$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               6.0               11.0
n_event_pct                          25.0               26.0
time-to-event-wk-10th                 5.1               28.6
time-to-event-wk-25th                24.3               44.3
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.3               44.7
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9823    0.5231    0.3524    2.7380    0.9727


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               7.0               10.0
n_event_pct                          29.0               23.0
time-to-event-wk-10th                11.0               20.3
time-to-event-wk-25th                15.9               43.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9               45.3
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6131    0.5059    0.2275    1.6530    0.3336



$Disdur_greater_12wk
$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               3.0               13.0
```

```
n_event_pct                          13.0              28.0
time-to-event-wk-10th                11.3              15.4
time-to-event-wk-25th                  NA              25.4
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA              35.9
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6710    0.6429    0.4739    5.8910    0.4246


$Disdur_greater_12wk$Pyrexia
$Disdur_greater_12wk$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               7.0              10.0
n_event_pct                          30.0              22.0
time-to-event-wk-10th                 5.1              25.1
time-to-event-wk-25th                15.1              46.4
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.1              46.4
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6063    0.5019    0.2267    1.6220    0.3189


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               7.0              12.0
n_event_pct                          30.0              26.0
time-to-event-wk-10th                 3.1               7.1
time-to-event-wk-25th                28.6              25.9
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.4              35.0
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7423    0.4789    0.2904    1.8980    0.5338


$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$stats_num
```

```
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0               46.0
n_event                              9.0               10.0
n_event_pct                         39.0               22.0
time-to-event-wk-10th                2.1               11.3
time-to-event-wk-25th               13.1               34.0
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          13.1                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_greater_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4901    0.4669    0.1963    1.2240    0.1267



$Gender_Male
$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                17               37.0
n_event                               2               10.0
n_event_pct                          12               27.0
time-to-event-wk-10th                14               15.0
time-to-event-wk-25th                NA               38.6
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA               38.6
time-to-event-wk-50th-hici           NA                 NA

$Gender_Male$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3090    0.7872    0.4935   10.8000    0.2879


$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               37.0
n_event                              4.0               10.0
n_event_pct                         24.0               27.0
time-to-event-wk-10th                2.3                3.4
time-to-event-wk-25th               33.1               19.3
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          33.1               35.0
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.9180    0.6035    0.2813    2.9960    0.8872


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               7.0               11.0
n_event_pct                          41.0               30.0
time-to-event-wk-10th                 1.0                1.7
time-to-event-wk-25th                13.0               27.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            7.4               31.9
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6666    0.4951    0.2526    1.7590    0.4127



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 1               11.0
n_event_pct                             6               32.0
time-to-event-wk-10th                  NA               15.3
time-to-event-wk-25th                  NA               41.4
time-to-event-wk-50th                  NA               54.3
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               41.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   5.5070    1.0460    0.7090   42.7700    0.1029



\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem SUE nach SOC, das bei mindestens 5% der
Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
```

```
n_all         32  72
n_event        5   8
n_event_pct   16  11

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.71111111 0.52901901  0.2521365 2.0055766 0.5192833
OR_TRTvsCTRL   0.67500000 0.61454214  0.2023972 2.2511425 0.5224523
ARR_TRTvsCTRL -0.04513889 0.07410543 -0.1903829 0.1001051 0.5424468


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        5   6
n_event_pct   16   8

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.53333333 0.56703419  0.1755247 1.62053759 0.2676069
OR_TRTvsCTRL   0.49090909 0.64719025  0.1380739 1.74538168 0.2716102
ARR_TRTvsCTRL -0.07291667 0.07197798 -0.2139909 0.06815758 0.3110404


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         32  72
n_event        1   7
n_event_pct    3  10

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats
                estimate         se      lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  3.11111111 1.04772050  0.39911147 24.25140 0.2786819
OR_TRTvsCTRL  3.33846154 1.09110028  0.39336900 28.33300 0.2692214
ARR_TRTvsCTRL 0.06597222 0.04653035 -0.02522559  0.15717 0.1562398


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         32  72
n_event       15  45
n_event_pct   47  62

$Ageonset_less_equal_12wk$`Infections and infestations`$stats
              estimate        se      lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.333333 0.2091650  0.88490604 2.009002 0.1690126
OR_TRTvsCTRL  1.888889 0.4298249  0.81346483 4.386055 0.1389677
ARR_TRTvsCTRL 0.156250 0.1050580 -0.04965997 0.362160 0.1369427
```

```
$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`
$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         32  72
n_event        2   3
n_event_pct    6   4

$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.66666667 0.88780316  0.1170063 3.79846525 0.6478823
OR_TRTvsCTRL   0.65217391 0.93870092  0.1035952 4.10569890 0.6488524
ARR_TRTvsCTRL -0.02083333 0.04884307 -0.1165640 0.07489733 0.6697173


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         32  72
n_event        2   3
n_event_pct    6   4

$Ageonset_less_equal_12wk$Investigations$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.66666667 0.88780316  0.1170063 3.79846525 0.6478823
OR_TRTvsCTRL   0.65217391 0.93870092  0.1035952 4.10569890 0.6488524
ARR_TRTvsCTRL -0.02083333 0.04884307 -0.1165640 0.07489733 0.6697173


$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         32  72
n_event        5   8
n_event_pct   16  11

$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.71111111 0.52901901  0.2521365 2.0055766 0.5192833
OR_TRTvsCTRL   0.67500000 0.61454214  0.2023972 2.2511425 0.5224523
ARR_TRTvsCTRL -0.04513889 0.07410543 -0.1903829 0.1001051 0.5424468


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       25  44
n_event_pct   78  61

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.7822222 0.13262120  0.6031742 1.01441935 0.06402373
```

```
OR_TRTvsCTRL   0.4400000 0.49122164  0.1680057 1.15234175 0.09466170
ARR_TRTvsCTRL -0.1701389 0.09295876 -0.3523347 0.01205693 0.06721076



$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Cardiac disorders`
$Ageonset_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Cardiac disorders`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$`Infections and infestations`
$Ageonset_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all          9   8
n_event        4   2
n_event_pct   44  25

$Ageonset_greater_12wk$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5625000 0.7168604  0.1380161 2.2925311 0.4221963
OR_TRTvsCTRL   0.4166667 1.0567245  0.0525174 3.3057825 0.4074021
ARR_TRTvsCTRL -0.1944444 0.2255490 -0.6365123 0.2476234 0.3886357


$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`
$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Investigations
$Ageonset_greater_12wk$Investigations$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0
```

```
$Ageonset_greater_12wk$Investigations$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          9   8
n_event        5   4
n_event_pct   56  50

$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90000000 0.4624812  0.3635614 2.2279593 0.8197895
OR_TRTvsCTRL   0.80000000 0.9746794  0.1184244 5.4042898 0.8189152
ARR_TRTvsCTRL -0.05555556 0.2422495 -0.5303559 0.4192448 0.8186109



$Agetrt_less_180d
$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        3   4
n_event_pct   19   8

$Agetrt_less_180d$`Cardiac disorders`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4353741 0.7074074  0.10882193 1.7418425 0.2397992
OR_TRTvsCTRL   0.3851852 0.8261226  0.07629089 1.9447620 0.2481601
ARR_TRTvsCTRL -0.1058673 0.1051259 -0.31191036 0.1001757 0.3139094


$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        4   4
n_event_pct   25   8

$Agetrt_less_180d$`Gastrointestinal disorders`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3265306 0.6458265  0.09208638 1.15785025 0.08309174
OR_TRTvsCTRL   0.2666667 0.7781745  0.05802102 1.22560936 0.08940702
ARR_TRTvsCTRL -0.1683673 0.1151031 -0.39396529 0.05723059 0.14353513


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site conditions`$ntab
```

```
            CTRL TRT
n_all         16  49
n_event        1   5
n_event_pct    6  10

$Agetrt_less_180d$`General disorders and administration site conditions`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.63265306 1.05692565  0.2057014 12.9583783 0.6427882
OR_TRTvsCTRL  1.70454545 1.13551483  0.1841012 15.7819465 0.6386026
ARR_TRTvsCTRL 0.03954082 0.07437794 -0.1062373  0.1853189 0.5949891


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         16  49
n_event        8  31
n_event_pct   50  63

$Agetrt_less_180d$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2653061 0.2726718  0.7414758 2.1592069 0.3881408
OR_TRTvsCTRL  1.7222222 0.5812174  0.5512595 5.3804959 0.3496312
ARR_TRTvsCTRL 0.1326531 0.1427162 -0.1470656 0.4123717 0.3526361


$Agetrt_less_180d$`Injury, poisoning and procedural complications`
$Agetrt_less_180d$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         16  49
n_event        1   2
n_event_pct    6   4

$Agetrt_less_180d$`Injury, poisoning and procedural complications`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 1.19041667  0.06333874 6.7334618 0.7203966
OR_TRTvsCTRL   0.63829787 1.26013621  0.05399997 7.5448964 0.7216375
ARR_TRTvsCTRL -0.02168367 0.06679144 -0.15259249 0.1092251 0.7454479


$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$Investigations$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718
```

```
$Agetrt_less_180d$`Metabolism and nutrition disorders`
$Agetrt_less_180d$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        4   7
n_event_pct   25  14

$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5714286 0.5567306  0.1918987 1.7015782 0.3148091
OR_TRTvsCTRL   0.5000000 0.7071068  0.1250488 1.9992191 0.3269587
ARR_TRTvsCTRL -0.1071429 0.1192380 -0.3408451 0.1265594 0.3688856


$Agetrt_less_180d$`Psychiatric disorders`
$Agetrt_less_180d$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$`Psychiatric disorders`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event       13  27
n_event_pct   81  55

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.6781790 0.1762156  0.48011944  0.95794227 0.02753839
OR_TRTvsCTRL   0.2832168 0.7019601  0.07154997  1.12105911 0.07230841
ARR_TRTvsCTRL -0.2614796 0.1207079 -0.49806276 -0.02489642 0.03029458



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Cardiac disorders`
$Agetrt_greater_equal_180d$`Cardiac disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        4   5
n_event_pct   16  16

$Agetrt_greater_equal_180d$`Cardiac disorders`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.008064516 0.61460714  0.3022274 3.3623496 0.9895729
```

```
OR_TRTvsCTRL  1.009615385 0.73217524  0.2403960 4.2401835 0.9895720
ARR_TRTvsCTRL 0.001290323 0.09869009 -0.1921387 0.1947193 0.9895684


$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         25  31
n_event        1   2
n_event_pct    4   6

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.61290323 1.19488156  0.15506839 16.7761900 0.6891052
OR_TRTvsCTRL  1.65517241 1.25544790  0.14132014 19.3857420 0.6881442
ARR_TRTvsCTRL 0.02451613 0.05901607 -0.09115325  0.1401855 0.6778385


$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         25  31
n_event        0   2
n_event_pct    0   6

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  4.06250000 1.52652824  0.20389669 80.9424911 0.3584661
OR_TRTvsCTRL  4.32203390 1.57261375  0.19818780 94.2539187 0.3519777
ARR_TRTvsCTRL 0.06451613 0.04412365 -0.02196464  0.1509969 0.1436956


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         25  31
n_event       11  16
n_event_pct   44  52

$Agetrt_greater_equal_180d$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.17302053 0.2848702  0.6711563 2.0501591 0.5753483
OR_TRTvsCTRL  1.35757576 0.5399114  0.4711841 3.9114474 0.5712544
ARR_TRTvsCTRL 0.07612903 0.1338362 -0.1861851 0.3384431 0.5694766


$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`
$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         25  31
n_event        2   1
```

```
n_event_pct    8   3

$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.40322581 1.1948816  0.03876710 4.19404750 0.4471803
OR_TRTvsCTRL   0.38333333 1.2557116  0.03271244 4.49200497 0.4451109
ARR_TRTvsCTRL -0.04774194 0.0628571 -0.17093960 0.07545572 0.4475348


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       17  21
n_event_pct   68  68

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.996204934 0.1848905  0.6933772 1.4312905 0.9835926
OR_TRTvsCTRL   0.988235294 0.5757105  0.3197531 3.0542601 0.9835996
ARR_TRTvsCTRL -0.002580645 0.1255114 -0.2485784 0.2434172 0.9835958



$Gender_Male
$Gender_Male$`Cardiac disorders`
$Gender_Male$`Cardiac disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        4   4
n_event_pct   24  11

$Gender_Male$`Cardiac disorders`$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.6435444  0.13015510 1.62193414 0.2268663
OR_TRTvsCTRL   0.3939394 0.7792471  0.08553287 1.81436969 0.2319076
ARR_TRTvsCTRL -0.1271860 0.1148483 -0.35228453 0.09791251 0.2681097


$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        3   2
n_event_pct   18   5

$Gender_Male$`Gastrointestinal disorders`$stats
                 estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3063063 0.8645709  0.05626417 1.66755432 0.1711540
OR_TRTvsCTRL   0.2666667 0.9660918  0.04014486 1.77136292 0.1712660
ARR_TRTvsCTRL -0.1224165 0.0996529 -0.31773262 0.07289956 0.2192859
```

```
$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  37
n_event        1   4
n_event_pct    6  11

$Gender_Male$`General disorders and administration site conditions`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.83783784 1.07895757  0.2217670 15.2306185 0.5727177
OR_TRTvsCTRL  1.93939394 1.15879378  0.2001239 18.7946001 0.5675877
ARR_TRTvsCTRL 0.04928458 0.07656783 -0.1007856  0.1993548 0.5197880


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  37
n_event        8  19
n_event_pct   47  51

$Gender_Male$`Infections and infestations`$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.09121622 0.3029538  0.6026096 1.975994 0.7732402
OR_TRTvsCTRL  1.18750000 0.5867693  0.3759886 3.750529 0.7696175
ARR_TRTvsCTRL 0.04292528 0.1463107 -0.2438384 0.329689 0.7692283


$Gender_Male$Investigations
$Gender_Male$Investigations$ntab
            CTRL TRT
n_all         17  37
n_event        1   1
n_event_pct    6   3

$Gender_Male$Investigations$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 1.38352790  0.03052011 6.91684875 0.5740363
OR_TRTvsCTRL   0.4444444 1.44577930  0.02613171 7.55904710 0.5748692
ARR_TRTvsCTRL -0.0317965 0.06298717 -0.15524909 0.09165609 0.6136929


$Gender_Male$`Metabolism and nutrition disorders`
$Gender_Male$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         17  37
n_event        2   2
n_event_pct   12   5

$Gender_Male$`Metabolism and nutrition disorders`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.95611163  0.07053481 2.9928909 0.4159867
```

```
OR_TRTvsCTRL   0.4285714 1.04653624  0.05510740 3.3330089 0.4181580
ARR_TRTvsCTRL -0.0635930 0.08653439 -0.23319729 0.1060113 0.4624083


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event       12  24
n_event_pct   71  65

$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.9189189 0.1978622  0.6235289 1.3542467 0.6691208
OR_TRTvsCTRL   0.7692308 0.6339740  0.2220327 2.6649945 0.6789908
ARR_TRTvsCTRL -0.0572337 0.1355435 -0.3228942 0.2084268 0.6728402



$Gender_Female
$Gender_Female$`Cardiac disorders`
$Gender_Female$`Cardiac disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        3   5
n_event_pct   12  12

$Gender_Female$`Cardiac disorders`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.93023256 0.68440547  0.2432341 3.5576116 0.9158447
OR_TRTvsCTRL   0.92105263 0.77927413  0.1999701 4.2423236 0.9159539
ARR_TRTvsCTRL -0.00872093 0.08334878 -0.1720815 0.1546397 0.9166680


$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event        2   4
n_event_pct    8   9

$Gender_Female$`Gastrointestinal disorders`$stats
                  estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.116279070 0.82769410  0.2204135 5.653368 0.8942721
OR_TRTvsCTRL  1.128205128 0.90614324  0.1910194 6.663442 0.8940966
ARR_TRTvsCTRL 0.009689922 0.07172839 -0.1308951 0.150275 0.8925392


$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         24  43
n_event        0   3
n_event_pct    0   7
```

```
$Gender_Female$`General disorders and administration site conditions`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.97727273 1.49096848  0.214028053 73.9094626 0.3544601
OR_TRTvsCTRL  4.23456790 1.53336948  0.209702028 85.5097371 0.3465777
ARR_TRTvsCTRL 0.06976744 0.03884972 -0.006376618  0.1459115 0.0725218


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$ntab
            CTRL TRT
n_all         24  43
n_event       11  28
n_event_pct   46  65

$Gender_Female$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.4207188 0.2483967  0.8731172 2.3117653 0.1574446
OR_TRTvsCTRL  2.2060606 0.5198203  0.7964263 6.1106761 0.1279889
ARR_TRTvsCTRL 0.1928295 0.1250075 -0.0521808 0.4378397 0.1229418


$Gender_Female$`Injury, poisoning and procedural complications`
$Gender_Female$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         24  43
n_event        3   2
n_event_pct   12   5

$Gender_Female$`Injury, poisoning and procedural complications`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.37209302 0.87659047  0.06675693 2.07399014 0.2594079
OR_TRTvsCTRL   0.34146341 0.95149494  0.05289690 2.20423626 0.2587751
ARR_TRTvsCTRL -0.07848837 0.07475726 -0.22500990 0.06803316 0.2937596


$Gender_Female$Investigations
$Gender_Female$Investigations$ntab
            CTRL TRT
n_all         24  43
n_event        2   2
n_event_pct    8   5

$Gender_Female$Investigations$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.96699406  0.08387566 3.71406607 0.5464751
OR_TRTvsCTRL   0.53658537 1.03433302  0.07066640 4.07440958 0.5472635
ARR_TRTvsCTRL -0.03682171 0.06491707 -0.16405683 0.09041342 0.5705705


$Gender_Female$`Metabolism and nutrition disorders`
$Gender_Female$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         24  43
```

```
n_event        3   6
n_event_pct   12  14

$Gender_Female$`Metabolism and nutrition disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.11627907 0.65960406  0.3064198 4.0665749 0.8675525
OR_TRTvsCTRL  1.13513514 0.75805414  0.2569157 5.0153866 0.8672074
ARR_TRTvsCTRL 0.01453488 0.08572922 -0.1534913 0.1825611 0.8653687


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       18  24
n_event_pct   75  56

$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.7441860 0.1797213  0.5232419 1.05842615 0.10017343
OR_TRTvsCTRL   0.4210526 0.5626015  0.1397813 1.26830489 0.12417196
ARR_TRTvsCTRL -0.1918605 0.1163952 -0.4199909 0.03626995 0.09928012



$Region_Europe
$Region_Europe$`Cardiac disorders`
$Region_Europe$`Cardiac disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        1   3
n_event_pct    6  10

$Region_Europe$`Cardiac disorders`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 1.11408100  0.1914880 15.0923333 0.6338661
OR_TRTvsCTRL  1.77777778 1.19702563  0.1702031 18.5689583 0.6307571
ARR_TRTvsCTRL 0.04117647 0.07909909 -0.1138549  0.1962078 0.6026676


$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        3   2
n_event_pct   18   7

$Region_Europe$`Gastrointestinal disorders`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3777778 0.8609161  0.06989133 2.04197063 0.2581758
OR_TRTvsCTRL   0.3333333 0.9697815  0.04981948 2.23027424 0.2572793
ARR_TRTvsCTRL -0.1098039 0.1030671 -0.31181168 0.09220384 0.2867114
```

```
$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         17  30
n_event        0   5
n_event_pct    0  17

$Region_Europe$`General disorders and administration site conditions`$stats
               estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  6.3870968 1.44706757 0.37459101 108.9054585 0.20005140
OR_TRTvsCTRL  7.5490196 1.50936302 0.39184871 145.4329070 0.18048859
ARR_TRTvsCTRL 0.1666667 0.06804138 0.03330801   0.3000253 0.01430588


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  30
n_event        7  18
n_event_pct   41  60

$Region_Europe$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.4571429 0.3259691  0.7691955 2.7603713 0.2481114
OR_TRTvsCTRL  2.1428571 0.6178560  0.6383711 7.1930519 0.2173804
ARR_TRTvsCTRL 0.1882353 0.1491573 -0.1041077 0.4805783 0.2069519


$Region_Europe$`Injury, poisoning and procedural complications`
$Region_Europe$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         17  30
n_event        2   3
n_event_pct   12  10

$Region_Europe$`Injury, poisoning and procedural complications`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.86091606  0.1572555 4.5944339 0.8502696
OR_TRTvsCTRL   0.83333333 0.96800673  0.1249827 5.5563242 0.8506043
ARR_TRTvsCTRL -0.01764706 0.09542667 -0.2046799 0.1693858 0.8532855


$Region_Europe$Investigations
$Region_Europe$Investigations$ntab
            CTRL TRT
n_all         17  30
n_event        1   3
n_event_pct    6  10

$Region_Europe$Investigations$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 1.11408100  0.1914880 15.0923333 0.6338661
OR_TRTvsCTRL  1.77777778 1.19702563  0.1702031 18.5689583 0.6307571
ARR_TRTvsCTRL 0.04117647 0.07909909 -0.1138549  0.1962078 0.6026676
```

```
$Region_Europe$`Metabolism and nutrition disorders`
$Region_Europe$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        3   4
n_event_pct   18  13

$Region_Europe$`Metabolism and nutrition disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.75555556 0.7008398  0.1912980 2.9841617 0.6891922
OR_TRTvsCTRL   0.71794872 0.8326004  0.1404050 3.6711673 0.6906460
ARR_TRTvsCTRL -0.04313725 0.1113580 -0.2613949 0.1751204 0.6984789


$Region_Europe$`Psychiatric disorders`
$Region_Europe$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Psychiatric disorders`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event       11  19
n_event_pct   65  63

$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.97878788 0.2266800  0.6276799 1.5262965 0.9246451
OR_TRTvsCTRL   0.94214876 0.6333375  0.2722837 3.2599982 0.9250359
ARR_TRTvsCTRL -0.01372549 0.1455146 -0.2989288 0.2714778 0.9248519



$Region_Asia_Pacific
$Region_Asia_Pacific$`Cardiac disorders`
$Region_Asia_Pacific$`Cardiac disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$`Cardiac disorders`$stats
```

```
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$`Infections and infestations`
$Region_Asia_Pacific$`Infections and infestations`$ntab
            CTRL TRT
n_all          2  12
n_event        0   6
n_event_pct    0  50

$Region_Asia_Pacific$`Infections and infestations`$stats
              estimate        se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL       3.0 1.3204506 0.2255027  39.9108364 0.4054100546
OR_TRTvsCTRL       5.0 1.6455067 0.1987523 125.7847088 0.3280345432
ARR_TRTvsCTRL      0.5 0.1443376 0.2171036   0.7828964 0.0005320055


$Region_Asia_Pacific$`Metabolism and nutrition disorders`
$Region_Asia_Pacific$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$`Metabolism and nutrition disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`
$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          2  12
n_event        1   2
n_event_pct   50  17

$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.3333333 0.9574271  0.051040546 2.1769185 0.2511903
OR_TRTvsCTRL   0.2000000 1.6124515  0.008482205 4.7157551 0.3182158
ARR_TRTvsCTRL -0.3333333 0.3695593 -1.057656246 0.3909896 0.3670700



$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$ntab
            CTRL TRT
n_all         22  38
```

```
n_event        6   5
n_event_pct   27  13

$Region_Northamerica$`Cardiac disorders`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4824561 0.5430436  0.1664249 1.39861240 0.1795358
OR_TRTvsCTRL   0.4040404 0.6778419  0.1070150 1.52547433 0.1812391
ARR_TRTvsCTRL -0.1411483 0.1096484 -0.3560553 0.07375863 0.1979964


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        2   4
n_event_pct    9  11

$Region_Northamerica$`Gastrointestinal disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.15789474 0.82354700  0.2304966 5.8166584 0.8587114
OR_TRTvsCTRL  1.17647059 0.91072046  0.1974124 7.0111255 0.8583688
ARR_TRTvsCTRL 0.01435407 0.07896246 -0.1404095 0.1691176 0.8557527


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         22  38
n_event        1   2
n_event_pct    5   5

$Region_Northamerica$`General disorders and administration site
conditions`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.157894737 1.19508563  0.11127827 12.048357 0.9023669
OR_TRTvsCTRL  1.166666667 1.25514813  0.09966961 13.656230 0.9022538
ARR_TRTvsCTRL 0.007177033 0.05730921 -0.10514696  0.119501 0.9003387


$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$ntab
            CTRL TRT
n_all         22  38
n_event       12  23
n_event_pct   55  61

$Region_Northamerica$`Infections and infestations`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.10964912 0.2346087  0.7006262 1.757458 0.6574199
OR_TRTvsCTRL  1.27777778 0.5417363  0.4419046 3.694725 0.6509264
ARR_TRTvsCTRL 0.05980861 0.1325031 -0.1998928 0.319510 0.6517193


$Region_Northamerica$Investigations
```

```
$Region_Northamerica$Investigations$ntab
            CTRL TRT
n_all         22  38
n_event        2   0
n_event_pct    9   0

$Region_Northamerica$Investigations$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.11794872 1.5267222  0.005917591 2.35093991 0.1614948
OR_TRTvsCTRL   0.10649351 1.5731352  0.004878294 2.32476083 0.1545336
ARR_TRTvsCTRL -0.09090909 0.0612909 -0.211037041 0.02921886 0.1380107


$Region_Northamerica$`Metabolism and nutrition disorders`
$Region_Northamerica$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        2   3
n_event_pct    9   8

$Region_Northamerica$`Metabolism and nutrition disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.86842105 0.87267577  0.1570028 4.8034503 0.8715720
OR_TRTvsCTRL   0.85714286 0.95493705  0.1318892 5.5705374 0.8717587
ARR_TRTvsCTRL -0.01196172 0.07530019 -0.1595474 0.1356239 0.8737840


$Region_Northamerica$`Nervous system disorders`
$Region_Northamerica$`Nervous system disorders`$ntab
            CTRL TRT
n_all         22  38
n_event        0   2
n_event_pct    0   5

$Region_Northamerica$`Nervous system disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.94871795 1.52672221  0.14793977 58.7734976 0.4787618
OR_TRTvsCTRL  3.08219178 1.57220918  0.14144669 67.1624512 0.4740152
ARR_TRTvsCTRL 0.05263158 0.03622354 -0.01836525  0.1236284 0.1462331


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       18  27
n_event_pct   82  71

$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.8684211 0.1442992  0.6544894 1.1522800 0.3282321
OR_TRTvsCTRL   0.5454545 0.6584084  0.1500791 1.9824254 0.3572553
ARR_TRTvsCTRL -0.1076555 0.1103378 -0.3239136 0.1086026 0.3292180
```

```
$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        3   7
n_event_pct   13  15

$Disdur_greater_12wk$`Cardiac disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.16666667 0.64107183  0.3320974 4.0985300 0.8099754
OR_TRTvsCTRL  1.19658120 0.74285362  0.2790127 5.1316889 0.8090953
ARR_TRTvsCTRL 0.02173913 0.08795504 -0.1506496 0.1941278 0.8047830


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        1   4
n_event_pct    4   9

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.00000000 1.08847720  0.23687353 16.8866486 0.5242522
OR_TRTvsCTRL  2.09523810 1.14859221  0.22057177 19.9029222 0.5195902
ARR_TRTvsCTRL 0.04347826 0.05944872 -0.07303908  0.1599956 0.4645608


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all         23  46
n_event        0   3
n_event_pct    0   7

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.57446809 1.49089605  0.192379330 66.4147344 0.3928853
OR_TRTvsCTRL  3.78160920 1.53338057  0.187266777 76.3646834 0.3856888
ARR_TRTvsCTRL 0.06521739 0.03640475 -0.006134617  0.1365694 0.0732207


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         23  46
n_event       11  28
n_event_pct   48  61

$Disdur_greater_12wk$`Infections and infestations`$stats
```

```
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2727273 0.2478023  0.7830791 2.0685454 0.3304522
OR_TRTvsCTRL  1.6969697 0.5152788  0.6181131 4.6588660 0.3047379
ARR_TRTvsCTRL 0.1304348 0.1265976 -0.1176920 0.3785616 0.3028646


$Disdur_greater_12wk$`Metabolism and nutrition disorders`
$Disdur_greater_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         23  46
n_event        3   5
n_event_pct   13  11

$Disdur_greater_12wk$`Metabolism and nutrition disorders`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83333333 0.68418999  0.2179893 3.1856813 0.7898711
OR_TRTvsCTRL   0.81300813 0.77956628  0.1764115 3.7468206 0.7905855
ARR_TRTvsCTRL -0.02173913 0.08388968 -0.1861599 0.1426816 0.7955276


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       16  29
n_event_pct   70  63

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90625000 0.1782284  0.6390572 1.2851574 0.5807255
OR_TRTvsCTRL   0.74632353 0.5465011  0.2557082 2.1782599 0.5923740
ARR_TRTvsCTRL -0.06521739 0.1194578 -0.2993503 0.1689155 0.5851036



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Cardiac disorders`
$Disdur_less_equal_12wk$`Cardiac disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        4   2
n_event_pct   22   6

$Disdur_less_equal_12wk$`Cardiac disorders`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2647059 0.8154954  0.05353190 1.30892421 0.10313299
OR_TRTvsCTRL   0.2187500 0.9234060  0.03580498 1.33644977 0.09978616
ARR_TRTvsCTRL -0.1633987 0.1059742 -0.37110428 0.04430689 0.12310455


$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all         18  34
```

```
n_event        4   2
n_event_pct   22   6

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2647059 0.8154954  0.05353190 1.30892421 0.10313299
OR_TRTvsCTRL   0.2187500 0.9234060  0.03580498 1.33644977 0.09978616
ARR_TRTvsCTRL -0.1633987 0.1059742 -0.37110428 0.04430689 0.12310455


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$ntab
            CTRL TRT
n_all         18  34
n_event        1   4
n_event_pct    6  12

$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.1176471 1.07936680  0.25532592 17.5635484 0.4869707
OR_TRTvsCTRL  2.2666667 1.15851494  0.23402268 21.9541871 0.4799741
ARR_TRTvsCTRL 0.0620915 0.07725333 -0.08932223  0.2135052 0.4215478


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         18  34
n_event        8  19
n_event_pct   44  56

$Disdur_less_equal_12wk$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2573529 0.3044080  0.6923801 2.2833359 0.4518657
OR_TRTvsCTRL  1.5833333 0.5867693  0.5013181 5.0007059 0.4335351
ARR_TRTvsCTRL 0.1143791 0.1448054 -0.1694342 0.3981924 0.4295969


$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`
$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3

$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`$stats
                  estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495
```

```
$Disdur_less_equal_12wk$Investigations
$Disdur_less_equal_12wk$Investigations$ntab
            CTRL TRT
n_all         18  34
n_event        3   1
n_event_pct   17   3

$Disdur_less_equal_12wk$Investigations$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1764706 1.1173030  0.01975251 1.5766031 0.1205452
OR_TRTvsCTRL   0.1515152 1.1959528  0.01453648 1.5792574 0.1145932
ARR_TRTvsCTRL -0.1372549 0.0924968 -0.31854530 0.0440355 0.1378386


$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`
$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        2   3
n_event_pct   11   9

$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.79411765 0.86508151  0.1457223 4.3275646 0.7898725
OR_TRTvsCTRL   0.77419355 0.96337500  0.1171718 5.1153557 0.7904985
ARR_TRTvsCTRL -0.02287582 0.08861794 -0.1965638 0.1508122 0.7962990


$Disdur_less_equal_12wk$`Psychiatric disorders`
$Disdur_less_equal_12wk$`Psychiatric disorders`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Psychiatric disorders`$stats
                estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         18  34
n_event       14  19
n_event_pct   78  56

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.7184874 0.1977191  0.48766364 1.05856597 0.09450355
OR_TRTvsCTRL   0.3619048 0.6638726  0.09851558 1.32948570 0.12577488
ARR_TRTvsCTRL -0.2189542 0.1298205 -0.47339777 0.03548928 0.09168181
```

```
\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem SUE nach SOC, das bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         32  72
n_event       15  45
n_event_pct   47  62

$Ageonset_less_equal_12wk$`Infections and infestations`$stats
              estimate        se      lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.333333 0.2091650  0.88490604 2.009002 0.1690126
OR_TRTvsCTRL  1.888889 0.4298249  0.81346483 4.386055 0.1389677
ARR_TRTvsCTRL 0.156250 0.1050580 -0.04965997 0.362160 0.1369427


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         32  72
n_event       25  44
n_event_pct   78  61

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats
                estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.7822222 0.13262120  0.6031742 1.01441935 0.06402373
OR_TRTvsCTRL   0.4400000 0.49122164  0.1680057 1.15234175 0.09466170
ARR_TRTvsCTRL -0.1701389 0.09295876 -0.3523347 0.01205693 0.06721076



$Agetrt_less_180d
$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         16  49
n_event        8  31
n_event_pct   50  63

$Agetrt_less_180d$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2653061 0.2726718  0.7414758 2.1592069 0.3881408
OR_TRTvsCTRL  1.7222222 0.5812174  0.5512595 5.3804959 0.3496312
ARR_TRTvsCTRL 0.1326531 0.1427162 -0.1470656 0.4123717 0.3526361
```

```
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         16  49
n_event       13  27
n_event_pct   81  55

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.6781790 0.1762156  0.48011944  0.95794227 0.02753839
OR_TRTvsCTRL   0.2832168 0.7019601  0.07154997  1.12105911 0.07230841
ARR_TRTvsCTRL -0.2614796 0.1207079 -0.49806276 -0.02489642 0.03029458



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$ntab
            CTRL TRT
n_all         25  31
n_event       11  16
n_event_pct   44  52

$Agetrt_greater_equal_180d$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.17302053 0.2848702  0.6711563 2.0501591 0.5753483
OR_TRTvsCTRL  1.35757576 0.5399114  0.4711841 3.9114474 0.5712544
ARR_TRTvsCTRL 0.07612903 0.1338362 -0.1861851 0.3384431 0.5694766


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$ntab
            CTRL TRT
n_all         25  31
n_event       17  21
n_event_pct   68  68

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.996204934 0.1848905  0.6933772 1.4312905 0.9835926
OR_TRTvsCTRL   0.988235294 0.5757105  0.3197531 3.0542601 0.9835996
ARR_TRTvsCTRL -0.002580645 0.1255114 -0.2485784 0.2434172 0.9835958



$Gender_Male
$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  37
n_event        8  19
```

```
n_event_pct   47  51

$Gender_Male$`Infections and infestations`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.09121622 0.3029538  0.6026096 1.975994 0.7732402
OR_TRTvsCTRL  1.18750000 0.5867693  0.3759886 3.750529 0.7696175
ARR_TRTvsCTRL 0.04292528 0.1463107 -0.2438384 0.329689 0.7692283


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  37
n_event       12  24
n_event_pct   71  65

$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.9189189 0.1978622  0.6235289 1.3542467 0.6691208
OR_TRTvsCTRL   0.7692308 0.6339740  0.2220327 2.6649945 0.6789908
ARR_TRTvsCTRL -0.0572337 0.1355435 -0.3228942 0.2084268 0.6728402



$Gender_Female
$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$ntab
            CTRL TRT
n_all         24  43
n_event       11  28
n_event_pct   46  65

$Gender_Female$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.4207188 0.2483967  0.8731172 2.3117653 0.1574446
OR_TRTvsCTRL  2.2060606 0.5198203  0.7964263 6.1106761 0.1279889
ARR_TRTvsCTRL 0.1928295 0.1250075 -0.0521808 0.4378397 0.1229418


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         24  43
n_event       18  24
n_event_pct   75  56

$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.7441860 0.1797213  0.5232419 1.05842615 0.10017343
OR_TRTvsCTRL   0.4210526 0.5626015  0.1397813 1.26830489 0.12417196
ARR_TRTvsCTRL -0.1918605 0.1163952 -0.4199909 0.03626995 0.09928012
```

```
$Region_Europe
$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$ntab
            CTRL TRT
n_all         17  30
n_event        7  18
n_event_pct   41  60

$Region_Europe$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.4571429 0.3259691  0.7691955 2.7603713 0.2481114
OR_TRTvsCTRL  2.1428571 0.6178560  0.6383711 7.1930519 0.2173804
ARR_TRTvsCTRL 0.1882353 0.1491573 -0.1041077 0.4805783 0.2069519


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         17  30
n_event       11  19
n_event_pct   65  63

$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.97878788 0.2266800  0.6276799 1.5262965 0.9246451
OR_TRTvsCTRL   0.94214876 0.6333375  0.2722837 3.2599982 0.9250359
ARR_TRTvsCTRL -0.01372549 0.1455146 -0.2989288 0.2714778 0.9248519



$Region_Northamerica
$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$ntab
            CTRL TRT
n_all         22  38
n_event       12  23
n_event_pct   55  61

$Region_Northamerica$`Infections and infestations`$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.10964912 0.2346087  0.7006262 1.757458 0.6574199
OR_TRTvsCTRL  1.27777778 0.5417363  0.4419046 3.694725 0.6509264
ARR_TRTvsCTRL 0.05980861 0.1325031 -0.1998928 0.319510 0.6517193


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         22  38
n_event       18  27
n_event_pct   82  71

$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.8684211 0.1442992  0.6544894 1.1522800 0.3282321
OR_TRTvsCTRL   0.5454545 0.6584084  0.1500791 1.9824254 0.3572553
ARR_TRTvsCTRL -0.1076555 0.1103378 -0.3239136 0.1086026 0.3292180



$Disdur_greater_12wk
$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         23  46
n_event       11  28
n_event_pct   48  61

$Disdur_greater_12wk$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2727273 0.2478023  0.7830791 2.0685454 0.3304522
OR_TRTvsCTRL  1.6969697 0.5152788  0.6181131 4.6588660 0.3047379
ARR_TRTvsCTRL 0.1304348 0.1265976 -0.1176920 0.3785616 0.3028646


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all         23  46
n_event       16  29
n_event_pct   70  63

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90625000 0.1782284  0.6390572 1.2851574 0.5807255
OR_TRTvsCTRL   0.74632353 0.5465011  0.2557082 2.1782599 0.5923740
ARR_TRTvsCTRL -0.06521739 0.1194578 -0.2993503 0.1689155 0.5851036



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$ntab
            CTRL TRT
n_all         18  34
n_event        8  19
n_event_pct   44  56

$Disdur_less_equal_12wk$`Infections and infestations`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.2573529 0.3044080  0.6923801 2.2833359 0.4518657
OR_TRTvsCTRL  1.5833333 0.5867693  0.5013181 5.0007059 0.4335351
ARR_TRTvsCTRL 0.1143791 0.1448054 -0.1694342 0.3981924 0.4295969


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
```

```
n_all         18  34
n_event       14  19
n_event_pct   78  56

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.7184874 0.1977191  0.48766364 1.05856597 0.09450355
OR_TRTvsCTRL   0.3619048 0.6638726  0.09851558 1.32948570 0.12577488
ARR_TRTvsCTRL -0.2189542 0.1298205 -0.47339777 0.03548928 0.09168181




\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines SUEs nach SOC, das bei mindestens 5% der
Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Cardiac disorders`
$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0                72
n_event                              5.0                 8
n_event_pct                         16.0                11
time-to-event-wk-10th               12.7                16
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6122    0.5746    0.1985    1.8880    0.3931


$Ageonset_less_equal_12wk$`Gastrointestinal disorders`
$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0                72
n_event                              5.0                 6
n_event_pct                         16.0                 8
time-to-event-wk-10th               15.3                NA
time-to-event-wk-25th               40.3                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          40.3                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.3797    0.6107    0.1147    1.2570    0.1128


$Ageonset_less_equal_12wk$`General disorders and administration site conditions`
$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32               72.0
n_event                                 1                7.0
n_event_pct                             3               10.0
time-to-event-wk-10th                  NA               46.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.4110    1.0700    0.2961   19.6300    0.4108


$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              15.0               45.0
n_event_pct                          47.0               62.0
time-to-event-wk-10th                 5.3                2.7
time-to-event-wk-25th                11.7                6.9
time-to-event-wk-50th                32.9               25.4
time-to-event-wk-75th                52.6               46.7
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.7               13.0
time-to-event-wk-50th-hici             NA               34.7

$Ageonset_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2540    0.3032    0.6922    2.2720    0.4554


$Ageonset_less_equal_12wk$`Injury, poisoning and procedural complications`
$Ageonset_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               2.0                  3
n_event_pct                           6.0                  4
time-to-event-wk-10th                47.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           47.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.52820   0.91720   0.08752   3.18800   0.48650


$Ageonset_less_equal_12wk$Investigations
$Ageonset_less_equal_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               2.0                  3
n_event_pct                           6.0                  4
time-to-event-wk-10th                40.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45970   0.91420   0.07661   2.75800   0.39520


$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`
$Ageonset_less_equal_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               5.0                  8
n_event_pct                          16.0                 11
time-to-event-wk-10th                 8.9                 14
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Metabolism and nutrition
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5627    0.5731    0.1830    1.7300    0.3157


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72.0
```

```
n_event                              25.0              44.0
n_event_pct                          78.0              61.0
time-to-event-wk-10th                 1.0               1.7
time-to-event-wk-25th                 3.3               5.7
time-to-event-wk-50th                 9.0              15.6
time-to-event-wk-75th                22.4                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            4.0              10.0
time-to-event-wk-50th-hici           15.7              32.7

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.63630   0.25520   0.38580   1.04900   0.07652



$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Cardiac disorders`
$Ageonset_greater_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0               8.0
n_event                               2.0               1.0
n_event_pct                          22.0              12.0
time-to-event-wk-10th                23.0              25.4
time-to-event-wk-25th                33.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           23.0              25.4
time-to-event-wk-50th-hici             NA                NA

$Ageonset_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.07200   1.31900   0.08084  14.22000   0.95780


$Ageonset_greater_12wk$`Infections and infestations`
$Ageonset_greater_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0               8.0
n_event                               4.0               2.0
n_event_pct                          44.0              25.0
time-to-event-wk-10th                 5.7               3.0
time-to-event-wk-25th                19.3              16.7
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            5.7               3.0
time-to-event-wk-50th-hici             NA                NA

$Ageonset_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9407    0.8807    0.1674    5.2850    0.9446
```

```
$Ageonset_greater_12wk$`Injury, poisoning and procedural complications`
$Ageonset_greater_12wk$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                50.6                  NA
time-to-event-wk-25th                55.5                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           50.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.522e-01 1.273e+05 0.000e+00       Inf 1.000e+00


$Ageonset_greater_12wk$Investigations
$Ageonset_greater_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                   8
n_event                               1.0                   0
n_event_pct                          11.0                   0
time-to-event-wk-10th                15.9                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           15.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8.0
n_event                               5.0                 4.0
n_event_pct                          56.0                50.0
time-to-event-wk-10th                 1.7                 0.6
time-to-event-wk-25th                16.4                 2.9
time-to-event-wk-50th                26.0                41.3
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
```

```
time-to-event-wk-50th-loci            1.7                0.6
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2390    0.7083    0.3093    4.9670    0.7619



$Agetrt_less_180d
$Agetrt_less_180d$`Cardiac disorders`
$Agetrt_less_180d$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               3.0                 4
n_event_pct                          19.0                 8
time-to-event-wk-10th                 9.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           14.3                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31380   0.78610   0.06722   1.46500   0.14040


$Agetrt_less_180d$`Gastrointestinal disorders`
$Agetrt_less_180d$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               4.0                 4
n_event_pct                          25.0                 8
time-to-event-wk-10th                13.6                NA
time-to-event-wk-25th                15.3                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.2174    0.7134    0.0537    0.8798    0.0324


$Agetrt_less_180d$`General disorders and administration site conditions`
$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16               49.0
```

```
n_event                                1                5.0
n_event_pct                            6               10.0
time-to-event-wk-10th                 NA               25.9
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3710    1.1020    0.1581   11.8900    0.7745


$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               8.0               31.0
n_event_pct                          50.0               63.0
time-to-event-wk-10th                 6.7                2.7
time-to-event-wk-25th                 9.9                6.7
time-to-event-wk-50th                32.9               25.3
time-to-event-wk-75th                33.4               43.6
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.7               10.6
time-to-event-wk-50th-hici             NA               34.7

$Agetrt_less_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0860    0.4011    0.4949    2.3840    0.8367


$Agetrt_less_180d$`Injury, poisoning and procedural complications`
$Agetrt_less_180d$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               1.0                  2
n_event_pct                           6.0                  4
time-to-event-wk-10th                47.1                 NA
time-to-event-wk-25th                47.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           47.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.41120   1.27300   0.03395   4.98100   0.48500
```

```
$Agetrt_less_180d$Investigations
$Agetrt_less_180d$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              2.0                 3
n_event_pct                         12.0                 6
time-to-event-wk-10th               17.9                NA
time-to-event-wk-25th               40.7                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          17.9                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.25010   0.97140   0.03726   1.67900   0.15360


$Agetrt_less_180d$`Metabolism and nutrition disorders`
$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0               49.0
n_event                              4.0                7.0
n_event_pct                         25.0               14.0
time-to-event-wk-10th                6.0                8.9
time-to-event-wk-25th               34.9                 NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           9.6                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4355    0.6406    0.1241    1.5290    0.1945


$Agetrt_less_180d$`Psychiatric disorders`
$Agetrt_less_180d$`Psychiatric disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                16                 49
n_event                               1                  0
n_event_pct                           6                  0
time-to-event-wk-10th                NA                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Agetrt_less_180d$`Psychiatric disorders`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.637e-10 4.413e+04 0.000e+00       Inf 9.996e-01


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                              13.0              27.0
n_event_pct                          81.0              55.0
time-to-event-wk-10th                 0.9               1.7
time-to-event-wk-25th                 4.7               5.0
time-to-event-wk-50th                 8.6              32.1
time-to-event-wk-75th                15.7                NA
time-to-event-wk-90th                22.4                NA
time-to-event-wk-50th-loci            3.4              10.0
time-to-event-wk-50th-hici           15.7                NA

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.396800  0.356000  0.197500  0.797300  0.009423



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Cardiac disorders`
$Agetrt_greater_equal_180d$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               4.0                 5
n_event_pct                          16.0                16
time-to-event-wk-10th                17.6                12
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           33.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8610    0.6916    0.2220    3.3400    0.8286


$Agetrt_greater_equal_180d$`Gastrointestinal disorders`
$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25                31
n_event                               1                 2
n_event_pct                           4                 6
time-to-event-wk-10th                NA                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2490    1.2390    0.1101   14.1600    0.8577


$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`
$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                 31
n_event                                 0                  2
n_event_pct                             0                  6
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.542e+08 1.732e+04 0.000e+00       Inf 9.991e-01


$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              11.0               16.0
n_event_pct                          44.0               52.0
time-to-event-wk-10th                 5.7                3.4
time-to-event-wk-25th                15.3                8.1
time-to-event-wk-50th                52.6               30.9
time-to-event-wk-75th                  NA               55.4
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.6               11.4
time-to-event-wk-50th-hici             NA               55.4

$Agetrt_greater_equal_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2220    0.3937    0.5648    2.6430    0.6108


$Agetrt_greater_equal_180d$`Injury, poisoning and procedural complications`
$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               2.0                 1
n_event_pct                           8.0                 3
time-to-event-wk-10th                50.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           50.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3674    1.2520    0.0316    4.2720    0.4238


$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                              17.0               21.0
n_event_pct                          68.0               68.0
time-to-event-wk-10th                 1.7                0.6
time-to-event-wk-25th                 4.0                5.7
time-to-event-wk-50th                15.9               11.6
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            4.6                7.1
time-to-event-wk-50th-hici           52.6               26.9

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9772    0.3297    0.5120    1.8650    0.9442



$Gender_Male
$Gender_Male$`Cardiac disorders`
$Gender_Male$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               4.0                4.0
n_event_pct                          24.0               11.0
time-to-event-wk-10th                 9.4               25.4
time-to-event-wk-25th                33.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           14.3                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Gender_Male$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4291    0.7232    0.1040    1.7710    0.2420


$Gender_Male$`Gastrointestinal disorders`
$Gender_Male$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37
n_event                               3.0                 2
n_event_pct                          18.0                 5
time-to-event-wk-10th                13.6                NA
time-to-event-wk-25th                40.3                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.3                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Male$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.28140   0.92780   0.04567   1.73400   0.17170


$Gender_Male$`General disorders and administration site conditions`
$Gender_Male$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 17               37.0
n_event                                1                4.0
n_event_pct                            6               11.0
time-to-event-wk-10th                 NA               25.9
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3590    1.1590    0.2432   22.8900    0.4591


$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               8.0               19.0
n_event_pct                          47.0               51.0
time-to-event-wk-10th                 5.3                2.7
time-to-event-wk-25th                13.9                6.0
time-to-event-wk-50th                33.4               28.6
```

```
time-to-event-wk-75th                52.6                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           13.9                 9.0
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1970    0.4243    0.5211    2.7500    0.6718


$Gender_Male$Investigations
$Gender_Male$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                  37
n_event                                 1                   1
n_event_pct                             6                   3
time-to-event-wk-10th                  NA                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3032    1.4410    0.0180    5.1050    0.4075


$Gender_Male$`Metabolism and nutrition disorders`
$Gender_Male$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                  37
n_event                               2.0                   2
n_event_pct                          12.0                   5
time-to-event-wk-10th                34.9                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           34.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4418    1.0240    0.0594    3.2860    0.4249


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37.0
n_event                              12.0                24.0
n_event_pct                          71.0                65.0
```

```
time-to-event-wk-10th                 0.7                0.7
time-to-event-wk-25th                 1.7                4.1
time-to-event-wk-50th                16.4               11.3
time-to-event-wk-75th                52.6                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.0                5.7
time-to-event-wk-50th-hici           52.6               26.9

$Gender_Male$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9298    0.3600    0.4592    1.8830    0.8398



$Gender_Female
$Gender_Female$`Cardiac disorders`
$Gender_Female$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               3.0                5.0
n_event_pct                          12.0               12.0
time-to-event-wk-10th                17.6               17.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1710    0.7521    0.2681    5.1130    0.8338


$Gender_Female$`Gastrointestinal disorders`
$Gender_Female$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               2.0                  4
n_event_pct                           8.0                  9
time-to-event-wk-10th                36.4                 25
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7723    0.8962    0.1334    4.4730    0.7731
```

```
$Gender_Female$`General disorders and administration site conditions`
$Gender_Female$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24                 43
n_event                                 0                  3
n_event_pct                             0                  7
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.224e+08 1.526e+04 0.000e+00       Inf 9.990e-01


$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              11.0               28.0
n_event_pct                          46.0               65.0
time-to-event-wk-10th                 6.7                3.1
time-to-event-wk-25th                11.7                8.1
time-to-event-wk-50th                19.3               25.4
time-to-event-wk-75th                  NA               43.6
time-to-event-wk-90th                  NA               55.4
time-to-event-wk-50th-loci           11.7               13.0
time-to-event-wk-50th-hici             NA               35.4

$Gender_Female$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3350    0.3646    0.6532    2.7270    0.4285


$Gender_Female$`Injury, poisoning and procedural complications`
$Gender_Female$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               3.0                  2
n_event_pct                          12.0                  5
time-to-event-wk-10th                47.1                 NA
time-to-event-wk-25th                50.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           47.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Injury, poisoning and procedural
```

```
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.30840   0.92880   0.04995   1.90400   0.20530


$Gender_Female$Investigations
$Gender_Female$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43
n_event                               2.0                 2
n_event_pct                           8.0                 5
time-to-event-wk-10th                40.7                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31190   1.04700   0.04007   2.42800   0.26590


$Gender_Female$`Metabolism and nutrition disorders`
$Gender_Female$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                43
n_event                               3.0                 6
n_event_pct                          12.0                14
time-to-event-wk-10th                 8.9                14
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Gender_Female$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9042    0.7304    0.2160    3.7840    0.8904


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                              18.0               24.0
n_event_pct                          75.0               56.0
time-to-event-wk-10th                 2.9                3.6
time-to-event-wk-25th                 4.3                8.6
time-to-event-wk-50th                11.4               32.1
time-to-event-wk-75th                26.0                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci            4.6                11.4
time-to-event-wk-50th-hici           15.9                  NA

$Gender_Female$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7173    0.3254    0.3790    1.3570    0.3072



$Region_Europe
$Region_Europe$`Cardiac disorders`
$Region_Europe$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                30
n_event                                 1                 3
n_event_pct                             6                10
time-to-event-wk-10th                  NA                16
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4880    1.1640    0.1519   14.5700    0.7329


$Region_Europe$`Gastrointestinal disorders`
$Region_Europe$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 17.0                30
n_event                                3.0                 2
n_event_pct                           18.0                 7
time-to-event-wk-10th                 15.3                NA
time-to-event-wk-25th                 40.3                NA
time-to-event-wk-50th                   NA                NA
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci            15.3                NA
time-to-event-wk-50th-hici              NA                NA

$Region_Europe$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.19320   0.98510   0.02802   1.33200   0.09512


$Region_Europe$`General disorders and administration site conditions`
$Region_Europe$`General disorders and administration site conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               30.0
n_event                                 0                5.0
```

```
n_event_pct                              0              17.0
time-to-event-wk-10th                   NA              23.4
time-to-event-wk-25th                   NA                NA
time-to-event-wk-50th                   NA                NA
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci              NA                NA
time-to-event-wk-50th-hici              NA                NA

$Region_Europe$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.228e+08 1.184e+04 0.000e+00       Inf 9.987e-01


$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               7.0              18.0
n_event_pct                          41.0              60.0
time-to-event-wk-10th                 6.7               2.9
time-to-event-wk-25th                13.9               6.7
time-to-event-wk-50th                32.9              18.0
time-to-event-wk-75th                  NA              35.9
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            9.9               7.1
time-to-event-wk-50th-hici             NA              35.9

$Region_Europe$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5620    0.4575    0.6373    3.8300    0.3294


$Region_Europe$`Injury, poisoning and procedural complications`
$Region_Europe$`Injury, poisoning and procedural complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               2.0                 3
n_event_pct                          12.0                10
time-to-event-wk-10th                47.1                36
time-to-event-wk-25th                47.1                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           47.1                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6691    0.9190    0.1105    4.0520    0.6619
```

```
$Region_Europe$Investigations
$Region_Europe$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               1.0                3.0
n_event_pct                           6.0               10.0
time-to-event-wk-10th                40.7               33.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1250    1.1640    0.1150   11.0100    0.9193


$Region_Europe$`Metabolism and nutrition disorders`
$Region_Europe$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               30.0
n_event                                 3                4.0
n_event_pct                            18               13.0
time-to-event-wk-10th                   6                7.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6020    0.7833    0.1297    2.7950    0.5170


$Region_Europe$`Psychiatric disorders`
$Region_Europe$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 30
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Psychiatric disorders`$stats_HR_TRTvsCTRL
        HR   SE_logHR  HR.lo95ci  HR.hi95ci    p.value
```

```
6.131e-170  2.023e+03  0.000e+00        Inf  8.473e-01


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                              11.0              19.0
n_event_pct                          65.0              63.0
time-to-event-wk-10th                 3.4               0.9
time-to-event-wk-25th                 6.1               5.7
time-to-event-wk-50th                13.0              11.5
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.0               8.6
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1780    0.3991    0.5389    2.5760    0.6812



$Region_Asia_Pacific
$Region_Asia_Pacific$`Cardiac disorders`
$Region_Asia_Pacific$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2                12
n_event                               0                 1
n_event_pct                           0                 8
time-to-event-wk-10th                NA                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Region_Asia_Pacific$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.385e+07 3.163e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$`Infections and infestations`
$Region_Asia_Pacific$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2              12.0
n_event                               0               6.0
n_event_pct                           0              50.0
time-to-event-wk-10th                NA               4.3
time-to-event-wk-25th                NA              16.9
time-to-event-wk-50th                NA              43.6
time-to-event-wk-75th                NA              43.6
```

```
time-to-event-wk-90th                  NA               43.6
time-to-event-wk-50th-loci             NA                4.3
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.501e+08 1.536e+04 0.000e+00       Inf 9.990e-01


$Region_Asia_Pacific$`Metabolism and nutrition disorders`
$Region_Asia_Pacific$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2                12
n_event                                 0                 1
n_event_pct                             0                 8
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Asia_Pacific$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.272e+07 4.420e+04 0.000e+00       Inf 9.997e-01


$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`
$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 2.0               12.0
n_event                               1.0                2.0
n_event_pct                          50.0               17.0
time-to-event-wk-10th                 0.9               12.3
time-to-event-wk-25th                 0.9                 NA
time-to-event-wk-50th                25.1                 NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci            0.9               12.3
time-to-event-wk-50th-hici            NA                  NA

$Region_Asia_Pacific$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.125100  1.466000  0.007071  2.215000  0.156300



$Region_Northamerica
$Region_Northamerica$`Cardiac disorders`
$Region_Northamerica$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22.0               38.0
```

```
n_event                              6.0               5.0
n_event_pct                         27.0              13.0
time-to-event-wk-10th               14.3              17.4
time-to-event-wk-25th               23.0                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          23.0                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.34780   0.61590   0.10400   1.16300   0.08644


$Region_Northamerica$`Gastrointestinal disorders`
$Region_Northamerica$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               2.0                 4
n_event_pct                           9.0                11
time-to-event-wk-10th                36.4                19
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1170    0.8680    0.2038    6.1200    0.8988


$Region_Northamerica$`General disorders and administration site conditions`
$Region_Northamerica$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22                38
n_event                               1                 2
n_event_pct                           5                 5
time-to-event-wk-10th                NA                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Region_Northamerica$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2450    1.2280    0.1121   13.8300    0.8585
```

```
$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                             12.0              23.0
n_event_pct                         55.0              61.0
time-to-event-wk-10th                5.3               2.7
time-to-event-wk-25th               11.7               7.1
time-to-event-wk-50th               19.3              27.6
time-to-event-wk-75th               52.6              55.4
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          11.7               9.0
time-to-event-wk-50th-hici            NA              46.7

$Region_Northamerica$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0280    0.3596    0.5082    2.0810    0.9381


$Region_Northamerica$Investigations
$Region_Northamerica$Investigations$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38
n_event                              2.0                 0
n_event_pct                          9.0                 0
time-to-event-wk-10th               17.9                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.901e-10 2.055e+04 0.000e+00       Inf 9.992e-01


$Region_Northamerica$`Metabolism and nutrition disorders`
$Region_Northamerica$`Metabolism and nutrition disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                              2.0               3.0
n_event_pct                          9.0               8.0
time-to-event-wk-10th               34.9              45.6
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7874    0.9145    0.1312    4.7270    0.7938


$Region_Northamerica$`Nervous system disorders`
$Region_Northamerica$`Nervous system disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                 38
n_event                                 0                  2
n_event_pct                             0                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.069e+08 1.811e+04 0.000e+00       Inf 9.991e-01


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                              18.0               27.0
n_event_pct                          82.0               71.0
time-to-event-wk-10th                 1.0                1.6
time-to-event-wk-25th                 2.9                4.1
time-to-event-wk-50th                13.9               14.6
time-to-event-wk-75th                22.4               43.4
time-to-event-wk-90th                52.6                 NA
time-to-event-wk-50th-loci            2.9                5.0
time-to-event-wk-50th-hici           17.9               32.1

$Region_Northamerica$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6579    0.3088    0.3592    1.2050    0.1752



$Disdur_greater_12wk
$Disdur_greater_12wk$`Cardiac disorders`
$Disdur_greater_12wk$`Cardiac disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               3.0                 7
n_event_pct                          13.0                15
time-to-event-wk-10th                14.3                12
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0050    0.6923    0.2589    3.9050    0.9937


$Disdur_greater_12wk$`Gastrointestinal disorders`
$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               1.0                 4
n_event_pct                           4.0                 9
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.3                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9300    1.1210    0.2144   17.3700    0.5576


$Disdur_greater_12wk$`General disorders and administration site conditions`
$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23                46
n_event                               0                 3
n_event_pct                           0                 7
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.202e+08 1.545e+04 0.000e+00       Inf 9.990e-01


$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
```

```
n_event                              11.0              28.0
n_event_pct                          48.0              61.0
time-to-event-wk-10th                 5.7               3.4
time-to-event-wk-25th                11.7               8.4
time-to-event-wk-50th                17.7              25.4
time-to-event-wk-75th                  NA              55.4
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           11.7              16.1
time-to-event-wk-50th-hici             NA              43.6

$Disdur_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1560    0.3704    0.5596    2.3900    0.6948


$Disdur_greater_12wk$`Metabolism and nutrition disorders`
$Disdur_greater_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                               3.0               5.0
n_event_pct                          13.0              11.0
time-to-event-wk-10th                 8.9              45.6
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6454    0.7371    0.1522    2.7370    0.5525


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                              16.0              29.0
n_event_pct                          70.0              63.0
time-to-event-wk-10th                 1.6               1.7
time-to-event-wk-25th                 3.1               5.7
time-to-event-wk-50th                13.9              11.9
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            3.4               8.6
time-to-event-wk-50th-hici           52.6              26.9

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8991    0.3156    0.4843    1.6690    0.7362
```

```
$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Cardiac disorders`
$Disdur_less_equal_12wk$`Cardiac disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              4.0                 2
n_event_pct                         22.0                 6
time-to-event-wk-10th                9.4                NA
time-to-event-wk-25th               33.6                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          33.6                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.28680   0.88600   0.05051   1.62800   0.15860


$Disdur_less_equal_12wk$`Gastrointestinal disorders`
$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              4.0                 2
n_event_pct                         22.0                 6
time-to-event-wk-10th               13.6                NA
time-to-event-wk-25th               36.4                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          36.4                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.18540   0.87200   0.03357   1.02400   0.05332


$Disdur_less_equal_12wk$`General disorders and administration site conditions`
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18                34.0
n_event                              1                 4.0
n_event_pct                          6                12.0
time-to-event-wk-10th               NA                25.9
time-to-event-wk-25th               NA                  NA
time-to-event-wk-50th               NA                  NA
time-to-event-wk-75th               NA                  NA
time-to-event-wk-90th               NA                  NA
time-to-event-wk-50th-loci          NA                  NA
time-to-event-wk-50th-hici          NA                  NA
```

```
$Disdur_less_equal_12wk$`General disorders and administration site
conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0830    1.1350    0.2251   19.2700    0.5181


$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0              34.0
n_event                               8.0              19.0
n_event_pct                          44.0              56.0
time-to-event-wk-10th                 8.7               2.7
time-to-event-wk-25th                19.3               5.0
time-to-event-wk-50th                32.9              25.3
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.9               7.1
time-to-event-wk-50th-hici             NA              35.4

$Disdur_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7420    0.4436    0.7301    4.1550    0.2109


$Disdur_less_equal_12wk$`Injury, poisoning and procedural complications`
$Disdur_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 1
n_event_pct                          11.0                 3
time-to-event-wk-10th                47.1                NA
time-to-event-wk-25th                50.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           47.1                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Injury, poisoning and procedural
complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.16280   1.23100   0.01457   1.81800   0.14030


$Disdur_less_equal_12wk$Investigations
$Disdur_less_equal_12wk$Investigations$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               3.0                 1
n_event_pct                          17.0                 3
time-to-event-wk-10th                17.9                NA
```

```
time-to-event-wk-25th                40.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.13180   1.16700   0.01339   1.29700   0.08234


$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`
$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  3
n_event_pct                          11.0                  9
time-to-event-wk-10th                34.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           34.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6827    0.9160    0.1134    4.1110    0.6769


$Disdur_less_equal_12wk$`Psychiatric disorders`
$Disdur_less_equal_12wk$`Psychiatric disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.179e-10 3.219e+04 0.000e+00       Inf 9.995e-01


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                18.0              34.0
n_event                              14.0              19.0
n_event_pct                          78.0              56.0
time-to-event-wk-10th                 1.0               1.0
time-to-event-wk-25th                 6.3               4.7
time-to-event-wk-50th                13.0              32.1
time-to-event-wk-75th                17.9                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.3               8.6
time-to-event-wk-50th-hici           17.9                NA

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6401    0.3661    0.3124    1.3120    0.2230




\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines SUEs nach SOC, das bei mindestens 10 Patienten
und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Infections and infestations`
$Ageonset_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              15.0              45.0
n_event_pct                          47.0              62.0
time-to-event-wk-10th                 5.3               2.7
time-to-event-wk-25th                11.7               6.9
time-to-event-wk-50th                32.9              25.4
time-to-event-wk-75th                52.6              46.7
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.7              13.0
time-to-event-wk-50th-hici             NA              34.7

$Ageonset_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2540    0.3032    0.6922    2.2720    0.4554


$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0              72.0
n_event                              25.0              44.0
n_event_pct                          78.0              61.0
time-to-event-wk-10th                 1.0               1.7
time-to-event-wk-25th                 3.3               5.7
time-to-event-wk-50th                 9.0              15.6
```

```
time-to-event-wk-75th                22.4                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            4.0               10.0
time-to-event-wk-50th-hici           15.7               32.7

$Ageonset_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.63630   0.25520   0.38580   1.04900   0.07652



$Agetrt_less_180d
$Agetrt_less_180d$`Infections and infestations`
$Agetrt_less_180d$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               8.0               31.0
n_event_pct                          50.0               63.0
time-to-event-wk-10th                 6.7                2.7
time-to-event-wk-25th                 9.9                6.7
time-to-event-wk-50th                32.9               25.3
time-to-event-wk-75th                33.4               43.6
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            8.7               10.6
time-to-event-wk-50th-hici             NA               34.7

$Agetrt_less_180d$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0860    0.4011    0.4949    2.3840    0.8367


$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_less_180d$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                              13.0               27.0
n_event_pct                          81.0               55.0
time-to-event-wk-10th                 0.9                1.7
time-to-event-wk-25th                 4.7                5.0
time-to-event-wk-50th                 8.6               32.1
time-to-event-wk-75th                15.7                 NA
time-to-event-wk-90th                22.4                 NA
time-to-event-wk-50th-loci            3.4               10.0
time-to-event-wk-50th-hici           15.7                 NA

$Agetrt_less_180d$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.396800  0.356000  0.197500  0.797300  0.009423



$Agetrt_greater_equal_180d
```

$Agetrt_greater_equal_180d$`Infections and infestations`
$Agetrt_greater_equal_180d$`Infections and infestations`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	25.0	31.0
n_event	11.0	16.0
n_event_pct	44.0	52.0
time-to-event-wk-10th	5.7	3.4
time-to-event-wk-25th	15.3	8.1
time-to-event-wk-50th	52.6	30.9
time-to-event-wk-75th	NA	55.4
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	17.6	11.4
time-to-event-wk-50th-hici	NA	55.4

$Agetrt_greater_equal_180d$`Infections and infestations`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
1.2220	0.3937	0.5648	2.6430	0.6108

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`
$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	25.0	31.0
n_event	17.0	21.0
n_event_pct	68.0	68.0
time-to-event-wk-10th	1.7	0.6
time-to-event-wk-25th	4.0	5.7
time-to-event-wk-50th	15.9	11.6
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	4.6	7.1
time-to-event-wk-50th-hici	52.6	26.9

$Agetrt_greater_equal_180d$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.9772	0.3297	0.5120	1.8650	0.9442

$Gender_Male
$Gender_Male$`Infections and infestations`
$Gender_Male$`Infections and infestations`$stats_num

	TRT01P=Control	TRT01P=ISIS 396443
n_all	17.0	37.0
n_event	8.0	19.0
n_event_pct	47.0	51.0
time-to-event-wk-10th	5.3	2.7
time-to-event-wk-25th	13.9	6.0
time-to-event-wk-50th	33.4	28.6
time-to-event-wk-75th	52.6	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	13.9	9.0

```
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1970    0.4243    0.5211    2.7500    0.6718


$Gender_Male$`Respiratory, thoracic and mediastinal disorders`
$Gender_Male$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              37.0
n_event                              12.0              24.0
n_event_pct                          71.0              65.0
time-to-event-wk-10th                 0.7               0.7
time-to-event-wk-25th                 1.7               4.1
time-to-event-wk-50th                16.4              11.3
time-to-event-wk-75th                52.6                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            1.0               5.7
time-to-event-wk-50th-hici           52.6              26.9

$Gender_Male$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9298    0.3600    0.4592    1.8830    0.8398



$Gender_Female
$Gender_Female$`Infections and infestations`
$Gender_Female$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              11.0              28.0
n_event_pct                          46.0              65.0
time-to-event-wk-10th                 6.7               3.1
time-to-event-wk-25th                11.7               8.1
time-to-event-wk-50th                19.3              25.4
time-to-event-wk-75th                  NA              43.6
time-to-event-wk-90th                  NA              55.4
time-to-event-wk-50th-loci           11.7              13.0
time-to-event-wk-50th-hici             NA              35.4

$Gender_Female$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3350    0.3646    0.6532    2.7270    0.4285


$Gender_Female$`Respiratory, thoracic and mediastinal disorders`
$Gender_Female$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0              43.0
n_event                              18.0              24.0
n_event_pct                          75.0              56.0
```

```
time-to-event-wk-10th                2.9               3.6
time-to-event-wk-25th                4.3               8.6
time-to-event-wk-50th               11.4              32.1
time-to-event-wk-75th               26.0                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           4.6              11.4
time-to-event-wk-50th-hici          15.9                NA

$Gender_Female$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7173    0.3254    0.3790    1.3570    0.3072



$Region_Europe
$Region_Europe$`Infections and infestations`
$Region_Europe$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                               7.0              18.0
n_event_pct                          41.0              60.0
time-to-event-wk-10th                 6.7               2.9
time-to-event-wk-25th                13.9               6.7
time-to-event-wk-50th                32.9              18.0
time-to-event-wk-75th                  NA              35.9
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            9.9               7.1
time-to-event-wk-50th-hici             NA              35.9

$Region_Europe$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5620    0.4575    0.6373    3.8300    0.3294


$Region_Europe$`Respiratory, thoracic and mediastinal disorders`
$Region_Europe$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0              30.0
n_event                              11.0              19.0
n_event_pct                          65.0              63.0
time-to-event-wk-10th                 3.4               0.9
time-to-event-wk-25th                 6.1               5.7
time-to-event-wk-50th                13.0              11.5
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci            6.0               8.6
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1780    0.3991    0.5389    2.5760    0.6812
```

```
$Region_Northamerica
$Region_Northamerica$`Infections and infestations`
$Region_Northamerica$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              12.0              23.0
n_event_pct                          55.0              61.0
time-to-event-wk-10th                 5.3               2.7
time-to-event-wk-25th                11.7               7.1
time-to-event-wk-50th                19.3              27.6
time-to-event-wk-75th                52.6              55.4
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           11.7               9.0
time-to-event-wk-50th-hici             NA              46.7

$Region_Northamerica$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0280    0.3596    0.5082    2.0810    0.9381


$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`
$Region_Northamerica$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                              18.0              27.0
n_event_pct                          82.0              71.0
time-to-event-wk-10th                 1.0               1.6
time-to-event-wk-25th                 2.9               4.1
time-to-event-wk-50th                13.9              14.6
time-to-event-wk-75th                22.4              43.4
time-to-event-wk-90th                52.6                NA
time-to-event-wk-50th-loci            2.9               5.0
time-to-event-wk-50th-hici           17.9              32.1

$Region_Northamerica$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6579    0.3088    0.3592    1.2050    0.1752



$Disdur_greater_12wk
$Disdur_greater_12wk$`Infections and infestations`
$Disdur_greater_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0              46.0
n_event                              11.0              28.0
n_event_pct                          48.0              61.0
time-to-event-wk-10th                 5.7               3.4
time-to-event-wk-25th                11.7               8.4
time-to-event-wk-50th                17.7              25.4
time-to-event-wk-75th                  NA              55.4
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           11.7               16.1
time-to-event-wk-50th-hici             NA               43.6

$Disdur_greater_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1560    0.3704    0.5596    2.3900    0.6948


$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                              16.0               29.0
n_event_pct                          70.0               63.0
time-to-event-wk-10th                 1.6                1.7
time-to-event-wk-25th                 3.1                5.7
time-to-event-wk-50th                13.9               11.9
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            3.4                8.6
time-to-event-wk-50th-hici           52.6               26.9

$Disdur_greater_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8991    0.3156    0.4843    1.6690    0.7362



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Infections and infestations`
$Disdur_less_equal_12wk$`Infections and infestations`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               8.0               19.0
n_event_pct                          44.0               56.0
time-to-event-wk-10th                 8.7                2.7
time-to-event-wk-25th                19.3                5.0
time-to-event-wk-50th                32.9               25.3
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.9                7.1
time-to-event-wk-50th-hici             NA               35.4

$Disdur_less_equal_12wk$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7420    0.4436    0.7301    4.1550    0.2109


$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal disorders`
$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                              18.0              34.0
n_event                            14.0              19.0
n_event_pct                        78.0              56.0
time-to-event-wk-10th               1.0               1.0
time-to-event-wk-25th               6.3               4.7
time-to-event-wk-50th              13.0              32.1
time-to-event-wk-75th              17.9                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci          6.3               8.6
time-to-event-wk-50th-hici         17.9                NA

$Disdur_less_equal_12wk$`Respiratory, thoracic and mediastinal
disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6401    0.3661    0.3124    1.3120    0.2230




\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem SUE nach PT, das bei mindestens 5% der
Patienten in einem Studienarm auftrat"

$Agetrt_less_180d
$Agetrt_less_180d$`Acute respiratory distress syndrome`
$Agetrt_less_180d$`Acute respiratory distress syndrome`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$`Acute respiratory distress syndrome`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Acute respiratory failure`
$Agetrt_less_180d$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         16  49
n_event        3   7
n_event_pct   19  14

$Agetrt_less_180d$`Acute respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.76190476 0.6271222  0.2228914 2.6044026 0.6645633
OR_TRTvsCTRL   0.72222222 0.7595545  0.1629810 3.2004042 0.6683319
ARR_TRTvsCTRL -0.04464286 0.1096378 -0.2595290 0.1702432 0.6838721


$Agetrt_less_180d$Agitation
```

```
$Agetrt_less_180d$Agitation$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$Agitation$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$Apnoea
$Agetrt_less_180d$Apnoea$ntab
            CTRL TRT
n_all         16  49
n_event        2   2
n_event_pct   12   4

$Agetrt_less_180d$Apnoea$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 0.95764912  0.04997715 2.13341975 0.2425131
OR_TRTvsCTRL   0.29787234 1.04532539  0.03839261 2.31106820 0.2466285
ARR_TRTvsCTRL -0.08418367 0.08737805 -0.25544151 0.08707417 0.3353258


$Agetrt_less_180d$Aspiration
$Agetrt_less_180d$Aspiration$ntab
            CTRL TRT
n_all         16  49
n_event        1   3
n_event_pct    6   6

$Agetrt_less_180d$Aspiration$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.97959184 1.11822411  0.10944882  8.7675701 0.9852884
OR_TRTvsCTRL   0.97826087 1.19236703  0.09451702 10.1251004 0.9852934
ARR_TRTvsCTRL -0.00127551 0.06953481 -0.13756124  0.1350102 0.9853648


$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$ntab
            CTRL TRT
n_all         16  49
n_event        2  10
n_event_pct   12  20

$Agetrt_less_180d$Atelectasis$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.63265306 0.7190910  0.3988435 6.6832123 0.4954269
OR_TRTvsCTRL  1.79487179 0.8349069  0.3494293 9.2195030 0.4835543
ARR_TRTvsCTRL 0.07908163 0.1007516 -0.1183879 0.2765511 0.4325023
```

```
$Agetrt_less_180d$`Body temperature increased`
$Agetrt_less_180d$`Body temperature increased`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$`Body temperature increased`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Bronchial secretion retention`
$Agetrt_less_180d$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         16  49
n_event        3   1
n_event_pct   19   2

$Agetrt_less_180d$`Bronchial secretion retention`$stats
                  estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.10884354 1.11822411  0.012160979 0.97417446 0.04732694
OR_TRTvsCTRL   0.09027778 1.19628163  0.008655738 0.94158088 0.04440131
ARR_TRTvsCTRL -0.16709184 0.09964676 -0.362395906 0.02821223 0.09357347


$Agetrt_less_180d$Bronchiolitis
$Agetrt_less_180d$Bronchiolitis$ntab
            CTRL TRT
n_all         16  49
n_event        0   3
n_event_pct    0   6

$Agetrt_less_180d$Bronchiolitis$stats
                 estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.38000000 1.48556075  0.129439060 43.7611337 0.55943183
OR_TRTvsCTRL  2.48387097 1.53877410  0.121708846 50.6915905 0.55434508
ARR_TRTvsCTRL 0.06122449 0.03424881 -0.005901935  0.1283509 0.07383432


$Agetrt_less_180d$Bronchitis
$Agetrt_less_180d$Bronchitis$ntab
            CTRL TRT
n_all         16  49
n_event        0   4
n_event_pct    0   8

$Agetrt_less_180d$Bronchitis$stats
                 estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.06000000 1.46403507 0.173593122 53.9399251 0.44491116
OR_TRTvsCTRL  3.26373626 1.51815885 0.166515972 63.9696856 0.43589168
```

```
ARR_TRTvsCTRL 0.08163265 0.03911489 0.004968874  0.1582964 0.03688843


$Agetrt_less_180d$`Bronchitis viral`
$Agetrt_less_180d$`Bronchitis viral`$ntab
            CTRL TRT
n_all         16  49
n_event        0   3
n_event_pct    0   6

$Agetrt_less_180d$`Bronchitis viral`$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.38000000 1.48556075  0.129439060 43.7611337 0.55943183
OR_TRTvsCTRL  2.48387097 1.53877410  0.121708846 50.6915905 0.55434508
ARR_TRTvsCTRL 0.06122449 0.03424881 -0.005901935  0.1283509 0.07383432


$Agetrt_less_180d$`Cardiac arrest`
$Agetrt_less_180d$`Cardiac arrest`$ntab
            CTRL TRT
n_all         16  49
n_event        1   1
n_event_pct    6   2

$Agetrt_less_180d$`Cardiac arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 1.38459086  0.02164502 4.92594746 0.4188901
OR_TRTvsCTRL   0.31250000 1.44481833  0.01840850 5.30495387 0.4207909
ARR_TRTvsCTRL -0.04209184 0.06379736 -0.16713236 0.08294868 0.5093989


$Agetrt_less_180d$`Cardio-respiratory arrest`
$Agetrt_less_180d$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$`Cardio-respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156


$Agetrt_less_180d$`Corona virus infection`
$Agetrt_less_180d$`Corona virus infection`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$`Corona virus infection`$stats
                estimate         se       lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$Cyanosis
$Agetrt_less_180d$Cyanosis$ntab
            CTRL TRT
n_all         16  49
n_event        1   1
n_event_pct    6   2

$Agetrt_less_180d$Cyanosis$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 1.38459086  0.02164502 4.92594746 0.4188901
OR_TRTvsCTRL   0.31250000 1.44481833  0.01840850 5.30495387 0.4207909
ARR_TRTvsCTRL -0.04209184 0.06379736 -0.16713236 0.08294868 0.5093989


$Agetrt_less_180d$Death
$Agetrt_less_180d$Death$ntab
            CTRL TRT
n_all         16  49
n_event        1   1
n_event_pct    6   2

$Agetrt_less_180d$Death$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 1.38459086  0.02164502 4.92594746 0.4188901
OR_TRTvsCTRL   0.31250000 1.44481833  0.01840850 5.30495387 0.4207909
ARR_TRTvsCTRL -0.04209184 0.06379736 -0.16713236 0.08294868 0.5093989


$Agetrt_less_180d$Dehydration
$Agetrt_less_180d$Dehydration$ntab
            CTRL TRT
n_all         16  49
n_event        1   1
n_event_pct    6   2

$Agetrt_less_180d$Dehydration$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 1.38459086  0.02164502 4.92594746 0.4188901
OR_TRTvsCTRL   0.31250000 1.44481833  0.01840850 5.30495387 0.4207909
ARR_TRTvsCTRL -0.04209184 0.06379736 -0.16713236 0.08294868 0.5093989


$Agetrt_less_180d$Dysphagia
$Agetrt_less_180d$Dysphagia$ntab
            CTRL TRT
n_all         16  49
n_event        1   2
n_event_pct    6   4
```

```
$Agetrt_less_180d$Dysphagia$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 1.19041667  0.06333874 6.7334618 0.7203966
OR_TRTvsCTRL   0.63829787 1.26013621  0.05399997 7.5448964 0.7216375
ARR_TRTvsCTRL -0.02168367 0.06679144 -0.15259249 0.1092251 0.7454479


$Agetrt_less_180d$Dyspnoea
$Agetrt_less_180d$Dyspnoea$ntab
            CTRL TRT
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$Dyspnoea$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156


$Agetrt_less_180d$`Failure to thrive`
$Agetrt_less_180d$`Failure to thrive`$ntab
            CTRL TRT
n_all         16  49
n_event        1   1
n_event_pct    6   2

$Agetrt_less_180d$`Failure to thrive`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 1.38459086  0.02164502 4.92594746 0.4188901
OR_TRTvsCTRL   0.31250000 1.44481833  0.01840850 5.30495387 0.4207909
ARR_TRTvsCTRL -0.04209184 0.06379736 -0.16713236 0.08294868 0.5093989


$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`
$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`$ntab
            CTRL TRT
n_all         16  49
n_event        1   2
n_event_pct    6   4

$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 1.19041667  0.06333874 6.7334618 0.7203966
OR_TRTvsCTRL   0.63829787 1.26013621  0.05399997 7.5448964 0.7216375
ARR_TRTvsCTRL -0.02168367 0.06679144 -0.15259249 0.1092251 0.7454479


$Agetrt_less_180d$`Gastrointestinal haemorrhage`
$Agetrt_less_180d$`Gastrointestinal haemorrhage`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
```

```
n_event_pct    6   0

$Agetrt_less_180d$`Gastrointestinal haemorrhage`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Heart rate decreased`
$Agetrt_less_180d$`Heart rate decreased`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$`Heart rate decreased`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$Hypoxia
$Agetrt_less_180d$Hypoxia$ntab
            CTRL TRT
n_all         16  49
n_event        1   2
n_event_pct    6   4

$Agetrt_less_180d$Hypoxia$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 1.19041667  0.06333874 6.7334618 0.7203966
OR_TRTvsCTRL   0.63829787 1.26013621  0.05399997 7.5448964 0.7216375
ARR_TRTvsCTRL -0.02168367 0.06679144 -0.15259249 0.1092251 0.7454479


$Agetrt_less_180d$`Lung disorder`
$Agetrt_less_180d$`Lung disorder`$ntab
            CTRL TRT
n_all         16  49
n_event        1   1
n_event_pct    6   2

$Agetrt_less_180d$`Lung disorder`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 1.38459086  0.02164502 4.92594746 0.4188901
OR_TRTvsCTRL   0.31250000 1.44481833  0.01840850 5.30495387 0.4207909
ARR_TRTvsCTRL -0.04209184 0.06379736 -0.16713236 0.08294868 0.5093989


$Agetrt_less_180d$`Oxygen saturation decreased`
$Agetrt_less_180d$`Oxygen saturation decreased`$ntab
            CTRL TRT
```

```
n_all         16  49
n_event        2   1
n_event_pct   12   2

$Agetrt_less_180d$`Oxygen saturation decreased`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1632653 1.19041667  0.01583468 1.68336545 0.1278903
OR_TRTvsCTRL   0.1458333 1.26184861  0.01229615 1.72959445 0.1270671
ARR_TRTvsCTRL -0.1045918 0.08511128 -0.27140689 0.06222322 0.2191156


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$ntab
            CTRL TRT
n_all         16  49
n_event        2  14
n_event_pct   12  29

$Agetrt_less_180d$Pneumonia$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2857143 0.6989423  0.58087293  8.9942043 0.2369057
OR_TRTvsCTRL  2.8000000 0.8194075  0.56192343 13.9520787 0.2089197
ARR_TRTvsCTRL 0.1607143 0.1048850 -0.04485659  0.3662852 0.1254509


$Agetrt_less_180d$`Pneumonia aspiration`
$Agetrt_less_180d$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         16  49
n_event        1   6
n_event_pct    6  12

$Agetrt_less_180d$`Pneumonia aspiration`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.95918367 1.04103722  0.25464940 15.0732758 0.5182683
OR_TRTvsCTRL  2.09302326 1.12097687  0.23259309 18.8343786 0.5099612
ARR_TRTvsCTRL 0.05994898 0.07651845 -0.09002443  0.2099224 0.4333583


$Agetrt_less_180d$`Pneumonia bacterial`
$Agetrt_less_180d$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         16  49
n_event        1   2
n_event_pct    6   4

$Agetrt_less_180d$`Pneumonia bacterial`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 1.19041667  0.06333874 6.7334618 0.7203966
OR_TRTvsCTRL   0.63829787 1.26013621  0.05399997 7.5448964 0.7216375
ARR_TRTvsCTRL -0.02168367 0.06679144 -0.15259249 0.1092251 0.7454479


$Agetrt_less_180d$`Pneumonia viral`
```

```
$Agetrt_less_180d$`Pneumonia viral`$ntab
           CTRL TRT
n_all        16  49
n_event       0   3
n_event_pct   0   6

$Agetrt_less_180d$`Pneumonia viral`$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.38000000 1.48556075  0.129439060 43.7611337 0.55943183
OR_TRTvsCTRL  2.48387097 1.53877410  0.121708846 50.6915905 0.55434508
ARR_TRTvsCTRL 0.06122449 0.03424881 -0.005901935  0.1283509 0.07383432


$Agetrt_less_180d$`Respiratory arrest`
$Agetrt_less_180d$`Respiratory arrest`$ntab
           CTRL TRT
n_all        16  49
n_event       2   2
n_event_pct  12   4

$Agetrt_less_180d$`Respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 0.95764912  0.04997715 2.13341975 0.2425131
OR_TRTvsCTRL   0.29787234 1.04532539  0.03839261 2.31106820 0.2466285
ARR_TRTvsCTRL -0.08418367 0.08737805 -0.25544151 0.08707417 0.3353258


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$ntab
           CTRL TRT
n_all        16  49
n_event       2  14
n_event_pct  12  29

$Agetrt_less_180d$`Respiratory distress`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2857143 0.6989423  0.58087293  8.9942043 0.2369057
OR_TRTvsCTRL  2.8000000 0.8194075  0.56192343 13.9520787 0.2089197
ARR_TRTvsCTRL 0.1607143 0.1048850 -0.04485659  0.3662852 0.1254509


$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$ntab
           CTRL TRT
n_all        16  49
n_event       9  12
n_event_pct  56  24

$Agetrt_less_180d$`Respiratory failure`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.4353741 0.3339705  0.22624889  0.83779705 0.01277829
OR_TRTvsCTRL   0.2522523 0.6035964  0.07727746  0.82341209 0.02249729
ARR_TRTvsCTRL -0.3176020 0.1384009 -0.58886274 -0.04634135 0.02174469
```

```
$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`
$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718


$Agetrt_less_180d$`Respiratory tract congestion`
$Agetrt_less_180d$`Respiratory tract congestion`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$`Respiratory tract congestion`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Respiratory tract infection`
$Agetrt_less_180d$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         16  49
n_event        1   6
n_event_pct    6  12

$Agetrt_less_180d$`Respiratory tract infection`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.95918367 1.04103722  0.25464940 15.0732758 0.5182683
OR_TRTvsCTRL  2.09302326 1.12097687  0.23259309 18.8343786 0.5099612
ARR_TRTvsCTRL 0.05994898 0.07651845 -0.09002443  0.2099224 0.4333583


$Agetrt_less_180d$`Respiratory tract infection viral`
$Agetrt_less_180d$`Respiratory tract infection viral`$ntab
            CTRL TRT
n_all         16  49
n_event        1   1
n_event_pct    6   2

$Agetrt_less_180d$`Respiratory tract infection viral`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 1.38459086  0.02164502 4.92594746 0.4188901
OR_TRTvsCTRL   0.31250000 1.44481833  0.01840850 5.30495387 0.4207909
```

```
ARR_TRTvsCTRL -0.04209184 0.06379736 -0.16713236 0.08294868 0.5093989


$Agetrt_less_180d$Retching
$Agetrt_less_180d$Retching$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$Retching$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Rhinovirus infection`
$Agetrt_less_180d$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         16  49
n_event        2   4
n_event_pct   12   8

$Agetrt_less_180d$`Rhinovirus infection`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 0.81675690  0.1317435 3.2372678 0.6018943
OR_TRTvsCTRL   0.62222222 0.91850465  0.1028284 3.7651137 0.6054670
ARR_TRTvsCTRL -0.04336735 0.09146536 -0.2226362 0.1359015 0.6354004


$Agetrt_less_180d$`Systemic infection`
$Agetrt_less_180d$`Systemic infection`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$`Systemic infection`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Tracheal haemorrhage`
$Agetrt_less_180d$`Tracheal haemorrhage`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$`Tracheal haemorrhage`$stats
                estimate         se       lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Tracheal obstruction`
$Agetrt_less_180d$`Tracheal obstruction`$ntab
            CTRL TRT
n_all         16  49
n_event        1   0
n_event_pct    6   0

$Agetrt_less_180d$`Tracheal obstruction`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1133333 1.60867745  0.004842269 2.65256717 0.1758807
OR_TRTvsCTRL   0.1043771 1.65872988  0.004042889 2.69475123 0.1730923
ARR_TRTvsCTRL -0.0625000 0.06051536 -0.181107935 0.05610794 0.3016996


$Agetrt_less_180d$`Urinary tract infection`
$Agetrt_less_180d$`Urinary tract infection`$ntab
            CTRL TRT
n_all         16  49
n_event        0   3
n_event_pct    0   6

$Agetrt_less_180d$`Urinary tract infection`$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.38000000 1.48556075  0.129439060 43.7611337 0.55943183
OR_TRTvsCTRL  2.48387097 1.53877410  0.121708846 50.6915905 0.55434508
ARR_TRTvsCTRL 0.06122449 0.03424881 -0.005901935  0.1283509 0.07383432


$Agetrt_less_180d$`Viral infection`
$Agetrt_less_180d$`Viral infection`$ntab
            CTRL TRT
n_all         16  49
n_event        0   3
n_event_pct    0   6

$Agetrt_less_180d$`Viral infection`$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.38000000 1.48556075  0.129439060 43.7611337 0.55943183
OR_TRTvsCTRL  2.48387097 1.53877410  0.121708846 50.6915905 0.55434508
ARR_TRTvsCTRL 0.06122449 0.03424881 -0.005901935  0.1283509 0.07383432


$Agetrt_less_180d$`Viral upper respiratory tract infection`
$Agetrt_less_180d$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         16  49
n_event        2   2
n_event_pct   12   4
```

```
$Agetrt_less_180d$`Viral upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.32653061 0.95764912  0.04997715 2.13341975 0.2425131
OR_TRTvsCTRL   0.29787234 1.04532539  0.03839261 2.31106820 0.2466285
ARR_TRTvsCTRL -0.08418367 0.08737805 -0.25544151 0.08707417 0.3353258


$Agetrt_less_180d$Vomiting
$Agetrt_less_180d$Vomiting$ntab
            CTRL TRT
n_all         16  49
n_event        1   2
n_event_pct    6   4

$Agetrt_less_180d$Vomiting$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.65306122 1.19041667  0.06333874 6.7334618 0.7203966
OR_TRTvsCTRL   0.63829787 1.26013621  0.05399997 7.5448964 0.7216375
ARR_TRTvsCTRL -0.02168367 0.06679144 -0.15259249 0.1092251 0.7454479


$Agetrt_less_180d$`Weight gain poor`
$Agetrt_less_180d$`Weight gain poor`$ntab
            CTRL TRT
n_all         16  49
n_event        2   3
n_event_pct   12   6

$Agetrt_less_180d$`Weight gain poor`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.48979592 0.86627084  0.08966936 2.6753847 0.4099663
OR_TRTvsCTRL   0.45652174 0.96254924  0.06920509 3.0115138 0.4152856
ARR_TRTvsCTRL -0.06377551 0.08949256 -0.23917770 0.1116267 0.4760718



$Region_Europe
$Region_Europe$`Acute respiratory distress syndrome`
$Region_Europe$`Acute respiratory distress syndrome`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Acute respiratory distress syndrome`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Acute respiratory failure`
$Region_Europe$`Acute respiratory failure`$ntab
            CTRL TRT
```

```
n_all         17  30
n_event        2   0
n_event_pct   12   0

$Region_Europe$`Acute respiratory failure`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1161290 1.52058751  0.005896772 2.28700568 0.1567945
OR_TRTvsCTRL   0.1016393 1.58028574  0.004591136 2.25010878 0.1479588
ARR_TRTvsCTRL -0.1176471 0.07814249 -0.270803525 0.03550941 0.1321839


$Region_Europe$Agitation
$Region_Europe$Agitation$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$Agitation$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$Apnoea
$Region_Europe$Apnoea$ntab
            CTRL TRT
n_all         17  30
n_event        1   2
n_event_pct    6   7

$Region_Europe$Apnoea$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.133333333 1.18652566  0.11076057 11.5965855 0.9159893
OR_TRTvsCTRL  1.142857143 1.26420500  0.09591769 13.6171178 0.9158801
ARR_TRTvsCTRL 0.007843137 0.07301192 -0.13525759  0.1509439 0.9144536


$Region_Europe$Atelectasis
$Region_Europe$Atelectasis$ntab
            CTRL TRT
n_all         17  30
n_event        3   7
n_event_pct   18  23

$Region_Europe$Atelectasis$stats
                estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.32222222 0.6197045  0.3924742 4.454488 0.6521906
OR_TRTvsCTRL  1.42028986 0.7688285  0.3147378 6.409218 0.6481326
ARR_TRTvsCTRL 0.05686275 0.1204646 -0.1792435 0.292969 0.6369062


$Region_Europe$`Body temperature increased`
```

```
$Region_Europe$`Body temperature increased`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Body temperature increased`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Bronchial secretion retention`
$Region_Europe$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         17  30
n_event        2   1
n_event_pct   12   3

$Region_Europe$`Bronchial secretion retention`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.28333333 1.18652566  0.02769014 2.89914637 0.2878376
OR_TRTvsCTRL   0.25862069 1.26536533  0.02165620 3.08847571 0.2851704
ARR_TRTvsCTRL -0.08431373 0.08473679 -0.25039477 0.08176732 0.3197327


$Region_Europe$Bronchitis
$Region_Europe$Bronchitis$ntab
            CTRL TRT
n_all         17  30
n_event        0   4
n_event_pct    0  13

$Region_Europe$Bronchitis$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  5.2258065 1.46096153 0.29825011  91.5642690 0.25769180
OR_TRTvsCTRL  5.9433962 1.52220266 0.30083851 117.4183396 0.24165650
ARR_TRTvsCTRL 0.1333333 0.06206329 0.01169152   0.2549751 0.03168639


$Region_Europe$`Candida sepsis`
$Region_Europe$`Candida sepsis`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Candida sepsis`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457
```

```
$Region_Europe$`Cardio-respiratory arrest`
$Region_Europe$`Cardio-respiratory arrest`$ntab
           CTRL TRT
n_all        17  30
n_event       1   2
n_event_pct   6   7

$Region_Europe$`Cardio-respiratory arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.133333333 1.18652566  0.11076057 11.5965855 0.9159893
OR_TRTvsCTRL  1.142857143 1.26420500  0.09591769 13.6171178 0.9158801
ARR_TRTvsCTRL 0.007843137 0.07301192 -0.13525759  0.1509439 0.9144536


$Region_Europe$Dysphagia
$Region_Europe$Dysphagia$ntab
           CTRL TRT
n_all        17  30
n_event       1   0
n_event_pct   6   0

$Region_Europe$Dysphagia$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$Dyspnoea
$Region_Europe$Dyspnoea$ntab
           CTRL TRT
n_all        17  30
n_event       1   1
n_event_pct   6   3

$Region_Europe$Dyspnoea$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5666667 1.38124695  0.03781013 8.4927277 0.6809178
OR_TRTvsCTRL   0.5517241 1.44809625  0.03229239 9.4263541 0.6813057
ARR_TRTvsCTRL -0.0254902 0.06580836 -0.15447221 0.1034918 0.6985047


$Region_Europe$`Feeding disorder of infancy or early childhood`
$Region_Europe$`Feeding disorder of infancy or early childhood`$ntab
           CTRL TRT
n_all        17  30
n_event       2   1
n_event_pct  12   3

$Region_Europe$`Feeding disorder of infancy or early childhood`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.28333333 1.18652566  0.02769014 2.89914637 0.2878376
OR_TRTvsCTRL   0.25862069 1.26536533  0.02165620 3.08847571 0.2851704
```

```
ARR_TRTvsCTRL -0.08431373 0.08473679 -0.25039477 0.08176732 0.3197327


$Region_Europe$`Gastrointestinal haemorrhage`
$Region_Europe$`Gastrointestinal haemorrhage`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Gastrointestinal haemorrhage`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Head injury`
$Region_Europe$`Head injury`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Head injury`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Heart rate decreased`
$Region_Europe$`Heart rate decreased`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Heart rate decreased`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Lower respiratory tract infection`
$Region_Europe$`Lower respiratory tract infection`$ntab
            CTRL TRT
n_all         17  30
n_event        0   2
n_event_pct    0   7

$Region_Europe$`Lower respiratory tract infection`$stats
                estimate       se      lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL  2.90322581 1.520588  0.14741931 57.1751420 0.4833479
OR_TRTvsCTRL  3.07017544 1.578680  0.13911960 67.7544859 0.4773617
ARR_TRTvsCTRL 0.06666667 0.045542 -0.02259402  0.1559274 0.1432349


$Region_Europe$`Lung disorder`
$Region_Europe$`Lung disorder`$ntab
            CTRL TRT
n_all         17  30
n_event        1   1
n_event_pct    6   3

$Region_Europe$`Lung disorder`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5666667 1.38124695  0.03781013 8.4927277 0.6809178
OR_TRTvsCTRL   0.5517241 1.44809625  0.03229239 9.4263541 0.6813057
ARR_TRTvsCTRL -0.0254902 0.06580836 -0.15447221 0.1034918 0.6985047


$Region_Europe$`Medical observation`
$Region_Europe$`Medical observation`$ntab
            CTRL TRT
n_all         17  30
n_event        0   2
n_event_pct    0   7

$Region_Europe$`Medical observation`$stats
                estimate       se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.90322581 1.520588  0.14741931 57.1751420 0.4833479
OR_TRTvsCTRL  3.07017544 1.578680  0.13911960 67.7544859 0.4773617
ARR_TRTvsCTRL 0.06666667 0.045542 -0.02259402  0.1559274 0.1432349


$Region_Europe$`Oxygen saturation decreased`
$Region_Europe$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         17  30
n_event        1   1
n_event_pct    6   3

$Region_Europe$`Oxygen saturation decreased`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5666667 1.38124695  0.03781013 8.4927277 0.6809178
OR_TRTvsCTRL   0.5517241 1.44809625  0.03229239 9.4263541 0.6813057
ARR_TRTvsCTRL -0.0254902 0.06580836 -0.15447221 0.1034918 0.6985047


$Region_Europe$Pneumonia
$Region_Europe$Pneumonia$ntab
            CTRL TRT
n_all         17  30
n_event        2   6
n_event_pct   12  20
```

```
$Region_Europe$Pneumonia$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 0.7579642  0.3848297  7.5098154 0.4838834
OR_TRTvsCTRL  1.87500000 0.8803408  0.3339287 10.5280698 0.4751954
ARR_TRTvsCTRL 0.08235294 0.1069560 -0.1272769  0.2919828 0.4413174


$Region_Europe$`Pneumonia aspiration`
$Region_Europe$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         17  30
n_event        2   3
n_event_pct   12  10

$Region_Europe$`Pneumonia aspiration`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.85000000 0.86091606  0.1572555 4.5944339 0.8502696
OR_TRTvsCTRL   0.83333333 0.96800673  0.1249827 5.5563242 0.8506043
ARR_TRTvsCTRL -0.01764706 0.09542667 -0.2046799 0.1693858 0.8532855


$Region_Europe$`Pneumonia pseudomonal`
$Region_Europe$`Pneumonia pseudomonal`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Pneumonia pseudomonal`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$Pyrexia
$Region_Europe$Pyrexia$ntab
            CTRL TRT
n_all         17  30
n_event        0   3
n_event_pct    0  10

$Region_Europe$Pyrexia$stats
              estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.064516 1.48253184  0.222369622 74.2920332 0.34421066
OR_TRTvsCTRL  4.454545 1.54247229  0.216694854 91.5710496 0.33278158
ARR_TRTvsCTRL 0.100000 0.05477226 -0.007351649  0.2073516 0.06788915


$Region_Europe$`Respiratory arrest`
$Region_Europe$`Respiratory arrest`$ntab
            CTRL TRT
n_all         17  30
n_event        0   4
```

```
n_event_pct    0  13

$Region_Europe$`Respiratory arrest`$stats
               estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  5.2258065 1.46096153 0.29825011  91.5642690 0.25769180
OR_TRTvsCTRL  5.9433962 1.52220266 0.30083851 117.4183396 0.24165650
ARR_TRTvsCTRL 0.1333333 0.06206329 0.01169152   0.2549751 0.03168639


$Region_Europe$`Respiratory disorder`
$Region_Europe$`Respiratory disorder`$ntab
            CTRL TRT
n_all         17  30
n_event        0   2
n_event_pct    0   7

$Region_Europe$`Respiratory disorder`$stats
                estimate       se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.90322581 1.520588  0.14741931 57.1751420 0.4833479
OR_TRTvsCTRL  3.07017544 1.578680  0.13911960 67.7544859 0.4773617
ARR_TRTvsCTRL 0.06666667 0.045542 -0.02259402  0.1559274 0.1432349


$Region_Europe$`Respiratory distress`
$Region_Europe$`Respiratory distress`$ntab
            CTRL TRT
n_all         17  30
n_event        2   8
n_event_pct   12  27

$Region_Europe$`Respiratory distress`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2666667 0.7299611  0.54205541  9.4783258 0.2622739
OR_TRTvsCTRL  2.7272727 0.8585576  0.50690081 14.6735148 0.2425687
ARR_TRTvsCTRL 0.1490196 0.1123600 -0.07120192  0.3692411 0.1847505


$Region_Europe$`Respiratory failure`
$Region_Europe$`Respiratory failure`$ntab
            CTRL TRT
n_all         17  30
n_event        8   9
n_event_pct   47  30

$Region_Europe$`Respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6375000 0.3794130  0.3030562 1.3410258 0.2353964
OR_TRTvsCTRL   0.4821429 0.6283640  0.1407056 1.6521144 0.2456521
ARR_TRTvsCTRL -0.1705882 0.1471564 -0.4590094 0.1178329 0.2463620


$Region_Europe$`Respiratory tract congestion`
$Region_Europe$`Respiratory tract congestion`$ntab
            CTRL TRT
```

```
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Respiratory tract congestion`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Respiratory tract infection`
$Region_Europe$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         17  30
n_event        1   6
n_event_pct    6  20

$Region_Europe$`Respiratory tract infection`$stats
               estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.4000000 1.03658565  0.4457954 25.9311764 0.2377684
OR_TRTvsCTRL  4.0000000 1.12731244  0.4390257 36.4443391 0.2187968
ARR_TRTvsCTRL 0.1411765 0.09268225 -0.0404774  0.3228303 0.1277009


$Region_Europe$`Respiratory tract infection viral`
$Region_Europe$`Respiratory tract infection viral`$ntab
            CTRL TRT
n_all         17  30
n_event        1   1
n_event_pct    6   3

$Region_Europe$`Respiratory tract infection viral`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5666667 1.38124695  0.03781013 8.4927277 0.6809178
OR_TRTvsCTRL   0.5517241 1.44809625  0.03229239 9.4263541 0.6813057
ARR_TRTvsCTRL -0.0254902 0.06580836 -0.15447221 0.1034918 0.6985047


$Region_Europe$`Rhinovirus infection`
$Region_Europe$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         17  30
n_event        1   3
n_event_pct    6  10

$Region_Europe$`Rhinovirus infection`$stats
               estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.70000000 1.11408100  0.1914880 15.0923333 0.6338661
OR_TRTvsCTRL  1.77777778 1.19702563  0.1702031 18.5689583 0.6307571
ARR_TRTvsCTRL 0.04117647 0.07909909 -0.1138549  0.1962078 0.6026676


$Region_Europe$`Salivary hypersecretion`
```

```
$Region_Europe$`Salivary hypersecretion`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Salivary hypersecretion`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Systemic infection`
$Region_Europe$`Systemic infection`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Systemic infection`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Tracheal haemorrhage`
$Region_Europe$`Tracheal haemorrhage`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Tracheal haemorrhage`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Region_Europe$`Tracheal obstruction`
$Region_Europe$`Tracheal obstruction`$ntab
            CTRL TRT
n_all         17  30
n_event        1   0
n_event_pct    6   0

$Region_Europe$`Tracheal obstruction`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.19354839 1.60588077  0.008314983 4.50523808 0.3064811
OR_TRTvsCTRL   0.18032787 1.66134271  0.006949049 4.67950949 0.3025029
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457
```

```
$Region_Europe$`Viral infection`
$Region_Europe$`Viral infection`$ntab
            CTRL TRT
n_all         17  30
n_event        0   4
n_event_pct    0  13

$Region_Europe$`Viral infection`$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  5.2258065 1.46096153 0.29825011  91.5642690 0.25769180
OR_TRTvsCTRL  5.9433962 1.52220266 0.30083851 117.4183396 0.24165650
ARR_TRTvsCTRL 0.1333333 0.06206329 0.01169152   0.2549751 0.03168639


$Region_Europe$Vomiting
$Region_Europe$Vomiting$ntab
            CTRL TRT
n_all         17  30
n_event        0   2
n_event_pct    0   7

$Region_Europe$Vomiting$stats
                 estimate       se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.90322581 1.520588  0.14741931 57.1751420 0.4833479
OR_TRTvsCTRL  3.07017544 1.578680  0.13911960 67.7544859 0.4773617
ARR_TRTvsCTRL 0.06666667 0.045542 -0.02259402  0.1559274 0.1432349


$Region_Europe$`Weight gain poor`
$Region_Europe$`Weight gain poor`$ntab
            CTRL TRT
n_all         17  30
n_event        1   2
n_event_pct    6   7

$Region_Europe$`Weight gain poor`$stats
                  estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.133333333 1.18652566  0.11076057 11.5965855 0.9159893
OR_TRTvsCTRL  1.142857143 1.26420500  0.09591769 13.6171178 0.9158801
ARR_TRTvsCTRL 0.007843137 0.07301192 -0.13525759  0.1509439 0.9144536



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Acute respiratory distress syndrome`
$Disdur_less_equal_12wk$`Acute respiratory distress syndrome`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Acute respiratory distress syndrome`$stats
                  estimate        se       lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Acute respiratory failure`
$Disdur_less_equal_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         18  34
n_event        4   4
n_event_pct   22  12

$Disdur_less_equal_12wk$`Acute respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5294118 0.6442303  0.1497696 1.8713862 0.3235411
OR_TRTvsCTRL   0.4666667 0.7776644  0.1016384 2.1426731 0.3270677
ARR_TRTvsCTRL -0.1045752 0.1124959 -0.3250630 0.1159127 0.3525828


$Disdur_less_equal_12wk$Agitation
$Disdur_less_equal_12wk$Agitation$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$Agitation$stats
                estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$Apnoea
$Disdur_less_equal_12wk$Apnoea$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$Apnoea$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$Aspiration
$Disdur_less_equal_12wk$Aspiration$ntab
            CTRL TRT
n_all         18  34
n_event        1   2
n_event_pct    6   6
```

```
$Disdur_less_equal_12wk$Aspiration$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 1.18955146  0.10286687 10.8986228 0.9616761
OR_TRTvsCTRL  1.062500000 1.26098118  0.08973871 12.5799253 0.9616546
ARR_TRTvsCTRL 0.003267974 0.06740389 -0.12884123  0.1353772 0.9613309


$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$ntab
           CTRL TRT
n_all        18  34
n_event       1   8
n_event_pct   6  24

$Disdur_less_equal_12wk$Atelectasis$stats
               estimate         se      lo95ci    hi95ci     pvalue
RR_TRTvsCTRL  4.2352941 1.01981993 0.573867039 31.257617 0.15695135
OR_TRTvsCTRL  5.2307692 1.10557002 0.599104599 45.669732 0.13450626
ARR_TRTvsCTRL 0.1797386 0.09059268 0.002180166  0.357297 0.04725254


$Disdur_less_equal_12wk$`Body temperature increased`
$Disdur_less_equal_12wk$`Body temperature increased`$ntab
           CTRL TRT
n_all        18  34
n_event       1   0
n_event_pct   6   0

$Disdur_less_equal_12wk$`Body temperature increased`$stats
                estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Bronchial secretion retention`
$Disdur_less_equal_12wk$`Bronchial secretion retention`$ntab
           CTRL TRT
n_all        18  34
n_event       4   1
n_event_pct  22   3

$Disdur_less_equal_12wk$`Bronchial secretion retention`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.1323529 1.0793668  0.01595787 1.097721774 0.06098794
OR_TRTvsCTRL   0.1060606 1.1626399  0.01086209 1.035607067 0.05362288
ARR_TRTvsCTRL -0.1928105 0.1021851 -0.39308966 0.007468748 0.05917732


$Disdur_less_equal_12wk$Bronchitis
$Disdur_less_equal_12wk$Bronchitis$ntab
           CTRL TRT
n_all        18  34
n_event       0   4
```

```
n_event_pct    0  12

$Disdur_less_equal_12wk$Bronchitis$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.8857143 1.46322220 0.277607419  85.985469 0.27830946
OR_TRTvsCTRL  5.4590164 1.51956019 0.277755343 107.291761 0.26401687
ARR_TRTvsCTRL 0.1176471 0.05525508 0.009349083   0.225945 0.03324081


$Disdur_less_equal_12wk$`Bronchitis viral`
$Disdur_less_equal_12wk$`Bronchitis viral`$ntab
            CTRL TRT
n_all         18  34
n_event        0   2
n_event_pct    0   6

$Disdur_less_equal_12wk$`Bronchitis viral`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.71428571 1.52275966  0.13723983 53.6822779 0.5119938
OR_TRTvsCTRL  2.84615385 1.57633223  0.12956328 62.5222782 0.5069811
ARR_TRTvsCTRL 0.05882353 0.04035261 -0.02026613  0.1379132 0.1449128


$Disdur_less_equal_12wk$`Candida sepsis`
$Disdur_less_equal_12wk$`Candida sepsis`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Candida sepsis`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Cardiac arrest`
$Disdur_less_equal_12wk$`Cardiac arrest`$ntab
            CTRL TRT
n_all         18  34
n_event        1   1
n_event_pct    6   3

$Disdur_less_equal_12wk$`Cardiac arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 1.38384706  0.03514478 7.97492008 0.6458175
OR_TRTvsCTRL   0.51515152 1.44538111  0.03031268 8.75478761 0.6463016
ARR_TRTvsCTRL -0.02614379 0.06127447 -0.14623955 0.09395197 0.6696220


$Disdur_less_equal_12wk$`Cardio-respiratory arrest`
$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$ntab
            CTRL TRT
```

```
n_all         18  34
n_event        3   1
n_event_pct   17   3

$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1764706 1.1173030  0.01975251 1.5766031 0.1205452
OR_TRTvsCTRL   0.1515152 1.1959528  0.01453648 1.5792574 0.1145932
ARR_TRTvsCTRL -0.1372549 0.0924968 -0.31854530 0.0440355 0.1378386


$Disdur_less_equal_12wk$`Corona virus infection`
$Disdur_less_equal_12wk$`Corona virus infection`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Corona virus infection`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$Cyanosis
$Disdur_less_equal_12wk$Cyanosis$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$Cyanosis$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$Death
$Disdur_less_equal_12wk$Death$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$Death$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$Dysphagia
```

```
$Disdur_less_equal_12wk$Dysphagia$ntab
            CTRL TRT
n_all         18  34
n_event        1   1
n_event_pct    6   3

$Disdur_less_equal_12wk$Dysphagia$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 1.38384706  0.03514478 7.97492008 0.6458175
OR_TRTvsCTRL   0.51515152 1.44538111  0.03031268 8.75478761 0.6463016
ARR_TRTvsCTRL -0.02614379 0.06127447 -0.14623955 0.09395197 0.6696220


$Disdur_less_equal_12wk$Dyspnoea
$Disdur_less_equal_12wk$Dyspnoea$ntab
            CTRL TRT
n_all         18  34
n_event        2   0
n_event_pct   11   0

$Disdur_less_equal_12wk$Dyspnoea$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.10857143 1.52275966  0.005489593 2.14729112 0.1448110
OR_TRTvsCTRL   0.09565217 1.57784396  0.004341418 2.10745379 0.1368838
ARR_TRTvsCTRL -0.11111111 0.07407407 -0.256293628 0.03407141 0.1336144


$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`
$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`$ntab
            CTRL TRT
n_all         18  34
n_event        1   1
n_event_pct    6   3

$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 1.38384706  0.03514478 7.97492008 0.6458175
OR_TRTvsCTRL   0.51515152 1.44538111  0.03031268 8.75478761 0.6463016
ARR_TRTvsCTRL -0.02614379 0.06127447 -0.14623955 0.09395197 0.6696220


$Disdur_less_equal_12wk$`Femur fracture`
$Disdur_less_equal_12wk$`Femur fracture`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Femur fracture`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837
```

```
$Disdur_less_equal_12wk$`Gastrointestinal haemorrhage`
$Disdur_less_equal_12wk$`Gastrointestinal haemorrhage`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Gastrointestinal haemorrhage`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Heart rate decreased`
$Disdur_less_equal_12wk$`Heart rate decreased`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Heart rate decreased`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$Hypoxia
$Disdur_less_equal_12wk$Hypoxia$ntab
            CTRL TRT
n_all         18  34
n_event        1   1
n_event_pct    6   3

$Disdur_less_equal_12wk$Hypoxia$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 1.38384706  0.03514478 7.97492008 0.6458175
OR_TRTvsCTRL   0.51515152 1.44538111  0.03031268 8.75478761 0.6463016
ARR_TRTvsCTRL -0.02614379 0.06127447 -0.14623955 0.09395197 0.6696220


$Disdur_less_equal_12wk$`Oxygen saturation decreased`
$Disdur_less_equal_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         18  34
n_event        2   1
n_event_pct   11   3

$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.26470588 1.18955146  0.02571672 2.72465571 0.2638481
OR_TRTvsCTRL   0.24242424 1.26206301  0.02043177 2.87637844 0.2615151
```

```
ARR_TRTvsCTRL -0.08169935 0.07953979 -0.23759446 0.07419577 0.3043495


$Disdur_less_equal_12wk$Pneumonia
$Disdur_less_equal_12wk$Pneumonia$ntab
            CTRL TRT
n_all         18  34
n_event        2   8
n_event_pct   11  24

$Disdur_less_equal_12wk$Pneumonia$stats
              estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.117647 0.7348692  0.50157031  8.9407786 0.3072517
OR_TRTvsCTRL  2.461538 0.8520338  0.46339802 13.0755234 0.2904115
ARR_TRTvsCTRL 0.124183 0.1038222 -0.07930478  0.3276708 0.2316528


$Disdur_less_equal_12wk$`Pneumonia aspiration`
$Disdur_less_equal_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         18  34
n_event        3   4
n_event_pct   17  12

$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.70588235 0.7059504  0.1769401 2.8160374 0.6217392
OR_TRTvsCTRL   0.66666667 0.8266398  0.1319082 3.3693475 0.6237816
ARR_TRTvsCTRL -0.04901961 0.1037746 -0.2524141 0.1543749 0.6366656


$Disdur_less_equal_12wk$`Pneumonia bacterial`
$Disdur_less_equal_12wk$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         18  34
n_event        1   2
n_event_pct    6   6

$Disdur_less_equal_12wk$`Pneumonia bacterial`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 1.18955146  0.10286687 10.8986228 0.9616761
OR_TRTvsCTRL  1.062500000 1.26098118  0.08973871 12.5799253 0.9616546
ARR_TRTvsCTRL 0.003267974 0.06740389 -0.12884123  0.1353772 0.9613309


$Disdur_less_equal_12wk$`Pneumonia parainfluenzae viral`
$Disdur_less_equal_12wk$`Pneumonia parainfluenzae viral`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Pneumonia parainfluenzae viral`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
n_all         18  34
n_event        0   2
n_event_pct    0   6

$Disdur_less_equal_12wk$Pyrexia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.71428571 1.52275966  0.13723983 53.6822779 0.5119938
OR_TRTvsCTRL  2.84615385 1.57633223  0.12956328 62.5222782 0.5069811
ARR_TRTvsCTRL 0.05882353 0.04035261 -0.02026613  0.1379132 0.1449128


$Disdur_less_equal_12wk$`Respiratory arrest`
$Disdur_less_equal_12wk$`Respiratory arrest`$ntab
            CTRL TRT
n_all         18  34
n_event        3   2
n_event_pct   17   6

$Disdur_less_equal_12wk$`Respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3529412 0.86508151  0.06476548 1.92336205 0.2286362
OR_TRTvsCTRL   0.3125000 0.96501295  0.04714433 2.07143131 0.2280792
ARR_TRTvsCTRL -0.1078431 0.09666635 -0.29730569 0.08161942 0.2645838


$Disdur_less_equal_12wk$`Respiratory distress`
$Disdur_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         18  34
n_event        3   8
n_event_pct   17  24

$Disdur_less_equal_12wk$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.41176471 0.6110368  0.4262328 4.6760357 0.5725139
OR_TRTvsCTRL  1.53846154 0.7506408  0.3532971 6.6993584 0.5660443
ARR_TRTvsCTRL 0.06862745 0.1140532 -0.1549127 0.2921676 0.5473643


$Disdur_less_equal_12wk$`Respiratory failure`
$Disdur_less_equal_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         18  34
n_event        7   9
n_event_pct   39  26
```

```
$Disdur_less_equal_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6806723 0.4110972  0.3040965 1.5235779 0.3494143
OR_TRTvsCTRL   0.5657143 0.6203848  0.1676967 1.9084012 0.3584899
ARR_TRTvsCTRL -0.1241830 0.1375777 -0.3938304 0.1454643 0.3667175


$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`
$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$`Respiratory tract infection`
$Disdur_less_equal_12wk$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         18  34
n_event        1   5
n_event_pct    6  15

$Disdur_less_equal_12wk$`Respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.64705882 1.05595108  0.33414611 20.9696306 0.3565966
OR_TRTvsCTRL  2.93103448 1.13723625  0.31550313 27.2294067 0.3443595
ARR_TRTvsCTRL 0.09150327 0.08126588 -0.06777494  0.2507815 0.2601765


$Disdur_less_equal_12wk$`Respirovirus test positive`
$Disdur_less_equal_12wk$`Respirovirus test positive`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Respirovirus test positive`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$Retching
$Disdur_less_equal_12wk$Retching$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
```

```
n_event_pct    6   0

$Disdur_less_equal_12wk$Retching$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Rhinovirus infection`
$Disdur_less_equal_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         18  34
n_event        1   2
n_event_pct    6   6

$Disdur_less_equal_12wk$`Rhinovirus infection`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.058823529 1.18955146  0.10286687 10.8986228 0.9616761
OR_TRTvsCTRL  1.062500000 1.26098118  0.08973871 12.5799253 0.9616546
ARR_TRTvsCTRL 0.003267974 0.06740389 -0.12884123  0.1353772 0.9613309


$Disdur_less_equal_12wk$`Systemic infection`
$Disdur_less_equal_12wk$`Systemic infection`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Systemic infection`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Tracheal haemorrhage`
$Disdur_less_equal_12wk$`Tracheal haemorrhage`$ntab
            CTRL TRT
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Tracheal haemorrhage`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Tracheal obstruction`
$Disdur_less_equal_12wk$`Tracheal obstruction`$ntab
            CTRL TRT
```

```
n_all         18  34
n_event        1   0
n_event_pct    6   0

$Disdur_less_equal_12wk$`Tracheal obstruction`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.18095238 1.6079377  0.007742572 4.22905523 0.2877020
OR_TRTvsCTRL   0.16908213 1.6591549  0.006543686 4.36890823 0.2840568
ARR_TRTvsCTRL -0.05555556 0.0539903 -0.161374590 0.05026348 0.3034837


$Disdur_less_equal_12wk$`Viral infection`
$Disdur_less_equal_12wk$`Viral infection`$ntab
            CTRL TRT
n_all         18  34
n_event        0   3
n_event_pct    0   9

$Disdur_less_equal_12wk$`Viral infection`$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.80000000 1.48475967  0.206992149 69.7610999 0.36858015
OR_TRTvsCTRL  4.11111111 1.53997220  0.200970588 84.0980501 0.35861925
ARR_TRTvsCTRL 0.08823529 0.04864331 -0.007103837  0.1835744 0.06968933


$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`
$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         18  34
n_event        2   2
n_event_pct   11   6

$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 0.95657341  0.08120015 3.4516786 0.5061391
OR_TRTvsCTRL   0.50000000 1.04582503  0.06438165 3.8830938 0.5074744
ARR_TRTvsCTRL -0.05228758 0.08435225 -0.21761495 0.1130398 0.5353422


$Disdur_less_equal_12wk$Vomiting
$Disdur_less_equal_12wk$Vomiting$ntab
            CTRL TRT
n_all         18  34
n_event        1   1
n_event_pct    6   3

$Disdur_less_equal_12wk$Vomiting$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 1.38384706  0.03514478 7.97492008 0.6458175
OR_TRTvsCTRL   0.51515152 1.44538111  0.03031268 8.75478761 0.6463016
ARR_TRTvsCTRL -0.02614379 0.06127447 -0.14623955 0.09395197 0.6696220


$Disdur_less_equal_12wk$`Weight gain poor`
```

```
$Disdur_less_equal_12wk$`Weight gain poor`$ntab
            CTRL TRT
n_all         18  34
n_event        1   1
n_event_pct    6   3

$Disdur_less_equal_12wk$`Weight gain poor`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.52941176 1.38384706  0.03514478 7.97492008 0.6458175
OR_TRTvsCTRL   0.51515152 1.44538111  0.03031268 8.75478761 0.6463016
ARR_TRTvsCTRL -0.02614379 0.06127447 -0.14623955 0.09395197 0.6696220



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event        7  10
n_event_pct   22  14

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.63492063 0.44465521  0.2656001 1.5177863 0.3069750
OR_TRTvsCTRL   0.57603687 0.54679628  0.1972497 1.6822251 0.3130920
ARR_TRTvsCTRL -0.07986111 0.08367598 -0.2438630 0.0841408 0.3398767


$Ageonset_less_equal_12wk$Apnoea
$Ageonset_less_equal_12wk$Apnoea$ntab
            CTRL TRT
n_all         32  72
n_event        2   2
n_event_pct    6   3

$Ageonset_less_equal_12wk$Apnoea$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.44444444 0.97716995  0.06547099 3.01707462 0.4066087
OR_TRTvsCTRL   0.42857143 1.02353263  0.05764885 3.18607335 0.4077741
ARR_TRTvsCTRL -0.03472222 0.04696957 -0.12678089 0.05733644 0.4597556


$Ageonset_less_equal_12wk$`Apparent life threatening event`
$Ageonset_less_equal_12wk$`Apparent life threatening event`$ntab
            CTRL TRT
n_all         32  72
n_event        2   0
n_event_pct    6   0

$Ageonset_less_equal_12wk$`Apparent life threatening event`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.09041096 1.53492617  0.004463644 1.83127092 0.1173951
OR_TRTvsCTRL   0.08413793 1.56415472  0.003922662 1.80469053 0.1135321
```

```
ARR_TRTvsCTRL -0.06250000 0.04279082 -0.146368475 0.02136848 0.1441270


$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         32  72
n_event        4  14
n_event_pct   12  19

$Ageonset_less_equal_12wk$Atelectasis$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.55555556 0.52563265  0.55522141 4.3581768 0.4005870
OR_TRTvsCTRL  1.68965517 0.61186946  0.50930021 5.6056027 0.3913073
ARR_TRTvsCTRL 0.06944444 0.07478948 -0.07714024 0.2160291 0.3531315


$Ageonset_less_equal_12wk$`Bronchial secretion retention`
$Ageonset_less_equal_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         32  72
n_event        4   1
n_event_pct   12   1

$Ageonset_less_equal_12wk$`Bronchial secretion retention`$stats
                 estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.11111111 1.09766166  0.01292487 0.955187842 0.04531355
OR_TRTvsCTRL   0.09859155 1.14008719  0.01055348 0.921050969 0.04214366
ARR_TRTvsCTRL -0.11111111 0.06006822 -0.22884265 0.006620433 0.06434977


$Ageonset_less_equal_12wk$Bronchiolitis
$Ageonset_less_equal_12wk$Bronchiolitis$ntab
            CTRL TRT
n_all         32  72
n_event        1   4
n_event_pct    3   6

$Ageonset_less_equal_12wk$Bronchiolitis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.77777778 1.09766166  0.20679793 15.2830055 0.6001585
OR_TRTvsCTRL  1.82352941 1.13884325  0.19567153 16.9940896 0.5978257
ARR_TRTvsCTRL 0.02430556 0.04092411 -0.05590423  0.1045153 0.5525671


$Ageonset_less_equal_12wk$Bronchitis
$Ageonset_less_equal_12wk$Bronchitis$ntab
            CTRL TRT
n_all         32  72
n_event        0   4
n_event_pct    0   6

$Ageonset_less_equal_12wk$Bronchitis$stats
                estimate         se      lo95ci     hi95ci     pvalue
```

```
RR_TRTvsCTRL  4.06849315 1.47587959 0.225508339 73.4014388 0.34170372
OR_TRTvsCTRL  4.27007299 1.50585192 0.223178228 81.6993824 0.33504936
ARR_TRTvsCTRL 0.05555556 0.02699515 0.002646038  0.1084651 0.03959176


$Ageonset_less_equal_12wk$`Cardiac arrest`
$Ageonset_less_equal_12wk$`Cardiac arrest`$ntab
            CTRL TRT
n_all         32  72
n_event        2   2
n_event_pct    6   3

$Ageonset_less_equal_12wk$`Cardiac arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.44444444 0.97716995  0.06547099 3.01707462 0.4066087
OR_TRTvsCTRL   0.42857143 1.02353263  0.05764885 3.18607335 0.4077741
ARR_TRTvsCTRL -0.03472222 0.04696957 -0.12678089 0.05733644 0.4597556


$Ageonset_less_equal_12wk$`Cardio-respiratory arrest`
$Ageonset_less_equal_12wk$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         32  72
n_event        3   4
n_event_pct    9   6

$Ageonset_less_equal_12wk$`Cardio-respiratory arrest`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.59259259 0.73361737  0.1407019 2.49581537 0.4756948
OR_TRTvsCTRL   0.56862745 0.79531250  0.1196345 2.70270752 0.4778149
ARR_TRTvsCTRL -0.03819444 0.05817016 -0.1522059 0.07581697 0.5114390


$Ageonset_less_equal_12wk$Dyspnoea
$Ageonset_less_equal_12wk$Dyspnoea$ntab
            CTRL TRT
n_all         32  72
n_event        2   4
n_event_pct    6   6

$Ageonset_less_equal_12wk$Dyspnoea$stats
                  estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.888888889 0.83956007  0.1714797 4.60767994 0.8884298
OR_TRTvsCTRL   0.882352941 0.89333041  0.1531927 5.08213923 0.8885743
ARR_TRTvsCTRL -0.006944444 0.05059439 -0.1061076 0.09221875 0.8908275


$Ageonset_less_equal_12wk$`Feeding disorder of infancy or early childhood`
$Ageonset_less_equal_12wk$`Feeding disorder of infancy or early childhood`$ntab
            CTRL TRT
n_all         32  72
n_event        2   2
n_event_pct    6   3
```

```
$Ageonset_less_equal_12wk$`Feeding disorder of infancy or early childhood`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.44444444 0.97716995  0.06547099 3.01707462 0.4066087
OR_TRTvsCTRL   0.42857143 1.02353263  0.05764885 3.18607335 0.4077741
ARR_TRTvsCTRL -0.03472222 0.04696957 -0.12678089 0.05733644 0.4597556


$Ageonset_less_equal_12wk$Hypoxia
$Ageonset_less_equal_12wk$Hypoxia$ntab
            CTRL TRT
n_all         32  72
n_event        1   4
n_event_pct    3   6

$Ageonset_less_equal_12wk$Hypoxia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.77777778 1.09766166  0.20679793 15.2830055 0.6001585
OR_TRTvsCTRL  1.82352941 1.13884325  0.19567153 16.9940896 0.5978257
ARR_TRTvsCTRL 0.02430556 0.04092411 -0.05590423  0.1045153 0.5525671


$Ageonset_less_equal_12wk$`Lower respiratory tract infection`
$Ageonset_less_equal_12wk$`Lower respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        0   4
n_event_pct    0   6

$Ageonset_less_equal_12wk$`Lower respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.06849315 1.47587959 0.225508339 73.4014388 0.34170372
OR_TRTvsCTRL  4.27007299 1.50585192 0.223178228 81.6993824 0.33504936
ARR_TRTvsCTRL 0.05555556 0.02699515 0.002646038  0.1084651 0.03959176


$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         32  72
n_event        2   1
n_event_pct    6   1

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.22222222 1.20617624  0.02089722 2.36312426 0.2124049
OR_TRTvsCTRL   0.21126761 1.24395251  0.01844925 2.41928596 0.2113909
ARR_TRTvsCTRL -0.04861111 0.04495861 -0.13672837 0.03950615 0.2795898


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$ntab
            CTRL TRT
n_all         32  72
n_event        4  18
```

```
n_event_pct   12  25

$Ageonset_less_equal_12wk$Pneumonia$stats
              estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.000000 0.51031036  0.73561915 5.4375963 0.1743731
OR_TRTvsCTRL  2.333333 0.59982361  0.72012188 7.5604486 0.1577797
ARR_TRTvsCTRL 0.125000 0.07760242 -0.02709795 0.2770979 0.1072289


$Ageonset_less_equal_12wk$`Pneumonia aspiration`
$Ageonset_less_equal_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         32  72
n_event        3   8
n_event_pct    9  11

$Ageonset_less_equal_12wk$`Pneumonia aspiration`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.18518519 0.64280203  0.3362267 4.1777292 0.7915410
OR_TRTvsCTRL  1.20833333 0.71305055  0.2987012 4.8880595 0.7907031
ARR_TRTvsCTRL 0.01736111 0.06345685 -0.1070120 0.1417342 0.7844003


$Ageonset_less_equal_12wk$`Pneumonia bacterial`
$Ageonset_less_equal_12wk$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         32  72
n_event        2   3
n_event_pct    6   4

$Ageonset_less_equal_12wk$`Pneumonia bacterial`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.66666667 0.88780316  0.1170063 3.79846525 0.6478823
OR_TRTvsCTRL   0.65217391 0.93870092  0.1035952 4.10569890 0.6488524
ARR_TRTvsCTRL -0.02083333 0.04884307 -0.1165640 0.07489733 0.6697173


$Ageonset_less_equal_12wk$`Pneumonia viral`
$Ageonset_less_equal_12wk$`Pneumonia viral`$ntab
            CTRL TRT
n_all         32  72
n_event        2   6
n_event_pct    6   8

$Ageonset_less_equal_12wk$`Pneumonia viral`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.33333333 0.78837033  0.28436536 6.2517381 0.7151806
OR_TRTvsCTRL  1.36363636 0.84566631  0.25993580 7.1537053 0.7137995
ARR_TRTvsCTRL 0.02083333 0.05377743 -0.08456848 0.1262352 0.6984607


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$ntab
            CTRL TRT
```

```
n_all         32  72
n_event        0   4
n_event_pct    0   6

$Ageonset_less_equal_12wk$Pyrexia$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.06849315 1.47587959 0.225508339 73.4014388 0.34170372
OR_TRTvsCTRL  4.27007299 1.50585192 0.223178228 81.6993824 0.33504936
ARR_TRTvsCTRL 0.05555556 0.02699515 0.002646038  0.1084651 0.03959176


$Ageonset_less_equal_12wk$`Respiratory arrest`
$Ageonset_less_equal_12wk$`Respiratory arrest`$ntab
            CTRL TRT
n_all         32  72
n_event        3   5
n_event_pct    9   7

$Ageonset_less_equal_12wk$`Respiratory arrest`$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.74074074 0.69870913  0.1883319 2.91345637 0.6675500
OR_TRTvsCTRL   0.72139303 0.76337505  0.1615794 3.22075704 0.6687974
ARR_TRTvsCTRL -0.02430556 0.05960332 -0.1411259 0.09251481 0.6834289


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         32  72
n_event        6  20
n_event_pct   19  28

$Ageonset_less_equal_12wk$`Respiratory distress`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.48148148 0.41415912  0.65790524 3.3360236 0.3426138
OR_TRTvsCTRL  1.66666667 0.52379287  0.59702903 4.6526679 0.3294395
ARR_TRTvsCTRL 0.09027778 0.08687401 -0.07999215 0.2605477 0.2987208


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event       15  18
n_event_pct   47  25

$Ageonset_less_equal_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.5333333 0.2776389  0.3095082  0.91902082 0.02356652
OR_TRTvsCTRL   0.3777778 0.4467262  0.1573919  0.90675595 0.02932621
ARR_TRTvsCTRL -0.2187500 0.1019125 -0.4184947 -0.01900525 0.03183709


$Ageonset_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`
```

```
$Ageonset_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         32  72
n_event        3   4
n_event_pct    9   6

$Ageonset_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$stats
                  estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.59259259 0.73361737  0.1407019 2.49581537 0.4756948
OR_TRTvsCTRL   0.56862745 0.79531250  0.1196345 2.70270752 0.4778149
ARR_TRTvsCTRL -0.03819444 0.05817016 -0.1522059 0.07581697 0.5114390


$Ageonset_less_equal_12wk$`Respiratory tract infection`
$Ageonset_less_equal_12wk$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        1   5
n_event_pct    3   7

$Ageonset_less_equal_12wk$`Respiratory tract infection`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.22222222 1.07464464  0.2704259 18.2610887 0.4574554
OR_TRTvsCTRL  2.31343284 1.11677367  0.2592134 20.6469720 0.4526335
ARR_TRTvsCTRL 0.03819444 0.04293683 -0.0459602  0.1223491 0.3737077


$Ageonset_less_equal_12wk$`Rhinovirus infection`
$Ageonset_less_equal_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         32  72
n_event        2   7
n_event_pct    6  10

$Ageonset_less_equal_12wk$`Rhinovirus infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.55555556 0.77312241  0.34182399 7.0789446 0.5676666
OR_TRTvsCTRL  1.61538462 0.83160994  0.31652519 8.2441067 0.5641554
ARR_TRTvsCTRL 0.03472222 0.05522756 -0.07352181 0.1429662 0.5295377


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        0   4
n_event_pct    0   6

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.06849315 1.47587959 0.225508339 73.4014388 0.34170372
OR_TRTvsCTRL  4.27007299 1.50585192 0.223178228 81.6993824 0.33504936
ARR_TRTvsCTRL 0.05555556 0.02699515 0.002646038  0.1084651 0.03959176
```

```
$Ageonset_less_equal_12wk$`Viral infection`
$Ageonset_less_equal_12wk$`Viral infection`$ntab
            CTRL TRT
n_all         32  72
n_event        1   5
n_event_pct    3   7

$Ageonset_less_equal_12wk$`Viral infection`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.22222222 1.07464464  0.2704259 18.2610887 0.4574554
OR_TRTvsCTRL  2.31343284 1.11677367  0.2592134 20.6469720 0.4526335
ARR_TRTvsCTRL 0.03819444 0.04293683 -0.0459602  0.1223491 0.3737077


$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         32  72
n_event        6   2
n_event_pct   19   3

$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`$stats
                estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.1481481 0.78837033  0.03159615  0.69463757 0.01542945
OR_TRTvsCTRL   0.1238095 0.84818272  0.02348441  0.65272236 0.01378085
ARR_TRTvsCTRL -0.1597222 0.07166469 -0.30018244 -0.01926201 0.02583097


$Ageonset_less_equal_12wk$`Weight gain poor`
$Ageonset_less_equal_12wk$`Weight gain poor`$ntab
            CTRL TRT
n_all         32  72
n_event        2   3
n_event_pct    6   4

$Ageonset_less_equal_12wk$`Weight gain poor`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.66666667 0.88780316  0.1170063 3.79846525 0.6478823
OR_TRTvsCTRL   0.65217391 0.93870092  0.1035952 4.10569890 0.6488524
ARR_TRTvsCTRL -0.02083333 0.04884307 -0.1165640 0.07489733 0.6697173



$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Acute respiratory failure`
$Ageonset_greater_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Acute respiratory failure`$stats
                estimate        se      lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$`Bronchial secretion retention`
$Ageonset_greater_12wk$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Bronchial secretion retention`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Candida sepsis`
$Ageonset_greater_12wk$`Candida sepsis`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Candida sepsis`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Cardio-respiratory arrest`
$Ageonset_greater_12wk$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Cardio-respiratory arrest`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$`Femur fracture`
$Ageonset_greater_12wk$`Femur fracture`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0
```

```
$Ageonset_greater_12wk$`Femur fracture`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$Pneumonia
$Ageonset_greater_12wk$Pneumonia$ntab
            CTRL TRT
n_all          9   8
n_event        1   1
n_event_pct   11  12

$Ageonset_greater_12wk$Pneumonia$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.12500000 1.3281148  0.08330272 15.1930819 0.9293327
OR_TRTvsCTRL  1.14285714 1.5059406  0.05972181 21.8701078 0.9293444
ARR_TRTvsCTRL 0.01388889 0.1569898 -0.29380556  0.3215833 0.9295031


$Ageonset_greater_12wk$`Pneumonia aspiration`
$Ageonset_greater_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all          9   8
n_event        2   0
n_event_pct   22   0

$Ageonset_greater_12wk$`Pneumonia aspiration`$stats
                estimate        se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.2222222 1.4794894  0.012230489 4.0376730 0.3093346
OR_TRTvsCTRL   0.1764706 1.6281832  0.007257053 4.2912553 0.2867131
ARR_TRTvsCTRL -0.2222222 0.1385799 -0.493833842 0.0493894 0.1088094


$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`
$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Pneumonia pseudomonal`
$Ageonset_greater_12wk$`Pneumonia pseudomonal`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
```

```
n_event_pct   11   0

$Ageonset_greater_12wk$`Pneumonia pseudomonal`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Respiratory arrest`
$Ageonset_greater_12wk$`Respiratory arrest`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Respiratory arrest`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Respiratory distress`
$Ageonset_greater_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all          9   8
n_event        2   1
n_event_pct   22  12

$Ageonset_greater_12wk$`Respiratory distress`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.56250000 1.1242281  0.06211233 5.0940974 0.6088008
OR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
ARR_TRTvsCTRL -0.09722222 0.1813181 -0.45259923 0.2581548 0.5918225


$Ageonset_greater_12wk$`Respiratory failure`
$Ageonset_greater_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all          9   8
n_event        1   2
n_event_pct   11  25

$Ageonset_greater_12wk$`Respiratory failure`$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2500000 1.1242281  0.2484493 20.3763897 0.4707116
OR_TRTvsCTRL  2.6666667 1.3385315  0.1934678 36.7560505 0.4637017
ARR_TRTvsCTRL 0.1388889 0.1855032 -0.2246907  0.5024685 0.4540295


$Ageonset_greater_12wk$`Respiratory tract infection`
$Ageonset_greater_12wk$`Respiratory tract infection`$ntab
            CTRL TRT
```

```
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Respiratory tract infection`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494


$Ageonset_greater_12wk$`Respirovirus test positive`
$Ageonset_greater_12wk$`Respirovirus test positive`$ntab
            CTRL TRT
n_all          9   8
n_event        1   0
n_event_pct   11   0

$Ageonset_greater_12wk$`Respirovirus test positive`$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.3703704 1.5670212  0.01717059 7.98890268 0.5261807
OR_TRTvsCTRL   0.3333333 1.7035142  0.01182619 9.39534430 0.5189859
ARR_TRTvsCTRL -0.1111111 0.1047566 -0.31643020 0.09420797 0.2888444


$Ageonset_greater_12wk$`Viral upper respiratory tract infection`
$Ageonset_greater_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all          9   8
n_event        0   1
n_event_pct    0  12

$Ageonset_greater_12wk$`Viral upper respiratory tract infection`$stats
              estimate        se     lo95ci      hi95ci    pvalue
RR_TRTvsCTRL  3.333333 1.5670212  0.1545354  71.9001241 0.4422975
OR_TRTvsCTRL  3.800000 1.7044833  0.1345627 107.3105378 0.4334925
ARR_TRTvsCTRL 0.125000 0.1169268 -0.1041723   0.3541723 0.2850494



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Acute respiratory failure`
$Agetrt_greater_equal_180d$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         25  31
n_event        6   4
n_event_pct   24  13

$Agetrt_greater_equal_180d$`Acute respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5376344 0.5868634  0.1701955 1.69834553 0.2903080
OR_TRTvsCTRL   0.4691358 0.7115724  0.1163073 1.89230050 0.2874879
ARR_TRTvsCTRL -0.1109677 0.1045048 -0.3157934 0.09385793 0.2883068
```

```
$Agetrt_greater_equal_180d$`Apparent life threatening event`
$Agetrt_greater_equal_180d$`Apparent life threatening event`$ntab
            CTRL TRT
n_all         25  31
n_event        2   0
n_event_pct    8   0

$Agetrt_greater_equal_180d$`Apparent life threatening event`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1625000 1.52652824  0.008155868 3.23769964 0.2339154
OR_TRTvsCTRL   0.1492063 1.57299054  0.006836839 3.25626150 0.2264969
ARR_TRTvsCTRL -0.0800000 0.05425864 -0.186344980 0.02634498 0.1403687


$Agetrt_greater_equal_180d$Atelectasis
$Agetrt_greater_equal_180d$Atelectasis$ntab
            CTRL TRT
n_all         25  31
n_event        2   4
n_event_pct    8  13

$Agetrt_greater_equal_180d$Atelectasis$stats
                 estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.61290323 0.82325083  0.3212595  8.0976815 0.5614639
OR_TRTvsCTRL  1.70370370 0.91132612  0.2855432 10.1652080 0.5587848
ARR_TRTvsCTRL 0.04903226 0.08105095 -0.1098247  0.2078892 0.5452082


$Agetrt_greater_equal_180d$`Bronchial secretion retention`
$Agetrt_greater_equal_180d$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         25  31
n_event        2   0
n_event_pct    8   0

$Agetrt_greater_equal_180d$`Bronchial secretion retention`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.1625000 1.52652824  0.008155868 3.23769964 0.2339154
OR_TRTvsCTRL   0.1492063 1.57299054  0.006836839 3.25626150 0.2264969
ARR_TRTvsCTRL -0.0800000 0.05425864 -0.186344980 0.02634498 0.1403687


$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`
$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         25  31
n_event        3   4
n_event_pct   12  13

$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$stats
                  estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.075268817 0.71489529  0.2648482 4.3655304 0.9191438
OR_TRTvsCTRL  1.086419753 0.81598095  0.2194994 5.3772707 0.9190897
```

```
ARR_TRTvsCTRL 0.009032258 0.08859603 -0.1646128 0.1826773 0.9187973


$Agetrt_greater_equal_180d$Dyspnoea
$Agetrt_greater_equal_180d$Dyspnoea$ntab
            CTRL TRT
n_all         25  31
n_event        0   3
n_event_pct    0  10

$Agetrt_greater_equal_180d$Dyspnoea$stats
                estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  5.68750000 1.48862445  0.307469458 105.2060795 0.24292671
OR_TRTvsCTRL  6.26315789 1.53623491  0.308423766 127.1858757 0.23237103
ARR_TRTvsCTRL 0.09677419 0.05310032 -0.007300513   0.2008489 0.06838238


$Agetrt_greater_equal_180d$Hypoxia
$Agetrt_greater_equal_180d$Hypoxia$ntab
            CTRL TRT
n_all         25  31
n_event        0   2
n_event_pct    0   6

$Agetrt_greater_equal_180d$Hypoxia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  4.06250000 1.52652824  0.20389669 80.9424911 0.3584661
OR_TRTvsCTRL  4.32203390 1.57261375  0.19818780 94.2539187 0.3519777
ARR_TRTvsCTRL 0.06451613 0.04412365 -0.02196464  0.1509969 0.1436956


$Agetrt_greater_equal_180d$`Lower respiratory tract infection`
$Agetrt_greater_equal_180d$`Lower respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        0   4
n_event_pct    0  13

$Agetrt_greater_equal_180d$`Lower respiratory tract infection`$stats
               estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  7.3125000 1.4671437 0.41231666 129.6883230 0.17506917
OR_TRTvsCTRL  8.3454545 1.5158501 0.42771654 162.8335705 0.16160680
ARR_TRTvsCTRL 0.1290323 0.0602101 0.01102263   0.2470419 0.03211041


$Agetrt_greater_equal_180d$Pneumonia
$Agetrt_greater_equal_180d$Pneumonia$ntab
            CTRL TRT
n_all         25  31
n_event        3   5
n_event_pct   12  16

$Agetrt_greater_equal_180d$Pneumonia$stats
                estimate         se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL  1.34408602 0.67902523  0.3551728 5.0864455 0.6632009
OR_TRTvsCTRL  1.41025641 0.78565222  0.3023777 6.5772821 0.6617038
ARR_TRTvsCTRL 0.04129032 0.09267003 -0.1403396 0.2229202 0.6559130


$Agetrt_greater_equal_180d$`Pneumonia aspiration`
$Agetrt_greater_equal_180d$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         25  31
n_event        4   2
n_event_pct   16   6

$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.40322581 0.82325083  0.08031487 2.02442037 0.2699149
OR_TRTvsCTRL   0.36206897 0.91219614  0.06057990 2.16398411 0.2654043
ARR_TRTvsCTRL -0.09548387 0.08557393 -0.26320568 0.07223794 0.2645053


$Agetrt_greater_equal_180d$`Pneumonia viral`
$Agetrt_greater_equal_180d$`Pneumonia viral`$ntab
            CTRL TRT
n_all         25  31
n_event        2   3
n_event_pct    8  10

$Agetrt_greater_equal_180d$`Pneumonia viral`$stats
                 estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.20967742 0.87239628  0.2188187 6.687359 0.8272761
OR_TRTvsCTRL  1.23214286 0.95526220  0.1894700 8.012752 0.8270151
ARR_TRTvsCTRL 0.01677419 0.07591866 -0.1320237 0.165572 0.8251317


$Agetrt_greater_equal_180d$Pyrexia
$Agetrt_greater_equal_180d$Pyrexia$ntab
            CTRL TRT
n_all         25  31
n_event        0   2
n_event_pct    0   6

$Agetrt_greater_equal_180d$Pyrexia$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  4.06250000 1.52652824  0.20389669 80.9424911 0.3584661
OR_TRTvsCTRL  4.32203390 1.57261375  0.19818780 94.2539187 0.3519777
ARR_TRTvsCTRL 0.06451613 0.04412365 -0.02196464  0.1509969 0.1436956


$Agetrt_greater_equal_180d$`Respiratory arrest`
$Agetrt_greater_equal_180d$`Respiratory arrest`$ntab
            CTRL TRT
n_all         25  31
n_event        2   3
n_event_pct    8  10
```

```
$Agetrt_greater_equal_180d$`Respiratory arrest`$stats
                estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL  1.20967742 0.87239628  0.2188187 6.687359 0.8272761
OR_TRTvsCTRL  1.23214286 0.95526220  0.1894700 8.012752 0.8270151
ARR_TRTvsCTRL 0.01677419 0.07591866 -0.1320237 0.165572 0.8251317


$Agetrt_greater_equal_180d$`Respiratory disorder`
$Agetrt_greater_equal_180d$`Respiratory disorder`$ntab
            CTRL TRT
n_all         25  31
n_event        0   2
n_event_pct    0   6

$Agetrt_greater_equal_180d$`Respiratory disorder`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  4.06250000 1.52652824  0.20389669 80.9424911 0.3584661
OR_TRTvsCTRL  4.32203390 1.57261375  0.19818780 94.2539187 0.3519777
ARR_TRTvsCTRL 0.06451613 0.04412365 -0.02196464  0.1509969 0.1436956


$Agetrt_greater_equal_180d$`Respiratory distress`
$Agetrt_greater_equal_180d$`Respiratory distress`$ntab
            CTRL TRT
n_all         25  31
n_event        6   7
n_event_pct   24  23

$Agetrt_greater_equal_180d$`Respiratory distress`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.94086022 0.4870993  0.3621641 2.4442453 0.9004044
OR_TRTvsCTRL   0.92361111 0.6354699  0.2658130 3.2092397 0.9004856
ARR_TRTvsCTRL -0.01419355 0.1137334 -0.2371069 0.2087198 0.9006845


$Agetrt_greater_equal_180d$`Respiratory failure`
$Agetrt_greater_equal_180d$`Respiratory failure`$ntab
            CTRL TRT
n_all         25  31
n_event        7   8
n_event_pct   28  26

$Agetrt_greater_equal_180d$`Respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.92165899 0.4422658  0.3873583 2.1929445 0.8536533
OR_TRTvsCTRL   0.89440994 0.6057152  0.2728669 2.9317192 0.8538328
ARR_TRTvsCTRL -0.02193548 0.1193330 -0.2558238 0.2119529 0.8541567


$Agetrt_greater_equal_180d$`Rhinovirus infection`
$Agetrt_greater_equal_180d$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         25  31
n_event        0   3
```

```
n_event_pct    0  10

$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats
                estimate         se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  5.68750000 1.48862445  0.307469458 105.2060795 0.24292671
OR_TRTvsCTRL  6.26315789 1.53623491  0.308423766 127.1858757 0.23237103
ARR_TRTvsCTRL 0.09677419 0.05310032 -0.007300513   0.2008489 0.06838238


$Agetrt_greater_equal_180d$`Upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        0   2
n_event_pct    0   6

$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  4.06250000 1.52652824  0.20389669 80.9424911 0.3584661
OR_TRTvsCTRL  4.32203390 1.57261375  0.19818780 94.2539187 0.3519777
ARR_TRTvsCTRL 0.06451613 0.04412365 -0.02196464  0.1509969 0.1436956


$Agetrt_greater_equal_180d$`Viral infection`
$Agetrt_greater_equal_180d$`Viral infection`$ntab
            CTRL TRT
n_all         25  31
n_event        1   2
n_event_pct    4   6

$Agetrt_greater_equal_180d$`Viral infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.61290323 1.19488156  0.15506839 16.7761900 0.6891052
OR_TRTvsCTRL  1.65517241 1.25544790  0.14132014 19.3857420 0.6881442
ARR_TRTvsCTRL 0.02451613 0.05901607 -0.09115325  0.1401855 0.6778385


$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         25  31
n_event        4   1
n_event_pct   16   3

$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.2016129 1.08523819  0.02403045 1.69151070 0.1400443
OR_TRTvsCTRL   0.1750000 1.15366910  0.01824035 1.67897010 0.1308381
ARR_TRTvsCTRL -0.1277419 0.07989378 -0.28433086 0.02884699 0.1098434



$Gender_Male
$Gender_Male$`Acute respiratory failure`
```

```
$Gender_Male$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         17  37
n_event        3   5
n_event_pct   18  14

$Gender_Male$`Acute respiratory failure`$stats
                 estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.76576577 0.6689415  0.2063915 2.841188 0.6899248
OR_TRTvsCTRL   0.72916667 0.7975035  0.1527533 3.480672 0.6920666
ARR_TRTvsCTRL -0.04133545 0.1082012 -0.2534059 0.170735 0.7024435


$Gender_Male$Apnoea
$Gender_Male$Apnoea$ntab
            CTRL TRT
n_all         17  37
n_event        1   2
n_event_pct    6   5

$Gender_Male$Apnoea$stats
                  estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.918918919 1.1891802  0.08933985  9.4516836 0.9433137
OR_TRTvsCTRL   0.914285714 1.2613768  0.07716068 10.8334757 0.9433634
ARR_TRTvsCTRL -0.004769475 0.0681074 -0.13825752  0.1287186 0.9441708


$Gender_Male$`Apparent life threatening event`
$Gender_Male$`Apparent life threatening event`$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$`Apparent life threatening event`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$Aspiration
$Gender_Male$Aspiration$ntab
            CTRL TRT
n_all         17  37
n_event        1   1
n_event_pct    6   3

$Gender_Male$Aspiration$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 1.38352790  0.03052011 6.91684875 0.5740363
OR_TRTvsCTRL   0.4444444 1.44577930  0.02613171 7.55904710 0.5748692
ARR_TRTvsCTRL -0.0317965 0.06298717 -0.15524909 0.09165609 0.6136929
```

```
$Gender_Male$Atelectasis
$Gender_Male$Atelectasis$ntab
            CTRL TRT
n_all         17  37
n_event        0   4
n_event_pct    0  11

$Gender_Male$Atelectasis$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.2631579 1.46299381 0.242342081 74.9952925 0.32162440
OR_TRTvsCTRL  4.7014925 1.51961042 0.239188898 92.4124501 0.30839139
ARR_TRTvsCTRL 0.1081081 0.05104866 0.008054565  0.2081617 0.03419658


$Gender_Male$`Bronchial secretion retention`
$Gender_Male$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         17  37
n_event        3   1
n_event_pct   18   3

$Gender_Male$`Bronchial secretion retention`$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.1531532 1.11690769  0.01715586 1.36722342 0.09297266
OR_TRTvsCTRL   0.1296296 1.19688750  0.01241400 1.35362001 0.08782408
ARR_TRTvsCTRL -0.1494436 0.09622612 -0.33804329 0.03915617 0.12041222


$Gender_Male$Bronchiolitis
$Gender_Male$Bronchiolitis$ntab
            CTRL TRT
n_all         17  37
n_event        1   3
n_event_pct    6   8

$Gender_Male$Bronchiolitis$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.37837838 1.11690769  0.1544027 12.3050107 0.7738688
OR_TRTvsCTRL  1.41176471 1.19383629  0.1360088 14.6540482 0.7726956
ARR_TRTvsCTRL 0.02225755 0.07259729 -0.1200305  0.1645456 0.7591560


$Gender_Male$Bronchitis
$Gender_Male$Bronchitis$ntab
            CTRL TRT
n_all         17  37
n_event        0   3
n_event_pct    0   8

$Gender_Male$Bronchitis$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.31578947 1.48453459  0.180696116 60.8450259 0.41940405
OR_TRTvsCTRL  3.55072464 1.54007878  0.173539986 72.6498009 0.41063101
```

```
ARR_TRTvsCTRL 0.08108108 0.04487428 -0.006870893  0.1690331 0.07078572


$Gender_Male$`Bronchitis viral`
$Gender_Male$`Bronchitis viral`$ntab
            CTRL TRT
n_all         17  37
n_event        0   2
n_event_pct    0   5

$Gender_Male$`Bronchitis viral`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.36842105 1.52254020  0.11980373 46.821732 0.5711858
OR_TRTvsCTRL  2.46478873 1.57648719  0.11216862 54.161169 0.5671692
ARR_TRTvsCTRL 0.05405405 0.03717461 -0.01880684  0.126915 0.1459301


$Gender_Male$`Candida sepsis`
$Gender_Male$`Candida sepsis`$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$`Candida sepsis`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$`Cardiac arrest`
$Gender_Male$`Cardiac arrest`$ntab
            CTRL TRT
n_all         17  37
n_event        1   2
n_event_pct    6   5

$Gender_Male$`Cardiac arrest`$stats
                  estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.918918919 1.1891802  0.08933985  9.4516836 0.9433137
OR_TRTvsCTRL   0.914285714 1.2613768  0.07716068 10.8334757 0.9433634
ARR_TRTvsCTRL -0.004769475 0.0681074 -0.13825752  0.1287186 0.9441708


$Gender_Male$`Cardio-respiratory arrest`
$Gender_Male$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         17  37
n_event        3   2
n_event_pct   18   5

$Gender_Male$`Cardio-respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.3063063 0.8645709  0.05626417 1.66755432 0.1711540
OR_TRTvsCTRL   0.2666667 0.9660918  0.04014486 1.77136292 0.1712660
ARR_TRTvsCTRL -0.1224165 0.0996529 -0.31773262 0.07289956 0.2192859


$Gender_Male$`Corona virus infection`
$Gender_Male$`Corona virus infection`$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$`Corona virus infection`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$Cyanosis
$Gender_Male$Cyanosis$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$Cyanosis$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$Death
$Gender_Male$Death$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$Death$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$Dehydration
$Gender_Male$Dehydration$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0
```

```
$Gender_Male$Dehydration$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$Dysphagia
$Gender_Male$Dysphagia$ntab
            CTRL TRT
n_all         17  37
n_event        1   1
n_event_pct    6   3

$Gender_Male$Dysphagia$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 1.38352790  0.03052011 6.91684875 0.5740363
OR_TRTvsCTRL   0.4444444 1.44577930  0.02613171 7.55904710 0.5748692
ARR_TRTvsCTRL -0.0317965 0.06298717 -0.15524909 0.09165609 0.6136929


$Gender_Male$Dyspnoea
$Gender_Male$Dyspnoea$ntab
            CTRL TRT
n_all         17  37
n_event        1   1
n_event_pct    6   3

$Gender_Male$Dyspnoea$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 1.38352790  0.03052011 6.91684875 0.5740363
OR_TRTvsCTRL   0.4444444 1.44577930  0.02613171 7.55904710 0.5748692
ARR_TRTvsCTRL -0.0317965 0.06298717 -0.15524909 0.09165609 0.6136929


$Gender_Male$`Failure to thrive`
$Gender_Male$`Failure to thrive`$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$`Failure to thrive`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$Hypoxia
$Gender_Male$Hypoxia$ntab
            CTRL TRT
n_all         17  37
n_event        1   2
```

```
n_event_pct    6   5

$Gender_Male$Hypoxia$stats
                  estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.918918919 1.1891802  0.08933985  9.4516836 0.9433137
OR_TRTvsCTRL   0.914285714 1.2613768  0.07716068 10.8334757 0.9433634
ARR_TRTvsCTRL -0.004769475 0.0681074 -0.13825752  0.1287186 0.9441708


$Gender_Male$`Lower respiratory tract infection`
$Gender_Male$`Lower respiratory tract infection`$ntab
            CTRL TRT
n_all         17  37
n_event        0   2
n_event_pct    0   5

$Gender_Male$`Lower respiratory tract infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.36842105 1.52254020  0.11980373 46.821732 0.5711858
OR_TRTvsCTRL  2.46478873 1.57648719  0.11216862 54.161169 0.5671692
ARR_TRTvsCTRL 0.05405405 0.03717461 -0.01880684  0.126915 0.1459301


$Gender_Male$`Oxygen saturation decreased`
$Gender_Male$`Oxygen saturation decreased`$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$`Oxygen saturation decreased`$stats
                  estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$Pneumonia
$Gender_Male$Pneumonia$ntab
            CTRL TRT
n_all         17  37
n_event        3   5
n_event_pct   18  14

$Gender_Male$Pneumonia$stats
                  estimate        se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.76576577 0.6689415  0.2063915 2.841188 0.6899248
OR_TRTvsCTRL   0.72916667 0.7975035  0.1527533 3.480672 0.6920666
ARR_TRTvsCTRL -0.04133545 0.1082012 -0.2534059 0.170735 0.7024435


$Gender_Male$`Pneumonia aspiration`
$Gender_Male$`Pneumonia aspiration`$ntab
            CTRL TRT
```

```
n_all         17  37
n_event        2   2
n_event_pct   12   5

$Gender_Male$`Pneumonia aspiration`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 0.95611163  0.07053481 2.9928909 0.4159867
OR_TRTvsCTRL   0.4285714 1.04653624  0.05510740 3.3330089 0.4181580
ARR_TRTvsCTRL -0.0635930 0.08653439 -0.23319729 0.1060113 0.4624083


$Gender_Male$`Pneumonia viral`
$Gender_Male$`Pneumonia viral`$ntab
            CTRL TRT
n_all         17  37
n_event        1   3
n_event_pct    6   8

$Gender_Male$`Pneumonia viral`$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.37837838 1.11690769  0.1544027 12.3050107 0.7738688
OR_TRTvsCTRL  1.41176471 1.19383629  0.1360088 14.6540482 0.7726956
ARR_TRTvsCTRL 0.02225755 0.07259729 -0.1200305  0.1645456 0.7591560


$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$ntab
            CTRL TRT
n_all         17  37
n_event        0   3
n_event_pct    0   8

$Gender_Male$Pyrexia$stats
                estimate         se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.31578947 1.48453459  0.180696116 60.8450259 0.41940405
OR_TRTvsCTRL  3.55072464 1.54007878  0.173539986 72.6498009 0.41063101
ARR_TRTvsCTRL 0.08108108 0.04487428 -0.006870893  0.1690331 0.07078572


$Gender_Male$`Respiratory arrest`
$Gender_Male$`Respiratory arrest`$ntab
            CTRL TRT
n_all         17  37
n_event        2   3
n_event_pct   12   8

$Gender_Male$`Respiratory arrest`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.68918919 0.86457086  0.1265944 3.7519972 0.6667969
OR_TRTvsCTRL   0.66176471 0.96406004  0.1000217 4.3783754 0.6684793
ARR_TRTvsCTRL -0.03656598 0.09011076 -0.2131798 0.1400479 0.6848975


$Gender_Male$`Respiratory distress`
```

```
$Gender_Male$`Respiratory distress`$ntab
            CTRL TRT
n_all         17  37
n_event        1  10
n_event_pct    6  27

$Gender_Male$`Respiratory distress`$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.5945946 1.00704987 0.63832932 33.0711732 0.12997371
OR_TRTvsCTRL  5.9259259 1.09523378 0.69261443 50.7015112 0.10424390
ARR_TRTvsCTRL 0.2114467 0.09266634 0.02982405  0.3930694 0.02250072


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$ntab
            CTRL TRT
n_all         17  37
n_event        7  11
n_event_pct   41  30

$Gender_Male$`Respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7220077 0.3845981  0.3397593 1.5343072 0.3970460
OR_TRTvsCTRL   0.6043956 0.6101047  0.1828097 1.9982204 0.4091949
ARR_TRTvsCTRL -0.1144674 0.1410467 -0.3909139 0.1619791 0.4170460


$Gender_Male$`Respiratory syncytial virus bronchiolitis`
$Gender_Male$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         17  37
n_event        1   1
n_event_pct    6   3

$Gender_Male$`Respiratory syncytial virus bronchiolitis`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 1.38352790  0.03052011 6.91684875 0.5740363
OR_TRTvsCTRL   0.4444444 1.44577930  0.02613171 7.55904710 0.5748692
ARR_TRTvsCTRL -0.0317965 0.06298717 -0.15524909 0.09165609 0.6136929


$Gender_Male$`Respiratory tract infection`
$Gender_Male$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         17  37
n_event        0   2
n_event_pct    0   5

$Gender_Male$`Respiratory tract infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.36842105 1.52254020  0.11980373 46.821732 0.5711858
OR_TRTvsCTRL  2.46478873 1.57648719  0.11216862 54.161169 0.5671692
ARR_TRTvsCTRL 0.05405405 0.03717461 -0.01880684  0.126915 0.1459301
```

```
$Gender_Male$`Rhinovirus infection`
$Gender_Male$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         17  37
n_event        0   5
n_event_pct    0  14

$Gender_Male$`Rhinovirus infection`$stats
                estimate         se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  5.2105263 1.44911933 0.30436099  89.2019205 0.25466460
OR_TRTvsCTRL  5.9230769 1.50656240 0.30914280 113.4842558 0.23770667
ARR_TRTvsCTRL 0.1351351 0.05620273 0.02497981   0.2452905 0.01619802


$Gender_Male$`Salivary hypersecretion`
$Gender_Male$`Salivary hypersecretion`$ntab
            CTRL TRT
n_all         17  37
n_event        1   0
n_event_pct    6   0

$Gender_Male$`Salivary hypersecretion`$stats
                  estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.15789474 1.60772987  0.006758736 3.68866994 0.2509293
OR_TRTvsCTRL   0.14666667 1.65949974  0.005672346 3.79227797 0.2473828
ARR_TRTvsCTRL -0.05882353 0.05706721 -0.170673198 0.05302614 0.3026457


$Gender_Male$`Upper respiratory tract infection`
$Gender_Male$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         17  37
n_event        0   2
n_event_pct    0   5

$Gender_Male$`Upper respiratory tract infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.36842105 1.52254020  0.11980373 46.821732 0.5711858
OR_TRTvsCTRL  2.46478873 1.57648719  0.11216862 54.161169 0.5671692
ARR_TRTvsCTRL 0.05405405 0.03717461 -0.01880684  0.126915 0.1459301


$Gender_Male$`Viral infection`
$Gender_Male$`Viral infection`$ntab
            CTRL TRT
n_all         17  37
n_event        0   2
n_event_pct    0   5

$Gender_Male$`Viral infection`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.36842105 1.52254020  0.11980373 46.821732 0.5711858
OR_TRTvsCTRL  2.46478873 1.57648719  0.11216862 54.161169 0.5671692
```

```
ARR_TRTvsCTRL 0.05405405 0.03717461 -0.01880684  0.126915 0.1459301


$Gender_Male$`Viral upper respiratory tract infection`
$Gender_Male$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         17  37
n_event        3   1
n_event_pct   18   3

$Gender_Male$`Viral upper respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.1531532 1.11690769  0.01715586 1.36722342 0.09297266
OR_TRTvsCTRL   0.1296296 1.19688750  0.01241400 1.35362001 0.08782408
ARR_TRTvsCTRL -0.1494436 0.09622612 -0.33804329 0.03915617 0.12041222


$Gender_Male$Vomiting
$Gender_Male$Vomiting$ntab
            CTRL TRT
n_all         17  37
n_event        1   1
n_event_pct    6   3

$Gender_Male$Vomiting$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4594595 1.38352790  0.03052011 6.91684875 0.5740363
OR_TRTvsCTRL   0.4444444 1.44577930  0.02613171 7.55904710 0.5748692
ARR_TRTvsCTRL -0.0317965 0.06298717 -0.15524909 0.09165609 0.6136929


$Gender_Male$`Weight gain poor`
$Gender_Male$`Weight gain poor`$ntab
            CTRL TRT
n_all         17  37
n_event        1   2
n_event_pct    6   5

$Gender_Male$`Weight gain poor`$stats
                   estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.918918919 1.1891802  0.08933985  9.4516836 0.9433137
OR_TRTvsCTRL   0.914285714 1.2613768  0.07716068 10.8334757 0.9433634
ARR_TRTvsCTRL -0.004769475 0.0681074 -0.13825752  0.1287186 0.9441708



$Gender_Female
$Gender_Female$`Acute respiratory failure`
$Gender_Female$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         24  43
n_event        6   6
n_event_pct   25  14
```

```
$Gender_Female$`Acute respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5581395 0.5180838  0.2021850 1.54076548 0.2603421
OR_TRTvsCTRL   0.4864865 0.6449154  0.1374415 1.72196291 0.2638779
ARR_TRTvsCTRL -0.1104651 0.1029792 -0.3123006 0.09137032 0.2834085


$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$ntab
            CTRL TRT
n_all         24  43
n_event        4  10
n_event_pct   17  23

$Gender_Female$Atelectasis$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39534884 0.53392651  0.4900086 3.9733961 0.5326592
OR_TRTvsCTRL  1.51515152 0.65597487  0.4188796 5.4805341 0.5264516
ARR_TRTvsCTRL 0.06589147 0.09968759 -0.1294926 0.2612756 0.5086253


$Gender_Female$`Bronchial secretion retention`
$Gender_Female$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         24  43
n_event        2   0
n_event_pct    8   0

$Gender_Female$`Bronchial secretion retention`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.11363636 1.52881416  0.005677908 2.27429239 0.1548786
OR_TRTvsCTRL   0.10344828 1.57080646  0.004760476 2.24799916 0.1486604
ARR_TRTvsCTRL -0.08333333 0.05641693 -0.193908491 0.02724182 0.1396494


$Gender_Female$`Cardio-respiratory arrest`
$Gender_Female$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         24  43
n_event        2   3
n_event_pct    8   7

$Gender_Female$`Cardio-respiratory arrest`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83720930 0.87659047  0.1502031 4.6664778 0.8393728
OR_TRTvsCTRL   0.82500000 0.95067759  0.1280076 5.3170676 0.8396412
ARR_TRTvsCTRL -0.01356589 0.06849943 -0.1478223 0.1206905 0.8430107


$Gender_Female$Dyspnoea
$Gender_Female$Dyspnoea$ntab
            CTRL TRT
n_all         24  43
n_event        1   3
```

```
n_event_pct    4   7

$Gender_Female$Dyspnoea$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.67441860 1.12623748  0.18416579 15.2236615 0.6471762
OR_TRTvsCTRL  1.72500000 1.18398125  0.16942693 17.5628812 0.6451551
ARR_TRTvsCTRL 0.02810078 0.05633005 -0.08230409  0.1385056 0.6178784


$Gender_Female$`Feeding disorder of infancy or early childhood`
$Gender_Female$`Feeding disorder of infancy or early childhood`$ntab
            CTRL TRT
n_all         24  43
n_event        2   2
n_event_pct    8   5

$Gender_Female$`Feeding disorder of infancy or early childhood`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.96699406  0.08387566 3.71406607 0.5464751
OR_TRTvsCTRL   0.53658537 1.03433302  0.07066640 4.07440958 0.5472635
ARR_TRTvsCTRL -0.03682171 0.06491707 -0.16405683 0.09041342 0.5705705


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$ntab
            CTRL TRT
n_all         24  43
n_event        2  14
n_event_pct    8  33

$Gender_Female$Pneumonia$stats
                estimate         se     lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  3.9069767 0.71169241 0.96838298 15.7628414 0.055515284
OR_TRTvsCTRL  5.3103448 0.80707241 1.09179586 25.8287866 0.038566560
ARR_TRTvsCTRL 0.2422481 0.09104581 0.06380156  0.4206946 0.007797209


$Gender_Female$`Pneumonia aspiration`
$Gender_Female$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         24  43
n_event        3   6
n_event_pct   12  14

$Gender_Female$`Pneumonia aspiration`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.11627907 0.65960406  0.3064198 4.0665749 0.8675525
OR_TRTvsCTRL  1.13513514 0.75805414  0.2569157 5.0153866 0.8672074
ARR_TRTvsCTRL 0.01453488 0.08572922 -0.1534913 0.1825611 0.8653687


$Gender_Female$`Pneumonia bacterial`
$Gender_Female$`Pneumonia bacterial`$ntab
            CTRL TRT
```

```
n_all         24  43
n_event        2   2
n_event_pct    8   5

$Gender_Female$`Pneumonia bacterial`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.96699406  0.08387566 3.71406607 0.5464751
OR_TRTvsCTRL   0.53658537 1.03433302  0.07066640 4.07440958 0.5472635
ARR_TRTvsCTRL -0.03682171 0.06491707 -0.16405683 0.09041342 0.5705705


$Gender_Female$`Pneumonia viral`
$Gender_Female$`Pneumonia viral`$ntab
            CTRL TRT
n_all         24  43
n_event        1   3
n_event_pct    4   7

$Gender_Female$`Pneumonia viral`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.67441860 1.12623748  0.18416579 15.2236615 0.6471762
OR_TRTvsCTRL  1.72500000 1.18398125  0.16942693 17.5628812 0.6451551
ARR_TRTvsCTRL 0.02810078 0.05633005 -0.08230409  0.1385056 0.6178784


$Gender_Female$`Respiratory arrest`
$Gender_Female$`Respiratory arrest`$ntab
            CTRL TRT
n_all         24  43
n_event        2   2
n_event_pct    8   5

$Gender_Female$`Respiratory arrest`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.96699406  0.08387566 3.71406607 0.5464751
OR_TRTvsCTRL   0.53658537 1.03433302  0.07066640 4.07440958 0.5472635
ARR_TRTvsCTRL -0.03682171 0.06491707 -0.16405683 0.09041342 0.5705705


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$ntab
            CTRL TRT
n_all         24  43
n_event        7  11
n_event_pct   29  26

$Gender_Female$`Respiratory distress`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.87707641 0.4109060  0.3919887 1.9624620 0.7495749
OR_TRTvsCTRL   0.83482143 0.5690692  0.2736535 2.5467492 0.7510536
ARR_TRTvsCTRL -0.03585271 0.1141731 -0.2596279 0.1879225 0.7535054


$Gender_Female$`Respiratory failure`
```

```
$Gender_Female$`Respiratory failure`$ntab
            CTRL TRT
n_all         24  43
n_event        9   9
n_event_pct   38  21

$Gender_Female$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.5581395 0.3966103  0.2565355 1.21433384 0.1414736
OR_TRTvsCTRL   0.4411765 0.5641814  0.1460092 1.33304381 0.1469363
ARR_TRTvsCTRL -0.1656977 0.1166805 -0.3943873 0.06299193 0.1555794


$Gender_Female$`Respiratory syncytial virus bronchiolitis`
$Gender_Female$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         24  43
n_event        2   3
n_event_pct    8   7

$Gender_Female$`Respiratory syncytial virus bronchiolitis`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83720930 0.87659047  0.1502031 4.6664778 0.8393728
OR_TRTvsCTRL   0.82500000 0.95067759  0.1280076 5.3170676 0.8396412
ARR_TRTvsCTRL -0.01356589 0.06849943 -0.1478223 0.1206905 0.8430107


$Gender_Female$`Respiratory tract infection`
$Gender_Female$`Respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        1   4
n_event_pct    4   9

$Gender_Female$`Respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.23255814 1.08861266  0.26434677 18.8552177 0.4606529
OR_TRTvsCTRL  2.35897436 1.14852918  0.24836672 22.4054172 0.4549187
ARR_TRTvsCTRL 0.05135659 0.06021515 -0.06666294  0.1693761 0.3937232


$Gender_Female$`Rhinovirus infection`
$Gender_Female$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         24  43
n_event        2   2
n_event_pct    8   5

$Gender_Female$`Rhinovirus infection`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.55813953 0.96699406  0.08387566 3.71406607 0.5464751
OR_TRTvsCTRL   0.53658537 1.03433302  0.07066640 4.07440958 0.5472635
ARR_TRTvsCTRL -0.03682171 0.06491707 -0.16405683 0.09041342 0.5705705
```

```
$Gender_Female$`Urinary tract infection`
$Gender_Female$`Urinary tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        0   3
n_event_pct    0   7

$Gender_Female$`Urinary tract infection`$stats
                 estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.97727273 1.49096848  0.214028053 73.9094626 0.3544601
OR_TRTvsCTRL  4.23456790 1.53336948  0.209702028 85.5097371 0.3465777
ARR_TRTvsCTRL 0.06976744 0.03884972 -0.006376618  0.1459115 0.0725218


$Gender_Female$`Viral infection`
$Gender_Female$`Viral infection`$ntab
            CTRL TRT
n_all         24  43
n_event        1   3
n_event_pct    4   7

$Gender_Female$`Viral infection`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.67441860 1.12623748  0.18416579 15.2236615 0.6471762
OR_TRTvsCTRL  1.72500000 1.18398125  0.16942693 17.5628812 0.6451551
ARR_TRTvsCTRL 0.02810078 0.05633005 -0.08230409  0.1385056 0.6178784


$Gender_Female$`Viral upper respiratory tract infection`
$Gender_Female$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         24  43
n_event        3   2
n_event_pct   12   5

$Gender_Female$`Viral upper respiratory tract infection`$stats
                  estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.37209302 0.87659047  0.06675693 2.07399014 0.2594079
OR_TRTvsCTRL   0.34146341 0.95149494  0.05289690 2.20423626 0.2587751
ARR_TRTvsCTRL -0.07848837 0.07475726 -0.22500990 0.06803316 0.2937596



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        7  11
n_event_pct   32  29

$Region_Northamerica$`Acute respiratory failure`$stats
                  estimate        se     lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.90977444 0.4024871  0.4133672 2.0023104 0.8142587
OR_TRTvsCTRL   0.87301587 0.5809216  0.2796023 2.7258599 0.8151642
ARR_TRTvsCTRL -0.02870813 0.1235864 -0.2709331 0.2135168 0.8163112


$Region_Northamerica$`Apparent life threatening event`
$Region_Northamerica$`Apparent life threatening event`$ntab
            CTRL TRT
n_all         22  38
n_event        2   0
n_event_pct    9   0

$Region_Northamerica$`Apparent life threatening event`$stats
                 estimate        se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.11794872 1.5267222  0.005917591 2.35093991 0.1614948
OR_TRTvsCTRL   0.10649351 1.5731352  0.004878294 2.32476083 0.1545336
ARR_TRTvsCTRL -0.09090909 0.0612909 -0.211037041 0.02921886 0.1380107


$Region_Northamerica$Aspiration
$Region_Northamerica$Aspiration$ntab
            CTRL TRT
n_all         22  38
n_event        1   3
n_event_pct    5   8

$Region_Northamerica$Aspiration$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.73684211 1.12319322  0.1921748 15.6972703 0.6230608
OR_TRTvsCTRL  1.80000000 1.18723368  0.1756699 18.4436828 0.6205371
ARR_TRTvsCTRL 0.03349282 0.06233575 -0.0886830  0.1556686 0.5910623


$Region_Northamerica$Atelectasis
$Region_Northamerica$Atelectasis$ntab
            CTRL TRT
n_all         22  38
n_event        1   6
n_event_pct    5  16

$Region_Northamerica$Atelectasis$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.4736842 1.04637294  0.44680299 27.0062695 0.2340344
OR_TRTvsCTRL  3.9375000 1.11603571  0.44182394 35.0906884 0.2194288
ARR_TRTvsCTRL 0.1124402 0.07396792 -0.03253427  0.2574147 0.1284806


$Region_Northamerica$`Bronchial secretion retention`
$Region_Northamerica$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all         22  38
n_event        3   0
n_event_pct   14   0
```

```
$Region_Northamerica$`Bronchial secretion retention`$stats
                 estimate       se       lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.08424908 1.488823  0.004552778 1.559028057 0.09657297
OR_TRTvsCTRL   0.07235622 1.537196  0.003556416 1.472106135 0.08756107
ARR_TRTvsCTRL -0.13636364 0.073165 -0.279764411 0.007037138 0.06235229


$Region_Northamerica$Bronchiolitis
$Region_Northamerica$Bronchiolitis$ntab
            CTRL TRT
n_all         22  38
n_event        1   3
n_event_pct    5   8

$Region_Northamerica$Bronchiolitis$stats
                estimate         se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.73684211 1.12319322  0.1921748 15.6972703 0.6230608
OR_TRTvsCTRL  1.80000000 1.18723368  0.1756699 18.4436828 0.6205371
ARR_TRTvsCTRL 0.03349282 0.06233575 -0.0886830  0.1556686 0.5910623


$Region_Northamerica$`Bronchitis viral`
$Region_Northamerica$`Bronchitis viral`$ntab
            CTRL TRT
n_all         22  38
n_event        0   2
n_event_pct    0   5

$Region_Northamerica$`Bronchitis viral`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.94871795 1.52672221  0.14793977 58.7734976 0.4787618
OR_TRTvsCTRL  3.08219178 1.57220918  0.14144669 67.1624512 0.4740152
ARR_TRTvsCTRL 0.05263158 0.03622354 -0.01836525  0.1236284 0.1462331


$Region_Northamerica$`Cardiac arrest`
$Region_Northamerica$`Cardiac arrest`$ntab
            CTRL TRT
n_all         22  38
n_event        2   1
n_event_pct    9   3

$Region_Northamerica$`Cardiac arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.2894737 1.19508563  0.02781957 3.01208915 0.2995849
OR_TRTvsCTRL   0.2702703 1.25579737  0.02306012 3.16763354 0.2974885
ARR_TRTvsCTRL -0.0645933 0.06656478 -0.19505788 0.06587128 0.3318559


$Region_Northamerica$`Cardio-respiratory arrest`
$Region_Northamerica$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         22  38
n_event        4   3
```

```
n_event_pct   18   8

$Region_Northamerica$`Cardio-respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.4342105 0.71523632  0.10687843 1.76404886 0.2434674
OR_TRTvsCTRL   0.3857143 0.81698245  0.07777661 1.91285673 0.2435863
ARR_TRTvsCTRL -0.1028708 0.09314171 -0.28542520 0.07968358 0.2693959


$Region_Northamerica$Dysphagia
$Region_Northamerica$Dysphagia$ntab
            CTRL TRT
n_all         22  38
n_event        0   2
n_event_pct    0   5

$Region_Northamerica$Dysphagia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.94871795 1.52672221  0.14793977 58.7734976 0.4787618
OR_TRTvsCTRL  3.08219178 1.57220918  0.14144669 67.1624512 0.4740152
ARR_TRTvsCTRL 0.05263158 0.03622354 -0.01836525  0.1236284 0.1462331


$Region_Northamerica$Hypoxia
$Region_Northamerica$Hypoxia$ntab
            CTRL TRT
n_all         22  38
n_event        1   4
n_event_pct    5  11

$Region_Northamerica$Hypoxia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.31578947 1.08546288  0.27589981 19.4377841 0.4391474
OR_TRTvsCTRL  2.47058824 1.15196823  0.25837068 23.6242216 0.4323715
ARR_TRTvsCTRL 0.05980861 0.06671354 -0.07094753  0.1905648 0.3699864


$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$ntab
            CTRL TRT
n_all         22  38
n_event        3   8
n_event_pct   14  21

$Region_Northamerica$Pneumonia$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.54385965 0.62174191  0.4564363 5.2219834 0.4848657
OR_TRTvsCTRL  1.68888889 0.73776571  0.3977533 7.1711431 0.4774880
ARR_TRTvsCTRL 0.07416268 0.09862522 -0.1191392 0.2674646 0.4520723


$Region_Northamerica$`Pneumonia aspiration`
$Region_Northamerica$`Pneumonia aspiration`$ntab
            CTRL TRT
```

```
n_all         22  38
n_event        3   5
n_event_pct   14  13

$Region_Northamerica$`Pneumonia aspiration`$stats
                  estimate         se     lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.964912281 0.67938428  0.2547973 3.654103 0.9580712
OR_TRTvsCTRL   0.959595960 0.78502735  0.2060022 4.469973 0.9581008
ARR_TRTvsCTRL -0.004784689 0.09143367 -0.1839914 0.174422 0.9582661


$Region_Northamerica$`Pneumonia bacterial`
$Region_Northamerica$`Pneumonia bacterial`$ntab
            CTRL TRT
n_all         22  38
n_event        2   3
n_event_pct    9   8

$Region_Northamerica$`Pneumonia bacterial`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.86842105 0.87267577  0.1570028 4.8034503 0.8715720
OR_TRTvsCTRL   0.85714286 0.95493705  0.1318892 5.5705374 0.8717587
ARR_TRTvsCTRL -0.01196172 0.07530019 -0.1595474 0.1356239 0.8737840


$Region_Northamerica$`Pneumonia viral`
$Region_Northamerica$`Pneumonia viral`$ntab
            CTRL TRT
n_all         22  38
n_event        2   5
n_event_pct    9  13

$Region_Northamerica$`Pneumonia viral`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.44736842 0.79260940  0.3061320 6.8430457 0.6408624
OR_TRTvsCTRL  1.51515152 0.88334763  0.2682558 8.5578157 0.6380784
ARR_TRTvsCTRL 0.04066986 0.08224094 -0.1205194 0.2018591 0.6209384


$Region_Northamerica$`Respiratory arrest`
$Region_Northamerica$`Respiratory arrest`$ntab
            CTRL TRT
n_all         22  38
n_event        4   1
n_event_pct   18   3

$Region_Northamerica$`Respiratory arrest`$stats
                estimate       se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.1447368 1.085463  0.01724374 1.21486151 0.07496835
OR_TRTvsCTRL   0.1216216 1.154375  0.01265915 1.16846826 0.06798725
ARR_TRTvsCTRL -0.1555024 0.086233 -0.32451596 0.01351118 0.07134397


$Region_Northamerica$`Respiratory distress`
```

```
$Region_Northamerica$`Respiratory distress`$ntab
            CTRL TRT
n_all         22  38
n_event        6  12
n_event_pct   27  32

$Region_Northamerica$`Respiratory distress`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.1578947 0.4221726  0.5061919 2.6486405 0.7283963
OR_TRTvsCTRL  1.2307692 0.5924201  0.3853965 3.9304792 0.7259684
ARR_TRTvsCTRL 0.0430622 0.1212507 -0.1945848 0.2807092 0.7224772


$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        7  11
n_event_pct   32  29

$Region_Northamerica$`Respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90977444 0.4024871  0.4133672 2.0023104 0.8142587
OR_TRTvsCTRL   0.87301587 0.5809216  0.2796023 2.7258599 0.8151642
ARR_TRTvsCTRL -0.02870813 0.1235864 -0.2709331 0.2135168 0.8163112


$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`
$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all         22  38
n_event        3   3
n_event_pct   14   8

$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`$stats
                 estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.57894737 0.77129523  0.12767663 2.6252265 0.4785696
OR_TRTvsCTRL   0.54285714 0.86479458  0.09967152 2.9566509 0.4799263
ARR_TRTvsCTRL -0.05741627 0.08524472 -0.22449285 0.1096603 0.5005998


$Region_Northamerica$`Rhinovirus infection`
$Region_Northamerica$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         22  38
n_event        1   4
n_event_pct    5  11

$Region_Northamerica$`Rhinovirus infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.31578947 1.08546288  0.27589981 19.4377841 0.4391474
OR_TRTvsCTRL  2.47058824 1.15196823  0.25837068 23.6242216 0.4323715
ARR_TRTvsCTRL 0.05980861 0.06671354 -0.07094753  0.1905648 0.3699864
```

```
$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        0   4
n_event_pct    0  11

$Region_Northamerica$`Upper respiratory tract infection`$stats
               estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  5.3076923 1.46734554 0.299156849  94.169991 0.25531463
OR_TRTvsCTRL  5.8695652 1.51514097 0.301242051 114.365825 0.24278123
ARR_TRTvsCTRL 0.1052632 0.04978449 0.007687351   0.202839 0.03448312


$Region_Northamerica$`Viral upper respiratory tract infection`
$Region_Northamerica$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         22  38
n_event        6   3
n_event_pct   27   8

$Region_Northamerica$`Viral upper respiratory tract infection`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.2894737 0.6543926  0.08027662 1.04382831 0.05817000
OR_TRTvsCTRL   0.2285714 0.7688117  0.05065336 1.03142023 0.05489273
ARR_TRTvsCTRL -0.1937799 0.1045434 -0.39868120 0.01112139 0.06379879



$Disdur_greater_12wk
$Disdur_greater_12wk$`Acute respiratory failure`
$Disdur_greater_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         23  46
n_event        5   7
n_event_pct   22  15

$Disdur_greater_12wk$`Acute respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.70000000 0.5269153  0.2492223 1.9661162 0.4984622
OR_TRTvsCTRL   0.64615385 0.6511941  0.1803178 2.3154390 0.5024491
ARR_TRTvsCTRL -0.06521739 0.1010038 -0.2631813 0.1327465 0.5184787


$Disdur_greater_12wk$`Apparent life threatening event`
$Disdur_greater_12wk$`Apparent life threatening event`$ntab
            CTRL TRT
n_all         23  46
n_event        2   0
n_event_pct    9   0

$Disdur_greater_12wk$`Apparent life threatening event`$stats
                estimate         se       lo95ci   hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.10212766 1.52874352  0.005103575 2.043677 0.1355883
OR_TRTvsCTRL   0.09247312 1.57099236  0.004253872 2.010234 0.1296461
ARR_TRTvsCTRL -0.08695652 0.05875338 -0.202111040 0.028198 0.1388664


$Disdur_greater_12wk$Atelectasis
$Disdur_greater_12wk$Atelectasis$ntab
            CTRL TRT
n_all         23  46
n_event        3   6
n_event_pct   13  13

$Disdur_greater_12wk$Atelectasis$stats
              estimate         se     lo95ci   hi95ci pvalue
RR_TRTvsCTRL         1 0.65938047  0.2746214 3.641377      1
OR_TRTvsCTRL         1 0.75828754  0.2262270 4.420339      1
ARR_TRTvsCTRL        0 0.08600615 -0.1685690 0.168569      1


$Disdur_greater_12wk$Bronchiolitis
$Disdur_greater_12wk$Bronchiolitis$ntab
            CTRL TRT
n_all         23  46
n_event        1   3
n_event_pct    4   7

$Disdur_greater_12wk$Bronchiolitis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.50000000 1.12610654  0.16502420 13.6343640 0.7188028
OR_TRTvsCTRL  1.53488372 1.18407926  0.15072503 15.6302373 0.7174669
ARR_TRTvsCTRL 0.02173913 0.05597746 -0.08797467  0.1314529 0.6977533


$Disdur_greater_12wk$`Cardio-respiratory arrest`
$Disdur_greater_12wk$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all         23  46
n_event        2   4
n_event_pct    9   9

$Disdur_greater_12wk$`Cardio-respiratory arrest`$stats
              estimate         se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.82751593  0.1975228 5.0627075      1
OR_TRTvsCTRL         1 0.90632697  0.1692517 5.9083595      1
ARR_TRTvsCTRL        0 0.07195791 -0.1410349 0.1410349      1


$Disdur_greater_12wk$Dyspnoea
$Disdur_greater_12wk$Dyspnoea$ntab
            CTRL TRT
n_all         23  46
n_event        0   4
n_event_pct    0   9
```

```
$Disdur_greater_12wk$Dyspnoea$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.59574468 1.46944852 0.257963965 81.8752696 0.29931972
OR_TRTvsCTRL  4.97647059 1.51271439 0.256623615 96.5042111 0.28877074
ARR_TRTvsCTRL 0.08695652 0.04154492 0.005529981  0.1683831 0.03634269


$Disdur_greater_12wk$Hypoxia
$Disdur_greater_12wk$Hypoxia$ntab
            CTRL TRT
n_all         23  46
n_event        0   3
n_event_pct    0   7

$Disdur_greater_12wk$Hypoxia$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.57446809 1.49089605  0.192379330 66.4147344 0.3928853
OR_TRTvsCTRL  3.78160920 1.53338057  0.187266777 76.3646834 0.3856888
ARR_TRTvsCTRL 0.06521739 0.03640475 -0.006134617  0.1365694 0.0732207


$Disdur_greater_12wk$`Lower respiratory tract infection`
$Disdur_greater_12wk$`Lower respiratory tract infection`$ntab
            CTRL TRT
n_all         23  46
n_event        0   4
n_event_pct    0   9

$Disdur_greater_12wk$`Lower respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.59574468 1.46944852 0.257963965 81.8752696 0.29931972
OR_TRTvsCTRL  4.97647059 1.51271439 0.256623615 96.5042111 0.28877074
ARR_TRTvsCTRL 0.08695652 0.04154492 0.005529981  0.1683831 0.03634269


$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$ntab
            CTRL TRT
n_all         23  46
n_event        3  11
n_event_pct   13  24

$Disdur_greater_12wk$Pneumonia$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.8333333 0.59918698  0.56651649 5.9329449 0.3117307
OR_TRTvsCTRL  2.0952381 0.70909368  0.52197745 8.4103684 0.2968944
ARR_TRTvsCTRL 0.1086957 0.09426952 -0.07606922 0.2934605 0.2488978


$Disdur_greater_12wk$`Pneumonia aspiration`
$Disdur_greater_12wk$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all         23  46
n_event        2   4
```

```
n_event_pct    9   9

$Disdur_greater_12wk$`Pneumonia aspiration`$stats
              estimate         se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.82751593  0.1975228 5.0627075      1
OR_TRTvsCTRL         1 0.90632697  0.1692517 5.9083595      1
ARR_TRTvsCTRL        0 0.07195791 -0.1410349 0.1410349      1


$Disdur_greater_12wk$`Pneumonia viral`
$Disdur_greater_12wk$`Pneumonia viral`$ntab
            CTRL TRT
n_all         23  46
n_event        2   5
n_event_pct    9  11

$Disdur_greater_12wk$`Pneumonia viral`$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.25000000 0.79673246  0.2622588 5.9578547 0.7794212
OR_TRTvsCTRL  1.28048780 0.87864059  0.2288101 7.1659814 0.7784109
ARR_TRTvsCTRL 0.02173913 0.07455244 -0.1243810 0.1678592 0.7705962


$Disdur_greater_12wk$`Respiratory arrest`
$Disdur_greater_12wk$`Respiratory arrest`$ntab
            CTRL TRT
n_all         23  46
n_event        1   3
n_event_pct    4   7

$Disdur_greater_12wk$`Respiratory arrest`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.50000000 1.12610654  0.16502420 13.6343640 0.7188028
OR_TRTvsCTRL  1.53488372 1.18407926  0.15072503 15.6302373 0.7174669
ARR_TRTvsCTRL 0.02173913 0.05597746 -0.08797467  0.1314529 0.6977533


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         23  46
n_event        5  13
n_event_pct   22  28

$Disdur_greater_12wk$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.30000000 0.4601149  0.5275855 3.2032721 0.5685321
OR_TRTvsCTRL  1.41818182 0.6023136  0.4355536 4.6176623 0.5618768
ARR_TRTvsCTRL 0.06521739 0.1086484 -0.1477295 0.2781643 0.5483323


$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$ntab
            CTRL TRT
```

```
n_all         23  46
n_event        9  11
n_event_pct   39  24

$Disdur_greater_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL   0.6111111 0.3698686  0.2959971 1.26169080 0.1830278
OR_TRTvsCTRL   0.4888889 0.5495636  0.1665025 1.43548808 0.1928615
ARR_TRTvsCTRL -0.1521739 0.1196296 -0.3866437 0.08229588 0.2033583


$Disdur_greater_12wk$`Rhinovirus infection`
$Disdur_greater_12wk$`Rhinovirus infection`$ntab
            CTRL TRT
n_all         23  46
n_event        1   5
n_event_pct    4  11

$Disdur_greater_12wk$`Rhinovirus infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.50000000 1.06526176  0.30987573 20.1693759 0.3897033
OR_TRTvsCTRL  2.68292683 1.12687390  0.29472164 24.4233724 0.3811426
ARR_TRTvsCTRL 0.06521739 0.06256418 -0.05740614  0.1878409 0.2972226


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all         23  46
n_event        0   3
n_event_pct    0   7

$Disdur_greater_12wk$`Upper respiratory tract infection`$stats
                estimate         se       lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.57446809 1.49089605  0.192379330 66.4147344 0.3928853
OR_TRTvsCTRL  3.78160920 1.53338057  0.187266777 76.3646834 0.3856888
ARR_TRTvsCTRL 0.06521739 0.03640475 -0.006134617  0.1365694 0.0732207


$Disdur_greater_12wk$`Viral upper respiratory tract infection`
$Disdur_greater_12wk$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all         23  46
n_event        4   1
n_event_pct   17   2

$Disdur_greater_12wk$`Viral upper respiratory tract infection`$stats
                estimate         se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.1250000 1.08847720  0.01480460 1.055415536 0.05607999
OR_TRTvsCTRL   0.1055556 1.15102294  0.01105932 1.007473418 0.05076094
ARR_TRTvsCTRL -0.1521739 0.08190678 -0.31270825 0.008360422 0.06318441
```

```
$Region_Asia_Pacific
$Region_Asia_Pacific$Atelectasis
$Region_Asia_Pacific$Atelectasis$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$Atelectasis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$Dyspnoea
$Region_Asia_Pacific$Dyspnoea$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17

$Region_Asia_Pacific$Dyspnoea$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353


$Region_Asia_Pacific$`Failure to thrive`
$Region_Asia_Pacific$`Failure to thrive`$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$`Failure to thrive`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$`Lower respiratory tract infection`
$Region_Asia_Pacific$`Lower respiratory tract infection`$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$`Lower respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
```

```
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$`Lung infection`
$Region_Asia_Pacific$`Lung infection`$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$`Lung infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$Nasopharyngitis
$Region_Asia_Pacific$Nasopharyngitis$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$Nasopharyngitis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$Pneumonia
$Region_Asia_Pacific$Pneumonia$ntab
            CTRL TRT
n_all          2  12
n_event        0   5
n_event_pct    0  42

$Region_Asia_Pacific$Pneumonia$stats
                estimate        se    lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  2.5384615 1.3310003 0.1869051 34.4762553 0.483993933
OR_TRTvsCTRL  3.6666667 1.6477717 0.1451061 92.6525185 0.430398971
ARR_TRTvsCTRL 0.4166667 0.1423188 0.1377270  0.6956063 0.003414791


$Region_Asia_Pacific$`Pneumonia parainfluenzae viral`
$Region_Asia_Pacific$`Pneumonia parainfluenzae viral`$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$`Pneumonia parainfluenzae viral`$stats
                estimate         se      lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$`Respiratory distress`
$Region_Asia_Pacific$`Respiratory distress`$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$`Respiratory distress`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$`Respiratory failure`
$Region_Asia_Pacific$`Respiratory failure`$ntab
            CTRL TRT
n_all          2  12
n_event        1   0
n_event_pct   50   0

$Region_Asia_Pacific$`Respiratory failure`$stats
                 estimate        se       lo95ci    hi95ci     pvalue
RR_TRTvsCTRL   0.07692308 1.5021352  0.004049830 1.4610883 0.08772255
OR_TRTvsCTRL   0.04000000 1.8475209  0.001070157 1.4951081 0.08146162
ARR_TRTvsCTRL -0.50000000 0.3535534 -1.192951912 0.1929519 0.15729921


$Region_Asia_Pacific$`Sinus tachycardia`
$Region_Asia_Pacific$`Sinus tachycardia`$ntab
            CTRL TRT
n_all          2  12
n_event        0   1
n_event_pct    0   8

$Region_Asia_Pacific$`Sinus tachycardia`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  0.69230769 1.50213523  0.03644847 13.1497951 0.8066102
OR_TRTvsCTRL  0.65217391 1.77584436  0.02007992 21.1818985 0.8097884
ARR_TRTvsCTRL 0.08333333 0.07978559 -0.07304355  0.2397102 0.2962699


$Region_Asia_Pacific$`Urinary tract infection`
$Region_Asia_Pacific$`Urinary tract infection`$ntab
            CTRL TRT
n_all          2  12
n_event        0   2
n_event_pct    0  17
```

```
$Region_Asia_Pacific$`Urinary tract infection`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1538462 1.4105827  0.07268716 18.3163144 0.9191948
OR_TRTvsCTRL  1.1904762 1.7015399  0.04240014 33.4252080 0.9183852
ARR_TRTvsCTRL 0.1666667 0.1075829 -0.04419189  0.3775252 0.1213353



\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem SUE nach PT, das bei mindestens 10 Patienten
und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event        7  10
n_event_pct   22  14

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats
                 estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.63492063 0.44465521  0.2656001 1.5177863 0.3069750
OR_TRTvsCTRL   0.57603687 0.54679628  0.1972497 1.6822251 0.3130920
ARR_TRTvsCTRL -0.07986111 0.08367598 -0.2438630 0.0841408 0.3398767


$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$ntab
            CTRL TRT
n_all         32  72
n_event        4  14
n_event_pct   12  19

$Ageonset_less_equal_12wk$Atelectasis$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.55555556 0.52563265  0.55522141 4.3581768 0.4005870
OR_TRTvsCTRL  1.68965517 0.61186946  0.50930021 5.6056027 0.3913073
ARR_TRTvsCTRL 0.06944444 0.07478948 -0.07714024 0.2160291 0.3531315


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$ntab
            CTRL TRT
n_all         32  72
n_event        4  18
n_event_pct   12  25

$Ageonset_less_equal_12wk$Pneumonia$stats
              estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  2.000000 0.51031036  0.73561915 5.4375963 0.1743731
OR_TRTvsCTRL  2.333333 0.59982361  0.72012188 7.5604486 0.1577797
```

```
ARR_TRTvsCTRL 0.125000 0.07760242 -0.02709795 0.2770979 0.1072289


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         32  72
n_event        6  20
n_event_pct   19  28

$Ageonset_less_equal_12wk$`Respiratory distress`$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.48148148 0.41415912  0.65790524 3.3360236 0.3426138
OR_TRTvsCTRL  1.66666667 0.52379287  0.59702903 4.6526679 0.3294395
ARR_TRTvsCTRL 0.09027778 0.08687401 -0.07999215 0.2605477 0.2987208


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         32  72
n_event       15  18
n_event_pct   47  25

$Ageonset_less_equal_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.5333333 0.2776389  0.3095082  0.91902082 0.02356652
OR_TRTvsCTRL   0.3777778 0.4467262  0.1573919  0.90675595 0.02932621
ARR_TRTvsCTRL -0.2187500 0.1019125 -0.4184947 -0.01900525 0.03183709



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        7  11
n_event_pct   32  29

$Region_Northamerica$`Acute respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90977444 0.4024871  0.4133672 2.0023104 0.8142587
OR_TRTvsCTRL   0.87301587 0.5809216  0.2796023 2.7258599 0.8151642
ARR_TRTvsCTRL -0.02870813 0.1235864 -0.2709331 0.2135168 0.8163112


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$ntab
            CTRL TRT
n_all         22  38
n_event        6  12
n_event_pct   27  32
```

```
$Region_Northamerica$`Respiratory distress`$stats
               estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.1578947 0.4221726  0.5061919 2.6486405 0.7283963
OR_TRTvsCTRL  1.2307692 0.5924201  0.3853965 3.9304792 0.7259684
ARR_TRTvsCTRL 0.0430622 0.1212507 -0.1945848 0.2807092 0.7224772


$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$ntab
            CTRL TRT
n_all         22  38
n_event        7  11
n_event_pct   32  29

$Region_Northamerica$`Respiratory failure`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.90977444 0.4024871  0.4133672 2.0023104 0.8142587
OR_TRTvsCTRL   0.87301587 0.5809216  0.2796023 2.7258599 0.8151642
ARR_TRTvsCTRL -0.02870813 0.1235864 -0.2709331 0.2135168 0.8163112



$Agetrt_less_180d
$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$ntab
            CTRL TRT
n_all         16  49
n_event        2  10
n_event_pct   12  20

$Agetrt_less_180d$Atelectasis$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.63265306 0.7190910  0.3988435 6.6832123 0.4954269
OR_TRTvsCTRL  1.79487179 0.8349069  0.3494293 9.2195030 0.4835543
ARR_TRTvsCTRL 0.07908163 0.1007516 -0.1183879 0.2765511 0.4325023


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$ntab
            CTRL TRT
n_all         16  49
n_event        2  14
n_event_pct   12  29

$Agetrt_less_180d$Pneumonia$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2857143 0.6989423  0.58087293  8.9942043 0.2369057
OR_TRTvsCTRL  2.8000000 0.8194075  0.56192343 13.9520787 0.2089197
ARR_TRTvsCTRL 0.1607143 0.1048850 -0.04485659  0.3662852 0.1254509


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$ntab
            CTRL TRT
```

```
n_all         16  49
n_event        2  14
n_event_pct   12  29

$Agetrt_less_180d$`Respiratory distress`$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.2857143 0.6989423  0.58087293  8.9942043 0.2369057
OR_TRTvsCTRL  2.8000000 0.8194075  0.56192343 13.9520787 0.2089197
ARR_TRTvsCTRL 0.1607143 0.1048850 -0.04485659  0.3662852 0.1254509


$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$ntab
            CTRL TRT
n_all         16  49
n_event        9  12
n_event_pct   56  24

$Agetrt_less_180d$`Respiratory failure`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.4353741 0.3339705  0.22624889  0.83779705 0.01277829
OR_TRTvsCTRL   0.2522523 0.6035964  0.07727746  0.82341209 0.02249729
ARR_TRTvsCTRL -0.3176020 0.1384009 -0.58886274 -0.04634135 0.02174469



$Gender_Female
$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$ntab
            CTRL TRT
n_all         24  43
n_event        4  10
n_event_pct   17  23

$Gender_Female$Atelectasis$stats
                estimate         se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.39534884 0.53392651  0.4900086 3.9733961 0.5326592
OR_TRTvsCTRL  1.51515152 0.65597487  0.4188796 5.4805341 0.5264516
ARR_TRTvsCTRL 0.06589147 0.09968759 -0.1294926 0.2612756 0.5086253


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$ntab
            CTRL TRT
n_all         24  43
n_event        2  14
n_event_pct    8  33

$Gender_Female$Pneumonia$stats
               estimate         se     lo95ci     hi95ci      pvalue
RR_TRTvsCTRL  3.9069767 0.71169241 0.96838298 15.7628414 0.055515284
OR_TRTvsCTRL  5.3103448 0.80707241 1.09179586 25.8287866 0.038566560
ARR_TRTvsCTRL 0.2422481 0.09104581 0.06380156  0.4206946 0.007797209
```

```
$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$ntab
            CTRL TRT
n_all         24  43
n_event        7  11
n_event_pct   29  26

$Gender_Female$`Respiratory distress`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.87707641 0.4109060  0.3919887 1.9624620 0.7495749
OR_TRTvsCTRL   0.83482143 0.5690692  0.2736535 2.5467492 0.7510536
ARR_TRTvsCTRL -0.03585271 0.1141731 -0.2596279 0.1879225 0.7535054



$Disdur_greater_12wk
$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$ntab
            CTRL TRT
n_all         23  46
n_event        3  11
n_event_pct   13  24

$Disdur_greater_12wk$Pneumonia$stats
                estimate         se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.8333333 0.59918698  0.56651649 5.9329449 0.3117307
OR_TRTvsCTRL  2.0952381 0.70909368  0.52197745 8.4103684 0.2968944
ARR_TRTvsCTRL 0.1086957 0.09426952 -0.07606922 0.2934605 0.2488978


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$ntab
            CTRL TRT
n_all         23  46
n_event        5  13
n_event_pct   22  28

$Disdur_greater_12wk$`Respiratory distress`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.30000000 0.4601149  0.5275855 3.2032721 0.5685321
OR_TRTvsCTRL  1.41818182 0.6023136  0.4355536 4.6176623 0.5618768
ARR_TRTvsCTRL 0.06521739 0.1086484 -0.1477295 0.2781643 0.5483323


$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$ntab
            CTRL TRT
n_all         23  46
n_event        9  11
n_event_pct   39  24

$Disdur_greater_12wk$`Respiratory failure`$stats
                estimate        se     lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.6111111 0.3698686  0.2959971 1.26169080 0.1830278
OR_TRTvsCTRL   0.4888889 0.5495636  0.1665025 1.43548808 0.1928615
ARR_TRTvsCTRL -0.1521739 0.1196296 -0.3866437 0.08229588 0.2033583



$Gender_Male
$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$ntab
            CTRL TRT
n_all         17  37
n_event        1  10
n_event_pct    6  27

$Gender_Male$`Respiratory distress`$stats
               estimate         se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  4.5945946 1.00704987 0.63832932 33.0711732 0.12997371
OR_TRTvsCTRL  5.9259259 1.09523378 0.69261443 50.7015112 0.10424390
ARR_TRTvsCTRL 0.2114467 0.09266634 0.02982405  0.3930694 0.02250072


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$ntab
            CTRL TRT
n_all         17  37
n_event        7  11
n_event_pct   41  30

$Gender_Male$`Respiratory failure`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.7220077 0.3845981  0.3397593 1.5343072 0.3970460
OR_TRTvsCTRL   0.6043956 0.6101047  0.1828097 1.9982204 0.4091949
ARR_TRTvsCTRL -0.1144674 0.1410467 -0.3909139 0.1619791 0.4170460




\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines SUEs nach PT, das bei mindestens 5% der
Patienten in einem Studienarm auftrat"

$Agetrt_less_180d
$Agetrt_less_180d$`Acute respiratory distress syndrome`
$Agetrt_less_180d$`Acute respiratory distress syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                49
n_event                                 1                 0
n_event_pct                             6                 0
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
```

```
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Acute respiratory distress syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.753e-11 4.354e+04 0.000e+00       Inf 9.996e-01


$Agetrt_less_180d$`Acute respiratory failure`
$Agetrt_less_180d$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               3.0                  7
n_event_pct                          19.0                 14
time-to-event-wk-10th                 8.6                 13
time-to-event-wk-25th                22.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5693    0.6953    0.1457    2.2240    0.4178


$Agetrt_less_180d$Agitation
$Agetrt_less_180d$Agitation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                 49
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Agitation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.637e-10 4.413e+04 0.000e+00       Inf 9.996e-01


$Agetrt_less_180d$Apnoea
$Agetrt_less_180d$Apnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  2
n_event_pct                          12.0                  4
time-to-event-wk-10th                 6.3                 NA
time-to-event-wk-25th                  NA                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Apnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29180   1.00900   0.04037   2.11000   0.22240


$Agetrt_less_180d$Aspiration
$Agetrt_less_180d$Aspiration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               1.0                 3
n_event_pct                           6.0                 6
time-to-event-wk-10th                40.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.3                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.81040   1.16600   0.08241   7.97100   0.85700


$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0               10.0
n_event_pct                          12.0               20.0
time-to-event-wk-10th                17.6               14.4
time-to-event-wk-25th                32.9               44.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2360    0.7855    0.2650    5.7620    0.7876


$Agetrt_less_180d$`Body temperature increased`
$Agetrt_less_180d$`Body temperature increased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               1.0                 0
```

```
n_event_pct                             6.0                  0
time-to-event-wk-10th                  47.1                 NA
time-to-event-wk-25th                  47.1                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci             47.1                 NA
time-to-event-wk-50th-hici               NA                 NA

$Agetrt_less_180d$`Body temperature increased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.920e-11 4.048e+04 0.000e+00       Inf 9.995e-01


$Agetrt_less_180d$`Bronchial secretion retention`
$Agetrt_less_180d$`Bronchial secretion retention`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                 49
n_event                              3.0                  1
n_event_pct                         19.0                  2
time-to-event-wk-10th                6.1                 NA
time-to-event-wk-25th               40.7                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          40.7                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.073250  1.215000  0.006768  0.792800  0.031480


$Agetrt_less_180d$Bronchiolitis
$Agetrt_less_180d$Bronchiolitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                16                 49
n_event                               0                  3
n_event_pct                           0                  6
time-to-event-wk-10th                NA                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Agetrt_less_180d$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.007e+08 2.253e+04 0.000e+00       Inf 9.993e-01


$Agetrt_less_180d$Bronchitis
$Agetrt_less_180d$Bronchitis$stats_num
```

```
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 16                 49
n_event                                0                  4
n_event_pct                            0                  8
time-to-event-wk-10th                 NA                 40
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$Bronchitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.896e+08 1.539e+04 0.000e+00       Inf 9.990e-01


$Agetrt_less_180d$`Bronchitis viral`
$Agetrt_less_180d$`Bronchitis viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 16                 49
n_event                                0                  3
n_event_pct                            0                  6
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$`Bronchitis viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.893e+08 1.747e+04 0.000e+00       Inf 9.991e-01


$Agetrt_less_180d$`Cardiac arrest`
$Agetrt_less_180d$`Cardiac arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 16                 49
n_event                                1                  1
n_event_pct                            6                  2
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$`Cardiac arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29550   1.42800   0.01801   4.84900   0.39310
```

```
$Agetrt_less_180d$`Cardio-respiratory arrest`
$Agetrt_less_180d$`Cardio-respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49
n_event                              2.0                 1
n_event_pct                         12.0                 2
time-to-event-wk-10th               14.3                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.115400  1.256000  0.009854  1.352000  0.085530


$Agetrt_less_180d$`Corona virus infection`
$Agetrt_less_180d$`Corona virus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                16                49
n_event                               1                 0
n_event_pct                           6                 0
time-to-event-wk-10th                34                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            34                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$`Corona virus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.651e-10 1.441e+05 0.000e+00       Inf 9.999e-01


$Agetrt_less_180d$Cyanosis
$Agetrt_less_180d$Cyanosis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                16                49
n_event                               1                 1
n_event_pct                           6                 2
time-to-event-wk-10th                NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Agetrt_less_180d$Cyanosis$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.182000  1.548000  0.008764  3.778000  0.270900


$Agetrt_less_180d$Death
$Agetrt_less_180d$Death$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                 49
n_event                                 1                  1
n_event_pct                             6                  2
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Death$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.2854    1.4300    0.0173    4.7070    0.3806


$Agetrt_less_180d$Dehydration
$Agetrt_less_180d$Dehydration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                 49
n_event                                 1                  1
n_event_pct                             6                  2
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Dehydration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.148300  1.647000  0.005878  3.743000  0.246600


$Agetrt_less_180d$Dysphagia
$Agetrt_less_180d$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                 49
n_event                                 1                  2
n_event_pct                             6                  4
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.46240   1.23500   0.04106   5.20700   0.53240


$Agetrt_less_180d$Dyspnoea
$Agetrt_less_180d$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  1
n_event_pct                          12.0                  2
time-to-event-wk-10th                24.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.12070   1.23900   0.01065   1.36800   0.08781


$Agetrt_less_180d$`Failure to thrive`
$Agetrt_less_180d$`Failure to thrive`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16                 49
n_event                               1                  1
n_event_pct                           6                  2
time-to-event-wk-10th                NA                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Agetrt_less_180d$`Failure to thrive`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26770   1.43300   0.01613   4.44400   0.35790


$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`
$Agetrt_less_180d$`Feeding disorder of infancy or early childhood`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16                 49
n_event                               1                  2
n_event_pct                           6                  4
time-to-event-wk-10th                NA                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.67580   1.23100   0.06051   7.54800   0.75030


$Agetrt_less_180d$`Gastrointestinal haemorrhage`
$Agetrt_less_180d$`Gastrointestinal haemorrhage`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               1.0                 0
n_event_pct                           6.0                 0
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.3                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Gastrointestinal haemorrhage`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.292e-10 3.500e+04 0.000e+00       Inf 9.995e-01


$Agetrt_less_180d$`Heart rate decreased`
$Agetrt_less_180d$`Heart rate decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               1.0                 0
n_event_pct                           6.0                 0
time-to-event-wk-10th                49.6                NA
time-to-event-wk-25th                49.6                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           49.6                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Heart rate decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.074e-11 5.821e+04 0.000e+00       Inf 9.997e-01


$Agetrt_less_180d$Hypoxia
$Agetrt_less_180d$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                49
n_event                                 1                 2
```

```
n_event_pct                               6                  4
time-to-event-wk-10th                    NA                 NA
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               NA                 NA
time-to-event-wk-50th-hici               NA                 NA

$Agetrt_less_180d$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39520   1.27700   0.03232   4.83300   0.46740


$Agetrt_less_180d$`Lung disorder`
$Agetrt_less_180d$`Lung disorder`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               1.0                  1
n_event_pct                           6.0                  2
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Lung disorder`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26480   1.43600   0.01588   4.41500   0.35460


$Agetrt_less_180d$`Oxygen saturation decreased`
$Agetrt_less_180d$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  1
n_event_pct                          12.0                  2
time-to-event-wk-10th                17.9                 NA
time-to-event-wk-25th                40.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.097470  1.291000  0.007766  1.223000  0.071260


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0               14.0
n_event_pct                          12.0               29.0
time-to-event-wk-10th                13.9                5.0
time-to-event-wk-25th                  NA               33.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.9               42.4
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.8540    0.7624    0.4160    8.2620    0.4182


$Agetrt_less_180d$`Pneumonia aspiration`
$Agetrt_less_180d$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16               49.0
n_event                               1                6.0
n_event_pct                           6               12.0
time-to-event-wk-10th                NA               32.7
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Agetrt_less_180d$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2600    1.0980    0.1465   10.8300    0.8333


$Agetrt_less_180d$`Pneumonia bacterial`
$Agetrt_less_180d$`Pneumonia bacterial`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               1.0                  2
n_event_pct                           6.0                  4
time-to-event-wk-10th                36.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           36.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42510   1.27000   0.03528   5.12300   0.50060
```

```
$Agetrt_less_180d$`Pneumonia viral`
$Agetrt_less_180d$`Pneumonia viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 16                 49
n_event                                0                  3
n_event_pct                            0                  6
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.397e+08 2.264e+04 0.000e+00       Inf 9.993e-01


$Agetrt_less_180d$`Respiratory arrest`
$Agetrt_less_180d$`Respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                 49
n_event                              2.0                  2
n_event_pct                         12.0                  4
time-to-event-wk-10th               18.2                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          16.0                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_less_180d$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.14930   1.05800   0.01878   1.18800   0.07225


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               16.0                49.0
n_event                              2.0                14.0
n_event_pct                         12.0                29.0
time-to-event-wk-10th               15.4                 8.9
time-to-event-wk-25th                 NA                35.0
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci          15.4                43.4
time-to-event-wk-50th-hici            NA                  NA

$Agetrt_less_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
```

```
      HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.3150    0.7721    0.2895    5.9700    0.7231


$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               9.0               12.0
n_event_pct                          56.0               24.0
time-to-event-wk-10th                 1.0                4.1
time-to-event-wk-25th                 6.1               32.1
time-to-event-wk-50th                13.0                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            6.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.229800  0.477600  0.090120  0.585900  0.002074


$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`
$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  3
n_event_pct                          12.0                  6
time-to-event-wk-10th                22.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Respiratory syncytial virus bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.35970   0.92480   0.05872   2.20300   0.26880


$Agetrt_less_180d$`Respiratory tract congestion`
$Agetrt_less_180d$`Respiratory tract congestion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                 49
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.180e-11 3.780e+04 0.000e+00       Inf 9.995e-01


$Agetrt_less_180d$`Respiratory tract infection`
$Agetrt_less_180d$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0              49.0
n_event                               1.0               6.0
n_event_pct                           6.0              12.0
time-to-event-wk-10th                32.9              35.4
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           32.9                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_less_180d$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7180    1.0920    0.2022   14.6000    0.6200


$Agetrt_less_180d$`Respiratory tract infection viral`
$Agetrt_less_180d$`Respiratory tract infection viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16                 49
n_event                               1                  1
n_event_pct                           6                  2
time-to-event-wk-10th                NA                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Agetrt_less_180d$`Respiratory tract infection viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.20850   1.47900   0.01148   3.78700   0.28920


$Agetrt_less_180d$Retching
$Agetrt_less_180d$Retching$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                49
n_event                               1.0                 0
n_event_pct                           6.0                 0
time-to-event-wk-10th                36.4                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           36.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$Retching$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.166e-10 3.916e+04 0.000e+00       Inf 9.995e-01


$Agetrt_less_180d$`Rhinovirus infection`
$Agetrt_less_180d$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0                4.0
n_event_pct                          12.0                8.0
time-to-event-wk-10th                 9.9               45.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.37090   0.90930   0.06242   2.20400   0.27540


$Agetrt_less_180d$`Systemic infection`
$Agetrt_less_180d$`Systemic infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                48.3                 NA
time-to-event-wk-25th                48.3                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           48.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Systemic infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.920e-11 4.048e+04 0.000e+00       Inf 9.995e-01


$Agetrt_less_180d$`Tracheal haemorrhage`
$Agetrt_less_180d$`Tracheal haemorrhage`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               1.0                  0
n_event_pct                           6.0                  0
```

```
time-to-event-wk-10th                47.1                 NA
time-to-event-wk-25th                47.1                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           47.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Tracheal haemorrhage`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.920e-11 4.048e+04 0.000e+00       Inf 9.995e-01


$Agetrt_less_180d$`Tracheal obstruction`
$Agetrt_less_180d$`Tracheal obstruction`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                48.4                 NA
time-to-event-wk-25th                48.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           48.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Tracheal obstruction`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.074e-11 5.821e+04 0.000e+00       Inf 9.997e-01


$Agetrt_less_180d$`Urinary tract infection`
$Agetrt_less_180d$`Urinary tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                 49
n_event                                 0                  3
n_event_pct                             0                  6
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Urinary tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.313e+08 1.973e+04 0.000e+00       Inf 9.992e-01


$Agetrt_less_180d$`Viral infection`
$Agetrt_less_180d$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  16                 49
n_event                                 0                  3
n_event_pct                             0                  6
time-to-event-wk-10th                  NA                 55
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.957e+08 2.010e+04 0.000e+00       Inf 9.992e-01


$Agetrt_less_180d$`Viral upper respiratory tract infection`
$Agetrt_less_180d$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  2
n_event_pct                          12.0                  4
time-to-event-wk-10th                33.4                 NA
time-to-event-wk-25th                33.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.2473    1.0140    0.0339    1.8030    0.1681


$Agetrt_less_180d$Vomiting
$Agetrt_less_180d$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  16                 49
n_event                                 1                  2
n_event_pct                             6                  4
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47500   1.23900   0.04188   5.38800   0.54800
```

```
$Agetrt_less_180d$`Weight gain poor`
$Agetrt_less_180d$`Weight gain poor`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0                 49
n_event                               2.0                  3
n_event_pct                          12.0                  6
time-to-event-wk-10th                34.9                 NA
time-to-event-wk-25th                34.9                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           34.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Weight gain poor`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31000   0.95050   0.04811   1.99700   0.21780



$Region_Europe
$Region_Europe$`Acute respiratory distress syndrome`
$Region_Europe$`Acute respiratory distress syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17                 30
n_event                               1                  0
n_event_pct                           6                  0
time-to-event-wk-10th                NA                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Region_Europe$`Acute respiratory distress syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.263e-10 2.667e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$`Acute respiratory failure`
$Region_Europe$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               2.0                  0
n_event_pct                          12.0                  0
time-to-event-wk-10th                16.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Region_Europe$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.963e-11 3.130e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$Agitation
$Region_Europe$Agitation$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                30
n_event                                1                 0
n_event_pct                            6                 0
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$Agitation$stats_HR_TRTvsCTRL
        HR   SE_logHR  HR.lo95ci  HR.hi95ci    p.value
6.131e-170  2.023e+03  0.000e+00        Inf  8.473e-01


$Region_Europe$Apnoea
$Region_Europe$Apnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                30
n_event                                1                 2
n_event_pct                            6                 7
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$Apnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.63290   1.28300   0.05116   7.82900   0.72150


$Region_Europe$Atelectasis
$Region_Europe$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              30.0
n_event                              3.0               7.0
n_event_pct                         18.0              23.0
time-to-event-wk-10th               17.6              11.4
time-to-event-wk-25th               32.9              18.0
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
```

```
time-to-event-wk-50th-loci           32.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3090    0.7001    0.3319    5.1630    0.7006


$Region_Europe$`Body temperature increased`
$Region_Europe$`Body temperature increased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                47.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           47.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Body temperature increased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.823e-09 5.157e+04 0.000e+00       Inf 9.997e-01


$Region_Europe$`Bronchial secretion retention`
$Region_Europe$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               2.0                  1
n_event_pct                          12.0                  3
time-to-event-wk-10th                40.7                 NA
time-to-event-wk-25th                40.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.1532    1.2510    0.0132    1.7770    0.1335


$Region_Europe$Bronchitis
$Region_Europe$Bronchitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                30.0
n_event                                 0                 4.0
n_event_pct                             0                13.0
time-to-event-wk-10th                  NA                11.7
time-to-event-wk-25th                  NA                  NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Bronchitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.897e+08 1.312e+04 0.000e+00       Inf 9.988e-01


$Region_Europe$`Candida sepsis`
$Region_Europe$`Candida sepsis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               1.0                 0
n_event_pct                           6.0                 0
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           22.6                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Candida sepsis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.599e-10 2.836e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$`Cardio-respiratory arrest`
$Region_Europe$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                30
n_event                                1                 2
n_event_pct                            6                 7
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.01600   1.23600   0.09009  11.47000   0.98950


$Region_Europe$Dysphagia
$Region_Europe$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                30
n_event                                1                 0
```

```
n_event_pct                               6                  0
time-to-event-wk-10th                    NA                 NA
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               NA                 NA
time-to-event-wk-50th-hici               NA                 NA

$Region_Europe$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.341e-12 3.528e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$Dyspnoea
$Region_Europe$Dyspnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 30
n_event                                1                  1
n_event_pct                            6                  3
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47440   1.43100   0.02869   7.84400   0.60240


$Region_Europe$`Feeding disorder of infancy or early childhood`
$Region_Europe$`Feeding disorder of infancy or early childhood`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                 30
n_event                              2.0                  1
n_event_pct                         12.0                  3
time-to-event-wk-10th                8.9                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.1989    1.2640    0.0167    2.3690    0.2014


$Region_Europe$`Gastrointestinal haemorrhage`
```

```
$Region_Europe$`Gastrointestinal haemorrhage`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 30
n_event                                1                  0
n_event_pct                            6                  0
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Gastrointestinal haemorrhage`$stats_HR_TRTvsCTRL
        HR   SE_logHR  HR.lo95ci  HR.hi95ci    p.value
3.264e-166  1.845e+03  0.000e+00        Inf  8.364e-01


$Region_Europe$`Head injury`
$Region_Europe$`Head injury`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 30
n_event                                1                  0
n_event_pct                            6                  0
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Head injury`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.787e-54 3.605e+04 0.000e+00       Inf 9.973e-01


$Region_Europe$`Heart rate decreased`
$Region_Europe$`Heart rate decreased`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                 30
n_event                              1.0                  0
n_event_pct                          6.0                  0
time-to-event-wk-10th               49.6                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          49.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Heart rate decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.959e-08 5.023e+04 0.000e+00       Inf 9.997e-01
```

```
$Region_Europe$`Lower respiratory tract infection`
$Region_Europe$`Lower respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                30
n_event                                0                 2
n_event_pct                            0                 7
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Lower respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.117e+08 2.034e+04 0.000e+00       Inf 9.992e-01


$Region_Europe$`Lung disorder`
$Region_Europe$`Lung disorder`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                30
n_event                                1                 1
n_event_pct                            6                 3
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Lung disorder`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40810   1.44500   0.02401   6.93500   0.53520


$Region_Europe$`Medical observation`
$Region_Europe$`Medical observation`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                30
n_event                                0                 2
n_event_pct                            0                 7
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA
```

```
$Region_Europe$`Medical observation`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.567e+08 1.951e+04 0.000e+00       Inf 9.992e-01


$Region_Europe$`Oxygen saturation decreased`
$Region_Europe$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30
n_event                               1.0                 1
n_event_pct                           6.0                 3
time-to-event-wk-10th                40.7                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Europe$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.27570   1.46400   0.01563   4.86200   0.37890


$Region_Europe$Pneumonia
$Region_Europe$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                30.0
n_event                               2.0                 6.0
n_event_pct                          12.0                20.0
time-to-event-wk-10th                13.9                10.6
time-to-event-wk-25th                  NA                42.4
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                42.4
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2760    0.8270    0.2523    6.4530    0.7682


$Region_Europe$`Pneumonia aspiration`
$Region_Europe$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                30.0
n_event                                 2                 3.0
n_event_pct                            12                10.0
time-to-event-wk-10th                  11                27.9
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
```

```
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Region_Europe$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8150    0.9252    0.1329    4.9970    0.8250


$Region_Europe$`Pneumonia pseudomonal`
$Region_Europe$`Pneumonia pseudomonal`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 30
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Pneumonia pseudomonal`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.889e-10 2.821e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$Pyrexia
$Region_Europe$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               30.0
n_event                                 0                3.0
n_event_pct                             0               10.0
time-to-event-wk-10th                  NA               46.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.114e+08 1.526e+04 0.000e+00       Inf 9.990e-01


$Region_Europe$`Respiratory arrest`
$Region_Europe$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               30.0
n_event                                 0                4.0
n_event_pct                             0               13.0
time-to-event-wk-10th                  NA               27.3
time-to-event-wk-25th                  NA                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.115e+08 1.390e+04 0.000e+00       Inf 9.989e-01


$Region_Europe$`Respiratory disorder`
$Region_Europe$`Respiratory disorder`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 30
n_event                                 0                  2
n_event_pct                             0                  7
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory disorder`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.708e+08 1.935e+04 0.000e+00       Inf 9.992e-01


$Region_Europe$`Respiratory distress`
$Region_Europe$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               2.0                8.0
n_event_pct                          12.0               27.0
time-to-event-wk-10th                15.4               10.6
time-to-event-wk-25th                  NA               24.3
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               25.9
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.5270    0.8001    0.5268   12.1300    0.2465


$Region_Europe$`Respiratory failure`
$Region_Europe$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               30.0
n_event                               8.0                9.0
```

```
n_event_pct                           47.0               30.0
time-to-event-wk-10th                  3.4                5.1
time-to-event-wk-25th                  9.1               27.0
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci             6.1               31.9
time-to-event-wk-50th-hici              NA                 NA

$Region_Europe$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4935    0.5009    0.1849    1.3170    0.1586


$Region_Europe$`Respiratory tract congestion`
$Region_Europe$`Respiratory tract congestion`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 30
n_event                                1                  0
n_event_pct                            6                  0
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Respiratory tract congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.936e-10 2.765e+04 0.000e+00       Inf 9.994e-01


$Region_Europe$`Respiratory tract infection`
$Region_Europe$`Respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               30.0
n_event                              1.0                6.0
n_event_pct                          6.0               20.0
time-to-event-wk-10th               32.9                9.3
time-to-event-wk-25th                 NA               40.1
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          32.9               40.1
time-to-event-wk-50th-hici            NA                 NA

$Region_Europe$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9540    1.1030    0.2249   16.9800    0.5435


$Region_Europe$`Respiratory tract infection viral`
$Region_Europe$`Respiratory tract infection viral`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 30
n_event                                 1                  1
n_event_pct                             6                  3
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Respiratory tract infection viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.44680   1.43500   0.02685   7.43700   0.57450


$Region_Europe$`Rhinovirus infection`
$Region_Europe$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 30
n_event                                 1                  3
n_event_pct                             6                 10
time-to-event-wk-10th                  NA                 18
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7870    1.1580    0.1849   17.2800    0.6159


$Region_Europe$`Salivary hypersecretion`
$Region_Europe$`Salivary hypersecretion`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 30
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                40.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Salivary hypersecretion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.286e-10 5.681e+04 0.000e+00       Inf 9.997e-01
```

```
$Region_Europe$`Systemic infection`
$Region_Europe$`Systemic infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                30
n_event                              1.0                 0
n_event_pct                          6.0                 0
time-to-event-wk-10th               48.3                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          48.3                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Systemic infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.823e-09 5.157e+04 0.000e+00       Inf 9.997e-01


$Region_Europe$`Tracheal haemorrhage`
$Region_Europe$`Tracheal haemorrhage`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                30
n_event                              1.0                 0
n_event_pct                          6.0                 0
time-to-event-wk-10th               47.1                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          47.1                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Tracheal haemorrhage`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.823e-09 5.157e+04 0.000e+00       Inf 9.997e-01


$Region_Europe$`Tracheal obstruction`
$Region_Europe$`Tracheal obstruction`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                30
n_event                              1.0                 0
n_event_pct                          6.0                 0
time-to-event-wk-10th               48.4                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          48.4                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Europe$`Tracheal obstruction`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.959e-08 5.023e+04 0.000e+00       Inf 9.997e-01


$Region_Europe$`Viral infection`
$Region_Europe$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17               30.0
n_event                                 0                4.0
n_event_pct                             0               13.0
time-to-event-wk-10th                  NA               31.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.084e+08 1.348e+04 0.000e+00       Inf 9.988e-01


$Region_Europe$Vomiting
$Region_Europe$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 30
n_event                                 0                  2
n_event_pct                             0                  7
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.262e+08 1.870e+04 0.000e+00       Inf 9.992e-01


$Region_Europe$`Weight gain poor`
$Region_Europe$`Weight gain poor`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 30
n_event                                 1                  2
n_event_pct                             6                  7
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Region_Europe$`Weight gain poor`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.90570   1.23700   0.08012  10.24000   0.93620



$Disdur_less_equal_12wk
$Disdur_less_equal_12wk$`Acute respiratory distress syndrome`
$Disdur_less_equal_12wk$`Acute respiratory distress syndrome`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Acute respiratory distress syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.509e-10 4.336e+04 0.000e+00       Inf 9.996e-01


$Disdur_less_equal_12wk$`Acute respiratory failure`
$Disdur_less_equal_12wk$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               4.0                4.0
n_event_pct                          22.0               12.0
time-to-event-wk-10th                 8.6               32.7
time-to-event-wk-25th                22.4                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4392    0.7240    0.1063    1.8150    0.2558


$Disdur_less_equal_12wk$Agitation
$Disdur_less_equal_12wk$Agitation$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
```

```
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Disdur_less_equal_12wk$Agitation$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.179e-10 3.219e+04 0.000e+00       Inf 9.995e-01


$Disdur_less_equal_12wk$Apnoea
$Disdur_less_equal_12wk$Apnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               2.0                 2
n_event_pct                          11.0                 6
time-to-event-wk-10th                 6.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Apnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.52060   1.01200   0.07161   3.78400   0.51890


$Disdur_less_equal_12wk$Aspiration
$Disdur_less_equal_12wk$Aspiration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               1.0                 2
n_event_pct                           6.0                 6
time-to-event-wk-10th                40.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.3                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.97550   1.23200   0.08723  10.91000   0.98400


$Disdur_less_equal_12wk$Atelectasis
$Disdur_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
```

```
n_event                                1.0                8.0
n_event_pct                            6.0               24.0
time-to-event-wk-10th                 32.9               14.4
time-to-event-wk-25th                   NA               44.0
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            32.9               44.0
time-to-event-wk-50th-hici              NA                 NA

$Disdur_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   4.7060    1.0700    0.5778   38.3300    0.1478


$Disdur_less_equal_12wk$`Body temperature increased`
$Disdur_less_equal_12wk$`Body temperature increased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               1.0                 0
n_event_pct                           6.0                 0
time-to-event-wk-10th                47.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           47.1                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Body temperature increased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.778e-10 3.319e+04 0.000e+00       Inf 9.995e-01


$Disdur_less_equal_12wk$`Bronchial secretion retention`
$Disdur_less_equal_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               4.0                 1
n_event_pct                          22.0                 3
time-to-event-wk-10th                 6.1                NA
time-to-event-wk-25th                40.7                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           40.7                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.11370   1.13300   0.01234   1.04900   0.05513


$Disdur_less_equal_12wk$Bronchitis
```

```
$Disdur_less_equal_12wk$Bronchitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 18                 34
n_event                                0                  4
n_event_pct                            0                 12
time-to-event-wk-10th                 NA                 40
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$Bronchitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.675e+08 1.293e+04 0.000e+00       Inf 9.988e-01


$Disdur_less_equal_12wk$`Bronchitis viral`
$Disdur_less_equal_12wk$`Bronchitis viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 18                 34
n_event                                0                  2
n_event_pct                            0                  6
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Bronchitis viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.583e+08 2.582e+04 0.000e+00       Inf 9.994e-01


$Disdur_less_equal_12wk$`Candida sepsis`
$Disdur_less_equal_12wk$`Candida sepsis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 18                 34
n_event                                1                  0
n_event_pct                            6                  0
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Candida sepsis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.819e-10 3.829e+04 0.000e+00       Inf 9.996e-01
```

```
$Disdur_less_equal_12wk$`Cardiac arrest`
$Disdur_less_equal_12wk$`Cardiac arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 18                34
n_event                                1                 1
n_event_pct                            6                 3
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Cardiac arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.73930   1.44900   0.04319  12.66000   0.83490


$Disdur_less_equal_12wk$`Cardio-respiratory arrest`
$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                34
n_event                              3.0                 1
n_event_pct                         17.0                 3
time-to-event-wk-10th               23.0                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          33.6                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_less_equal_12wk$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.19180   1.18800   0.01868   1.97000   0.16470


$Disdur_less_equal_12wk$`Corona virus infection`
$Disdur_less_equal_12wk$`Corona virus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 18                34
n_event                                1                 0
n_event_pct                            6                 0
time-to-event-wk-10th                 34                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            34                NA
time-to-event-wk-50th-hici            NA                NA
```

```
$Disdur_less_equal_12wk$`Corona virus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.013e-09 1.003e+05 0.000e+00       Inf 9.998e-01


$Disdur_less_equal_12wk$Cyanosis
$Disdur_less_equal_12wk$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                34
n_event                                 1                 0
n_event_pct                             6                 0
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.380e-10 3.878e+04 0.000e+00       Inf 9.996e-01


$Disdur_less_equal_12wk$Death
$Disdur_less_equal_12wk$Death$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                34
n_event                                 1                 0
n_event_pct                             6                 0
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$Death$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.645e-10 2.901e+04 0.000e+00       Inf 9.994e-01


$Disdur_less_equal_12wk$Dysphagia
$Disdur_less_equal_12wk$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                34
n_event                                 1                 1
n_event_pct                             6                 3
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
```

```
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Disdur_less_equal_12wk$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47410   1.45200   0.02753   8.16200   0.60720


$Disdur_less_equal_12wk$Dyspnoea
$Disdur_less_equal_12wk$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                24.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           24.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.543e-10 2.115e+04 0.000e+00       Inf 9.992e-01


$Disdur_less_equal_12wk$`Feeding disorder of infancy or early childhood`
$Disdur_less_equal_12wk$`Feeding disorder of infancy or early
childhood`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18                 34
n_event                               1                  1
n_event_pct                           6                  3
time-to-event-wk-10th                NA                 NA
time-to-event-wk-25th                NA                 NA
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA                 NA
time-to-event-wk-50th-hici           NA                 NA

$Disdur_less_equal_12wk$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.49430   1.41800   0.03072   7.95600   0.61920


$Disdur_less_equal_12wk$`Femur fracture`
$Disdur_less_equal_12wk$`Femur fracture`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               1.0                  0
n_event_pct                           6.0                  0
```

```
time-to-event-wk-10th                50.6                 NA
time-to-event-wk-25th                53.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           50.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Femur fracture`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.556e-11 6.214e+04 0.000e+00       Inf 9.997e-01


$Disdur_less_equal_12wk$`Gastrointestinal haemorrhage`
$Disdur_less_equal_12wk$`Gastrointestinal haemorrhage`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Gastrointestinal haemorrhage`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.849e-10 3.291e+04 0.000e+00       Inf 9.995e-01


$Disdur_less_equal_12wk$`Heart rate decreased`
$Disdur_less_equal_12wk$`Heart rate decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 18.0                 34
n_event                                1.0                  0
n_event_pct                            6.0                  0
time-to-event-wk-10th                 49.6                 NA
time-to-event-wk-25th                 53.1                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci            49.6                 NA
time-to-event-wk-50th-hici              NA                 NA

$Disdur_less_equal_12wk$`Heart rate decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.634e-10 3.667e+04 0.000e+00       Inf 9.995e-01


$Disdur_less_equal_12wk$Hypoxia
$Disdur_less_equal_12wk$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  18                 34
n_event                                 1                  1
n_event_pct                             6                  3
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45590   1.44400   0.02689   7.73100   0.58660


$Disdur_less_equal_12wk$`Oxygen saturation decreased`
$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  1
n_event_pct                          11.0                  3
time-to-event-wk-10th                40.7                 NA
time-to-event-wk-25th                40.7                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           40.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.20520   1.23000   0.01842   2.28600   0.19780


$Disdur_less_equal_12wk$Pneumonia
$Disdur_less_equal_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34.0
n_event                               2.0                 8.0
n_event_pct                          11.0                24.0
time-to-event-wk-10th                13.9                 5.0
time-to-event-wk-25th                  NA                42.4
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                42.4
time-to-event-wk-50th-hici             NA                  NA

$Disdur_less_equal_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.4590    0.8068    0.5058   11.9500    0.2648
```

```
$Disdur_less_equal_12wk$`Pneumonia aspiration`
$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 18               34.0
n_event                                3                4.0
n_event_pct                           17               12.0
time-to-event-wk-10th                  9               32.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6667    0.7850    0.1431    3.1050    0.6055


$Disdur_less_equal_12wk$`Pneumonia bacterial`
$Disdur_less_equal_12wk$`Pneumonia bacterial`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0               34.0
n_event                              1.0                2.0
n_event_pct                          6.0                6.0
time-to-event-wk-10th               36.6               45.3
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          36.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.00700   1.25600   0.08579  11.81000   0.99590


$Disdur_less_equal_12wk$`Pneumonia parainfluenzae viral`
$Disdur_less_equal_12wk$`Pneumonia parainfluenzae viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 18                 34
n_event                                1                  0
n_event_pct                            6                  0
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Pneumonia parainfluenzae viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
5.602e-10 2.909e+04 0.000e+00       Inf 9.994e-01


$Disdur_less_equal_12wk$Pyrexia
$Disdur_less_equal_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 0                  2
n_event_pct                             0                  6
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.357e+08 1.964e+04 0.000e+00       Inf 9.992e-01


$Disdur_less_equal_12wk$`Respiratory arrest`
$Disdur_less_equal_12wk$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               3.0                  2
n_event_pct                          17.0                  6
time-to-event-wk-10th                19.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           20.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26230   0.94900   0.04083   1.68500   0.15850


$Disdur_less_equal_12wk$`Respiratory distress`
$Disdur_less_equal_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               3.0                8.0
n_event_pct                          17.0               24.0
time-to-event-wk-10th                11.7               15.6
time-to-event-wk-25th                  NA               43.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               43.4
time-to-event-wk-50th-hici             NA                 NA
```

```
$Disdur_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4150    0.6892    0.3665    5.4630    0.6145


$Disdur_less_equal_12wk$`Respiratory failure`
$Disdur_less_equal_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               7.0                9.0
n_event_pct                          39.0               26.0
time-to-event-wk-10th                 6.1                3.1
time-to-event-wk-25th                13.0               32.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           10.6               43.4
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5422    0.5181    0.1964    1.4970    0.2375


$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`
$Disdur_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  2
n_event_pct                          11.0                  6
time-to-event-wk-10th                22.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respiratory syncytial virus
bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4430    1.0060    0.0617    3.1810    0.4182


$Disdur_less_equal_12wk$`Respiratory tract infection`
$Disdur_less_equal_12wk$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0               34.0
n_event                               1.0                5.0
n_event_pct                           6.0               15.0
time-to-event-wk-10th                32.9               35.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3140    1.0970    0.2695   19.8700    0.4443


$Disdur_less_equal_12wk$`Respirovirus test positive`
$Disdur_less_equal_12wk$`Respirovirus test positive`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Respirovirus test positive`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.514e-10 2.812e+04 0.000e+00       Inf 9.994e-01


$Disdur_less_equal_12wk$Retching
$Disdur_less_equal_12wk$Retching$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                36.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           36.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$Retching$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.684e-10 3.695e+04 0.000e+00       Inf 9.995e-01


$Disdur_less_equal_12wk$`Rhinovirus infection`
$Disdur_less_equal_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18               34.0
n_event                                 1                2.0
n_event_pct                             6                6.0
```

```
time-to-event-wk-10th                  NA               45.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.06900   1.24700   0.09288  12.30000   0.95730


$Disdur_less_equal_12wk$`Systemic infection`
$Disdur_less_equal_12wk$`Systemic infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               1.0                 0
n_event_pct                           6.0                 0
time-to-event-wk-10th                48.3                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           48.3                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Systemic infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.778e-10 3.319e+04 0.000e+00       Inf 9.995e-01


$Disdur_less_equal_12wk$`Tracheal haemorrhage`
$Disdur_less_equal_12wk$`Tracheal haemorrhage`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                34
n_event                               1.0                 0
n_event_pct                           6.0                 0
time-to-event-wk-10th                47.1                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           47.1                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_less_equal_12wk$`Tracheal haemorrhage`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.778e-10 3.319e+04 0.000e+00       Inf 9.995e-01


$Disdur_less_equal_12wk$`Tracheal obstruction`
$Disdur_less_equal_12wk$`Tracheal obstruction`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                18.0                 34
n_event                               1.0                  0
n_event_pct                           6.0                  0
time-to-event-wk-10th                48.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           48.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Tracheal obstruction`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.705e-10 5.157e+04 0.000e+00       Inf 9.997e-01


$Disdur_less_equal_12wk$`Viral infection`
$Disdur_less_equal_12wk$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  18                 34
n_event                                 0                  3
n_event_pct                             0                  9
time-to-event-wk-10th                  NA                 55
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.119e+08 1.621e+04 0.000e+00       Inf 9.990e-01


$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`
$Disdur_less_equal_12wk$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                18.0                 34
n_event                               2.0                  2
n_event_pct                          11.0                  6
time-to-event-wk-10th                33.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.4                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_less_equal_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39290   1.02800   0.05237   2.94800   0.36360
```

```
$Disdur_less_equal_12wk$Vomiting
$Disdur_less_equal_12wk$Vomiting$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 18                 34
n_event                                1                  1
n_event_pct                            6                  3
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.39840   1.41600   0.02482   6.39500   0.51580


$Disdur_less_equal_12wk$`Weight gain poor`
$Disdur_less_equal_12wk$`Weight gain poor`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               18.0                 34
n_event                              1.0                  1
n_event_pct                          6.0                  3
time-to-event-wk-10th               34.9                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          34.9                 NA
time-to-event-wk-50th-hici            NA                 NA

$Disdur_less_equal_12wk$`Weight gain poor`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47620   1.43900   0.02836   7.99800   0.60630



$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0                 72
n_event                              7.0                 10
n_event_pct                         22.0                 14
time-to-event-wk-10th                8.6                 13
time-to-event-wk-25th               22.4                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          52.6                 NA
time-to-event-wk-50th-hici            NA                 NA
```

```
$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4959    0.4990    0.1865    1.3180    0.1598


$Ageonset_less_equal_12wk$Apnoea
$Ageonset_less_equal_12wk$Apnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32                 72
n_event                                 2                  2
n_event_pct                             6                  3
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Apnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.34920   1.00200   0.04905   2.48700   0.29350


$Ageonset_less_equal_12wk$`Apparent life threatening event`
$Ageonset_less_equal_12wk$`Apparent life threatening event`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32                 72
n_event                                 2                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Apparent life threatening event`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.809e-10 2.221e+04 0.000e+00       Inf 9.992e-01


$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               4.0               14.0
n_event_pct                          12.0               19.0
time-to-event-wk-10th                17.6               14.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2470    0.5691    0.4088    3.8040    0.6980


$Ageonset_less_equal_12wk$`Bronchial secretion retention`
$Ageonset_less_equal_12wk$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               4.0                 1
n_event_pct                          12.0                 1
time-to-event-wk-10th                 8.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.085250  1.120000  0.009484  0.766200  0.027970


$Ageonset_less_equal_12wk$Bronchiolitis
$Ageonset_less_equal_12wk$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32                72
n_event                               1                 4
n_event_pct                           3                 6
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7780    1.1240    0.1964   16.1100    0.6086


$Ageonset_less_equal_12wk$Bronchitis
$Ageonset_less_equal_12wk$Bronchitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32                72
n_event                               0                 4
n_event_pct                           0                 6
time-to-event-wk-10th                 NA                NA
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Bronchitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.790e+08 1.356e+04 0.000e+00       Inf 9.989e-01


$Ageonset_less_equal_12wk$`Cardiac arrest`
$Ageonset_less_equal_12wk$`Cardiac arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32                 72
n_event                                 2                  2
n_event_pct                             6                  3
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Cardiac arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3928    1.0050    0.0548    2.8150    0.3524


$Ageonset_less_equal_12wk$`Cardio-respiratory arrest`
$Ageonset_less_equal_12wk$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               3.0                  4
n_event_pct                           9.0                  6
time-to-event-wk-10th                17.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5019    0.7693    0.1111    2.2670    0.3702


$Ageonset_less_equal_12wk$Dyspnoea
$Ageonset_less_equal_12wk$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
```

```
n_event                                2.0                  4
n_event_pct                            6.0                  6
time-to-event-wk-10th                 24.4                 NA
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Ageonset_less_equal_12wk$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6606    0.8748    0.1189    3.6690    0.6355


$Ageonset_less_equal_12wk$`Feeding disorder of infancy or early childhood`
$Ageonset_less_equal_12wk$`Feeding disorder of infancy or early
childhood`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32                 72
n_event                                 2                  2
n_event_pct                             6                  3
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40360   1.00200   0.05658   2.87800   0.36530


$Ageonset_less_equal_12wk$Hypoxia
$Ageonset_less_equal_12wk$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32                 72
n_event                                 1                  4
n_event_pct                             3                  6
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5230    1.1260    0.1677   13.8300    0.7086
```

```
$Ageonset_less_equal_12wk$`Lower respiratory tract infection`
$Ageonset_less_equal_12wk$`Lower respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 32                72
n_event                                0                 4
n_event_pct                            0                 6
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Lower respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.468e+08 1.482e+04 0.000e+00       Inf 9.989e-01


$Ageonset_less_equal_12wk$`Oxygen saturation decreased`
$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0                72
n_event                              2.0                 1
n_event_pct                          6.0                 1
time-to-event-wk-10th               40.7                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.15160   1.23100   0.01358   1.69400   0.12550


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              4.0              18.0
n_event_pct                         12.0              25.0
time-to-event-wk-10th               13.7               9.0
time-to-event-wk-25th                 NA              35.9
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$Pneumonia$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6660    0.5539    0.5627    4.9340    0.3567


$Ageonset_less_equal_12wk$`Pneumonia aspiration`
$Ageonset_less_equal_12wk$`Pneumonia aspiration`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              3.0               8.0
n_event_pct                          9.0              11.0
time-to-event-wk-10th               15.7              32.7
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9253    0.6814    0.2434    3.5180    0.9093


$Ageonset_less_equal_12wk$`Pneumonia bacterial`
$Ageonset_less_equal_12wk$`Pneumonia bacterial`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72
n_event                              2.0                3
n_event_pct                          6.0                4
time-to-event-wk-10th               36.6               NA
time-to-event-wk-25th                 NA               NA
time-to-event-wk-50th                 NA               NA
time-to-event-wk-75th                 NA               NA
time-to-event-wk-90th                 NA               NA
time-to-event-wk-50th-loci            NA               NA
time-to-event-wk-50th-hici            NA               NA

$Ageonset_less_equal_12wk$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45060   0.91720   0.07467   2.72000   0.38480


$Ageonset_less_equal_12wk$`Pneumonia viral`
$Ageonset_less_equal_12wk$`Pneumonia viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0              72.0
n_event                              2.0               6.0
n_event_pct                          6.0               8.0
time-to-event-wk-10th               52.6              46.7
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          52.6                NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_less_equal_12wk$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2840    0.8225    0.2562    6.4390    0.7609


$Ageonset_less_equal_12wk$Pyrexia
$Ageonset_less_equal_12wk$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  32                  72
n_event                                 0                   4
n_event_pct                             0                   6
time-to-event-wk-10th                  NA                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_less_equal_12wk$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.804e+08 1.473e+04 0.000e+00       Inf 9.989e-01


$Ageonset_less_equal_12wk$`Respiratory arrest`
$Ageonset_less_equal_12wk$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                  72
n_event                               3.0                   5
n_event_pct                           9.0                   7
time-to-event-wk-10th                20.4                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_less_equal_12wk$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4718    0.7400    0.1106    2.0120    0.3101


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72.0
n_event                               6.0                20.0
n_event_pct                          19.0                28.0
time-to-event-wk-10th                11.0                 8.9
time-to-event-wk-25th                28.6                25.9
time-to-event-wk-50th                  NA                  NA
```

```
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2360    0.4691    0.4929    3.1010    0.6511


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              15.0               18.0
n_event_pct                          47.0               25.0
time-to-event-wk-10th                 3.4               10.0
time-to-event-wk-25th                 9.1               32.1
time-to-event-wk-50th                21.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.379200  0.357500  0.188200  0.764100  0.006681


$Ageonset_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`
$Ageonset_less_equal_12wk$`Respiratory syncytial virus bronchiolitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                 72
n_event                               3.0                  4
n_event_pct                           9.0                  6
time-to-event-wk-10th                22.4                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Respiratory syncytial virus
bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.36800   0.76930   0.08148   1.66200   0.19380


$Ageonset_less_equal_12wk$`Respiratory tract infection`
$Ageonset_less_equal_12wk$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32                 72
n_event                               1                  5
```

```
n_event_pct                              3                  7
time-to-event-wk-10th                   NA                 NA
time-to-event-wk-25th                   NA                 NA
time-to-event-wk-50th                   NA                 NA
time-to-event-wk-75th                   NA                 NA
time-to-event-wk-90th                   NA                 NA
time-to-event-wk-50th-loci              NA                 NA
time-to-event-wk-50th-hici              NA                 NA

$Ageonset_less_equal_12wk$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.7020    1.0990    0.1974   14.6800    0.6284


$Ageonset_less_equal_12wk$`Rhinovirus infection`
$Ageonset_less_equal_12wk$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 32               72.0
n_event                                2                7.0
n_event_pct                            6               10.0
time-to-event-wk-10th                 NA               45.3
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3480    0.8077    0.2769    6.5660    0.7113


$Ageonset_less_equal_12wk$`Upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 32                72
n_event                                0                 4
n_event_pct                            0                 6
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.915e+08 1.458e+04 0.000e+00       Inf 9.989e-01


$Ageonset_less_equal_12wk$`Viral infection`
$Ageonset_less_equal_12wk$`Viral infection`$stats_num
```

```
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0                72
n_event                              1.0                 5
n_event_pct                          3.0                 7
time-to-event-wk-10th                 NA                55
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          44.1                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5540    1.0960    0.1814   13.3100    0.6876


$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`
$Ageonset_less_equal_12wk$`Viral upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0                72
n_event                              6.0                 2
n_event_pct                         19.0                 3
time-to-event-wk-10th               11.7                NA
time-to-event-wk-25th               37.3                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          33.4                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.098010  0.824000  0.019490  0.492800  0.004821


$Ageonset_less_equal_12wk$`Weight gain poor`
$Ageonset_less_equal_12wk$`Weight gain poor`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0                72
n_event                              2.0                 3
n_event_pct                          6.0                 4
time-to-event-wk-10th               34.9                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_less_equal_12wk$`Weight gain poor`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5068    0.9140    0.0845    3.0400    0.4571
```

```
$Ageonset_greater_12wk
$Ageonset_greater_12wk$`Acute respiratory failure`
$Ageonset_greater_12wk$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0               8.0
n_event                              2.0               1.0
n_event_pct                         22.0              12.0
time-to-event-wk-10th               16.4              25.4
time-to-event-wk-25th               26.0                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          16.4              25.4
time-to-event-wk-50th-hici            NA                NA

$Ageonset_greater_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9680    1.4020    0.1262   30.7000    0.6290


$Ageonset_greater_12wk$`Bronchial secretion retention`
$Ageonset_greater_12wk$`Bronchial secretion retention`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                 8
n_event                              1.0                 0
n_event_pct                         11.0                 0
time-to-event-wk-10th               19.9                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          19.9                NA
time-to-event-wk-50th-hici            NA                NA

$Ageonset_greater_12wk$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.140e-10 4.262e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Candida sepsis`
$Ageonset_greater_12wk$`Candida sepsis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                9.0                 8
n_event                              1.0                 0
n_event_pct                         11.0                 0
time-to-event-wk-10th               22.6                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          22.6                NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Candida sepsis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.017e-09 4.176e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Cardio-respiratory arrest`
$Ageonset_greater_12wk$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               2.0                1.0
n_event_pct                          22.0               12.0
time-to-event-wk-10th                23.0               25.4
time-to-event-wk-25th                33.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           23.0               25.4
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.07200   1.31900   0.08084  14.22000   0.95780


$Ageonset_greater_12wk$`Femur fracture`
$Ageonset_greater_12wk$`Femur fracture`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                50.6                 NA
time-to-event-wk-25th                55.5                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           50.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Femur fracture`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.522e-01 1.273e+05 0.000e+00       Inf 1.000e+00


$Ageonset_greater_12wk$Pneumonia
$Ageonset_greater_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               1.0                1.0
n_event_pct                          11.0               12.0
time-to-event-wk-10th                 5.7               30.4
time-to-event-wk-25th                  NA               30.4
time-to-event-wk-50th                  NA                 NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            5.7                30.4
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.1810    1.4550    0.1259   37.7800    0.5920


$Ageonset_greater_12wk$`Pneumonia aspiration`
$Ageonset_greater_12wk$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               2.0                  0
n_event_pct                          22.0                  0
time-to-event-wk-10th                 1.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            1.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.616e-10 2.873e+04 0.000e+00       Inf 9.994e-01


$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`
$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                19.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Pneumonia parainfluenzae viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Pneumonia pseudomonal`
$Ageonset_greater_12wk$`Pneumonia pseudomonal`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
```

```
time-to-event-wk-10th                15.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Pneumonia pseudomonal`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.446e-09 4.265e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Respiratory arrest`
$Ageonset_greater_12wk$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                  8
n_event                               1.0                  0
n_event_pct                          11.0                  0
time-to-event-wk-10th                19.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.140e-10 4.262e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Respiratory distress`
$Ageonset_greater_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                8.0
n_event                               2.0                1.0
n_event_pct                          22.0               12.0
time-to-event-wk-10th                 2.3                0.6
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci            2.3                0.6
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_greater_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.72320   1.24700   0.06275   8.33600   0.79500


$Ageonset_greater_12wk$`Respiratory failure`
$Ageonset_greater_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                9.0               8.0
n_event                              1.0               2.0
n_event_pct                         11.0              25.0
time-to-event-wk-10th               19.3               0.6
time-to-event-wk-25th                 NA               5.1
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          19.3               0.6
time-to-event-wk-50th-hici            NA                NA

$Ageonset_greater_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.3050    1.2530    0.2834   38.5400    0.3402


$Ageonset_greater_12wk$`Respiratory tract infection`
$Ageonset_greater_12wk$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   9                   8
n_event                                 0                   1
n_event_pct                             0                  12
time-to-event-wk-10th                  NA                   3
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                   3
time-to-event-wk-50th-hici             NA                  NA

$Ageonset_greater_12wk$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.316e+09 4.526e+04 0.000e+00       Inf 9.996e-01


$Ageonset_greater_12wk$`Respirovirus test positive`
$Ageonset_greater_12wk$`Respirovirus test positive`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 9.0                 8
n_event                               1.0                 0
n_event_pct                          11.0                 0
time-to-event-wk-10th                15.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.9                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_greater_12wk$`Respirovirus test positive`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.936e-10 4.279e+04 0.000e+00       Inf 9.996e-01
```

```
$Ageonset_greater_12wk$`Viral upper respiratory tract infection`
$Ageonset_greater_12wk$`Viral upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  9                8.0
n_event                                0                1.0
n_event_pct                            0               12.0
time-to-event-wk-10th                 NA               16.7
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA               16.7
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_greater_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.069e+10 4.364e+04 0.000e+00       Inf 9.996e-01



$Agetrt_greater_equal_180d
$Agetrt_greater_equal_180d$`Acute respiratory failure`
$Agetrt_greater_equal_180d$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 25.0              31.0
n_event                                6.0               4.0
n_event_pct                           24.0              13.0
time-to-event-wk-10th                 13.9              19.9
time-to-event-wk-25th                 26.0                NA
time-to-event-wk-50th                   NA                NA
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci            26.0                NA
time-to-event-wk-50th-hici              NA                NA

$Agetrt_greater_equal_180d$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4615    0.6596    0.1267    1.6810    0.2410


$Agetrt_greater_equal_180d$`Apparent life threatening event`
$Agetrt_greater_equal_180d$`Apparent life threatening event`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 25                 31
n_event                                2                  0
n_event_pct                            8                  0
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA
```

```
$Agetrt_greater_equal_180d$`Apparent life threatening event`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.108e-09 1.770e+04 0.000e+00       Inf 9.991e-01


$Agetrt_greater_equal_180d$Atelectasis
$Agetrt_greater_equal_180d$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25               31.0
n_event                                 2                4.0
n_event_pct                             8               13.0
time-to-event-wk-10th                  NA               11.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4250    0.8716    0.2583    7.8670    0.6842


$Agetrt_greater_equal_180d$`Bronchial secretion retention`
$Agetrt_greater_equal_180d$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               2.0                 0
n_event_pct                           8.0                 0
time-to-event-wk-10th                19.9                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.007e-09 1.772e+04 0.000e+00       Inf 9.991e-01


$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`
$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25               31.0
n_event                                 3                4.0
n_event_pct                            12               13.0
time-to-event-wk-10th                  23               17.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_greater_equal_180d$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9800    0.7888    0.2088    4.5990    0.9795


$Agetrt_greater_equal_180d$Dyspnoea
$Agetrt_greater_equal_180d$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25               31.0
n_event                                 0                3.0
n_event_pct                             0               10.0
time-to-event-wk-10th                  NA               29.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.469e+08 1.402e+04 0.000e+00       Inf 9.989e-01


$Agetrt_greater_equal_180d$Hypoxia
$Agetrt_greater_equal_180d$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                31
n_event                                 0                 2
n_event_pct                             0                 6
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.859e+08 2.839e+04 0.000e+00       Inf 9.994e-01


$Agetrt_greater_equal_180d$`Lower respiratory tract infection`
$Agetrt_greater_equal_180d$`Lower respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                31
n_event                                 0                 4
n_event_pct                             0                13
time-to-event-wk-10th                  NA                35
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Lower respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.175e+09 2.018e+04 0.000e+00       Inf 9.992e-01


$Agetrt_greater_equal_180d$Pneumonia
$Agetrt_greater_equal_180d$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               3.0                5.0
n_event_pct                          12.0               16.0
time-to-event-wk-10th                13.7               15.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2110    0.7459    0.2807    5.2240    0.7975


$Agetrt_greater_equal_180d$`Pneumonia aspiration`
$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               4.0                 2
n_event_pct                          16.0                 6
time-to-event-wk-10th                15.7                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4204    0.8835    0.0744    2.3750    0.3267


$Agetrt_greater_equal_180d$`Pneumonia viral`
$Agetrt_greater_equal_180d$`Pneumonia viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                25.0               31.0
n_event                               2.0                3.0
n_event_pct                           8.0               10.0
time-to-event-wk-10th                52.6               46.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           52.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0710    0.9413    0.1693    6.7770    0.9419


$Agetrt_greater_equal_180d$Pyrexia
$Agetrt_greater_equal_180d$Pyrexia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                 31
n_event                                 0                  2
n_event_pct                             0                  6
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.542e+08 1.732e+04 0.000e+00       Inf 9.991e-01


$Agetrt_greater_equal_180d$`Respiratory arrest`
$Agetrt_greater_equal_180d$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0               31.0
n_event                               2.0                3.0
n_event_pct                           8.0               10.0
time-to-event-wk-10th                26.4               27.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2030    0.9300    0.1943    7.4420    0.8427
```

```
$Agetrt_greater_equal_180d$`Respiratory disorder`
$Agetrt_greater_equal_180d$`Respiratory disorder`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 25                 31
n_event                                0                  2
n_event_pct                            0                  6
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$`Respiratory disorder`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.085e+08 1.735e+04 0.000e+00       Inf 9.991e-01


$Agetrt_greater_equal_180d$`Respiratory distress`
$Agetrt_greater_equal_180d$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0               31.0
n_event                              6.0                7.0
n_event_pct                         24.0               23.0
time-to-event-wk-10th                3.1                7.1
time-to-event-wk-25th               28.6               25.9
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          28.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8408    0.5616    0.2797    2.5280    0.7576


$Agetrt_greater_equal_180d$`Respiratory failure`
$Agetrt_greater_equal_180d$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               25.0                 31
n_event                              7.0                  8
n_event_pct                         28.0                 26
time-to-event-wk-10th               13.1                 10
time-to-event-wk-25th               19.3                 27
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          21.9                 34
time-to-event-wk-50th-hici            NA                 NA

$Agetrt_greater_equal_180d$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.8191    0.5225    0.2941    2.2810    0.7026


$Agetrt_greater_equal_180d$`Rhinovirus infection`
$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25               31.0
n_event                                 0                3.0
n_event_pct                             0               10.0
time-to-event-wk-10th                  NA               21.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.853e+08 2.278e+04 0.000e+00       Inf 9.993e-01


$Agetrt_greater_equal_180d$`Upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                31
n_event                                 0                 2
n_event_pct                             0                 6
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.022e+09 2.793e+04 0.000e+00       Inf 9.994e-01


$Agetrt_greater_equal_180d$`Viral infection`
$Agetrt_greater_equal_180d$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  25                31
n_event                                 1                 2
n_event_pct                             4                 6
time-to-event-wk-10th                  NA                41
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_greater_equal_180d$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.1980    1.3090    0.1691   28.5700    0.5472


$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`
$Agetrt_greater_equal_180d$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                25.0                31
n_event                               4.0                 1
n_event_pct                          16.0                 3
time-to-event-wk-10th                17.6                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           37.3                NA
time-to-event-wk-50th-hici             NA                NA

$Agetrt_greater_equal_180d$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.17920   1.13700   0.01932   1.66300   0.13040



$Gender_Male
$Gender_Male$`Acute respiratory failure`
$Gender_Male$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                37.0
n_event                               3.0                 5.0
n_event_pct                          18.0                14.0
time-to-event-wk-10th                22.4                25.4
time-to-event-wk-25th                52.6                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           22.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6647    0.7390    0.1562    2.8290    0.5804


$Gender_Male$Apnoea
$Gender_Male$Apnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                  37
n_event                                 1                   2
n_event_pct                             6                   5
```

```
time-to-event-wk-10th                  NA                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Apnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  1.08200   1.23800   0.09561  12.25000   0.94900


$Gender_Male$`Apparent life threatening event`
$Gender_Male$`Apparent life threatening event`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                  37
n_event                                 1                   0
n_event_pct                             6                   0
time-to-event-wk-10th                  NA                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Apparent life threatening event`$stats_HR_TRTvsCTRL
        HR   SE_logHR  HR.lo95ci  HR.hi95ci    p.value
2.877e-134  1.689e+03  0.000e+00        Inf  8.555e-01


$Gender_Male$Aspiration
$Gender_Male$Aspiration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                  37
n_event                               1.0                   1
n_event_pct                           6.0                   3
time-to-event-wk-10th                40.3                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           40.3                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.56770   1.47600   0.03144  10.25000   0.70130


$Gender_Male$Atelectasis
$Gender_Male$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                 17                 37
n_event                                0                  4
n_event_pct                            0                 11
time-to-event-wk-10th                 NA                 18
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.972e+08 1.370e+04 0.000e+00       Inf 9.989e-01


$Gender_Male$`Bronchial secretion retention`
$Gender_Male$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               3.0                  1
n_event_pct                          18.0                  3
time-to-event-wk-10th                 6.1                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           19.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.14870   1.17500   0.01486   1.48800   0.10490


$Gender_Male$Bronchiolitis
$Gender_Male$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 37
n_event                                1                  3
n_event_pct                            6                  8
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.61070   1.23800   0.05393   6.91500   0.69040
```

```
$Gender_Male$Bronchitis
$Gender_Male$Bronchitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 37
n_event                                0                  3
n_event_pct                            0                  8
time-to-event-wk-10th                 NA                 40
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$Bronchitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.483e+08 1.565e+04 0.000e+00       Inf 9.990e-01


$Gender_Male$`Bronchitis viral`
$Gender_Male$`Bronchitis viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                 37
n_event                                0                  2
n_event_pct                            0                  5
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Bronchitis viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.664e+08 1.997e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$`Candida sepsis`
$Gender_Male$`Candida sepsis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                 37
n_event                              1.0                  0
n_event_pct                          6.0                  0
time-to-event-wk-10th               22.6                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          22.6                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Candida sepsis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
2.502e-10 3.607e+04 0.000e+00       Inf 9.995e-01


$Gender_Male$`Cardiac arrest`
$Gender_Male$`Cardiac arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 1                  2
n_event_pct                             6                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Cardiac arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.94300   1.24300   0.08254  10.77000   0.96240


$Gender_Male$`Cardio-respiratory arrest`
$Gender_Male$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               3.0                  2
n_event_pct                          18.0                  5
time-to-event-wk-10th                14.3                 NA
time-to-event-wk-25th                33.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29500   0.93520   0.04719   1.84500   0.19180


$Gender_Male$`Corona virus infection`
$Gender_Male$`Corona virus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  34                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             34                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Gender_Male$`Corona virus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.616e-06 1.471e+05 0.000e+00       Inf 9.999e-01


$Gender_Male$Cyanosis
$Gender_Male$Cyanosis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Cyanosis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.675e-10 2.842e+04 0.000e+00       Inf 9.994e-01


$Gender_Male$Death
$Gender_Male$Death$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Death$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.124e-10 2.810e+04 0.000e+00       Inf 9.994e-01


$Gender_Male$Dehydration
$Gender_Male$Dehydration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 1                  0
n_event_pct                             6                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
```

```
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Dehydration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.957e-10 2.838e+04 0.000e+00       Inf 9.994e-01


$Gender_Male$Dysphagia
$Gender_Male$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                  37
n_event                                 1                   1
n_event_pct                             6                   3
time-to-event-wk-10th                  NA                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.54600   1.42500   0.03346   8.91000   0.67100


$Gender_Male$Dyspnoea
$Gender_Male$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                  37
n_event                               1.0                   1
n_event_pct                           6.0                   3
time-to-event-wk-10th                24.4                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           24.4                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.182800  1.511000  0.009454  3.533000  0.260700


$Gender_Male$`Failure to thrive`
$Gender_Male$`Failure to thrive`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                  37
n_event                                 1                   0
n_event_pct                             6                   0
time-to-event-wk-10th                  NA                  NA
```

```
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Failure to thrive`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.957e-10 2.838e+04 0.000e+00       Inf 9.994e-01


$Gender_Male$Hypoxia
$Gender_Male$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 1                  2
n_event_pct                             6                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.68220   1.25600   0.05816   8.00100   0.76080


$Gender_Male$`Lower respiratory tract infection`
$Gender_Male$`Lower respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 0                  2
n_event_pct                             0                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Lower respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.011e+08 2.144e+04 0.000e+00       Inf 9.993e-01


$Gender_Male$`Oxygen saturation decreased`
$Gender_Male$`Oxygen saturation decreased`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
```

```
n_event                                   1                  0
n_event_pct                               6                  0
time-to-event-wk-10th                    NA                 NA
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               NA                 NA
time-to-event-wk-50th-hici               NA                 NA

$Gender_Male$`Oxygen saturation decreased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.883e-10 3.414e+04 0.000e+00       Inf 9.995e-01


$Gender_Male$Pneumonia
$Gender_Male$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0               37.0
n_event                               3.0                5.0
n_event_pct                          18.0               14.0
time-to-event-wk-10th                11.3               30.4
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7076    0.7416    0.1654    3.0270    0.6409


$Gender_Male$`Pneumonia aspiration`
$Gender_Male$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               2.0                  2
n_event_pct                          12.0                  5
time-to-event-wk-10th                17.9                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           17.9                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40830   1.02100   0.05522   3.01900   0.38030


$Gender_Male$`Pneumonia viral`
```

```
$Gender_Male$`Pneumonia viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                37
n_event                              1.0                 3
n_event_pct                          6.0                 8
time-to-event-wk-10th               52.6                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          52.6                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1190    1.1850    0.1098   11.4100    0.9244


$Gender_Male$Pyrexia
$Gender_Male$Pyrexia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                17              37.0
n_event                               0               3.0
n_event_pct                           0               8.0
time-to-event-wk-10th                NA              46.7
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Gender_Male$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.439e+08 1.555e+04 0.000e+00       Inf 9.990e-01


$Gender_Male$`Respiratory arrest`
$Gender_Male$`Respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0              37.0
n_event                              2.0               3.0
n_event_pct                         12.0               8.0
time-to-event-wk-10th               19.9              40.6
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          19.9                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.52250   0.94830   0.08145   3.35200   0.49370
```

```
$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17               37.0
n_event                                1               10.0
n_event_pct                            6               27.0
time-to-event-wk-10th                 NA                3.4
time-to-event-wk-25th                 NA               19.3
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA               35.0
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.8680    1.0560    0.4886   30.6300    0.2000


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               37.0
n_event                              7.0               11.0
n_event_pct                         41.0               30.0
time-to-event-wk-10th                1.0                1.7
time-to-event-wk-25th               13.0               27.0
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           7.4               31.9
time-to-event-wk-50th-hici            NA                 NA

$Gender_Male$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6666    0.4951    0.2526    1.7590    0.4127


$Gender_Male$`Respiratory syncytial virus bronchiolitis`
$Gender_Male$`Respiratory syncytial virus bronchiolitis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                 37
n_event                              1.0                  1
n_event_pct                          6.0                  3
time-to-event-wk-10th               22.4                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci          22.4                 NA
time-to-event-wk-50th-hici            NA                 NA
```

```
$Gender_Male$`Respiratory syncytial virus bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.3398    1.6610    0.0131    8.8160    0.5158


$Gender_Male$`Respiratory tract infection`
$Gender_Male$`Respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17                37
n_event                                0                 2
n_event_pct                            0                 5
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.967e+08 2.012e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$`Rhinovirus infection`
$Gender_Male$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 17              37.0
n_event                                0               5.0
n_event_pct                            0              14.0
time-to-event-wk-10th                 NA              12.1
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Gender_Male$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.700e+08 1.218e+04 0.000e+00       Inf 9.987e-01


$Gender_Male$`Salivary hypersecretion`
$Gender_Male$`Salivary hypersecretion`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0                37
n_event                              1.0                 0
n_event_pct                          6.0                 0
time-to-event-wk-10th               40.3                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
```

```
time-to-event-wk-50th-loci           40.3                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Salivary hypersecretion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.863e-25 4.888e+04 0.000e+00       Inf 9.991e-01


$Gender_Male$`Upper respiratory tract infection`
$Gender_Male$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 0                  2
n_event_pct                             0                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.997e+08 2.119e+04 0.000e+00       Inf 9.993e-01


$Gender_Male$`Viral infection`
$Gender_Male$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                 37
n_event                                 0                  2
n_event_pct                             0                  5
time-to-event-wk-10th                  NA                 41
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Male$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.344e+08 1.967e+04 0.000e+00       Inf 9.992e-01


$Gender_Male$`Viral upper respiratory tract infection`
$Gender_Male$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                 37
n_event                               3.0                  1
n_event_pct                          18.0                  3
time-to-event-wk-10th                17.6                 NA
time-to-event-wk-25th                33.4                 NA
```

```
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           17.6                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.10660   1.19000   0.01036   1.09800   0.05994


$Gender_Male$Vomiting
$Gender_Male$Vomiting$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  17                  37
n_event                                 1                   1
n_event_pct                             6                   3
time-to-event-wk-10th                  NA                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci             NA                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.41150   1.44200   0.02436   6.95300   0.53820


$Gender_Male$`Weight gain poor`
$Gender_Male$`Weight gain poor`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                17.0                  37
n_event                               1.0                   2
n_event_pct                           6.0                   5
time-to-event-wk-10th                34.9                  NA
time-to-event-wk-25th                  NA                  NA
time-to-event-wk-50th                  NA                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           34.9                  NA
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Weight gain poor`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.93180   1.25400   0.07985  10.87000   0.95500



$Gender_Female
$Gender_Female$`Acute respiratory failure`
$Gender_Female$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                24.0               43.0
n_event                               6.0                6.0
n_event_pct                          25.0               14.0
time-to-event-wk-10th                 8.6               19.9
time-to-event-wk-25th                26.0                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           26.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4832    0.5965    0.1501    1.5550    0.2227


$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               4.0               10.0
n_event_pct                          17.0               23.0
time-to-event-wk-10th                17.6               13.1
time-to-event-wk-25th                  NA               32.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9               44.0
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2430    0.6064    0.3786    4.0780    0.7202


$Gender_Female$`Bronchial secretion retention`
$Gender_Female$`Bronchial secretion retention`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               2.0                  0
n_event_pct                           8.0                  0
time-to-event-wk-10th                40.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.353e-10 1.968e+04 0.000e+00       Inf 9.991e-01
```

```
$Gender_Female$`Cardio-respiratory arrest`
$Gender_Female$`Cardio-respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 24                 43
n_event                                2                  3
n_event_pct                            8                  7
time-to-event-wk-10th                 23                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2170    0.9525    0.1881    7.8690    0.8369


$Gender_Female$Dyspnoea
$Gender_Female$Dyspnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 24                 43
n_event                                1                  3
n_event_pct                            4                  7
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3460    1.1810    0.1329   13.6300    0.8015


$Gender_Female$`Feeding disorder of infancy or early childhood`
$Gender_Female$`Feeding disorder of infancy or early childhood`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 24                 43
n_event                                2                  2
n_event_pct                            8                  5
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Gender_Female$`Feeding disorder of infancy or early
childhood`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.43030   1.03500   0.05656   3.27400   0.41540


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               2.0               14.0
n_event_pct                           8.0               33.0
time-to-event-wk-10th                13.7                6.9
time-to-event-wk-25th                  NA               25.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               33.1
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  3.62800   0.76150   0.81560  16.14000   0.09059


$Gender_Female$`Pneumonia aspiration`
$Gender_Female$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               3.0                6.0
n_event_pct                          12.0               14.0
time-to-event-wk-10th                15.7               28.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0840    0.7242    0.2621    4.4810    0.9115


$Gender_Female$`Pneumonia bacterial`
$Gender_Female$`Pneumonia bacterial`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               2.0                  2
n_event_pct                           8.0                  5
time-to-event-wk-10th                36.6                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
```

```
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48260   1.02500   0.06471   3.59900   0.47730


$Gender_Female$`Pneumonia viral`
$Gender_Female$`Pneumonia viral`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24               43.0
n_event                                 1                3.0
n_event_pct                             4                7.0
time-to-event-wk-10th                  NA               46.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.6440    1.2400    0.3206   41.4300    0.2971


$Gender_Female$`Respiratory arrest`
$Gender_Female$`Respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 24.0                43
n_event                                2.0                 2
n_event_pct                            8.0                 5
time-to-event-wk-10th                 26.4                NA
time-to-event-wk-25th                   NA                NA
time-to-event-wk-50th                   NA                NA
time-to-event-wk-75th                   NA                NA
time-to-event-wk-90th                   NA                NA
time-to-event-wk-50th-loci              NA                NA
time-to-event-wk-50th-hici              NA                NA

$Gender_Female$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.63320   1.04000   0.08241   4.86500   0.66050


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                 24.0                43
n_event                                7.0                11
n_event_pct                           29.0                26
time-to-event-wk-10th                 11.0                20.3
time-to-event-wk-25th                 15.9                43.4
time-to-event-wk-50th                   NA                  NA
```

```
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci           15.9                45.3
time-to-event-wk-50th-hici             NA                  NA

$Gender_Female$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6971    0.4961    0.2637    1.8430    0.4670


$Gender_Female$`Respiratory failure`
$Gender_Female$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               9.0                9.0
n_event_pct                          38.0               21.0
time-to-event-wk-10th                 4.6               16.1
time-to-event-wk-25th                15.7               43.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.7                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5155    0.4916    0.1967    1.3510    0.1776


$Gender_Female$`Respiratory syncytial virus bronchiolitis`
$Gender_Female$`Respiratory syncytial virus bronchiolitis`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               2.0                  3
n_event_pct                           8.0                  7
time-to-event-wk-10th                17.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Respiratory syncytial virus bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6414    0.9378    0.1021    4.0310    0.6359


$Gender_Female$`Respiratory tract infection`
$Gender_Female$`Respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24               43.0
n_event                                 1                4.0
n_event_pct                             4                9.0
```

```
time-to-event-wk-10th                  NA               40.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4480    1.1490    0.1525   13.7600    0.7470


$Gender_Female$`Rhinovirus infection`
$Gender_Female$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24                 43
n_event                                 2                  2
n_event_pct                             8                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42340   1.02500   0.05684   3.15400   0.40150


$Gender_Female$`Urinary tract infection`
$Gender_Female$`Urinary tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  24                 43
n_event                                 0                  3
n_event_pct                             0                  7
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Urinary tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.873e+08 1.578e+04 0.000e+00       Inf 9.990e-01


$Gender_Female$`Viral infection`
$Gender_Female$`Viral infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                24.0                 43
n_event                               1.0                  3
n_event_pct                           4.0                  7
time-to-event-wk-10th                  NA                 55
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           44.1                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Viral infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3250    1.1790    0.1314   13.3600    0.8114


$Gender_Female$`Viral upper respiratory tract infection`
$Gender_Female$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0                 43
n_event                               3.0                  2
n_event_pct                          12.0                  5
time-to-event-wk-10th                37.3                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.35570   0.93030   0.05744   2.20300   0.26650



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38.0
n_event                               7.0                 11.0
n_event_pct                          32.0                 29.0
time-to-event-wk-10th                13.0                  9.0
time-to-event-wk-25th                22.4                 25.4
time-to-event-wk-50th                  NA                   NA
time-to-event-wk-75th                  NA                   NA
time-to-event-wk-90th                  NA                   NA
time-to-event-wk-50th-loci           22.4                 28.0
time-to-event-wk-50th-hici             NA                   NA

$Region_Northamerica$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8485    0.4860    0.3273    2.2000    0.7354
```

```
$Region_Northamerica$`Apparent life threatening event`
$Region_Northamerica$`Apparent life threatening event`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                 38
n_event                                 2                  0
n_event_pct                             9                  0
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Apparent life threatening event`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.542e-10 1.953e+04 0.000e+00       Inf 9.991e-01


$Region_Northamerica$Aspiration
$Region_Northamerica$Aspiration$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                 38
n_event                                 1                  3
n_event_pct                             5                  8
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.9030    1.1590    0.1963   18.4500    0.5788


$Region_Northamerica$Atelectasis
$Region_Northamerica$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22               38.0
n_event                                 1                6.0
n_event_pct                             5               16.0
time-to-event-wk-10th                  NA               13.1
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA
```

```
$Region_Northamerica$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.5570    1.0830    0.4260   29.7000    0.2412


$Region_Northamerica$`Bronchial secretion retention`
$Region_Northamerica$`Bronchial secretion retention`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38
n_event                              3.0                 0
n_event_pct                         14.0                 0
time-to-event-wk-10th               19.9                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.024e-10 1.598e+04 0.000e+00       Inf 9.989e-01


$Region_Northamerica$Bronchiolitis
$Region_Northamerica$Bronchiolitis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22               38.0
n_event                              1                3.0
n_event_pct                          5                8.0
time-to-event-wk-10th               NA               32.1
time-to-event-wk-25th               NA                 NA
time-to-event-wk-50th               NA                 NA
time-to-event-wk-75th               NA                 NA
time-to-event-wk-90th               NA                 NA
time-to-event-wk-50th-loci          NA                 NA
time-to-event-wk-50th-hici          NA                 NA

$Region_Northamerica$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5720    1.1550    0.1633   15.1200    0.6956


$Region_Northamerica$`Bronchitis viral`
$Region_Northamerica$`Bronchitis viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22                38
n_event                              0                 2
n_event_pct                          0                 5
time-to-event-wk-10th               NA                NA
time-to-event-wk-25th               NA                NA
time-to-event-wk-50th               NA                NA
time-to-event-wk-75th               NA                NA
time-to-event-wk-90th               NA                NA
```

```
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Bronchitis viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.402e+09 2.553e+04 0.000e+00       Inf 9.993e-01


$Region_Northamerica$`Cardiac arrest`
$Region_Northamerica$`Cardiac arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               2.0                  1
n_event_pct                           9.0                  3
time-to-event-wk-10th                12.7                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Cardiac arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.26720   1.22500   0.02421   2.94800   0.28130


$Region_Northamerica$`Cardio-respiratory arrest`
$Region_Northamerica$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                 38
n_event                               4.0                  3
n_event_pct                          18.0                  8
time-to-event-wk-10th                17.6                 NA
time-to-event-wk-25th                33.6                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           33.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31570   0.77270   0.06945   1.43600   0.13570


$Region_Northamerica$Dysphagia
$Region_Northamerica$Dysphagia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22                 38
n_event                                 0                  2
n_event_pct                             0                  5
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.798e+08 1.847e+04 0.000e+00       Inf 9.991e-01


$Region_Northamerica$Hypoxia
$Region_Northamerica$Hypoxia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  22               38.0
n_event                                 1                4.0
n_event_pct                             5               11.0
time-to-event-wk-10th                  NA               36.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0990    1.1190    0.2341   18.8100    0.5077


$Region_Northamerica$Pneumonia
$Region_Northamerica$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               3.0                8.0
n_event_pct                          14.0               21.0
time-to-event-wk-10th                11.3                6.9
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6170    0.6804    0.4260    6.1340    0.4802


$Region_Northamerica$`Pneumonia aspiration`
$Region_Northamerica$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               3.0                5.0
```

```
n_event_pct                          14.0              13.0
time-to-event-wk-10th                15.7              32.7
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8196    0.7336    0.1946    3.4520    0.7863


$Region_Northamerica$`Pneumonia bacterial`
$Region_Northamerica$`Pneumonia bacterial`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                              2.0               3.0
n_event_pct                          9.0               8.0
time-to-event-wk-10th               36.6              45.3
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          36.6                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Pneumonia bacterial`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7110    0.9155    0.1182    4.2780    0.7095


$Region_Northamerica$`Pneumonia viral`
$Region_Northamerica$`Pneumonia viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0              38.0
n_event                              2.0               5.0
n_event_pct                          9.0              13.0
time-to-event-wk-10th               52.6              27.6
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          52.6                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3930    0.8449    0.2660    7.2970    0.6947


$Region_Northamerica$`Respiratory arrest`
$Region_Northamerica$`Respiratory arrest`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0                38
n_event                               4.0                 1
n_event_pct                          18.0                 3
time-to-event-wk-10th                19.9                NA
time-to-event-wk-25th                26.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           20.4                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.10790   1.12200   0.01197   0.97260   0.04718


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               6.0              12.0
n_event_pct                          27.0              32.0
time-to-event-wk-10th                 3.1               7.1
time-to-event-wk-25th                28.6              21.9
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           15.9              43.4
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9881    0.5029    0.3687    2.6480    0.9810


$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0              38.0
n_event                               7.0              11.0
n_event_pct                          32.0              29.0
time-to-event-wk-10th                13.1               4.1
time-to-event-wk-25th                18.1              32.1
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           18.1              43.4
time-to-event-wk-50th-hici             NA                NA

$Region_Northamerica$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8025    0.4849    0.3102    2.0760    0.6501
```

```
$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`
$Region_Northamerica$`Respiratory syncytial virus bronchiolitis`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38
n_event                              3.0                 3
n_event_pct                         14.0                 8
time-to-event-wk-10th               17.7                34
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          22.4                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Respiratory syncytial virus
bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.42960   0.82440   0.08537   2.16200   0.30540


$Region_Northamerica$`Rhinovirus infection`
$Region_Northamerica$`Rhinovirus infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                22              38.0
n_event                               1               4.0
n_event_pct                           5              11.0
time-to-event-wk-10th                NA              45.3
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Region_Northamerica$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.0530    1.1190    0.2289   18.4000    0.5205


$Region_Northamerica$`Upper respiratory tract infection`
$Region_Northamerica$`Upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                22              38.0
n_event                               0               4.0
n_event_pct                           0              11.0
time-to-event-wk-10th                NA              30.9
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA
```

```
$Region_Northamerica$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.606e+08 1.307e+04 0.000e+00       Inf 9.988e-01


$Region_Northamerica$`Viral upper respiratory tract infection`
$Region_Northamerica$`Viral upper respiratory tract infection`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               22.0                38
n_event                              6.0                 3
n_event_pct                         27.0                 8
time-to-event-wk-10th               11.7                NA
time-to-event-wk-25th               33.4                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          33.4                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Northamerica$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.24610   0.71120   0.06106   0.99190   0.04867



$Disdur_greater_12wk
$Disdur_greater_12wk$`Acute respiratory failure`
$Disdur_greater_12wk$`Acute respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                23              46.0
n_event                               5               7.0
n_event_pct                          22              15.0
time-to-event-wk-10th                13              19.9
time-to-event-wk-25th                26                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           26                NA
time-to-event-wk-50th-hici           NA                NA

$Disdur_greater_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6034    0.5875    0.1908    1.9080    0.3898


$Disdur_greater_12wk$`Apparent life threatening event`
$Disdur_greater_12wk$`Apparent life threatening event`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                23                46
n_event                               2                 0
n_event_pct                           9                 0
time-to-event-wk-10th                NA                NA
time-to-event-wk-25th                NA                NA
```

```
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Apparent life threatening event`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
5.790e-10 2.045e+04 0.000e+00       Inf 9.992e-01


$Disdur_greater_12wk$Atelectasis
$Disdur_greater_12wk$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23                 46
n_event                                 3                  6
n_event_pct                            13                 13
time-to-event-wk-10th                  11                 18
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8448    0.7132    0.2088    3.4180    0.8130


$Disdur_greater_12wk$Bronchiolitis
$Disdur_greater_12wk$Bronchiolitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23                 46
n_event                                 1                  3
n_event_pct                             4                  7
time-to-event-wk-10th                  NA                 NA
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5500    1.1580    0.1603   14.9900    0.7049


$Disdur_greater_12wk$`Cardio-respiratory arrest`
$Disdur_greater_12wk$`Cardio-respiratory arrest`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               2.0                4.0
```

```
n_event_pct                             9.0                9.0
time-to-event-wk-10th                  17.6               25.4
time-to-event-wk-25th                    NA                 NA
time-to-event-wk-50th                    NA                 NA
time-to-event-wk-75th                    NA                 NA
time-to-event-wk-90th                    NA                 NA
time-to-event-wk-50th-loci               NA                 NA
time-to-event-wk-50th-hici               NA                 NA

$Disdur_greater_12wk$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8262    0.8684    0.1506    4.5320    0.8260


$Disdur_greater_12wk$Dyspnoea
$Disdur_greater_12wk$Dyspnoea$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 23                46.0
n_event                                0                 4.0
n_event_pct                            0                 9.0
time-to-event-wk-10th                 NA                29.7
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci            NA                  NA
time-to-event-wk-50th-hici            NA                  NA

$Disdur_greater_12wk$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.211e+08 1.382e+04 0.000e+00       Inf 9.989e-01


$Disdur_greater_12wk$Hypoxia
$Disdur_greater_12wk$Hypoxia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                 23                  46
n_event                                0                   3
n_event_pct                            0                   7
time-to-event-wk-10th                 NA                  NA
time-to-event-wk-25th                 NA                  NA
time-to-event-wk-50th                 NA                  NA
time-to-event-wk-75th                 NA                  NA
time-to-event-wk-90th                 NA                  NA
time-to-event-wk-50th-loci            NA                  NA
time-to-event-wk-50th-hici            NA                  NA

$Disdur_greater_12wk$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.736e+08 1.619e+04 0.000e+00       Inf 9.990e-01


$Disdur_greater_12wk$`Lower respiratory tract infection`
$Disdur_greater_12wk$`Lower respiratory tract infection`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 0                4.0
n_event_pct                             0                9.0
time-to-event-wk-10th                  NA               38.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Lower respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.347e+08 1.364e+04 0.000e+00       Inf 9.989e-01


$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               3.0               11.0
n_event_pct                          13.0               24.0
time-to-event-wk-10th                11.3               10.6
time-to-event-wk-25th                  NA               35.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3910    0.6539    0.3861    5.0100    0.6138


$Disdur_greater_12wk$`Pneumonia aspiration`
$Disdur_greater_12wk$`Pneumonia aspiration`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               2.0                4.0
n_event_pct                           9.0                9.0
time-to-event-wk-10th                15.7               28.7
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9021    0.8694    0.1642    4.9580    0.9057
```

```
$Disdur_greater_12wk$`Pneumonia viral`
$Disdur_greater_12wk$`Pneumonia viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0              46.0
n_event                              2.0               5.0
n_event_pct                          9.0              11.0
time-to-event-wk-10th               52.6              27.6
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          52.6                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_greater_12wk$`Pneumonia viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2410    0.8392    0.2395    6.4260    0.7972


$Disdur_greater_12wk$`Respiratory arrest`
$Disdur_greater_12wk$`Respiratory arrest`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                23                46
n_event                               1                 3
n_event_pct                           4                 7
time-to-event-wk-10th                NA                NA
time-to-event-wk-25th                NA                NA
time-to-event-wk-50th                NA                NA
time-to-event-wk-75th                NA                NA
time-to-event-wk-90th                NA                NA
time-to-event-wk-50th-loci           NA                NA
time-to-event-wk-50th-hici           NA                NA

$Disdur_greater_12wk$`Respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3150    1.1580    0.1359   12.7300    0.8130


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0              46.0
n_event                              5.0              13.0
n_event_pct                         22.0              28.0
time-to-event-wk-10th               11.0               7.1
time-to-event-wk-25th               28.6              23.9
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          28.6              35.0
time-to-event-wk-50th-hici            NA                NA

$Disdur_greater_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1630    0.5297    0.4119    3.2860    0.7752


$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               9.0                11
n_event_pct                          39.0                24
time-to-event-wk-10th                 3.4                10
time-to-event-wk-25th                13.1                34
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           13.1                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5414    0.4563    0.2214    1.3240    0.1787


$Disdur_greater_12wk$`Rhinovirus infection`
$Disdur_greater_12wk$`Rhinovirus infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23               46.0
n_event                                 1                5.0
n_event_pct                             4               11.0
time-to-event-wk-10th                  NA               21.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.3220    1.0990    0.2695   20.0100    0.4433


$Disdur_greater_12wk$`Upper respiratory tract infection`
$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  23                46
n_event                                 0                 3
n_event_pct                             0                 7
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
```

```
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.344e+08 1.555e+04 0.000e+00       Inf 9.990e-01


$Disdur_greater_12wk$`Viral upper respiratory tract infection`
$Disdur_greater_12wk$`Viral upper respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0                46
n_event                               4.0                 1
n_event_pct                          17.0                 2
time-to-event-wk-10th                11.7                NA
time-to-event-wk-25th                37.3                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           37.3                NA
time-to-event-wk-50th-hici             NA                NA

$Disdur_greater_12wk$`Viral upper respiratory tract
infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.09551   1.12000   0.01064   0.85720   0.03594



$Region_Asia_Pacific
$Region_Asia_Pacific$Atelectasis
$Region_Asia_Pacific$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2                12
n_event                                 0                 1
n_event_pct                             0                 8
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                28
time-to-event-wk-50th-hici             NA                NA

$Region_Asia_Pacific$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.355e+07 3.107e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$Dyspnoea
$Region_Asia_Pacific$Dyspnoea$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2               12.0
n_event                                 0                2.0
n_event_pct                             0               17.0
```

```
time-to-event-wk-10th                  NA               12.3
time-to-event-wk-25th                  NA                 NA
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               12.3
time-to-event-wk-50th-hici             NA                 NA

$Region_Asia_Pacific$Dyspnoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.266e+07 2.318e+04 0.000e+00       Inf 9.994e-01


$Region_Asia_Pacific$`Failure to thrive`
$Region_Asia_Pacific$`Failure to thrive`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2                12
n_event                                 0                 1
n_event_pct                             0                 8
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Asia_Pacific$`Failure to thrive`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.272e+07 4.420e+04 0.000e+00       Inf 9.997e-01


$Region_Asia_Pacific$`Lower respiratory tract infection`
$Region_Asia_Pacific$`Lower respiratory tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2                12
n_event                                 0                 1
n_event_pct                             0                 8
time-to-event-wk-10th                  NA                35
time-to-event-wk-25th                  NA                35
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                35
time-to-event-wk-50th-hici             NA                NA

$Region_Asia_Pacific$`Lower respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.307e-05 8.662e+04 0.000e+00       Inf 9.999e-01


$Region_Asia_Pacific$`Lung infection`
$Region_Asia_Pacific$`Lung infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                  2                 12
n_event                                0                  1
n_event_pct                            0                  8
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Asia_Pacific$`Lung infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.385e+07 3.163e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$Nasopharyngitis
$Region_Asia_Pacific$Nasopharyngitis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  2                 12
n_event                                0                  1
n_event_pct                            0                  8
time-to-event-wk-10th                 NA                 NA
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Region_Asia_Pacific$Nasopharyngitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.632e+07 3.281e+04 0.000e+00       Inf 9.996e-01


$Region_Asia_Pacific$Pneumonia
$Region_Asia_Pacific$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                  2               12.0
n_event                                0                5.0
n_event_pct                            0               42.0
time-to-event-wk-10th                 NA               20.0
time-to-event-wk-25th                 NA               25.3
time-to-event-wk-50th                 NA               43.6
time-to-event-wk-75th                 NA               43.6
time-to-event-wk-90th                 NA               43.6
time-to-event-wk-50th-loci            NA               20.0
time-to-event-wk-50th-hici            NA                 NA

$Region_Asia_Pacific$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.077e+08 1.830e+04 0.000e+00       Inf 9.992e-01
```

```
$Region_Asia_Pacific$`Pneumonia parainfluenzae viral`
$Region_Asia_Pacific$`Pneumonia parainfluenzae viral`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  2                12
n_event                                0                 1
n_event_pct                            0                 8
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Pneumonia parainfluenzae viral`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.234e-03 1.671e+05 0.000e+00       Inf 1.000e+00


$Region_Asia_Pacific$`Respiratory distress`
$Region_Asia_Pacific$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                  2                12
n_event                                0                 1
n_event_pct                            0                 8
time-to-event-wk-10th                 NA                NA
time-to-event-wk-25th                 NA                NA
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci            NA                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.732e+07 3.123e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$`Respiratory failure`
$Region_Asia_Pacific$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                2.0                12
n_event                              1.0                 0
n_event_pct                         50.0                 0
time-to-event-wk-10th                0.9                NA
time-to-event-wk-25th                0.9                NA
time-to-event-wk-50th               25.1                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci           0.9                NA
time-to-event-wk-50th-hici            NA                NA

$Region_Asia_Pacific$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
8.188e-28 8.557e+04 0.000e+00       Inf 9.994e-01


$Region_Asia_Pacific$`Sinus tachycardia`
$Region_Asia_Pacific$`Sinus tachycardia`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2                12
n_event                                 0                 1
n_event_pct                             0                 8
time-to-event-wk-10th                  NA                NA
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA                NA
time-to-event-wk-50th-hici             NA                NA

$Region_Asia_Pacific$`Sinus tachycardia`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.385e+07 3.163e+04 0.000e+00       Inf 9.995e-01


$Region_Asia_Pacific$`Urinary tract infection`
$Region_Asia_Pacific$`Urinary tract infection`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                   2              12.0
n_event                                 0               2.0
n_event_pct                             0              17.0
time-to-event-wk-10th                  NA              26.9
time-to-event-wk-25th                  NA                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci             NA              26.9
time-to-event-wk-50th-hici             NA                NA

$Region_Asia_Pacific$`Urinary tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.423e+07 2.038e+04 0.000e+00       Inf 9.993e-01




\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines SUEs nach PT, das bei mindestens 10 Patienten
und 1% der Patienten in einem Studienarm auftrat"

$Ageonset_less_equal_12wk
$Ageonset_less_equal_12wk$`Acute respiratory failure`
$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0                72
n_event                               7.0                10
```

```
n_event_pct                          22.0                14
time-to-event-wk-10th                 8.6                13
time-to-event-wk-25th                22.4                NA
time-to-event-wk-50th                  NA                NA
time-to-event-wk-75th                  NA                NA
time-to-event-wk-90th                  NA                NA
time-to-event-wk-50th-loci           52.6                NA
time-to-event-wk-50th-hici             NA                NA

$Ageonset_less_equal_12wk$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.4959    0.4990    0.1865    1.3180    0.1598


$Ageonset_less_equal_12wk$Atelectasis
$Ageonset_less_equal_12wk$Atelectasis$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              4.0               14.0
n_event_pct                         12.0               19.0
time-to-event-wk-10th               17.6               14.4
time-to-event-wk-25th                 NA                 NA
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2470    0.5691    0.4088    3.8040    0.6980


$Ageonset_less_equal_12wk$Pneumonia
$Ageonset_less_equal_12wk$Pneumonia$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               32.0               72.0
n_event                              4.0               18.0
n_event_pct                         12.0               25.0
time-to-event-wk-10th               13.7                9.0
time-to-event-wk-25th                 NA               35.9
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci            NA                 NA
time-to-event-wk-50th-hici            NA                 NA

$Ageonset_less_equal_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.6660    0.5539    0.5627    4.9340    0.3567


$Ageonset_less_equal_12wk$`Respiratory distress`
$Ageonset_less_equal_12wk$`Respiratory distress`$stats_num
```

```
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                               6.0               20.0
n_event_pct                          19.0               28.0
time-to-event-wk-10th                11.0                8.9
time-to-event-wk-25th                28.6               25.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2360    0.4691    0.4929    3.1010    0.6511


$Ageonset_less_equal_12wk$`Respiratory failure`
$Ageonset_less_equal_12wk$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                32.0               72.0
n_event                              15.0               18.0
n_event_pct                          47.0               25.0
time-to-event-wk-10th                 3.4               10.0
time-to-event-wk-25th                 9.1               32.1
time-to-event-wk-50th                21.9                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.0                 NA
time-to-event-wk-50th-hici             NA                 NA

$Ageonset_less_equal_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.379200  0.357500  0.188200  0.764100  0.006681



$Region_Northamerica
$Region_Northamerica$`Acute respiratory failure`
$Region_Northamerica$`Acute respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               7.0               11.0
n_event_pct                          32.0               29.0
time-to-event-wk-10th                13.0                9.0
time-to-event-wk-25th                22.4               25.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           22.4               28.0
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
   0.8485    0.4860    0.3273    2.2000    0.7354


$Region_Northamerica$`Respiratory distress`
$Region_Northamerica$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               6.0               12.0
n_event_pct                          27.0               32.0
time-to-event-wk-10th                 3.1                7.1
time-to-event-wk-25th                28.6               21.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9               43.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9881    0.5029    0.3687    2.6480    0.9810


$Region_Northamerica$`Respiratory failure`
$Region_Northamerica$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                22.0               38.0
n_event                               7.0               11.0
n_event_pct                          32.0               29.0
time-to-event-wk-10th                13.1                4.1
time-to-event-wk-25th                18.1               32.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           18.1               43.4
time-to-event-wk-50th-hici             NA                 NA

$Region_Northamerica$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8025    0.4849    0.3102    2.0760    0.6501



$Agetrt_less_180d
$Agetrt_less_180d$Atelectasis
$Agetrt_less_180d$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0               10.0
n_event_pct                          12.0               20.0
time-to-event-wk-10th                17.6               14.4
time-to-event-wk-25th                32.9               44.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
```

```
time-to-event-wk-50th-loci           17.6                 NA
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2360    0.7855    0.2650    5.7620    0.7876


$Agetrt_less_180d$Pneumonia
$Agetrt_less_180d$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0               14.0
n_event_pct                          12.0               29.0
time-to-event-wk-10th                13.9                5.0
time-to-event-wk-25th                  NA               33.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           13.9               42.4
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.8540    0.7624    0.4160    8.2620    0.4182


$Agetrt_less_180d$`Respiratory distress`
$Agetrt_less_180d$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               2.0               14.0
n_event_pct                          12.0               29.0
time-to-event-wk-10th                15.4                8.9
time-to-event-wk-25th                  NA               35.0
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.4               43.4
time-to-event-wk-50th-hici             NA                 NA

$Agetrt_less_180d$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3150    0.7721    0.2895    5.9700    0.7231


$Agetrt_less_180d$`Respiratory failure`
$Agetrt_less_180d$`Respiratory failure`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                16.0               49.0
n_event                               9.0               12.0
n_event_pct                          56.0               24.0
time-to-event-wk-10th                 1.0                4.1
time-to-event-wk-25th                 6.1               32.1
```

```
time-to-event-wk-50th                13.0                  NA
time-to-event-wk-75th                  NA                  NA
time-to-event-wk-90th                  NA                  NA
time-to-event-wk-50th-loci            6.1                  NA
time-to-event-wk-50th-hici             NA                  NA

$Agetrt_less_180d$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
 0.229800  0.477600  0.090120  0.585900  0.002074



$Gender_Female
$Gender_Female$Atelectasis
$Gender_Female$Atelectasis$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               4.0               10.0
n_event_pct                          17.0               23.0
time-to-event-wk-10th                17.6               13.1
time-to-event-wk-25th                  NA               32.1
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           32.9               44.0
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Atelectasis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2430    0.6064    0.3786    4.0780    0.7202


$Gender_Female$Pneumonia
$Gender_Female$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                24.0               43.0
n_event                               2.0               14.0
n_event_pct                           8.0               33.0
time-to-event-wk-10th                13.7                6.9
time-to-event-wk-25th                  NA               25.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA               33.1
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  3.62800   0.76150   0.81560  16.14000   0.09059


$Gender_Female$`Respiratory distress`
$Gender_Female$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
```

```
n_all                                24.0               43.0
n_event                               7.0               11.0
n_event_pct                          29.0               26.0
time-to-event-wk-10th                11.0               20.3
time-to-event-wk-25th                15.9               43.4
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           15.9               45.3
time-to-event-wk-50th-hici             NA                 NA

$Gender_Female$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6971    0.4961    0.2637    1.8430    0.4670



$Disdur_greater_12wk
$Disdur_greater_12wk$Pneumonia
$Disdur_greater_12wk$Pneumonia$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               3.0               11.0
n_event_pct                          13.0               24.0
time-to-event-wk-10th                11.3               10.6
time-to-event-wk-25th                  NA               35.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci             NA                 NA
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3910    0.6539    0.3861    5.0100    0.6138


$Disdur_greater_12wk$`Respiratory distress`
$Disdur_greater_12wk$`Respiratory distress`$stats_num
                           TRT01P=Control TRT01P=ISIS 396443
n_all                                23.0               46.0
n_event                               5.0               13.0
n_event_pct                          22.0               28.0
time-to-event-wk-10th                11.0                7.1
time-to-event-wk-25th                28.6               23.9
time-to-event-wk-50th                  NA                 NA
time-to-event-wk-75th                  NA                 NA
time-to-event-wk-90th                  NA                 NA
time-to-event-wk-50th-loci           28.6               35.0
time-to-event-wk-50th-hici             NA                 NA

$Disdur_greater_12wk$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1630    0.5297    0.4119    3.2860    0.7752
```

```
$Disdur_greater_12wk$`Respiratory failure`
$Disdur_greater_12wk$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               23.0                46
n_event                              9.0                11
n_event_pct                         39.0                24
time-to-event-wk-10th                3.4                10
time-to-event-wk-25th               13.1                34
time-to-event-wk-50th                 NA                NA
time-to-event-wk-75th                 NA                NA
time-to-event-wk-90th                 NA                NA
time-to-event-wk-50th-loci          13.1                NA
time-to-event-wk-50th-hici            NA                NA

$Disdur_greater_12wk$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5414    0.4563    0.2214    1.3240    0.1787



$Gender_Male
$Gender_Male$`Respiratory distress`
$Gender_Male$`Respiratory distress`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                                17               37.0
n_event                               1               10.0
n_event_pct                           6               27.0
time-to-event-wk-10th                NA                3.4
time-to-event-wk-25th                NA               19.3
time-to-event-wk-50th                NA                 NA
time-to-event-wk-75th                NA                 NA
time-to-event-wk-90th                NA                 NA
time-to-event-wk-50th-loci           NA               35.0
time-to-event-wk-50th-hici           NA                 NA

$Gender_Male$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.8680    1.0560    0.4886   30.6300    0.2000


$Gender_Male$`Respiratory failure`
$Gender_Male$`Respiratory failure`$stats_num
                          TRT01P=Control TRT01P=ISIS 396443
n_all                               17.0               37.0
n_event                              7.0               11.0
n_event_pct                         41.0               30.0
time-to-event-wk-10th                1.0                1.7
time-to-event-wk-25th               13.0               27.0
time-to-event-wk-50th                 NA                 NA
time-to-event-wk-75th                 NA                 NA
time-to-event-wk-90th                 NA                 NA
time-to-event-wk-50th-loci           7.4               31.9
```

```
time-to-event-wk-50th-hici             NA                  NA

$Gender_Male$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6666    0.4951    0.2526    1.7590    0.4127



\#############################################################################
```

ENDEAR
p-Values for SG Interaction
[[1]]
[1] "Überlebensrate"

[[2]]
	p Value of SG Interaction
AGEONSET	0.0416
AGETRT	0.0806
SEX	0.4565
REGION	0.2069
DISDUR	0.6156

\##
[[1]]
[1] "Zeit bis zum Tod"

[[2]]
	p Value of SG Interaction
AGEONSET	0.0214
AGETRT	0.0921
SEX	0.8420
REGION	0.1043
DISDUR	0.5641

\##
[[1]]
[1] "Zeit bis zum Tod oder permanenter Beatmung (>=16 Stunden Beatmung/Tag für >21 Tage in der Abwesenheit eines akuten reversiblen Ereignisses oder Tracheostomie)"

[[2]]
	p Value of SG Interaction
AGEONSET	0.3744
AGETRT	0.0440
SEX	0.0275
REGION	0.0017
DISDUR	0.0026

\##
[[1]]
[1] "Zeit bis zu permanenter Beatmung (>=16 Stunden Beatmung/Tag für >21 Tage in der Abwesenheit eines akuten reversiblen Ereignisses oder Tracheostomie)"

[[2]]
	p Value of SG Interaction
AGEONSET	0.1566
AGETRT	0.2711
SEX	0.0049
REGION	0.0337
DISDUR	0.0015

```
\#############################################################################
[[1]]
[1] "Anzahl der Stunden mit Beatmung (Std.) für Patienten die zu Baseline keine
Beatmung benötigten"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.5184
AGETRT                      0.0597
SEX                         0.2202
REGION                      0.0030
DISDUR                      0.0007


\#############################################################################
[[1]]
[1] "Anteil an Patienten, die keine permanente Beatmung benötigen (>=16 Stunden
Beatmung/Tag für >21 Tage in der Abwesenheit eines akuten reversiblen
Ereignisses oder Tracheostomie)"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.2131
AGETRT                      0.5434
SEX                         0.0128
REGION                      0.5451
DISDUR                      0.0074


\#############################################################################
[[1]]
[1] "Zeit bis zur Beatmung (unabhängig von der Dauer) für Patienten die zu
Baseline keine Beatmung benötigten"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.9206
AGETRT                      0.0992
SEX                         0.1201
REGION                      0.0128
DISDUR                      0.0475


\#############################################################################
[[1]]
[1] "Anteil an Patienten, die keine Beatmung benötigen und zu Baseline keine
Beatmung benötigten (unabhängig von der Dauer)"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.4954
AGETRT                      0.6872
```

```
SEX                         0.3278
REGION                      0.0728
DISDUR                      0.4620


\#############################################################################
[[1]]
[1] "HINE-Responder (Subskala 2)"

[[2]]
         p Value of SG Interaction: Overall p Value of SG Interaction: Day 64
AGEONSET                             0.5603                             0.4478
AGETRT                               0.1214                             0.1067
SEX                                  0.1830                             0.3352
REGION                               0.5299                             0.2126
DISDUR                               0.0036                             0.0087
         p Value of SG Interaction: Day 183 p Value of SG Interaction: Day 302
AGEONSET                             0.2926                              0.9162
AGETRT                               0.0129                              0.8347
SEX                                  0.0945                              0.3946
REGION                               0.5144                              0.7427
DISDUR                               0.0001                              0.3175
         p Value of SG Interaction: Day 394
AGEONSET                             0.4756
AGETRT                               0.9338
SEX                                  0.0660
REGION                               0.6192
DISDUR                               0.6499


\#############################################################################
[[1]]
[1] "Zeit bis zum HINE-Responder (Subskala 2)"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.0049
AGETRT                      0.6445
SEX                         0.2480
REGION                      0.2231
DISDUR                      0.0041


\#############################################################################
[[1]]
[1] "Veränderung des HINE-Scores (Subskala 2) von Baseline"

[[2]]
         p Value of SG Interaction: Day 64 p Value of SG Interaction: Day 183
AGEONSET                           0.9231                             0.1605
AGETRT                             0.5323                             0.2117
SEX                                0.9605                             0.3911
REGION                             0.3764                             0.9188
DISDUR                             0.2779                             0.0093
```

```
         p Value of SG Interaction: Day 302 p Value of SG Interaction: Day 394
AGEONSET                            0.2696                             0.8943
AGETRT                              0.4594                             0.4161
SEX                                 0.6201                             0.9159
REGION                              0.6199                             0.5988
DISDUR                              0.1287                             0.3166


\#############################################################################
[[1]]
[1] "CHOP INTEND-Responder"

[[2]]
         p Value of SG Interaction: Overall p Value of SG Interaction: Day 64
AGEONSET                            0.2146                            0.2557
AGETRT                              0.8208                            0.5737
SEX                                 0.8210                            0.5873
REGION                              0.3258                            0.6090
DISDUR                              0.4220                            0.1774
         p Value of SG Interaction: Day 183 p Value of SG Interaction: Day 302
AGEONSET                            0.3542                             0.0862
AGETRT                              0.4151                             0.8457
SEX                                 0.2168                             0.4343
REGION                              0.5279                             0.8147
DISDUR                              0.2392                             0.8725
         p Value of SG Interaction: Day 394
AGEONSET                            0.4370
AGETRT                              0.9750
SEX                                 0.1748
REGION                              0.6397
DISDUR                              0.5617


\#############################################################################
[[1]]
[1] "Zeit bis zum CHOP INTEND Responder"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.3374
AGETRT                      0.5277
SEX                         0.2490
REGION                      0.7434
DISDUR                      0.7177


\#############################################################################
[[1]]
[1] "Veränderung des CHOP INTEND von Baseline"

[[2]]
         p Value of SG Interaction: Day 64 p Value of SG Interaction: Day 183
AGEONSET                            0.2332                             0.4317
AGETRT                              0.1828                             0.0150
```

```
SEX                                 0.4924                                 0.6527
REGION                              0.0411                                 0.0254
DISDUR                              0.0098                                 0.0003
         p Value of SG Interaction: Day 302 p Value of SG Interaction: Day 394
AGEONSET                             0.5432                                 0.8669
AGETRT                               0.0263                                 0.0722
SEX                                  0.1350                                 0.0323
REGION                               0.4704                                 0.5574
DISDUR                               0.0084                                 0.1278


\##############################################################################
[[1]]
[1] "Veränderung des HINE-Scores (Subskala 1) von Baseline"

[[2]]
         p Value of SG Interaction: Day 64 p Value of SG Interaction: Day 183
AGEONSET                                NA                                  NA
AGETRT                                  NA                              0.0509
SEX                                     NA                              0.2307
REGION                                  NA                              0.6529
DISDUR                                  NA                              0.0301
         p Value of SG Interaction: Day 302 p Value of SG Interaction: Day 394
AGEONSET                                 NA                                 0.3728
AGETRT                                   NA                                 0.7653
SEX                                      NA                                 0.5461
REGION                                   NA                                 0.5286
DISDUR                                   NA                                 0.8474


\##############################################################################
[[1]]
[1] "Veränderung des HINE-Scores (Subskala 3) von Baseline"

[[2]]
         p Value of SG Interaction: Day 64 p Value of SG Interaction: Day 183
AGEONSET                                NA                                  NA
AGETRT                                  NA                              0.3883
SEX                                     NA                              0.2800
REGION                                  NA                              0.9742
DISDUR                                  NA                              0.1171
         p Value of SG Interaction: Day 302 p Value of SG Interaction: Day 394
AGEONSET                                 NA                                 0.0272
AGETRT                                   NA                                 0.3599
SEX                                      NA                                 0.6824
REGION                                   NA                                 0.2454
DISDUR                                   NA                                 0.9955


\##############################################################################
[[1]]
[1] "Anteil von Hospitalisierungszeiten"

[[2]]
```

```
         p Value of SG Interaction
AGEONSET                    0.0573
AGETRT                      0.1777
SEX                         0.5144
REGION                      0.0803
DISDUR                      0.6278


\#############################################################################
[[1]]
[1] "Häufigkeit von Hospitalisierungen"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.4452
AGETRT                      0.5246
SEX                         0.3492
REGION                      0.8536
DISDUR                      0.1899


\#############################################################################
[[1]]
[1] "Zeit bis zur Hospitalisierung"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.8492
AGETRT                      0.2451
SEX                         0.1261
REGION                      0.1913
DISDUR                      0.4006


\#############################################################################
[[1]]
[1] "Häufigkeit von schwerwiegenden respiratorischen Ereignissen"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.2171
AGETRT                      0.0441
SEX                         0.8665
REGION                      0.7364
DISDUR                      0.2570


\#############################################################################
[[1]]
[1] "Zeit bis zu schwerwiegenden respiratorischen Ereignissen"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.3994
```

```
AGETRT                      0.0519
SEX                         0.5773
REGION                      0.3209
DISDUR                      0.3332


\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem UE"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.9163
AGETRT                      0.1558
SEX                         0.2995
REGION                      0.8436
DISDUR                      0.1384


\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem milden UE"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.5250
AGETRT                      0.4909
SEX                         0.5389
REGION                      0.0835
DISDUR                      0.4913


\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten UE"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.5403
AGETRT                      0.6760
SEX                         0.1415
REGION                      0.7252
DISDUR                      0.6177


\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten oder schweren UE"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.4841
AGETRT                      0.3731
SEX                         0.8158
```

```
REGION                      0.9033
DISDUR                      0.3151


\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem schweren UE"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.8794
AGETRT                      0.1746
SEX                         0.8086
REGION                      0.6769
DISDUR                      0.1414


\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.8339
AGETRT                      0.6675
SEX                         0.7371
REGION                      0.6146
DISDUR                      0.5851


\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem schwerwiegenden UE"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.7026
AGETRT                      0.7384
SEX                         0.4216
REGION                      0.4510
DISDUR                      0.4540


\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schwerwiegenden UEs"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.6225
AGETRT                      0.1338
SEX                         0.7578
REGION                      0.8496
DISDUR                      0.4258
```

```
\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines milden UEs"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.3301
AGETRT                      0.4920
SEX                         0.8932
REGION                      0.0331
DISDUR                      0.3093


\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten UEs"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.6521
AGETRT                      0.1301
SEX                         0.2003
REGION                      0.9013
DISDUR                      0.2263


\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten oder schweren UEs"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.6058
AGETRT                      0.0701
SEX                         0.6761
REGION                      0.4204
DISDUR                      0.2209


\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schweren UEs"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.5605
AGETRT                      0.1044
SEX                         0.8945
REGION                      0.7462
DISDUR                      0.2094
```

```
\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem UE das zum Therapieabbruch führte"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.0416
AGETRT                      0.0806
SEX                         0.4565
REGION                      0.2069
DISDUR                      0.6156


\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs das zum Therapieabbruch führte"

[[2]]
         p Value of SG Interaction
AGEONSET                    0.0210
AGETRT                      0.0918
SEX                         0.8553
REGION                      0.1046
DISDUR                      0.5600


\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem UE nach SOC, das bei mindestens 10% der
Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Blood and lymphatic system disorders`
         p Value of SG Interaction
AGEONSET                    0.5118
AGETRT                      0.3501
SEX                         0.4604
REGION                      0.9079
DISDUR                      0.0826

$`Cardiac disorders`
         p Value of SG Interaction
AGEONSET                    0.2198
AGETRT                      0.2450
SEX                         0.1476
REGION                      0.2360
DISDUR                      0.3858

$`Congenital, familial and genetic disorders`
         p Value of SG Interaction
AGEONSET                    0.5723
AGETRT                      0.2275
SEX                         0.5300
REGION                      0.4808
```

```
DISDUR                      0.1744

$`Ear and labyrinth disorders`
         p Value of SG Interaction
AGEONSET                    0.9993
AGETRT                      0.6610
SEX                         0.2029
REGION                      0.9944
DISDUR                      0.7845

$`Eye disorders`
         p Value of SG Interaction
AGEONSET                    0.4108
AGETRT                      0.2436
SEX                         0.6972
REGION                      0.0082
DISDUR                      0.0671

$`Gastrointestinal disorders`
         p Value of SG Interaction
AGEONSET                    0.1520
AGETRT                      0.5555
SEX                         0.9972
REGION                      0.6251
DISDUR                      0.0612

$`General disorders and administration site conditions`
         p Value of SG Interaction
AGEONSET                    0.5920
AGETRT                      0.9142
SEX                         0.6927
REGION                      0.8460
DISDUR                      0.1550

$`Hepatobiliary disorders`
         p Value of SG Interaction
AGEONSET                    0.8010
AGETRT                      0.5644
SEX                         0.3177
REGION                      0.6540
DISDUR                      0.3723

$`Immune system disorders`
         p Value of SG Interaction
AGEONSET                    0.4862
AGETRT                      0.9651
SEX                         0.3526
REGION                      0.7772
DISDUR                      0.9504

$`Infections and infestations`
         p Value of SG Interaction
AGEONSET                    0.0812
AGETRT                      0.8962
```

```
SEX                         0.2931
REGION                      0.0548
DISDUR                      0.1842

$`Injury, poisoning and procedural complications`
         p Value of SG Interaction
AGEONSET                    0.6620
AGETRT                      0.3821
SEX                         0.9835
REGION                      0.2500
DISDUR                      0.1266

$Investigations
         p Value of SG Interaction
AGEONSET                    0.9784
AGETRT                      0.5812
SEX                         0.9778
REGION                      0.1568
DISDUR                      0.3443

$`Metabolism and nutrition disorders`
         p Value of SG Interaction
AGEONSET                    0.7003
AGETRT                      0.9185
SEX                         0.4035
REGION                      0.5323
DISDUR                      0.6630

$`Musculoskeletal and connective tissue disorders`
         p Value of SG Interaction
AGEONSET                    0.4037
AGETRT                      0.6378
SEX                         0.3991
REGION                      0.9797
DISDUR                      0.6752

$`Nervous system disorders`
         p Value of SG Interaction
AGEONSET                    0.1756
AGETRT                      0.3699
SEX                         0.7137
REGION                      0.0200
DISDUR                      0.1478

$`Psychiatric disorders`
         p Value of SG Interaction
AGEONSET                    0.8503
AGETRT                      0.5265
SEX                         0.3033
REGION                      0.2924
DISDUR                      0.4229

$`Renal and urinary disorders`
         p Value of SG Interaction
```

```
AGEONSET                    0.9756
AGETRT                      0.1948
SEX                         0.1381
REGION                      0.9975
DISDUR                      0.7692

$`Reproductive system and breast disorders`
         p Value of SG Interaction
AGEONSET                    0.5439
AGETRT                      0.6948
SEX                         0.5315
REGION                      0.8723
DISDUR                      0.4625

$`Respiratory, thoracic and mediastinal disorders`
         p Value of SG Interaction
AGEONSET                    0.4253
AGETRT                      0.1572
SEX                         0.6889
REGION                      0.8562
DISDUR                      0.1691

$`Skin and subcutaneous tissue disorders`
         p Value of SG Interaction
AGEONSET                    0.2608
AGETRT                      0.6975
SEX                         0.3356
REGION                      0.5779
DISDUR                      0.1373

$`Surgical and medical procedures`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Vascular disorders`
         p Value of SG Interaction
AGEONSET                    0.1214
AGETRT                      0.3008
SEX                         0.4187
REGION                      0.9436
DISDUR                      0.9906


\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs nach SOC, das bei mindestens 10% der
Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Blood and lymphatic system disorders`
```

```
         p Value of SG Interaction
AGEONSET                    0.6665
AGETRT                      0.6099
SEX                         0.4563
REGION                      0.6871
DISDUR                      0.0649

$`Cardiac disorders`
         p Value of SG Interaction
AGEONSET                    0.0529
AGETRT                      0.2749
SEX                         0.3384
REGION                      0.3124
DISDUR                      0.6420

$`Congenital, familial and genetic disorders`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.4848
SEX                         0.9278
REGION                      0.5047
DISDUR                      0.4605

$`Ear and labyrinth disorders`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.5707
SEX                         0.1023
REGION                      1.0000
DISDUR                      0.5226

$`Eye disorders`
         p Value of SG Interaction
AGEONSET                    0.4484
AGETRT                      0.2050
SEX                         0.6821
REGION                      0.0279
DISDUR                      0.0941

$`Gastrointestinal disorders`
         p Value of SG Interaction
AGEONSET                    0.4015
AGETRT                      0.2166
SEX                         0.8121
REGION                      0.7509
DISDUR                      0.0713

$`General disorders and administration site conditions`
         p Value of SG Interaction
AGEONSET                    0.3499
AGETRT                      0.6011
SEX                         0.6123
REGION                      0.4915
DISDUR                      0.4896
```

$`Hepatobiliary disorders`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Immune system disorders`
         p Value of SG Interaction
AGEONSET   0.4125
AGETRT   0.7125
SEX   0.2323
REGION   0.4391
DISDUR   0.7868

$`Infections and infestations`
         p Value of SG Interaction
AGEONSET   0.6174
AGETRT   0.6628
SEX   0.3499
REGION   0.1103
DISDUR   0.1902

$`Injury, poisoning and procedural complications`
         p Value of SG Interaction
AGEONSET   0.7431
AGETRT   0.3035
SEX   0.9947
REGION   0.0677
DISDUR   0.2217

$Investigations
         p Value of SG Interaction
AGEONSET   0.4511
AGETRT   0.3052
SEX   0.9412
REGION   0.2049
DISDUR   0.3432

$`Metabolism and nutrition disorders`
         p Value of SG Interaction
AGEONSET   0.5271
AGETRT   0.6832
SEX   0.6973
REGION   0.6946
DISDUR   0.9880

$`Musculoskeletal and connective tissue disorders`
         p Value of SG Interaction
AGEONSET   0.1026
AGETRT   0.4606
SEX   0.3468

```
REGION                     0.7168
DISDUR                     0.2709

$`Nervous system disorders`
         p Value of SG Interaction
AGEONSET                   0.1524
AGETRT                     0.3994
SEX                        0.7308
REGION                     0.0240
DISDUR                     0.1607

$`Psychiatric disorders`
         p Value of SG Interaction
AGEONSET                   0.6021
AGETRT                     0.4294
SEX                        0.3307
REGION                     0.2982
DISDUR                     0.3986

$`Renal and urinary disorders`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.1216
SEX                        0.0602
REGION                     1.0000
DISDUR                     0.7245

$`Reproductive system and breast disorders`
         p Value of SG Interaction
AGEONSET                   0.9999
AGETRT                     1.0000
SEX                        1.0000
REGION                     1.0000
DISDUR                     1.0000

$`Respiratory, thoracic and mediastinal disorders`
         p Value of SG Interaction
AGEONSET                   0.2811
AGETRT                     0.1116
SEX                        0.3714
REGION                     0.4018
DISDUR                     0.0346

$`Skin and subcutaneous tissue disorders`
         p Value of SG Interaction
AGEONSET                   0.1296
AGETRT                     0.4240
SEX                        0.4081
REGION                     0.3934
DISDUR                     0.1278

$`Surgical and medical procedures`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Vascular disorders`
         p Value of SG Interaction
AGEONSET                    0.0963
AGETRT                      0.2595
SEX                         0.1877
REGION                      0.6055
DISDUR                      0.9278


\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem UE nach PT, das bei mindestens 10% der
Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Abdominal discomfort`
         p Value of SG Interaction
AGEONSET                    0.6654
AGETRT                      0.8061
SEX                         0.8955
REGION                      0.3359
DISDUR                      0.4441

$`Abdominal distension`
         p Value of SG Interaction
AGEONSET                    0.7813
AGETRT                      0.5757
SEX                         0.5434
REGION                      0.7386
DISDUR                      0.8874

$`Abdominal pain upper`
         p Value of SG Interaction
AGEONSET                    0.2221
AGETRT                      0.1069
SEX                         0.1054
REGION                      0.8720
DISDUR                      0.3212

$`Acquired phimosis`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Acute respiratory distress syndrome`
         p Value of SG Interaction
```

```
AGEONSET                    0.8084
AGETRT                      0.0591
SEX                         0.7605
REGION                      0.2851
DISDUR                      0.2869

$`Acute respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.9483
AGETRT                      0.9830
SEX                         0.9682
REGION                      0.8950
DISDUR                      0.2004

$`Adenovirus infection`
         p Value of SG Interaction
AGEONSET                    0.6526
AGETRT                      0.1940
SEX                         0.8080
REGION                      0.6807
DISDUR                      0.2357

$Agitation
         p Value of SG Interaction
AGEONSET                    0.7204
AGETRT                      0.6289
SEX                         0.6031
REGION                      0.6702
DISDUR                      0.7351

$`Agitation postoperative`
         p Value of SG Interaction
AGEONSET                    0.7813
AGETRT                      0.5757
SEX                         0.5434
REGION                      0.7386
DISDUR                      0.8874

$`Alanine aminotransferase increased`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$Amblyopia
         p Value of SG Interaction
AGEONSET                    0.0172
AGETRT                      0.2479
SEX                         0.1552
REGION                      0.0000
DISDUR                      0.1949
```

```
$Anaemia
         p Value of SG Interaction
AGEONSET                    0.8042
AGETRT                      0.3911
SEX                         0.4591
REGION                      0.9218
DISDUR                      0.0527

$Anxiety
         p Value of SG Interaction
AGEONSET                    0.0957
AGETRT                      0.8253
SEX                         0.2245
REGION                      0.9617
DISDUR                      0.6261

$`Aphthous ulcer`
         p Value of SG Interaction
AGEONSET                    0.7727
AGETRT                      0.5787
SEX                         0.4899
REGION                      0.5008
DISDUR                      0.8705

$Apnoea
         p Value of SG Interaction
AGEONSET                    0.7370
AGETRT                      0.5495
SEX                         0.2807
REGION                      0.9395
DISDUR                      0.7324

$`Apparent life threatening event`
         p Value of SG Interaction
AGEONSET                    0.3675
AGETRT                      0.1079
SEX                         0.5339
REGION                      0.1215
DISDUR                      0.0712

$`Application site rash`
         p Value of SG Interaction
AGEONSET                    0.4591
AGETRT                      0.0753
SEX                         0.2101
REGION                      0.6192
DISDUR                      0.0002

$`Arthropod bite`
         p Value of SG Interaction
AGEONSET                    0.7860
AGETRT                      0.5736
SEX                         0.4020
REGION                      0.7201
```

```
DISDUR                      0.7542

$`Aspartate aminotransferase increased`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$Aspiration
         p Value of SG Interaction
AGEONSET                    0.8098
AGETRT                      0.8560
SEX                         0.0882
REGION                      0.9680
DISDUR                      0.7022

$Atelectasis
         p Value of SG Interaction
AGEONSET                    0.9576
AGETRT                      0.6798
SEX                         0.3664
REGION                      0.3418
DISDUR                      0.9811

$`Back pain`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$Bacteraemia
         p Value of SG Interaction
AGEONSET                    0.5294
AGETRT                      0.2656
SEX                         0.0571
REGION                      0.3835
DISDUR                      0.3117

$`Bacterial disease carrier`
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Bacterial infection`
         p Value of SG Interaction
AGEONSET                    0.7844
AGETRT                      0.5743
```

```
SEX                         0.5639
REGION                      0.7264
DISDUR                      0.7980

$`Bacterial tracheitis`
          p Value of SG Interaction
AGEONSET                    0.2812
AGETRT                      0.7494
SEX                         0.9366
REGION                      0.1234
DISDUR                      0.0813

$Balanoposthitis
          p Value of SG Interaction
AGEONSET                    0.7711
AGETRT                      0.5792
SEX                         0.4885
REGION                      0.6303
DISDUR                      0.8258

$`Blood chloride decreased`
          p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$`Blood iron decreased`
          p Value of SG Interaction
AGEONSET                    0.7911
AGETRT                      0.5709
SEX                         0.6096
REGION                      0.7120
DISDUR                      0.6138

$`Blood potassium decreased`
          p Value of SG Interaction
AGEONSET                    0.6711
AGETRT                      0.8095
SEX                         0.3549
REGION                      0.3562
DISDUR                      0.5669

$`Blood sodium decreased`
          p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$`Body temperature decreased`
          p Value of SG Interaction
```

```
AGEONSET                    0.7672
AGETRT                      0.4091
SEX                         0.0904
REGION                      0.9806
DISDUR                      0.3583

$`Body temperature increased`
         p Value of SG Interaction
AGEONSET                    0.9561
AGETRT                      0.2318
SEX                         0.4017
REGION                      0.9977
DISDUR                      0.1494

$`Bone marrow disorder`
         p Value of SG Interaction
AGEONSET                    0.0161
AGETRT                      0.2599
SEX                         0.2189
REGION                      0.2525
DISDUR                      0.9596

$Bradycardia
         p Value of SG Interaction
AGEONSET                    0.1661
AGETRT                      0.3025
SEX                         0.5854
REGION                      0.4819
DISDUR                      0.0807

$`Brain injury`
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606

$`Breath holding`
         p Value of SG Interaction
AGEONSET                    0.7744
AGETRT                      0.5782
SEX                         0.4693
REGION                      0.7643
DISDUR                      0.9157

$`Bronchial obstruction`
         p Value of SG Interaction
AGEONSET                    0.7995
AGETRT                      0.5655
SEX                         0.6714
REGION                      0.7461
DISDUR                      0.4046
```

$`Bronchial secretion retention`
	p Value of SG Interaction
AGEONSET	0.9033
AGETRT	0.9978
SEX	0.8311
REGION	0.8453
DISDUR	0.7043

$Bronchiolitis
	p Value of SG Interaction
AGEONSET	0.9088
AGETRT	0.2647
SEX	0.8846
REGION	0.8021
DISDUR	0.8354

$Bronchitis
	p Value of SG Interaction
AGEONSET	0.7133
AGETRT	0.5058
SEX	0.8662
REGION	0.7924
DISDUR	0.3520

$`Bronchitis viral`
	p Value of SG Interaction
AGEONSET	0.5459
AGETRT	0.1775
SEX	0.3559
REGION	0.8771
DISDUR	0.0770

$`C-reactive protein increased`
	p Value of SG Interaction
AGEONSET	0.9830
AGETRT	0.2203
SEX	0.5548
REGION	0.9706
DISDUR	0.7346

$`Candida infection`
	p Value of SG Interaction
AGEONSET	0.2394
AGETRT	0.1573
SEX	0.0201
REGION	0.7441
DISDUR	0.5128

$`Candida nappy rash`
	p Value of SG Interaction
AGEONSET	0.8283
AGETRT	0.2370
SEX	0.9173
REGION	0.2213

```
DISDUR                      0.1607

$`Candida sepsis`
         p Value of SG Interaction
AGEONSET                    0.0166
AGETRT                      0.2564
SEX                         0.0951
REGION                      0.2337
DISDUR                      0.6358

$`Cardiac arrest`
         p Value of SG Interaction
AGEONSET                    0.7256
AGETRT                      0.6256
SEX                         0.6877
REGION                      0.3688
DISDUR                      0.6299

$`Cardio-respiratory arrest`
         p Value of SG Interaction
AGEONSET                    0.6635
AGETRT                      0.2960
SEX                         0.2210
REGION                      0.5338
DISDUR                      0.3438

$Catarrh
         p Value of SG Interaction
AGEONSET                    0.0164
AGETRT                      0.2579
SEX                         0.2052
REGION                      0.2415
DISDUR                      0.7664

$`Catheter site inflammation`
         p Value of SG Interaction
AGEONSET                    0.8057
AGETRT                      0.2373
SEX                         0.7411
REGION                      0.9181
DISDUR                      0.1232

$Cellulitis
         p Value of SG Interaction
AGEONSET                    0.7779
AGETRT                      0.0608
SEX                         0.1349
REGION                      0.9694
DISDUR                      0.0014

$Chalazion
         p Value of SG Interaction
AGEONSET                    0.7438
AGETRT                      0.3623
```

```
SEX                         0.6497
REGION                      0.8546
DISDUR                      0.2579

$Choking
         p Value of SG Interaction
AGEONSET                    0.8208
AGETRT                      0.8810
SEX                         0.0549
REGION                      0.2465
DISDUR                      0.7764

$`Chronic respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.6499
AGETRT                      0.1930
SEX                         0.1996
REGION                      0.6886
DISDUR                      0.2035

$Clonus
         p Value of SG Interaction
AGEONSET                    0.7711
AGETRT                      0.5792
SEX                         0.4885
REGION                      0.6303
DISDUR                      0.8258

$`Congenital diaphragmatic hernia`
         p Value of SG Interaction
AGEONSET                    0.7599
AGETRT                      0.3696
SEX                         0.5547
REGION                      0.8115
DISDUR                      0.5464

$Conjunctivitis
         p Value of SG Interaction
AGEONSET                    0.8606
AGETRT                      0.3662
SEX                         0.6186
REGION                      0.5962
DISDUR                      0.9538

$`Conjunctivitis bacterial`
         p Value of SG Interaction
AGEONSET                    0.9846
AGETRT                      0.6563
SEX                         0.8122
REGION                      0.9992
DISDUR                      0.4397

$Constipation
         p Value of SG Interaction
```

```
AGEONSET                    0.5055
AGETRT                      0.0783
SEX                         0.7124
REGION                      0.2914
DISDUR                      0.1913

$Contusion
         p Value of SG Interaction
AGEONSET                    0.7916
AGETRT                      0.5706
SEX                         0.6132
REGION                      0.6966
DISDUR                      0.6004

$`Corona virus infection`
         p Value of SG Interaction
AGEONSET                    0.2948
AGETRT                      0.0090
SEX                         0.8445
REGION                      0.3047
DISDUR                      0.0000

$Cough
         p Value of SG Interaction
AGEONSET                    0.9273
AGETRT                      0.7750
SEX                         0.2661
REGION                      0.6544
DISDUR                      0.3423

$Crying
         p Value of SG Interaction
AGEONSET                    0.7813
AGETRT                      0.5757
SEX                         0.5434
REGION                      0.7386
DISDUR                      0.8874

$Cryptorchism
         p Value of SG Interaction
AGEONSET                    0.4591
AGETRT                      0.0753
SEX                         0.2101
REGION                      0.6192
DISDUR                      0.0002

$Cyanosis
         p Value of SG Interaction
AGEONSET                    0.0673
AGETRT                      0.0507
SEX                         0.0175
REGION                      0.8849
DISDUR                      0.4947
```

```
$Death
         p Value of SG Interaction
AGEONSET                    0.7771
AGETRT                      0.4064
SEX                         0.1368
REGION                      0.3880
DISDUR                      0.1424

$`Decubitus ulcer`
         p Value of SG Interaction
AGEONSET                    0.2468
AGETRT                      0.1533
SEX                         0.1803
REGION                      0.0639
DISDUR                      0.9057

$`Deformity thorax`
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$Dehydration
         p Value of SG Interaction
AGEONSET                    0.5713
AGETRT                      0.9572
SEX                         0.4006
REGION                      0.5027
DISDUR                      0.5023

$`Delayed fontanelle closure`
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$`Delayed recovery from anaesthesia`
         p Value of SG Interaction
AGEONSET                    0.7599
AGETRT                      0.3696
SEX                         0.4171
REGION                      0.5844
DISDUR                      0.5464

$Dermatitis
         p Value of SG Interaction
AGEONSET                    0.7438
AGETRT                      0.3623
SEX                         0.6497
REGION                      0.8546
```

```
DISDUR                      0.2579

$`Dermatitis allergic`
         p Value of SG Interaction
AGEONSET                    0.8054
AGETRT                      0.5611
SEX                         0.2941
REGION                      0.6329
DISDUR                      0.2849

$`Dermatitis atopic`
         p Value of SG Interaction
AGEONSET                    0.3342
AGETRT                      0.6624
SEX                         0.8770
REGION                      0.2256
DISDUR                      0.1614

$`Dermatitis contact`
         p Value of SG Interaction
AGEONSET                    0.4976
AGETRT                      0.2213
SEX                         0.5310
REGION                      0.6914
DISDUR                      0.0155

$`Dermatitis diaper`
         p Value of SG Interaction
AGEONSET                    0.5001
AGETRT                      0.8354
SEX                         0.7750
REGION                      0.7730
DISDUR                      0.5167

$`Developmental hip dysplasia`
         p Value of SG Interaction
AGEONSET                    0.8057
AGETRT                      0.2373
SEX                         0.7411
REGION                      0.9181
DISDUR                      0.1232

$`Device malfunction`
         p Value of SG Interaction
AGEONSET                    0.4591
AGETRT                      0.0753
SEX                         0.2101
REGION                      0.6192
DISDUR                      0.0002

$`Device occlusion`
         p Value of SG Interaction
AGEONSET                    0.7950
AGETRT                      0.0608
```

```
SEX                         0.5151
REGION                      0.3323
DISDUR                      0.0001

$Diarrhoea
         p Value of SG Interaction
AGEONSET                    0.7211
AGETRT                      0.2374
SEX                         0.7993
REGION                      0.8690
DISDUR                      0.0883

$`Diarrhoea haemorrhagic`
         p Value of SG Interaction
AGEONSET                    0.0171
AGETRT                      0.2504
SEX                         0.1653
REGION                      0.4991
DISDUR                      0.2805

$Discomfort
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Drooling
         p Value of SG Interaction
AGEONSET                    0.7916
AGETRT                      0.5706
SEX                         0.6132
REGION                      0.6966
DISDUR                      0.6004

$`Drug hypersensitivity`
         p Value of SG Interaction
AGEONSET                    0.0966
AGETRT                      0.1893
SEX                         0.9101
REGION                      0.9692
DISDUR                      0.4058

$`Drug intolerance`
         p Value of SG Interaction
AGEONSET                    0.7419
AGETRT                      0.3613
SEX                         0.6607
REGION                      0.8590
DISDUR                      0.2335

$`Dry eye`
         p Value of SG Interaction
```

```
AGEONSET                    0.7694
AGETRT                      0.4086
SEX                         0.0944
REGION                      0.1781
DISDUR                      0.2531

$`Dry skin`
         p Value of SG Interaction
AGEONSET                    0.7950
AGETRT                      0.0608
SEX                         0.5151
REGION                      0.3323
DISDUR                      0.0001

$Dysphagia
         p Value of SG Interaction
AGEONSET                    0.4868
AGETRT                      0.3537
SEX                         0.8190
REGION                      0.8843
DISDUR                      0.4106

$Dyspnoea
         p Value of SG Interaction
AGEONSET                    0.7221
AGETRT                      0.1181
SEX                         0.9997
REGION                      0.1598
DISDUR                      0.0828

$`Ear disorder`
         p Value of SG Interaction
AGEONSET                    0.7776
AGETRT                      0.5771
SEX                         0.4505
REGION                      0.7526
DISDUR                      0.9934

$`Ear haemorrhage`
         p Value of SG Interaction
AGEONSET                    0.5363
AGETRT                      0.2671
SEX                         0.3259
REGION                      0.3472
DISDUR                      0.0953

$`Ear infection`
         p Value of SG Interaction
AGEONSET                    0.7185
AGETRT                      0.6817
SEX                         0.0774
REGION                      0.8325
DISDUR                      0.8890
```

$`Ear pain`
	p Value of SG Interaction
AGEONSET	0.7419
AGETRT	0.3613
SEX	0.6607
REGION	0.8590
DISDUR	0.2335

$Ecchymosis
	p Value of SG Interaction
AGEONSET	0.6565
AGETRT	0.1952
SEX	0.8342
REGION	0.6688
DISDUR	0.2899

$Eczema
	p Value of SG Interaction
AGEONSET	0.5401
AGETRT	0.9772
SEX	0.1533
REGION	0.2101
DISDUR	0.9266

$`Eczema infected`
	p Value of SG Interaction
AGEONSET	0.7966
AGETRT	0.5675
SEX	0.3421
REGION	0.4948
DISDUR	0.4735

$`Electrocardiogram ST-T segment abnormal`
	p Value of SG Interaction
AGEONSET	0.8038
AGETRT	0.0598
SEX	0.4613
REGION	0.9227
DISDUR	0.0545

$`Endotracheal intubation complication`
	p Value of SG Interaction
AGEONSET	0.4591
AGETRT	0.0753
SEX	0.2101
REGION	0.6192
DISDUR	0.0002

$Enteritis
	p Value of SG Interaction
AGEONSET	0.4884
AGETRT	0.0783
SEX	0.1429
REGION	0.1734

```
DISDUR                      0.0541

$Enterobiasis
         p Value of SG Interaction
AGEONSET                    0.7995
AGETRT                      0.5655
SEX                         0.6714
REGION                      0.4922
DISDUR                      0.4046

$`Enterococcal infection`
         p Value of SG Interaction
AGEONSET                    0.7727
AGETRT                      0.5787
SEX                         0.4899
REGION                      0.5008
DISDUR                      0.8705

$`Epigastric discomfort`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$Erythema
         p Value of SG Interaction
AGEONSET                    0.0277
AGETRT                      0.5703
SEX                         0.6815
REGION                      0.0018
DISDUR                      0.4328

$`Escherichia infection`
         p Value of SG Interaction
AGEONSET                    0.7744
AGETRT                      0.5782
SEX                         0.4998
REGION                      0.6436
DISDUR                      0.9157

$Excoriation
         p Value of SG Interaction
AGEONSET                    0.7559
AGETRT                      0.4108
SEX                         0.0718
REGION                      0.1478
DISDUR                      0.4617

$`Exposure to communicable disease`
         p Value of SG Interaction
AGEONSET                    0.7765
AGETRT                      0.3739
```

```
SEX                         0.4568
REGION                      0.6525
DISDUR                      0.9763

$`Eye infection`
         p Value of SG Interaction
AGEONSET                    0.7593
AGETRT                      0.3694
SEX                         0.5581
REGION                      0.8132
DISDUR                      0.5336

$`Eye movement disorder`
         p Value of SG Interaction
AGEONSET                    0.7844
AGETRT                      0.5743
SEX                         0.5639
REGION                      0.7264
DISDUR                      0.7980

$`Failure to thrive`
         p Value of SG Interaction
AGEONSET                    0.2678
AGETRT                      0.8732
SEX                         0.3611
REGION                      0.7613
DISDUR                      0.9735

$Fatigue
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Feeding disorder of infancy or early childhood`
         p Value of SG Interaction
AGEONSET                    0.6261
AGETRT                      0.7828
SEX                         0.7681
REGION                      0.2072
DISDUR                      0.8419

$`Feeding intolerance`
         p Value of SG Interaction
AGEONSET                    0.6102
AGETRT                      0.8970
SEX                         0.2143
REGION                      0.9073
DISDUR                      0.7324

$`Feeding tube complication`
         p Value of SG Interaction
```

```
AGEONSET                    0.5390
AGETRT                      0.9457
SEX                         0.6802
REGION                      0.1769
DISDUR                      0.5744

$`Femur fracture`
         p Value of SG Interaction
AGEONSET                    0.0984
AGETRT                      0.4192
SEX                         0.9305
REGION                      0.9428
DISDUR                      0.0730

$Flatulence
         p Value of SG Interaction
AGEONSET                    0.7894
AGETRT                      0.6390
SEX                         0.7627
REGION                      0.8323
DISDUR                      0.9384

$`Food allergy`
         p Value of SG Interaction
AGEONSET                    0.8208
AGETRT                      0.5458
SEX                         0.8459
REGION                      0.5507
DISDUR                      0.0812

$`Food intolerance`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Fungal infection`
         p Value of SG Interaction
AGEONSET                    0.0617
AGETRT                      0.2366
SEX                         0.1748
REGION                      0.8905
DISDUR                      0.8479

$`Fungal skin infection`
         p Value of SG Interaction
AGEONSET                    0.0611
AGETRT                      0.8713
SEX                         0.7328
REGION                      0.9209
DISDUR                      0.1629
```

$`Gastric haemorrhage`
	p Value of SG Interaction
AGEONSET	0.7505
AGETRT	0.3657
SEX	0.3693
REGION	0.8378
DISDUR	0.3606

$Gastritis
	p Value of SG Interaction
AGEONSET	0.9179
AGETRT	0.4964
SEX	0.7174
REGION	0.9401
DISDUR	0.5315

$Gastroenteritis
	p Value of SG Interaction
AGEONSET	0.7481
AGETRT	0.3645
SEX	0.3577
REGION	0.4841
DISDUR	0.3208

$`Gastroenteritis rotavirus`
	p Value of SG Interaction
AGEONSET	0.7995
AGETRT	0.5655
SEX	0.6714
REGION	0.7461
DISDUR	0.4046

$`Gastroenteritis viral`
	p Value of SG Interaction
AGEONSET	0.2438
AGETRT	0.4351
SEX	0.3901
REGION	0.4949
DISDUR	0.6563

$`Gastrointestinal haemorrhage`
	p Value of SG Interaction
AGEONSET	0.4878
AGETRT	0.0783
SEX	0.1271
REGION	0.1719
DISDUR	0.0496

$`Gastrointestinal motility disorder`
	p Value of SG Interaction
AGEONSET	0.4591
AGETRT	0.0753
SEX	0.2101
REGION	0.6192

```
DISDUR                      0.0002

$`Gastrointestinal tract irritation`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Gastrooesophageal reflux disease`
         p Value of SG Interaction
AGEONSET                    0.0841
AGETRT                      0.0656
SEX                         0.9155
REGION                      0.2289
DISDUR                      0.0241

$`General physical health deterioration`
         p Value of SG Interaction
AGEONSET                    0.7818
AGETRT                      0.5755
SEX                         0.4260
REGION                      0.6742
DISDUR                      0.8724

$Glycosuria
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Granuloma annulare`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$Haematochezia
         p Value of SG Interaction
AGEONSET                    0.7023
AGETRT                      0.8267
SEX                         0.4444
REGION                      0.4905
DISDUR                      0.5507

$`Hand-foot-and-mouth disease`
         p Value of SG Interaction
AGEONSET                    0.7874
AGETRT                      0.4020
```

```
SEX                         0.1147
REGION                      0.3563
DISDUR                      0.7478

$`Head injury`
         p Value of SG Interaction
AGEONSET                    0.5425
AGETRT                      0.2671
SEX                         0.3721
REGION                      0.3590
DISDUR                      0.0186

$`Head lag abnormal`
         p Value of SG Interaction
AGEONSET                    0.5289
AGETRT                      0.2655
SEX                         0.2808
REGION                      0.2989
DISDUR                      0.3292

$`Heart rate decreased`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Heart rate increased`
         p Value of SG Interaction
AGEONSET                    0.7455
AGETRT                      0.4111
SEX                         0.8142
REGION                      0.9907
DISDUR                      0.0306

$`Heart rate irregular`
         p Value of SG Interaction
AGEONSET                    0.7627
AGETRT                      0.3706
SEX                         0.4325
REGION                      0.8028
DISDUR                      0.6122

$Hepatomegaly
         p Value of SG Interaction
AGEONSET                    0.8010
AGETRT                      0.5644
SEX                         0.3177
REGION                      0.6540
DISDUR                      0.3723

$Hordeolum
         p Value of SG Interaction
```

```
AGEONSET                    0.5363
AGETRT                      0.2671
SEX                         0.3259
REGION                      0.3472
DISDUR                      0.0953

$`Human rhinovirus test positive`
         p Value of SG Interaction
AGEONSET                    0.7911
AGETRT                      0.5709
SEX                         0.6096
REGION                      0.7120
DISDUR                      0.6138

$Hydronephrosis
         p Value of SG Interaction
AGEONSET                    0.8010
AGETRT                      0.5644
SEX                         0.3177
REGION                      0.6540
DISDUR                      0.3723

$Hyperaemia
         p Value of SG Interaction
AGEONSET                    0.0166
AGETRT                      0.2564
SEX                         0.0951
REGION                      0.2337
DISDUR                      0.6358

$Hypercapnia
         p Value of SG Interaction
AGEONSET                    0.7844
AGETRT                      0.5743
SEX                         0.5639
REGION                      0.7264
DISDUR                      0.7980

$Hyperglycaemia
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.2599
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$Hyperhidrosis
         p Value of SG Interaction
AGEONSET                    0.4866
AGETRT                      0.0783
SEX                         0.1470
REGION                      0.5475
DISDUR                      0.0414
```

$Hyperkeratosis
	p Value of SG Interaction
AGEONSET	0.6993
AGETRT	0.4209
SEX	0.4253
REGION	0.5047
DISDUR	0.6358

$Hypersensitivity
	p Value of SG Interaction
AGEONSET	0.5354
AGETRT	0.3811
SEX	0.1658
REGION	0.1785
DISDUR	0.1486

$Hypertension
	p Value of SG Interaction
AGEONSET	0.7926
AGETRT	0.5700
SEX	0.6203
REGION	0.6923
DISDUR	0.5739

$Hypoglycaemia
	p Value of SG Interaction
AGEONSET	0.3447
AGETRT	0.6574
SEX	0.7851
REGION	0.1980
DISDUR	0.5635

$Hypokalaemia
	p Value of SG Interaction
AGEONSET	0.2238
AGETRT	0.1596
SEX	0.3018
REGION	0.0990
DISDUR	0.0413

$Hypophagia
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$Hypopnoea
	p Value of SG Interaction
AGEONSET	0.7523
AGETRT	0.3665
SEX	0.3780
REGION	0.8330

```
DISDUR                      0.3923

$Hypothermia
          p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606

$Hypoventilation
          p Value of SG Interaction
AGEONSET                    0.6827
AGETRT                      0.8162
SEX                         0.9762
REGION                      0.5769
DISDUR                      0.8695

$Hypoxia
          p Value of SG Interaction
AGEONSET                    0.7769
AGETRT                      0.0562
SEX                         0.2592
REGION                      0.7353
DISDUR                      0.0241

$`Hypoxic-ischaemic encephalopathy`
          p Value of SG Interaction
AGEONSET                    0.8073
AGETRT                      0.5594
SEX                         0.2839
REGION                      0.6233
DISDUR                      0.2506

$`Impaired gastric emptying`
          p Value of SG Interaction
AGEONSET                    0.7244
AGETRT                      0.3501
SEX                         0.7630
REGION                      0.4449
DISDUR                      0.0807

$Impetigo
          p Value of SG Interaction
AGEONSET                    0.8157
AGETRT                      0.2382
SEX                         0.8167
REGION                      0.2636
DISDUR                      0.3101

$`Incision site erythema`
          p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
```

```
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Increased bronchial secretion`
         p Value of SG Interaction
AGEONSET                    0.7934
AGETRT                      0.0609
SEX                         0.1026
REGION                      0.3373
DISDUR                      0.1226

$`Increased upper airway secretion`
         p Value of SG Interaction
AGEONSET                    0.0661
AGETRT                      0.2261
SEX                         0.1072
REGION                      0.9719
DISDUR                      0.6790

$`Infantile colic`
         p Value of SG Interaction
AGEONSET                    0.7906
AGETRT                      0.5712
SEX                         0.3758
REGION                      0.7010
DISDUR                      0.6274

$`Infantile spitting up`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Inflammatory marker increased`
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$Influenza
         p Value of SG Interaction
AGEONSET                    0.5309
AGETRT                      0.1884
SEX                         0.5204
REGION                      0.6905
DISDUR                      0.4485

$`Influenza A virus test positive`
         p Value of SG Interaction
```

```
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Infusion site bruising`
         p Value of SG Interaction
AGEONSET                    0.0167
AGETRT                      0.2551
SEX                         0.1883
REGION                      0.4743
DISDUR                      0.5385

$`Infusion site extravasation`
         p Value of SG Interaction
AGEONSET                    0.4591
AGETRT                      0.0753
SEX                         0.2101
REGION                      0.6192
DISDUR                      0.0002

$`Injection site haematoma`
         p Value of SG Interaction
AGEONSET                    0.5213
AGETRT                      0.0727
SEX                         0.2414
REGION                      0.2700
DISDUR                      0.7364

$Intertrigo
         p Value of SG Interaction
AGEONSET                    0.7786
AGETRT                      0.5767
SEX                         0.5264
REGION                      0.5016
DISDUR                      0.9630

$`Iron deficiency`
         p Value of SG Interaction
AGEONSET                    0.7926
AGETRT                      0.5700
SEX                         0.6203
REGION                      0.6923
DISDUR                      0.5739

$Irritability
         p Value of SG Interaction
AGEONSET                    0.9376
AGETRT                      0.4542
SEX                         0.3449
REGION                      0.9737
DISDUR                      0.0475
```

$`Irritability postvaccinal`
	p Value of SG Interaction
AGEONSET	0.7599
AGETRT	0.3696
SEX	0.4171
REGION	0.5844
DISDUR	0.5464

$`Joint contracture`
	p Value of SG Interaction
AGEONSET	0.8636
AGETRT	0.3963
SEX	0.1634
REGION	0.6024
DISDUR	0.2498

$`Joint range of motion decreased`
	p Value of SG Interaction
AGEONSET	0.5363
AGETRT	0.2671
SEX	0.3259
REGION	0.3472
DISDUR	0.0953

$`Joint stiffness`
	p Value of SG Interaction
AGEONSET	0.5099
AGETRT	0.0761
SEX	0.0961
REGION	0.4685
DISDUR	0.6108

$`Keratosis pilaris`
	p Value of SG Interaction
AGEONSET	0.5265
AGETRT	0.2647
SEX	0.2673
REGION	0.3975
DISDUR	0.4464

$Kyphoscoliosis
	p Value of SG Interaction
AGEONSET	0.7523
AGETRT	0.3665
SEX	0.3780
REGION	0.8330
DISDUR	0.3923

$Kyphosis
	p Value of SG Interaction
AGEONSET	0.7754
AGETRT	0.2259
SEX	0.6346
REGION	0.9724

```
DISDUR                      0.4732

$Laceration
         p Value of SG Interaction
AGEONSET                    0.5363
AGETRT                      0.2671
SEX                         0.3259
REGION                      0.3472
DISDUR                      0.0953

$`Lacrimation increased`
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.0745
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$`Language disorder`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Left ventricular hypertrophy`
         p Value of SG Interaction
AGEONSET                    0.6914
AGETRT                      0.4238
SEX                         0.9064
REGION                      0.5406
DISDUR                      0.8722

$Leukocytosis
         p Value of SG Interaction
AGEONSET                    0.5084
AGETRT                      0.0765
SEX                         0.0993
REGION                      0.4743
DISDUR                      0.5385

$`Liver function test abnormal`
         p Value of SG Interaction
AGEONSET                    0.7906
AGETRT                      0.5712
SEX                         0.3758
REGION                      0.7010
DISDUR                      0.6274

$`Localised infection`
         p Value of SG Interaction
AGEONSET                    0.7627
AGETRT                      0.3706
```

```
SEX                         0.5378
REGION                      0.5960
DISDUR                      0.6122

$`Lower respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.9947
AGETRT                      0.0699
SEX                         0.5804
REGION                      0.7240
DISDUR                      0.3176

$`Lower respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                    0.6874
AGETRT                      0.8188
SEX                         0.9383
REGION                      0.9539
DISDUR                      0.9905

$`Lung disorder`
         p Value of SG Interaction
AGEONSET                    0.7771
AGETRT                      0.4064
SEX                         0.5499
REGION                      0.8109
DISDUR                      0.7236

$`Lung infection`
         p Value of SG Interaction
AGEONSET                    0.7786
AGETRT                      0.5767
SEX                         0.5264
REGION                      0.5016
DISDUR                      0.9630

$`Lymph node palpable`
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.2599
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$Malaise
         p Value of SG Interaction
AGEONSET                    0.7711
AGETRT                      0.5792
SEX                         0.4885
REGION                      0.6303
DISDUR                      0.8258

$`Mechanical ventilation`
         p Value of SG Interaction
```

```
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Medical device complication`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$`Medical observation`
         p Value of SG Interaction
AGEONSET                    0.6766
AGETRT                      0.4259
SEX                         0.9772
REGION                      0.3766
DISDUR                      0.7028

$Miliaria
         p Value of SG Interaction
AGEONSET                    0.6856
AGETRT                      0.8178
SEX                         0.2875
REGION                      0.7168
DISDUR                      0.9555

$`Mood swings`
         p Value of SG Interaction
AGEONSET                    0.8058
AGETRT                      0.5607
SEX                         0.7202
REGION                      0.4853
DISDUR                      0.2761

$`Moraxella infection`
         p Value of SG Interaction
AGEONSET                    0.7511
AGETRT                      0.3660
SEX                         0.3722
REGION                      0.8362
DISDUR                      0.3710

$`Moraxella test positive`
         p Value of SG Interaction
AGEONSET                    0.7911
AGETRT                      0.5709
SEX                         0.6096
REGION                      0.7120
DISDUR                      0.6138
```

$`Muscle contractions involuntary`
         p Value of SG Interaction
AGEONSET   0.7558
AGETRT   0.3681
SEX   0.3959
REGION   0.5679
DISDUR   0.4602

$`Muscle tightness`
         p Value of SG Interaction
AGEONSET   0.4591
AGETRT   0.0753
SEX   0.2101
REGION   0.6192
DISDUR   0.0002

$`Muscular weakness`
         p Value of SG Interaction
AGEONSET   0.5162
AGETRT   0.2599
SEX   0.0830
REGION   0.4431
DISDUR   0.9596

$Myopia
         p Value of SG Interaction
AGEONSET   0.7511
AGETRT   0.3660
SEX   0.3722
REGION   0.8362
DISDUR   0.3710

$`Naevus anaemicus`
         p Value of SG Interaction
AGEONSET   0.7706
AGETRT   0.5793
SEX   0.4917
REGION   0.6280
DISDUR   0.8109

$`Nasal congestion`
         p Value of SG Interaction
AGEONSET   0.1559
AGETRT   0.6605
SEX   0.4000
REGION   0.9947
DISDUR   0.2787

$`Nasal inflammation`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN

```
DISDUR                          NaN

$Nasopharyngitis
          p Value of SG Interaction
AGEONSET                     0.0550
AGETRT                       0.0668
SEX                          0.4379
REGION                       0.2929
DISDUR                       0.6132

$`Neutrophil count increased`
          p Value of SG Interaction
AGEONSET                     0.7523
AGETRT                       0.3665
SEX                          0.3780
REGION                       0.8330
DISDUR                       0.3923

$Nodule
          p Value of SG Interaction
AGEONSET                     0.7564
AGETRT                       0.3683
SEX                          0.3989
REGION                       0.8216
DISDUR                       0.4720

$`Nosocomial infection`
          p Value of SG Interaction
AGEONSET                     0.7916
AGETRT                       0.5706
SEX                          0.6132
REGION                       0.6966
DISDUR                       0.6004

$Nystagmus
          p Value of SG Interaction
AGEONSET                     0.0837
AGETRT                       0.6904
SEX                          0.5989
REGION                       0.0000
DISDUR                       0.0381

$`Obstructive airways disorder`
          p Value of SG Interaction
AGEONSET                     0.7337
AGETRT                       0.3563
SEX                          0.7092
REGION                       0.4802
DISDUR                       0.1457

$Oedema
          p Value of SG Interaction
AGEONSET                     0.5715
AGETRT                       0.7551
```

```
SEX                         0.2842
REGION                      0.0001
DISDUR                      0.0801

$`Oedema peripheral`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Oral candidiasis`
         p Value of SG Interaction
AGEONSET                    0.3197
AGETRT                      0.6516
SEX                         0.3540
REGION                      0.8043
DISDUR                      0.1109

$`Oral fungal infection`
         p Value of SG Interaction
AGEONSET                    0.7941
AGETRT                      0.5691
SEX                         0.6311
REGION                      0.7242
DISDUR                      0.5352

$`Oral herpes`
         p Value of SG Interaction
AGEONSET                    0.7706
AGETRT                      0.5793
SEX                         0.4917
REGION                      0.6280
DISDUR                      0.8109

$`Oropharyngeal pain`
         p Value of SG Interaction
AGEONSET                    0.0161
AGETRT                      0.2599
SEX                         0.2189
REGION                      0.2525
DISDUR                      0.9596

$`Orthopaedic examination`
         p Value of SG Interaction
AGEONSET                    0.7438
AGETRT                      0.3623
SEX                         0.6497
REGION                      0.8546
DISDUR                      0.2579

$`Otitis media`
         p Value of SG Interaction
```

```
AGEONSET                    0.2659
AGETRT                      0.0701
SEX                         0.7926
REGION                      0.7737
DISDUR                      0.7384

$`Otitis media acute`
         p Value of SG Interaction
AGEONSET                    0.7552
AGETRT                      0.5820
SEX                         0.5822
REGION                      0.8249
DISDUR                      0.4484

$`Ovarian cyst`
         p Value of SG Interaction
AGEONSET                    0.7683
AGETRT                      0.5799
SEX                         0.4641
REGION                      0.6190
DISDUR                      0.7524

$`Oxygen saturation decreased`
         p Value of SG Interaction
AGEONSET                    0.3655
AGETRT                      0.1240
SEX                         0.6149
REGION                      0.7516
DISDUR                      0.5936

$Pain
         p Value of SG Interaction
AGEONSET                    0.0213
AGETRT                      0.3800
SEX                         0.8348
REGION                      0.0571
DISDUR                      0.6418

$`Pain in extremity`
         p Value of SG Interaction
AGEONSET                    0.8208
AGETRT                      0.5458
SEX                         0.8459
REGION                      0.5507
DISDUR                      0.0812

$Pallor
         p Value of SG Interaction
AGEONSET                    0.7911
AGETRT                      0.5709
SEX                         0.6096
REGION                      0.7120
DISDUR                      0.6138
```

```
$`Parainfluenzae virus infection`
         p Value of SG Interaction
AGEONSET                    0.4937
AGETRT                      0.0782
SEX                         0.1311
REGION                      0.5254
DISDUR                      0.1120

$`Pectus carinatum`
         p Value of SG Interaction
AGEONSET                    0.7825
AGETRT                      0.4043
SEX                         0.5912
REGION                      0.9633
DISDUR                      0.9881

$`Penis disorder`
         p Value of SG Interaction
AGEONSET                    0.7744
AGETRT                      0.5782
SEX                         0.4693
REGION                      0.7643
DISDUR                      0.9157

$Pharyngitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pharyngitis streptococcal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Phimosis
         p Value of SG Interaction
AGEONSET                    0.4937
AGETRT                      0.0782
SEX                         0.1311
REGION                      0.5254
DISDUR                      0.1120

$`Pleural effusion`
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
```

```
DISDUR                      0.3606

$Pneumonia
         p Value of SG Interaction
AGEONSET                    0.6478
AGETRT                      0.9126
SEX                         0.3607
REGION                      0.6190
DISDUR                      0.9817

$`Pneumonia aspiration`
         p Value of SG Interaction
AGEONSET                    0.2934
AGETRT                      0.4574
SEX                         0.3668
REGION                      0.9269
DISDUR                      0.6234

$`Pneumonia bacterial`
         p Value of SG Interaction
AGEONSET                    0.6386
AGETRT                      0.3772
SEX                         0.1554
REGION                      0.8423
DISDUR                      0.4052

$`Pneumonia influenzal`
         p Value of SG Interaction
AGEONSET                    0.7700
AGETRT                      0.5795
SEX                         0.4737
REGION                      0.7794
DISDUR                      0.7962

$`Pneumonia moraxella`
         p Value of SG Interaction
AGEONSET                    0.7552
AGETRT                      0.5820
SEX                         0.5822
REGION                      0.8249
DISDUR                      0.4484

$`Pneumonia parainfluenzae viral`
         p Value of SG Interaction
AGEONSET                    0.0606
AGETRT                      0.8725
SEX                         0.7467
REGION                      0.3474
DISDUR                      0.1429

$`Pneumonia pneumococcal`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
```

```
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$`Pneumonia pseudomonal`
         p Value of SG Interaction
AGEONSET                    0.0161
AGETRT                      0.2599
SEX                         0.2189
REGION                      0.2525
DISDUR                      0.9596

$`Pneumonia respiratory syncytial viral`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$`Pneumonia viral`
         p Value of SG Interaction
AGEONSET                    0.7464
AGETRT                      0.9262
SEX                         0.3958
REGION                      0.9596
DISDUR                      0.5854

$Pneumothorax
         p Value of SG Interaction
AGEONSET                    0.7834
AGETRT                      0.5748
SEX                         0.5571
REGION                      0.7305
DISDUR                      0.8276

$`Positional plagiocephaly`
         p Value of SG Interaction
AGEONSET                    0.9685
AGETRT                      0.1945
SEX                         0.9312
REGION                      0.7075
DISDUR                      0.1833

$`Post procedural contusion`
         p Value of SG Interaction
AGEONSET                    0.5294
AGETRT                      0.2656
SEX                         0.0571
REGION                      0.3835
DISDUR                      0.3117

$`Post procedural haemorrhage`
         p Value of SG Interaction
```

```
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Post procedural swelling`
         p Value of SG Interaction
AGEONSET                    0.7593
AGETRT                      0.3694
SEX                         0.5581
REGION                      0.8132
DISDUR                      0.5336

$Presyncope
         p Value of SG Interaction
AGEONSET                    0.5084
AGETRT                      0.0765
SEX                         0.0993
REGION                      0.4743
DISDUR                      0.5385

$`Procedural complication`
         p Value of SG Interaction
AGEONSET                    0.7995
AGETRT                      0.5655
SEX                         0.6714
REGION                      0.7461
DISDUR                      0.4046

$`Procedural pain`
         p Value of SG Interaction
AGEONSET                    0.0959
AGETRT                      0.8250
SEX                         0.4232
REGION                      0.5063
DISDUR                      0.6456

$`Procedural site reaction`
         p Value of SG Interaction
AGEONSET                    0.8010
AGETRT                      0.5644
SEX                         0.3177
REGION                      0.6540
DISDUR                      0.3723

$`Pseudomonas infection`
         p Value of SG Interaction
AGEONSET                    0.0101
AGETRT                      0.2653
SEX                         0.1549
REGION                      0.9352
DISDUR                      0.2228
```

$`Pseudomonas test positive`
	p Value of SG Interaction
AGEONSET	0.7337
AGETRT	0.3563
SEX	0.7092
REGION	0.4802
DISDUR	0.1457

$Pyelonephritis
	p Value of SG Interaction
AGEONSET	0.7711
AGETRT	0.5792
SEX	0.4885
REGION	0.6303
DISDUR	0.8258

$Pyrexia
	p Value of SG Interaction
AGEONSET	0.5082
AGETRT	0.4128
SEX	0.8297
REGION	0.7569
DISDUR	0.7583

$Rash
	p Value of SG Interaction
AGEONSET	0.9615
AGETRT	0.3268
SEX	0.3574
REGION	0.3904
DISDUR	0.1811

$`Rash erythematous`
	p Value of SG Interaction
AGEONSET	0.5425
AGETRT	0.2671
SEX	0.3721
REGION	0.3109
DISDUR	0.0186

$`Rash macular`
	p Value of SG Interaction
AGEONSET	0.7749
AGETRT	0.5780
SEX	0.4662
REGION	0.7623
DISDUR	0.9308

$`Rash papular`
	p Value of SG Interaction
AGEONSET	0.7776
AGETRT	0.5771
SEX	0.4505
REGION	0.7526

```
DISDUR                      0.9934

$`Respiratory alkalosis`
         p Value of SG Interaction
AGEONSET                    0.7432
AGETRT                      0.5822
SEX                         0.6534
REGION                      0.8561
DISDUR                      0.2496

$`Respiratory arrest`
         p Value of SG Interaction
AGEONSET                    0.5418
AGETRT                      0.3377
SEX                         1.0000
REGION                      0.0235
DISDUR                      0.4630

$`Respiratory disorder`
         p Value of SG Interaction
AGEONSET                    0.6629
AGETRT                      0.1970
SEX                         0.8779
REGION                      0.3272
DISDUR                      0.3961

$`Respiratory distress`
         p Value of SG Interaction
AGEONSET                    0.7772
AGETRT                      0.4733
SEX                         0.8989
REGION                      0.2188
DISDUR                      0.3792

$`Respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.1375
AGETRT                      0.0934
SEX                         0.8356
REGION                      0.3895
DISDUR                      0.8715

$`Respiratory rate increased`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Respiratory syncytial virus bronchiolitis`
         p Value of SG Interaction
AGEONSET                    0.7301
AGETRT                      0.5518
```

```
SEX                         0.9602
REGION                      0.7385
DISDUR                      0.1956

$`Respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                    0.5480
AGETRT                      0.4682
SEX                         0.0287
REGION                      0.7990
DISDUR                      0.4244

$`Respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.5957
AGETRT                      0.3869
SEX                         0.3524
REGION                      0.6116
DISDUR                      0.8113

$`Respiratory tract infection bacterial`
         p Value of SG Interaction
AGEONSET                    0.5374
AGETRT                      0.2672
SEX                         0.3334
REGION                      0.3412
DISDUR                      0.0751

$`Respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                    0.9421
AGETRT                      0.9420
SEX                         0.6008
REGION                      0.9977
DISDUR                      0.2760

$`Respirovirus test positive`
         p Value of SG Interaction
AGEONSET                    0.0171
AGETRT                      0.2504
SEX                         0.1653
REGION                      0.4991
DISDUR                      0.2805

$Restlessness
         p Value of SG Interaction
AGEONSET                    0.0200
AGETRT                      0.0600
SEX                         0.1759
REGION                      0.2679
DISDUR                      0.8289

$Retching
         p Value of SG Interaction
```

```
AGEONSET                    0.5037
AGETRT                      0.0773
SEX                         0.1722
REGION                      0.4915
DISDUR                      0.3495

$Rhinitis
         p Value of SG Interaction
AGEONSET                    0.5302
AGETRT                      0.4643
SEX                         0.7032
REGION                      0.3489
DISDUR                      0.0936

$`Rhinitis allergic`
         p Value of SG Interaction
AGEONSET                    0.7627
AGETRT                      0.3706
SEX                         0.4325
REGION                      0.8028
DISDUR                      0.6122

$Rhinorrhoea
         p Value of SG Interaction
AGEONSET                    0.9374
AGETRT                      0.4092
SEX                         0.2630
REGION                      0.4700
DISDUR                      0.3326

$`Rhinovirus infection`
         p Value of SG Interaction
AGEONSET                    0.3196
AGETRT                      0.1668
SEX                         0.3911
REGION                      0.6694
DISDUR                      0.4416

$Rhonchi
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$Roseola
         p Value of SG Interaction
AGEONSET                    0.7966
AGETRT                      0.5675
SEX                         0.3421
REGION                      0.7342
DISDUR                      0.4735
```

```
$`Salivary hypersecretion`
         p Value of SG Interaction
AGEONSET                    0.2095
AGETRT                      0.3321
SEX                         0.7911
REGION                      0.0256
DISDUR                      0.8598

$`Scarlet fever`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Scoliosis
         p Value of SG Interaction
AGEONSET                    0.2100
AGETRT                      0.2070
SEX                         0.5802
REGION                      0.8998
DISDUR                      0.0909

$`Seasonal allergy`
         p Value of SG Interaction
AGEONSET                    0.2586
AGETRT                      0.8621
SEX                         0.7840
REGION                      0.7127
DISDUR                      0.7862

$Seizure
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606

$Sepsis
         p Value of SG Interaction
AGEONSET                    0.6762
AGETRT                      0.4259
SEX                         0.3310
REGION                      0.9409
DISDUR                      0.6928

$`Serratia infection`
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
```

```
DISDUR                      0.4464

$Shock
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606

$`Sinus congestion`
         p Value of SG Interaction
AGEONSET                    0.6462
AGETRT                      0.8713
SEX                         0.9966
REGION                      0.2839
DISDUR                      0.2287

$`Sinus tachycardia`
         p Value of SG Interaction
AGEONSET                    0.7786
AGETRT                      0.5767
SEX                         0.5264
REGION                      0.5016
DISDUR                      0.9630

$Sinusitis
         p Value of SG Interaction
AGEONSET                    0.0173
AGETRT                      0.2466
SEX                         0.1248
REGION                      0.5161
DISDUR                      0.1598

$`Skin candida`
         p Value of SG Interaction
AGEONSET                    0.9801
AGETRT                      0.0377
SEX                         0.1493
REGION                      0.2451
DISDUR                      0.0214

$`Skin infection`
         p Value of SG Interaction
AGEONSET                    0.4591
AGETRT                      0.0753
SEX                         0.2101
REGION                      0.6192
DISDUR                      0.0002

$`Skin oedema`
         p Value of SG Interaction
AGEONSET                    0.7593
AGETRT                      0.3694
```

```
SEX                         0.5581
REGION                      0.8132
DISDUR                      0.5336

$`Sleep apnoea syndrome`
         p Value of SG Interaction
AGEONSET                    0.1587
AGETRT                      0.0288
SEX                         0.0638
REGION                      0.0325
DISDUR                      0.1065

$`Sleep disorder`
         p Value of SG Interaction
AGEONSET                    0.2740
AGETRT                      0.9930
SEX                         0.5549
REGION                      0.9491
DISDUR                      0.0705

$Somnolence
         p Value of SG Interaction
AGEONSET                    0.7926
AGETRT                      0.5700
SEX                         0.6203
REGION                      0.6923
DISDUR                      0.5739

$`Sputum culture positive`
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.2599
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$`Sputum discoloured`
         p Value of SG Interaction
AGEONSET                    0.7934
AGETRT                      0.0609
SEX                         0.1490
REGION                      0.2408
DISDUR                      0.0521

$`Staphylococcal infection`
         p Value of SG Interaction
AGEONSET                    0.2439
AGETRT                      0.6646
SEX                         0.9326
REGION                      0.7843
DISDUR                      0.0567

$`Staphylococcal sepsis`
         p Value of SG Interaction
```

```
AGEONSET                    0.7627
AGETRT                      0.3706
SEX                         0.4325
REGION                      0.8028
DISDUR                      0.6122

$`Staphylococcal skin infection`
         p Value of SG Interaction
AGEONSET                    0.7706
AGETRT                      0.5793
SEX                         0.4917
REGION                      0.6280
DISDUR                      0.8109

$`Staphylococcus test positive`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Stoma complication`
         p Value of SG Interaction
AGEONSET                    0.2636
AGETRT                      0.0973
SEX                         0.2421
REGION                      0.6209
DISDUR                      0.8750

$`Stoma site abscess`
         p Value of SG Interaction
AGEONSET                    0.6808
AGETRT                      0.8151
SEX                         0.3229
REGION                      0.5843
DISDUR                      0.8165

$`Stoma site erythema`
         p Value of SG Interaction
AGEONSET                    0.2497
AGETRT                      0.6217
SEX                         0.7160
REGION                      0.0009
DISDUR                      0.0333

$`Stoma site haemorrhage`
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464
```

```
$`Stoma site infection`
         p Value of SG Interaction
AGEONSET                    0.5013
AGETRT                      0.8347
SEX                         0.3928
REGION                      0.0439
DISDUR                      0.0766

$`Stoma site inflammation`
         p Value of SG Interaction
AGEONSET                    0.0171
AGETRT                      0.2504
SEX                         0.1653
REGION                      0.4991
DISDUR                      0.2805

$`Stoma site irritation`
         p Value of SG Interaction
AGEONSET                    0.7829
AGETRT                      0.0610
SEX                         0.5887
REGION                      0.9627
DISDUR                      0.0008

$Stomatitis
         p Value of SG Interaction
AGEONSET                    0.5213
AGETRT                      0.0727
SEX                         0.2414
REGION                      0.2700
DISDUR                      0.7364

$Strabismus
         p Value of SG Interaction
AGEONSET                    0.0617
AGETRT                      0.8699
SEX                         0.7164
REGION                      0.0000
DISDUR                      0.1216

$`Supraventricular tachycardia`
         p Value of SG Interaction
AGEONSET                    0.7834
AGETRT                      0.5748
SEX                         0.5571
REGION                      0.7305
DISDUR                      0.8276

$`Surgical failure`
         p Value of SG Interaction
AGEONSET                    0.7926
AGETRT                      0.5700
SEX                         0.6203
REGION                      0.6923
```

```
DISDUR                      0.5739

$Swelling
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$`Systemic infection`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$Tachycardia
         p Value of SG Interaction
AGEONSET                    0.2155
AGETRT                      0.3020
SEX                         0.4178
REGION                      0.9009
DISDUR                      0.2898

$Tachypnoea
         p Value of SG Interaction
AGEONSET                    0.3172
AGETRT                      0.6666
SEX                         0.0295
REGION                      0.2635
DISDUR                      0.0093

$Teething
         p Value of SG Interaction
AGEONSET                    0.8633
AGETRT                      0.7785
SEX                         0.9166
REGION                      0.7456
DISDUR                      0.1638

$Thrombocytosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Thrombosis
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
```

```
SEX                         0.3616
REGION                      0.7201
DISDUR                      0.5609

$`Tongue atrophy`
         p Value of SG Interaction
AGEONSET                    0.5363
AGETRT                      0.2671
SEX                         0.3259
REGION                      0.3472
DISDUR                      0.0953

$`Tracheal haemorrhage`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Tracheal injury`
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Tracheal obstruction`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$Tracheitis
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Transaminases increased`
         p Value of SG Interaction
AGEONSET                    0.4937
AGETRT                      0.0782
SEX                         0.1311
REGION                      0.5254
DISDUR                      0.1120

$`Upper gastrointestinal haemorrhage`
         p Value of SG Interaction
```

```
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$`Upper respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                    0.1224
AGETRT                      0.2333
SEX                         0.4462
REGION                      0.7299
DISDUR                      0.9863

$`Upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.4088
AGETRT                      0.4348
SEX                         0.6310
REGION                      0.0085
DISDUR                      0.0558

$`Upper respiratory tract inflammation`
         p Value of SG Interaction
AGEONSET                    0.2415
AGETRT                      0.6624
SEX                         0.8770
REGION                      0.0355
DISDUR                      0.1614

$`Urinary retention`
         p Value of SG Interaction
AGEONSET                    0.7432
AGETRT                      0.5822
SEX                         0.6534
REGION                      0.8561
DISDUR                      0.2496

$`Urinary tract infection`
         p Value of SG Interaction
AGEONSET                    0.4113
AGETRT                      0.4531
SEX                         0.1288
REGION                      0.7535
DISDUR                      0.3408

$`Urine output decreased`
         p Value of SG Interaction
AGEONSET                    0.7941
AGETRT                      0.5691
SEX                         0.3559
REGION                      0.7242
DISDUR                      0.5352
```

```
$Urticaria
         p Value of SG Interaction
AGEONSET                    0.7627
AGETRT                      0.3706
SEX                         0.4325
REGION                      0.8028
DISDUR                      0.6122

$`Use of accessory respiratory muscles`
         p Value of SG Interaction
AGEONSET                    0.0643
AGETRT                      0.2325
SEX                         0.6276
REGION                      0.9524
DISDUR                      0.5487

$`Vaccination complication`
         p Value of SG Interaction
AGEONSET                    0.7992
AGETRT                      0.3949
SEX                         0.0913
REGION                      0.3184
DISDUR                      0.5602

$`Vaccination site reaction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Vasculitis
         p Value of SG Interaction
AGEONSET                    0.7706
AGETRT                      0.5793
SEX                         0.4917
REGION                      0.6280
DISDUR                      0.8109

$`Ventricular tachycardia`
         p Value of SG Interaction
AGEONSET                    0.7727
AGETRT                      0.5787
SEX                         0.4899
REGION                      0.5008
DISDUR                      0.8705

$`Vessel puncture site bruise`
         p Value of SG Interaction
AGEONSET                    0.3636
AGETRT                      0.1074
SEX                         0.5856
REGION                      0.1372
```

```
DISDUR                      0.2018

$`Vessel puncture site reaction`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Viral infection`
         p Value of SG Interaction
AGEONSET                    0.0504
AGETRT                      0.1116
SEX                         0.5540
REGION                      0.2155
DISDUR                      0.4858

$`Viral rash`
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Viral rhinitis`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Viral upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.1592
AGETRT                      0.5414
SEX                         0.2350
REGION                      0.6837
DISDUR                      0.8196

$`Vitamin A decreased`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Vitamin D decreased`
         p Value of SG Interaction
AGEONSET                    0.5374
AGETRT                      0.2672
```

```
SEX                         0.3334
REGION                      0.3412
DISDUR                      0.0751

$`Vitamin D deficiency`
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$Vomiting
         p Value of SG Interaction
AGEONSET                    0.7996
AGETRT                      0.9202
SEX                         0.4337
REGION                      0.8110
DISDUR                      0.9561

$`Weight decreased`
         p Value of SG Interaction
AGEONSET                    0.8193
AGETRT                      0.6618
SEX                         0.5475
REGION                      0.6145
DISDUR                      0.9357

$`Weight gain poor`
         p Value of SG Interaction
AGEONSET                    0.9830
AGETRT                      0.7955
SEX                         0.6941
REGION                      0.7083
DISDUR                      0.8197

$Wheezing
         p Value of SG Interaction
AGEONSET                    0.6711
AGETRT                      0.8095
SEX                         0.2786
REGION                      0.7488
DISDUR                      0.5669


\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines UEs nach PT, das bei mindestens 10% der
Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Abdominal discomfort`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Abdominal distension`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Abdominal pain upper`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Acquired phimosis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Acute respiratory distress syndrome`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.0367
SEX                        1.0000
REGION                     0.2673
DISDUR                     0.2772

$`Acute respiratory failure`
         p Value of SG Interaction
AGEONSET                   0.6186
AGETRT                     0.8580
SEX                        0.8980
REGION                     0.1636
DISDUR                     0.2303

$`Adenovirus infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Agitation
```

```
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.6033
SEX                         1.0000
REGION                      0.3976
DISDUR                      0.7033

$`Agitation postoperative`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Alanine aminotransferase increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Amblyopia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Anaemia
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.0449

$Anxiety
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Aphthous ulcer`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Apnoea
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.6120
SEX                         0.2389
REGION                      0.9698
DISDUR                      0.9045

$`Apparent life threatening event`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Application site rash`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Arthropod bite`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Aspartate aminotransferase increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Aspiration
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.3456
SEX                         0.0638
REGION                      1.0000
DISDUR                      0.6366

$Atelectasis
         p Value of SG Interaction
AGEONSET                    0.4795
AGETRT                      0.9268
SEX                         0.2835
```

```
REGION                     0.2267
DISDUR                     0.8204

$`Back pain`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Bacteraemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bacterial disease carrier`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bacterial infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bacterial tracheitis`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.4545
SEX                         0.3071
REGION                      1.0000
DISDUR                      0.0700

$Balanoposthitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Blood chloride decreased`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Blood iron decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Blood potassium decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Blood sodium decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Body temperature decreased`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.0578
REGION                     1.0000
DISDUR                     0.6796

$`Body temperature increased`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.1356
SEX                        0.2971
REGION                     1.0000
DISDUR                     0.1788

$`Bone marrow disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Bradycardia
```

```
         p Value of SG Interaction
AGEONSET                    0.0838
AGETRT                      0.2301
SEX                         0.5318
REGION                      0.4672
DISDUR                      0.0882

$`Brain injury`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Breath holding`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bronchial obstruction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bronchial secretion retention`
         p Value of SG Interaction
AGEONSET                    0.6188
AGETRT                      0.9198
SEX                         0.1254
REGION                      0.9734
DISDUR                      0.9661

$Bronchiolitis
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.2945
SEX                         0.9519
REGION                      0.7845
DISDUR                      0.7327

$Bronchitis
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.3603
REGION                      0.8097
DISDUR                      0.8078
```

```
$`Bronchitis viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`C-reactive protein increased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1299
SEX                         0.3912
REGION                      1.0000
DISDUR                      0.7715

$`Candida infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Candida nappy rash`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.2330
SEX                         1.0000
REGION                      0.2156
DISDUR                      0.0562

$`Candida sepsis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Cardiac arrest`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.6055
SEX                         0.2221
REGION                      0.4166
DISDUR                      0.7186

$`Cardio-respiratory arrest`
         p Value of SG Interaction
AGEONSET                    0.5945
AGETRT                      0.1328
SEX                         0.3151
```

```
REGION                      0.7359
DISDUR                      0.3326

$Catarrh
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Catheter site inflammation`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1853
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.1326

$Cellulitis
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0292
SEX                         0.1002
REGION                      1.0000
DISDUR                      0.0090

$Chalazion
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Choking
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.0362
REGION                      0.2236
DISDUR                      0.9974

$`Chronic respiratory failure`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Clonus
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Congenital diaphragmatic hernia`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Conjunctivitis
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.2392
SEX                        0.4858
REGION                     0.5379
DISDUR                     0.9343

$`Conjunctivitis bacterial`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.5125
SEX                        1.0000
REGION                     1.0000
DISDUR                     0.3132

$Constipation
         p Value of SG Interaction
AGEONSET                   0.0894
AGETRT                     0.0202
SEX                        0.4966
REGION                     0.3010
DISDUR                     0.2028

$Contusion
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Corona virus infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Cough
```

```
         p Value of SG Interaction
AGEONSET                    0.6835
AGETRT                      0.9452
SEX                         0.3621
REGION                      0.8568
DISDUR                      0.4545

$Crying
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Cryptorchism
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Cyanosis
         p Value of SG Interaction
AGEONSET                    0.0530
AGETRT                      0.0720
SEX                         0.0131
REGION                      1.0000
DISDUR                      0.5872

$Death
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.1229
REGION                      0.3078
DISDUR                      0.2795

$`Decubitus ulcer`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Deformity thorax`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Dehydration
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.5631
SEX                         0.2193
REGION                      1.0000
DISDUR                      0.8955

$`Delayed fontanelle closure`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Delayed recovery from anaesthesia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Dermatitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dermatitis allergic`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Dermatitis atopic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dermatitis contact`
         p Value of SG Interaction
AGEONSET                    0.5263
AGETRT                      0.3393
SEX                         0.9017
```

```
REGION                     1.0000
DISDUR                     0.2417

$`Dermatitis diaper`
         p Value of SG Interaction
AGEONSET                   0.4399
AGETRT                     0.9313
SEX                        0.7328
REGION                     0.5715
DISDUR                     0.5226

$`Developmental hip dysplasia`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.2008
SEX                        1.0000
REGION                     1.0000
DISDUR                     0.1353

$`Device malfunction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Device occlusion`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.0290
SEX                        1.0000
REGION                     0.2911
DISDUR                     0.0001

$Diarrhoea
         p Value of SG Interaction
AGEONSET                   0.3474
AGETRT                     0.0625
SEX                        0.7719
REGION                     0.7890
DISDUR                     0.0463

$`Diarrhoea haemorrhagic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Discomfort
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Drooling
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Drug hypersensitivity`
         p Value of SG Interaction
AGEONSET                   0.1855
AGETRT                     0.1252
SEX                        1.0000
REGION                     1.0000
DISDUR                     0.3610

$`Drug intolerance`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Dry eye`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.0556
REGION                     0.1703
DISDUR                     0.4983

$`Dry skin`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.0312
SEX                        1.0000
REGION                     0.2345
DISDUR                     0.0001

$Dysphagia
         p Value of SG Interaction
AGEONSET                   0.8745
AGETRT                     0.7524
SEX                        0.9104
REGION                     0.2136
DISDUR                     0.4493

$Dyspnoea
```

```
         p Value of SG Interaction
AGEONSET                    0.4886
AGETRT                      0.0593
SEX                         0.9740
REGION                      0.4397
DISDUR                      0.0571

$`Ear disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ear haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ear infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.4163
SEX                         0.0514
REGION                      0.6034
DISDUR                      0.2814

$`Ear pain`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Ecchymosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Eczema
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.5098
SEX                         1.0000
REGION                      0.2802
DISDUR                      0.4670
```

$`Eczema infected`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Electrocardiogram ST-T segment abnormal`
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   0.0463
SEX   1.0000
REGION   1.0000
DISDUR   0.0480

$`Endotracheal intubation complication`
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   1.0000
SEX   1.0000
REGION   1.0000
DISDUR   0.9999

$Enteritis
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Enterobiasis
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Enterococcal infection`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Epigastric discomfort`
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   1.0000
SEX   0.9999

```
REGION                      1.0000
DISDUR                      1.0000

$Erythema
         p Value of SG Interaction
AGEONSET                    0.3518
AGETRT                      0.3416
SEX                         0.3399
REGION                      0.3003
DISDUR                      0.4090

$`Escherichia infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Excoriation
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.0395
REGION                      0.1278
DISDUR                      0.9652

$`Exposure to communicable disease`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Eye infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Eye movement disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Failure to thrive`
         p Value of SG Interaction
AGEONSET                    0.3462
```

```
AGETRT                      0.7791
SEX                         0.3024
REGION                      0.8402
DISDUR                      0.8619

$Fatigue
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                          NA
DISDUR                      1.0000

$`Feeding disorder of infancy or early childhood`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.3787
SEX                         0.8496
REGION                      0.3300
DISDUR                      0.8786

$`Feeding intolerance`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Feeding tube complication`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.7236
SEX                         0.3465
REGION                      0.3061
DISDUR                      0.7100

$`Femur fracture`
         p Value of SG Interaction
AGEONSET                    0.1307
AGETRT                      1.0000
SEX                         0.5054
REGION                      1.0000
DISDUR                      0.1252

$Flatulence
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.6659
SEX                         0.6307
REGION                      1.0000
DISDUR                      0.3162

$`Food allergy`
```

```
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.9999

$`Food intolerance`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      0.9993
DISDUR                      1.0000

$`Fungal infection`
         p Value of SG Interaction
AGEONSET                    0.1960
AGETRT                      0.1730
SEX                         0.1127
REGION                      1.0000
DISDUR                      0.8361

$`Fungal skin infection`
         p Value of SG Interaction
AGEONSET                    0.2286
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.1547

$`Gastric haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Gastritis
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.3675
SEX                         1.0000
REGION                      0.7088
DISDUR                      0.4547

$Gastroenteritis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Gastroenteritis rotavirus`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastroenteritis viral`
         p Value of SG Interaction
AGEONSET                    0.6255
AGETRT                      0.9999
SEX                         0.1811
REGION                      1.0000
DISDUR                      0.9537

$`Gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      0.9993
DISDUR                      1.0000

$`Gastrointestinal motility disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastrointestinal tract irritation`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      0.9993
DISDUR                      1.0000

$`Gastrooesophageal reflux disease`
         p Value of SG Interaction
AGEONSET                    0.1242
AGETRT                      0.0238
SEX                         0.9237
REGION                      0.1301
DISDUR                      0.0223

$`General physical health deterioration`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Glycosuria
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Granuloma annulare`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Haematochezia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Hand-foot-and-mouth disease`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.0903
REGION                     0.2873
DISDUR                     0.6007

$`Head injury`
         p Value of SG Interaction
AGEONSET                   0.9999
AGETRT                     0.9999
SEX                        0.9999
REGION                     1.0000
DISDUR                     0.9997

$`Head lag abnormal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Heart rate decreased`
         p Value of SG Interaction
AGEONSET                   1.0000
```

```
AGETRT                     1.0000
SEX                        0.9999
REGION                     1.0000
DISDUR                     1.0000

$`Heart rate increased`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        1.0000
REGION                     1.0000
DISDUR                     0.2334

$`Heart rate irregular`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hepatomegaly
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hordeolum
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Human rhinovirus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hydronephrosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hyperaemia
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypercapnia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hyperglycaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hyperhidrosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hyperkeratosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypersensitivity
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1465
SEX                         1.0000
REGION                      0.1792
DISDUR                      0.5124

$Hypertension
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Hypoglycaemia
          p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Hypokalaemia
          p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Hypophagia
          p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Hypopnoea
          p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Hypothermia
          p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Hypoventilation
          p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Hypoxia
          p Value of SG Interaction
AGEONSET                     1.0000
AGETRT                       0.0187
SEX                          0.0861
```

```
REGION                     1.0000
DISDUR                     0.0466

$`Hypoxic-ischaemic encephalopathy`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Impaired gastric emptying`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.9999

$Impetigo
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1799
SEX                         1.0000
REGION                      0.2169
DISDUR                      0.4179

$`Incision site erythema`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Increased bronchial secretion`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0443
SEX                         0.0849
REGION                      0.2638
DISDUR                      0.1745

$`Increased upper airway secretion`
         p Value of SG Interaction
AGEONSET                    0.1706
AGETRT                      0.1637
SEX                         0.0605
REGION                      1.0000
DISDUR                      0.9861

$`Infantile colic`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Infantile spitting up`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Inflammatory marker increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Influenza
         p Value of SG Interaction
AGEONSET                     0.9999
AGETRT                       1.0000
SEX                          1.0000
REGION                       1.0000
DISDUR                       1.0000

$`Influenza A virus test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Infusion site bruising`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Infusion site extravasation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Injection site haematoma`
```

```
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.9999
SEX                         1.0000
REGION                      1.0000
DISDUR                      1.0000

$Intertrigo
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Iron deficiency`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Irritability
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.2071
SEX                         0.1935
REGION                      0.7563
DISDUR                      0.0047

$`Irritability postvaccinal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Joint contracture`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.5779
SEX                         0.1439
REGION                      1.0000
DISDUR                      0.5935

$`Joint range of motion decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Joint stiffness`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Keratosis pilaris`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Kyphoscoliosis
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Kyphosis
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   0.2049
SEX   1.0000
REGION   1.0000
DISDUR   0.2289

$Laceration
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Lacrimation increased`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Language disorder`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1

```
REGION                          1
DISDUR                          1

$`Left ventricular hypertrophy`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Leukocytosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Liver function test abnormal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Localised infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Lower respiratory tract infection`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.0321
SEX                        0.5068
REGION                     0.8426
DISDUR                     0.3915

$`Lower respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Lung disorder`
         p Value of SG Interaction
AGEONSET                   1.0000
```

```
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.4776

$`Lung infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Lymph node palpable`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Malaise
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Mechanical ventilation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Medical device complication`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Medical observation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Miliaria
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Mood swings`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Moraxella infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Moraxella test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Muscle contractions involuntary`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Muscle tightness`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Muscular weakness`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Myopia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Naevus anaemicus`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Nasal congestion`
         p Value of SG Interaction
AGEONSET                    0.1532
AGETRT                      0.7292
SEX                         0.4573
REGION                      1.0000
DISDUR                      0.3479

$`Nasal inflammation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Nasopharyngitis
         p Value of SG Interaction
AGEONSET                    0.1093
AGETRT                      0.1370
SEX                         0.6090
REGION                      0.0740
DISDUR                      0.8237

$`Neutrophil count increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Nodule
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Nosocomial infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Nystagmus
         p Value of SG Interaction
AGEONSET                   0.1075
AGETRT                     1.0000
SEX                        0.4408
REGION                     0.0253
DISDUR                     0.0338

$`Obstructive airways disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Oedema
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        1.0000
REGION                     0.9999
DISDUR                     1.0000

$`Oedema peripheral`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oral candidiasis`
         p Value of SG Interaction
AGEONSET                   0.2905
AGETRT                     0.5601
SEX                        0.3525
REGION                     0.7414
DISDUR                     0.1322

$`Oral fungal infection`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oral herpes`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oropharyngeal pain`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Orthopaedic examination`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Otitis media`
         p Value of SG Interaction
AGEONSET                   0.4167
AGETRT                     0.0431
SEX                        0.7953
REGION                     0.6157
DISDUR                     0.5807

$`Otitis media acute`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Ovarian cyst`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oxygen saturation decreased`
```

```
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.1414
SEX                         0.7404
REGION                      0.4573
DISDUR                      0.6647

$Pain
         p Value of SG Interaction
AGEONSET                    0.0200
AGETRT                      0.1723
SEX                         0.3230
REGION                      0.1158
DISDUR                      0.7871

$`Pain in extremity`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.9999

$Pallor
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Parainfluenzae virus infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pectus carinatum`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.7968

$`Penis disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Pharyngitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pharyngitis streptococcal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Phimosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pleural effusion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Pneumonia
         p Value of SG Interaction
AGEONSET                    0.9142
AGETRT                      0.8466
SEX                         0.4801
REGION                      0.5942
DISDUR                      0.7800

$`Pneumonia aspiration`
         p Value of SG Interaction
AGEONSET                    0.2803
AGETRT                      0.6532
SEX                         0.2444
REGION                      0.9711
DISDUR                      0.7064

$`Pneumonia bacterial`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.4824
SEX                         0.2036
```

```
REGION                     1.0000
DISDUR                     0.6190

$`Pneumonia influenzal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia moraxella`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia parainfluenzae viral`
         p Value of SG Interaction
AGEONSET                    0.1966
AGETRT                      1.0000
SEX                         1.0000
REGION                      0.4519
DISDUR                      0.1269

$`Pneumonia pneumococcal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia pseudomonal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia respiratory syncytial viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia viral`
         p Value of SG Interaction
AGEONSET                    1.0000
```

```
AGETRT                      0.3764
SEX                         0.3961
REGION                      0.7872
DISDUR                      0.6260

$Pneumothorax
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Positional plagiocephaly`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1096
SEX                         1.0000
REGION                      0.5863
DISDUR                      0.1443

$`Post procedural contusion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Post procedural haemorrhage`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Post procedural swelling`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Presyncope
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Procedural complication`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Procedural pain`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Procedural site reaction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pseudomonas infection`
         p Value of SG Interaction
AGEONSET                    0.0791
AGETRT                      0.2642
SEX                         0.0910
REGION                      0.9490
DISDUR                      0.2698

$`Pseudomonas test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Pyelonephritis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Pyrexia
         p Value of SG Interaction
AGEONSET                    0.6221
AGETRT                      0.4853
SEX                         0.7835
REGION                      0.4572
DISDUR                      0.3365
```

$Rash
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   0.1789
SEX   0.2199
REGION   0.2014
DISDUR   0.1218

$`Rash erythematous`
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   0.9999
SEX   1.0000
REGION   1.0000
DISDUR   0.9999

$`Rash macular`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Rash papular`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Respiratory alkalosis`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Respiratory arrest`
         p Value of SG Interaction
AGEONSET   0.4864
AGETRT   0.1859
SEX   0.9417
REGION   0.0207
DISDUR   0.5421

$`Respiratory disorder`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1

```
REGION                          1
DISDUR                          1

$`Respiratory distress`
         p Value of SG Interaction
AGEONSET                    0.9258
AGETRT                      0.7778
SEX                         0.9928
REGION                      0.1914
DISDUR                      0.4143

$`Respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.0885
AGETRT                      0.0492
SEX                         0.7278
REGION                      0.1147
DISDUR                      0.9109

$`Respiratory rate increased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9998
REGION                      0.9992
DISDUR                      1.0000

$`Respiratory syncytial virus bronchiolitis`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.5758
SEX                         0.8373
REGION                      0.5511
DISDUR                      0.2918

$`Respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.2489
SEX                         0.0138
REGION                      0.9216
DISDUR                      0.7371

$`Respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.1731
AGETRT                      0.0616
SEX                         0.1270
REGION                      0.7671
DISDUR                      0.5215

$`Respiratory tract infection bacterial`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.9750
SEX                         0.5333
REGION                      0.9986
DISDUR                      0.2400

$`Respirovirus test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Restlessness
         p Value of SG Interaction
AGEONSET                    0.0391
AGETRT                      0.0498
SEX                         0.1069
REGION                      0.2426
DISDUR                      0.8646

$Retching
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Rhinitis
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.2350
SEX                         0.7446
REGION                      1.0000
DISDUR                      0.0842

$`Rhinitis allergic`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Rhinorrhoea
```

```
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.5310
SEX                         0.0878
REGION                      0.2594
DISDUR                      0.2745

$`Rhinovirus infection`
         p Value of SG Interaction
AGEONSET                    0.1021
AGETRT                      0.1175
SEX                         0.3683
REGION                      0.7346
DISDUR                      0.4325

$Rhonchi
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Roseola
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Salivary hypersecretion`
         p Value of SG Interaction
AGEONSET                    0.2595
AGETRT                      0.2182
SEX                         0.7549
REGION                      0.0083
DISDUR                      0.6218

$`Scarlet fever`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Scoliosis
         p Value of SG Interaction
AGEONSET                    0.1216
AGETRT                      0.1593
SEX                         0.3318
REGION                      0.6822
DISDUR                      0.0717
```

$`Seasonal allergy`
         p Value of SG Interaction
AGEONSET   0.3977
AGETRT   0.7372
SEX   1.0000
REGION   0.5583
DISDUR   0.8602

$Seizure
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Sepsis
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Serratia infection`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Shock
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Sinus congestion`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Sinus tachycardia`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1

```
REGION                          1
DISDUR                          1

$Sinusitis
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.9999
SEX                         1.0000
REGION                      1.0000
DISDUR                      1.0000

$`Skin candida`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0172
SEX                         0.0770
REGION                      0.1419
DISDUR                      0.0227

$`Skin infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.9999

$`Skin oedema`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Sleep apnoea syndrome`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Sleep disorder`
         p Value of SG Interaction
AGEONSET                    0.6488
AGETRT                      0.6428
SEX                         0.2248
REGION                      0.4668
DISDUR                      0.4927

$Somnolence
         p Value of SG Interaction
AGEONSET                          1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sputum culture positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sputum discoloured`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.0267
SEX                        0.0772
REGION                     0.2243
DISDUR                     0.1110

$`Staphylococcal infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Staphylococcal sepsis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Staphylococcal skin infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Staphylococcus test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Stoma complication`
```

```
         p Value of SG Interaction
AGEONSET                    0.6233
AGETRT                      0.1218
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.5094

$`Stoma site abscess`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site erythema`
         p Value of SG Interaction
AGEONSET                    0.4511
AGETRT                      0.5750
SEX                         0.7947
REGION                      0.0371
DISDUR                      0.0207

$`Stoma site haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site infection`
         p Value of SG Interaction
AGEONSET                    0.7330
AGETRT                      0.2064
SEX                         0.5275
REGION                      0.0964
DISDUR                      0.0052

$`Stoma site inflammation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site irritation`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0443
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.0022
```

```
$Stomatitis
          p Value of SG Interaction
AGEONSET                     1.0000
AGETRT                       0.9999
SEX                          1.0000
REGION                       1.0000
DISDUR                       1.0000

$Strabismus
          p Value of SG Interaction
AGEONSET                     0.2621
AGETRT                       1.0000
SEX                          1.0000
REGION                       0.0673
DISDUR                       0.1369

$`Supraventricular tachycardia`
          p Value of SG Interaction
AGEONSET                           1
AGETRT                             1
SEX                                1
REGION                             1
DISDUR                             1

$`Surgical failure`
          p Value of SG Interaction
AGEONSET                           1
AGETRT                             1
SEX                                1
REGION                             1
DISDUR                             1

$Swelling
          p Value of SG Interaction
AGEONSET                           1
AGETRT                             1
SEX                                1
REGION                             1
DISDUR                             1

$`Systemic infection`
          p Value of SG Interaction
AGEONSET                     1.0000
AGETRT                       1.0000
SEX                          0.9999
REGION                       1.0000
DISDUR                       1.0000

$Tachycardia
          p Value of SG Interaction
AGEONSET                     0.0925
AGETRT                       0.3215
SEX                          0.3210
```

```
REGION                      0.9434
DISDUR                      0.3482

$Tachypnoea
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Teething
         p Value of SG Interaction
AGEONSET                    0.8145
AGETRT                      0.8558
SEX                         0.6400
REGION                      0.8342
DISDUR                      0.1375

$Thrombocytosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Thrombosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Tongue atrophy`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.9999

$`Tracheal haemorrhage`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Tracheal injury`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Tracheal obstruction`
         p Value of SG Interaction
AGEONSET                    0.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$Tracheitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Transaminases increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Upper gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Upper respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                    0.0596
AGETRT                      0.2029
SEX                         0.2534
REGION                      0.8790
DISDUR                      0.6675

$`Upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.9086
AGETRT                      0.2040
SEX                         0.5333
REGION                      0.0083
DISDUR                      0.0697

$`Upper respiratory tract inflammation`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Urinary retention`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Urinary tract infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Urine output decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Urticaria
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Use of accessory respiratory muscles`
         p Value of SG Interaction
AGEONSET                    0.1904
AGETRT                      0.1677
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.4598

$`Vaccination complication`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.0695
REGION                      0.2711
DISDUR                      0.6087
```

```
$`Vaccination site reaction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Vasculitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ventricular tachycardia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vessel puncture site bruise`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vessel puncture site reaction`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9998
REGION                      0.9992
DISDUR                      1.0000

$`Viral infection`
         p Value of SG Interaction
AGEONSET                    0.1072
AGETRT                      0.0860
SEX                         0.5035
REGION                      0.0910
DISDUR                      0.5079

$`Viral rash`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Viral rhinitis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Viral upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                   0.0581
AGETRT                     0.7978
SEX                        0.2540
REGION                     1.0000
DISDUR                     0.8108

$`Vitamin A decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Vitamin D decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Vitamin D deficiency`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Vomiting
         p Value of SG Interaction
AGEONSET                   0.3193
AGETRT                     0.6981
SEX                        0.4769
REGION                     0.8005
DISDUR                     0.7200

$`Weight decreased`
         p Value of SG Interaction
AGEONSET                   1.0000
```

```
AGETRT                     0.2767
SEX                        0.3169
REGION                     1.0000
DISDUR                     0.8321

$`Weight gain poor`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.7093
REGION                     0.8205
DISDUR                     0.8743

$Wheezing
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1


\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem milden UE nach SOC, das bei mindestens 10%
der Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Blood and lymphatic system disorders`
         p Value of SG Interaction
AGEONSET                   0.3317
AGETRT                     0.0098
SEX                        0.0211
REGION                     0.2317
DISDUR                     0.1130

$`Cardiac disorders`
         p Value of SG Interaction
AGEONSET                   0.1967
AGETRT                     0.6869
SEX                        0.8468
REGION                     0.7768
DISDUR                     0.6055

$`Congenital, familial and genetic disorders`
         p Value of SG Interaction
AGEONSET                   0.3684
AGETRT                     0.2065
SEX                        0.4440
REGION                     0.1221
DISDUR                     0.1232

$`Ear and labyrinth disorders`
         p Value of SG Interaction
```

```
AGEONSET                    0.8377
AGETRT                      0.8904
SEX                         0.3118
REGION                      0.8112
DISDUR                      0.7416

$`Eye disorders`
         p Value of SG Interaction
AGEONSET                    0.4108
AGETRT                      0.2436
SEX                         0.6972
REGION                      0.0082
DISDUR                      0.0671

$`Gastrointestinal disorders`
         p Value of SG Interaction
AGEONSET                    0.4379
AGETRT                      0.3443
SEX                         0.8222
REGION                      0.9144
DISDUR                      0.1747

$`General disorders and administration site conditions`
         p Value of SG Interaction
AGEONSET                    0.9598
AGETRT                      0.5053
SEX                         0.4831
REGION                      0.8613
DISDUR                      0.3008

$`Hepatobiliary disorders`
         p Value of SG Interaction
AGEONSET                    0.8010
AGETRT                      0.5644
SEX                         0.3177
REGION                      0.6540
DISDUR                      0.3723

$`Immune system disorders`
         p Value of SG Interaction
AGEONSET                    0.5239
AGETRT                      0.8146
SEX                         0.4230
REGION                      0.5919
DISDUR                      0.7967

$`Infections and infestations`
         p Value of SG Interaction
AGEONSET                    0.0660
AGETRT                      0.1051
SEX                         0.1691
REGION                      0.0686
DISDUR                      0.6373
```

$`Injury, poisoning and procedural complications`
          p Value of SG Interaction
AGEONSET   0.4638
AGETRT   0.6976
SEX   0.9825
REGION   0.3093
DISDUR   0.1623

$Investigations
          p Value of SG Interaction
AGEONSET   0.7182
AGETRT   0.5361
SEX   0.5068
REGION   0.6049
DISDUR   0.2557

$`Metabolism and nutrition disorders`
          p Value of SG Interaction
AGEONSET   0.7647
AGETRT   0.0967
SEX   0.7355
REGION   0.8825
DISDUR   0.4452

$`Musculoskeletal and connective tissue disorders`
          p Value of SG Interaction
AGEONSET   0.2915
AGETRT   0.5522
SEX   0.1918
REGION   0.9943
DISDUR   0.5827

$`Nervous system disorders`
          p Value of SG Interaction
AGEONSET   0.2157
AGETRT   0.5568
SEX   0.4975
REGION   0.0145
DISDUR   0.1448

$`Psychiatric disorders`
          p Value of SG Interaction
AGEONSET   0.4808
AGETRT   0.6250
SEX   0.7143
REGION   0.7903
DISDUR   0.3831

$`Renal and urinary disorders`
          p Value of SG Interaction
AGEONSET   0.7886
AGETRT   0.2322
SEX   0.1365
REGION   0.9537

```
DISDUR                      0.2423

$`Reproductive system and breast disorders`
         p Value of SG Interaction
AGEONSET                    0.6093
AGETRT                      0.3219
SEX                         0.6904
REGION                      0.7375
DISDUR                      0.7073

$`Respiratory, thoracic and mediastinal disorders`
         p Value of SG Interaction
AGEONSET                    0.0438
AGETRT                      0.7613
SEX                         0.2584
REGION                      0.5253
DISDUR                      0.6307

$`Skin and subcutaneous tissue disorders`
         p Value of SG Interaction
AGEONSET                    0.2266
AGETRT                      0.4691
SEX                         0.2822
REGION                      0.6010
DISDUR                      0.0503

$`Surgical and medical procedures`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vascular disorders`
         p Value of SG Interaction
AGEONSET                    0.0949
AGETRT                      0.1921
SEX                         0.3954
REGION                      0.9980
DISDUR                      0.9047


\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines milden UEs nach SOC, das bei mindestens 10% der
Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Blood and lymphatic system disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Cardiac disorders`
         p Value of SG Interaction
AGEONSET                    0.0748
AGETRT                      0.8810
SEX                         0.8492
REGION                      0.8142
DISDUR                      0.7107

$`Congenital, familial and genetic disorders`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.5386
SEX                         0.2978
REGION                      0.2984
DISDUR                      0.6285

$`Ear and labyrinth disorders`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.2492
REGION                      1.0000
DISDUR                      0.9973

$`Eye disorders`
         p Value of SG Interaction
AGEONSET                    0.4484
AGETRT                      0.2050
SEX                         0.6821
REGION                      0.0279
DISDUR                      0.0941

$`Gastrointestinal disorders`
         p Value of SG Interaction
AGEONSET                    0.2271
AGETRT                      0.1303
SEX                         0.9795
REGION                      0.9017
DISDUR                      0.2663

$`General disorders and administration site conditions`
         p Value of SG Interaction
AGEONSET                    0.2773
AGETRT                      0.2230
SEX                         0.4659
REGION                      0.3922
DISDUR                      0.5110

$`Hepatobiliary disorders`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Immune system disorders`
         p Value of SG Interaction
AGEONSET                    0.4473
AGETRT                      0.5823
SEX                         0.3067
REGION                      0.3629
DISDUR                      0.9025

$`Infections and infestations`
         p Value of SG Interaction
AGEONSET                    0.6105
AGETRT                      0.5045
SEX                         0.2920
REGION                      0.0401
DISDUR                      0.6528

$`Injury, poisoning and procedural complications`
         p Value of SG Interaction
AGEONSET                    0.3076
AGETRT                      0.6110
SEX                         0.9932
REGION                      0.0967
DISDUR                      0.2543

$Investigations
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.3248
SEX                         0.4298
REGION                      0.6509
DISDUR                      0.2835

$`Metabolism and nutrition disorders`
         p Value of SG Interaction
AGEONSET                    0.4350
AGETRT                      0.0969
SEX                         0.8175
REGION                      0.8401
DISDUR                      0.3556

$`Musculoskeletal and connective tissue disorders`
         p Value of SG Interaction
AGEONSET                    0.0952
AGETRT                      0.5226
SEX                         0.1976
REGION                      0.6799
DISDUR                      0.3828

$`Nervous system disorders`
```

```
         p Value of SG Interaction
AGEONSET                    0.2220
AGETRT                      0.4941
SEX                         0.5330
REGION                      0.0296
DISDUR                      0.1627

$`Psychiatric disorders`
         p Value of SG Interaction
AGEONSET                    0.1932
AGETRT                      0.4074
SEX                         0.7213
REGION                      0.8242
DISDUR                      0.1985

$`Renal and urinary disorders`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1879
SEX                         0.0862
REGION                      1.0000
DISDUR                      0.1905

$`Reproductive system and breast disorders`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      1.0000

$`Respiratory, thoracic and mediastinal disorders`
         p Value of SG Interaction
AGEONSET                    0.0576
AGETRT                      0.9902
SEX                         0.2494
REGION                      0.3902
DISDUR                      0.6363

$`Skin and subcutaneous tissue disorders`
         p Value of SG Interaction
AGEONSET                    0.1145
AGETRT                      0.2864
SEX                         0.3666
REGION                      0.4188
DISDUR                      0.0538

$`Surgical and medical procedures`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Vascular disorders`
         p Value of SG Interaction
AGEONSET                    0.1577
AGETRT                      0.1218
SEX                         0.2722
REGION                      1.0000
DISDUR                      0.9531


\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem milden UE nach PT, das bei mindestens 10%
der Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Abdominal discomfort`
         p Value of SG Interaction
AGEONSET                    0.6654
AGETRT                      0.8061
SEX                         0.8955
REGION                      0.3359
DISDUR                      0.4441

$`Abdominal distension`
         p Value of SG Interaction
AGEONSET                    0.7813
AGETRT                      0.5757
SEX                         0.5434
REGION                      0.7386
DISDUR                      0.8874

$`Abdominal pain upper`
         p Value of SG Interaction
AGEONSET                    0.2221
AGETRT                      0.1069
SEX                         0.1054
REGION                      0.8720
DISDUR                      0.3212

$`Acquired phimosis`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Acute respiratory distress syndrome`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$`Acute respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.5425
AGETRT                      0.2671
SEX                         0.3721
REGION                      0.3109
DISDUR                      0.0186

$`Adenovirus infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Agitation
         p Value of SG Interaction
AGEONSET                    0.7204
AGETRT                      0.6289
SEX                         0.6031
REGION                      0.6702
DISDUR                      0.7351

$`Agitation postoperative`
         p Value of SG Interaction
AGEONSET                    0.7813
AGETRT                      0.5757
SEX                         0.5434
REGION                      0.7386
DISDUR                      0.8874

$`Alanine aminotransferase increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Amblyopia
         p Value of SG Interaction
AGEONSET                    0.0172
AGETRT                      0.2479
SEX                         0.1552
REGION                      0.0000
DISDUR                      0.1949

$Anaemia
         p Value of SG Interaction
AGEONSET                    0.4937
AGETRT                      0.0782
```

```
SEX                         0.1311
REGION                      0.5254
DISDUR                      0.1120

$Anxiety
         p Value of SG Interaction
AGEONSET                    0.7966
AGETRT                      0.5675
SEX                         0.3421
REGION                      0.7342
DISDUR                      0.4735

$`Aphthous ulcer`
         p Value of SG Interaction
AGEONSET                    0.7727
AGETRT                      0.5787
SEX                         0.4899
REGION                      0.5008
DISDUR                      0.8705

$Apnoea
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Apparent life threatening event`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Application site rash`
         p Value of SG Interaction
AGEONSET                    0.4591
AGETRT                      0.0753
SEX                         0.2101
REGION                      0.6192
DISDUR                      0.0002

$`Arthropod bite`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Aspartate aminotransferase increased`
         p Value of SG Interaction
```

```
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$Aspiration
         p Value of SG Interaction
AGEONSET                    0.7573
AGETRT                      0.4107
SEX                         0.7442
REGION                      0.9871
DISDUR                      0.0121

$Atelectasis
         p Value of SG Interaction
AGEONSET                    0.1918
AGETRT                      0.3337
SEX                         0.5773
REGION                      0.7394
DISDUR                      0.6722

$`Back pain`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$Bacteraemia
         p Value of SG Interaction
AGEONSET                    0.5294
AGETRT                      0.2656
SEX                         0.0571
REGION                      0.3835
DISDUR                      0.3117

$`Bacterial disease carrier`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bacterial infection`
         p Value of SG Interaction
AGEONSET                    0.7844
AGETRT                      0.5743
SEX                         0.5639
REGION                      0.7264
DISDUR                      0.7980
```

```
$`Bacterial tracheitis`
         p Value of SG Interaction
AGEONSET                    0.2399
AGETRT                      0.7670
SEX                         0.6082
REGION                      0.0757
DISDUR                      0.5402

$Balanoposthitis
         p Value of SG Interaction
AGEONSET                    0.7711
AGETRT                      0.5792
SEX                         0.4885
REGION                      0.6303
DISDUR                      0.8258

$`Blood chloride decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Blood iron decreased`
         p Value of SG Interaction
AGEONSET                    0.7911
AGETRT                      0.5709
SEX                         0.6096
REGION                      0.7120
DISDUR                      0.6138

$`Blood potassium decreased`
         p Value of SG Interaction
AGEONSET                    0.7941
AGETRT                      0.5691
SEX                         0.3559
REGION                      0.7242
DISDUR                      0.5352

$`Blood sodium decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Body temperature decreased`
         p Value of SG Interaction
AGEONSET                    0.7672
AGETRT                      0.4091
SEX                         0.0904
REGION                      0.9806
```

```
DISDUR                      0.3583

$`Body temperature increased`
         p Value of SG Interaction
AGEONSET                    0.9561
AGETRT                      0.2318
SEX                         0.4017
REGION                      0.9977
DISDUR                      0.1494

$`Bone marrow disorder`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Bradycardia
         p Value of SG Interaction
AGEONSET                    0.0717
AGETRT                      0.3420
SEX                         0.8196
REGION                      0.3017
DISDUR                      0.1123

$`Brain injury`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Breath holding`
         p Value of SG Interaction
AGEONSET                    0.7744
AGETRT                      0.5782
SEX                         0.4693
REGION                      0.7643
DISDUR                      0.9157

$`Bronchial obstruction`
         p Value of SG Interaction
AGEONSET                    0.7995
AGETRT                      0.5655
SEX                         0.6714
REGION                      0.7461
DISDUR                      0.4046

$`Bronchial secretion retention`
         p Value of SG Interaction
AGEONSET                    0.6008
AGETRT                      0.9017
```

```
SEX                         0.2467
REGION                      0.7051
DISDUR                      0.4971

$Bronchiolitis
         p Value of SG Interaction
AGEONSET                    0.8377
AGETRT                      0.1223
SEX                         0.6191
REGION                      0.4577
DISDUR                      0.2342

$Bronchitis
         p Value of SG Interaction
AGEONSET                    0.9417
AGETRT                      0.9860
SEX                         0.3646
REGION                      0.9174
DISDUR                      0.8008

$`Bronchitis viral`
         p Value of SG Interaction
AGEONSET                    0.7141
AGETRT                      0.4116
SEX                         0.7090
REGION                      0.5331
DISDUR                      0.2664

$`C-reactive protein increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Candida infection`
         p Value of SG Interaction
AGEONSET                    0.2394
AGETRT                      0.1573
SEX                         0.0201
REGION                      0.7441
DISDUR                      0.5128

$`Candida nappy rash`
         p Value of SG Interaction
AGEONSET                    0.8283
AGETRT                      0.2370
SEX                         0.9173
REGION                      0.2213
DISDUR                      0.1607

$`Candida sepsis`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Cardiac arrest`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Cardio-respiratory arrest`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Catarrh
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Catheter site inflammation`
         p Value of SG Interaction
AGEONSET                    0.8057
AGETRT                      0.2373
SEX                         0.7411
REGION                      0.9181
DISDUR                      0.1232

$Cellulitis
         p Value of SG Interaction
AGEONSET                    0.7779
AGETRT                      0.0608
SEX                         0.1349
REGION                      0.9694
DISDUR                      0.0014

$Chalazion
         p Value of SG Interaction
AGEONSET                    0.7438
AGETRT                      0.3623
SEX                         0.6497
REGION                      0.8546
DISDUR                      0.2579
```

$Choking
	p Value of SG Interaction
AGEONSET	0.8208
AGETRT	0.8810
SEX	0.0549
REGION	0.2465
DISDUR	0.7764

$`Chronic respiratory failure`
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$Clonus
	p Value of SG Interaction
AGEONSET	0.7711
AGETRT	0.5792
SEX	0.4885
REGION	0.6303
DISDUR	0.8258

$`Congenital diaphragmatic hernia`
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$Conjunctivitis
	p Value of SG Interaction
AGEONSET	0.7556
AGETRT	0.5402
SEX	0.8605
REGION	0.8213
DISDUR	0.6584

$`Conjunctivitis bacterial`
	p Value of SG Interaction
AGEONSET	0.8325
AGETRT	0.8876
SEX	0.9524
REGION	0.8325
DISDUR	0.5935

$Constipation
	p Value of SG Interaction
AGEONSET	0.4764
AGETRT	0.1274
SEX	0.9172
REGION	0.3798

```
DISDUR                      0.3753

$Contusion
         p Value of SG Interaction
AGEONSET                    0.7916
AGETRT                      0.5706
SEX                         0.6132
REGION                      0.6966
DISDUR                      0.6004

$`Corona virus infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Cough
         p Value of SG Interaction
AGEONSET                    0.9728
AGETRT                      0.9438
SEX                         0.4821
REGION                      0.7036
DISDUR                      0.0966

$Crying
         p Value of SG Interaction
AGEONSET                    0.7813
AGETRT                      0.5757
SEX                         0.5434
REGION                      0.7386
DISDUR                      0.8874

$Cryptorchism
         p Value of SG Interaction
AGEONSET                    0.4591
AGETRT                      0.0753
SEX                         0.2101
REGION                      0.6192
DISDUR                      0.0002

$Cyanosis
         p Value of SG Interaction
AGEONSET                    0.7989
AGETRT                      0.3952
SEX                         0.0920
REGION                      0.9341
DISDUR                      0.5694

$Death
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Decubitus ulcer`
         p Value of SG Interaction
AGEONSET                    0.5099
AGETRT                      0.0761
SEX                         0.0961
REGION                      0.4685
DISDUR                      0.6108

$`Deformity thorax`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Dehydration
         p Value of SG Interaction
AGEONSET                    0.8201
AGETRT                      0.2381
SEX                         0.8508
REGION                      0.8770
DISDUR                      0.3940

$`Delayed fontanelle closure`
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$`Delayed recovery from anaesthesia`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Dermatitis
         p Value of SG Interaction
AGEONSET                    0.7438
AGETRT                      0.3623
SEX                         0.6497
REGION                      0.8546
DISDUR                      0.2579

$`Dermatitis allergic`
         p Value of SG Interaction
```

```
AGEONSET                    0.8054
AGETRT                      0.5611
SEX                         0.2941
REGION                      0.6329
DISDUR                      0.2849

$`Dermatitis atopic`
         p Value of SG Interaction
AGEONSET                    0.3342
AGETRT                      0.6624
SEX                         0.8770
REGION                      0.2256
DISDUR                      0.1614

$`Dermatitis contact`
         p Value of SG Interaction
AGEONSET                    0.4976
AGETRT                      0.2213
SEX                         0.5310
REGION                      0.6914
DISDUR                      0.0155

$`Dermatitis diaper`
         p Value of SG Interaction
AGEONSET                    0.4154
AGETRT                      0.9565
SEX                         0.6489
REGION                      0.6860
DISDUR                      0.1529

$`Developmental hip dysplasia`
         p Value of SG Interaction
AGEONSET                    0.5363
AGETRT                      0.2671
SEX                         0.3259
REGION                      0.3472
DISDUR                      0.0953

$`Device malfunction`
         p Value of SG Interaction
AGEONSET                    0.4591
AGETRT                      0.0753
SEX                         0.2101
REGION                      0.6192
DISDUR                      0.0002

$`Device occlusion`
         p Value of SG Interaction
AGEONSET                    0.7950
AGETRT                      0.0608
SEX                         0.5151
REGION                      0.3323
DISDUR                      0.0001
```

```
$Diarrhoea
         p Value of SG Interaction
AGEONSET                    0.5870
AGETRT                      0.4448
SEX                         0.5554
REGION                      0.6824
DISDUR                      0.1412

$`Diarrhoea haemorrhagic`
         p Value of SG Interaction
AGEONSET                    0.0171
AGETRT                      0.2504
SEX                         0.1653
REGION                      0.4991
DISDUR                      0.2805

$Discomfort
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Drooling
         p Value of SG Interaction
AGEONSET                    0.7916
AGETRT                      0.5706
SEX                         0.6132
REGION                      0.6966
DISDUR                      0.6004

$`Drug hypersensitivity`
         p Value of SG Interaction
AGEONSET                    0.0643
AGETRT                      0.2325
SEX                         0.6276
REGION                      0.9524
DISDUR                      0.5487

$`Drug intolerance`
         p Value of SG Interaction
AGEONSET                    0.7419
AGETRT                      0.3613
SEX                         0.6607
REGION                      0.8590
DISDUR                      0.2335

$`Dry eye`
         p Value of SG Interaction
AGEONSET                    0.7694
AGETRT                      0.4086
SEX                         0.0944
REGION                      0.1781
```

```
DISDUR                      0.2531

$`Dry skin`
          p Value of SG Interaction
AGEONSET                    0.7950
AGETRT                      0.0608
SEX                         0.5151
REGION                      0.3323
DISDUR                      0.0001

$Dysphagia
          p Value of SG Interaction
AGEONSET                    0.4840
AGETRT                      0.7928
SEX                         0.7043
REGION                      0.9920
DISDUR                      0.4864

$Dyspnoea
          p Value of SG Interaction
AGEONSET                    0.2078
AGETRT                      0.9805
SEX                         0.2191
REGION                      0.4362
DISDUR                      0.2806

$`Ear disorder`
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Ear haemorrhage`
          p Value of SG Interaction
AGEONSET                    0.5363
AGETRT                      0.2671
SEX                         0.3259
REGION                      0.3472
DISDUR                      0.0953

$`Ear infection`
          p Value of SG Interaction
AGEONSET                    0.8849
AGETRT                      0.9462
SEX                         0.0286
REGION                      0.3853
DISDUR                      0.7964

$`Ear pain`
          p Value of SG Interaction
AGEONSET                    0.7419
AGETRT                      0.3613
```

```
SEX                         0.6607
REGION                      0.8590
DISDUR                      0.2335

$Ecchymosis
         p Value of SG Interaction
AGEONSET                    0.6565
AGETRT                      0.1952
SEX                         0.8342
REGION                      0.6688
DISDUR                      0.2899

$Eczema
         p Value of SG Interaction
AGEONSET                    0.7950
AGETRT                      0.2345
SEX                         0.5151
REGION                      0.3738
DISDUR                      0.2219

$`Eczema infected`
         p Value of SG Interaction
AGEONSET                    0.7966
AGETRT                      0.5675
SEX                         0.3421
REGION                      0.4948
DISDUR                      0.4735

$`Electrocardiogram ST-T segment abnormal`
         p Value of SG Interaction
AGEONSET                    0.4937
AGETRT                      0.0782
SEX                         0.1311
REGION                      0.5254
DISDUR                      0.1120

$`Endotracheal intubation complication`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Enteritis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Enterobiasis
         p Value of SG Interaction
```

```
AGEONSET                    0.7995
AGETRT                      0.5655
SEX                         0.6714
REGION                      0.4922
DISDUR                      0.4046

$`Enterococcal infection`
         p Value of SG Interaction
AGEONSET                    0.7727
AGETRT                      0.5787
SEX                         0.4899
REGION                      0.5008
DISDUR                      0.8705

$`Epigastric discomfort`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Erythema
         p Value of SG Interaction
AGEONSET                    0.0277
AGETRT                      0.5703
SEX                         0.6815
REGION                      0.0018
DISDUR                      0.4328

$`Escherichia infection`
         p Value of SG Interaction
AGEONSET                    0.7744
AGETRT                      0.5782
SEX                         0.4998
REGION                      0.6436
DISDUR                      0.9157

$Excoriation
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Exposure to communicable disease`
         p Value of SG Interaction
AGEONSET                    0.7765
AGETRT                      0.3739
SEX                         0.4568
REGION                      0.6525
DISDUR                      0.9763
```

$`Eye infection`
	p Value of SG Interaction
AGEONSET	0.7593
AGETRT	0.3694
SEX	0.5581
REGION	0.8132
DISDUR	0.5336

$`Eye movement disorder`
	p Value of SG Interaction
AGEONSET	0.7844
AGETRT	0.5743
SEX	0.5639
REGION	0.7264
DISDUR	0.7980

$`Failure to thrive`
	p Value of SG Interaction
AGEONSET	0.1152
AGETRT	0.4756
SEX	0.8861
REGION	0.8137
DISDUR	0.9909

$Fatigue
	p Value of SG Interaction
AGEONSET	0.4878
AGETRT	0.0783
SEX	0.1271
REGION	0.1719
DISDUR	0.0496

$`Feeding disorder of infancy or early childhood`
	p Value of SG Interaction
AGEONSET	0.7989
AGETRT	0.2357
SEX	0.1644
REGION	0.8804
DISDUR	0.2298

$`Feeding intolerance`
	p Value of SG Interaction
AGEONSET	0.6921
AGETRT	0.4235
SEX	0.3823
REGION	0.9578
DISDUR	0.8509

$`Feeding tube complication`
	p Value of SG Interaction
AGEONSET	0.4090
AGETRT	0.8303
SEX	0.3513
REGION	0.2265

```
DISDUR                      0.7394

$`Femur fracture`
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606

$Flatulence
         p Value of SG Interaction
AGEONSET                    0.8641
AGETRT                      0.4073
SEX                         0.3893
REGION                      0.9750
DISDUR                      0.7110

$`Food allergy`
         p Value of SG Interaction
AGEONSET                    0.8208
AGETRT                      0.5458
SEX                         0.8459
REGION                      0.5507
DISDUR                      0.0812

$`Food intolerance`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Fungal infection`
         p Value of SG Interaction
AGEONSET                    0.0617
AGETRT                      0.2366
SEX                         0.1748
REGION                      0.8905
DISDUR                      0.8479

$`Fungal skin infection`
         p Value of SG Interaction
AGEONSET                    0.0611
AGETRT                      0.8713
SEX                         0.7328
REGION                      0.9209
DISDUR                      0.1629

$`Gastric haemorrhage`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Gastritis
         p Value of SG Interaction
AGEONSET                     0.9727
AGETRT                       0.6509
SEX                          0.9001
REGION                       0.6910
DISDUR                       0.6943

$Gastroenteritis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Gastroenteritis rotavirus`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Gastroenteritis viral`
         p Value of SG Interaction
AGEONSET                     0.2229
AGETRT                       0.1067
SEX                          0.6227
REGION                       0.1485
DISDUR                       0.3601

$`Gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Gastrointestinal motility disorder`
         p Value of SG Interaction
AGEONSET                     0.4591
AGETRT                       0.0753
SEX                          0.2101
REGION                       0.6192
DISDUR                       0.0002

$`Gastrointestinal tract irritation`
         p Value of SG Interaction
```

```
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Gastrooesophageal reflux disease`
         p Value of SG Interaction
AGEONSET                    0.2090
AGETRT                      0.0089
SEX                         0.9003
REGION                      0.1508
DISDUR                      0.0046

$`General physical health deterioration`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Glycosuria
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Granuloma annulare`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$Haematochezia
         p Value of SG Interaction
AGEONSET                    0.7023
AGETRT                      0.8267
SEX                         0.4444
REGION                      0.4905
DISDUR                      0.5507

$`Hand-foot-and-mouth disease`
         p Value of SG Interaction
AGEONSET                    0.7874
AGETRT                      0.4020
SEX                         0.1147
REGION                      0.3563
DISDUR                      0.7478
```

```
$`Head injury`
         p Value of SG Interaction
AGEONSET                    0.5425
AGETRT                      0.2671
SEX                         0.3721
REGION                      0.3590
DISDUR                      0.0186

$`Head lag abnormal`
         p Value of SG Interaction
AGEONSET                    0.5289
AGETRT                      0.2655
SEX                         0.2808
REGION                      0.2989
DISDUR                      0.3292

$`Heart rate decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Heart rate increased`
         p Value of SG Interaction
AGEONSET                    0.7455
AGETRT                      0.4111
SEX                         0.8142
REGION                      0.9907
DISDUR                      0.0306

$`Heart rate irregular`
         p Value of SG Interaction
AGEONSET                    0.7627
AGETRT                      0.3706
SEX                         0.4325
REGION                      0.8028
DISDUR                      0.6122

$Hepatomegaly
         p Value of SG Interaction
AGEONSET                    0.8010
AGETRT                      0.5644
SEX                         0.3177
REGION                      0.6540
DISDUR                      0.3723

$Hordeolum
         p Value of SG Interaction
AGEONSET                    0.5363
AGETRT                      0.2671
SEX                         0.3259
REGION                      0.3472
```

```
DISDUR                      0.0953

$`Human rhinovirus test positive`
         p Value of SG Interaction
AGEONSET                    0.7911
AGETRT                      0.5709
SEX                         0.6096
REGION                      0.7120
DISDUR                      0.6138

$Hydronephrosis
         p Value of SG Interaction
AGEONSET                    0.8010
AGETRT                      0.5644
SEX                         0.3177
REGION                      0.6540
DISDUR                      0.3723

$Hyperaemia
         p Value of SG Interaction
AGEONSET                    0.0166
AGETRT                      0.2564
SEX                         0.0951
REGION                      0.2337
DISDUR                      0.6358

$Hypercapnia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hyperglycaemia
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.2599
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$Hyperhidrosis
         p Value of SG Interaction
AGEONSET                    0.4866
AGETRT                      0.0783
SEX                         0.1470
REGION                      0.5475
DISDUR                      0.0414

$Hyperkeratosis
         p Value of SG Interaction
AGEONSET                    0.6993
AGETRT                      0.4209
```

```
SEX                         0.4253
REGION                      0.5047
DISDUR                      0.6358

$Hypersensitivity
         p Value of SG Interaction
AGEONSET                    0.5354
AGETRT                      0.3811
SEX                         0.1658
REGION                      0.1785
DISDUR                      0.1486

$Hypertension
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hypoglycaemia
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$Hypokalaemia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hypophagia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hypopnoea
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hypothermia
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hypoventilation
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hypoxia
         p Value of SG Interaction
AGEONSET                    0.6637
AGETRT                      0.8050
SEX                         0.8838
REGION                      0.6458
DISDUR                      0.4118

$`Hypoxic-ischaemic encephalopathy`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Impaired gastric emptying`
         p Value of SG Interaction
AGEONSET                    0.7244
AGETRT                      0.3501
SEX                         0.7630
REGION                      0.4449
DISDUR                      0.0807

$Impetigo
         p Value of SG Interaction
AGEONSET                    0.8157
AGETRT                      0.2382
SEX                         0.8167
REGION                      0.2636
DISDUR                      0.3101

$`Incision site erythema`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496
```

$`Increased bronchial secretion`
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$`Increased upper airway secretion`
	p Value of SG Interaction
AGEONSET	0.0661
AGETRT	0.2261
SEX	0.1072
REGION	0.9719
DISDUR	0.6790

$`Infantile colic`
	p Value of SG Interaction
AGEONSET	0.7906
AGETRT	0.5712
SEX	0.3758
REGION	0.7010
DISDUR	0.6274

$`Infantile spitting up`
	p Value of SG Interaction
AGEONSET	0.7541
AGETRT	0.3673
SEX	0.5891
REGION	0.8282
DISDUR	0.4255

$`Inflammatory marker increased`
	p Value of SG Interaction
AGEONSET	0.7523
AGETRT	0.3665
SEX	0.3780
REGION	0.8330
DISDUR	0.3923

$Influenza
	p Value of SG Interaction
AGEONSET	0.7995
AGETRT	0.5655
SEX	0.6714
REGION	0.4922
DISDUR	0.4046

$`Influenza A virus test positive`
	p Value of SG Interaction
AGEONSET	0.7541
AGETRT	0.3673
SEX	0.5891
REGION	0.8282

```
DISDUR                      0.4255

$`Infusion site bruising`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Infusion site extravasation`
         p Value of SG Interaction
AGEONSET                    0.4591
AGETRT                      0.0753
SEX                         0.2101
REGION                      0.6192
DISDUR                      0.0002

$`Injection site haematoma`
         p Value of SG Interaction
AGEONSET                    0.5213
AGETRT                      0.0727
SEX                         0.2414
REGION                      0.2700
DISDUR                      0.7364

$Intertrigo
         p Value of SG Interaction
AGEONSET                    0.7786
AGETRT                      0.5767
SEX                         0.5264
REGION                      0.5016
DISDUR                      0.9630

$`Iron deficiency`
         p Value of SG Interaction
AGEONSET                    0.7926
AGETRT                      0.5700
SEX                         0.6203
REGION                      0.6923
DISDUR                      0.5739

$Irritability
         p Value of SG Interaction
AGEONSET                    0.9376
AGETRT                      0.4542
SEX                         0.3449
REGION                      0.9737
DISDUR                      0.0475

$`Irritability postvaccinal`
         p Value of SG Interaction
AGEONSET                    0.7599
AGETRT                      0.3696
```

```
SEX                         0.4171
REGION                      0.5844
DISDUR                      0.5464

$`Joint contracture`
         p Value of SG Interaction
AGEONSET                    0.9730
AGETRT                      0.6511
SEX                         0.3107
REGION                      0.9963
DISDUR                      0.7334

$`Joint range of motion decreased`
         p Value of SG Interaction
AGEONSET                    0.5363
AGETRT                      0.2671
SEX                         0.3259
REGION                      0.3472
DISDUR                      0.0953

$`Joint stiffness`
         p Value of SG Interaction
AGEONSET                    0.5099
AGETRT                      0.0761
SEX                         0.0961
REGION                      0.4685
DISDUR                      0.6108

$`Keratosis pilaris`
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$Kyphoscoliosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Kyphosis
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.2599
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$Laceration
         p Value of SG Interaction
```

```
AGEONSET                    0.5363
AGETRT                      0.2671
SEX                         0.3259
REGION                      0.3472
DISDUR                      0.0953

$`Lacrimation increased`
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.0745
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$`Language disorder`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Left ventricular hypertrophy`
         p Value of SG Interaction
AGEONSET                    0.6914
AGETRT                      0.4238
SEX                         0.9064
REGION                      0.5406
DISDUR                      0.8722

$Leukocytosis
         p Value of SG Interaction
AGEONSET                    0.5084
AGETRT                      0.0765
SEX                         0.0993
REGION                      0.4743
DISDUR                      0.5385

$`Liver function test abnormal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Localised infection`
         p Value of SG Interaction
AGEONSET                    0.7627
AGETRT                      0.3706
SEX                         0.5378
REGION                      0.5960
DISDUR                      0.6122
```

```
$`Lower respiratory tract infection`
          p Value of SG Interaction
AGEONSET                     0.3582
AGETRT                       0.6467
SEX                          0.6495
REGION                       0.8659
DISDUR                       0.5092

$`Lower respiratory tract infection viral`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Lung disorder`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Lung infection`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Lymph node palpable`
          p Value of SG Interaction
AGEONSET                     0.5162
AGETRT                       0.2599
SEX                          0.0830
REGION                       0.4431
DISDUR                       0.9596

$Malaise
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Mechanical ventilation`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
```

```
DISDUR                         NaN

$`Medical device complication`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$`Medical observation`
         p Value of SG Interaction
AGEONSET                    0.6766
AGETRT                      0.4259
SEX                         0.9772
REGION                      0.3766
DISDUR                      0.7028

$Miliaria
         p Value of SG Interaction
AGEONSET                    0.6856
AGETRT                      0.8178
SEX                         0.2875
REGION                      0.7168
DISDUR                      0.9555

$`Mood swings`
         p Value of SG Interaction
AGEONSET                    0.8058
AGETRT                      0.5607
SEX                         0.7202
REGION                      0.4853
DISDUR                      0.2761

$`Moraxella infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Moraxella test positive`
         p Value of SG Interaction
AGEONSET                    0.7911
AGETRT                      0.5709
SEX                         0.6096
REGION                      0.7120
DISDUR                      0.6138

$`Muscle contractions involuntary`
         p Value of SG Interaction
AGEONSET                    0.7558
AGETRT                      0.3681
```

```
SEX                         0.3959
REGION                      0.5679
DISDUR                      0.4602

$`Muscle tightness`
         p Value of SG Interaction
AGEONSET                    0.4591
AGETRT                      0.0753
SEX                         0.2101
REGION                      0.6192
DISDUR                      0.0002

$`Muscular weakness`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Myopia
         p Value of SG Interaction
AGEONSET                    0.7511
AGETRT                      0.3660
SEX                         0.3722
REGION                      0.8362
DISDUR                      0.3710

$`Naevus anaemicus`
         p Value of SG Interaction
AGEONSET                    0.7706
AGETRT                      0.5793
SEX                         0.4917
REGION                      0.6280
DISDUR                      0.8109

$`Nasal congestion`
         p Value of SG Interaction
AGEONSET                    0.1559
AGETRT                      0.6605
SEX                         0.4000
REGION                      0.9947
DISDUR                      0.2787

$`Nasal inflammation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Nasopharyngitis
         p Value of SG Interaction
```

```
AGEONSET                    0.2181
AGETRT                      0.2271
SEX                         0.3645
REGION                      0.1730
DISDUR                      0.8475

$`Neutrophil count increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Nodule
         p Value of SG Interaction
AGEONSET                    0.7564
AGETRT                      0.3683
SEX                         0.3989
REGION                      0.8216
DISDUR                      0.4720

$`Nosocomial infection`
         p Value of SG Interaction
AGEONSET                    0.7916
AGETRT                      0.5706
SEX                         0.6132
REGION                      0.6966
DISDUR                      0.6004

$Nystagmus
         p Value of SG Interaction
AGEONSET                    0.0837
AGETRT                      0.6904
SEX                         0.5989
REGION                      0.0000
DISDUR                      0.0381

$`Obstructive airways disorder`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Oedema
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.2599
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596
```

$`Oedema peripheral`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$`Oral candidiasis`
         p Value of SG Interaction
AGEONSET   0.3499
AGETRT   0.8707
SEX   0.2471
REGION   0.8889
DISDUR   0.1638

$`Oral fungal infection`
         p Value of SG Interaction
AGEONSET   0.7941
AGETRT   0.5691
SEX   0.6311
REGION   0.7242
DISDUR   0.5352

$`Oral herpes`
         p Value of SG Interaction
AGEONSET   0.7706
AGETRT   0.5793
SEX   0.4917
REGION   0.6280
DISDUR   0.8109

$`Oropharyngeal pain`
         p Value of SG Interaction
AGEONSET   0.0161
AGETRT   0.2599
SEX   0.2189
REGION   0.2525
DISDUR   0.9596

$`Orthopaedic examination`
         p Value of SG Interaction
AGEONSET   0.7438
AGETRT   0.3623
SEX   0.6497
REGION   0.8546
DISDUR   0.2579

$`Otitis media`
         p Value of SG Interaction
AGEONSET   0.1152
AGETRT   0.1476
SEX   0.3932
REGION   0.9849

```
DISDUR                      0.9909

$`Otitis media acute`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Ovarian cyst`
         p Value of SG Interaction
AGEONSET                    0.7683
AGETRT                      0.5799
SEX                         0.4641
REGION                      0.6190
DISDUR                      0.7524

$`Oxygen saturation decreased`
         p Value of SG Interaction
AGEONSET                    0.5357
AGETRT                      0.9523
SEX                         0.6070
REGION                      0.5003
DISDUR                      0.8532

$Pain
         p Value of SG Interaction
AGEONSET                    0.3451
AGETRT                      0.6572
SEX                         0.7823
REGION                      0.0462
DISDUR                      0.5807

$`Pain in extremity`
         p Value of SG Interaction
AGEONSET                    0.8208
AGETRT                      0.5458
SEX                         0.8459
REGION                      0.5507
DISDUR                      0.0812

$Pallor
         p Value of SG Interaction
AGEONSET                    0.7911
AGETRT                      0.5709
SEX                         0.6096
REGION                      0.7120
DISDUR                      0.6138

$`Parainfluenzae virus infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Pectus carinatum`
         p Value of SG Interaction
AGEONSET                     0.7825
AGETRT                       0.4043
SEX                          0.5912
REGION                       0.9633
DISDUR                       0.9881

$`Penis disorder`
         p Value of SG Interaction
AGEONSET                     0.7744
AGETRT                       0.5782
SEX                          0.4693
REGION                       0.7643
DISDUR                       0.9157

$Pharyngitis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Pharyngitis streptococcal`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Phimosis
         p Value of SG Interaction
AGEONSET                     0.4937
AGETRT                       0.0782
SEX                          0.1311
REGION                       0.5254
DISDUR                       0.1120

$`Pleural effusion`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Pneumonia
         p Value of SG Interaction
```

```
AGEONSET                    0.8311
AGETRT                      0.6285
SEX                         0.7135
REGION                      0.9698
DISDUR                      0.7182

$`Pneumonia aspiration`
         p Value of SG Interaction
AGEONSET                    0.9216
AGETRT                      0.9745
SEX                         0.7032
REGION                      0.9494
DISDUR                      0.7320

$`Pneumonia bacterial`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pneumonia influenzal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pneumonia moraxella`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pneumonia parainfluenzae viral`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pneumonia pneumococcal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Pneumonia pseudomonal`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Pneumonia respiratory syncytial viral`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Pneumonia viral`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Pneumothorax
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Positional plagiocephaly`
          p Value of SG Interaction
AGEONSET                     0.6990
AGETRT                       0.4210
SEX                          0.4232
REGION                       0.9615
DISDUR                       0.6456

$`Post procedural contusion`
          p Value of SG Interaction
AGEONSET                     0.5294
AGETRT                       0.2656
SEX                          0.0571
REGION                       0.3835
DISDUR                       0.3117

$`Post procedural haemorrhage`
          p Value of SG Interaction
AGEONSET                     0.4878
AGETRT                       0.0783
SEX                          0.1271
REGION                       0.1719
```

```
DISDUR                      0.0496

$`Post procedural swelling`
         p Value of SG Interaction
AGEONSET                    0.7593
AGETRT                      0.3694
SEX                         0.5581
REGION                      0.8132
DISDUR                      0.5336

$Presyncope
         p Value of SG Interaction
AGEONSET                    0.5084
AGETRT                      0.0765
SEX                         0.0993
REGION                      0.4743
DISDUR                      0.5385

$`Procedural complication`
         p Value of SG Interaction
AGEONSET                    0.7995
AGETRT                      0.5655
SEX                         0.6714
REGION                      0.7461
DISDUR                      0.4046

$`Procedural pain`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$`Procedural site reaction`
         p Value of SG Interaction
AGEONSET                    0.8010
AGETRT                      0.5644
SEX                         0.3177
REGION                      0.6540
DISDUR                      0.3723

$`Pseudomonas infection`
         p Value of SG Interaction
AGEONSET                    0.0858
AGETRT                      0.6564
SEX                         0.5667
REGION                      0.1606
DISDUR                      0.0919

$`Pseudomonas test positive`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
```

```
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$Pyelonephritis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Pyrexia
         p Value of SG Interaction
AGEONSET                    0.8922
AGETRT                      0.8025
SEX                         0.7057
REGION                      0.7866
DISDUR                      0.7320

$Rash
         p Value of SG Interaction
AGEONSET                    0.8845
AGETRT                      0.4556
SEX                         0.2556
REGION                      0.4575
DISDUR                      0.2308

$`Rash erythematous`
         p Value of SG Interaction
AGEONSET                    0.5425
AGETRT                      0.2671
SEX                         0.3721
REGION                      0.3109
DISDUR                      0.0186

$`Rash macular`
         p Value of SG Interaction
AGEONSET                    0.7749
AGETRT                      0.5780
SEX                         0.4662
REGION                      0.7623
DISDUR                      0.9308

$`Rash papular`
         p Value of SG Interaction
AGEONSET                    0.7776
AGETRT                      0.5771
SEX                         0.4505
REGION                      0.7526
DISDUR                      0.9934

$`Respiratory alkalosis`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory arrest`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory disorder`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory distress`
         p Value of SG Interaction
AGEONSET                    0.4950
AGETRT                      0.8677
SEX                         0.5749
REGION                      0.2260
DISDUR                      0.8433

$`Respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.8084
AGETRT                      0.3877
SEX                         0.7605
REGION                      0.9075
DISDUR                      0.9891

$`Respiratory rate increased`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Respiratory syncytial virus bronchiolitis`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                    0.4011
AGETRT                      0.5970
SEX                         0.0266
REGION                      0.5868
DISDUR                      0.1380

$`Respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.2784
AGETRT                      0.2805
SEX                         0.1647
REGION                      0.6765
DISDUR                      0.8870

$`Respiratory tract infection bacterial`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                    0.6292
AGETRT                      0.8853
SEX                         0.1457
REGION                      0.8118
DISDUR                      0.6856

$`Respirovirus test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Restlessness
         p Value of SG Interaction
AGEONSET                    0.0069
AGETRT                      0.3739
SEX                         0.4568
REGION                      0.7565
DISDUR                      0.9763

$Retching
         p Value of SG Interaction
AGEONSET                    0.5037
AGETRT                      0.0773
SEX                         0.1722
REGION                      0.4915
```

```
DISDUR                      0.3495

$Rhinitis
         p Value of SG Interaction
AGEONSET                    0.5302
AGETRT                      0.4643
SEX                         0.7032
REGION                      0.3489
DISDUR                      0.0936

$`Rhinitis allergic`
         p Value of SG Interaction
AGEONSET                    0.7627
AGETRT                      0.3706
SEX                         0.4325
REGION                      0.8028
DISDUR                      0.6122

$Rhinorrhoea
         p Value of SG Interaction
AGEONSET                    0.9374
AGETRT                      0.4092
SEX                         0.2630
REGION                      0.4700
DISDUR                      0.3326

$`Rhinovirus infection`
         p Value of SG Interaction
AGEONSET                    0.7271
AGETRT                      0.6246
SEX                         0.2464
REGION                      0.6984
DISDUR                      0.6516

$Rhonchi
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$Roseola
         p Value of SG Interaction
AGEONSET                    0.7966
AGETRT                      0.5675
SEX                         0.3421
REGION                      0.7342
DISDUR                      0.4735

$`Salivary hypersecretion`
         p Value of SG Interaction
AGEONSET                    0.8185
AGETRT                      0.1234
```

```
SEX                         0.4657
REGION                      0.1202
DISDUR                      0.3211

$`Scarlet fever`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Scoliosis
         p Value of SG Interaction
AGEONSET                    0.2100
AGETRT                      0.2070
SEX                         0.5802
REGION                      0.8998
DISDUR                      0.0909

$`Seasonal allergy`
         p Value of SG Interaction
AGEONSET                    0.2586
AGETRT                      0.8621
SEX                         0.7840
REGION                      0.7127
DISDUR                      0.7862

$Seizure
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Sepsis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Serratia infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Shock
         p Value of SG Interaction
```

```
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Sinus congestion`
         p Value of SG Interaction
AGEONSET                    0.6462
AGETRT                      0.8713
SEX                         0.9966
REGION                      0.2839
DISDUR                      0.2287

$`Sinus tachycardia`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Sinusitis
         p Value of SG Interaction
AGEONSET                    0.0173
AGETRT                      0.2466
SEX                         0.1248
REGION                      0.5161
DISDUR                      0.1598

$`Skin candida`
         p Value of SG Interaction
AGEONSET                    0.8012
AGETRT                      0.0602
SEX                         0.1713
REGION                      0.2634
DISDUR                      0.0259

$`Skin infection`
         p Value of SG Interaction
AGEONSET                    0.4591
AGETRT                      0.0753
SEX                         0.2101
REGION                      0.6192
DISDUR                      0.0002

$`Skin oedema`
         p Value of SG Interaction
AGEONSET                    0.7593
AGETRT                      0.3694
SEX                         0.5581
REGION                      0.8132
DISDUR                      0.5336
```

$`Sleep apnoea syndrome`
	p Value of SG Interaction
AGEONSET	0.5037
AGETRT	0.0773
SEX	0.1722
REGION	0.4915
DISDUR	0.3495

$`Sleep disorder`
	p Value of SG Interaction
AGEONSET	0.7396
AGETRT	0.4107
SEX	0.8487
REGION	0.4912
DISDUR	0.0459

$Somnolence
	p Value of SG Interaction
AGEONSET	0.7926
AGETRT	0.5700
SEX	0.6203
REGION	0.6923
DISDUR	0.5739

$`Sputum culture positive`
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$`Sputum discoloured`
	p Value of SG Interaction
AGEONSET	0.4878
AGETRT	0.0783
SEX	0.1271
REGION	0.1719
DISDUR	0.0496

$`Staphylococcal infection`
	p Value of SG Interaction
AGEONSET	0.2439
AGETRT	0.6646
SEX	0.9326
REGION	0.7843
DISDUR	0.0567

$`Staphylococcal sepsis`
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN

```
DISDUR                         NaN

$`Staphylococcal skin infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Staphylococcus test positive`
         p Value of SG Interaction
AGEONSET                     0.7541
AGETRT                       0.3673
SEX                          0.5891
REGION                       0.8282
DISDUR                       0.4255

$`Stoma complication`
         p Value of SG Interaction
AGEONSET                     0.2636
AGETRT                       0.0973
SEX                          0.2421
REGION                       0.6209
DISDUR                       0.8750

$`Stoma site abscess`
         p Value of SG Interaction
AGEONSET                     0.7916
AGETRT                       0.5706
SEX                          0.6132
REGION                       0.6966
DISDUR                       0.6004

$`Stoma site erythema`
         p Value of SG Interaction
AGEONSET                     0.2497
AGETRT                       0.6217
SEX                          0.7160
REGION                       0.0009
DISDUR                       0.0333

$`Stoma site haemorrhage`
         p Value of SG Interaction
AGEONSET                     0.5265
AGETRT                       0.2647
SEX                          0.2673
REGION                       0.3975
DISDUR                       0.4464

$`Stoma site infection`
         p Value of SG Interaction
AGEONSET                     0.2489
AGETRT                       0.3735
```

```
SEX                         0.9800
REGION                      0.1142
DISDUR                      0.0455

$`Stoma site inflammation`
         p Value of SG Interaction
AGEONSET                    0.0171
AGETRT                      0.2504
SEX                         0.1653
REGION                      0.4991
DISDUR                      0.2805

$`Stoma site irritation`
         p Value of SG Interaction
AGEONSET                    0.7829
AGETRT                      0.0610
SEX                         0.5887
REGION                      0.9627
DISDUR                      0.0008

$Stomatitis
         p Value of SG Interaction
AGEONSET                    0.5213
AGETRT                      0.0727
SEX                         0.2414
REGION                      0.2700
DISDUR                      0.7364

$Strabismus
         p Value of SG Interaction
AGEONSET                    0.0617
AGETRT                      0.8699
SEX                         0.7164
REGION                      0.0000
DISDUR                      0.1216

$`Supraventricular tachycardia`
         p Value of SG Interaction
AGEONSET                    0.7834
AGETRT                      0.5748
SEX                         0.5571
REGION                      0.7305
DISDUR                      0.8276

$`Surgical failure`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Swelling
         p Value of SG Interaction
```

```
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$`Systemic infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Tachycardia
         p Value of SG Interaction
AGEONSET                    0.3711
AGETRT                      0.3109
SEX                         0.3194
REGION                      0.8535
DISDUR                      0.3288

$Tachypnoea
         p Value of SG Interaction
AGEONSET                    0.3172
AGETRT                      0.6666
SEX                         0.0295
REGION                      0.2635
DISDUR                      0.0093

$Teething
         p Value of SG Interaction
AGEONSET                    0.6219
AGETRT                      0.9712
SEX                         0.1969
REGION                      0.6989
DISDUR                      0.5264

$Thrombocytosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Thrombosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Tongue atrophy`
         p Value of SG Interaction
AGEONSET                    0.5363
AGETRT                      0.2671
SEX                         0.3259
REGION                      0.3472
DISDUR                      0.0953

$`Tracheal haemorrhage`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Tracheal injury`
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Tracheal obstruction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Tracheitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Transaminases increased`
         p Value of SG Interaction
AGEONSET                    0.4937
AGETRT                      0.0782
SEX                         0.1311
REGION                      0.5254
DISDUR                      0.1120

$`Upper gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
```

```
DISDUR                      0.3923

$`Upper respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                    0.4814
AGETRT                      0.4151
SEX                         0.8039
REGION                      0.3970
DISDUR                      0.6662

$`Upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.9343
AGETRT                      0.3596
SEX                         0.5419
REGION                      0.0170
DISDUR                      0.0710

$`Upper respiratory tract inflammation`
         p Value of SG Interaction
AGEONSET                    0.2415
AGETRT                      0.6624
SEX                         0.8770
REGION                      0.0355
DISDUR                      0.1614

$`Urinary retention`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Urinary tract infection`
         p Value of SG Interaction
AGEONSET                    0.5408
AGETRT                      0.7286
SEX                         0.4028
REGION                      0.9623
DISDUR                      0.3988

$`Urine output decreased`
         p Value of SG Interaction
AGEONSET                    0.7941
AGETRT                      0.5691
SEX                         0.3559
REGION                      0.7242
DISDUR                      0.5352

$Urticaria
         p Value of SG Interaction
AGEONSET                    0.7627
AGETRT                      0.3706
```

```
SEX                         0.4325
REGION                      0.8028
DISDUR                      0.6122

$`Use of accessory respiratory muscles`
         p Value of SG Interaction
AGEONSET                    0.0643
AGETRT                      0.2325
SEX                         0.6276
REGION                      0.9524
DISDUR                      0.5487

$`Vaccination complication`
         p Value of SG Interaction
AGEONSET                    0.7992
AGETRT                      0.3949
SEX                         0.0913
REGION                      0.3184
DISDUR                      0.5602

$`Vaccination site reaction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Vasculitis
         p Value of SG Interaction
AGEONSET                    0.7706
AGETRT                      0.5793
SEX                         0.4917
REGION                      0.6280
DISDUR                      0.8109

$`Ventricular tachycardia`
         p Value of SG Interaction
AGEONSET                    0.7727
AGETRT                      0.5787
SEX                         0.4899
REGION                      0.5008
DISDUR                      0.8705

$`Vessel puncture site bruise`
         p Value of SG Interaction
AGEONSET                    0.3636
AGETRT                      0.1074
SEX                         0.5856
REGION                      0.1372
DISDUR                      0.2018

$`Vessel puncture site reaction`
         p Value of SG Interaction
```

```
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Viral infection`
         p Value of SG Interaction
AGEONSET                    0.0109
AGETRT                      0.2595
SEX                         0.6843
REGION                      0.2982
DISDUR                      0.5840

$`Viral rash`
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Viral rhinitis`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Viral upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.9171
AGETRT                      0.4968
SEX                         0.2562
REGION                      0.8792
DISDUR                      0.4301

$`Vitamin A decreased`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Vitamin D decreased`
         p Value of SG Interaction
AGEONSET                    0.5374
AGETRT                      0.2672
SEX                         0.3334
REGION                      0.3412
DISDUR                      0.0751
```

```
$`Vitamin D deficiency`
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$Vomiting
         p Value of SG Interaction
AGEONSET                    0.9148
AGETRT                      0.8863
SEX                         0.5176
REGION                      0.9524
DISDUR                      0.7036

$`Weight decreased`
         p Value of SG Interaction
AGEONSET                    0.9326
AGETRT                      0.9808
SEX                         0.6266
REGION                      0.8934
DISDUR                      0.4173

$`Weight gain poor`
         p Value of SG Interaction
AGEONSET                    0.9482
AGETRT                      0.7223
SEX                         0.9197
REGION                      0.9997
DISDUR                      0.8028

$Wheezing
         p Value of SG Interaction
AGEONSET                    0.6711
AGETRT                      0.8095
SEX                         0.2786
REGION                      0.7488
DISDUR                      0.5669


\#############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines milden UEs nach PT, das bei mindestens 10% der
Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Abdominal discomfort`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Abdominal distension`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Abdominal pain upper`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Acquired phimosis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Acute respiratory distress syndrome`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Acute respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.9999
SEX                         0.9999
REGION                      1.0000
DISDUR                      0.9997

$`Adenovirus infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Agitation
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.6033
SEX                         1.0000
```

```
REGION                     0.3976
DISDUR                     0.7033

$`Agitation postoperative`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Alanine aminotransferase increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Amblyopia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Anaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Anxiety
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Aphthous ulcer`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Apnoea
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Apparent life threatening event`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Application site rash`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Arthropod bite`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Aspartate aminotransferase increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Aspiration
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        1.0000
REGION                     1.0000
DISDUR                     0.0194

$Atelectasis
         p Value of SG Interaction
AGEONSET                   0.1556
AGETRT                     0.5655
SEX                        0.2022
REGION                     0.9331
DISDUR                     0.9814

$`Back pain`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Bacteraemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bacterial disease carrier`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bacterial infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bacterial tracheitis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Balanoposthitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Blood chloride decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Blood iron decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Blood potassium decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Blood sodium decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Body temperature decreased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.0578
REGION                      1.0000
DISDUR                      0.6796

$`Body temperature increased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1356
SEX                         0.2971
REGION                      1.0000
DISDUR                      0.1788

$`Bone marrow disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Bradycardia
         p Value of SG Interaction
AGEONSET                    0.0547
AGETRT                      0.3637
SEX                         0.3285
```

```
REGION                      0.3696
DISDUR                      0.1794

$`Brain injury`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Breath holding`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bronchial obstruction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bronchial secretion retention`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Bronchiolitis
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0632
SEX                         1.0000
REGION                      0.4233
DISDUR                      0.2299

$Bronchitis
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.2260
REGION                      1.0000
DISDUR                      0.9554

$`Bronchitis viral`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                         NA
DISDUR                          1

$`C-reactive protein increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Candida infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Candida nappy rash`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.2330
SEX                        1.0000
REGION                     0.2156
DISDUR                     0.0562

$`Candida sepsis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Cardiac arrest`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Cardio-respiratory arrest`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Catarrh
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Catheter site inflammation`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1853
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.1326

$Cellulitis
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0292
SEX                         0.1002
REGION                      1.0000
DISDUR                      0.0090

$Chalazion
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Choking
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.0362
REGION                      0.2229
DISDUR                      0.9995

$`Chronic respiratory failure`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Clonus
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Congenital diaphragmatic hernia`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Conjunctivitis
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   0.5594
SEX   0.6909
REGION   0.7215
DISDUR   0.6273

$`Conjunctivitis bacterial`
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   1.0000
SEX   1.0000
REGION   1.0000
DISDUR   0.7595

$Constipation
         p Value of SG Interaction
AGEONSET   0.1032
AGETRT   0.0558
SEX   0.4423
REGION   0.3966
DISDUR   0.4803

$Contusion
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Corona virus infection`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Cough
         p Value of SG Interaction
AGEONSET   0.5918
AGETRT   0.8548
SEX   0.7609

```
REGION                      0.9991
DISDUR                      0.2279

$Crying
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Cryptorchism
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Cyanosis
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.0845
REGION                      1.0000
DISDUR                      0.6052

$Death
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Decubitus ulcer`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Deformity thorax`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Dehydration
         p Value of SG Interaction
AGEONSET                    1.0000
```

```
AGETRT                      0.2011
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.5497

$`Delayed fontanelle closure`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Delayed recovery from anaesthesia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Dermatitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dermatitis allergic`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Dermatitis atopic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dermatitis contact`
         p Value of SG Interaction
AGEONSET                    0.5263
AGETRT                      0.3393
SEX                         0.9017
REGION                      1.0000
DISDUR                      0.2417

$`Dermatitis diaper`
```

```
         p Value of SG Interaction
AGEONSET                    0.4214
AGETRT                      0.7840
SEX                         0.5581
REGION                      0.5452
DISDUR                      0.2147

$`Developmental hip dysplasia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Device malfunction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Device occlusion`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0290
SEX                         1.0000
REGION                      0.2911
DISDUR                      0.0001

$Diarrhoea
         p Value of SG Interaction
AGEONSET                    0.2774
AGETRT                      0.2078
SEX                         0.4189
REGION                      0.6897
DISDUR                      0.1170

$`Diarrhoea haemorrhagic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Discomfort
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$Drooling
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Drug hypersensitivity`
	p Value of SG Interaction
AGEONSET	0.2717
AGETRT	0.1926
SEX	1.0000
REGION	1.0000
DISDUR	0.4533

$`Drug intolerance`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Dry eye`
	p Value of SG Interaction
AGEONSET	1.0000
AGETRT	1.0000
SEX	0.0556
REGION	0.1703
DISDUR	0.4983

$`Dry skin`
	p Value of SG Interaction
AGEONSET	1.0000
AGETRT	0.0312
SEX	1.0000
REGION	0.2345
DISDUR	0.0001

$Dysphagia
	p Value of SG Interaction
AGEONSET	0.9254
AGETRT	0.5375
SEX	0.8055
REGION	1.0000
DISDUR	0.5242

$Dyspnoea
	p Value of SG Interaction
AGEONSET	0.2916
AGETRT	0.5760
SEX	0.1260

```
REGION                      0.4727
DISDUR                      0.3039

$`Ear disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ear haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ear infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.6027
SEX                         0.0112
REGION                      0.3792
DISDUR                      0.3671

$`Ear pain`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Ecchymosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Eczema
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1908
SEX                         1.0000
REGION                      0.3665
DISDUR                      0.1979

$`Eczema infected`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Electrocardiogram ST-T segment abnormal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Endotracheal intubation complication`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Enteritis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Enterobiasis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Enterococcal infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Epigastric discomfort`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Erythema
```

```
         p Value of SG Interaction
AGEONSET                    0.3518
AGETRT                      0.3416
SEX                         0.3399
REGION                      0.3003
DISDUR                      0.4090

$`Escherichia infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Excoriation
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      0.9993
DISDUR                      1.0000

$`Exposure to communicable disease`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Eye infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Eye movement disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Failure to thrive`
         p Value of SG Interaction
AGEONSET                    0.1039
AGETRT                      0.3870
SEX                         0.4667
REGION                      0.9105
DISDUR                      0.7932
```

```
$Fatigue
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                          NA
DISDUR                      1.0000

$`Feeding disorder of infancy or early childhood`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1697
SEX                         0.0943
REGION                      1.0000
DISDUR                      0.2290

$`Feeding intolerance`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Feeding tube complication`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.2031
SEX                         0.5110
REGION                      1.0000
DISDUR                      0.6959

$`Femur fracture`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Flatulence
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.6162

$`Food allergy`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
```

```
REGION                     1.0000
DISDUR                     0.9999

$`Food intolerance`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.9999
REGION                     0.9993
DISDUR                     1.0000

$`Fungal infection`
         p Value of SG Interaction
AGEONSET                   0.1960
AGETRT                     0.1730
SEX                        0.1127
REGION                     1.0000
DISDUR                     0.8361

$`Fungal skin infection`
         p Value of SG Interaction
AGEONSET                   0.2286
AGETRT                     1.0000
SEX                        1.0000
REGION                     1.0000
DISDUR                     0.1547

$`Gastric haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Gastritis
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.4876
SEX                        1.0000
REGION                     0.5872
DISDUR                     0.6378

$Gastroenteritis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastroenteritis rotavirus`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastroenteritis viral`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastrointestinal motility disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastrointestinal tract irritation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastrooesophageal reflux disease`
         p Value of SG Interaction
AGEONSET                   0.1720
AGETRT                     0.0069
SEX                        0.8311
REGION                     0.1364
DISDUR                     0.0051

$`General physical health deterioration`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Glycosuria
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Granuloma annulare`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Haematochezia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Hand-foot-and-mouth disease`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.0903
REGION                      0.2873
DISDUR                      0.6007

$`Head injury`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.9999
SEX                         0.9999
REGION                      1.0000
DISDUR                      0.9997

$`Head lag abnormal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Heart rate decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Heart rate increased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.2334

$`Heart rate irregular`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hepatomegaly
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hordeolum
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Human rhinovirus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hydronephrosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hyperaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Hypercapnia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hyperglycaemia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hyperhidrosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hyperkeratosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypersensitivity
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.1465
SEX                        1.0000
REGION                     0.1792
DISDUR                     0.5124

$Hypertension
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypoglycaemia
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypokalaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypophagia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypopnoea
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypothermia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypoventilation
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypoxia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Hypoxic-ischaemic encephalopathy`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Impaired gastric emptying`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.9999

$Impetigo
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1799
SEX                         1.0000
REGION                      0.2169
DISDUR                      0.4179

$`Incision site erythema`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Increased bronchial secretion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Increased upper airway secretion`
         p Value of SG Interaction
AGEONSET                    0.1706
AGETRT                      0.1637
SEX                         0.0605
REGION                      1.0000
DISDUR                      0.9861

$`Infantile colic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Infantile spitting up`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Inflammatory marker increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Influenza
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Influenza A virus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Infusion site bruising`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Infusion site extravasation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Injection site haematoma`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.9999
SEX                         1.0000
```

```
REGION                      1.0000
DISDUR                      1.0000

$Intertrigo
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Iron deficiency`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Irritability
         p Value of SG Interaction
AGEONSET                     1.0000
AGETRT                       0.2071
SEX                          0.1935
REGION                       0.7563
DISDUR                       0.0047

$`Irritability postvaccinal`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Joint contracture`
         p Value of SG Interaction
AGEONSET                     1.0000
AGETRT                       0.4660
SEX                          0.2509
REGION                       1.0000
DISDUR                       0.7568

$`Joint range of motion decreased`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Joint stiffness`
         p Value of SG Interaction
AGEONSET                          1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Keratosis pilaris`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Kyphoscoliosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Kyphosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Laceration
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Lacrimation increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Language disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Left ventricular hypertrophy`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Leukocytosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Liver function test abnormal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Localised infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Lower respiratory tract infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Lower respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Lung disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Lung infection`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Lymph node palpable`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Malaise
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Mechanical ventilation`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Medical device complication`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Medical observation`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Miliaria
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1

```
REGION                          1
DISDUR                          1

$`Mood swings`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Moraxella infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Moraxella test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Muscle contractions involuntary`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Muscle tightness`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Muscular weakness`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Myopia
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Naevus anaemicus`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Nasal congestion`
         p Value of SG Interaction
AGEONSET                   0.1532
AGETRT                     0.7292
SEX                        0.4573
REGION                     1.0000
DISDUR                     0.3479

$`Nasal inflammation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Nasopharyngitis
         p Value of SG Interaction
AGEONSET                   0.3142
AGETRT                     0.4054
SEX                        0.4317
REGION                     0.0692
DISDUR                     0.9834

$`Neutrophil count increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Nodule
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Nosocomial infection`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Nystagmus
         p Value of SG Interaction
AGEONSET                    0.1075
AGETRT                      1.0000
SEX                         0.4408
REGION                      0.0253
DISDUR                      0.0338

$`Obstructive airways disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Oedema
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oedema peripheral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oral candidiasis`
         p Value of SG Interaction
AGEONSET                    0.3087
AGETRT                      0.9327
SEX                         0.2673
REGION                      0.8551
DISDUR                      0.1895

$`Oral fungal infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Oral herpes`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oropharyngeal pain`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Orthopaedic examination`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Otitis media`
         p Value of SG Interaction
AGEONSET                    0.1220
AGETRT                      0.0949
SEX                         0.2674
REGION                      0.7822
DISDUR                      0.8641

$`Otitis media acute`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ovarian cyst`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oxygen saturation decreased`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.2402
SEX                         0.5687
```

```
REGION                     0.1815
DISDUR                     0.6899

$Pain
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pain in extremity`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.9999

$Pallor
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Parainfluenzae virus infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pectus carinatum`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.7968

$`Penis disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Pharyngitis
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pharyngitis streptococcal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Phimosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pleural effusion`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Pneumonia
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.2844
SEX                        0.7108
REGION                     0.9547
DISDUR                     0.6314

$`Pneumonia aspiration`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.4121
REGION                     0.6882
DISDUR                     0.6817

$`Pneumonia bacterial`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pneumonia influenzal`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia moraxella`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia parainfluenzae viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia pneumococcal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia pseudomonal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia respiratory syncytial viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Pneumothorax
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Positional plagiocephaly`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Post procedural contusion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Post procedural haemorrhage`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Post procedural swelling`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Presyncope
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Procedural complication`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Procedural pain`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Procedural site reaction`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pseudomonas infection`
         p Value of SG Interaction
AGEONSET                   0.2057
AGETRT                     0.5622
SEX                        0.3595
REGION                     0.1303
DISDUR                     0.1094

$`Pseudomonas test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Pyelonephritis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Pyrexia
         p Value of SG Interaction
AGEONSET                   0.4206
AGETRT                     0.8512
SEX                        0.6537
REGION                     0.2429
DISDUR                     0.4603

$Rash
         p Value of SG Interaction
AGEONSET                   1.0000
```

```
AGETRT                      0.3472
SEX                         0.1836
REGION                      0.2202
DISDUR                      0.1983

$`Rash erythematous`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.9999
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.9999

$`Rash macular`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Rash papular`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Respiratory alkalosis`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Respiratory arrest`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Respiratory disorder`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Respiratory distress`
```

```
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.2758
SEX                         0.4663
REGION                      0.4063
DISDUR                      0.8930

$`Respiratory failure`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.9154

$`Respiratory rate increased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9998
REGION                      0.9992
DISDUR                      1.0000

$`Respiratory syncytial virus bronchiolitis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.3555
SEX                         0.0379
REGION                      0.4244
DISDUR                      0.1624

$`Respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.2126
AGETRT                      0.1260
SEX                         0.1184
REGION                      1.0000
DISDUR                      0.9834

$`Respiratory tract infection bacterial`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respirovirus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Restlessness
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Retching
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Rhinitis
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.2350
SEX                         0.7446
REGION                      1.0000
DISDUR                      0.0842

$`Rhinitis allergic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Rhinorrhoea
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.5310
SEX                         0.0878
```

```
REGION                     0.2594
DISDUR                     0.2745

$`Rhinovirus infection`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.4921
SEX                        0.1802
REGION                     0.4511
DISDUR                     0.7914

$Rhonchi
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Roseola
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Salivary hypersecretion`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.0702
SEX                        0.2318
REGION                     0.0695
DISDUR                     0.1497

$`Scarlet fever`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Scoliosis
         p Value of SG Interaction
AGEONSET                   0.1216
AGETRT                     0.1593
SEX                        0.3318
REGION                     0.6822
DISDUR                     0.0717

$`Seasonal allergy`
         p Value of SG Interaction
AGEONSET                   0.3977
```

```
AGETRT                      0.7372
SEX                         1.0000
REGION                      0.5583
DISDUR                      0.8602

$Seizure
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Sepsis
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Serratia infection`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Shock
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Sinus congestion`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Sinus tachycardia`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Sinusitis
```

```
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.9999
SEX                         1.0000
REGION                      1.0000
DISDUR                      1.0000

$`Skin candida`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0458
SEX                         0.1048
REGION                      0.2361
DISDUR                      0.0269

$`Skin infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.9999

$`Skin oedema`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Sleep apnoea syndrome`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Sleep disorder`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      0.3736
DISDUR                      0.0609

$Somnolence
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1
```

```
$`Sputum culture positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Sputum discoloured`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Staphylococcal infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Staphylococcal sepsis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Staphylococcal skin infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Staphylococcus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma complication`
         p Value of SG Interaction
AGEONSET                    0.6233
AGETRT                      0.1218
SEX                         1.0000
```

```
REGION                     1.0000
DISDUR                     0.5094

$`Stoma site abscess`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site erythema`
         p Value of SG Interaction
AGEONSET                    0.4511
AGETRT                      0.5750
SEX                         0.7947
REGION                      0.0371
DISDUR                      0.0207

$`Stoma site haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site infection`
         p Value of SG Interaction
AGEONSET                    0.6448
AGETRT                      0.1259
SEX                         0.3978
REGION                      0.1440
DISDUR                      0.0051

$`Stoma site inflammation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site irritation`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0443
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.0022

$Stomatitis
         p Value of SG Interaction
AGEONSET                    1.0000
```

```
AGETRT                      0.9999
SEX                         1.0000
REGION                      1.0000
DISDUR                      1.0000

$Strabismus
         p Value of SG Interaction
AGEONSET                    0.2621
AGETRT                      1.0000
SEX                         1.0000
REGION                      0.0673
DISDUR                      0.1369

$`Supraventricular tachycardia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Surgical failure`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Swelling
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Systemic infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Tachycardia
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.6067
SEX                         0.0534
REGION                      0.5786
DISDUR                      0.5275

$Tachypnoea
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Teething
         p Value of SG Interaction
AGEONSET                    0.9494
AGETRT                      0.8502
SEX                         0.4072
REGION                      0.8341
DISDUR                      0.2794

$Thrombocytosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Thrombosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Tongue atrophy`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.9999

$`Tracheal haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Tracheal injury`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Tracheal obstruction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Tracheitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Transaminases increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Upper gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Upper respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.6720
AGETRT                      0.2192
SEX                         0.4290
REGION                      0.0089
DISDUR                      0.0846

$`Upper respiratory tract inflammation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Urinary retention`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Urinary tract infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Urine output decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Urticaria
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Use of accessory respiratory muscles`
         p Value of SG Interaction
AGEONSET                   0.1904
AGETRT                     0.1677
SEX                        1.0000
REGION                     1.0000
DISDUR                     0.4598

$`Vaccination complication`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.0695
REGION                     0.2711
DISDUR                     0.6087

$`Vaccination site reaction`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Vasculitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Ventricular tachycardia`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Vessel puncture site bruise`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Vessel puncture site reaction`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Viral infection`
         p Value of SG Interaction
AGEONSET                   0.0550
AGETRT                     0.2324
SEX                        0.6896
REGION                     0.2449
DISDUR                     0.6600

$`Viral rash`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Viral rhinitis`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Viral upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.3772
SEX                         0.1463
REGION                      1.0000
DISDUR                      0.3397

$`Vitamin A decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vitamin D decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vitamin D deficiency`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Vomiting
         p Value of SG Interaction
AGEONSET                    0.4436
AGETRT                      0.9061
SEX                         0.5199
REGION                      0.8236
DISDUR                      0.5157

$`Weight decreased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.3811
REGION                      1.0000
DISDUR                      0.4495
```

```
$`Weight gain poor`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.7808

$Wheezing
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1


\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten UE nach SOC, das bei mindestens
10% der Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1%
der Patienten in einem Studienarm auftrat"

$`Blood and lymphatic system disorders`
         p Value of SG Interaction
AGEONSET                    0.0565
AGETRT                      0.2381
SEX                         0.2362
REGION                      0.3222
DISDUR                      0.3975

$`Cardiac disorders`
         p Value of SG Interaction
AGEONSET                    0.0714
AGETRT                      0.2896
SEX                         0.2016
REGION                      0.3235
DISDUR                      0.4835

$`Congenital, familial and genetic disorders`
         p Value of SG Interaction
AGEONSET                    0.6856
AGETRT                      0.8178
SEX                         0.9529
REGION                      0.5649
DISDUR                      0.9555

$`Ear and labyrinth disorders`
         p Value of SG Interaction
AGEONSET                    0.7776
AGETRT                      0.5771
SEX                         0.4505
REGION                      0.7526
```

```
DISDUR                      0.9934

$`Eye disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Gastrointestinal disorders`
         p Value of SG Interaction
AGEONSET                    0.6555
AGETRT                      0.4487
SEX                         0.2450
REGION                      0.3122
DISDUR                      0.0526

$`General disorders and administration site conditions`
         p Value of SG Interaction
AGEONSET                    0.2772
AGETRT                      0.7583
SEX                         0.1050
REGION                      0.0319
DISDUR                      0.3825

$`Hepatobiliary disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Immune system disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Infections and infestations`
         p Value of SG Interaction
AGEONSET                    0.3340
AGETRT                      0.9869
SEX                         0.7631
REGION                      0.4943
DISDUR                      0.0241

$`Injury, poisoning and procedural complications`
         p Value of SG Interaction
AGEONSET                    0.3610
AGETRT                      0.0289
```

```
SEX                         0.8927
REGION                      0.4260
DISDUR                      0.0214

$Investigations
         p Value of SG Interaction
AGEONSET                    0.7323
AGETRT                      0.4642
SEX                         0.8006
REGION                      0.6599
DISDUR                      0.7289

$`Metabolism and nutrition disorders`
         p Value of SG Interaction
AGEONSET                    0.5417
AGETRT                      0.1261
SEX                         0.2784
REGION                      0.4830
DISDUR                      0.1081

$`Musculoskeletal and connective tissue disorders`
         p Value of SG Interaction
AGEONSET                    0.7696
AGETRT                      0.9433
SEX                         0.3664
REGION                      0.5890
DISDUR                      0.8643

$`Nervous system disorders`
         p Value of SG Interaction
AGEONSET                    0.8076
AGETRT                      0.0592
SEX                         0.4387
REGION                      0.9133
DISDUR                      0.3180

$`Psychiatric disorders`
         p Value of SG Interaction
AGEONSET                    0.4099
AGETRT                      0.0955
SEX                         0.0148
REGION                      0.0090
DISDUR                      0.3292

$`Renal and urinary disorders`
         p Value of SG Interaction
AGEONSET                    0.7432
AGETRT                      0.5822
SEX                         0.6534
REGION                      0.8561
DISDUR                      0.2496

$`Reproductive system and breast disorders`
         p Value of SG Interaction
```

```
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Respiratory, thoracic and mediastinal disorders`
         p Value of SG Interaction
AGEONSET                    0.6285
AGETRT                      0.4838
SEX                         0.1454
REGION                      0.9361
DISDUR                      0.3221

$`Skin and subcutaneous tissue disorders`
         p Value of SG Interaction
AGEONSET                    0.5552
AGETRT                      0.5431
SEX                         0.9388
REGION                      0.4370
DISDUR                      0.5772

$`Surgical and medical procedures`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vascular disorders`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.3616
REGION                      0.7201
DISDUR                      0.5609


\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten UEs nach SOC, das bei mindestens 10%
der Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Blood and lymphatic system disorders`
         p Value of SG Interaction
AGEONSET                    0.2228
AGETRT                      0.2016
SEX                         0.1471
REGION                      0.2524
DISDUR                      0.2346

$`Cardiac disorders`
```

```
         p Value of SG Interaction
AGEONSET                    0.0185
AGETRT                      0.2609
SEX                         0.2285
REGION                      0.2031
DISDUR                      0.5822

$`Congenital, familial and genetic disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ear and labyrinth disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Eye disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastrointestinal disorders`
         p Value of SG Interaction
AGEONSET                    0.4478
AGETRT                      0.2583
SEX                         0.3030
REGION                      0.1746
DISDUR                      0.0684

$`General disorders and administration site conditions`
         p Value of SG Interaction
AGEONSET                    0.7508
AGETRT                      0.9206
SEX                         0.0695
REGION                      0.0119
DISDUR                      0.3909

$`Hepatobiliary disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Immune system disorders`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Infections and infestations`
         p Value of SG Interaction
AGEONSET   0.8977
AGETRT   0.7207
SEX   0.6185
REGION   0.1370
DISDUR   0.0440

$`Injury, poisoning and procedural complications`
         p Value of SG Interaction
AGEONSET   0.1125
AGETRT   0.0049
SEX   0.9928
REGION   0.6089
DISDUR   0.0031

$Investigations
         p Value of SG Interaction
AGEONSET   0.9999
AGETRT   0.3228
SEX   0.9436
REGION   0.6970
DISDUR   0.7136

$`Metabolism and nutrition disorders`
         p Value of SG Interaction
AGEONSET   0.9999
AGETRT   0.5346
SEX   0.4763
REGION   0.4955
DISDUR   0.2577

$`Musculoskeletal and connective tissue disorders`
         p Value of SG Interaction
AGEONSET   0.9999
AGETRT   0.8950
SEX   0.2787
REGION   1.0000
DISDUR   0.4146

$`Nervous system disorders`
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   0.0473
SEX   1.0000

```
REGION                     1.0000
DISDUR                     0.2839

$`Psychiatric disorders`
         p Value of SG Interaction
AGEONSET                   0.0470
AGETRT                     0.0765
SEX                        0.0209
REGION                     0.0868
DISDUR                     0.7133

$`Renal and urinary disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Reproductive system and breast disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory, thoracic and mediastinal disorders`
         p Value of SG Interaction
AGEONSET                   0.8074
AGETRT                     0.1801
SEX                        0.1801
REGION                     0.8176
DISDUR                     0.2375

$`Skin and subcutaneous tissue disorders`
         p Value of SG Interaction
AGEONSET                   0.9999
AGETRT                     0.1132
SEX                        0.9979
REGION                     1.0000
DISDUR                     0.8866

$`Surgical and medical procedures`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vascular disorders`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1


\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten UE nach PT, das bei mindestens 10%
der Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Abdominal discomfort`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Abdominal distension`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Abdominal pain upper`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Acquired phimosis`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Acute respiratory distress syndrome`
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$`Acute respiratory failure`
         p Value of SG Interaction
```

```
AGEONSET                    0.7946
AGETRT                      0.0608
SEX                         0.6622
REGION                      0.2442
DISDUR                      0.0472

$`Adenovirus infection`
         p Value of SG Interaction
AGEONSET                    0.6526
AGETRT                      0.1940
SEX                         0.8080
REGION                      0.6807
DISDUR                      0.2357

$Agitation
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Agitation postoperative`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Alanine aminotransferase increased`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$Amblyopia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Anaemia
         p Value of SG Interaction
AGEONSET                    0.7432
AGETRT                      0.5822
SEX                         0.6534
REGION                      0.8561
DISDUR                      0.2496
```

```
$Anxiety
          p Value of SG Interaction
AGEONSET                     0.0069
AGETRT                       0.3739
SEX                          0.4568
REGION                       0.7565
DISDUR                       0.9763

$`Aphthous ulcer`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Apnoea
          p Value of SG Interaction
AGEONSET                     0.8212
AGETRT                       0.6241
SEX                          0.3176
REGION                       0.3390
DISDUR                       0.3776

$`Apparent life threatening event`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Application site rash`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Arthropod bite`
          p Value of SG Interaction
AGEONSET                     0.7860
AGETRT                       0.5736
SEX                          0.4020
REGION                       0.7201
DISDUR                       0.7542

$`Aspartate aminotransferase increased`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
```

```
DISDUR                          NaN

$Aspiration
         p Value of SG Interaction
AGEONSET                    0.9688
AGETRT                      0.1945
SEX                         0.0718
REGION                      0.9939
DISDUR                      0.4553

$Atelectasis
         p Value of SG Interaction
AGEONSET                    0.7221
AGETRT                      0.9207
SEX                         0.6356
REGION                      0.0926
DISDUR                      0.8294

$`Back pain`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Bacteraemia
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Bacterial disease carrier`
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Bacterial infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Bacterial tracheitis`
         p Value of SG Interaction
AGEONSET                    0.5663
AGETRT                      0.9610
```

```
SEX                         0.9704
REGION                      0.5283
DISDUR                      0.2552

$Balanoposthitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Blood chloride decreased`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$`Blood iron decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Blood potassium decreased`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$`Blood sodium decreased`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$`Body temperature decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Body temperature increased`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bone marrow disorder`
         p Value of SG Interaction
AGEONSET                    0.0161
AGETRT                      0.2599
SEX                         0.2189
REGION                      0.2525
DISDUR                      0.9596

$Bradycardia
         p Value of SG Interaction
AGEONSET                    0.7443
AGETRT                      0.3423
SEX                         0.3274
REGION                      0.7571
DISDUR                      0.1288

$`Brain injury`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Breath holding`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bronchial obstruction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bronchial secretion retention`
         p Value of SG Interaction
AGEONSET                    0.2593
AGETRT                      0.0887
SEX                         0.6294
REGION                      0.6580
DISDUR                      0.4508
```

```
$Bronchiolitis
          p Value of SG Interaction
AGEONSET                     0.4902
AGETRT                       0.0783
SEX                          0.1331
REGION                       0.5365
DISDUR                       0.0699

$Bronchitis
          p Value of SG Interaction
AGEONSET                     0.7100
AGETRT                       0.4147
SEX                          0.1799
REGION                       0.5148
DISDUR                       0.3531

$`Bronchitis viral`
          p Value of SG Interaction
AGEONSET                     0.7931
AGETRT                       0.5697
SEX                          0.3616
REGION                       0.7201
DISDUR                       0.5609

$`C-reactive protein increased`
          p Value of SG Interaction
AGEONSET                     0.9830
AGETRT                       0.2203
SEX                          0.5548
REGION                       0.9706
DISDUR                       0.7346

$`Candida infection`
          p Value of SG Interaction
AGEONSET                     0.5374
AGETRT                       0.2672
SEX                          0.3334
REGION                       0.3412
DISDUR                       0.0751

$`Candida nappy rash`
          p Value of SG Interaction
AGEONSET                         NaN
AGETRT                           NaN
SEX                              NaN
REGION                           NaN
DISDUR                           NaN

$`Candida sepsis`
          p Value of SG Interaction
AGEONSET                         NaN
AGETRT                           NaN
SEX                              NaN
REGION                           NaN
```

```
DISDUR                          NaN

$`Cardiac arrest`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Cardio-respiratory arrest`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Catarrh
         p Value of SG Interaction
AGEONSET                     0.0164
AGETRT                       0.2579
SEX                          0.2052
REGION                       0.2415
DISDUR                       0.7664

$`Catheter site inflammation`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Cellulitis
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Chalazion
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Choking
         p Value of SG Interaction
AGEONSET                     0.5294
AGETRT                       0.2656
```

```
SEX                         0.0571
REGION                      0.3835
DISDUR                      0.3117

$`Chronic respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$Clonus
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Congenital diaphragmatic hernia`
         p Value of SG Interaction
AGEONSET                    0.7599
AGETRT                      0.3696
SEX                         0.5547
REGION                      0.8115
DISDUR                      0.5464

$Conjunctivitis
         p Value of SG Interaction
AGEONSET                    0.7481
AGETRT                      0.3645
SEX                         0.3577
REGION                      0.4841
DISDUR                      0.3208

$`Conjunctivitis bacterial`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$Constipation
         p Value of SG Interaction
AGEONSET                    0.9605
AGETRT                      0.4567
SEX                         0.4776
REGION                      0.7202
DISDUR                      0.2417

$Contusion
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Corona virus infection`
         p Value of SG Interaction
AGEONSET                    0.4902
AGETRT                      0.0783
SEX                         0.1331
REGION                      0.5365
DISDUR                      0.0699

$Cough
         p Value of SG Interaction
AGEONSET                    0.8173
AGETRT                      0.3893
SEX                         0.5600
REGION                      0.9781
DISDUR                      0.3182

$Crying
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Cryptorchism
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Cyanosis
         p Value of SG Interaction
AGEONSET                    0.0209
AGETRT                      0.0091
SEX                         0.0206
REGION                      0.6162
DISDUR                      0.5384

$Death
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Decubitus ulcer`
         p Value of SG Interaction
AGEONSET                    0.3567
AGETRT                      0.6483
SEX                         0.6657
REGION                      0.1616
DISDUR                      0.6116

$`Deformity thorax`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Dehydration
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.0745
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$`Delayed fontanelle closure`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Delayed recovery from anaesthesia`
         p Value of SG Interaction
AGEONSET                    0.7599
AGETRT                      0.3696
SEX                         0.4171
REGION                      0.5844
DISDUR                      0.5464

$Dermatitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Dermatitis allergic`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$`Dermatitis atopic`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Dermatitis contact`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Dermatitis diaper`
         p Value of SG Interaction
AGEONSET                     0.8254
AGETRT                       0.8837
SEX                          0.8940
REGION                       0.8588
DISDUR                       0.4209

$`Developmental hip dysplasia`
         p Value of SG Interaction
AGEONSET                     0.7916
AGETRT                       0.5706
SEX                          0.6132
REGION                       0.6966
DISDUR                       0.6004

$`Device malfunction`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Device occlusion`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Diarrhoea
         p Value of SG Interaction
AGEONSET                     0.8990
AGETRT                       0.0225
```

```
SEX                         0.5488
REGION                      0.9242
DISDUR                      0.0638

$`Diarrhoea haemorrhagic`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Discomfort
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Drooling
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Drug hypersensitivity`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Drug intolerance`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Dry eye`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Dry skin`
          p Value of SG Interaction
```

```
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Dysphagia
         p Value of SG Interaction
AGEONSET                    0.5307
AGETRT                      0.9403
SEX                         0.0024
REGION                      0.9204
DISDUR                      0.5278

$Dyspnoea
         p Value of SG Interaction
AGEONSET                    0.2835
AGETRT                      0.7472
SEX                         0.5539
REGION                      0.2997
DISDUR                      0.9539

$`Ear disorder`
         p Value of SG Interaction
AGEONSET                    0.7776
AGETRT                      0.5771
SEX                         0.4505
REGION                      0.7526
DISDUR                      0.9934

$`Ear haemorrhage`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Ear infection`
         p Value of SG Interaction
AGEONSET                    0.6050
AGETRT                      0.8997
SEX                         0.6458
REGION                      0.9143
DISDUR                      0.5944

$`Ear pain`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN
```

```
$Ecchymosis
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Eczema
          p Value of SG Interaction
AGEONSET                     0.4937
AGETRT                       0.0782
SEX                          0.1311
REGION                       0.5254
DISDUR                       0.1120

$`Eczema infected`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Electrocardiogram ST-T segment abnormal`
          p Value of SG Interaction
AGEONSET                     0.7438
AGETRT                       0.3623
SEX                          0.6497
REGION                       0.8546
DISDUR                       0.2579

$`Endotracheal intubation complication`
          p Value of SG Interaction
AGEONSET                     0.4591
AGETRT                       0.0753
SEX                          0.2101
REGION                       0.6192
DISDUR                       0.0002

$Enteritis
          p Value of SG Interaction
AGEONSET                     0.4884
AGETRT                       0.0783
SEX                          0.1429
REGION                       0.1734
DISDUR                       0.0541

$Enterobiasis
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
```

```
DISDUR                          NaN

$`Enterococcal infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Epigastric discomfort`
         p Value of SG Interaction
AGEONSET                     0.4878
AGETRT                       0.0783
SEX                          0.1271
REGION                       0.1719
DISDUR                       0.0496

$Erythema
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Escherichia infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Excoriation
         p Value of SG Interaction
AGEONSET                     0.8010
AGETRT                       0.5644
SEX                          0.3177
REGION                       0.6540
DISDUR                       0.3723

$`Exposure to communicable disease`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Eye infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Eye movement disorder`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Failure to thrive`
         p Value of SG Interaction
AGEONSET                   0.5162
AGETRT                     0.0745
SEX                        0.0830
REGION                     0.4431
DISDUR                     0.9596

$Fatigue
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Feeding disorder of infancy or early childhood`
         p Value of SG Interaction
AGEONSET                   0.8063
AGETRT                     0.4161
SEX                        0.8759
REGION                     0.4766
DISDUR                     0.4676

$`Feeding intolerance`
         p Value of SG Interaction
AGEONSET                   0.6633
AGETRT                     0.8048
SEX                        0.2470
REGION                     0.9206
DISDUR                     0.4039

$`Feeding tube complication`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Femur fracture`
         p Value of SG Interaction
```

```
AGEONSET                    0.6556
AGETRT                      0.1950
SEX                         0.8284
REGION                      0.6715
DISDUR                      0.2772

$Flatulence
         p Value of SG Interaction
AGEONSET                    0.8010
AGETRT                      0.5644
SEX                         0.3177
REGION                      0.6540
DISDUR                      0.3723

$`Food allergy`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Food intolerance`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Fungal infection`
         p Value of SG Interaction
AGEONSET                    0.7711
AGETRT                      0.5792
SEX                         0.4885
REGION                      0.6303
DISDUR                      0.8258

$`Fungal skin infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Gastric haemorrhage`
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606
```

$Gastritis
          p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$Gastroenteritis
          p Value of SG Interaction
AGEONSET   0.7481
AGETRT   0.3645
SEX   0.3577
REGION   0.4841
DISDUR   0.3208

$`Gastroenteritis rotavirus`
          p Value of SG Interaction
AGEONSET   0.7995
AGETRT   0.5655
SEX   0.6714
REGION   0.7461
DISDUR   0.4046

$`Gastroenteritis viral`
          p Value of SG Interaction
AGEONSET   0.7627
AGETRT   0.3706
SEX   0.4325
REGION   0.8028
DISDUR   0.6122

$`Gastrointestinal haemorrhage`
          p Value of SG Interaction
AGEONSET   0.4878
AGETRT   0.0783
SEX   0.1271
REGION   0.1719
DISDUR   0.0496

$`Gastrointestinal motility disorder`
          p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$`Gastrointestinal tract irritation`
          p Value of SG Interaction
AGEONSET   0.4878
AGETRT   0.0783
SEX   0.1271
REGION   0.1719

```
DISDUR                      0.0496

$`Gastrooesophageal reflux disease`
         p Value of SG Interaction
AGEONSET                    0.2516
AGETRT                      0.3386
SEX                         0.6628
REGION                      0.7047
DISDUR                      0.5954

$`General physical health deterioration`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Glycosuria
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Granuloma annulare`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Haematochezia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Hand-foot-and-mouth disease`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Head injury`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Head lag abnormal`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Heart rate decreased`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Heart rate increased`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Heart rate irregular`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Hepatomegaly
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Hordeolum
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Human rhinovirus test positive`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hydronephrosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hyperaemia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hypercapnia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hyperglycaemia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hyperhidrosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hyperkeratosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

$Hypersensitivity
          p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$Hypertension
          p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$Hypoglycaemia
          p Value of SG Interaction
AGEONSET   0.4937
AGETRT   0.0782
SEX   0.1311
REGION   0.5254
DISDUR   0.1120

$Hypokalaemia
          p Value of SG Interaction
AGEONSET   0.2238
AGETRT   0.1596
SEX   0.3018
REGION   0.0990
DISDUR   0.0413

$Hypophagia
          p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$Hypopnoea
          p Value of SG Interaction
AGEONSET   0.7523
AGETRT   0.3665
SEX   0.3780
REGION   0.8330
DISDUR   0.3923

$Hypothermia
          p Value of SG Interaction
AGEONSET   0.7505
AGETRT   0.3657
SEX   0.3693
REGION   0.8378

```
DISDUR                      0.3606

$Hypoventilation
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$Hypoxia
         p Value of SG Interaction
AGEONSET                    0.7233
AGETRT                      0.0063
SEX                         0.2807
REGION                      0.8426
DISDUR                      0.0508

$`Hypoxic-ischaemic encephalopathy`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Impaired gastric emptying`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Impetigo
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Incision site erythema`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Increased bronchial secretion`
         p Value of SG Interaction
AGEONSET                    0.7934
AGETRT                      0.0609
```

```
SEX                         0.1026
REGION                      0.3373
DISDUR                      0.1226

$`Increased upper airway secretion`
         p Value of SG Interaction
AGEONSET                    0.7906
AGETRT                      0.5712
SEX                         0.3758
REGION                      0.7010
DISDUR                      0.6274

$`Infantile colic`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Infantile spitting up`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Inflammatory marker increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Influenza
         p Value of SG Interaction
AGEONSET                    0.5730
AGETRT                      0.2462
SEX                         0.6219
REGION                      0.9112
DISDUR                      0.6778

$`Influenza A virus test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Infusion site bruising`
         p Value of SG Interaction
```

```
AGEONSET                    0.0167
AGETRT                      0.2551
SEX                         0.1883
REGION                      0.4743
DISDUR                      0.5385

$`Infusion site extravasation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Injection site haematoma`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Intertrigo
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Iron deficiency`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Irritability
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Irritability postvaccinal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Joint contracture`
         p Value of SG Interaction
AGEONSET                    0.7408
AGETRT                      0.2148
SEX                         0.0454
REGION                      0.3067
DISDUR                      0.1463

$`Joint range of motion decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Joint stiffness`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Keratosis pilaris`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Kyphoscoliosis
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$Kyphosis
         p Value of SG Interaction
AGEONSET                    0.8054
AGETRT                      0.5611
SEX                         0.2941
REGION                      0.6329
DISDUR                      0.2849

$Laceration
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$`Lacrimation increased`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Language disorder`
         p Value of SG Interaction
AGEONSET                     0.7541
AGETRT                       0.3673
SEX                          0.5891
REGION                       0.8282
DISDUR                       0.4255

$`Left ventricular hypertrophy`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Leukocytosis
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Liver function test abnormal`
         p Value of SG Interaction
AGEONSET                     0.7906
AGETRT                       0.5712
SEX                          0.3758
REGION                       0.7010
DISDUR                       0.6274

$`Localised infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Lower respiratory tract infection`
         p Value of SG Interaction
AGEONSET                     0.5705
AGETRT                       0.1035
```

```
SEX                         0.4432
REGION                      0.8269
DISDUR                      0.0963

$`Lower respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                    0.6874
AGETRT                      0.8188
SEX                         0.9383
REGION                      0.9539
DISDUR                      0.9905

$`Lung disorder`
         p Value of SG Interaction
AGEONSET                    0.5124
AGETRT                      0.0756
SEX                         0.2033
REGION                      0.2399
DISDUR                      0.7396

$`Lung infection`
         p Value of SG Interaction
AGEONSET                    0.7786
AGETRT                      0.5767
SEX                         0.5264
REGION                      0.5016
DISDUR                      0.9630

$`Lymph node palpable`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Malaise
         p Value of SG Interaction
AGEONSET                    0.7711
AGETRT                      0.5792
SEX                         0.4885
REGION                      0.6303
DISDUR                      0.8258

$`Mechanical ventilation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Medical device complication`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Medical observation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Miliaria
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Mood swings`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Moraxella infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Moraxella test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Muscle contractions involuntary`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Muscle tightness`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Muscular weakness`
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.2599
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$Myopia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Naevus anaemicus`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Nasal congestion`
         p Value of SG Interaction
AGEONSET                    0.0171
AGETRT                      0.2504
SEX                         0.1653
REGION                      0.4991
DISDUR                      0.2805

$`Nasal inflammation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Nasopharyngitis
         p Value of SG Interaction
AGEONSET                    0.7457
AGETRT                      0.0919
SEX                         0.5370
REGION                      0.9278
```

```
DISDUR                      0.4225

$`Neutrophil count increased`
          p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$Nodule
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Nosocomial infection`
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Nystagmus
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Obstructive airways disorder`
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Oedema
          p Value of SG Interaction
AGEONSET                    0.2447
AGETRT                      0.6652
SEX                         0.9533
REGION                      0.0000
DISDUR                      0.0361

$`Oedema peripheral`
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Oral candidiasis`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Oral fungal infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Oral herpes`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Oropharyngeal pain`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Orthopaedic examination`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Otitis media`
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Otitis media acute`
         p Value of SG Interaction
```

```
AGEONSET                    0.7552
AGETRT                      0.5820
SEX                         0.5822
REGION                      0.8249
DISDUR                      0.4484

$`Ovarian cyst`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Oxygen saturation decreased`
         p Value of SG Interaction
AGEONSET                    0.8620
AGETRT                      0.5963
SEX                         0.9409
REGION                      0.8693
DISDUR                      0.8436

$Pain
         p Value of SG Interaction
AGEONSET                    0.0069
AGETRT                      0.3739
SEX                         0.4568
REGION                      0.7565
DISDUR                      0.9763

$`Pain in extremity`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Pallor
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Parainfluenzae virus infection`
         p Value of SG Interaction
AGEONSET                    0.4937
AGETRT                      0.0782
SEX                         0.1311
REGION                      0.5254
DISDUR                      0.1120
```

```
$`Pectus carinatum`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Penis disorder`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Pharyngitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pharyngitis streptococcal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Phimosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pleural effusion`
         p Value of SG Interaction
AGEONSET                     0.7505
AGETRT                       0.3657
SEX                          0.3693
REGION                       0.8378
DISDUR                       0.3606

$Pneumonia
         p Value of SG Interaction
AGEONSET                     0.0866
AGETRT                       0.6582
SEX                          0.7607
REGION                       0.5176
```

```
DISDUR                      0.3588

$`Pneumonia aspiration`
         p Value of SG Interaction
AGEONSET                    0.5565
AGETRT                      0.9352
SEX                         0.4197
REGION                      0.9668
DISDUR                      0.8352

$`Pneumonia bacterial`
         p Value of SG Interaction
AGEONSET                    0.5223
AGETRT                      0.0842
SEX                         0.1656
REGION                      0.6928
DISDUR                      0.1974

$`Pneumonia influenzal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pneumonia moraxella`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pneumonia parainfluenzae viral`
         p Value of SG Interaction
AGEONSET                    0.7481
AGETRT                      0.3645
SEX                         0.3577
REGION                      0.4841
DISDUR                      0.3208

$`Pneumonia pneumococcal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pneumonia pseudomonal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Pneumonia respiratory syncytial viral`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Pneumonia viral`
         p Value of SG Interaction
AGEONSET                   0.4818
AGETRT                     0.9469
SEX                        0.9118
REGION                     0.6957
DISDUR                     0.2136

$Pneumothorax
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Positional plagiocephaly`
         p Value of SG Interaction
AGEONSET                   0.5363
AGETRT                     0.2671
SEX                        0.3259
REGION                     0.3472
DISDUR                     0.0953

$`Post procedural contusion`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Post procedural haemorrhage`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Post procedural swelling`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Presyncope
         p Value of SG Interaction
AGEONSET                    0.5084
AGETRT                      0.0765
SEX                         0.0993
REGION                      0.4743
DISDUR                      0.5385

$`Procedural complication`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Procedural pain`
         p Value of SG Interaction
AGEONSET                    0.0068
AGETRT                      0.3743
SEX                         0.5298
REGION                      0.7467
DISDUR                      0.9478

$`Procedural site reaction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pseudomonas infection`
         p Value of SG Interaction
AGEONSET                    0.0650
AGETRT                      0.2307
SEX                         0.1276
REGION                      0.2176
DISDUR                      0.8932

$`Pseudomonas test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$Pyelonephritis
         p Value of SG Interaction
AGEONSET                    0.7711
AGETRT                      0.5792
SEX                         0.4885
REGION                      0.6303
DISDUR                      0.8258

$Pyrexia
         p Value of SG Interaction
AGEONSET                    0.4588
AGETRT                      0.6302
SEX                         0.4884
REGION                      0.0607
DISDUR                      0.8853

$Rash
         p Value of SG Interaction
AGEONSET                    0.7593
AGETRT                      0.3694
SEX                         0.5581
REGION                      0.8132
DISDUR                      0.5336

$`Rash erythematous`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Rash macular`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Rash papular`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory alkalosis`
         p Value of SG Interaction
AGEONSET                    0.7432
AGETRT                      0.5822
SEX                         0.6534
REGION                      0.8561
```

```
DISDUR                      0.2496

$`Respiratory arrest`
         p Value of SG Interaction
AGEONSET                    0.0600
AGETRT                      0.8739
SEX                         0.0742
REGION                      0.9104
DISDUR                      0.2637

$`Respiratory disorder`
         p Value of SG Interaction
AGEONSET                    0.7765
AGETRT                      0.3739
SEX                         0.4568
REGION                      0.6525
DISDUR                      0.9763

$`Respiratory distress`
         p Value of SG Interaction
AGEONSET                    0.9110
AGETRT                      0.0881
SEX                         0.6430
REGION                      0.6490
DISDUR                      0.0363

$`Respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.8800
AGETRT                      0.9006
SEX                         0.0526
REGION                      0.5352
DISDUR                      0.4305

$`Respiratory rate increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory syncytial virus bronchiolitis`
         p Value of SG Interaction
AGEONSET                    0.7941
AGETRT                      0.5691
SEX                         0.6311
REGION                      0.7242
DISDUR                      0.5352

$`Respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                    0.7432
AGETRT                      0.5822
```

```
SEX                         0.6534
REGION                      0.8561
DISDUR                      0.2496

$`Respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.6939
AGETRT                      0.6284
SEX                         0.8475
REGION                      0.7088
DISDUR                      0.5353

$`Respiratory tract infection bacterial`
         p Value of SG Interaction
AGEONSET                    0.5374
AGETRT                      0.2672
SEX                         0.3334
REGION                      0.3412
DISDUR                      0.0751

$`Respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                    0.7977
AGETRT                      0.2354
SEX                         0.0942
REGION                      0.9365
DISDUR                      0.2605

$`Respirovirus test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Restlessness
         p Value of SG Interaction
AGEONSET                    0.5213
AGETRT                      0.0727
SEX                         0.2414
REGION                      0.2700
DISDUR                      0.7364

$Retching
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Rhinitis
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Rhinitis allergic`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Rhinorrhoea
         p Value of SG Interaction
AGEONSET                    0.7564
AGETRT                      0.3683
SEX                         0.3989
REGION                      0.8216
DISDUR                      0.4720

$`Rhinovirus infection`
         p Value of SG Interaction
AGEONSET                    0.3901
AGETRT                      0.0056
SEX                         0.4381
REGION                      0.4705
DISDUR                      0.0331

$Rhonchi
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Roseola
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Salivary hypersecretion`
         p Value of SG Interaction
AGEONSET                    0.6526
AGETRT                      0.1940
SEX                         0.8080
REGION                      0.6807
DISDUR                      0.2357
```

```
$`Scarlet fever`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Scoliosis
          p Value of SG Interaction
AGEONSET                     0.7931
AGETRT                       0.5697
SEX                          0.6239
REGION                       0.6901
DISDUR                       0.5609

$`Seasonal allergy`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Seizure
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Sepsis
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Serratia infection`
          p Value of SG Interaction
AGEONSET                     0.5265
AGETRT                       0.2647
SEX                          0.2673
REGION                       0.3975
DISDUR                       0.4464

$Shock
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
```

```
DISDUR                          NaN

$`Sinus congestion`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Sinus tachycardia`
         p Value of SG Interaction
AGEONSET                     0.7786
AGETRT                       0.5767
SEX                          0.5264
REGION                       0.5016
DISDUR                       0.9630

$Sinusitis
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Skin candida`
         p Value of SG Interaction
AGEONSET                     0.7541
AGETRT                       0.3673
SEX                          0.5891
REGION                       0.8282
DISDUR                       0.4255

$`Skin infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Skin oedema`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Sleep apnoea syndrome`
         p Value of SG Interaction
AGEONSET                     0.3469
AGETRT                       0.6561
```

```
SEX                         0.0131
REGION                      0.1920
DISDUR                      0.6888

$`Sleep disorder`
         p Value of SG Interaction
AGEONSET                    0.0164
AGETRT                      0.2579
SEX                         0.2052
REGION                      0.2415
DISDUR                      0.7664

$Somnolence
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Sputum culture positive`
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.2599
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$`Sputum discoloured`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Staphylococcal infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Staphylococcal sepsis`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Staphylococcal skin infection`
         p Value of SG Interaction
```

```
AGEONSET                    0.7706
AGETRT                      0.5793
SEX                         0.4917
REGION                      0.6280
DISDUR                      0.8109

$`Staphylococcus test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Stoma complication`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Stoma site abscess`
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$`Stoma site erythema`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Stoma site haemorrhage`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Stoma site infection`
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.2599
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596
```

```
$`Stoma site inflammation`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Stoma site irritation`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Stomatitis
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Strabismus
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Supraventricular tachycardia`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Surgical failure`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Swelling
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
```

```
DISDUR                          NaN

$`Systemic infection`
          p Value of SG Interaction
AGEONSET                     0.4878
AGETRT                       0.0783
SEX                          0.1271
REGION                       0.1719
DISDUR                       0.0496

$Tachycardia
          p Value of SG Interaction
AGEONSET                     0.2767
AGETRT                       0.2809
SEX                          0.5782
REGION                       0.8088
DISDUR                       0.0491

$Tachypnoea
          p Value of SG Interaction
AGEONSET                         NaN
AGETRT                           NaN
SEX                              NaN
REGION                           NaN
DISDUR                           NaN

$Teething
          p Value of SG Interaction
AGEONSET                     0.7064
AGETRT                       0.6844
SEX                          0.0595
REGION                       0.3211
DISDUR                       0.1636

$Thrombocytosis
          p Value of SG Interaction
AGEONSET                         NaN
AGETRT                           NaN
SEX                              NaN
REGION                           NaN
DISDUR                           NaN

$Thrombosis
          p Value of SG Interaction
AGEONSET                     0.7931
AGETRT                       0.5697
SEX                          0.3616
REGION                       0.7201
DISDUR                       0.5609

$`Tongue atrophy`
          p Value of SG Interaction
AGEONSET                         NaN
AGETRT                           NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Tracheal haemorrhage`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Tracheal injury`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Tracheal obstruction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Tracheitis
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Transaminases increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Upper gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Upper respiratory tract congestion`
         p Value of SG Interaction
```

```
AGEONSET                   0.0171
AGETRT                     0.2504
SEX                        0.1653
REGION                     0.4991
DISDUR                     0.2805

$`Upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                   0.4413
AGETRT                     0.2689
SEX                        0.9494
REGION                     0.5759
DISDUR                     0.0466

$`Upper respiratory tract inflammation`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Urinary retention`
         p Value of SG Interaction
AGEONSET                   0.7432
AGETRT                     0.5822
SEX                        0.6534
REGION                     0.8561
DISDUR                     0.2496

$`Urinary tract infection`
         p Value of SG Interaction
AGEONSET                   0.5541
AGETRT                     0.7369
SEX                        0.1491
REGION                     0.5115
DISDUR                     0.7174

$`Urine output decreased`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Urticaria
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN
```

```
$`Use of accessory respiratory muscles`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vaccination complication`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vaccination site reaction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Vasculitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Ventricular tachycardia`
         p Value of SG Interaction
AGEONSET                    0.7727
AGETRT                      0.5787
SEX                         0.4899
REGION                      0.5008
DISDUR                      0.8705

$`Vessel puncture site bruise`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vessel puncture site reaction`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
```

```
DISDUR                      0.0496

$`Viral infection`
         p Value of SG Interaction
AGEONSET                    0.6966
AGETRT                      0.5292
SEX                         0.4437
REGION                      0.4653
DISDUR                      0.2717

$`Viral rash`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Viral rhinitis`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Viral upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.5891
AGETRT                      0.8010
SEX                         0.1907
REGION                      0.3264
DISDUR                      0.8421

$`Vitamin A decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vitamin D decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vitamin D deficiency`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Vomiting
         p Value of SG Interaction
AGEONSET                    0.9067
AGETRT                      0.5011
SEX                         0.8080
REGION                      0.9146
DISDUR                      0.3126

$`Weight decreased`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$`Weight gain poor`
         p Value of SG Interaction
AGEONSET                    0.7010
AGETRT                      0.4201
SEX                         0.2186
REGION                      0.4749
DISDUR                      0.5879

$Wheezing
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN


\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten UEs nach PT, das bei mindestens 10%
der Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Abdominal discomfort`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Abdominal distension`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Abdominal pain upper`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Acquired phimosis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Acute respiratory distress syndrome`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Acute respiratory failure`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.0491
SEX                        1.0000
REGION                     0.2245
DISDUR                     0.0662

$`Adenovirus infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Agitation
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.9999
REGION                     0.9992
DISDUR                     1.0000

$`Agitation postoperative`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Alanine aminotransferase increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Amblyopia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Anaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Anxiety
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Aphthous ulcer`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Apnoea
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.3054
SEX                         0.1285
REGION                      0.2793
DISDUR                      0.2848
```

```
$`Apparent life threatening event`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Application site rash`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Arthropod bite`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Aspartate aminotransferase increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Aspiration
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1191
SEX                         0.0484
REGION                      1.0000
DISDUR                      0.4336

$Atelectasis
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.6894
SEX                         0.5983
REGION                      0.0487
DISDUR                      0.9967

$`Back pain`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Bacteraemia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Bacterial disease carrier`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Bacterial infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Bacterial tracheitis`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.5029
SEX                        0.3889
REGION                     1.0000
DISDUR                     0.1229

$Balanoposthitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Blood chloride decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Blood iron decreased`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Blood potassium decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Blood sodium decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Body temperature decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Body temperature increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Bone marrow disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Bradycardia
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.3504
SEX                        0.3012
REGION                     1.0000
DISDUR                     0.2156

$`Brain injury`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Breath holding`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bronchial obstruction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bronchial secretion retention`
         p Value of SG Interaction
AGEONSET                    0.4176
AGETRT                      0.0531
SEX                         0.2363
REGION                      0.4060
DISDUR                      0.4490

$Bronchiolitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Bronchitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bronchitis viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`C-reactive protein increased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1299
SEX                         0.3912
REGION                      1.0000
DISDUR                      0.7715

$`Candida infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Candida nappy rash`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Candida sepsis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Cardiac arrest`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Cardio-respiratory arrest`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Catarrh
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Catheter site inflammation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Cellulitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Chalazion
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Choking
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Chronic respiratory failure`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Clonus
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Congenital diaphragmatic hernia`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Conjunctivitis
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Conjunctivitis bacterial`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Constipation
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.2153
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.1054

$Contusion
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Corona virus infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Cough
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.2683
SEX                         0.3106
REGION                      0.7675
DISDUR                      0.1195

$Crying
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Cryptorchism
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Cyanosis
         p Value of SG Interaction
AGEONSET                    0.0107
AGETRT                      0.0162
SEX                         0.0429
REGION                      1.0000
DISDUR                      0.8185

$Death
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Decubitus ulcer`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Deformity thorax`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Dehydration
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Delayed fontanelle closure`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Delayed recovery from anaesthesia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Dermatitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dermatitis allergic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dermatitis atopic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dermatitis contact`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dermatitis diaper`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
```

```
REGION                     1.0000
DISDUR                     0.5486

$`Developmental hip dysplasia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Device malfunction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Device occlusion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Diarrhoea
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0108
SEX                         0.3173
REGION                      1.0000
DISDUR                      0.0723

$`Diarrhoea haemorrhagic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Discomfort
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Drooling
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Drug hypersensitivity`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Drug intolerance`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dry eye`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dry skin`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Dysphagia
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.7685
SEX                         0.0040
REGION                      0.5301
DISDUR                      0.5996

$Dyspnoea
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.4619
SEX                         0.4782
REGION                      0.2547
DISDUR                      0.9054

$`Ear disorder`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ear haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ear infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ear pain`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Ecchymosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Eczema
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Eczema infected`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Electrocardiogram ST-T segment abnormal`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Endotracheal intubation complication`
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   1.0000
SEX   1.0000
REGION   1.0000
DISDUR   0.9999

$Enteritis
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Enterobiasis
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Enterococcal infection`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Epigastric discomfort`
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   1.0000
SEX   0.9999
REGION   1.0000
DISDUR   1.0000

$Erythema
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1

```
REGION                          1
DISDUR                          1

$`Escherichia infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Excoriation
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Exposure to communicable disease`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Eye infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Eye movement disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Failure to thrive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Fatigue
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Feeding disorder of infancy or early childhood`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.9999
SEX                         0.9261
REGION                      0.3857
DISDUR                      0.6064

$`Feeding intolerance`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Feeding tube complication`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Femur fracture`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Flatulence
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Food allergy`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Food intolerance`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Fungal infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Fungal skin infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastric haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Gastritis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Gastroenteritis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastroenteritis rotavirus`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Gastroenteritis viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      0.9993
DISDUR                      1.0000

$`Gastrointestinal motility disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastrointestinal tract irritation`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      0.9993
DISDUR                      1.0000

$`Gastrooesophageal reflux disease`
         p Value of SG Interaction
AGEONSET                    0.5814
AGETRT                      0.4148
SEX                         1.0000
REGION                      0.4443
DISDUR                      0.6393

$`General physical health deterioration`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Glycosuria
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Granuloma annulare`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Haematochezia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Hand-foot-and-mouth disease`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Head injury`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Head lag abnormal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Heart rate decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Heart rate increased`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Heart rate irregular`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hepatomegaly
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hordeolum
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Human rhinovirus test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hydronephrosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hyperaemia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypercapnia
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hyperglycaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hyperhidrosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hyperkeratosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypersensitivity
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypertension
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypoglycaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Hypokalaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypophagia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypopnoea
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypothermia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypoventilation
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypoxia
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0039
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.0538

$`Hypoxic-ischaemic encephalopathy`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Impaired gastric emptying`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Impetigo
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Incision site erythema`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Increased bronchial secretion`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.0443
SEX                        0.0849
REGION                     0.2638
DISDUR                     0.1745

$`Increased upper airway secretion`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Infantile colic`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Infantile spitting up`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Inflammatory marker increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Influenza
         p Value of SG Interaction
AGEONSET                   0.9999
AGETRT                     1.0000
SEX                        1.0000
REGION                     1.0000
DISDUR                     1.0000

$`Influenza A virus test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Infusion site bruising`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Infusion site extravasation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Injection site haematoma`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Intertrigo
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Iron deficiency`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Irritability
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Irritability postvaccinal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Joint contracture`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0472
SEX                         0.0451
REGION                      1.0000
DISDUR                      0.2416

$`Joint range of motion decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Joint stiffness`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Keratosis pilaris`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Kyphoscoliosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Kyphosis
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$Laceration
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Lacrimation increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Language disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Left ventricular hypertrophy`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Leukocytosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Liver function test abnormal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Localised infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Lower respiratory tract infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Lower respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Lung disorder`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.9999
SEX                        1.0000
REGION                     1.0000
DISDUR                     1.0000

$`Lung infection`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Lymph node palpable`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Malaise
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Mechanical ventilation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Medical device complication`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Medical observation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Miliaria
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Mood swings`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Moraxella infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Moraxella test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Muscle contractions involuntary`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Muscle tightness`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Muscular weakness`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Myopia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Naevus anaemicus`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Nasal congestion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Nasal inflammation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Nasopharyngitis
         p Value of SG Interaction
AGEONSET                    0.3260
AGETRT                      0.0565
SEX                         0.6110
REGION                      0.7995
DISDUR                      0.7529

$`Neutrophil count increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Nodule
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Nosocomial infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Nystagmus
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Obstructive airways disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Oedema
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        1.0000
REGION                     0.9999
DISDUR                     1.0000

$`Oedema peripheral`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oral candidiasis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oral fungal infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oral herpes`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oropharyngeal pain`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Orthopaedic examination`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Otitis media`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Otitis media acute`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Ovarian cyst`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oxygen saturation decreased`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.4773
SEX                        0.9826
REGION                     0.6044
DISDUR                     0.8922

$Pain
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pain in extremity`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Pallor
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Parainfluenzae virus infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pectus carinatum`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Penis disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Pharyngitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Pharyngitis streptococcal`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$Phimosis
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Pleural effusion`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$Pneumonia
	p Value of SG Interaction
AGEONSET	0.0376
AGETRT	0.5033
SEX	0.4440
REGION	0.4319
DISDUR	0.6284

$`Pneumonia aspiration`
	p Value of SG Interaction
AGEONSET	0.9999
AGETRT	0.8155
SEX	0.5900
REGION	0.9993
DISDUR	0.8774

$`Pneumonia bacterial`
	p Value of SG Interaction
AGEONSET	0.9999
AGETRT	1.0000
SEX	1.0000
REGION	1.0000
DISDUR	0.9988

$`Pneumonia influenzal`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1

```
REGION                          1
DISDUR                          1

$`Pneumonia moraxella`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pneumonia parainfluenzae viral`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pneumonia pneumococcal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pneumonia pseudomonal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pneumonia respiratory syncytial viral`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pneumonia viral`
         p Value of SG Interaction
AGEONSET                   0.9999
AGETRT                     1.0000
SEX                        1.0000
REGION                     1.0000
DISDUR                     1.0000

$Pneumothorax
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Positional plagiocephaly`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Post procedural contusion`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Post procedural haemorrhage`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Post procedural swelling`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Presyncope
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Procedural complication`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Procedural pain`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Procedural site reaction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pseudomonas infection`
         p Value of SG Interaction
AGEONSET                    0.2522
AGETRT                      0.2140
SEX                         0.0840
REGION                      0.2060
DISDUR                      0.7264

$`Pseudomonas test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Pyelonephritis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Pyrexia
         p Value of SG Interaction
AGEONSET                    0.8538
AGETRT                      0.7328
SEX                         0.4062
REGION                      0.0348
DISDUR                      0.7905

$Rash
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Rash erythematous`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Rash macular`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Rash papular`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Respiratory alkalosis`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Respiratory arrest`
	p Value of SG Interaction
AGEONSET	0.2082
AGETRT	1.0000
SEX	0.0594
REGION	1.0000
DISDUR	0.2307

$`Respiratory disorder`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Respiratory distress`
	p Value of SG Interaction
AGEONSET	0.7254
AGETRT	0.0467
SEX	0.5711

```
REGION                     0.6212
DISDUR                     0.0445

$`Respiratory failure`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.9749
SEX                        0.0321
REGION                     0.3453
DISDUR                     0.4519

$`Respiratory rate increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory syncytial virus bronchiolitis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory tract infection`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.1590
SEX                        0.4125
REGION                     0.7998
DISDUR                     0.2712

$`Respiratory tract infection bacterial`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                   1.0000
```

```
AGETRT                      0.1897
SEX                         0.0775
REGION                      1.0000
DISDUR                      0.2503

$`Respirovirus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Restlessness
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.9999
SEX                         1.0000
REGION                      1.0000
DISDUR                      1.0000

$Retching
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Rhinitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Rhinitis allergic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Rhinorrhoea
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Rhinovirus infection`
```

```
         p Value of SG Interaction
AGEONSET                    0.1980
AGETRT                      0.0037
SEX                         0.5038
REGION                      0.3121
DISDUR                      0.0423

$Rhonchi
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Roseola
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Salivary hypersecretion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Scarlet fever`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Scoliosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Seasonal allergy`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$Seizure
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Sepsis
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Serratia infection`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Shock
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Sinus congestion`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Sinus tachycardia`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Sinusitis
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1

```
REGION                          1
DISDUR                          1

$`Skin candida`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Skin infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Skin oedema`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sleep apnoea syndrome`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sleep disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Somnolence
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sputum culture positive`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sputum discoloured`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Staphylococcal infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Staphylococcal sepsis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Staphylococcal skin infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Staphylococcus test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Stoma complication`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Stoma site abscess`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site erythema`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site inflammation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site irritation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Stomatitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Strabismus
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Supraventricular tachycardia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Surgical failure`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Swelling
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Systemic infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$Tachycardia
         p Value of SG Interaction
AGEONSET                    0.2196
AGETRT                      0.1126
SEX                         0.2630
REGION                      0.5936
DISDUR                      0.0069

$Tachypnoea
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Teething
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.4062
SEX                         0.0368
REGION                      0.9110
DISDUR                      0.4152

$Thrombocytosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Thrombosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Tongue atrophy`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Tracheal haemorrhage`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Tracheal injury`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Tracheal obstruction`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Tracheitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Transaminases increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Upper gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Upper respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                   0.3778
AGETRT                     0.2150
SEX                        0.9606
REGION                     0.2633
DISDUR                     0.0786

$`Upper respiratory tract inflammation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Urinary retention`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Urinary tract infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Urine output decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Urticaria
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Use of accessory respiratory muscles`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vaccination complication`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vaccination site reaction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Vasculitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ventricular tachycardia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vessel puncture site bruise`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vessel puncture site reaction`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9998
REGION                      0.9992
DISDUR                      1.0000

$`Viral infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.3914
SEX                         0.2252
REGION                      0.3775
DISDUR                      0.3018

$`Viral rash`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Viral rhinitis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Viral upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.3112
AGETRT                      0.4075
SEX                         0.1012
REGION                      1.0000
DISDUR                      0.9360

$`Vitamin A decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vitamin D decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vitamin D deficiency`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Vomiting
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.3622
SEX                         0.4292
REGION                      0.7132
DISDUR                      0.1638

$`Weight decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Weight gain poor`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Wheezing
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1


\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem schweren UE nach SOC, das bei mindestens 5%
der Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Blood and lymphatic system disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Cardiac disorders`
         p Value of SG Interaction
AGEONSET                    0.8609
AGETRT                      0.2385
SEX                         0.4052
REGION                      0.2030
DISDUR                      0.5864

$`Congenital, familial and genetic disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Ear and labyrinth disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Eye disorders`
         p Value of SG Interaction
```

```
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Gastrointestinal disorders`
         p Value of SG Interaction
AGEONSET                    0.7346
AGETRT                      0.3681
SEX                         0.5084
REGION                      0.9183
DISDUR                      0.7325

$`General disorders and administration site conditions`
         p Value of SG Interaction
AGEONSET                    0.8523
AGETRT                      0.8055
SEX                         0.6899
REGION                      0.4414
DISDUR                      0.7336

$`Hepatobiliary disorders`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Immune system disorders`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$`Infections and infestations`
         p Value of SG Interaction
AGEONSET                    0.5767
AGETRT                      0.8151
SEX                         0.6245
REGION                      0.8456
DISDUR                      0.2677

$`Injury, poisoning and procedural complications`
         p Value of SG Interaction
AGEONSET                    0.2722
AGETRT                      0.9880
SEX                         0.0233
REGION                      0.9493
DISDUR                      0.1535
```

$Investigations
	p Value of SG Interaction
AGEONSET	0.7772
AGETRT	0.3256
SEX	0.5101
REGION	0.3190
DISDUR	0.3669

$`Metabolism and nutrition disorders`
	p Value of SG Interaction
AGEONSET	0.7914
AGETRT	0.3999
SEX	0.5368
REGION	0.9488
DISDUR	0.6693

$`Musculoskeletal and connective tissue disorders`
	p Value of SG Interaction
AGEONSET	0.7523
AGETRT	0.3665
SEX	0.3780
REGION	0.8330
DISDUR	0.3923

$`Nervous system disorders`
	p Value of SG Interaction
AGEONSET	0.6914
AGETRT	0.8210
SEX	0.9064
REGION	0.5406
DISDUR	0.8722

$`Psychiatric disorders`
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$`Renal and urinary disorders`
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$`Reproductive system and breast disorders`
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN

```
DISDUR                         NaN

$`Respiratory, thoracic and mediastinal disorders`
         p Value of SG Interaction
AGEONSET                    0.4334
AGETRT                      0.2508
SEX                         0.8939
REGION                      0.8953
DISDUR                      0.4837

$`Skin and subcutaneous tissue disorders`
         p Value of SG Interaction
AGEONSET                    0.7926
AGETRT                      0.5700
SEX                         0.6203
REGION                      0.6923
DISDUR                      0.5739

$`Surgical and medical procedures`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Vascular disorders`
         p Value of SG Interaction
AGEONSET                    0.6228
AGETRT                      0.8897
SEX                         0.7808
REGION                      0.8844
DISDUR                      0.8910


\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schweren UEs nach SOC, das bei mindestens 5%
der Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Blood and lymphatic system disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Cardiac disorders`
         p Value of SG Interaction
AGEONSET                    0.5489
AGETRT                      0.1086
SEX                         0.7128
```

```
REGION                     0.3906
DISDUR                     0.5367

$`Congenital, familial and genetic disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ear and labyrinth disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Eye disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastrointestinal disorders`
         p Value of SG Interaction
AGEONSET                    0.5424
AGETRT                      0.1016
SEX                         0.4120
REGION                      0.4316
DISDUR                      0.9545

$`General disorders and administration site conditions`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.3441
REGION                      0.4045
DISDUR                      0.3792

$`Hepatobiliary disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Immune system disorders`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Infections and infestations`
         p Value of SG Interaction
AGEONSET                    0.8549
AGETRT                      0.7605
SEX                         0.7577
REGION                      0.7272
DISDUR                      0.3160

$`Injury, poisoning and procedural complications`
         p Value of SG Interaction
AGEONSET                    0.6607
AGETRT                      0.5293
SEX                         0.0080
REGION                      0.6949
DISDUR                      0.9268

$Investigations
         p Value of SG Interaction
AGEONSET                    0.7234
AGETRT                      0.1158
SEX                         0.2606
REGION                      0.1827
DISDUR                      0.6568

$`Metabolism and nutrition disorders`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.7751

$`Musculoskeletal and connective tissue disorders`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Nervous system disorders`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Psychiatric disorders`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Renal and urinary disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Reproductive system and breast disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory, thoracic and mediastinal disorders`
         p Value of SG Interaction
AGEONSET                    0.2039
AGETRT                      0.1040
SEX                         0.7666
REGION                      0.7169
DISDUR                      0.5160

$`Skin and subcutaneous tissue disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Surgical and medical procedures`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vascular disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem schweren UE nach PT, das bei mindestens 5%
der Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Abdominal discomfort`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Abdominal distension`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Abdominal pain upper`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Acquired phimosis`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Acute respiratory distress syndrome`
         p Value of SG Interaction
AGEONSET                    0.5079
AGETRT                      0.0766
SEX                         0.1865
REGION                      0.2259
DISDUR                      0.5153

$`Acute respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.9361
AGETRT                      0.8076
SEX                         0.8628
REGION                      0.7489
```

```
DISDUR                      0.0612

$`Adenovirus infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Agitation
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Agitation postoperative`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Alanine aminotransferase increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Amblyopia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Anaemia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Anxiety
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Aphthous ulcer`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Apnoea
         p Value of SG Interaction
AGEONSET                   0.5501
AGETRT                     0.0090
SEX                        0.5466
REGION                     0.7583
DISDUR                     0.0489

$`Apparent life threatening event`
         p Value of SG Interaction
AGEONSET                   0.3675
AGETRT                     0.1079
SEX                        0.5339
REGION                     0.1215
DISDUR                     0.0712

$`Application site rash`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Arthropod bite`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Aspartate aminotransferase increased`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Aspiration
         p Value of SG Interaction
```

```
AGEONSET                    0.9290
AGETRT                      0.7314
SEX                         0.5366
REGION                      0.9351
DISDUR                      0.5247

$Atelectasis
         p Value of SG Interaction
AGEONSET                    0.7809
AGETRT                      0.5018
SEX                         0.2200
REGION                      0.9849
DISDUR                      0.6213

$`Back pain`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Bacteraemia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bacterial disease carrier`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bacterial infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bacterial tracheitis`
         p Value of SG Interaction
AGEONSET                    0.8283
AGETRT                      0.2370
SEX                         0.2694
REGION                      0.8486
DISDUR                      0.7859
```

```
$Balanoposthitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Blood chloride decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Blood iron decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Blood potassium decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Blood sodium decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Body temperature decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Body temperature increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$`Bone marrow disorder`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Bradycardia
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Brain injury`
         p Value of SG Interaction
AGEONSET                     0.7505
AGETRT                       0.3657
SEX                          0.3693
REGION                       0.8378
DISDUR                       0.3606

$`Breath holding`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Bronchial obstruction`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Bronchial secretion retention`
         p Value of SG Interaction
AGEONSET                     0.2009
AGETRT                       0.2928
SEX                          0.4140
REGION                       0.6794
DISDUR                       0.5537

$Bronchiolitis
         p Value of SG Interaction
AGEONSET                     0.7852
AGETRT                       0.3902
```

```
SEX                         0.6898
REGION                      0.9518
DISDUR                      0.9371

$Bronchitis
         p Value of SG Interaction
AGEONSET                    0.7926
AGETRT                      0.5700
SEX                         0.6203
REGION                      0.6923
DISDUR                      0.5739

$`Bronchitis viral`
         p Value of SG Interaction
AGEONSET                    0.6479
AGETRT                      0.3097
SEX                         0.3924
REGION                      0.7994
DISDUR                      0.1944

$`C-reactive protein increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Candida infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Candida nappy rash`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Candida sepsis`
         p Value of SG Interaction
AGEONSET                    0.0166
AGETRT                      0.2564
SEX                         0.0951
REGION                      0.2337
DISDUR                      0.6358

$`Cardiac arrest`
         p Value of SG Interaction
```

```
AGEONSET                    0.7256
AGETRT                      0.6256
SEX                         0.6877
REGION                      0.3688
DISDUR                      0.6299

$`Cardio-respiratory arrest`
         p Value of SG Interaction
AGEONSET                    0.6635
AGETRT                      0.2960
SEX                         0.2210
REGION                      0.5338
DISDUR                      0.3438

$Catarrh
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Catheter site inflammation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Cellulitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Chalazion
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Choking
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Chronic respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606

$Clonus
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Congenital diaphragmatic hernia`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Conjunctivitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Conjunctivitis bacterial`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Constipation
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Contusion
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$`Corona virus infection`
         p Value of SG Interaction
AGEONSET                    0.4591
AGETRT                      0.0753
SEX                         0.2101
REGION                      0.6192
DISDUR                      0.0002

$Cough
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Crying
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Cryptorchism
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Cyanosis
         p Value of SG Interaction
AGEONSET                    0.5099
AGETRT                      0.0761
SEX                         0.0961
REGION                      0.4685
DISDUR                      0.6108

$Death
         p Value of SG Interaction
AGEONSET                    0.7771
AGETRT                      0.4064
SEX                         0.1368
REGION                      0.3880
DISDUR                      0.1424

$`Decubitus ulcer`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Deformity thorax`
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$Dehydration
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Delayed fontanelle closure`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Delayed recovery from anaesthesia`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Dermatitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Dermatitis allergic`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Dermatitis atopic`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Dermatitis contact`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Dermatitis diaper`
         p Value of SG Interaction
AGEONSET                    0.7926
AGETRT                      0.5700
SEX                         0.6203
REGION                      0.6923
DISDUR                      0.5739

$`Developmental hip dysplasia`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Device malfunction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Device occlusion`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Diarrhoea
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Diarrhoea haemorrhagic`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Discomfort
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Drooling
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Drug hypersensitivity`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$`Drug intolerance`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Dry eye`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Dry skin`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$Dysphagia
         p Value of SG Interaction
AGEONSET                    0.6006
AGETRT                      0.1558
SEX                         0.1447
REGION                      0.8899
DISDUR                      0.9901

$Dyspnoea
         p Value of SG Interaction
AGEONSET                    0.9766
AGETRT                      0.0380
SEX                         0.0605
REGION                      0.6956
DISDUR                      0.3326

$`Ear disorder`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Ear haemorrhage`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Ear infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Ear pain`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Ecchymosis
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Eczema
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Eczema infected`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Electrocardiogram ST-T segment abnormal`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Endotracheal intubation complication`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Enteritis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Enterobiasis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Enterococcal infection`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Epigastric discomfort`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Erythema
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Escherichia infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Excoriation
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Exposure to communicable disease`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Eye infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Eye movement disorder`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Failure to thrive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Fatigue
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Feeding disorder of infancy or early childhood`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Feeding intolerance`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Feeding tube complication`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.3616
REGION                      0.7201
DISDUR                      0.5609

$`Femur fracture`
         p Value of SG Interaction
AGEONSET                    0.0171
AGETRT                      0.2504
SEX                         0.1653
REGION                      0.4991
```

```
DISDUR                      0.2805

$Flatulence
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Food allergy`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Food intolerance`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Fungal infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Fungal skin infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Gastric haemorrhage`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Gastritis
         p Value of SG Interaction
AGEONSET                    0.7926
AGETRT                      0.5700
```

```
SEX                         0.6203
REGION                      0.6923
DISDUR                      0.5739

$Gastroenteritis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Gastroenteritis rotavirus`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Gastroenteritis viral`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Gastrointestinal motility disorder`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Gastrointestinal tract irritation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Gastrooesophageal reflux disease`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`General physical health deterioration`
         p Value of SG Interaction
AGEONSET                    0.7818
AGETRT                      0.5755
SEX                         0.4260
REGION                      0.6742
DISDUR                      0.8724

$Glycosuria
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Granuloma annulare`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Haematochezia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Hand-foot-and-mouth disease`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Head injury`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Head lag abnormal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Heart rate decreased`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Heart rate increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Heart rate irregular`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hepatomegaly
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hordeolum
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Human rhinovirus test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$Hydronephrosis
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hyperaemia
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hypercapnia
         p Value of SG Interaction
AGEONSET                     0.7844
AGETRT                       0.5743
SEX                          0.5639
REGION                       0.7264
DISDUR                       0.7980

$Hyperglycaemia
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hyperhidrosis
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hyperkeratosis
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hypersensitivity
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Hypertension
         p Value of SG Interaction
AGEONSET                     0.7926
AGETRT                       0.5700
SEX                          0.6203
REGION                       0.6923
DISDUR                       0.5739

$Hypoglycaemia
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hypokalaemia
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hypophagia
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hypopnoea
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hypothermia
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hypoventilation
         p Value of SG Interaction
```

```
AGEONSET                    0.7926
AGETRT                      0.5700
SEX                         0.6203
REGION                      0.6923
DISDUR                      0.5739

$Hypoxia
         p Value of SG Interaction
AGEONSET                    0.9087
AGETRT                      0.4403
SEX                         0.2242
REGION                      0.9017
DISDUR                      0.1310

$`Hypoxic-ischaemic encephalopathy`
         p Value of SG Interaction
AGEONSET                    0.8073
AGETRT                      0.5594
SEX                         0.2839
REGION                      0.6233
DISDUR                      0.2506

$`Impaired gastric emptying`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Impetigo
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Incision site erythema`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Increased bronchial secretion`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN
```

```
$`Increased upper airway secretion`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Infantile colic`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Infantile spitting up`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Inflammatory marker increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Influenza
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Influenza A virus test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Infusion site bruising`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                         NaN

$`Infusion site extravasation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Injection site haematoma`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Intertrigo
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Iron deficiency`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Irritability
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Irritability postvaccinal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Joint contracture`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Joint range of motion decreased`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Joint stiffness`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Keratosis pilaris`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Kyphoscoliosis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Kyphosis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Laceration
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Lacrimation increased`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Language disorder`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Left ventricular hypertrophy`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Leukocytosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Liver function test abnormal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Localised infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Lower respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.6646
AGETRT                      0.1974
SEX                         0.8896
REGION                      0.3330
DISDUR                      0.4278
```

$`Lower respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$`Lung disorder`
         p Value of SG Interaction
AGEONSET   0.7995
AGETRT   0.5655
SEX   0.6714
REGION   0.7461
DISDUR   0.4046

$`Lung infection`
         p Value of SG Interaction
AGEONSET   0.7786
AGETRT   0.5767
SEX   0.5264
REGION   0.5016
DISDUR   0.9630

$`Lymph node palpable`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$Malaise
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$`Mechanical ventilation`
         p Value of SG Interaction
AGEONSET   0.7541
AGETRT   0.3673
SEX   0.5891
REGION   0.8282
DISDUR   0.4255

$`Medical device complication`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN

```
DISDUR                          NaN

$`Medical observation`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Miliaria
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Mood swings`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Moraxella infection`
          p Value of SG Interaction
AGEONSET                     0.7511
AGETRT                       0.3660
SEX                          0.3722
REGION                       0.8362
DISDUR                       0.3710

$`Moraxella test positive`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Muscle contractions involuntary`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Muscle tightness`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Muscular weakness`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Myopia
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Naevus anaemicus`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Nasal congestion`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Nasal inflammation`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Nasopharyngitis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Neutrophil count increased`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Nodule
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Nosocomial infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Nystagmus
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Obstructive airways disorder`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$Oedema
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Oedema peripheral`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Oral candidiasis`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Oral fungal infection`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Oral herpes`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Oropharyngeal pain`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Orthopaedic examination`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Otitis media`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Otitis media acute`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
```

```
DISDUR                          NaN

$`Ovarian cyst`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Oxygen saturation decreased`
         p Value of SG Interaction
AGEONSET                     0.3936
AGETRT                       0.0946
SEX                          0.1515
REGION                       0.4780
DISDUR                       0.6545

$Pain
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Pain in extremity`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Pallor
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Parainfluenzae virus infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Pectus carinatum`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Penis disorder`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Pharyngitis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Pharyngitis streptococcal`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Phimosis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Pleural effusion`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Pneumonia
         p Value of SG Interaction
AGEONSET                    0.3657
AGETRT                      0.9418
SEX                         0.2124
REGION                      0.8837
DISDUR                      0.5235

$`Pneumonia aspiration`
         p Value of SG Interaction
```

```
AGEONSET                    0.0111
AGETRT                      0.2556
SEX                         0.0188
REGION                      0.9982
DISDUR                      0.3265

$`Pneumonia bacterial`
         p Value of SG Interaction
AGEONSET                    0.9811
AGETRT                      0.6548
SEX                         0.5431
REGION                      0.9989
DISDUR                      0.9161

$`Pneumonia influenzal`
         p Value of SG Interaction
AGEONSET                    0.7700
AGETRT                      0.5795
SEX                         0.4737
REGION                      0.7794
DISDUR                      0.7962

$`Pneumonia moraxella`
         p Value of SG Interaction
AGEONSET                    0.7552
AGETRT                      0.5820
SEX                         0.5822
REGION                      0.8249
DISDUR                      0.4484

$`Pneumonia parainfluenzae viral`
         p Value of SG Interaction
AGEONSET                    0.0171
AGETRT                      0.2504
SEX                         0.1653
REGION                      0.4991
DISDUR                      0.2805

$`Pneumonia pneumococcal`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$`Pneumonia pseudomonal`
         p Value of SG Interaction
AGEONSET                    0.0161
AGETRT                      0.2599
SEX                         0.2189
REGION                      0.2525
DISDUR                      0.9596
```

```
$`Pneumonia respiratory syncytial viral`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$`Pneumonia viral`
         p Value of SG Interaction
AGEONSET                    0.7542
AGETRT                      0.8348
SEX                         0.1734
REGION                      0.7060
DISDUR                      0.5586

$Pneumothorax
         p Value of SG Interaction
AGEONSET                    0.7834
AGETRT                      0.5748
SEX                         0.5571
REGION                      0.7305
DISDUR                      0.8276

$`Positional plagiocephaly`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Post procedural contusion`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Post procedural haemorrhage`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Post procedural swelling`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$Presyncope
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Procedural complication`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Procedural pain`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Procedural site reaction`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Pseudomonas infection`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Pseudomonas test positive`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Pyelonephritis
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Pyrexia
         p Value of SG Interaction
AGEONSET                     0.7075
AGETRT                       0.4164
SEX                          0.7685
REGION                       0.9624
DISDUR                       0.4138

$Rash
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Rash erythematous`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Rash macular`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Rash papular`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Respiratory alkalosis`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Respiratory arrest`
         p Value of SG Interaction
```

```
AGEONSET                    0.7491
AGETRT                      0.2445
SEX                         0.3336
REGION                      0.0172
DISDUR                      0.8291

$`Respiratory disorder`
         p Value of SG Interaction
AGEONSET                    0.7426
AGETRT                      0.3616
SEX                         0.3322
REGION                      0.5149
DISDUR                      0.2414

$`Respiratory distress`
         p Value of SG Interaction
AGEONSET                    0.6874
AGETRT                      0.0839
SEX                         0.0681
REGION                      0.7346
DISDUR                      0.1133

$`Respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.0626
AGETRT                      0.0302
SEX                         0.7719
REGION                      0.3458
DISDUR                      0.8145

$`Respiratory rate increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory syncytial virus bronchiolitis`
         p Value of SG Interaction
AGEONSET                    0.6309
AGETRT                      0.3795
SEX                         0.8000
REGION                      0.8634
DISDUR                      0.0971

$`Respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.9450
AGETRT                      0.9878
SEX                         0.5432
REGION                      0.9254
DISDUR                      0.6088

$`Respiratory tract infection bacterial`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                    0.5213
AGETRT                      0.0727
SEX                         0.2414
REGION                      0.2700
DISDUR                      0.7364

$`Respirovirus test positive`
         p Value of SG Interaction
AGEONSET                    0.0171
AGETRT                      0.2504
SEX                         0.1653
REGION                      0.4991
DISDUR                      0.2805

$Restlessness
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Retching
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Rhinitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$`Rhinitis allergic`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Rhinorrhoea
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Rhinovirus infection`
         p Value of SG Interaction
AGEONSET                     0.7865
AGETRT                       0.6306
SEX                          0.9574
REGION                       0.8685
DISDUR                       0.7489

$Rhonchi
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Roseola
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Salivary hypersecretion`
         p Value of SG Interaction
AGEONSET                     0.0161
AGETRT                       0.2599
SEX                          0.2189
REGION                       0.2525
DISDUR                       0.9596

$`Scarlet fever`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Scoliosis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Seasonal allergy`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Seizure
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606

$Sepsis
         p Value of SG Interaction
AGEONSET                    0.6762
AGETRT                      0.4259
SEX                         0.3310
REGION                      0.9409
DISDUR                      0.6928

$`Serratia infection`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Shock
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606

$`Sinus congestion`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Sinus tachycardia`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Sinusitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Skin candida`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Skin infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Skin oedema`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Sleep apnoea syndrome`
         p Value of SG Interaction
AGEONSET                    0.4937
AGETRT                      0.0782
SEX                         0.1311
REGION                      0.5254
DISDUR                      0.1120
```

```
$`Sleep disorder`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Somnolence
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Sputum culture positive`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Sputum discoloured`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Staphylococcal infection`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Staphylococcal sepsis`
          p Value of SG Interaction
AGEONSET                     0.7627
AGETRT                       0.3706
SEX                          0.4325
REGION                       0.8028
DISDUR                       0.6122

$`Staphylococcal skin infection`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
```

```
DISDUR                          NaN

$`Staphylococcus test positive`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Stoma complication`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Stoma site abscess`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Stoma site erythema`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Stoma site haemorrhage`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Stoma site infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Stoma site inflammation`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Stoma site irritation`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Stomatitis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Strabismus
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Supraventricular tachycardia`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Surgical failure`
         p Value of SG Interaction
AGEONSET                    0.7926
AGETRT                      0.5700
SEX                         0.6203
REGION                      0.6923
DISDUR                      0.5739

$Swelling
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Systemic infection`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Tachycardia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Tachypnoea
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Teething
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Thrombocytosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Thrombosis
         p Value of SG Interaction
AGEONSET                     0.7931
AGETRT                       0.5697
SEX                          0.3616
REGION                       0.7201
DISDUR                       0.5609

$`Tongue atrophy`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Tracheal haemorrhage`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Tracheal injury`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Tracheal obstruction`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$Tracheitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Transaminases increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Upper gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Upper respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$`Upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.5343
AGETRT                      0.5222
SEX                         0.2058
REGION                      0.3115
DISDUR                      0.3395

$`Upper respiratory tract inflammation`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Urinary retention`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Urinary tract infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Urine output decreased`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Urticaria
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Use of accessory respiratory muscles`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Vaccination complication`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Vaccination site reaction`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Vasculitis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Ventricular tachycardia`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Vessel puncture site bruise`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Vessel puncture site reaction`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Viral infection`
         p Value of SG Interaction
```

```
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Viral rash`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Viral rhinitis`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Viral upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.1978
AGETRT                      0.8542
SEX                         0.9119
REGION                      0.0489
DISDUR                      0.8411

$`Vitamin A decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vitamin D decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vitamin D deficiency`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$Vomiting
         p Value of SG Interaction
AGEONSET                    0.4937
AGETRT                      0.0782
SEX                         0.1311
REGION                      0.5254
DISDUR                      0.1120

$`Weight decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Weight gain poor`
         p Value of SG Interaction
AGEONSET                    0.7914
AGETRT                      0.3999
SEX                         0.5368
REGION                      0.9488
DISDUR                      0.6693

$Wheezing
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN


\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines schweren UEs nach PT, das bei mindestens 5% der
Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Abdominal discomfort`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Abdominal distension`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Abdominal pain upper`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Acquired phimosis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Acute respiratory distress syndrome`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Acute respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.6468
AGETRT                      0.6655
SEX                         0.9966
REGION                      0.1284
DISDUR                      0.0845

$`Adenovirus infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Agitation
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Agitation postoperative`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Alanine aminotransferase increased`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Amblyopia
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Anaemia
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Anxiety
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Aphthous ulcer`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Apnoea
         p Value of SG Interaction
AGEONSET                     0.9999
AGETRT                       0.0210
SEX                          0.3055
REGION                       0.5490
DISDUR                       0.0788

$`Apparent life threatening event`
         p Value of SG Interaction
AGEONSET                          1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Application site rash`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Arthropod bite`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Aspartate aminotransferase increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Aspiration
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.3865
REGION                     1.0000
DISDUR                     0.4685

$Atelectasis
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.6069
SEX                        0.1796
REGION                     0.9359
DISDUR                     0.5773

$`Back pain`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Bacteraemia
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bacterial disease carrier`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bacterial infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bacterial tracheitis`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.2590
SEX                         0.1837
REGION                      1.0000
DISDUR                      0.4695

$Balanoposthitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Blood chloride decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Blood iron decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Blood potassium decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Blood sodium decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Body temperature decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Body temperature increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bone marrow disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Bradycardia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Brain injury`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Breath holding`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Bronchial obstruction`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Bronchial secretion retention`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.5577
SEX                        0.4126
REGION                     0.4667
DISDUR                     0.3448

$Bronchiolitis
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.3234
SEX                        0.3142
REGION                     0.7455
DISDUR                     0.4433

$Bronchitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Bronchitis viral`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`C-reactive protein increased`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Candida infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Candida nappy rash`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Candida sepsis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Cardiac arrest`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.6055
SEX                        0.2221
REGION                     0.4166
DISDUR                     0.7186

$`Cardio-respiratory arrest`
         p Value of SG Interaction
AGEONSET                   0.5945
AGETRT                     0.1328
SEX                        0.3151
REGION                     0.7359
DISDUR                     0.3326

$Catarrh
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Catheter site inflammation`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Cellulitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Chalazion
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Choking
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Chronic respiratory failure`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Clonus
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Congenital diaphragmatic hernia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Conjunctivitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Conjunctivitis bacterial`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Constipation
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Contusion
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Corona virus infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Cough
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Crying
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Cryptorchism
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Cyanosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Death
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.1229
REGION                     0.3078
DISDUR                     0.2795

$`Decubitus ulcer`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Deformity thorax`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Dehydration
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Delayed fontanelle closure`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Delayed recovery from anaesthesia`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Dermatitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Dermatitis allergic`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Dermatitis atopic`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Dermatitis contact`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Dermatitis diaper`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Developmental hip dysplasia`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Device malfunction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Device occlusion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Diarrhoea
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Diarrhoea haemorrhagic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Discomfort
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Drooling
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Drug hypersensitivity`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Drug intolerance`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dry eye`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dry skin`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Dysphagia
         p Value of SG Interaction
AGEONSET                    0.5157
AGETRT                      0.0688
SEX                         0.1261
REGION                      0.4349
DISDUR                      0.8211

$Dyspnoea
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0186
SEX                         0.0301
REGION                      0.8734
DISDUR                      0.3726

$`Ear disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Ear haemorrhage`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Ear infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Ear pain`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Ecchymosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Eczema
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Eczema infected`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Electrocardiogram ST-T segment abnormal`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Endotracheal intubation complication`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Enteritis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Enterobiasis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Enterococcal infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Epigastric discomfort`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Erythema
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Escherichia infection`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Excoriation
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Exposure to communicable disease`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Eye infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Eye movement disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Failure to thrive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Fatigue
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Feeding disorder of infancy or early childhood`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Feeding intolerance`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Feeding tube complication`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Femur fracture`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Flatulence
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Food allergy`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Food intolerance`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1

```
REGION                          1
DISDUR                          1

$`Fungal infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Fungal skin infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastric haemorrhage`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Gastritis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Gastroenteritis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastroenteritis rotavirus`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastroenteritis viral`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastrointestinal motility disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastrointestinal tract irritation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastrooesophageal reflux disease`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`General physical health deterioration`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Glycosuria
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Granuloma annulare`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Haematochezia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Hand-foot-and-mouth disease`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Head injury`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Head lag abnormal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Heart rate decreased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Heart rate increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Heart rate irregular`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hepatomegaly
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hordeolum
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Human rhinovirus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hydronephrosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hyperaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypercapnia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Hyperglycaemia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hyperhidrosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hyperkeratosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypersensitivity
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypertension
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypoglycaemia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypokalaemia
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypophagia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypopnoea
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypothermia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypoventilation
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypoxia
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.2332
SEX                        0.1447
REGION                     1.0000
DISDUR                     0.1321

$`Hypoxic-ischaemic encephalopathy`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Impaired gastric emptying`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Impetigo
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Incision site erythema`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Increased bronchial secretion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Increased upper airway secretion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Infantile colic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Infantile spitting up`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Inflammatory marker increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Influenza
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Influenza A virus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Infusion site bruising`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Infusion site extravasation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Injection site haematoma`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Intertrigo
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Iron deficiency`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Irritability
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Irritability postvaccinal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Joint contracture`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Joint range of motion decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Joint stiffness`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Keratosis pilaris`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Kyphoscoliosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Kyphosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Laceration
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Lacrimation increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Language disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Left ventricular hypertrophy`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Leukocytosis
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Liver function test abnormal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Localised infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Lower respiratory tract infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Lower respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Lung disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Lung infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Lymph node palpable`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Malaise
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Mechanical ventilation`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Medical device complication`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Medical observation`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Miliaria
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Mood swings`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1

```
REGION                          1
DISDUR                          1

$`Moraxella infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Moraxella test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Muscle contractions involuntary`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Muscle tightness`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Muscular weakness`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Myopia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Naevus anaemicus`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Nasal congestion`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Nasal inflammation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Nasopharyngitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Neutrophil count increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Nodule
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Nosocomial infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Nystagmus
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Obstructive airways disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Oedema
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oedema peripheral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oral candidiasis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oral fungal infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oral herpes`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Oropharyngeal pain`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Orthopaedic examination`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Otitis media`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Otitis media acute`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ovarian cyst`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oxygen saturation decreased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0696
SEX                         0.1471
REGION                      0.2210
DISDUR                      0.7629

$Pain
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Pain in extremity`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Pallor
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Parainfluenzae virus infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pectus carinatum`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Penis disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Pharyngitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pharyngitis streptococcal`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Phimosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pleural effusion`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Pneumonia
         p Value of SG Interaction
AGEONSET                   0.1191
AGETRT                     0.9411
SEX                        0.2187
REGION                     0.8045
DISDUR                     0.4715

$`Pneumonia aspiration`
         p Value of SG Interaction
AGEONSET                   0.0709
AGETRT                     0.2679
SEX                        0.0066
REGION                     1.0000
DISDUR                     0.4359

$`Pneumonia bacterial`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.5012
SEX                        0.3971
REGION                     1.0000
DISDUR                     0.8275

$`Pneumonia influenzal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pneumonia moraxella`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia parainfluenzae viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia pneumococcal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia pseudomonal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia respiratory syncytial viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia viral`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.0369
REGION                      1.0000
DISDUR                      0.7961

$Pneumothorax
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Positional plagiocephaly`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Post procedural contusion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Post procedural haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Post procedural swelling`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Presyncope
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Procedural complication`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Procedural pain`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Procedural site reaction`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pseudomonas infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pseudomonas test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Pyelonephritis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Pyrexia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Rash
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Rash erythematous`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Rash macular`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Rash papular`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Respiratory alkalosis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Respiratory arrest`
         p Value of SG Interaction
AGEONSET                   0.9999
AGETRT                     0.1660
SEX                        0.2907
REGION                     0.0074
DISDUR                     0.9454

$`Respiratory disorder`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.9998
REGION                     1.0000
DISDUR                     1.0000

$`Respiratory distress`
         p Value of SG Interaction
AGEONSET                   0.4596
AGETRT                     0.1105
SEX                        0.0600
REGION                     0.7210
DISDUR                     0.1012

$`Respiratory failure`
```

```
         p Value of SG Interaction
AGEONSET                    0.0477
AGETRT                      0.0356
SEX                         0.9325
REGION                      0.1210
DISDUR                      0.8895

$`Respiratory rate increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory syncytial virus bronchiolitis`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.4212
SEX                         0.9996
REGION                      1.0000
DISDUR                      0.1881

$`Respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.3558
REGION                      1.0000
DISDUR                      0.4757

$`Respiratory tract infection bacterial`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.9999
SEX                         1.0000
REGION                      1.0000
DISDUR                      1.0000
```

```
$`Respirovirus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Restlessness
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Retching
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Rhinitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Rhinitis allergic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Rhinorrhoea
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Rhinovirus infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.7142
SEX                         0.9684
```

```
REGION                     1.0000
DISDUR                     0.8364

$Rhonchi
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Roseola
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Salivary hypersecretion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Scarlet fever`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Scoliosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Seasonal allergy`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Seizure
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Sepsis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Serratia infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Shock
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sinus congestion`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sinus tachycardia`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Sinusitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Skin candida`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Skin infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Skin oedema`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Sleep apnoea syndrome`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Sleep disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Somnolence
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Sputum culture positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Sputum discoloured`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Staphylococcal infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Staphylococcal sepsis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Staphylococcal skin infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Staphylococcus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma complication`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site abscess`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Stoma site erythema`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Stoma site haemorrhage`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Stoma site infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Stoma site inflammation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Stoma site irritation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Stomatitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Strabismus
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Supraventricular tachycardia`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Surgical failure`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Swelling
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Systemic infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Tachycardia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Tachypnoea
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Teething
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Thrombocytosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Thrombosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Tongue atrophy`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Tracheal haemorrhage`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Tracheal injury`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Tracheal obstruction`
         p Value of SG Interaction
AGEONSET                    0.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000
```

```
$Tracheitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Transaminases increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Upper gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Upper respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.9999

$`Upper respiratory tract inflammation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Urinary retention`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Urinary tract infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Urine output decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Urticaria
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Use of accessory respiratory muscles`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Vaccination complication`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Vaccination site reaction`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Vasculitis
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Ventricular tachycardia`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Vessel puncture site bruise`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Vessel puncture site reaction`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Viral infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Viral rash`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Viral rhinitis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Viral upper respiratory tract infection`
```

```
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.4206
SEX                         0.3027
REGION                      1.0000
DISDUR                      0.4575

$`Vitamin A decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vitamin D decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vitamin D deficiency`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Vomiting
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Weight decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Weight gain poor`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.7751
```

```
$Wheezing
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1


\##############################################################################
[[1]]
[1] "Patienten mit mindestens einem moderaten oder schweren UE nach SOC, das bei
mindestens 10% der Patienten in einem Studienarm oder bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Blood and lymphatic system disorders`
         p Value of SG Interaction
AGEONSET                    0.0565
AGETRT                      0.2381
SEX                         0.2362
REGION                      0.3222
DISDUR                      0.3975

$`Cardiac disorders`
         p Value of SG Interaction
AGEONSET                    0.2999
AGETRT                      0.1316
SEX                         0.1719
REGION                      0.1522
DISDUR                      0.2249

$`Congenital, familial and genetic disorders`
         p Value of SG Interaction
AGEONSET                    0.6856
AGETRT                      0.8178
SEX                         0.9529
REGION                      0.5649
DISDUR                      0.9555

$`Ear and labyrinth disorders`
         p Value of SG Interaction
AGEONSET                    0.7776
AGETRT                      0.5771
SEX                         0.4505
REGION                      0.7526
DISDUR                      0.9934

$`Eye disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                         NaN

$`Gastrointestinal disorders`
         p Value of SG Interaction
AGEONSET                    0.3733
AGETRT                      0.9822
SEX                         0.7818
REGION                      0.1816
DISDUR                      0.1137

$`General disorders and administration site conditions`
         p Value of SG Interaction
AGEONSET                    0.2639
AGETRT                      0.6909
SEX                         0.1689
REGION                      0.1210
DISDUR                      0.3259

$`Hepatobiliary disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Immune system disorders`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$`Infections and infestations`
         p Value of SG Interaction
AGEONSET                    0.1294
AGETRT                      0.7663
SEX                         0.9305
REGION                      0.5131
DISDUR                      0.0343

$`Injury, poisoning and procedural complications`
         p Value of SG Interaction
AGEONSET                    0.9912
AGETRT                      0.1633
SEX                         0.3821
REGION                      0.8625
DISDUR                      0.0247

$Investigations
         p Value of SG Interaction
AGEONSET                    0.8779
AGETRT                      0.2387
```

```
SEX                         0.5645
REGION                      0.3292
DISDUR                      0.4299

$`Metabolism and nutrition disorders`
         p Value of SG Interaction
AGEONSET                    0.4950
AGETRT                      0.0717
SEX                         0.2043
REGION                      0.4508
DISDUR                      0.0923

$`Musculoskeletal and connective tissue disorders`
         p Value of SG Interaction
AGEONSET                    0.7696
AGETRT                      0.9433
SEX                         0.3664
REGION                      0.5890
DISDUR                      0.8643

$`Nervous system disorders`
         p Value of SG Interaction
AGEONSET                    0.9135
AGETRT                      0.1341
SEX                         0.6428
REGION                      0.8892
DISDUR                      0.5519

$`Psychiatric disorders`
         p Value of SG Interaction
AGEONSET                    0.4099
AGETRT                      0.0955
SEX                         0.0148
REGION                      0.0090
DISDUR                      0.3292

$`Renal and urinary disorders`
         p Value of SG Interaction
AGEONSET                    0.7432
AGETRT                      0.5822
SEX                         0.6534
REGION                      0.8561
DISDUR                      0.2496

$`Reproductive system and breast disorders`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Respiratory, thoracic and mediastinal disorders`
         p Value of SG Interaction
```

```
AGEONSET                    0.9988
AGETRT                      0.2933
SEX                         0.4907
REGION                      0.7516
DISDUR                      0.3384

$`Skin and subcutaneous tissue disorders`
         p Value of SG Interaction
AGEONSET                    0.6702
AGETRT                      0.7530
SEX                         0.8915
REGION                      0.7232
DISDUR                      0.4576

$`Surgical and medical procedures`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Vascular disorders`
         p Value of SG Interaction
AGEONSET                    0.6228
AGETRT                      0.8897
SEX                         0.7808
REGION                      0.8844
DISDUR                      0.8910


\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten oder schweren UEs nach SOC, das bei
mindestens 10% der Patienten in einem Studienarm oder bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Blood and lymphatic system disorders`
         p Value of SG Interaction
AGEONSET                    0.2228
AGETRT                      0.2016
SEX                         0.1471
REGION                      0.2524
DISDUR                      0.2346

$`Cardiac disorders`
         p Value of SG Interaction
AGEONSET                    0.0956
AGETRT                      0.1032
SEX                         0.3124
REGION                      0.1693
DISDUR                      0.3681

$`Congenital, familial and genetic disorders`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ear and labyrinth disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Eye disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastrointestinal disorders`
         p Value of SG Interaction
AGEONSET                    0.2755
AGETRT                      0.6840
SEX                         0.9196
REGION                      0.0722
DISDUR                      0.1214

$`General disorders and administration site conditions`
         p Value of SG Interaction
AGEONSET                    0.6936
AGETRT                      0.8633
SEX                         0.1055
REGION                      0.0370
DISDUR                      0.3819

$`Hepatobiliary disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Immune system disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Infections and infestations`
         p Value of SG Interaction
AGEONSET   0.6337
AGETRT   0.5747
SEX   0.9079
REGION   0.3728
DISDUR   0.0532

$`Injury, poisoning and procedural complications`
         p Value of SG Interaction
AGEONSET   0.4710
AGETRT   0.0390
SEX   0.4661
REGION   0.9783
DISDUR   0.0051

$Investigations
         p Value of SG Interaction
AGEONSET   0.5310
AGETRT   0.1340
SEX   0.7529
REGION   0.5440
DISDUR   0.4087

$`Metabolism and nutrition disorders`
         p Value of SG Interaction
AGEONSET   0.9999
AGETRT   0.5101
SEX   0.4709
REGION   0.5368
DISDUR   0.2468

$`Musculoskeletal and connective tissue disorders`
         p Value of SG Interaction
AGEONSET   0.9999
AGETRT   0.8950
SEX   0.2787
REGION   1.0000
DISDUR   0.4146

$`Nervous system disorders`
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   0.0855
SEX   0.3666
REGION   1.0000
DISDUR   0.5516

$`Psychiatric disorders`
         p Value of SG Interaction
AGEONSET   0.0470
AGETRT   0.0765
SEX   0.0209

```
REGION                     0.0868
DISDUR                     0.7133

$`Renal and urinary disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Reproductive system and breast disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory, thoracic and mediastinal disorders`
         p Value of SG Interaction
AGEONSET                    0.5692
AGETRT                      0.0790
SEX                         0.4592
REGION                      0.4034
DISDUR                      0.2283

$`Skin and subcutaneous tissue disorders`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.4505
SEX                         0.7991
REGION                      1.0000
DISDUR                      0.6281

$`Surgical and medical procedures`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vascular disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1


\##############################################################################
[[1]]
```

[1] "Patienten mit mindestens einem moderaten oder schweren UE nach PT, das bei mindestens 10% der Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Abdominal discomfort`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$`Abdominal distension`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$`Abdominal pain upper`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$`Acquired phimosis`
         p Value of SG Interaction
AGEONSET   0.7541
AGETRT   0.3673
SEX   0.5891
REGION   0.8282
DISDUR   0.4255

$`Acute respiratory distress syndrome`
         p Value of SG Interaction
AGEONSET   0.8084
AGETRT   0.0591
SEX   0.7605
REGION   0.2851
DISDUR   0.2869

$`Acute respiratory failure`
         p Value of SG Interaction
AGEONSET   0.9361
AGETRT   0.8076
SEX   0.8628
REGION   0.7489
DISDUR   0.0612

$`Adenovirus infection`
         p Value of SG Interaction

```
AGEONSET                    0.6526
AGETRT                      0.1940
SEX                         0.8080
REGION                      0.6807
DISDUR                      0.2357

$Agitation
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Agitation postoperative`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Alanine aminotransferase increased`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$Amblyopia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Anaemia
         p Value of SG Interaction
AGEONSET                    0.7432
AGETRT                      0.5822
SEX                         0.6534
REGION                      0.8561
DISDUR                      0.2496

$Anxiety
         p Value of SG Interaction
AGEONSET                    0.0069
AGETRT                      0.3739
SEX                         0.4568
REGION                      0.7565
DISDUR                      0.9763
```

```
$`Aphthous ulcer`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Apnoea
          p Value of SG Interaction
AGEONSET                     0.7370
AGETRT                       0.5495
SEX                          0.2807
REGION                       0.9395
DISDUR                       0.7324

$`Apparent life threatening event`
          p Value of SG Interaction
AGEONSET                     0.3675
AGETRT                       0.1079
SEX                          0.5339
REGION                       0.1215
DISDUR                       0.0712

$`Application site rash`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Arthropod bite`
          p Value of SG Interaction
AGEONSET                     0.7860
AGETRT                       0.5736
SEX                          0.4020
REGION                       0.7201
DISDUR                       0.7542

$`Aspartate aminotransferase increased`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Aspiration
          p Value of SG Interaction
AGEONSET                     0.9269
AGETRT                       0.4928
SEX                          0.0824
REGION                       0.9428
```

```
DISDUR                      0.3213

$Atelectasis
          p Value of SG Interaction
AGEONSET                    0.6168
AGETRT                      0.8430
SEX                         0.1367
REGION                      0.3396
DISDUR                      0.8954

$`Back pain`
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Bacteraemia
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bacterial disease carrier`
          p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Bacterial infection`
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bacterial tracheitis`
          p Value of SG Interaction
AGEONSET                    0.5663
AGETRT                      0.9610
SEX                         0.9704
REGION                      0.5283
DISDUR                      0.2552

$Balanoposthitis
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Blood chloride decreased`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$`Blood iron decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Blood potassium decreased`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$`Blood sodium decreased`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$`Body temperature decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Body temperature increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bone marrow disorder`
         p Value of SG Interaction
```

```
AGEONSET                    0.0161
AGETRT                      0.2599
SEX                         0.2189
REGION                      0.2525
DISDUR                      0.9596

$Bradycardia
         p Value of SG Interaction
AGEONSET                    0.7443
AGETRT                      0.3423
SEX                         0.3274
REGION                      0.7571
DISDUR                      0.1288

$`Brain injury`
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606

$`Breath holding`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bronchial obstruction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bronchial secretion retention`
         p Value of SG Interaction
AGEONSET                    0.8072
AGETRT                      0.7596
SEX                         0.7471
REGION                      0.8133
DISDUR                      0.3322

$Bronchiolitis
         p Value of SG Interaction
AGEONSET                    0.9712
AGETRT                      0.9571
SEX                         0.7981
REGION                      0.8170
DISDUR                      0.4172
```

$Bronchitis
	p Value of SG Interaction
AGEONSET	0.6441
AGETRT	0.3129
SEX	0.4236
REGION	0.8646
DISDUR	0.2720

$`Bronchitis viral`
	p Value of SG Interaction
AGEONSET	0.6479
AGETRT	0.3097
SEX	0.3924
REGION	0.7994
DISDUR	0.1944

$`C-reactive protein increased`
	p Value of SG Interaction
AGEONSET	0.9830
AGETRT	0.2203
SEX	0.5548
REGION	0.9706
DISDUR	0.7346

$`Candida infection`
	p Value of SG Interaction
AGEONSET	0.5374
AGETRT	0.2672
SEX	0.3334
REGION	0.3412
DISDUR	0.0751

$`Candida nappy rash`
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$`Candida sepsis`
	p Value of SG Interaction
AGEONSET	0.0166
AGETRT	0.2564
SEX	0.0951
REGION	0.2337
DISDUR	0.6358

$`Cardiac arrest`
	p Value of SG Interaction
AGEONSET	0.7256
AGETRT	0.6256
SEX	0.6877
REGION	0.3688

```
DISDUR                      0.6299

$`Cardio-respiratory arrest`
         p Value of SG Interaction
AGEONSET                    0.6635
AGETRT                      0.2960
SEX                         0.2210
REGION                      0.5338
DISDUR                      0.3438

$Catarrh
         p Value of SG Interaction
AGEONSET                    0.0164
AGETRT                      0.2579
SEX                         0.2052
REGION                      0.2415
DISDUR                      0.7664

$`Catheter site inflammation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Cellulitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Chalazion
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Choking
         p Value of SG Interaction
AGEONSET                    0.5294
AGETRT                      0.2656
SEX                         0.0571
REGION                      0.3835
DISDUR                      0.3117

$`Chronic respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.6499
AGETRT                      0.1930
```

```
SEX                         0.1996
REGION                      0.6886
DISDUR                      0.2035

$Clonus
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Congenital diaphragmatic hernia`
         p Value of SG Interaction
AGEONSET                    0.7599
AGETRT                      0.3696
SEX                         0.5547
REGION                      0.8115
DISDUR                      0.5464

$Conjunctivitis
         p Value of SG Interaction
AGEONSET                    0.7481
AGETRT                      0.3645
SEX                         0.3577
REGION                      0.4841
DISDUR                      0.3208

$`Conjunctivitis bacterial`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$Constipation
         p Value of SG Interaction
AGEONSET                    0.9605
AGETRT                      0.4567
SEX                         0.4776
REGION                      0.7202
DISDUR                      0.2417

$Contusion
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Corona virus infection`
         p Value of SG Interaction
```

```
AGEONSET                   0.2948
AGETRT                     0.0090
SEX                        0.8445
REGION                     0.3047
DISDUR                     0.0000

$Cough
         p Value of SG Interaction
AGEONSET                   0.8173
AGETRT                     0.3893
SEX                        0.5600
REGION                     0.9781
DISDUR                     0.3182

$Crying
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Cryptorchism
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Cyanosis
         p Value of SG Interaction
AGEONSET                   0.0209
AGETRT                     0.0091
SEX                        0.0206
REGION                     0.6162
DISDUR                     0.5384

$Death
         p Value of SG Interaction
AGEONSET                   0.7771
AGETRT                     0.4064
SEX                        0.1368
REGION                     0.3880
DISDUR                     0.1424

$`Decubitus ulcer`
         p Value of SG Interaction
AGEONSET                   0.3567
AGETRT                     0.6483
SEX                        0.6657
REGION                     0.1616
DISDUR                     0.6116
```

$`Deformity thorax`
	p Value of SG Interaction
AGEONSET	0.7523
AGETRT	0.3665
SEX	0.3780
REGION	0.8330
DISDUR	0.3923

$Dehydration
	p Value of SG Interaction
AGEONSET	0.5162
AGETRT	0.0745
SEX	0.0830
REGION	0.4431
DISDUR	0.9596

$`Delayed fontanelle closure`
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$`Delayed recovery from anaesthesia`
	p Value of SG Interaction
AGEONSET	0.7599
AGETRT	0.3696
SEX	0.4171
REGION	0.5844
DISDUR	0.5464

$Dermatitis
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$`Dermatitis allergic`
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$`Dermatitis atopic`
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN

```
DISDUR                          NaN

$`Dermatitis contact`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Dermatitis diaper`
         p Value of SG Interaction
AGEONSET                     0.9785
AGETRT                       0.6537
SEX                          0.8572
REGION                       0.9984
DISDUR                       0.3253

$`Developmental hip dysplasia`
         p Value of SG Interaction
AGEONSET                     0.7916
AGETRT                       0.5706
SEX                          0.6132
REGION                       0.6966
DISDUR                       0.6004

$`Device malfunction`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Device occlusion`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Diarrhoea
         p Value of SG Interaction
AGEONSET                     0.8990
AGETRT                       0.0225
SEX                          0.5488
REGION                       0.9242
DISDUR                       0.0638

$`Diarrhoea haemorrhagic`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Discomfort
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Drooling
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Drug hypersensitivity`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$`Drug intolerance`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Dry eye`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Dry skin`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Dysphagia
         p Value of SG Interaction
```

```
AGEONSET                    0.9846
AGETRT                      0.2337
SEX                         0.4723
REGION                      0.8066
DISDUR                      0.6760

$Dyspnoea
         p Value of SG Interaction
AGEONSET                    0.3835
AGETRT                      0.1183
SEX                         0.4790
REGION                      0.2000
DISDUR                      0.5713

$`Ear disorder`
         p Value of SG Interaction
AGEONSET                    0.7776
AGETRT                      0.5771
SEX                         0.4505
REGION                      0.7526
DISDUR                      0.9934

$`Ear haemorrhage`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Ear infection`
         p Value of SG Interaction
AGEONSET                    0.6050
AGETRT                      0.8997
SEX                         0.6458
REGION                      0.9143
DISDUR                      0.5944

$`Ear pain`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Ecchymosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$Eczema
          p Value of SG Interaction
AGEONSET                     0.4937
AGETRT                       0.0782
SEX                          0.1311
REGION                       0.5254
DISDUR                       0.1120

$`Eczema infected`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Electrocardiogram ST-T segment abnormal`
          p Value of SG Interaction
AGEONSET                     0.7438
AGETRT                       0.3623
SEX                          0.6497
REGION                       0.8546
DISDUR                       0.2579

$`Endotracheal intubation complication`
          p Value of SG Interaction
AGEONSET                     0.4591
AGETRT                       0.0753
SEX                          0.2101
REGION                       0.6192
DISDUR                       0.0002

$Enteritis
          p Value of SG Interaction
AGEONSET                     0.4884
AGETRT                       0.0783
SEX                          0.1429
REGION                       0.1734
DISDUR                       0.0541

$Enterobiasis
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Enterococcal infection`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
```

```
DISDUR                          NaN

$`Epigastric discomfort`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$Erythema
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Escherichia infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Excoriation
         p Value of SG Interaction
AGEONSET                    0.8010
AGETRT                      0.5644
SEX                         0.3177
REGION                      0.6540
DISDUR                      0.3723

$`Exposure to communicable disease`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Eye infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Eye movement disorder`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Failure to thrive`
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.0745
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$Fatigue
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Feeding disorder of infancy or early childhood`
         p Value of SG Interaction
AGEONSET                    0.8063
AGETRT                      0.4161
SEX                         0.8759
REGION                      0.4766
DISDUR                      0.4676

$`Feeding intolerance`
         p Value of SG Interaction
AGEONSET                    0.6633
AGETRT                      0.8048
SEX                         0.2470
REGION                      0.9206
DISDUR                      0.4039

$`Feeding tube complication`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.3616
REGION                      0.7201
DISDUR                      0.5609

$`Femur fracture`
         p Value of SG Interaction
AGEONSET                    0.0876
AGETRT                      0.6950
SEX                         0.5372
REGION                      0.9988
DISDUR                      0.1308

$Flatulence
         p Value of SG Interaction
```

```
AGEONSET                    0.8010
AGETRT                      0.5644
SEX                         0.3177
REGION                      0.6540
DISDUR                      0.3723

$`Food allergy`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Food intolerance`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Fungal infection`
         p Value of SG Interaction
AGEONSET                    0.7711
AGETRT                      0.5792
SEX                         0.4885
REGION                      0.6303
DISDUR                      0.8258

$`Fungal skin infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Gastric haemorrhage`
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606

$Gastritis
         p Value of SG Interaction
AGEONSET                    0.7926
AGETRT                      0.5700
SEX                         0.6203
REGION                      0.6923
DISDUR                      0.5739
```

$Gastroenteritis
	p Value of SG Interaction
AGEONSET	0.7481
AGETRT	0.3645
SEX	0.3577
REGION	0.4841
DISDUR	0.3208

$`Gastroenteritis rotavirus`
	p Value of SG Interaction
AGEONSET	0.7995
AGETRT	0.5655
SEX	0.6714
REGION	0.7461
DISDUR	0.4046

$`Gastroenteritis viral`
	p Value of SG Interaction
AGEONSET	0.7627
AGETRT	0.3706
SEX	0.4325
REGION	0.8028
DISDUR	0.6122

$`Gastrointestinal haemorrhage`
	p Value of SG Interaction
AGEONSET	0.4878
AGETRT	0.0783
SEX	0.1271
REGION	0.1719
DISDUR	0.0496

$`Gastrointestinal motility disorder`
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$`Gastrointestinal tract irritation`
	p Value of SG Interaction
AGEONSET	0.4878
AGETRT	0.0783
SEX	0.1271
REGION	0.1719
DISDUR	0.0496

$`Gastrooesophageal reflux disease`
	p Value of SG Interaction
AGEONSET	0.2516
AGETRT	0.3386
SEX	0.6628
REGION	0.7047

```
DISDUR                      0.5954

$`General physical health deterioration`
         p Value of SG Interaction
AGEONSET                    0.7818
AGETRT                      0.5755
SEX                         0.4260
REGION                      0.6742
DISDUR                      0.8724

$Glycosuria
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Granuloma annulare`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Haematochezia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Hand-foot-and-mouth disease`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Head injury`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Head lag abnormal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Heart rate decreased`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Heart rate increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Heart rate irregular`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hepatomegaly
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hordeolum
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Human rhinovirus test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hydronephrosis
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hyperaemia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hypercapnia
         p Value of SG Interaction
AGEONSET                    0.7844
AGETRT                      0.5743
SEX                         0.5639
REGION                      0.7264
DISDUR                      0.7980

$Hyperglycaemia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hyperhidrosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hyperkeratosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hypersensitivity
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

$Hypertension
	p Value of SG Interaction
AGEONSET	0.7926
AGETRT	0.5700
SEX	0.6203
REGION	0.6923
DISDUR	0.5739

$Hypoglycaemia
	p Value of SG Interaction
AGEONSET	0.4937
AGETRT	0.0782
SEX	0.1311
REGION	0.5254
DISDUR	0.1120

$Hypokalaemia
	p Value of SG Interaction
AGEONSET	0.2238
AGETRT	0.1596
SEX	0.3018
REGION	0.0990
DISDUR	0.0413

$Hypophagia
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$Hypopnoea
	p Value of SG Interaction
AGEONSET	0.7523
AGETRT	0.3665
SEX	0.3780
REGION	0.8330
DISDUR	0.3923

$Hypothermia
	p Value of SG Interaction
AGEONSET	0.7505
AGETRT	0.3657
SEX	0.3693
REGION	0.8378
DISDUR	0.3606

$Hypoventilation
	p Value of SG Interaction
AGEONSET	0.6827
AGETRT	0.8162
SEX	0.9762
REGION	0.5769

```
DISDUR                      0.8695

$Hypoxia
         p Value of SG Interaction
AGEONSET                    0.9368
AGETRT                      0.0460
SEX                         0.2378
REGION                      0.9418
DISDUR                      0.0397

$`Hypoxic-ischaemic encephalopathy`
         p Value of SG Interaction
AGEONSET                    0.8073
AGETRT                      0.5594
SEX                         0.2839
REGION                      0.6233
DISDUR                      0.2506

$`Impaired gastric emptying`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Impetigo
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Incision site erythema`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Increased bronchial secretion`
         p Value of SG Interaction
AGEONSET                    0.7934
AGETRT                      0.0609
SEX                         0.1026
REGION                      0.3373
DISDUR                      0.1226

$`Increased upper airway secretion`
         p Value of SG Interaction
AGEONSET                    0.7906
AGETRT                      0.5712
```

```
SEX                         0.3758
REGION                      0.7010
DISDUR                      0.6274

$`Infantile colic`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Infantile spitting up`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Inflammatory marker increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Influenza
         p Value of SG Interaction
AGEONSET                    0.5730
AGETRT                      0.2462
SEX                         0.6219
REGION                      0.9112
DISDUR                      0.6778

$`Influenza A virus test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Infusion site bruising`
         p Value of SG Interaction
AGEONSET                    0.0167
AGETRT                      0.2551
SEX                         0.1883
REGION                      0.4743
DISDUR                      0.5385

$`Infusion site extravasation`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Injection site haematoma`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Intertrigo
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Iron deficiency`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Irritability
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Irritability postvaccinal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Joint contracture`
         p Value of SG Interaction
AGEONSET                    0.7408
AGETRT                      0.2148
SEX                         0.0454
REGION                      0.3067
DISDUR                      0.1463
```

```
$`Joint range of motion decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Joint stiffness`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Keratosis pilaris`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Kyphoscoliosis
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$Kyphosis
         p Value of SG Interaction
AGEONSET                    0.8054
AGETRT                      0.5611
SEX                         0.2941
REGION                      0.6329
DISDUR                      0.2849

$Laceration
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Lacrimation increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$`Language disorder`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Left ventricular hypertrophy`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Leukocytosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Liver function test abnormal`
         p Value of SG Interaction
AGEONSET                    0.7906
AGETRT                      0.5712
SEX                         0.3758
REGION                      0.7010
DISDUR                      0.6274

$`Localised infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Lower respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.5139
AGETRT                      0.0565
SEX                         0.7265
REGION                      0.6370
DISDUR                      0.0855

$`Lower respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                    0.6874
AGETRT                      0.8188
```

```
SEX                         0.9383
REGION                      0.9539
DISDUR                      0.9905

$`Lung disorder`
         p Value of SG Interaction
AGEONSET                    0.7771
AGETRT                      0.4064
SEX                         0.5499
REGION                      0.8109
DISDUR                      0.7236

$`Lung infection`
         p Value of SG Interaction
AGEONSET                    0.7786
AGETRT                      0.5767
SEX                         0.5264
REGION                      0.5016
DISDUR                      0.9630

$`Lymph node palpable`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Malaise
         p Value of SG Interaction
AGEONSET                    0.7711
AGETRT                      0.5792
SEX                         0.4885
REGION                      0.6303
DISDUR                      0.8258

$`Mechanical ventilation`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Medical device complication`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Medical observation`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Miliaria
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Mood swings`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Moraxella infection`
         p Value of SG Interaction
AGEONSET                     0.7511
AGETRT                       0.3660
SEX                          0.3722
REGION                       0.8362
DISDUR                       0.3710

$`Moraxella test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Muscle contractions involuntary`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Muscle tightness`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Muscular weakness`
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.2599
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$Myopia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Naevus anaemicus`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Nasal congestion`
         p Value of SG Interaction
AGEONSET                    0.0171
AGETRT                      0.2504
SEX                         0.1653
REGION                      0.4991
DISDUR                      0.2805

$`Nasal inflammation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Nasopharyngitis
         p Value of SG Interaction
AGEONSET                    0.7457
AGETRT                      0.0919
SEX                         0.5370
REGION                      0.9278
DISDUR                      0.4225

$`Neutrophil count increased`
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
```

```
DISDUR                      0.3923

$Nodule
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Nosocomial infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Nystagmus
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Obstructive airways disorder`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$Oedema
         p Value of SG Interaction
AGEONSET                    0.2447
AGETRT                      0.6652
SEX                         0.9533
REGION                      0.0000
DISDUR                      0.0361

$`Oedema peripheral`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Oral candidiasis`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
```

```
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Oral fungal infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Oral herpes`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Oropharyngeal pain`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Orthopaedic examination`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Otitis media`
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Otitis media acute`
         p Value of SG Interaction
AGEONSET                    0.7552
AGETRT                      0.5820
SEX                         0.5822
REGION                      0.8249
DISDUR                      0.4484

$`Ovarian cyst`
         p Value of SG Interaction
```

```
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Oxygen saturation decreased`
         p Value of SG Interaction
AGEONSET                    0.5377
AGETRT                      0.1722
SEX                         0.4037
REGION                      0.6456
DISDUR                      0.6789

$Pain
         p Value of SG Interaction
AGEONSET                    0.0069
AGETRT                      0.3739
SEX                         0.4568
REGION                      0.7565
DISDUR                      0.9763

$`Pain in extremity`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Pallor
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Parainfluenzae virus infection`
         p Value of SG Interaction
AGEONSET                    0.4937
AGETRT                      0.0782
SEX                         0.1311
REGION                      0.5254
DISDUR                      0.1120

$`Pectus carinatum`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN
```

```
$`Penis disorder`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Pharyngitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pharyngitis streptococcal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Phimosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pleural effusion`
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606

$Pneumonia
         p Value of SG Interaction
AGEONSET                    0.6265
AGETRT                      0.7106
SEX                         0.2245
REGION                      0.5178
DISDUR                      0.8880

$`Pneumonia aspiration`
         p Value of SG Interaction
AGEONSET                    0.3174
AGETRT                      0.5392
SEX                         0.4685
REGION                      0.9679
```

```
DISDUR                      0.6755

$`Pneumonia bacterial`
         p Value of SG Interaction
AGEONSET                    0.6386
AGETRT                      0.3772
SEX                         0.1554
REGION                      0.8423
DISDUR                      0.4052

$`Pneumonia influenzal`
         p Value of SG Interaction
AGEONSET                    0.7700
AGETRT                      0.5795
SEX                         0.4737
REGION                      0.7794
DISDUR                      0.7962

$`Pneumonia moraxella`
         p Value of SG Interaction
AGEONSET                    0.7552
AGETRT                      0.5820
SEX                         0.5822
REGION                      0.8249
DISDUR                      0.4484

$`Pneumonia parainfluenzae viral`
         p Value of SG Interaction
AGEONSET                    0.0606
AGETRT                      0.8725
SEX                         0.7467
REGION                      0.3474
DISDUR                      0.1429

$`Pneumonia pneumococcal`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$`Pneumonia pseudomonal`
         p Value of SG Interaction
AGEONSET                    0.0161
AGETRT                      0.2599
SEX                         0.2189
REGION                      0.2525
DISDUR                      0.9596

$`Pneumonia respiratory syncytial viral`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
```

```
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$`Pneumonia viral`
         p Value of SG Interaction
AGEONSET                    0.7464
AGETRT                      0.9262
SEX                         0.3958
REGION                      0.9596
DISDUR                      0.5854

$Pneumothorax
         p Value of SG Interaction
AGEONSET                    0.7834
AGETRT                      0.5748
SEX                         0.5571
REGION                      0.7305
DISDUR                      0.8276

$`Positional plagiocephaly`
         p Value of SG Interaction
AGEONSET                    0.5363
AGETRT                      0.2671
SEX                         0.3259
REGION                      0.3472
DISDUR                      0.0953

$`Post procedural contusion`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Post procedural haemorrhage`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Post procedural swelling`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Presyncope
         p Value of SG Interaction
```

```
AGEONSET                    0.5084
AGETRT                      0.0765
SEX                         0.0993
REGION                      0.4743
DISDUR                      0.5385

$`Procedural complication`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Procedural pain`
         p Value of SG Interaction
AGEONSET                    0.0068
AGETRT                      0.3743
SEX                         0.5298
REGION                      0.7467
DISDUR                      0.9478

$`Procedural site reaction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Pseudomonas infection`
         p Value of SG Interaction
AGEONSET                    0.0650
AGETRT                      0.2307
SEX                         0.1276
REGION                      0.2176
DISDUR                      0.8932

$`Pseudomonas test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Pyelonephritis
         p Value of SG Interaction
AGEONSET                    0.7711
AGETRT                      0.5792
SEX                         0.4885
REGION                      0.6303
DISDUR                      0.8258
```

```
$Pyrexia
         p Value of SG Interaction
AGEONSET                    0.4041
AGETRT                      0.4773
SEX                         0.4453
REGION                      0.0699
DISDUR                      0.7017

$Rash
         p Value of SG Interaction
AGEONSET                    0.7593
AGETRT                      0.3694
SEX                         0.5581
REGION                      0.8132
DISDUR                      0.5336

$`Rash erythematous`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Rash macular`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Rash papular`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory alkalosis`
         p Value of SG Interaction
AGEONSET                    0.7432
AGETRT                      0.5822
SEX                         0.6534
REGION                      0.8561
DISDUR                      0.2496

$`Respiratory arrest`
         p Value of SG Interaction
AGEONSET                    0.5418
AGETRT                      0.3377
SEX                         1.0000
REGION                      0.0235
```

```
DISDUR                      0.4630

$`Respiratory disorder`
          p Value of SG Interaction
AGEONSET                    0.6629
AGETRT                      0.1970
SEX                         0.8779
REGION                      0.3272
DISDUR                      0.3961

$`Respiratory distress`
          p Value of SG Interaction
AGEONSET                    0.7064
AGETRT                      0.3289
SEX                         0.7863
REGION                      0.2254
DISDUR                      0.9007

$`Respiratory failure`
          p Value of SG Interaction
AGEONSET                    0.1183
AGETRT                      0.0710
SEX                         0.7205
REGION                      0.3383
DISDUR                      0.8203

$`Respiratory rate increased`
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory syncytial virus bronchiolitis`
          p Value of SG Interaction
AGEONSET                    0.7301
AGETRT                      0.5518
SEX                         0.9602
REGION                      0.7385
DISDUR                      0.1956

$`Respiratory tract congestion`
          p Value of SG Interaction
AGEONSET                    0.7432
AGETRT                      0.5822
SEX                         0.6534
REGION                      0.8561
DISDUR                      0.2496

$`Respiratory tract infection`
          p Value of SG Interaction
AGEONSET                    0.6389
AGETRT                      0.8038
```

```
SEX                         0.9953
REGION                      0.5456
DISDUR                      0.6900

$`Respiratory tract infection bacterial`
         p Value of SG Interaction
AGEONSET                    0.5374
AGETRT                      0.2672
SEX                         0.3334
REGION                      0.3412
DISDUR                      0.0751

$`Respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                    0.5585
AGETRT                      0.9664
SEX                         0.4902
REGION                      0.7907
DISDUR                      0.2610

$`Respirovirus test positive`
         p Value of SG Interaction
AGEONSET                    0.0171
AGETRT                      0.2504
SEX                         0.1653
REGION                      0.4991
DISDUR                      0.2805

$Restlessness
         p Value of SG Interaction
AGEONSET                    0.5213
AGETRT                      0.0727
SEX                         0.2414
REGION                      0.2700
DISDUR                      0.7364

$Retching
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Rhinitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Rhinitis allergic`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Rhinorrhoea
         p Value of SG Interaction
AGEONSET                    0.7564
AGETRT                      0.3683
SEX                         0.3989
REGION                      0.8216
DISDUR                      0.4720

$`Rhinovirus infection`
         p Value of SG Interaction
AGEONSET                    0.4935
AGETRT                      0.2029
SEX                         0.7966
REGION                      0.5803
DISDUR                      0.2497

$Rhonchi
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Roseola
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Salivary hypersecretion`
         p Value of SG Interaction
AGEONSET                    0.0830
AGETRT                      0.6895
SEX                         0.6091
REGION                      0.2755
DISDUR                      0.3211

$`Scarlet fever`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$Scoliosis
          p Value of SG Interaction
AGEONSET                     0.7931
AGETRT                       0.5697
SEX                          0.6239
REGION                       0.6901
DISDUR                       0.5609

$`Seasonal allergy`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Seizure
          p Value of SG Interaction
AGEONSET                     0.7505
AGETRT                       0.3657
SEX                          0.3693
REGION                       0.8378
DISDUR                       0.3606

$Sepsis
          p Value of SG Interaction
AGEONSET                     0.6762
AGETRT                       0.4259
SEX                          0.3310
REGION                       0.9409
DISDUR                       0.6928

$`Serratia infection`
          p Value of SG Interaction
AGEONSET                     0.5265
AGETRT                       0.2647
SEX                          0.2673
REGION                       0.3975
DISDUR                       0.4464

$Shock
          p Value of SG Interaction
AGEONSET                     0.7505
AGETRT                       0.3657
SEX                          0.3693
REGION                       0.8378
DISDUR                       0.3606

$`Sinus congestion`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
```

```
DISDUR                          NaN

$`Sinus tachycardia`
         p Value of SG Interaction
AGEONSET                    0.7786
AGETRT                      0.5767
SEX                         0.5264
REGION                      0.5016
DISDUR                      0.9630

$Sinusitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Skin candida`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Skin infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Skin oedema`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Sleep apnoea syndrome`
         p Value of SG Interaction
AGEONSET                    0.2328
AGETRT                      0.1590
SEX                         0.0025
REGION                      0.0866
DISDUR                      0.2039

$`Sleep disorder`
         p Value of SG Interaction
AGEONSET                    0.0164
AGETRT                      0.2579
```

```
SEX                         0.2052
REGION                      0.2415
DISDUR                      0.7664

$Somnolence
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Sputum culture positive`
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.2599
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$`Sputum discoloured`
         p Value of SG Interaction
AGEONSET                    0.7541
AGETRT                      0.3673
SEX                         0.5891
REGION                      0.8282
DISDUR                      0.4255

$`Staphylococcal infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Staphylococcal sepsis`
         p Value of SG Interaction
AGEONSET                    0.7627
AGETRT                      0.3706
SEX                         0.4325
REGION                      0.8028
DISDUR                      0.6122

$`Staphylococcal skin infection`
         p Value of SG Interaction
AGEONSET                    0.7706
AGETRT                      0.5793
SEX                         0.4917
REGION                      0.6280
DISDUR                      0.8109

$`Staphylococcus test positive`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Stoma complication`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Stoma site abscess`
         p Value of SG Interaction
AGEONSET                    0.7523
AGETRT                      0.3665
SEX                         0.3780
REGION                      0.8330
DISDUR                      0.3923

$`Stoma site erythema`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Stoma site haemorrhage`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Stoma site infection`
         p Value of SG Interaction
AGEONSET                    0.5162
AGETRT                      0.2599
SEX                         0.0830
REGION                      0.4431
DISDUR                      0.9596

$`Stoma site inflammation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Stoma site irritation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Stomatitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Strabismus
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Supraventricular tachycardia`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Surgical failure`
         p Value of SG Interaction
AGEONSET                    0.7926
AGETRT                      0.5700
SEX                         0.6203
REGION                      0.6923
DISDUR                      0.5739

$Swelling
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Systemic infection`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
```

```
DISDUR                      0.0496

$Tachycardia
         p Value of SG Interaction
AGEONSET                    0.2767
AGETRT                      0.2809
SEX                         0.5782
REGION                      0.8088
DISDUR                      0.0491

$Tachypnoea
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Teething
         p Value of SG Interaction
AGEONSET                    0.7064
AGETRT                      0.6844
SEX                         0.0595
REGION                      0.3211
DISDUR                      0.1636

$Thrombocytosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Thrombosis
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.3616
REGION                      0.7201
DISDUR                      0.5609

$`Tongue atrophy`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Tracheal haemorrhage`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
```

```
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Tracheal injury`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Tracheal obstruction`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$Tracheitis
         p Value of SG Interaction
AGEONSET                    0.5265
AGETRT                      0.2647
SEX                         0.2673
REGION                      0.3975
DISDUR                      0.4464

$`Transaminases increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Upper gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Upper respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                    0.0171
AGETRT                      0.2504
SEX                         0.1653
REGION                      0.4991
DISDUR                      0.2805

$`Upper respiratory tract infection`
         p Value of SG Interaction
```

```
AGEONSET                   0.3634
AGETRT                     0.5524
SEX                        0.7255
REGION                     0.2307
DISDUR                     0.2587

$`Upper respiratory tract inflammation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Urinary retention`
         p Value of SG Interaction
AGEONSET                   0.7432
AGETRT                     0.5822
SEX                        0.6534
REGION                     0.8561
DISDUR                     0.2496

$`Urinary tract infection`
         p Value of SG Interaction
AGEONSET                   0.5541
AGETRT                     0.7369
SEX                        0.1491
REGION                     0.5115
DISDUR                     0.7174

$`Urine output decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Urticaria
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Use of accessory respiratory muscles`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Vaccination complication`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vaccination site reaction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Vasculitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Ventricular tachycardia`
         p Value of SG Interaction
AGEONSET                     0.7727
AGETRT                       0.5787
SEX                          0.4899
REGION                       0.5008
DISDUR                       0.8705

$`Vessel puncture site bruise`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vessel puncture site reaction`
         p Value of SG Interaction
AGEONSET                     0.4878
AGETRT                       0.0783
SEX                          0.1271
REGION                       0.1719
DISDUR                       0.0496

$`Viral infection`
         p Value of SG Interaction
AGEONSET                     0.6966
AGETRT                       0.5292
SEX                          0.4437
REGION                       0.4653
```

```
DISDUR                      0.2717

$`Viral rash`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Viral rhinitis`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Viral upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.1652
AGETRT                      0.8719
SEX                         0.3292
REGION                      0.7542
DISDUR                      0.8477

$`Vitamin A decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vitamin D decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vitamin D deficiency`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Vomiting
         p Value of SG Interaction
AGEONSET                    0.8403
AGETRT                      0.8602
```

```
SEX                         0.6522
REGION                      0.6993
DISDUR                      0.8443

$`Weight decreased`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457

$`Weight gain poor`
         p Value of SG Interaction
AGEONSET                    0.9329
AGETRT                      0.9810
SEX                         0.6645
REGION                      0.5715
DISDUR                      0.9365

$Wheezing
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN


\################################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines moderaten oder schweren UEs nach PT, das bei
mindestens 10% der Patienten in einem Studienarm oder bei mindestens 10
Patienten und 1% der Patienten in einem Studienarm auftrat"

$`Abdominal discomfort`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Abdominal distension`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Abdominal pain upper`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Acquired phimosis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Acute respiratory distress syndrome`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.0367
SEX                        1.0000
REGION                     0.2673
DISDUR                     0.2772

$`Acute respiratory failure`
         p Value of SG Interaction
AGEONSET                   0.6827
AGETRT                     0.6516
SEX                        0.9822
REGION                     0.1278
DISDUR                     0.0818

$`Adenovirus infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Agitation
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.9999
REGION                     0.9992
DISDUR                     1.0000

$`Agitation postoperative`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Alanine aminotransferase increased`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Amblyopia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Anaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Anxiety
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Aphthous ulcer`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Apnoea
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.6120
SEX                         0.2389
REGION                      0.9698
DISDUR                      0.9045

$`Apparent life threatening event`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Application site rash`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Arthropod bite`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Aspartate aminotransferase increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Aspiration
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.2406
SEX                         0.0660
REGION                      1.0000
DISDUR                      0.3090

$Atelectasis
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.8711
SEX                         0.1174
REGION                      0.2771
DISDUR                      0.7530

$`Back pain`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Bacteraemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Bacterial disease carrier`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Bacterial infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Bacterial tracheitis`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.5029
SEX                        0.3889
REGION                     1.0000
DISDUR                     0.1229

$Balanoposthitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Blood chloride decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Blood iron decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Blood potassium decreased`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Blood sodium decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Body temperature decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Body temperature increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Bone marrow disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Bradycardia
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.3504
SEX                        0.3012
REGION                     1.0000
DISDUR                     0.2156

$`Brain injury`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Breath holding`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bronchial obstruction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bronchial secretion retention`
         p Value of SG Interaction
AGEONSET                    0.6484
AGETRT                      0.1805
SEX                         0.1553
REGION                      0.9451
DISDUR                      0.2908

$Bronchiolitis
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.9675
SEX                         0.7704
REGION                      0.6141
DISDUR                      0.4617

$Bronchitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bronchitis viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`C-reactive protein increased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1299
SEX                         0.3912
REGION                      1.0000
DISDUR                      0.7715
```

```
$`Candida infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Candida nappy rash`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Candida sepsis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Cardiac arrest`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.6055
SEX                         0.2221
REGION                      0.4166
DISDUR                      0.7186

$`Cardio-respiratory arrest`
         p Value of SG Interaction
AGEONSET                    0.5945
AGETRT                      0.1328
SEX                         0.3151
REGION                      0.7359
DISDUR                      0.3326

$Catarrh
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Catheter site inflammation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Cellulitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Chalazion
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Choking
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Chronic respiratory failure`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Clonus
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Congenital diaphragmatic hernia`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Conjunctivitis
         p Value of SG Interaction
AGEONSET                   1.0000
```

```
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Conjunctivitis bacterial`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Constipation
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.2153
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.1054

$Contusion
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Corona virus infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Cough
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.2683
SEX                         0.3106
REGION                      0.7675
DISDUR                      0.1195

$Crying
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Cryptorchism
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Cyanosis
         p Value of SG Interaction
AGEONSET                    0.0121
AGETRT                      0.0165
SEX                         0.0418
REGION                      1.0000
DISDUR                      0.8111

$Death
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.1229
REGION                      0.3078
DISDUR                      0.2795

$`Decubitus ulcer`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Deformity thorax`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Dehydration
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Delayed fontanelle closure`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Delayed recovery from anaesthesia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Dermatitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dermatitis allergic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dermatitis atopic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dermatitis contact`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dermatitis diaper`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.5574
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.2260

$`Developmental hip dysplasia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Device malfunction`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Device occlusion`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Diarrhoea
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.0108
SEX                        0.3173
REGION                     1.0000
DISDUR                     0.0723

$`Diarrhoea haemorrhagic`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Discomfort
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Drooling
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Drug hypersensitivity`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Drug intolerance`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Dry eye`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Dry skin`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Dysphagia
         p Value of SG Interaction
AGEONSET                   0.5908
AGETRT                     0.2842
SEX                        0.6682
REGION                     0.2102
DISDUR                     0.8662

$Dyspnoea
         p Value of SG Interaction
AGEONSET                   0.9999
AGETRT                     0.1356
SEX                        0.1055
REGION                     0.2961
DISDUR                     0.5204

$`Ear disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Ear haemorrhage`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ear infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ear pain`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Ecchymosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Eczema
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Eczema infected`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Electrocardiogram ST-T segment abnormal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Endotracheal intubation complication`
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   1.0000
SEX   1.0000
REGION   1.0000
DISDUR   0.9999

$Enteritis
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Enterobiasis
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Enterococcal infection`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Epigastric discomfort`
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   1.0000
SEX   0.9999
REGION   1.0000
DISDUR   1.0000

$Erythema
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Escherichia infection`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1

```
REGION                          1
DISDUR                          1

$Excoriation
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Exposure to communicable disease`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Eye infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Eye movement disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Failure to thrive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Fatigue
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Feeding disorder of infancy or early childhood`
         p Value of SG Interaction
AGEONSET                   1.0000
```

```
AGETRT                      0.9999
SEX                         0.9261
REGION                      0.3857
DISDUR                      0.6064

$`Feeding intolerance`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Feeding tube complication`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Femur fracture`
         p Value of SG Interaction
AGEONSET                    0.2108
AGETRT                      1.0000
SEX                         0.3367
REGION                      1.0000
DISDUR                      0.1824

$Flatulence
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Food allergy`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Food intolerance`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Fungal infection`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Fungal skin infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastric haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Gastritis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Gastroenteritis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastroenteritis rotavirus`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastroenteritis viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   1.0000
SEX   0.9999
REGION   0.9993
DISDUR   1.0000

$`Gastrointestinal motility disorder`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Gastrointestinal tract irritation`
         p Value of SG Interaction
AGEONSET   1.0000
AGETRT   1.0000
SEX   0.9999
REGION   0.9993
DISDUR   1.0000

$`Gastrooesophageal reflux disease`
         p Value of SG Interaction
AGEONSET   0.5814
AGETRT   0.4148
SEX   1.0000
REGION   0.4443
DISDUR   0.6393

$`General physical health deterioration`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Glycosuria
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Granuloma annulare`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1

```
REGION                          1
DISDUR                          1

$Haematochezia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Hand-foot-and-mouth disease`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Head injury`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Head lag abnormal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Heart rate decreased`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.9999
REGION                     1.0000
DISDUR                     1.0000

$`Heart rate increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Heart rate irregular`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hepatomegaly
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hordeolum
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Human rhinovirus test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hydronephrosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hyperaemia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypercapnia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hyperglycaemia
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hyperhidrosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hyperkeratosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypersensitivity
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypertension
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypoglycaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypokalaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Hypophagia
          p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Hypopnoea
          p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Hypothermia
          p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Hypoventilation
          p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$Hypoxia
          p Value of SG Interaction
AGEONSET                     1.0000
AGETRT                       0.0203
SEX                          0.1208
REGION                       1.0000
DISDUR                       0.0565

$`Hypoxic-ischaemic encephalopathy`
          p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Impaired gastric emptying`
          p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
```

```
REGION                          1
DISDUR                          1

$Impetigo
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Incision site erythema`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Increased bronchial secretion`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.0443
SEX                        0.0849
REGION                     0.2638
DISDUR                     0.1745

$`Increased upper airway secretion`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Infantile colic`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Infantile spitting up`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Inflammatory marker increased`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Influenza
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      1.0000

$`Influenza A virus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Infusion site bruising`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Infusion site extravasation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Injection site haematoma`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Intertrigo
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Iron deficiency`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Irritability
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Irritability postvaccinal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Joint contracture`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0472
SEX                         0.0451
REGION                      1.0000
DISDUR                      0.2416

$`Joint range of motion decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Joint stiffness`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Keratosis pilaris`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$Kyphoscoliosis
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$Kyphosis
	p Value of SG Interaction
AGEONSET	1.0000
AGETRT	1.0000
SEX	0.9999
REGION	1.0000
DISDUR	1.0000

$Laceration
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Lacrimation increased`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Language disorder`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Left ventricular hypertrophy`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$Leukocytosis
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1

```
REGION                          1
DISDUR                          1

$`Liver function test abnormal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Localised infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Lower respiratory tract infection`
         p Value of SG Interaction
AGEONSET                   0.9999
AGETRT                     1.0000
SEX                        1.0000
REGION                     1.0000
DISDUR                     1.0000

$`Lower respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Lung disorder`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        1.0000
REGION                     1.0000
DISDUR                     0.4776

$`Lung infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Lymph node palpable`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Malaise
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Mechanical ventilation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Medical device complication`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Medical observation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Miliaria
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Mood swings`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Moraxella infection`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Moraxella test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Muscle contractions involuntary`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Muscle tightness`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Muscular weakness`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Myopia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Naevus anaemicus`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Nasal congestion`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Nasal inflammation`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$Nasopharyngitis
	p Value of SG Interaction
AGEONSET	0.3260
AGETRT	0.0565
SEX	0.6110
REGION	0.7995
DISDUR	0.7529

$`Neutrophil count increased`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$Nodule
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Nosocomial infection`
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$Nystagmus
	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1

```
REGION                          1
DISDUR                          1

$`Obstructive airways disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Oedema
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        1.0000
REGION                     0.9999
DISDUR                     1.0000

$`Oedema peripheral`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oral candidiasis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oral fungal infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oral herpes`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oropharyngeal pain`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Orthopaedic examination`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Otitis media`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Otitis media acute`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Ovarian cyst`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Oxygen saturation decreased`
         p Value of SG Interaction
AGEONSET                   0.9999
AGETRT                     0.1311
SEX                        0.5282
REGION                     0.8009
DISDUR                     0.7071

$Pain
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pain in extremity`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Pallor
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Parainfluenzae virus infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pectus carinatum`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Penis disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Pharyngitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pharyngitis streptococcal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Phimosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pleural effusion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Pneumonia
         p Value of SG Interaction
AGEONSET                    0.9545
AGETRT                      0.5078
SEX                         0.3110
REGION                      0.5123
DISDUR                      0.9327

$`Pneumonia aspiration`
         p Value of SG Interaction
AGEONSET                    0.3142
AGETRT                      0.8059
SEX                         0.3283
REGION                      0.9890
DISDUR                      0.7830

$`Pneumonia bacterial`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.4824
SEX                         0.2036
REGION                      1.0000
DISDUR                      0.6190

$`Pneumonia influenzal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia moraxella`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Pneumonia parainfluenzae viral`
         p Value of SG Interaction
AGEONSET                    0.1966
AGETRT                      1.0000
SEX                         1.0000
REGION                      0.4519
DISDUR                      0.1269

$`Pneumonia pneumococcal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia pseudomonal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia respiratory syncytial viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia viral`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.3764
SEX                         0.3961
REGION                      0.7872
DISDUR                      0.6260

$Pneumothorax
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Positional plagiocephaly`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Post procedural contusion`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Post procedural haemorrhage`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Post procedural swelling`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Presyncope
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Procedural complication`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Procedural pain`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Procedural site reaction`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pseudomonas infection`
         p Value of SG Interaction
AGEONSET                    0.2522
AGETRT                      0.2140
SEX                         0.0840
REGION                      0.2060
DISDUR                      0.7264

$`Pseudomonas test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Pyelonephritis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Pyrexia
         p Value of SG Interaction
AGEONSET                    0.7991
AGETRT                      0.5752
SEX                         0.3456
REGION                      0.0382
DISDUR                      0.5933

$Rash
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Rash erythematous`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Rash macular`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Rash papular`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory alkalosis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory arrest`
         p Value of SG Interaction
AGEONSET                    0.4864
AGETRT                      0.1859
SEX                         0.9417
REGION                      0.0207
DISDUR                      0.5421

$`Respiratory disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory distress`
         p Value of SG Interaction
AGEONSET                    0.9525
AGETRT                      0.5621
SEX                         0.6660
REGION                      0.1851
DISDUR                      0.9457

$`Respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.0788
AGETRT                      0.0350
SEX                         0.5843
```

```
REGION                     0.1045
DISDUR                     0.9634

$`Respiratory rate increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory syncytial virus bronchiolitis`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.5758
SEX                         0.8373
REGION                      0.5511
DISDUR                      0.2918

$`Respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.1973
SEX                         0.4450
REGION                      0.8301
DISDUR                      0.3032

$`Respiratory tract infection bacterial`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.5024
SEX                         0.2664
REGION                      0.5654
DISDUR                      0.2654

$`Respirovirus test positive`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Restlessness
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.9999
SEX                         1.0000
REGION                      1.0000
DISDUR                      1.0000

$Retching
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Rhinitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Rhinitis allergic`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Rhinorrhoea
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Rhinovirus infection`
         p Value of SG Interaction
AGEONSET                    0.1543
AGETRT                      0.1903
SEX                         0.8483
REGION                      0.2563
DISDUR                      0.3968

$Rhonchi
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Roseola
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Salivary hypersecretion`
         p Value of SG Interaction
AGEONSET                    0.1425
AGETRT                      1.0000
SEX                         0.4332
REGION                      0.1503
DISDUR                      0.3424

$`Scarlet fever`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Scoliosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Seasonal allergy`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Seizure
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Sepsis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Serratia infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Shock
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Sinus congestion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Sinus tachycardia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Sinusitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Skin candida`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Skin infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Skin oedema`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sleep apnoea syndrome`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sleep disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Somnolence
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sputum culture positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sputum discoloured`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Staphylococcal infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Staphylococcal sepsis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Staphylococcal skin infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Staphylococcus test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Stoma complication`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Stoma site abscess`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Stoma site erythema`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site inflammation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site irritation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Stomatitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Strabismus
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

$`Supraventricular tachycardia`

	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Surgical failure`

	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$Swelling

	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$`Systemic infection`

	p Value of SG Interaction
AGEONSET	1.0000
AGETRT	1.0000
SEX	0.9999
REGION	1.0000
DISDUR	1.0000

$Tachycardia

	p Value of SG Interaction
AGEONSET	0.2196
AGETRT	0.1126
SEX	0.2630
REGION	0.5936
DISDUR	0.0069

$Tachypnoea

	p Value of SG Interaction
AGEONSET	1
AGETRT	1
SEX	1
REGION	1
DISDUR	1

$Teething

	p Value of SG Interaction
AGEONSET	1.0000
AGETRT	0.4062
SEX	0.0368

```
REGION                      0.9110
DISDUR                      0.4152

$Thrombocytosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Thrombosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Tongue atrophy`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Tracheal haemorrhage`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Tracheal injury`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Tracheal obstruction`
         p Value of SG Interaction
AGEONSET                    0.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$Tracheitis
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Transaminases increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Upper gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Upper respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                   0.3331
AGETRT                     0.4042
SEX                        0.7819
REGION                     0.1974
DISDUR                     0.2526

$`Upper respiratory tract inflammation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Urinary retention`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Urinary tract infection`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Urine output decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Urticaria
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Use of accessory respiratory muscles`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vaccination complication`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vaccination site reaction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Vasculitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Ventricular tachycardia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vessel puncture site bruise`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vessel puncture site reaction`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9998
REGION                      0.9992
DISDUR                      1.0000

$`Viral infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.3929
SEX                         0.2286
REGION                      0.3831
DISDUR                      0.3031

$`Viral rash`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Viral rhinitis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Viral upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.0589
AGETRT                      0.8827
SEX                         0.2596
```

```
REGION                     1.0000
DISDUR                     0.8655

$`Vitamin A decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vitamin D decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vitamin D deficiency`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Vomiting
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.8103
SEX                         0.7431
REGION                      0.5752
DISDUR                      0.8181

$`Weight decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Weight gain poor`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      0.4740
DISDUR                      0.9612

$Wheezing
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1


\#############################################################################
[[1]]
[1] "Patienten mit mindestens einem SUE nach SOC, das bei mindestens 5% der
Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Blood and lymphatic system disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Cardiac disorders`
         p Value of SG Interaction
AGEONSET                    0.7494
AGETRT                      0.4205
SEX                         0.2510
REGION                      0.2907
DISDUR                      0.5626

$`Congenital, familial and genetic disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Ear and labyrinth disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Eye disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Gastrointestinal disorders`
         p Value of SG Interaction
```

```
AGEONSET                    0.6179
AGETRT                      0.0855
SEX                         0.2769
REGION                      0.4982
DISDUR                      0.0618

$`General disorders and administration site conditions`
         p Value of SG Interaction
AGEONSET                    0.6385
AGETRT                      0.8035
SEX                         0.9546
REGION                      0.3226
DISDUR                      0.6458

$`Hepatobiliary disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Immune system disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Infections and infestations`
         p Value of SG Interaction
AGEONSET                    0.1814
AGETRT                      0.7853
SEX                         0.4000
REGION                      0.5049
DISDUR                      0.1763

$`Injury, poisoning and procedural complications`
         p Value of SG Interaction
AGEONSET                    0.4402
AGETRT                      0.7643
SEX                         0.1911
REGION                      0.9373
DISDUR                      0.6618

$Investigations
         p Value of SG Interaction
AGEONSET                    0.4569
AGETRT                      0.7841
SEX                         0.7497
REGION                      0.4081
DISDUR                      0.1779
```

```
$`Metabolism and nutrition disorders`
         p Value of SG Interaction
AGEONSET                    0.7608
AGETRT                      0.4029
SEX                         0.6402
REGION                      0.8456
DISDUR                      0.8428

$`Musculoskeletal and connective tissue disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Nervous system disorders`
         p Value of SG Interaction
AGEONSET                    0.6914
AGETRT                      0.8210
SEX                         0.9064
REGION                      0.5406
DISDUR                      0.8722

$`Psychiatric disorders`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Renal and urinary disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Reproductive system and breast disorders`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory, thoracic and mediastinal disorders`
         p Value of SG Interaction
AGEONSET                    0.6737
AGETRT                      0.1625
SEX                         0.6512
REGION                      0.6230
```

```
DISDUR                      0.3597

$`Skin and subcutaneous tissue disorders`
         p Value of SG Interaction
AGEONSET                    0.7438
AGETRT                      0.3623
SEX                         0.6497
REGION                      0.8546
DISDUR                      0.2579

$`Surgical and medical procedures`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vascular disorders`
         p Value of SG Interaction
AGEONSET                    0.6808
AGETRT                      0.8151
SEX                         0.9907
REGION                      0.9468
DISDUR                      0.8165


\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines SUEs nach SOC, das bei mindestens 5% der
Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Blood and lymphatic system disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Cardiac disorders`
         p Value of SG Interaction
AGEONSET                    0.7076
AGETRT                      0.2992
SEX                         0.3664
REGION                      0.4305
DISDUR                      0.5991

$`Congenital, familial and genetic disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Ear and labyrinth disorders`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Eye disorders`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastrointestinal disorders`
         p Value of SG Interaction
AGEONSET                   0.9999
AGETRT                     0.1599
SEX                        0.3565
REGION                     0.5227
DISDUR                     0.1123

$`General disorders and administration site conditions`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.2324
SEX                        0.3345
REGION                     0.3691
DISDUR                     0.2521

$`Hepatobiliary disorders`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Immune system disorders`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Infections and infestations`
         p Value of SG Interaction
AGEONSET                   0.6947
```

```
AGETRT                      0.7675
SEX                         0.8236
REGION                      0.2947
DISDUR                      0.1935

$`Injury, poisoning and procedural complications`
         p Value of SG Interaction
AGEONSET                    0.5260
AGETRT                      0.8932
SEX                         0.2167
REGION                      0.4867
DISDUR                      0.8106

$Investigations
         p Value of SG Interaction
AGEONSET                    0.4917
AGETRT                      0.4254
SEX                         0.9484
REGION                      0.1787
DISDUR                      0.4711

$`Metabolism and nutrition disorders`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.7234
SEX                         0.6407
REGION                      0.7922
DISDUR                      0.9531

$`Musculoskeletal and connective tissue disorders`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Nervous system disorders`
         p Value of SG Interaction
AGEONSET                          1
AGETRT                            1
SEX                               1
REGION                            1
DISDUR                            1

$`Psychiatric disorders`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      0.9992
DISDUR                      1.0000

$`Renal and urinary disorders`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Reproductive system and breast disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory, thoracic and mediastinal disorders`
         p Value of SG Interaction
AGEONSET                    0.3994
AGETRT                      0.0519
SEX                         0.5773
REGION                      0.3209
DISDUR                      0.3332

$`Skin and subcutaneous tissue disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Surgical and medical procedures`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vascular disorders`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1


\################################################################################
[[1]]
[1] "Patienten mit mindestens einem SUE nach PT, das bei mindestens 5% der
Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"
```

$`Abdominal discomfort`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$`Abdominal distension`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$`Abdominal pain upper`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$`Acquired phimosis`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$`Acute respiratory distress syndrome`
         p Value of SG Interaction
AGEONSET   0.8084
AGETRT   0.0591
SEX   0.7605
REGION   0.2851
DISDUR   0.2869

$`Acute respiratory failure`
         p Value of SG Interaction
AGEONSET   0.9213
AGETRT   0.6587
SEX   0.6885
REGION   0.8047
DISDUR   0.3597

$`Adenovirus infection`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN

```
DISDUR                          NaN

$Agitation
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Agitation postoperative`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Alanine aminotransferase increased`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Amblyopia
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Anaemia
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Anxiety
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Aphthous ulcer`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Apnoea
         p Value of SG Interaction
AGEONSET                    0.6753
AGETRT                      0.2313
SEX                         0.3867
REGION                      0.8758
DISDUR                      0.5334

$`Apparent life threatening event`
         p Value of SG Interaction
AGEONSET                    0.3675
AGETRT                      0.1079
SEX                         0.5339
REGION                      0.1215
DISDUR                      0.0712

$`Application site rash`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Arthropod bite`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Aspartate aminotransferase increased`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Aspiration
         p Value of SG Interaction
AGEONSET                    0.9420
AGETRT                      0.9861
SEX                         0.3660
REGION                      0.7964
DISDUR                      0.6894

$Atelectasis
         p Value of SG Interaction
```

```
AGEONSET                   0.7239
AGETRT                     0.8364
SEX                        0.6867
REGION                     0.9089
DISDUR                     0.9690

$`Back pain`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Bacteraemia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bacterial disease carrier`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bacterial infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Bacterial tracheitis`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Balanoposthitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Blood chloride decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Blood iron decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Blood potassium decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Blood sodium decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Body temperature decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Body temperature increased`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Bone marrow disorder`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$Bradycardia
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Brain injury`
         p Value of SG Interaction
AGEONSET                     0.7505
AGETRT                       0.3657
SEX                          0.3693
REGION                       0.8378
DISDUR                       0.3606

$`Breath holding`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Bronchial obstruction`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Bronchial secretion retention`
         p Value of SG Interaction
AGEONSET                     0.9802
AGETRT                       0.2995
SEX                          0.5049
REGION                       0.7124
DISDUR                       0.6675

$Bronchiolitis
         p Value of SG Interaction
AGEONSET                     0.7852
AGETRT                       0.3902
SEX                          0.6898
REGION                       0.9518
DISDUR                       0.9371

$Bronchitis
         p Value of SG Interaction
AGEONSET                     0.5849
AGETRT                       0.2417
```

```
SEX                         0.2702
REGION                      0.2139
DISDUR                      0.3130

$`Bronchitis viral`
         p Value of SG Interaction
AGEONSET                    0.6479
AGETRT                      0.3097
SEX                         0.3924
REGION                      0.7994
DISDUR                      0.1944

$`C-reactive protein increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Candida infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Candida nappy rash`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Candida sepsis`
         p Value of SG Interaction
AGEONSET                    0.0166
AGETRT                      0.2564
SEX                         0.0951
REGION                      0.2337
DISDUR                      0.6358

$`Cardiac arrest`
         p Value of SG Interaction
AGEONSET                    0.7256
AGETRT                      0.6256
SEX                         0.6877
REGION                      0.3688
DISDUR                      0.6299

$`Cardio-respiratory arrest`
         p Value of SG Interaction
```

```
AGEONSET                    0.6635
AGETRT                      0.2960
SEX                         0.2210
REGION                      0.5338
DISDUR                      0.3438

$Catarrh
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Catheter site inflammation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Cellulitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Chalazion
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Choking
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Chronic respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606
```

```
$Clonus
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Congenital diaphragmatic hernia`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Conjunctivitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Conjunctivitis bacterial`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Constipation
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Contusion
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Corona virus infection`
         p Value of SG Interaction
AGEONSET                     0.4591
AGETRT                       0.0753
SEX                          0.2101
REGION                       0.6192
```

```
DISDUR                      0.0002

$Cough
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Crying
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Cryptorchism
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Cyanosis
         p Value of SG Interaction
AGEONSET                    0.7989
AGETRT                      0.3952
SEX                         0.0920
REGION                      0.9341
DISDUR                      0.5694

$Death
         p Value of SG Interaction
AGEONSET                    0.7771
AGETRT                      0.4064
SEX                         0.1368
REGION                      0.3880
DISDUR                      0.1424

$`Decubitus ulcer`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Deformity thorax`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Dehydration
         p Value of SG Interaction
AGEONSET                    0.8038
AGETRT                      0.3914
SEX                         0.0828
REGION                      0.9227
DISDUR                      0.8058

$`Delayed fontanelle closure`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Delayed recovery from anaesthesia`
         p Value of SG Interaction
AGEONSET                    0.7599
AGETRT                      0.3696
SEX                         0.4171
REGION                      0.5844
DISDUR                      0.5464

$Dermatitis
         p Value of SG Interaction
AGEONSET                    0.7438
AGETRT                      0.3623
SEX                         0.6497
REGION                      0.8546
DISDUR                      0.2579

$`Dermatitis allergic`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Dermatitis atopic`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Dermatitis contact`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Dermatitis diaper`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Developmental hip dysplasia`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Device malfunction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Device occlusion`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Diarrhoea
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Diarrhoea haemorrhagic`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$Discomfort
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Drooling
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Drug hypersensitivity`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Drug intolerance`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Dry eye`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Dry skin`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Dysphagia
         p Value of SG Interaction
AGEONSET                    0.9422
AGETRT                      0.7255
SEX                         0.4643
REGION                      0.1525
```

```
DISDUR                      0.3472

$Dyspnoea
          p Value of SG Interaction
AGEONSET                    0.9649
AGETRT                      0.0174
SEX                         0.3947
REGION                      0.5557
DISDUR                      0.0268

$`Ear disorder`
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Ear haemorrhage`
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Ear infection`
          p Value of SG Interaction
AGEONSET                    0.7558
AGETRT                      0.3681
SEX                         0.3959
REGION                      0.5679
DISDUR                      0.4602

$`Ear pain`
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Ecchymosis
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Eczema
          p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Eczema infected`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Electrocardiogram ST-T segment abnormal`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Endotracheal intubation complication`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Enteritis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Enterobiasis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Enterococcal infection`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Epigastric discomfort`
         p Value of SG Interaction
```

```
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Erythema
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Escherichia infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Excoriation
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Exposure to communicable disease`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Eye infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Eye movement disorder`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN
```

$`Failure to thrive`
	p Value of SG Interaction
AGEONSET	0.7746
AGETRT	0.4072
SEX	0.1425
REGION	0.4113
DISDUR	0.4563

$Fatigue
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN
DISDUR	NaN

$`Feeding disorder of infancy or early childhood`
	p Value of SG Interaction
AGEONSET	0.7005
AGETRT	0.7974
SEX	0.4760
REGION	0.2563
DISDUR	0.8912

$`Feeding intolerance`
	p Value of SG Interaction
AGEONSET	0.6633
AGETRT	0.8048
SEX	0.2470
REGION	0.9206
DISDUR	0.4039

$`Feeding tube complication`
	p Value of SG Interaction
AGEONSET	0.7931
AGETRT	0.5697
SEX	0.3616
REGION	0.7201
DISDUR	0.5609

$`Femur fracture`
	p Value of SG Interaction
AGEONSET	0.0171
AGETRT	0.2504
SEX	0.1653
REGION	0.4991
DISDUR	0.2805

$Flatulence
	p Value of SG Interaction
AGEONSET	NaN
AGETRT	NaN
SEX	NaN
REGION	NaN

```
DISDUR                          NaN

$`Food allergy`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Food intolerance`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Fungal infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Fungal skin infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Gastric haemorrhage`
         p Value of SG Interaction
AGEONSET                     0.7505
AGETRT                       0.3657
SEX                          0.3693
REGION                       0.8378
DISDUR                       0.3606

$Gastritis
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Gastroenteritis
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Gastroenteritis rotavirus`
         p Value of SG Interaction
AGEONSET                    0.7995
AGETRT                      0.5655
SEX                         0.6714
REGION                      0.7461
DISDUR                      0.4046

$`Gastroenteritis viral`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Gastrointestinal motility disorder`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Gastrointestinal tract irritation`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Gastrooesophageal reflux disease`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`General physical health deterioration`
         p Value of SG Interaction
```

```
AGEONSET                    0.7818
AGETRT                      0.5755
SEX                         0.4260
REGION                      0.6742
DISDUR                      0.8724

$Glycosuria
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Granuloma annulare`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Haematochezia
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Hand-foot-and-mouth disease`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Head injury`
         p Value of SG Interaction
AGEONSET                    0.5425
AGETRT                      0.2671
SEX                         0.3721
REGION                      0.3590
DISDUR                      0.0186

$`Head lag abnormal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Heart rate decreased`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$`Heart rate increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Heart rate irregular`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hepatomegaly
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hordeolum
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Human rhinovirus test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Hydronephrosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$Hyperaemia
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hypercapnia
         p Value of SG Interaction
AGEONSET                     0.7844
AGETRT                       0.5743
SEX                          0.5639
REGION                       0.7264
DISDUR                       0.7980

$Hyperglycaemia
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hyperhidrosis
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hyperkeratosis
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hypersensitivity
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Hypertension
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Hypoglycaemia
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Hypokalaemia
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Hypophagia
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Hypopnoea
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Hypothermia
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Hypoventilation
         p Value of SG Interaction
AGEONSET                   0.7926
AGETRT                     0.5700
SEX                        0.6203
REGION                     0.6923
DISDUR                     0.5739

$Hypoxia
         p Value of SG Interaction
```

```
AGEONSET                    0.8013
AGETRT                      0.2666
SEX                         0.3725
REGION                      0.7987
DISDUR                      0.0591

$`Hypoxic-ischaemic encephalopathy`
         p Value of SG Interaction
AGEONSET                    0.8073
AGETRT                      0.5594
SEX                         0.2839
REGION                      0.6233
DISDUR                      0.2506

$`Impaired gastric emptying`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Impetigo
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Incision site erythema`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Increased bronchial secretion`
         p Value of SG Interaction
AGEONSET                    0.7599
AGETRT                      0.3696
SEX                         0.4171
REGION                      0.5844
DISDUR                      0.5464

$`Increased upper airway secretion`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Infantile colic`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Infantile spitting up`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Inflammatory marker increased`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Influenza
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Influenza A virus test positive`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Infusion site bruising`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Infusion site extravasation`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
```

```
DISDUR                          NaN

$`Injection site haematoma`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Intertrigo
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Iron deficiency`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Irritability
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Irritability postvaccinal`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Joint contracture`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Joint range of motion decreased`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Joint stiffness`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Keratosis pilaris`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Kyphoscoliosis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Kyphosis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Laceration
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Lacrimation increased`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Language disorder`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Left ventricular hypertrophy`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Leukocytosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Liver function test abnormal`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Localised infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Lower respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.5139
AGETRT                      0.0565
SEX                         0.7265
REGION                      0.6370
DISDUR                      0.0855

$`Lower respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                    0.7627
AGETRT                      0.3706
SEX                         0.5378
REGION                      0.5960
DISDUR                      0.6122
```

```
$`Lung disorder`
         p Value of SG Interaction
AGEONSET                    0.7771
AGETRT                      0.4064
SEX                         0.5499
REGION                      0.8109
DISDUR                      0.7236

$`Lung infection`
         p Value of SG Interaction
AGEONSET                    0.7786
AGETRT                      0.5767
SEX                         0.5264
REGION                      0.5016
DISDUR                      0.9630

$`Lymph node palpable`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Malaise
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Mechanical ventilation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Medical device complication`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Medical observation`
         p Value of SG Interaction
AGEONSET                    0.6766
AGETRT                      0.4259
SEX                         0.9772
REGION                      0.3766
```

```
DISDUR                      0.7028

$Miliaria
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Mood swings`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Moraxella infection`
         p Value of SG Interaction
AGEONSET                    0.7511
AGETRT                      0.3660
SEX                         0.3722
REGION                      0.8362
DISDUR                      0.3710

$`Moraxella test positive`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Muscle contractions involuntary`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Muscle tightness`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Muscular weakness`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Myopia
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Naevus anaemicus`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Nasal congestion`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Nasal inflammation`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Nasopharyngitis
         p Value of SG Interaction
AGEONSET                   0.7966
AGETRT                     0.5675
SEX                        0.3421
REGION                     0.4948
DISDUR                     0.4735

$`Neutrophil count increased`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Nodule
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Nosocomial infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Nystagmus
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Obstructive airways disorder`
         p Value of SG Interaction
AGEONSET                     0.7337
AGETRT                       0.3563
SEX                          0.7092
REGION                       0.4802
DISDUR                       0.1457

$Oedema
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Oedema peripheral`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Oral candidiasis`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$`Oral fungal infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Oral herpes`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Oropharyngeal pain`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Orthopaedic examination`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Otitis media`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Otitis media acute`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Ovarian cyst`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
```

```
DISDUR                          NaN

$`Oxygen saturation decreased`
         p Value of SG Interaction
AGEONSET                    0.5193
AGETRT                      0.0842
SEX                         0.7392
REGION                      0.9491
DISDUR                      0.3472

$Pain
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Pain in extremity`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Pallor
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Parainfluenzae virus infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Pectus carinatum`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Penis disorder`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Pharyngitis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Pharyngitis streptococcal`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Phimosis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Pleural effusion`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Pneumonia
         p Value of SG Interaction
AGEONSET                    0.6100
AGETRT                      0.4518
SEX                         0.0723
REGION                      0.5641
DISDUR                      0.6125

$`Pneumonia aspiration`
         p Value of SG Interaction
AGEONSET                    0.1493
AGETRT                      0.2089
SEX                         0.5314
REGION                      0.9894
DISDUR                      0.9260

$`Pneumonia bacterial`
         p Value of SG Interaction
```

```
AGEONSET                    0.8418
AGETRT                      0.8593
SEX                         0.3896
REGION                      0.9921
DISDUR                      0.9198

$`Pneumonia influenzal`
         p Value of SG Interaction
AGEONSET                    0.7700
AGETRT                      0.5795
SEX                         0.4737
REGION                      0.7794
DISDUR                      0.7962

$`Pneumonia moraxella`
         p Value of SG Interaction
AGEONSET                    0.7552
AGETRT                      0.5820
SEX                         0.5822
REGION                      0.8249
DISDUR                      0.4484

$`Pneumonia parainfluenzae viral`
         p Value of SG Interaction
AGEONSET                    0.0606
AGETRT                      0.8725
SEX                         0.7467
REGION                      0.3474
DISDUR                      0.1429

$`Pneumonia pneumococcal`
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.6239
REGION                      0.6901
DISDUR                      0.5609

$`Pneumonia pseudomonal`
         p Value of SG Interaction
AGEONSET                    0.0161
AGETRT                      0.2599
SEX                         0.2189
REGION                      0.2525
DISDUR                      0.9596

$`Pneumonia respiratory syncytial viral`
         p Value of SG Interaction
AGEONSET                    0.7337
AGETRT                      0.3563
SEX                         0.7092
REGION                      0.4802
DISDUR                      0.1457
```

```
$`Pneumonia viral`
          p Value of SG Interaction
AGEONSET                     0.8248
AGETRT                       0.6661
SEX                          0.5733
REGION                       0.9483
DISDUR                       0.7992

$Pneumothorax
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Positional plagiocephaly`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Post procedural contusion`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Post procedural haemorrhage`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Post procedural swelling`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Presyncope
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
```

```
DISDUR                          NaN

$`Procedural complication`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Procedural pain`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Procedural site reaction`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Pseudomonas infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Pseudomonas test positive`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Pyelonephritis
         p Value of SG Interaction
AGEONSET                     0.7711
AGETRT                       0.5792
SEX                          0.4885
REGION                       0.6303
DISDUR                       0.8258

$Pyrexia
         p Value of SG Interaction
AGEONSET                     0.5642
AGETRT                       0.7428
```

```
SEX                         0.4057
REGION                      0.5578
DISDUR                      0.9710

$Rash
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Rash erythematous`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Rash macular`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Rash papular`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory alkalosis`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory arrest`
         p Value of SG Interaction
AGEONSET                    0.5418
AGETRT                      0.3377
SEX                         1.0000
REGION                      0.0235
DISDUR                      0.4630

$`Respiratory disorder`
         p Value of SG Interaction
```

```
AGEONSET                    0.6629
AGETRT                      0.1970
SEX                         0.8779
REGION                      0.3272
DISDUR                      0.3961

$`Respiratory distress`
         p Value of SG Interaction
AGEONSET                    0.3909
AGETRT                      0.3080
SEX                         0.2075
REGION                      0.7440
DISDUR                      0.6628

$`Respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.1375
AGETRT                      0.0934
SEX                         0.8356
REGION                      0.3895
DISDUR                      0.8715

$`Respiratory rate increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Respiratory syncytial virus bronchiolitis`
         p Value of SG Interaction
AGEONSET                    0.7301
AGETRT                      0.5518
SEX                         0.9602
REGION                      0.7385
DISDUR                      0.1956

$`Respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                    0.5124
AGETRT                      0.0756
SEX                         0.2033
REGION                      0.2399
DISDUR                      0.7396

$`Respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.4444
AGETRT                      0.5022
SEX                         0.6245
REGION                      0.4278
DISDUR                      0.6525
```

$`Respiratory tract infection bacterial`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$`Respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET   0.7874
AGETRT   0.4020
SEX   0.1335
REGION   0.8450
DISDUR   0.4563

$`Respirovirus test positive`
         p Value of SG Interaction
AGEONSET   0.0171
AGETRT   0.2504
SEX   0.1653
REGION   0.4991
DISDUR   0.2805

$Restlessness
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$Retching
         p Value of SG Interaction
AGEONSET   0.5037
AGETRT   0.0773
SEX   0.1722
REGION   0.4915
DISDUR   0.3495

$Rhinitis
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN
DISDUR   NaN

$`Rhinitis allergic`
         p Value of SG Interaction
AGEONSET   NaN
AGETRT   NaN
SEX   NaN
REGION   NaN

```
DISDUR                          NaN

$Rhinorrhoea
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Rhinovirus infection`
          p Value of SG Interaction
AGEONSET                     0.7843
AGETRT                       0.1639
SEX                          0.1413
REGION                       0.9672
DISDUR                       0.1218

$Rhonchi
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Roseola
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Salivary hypersecretion`
          p Value of SG Interaction
AGEONSET                     0.5366
AGETRT                       0.2672
SEX                          0.0438
REGION                       0.3313
DISDUR                       0.0882

$`Scarlet fever`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$Scoliosis
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Seasonal allergy`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Seizure
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Sepsis
         p Value of SG Interaction
AGEONSET                    0.7931
AGETRT                      0.5697
SEX                         0.3616
REGION                      0.7201
DISDUR                      0.5609

$`Serratia infection`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Shock
         p Value of SG Interaction
AGEONSET                    0.7505
AGETRT                      0.3657
SEX                         0.3693
REGION                      0.8378
DISDUR                      0.3606

$`Sinus congestion`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Sinus tachycardia`
         p Value of SG Interaction
```

```
AGEONSET                    0.7786
AGETRT                      0.5767
SEX                         0.5264
REGION                      0.5016
DISDUR                      0.9630

$Sinusitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Skin candida`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Skin infection`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Skin oedema`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Sleep apnoea syndrome`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Sleep disorder`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN
```

```
$Somnolence
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Sputum culture positive`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Sputum discoloured`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Staphylococcal infection`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Staphylococcal sepsis`
          p Value of SG Interaction
AGEONSET                     0.7627
AGETRT                       0.3706
SEX                          0.4325
REGION                       0.8028
DISDUR                       0.6122

$`Staphylococcal skin infection`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Staphylococcus test positive`
          p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
```

```
DISDUR                          NaN

$`Stoma complication`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Stoma site abscess`
         p Value of SG Interaction
AGEONSET                     0.7523
AGETRT                       0.3665
SEX                          0.3780
REGION                       0.8330
DISDUR                       0.3923

$`Stoma site erythema`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Stoma site haemorrhage`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Stoma site infection`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Stoma site inflammation`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
SEX                             NaN
REGION                          NaN
DISDUR                          NaN

$`Stoma site irritation`
         p Value of SG Interaction
AGEONSET                        NaN
AGETRT                          NaN
```

```
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Stomatitis
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$Strabismus
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Supraventricular tachycardia`
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Surgical failure`
         p Value of SG Interaction
AGEONSET                   0.7926
AGETRT                     0.5700
SEX                        0.6203
REGION                     0.6923
DISDUR                     0.5739

$Swelling
         p Value of SG Interaction
AGEONSET                      NaN
AGETRT                        NaN
SEX                           NaN
REGION                        NaN
DISDUR                        NaN

$`Systemic infection`
         p Value of SG Interaction
AGEONSET                   0.4878
AGETRT                     0.0783
SEX                        0.1271
REGION                     0.1719
DISDUR                     0.0496

$Tachycardia
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Tachypnoea
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Teething
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Thrombocytosis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Thrombosis
         p Value of SG Interaction
AGEONSET                     0.7931
AGETRT                       0.5697
SEX                          0.3616
REGION                       0.7201
DISDUR                       0.5609

$`Tongue atrophy`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Tracheal haemorrhage`
         p Value of SG Interaction
AGEONSET                     0.4878
AGETRT                       0.0783
SEX                          0.1271
REGION                       0.1719
DISDUR                       0.0496
```

```
$`Tracheal injury`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Tracheal obstruction`
         p Value of SG Interaction
AGEONSET                    0.4878
AGETRT                      0.0783
SEX                         0.1271
REGION                      0.1719
DISDUR                      0.0496

$Tracheitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Transaminases increased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Upper gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Upper respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.5616
AGETRT                      0.7413
SEX                         0.9304
REGION                      0.2974
```

```
DISDUR                      0.9439

$`Upper respiratory tract inflammation`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Urinary retention`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Urinary tract infection`
         p Value of SG Interaction
AGEONSET                    0.6326
AGETRT                      0.3193
SEX                         0.3181
REGION                      0.4005
DISDUR                      0.5818

$`Urine output decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Urticaria
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Use of accessory respiratory muscles`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vaccination complication`
         p Value of SG Interaction
AGEONSET                    0.7683
AGETRT                      0.5799
```

```
SEX                         0.4641
REGION                      0.6190
DISDUR                      0.7524

$`Vaccination site reaction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Vasculitis
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Ventricular tachycardia`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vessel puncture site bruise`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vessel puncture site reaction`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Viral infection`
         p Value of SG Interaction
AGEONSET                    0.7550
AGETRT                      0.6646
SEX                         0.6838
REGION                      0.2401
DISDUR                      0.4215

$`Viral rash`
         p Value of SG Interaction
```

```
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Viral rhinitis`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Viral upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.0347
AGETRT                      0.6647
SEX                         0.5586
REGION                      0.1667
DISDUR                      0.6987

$`Vitamin A decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vitamin D decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Vitamin D deficiency`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$Vomiting
         p Value of SG Interaction
AGEONSET                    0.9205
AGETRT                      0.4474
SEX                         0.2697
REGION                      0.5231
DISDUR                      0.2729
```

```
$`Weight decreased`
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN

$`Weight gain poor`
         p Value of SG Interaction
AGEONSET                    0.8266
AGETRT                      0.4072
SEX                         0.7601
REGION                      0.9759
DISDUR                      0.8961

$Wheezing
         p Value of SG Interaction
AGEONSET                       NaN
AGETRT                         NaN
SEX                            NaN
REGION                         NaN
DISDUR                         NaN


\##############################################################################
[[1]]
[1] "Zeit bis zum Erleiden eines SUEs nach PT, das bei mindestens 5% der
Patienten in einem Studienarm oder bei mindestens 10 Patienten und 1% der
Patienten in einem Studienarm auftrat"

$`Abdominal discomfort`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Abdominal distension`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Abdominal pain upper`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Acquired phimosis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Acute respiratory distress syndrome`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0367
SEX                         1.0000
REGION                      0.2673
DISDUR                      0.2772

$`Acute respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.6916
AGETRT                      0.8540
SEX                         0.6736
REGION                      0.1421
DISDUR                      0.3824

$`Adenovirus infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Agitation
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      0.9992
DISDUR                      1.0000

$`Agitation postoperative`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Alanine aminotransferase increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Amblyopia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Anaemia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Anxiety
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Aphthous ulcer`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Apnoea
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.9999
SEX                        0.1240
REGION                     0.5537
DISDUR                     0.9969

$`Apparent life threatening event`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Application site rash`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Arthropod bite`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Aspartate aminotransferase increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Aspiration
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.2197
REGION                     1.0000
DISDUR                     0.8133

$Atelectasis
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.8026
SEX                        0.1545
REGION                     0.6818
DISDUR                     0.9787

$`Back pain`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Bacteraemia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Bacterial disease carrier`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bacterial infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Bacterial tracheitis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Balanoposthitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Blood chloride decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Blood iron decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Blood potassium decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Blood sodium decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Body temperature decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Body temperature increased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Bone marrow disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Bradycardia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Brain injury`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Breath holding`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Bronchial obstruction`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Bronchial secretion retention`
         p Value of SG Interaction
AGEONSET                   0.7540
AGETRT                     0.5592
SEX                        0.3625
REGION                     0.4939
DISDUR                     0.5113

$Bronchiolitis
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.3234
SEX                        0.3142
REGION                     0.7455
DISDUR                     0.4433

$Bronchitis
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.9999
REGION                     1.0000
DISDUR                     0.9999

$`Bronchitis viral`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`C-reactive protein increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Candida infection`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Candida nappy rash`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Candida sepsis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Cardiac arrest`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.6055
SEX                        0.2221
REGION                     0.4166
DISDUR                     0.7186

$`Cardio-respiratory arrest`
         p Value of SG Interaction
AGEONSET                   0.5945
AGETRT                     0.1328
SEX                        0.3151
REGION                     0.7359
DISDUR                     0.3326

$Catarrh
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Catheter site inflammation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Cellulitis
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Chalazion
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Choking
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Chronic respiratory failure`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Clonus
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Congenital diaphragmatic hernia`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Conjunctivitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Conjunctivitis bacterial`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Constipation
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Contusion
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Corona virus infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Cough
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Crying
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Cryptorchism
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Cyanosis
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.0804
REGION                      1.0000
DISDUR                      0.5935

$Death
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.1229
REGION                      0.3078
DISDUR                      0.2795

$`Decubitus ulcer`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Deformity thorax`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Dehydration
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.0733
REGION                      1.0000
DISDUR                      0.7664

$`Delayed fontanelle closure`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Delayed recovery from anaesthesia`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Dermatitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Dermatitis allergic`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Dermatitis atopic`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Dermatitis contact`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Dermatitis diaper`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Developmental hip dysplasia`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Device malfunction`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Device occlusion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Diarrhoea
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Diarrhoea haemorrhagic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Discomfort
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Drooling
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Drug hypersensitivity`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Drug intolerance`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dry eye`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Dry skin`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Dysphagia
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.3563
REGION                      0.1030
DISDUR                      0.3293

$Dyspnoea
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0097
SEX                         0.3873
REGION                      0.7500
DISDUR                      0.0347

$`Ear disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ear haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Ear infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Ear pain`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Ecchymosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Eczema
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Eczema infected`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Electrocardiogram ST-T segment abnormal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Endotracheal intubation complication`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Enteritis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Enterobiasis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Enterococcal infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Epigastric discomfort`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Erythema
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Escherichia infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Excoriation
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Exposure to communicable disease`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Eye infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Eye movement disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Failure to thrive`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.1236
REGION                      0.5208
DISDUR                      0.2565

$Fatigue
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Feeding disorder of infancy or early childhood`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.3337
SEX                         1.0000
REGION                      0.3504
DISDUR                      0.9284
```

$`Feeding intolerance`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Feeding tube complication`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Femur fracture`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$Flatulence
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Food allergy`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Food intolerance`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1
REGION   1
DISDUR   1

$`Fungal infection`
         p Value of SG Interaction
AGEONSET   1
AGETRT   1
SEX   1

```
REGION                          1
DISDUR                          1

$`Fungal skin infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastric haemorrhage`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Gastritis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Gastroenteritis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastroenteritis rotavirus`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastroenteritis viral`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                   1.0000
```

```
AGETRT                      1.0000
SEX                         0.9999
REGION                      0.9993
DISDUR                      1.0000

$`Gastrointestinal motility disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastrointestinal tract irritation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Gastrooesophageal reflux disease`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`General physical health deterioration`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Glycosuria
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Granuloma annulare`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Haematochezia
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Hand-foot-and-mouth disease`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Head injury`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      0.9999
SEX                         0.9999
REGION                      1.0000
DISDUR                      0.9997

$`Head lag abnormal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Heart rate decreased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Heart rate increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Heart rate irregular`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Hepatomegaly
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hordeolum
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Human rhinovirus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hydronephrosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hyperaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hypercapnia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Hyperglycaemia
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Hyperhidrosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hyperkeratosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypersensitivity
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypertension
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypoglycaemia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypokalaemia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypophagia
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypopnoea
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypothermia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypoventilation
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Hypoxia
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.1221
SEX                        0.1894
REGION                     1.0000
DISDUR                     0.0767

$`Hypoxic-ischaemic encephalopathy`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Impaired gastric emptying`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Impetigo
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Incision site erythema`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Increased bronchial secretion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Increased upper airway secretion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Infantile colic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Infantile spitting up`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Inflammatory marker increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Influenza
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Influenza A virus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Infusion site bruising`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Infusion site extravasation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Injection site haematoma`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Intertrigo
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Iron deficiency`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Irritability
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Irritability postvaccinal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Joint contracture`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Joint range of motion decreased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Joint stiffness`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Keratosis pilaris`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Kyphoscoliosis
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Kyphosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Laceration
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Lacrimation increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Language disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Left ventricular hypertrophy`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Leukocytosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Liver function test abnormal`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Localised infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Lower respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      1.0000

$`Lower respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Lung disorder`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         1.0000
REGION                      1.0000
DISDUR                      0.4776

$`Lung infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Lymph node palpable`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Malaise
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Mechanical ventilation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Medical device complication`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Medical observation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Miliaria
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Mood swings`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Moraxella infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Moraxella test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Muscle contractions involuntary`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Muscle tightness`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Muscular weakness`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Myopia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Naevus anaemicus`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Nasal congestion`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Nasal inflammation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Nasopharyngitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Neutrophil count increased`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Nodule
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Nosocomial infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Nystagmus
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Obstructive airways disorder`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Oedema
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oedema peripheral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oral candidiasis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oral fungal infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oral herpes`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oropharyngeal pain`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Orthopaedic examination`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Otitis media`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Otitis media acute`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ovarian cyst`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Oxygen saturation decreased`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.9999
SEX                         0.3929
REGION                      0.6866
DISDUR                      0.6903

$Pain
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pain in extremity`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Pallor
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Parainfluenzae virus infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pectus carinatum`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Penis disorder`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Pharyngitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pharyngitis streptococcal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Phimosis
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pleural effusion`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Pneumonia
         p Value of SG Interaction
AGEONSET                   0.9572
AGETRT                     0.6726
SEX                        0.1096
REGION                     0.6547
DISDUR                     0.5456

$`Pneumonia aspiration`
         p Value of SG Interaction
AGEONSET                   0.2130
AGETRT                     0.3067
SEX                        0.4290
REGION                     0.9922
DISDUR                     0.9779

$`Pneumonia bacterial`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.7593
SEX                        0.3116
REGION                     1.0000
DISDUR                     0.9899

$`Pneumonia influenzal`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pneumonia moraxella`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pneumonia parainfluenzae viral`
```

```
         p Value of SG Interaction
AGEONSET                    0.1966
AGETRT                      1.0000
SEX                         1.0000
REGION                      0.4519
DISDUR                      0.1269

$`Pneumonia pneumococcal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia pseudomonal`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia respiratory syncytial viral`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Pneumonia viral`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.3234
SEX                         0.5641
REGION                      0.7396
DISDUR                      0.5963

$Pneumothorax
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Positional plagiocephaly`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Post procedural contusion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Post procedural haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Post procedural swelling`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Presyncope
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Procedural complication`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Procedural pain`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Procedural site reaction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Pseudomonas infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Pseudomonas test positive`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Pyelonephritis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Pyrexia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Rash
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Rash erythematous`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Rash macular`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Rash papular`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory alkalosis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory arrest`
         p Value of SG Interaction
AGEONSET                    0.4776
AGETRT                      0.1725
SEX                         0.9652
REGION                      0.0214
DISDUR                      0.5117

$`Respiratory disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory distress`
         p Value of SG Interaction
AGEONSET                    0.7185
AGETRT                      0.4682
SEX                         0.0958
REGION                      0.5447
DISDUR                      0.8379

$`Respiratory failure`
         p Value of SG Interaction
AGEONSET                    0.0887
AGETRT                      0.0504
SEX                         0.7284
REGION                      0.1147
DISDUR                      0.9121

$`Respiratory rate increased`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory syncytial virus bronchiolitis`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.5758
SEX                         0.8373
REGION                      0.5511
DISDUR                      0.2918

$`Respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory tract infection`
         p Value of SG Interaction
AGEONSET                    0.2352
AGETRT                      1.0000
SEX                         0.2805
REGION                      1.0000
DISDUR                      0.6453

$`Respiratory tract infection bacterial`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Respiratory tract infection viral`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.0820
REGION                      1.0000
DISDUR                      0.3573

$`Respirovirus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$Restlessness
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Retching
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Rhinitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Rhinitis allergic`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Rhinorrhoea
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Rhinovirus infection`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.0393
SEX                         0.0606
REGION                      0.9954
DISDUR                      0.1828

$Rhonchi
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$Roseola
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Salivary hypersecretion`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.9999
REGION                     1.0000
DISDUR                     1.0000

$`Scarlet fever`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Scoliosis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Seasonal allergy`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Seizure
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Sepsis
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Serratia infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Shock
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sinus congestion`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Sinus tachycardia`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Sinusitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Skin candida`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Skin infection`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Skin oedema`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Sleep apnoea syndrome`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Sleep disorder`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Somnolence
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Sputum culture positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Sputum discoloured`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Staphylococcal infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Staphylococcal sepsis`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Staphylococcal skin infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Staphylococcus test positive`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma complication`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site abscess`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Stoma site erythema`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
```

```
REGION                          1
DISDUR                          1

$`Stoma site haemorrhage`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Stoma site infection`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Stoma site inflammation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Stoma site irritation`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Stomatitis
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Strabismus
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Supraventricular tachycardia`
         p Value of SG Interaction
AGEONSET                        1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Surgical failure`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Swelling
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Systemic infection`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     1.0000
SEX                        0.9999
REGION                     1.0000
DISDUR                     1.0000

$Tachycardia
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Tachypnoea
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Teething
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$Thrombocytosis
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Thrombosis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Tongue atrophy`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Tracheal haemorrhage`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$`Tracheal injury`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Tracheal obstruction`
         p Value of SG Interaction
AGEONSET                    0.0000
AGETRT                      1.0000
SEX                         0.9999
REGION                      1.0000
DISDUR                      1.0000

$Tracheitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

```
$`Transaminases increased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Upper gastrointestinal haemorrhage`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Upper respiratory tract congestion`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Upper respiratory tract inflammation`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Urinary retention`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Urinary tract infection`
         p Value of SG Interaction
AGEONSET                    0.9999
AGETRT                      1.0000
SEX                         1.0000
```

```
REGION                      1.0000
DISDUR                      1.0000

$`Urine output decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Urticaria
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Use of accessory respiratory muscles`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vaccination complication`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vaccination site reaction`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Vasculitis
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Ventricular tachycardia`
         p Value of SG Interaction
AGEONSET                         1
```

```
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Vessel puncture site bruise`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Vessel puncture site reaction`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Viral infection`
         p Value of SG Interaction
AGEONSET                   1.0000
AGETRT                     0.4559
SEX                        0.3304
REGION                     0.2546
DISDUR                     0.3885

$`Viral rash`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Viral rhinitis`
         p Value of SG Interaction
AGEONSET                        1
AGETRT                          1
SEX                             1
REGION                          1
DISDUR                          1

$`Viral upper respiratory tract infection`
         p Value of SG Interaction
AGEONSET                   0.0206
AGETRT                     0.9397
SEX                        0.5258
REGION                     1.0000
DISDUR                     0.4098

$`Vitamin A decreased`
```

```
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vitamin D decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Vitamin D deficiency`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$Vomiting
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.2314
SEX                         0.1818
REGION                      0.4400
DISDUR                      0.2204

$`Weight decreased`
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1

$`Weight gain poor`
         p Value of SG Interaction
AGEONSET                    1.0000
AGETRT                      0.9999
SEX                         0.6615
REGION                      0.9817
DISDUR                      0.9639

$Wheezing
         p Value of SG Interaction
AGEONSET                         1
AGETRT                           1
SEX                              1
REGION                           1
DISDUR                           1
```

\##

Anhang 4-G zu Modul 4 A.1

Primäranalyse EMBRACE ITT

Stand: 01.12.2020

```
Results for EMBRACE ITT-Population[[1]]
[1] "Survival rate"

$ntab
            CTRL TRT
n_all          7  14
n_event        6  14
n_event_pct   86 100

$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1897436 0.1764795  0.8418482   1.681407 0.3248871
OR_TRTvsCTRL  6.6923077 1.6998466  0.2391464 187.278498 0.2634338
ARR_TRTvsCTRL 0.1428571 0.1322600 -0.1163677   0.402082 0.2800872


\#############################################################################
#
[[1]]
[1] "Time to death"

$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               41.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          41.3         NA
time-to-event-wk-50th-hici            NA         NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


\#############################################################################
#
[[1]]
[1] "Time to death or permanent ventilation"

$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               41.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
```

```
time-to-event-wk-50th-loci          41.3         NA
time-to-event-wk-50th-hici            NA         NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


\#############################################################################
#
[[1]]
[1] "Time to permanent ventilation"

$stats_num
                            ARMCD=CONTROL ARMCD=ISIS
n_all                                   7         14
n_event                                 0          0
n_event_pct                             0          0
time-to-event-wk-10th                  NA         NA
time-to-event-wk-25th                  NA         NA
time-to-event-wk-50th                  NA         NA
time-to-event-wk-75th                  NA         NA
time-to-event-wk-90th                  NA         NA
time-to-event-wk-50th-loci             NA         NA
time-to-event-wk-50th-hici             NA         NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
       NA         0        NA        NA        NA


\#############################################################################
#
[[1]]
[1] "Number of hours of ventilatory support (only patients that receive no
ventilation at baseline)"

$numbers_eachgrp
         CONTROL        ISIS
N      3.0000000 11.00000000
n      3.0000000 11.00000000
mean   0.1112319  0.04101983
sd     0.1926593  0.13284449
se     0.1112319  0.04005412
median 0.0000000  0.00000000
min    0.0000000  0.00000000
max    0.3336957  0.44146825
sum    0.3336957  0.45121816

$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      ISIS   0.04     0.044        -0.060         0.135
2   CONTROL   0.15     0.095        -0.061         0.359
```

```
$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv

     -0.1112319       0.1068077      -0.3463141       0.1238503       0.3200285


$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
-0.4500 -1.7470  0.8370  0.4903


\#############################################################################
#
[[1]]
[1] "Percent of subjects not requiring permanent ventilation"

$ntab
            CTRL TRT
n_all          7  14
n_event        6  14
n_event_pct   86 100

$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1897436 0.1764795  0.8418482   1.681407 0.3248871
OR_TRTvsCTRL  6.6923077 1.6998466  0.2391464 187.278498 0.2634338
ARR_TRTvsCTRL 0.1428571 0.1322600 -0.1163677   0.402082 0.2800872


\#############################################################################
#
[[1]]
[1] "Time to ventilation (regardless of the ventilation duration) only for
patients that receive no ventilation at baseline"

$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                3.0       11.0
n_event                              1.0        3.0
n_event_pct                         33.0       27.0
time-to-event-wk-10th               10.3       17.1
time-to-event-wk-25th               10.3       35.1
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          10.3       17.1
time-to-event-wk-50th-hici            NA         NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.042e-09 2.100e+04 0.000e+00       Inf 9.992e-01


\#############################################################################
```

```
#
[[1]]
[1] "Percent of subjects not requiring ventilation (regardless of the
ventilation duration) only for patients that receive no ventilation at
baseline"

$ntab
            CTRL TRT
n_all          3  11
n_event        2   8
n_event_pct   67  73

$stats
                estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.09090909 0.4480598  0.45331425  2.6252928 0.8460225
OR_TRTvsCTRL  1.33333333 1.3994046  0.08585456 20.7068540 0.8371232
ARR_TRTvsCTRL 0.06060606 0.3034891 -0.53422163  0.6554338 0.8417170


\#############################################################################
#
[[1]]
[1] "HINE-Responder – section 2"

$`64`
$`64`$ntab
            CTRL TRT
n_all          7  14
n_event        0   6
n_event_pct    0  43

$`64`$stats
                estimate       se    lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   6.9333333 1.400778 0.4452434 107.9659031 0.166869740
OR_TRTvsCTRL  11.4705882 1.550750 0.5490155 239.6551428 0.115650751
ARR_TRTvsCTRL  0.4285714 0.132260 0.1693466   0.6877963 0.001193745


$`183`
$`183`$ntab
            CTRL TRT
n_all          7  14
n_event        1  11
n_event_pct   14  79

$`183`$stats
                estimate        se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL   5.5000000 0.9362817 0.8778055  34.4609382 0.0686427189
OR_TRTvsCTRL  22.0000000 1.2613124 1.8569131 260.6476315 0.0142596304
ARR_TRTvsCTRL  0.6428571 0.1718108 0.3061142   0.9796001 0.0001828106


$`302`
$`302`$ntab
```

```
            CTRL TRT
n_all          7  14
n_event        0  11
n_event_pct    0  79

$`302`$stats
                 estimate        se    lo95ci      hi95ci       pvalue
RR_TRTvsCTRL  12.2666667 1.3766953 0.8258125  182.209786 6.861531e-02
OR_TRTvsCTRL  49.2857143 1.5830364 2.2143081 1096.993499 1.381163e-02
ARR_TRTvsCTRL  0.7857143 0.1096642 0.5707764    1.000652 7.793766e-13


$`422`
$`422`$ntab
            CTRL TRT
n_all          7  14
n_event        0   6
n_event_pct    0  43

$`422`$stats
                 estimate       se    lo95ci      hi95ci      pvalue
RR_TRTvsCTRL   6.9333333 1.400778 0.4452434 107.9659031 0.166869740
OR_TRTvsCTRL  11.4705882 1.550750 0.5490155 239.6551428 0.115650751
ARR_TRTvsCTRL  0.4285714 0.132260 0.1693466   0.6877963 0.001193745



\##############################################################################
#
[[1]]
[1] "Time to motor milestone responders  (HINE – section 2)"

$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0       12.0
n_event_pct                         14.0       86.0
time-to-event-wk-10th               26.6        9.1
time-to-event-wk-25th                 NA        9.1
time-to-event-wk-50th                 NA       25.6
time-to-event-wk-75th                 NA       27.0
time-to-event-wk-90th                 NA       43.0
time-to-event-wk-50th-loci          26.6        9.1
time-to-event-wk-50th-hici            NA       27.0

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  11.3400    1.0690    1.3950   92.0700    0.0231


\##############################################################################
#
[[1]]
[1] "Change from baseline in HINE– section 2"
```

```
$`64`
$`64`$base
         CONTROL      ISIS
N       7.000000 14.000000
n       7.000000 14.000000
mean    3.857143  5.642857
sd      3.579040  5.168055
se      1.352750  1.381221
median  5.000000  5.000000
min     0.000000  0.000000
max     9.000000 17.000000
sum    27.000000 79.000000

$`64`$numbers_eachgrp
          CONTROL       ISIS
N       7.0000000 14.0000000
n       7.0000000 14.0000000
mean   -0.4285714  0.5714286
sd      1.1338934  1.7851648
se      0.4285714  0.4771053
median  0.0000000  0.5000000
min    -2.0000000 -4.0000000
max     1.0000000  3.0000000
sum    -3.0000000  8.0000000

$`64`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      ISIS   1.18     0.335         0.476         1.888
2   CONTROL  -0.52     0.438        -1.438         0.408

$`64`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv

    1.697078890     0.557412005     0.521042358     2.873115422     0.007323746


$`64`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
 0.600 -0.332  1.526  0.208


$`183`
$`183`$base
         CONTROL      ISIS
N       7.000000 14.000000
n       7.000000 14.000000
mean    3.857143  5.642857
sd      3.579040  5.168055
se      1.352750  1.381221
median  5.000000  5.000000
min     0.000000  0.000000
max     9.000000 17.000000
sum    27.000000 79.000000
```

```
$`183`$numbers_eachgrp
          CONTROL       ISIS
N       7.0000000 14.0000000
n       7.0000000 14.0000000
mean    0.0000000  2.2142857
sd      0.8164966  2.8332795
se      0.3086067  0.7572258
median  0.0000000  1.5000000
min    -1.0000000 -3.0000000
max     1.0000000  8.0000000
sum     0.0000000 31.0000000

$`183`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      ISIS   2.98     0.572         1.779         4.190
2   CONTROL  -0.09     0.748        -1.671         1.484

$`183`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv

    3.078002963     0.952383104     1.068650253     5.087355673     0.004899306


$`183`$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.8900 -0.0650  1.8450  0.0678


$`302`
$`302`$base
         CONTROL      ISIS
N       7.000000 14.000000
n       7.000000 14.000000
mean    3.857143  5.642857
sd      3.579040  5.168055
se      1.352750  1.381221
median  5.000000  5.000000
min     0.000000  0.000000
max     9.000000 17.000000
sum    27.000000 79.000000

$`302`$numbers_eachgrp
          CONTROL      ISIS
N       7.0000000 14.000000
n       4.0000000 12.000000
mean   -0.7500000  3.750000
sd      1.2583057  2.598076
se      0.6291529  0.750000
median -1.0000000  3.000000
min    -2.0000000 -1.000000
max     1.0000000  8.000000
sum    -3.0000000 45.000000
```

```
$`302`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      ISIS   4.04     0.618         2.693         5.385
2   CONTROL  -0.88     1.047        -3.163         1.399

$`302`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv

     4.92099648      1.21997985      2.26288873      7.57910422      0.00165823


$`302`$Hedgesg_TRTvsCTRL
   est lo95ci hi95ci     pv
1.7900 0.4530 3.1290 0.0087


$`422`
$`422`$base
         CONTROL      ISIS
N       7.000000 14.000000
n       7.000000 14.000000
mean    3.857143  5.642857
sd      3.579040  5.168055
se      1.352750  1.381221
median  5.000000  5.000000
min     0.000000  0.000000
max     9.000000 17.000000
sum    27.000000 79.000000

$`422`$numbers_eachgrp
        CONTROL      ISIS
N       7.00000 14.000000
n       2.00000  7.000000
mean    0.50000  5.571429
sd      2.12132  4.314979
se      1.50000  1.630909
median  0.50000  5.000000
min    -1.00000  1.000000
max     2.00000 13.000000
sum     1.00000 39.000000

$`422`$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      ISIS   6.74     1.748         2.246        11.234
2   CONTROL   0.19     2.893        -7.246         7.628

$`422`$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv

      6.5489577       3.4270109      -2.2604543      15.3583697       0.1142422


$`422`$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
```

```
 1.1100 -0.6070  2.8190  0.2055



\#############################################################################
#
[[1]]
[1] "Number/frequency of hospitalizations"

$numbers_eachgrp
          CONTROL        ISIS
N      7.00000000 14.00000000
n      7.00000000 14.00000000
mean   0.04422159  0.04436753
sd     0.09996732  0.10795918
se     0.03778410  0.02885330
median 0.00000000  0.00000000
min    0.00000000  0.00000000
max    0.26956522  0.40714286
sum    0.30955110  0.62114547

$ls_mw
  TRTvsCTRL LSMean LSMean_se LSMean_lo95ci LSMean_hi95ci
1      ISIS   0.04     0.030        -0.020         0.104
2   CONTROL   0.04     0.041        -0.043         0.129

$diffgrp_TRTvsCTRL
       LSM_Diff     LSM_Diff_se LSM_Diff_lo95ci LSM_Diff_hi95ci     LSM_Diff_pv

   -0.001050104     0.050132117    -0.106373774     0.104273566     0.983518599


$Hedgesg_TRTvsCTRL
    est  lo95ci  hi95ci      pv
 0.0000 -0.9060  0.9090  0.9977


\#############################################################################
#
[[1]]
[1] "numhosp/ptyear in rate"

$nsubj

CONTROL    ISIS
      7      14

$numbers_eachgrp
         CONTROL       ISIS
n      7.0000000 14.0000000
mean   0.7142857  1.6428571
sd     0.9511897  2.8448913
se     0.3595159  0.7603292
median 0.0000000  0.0000000
```

```
min    0.0000000  0.0000000
max    2.0000000 10.0000000
sum    5.0000000 23.0000000

$n_ptyear
     CTRL       TRT
 5.637235 13.023956

$rate_unadj
     CTRL       TRT
0.8869597 1.7659765

$rate_adj
            CTRL       TRT
est    0.9865040 1.2336897
lo95ci 0.2468061 0.5160586
hi95ci 3.9431367 2.9492584

$RR_TRTvsCTRL
      est    lo95ci    hi95ci        se        pv
1.2505674 0.2393927 6.5328600 0.8435091 0.7909479


\#############################################################################
#
[[1]]
[1] "Time to hospitalization"

$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              3.0        6.0
n_event_pct                         43.0       43.0
time-to-event-wk-10th                2.3        3.3
time-to-event-wk-25th               10.3        9.9
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3        5.7
time-to-event-wk-50th-hici            NA         NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.9937    0.7091    0.2475    3.9890    0.9929


\#############################################################################
#
[[1]]
[1] "Number/frequency of serious respiratory events"

$nsubj

CONTROL    ISIS
```

```
      7      14

$numbers_eachgrp
         CONTROL      ISIS
n      7.0000000 14.000000
mean   1.1428571  1.357143
sd     1.4638501  2.817723
se     0.5532833  0.753068
median 0.0000000  0.000000
min    0.0000000  0.000000
max    3.0000000 10.000000
sum    8.0000000 19.000000

$n_ptyear
     CTRL       TRT
 5.637235 13.023956

$rate_unadj
    CTRL      TRT
1.419136 1.458850

$rate_adj
            CTRL       TRT
est    1.6099109 0.7950811
lo95ci 0.3039169 0.2356877
hi95ci 8.5280323 2.6821678

$RR_TRTvsCTRL
       est     lo95ci     hi95ci         se         pv
0.49386656 0.05618378 4.34118463 1.10901894 0.52468599


\##############################################################################
#
[[1]]
[1] "Time to serious respiratory events"

$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              3.0        4.0
n_event_pct                         43.0       29.0
time-to-event-wk-10th               10.3        3.3
time-to-event-wk-25th               19.1        9.9
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          10.3        5.7
time-to-event-wk-50th-hici            NA         NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7839    0.7673    0.1742    3.5270    0.7510
```

```
\#############################################################################
#
[[1]]
[1] "Number of patients with AEs (total)"

$ntab
            CTRL TRT
n_all          7  14
n_event        6  14
n_event_pct   86 100

$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.1897436 0.1764795  0.8418482   1.681407 0.3248871
OR_TRTvsCTRL  6.6923077 1.6998466  0.2391464 187.278498 0.2634338
ARR_TRTvsCTRL 0.1428571 0.1322600 -0.1163677   0.402082 0.2800872


\#############################################################################
#
[[1]]
[1] "Number of patients with mild AEs"

$ntab
            CTRL TRT
n_all          7  14
n_event        6  11
n_event_pct   86  79

$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.91666667 0.2080626  0.60968883 1.3782076 0.6758023
OR_TRTvsCTRL   0.61111111 1.2613124  0.05158092 7.2402120 0.6962056
ARR_TRTvsCTRL -0.07142857 0.1718108 -0.40817155 0.2653144 0.6776005


\#############################################################################
#
[[1]]
[1] "Number of patients with moderate AEs"

$ntab
            CTRL TRT
n_all          7  14
n_event        5  10
n_event_pct   71  71

$stats
              estimate        se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.2927700  0.5633700 1.7750324      1
OR_TRTvsCTRL         1 1.0246951  0.1342079 7.4511281      1
ARR_TRTvsCTRL        0 0.2091214 -0.4098705 0.4098705      1
```

```
\#############################################################################
#
[[1]]
[1] "Number of patients with moderate or severe AEs"

$ntab
            CTRL TRT
n_all          7  14
n_event        5  10
n_event_pct   71  71

$stats
              estimate        se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.2927700  0.5633700 1.7750324      1
OR_TRTvsCTRL         1 1.0246951  0.1342079 7.4511281      1
ARR_TRTvsCTRL        0 0.2091214 -0.4098705 0.4098705      1


\#############################################################################
#
[[1]]
[1] "Number of patients with severe AEs"

$ntab
            CTRL TRT
n_all          7  14
n_event        3   5
n_event_pct   43  36

$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83333333 0.5648430  0.2754378 2.5212388 0.7468598
OR_TRTvsCTRL   0.74074074 0.9457507  0.1160491 4.7281442 0.7510016
ARR_TRTvsCTRL -0.07142857 0.2266822 -0.5157176 0.3728605 0.7526824


\#############################################################################
#
[[1]]
[1] "Time to AE"

$stats_num
                          ARMCD=CONTROL ARMCD=ISIS
n_all                               7.0       14.0
n_event                             6.0       14.0
n_event_pct                        86.0      100.0
time-to-event-wk-10th               0.1        0.1
time-to-event-wk-25th               0.1        0.3
time-to-event-wk-50th               1.3        1.8
time-to-event-wk-75th               2.3        5.0
time-to-event-wk-90th                NA       12.9
time-to-event-wk-50th-loci          0.1        0.1
time-to-event-wk-50th-hici          2.3        5.0
```

```
$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0680    0.4991    0.4014    2.8400    0.8955


\#############################################################################
#
[[1]]
[1] "Number of patients with SAEs"

$ntab
            CTRL TRT
n_all          7  14
n_event        3   5
n_event_pct   43  36

$stats
                  estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.83333333 0.5648430  0.2754378 2.5212388 0.7468598
OR_TRTvsCTRL   0.74074074 0.9457507  0.1160491 4.7281442 0.7510016
ARR_TRTvsCTRL -0.07142857 0.2266822 -0.5157176 0.3728605 0.7526824


\#############################################################################
#
[[1]]
[1] "Time to SAE"

$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              3.0        5.0
n_event_pct                         43.0       36.0
time-to-event-wk-10th                2.3        3.3
time-to-event-wk-25th               10.3        9.9
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3        5.7
time-to-event-wk-50th-hici            NA         NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8093    0.7323    0.1927    3.4000    0.7726


\#############################################################################
#
[[1]]
[1] "Time to AE differentiated by severity  -  mild"

$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
```

```
n_all                                7.0       14.0
n_event                              6.0       11.0
n_event_pct                         86.0       79.0
time-to-event-wk-10th                0.1        0.1
time-to-event-wk-25th                0.1        0.3
time-to-event-wk-50th                1.3        3.9
time-to-event-wk-75th                2.3       14.1
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           0.1        0.1
time-to-event-wk-50th-hici           2.3       14.1

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6530    0.5256    0.2331    1.8290    0.4175


\#############################################################################
#
[[1]]
[1] "Time to AE differentiated by severity  -  moderate"

$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              5.0       10.0
n_event_pct                         71.0       71.0
time-to-event-wk-10th               10.9        2.7
time-to-event-wk-25th               12.4        3.0
time-to-event-wk-50th               30.6       14.7
time-to-event-wk-75th               40.1         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          10.9        2.9
time-to-event-wk-50th-hici            NA         NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.5670    0.5620    0.5207    4.7140    0.4243


\#############################################################################
#
[[1]]
[1] "Time to AE differentiated by severity  -  moderate or severe"

$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              5.0       10.0
n_event_pct                         71.0       71.0
time-to-event-wk-10th                2.3        2.7
time-to-event-wk-25th               10.3        3.0
time-to-event-wk-50th               15.6       14.7
time-to-event-wk-75th               30.6         NA
time-to-event-wk-90th                 NA         NA
```

```
time-to-event-wk-50th-loci           2.3        2.9
time-to-event-wk-50th-hici            NA         NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1530    0.5515    0.3913    3.4000    0.7958


\#############################################################################
#
[[1]]
[1] "Time to AE differentiated by severity  -  severe"

$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              3.0        5.0
n_event_pct                         43.0       36.0
time-to-event-wk-10th                2.3        5.7
time-to-event-wk-25th               10.3       10.1
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3        9.9
time-to-event-wk-50th-hici            NA         NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7948    0.7330    0.1889    3.3430    0.7540


\#############################################################################
#
[[1]]
[1] "Number of patients with AEs leading to discontinuation"

$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$stats
                 estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


\#############################################################################
#
[[1]]
[1] "Time to AE causing discontinuation of therapy"
```

```
$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               41.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          41.3         NA
time-to-event-wk-50th-hici            NA         NA

$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


\#############################################################################
#
[[1]]
[1] "Number of patients with AEs according to SOC at least in 10% Patients in
one Study Arm"


\#############################################################################
#
[[1]]
[1] "Number of patients with AEs according to SOC at least 10 Patients and 1%
Patients in one Study Arm"


\#############################################################################
#
[[1]]
[1] "Time to AEs according to SOC at least in 10% Patients in one Study Arm"


\#############################################################################
#
[[1]]
[1] "Time to AEs according to SOC at least 10 Patients and 1% Patients in one
Study Arm"


\#############################################################################
#
[[1]]
[1] "Number of patients with AEs according to PT at least in 10% Patients in
one Study Arm"


\#############################################################################
#
```

```
[[1]]
[1] "Number of patients with AEs according to PT at least 10 Patients and 1%
Patients in one Study Arm"


\#############################################################################
#
[[1]]
[1] "Time to AEs according to PT at least in 10% Patients in one Study Arm"


\#############################################################################
#
[[1]]
[1] "Time to AEs according to PT at least 10 Patients and 1% Patients in one
Study Arm"


\#############################################################################
#
[[1]]
[1] "Number of patients with mild AEs according to SOC at least in 10% Patients
in one Study Arm"

$`Cardiac disorders`
$`Cardiac disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        2   2
n_event_pct   29  14

$`Cardiac disorders`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5000000 0.8864053  0.08799550 2.8410543 0.4342290
OR_TRTvsCTRL   0.4166667 1.1328430  0.04523879 3.8376600 0.4396368
ARR_TRTvsCTRL -0.1428571 0.1946815 -0.52442581 0.2387115 0.4630710


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        3   7
n_event_pct   43  50

$`Gastrointestinal disorders`$stats
                 estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.16666667 0.5117663  0.4278884 3.1809956 0.7632521
OR_TRTvsCTRL  1.33333333 0.9322272  0.2144991 8.2880431 0.7576285
ARR_TRTvsCTRL 0.07142857 0.2298751 -0.3791184 0.5219755 0.7560076


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$ntab
```

```
            CTRL TRT
n_all          7  14
n_event        1   7
n_event_pct   14  50

$`General disorders and administration site conditions`$stats
               estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.5000000 0.9636241  0.52945580 23.1369642 0.19358261
OR_TRTvsCTRL  6.0000000 1.2051477  0.56536338 63.6758606 0.13707950
ARR_TRTvsCTRL 0.3571429 0.1880156 -0.01136089  0.7256466 0.05749368


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all          7  14
n_event        3   9
n_event_pct   43  64

$`Infections and infestations`$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.5000000 0.4797486  0.5857719  3.8410859 0.3980206
OR_TRTvsCTRL  2.4000000 0.9457507  0.3759991 15.3191872 0.3546089
ARR_TRTvsCTRL 0.2142857 0.2266822 -0.2300033  0.6585747 0.3444990


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all          7  14
n_event        2   4
n_event_pct   29  29

$`Injury, poisoning and procedural complications`$stats
              estimate        se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.7319251  0.2382233 4.1977419      1
OR_TRTvsCTRL         1 1.0246951  0.1342079 7.4511281      1
ARR_TRTvsCTRL        0 0.2091214 -0.4098705 0.4098705      1


$Investigations
$Investigations$ntab
            CTRL TRT
n_all          7  14
n_event        0   2
n_event_pct    0  14

$Investigations$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.6666667 1.48604621  0.14489183 49.0787574 0.5092371
OR_TRTvsCTRL  3.0000000 1.61658075  0.12620752 71.3111249 0.4967640
ARR_TRTvsCTRL 0.1428571 0.09352195 -0.04044252  0.3261568 0.1266305
```

```
$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        1   1
n_event_pct   14   7

$`Metabolism and nutrition disorders`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
OR_TRTvsCTRL   0.46153846 1.4978617  0.02450336 8.6934089 0.6057177
ARR_TRTvsCTRL -0.07142857 0.1490984 -0.36365599 0.2207988 0.6318887


$`Musculoskeletal and connective tissue disorders`
$`Musculoskeletal and connective tissue disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        0   5
n_event_pct    0  36

$`Musculoskeletal and connective tissue disorders`$stats
               estimate        se    lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  5.8666667 1.4107273 0.3694691  93.1546778 0.209781573
OR_TRTvsCTRL  8.6842105 1.5557682 0.4115836 183.2325522 0.164726355
ARR_TRTvsCTRL 0.3571429 0.1280602 0.1061495   0.6081363 0.005289282


$`Psychiatric disorders`
$`Psychiatric disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Psychiatric disorders`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        1   9
n_event_pct   14  64

$`Respiratory, thoracic and mediastinal disorders`$stats
              estimate        se    lo95ci      hi95ci      pvalue
RR_TRTvsCTRL       4.5 0.9470087 0.7032622  28.7943808 0.112231992
OR_TRTvsCTRL      10.8 1.2156388 0.9969425 116.9977226 0.050295175
ARR_TRTvsCTRL      0.5 0.1840981 0.1391743   0.8608257 0.006608738
```

```
$`Skin and subcutaneous tissue disorders`
$`Skin and subcutaneous tissue disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        3   4
n_event_pct   43  29

$`Skin and subcutaneous tissue disorders`$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.6666667 0.6074929  0.20267951 2.1928435 0.5044911
OR_TRTvsCTRL   0.5333333 0.9660918  0.08028971 3.5427258 0.5152584
ARR_TRTvsCTRL -0.1428571 0.2226268 -0.57919761 0.2934833 0.5210752


$`Vascular disorders`
$`Vascular disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        2   0
n_event_pct   29   0

$`Vascular disorders`$stats
                 estimate        se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.10666667 1.4860462  0.005795673 1.96315029 0.13205664
OR_TRTvsCTRL   0.07586207 1.6281228  0.003120068 1.84452813 0.11320881
ARR_TRTvsCTRL -0.28571429 0.1707469 -0.620372147 0.04894358 0.09426431



\#############################################################################
#
[[1]]
[1] "Number of patients with mild AEs according to SOC at least 10 Patients and
1% Patients in one Study Arm"


\#############################################################################
#
[[1]]
[1] "Time to mild AEs according to SOC at least in 10% Patients in one Study
Arm"

$`Cardiac disorders`
$`Cardiac disorders`$stats_num
                          ARMCD=CONTROL ARMCD=ISIS
n_all                               7.0       14.0
n_event                             2.0        2.0
n_event_pct                        29.0       14.0
time-to-event-wk-10th               0.1        4.1
time-to-event-wk-25th              41.0         NA
time-to-event-wk-50th                NA         NA
time-to-event-wk-75th                NA         NA
```

```
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           0.1         NA
time-to-event-wk-50th-hici            NA         NA

$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45030   1.00400   0.06295   3.22100   0.42680


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              3.0        7.0
n_event_pct                         43.0       50.0
time-to-event-wk-10th                2.3        0.3
time-to-event-wk-25th                3.7        9.3
time-to-event-wk-50th               40.4       54.0
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3        0.6
time-to-event-wk-50th-hici            NA         NA

$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2710    0.6984    0.3234    4.9980    0.7310


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        7.0
n_event_pct                         14.0       50.0
time-to-event-wk-10th                2.3        0.6
time-to-event-wk-25th                 NA        2.9
time-to-event-wk-50th                 NA       34.6
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3        1.7
time-to-event-wk-50th-hici            NA         NA

$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   4.1740    1.0710    0.5119   34.0300    0.1820


$`Infections and infestations`
$`Infections and infestations`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              3.0        9.0
n_event_pct                         43.0       64.0
time-to-event-wk-10th                4.4        1.1
```

```
time-to-event-wk-25th                8.4       12.9
time-to-event-wk-50th                 NA       29.5
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           4.4        5.0
time-to-event-wk-50th-hici            NA         NA

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.4710    0.6735    0.3930    5.5080    0.5665


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              2.0        4.0
n_event_pct                         29.0       29.0
time-to-event-wk-10th                2.7        0.1
time-to-event-wk-25th               37.9       49.1
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.7        2.0
time-to-event-wk-50th-hici            NA         NA

$`Injury, poisoning and procedural complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.1740    0.8757    0.2110    6.5320    0.8547


$Investigations
$Investigations$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7       14.0
n_event                              0        2.0
n_event_pct                          0       14.0
time-to-event-wk-10th               NA       43.4
time-to-event-wk-25th               NA         NA
time-to-event-wk-50th               NA         NA
time-to-event-wk-75th               NA         NA
time-to-event-wk-90th               NA         NA
time-to-event-wk-50th-loci          NA       43.4
time-to-event-wk-50th-hici          NA         NA

$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.082e+09 3.045e+04 0.000e+00       Inf 9.995e-01


$`Metabolism and nutrition disorders`
$`Metabolism and nutrition disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
```

```
n_event                              1.0          1
n_event_pct                         14.0          7
time-to-event-wk-10th                2.4         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.4         NA
time-to-event-wk-50th-hici            NA         NA

$`Metabolism and nutrition disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.35630   1.42300   0.02192   5.79400   0.46830


$`Musculoskeletal and connective tissue disorders`
$`Musculoskeletal and connective tissue disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7       14.0
n_event                                0        5.0
n_event_pct                            0       36.0
time-to-event-wk-10th                 NA        1.6
time-to-event-wk-25th                 NA       13.3
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA        5.3
time-to-event-wk-50th-hici            NA         NA

$`Musculoskeletal and connective tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.771e+08 1.290e+04 0.000e+00       Inf 9.988e-01


$`Psychiatric disorders`
$`Psychiatric disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th                0.9         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           0.9         NA
time-to-event-wk-50th-hici            NA         NA

$`Psychiatric disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$`Respiratory, thoracic and mediastinal disorders`
```

```
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        9.0
n_event_pct                         14.0       64.0
time-to-event-wk-10th                1.3        5.0
time-to-event-wk-25th                 NA       10.7
time-to-event-wk-50th                 NA       26.1
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           1.3        9.4
time-to-event-wk-50th-hici            NA         NA

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   5.3320    1.0550    0.6739   42.1900    0.1127


$`Skin and subcutaneous tissue disorders`
$`Skin and subcutaneous tissue disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              3.0        4.0
n_event_pct                         43.0       29.0
time-to-event-wk-10th                0.1        1.9
time-to-event-wk-25th                1.1       54.3
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           0.1        4.4
time-to-event-wk-50th-hici            NA         NA

$`Skin and subcutaneous tissue disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.5644    0.8255    0.1119    2.8460    0.4884


$`Vascular disorders`
$`Vascular disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              2.0          0
n_event_pct                         29.0          0
time-to-event-wk-10th                1.1         NA
time-to-event-wk-25th               41.0         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           1.1         NA
time-to-event-wk-50th-hici            NA         NA

$`Vascular disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.502e-10 3.544e+04 0.000e+00       Inf 9.995e-01
```

```
\#############################################################################
#
[[1]]
[1] "Time to mild AEs according to SOC at least 10 Patients and 1% Patients in
one Study Arm"


\#############################################################################
#
[[1]]
[1] "Number of patients with mild AEs according to PT at least in 10% Patients
in one Study Arm"

$`Aphthous ulcer`
$`Aphthous ulcer`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Aphthous ulcer`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Constipation
$Constipation$ntab
            CTRL TRT
n_all          7  14
n_event        1   1
n_event_pct   14   7

$Constipation$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
OR_TRTvsCTRL   0.46153846 1.4978617  0.02450336 8.6934089 0.6057177
ARR_TRTvsCTRL -0.07142857 0.1490984 -0.36365599 0.2207988 0.6318887


$Contusion
$Contusion$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$Contusion$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
```

```
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Cough
$Cough$ntab
            CTRL TRT
n_all          7  14
n_event        1   7
n_event_pct   14  50

$Cough$stats
               estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  3.5000000 0.9636241  0.52945580 23.1369642 0.19358261
OR_TRTvsCTRL  6.0000000 1.2051477  0.56536338 63.6758606 0.13707950
ARR_TRTvsCTRL 0.3571429 0.1880156 -0.01136089  0.7256466 0.05749368


$Diarrhoea
$Diarrhoea$ntab
            CTRL TRT
n_all          7  14
n_event        0   2
n_event_pct    0  14

$Diarrhoea$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.6666667 1.48604621  0.14489183 49.0787574 0.5092371
OR_TRTvsCTRL  3.0000000 1.61658075  0.12620752 71.3111249 0.4967640
ARR_TRTvsCTRL 0.1428571 0.09352195 -0.04044252  0.3261568 0.1266305


$Erythema
$Erythema$ntab
            CTRL TRT
n_all          7  14
n_event        2   1
n_event_pct   29   7

$Erythema$stats
                estimate        se      lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.2500000 1.1338934  0.02708745 2.307341 0.2214821
OR_TRTvsCTRL   0.1923077 1.3330128  0.01410373 2.622160 0.2161646
ARR_TRTvsCTRL -0.2142857 0.1840981 -0.57511145 0.146540 0.2444340


$Flushing
$Flushing$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$Flushing$stats
```

```
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Gastroenteritis
$Gastroenteritis$ntab
            CTRL TRT
n_all          7  14
n_event        0   2
n_event_pct    0  14

$Gastroenteritis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.6666667 1.48604621  0.14489183 49.0787574 0.5092371
OR_TRTvsCTRL  3.0000000 1.61658075  0.12620752 71.3111249 0.4967640
ARR_TRTvsCTRL 0.1428571 0.09352195 -0.04044252  0.3261568 0.1266305


$Hypertension
$Hypertension$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$Hypertension$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Hypokalaemia
$Hypokalaemia$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$Hypokalaemia$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Intermittent explosive disorder`
$`Intermittent explosive disorder`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0
```

```
$`Intermittent explosive disorder`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Irritability
$Irritability$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$Irritability$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Nasal congestion`
$`Nasal congestion`$ntab
            CTRL TRT
n_all          7  14
n_event        0   3
n_event_pct    0  21

$`Nasal congestion`$stats
               estimate        se        lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  3.7333333 1.4470825  0.2189464726  63.6583801 0.36265618
OR_TRTvsCTRL  4.5652174 1.5830364  0.2051060468 101.6118742 0.33745238
ARR_TRTvsCTRL 0.2142857 0.1096642 -0.0006521887   0.4292236 0.05069923


$`Pain in extremity`
$`Pain in extremity`$ntab
            CTRL TRT
n_all          7  14
n_event        0   3
n_event_pct    0  21

$`Pain in extremity`$stats
               estimate        se        lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  3.7333333 1.4470825  0.2189464726  63.6583801 0.36265618
OR_TRTvsCTRL  4.5652174 1.5830364  0.2051060468 101.6118742 0.33745238
ARR_TRTvsCTRL 0.2142857 0.1096642 -0.0006521887   0.4292236 0.05069923


$`Procedural pain`
$`Procedural pain`$ntab
            CTRL TRT
n_all          7  14
```

```
n_event        0   3
n_event_pct    0  21

$`Procedural pain`$stats
               estimate        se         lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  3.7333333 1.4470825  0.2189464726  63.6583801 0.36265618
OR_TRTvsCTRL  4.5652174 1.5830364  0.2051060468 101.6118742 0.33745238
ARR_TRTvsCTRL 0.2142857 0.1096642 -0.0006521887   0.4292236 0.05069923


$`Procedural vomiting`
$`Procedural vomiting`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Procedural vomiting`$stats
                estimate       se        lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Pyrexia
$Pyrexia$ntab
            CTRL TRT
n_all          7  14
n_event        1   6
n_event_pct   14  43

$Pyrexia$stats
               estimate        se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  3.0000000 0.9759001  0.44303048 20.3146294 0.2602745
OR_TRTvsCTRL  4.5000000 1.2076147  0.42197721 47.9883740 0.2129501
ARR_TRTvsCTRL 0.2857143 0.1870439 -0.08088503  0.6523136 0.1266305


$`Respiratory tract infection`
$`Respiratory tract infection`$ntab
            CTRL TRT
n_all          7  14
n_event        1   2
n_event_pct   14  14

$`Respiratory tract infection`$stats
              estimate        se      lo95ci     hi95ci pvalue
RR_TRTvsCTRL         1 1.1338934  0.10834981  9.2293651      1
OR_TRTvsCTRL         1 1.3228757  0.07481113 13.3669954      1
ARR_TRTvsCTRL        0 0.1619848 -0.31748432  0.3174843      1


$Rhinorrhoea
$Rhinorrhoea$ntab
```

```
            CTRL TRT
n_all          7  14
n_event        0   2
n_event_pct    0  14

$Rhinorrhoea$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.6666667 1.48604621  0.14489183 49.0787574 0.5092371
OR_TRTvsCTRL  3.0000000 1.61658075  0.12620752 71.3111249 0.4967640
ARR_TRTvsCTRL 0.1428571 0.09352195 -0.04044252  0.3261568 0.1266305


$`Skin irritation`
$`Skin irritation`$ntab
            CTRL TRT
n_all          7  14
n_event        1   1
n_event_pct   14   7

$`Skin irritation`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
OR_TRTvsCTRL   0.46153846 1.4978617  0.02450336 8.6934089 0.6057177
ARR_TRTvsCTRL -0.07142857 0.1490984 -0.36365599 0.2207988 0.6318887


$Tachycardia
$Tachycardia$ntab
            CTRL TRT
n_all          7  14
n_event        2   2
n_event_pct   29  14

$Tachycardia$stats
                estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.5000000 0.8864053  0.08799550 2.8410543 0.4342290
OR_TRTvsCTRL   0.4166667 1.1328430  0.04523879 3.8376600 0.4396368
ARR_TRTvsCTRL -0.1428571 0.1946815 -0.52442581 0.2387115 0.4630710


$Teething
$Teething$ntab
            CTRL TRT
n_all          7  14
n_event        2   1
n_event_pct   29   7

$Teething$stats
                estimate        se      lo95ci   hi95ci    pvalue
RR_TRTvsCTRL   0.2500000 1.1338934  0.02708745 2.307341 0.2214821
OR_TRTvsCTRL   0.1923077 1.3330128  0.01410373 2.622160 0.2161646
ARR_TRTvsCTRL -0.2142857 0.1840981 -0.57511145 0.146540 0.2444340
```

```
$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$ntab
            CTRL TRT
n_all          7  14
n_event        2   4
n_event_pct   29  29

$`Upper respiratory tract infection`$stats
              estimate        se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.7319251  0.2382233 4.1977419      1
OR_TRTvsCTRL         1 1.0246951  0.1342079 7.4511281      1
ARR_TRTvsCTRL        0 0.2091214 -0.4098705 0.4098705      1


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all          7  14
n_event        0   2
n_event_pct    0  14

$`Viral upper respiratory tract infection`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.6666667 1.48604621  0.14489183 49.0787574 0.5092371
OR_TRTvsCTRL  3.0000000 1.61658075  0.12620752 71.3111249 0.4967640
ARR_TRTvsCTRL 0.1428571 0.09352195 -0.04044252  0.3261568 0.1266305


$Vomiting
$Vomiting$ntab
            CTRL TRT
n_all          7  14
n_event        1   4
n_event_pct   14  29

$Vomiting$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.0000000 1.0177005  0.2721208 14.6993531 0.4958136
OR_TRTvsCTRL  2.4000000 1.2315302  0.2147488 26.8220310 0.4771593
ARR_TRTvsCTRL 0.1428571 0.1790809 -0.2081350  0.4938493 0.4250307



\#############################################################################
#
[[1]]
[1] "Number of patients with mild AEs according to PT at least 10 Patients and
1% Patients in one Study Arm"


\#############################################################################
#
[[1]]
[1] "Time to mild AEs according to PT at least in 10% Patients in one Study
```

Arm"

$`Aphthous ulcer`
$`Aphthous ulcer`$stats_num

	ARMCD=CONTROL	ARMCD=ISIS
n_all	7.0	14
n_event	1.0	0
n_event_pct	14.0	0
time-to-event-wk-10th	11.9	NA
time-to-event-wk-25th	NA	NA
time-to-event-wk-50th	NA	NA
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	11.9	NA
time-to-event-wk-50th-hici	NA	NA

$`Aphthous ulcer`$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
3.000e-10	4.472e+04	0.000e+00	Inf	9.996e-01

$Constipation
$Constipation$stats_num

	ARMCD=CONTROL	ARMCD=ISIS
n_all	7.0	14
n_event	1.0	1
n_event_pct	14.0	7
time-to-event-wk-10th	40.4	55
time-to-event-wk-25th	NA	NA
time-to-event-wk-50th	NA	NA
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	40.4	55
time-to-event-wk-50th-hici	NA	NA

$Constipation$stats_HR_TRTvsCTRL

HR	SE_logHR	HR.lo95ci	HR.hi95ci	p.value
0.26390	1.53300	0.01308	5.32300	0.38480

$Contusion
$Contusion$stats_num

	ARMCD=CONTROL	ARMCD=ISIS
n_all	7.0	14
n_event	1.0	0
n_event_pct	14.0	0
time-to-event-wk-10th	2.7	NA
time-to-event-wk-25th	NA	NA
time-to-event-wk-50th	NA	NA
time-to-event-wk-75th	NA	NA
time-to-event-wk-90th	NA	NA
time-to-event-wk-50th-loci	2.7	NA
time-to-event-wk-50th-hici	NA	NA

```
$Contusion$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$Cough
$Cough$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        7.0
n_event_pct                         14.0       50.0
time-to-event-wk-10th                1.3        5.0
time-to-event-wk-25th                 NA       14.0
time-to-event-wk-50th                 NA       50.0
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           1.3        9.4
time-to-event-wk-50th-hici            NA         NA

$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.5770    1.0710    0.4388   29.1700    0.2338


$Diarrhoea
$Diarrhoea$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7         14
n_event                                0          2
n_event_pct                            0         14
time-to-event-wk-10th                 NA         50
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         50
time-to-event-wk-50th-hici            NA         NA

$Diarrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.450e+08 1.995e+04 0.000e+00       Inf 9.992e-01


$Erythema
$Erythema$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              2.0          1
n_event_pct                         29.0          7
time-to-event-wk-10th                0.1         NA
time-to-event-wk-25th                1.1         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
```

```
time-to-event-wk-50th-loci           0.1         NA
time-to-event-wk-50th-hici            NA         NA

$Erythema$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.27590   1.23400   0.02455   3.10000   0.29680


$Flushing
$Flushing$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th                1.1         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           1.1         NA
time-to-event-wk-50th-hici            NA         NA

$Flushing$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$Gastroenteritis
$Gastroenteritis$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7       14.0
n_event                                0        2.0
n_event_pct                            0       14.0
time-to-event-wk-10th                 NA       34.9
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$Gastroenteritis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.503e+08 1.885e+04 0.000e+00       Inf 9.992e-01


$Hypertension
$Hypertension$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7         14
n_event                                1          0
n_event_pct                           14          0
time-to-event-wk-10th                 41         NA
time-to-event-wk-25th                 NA         NA
```

```
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            41         NA
time-to-event-wk-50th-hici            NA         NA

$Hypertension$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$Hypokalaemia
$Hypokalaemia$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th                2.4         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.4         NA
time-to-event-wk-50th-hici            NA         NA

$Hypokalaemia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.026e-10 4.684e+04 0.000e+00       Inf 9.996e-01


$`Intermittent explosive disorder`
$`Intermittent explosive disorder`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th                0.9         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           0.9         NA
time-to-event-wk-50th-hici            NA         NA

$`Intermittent explosive disorder`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$Irritability
$Irritability$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
```

```
n_event_pct                          14.0          0
time-to-event-wk-10th                 2.4         NA
time-to-event-wk-25th                  NA         NA
time-to-event-wk-50th                  NA         NA
time-to-event-wk-75th                  NA         NA
time-to-event-wk-90th                  NA         NA
time-to-event-wk-50th-loci            2.4         NA
time-to-event-wk-50th-hici             NA         NA

$Irritability$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$`Nasal congestion`
$`Nasal congestion`$stats_num
                          ARMCD=CONTROL ARMCD=ISIS
n_all                                 7       14.0
n_event                               0        3.0
n_event_pct                           0       21.0
time-to-event-wk-10th                NA        9.4
time-to-event-wk-25th                NA         NA
time-to-event-wk-50th                NA         NA
time-to-event-wk-75th                NA         NA
time-to-event-wk-90th                NA         NA
time-to-event-wk-50th-loci           NA       25.1
time-to-event-wk-50th-hici           NA         NA

$`Nasal congestion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.045e+08 2.443e+04 0.000e+00       Inf 9.993e-01


$`Pain in extremity`
$`Pain in extremity`$stats_num
                          ARMCD=CONTROL ARMCD=ISIS
n_all                                 7       14.0
n_event                               0        3.0
n_event_pct                           0       21.0
time-to-event-wk-10th                NA       13.3
time-to-event-wk-25th                NA         NA
time-to-event-wk-50th                NA         NA
time-to-event-wk-75th                NA         NA
time-to-event-wk-90th                NA         NA
time-to-event-wk-50th-loci           NA       39.4
time-to-event-wk-50th-hici           NA         NA

$`Pain in extremity`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.515e+08 1.516e+04 0.000e+00       Inf 9.990e-01


$`Procedural pain`
$`Procedural pain`$stats_num
```

```
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7       14.0
n_event                                0        3.0
n_event_pct                            0       21.0
time-to-event-wk-10th                 NA        0.1
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA        2.0
time-to-event-wk-50th-hici            NA         NA

$`Procedural pain`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.111e+09 2.474e+04 0.000e+00       Inf 9.993e-01


$`Procedural vomiting`
$`Procedural vomiting`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               37.9         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          37.9         NA
time-to-event-wk-50th-hici            NA         NA

$`Procedural vomiting`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$Pyrexia
$Pyrexia$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        6.0
n_event_pct                         14.0       43.0
time-to-event-wk-10th                2.3        0.6
time-to-event-wk-25th                 NA        2.9
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3        1.7
time-to-event-wk-50th-hici            NA         NA

$Pyrexia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.4500    1.0820    0.4143   28.7400    0.2521
```

```
$`Respiratory tract infection`
$`Respiratory tract infection`$stats_num
                          ARMCD=CONTROL ARMCD=ISIS
n_all                               7.0       14.0
n_event                             1.0        2.0
n_event_pct                        14.0       14.0
time-to-event-wk-10th               8.4       36.6
time-to-event-wk-25th                NA         NA
time-to-event-wk-50th                NA         NA
time-to-event-wk-75th                NA         NA
time-to-event-wk-90th                NA         NA
time-to-event-wk-50th-loci          8.4         NA
time-to-event-wk-50th-hici           NA         NA

$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.95440   1.22700   0.08618  10.57000   0.96960


$Rhinorrhoea
$Rhinorrhoea$stats_num
                          ARMCD=CONTROL ARMCD=ISIS
n_all                                7       14.0
n_event                              0        2.0
n_event_pct                          0       14.0
time-to-event-wk-10th               NA       26.4
time-to-event-wk-25th               NA         NA
time-to-event-wk-50th               NA         NA
time-to-event-wk-75th               NA         NA
time-to-event-wk-90th               NA         NA
time-to-event-wk-50th-loci          NA         NA
time-to-event-wk-50th-hici          NA         NA

$Rhinorrhoea$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.397e+09 3.217e+04 0.000e+00       Inf 9.995e-01


$`Skin irritation`
$`Skin irritation`$stats_num
                          ARMCD=CONTROL ARMCD=ISIS
n_all                               7.0         14
n_event                             1.0          1
n_event_pct                        14.0          7
time-to-event-wk-10th               9.1         NA
time-to-event-wk-25th                NA         NA
time-to-event-wk-50th                NA         NA
time-to-event-wk-75th                NA         NA
time-to-event-wk-90th                NA         NA
time-to-event-wk-50th-loci          9.1         NA
time-to-event-wk-50th-hici           NA         NA

$`Skin irritation`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.48990   1.42100   0.03021   7.94500   0.61570


$Tachycardia
$Tachycardia$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              2.0        2.0
n_event_pct                         29.0       14.0
time-to-event-wk-10th                0.1        9.3
time-to-event-wk-25th               41.0         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           0.1         NA
time-to-event-wk-50th-hici            NA         NA

$Tachycardia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.45030   1.00400   0.06295   3.22100   0.42680


$Teething
$Teething$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              2.0          1
n_event_pct                         29.0          7
time-to-event-wk-10th                3.7         54
time-to-event-wk-25th               12.1         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           3.7         54
time-to-event-wk-50th-hici            NA         NA

$Teething$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.19600   1.28200   0.01588   2.42000   0.20380


$`Upper respiratory tract infection`
$`Upper respiratory tract infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              2.0        4.0
n_event_pct                         29.0       29.0
time-to-event-wk-10th                4.4       12.9
time-to-event-wk-25th               20.4       49.6
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           4.4       24.1
```

```
time-to-event-wk-50th-hici            NA         NA

$`Upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8528    0.9029    0.1453    5.0050    0.8600


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7       14.0
n_event                                0        2.0
n_event_pct                            0       14.0
time-to-event-wk-10th                 NA       41.1
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.066e+08 3.098e+04 0.000e+00       Inf 9.995e-01


$Vomiting
$Vomiting$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        4.0
n_event_pct                         14.0       29.0
time-to-event-wk-10th                2.3        0.6
time-to-event-wk-25th                 NA       26.4
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3        9.3
time-to-event-wk-50th-hici            NA         NA

$Vomiting$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   2.2290    1.1200    0.2480   20.0400    0.4743



\##############################################################################
#
[[1]]
[1] "Time to mild AEs according to PT at least 10 Patients and 1% Patients in
one Study Arm"


\##############################################################################
```

```
#
[[1]]
[1] "Number of patients with moderate AEs according to SOC at least in 10%
Patients in one Study Arm"

$`Immune system disorders`
$`Immune system disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Immune system disorders`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all          7  14
n_event        2  10
n_event_pct   29  71

$`Infections and infestations`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.5000000 0.6210590 0.74010549  8.4447421 0.14011357
OR_TRTvsCTRL  6.2500000 1.0246951 0.83879916 46.5695507 0.07370885
ARR_TRTvsCTRL 0.4285714 0.2091214 0.01870093  0.8384419 0.04042398


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all          7  14
n_event        1   1
n_event_pct   14   7

$`Injury, poisoning and procedural complications`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
OR_TRTvsCTRL   0.46153846 1.4978617  0.02450336 8.6934089 0.6057177
ARR_TRTvsCTRL -0.07142857 0.1490984 -0.36365599 0.2207988 0.6318887


$Investigations
$Investigations$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0
```

```
$Investigations$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        4   2
n_event_pct   57  14

$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci      hi95ci     pvalue
RR_TRTvsCTRL   0.2500000 0.7319251  0.05955583  1.04943548 0.05821988
OR_TRTvsCTRL   0.1250000 1.0801234  0.01504899  1.03827587 0.05420575
ARR_TRTvsCTRL -0.4285714 0.2091214 -0.83844193 -0.01870093 0.04042398



\#############################################################################
#
[[1]]
[1] "Number of patients with moderate AEs according to SOC at least 10 Patients
and 1% Patients in one Study Arm"

$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all          7  14
n_event        2  10
n_event_pct   29  71

$`Infections and infestations`$stats
                estimate        se     lo95ci     hi95ci     pvalue
RR_TRTvsCTRL  2.5000000 0.6210590 0.74010549  8.4447421 0.14011357
OR_TRTvsCTRL  6.2500000 1.0246951 0.83879916 46.5695507 0.07370885
ARR_TRTvsCTRL 0.4285714 0.2091214 0.01870093  0.8384419 0.04042398



\#############################################################################
#
[[1]]
[1] "Time to moderate AEs according to SOC at least in 10% Patients in one
Study Arm"

$`Immune system disorders`
$`Immune system disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
```

```
n_event_pct                          14.0          0
time-to-event-wk-10th                13.3         NA
time-to-event-wk-25th                  NA         NA
time-to-event-wk-50th                  NA         NA
time-to-event-wk-75th                  NA         NA
time-to-event-wk-90th                  NA         NA
time-to-event-wk-50th-loci           13.3         NA
time-to-event-wk-50th-hici             NA         NA

$`Immune system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$`Infections and infestations`
$`Infections and infestations`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              2.0       10.0
n_event_pct                         29.0       71.0
time-to-event-wk-10th               10.9        2.9
time-to-event-wk-25th               30.6        7.4
time-to-event-wk-50th                 NA       26.6
time-to-event-wk-75th                 NA       48.7
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          10.9        7.3
time-to-event-wk-50th-hici            NA       38.1

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.4450    0.7780    0.7499   15.8300    0.1119


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          1
n_event_pct                         14.0          7
time-to-event-wk-10th               15.6         52
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          15.6         52
time-to-event-wk-50th-hici            NA         NA

$`Injury, poisoning and procedural complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40490   1.44100   0.02404   6.82200   0.53040


$Investigations
$Investigations$stats_num
```

```
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               41.1         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          41.1         NA
time-to-event-wk-50th-hici            NA         NA

$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              4.0        2.0
n_event_pct                         57.0       14.0
time-to-event-wk-10th               12.4        9.9
time-to-event-wk-25th               21.0         NA
time-to-event-wk-50th               40.1         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          12.4         NA
time-to-event-wk-50th-hici            NA         NA

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.23000   0.87040   0.04177   1.26600   0.09127



\#############################################################################
#
[[1]]
[1] "Time to moderate AEs according to SOC at least 10 Patients and 1% Patients
in one Study Arm"

$`Infections and infestations`
$`Infections and infestations`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              2.0       10.0
n_event_pct                         29.0       71.0
time-to-event-wk-10th               10.9        2.9
time-to-event-wk-25th               30.6        7.4
time-to-event-wk-50th                 NA       26.6
time-to-event-wk-75th                 NA       48.7
time-to-event-wk-90th                 NA         NA
```

```
time-to-event-wk-50th-loci          10.9        7.3
time-to-event-wk-50th-hici            NA       38.1

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   3.4450    0.7780    0.7499   15.8300    0.1119



\#############################################################################
#
[[1]]
[1] "Number of patients with moderate AEs according to PT at least in 10%
Patients in one Study Arm"

$Aspiration
$Aspiration$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$Aspiration$stats
                 estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Bronchitis
$Bronchitis$ntab
            CTRL TRT
n_all          7  14
n_event        1   2
n_event_pct   14  14

$Bronchitis$stats
              estimate        se      lo95ci     hi95ci pvalue
RR_TRTvsCTRL         1 1.1338934  0.10834981  9.2293651      1
OR_TRTvsCTRL         1 1.3228757  0.07481113 13.3669954      1
ARR_TRTvsCTRL        0 0.1619848 -0.31748432  0.3174843      1


$`Drug hypersensitivity`
$`Drug hypersensitivity`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Drug hypersensitivity`$stats
                 estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
```

```
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Hypoxia
$Hypoxia$ntab
            CTRL TRT
n_all          7  14
n_event        2   0
n_event_pct   29   0

$Hypoxia$stats
                  estimate        se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.10666667 1.4860462  0.005795673 1.96315029 0.13205664
OR_TRTvsCTRL   0.07586207 1.6281228  0.003120068 1.84452813 0.11320881
ARR_TRTvsCTRL -0.28571429 0.1707469 -0.620372147 0.04894358 0.09426431


$`Increased bronchial secretion`
$`Increased bronchial secretion`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Increased bronchial secretion`$stats
                  estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Larynx irritation`
$`Larynx irritation`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Larynx irritation`$stats
                  estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Muscle strain`
$`Muscle strain`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Muscle strain`$stats
                  estimate       se       lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all          7  14
n_event        0   2
n_event_pct    0  14

$Pneumonia$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.6666667 1.48604621  0.14489183 49.0787574 0.5092371
OR_TRTvsCTRL  3.0000000 1.61658075  0.12620752 71.3111249 0.4967640
ARR_TRTvsCTRL 0.1428571 0.09352195 -0.04044252  0.3261568 0.1266305


$`Respiratory tract infection`
$`Respiratory tract infection`$ntab
            CTRL TRT
n_all          7  14
n_event        0   2
n_event_pct    0  14

$`Respiratory tract infection`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.6666667 1.48604621  0.14489183 49.0787574 0.5092371
OR_TRTvsCTRL  3.0000000 1.61658075  0.12620752 71.3111249 0.4967640
ARR_TRTvsCTRL 0.1428571 0.09352195 -0.04044252  0.3261568 0.1266305


$`Sleep apnoea syndrome`
$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Sleep apnoea syndrome`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Urine output increased`
$`Urine output increased`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0
```

```
$`Urine output increased`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all          7  14
n_event        1   2
n_event_pct   14  14

$`Viral upper respiratory tract infection`$stats
              estimate        se      lo95ci     hi95ci pvalue
RR_TRTvsCTRL         1 1.1338934  0.10834981  9.2293651      1
OR_TRTvsCTRL         1 1.3228757  0.07481113 13.3669954      1
ARR_TRTvsCTRL        0 0.1619848 -0.31748432  0.3174843      1



\#############################################################################
#
[[1]]
[1] "Number of patients with moderate AEs according to PT at least 10 Patients
and 1% Patients in one Study Arm"


\#############################################################################
#
[[1]]
[1] "Time to moderate AEs according to PT at least in 10% Patients in one Study
Arm"

$Aspiration
$Aspiration$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7         14
n_event                                1          0
n_event_pct                           14          0
time-to-event-wk-10th                 21         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            21         NA
time-to-event-wk-50th-hici            NA         NA

$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.026e-10 4.684e+04 0.000e+00       Inf 9.996e-01
```

```
$Bronchitis
$Bronchitis$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        2.0
n_event_pct                         14.0       14.0
time-to-event-wk-10th               30.6       19.6
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          30.6         NA
time-to-event-wk-50th-hici            NA         NA

$Bronchitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2230    1.2310    0.1096   13.6400    0.8701


$`Drug hypersensitivity`
$`Drug hypersensitivity`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               13.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          13.3         NA
time-to-event-wk-50th-hici            NA         NA

$`Drug hypersensitivity`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$Hypoxia
$Hypoxia$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              2.0          0
n_event_pct                         29.0          0
time-to-event-wk-10th               21.0         NA
time-to-event-wk-25th               40.1         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          21.0         NA
time-to-event-wk-50th-hici            NA         NA

$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
1.283e-10 3.682e+04 0.000e+00       Inf 9.995e-01


$`Increased bronchial secretion`
$`Increased bronchial secretion`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               40.1         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.1         NA
time-to-event-wk-50th-hici            NA         NA

$`Increased bronchial secretion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Larynx irritation`
$`Larynx irritation`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               12.4         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          12.4         NA
time-to-event-wk-50th-hici            NA         NA

$`Larynx irritation`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$`Muscle strain`
$`Muscle strain`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               15.6         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          15.6         NA
time-to-event-wk-50th-hici            NA         NA
```

```
$`Muscle strain`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$Pneumonia
$Pneumonia$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7       14.0
n_event                                0        2.0
n_event_pct                            0       14.0
time-to-event-wk-10th                 NA       27.4
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.476e+08 2.996e+04 0.000e+00       Inf 9.995e-01


$`Respiratory tract infection`
$`Respiratory tract infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7       14.0
n_event                                0        2.0
n_event_pct                            0       14.0
time-to-event-wk-10th                 NA       25.1
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.509e+08 3.002e+04 0.000e+00       Inf 9.995e-01


$`Sleep apnoea syndrome`
$`Sleep apnoea syndrome`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               35.6         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
```

```
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          35.6         NA
time-to-event-wk-50th-hici            NA         NA

$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.570e-10 5.047e+04 0.000e+00       Inf 9.996e-01


$`Urine output increased`
$`Urine output increased`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               41.1         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          41.1         NA
time-to-event-wk-50th-hici            NA         NA

$`Urine output increased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        2.0
n_event_pct                         14.0       14.0
time-to-event-wk-10th               10.9       39.3
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          10.9         NA
time-to-event-wk-50th-hici            NA         NA

$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7359    1.2270    0.0664    8.1570    0.8027



\##############################################################################
#
[[1]]
[1] "Time to moderate AEs according to PT at least 10 Patients and 1% Patients
in one Study Arm"
```

```
\##############################################################################
#
[[1]]
[1] "Number of patients with severe AEs according to SOC at least in 5%
Patients in one Study Arm"

$`Cardiac disorders`
$`Cardiac disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Cardiac disorders`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`General disorders and administration site conditions`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all          7  14
n_event        2   4
n_event_pct   29  29

$`Infections and infestations`$stats
              estimate        se     lo95ci    hi95ci pvalue
RR_TRTvsCTRL         1 0.7319251  0.2382233 4.1977419      1
OR_TRTvsCTRL         1 1.0246951  0.1342079 7.4511281      1
ARR_TRTvsCTRL        0 0.2091214 -0.4098705 0.4098705      1


$`Nervous system disorders`
$`Nervous system disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        2   0
```

```
n_event_pct   29   0

$`Nervous system disorders`$stats
                 estimate        se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.10666667 1.4860462  0.005795673 1.96315029 0.13205664
OR_TRTvsCTRL   0.07586207 1.6281228  0.003120068 1.84452813 0.11320881
ARR_TRTvsCTRL -0.28571429 0.1707469 -0.620372147 0.04894358 0.09426431


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        2   3
n_event_pct   29  21

$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.75000000 0.7867958  0.16044991 3.5057671 0.7146356
OR_TRTvsCTRL   0.68181818 1.0603030  0.08533693 5.4475361 0.7179423
ARR_TRTvsCTRL -0.07142857 0.2029304 -0.46916490 0.3263078 0.7248491



\#############################################################################
#
[[1]]
[1] "Number of patients with severe AEs according to SOC at least 10 Patients
and 1% Patients in one Study Arm"


\#############################################################################
#
[[1]]
[1] "Time to severe AEs according to SOC at least in 5% Patients in one Study
Arm"

$`Cardiac disorders`
$`Cardiac disorders`$stats_num
                          ARMCD=CONTROL ARMCD=ISIS
n_all                               7.0         14
n_event                             1.0          0
n_event_pct                        14.0          0
time-to-event-wk-10th              40.9         NA
time-to-event-wk-25th                NA         NA
time-to-event-wk-50th                NA         NA
time-to-event-wk-75th                NA         NA
time-to-event-wk-90th                NA         NA
time-to-event-wk-50th-loci         40.9         NA
time-to-event-wk-50th-hici           NA         NA

$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01
```

```
$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               41.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          41.3         NA
time-to-event-wk-50th-hici            NA         NA

$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Infections and infestations`
$`Infections and infestations`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              2.0        4.0
n_event_pct                         29.0       29.0
time-to-event-wk-10th                2.3        5.7
time-to-event-wk-25th               10.3       40.0
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3       10.1
time-to-event-wk-50th-hici            NA         NA

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.8657    0.8685    0.1578    4.7490    0.8681


$`Nervous system disorders`
$`Nervous system disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              2.0          0
n_event_pct                         29.0          0
time-to-event-wk-10th               19.1         NA
time-to-event-wk-25th               40.9         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          19.1         NA
time-to-event-wk-50th-hici            NA         NA
```

```
$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.283e-10 3.682e+04 0.000e+00       Inf 9.995e-01


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              2.0        3.0
n_event_pct                         29.0       21.0
time-to-event-wk-10th                2.3       10.1
time-to-event-wk-25th               40.9         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3       14.9
time-to-event-wk-50th-hici            NA         NA

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.6196    0.9150    0.1031    3.7240    0.6009



\#############################################################################
#
[[1]]
[1] "Time to severe AEs according to SOC at least 10 Patients and 1% Patients
in one Study Arm"


\#############################################################################
#
[[1]]
[1] "Number of patients with severe AEs according to PT at least in 5% Patients
in one Study Arm"

$`Acute respiratory failure`
$`Acute respiratory failure`$ntab
            CTRL TRT
n_all          7  14
n_event        1   1
n_event_pct   14   7

$`Acute respiratory failure`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
OR_TRTvsCTRL   0.46153846 1.4978617  0.02450336 8.6934089 0.6057177
ARR_TRTvsCTRL -0.07142857 0.1490984 -0.36365599 0.2207988 0.6318887


$`Brain death`
$`Brain death`$ntab
```

```
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Brain death`$stats
                 estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Bronchial secretion retention`
$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$`Bronchial secretion retention`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$Bronchiolitis
$Bronchiolitis$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$Bronchiolitis$stats
                 estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Cardio-respiratory arrest`
$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Cardio-respiratory arrest`$stats
                 estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872
```

```
$`Chronic respiratory failure`
$`Chronic respiratory failure`$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$`Chronic respiratory failure`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$Cough
$Cough$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$Cough$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$`Enterovirus infection`
$`Enterovirus infection`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Enterovirus infection`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Hypoxia
$Hypoxia$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$Hypoxia$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872
```

```
$`Hypoxic-ischaemic encephalopathy`
$`Hypoxic-ischaemic encephalopathy`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Hypoxic-ischaemic encephalopathy`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Loss of consciousness`
$`Loss of consciousness`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Loss of consciousness`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Lower respiratory tract infection`
$`Lower respiratory tract infection`$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$`Lower respiratory tract infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all          7  14
n_event        0   4
n_event_pct    0  29

$Pneumonia$stats
                estimate        se     lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  4.8000000 1.4249756 0.29396781  78.3759279 0.27098287
```

```
OR_TRTvsCTRL  6.4285714 1.5655011 0.29892176 138.2519973 0.23459767
ARR_TRTvsCTRL 0.2857143 0.1207363 0.04907544   0.5223531 0.01796048


$`Pneumonia aspiration`
$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$`Pneumonia aspiration`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$`Pneumonia haemophilus`
$`Pneumonia haemophilus`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Pneumonia haemophilus`$stats
                estimate       se        lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Respiratory distress`
$`Respiratory distress`$ntab
            CTRL TRT
n_all          7  14
n_event        1   2
n_event_pct   14  14

$`Respiratory distress`$stats
              estimate        se      lo95ci     hi95ci pvalue
RR_TRTvsCTRL         1 1.1338934  0.10834981  9.2293651      1
OR_TRTvsCTRL         1 1.3228757  0.07481113 13.3669954      1
ARR_TRTvsCTRL        0 0.1619848 -0.31748432  0.3174843      1


$`Respiratory failure`
$`Respiratory failure`$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$`Respiratory failure`$stats
```

```
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$`Respiratory syncytial virus bronchiolitis`
$`Respiratory syncytial virus bronchiolitis`$ntab
           CTRL TRT
n_all         7  14
n_event       0   1
n_event_pct   0   7

$`Respiratory syncytial virus bronchiolitis`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$`Respiratory syncytial virus infection`
$`Respiratory syncytial virus infection`$ntab
           CTRL TRT
n_all         7  14
n_event       0   1
n_event_pct   0   7

$`Respiratory syncytial virus infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$`Respiratory tract infection`
$`Respiratory tract infection`$ntab
           CTRL TRT
n_all         7  14
n_event       1   0
n_event_pct  14   0

$`Respiratory tract infection`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Restrictive pulmonary disease`
$`Restrictive pulmonary disease`$ntab
           CTRL TRT
n_all         7  14
n_event       0   1
n_event_pct   0   7
```

```
$`Restrictive pulmonary disease`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$`Rhinovirus infection`
$`Rhinovirus infection`$ntab
            CTRL TRT
n_all          7  14
n_event        1   1
n_event_pct   14   7

$`Rhinovirus infection`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
OR_TRTvsCTRL   0.46153846 1.4978617  0.02450336 8.6934089 0.6057177
ARR_TRTvsCTRL -0.07142857 0.1490984 -0.36365599 0.2207988 0.6318887



\#############################################################################
#
[[1]]
[1] "Number of patients with severe AEs according to PT at least 10 Patients
and 1% Patients in one Study Arm"


\#############################################################################
#
[[1]]
[1] "Time to severe AEs according to PT at least in 5% Patients in one Study
Arm"

$`Acute respiratory failure`
$`Acute respiratory failure`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          1
n_event_pct                         14.0          7
time-to-event-wk-10th               19.1         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          19.1         NA
time-to-event-wk-50th-hici            NA         NA

$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47140   1.41500   0.02945   7.54600   0.59500
```

```
$`Brain death`
$`Brain death`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               41.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          41.3         NA
time-to-event-wk-50th-hici            NA         NA

$`Brain death`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Bronchial secretion retention`
$`Bronchial secretion retention`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7         14
n_event                              0          1
n_event_pct                          0          7
time-to-event-wk-10th               NA         NA
time-to-event-wk-25th               NA         NA
time-to-event-wk-50th               NA         NA
time-to-event-wk-75th               NA         NA
time-to-event-wk-90th               NA         NA
time-to-event-wk-50th-loci          NA         NA
time-to-event-wk-50th-hici          NA         NA

$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.069e+08 4.261e+04 0.000e+00       Inf 9.996e-01


$Bronchiolitis
$Bronchiolitis$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               40.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.3         NA
time-to-event-wk-50th-hici            NA         NA

$Bronchiolitis$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Cardio-respiratory arrest`
$`Cardio-respiratory arrest`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               40.9         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.9         NA
time-to-event-wk-50th-hici            NA         NA

$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Chronic respiratory failure`
$`Chronic respiratory failure`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7         14
n_event                                0          1
n_event_pct                            0          7
time-to-event-wk-10th                 NA         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$`Chronic respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.722e+08 4.245e+04 0.000e+00       Inf 9.996e-01


$Cough
$Cough$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7         14
n_event                                0          1
n_event_pct                            0          7
time-to-event-wk-10th                 NA         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
```

```
time-to-event-wk-50th-hici            NA         NA

$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.069e+08 4.261e+04 0.000e+00       Inf 9.996e-01


$`Enterovirus infection`
$`Enterovirus infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th                2.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3         NA
time-to-event-wk-50th-hici            NA         NA

$`Enterovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.026e-10 4.684e+04 0.000e+00       Inf 9.996e-01


$Hypoxia
$Hypoxia$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th                2.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3         NA
time-to-event-wk-50th-hici            NA         NA

$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.026e-10 4.684e+04 0.000e+00       Inf 9.996e-01


$`Hypoxic-ischaemic encephalopathy`
$`Hypoxic-ischaemic encephalopathy`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               40.9         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
```

```
time-to-event-wk-75th                  NA         NA
time-to-event-wk-90th                  NA         NA
time-to-event-wk-50th-loci          40.9          NA
time-to-event-wk-50th-hici            NA         NA

$`Hypoxic-ischaemic encephalopathy`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Loss of consciousness`
$`Loss of consciousness`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               19.1          NA
time-to-event-wk-25th                 NA          NA
time-to-event-wk-50th                 NA          NA
time-to-event-wk-75th                 NA          NA
time-to-event-wk-90th                 NA          NA
time-to-event-wk-50th-loci          19.1          NA
time-to-event-wk-50th-hici            NA          NA

$`Loss of consciousness`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.026e-10 4.684e+04 0.000e+00       Inf 9.996e-01


$`Lower respiratory tract infection`
$`Lower respiratory tract infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7         14
n_event                              0          1
n_event_pct                          0          7
time-to-event-wk-10th               NA          NA
time-to-event-wk-25th               NA          NA
time-to-event-wk-50th               NA          NA
time-to-event-wk-75th               NA          NA
time-to-event-wk-90th               NA          NA
time-to-event-wk-50th-loci          NA          NA
time-to-event-wk-50th-hici          NA          NA

$`Lower respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.069e+08 4.261e+04 0.000e+00       Inf 9.996e-01


$Pneumonia
$Pneumonia$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7       14.0
n_event                              0        4.0
n_event_pct                          0       29.0
```

```
time-to-event-wk-10th                  NA       10.1
time-to-event-wk-25th                  NA       40.0
time-to-event-wk-50th                  NA         NA
time-to-event-wk-75th                  NA         NA
time-to-event-wk-90th                  NA         NA
time-to-event-wk-50th-loci             NA       17.7
time-to-event-wk-50th-hici             NA         NA

$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.732e+08 2.145e+04 0.000e+00       Inf 9.992e-01


$`Pneumonia aspiration`
$`Pneumonia aspiration`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7         14
n_event                                0          1
n_event_pct                            0          7
time-to-event-wk-10th                 NA         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
7.722e+08 4.245e+04 0.000e+00       Inf 9.996e-01


$`Pneumonia haemophilus`
$`Pneumonia haemophilus`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               10.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          10.3         NA
time-to-event-wk-50th-hici            NA         NA

$`Pneumonia haemophilus`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$`Respiratory distress`
$`Respiratory distress`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
```

```
n_all                                7.0       14.0
n_event                              1.0        2.0
n_event_pct                         14.0       14.0
time-to-event-wk-10th               40.9       10.1
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.9         NA
time-to-event-wk-50th-hici            NA         NA

$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0240    1.2270    0.0925   11.3400    0.9844


$`Respiratory failure`
$`Respiratory failure`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7       14.0
n_event                                0        1.0
n_event_pct                            0        7.0
time-to-event-wk-10th                 NA       47.6
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA       47.6
time-to-event-wk-50th-hici            NA         NA

$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
4.534e+08 4.761e+04 0.000e+00       Inf 9.997e-01


$`Respiratory syncytial virus bronchiolitis`
$`Respiratory syncytial virus bronchiolitis`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7         14
n_event                                0          1
n_event_pct                            0          7
time-to-event-wk-10th                 NA         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$`Respiratory syncytial virus bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.069e+08 4.261e+04 0.000e+00       Inf 9.996e-01
```

```
$`Respiratory syncytial virus infection`
$`Respiratory syncytial virus infection`$stats_num
                          ARMCD=CONTROL ARMCD=ISIS
n_all                                 7         14
n_event                               0          1
n_event_pct                           0          7
time-to-event-wk-10th                NA         NA
time-to-event-wk-25th                NA         NA
time-to-event-wk-50th                NA         NA
time-to-event-wk-75th                NA         NA
time-to-event-wk-90th                NA         NA
time-to-event-wk-50th-loci           NA         NA
time-to-event-wk-50th-hici           NA         NA

$`Respiratory syncytial virus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.069e+08 4.261e+04 0.000e+00       Inf 9.996e-01


$`Respiratory tract infection`
$`Respiratory tract infection`$stats_num
                          ARMCD=CONTROL ARMCD=ISIS
n_all                               7.0         14
n_event                             1.0          0
n_event_pct                        14.0          0
time-to-event-wk-10th              19.6         NA
time-to-event-wk-25th                NA         NA
time-to-event-wk-50th                NA         NA
time-to-event-wk-75th                NA         NA
time-to-event-wk-90th                NA         NA
time-to-event-wk-50th-loci         19.6         NA
time-to-event-wk-50th-hici           NA         NA

$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$`Restrictive pulmonary disease`
$`Restrictive pulmonary disease`$stats_num
                          ARMCD=CONTROL ARMCD=ISIS
n_all                                 7         14
n_event                               0          1
n_event_pct                           0          7
time-to-event-wk-10th                NA         NA
time-to-event-wk-25th                NA         NA
time-to-event-wk-50th                NA         NA
time-to-event-wk-75th                NA         NA
time-to-event-wk-90th                NA         NA
time-to-event-wk-50th-loci           NA         NA
time-to-event-wk-50th-hici           NA         NA

$`Restrictive pulmonary disease`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
7.722e+08 4.245e+04 0.000e+00       Inf 9.996e-01


$`Rhinovirus infection`
$`Rhinovirus infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        1.0
n_event_pct                         14.0        7.0
time-to-event-wk-10th                2.3       47.6
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3       47.6
time-to-event-wk-50th-hici            NA         NA

$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.29810   1.44200   0.01764   5.03800   0.40150



\#############################################################################
#
[[1]]
[1] "Time to severe AEs according to PT at least 10 Patients and 1% Patients in
one Study Arm"


\#############################################################################
#
[[1]]
[1] "Number of patients with moderate or severe AEs according to SOC at least
in 10% Patients in one Study Arm"

$`Cardiac disorders`
$`Cardiac disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Cardiac disorders`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all          7  14
```

```
n_event        1   1
n_event_pct   14   7

$`General disorders and administration site conditions`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
OR_TRTvsCTRL   0.46153846 1.4978617  0.02450336 8.6934089 0.6057177
ARR_TRTvsCTRL -0.07142857 0.1490984 -0.36365599 0.2207988 0.6318887


$`Immune system disorders`
$`Immune system disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Immune system disorders`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all          7  14
n_event        4  10
n_event_pct   57  71

$`Infections and infestations`$stats
                estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.2500000 0.3683942  0.6072008  2.5732840 0.5447010
OR_TRTvsCTRL  1.8750000 0.9660918  0.2822685 12.4548955 0.5152584
ARR_TRTvsCTRL 0.1428571 0.2226268 -0.2934833  0.5791976 0.5210752


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$ntab
            CTRL TRT
n_all          7  14
n_event        1   1
n_event_pct   14   7

$`Injury, poisoning and procedural complications`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
OR_TRTvsCTRL   0.46153846 1.4978617  0.02450336 8.6934089 0.6057177
ARR_TRTvsCTRL -0.07142857 0.1490984 -0.36365599 0.2207988 0.6318887


$Investigations
$Investigations$ntab
```

```
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$Investigations$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Nervous system disorders`
$`Nervous system disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        2   0
n_event_pct   29   0

$`Nervous system disorders`$stats
                 estimate        se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.10666667 1.4860462  0.005795673 1.96315029 0.13205664
OR_TRTvsCTRL   0.07586207 1.6281228  0.003120068 1.84452813 0.11320881
ARR_TRTvsCTRL -0.28571429 0.1707469 -0.620372147 0.04894358 0.09426431


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        4   3
n_event_pct   57  21

$`Respiratory, thoracic and mediastinal disorders`$stats
                estimate        se      lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.3750000 0.6074929  0.11400723 1.23347445 0.10640761
OR_TRTvsCTRL   0.2045455 1.0037807  0.02860027 1.46288282 0.11388084
ARR_TRTvsCTRL -0.3571429 0.2168217 -0.78210564 0.06781992 0.09952253



\#############################################################################
#
[[1]]
[1] "Number of patients with moderate or severe AEs according to SOC at least
10 Patients and 1% Patients in one Study Arm"

$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all          7  14
n_event        4  10
n_event_pct   57  71
```

```
$`Infections and infestations`$stats
               estimate        se     lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.2500000 0.3683942  0.6072008  2.5732840 0.5447010
OR_TRTvsCTRL  1.8750000 0.9660918  0.2822685 12.4548955 0.5152584
ARR_TRTvsCTRL 0.1428571 0.2226268 -0.2934833  0.5791976 0.5210752



\################################################################################
#
[[1]]
[1] "Time to moderate or severe AEs according to SOC at least in 10% Patients
in one Study Arm"

$`Cardiac disorders`
$`Cardiac disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               40.9         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.9         NA
time-to-event-wk-50th-hici            NA         NA

$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          1
n_event_pct                         14.0          7
time-to-event-wk-10th               41.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          41.3         NA
time-to-event-wk-50th-hici            NA         NA

$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47140   1.41500   0.02945   7.54600   0.59500


$`Immune system disorders`
$`Immune system disorders`$stats_num
```

```
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               13.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          13.3         NA
time-to-event-wk-50th-hici            NA         NA

$`Immune system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$`Infections and infestations`
$`Infections and infestations`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              4.0       10.0
n_event_pct                         57.0       71.0
time-to-event-wk-10th                2.3        2.9
time-to-event-wk-25th               10.3        7.4
time-to-event-wk-50th               30.6       22.6
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3        5.7
time-to-event-wk-50th-hici            NA         NA

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3480    0.5947    0.4201    4.3220    0.6159


$`Injury, poisoning and procedural complications`
$`Injury, poisoning and procedural complications`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          1
n_event_pct                         14.0          7
time-to-event-wk-10th               15.6         52
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          15.6         52
time-to-event-wk-50th-hici            NA         NA

$`Injury, poisoning and procedural complications`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.40490   1.44100   0.02404   6.82200   0.53040
```

```
$Investigations
$Investigations$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               41.1         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          41.1         NA
time-to-event-wk-50th-hici            NA         NA

$Investigations$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Nervous system disorders`
$`Nervous system disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              2.0          0
n_event_pct                         29.0          0
time-to-event-wk-10th               19.1         NA
time-to-event-wk-25th               40.9         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          19.1         NA
time-to-event-wk-50th-hici            NA         NA

$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.283e-10 3.682e+04 0.000e+00       Inf 9.995e-01


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              4.0        3.0
n_event_pct                         57.0       21.0
time-to-event-wk-10th                2.3        9.9
time-to-event-wk-25th               12.4         NA
time-to-event-wk-50th               35.6         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3       14.9
time-to-event-wk-50th-hici            NA         NA

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
```

```
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.31360   0.76730   0.06972   1.41100   0.13070



\#############################################################################
#
[[1]]
[1] "Time to moderate or severe AEs according to SOC at least 10 Patients and
1% Patients in one Study Arm"

$`Infections and infestations`
$`Infections and infestations`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              4.0       10.0
n_event_pct                         57.0       71.0
time-to-event-wk-10th                2.3        2.9
time-to-event-wk-25th               10.3        7.4
time-to-event-wk-50th               30.6       22.6
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3        5.7
time-to-event-wk-50th-hici            NA         NA

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.3480    0.5947    0.4201    4.3220    0.6159



\#############################################################################
#
[[1]]
[1] "Number of patients with moderate or severe AEs according to PT at least in
10% Patients in one Study Arm"

$`Acute respiratory failure`
$`Acute respiratory failure`$ntab
            CTRL TRT
n_all          7  14
n_event        1   1
n_event_pct   14   7

$`Acute respiratory failure`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
OR_TRTvsCTRL   0.46153846 1.4978617  0.02450336 8.6934089 0.6057177
ARR_TRTvsCTRL -0.07142857 0.1490984 -0.36365599 0.2207988 0.6318887


$Aspiration
$Aspiration$ntab
            CTRL TRT
```

```
n_all          7  14
n_event        1   0
n_event_pct   14   0

$Aspiration$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Brain death`
$`Brain death`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Brain death`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Bronchiolitis
$Bronchiolitis$ntab
            CTRL TRT
n_all          7  14
n_event        1   1
n_event_pct   14   7

$Bronchiolitis$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
OR_TRTvsCTRL   0.46153846 1.4978617  0.02450336 8.6934089 0.6057177
ARR_TRTvsCTRL -0.07142857 0.1490984 -0.36365599 0.2207988 0.6318887


$Bronchitis
$Bronchitis$ntab
            CTRL TRT
n_all          7  14
n_event        1   2
n_event_pct   14  14

$Bronchitis$stats
              estimate        se      lo95ci     hi95ci pvalue
RR_TRTvsCTRL         1 1.1338934  0.10834981  9.2293651      1
OR_TRTvsCTRL         1 1.3228757  0.07481113 13.3669954      1
ARR_TRTvsCTRL        0 0.1619848 -0.31748432  0.3174843      1


$`Cardio-respiratory arrest`
```

```
$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Cardio-respiratory arrest`$stats
                 estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Cough
$Cough$ntab
            CTRL TRT
n_all          7  14
n_event        0   2
n_event_pct    0  14

$Cough$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.6666667 1.48604621  0.14489183 49.0787574 0.5092371
OR_TRTvsCTRL  3.0000000 1.61658075  0.12620752 71.3111249 0.4967640
ARR_TRTvsCTRL 0.1428571 0.09352195 -0.04044252  0.3261568 0.1266305


$`Drug hypersensitivity`
$`Drug hypersensitivity`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Drug hypersensitivity`$stats
                 estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Enterovirus infection`
$`Enterovirus infection`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Enterovirus infection`$stats
                 estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872
```

```
$Hypoxia
$Hypoxia$ntab
            CTRL TRT
n_all          7  14
n_event        2   0
n_event_pct   29   0

$Hypoxia$stats
                 estimate        se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.10666667 1.4860462  0.005795673 1.96315029 0.13205664
OR_TRTvsCTRL   0.07586207 1.6281228  0.003120068 1.84452813 0.11320881
ARR_TRTvsCTRL -0.28571429 0.1707469 -0.620372147 0.04894358 0.09426431


$`Hypoxic-ischaemic encephalopathy`
$`Hypoxic-ischaemic encephalopathy`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Hypoxic-ischaemic encephalopathy`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Increased bronchial secretion`
$`Increased bronchial secretion`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Increased bronchial secretion`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Larynx irritation`
$`Larynx irritation`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Larynx irritation`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
```

```
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Loss of consciousness`
$`Loss of consciousness`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Loss of consciousness`$stats
                 estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Muscle strain`
$`Muscle strain`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Muscle strain`$stats
                 estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all          7  14
n_event        0   5
n_event_pct    0  36

$Pneumonia$stats
                estimate        se    lo95ci      hi95ci      pvalue
RR_TRTvsCTRL  5.8666667 1.4107273 0.3694691  93.1546778 0.209781573
OR_TRTvsCTRL  8.6842105 1.5557682 0.4115836 183.2325522 0.164726355
ARR_TRTvsCTRL 0.3571429 0.1280602 0.1061495   0.6081363 0.005289282


$`Pneumonia aspiration`
$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all          7  14
n_event        0   2
n_event_pct    0  14

$`Pneumonia aspiration`$stats
                estimate         se      lo95ci     hi95ci    pvalue
```

```
RR_TRTvsCTRL  2.6666667 1.48604621  0.14489183 49.0787574 0.5092371
OR_TRTvsCTRL  3.0000000 1.61658075  0.12620752 71.3111249 0.4967640
ARR_TRTvsCTRL 0.1428571 0.09352195 -0.04044252  0.3261568 0.1266305


$`Pneumonia haemophilus`
$`Pneumonia haemophilus`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Pneumonia haemophilus`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Respiratory distress`
$`Respiratory distress`$ntab
            CTRL TRT
n_all          7  14
n_event        1   2
n_event_pct   14  14

$`Respiratory distress`$stats
              estimate        se      lo95ci     hi95ci pvalue
RR_TRTvsCTRL         1 1.1338934  0.10834981  9.2293651      1
OR_TRTvsCTRL         1 1.3228757  0.07481113 13.3669954      1
ARR_TRTvsCTRL        0 0.1619848 -0.31748432  0.3174843      1


$`Respiratory failure`
$`Respiratory failure`$ntab
            CTRL TRT
n_all          7  14
n_event        0   2
n_event_pct    0  14

$`Respiratory failure`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.6666667 1.48604621  0.14489183 49.0787574 0.5092371
OR_TRTvsCTRL  3.0000000 1.61658075  0.12620752 71.3111249 0.4967640
ARR_TRTvsCTRL 0.1428571 0.09352195 -0.04044252  0.3261568 0.1266305


$`Respiratory tract infection`
$`Respiratory tract infection`$ntab
            CTRL TRT
n_all          7  14
n_event        1   2
n_event_pct   14  14
```

```
$`Respiratory tract infection`$stats
              estimate        se      lo95ci     hi95ci pvalue
RR_TRTvsCTRL         1 1.1338934  0.10834981  9.2293651      1
OR_TRTvsCTRL         1 1.3228757  0.07481113 13.3669954      1
ARR_TRTvsCTRL        0 0.1619848 -0.31748432  0.3174843      1


$`Rhinovirus infection`
$`Rhinovirus infection`$ntab
            CTRL TRT
n_all          7  14
n_event        1   2
n_event_pct   14  14

$`Rhinovirus infection`$stats
              estimate        se      lo95ci     hi95ci pvalue
RR_TRTvsCTRL         1 1.1338934  0.10834981  9.2293651      1
OR_TRTvsCTRL         1 1.3228757  0.07481113 13.3669954      1
ARR_TRTvsCTRL        0 0.1619848 -0.31748432  0.3174843      1


$`Sleep apnoea syndrome`
$`Sleep apnoea syndrome`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Sleep apnoea syndrome`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Urine output increased`
$`Urine output increased`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Urine output increased`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$ntab
            CTRL TRT
n_all          7  14
n_event        1   2
```

```
n_event_pct   14  14

$`Viral upper respiratory tract infection`$stats
              estimate        se      lo95ci     hi95ci pvalue
RR_TRTvsCTRL         1 1.1338934  0.10834981  9.2293651      1
OR_TRTvsCTRL         1 1.3228757  0.07481113 13.3669954      1
ARR_TRTvsCTRL        0 0.1619848 -0.31748432  0.3174843      1



\#############################################################################
#
[[1]]
[1] "Number of patients with moderate or severe AEs according to PT at least 10
Patients and 1% Patients in one Study Arm"


\#############################################################################
#
[[1]]
[1] "Time to moderate or severe AEs according to PT at least in 10% Patients in
one Study Arm"

$`Acute respiratory failure`
$`Acute respiratory failure`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          1
n_event_pct                         14.0          7
time-to-event-wk-10th               19.1         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          19.1         NA
time-to-event-wk-50th-hici            NA         NA

$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47140   1.41500   0.02945   7.54600   0.59500


$Aspiration
$Aspiration$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7         14
n_event                              1          0
n_event_pct                         14          0
time-to-event-wk-10th               21         NA
time-to-event-wk-25th               NA         NA
time-to-event-wk-50th               NA         NA
time-to-event-wk-75th               NA         NA
time-to-event-wk-90th               NA         NA
time-to-event-wk-50th-loci          21         NA
```

```
time-to-event-wk-50th-hici            NA         NA

$Aspiration$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.026e-10 4.684e+04 0.000e+00       Inf 9.996e-01


$`Brain death`
$`Brain death`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               41.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          41.3         NA
time-to-event-wk-50th-hici            NA         NA

$`Brain death`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$Bronchiolitis
$Bronchiolitis$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          1
n_event_pct                         14.0          7
time-to-event-wk-10th               40.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.3         NA
time-to-event-wk-50th-hici            NA         NA

$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.46290   1.41500   0.02889   7.41600   0.58630


$Bronchitis
$Bronchitis$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        2.0
n_event_pct                         14.0       14.0
time-to-event-wk-10th               30.6       19.6
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
```

```
time-to-event-wk-75th                  NA         NA
time-to-event-wk-90th                  NA         NA
time-to-event-wk-50th-loci           30.6         NA
time-to-event-wk-50th-hici             NA         NA

$Bronchitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2230    1.2310    0.1096   13.6400    0.8701


$`Cardio-respiratory arrest`
$`Cardio-respiratory arrest`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               40.9         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.9         NA
time-to-event-wk-50th-hici            NA         NA

$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$Cough
$Cough$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7       14.0
n_event                                0        2.0
n_event_pct                            0       14.0
time-to-event-wk-10th                 NA       30.3
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.476e+08 2.996e+04 0.000e+00       Inf 9.995e-01


$`Drug hypersensitivity`
$`Drug hypersensitivity`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
```

```
time-to-event-wk-10th               13.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          13.3         NA
time-to-event-wk-50th-hici            NA         NA

$`Drug hypersensitivity`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$`Enterovirus infection`
$`Enterovirus infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th                2.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3         NA
time-to-event-wk-50th-hici            NA         NA

$`Enterovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.026e-10 4.684e+04 0.000e+00       Inf 9.996e-01


$Hypoxia
$Hypoxia$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              2.0          0
n_event_pct                         29.0          0
time-to-event-wk-10th                2.3         NA
time-to-event-wk-25th               21.0         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3         NA
time-to-event-wk-50th-hici            NA         NA

$Hypoxia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.576e-10 3.476e+04 0.000e+00       Inf 9.995e-01


$`Hypoxic-ischaemic encephalopathy`
$`Hypoxic-ischaemic encephalopathy`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
```

```
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               40.9         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.9         NA
time-to-event-wk-50th-hici            NA         NA

$`Hypoxic-ischaemic encephalopathy`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Increased bronchial secretion`
$`Increased bronchial secretion`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               40.1         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.1         NA
time-to-event-wk-50th-hici            NA         NA

$`Increased bronchial secretion`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Larynx irritation`
$`Larynx irritation`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               12.4         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          12.4         NA
time-to-event-wk-50th-hici            NA         NA

$`Larynx irritation`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01
```

```
$`Loss of consciousness`
$`Loss of consciousness`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               19.1         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          19.1         NA
time-to-event-wk-50th-hici            NA         NA

$`Loss of consciousness`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.026e-10 4.684e+04 0.000e+00       Inf 9.996e-01


$`Muscle strain`
$`Muscle strain`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               15.6         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          15.6         NA
time-to-event-wk-50th-hici            NA         NA

$`Muscle strain`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$Pneumonia
$Pneumonia$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7       14.0
n_event                                0        5.0
n_event_pct                            0       36.0
time-to-event-wk-10th                 NA       10.1
time-to-event-wk-25th                 NA       27.4
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA       17.7
time-to-event-wk-50th-hici            NA         NA

$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
1.043e+09 1.907e+04 0.000e+00       Inf 9.991e-01


$`Pneumonia aspiration`
$`Pneumonia aspiration`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7         14
n_event                                0          2
n_event_pct                            0         14
time-to-event-wk-10th                 NA         31
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.476e+08 2.996e+04 0.000e+00       Inf 9.995e-01


$`Pneumonia haemophilus`
$`Pneumonia haemophilus`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               10.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          10.3         NA
time-to-event-wk-50th-hici            NA         NA

$`Pneumonia haemophilus`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$`Respiratory distress`
$`Respiratory distress`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        2.0
n_event_pct                         14.0       14.0
time-to-event-wk-10th               40.9        9.9
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.9         NA
time-to-event-wk-50th-hici            NA         NA
```

```
$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0240    1.2270    0.0925   11.3400    0.9844


$`Respiratory failure`
$`Respiratory failure`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7       14.0
n_event                                0        2.0
n_event_pct                            0       14.0
time-to-event-wk-10th                 NA       47.6
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA       47.6
time-to-event-wk-50th-hici            NA         NA

$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.754e+08 3.119e+04 0.000e+00       Inf 9.995e-01


$`Respiratory tract infection`
$`Respiratory tract infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        2.0
n_event_pct                         14.0       14.0
time-to-event-wk-10th               19.6       25.1
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          19.6         NA
time-to-event-wk-50th-hici            NA         NA

$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.99400   1.22500   0.09001  10.98000   0.99610


$`Rhinovirus infection`
$`Rhinovirus infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        2.0
n_event_pct                         14.0       14.0
time-to-event-wk-10th                2.3       47.6
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
```

```
time-to-event-wk-90th                  NA         NA
time-to-event-wk-50th-loci            2.3       47.6
time-to-event-wk-50th-hici             NA         NA

$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.67280   1.23200   0.06012   7.52900   0.74780


$`Sleep apnoea syndrome`
$`Sleep apnoea syndrome`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               35.6         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          35.6         NA
time-to-event-wk-50th-hici            NA         NA

$`Sleep apnoea syndrome`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.570e-10 5.047e+04 0.000e+00       Inf 9.996e-01


$`Urine output increased`
$`Urine output increased`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               41.1         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          41.1         NA
time-to-event-wk-50th-hici            NA         NA

$`Urine output increased`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Viral upper respiratory tract infection`
$`Viral upper respiratory tract infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        2.0
n_event_pct                         14.0       14.0
time-to-event-wk-10th               10.9       39.3
```

```
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          10.9         NA
time-to-event-wk-50th-hici            NA         NA

$`Viral upper respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7359    1.2270    0.0664    8.1570    0.8027



\#############################################################################
#
[[1]]
[1] "Time to moderate or severe AEs according to PT at least 10 Patients and 1%
Patients in one Study Arm"


\#############################################################################
#
[[1]]
[1] "Number of patients with SAEs according to SOC at least in 5% Patients in
one Study Arm"

$`Cardiac disorders`
$`Cardiac disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Cardiac disorders`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$`Gastrointestinal disorders`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869
```

```
$`General disorders and administration site conditions`
$`General disorders and administration site conditions`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`General disorders and administration site conditions`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Infections and infestations`
$`Infections and infestations`$ntab
            CTRL TRT
n_all          7  14
n_event        2   5
n_event_pct   29  36

$`Infections and infestations`$stats
                estimate        se     lo95ci    hi95ci    pvalue
RR_TRTvsCTRL  1.25000000 0.6969321  0.3189190 4.8993634 0.7488321
OR_TRTvsCTRL  1.38888889 1.0055402  0.1935308 9.9674687 0.7438993
ARR_TRTvsCTRL 0.07142857 0.2134337 -0.3468938 0.4897509 0.7378786


$`Nervous system disorders`
$`Nervous system disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        2   0
n_event_pct   29   0

$`Nervous system disorders`$stats
                 estimate        se       lo95ci     hi95ci     pvalue
RR_TRTvsCTRL   0.10666667 1.4860462  0.005795673 1.96315029 0.13205664
OR_TRTvsCTRL   0.07586207 1.6281228  0.003120068 1.84452813 0.11320881
ARR_TRTvsCTRL -0.28571429 0.1707469 -0.620372147 0.04894358 0.09426431


$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$ntab
            CTRL TRT
n_all          7  14
n_event        2   3
n_event_pct   29  21

$`Respiratory, thoracic and mediastinal disorders`$stats
                 estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.75000000 0.7867958  0.16044991 3.5057671 0.7146356
OR_TRTvsCTRL   0.68181818 1.0603030  0.08533693 5.4475361 0.7179423
ARR_TRTvsCTRL -0.07142857 0.2029304 -0.46916490 0.3263078 0.7248491
```

```
\################################################################################
#
[[1]]
[1] "Number of patients with SAEs according to SOC at least 10 Patients and 1%
Patients in one Study Arm"


\################################################################################
#
[[1]]
[1] "Time to SAEs according to SOC at least in 5% Patients in one Study Arm"

$`Cardiac disorders`
$`Cardiac disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               40.9         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.9         NA
time-to-event-wk-50th-hici            NA         NA

$`Cardiac disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Gastrointestinal disorders`
$`Gastrointestinal disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7         14
n_event                              0          1
n_event_pct                          0          7
time-to-event-wk-10th               NA         NA
time-to-event-wk-25th               NA         NA
time-to-event-wk-50th               NA         NA
time-to-event-wk-75th               NA         NA
time-to-event-wk-90th               NA         NA
time-to-event-wk-50th-loci          NA         NA
time-to-event-wk-50th-hici          NA         NA

$`Gastrointestinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.069e+08 4.261e+04 0.000e+00       Inf 9.996e-01


$`General disorders and administration site conditions`
```

```
$`General disorders and administration site conditions`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               41.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          41.3         NA
time-to-event-wk-50th-hici            NA         NA

$`General disorders and administration site conditions`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Infections and infestations`
$`Infections and infestations`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              2.0        5.0
n_event_pct                         29.0       36.0
time-to-event-wk-10th                2.3        5.7
time-to-event-wk-25th               10.3       10.1
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3        9.9
time-to-event-wk-50th-hici            NA         NA

$`Infections and infestations`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.2210    0.8388    0.2360    6.3220    0.8115


$`Nervous system disorders`
$`Nervous system disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              2.0          0
n_event_pct                         29.0          0
time-to-event-wk-10th               19.1         NA
time-to-event-wk-25th               40.9         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          19.1         NA
time-to-event-wk-50th-hici            NA         NA

$`Nervous system disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.283e-10 3.682e+04 0.000e+00       Inf 9.995e-01
```

```
$`Respiratory, thoracic and mediastinal disorders`
$`Respiratory, thoracic and mediastinal disorders`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              2.0        3.0
n_event_pct                         29.0       21.0
time-to-event-wk-10th               19.1        9.9
time-to-event-wk-25th               40.9         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          19.1       14.9
time-to-event-wk-50th-hici            NA         NA

$`Respiratory, thoracic and mediastinal disorders`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   0.7984    0.9150    0.1329    4.7980    0.8056



\#############################################################################
#
[[1]]
[1] "Time to SAEs according to SOC at least 10 Patients and 1% Patients in one
Study Arm"


\#############################################################################
#
[[1]]
[1] "Number of patients with SAEs according to PT at least in 5% Patients in
one Study Arm"

$`Acute respiratory failure`
$`Acute respiratory failure`$ntab
            CTRL TRT
n_all          7  14
n_event        1   1
n_event_pct   14   7

$`Acute respiratory failure`$stats
                  estimate        se      lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.50000000 1.3363062  0.03643377 6.8617661 0.6039673
OR_TRTvsCTRL   0.46153846 1.4978617  0.02450336 8.6934089 0.6057177
ARR_TRTvsCTRL -0.07142857 0.1490984 -0.36365599 0.2207988 0.6318887


$`Brain death`
$`Brain death`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
```

```
n_event_pct   14   0

$`Brain death`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Bronchial secretion retention`
$`Bronchial secretion retention`$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$`Bronchial secretion retention`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$Bronchiolitis
$Bronchiolitis$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$Bronchiolitis$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Cardio-respiratory arrest`
$`Cardio-respiratory arrest`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Cardio-respiratory arrest`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Cough
$Cough$ntab
            CTRL TRT
```

```
n_all          7  14
n_event        0   1
n_event_pct    0   7

$Cough$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$Dysphagia
$Dysphagia$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$Dysphagia$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$`Enterovirus infection`
$`Enterovirus infection`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Enterovirus infection`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$Gastroenteritis
$Gastroenteritis$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$Gastroenteritis$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$`Hypoxic-ischaemic encephalopathy`
```

```
$`Hypoxic-ischaemic encephalopathy`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Hypoxic-ischaemic encephalopathy`$stats
                 estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Loss of consciousness`
$`Loss of consciousness`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Loss of consciousness`$stats
                 estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Lower respiratory tract infection`
$`Lower respiratory tract infection`$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$`Lower respiratory tract infection`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$`Parainfluenzae virus infection`
$`Parainfluenzae virus infection`$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$`Parainfluenzae virus infection`$stats
                 estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869
```

```
$Pneumonia
$Pneumonia$ntab
            CTRL TRT
n_all          7  14
n_event        0   3
n_event_pct    0  21

$Pneumonia$stats
               estimate        se         lo95ci      hi95ci     pvalue
RR_TRTvsCTRL  3.7333333 1.4470825  0.2189464726  63.6583801 0.36265618
OR_TRTvsCTRL  4.5652174 1.5830364  0.2051060468 101.6118742 0.33745238
ARR_TRTvsCTRL 0.2142857 0.1096642 -0.0006521887   0.4292236 0.05069923


$`Pneumonia aspiration`
$`Pneumonia aspiration`$ntab
            CTRL TRT
n_all          7  14
n_event        0   2
n_event_pct    0  14

$`Pneumonia aspiration`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.6666667 1.48604621  0.14489183 49.0787574 0.5092371
OR_TRTvsCTRL  3.0000000 1.61658075  0.12620752 71.3111249 0.4967640
ARR_TRTvsCTRL 0.1428571 0.09352195 -0.04044252  0.3261568 0.1266305


$`Pneumonia haemophilus`
$`Pneumonia haemophilus`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Pneumonia haemophilus`$stats
                estimate       se       lo95ci    hi95ci    pvalue
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Respiratory distress`
$`Respiratory distress`$ntab
            CTRL TRT
n_all          7  14
n_event        1   2
n_event_pct   14  14

$`Respiratory distress`$stats
              estimate        se      lo95ci     hi95ci pvalue
RR_TRTvsCTRL         1 1.1338934  0.10834981  9.2293651      1
OR_TRTvsCTRL         1 1.3228757  0.07481113 13.3669954      1
```

```
ARR_TRTvsCTRL        0 0.1619848 -0.31748432  0.3174843      1


$`Respiratory failure`
$`Respiratory failure`$ntab
            CTRL TRT
n_all          7  14
n_event        0   2
n_event_pct    0  14

$`Respiratory failure`$stats
               estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  2.6666667 1.48604621  0.14489183 49.0787574 0.5092371
OR_TRTvsCTRL  3.0000000 1.61658075  0.12620752 71.3111249 0.4967640
ARR_TRTvsCTRL 0.1428571 0.09352195 -0.04044252  0.3261568 0.1266305


$`Respiratory syncytial virus bronchiolitis`
$`Respiratory syncytial virus bronchiolitis`$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$`Respiratory syncytial virus bronchiolitis`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$`Respiratory syncytial virus infection`
$`Respiratory syncytial virus infection`$ntab
            CTRL TRT
n_all          7  14
n_event        0   1
n_event_pct    0   7

$`Respiratory syncytial virus infection`$stats
                estimate         se      lo95ci     hi95ci    pvalue
RR_TRTvsCTRL  1.60000000 1.57321327  0.07328219 34.9334556 0.7651278
OR_TRTvsCTRL  1.66666667 1.69530943  0.06008952 46.2273242 0.7631727
ARR_TRTvsCTRL 0.07142857 0.06883029 -0.06347633  0.2063335 0.2993869


$`Respiratory tract infection`
$`Respiratory tract infection`$ntab
            CTRL TRT
n_all          7  14
n_event        1   0
n_event_pct   14   0

$`Respiratory tract infection`$stats
                estimate       se       lo95ci    hi95ci    pvalue
```

```
RR_TRTvsCTRL   0.1777778 1.573213  0.008142465 3.8814951 0.2722509
OR_TRTvsCTRL   0.1494253 1.699847  0.005339641 4.1815387 0.2634338
ARR_TRTvsCTRL -0.1428571 0.132260 -0.402082007 0.1163677 0.2800872


$`Rhinovirus infection`
$`Rhinovirus infection`$ntab
            CTRL TRT
n_all          7  14
n_event        1   2
n_event_pct   14  14

$`Rhinovirus infection`$stats
              estimate        se      lo95ci     hi95ci pvalue
RR_TRTvsCTRL         1 1.1338934  0.10834981  9.2293651      1
OR_TRTvsCTRL         1 1.3228757  0.07481113 13.3669954      1
ARR_TRTvsCTRL        0 0.1619848 -0.31748432  0.3174843      1



\#############################################################################
#
[[1]]
[1] "Number of patients with SAEs according to PT at least 10 Patients and 1%
Patients in one Study Arm"


\#############################################################################
#
[[1]]
[1] "Time to SAEs according to PT at least in 5% Patients in one Study Arm"

$`Acute respiratory failure`
$`Acute respiratory failure`$stats_num
                          ARMCD=CONTROL ARMCD=ISIS
n_all                               7.0         14
n_event                             1.0          1
n_event_pct                        14.0          7
time-to-event-wk-10th              19.1          NA
time-to-event-wk-25th                NA          NA
time-to-event-wk-50th                NA          NA
time-to-event-wk-75th                NA          NA
time-to-event-wk-90th                NA          NA
time-to-event-wk-50th-loci         19.1          NA
time-to-event-wk-50th-hici           NA          NA

$`Acute respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.47140   1.41500   0.02945   7.54600   0.59500


$`Brain death`
$`Brain death`$stats_num
                          ARMCD=CONTROL ARMCD=ISIS
```

```
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               41.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          41.3         NA
time-to-event-wk-50th-hici            NA         NA

$`Brain death`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Bronchial secretion retention`
$`Bronchial secretion retention`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7         14
n_event                              0          1
n_event_pct                          0          7
time-to-event-wk-10th               NA         NA
time-to-event-wk-25th               NA         NA
time-to-event-wk-50th               NA         NA
time-to-event-wk-75th               NA         NA
time-to-event-wk-90th               NA         NA
time-to-event-wk-50th-loci          NA         NA
time-to-event-wk-50th-hici          NA         NA

$`Bronchial secretion retention`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.069e+08 4.261e+04 0.000e+00       Inf 9.996e-01


$Bronchiolitis
$Bronchiolitis$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               40.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.3         NA
time-to-event-wk-50th-hici            NA         NA

$Bronchiolitis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01
```

```
$`Cardio-respiratory arrest`
$`Cardio-respiratory arrest`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               40.9         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.9         NA
time-to-event-wk-50th-hici            NA         NA

$`Cardio-respiratory arrest`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$Cough
$Cough$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7         14
n_event                                0          1
n_event_pct                            0          7
time-to-event-wk-10th                 NA         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$Cough$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.069e+08 4.261e+04 0.000e+00       Inf 9.996e-01


$Dysphagia
$Dysphagia$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7         14
n_event                                0          1
n_event_pct                            0          7
time-to-event-wk-10th                 NA         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$Dysphagia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
```

```
8.069e+08 4.261e+04 0.000e+00       Inf 9.996e-01


$`Enterovirus infection`
$`Enterovirus infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th                2.3         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci           2.3         NA
time-to-event-wk-50th-hici            NA         NA

$`Enterovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.026e-10 4.684e+04 0.000e+00       Inf 9.996e-01


$Gastroenteritis
$Gastroenteritis$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7         14
n_event                                0          1
n_event_pct                            0          7
time-to-event-wk-10th                 NA         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$Gastroenteritis$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.194e+09 4.461e+04 0.000e+00       Inf 9.996e-01


$`Hypoxic-ischaemic encephalopathy`
$`Hypoxic-ischaemic encephalopathy`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               40.9         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.9         NA
time-to-event-wk-50th-hici            NA         NA
```

```
$`Hypoxic-ischaemic encephalopathy`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
1.720e-10 4.992e+04 0.000e+00       Inf 9.996e-01


$`Loss of consciousness`
$`Loss of consciousness`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               19.1         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          19.1         NA
time-to-event-wk-50th-hici            NA         NA

$`Loss of consciousness`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
2.026e-10 4.684e+04 0.000e+00       Inf 9.996e-01


$`Lower respiratory tract infection`
$`Lower respiratory tract infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7         14
n_event                              0          1
n_event_pct                          0          7
time-to-event-wk-10th               NA         NA
time-to-event-wk-25th               NA         NA
time-to-event-wk-50th               NA         NA
time-to-event-wk-75th               NA         NA
time-to-event-wk-90th               NA         NA
time-to-event-wk-50th-loci          NA         NA
time-to-event-wk-50th-hici          NA         NA

$`Lower respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.069e+08 4.261e+04 0.000e+00       Inf 9.996e-01


$`Parainfluenzae virus infection`
$`Parainfluenzae virus infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7         14
n_event                              0          1
n_event_pct                          0          7
time-to-event-wk-10th               NA         NA
time-to-event-wk-25th               NA         NA
time-to-event-wk-50th               NA         NA
time-to-event-wk-75th               NA         NA
```

```
time-to-event-wk-90th                  NA         NA
time-to-event-wk-50th-loci             NA         NA
time-to-event-wk-50th-hici             NA         NA

$`Parainfluenzae virus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.069e+08 4.261e+04 0.000e+00       Inf 9.996e-01


$Pneumonia
$Pneumonia$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7       14.0
n_event                                0        3.0
n_event_pct                            0       21.0
time-to-event-wk-10th                 NA       10.1
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA       17.7
time-to-event-wk-50th-hici            NA         NA

$Pneumonia$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
9.045e+08 2.443e+04 0.000e+00       Inf 9.993e-01


$`Pneumonia aspiration`
$`Pneumonia aspiration`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7         14
n_event                                0          2
n_event_pct                            0         14
time-to-event-wk-10th                 NA         31
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$`Pneumonia aspiration`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.476e+08 2.996e+04 0.000e+00       Inf 9.995e-01


$`Pneumonia haemophilus`
$`Pneumonia haemophilus`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               10.3         NA
```

```
time-to-event-wk-25th                  NA         NA
time-to-event-wk-50th                  NA         NA
time-to-event-wk-75th                  NA         NA
time-to-event-wk-90th                  NA         NA
time-to-event-wk-50th-loci          10.3          NA
time-to-event-wk-50th-hici            NA         NA

$`Pneumonia haemophilus`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$`Respiratory distress`
$`Respiratory distress`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0       14.0
n_event                              1.0        2.0
n_event_pct                         14.0       14.0
time-to-event-wk-10th               40.9        9.9
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          40.9         NA
time-to-event-wk-50th-hici            NA         NA

$`Respiratory distress`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
   1.0240    1.2270    0.0925   11.3400    0.9844


$`Respiratory failure`
$`Respiratory failure`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7       14.0
n_event                              0        2.0
n_event_pct                          0       14.0
time-to-event-wk-10th               NA       47.6
time-to-event-wk-25th               NA         NA
time-to-event-wk-50th               NA         NA
time-to-event-wk-75th               NA         NA
time-to-event-wk-90th               NA         NA
time-to-event-wk-50th-loci          NA       47.6
time-to-event-wk-50th-hici          NA         NA

$`Respiratory failure`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
6.754e+08 3.119e+04 0.000e+00       Inf 9.995e-01


$`Respiratory syncytial virus bronchiolitis`
$`Respiratory syncytial virus bronchiolitis`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7         14
```

```
n_event                                0          1
n_event_pct                            0          7
time-to-event-wk-10th                 NA         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$`Respiratory syncytial virus bronchiolitis`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.069e+08 4.261e+04 0.000e+00       Inf 9.996e-01


$`Respiratory syncytial virus infection`
$`Respiratory syncytial virus infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                  7         14
n_event                                0          1
n_event_pct                            0          7
time-to-event-wk-10th                 NA         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci            NA         NA
time-to-event-wk-50th-hici            NA         NA

$`Respiratory syncytial virus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
8.069e+08 4.261e+04 0.000e+00       Inf 9.996e-01


$`Respiratory tract infection`
$`Respiratory tract infection`$stats_num
                           ARMCD=CONTROL ARMCD=ISIS
n_all                                7.0         14
n_event                              1.0          0
n_event_pct                         14.0          0
time-to-event-wk-10th               19.6         NA
time-to-event-wk-25th                 NA         NA
time-to-event-wk-50th                 NA         NA
time-to-event-wk-75th                 NA         NA
time-to-event-wk-90th                 NA         NA
time-to-event-wk-50th-loci          19.6         NA
time-to-event-wk-50th-hici            NA         NA

$`Respiratory tract infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
3.000e-10 4.472e+04 0.000e+00       Inf 9.996e-01


$`Rhinovirus infection`
```

```
$`Rhinovirus infection`$stats_num
                            ARMCD=CONTROL ARMCD=ISIS
n_all                                 7.0       14.0
n_event                               1.0        2.0
n_event_pct                          14.0       14.0
time-to-event-wk-10th                 2.3       47.6
time-to-event-wk-25th                  NA         NA
time-to-event-wk-50th                  NA         NA
time-to-event-wk-75th                  NA         NA
time-to-event-wk-90th                  NA         NA
time-to-event-wk-50th-loci            2.3       47.6
time-to-event-wk-50th-hici             NA         NA

$`Rhinovirus infection`$stats_HR_TRTvsCTRL
       HR  SE_logHR HR.lo95ci HR.hi95ci   p.value
  0.67280   1.23200   0.06012   7.52900   0.74780



\#############################################################################
#
[[1]]
[1] "Time to SAEs according to PT at least 10 Patients and 1% Patients in one
Study Arm"


\#############################################################################
#
```

Anhang 4-G zu Modul 4 A.1

Meta-Analyse 1

ENDEAR und EMBRACE

Stand: 01.12.2020

```
> cat("Results for Metaanalysis")
Results for Metaanalysis
> for(i in mergeList){
+   print(i)
+   cat("\n\\#############################################################################################\n")
+ }
[[1]]
[1] "Survival Rate"

$Endpunkt
[1] "Survival Rate" "Survival Rate" "Survival Rate"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,9137" "0,7917" "0,8706"

$Schaetzer
[1] "1,38" "3,39" "0,23"

$ci_lower
[1] "1,074" "1,464" "0,070"

$ci_upper
[1] "1,772" "7,850" "0,394"

$pvalue
[1] "0,0118" "0,0044" "0,0050"


\#############################################################################
[[1]]
[1] "Time to death"

$Endpunkt
[1] "Time to death"
```

```
$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,9996"

$Schaetzer
[1] "0,37"

$ci_lower
[1] "0,179"

$ci_upper
[1] "0,774"

$pvalue
[1] "0,0082"


\##############################################################################
[[1]]
[1] "Time to death or permanent ventilation"

$Endpunkt
[1] "Time to death or permanent ventilation"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,9996"

$Schaetzer
[1] "0,53"

$ci_lower
[1] "0,316"
```

```
$ci_upper
[1] "0,891"

$pvalue
[1] "0,0166"


\##############################################################################
[[1]]
[1] "Percent of subjects not requiring permanent ventilation"

$Endpunkt
[1] "Percent of subjects not requiring permanent ventilation"
[2] "Percent of subjects not requiring permanent ventilation"
[3] "Percent of subjects not requiring permanent ventilation"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,7158" "0,9198" "0,7704"

$Schaetzer
[1] "1,11" "1,59" "0,08"

$ci_lower
[1] "0,898"  "0,695"  "-0,074"

$ci_upper
[1] "1,377" "3,617" "0,239"

$pvalue
[1] "0,3295" "0,2734" "0,3021"


\##############################################################################
[[1]]
```

```
[1] "HINE-Responder-section 2 Day 64"

$Endpunkt
[1] "HINE-Responder-section 2 Day 64" "HINE-Responder-section 2 Day 64" "HINE-Responder-section 2 Day 64"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,5432" "0,4879" "0,3975"

$Schaetzer
[1] "1,76" "2,15" "0,15"

$ci_lower
[1] "0,894"  "0,899"  "-0,003"

$ci_upper
[1] "3,453" "5,159" "0,302"

$pvalue
[1] "0,1021" "0,0851" "0,0554"


\##############################################################################
[[1]]
[1] "HINE-Responder-section 2 Day 183"

$Endpunkt
[1] "HINE-Responder-section 2 Day 183" "HINE-Responder-section 2 Day 183" "HINE-Responder-section 2 Day 183"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,2287" "0,8995" "0,4840"

$Schaetzer
```

```
[1] "4,14"  "12,14" "0,34"

$ci_lower
[1] "1,609" "3,070" "0,215"

$ci_upper
[1] "10,673" "48,038" "0,458"

$pvalue
[1] "0,0032" "0,0004" "0,0000"


\##############################################################################
[[1]]
[1] "HINE-Responder-section 2 Day 302"

$Endpunkt
[1] "HINE-Responder-section 2 Day 302" "HINE-Responder-section 2 Day 302" "HINE-Responder-section 2 Day 302"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,5454" "0,7912" "0,0222"

$Schaetzer
[1] "12,49" "39,58" "0,30"

$ci_lower
[1] "1,866" "3,811" "0,206"

$ci_upper
[1] "83,679"  "411,081" "0,396"

$pvalue
[1] "0,0093" "0,0021" "0,0000"
```

```
\#############################################################################
[[1]]
[1] "Time to motor milestone responders"

$Endpunkt
[1] "Time to motor milestone responders  (HINE section 2)"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,8091"

$Schaetzer
[1] "3,13"

$ci_lower
[1] "1,519"

$ci_upper
[1] "6,441"

$pvalue
[1] "0,0020"


\#############################################################################
[[1]]
[1] "Change from baseline in HINE-section 2 Day 64"

$Endpunkt
[1] "Change from baseline in HINE-section 2 Day 64"

$Effektmass
[1] "Hedges g"

$Heterog_p_Wert
[1] "0,4523"
```

```
$Schaetzer
[1] "0,50"

$ci_lower
[1] "0,094"

$ci_upper
[1] "0,898"

$pvalue
[1] "0,0155"


\##############################################################################
[[1]]
[1] "Change from baseline in HINE-section 2 Day 183"

$Endpunkt
[1] "Change from baseline in HINE-section 2 Day 183"

$Effektmass
[1] "Hedges g"

$Heterog_p_Wert
[1] "0,6223"

$Schaetzer
[1] "0,98"

$ci_lower
[1] "0,495"

$ci_upper
[1] "1,470"

$pvalue
[1] "0,0001"
```

```
\##############################################################################
[[1]]
[1] "Frequency of hospitalization"

$Endpunkt
[1] "Frequency of hospitalization"

$Effektmass
[1] "IRR"

$Heterog_p_Wert
[1] "0,0546"

$Schaetzer
[1] "0,81"

$ci_lower
[1] "0,592"

$ci_upper
[1] "1,118"

$pvalue
[1] "0,2031"


\##############################################################################
[[1]]
[1] "Time to hospitalization"

$Endpunkt
[1] "Time to hospitalization"

$Effektmass
[1] "HR"
```

```
$Heterog_p_Wert
[1] "0,8617"

$Schaetzer
[1] "0,98"

$ci_lower
[1] "0,665"

$ci_upper
[1] "1,442"

$pvalue
[1] "0,9148"


\##############################################################################
[[1]]
[1] "Frequency of serious respiratory events"

$Endpunkt
[1] "Frequency of serious respiratory events"

$Effektmass
[1] "IRR"

$Heterog_p_Wert
[1] "0,1664"

$Schaetzer
[1] "0,71"

$ci_lower
[1] "0,446"

$ci_upper
[1] "1,136"
```

```
$pvalue
[1] "0,1538"


\##############################################################################
[[1]]
[1] "Time to serious respiratory events"

$Endpunkt
[1] "Time to serious respiratory events"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,3295"

$Schaetzer
[1] "0,80"

$ci_lower
[1] "0,512"

$ci_upper
[1] "1,249"

$pvalue
[1] "0,3253"


\##############################################################################
[[1]]
[1] "Number of patients with adverse events"

$Endpunkt
[1] "Number of patients with adverse events" "Number of patients with adverse events"
[3] "Number of patients with adverse events"
```

```
$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,8637" "0,7744" "0,8595"

$Schaetzer
[1] "0,99"  "0,75"  "-0,01"

$ci_lower
[1] "0,926"  "0,101"  "-0,075"

$ci_upper
[1] "1,053" "5,630" "0,050"

$pvalue
[1] "0,6975" "0,7836" "0,6994"


\################################################################################
[[1]]
[1] "Time to adverse events"

$Endpunkt
[1] "Time to adverse events"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,5831"

$Schaetzer
[1] "0,91"

$ci_lower
[1] "0,625"
```

```
$ci_upper
[1] "1,324"

$pvalue
[1] "0,6200"


\################################################################################
[[1]]
[1] "Number of patients with mild adverse events"

$Endpunkt
[1] "Number of patients with mild adverse events" "Number of patients with mild adverse events"
[3] "Number of patients with mild adverse events"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,3905" "0,4530" "0,3893"

$Schaetzer
[1] "1,05" "1,25" "0,04"

$ci_lower
[1] "0,808"  "0,580"  "-0,132"

$ci_upper
[1] "1,375" "2,675" "0,210"

$pvalue
[1] "0,6981" "0,5731" "0,6557"


\################################################################################
[[1]]
[1] "Time to mild adverse events"
```

```
$Endpunkt
[1] "Time to mild adverse events"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,2555"

$Schaetzer
[1] "0,96"

$ci_lower
[1] "0,605"

$ci_upper
[1] "1,514"

$pvalue
[1] "0,8499"


\##############################################################################
[[1]]
[1] "Number of patients with moderate adverse events"

$Endpunkt
[1] "Number of patients with moderate adverse events" "Number of patients with moderate adverse events"
[3] "Number of patients with moderate adverse events"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,3646" "0,3390" "0,3099"

$Schaetzer
[1] "1,00" "1,00" "0,01"
```

```
$ci_lower
[1] "0,802"  "0,440"  "-0,154"

$ci_upper
[1] "1,253" "2,271" "0,167"

$pvalue
[1] "0,9804" "0,9986" "0,9363"


\##############################################################################
[[1]]
[1] "Time to moderate adverse events"

$Endpunkt
[1] "Time to moderate adverse events"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,0956"

$Schaetzer
[1] "0,84"

$ci_lower
[1] "0,542"

$ci_upper
[1] "1,317"

$pvalue
[1] "0,4559"


\##############################################################################
```

```
[[1]]
[1] "Number of patients with moderate and severe adverse events"

$Endpunkt
[1] "Number of patients with moderate and severe adverse events"
[2] "Number of patients with moderate and severe adverse events"
[3] "Number of patients with moderate and severe adverse events"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,2136" "0,1060" "0,1426"

$Schaetzer
[1] "0,86"  "0,37"  "-0,12"

$ci_lower
[1] "0,763"  "0,090"  "-0,229"

$ci_upper
[1] "0,979"  "1,488"  "-0,017"

$pvalue
[1] "0,0222" "0,1599" "0,0229"


\##############################################################################
[[1]]
[1] "Time to moderate and severe adverse events"

$Endpunkt
[1] "Time to moderate and severe adverse events"

$Effektmass
[1] "HR"

$Heterog_p_Wert
```

```
[1] "0,4802"

$Schaetzer
[1] "0,70"

$ci_lower
[1] "0,466"

$ci_upper
[1] "1,038"

$pvalue
[1] "0,0754"


\##############################################################################
[[1]]
[1] "Number of patients with severe adverse events"

$Endpunkt
[1] "Number of patients with severe adverse events" "Number of patients with severe adverse events"
[3] "Number of patients with severe adverse events"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,3556" "0,3675" "0,3623"

$Schaetzer
[1] "0,72"  "0,35"  "-0,22"

$ci_lower
[1] "0,567"  "0,147"  "-0,383"

$ci_upper
[1] "0,912"  "0,819"  "-0,066"
```

```
$pvalue
[1] "0,0065" "0,0157" "0,0054"


\##############################################################################
[[1]]
[1] "Time to severe adverse events"

$Endpunkt
[1] "Time to severe adverse events"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,4667"

$Schaetzer
[1] "0,60"

$ci_lower
[1] "0,385"

$ci_upper
[1] "0,929"

$pvalue
[1] "0,0220"


\##############################################################################
[[1]]
[1] "Number of patients with serious adverse events"

$Endpunkt
[1] "Number of patients with serious adverse events" "Number of patients with serious adverse events"
[3] "Number of patients with serious adverse events"
```

```
$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,5022" "0,2327" "0,4404"

$Schaetzer
[1] "0,81"  "0,24"  "-0,18"

$ci_lower
[1] "0,702"  "0,061"  "-0,294"

$ci_upper
[1] "0,928"  "0,954"  "-0,069"

$pvalue
[1] "0,0025" "0,0427" "0,0016"


\################################################################################
[[1]]
[1] "Time to serious adverse events"

$Endpunkt
[1] "Time to serious adverse events"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,6465"

$Schaetzer
[1] "0,76"

$ci_lower
[1] "0,510"
```

```
$ci_upper
[1] "1,128"

$pvalue
[1] "0,1723"


\##############################################################################
[[1]]
[1] "Number of patients with adverse events leading to discontinuation of therapy"

$Endpunkt
[1] "Number of patients with adverse events leading to discontinuation of therapy"
[2] "Number of patients with adverse events leading to discontinuation of therapy"
[3] "Number of patients with adverse events leading to discontinuation of therapy"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,7698" "0,7917" "0,8706"

$Schaetzer
[1] "0,41"  "0,29"  "-0,23"

$ci_lower
[1] "0,221"  "0,127"  "-0,394"

$ci_upper
[1] "0,754"  "0,683"  "-0,070"

$pvalue
[1] "0,0042" "0,0044" "0,0050"


\##############################################################################
[[1]]
[1] "Time to adverse events leading to discontinuation of therapy"
```

```
$Endpunkt
[1] "Time to adverse events leading to discontinuation of therapy"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,9996"

$Schaetzer
[1] "0,37"

$ci_lower
[1] "0,177"

$ci_upper
[1] "0,769"

$pvalue
[1] "0,0078"


\################################################################################
[[1]]
[1] "Number of patients with 10% AEs according to SOC"

$`Cardiac disorders`
                              Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct SOC Cardiac disorders         RR         0,9384      0,72    0,415    1,238 0,2328
2 Any AEs 10 pct SOC Cardiac disorders         OR         0,8914      0,62    0,273    1,387 0,2419
3 Any AEs 10 pct SOC Cardiac disorders        ARR         0,8442     -0,10   -0,261    0,069 0,2540

$`Gastrointestinal disorders`
                                       Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct SOC Gastrointestinal disorders         RR         0,6162      1,03    0,782    1,352 0,8397
2 Any AEs 10 pct SOC Gastrointestinal disorders         OR         0,6162      1,08    0,503    2,310 0,8472
3 Any AEs 10 pct SOC Gastrointestinal disorders        ARR         0,6086      0,02   -0,158    0,192 0,8490
```

$`General disorders and administration site conditions`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct SOC General disorders and administration site conditions	RR	0,7187	0,95	0,731	1,222	0,6690
2	Any AEs 10 pct SOC General disorders and administration site conditions	OR	0,7255	0,84	0,388	1,838	0,6703
3	Any AEs 10 pct SOC General disorders and administration site conditions	ARR	0,7201	-0,04	-0,209	0,134	0,6700

$`Infections and infestations`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct SOC Infections and infestations	RR	0,4938	1,09	0,898	1,332	0,3755
2	Any AEs 10 pct SOC Infections and infestations	OR	0,4703	1,52	0,630	3,657	0,3518
3	Any AEs 10 pct SOC Infections and infestations	ARR	0,4480	0,07	-0,077	0,224	0,3405

$`Injury, poisoning and procedural complications`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct SOC Injury, poisoning and procedural complications	RR	0,8330	0,95	0,503	1,813	0,8874
2	Any AEs 10 pct SOC Injury, poisoning and procedural complications	OR	0,8316	0,94	0,403	2,204	0,8906
3	Any AEs 10 pct SOC Injury, poisoning and procedural complications	ARR	0,8296	-0,01	-0,167	0,146	0,8958

$Investigations

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct SOC Investigations	RR	0,9839	0,77	0,445	1,326	0,3428
2	Any AEs 10 pct SOC Investigations	OR	0,9866	0,69	0,311	1,512	0,3494
3	Any AEs 10 pct SOC Investigations	ARR	0,9903	-0,08	-0,248	0,090	0,3577

$`Metabolism and nutrition disorders`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper
1	Any AEs 10 pct SOC Metabolism and nutrition disorders	RR	0,6336	0,53	0,281	1,009
2	Any AEs 10 pct SOC Metabolism and nutrition disorders	OR	0,6287	0,43	0,186	1,015
3	Any AEs 10 pct SOC Metabolism and nutrition disorders	ARR	0,6459	-0,15	-0,311	0,005

```
  pvalue
1 0,0534
2 0,0541
3 0,0569

$`Musculoskeletal and connective tissue disorders`
                                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Any AEs 10 pct SOC Musculoskeletal and connective tissue disorders         RR         0,2675      1,37
2 Any AEs 10 pct SOC Musculoskeletal and connective tissue disorders         OR         0,1600      1,47
3 Any AEs 10 pct SOC Musculoskeletal and connective tissue disorders        ARR         0,0390      0,05
  ci_lower ci_upper pvalue
1    0,543    3,458 0,5051
2    0,501    4,318 0,4830
3   -0,075    0,169 0,4522

$`Nervous system disorders`
                                      Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct SOC Nervous system disorders         RR         0,0931      1,26    0,341    4,637 0,7314
2 Any AEs 10 pct SOC Nervous system disorders         OR         0,0687      1,36    0,321    5,771 0,6760
3 Any AEs 10 pct SOC Nervous system disorders        ARR         0,0362      0,05   -0,048    0,140 0,3385

$`Respiratory, thoracic and mediastinal disorders`
                                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Any AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         RR         0,2326      0,89
2 Any AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         OR         0,1878      0,55
3 Any AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders        ARR         0,1712     -0,09
  ci_lower ci_upper pvalue
1    0,752    1,044 0,1491
2    0,197    1,524 0,2492
3   -0,225    0,041 0,1734

$`Skin and subcutaneous tissue disorders`
                                                    Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Any AEs 10 pct SOC Skin and subcutaneous tissue disorders         RR         0,9695      0,78    0,467
2 Any AEs 10 pct SOC Skin and subcutaneous tissue disorders         OR         0,9779      0,70    0,321
3 Any AEs 10 pct SOC Skin and subcutaneous tissue disorders        ARR         0,9889     -0,08   -0,251
  ci_upper pvalue
1    1,315 0,3566
```

```
2    1,516 0,3633
3    0,093 0,3698


\##############################################################################
[[1]]
[1] "Time to 10% AEs according to SOC"

$`Cardiac disorders`
                                      Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to any AEs 10 pct SOC Cardiac disorders         HR         0,8021      0,61    0,312    1,195 0,1495

$`Gastrointestinal disorders`
                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Time to any AEs 10 pct SOC Gastrointestinal disorders         HR         0,6137      0,98    0,619    1,561
  pvalue
1 0,9414

$`General disorders and administration site conditions`
                                                                                Endpunkt Effektmass Heterog_p_Wert
1 Time to any AEs 10 pct SOC General disorders and administration site conditions         HR         0,3085
  Schaetzer ci_lower ci_upper pvalue
1      0,62    0,396    0,986 0,0433

$`Infections and infestations`
                                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Time to any AEs 10 pct SOC Infections and infestations         HR         0,5257      1,19    0,777
  ci_upper pvalue
1    1,807 0,4298

$`Injury, poisoning and procedural complications`
                                                                      Endpunkt Effektmass Heterog_p_Wert
1 Time to any AEs 10 pct SOC Injury, poisoning and procedural complications         HR         0,9694
  Schaetzer ci_lower ci_upper pvalue
1      0,75    0,354    1,570 0,4390

$Investigations
                                    Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
```

```
1 Time to any AEs 10 pct SOC Investigations         HR         0,8516      0,65    0,334    1,252 0,1958

$`Respiratory, thoracic and mediastinal disorders`
                                                                                Endpunkt Effektmass Heterog_p_Wert
1 Time to any AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         HR         0,0954
  Schaetzer ci_lower ci_upper pvalue
1      0,65    0,430    0,991 0,0452

$`Skin and subcutaneous tissue disorders`
                                                                Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Time to any AEs 10 pct SOC Skin and subcutaneous tissue disorders         HR         0,9996      0,67
  ci_lower ci_upper pvalue
1    0,345    1,284 0,2249


\##############################################################################
[[1]]
[1] "Number of patients with 10% AEs according to PT"

$`Acute respiratory failure`
                                      Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Acute respiratory failure         RR         0,8198      0,58    0,279    1,204 0,1436
2 Any AEs 10 pct PT Acute respiratory failure         OR         0,8644      0,51    0,202    1,266 0,1455
3 Any AEs 10 pct PT Acute respiratory failure        ARR         0,9484     -0,11   -0,253    0,043 0,1630

$`Bronchial secretion retention`
                                       Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Any AEs 10 pct PT Bronchial secretion retention         RR         0,1897      0,39    0,132    1,160
2 Any AEs 10 pct PT Bronchial secretion retention         OR         0,1988      0,34    0,102    1,153
3 Any AEs 10 pct PT Bronchial secretion retention        ARR         0,2750     -0,10   -0,226    0,017
  pvalue
1 0,0907
2 0,0835
3 0,0913

$Bronchiolitis
                         Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Bronchiolitis         RR         0,6581      1,19    0,390    3,639 0,7591
```

```
2 Any AEs 10 pct PT Bronchiolitis         OR         0,6823      1,26    0,351    4,509 0,7240
3 Any AEs 10 pct PT Bronchiolitis        ARR         0,7541      0,02   -0,078    0,127 0,6403

$`Cardio-respiratory arrest`
                                    Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Cardio-respiratory arrest         RR         0,6842      0,47    0,156    1,397 0,1734
2 Any AEs 10 pct PT Cardio-respiratory arrest         OR         0,6219      0,43    0,126    1,456 0,1746
3 Any AEs 10 pct PT Cardio-respiratory arrest        ARR         0,4458     -0,07   -0,179    0,042 0,2264

$Constipation
                        Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Constipation         RR         0,2410      1,47    0,777    2,763 0,2378
2 Any AEs 10 pct PT Constipation         OR         0,2109      1,68    0,720    3,907 0,2306
3 Any AEs 10 pct PT Constipation        ARR         0,1608      0,10   -0,061    0,254 0,2292

$Cough
                 Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Cough         RR         0,0722      0,74    0,325    1,706 0,4850
2 Any AEs 10 pct PT Cough         OR         0,0285      0,69    0,253    1,895 0,4743
3 Any AEs 10 pct PT Cough        ARR         0,0001      0,00   -0,129    0,136 0,9557

$Diarrhoea
                     Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Diarrhoea         RR         0,4821      0,88    0,383    2,026 0,7645
2 Any AEs 10 pct PT Diarrhoea         OR         0,4701      0,86    0,320    2,322 0,7686
3 Any AEs 10 pct PT Diarrhoea        ARR         0,4448     -0,02   -0,152    0,114 0,7751

$Dysphagia
                     Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Dysphagia         RR         0,3192      0,58    0,257    1,299 0,1841
2 Any AEs 10 pct PT Dysphagia         OR         0,3113      0,52    0,197    1,380 0,1895
3 Any AEs 10 pct PT Dysphagia        ARR         0,3024     -0,09   -0,226    0,053 0,2225

$Dyspnoea
                    Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Dyspnoea         RR         0,3784      0,70    0,265    1,829 0,4624
2 Any AEs 10 pct PT Dyspnoea         OR         0,3754      0,66    0,219    1,989 0,4598
3 Any AEs 10 pct PT Dyspnoea        ARR         0,3880     -0,05   -0,167    0,075 0,4573
```

$`Gastrooesophageal reflux disease`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct PT Gastrooesophageal reflux disease	RR	0,3944	0,71	0,314	1,607	0,4115
2	Any AEs 10 pct PT Gastrooesophageal reflux disease	OR	0,3849	0,67	0,251	1,775	0,4183
3	Any AEs 10 pct PT Gastrooesophageal reflux disease	ARR	0,3693	-0,05	-0,189	0,083	0,4457

$`Nasal congestion`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct PT Nasal congestion	RR	0,2895	1,01	0,377	2,685	0,9912
2	Any AEs 10 pct PT Nasal congestion	OR	0,2431	1,01	0,328	3,093	0,9899
3	Any AEs 10 pct PT Nasal congestion	ARR	0,1633	-0,00	-0,121	0,113	0,9512

$Pneumonia

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct PT Pneumonia	RR	0,2946	1,89	0,911	3,903	0,0876
2	Any AEs 10 pct PT Pneumonia	OR	0,1110	2,32	0,924	5,852	0,0732
3	Any AEs 10 pct PT Pneumonia	ARR	0,0037	0,19	0,051	0,337	0,0078

$`Pneumonia aspiration`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct PT Pneumonia aspiration	RR	0,2205	0,79	0,332	1,877	0,5926
2	Any AEs 10 pct PT Pneumonia aspiration	OR	0,1863	0,76	0,275	2,116	0,6025
3	Any AEs 10 pct PT Pneumonia aspiration	ARR	0,1304	-0,03	-0,164	0,097	0,6158

$Pyrexia

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct PT Pyrexia	RR	0,3345	0,99	0,721	1,358	0,9492
2	Any AEs 10 pct PT Pyrexia	OR	0,2752	1,00	0,477	2,106	0,9957
3	Any AEs 10 pct PT Pyrexia	ARR	0,2227	0,01	-0,172	0,187	0,9341

$`Respiratory distress`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct PT Respiratory distress	RR	0,6090	0,94	0,531	1,668	0,8346

```
2 Any AEs 10 pct PT Respiratory distress         OR         0,6064      0,91    0,406    2,044 0,8211
3 Any AEs 10 pct PT Respiratory distress        ARR         0,6040     -0,02   -0,185    0,145 0,8124

$`Respiratory failure`
                              Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Respiratory failure         RR         0,1981      0,69    0,404    1,164 0,1624
2 Any AEs 10 pct PT Respiratory failure         OR         0,1498      0,60    0,272    1,307 0,1965
3 Any AEs 10 pct PT Respiratory failure        ARR         0,0780     -0,09   -0,259    0,077 0,2884

$`Respiratory tract infection`
                                       Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Respiratory tract infection         RR         0,7289      2,61    0,709    9,644 0,1491
2 Any AEs 10 pct PT Respiratory tract infection         OR         0,5902      2,96    0,704   12,468 0,1384
3 Any AEs 10 pct PT Respiratory tract infection        ARR         0,2703      0,07   -0,021    0,167 0,1286

$`Rhinovirus infection`
                                Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Rhinovirus infection         RR         0,5990      0,96    0,413    2,215 0,9168
2 Any AEs 10 pct PT Rhinovirus infection         OR         0,6015      0,92    0,328    2,567 0,8700
3 Any AEs 10 pct PT Rhinovirus infection        ARR         0,6166     -0,02   -0,144    0,113 0,8132

$Tachycardia
                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Tachycardia         RR         0,9584      0,73    0,321    1,665 0,4558
2 Any AEs 10 pct PT Tachycardia         OR         0,8493      0,66    0,213    2,050 0,4738
3 Any AEs 10 pct PT Tachycardia        ARR         0,7240     -0,04   -0,154    0,078 0,5232

$Teething
                       Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Teething         RR         0,1724      1,75    0,582    5,263 0,3190
2 Any AEs 10 pct PT Teething         OR         0,1664      1,95    0,571    6,668 0,2860
3 Any AEs 10 pct PT Teething        ARR         0,1829      0,09   -0,027    0,198 0,1370

$`Upper respiratory tract infection`
                                            Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Any AEs 10 pct PT Upper respiratory tract infection         RR         0,4550      1,45    0,759    2,776
2 Any AEs 10 pct PT Upper respiratory tract infection         OR         0,4004      1,67    0,713    3,928
3 Any AEs 10 pct PT Upper respiratory tract infection        ARR         0,3100      0,10   -0,051    0,259
```

```
  pvalue
1 0,2599
2 0,2369
3 0,1872

$`Viral upper respiratory tract infection`
                                                    Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Any AEs 10 pct PT Viral upper respiratory tract infection         RR         0,6150      0,54    0,222
2 Any AEs 10 pct PT Viral upper respiratory tract infection         OR         0,5729      0,49    0,173
3 Any AEs 10 pct PT Viral upper respiratory tract infection        ARR         0,4734     -0,08   -0,211
  ci_upper pvalue
1    1,333 0,1829
2    1,399 0,1834
3    0,047 0,2108

$Vomiting
                    Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Vomiting         RR         0,5231      0,96    0,450    2,041 0,9118
2 Any AEs 10 pct PT Vomiting         OR         0,5089      0,95    0,376    2,416 0,9196
3 Any AEs 10 pct PT Vomiting        ARR         0,4761     -0,01   -0,147    0,136 0,9397


\##############################################################################
[[1]]
[1] "Time to 10% AEs according to PT"

$`Acute respiratory failure`
                                             Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Time to any AEs 10 pct PT Acute respiratory failure         HR         0,6883      0,50    0,221    1,144
  pvalue
1 0,1011

$Bronchiolitis
                                Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to any AEs 10 pct PT Bronchiolitis         HR         0,6069      1,12    0,336    3,696 0,8585

$Pyrexia
                           Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
```

```
1 Time to any AEs 10 pct PT Pyrexia         HR         0,2022      0,74    0,452    1,203 0,2222

$`Respiratory distress`
                                        Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to any AEs 10 pct PT Respiratory distress         HR         0,4966      0,82    0,414    1,623 0,5676

$`Rhinovirus infection`
                                        Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to any AEs 10 pct PT Rhinovirus infection         HR         0,8486      0,79    0,305    2,049 0,6281

$Tachycardia
                                Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to any AEs 10 pct PT Tachycardia         HR         0,8728      0,67    0,249    1,817 0,4343


\##############################################################################
[[1]]
[1] "Number of patients with 10% mild AEs according to SOC"

$`Cardiac disorders`
                                Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct SOC Cardiac disorders         RR         0,8708      0,69    0,328    1,444 0,3237
2 Mild AEs 10 pct SOC Cardiac disorders         OR         0,9010      0,60    0,219    1,654 0,3253
3 Mild AEs 10 pct SOC Cardiac disorders        ARR         0,7730     -0,06   -0,194    0,070 0,3590

$`Gastrointestinal disorders`
                                        Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct SOC Gastrointestinal disorders         RR         0,6635      0,98    0,713    1,358 0,9220
2 Mild AEs 10 pct SOC Gastrointestinal disorders         OR         0,6675      0,97    0,463    2,021 0,9293
3 Mild AEs 10 pct SOC Gastrointestinal disorders        ARR         0,6594     -0,01   -0,190    0,172 0,9226

$`General disorders and administration site conditions`
                                                                    Endpunkt Effektmass Heterog_p_Wert
1 Mild AEs 10 pct SOC General disorders and administration site conditions         RR         0,2790
2 Mild AEs 10 pct SOC General disorders and administration site conditions         OR         0,2264
3 Mild AEs 10 pct SOC General disorders and administration site conditions        ARR         0,1737
  Schaetzer ci_lower ci_upper pvalue
1      0,90    0,627    1,292 0,5685
```

```
2      0,82    0,395    1,721 0,6073
3     -0,04   -0,220    0,141 0,6689

$`Infections and infestations`
                                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Mild AEs 10 pct SOC Infections and infestations         RR         0,2077      1,03    0,751    1,408
2 Mild AEs 10 pct SOC Infections and infestations         OR         0,1305      1,14    0,542    2,413
3 Mild AEs 10 pct SOC Infections and infestations        ARR         0,0406      0,07   -0,107    0,242
  pvalue
1 0,8628
2 0,7257
3 0,4476

$`Injury, poisoning and procedural complications`
                                                              Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Mild AEs 10 pct SOC Injury, poisoning and procedural complications         RR         0,9244      0,67
2 Mild AEs 10 pct SOC Injury, poisoning and procedural complications         OR         0,9531      0,61
3 Mild AEs 10 pct SOC Injury, poisoning and procedural complications        ARR         0,9957     -0,08
  ci_lower ci_upper pvalue
1    0,335    1,356 0,2680
2    0,248    1,481 0,2718
3   -0,232    0,069 0,2886

$Investigations
                            Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct SOC Investigations         RR         0,5129      0,93    0,496    1,732 0,8114
2 Mild AEs 10 pct SOC Investigations         OR         0,4958      0,91    0,395    2,106 0,8293
3 Mild AEs 10 pct SOC Investigations        ARR         0,4565     -0,01   -0,169    0,145 0,8828

$`Metabolism and nutrition disorders`
                                                    Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Mild AEs 10 pct SOC Metabolism and nutrition disorders         RR         0,5164      0,67    0,287
2 Mild AEs 10 pct SOC Metabolism and nutrition disorders         OR         0,4848      0,62    0,228
3 Mild AEs 10 pct SOC Metabolism and nutrition disorders        ARR         0,4217     -0,06   -0,191
  ci_upper pvalue
1    1,573 0,3597
2    1,707 0,3586
3    0,073 0,3785
```

```
$`Musculoskeletal and connective tissue disorders`
                                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Mild AEs 10 pct SOC Musculoskeletal and connective tissue disorders         RR         0,2144      1,17
2 Mild AEs 10 pct SOC Musculoskeletal and connective tissue disorders         OR         0,1280      1,21
3 Mild AEs 10 pct SOC Musculoskeletal and connective tissue disorders        ARR         0,0308      0,02
  ci_lower ci_upper pvalue
1    0,448    3,038 0,7530
2    0,401    3,662 0,7334
3   -0,097    0,140 0,7238

$`Respiratory, thoracic and mediastinal disorders`
                                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Mild AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         RR         0,1155      0,90
2 Mild AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         OR         0,0397      0,86
3 Mild AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders        ARR         0,0003      0,07
  ci_lower ci_upper pvalue
1    0,637    1,279 0,5641
2    0,408    1,807 0,6870
3   -0,102    0,240 0,4305

$`Skin and subcutaneous tissue disorders`
                                                        Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Mild AEs 10 pct SOC Skin and subcutaneous tissue disorders         RR         0,9536      0,80    0,468
2 Mild AEs 10 pct SOC Skin and subcutaneous tissue disorders         OR         0,9573      0,73    0,331
3 Mild AEs 10 pct SOC Skin and subcutaneous tissue disorders        ARR         0,9625     -0,07   -0,237
  ci_upper pvalue
1    1,376 0,4234
2    1,599 0,4288
3    0,102 0,4352


\##############################################################################
[[1]]
[1] "Time to 10% mild AEs according to SOC"

$`Cardiac disorders`
                                     Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
```

```
1 Time to mild AEs 10 pct SOC Cardiac disorders         HR         0,7885      0,61    0,251    1,472 0,2697

$`Gastrointestinal disorders`
                                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Time to mild AEs 10 pct SOC Gastrointestinal disorders         HR         0,6705      0,91    0,556
  ci_upper pvalue
1    1,480 0,6958

$`General disorders and administration site conditions`
                                                                                Endpunkt Effektmass Heterog_p_Wert
1 Time to mild AEs 10 pct SOC General disorders and administration site conditions         HR         0,1729
  Schaetzer ci_lower ci_upper pvalue
1      0,67    0,399    1,128 0,1319

$`Injury, poisoning and procedural complications`
                                                                     Endpunkt Effektmass Heterog_p_Wert
1 Time to mild AEs 10 pct SOC Injury, poisoning and procedural complications         HR         0,8097
  Schaetzer ci_lower ci_upper pvalue
1      0,51    0,229    1,135 0,0991

$`Skin and subcutaneous tissue disorders`
                                                            Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Time to mild AEs 10 pct SOC Skin and subcutaneous tissue disorders         HR         0,9996      0,68
  ci_lower ci_upper pvalue
1    0,344    1,330 0,2575


\#############################################################################
[[1]]
[1] "Number of patients with 10% mild AEs according to PT"

$Constipation
                        Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Constipation         RR         0,2417      1,45    0,734    2,872 0,2838
2 Mild AEs 10 pct PT Constipation         OR         0,2161      1,63    0,677    3,916 0,2762
3 Mild AEs 10 pct PT Constipation        ARR         0,1735      0,09   -0,065    0,238 0,2637

$Cough
```

```
                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Cough         RR         0,0505      0,64    0,246    1,654 0,3549
2 Mild AEs 10 pct PT Cough         OR         0,0213      0,57    0,186    1,745 0,3240
3 Mild AEs 10 pct PT Cough        ARR         0,0001     -0,02   -0,143    0,103 0,7503

$Diarrhoea
                      Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Diarrhoea         RR         0,4073      0,74    0,309    1,768 0,4972
2 Mild AEs 10 pct PT Diarrhoea         OR         0,3997      0,70    0,253    1,957 0,5003
3 Mild AEs 10 pct PT Diarrhoea        ARR         0,3914     -0,04   -0,173    0,087 0,5128

$`Gastrooesophageal reflux disease`
                                              Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Mild AEs 10 pct PT Gastrooesophageal reflux disease         RR         0,4242      0,78    0,305    1,985
2 Mild AEs 10 pct PT Gastrooesophageal reflux disease         OR         0,4175      0,75    0,254    2,200
3 Mild AEs 10 pct PT Gastrooesophageal reflux disease        ARR         0,4143     -0,03   -0,157    0,089
  pvalue
1 0,5991
2 0,5978
3 0,5902

$`Nasal congestion`
                             Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Nasal congestion         RR         0,2895      1,01    0,377    2,685 0,9912
2 Mild AEs 10 pct PT Nasal congestion         OR         0,2431      1,01    0,328    3,093 0,9899
3 Mild AEs 10 pct PT Nasal congestion        ARR         0,1633     -0,00   -0,121    0,113 0,9512

$Pyrexia
                       Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Pyrexia         RR         0,3142      0,97    0,644    1,446 0,8632
2 Mild AEs 10 pct PT Pyrexia         OR         0,2595      0,94    0,451    1,973 0,8771
3 Mild AEs 10 pct PT Pyrexia        ARR         0,2070     -0,01   -0,187    0,174 0,9437

$Tachycardia
                         Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Tachycardia         RR         0,3508      0,50    0,196    1,269 0,1445
2 Mild AEs 10 pct PT Tachycardia         OR         0,7417      0,31    0,082    1,192 0,0887
3 Mild AEs 10 pct PT Tachycardia        ARR         0,8259     -0,09   -0,194    0,021 0,1150
```

```
$Teething
                     Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Teething         RR         0,1966      1,48    0,394    5,559 0,5619
2 Mild AEs 10 pct PT Teething         OR         0,1917      1,61    0,380    6,832 0,5177
3 Mild AEs 10 pct PT Teething        ARR         0,2281      0,05   -0,041    0,148 0,2653

$`Upper respiratory tract infection`
                                                Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Mild AEs 10 pct PT Upper respiratory tract infection         RR         0,6702      1,32    0,522    3,310
2 Mild AEs 10 pct PT Upper respiratory tract infection         OR         0,6490      1,37    0,473    3,992
3 Mild AEs 10 pct PT Upper respiratory tract infection        ARR         0,5879      0,04   -0,087    0,160
  pvalue
1 0,5608
2 0,5589
3 0,5627

$Vomiting
                     Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Vomiting         RR         0,5852      1,10    0,465    2,621 0,8218
2 Mild AEs 10 pct PT Vomiting         OR         0,5692      1,13    0,407    3,109 0,8203
3 Mild AEs 10 pct PT Vomiting        ARR         0,5287      0,01   -0,115    0,144 0,8271


\##############################################################################
[[1]]
[1] "Time to 10% mild AEs according to PT"

$Pyrexia
                           Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to mild AEs 10 pct PT Pyrexia         HR         0,2255      0,80    0,462    1,380 0,4213

$Tachycardia
                              Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to mild AEs 10 pct PT Tachycardia         HR         0,3949      0,39    0,122    1,236 0,1092


\##############################################################################
```

```
[[1]]
[1] "Number of patients with 10% moderate AEs according to SOC"

$`Gastrointestinal disorders`
                                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Moderate AEs 10 pct SOC Gastrointestinal disorders         RR         0,5536      1,02    0,509    2,041
2 Moderate AEs 10 pct SOC Gastrointestinal disorders         OR         0,5397      1,03    0,426    2,495
3 Moderate AEs 10 pct SOC Gastrointestinal disorders        ARR         0,5080      0,01   -0,141    0,157
  pvalue
1 0,9574
2 0,9466
3 0,9151

$`General disorders and administration site conditions`
                                                                  Endpunkt Effektmass Heterog_p_Wert
1 Moderate AEs 10 pct SOC General disorders and administration site conditions         RR         0,5761
2 Moderate AEs 10 pct SOC General disorders and administration site conditions         OR         0,5651
3 Moderate AEs 10 pct SOC General disorders and administration site conditions        ARR         0,5432
  Schaetzer ci_lower ci_upper pvalue
1      1,06    0,581    1,946 0,8427
2      1,10    0,481    2,499 0,8267
3      0,02   -0,136    0,182 0,7798

$`Infections and infestations`
                                         Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Moderate AEs 10 pct SOC Infections and infestations         RR         0,6786      1,85    1,202    2,857
2 Moderate AEs 10 pct SOC Infections and infestations         OR         0,3910      3,28    1,523    7,079
3 Moderate AEs 10 pct SOC Infections and infestations        ARR         0,3838      0,30    0,125    0,467
  pvalue
1 0,0053
2 0,0024
3 0,0007

$Investigations
                                Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Moderate AEs 10 pct SOC Investigations         RR         0,4994      0,69    0,278    1,728 0,4314
2 Moderate AEs 10 pct SOC Investigations         OR         0,4661      0,65    0,227    1,886 0,4318
3 Moderate AEs 10 pct SOC Investigations        ARR         0,3965     -0,05   -0,172    0,078 0,4645
```

```
$`Respiratory, thoracic and mediastinal disorders`
                                                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Moderate AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         RR         0,8596      0,84
2 Moderate AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         OR         0,8114      0,72
3 Moderate AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders        ARR         0,8108     -0,08
  ci_lower ci_upper pvalue
1    0,567    1,233 0,3667
2    0,346    1,505 0,3839
3   -0,262    0,100 0,3809


\##############################################################################
[[1]]
[1] "Time to 10% moderate AEs according to SOC"

$`Infections and infestations`
                                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Time to moderate AEs 10 pct SOC Infections and infestations         HR         0,5725      2,00    1,126
  ci_upper pvalue
1    3,564 0,0180

$`Respiratory, thoracic and mediastinal disorders`
                                                                Endpunkt Effektmass Heterog_p_Wert
1 Time to moderate AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         HR         0,8456
  Schaetzer ci_lower ci_upper pvalue
1      0,72    0,417    1,228 0,2245


\##############################################################################
[[1]]
[1] "Number of patients with 10% moderate AEs according to PT"

$Pneumonia
                         Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Moderate AEs 10 pct PT Pneumonia         RR         0,8431      5,00    0,988   25,286 0,0517
2 Moderate AEs 10 pct PT Pneumonia         OR         0,9638      6,54    1,100   38,877 0,0390
3 Moderate AEs 10 pct PT Pneumonia        ARR         0,3527      0,12    0,032    0,208 0,0075
```

$`Pneumonia aspiration`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Moderate AEs 10 pct PT Pneumonia aspiration	RR	0,3364	0,64	0,213	1,903	0,4193
2	Moderate AEs 10 pct PT Pneumonia aspiration	OR	0,3394	0,60	0,176	2,028	0,4092
3	Moderate AEs 10 pct PT Pneumonia aspiration	ARR	0,3845	-0,05	-0,159	0,062	0,3889

$Pyrexia

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Moderate AEs 10 pct PT Pyrexia	RR	0,6584	1,27	0,621	2,586	0,5146
2	Moderate AEs 10 pct PT Pyrexia	OR	0,6486	1,36	0,553	3,331	0,5047
3	Moderate AEs 10 pct PT Pyrexia	ARR	0,6292	0,05	-0,094	0,200	0,4781

$`Respiratory distress`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Moderate AEs 10 pct PT Respiratory distress	RR	0,6702	1,32	0,522	3,310	0,5608
2	Moderate AEs 10 pct PT Respiratory distress	OR	0,6490	1,37	0,473	3,992	0,5589
3	Moderate AEs 10 pct PT Respiratory distress	ARR	0,5879	0,04	-0,087	0,160	0,5627

$`Upper respiratory tract infection`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Moderate AEs 10 pct PT Upper respiratory tract infection	RR	0,6308	1,22	0,478	3,106	0,6788
2	Moderate AEs 10 pct PT Upper respiratory tract infection	OR	0,6112	1,26	0,428	3,687	0,6789
3	Moderate AEs 10 pct PT Upper respiratory tract infection	ARR	0,5563	0,02	-0,097	0,146	0,6943

\##
[[1]]
[1] "Time to 10% moderate AEs according to PT"

\##
[[1]]
[1] "Number of patients with 5% severe AEs according to SOC"

$`Cardiac disorders`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Severe AEs 5 pct SOC Cardiac disorders	RR	0,6774	0,48	0,190	1,212	0,1205
2	Severe AEs 5 pct SOC Cardiac disorders	OR	0,6277	0,43	0,147	1,251	0,1209
3	Severe AEs 5 pct SOC Cardiac disorders	ARR	0,5006	-0,09	-0,221	0,033	0,1483

$`General disorders and administration site conditions`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Severe AEs 5 pct SOC General disorders and administration site conditions	RR	0,2708	1,00	0,176	5,651	0,9968
2	Severe AEs 5 pct SOC General disorders and administration site conditions	OR	0,2559	1,06	0,161	7,000	0,9500
3	Severe AEs 5 pct SOC General disorders and administration site conditions	ARR	0,2811	0,02	-0,046	0,088	0,5355

$`Infections and infestations`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Severe AEs 5 pct SOC Infections and infestations	RR	0,5603	0,87	0,553	1,379	0,5608
2	Severe AEs 5 pct SOC Infections and infestations	OR	0,5528	0,80	0,380	1,703	0,5695
3	Severe AEs 5 pct SOC Infections and infestations	ARR	0,5440	-0,05	-0,229	0,127	0,5765

$`Respiratory, thoracic and mediastinal disorders`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Severe AEs 5 pct SOC Respiratory, thoracic and mediastinal disorders	RR	0,3486	0,72	0,540	0,956	0,0234
2	Severe AEs 5 pct SOC Respiratory, thoracic and mediastinal disorders	OR	0,4400	0,42	0,194	0,926	0,0312
3	Severe AEs 5 pct SOC Respiratory, thoracic and mediastinal disorders	ARR	0,3989	-0,20	-0,372	-0,029	0,0218

```
\##############################################################################
[[1]]
[1] "Time to 5% severe AEs according to SOC"

$`Infections and infestations`
                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Time to severe AEs 5 pct SOC Infections and infestations         HR         0,6717      0,76    0,424
  ci_upper pvalue
1    1,375 0,3694

$`Respiratory, thoracic and mediastinal disorders`
                                                                    Endpunkt Effektmass Heterog_p_Wert
1 Time to severe AEs 5 pct SOC Respiratory, thoracic and mediastinal disorders         HR         0,4207
  Schaetzer ci_lower ci_upper pvalue
1      0,56    0,350    0,894 0,0152


\##############################################################################
[[1]]
[1] "Number of patients with 5% severe AEs according to PT"

$`Acute respiratory failure`
                                       Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Severe AEs 5 pct PT Acute respiratory failure         RR         0,8861      0,64    0,300    1,356 0,2430
2 Severe AEs 5 pct PT Acute respiratory failure         OR         0,9264      0,57    0,225    1,464 0,2452
3 Severe AEs 5 pct PT Acute respiratory failure        ARR         0,9970     -0,08   -0,226    0,062 0,2644

$`Bronchial secretion retention`
                                         Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Severe AEs 5 pct PT Bronchial secretion retention         RR         0,0863      0,30    0,055    1,681
2 Severe AEs 5 pct PT Bronchial secretion retention         OR         0,0987      0,24    0,037    1,535
3 Severe AEs 5 pct PT Bronchial secretion retention        ARR         0,2895     -0,10   -0,200    0,003
  pvalue
1 0,1721
2 0,1317
3 0,0560

$Bronchiolitis
```

```
                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Severe AEs 5 pct PT Bronchiolitis         RR         0,2708      1,00    0,176    5,651 0,9968
2 Severe AEs 5 pct PT Bronchiolitis         OR         0,2559      1,06    0,161    7,000 0,9500
3 Severe AEs 5 pct PT Bronchiolitis        ARR         0,2811      0,02   -0,046    0,088 0,5355

$`Cardio-respiratory arrest`
                                      Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Severe AEs 5 pct PT Cardio-respiratory arrest         RR         0,6842      0,47    0,156    1,397 0,1734
2 Severe AEs 5 pct PT Cardio-respiratory arrest         OR         0,6219      0,43    0,126    1,456 0,1746
3 Severe AEs 5 pct PT Cardio-respiratory arrest        ARR         0,4458     -0,07   -0,179    0,042 0,2264

$Pneumonia
                       Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Severe AEs 5 pct PT Pneumonia         RR         0,3601      1,21    0,469    3,096 0,6984
2 Severe AEs 5 pct PT Pneumonia         OR         0,3003      1,25    0,420    3,696 0,6924
3 Severe AEs 5 pct PT Pneumonia        ARR         0,1921      0,02   -0,099    0,142 0,7298

$`Respiratory distress`
                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Severe AEs 5 pct PT Respiratory distress         RR         0,5216      0,85    0,406    1,799 0,6782
2 Severe AEs 5 pct PT Respiratory distress         OR         0,5425      0,80    0,312    2,045 0,6397
3 Severe AEs 5 pct PT Respiratory distress        ARR         0,5741     -0,04   -0,179    0,105 0,6082

$`Respiratory failure`
                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Severe AEs 5 pct PT Respiratory failure         RR         0,2894      0,51    0,279    0,944 0,0320
2 Severe AEs 5 pct PT Respiratory failure         OR         0,2570      0,41    0,180    0,952 0,0379
3 Severe AEs 5 pct PT Respiratory failure        ARR         0,1868     -0,16   -0,316    0,006 0,0585

$`Respiratory syncytial virus bronchiolitis`
                                                        Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Severe AEs 5 pct PT Respiratory syncytial virus bronchiolitis         RR         0,3601      0,72    0,183
2 Severe AEs 5 pct PT Respiratory syncytial virus bronchiolitis         OR         0,3635      0,68    0,153
3 Severe AEs 5 pct PT Respiratory syncytial virus bronchiolitis        ARR         0,4306     -0,03   -0,118
  ci_upper pvalue
1    2,845 0,6407
2    3,031 0,6148
3    0,059 0,5145
```

```
$`Rhinovirus infection`
                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Severe AEs 5 pct PT Rhinovirus infection         RR         0,9470      0,70    0,205    2,401 0,5720
2 Severe AEs 5 pct PT Rhinovirus infection         OR         1,0000      0,67    0,164    2,705 0,5704
3 Severe AEs 5 pct PT Rhinovirus infection        ARR         0,8639     -0,02   -0,116    0,068 0,6054


\#############################################################################
[[1]]
[1] "Time to 5% severe AEs according to PT"

$`Acute respiratory failure`
                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Time to severe AEs 5 pct PT Acute respiratory failure         HR         0,7214      0,53    0,230    1,245
  pvalue
1 0,1465

$`Respiratory distress`
                                           Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Time to severe AEs 5 pct PT Respiratory distress         HR         0,4396      0,75    0,324    1,737
  pvalue
1 0,5016

$`Rhinovirus infection`
                                           Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Time to severe AEs 5 pct PT Rhinovirus infection         HR         0,9996      0,62    0,138    2,760
  pvalue
1 0,5267


\#############################################################################
[[1]]
[1] "Number of patients with 10% moderate or severe AEs according to SOC"

$`Cardiac disorders`
                                              Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Moderate or severe AEs 10 pct SOC Cardiac disorders         RR         0,4761      0,75    0,361    1,538
```

```
2 Moderate or severe AEs 10 pct SOC Cardiac disorders         OR         0,4540      0,69    0,278    1,705
3 Moderate or severe AEs 10 pct SOC Cardiac disorders        ARR         0,4225     -0,06   -0,207    0,085
  pvalue
1 0,4262
2 0,4195
3 0,4113

$`Gastrointestinal disorders`
                                                        Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Moderate or severe AEs 10 pct SOC Gastrointestinal disorders         RR         0,5129      0,93    0,496
2 Moderate or severe AEs 10 pct SOC Gastrointestinal disorders         OR         0,4958      0,91    0,395
3 Moderate or severe AEs 10 pct SOC Gastrointestinal disorders        ARR         0,4565     -0,01   -0,169
  ci_upper pvalue
1    1,732 0,8114
2    2,106 0,8293
3    0,145 0,8828

$`General disorders and administration site conditions`
                                                                                Endpunkt Effektmass
1 Moderate or severe AEs 10 pct SOC General disorders and administration site conditions         RR
2 Moderate or severe AEs 10 pct SOC General disorders and administration site conditions         OR
3 Moderate or severe AEs 10 pct SOC General disorders and administration site conditions        ARR
  Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1         0,7488      1,09    0,624    1,891 0,7705
2         0,7481      1,13    0,509    2,495 0,7691
3         0,7472      0,03   -0,142    0,193 0,7673

$`Infections and infestations`
                                                      Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Moderate or severe AEs 10 pct SOC Infections and infestations         RR         0,8246      1,32    0,983
2 Moderate or severe AEs 10 pct SOC Infections and infestations         OR         0,5954      2,11    0,986
3 Moderate or severe AEs 10 pct SOC Infections and infestations        ARR         0,7024      0,17    0,002
  ci_upper pvalue
1    1,778 0,0653
2    4,508 0,0545
3    0,348 0,0479

$Investigations
```

```
                                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Moderate or severe AEs 10 pct SOC Investigations         RR         0,6719      0,49    0,228    1,052
2 Moderate or severe AEs 10 pct SOC Investigations         OR         0,6429      0,42    0,163    1,065
3 Moderate or severe AEs 10 pct SOC Investigations        ARR         0,5867     -0,13   -0,275    0,015
  pvalue
1 0,0673
2 0,0676
3 0,0782

$`Respiratory, thoracic and mediastinal disorders`
                                                                                Endpunkt Effektmass Heterog_p_Wert
1 Moderate or severe AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         RR         0,5085
2 Moderate or severe AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         OR         0,5039
3 Moderate or severe AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders        ARR         0,5045
  Schaetzer ci_lower ci_upper pvalue
1      0,82    0,649    1,025 0,0805
2      0,51    0,218    1,169 0,1106
3     -0,14   -0,303    0,018 0,0826


\##############################################################################
[[1]]
[1] "Time to 10% moderate or severe AEs according to SOC"

$`General disorders and administration site conditions`
                                                                                              Endpunkt Effektmass
1 Time to moderate or severe AEs 10 pct SOC General disorders and administration site conditions         HR
  Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1         0,8489      0,92    0,471    1,790 0,8031

$`Infections and infestations`
                                                                     Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Time to moderate or severe AEs 10 pct SOC Infections and infestations         HR         0,9375      1,42
  ci_lower ci_upper pvalue
1    0,882    2,302 0,1485

$`Respiratory, thoracic and mediastinal disorders`
                                                                                  Endpunkt Effektmass
```

```
1 Time to moderate or severe AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         HR
  Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1         0,4922      0,71    0,459    1,098 0,1234


\#############################################################################
[[1]]
[1] "Number of patients with 10% moderate or severe AEs according to PT"

$`Acute respiratory failure`
                                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Moderate or severe AEs 10 pct PT Acute respiratory failure         RR         0,8861      0,64    0,300
2 Moderate or severe AEs 10 pct PT Acute respiratory failure         OR         0,9264      0,57    0,225
3 Moderate or severe AEs 10 pct PT Acute respiratory failure        ARR         0,9970     -0,08   -0,226
  ci_upper pvalue
1    1,356 0,2430
2    1,464 0,2452
3    0,062 0,2644

$`Bronchial secretion retention`
                                                    Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Moderate or severe AEs 10 pct PT Bronchial secretion retention         RR         0,1423      0,33    0,100
2 Moderate or severe AEs 10 pct PT Bronchial secretion retention         OR         0,1539      0,28    0,075
3 Moderate or severe AEs 10 pct PT Bronchial secretion retention        ARR         0,2548     -0,12   -0,236
  ci_upper pvalue
1    1,069 0,0643
2    1,027 0,0549
3    0,002 0,0547

$`Cardio-respiratory arrest`
                                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Moderate or severe AEs 10 pct PT Cardio-respiratory arrest         RR         0,6842      0,47    0,156
2 Moderate or severe AEs 10 pct PT Cardio-respiratory arrest         OR         0,6219      0,43    0,126
3 Moderate or severe AEs 10 pct PT Cardio-respiratory arrest        ARR         0,4458     -0,07   -0,179
  ci_upper pvalue
1    1,397 0,1734
2    1,456 0,1746
3    0,042 0,2264
```

$Dysphagia

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Moderate or severe AEs 10 pct PT Dysphagia	RR	0,2818	0,53	0,201	1,390	0,1963
2	Moderate or severe AEs 10 pct PT Dysphagia	OR	0,2839	0,48	0,159	1,451	0,1938
3	Moderate or severe AEs 10 pct PT Dysphagia	ARR	0,3185	-0,08	-0,205	0,045	0,2105

$Dyspnoea

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Moderate or severe AEs 10 pct PT Dyspnoea	RR	0,2122	0,45	0,129	1,560	0,2072
2	Moderate or severe AEs 10 pct PT Dyspnoea	OR	0,2249	0,40	0,102	1,575	0,1905
3	Moderate or severe AEs 10 pct PT Dyspnoea	ARR	0,3349	-0,07	-0,180	0,033	0,1749

$Pneumonia

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Moderate or severe AEs 10 pct PT Pneumonia	RR	0,4223	1,98	0,902	4,362	0,0887
2	Moderate or severe AEs 10 pct PT Pneumonia	OR	0,2701	2,42	0,925	6,328	0,0715
3	Moderate or severe AEs 10 pct PT Pneumonia	ARR	0,0934	0,15	0,010	0,289	0,0355

$`Pneumonia aspiration`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Moderate or severe AEs 10 pct PT Pneumonia aspiration	RR	0,1933	0,72	0,295	1,749	0,4658
2	Moderate or severe AEs 10 pct PT Pneumonia aspiration	OR	0,1644	0,68	0,241	1,935	0,4724
3	Moderate or severe AEs 10 pct PT Pneumonia aspiration	ARR	0,1194	-0,05	-0,175	0,083	0,4858

$Pyrexia

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Moderate or severe AEs 10 pct PT Pyrexia	RR	0,7059	1,39	0,690	2,804	0,3561
2	Moderate or severe AEs 10 pct PT Pyrexia	OR	0,7008	1,54	0,631	3,739	0,3439
3	Moderate or severe AEs 10 pct PT Pyrexia	ARR	0,6955	0,08	-0,072	0,225	0,3138

$`Respiratory distress`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper
1	Moderate or severe AEs 10 pct PT Respiratory distress	RR	0,6375	0,98	0,537	1,781

```
2 Moderate or severe AEs 10 pct PT Respiratory distress         OR         0,6308      0,96    0,421    2,195
3 Moderate or severe AEs 10 pct PT Respiratory distress        ARR         0,6256     -0,01   -0,170    0,152
  pvalue
1 0,9424
2 0,9255
3 0,9119

$`Respiratory failure`
                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Moderate or severe AEs 10 pct PT Respiratory failure         RR         0,1861      0,65    0,382    1,120
2 Moderate or severe AEs 10 pct PT Respiratory failure         OR         0,1396      0,56    0,254    1,234
3 Moderate or severe AEs 10 pct PT Respiratory failure        ARR         0,0710     -0,10   -0,270    0,065
  pvalue
1 0,1221
2 0,1504
3 0,2286

$`Rhinovirus infection`
                                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Moderate or severe AEs 10 pct PT Rhinovirus infection         RR         0,8870      1,33    0,517    3,438
2 Moderate or severe AEs 10 pct PT Rhinovirus infection         OR         0,8074      1,40    0,447    4,370
3 Moderate or severe AEs 10 pct PT Rhinovirus infection        ARR         0,7099      0,03   -0,084    0,146
  pvalue
1 0,5511
2 0,5649
3 0,5972

$`Upper respiratory tract infection`
                                                             Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Moderate or severe AEs 10 pct PT Upper respiratory tract infection         RR         0,7425      1,51
2 Moderate or severe AEs 10 pct PT Upper respiratory tract infection         OR         0,7202      1,62
3 Moderate or severe AEs 10 pct PT Upper respiratory tract infection        ARR         0,6534      0,06
  ci_lower ci_upper pvalue
1    0,611    3,717 0,3729
2    0,568    4,629 0,3667
3   -0,066    0,187 0,3490

$`Viral upper respiratory tract infection`
```

```
                                                                    Endpunkt Effektmass Heterog_p_Wert
1 Moderate or severe AEs 10 pct PT Viral upper respiratory tract infection         RR         0,6088
2 Moderate or severe AEs 10 pct PT Viral upper respiratory tract infection         OR         0,5624
3 Moderate or severe AEs 10 pct PT Viral upper respiratory tract infection        ARR         0,4465
  Schaetzer ci_lower ci_upper pvalue
1      0,55    0,208    1,438 0,2212
2      0,50    0,167    1,518 0,2225
3     -0,07   -0,191    0,052 0,2609


\#############################################################################
[[1]]
[1] "Time to 10% moderate or severe AEs according to PT"

$`Acute respiratory failure`
                                                          Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Time to moderate or severe AEs 10 pct PT Acute respiratory failure         HR         0,7378      0,55
  ci_lower ci_upper pvalue
1    0,237    1,282 0,1667

$`Respiratory distress`
                                                        Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Time to moderate or severe AEs 10 pct PT Respiratory distress         HR         0,5277      0,87    0,429
  ci_upper pvalue
1    1,760 0,6970

$`Rhinovirus infection`
                                                        Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Time to moderate or severe AEs 10 pct PT Rhinovirus infection         HR         0,6408      1,13    0,387
  ci_upper pvalue
1    3,298 0,8241


\#############################################################################
[[1]]
[1] "Number of patients with 5% SAEs according to SOC"

$`Cardiac disorders`
```

```
                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 SAEs 5 pct SOC Cardiac disorders         RR         0,5620      0,61    0,254    1,453 0,2629
2 SAEs 5 pct SOC Cardiac disorders         OR         0,5258      0,56    0,200    1,551 0,2630
3 SAEs 5 pct SOC Cardiac disorders        ARR         0,4471     -0,07   -0,201    0,060 0,2876

$`Gastrointestinal disorders`
                                    Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 SAEs 5 pct SOC Gastrointestinal disorders         RR         0,3935      0,73    0,257    2,097 0,5631
2 SAEs 5 pct SOC Gastrointestinal disorders         OR         0,3913      0,70    0,215    2,281 0,5553
3 SAEs 5 pct SOC Gastrointestinal disorders        ARR         0,4108     -0,04   -0,149    0,076 0,5277

$`General disorders and administration site conditions`
                                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 SAEs 5 pct SOC General disorders and administration site conditions         RR         0,1539      1,51
2 SAEs 5 pct SOC General disorders and administration site conditions         OR         0,1517      1,72
3 SAEs 5 pct SOC General disorders and administration site conditions        ARR         0,2266      0,06
  ci_lower ci_upper pvalue
1    0,280    8,132 0,6312
2    0,277   10,704 0,5601
3   -0,021    0,133 0,1524

$`Infections and infestations`
                                     Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 SAEs 5 pct SOC Infections and infestations         RR         0,5179      1,30    0,901    1,882 0,1595
2 SAEs 5 pct SOC Infections and infestations         OR         0,4546      1,76    0,840    3,684 0,1340
3 SAEs 5 pct SOC Infections and infestations        ARR         0,4172      0,14   -0,036    0,325 0,1160

$`Respiratory, thoracic and mediastinal disorders`
                                                       Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 SAEs 5 pct SOC Respiratory, thoracic and mediastinal disorders         RR         0,5407      0,84    0,652
2 SAEs 5 pct SOC Respiratory, thoracic and mediastinal disorders         OR         0,5630      0,58    0,262
3 SAEs 5 pct SOC Respiratory, thoracic and mediastinal disorders        ARR         0,5490     -0,12   -0,286
  ci_upper pvalue
1    1,074 0,1614
2    1,296 0,1858
3    0,049 0,1652
```

```
\#############################################################################
[[1]]
[1] "Time to 5% SAEs according to SOC"

$`Infections and infestations`
                                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Time to SAEs 5 pct SOC Infections and infestations         HR         0,6781      1,35    0,800    2,272
  pvalue
1 0,2627

$`Respiratory, thoracic and mediastinal disorders`
                                                                Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Time to SAEs 5 pct SOC Respiratory, thoracic and mediastinal disorders         HR         0,3295      0,80
  ci_lower ci_upper pvalue
1    0,512    1,249 0,3253


\#############################################################################
[[1]]
[1] "Number of patients with 5% SAEs according to PT"

$`Acute respiratory failure`
                                Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 SAEs 5 pct PT Acute respiratory failure         RR         0,8861      0,64    0,300    1,356 0,2430
2 SAEs 5 pct PT Acute respiratory failure         OR         0,9264      0,57    0,225    1,464 0,2452
3 SAEs 5 pct PT Acute respiratory failure        ARR         0,9970     -0,08   -0,226    0,062 0,2644

$`Bronchial secretion retention`
                                   Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 SAEs 5 pct PT Bronchial secretion retention         RR         0,0863      0,30    0,055    1,681 0,1721
2 SAEs 5 pct PT Bronchial secretion retention         OR         0,0987      0,24    0,037    1,535 0,1317
3 SAEs 5 pct PT Bronchial secretion retention        ARR         0,2895     -0,10   -0,200    0,003 0,0560

$Bronchiolitis
                     Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 SAEs 5 pct PT Bronchiolitis         RR         0,2708      1,00    0,176    5,651 0,9968
2 SAEs 5 pct PT Bronchiolitis         OR         0,2559      1,06    0,161    7,000 0,9500
3 SAEs 5 pct PT Bronchiolitis        ARR         0,2811      0,02   -0,046    0,088 0,5355
```

$`Cardio-respiratory arrest`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	SAEs 5 pct PT Cardio-respiratory arrest	RR	0,6842	0,47	0,156	1,397	0,1734
2	SAEs 5 pct PT Cardio-respiratory arrest	OR	0,6219	0,43	0,126	1,456	0,1746
3	SAEs 5 pct PT Cardio-respiratory arrest	ARR	0,4458	-0,07	-0,179	0,042	0,2264

$Pneumonia

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	SAEs 5 pct PT Pneumonia	RR	0,6248	2,09	0,882	4,963	0,0939
2	SAEs 5 pct PT Pneumonia	OR	0,5360	2,48	0,894	6,872	0,0811
3	SAEs 5 pct PT Pneumonia	ARR	0,3656	0,13	-0,002	0,264	0,0532

$`Pneumonia aspiration`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	SAEs 5 pct PT Pneumonia aspiration	RR	0,2895	1,01	0,377	2,685	0,9912
2	SAEs 5 pct PT Pneumonia aspiration	OR	0,2431	1,01	0,328	3,093	0,9899
3	SAEs 5 pct PT Pneumonia aspiration	ARR	0,1633	-0,00	-0,121	0,113	0,9512

$`Respiratory distress`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	SAEs 5 pct PT Respiratory distress	RR	0,9155	1,36	0,695	2,677	0,3662
2	SAEs 5 pct PT Respiratory distress	OR	0,8513	1,51	0,624	3,633	0,3629
3	SAEs 5 pct PT Respiratory distress	ARR	0,7928	0,07	-0,080	0,223	0,3535

$`Respiratory failure`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	SAEs 5 pct PT Respiratory failure	RR	0,1981	0,69	0,404	1,164	0,1624
2	SAEs 5 pct PT Respiratory failure	OR	0,1498	0,60	0,272	1,307	0,1965
3	SAEs 5 pct PT Respiratory failure	ARR	0,0780	-0,09	-0,259	0,077	0,2884

$`Respiratory syncytial virus bronchiolitis`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	SAEs 5 pct PT Respiratory syncytial virus bronchiolitis	RR	0,4498	0,88	0,239	3,207	0,8416
2	SAEs 5 pct PT Respiratory syncytial virus bronchiolitis	OR	0,4440	0,85	0,206		
3	SAEs 5 pct PT Respiratory syncytial virus bronchiolitis	ARR	0,4589	-0,02	-0,108		

```
2    3,503 0,8217
3    0,075 0,7164

$`Rhinovirus infection`
                            Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 SAEs 5 pct PT Rhinovirus infection         RR         0,8848      1,67    0,511    5,457 0,3956
2 SAEs 5 pct PT Rhinovirus infection         OR         0,9699      1,90    0,452    7,966 0,3818
3 SAEs 5 pct PT Rhinovirus infection        ARR         0,7312      0,04   -0,049    0,130 0,3743


\##############################################################################
[[1]]
[1] "Time to 5% SAEs according to PT"

$`Acute respiratory failure`
                                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Time to SAEs 5 pct PT Acute respiratory failure         HR         0,7505      0,56    0,243    1,309
  pvalue
1 0,1822

$`Respiratory distress`
                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to SAEs 5 pct PT Respiratory distress         HR         0,7503      1,26    0,581    2,730 0,5587

$`Rhinovirus infection`
                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to SAEs 5 pct PT Rhinovirus infection         HR         0,5323      1,33    0,337    5,219 0,6864


\##############################################################################
[[1]]
[1] "HINE-Responder-section 2 Day 64 TOTSCORE"

$Endpunkt
[1] "HINE-Responder-section 2 Day 64 TOTSCORE" "HINE-Responder-section 2 Day 64 TOTSCORE"
[3] "HINE-Responder-section 2 Day 64 TOTSCORE"

$Effektmass
```

```
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,8735" "0,8600" "0,8529"

$Schaetzer
[1] "1,29" "1,53" "0,10"

$ci_lower
[1] "0,804"  "0,715"  "-0,076"

$ci_upper
[1] "2,084" "3,258" "0,276"

$pvalue
[1] "0,2884" "0,2747" "0,2642"


\##############################################################################
[[1]]
[1] "HINE-Responder-section 2 Day 183 TOTSCORE"

$Endpunkt
[1] "HINE-Responder-section 2 Day 183 TOTSCORE" "HINE-Responder-section 2 Day 183 TOTSCORE"
[3] "HINE-Responder-section 2 Day 183 TOTSCORE"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,0813" "0,8789" "0,7195"

$Schaetzer
[1] "2,37" "7,04" "0,37"

$ci_lower
[1] "1,319" "2,611" "0,228"
```

```
$ci_upper
[1] "4,274"  "18,985" "0,514"

$pvalue
[1] "0,0039" "0,0001" "0,0000"


\##############################################################################
[[1]]
[1] "HINE-Responder-section 2 Day 302 TOTSCORE"

$Endpunkt
[1] "HINE-Responder-section 2 Day 302 TOTSCORE" "HINE-Responder-section 2 Day 302 TOTSCORE"
[3] "HINE-Responder-section 2 Day 302 TOTSCORE"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,6416" "0,2590" "0,0231"

$Schaetzer
[1] "4,03" "6,23" "0,32"

$ci_lower
[1] "1,616" "2,099" "0,184"

$ci_upper
[1] "10,046" "18,514" "0,448"

$pvalue
[1] "0,0028" "0,0010" "0,0000"


\##############################################################################
[[1]]
[1] "Time to motor milestone responders  (HINE section 2) TOTSCORE"
```

```
$Endpunkt
[1] "Time to motor milestone responders  (HINE section 2) TOTSCORE"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,2102"

$Schaetzer
[1] "2,11"

$ci_lower
[1] "1,209"

$ci_upper
[1] "3,671"

$pvalue
[1] "0,0085"


\##############################################################################
[[1]]
[1] "Change from baseline in HINE-section 2 Day 64 TOTSCORE"

$Endpunkt
[1] "Change from baseline in HINE-section 2 Day 64 TOTSCORE"

$Effektmass
[1] "Hedges g"

$Heterog_p_Wert
[1] "0,7528"

$Schaetzer
[1] "0,34"
```

```
$ci_lower
[1] "-0,060"

$ci_upper
[1] "0,733"

$pvalue
[1] "0,0961"


\##############################################################################
[[1]]
[1] "Change from baseline in HINE-section 2 Day 183 TOTSCORE"

$Endpunkt
[1] "Change from baseline in HINE-section 2 Day 183 TOTSCORE"

$Effektmass
[1] "Hedges g"

$Heterog_p_Wert
[1] "0,8430"

$Schaetzer
[1] "1,10"

$ci_lower
[1] "0,612"

$ci_upper
[1] "1,596"

$pvalue
[1] "0,0000"


\##############################################################################
```

```
> sink()
```

Anhang 4-G zu Modul 4 A.1

Meta-Analyse 2

ENDEAR und EMBRACE

Stand: 01.12.2020

```
> cat("Results for Metaanalysis")
Results for Metaanalysis
> for(i in mergeList){
+   print(i)
+   cat("\n\\#############################################################################################\n")
+ }
[[1]]
[1] "Survival Rate"

$Endpunkt
[1] "Survival Rate" "Survival Rate" "Survival Rate"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,8008" "0,9592" "0,8491"

$Schaetzer
[1] "1,36" "3,28" "0,22"

$ci_lower
[1] "1,061" "1,417" "0,061"

$ci_upper
[1] "1,735" "7,594" "0,384"

$pvalue
[1] "0,0149" "0,0055" "0,0068"


\#############################################################################
[[1]]
[1] "Time to death"

$Endpunkt
[1] "Time to death"
```

```
$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,9997"

$Schaetzer
[1] "0,37"

$ci_lower
[1] "0,179"

$ci_upper
[1] "0,774"

$pvalue
[1] "0,0082"


\##############################################################################
[[1]]
[1] "Time to death or permanent ventilation"

$Endpunkt
[1] "Time to death or permanent ventilation"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,9997"

$Schaetzer
[1] "0,53"

$ci_lower
[1] "0,316"
```

```
$ci_upper
[1] "0,891"

$pvalue
[1] "0,0166"


\##############################################################################
[[1]]
[1] "Percent of subjects not requiring permanent ventilation"

$Endpunkt
[1] "Percent of subjects not requiring permanent ventilation"
[2] "Percent of subjects not requiring permanent ventilation"
[3] "Percent of subjects not requiring permanent ventilation"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,5668" "0,7393" "0,6104"

$Schaetzer
[1] "1,10" "1,55" "0,08"

$ci_lower
[1] "0,888"  "0,681"  "-0,081"

$ci_upper
[1] "1,361" "3,547" "0,232"

$pvalue
[1] "0,3848" "0,2944" "0,3454"


\##############################################################################
[[1]]
```

```
[1] "HINE-Responder-section 2 Day 64"

$Endpunkt
[1] "HINE-Responder-section 2 Day 64" "HINE-Responder-section 2 Day 64" "HINE-Responder-section 2 Day 64"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,5960" "0,5930" "0,6148"

$Schaetzer
[1] "1,74" "2,11" "0,14"

$ci_lower
[1] "0,883"  "0,879"  "-0,011"

$ci_upper
[1] "3,429" "5,063" "0,294"

$pvalue
[1] "0,1093" "0,0944" "0,0693"


\##############################################################################
[[1]]
[1] "HINE-Responder-section 2 Day 183"

$Endpunkt
[1] "HINE-Responder-section 2 Day 183" "HINE-Responder-section 2 Day 183" "HINE-Responder-section 2 Day 183"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,3322" "0,8644" "0,3585"

$Schaetzer
```

```
[1] "4,75"  "12,31" "0,34"

$ci_lower
[1] "1,783" "3,116" "0,219"

$ci_upper
[1] "12,645" "48,608" "0,461"

$pvalue
[1] "0,0018" "0,0003" "0,0000"


\##############################################################################
[[1]]
[1] "HINE-Responder-section 2 Day 302"

$Endpunkt
[1] "HINE-Responder-section 2 Day 302" "HINE-Responder-section 2 Day 302" "HINE-Responder-section 2 Day 302"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,6169" "0,7912" "0,0222"

$Schaetzer
[1] "13,98" "39,58" "0,30"

$ci_lower
[1] "2,050" "3,811" "0,206"

$ci_upper
[1] "95,286"  "411,081" "0,396"

$pvalue
[1] "0,0071" "0,0021" "0,0000"
```

```
\#############################################################################
[[1]]
[1] "Time to motor milestone responders"

$Endpunkt
[1] "Time to motor milestone responders  (HINE section 2)"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,5955"

$Schaetzer
[1] "3,03"

$ci_lower
[1] "1,465"

$ci_upper
[1] "6,265"

$pvalue
[1] "0,0028"


\#############################################################################
[[1]]
[1] "Change from baseline in HINE-section 2 Day 64"

$Endpunkt
[1] "Change from baseline in HINE-section 2 Day 64"

$Effektmass
[1] "Hedges g"

$Heterog_p_Wert
[1] "0,4473"
```

```
$Schaetzer
[1] "0,50"

$ci_lower
[1] "0,095"

$ci_upper
[1] "0,899"

$pvalue
[1] "0,0155"


\##############################################################################
[[1]]
[1] "Change from baseline in HINE-section 2 Day 183"

$Endpunkt
[1] "Change from baseline in HINE-section 2 Day 183"

$Effektmass
[1] "Hedges g"

$Heterog_p_Wert
[1] "0,8297"

$Schaetzer
[1] "0,97"

$ci_lower
[1] "0,481"

$ci_upper
[1] "1,450"

$pvalue
[1] "0,0001"
```

```
\##############################################################################
[[1]]
[1] "Time to hospitalization"

$Endpunkt
[1] "Time to hospitalization"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,2987"

$Schaetzer
[1] "1,01"

$ci_lower
[1] "0,681"

$ci_upper
[1] "1,488"

$pvalue
[1] "0,9719"


\##############################################################################
[[1]]
[1] "Frequency of serious respiratory events"

$Endpunkt
[1] "Frequency of serious respiratory events"

$Effektmass
[1] "IRR"
```

```
$Heterog_p_Wert
[1] "0,0060"

$Schaetzer
[1] "0,85"

$ci_lower
[1] "0,544"

$ci_upper
[1] "1,343"

$pvalue
[1] "0,4963"


\##############################################################################
[[1]]
[1] "Time to serious respiratory events"

$Endpunkt
[1] "Time to serious respiratory events"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,9993"

$Schaetzer
[1] "0,76"

$ci_lower
[1] "0,478"

$ci_upper
[1] "1,198"
```

```
$pvalue
[1] "0,2338"


\################################################################################
[[1]]
[1] "Number of patients with adverse events"

$Endpunkt
[1] "Number of patients with adverse events" "Number of patients with adverse events"
[3] "Number of patients with adverse events"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,9519" "0,9368" "0,9560"

$Schaetzer
[1] "0,99"  "0,67"  "-0,01"

$ci_lower
[1] "0,925"  "0,090"  "-0,076"

$ci_upper
[1] "1,052" "5,008" "0,049"

$pvalue
[1] "0,6740" "0,6973" "0,6737"


\################################################################################
[[1]]
[1] "Time to adverse events"

$Endpunkt
[1] "Time to adverse events"
```

```
$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,4283"

$Schaetzer
[1] "0,90"

$ci_lower
[1] "0,619"

$ci_upper
[1] "1,316"

$pvalue
[1] "0,5949"


\##############################################################################
[[1]]
[1] "Number of patients with mild adverse events"

$Endpunkt
[1] "Number of patients with mild adverse events" "Number of patients with mild adverse events"
[3] "Number of patients with mild adverse events"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,2896" "0,2885" "0,2436"

$Schaetzer
[1] "1,05" "1,21" "0,03"

$ci_lower
[1] "0,801"  "0,565"  "-0,141"
```

```
$ci_upper
[1] "1,379" "2,606" "0,203"

$pvalue
[1] "0,7203" "0,6199" "0,7229"


\##############################################################################
[[1]]
[1] "Time to mild adverse events"

$Endpunkt
[1] "Time to mild adverse events"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,1489"

$Schaetzer
[1] "0,96"

$ci_lower
[1] "0,600"

$ci_upper
[1] "1,521"

$pvalue
[1] "0,8480"


\##############################################################################
[[1]]
[1] "Number of patients with moderate adverse events"
```

```
$Endpunkt
[1] "Number of patients with moderate adverse events" "Number of patients with moderate adverse events"
[3] "Number of patients with moderate adverse events"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,4973" "0,5186" "0,4831"

$Schaetzer
[1] "1,00"  "0,97"  "-0,00"

$ci_lower
[1] "0,802"  "0,427"  "-0,160"

$ci_upper
[1] "1,244" "2,202" "0,159"

$pvalue
[1] "0,9943" "0,9408" "0,9941"


\################################################################################
[[1]]
[1] "Time to moderate adverse events"

$Endpunkt
[1] "Time to moderate adverse events"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,9993"

$Schaetzer
[1] "0,78"
```

```
$ci_lower
[1] "0,497"

$ci_upper
[1] "1,231"

$pvalue
[1] "0,2885"


\##############################################################################
[[1]]
[1] "Number of patients with moderate and severe adverse events"

$Endpunkt
[1] "Number of patients with moderate and severe adverse events"
[2] "Number of patients with moderate and severe adverse events"
[3] "Number of patients with moderate and severe adverse events"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,2826" "0,1844" "0,2436"

$Schaetzer
[1] "0,86"  "0,34"  "-0,13"

$ci_lower
[1] "0,764"  "0,083"  "-0,231"

$ci_upper
[1] "0,979"  "1,362"  "-0,020"

$pvalue
[1] "0,0218" "0,1266" "0,0199"
```

```
\#############################################################################
[[1]]
[1] "Time to moderate and severe adverse events"

$Endpunkt
[1] "Time to moderate and severe adverse events"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,1783"

$Schaetzer
[1] "0,71"

$ci_lower
[1] "0,472"

$ci_upper
[1] "1,060"

$pvalue
[1] "0,0932"


\#############################################################################
[[1]]
[1] "Number of patients with severe adverse events"

$Endpunkt
[1] "Number of patients with severe adverse events" "Number of patients with severe adverse events"
[3] "Number of patients with severe adverse events"

$Effektmass
[1] "RR"  "OR"  "ARR"
```

```
$Heterog_p_Wert
[1] "0,0671" "0,0863" "0,0334"

$Schaetzer
[1] "0,74"  "0,38"  "-0,19"

$ci_lower
[1] "0,584"  "0,160"  "-0,348"

$ci_upper
[1] "0,938"  "0,896"  "-0,036"

$pvalue
[1] "0,0129" "0,0272" "0,0160"


\################################################################################
[[1]]
[1] "Time to severe adverse events"

$Endpunkt
[1] "Time to severe adverse events"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,1402"

$Schaetzer
[1] "0,61"

$ci_lower
[1] "0,393"

$ci_upper
[1] "0,957"
```

```
$pvalue
[1] "0,0313"


\################################################################################
[[1]]
[1] "Number of patients with serious adverse events"

$Endpunkt
[1] "Number of patients with serious adverse events" "Number of patients with serious adverse events"
[3] "Number of patients with serious adverse events"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,1116" "0,0506" "0,0473"

$Schaetzer
[1] "0,82"  "0,30"  "-0,17"

$ci_lower
[1] "0,709"  "0,076"  "-0,277"

$ci_upper
[1] "0,937"  "1,204"  "-0,053"

$pvalue
[1] "0,0040" "0,0897" "0,0038"


\################################################################################
[[1]]
[1] "Time to serious adverse events"

$Endpunkt
[1] "Time to serious adverse events"
```

```
$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,2063"

$Schaetzer
[1] "0,78"

$ci_lower
[1] "0,521"

$ci_upper
[1] "1,161"

$pvalue
[1] "0,2184"


\##############################################################################
[[1]]
[1] "Number of patients with adverse events leading to discontinuation of therapy"

$Endpunkt
[1] "Number of patients with adverse events leading to discontinuation of therapy"
[2] "Number of patients with adverse events leading to discontinuation of therapy"
[3] "Number of patients with adverse events leading to discontinuation of therapy"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,9997" "0,9592" "0,8491"

$Schaetzer
[1] "0,42"  "0,30"  "-0,22"

$ci_lower
```

```
[1] "0,225"  "0,132"  "-0,384"

$ci_upper
[1] "0,769"  "0,705"  "-0,061"

$pvalue
[1] "0,0051" "0,0055" "0,0068"


\##############################################################################
[[1]]
[1] "Time to adverse events leading to discontinuation of therapy"

$Endpunkt
[1] "Time to adverse events leading to discontinuation of therapy"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,9997"

$Schaetzer
[1] "0,37"

$ci_lower
[1] "0,177"

$ci_upper
[1] "0,769"

$pvalue
[1] "0,0078"


\##############################################################################
[[1]]
[1] "Number of patients with 10% AEs according to SOC"
```

$`Cardiac disorders`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct SOC Cardiac disorders	RR	0,9505	0,71	0,396	1,256	0,2356
2	Any AEs 10 pct SOC Cardiac disorders	OR	0,8914	0,62	0,273	1,387	0,2419
3	Any AEs 10 pct SOC Cardiac disorders	ARR	0,8442	-0,10	-0,261	0,069	0,2540

$`Gastrointestinal disorders`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct SOC Gastrointestinal disorders	RR	0,7121	1,06	0,804	1,389	0,6928
2	Any AEs 10 pct SOC Gastrointestinal disorders	OR	0,7274	1,17	0,547	2,512	0,6830
3	Any AEs 10 pct SOC Gastrointestinal disorders	ARR	0,7165	0,04	-0,138	0,211	0,6832

$`General disorders and administration site conditions`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct SOC General disorders and administration site conditions	RR	0,5889	0,95	0,730	1,230	0,6859
2	Any AEs 10 pct SOC General disorders and administration site conditions	OR	0,5833	0,86	0,398	1,874	0,7106
3	Any AEs 10 pct SOC General disorders and administration site conditions	ARR	0,5772	-0,03	-0,206	0,139	0,7032

$`Infections and infestations`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct SOC Infections and infestations	RR	0,6775	1,09	0,895	1,322	0,3966
2	Any AEs 10 pct SOC Infections and infestations	OR	0,6811	1,47	0,609	3,529	0,3938
3	Any AEs 10 pct SOC Infections and infestations	ARR	0,6665	0,07	-0,084	0,216	0,3856

$`Injury, poisoning and procedural complications`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct SOC Injury, poisoning and procedural complications	RR	0,5783	0,93	0,487	1,788	0,8358
2	Any AEs 10 pct SOC Injury, poisoning and procedural complications	OR	0,5663	0,91	0,387	2,130	0,8232
3	Any AEs 10 pct SOC Injury, poisoning and procedural complications	ARR	0,5411	-0,02	-0,175	0,132	0,7853

$Investigations

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct SOC Investigations	RR	0,6529	0,79	0,459	1,368	0,4035
2	Any AEs 10 pct SOC Investigations	OR	0,6521	0,72	0,325	1,584	0,4121
3	Any AEs 10 pct SOC Investigations	ARR	0,6512	-0,07	-0,238	0,100	0,4231

$`Musculoskeletal and connective tissue disorders`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct SOC Musculoskeletal and connective tissue disorders	RR	0,2487	1,37	0,542	3,478	0,5032
2	Any AEs 10 pct SOC Musculoskeletal and connective tissue disorders	OR	0,1769	1,45	0,495	4,273	0,4962
3	Any AEs 10 pct SOC Musculoskeletal and connective tissue disorders	ARR	0,0729	0,04	-0,081	0,164	0,5066

$`Nervous system disorders`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct SOC Nervous system disorders	RR	0,1620	1,39	0,377	5,132	0,6201
2	Any AEs 10 pct SOC Nervous system disorders	OR	0,1403	1,50	0,358	6,330	0,5775
3	Any AEs 10 pct SOC Nervous system disorders	ARR	0,1202	0,05	-0,044	0,145	0,2921

$`Respiratory, thoracic and mediastinal disorders`

	Endpunkt	Effektmass	Heterog_p_Wert	Schaetzer	ci_lower	ci_upper	pvalue
1	Any AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders	RR	0,3100	0,89	0,754	1,043	0,1460
2	Any AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders	OR	0,3106	0,52	0,188	1,454	0,2142
3	Any AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders	ARR	0,2862	-0,10	-0,229	0,036	0,1529

\##
[[1]]
[1] "Time to 10% AEs according to SOC"

```
$`Cardiac disorders`
                                      Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to any AEs 10 pct SOC Cardiac disorders         HR         0,8098      0,58    0,291    1,145 0,1156

$`Gastrointestinal disorders`
                                             Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Time to any AEs 10 pct SOC Gastrointestinal disorders         HR         0,9390      1,01    0,634    1,598
  pvalue
1 0,9775

$`General disorders and administration site conditions`
                                                                        Endpunkt Effektmass Heterog_p_Wert
1 Time to any AEs 10 pct SOC General disorders and administration site conditions         HR         0,5393
  Schaetzer ci_lower ci_upper pvalue
1      0,61    0,384    0,961 0,0333

$`Infections and infestations`
                                              Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Time to any AEs 10 pct SOC Infections and infestations         HR         0,3018      1,20    0,779
  ci_upper pvalue
1    1,833 0,4135

$Investigations
                                   Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to any AEs 10 pct SOC Investigations         HR         0,9299      0,65    0,336    1,262 0,2044

$`Respiratory, thoracic and mediastinal disorders`
                                                            Endpunkt Effektmass Heterog_p_Wert
1 Time to any AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         HR         0,1535
  Schaetzer ci_lower ci_upper pvalue
1      0,65    0,425    0,980 0,0399


\##############################################################################
[[1]]
[1] "Number of patients with 10% AEs according to PT"

$Bronchiolitis
```

```
                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Bronchiolitis         RR         0,9855      1,36    0,445    4,153 0,5905
2 Any AEs 10 pct PT Bronchiolitis         OR         0,9722      1,42    0,397    5,091 0,5895
3 Any AEs 10 pct PT Bronchiolitis        ARR         0,8724      0,03   -0,074    0,130 0,5898

$Constipation
                         Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Constipation         RR         0,3790      1,50    0,794    2,822 0,2129
2 Any AEs 10 pct PT Constipation         OR         0,3456      1,73    0,744    4,032 0,2029
3 Any AEs 10 pct PT Constipation        ARR         0,2690      0,10   -0,054    0,259 0,1997

$Cough
                 Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Cough         RR         0,0566      0,75    0,328    1,727 0,5023
2 Any AEs 10 pct PT Cough         OR         0,0285      0,69    0,253    1,895 0,4743
3 Any AEs 10 pct PT Cough        ARR         0,0001      0,00   -0,129    0,136 0,9557

$Diarrhoea
                     Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Diarrhoea         RR         0,3221      0,91    0,397    2,101 0,8306
2 Any AEs 10 pct PT Diarrhoea         OR         0,3038      0,90    0,334    2,428 0,8363
3 Any AEs 10 pct PT Diarrhoea        ARR         0,2804     -0,01   -0,148    0,119 0,8306

$Pyrexia
                   Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Pyrexia         RR         0,2934      0,99    0,720    1,359 0,9476
2 Any AEs 10 pct PT Pyrexia         OR         0,2752      1,00    0,477    2,106 0,9957
3 Any AEs 10 pct PT Pyrexia        ARR         0,2227      0,01   -0,172    0,187 0,9341

$Tachycardia
                      Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Tachycardia         RR         0,9470      0,70    0,276    1,801 0,4645
2 Any AEs 10 pct PT Tachycardia         OR         0,8493      0,66    0,213    2,050 0,4738
3 Any AEs 10 pct PT Tachycardia        ARR         0,7240     -0,04   -0,154    0,078 0,5232

$`Upper respiratory tract infection`
                                            Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Any AEs 10 pct PT Upper respiratory tract infection         RR         0,9841      1,36    0,718    2,591
```

```
2 Any AEs 10 pct PT Upper respiratory tract infection         OR         0,9928      1,52    0,650    3,564
3 Any AEs 10 pct PT Upper respiratory tract infection        ARR         0,9936      0,08   -0,077    0,238
  pvalue
1 0,3428
2 0,3331
3 0,3150

$`Viral upper respiratory tract infection`
                                                    Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Any AEs 10 pct PT Viral upper respiratory tract infection         RR         0,8277      0,57    0,231
2 Any AEs 10 pct PT Viral upper respiratory tract infection         OR         0,7981      0,52    0,182
3 Any AEs 10 pct PT Viral upper respiratory tract infection        ARR         0,7013     -0,08   -0,206
  ci_upper pvalue
1    1,390 0,2150
2    1,470 0,2161
3    0,051 0,2389

$Vomiting
                    Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Any AEs 10 pct PT Vomiting         RR         0,3534      0,99    0,464    2,103 0,9736
2 Any AEs 10 pct PT Vomiting         OR         0,3328      0,99    0,391    2,513 0,9851
3 Any AEs 10 pct PT Vomiting        ARR         0,3034      0,00   -0,142    0,142 0,9989


\##############################################################################
[[1]]
[1] "Time to 10% AEs according to PT"

$Bronchiolitis
                                Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to any AEs 10 pct PT Bronchiolitis         HR         0,7692      1,19    0,359    3,945 0,7764

$Pyrexia
                           Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to any AEs 10 pct PT Pyrexia         HR         0,3360      0,72    0,443    1,180 0,1945

$Tachycardia
                              Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
```

```
1 Time to any AEs 10 pct PT Tachycardia         HR         0,7746      0,60    0,211    1,686 0,3300

$`Upper respiratory tract infection`
                                                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Time to any AEs 10 pct PT Upper respiratory tract infection         HR         0,9994      1,20    0,557
  ci_upper pvalue
1    2,591 0,6405


\#############################################################################
[[1]]
[1] "Number of patients with 10% mild AEs according to SOC"

$`Cardiac disorders`
                               Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct SOC Cardiac disorders         RR         0,9913      0,66    0,291    1,501 0,3220
2 Mild AEs 10 pct SOC Cardiac disorders         OR         0,9010      0,60    0,219    1,654 0,3253
3 Mild AEs 10 pct SOC Cardiac disorders        ARR         0,7730     -0,06   -0,194    0,070 0,3590

$`Gastrointestinal disorders`
                                         Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct SOC Gastrointestinal disorders         RR         0,6694      1,02    0,740    1,409 0,8975
2 Mild AEs 10 pct SOC Gastrointestinal disorders         OR         0,6730      1,05    0,501    2,186 0,9047
3 Mild AEs 10 pct SOC Gastrointestinal disorders        ARR         0,6652      0,01   -0,169    0,193 0,8981

$`General disorders and administration site conditions`
                                                                      Endpunkt Effektmass Heterog_p_Wert
1 Mild AEs 10 pct SOC General disorders and administration site conditions         RR         0,2471
2 Mild AEs 10 pct SOC General disorders and administration site conditions         OR         0,2264
3 Mild AEs 10 pct SOC General disorders and administration site conditions        ARR         0,1737
  Schaetzer ci_lower ci_upper pvalue
1      0,90    0,626    1,292 0,5655
2      0,82    0,395    1,721 0,6073
3     -0,04   -0,220    0,141 0,6689

$`Infections and infestations`
                                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Mild AEs 10 pct SOC Infections and infestations         RR         0,3142      1,03    0,755    1,409
```

```
2 Mild AEs 10 pct SOC Infections and infestations         OR         0,3021      1,10    0,525    2,326
3 Mild AEs 10 pct SOC Infections and infestations        ARR         0,2501      0,03   -0,148    0,210
  pvalue
1 0,8473
2 0,7931
3 0,7367

$`Injury, poisoning and procedural complications`
                                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Mild AEs 10 pct SOC Injury, poisoning and procedural complications         RR         0,7598      0,65
2 Mild AEs 10 pct SOC Injury, poisoning and procedural complications         OR         0,7511      0,58
3 Mild AEs 10 pct SOC Injury, poisoning and procedural complications        ARR         0,7335     -0,09
  ci_lower ci_upper pvalue
1    0,318    1,320 0,2318
2    0,236    1,420 0,2326
3   -0,237    0,059 0,2376

$Investigations
                           Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct SOC Investigations         RR         0,3436      0,95    0,506    1,768 0,8615
2 Mild AEs 10 pct SOC Investigations         OR         0,3216      0,94    0,407    2,175 0,8874
3 Mild AEs 10 pct SOC Investigations        ARR         0,2904     -0,01   -0,163    0,152 0,9503

$`Musculoskeletal and connective tissue disorders`
                                                              Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Mild AEs 10 pct SOC Musculoskeletal and connective tissue disorders         RR         0,1995      1,17
2 Mild AEs 10 pct SOC Musculoskeletal and connective tissue disorders         OR         0,1424      1,20
3 Mild AEs 10 pct SOC Musculoskeletal and connective tissue disorders        ARR         0,0595      0,02
  ci_lower ci_upper pvalue
1    0,447    3,053 0,7516
2    0,396    3,620 0,7499
3   -0,103    0,135 0,7894

$`Respiratory, thoracic and mediastinal disorders`
                                                              Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Mild AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         RR         0,0911      0,90
2 Mild AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         OR         0,0397      0,86
3 Mild AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders        ARR         0,0003      0,07
```

```
  ci_lower ci_upper pvalue
1    0,638    1,282 0,5721
2    0,408    1,807 0,6870
3   -0,102    0,240 0,4305


\#############################################################################
[[1]]
[1] "Time to 10% mild AEs according to SOC"

$`Cardiac disorders`
                                        Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to mild AEs 10 pct SOC Cardiac disorders         HR         0,8361      0,55    0,220    1,373 0,2002

$`Gastrointestinal disorders`
                                                Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Time to mild AEs 10 pct SOC Gastrointestinal disorders         HR         0,9988      0,93    0,571
  ci_upper pvalue
1    1,520 0,7770

$`General disorders and administration site conditions`
                                                                          Endpunkt Effektmass Heterog_p_Wert
1 Time to mild AEs 10 pct SOC General disorders and administration site conditions         HR         0,2955
  Schaetzer ci_lower ci_upper pvalue
1      0,66    0,390    1,103 0,1120

$`Infections and infestations`
                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Time to mild AEs 10 pct SOC Infections and infestations         HR         0,9993      0,85    0,520
  ci_upper pvalue
1    1,397 0,5258


\#############################################################################
[[1]]
[1] "Number of patients with 10% mild AEs according to PT"

$Constipation
```

```
                         Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Constipation         RR         0,3792      1,49    0,752    2,943 0,2535
2 Mild AEs 10 pct PT Constipation         OR         0,3525      1,69    0,701    4,051 0,2436
3 Mild AEs 10 pct PT Constipation        ARR         0,2884      0,09   -0,059    0,244 0,2319

$Cough
                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Cough         RR         0,0394      0,65    0,249    1,681 0,3711
2 Mild AEs 10 pct PT Cough         OR         0,0213      0,57    0,186    1,745 0,3240
3 Mild AEs 10 pct PT Cough        ARR         0,0001     -0,02   -0,143    0,103 0,7503

$Diarrhoea
                     Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Diarrhoea         RR         0,2650      0,77    0,322    1,839 0,5557
2 Mild AEs 10 pct PT Diarrhoea         OR         0,2515      0,74    0,265    2,052 0,5594
3 Mild AEs 10 pct PT Diarrhoea        ARR         0,2425     -0,04   -0,169    0,091 0,5583

$Pyrexia
                   Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Pyrexia         RR         0,2764      0,96    0,642    1,448 0,8606
2 Mild AEs 10 pct PT Pyrexia         OR         0,2595      0,94    0,451    1,973 0,8771
3 Mild AEs 10 pct PT Pyrexia        ARR         0,2070     -0,01   -0,187    0,174 0,9437

$Tachycardia
                      Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Tachycardia         RR         0,5151      0,40    0,133    1,227 0,1098
2 Mild AEs 10 pct PT Tachycardia         OR         0,7417      0,31    0,082    1,192 0,0887
3 Mild AEs 10 pct PT Tachycardia        ARR         0,8259     -0,09   -0,194    0,021 0,1150

$`Upper respiratory tract infection`
                                               Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Mild AEs 10 pct PT Upper respiratory tract infection         RR         0,4904      1,10    0,439    2,778
2 Mild AEs 10 pct PT Upper respiratory tract infection         OR         0,4784      1,12    0,387    3,266
3 Mild AEs 10 pct PT Upper respiratory tract infection        ARR         0,4540      0,02   -0,107    0,140
  pvalue
1 0,8340
2 0,8295
3 0,7940
```

```
$Vomiting
                      Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Mild AEs 10 pct PT Vomiting         RR         0,4053      1,15    0,484    2,726 0,7535
2 Mild AEs 10 pct PT Vomiting         OR         0,3812      1,18    0,426    3,260 0,7510
3 Mild AEs 10 pct PT Vomiting        ARR         0,3411      0,02   -0,110    0,149 0,7721


\################################################################################
[[1]]
[1] "Time to 10% mild AEs according to PT"

$Pyrexia
                            Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to mild AEs 10 pct PT Pyrexia         HR         0,3658      0,78    0,450    1,349 0,3738

$Tachycardia
                               Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Time to mild AEs 10 pct PT Tachycardia         HR         0,7373      0,30    0,089    1,045 0,0588


\################################################################################
[[1]]
[1] "Number of patients with 10% moderate AEs according to SOC"

$`Gastrointestinal disorders`
                                              Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Moderate AEs 10 pct SOC Gastrointestinal disorders         RR         0,3770      1,05    0,522    2,093
2 Moderate AEs 10 pct SOC Gastrointestinal disorders         OR         0,3561      1,07    0,441    2,586
3 Moderate AEs 10 pct SOC Gastrointestinal disorders        ARR         0,3272      0,01   -0,135    0,164
  pvalue
1 0,9007
2 0,8845
3 0,8507

$`General disorders and administration site conditions`
                                                                          Endpunkt Effektmass Heterog_p_Wert
1 Moderate AEs 10 pct SOC General disorders and administration site conditions         RR         0,3941
```

```
2 Moderate AEs 10 pct SOC General disorders and administration site conditions         OR         0,3754
3 Moderate AEs 10 pct SOC General disorders and administration site conditions        ARR         0,3542
  Schaetzer ci_lower ci_upper pvalue
1      1,08    0,592    1,984 0,7944
2      1,13    0,496    2,578 0,7703
3      0,03   -0,130    0,190 0,7130

$`Infections and infestations`
                                              Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Moderate AEs 10 pct SOC Infections and infestations         RR         0,9635      1,79    1,180    2,700
2 Moderate AEs 10 pct SOC Infections and infestations         OR         0,6446      3,18    1,475    6,840
3 Moderate AEs 10 pct SOC Infections and infestations        ARR         0,7226      0,28    0,110    0,452
  pvalue
1 0,0060
2 0,0031
3 0,0013

$Investigations
                               Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Moderate AEs 10 pct SOC Investigations         RR         0,6960      0,72    0,290    1,805 0,4883
2 Moderate AEs 10 pct SOC Investigations         OR         0,6728      0,69    0,239    1,983 0,4890
3 Moderate AEs 10 pct SOC Investigations        ARR         0,6029     -0,04   -0,167    0,083 0,5082

$`Respiratory, thoracic and mediastinal disorders`
                                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Moderate AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         RR         0,9266      0,85
2 Moderate AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         OR         0,9535      0,73
3 Moderate AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders        ARR         0,9822     -0,08
  ci_lower ci_upper pvalue
1    0,584    1,242 0,4046
2    0,351    1,534 0,4104
3   -0,256    0,105 0,4101


\##############################################################################
[[1]]
[1] "Time to 10% moderate AEs according to SOC"
```

```
$`Infections and infestations`
                                                    Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Time to moderate AEs 10 pct SOC Infections and infestations         HR         0,5272      2,01    1,129
  ci_upper pvalue
1    3,582 0,0177

$`Respiratory, thoracic and mediastinal disorders`
                                                                 Endpunkt Effektmass Heterog_p_Wert
1 Time to moderate AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         HR         0,5505
  Schaetzer ci_lower ci_upper pvalue
1      0,74    0,430    1,267 0,2707


\#############################################################################
[[1]]
[1] "Number of patients with 10% moderate AEs according to PT"

$Pyrexia
                      Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Moderate AEs 10 pct PT Pyrexia         RR         0,4636      1,30    0,638    2,656 0,4685
2 Moderate AEs 10 pct PT Pyrexia         OR         0,4437      1,41    0,574    3,457 0,4551
3 Moderate AEs 10 pct PT Pyrexia        ARR         0,4185      0,06   -0,088    0,207 0,4282

$`Upper respiratory tract infection`
                                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Moderate AEs 10 pct PT Upper respiratory tract infection         RR         0,4445      1,28    0,501
2 Moderate AEs 10 pct PT Upper respiratory tract infection         OR         0,4158      1,32    0,450
3 Moderate AEs 10 pct PT Upper respiratory tract infection        ARR         0,3610      0,03   -0,093
  ci_upper pvalue
1    3,252 0,6099
2    3,890 0,6103
3    0,151 0,6451


\#############################################################################
[[1]]
[1] "Time to 10% moderate AEs according to PT"
```

```
\##############################################################################
[[1]]
[1] "Number of patients with 5% severe AEs according to SOC"

$`Cardiac disorders`
                                Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Severe AEs 5 pct SOC Cardiac disorders         RR         0,8951      0,50    0,199    1,268 0,1450
2 Severe AEs 5 pct SOC Cardiac disorders         OR         0,8594      0,45    0,155    1,318 0,1457
3 Severe AEs 5 pct SOC Cardiac disorders        ARR         0,7355     -0,09   -0,216    0,038 0,1699

$`General disorders and administration site conditions`
                                                                    Endpunkt Effektmass Heterog_p_Wert
1 Severe AEs 5 pct SOC General disorders and administration site conditions         RR         0,3896
2 Severe AEs 5 pct SOC General disorders and administration site conditions         OR         0,3863
3 Severe AEs 5 pct SOC General disorders and administration site conditions        ARR         0,4500
  Schaetzer ci_lower ci_upper pvalue
1      1,17    0,206    6,618 0,8617
2      1,25    0,190    8,178 0,8188
3      0,02   -0,044    0,089 0,5122

$`Infections and infestations`
                                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Severe AEs 5 pct SOC Infections and infestations         RR         0,2439      0,90    0,572    1,426
2 Severe AEs 5 pct SOC Infections and infestations         OR         0,2321      0,85    0,399    1,796
3 Severe AEs 5 pct SOC Infections and infestations        ARR         0,1814     -0,03   -0,209    0,145
  pvalue
1 0,6633
2 0,6640
3 0,7224

$`Respiratory, thoracic and mediastinal disorders`
                                                              Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Severe AEs 5 pct SOC Respiratory, thoracic and mediastinal disorders         RR         0,0671      0,75
2 Severe AEs 5 pct SOC Respiratory, thoracic and mediastinal disorders         OR         0,1106      0,46
3 Severe AEs 5 pct SOC Respiratory, thoracic and mediastinal disorders        ARR         0,0419     -0,16
  ci_lower ci_upper pvalue
1    0,563    0,996 0,0472
```

```
2    0,209    0,998 0,0494
3   -0,331    0,006 0,0580


\##############################################################################
[[1]]
[1] "Time to 5% severe AEs according to SOC"

$`Infections and infestations`
                                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Time to severe AEs 5 pct SOC Infections and infestations         HR         0,4947      0,78    0,433
  ci_upper pvalue
1    1,402 0,4052

$`Respiratory, thoracic and mediastinal disorders`
                                                                      Endpunkt Effektmass Heterog_p_Wert
1 Time to severe AEs 5 pct SOC Respiratory, thoracic and mediastinal disorders         HR         0,1248
  Schaetzer ci_lower ci_upper pvalue
1      0,57    0,358    0,924 0,0222


\##############################################################################
[[1]]
[1] "Number of patients with 5% severe AEs according to PT"

$Bronchiolitis
                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Severe AEs 5 pct PT Bronchiolitis         RR         0,3896      1,17    0,206    6,618 0,8617
2 Severe AEs 5 pct PT Bronchiolitis         OR         0,3863      1,25    0,190    8,178 0,8188
3 Severe AEs 5 pct PT Bronchiolitis        ARR         0,4500      0,02   -0,044    0,089 0,5122


\##############################################################################
[[1]]
[1] "Time to 5% severe AEs according to PT"


\##############################################################################
```

```
[[1]]
[1] "Number of patients with 10% moderate or severe AEs according to SOC"

$`Cardiac disorders`
                                              Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Moderate or severe AEs 10 pct SOC Cardiac disorders         RR         0,6729      0,77    0,371    1,581
2 Moderate or severe AEs 10 pct SOC Cardiac disorders         OR         0,6610      0,71    0,289    1,769
3 Moderate or severe AEs 10 pct SOC Cardiac disorders        ARR         0,6345     -0,05   -0,200    0,091
  pvalue
1 0,4708
2 0,4674
3 0,4597

$`Gastrointestinal disorders`
                                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Moderate or severe AEs 10 pct SOC Gastrointestinal disorders         RR         0,3436      0,95    0,506
2 Moderate or severe AEs 10 pct SOC Gastrointestinal disorders         OR         0,3216      0,94    0,407
3 Moderate or severe AEs 10 pct SOC Gastrointestinal disorders        ARR         0,2904     -0,01   -0,163
  ci_upper pvalue
1    1,768 0,8615
2    2,175 0,8874
3    0,152 0,9503

$`General disorders and administration site conditions`
                                                                        Endpunkt Effektmass
1 Moderate or severe AEs 10 pct SOC General disorders and administration site conditions         RR
2 Moderate or severe AEs 10 pct SOC General disorders and administration site conditions         OR
3 Moderate or severe AEs 10 pct SOC General disorders and administration site conditions        ARR
  Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1         0,8813      1,12    0,644    1,954 0,6843
2         0,8836      1,18    0,533    2,616 0,6820
3         0,8869      0,04   -0,132    0,203 0,6790

$`Infections and infestations`
                                                Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 Moderate or severe AEs 10 pct SOC Infections and infestations         RR         0,9116      1,29    0,970
2 Moderate or severe AEs 10 pct SOC Infections and infestations         OR         0,8290      2,05    0,960
3 Moderate or severe AEs 10 pct SOC Infections and infestations        ARR         0,9669      0,16   -0,008
```

```
  ci_upper pvalue
1    1,728 0,0796
2    4,389 0,0636
3    0,337 0,0609

$Investigations
                                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Moderate or severe AEs 10 pct SOC Investigations         RR         0,8932      0,51    0,235    1,085
2 Moderate or severe AEs 10 pct SOC Investigations         OR         0,8790      0,43    0,170    1,109
3 Moderate or severe AEs 10 pct SOC Investigations        ARR         0,8379     -0,12   -0,267    0,021
  pvalue
1 0,0799
2 0,0812
3 0,0937

$`Respiratory, thoracic and mediastinal disorders`
                                                                                Endpunkt Effektmass Heterog_p_Wert
1 Moderate or severe AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         RR         0,2269
2 Moderate or severe AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         OR         0,3165
3 Moderate or severe AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders        ARR         0,2320
  Schaetzer ci_lower ci_upper pvalue
1      0,84    0,672    1,048 0,1224
2      0,52    0,225    1,209 0,1291
3     -0,12   -0,282    0,033 0,1202


\##############################################################################
[[1]]
[1] "Time to 10% moderate or severe AEs according to SOC"

$`General disorders and administration site conditions`
                                                                                      Endpunkt Effektmass
1 Time to moderate or severe AEs 10 pct SOC General disorders and administration site conditions         HR
  Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1         0,9623      0,94    0,481    1,826 0,8490

$`Infections and infestations`
                                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer
```

```
1 Time to moderate or severe AEs 10 pct SOC Infections and infestations         HR         0,4791      1,49
  ci_lower ci_upper pvalue
1    0,915    2,418 0,1093

$`Respiratory, thoracic and mediastinal disorders`
                                                                                 Endpunkt Effektmass
1 Time to moderate or severe AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders         HR
  Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1         0,1838      0,72    0,466    1,126 0,1523


\##############################################################################
[[1]]
[1] "Number of patients with 10% moderate or severe AEs according to PT"

$Pyrexia
                                  Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 Moderate or severe AEs 10 pct PT Pyrexia         RR         0,5039      1,43    0,708    2,877 0,3198
2 Moderate or severe AEs 10 pct PT Pyrexia         OR         0,4869      1,59    0,654    3,878 0,3050
3 Moderate or severe AEs 10 pct PT Pyrexia        ARR         0,4707      0,08   -0,066    0,232 0,2747

$`Upper respiratory tract infection`
                                                                Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Moderate or severe AEs 10 pct PT Upper respiratory tract infection         RR         0,5395      1,57
2 Moderate or severe AEs 10 pct PT Upper respiratory tract infection         OR         0,5058      1,71
3 Moderate or severe AEs 10 pct PT Upper respiratory tract infection        ARR         0,4355      0,07
  ci_lower ci_upper pvalue
1    0,638    3,880 0,3252
2    0,597    4,872 0,3191
3   -0,062    0,192 0,3134

$`Viral upper respiratory tract infection`
                                                                  Endpunkt Effektmass Heterog_p_Wert
1 Moderate or severe AEs 10 pct PT Viral upper respiratory tract infection         RR         0,8189
2 Moderate or severe AEs 10 pct PT Viral upper respiratory tract infection         OR         0,7847
3 Moderate or severe AEs 10 pct PT Viral upper respiratory tract infection        ARR         0,6681
  Schaetzer ci_lower ci_upper pvalue
1      0,57    0,219    1,510 0,2610
```

```
2      0,53    0,176    1,604 0,2621
3     -0,07   -0,186    0,056 0,2913


\##############################################################################
[[1]]
[1] "Time to 10% moderate or severe AEs according to PT"


\##############################################################################
[[1]]
[1] "Number of patients with 5% SAEs according to SOC"

$`Cardiac disorders`
                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 SAEs 5 pct SOC Cardiac disorders         RR         0,7689      0,63    0,265    1,512 0,3030
2 SAEs 5 pct SOC Cardiac disorders         OR         0,7442      0,58    0,210    1,626 0,3039
3 SAEs 5 pct SOC Cardiac disorders        ARR         0,6678     -0,07   -0,196    0,064 0,3225

$`Gastrointestinal disorders`
                                    Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 SAEs 5 pct SOC Gastrointestinal disorders         RR         0,2572      0,78    0,272    2,221 0,6381
2 SAEs 5 pct SOC Gastrointestinal disorders         OR         0,2473      0,75    0,229    2,430 0,6270
3 SAEs 5 pct SOC Gastrointestinal disorders        ARR         0,2552     -0,03   -0,146    0,080 0,5677

$`General disorders and administration site conditions`
                                                                 Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 SAEs 5 pct SOC General disorders and administration site conditions         RR         0,2376      1,75
2 SAEs 5 pct SOC General disorders and administration site conditions         OR         0,2452      2,00
3 SAEs 5 pct SOC General disorders and administration site conditions        ARR         0,3713      0,06
  ci_lower ci_upper pvalue
1    0,325    9,435 0,5138
2    0,322   12,364 0,4575
3   -0,019    0,135 0,1411

$`Infections and infestations`
                                     Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 SAEs 5 pct SOC Infections and infestations         RR         0,2566      1,34    0,933    1,932 0,1128
```

```
2 SAEs 5 pct SOC Infections and infestations         OR         0,2128      1,82    0,870    3,830 0,1117
3 SAEs 5 pct SOC Infections and infestations        ARR         0,1074      0,18    0,001    0,352 0,0492

$`Respiratory, thoracic and mediastinal disorders`
                                                      Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower
1 SAEs 5 pct SOC Respiratory, thoracic and mediastinal disorders         RR         0,1318      0,86    0,673
2 SAEs 5 pct SOC Respiratory, thoracic and mediastinal disorders         OR         0,1590      0,63    0,283
3 SAEs 5 pct SOC Respiratory, thoracic and mediastinal disorders        ARR         0,0824     -0,09   -0,250
  ci_upper pvalue
1    1,107 0,2476
2    1,405 0,2597
3    0,080 0,3103


\#############################################################################
[[1]]
[1] "Time to 5% SAEs according to SOC"

$`Infections and infestations`
                                          Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper
1 Time to SAEs 5 pct SOC Infections and infestations         HR         0,4371      1,38    0,817    2,323
  pvalue
1 0,2290

$`Respiratory, thoracic and mediastinal disorders`
                                                             Endpunkt Effektmass Heterog_p_Wert Schaetzer
1 Time to SAEs 5 pct SOC Respiratory, thoracic and mediastinal disorders         HR         0,9993      0,76
  ci_lower ci_upper pvalue
1    0,478    1,198 0,2338


\#############################################################################
[[1]]
[1] "Number of patients with 5% SAEs according to PT"

$Bronchiolitis
                     Endpunkt Effektmass Heterog_p_Wert Schaetzer ci_lower ci_upper pvalue
1 SAEs 5 pct PT Bronchiolitis         RR         0,3896      1,17    0,206    6,618 0,8617
```

```
2 SAEs 5 pct PT Bronchiolitis         OR         0,3863      1,25    0,190    8,178 0,8188
3 SAEs 5 pct PT Bronchiolitis        ARR         0,4500      0,02   -0,044    0,089 0,5122


\##############################################################################
[[1]]
[1] "Time to 5% SAEs according to PT"


\##############################################################################
[[1]]
[1] "HINE-Responder-section 2 Day 64 TOTSCORE"

$Endpunkt
[1] "HINE-Responder-section 2 Day 64 TOTSCORE" "HINE-Responder-section 2 Day 64 TOTSCORE"
[3] "HINE-Responder-section 2 Day 64 TOTSCORE"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,9739" "1,0000" "0,9718"

$Schaetzer
[1] "1,28" "1,50" "0,10"

$ci_lower
[1] "0,793"  "0,701"  "-0,080"

$ci_upper
[1] "2,078" "3,211" "0,270"

$pvalue
[1] "0,3100" "0,2964" "0,2870"


\##############################################################################
[[1]]
```

```
[1] "HINE-Responder-section 2 Day 183 TOTSCORE"

$Endpunkt
[1] "HINE-Responder-section 2 Day 183 TOTSCORE" "HINE-Responder-section 2 Day 183 TOTSCORE"
[3] "HINE-Responder-section 2 Day 183 TOTSCORE"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,1910" "0,9877" "0,9916"

$Schaetzer
[1] "2,81" "7,18" "0,38"

$ci_lower
[1] "1,491" "2,671" "0,235"

$ci_upper
[1] "5,297"  "19,321" "0,521"

$pvalue
[1] "0,0014" "0,0001" "0,0000"


\################################################################################
[[1]]
[1] "HINE-Responder-section 2 Day 302 TOTSCORE"

$Endpunkt
[1] "HINE-Responder-section 2 Day 302 TOTSCORE" "HINE-Responder-section 2 Day 302 TOTSCORE"
[3] "HINE-Responder-section 2 Day 302 TOTSCORE"

$Effektmass
[1] "RR"  "OR"  "ARR"

$Heterog_p_Wert
[1] "0,5529" "0,2590" "0,0231"
```

```
$Schaetzer
[1] "4,11" "6,23" "0,32"

$ci_lower
[1] "1,647" "2,099" "0,184"

$ci_upper
[1] "10,276" "18,514" "0,448"

$pvalue
[1] "0,0025" "0,0010" "0,0000"


\##############################################################################
[[1]]
[1] "Time to motor milestone responders  (HINE section 2) TOTSCORE"

$Endpunkt
[1] "Time to motor milestone responders  (HINE section 2) TOTSCORE"

$Effektmass
[1] "HR"

$Heterog_p_Wert
[1] "0,1419"

$Schaetzer
[1] "2,09"

$ci_lower
[1] "1,192"

$ci_upper
[1] "3,668"

$pvalue
[1] "0,0101"
```

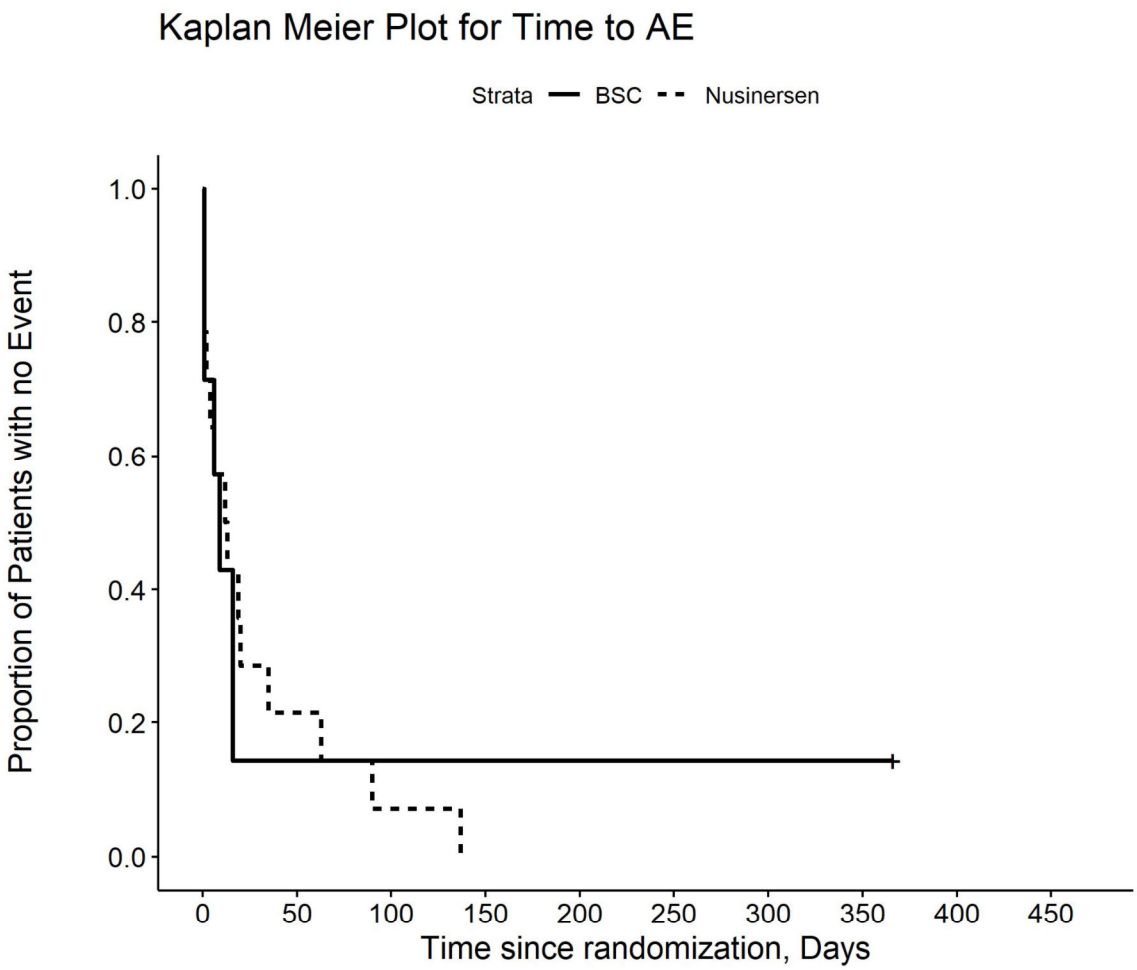
```
\##############################################################################
[[1]]
[1] "Change from baseline in HINE-section 2 Day 64 TOTSCORE"

$Endpunkt
[1] "Change from baseline in HINE-section 2 Day 64 TOTSCORE"

$Effektmass
[1] "Hedges g"

$Heterog_p_Wert
[1] "0,7528"

$Schaetzer
[1] "0,34"

$ci_lower
[1] "-0,060"

$ci_upper
[1] "0,733"

$pvalue
[1] "0,0961"


\##############################################################################
[[1]]
[1] "Change from baseline in HINE-section 2 Day 183 TOTSCORE"

$Endpunkt
[1] "Change from baseline in HINE-section 2 Day 183 TOTSCORE"

$Effektmass
[1] "Hedges g"
```

```
$Heterog_p_Wert
[1] "0,7182"

$Schaetzer
[1] "1,11"

$ci_lower
[1] "0,621"

$ci_upper
[1] "1,608"

$pvalue
[1] "0,0000"


\#############################################################################

> sink()
```

Anhang 4-G zu Modul 4 A.1

Abbildungen

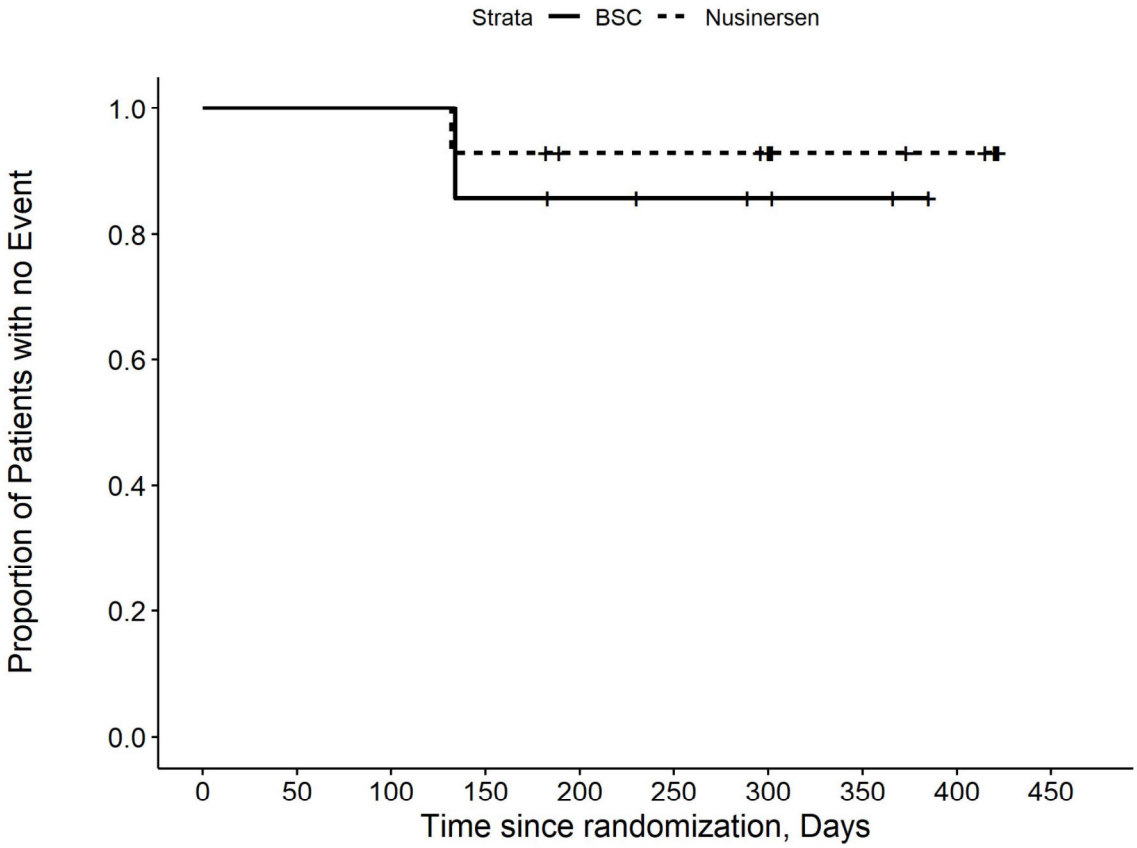
Stand: 01.12.2020



Number at risk

BSC	7	1	1	1	1	1	1	1	0	0
Nusinersen	14	3	1	0	0	0	0	0	0	0

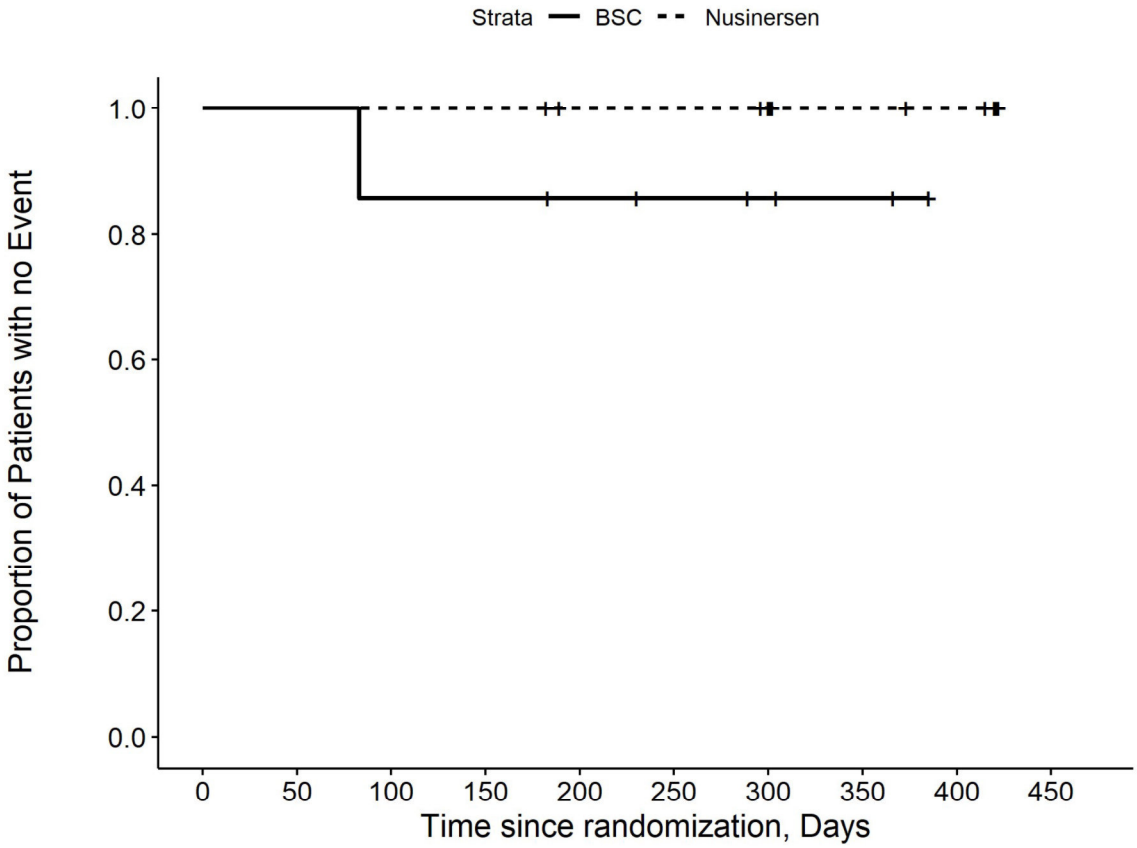
Kaplan Meier Plot for Time to AE by PT pct
Acute respiratory failure



Number at risk

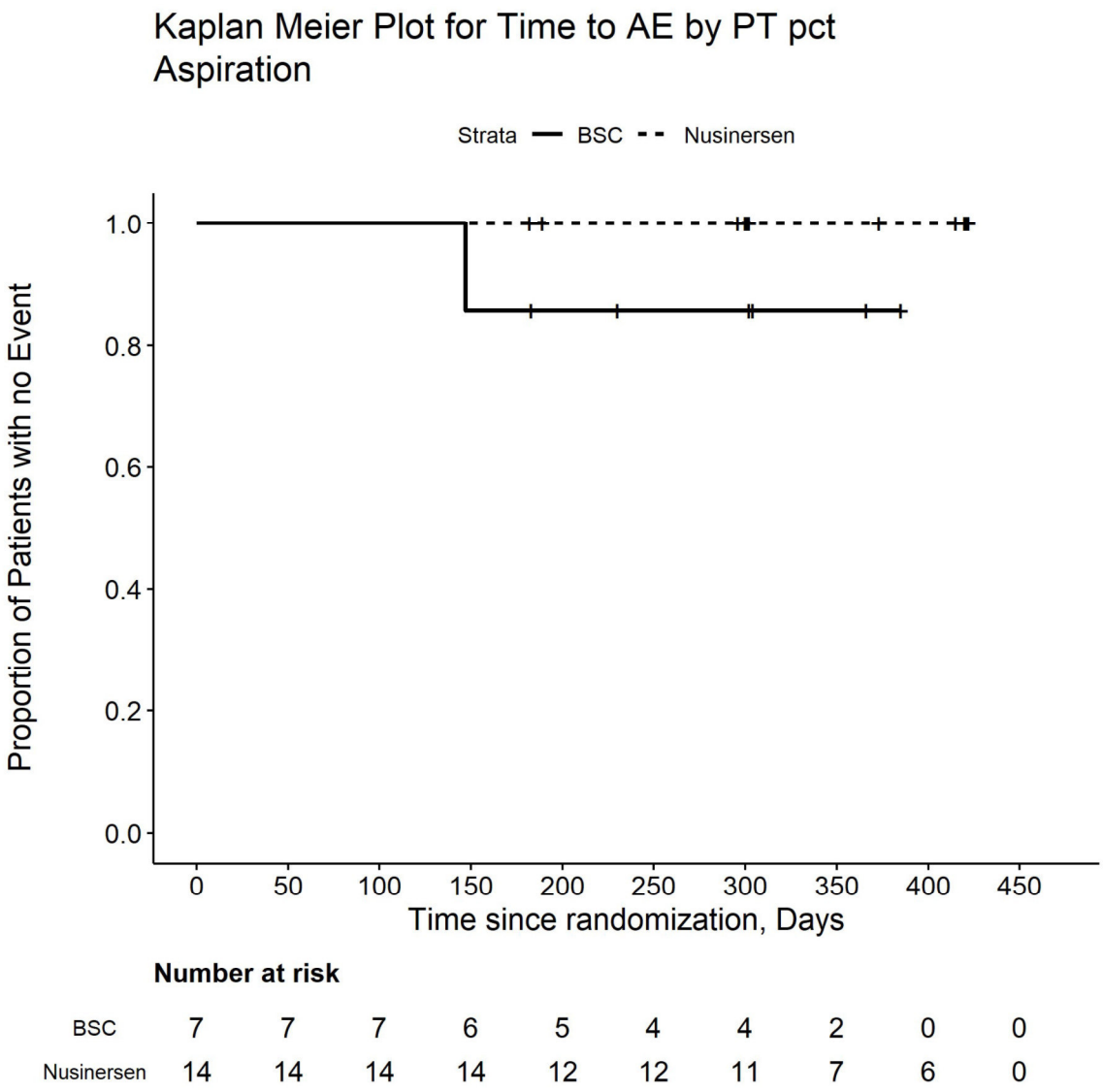
BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	13	11	11	10	6	5	0

Kaplan Meier Plot for Time to AE by PT pct
Aphthous ulcer



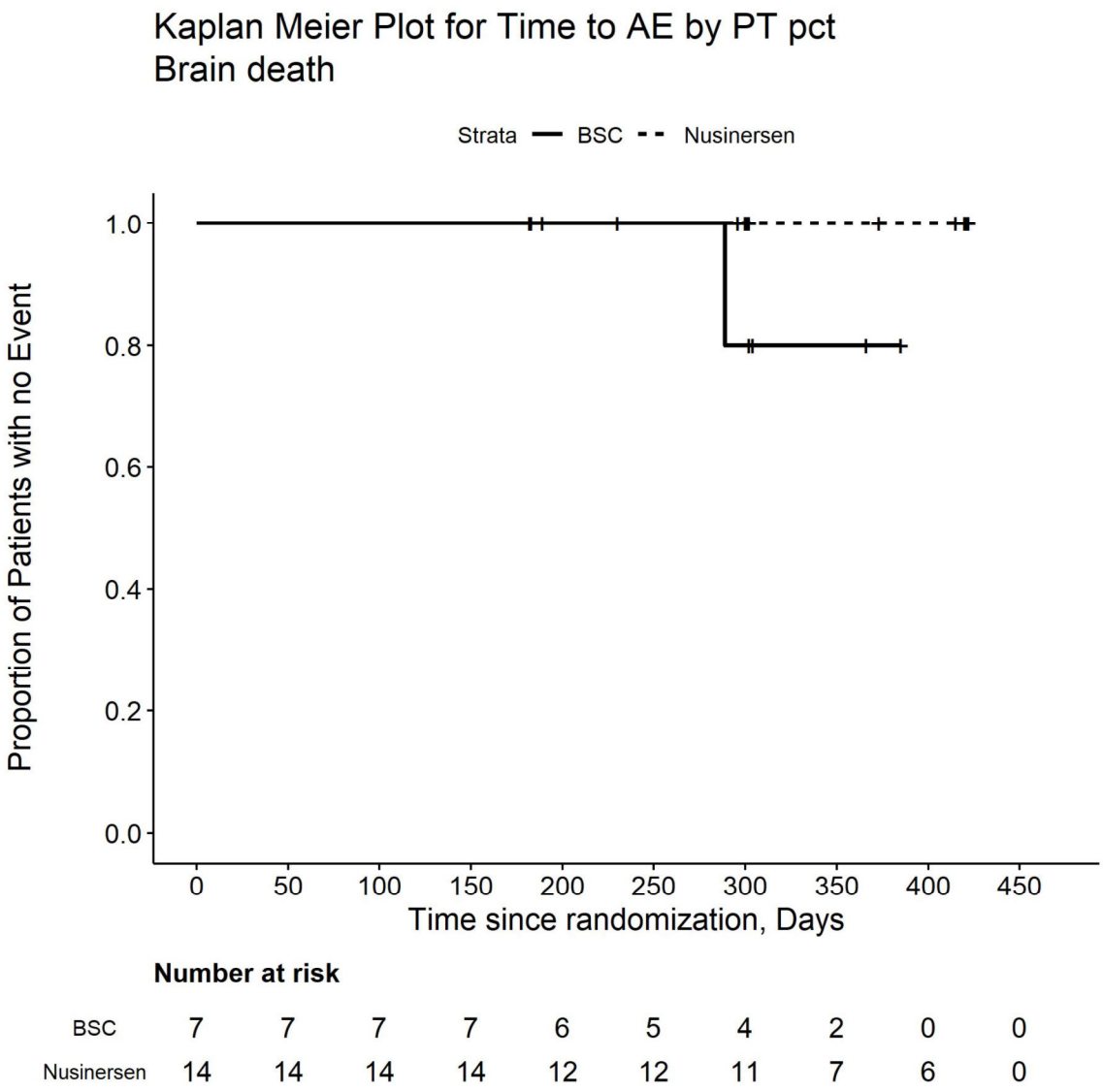
Number at risk

BSC	7	7	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



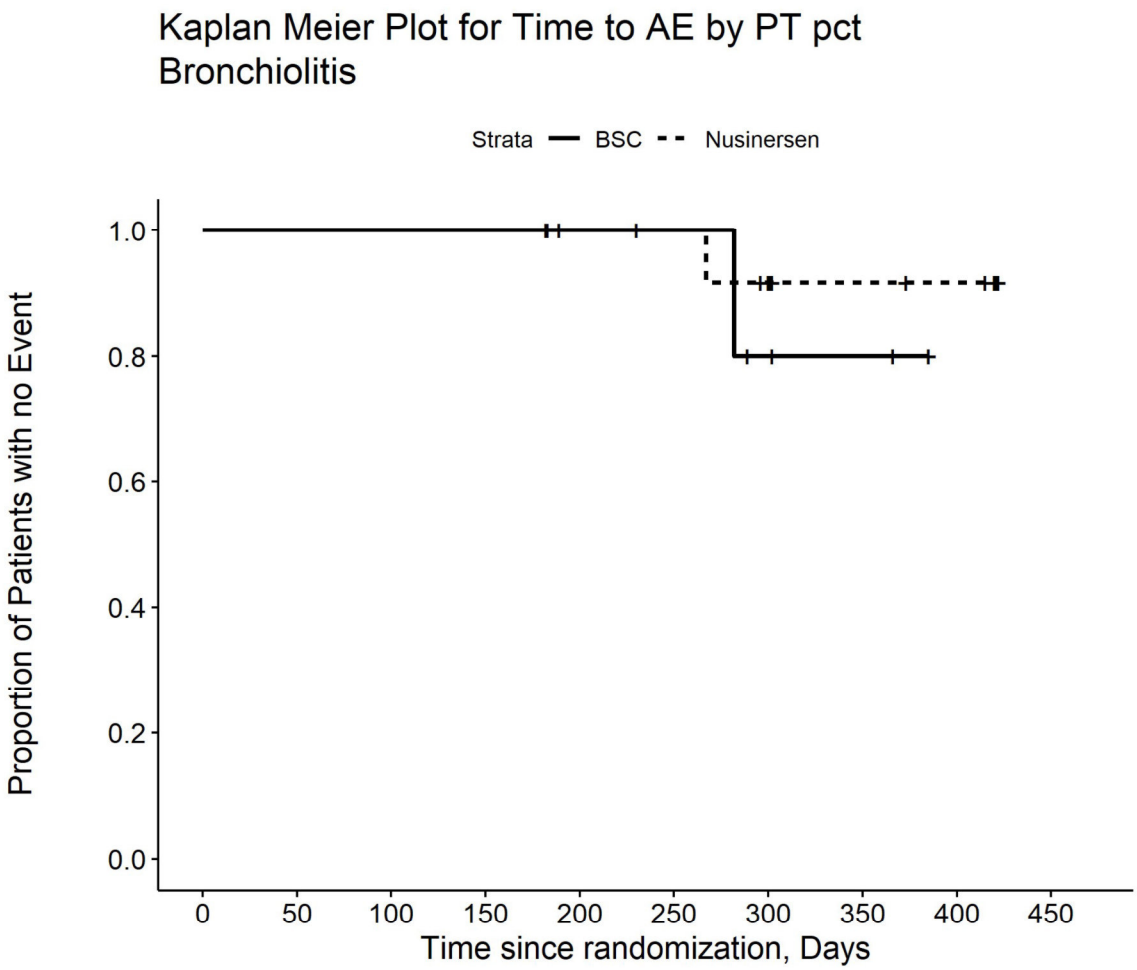
Number at risk

BSC	7	7	7	6	5	4	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

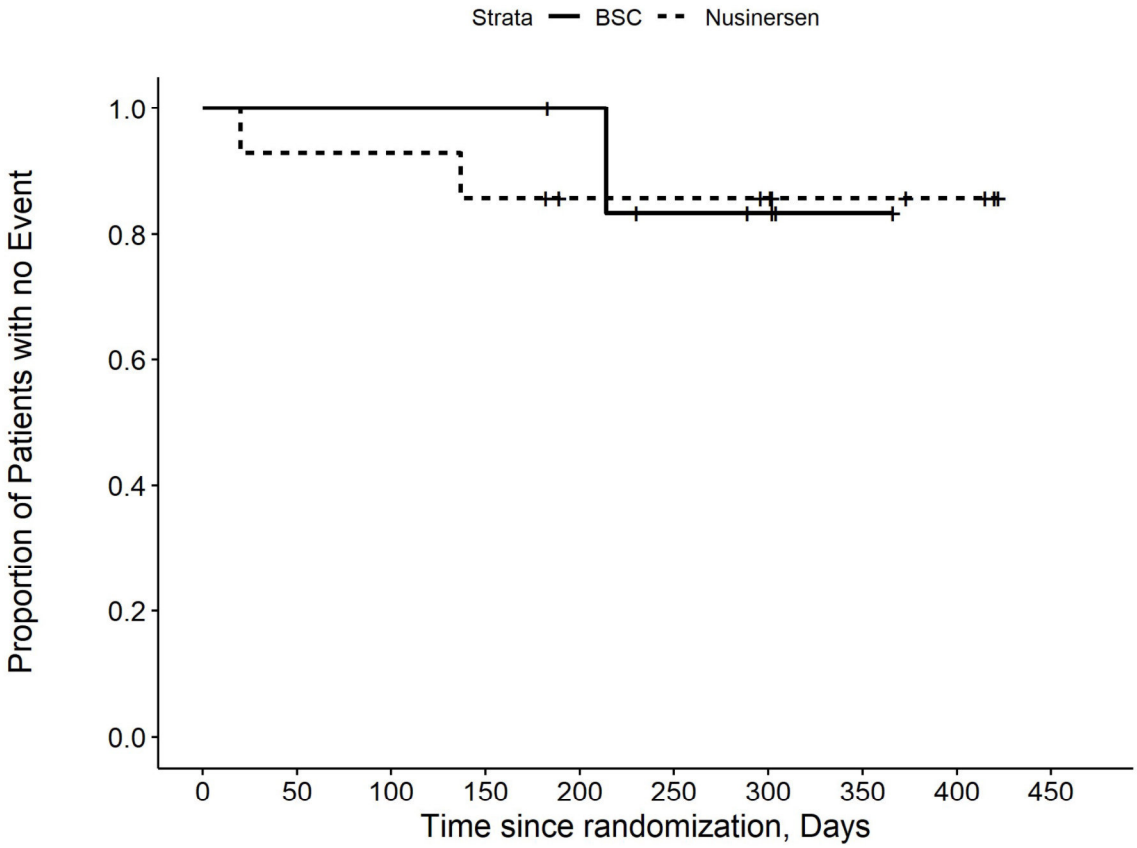
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

BSC	7	7	7	7	6	5	3	2	0	0
Nusinersen	14	14	14	14	12	12	10	6	5	0

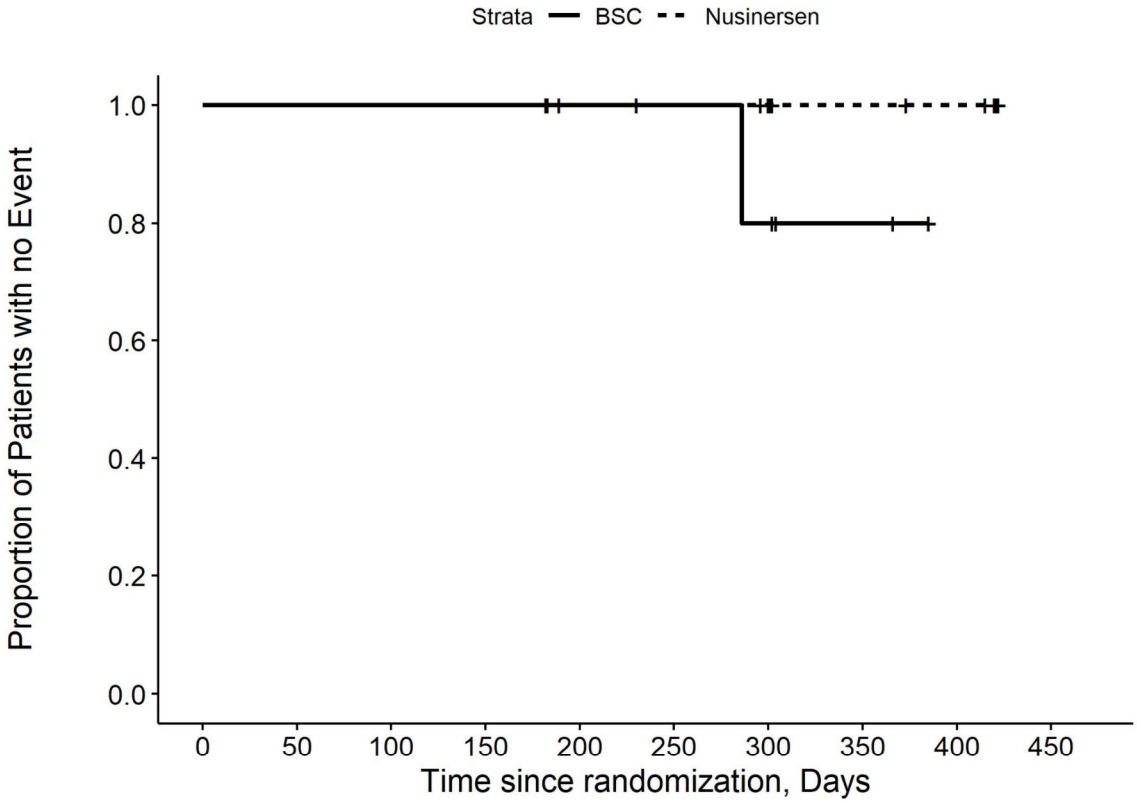
Kaplan Meier Plot for Time to AE by PT pct
Bronchitis



Number at risk

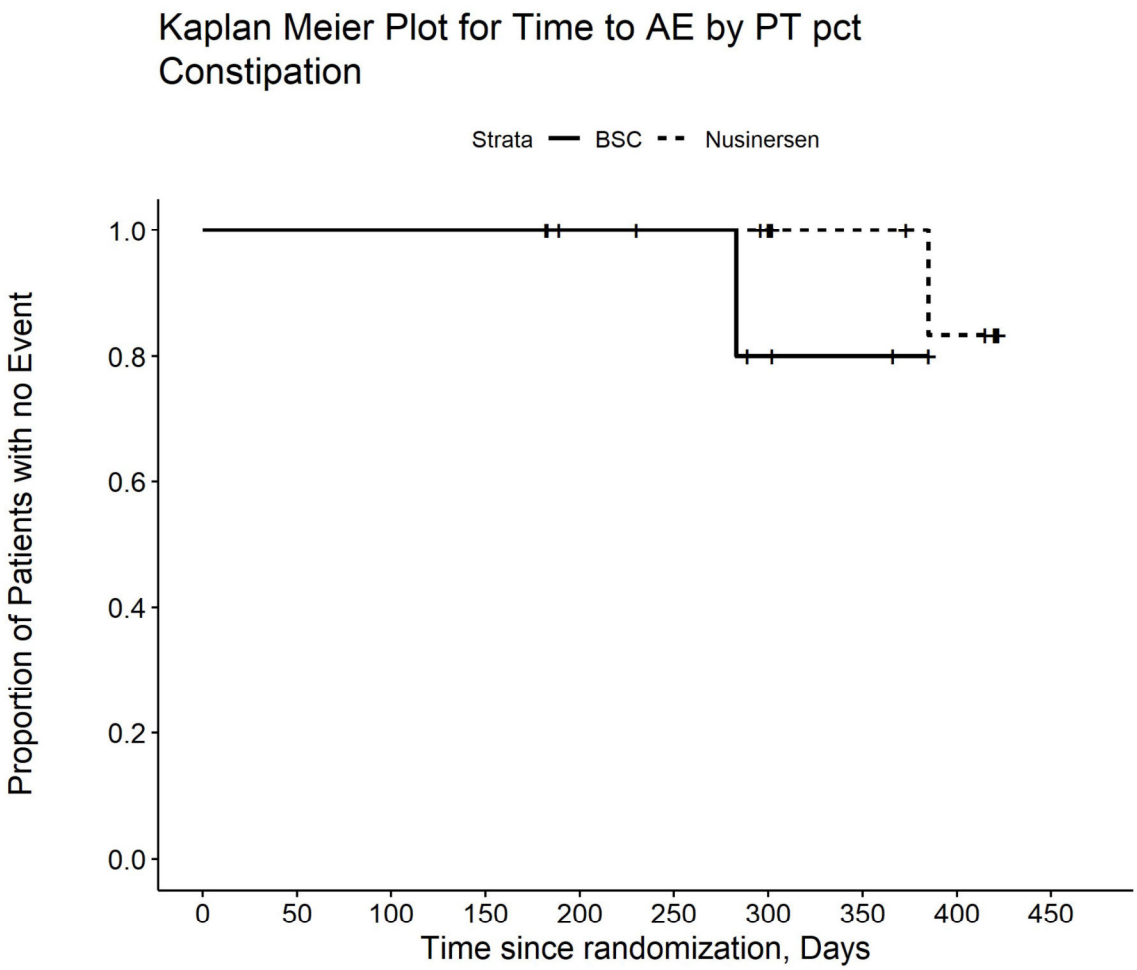
BSC	7	7	7	7	6	4	3	1	0	0
Nusinersen	14	13	13	12	10	10	9	6	5	0

Kaplan Meier Plot for
Time to AE by PT pct
Cardio : respiratory arrest



Number at risk

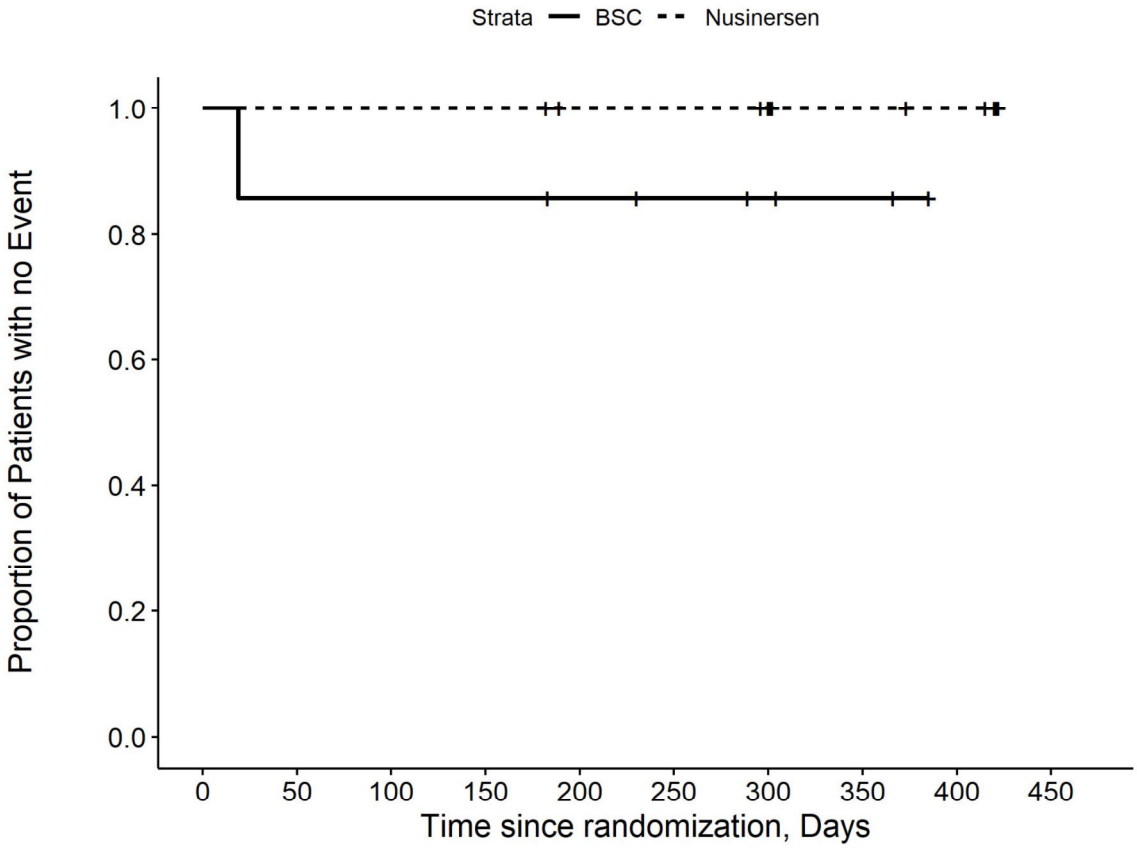
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

BSC	7	7	7	7	6	5	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	5	0

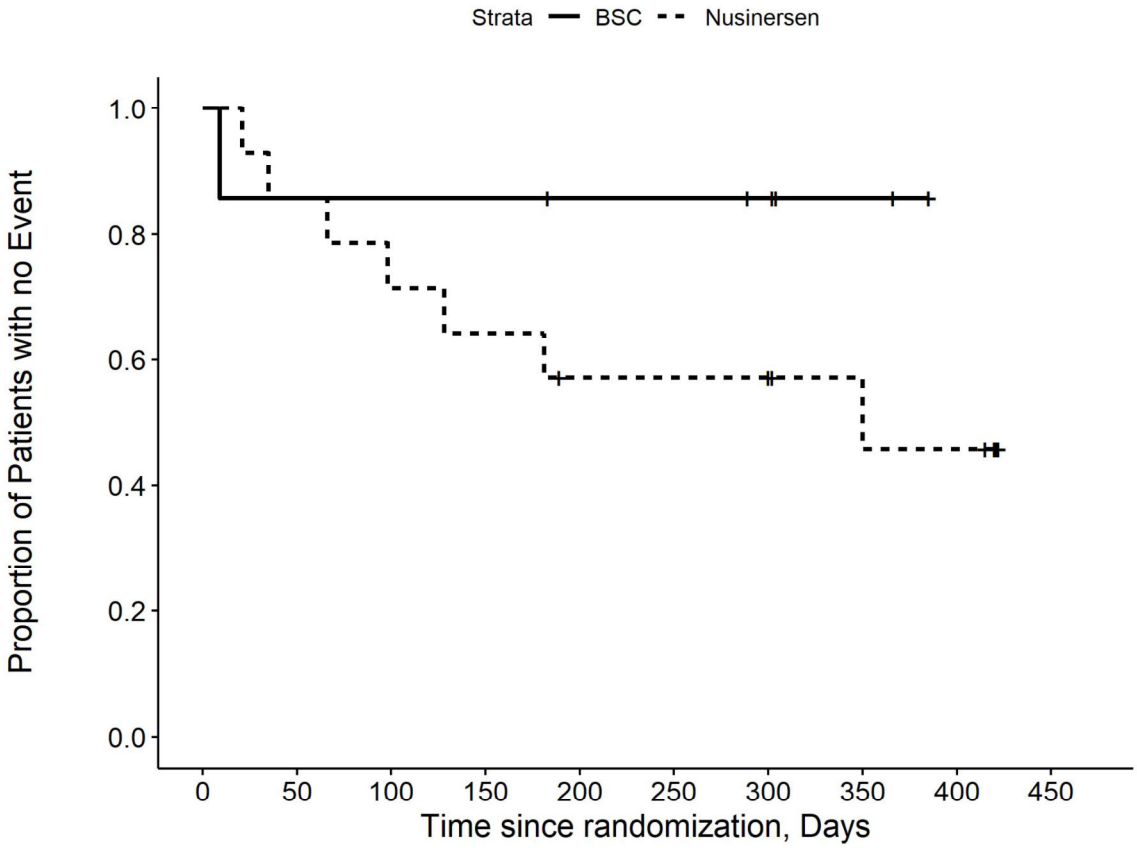
Kaplan Meier Plot for Time to AE by PT pct Contusion



Number at risk

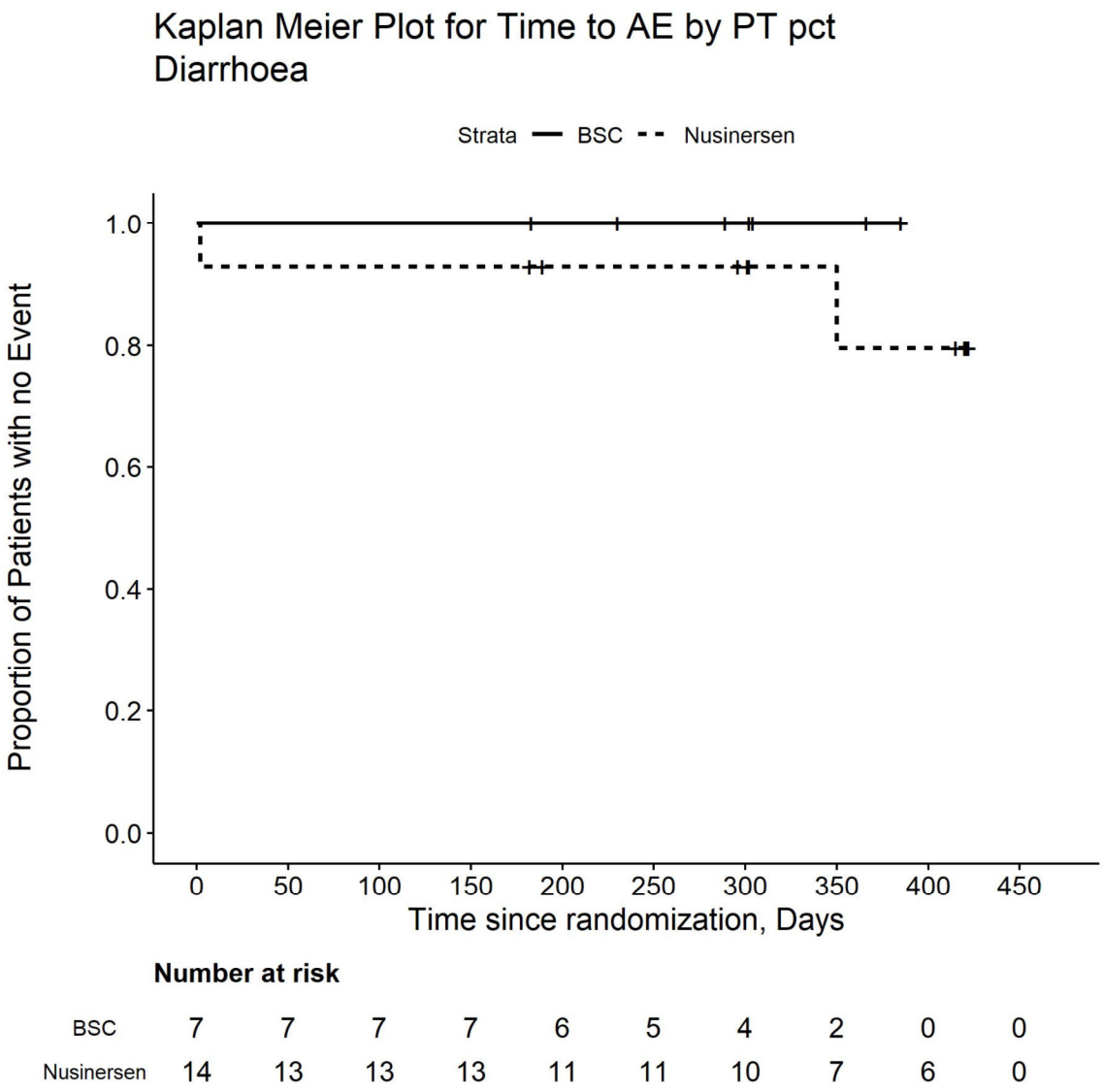
BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for Time to AE by PT pct Cough



Number at risk

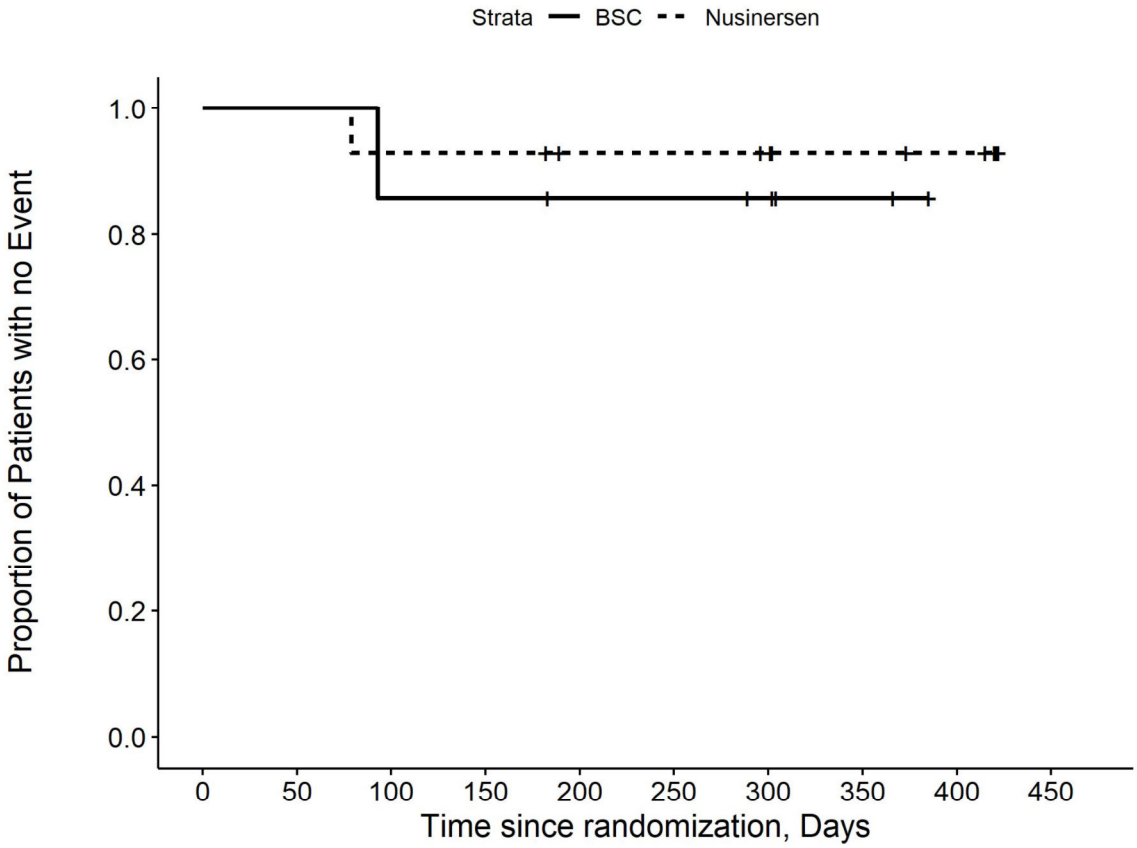
BSC	7	6	6	6	5	5	4	2	0	0
Nusinersen	14	12	10	9	7	7	7	5	4	0



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	13	13	11	11	10	7	6	0

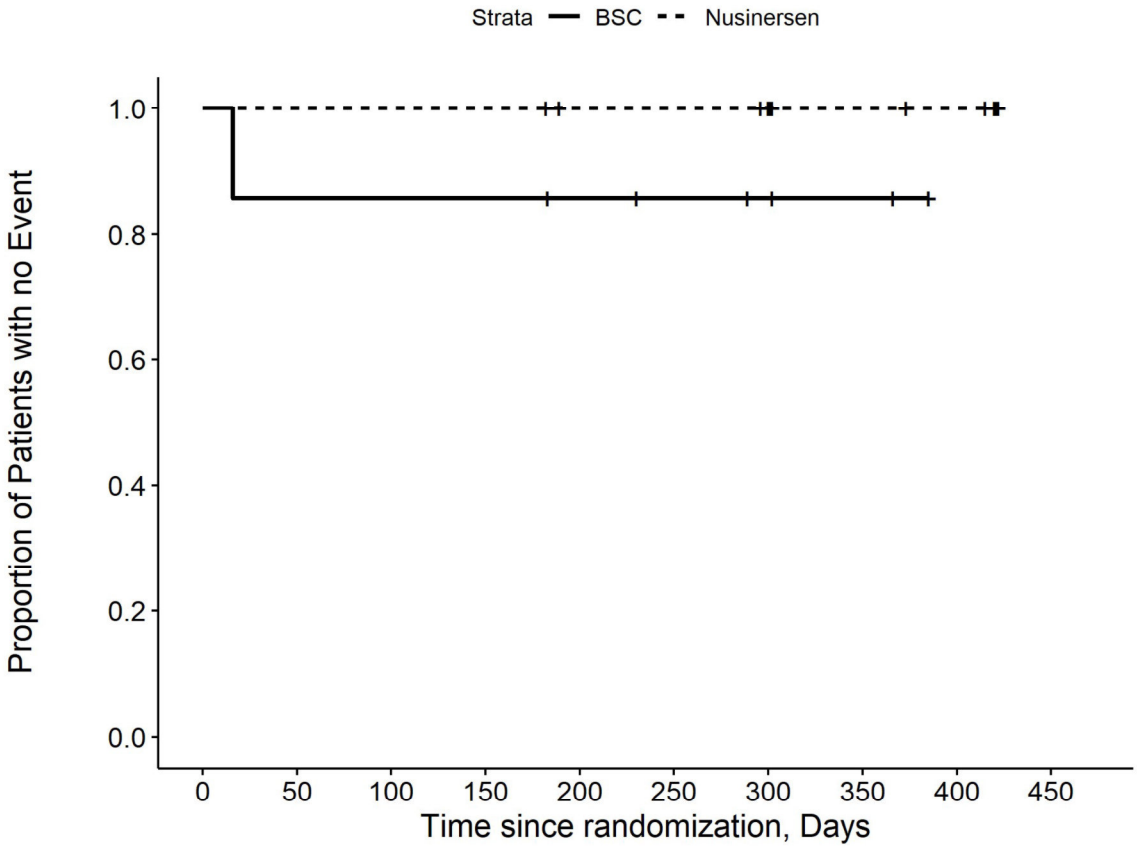
Kaplan Meier Plot for Time to AE by PT pct Drug hypersensitivity



Number at risk

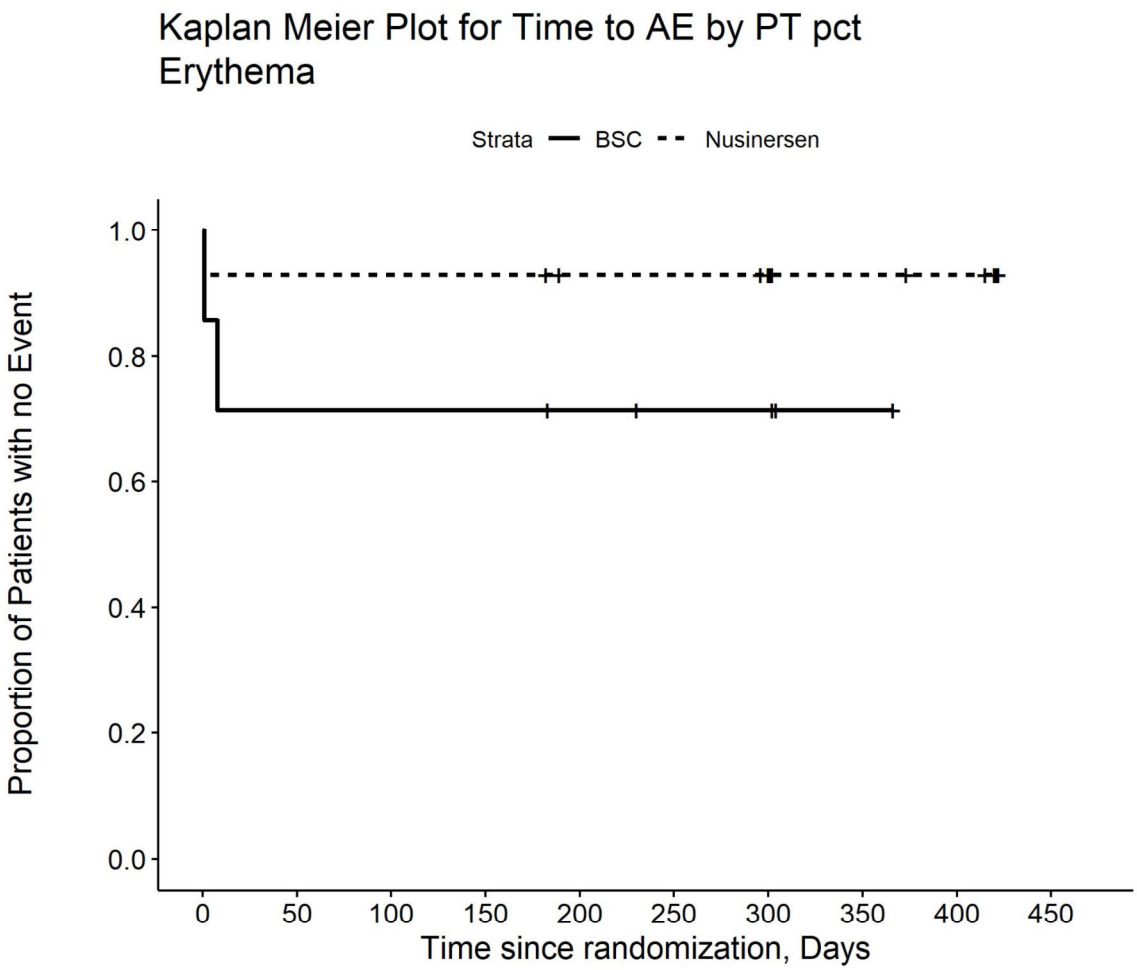
BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	14	13	13	11	11	10	7	6	0

Kaplan Meier Plot for Time to AE by PT pct
Enterovirus infection



Number at risk

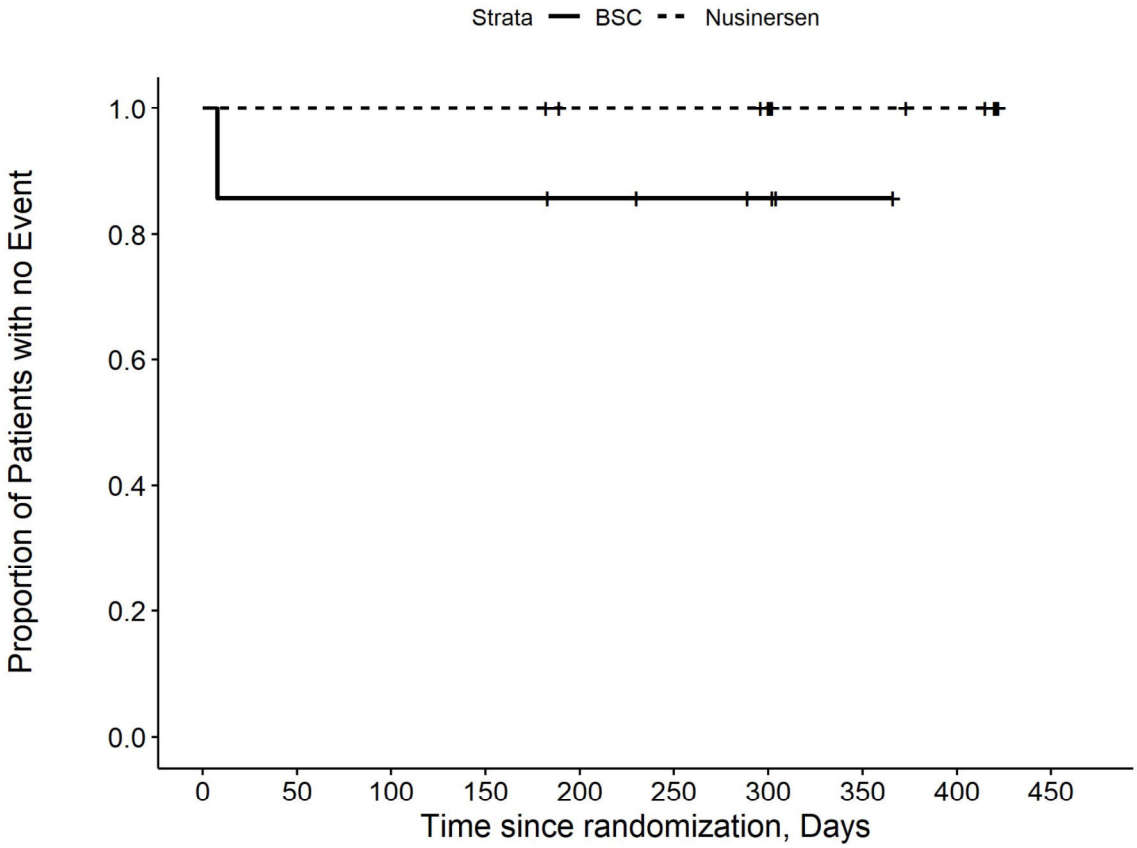
BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

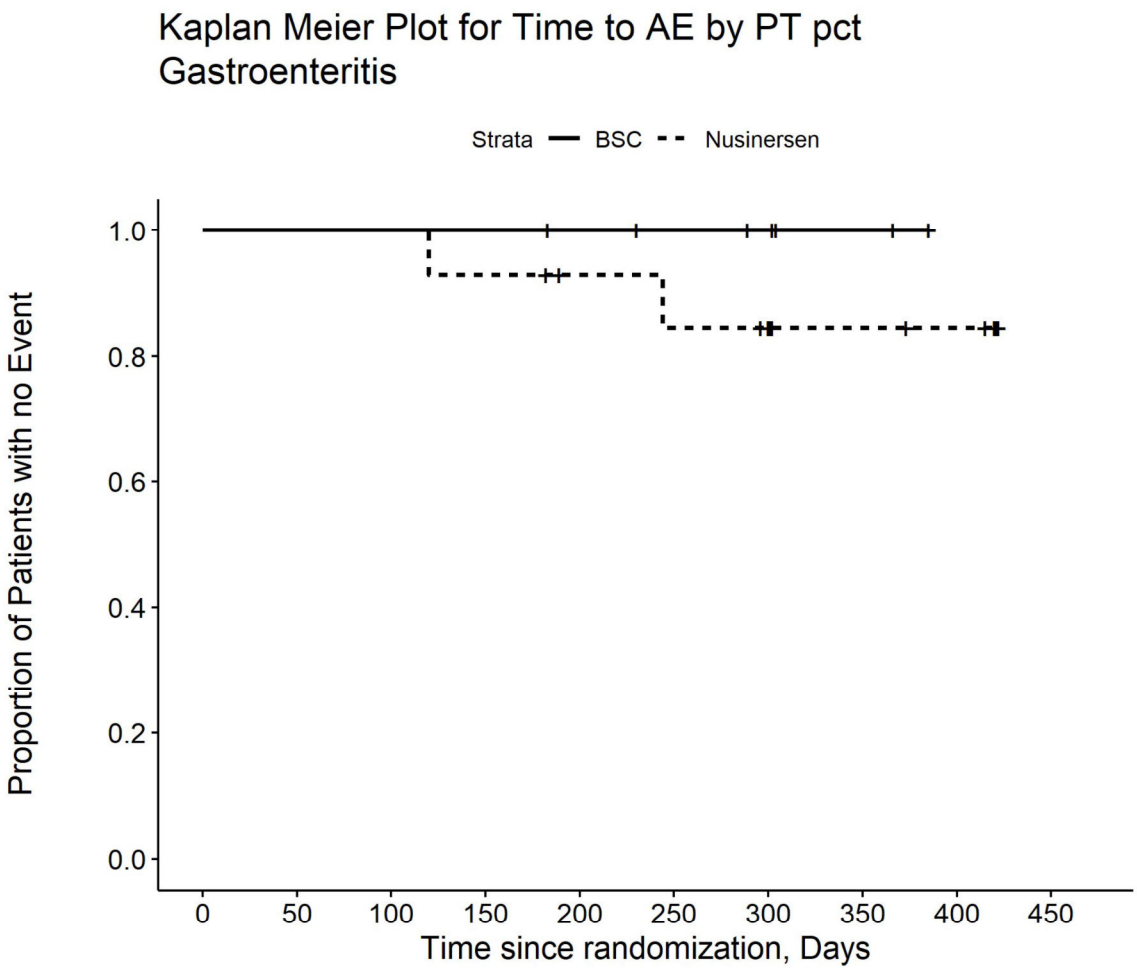
BSC	7	5	5	5	4	3	3	1	0	0
Nusinersen	14	13	13	13	11	11	10	7	6	0

Kaplan Meier Plot for Time to AE by PT pct Flushing



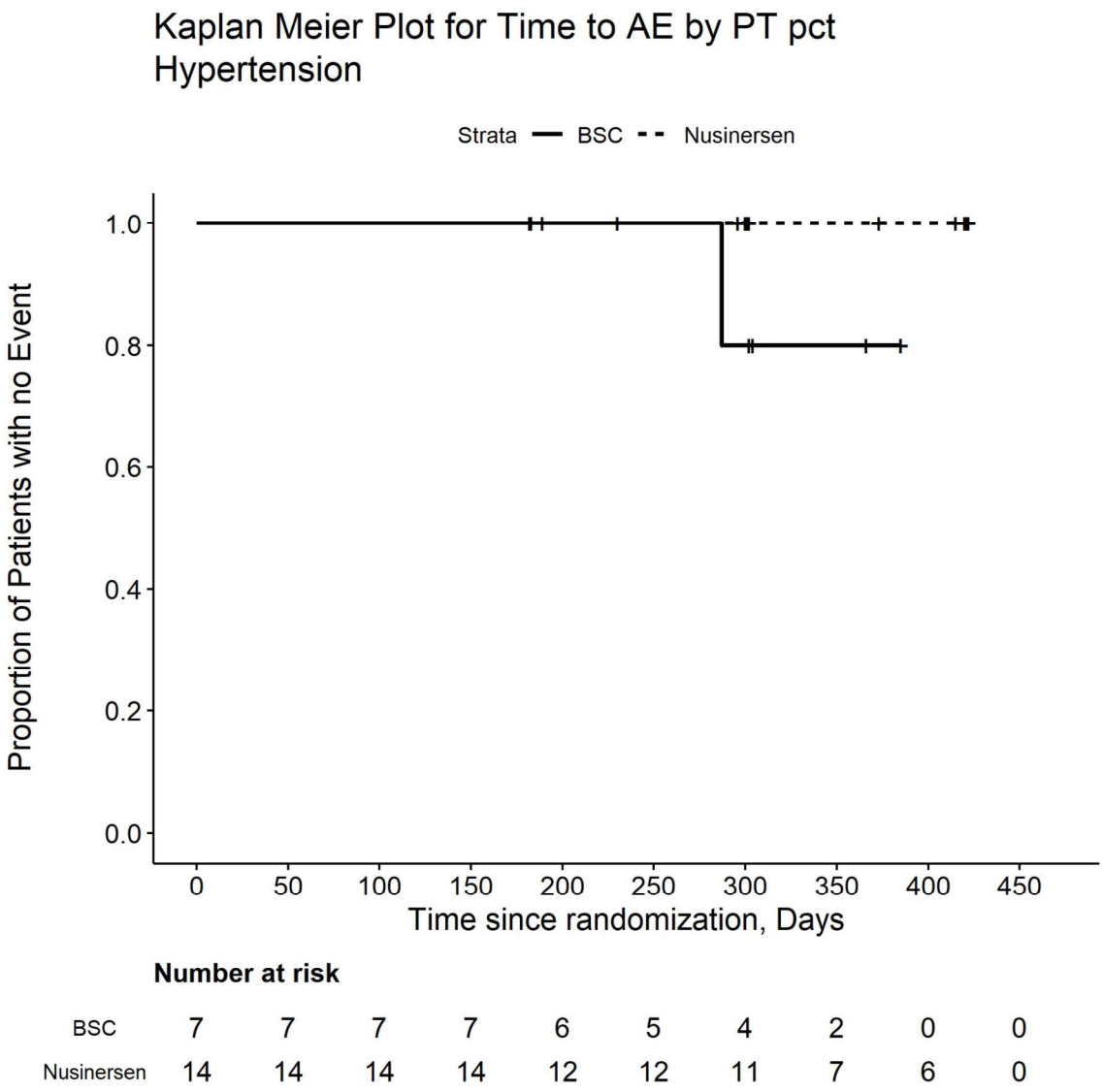
Number at risk

BSC	7	6	6	6	5	4	3	1	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



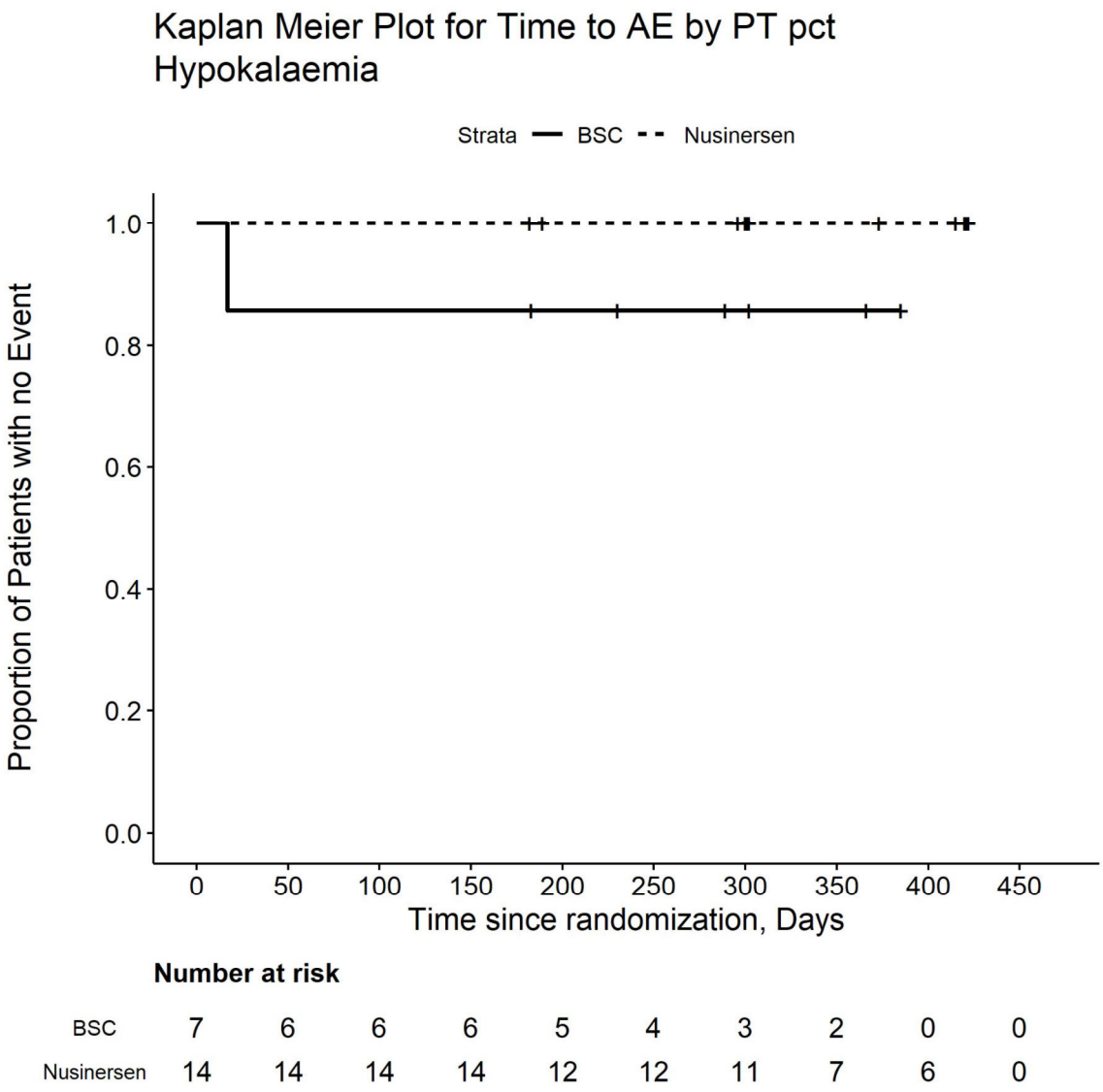
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	11	10	9	6	5	0



Number at risk

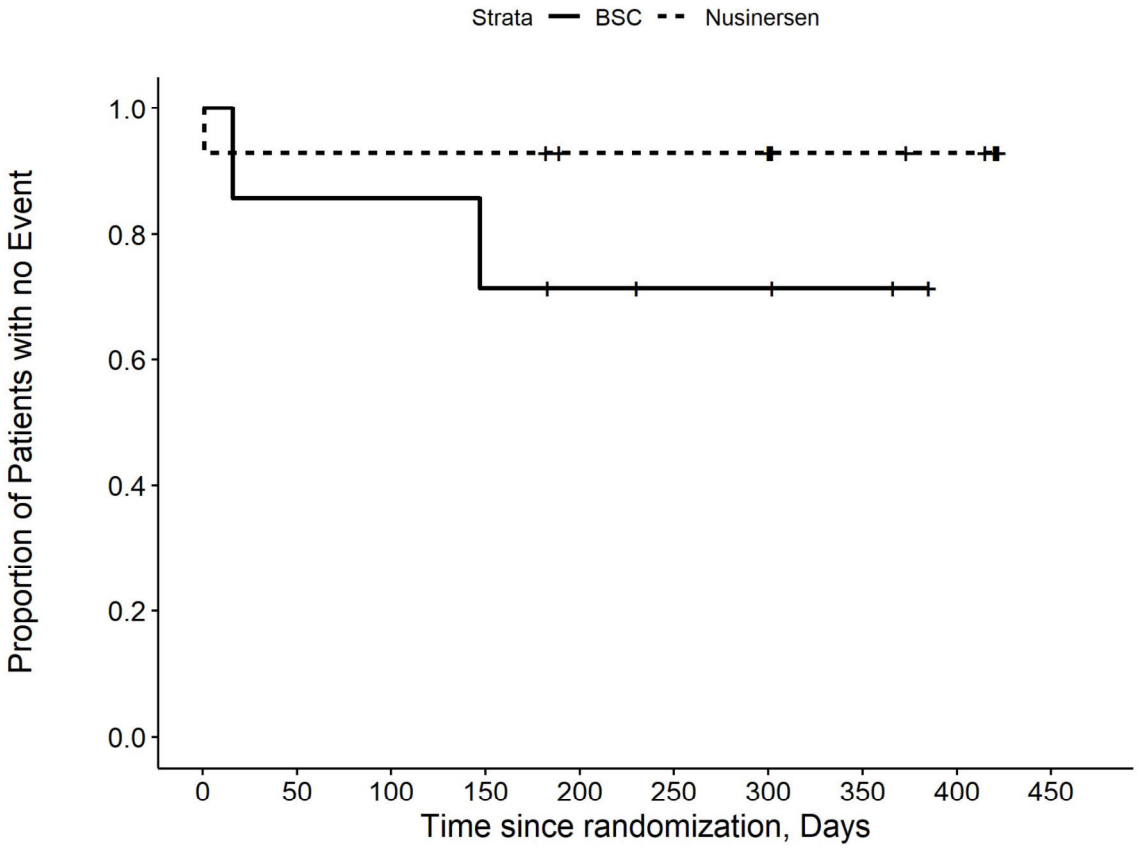
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

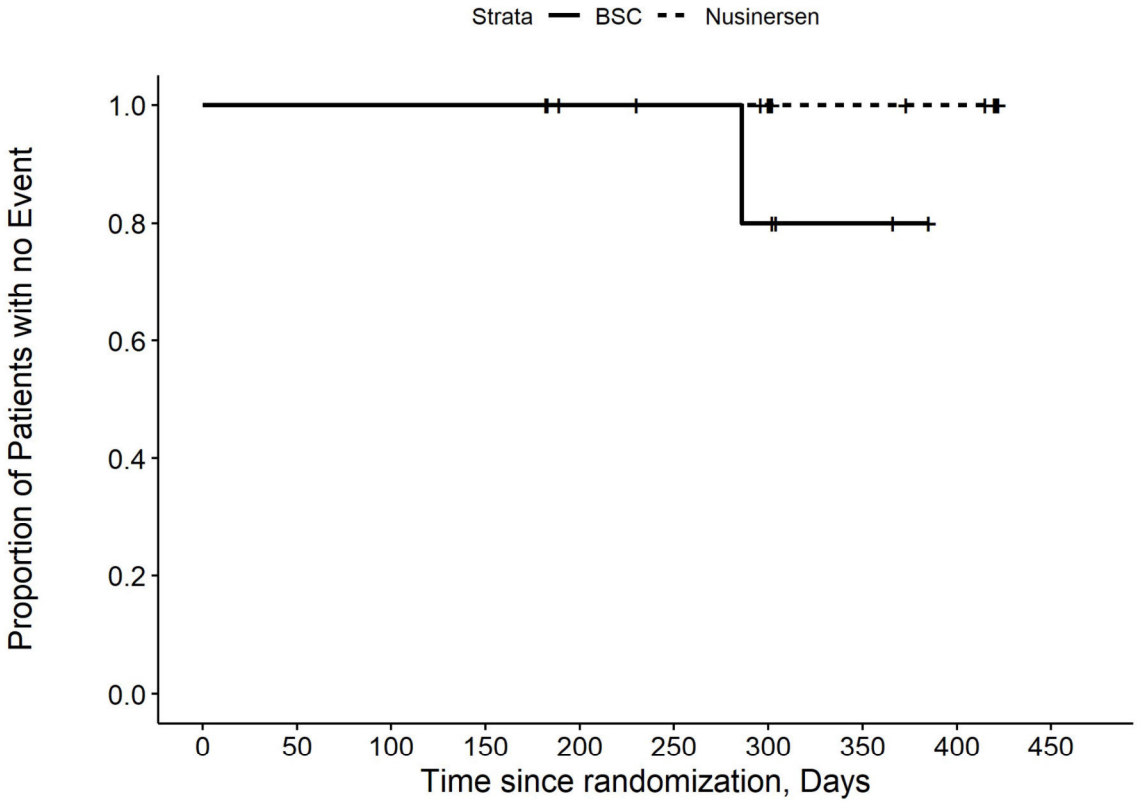
Kaplan Meier Plot for Time to AE by PT pct Hypoxia



Number at risk

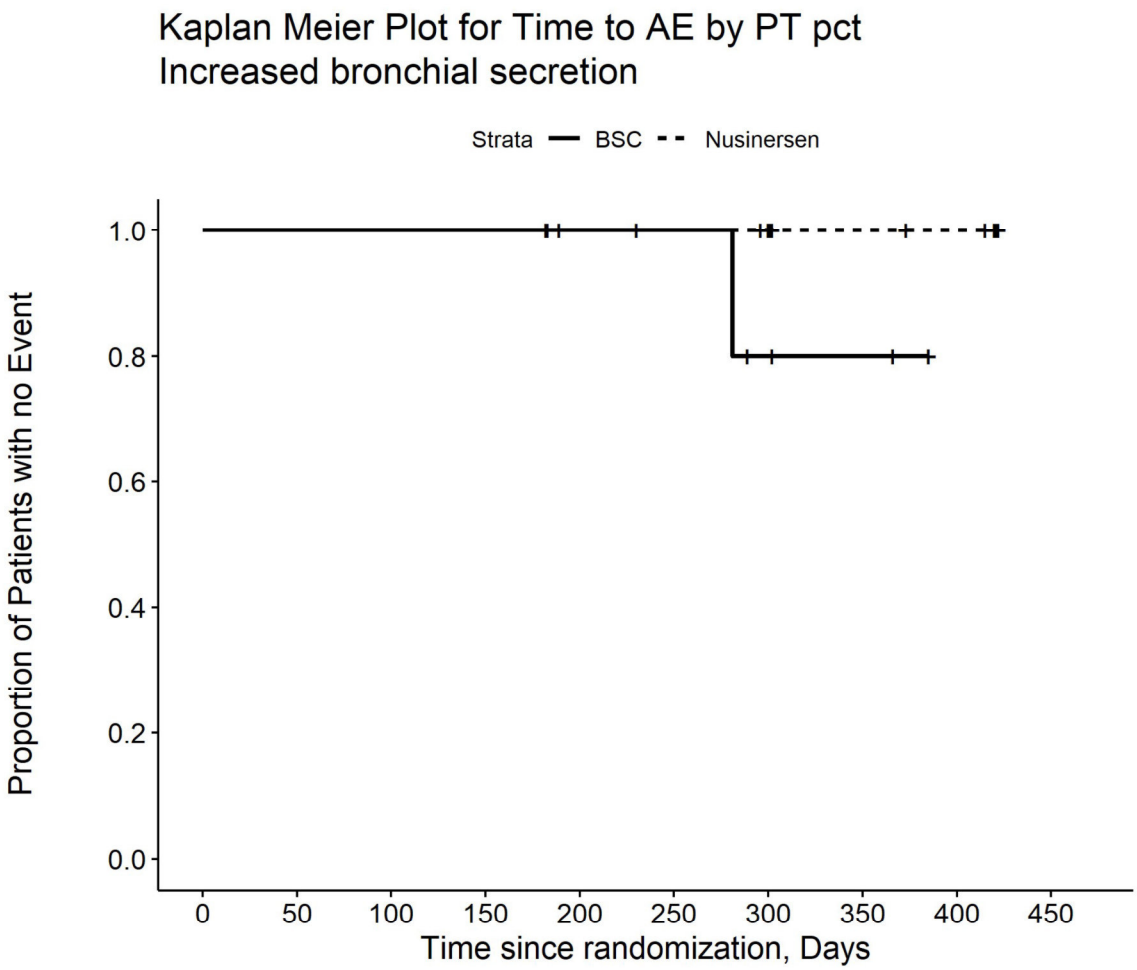
BSC	7	6	6	5	4	3	3	2	0	0
Nusinersen	14	13	13	13	11	11	11	7	6	0

Kaplan Meier Plot for
Time to AE by PT pct
Hypoxic : ischaemic encephalopathy



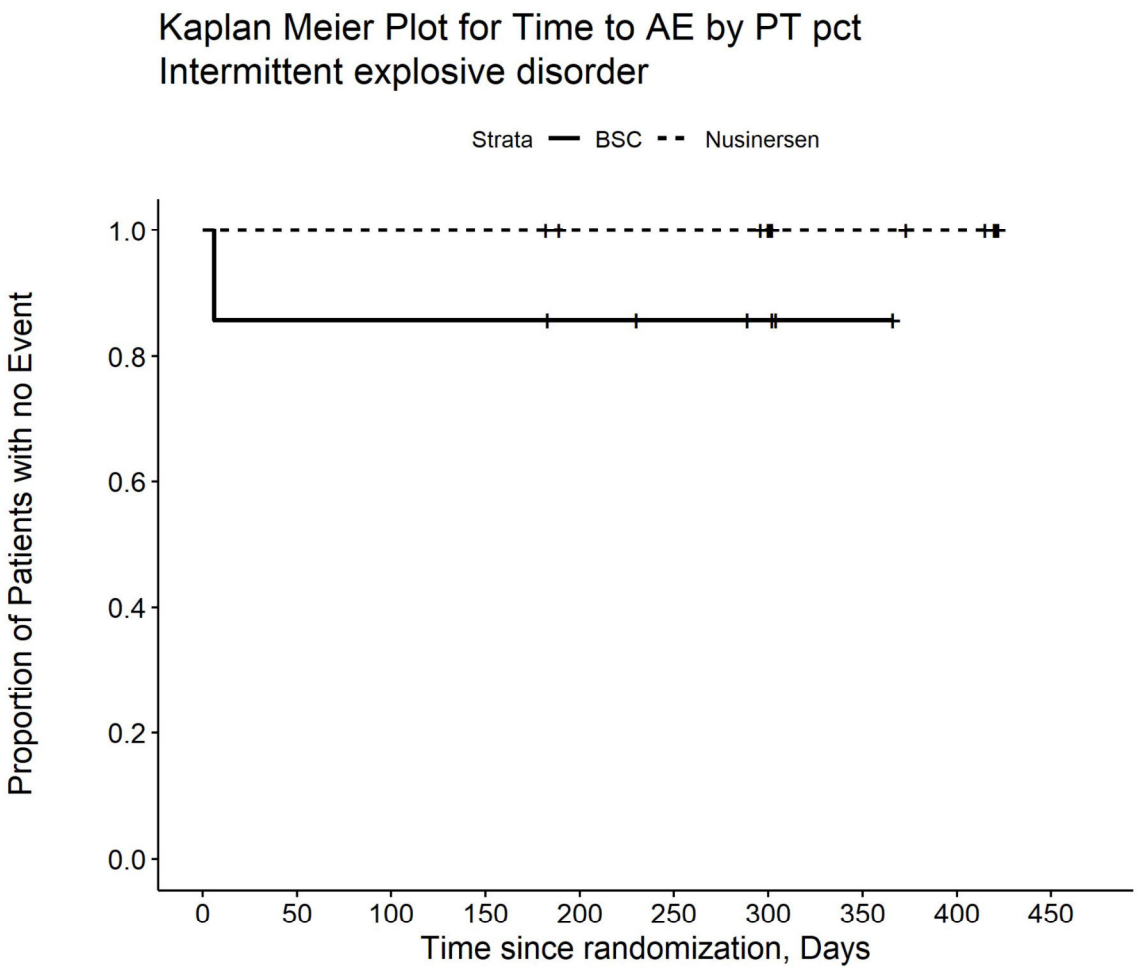
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



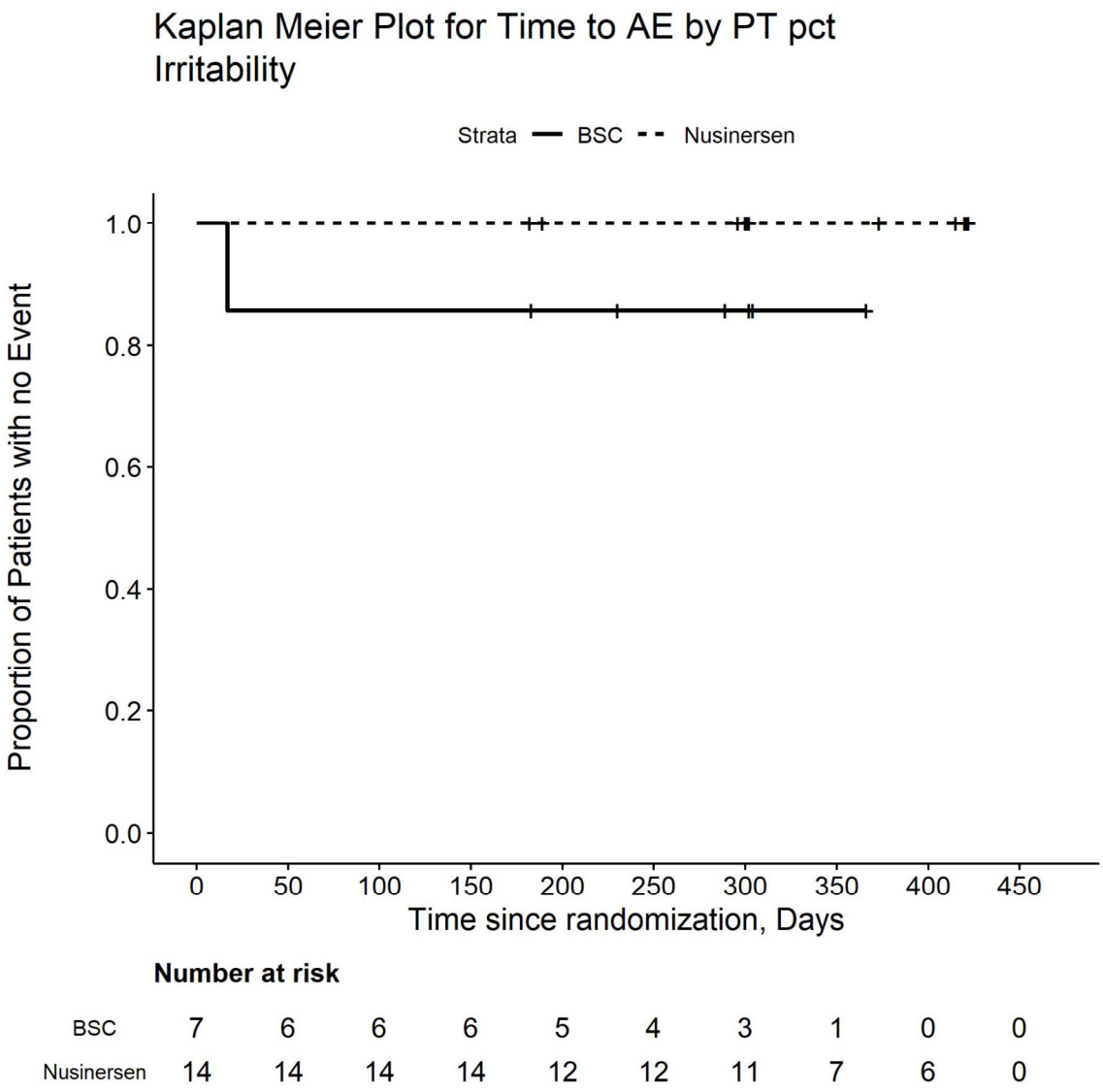
Number at risk

BSC	7	7	7	7	6	5	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



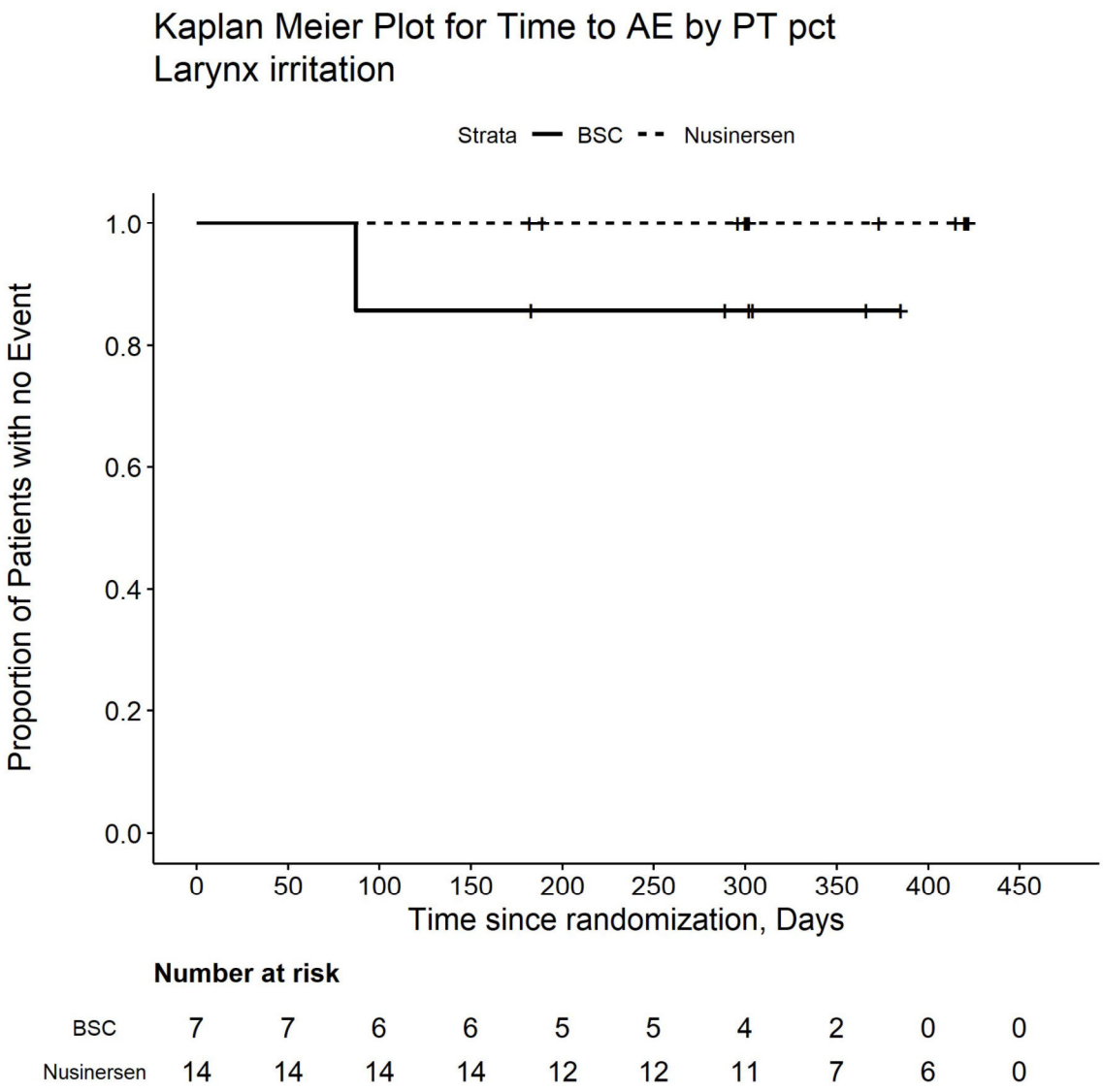
Number at risk

BSC	7	6	6	6	5	4	3	1	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



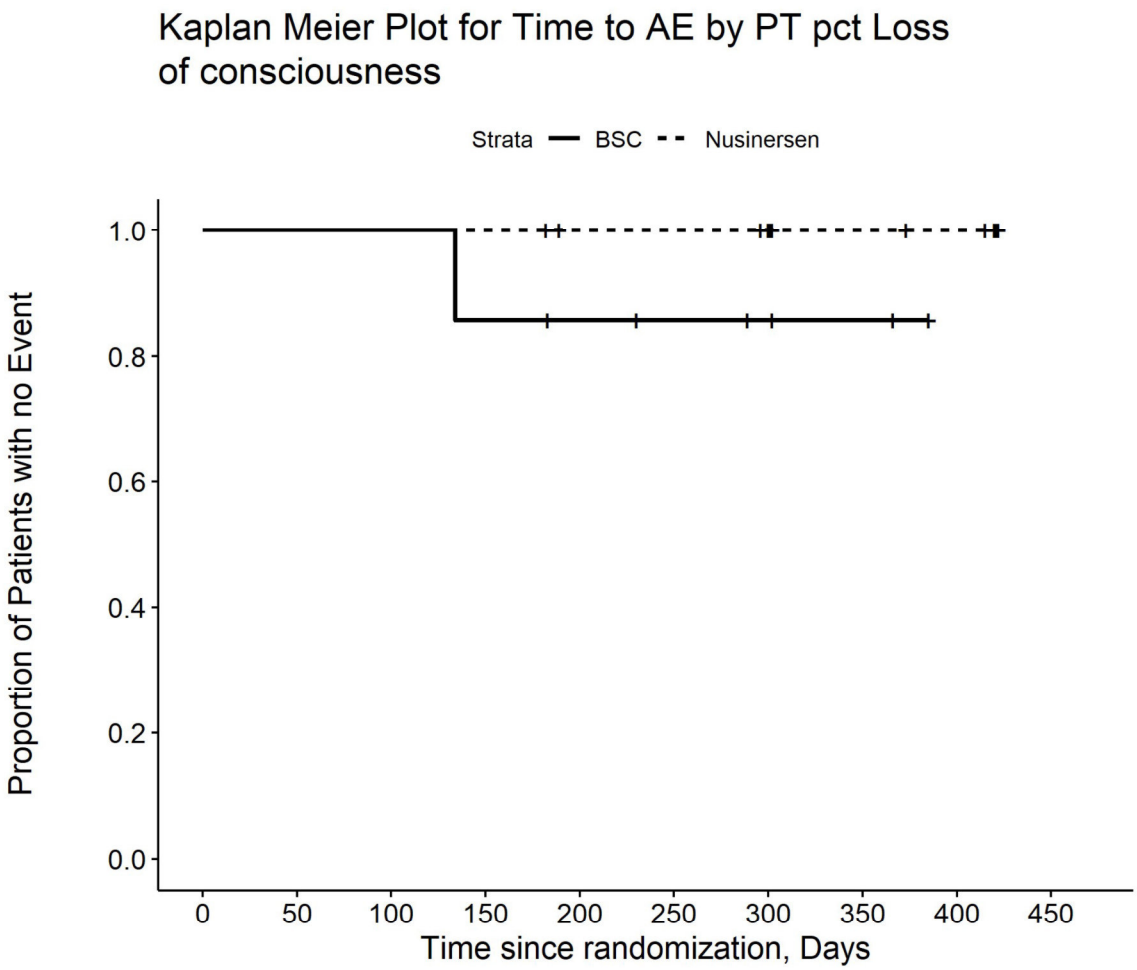
Number at risk

BSC	7	6	6	6	5	4	3	1	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



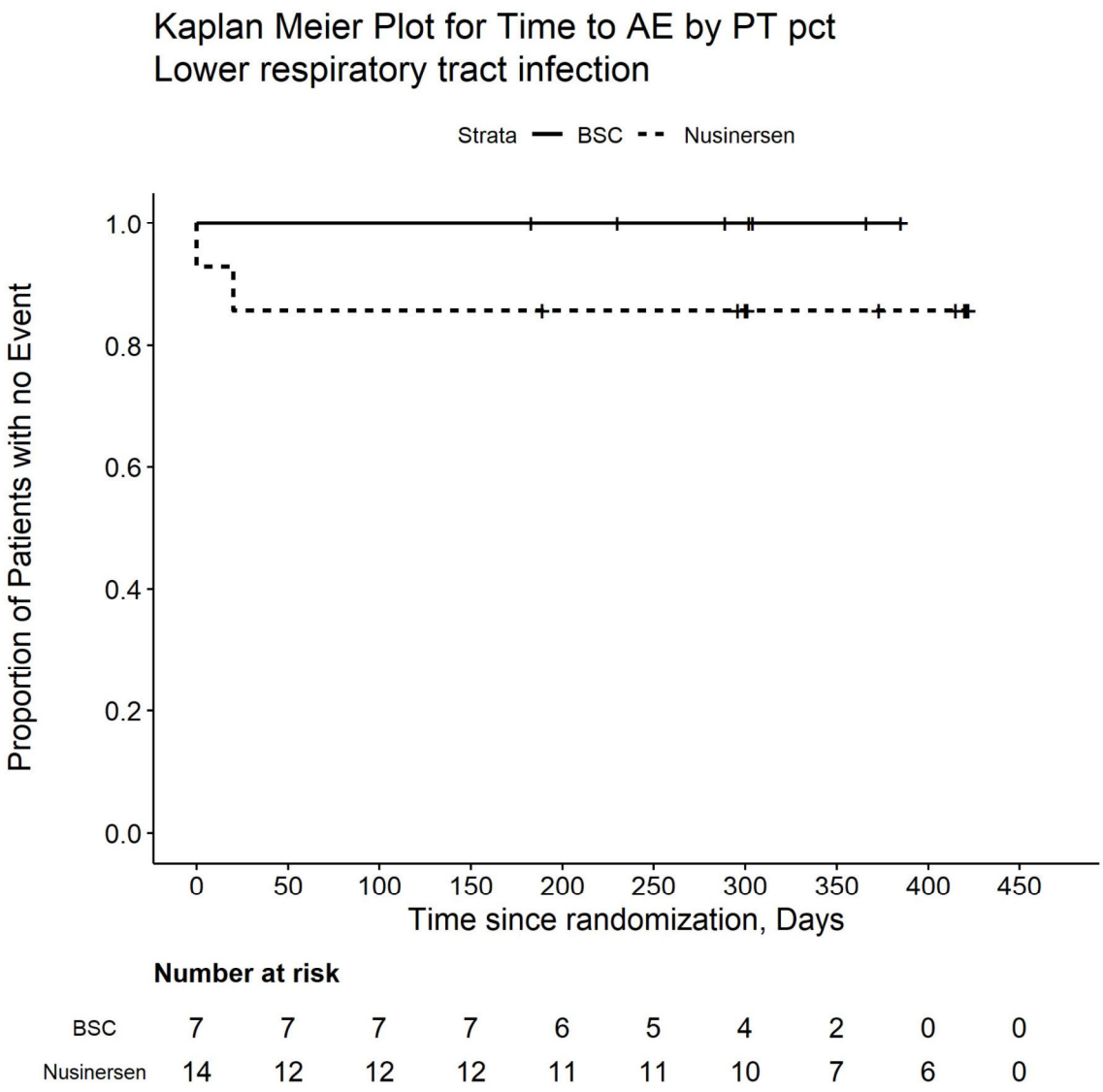
Number at risk

BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

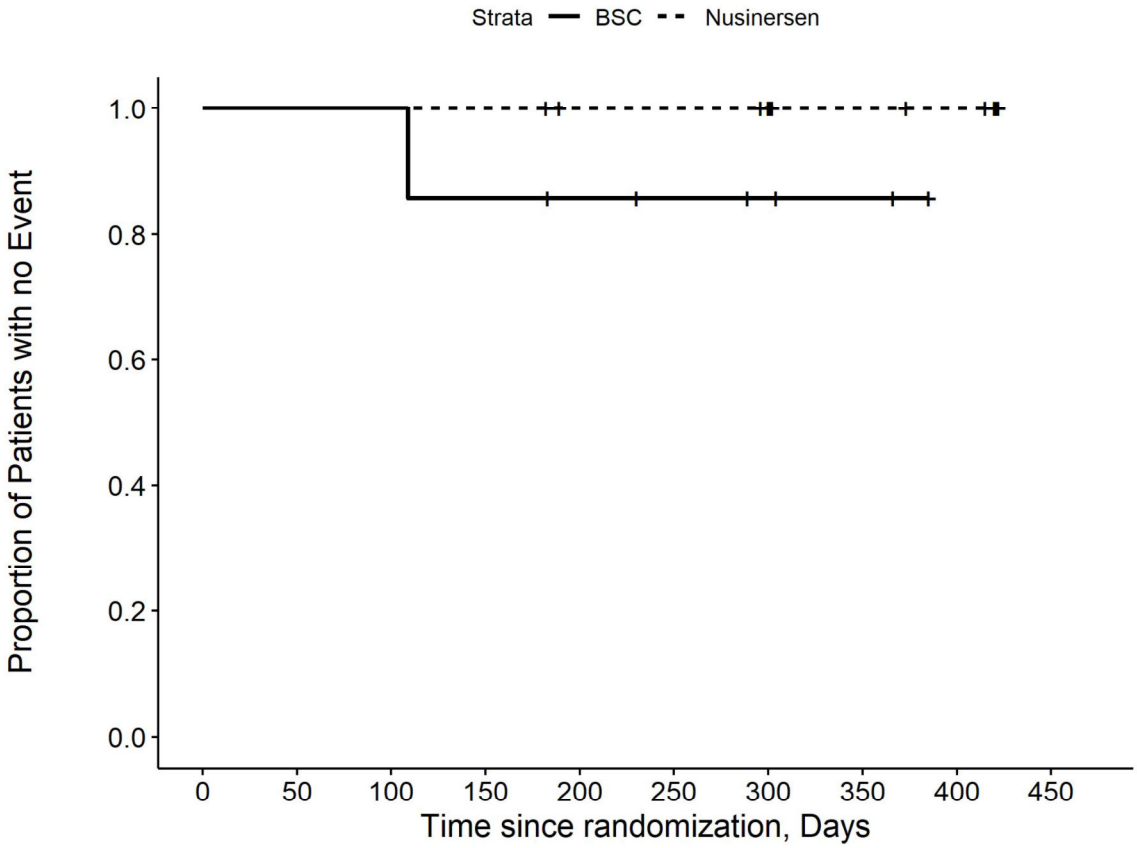
BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	12	12	12	11	11	10	7	6	0

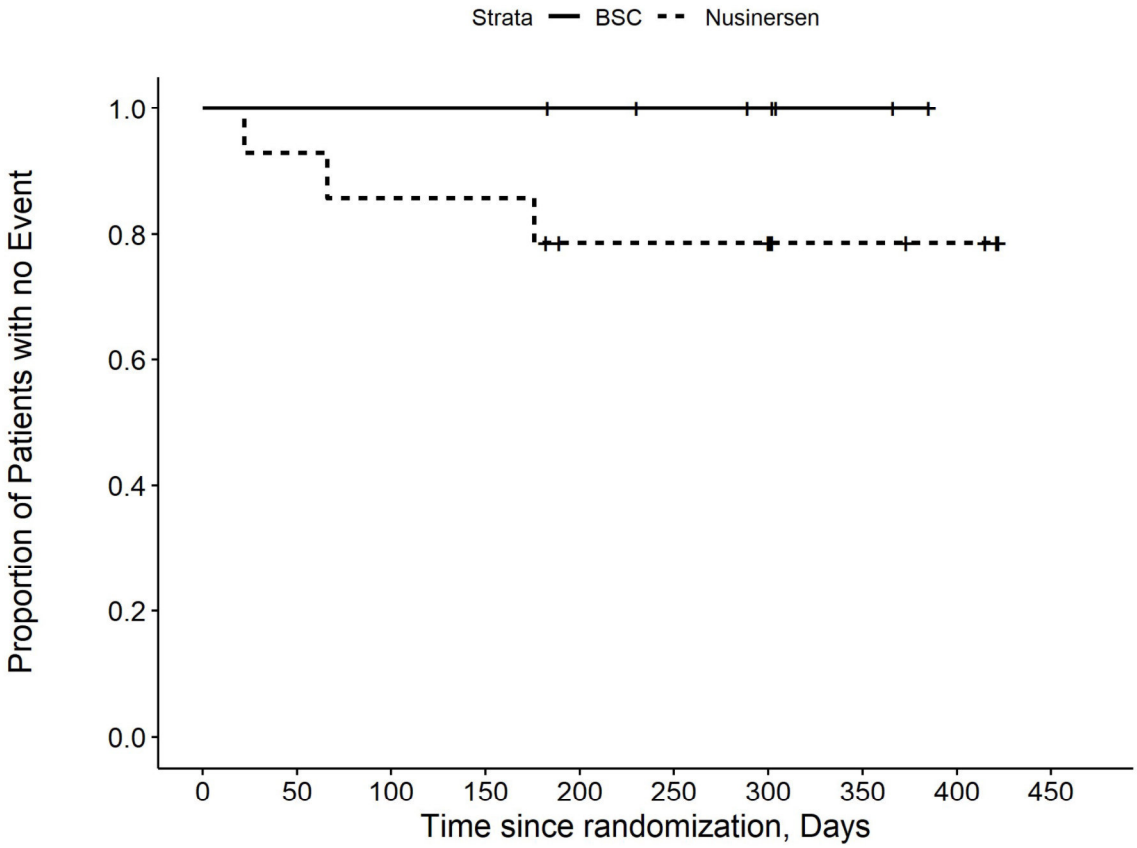
Kaplan Meier Plot for Time to AE by PT pct
Muscle strain



Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

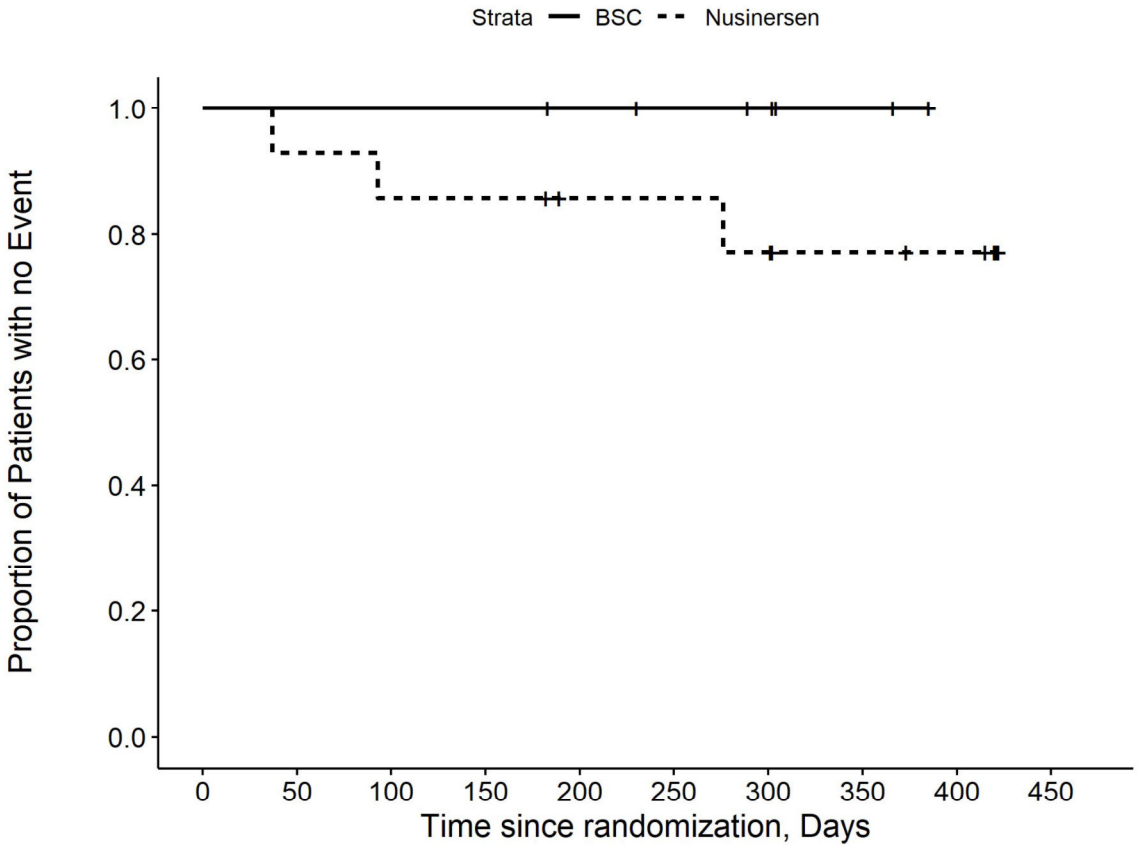
Kaplan Meier Plot for Time to AE by PT pct
Nasal congestion



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	12	12	9	9	9	5	4	0

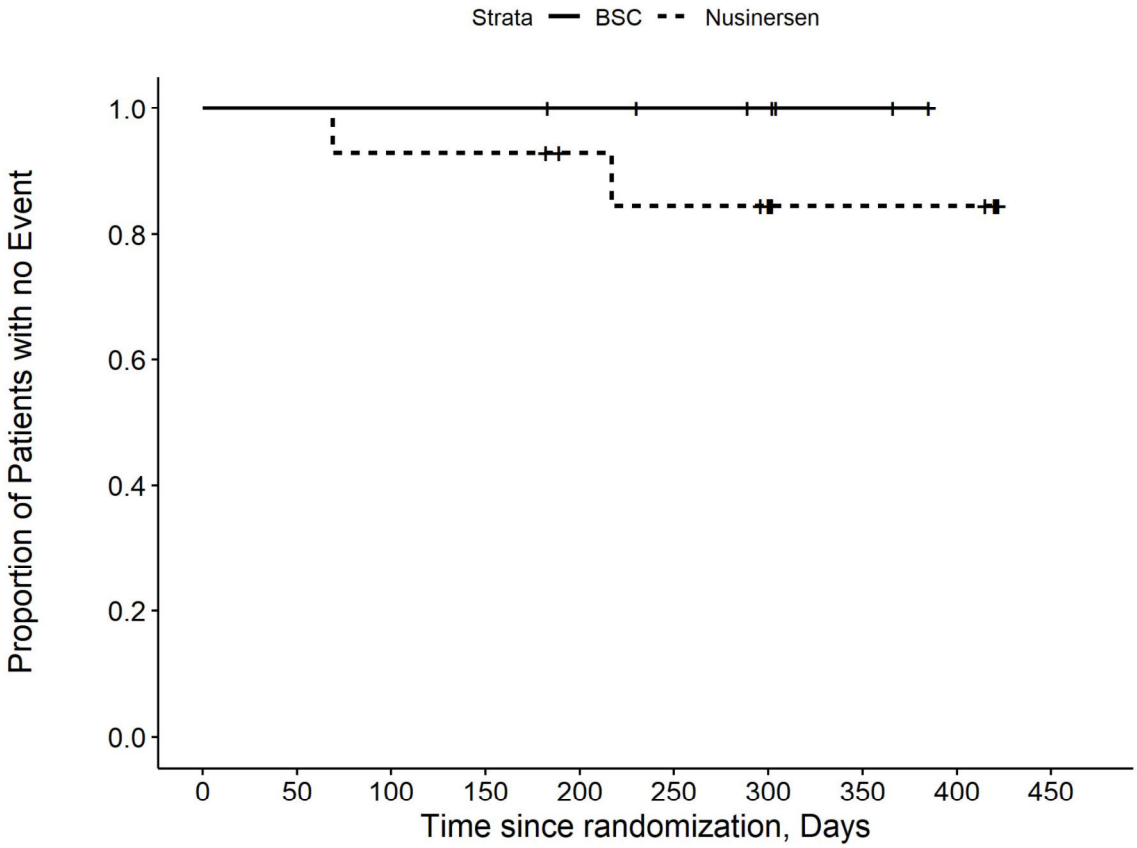
Kaplan Meier Plot for Time to AE by PT pct Pain in extremity



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	12	12	10	10	9	6	5	0

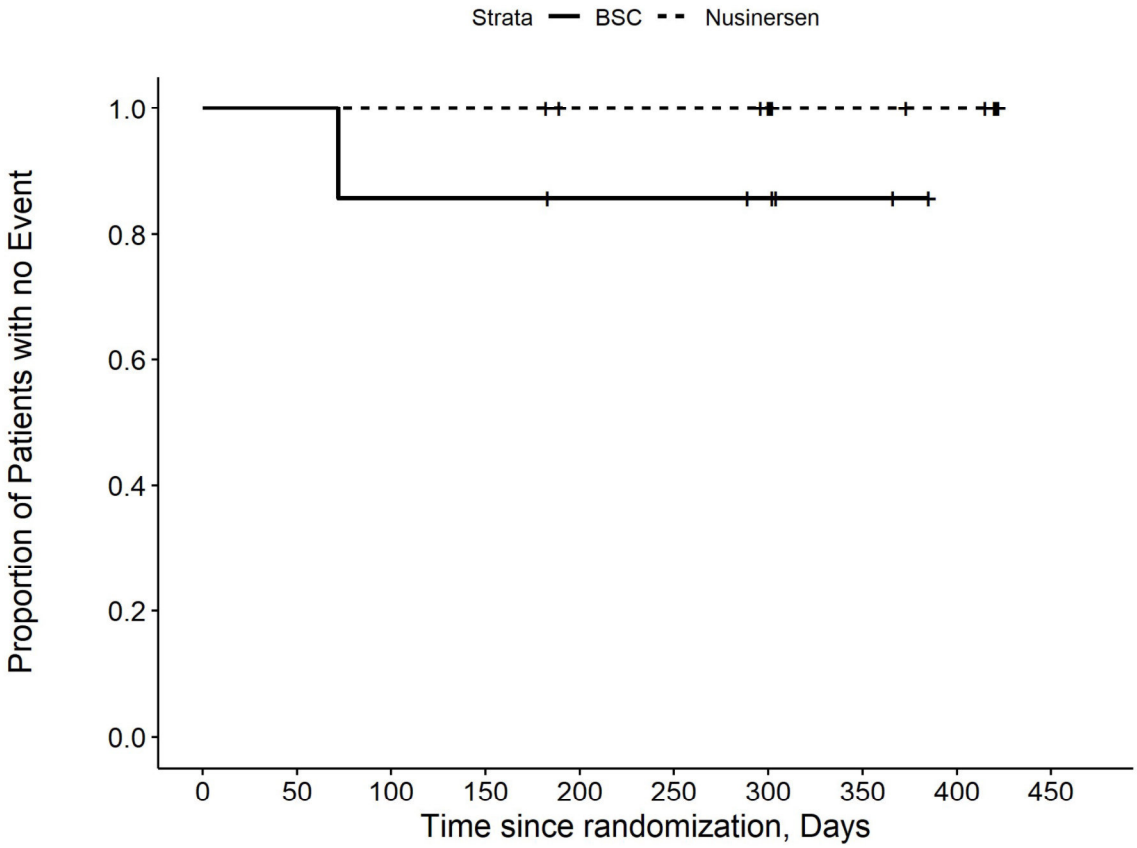
Kaplan Meier Plot for Time to AE by PT pct
Pneumonia aspiration



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	13	13	11	10	9	5	5	0

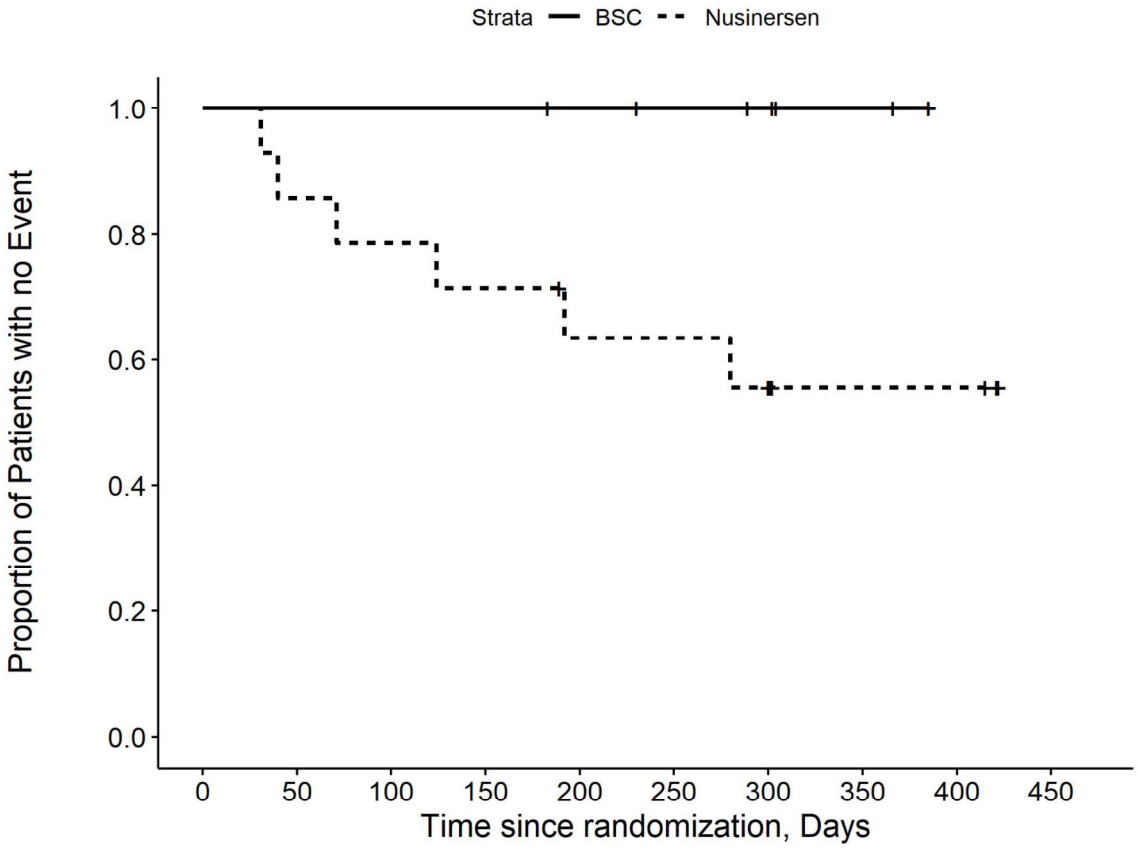
Kaplan Meier Plot for Time to AE by PT pct
Pneumonia haemophilus



Number at risk

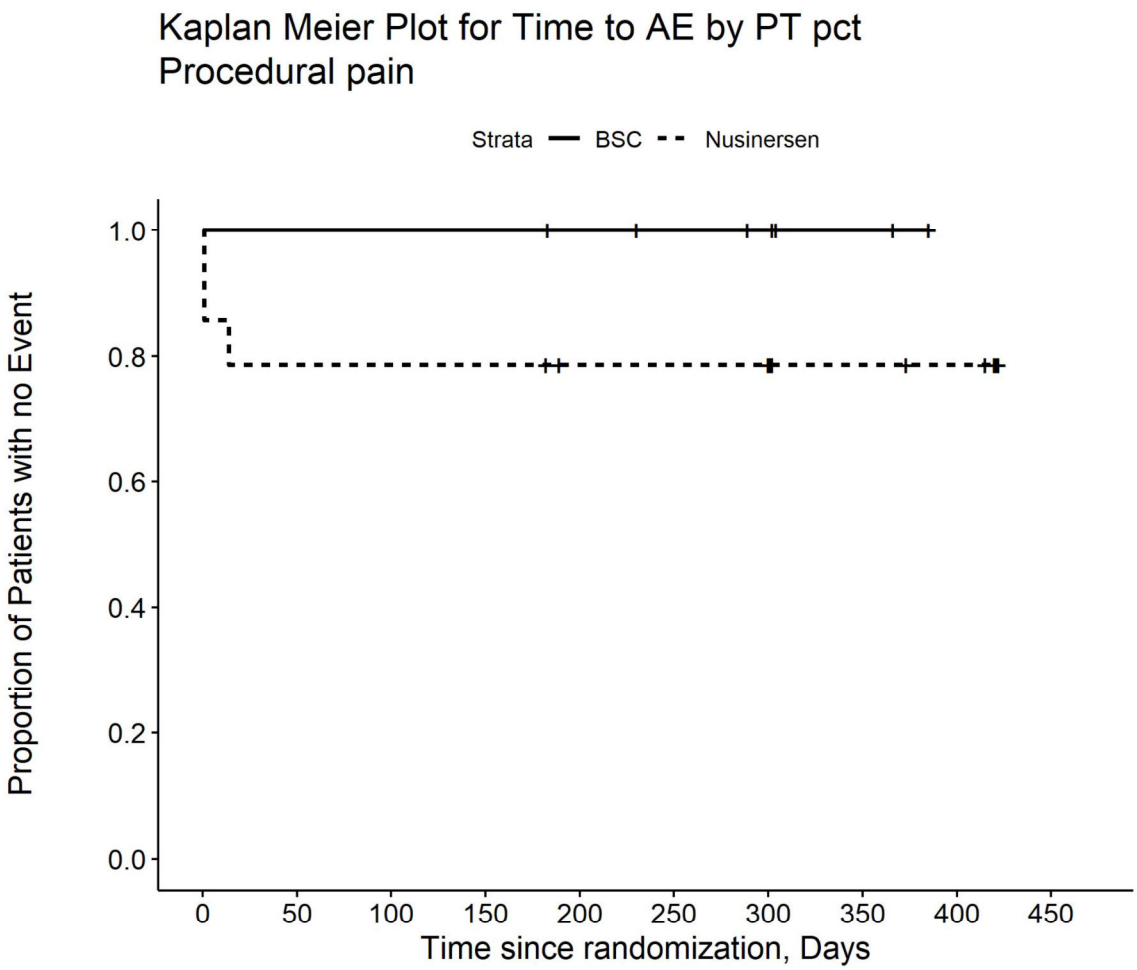
BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for Time to AE by PT pct Pneumonia



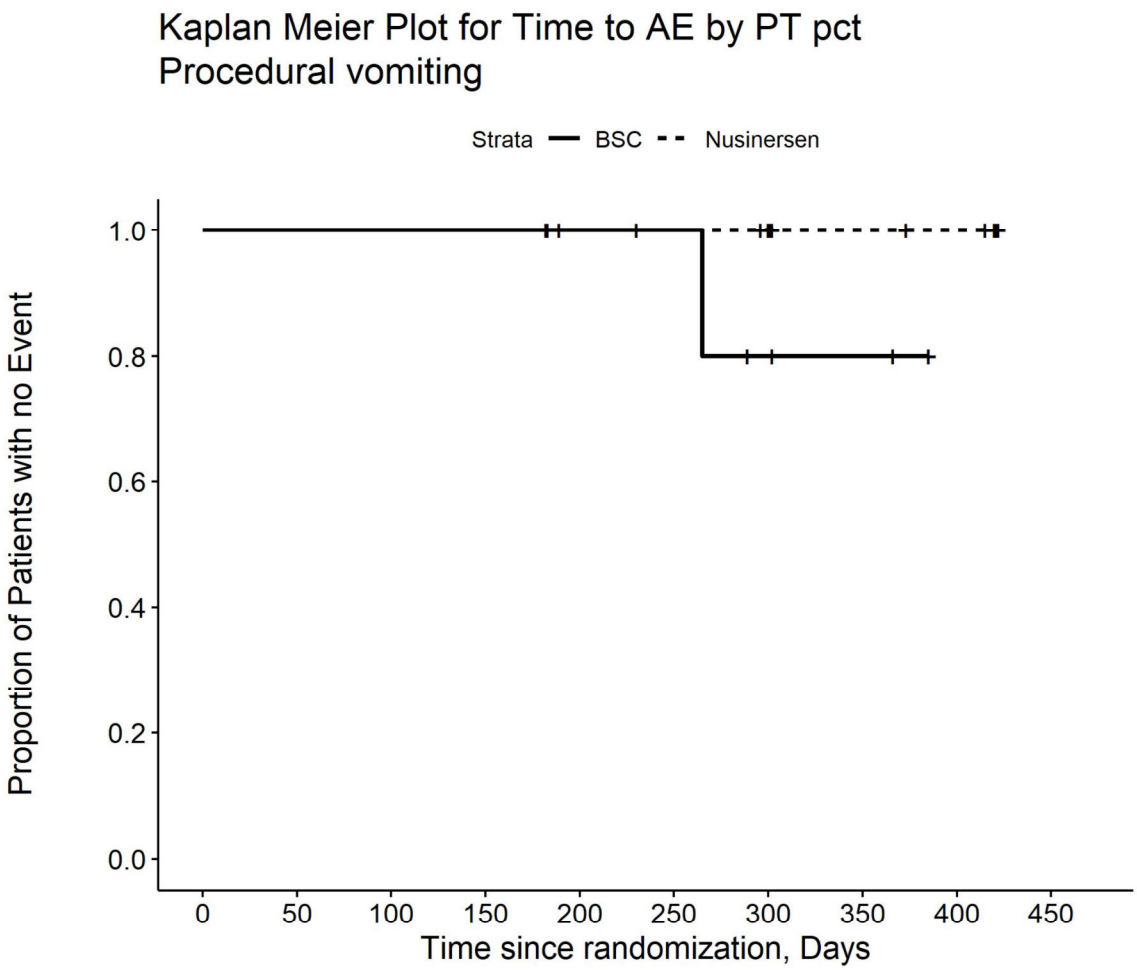
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	12	11	10	8	8	7	4	4	0



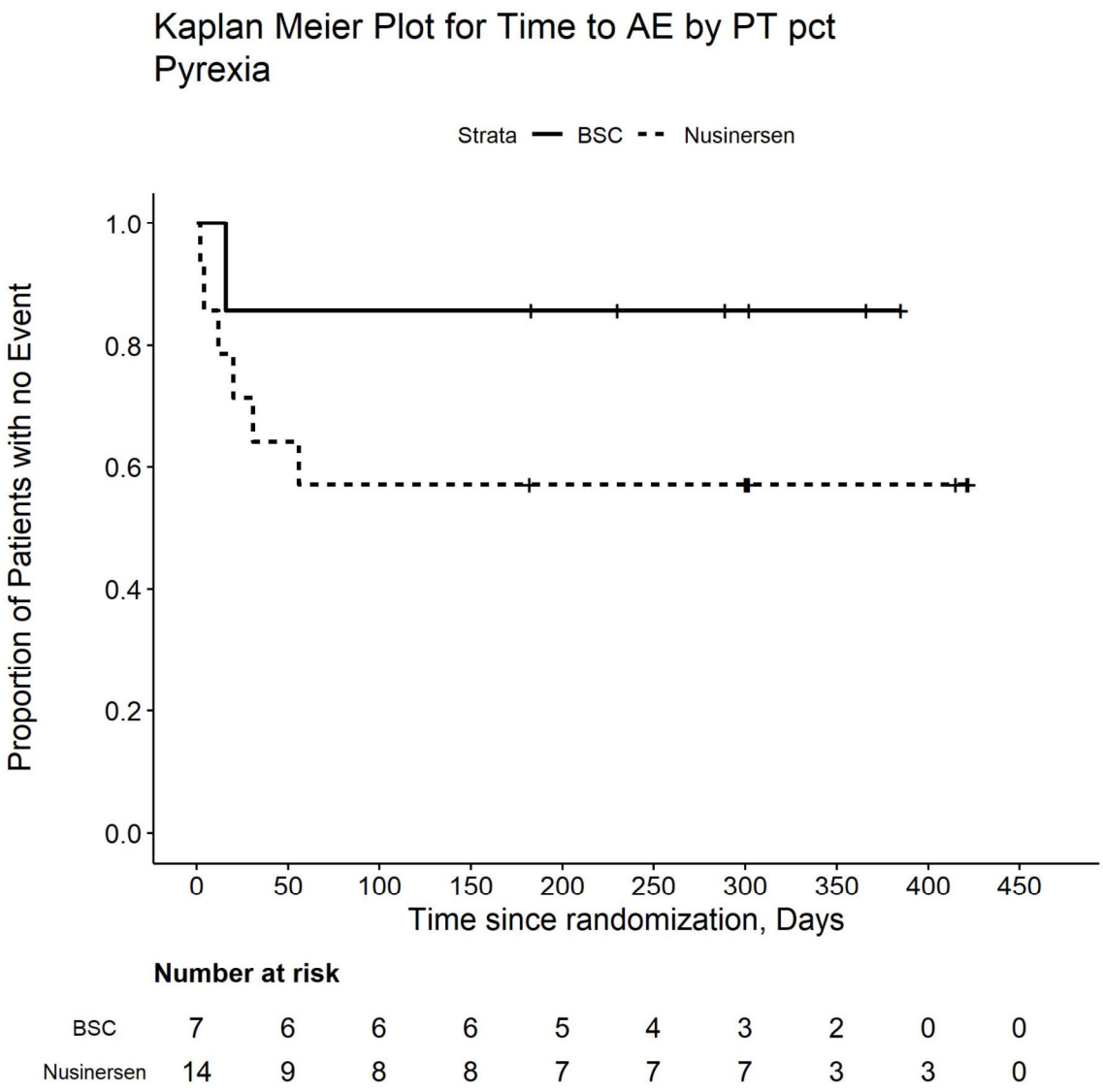
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	11	11	11	9	9	9	6	5	0



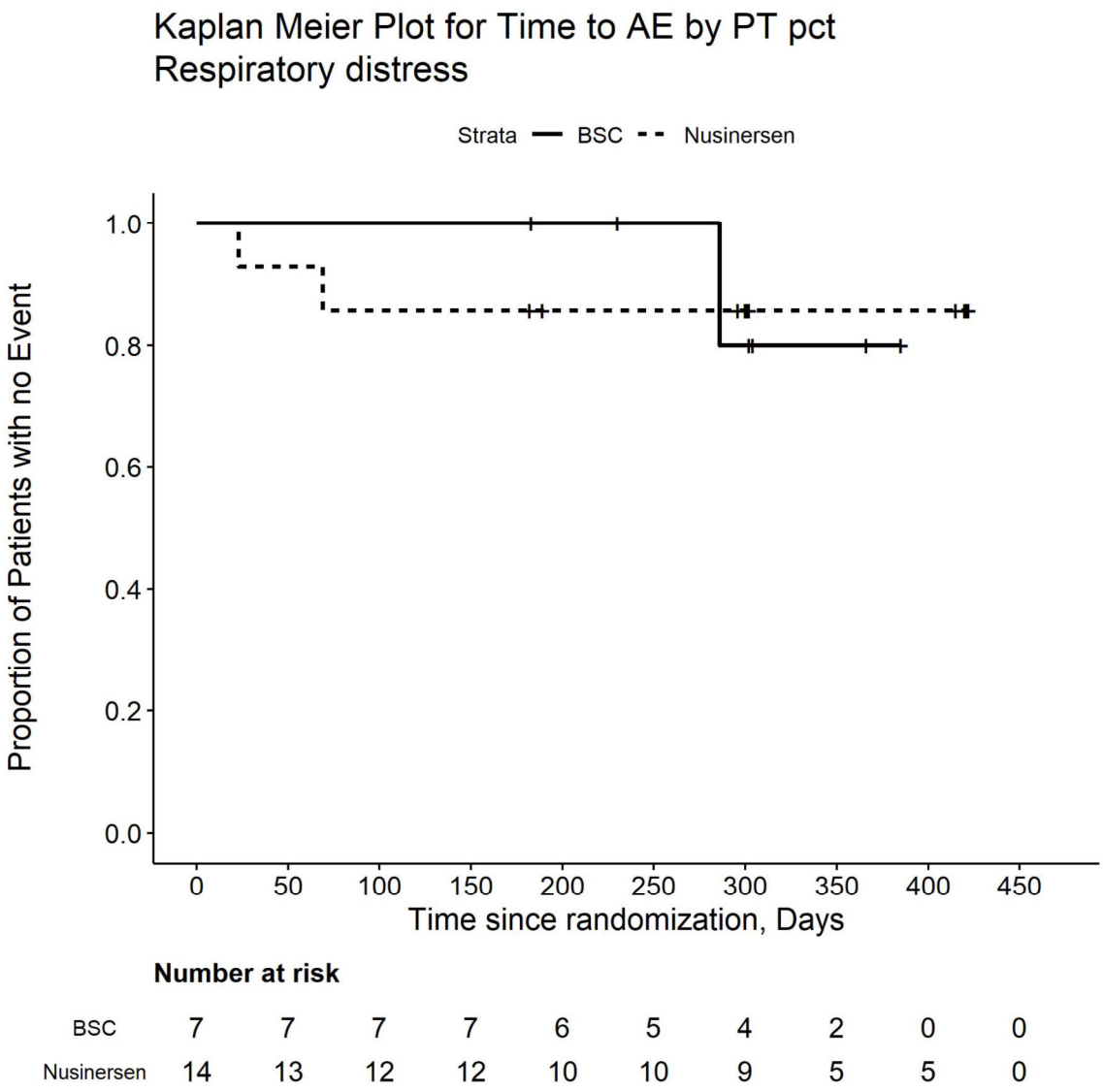
Number at risk

BSC	7	7	7	7	6	5	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

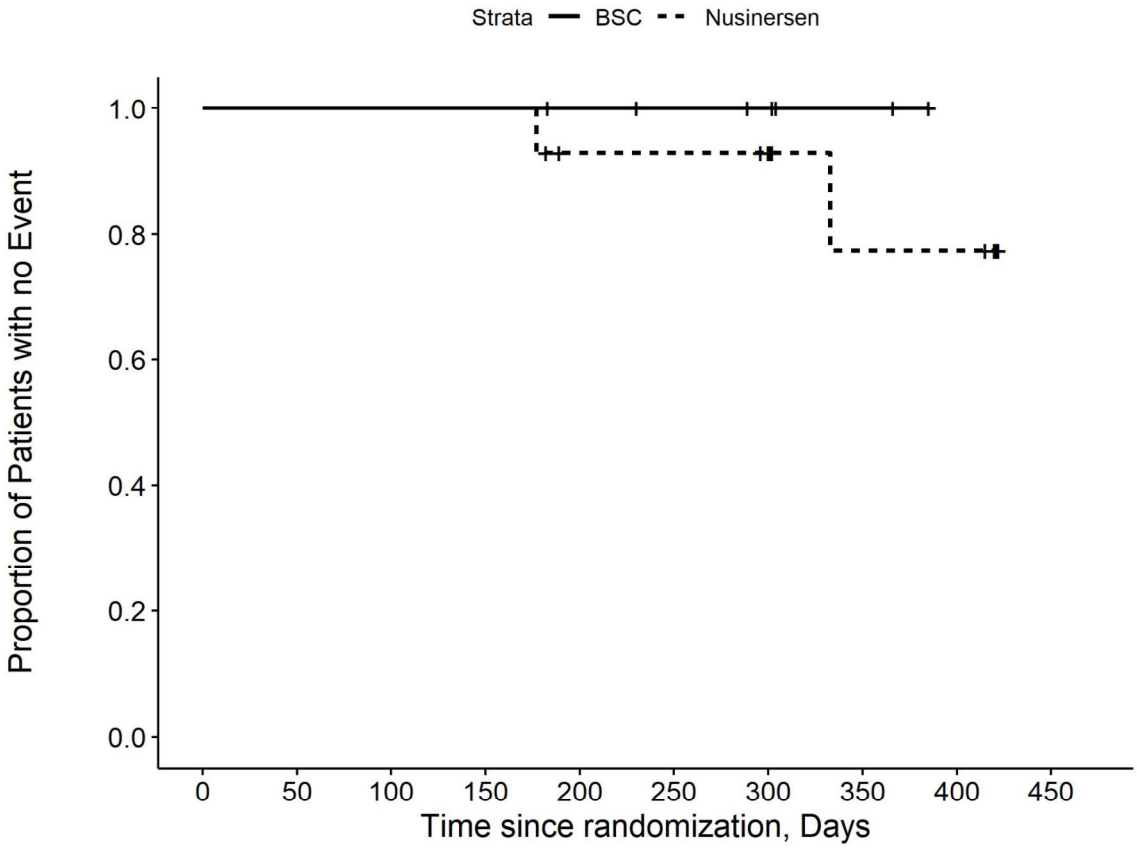
BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	9	8	8	7	7	7	3	3	0



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	12	12	10	10	9	5	5	0

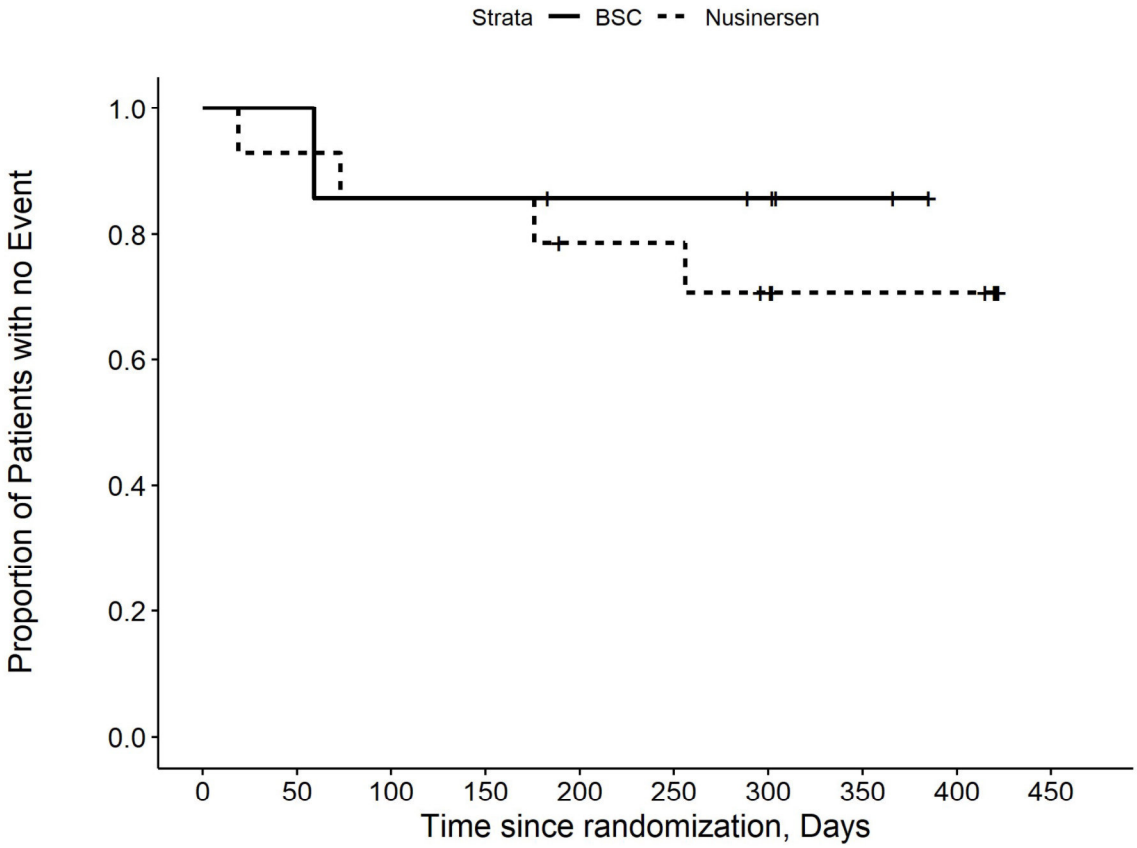
Kaplan Meier Plot for Time to AE by PT pct
Respiratory failure



Number at risk

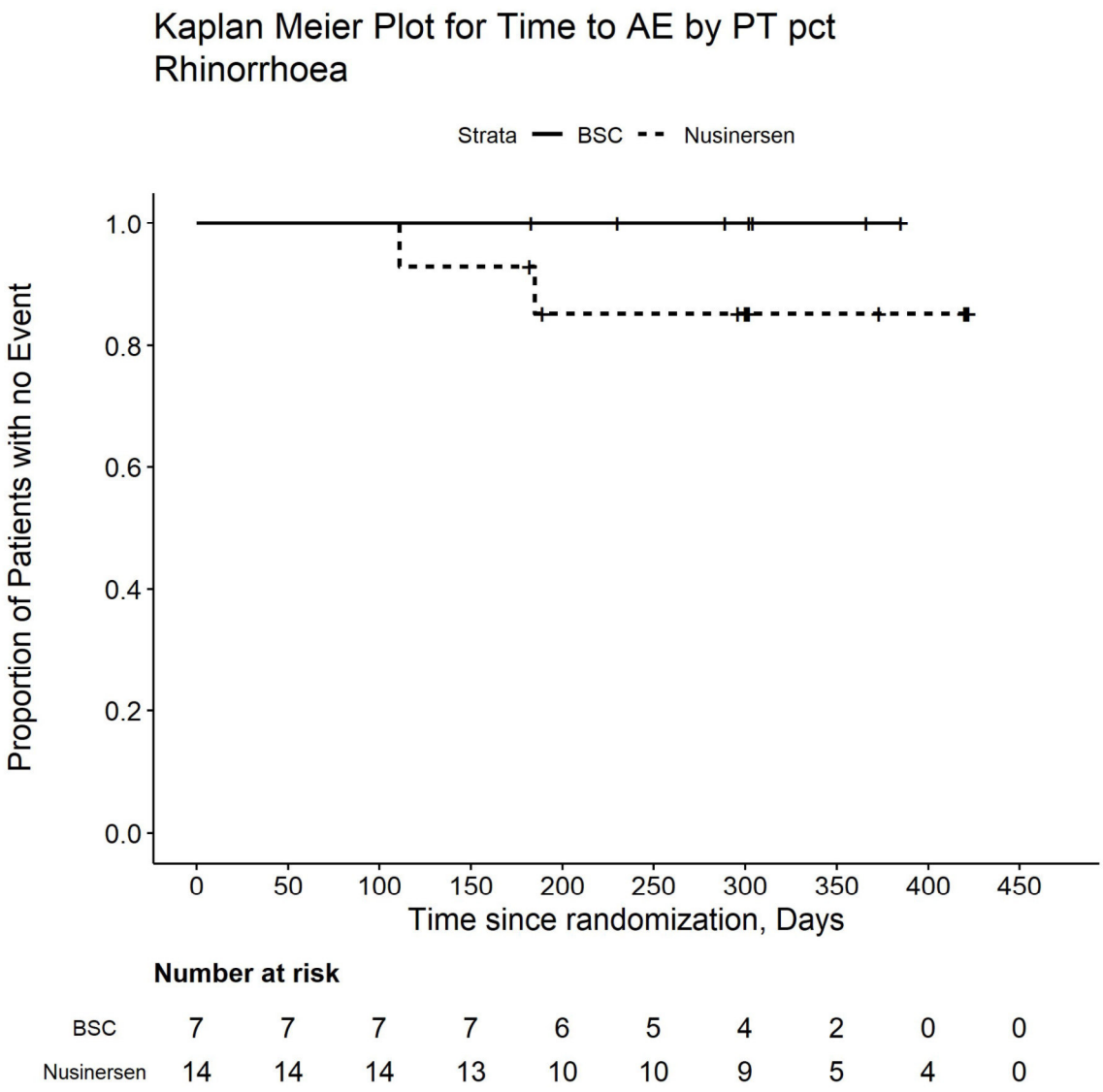
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	11	11	10	5	5	0

Kaplan Meier Plot for Time to AE by PT pct
Respiratory tract infection



Number at risk

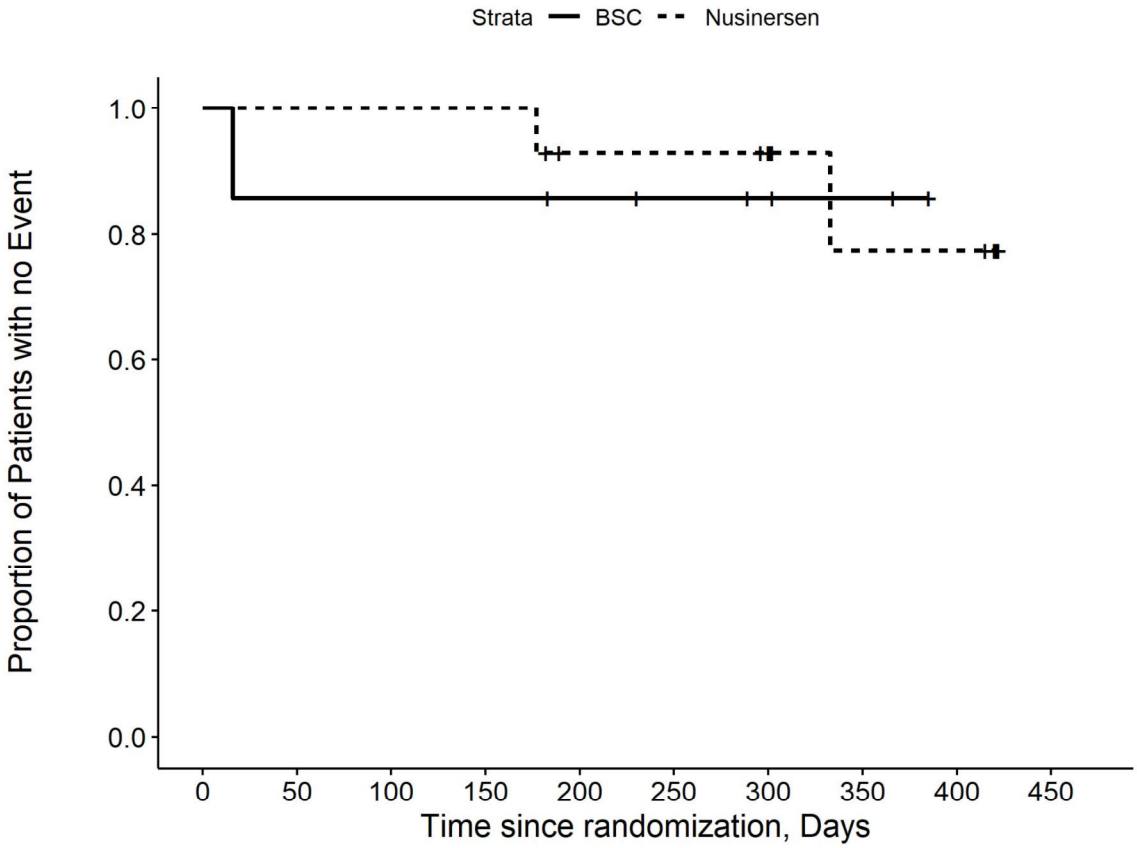
BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	13	12	12	10	10	8	6	6	0



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	10	10	9	5	4	0

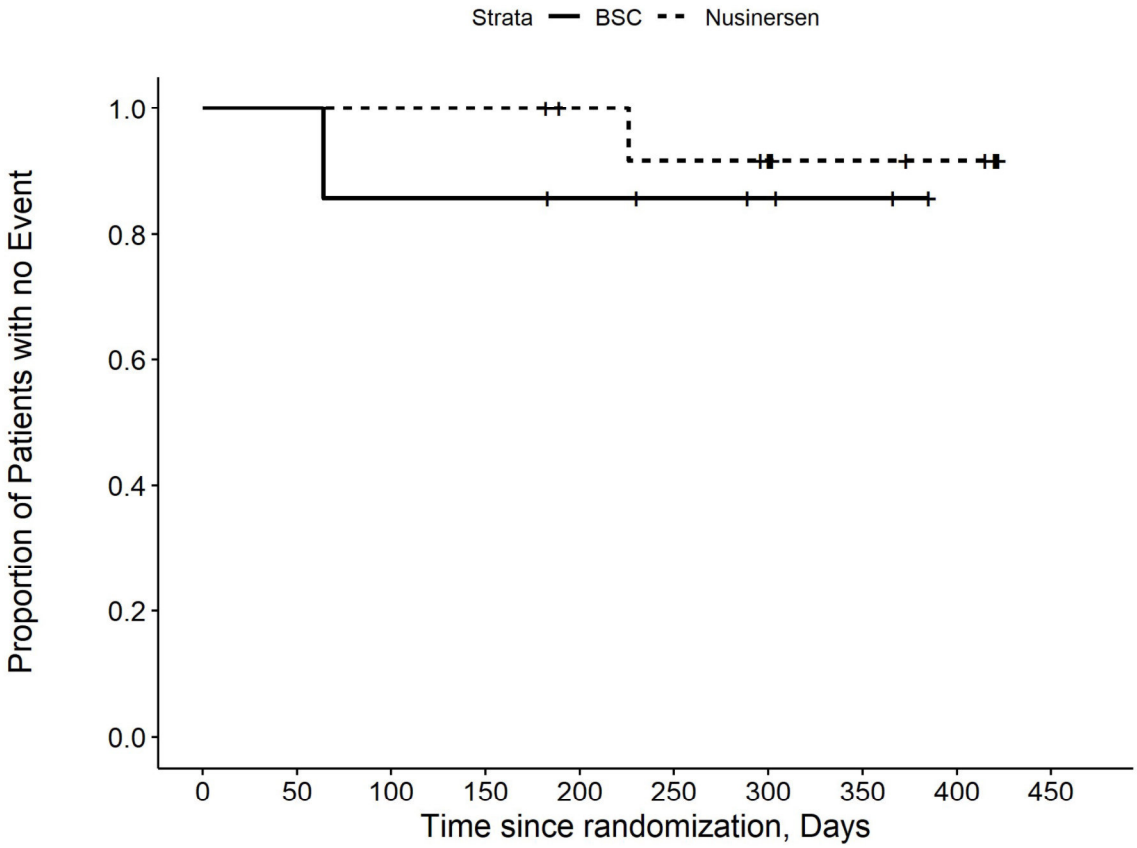
Kaplan Meier Plot for Time to AE by PT pct
Rhinovirus infection



Number at risk

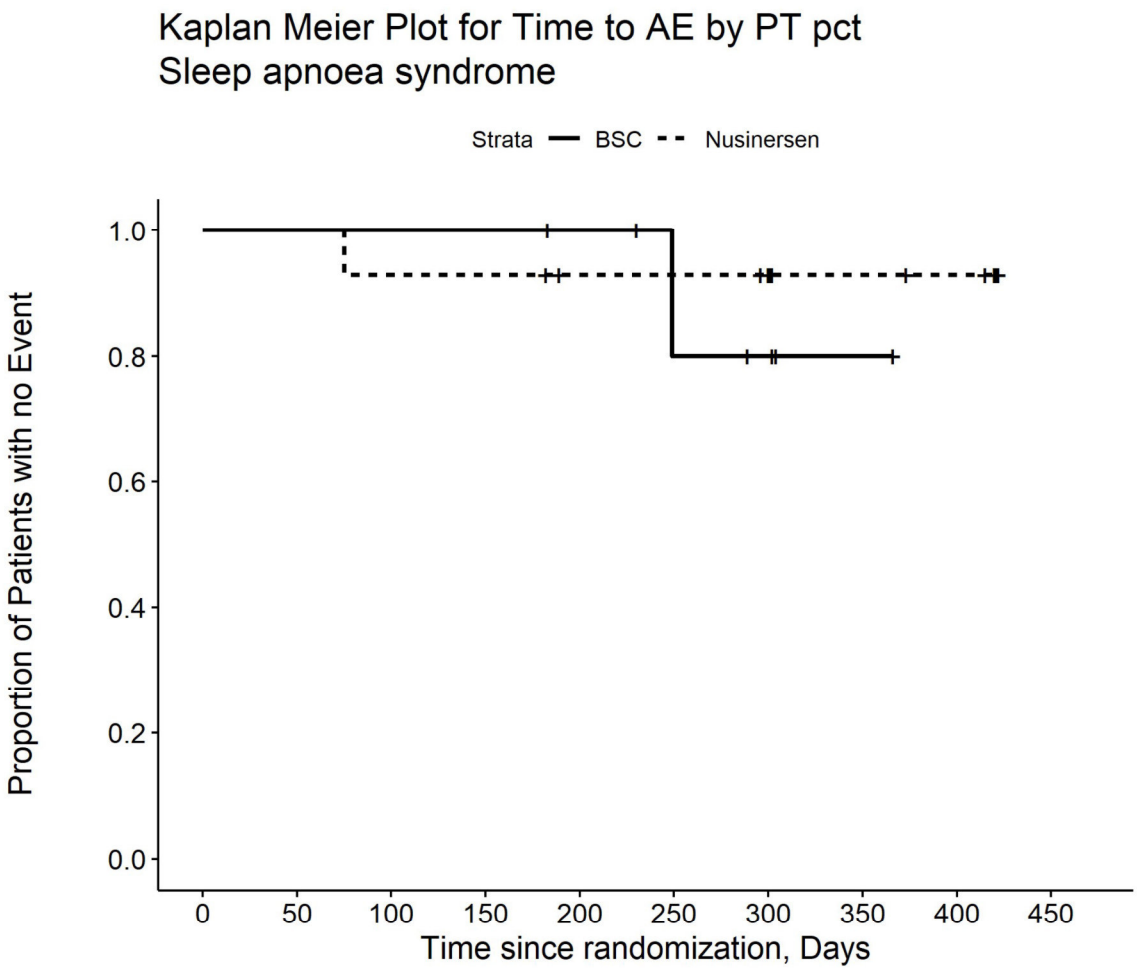
BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	11	11	10	5	5	0

Kaplan Meier Plot for Time to AE by PT pct Skin irritation



Number at risk

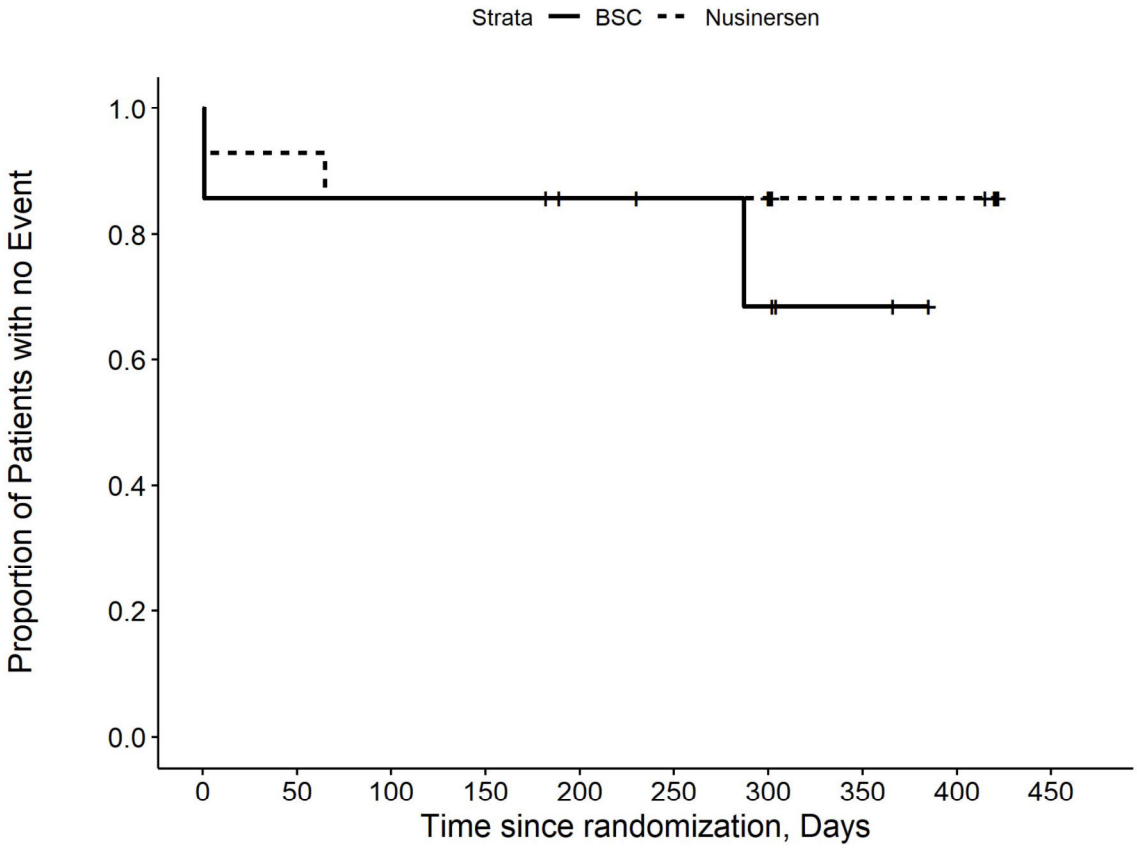
BSC	7	7	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	11	10	7	6	0



Number at risk

BSC	7	7	7	7	6	4	3	1	0	0
Nusinersen	14	14	13	13	11	11	10	6	5	0

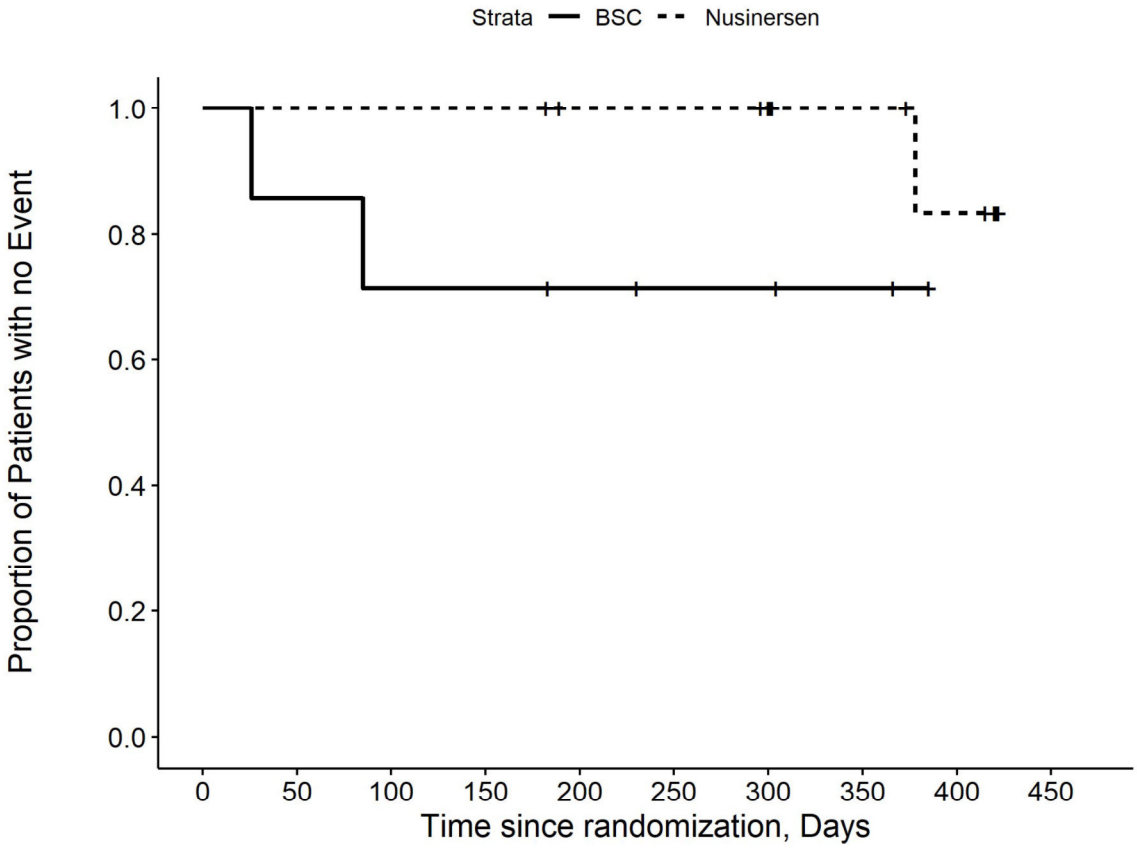
Kaplan Meier Plot for Time to AE by PT pct Tachycardia



Number at risk

BSC	7	6	6	6	6	5	4	2	0	0
Nusinersen	14	13	12	12	10	10	10	6	6	0

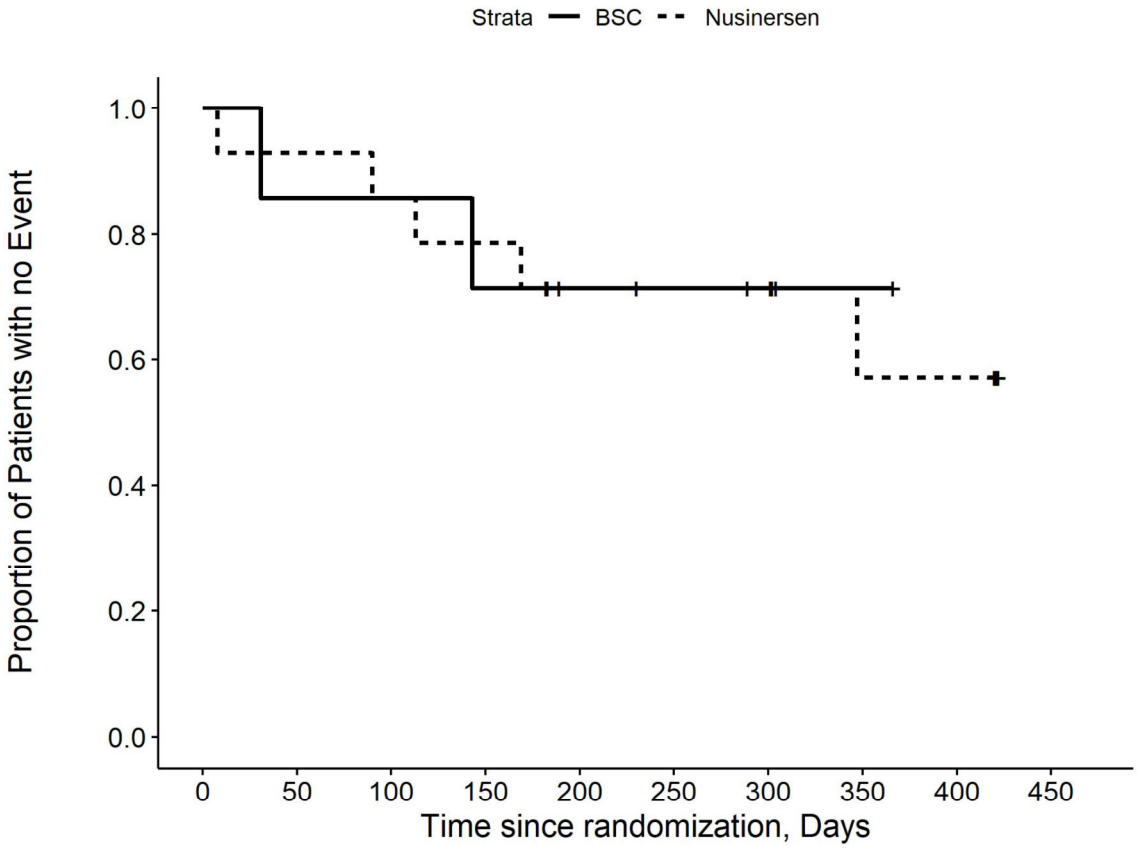
Kaplan Meier Plot for Time to AE by PT pct Teething



Number at risk

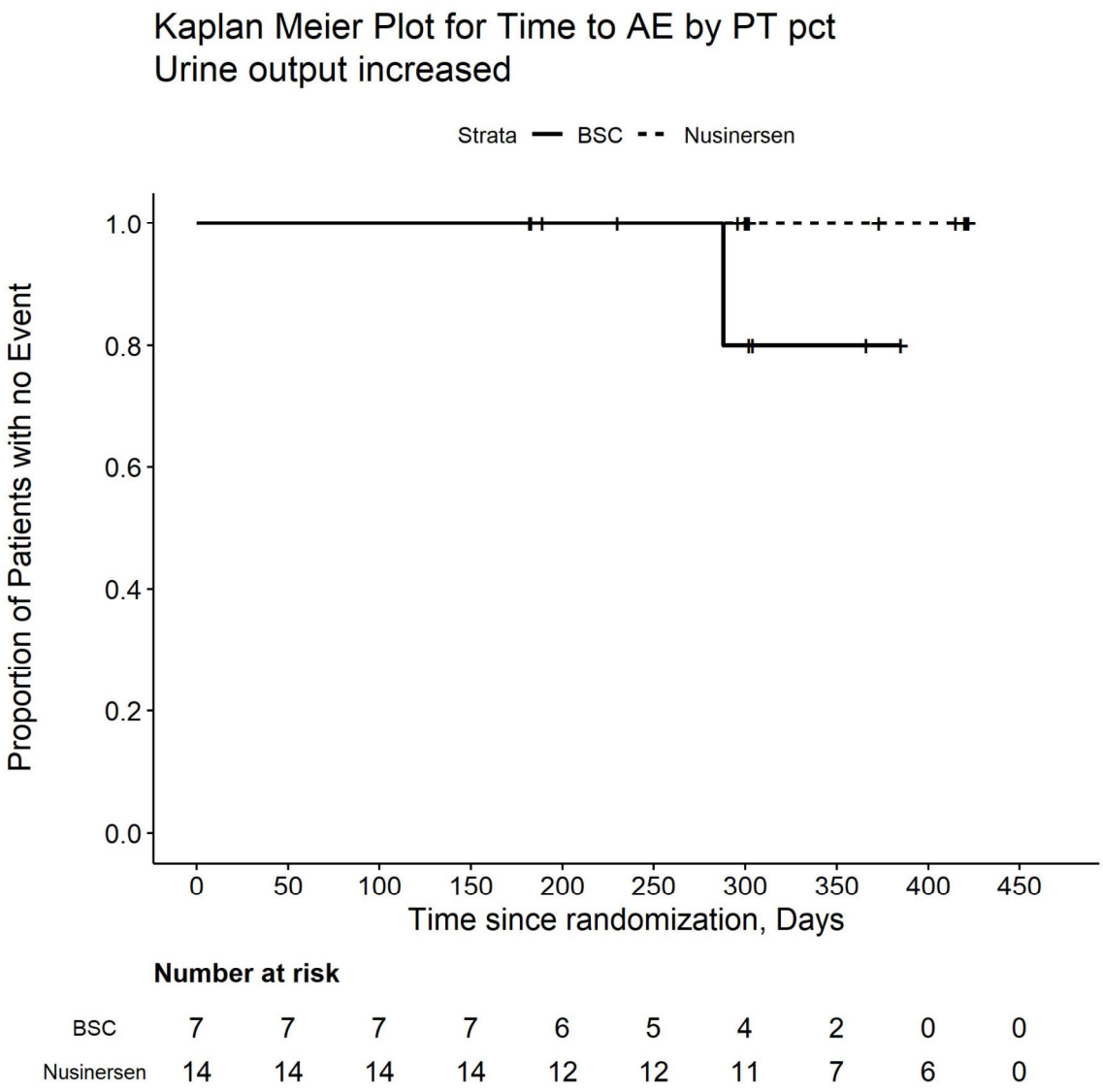
BSC	7	6	5	5	4	3	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	5	0

Kaplan Meier Plot for Time to AE by PT pct
Upper respiratory tract infection



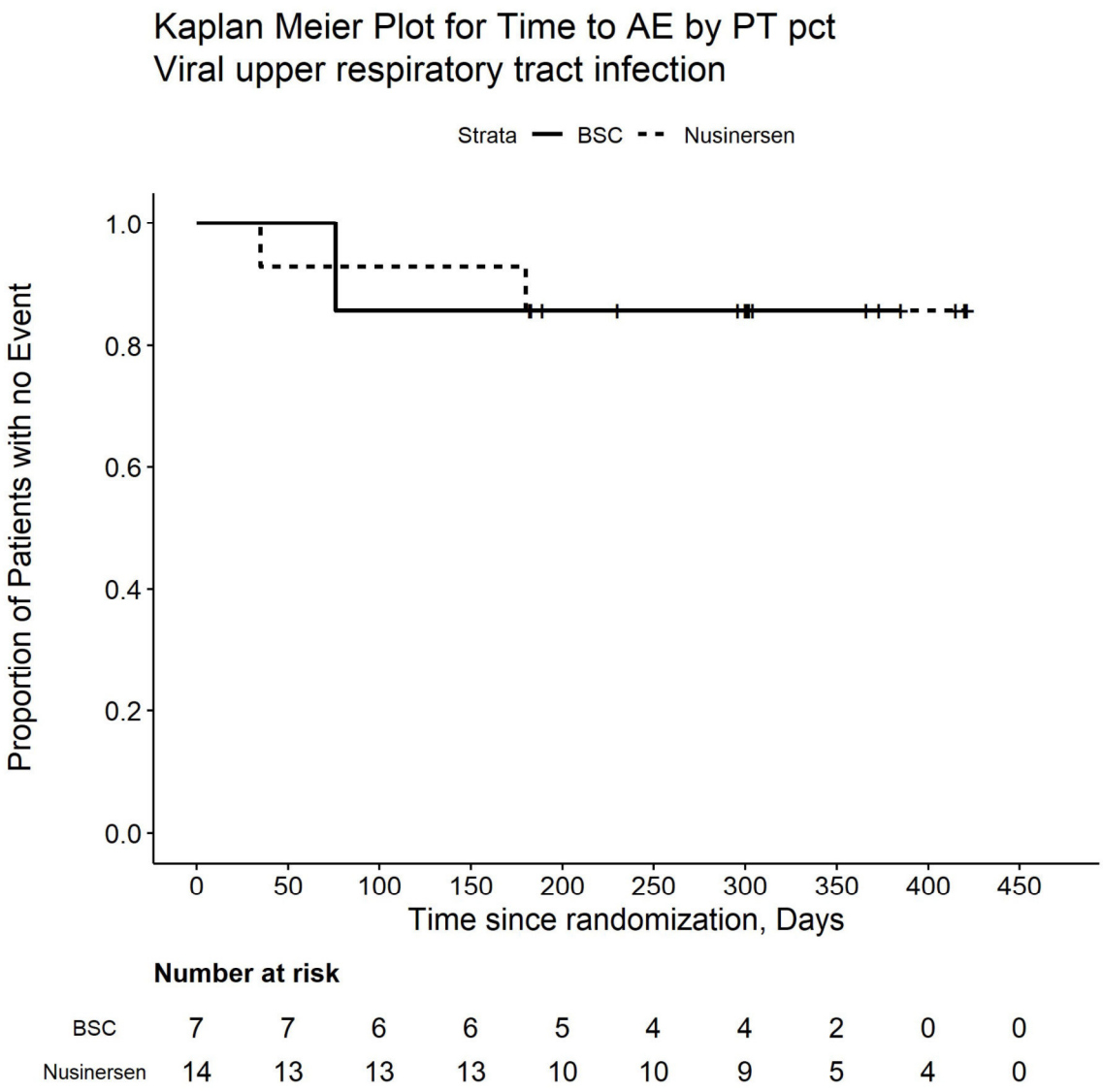
Number at risk

BSC	7	6	6	5	4	3	2	1	0	0
Nusinersen	14	13	12	11	8	8	8	4	4	0



Number at risk

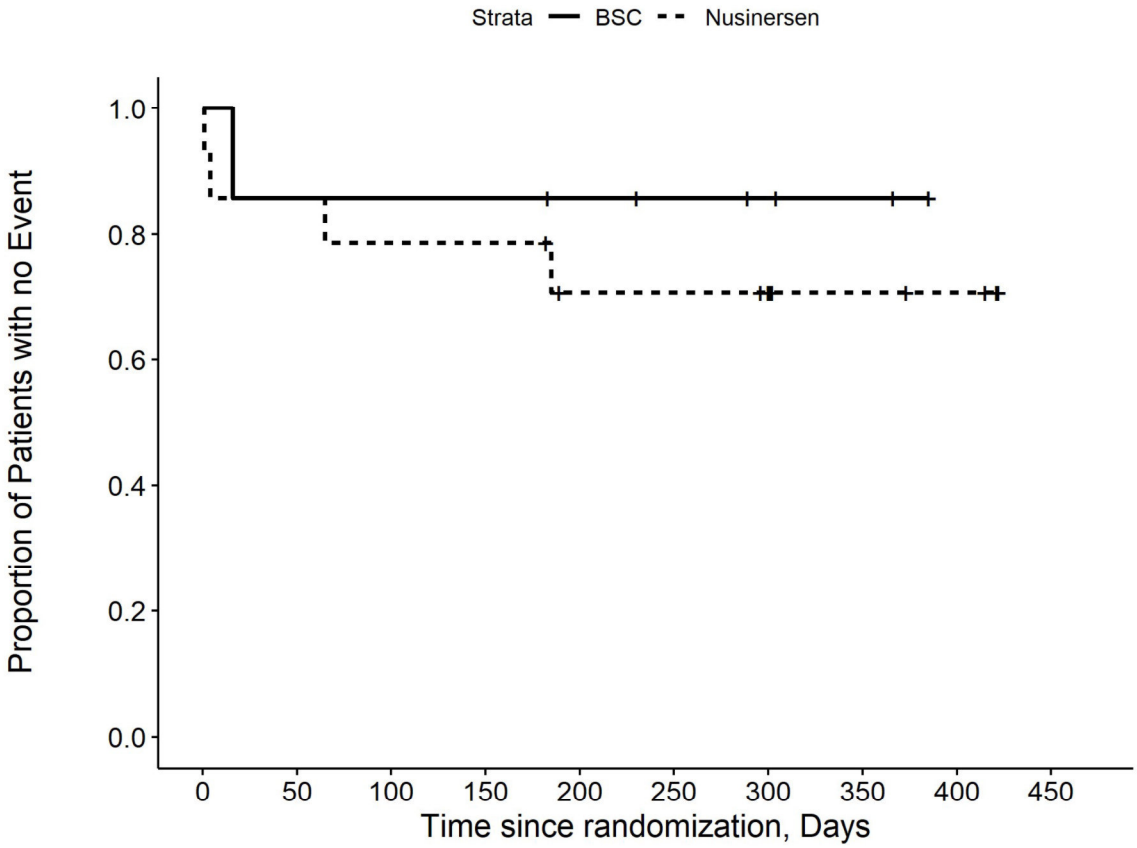
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

BSC	7	7	6	6	5	4	4	2	0	0
Nusinersen	14	13	13	13	10	10	9	5	4	0

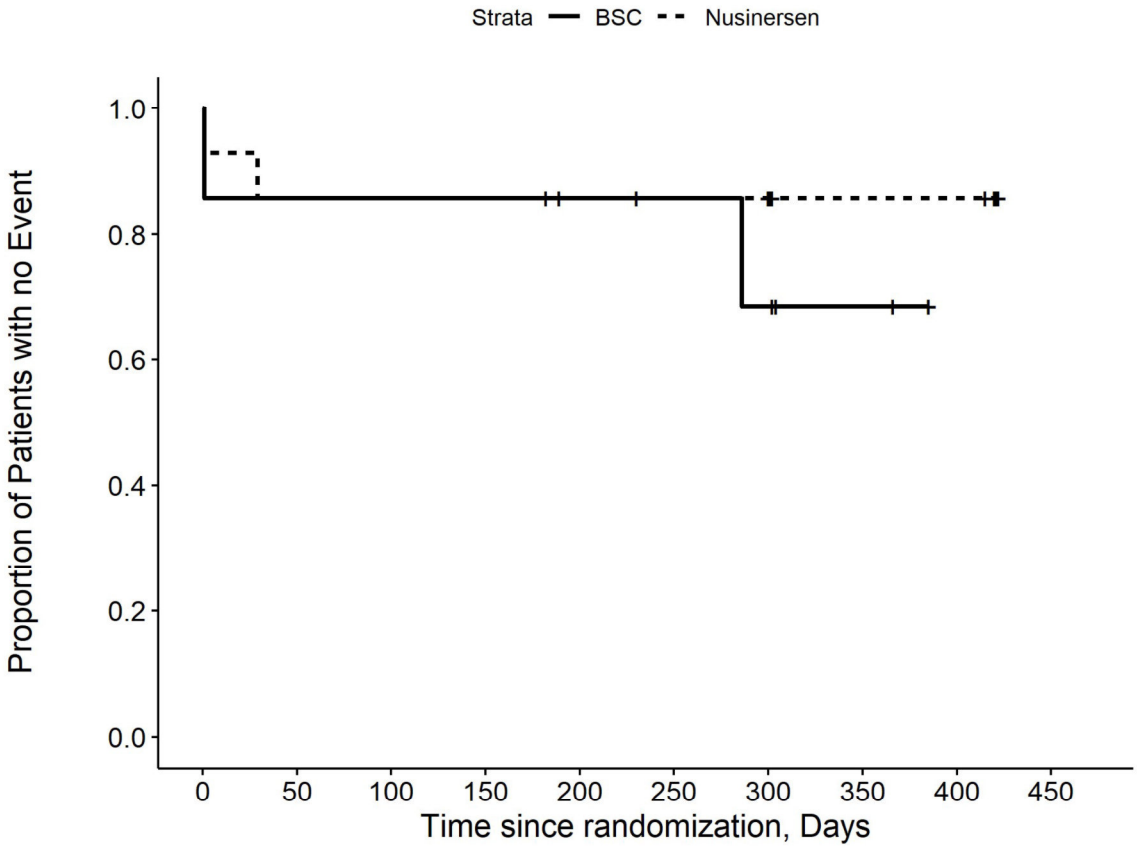
Kaplan Meier Plot for Time to AE by PT pct Vomiting



Number at risk

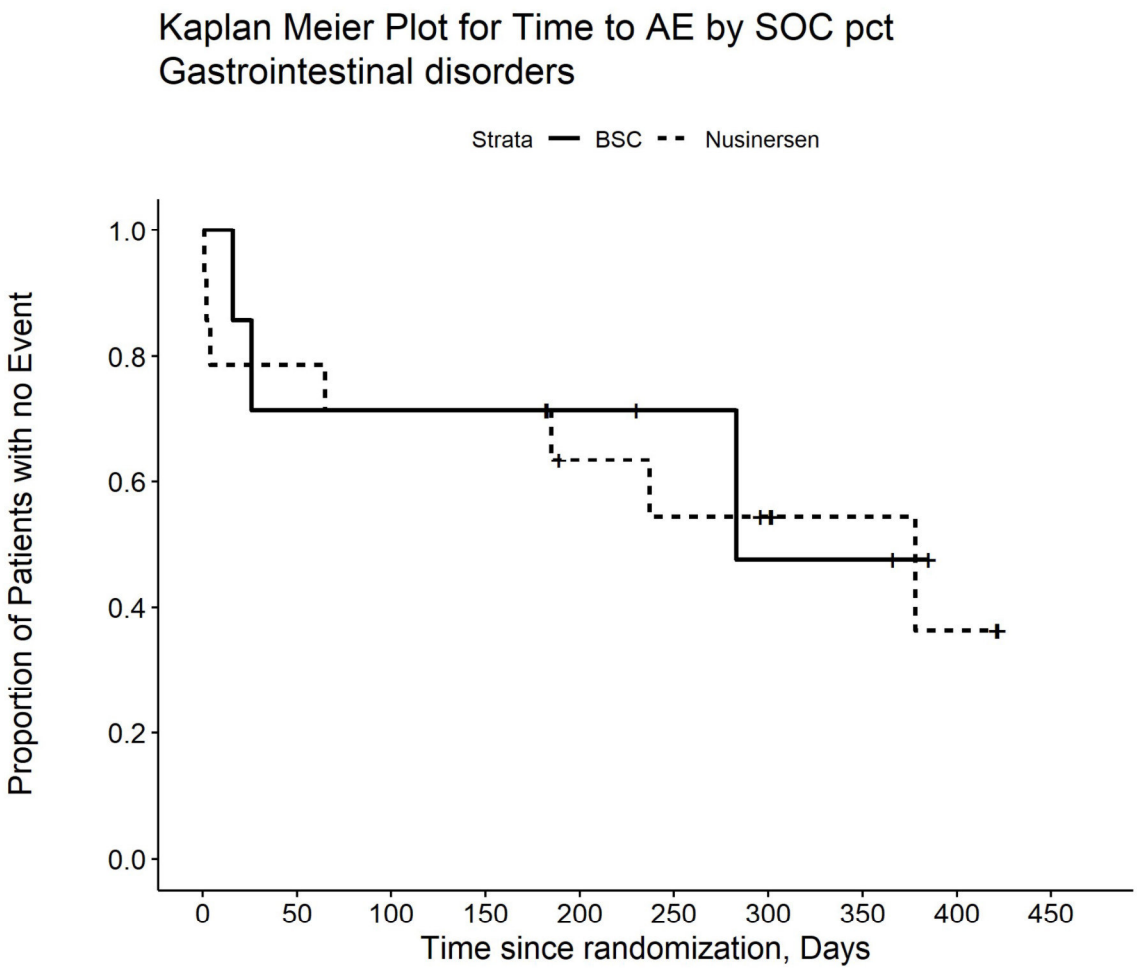
BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	12	11	11	8	8	7	4	3	0

Kaplan Meier Plot for Time to AE by SOC pct
Cardiac disorders



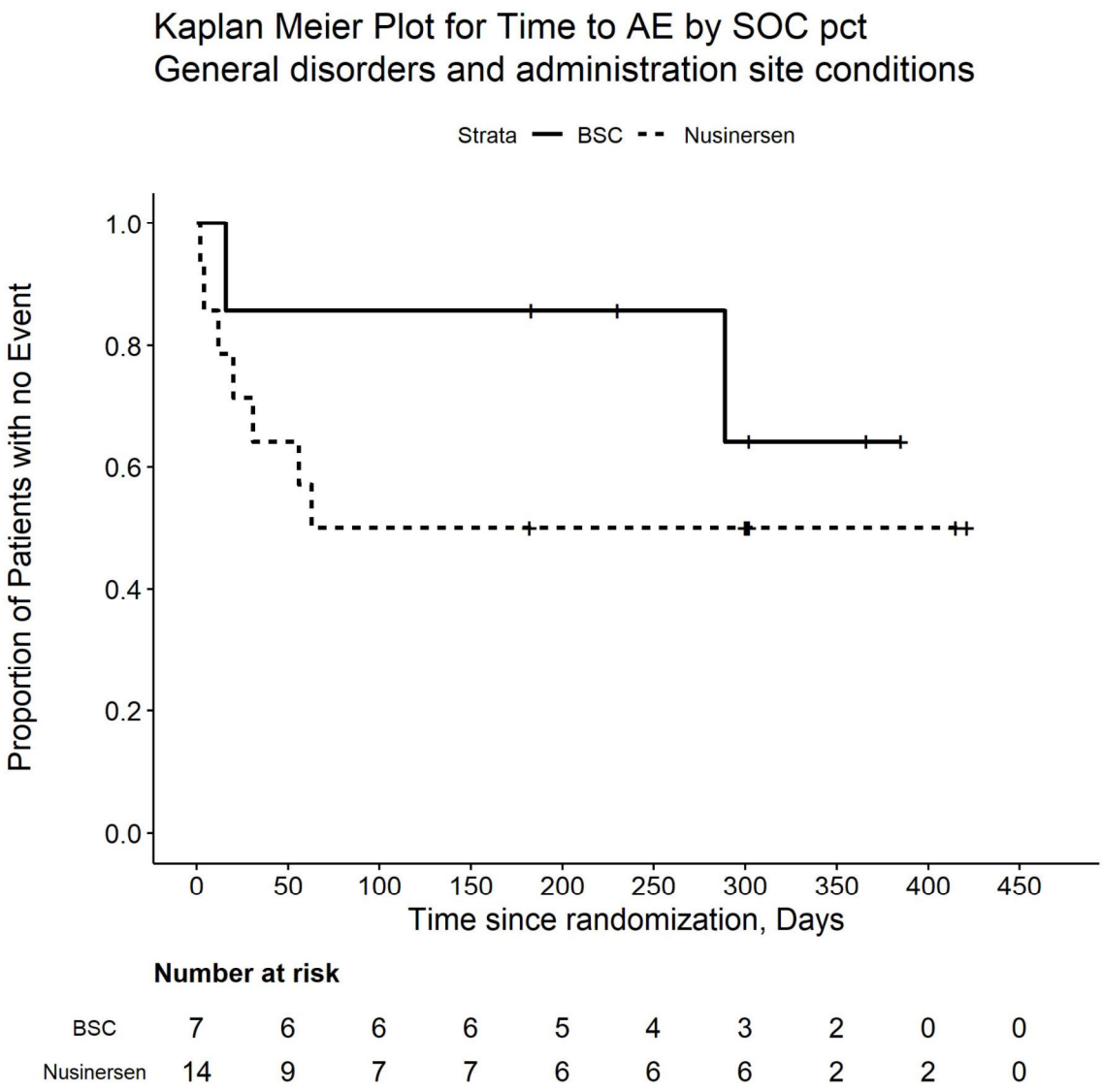
Number at risk

BSC	7	6	6	6	6	5	4	2	0	0
Nusinersen	14	12	12	12	10	10	10	6	6	0



Number at risk

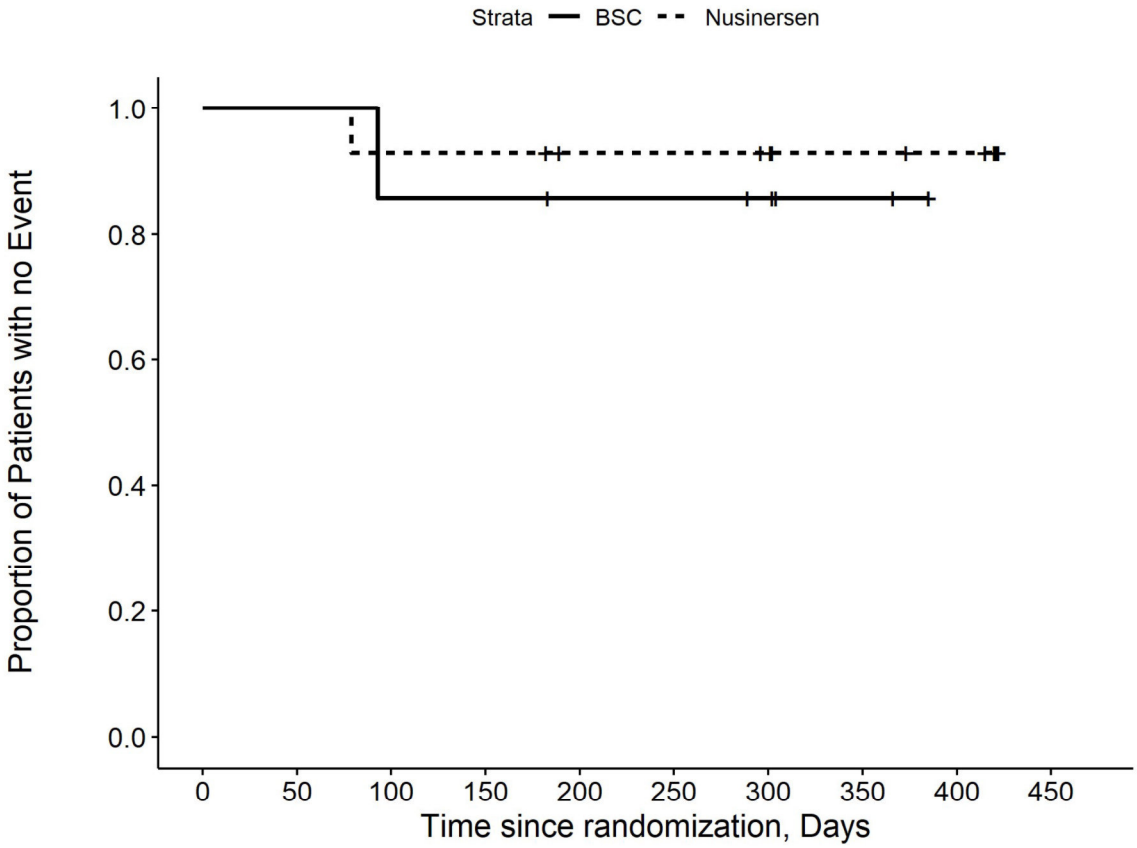
BSC	7	5	5	5	4	3	2	2	0	0
Nusinersen	14	11	10	10	7	6	5	3	2	0



Number at risk

BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	9	7	7	6	6	6	2	2	0

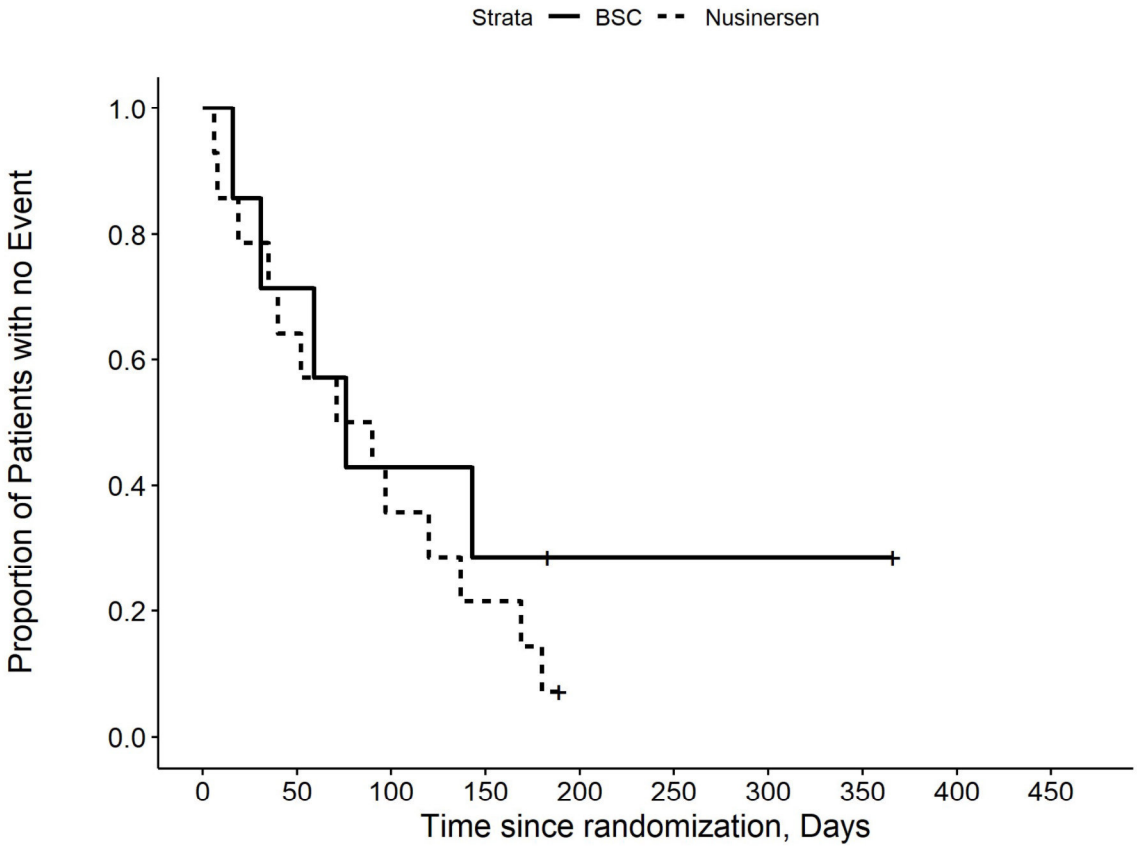
Kaplan Meier Plot for Time to AE by SOC pct
Immune system disorders



Number at risk

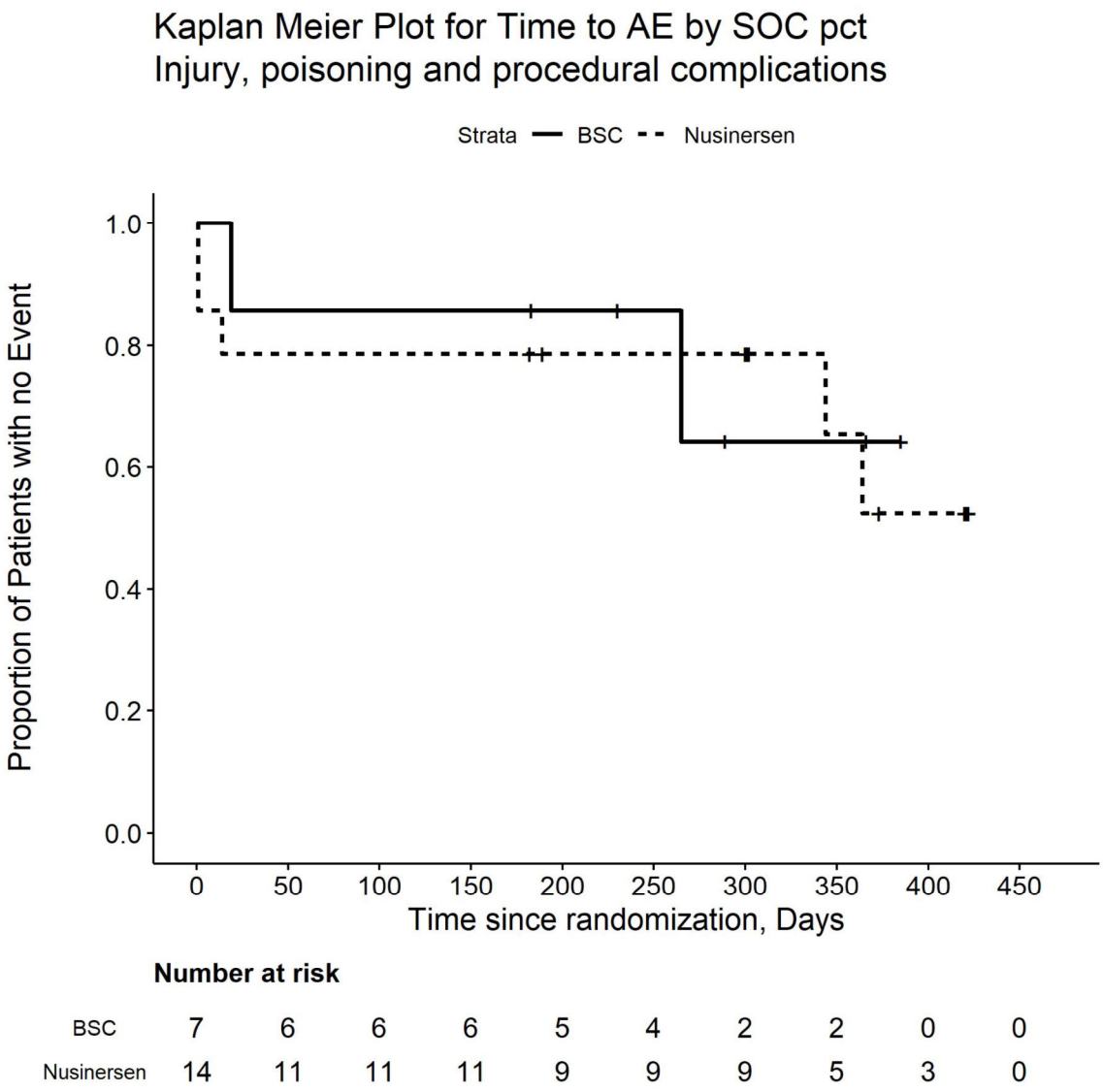
BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	14	13	13	11	11	10	7	6	0

Kaplan Meier Plot for Time to AE by SOC pct
Infections and infestations



Number at risk

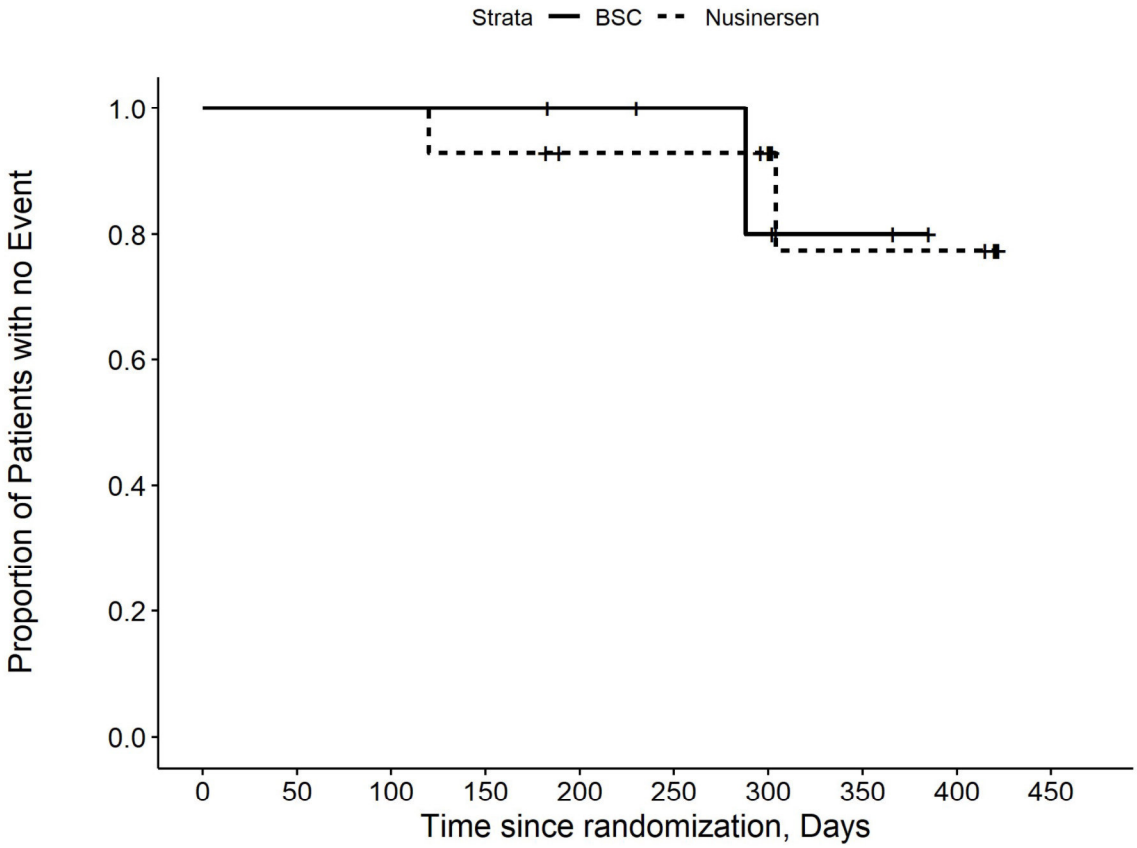
BSC	7	5	3	2	1	1	1	1	0	0
Nusinersen	14	9	5	3	0	0	0	0	0	0



Number at risk

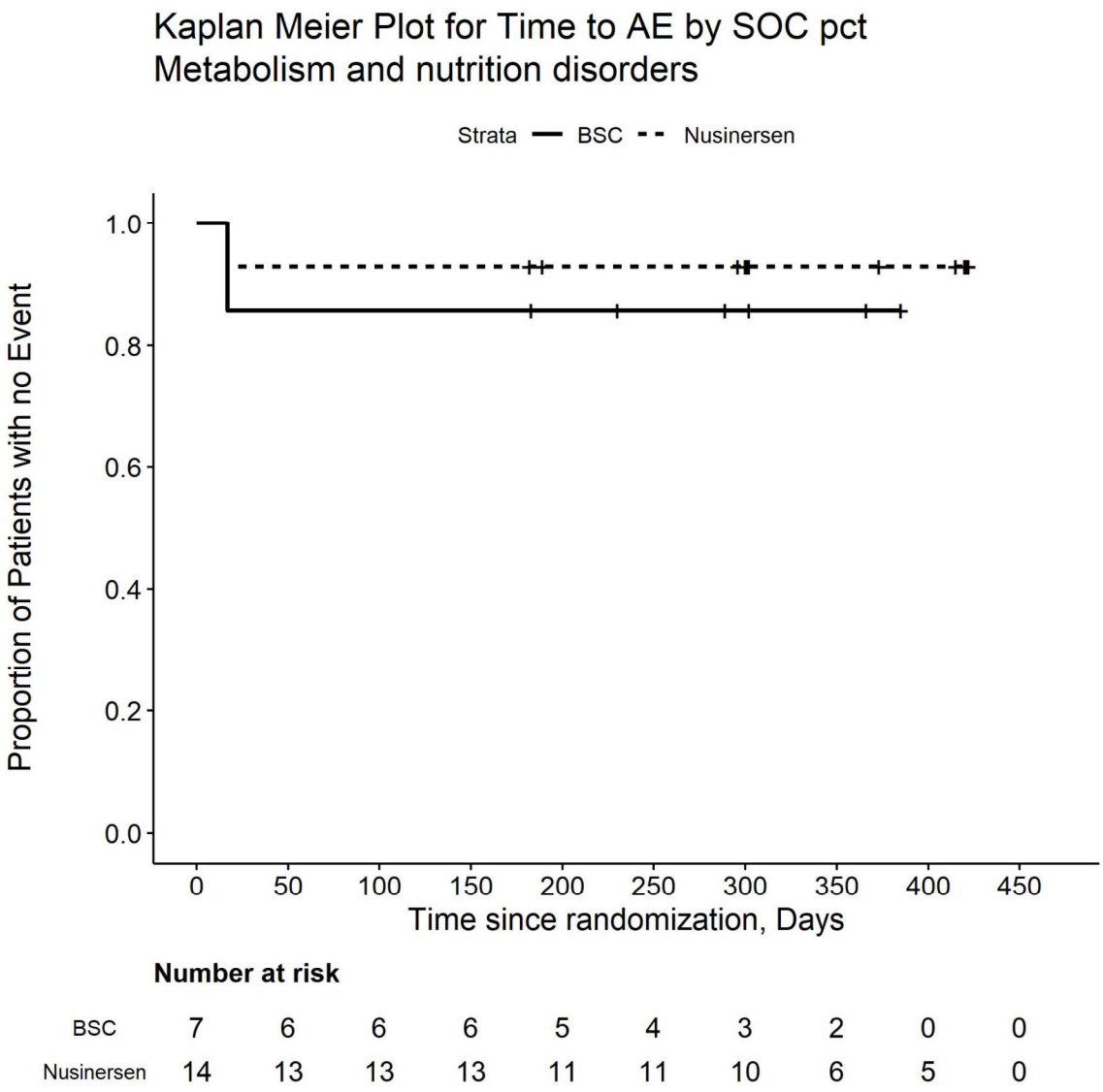
BSC	7	6	6	6	5	4	2	2	0	0
Nusinersen	14	11	11	11	9	9	9	5	3	0

Kaplan Meier Plot for Time to AE by SOC pct Investigations



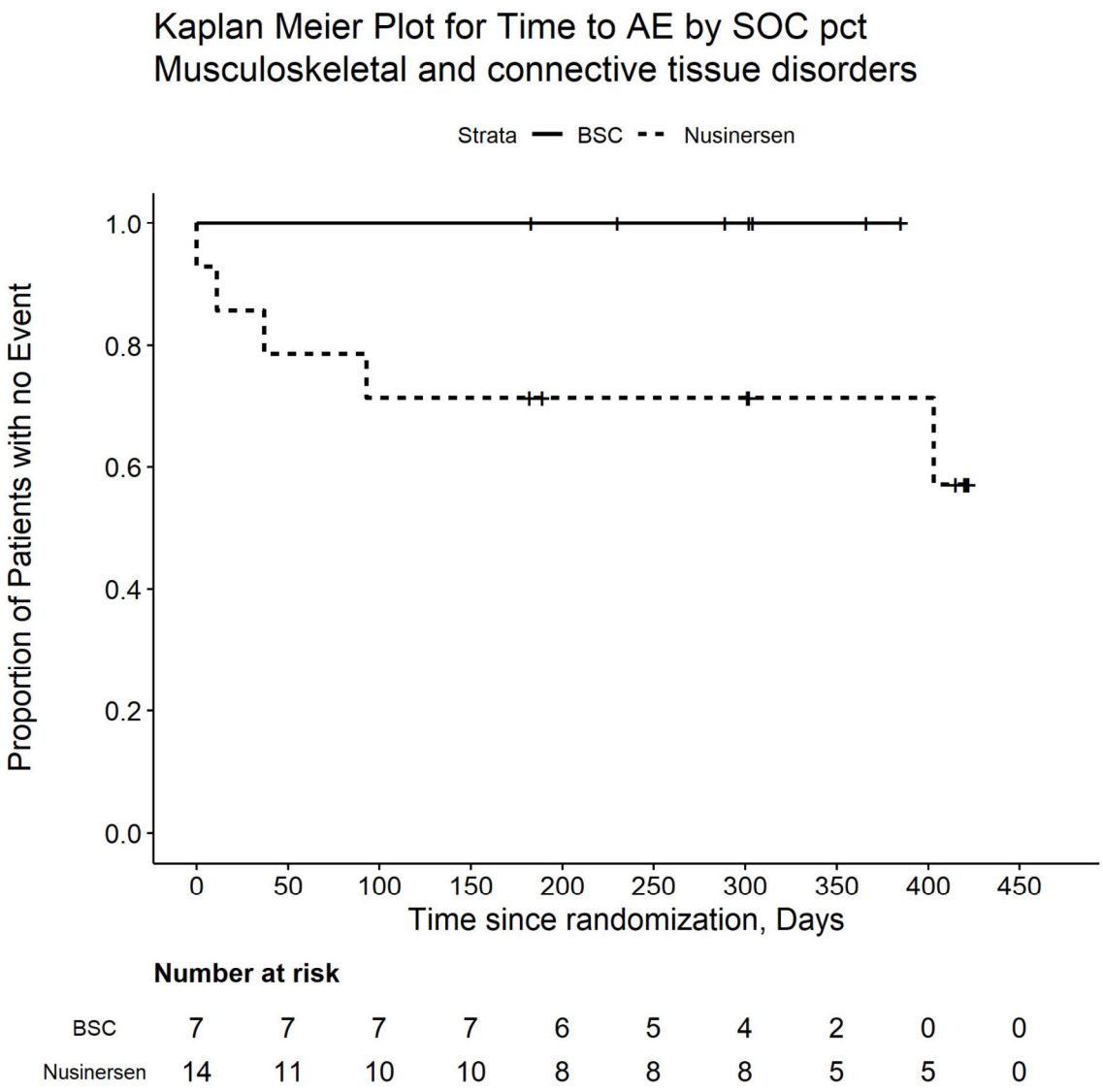
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	11	11	10	5	5	0



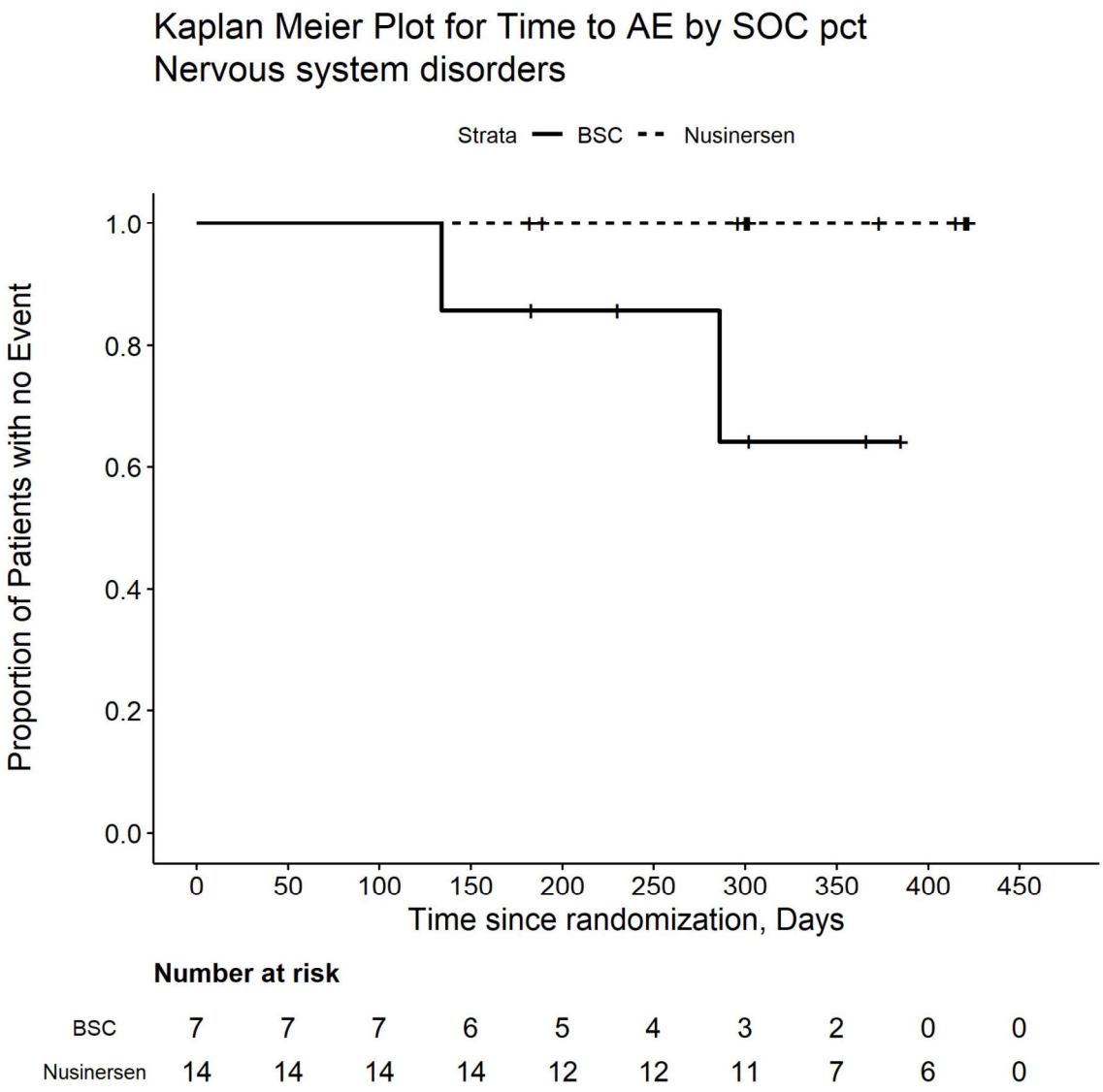
Number at risk

BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	13	13	13	11	11	10	6	5	0



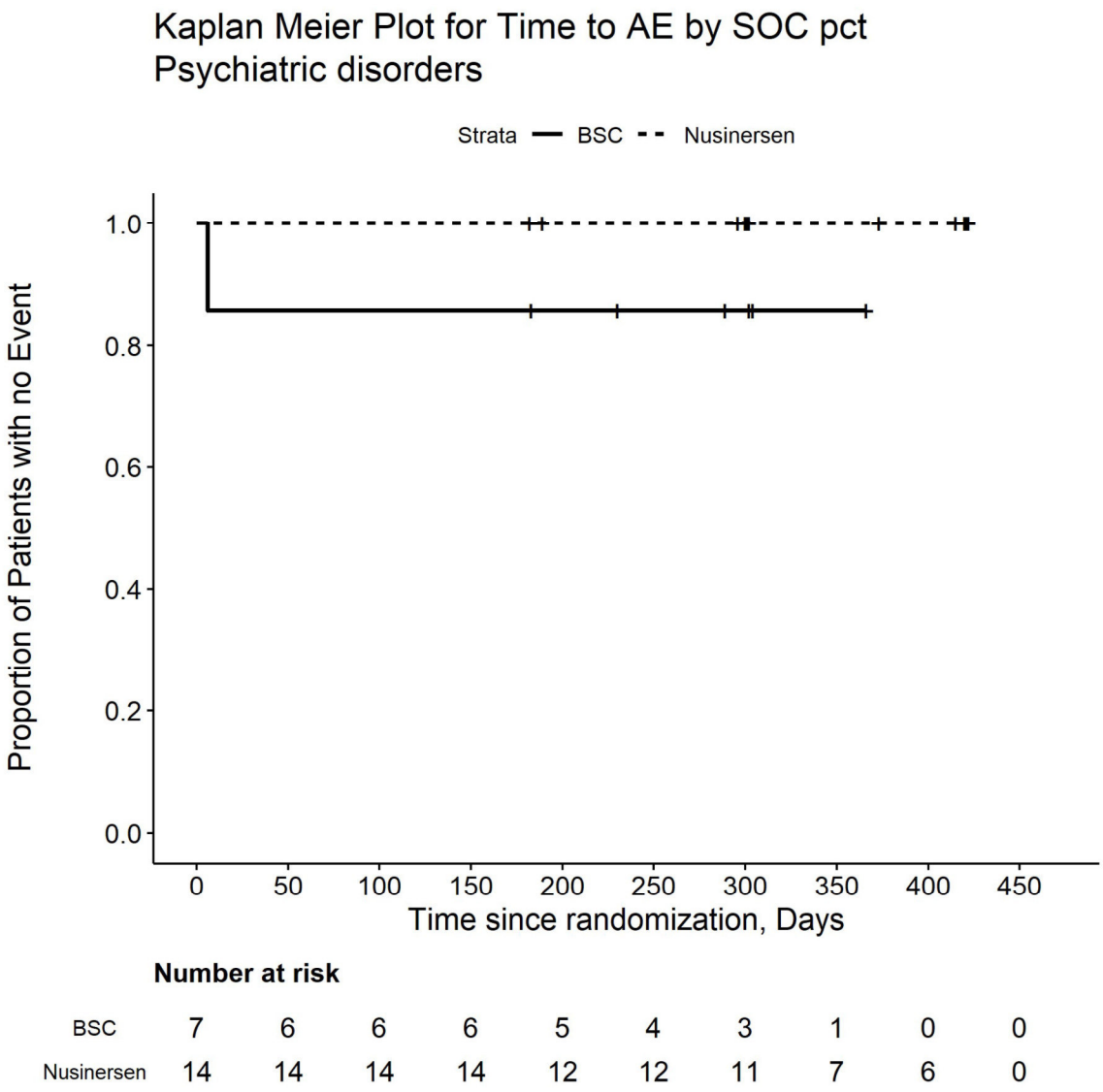
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	11	10	10	8	8	8	5	5	0



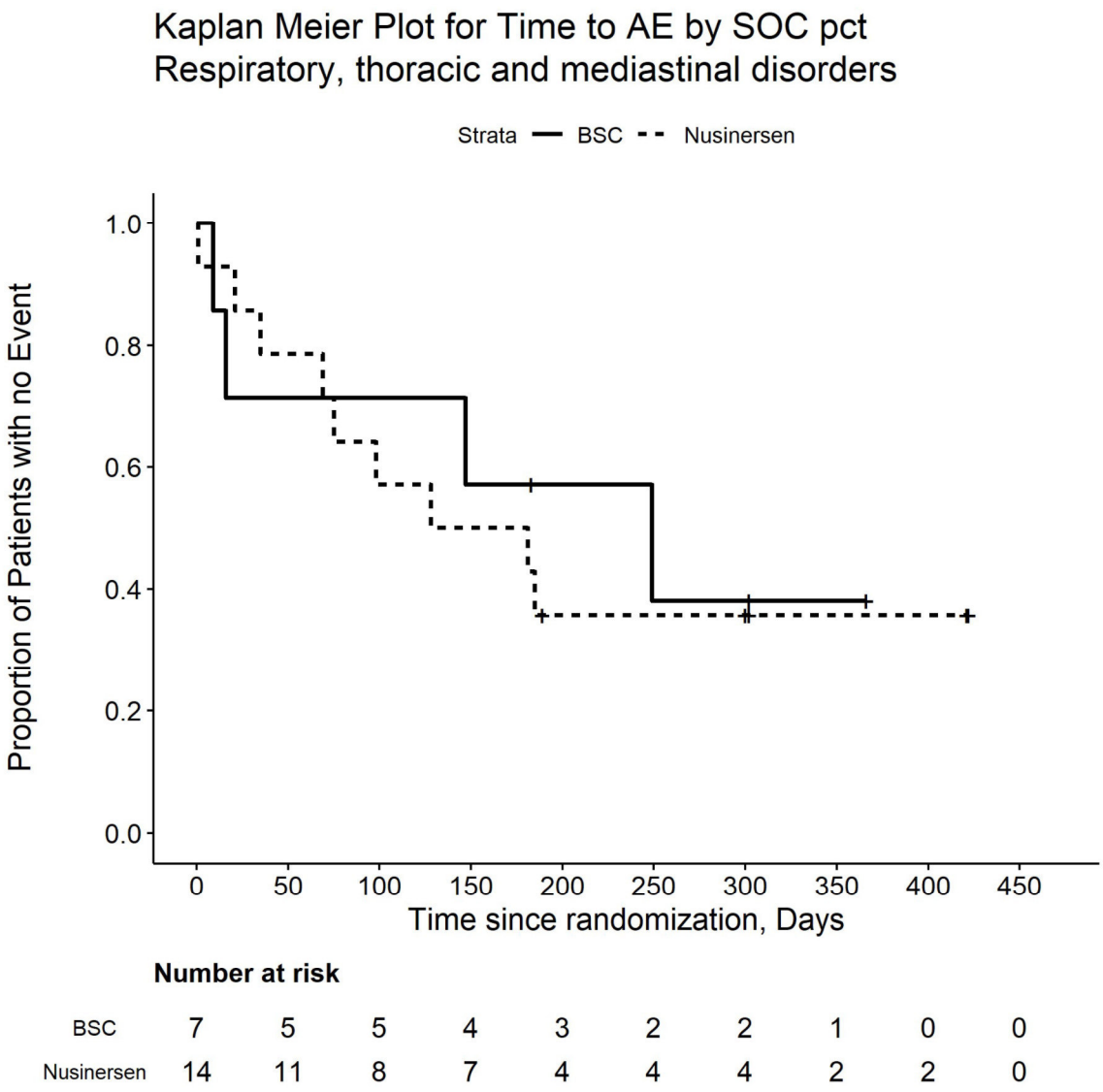
Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



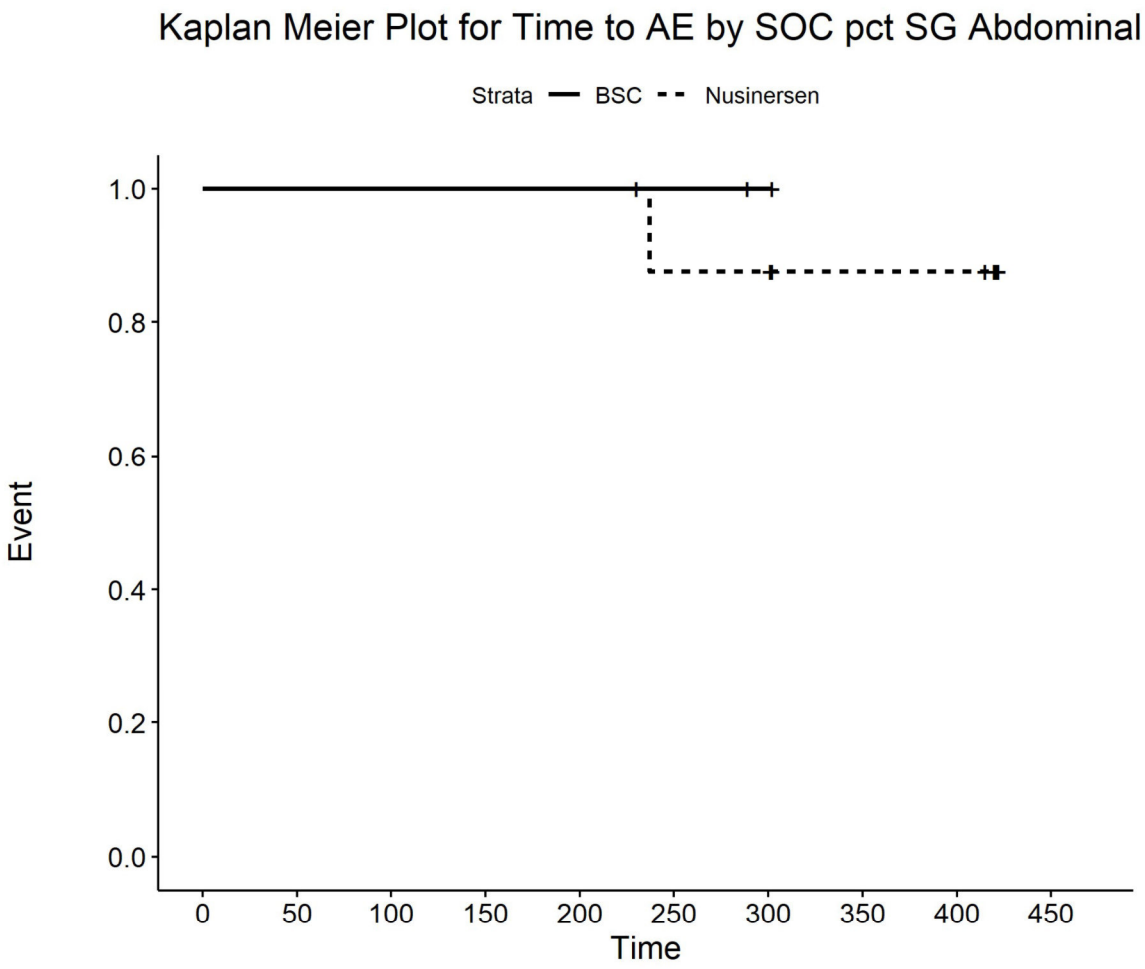
Number at risk

BSC	7	6	6	6	5	4	3	1	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



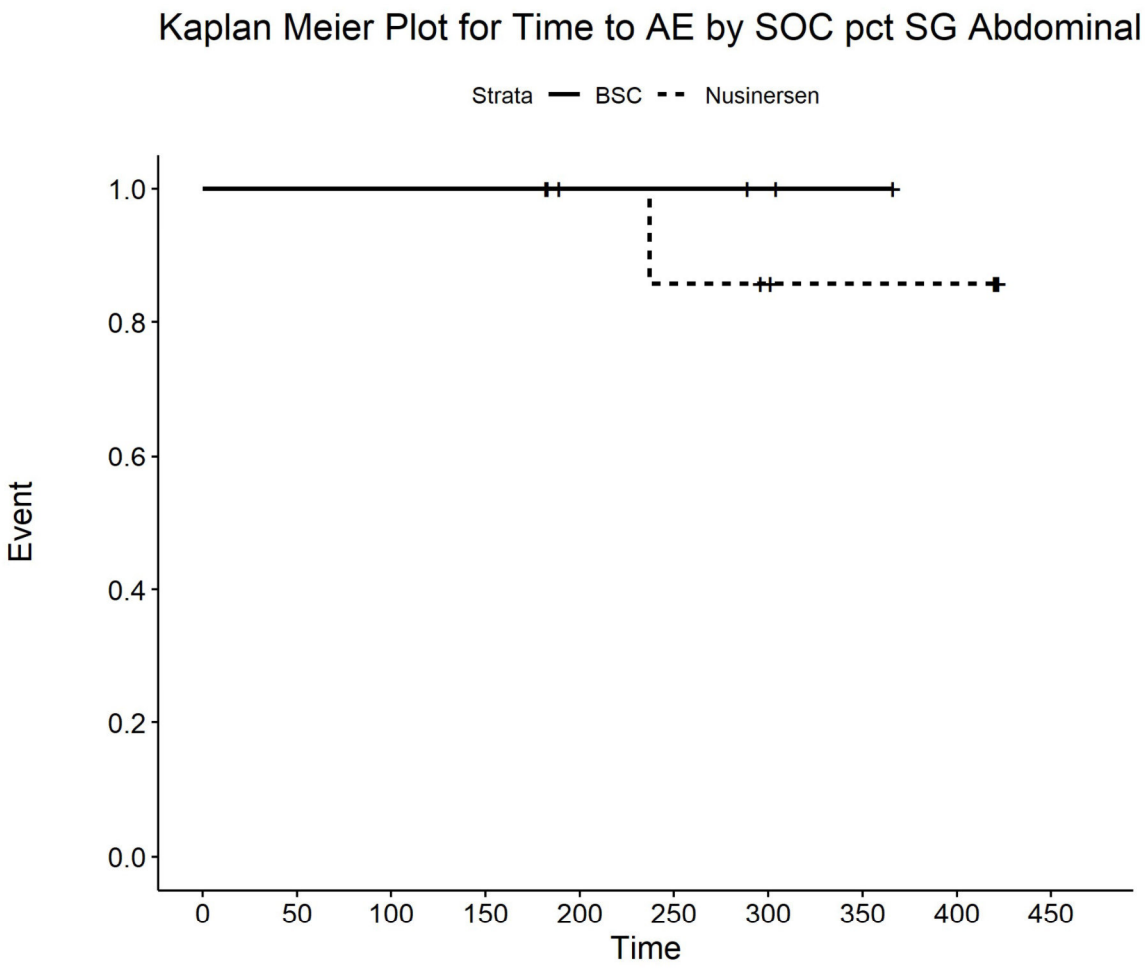
Number at risk

BSC	7	5	5	4	3	2	2	1	0	0
Nusinersen	14	11	8	7	4	4	4	2	2	0



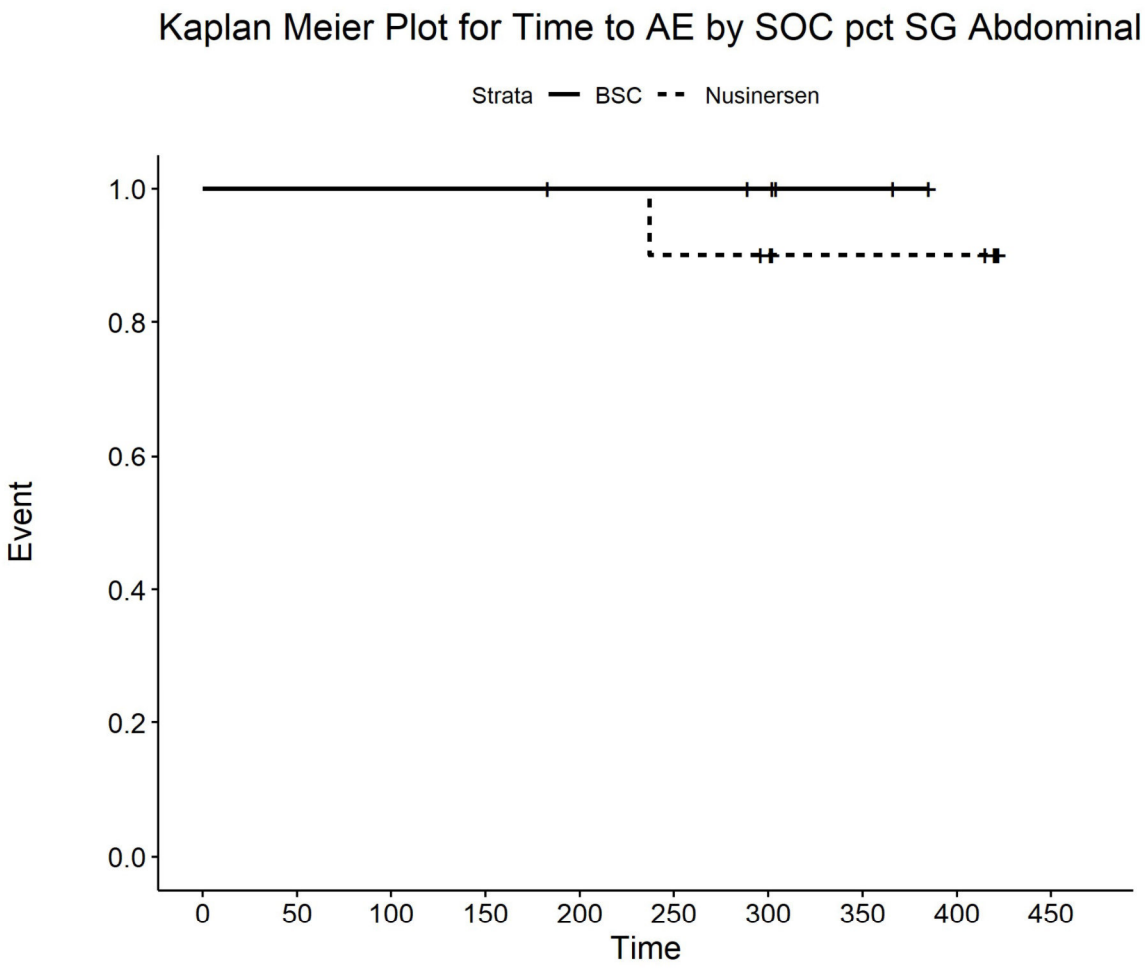
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	5	0



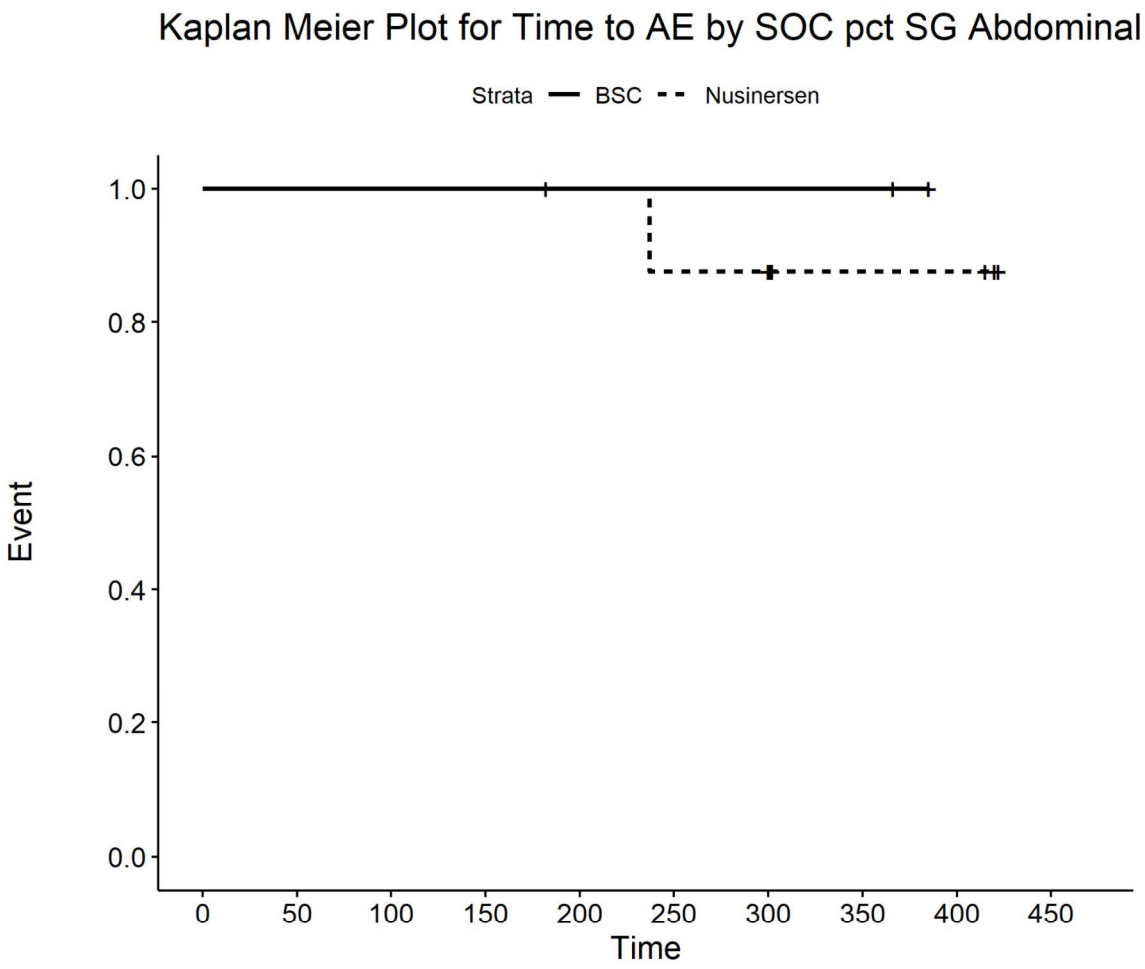
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	4	0



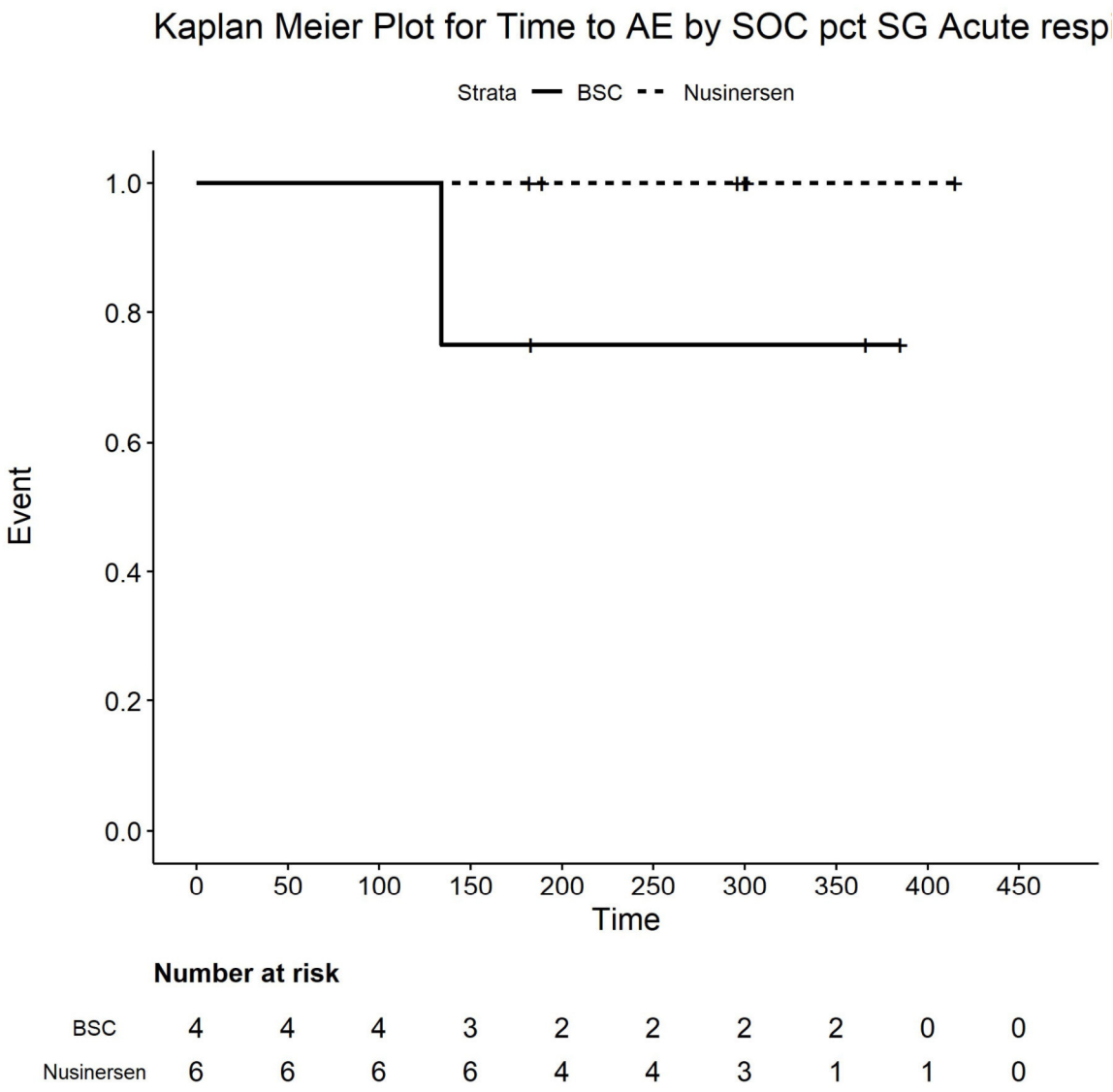
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	6	0



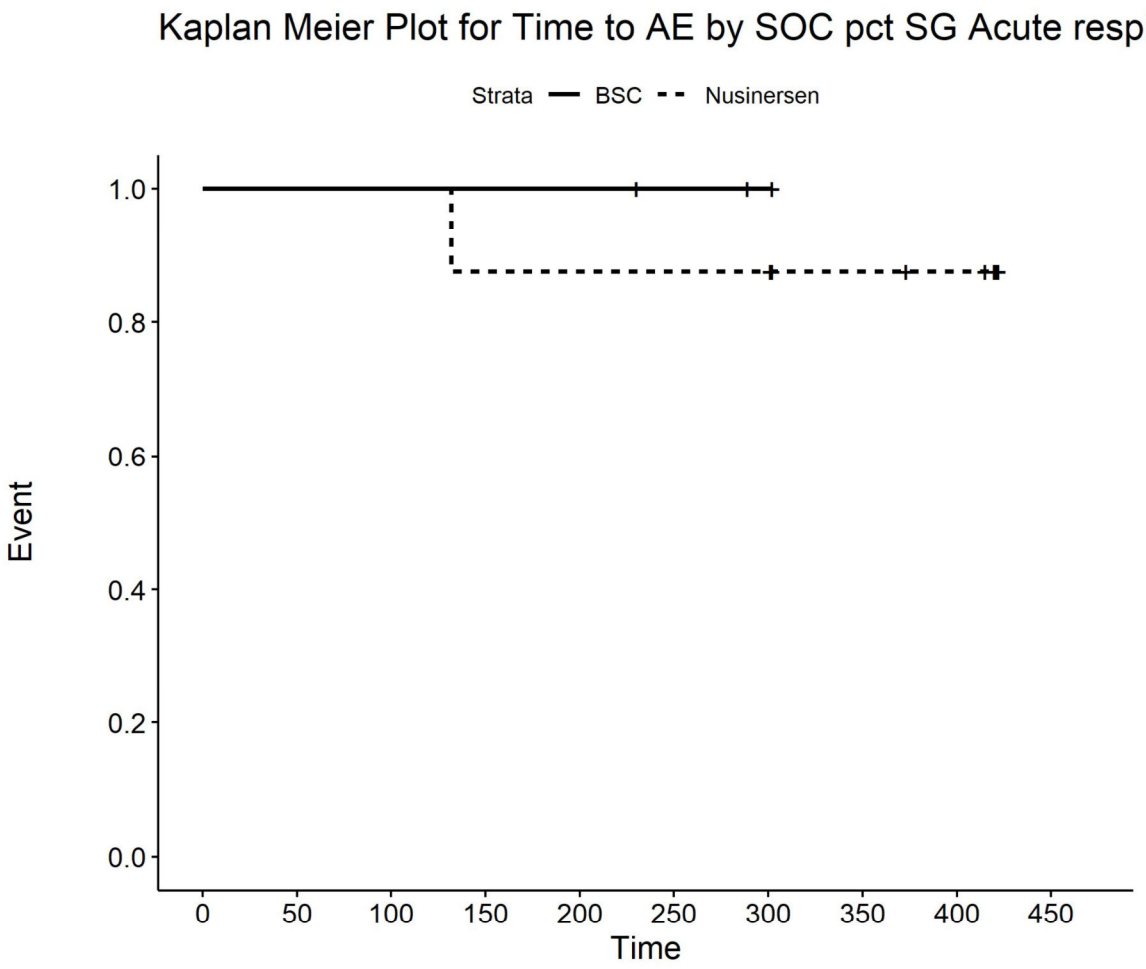
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	3	0



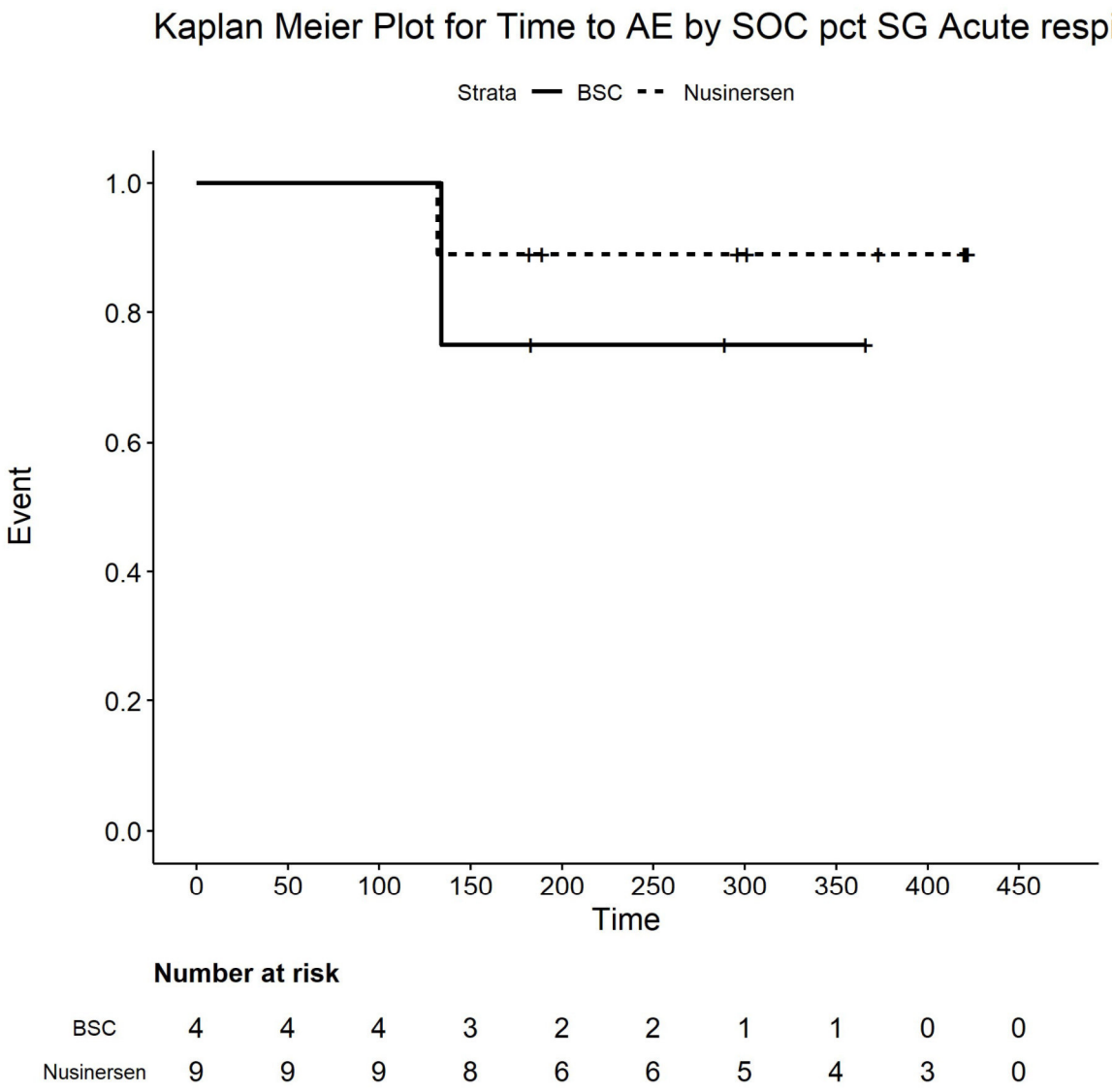
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



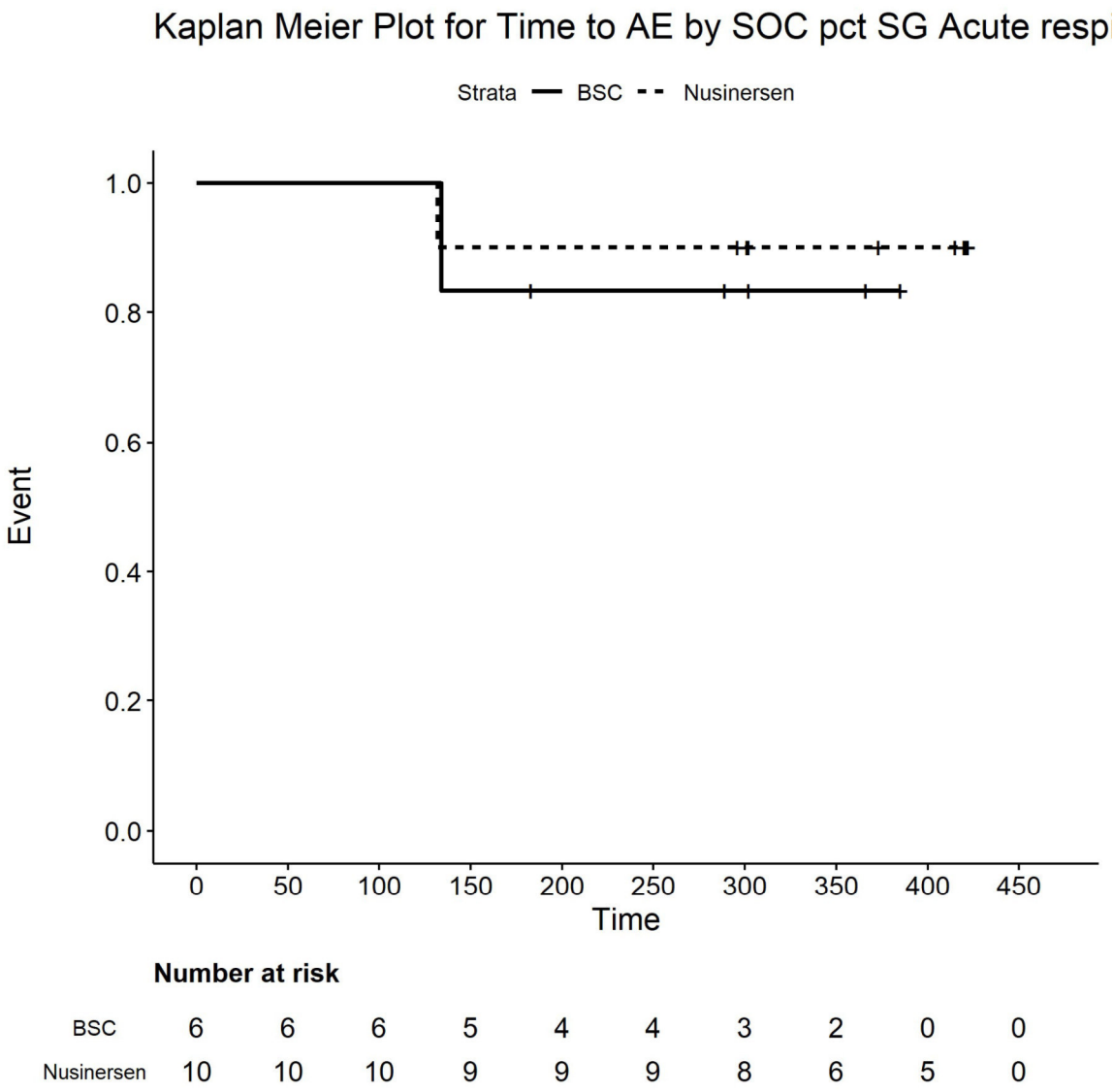
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



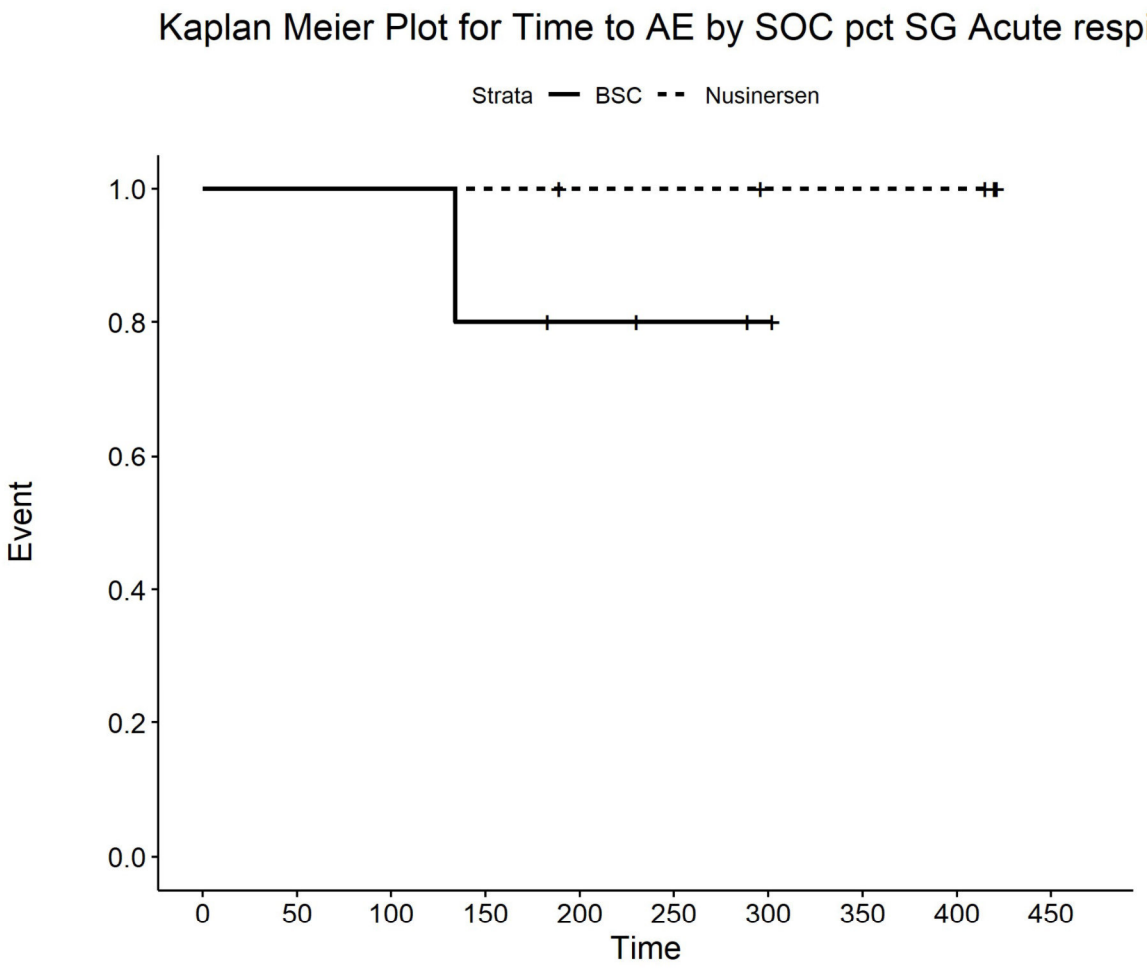
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



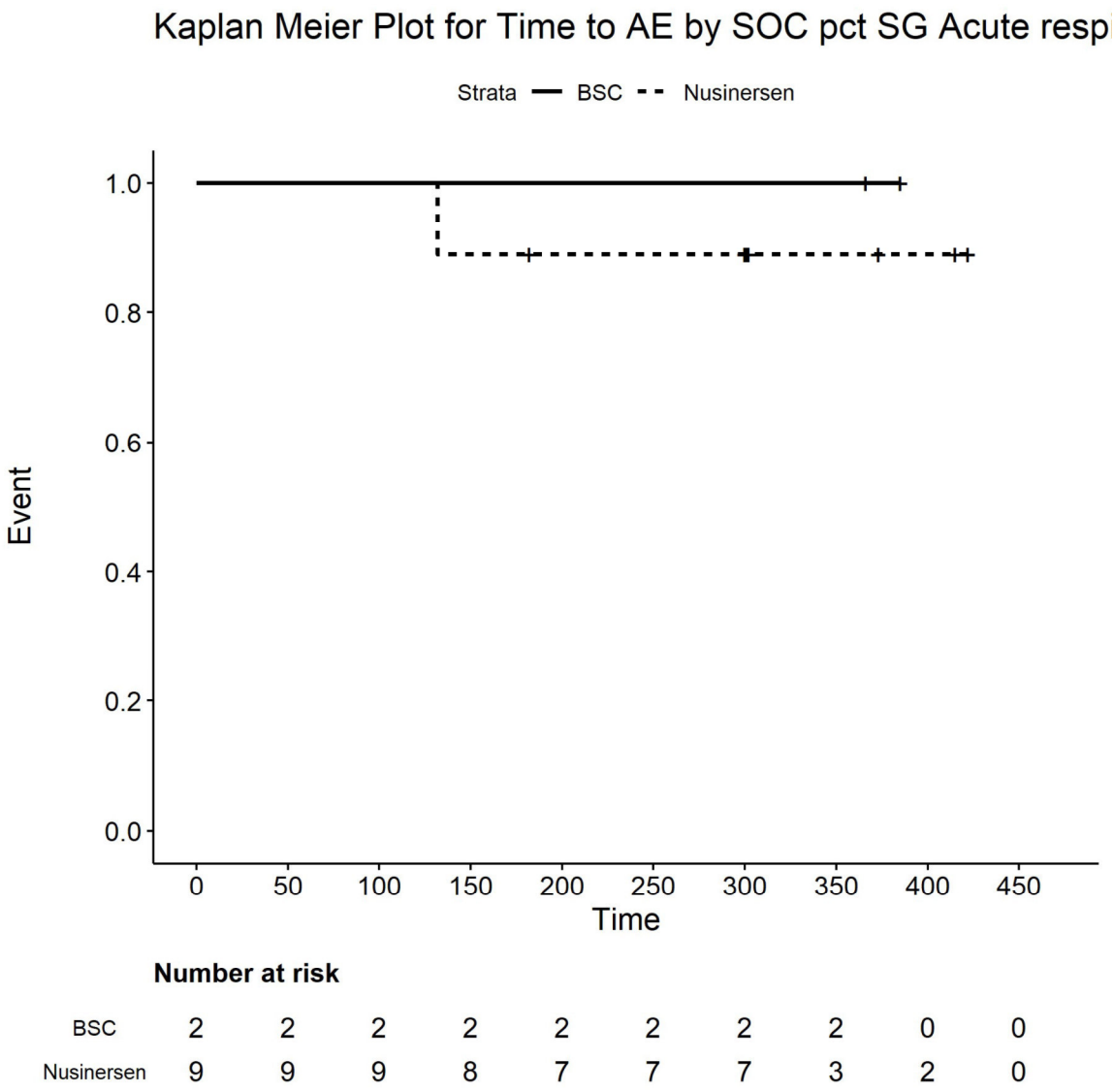
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



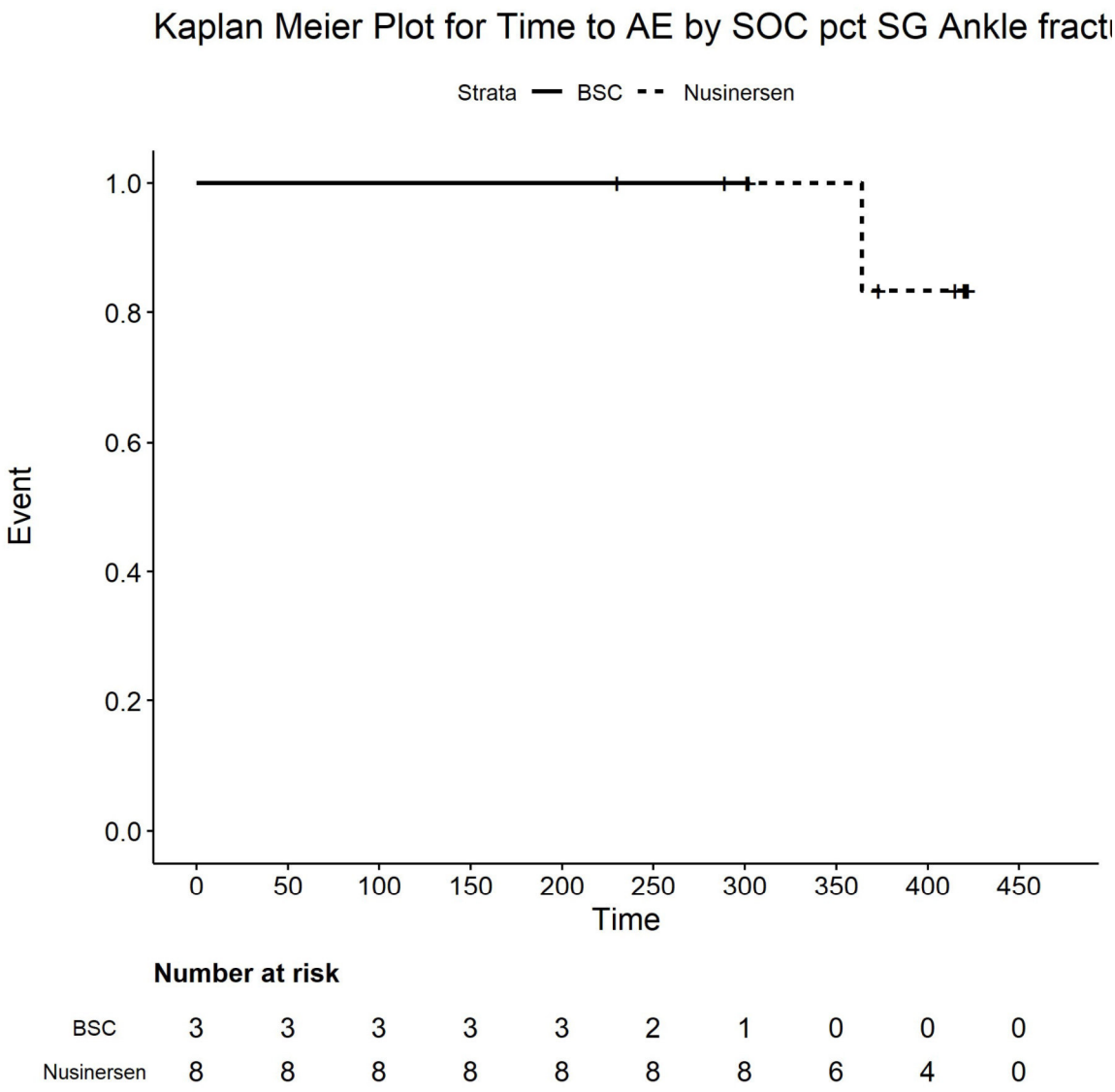
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



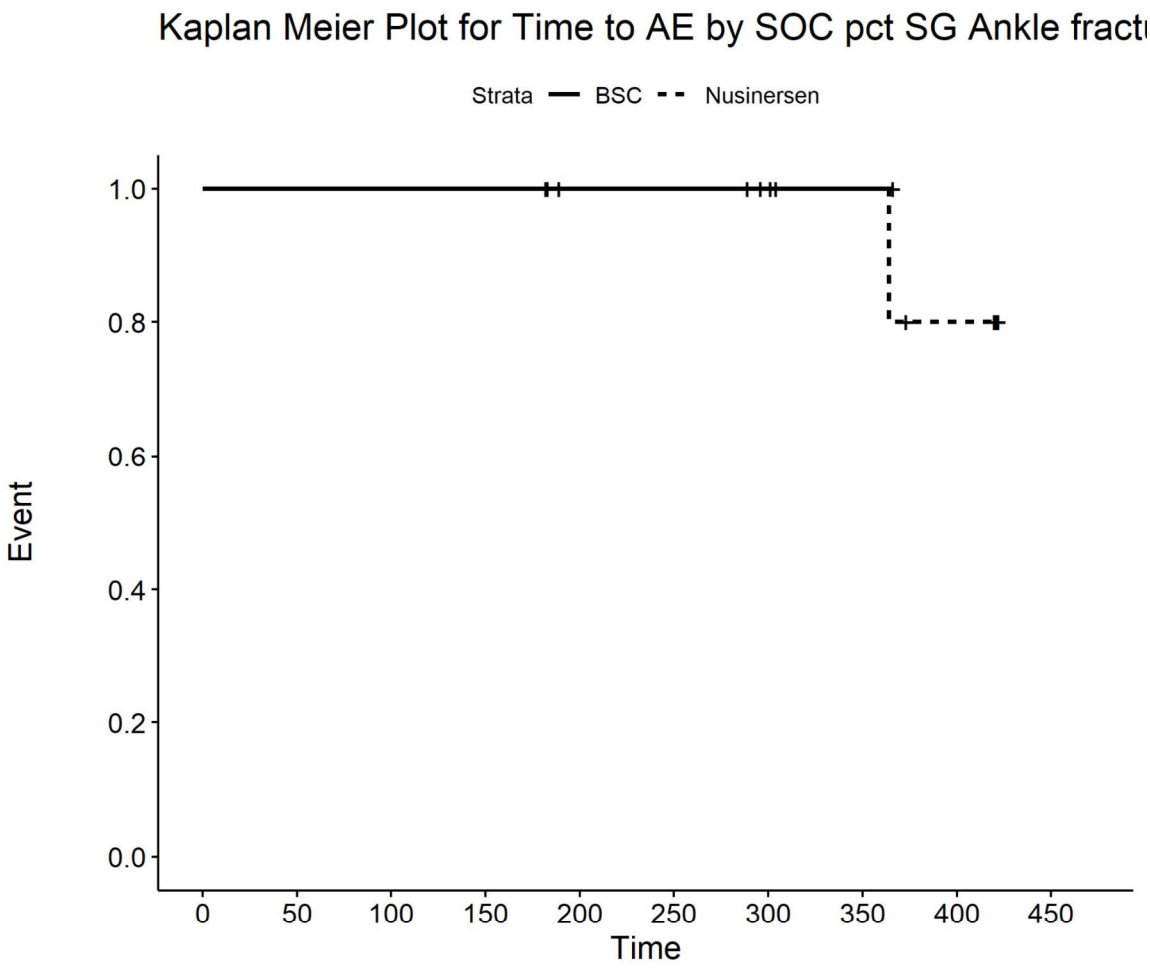
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



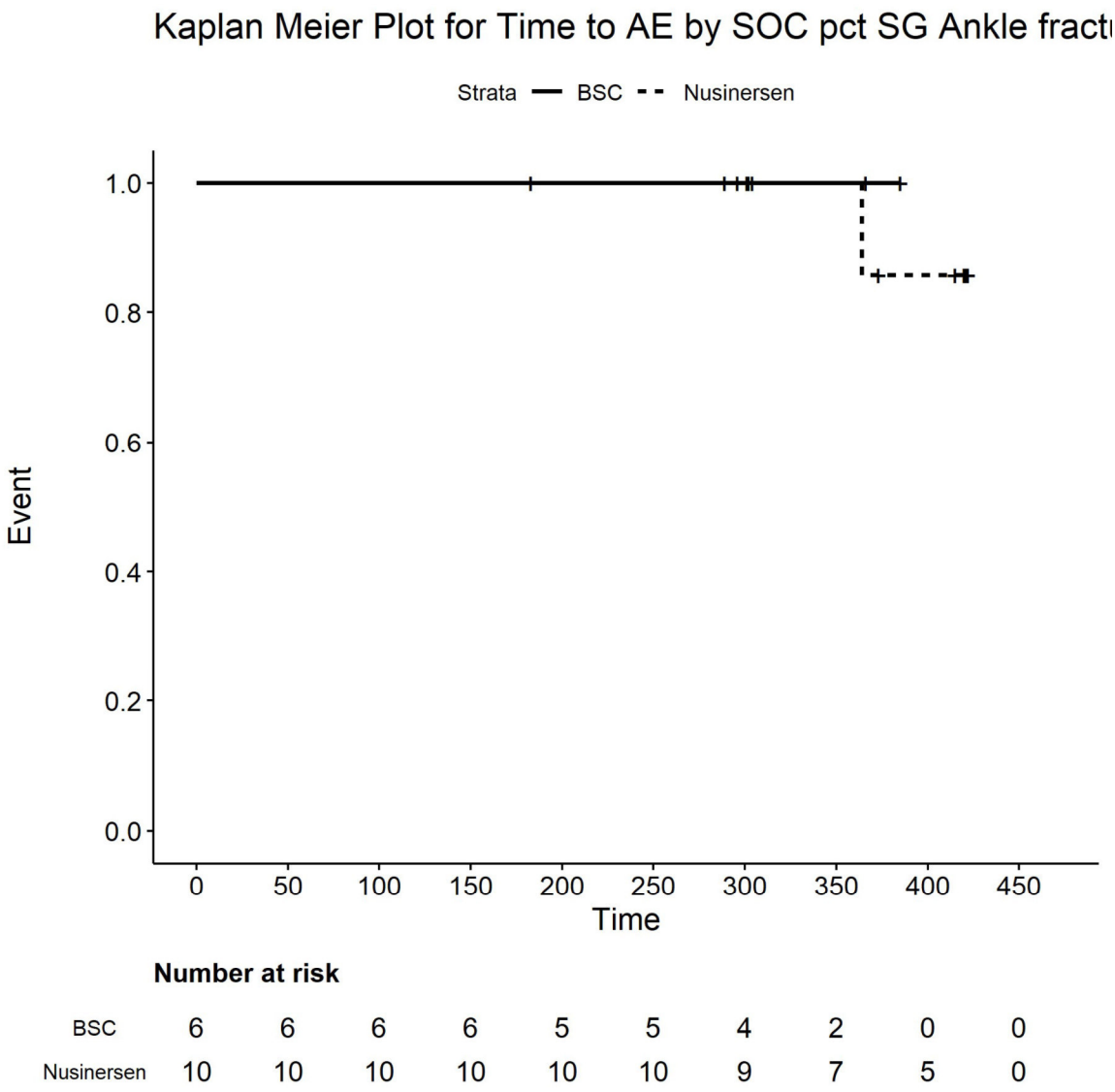
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	4	0



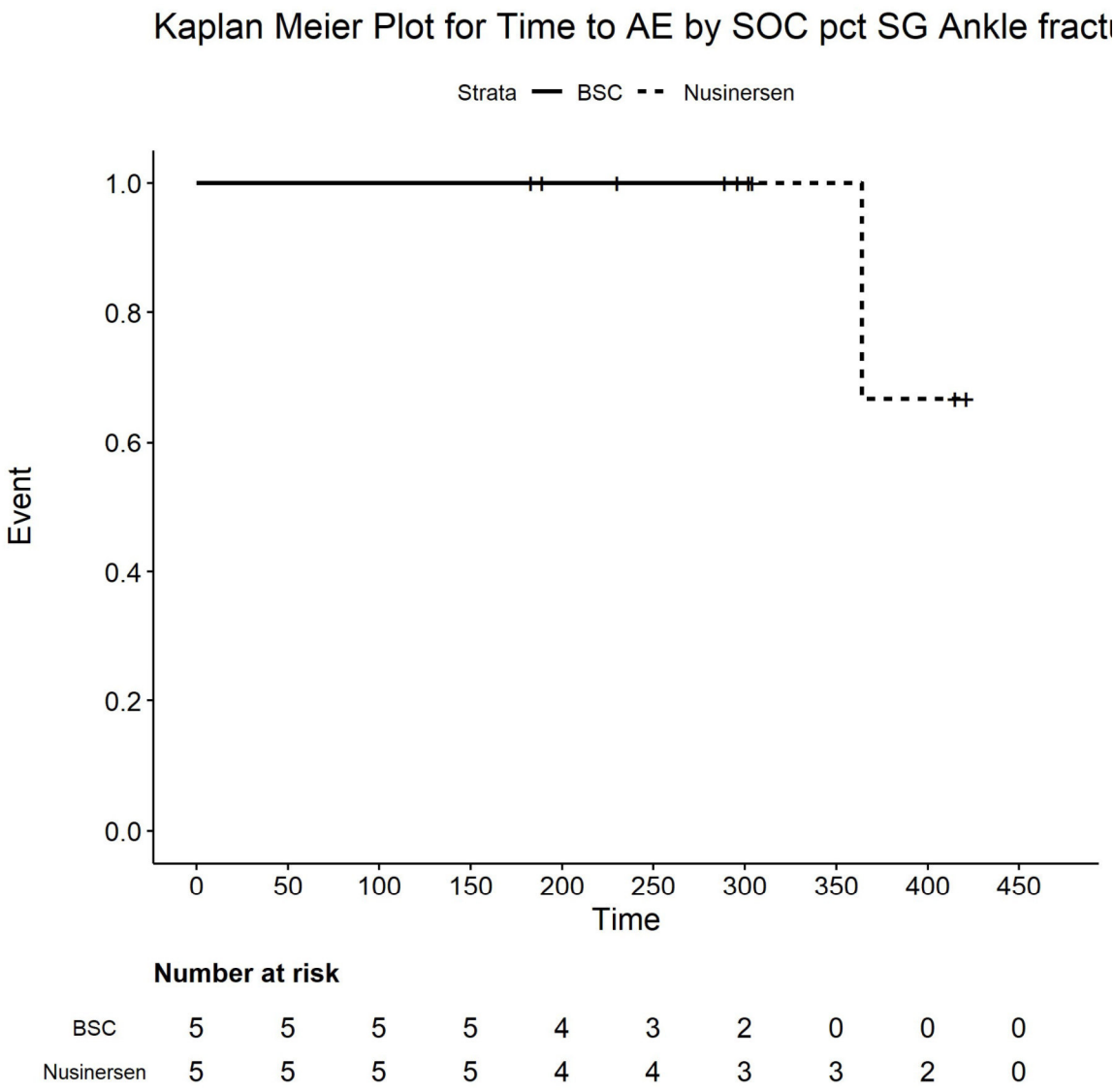
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	3	0



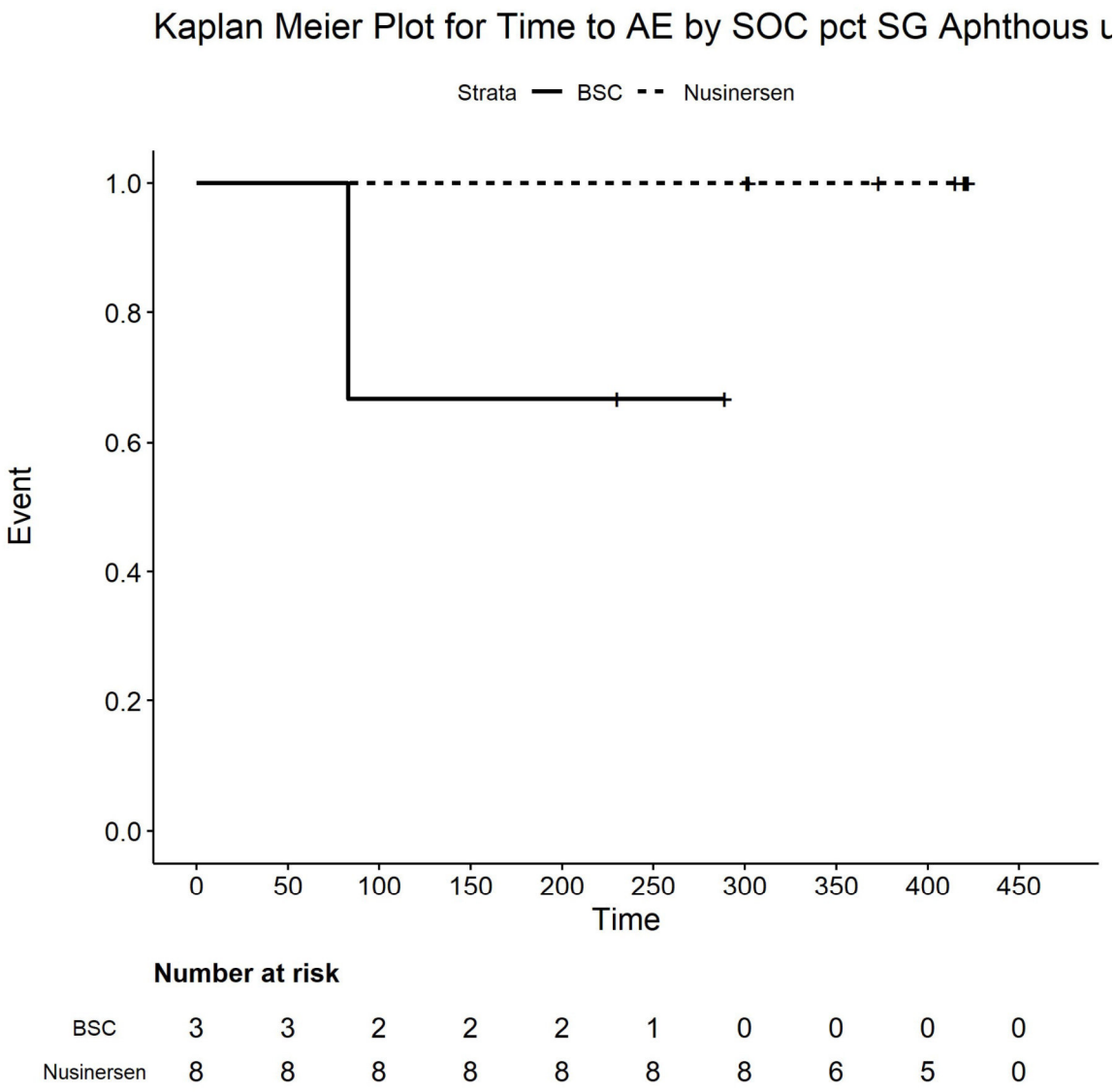
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	5	0



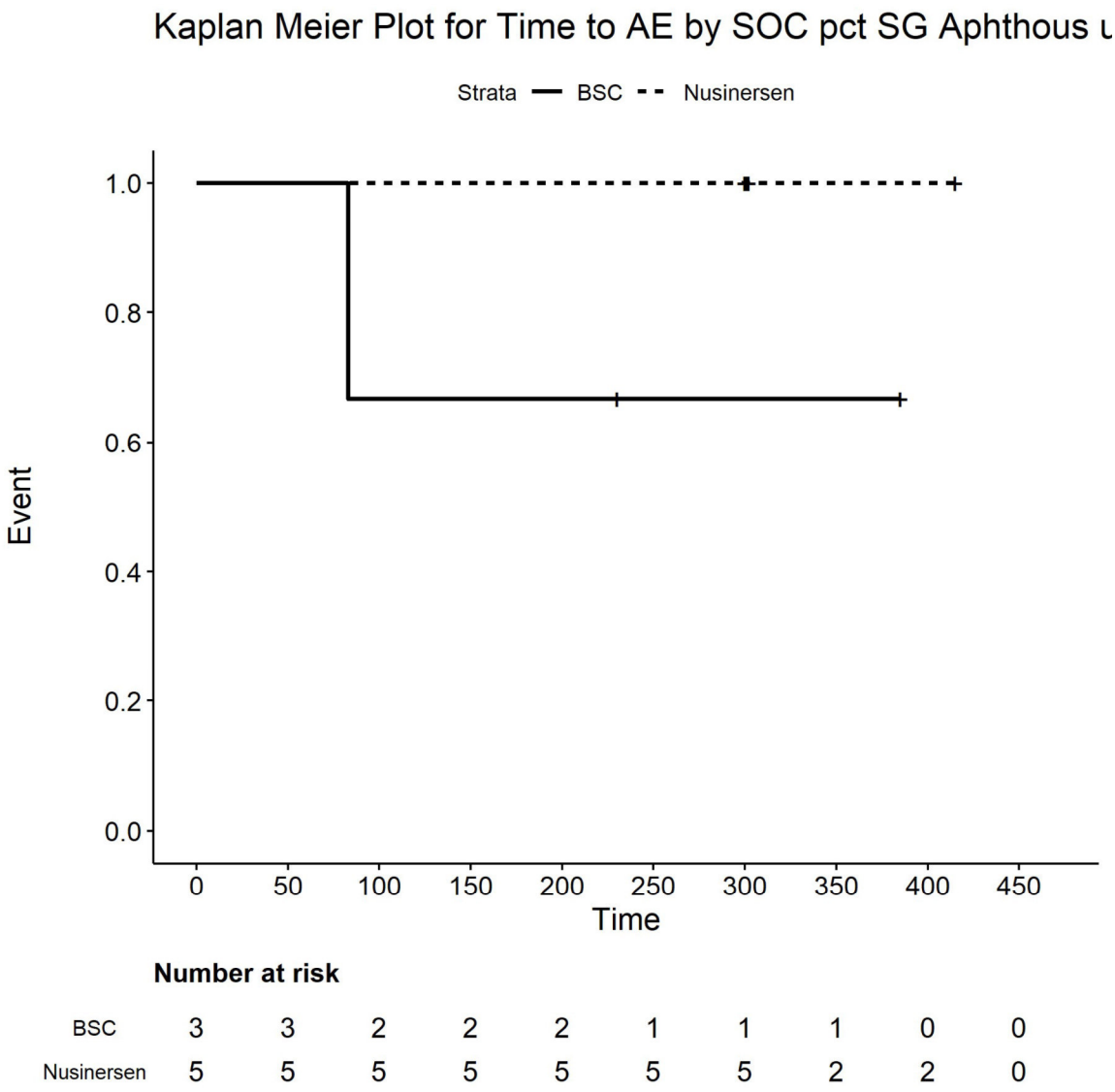
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	2	0



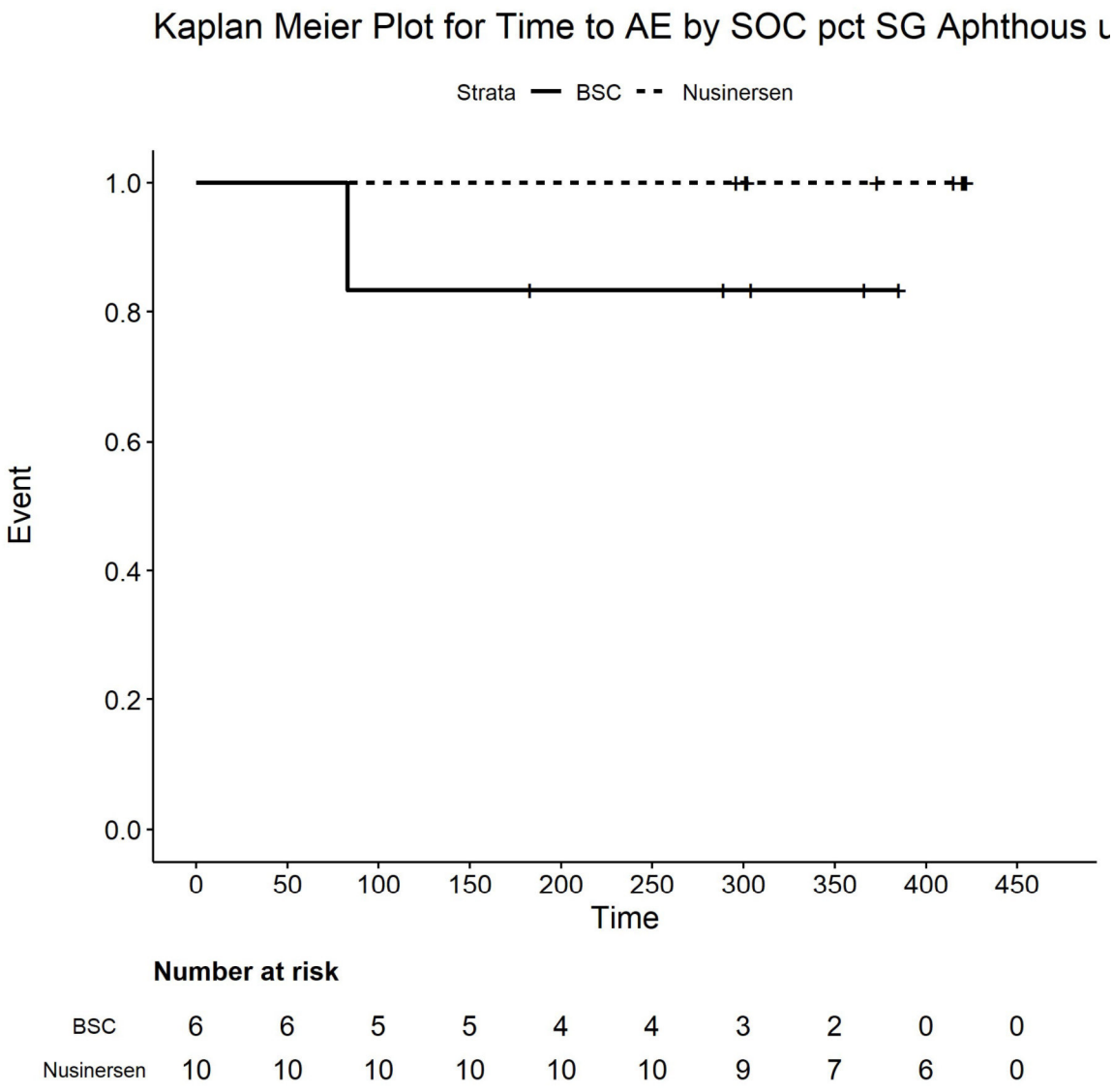
Number at risk

BSC	3	3	2	2	2	1	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



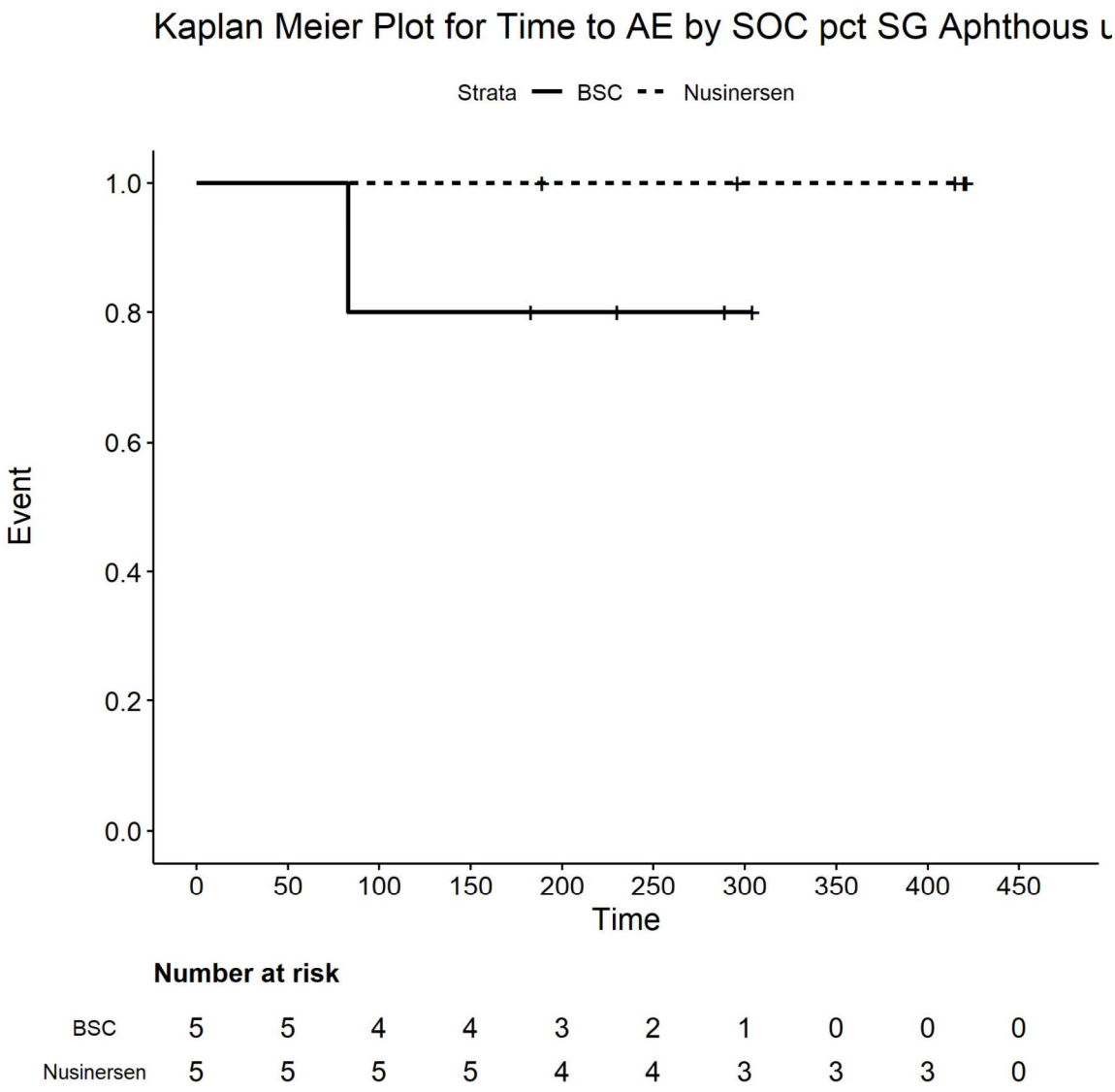
Number at risk

BSC	3	3	2	2	2	1	1	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



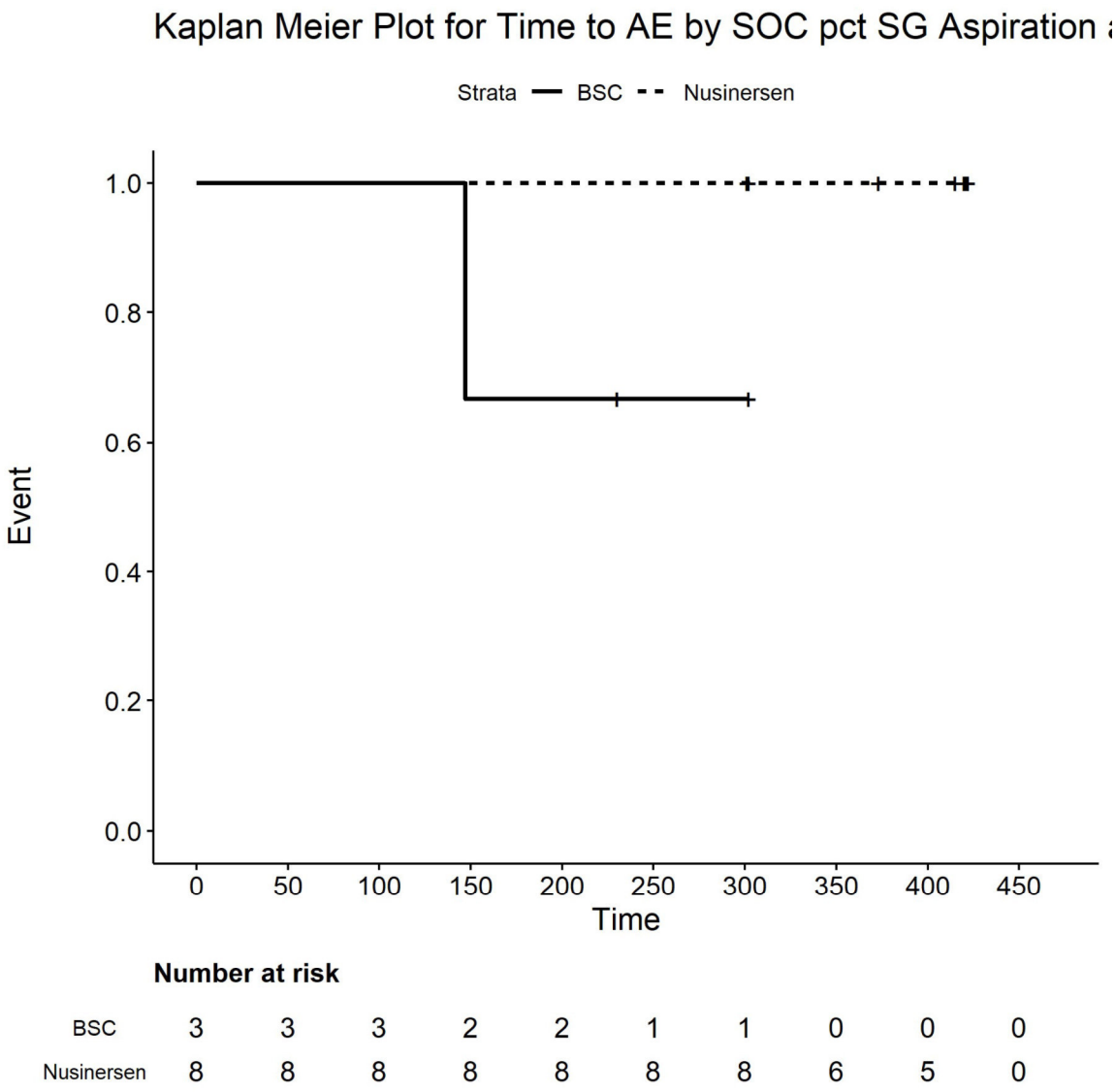
Number at risk

BSC	6	6	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



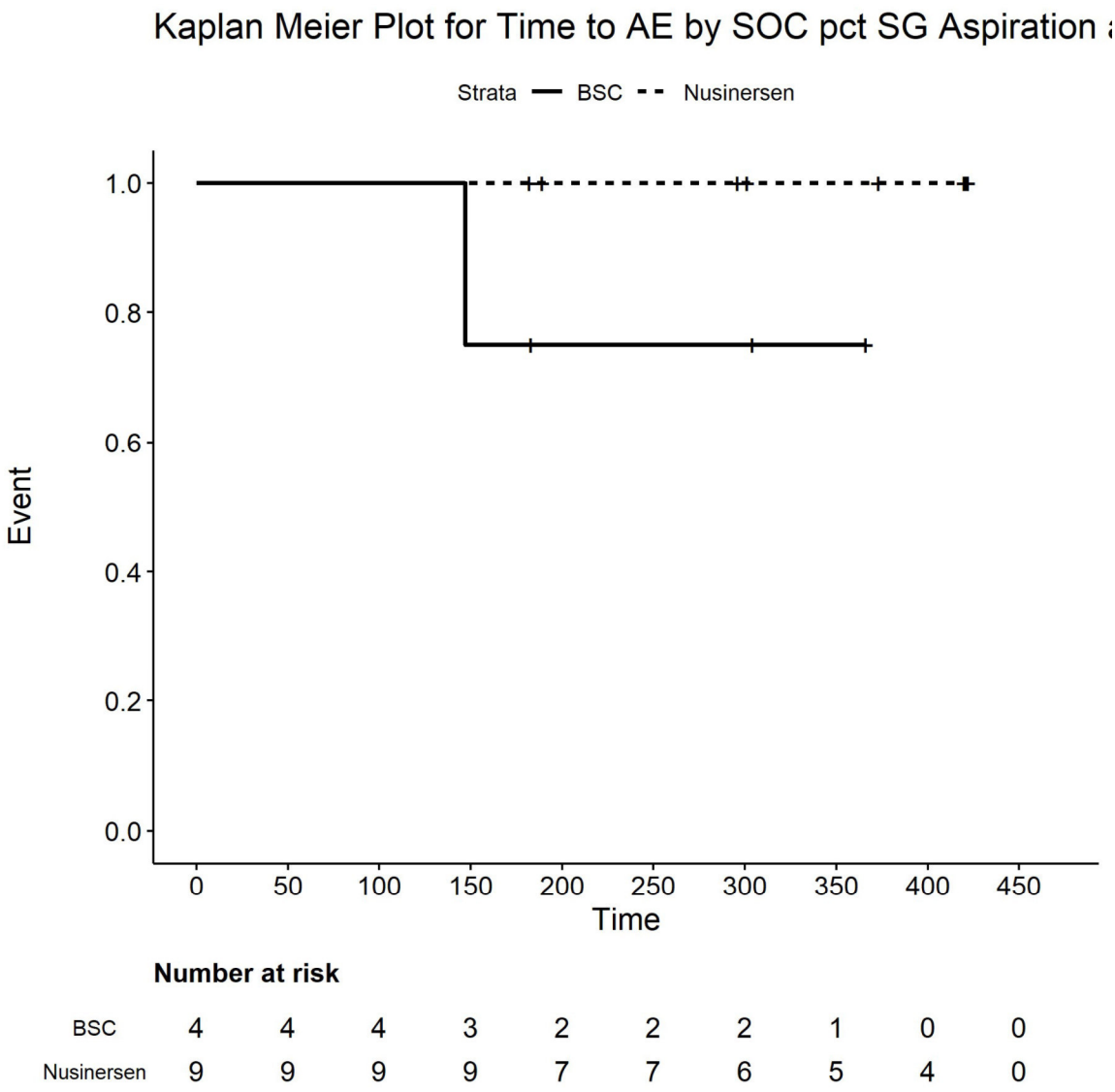
Number at risk

BSC	5	5	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



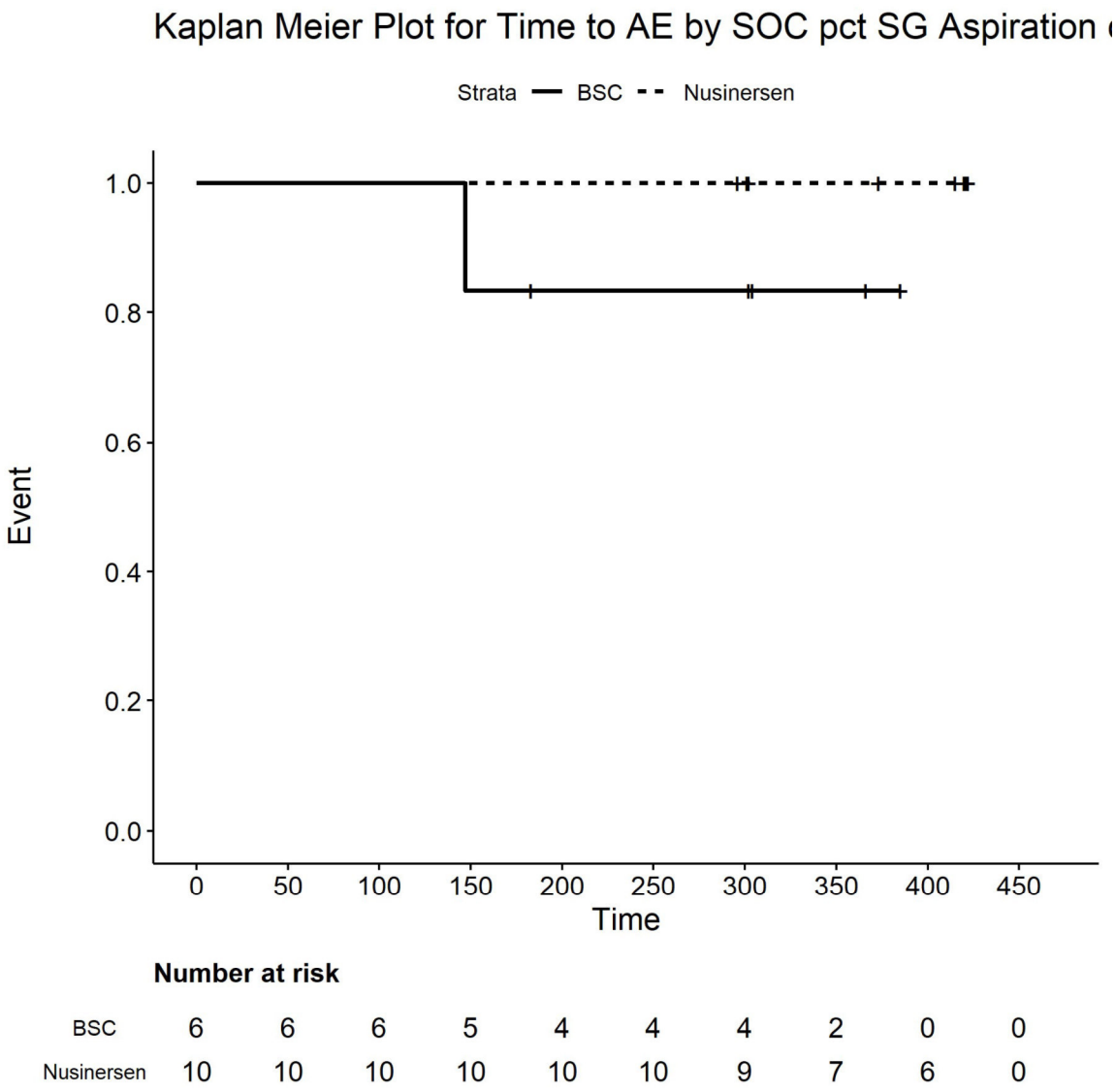
Number at risk

BSC	3	3	3	2	2	1	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



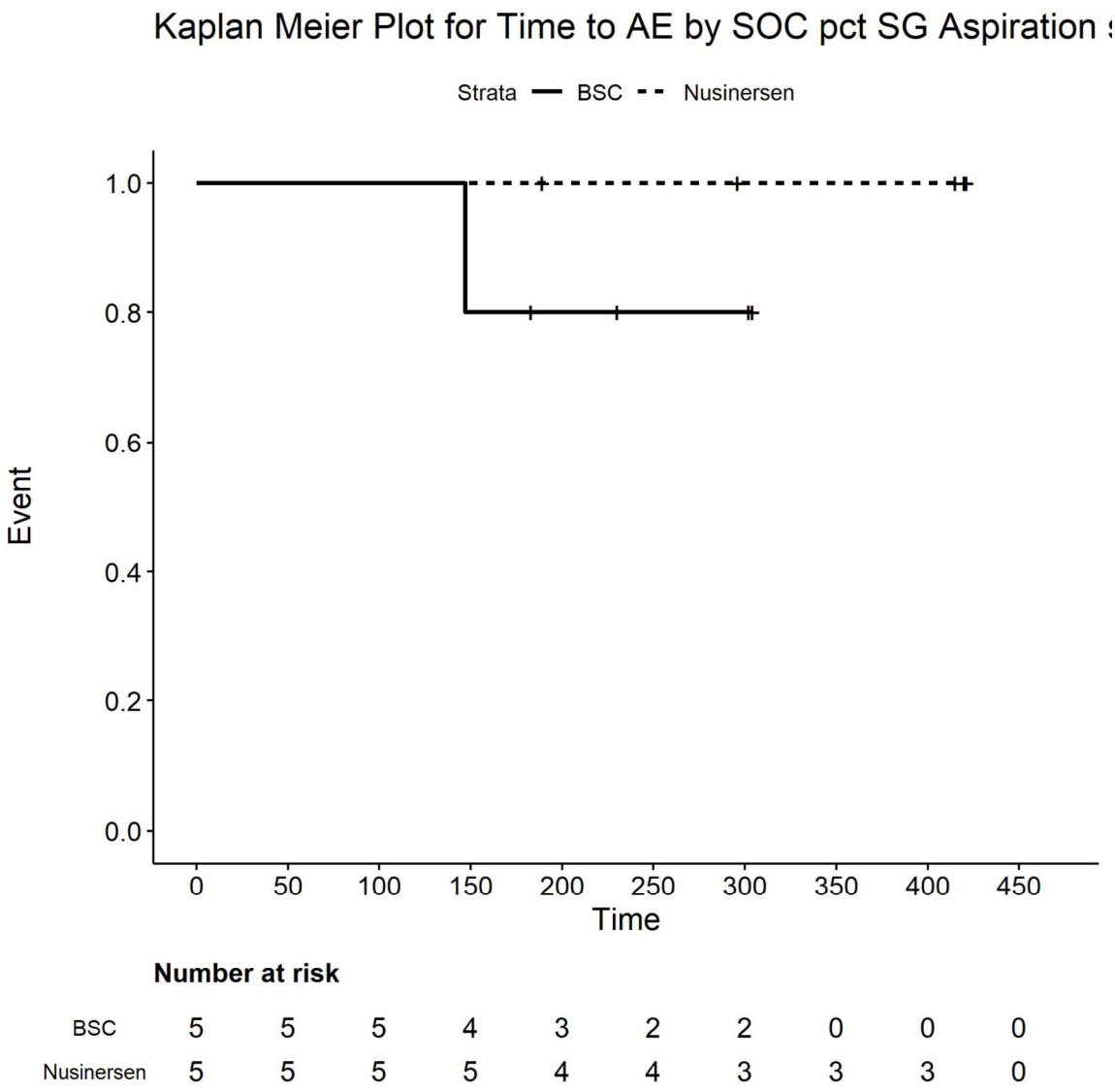
Number at risk

BSC	4	4	4	3	2	2	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



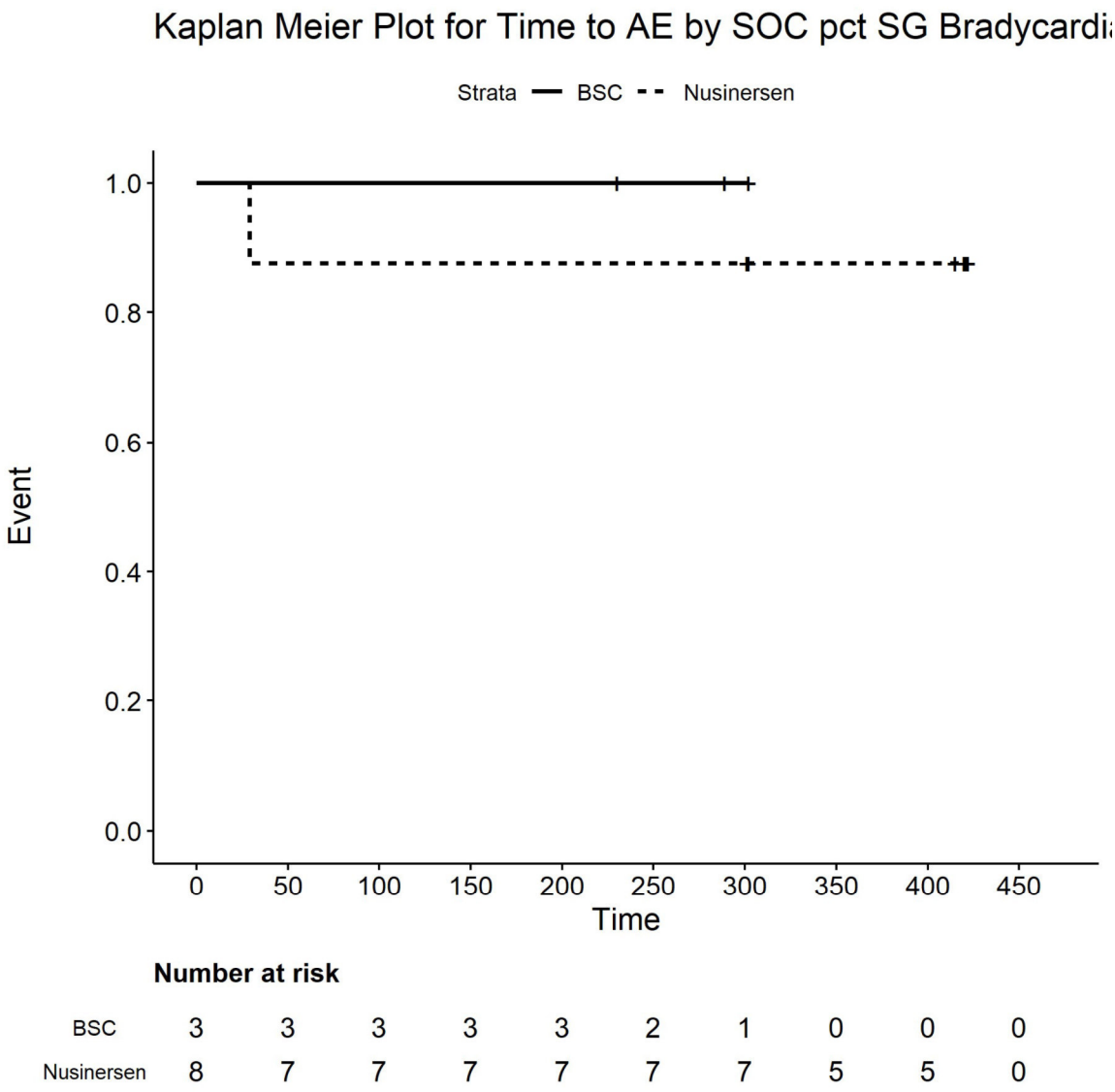
Number at risk

BSC	6	6	6	5	4	4	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



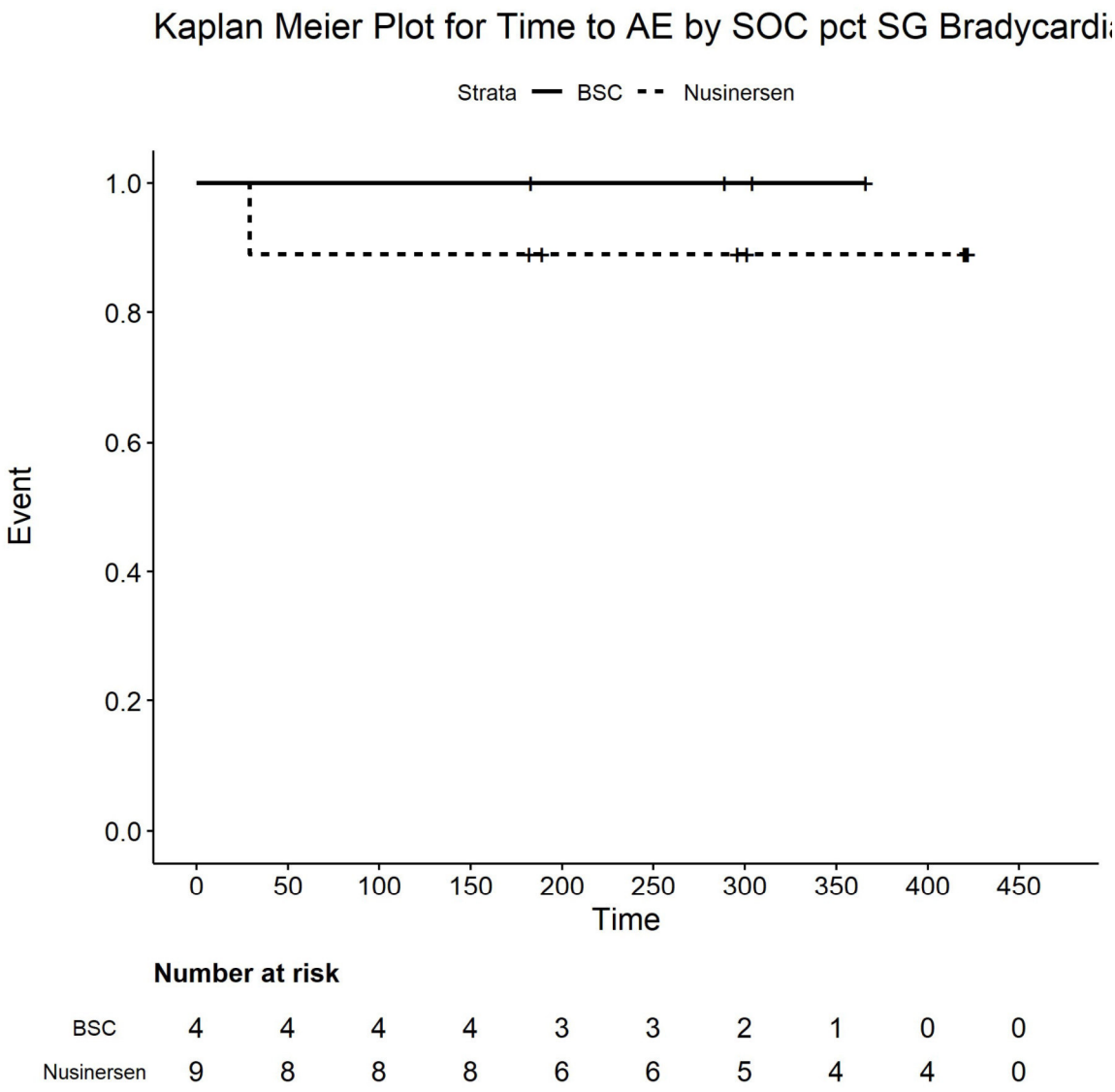
Number at risk

BSC	5	5	5	4	3	2	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



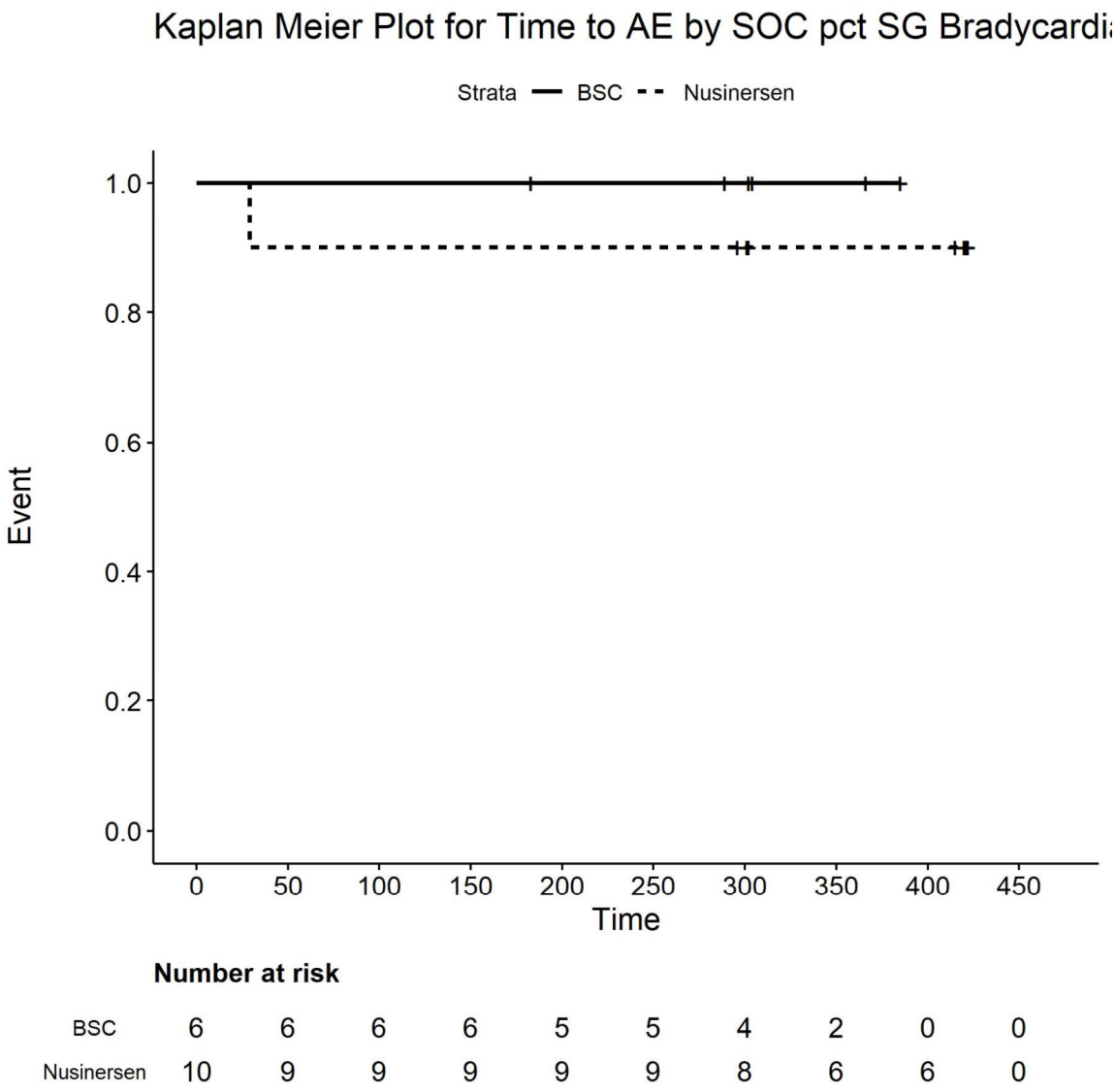
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	5	0



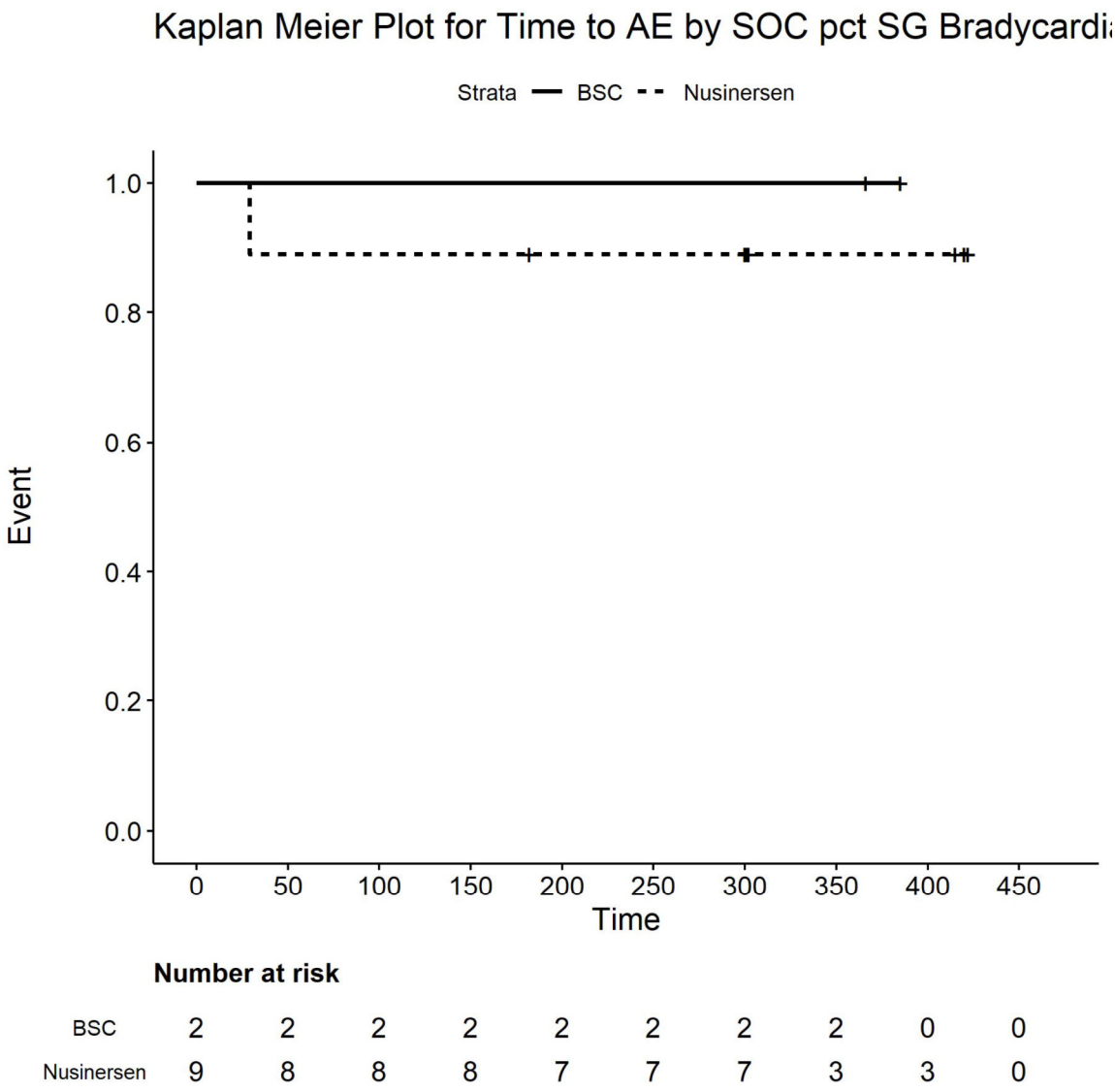
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	4	0



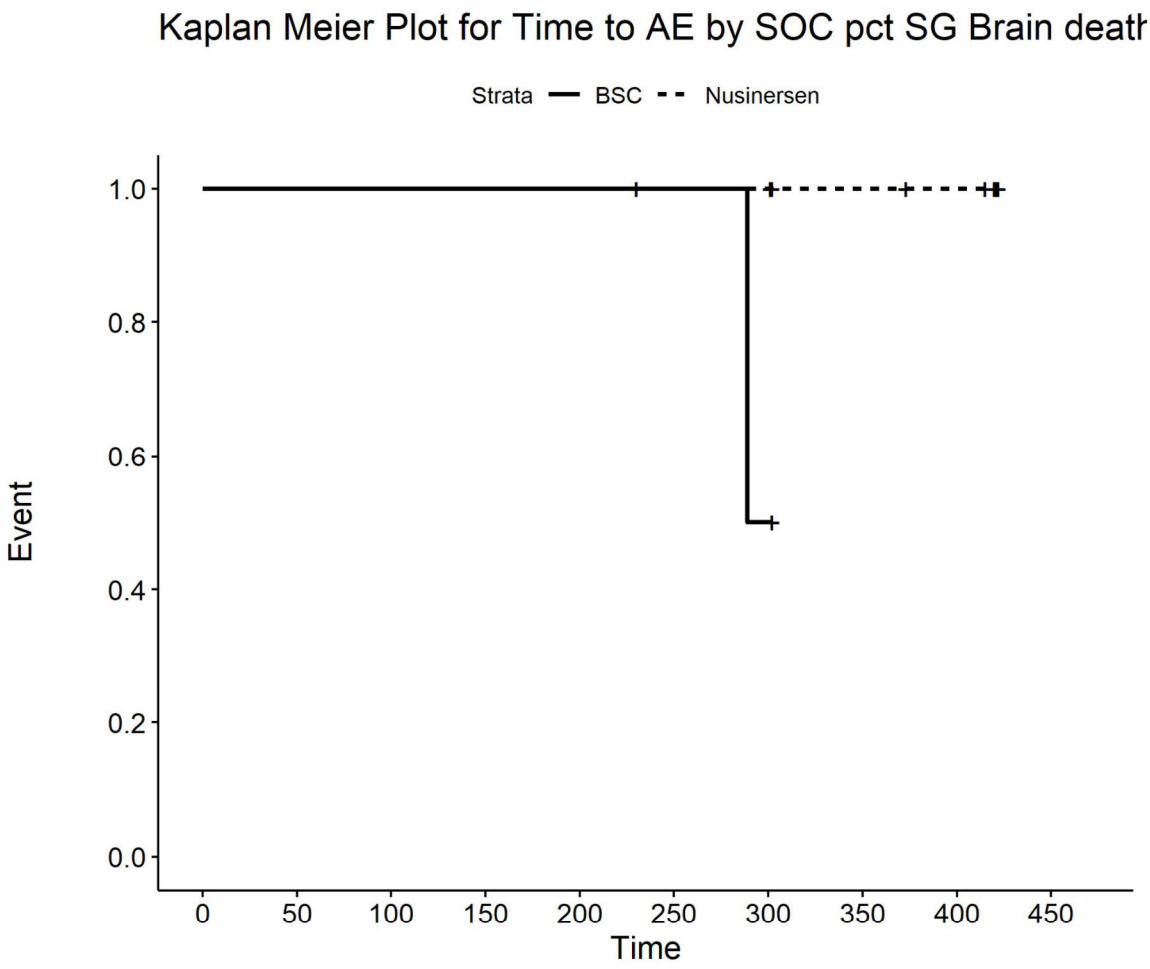
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	6	0



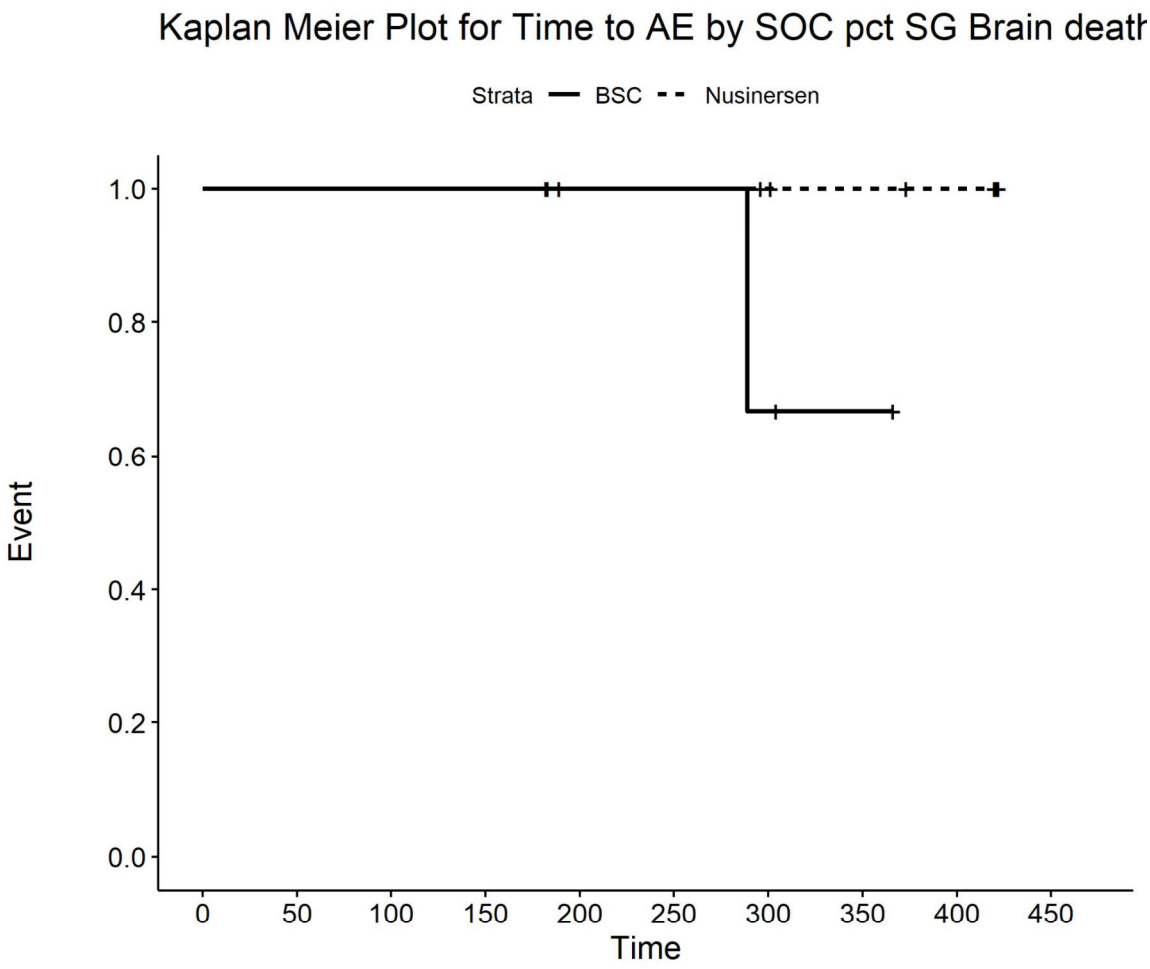
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	3	0



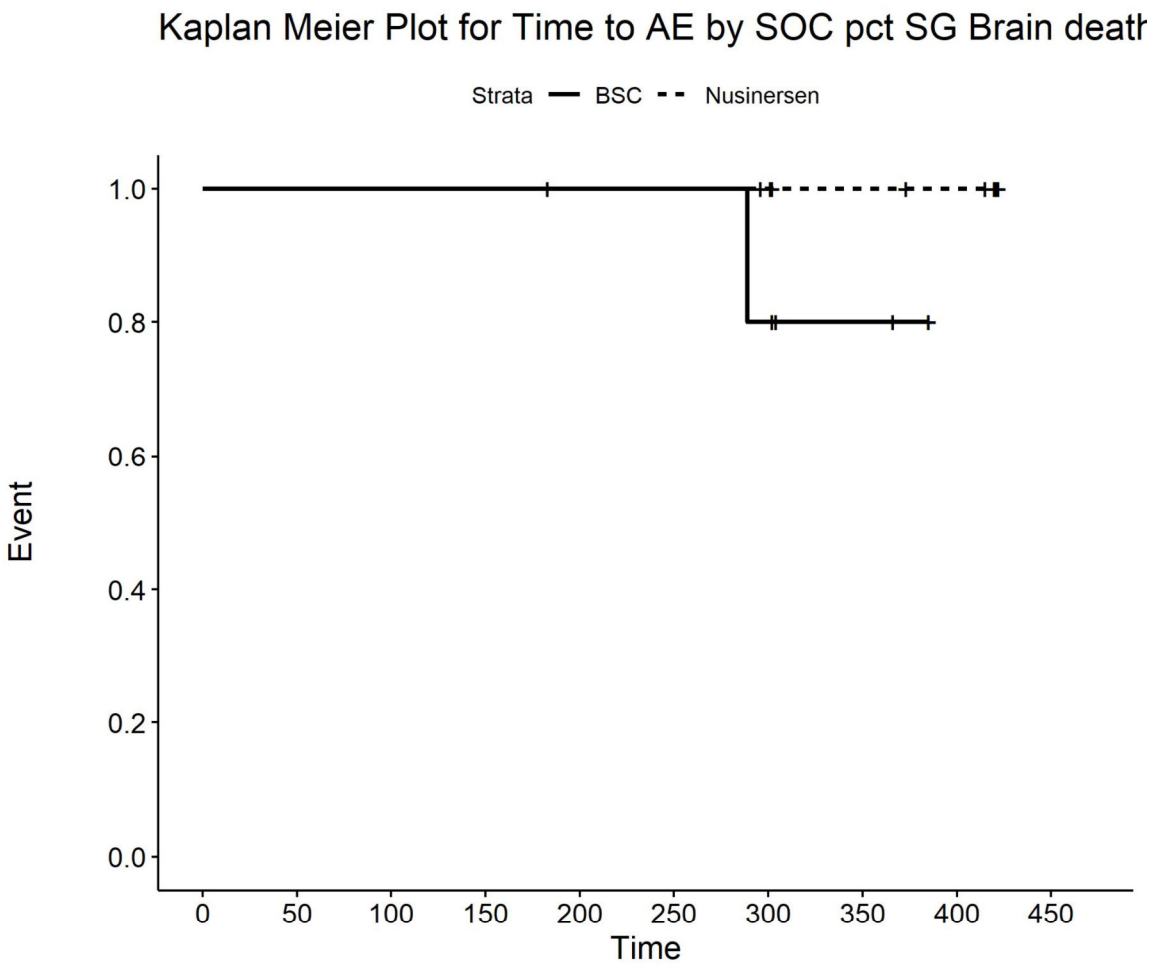
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



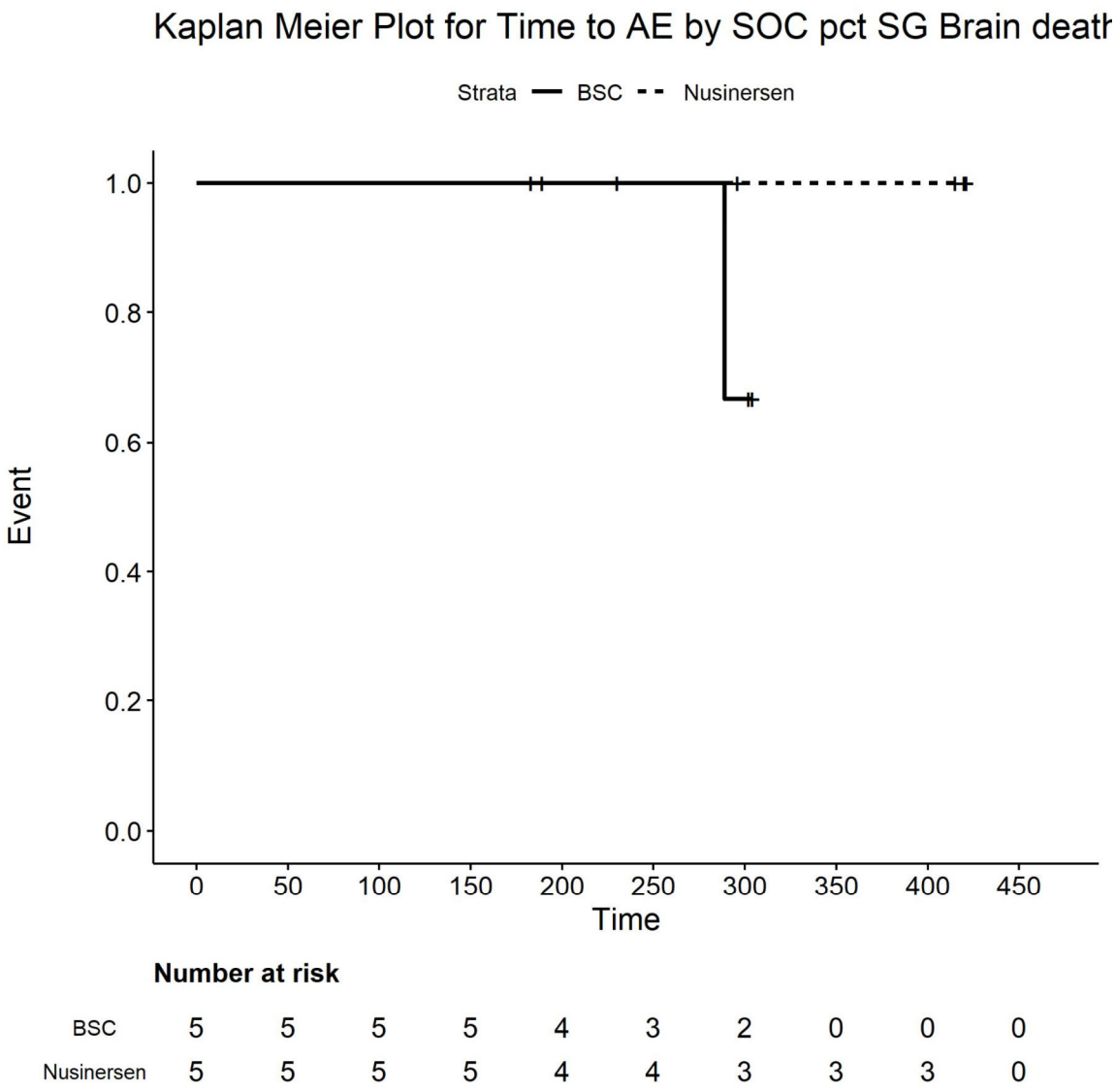
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



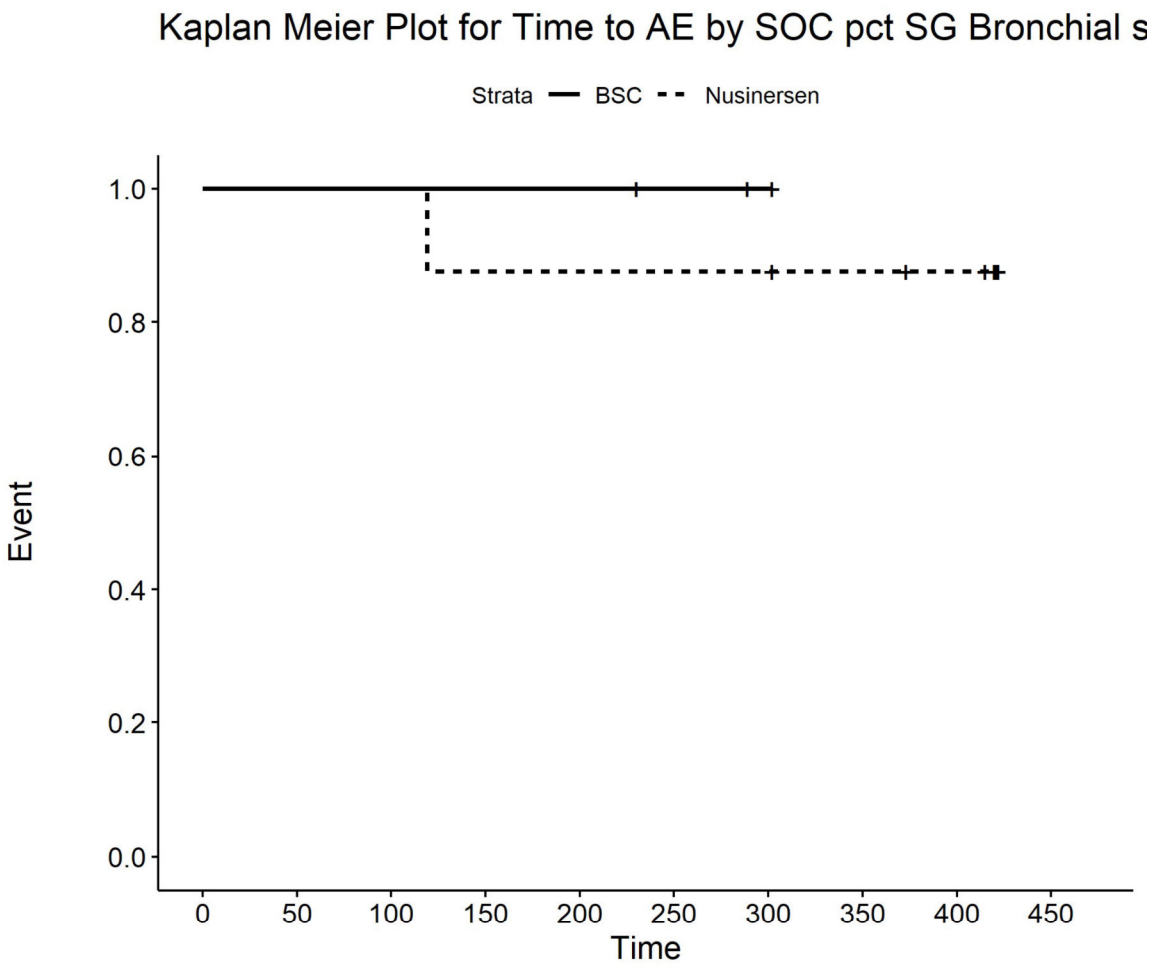
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



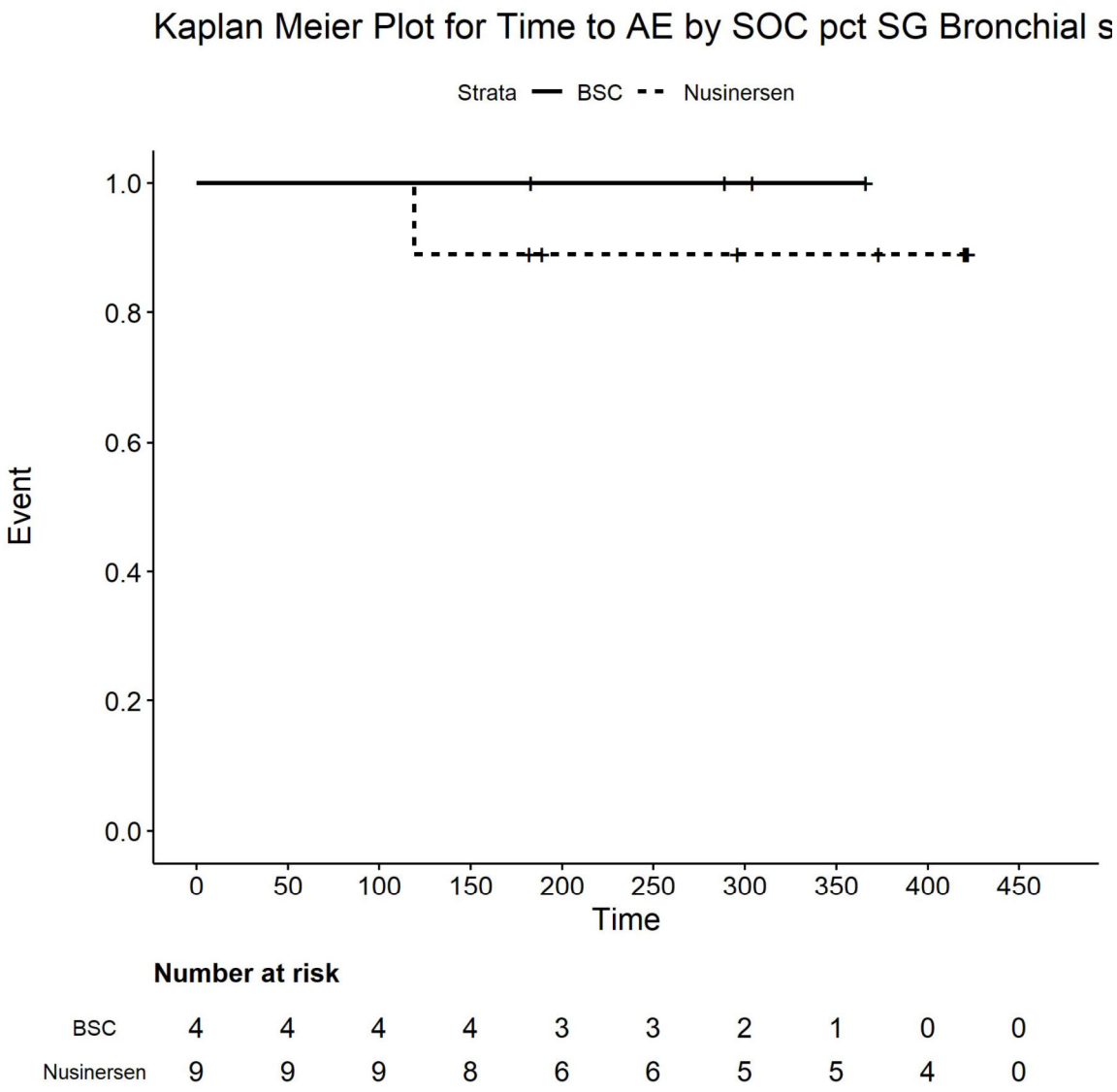
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



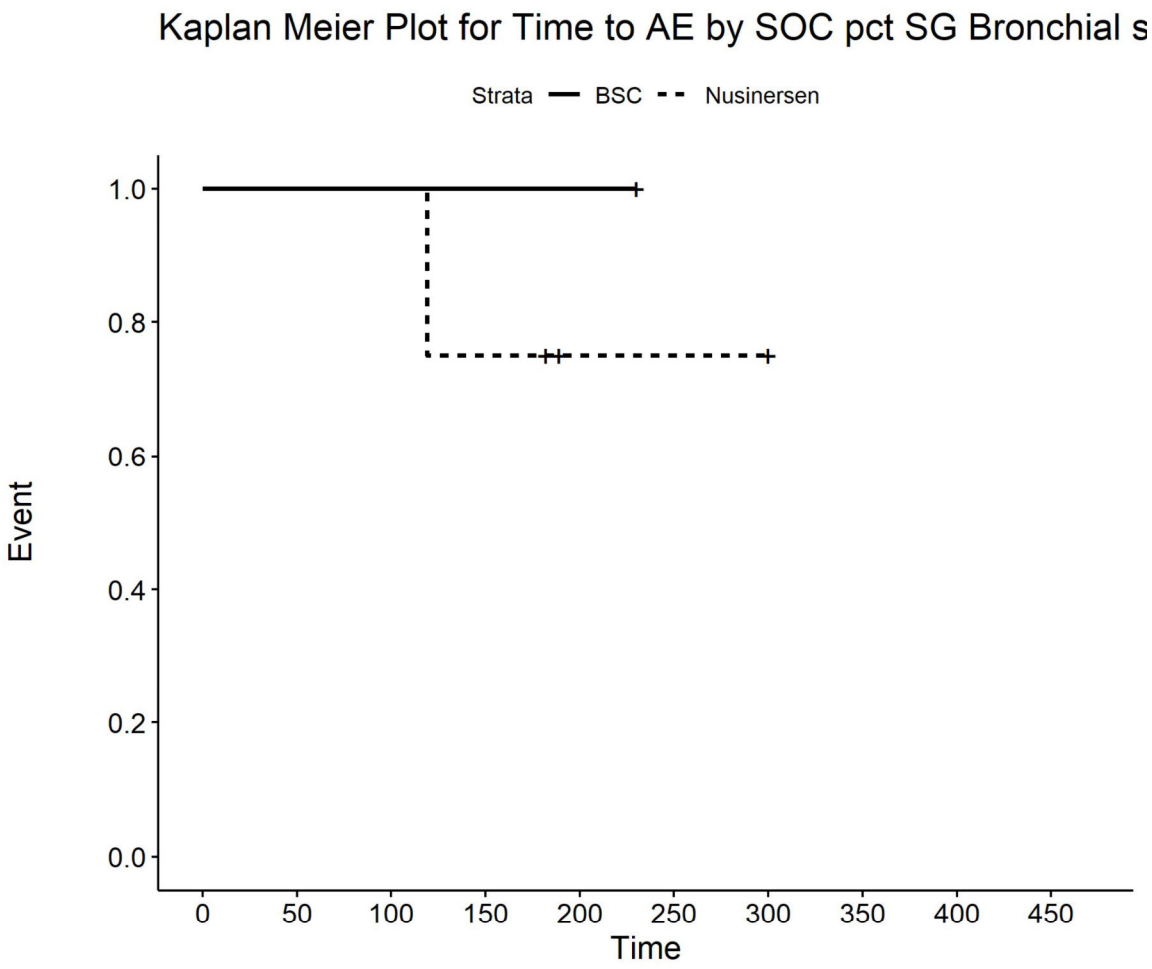
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	6	5	0



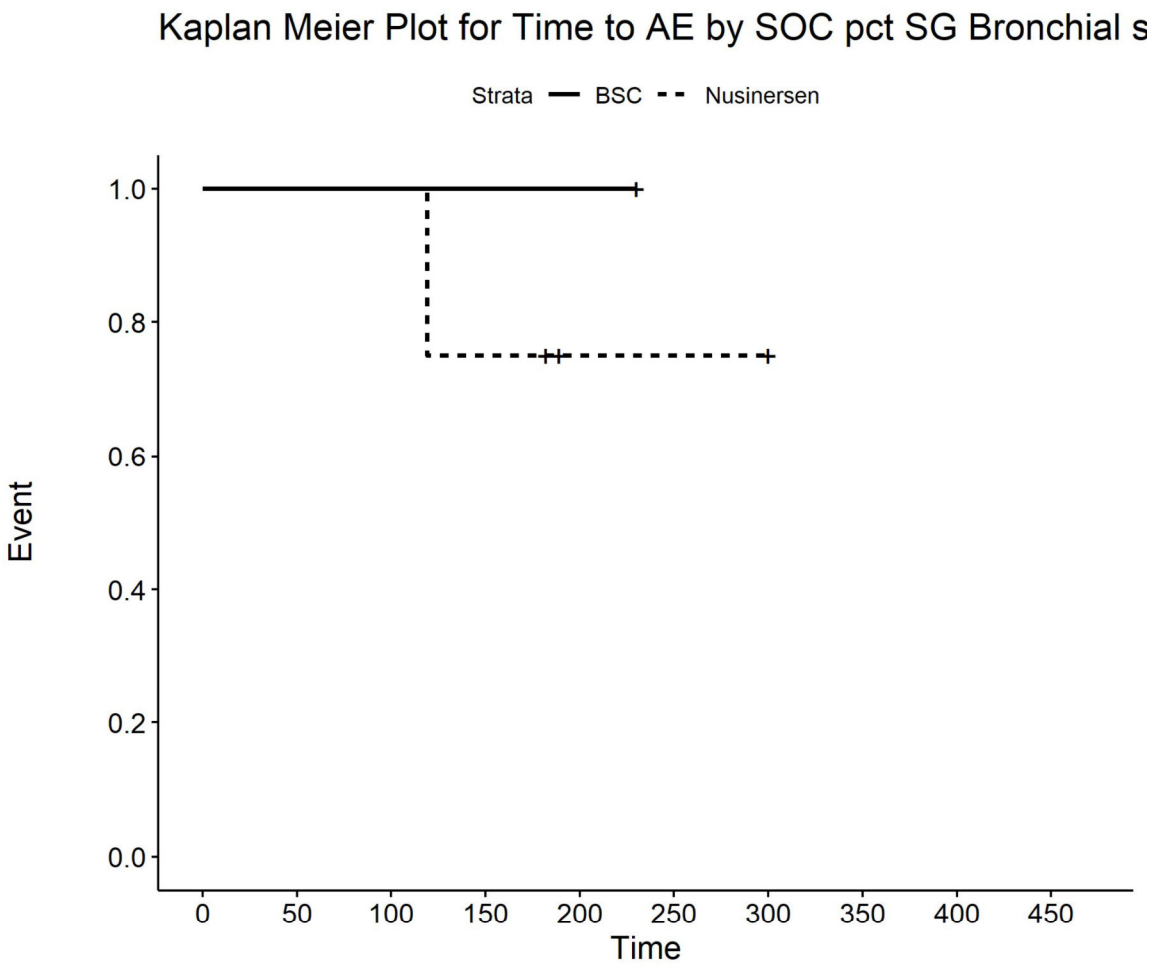
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	5	4	0



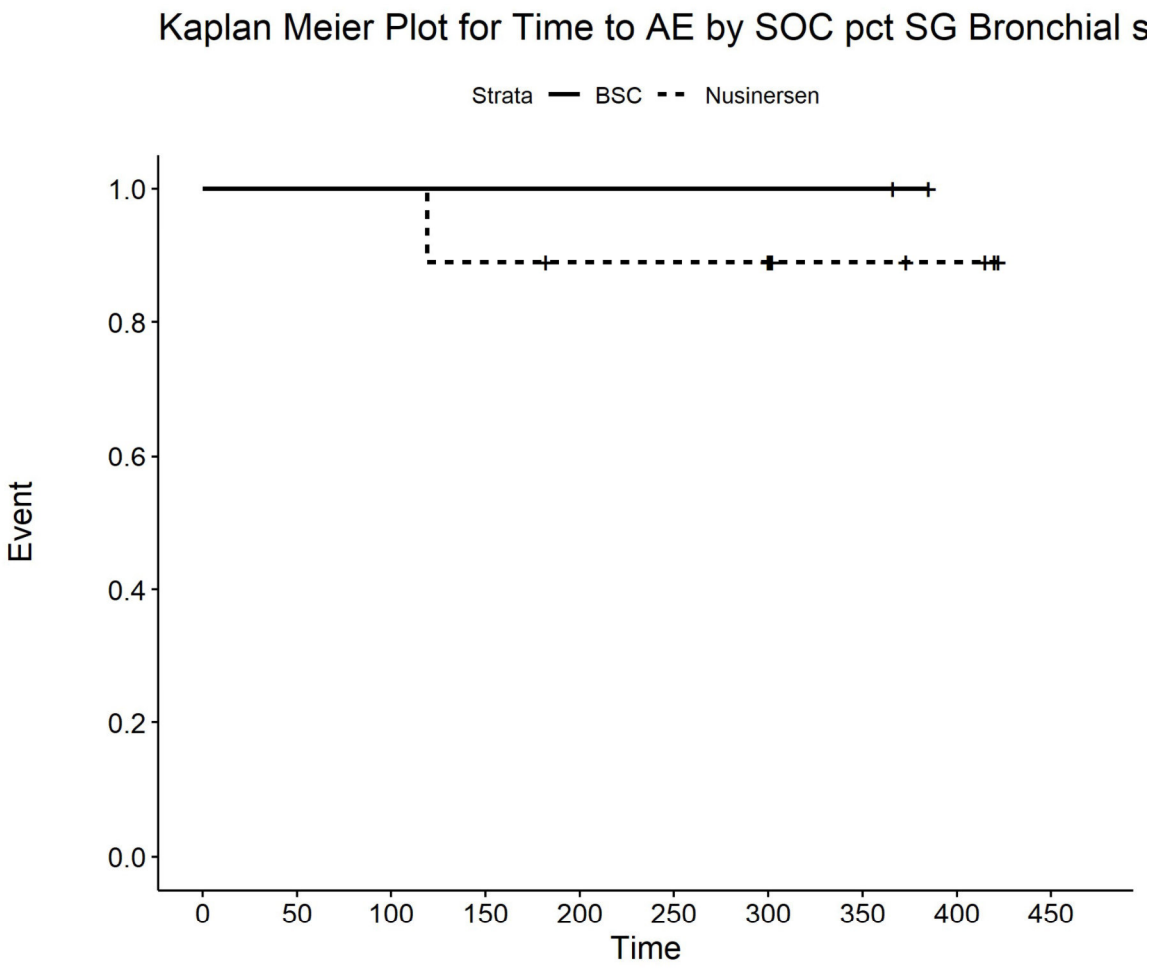
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



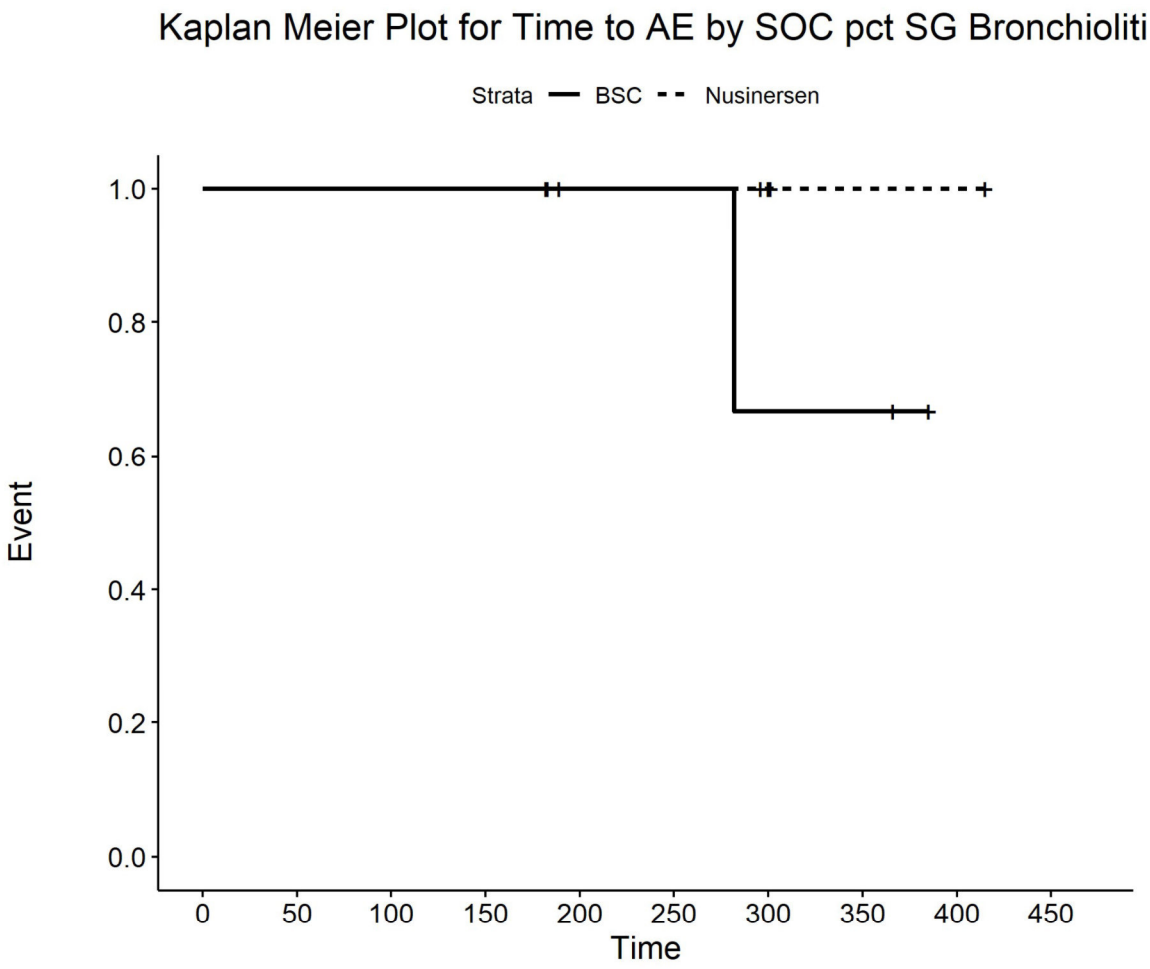
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



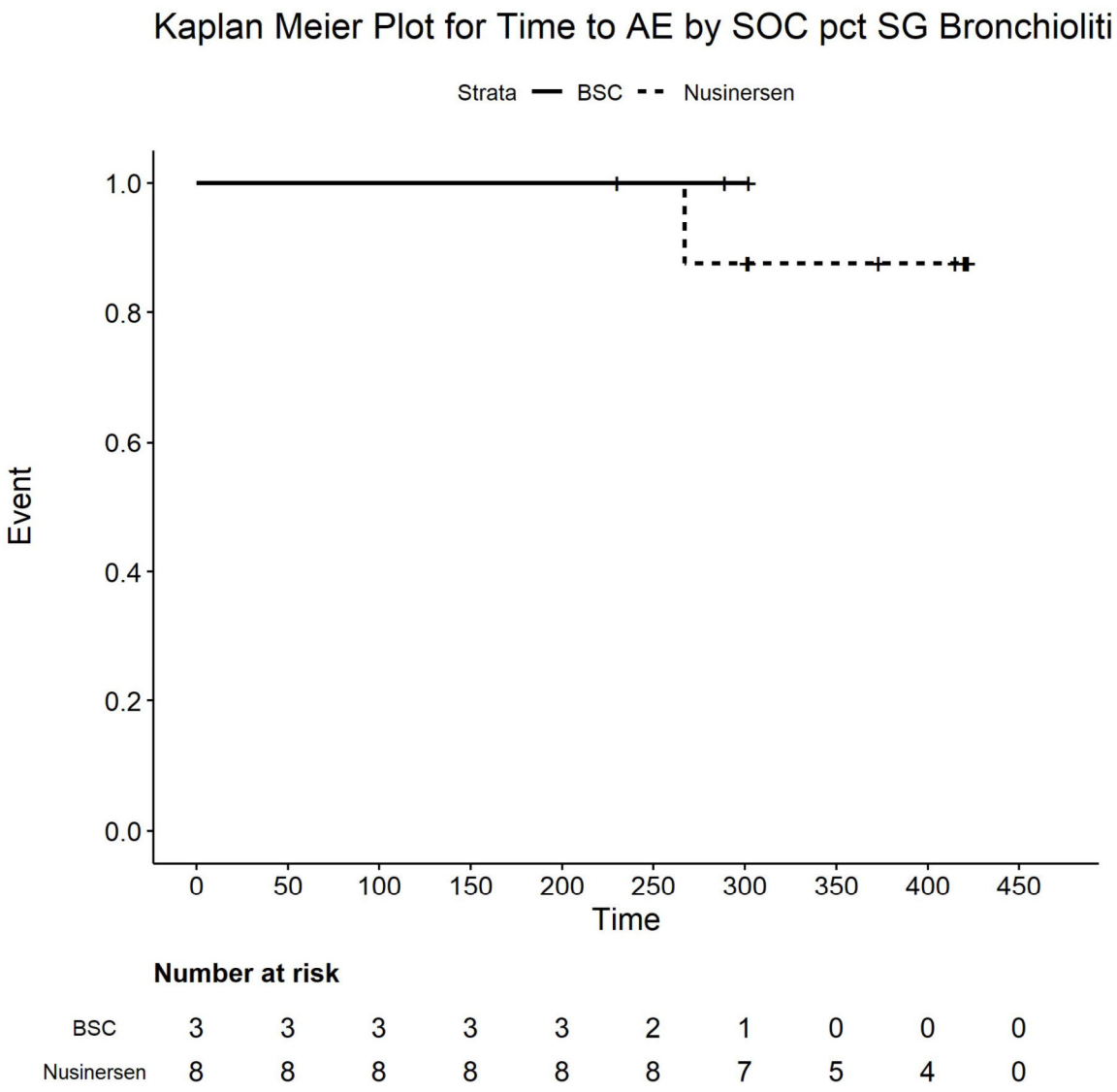
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	4	3	0



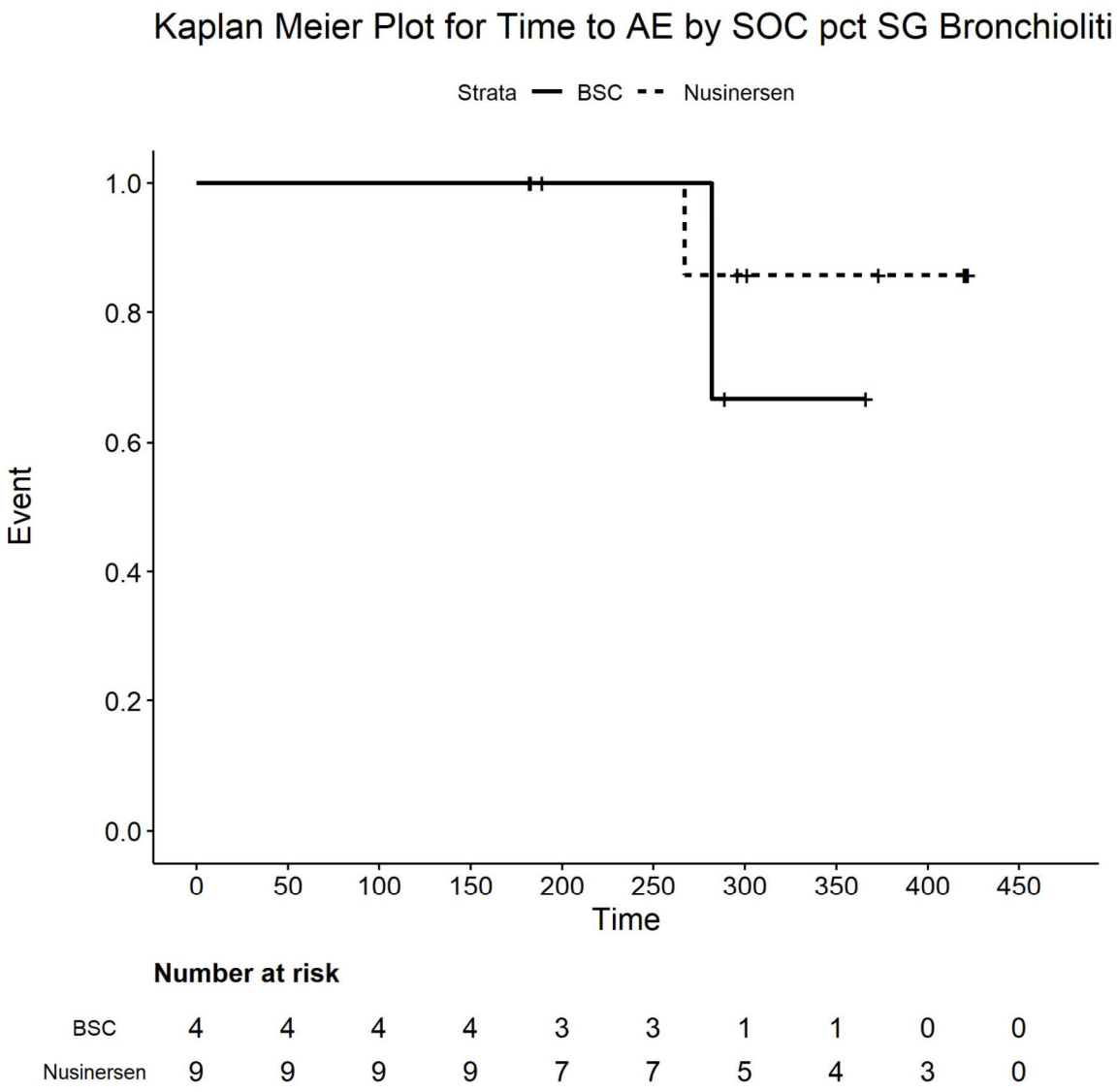
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



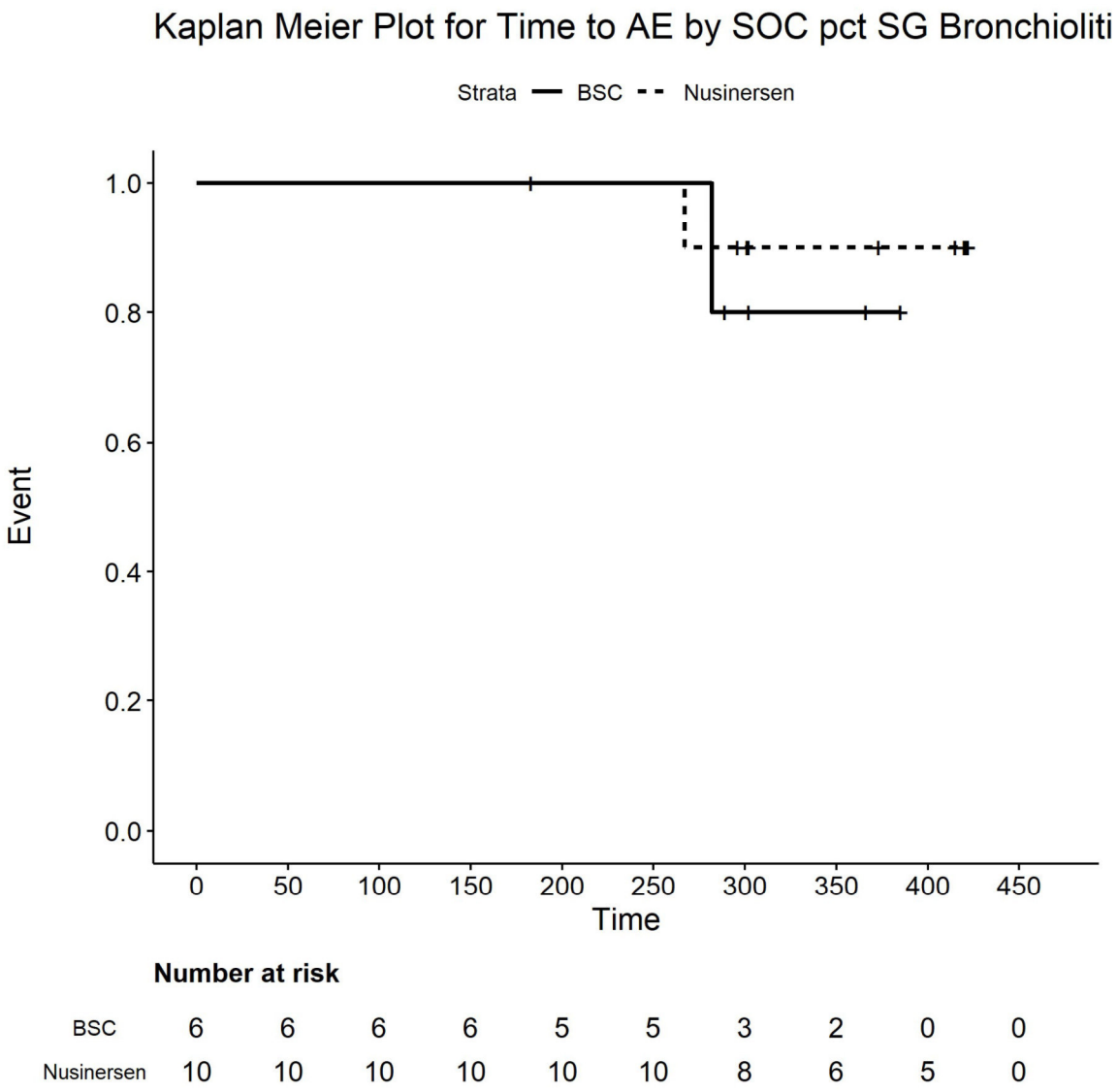
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	7	5	4	0



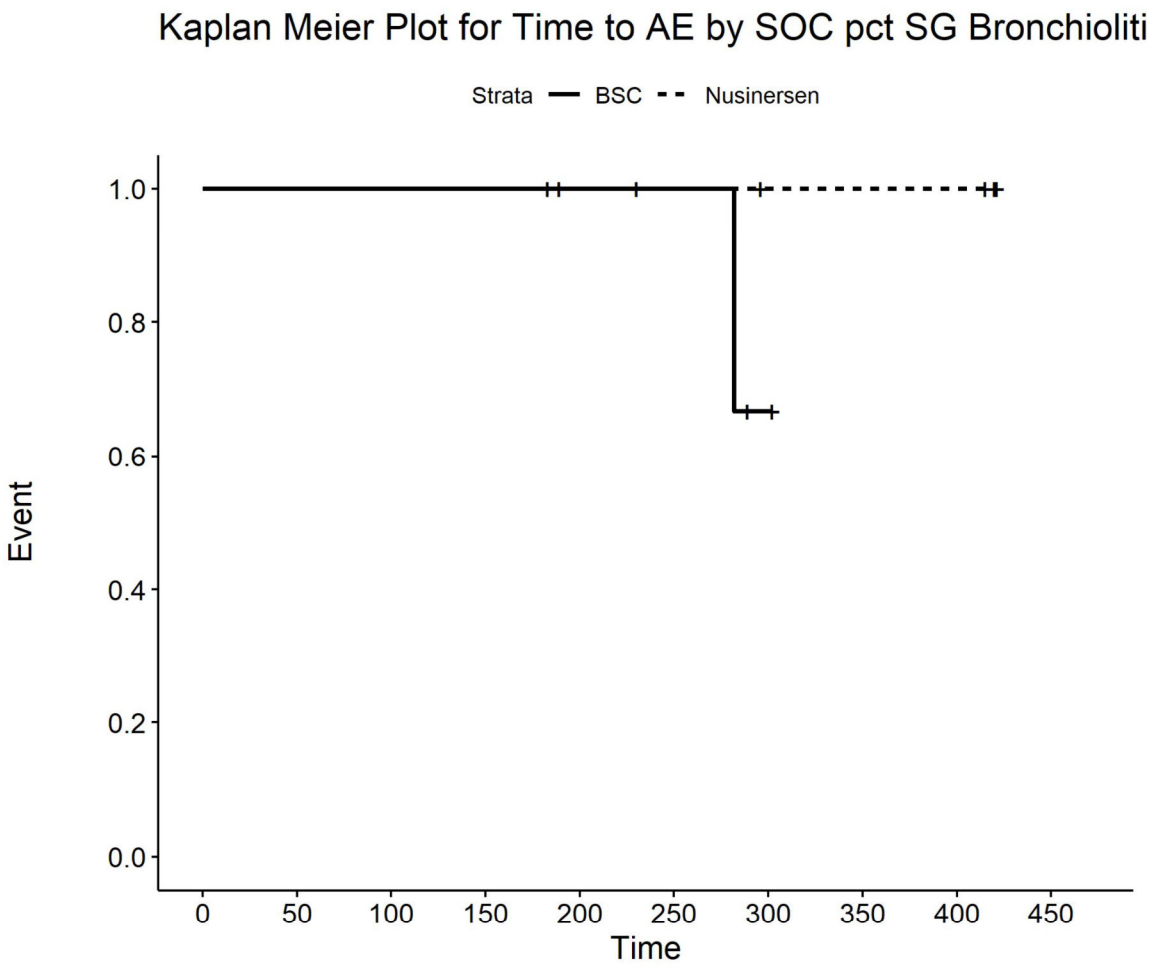
Number at risk

BSC	4	4	4	4	3	3	1	1	0	0
Nusinersen	9	9	9	9	7	7	5	4	3	0



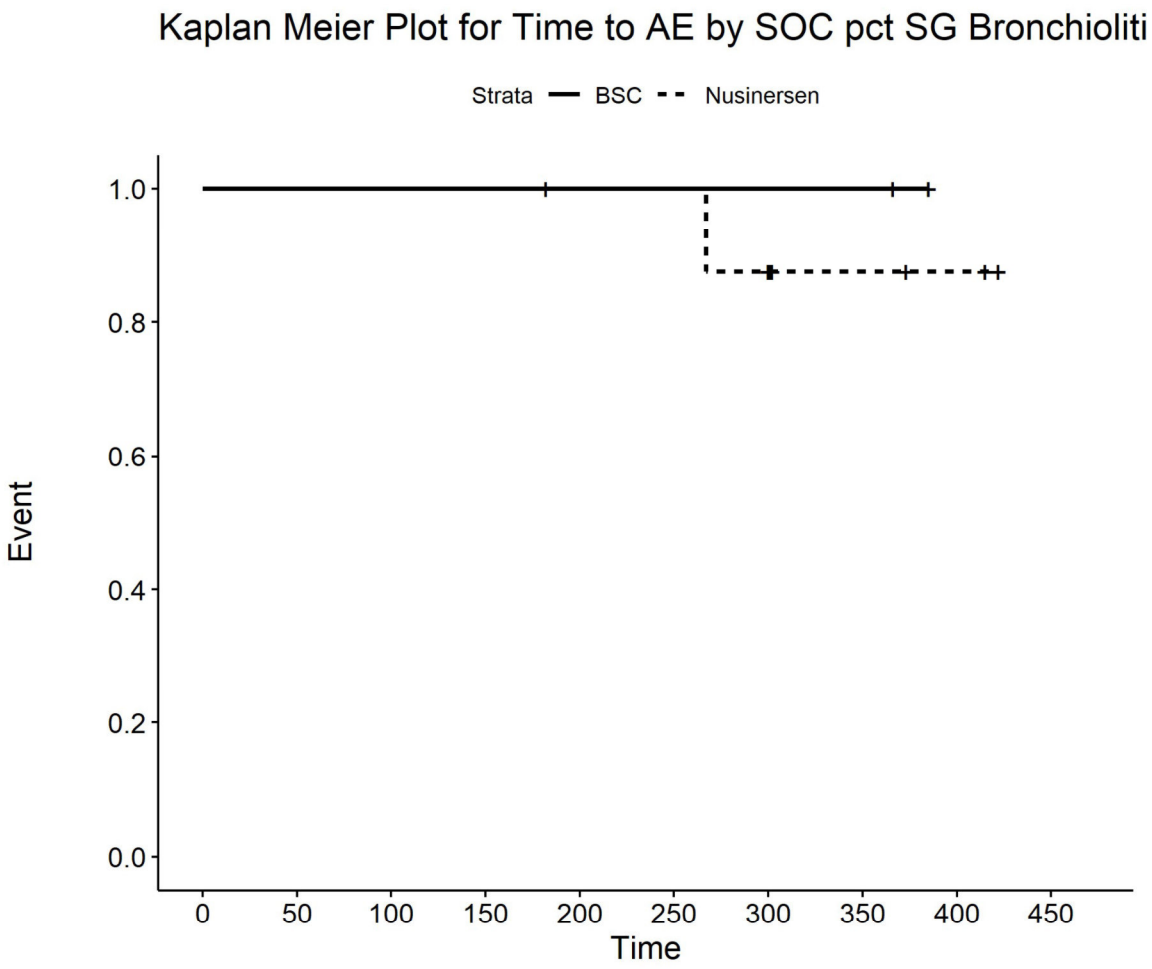
Number at risk

BSC	6	6	6	6	5	5	3	2	0	0
Nusinersen	10	10	10	10	10	10	8	6	5	0



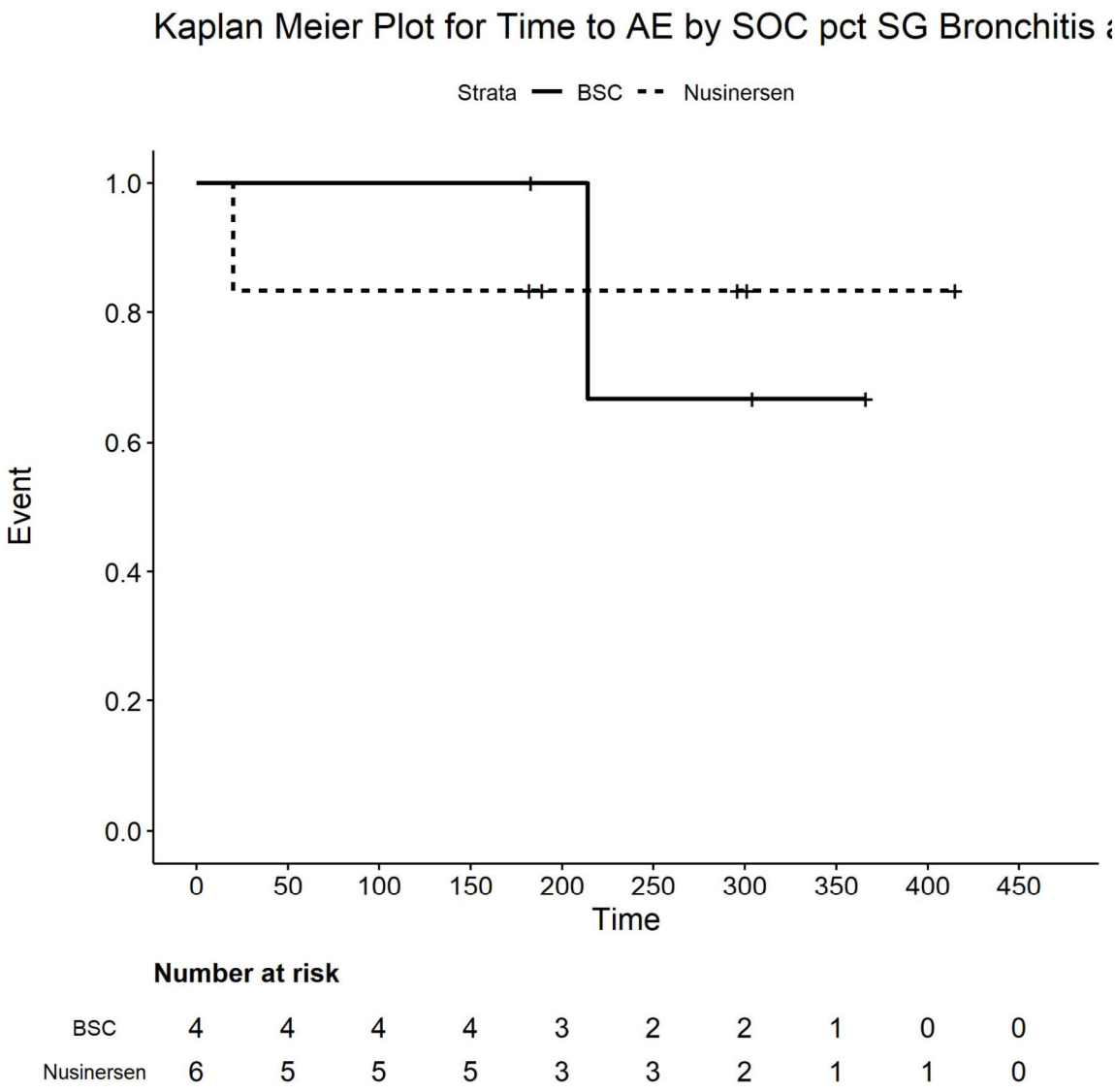
Number at risk

BSC	5	5	5	5	4	3	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



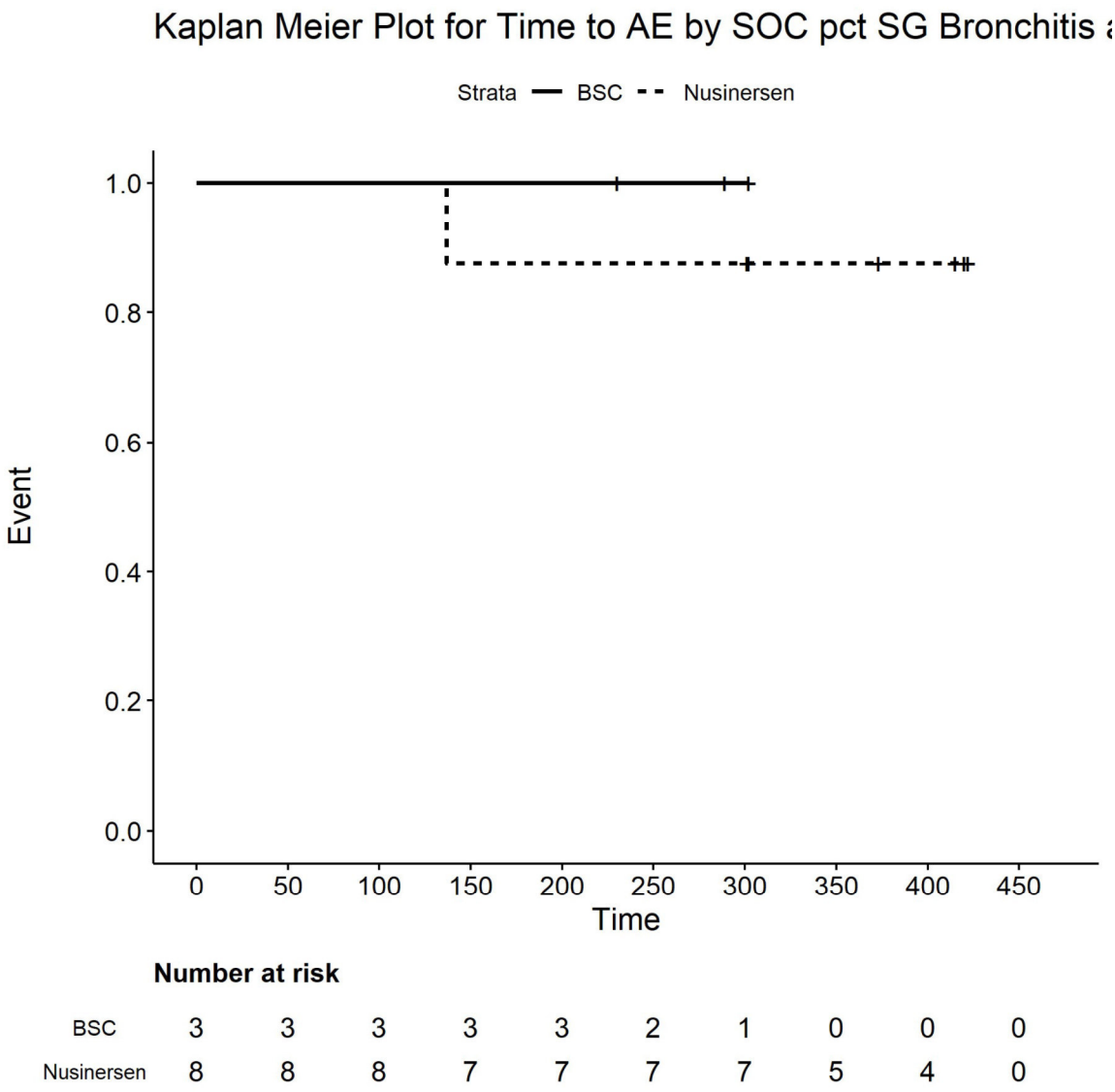
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	7	3	2	0



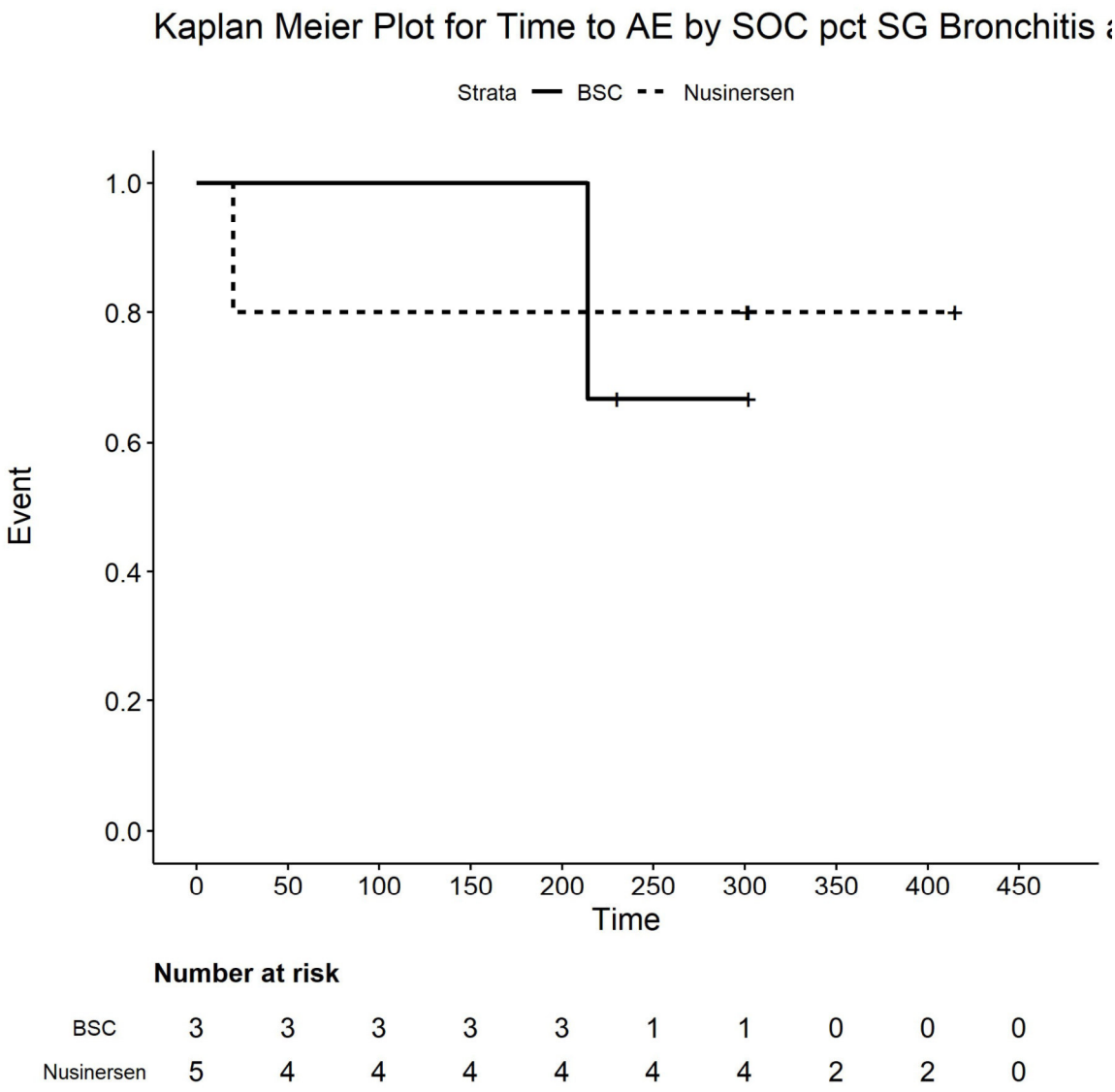
Number at risk

BSC	4	4	4	4	3	2	2	1	0	0
Nusinersen	6	5	5	5	3	3	2	1	1	0



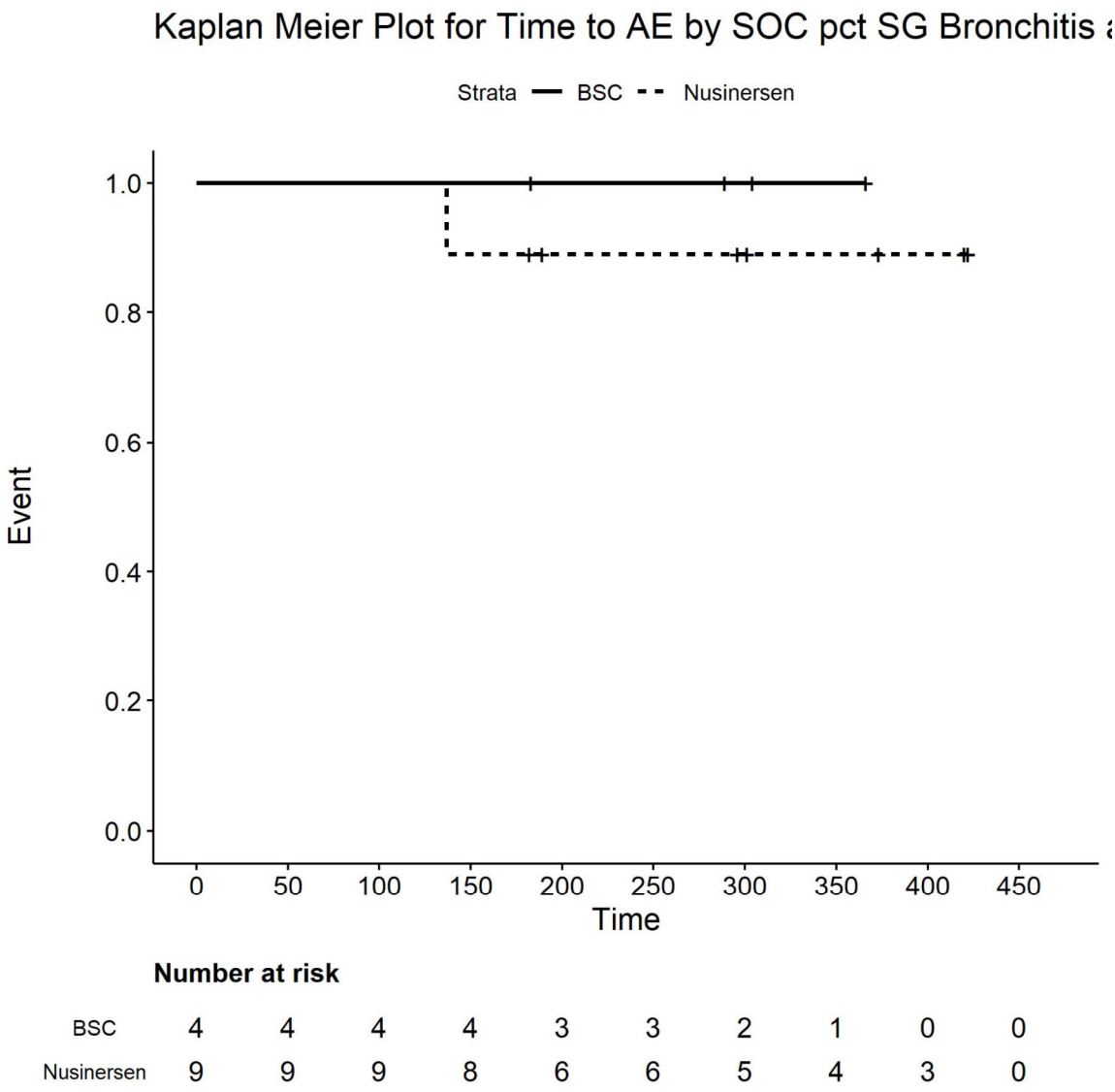
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



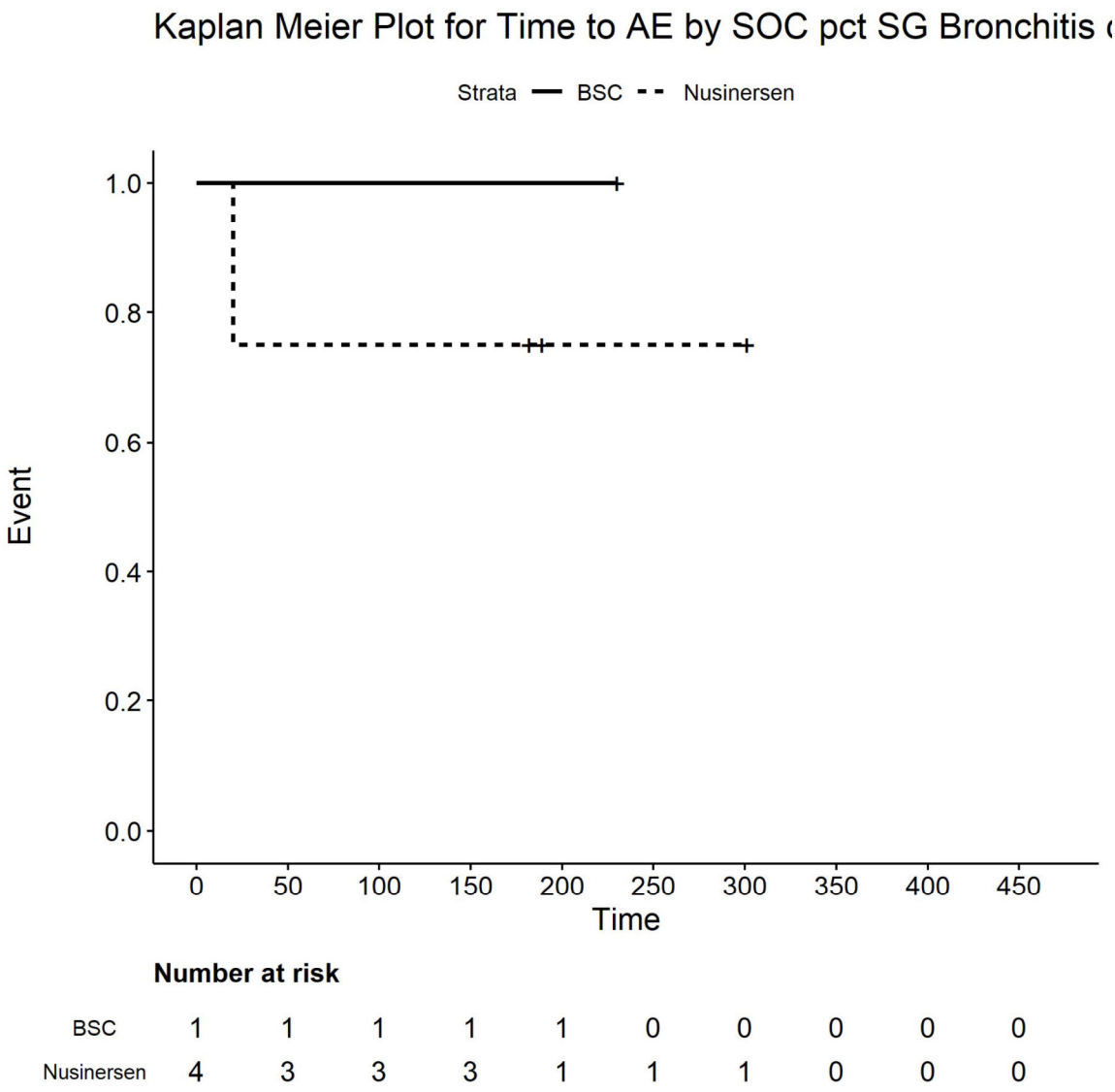
Number at risk

BSC	3	3	3	3	3	1	1	0	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



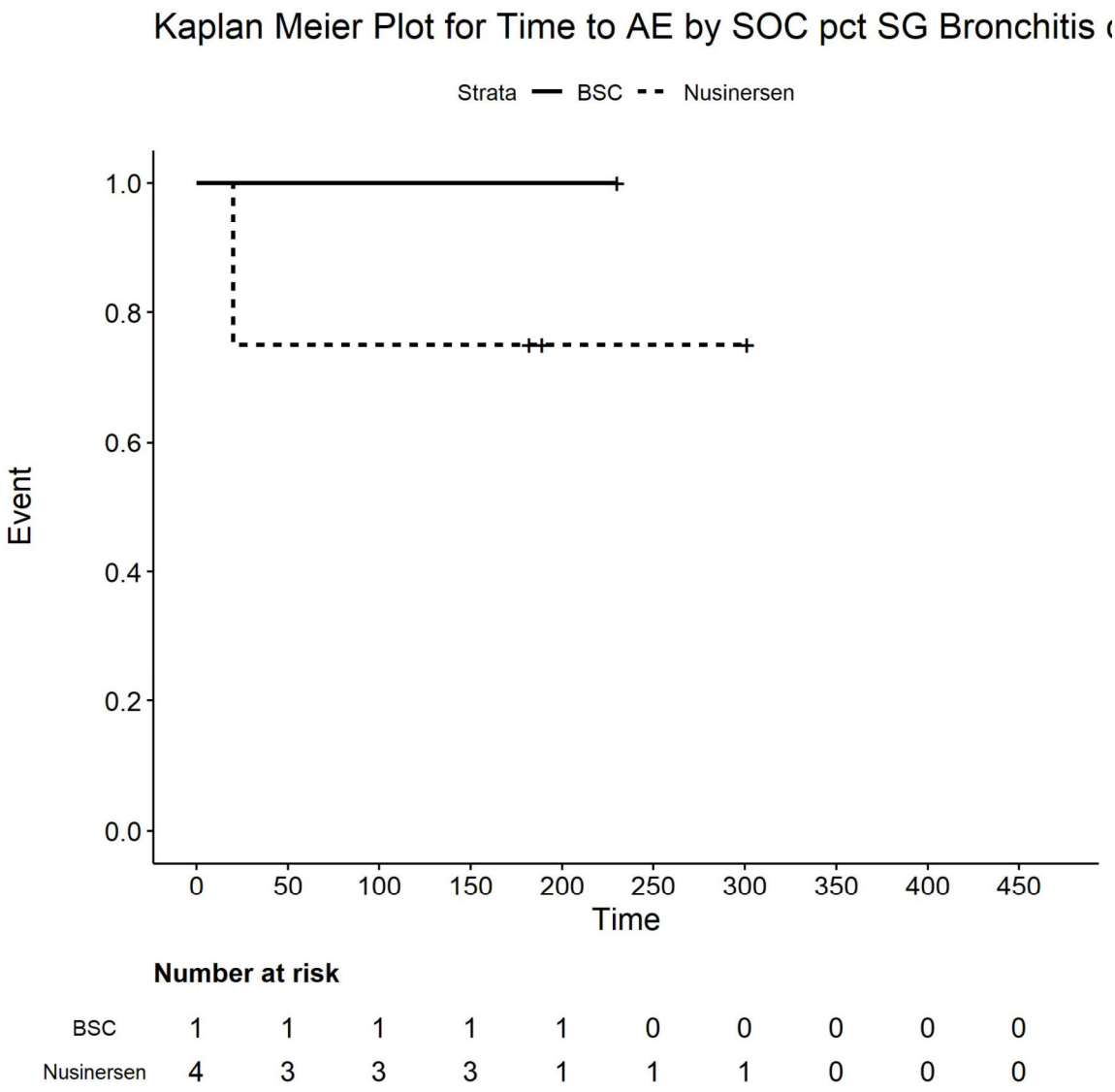
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



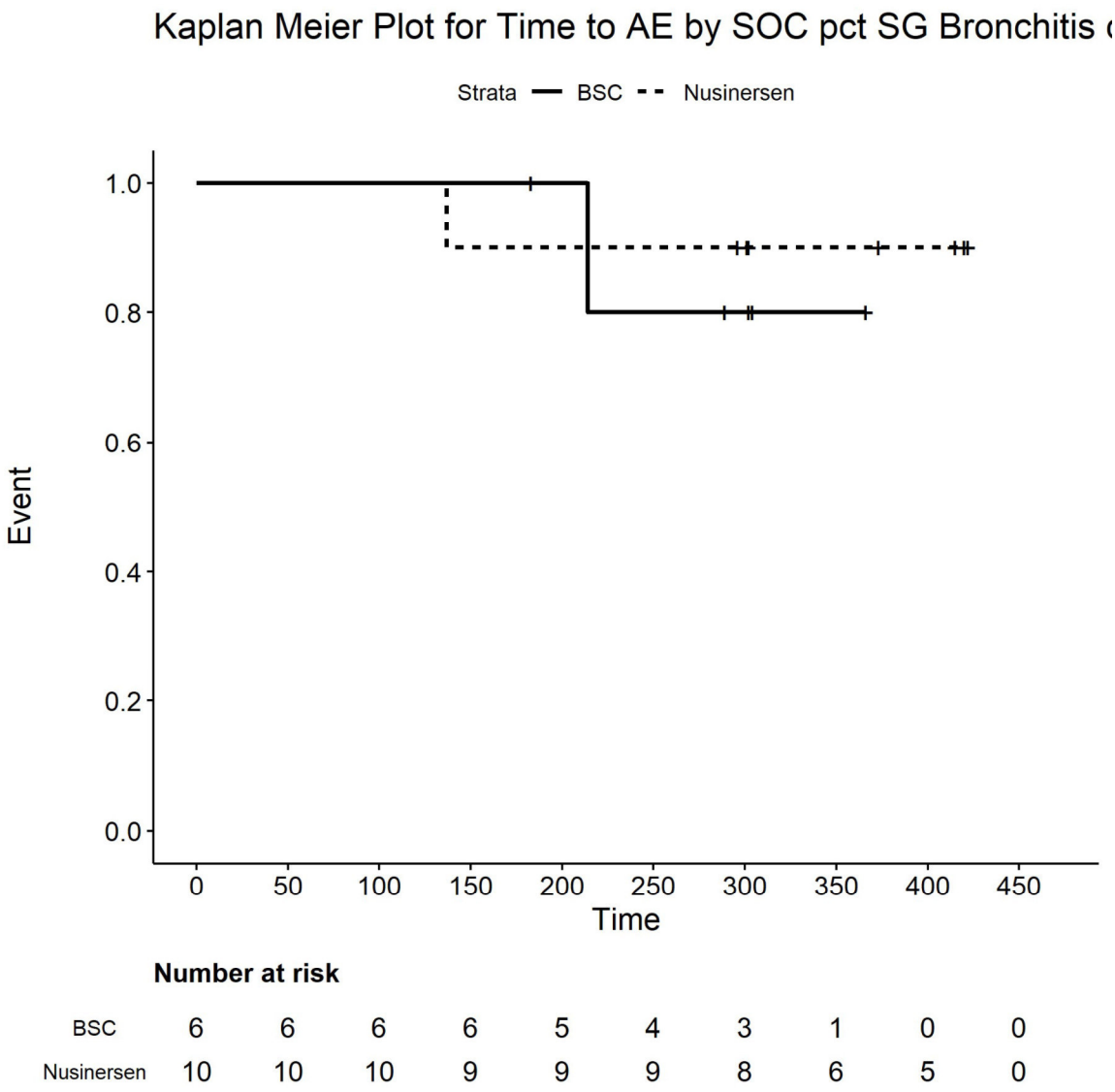
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



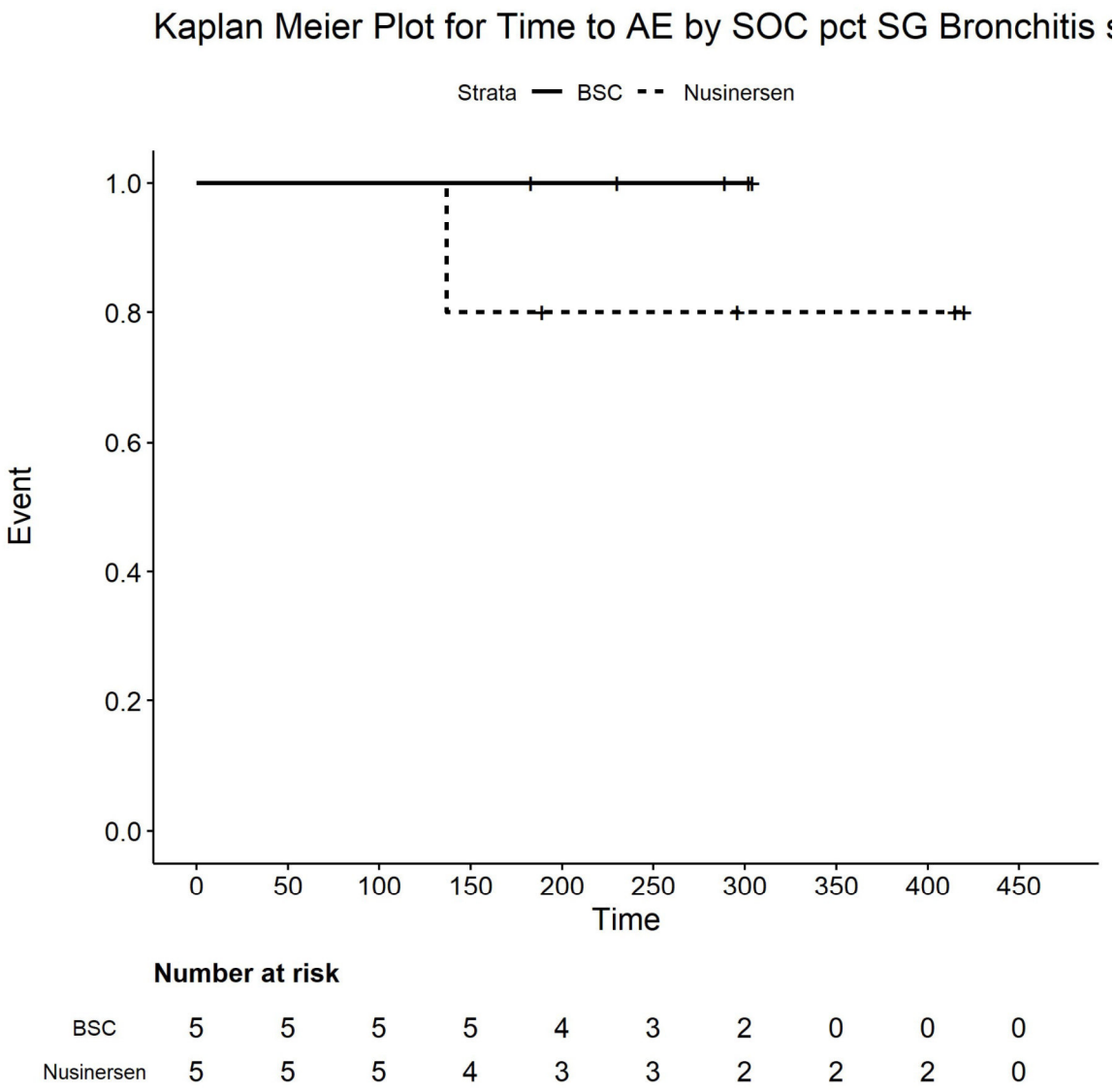
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



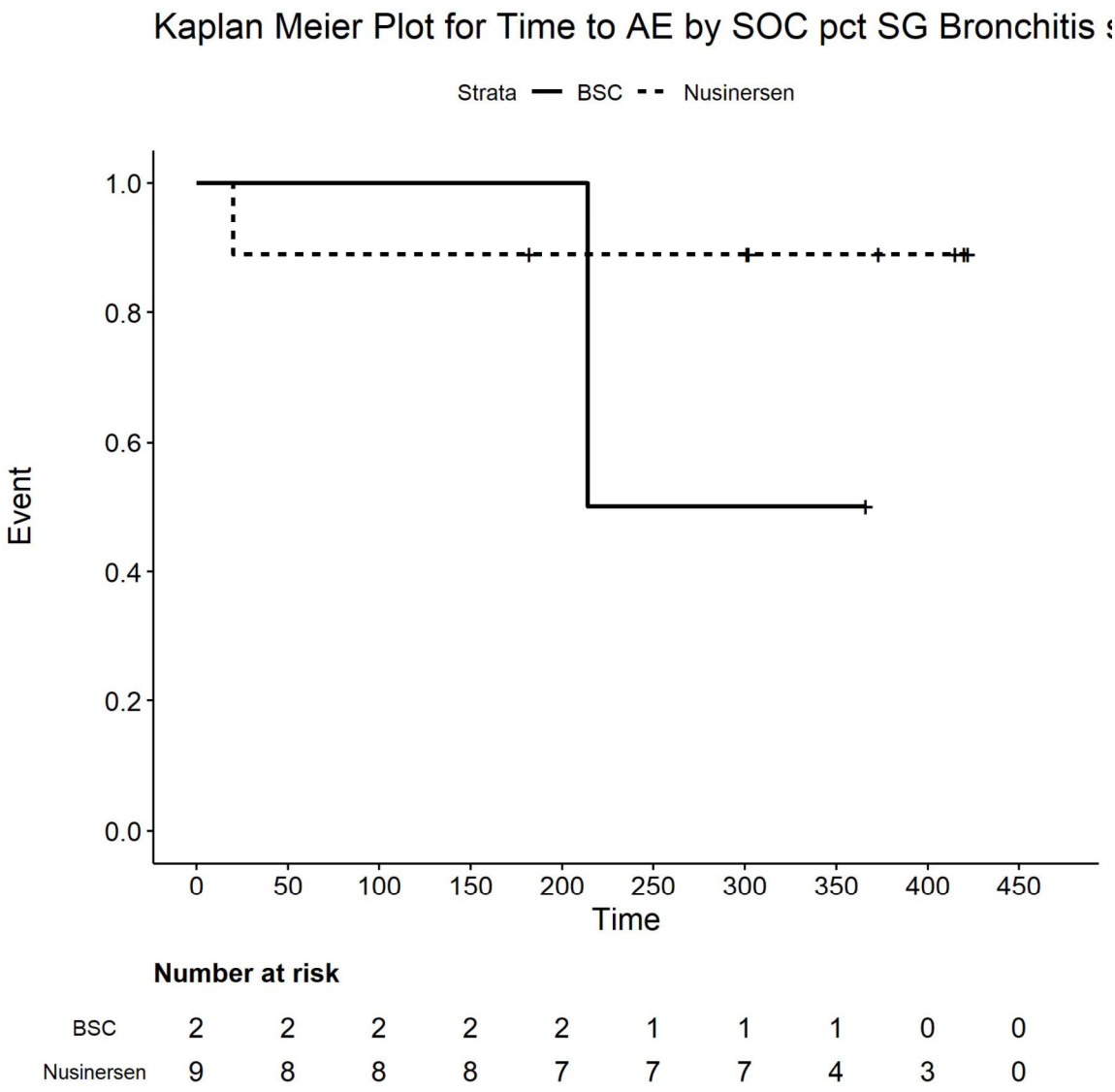
Number at risk

BSC	6	6	6	6	5	4	3	1	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



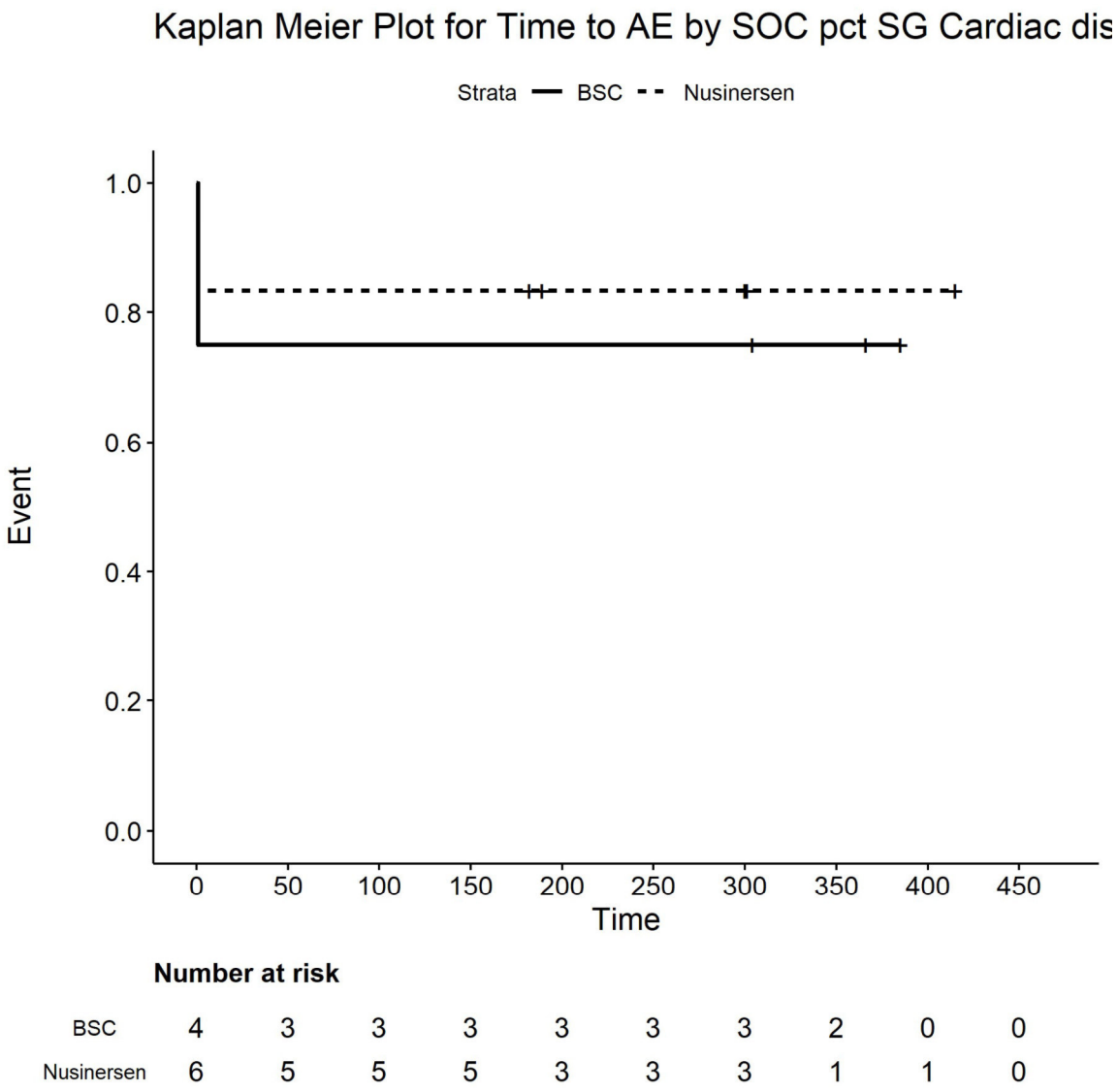
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	4	3	3	2	2	2	0



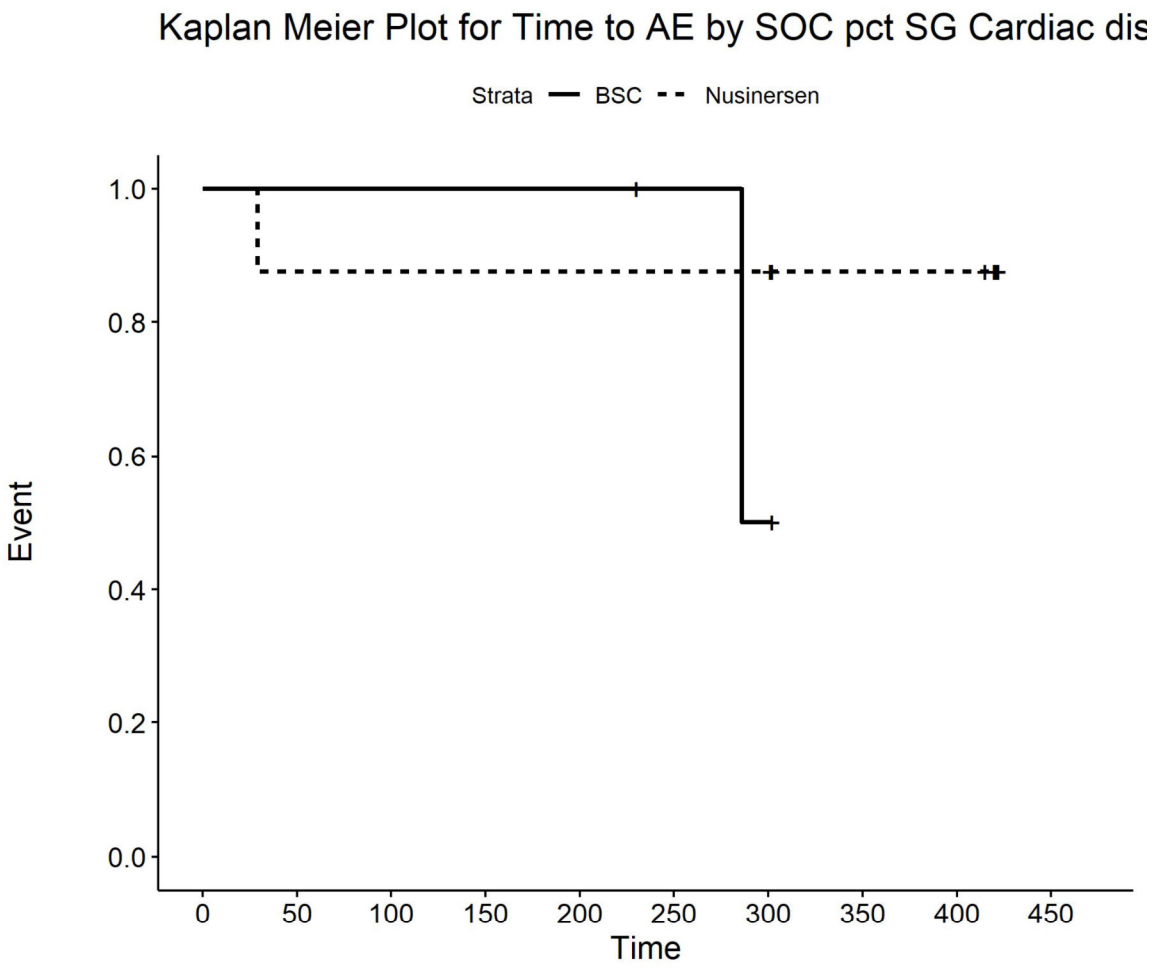
Number at risk

BSC	2	2	2	2	2	1	1	1	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



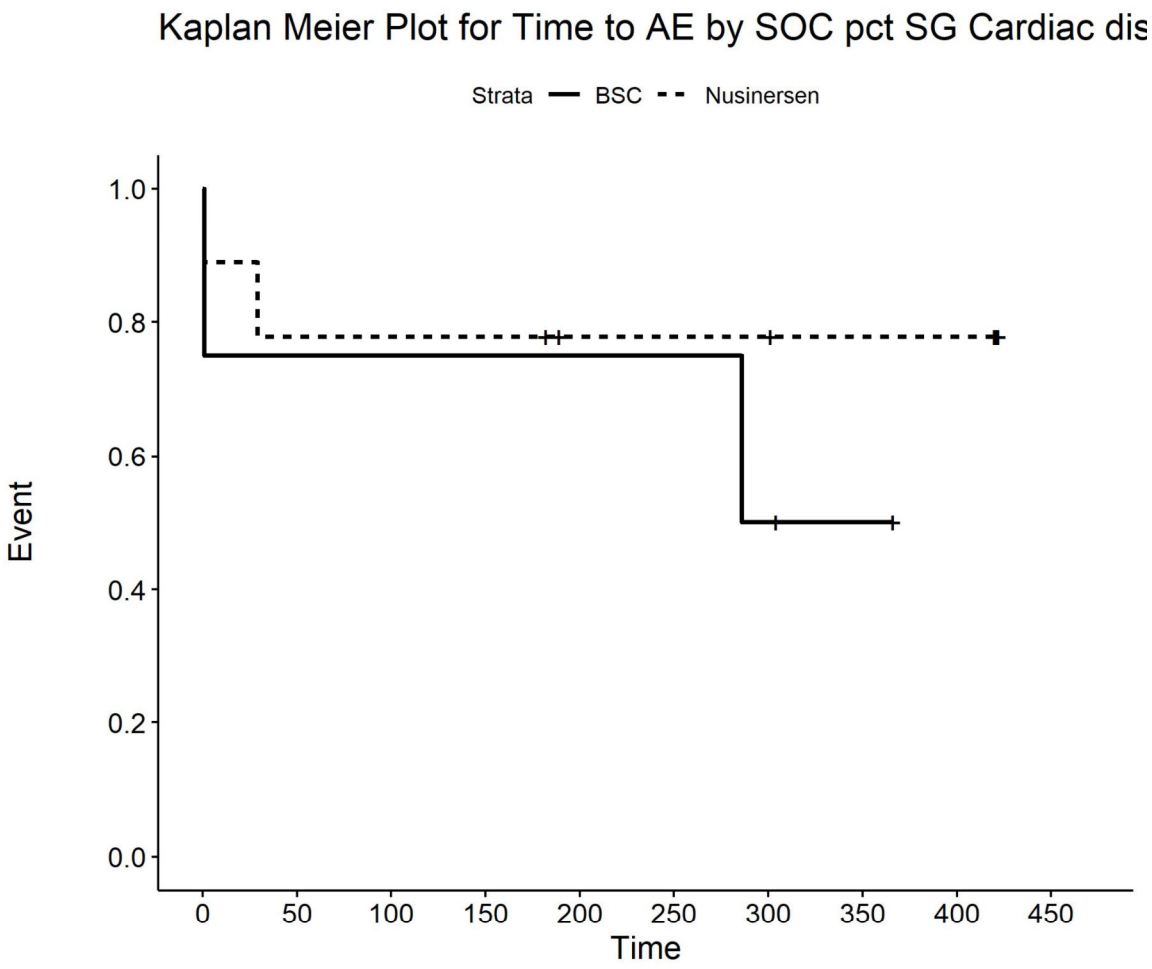
Number at risk

BSC	4	3	3	3	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	3	1	1	0



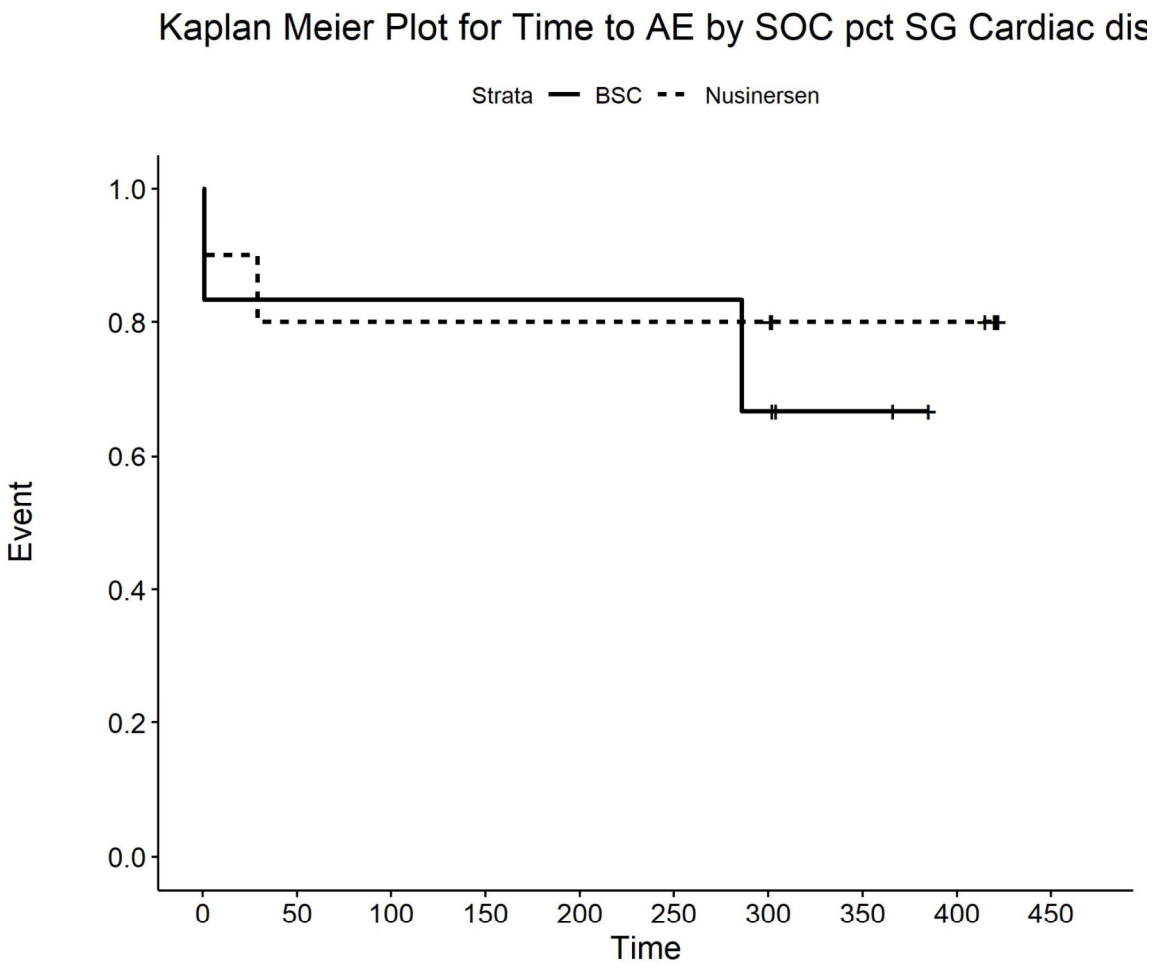
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	5	0



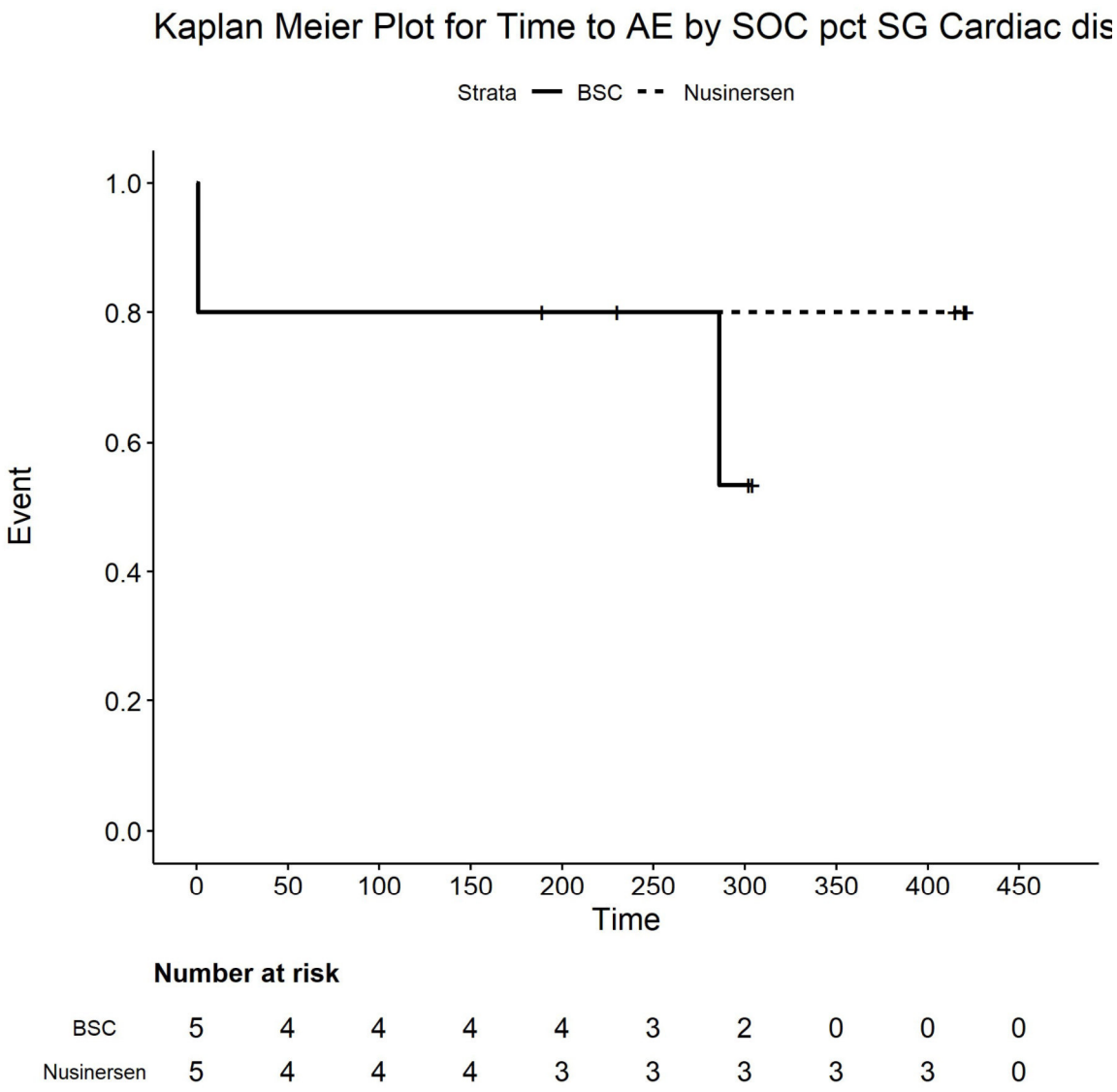
Number at risk

BSC	4	3	3	3	3	3	2	1	0	0
Nusinersen	9	7	7	7	5	5	5	4	4	0



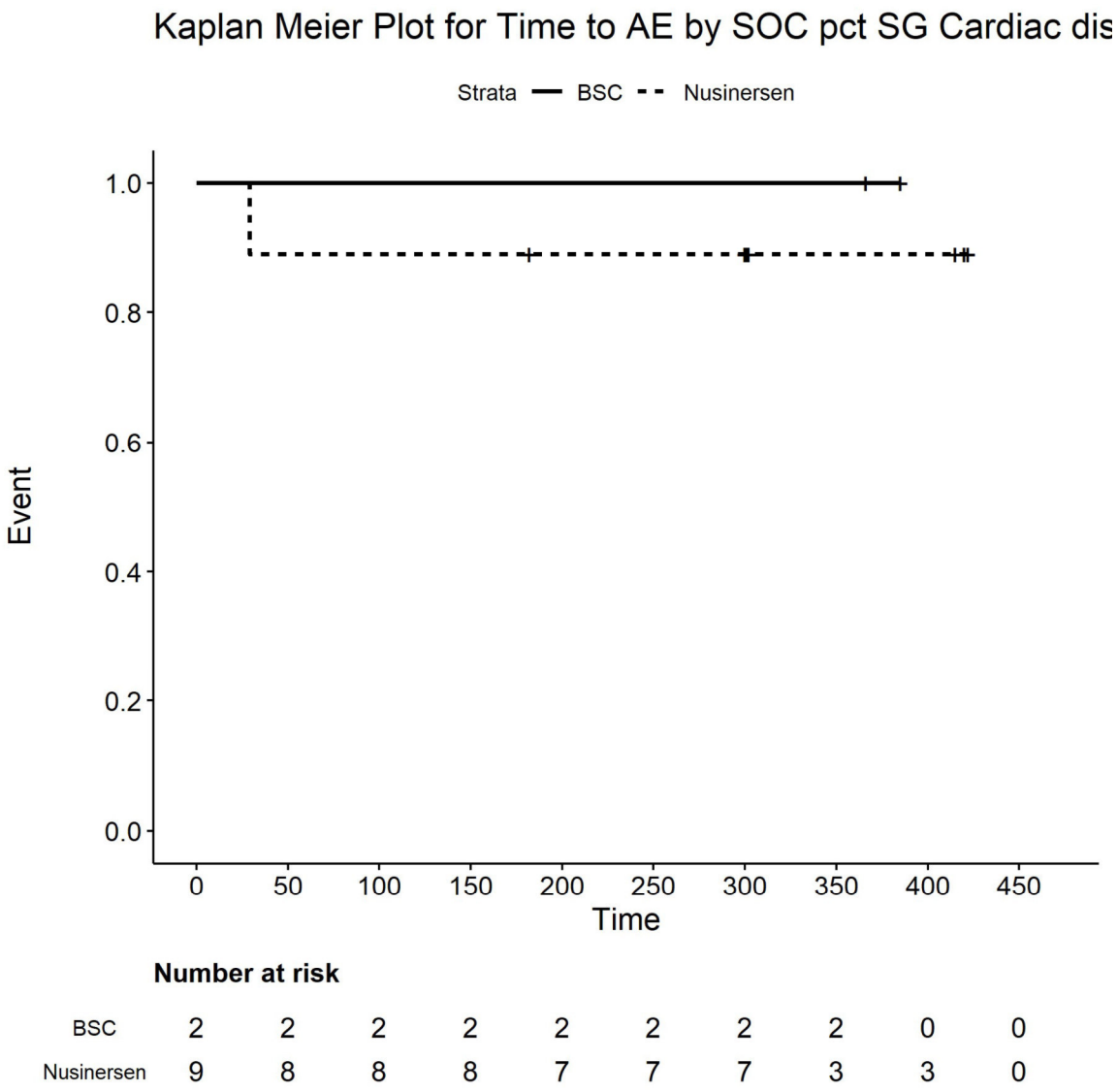
Number at risk

BSC	6	5	5	5	5	5	4	2	0	0
Nusinersen	10	8	8	8	8	8	8	6	6	0



Number at risk

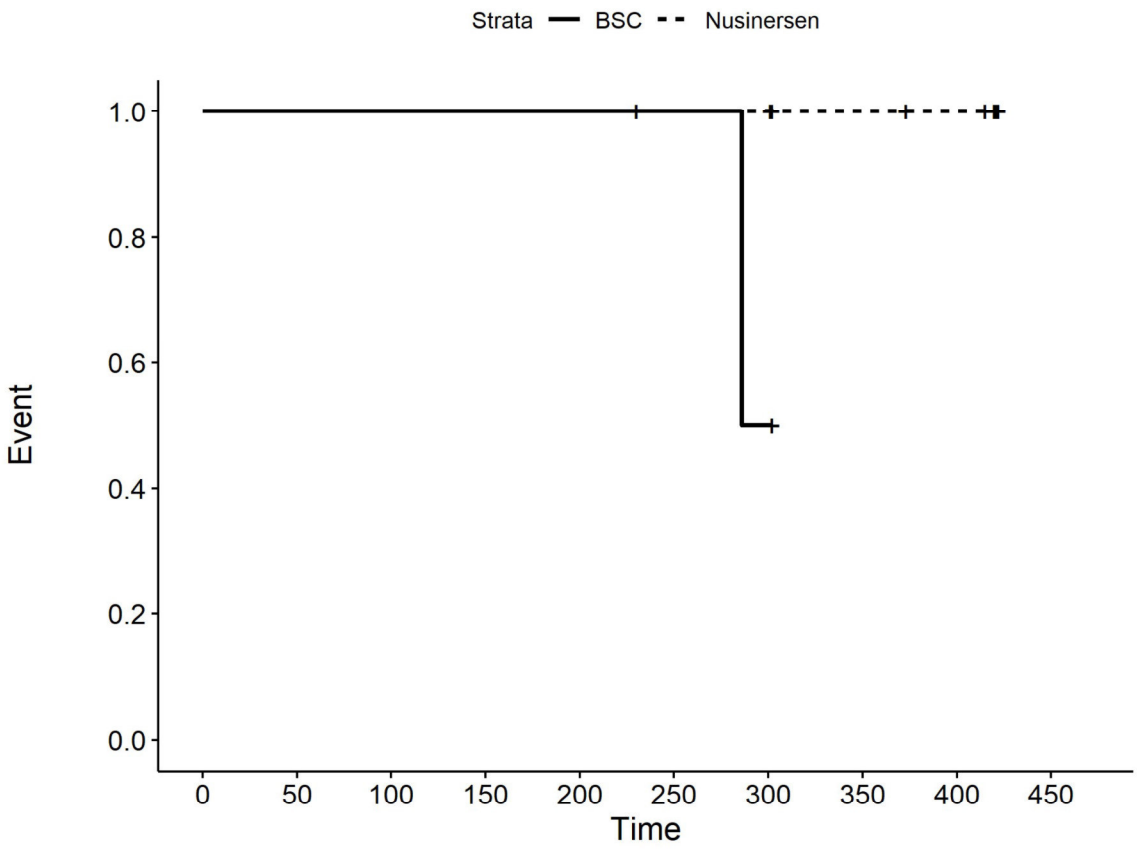
BSC	5	4	4	4	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	3	3	3	0



Number at risk

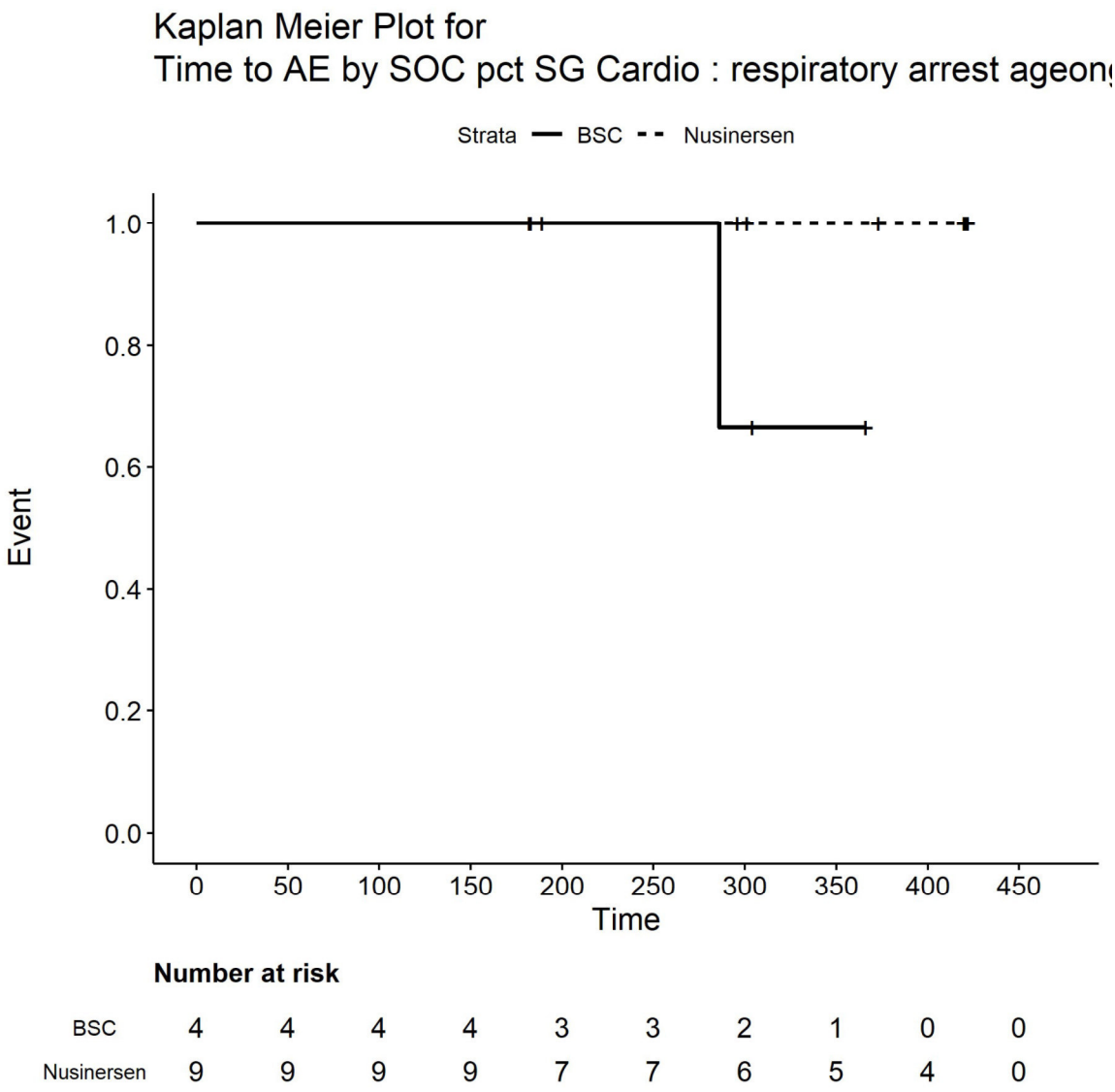
BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	3	0

Kaplan Meier Plot for
Time to AE by SOC pct SG Cardio : respiratory arrest agefdc

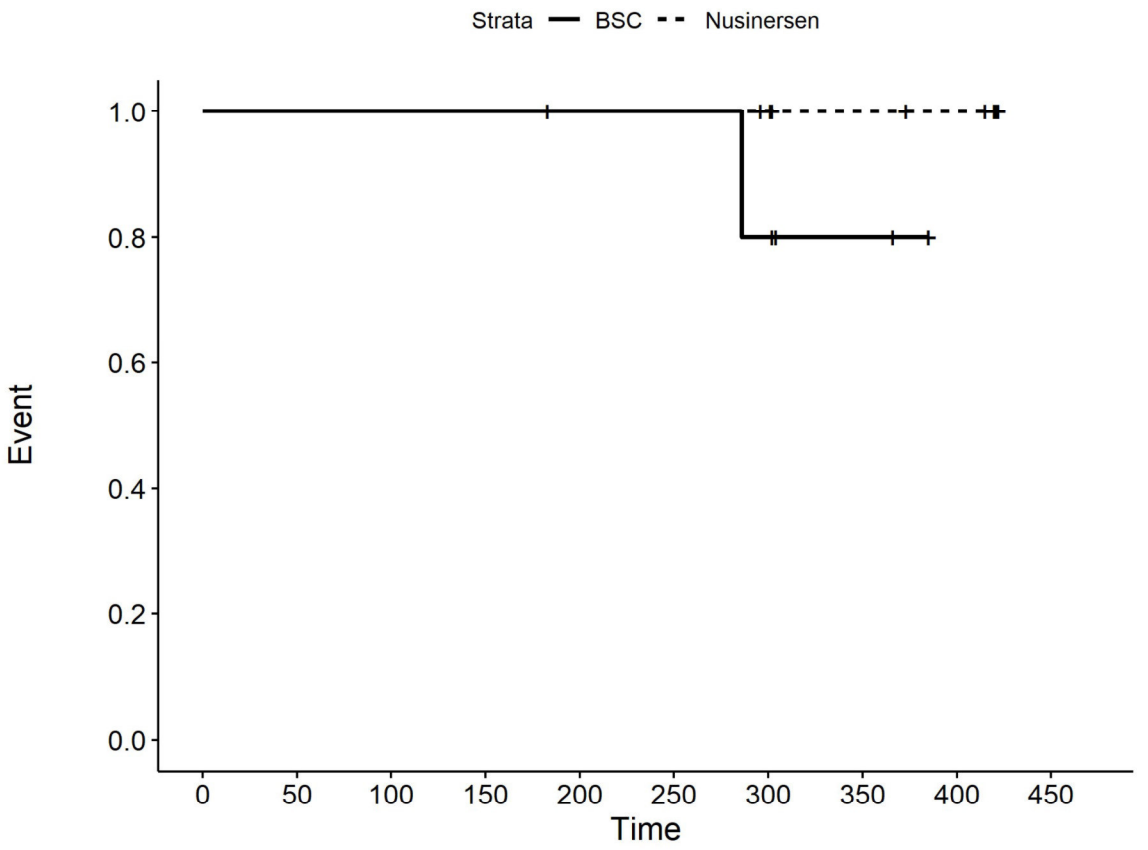


Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0


Kaplan Meier Plot for
Time to AE by SOC pct SG Cardio : respiratory arrest ageon
Strata BSC Nusinersen
Event
1.0
0.8
0.6
0.4
0.2
0.0
0
50
100
150
200
250
300
350
400
450
Time
Number at risk
BSC 4 4 4 4 3 3 2 1 0 0
Nusinersen 9 9 9 9 7 7 6 5 4 0

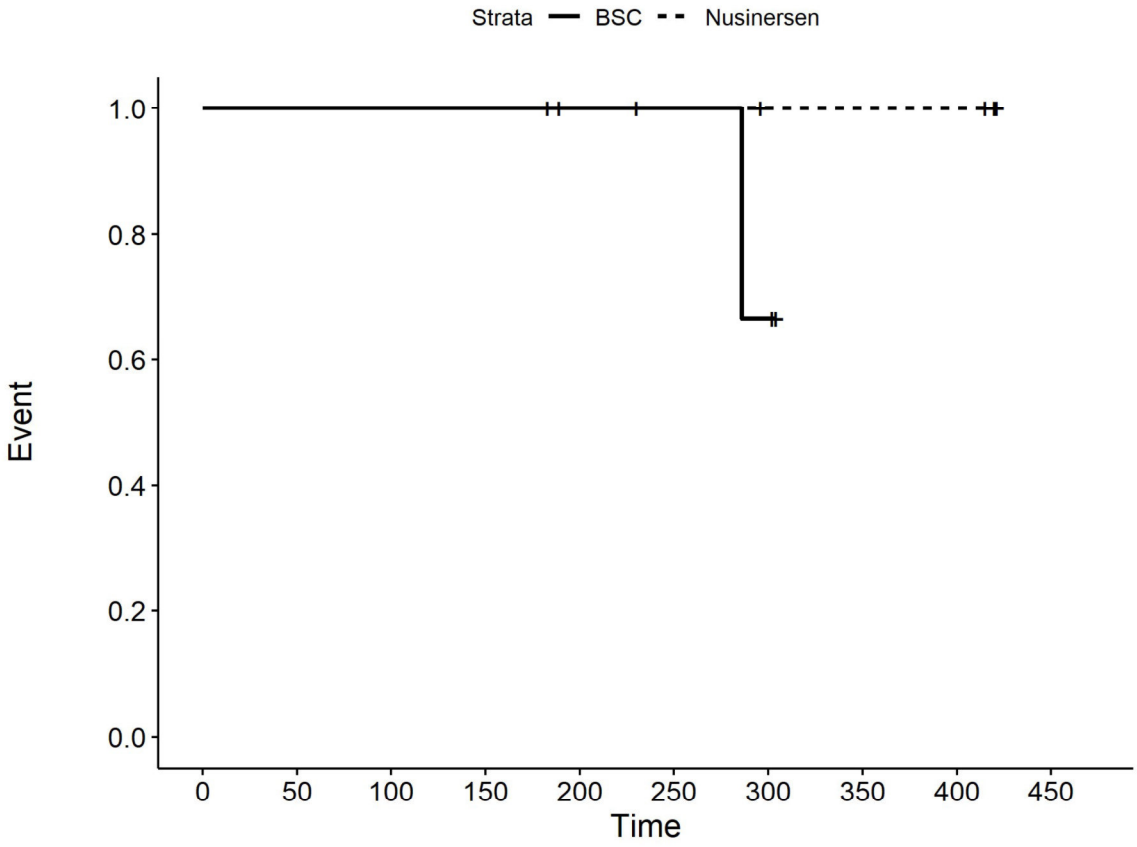
Kaplan Meier Plot for
Time to AE by SOC pct SG Cardio : respiratory arrest countr



Number at risk

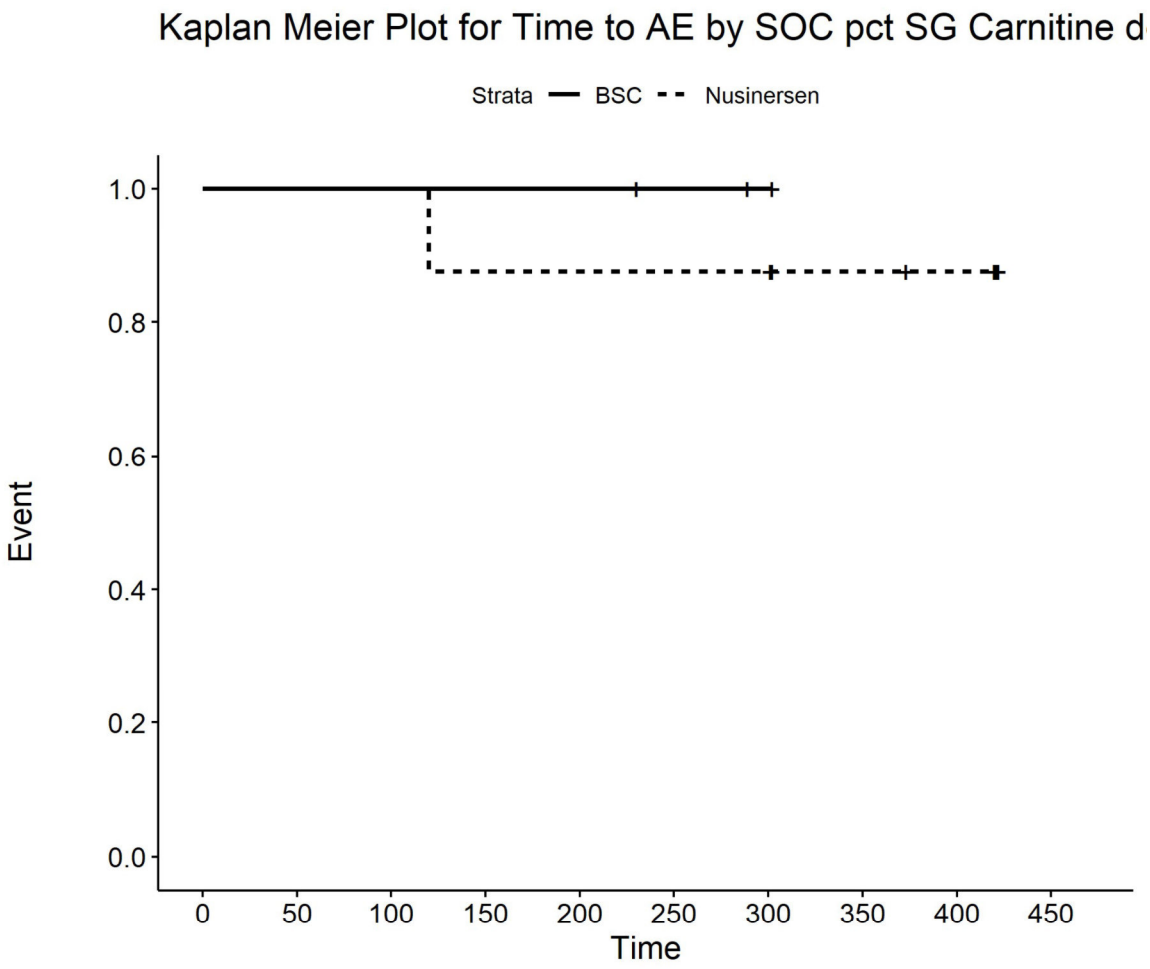
BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0

Kaplan Meier Plot for
Time to AE by SOC pct SG Cardio : respiratory arrest sex f



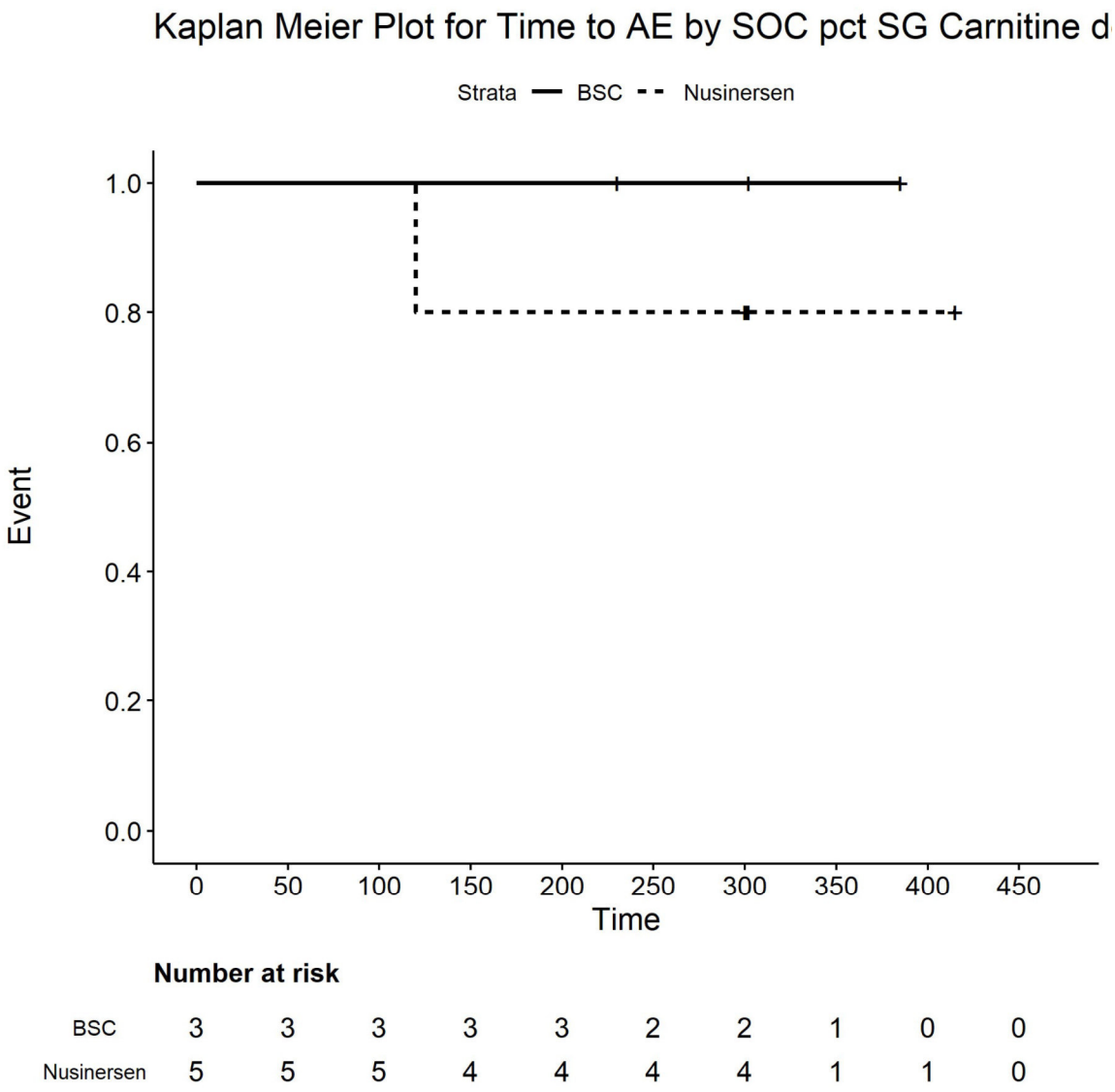
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



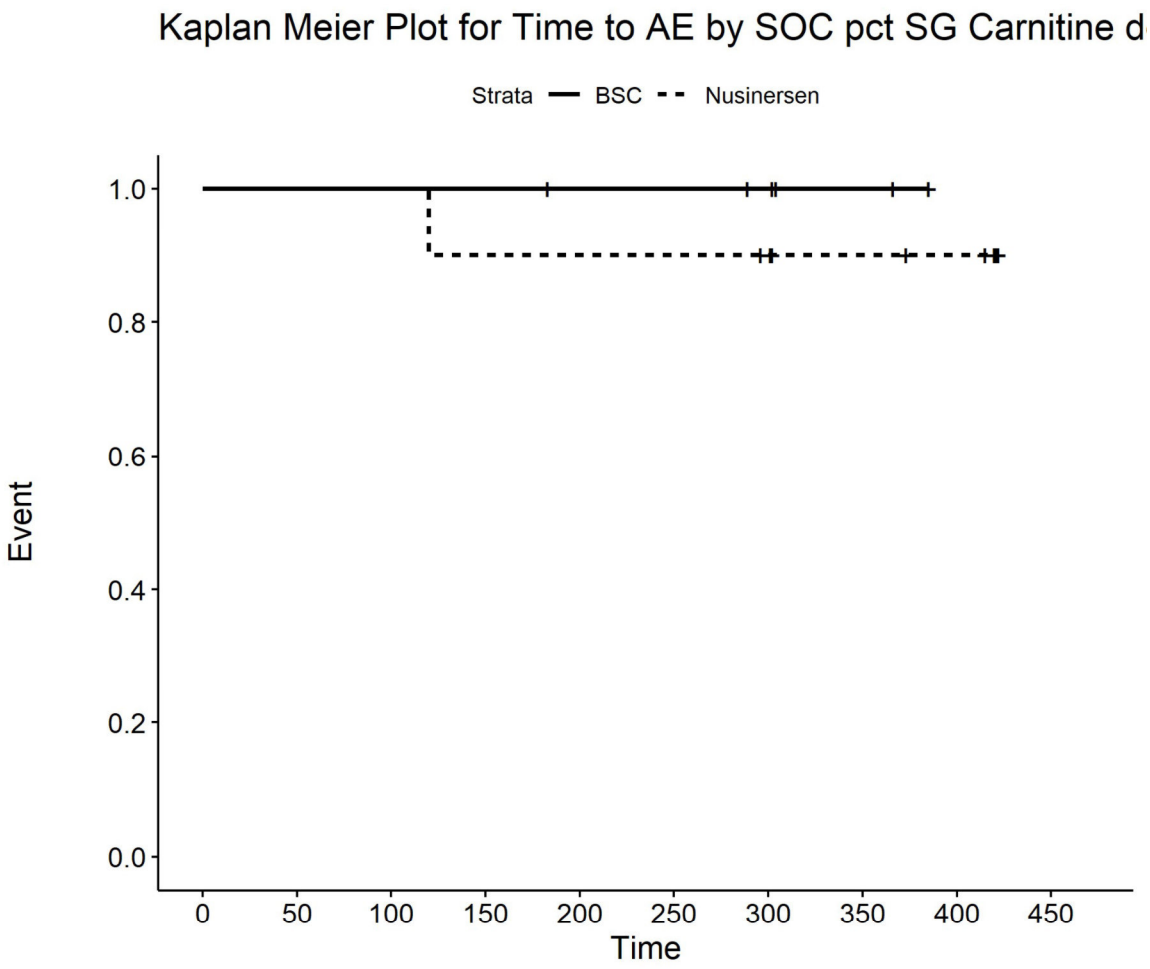
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



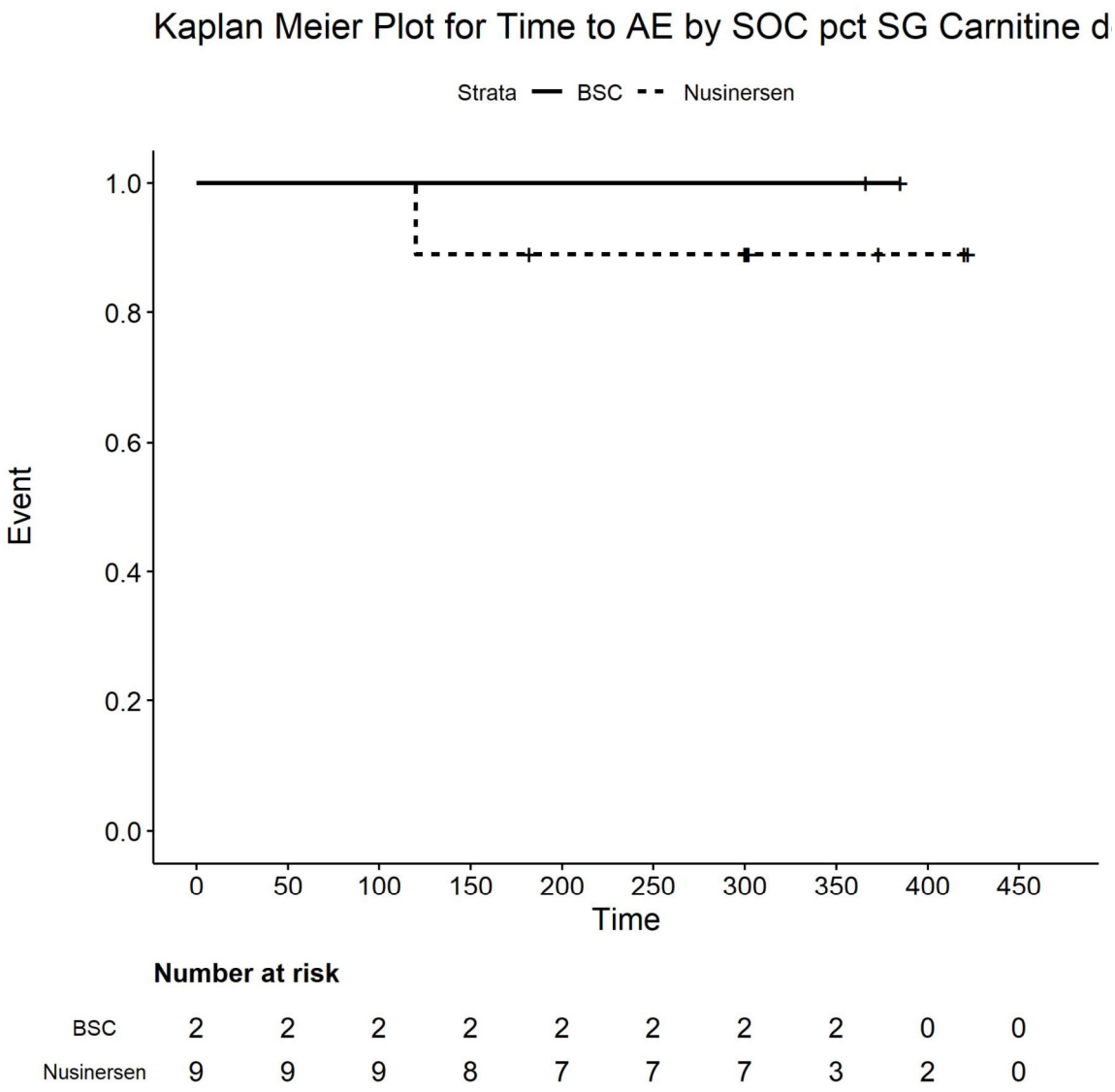
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	4	4	4	4	1	1	0



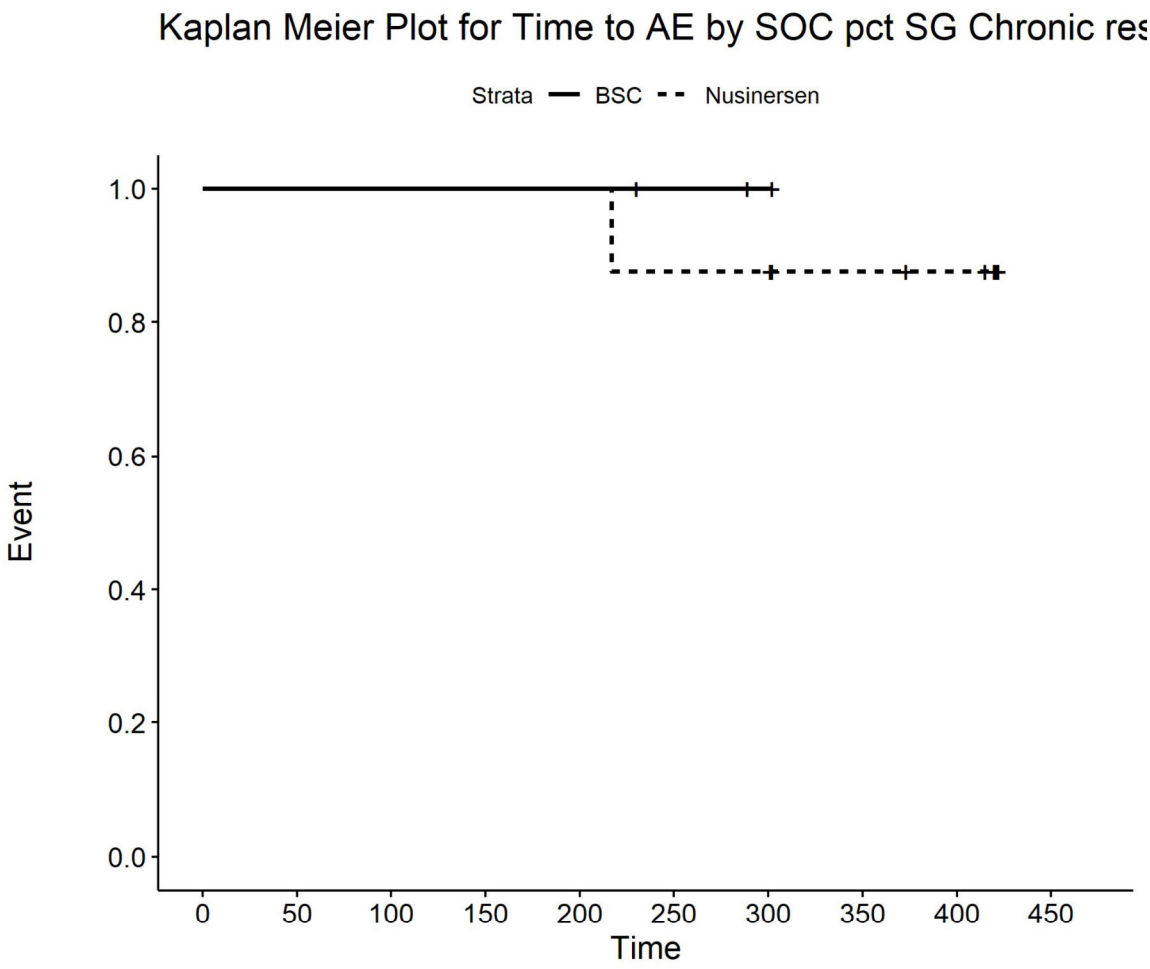
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



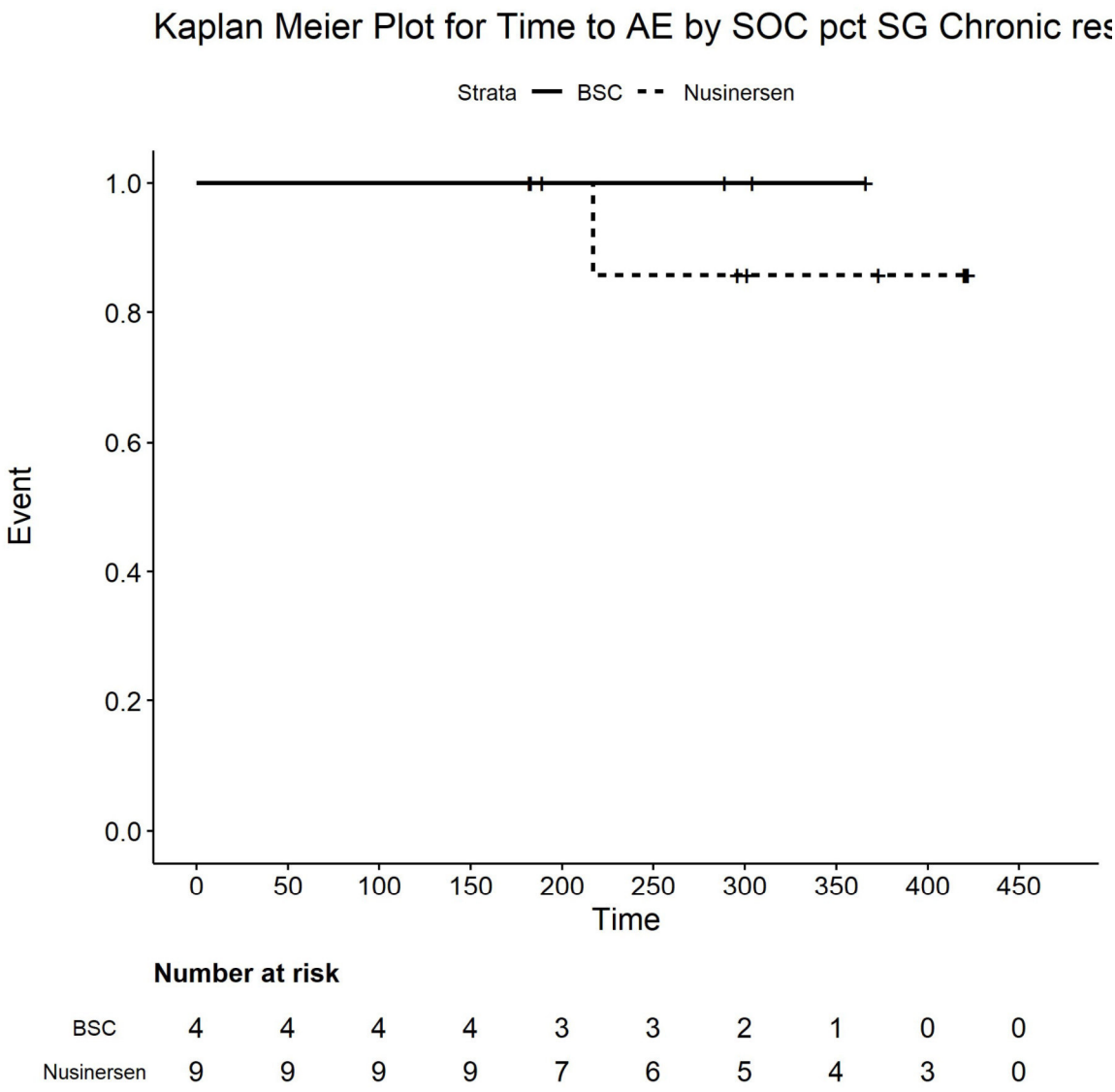
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



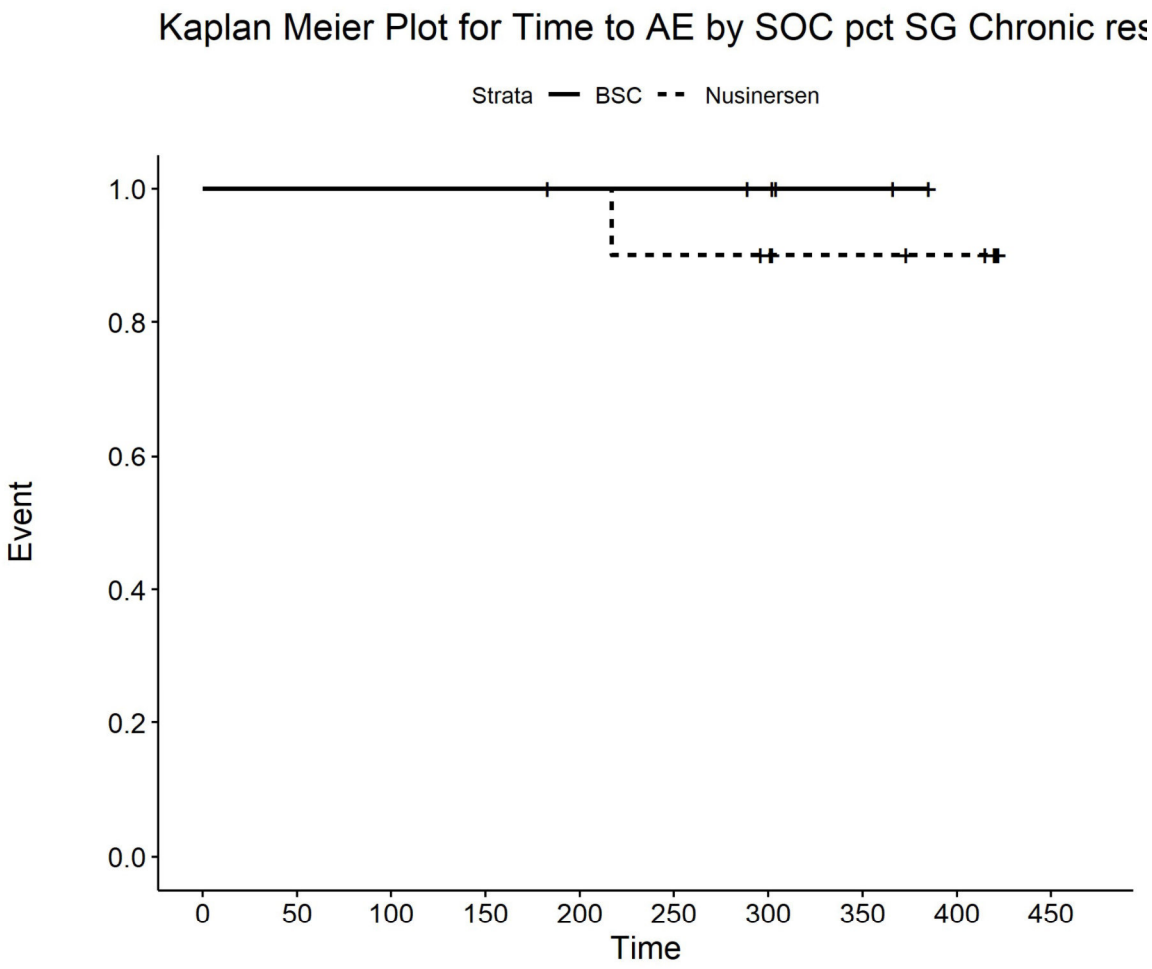
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



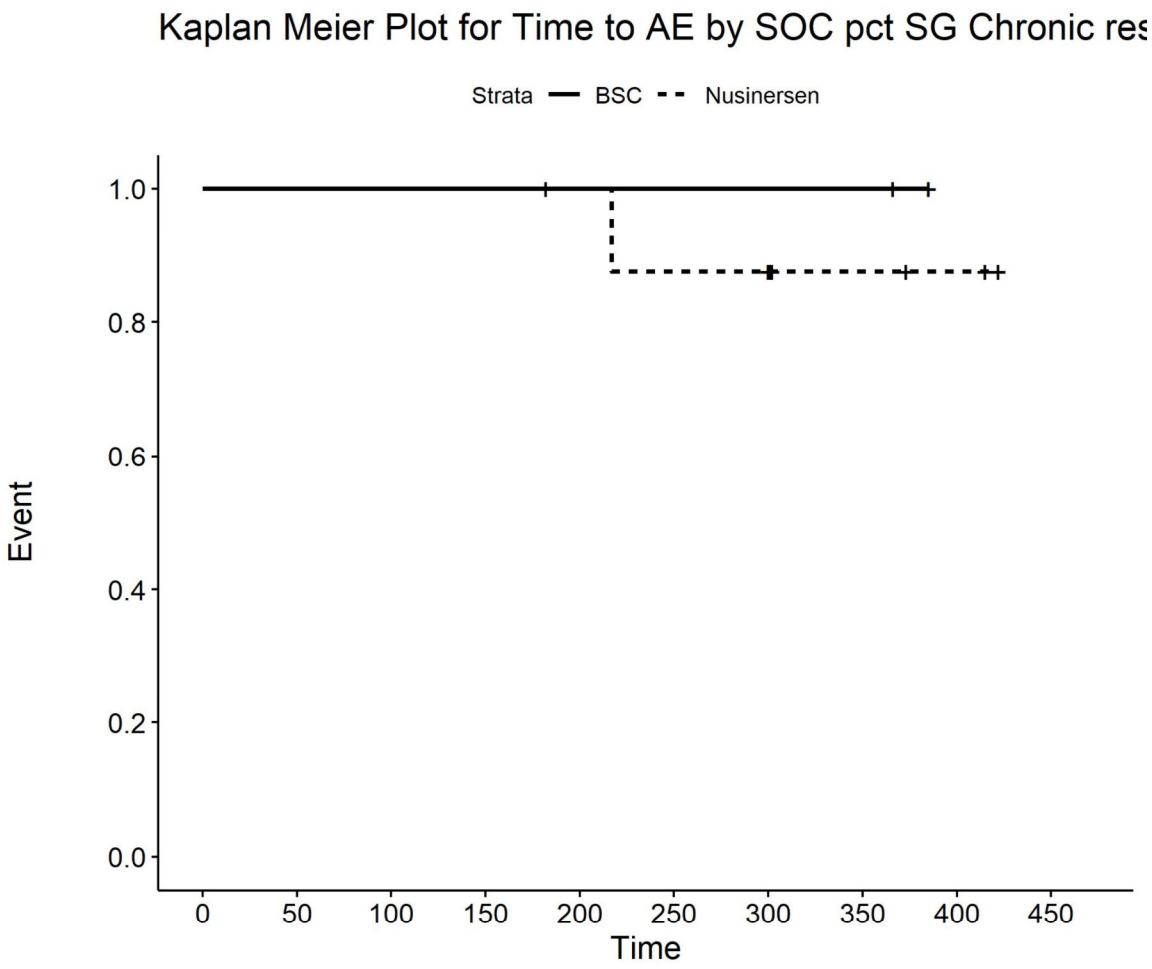
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



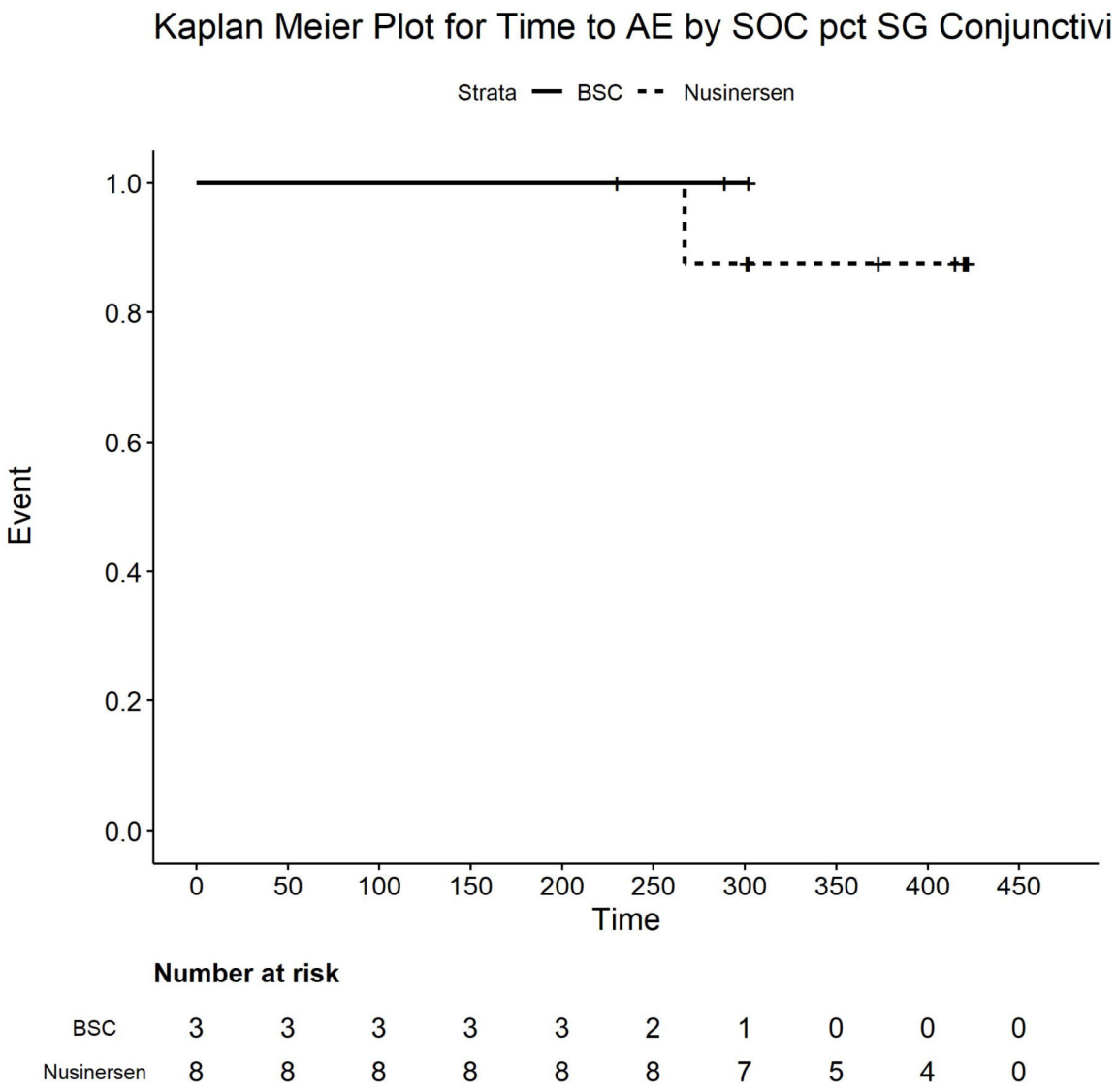
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



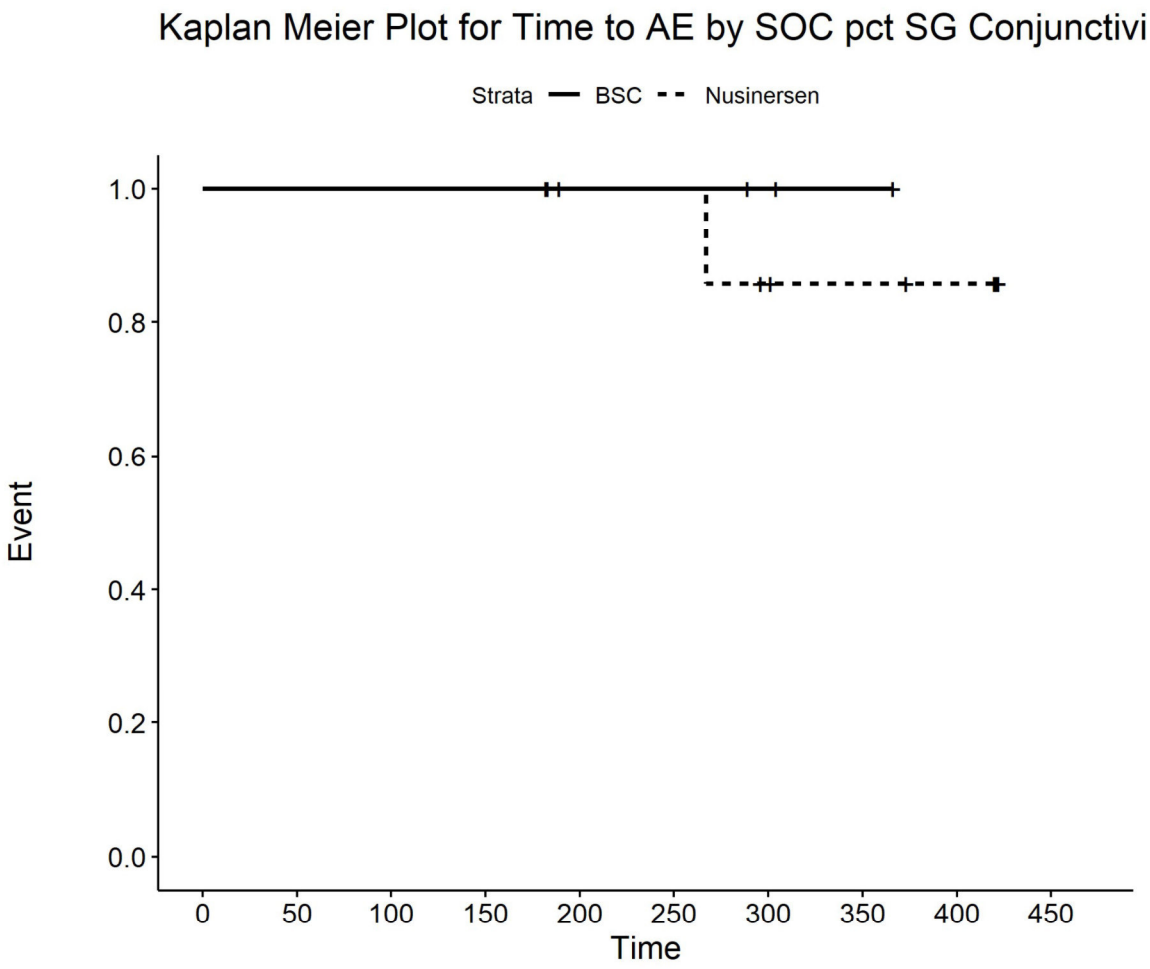
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	2	0



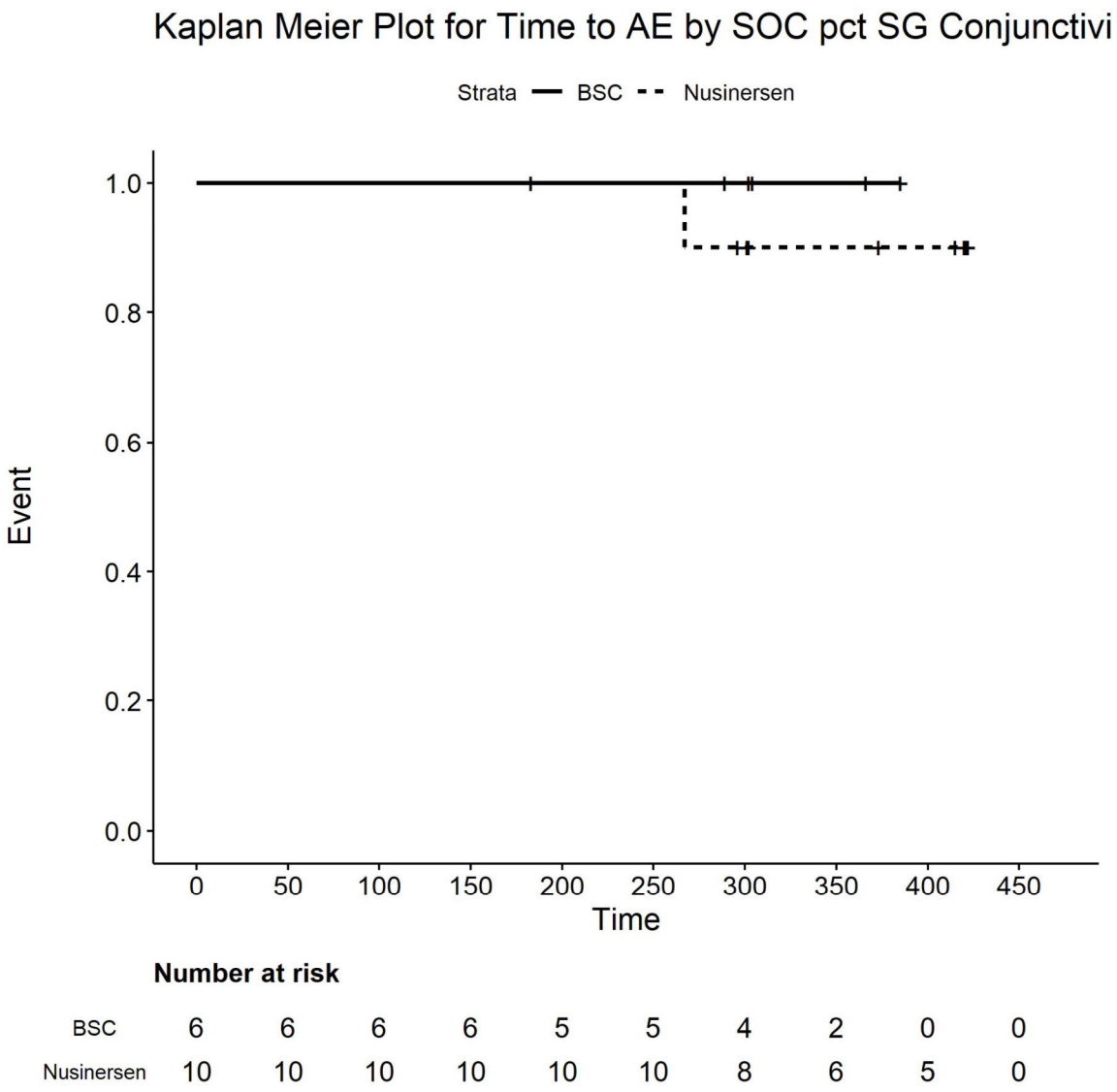
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	7	5	4	0



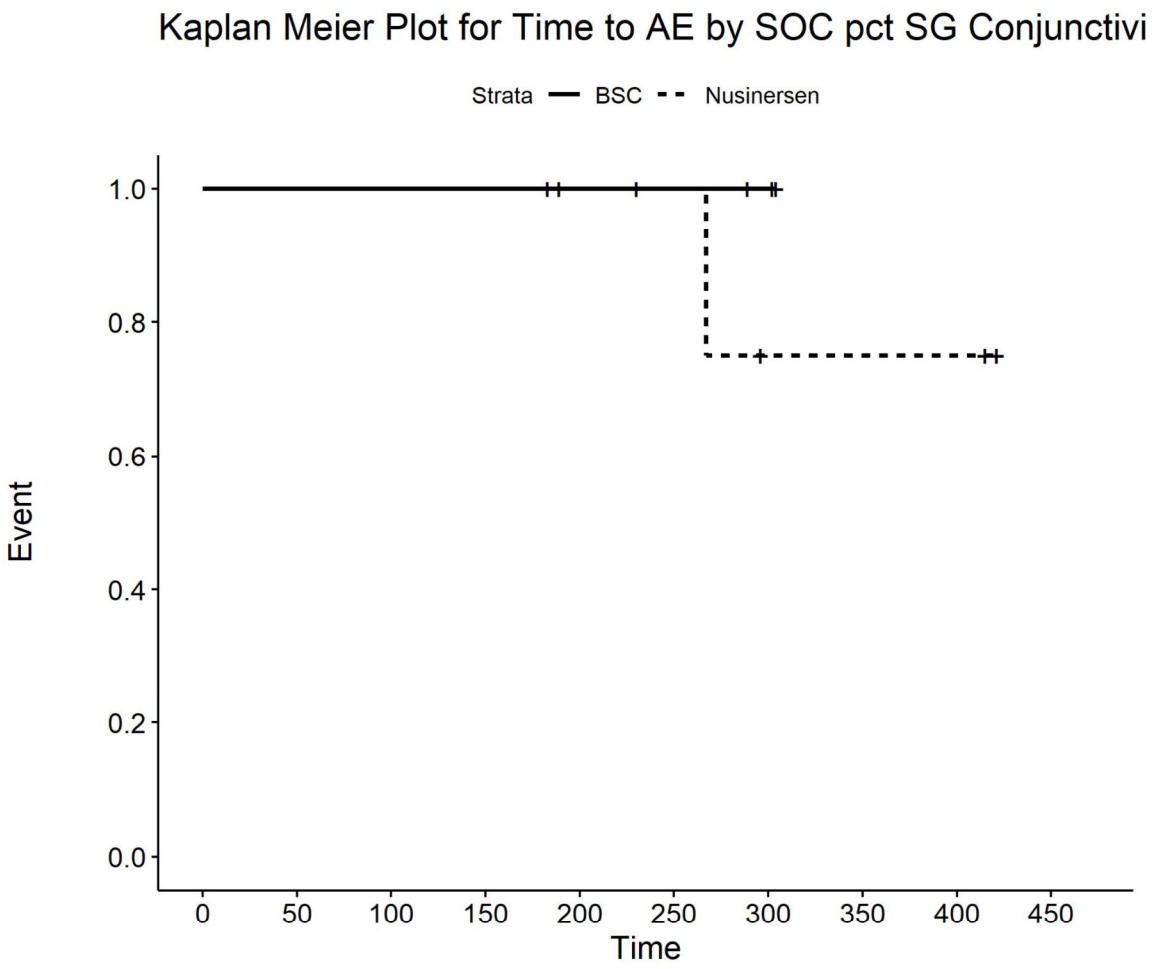
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	5	4	3	0



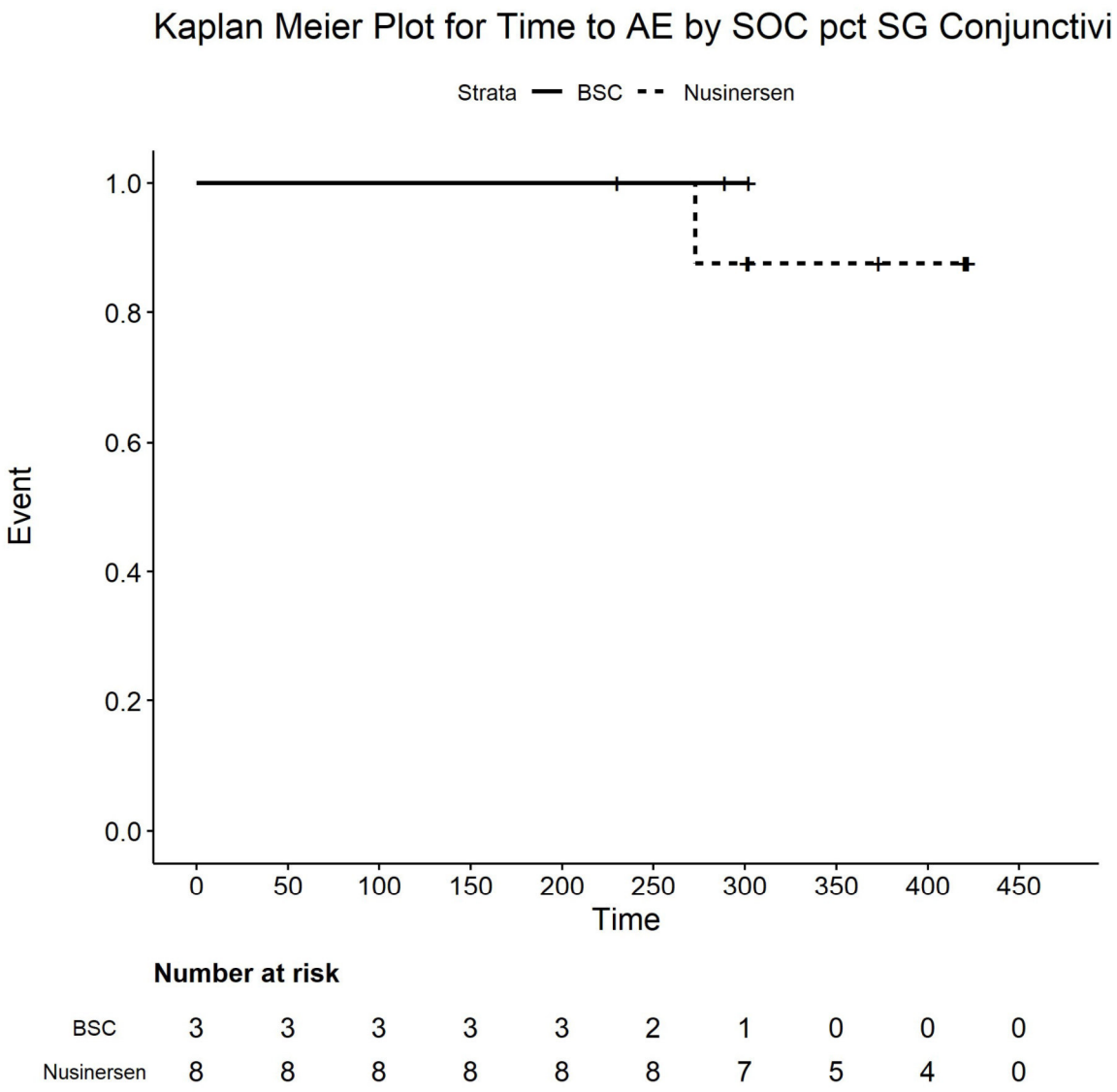
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	8	6	5	0



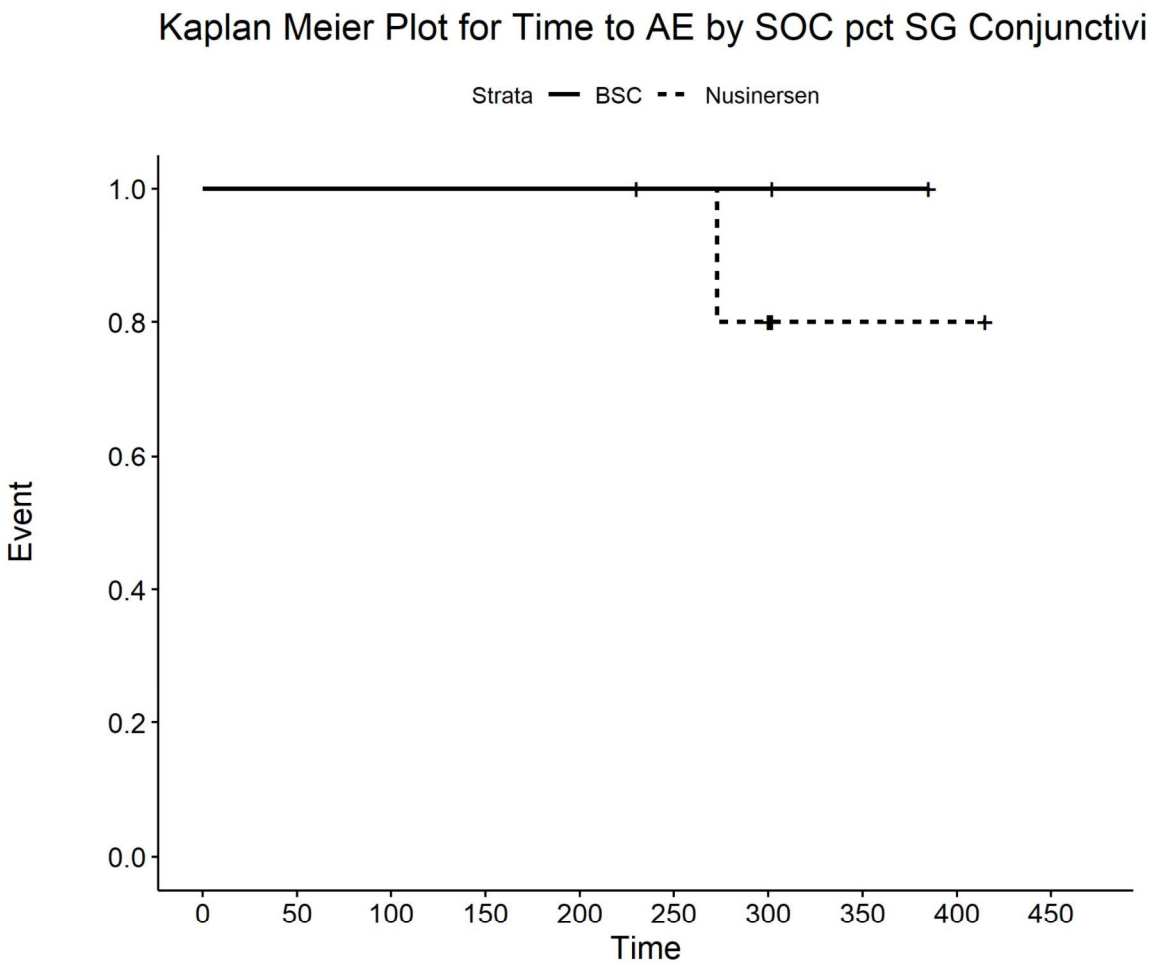
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	2	2	2	0



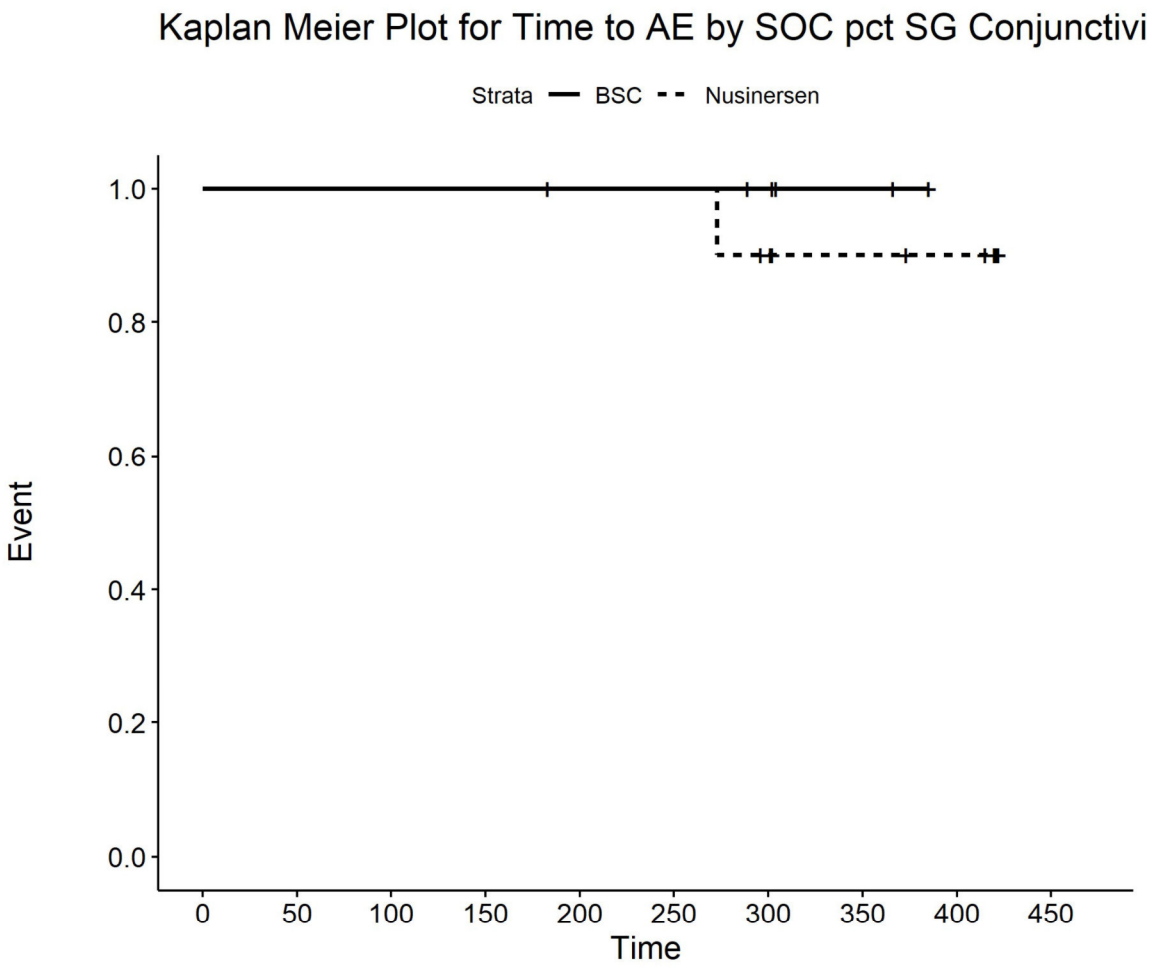
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	7	5	4	0



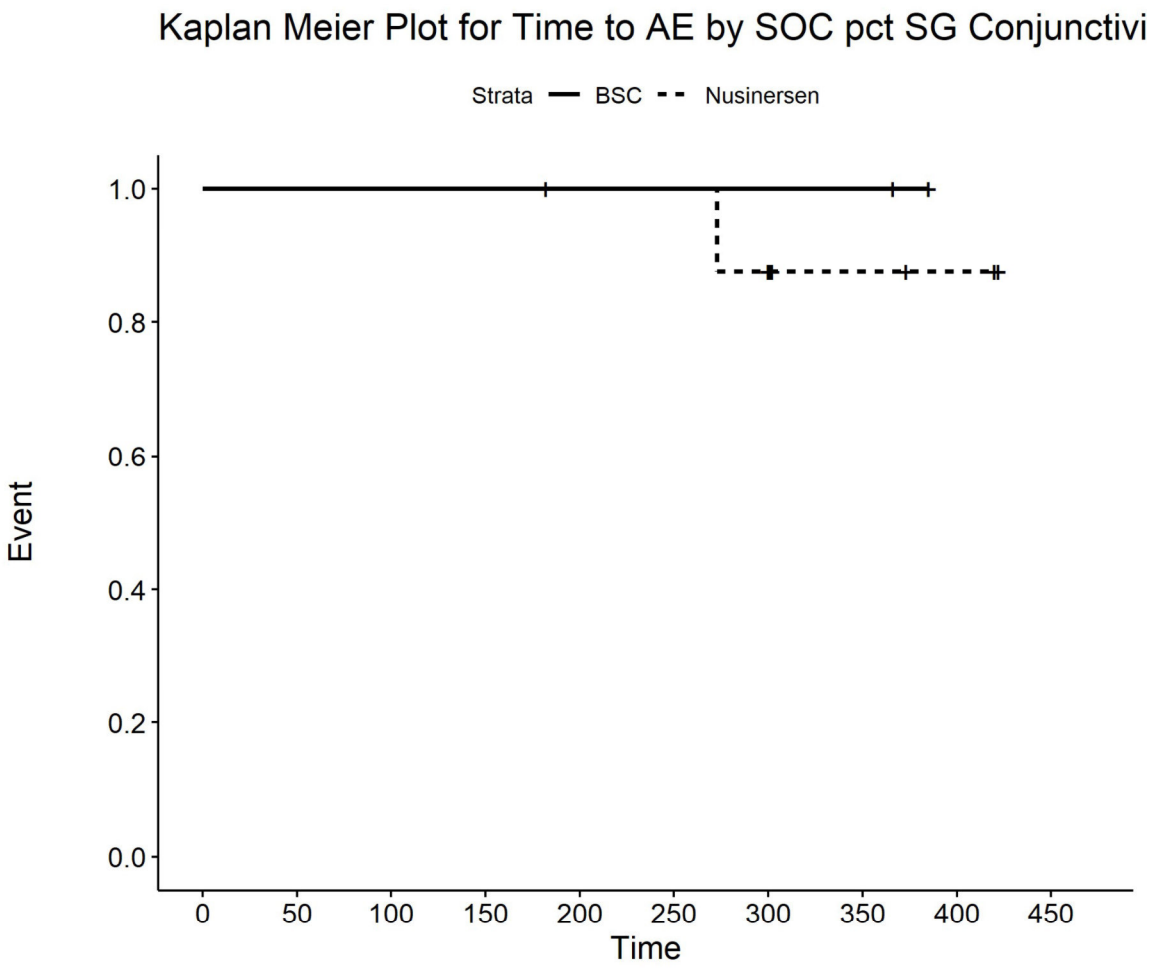
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	4	1	1	0



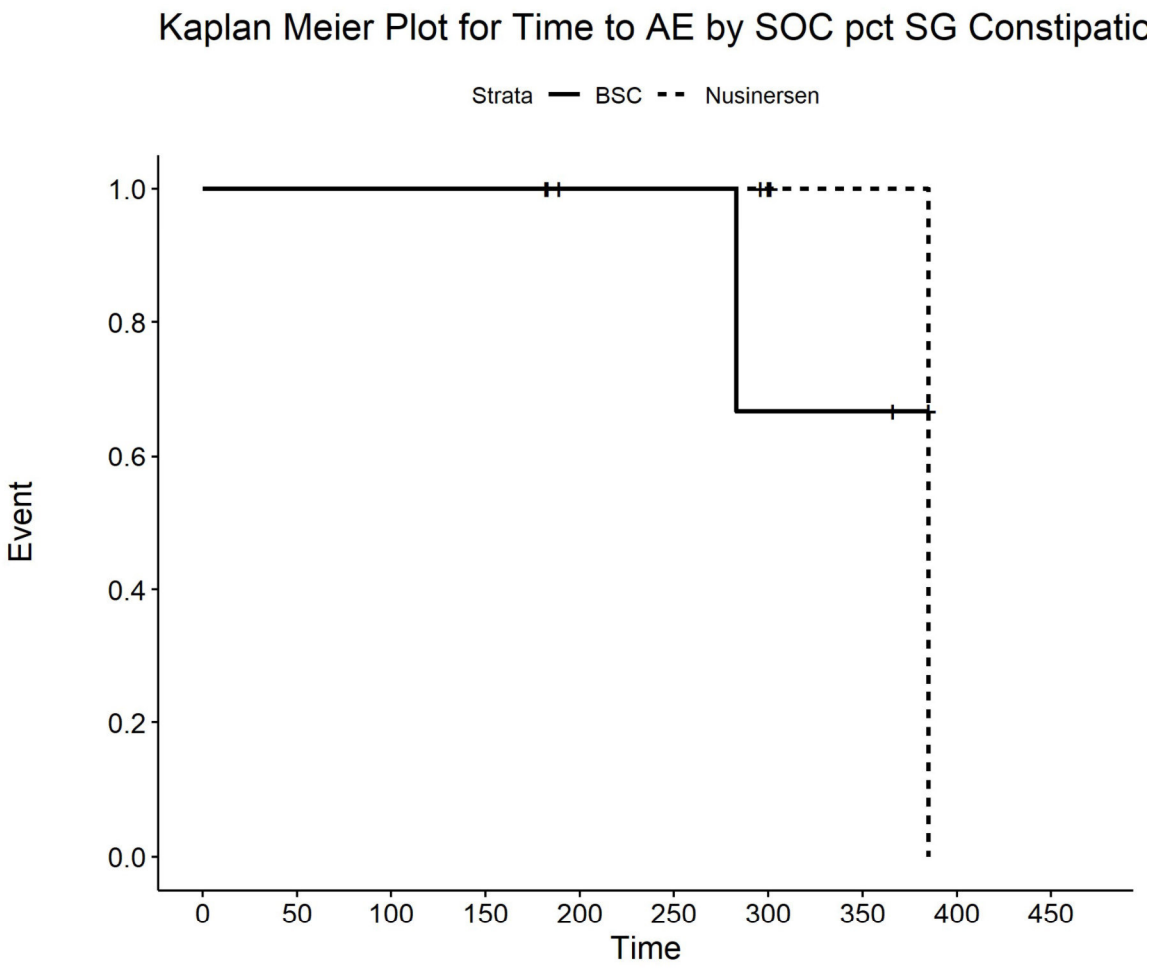
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	8	6	5	0



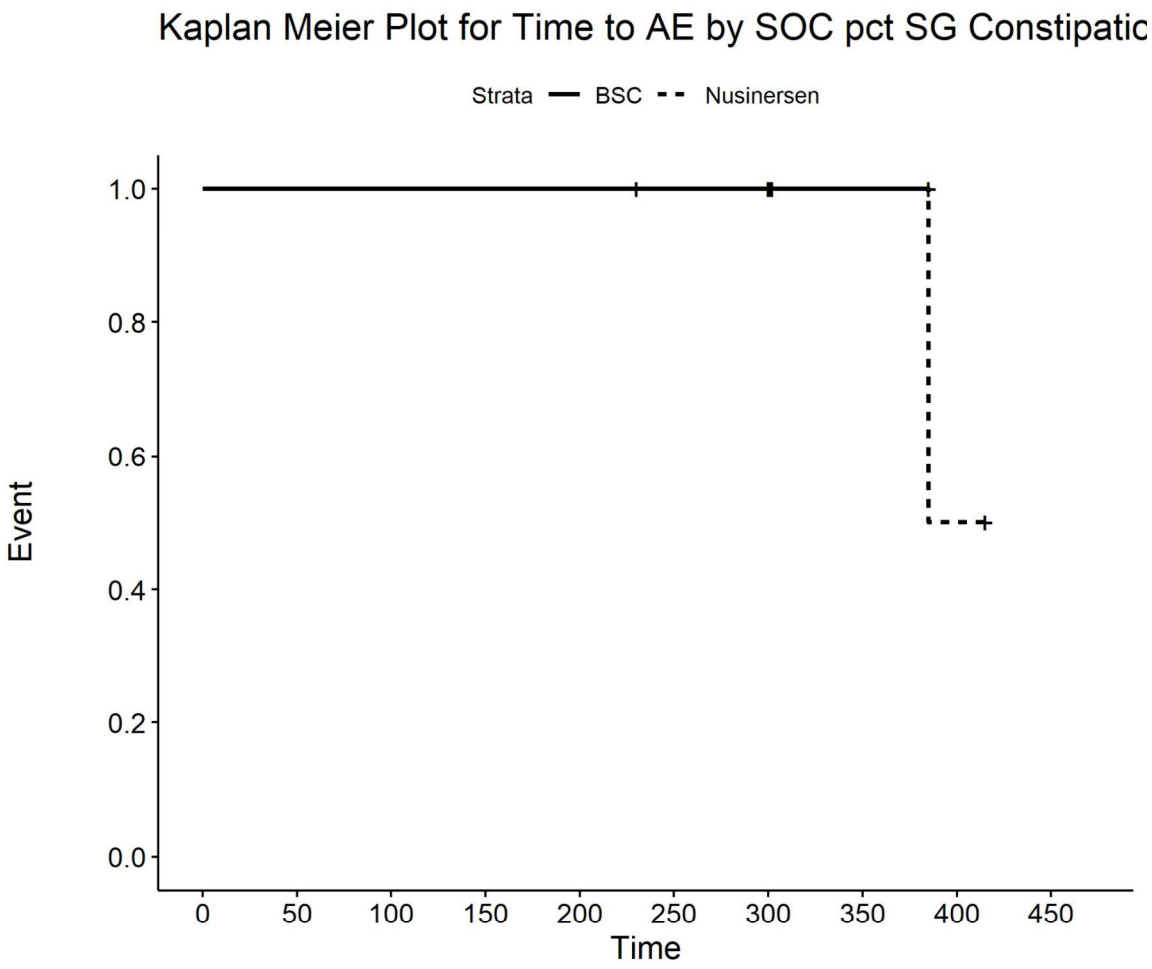
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	7	3	2	0



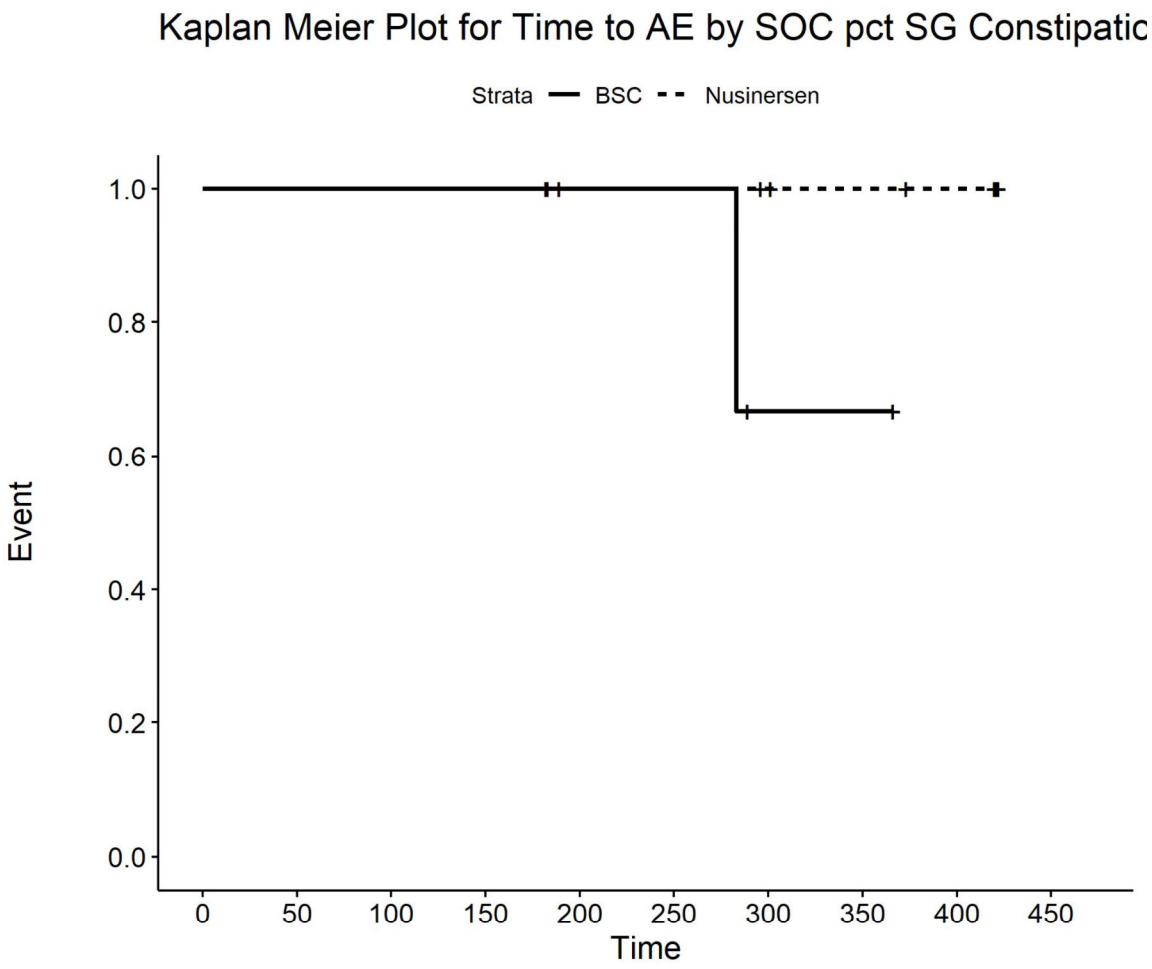
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	0	0



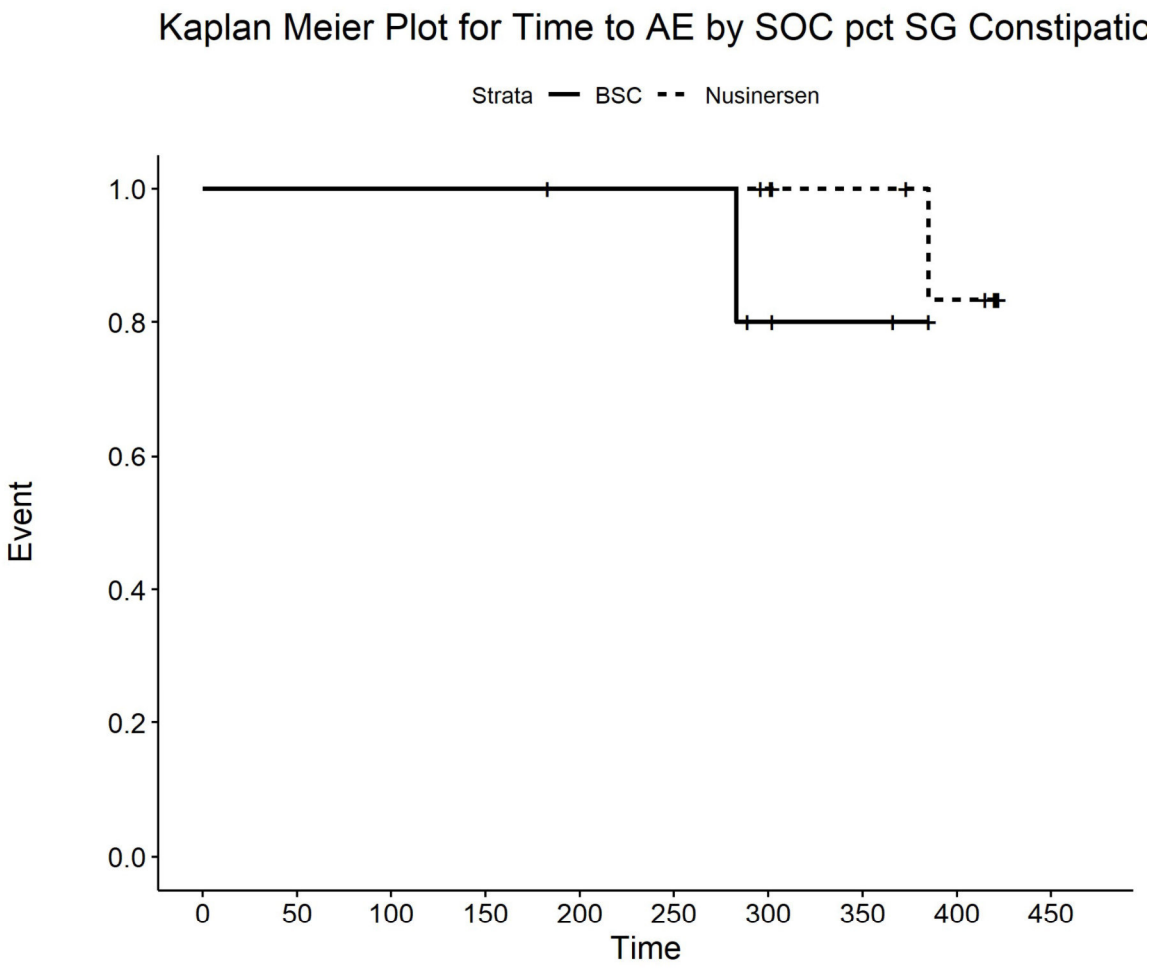
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	1	0



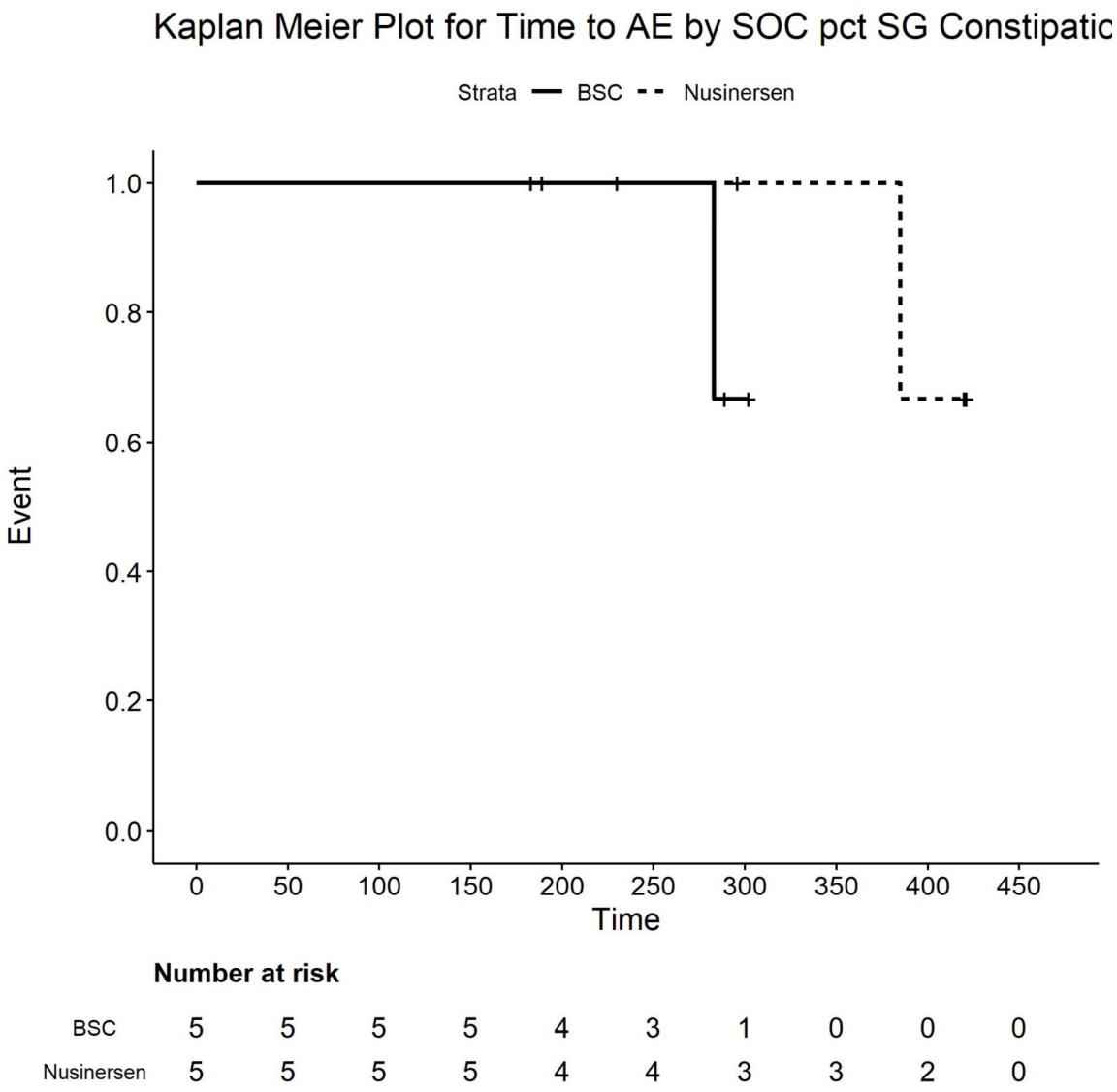
Number at risk

BSC	4	4	4	4	3	3	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



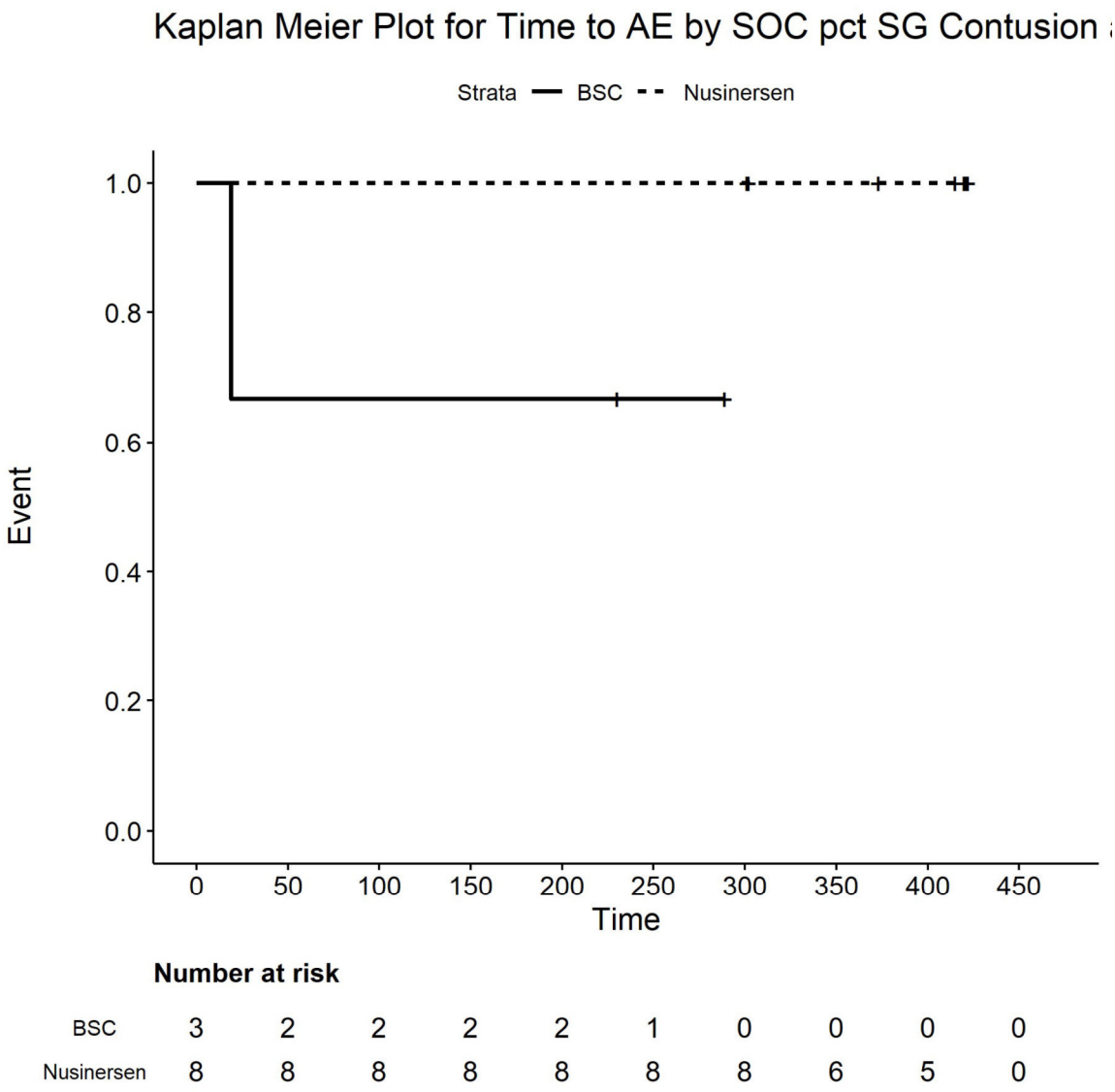
Number at risk

BSC	6	6	6	6	5	5	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	5	0



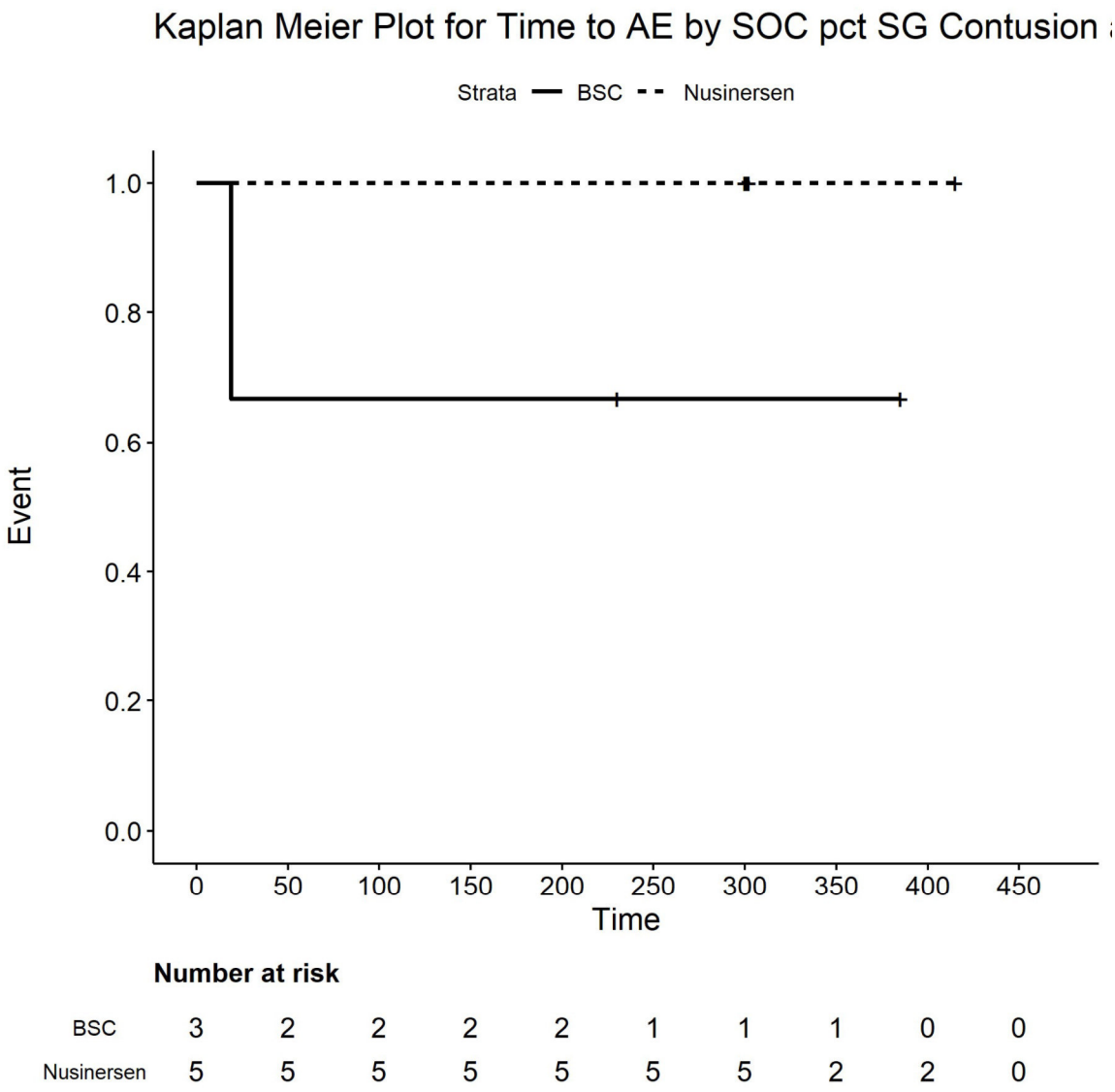
Number at risk

BSC	5	5	5	5	4	3	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	2	0



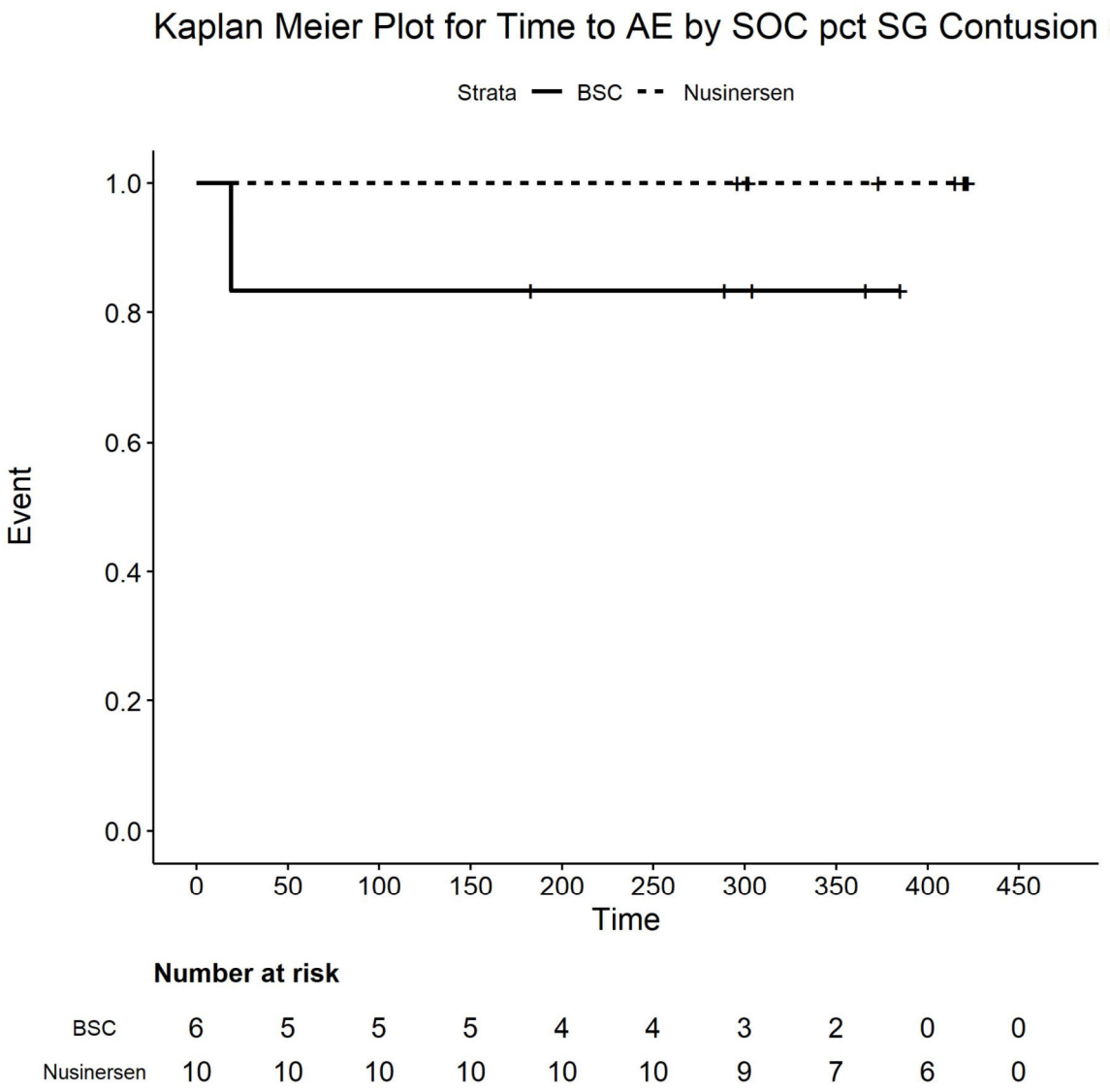
Number at risk

BSC	3	2	2	2	2	1	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



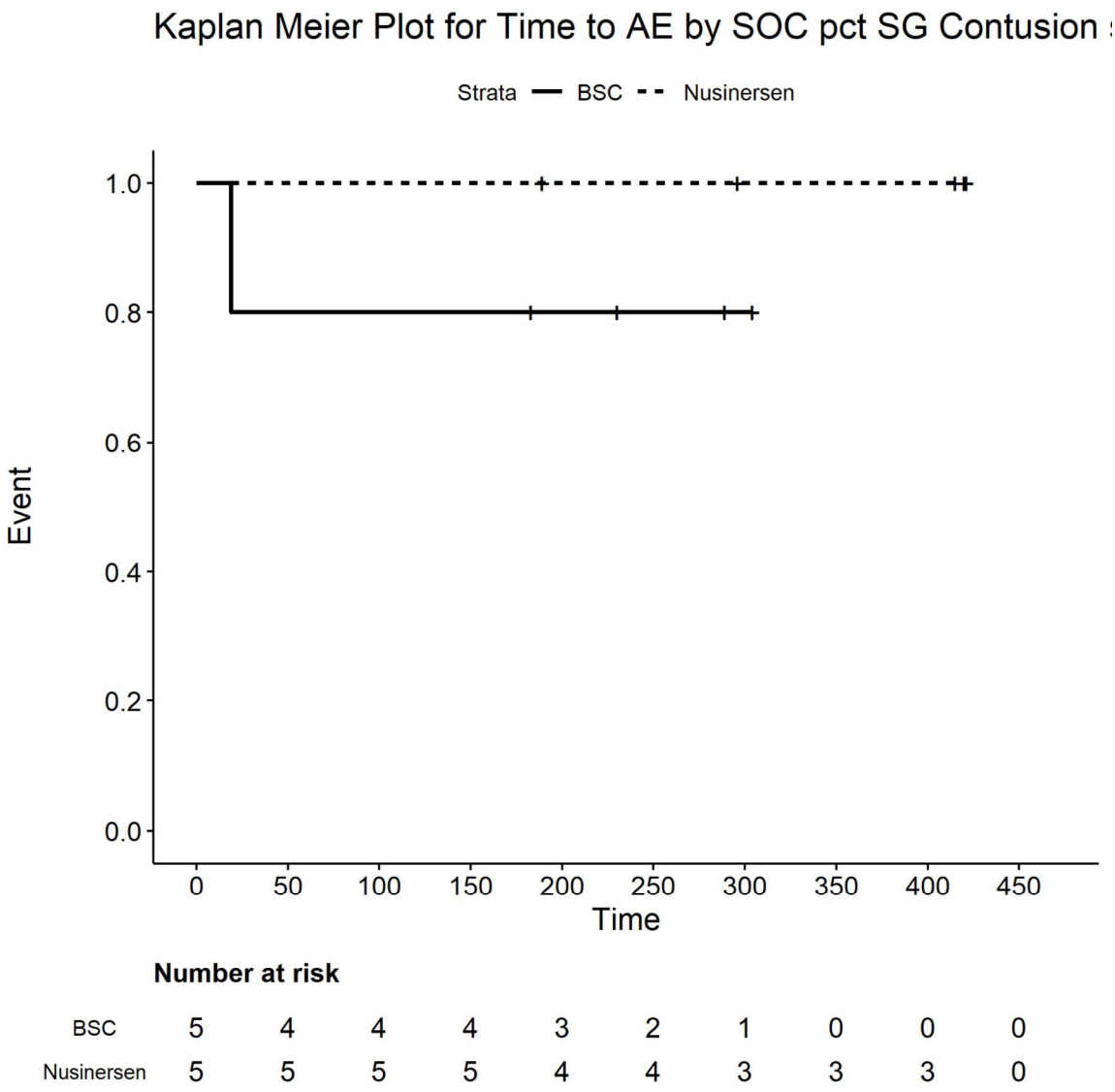
Number at risk

BSC	3	2	2	2	2	1	1	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



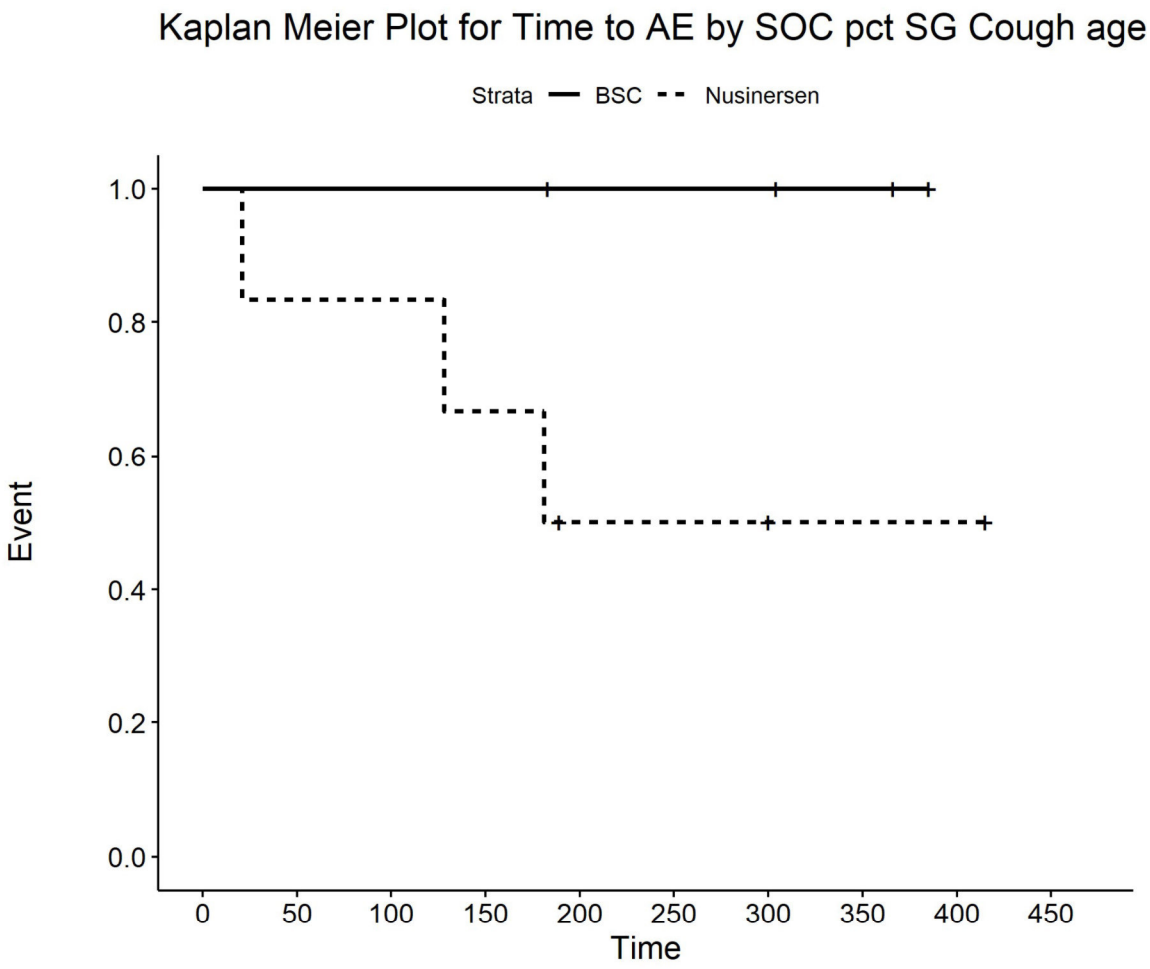
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



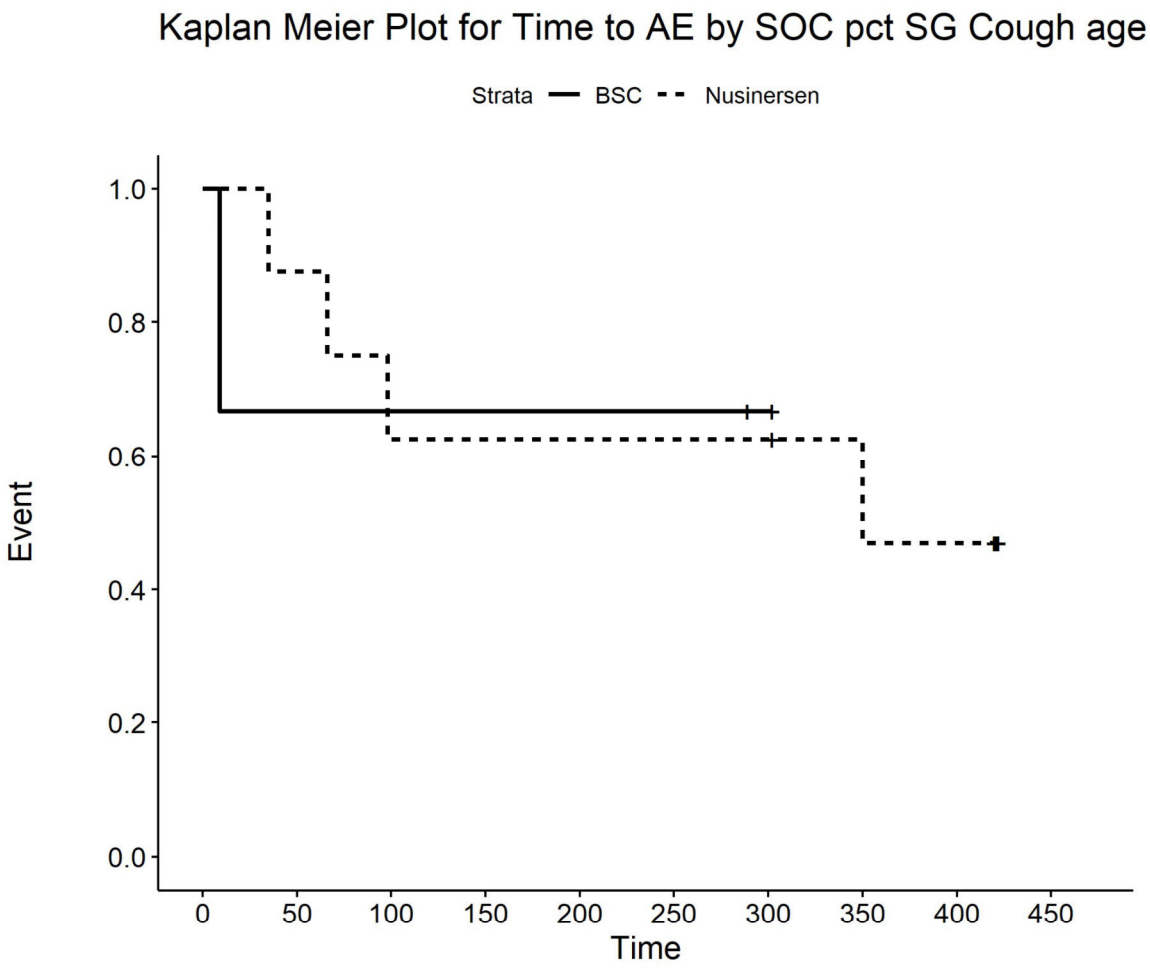
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



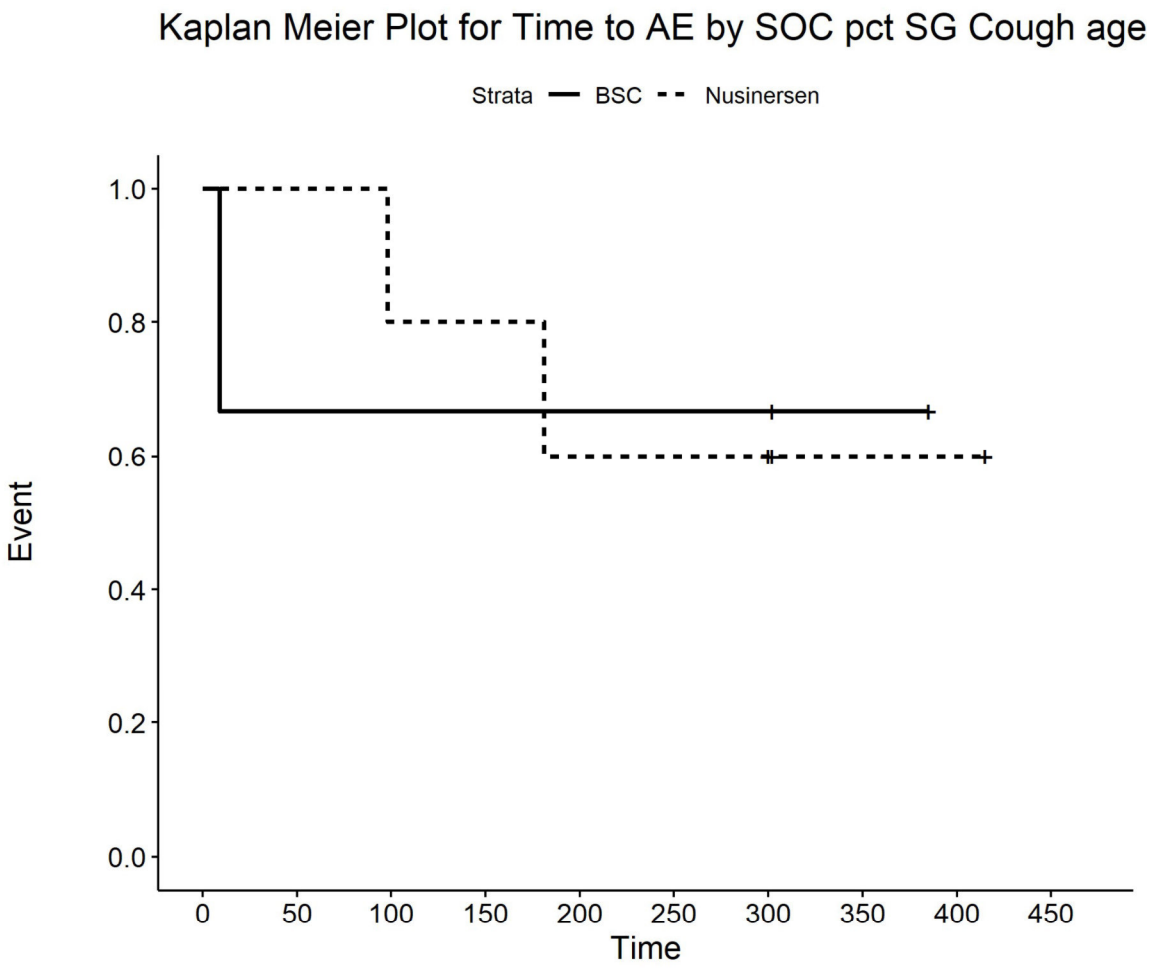
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	4	2	2	2	1	1	0



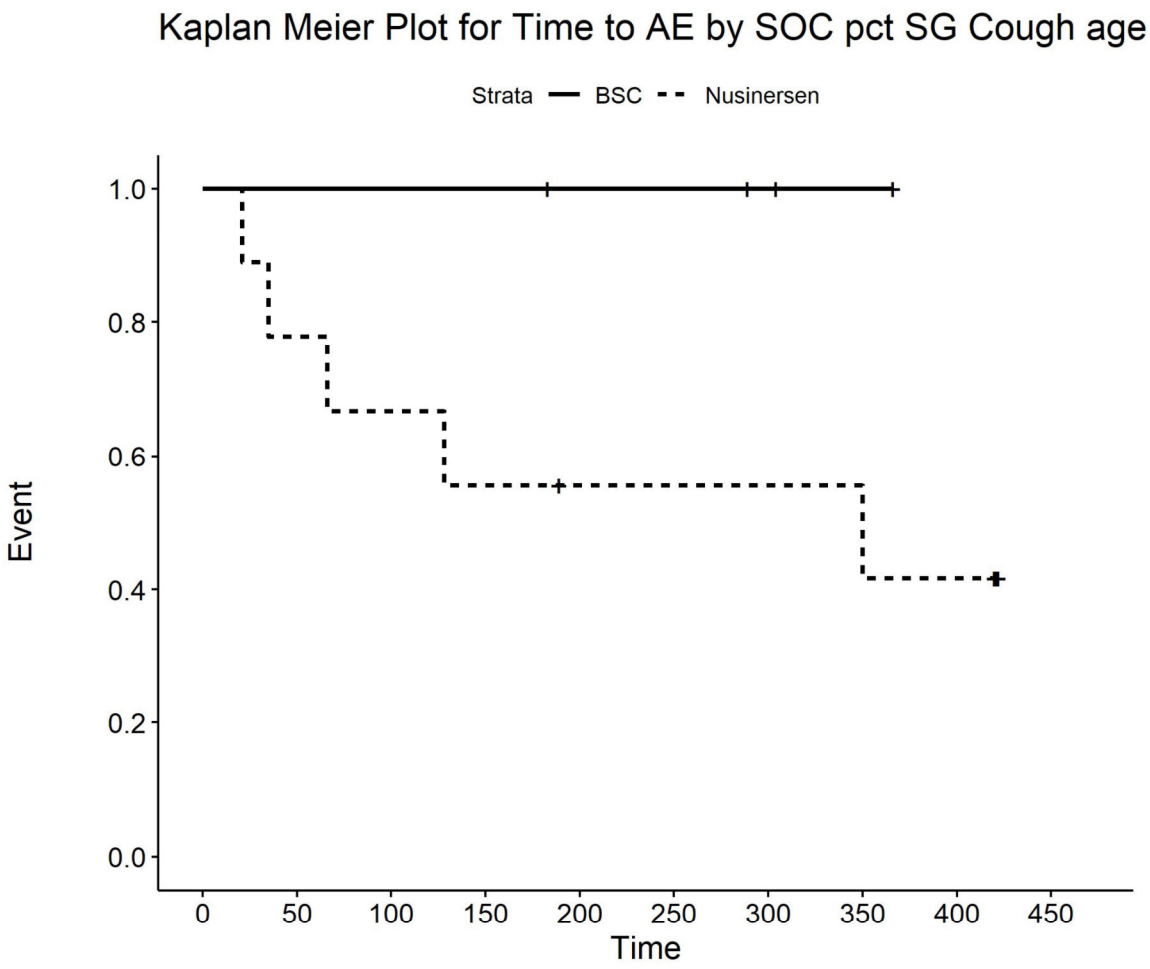
Number at risk

BSC	3	2	2	2	2	2	1	0	0	0
Nusinersen	8	7	5	5	5	5	5	4	3	0



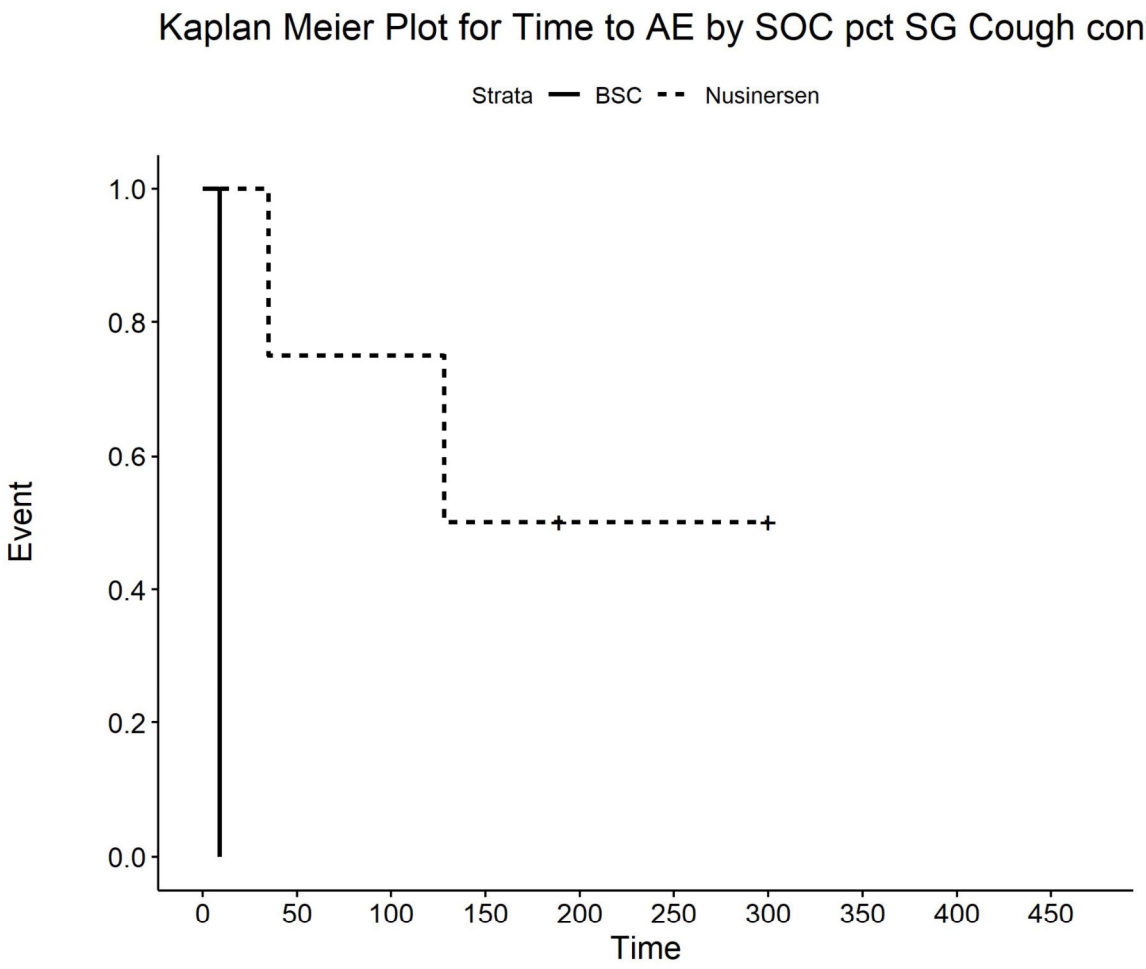
Number at risk

BSC	3	2	2	2	2	2	2	1	0	0
Nusinersen	5	5	4	4	3	3	3	1	1	0



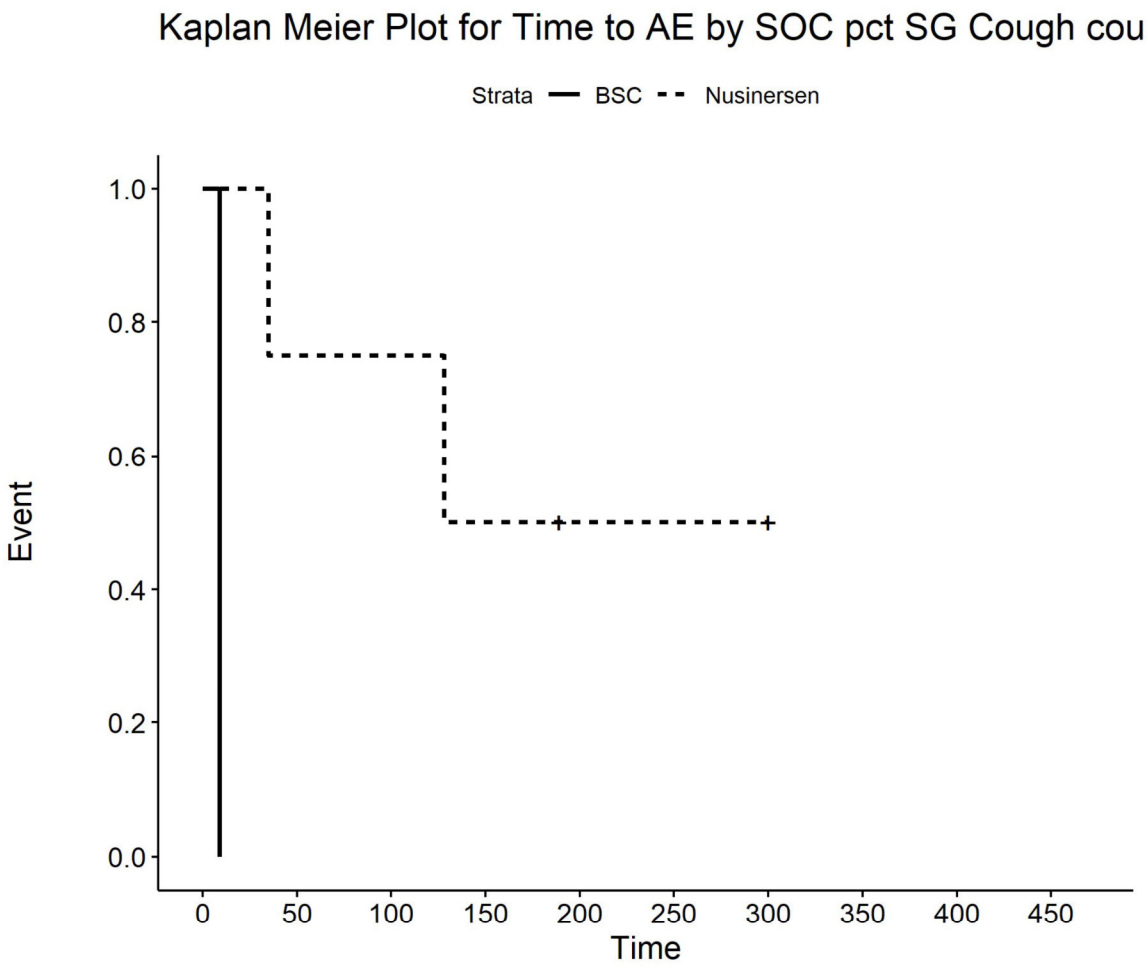
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	7	6	5	4	4	4	4	3	0



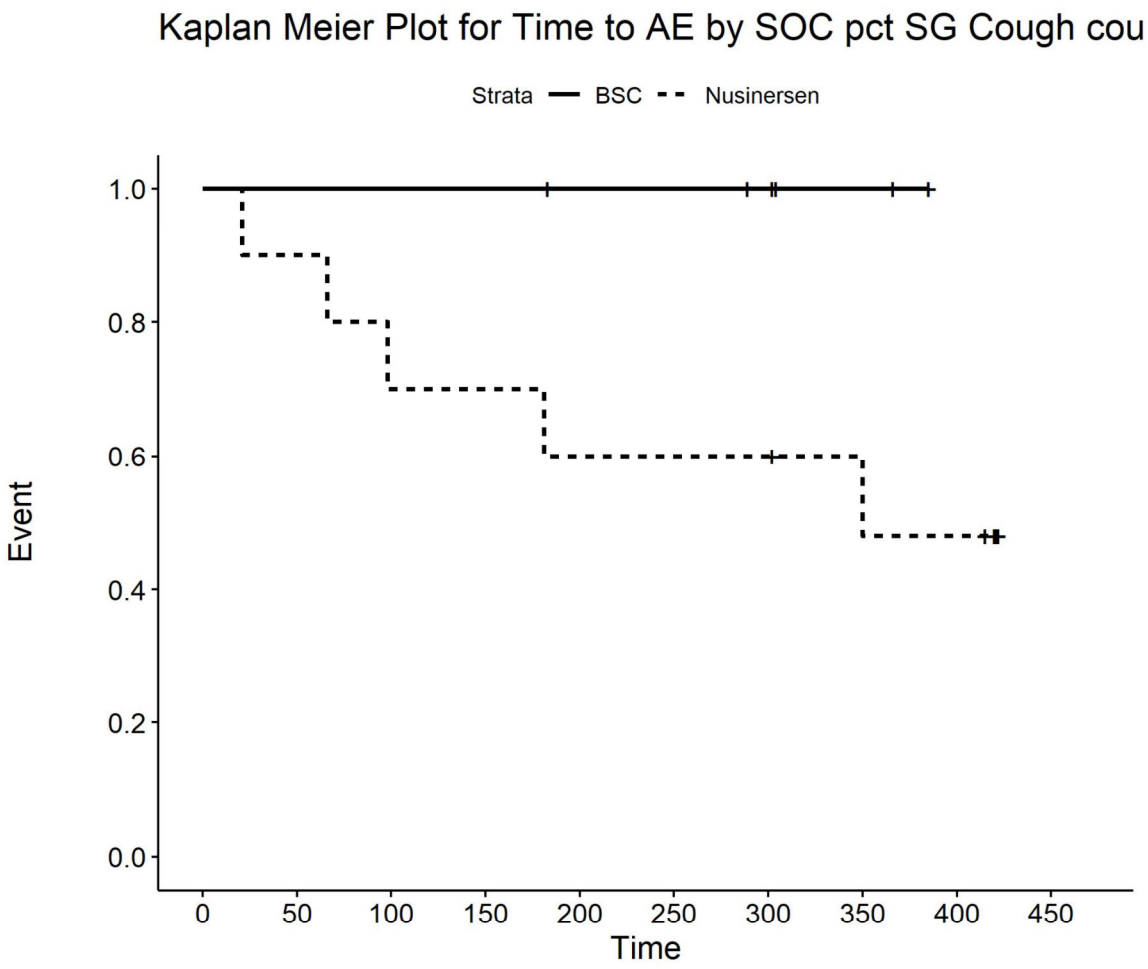
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



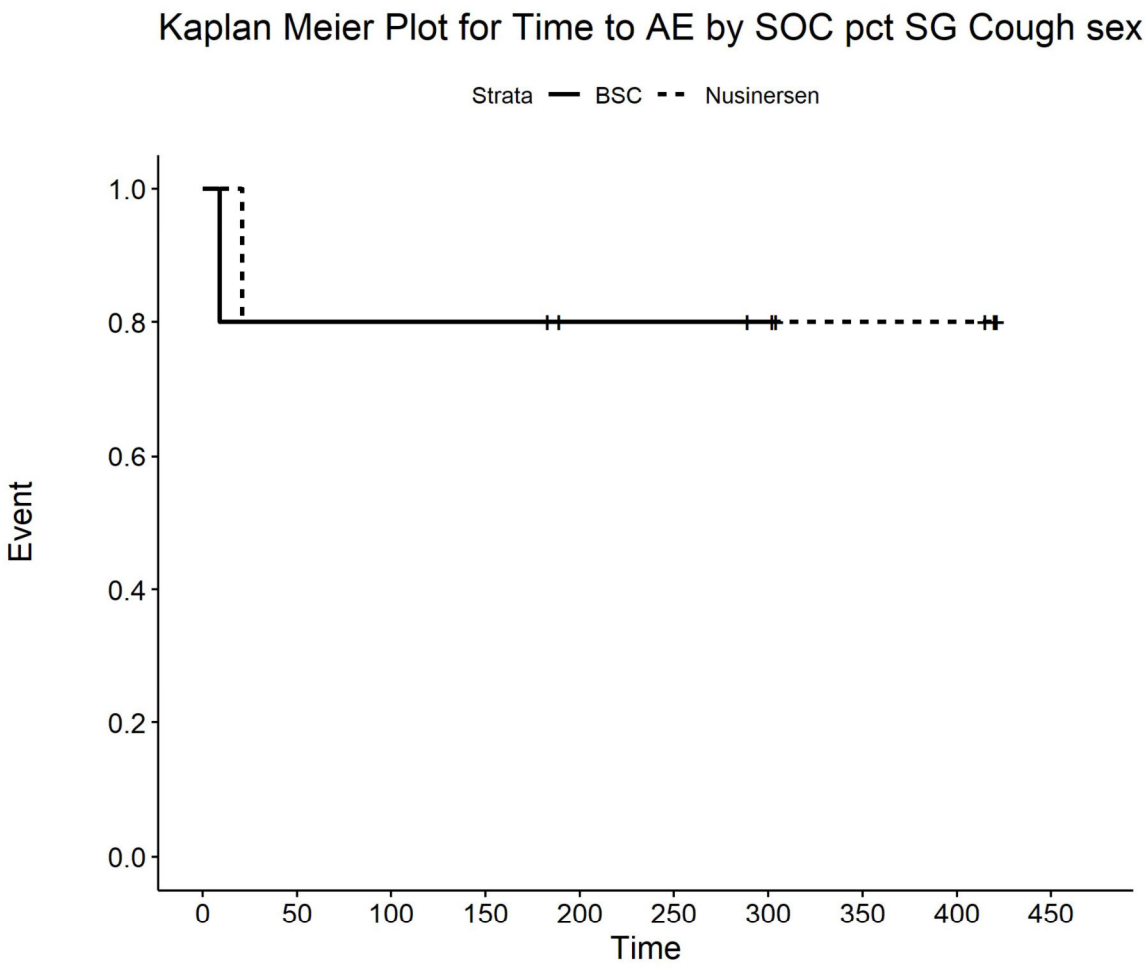
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



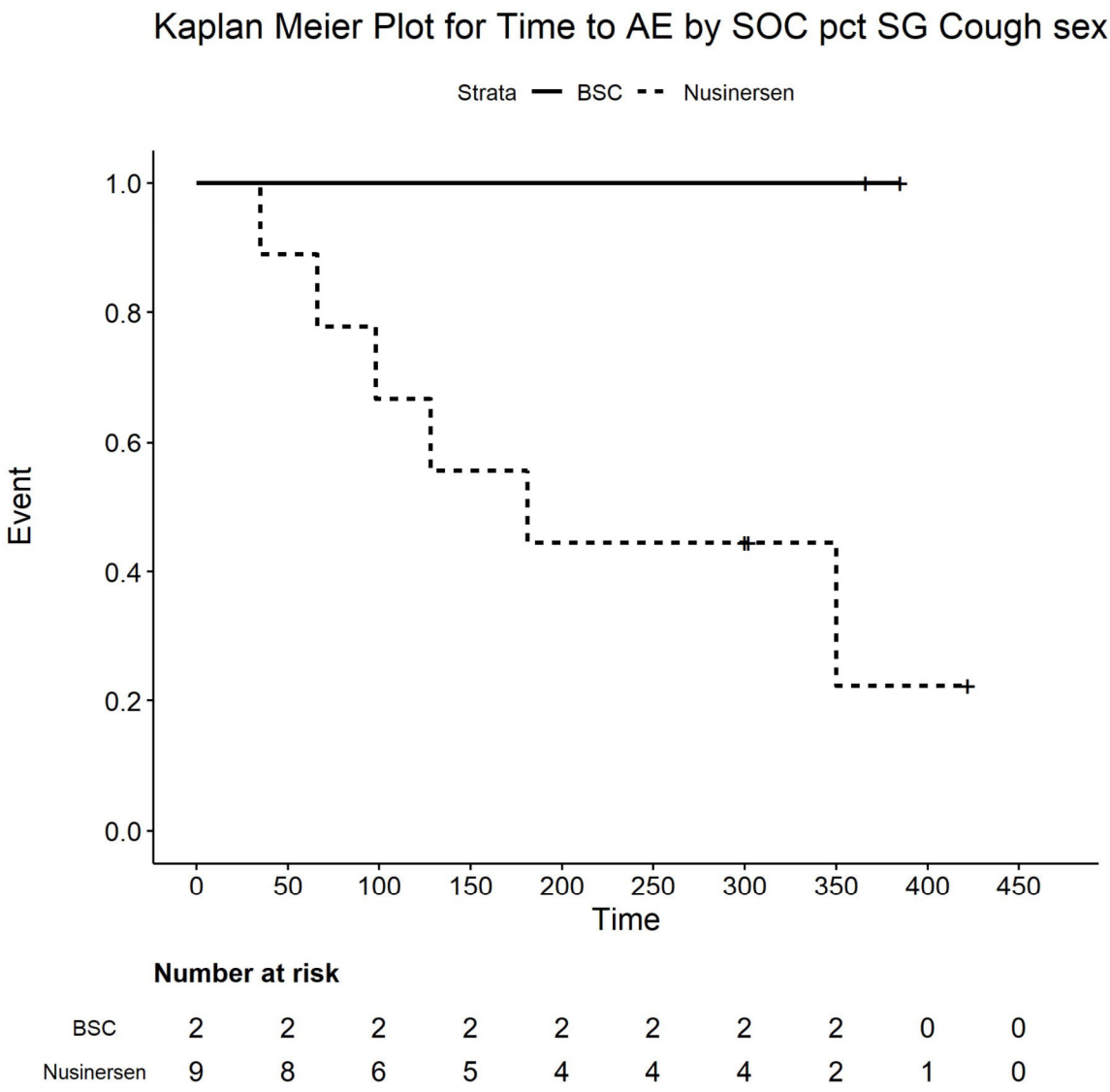
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	7	7	6	6	6	5	4	0



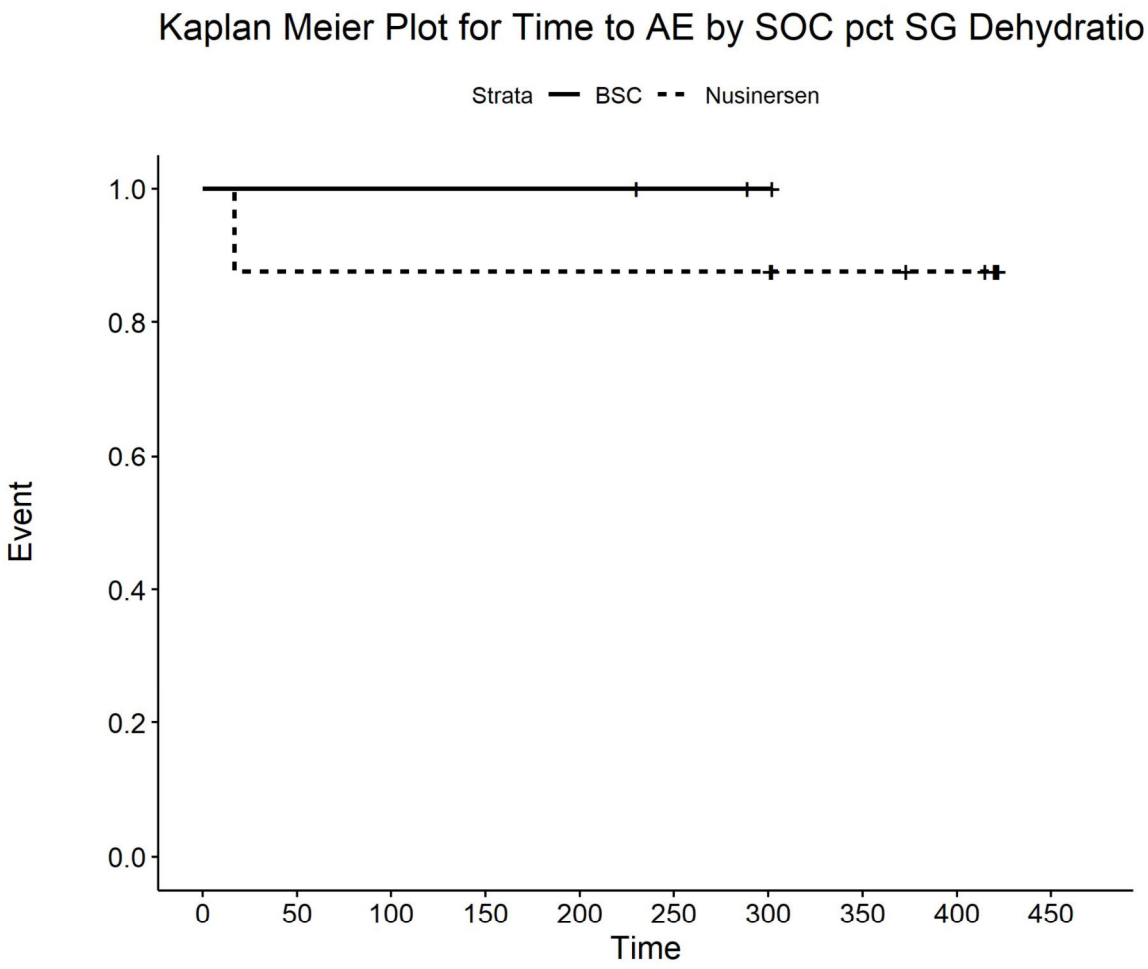
Number at risk

BSC	5	4	4	4	3	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	3	3	3	0



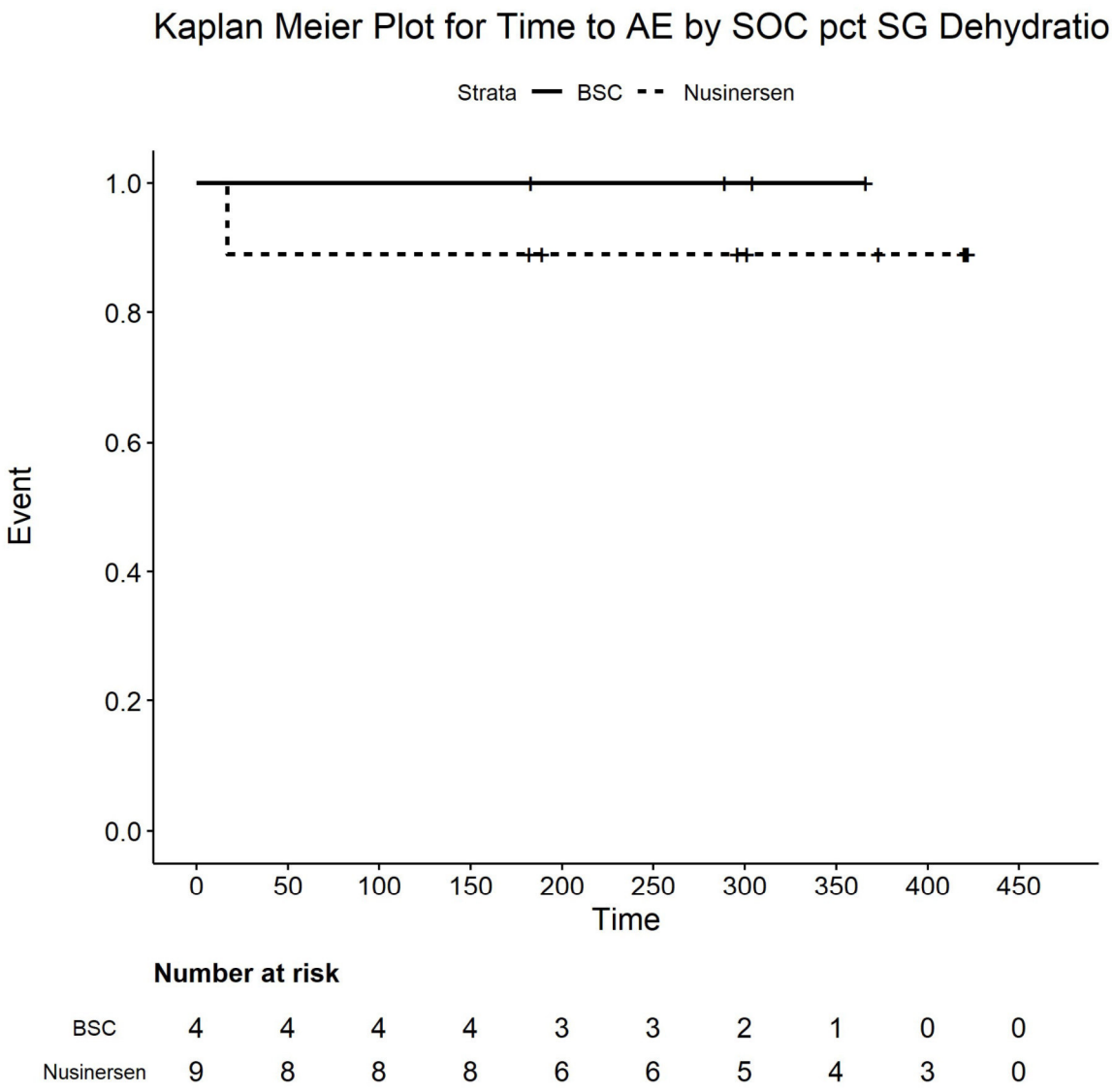
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	6	5	4	4	4	2	1	0



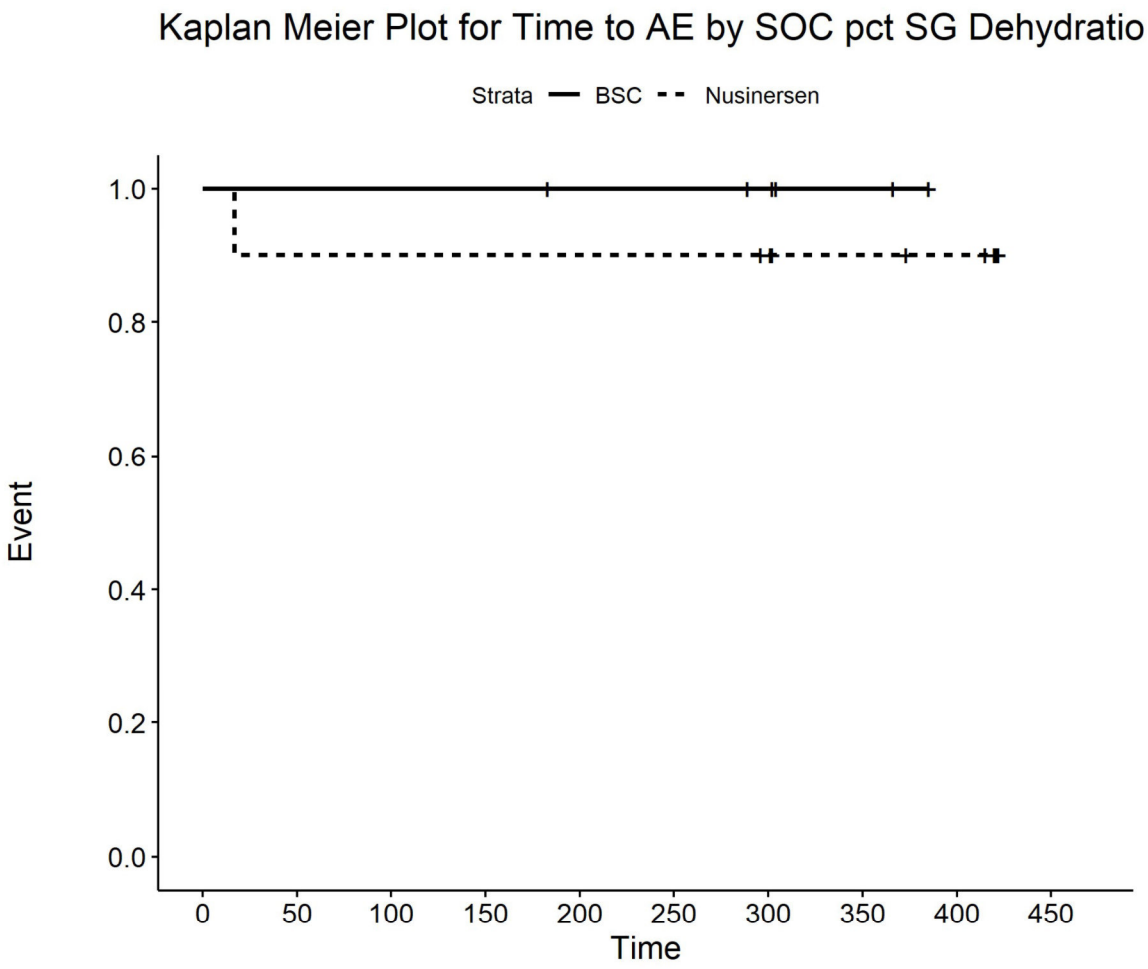
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



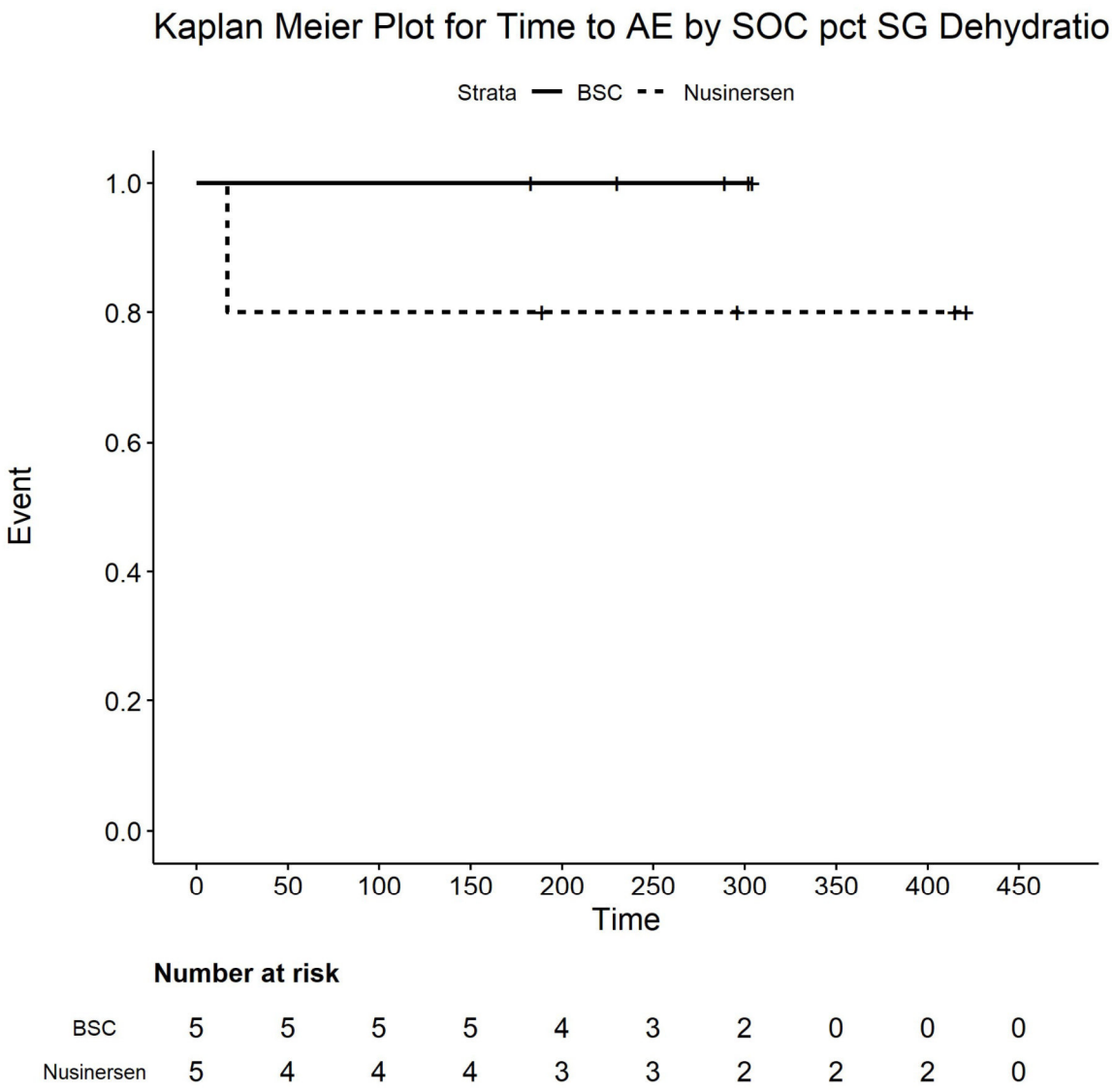
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



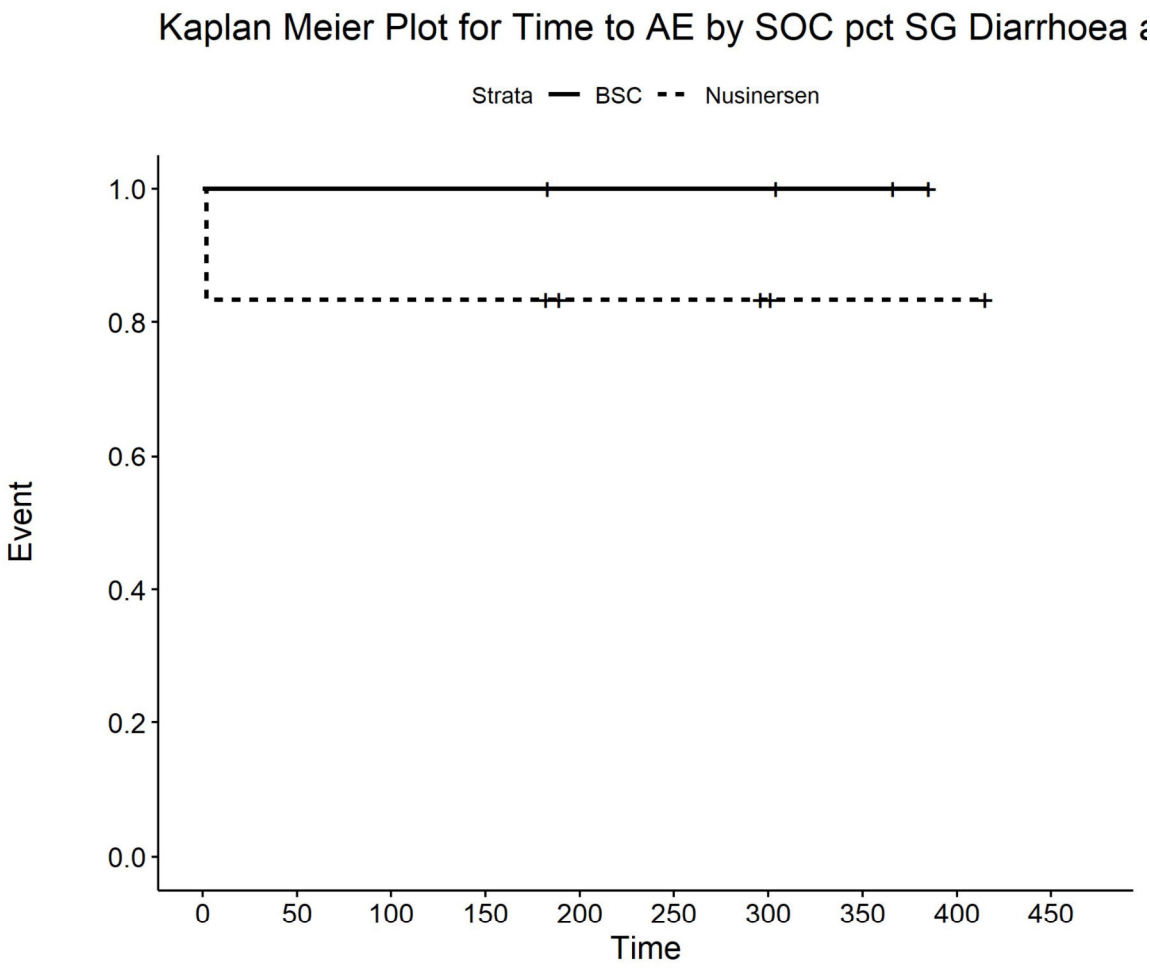
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



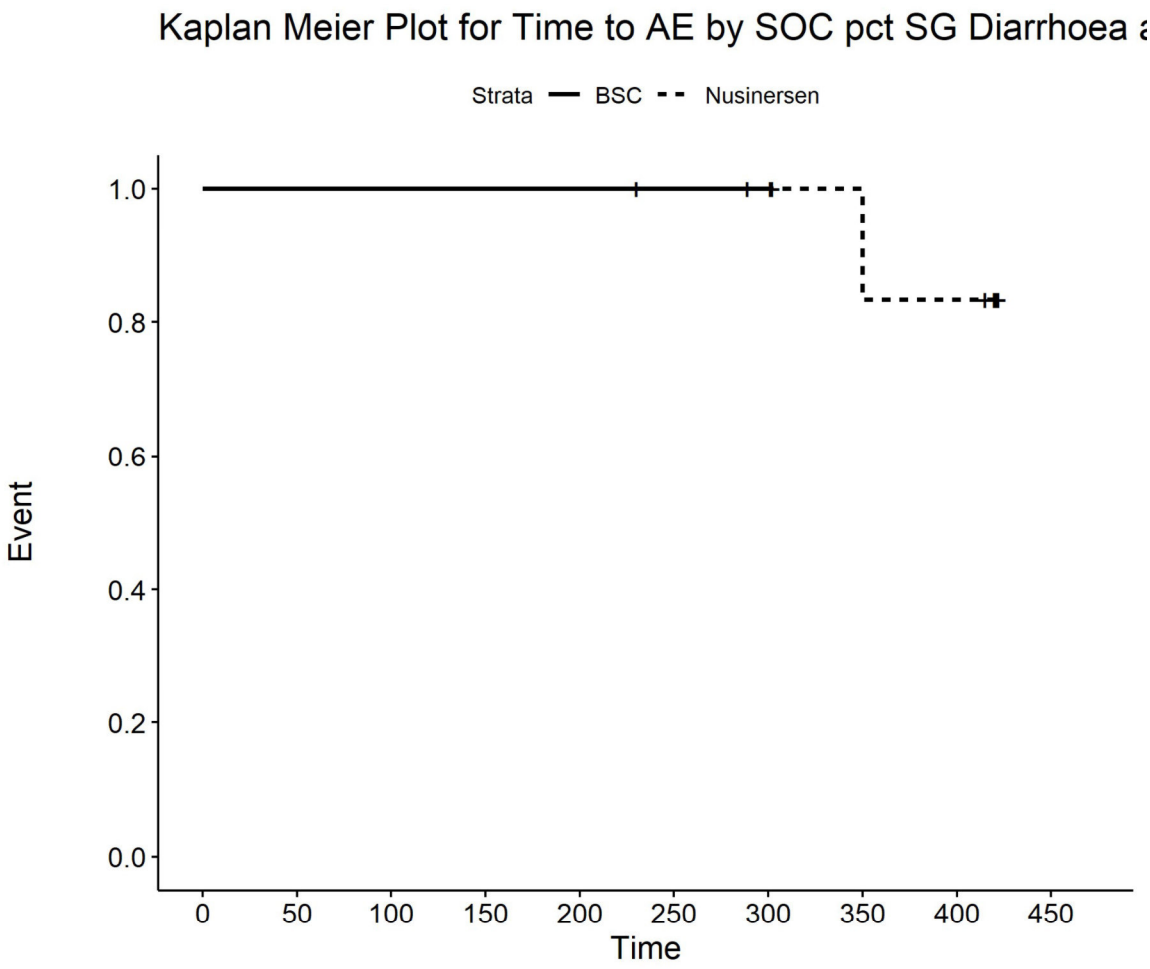
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	2	2	2	0



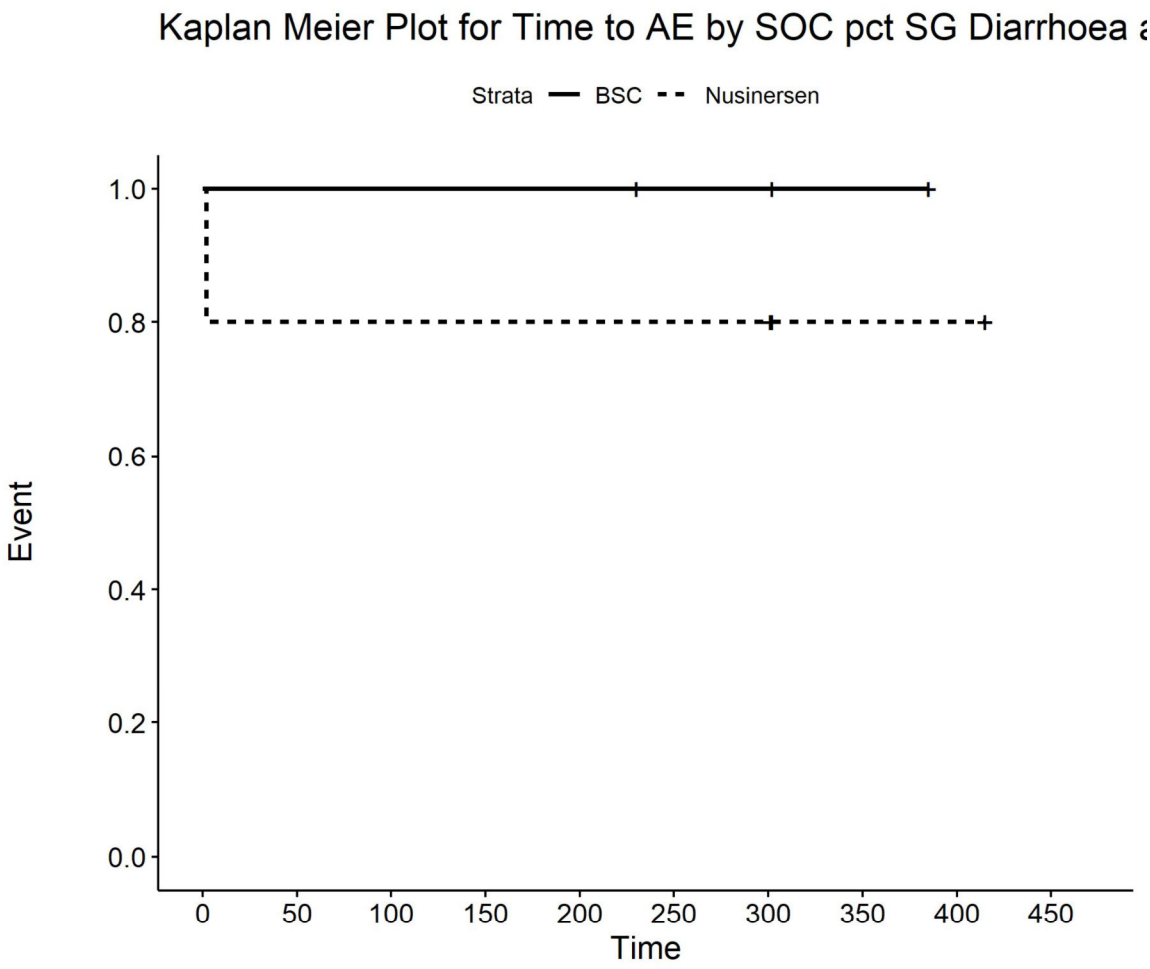
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	2	1	1	0



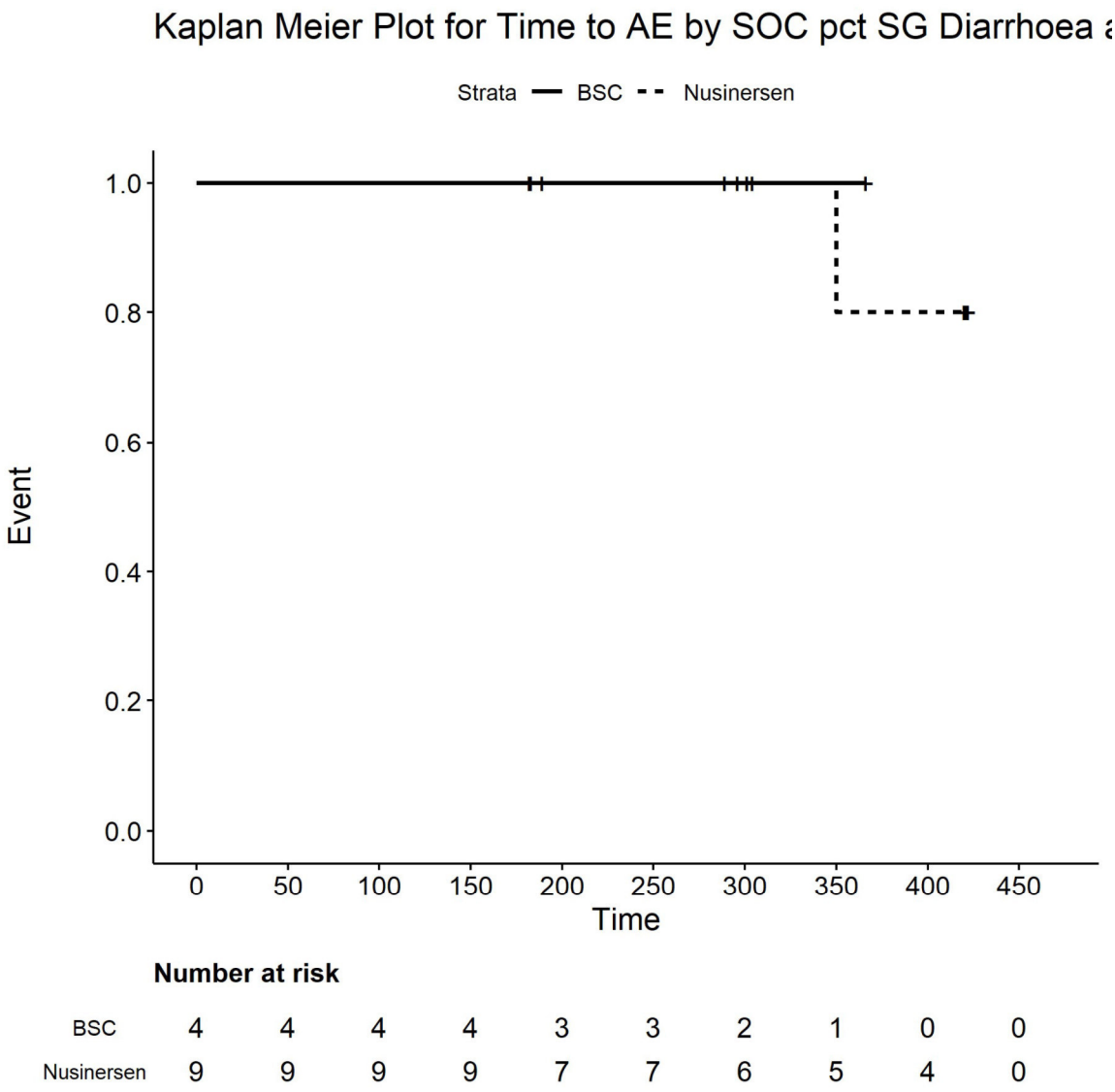
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



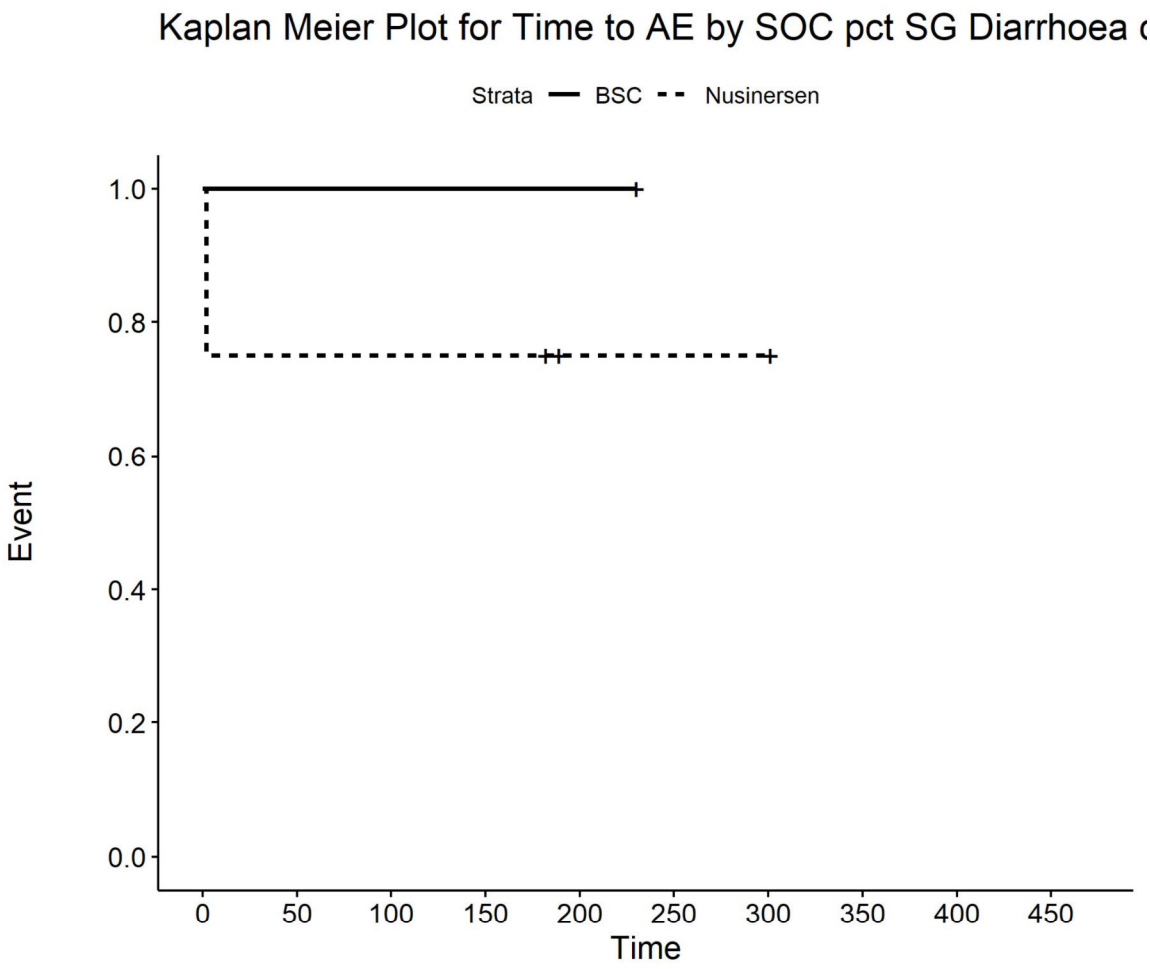
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



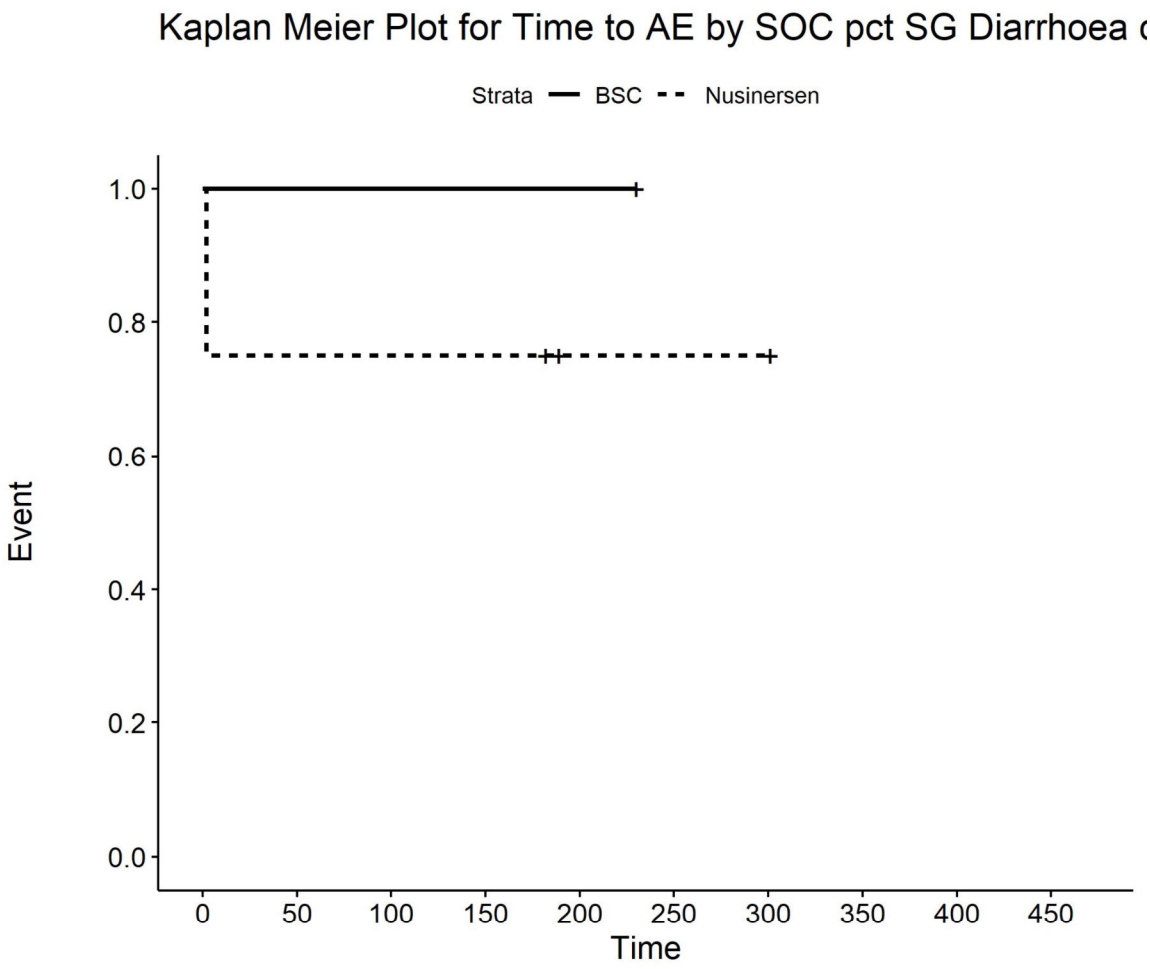
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



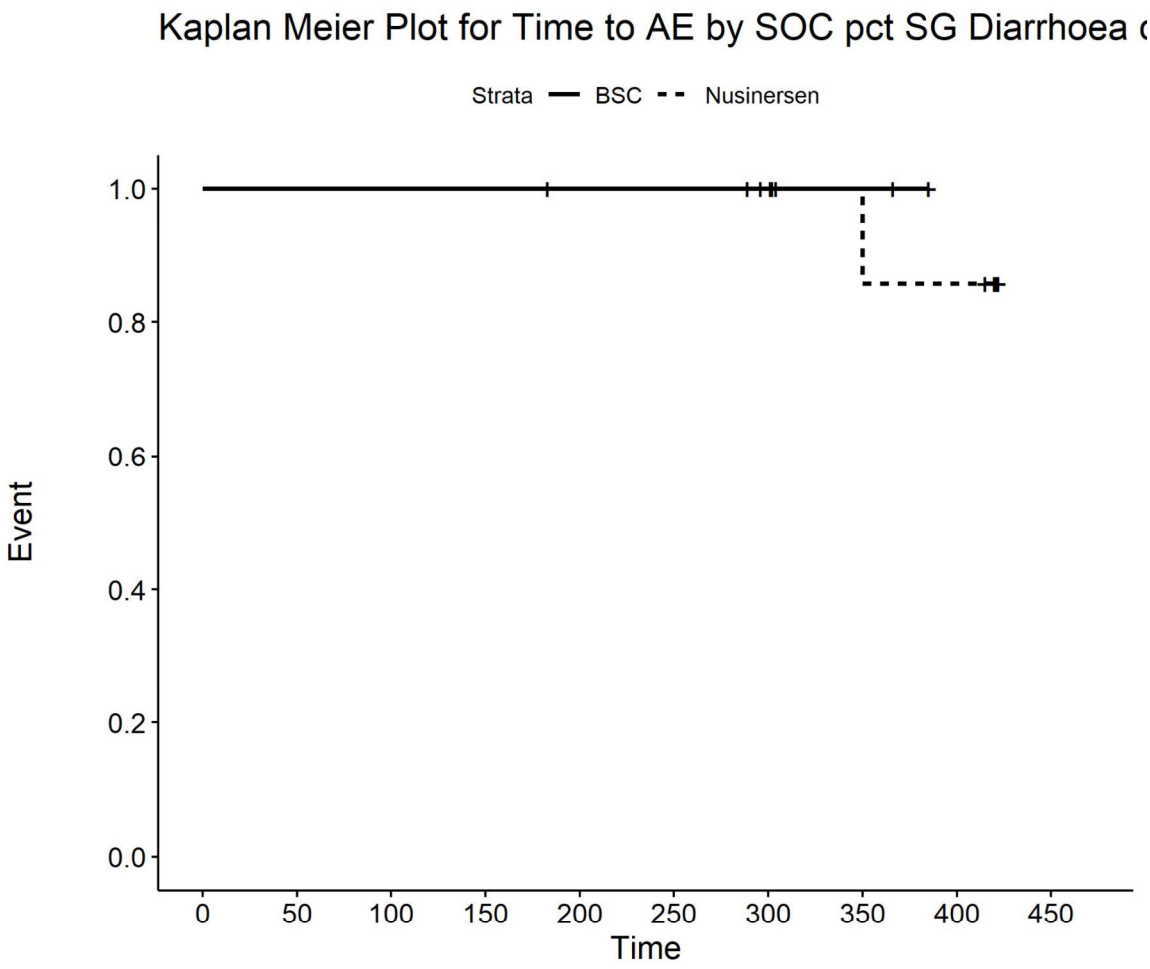
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



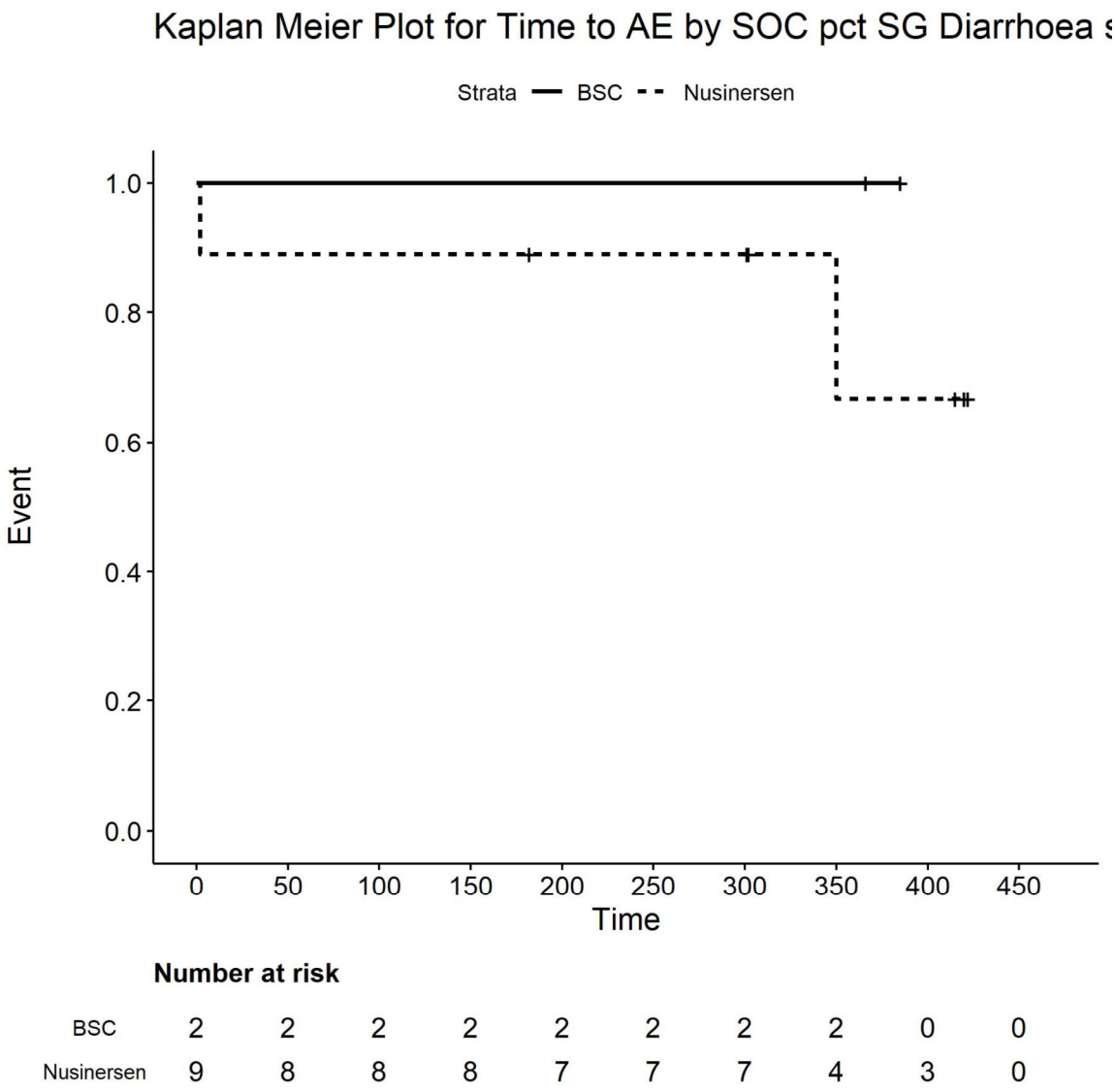
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



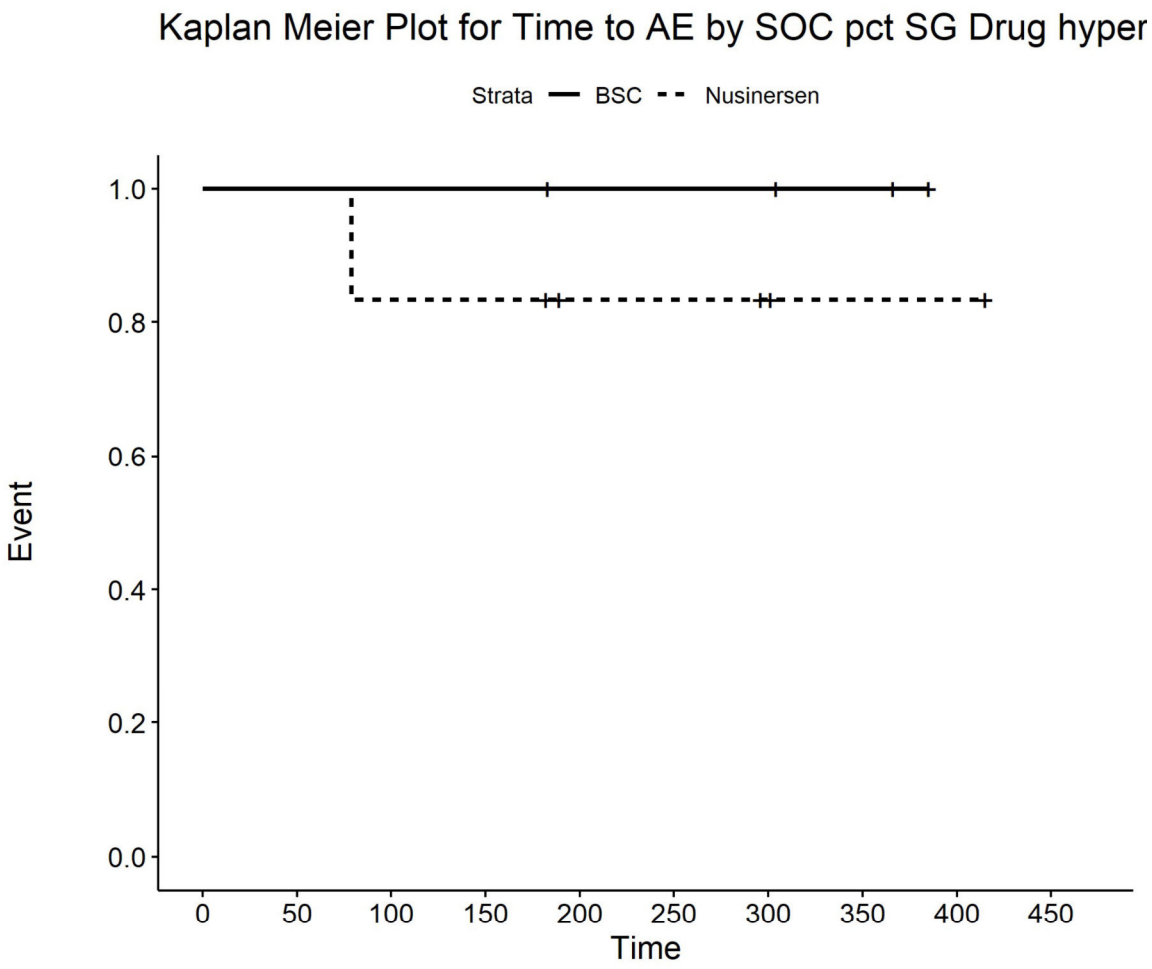
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



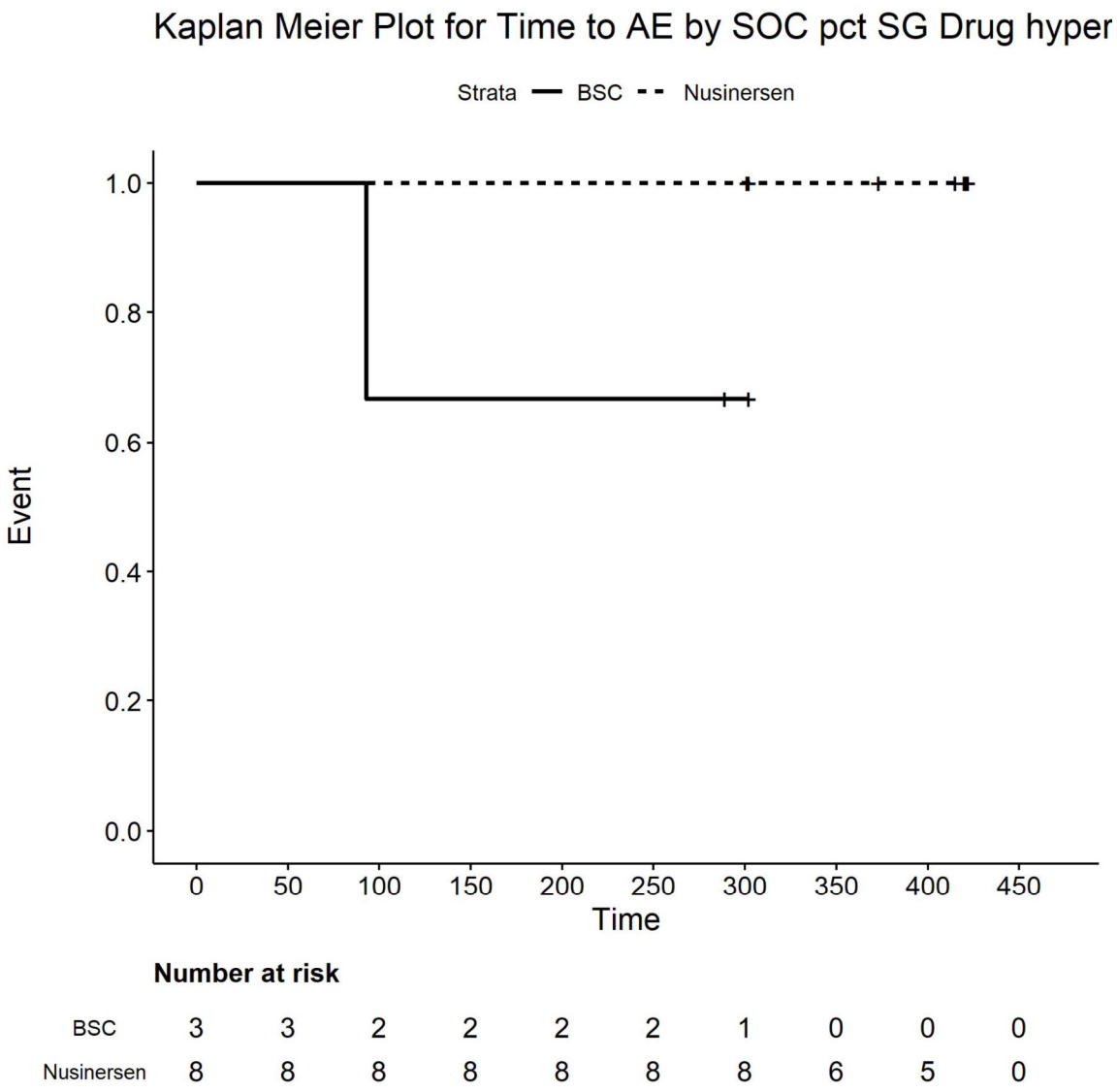
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



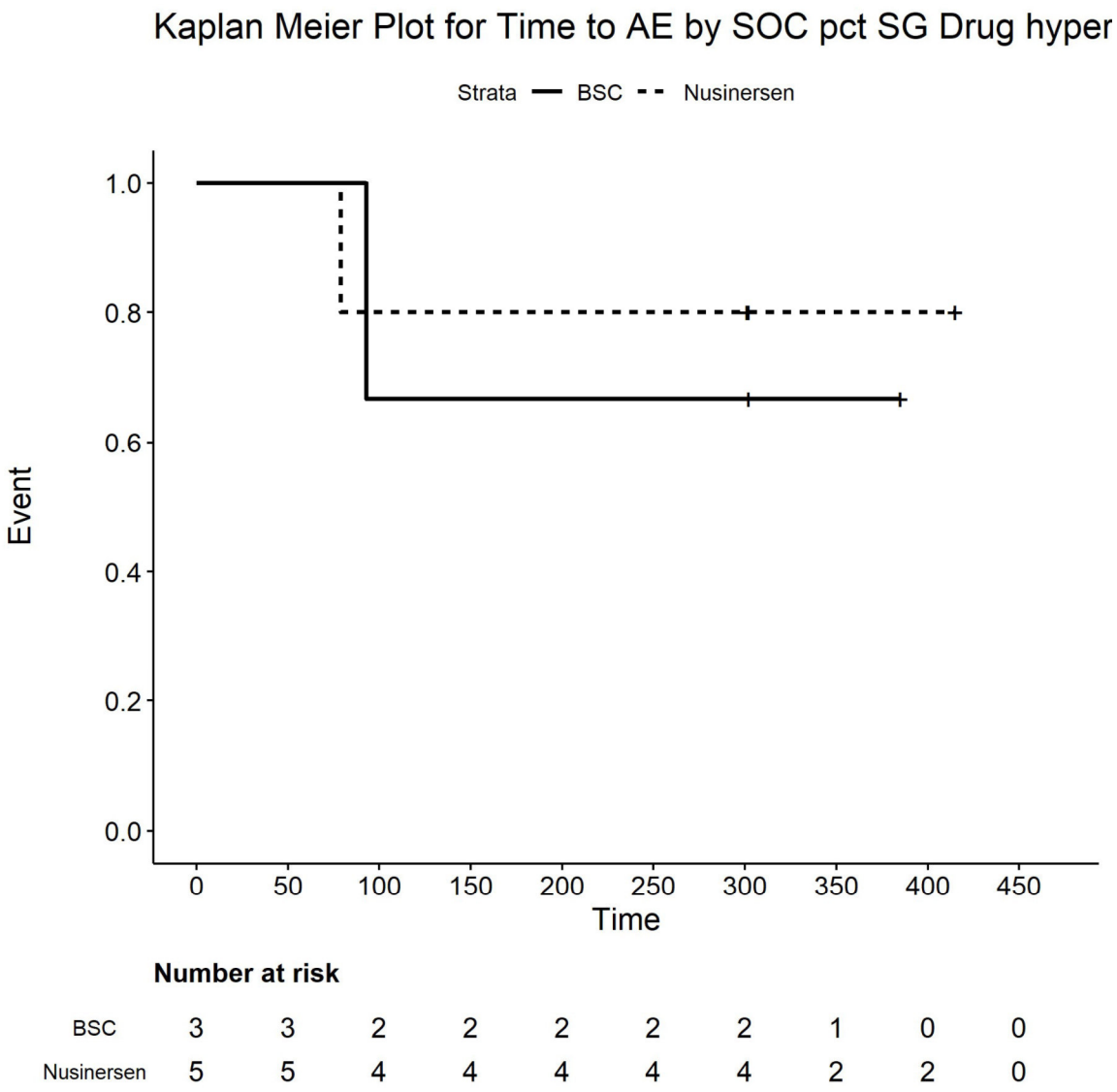
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



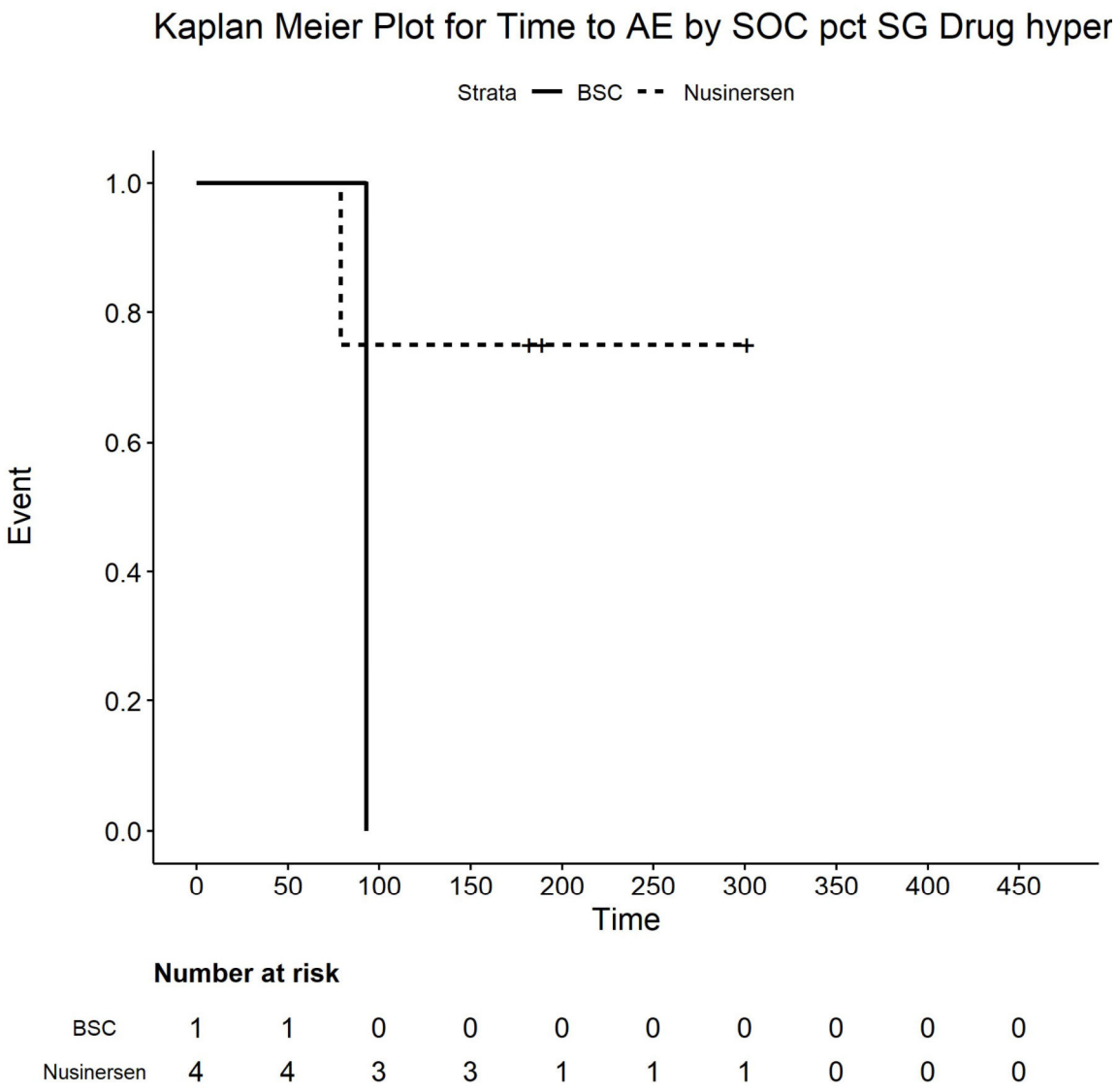
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



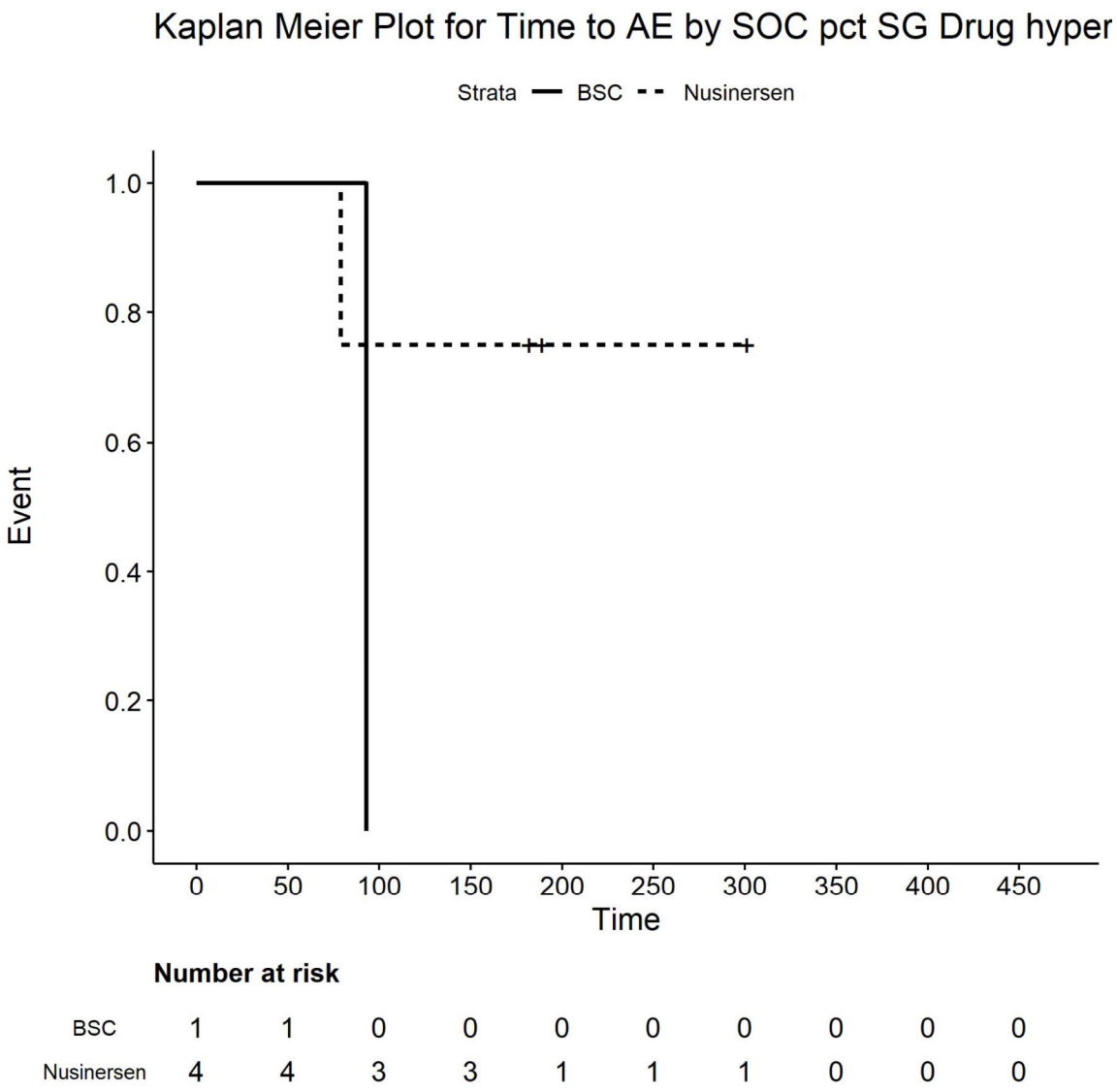
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



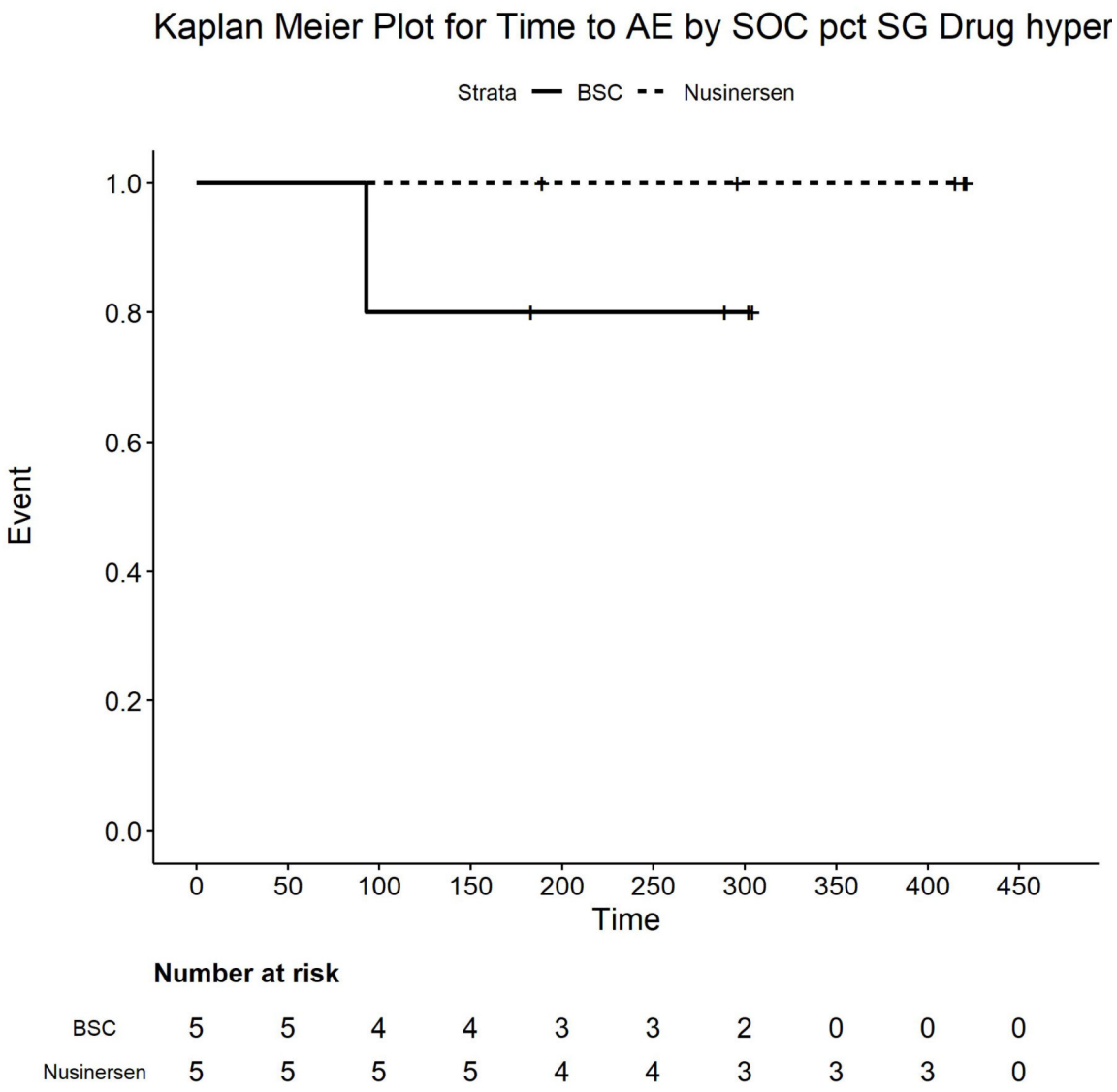
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



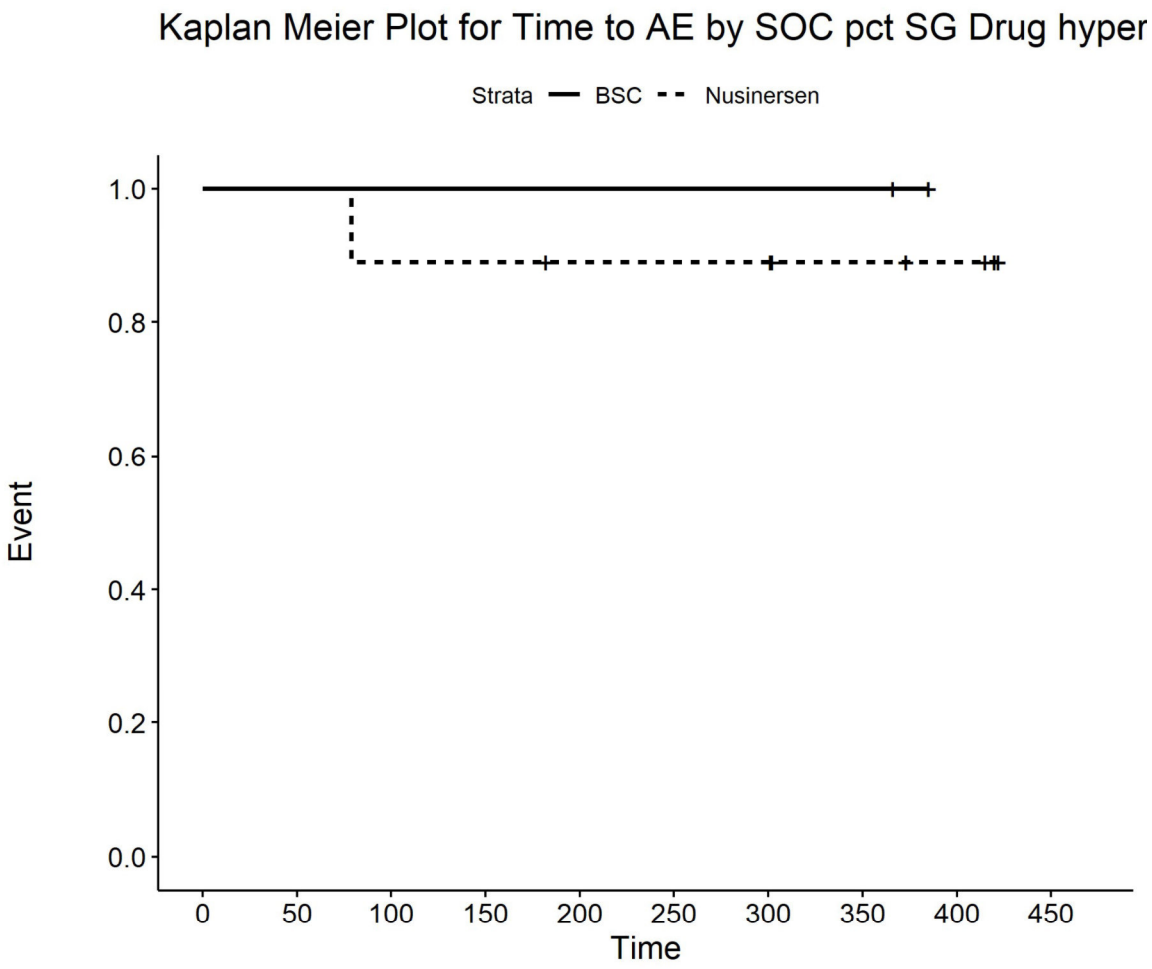
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



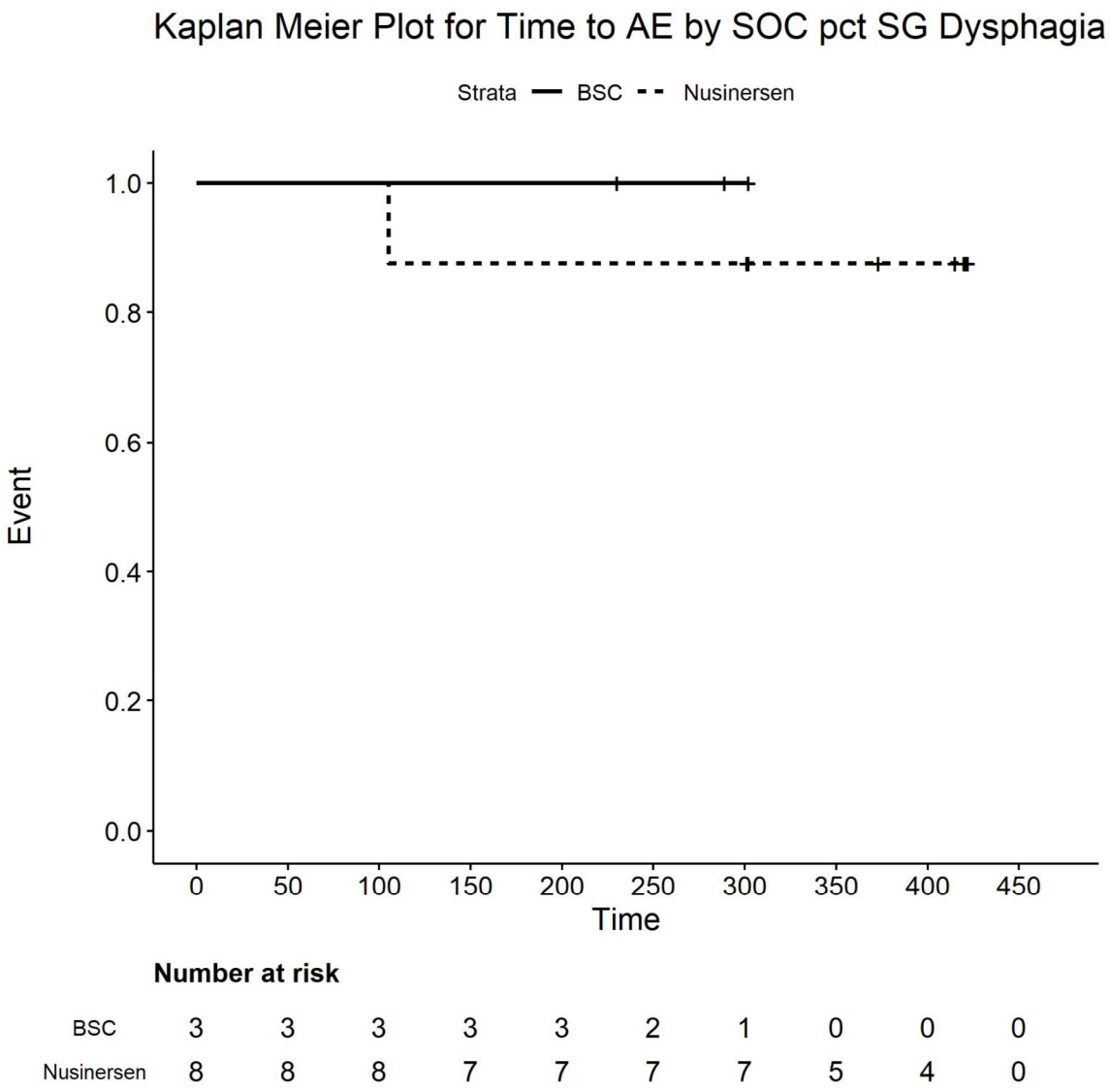
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



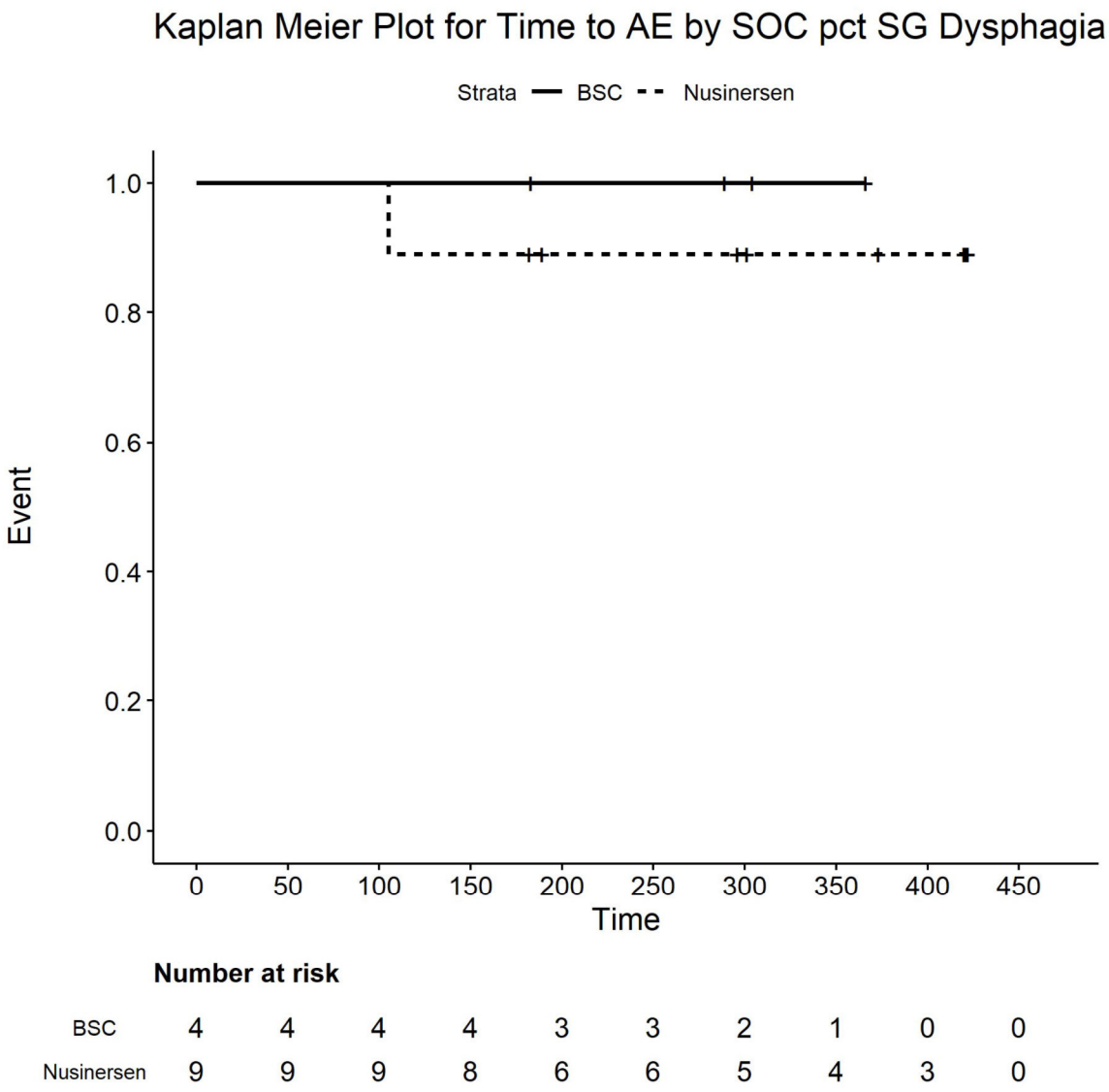
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



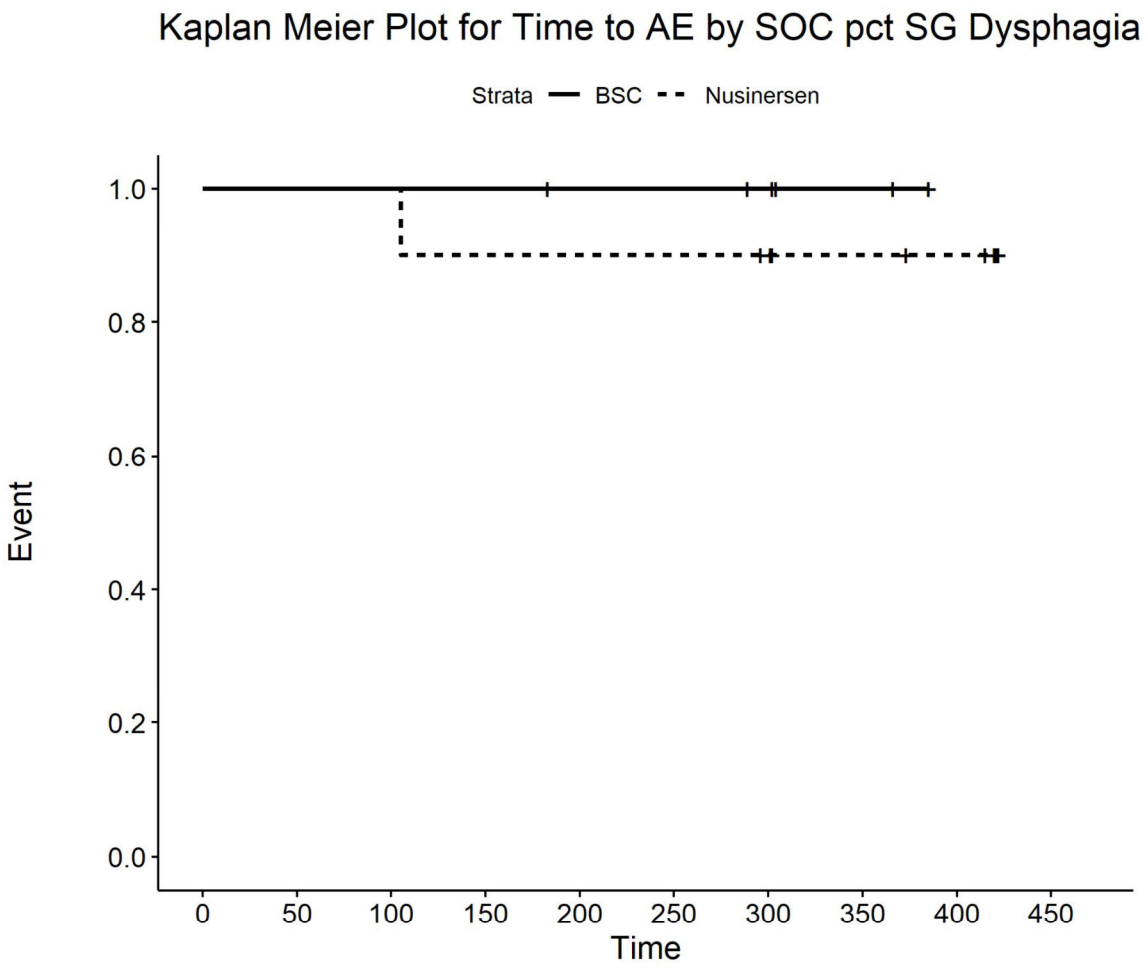
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



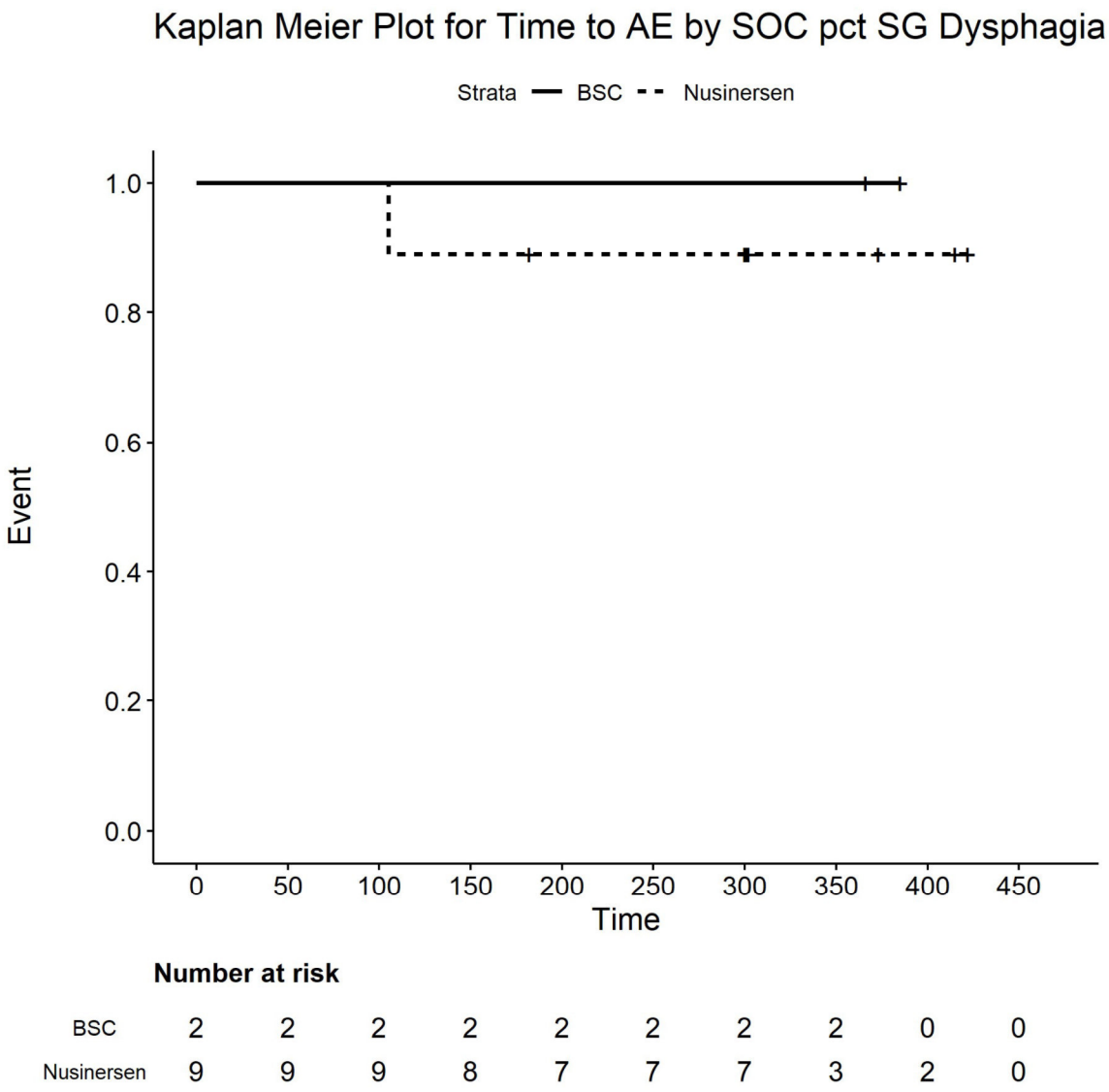
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



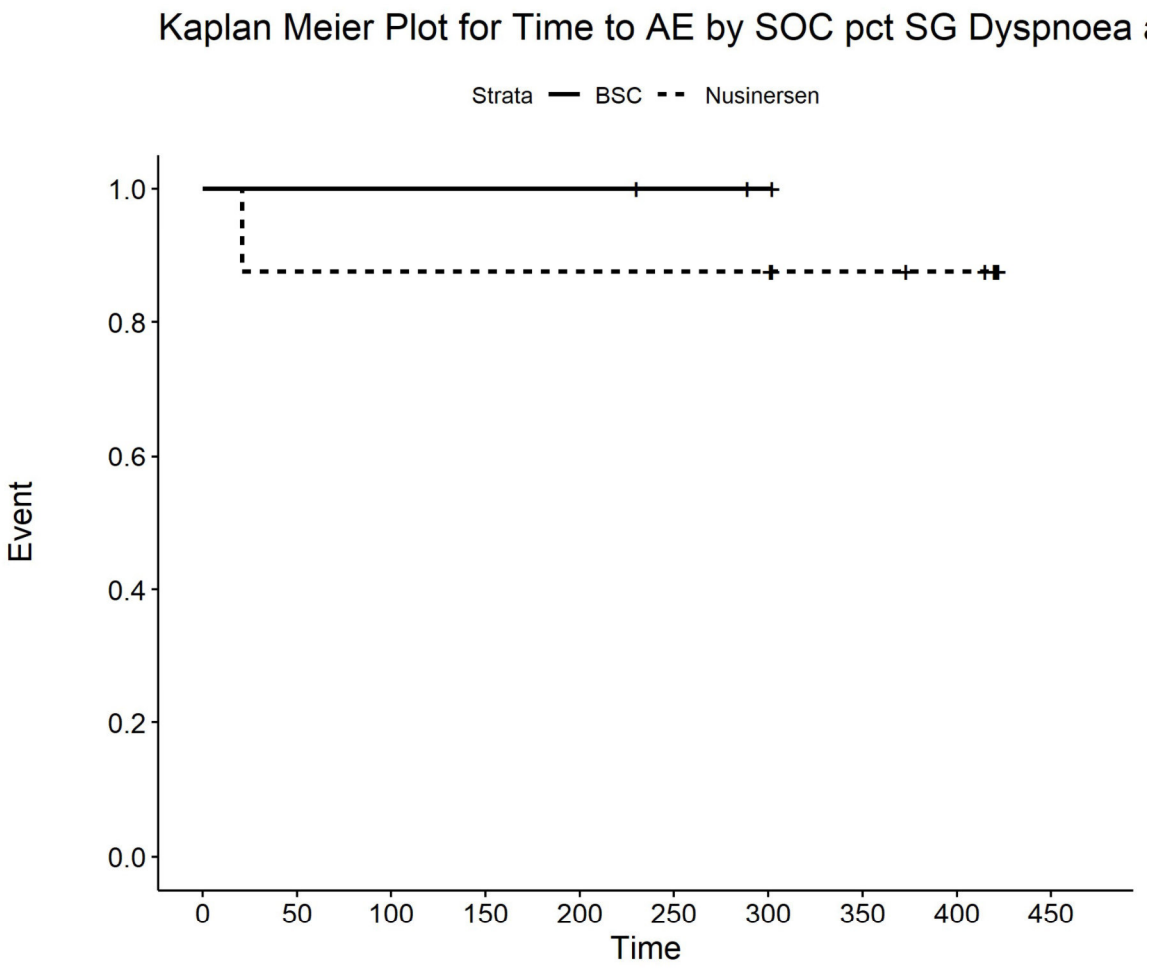
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



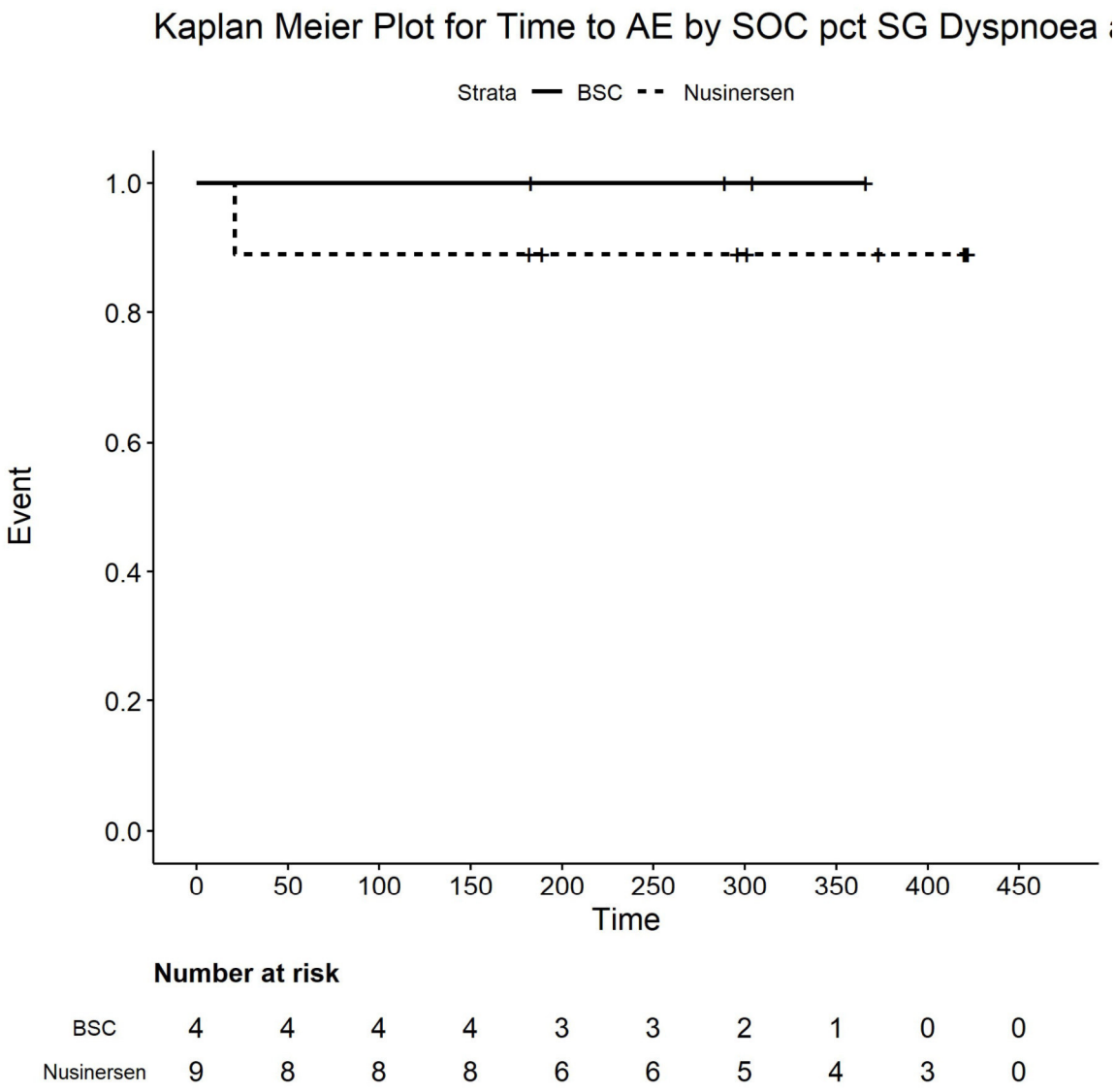
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



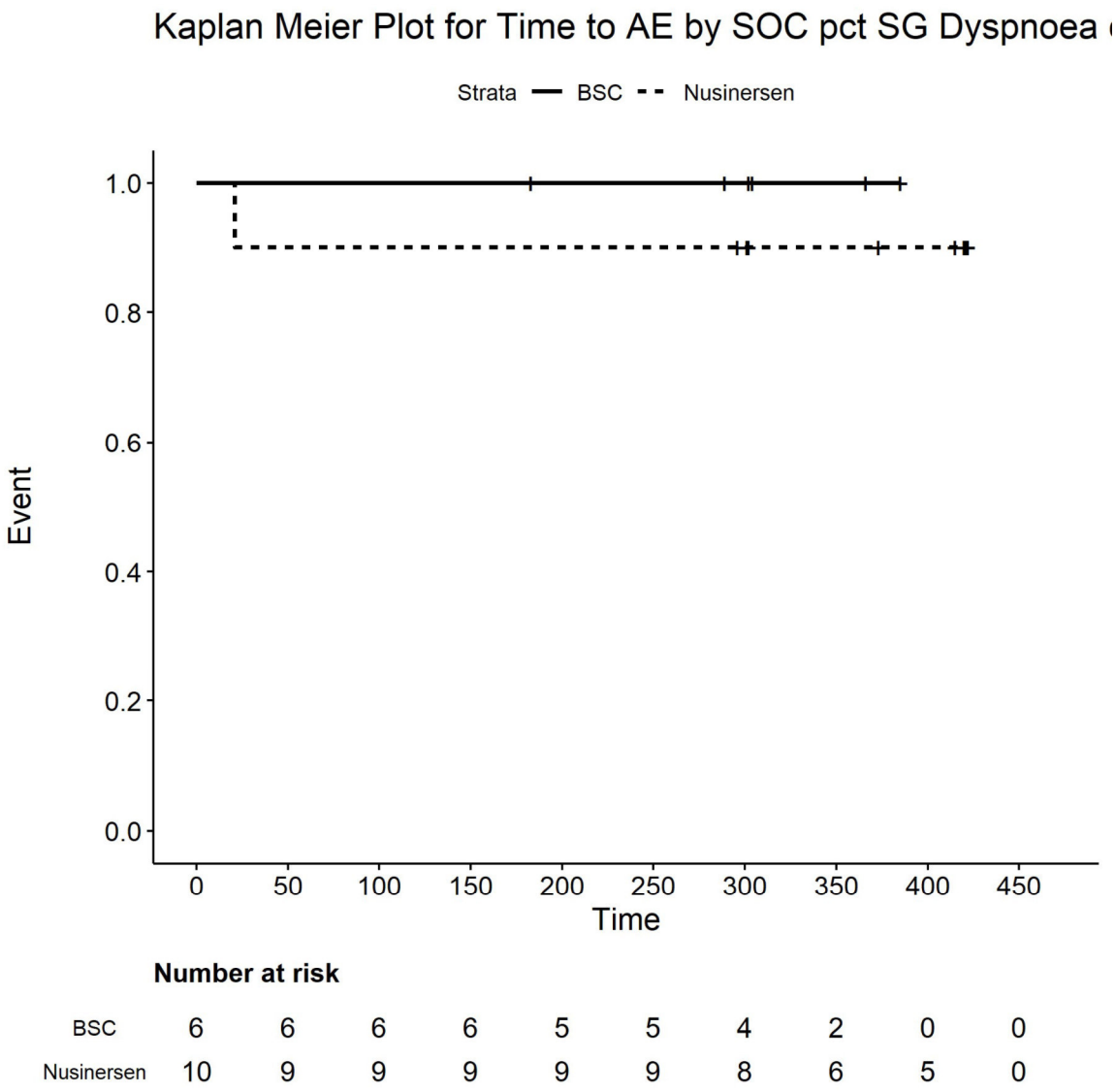
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



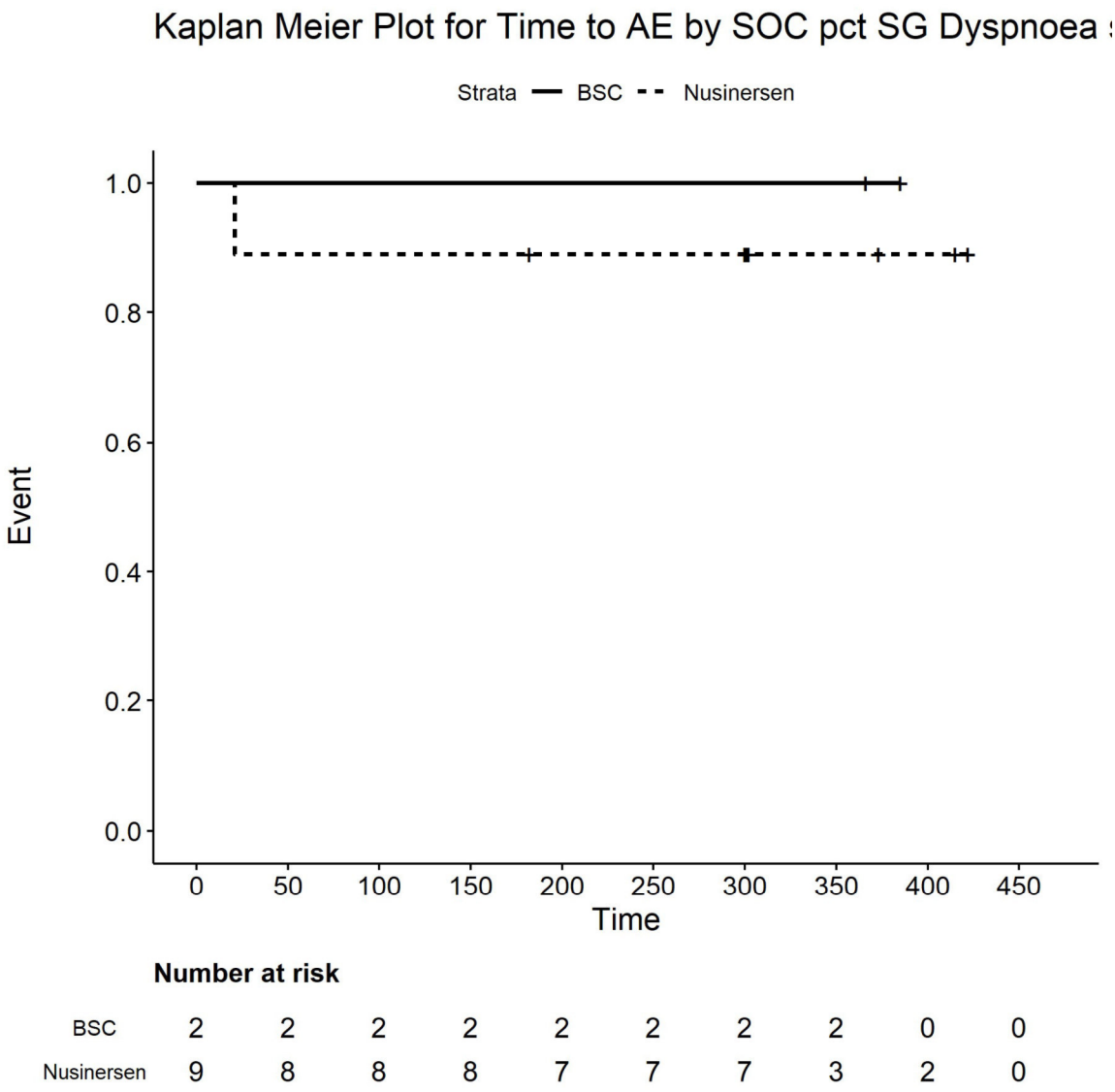
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



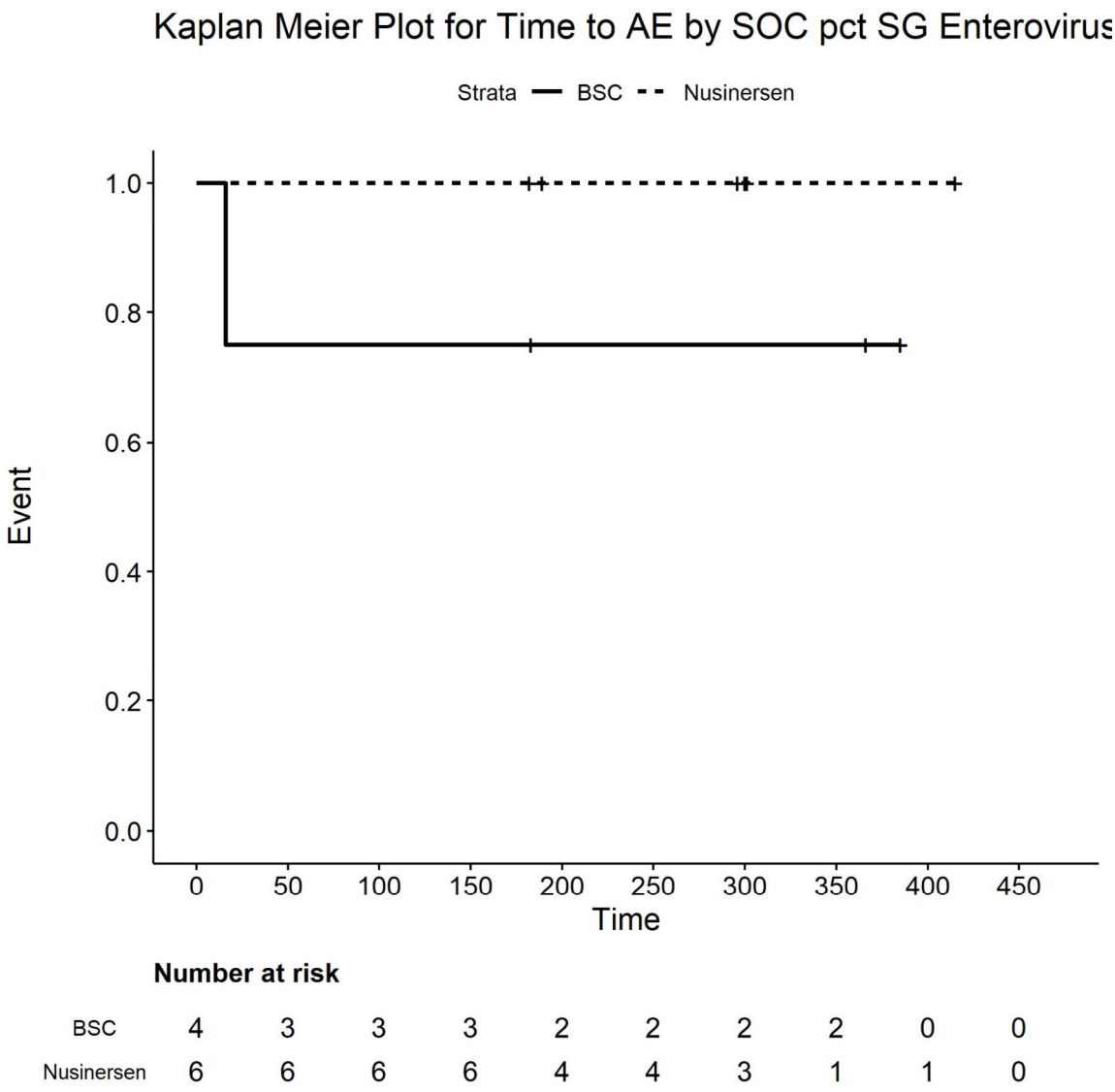
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



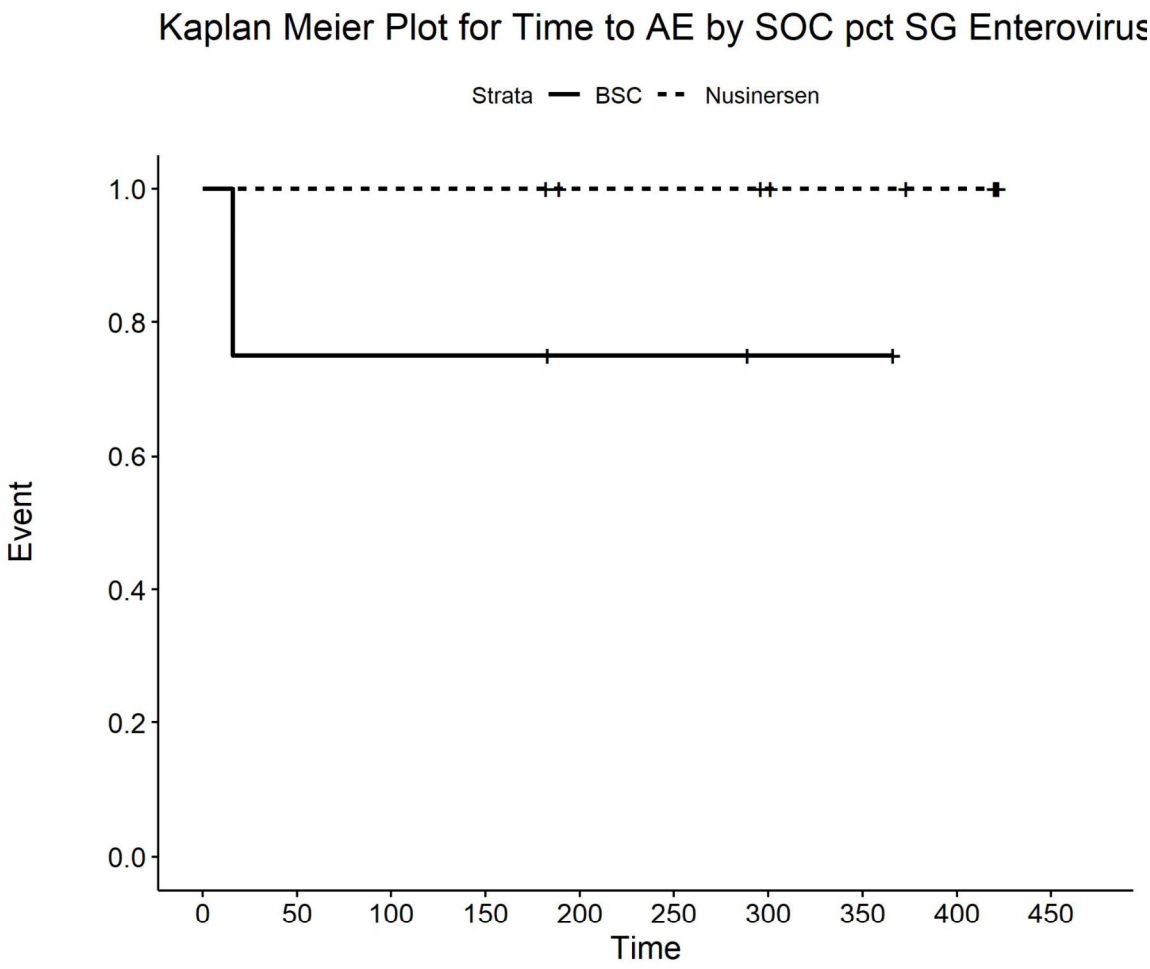
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	2	0



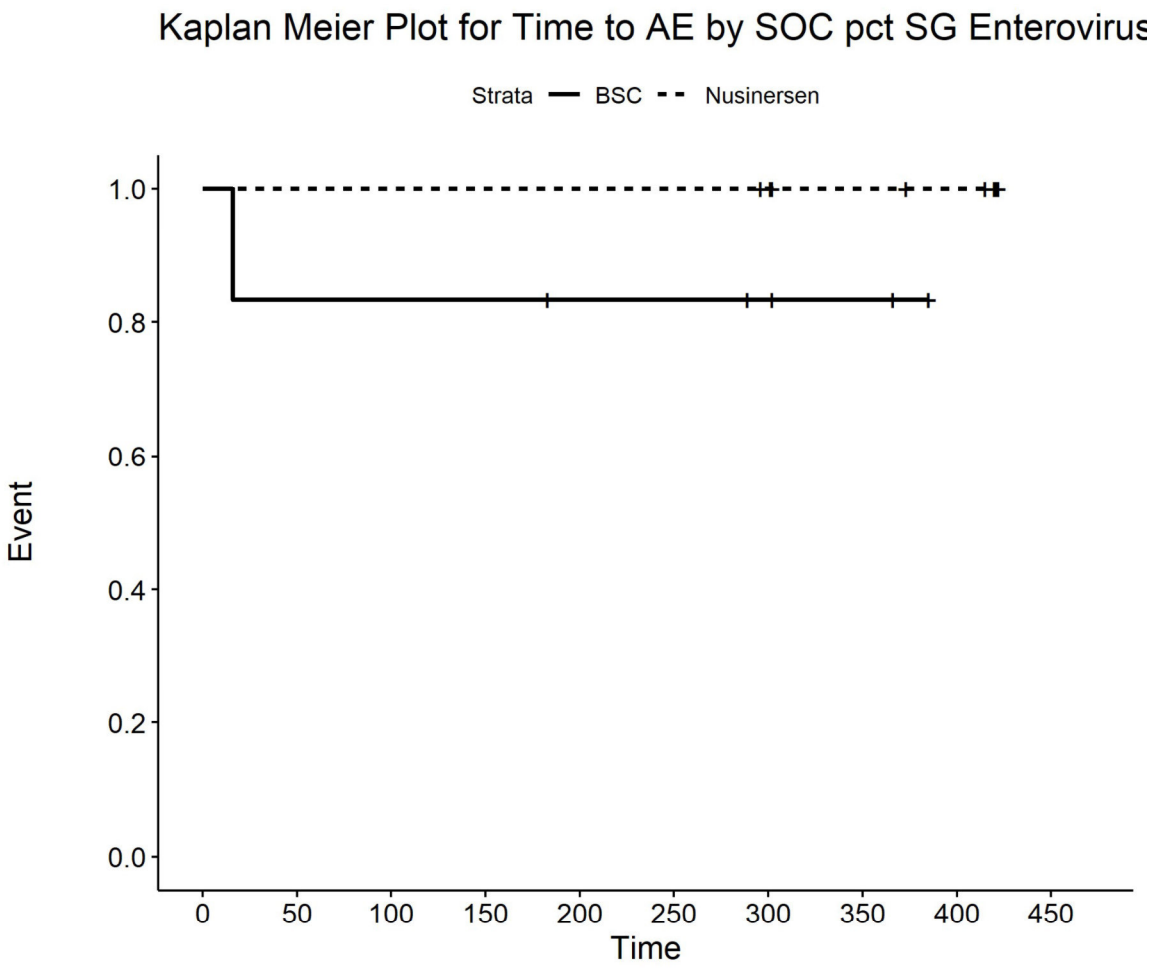
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



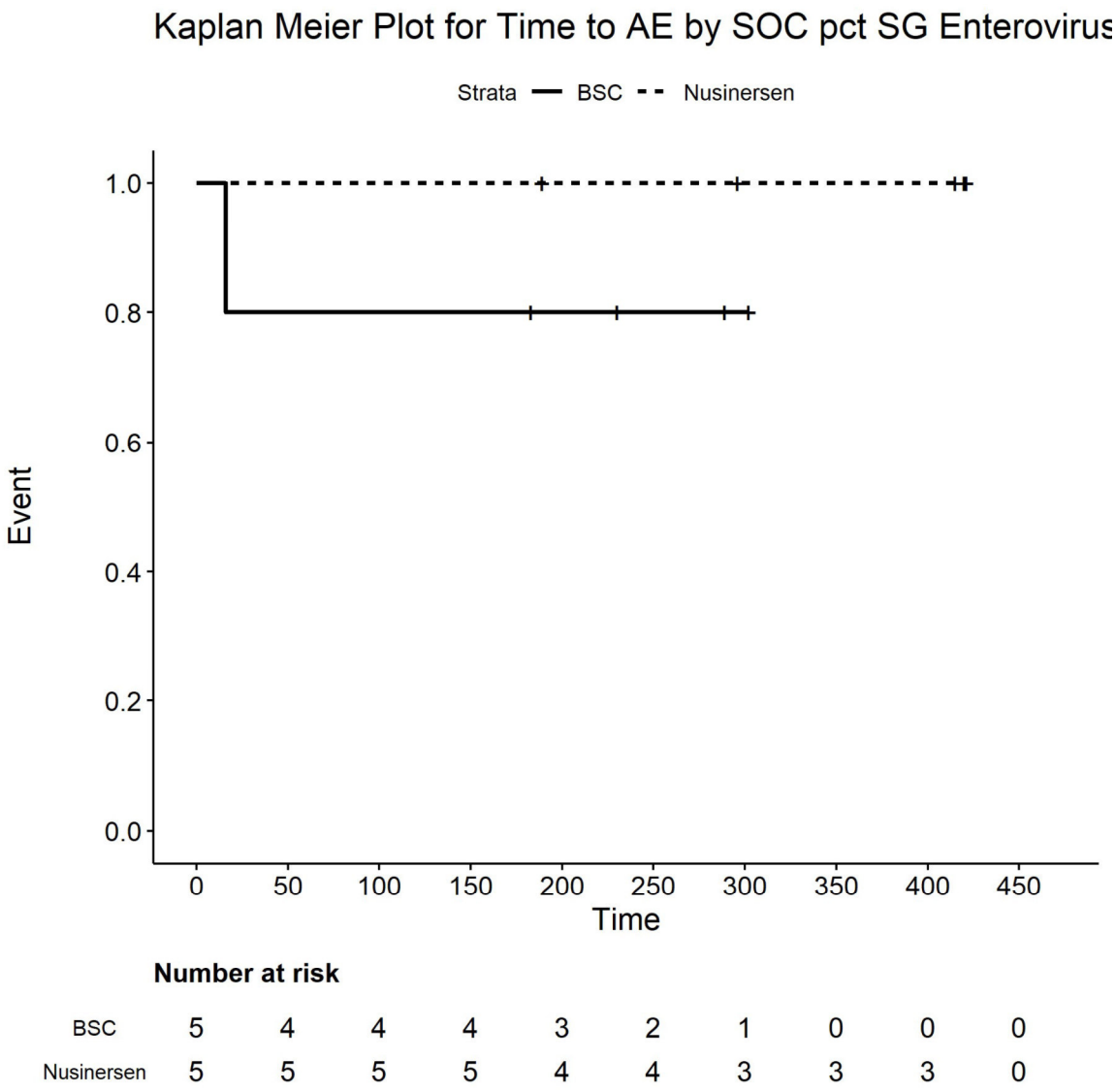
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



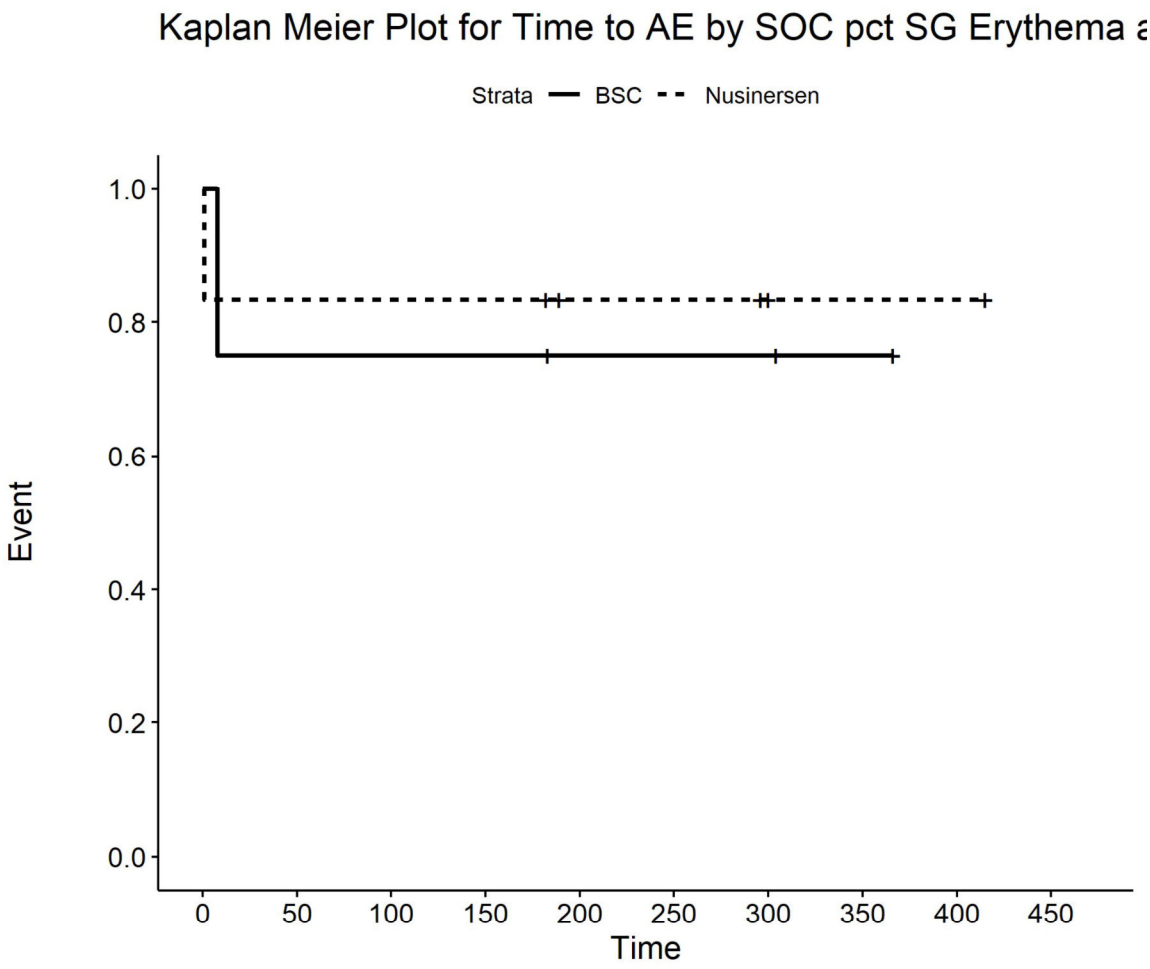
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



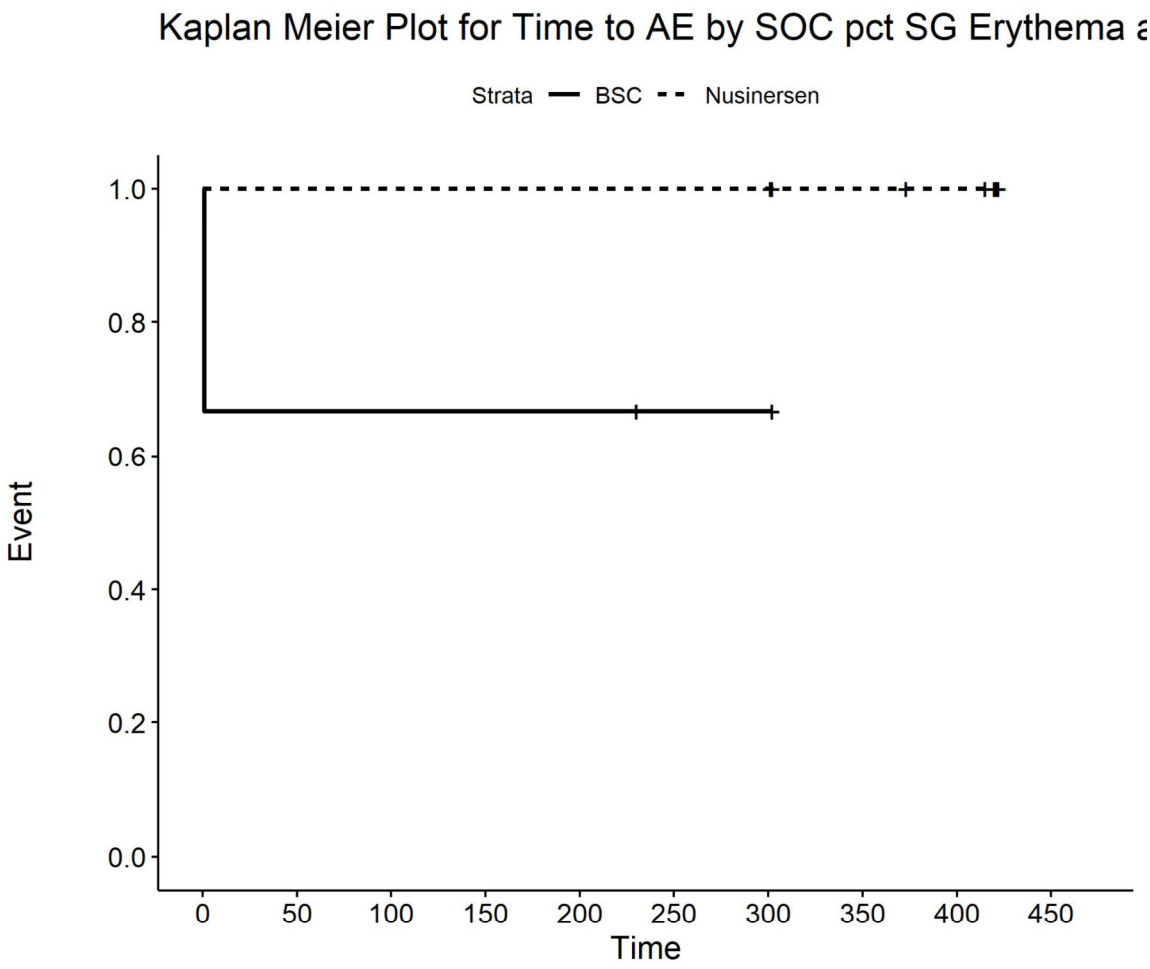
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



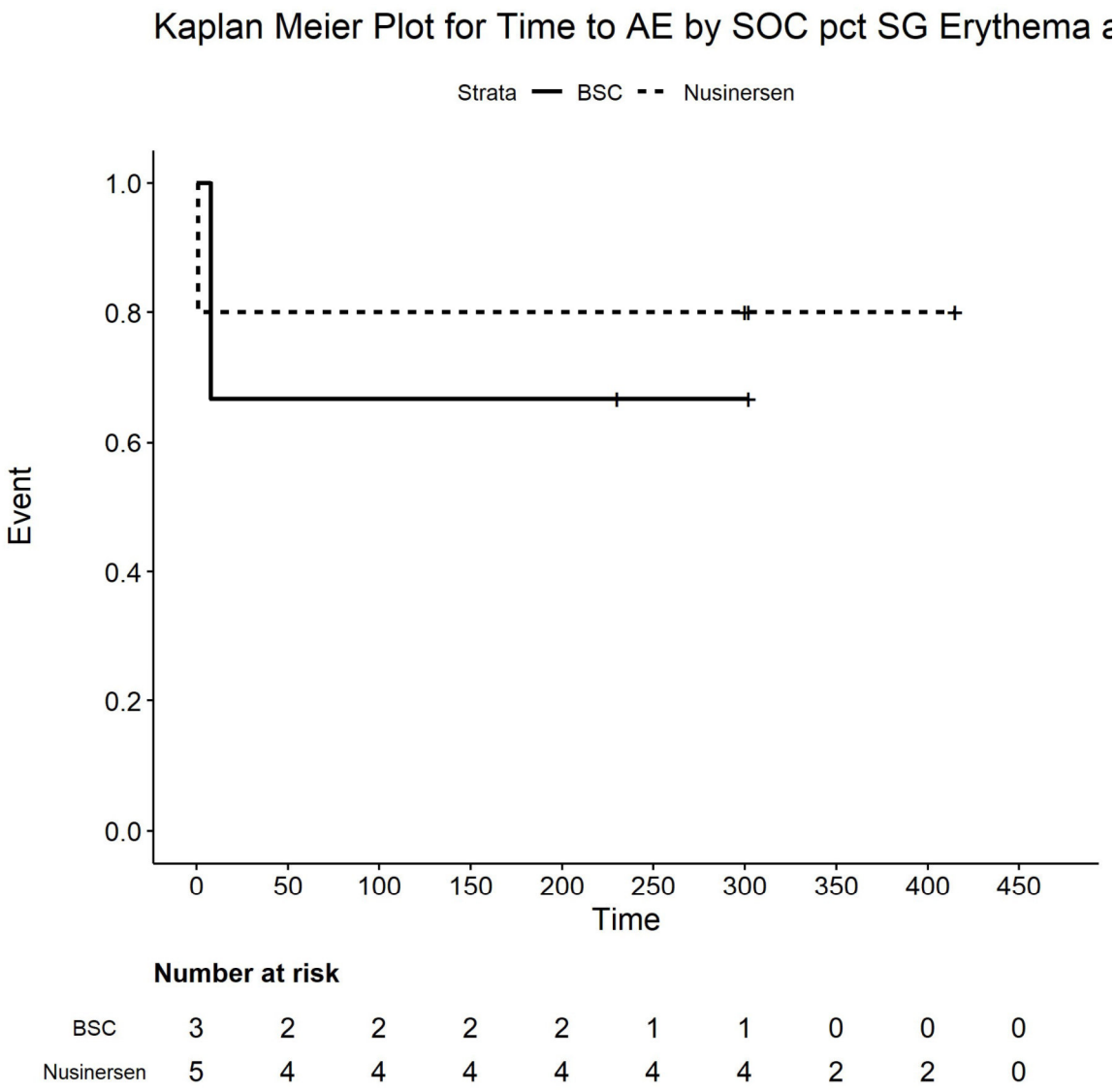
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	5	5	5	3	3	2	1	1	0



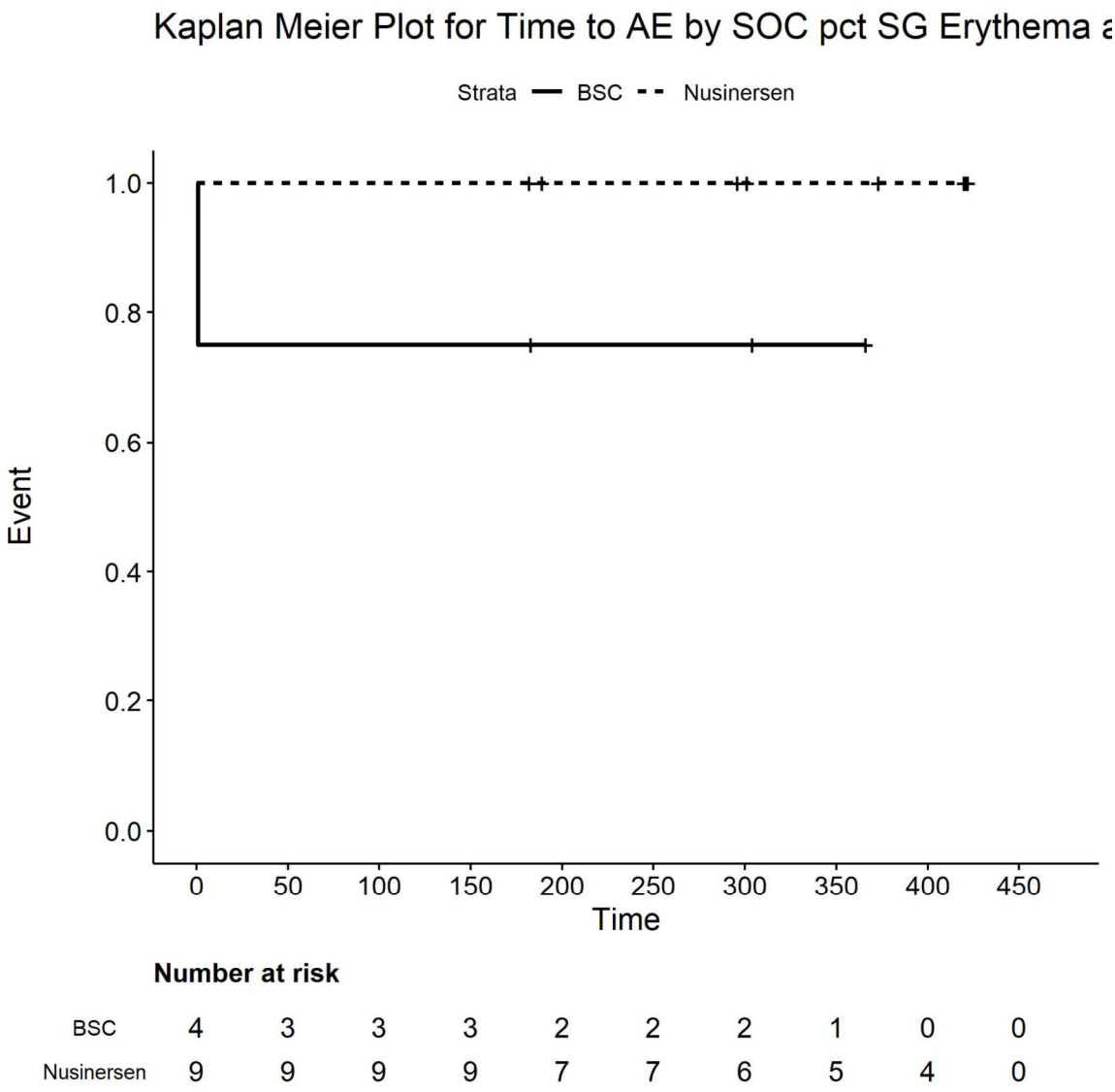
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



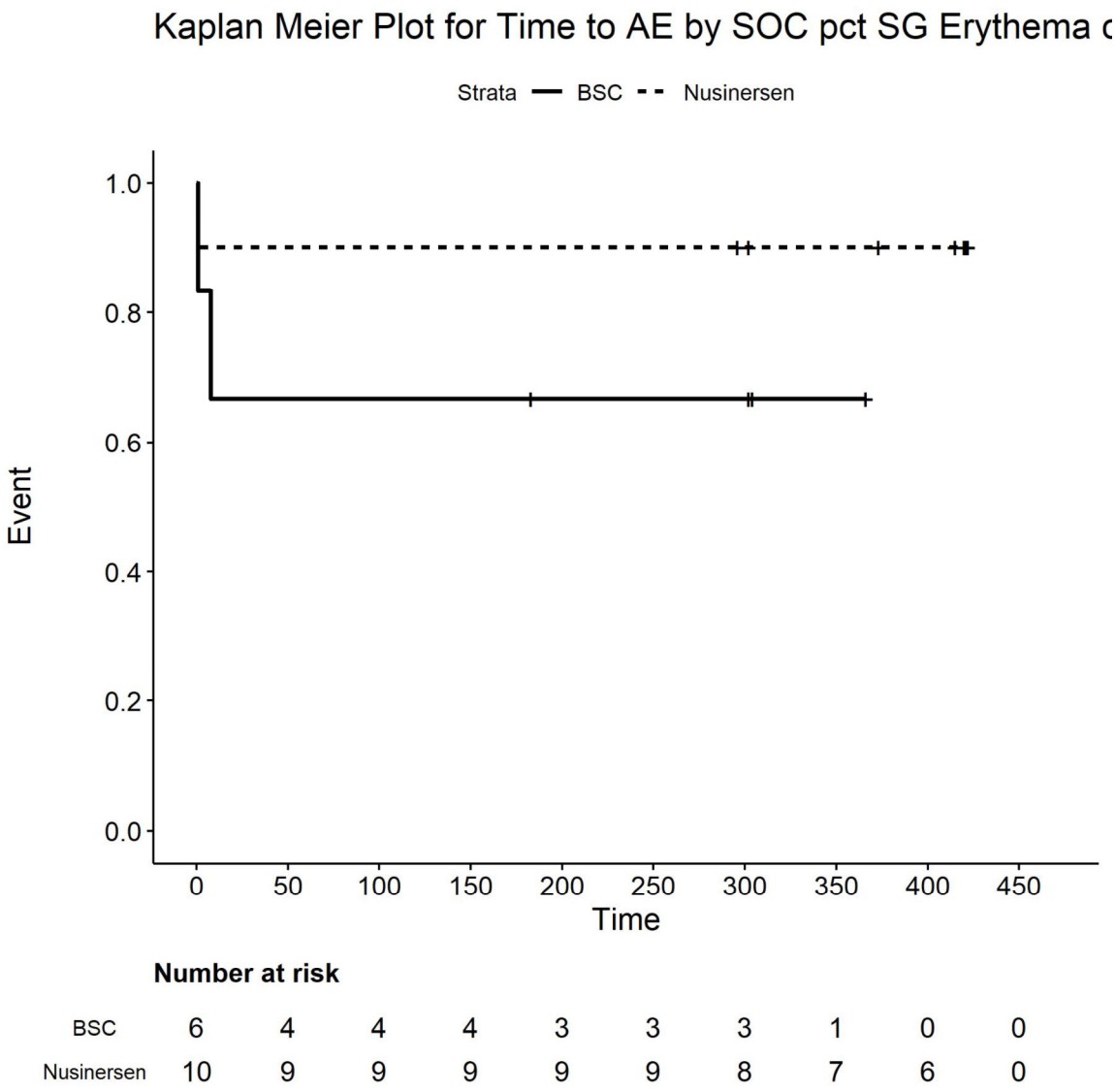
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



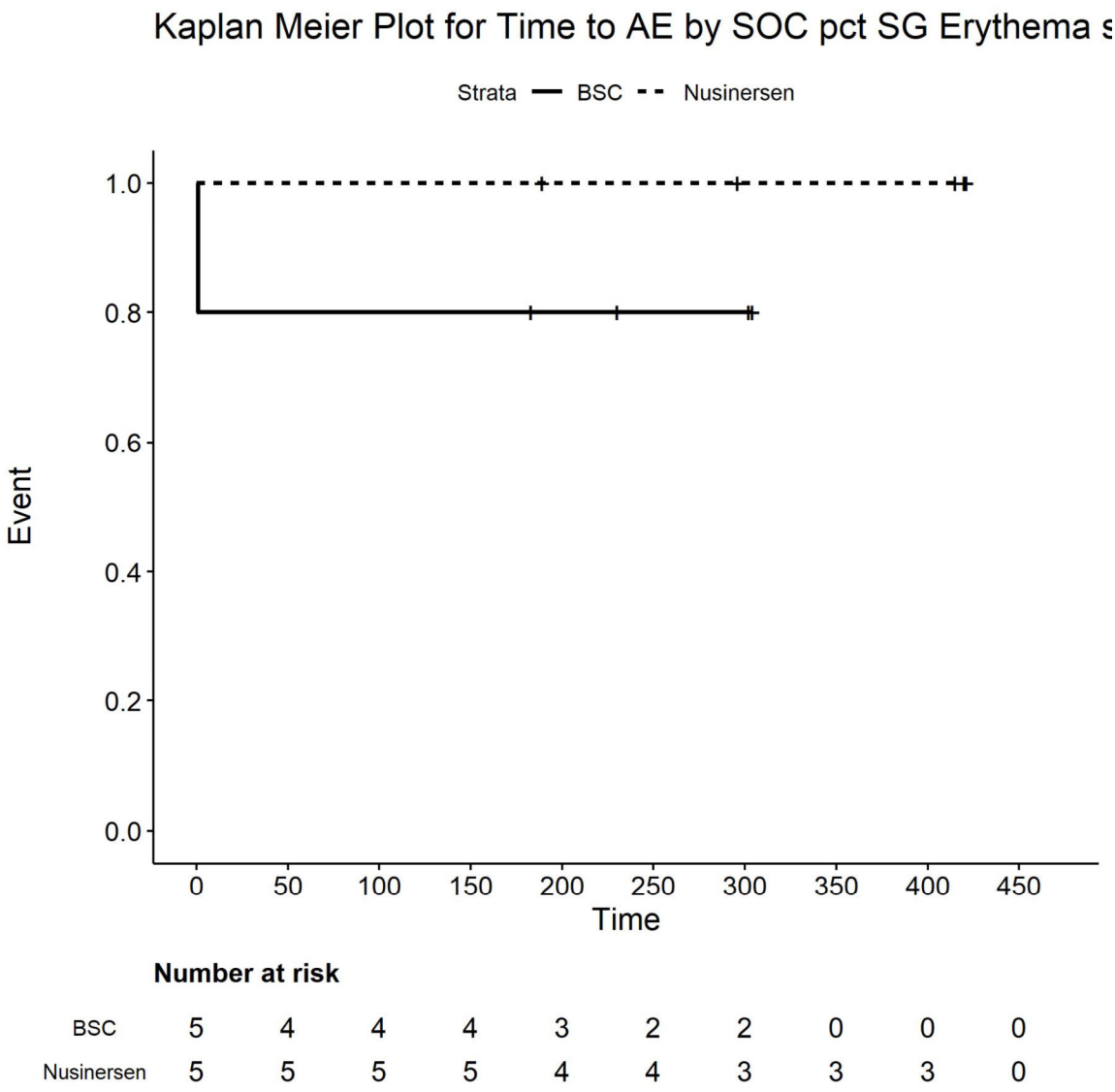
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



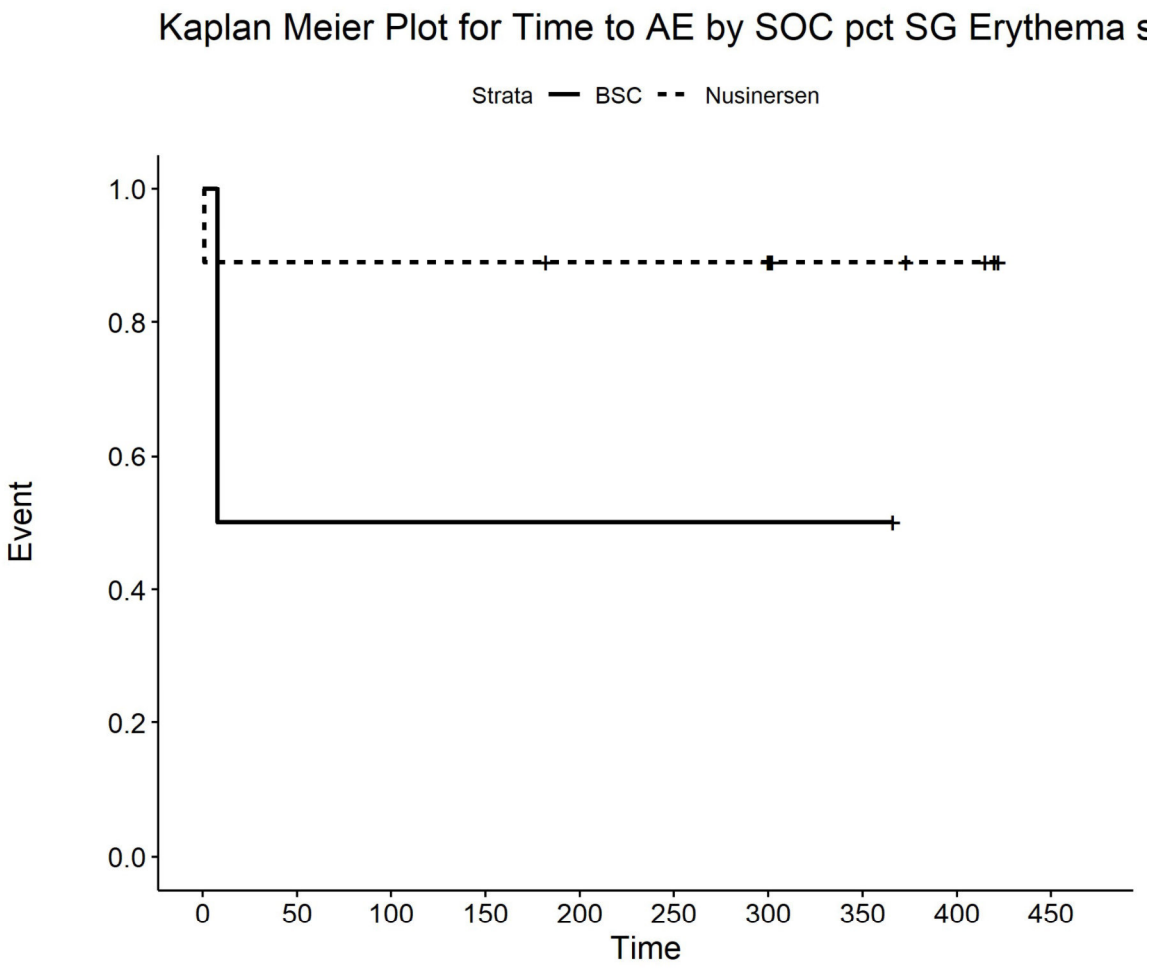
Number at risk

BSC	6	4	4	4	3	3	3	1	0	0
Nusinersen	10	9	9	9	9	9	8	7	6	0



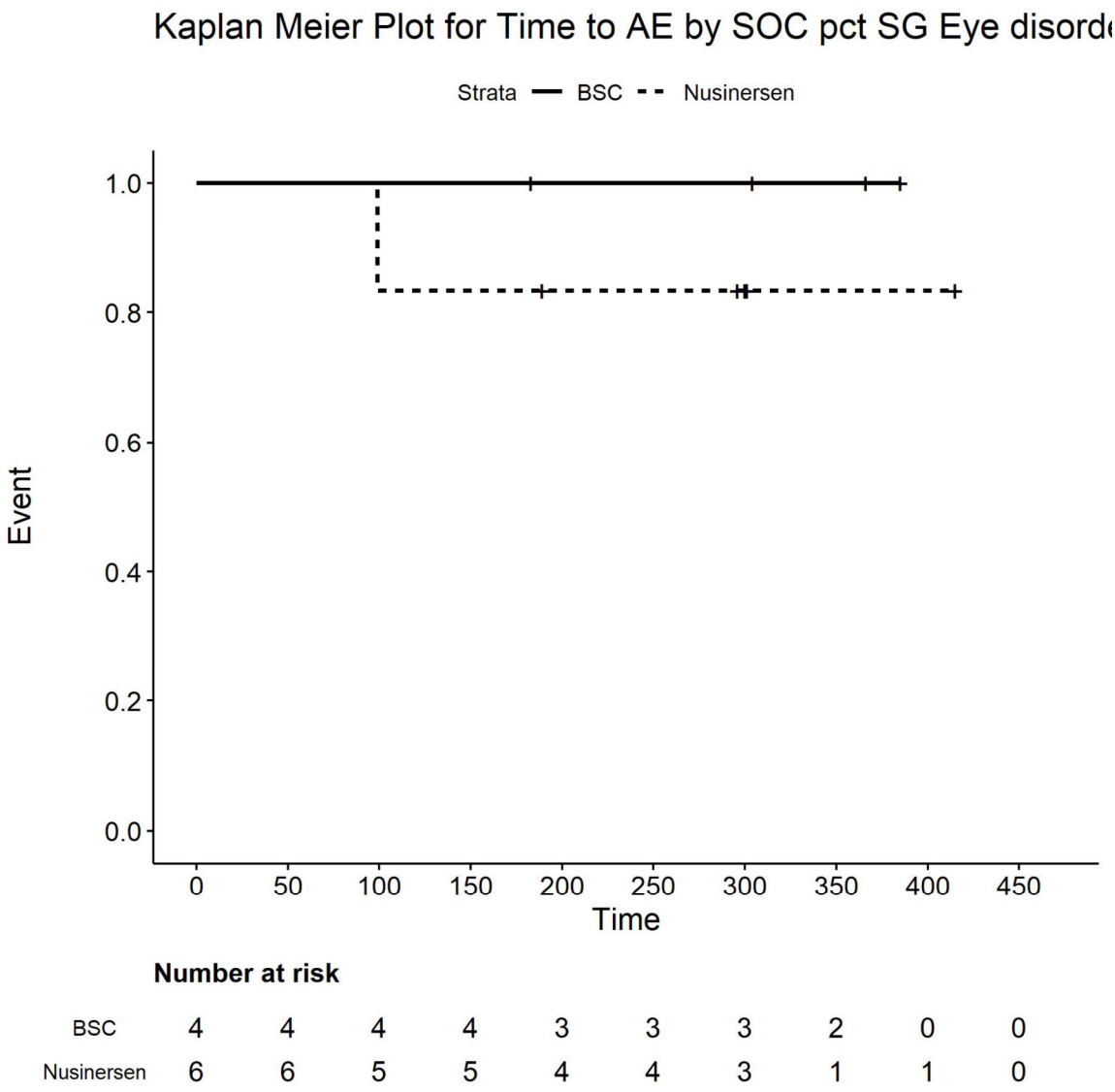
Number at risk

BSC	5	4	4	4	3	2	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



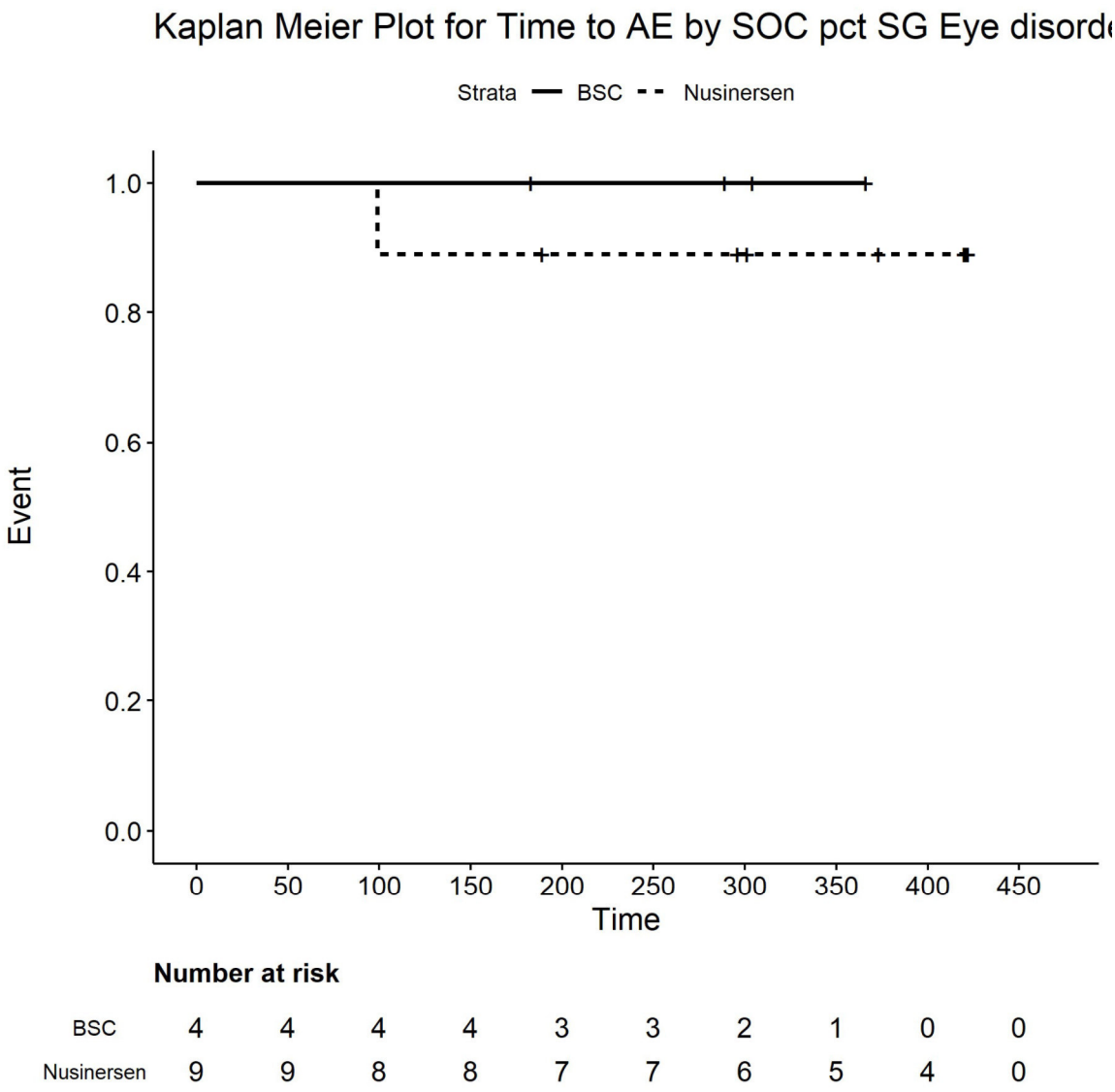
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



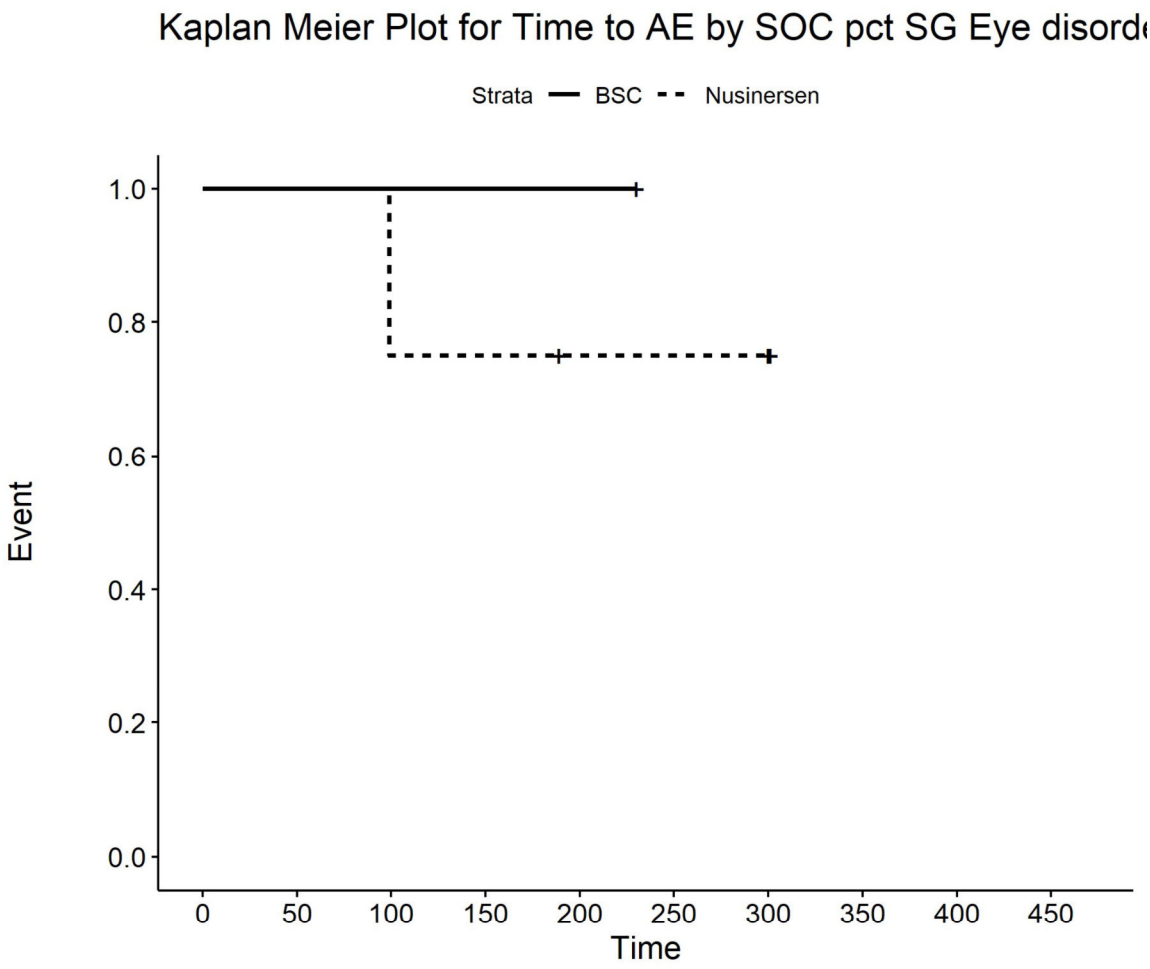
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	4	4	3	1	1	0



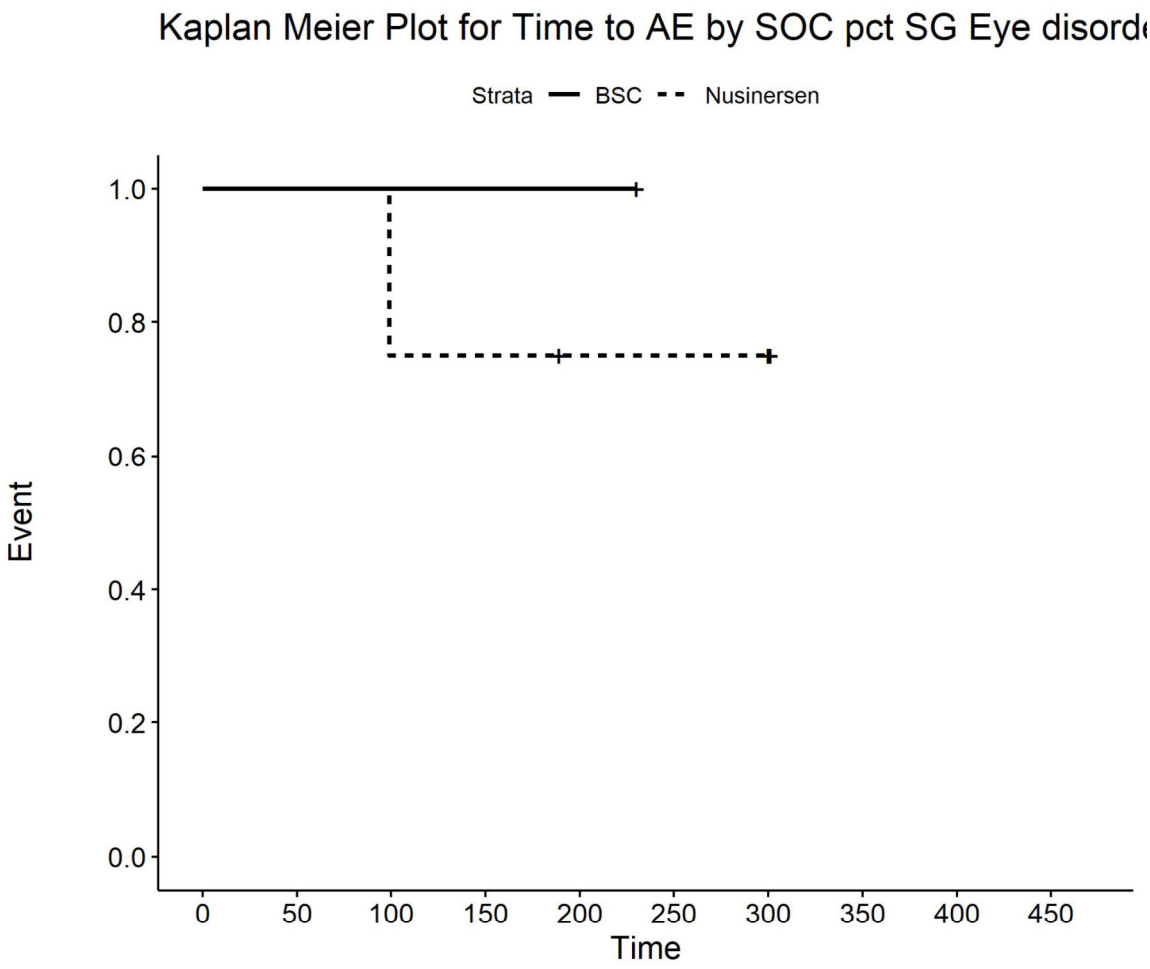
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	7	7	6	5	4	0



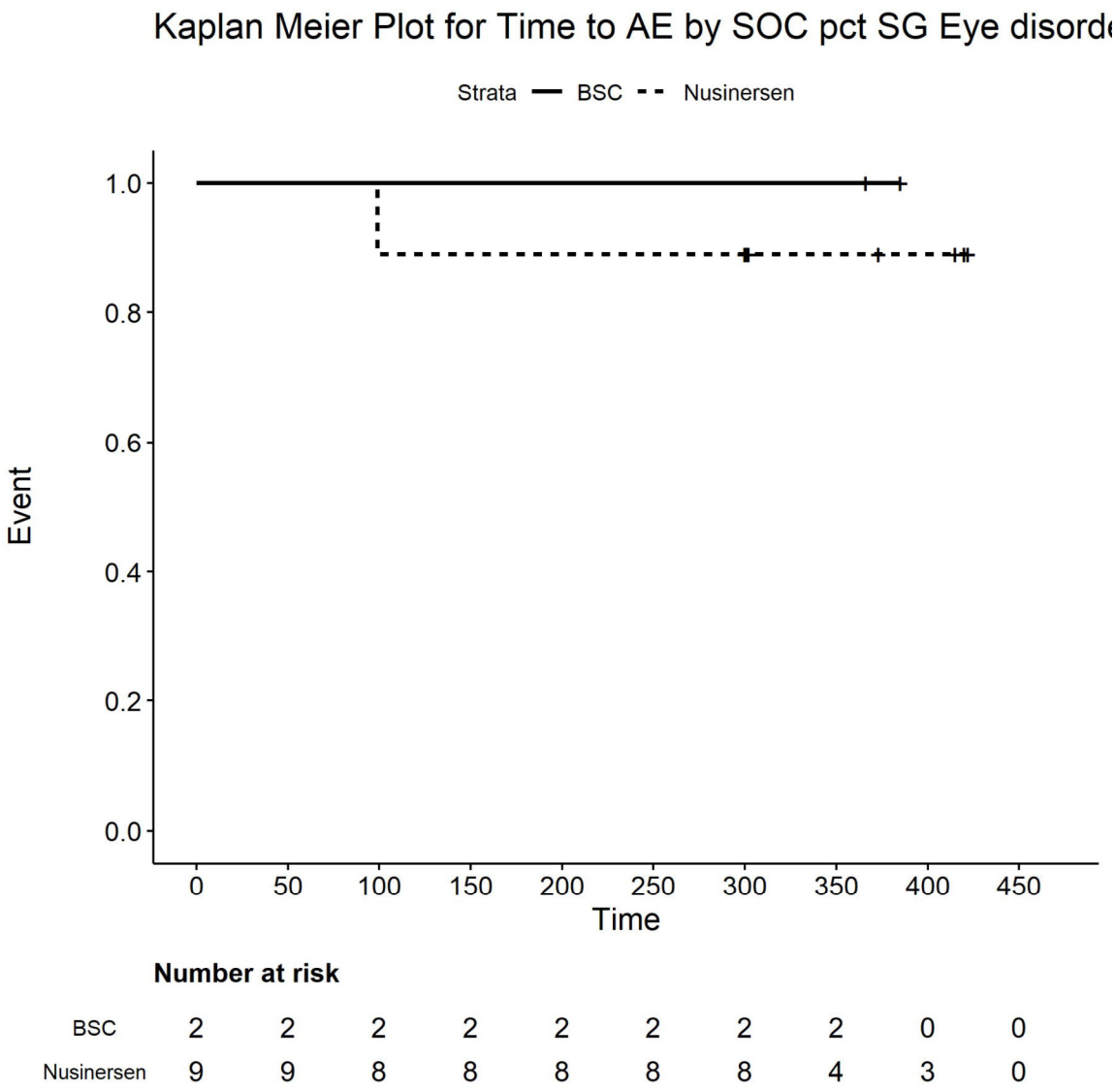
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	2	2	2	0	0	0



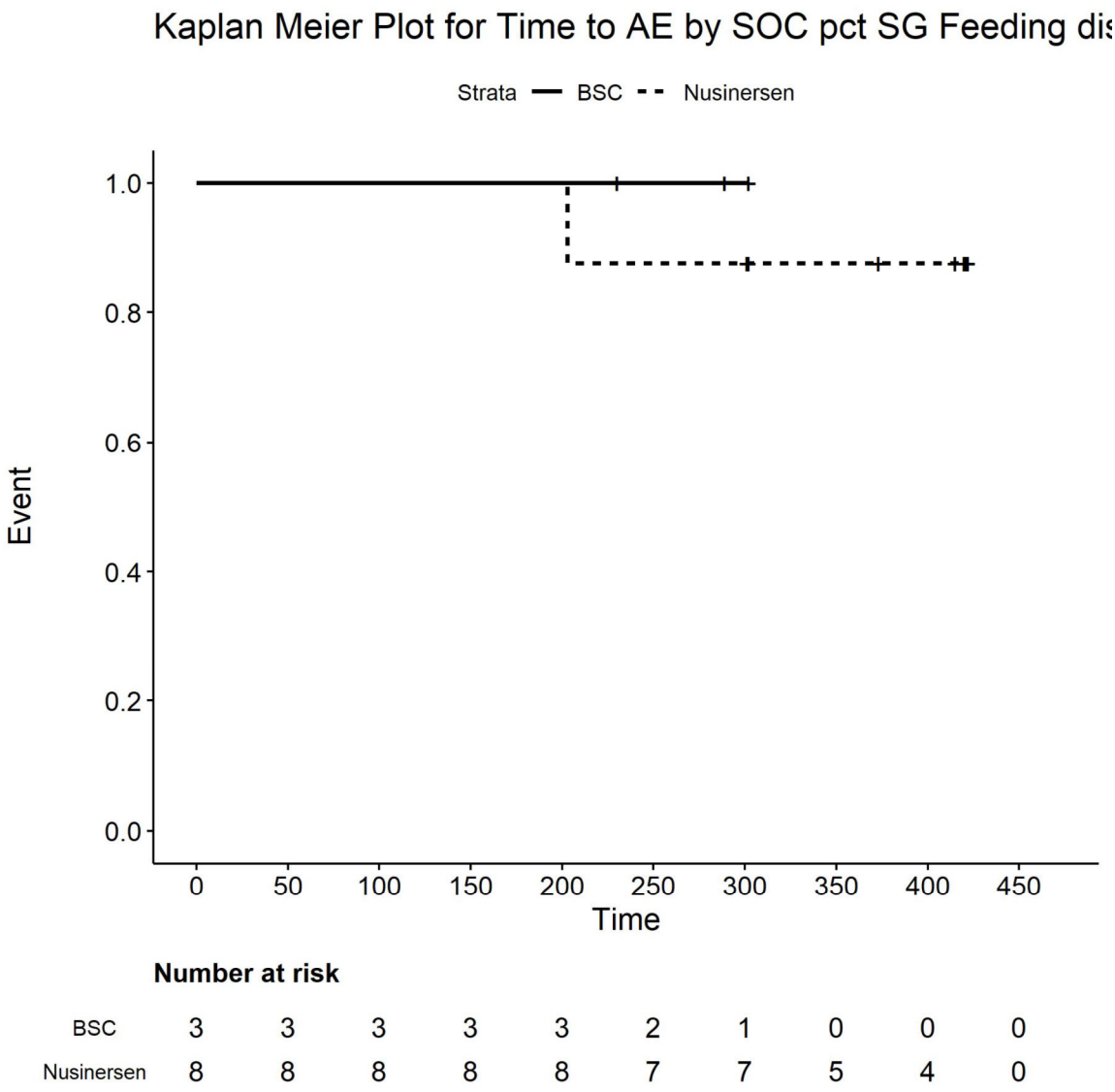
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	2	2	2	0	0	0



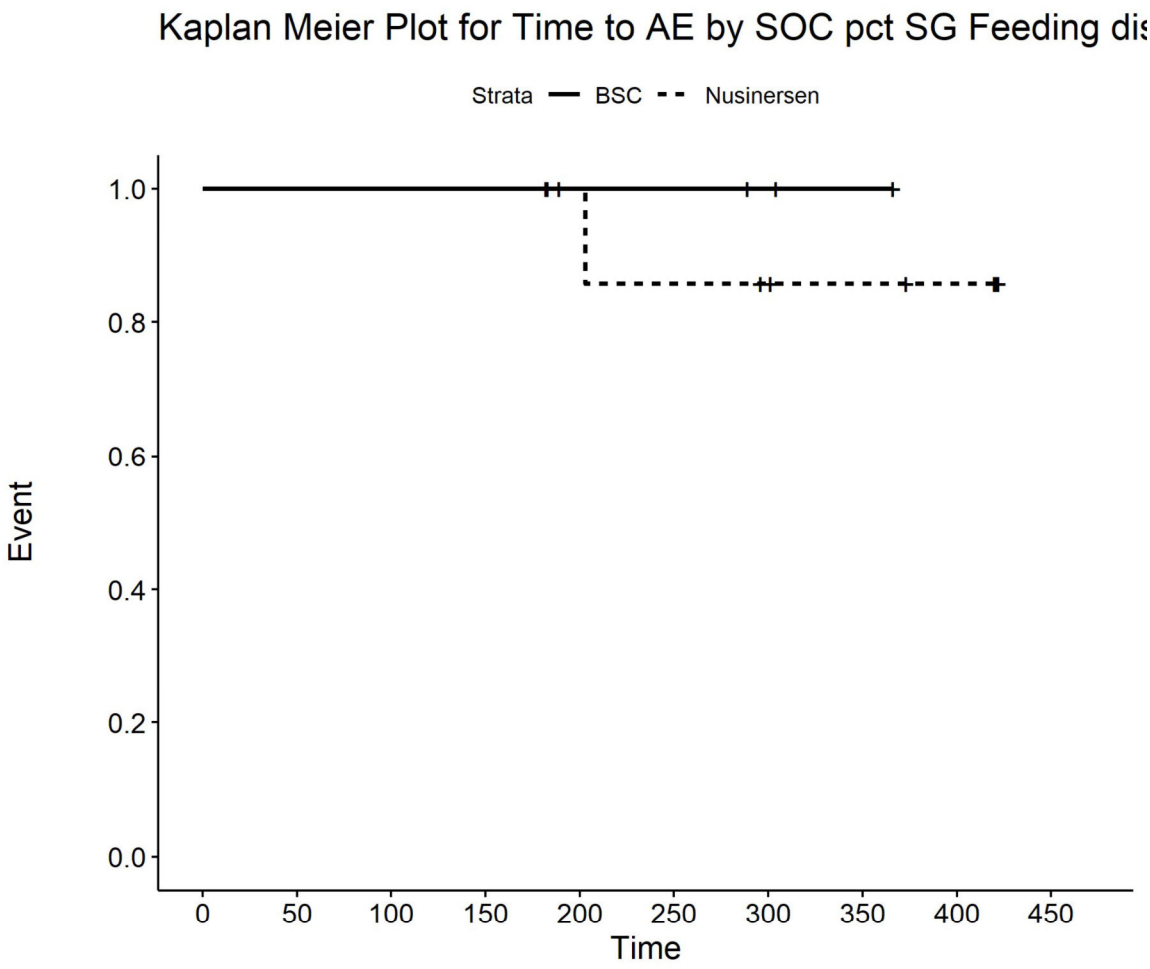
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	8	8	8	4	3	0



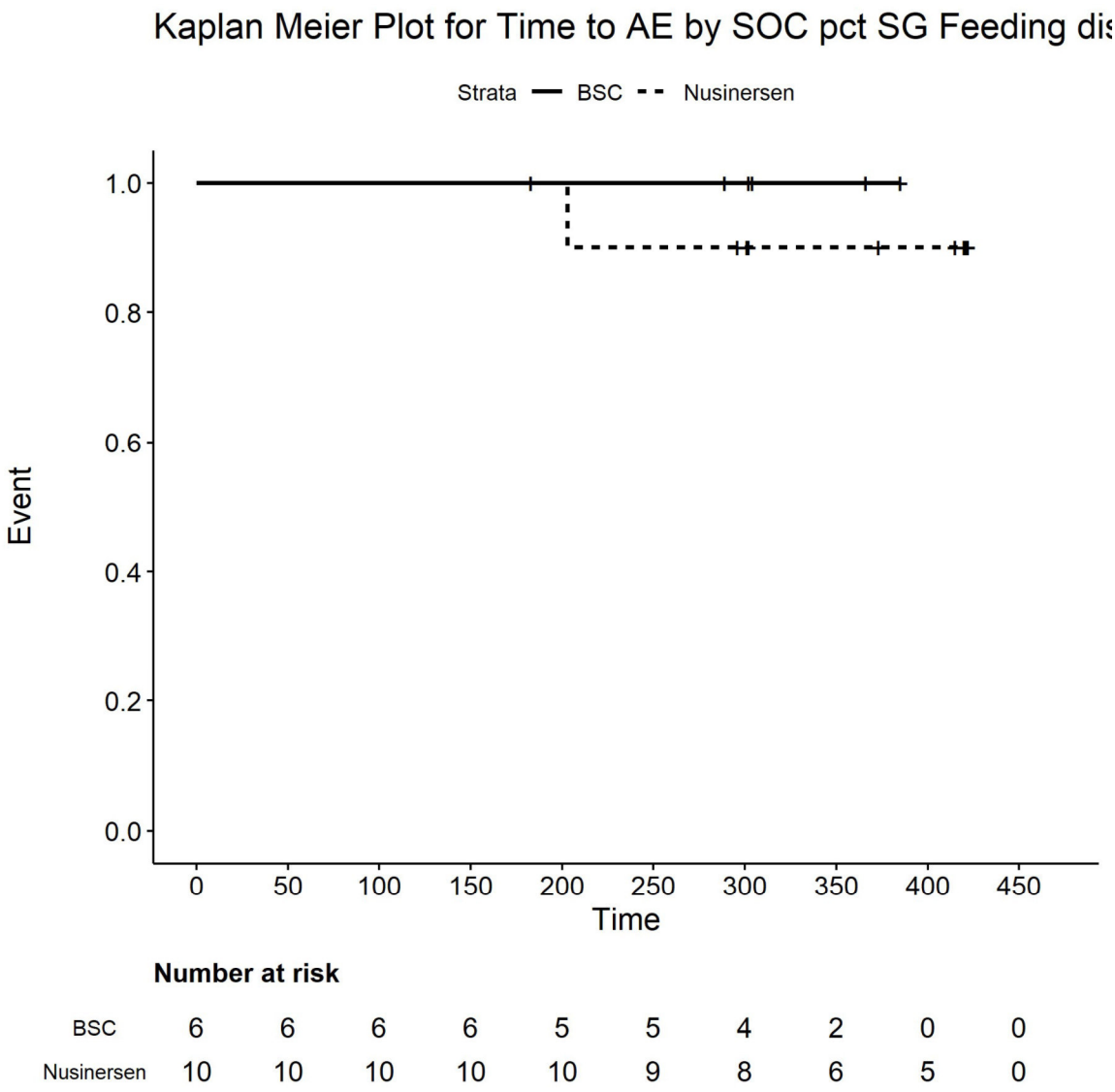
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



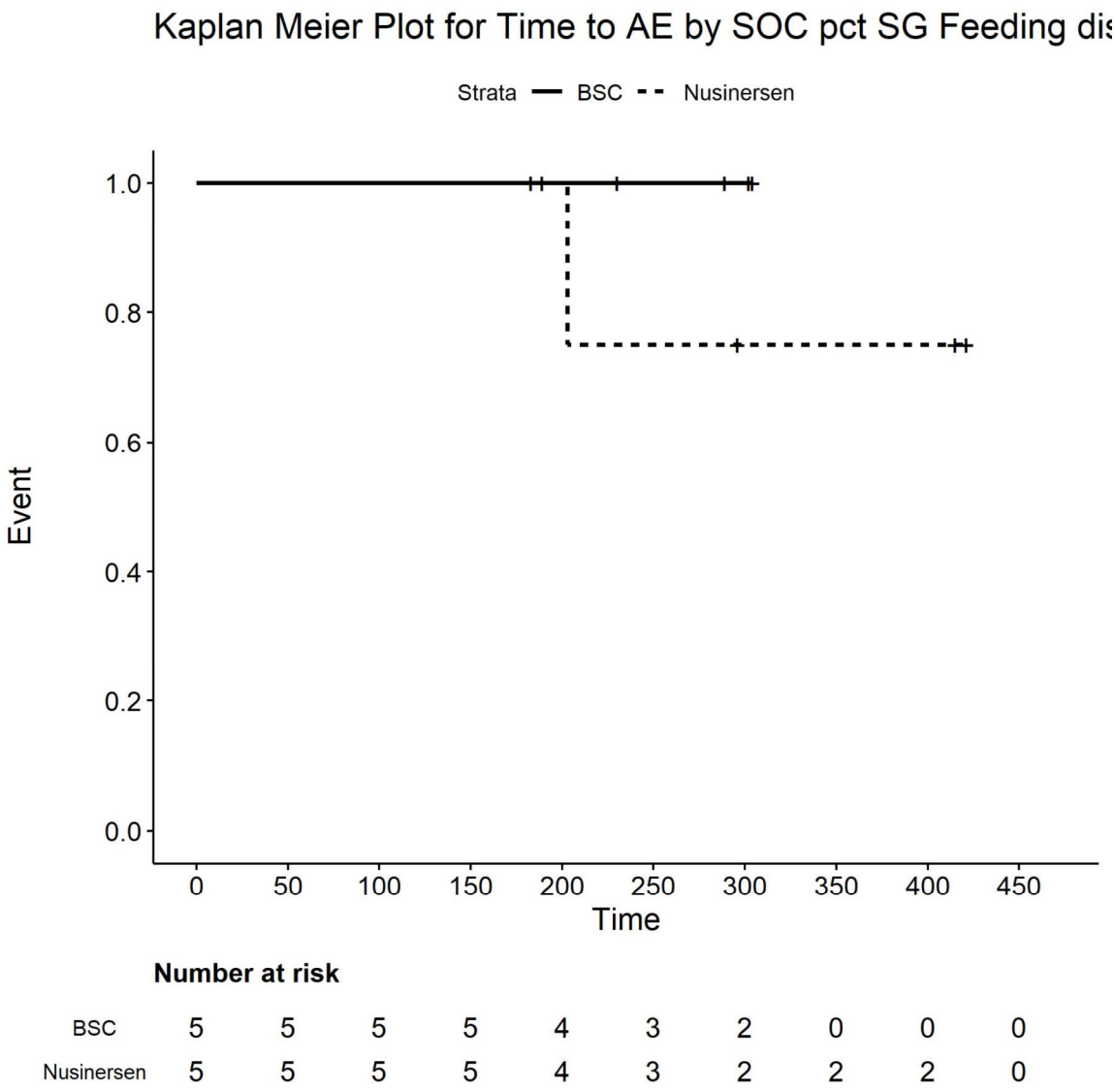
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



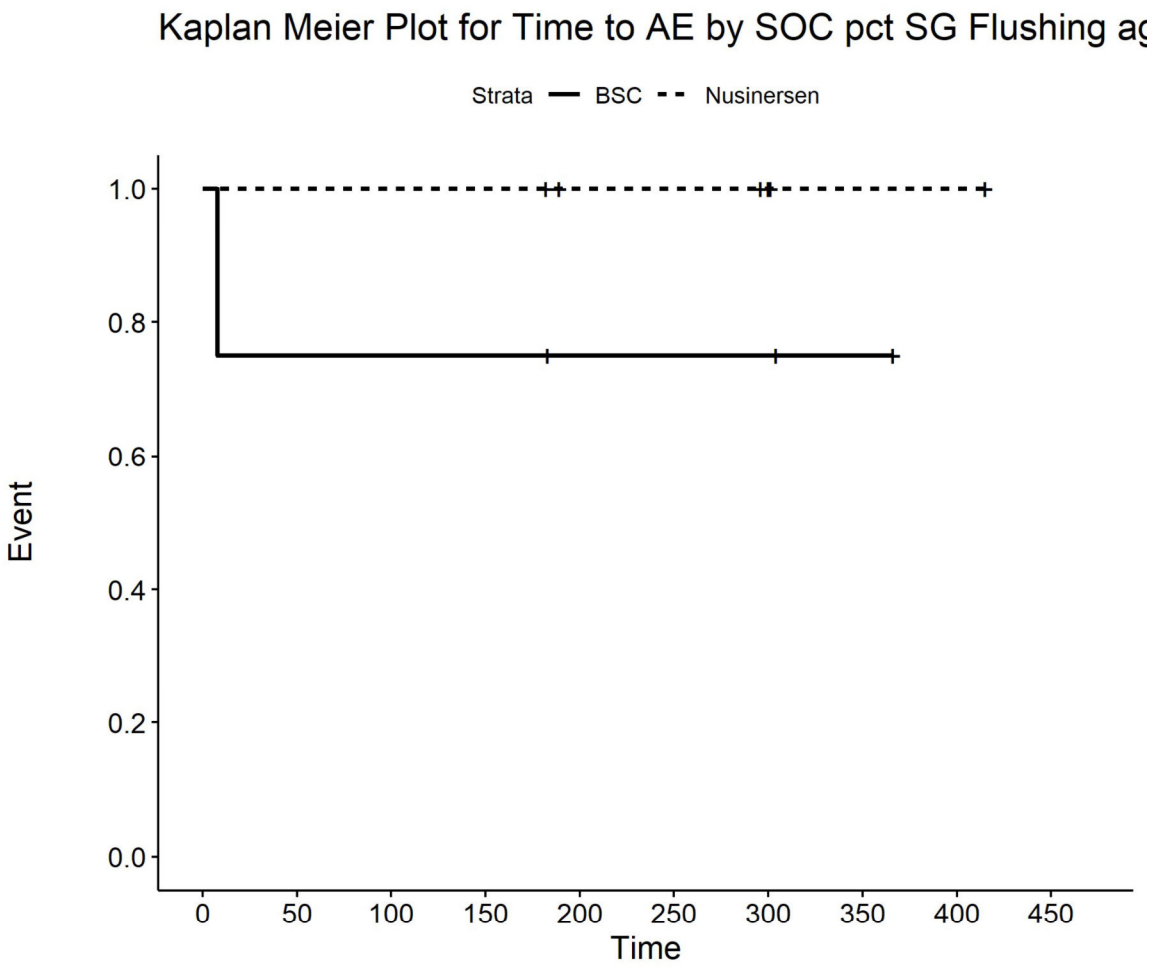
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



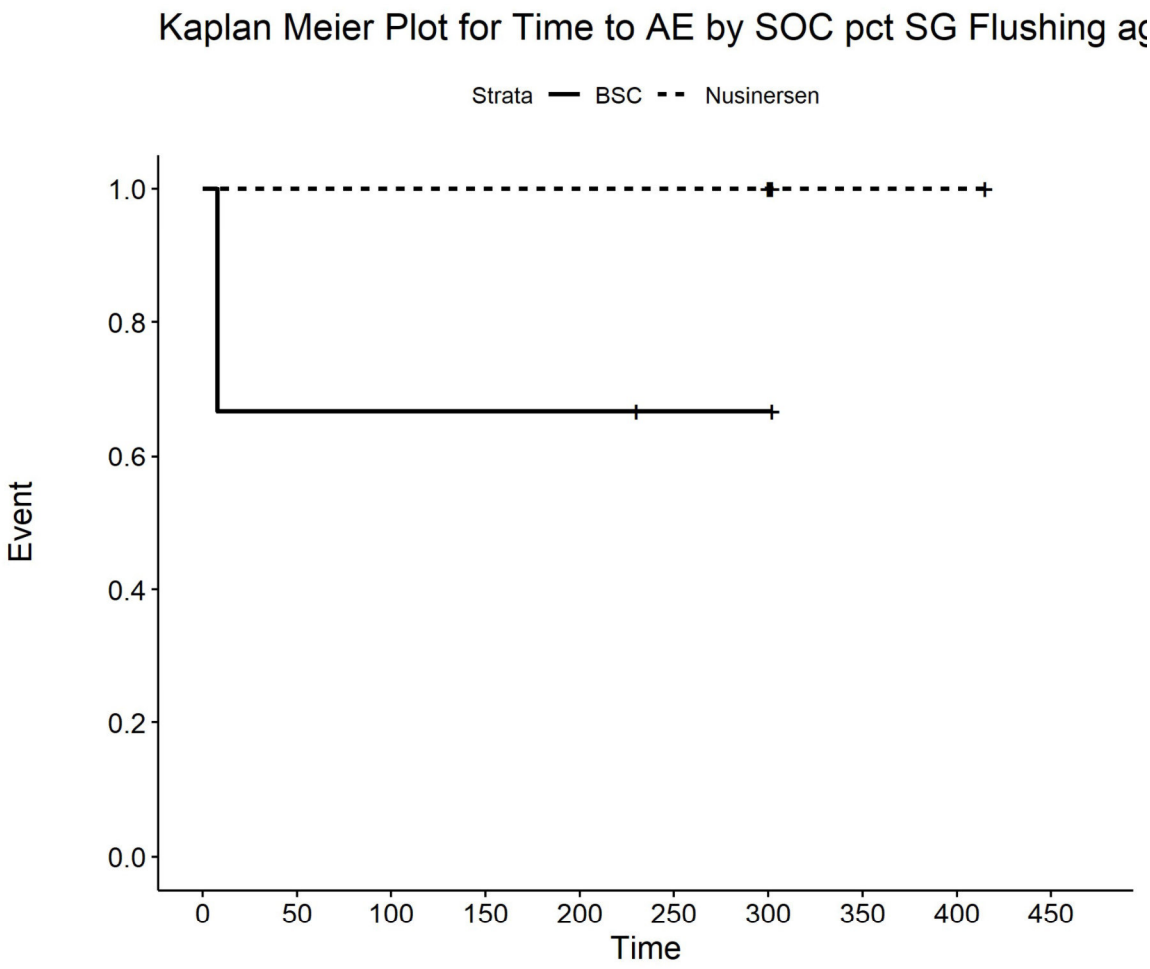
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	3	2	2	2	0



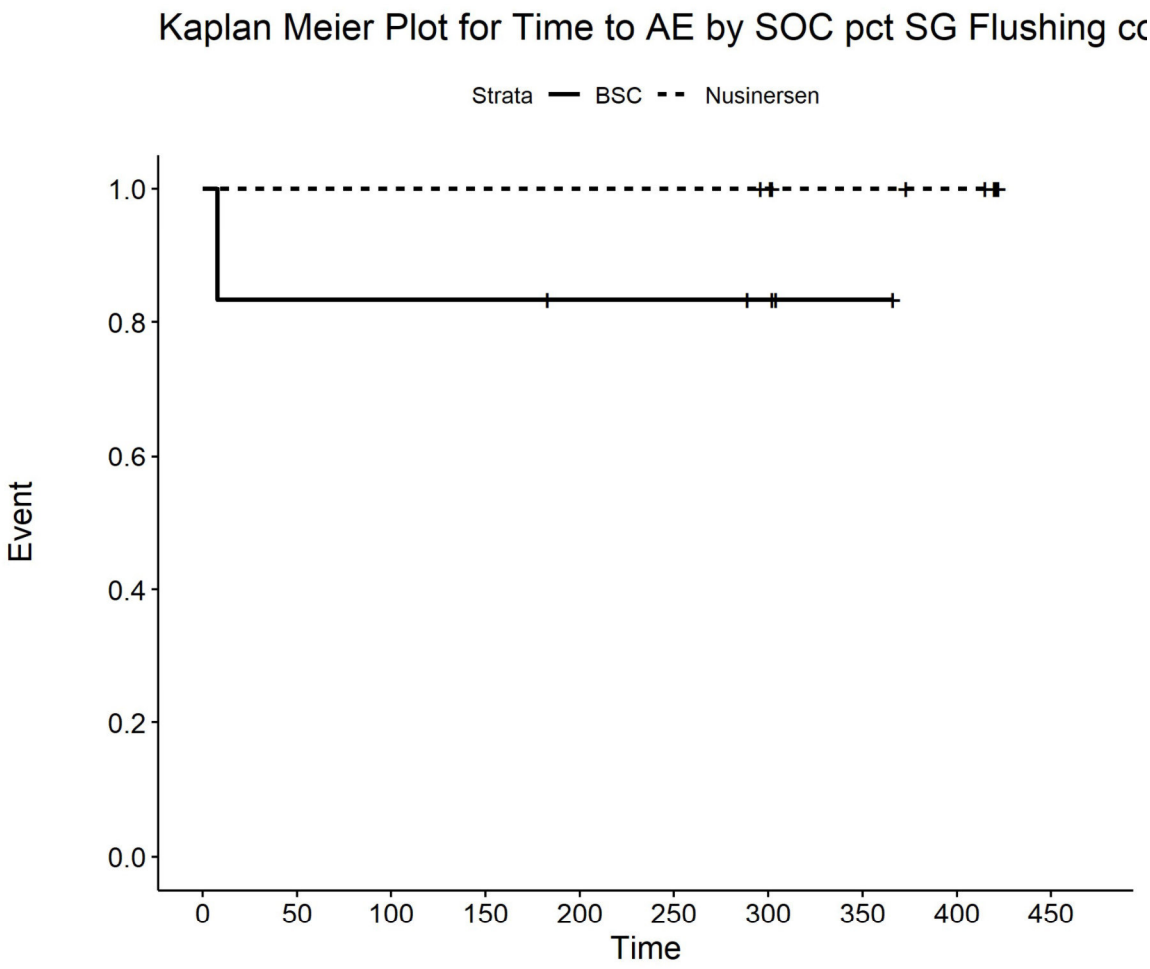
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



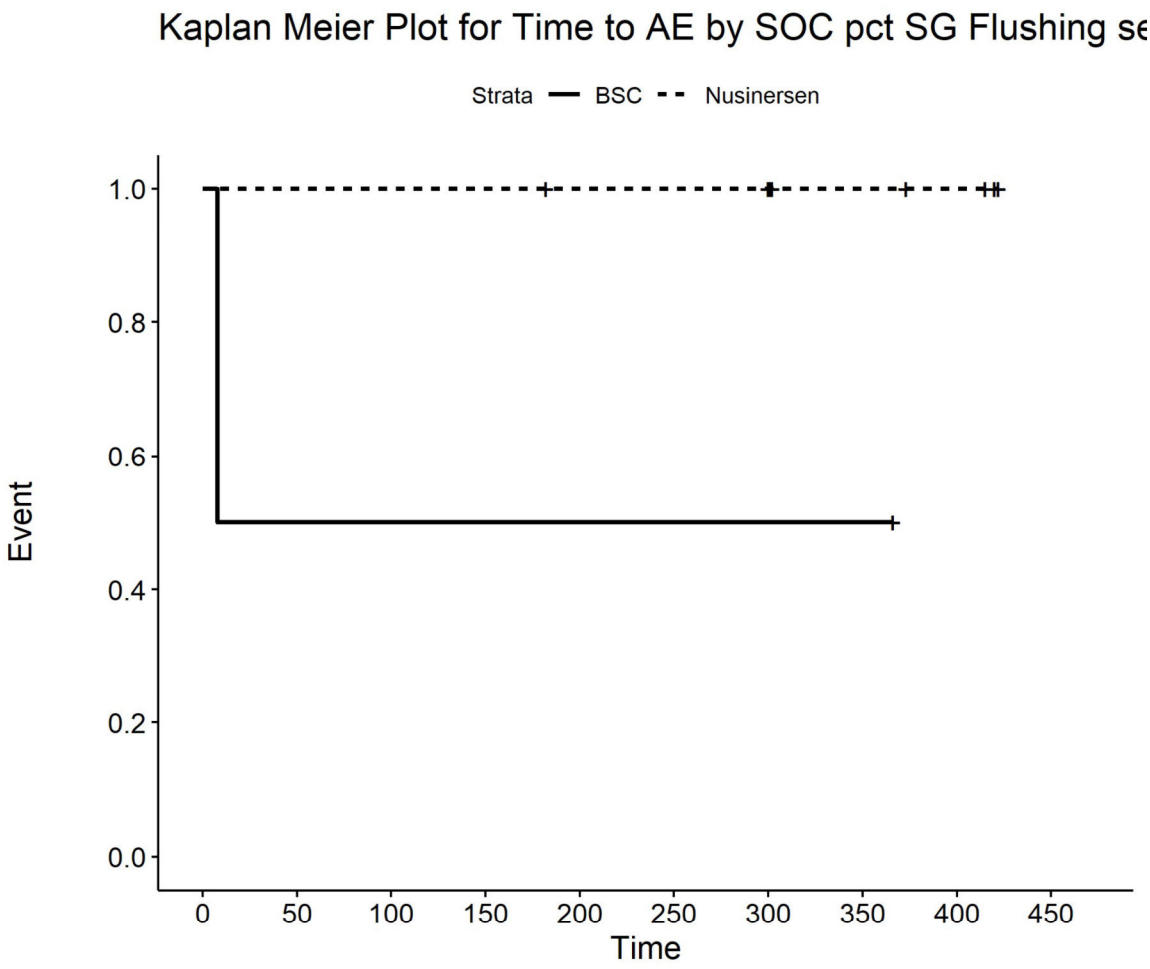
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



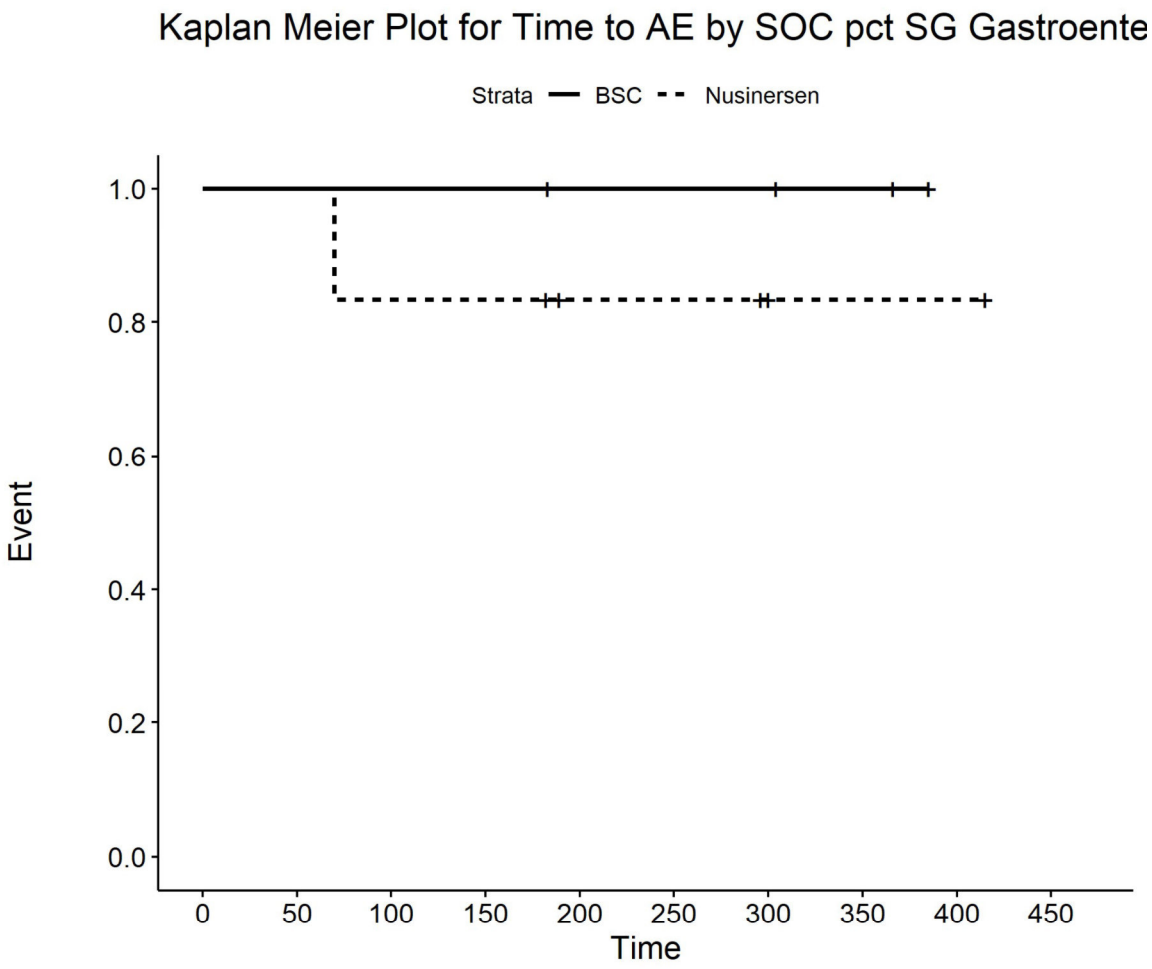
Number at risk

BSC	6	5	5	5	4	4	3	1	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



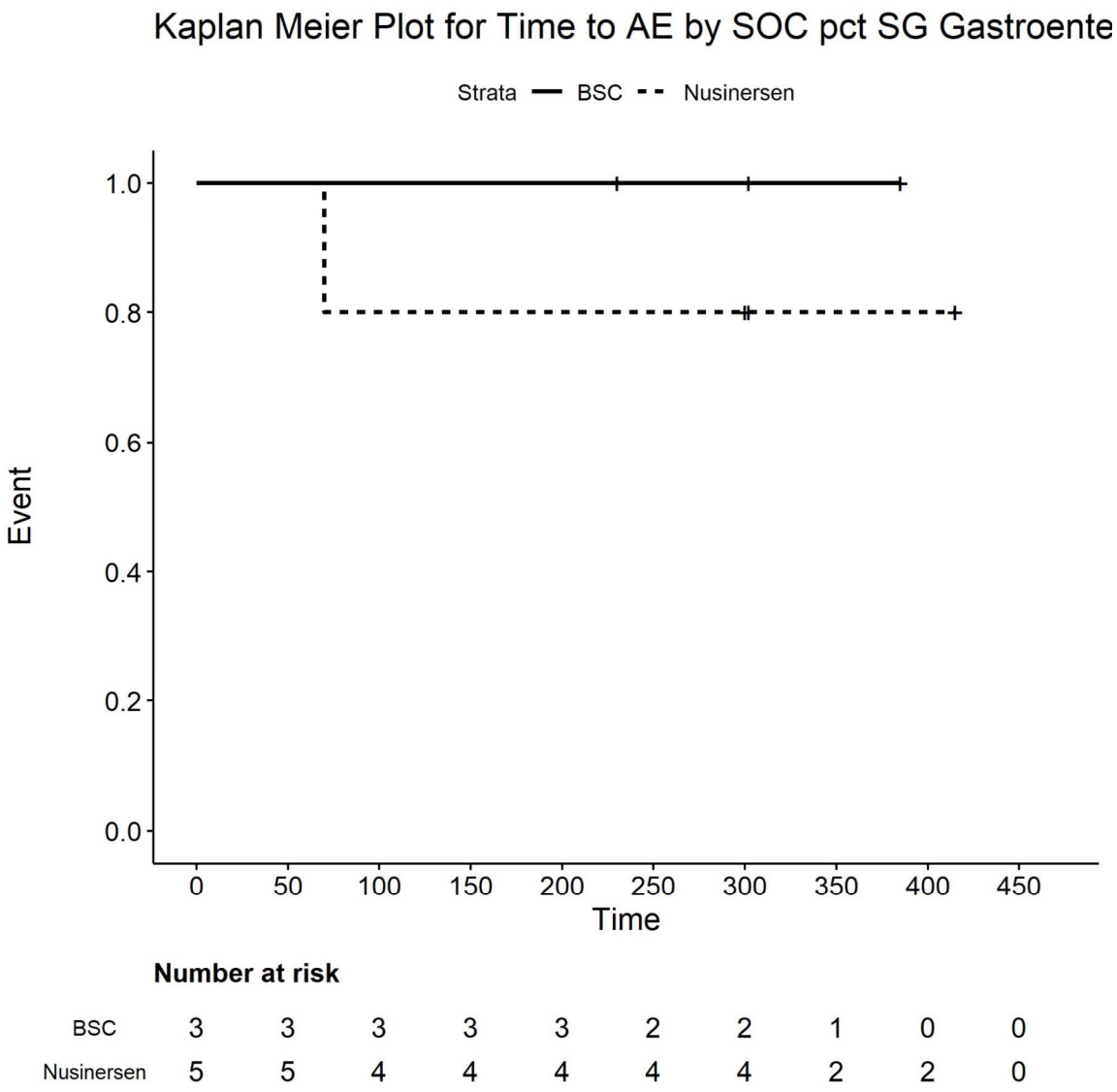
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



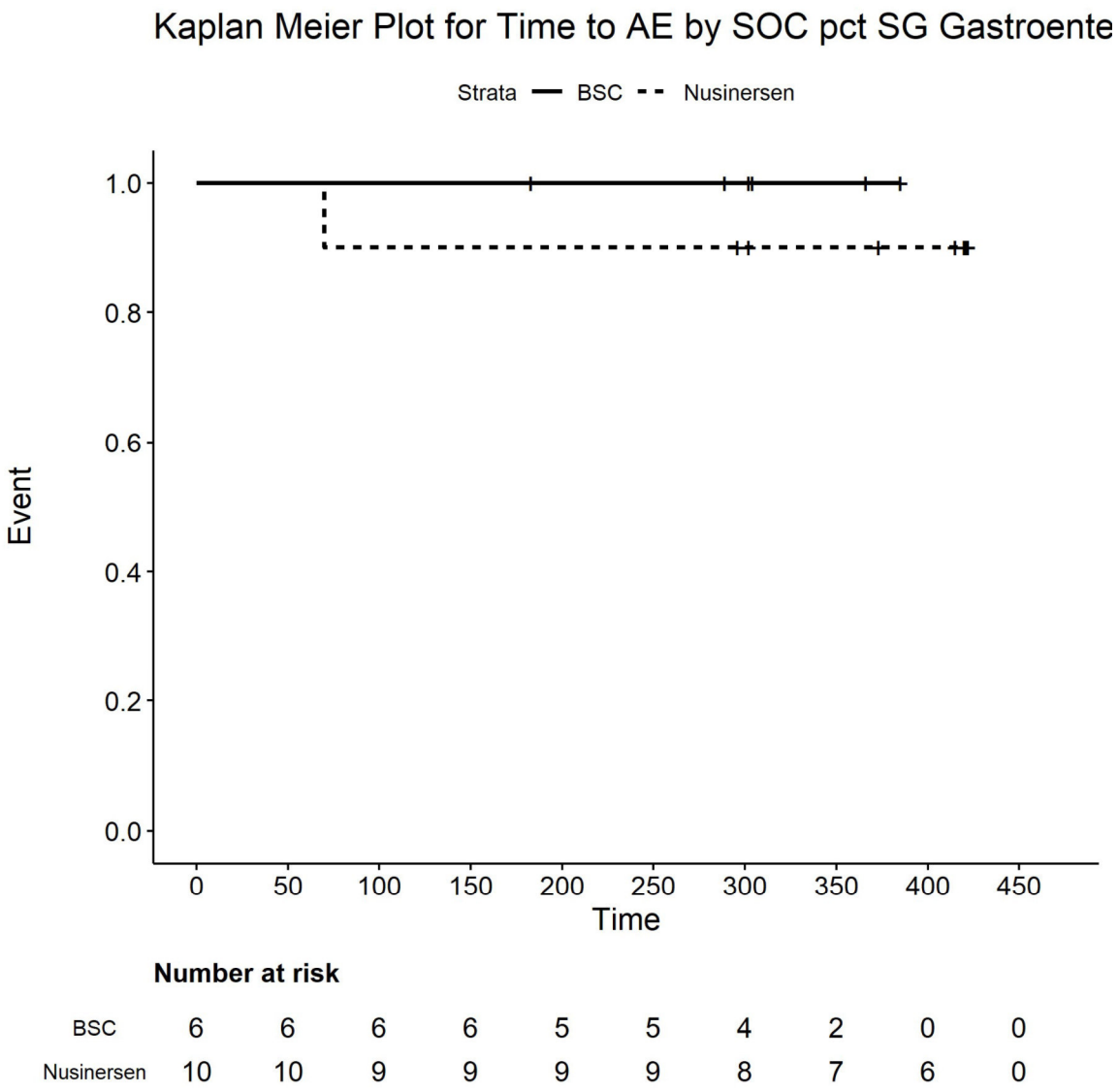
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



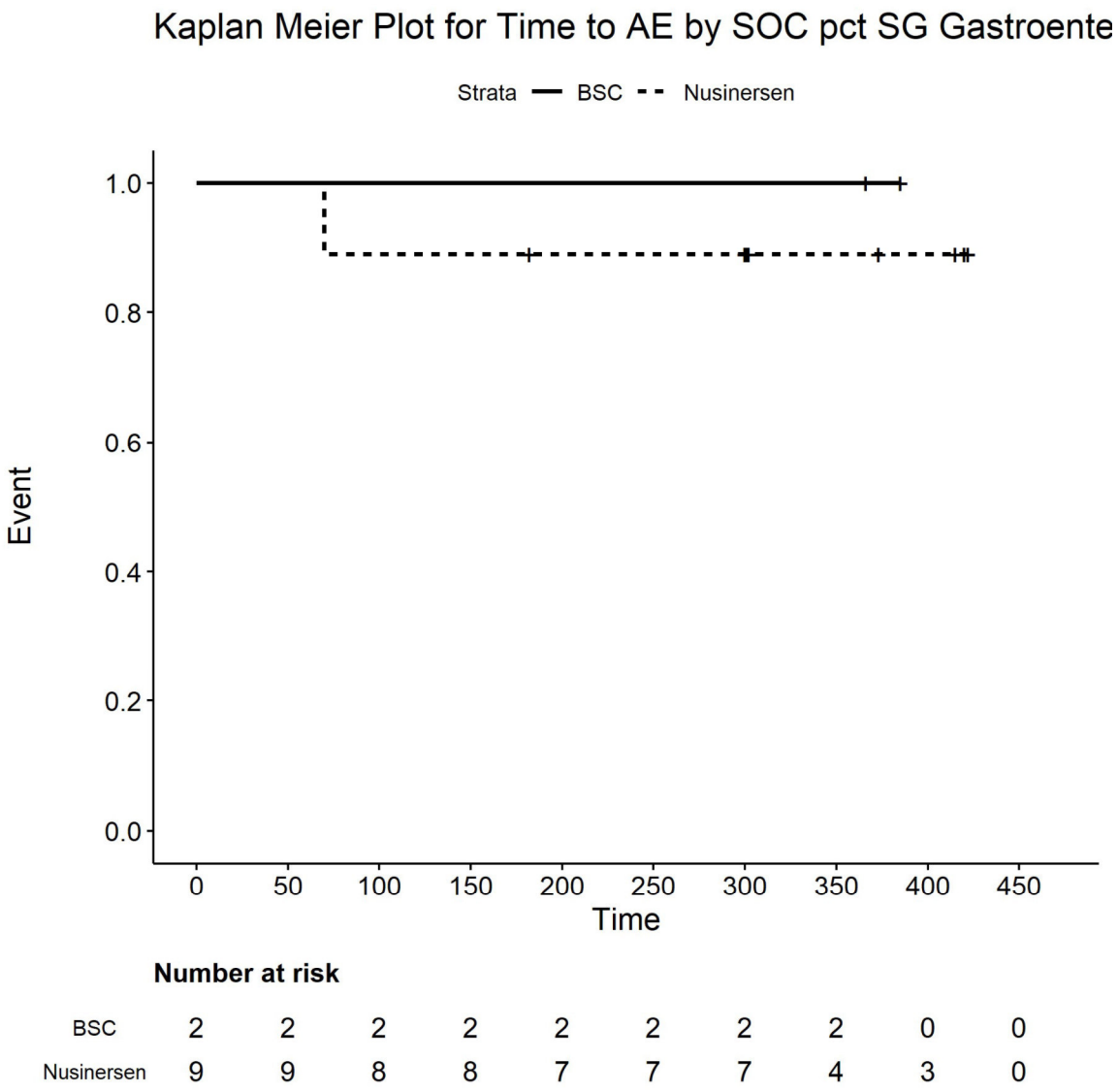
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



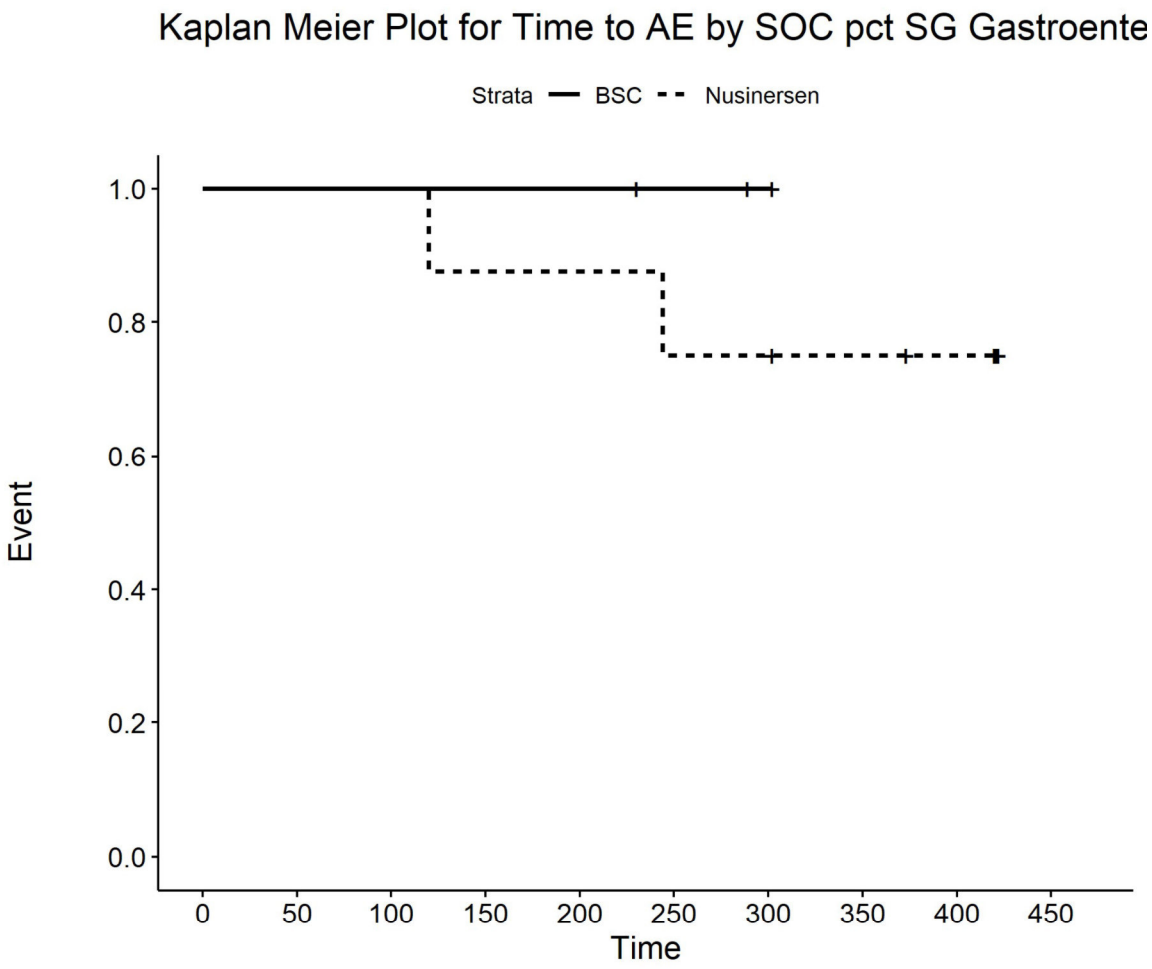
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



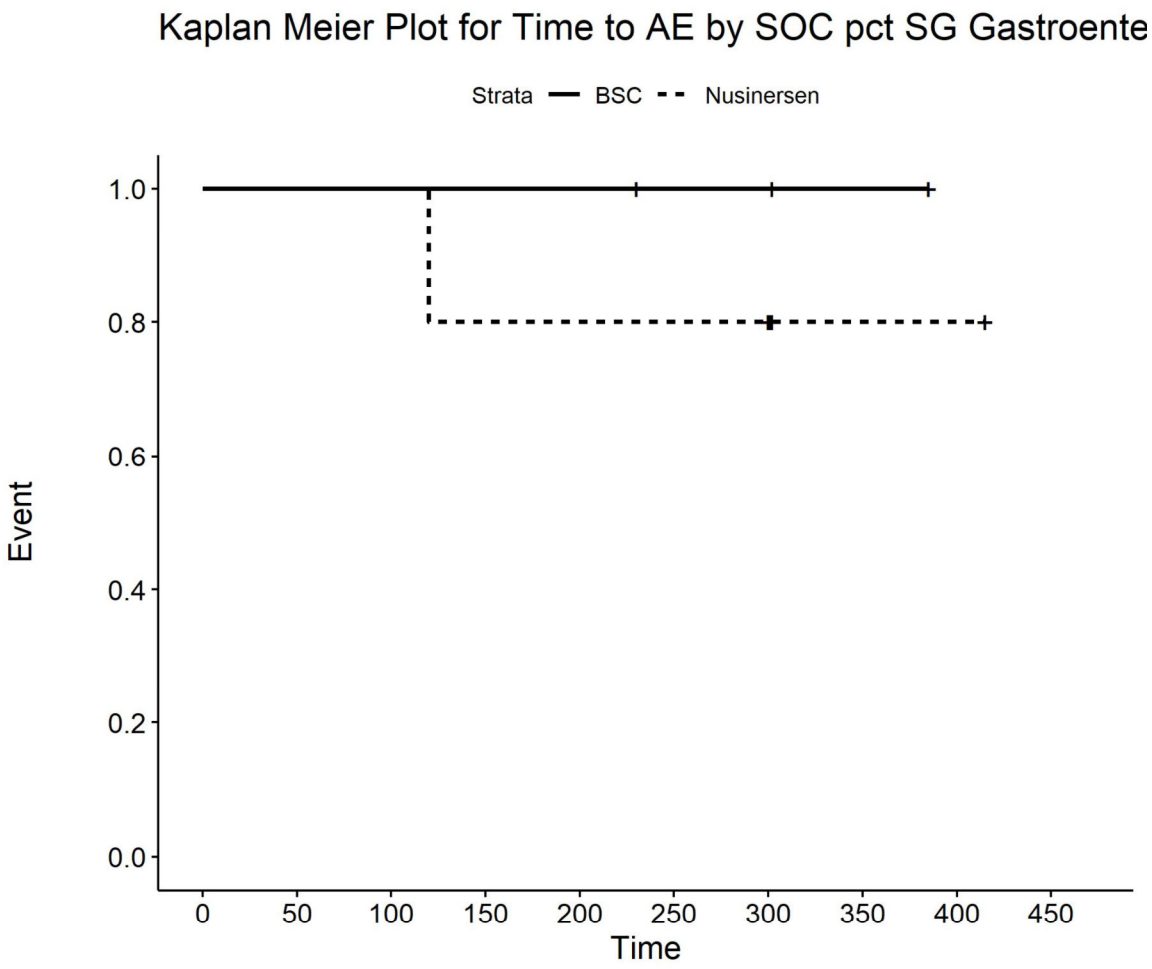
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



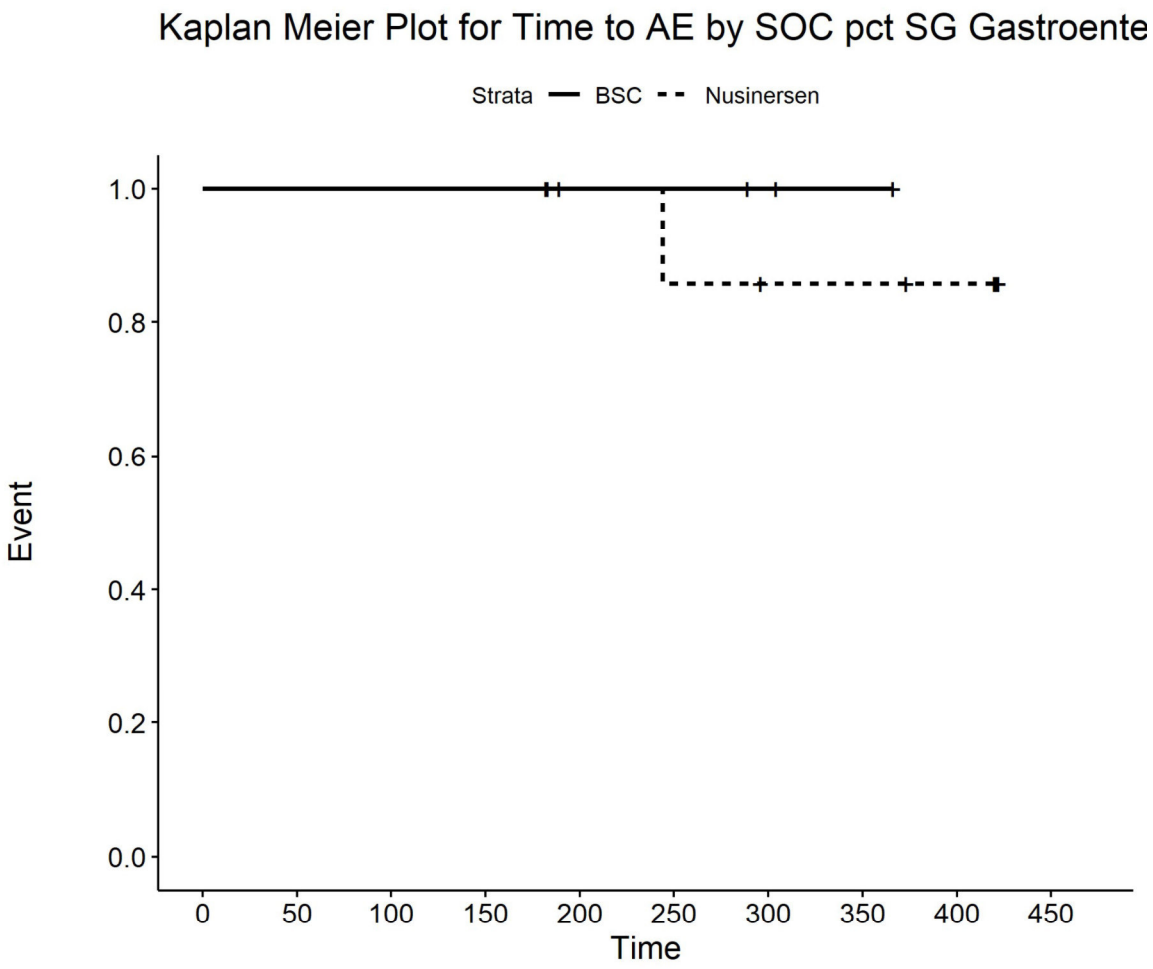
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	6	6	5	4	0



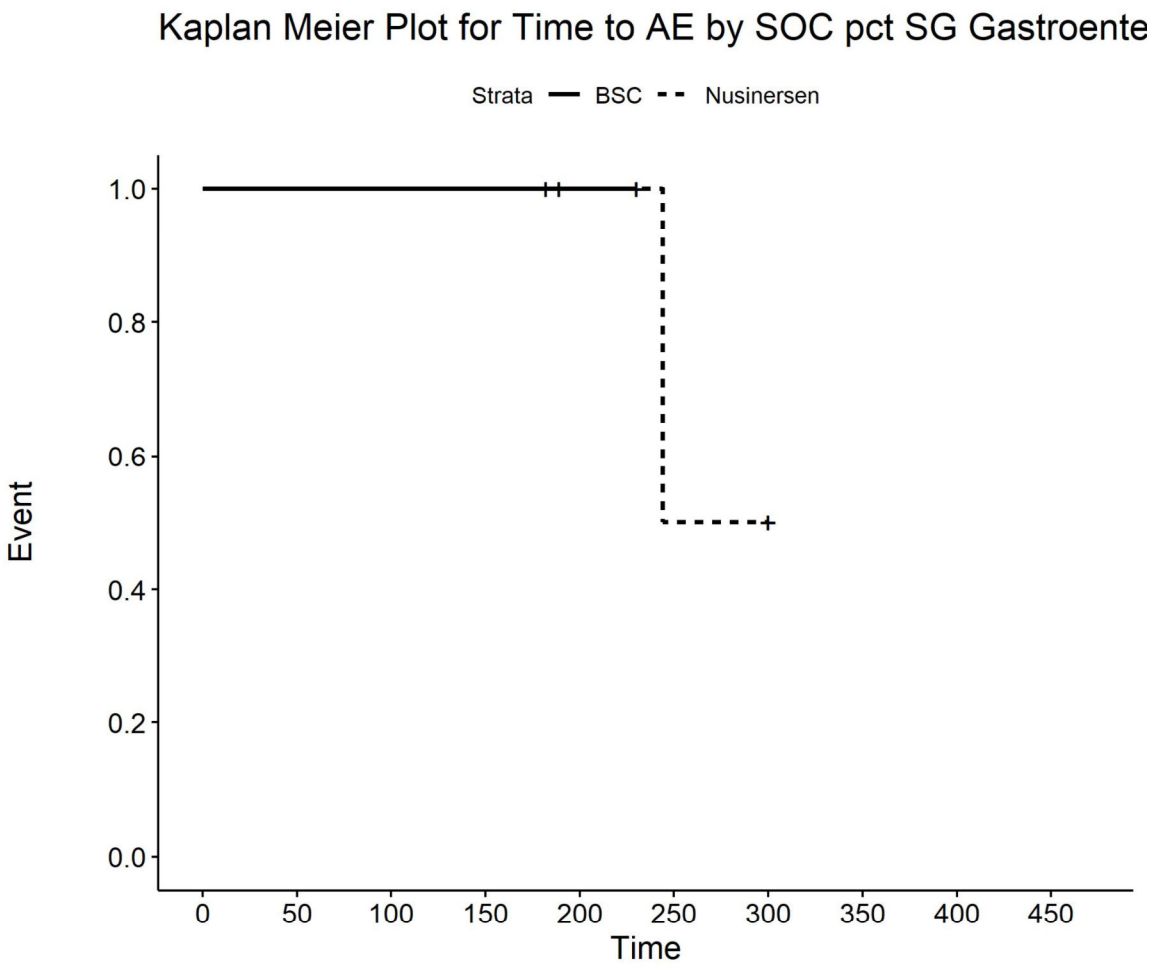
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	4	4	4	4	1	1	0



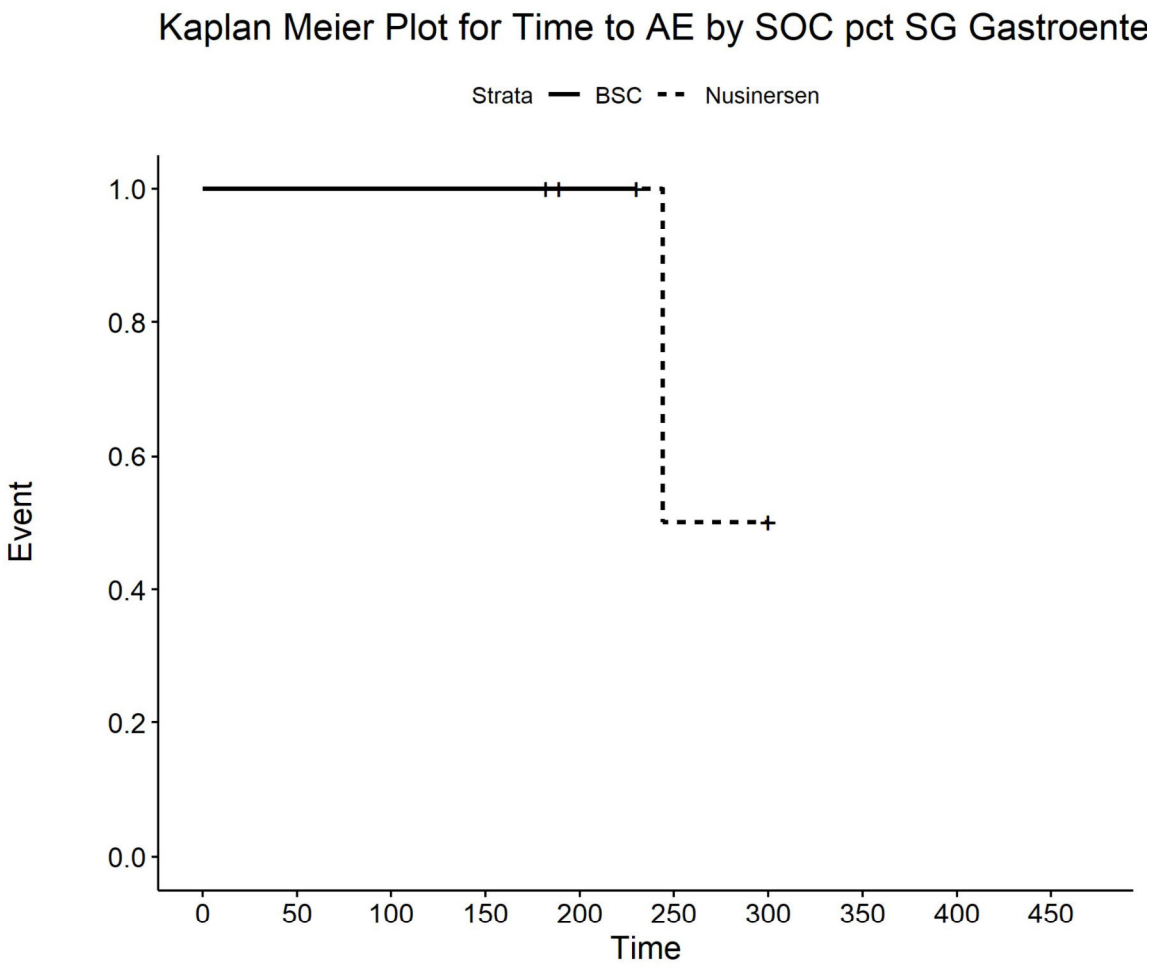
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	5	4	0



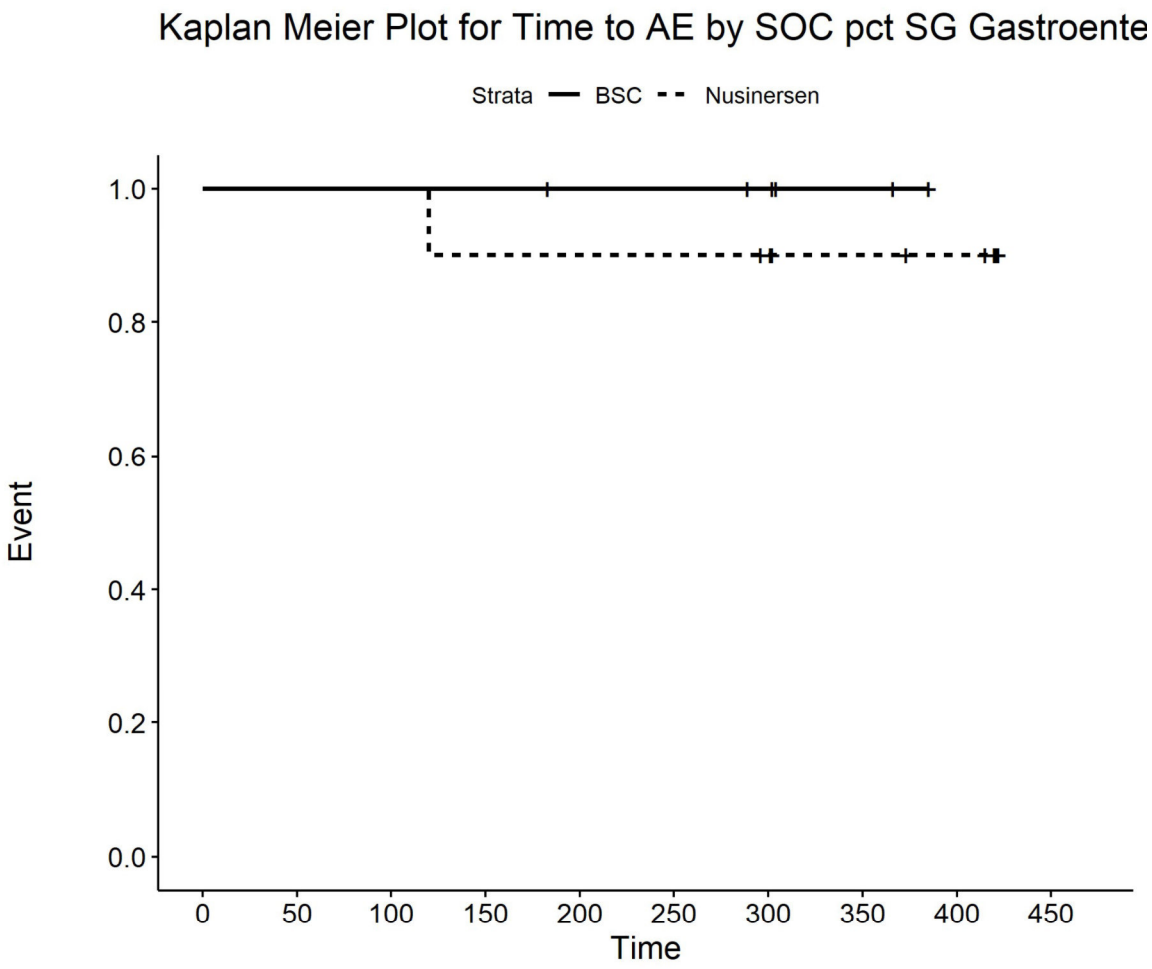
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	4	2	1	1	0	0	0



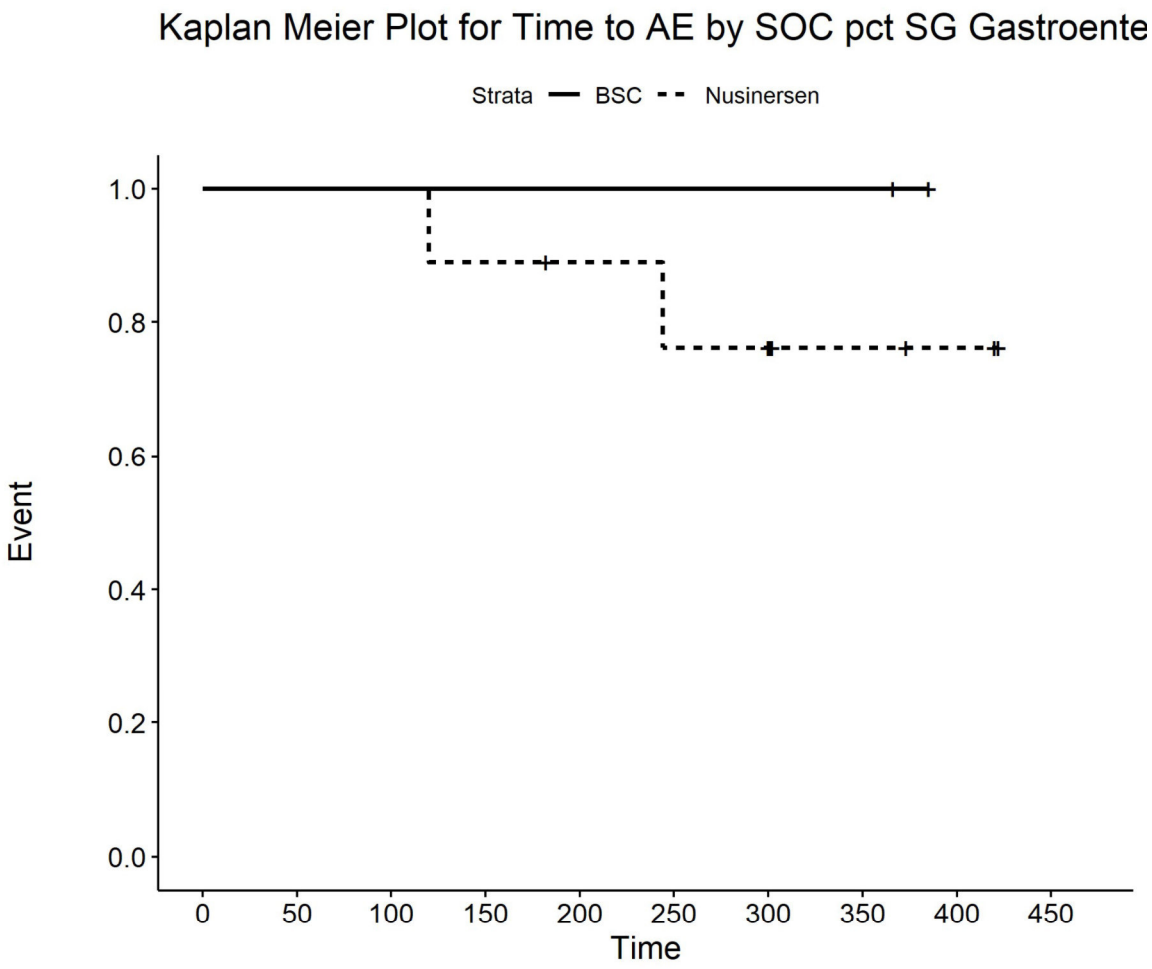
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	4	2	1	1	0	0	0



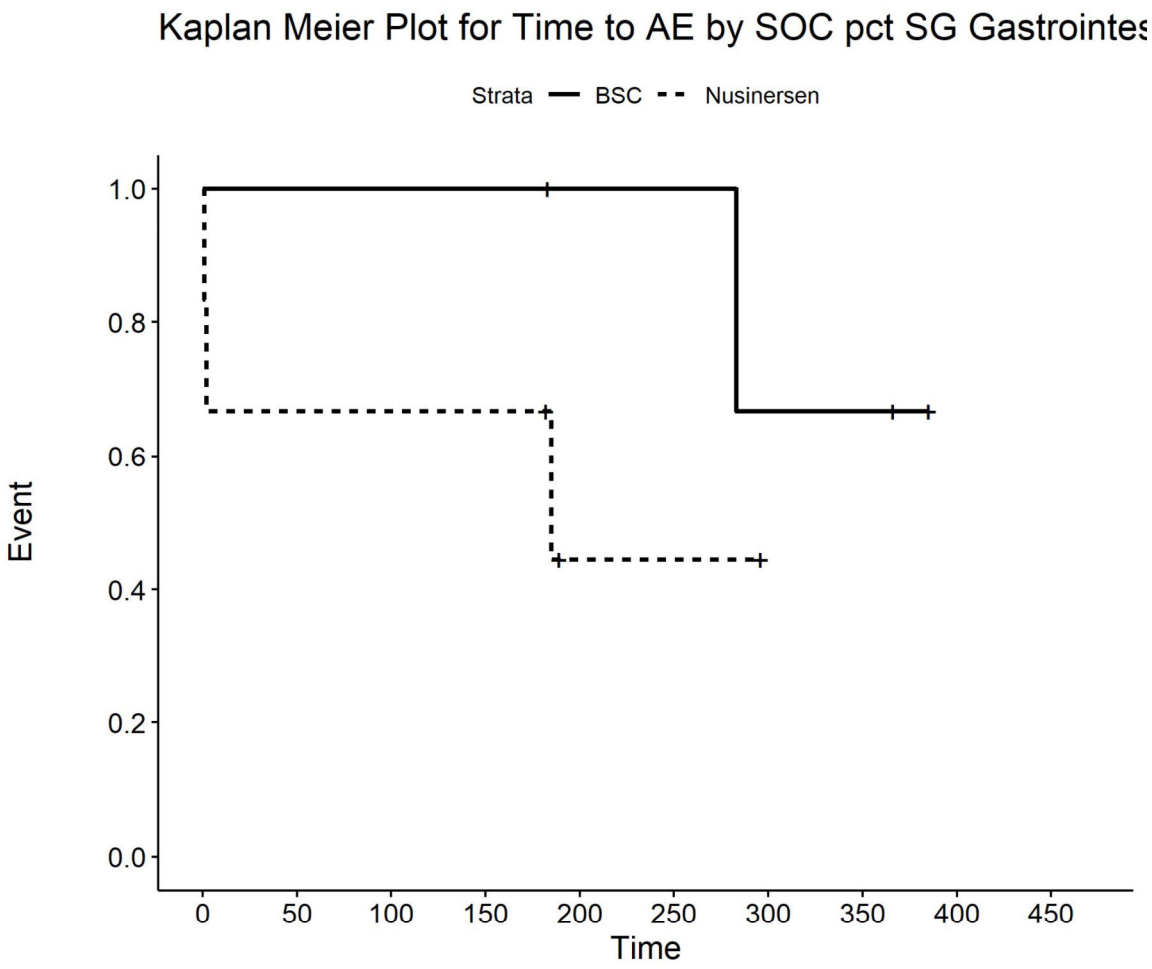
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



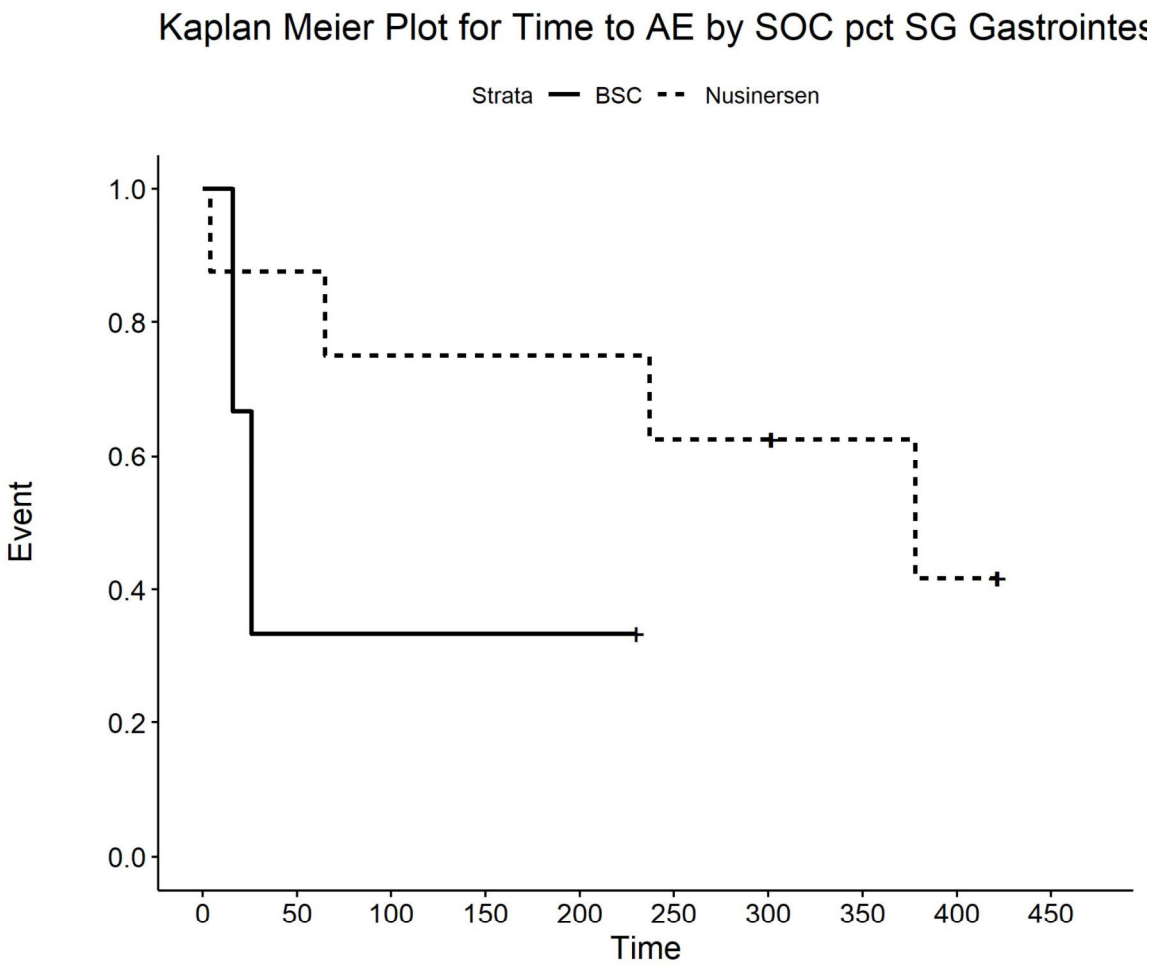
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	6	6	3	2	0



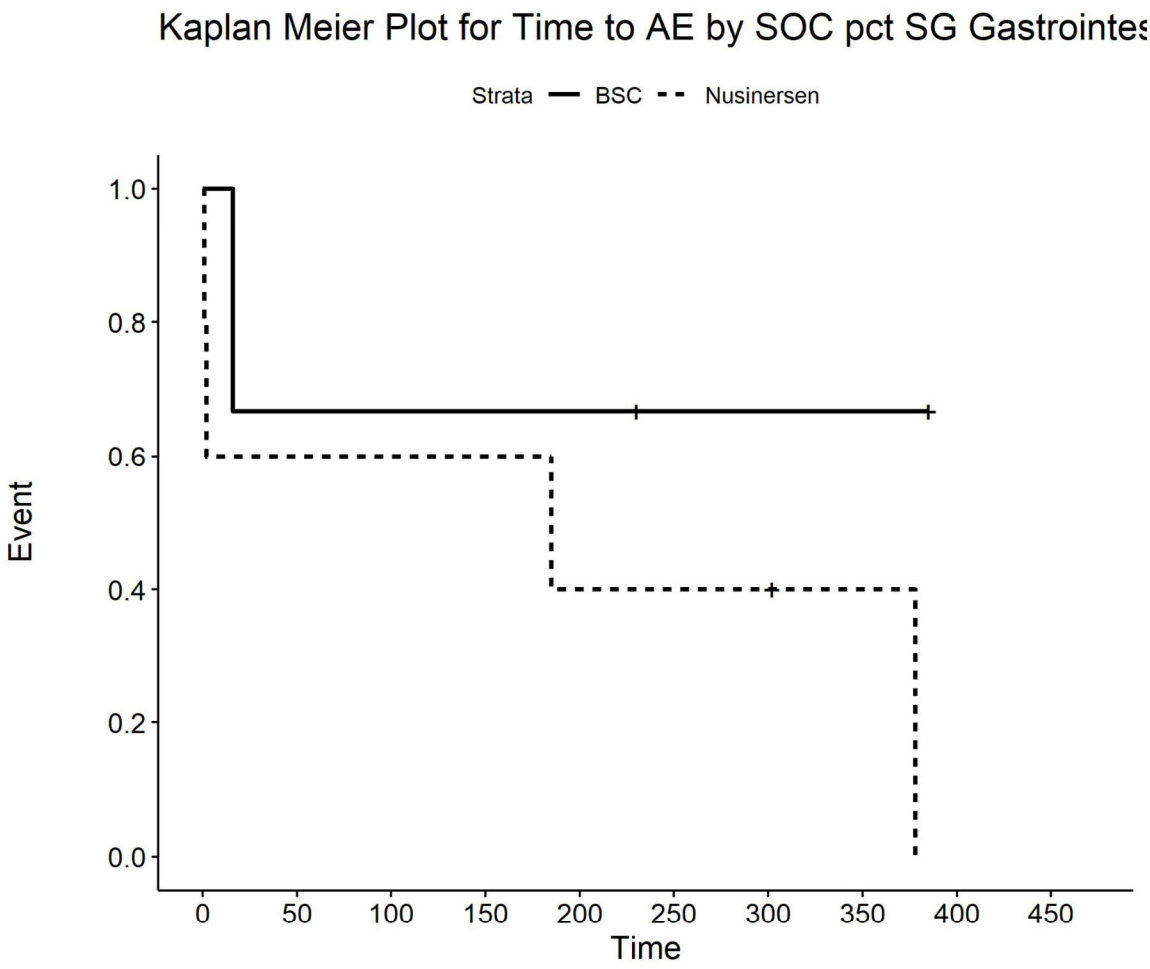
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	4	4	4	1	1	0	0	0	0



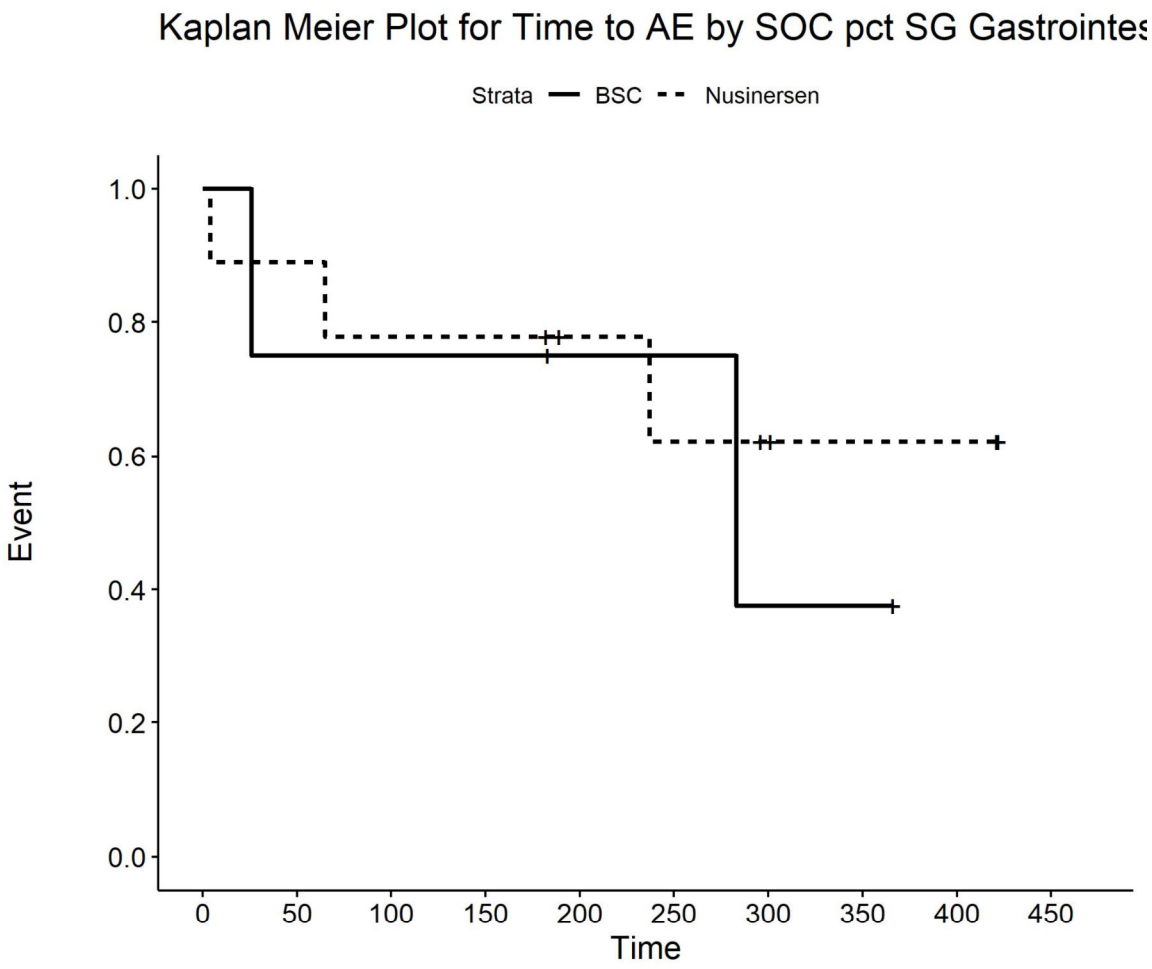
Number at risk

BSC	3	1	1	1	1	0	0	0	0	0
Nusinersen	8	7	6	6	6	5	5	3	2	0



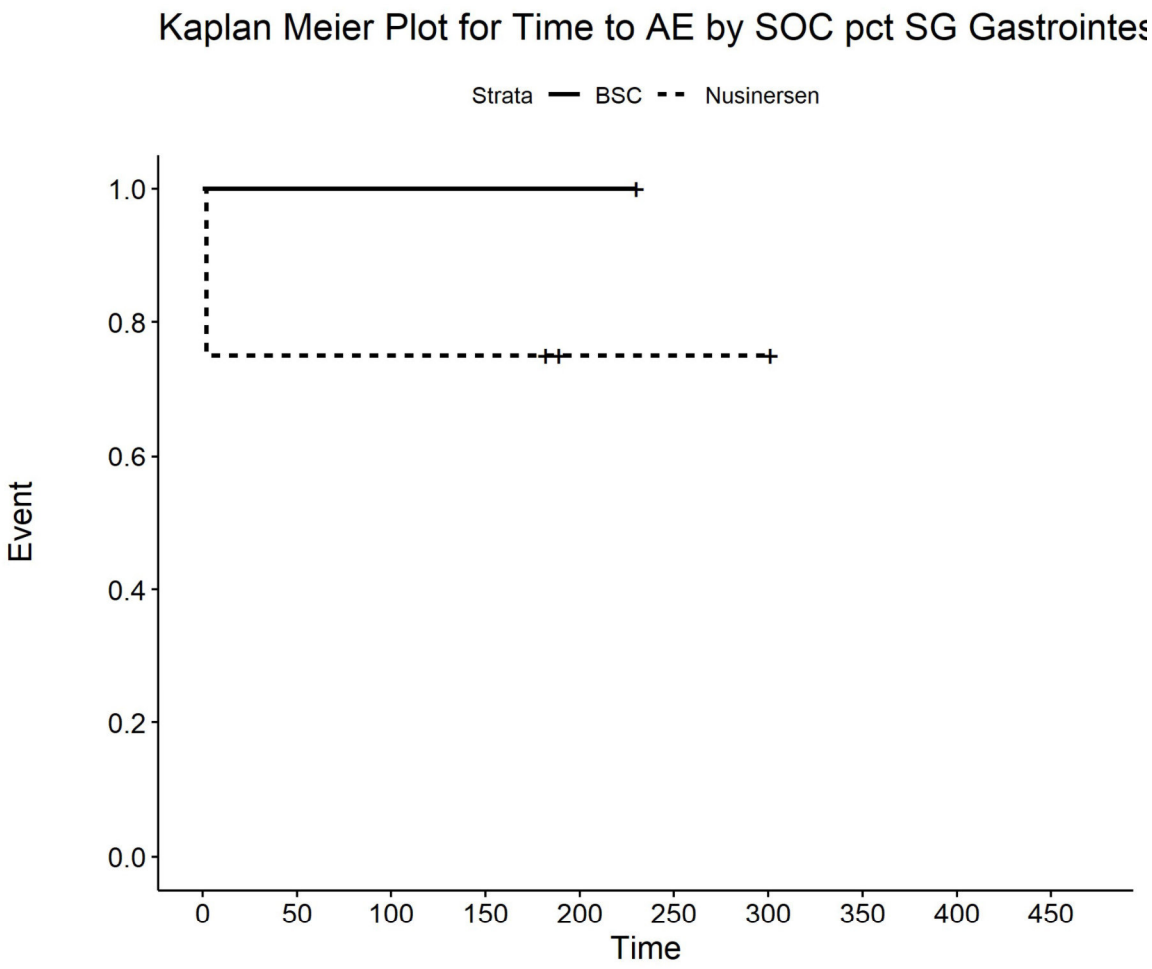
Number at risk

BSC	3	2	2	2	2	1	1	1	0	0
Nusinersen	5	3	3	3	2	2	2	1	0	0



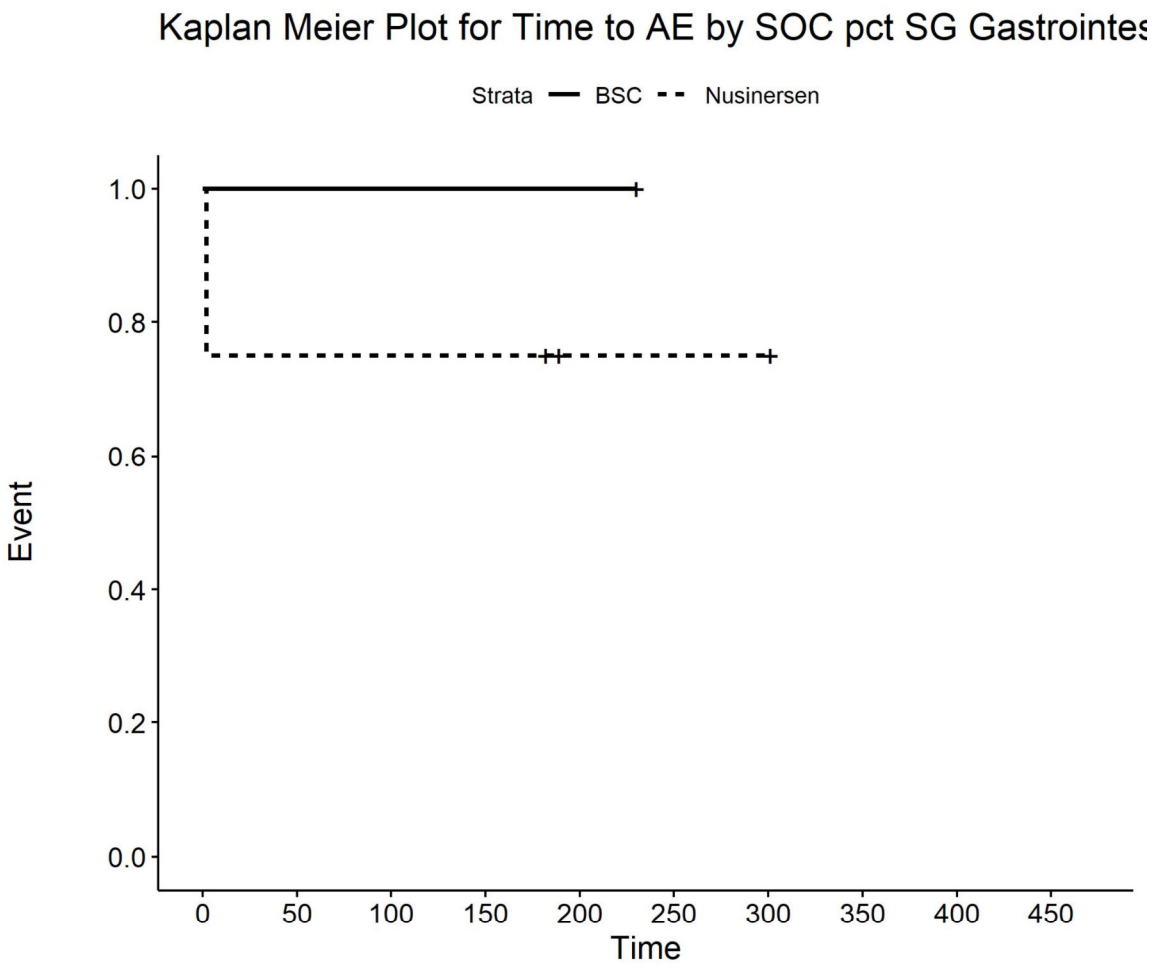
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	8	7	7	5	4	3	2	2	0



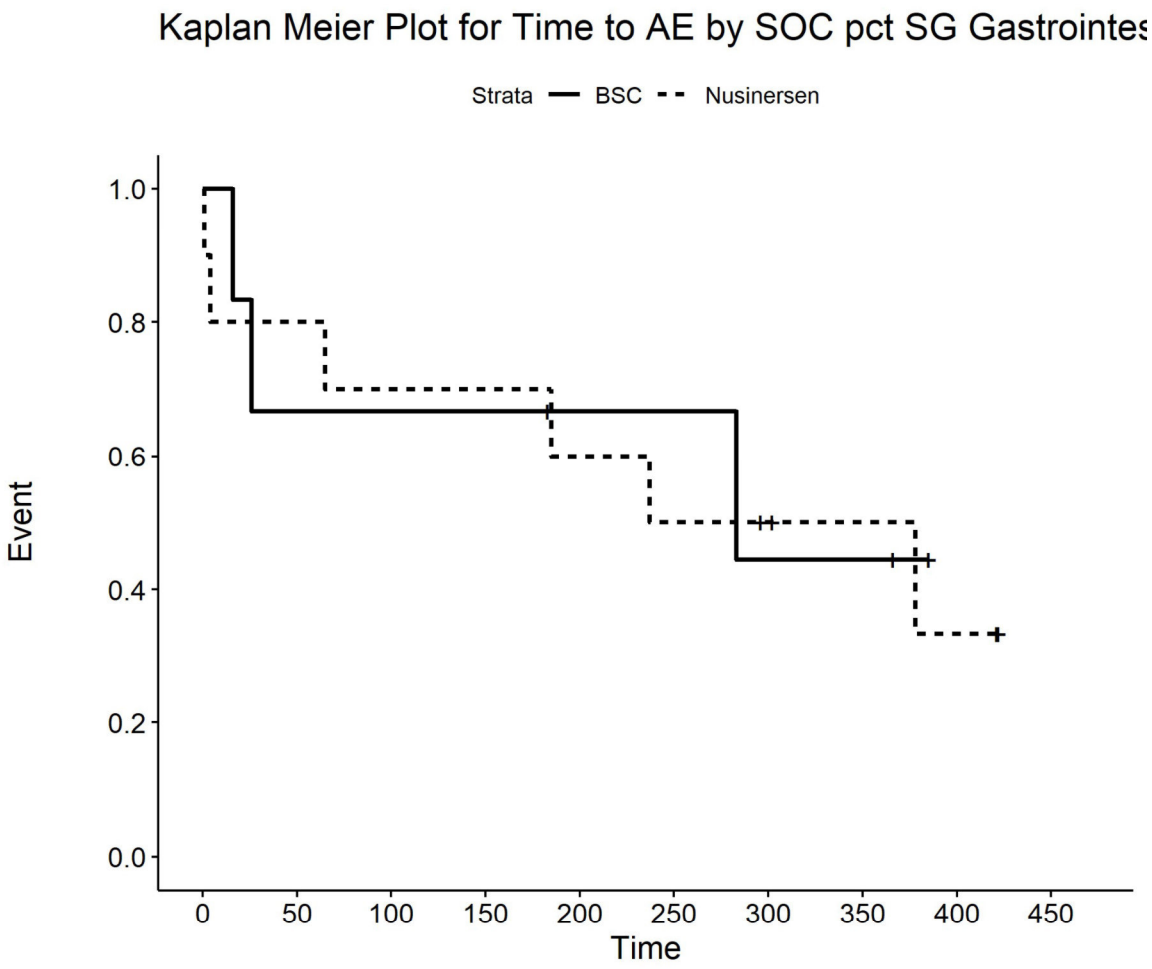
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



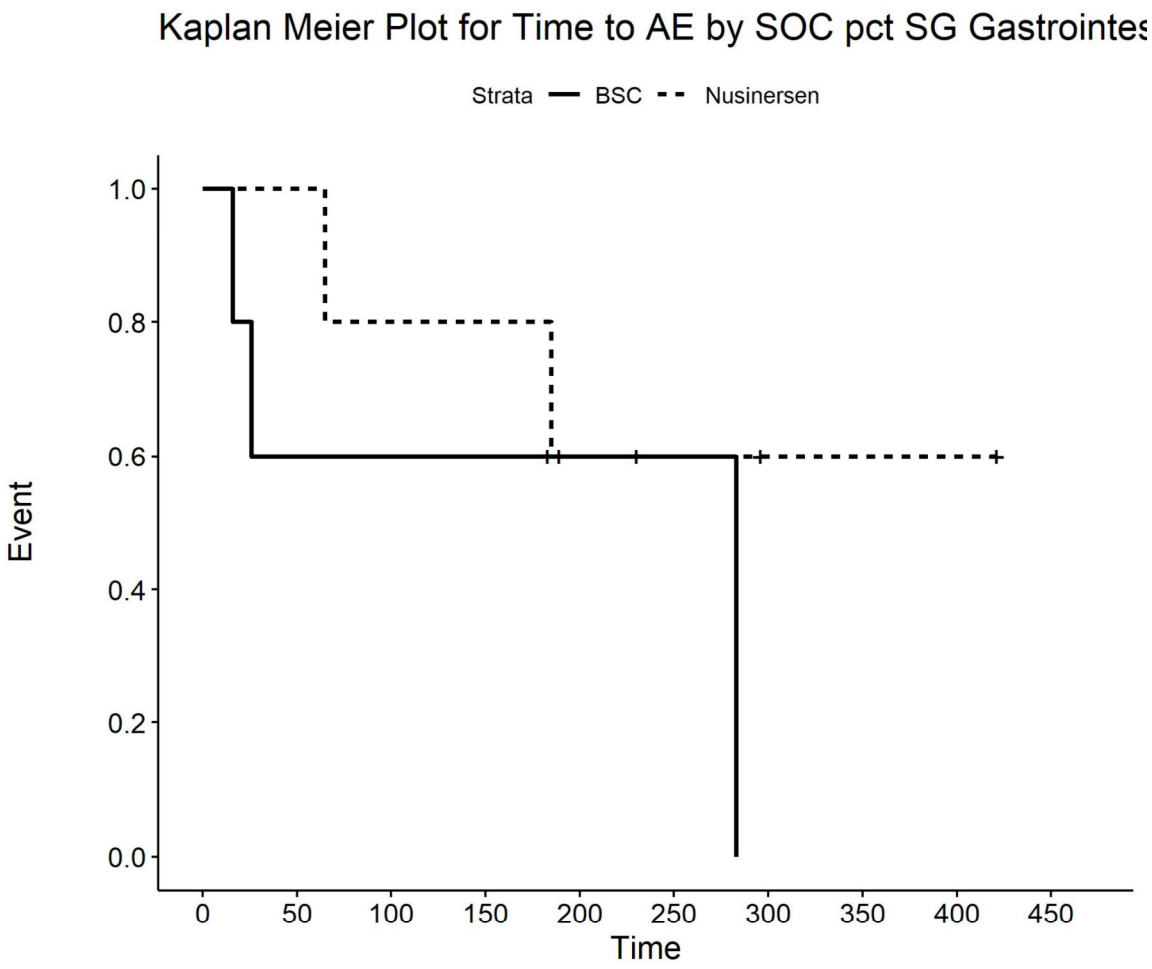
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



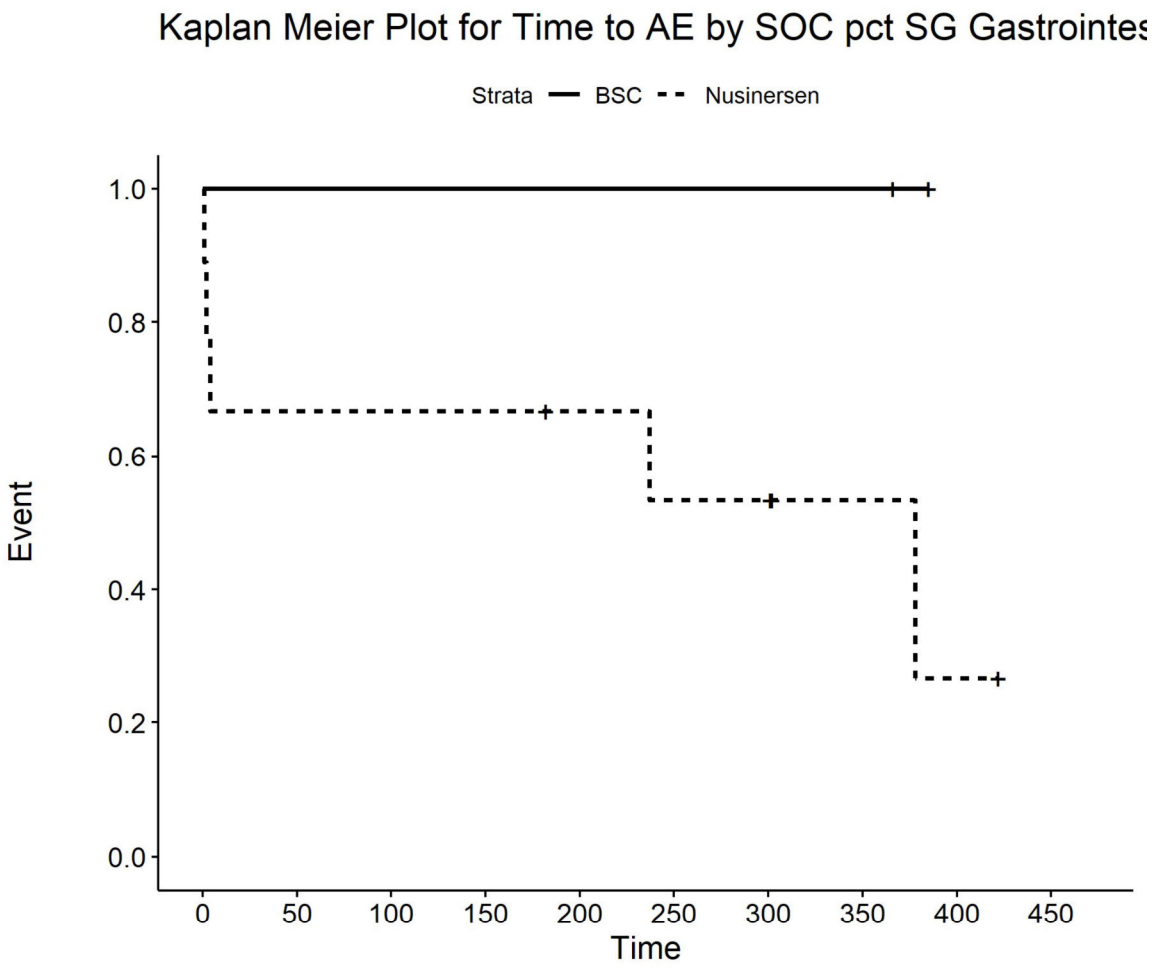
Number at risk

BSC	6	4	4	4	3	3	2	2	0	0
Nusinersen	10	8	7	7	6	5	4	3	2	0



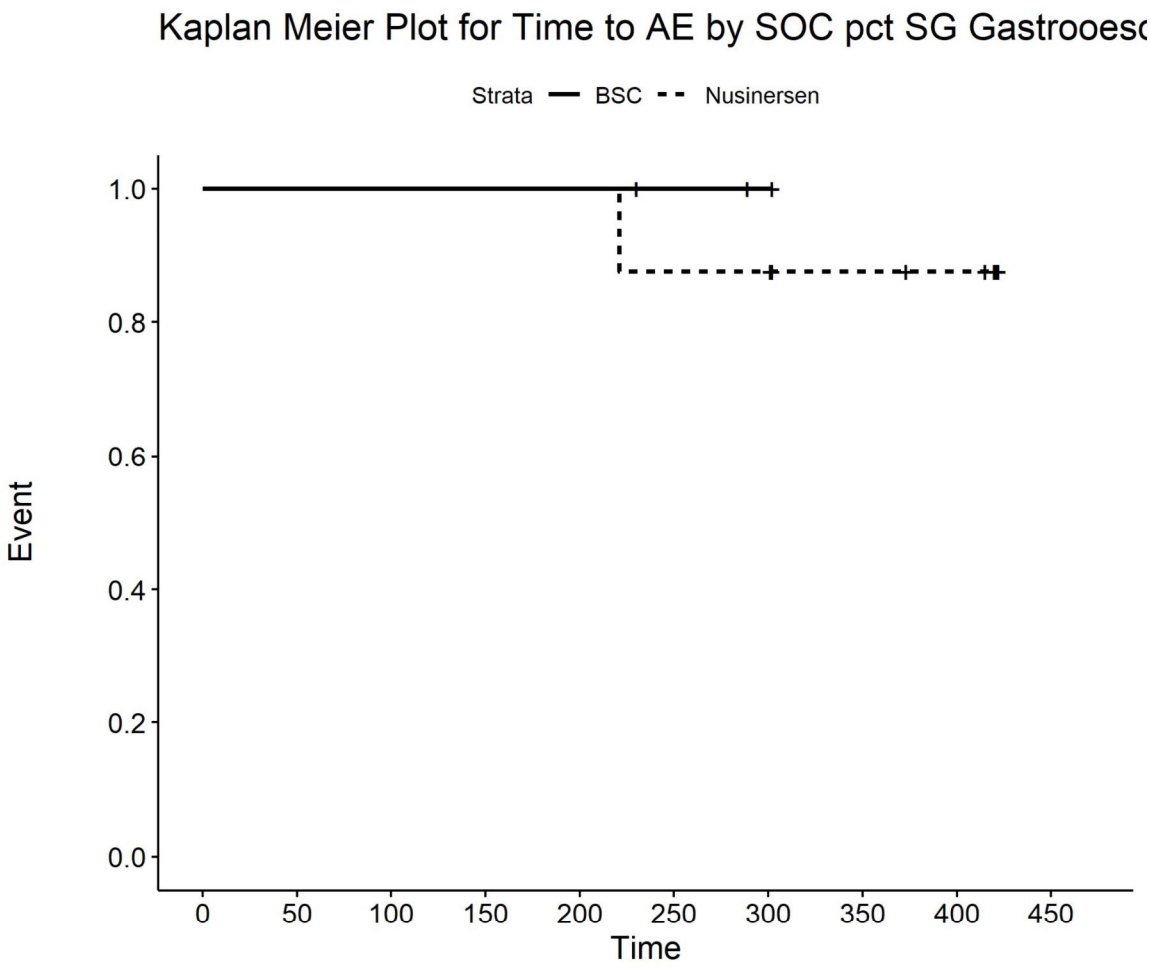
Number at risk

BSC	5	3	3	3	2	1	0	0	0	0
Nusinersen	5	5	4	4	2	2	1	1	1	0



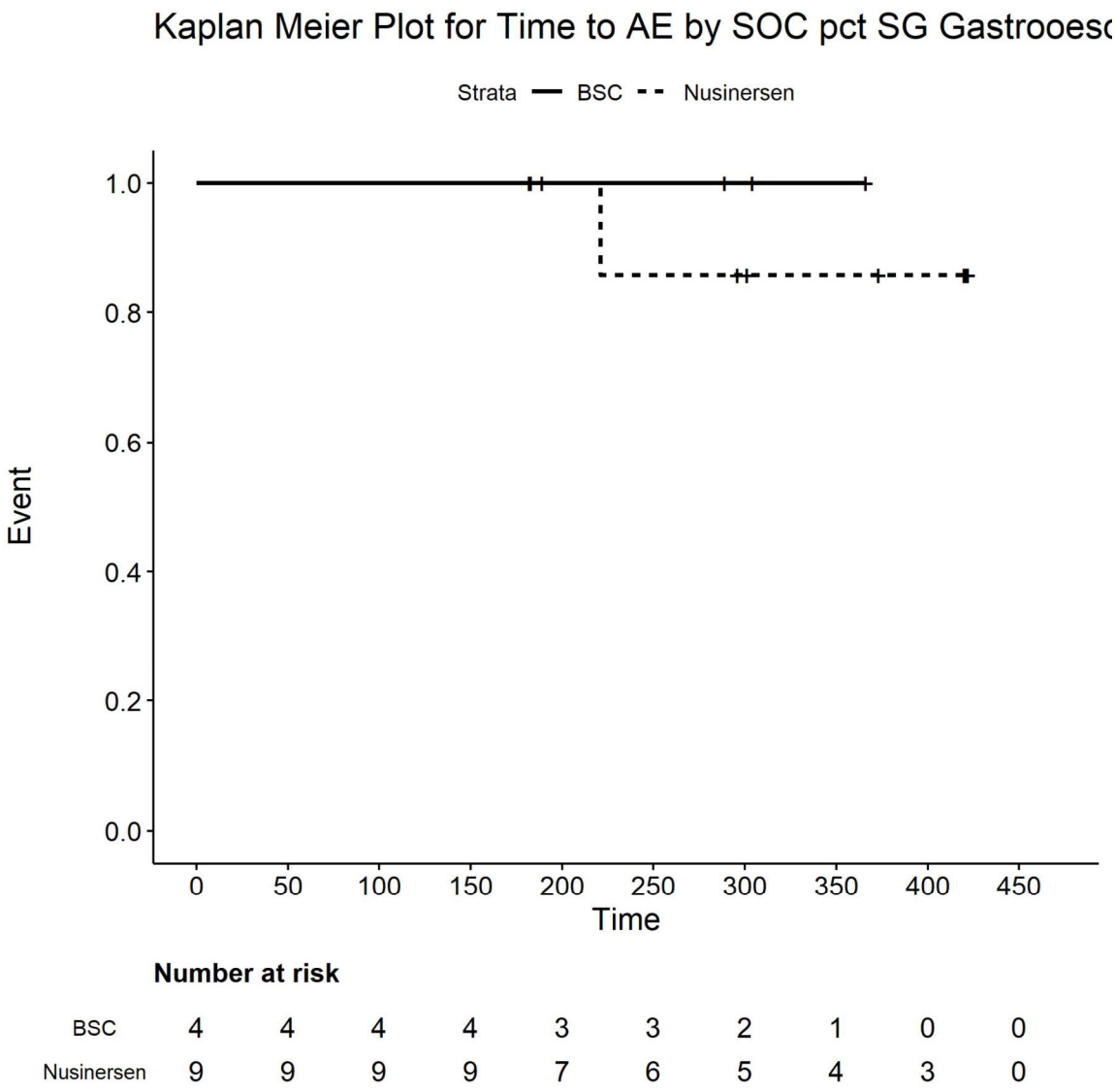
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	6	6	6	5	4	4	2	1	0



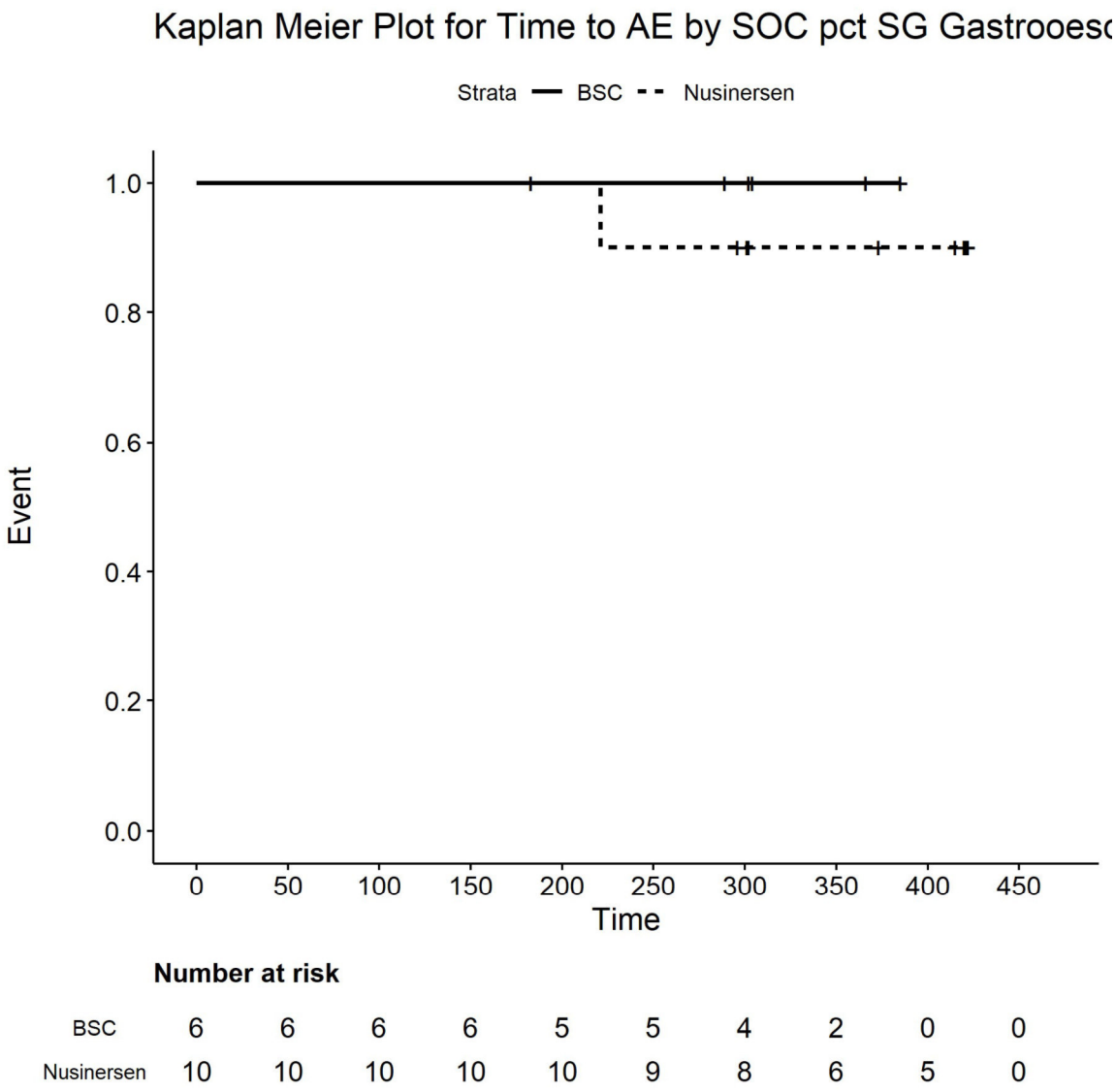
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



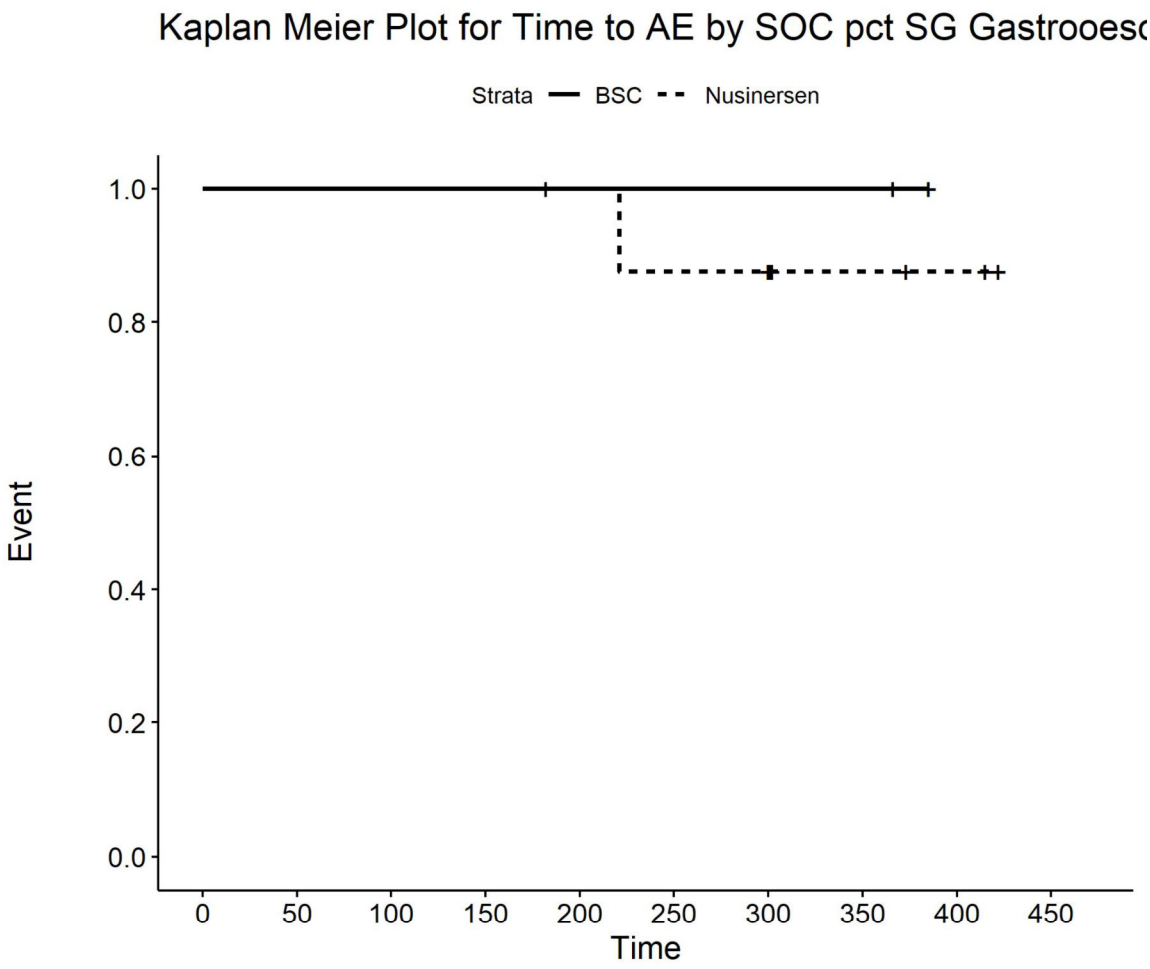
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



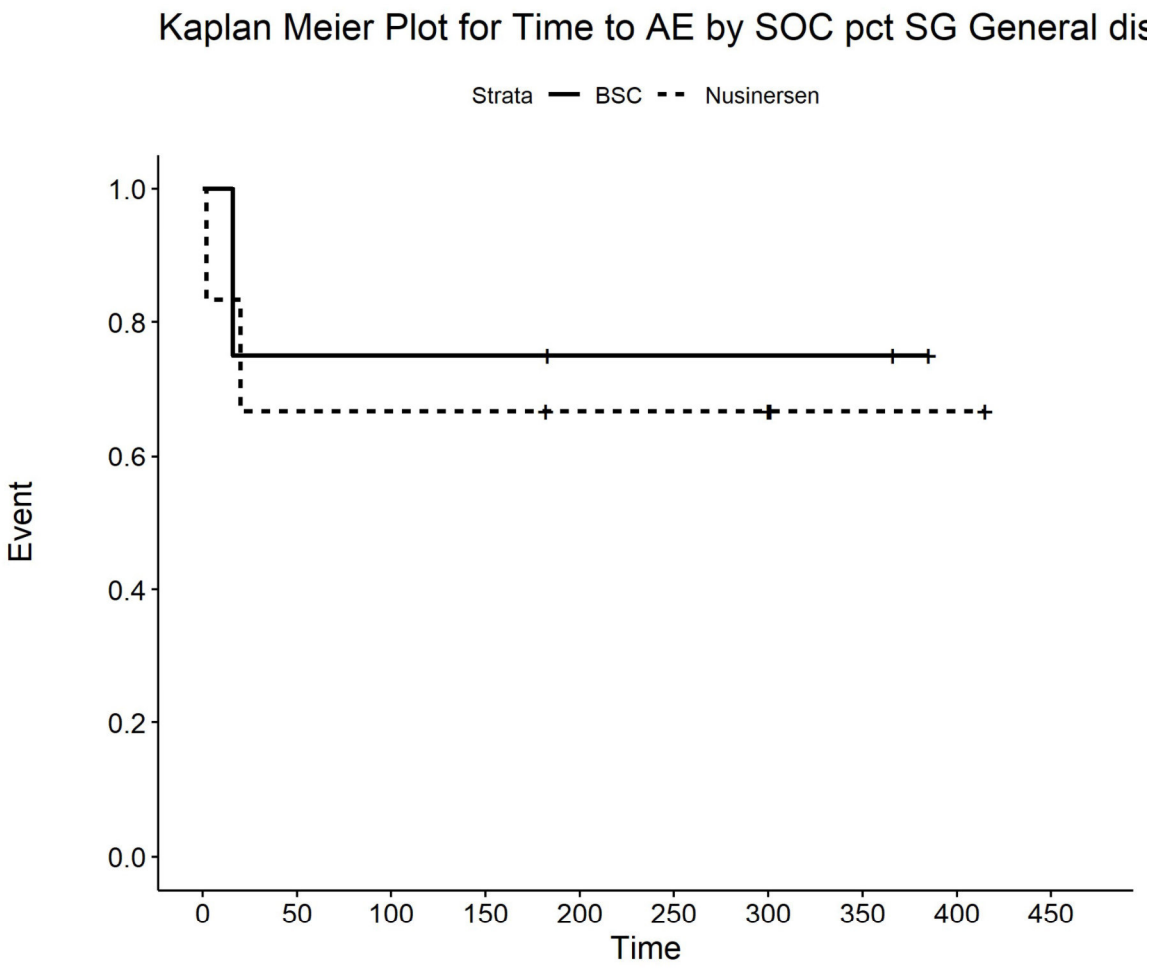
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



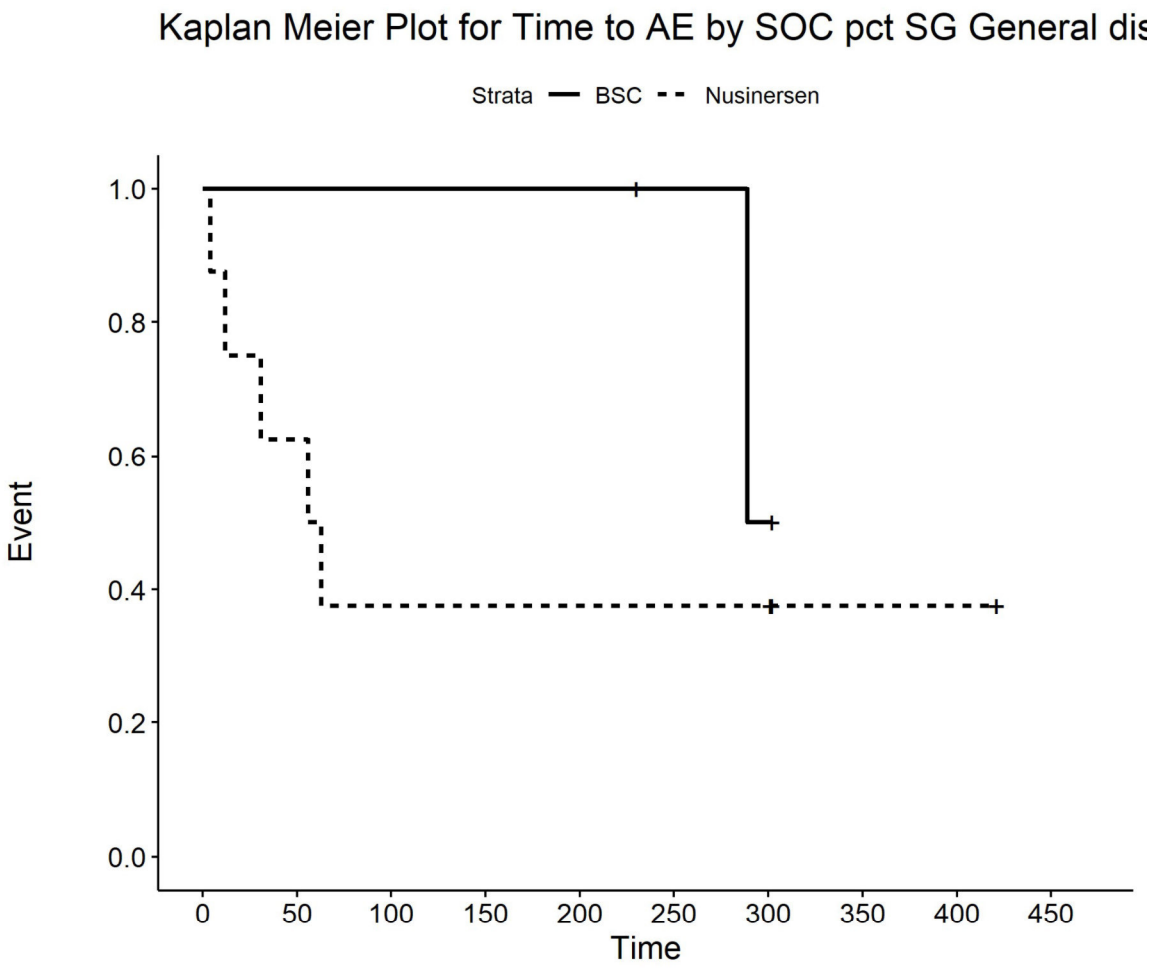
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	2	0



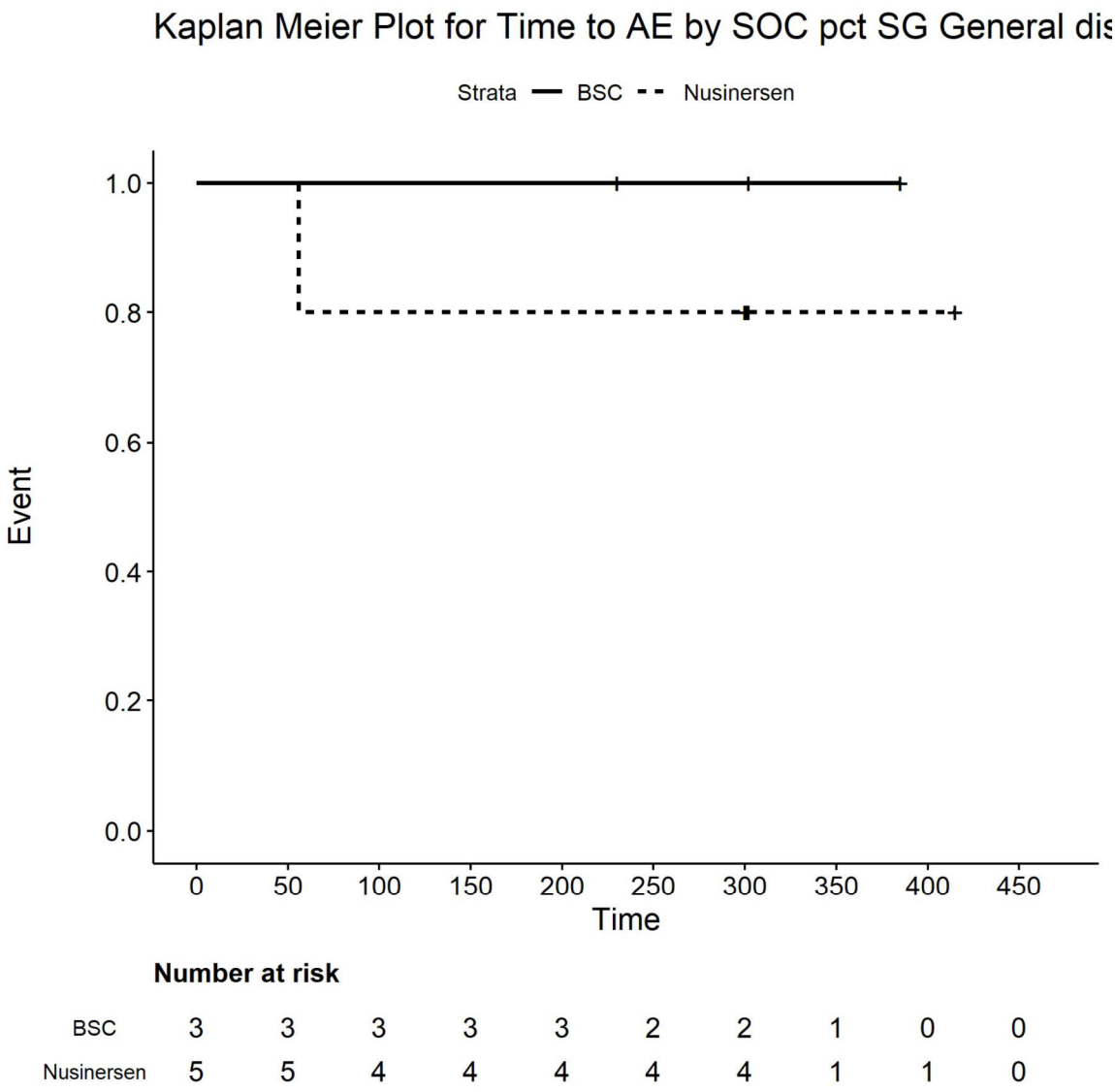
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	4	4	4	3	3	3	1	1	0



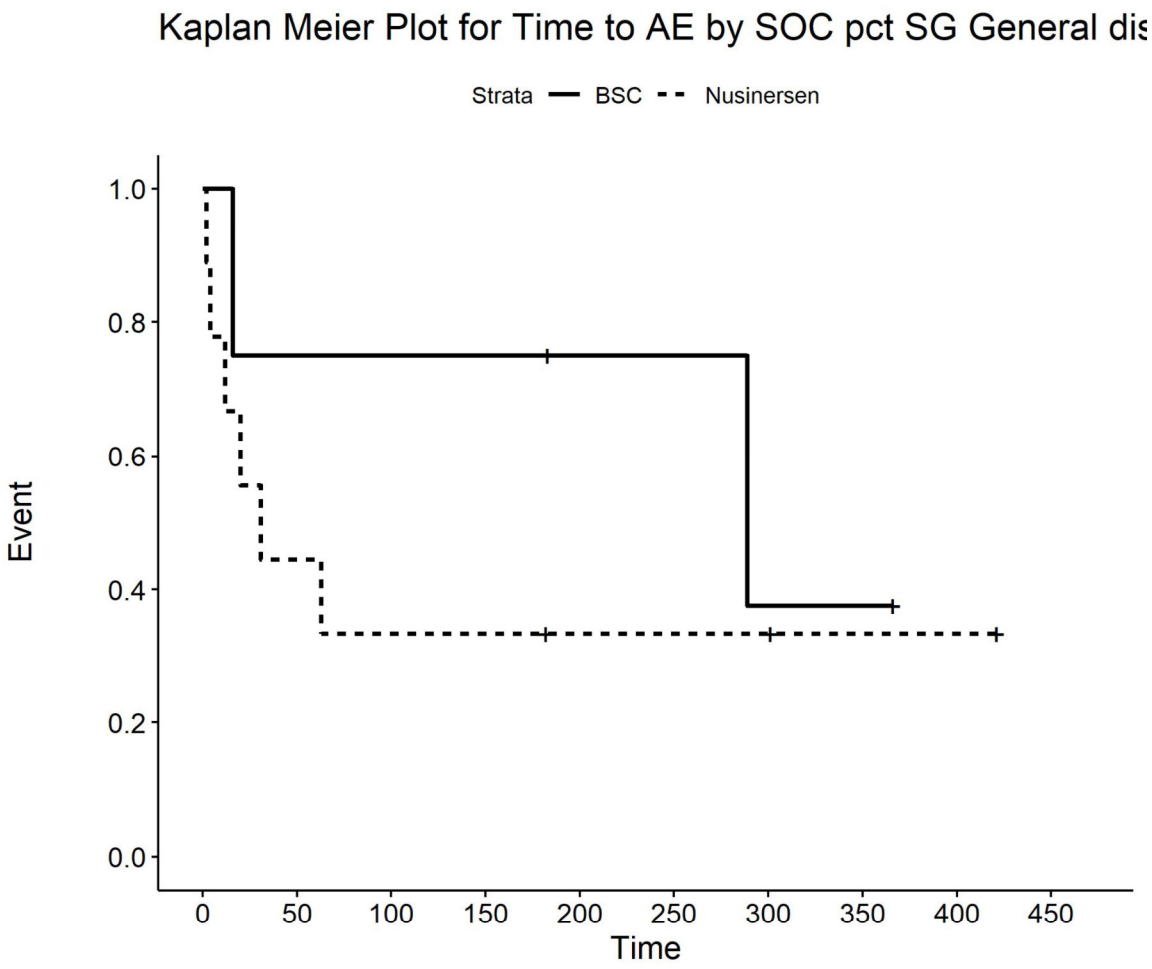
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	5	3	3	3	3	3	1	1	0



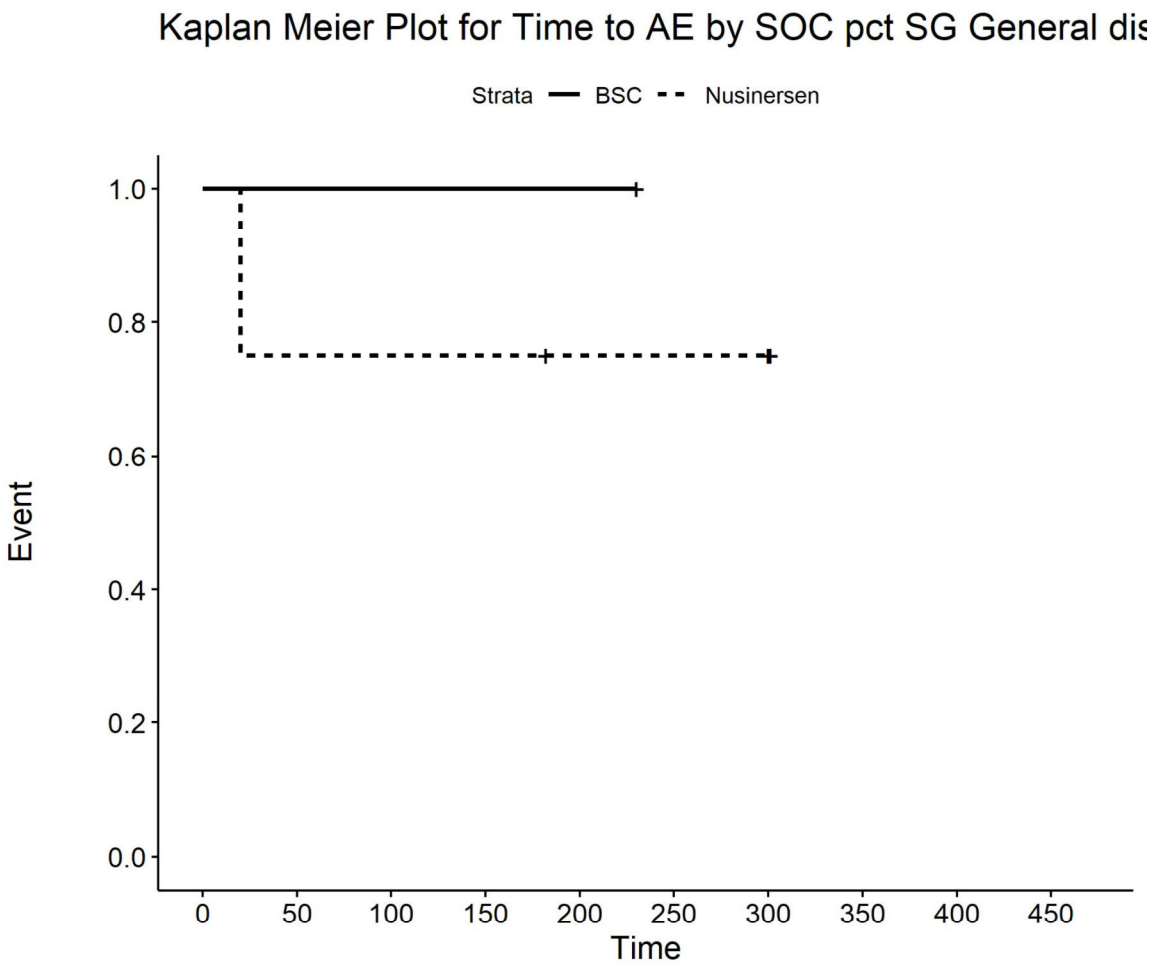
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	1	1	0



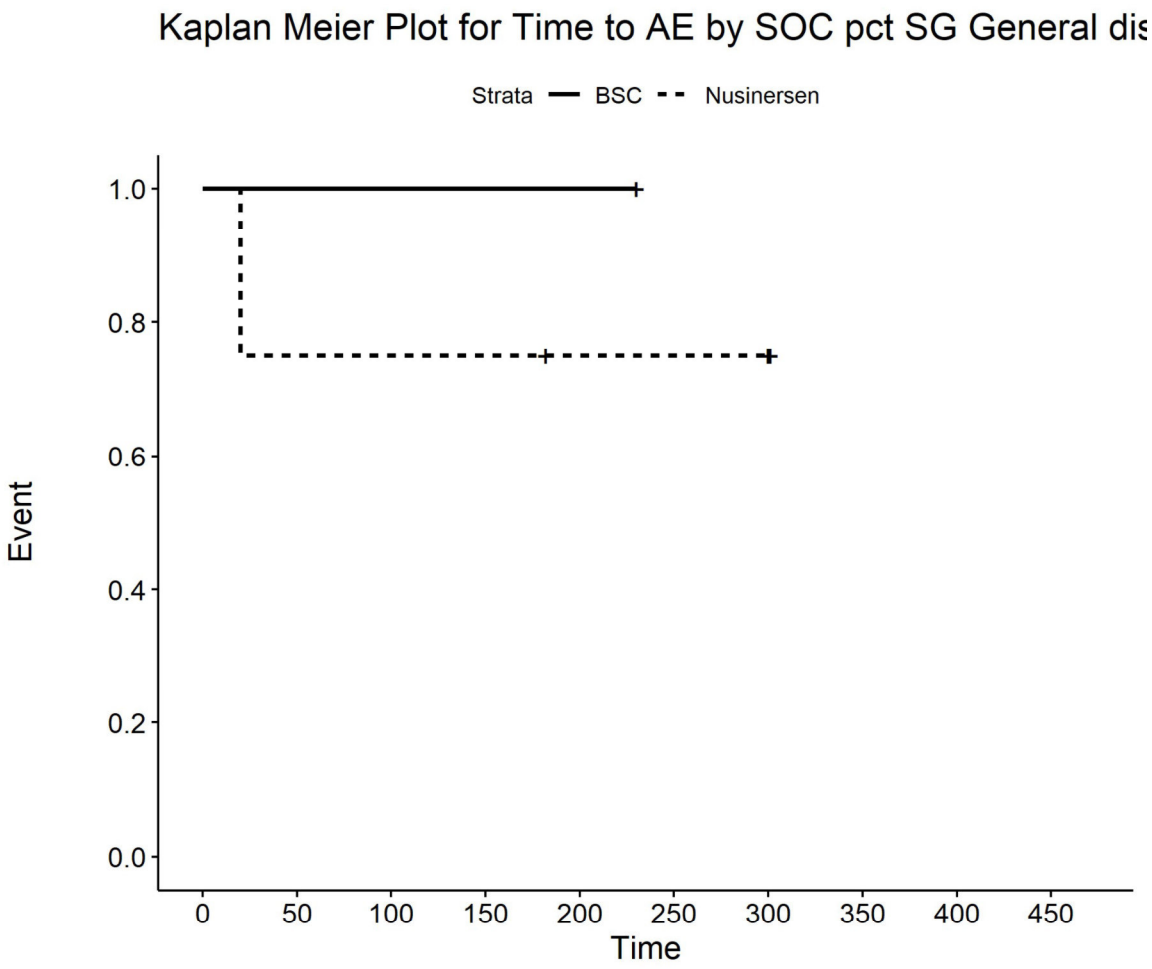
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	4	3	3	2	2	2	1	1	0



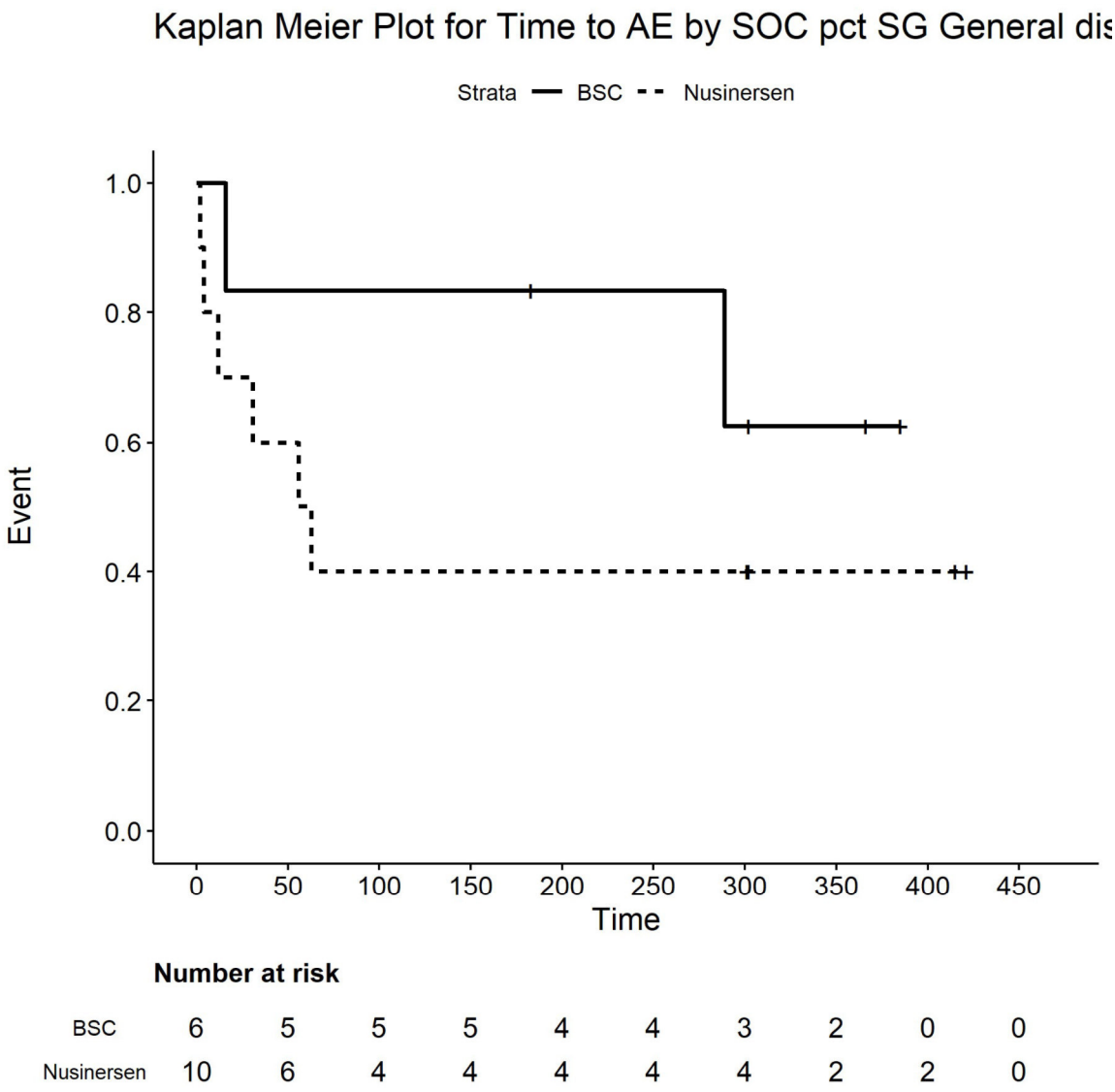
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



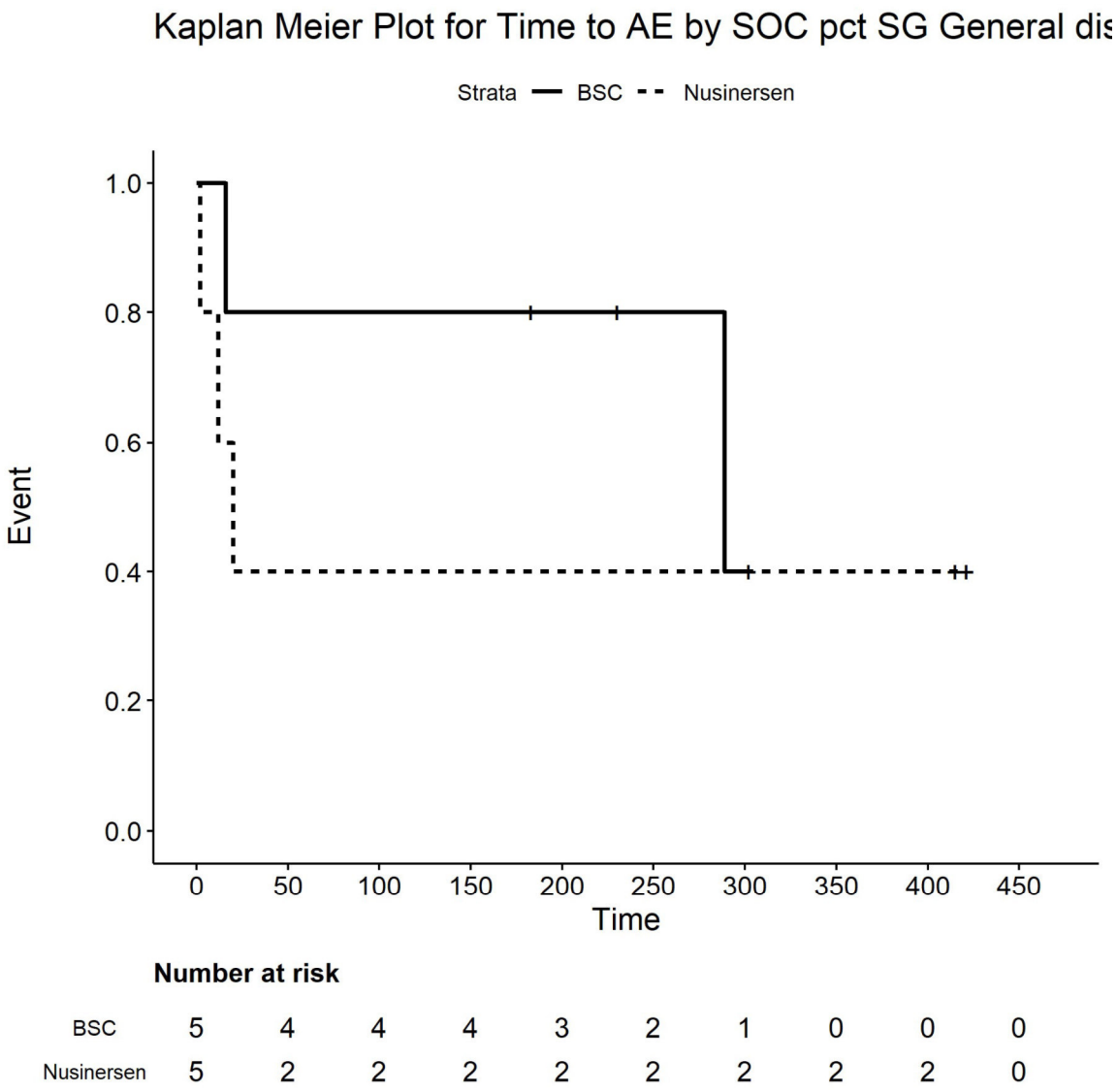
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



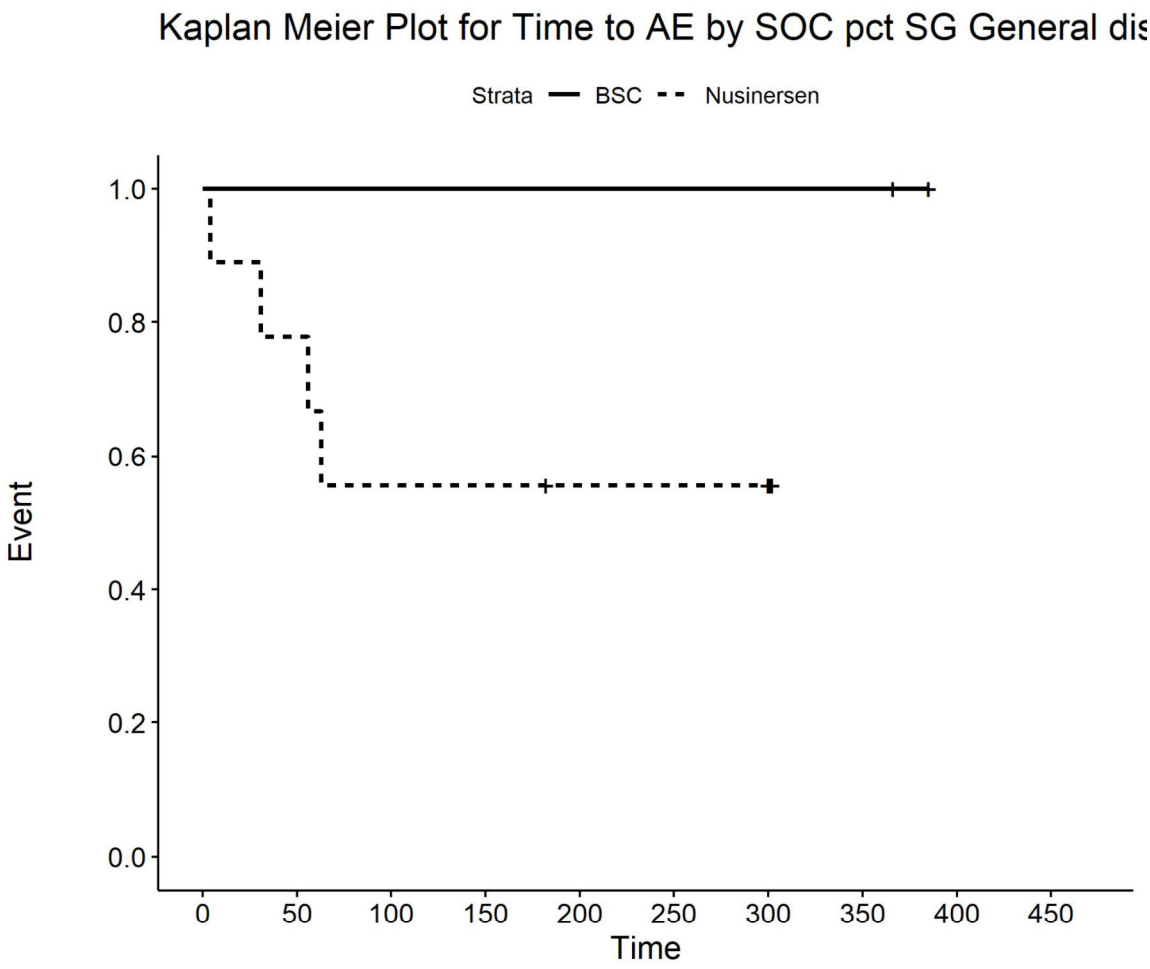
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	6	4	4	4	4	4	2	2	0



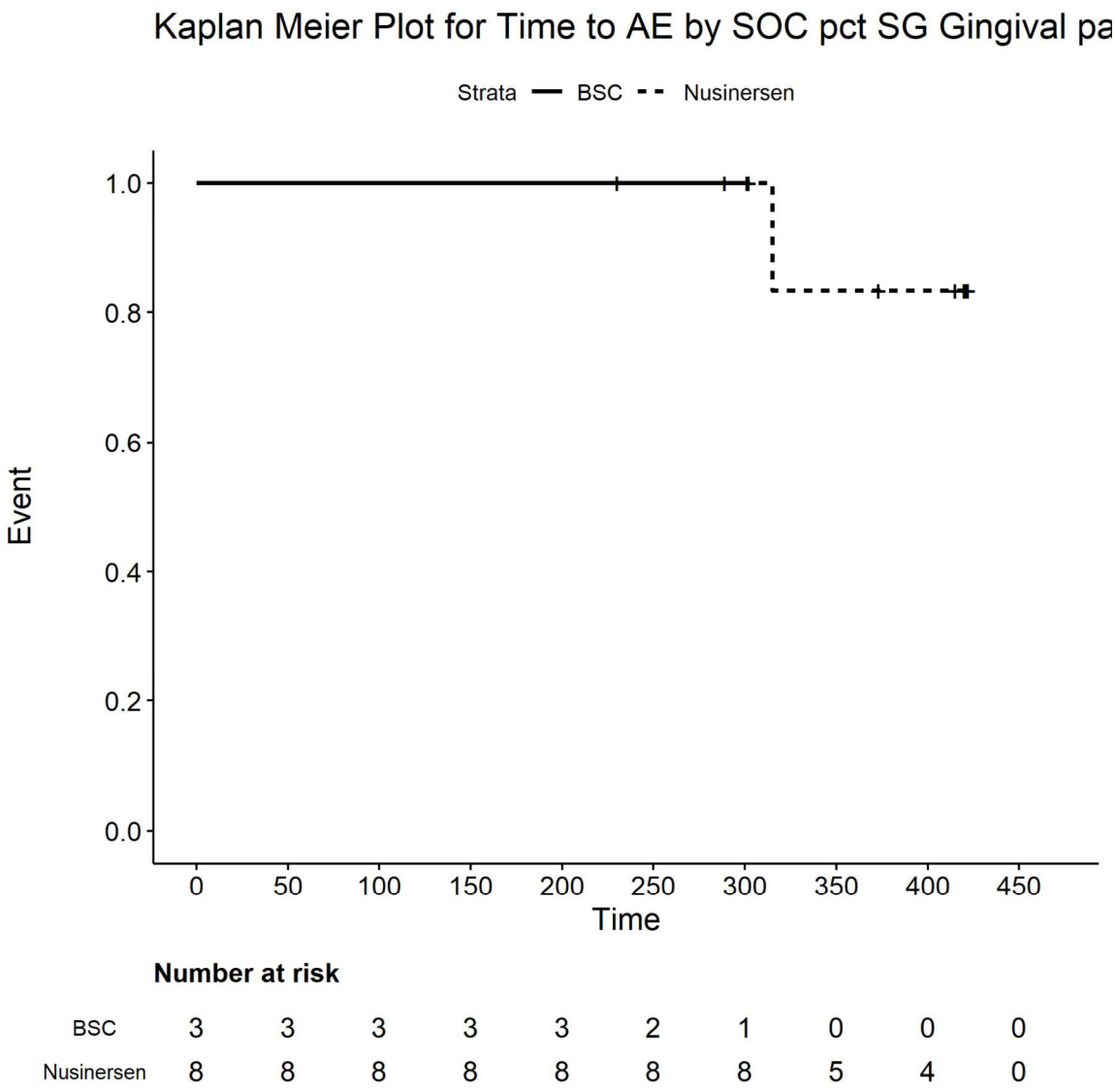
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	2	2	2	2	2	2	2	2	0



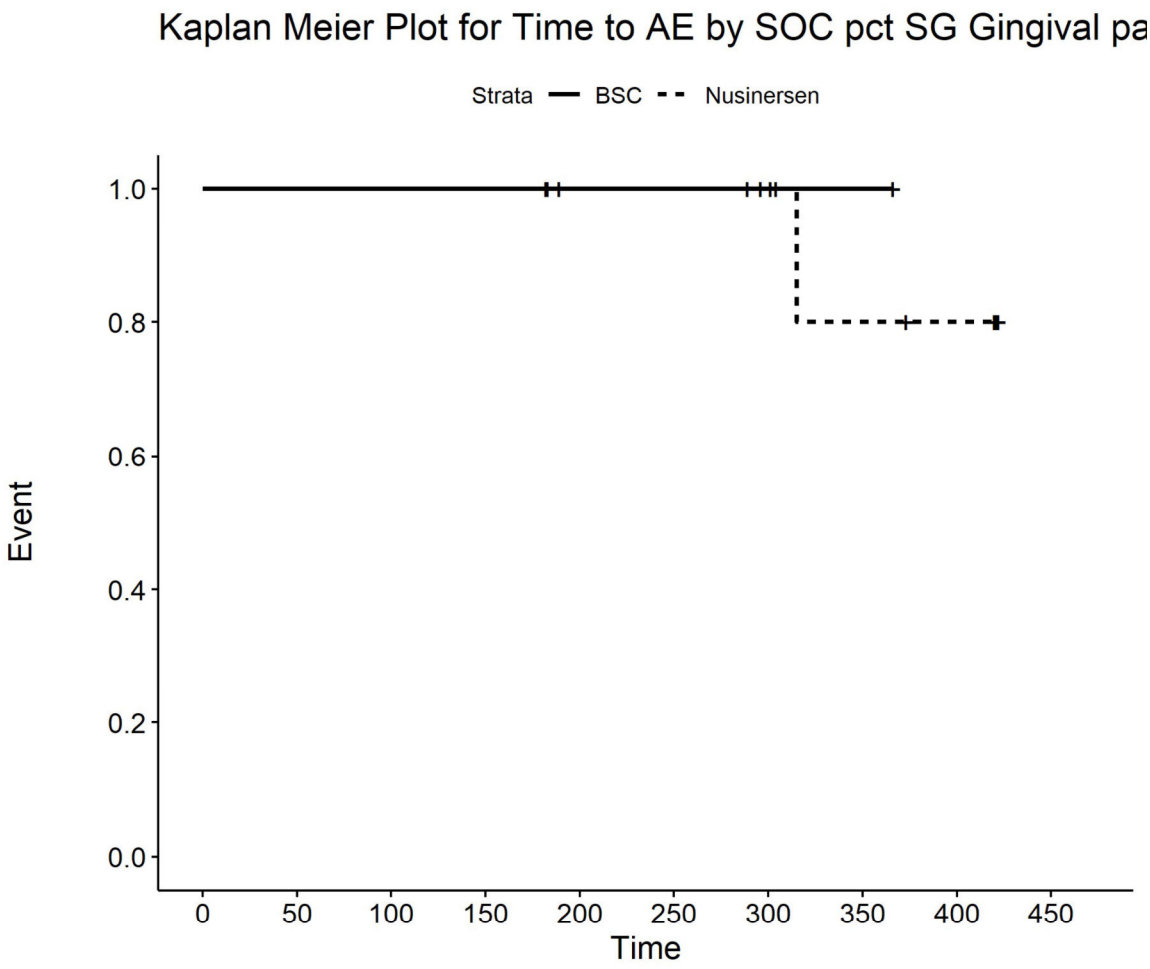
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	5	5	4	4	4	0	0	0



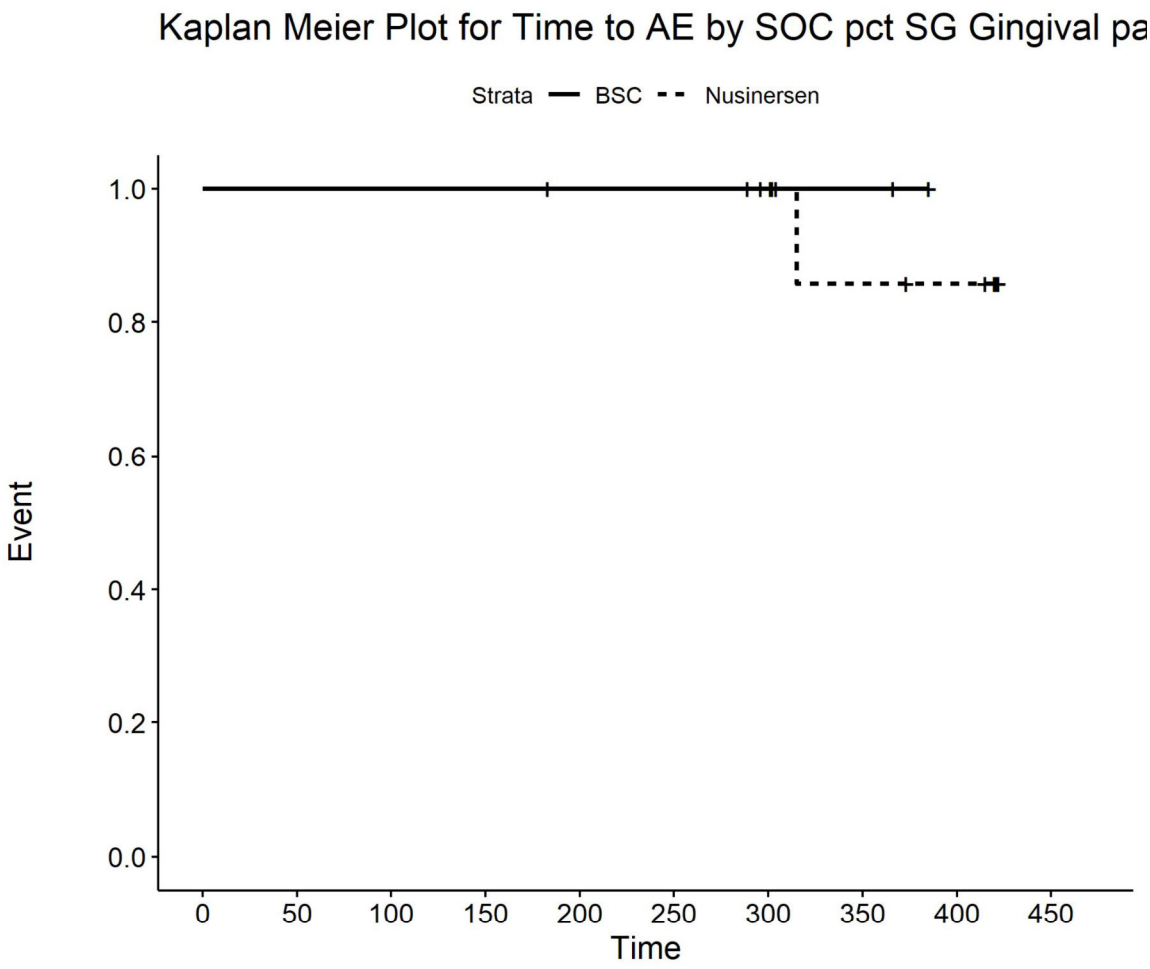
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	5	4	0



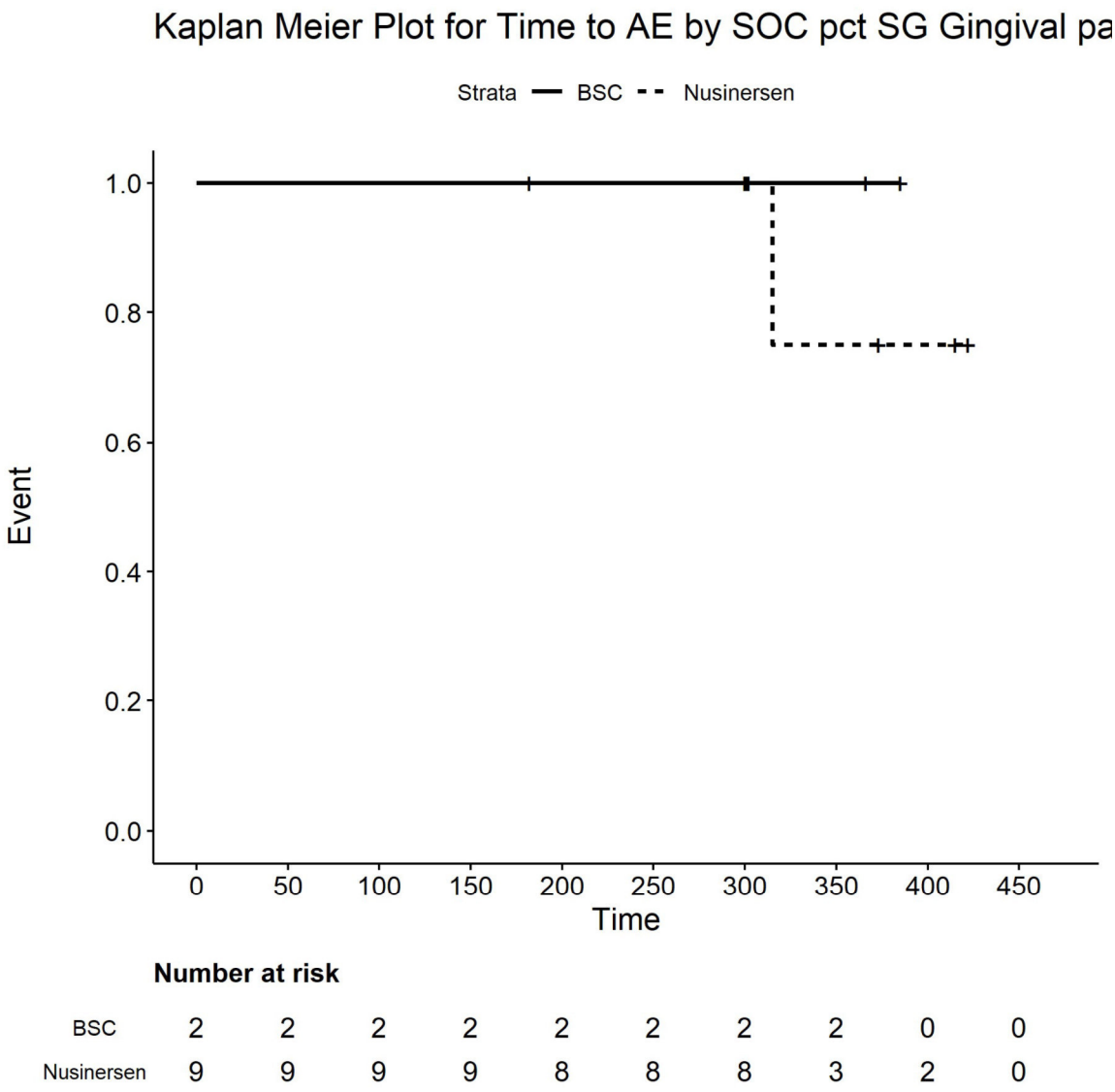
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	4	3	0



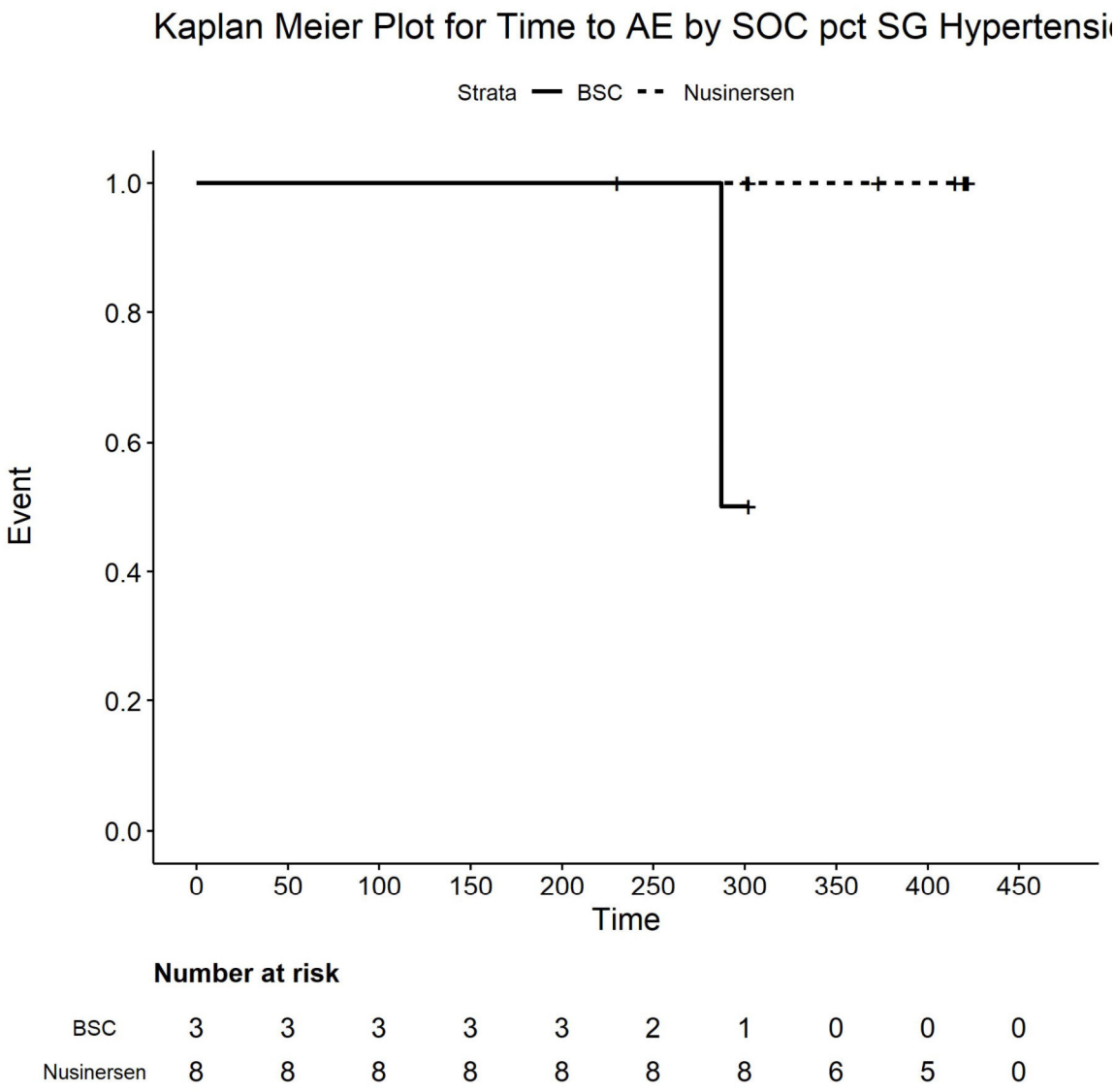
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	6	5	0



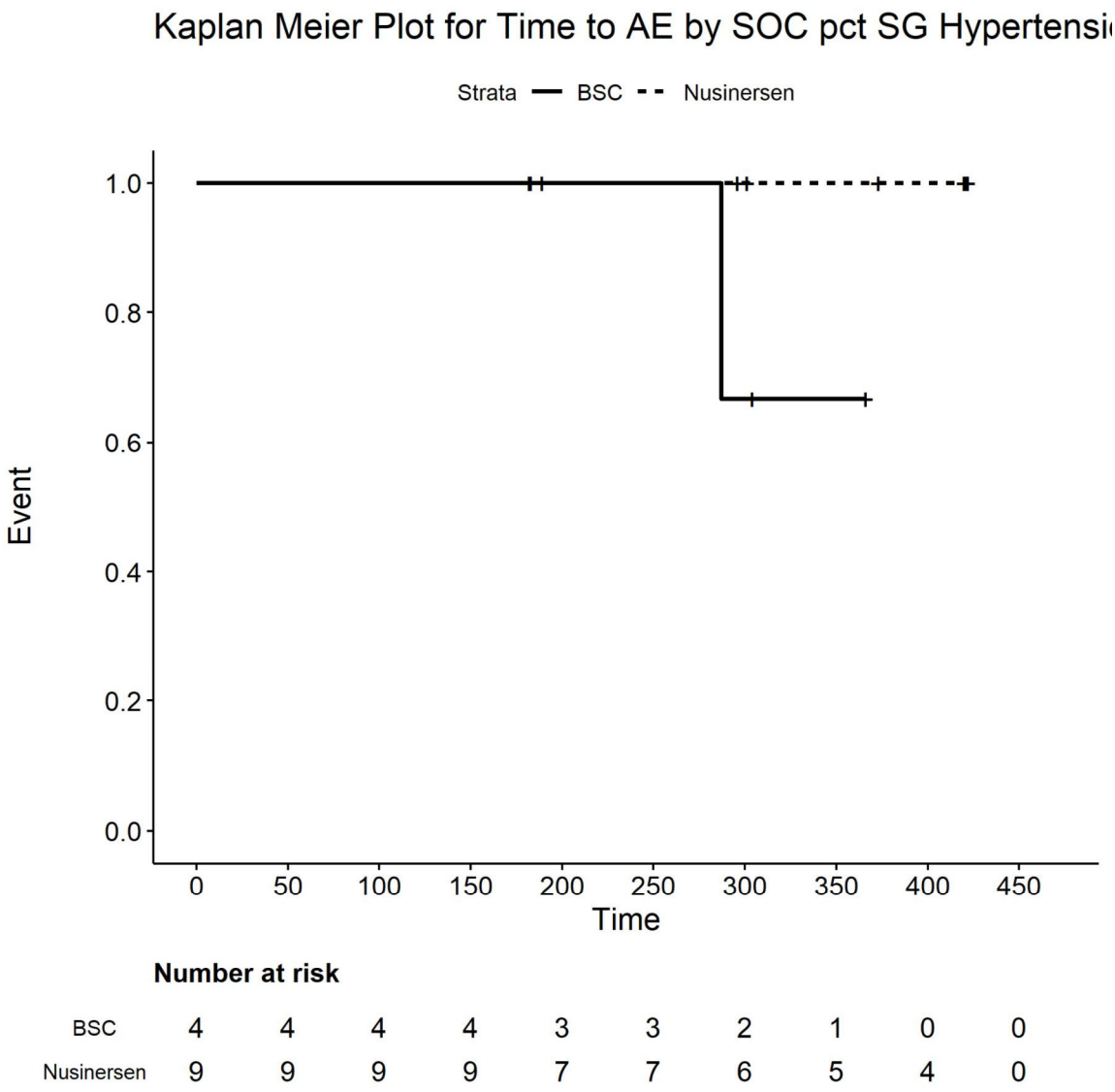
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	8	3	2	0



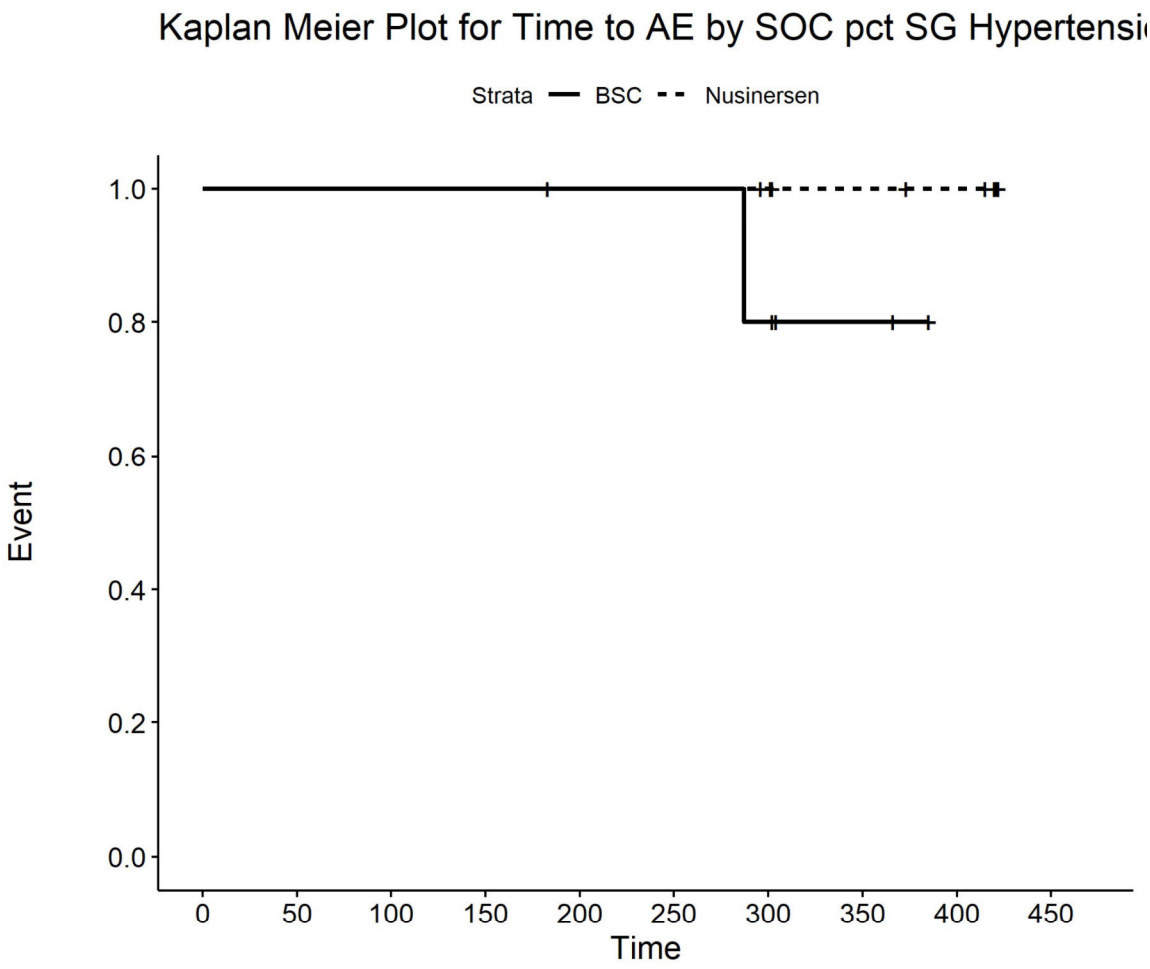
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



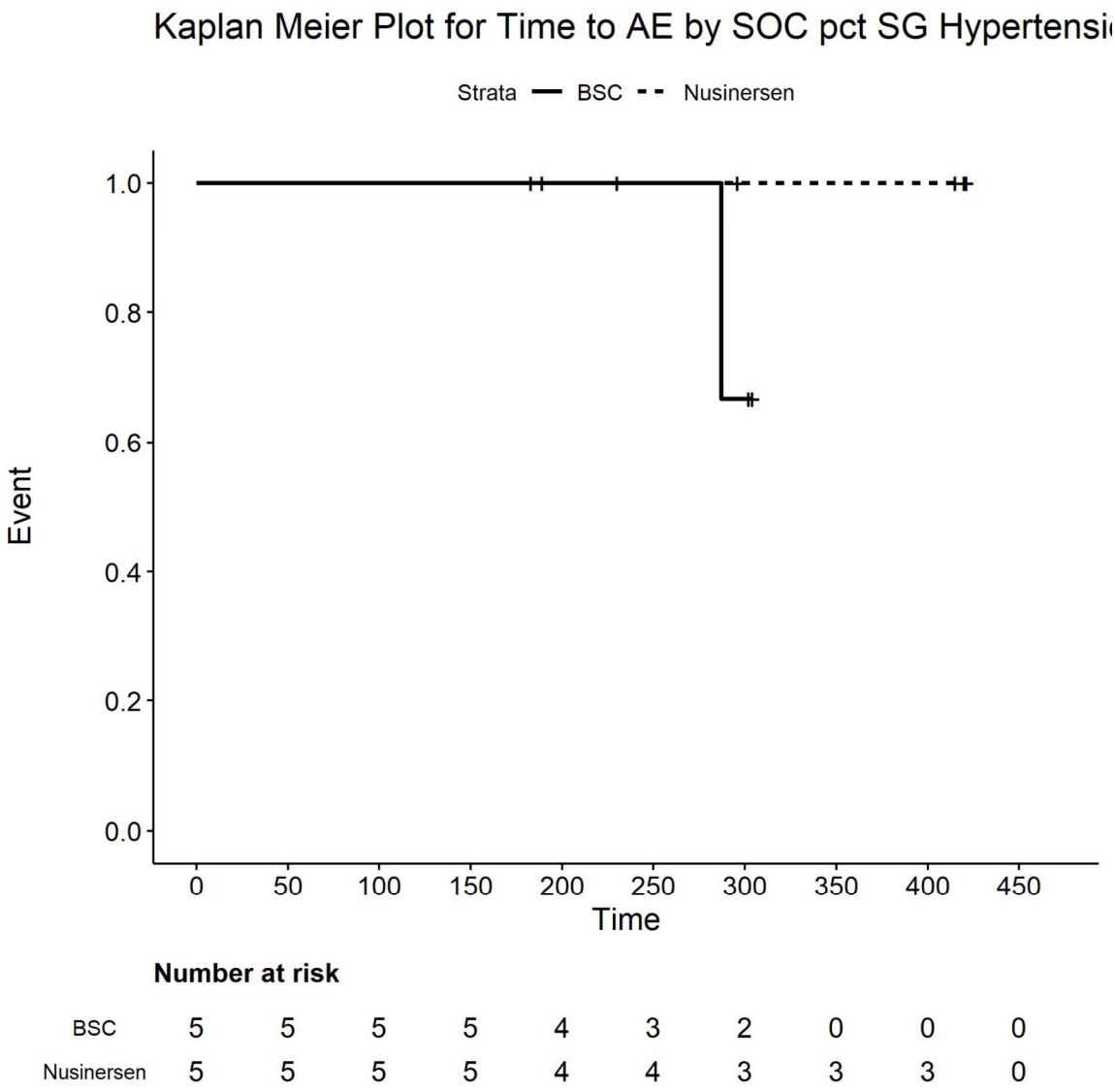
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



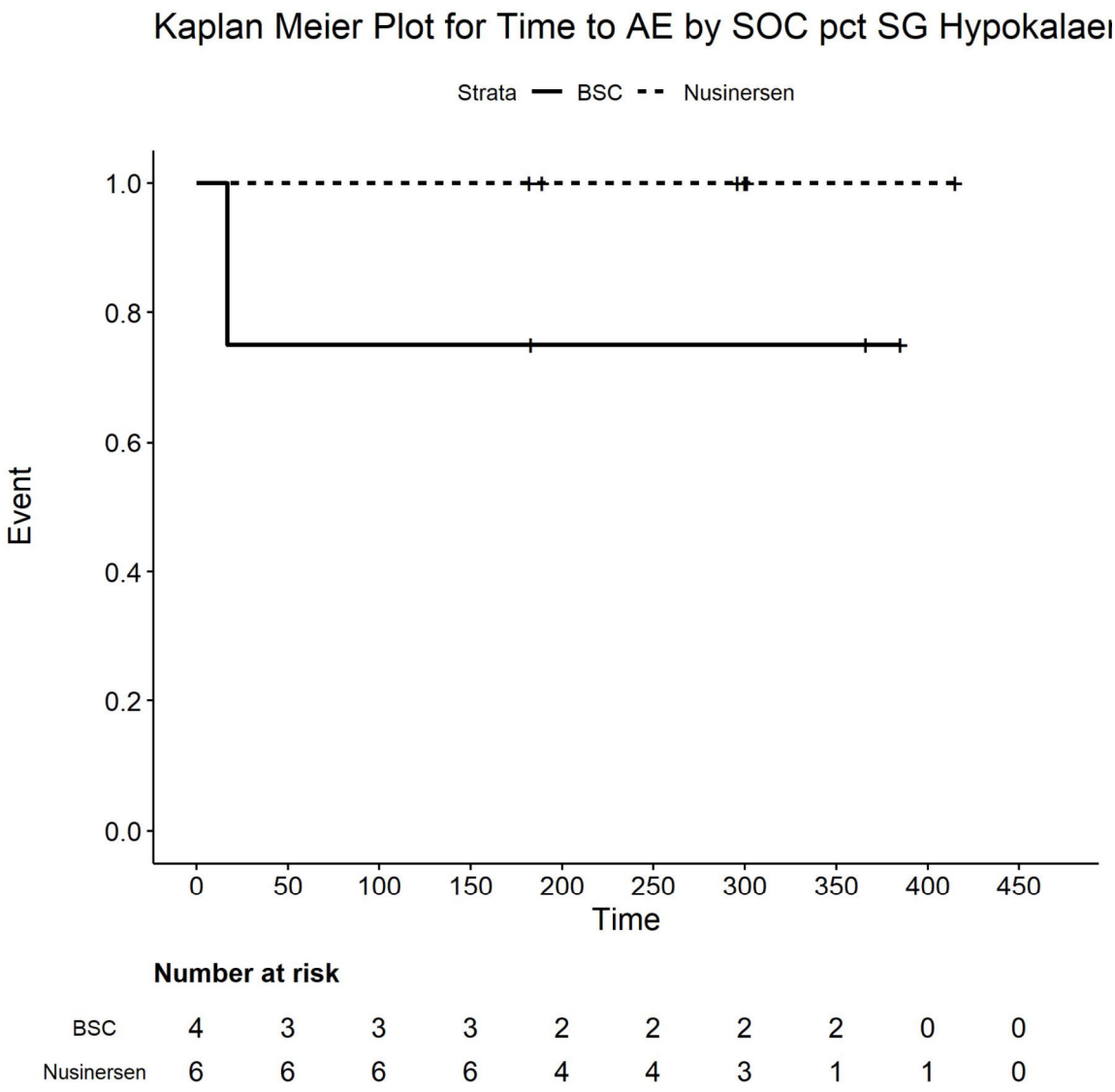
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



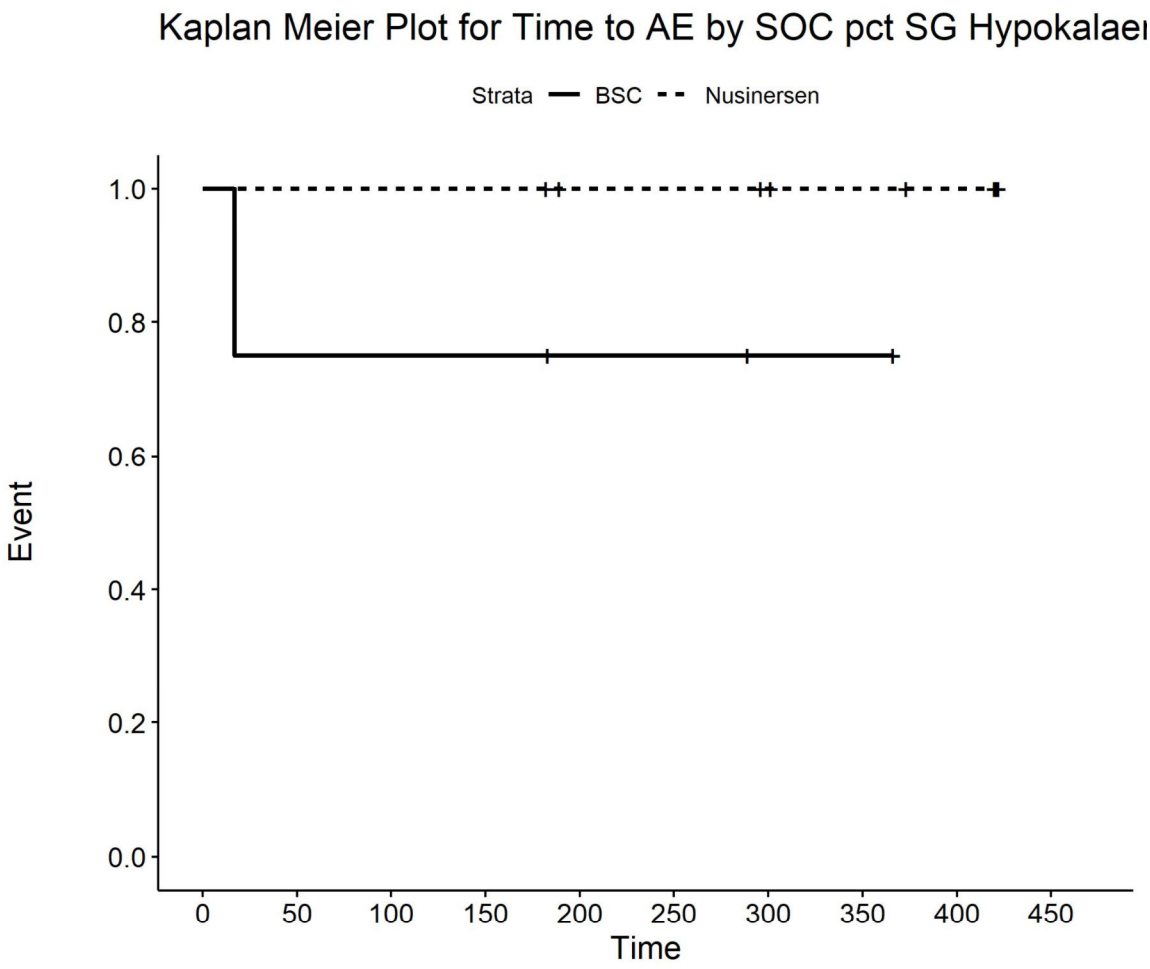
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



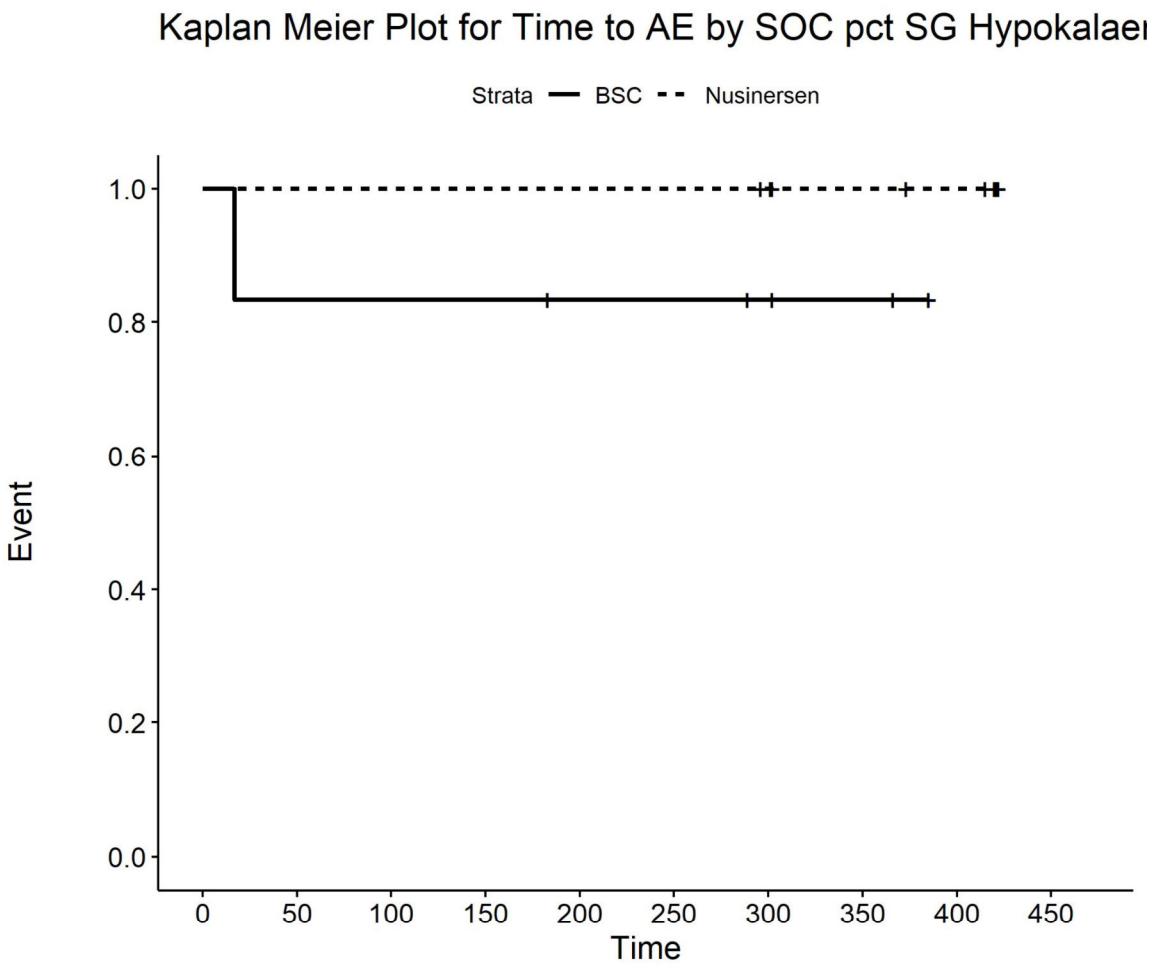
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



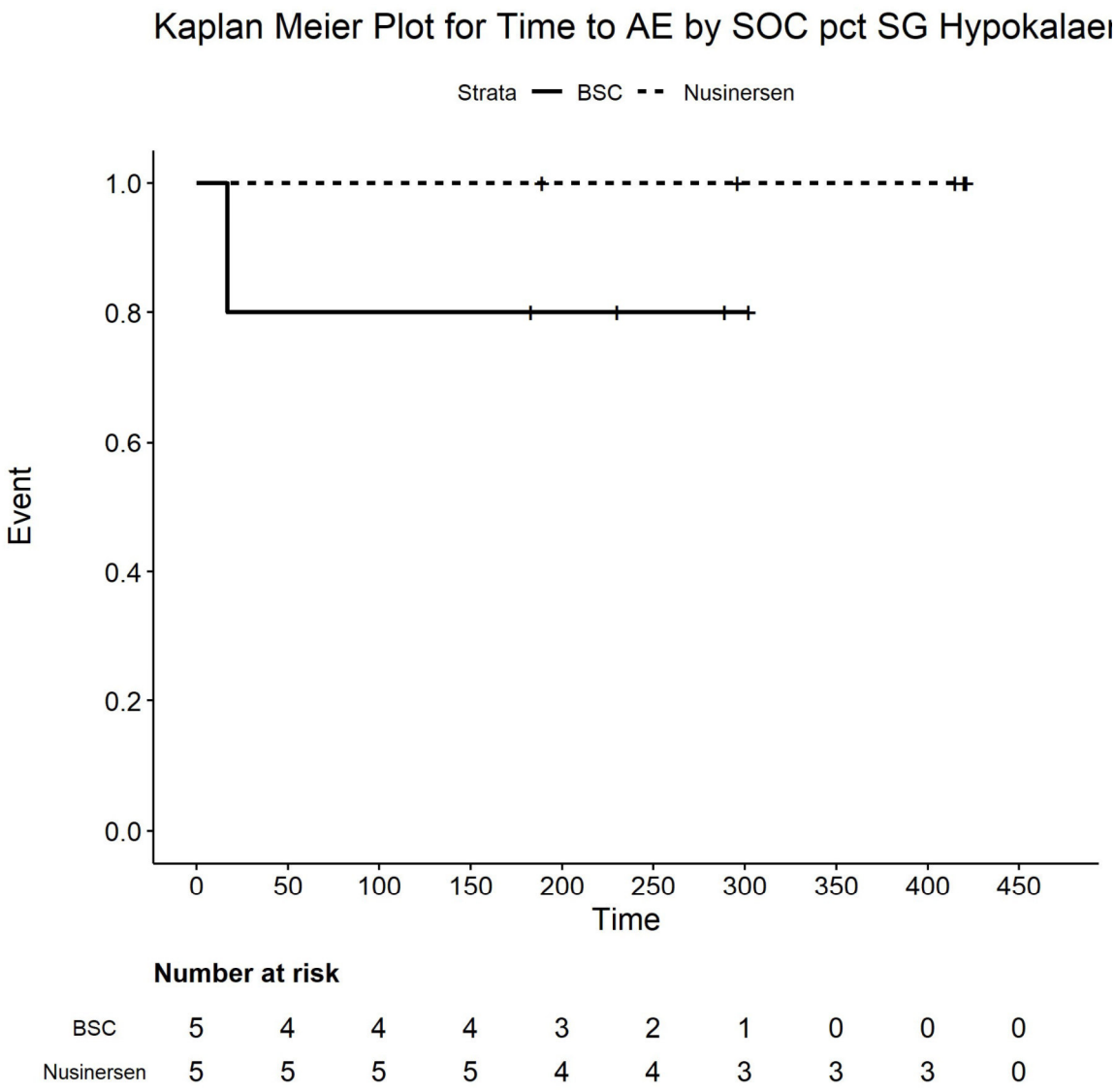
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



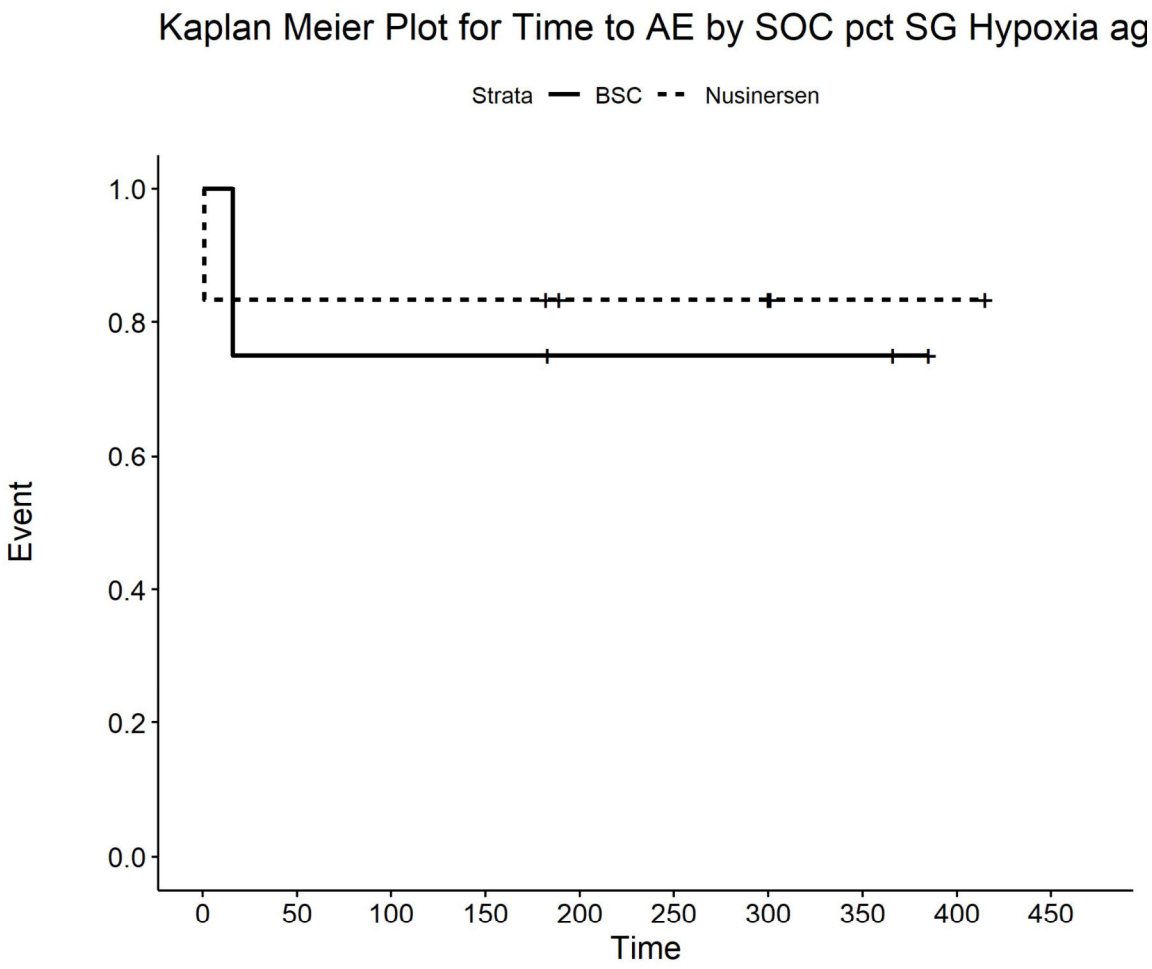
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



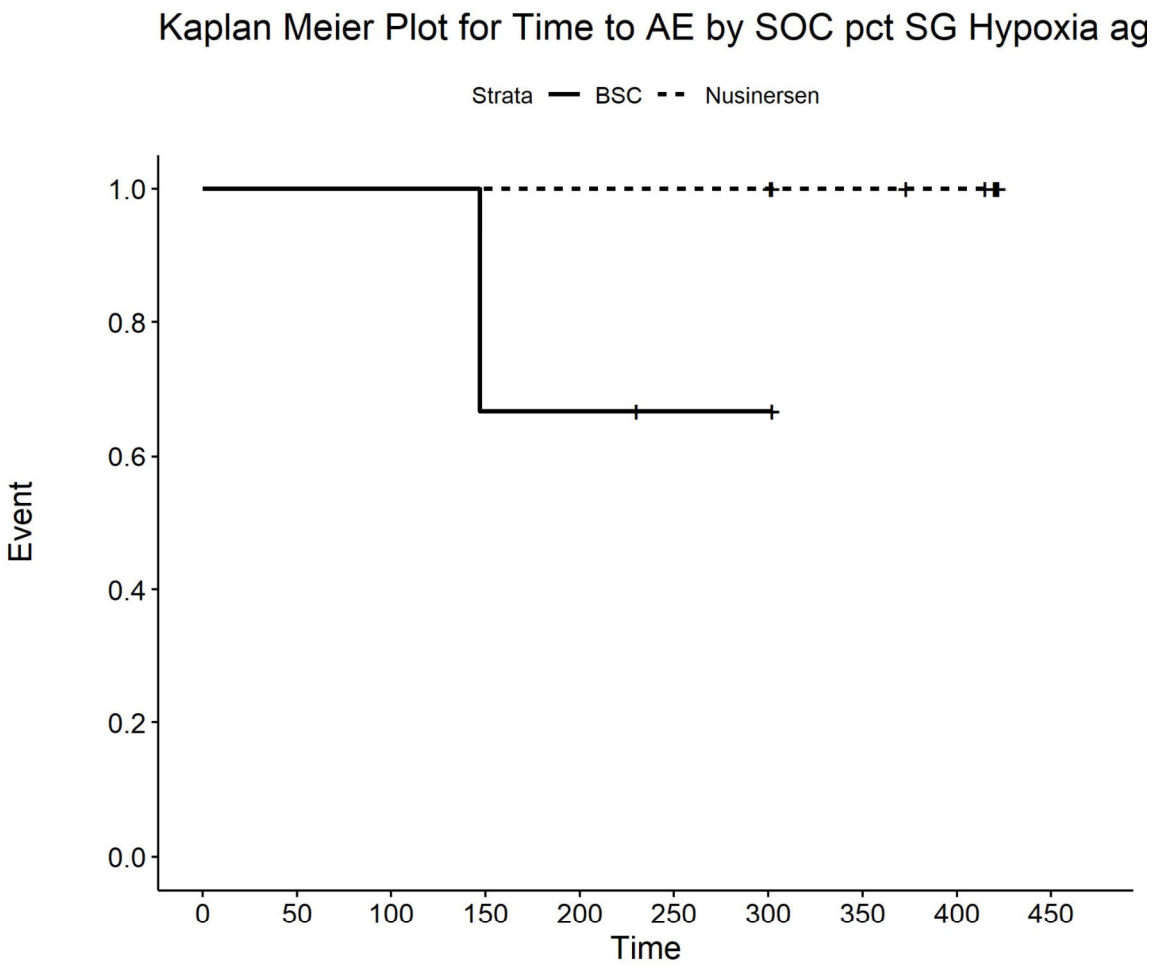
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



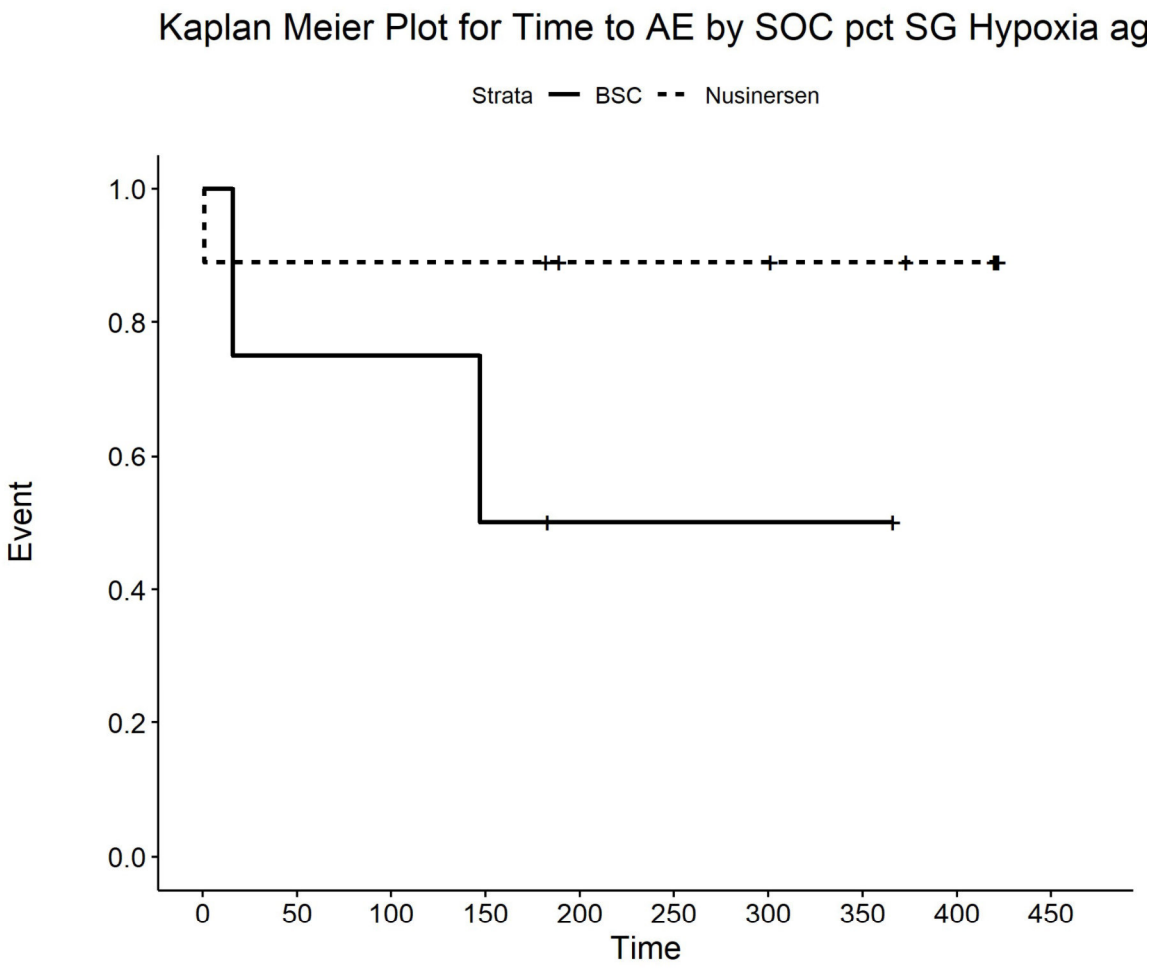
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	5	5	5	3	3	3	1	1	0



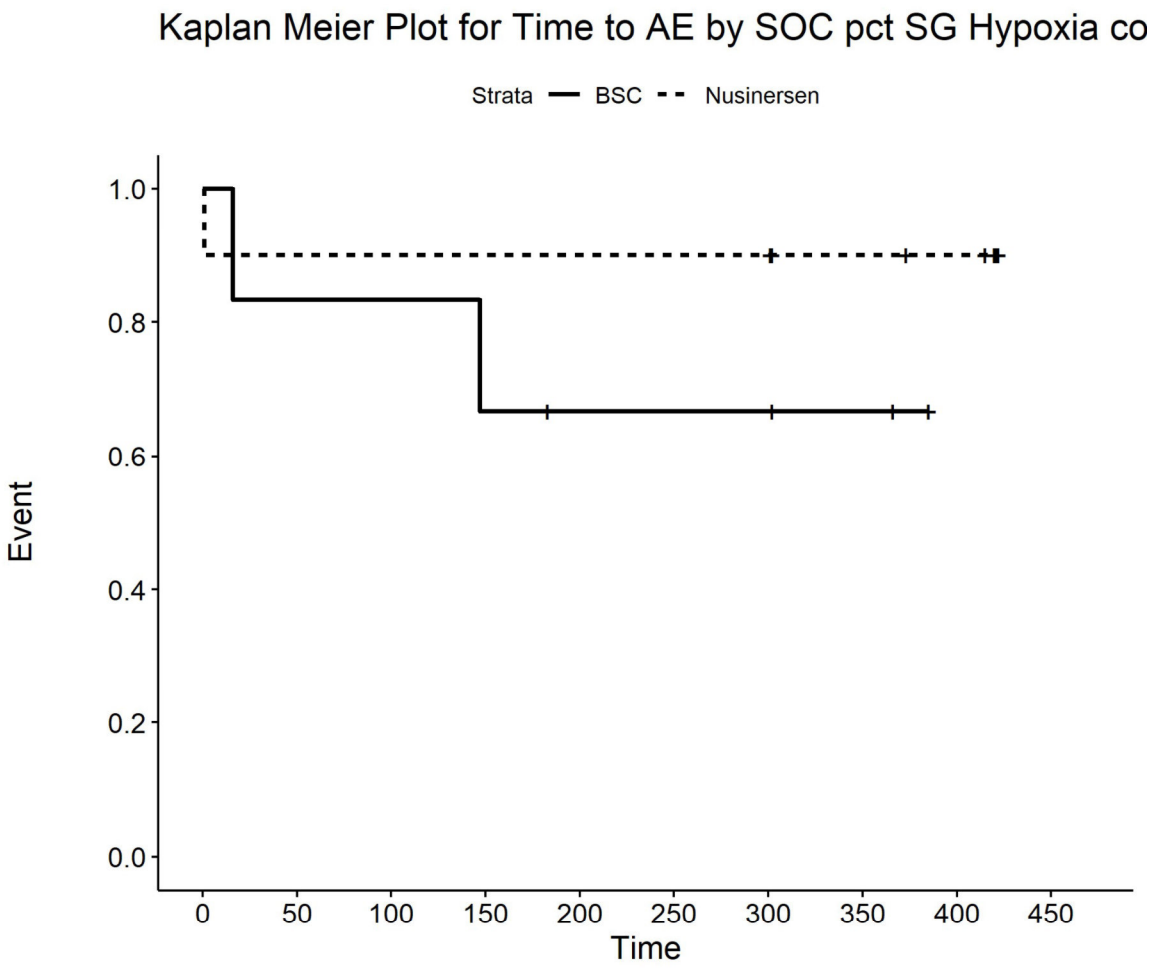
Number at risk

BSC	3	3	3	2	2	1	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



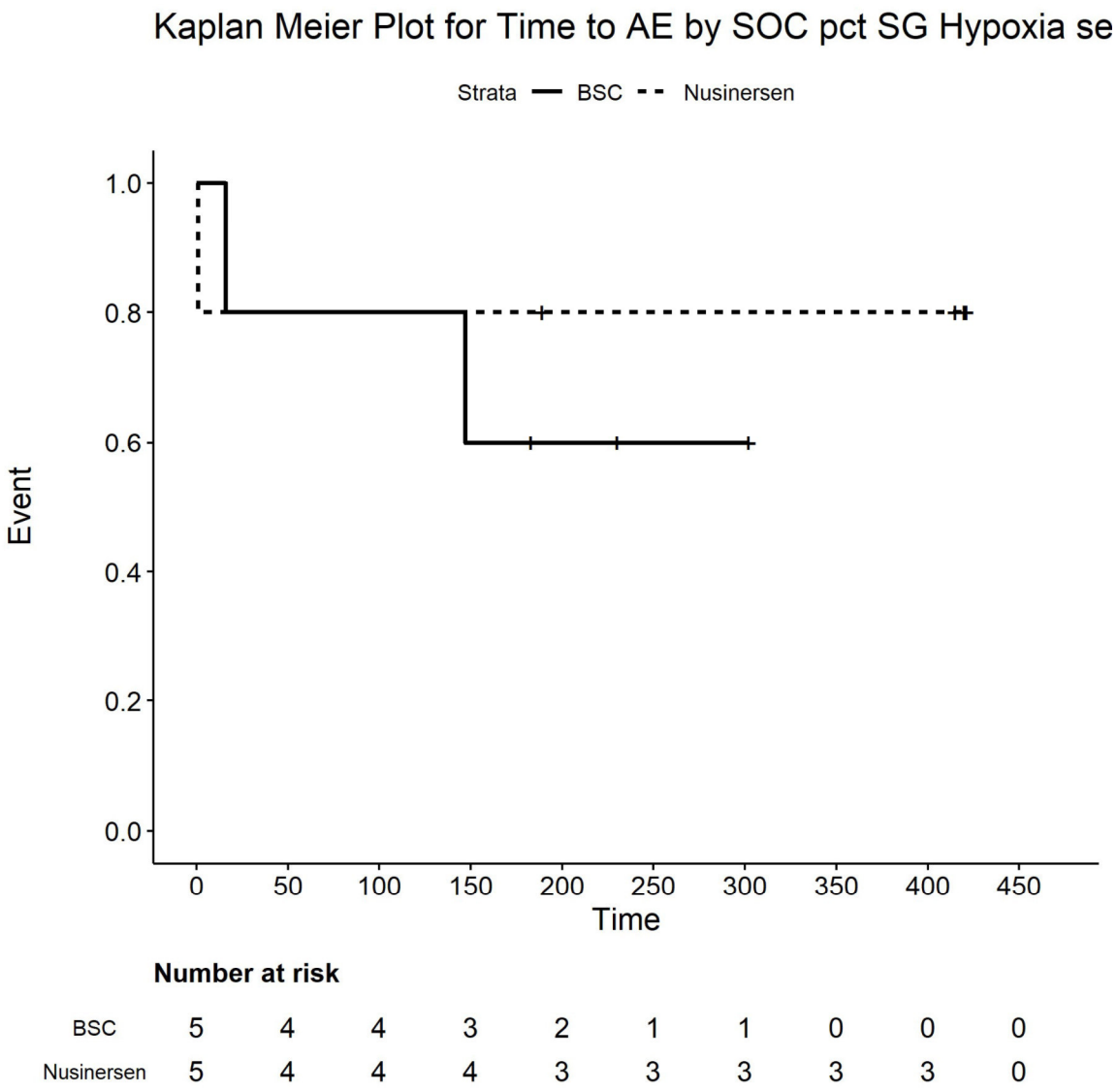
Number at risk

BSC	4	3	3	2	1	1	1	1	0	0
Nusinersen	9	8	8	8	6	6	6	5	4	0



Number at risk

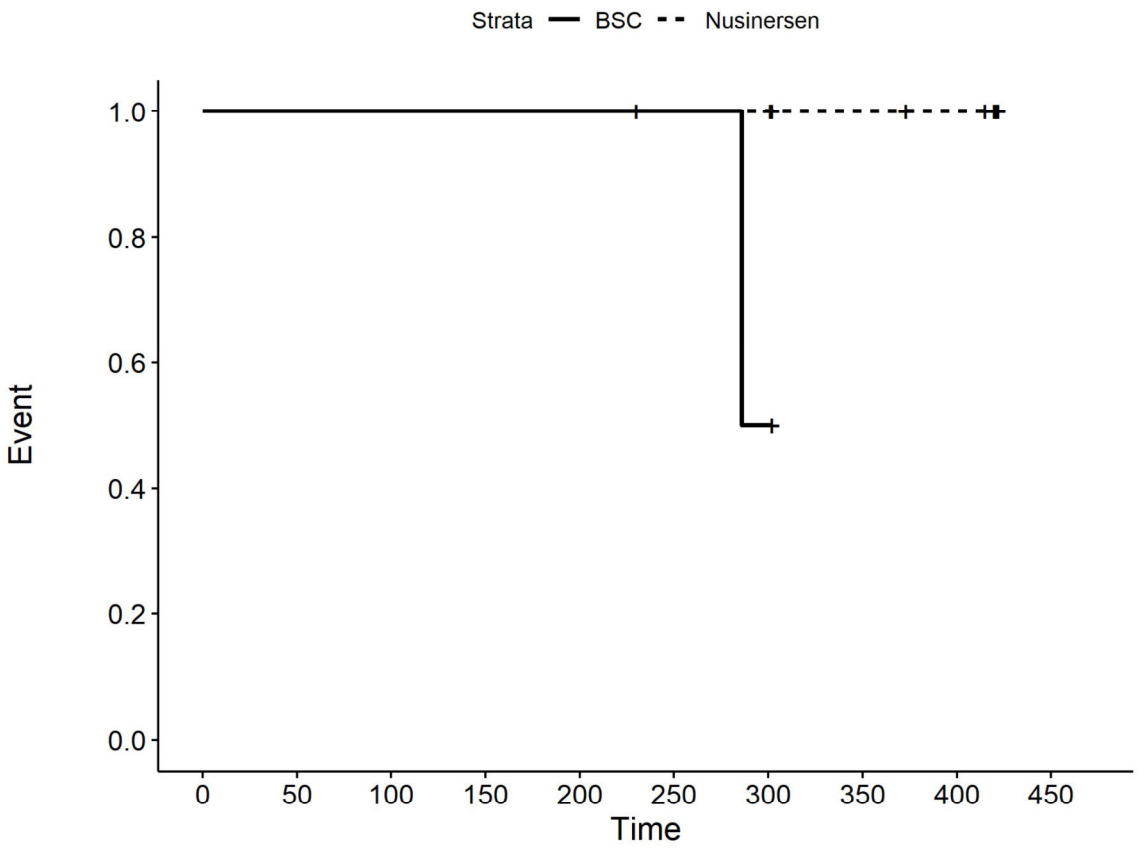
BSC	6	5	5	4	3	3	3	2	0	0
Nusinersen	10	9	9	9	9	9	9	7	6	0



Number at risk

BSC	5	4	4	3	2	1	1	0	0	0
Nusinersen	5	4	4	4	3	3	3	3	3	0

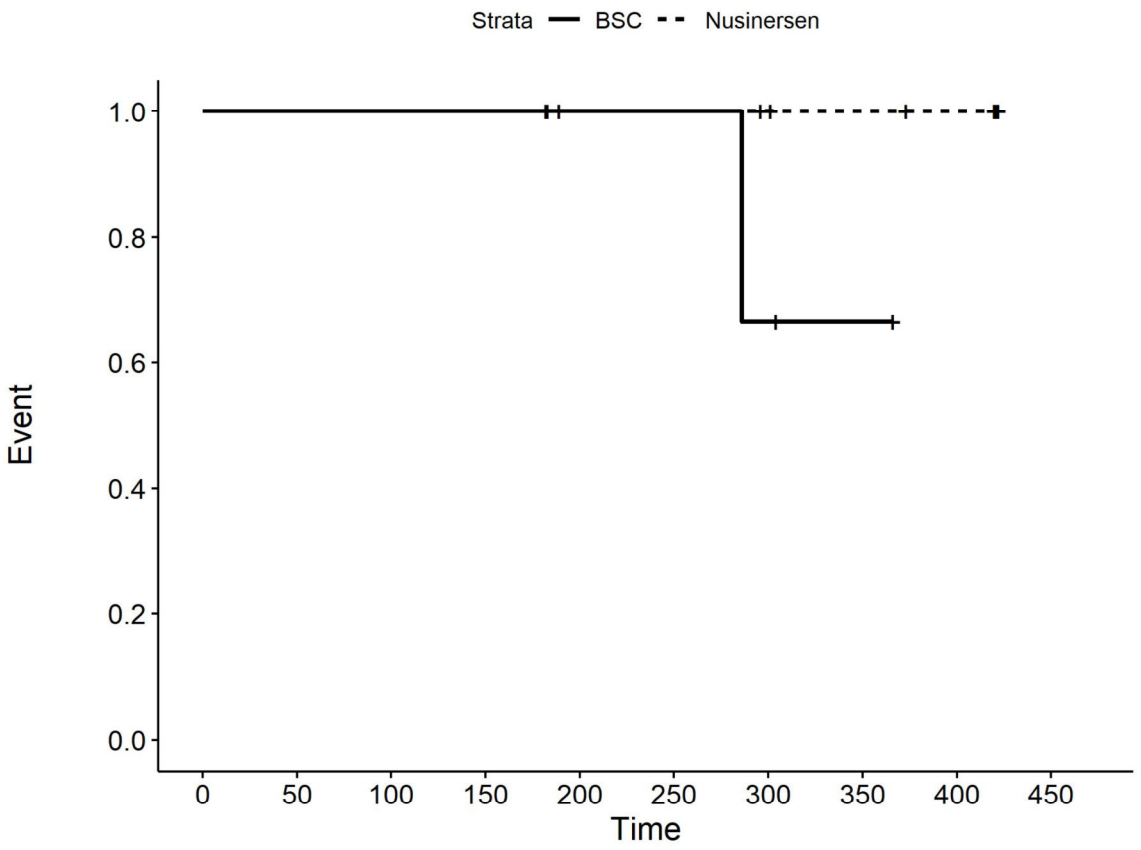
Kaplan Meier Plot for
Time to AE by SOC pct SG Hypoxic : ischaemic encephalopa



Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0

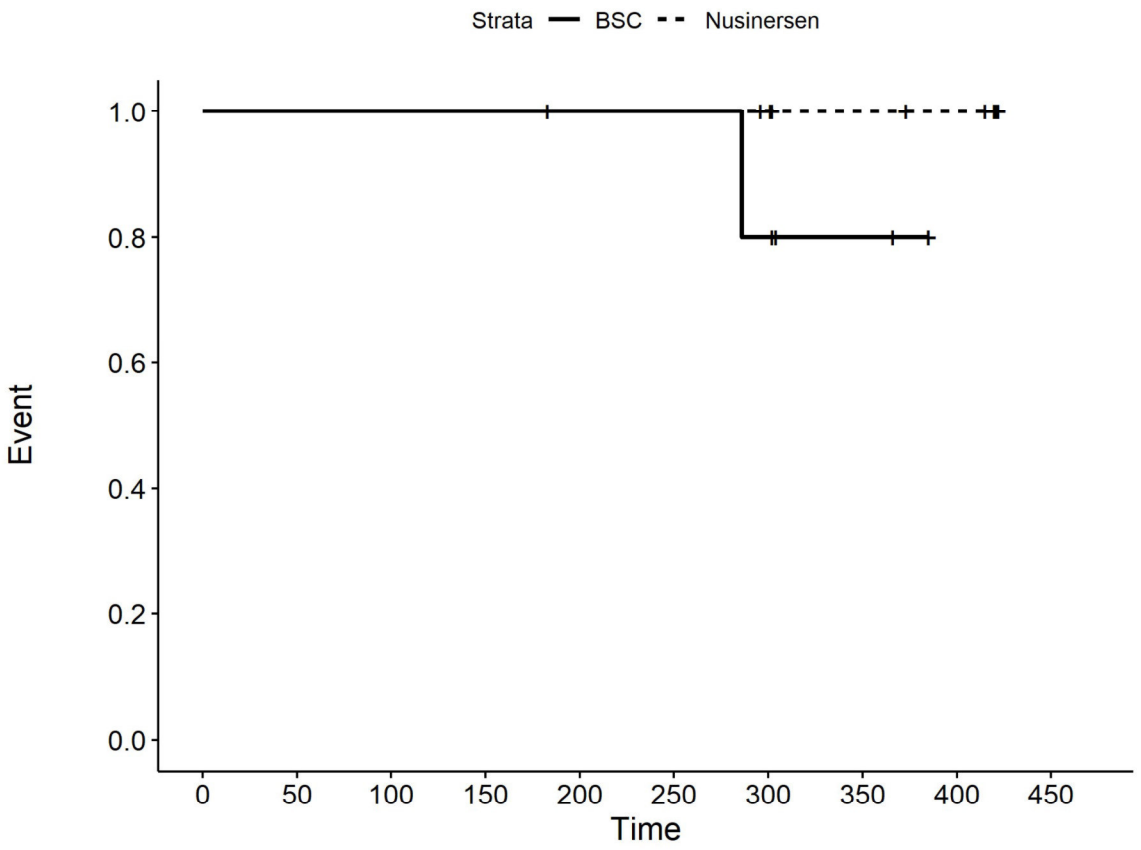
Kaplan Meier Plot for
Time to AE by SOC pct SG Hypoxic : ischaemic encephalopa



Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0

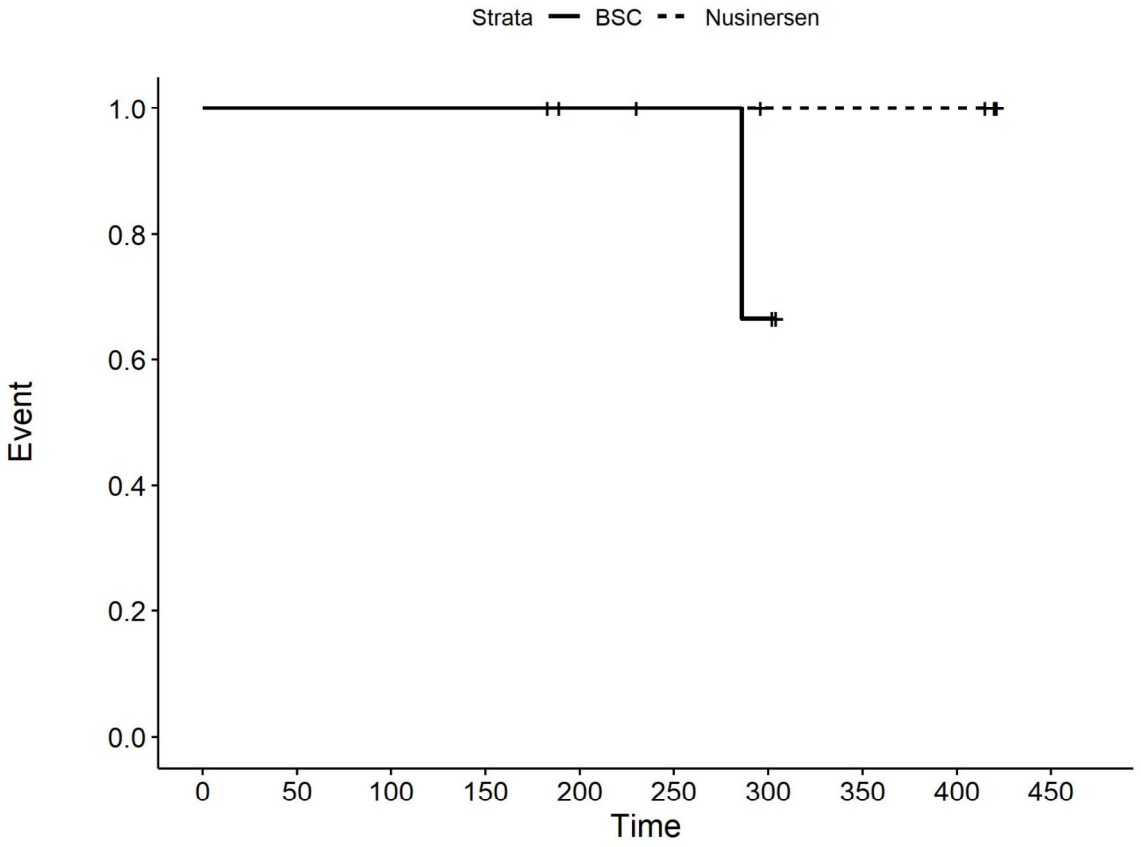
Kaplan Meier Plot for
Time to AE by SOC pct SG Hypoxic : ischaemic encephalopa



Number at risk

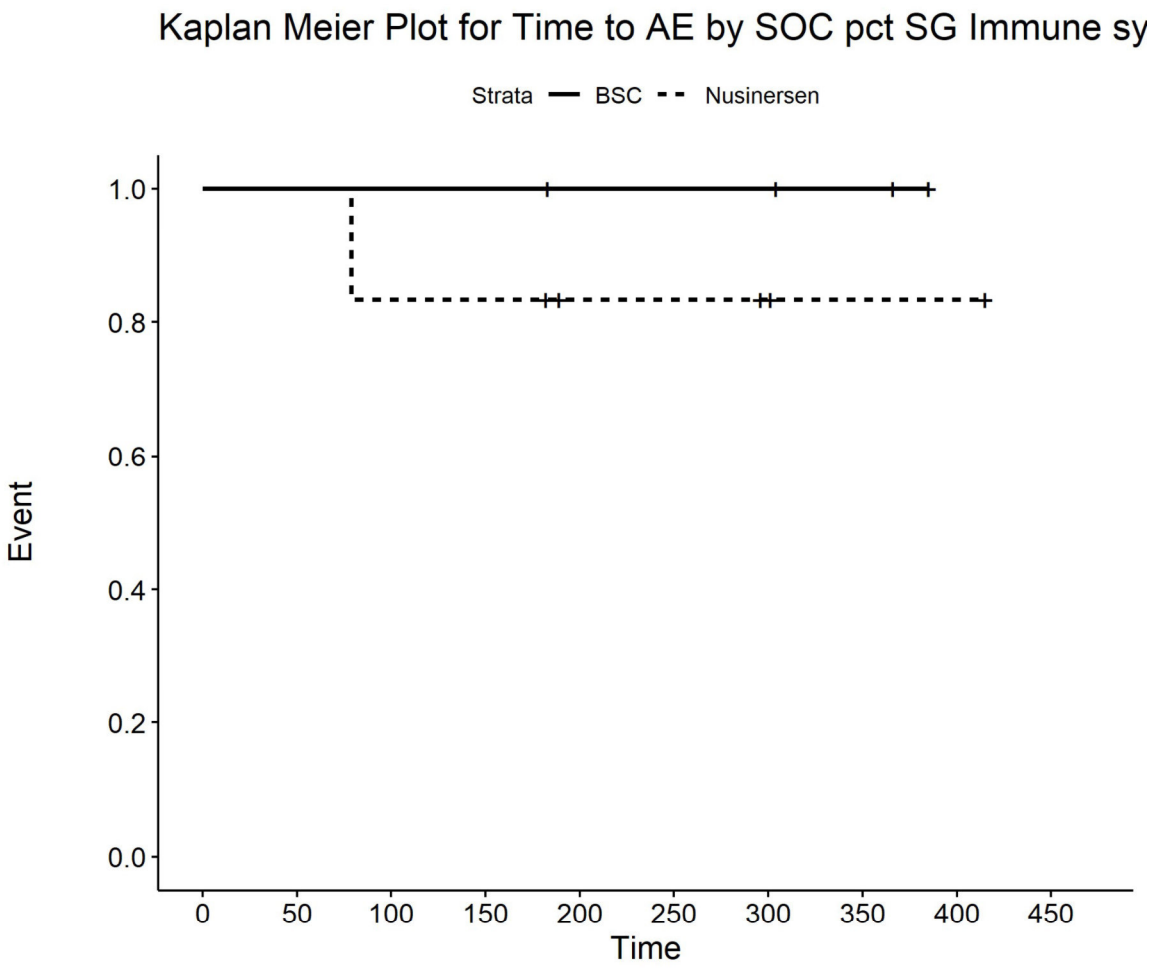
BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0

Kaplan Meier Plot for
Time to AE by SOC pct SG Hypoxic : ischaemic encephalopa



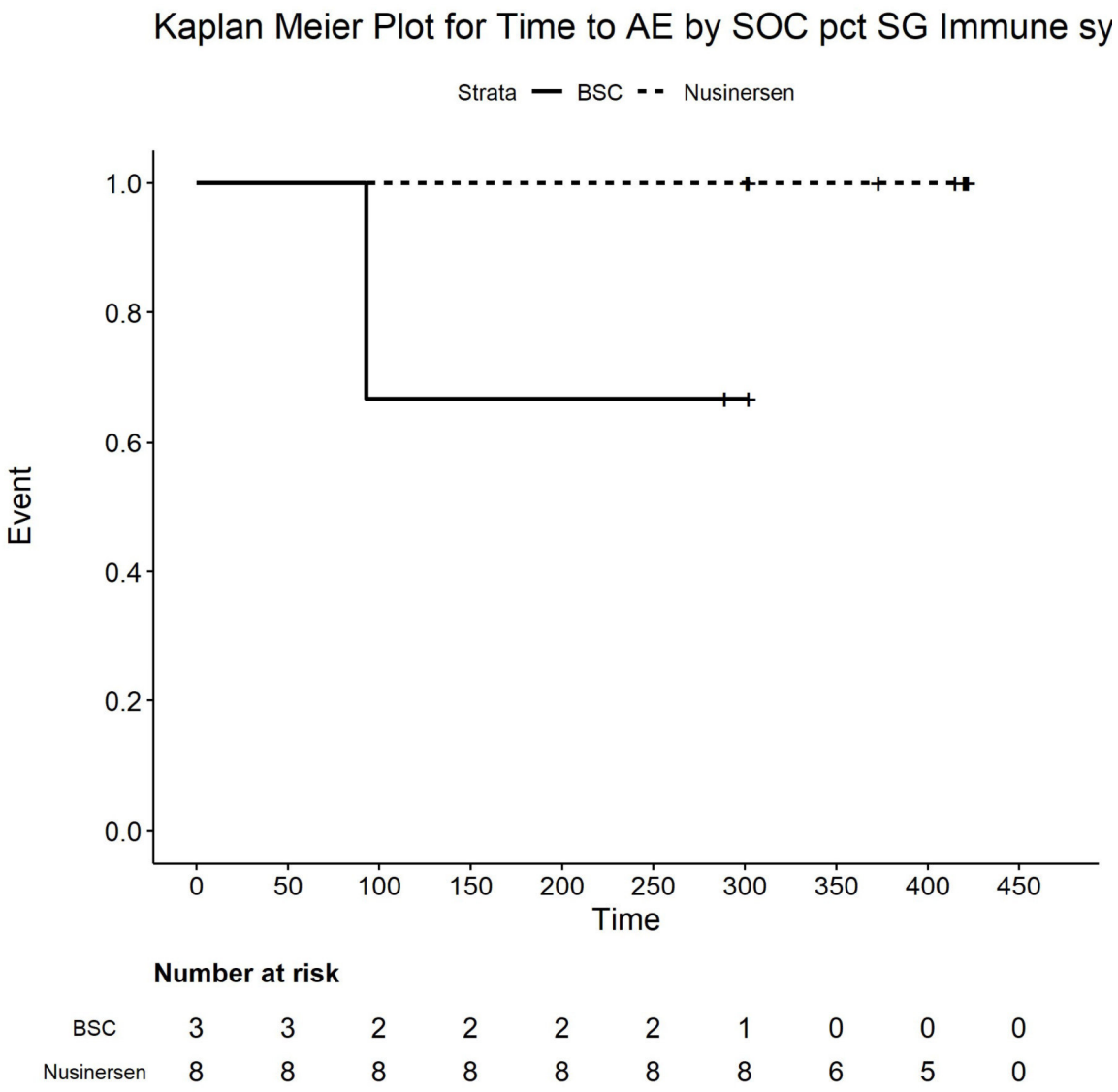
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



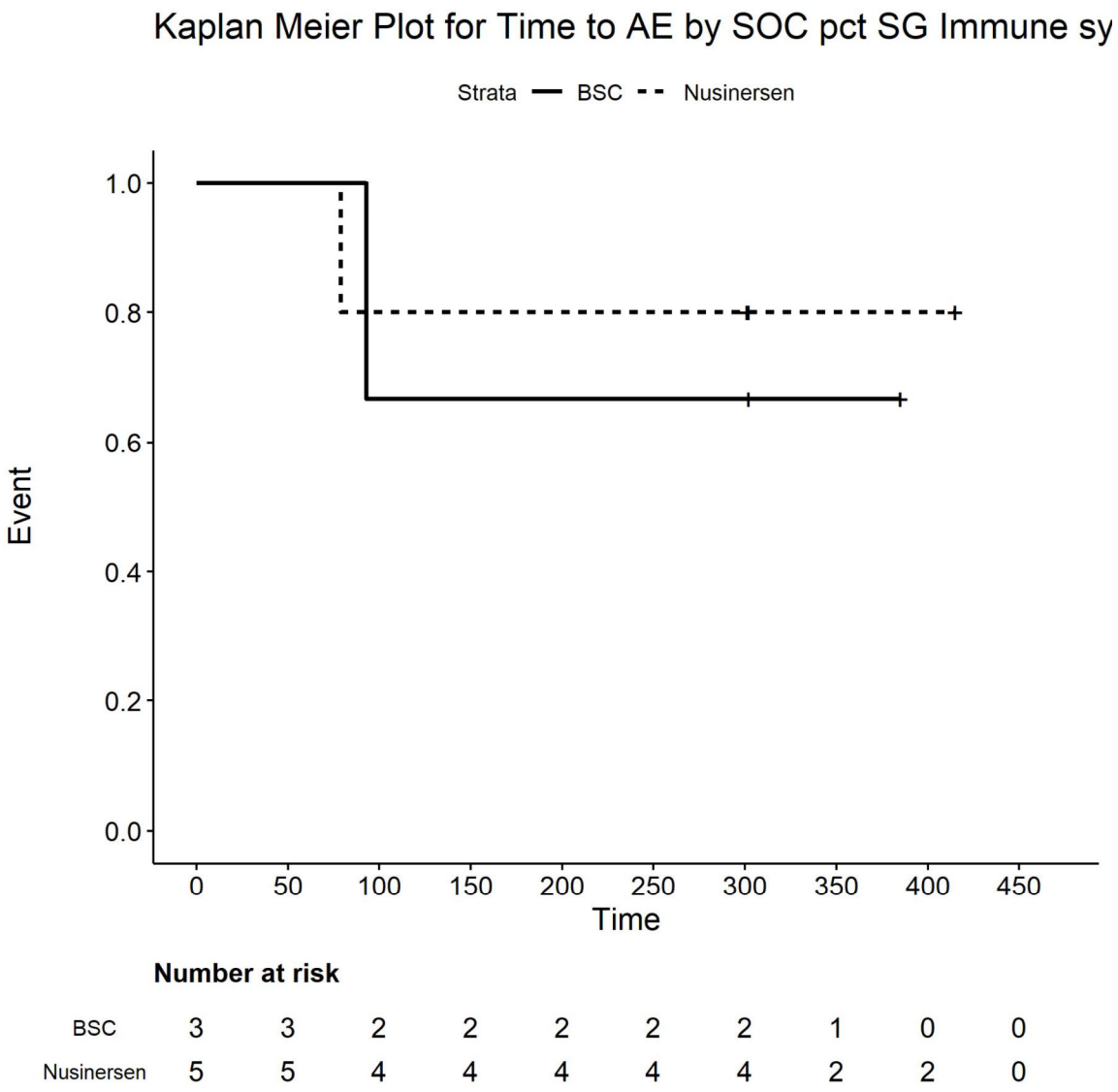
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



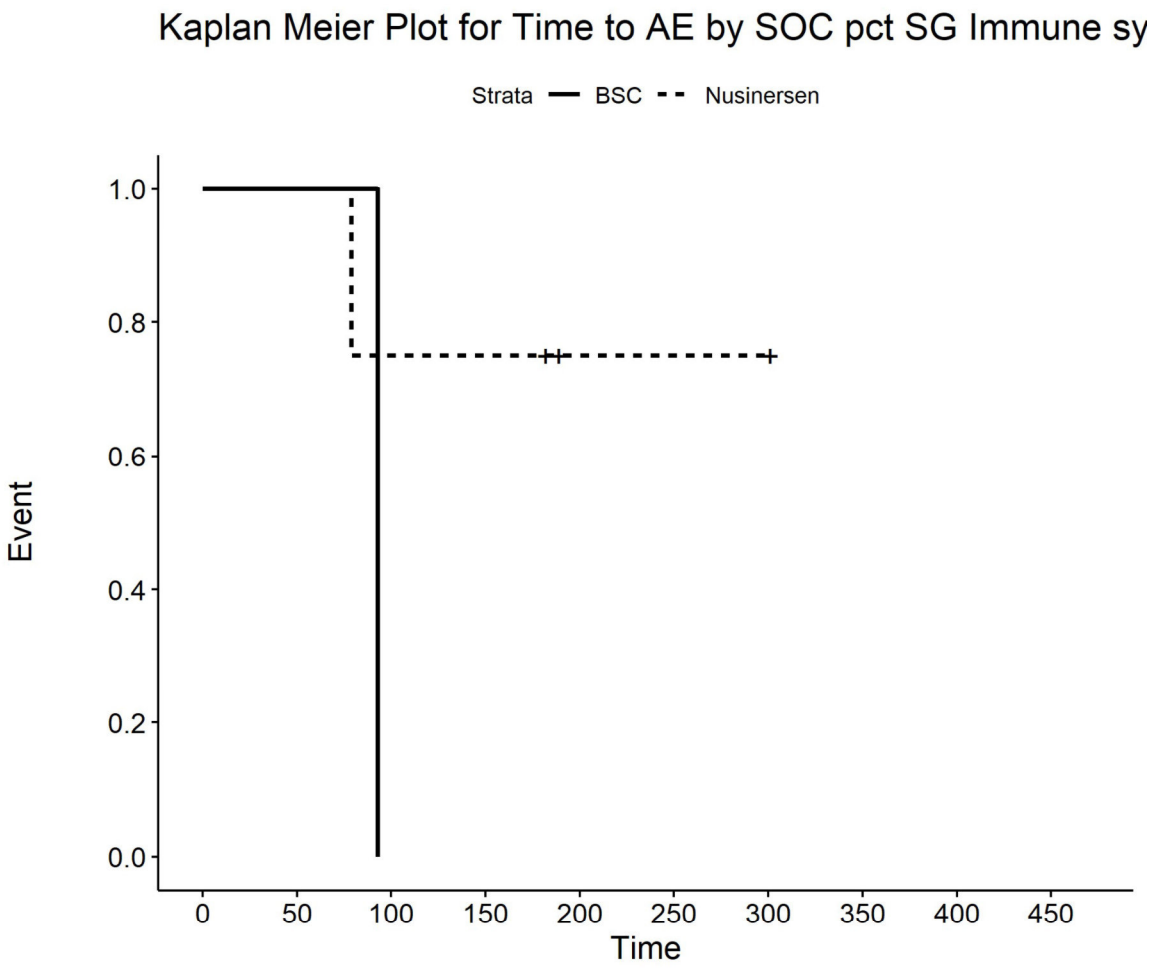
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



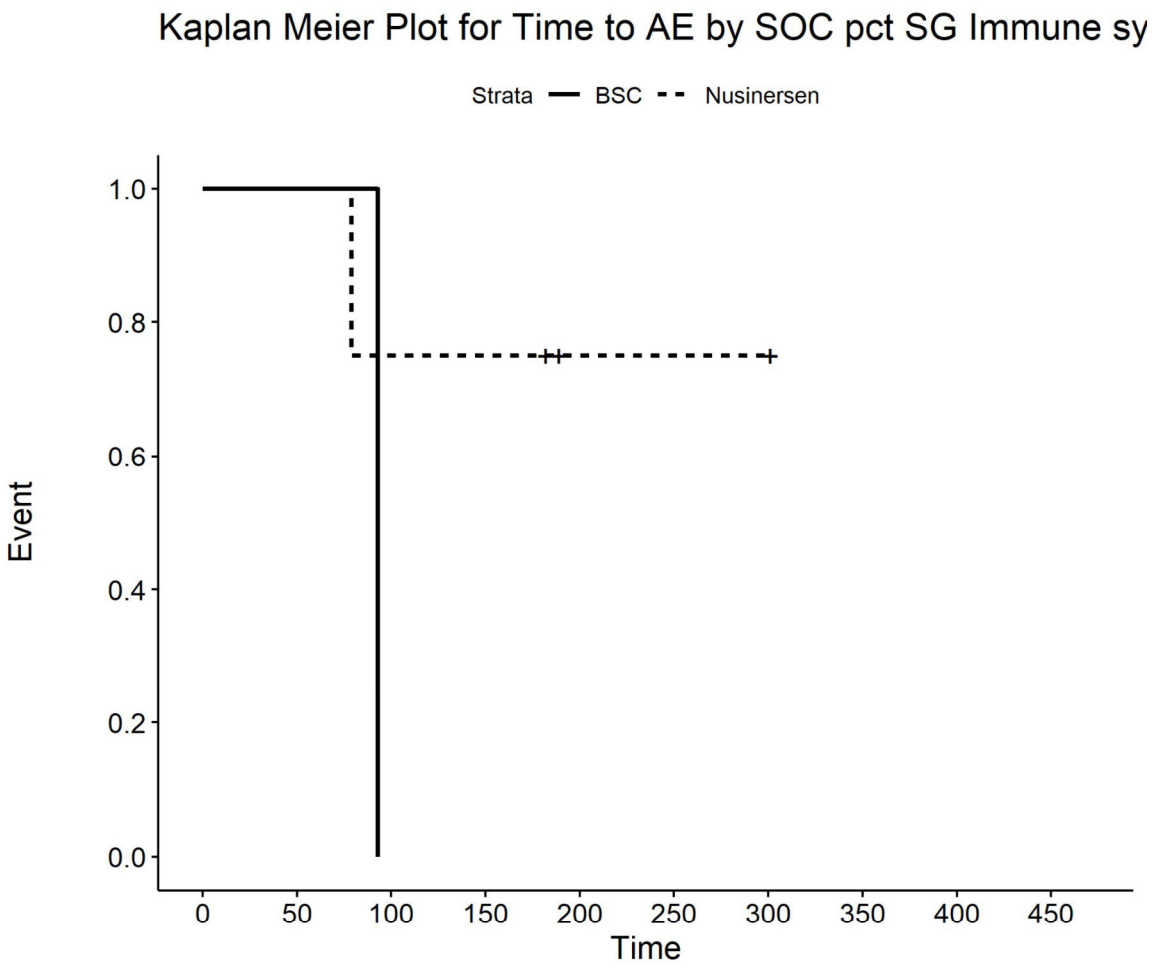
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



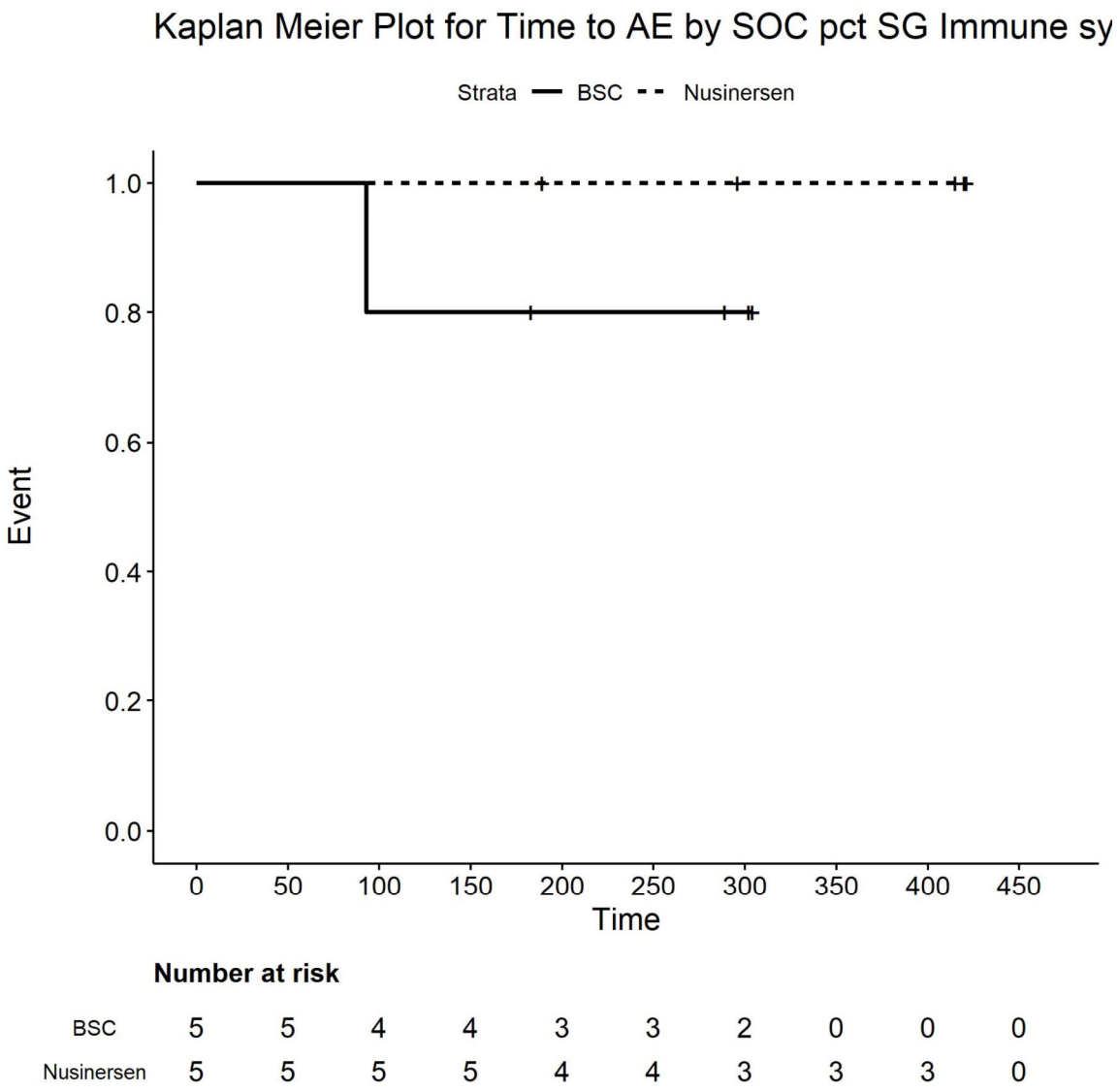
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



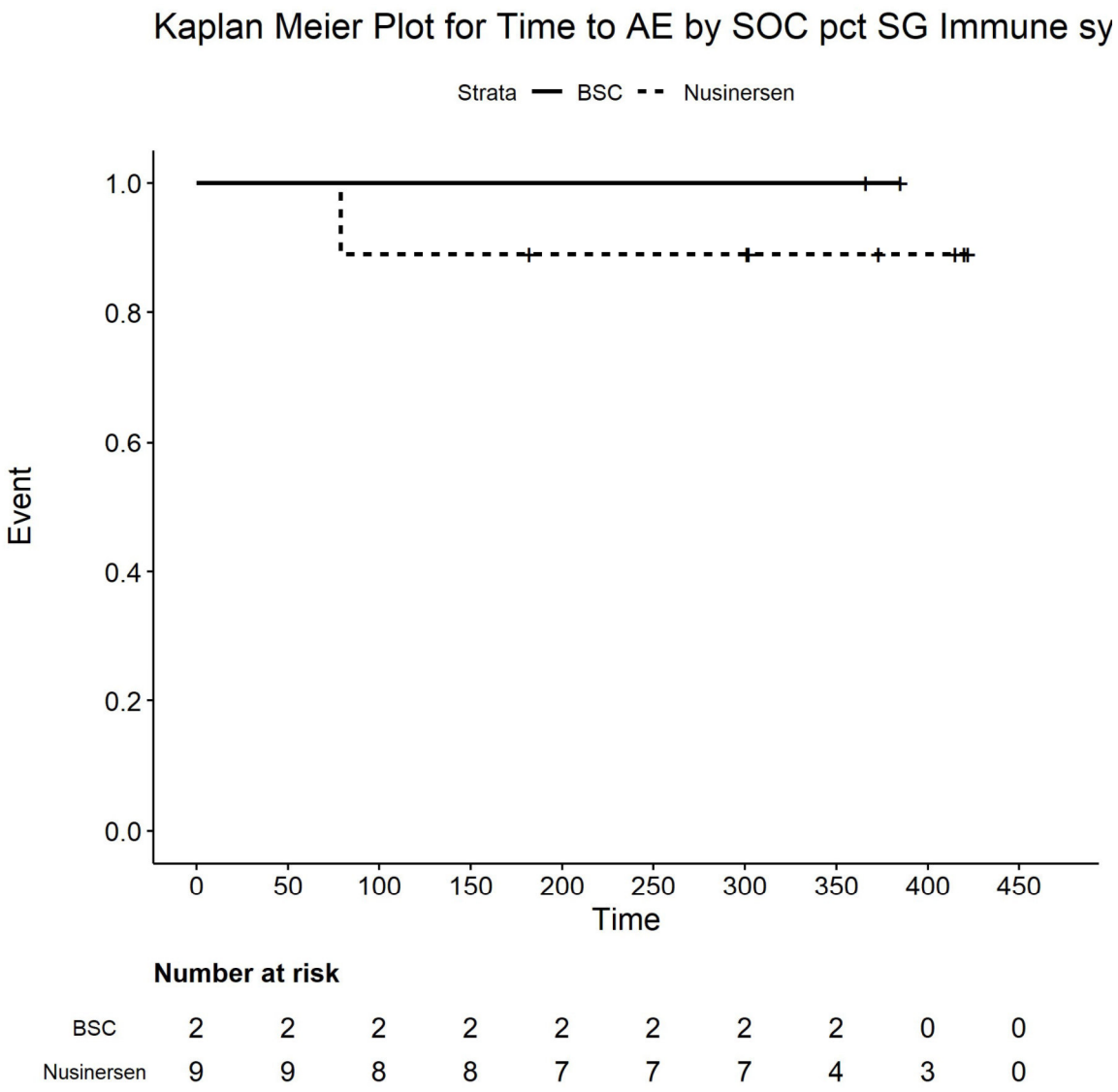
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



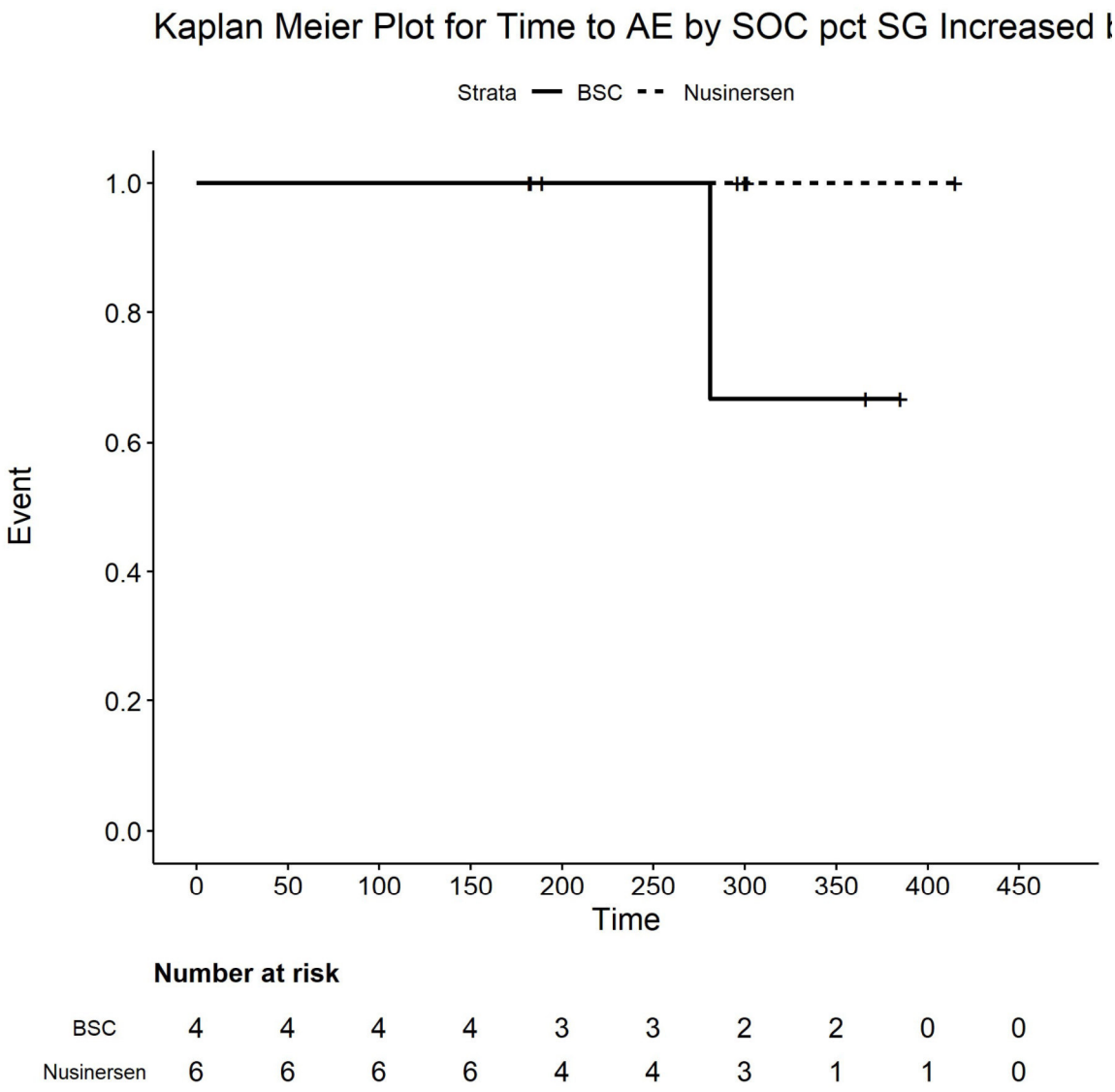
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



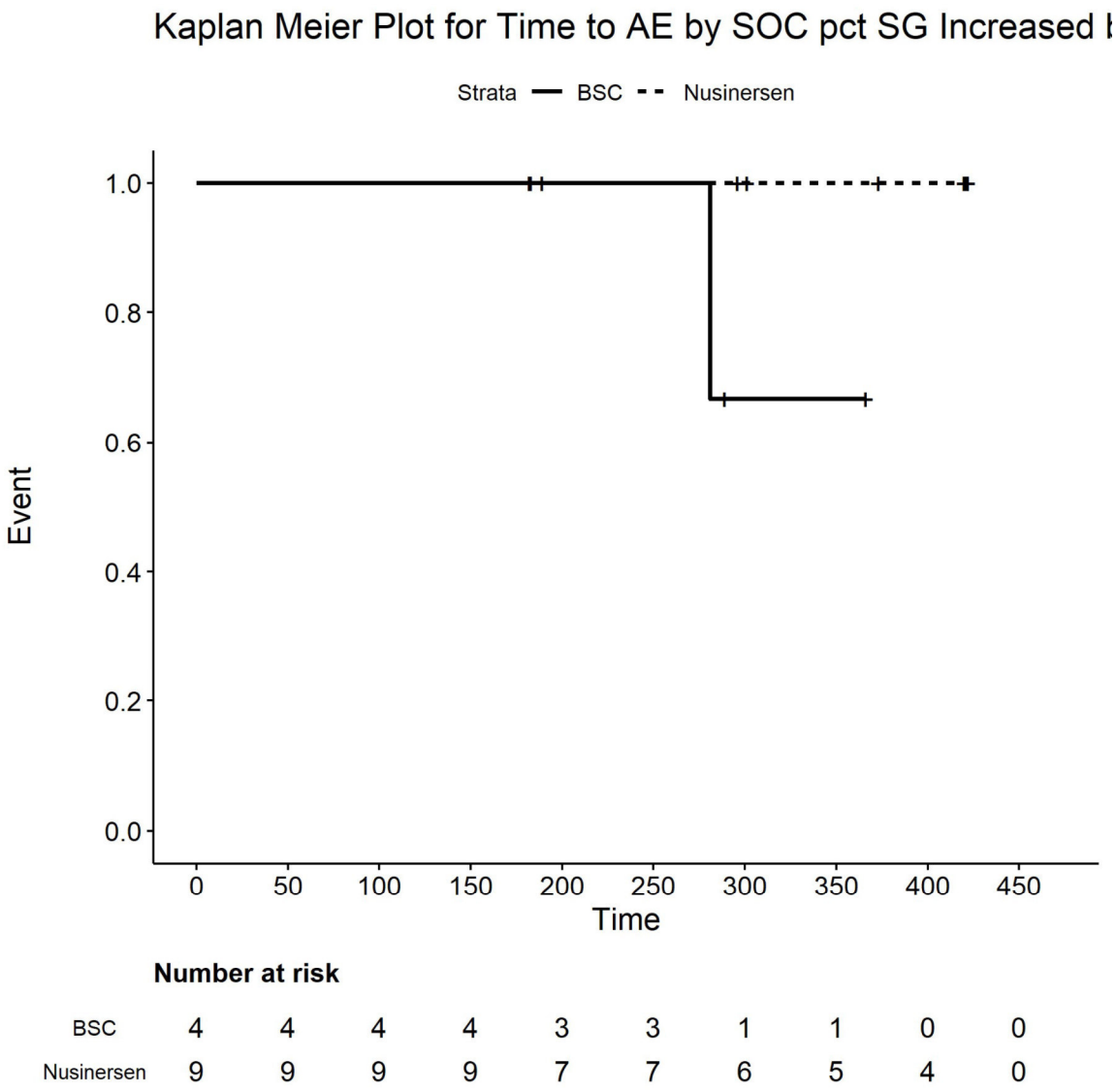
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



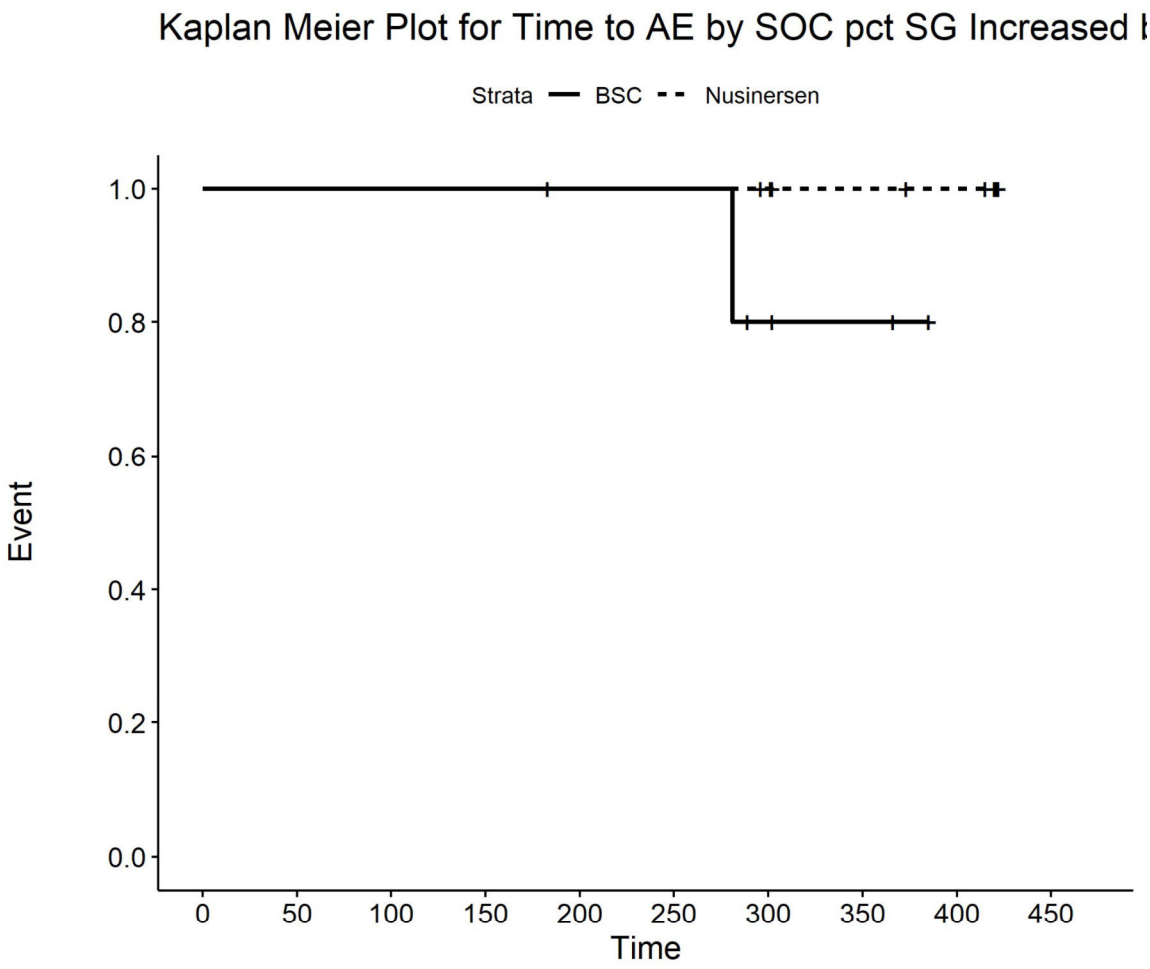
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



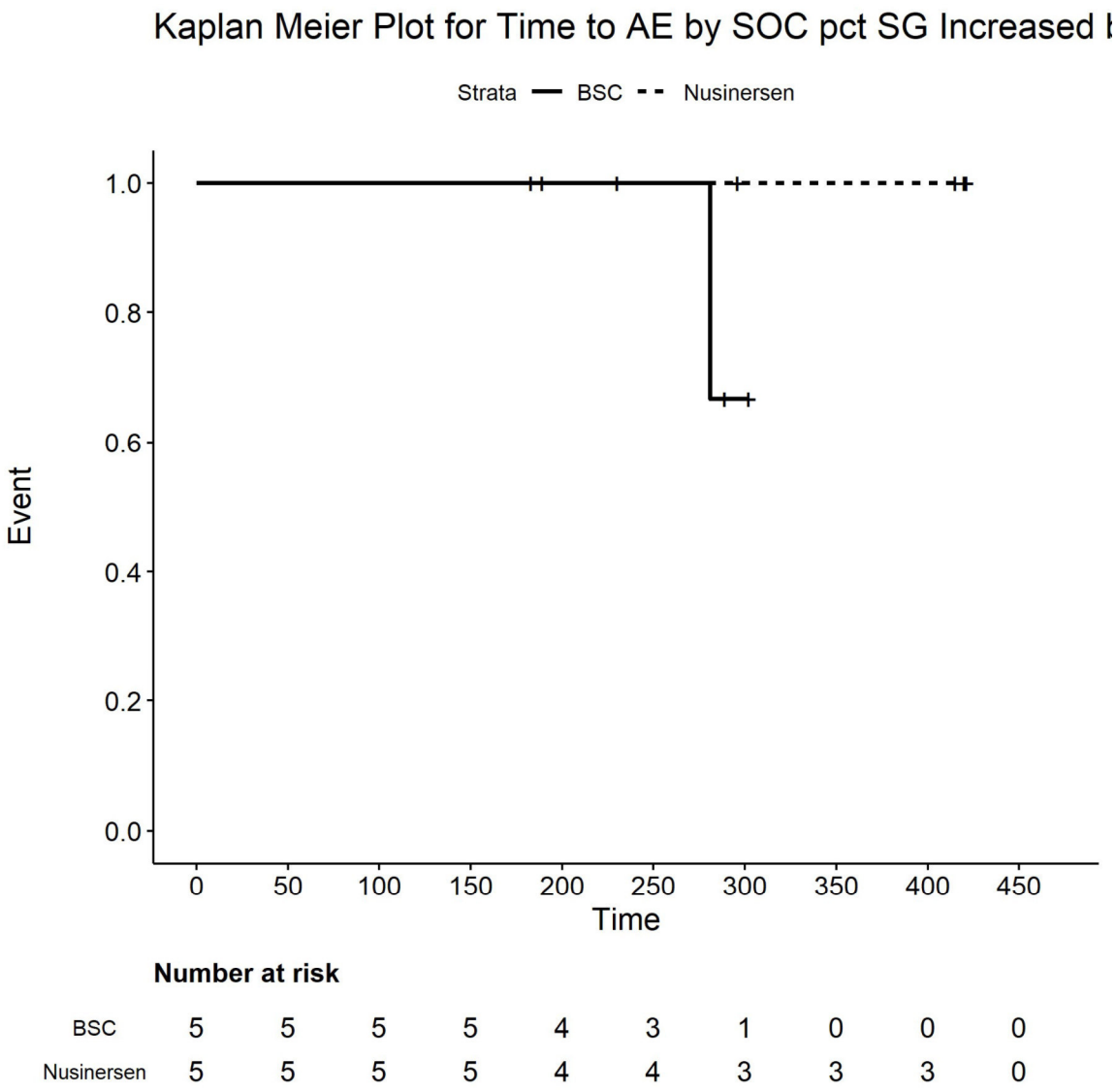
Number at risk

BSC	4	4	4	4	3	3	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



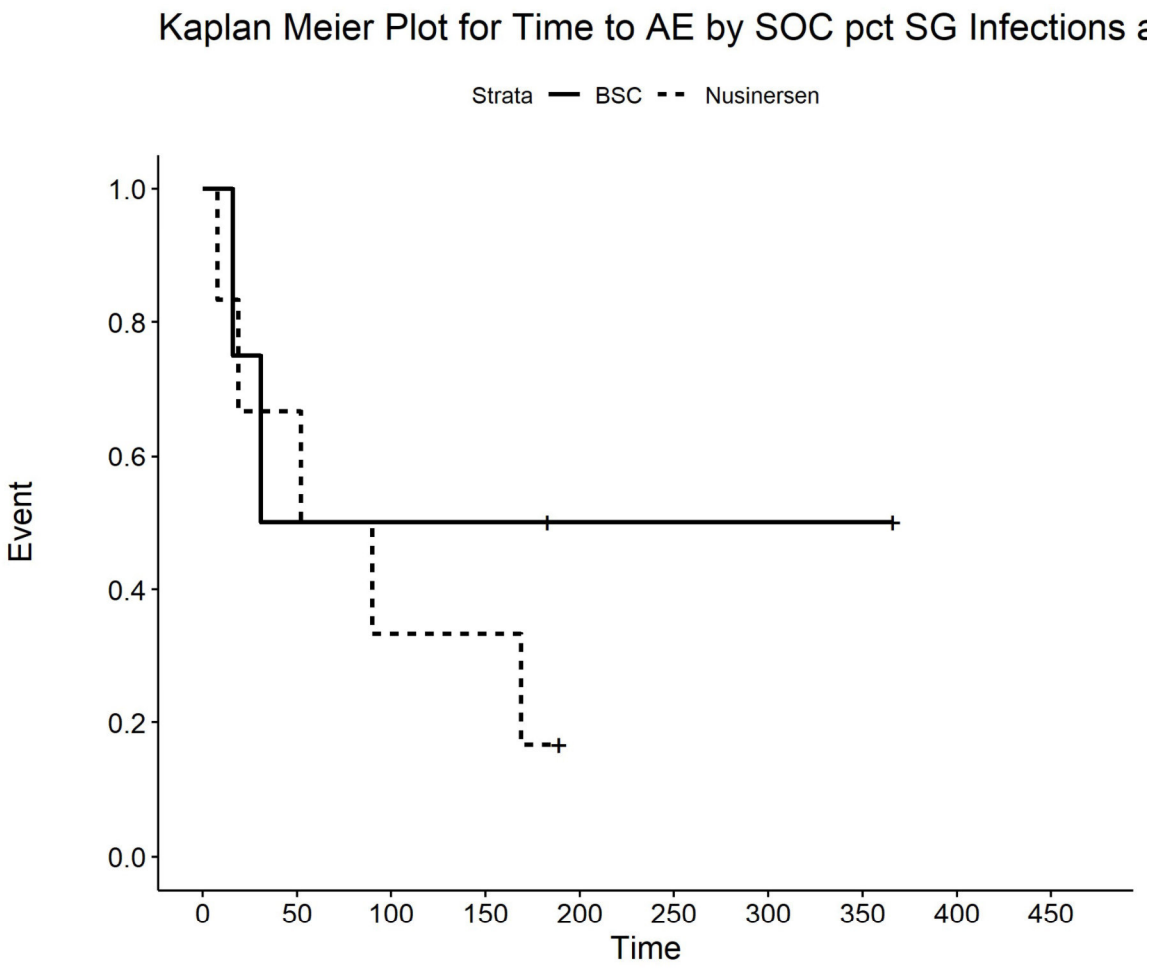
Number at risk

BSC	6	6	6	6	5	5	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



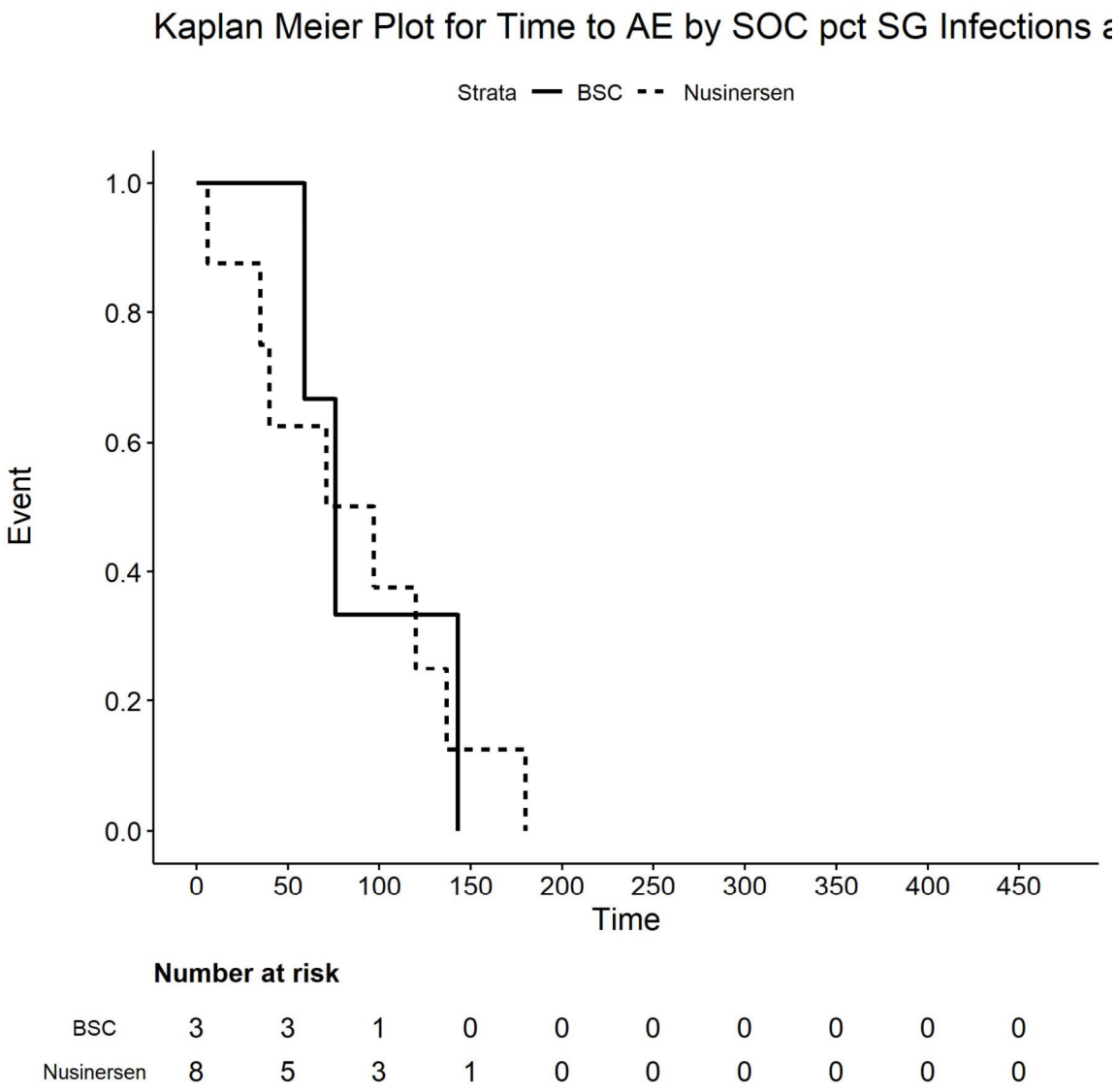
Number at risk

BSC	5	5	5	5	4	3	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



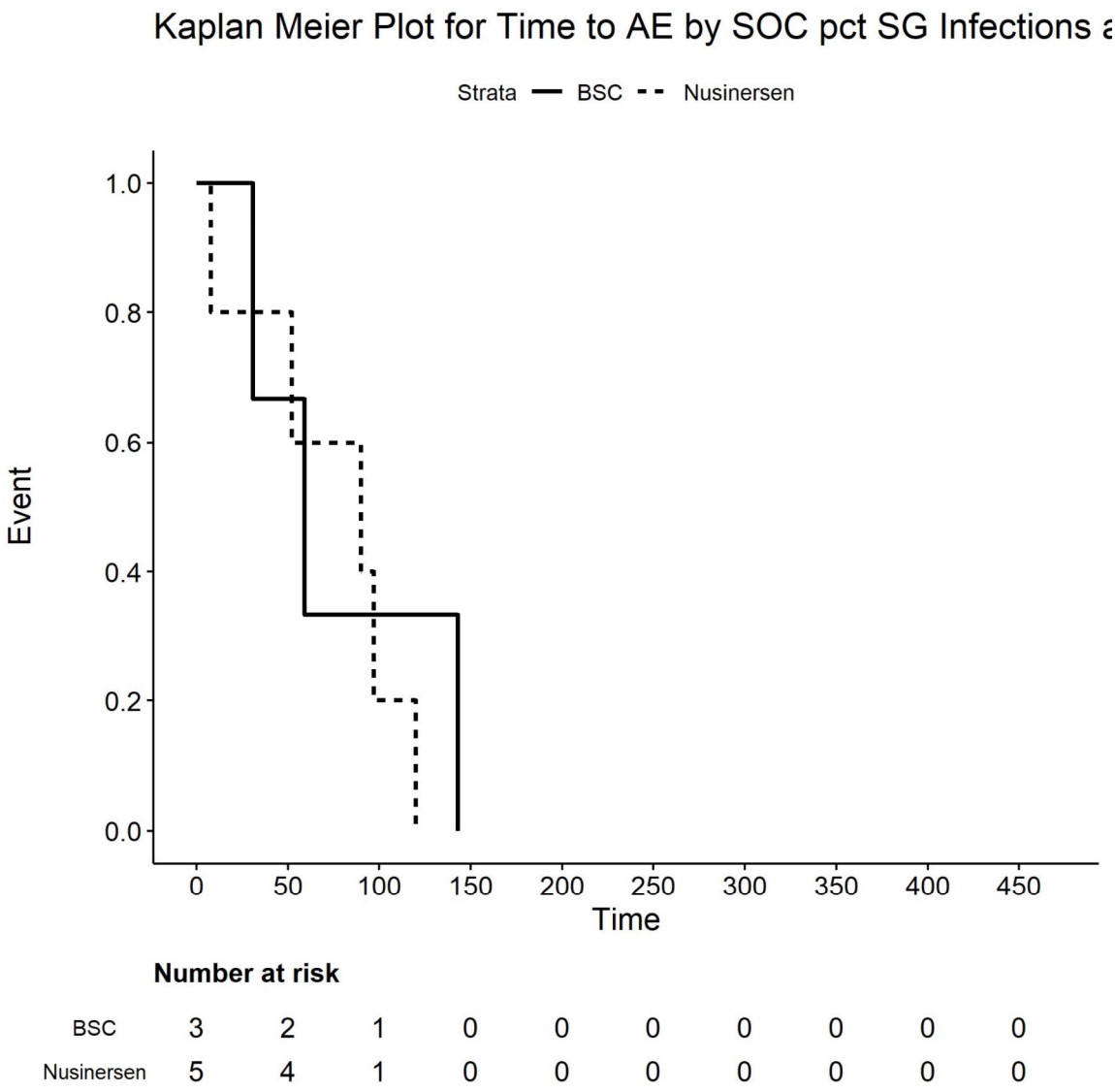
Number at risk

BSC	4	2	2	2	1	1	1	1	0	0
Nusinersen	6	4	2	2	0	0	0	0	0	0



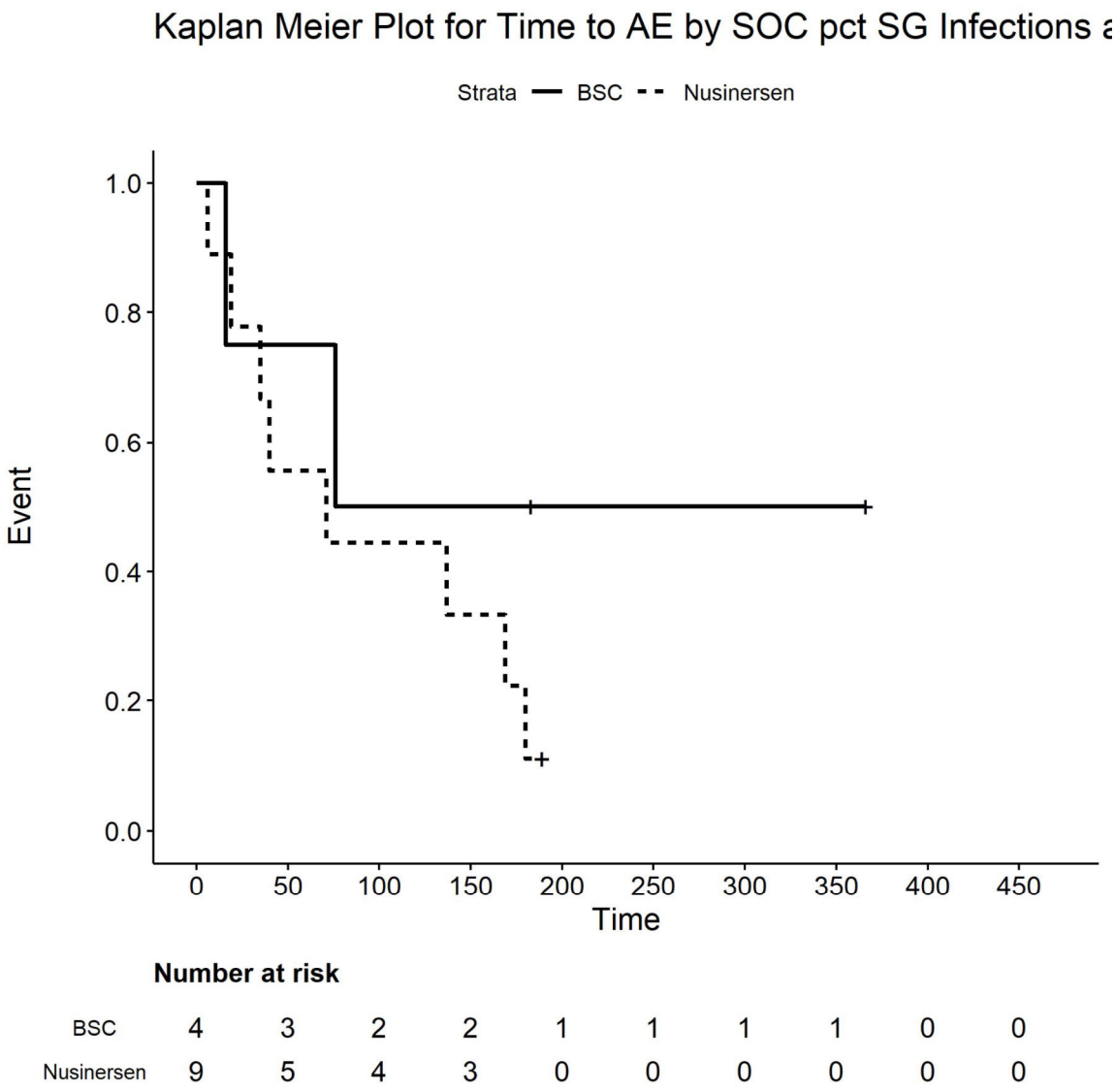
Number at risk

BSC	3	3	1	0	0	0	0	0	0	0
Nusinersen	8	5	3	1	0	0	0	0	0	0



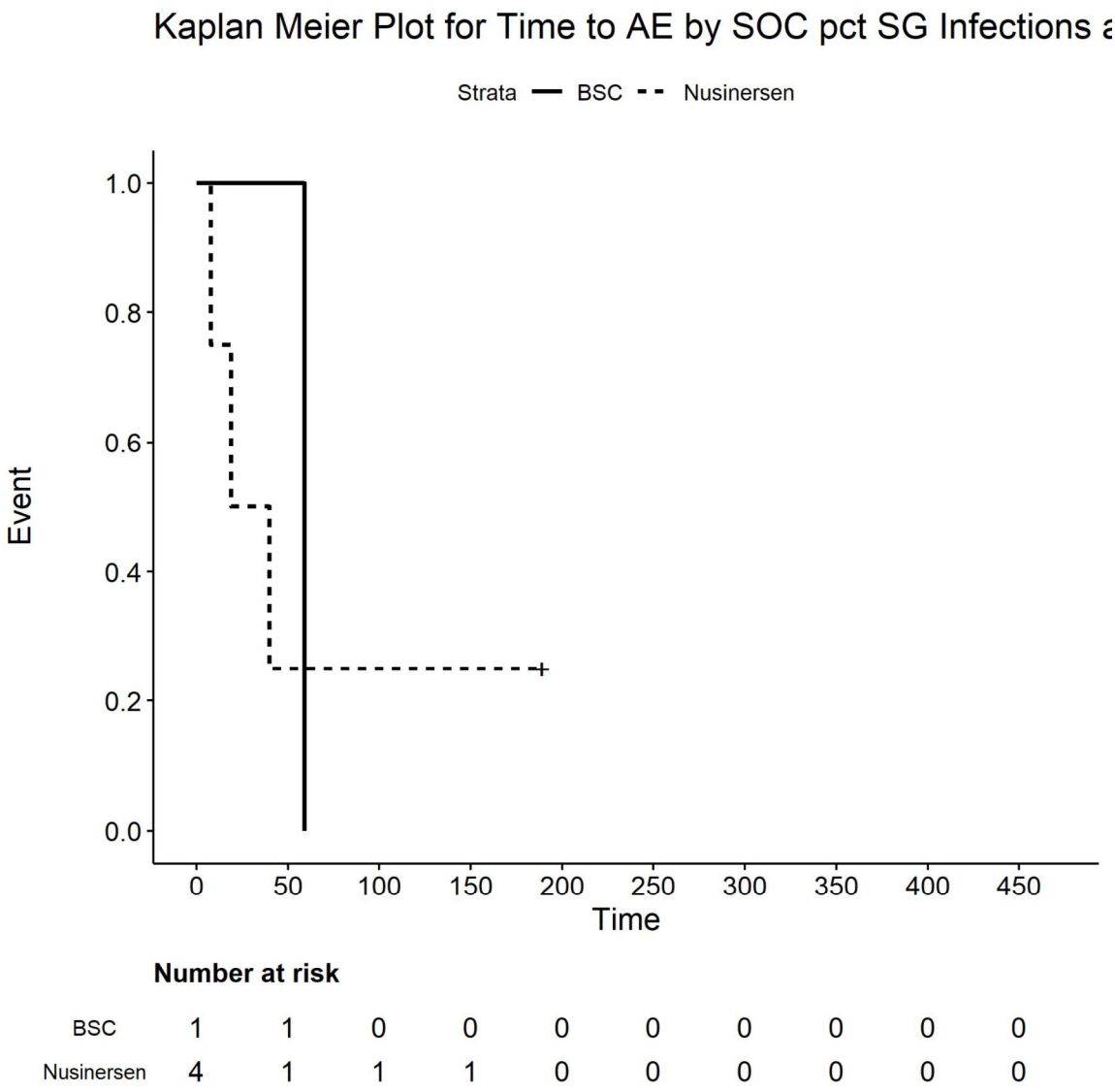
Number at risk

BSC	3	2	1	0	0	0	0	0	0	0
Nusinersen	5	4	1	0	0	0	0	0	0	0



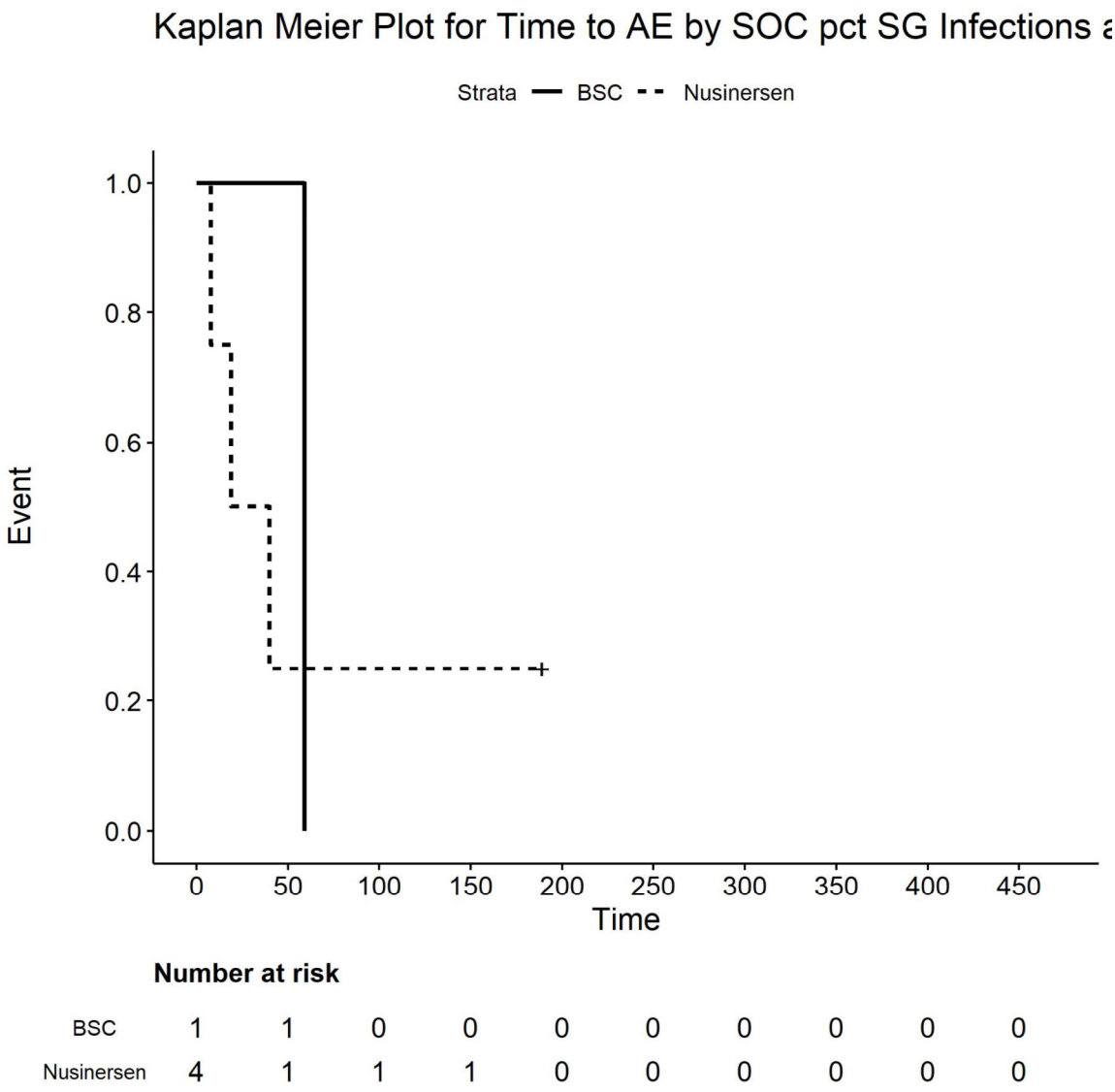
Number at risk

BSC	4	3	2	2	1	1	1	1	0	0
Nusinersen	9	5	4	3	0	0	0	0	0	0



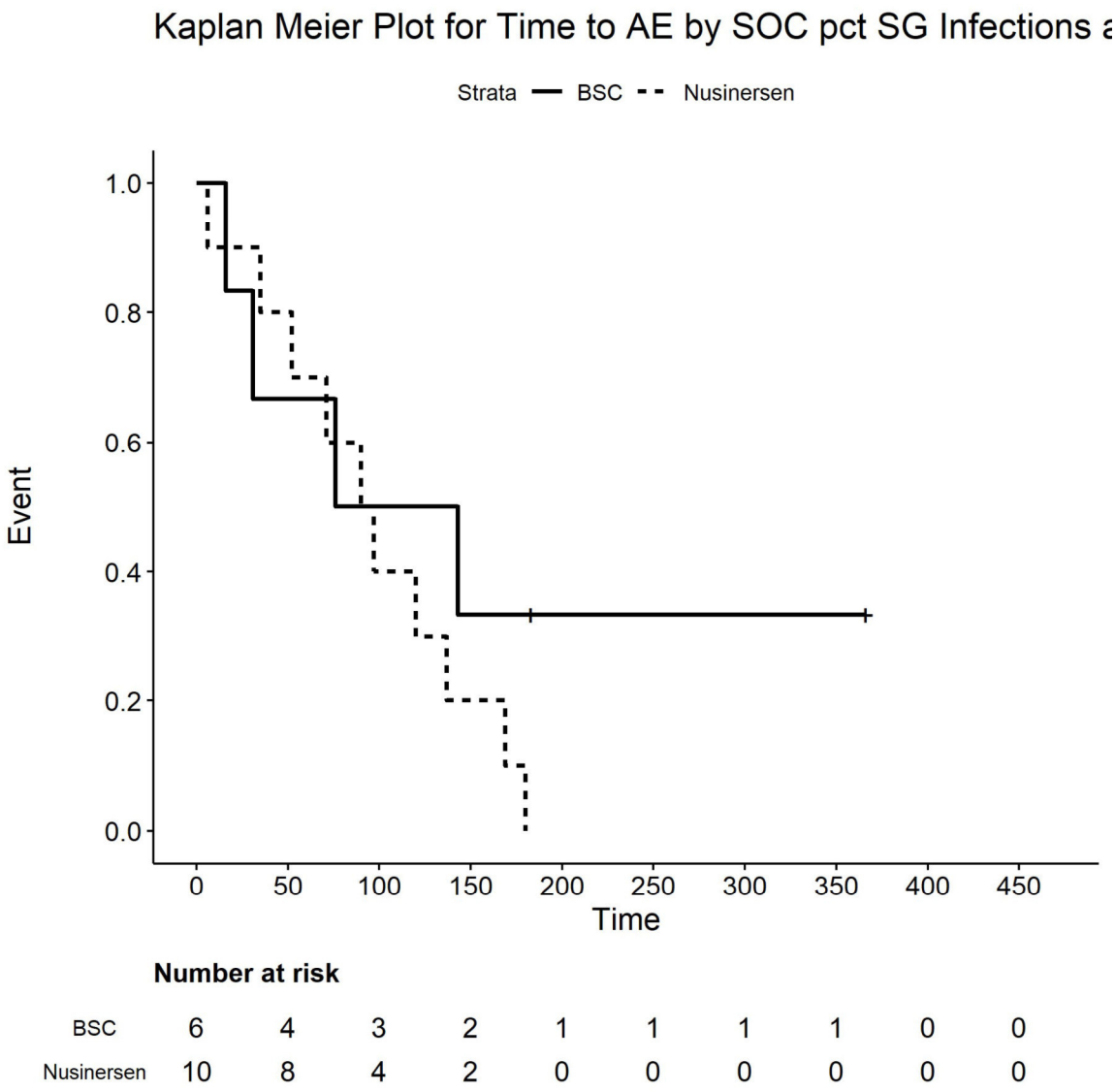
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	1	1	1	0	0	0	0	0	0



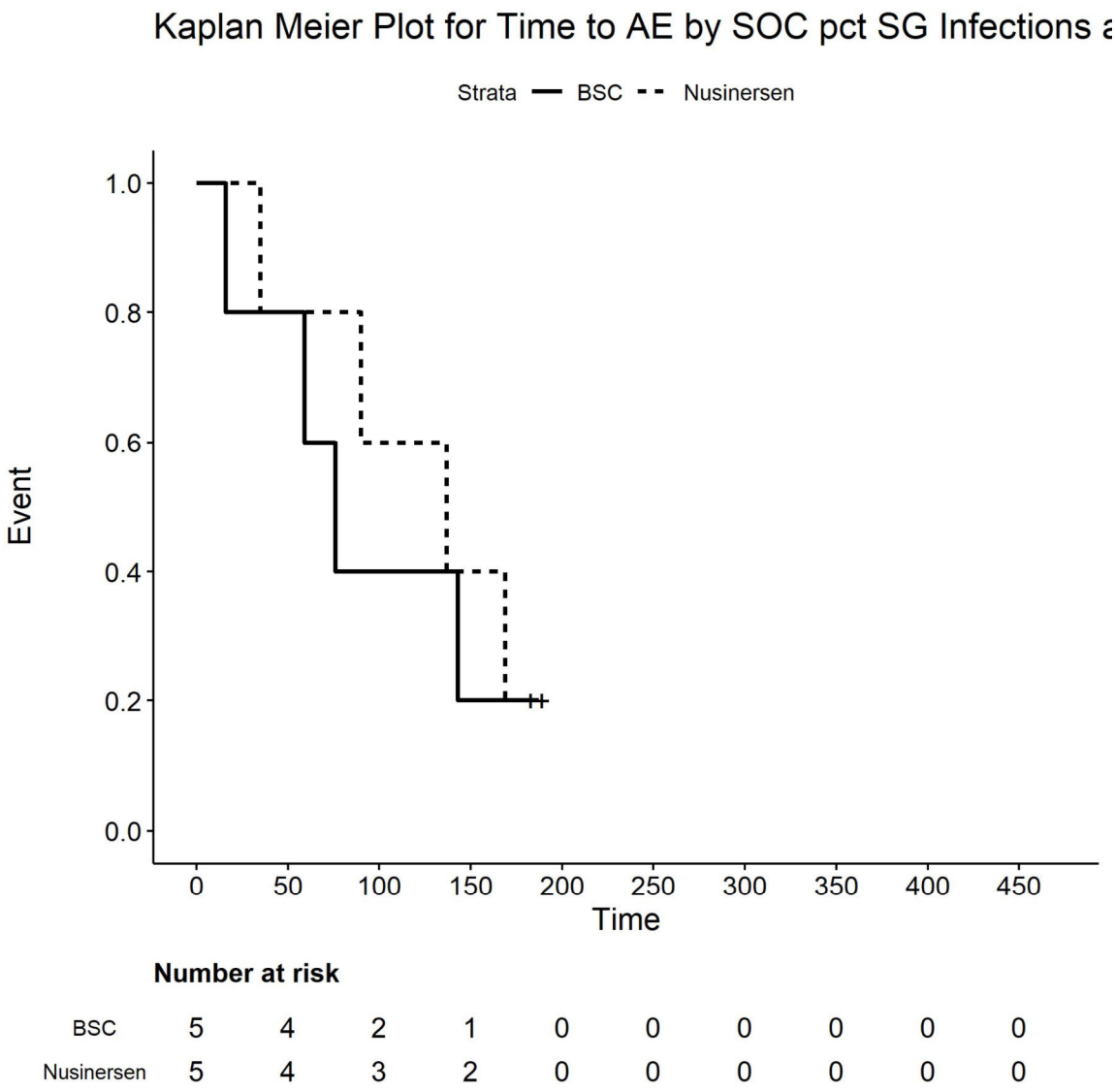
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	1	1	1	0	0	0	0	0	0



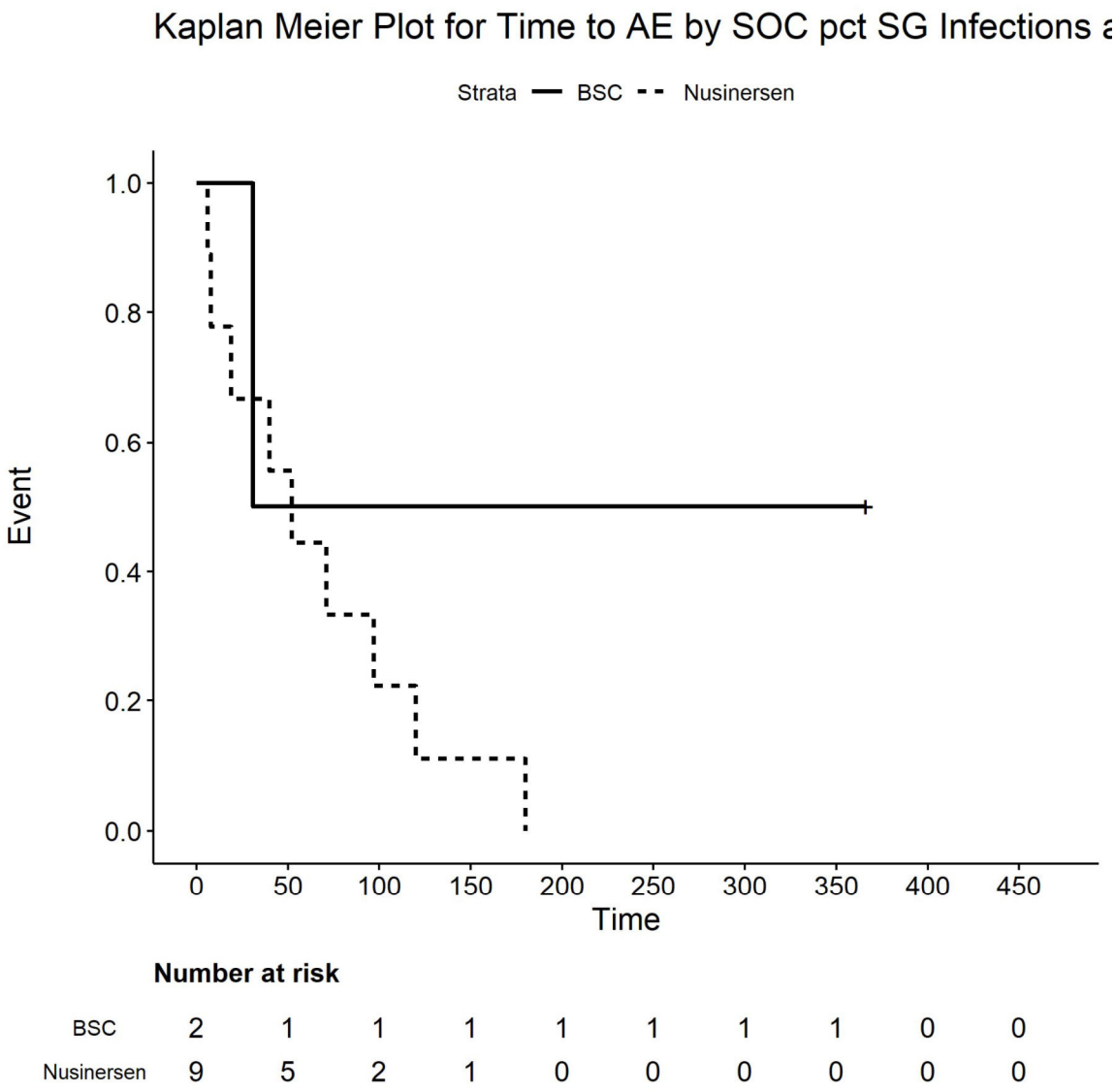
Number at risk

BSC	6	4	3	2	1	1	1	1	0	0
Nusinersen	10	8	4	2	0	0	0	0	0	0



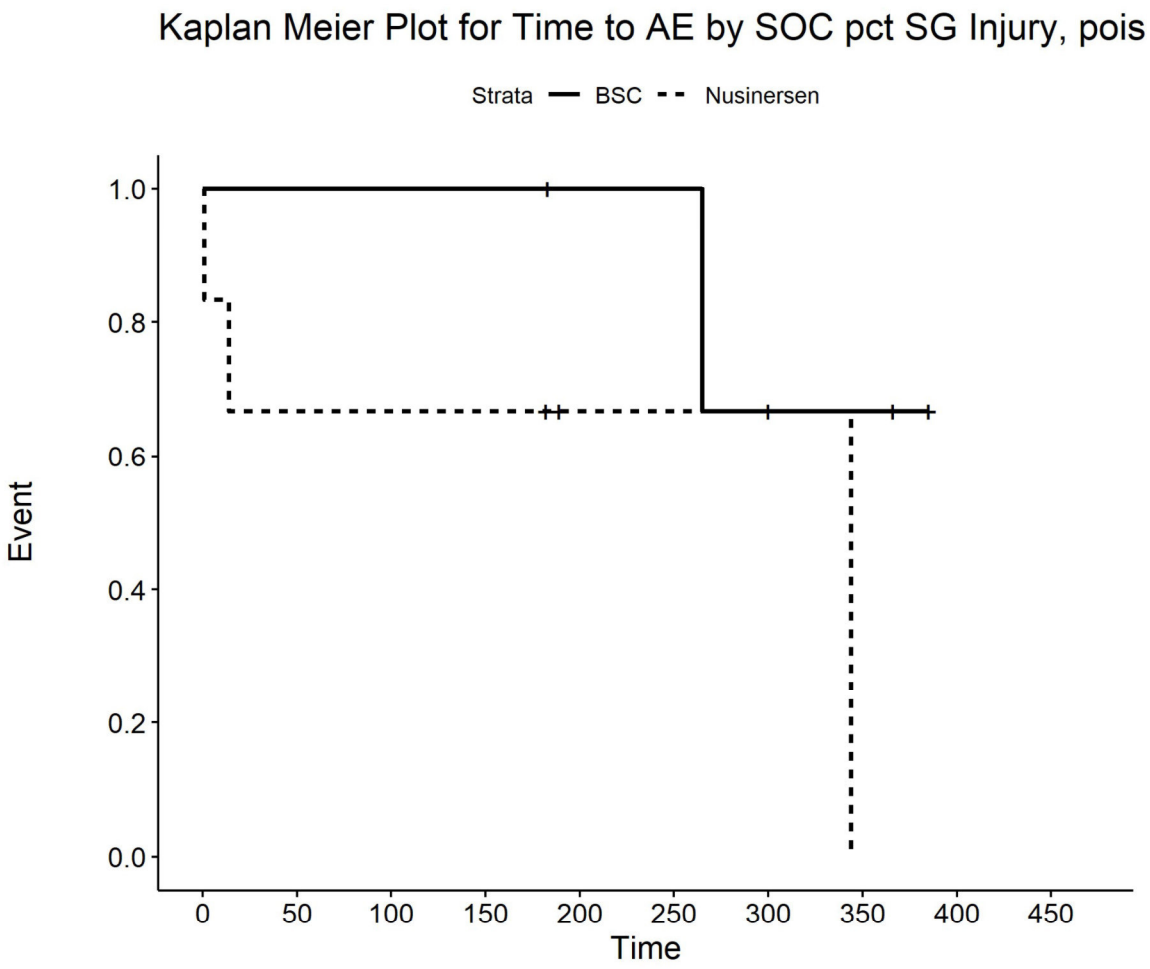
Number at risk

BSC	5	4	2	1	0	0	0	0	0	0
Nusinersen	5	4	3	2	0	0	0	0	0	0



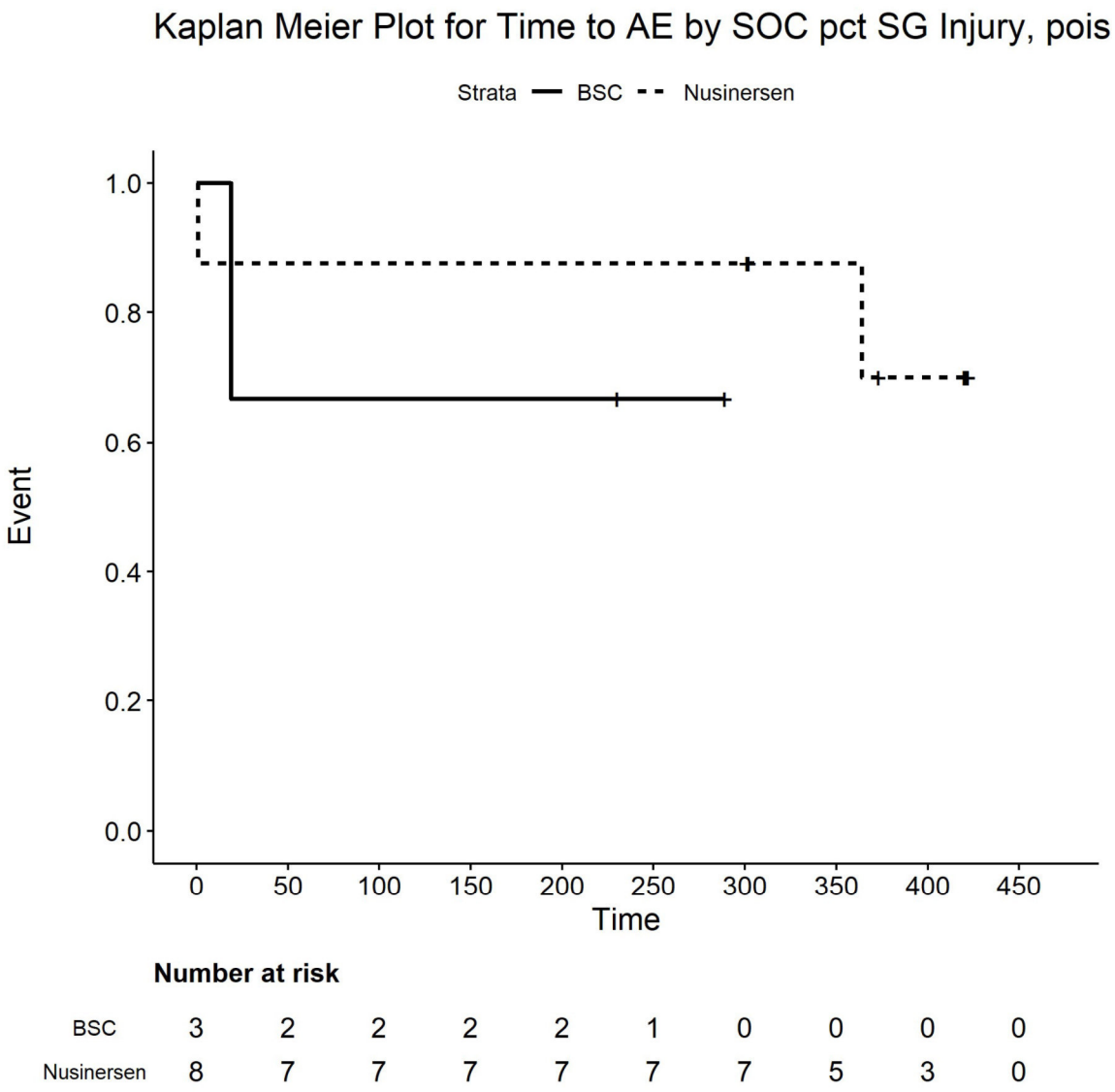
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	5	2	1	0	0	0	0	0	0



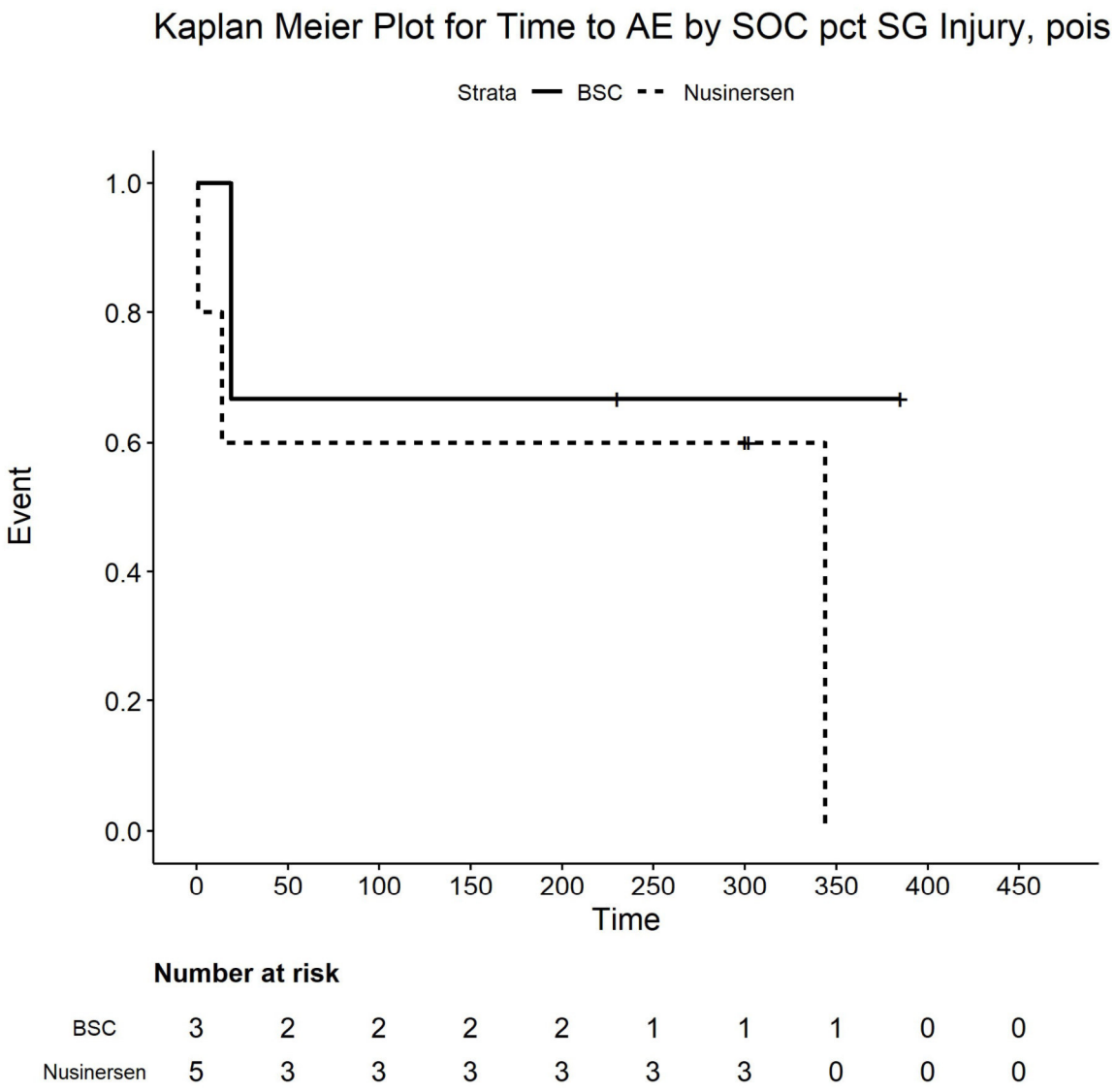
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	4	4	4	2	2	2	0	0	0



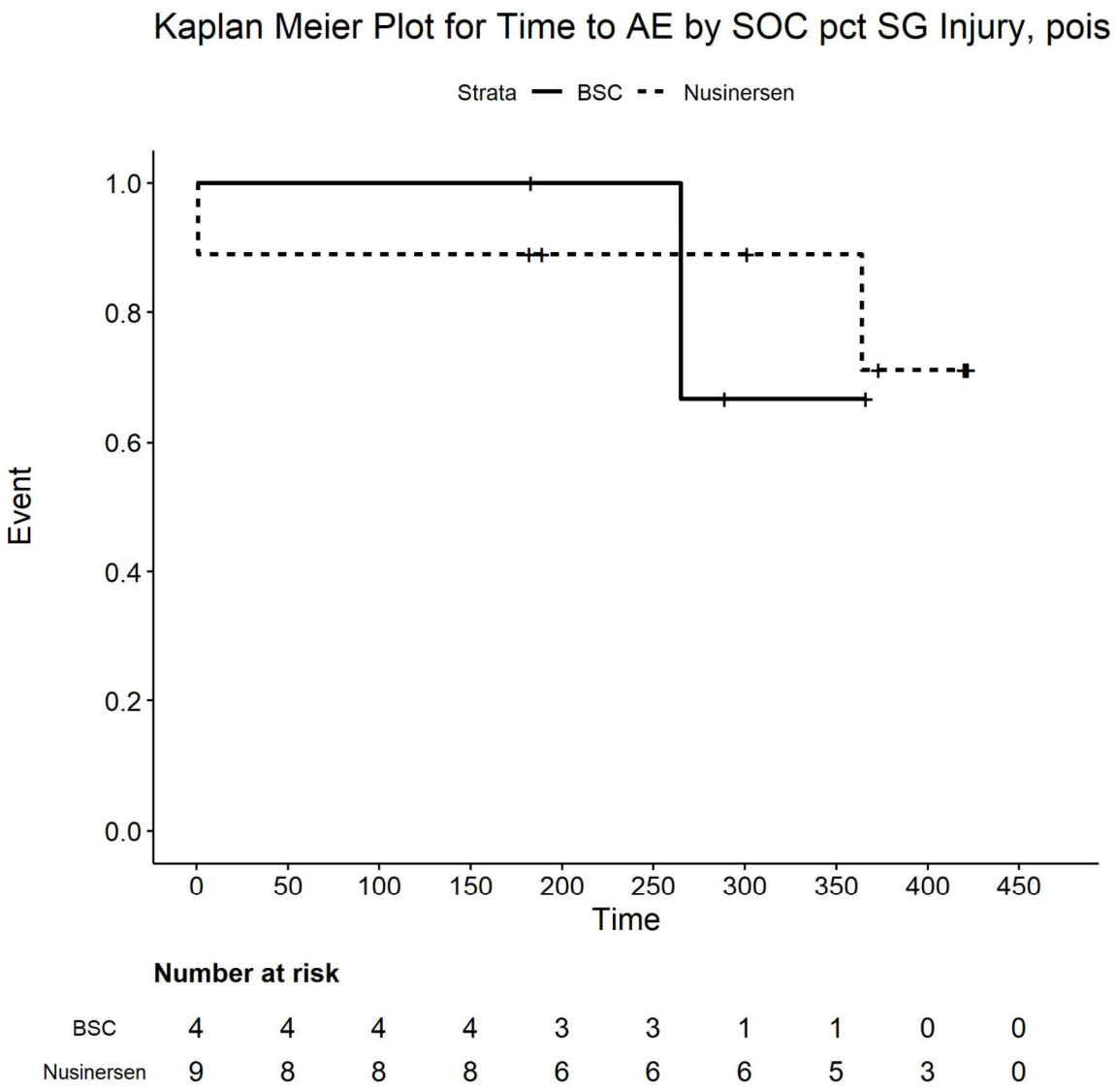
Number at risk

BSC	3	2	2	2	2	1	0	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	3	0



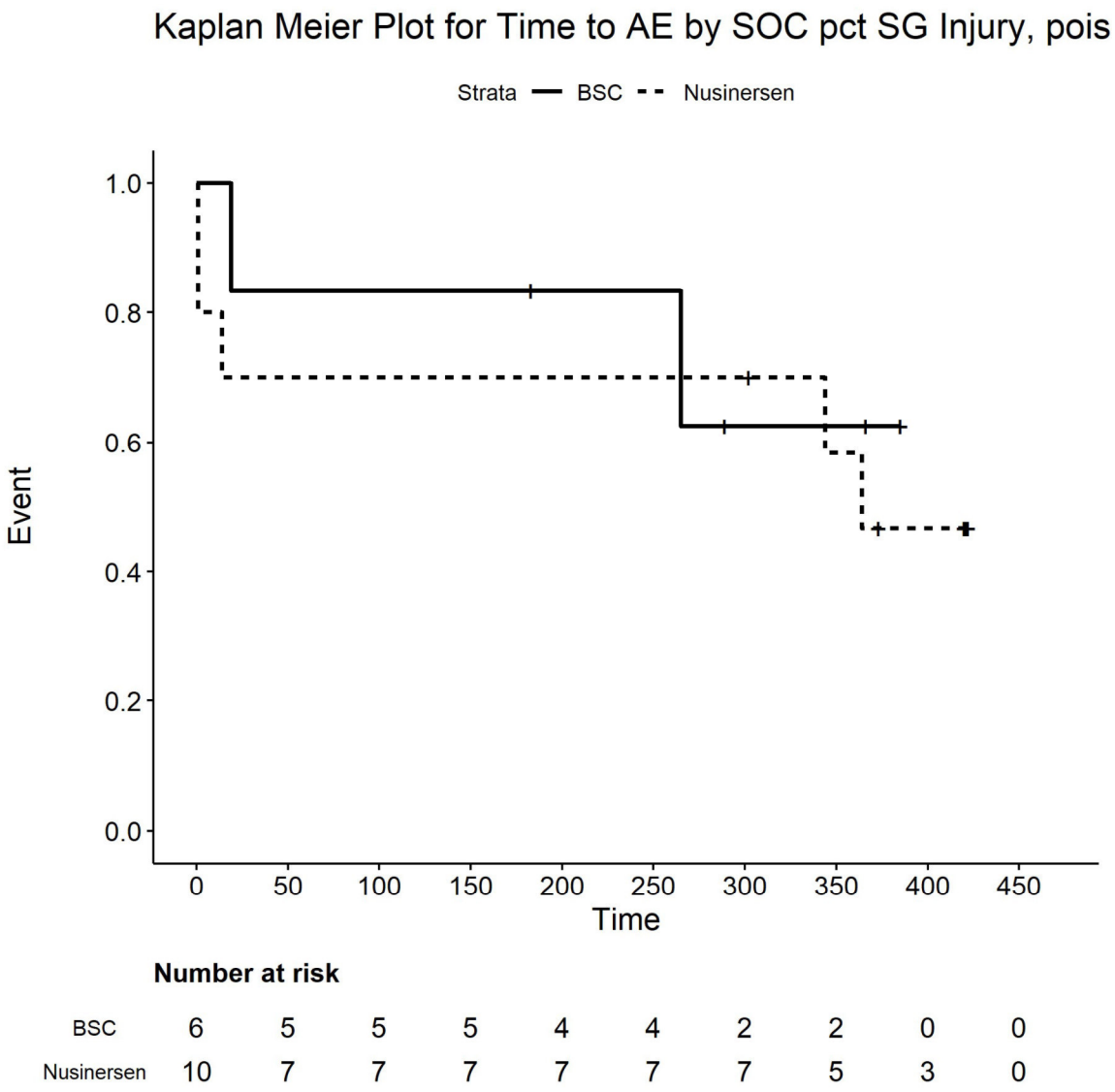
Number at risk

BSC	3	2	2	2	2	1	1	1	0	0
Nusinersen	5	3	3	3	3	3	3	0	0	0



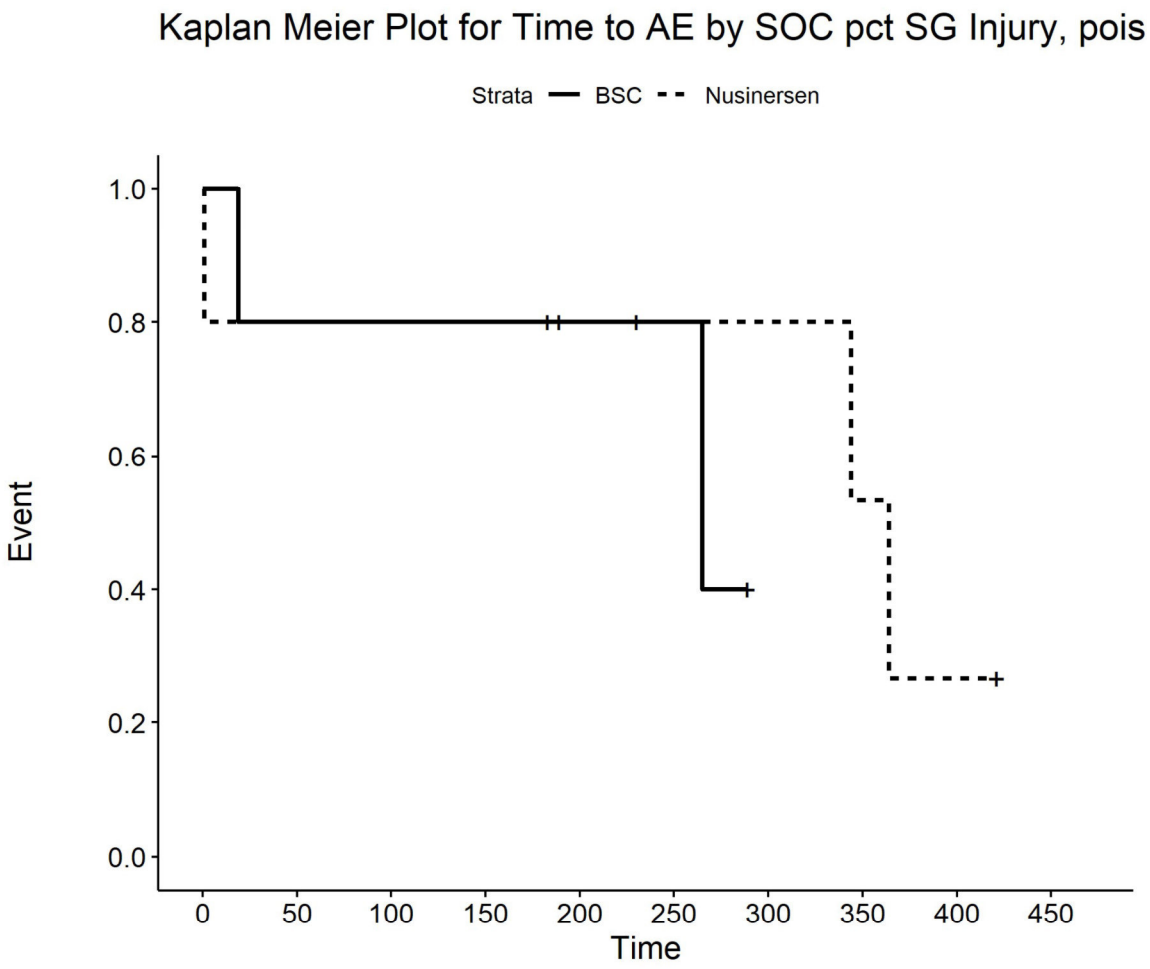
Number at risk

BSC	4	4	4	4	3	3	1	1	0	0
Nusinersen	9	8	8	8	6	6	6	5	3	0



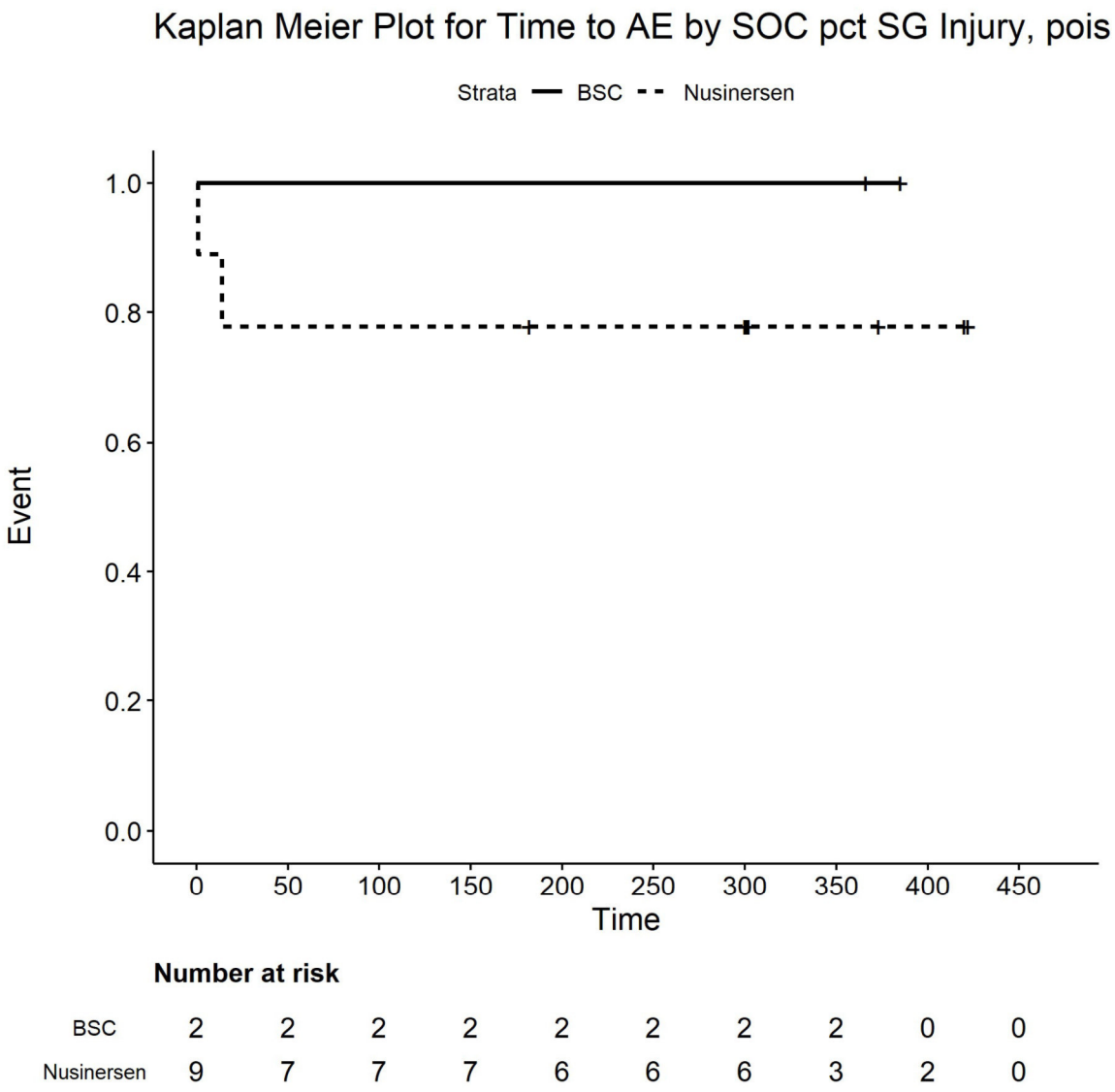
Number at risk

BSC	6	5	5	5	4	4	2	2	0	0
Nusinersen	10	7	7	7	7	7	7	5	3	0



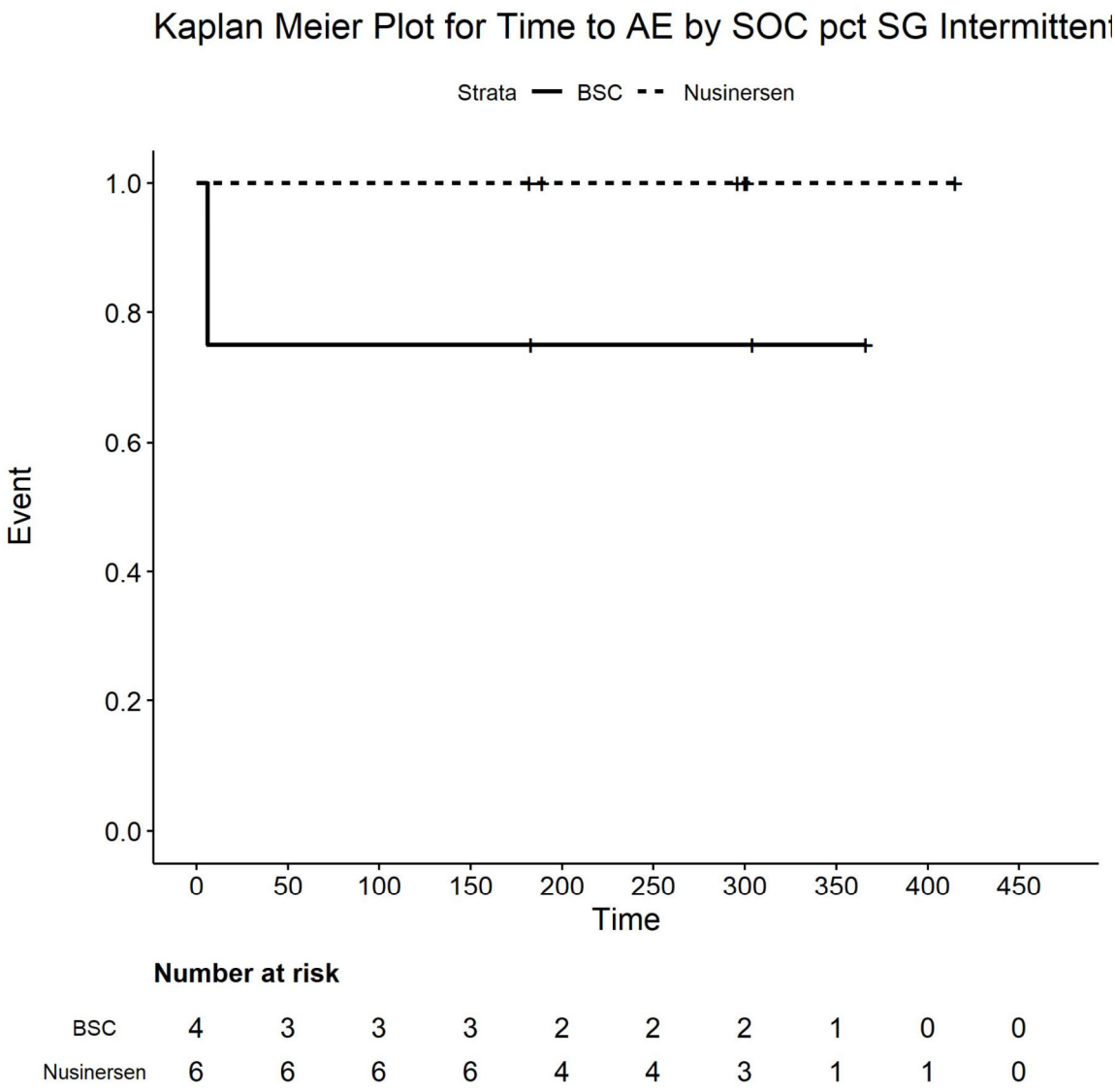
Number at risk

BSC	5	4	4	4	3	2	0	0	0	0
Nusinersen	5	4	4	4	3	3	3	2	1	0



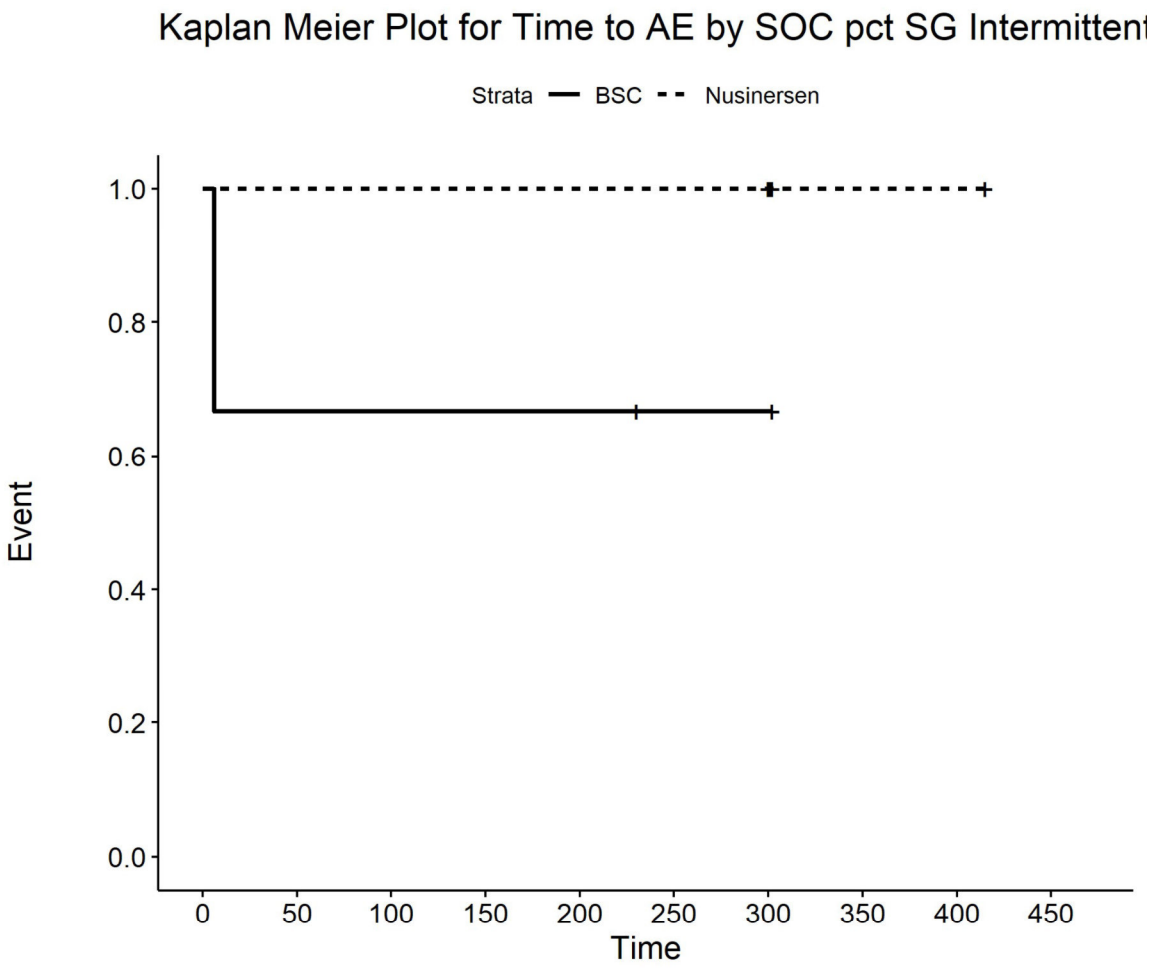
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	7	7	6	6	6	3	2	0



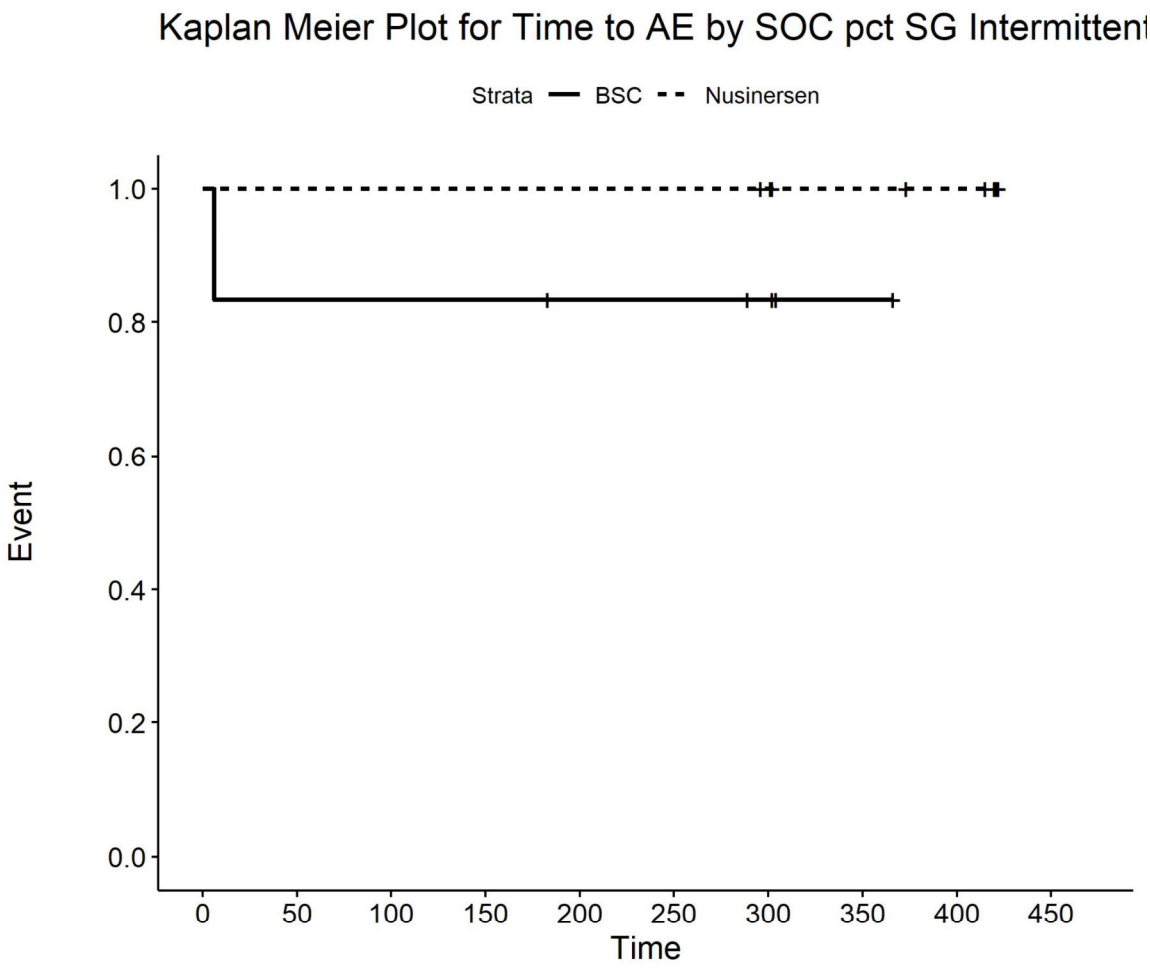
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



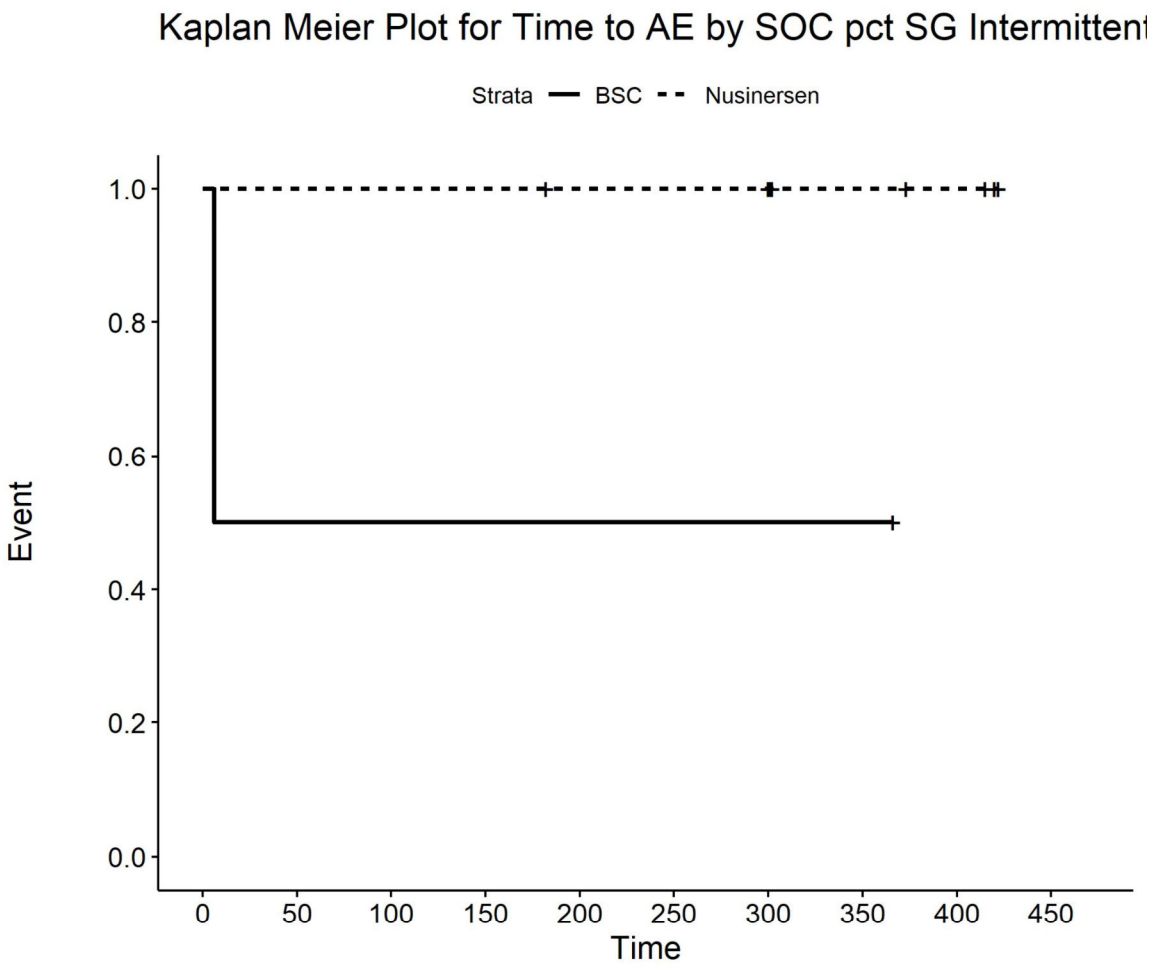
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



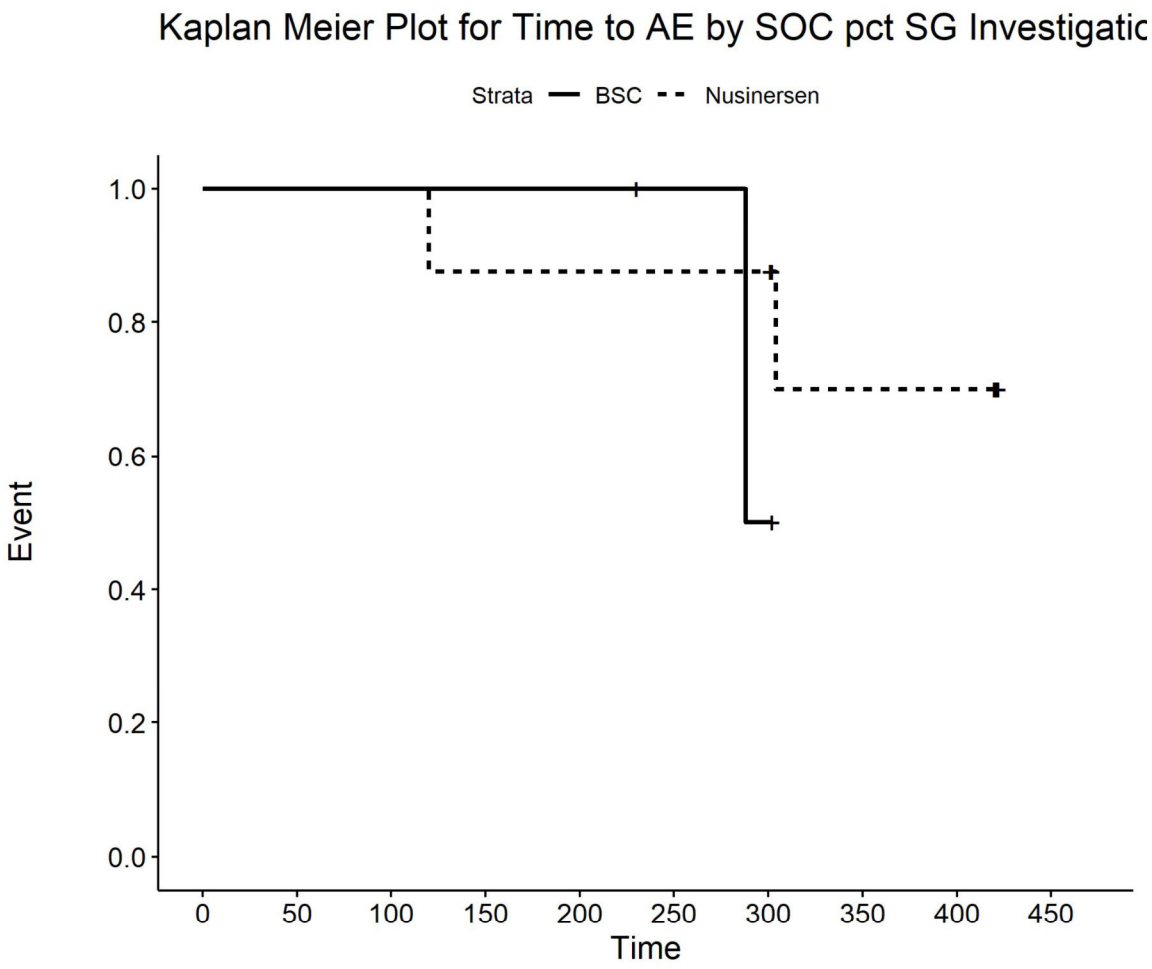
Number at risk

BSC	6	5	5	5	4	4	3	1	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



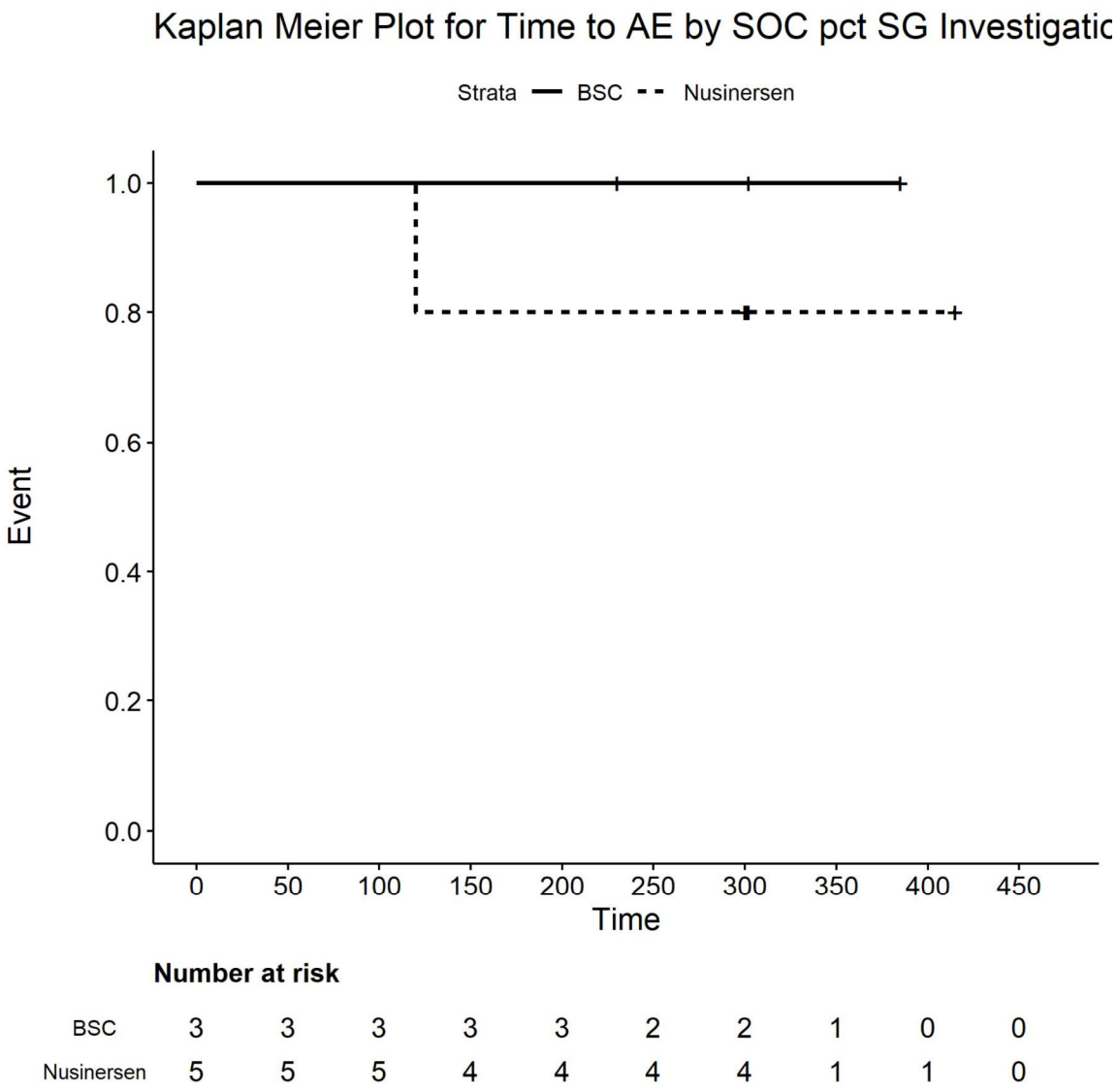
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



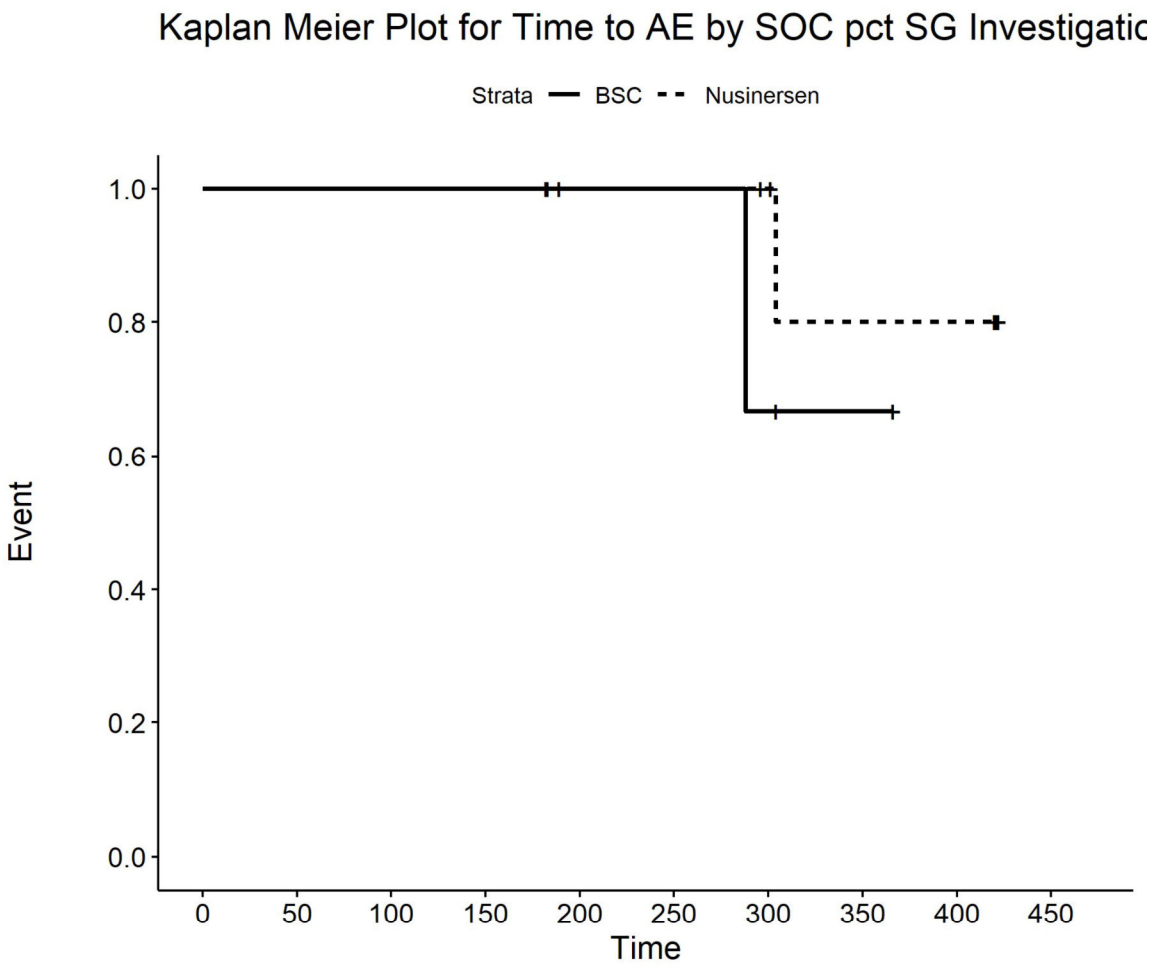
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	4	4	0



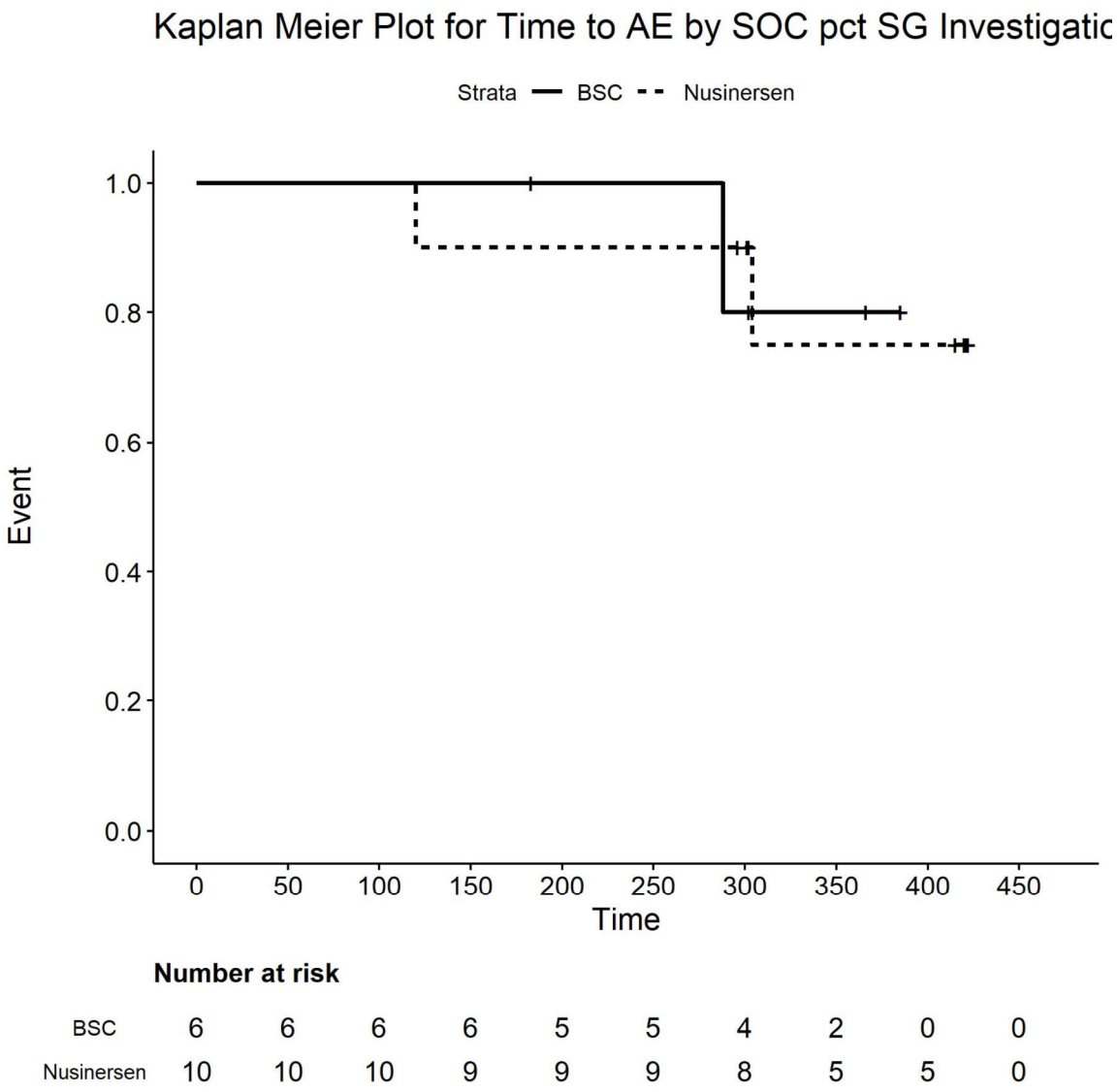
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	4	4	4	4	1	1	0



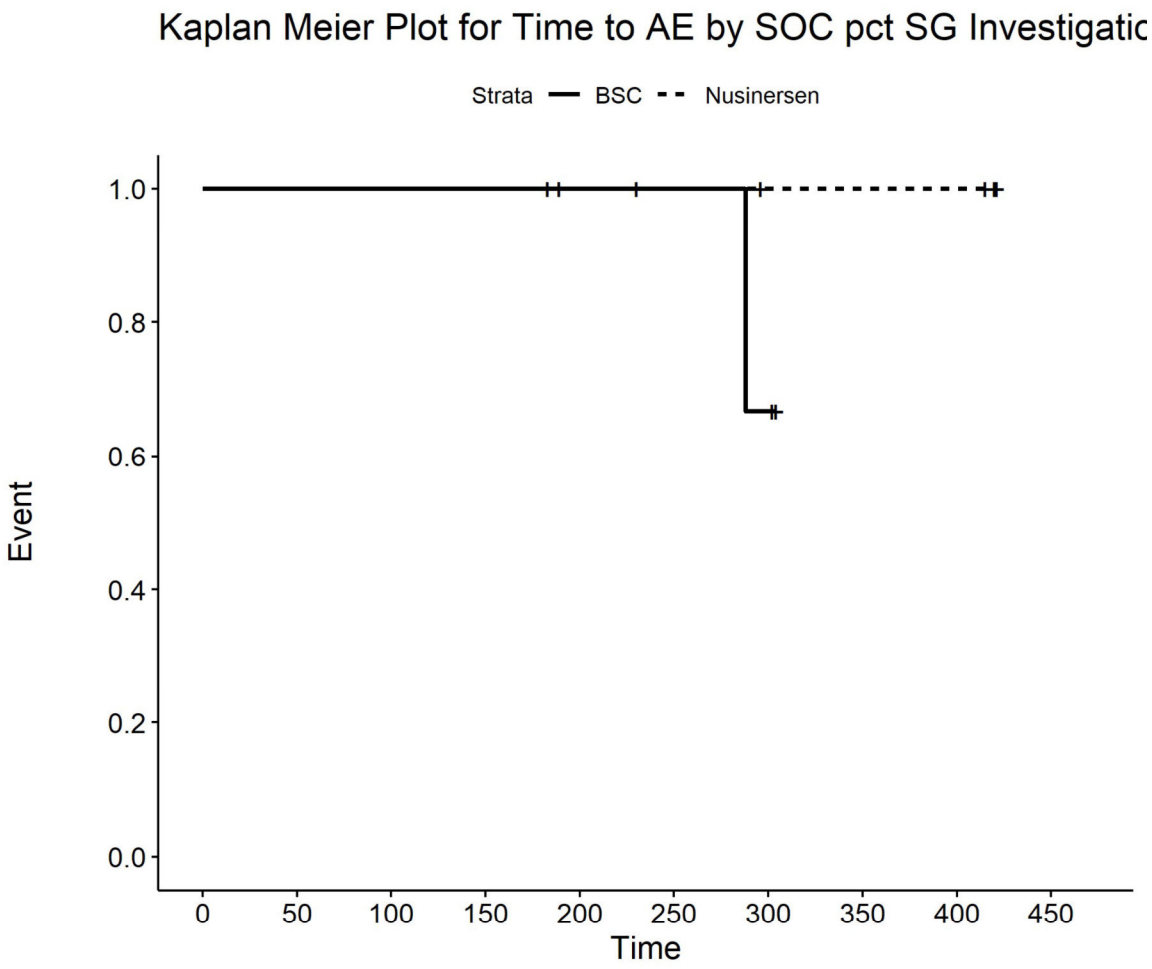
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	4	4	0



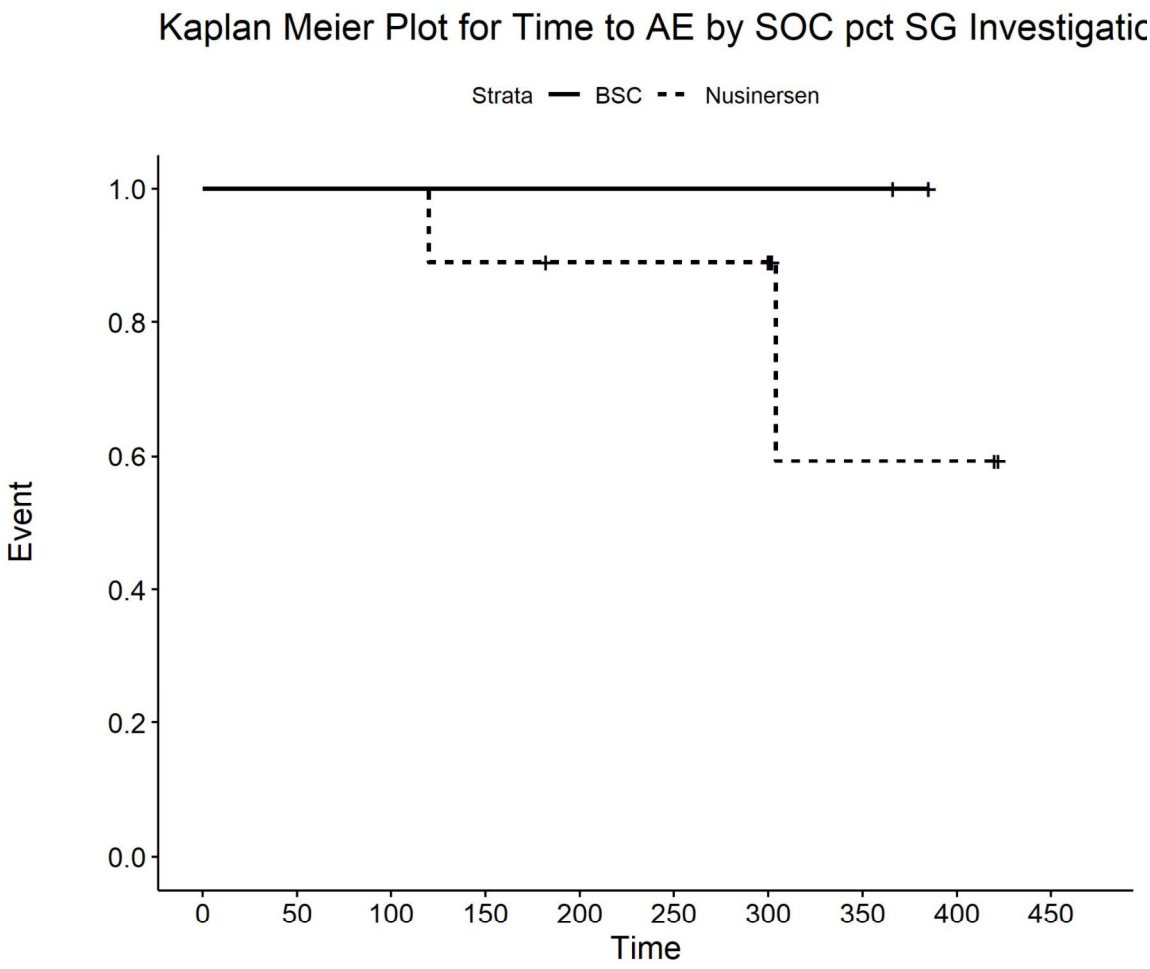
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	5	5	0



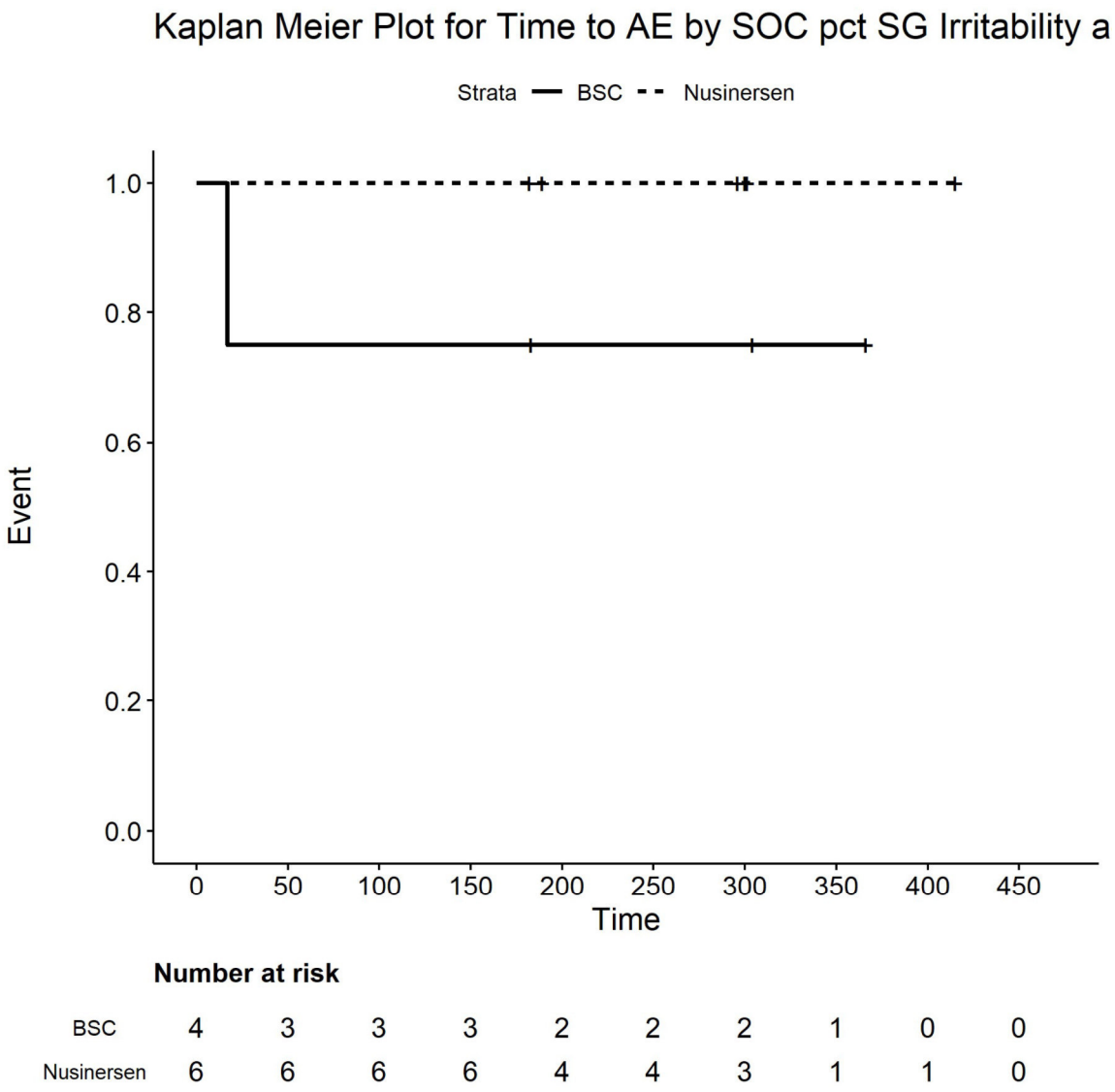
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



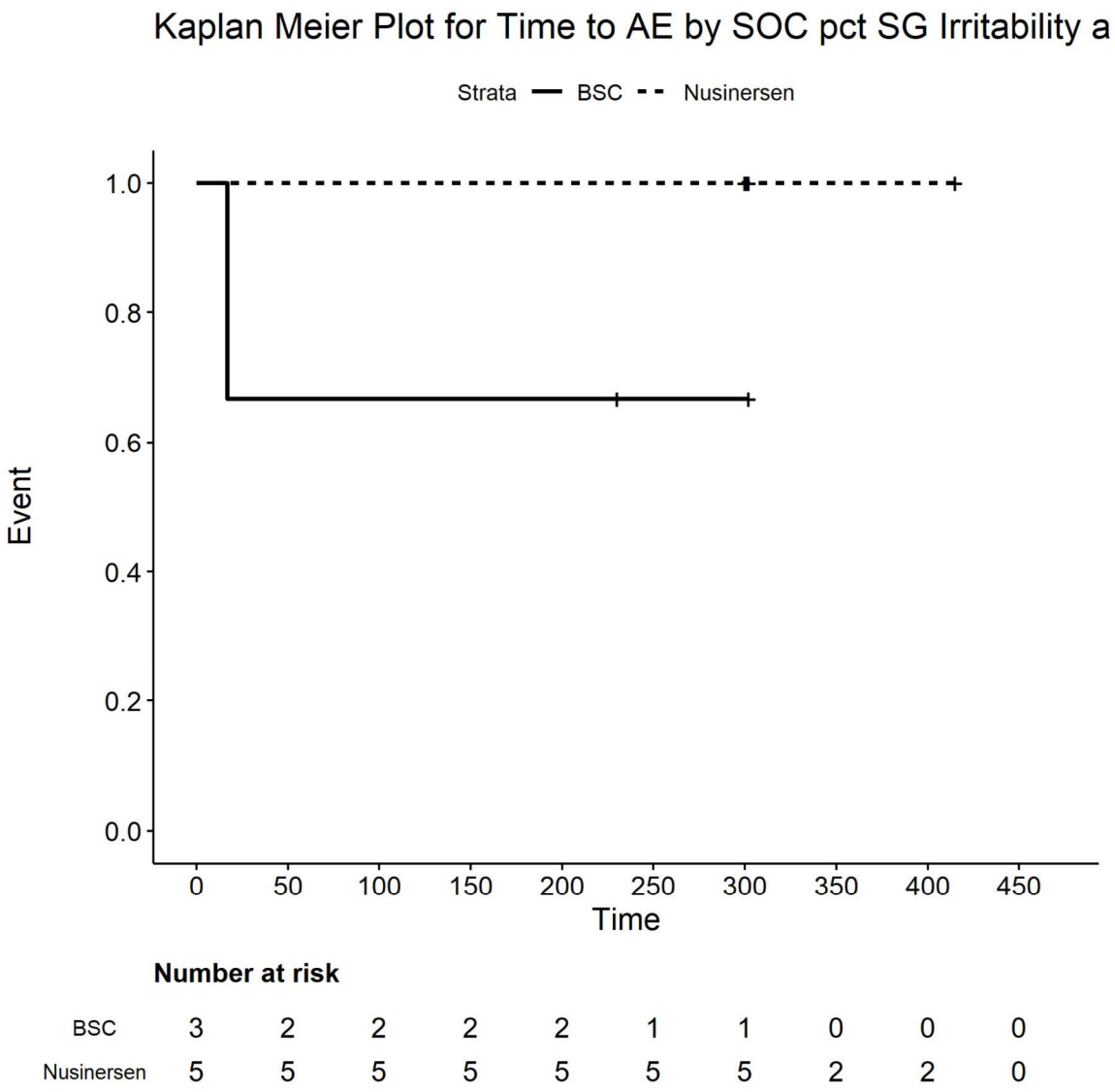
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	2	2	0



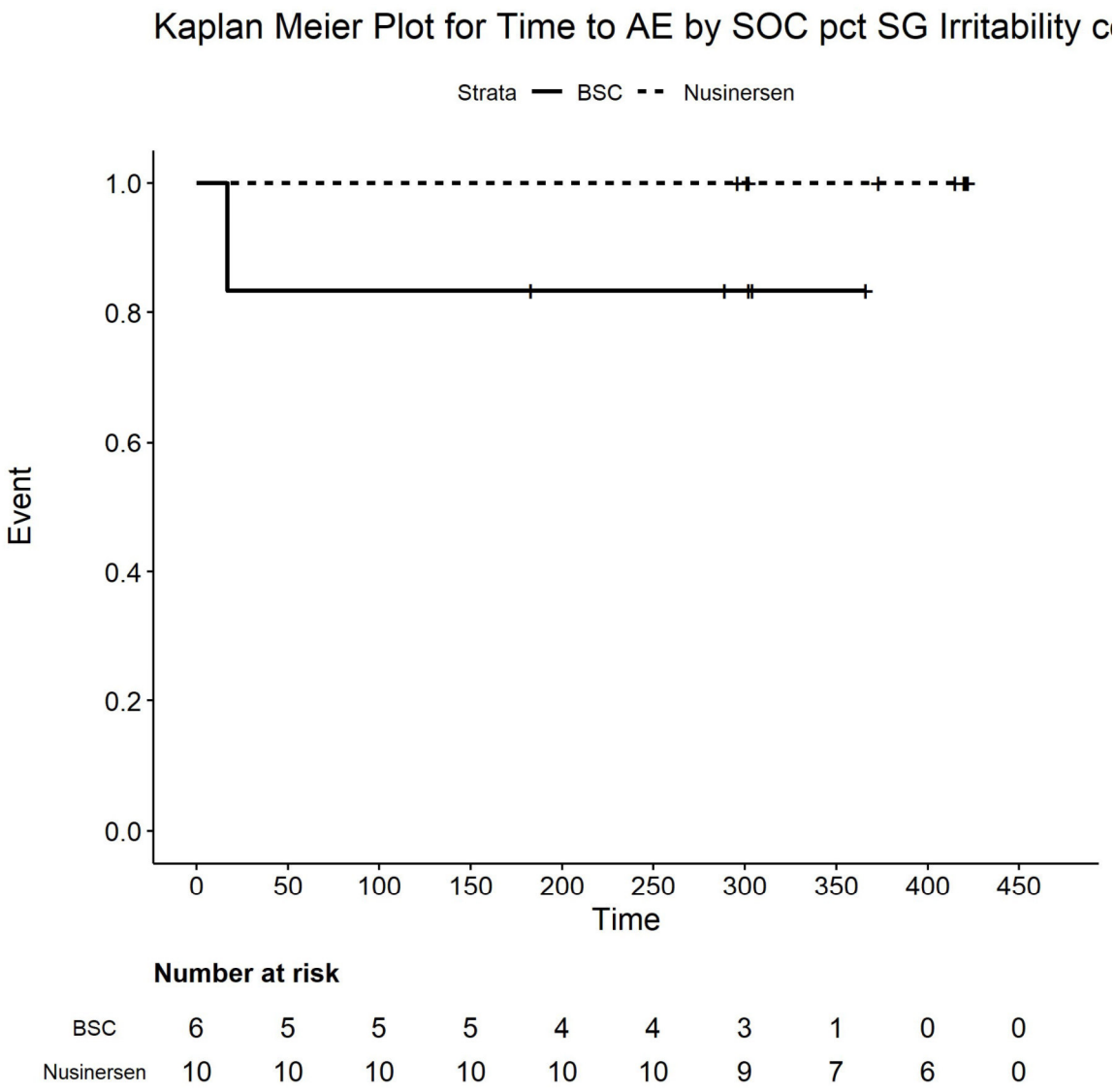
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



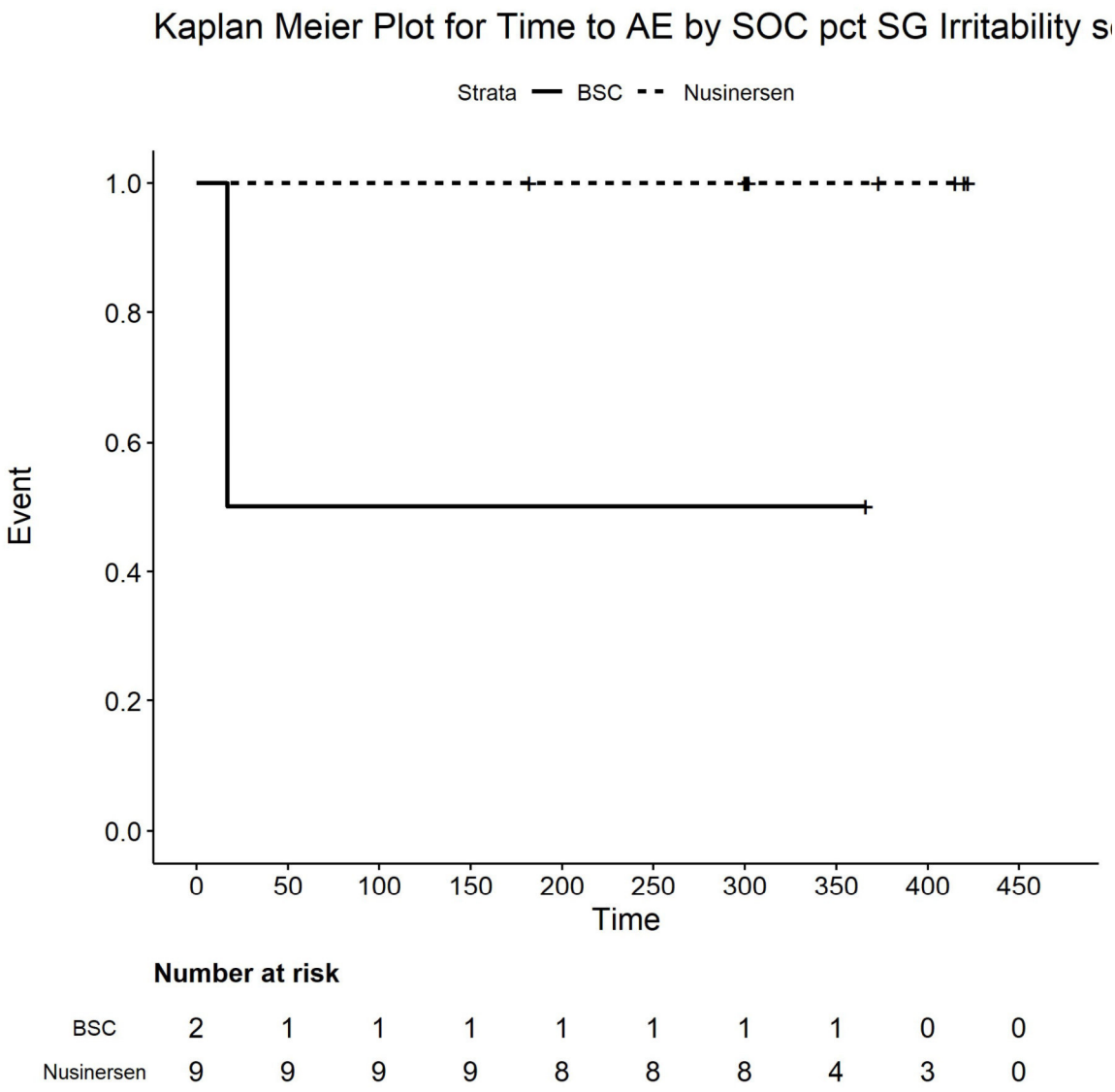
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



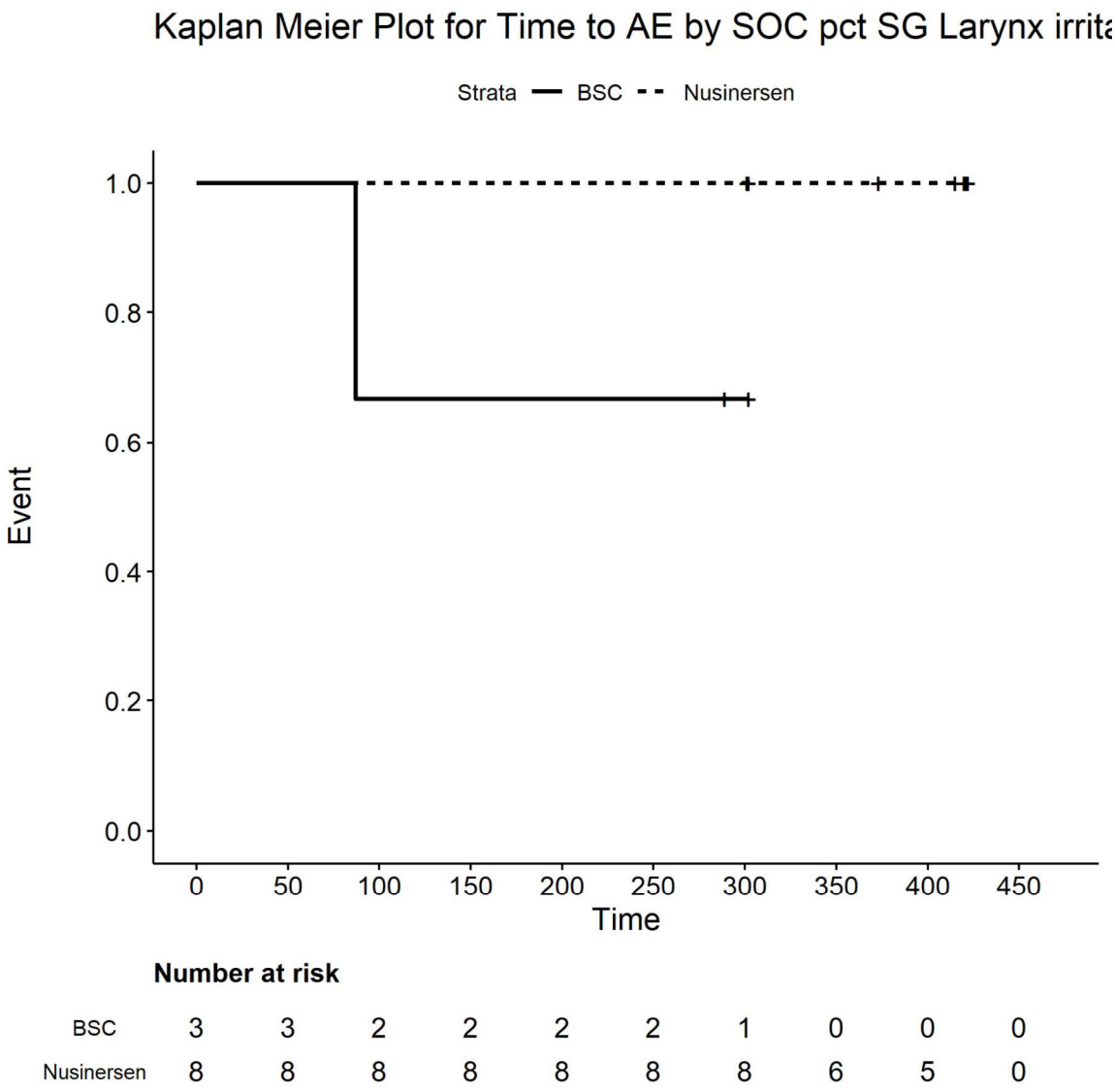
Number at risk

BSC	6	5	5	5	4	4	3	1	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



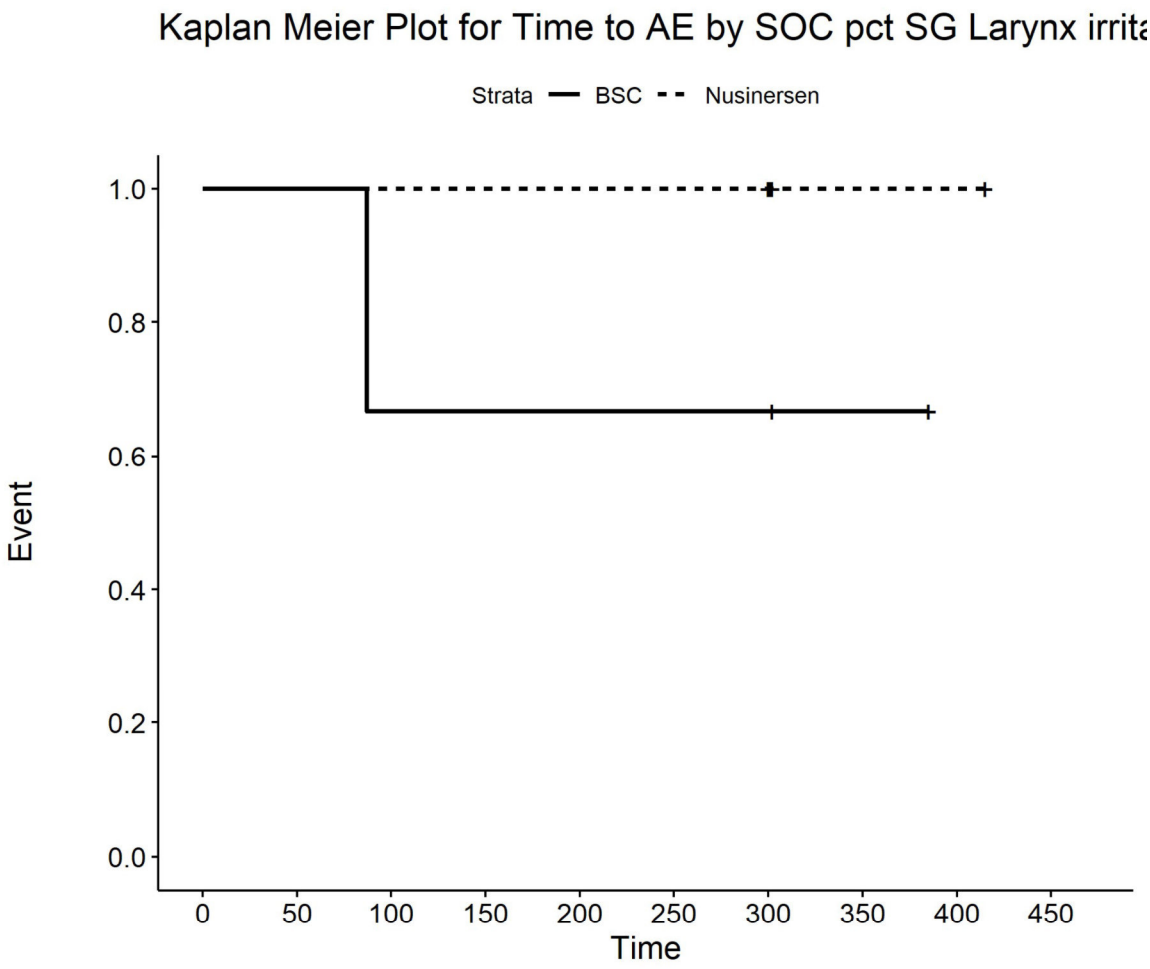
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



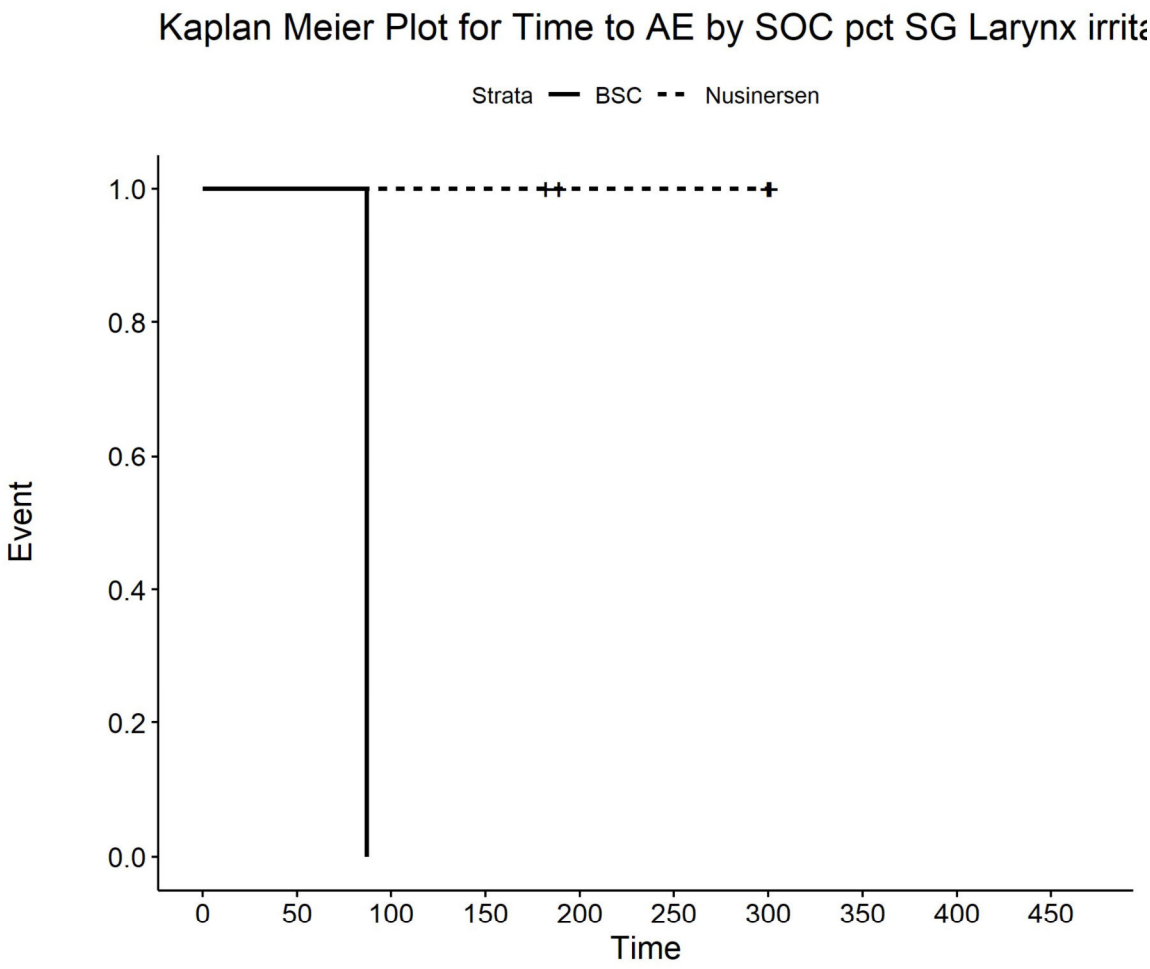
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



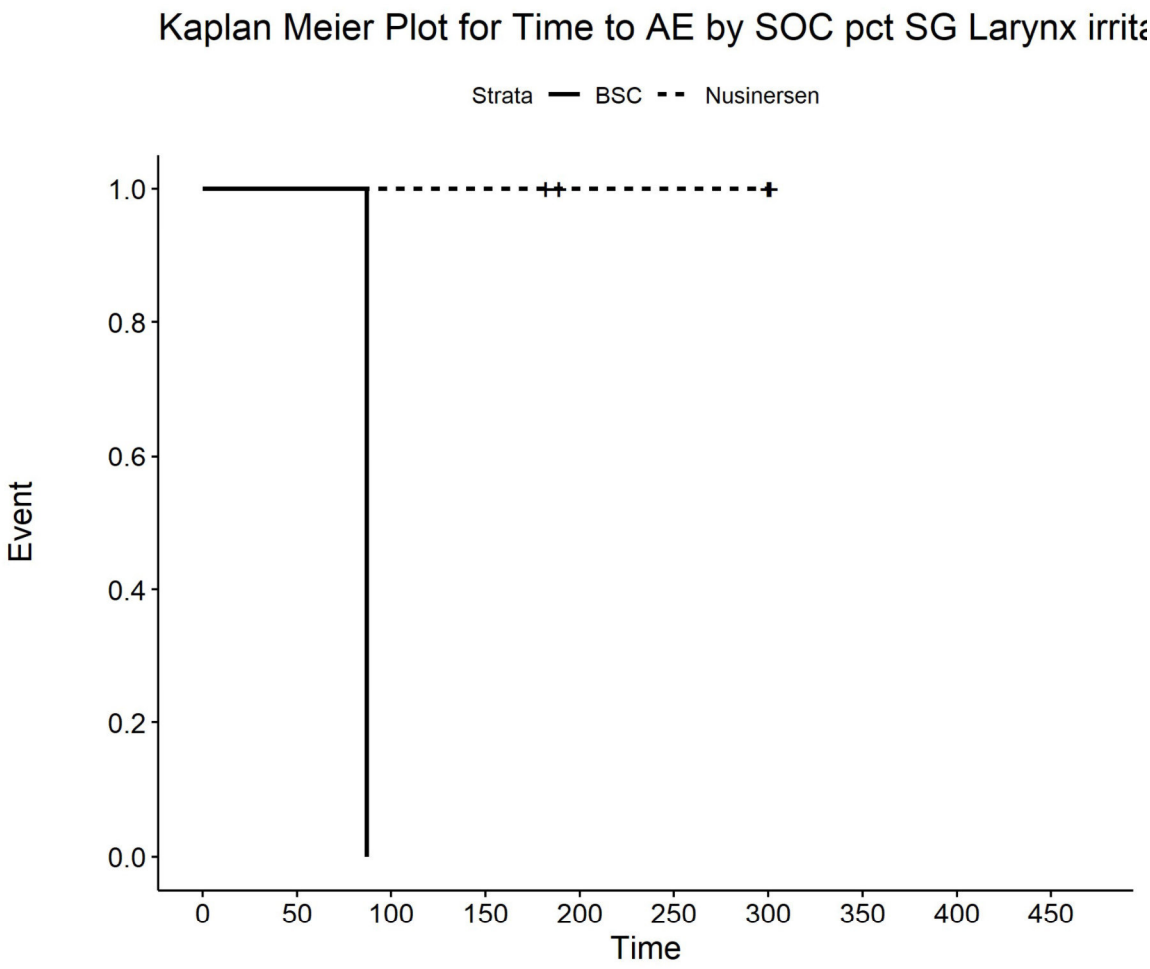
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



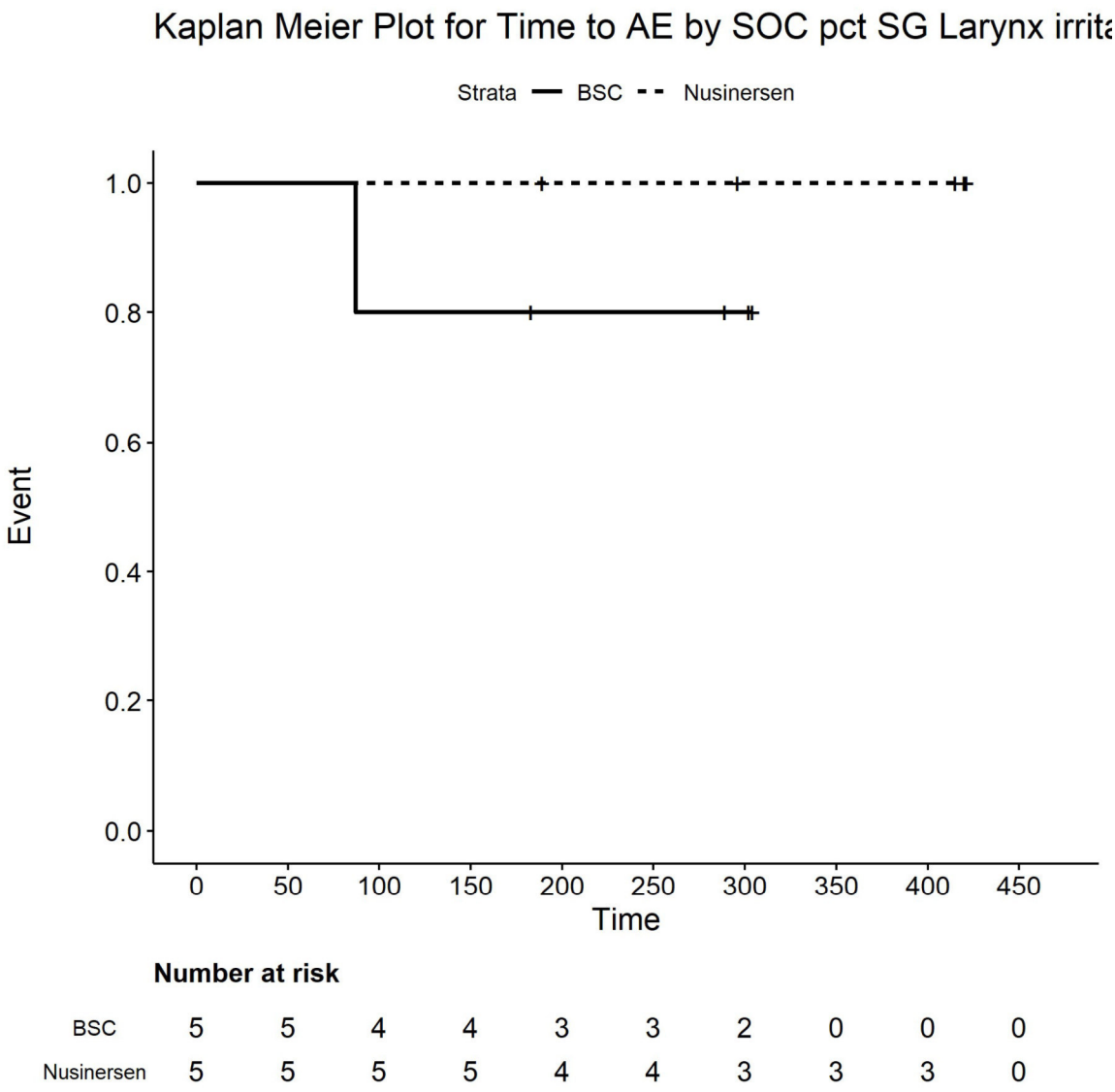
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



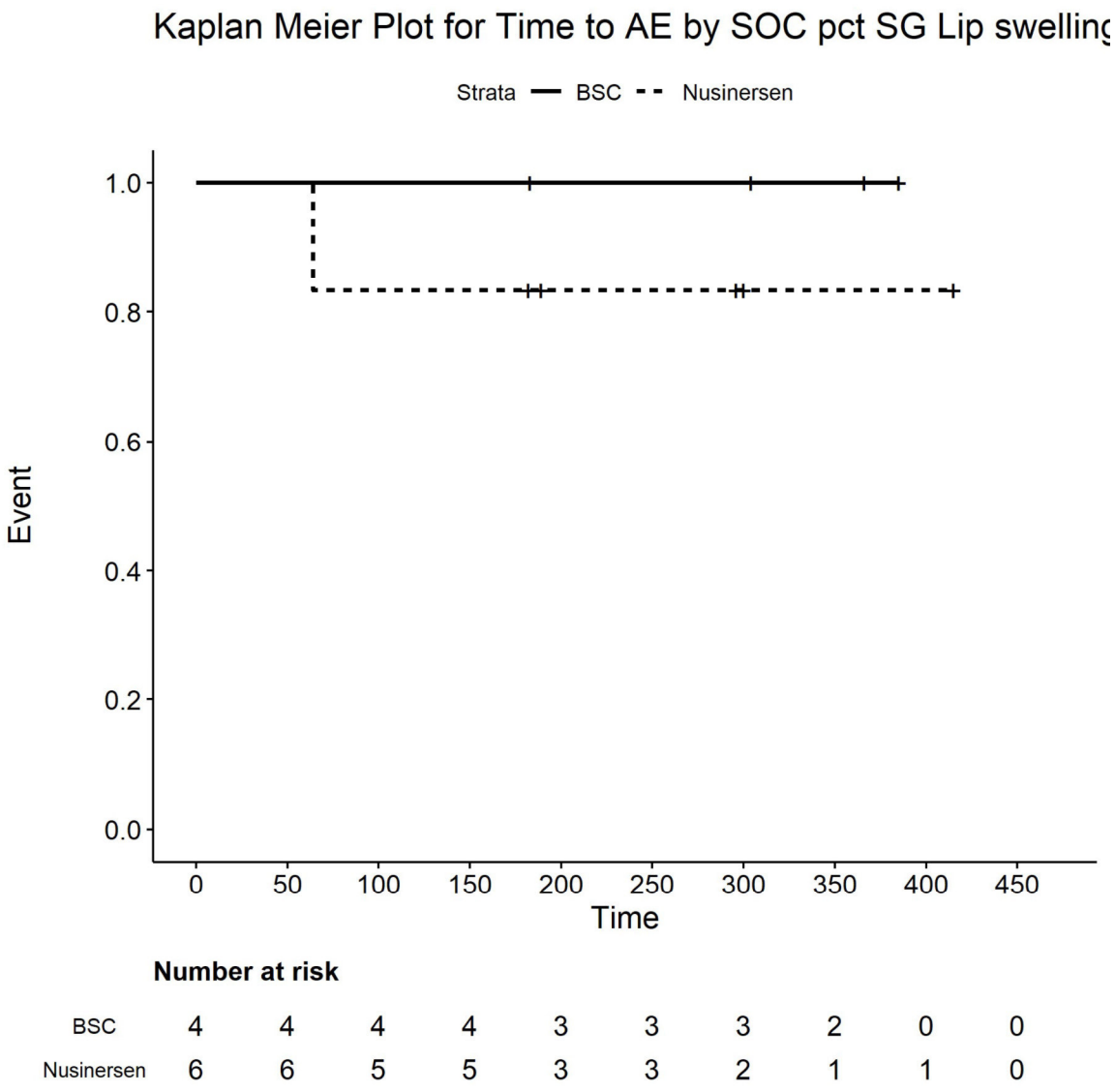
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



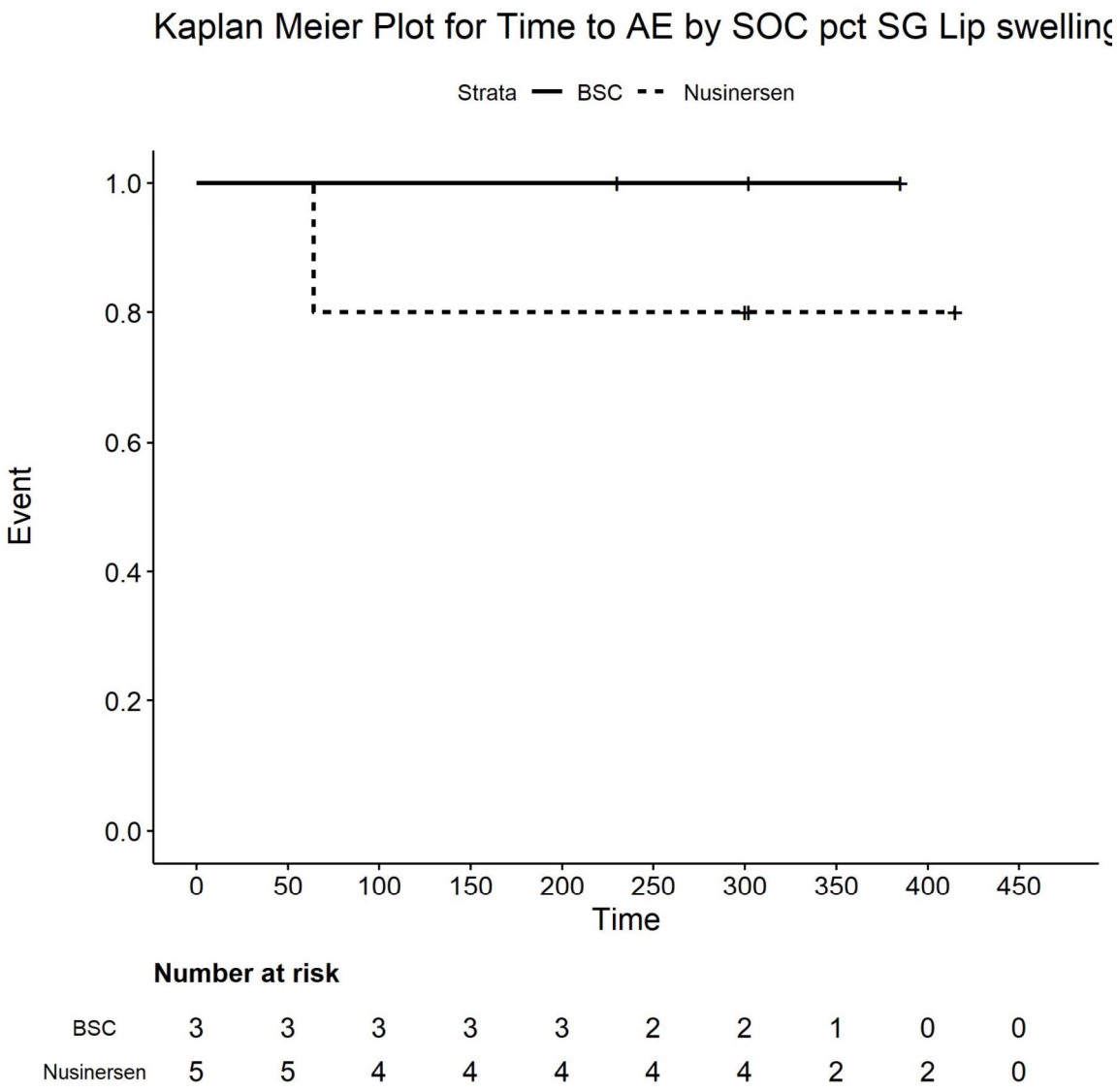
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



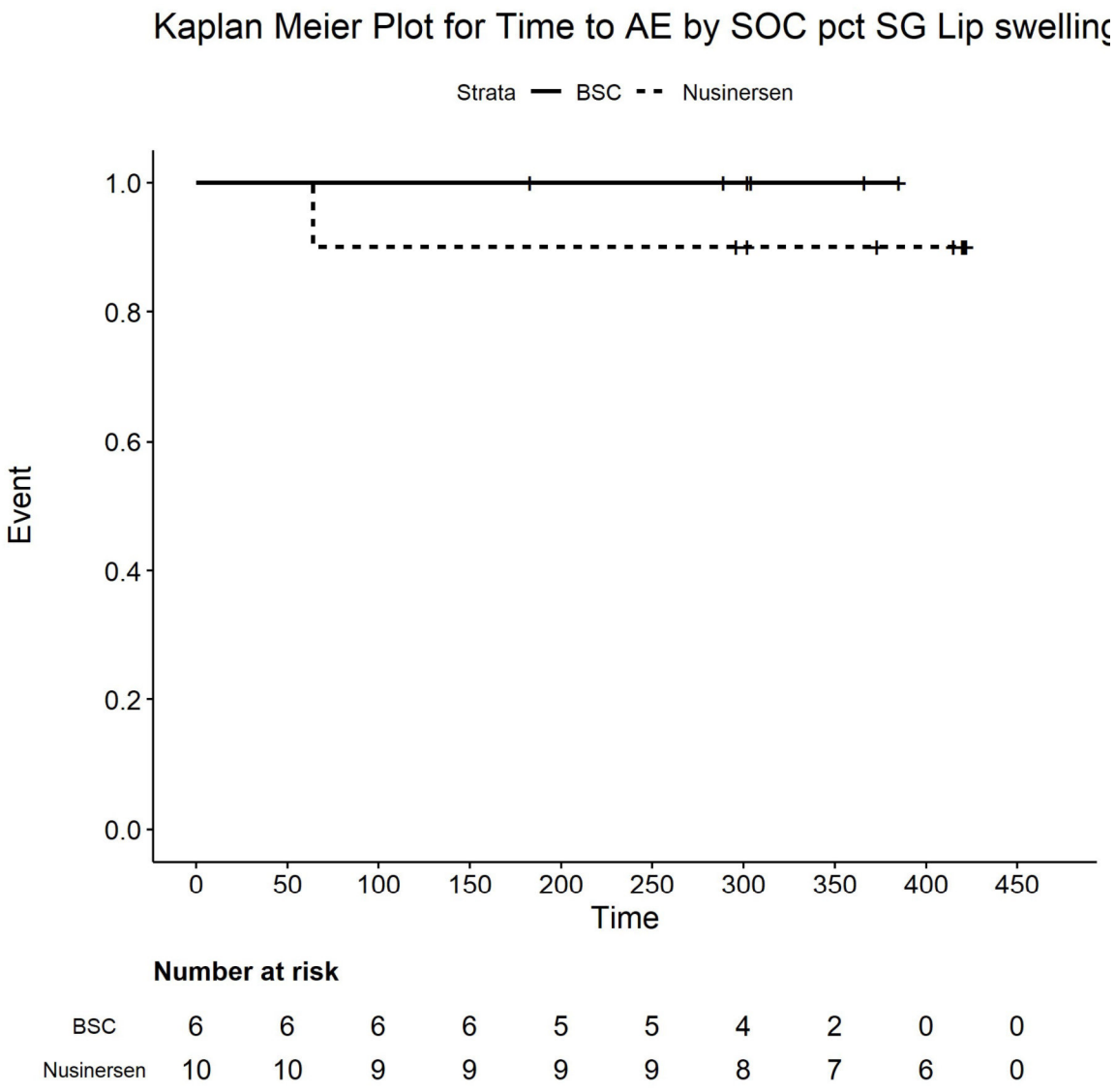
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



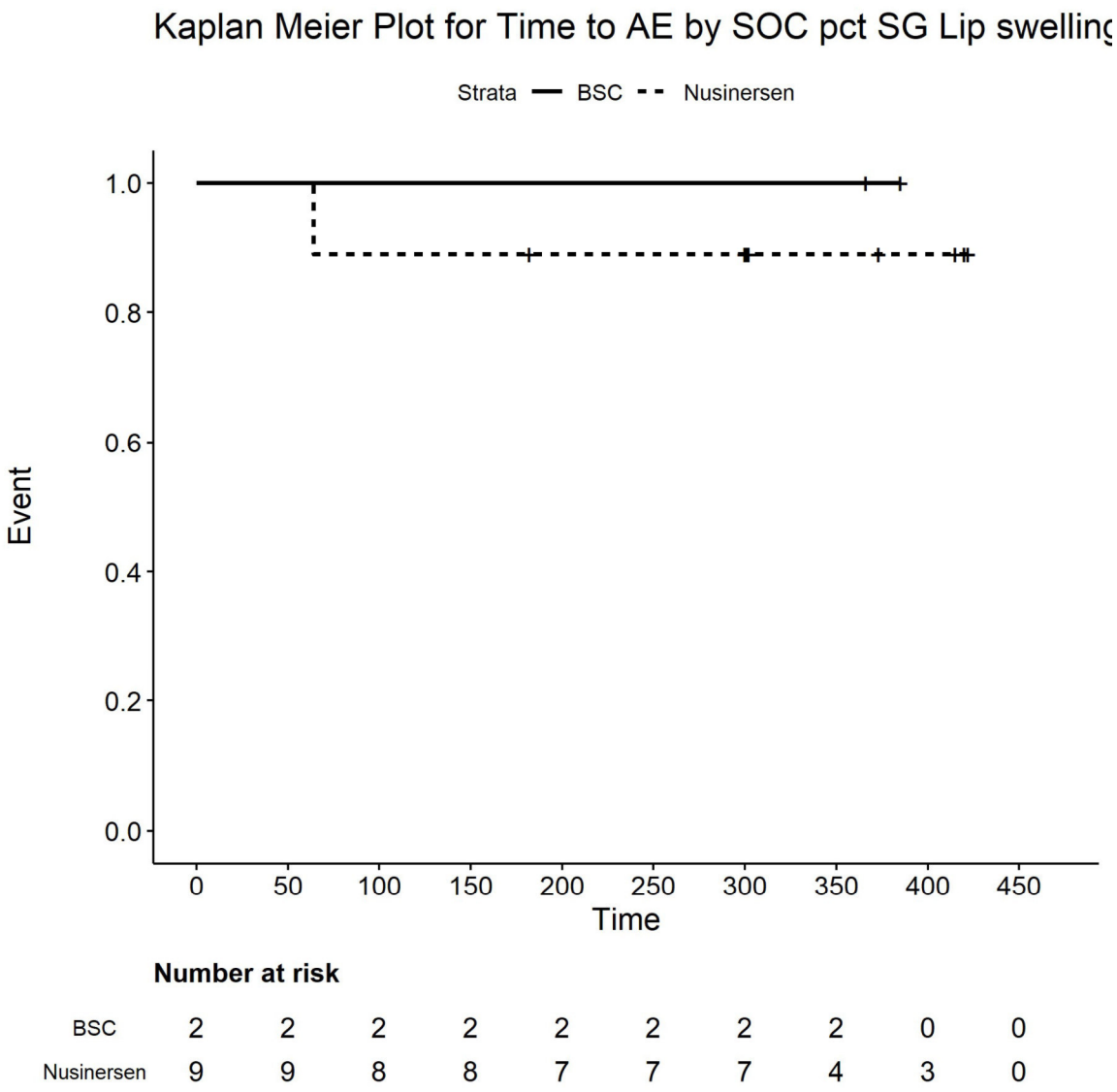
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



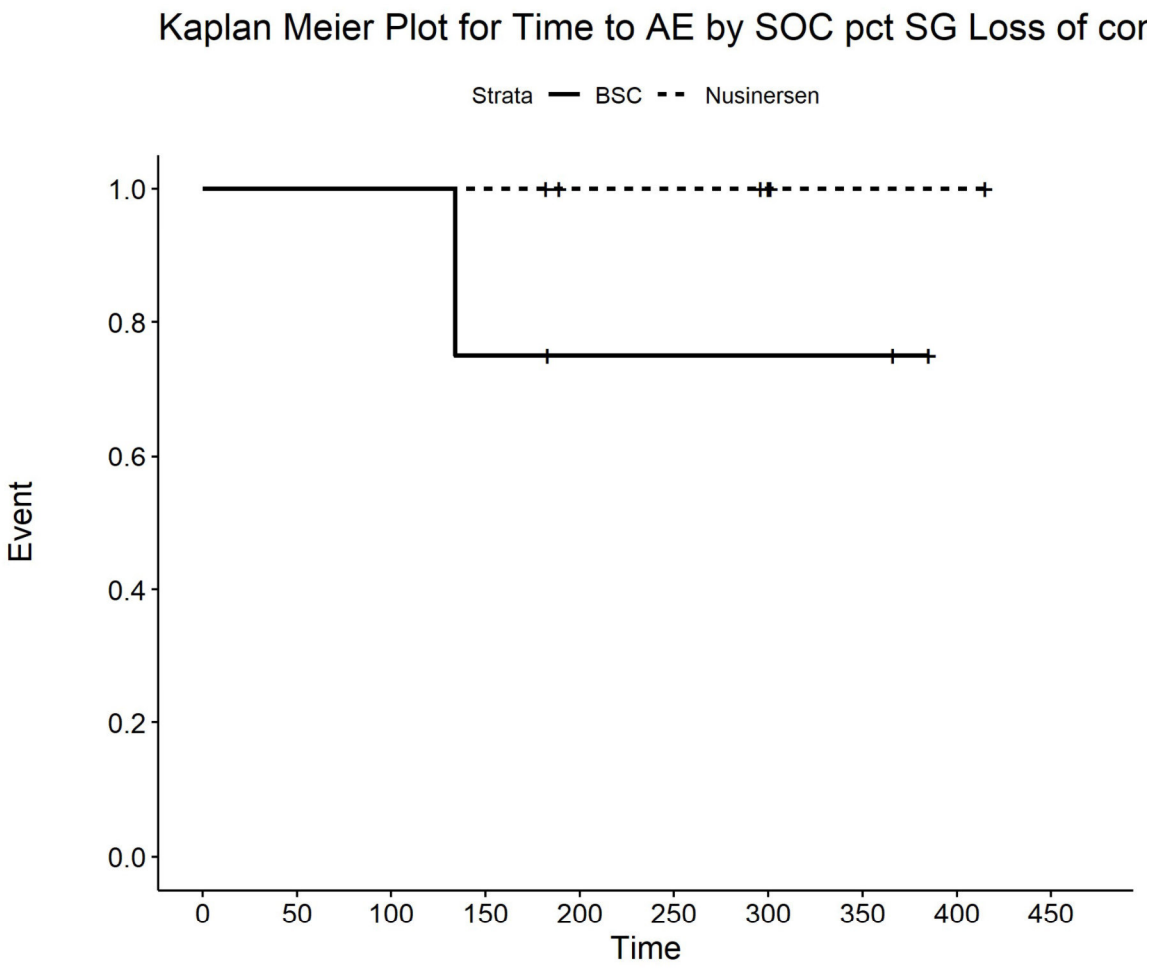
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



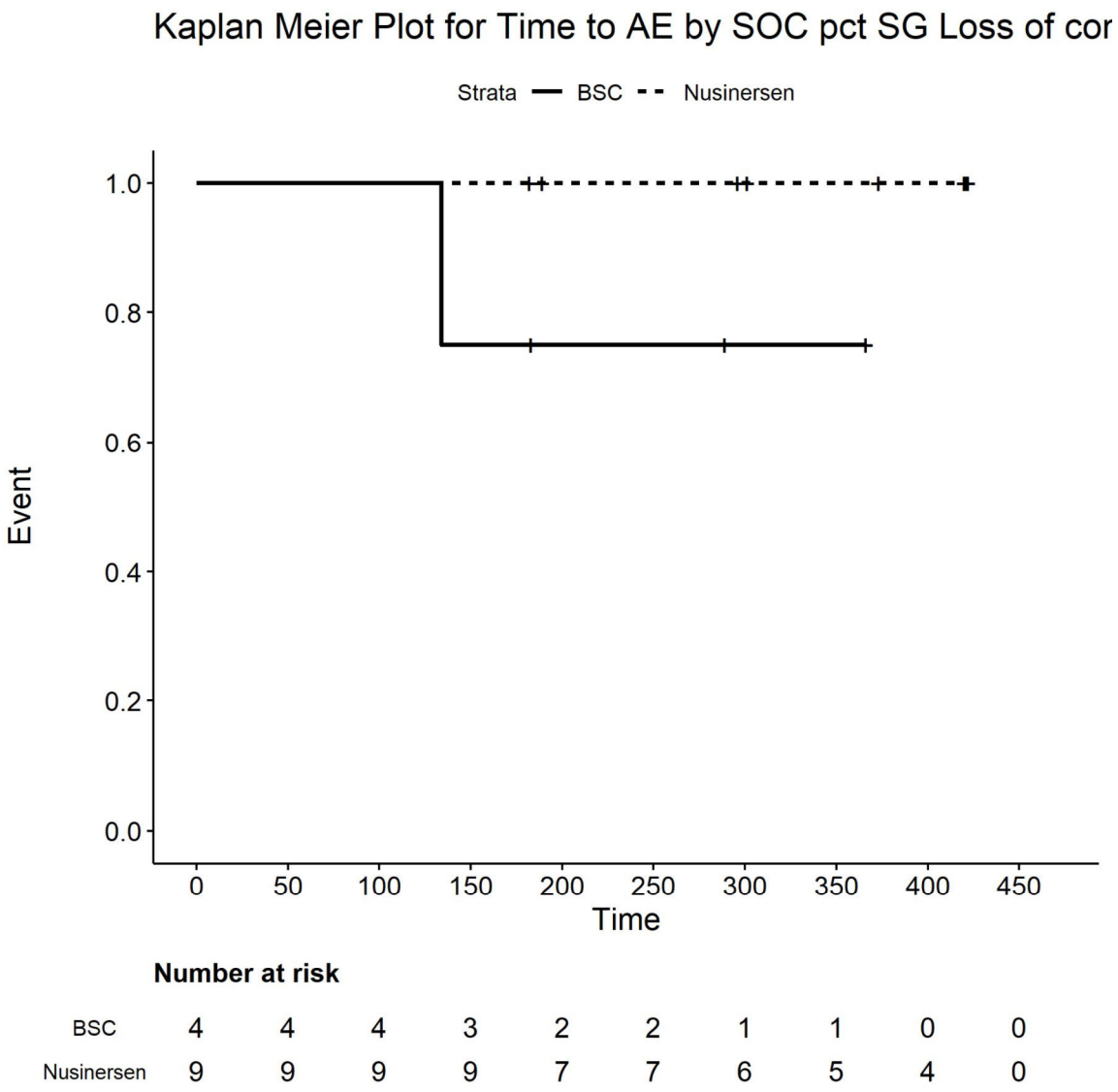
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



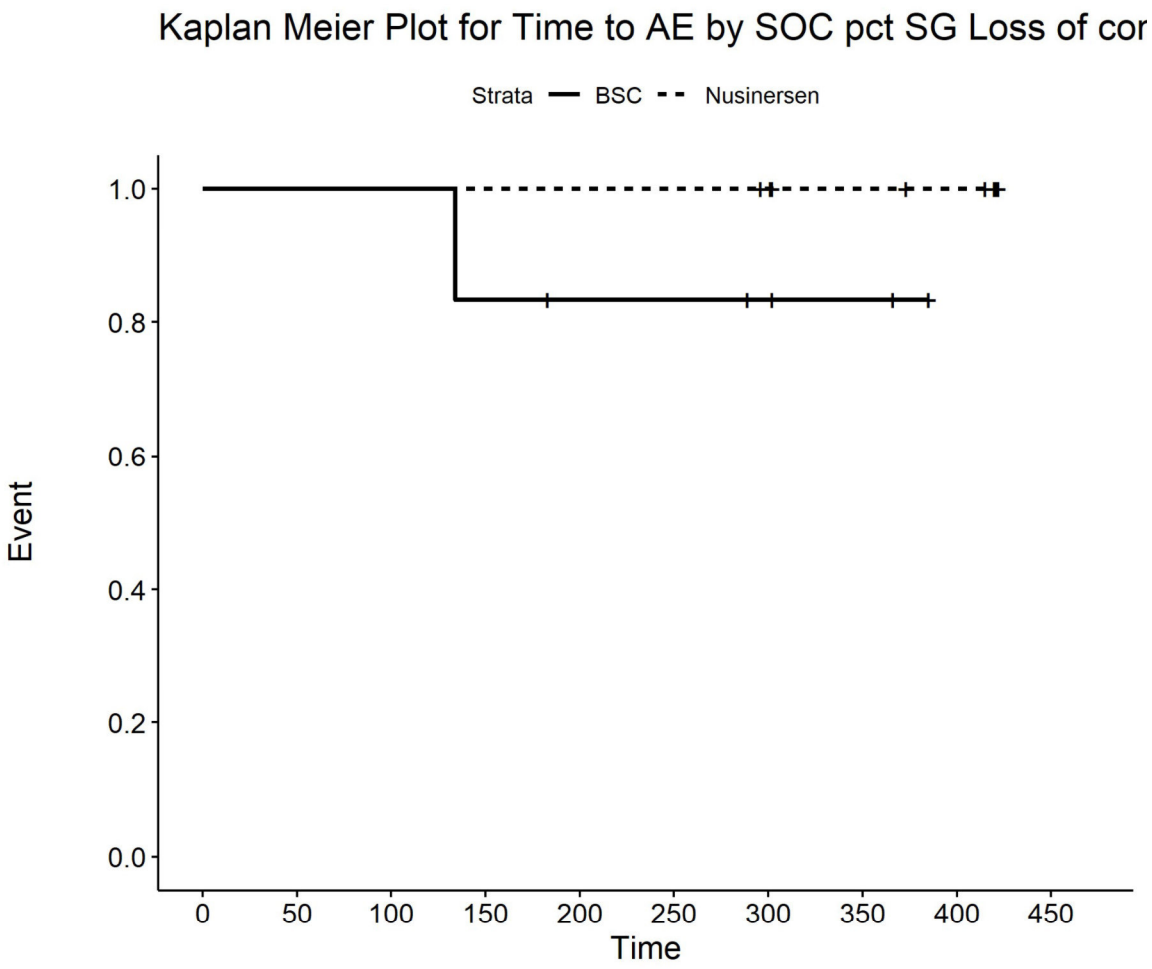
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



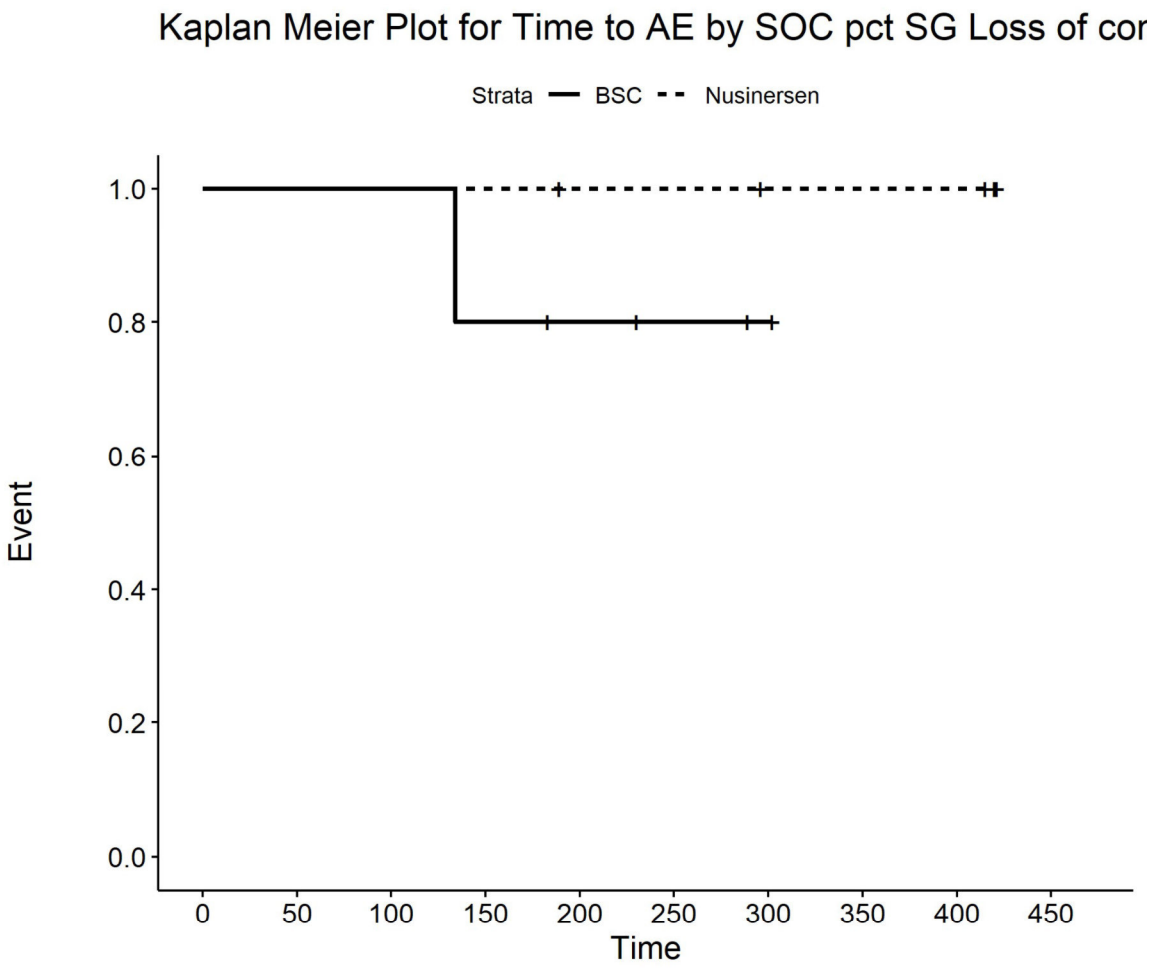
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



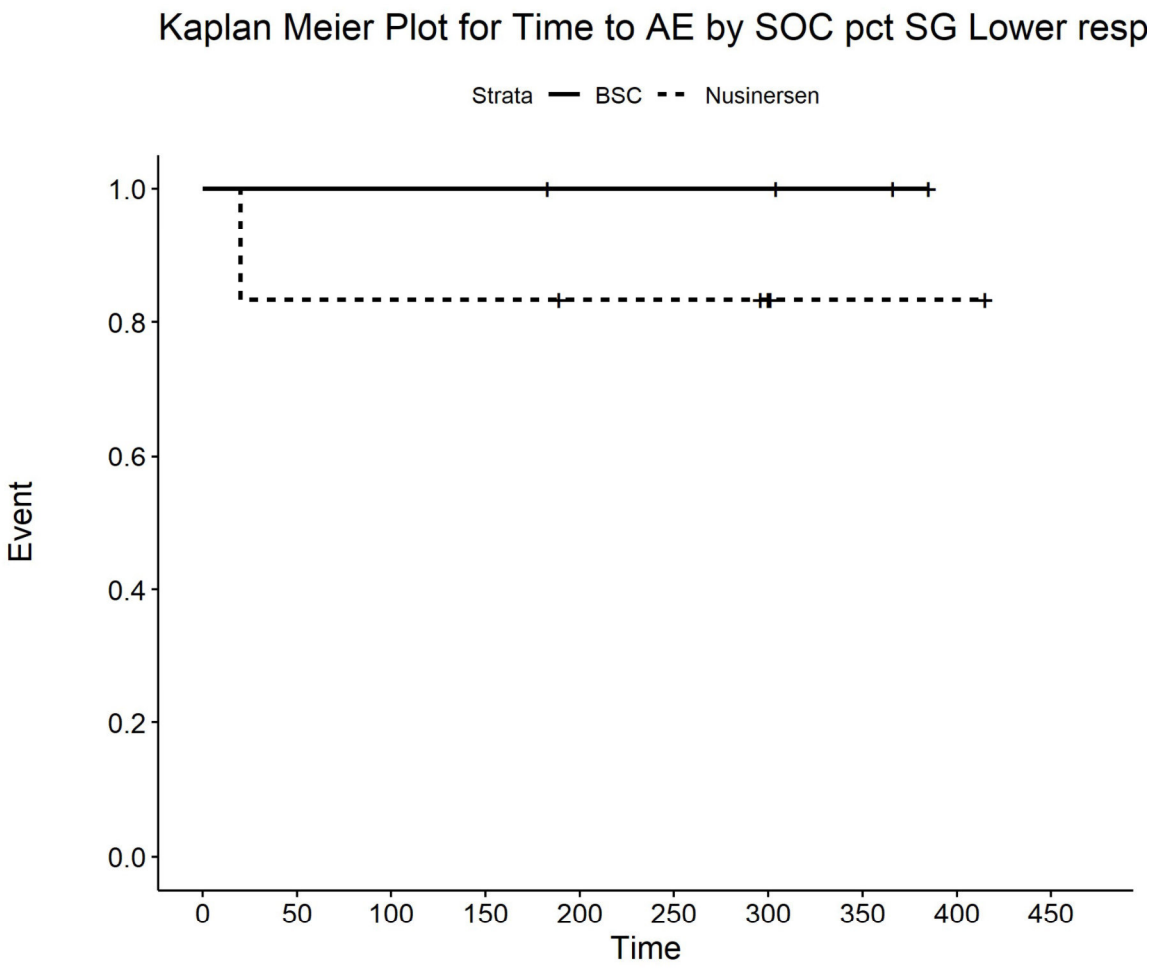
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



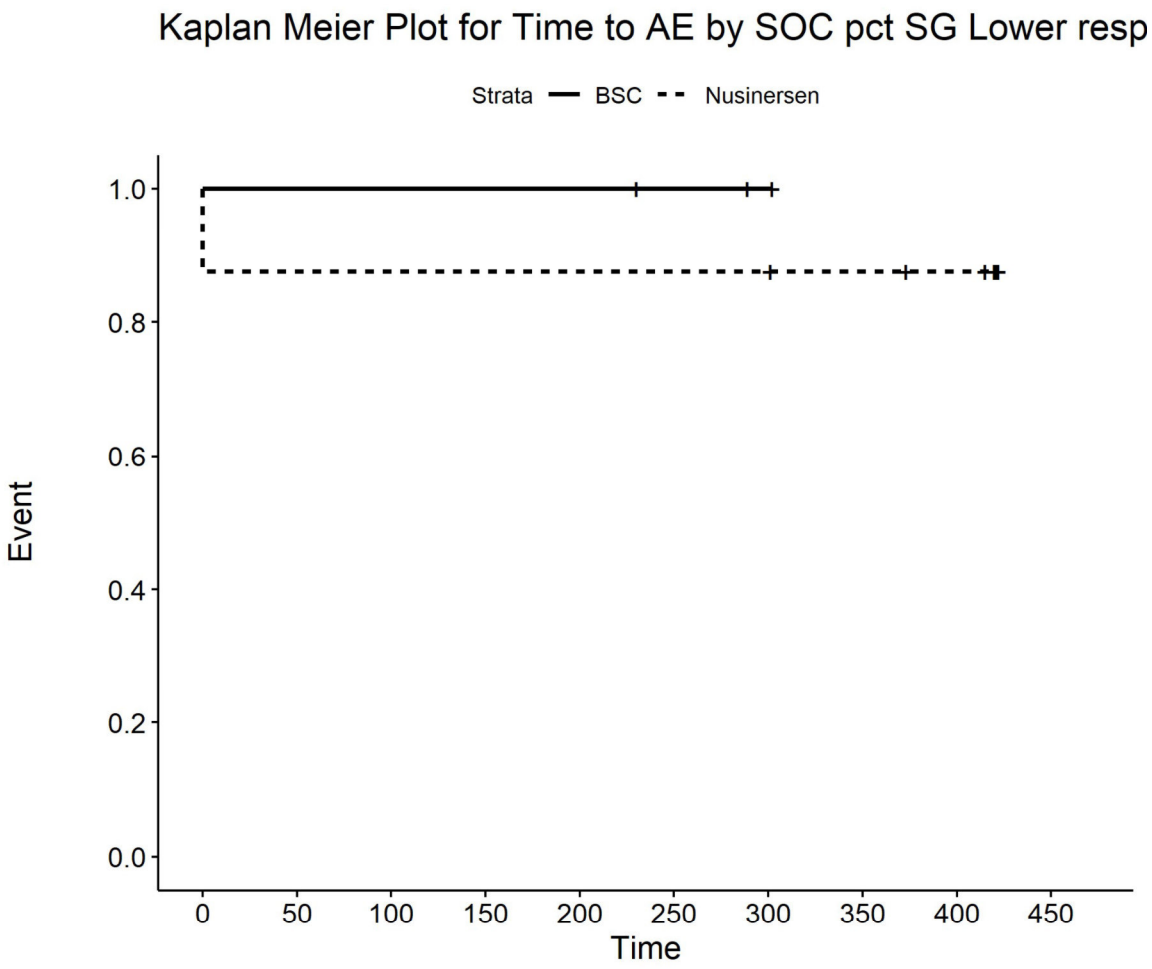
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



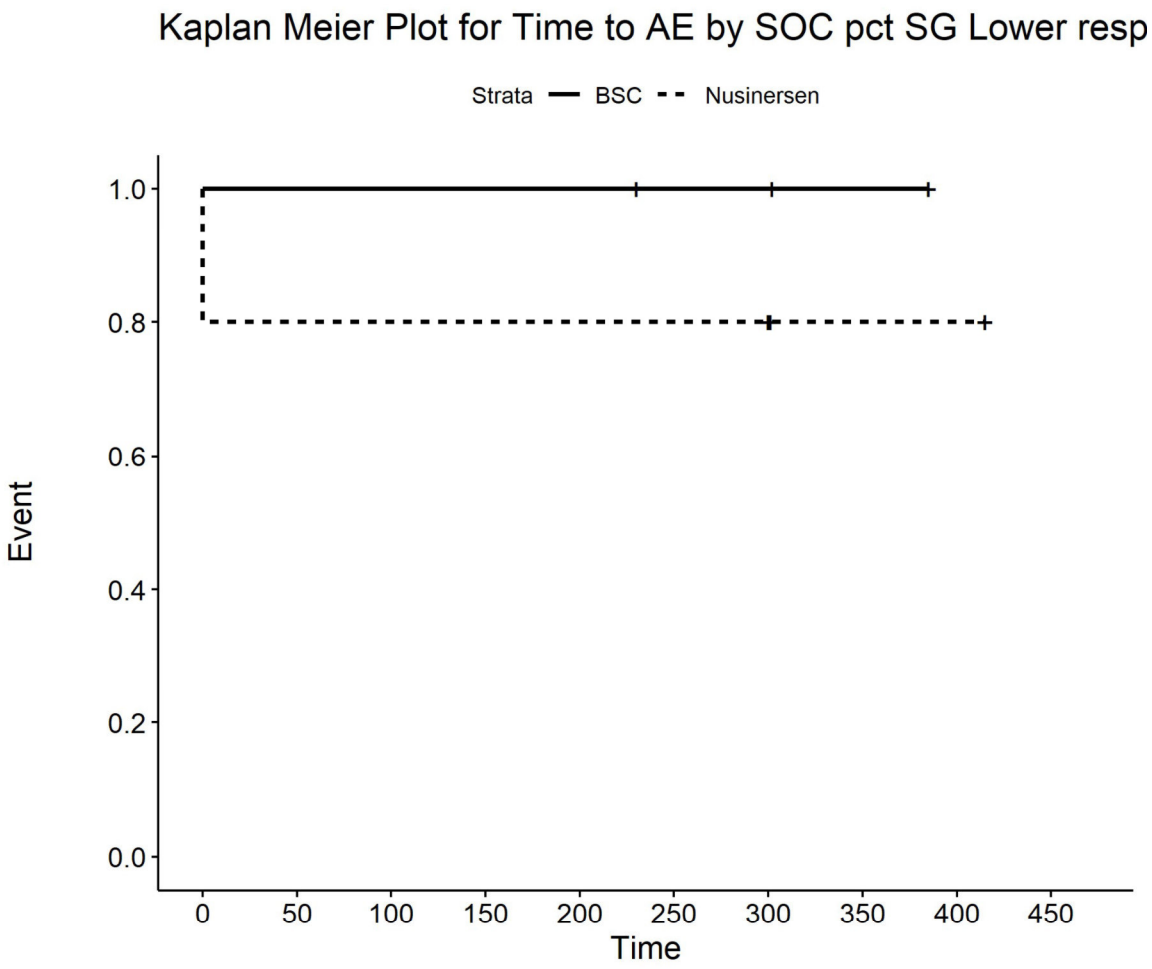
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	4	4	3	1	1	0



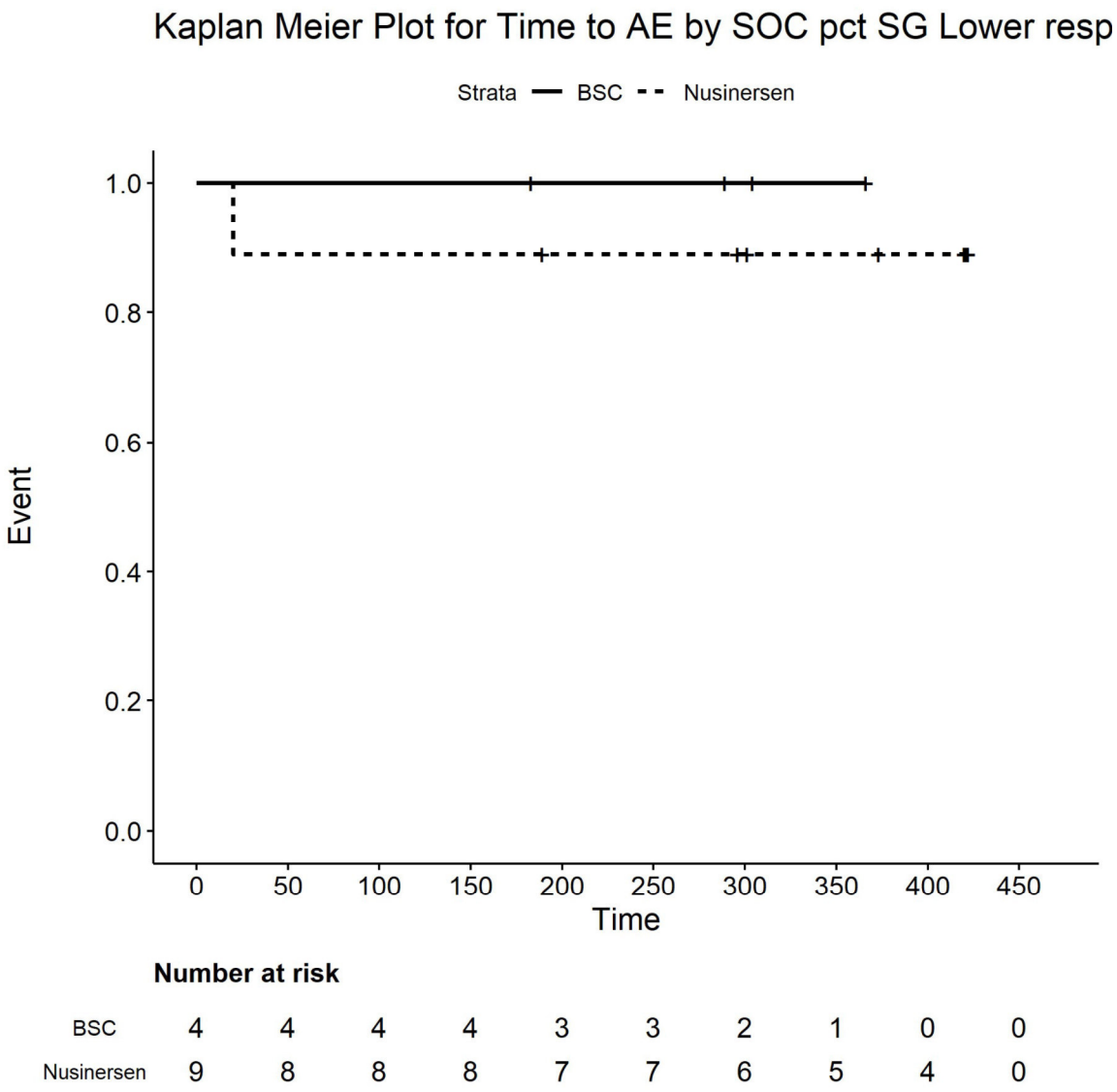
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	6	5	0



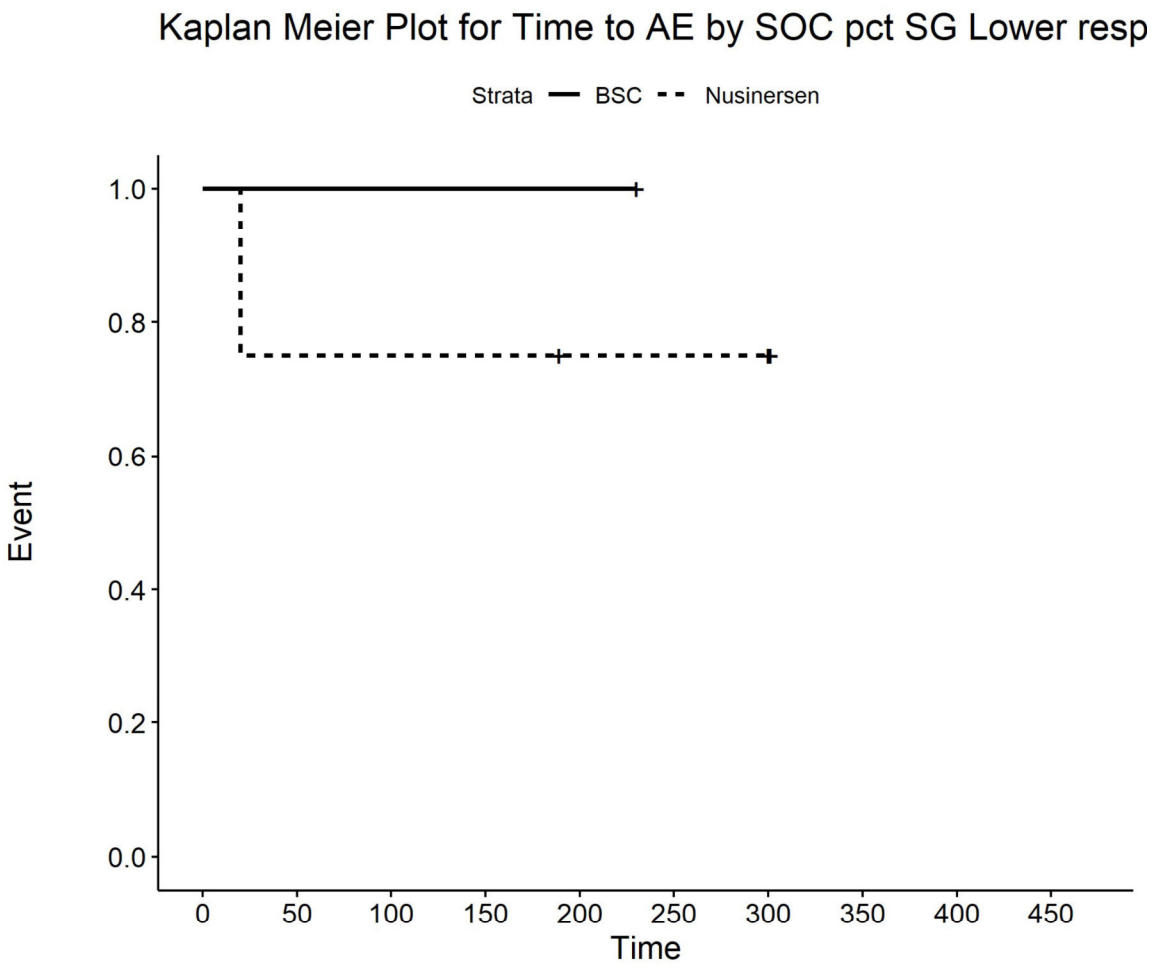
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



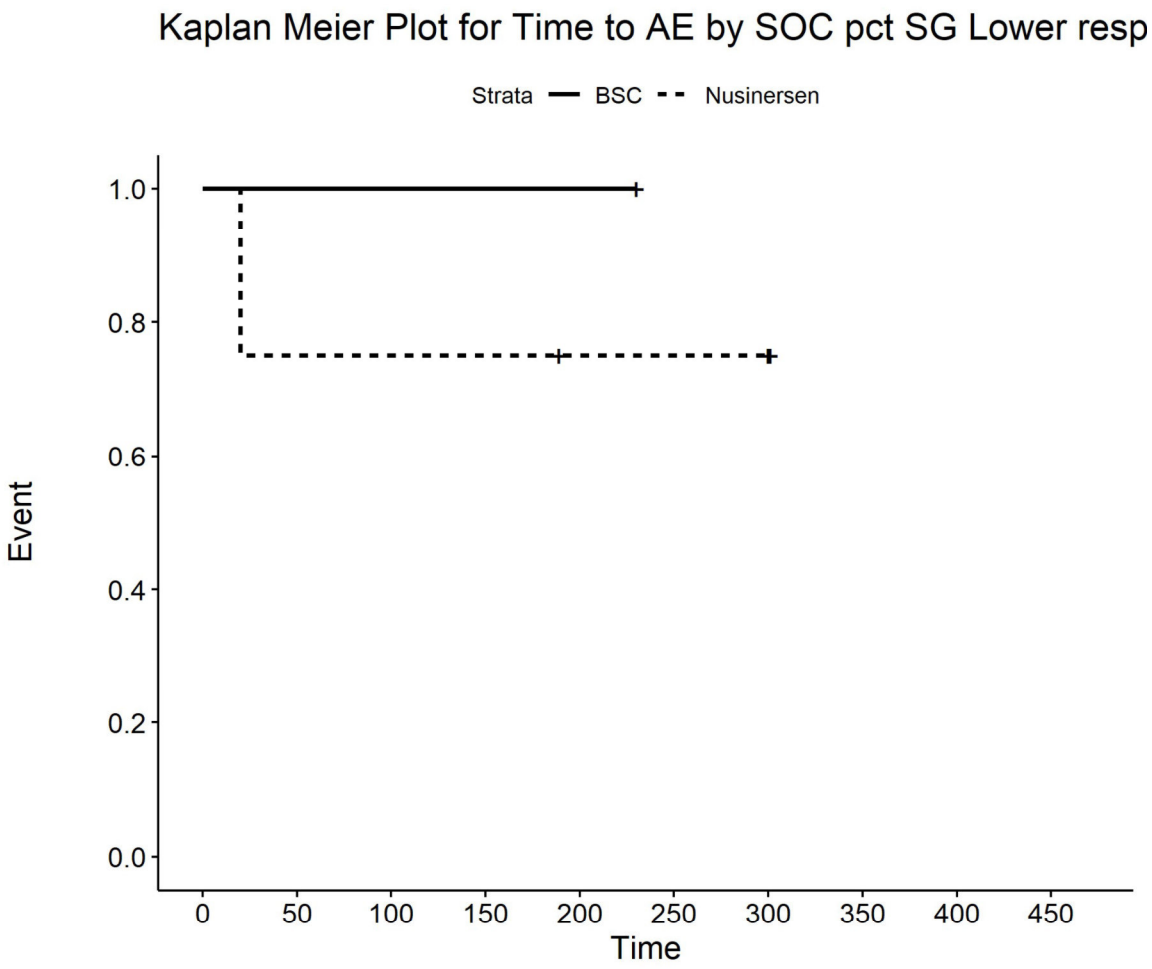
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	7	7	6	5	4	0



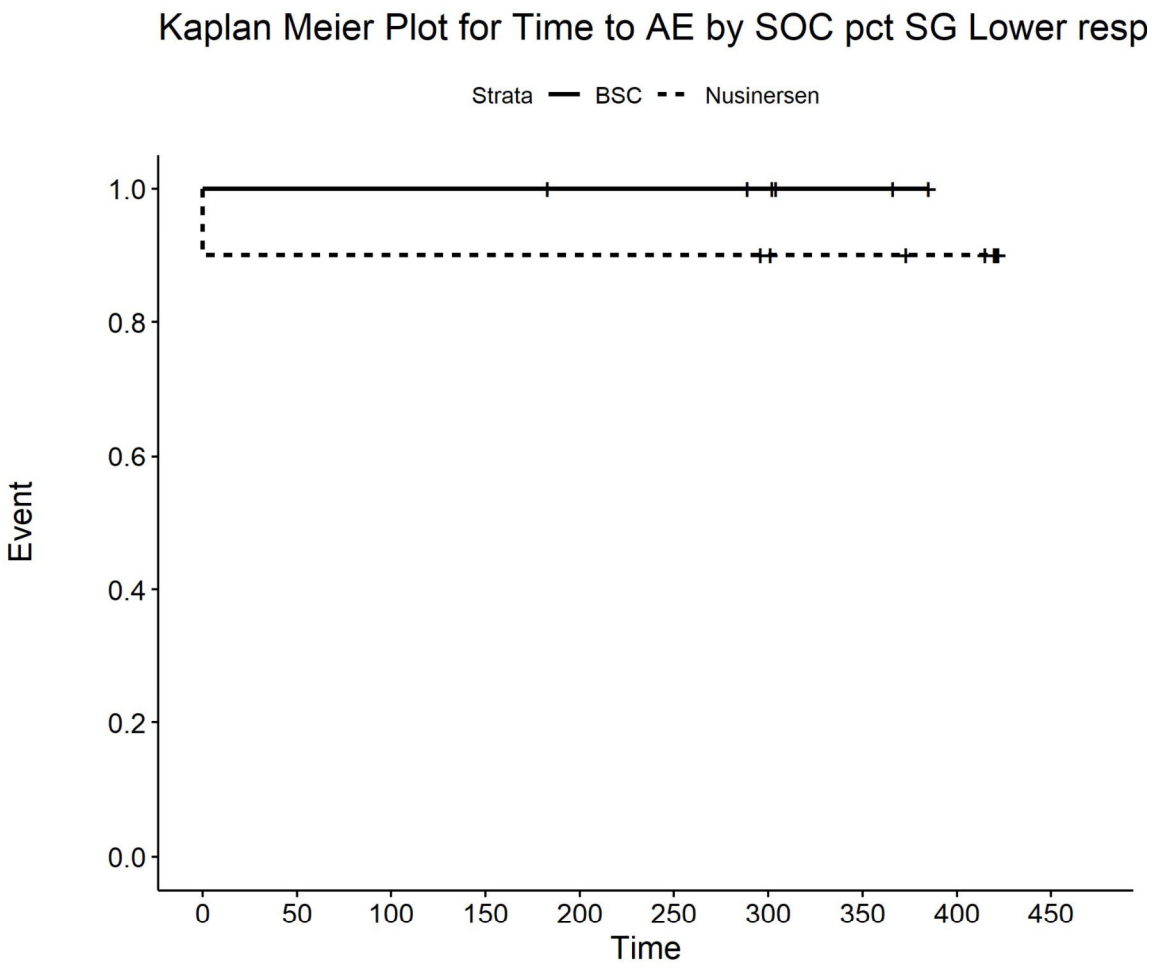
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



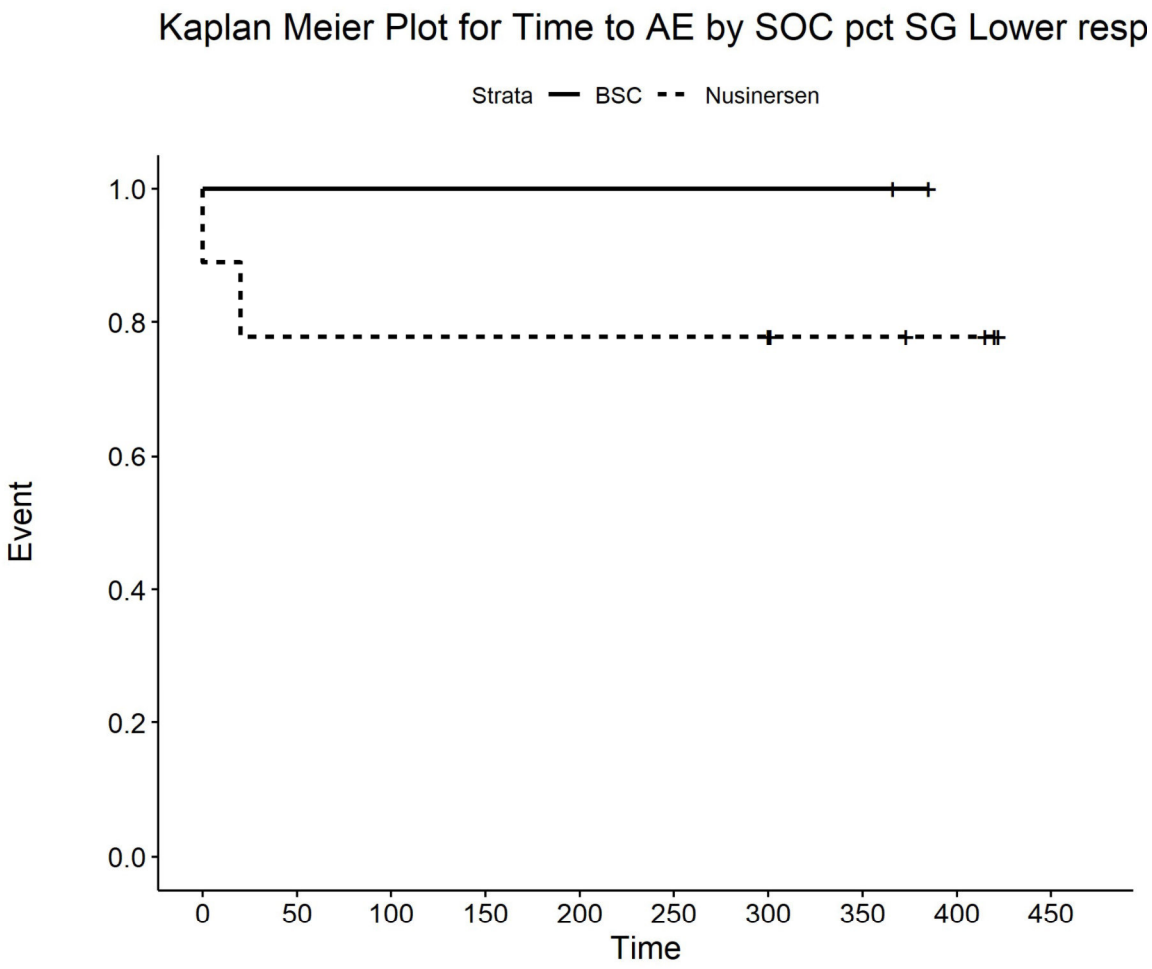
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



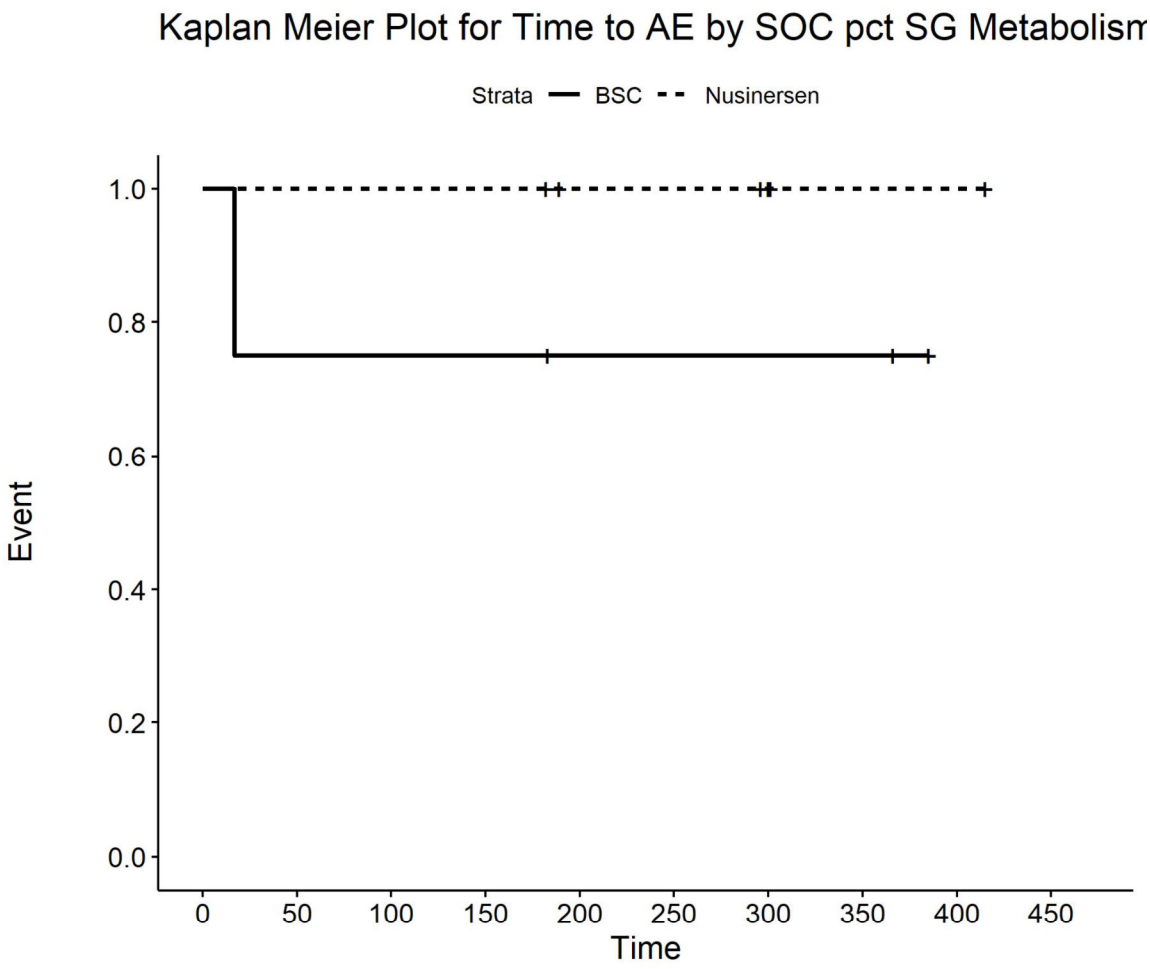
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	7	6	0



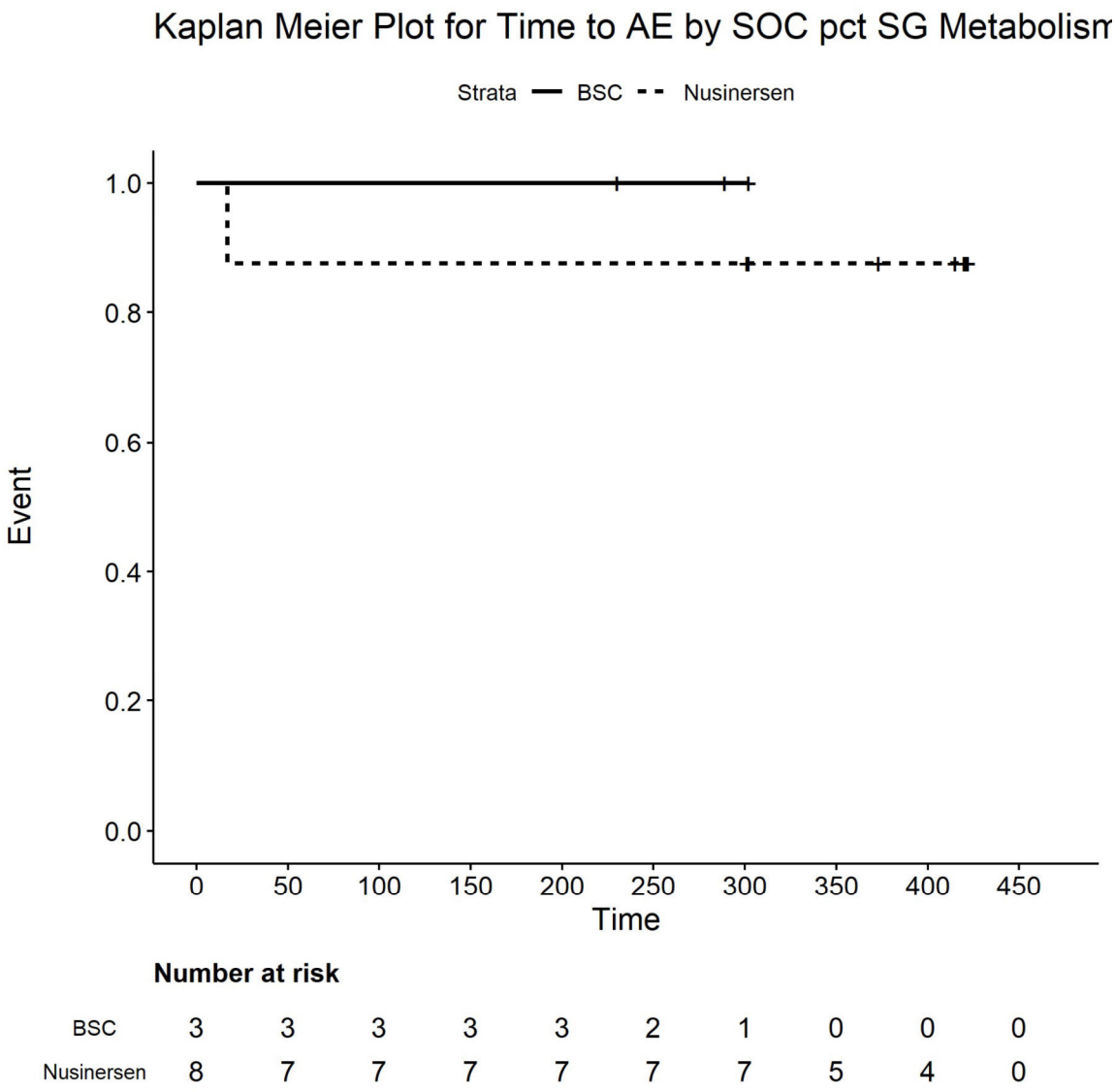
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	7	7	7	7	7	4	3	0



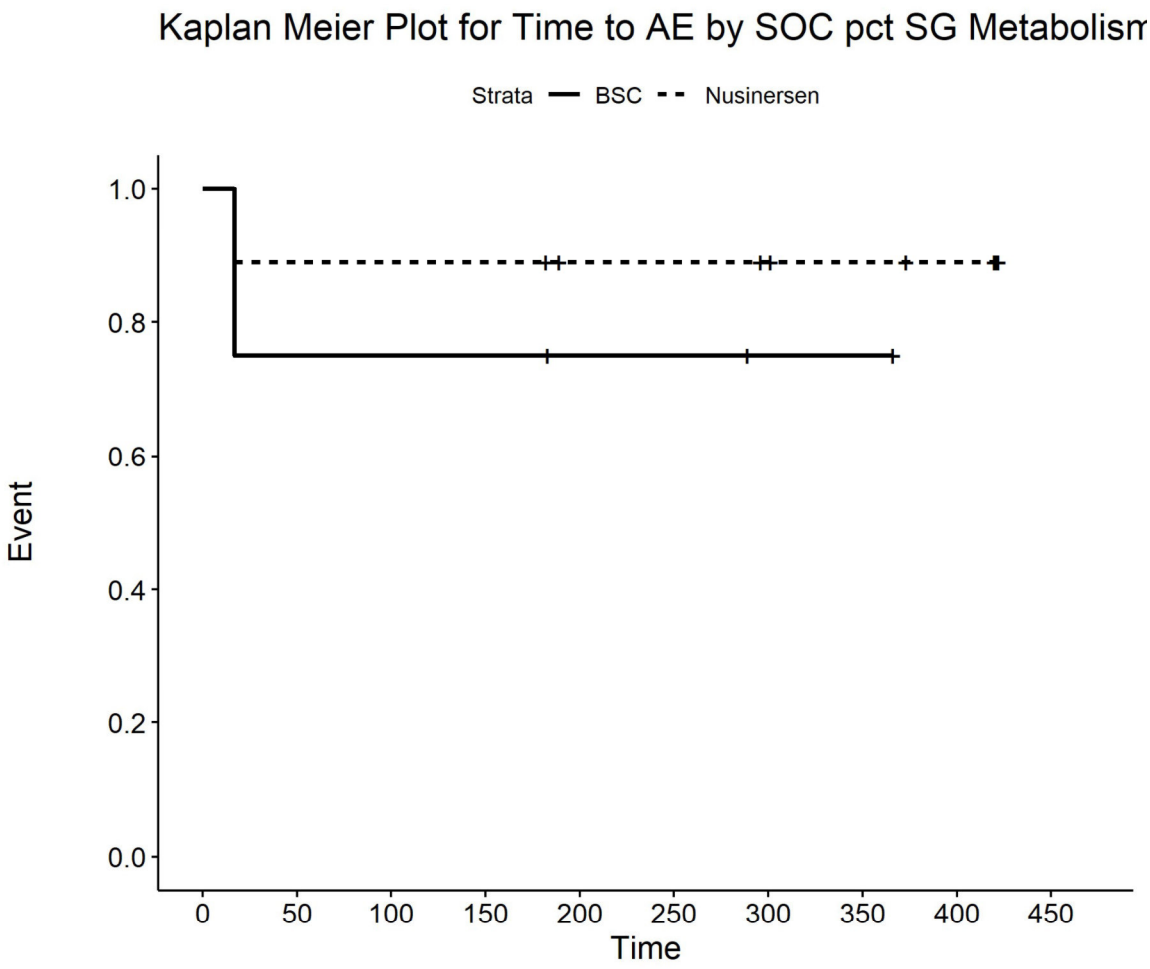
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



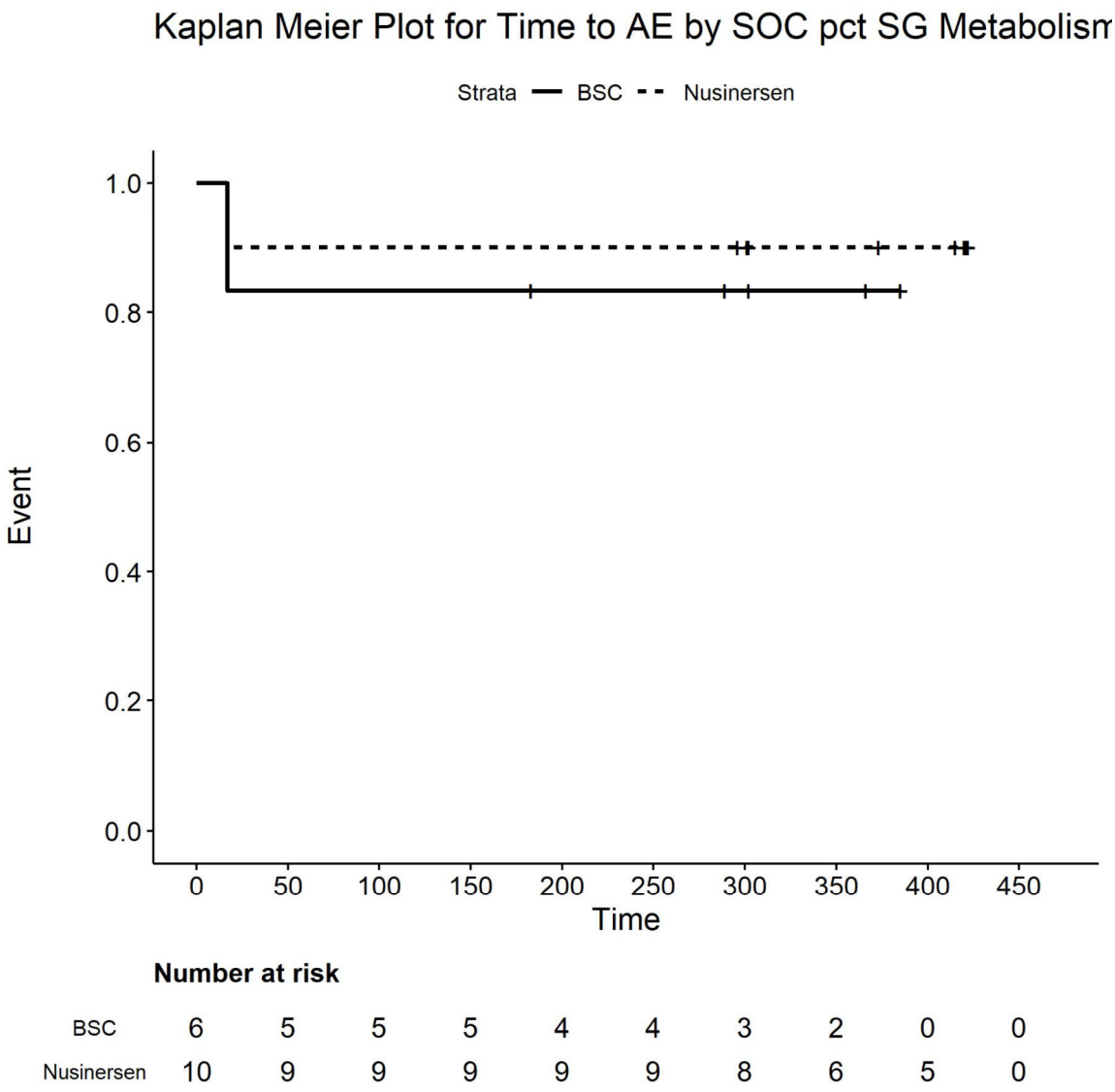
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



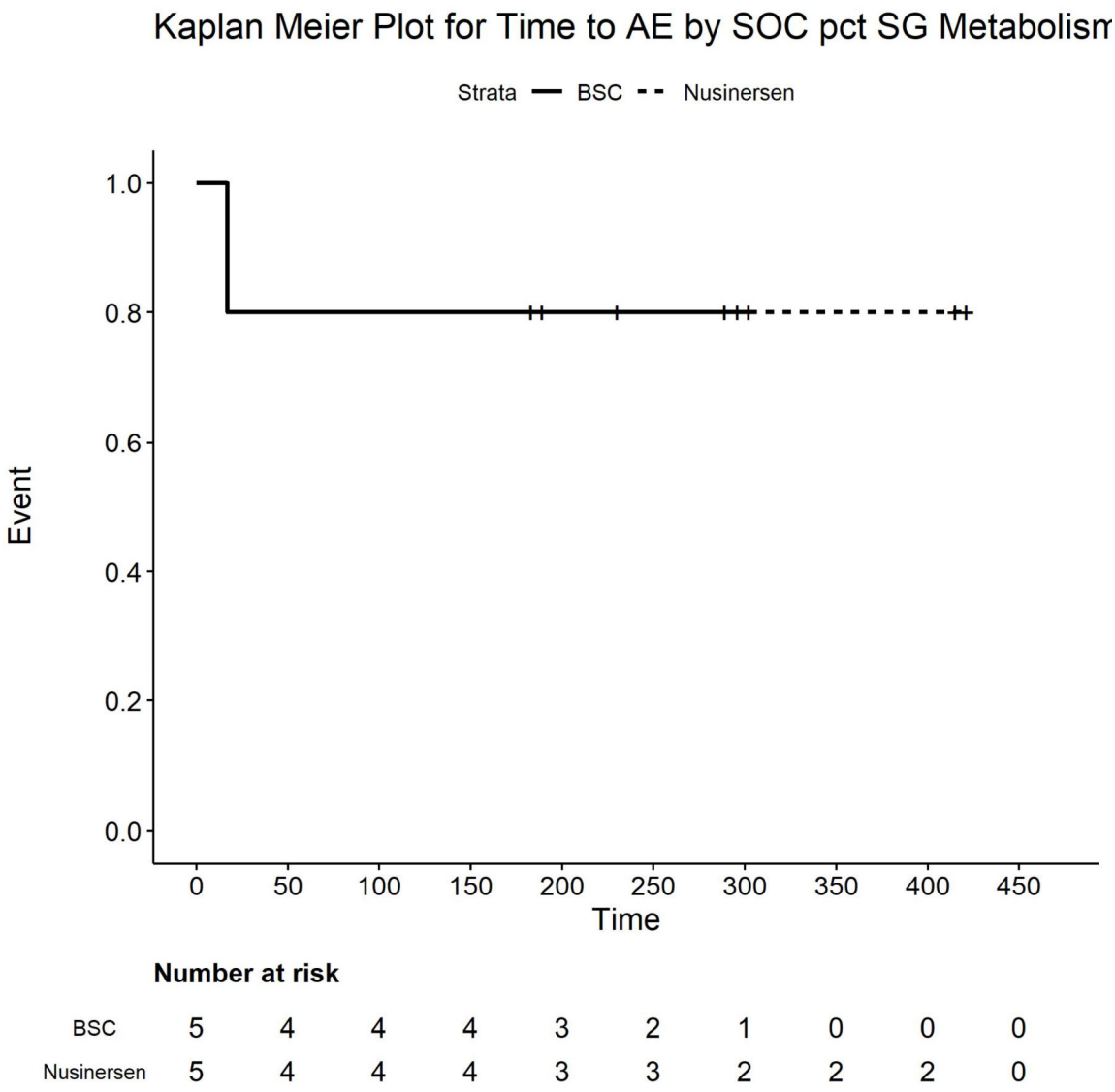
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



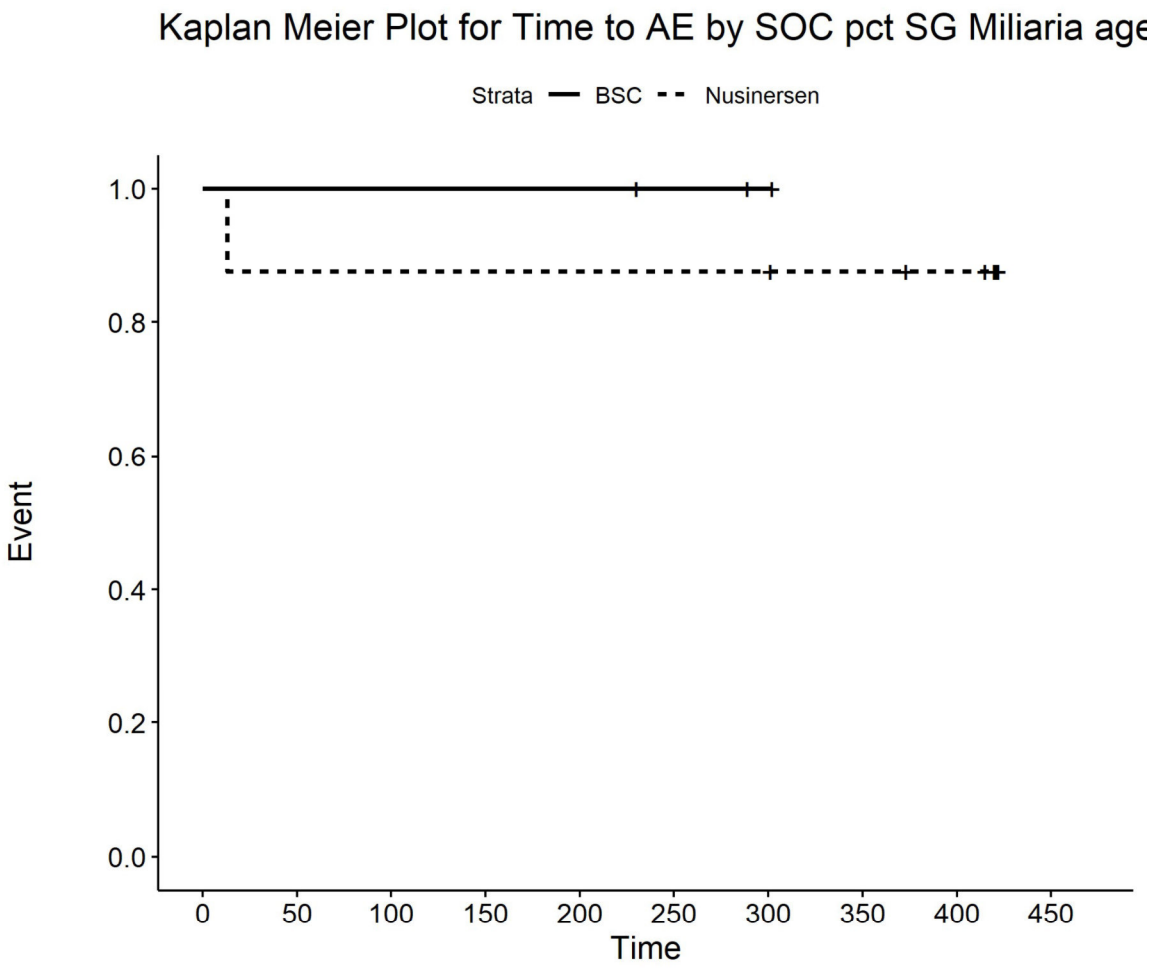
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



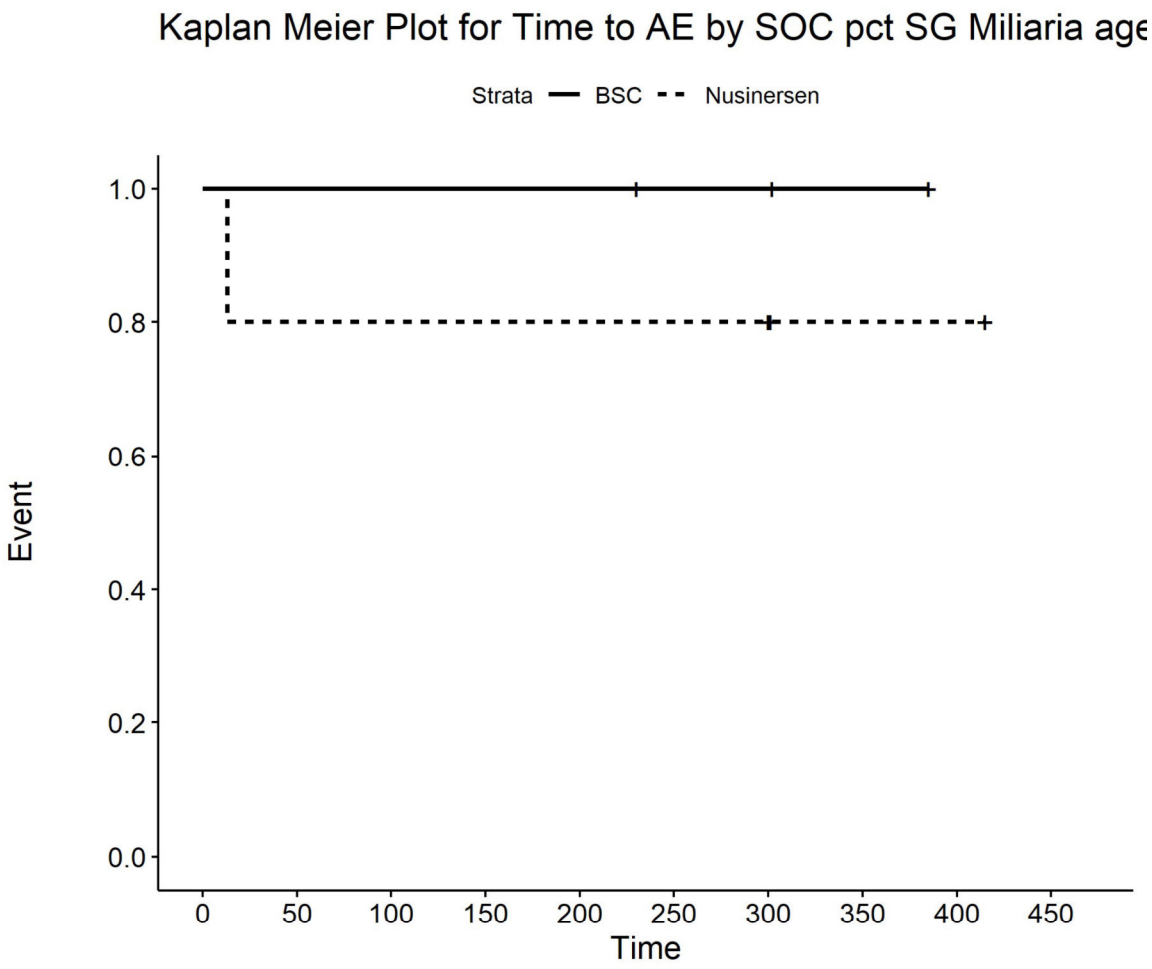
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	4	4	4	3	3	2	2	2	0



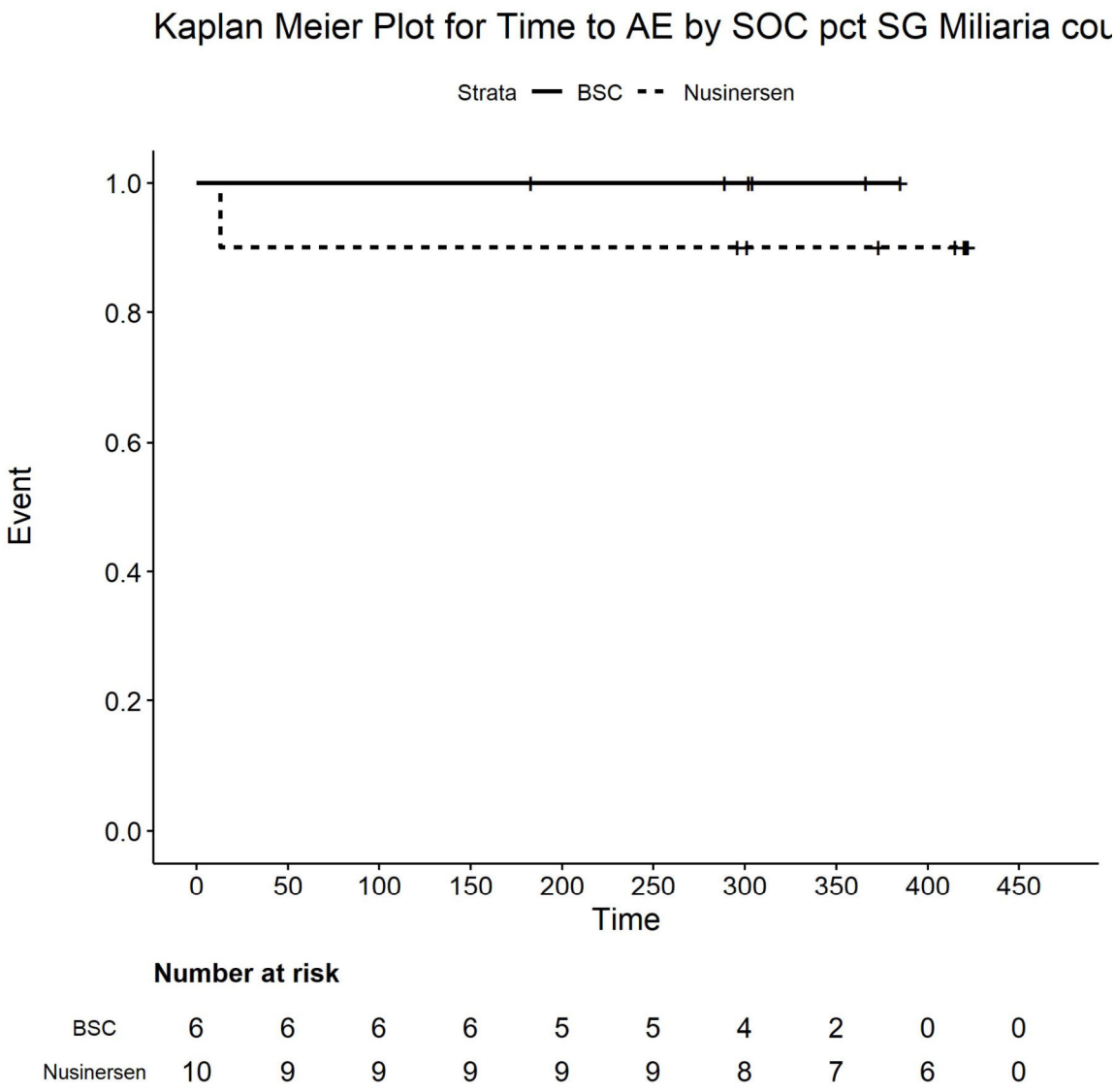
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	6	5	0



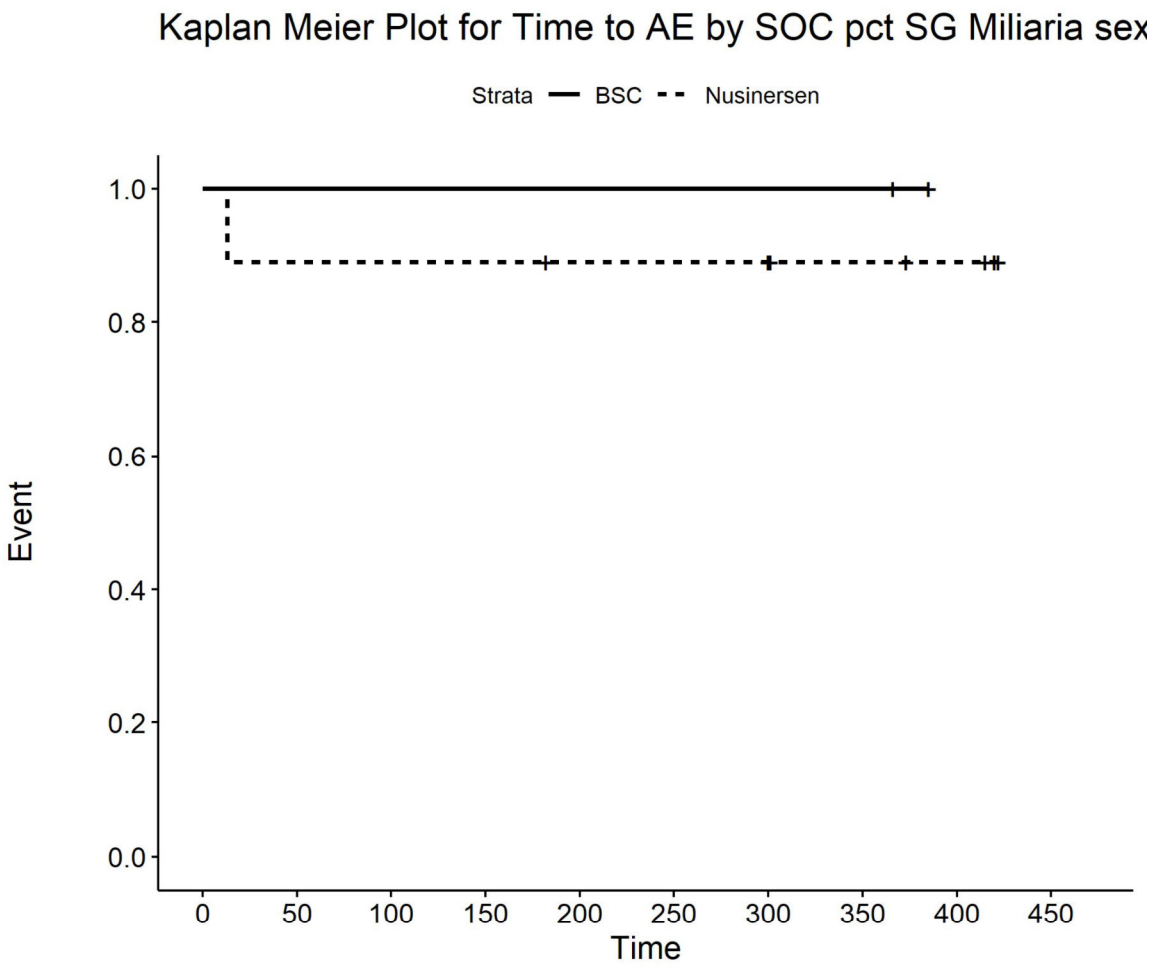
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



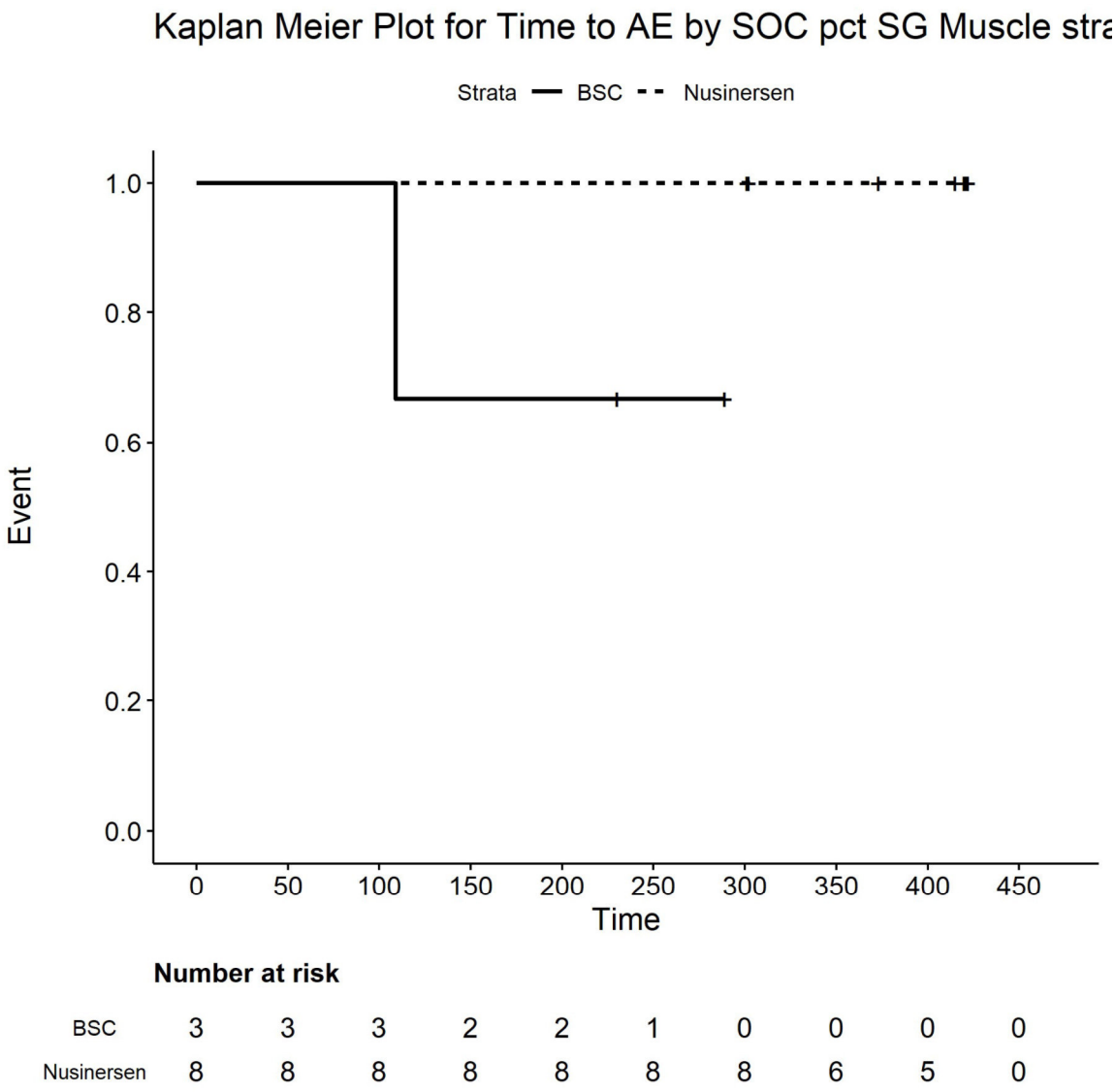
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	7	6	0



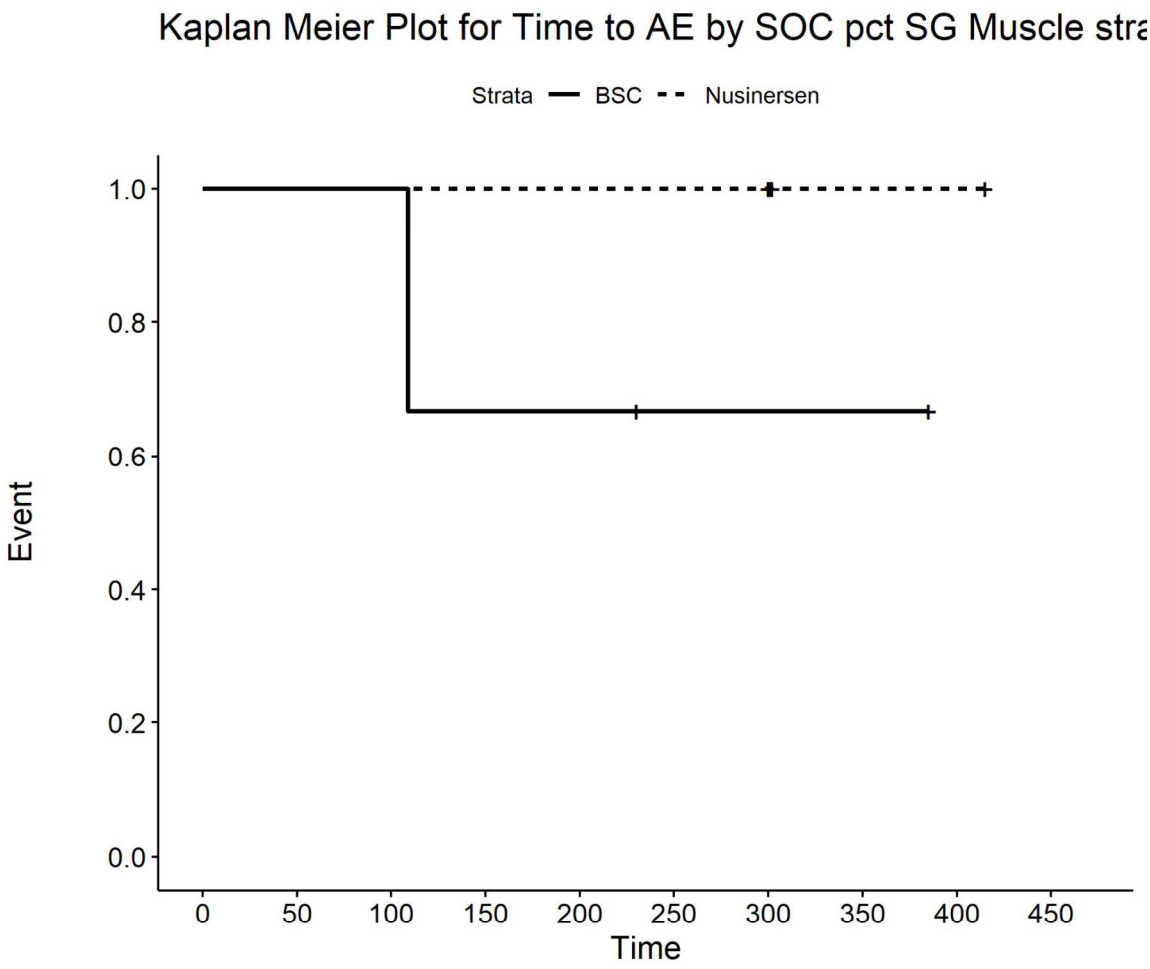
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



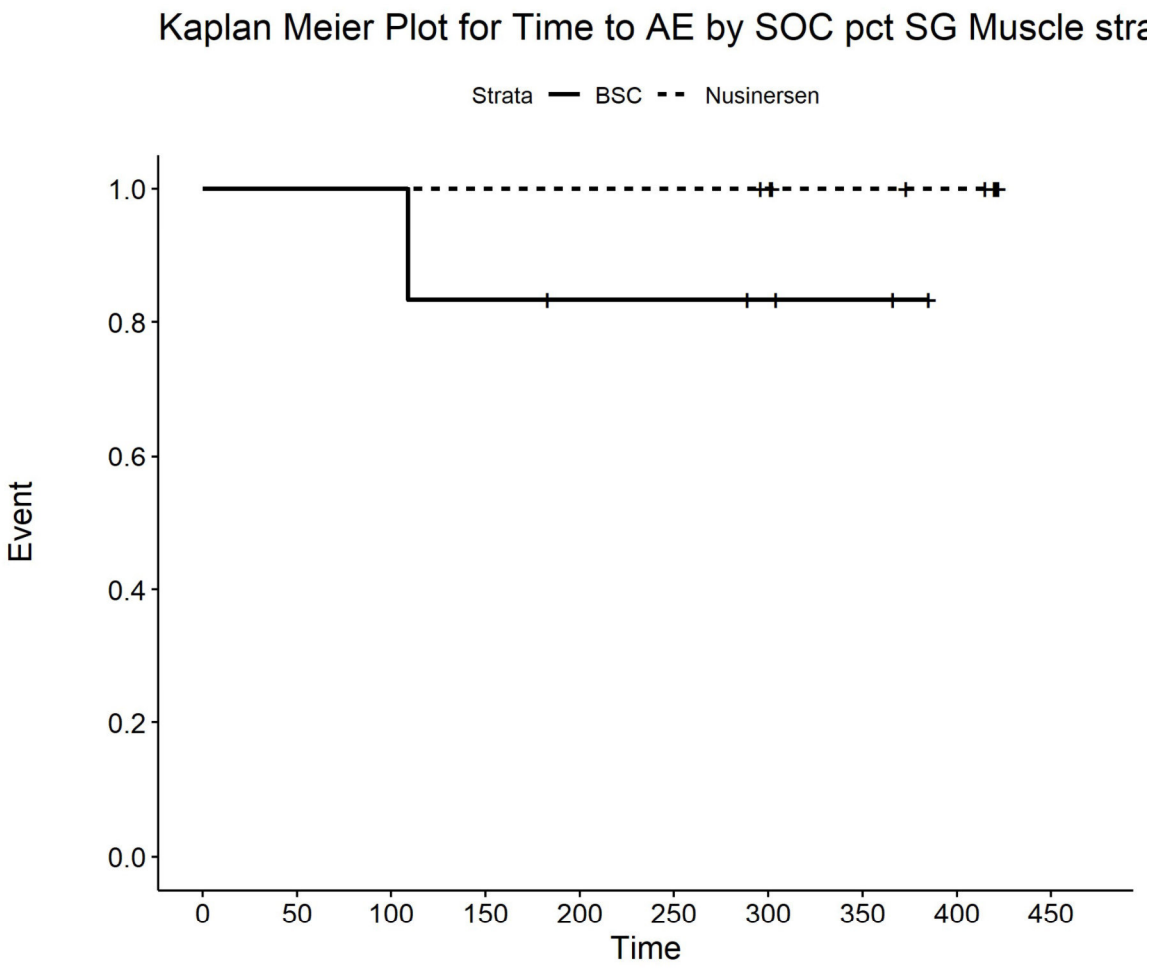
Number at risk

BSC	3	3	3	2	2	1	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



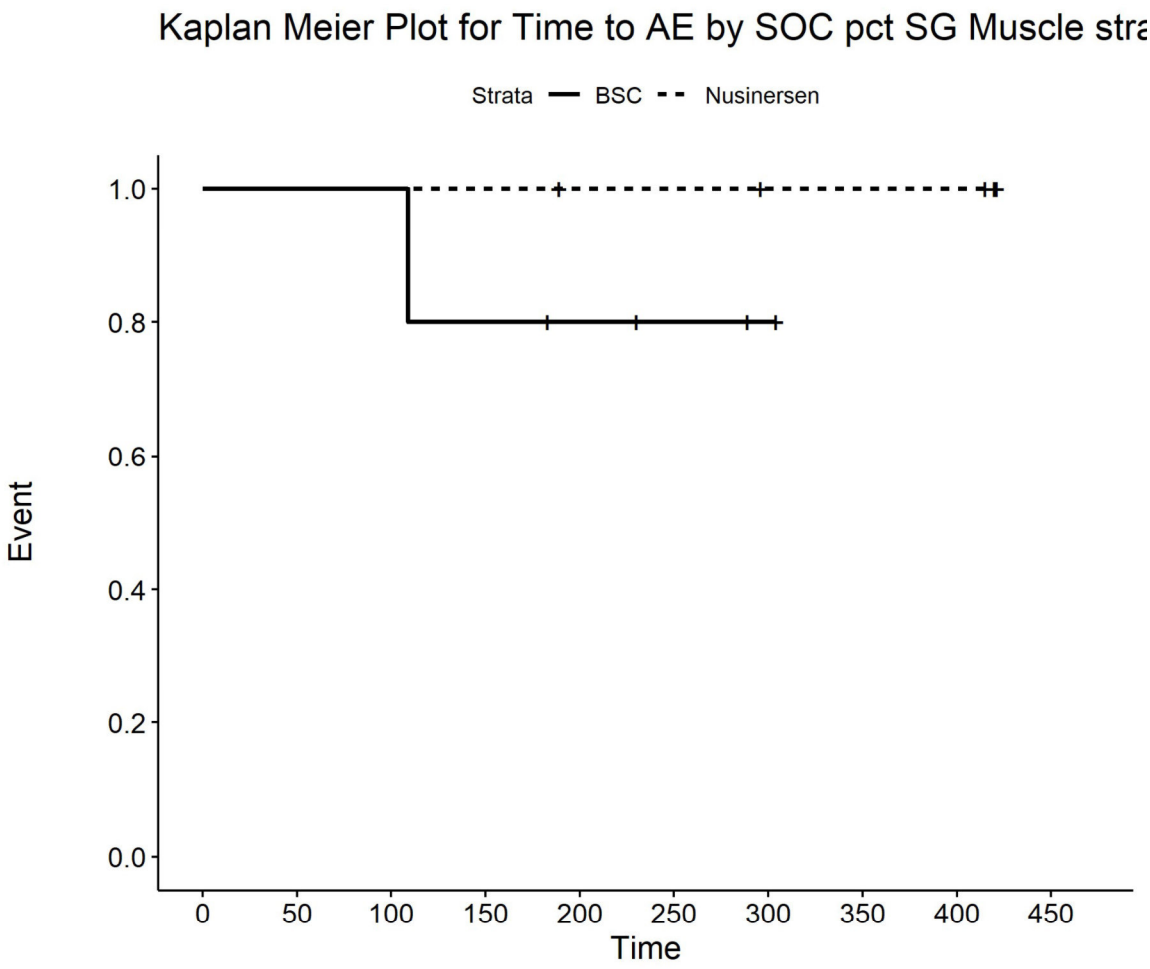
Number at risk

BSC	3	3	3	2	2	1	1	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



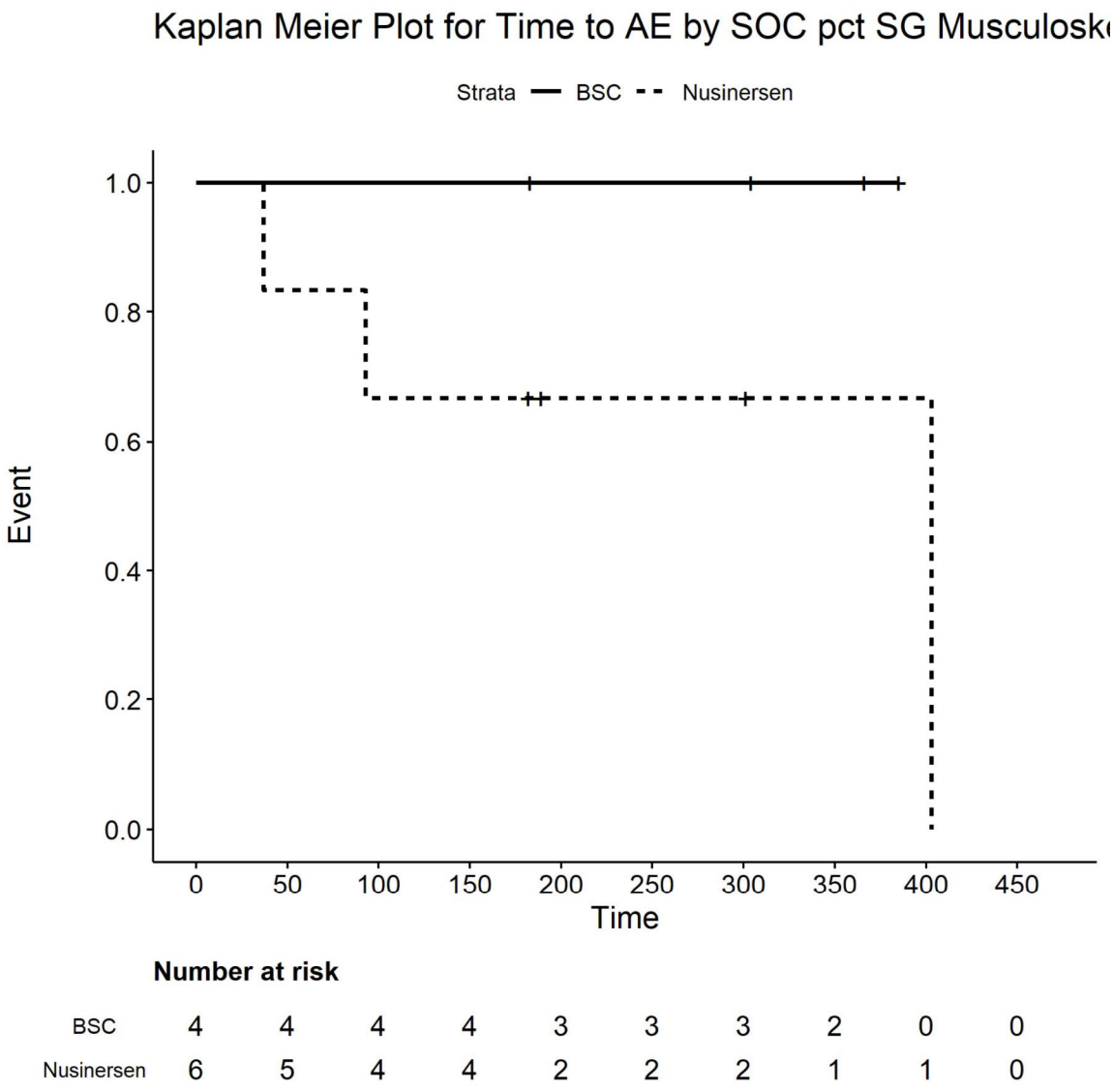
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



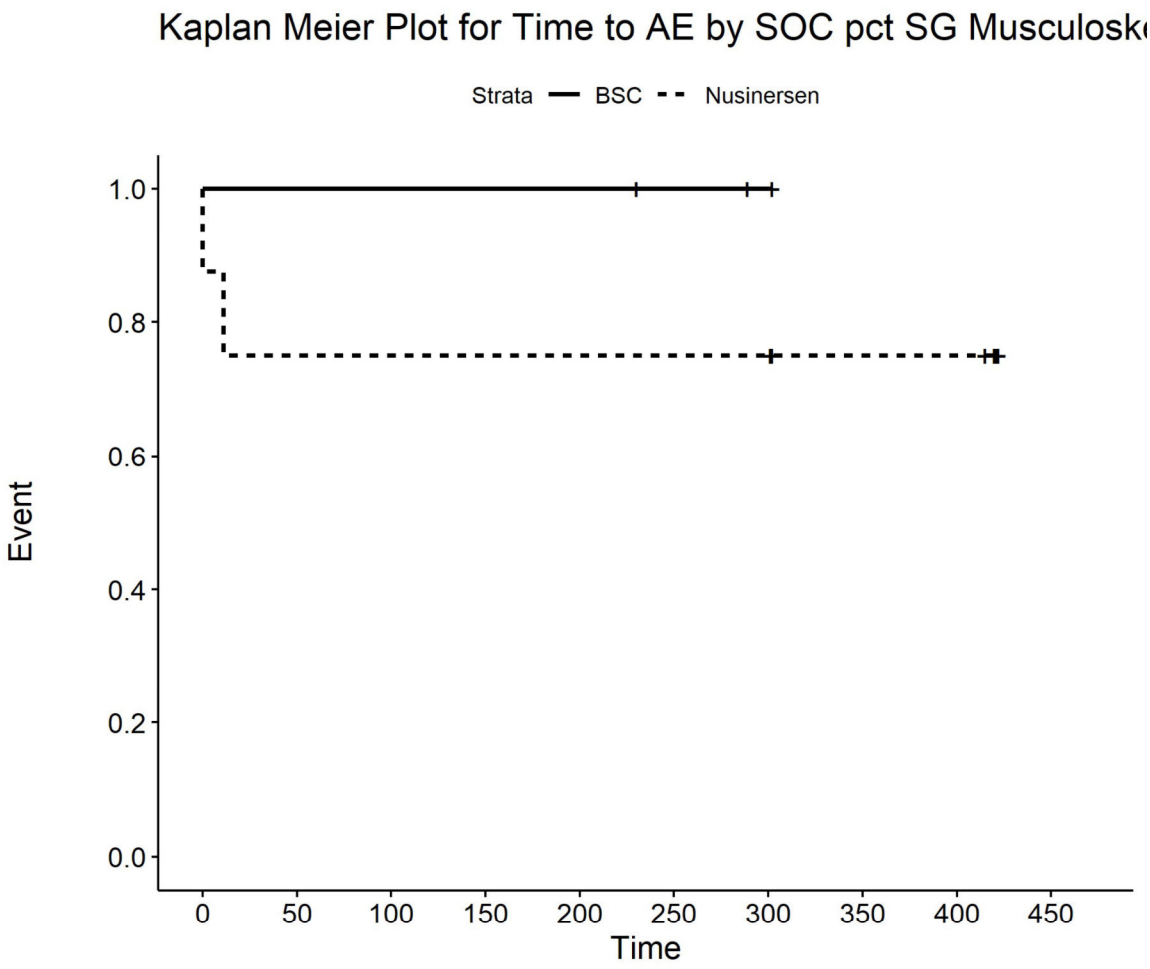
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



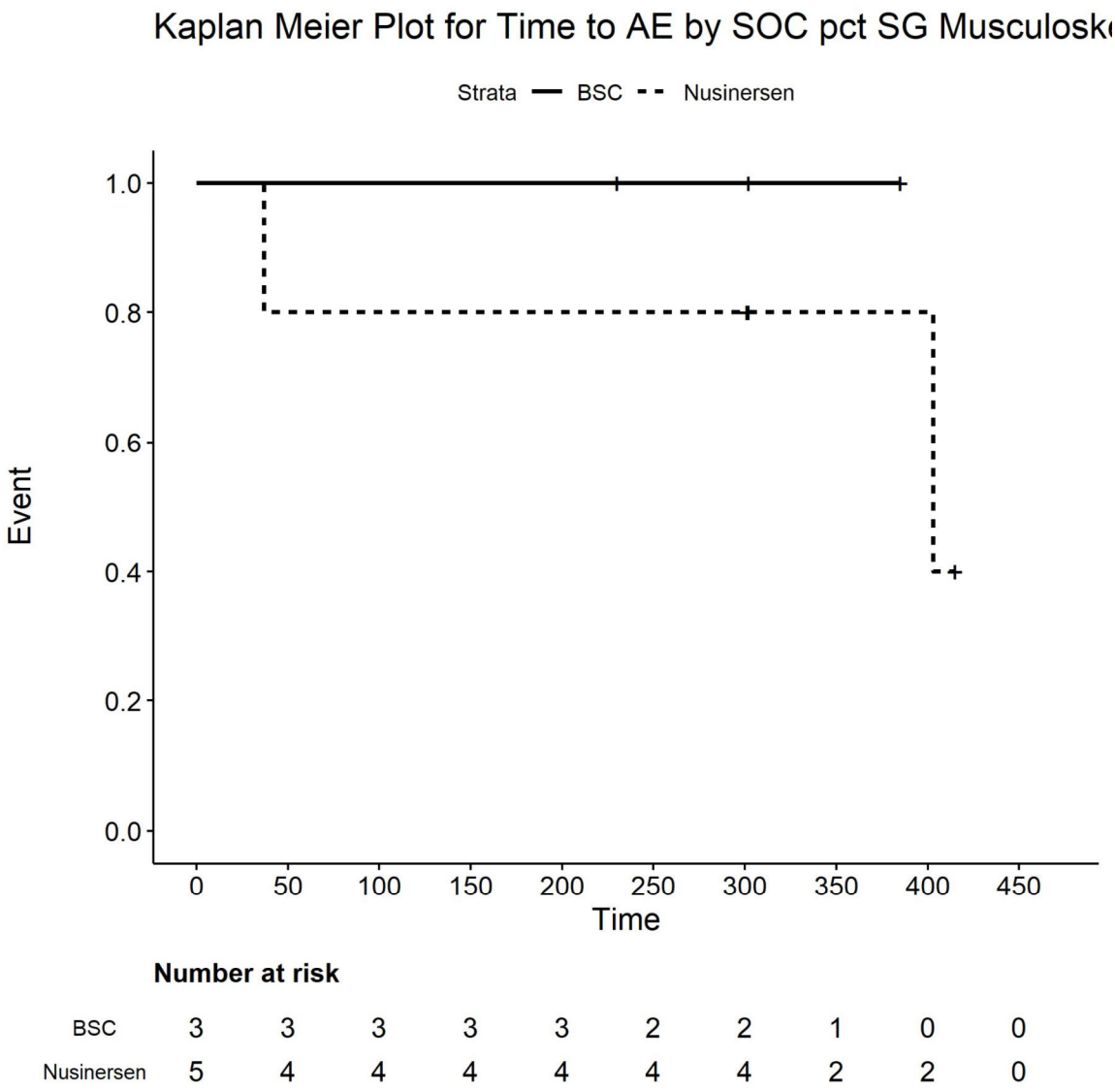
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	4	4	2	2	2	1	1	0



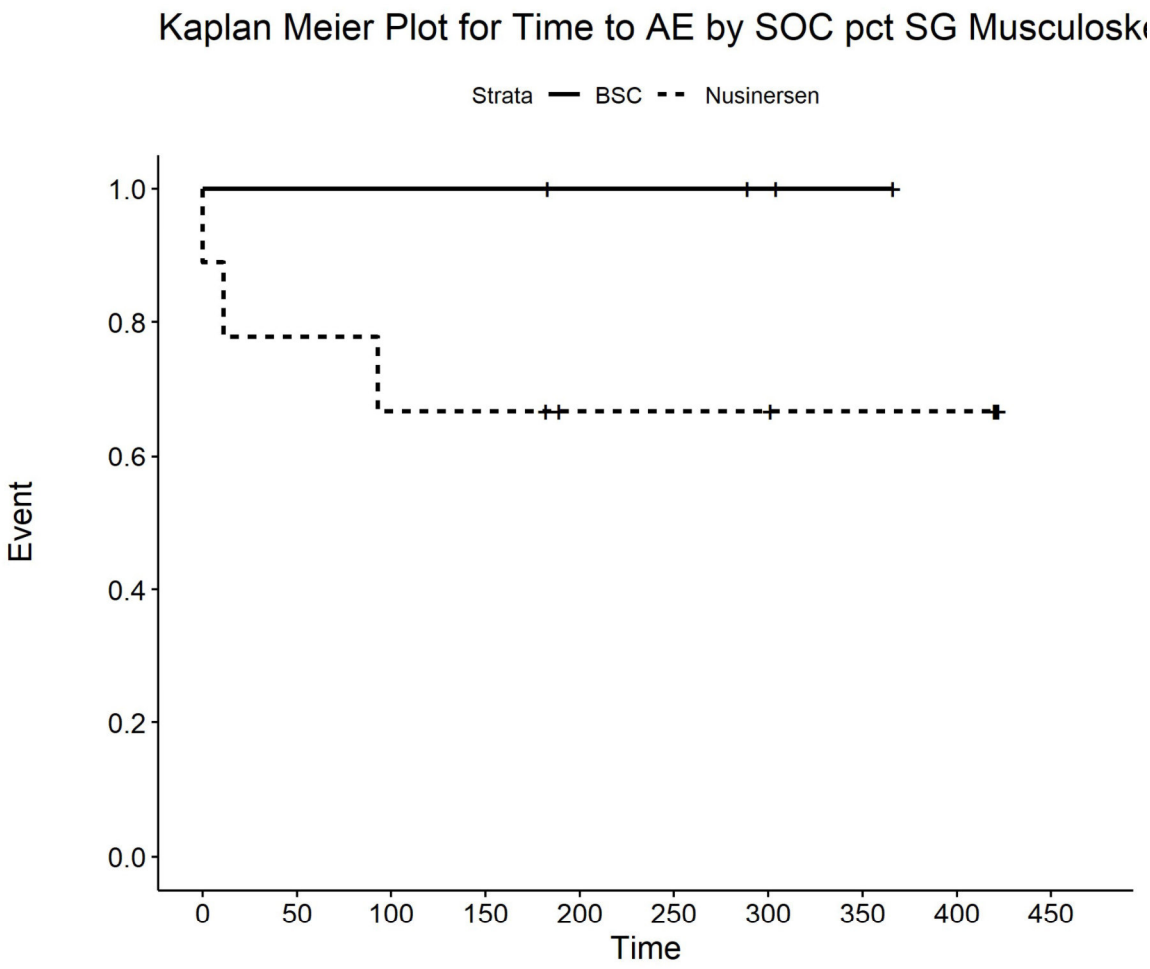
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	6	6	6	6	6	6	4	4	0



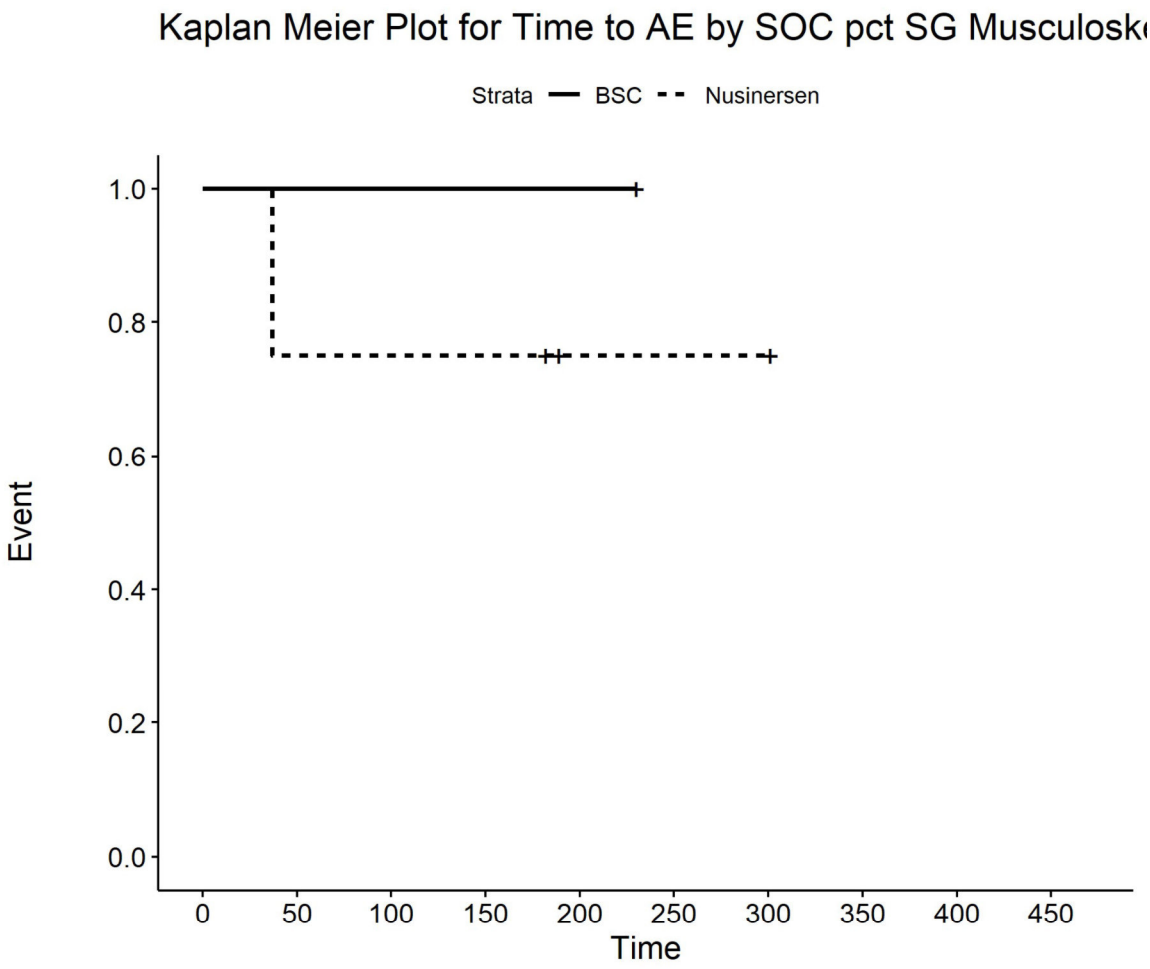
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



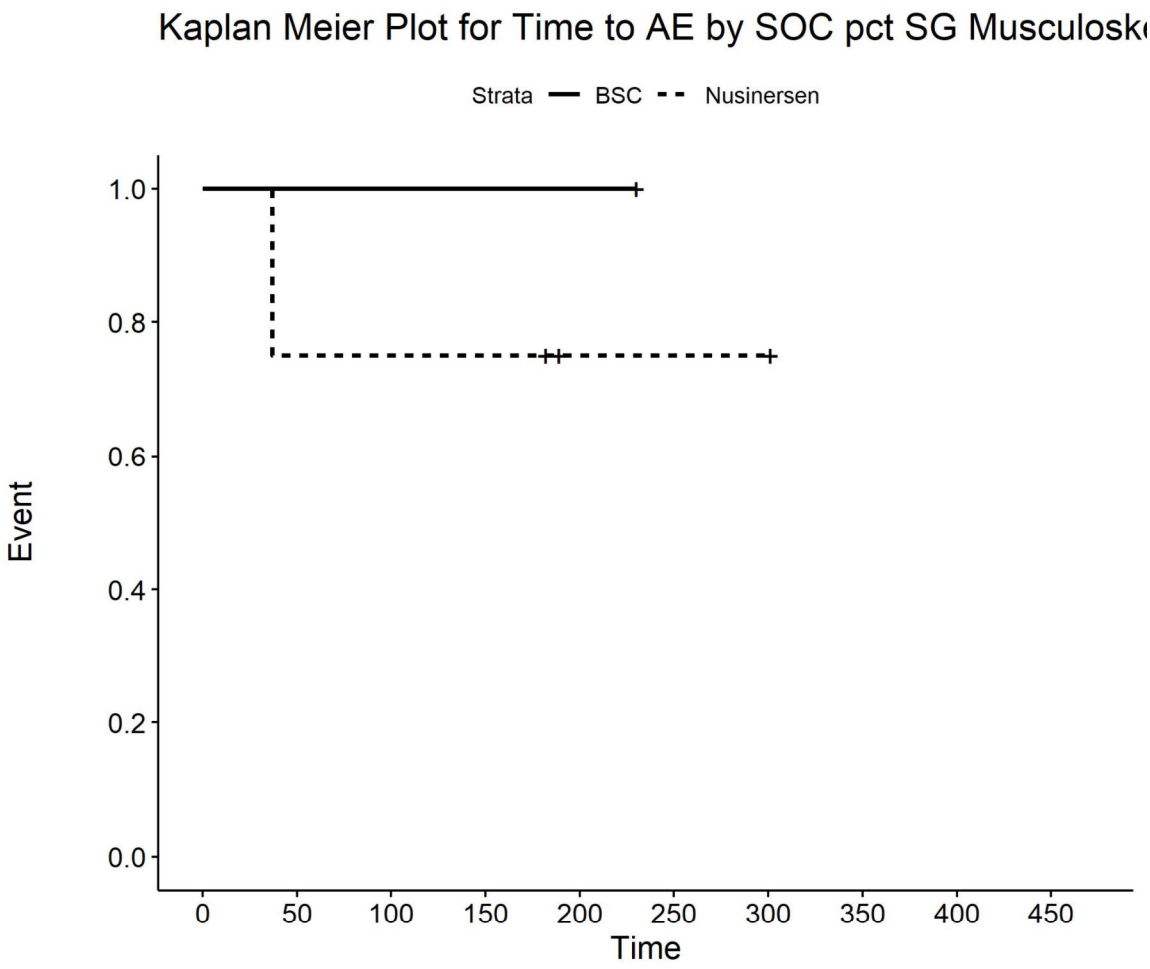
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	7	6	6	4	4	4	3	3	0



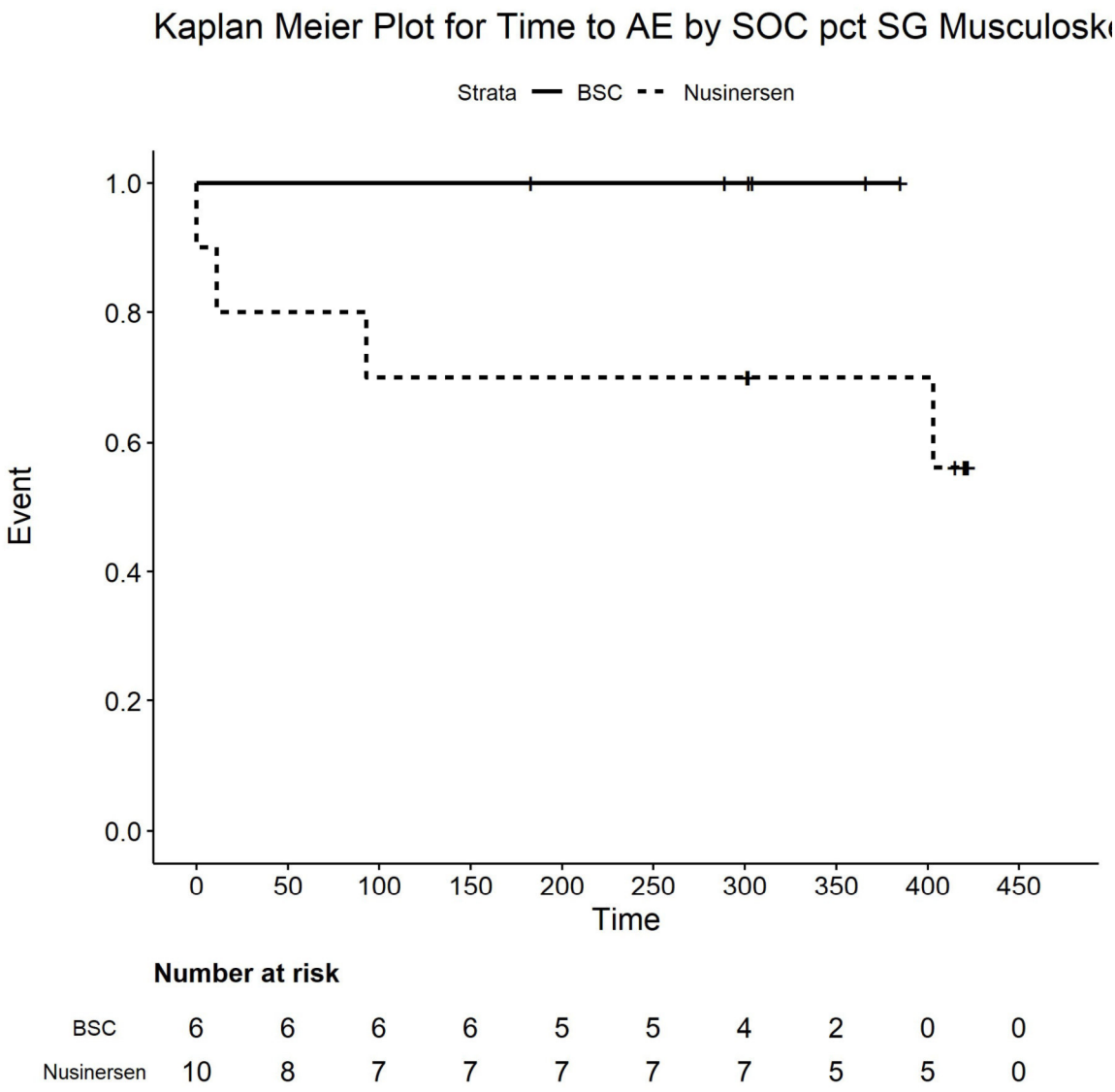
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



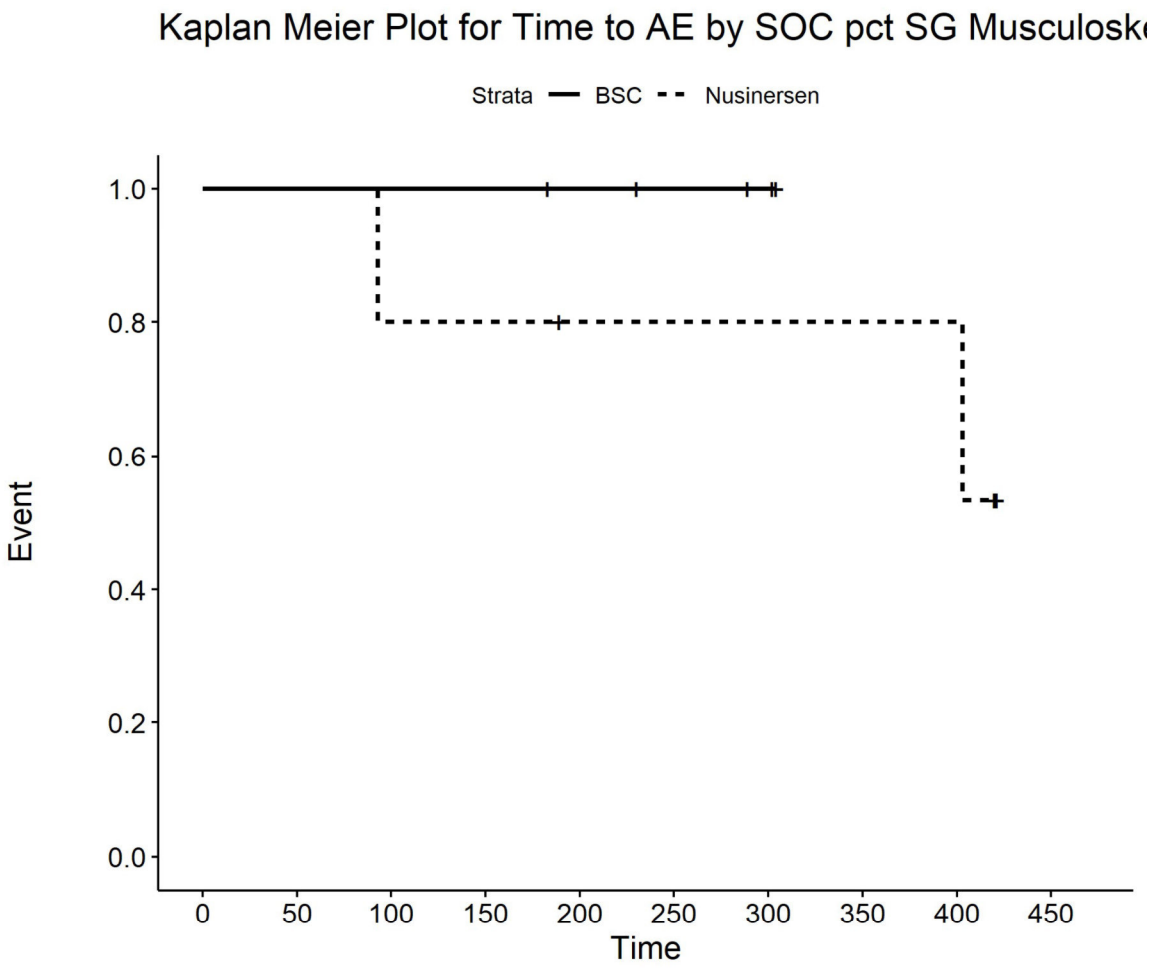
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



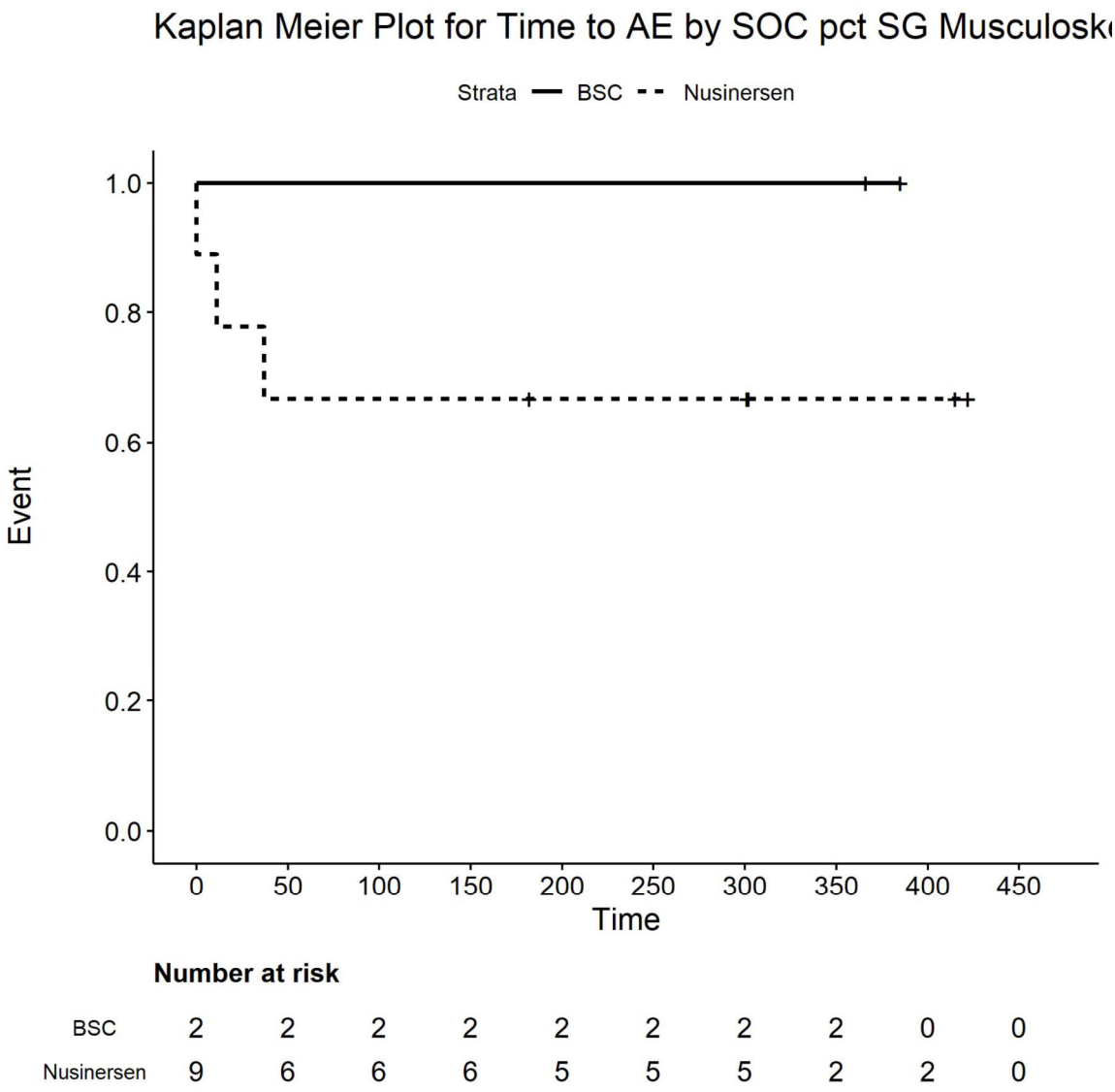
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	8	7	7	7	7	7	5	5	0



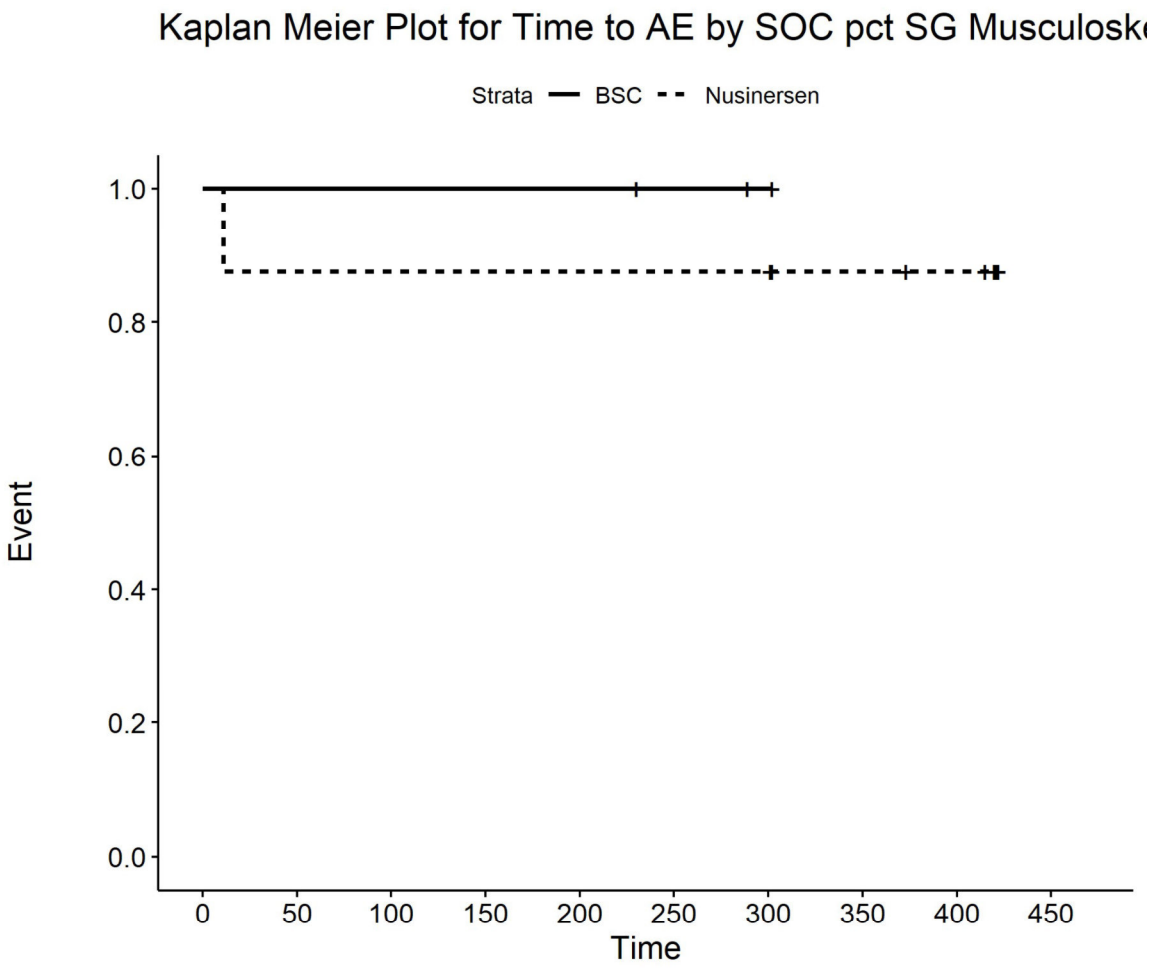
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	4	4	3	3	3	3	3	0



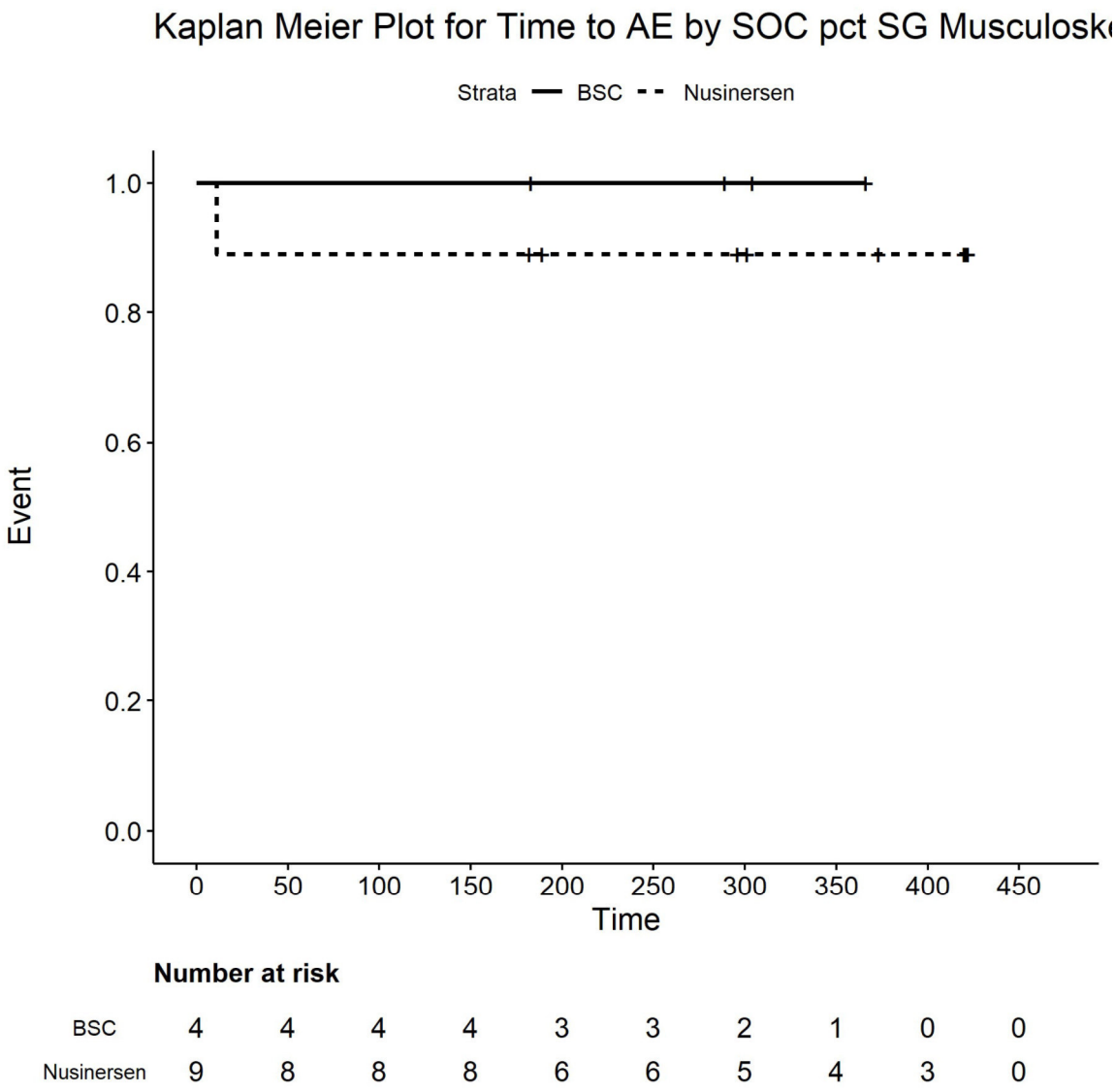
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	6	6	6	5	5	5	2	2	0



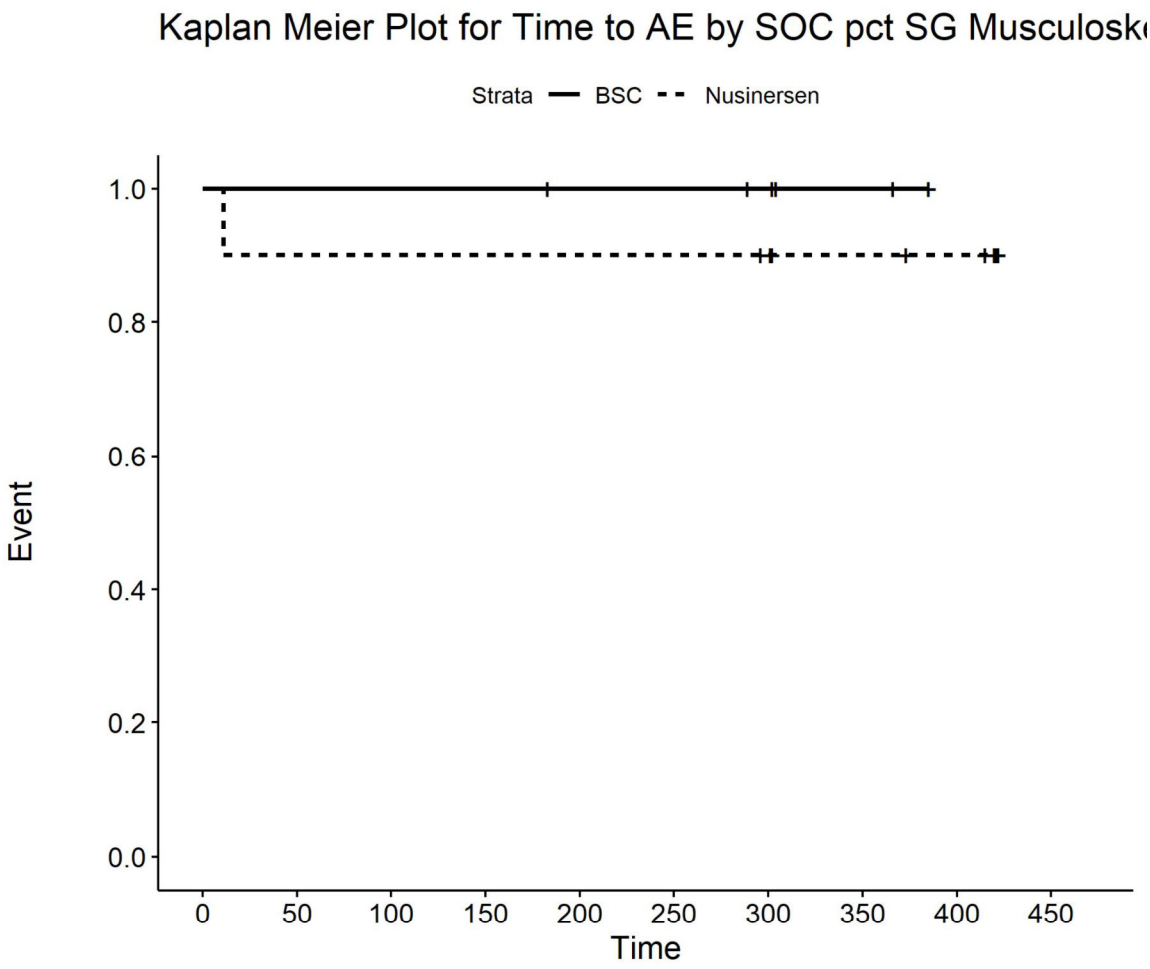
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



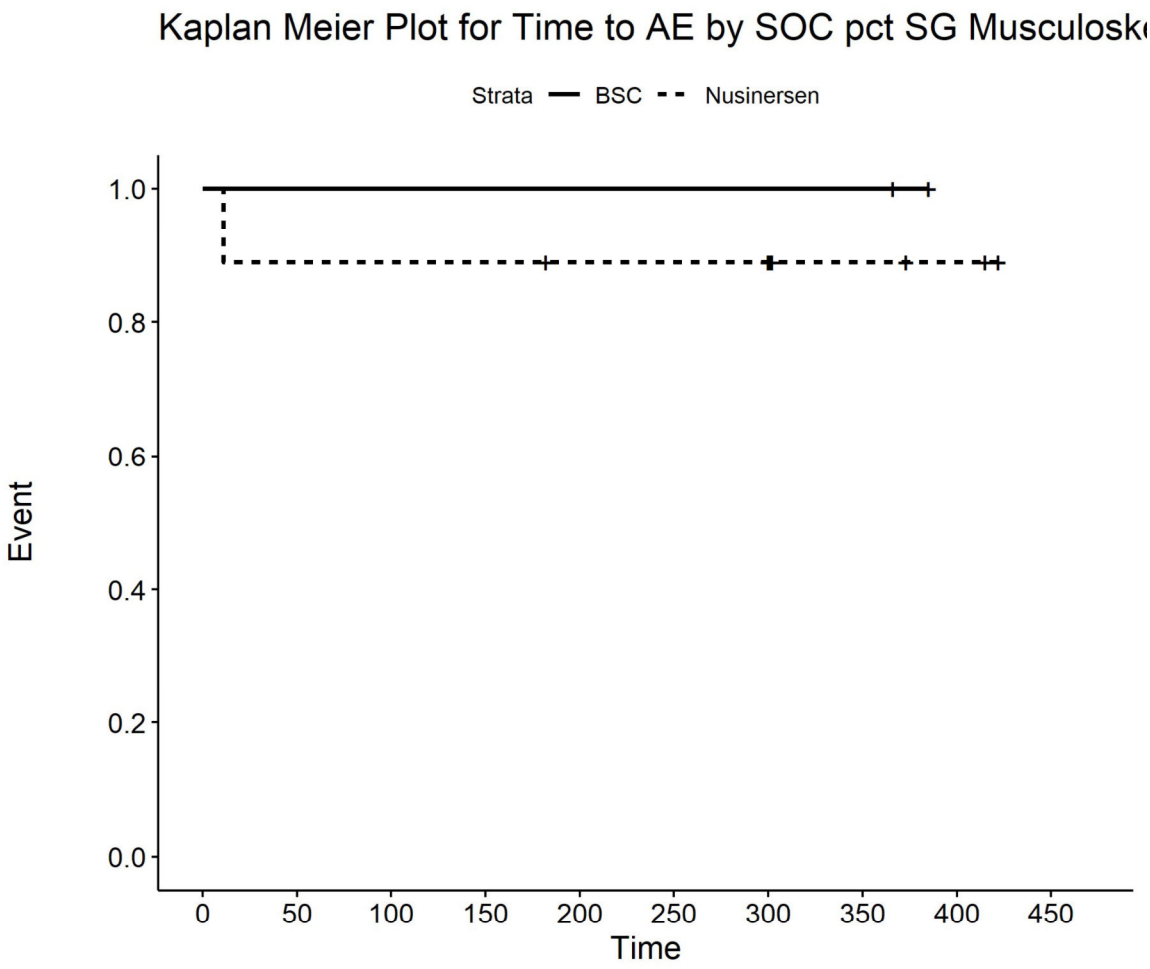
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



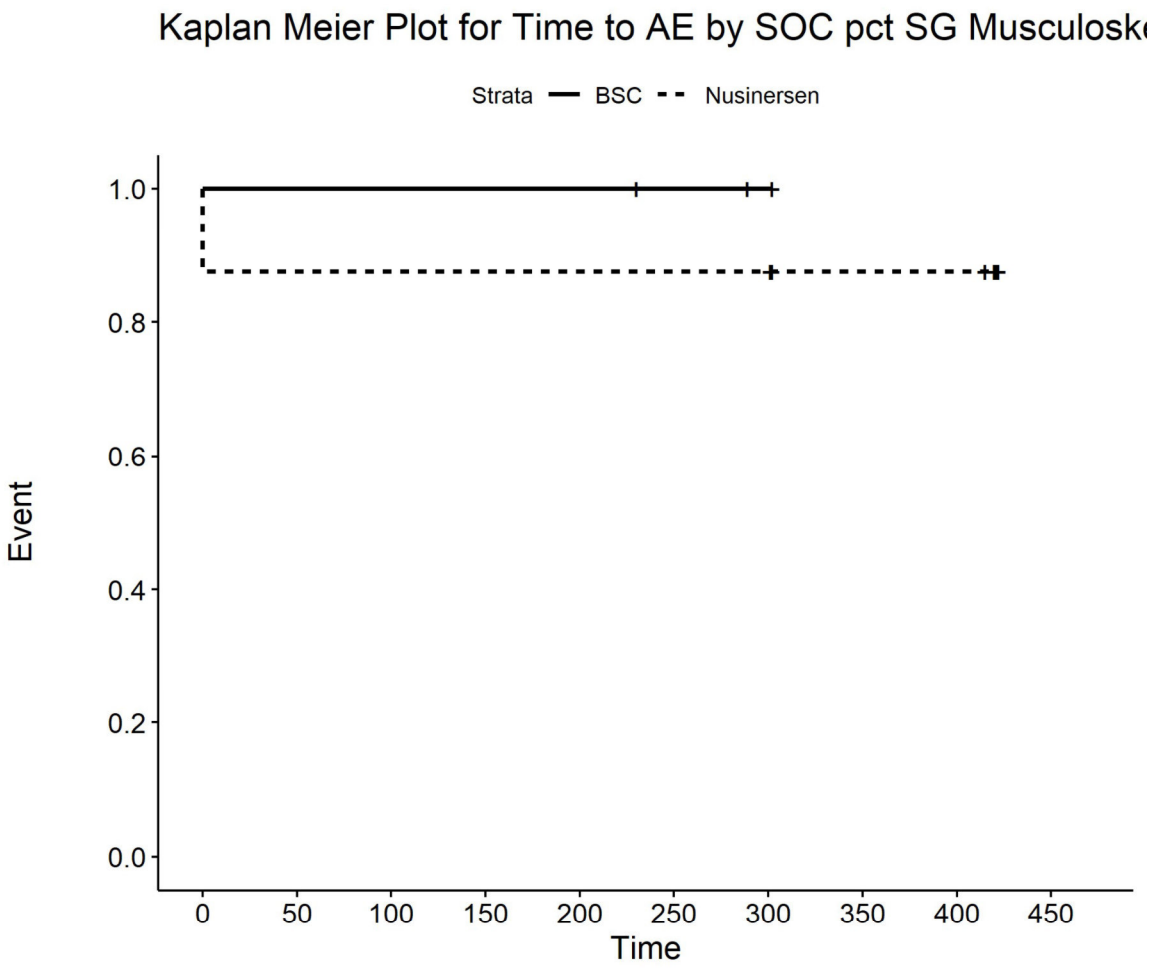
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



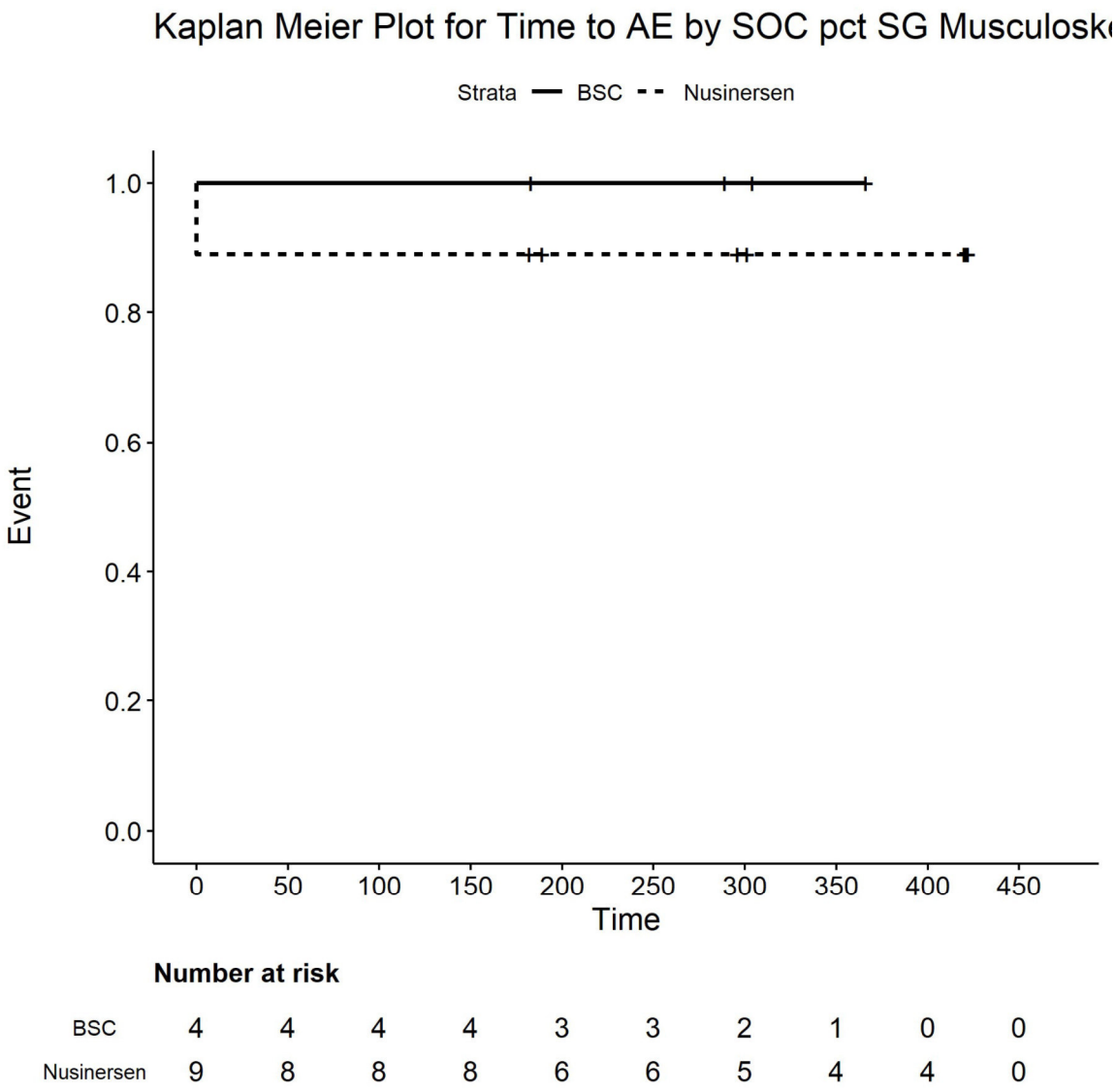
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	2	0



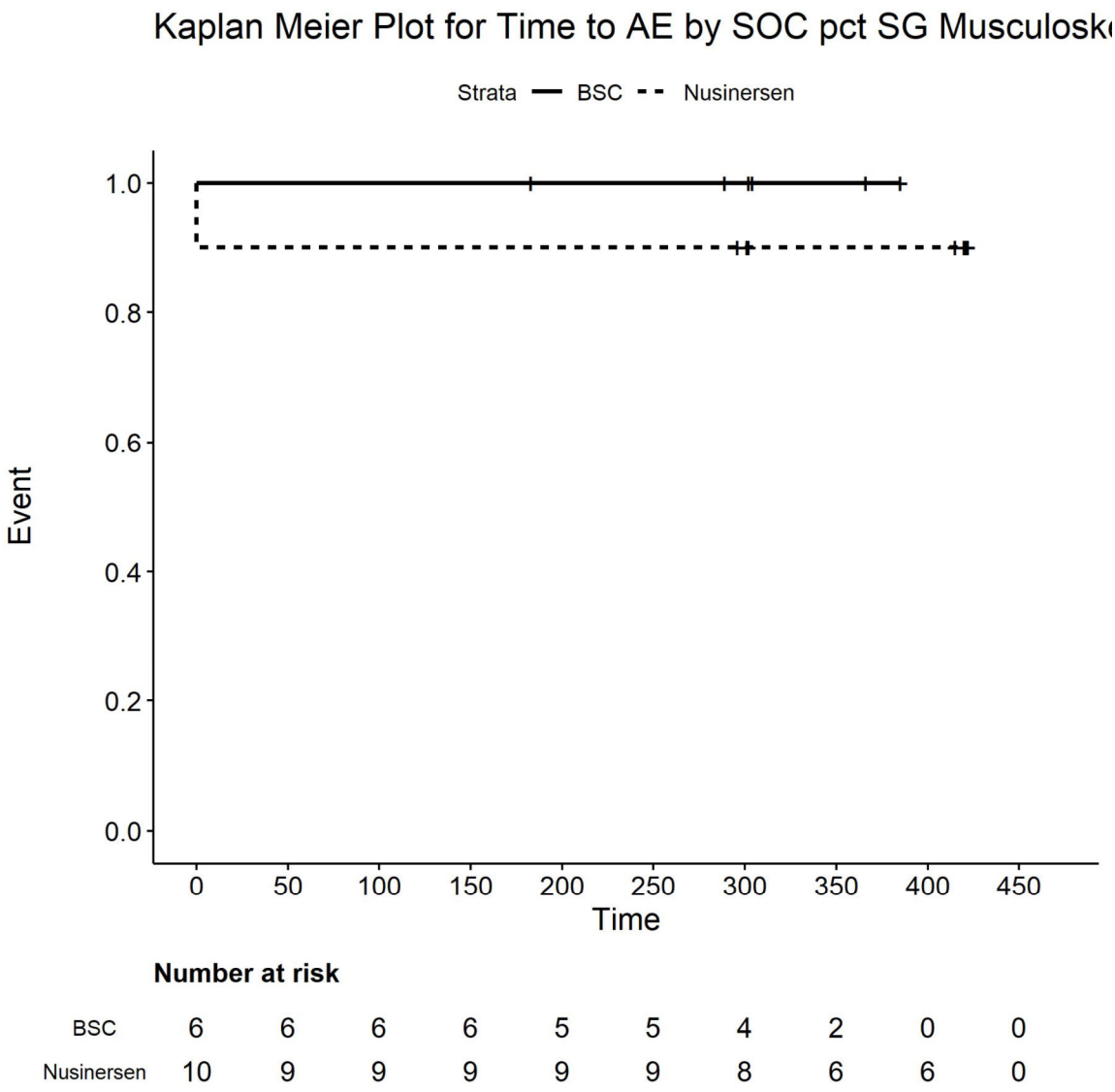
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	5	0



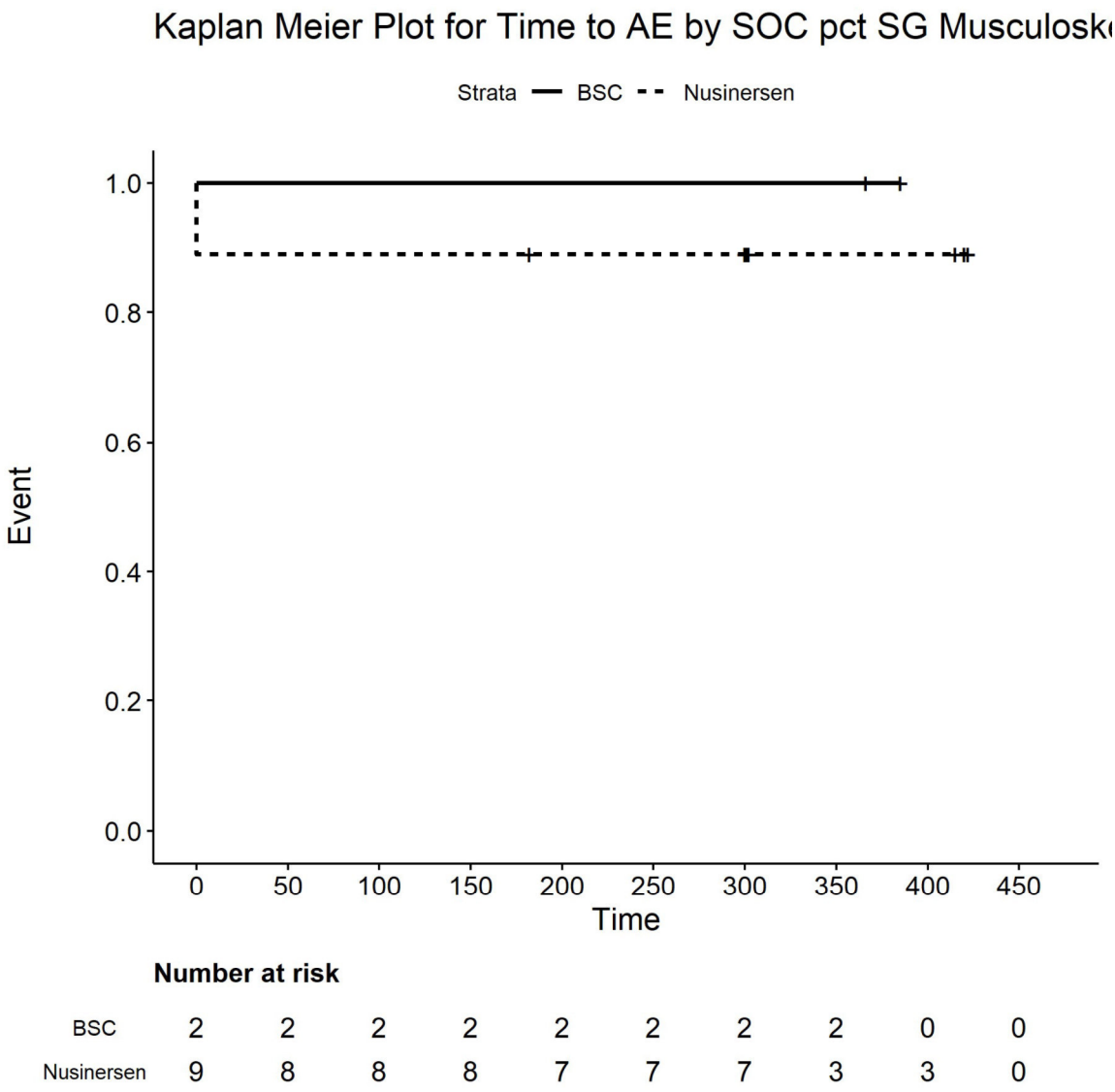
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	4	0



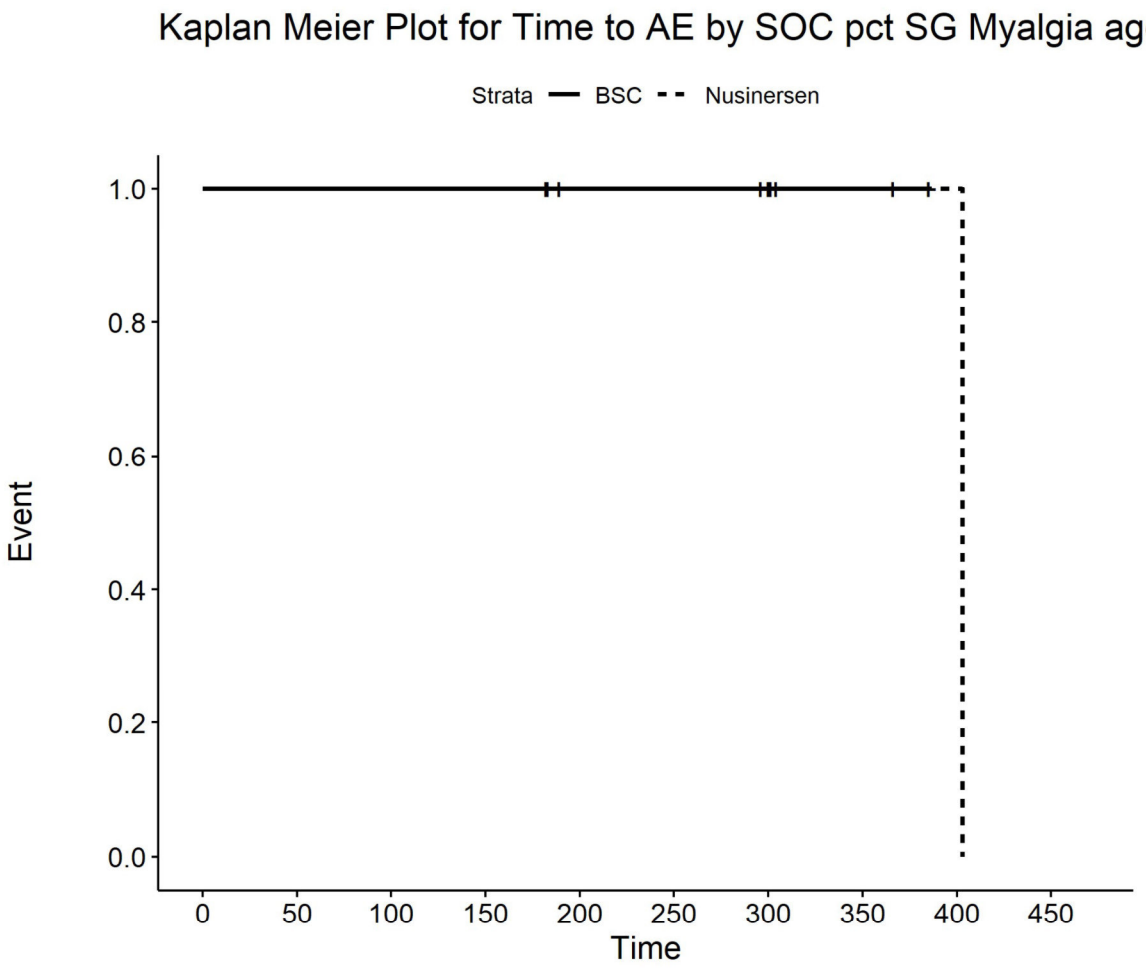
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	6	0



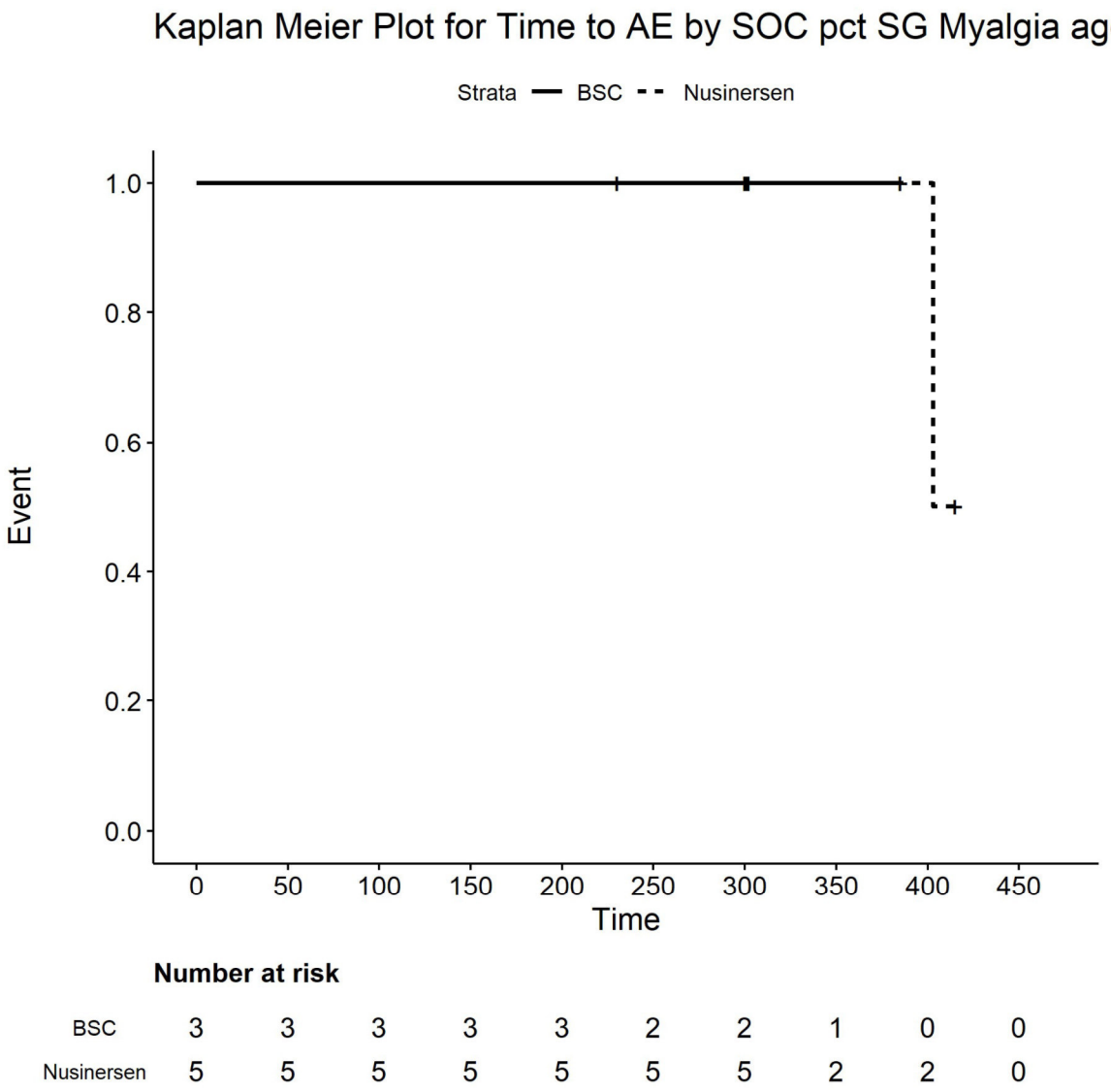
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	3	0



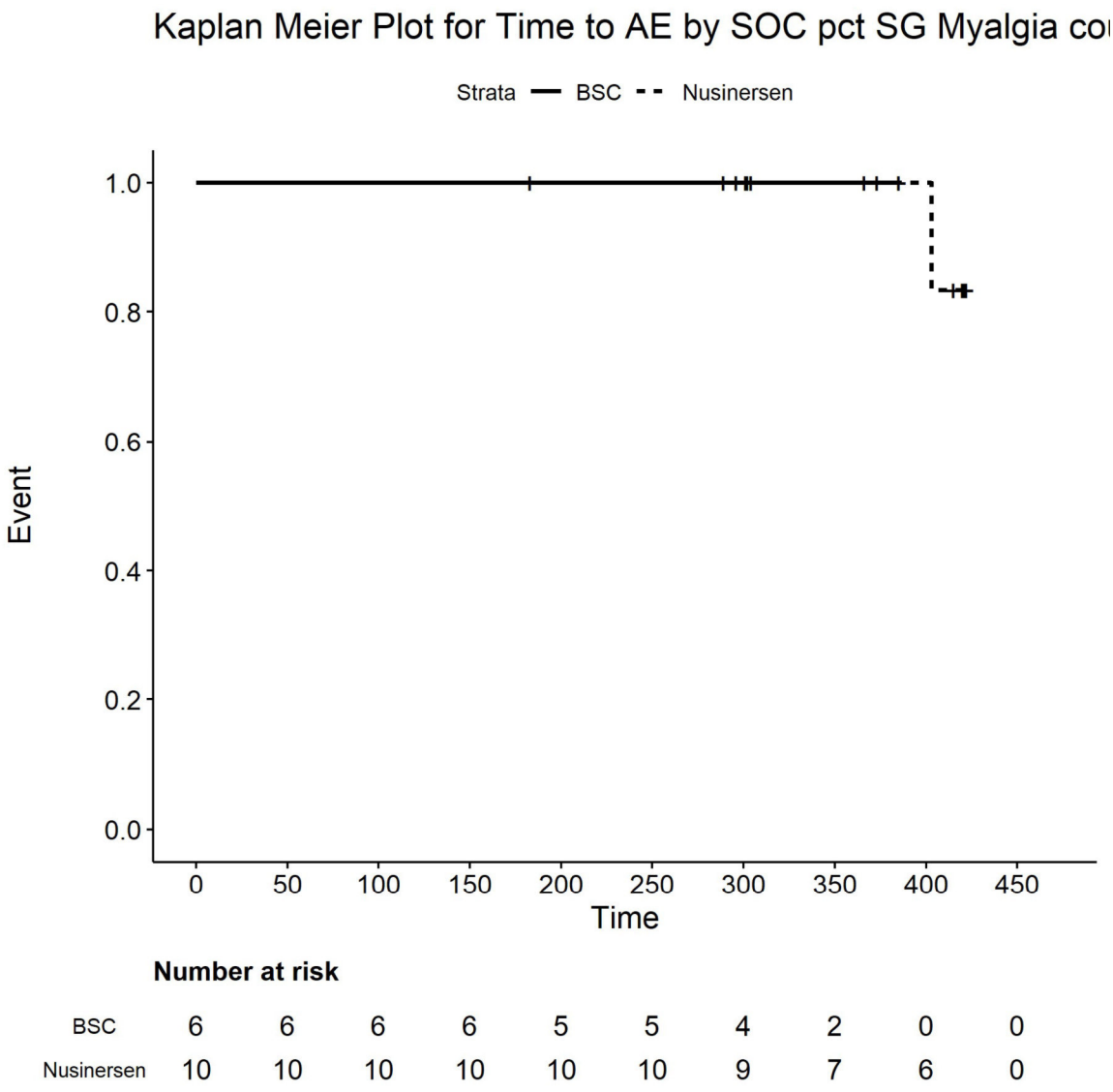
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



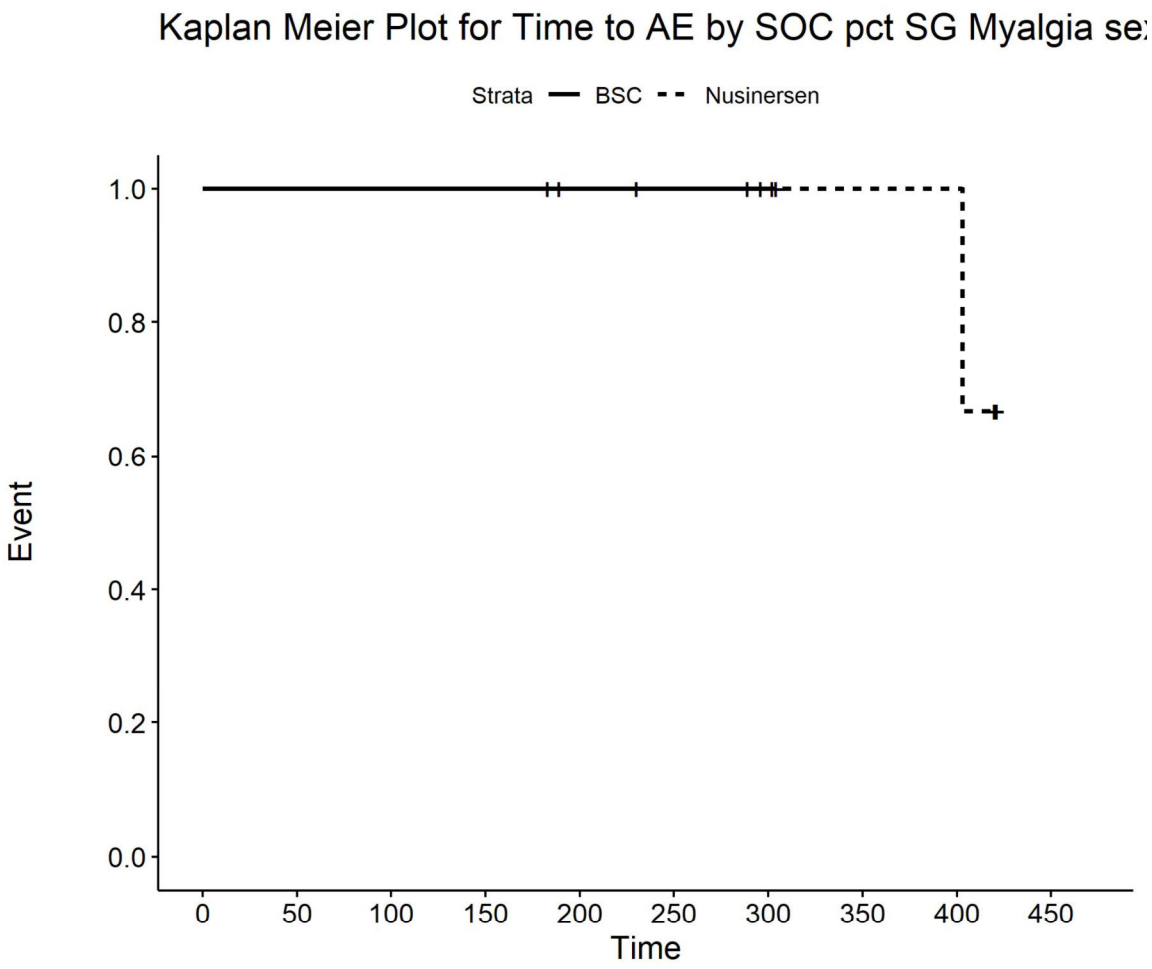
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



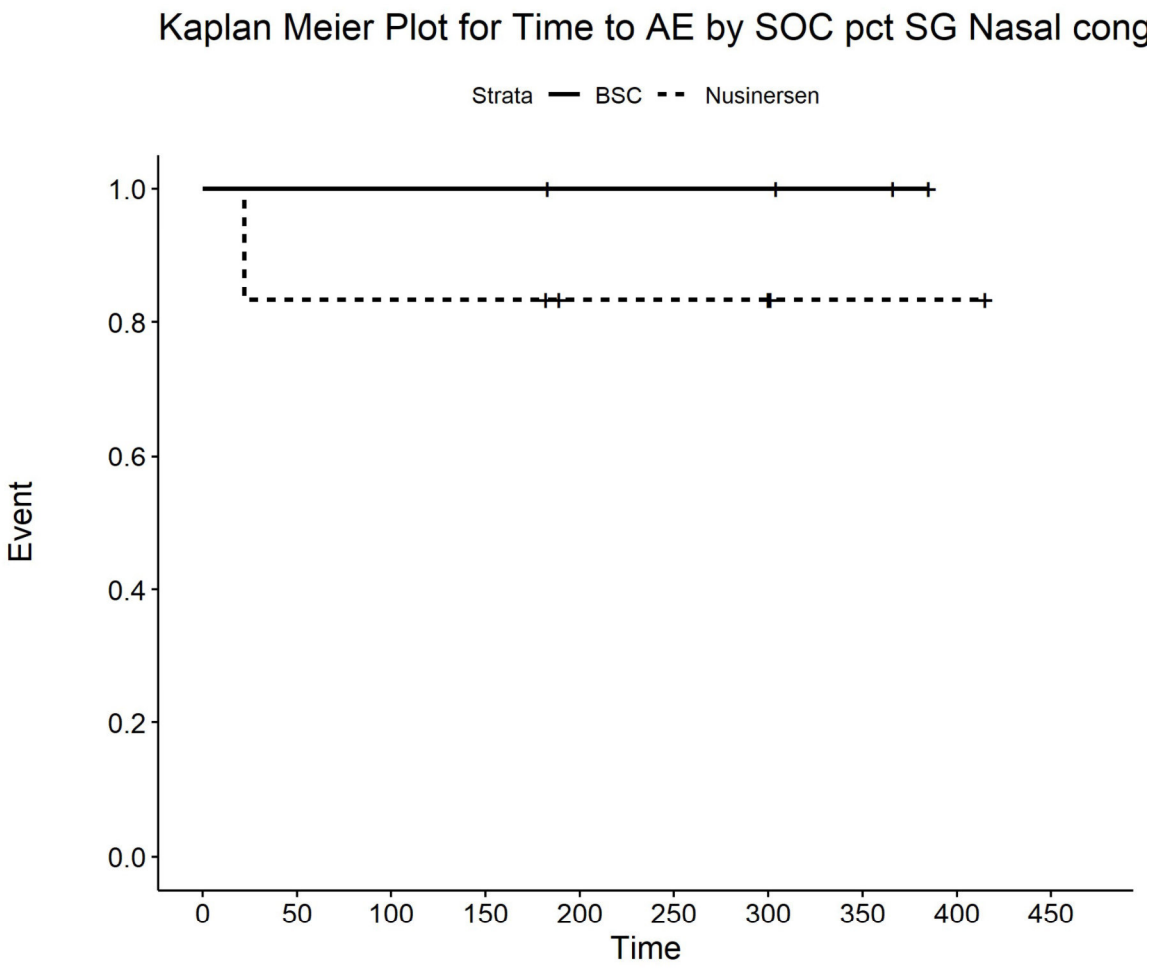
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



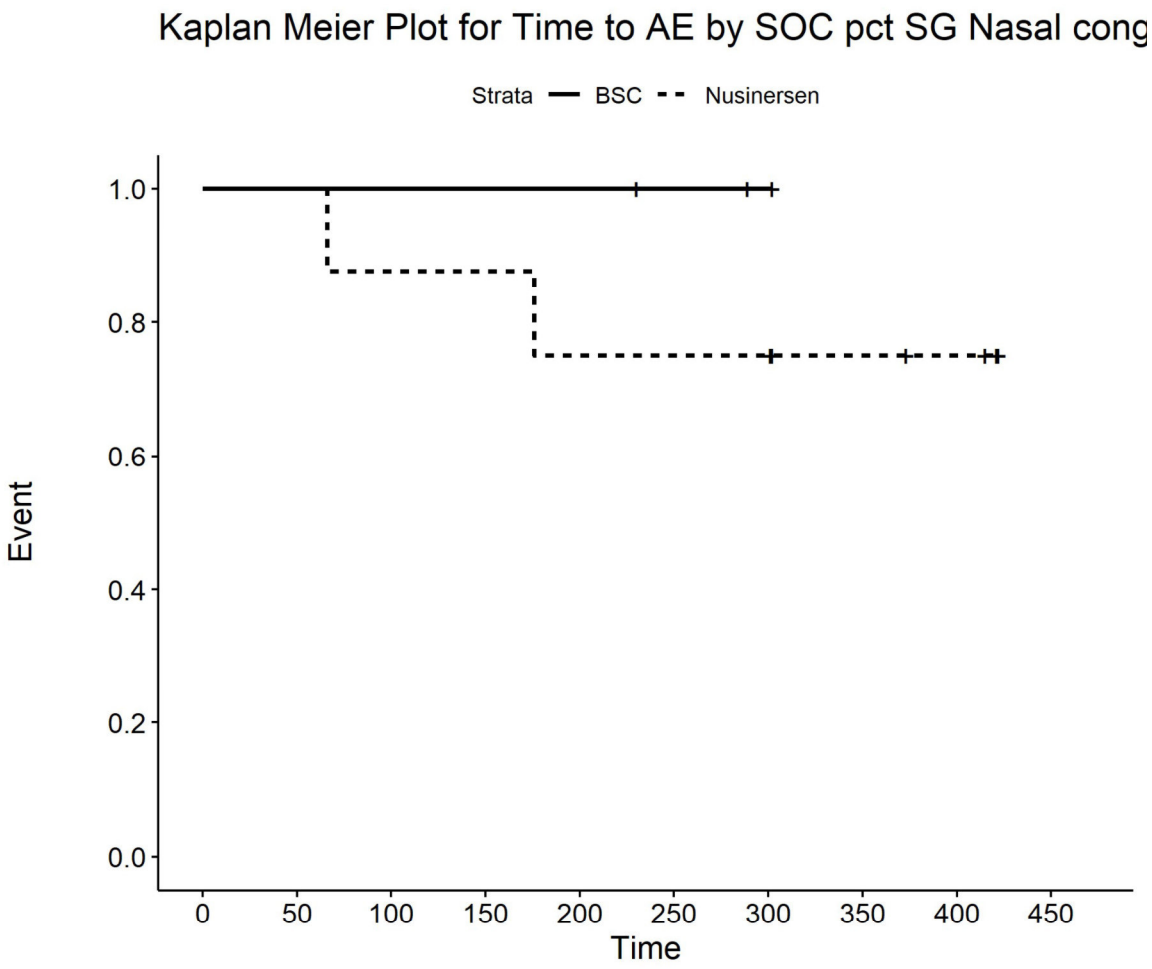
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



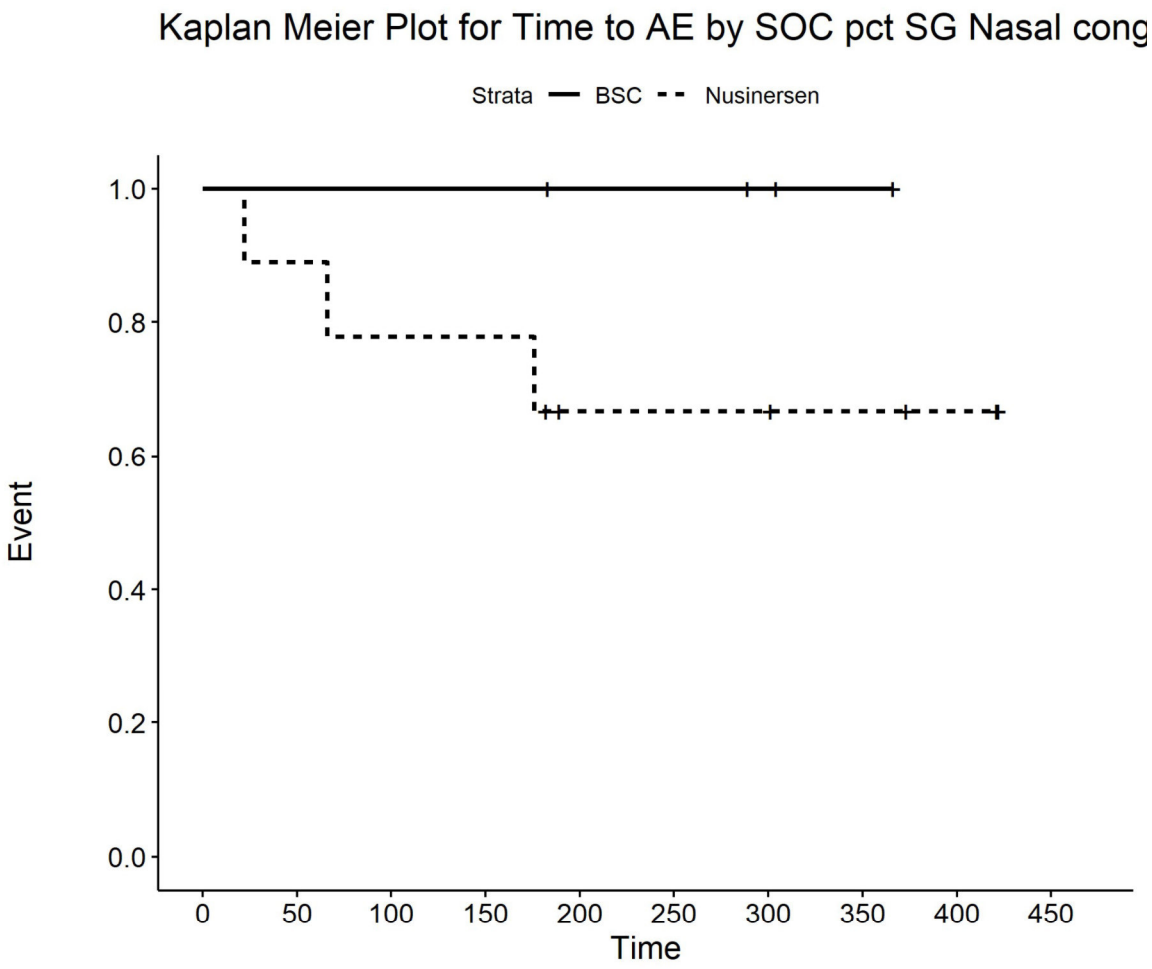
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	3	1	1	0



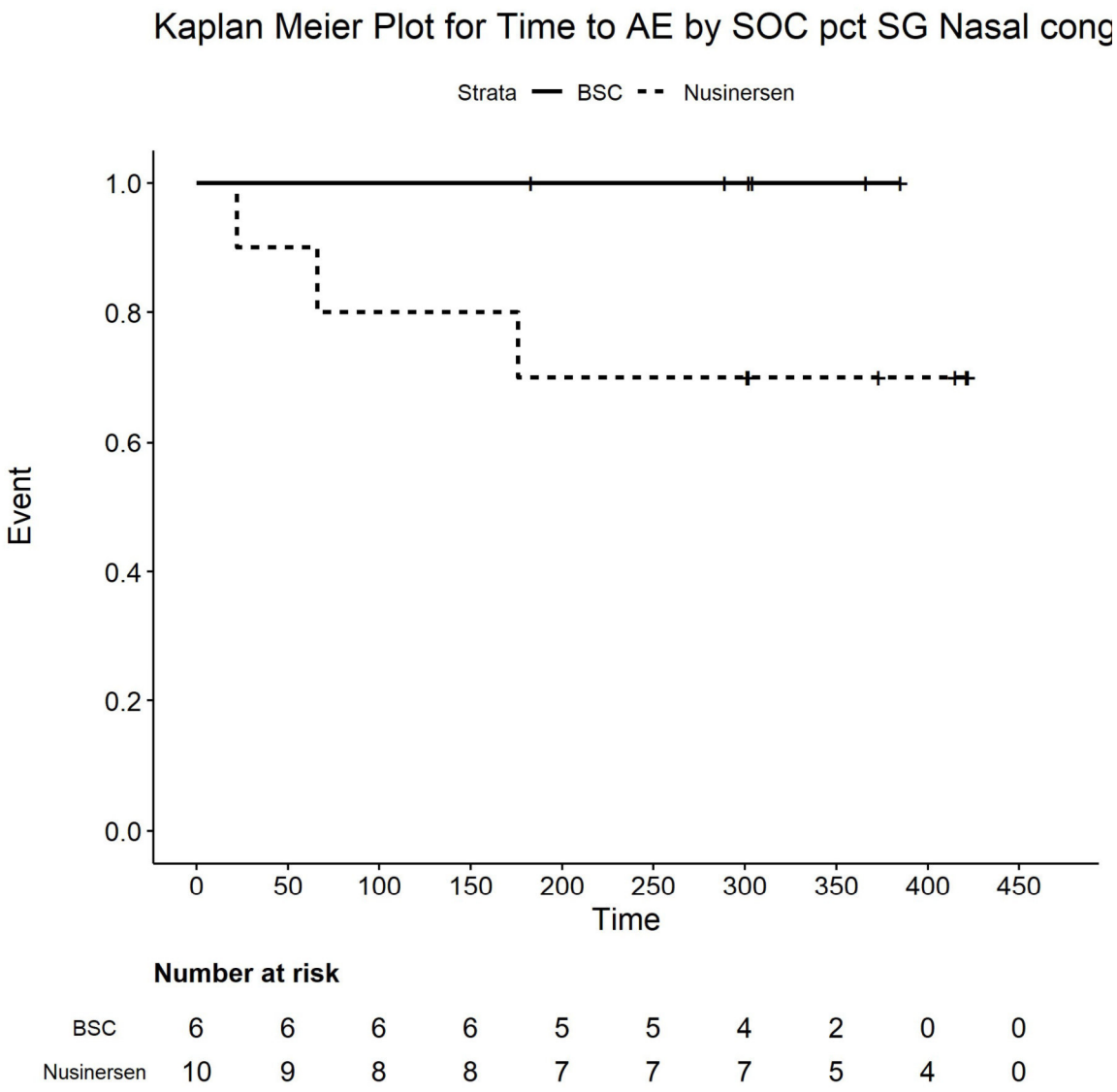
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	6	6	6	4	3	0



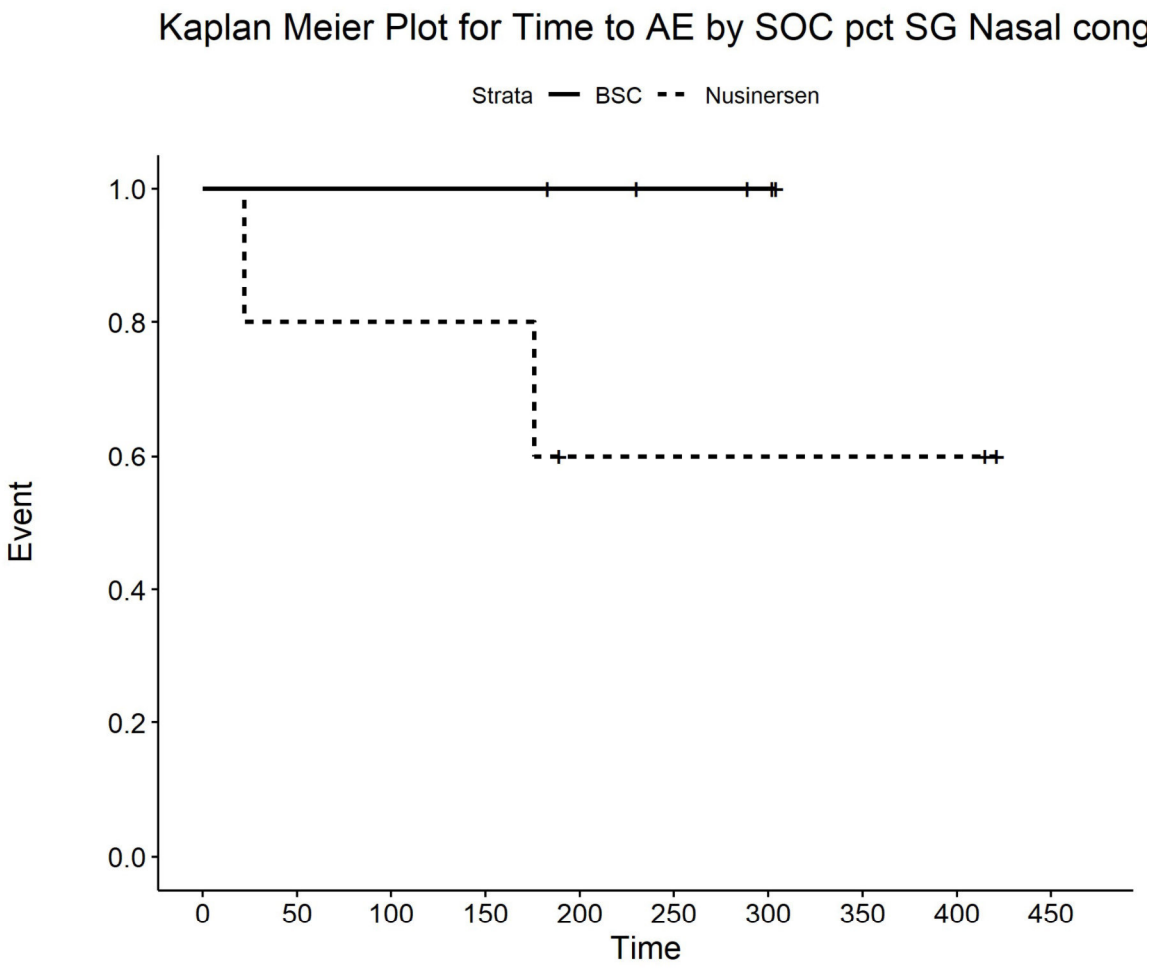
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	7	7	4	4	4	3	2	0



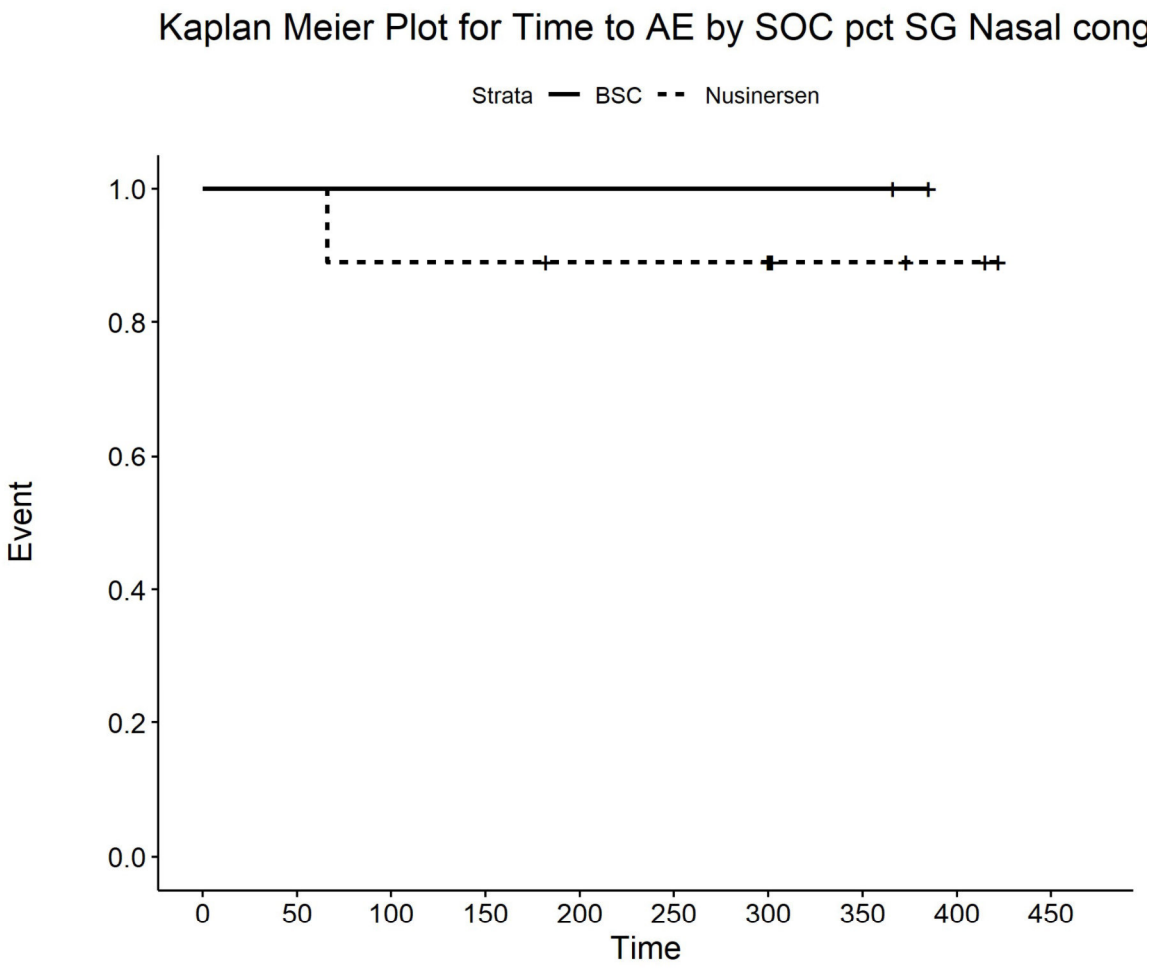
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	8	8	7	7	7	5	4	0



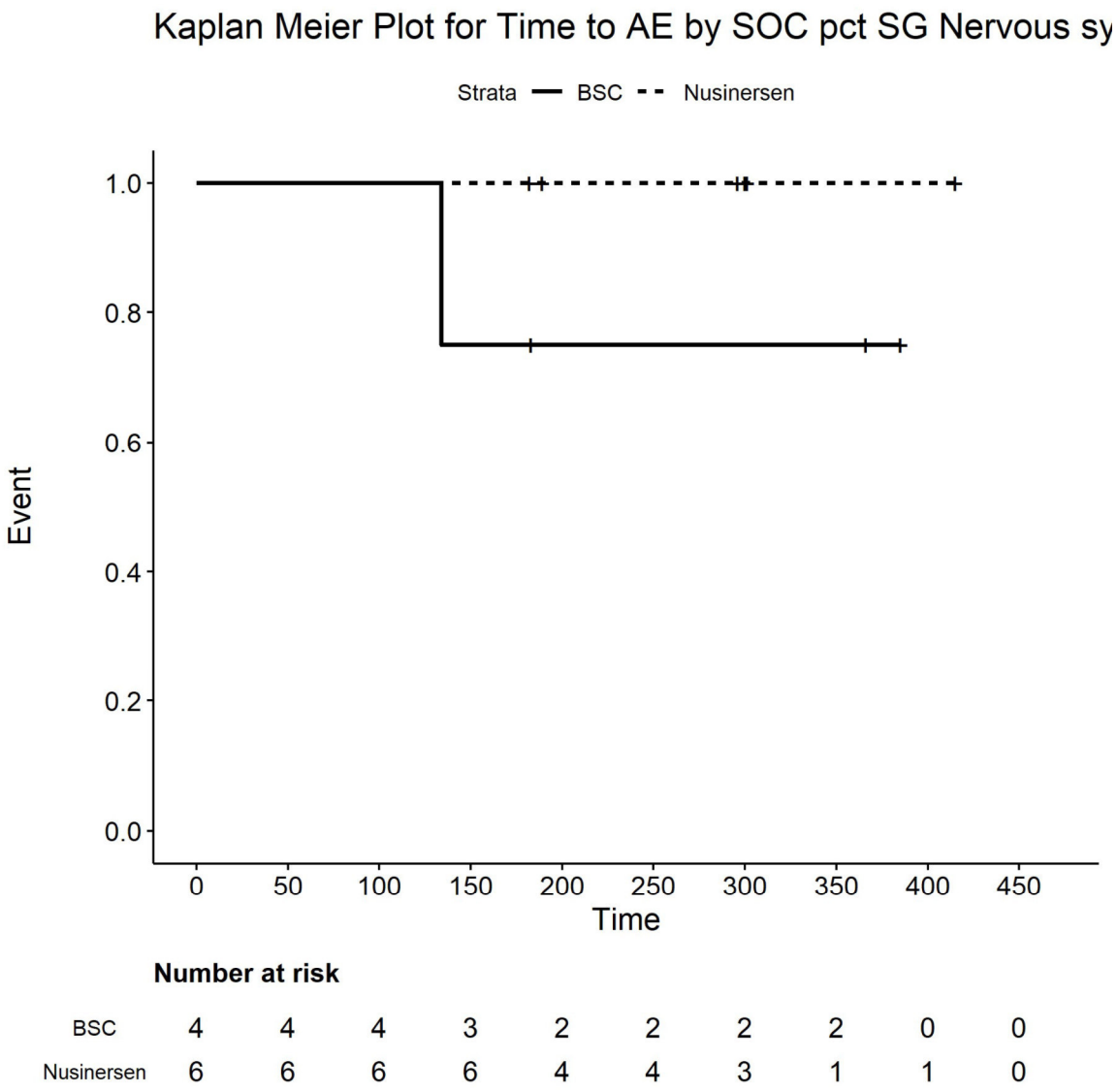
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	4	4	4	2	2	2	2	2	0



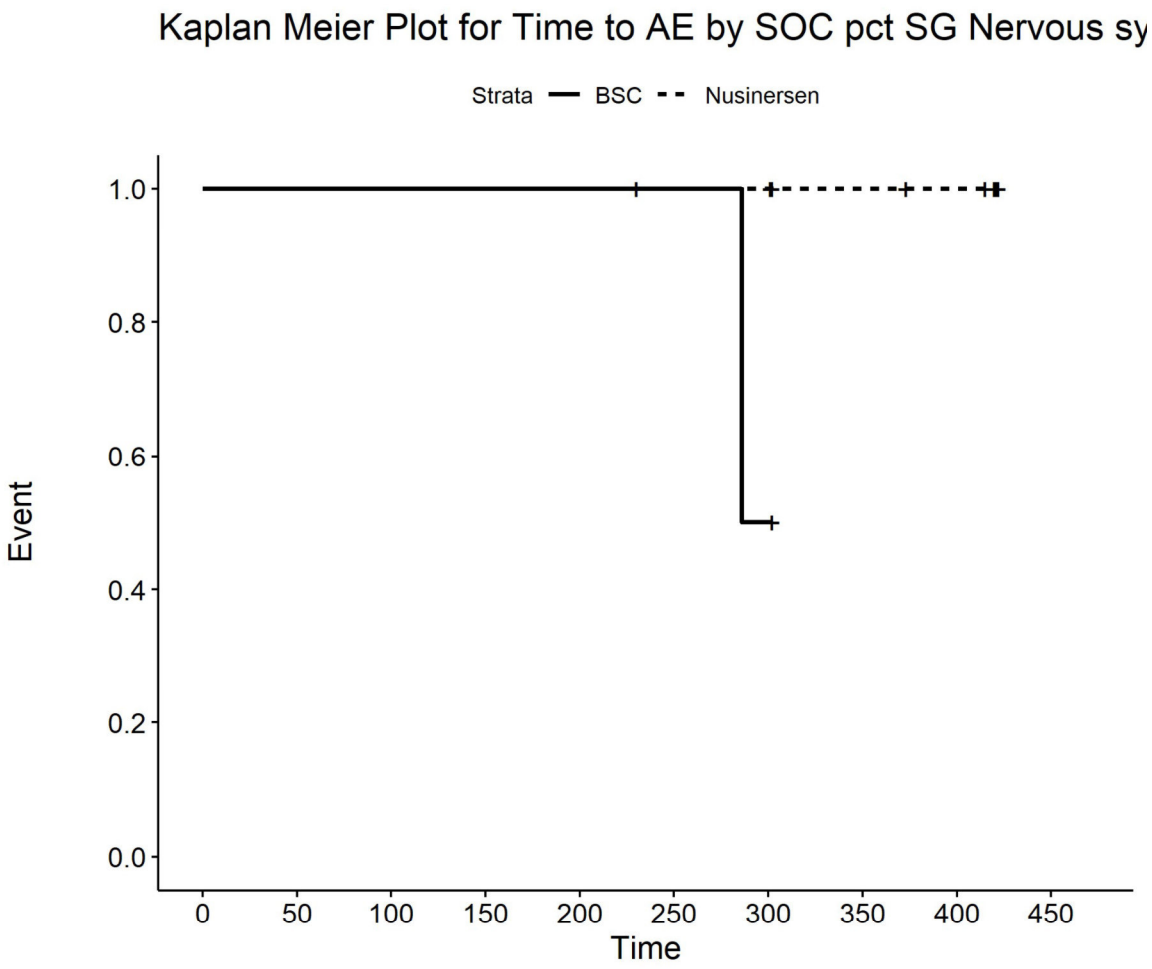
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	2	0



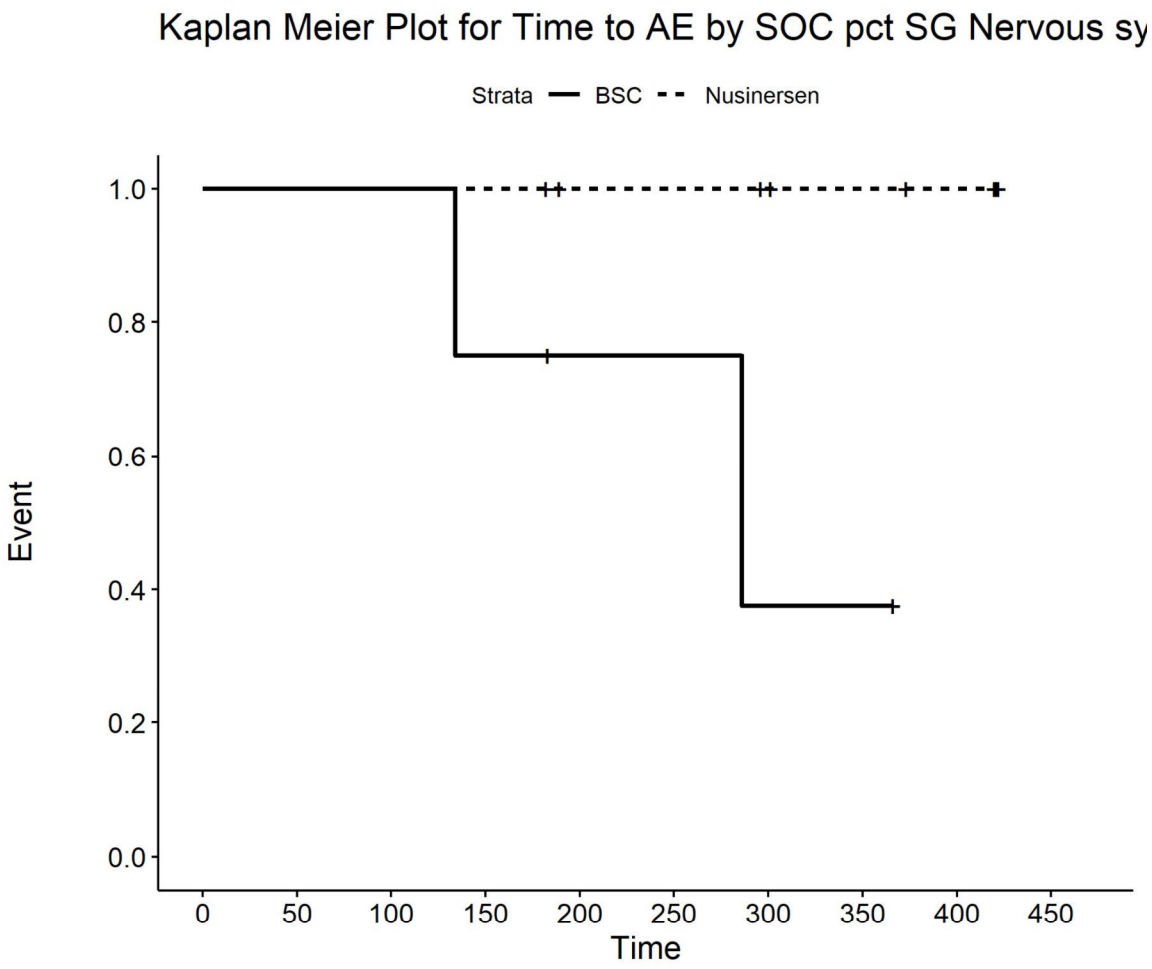
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



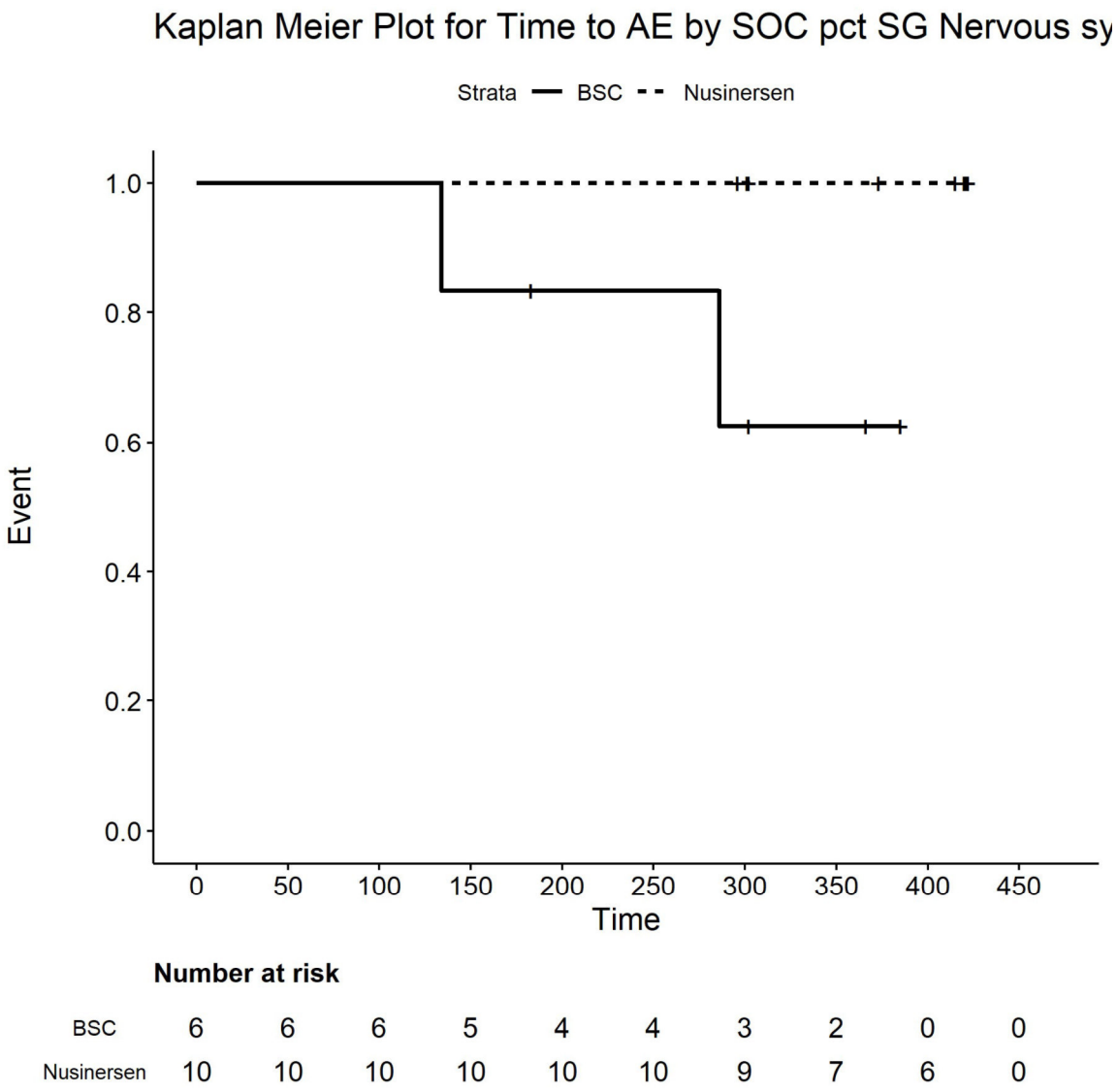
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



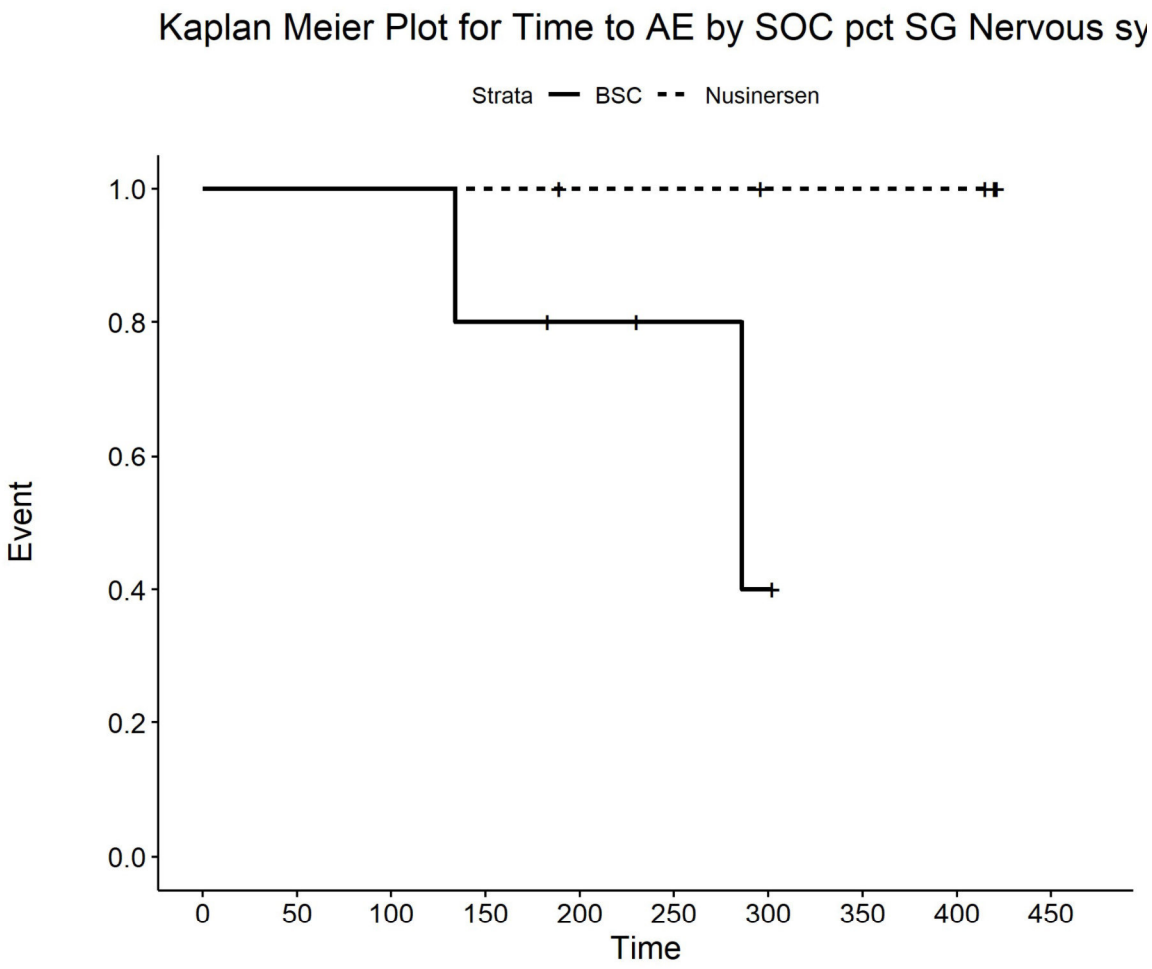
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



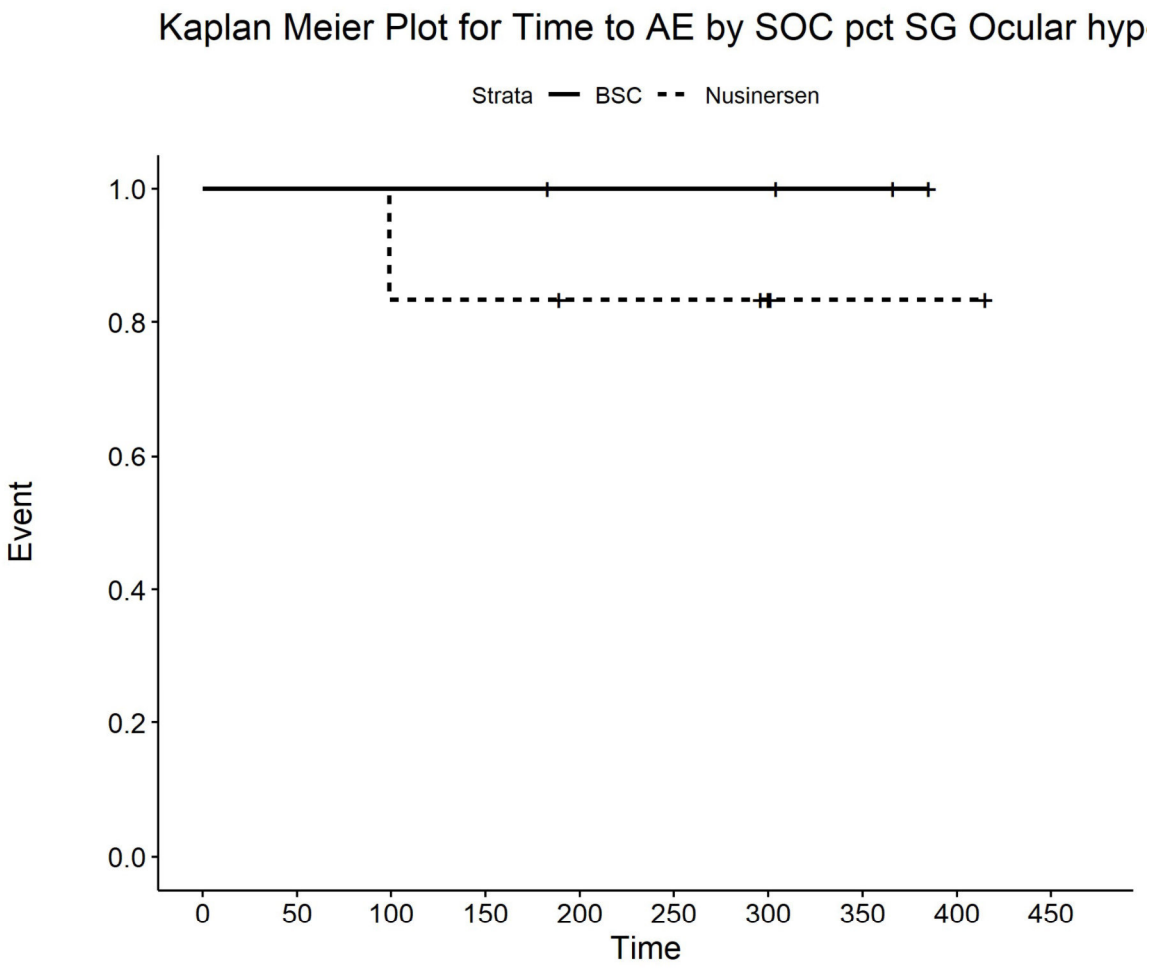
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



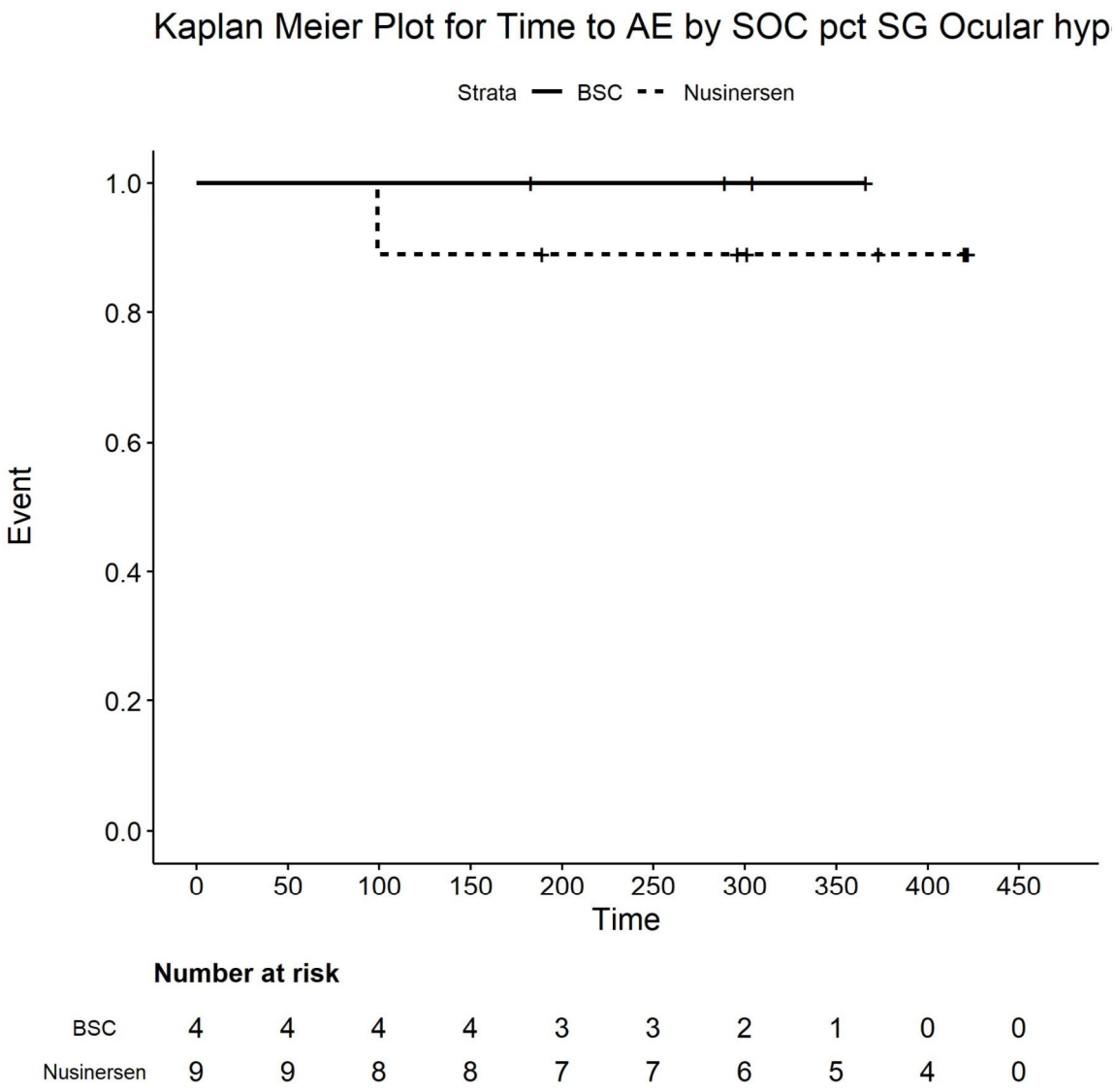
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



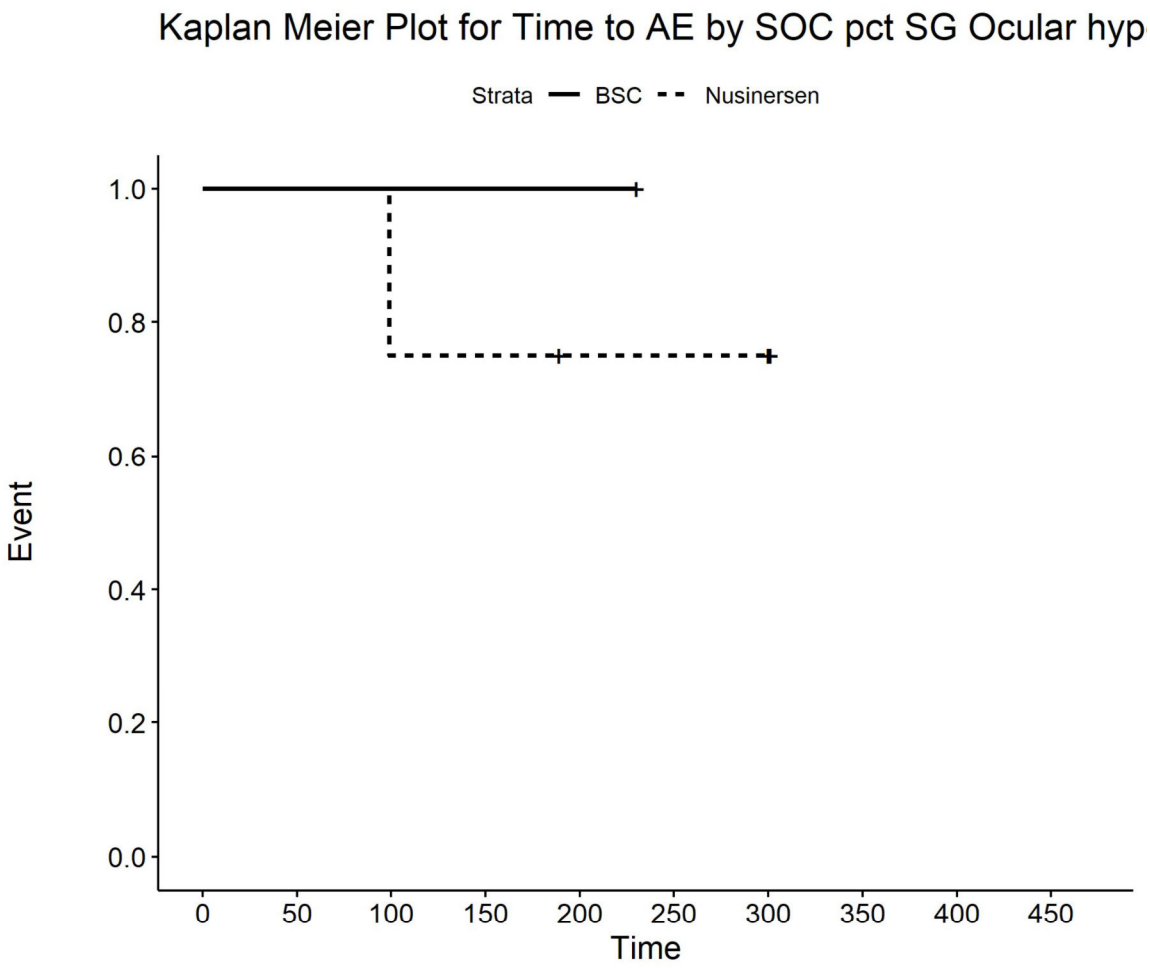
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	4	4	3	1	1	0



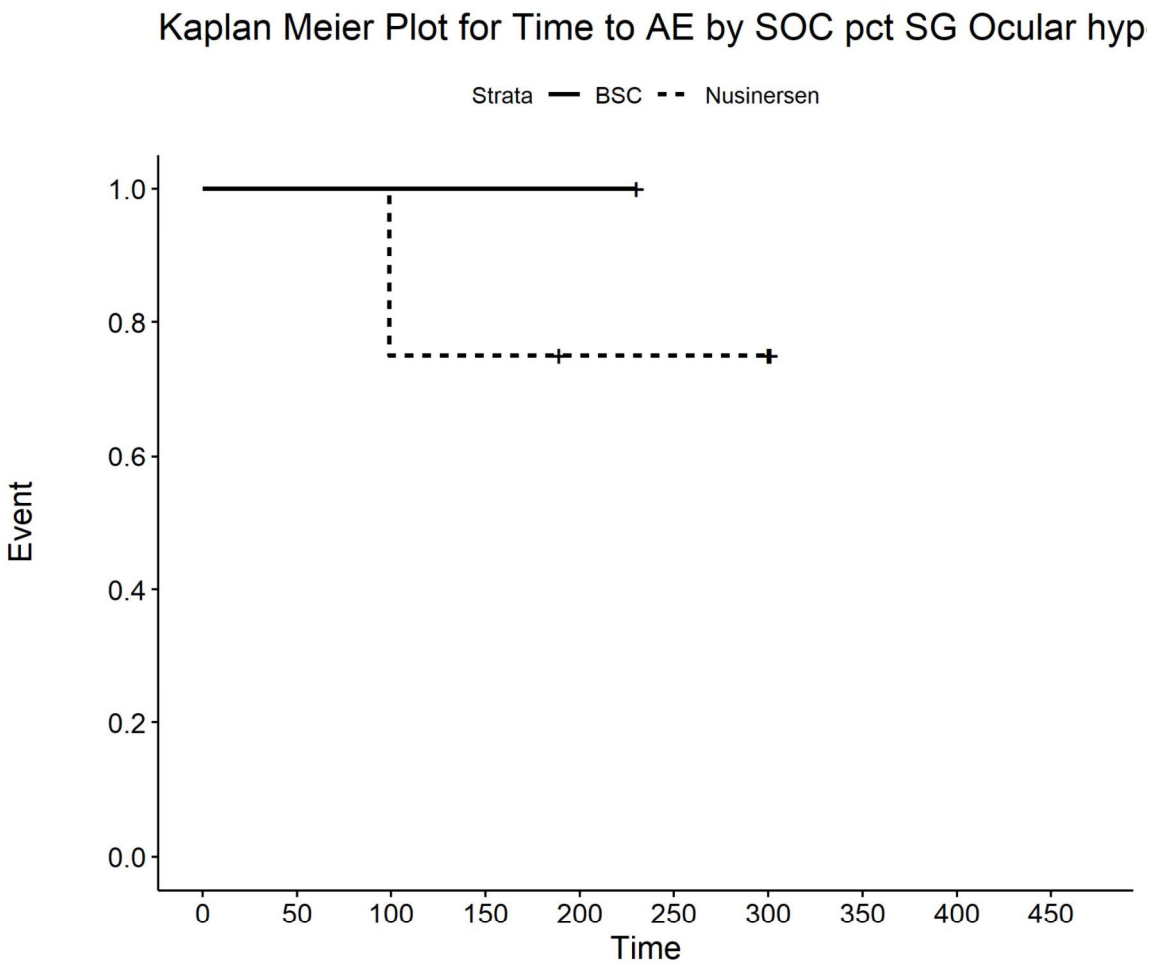
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	7	7	6	5	4	0



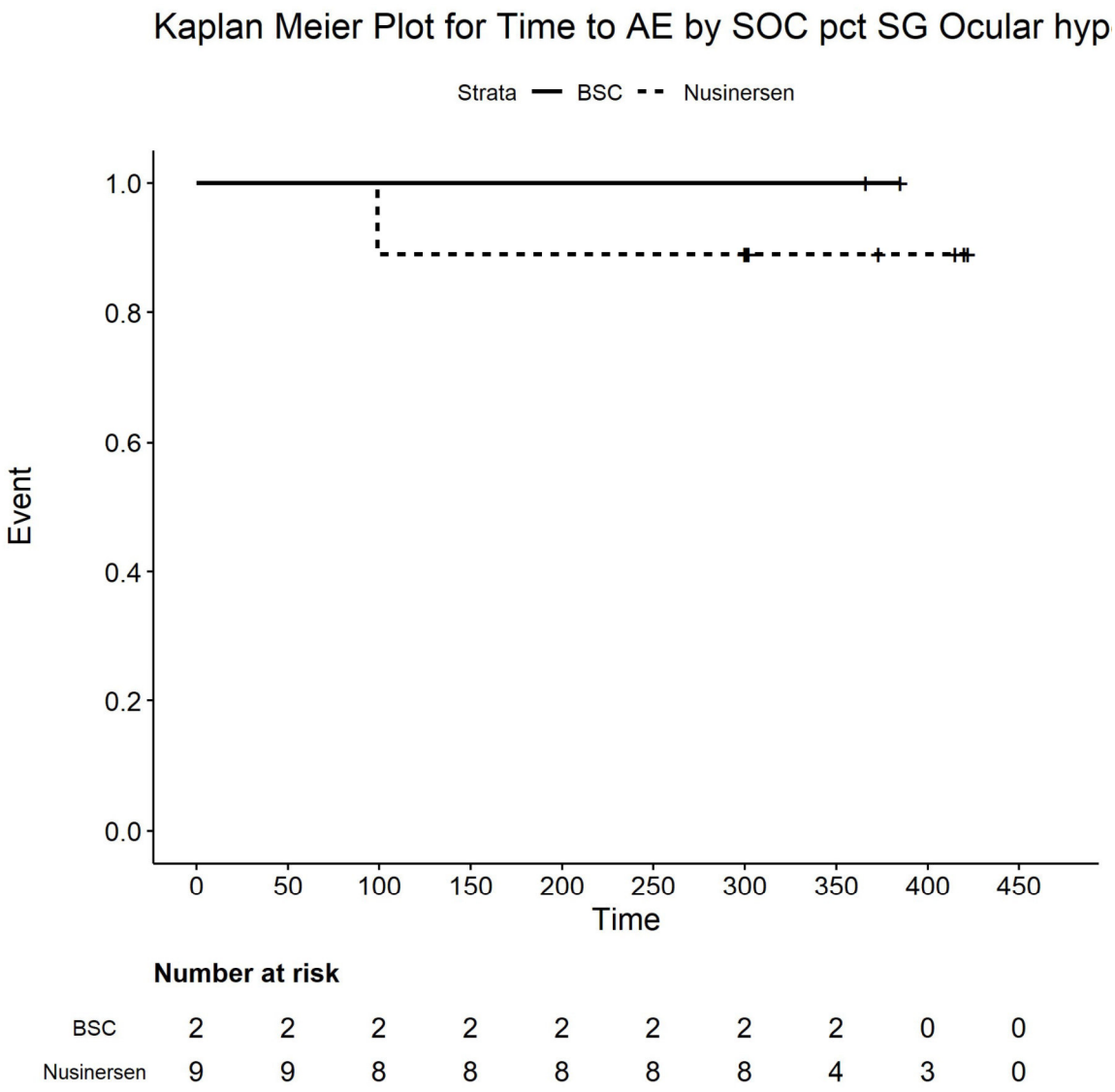
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	2	2	2	0	0	0



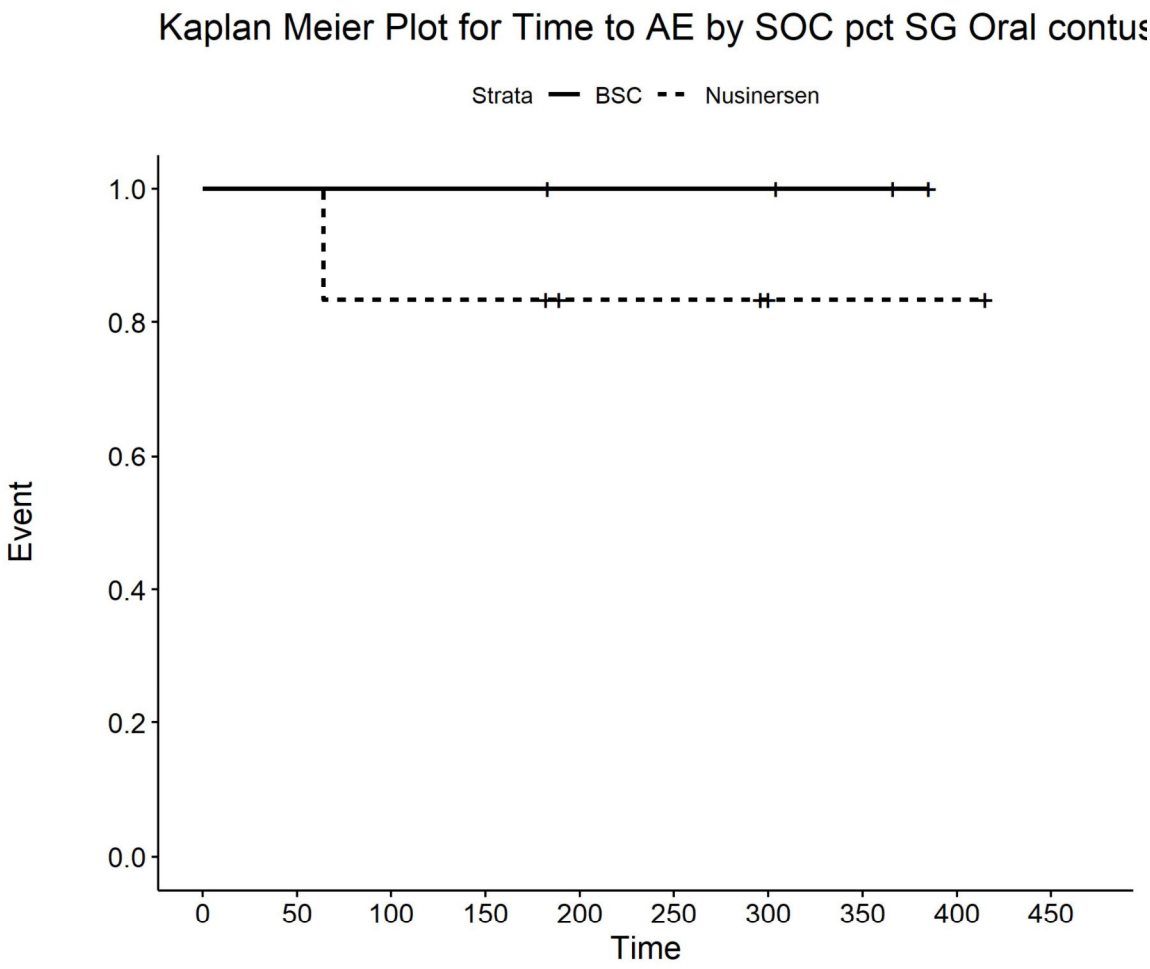
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	2	2	2	0	0	0



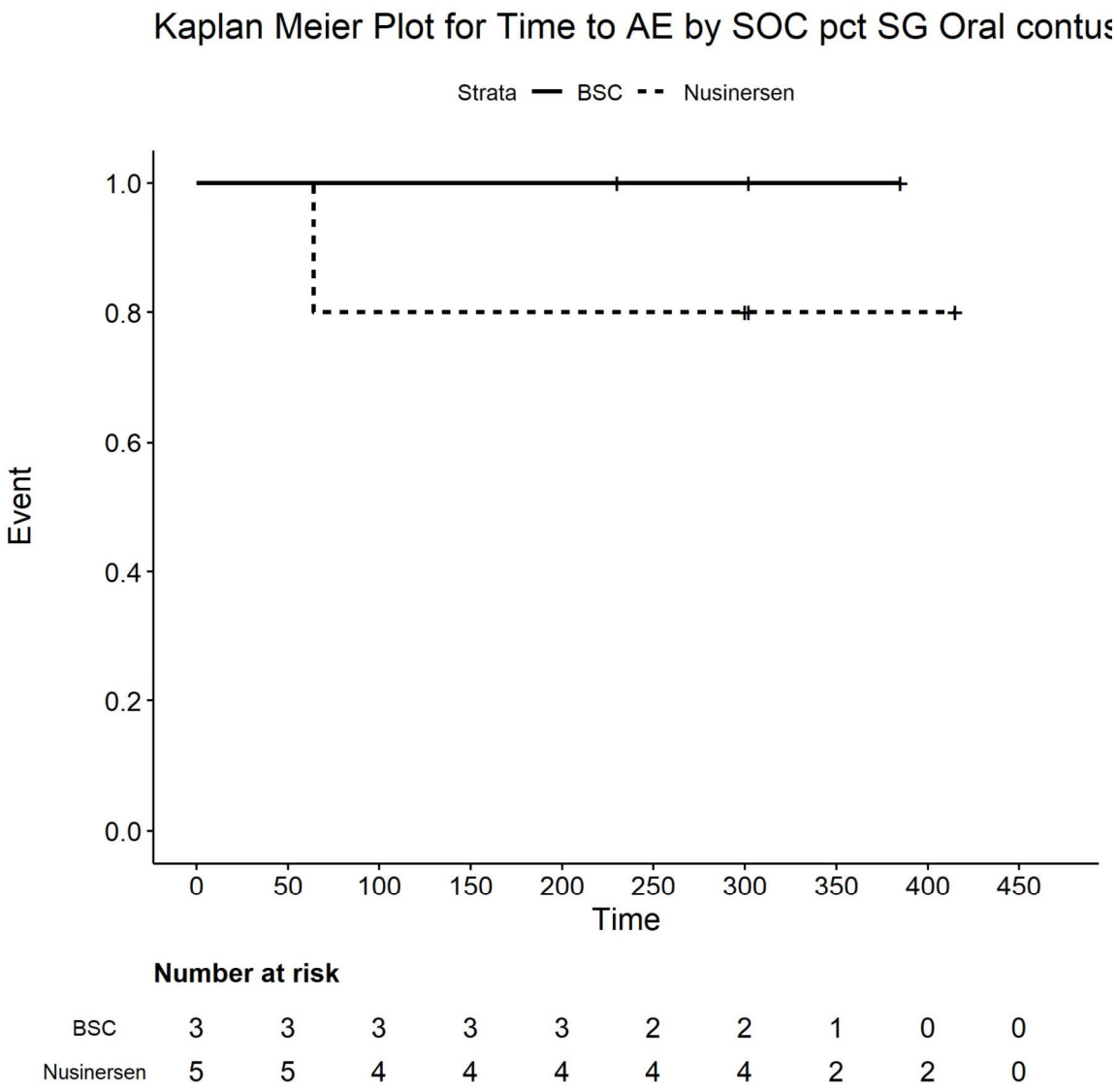
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	8	8	8	4	3	0



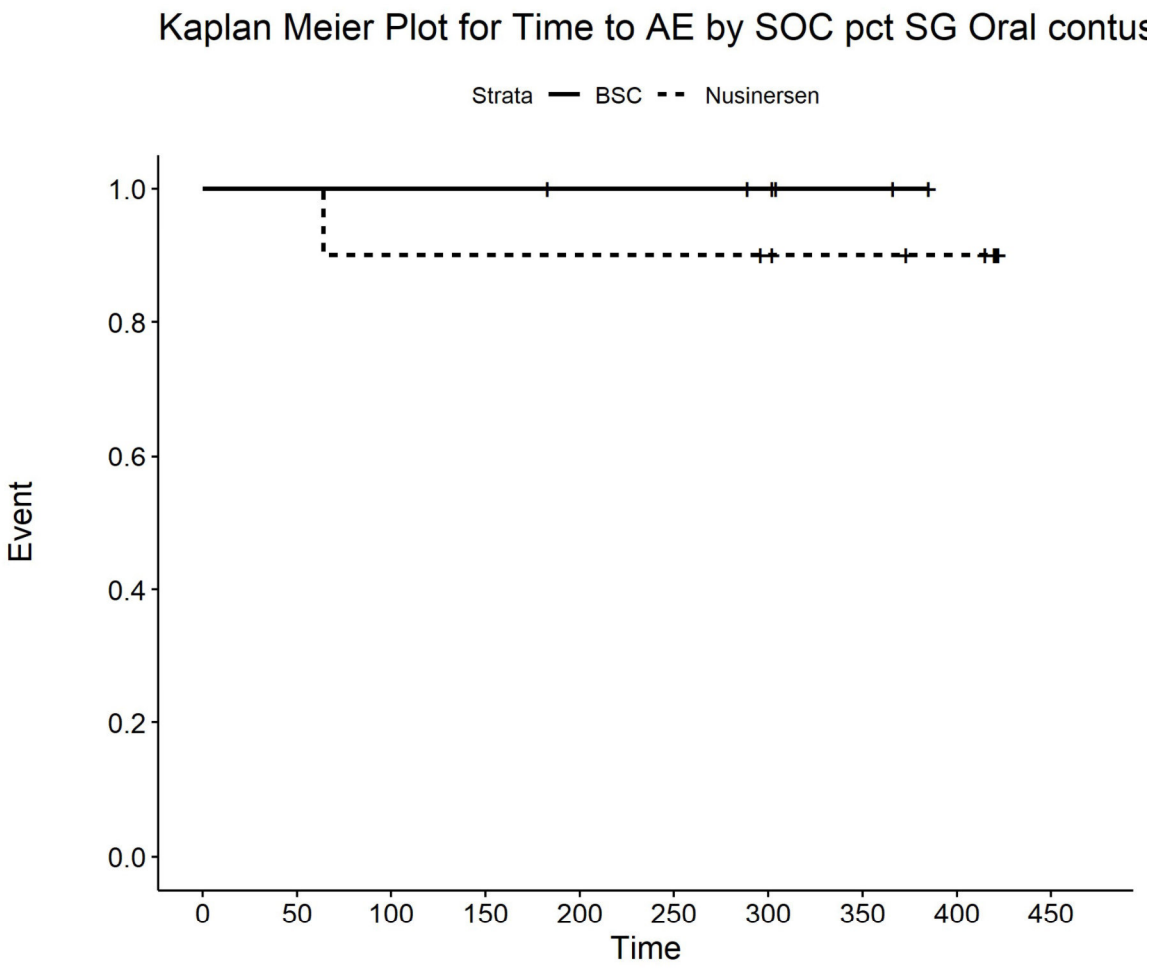
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



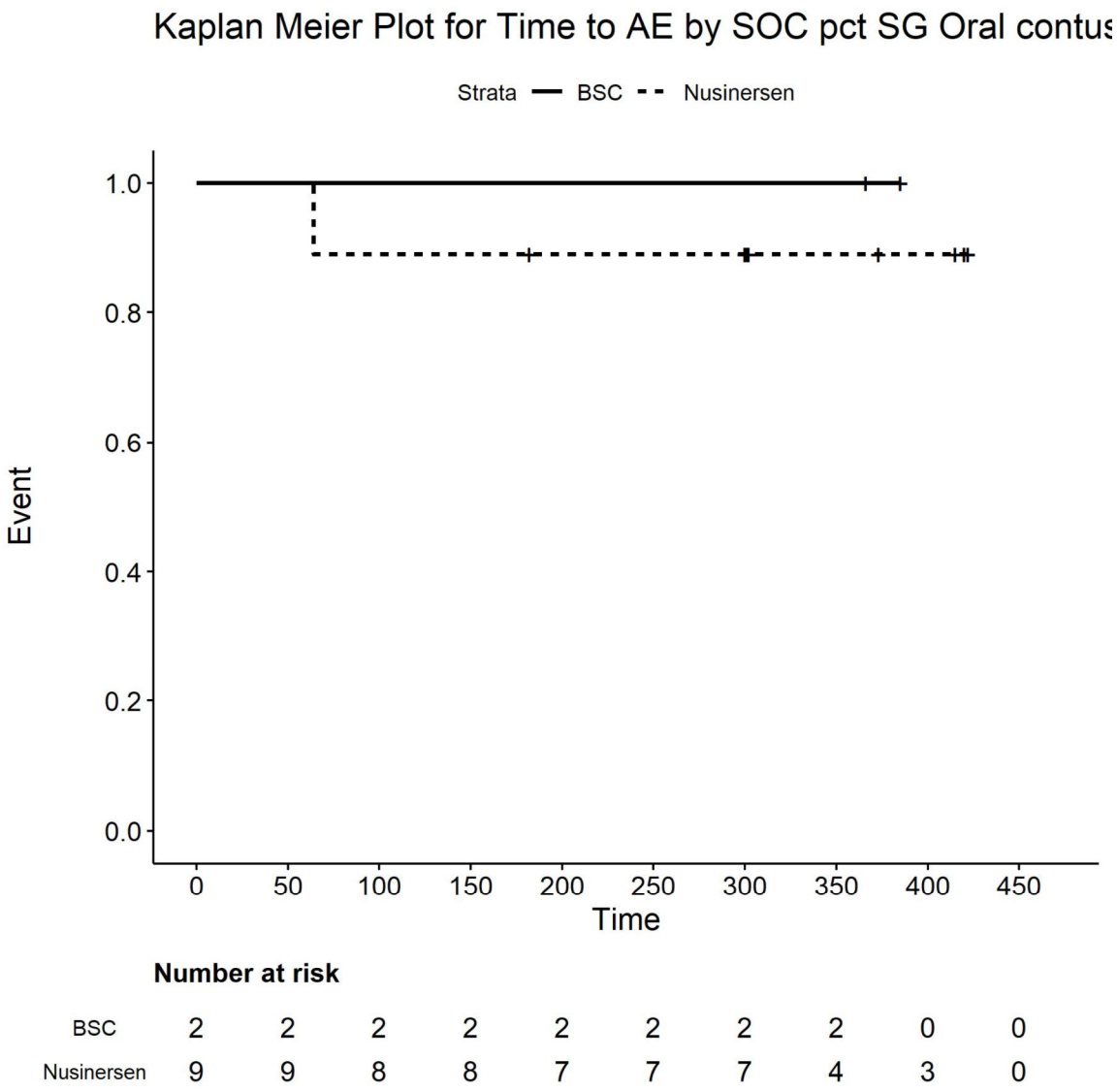
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



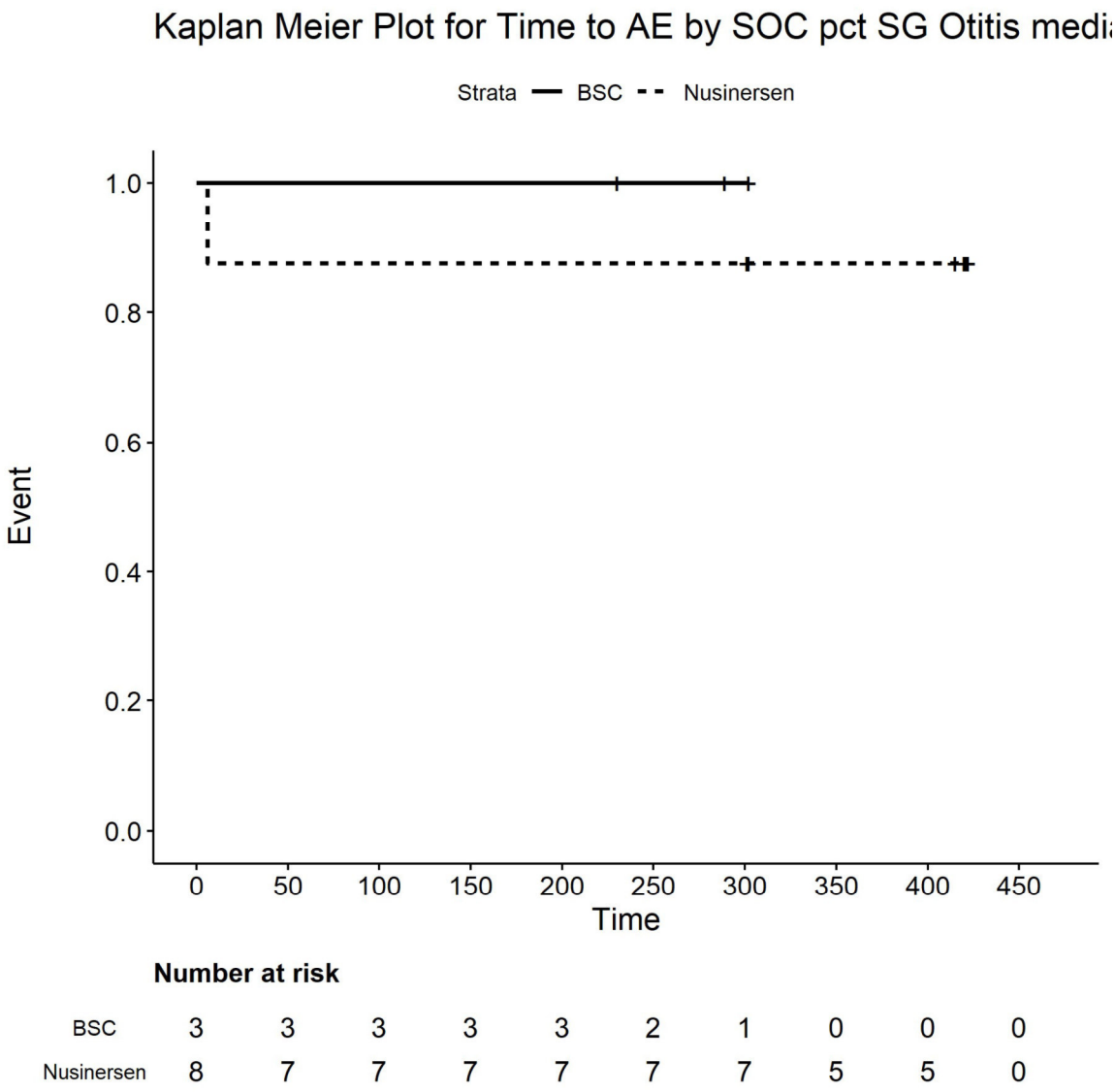
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



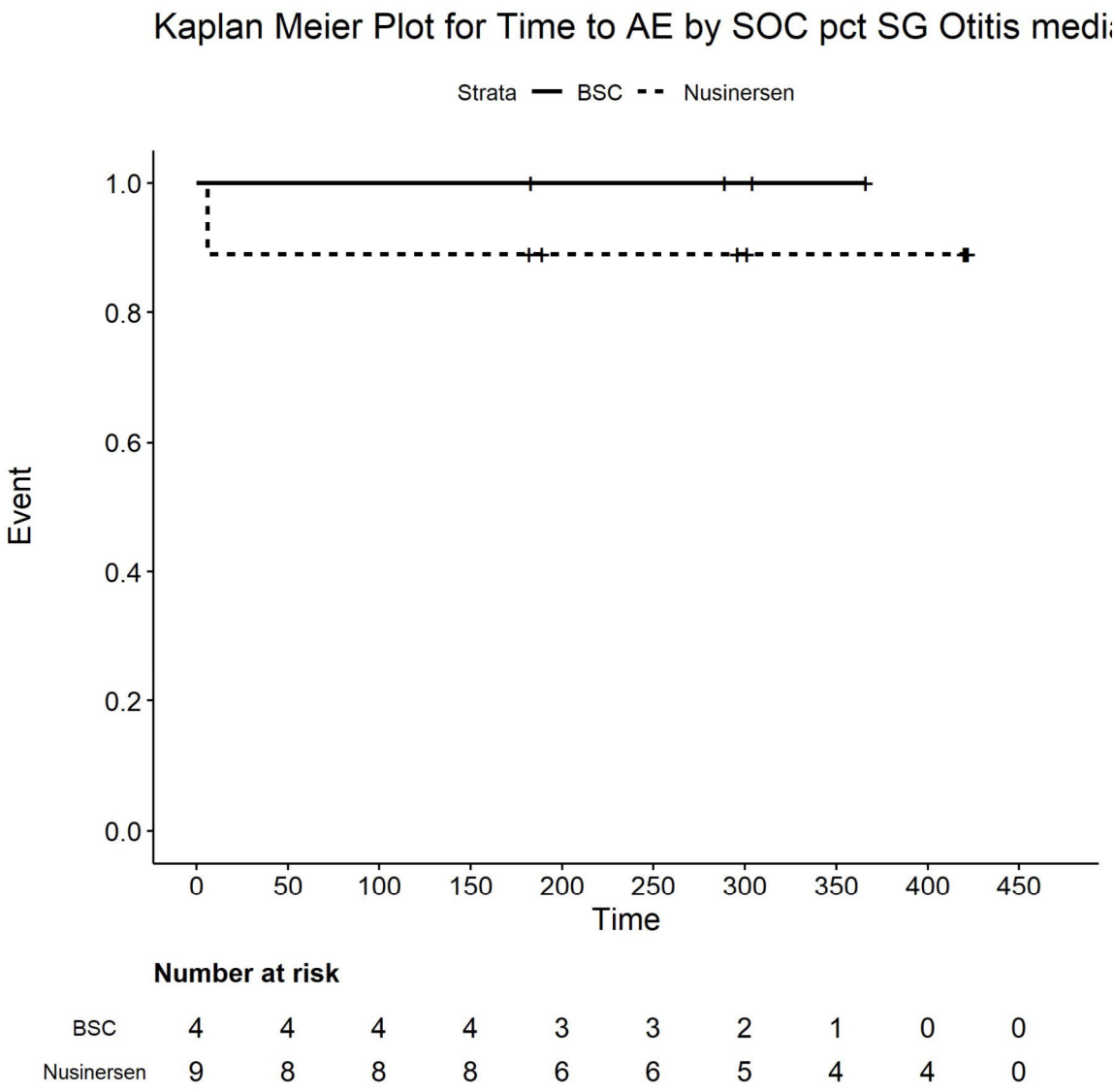
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



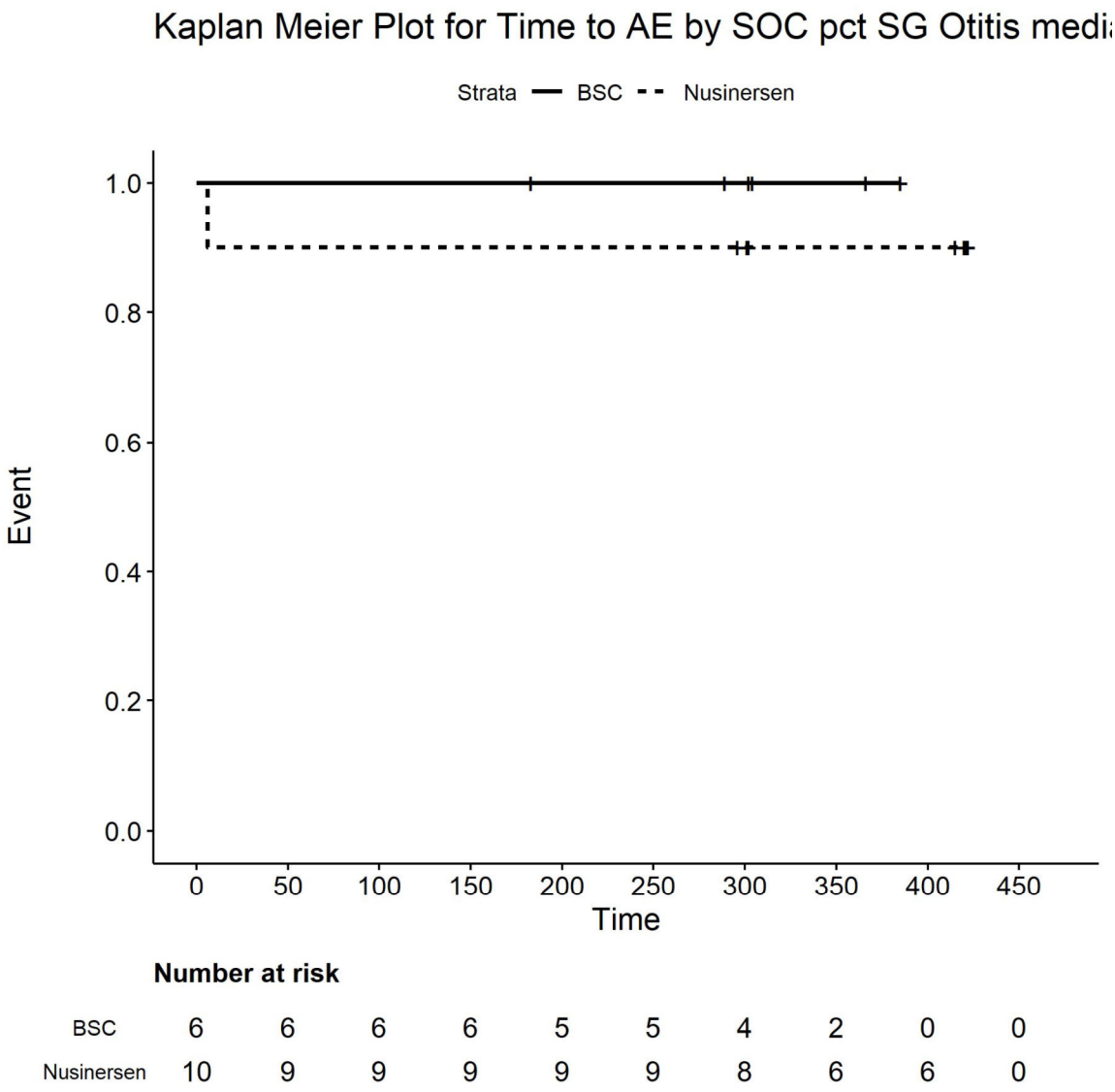
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	5	0



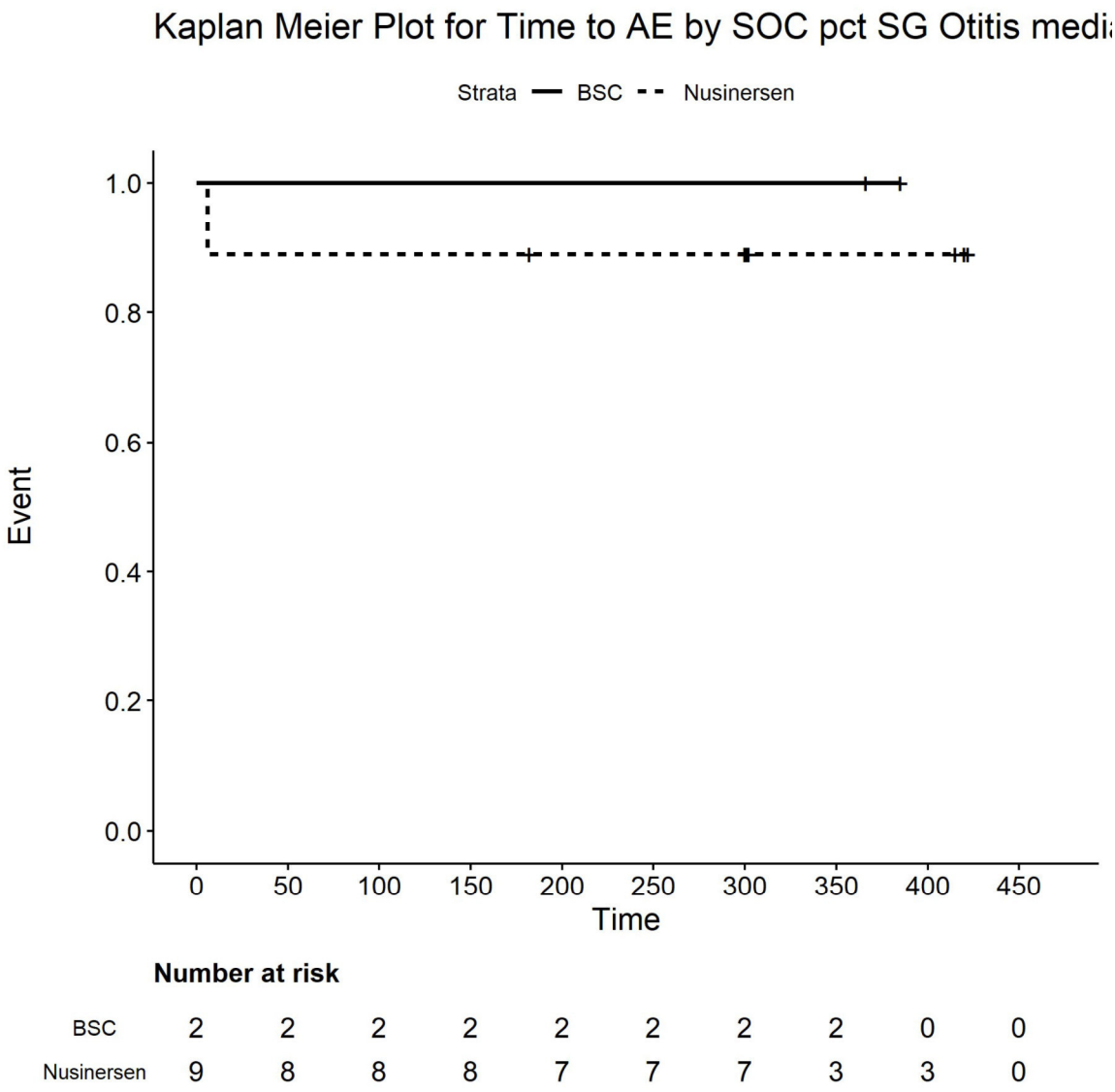
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	4	0



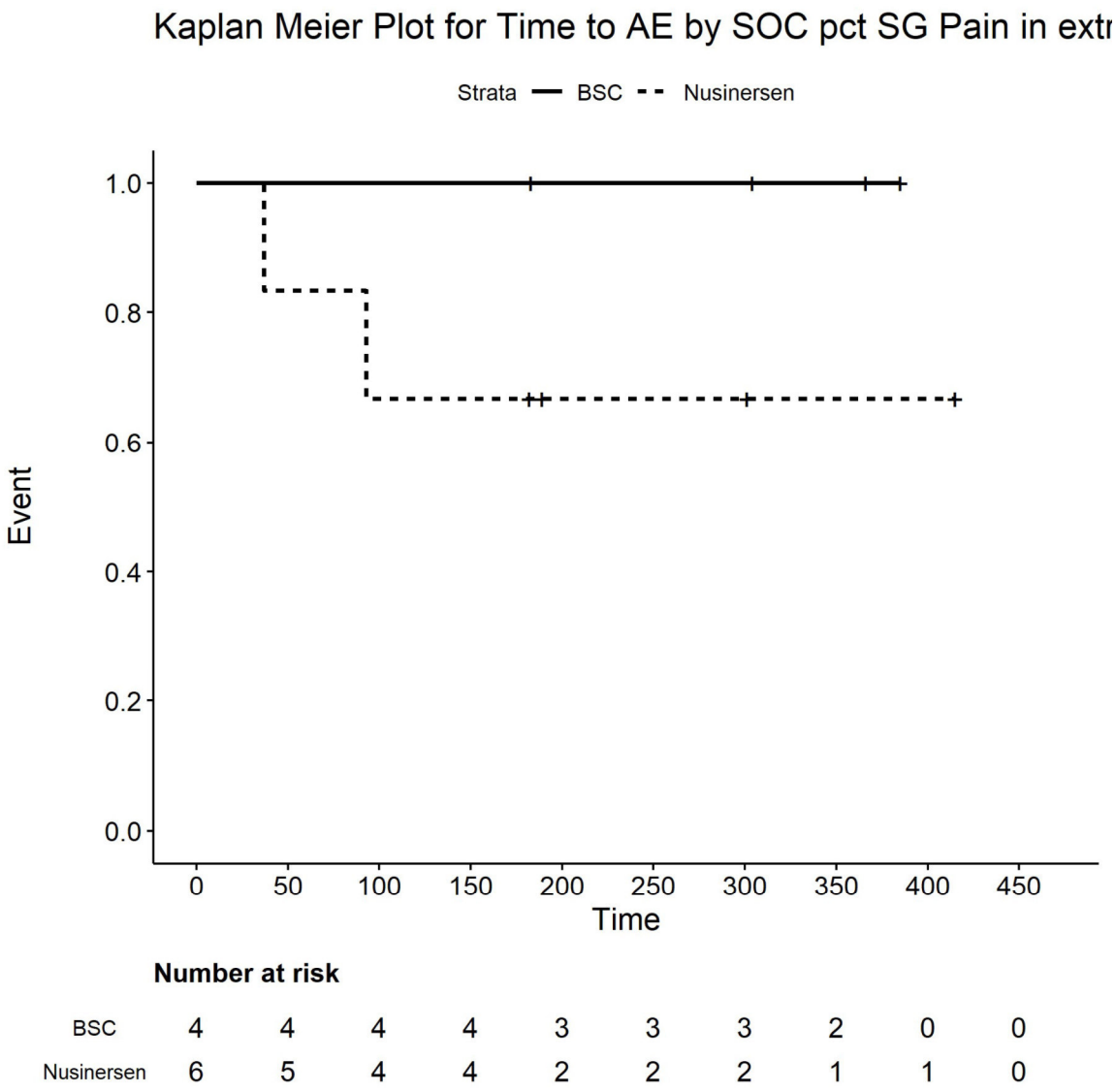
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	6	0



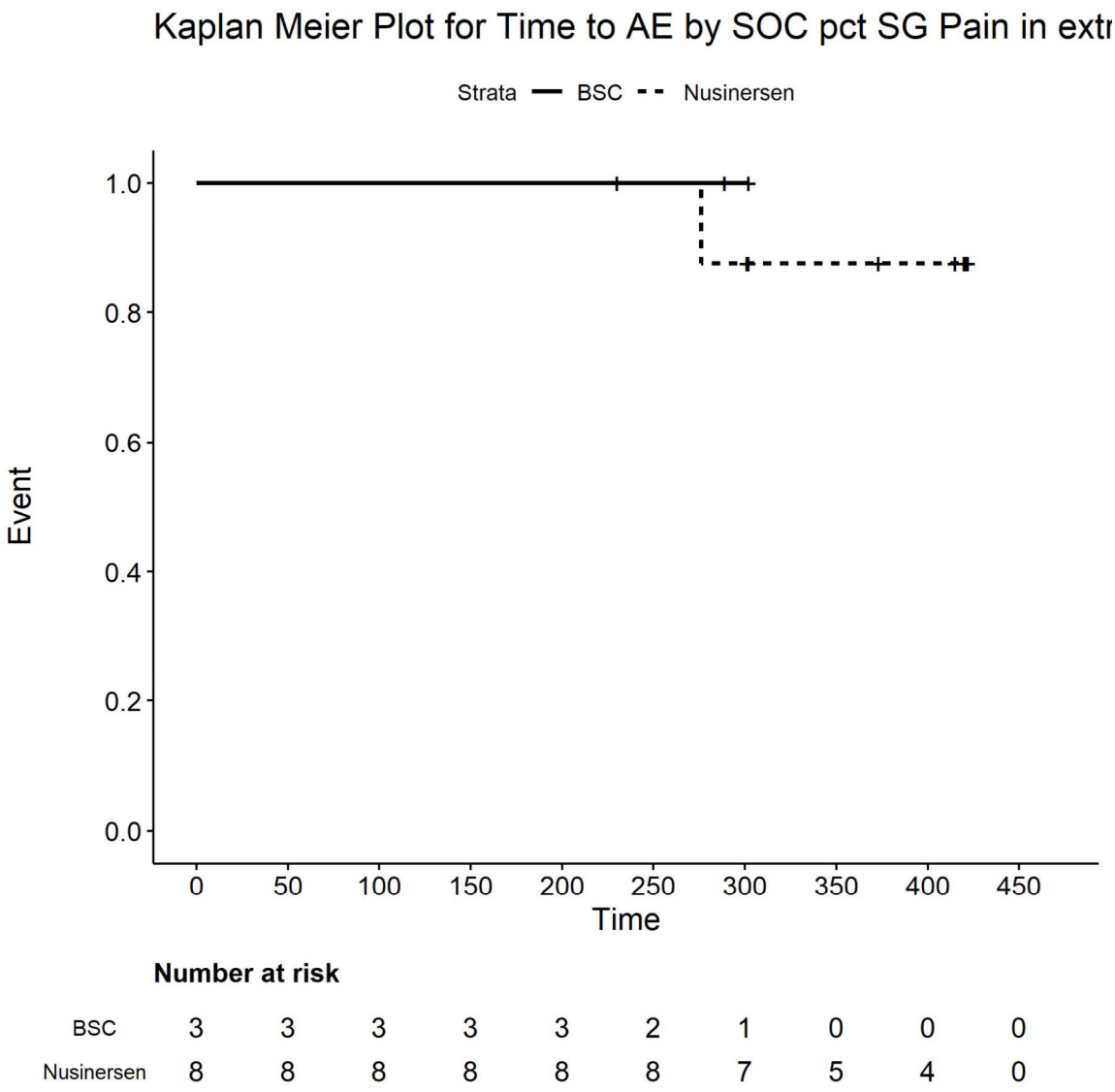
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	3	0



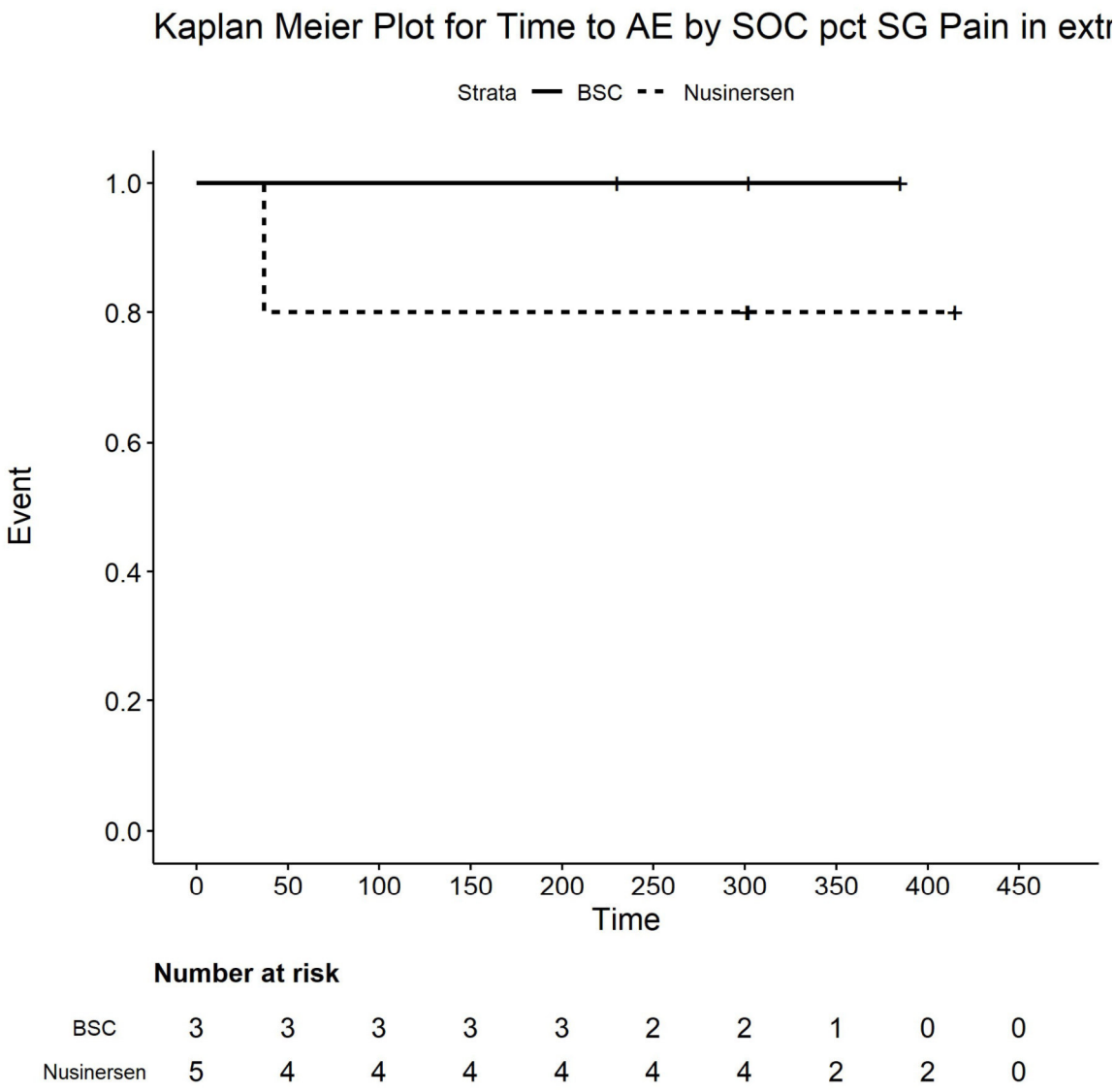
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	4	4	2	2	2	1	1	0



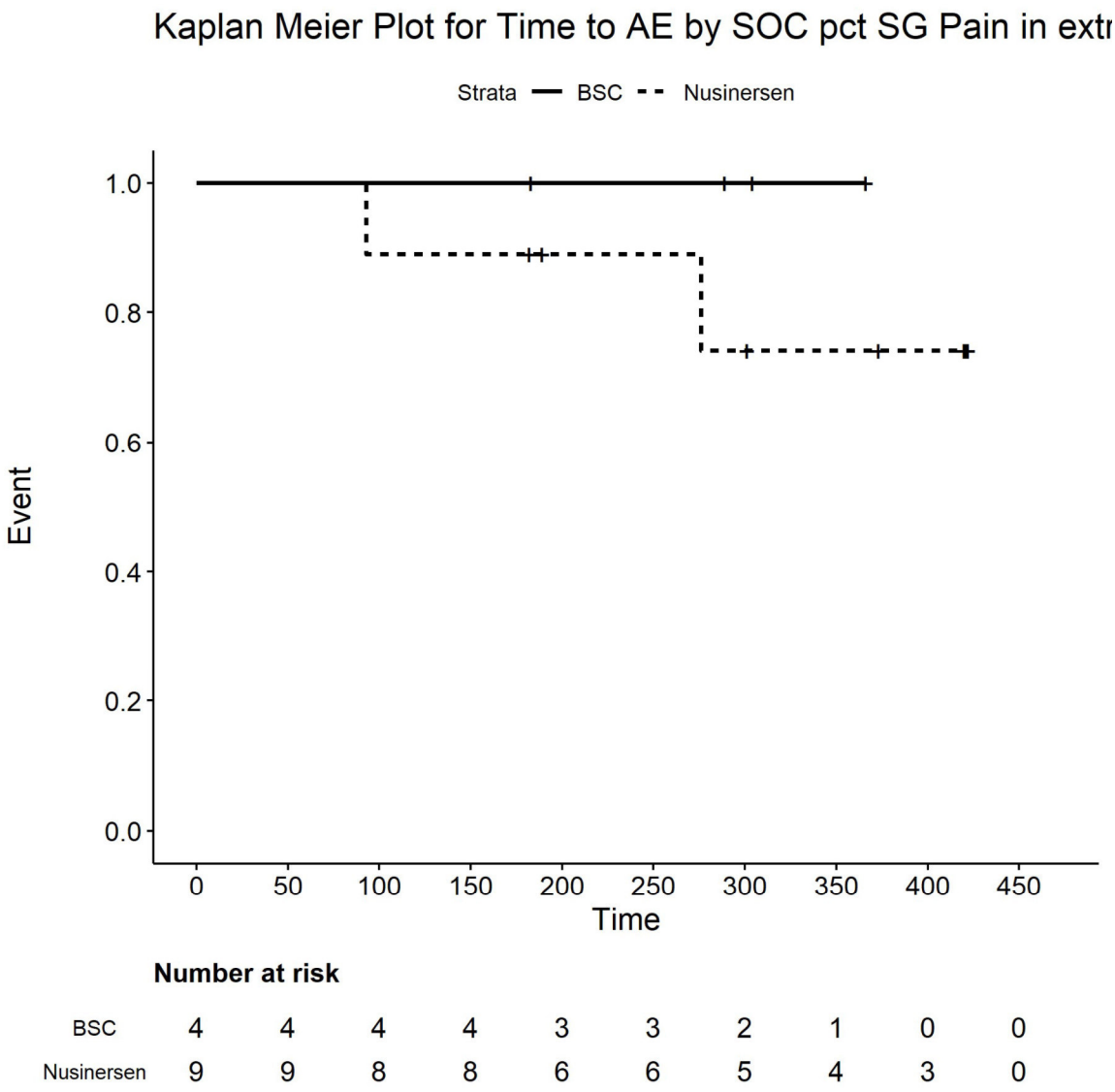
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	7	5	4	0



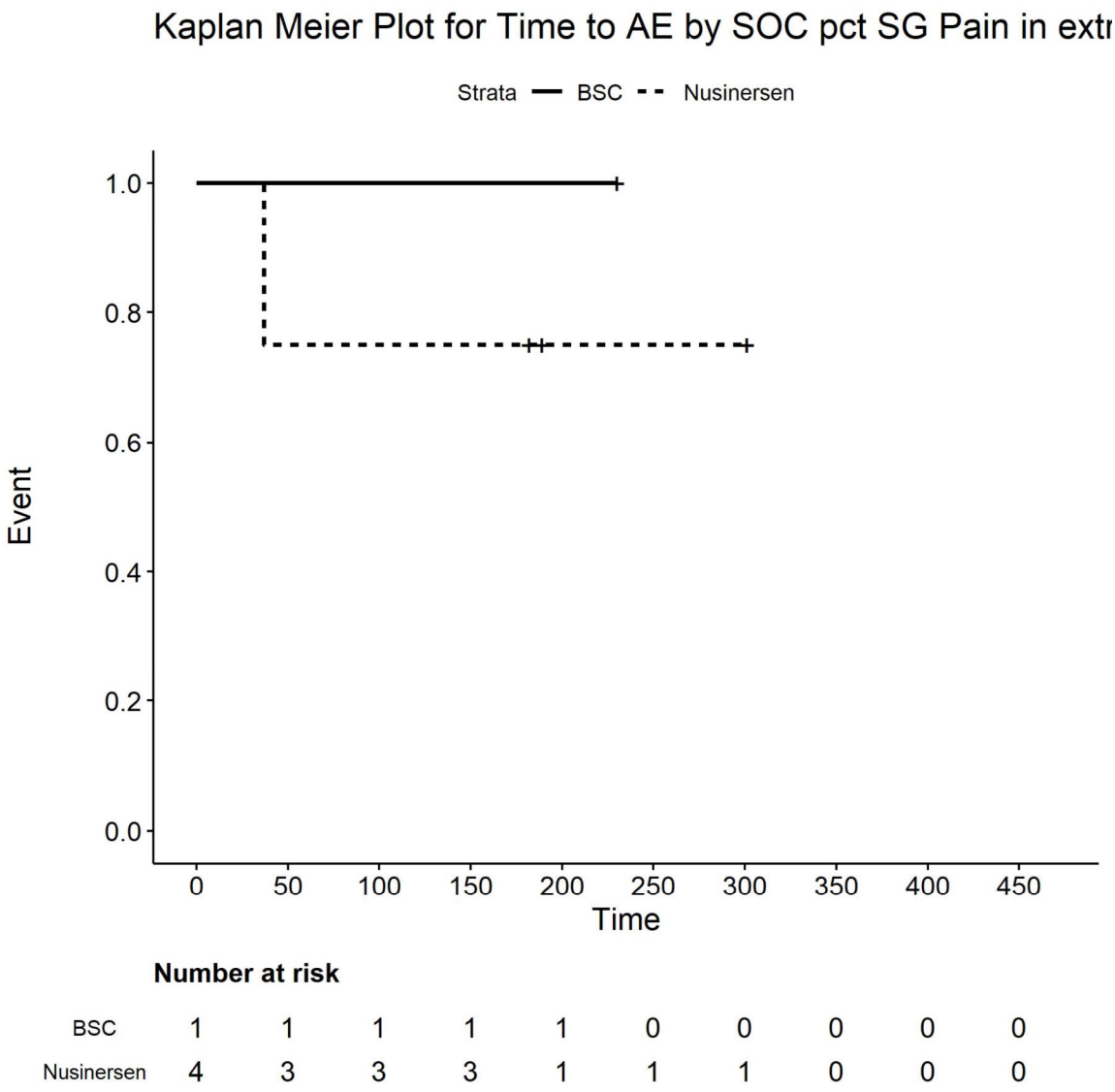
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



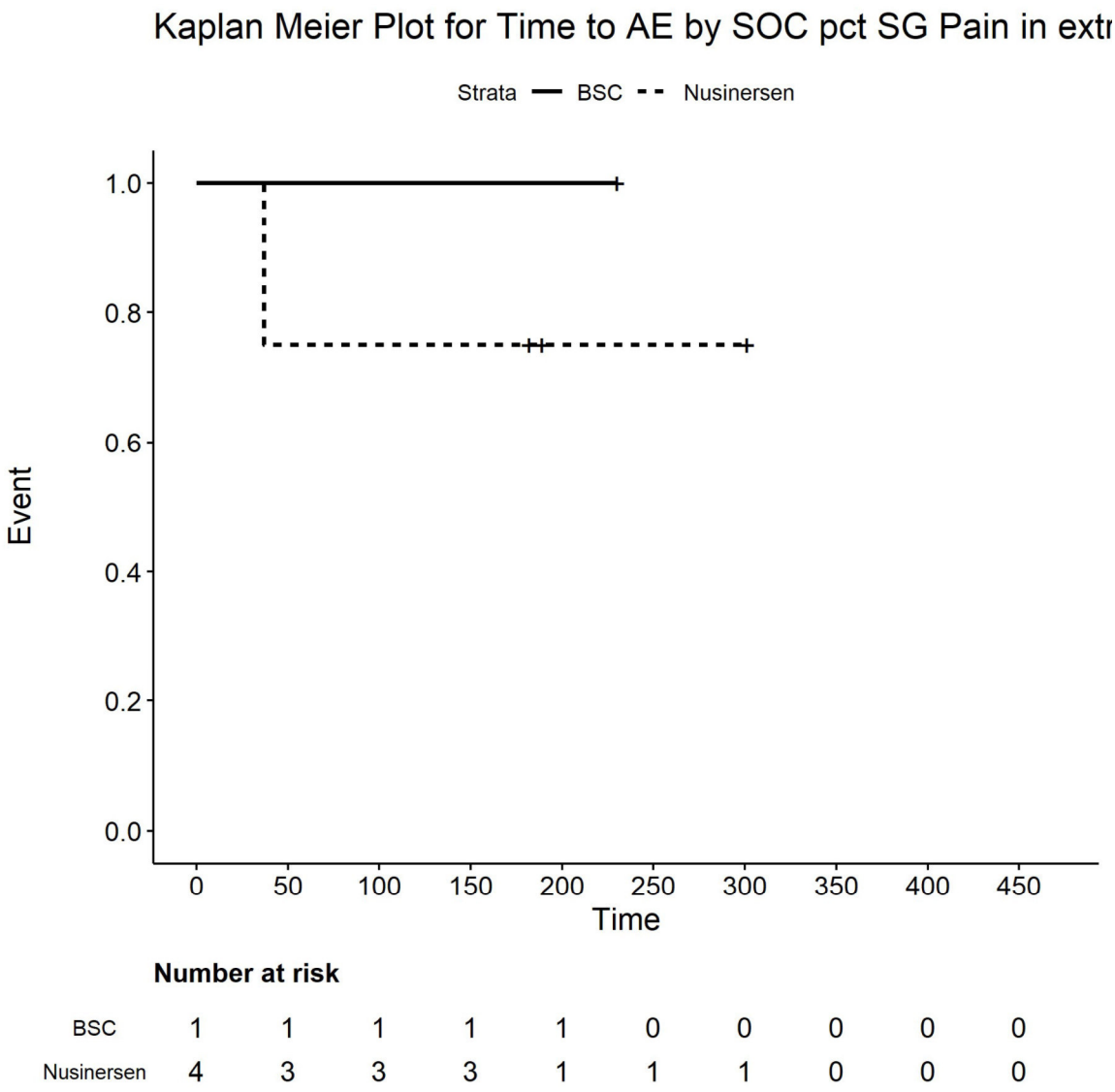
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



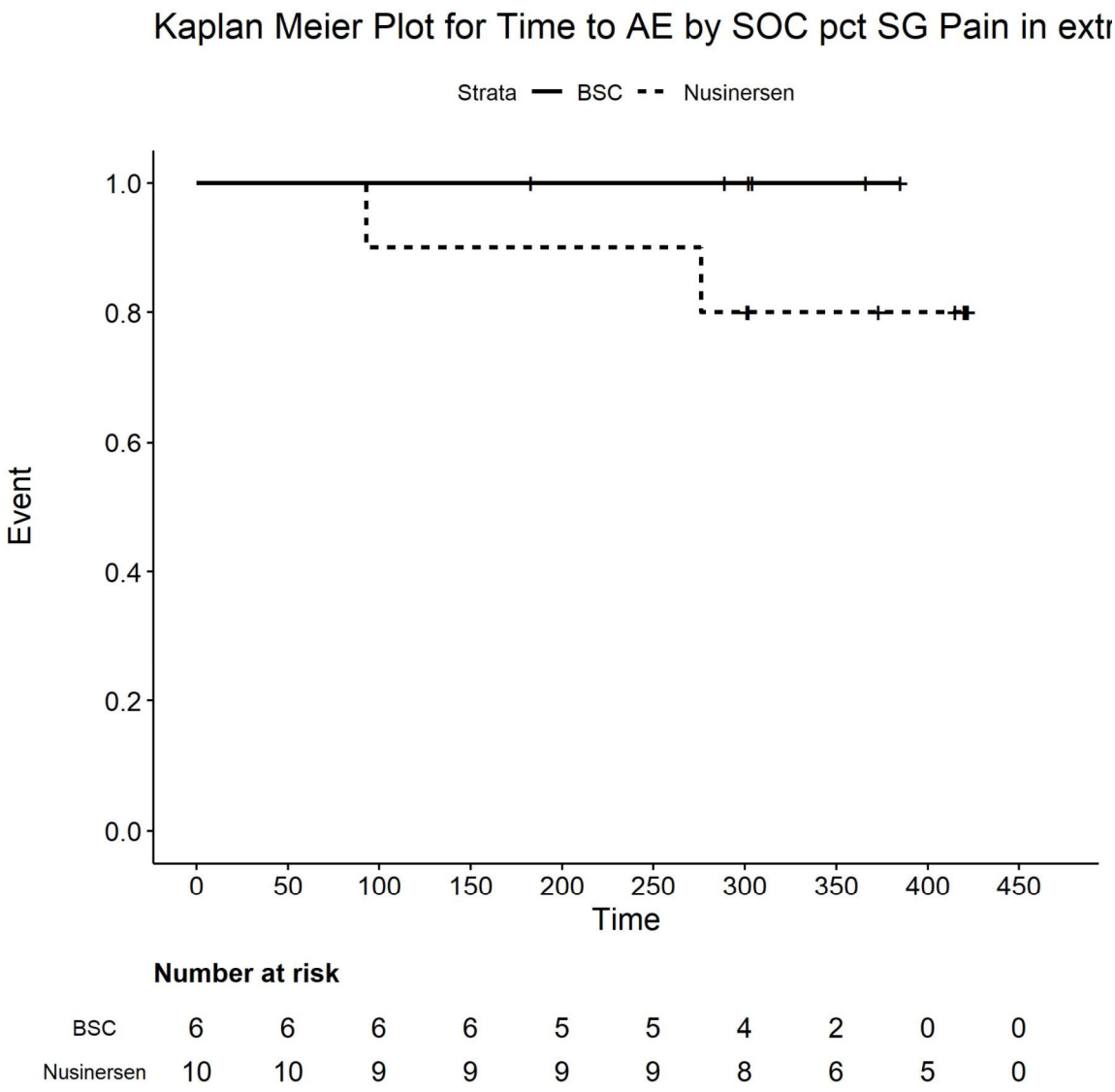
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



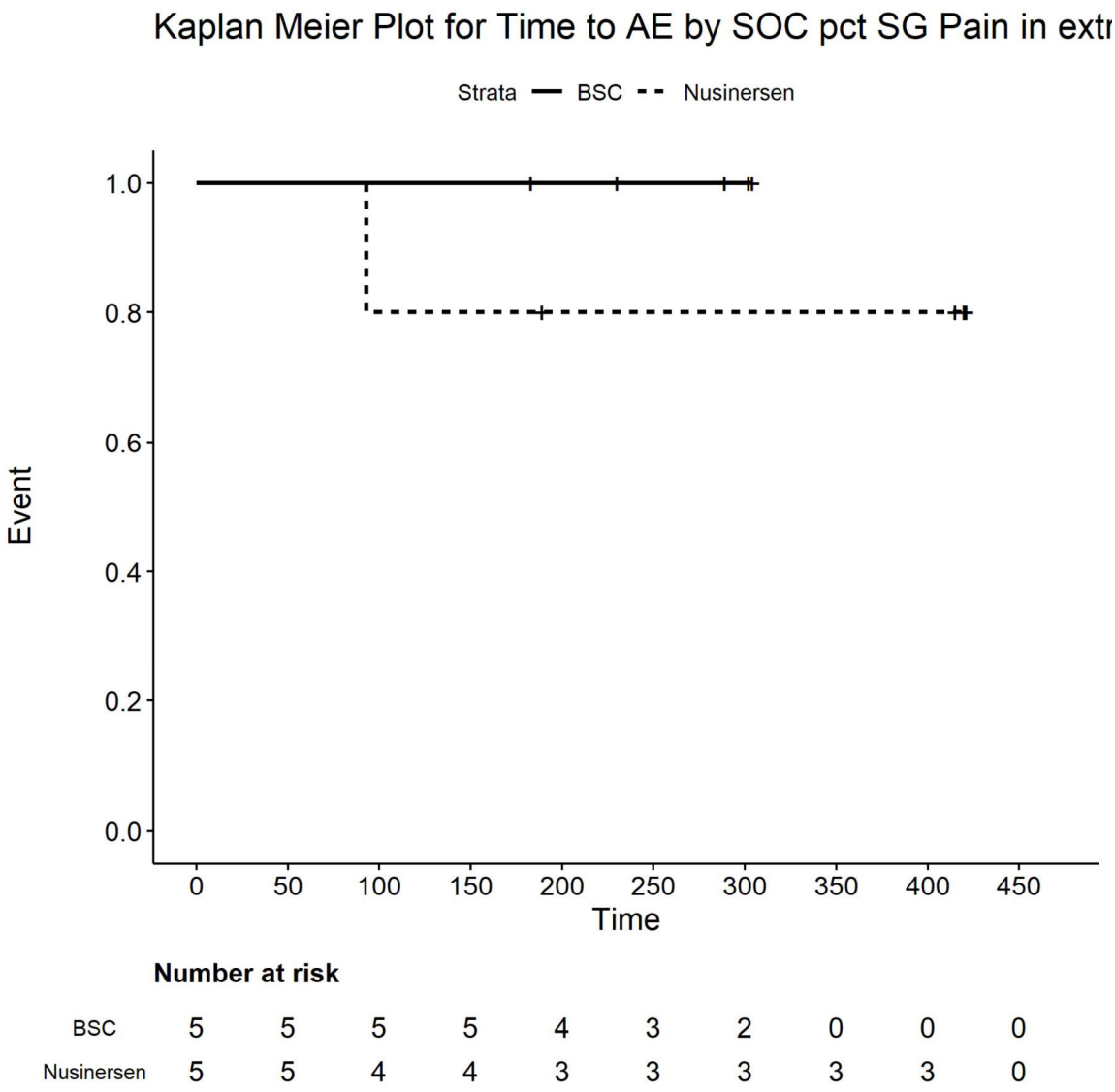
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



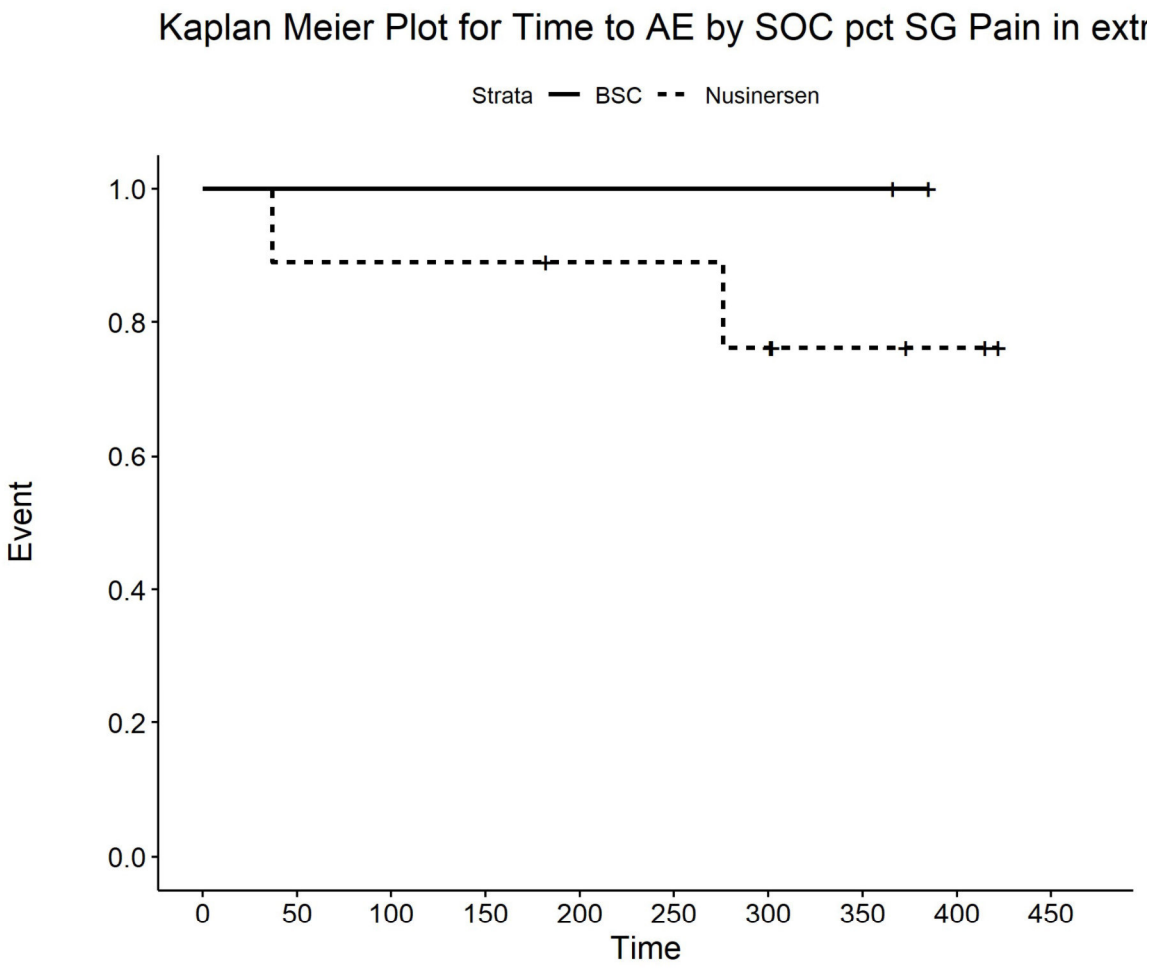
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



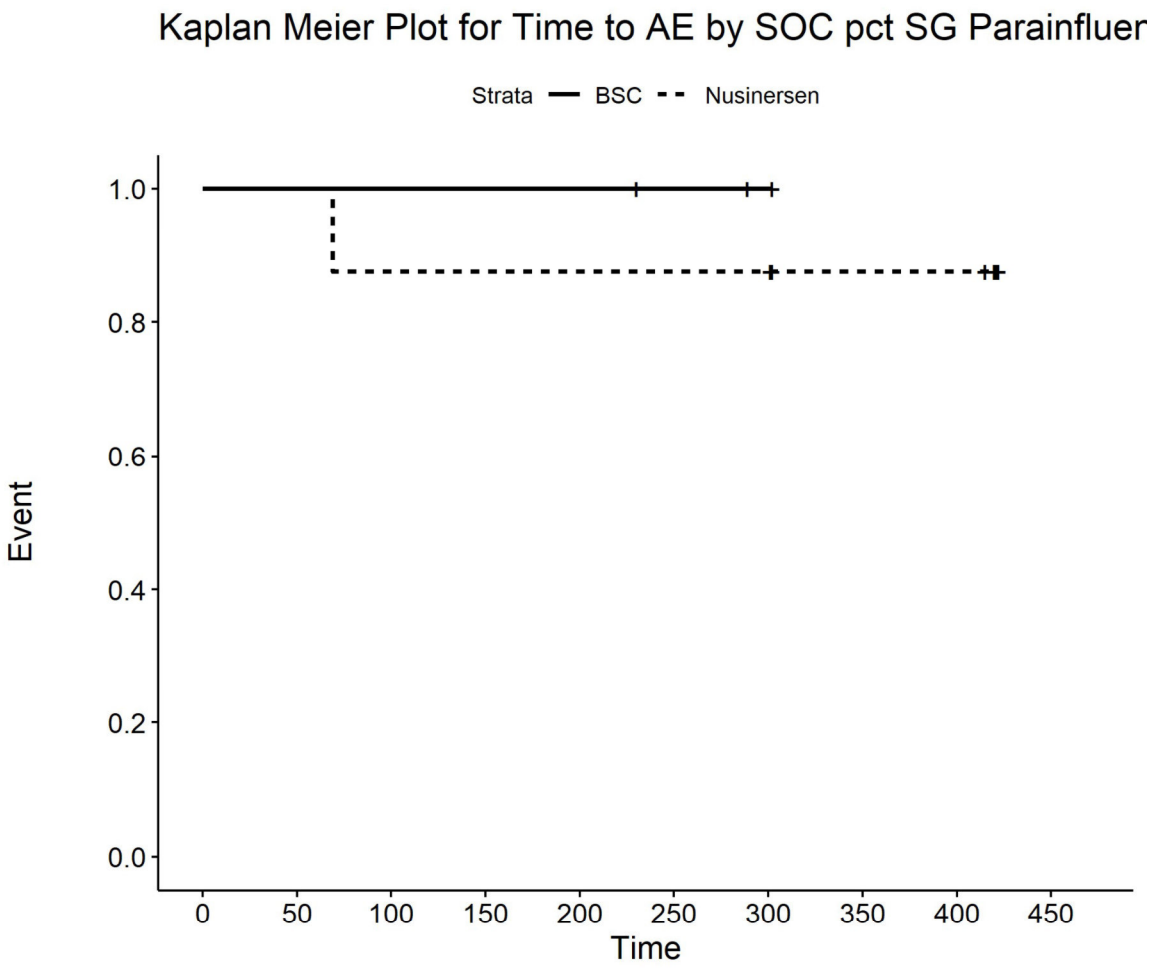
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	4	4	3	3	3	3	3	0



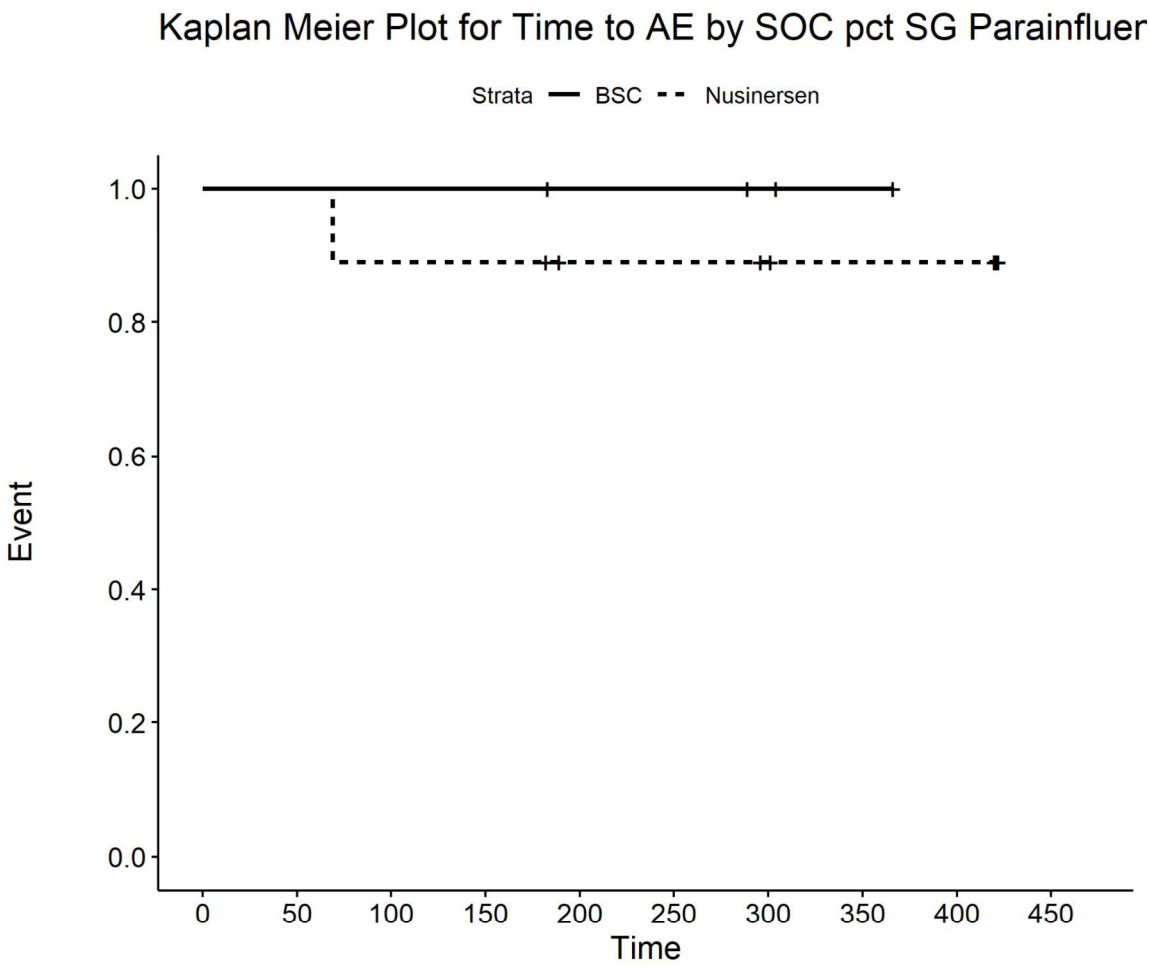
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	6	3	2	0



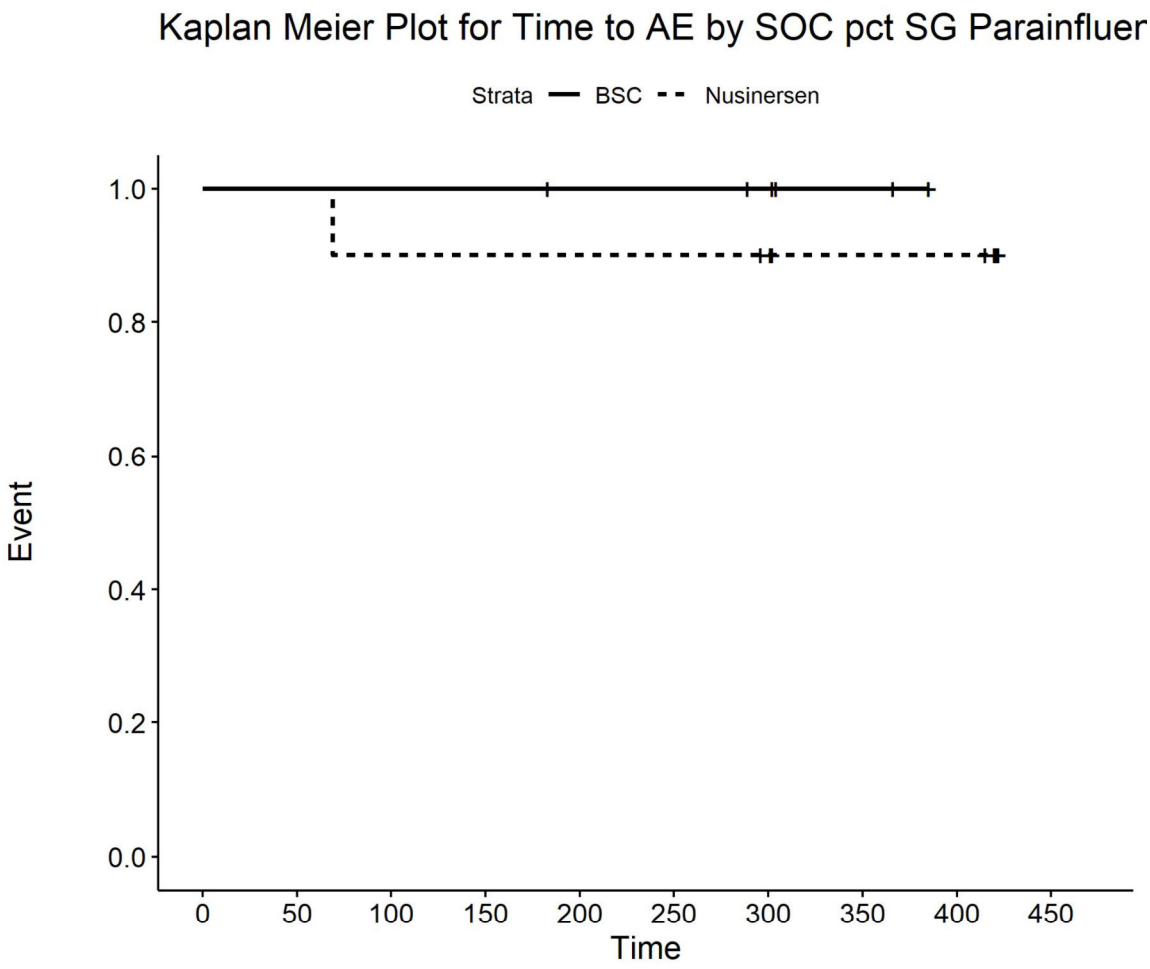
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	5	0



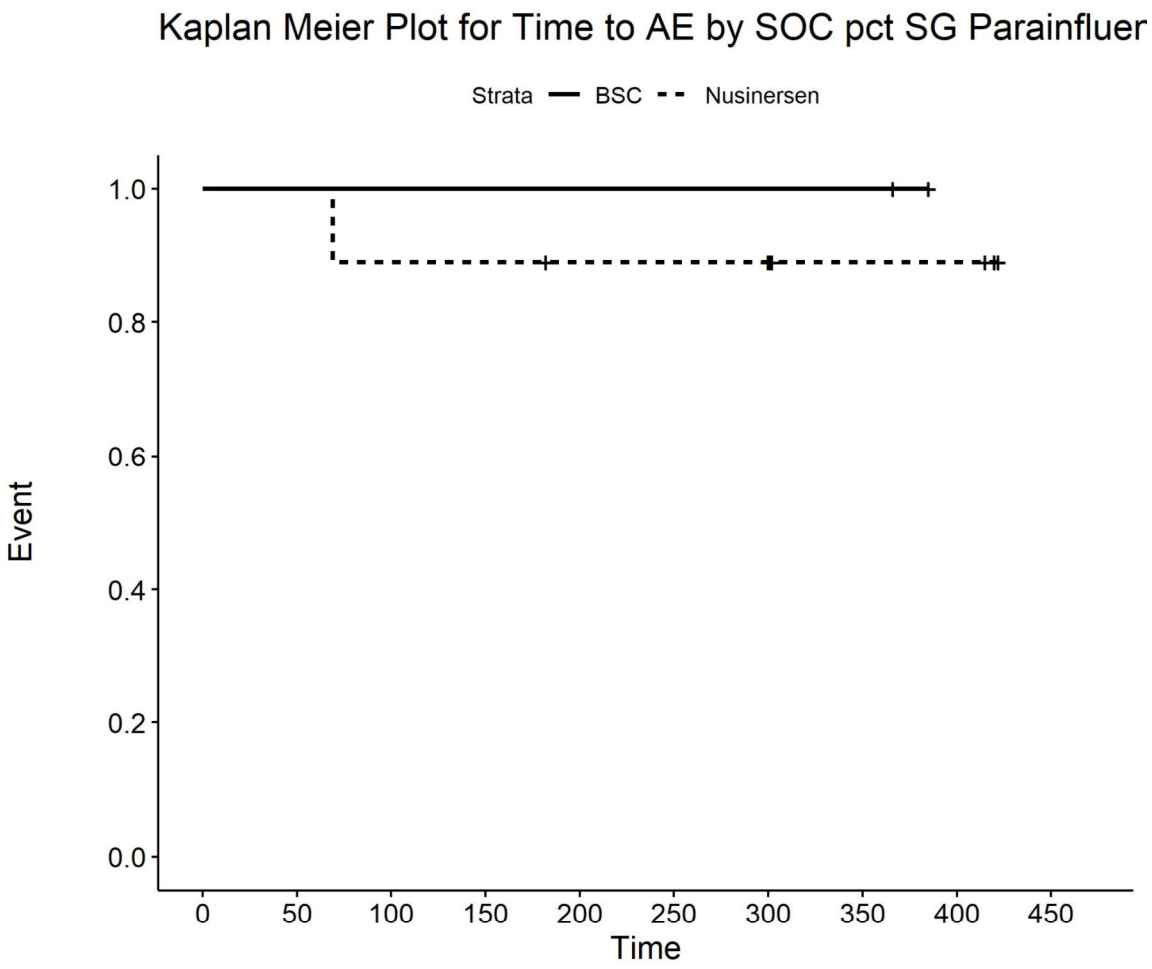
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	4	0



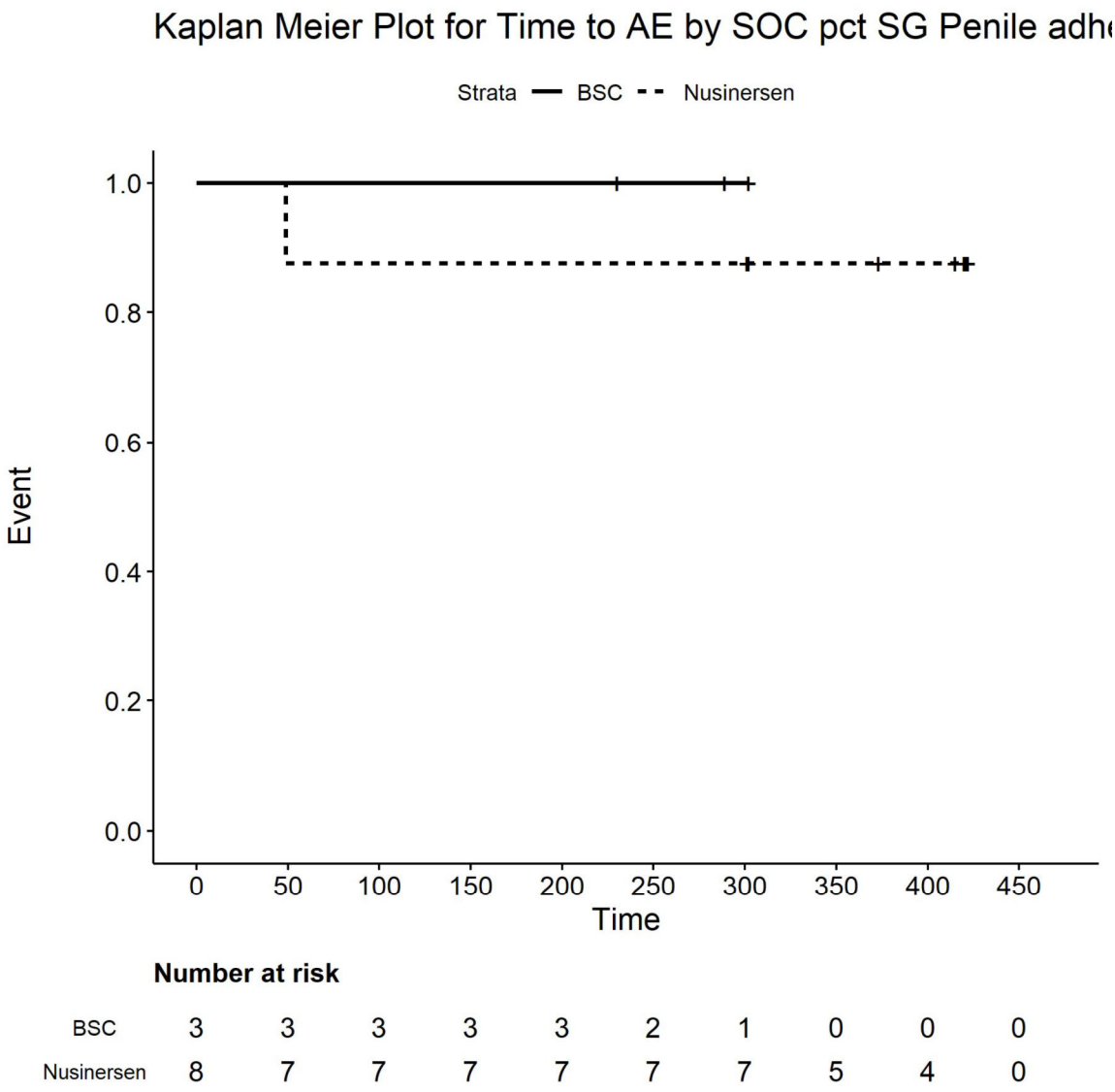
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	6	0



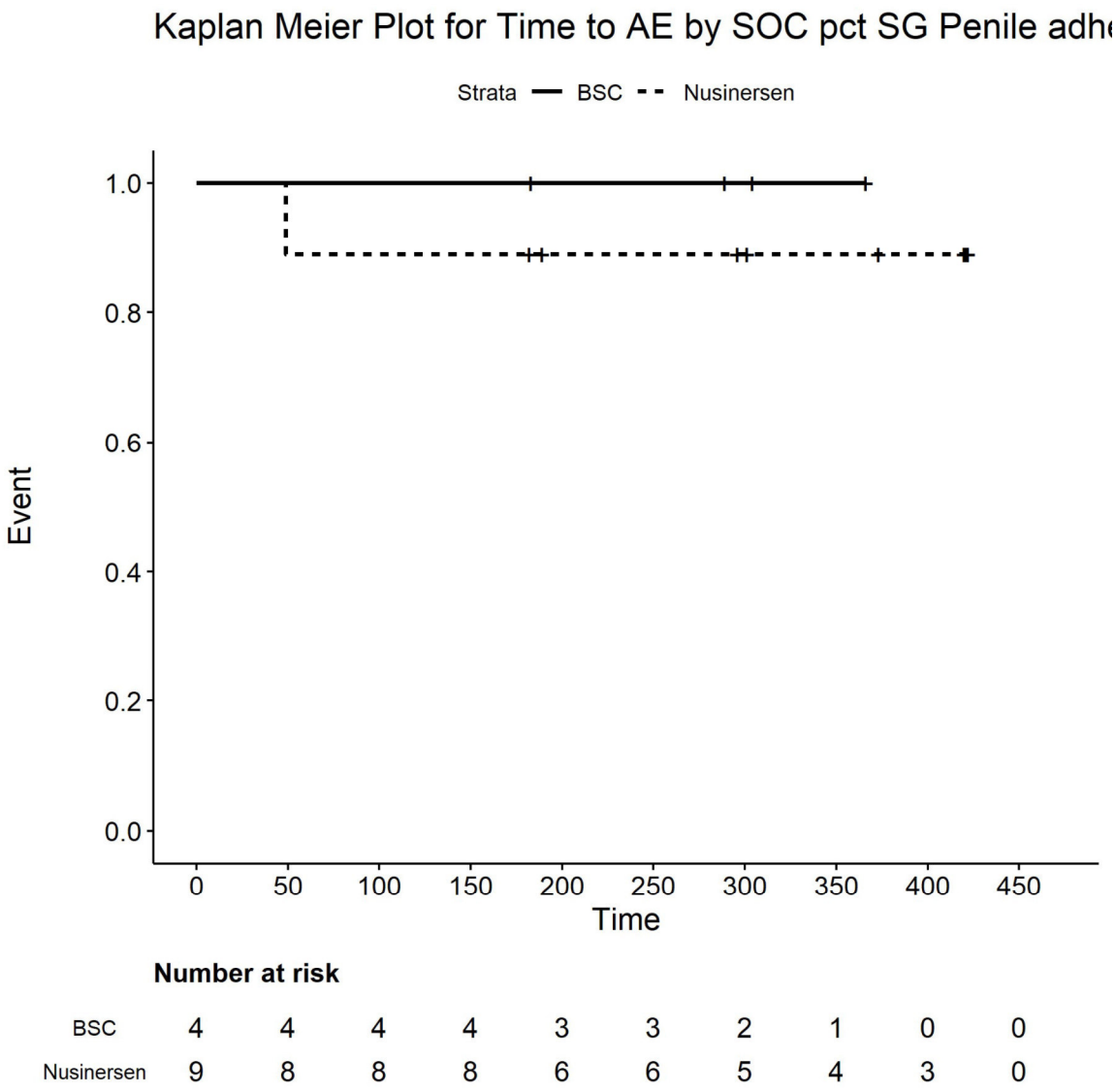
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	3	0



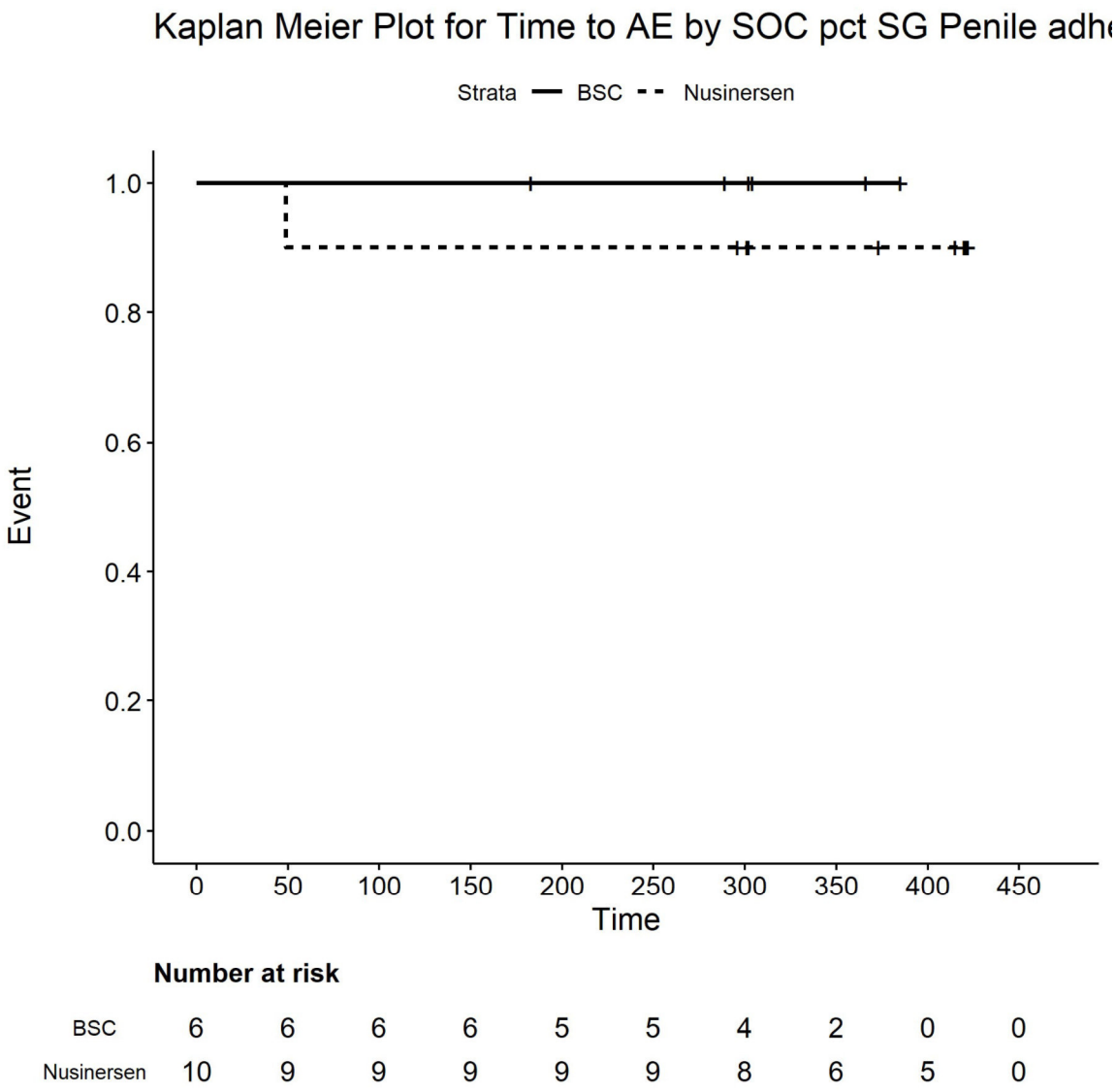
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



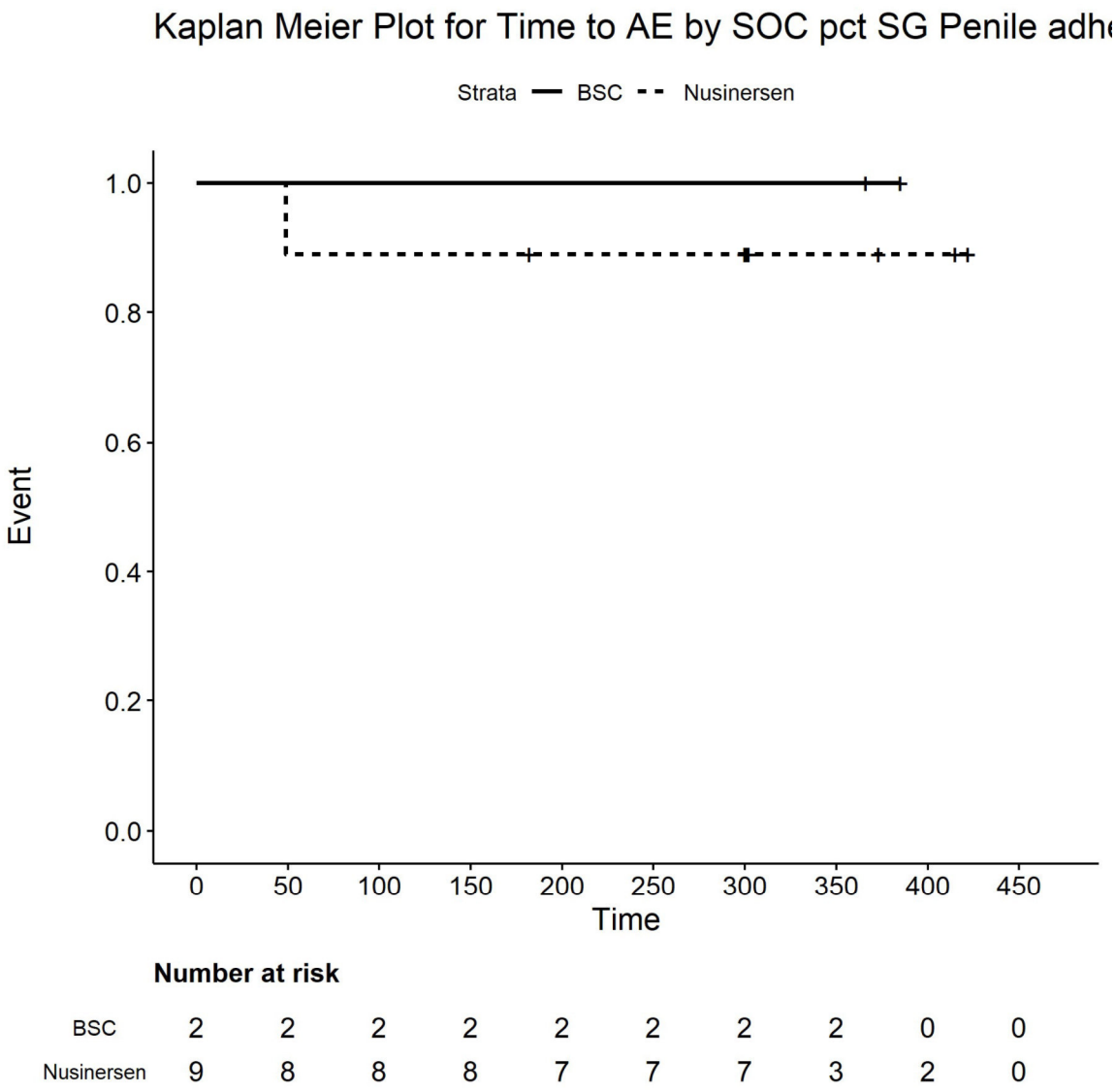
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



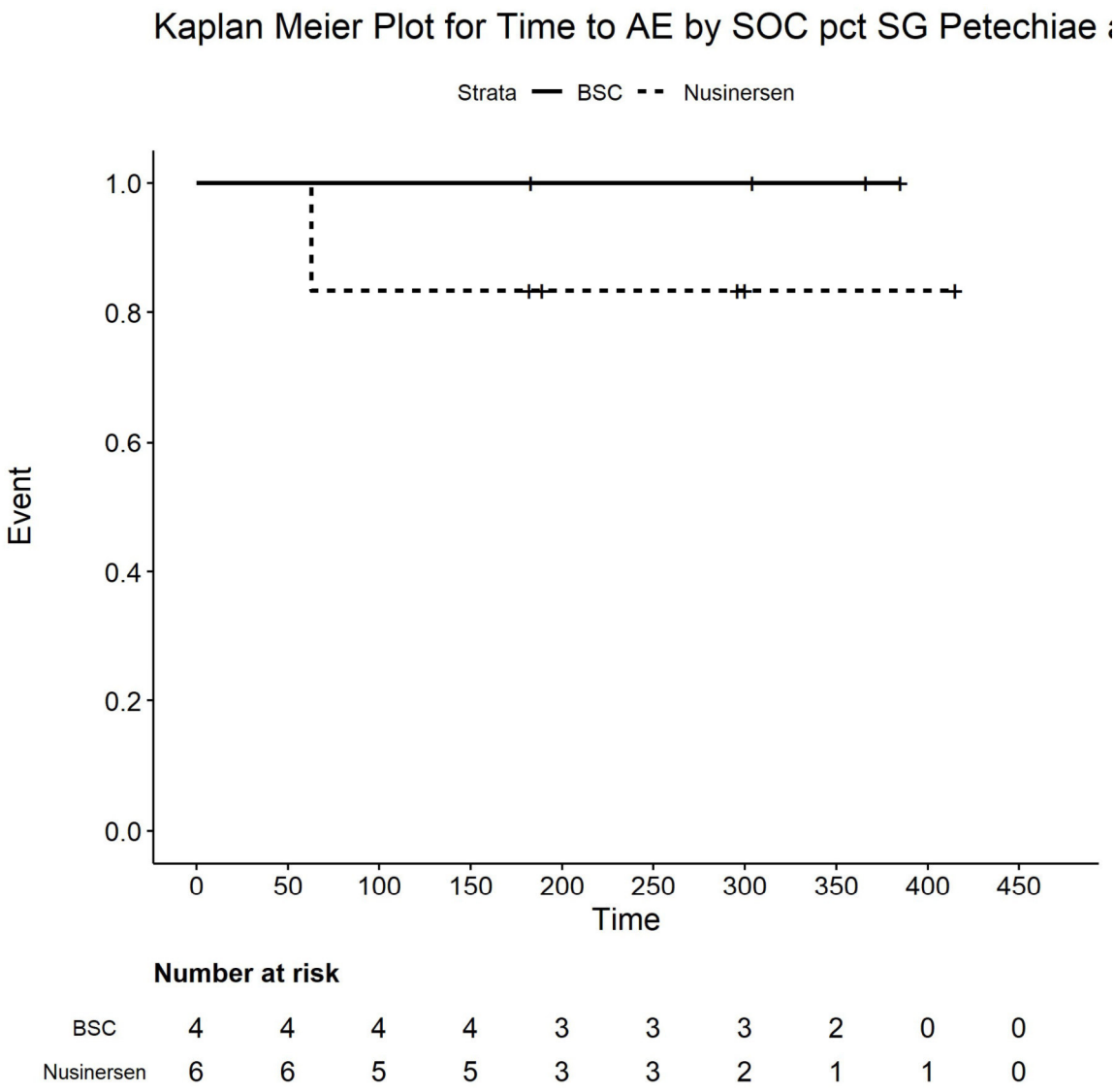
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



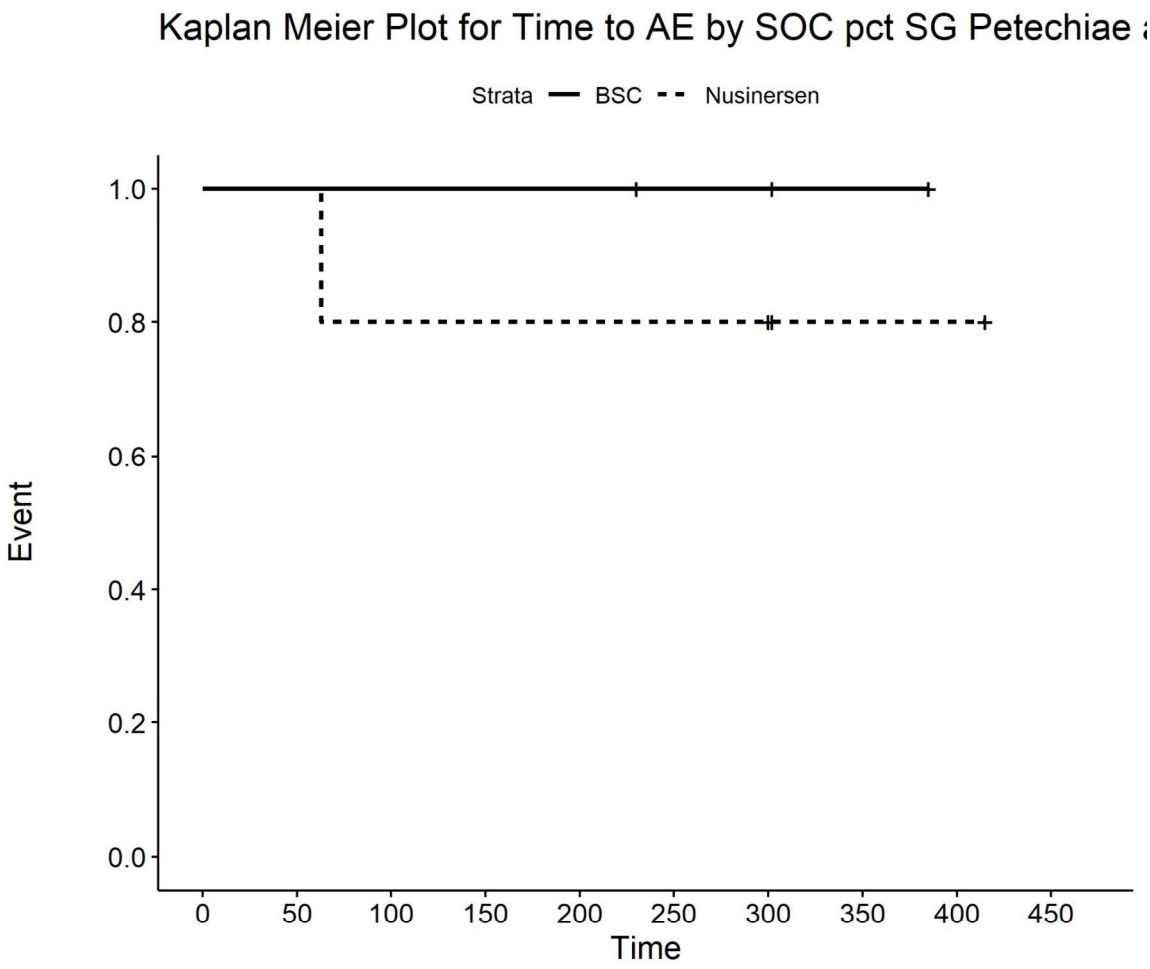
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	2	0



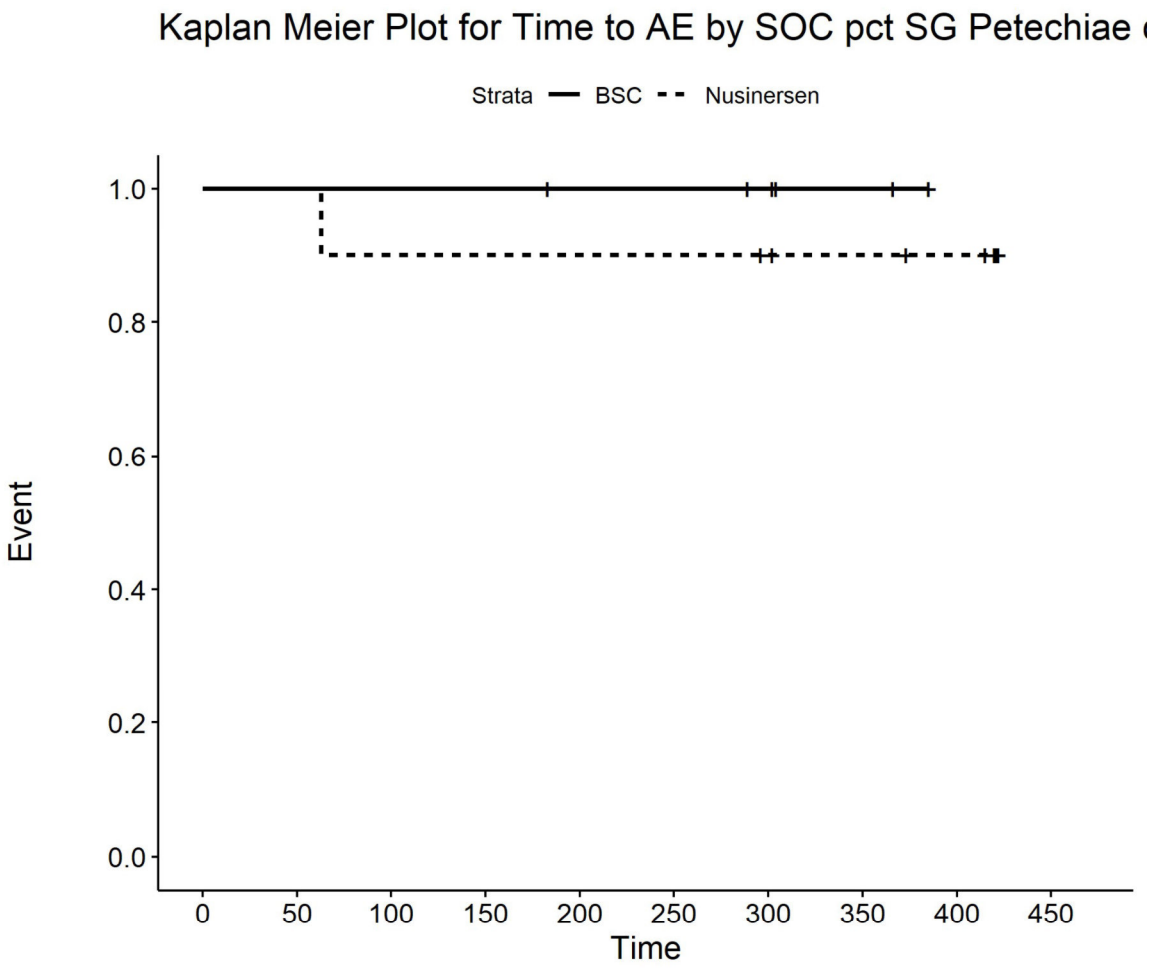
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



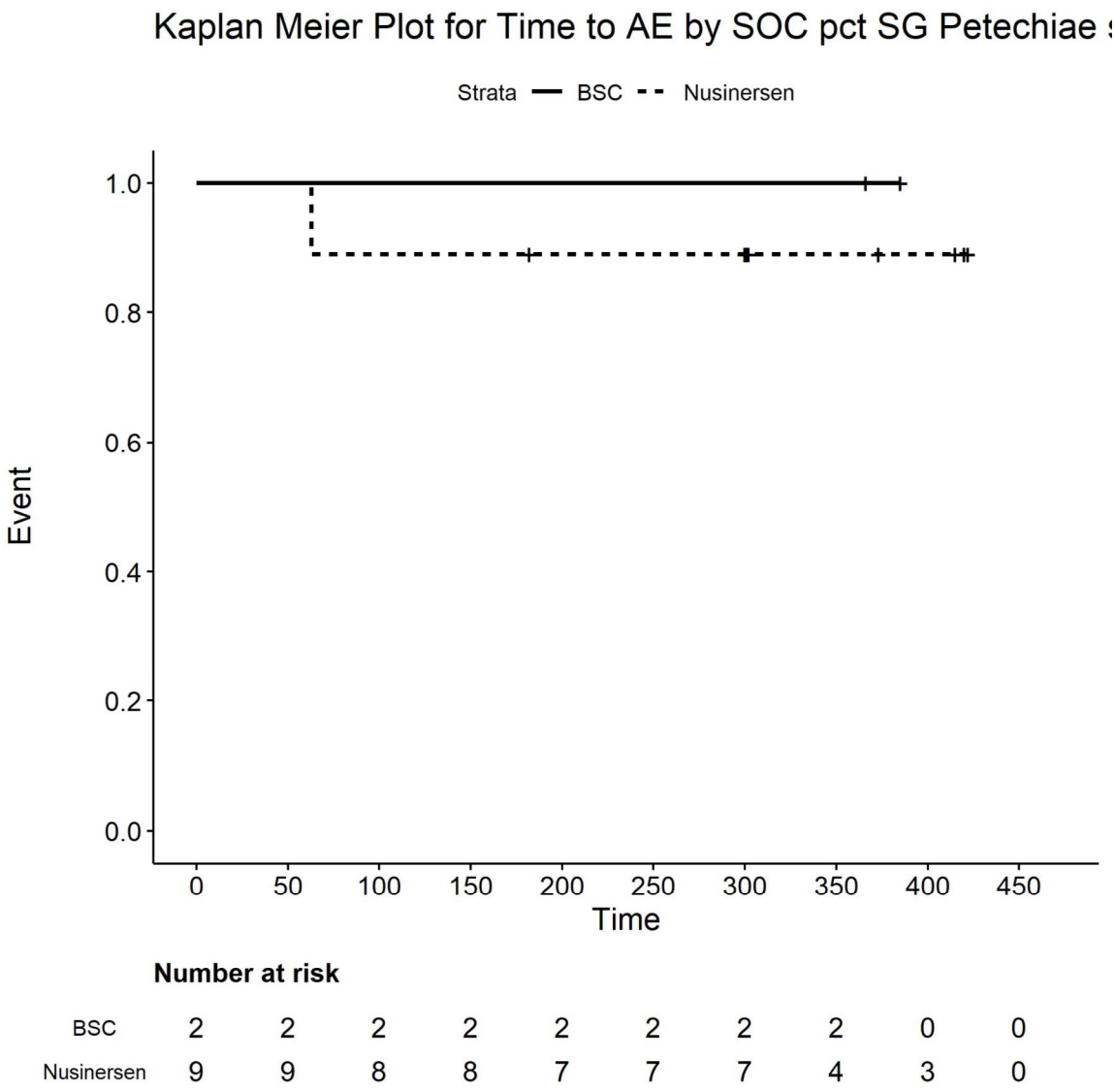
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



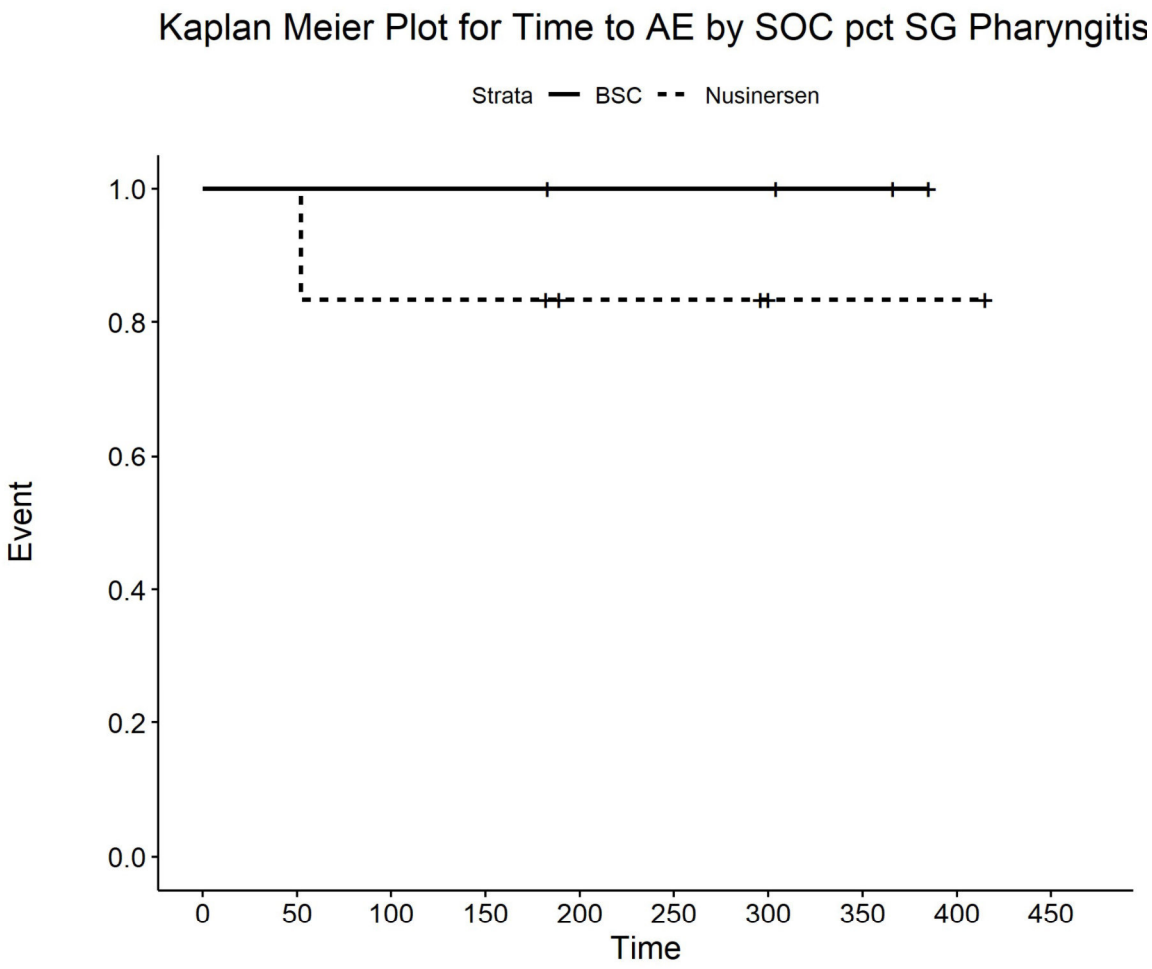
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



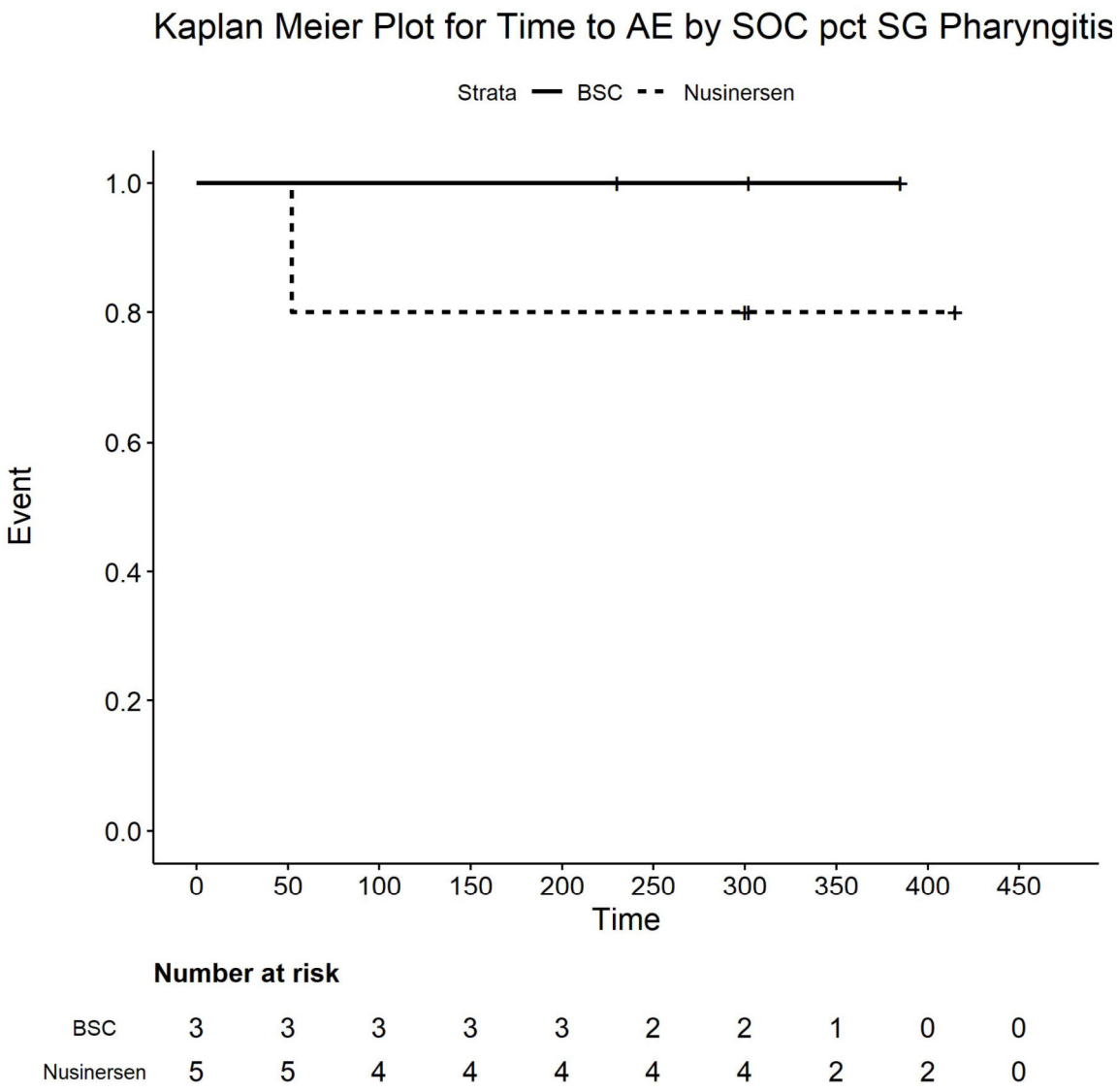
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



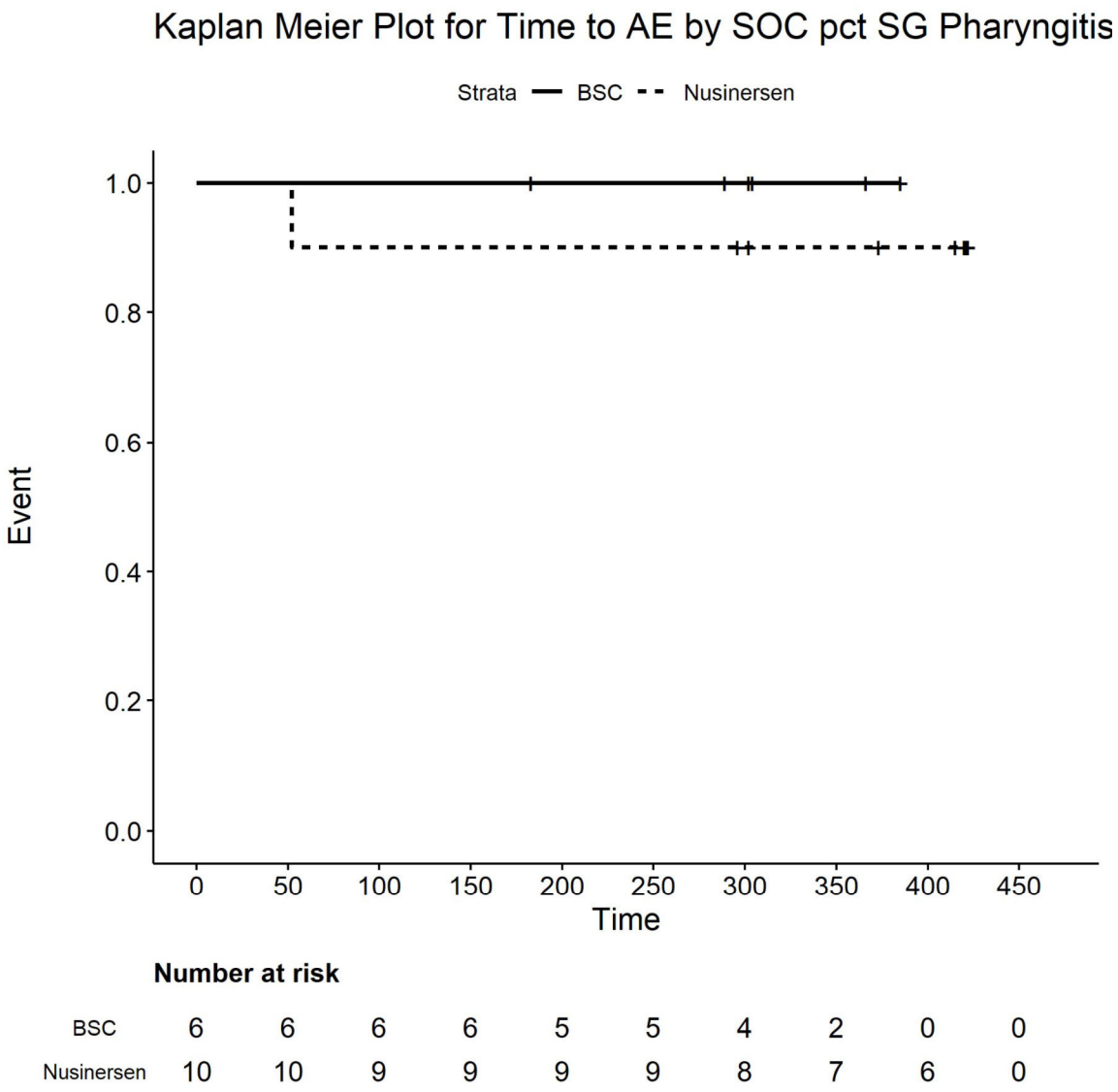
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



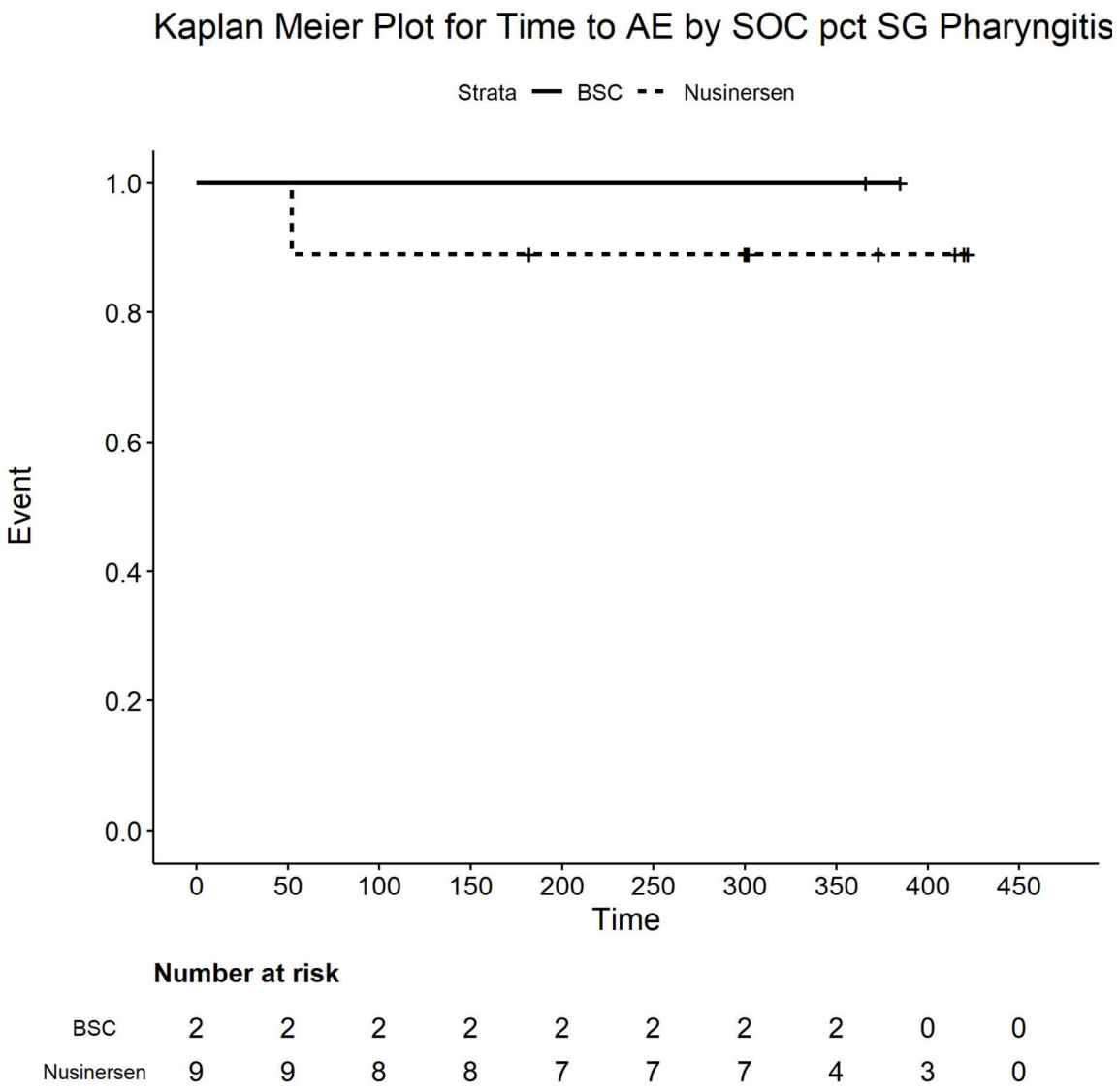
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



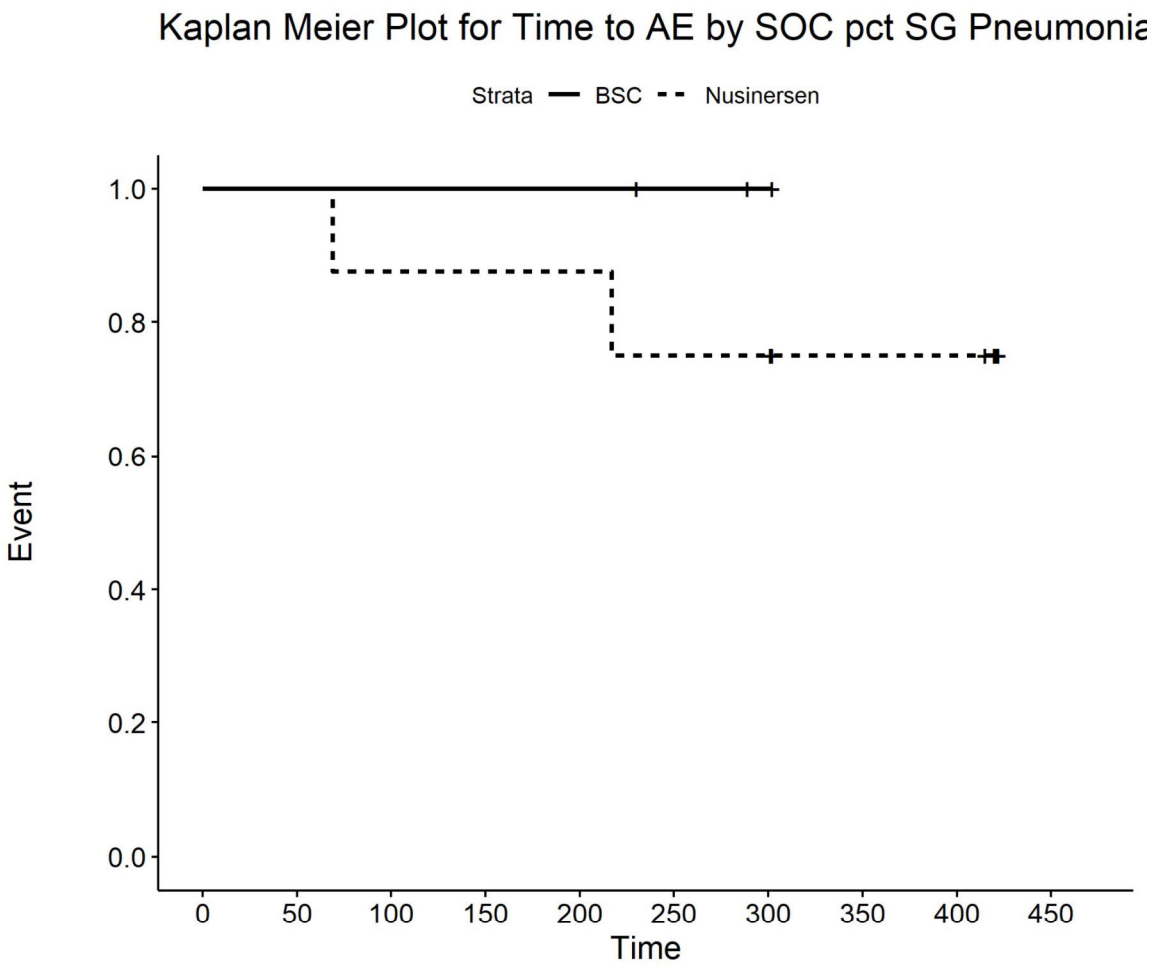
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



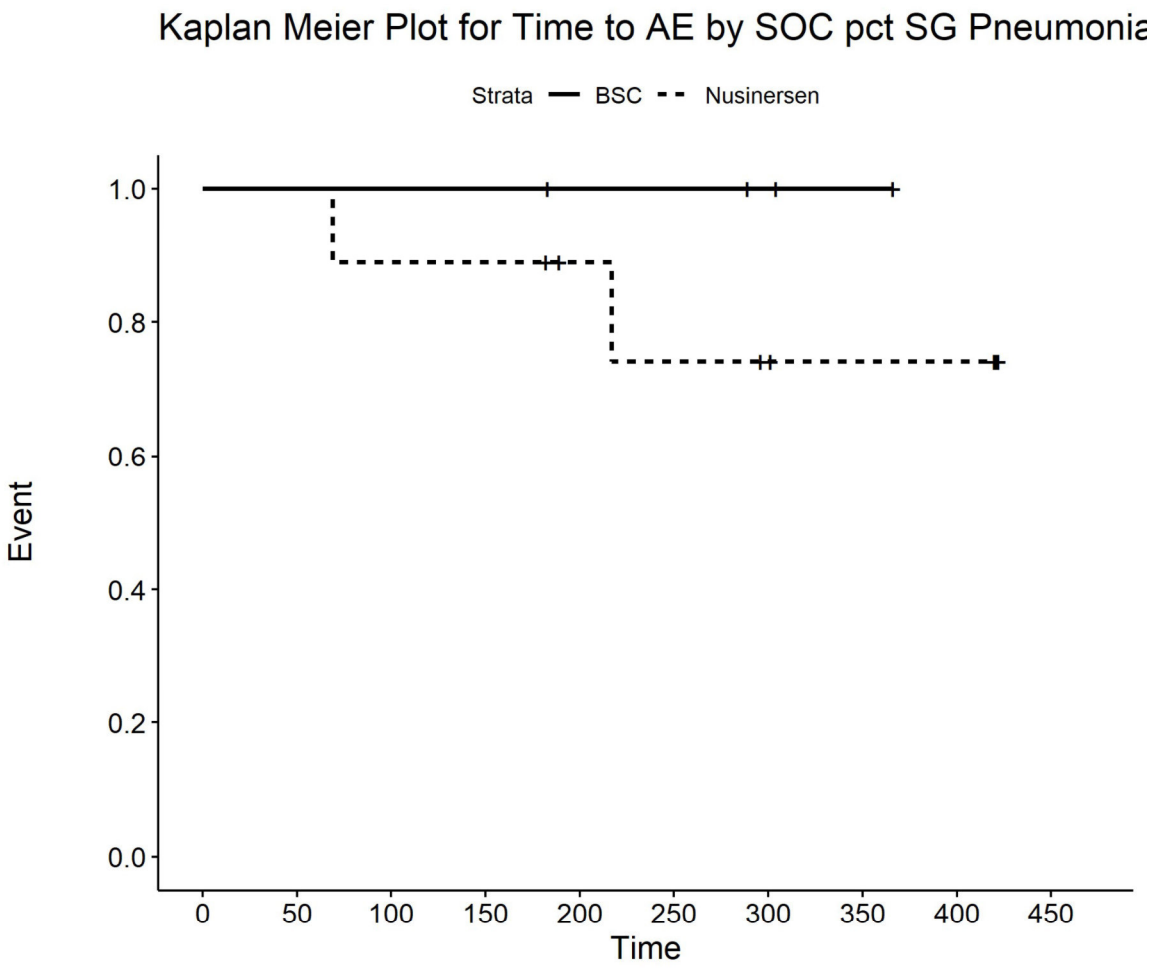
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



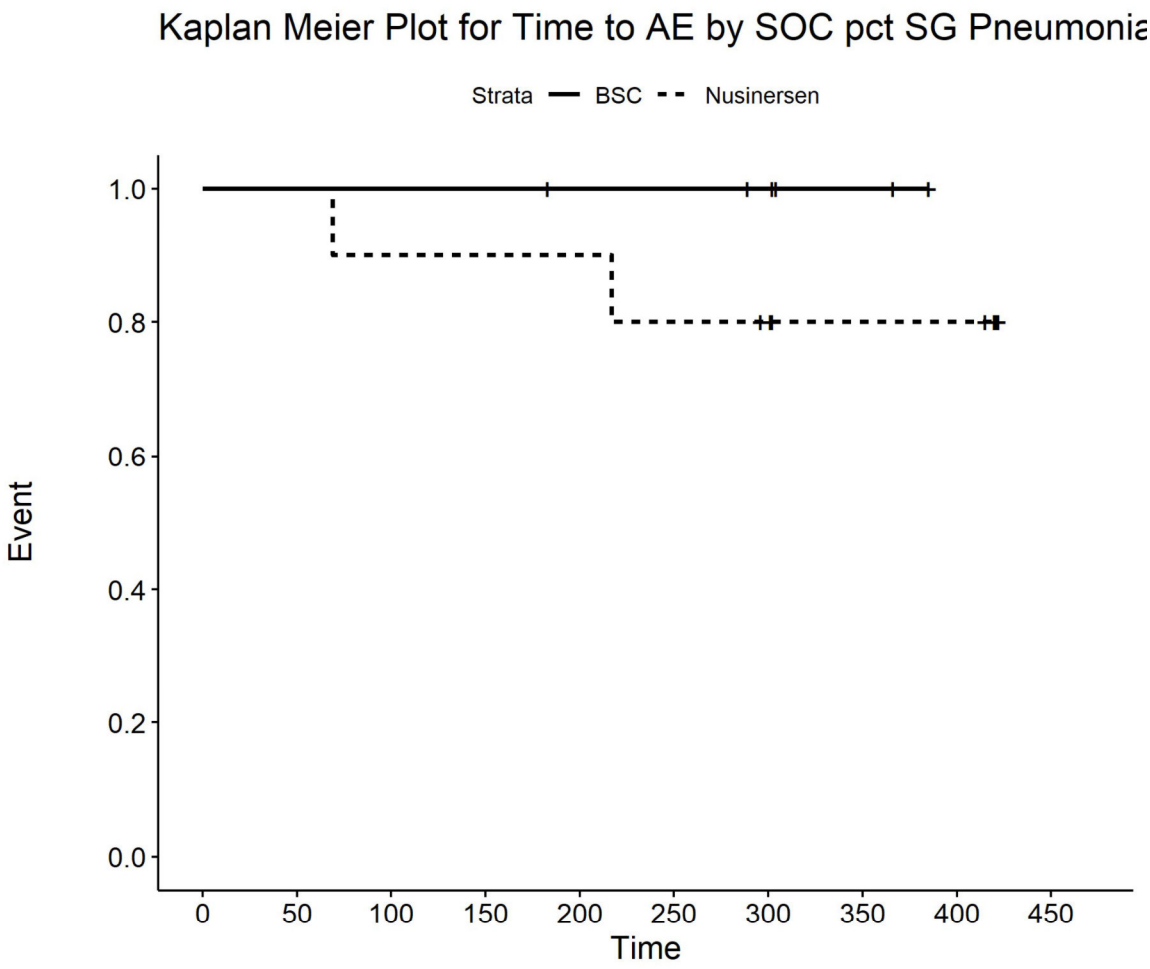
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	6	6	4	4	0



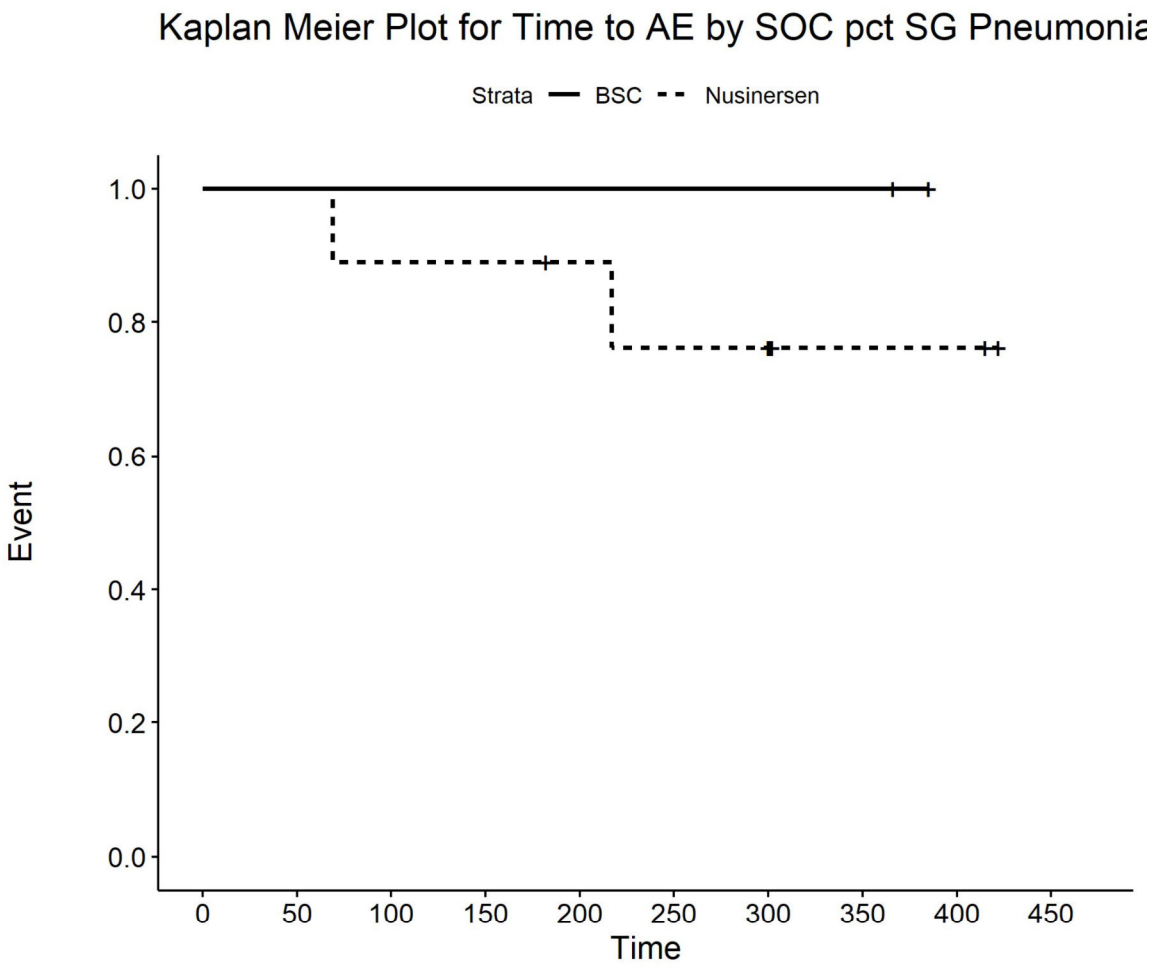
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	5	4	3	3	0



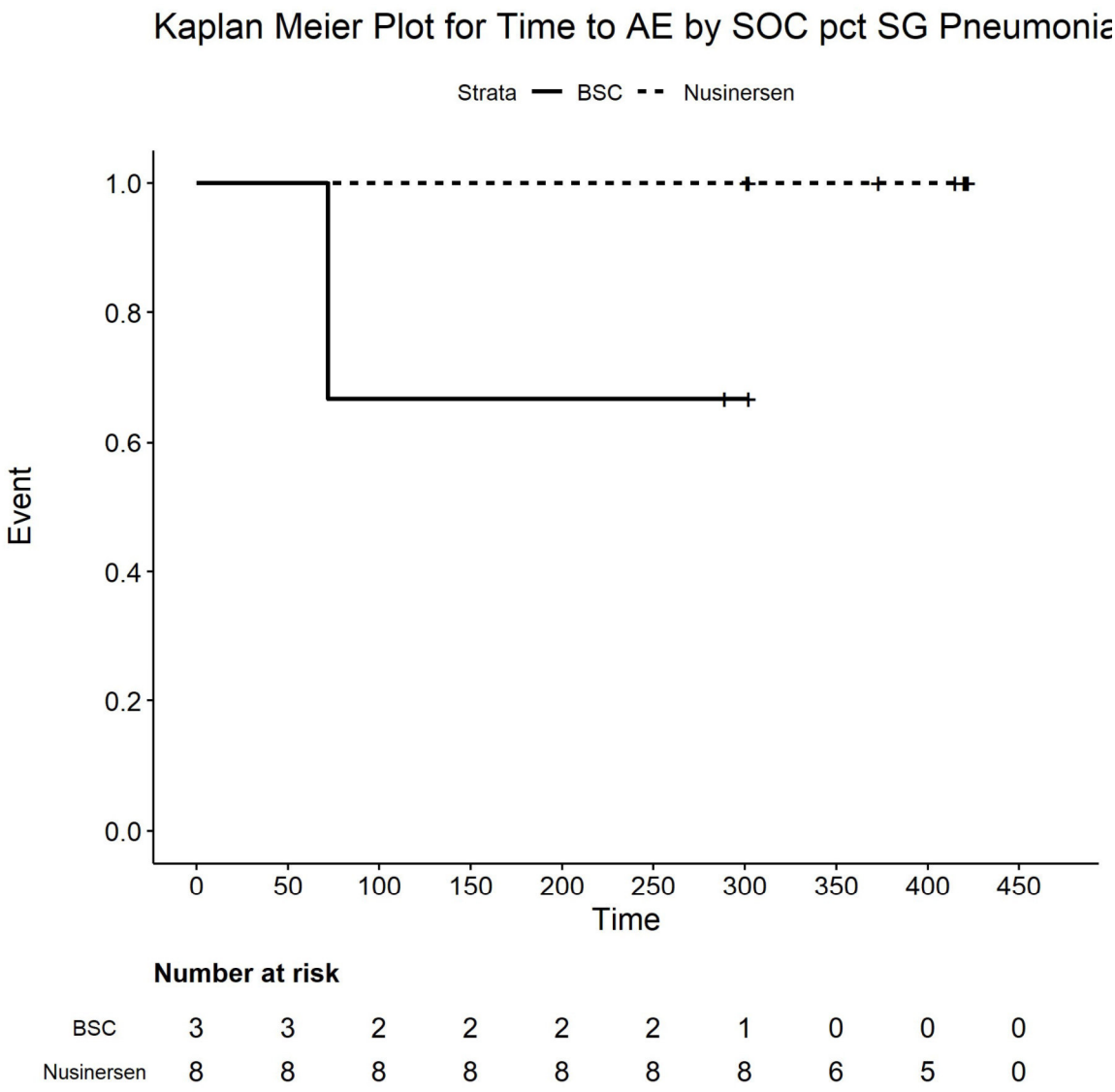
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	8	7	5	5	0



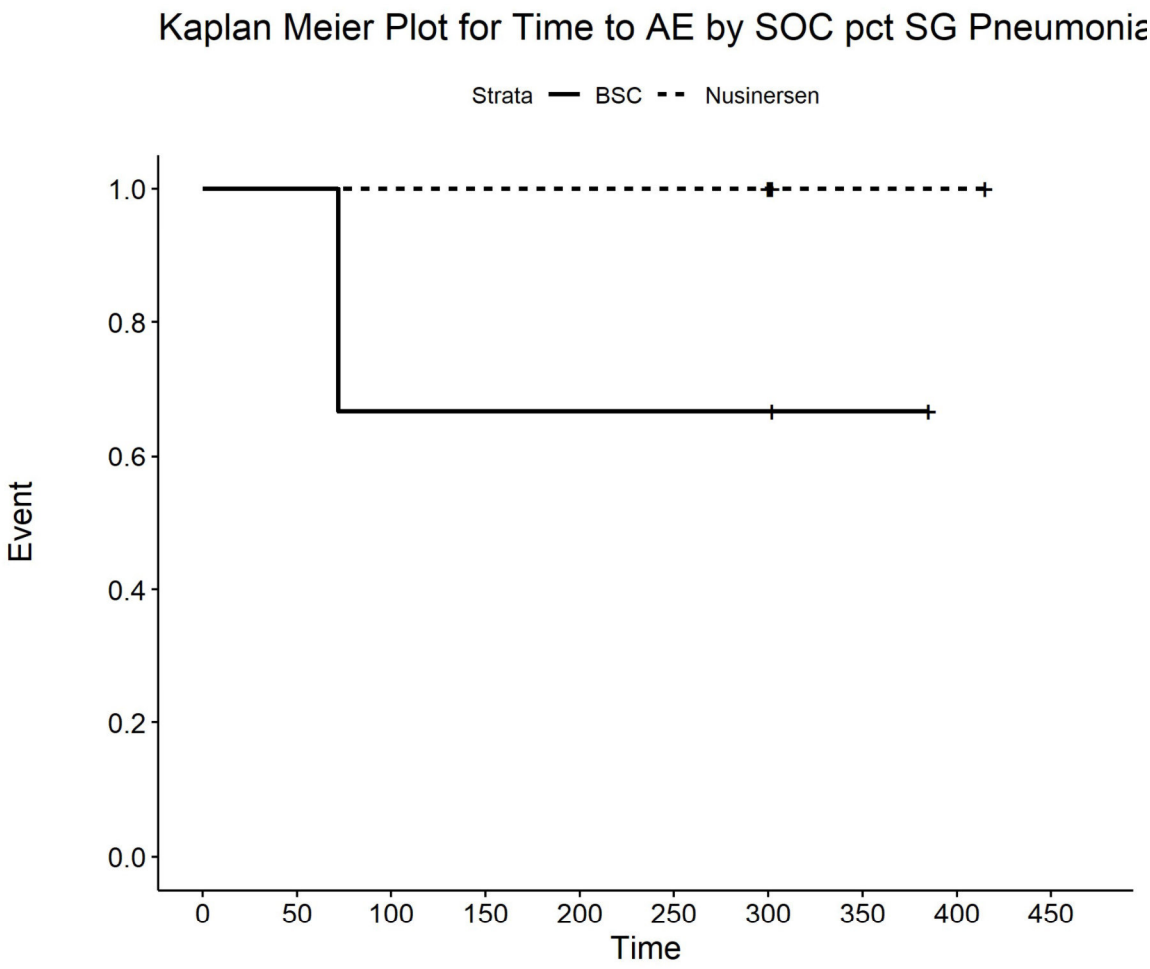
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	6	6	2	2	0



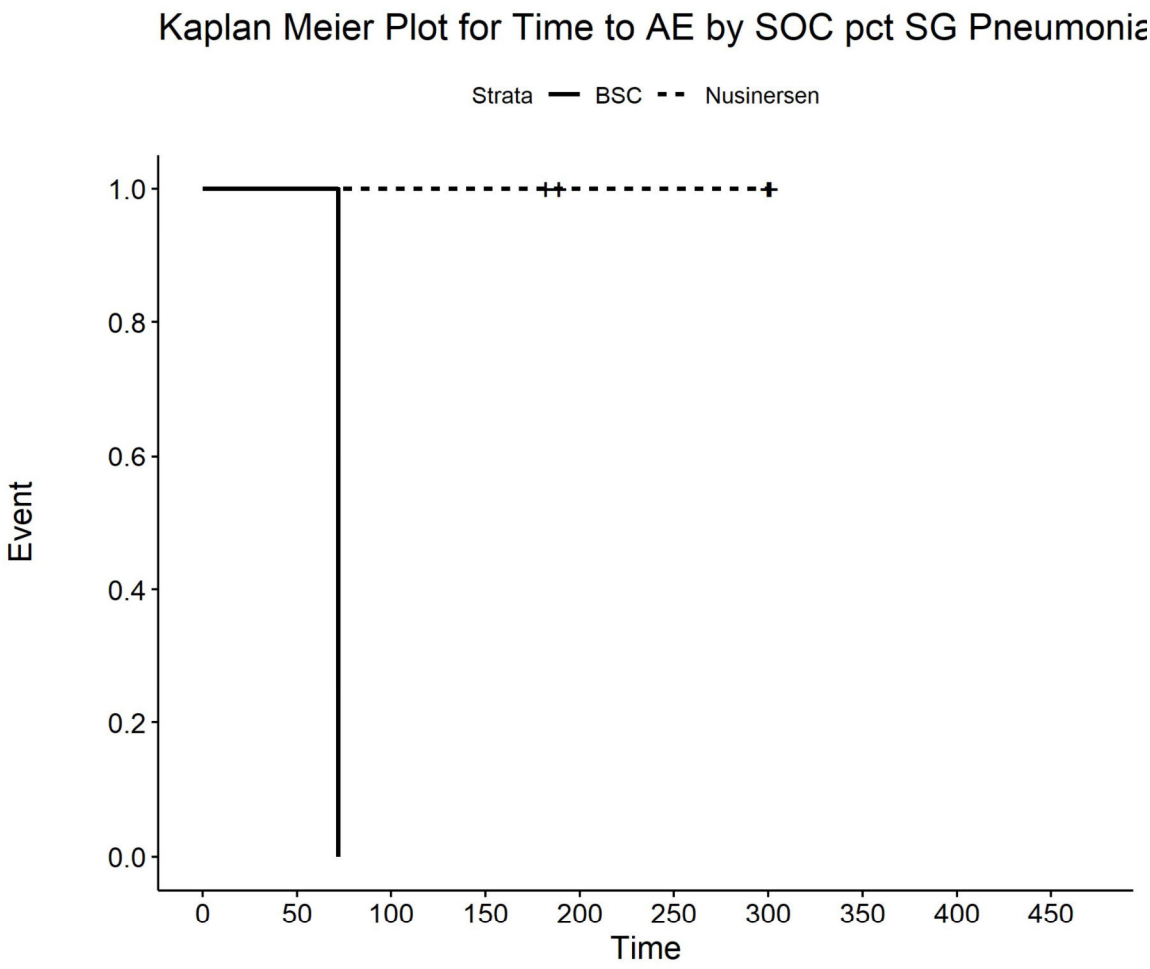
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



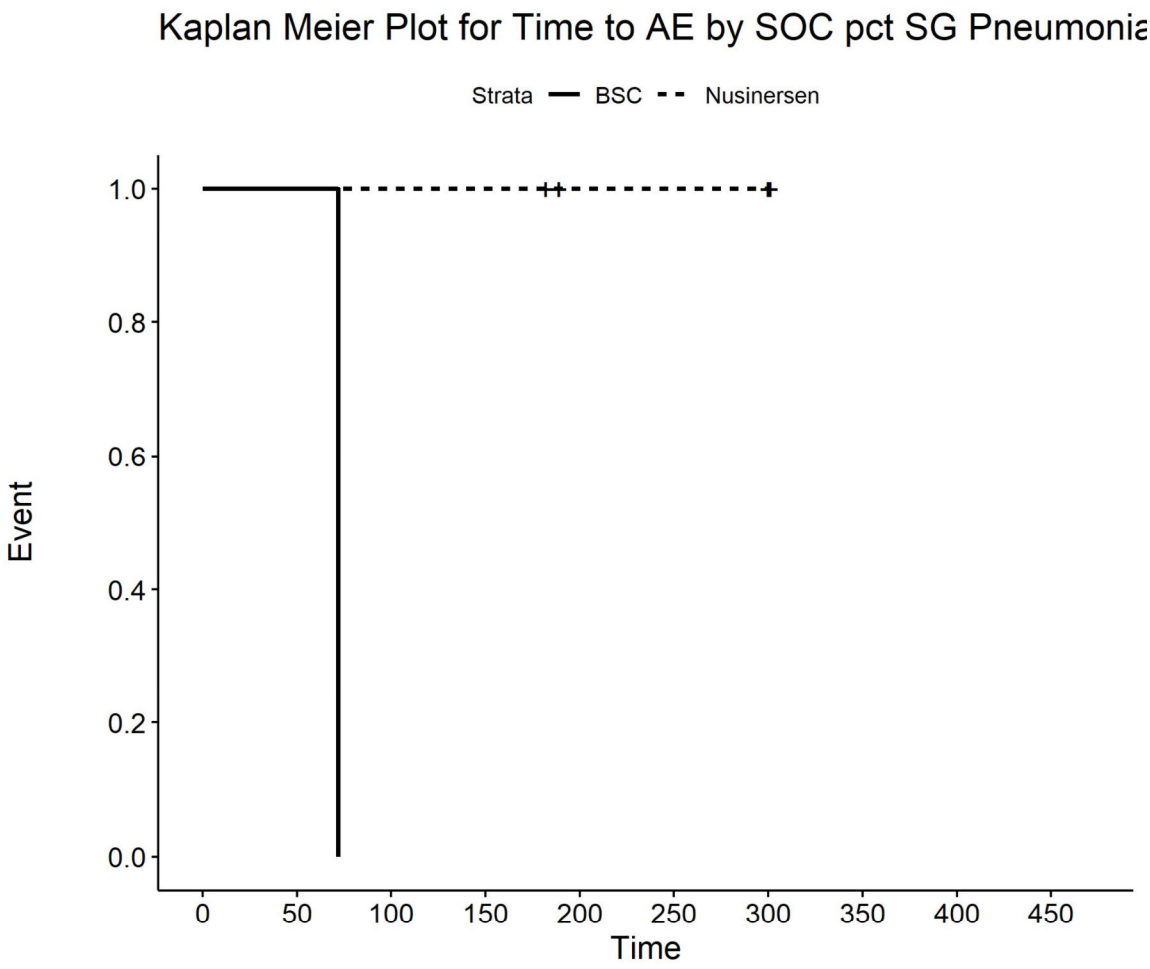
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



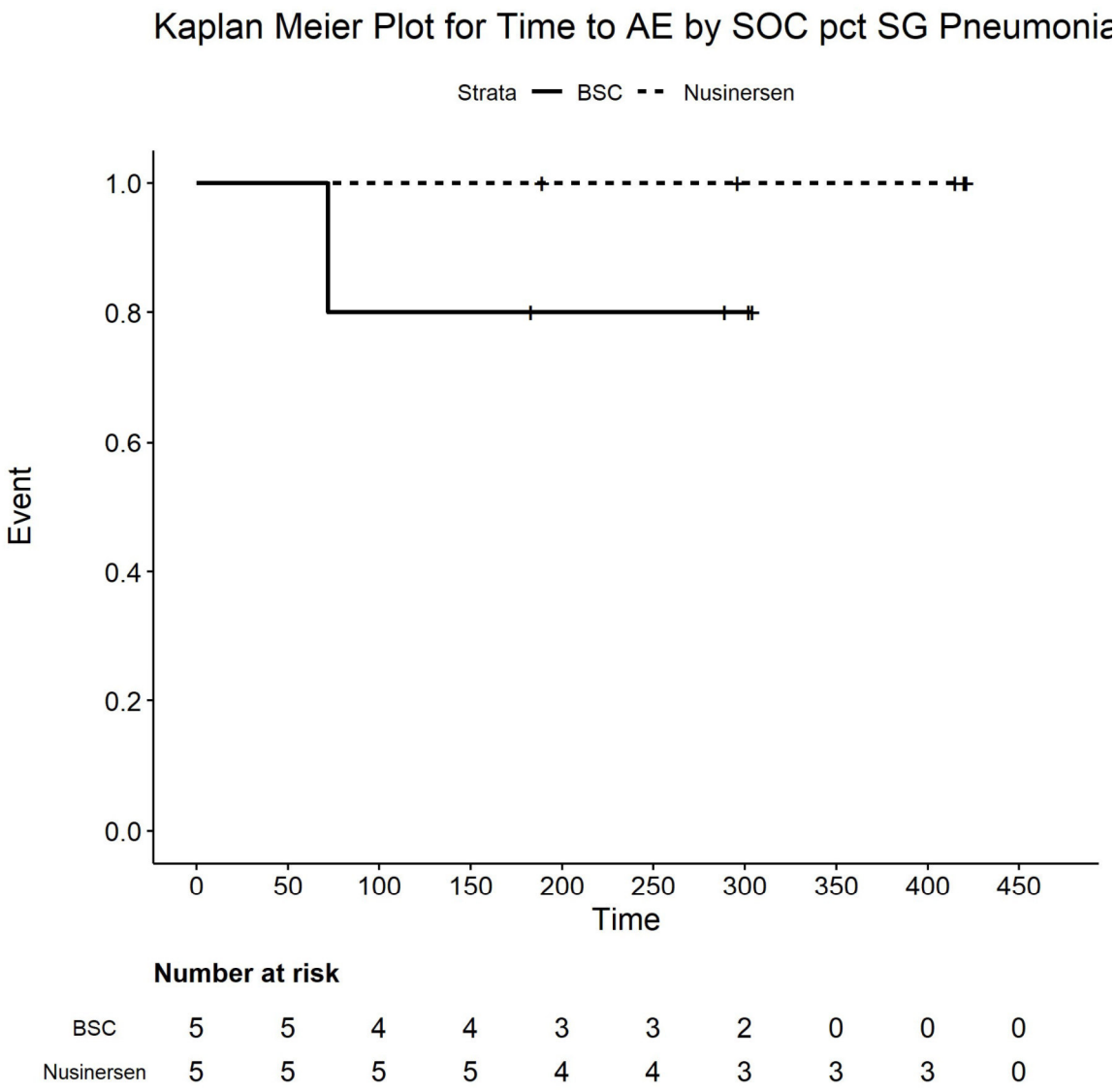
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



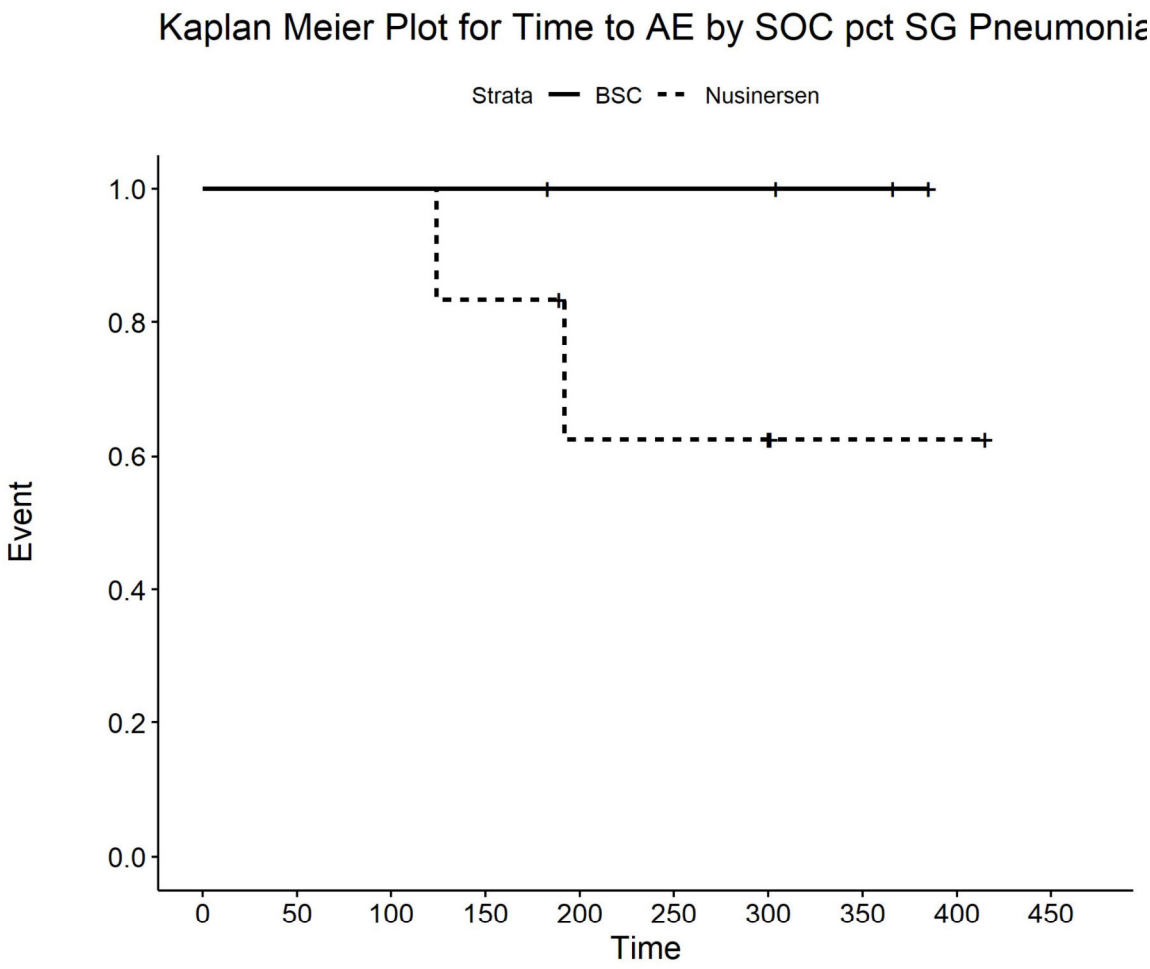
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



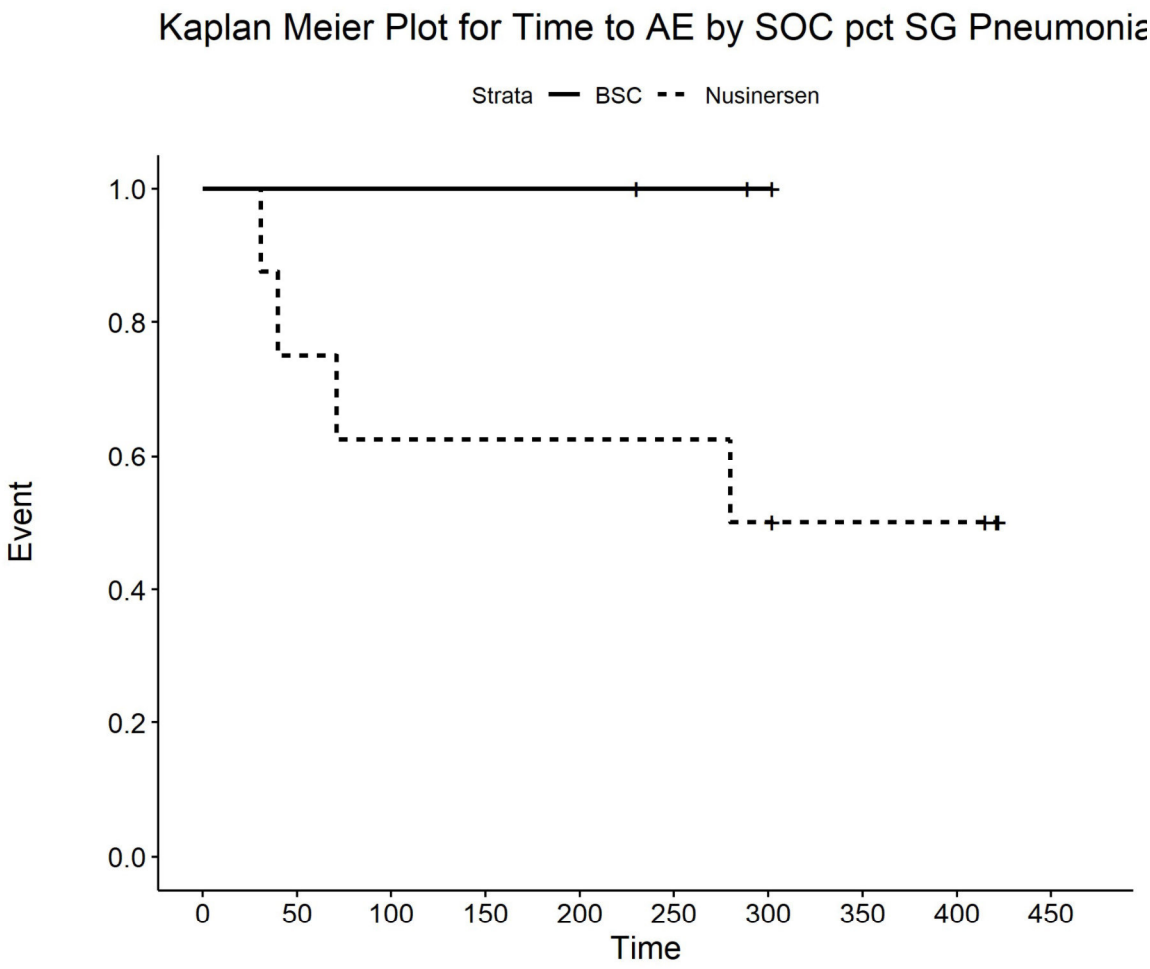
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



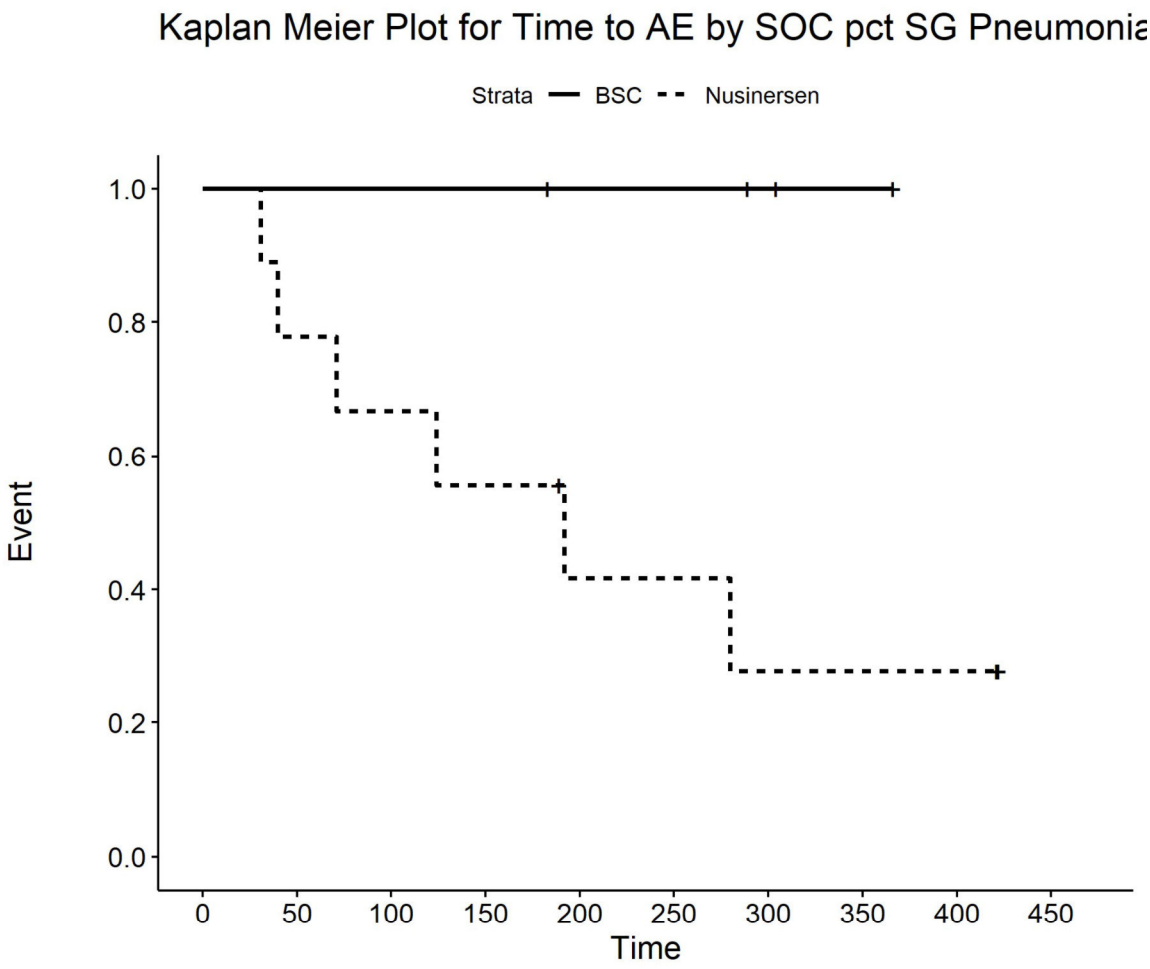
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	5	3	3	3	1	1	0



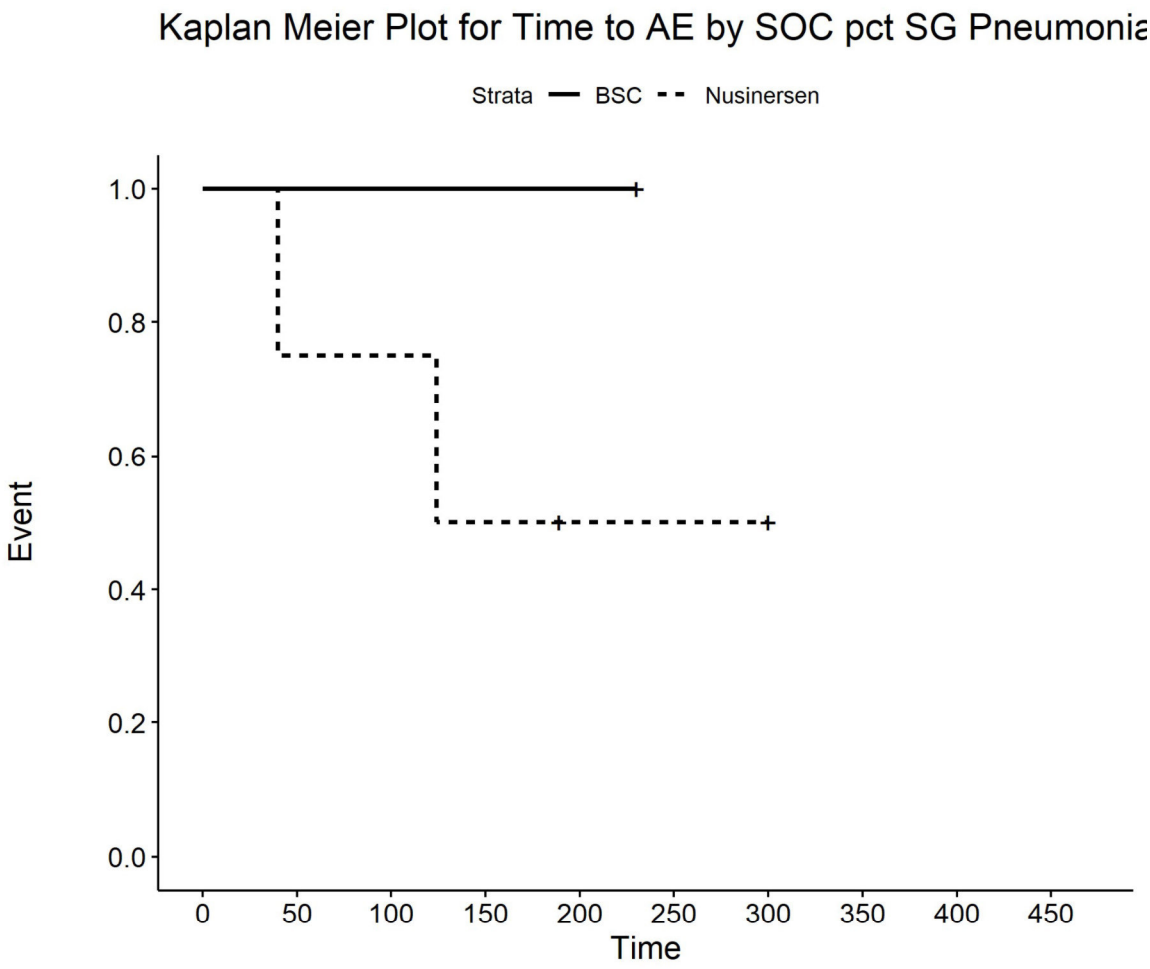
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	6	5	5	5	5	4	3	3	0



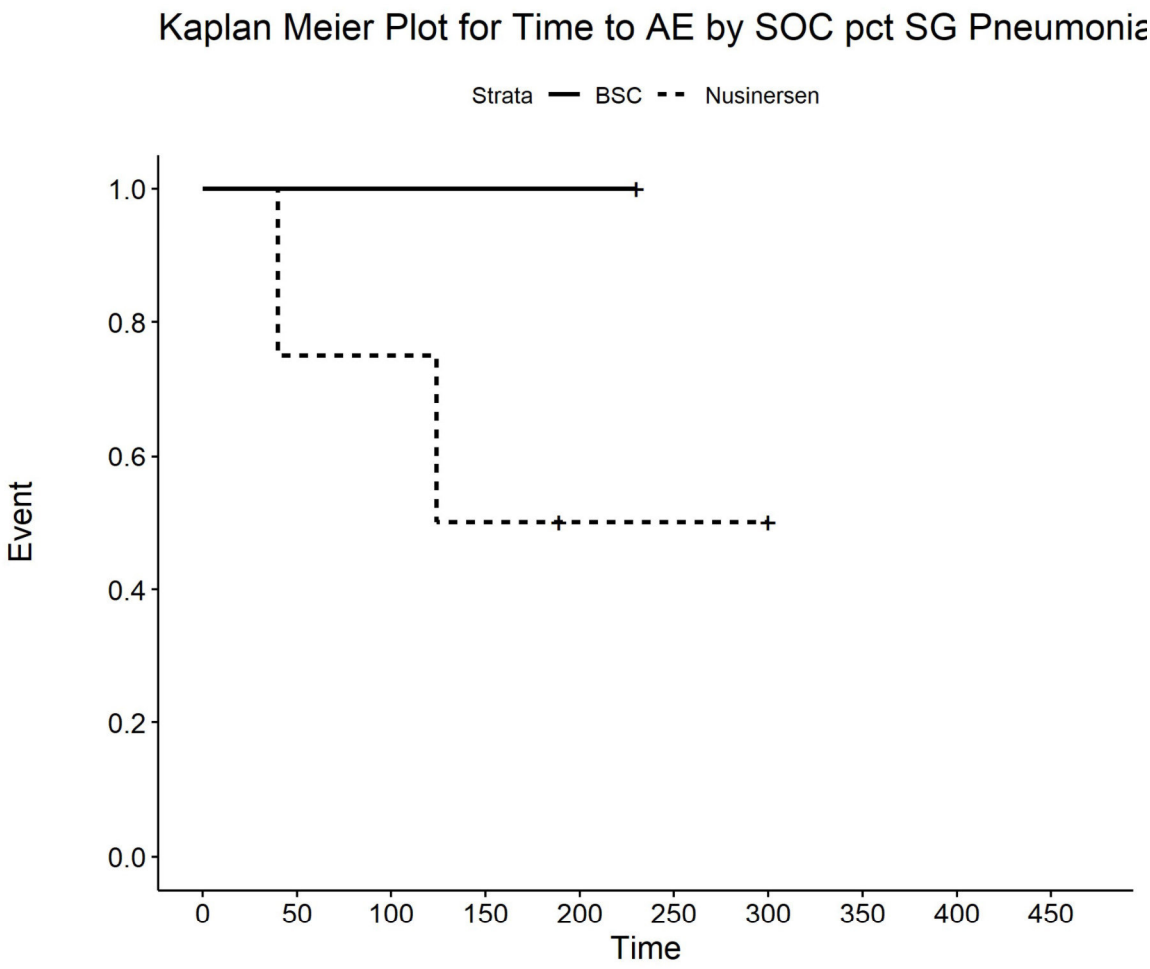
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	7	6	5	3	3	2	2	2	0



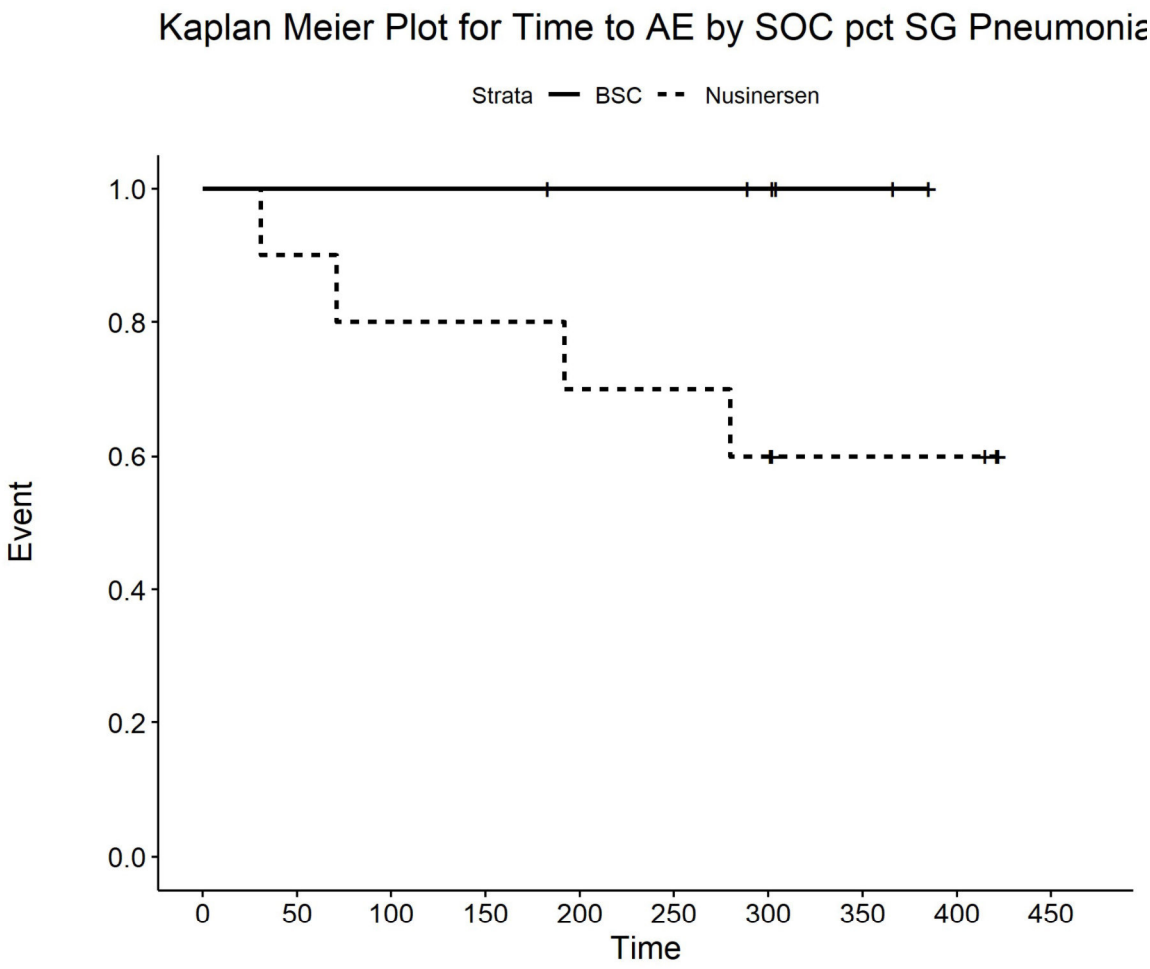
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



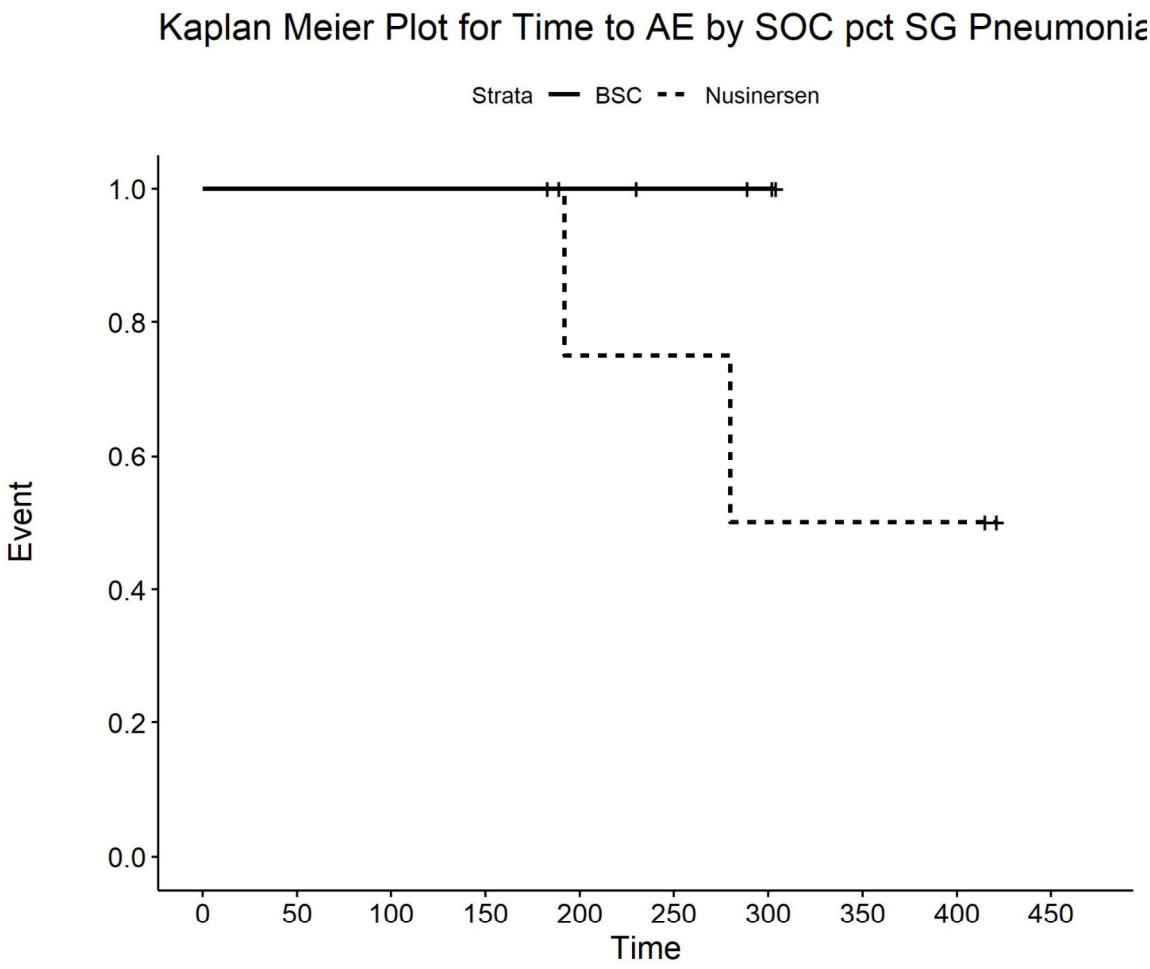
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



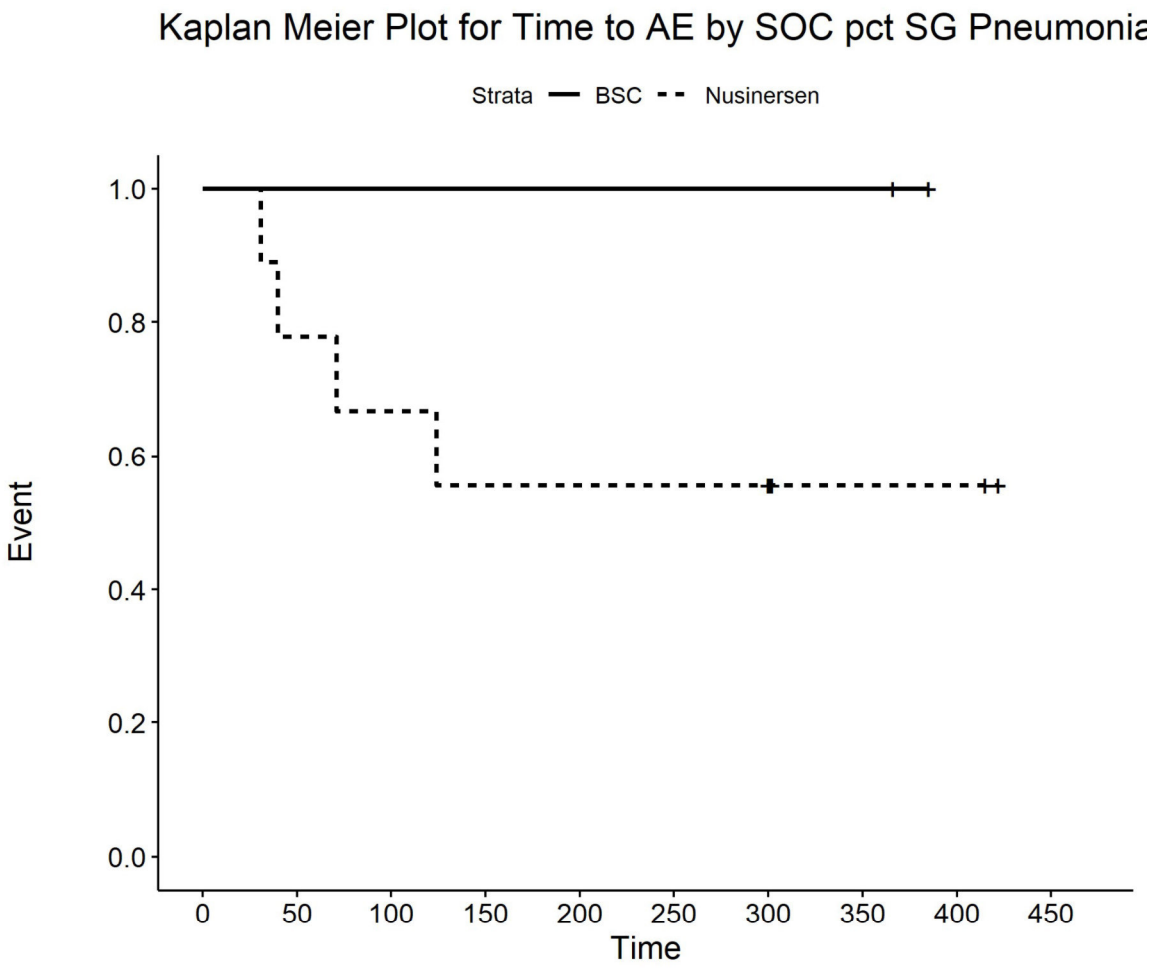
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	8	8	7	7	6	4	4	0



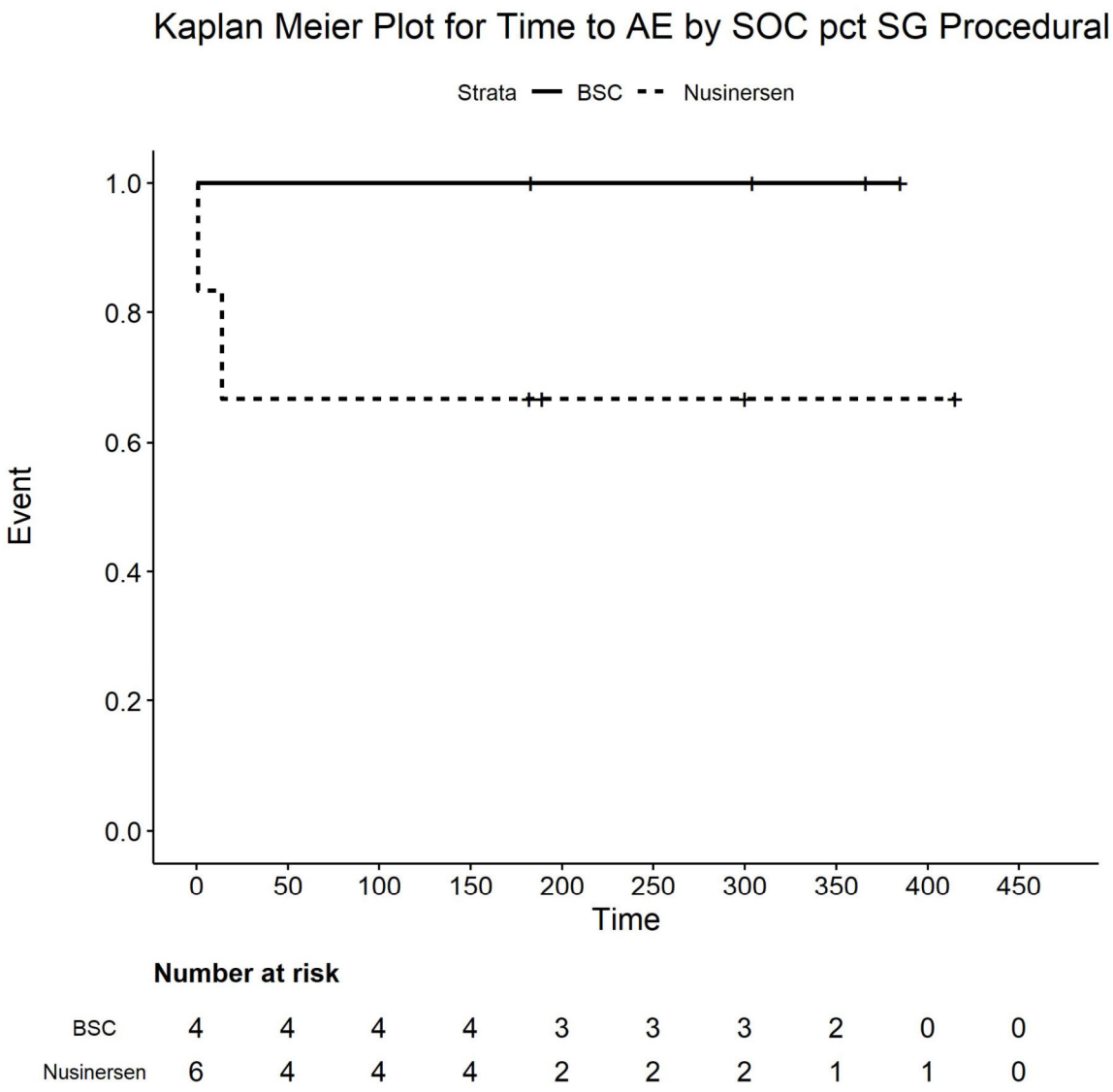
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	3	3	2	2	2	0



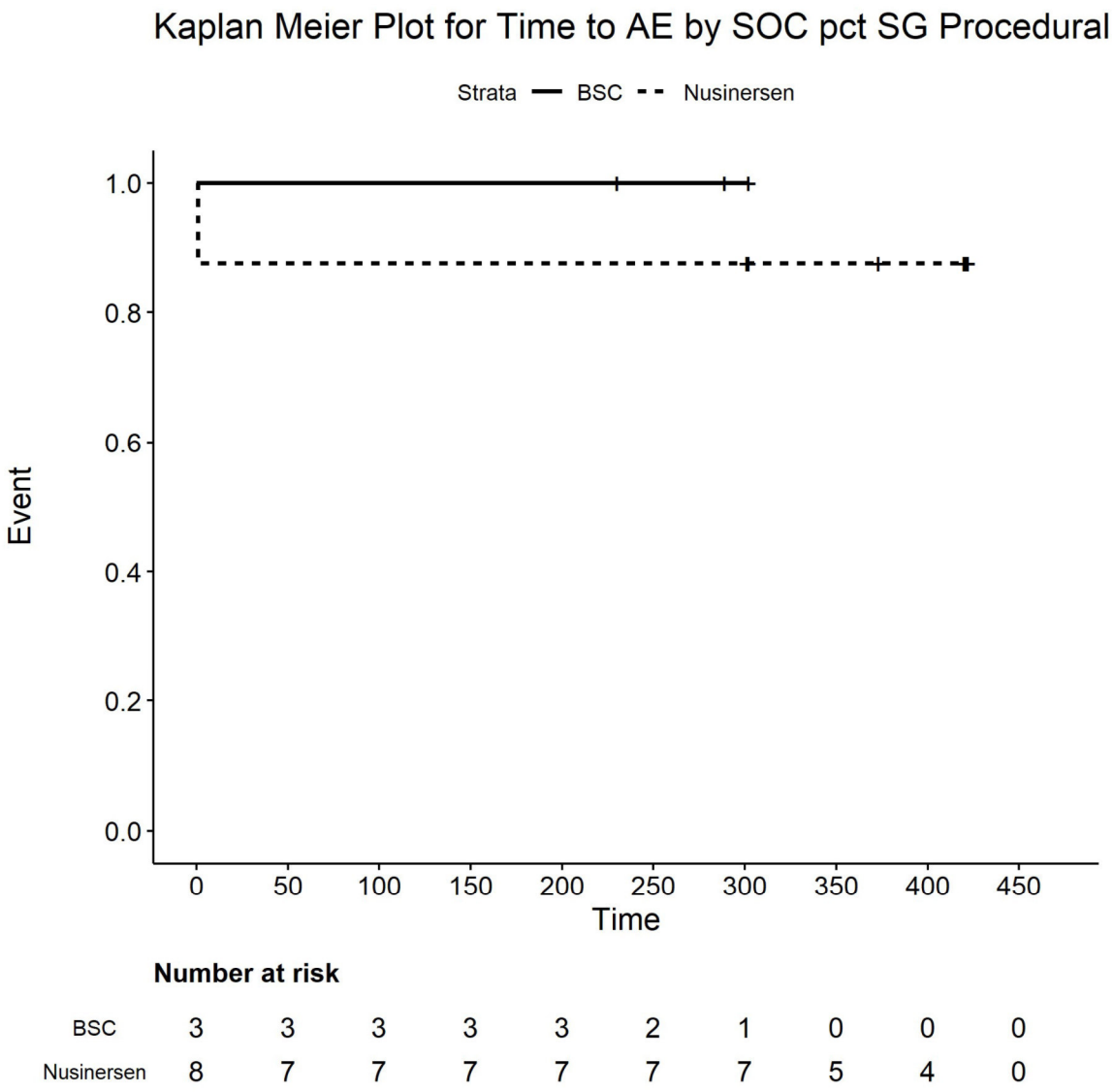
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	6	5	5	5	5	2	2	0



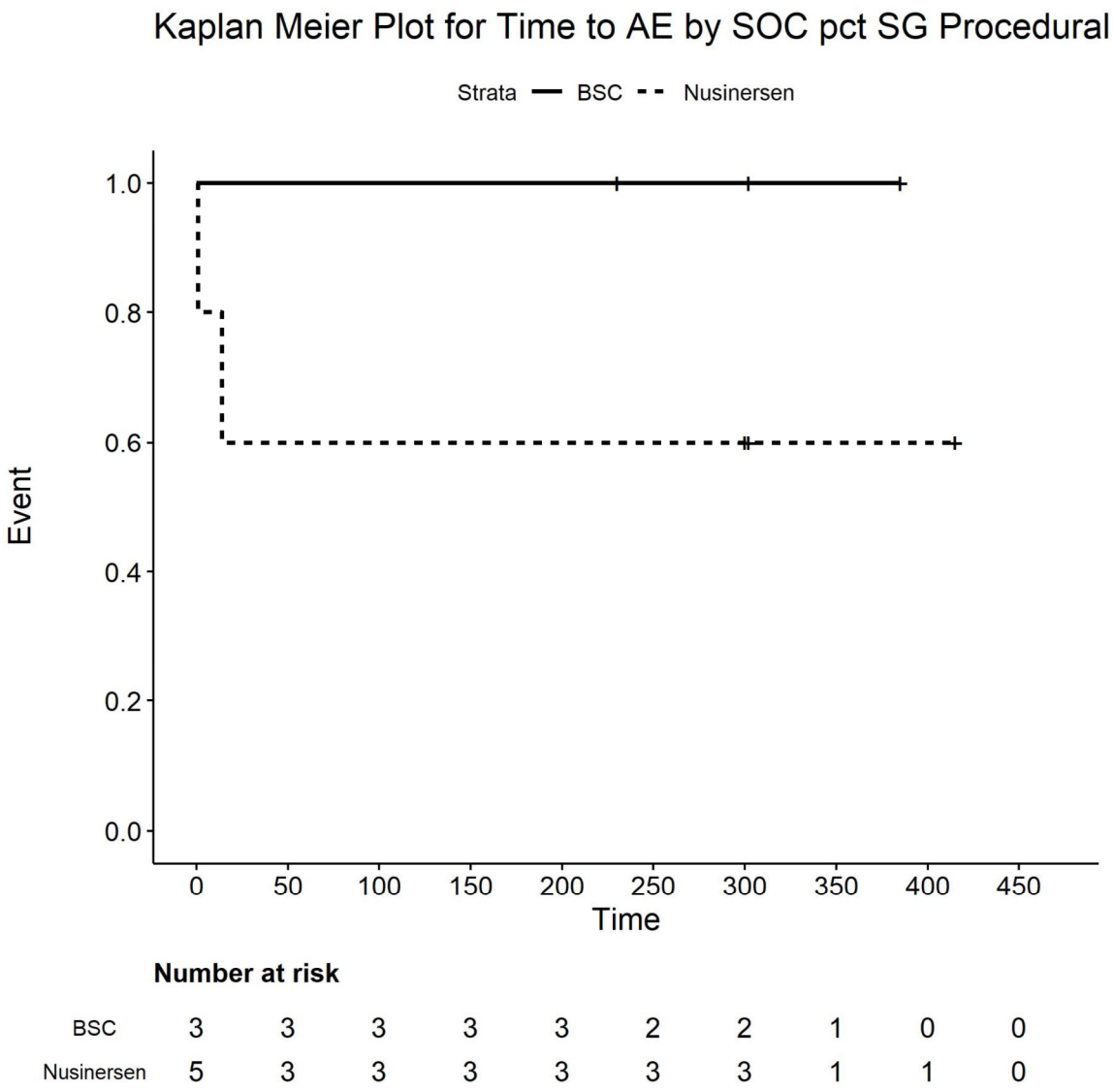
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	4	4	4	2	2	2	1	1	0



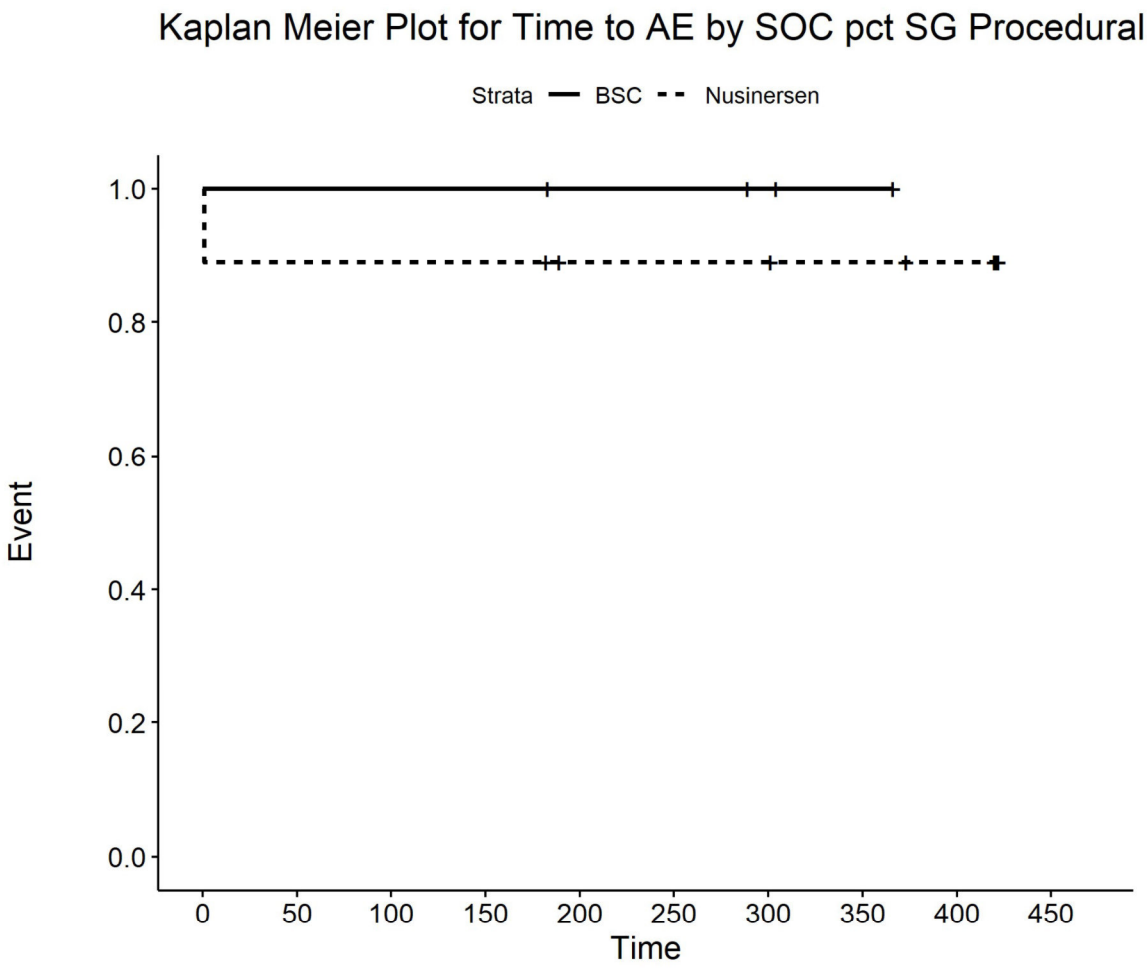
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



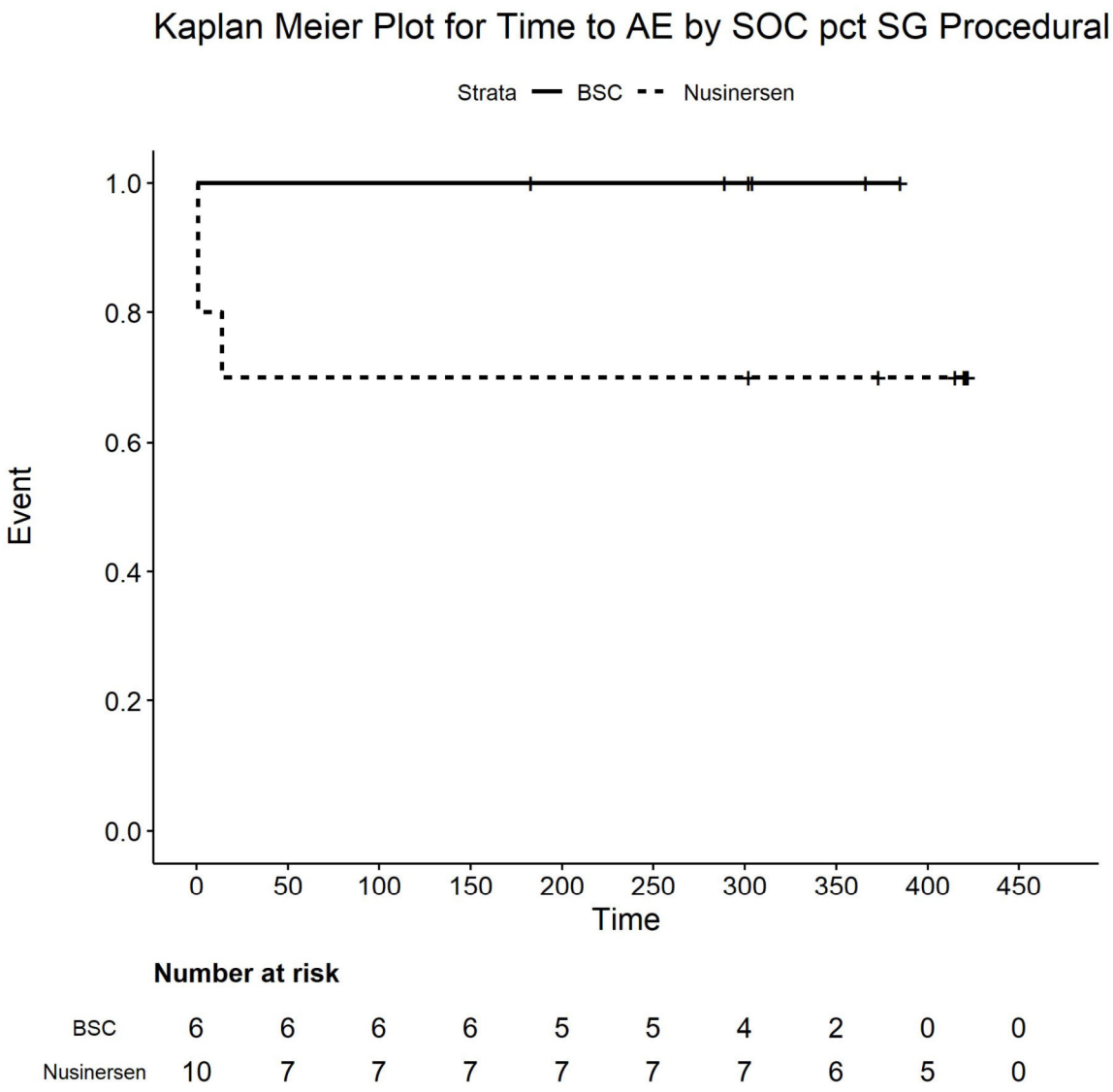
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	3	3	3	3	3	3	1	1	0



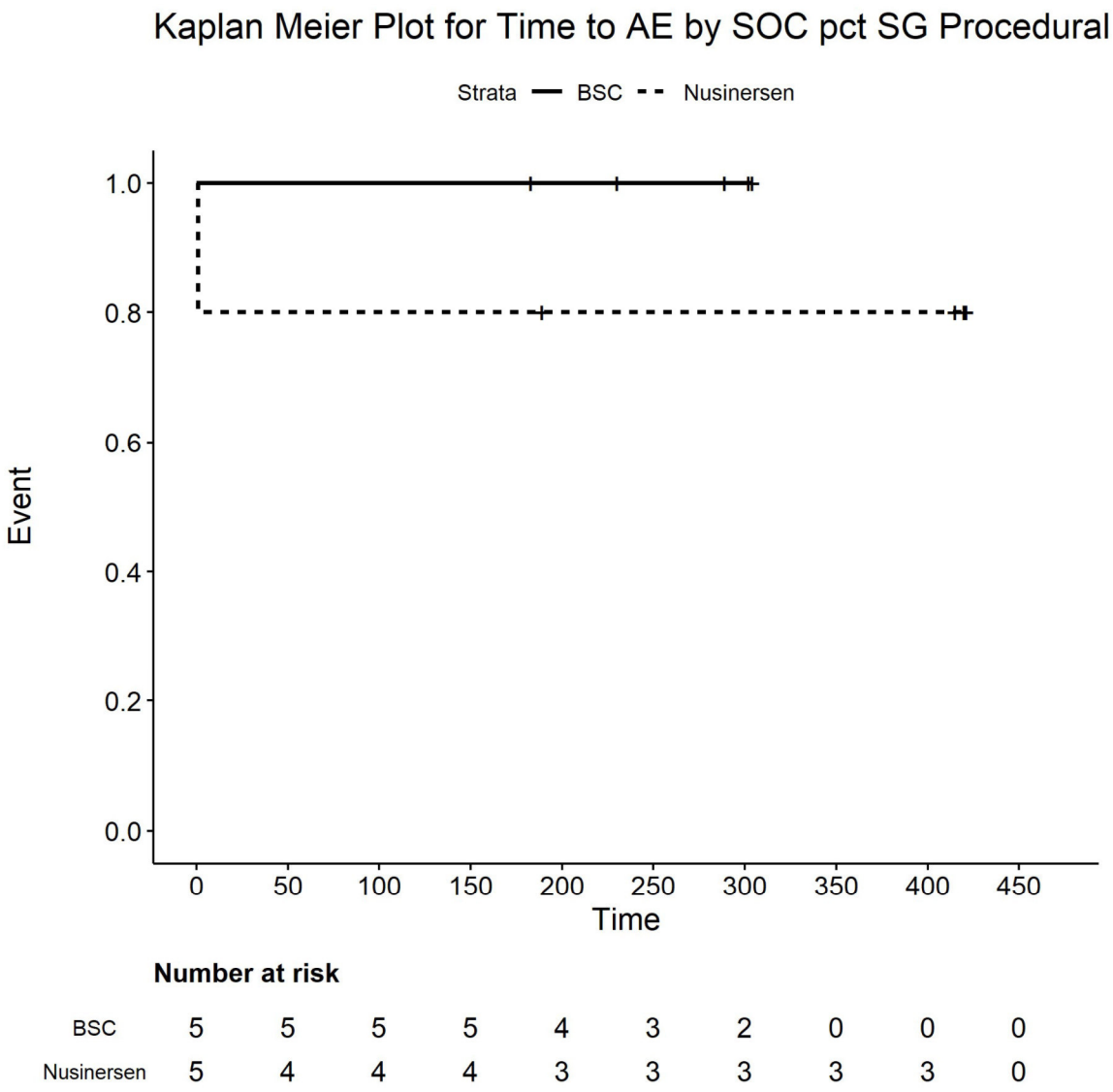
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	6	5	4	0



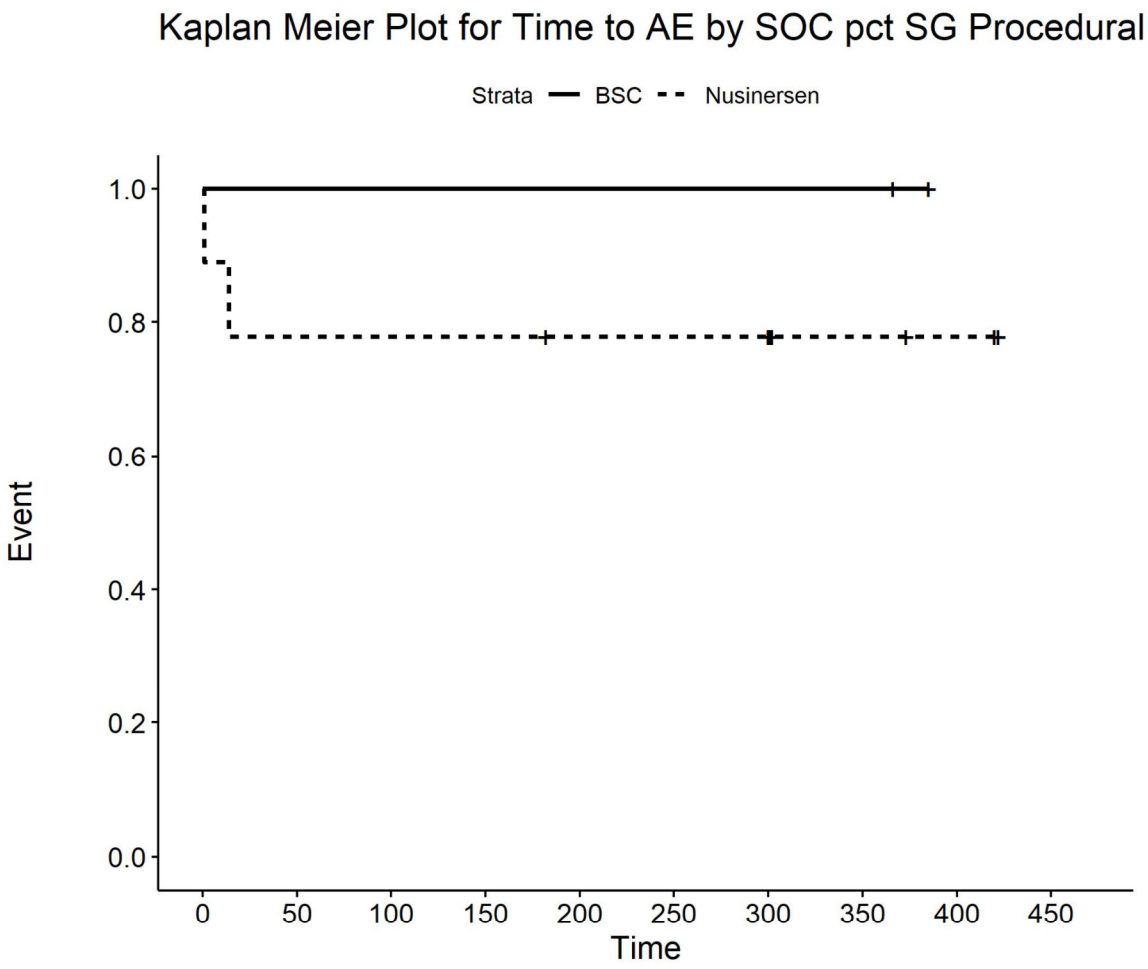
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	7	7	7	7	7	7	6	5	0



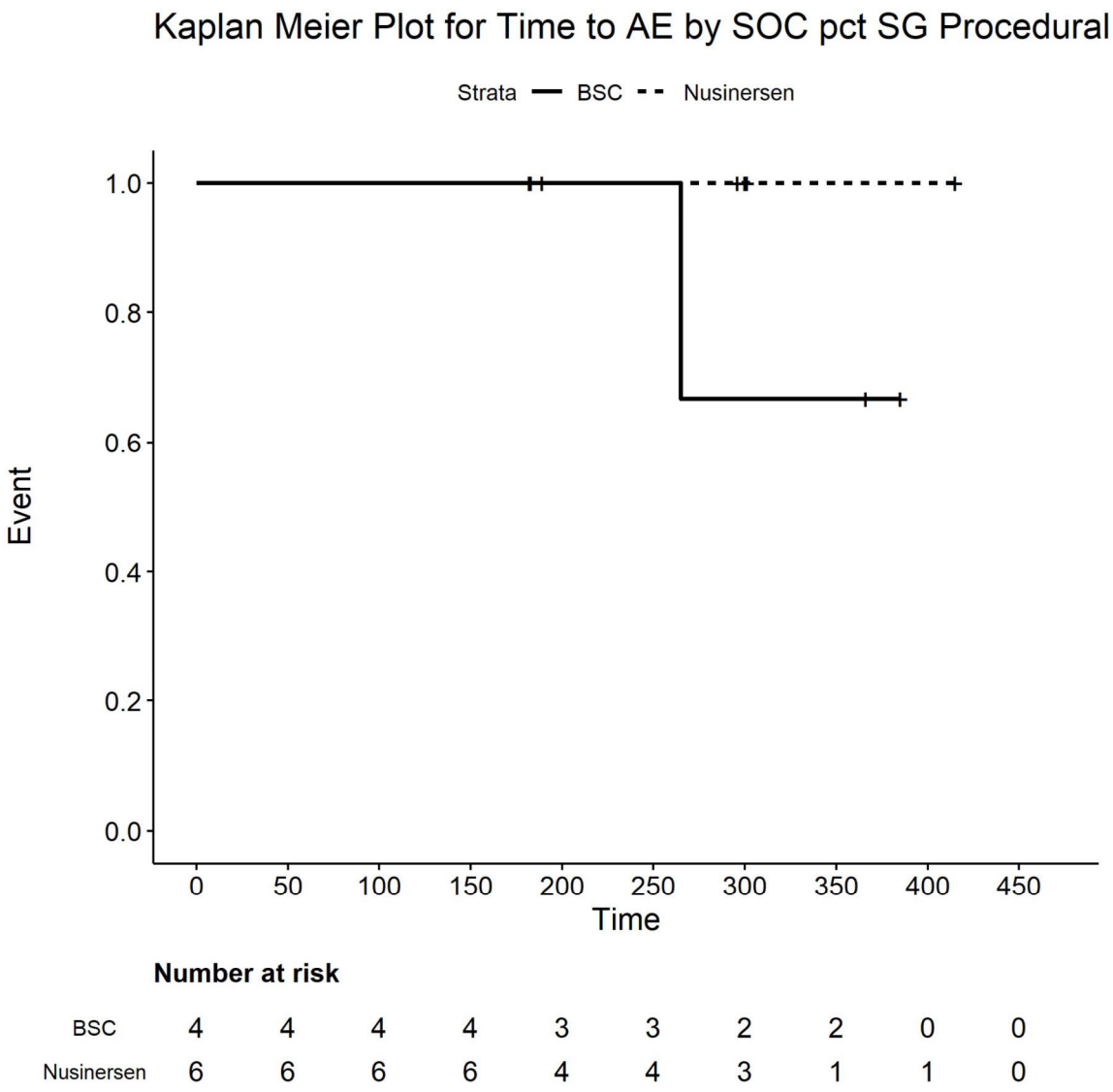
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	3	3	3	0



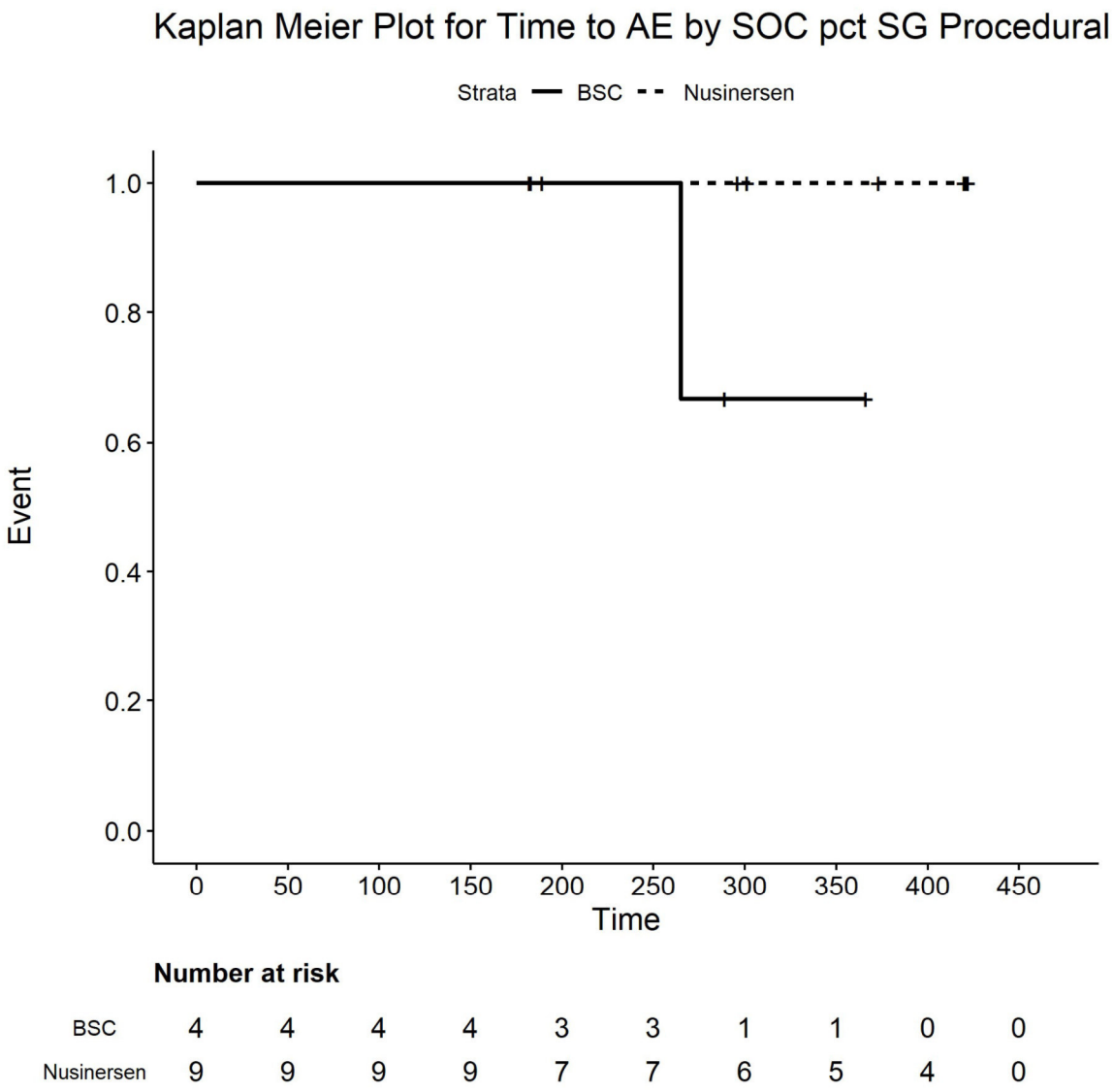
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	7	7	6	6	6	3	2	0



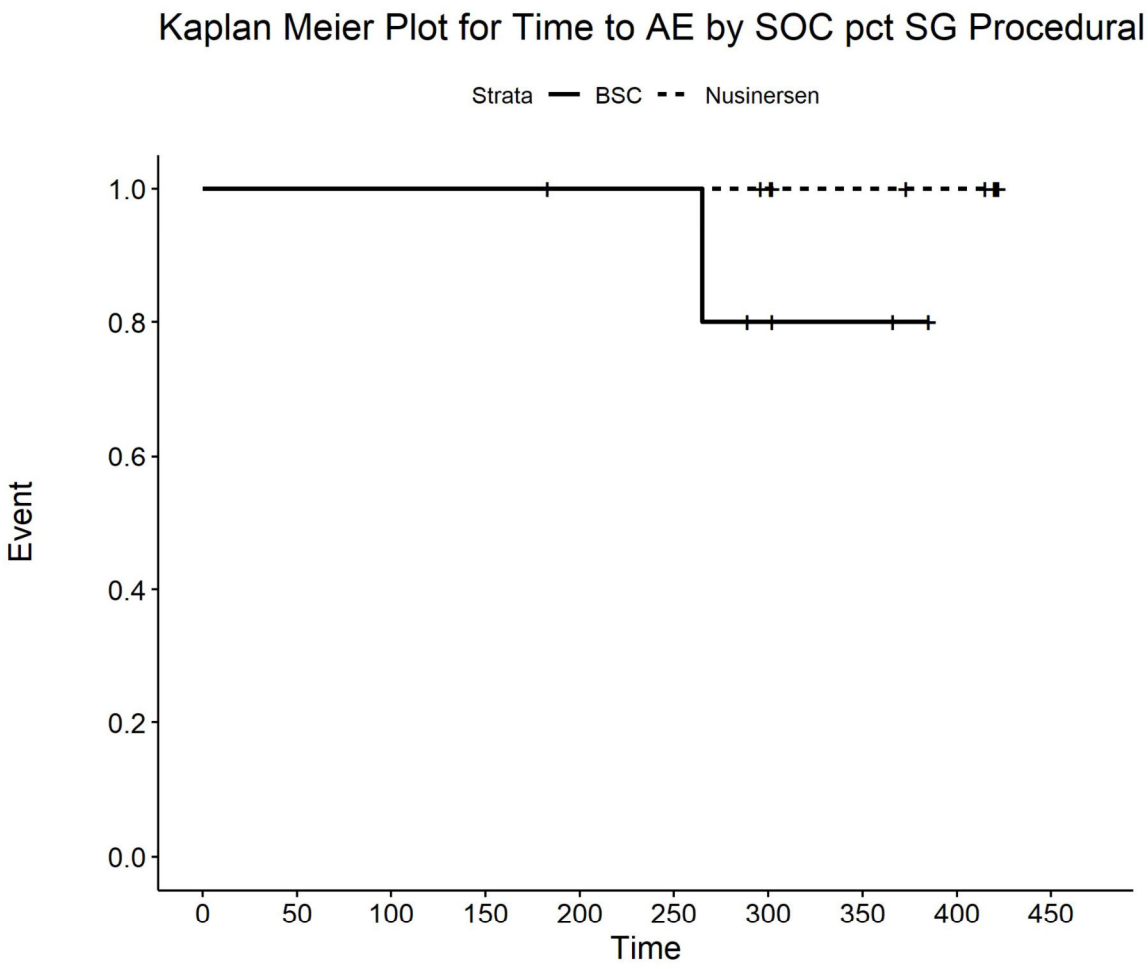
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



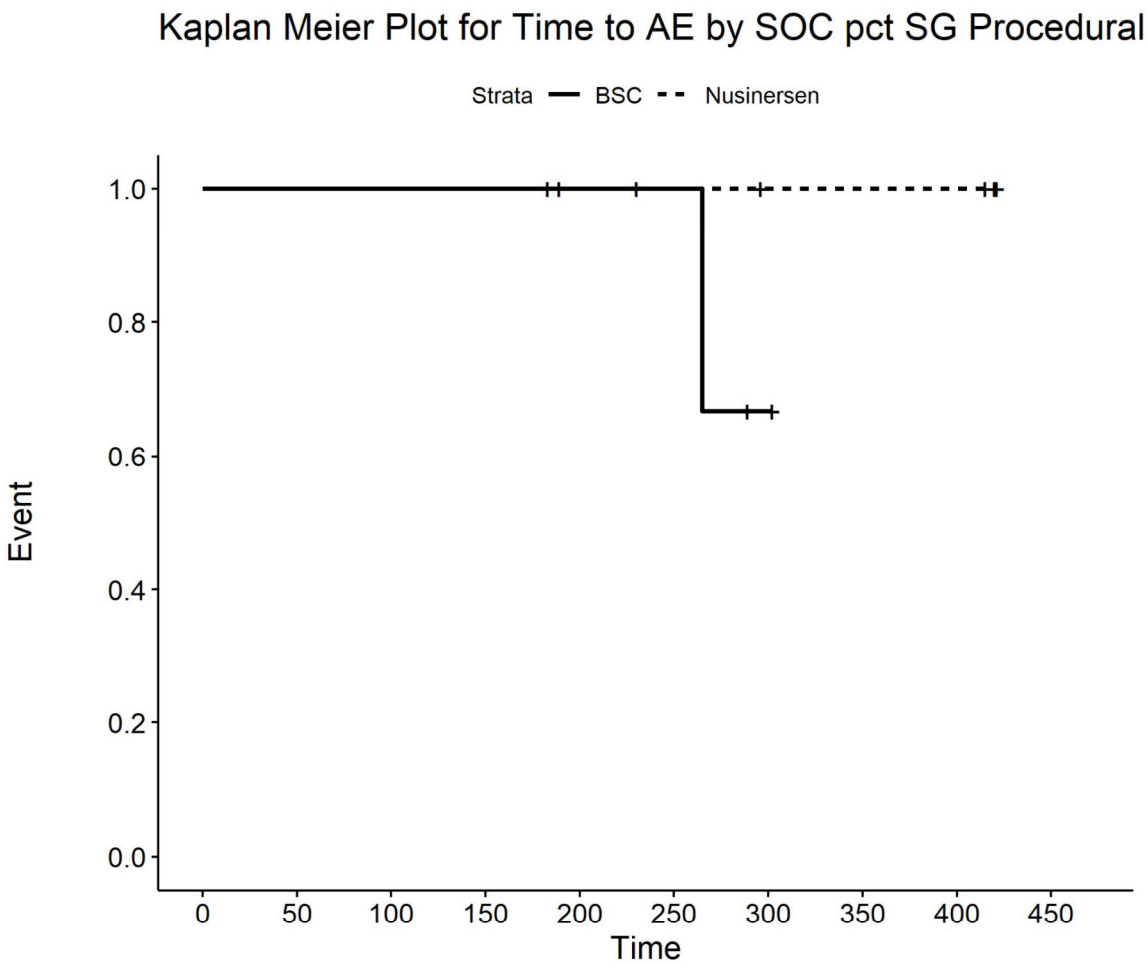
Number at risk

BSC	4	4	4	4	3	3	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



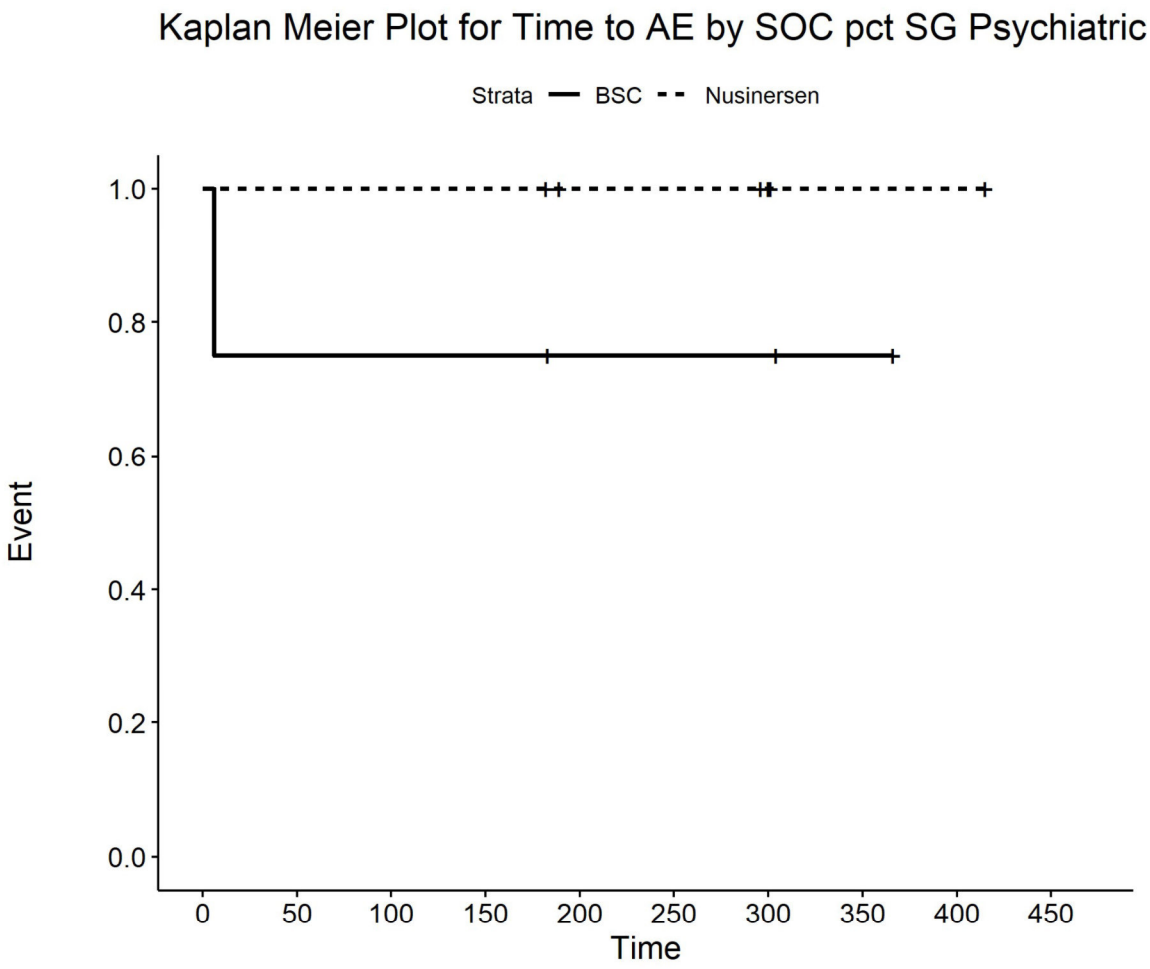
Number at risk

BSC	6	6	6	6	5	5	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



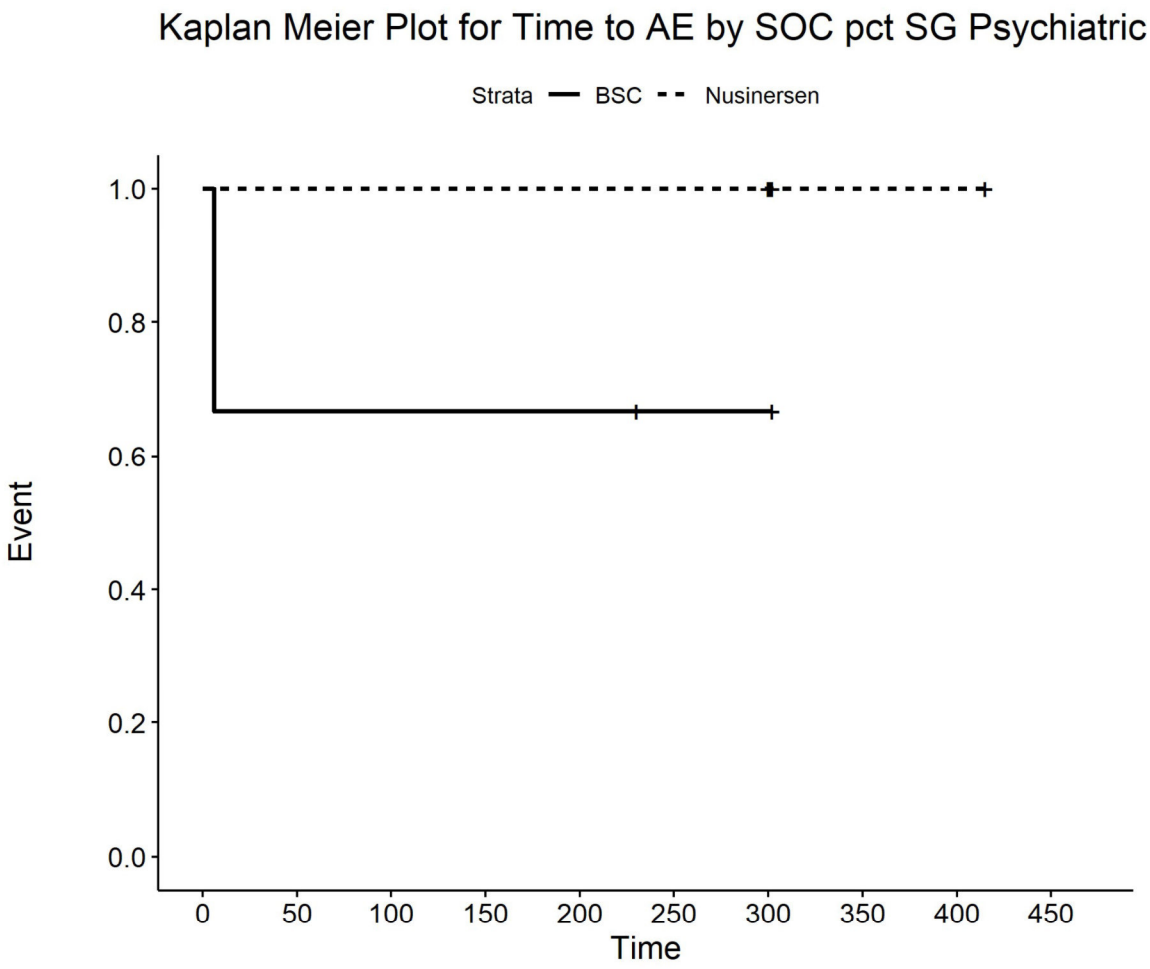
Number at risk

BSC	5	5	5	5	4	3	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



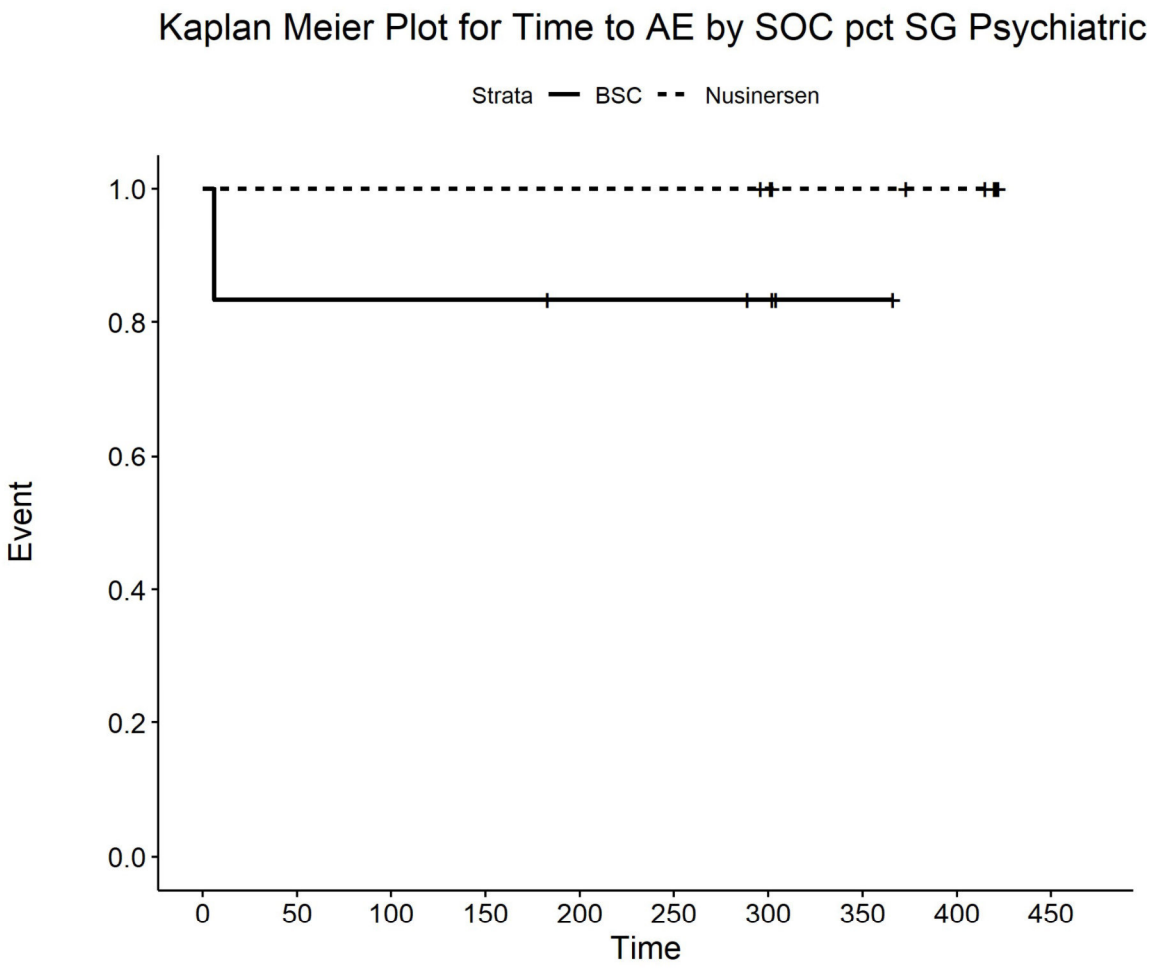
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



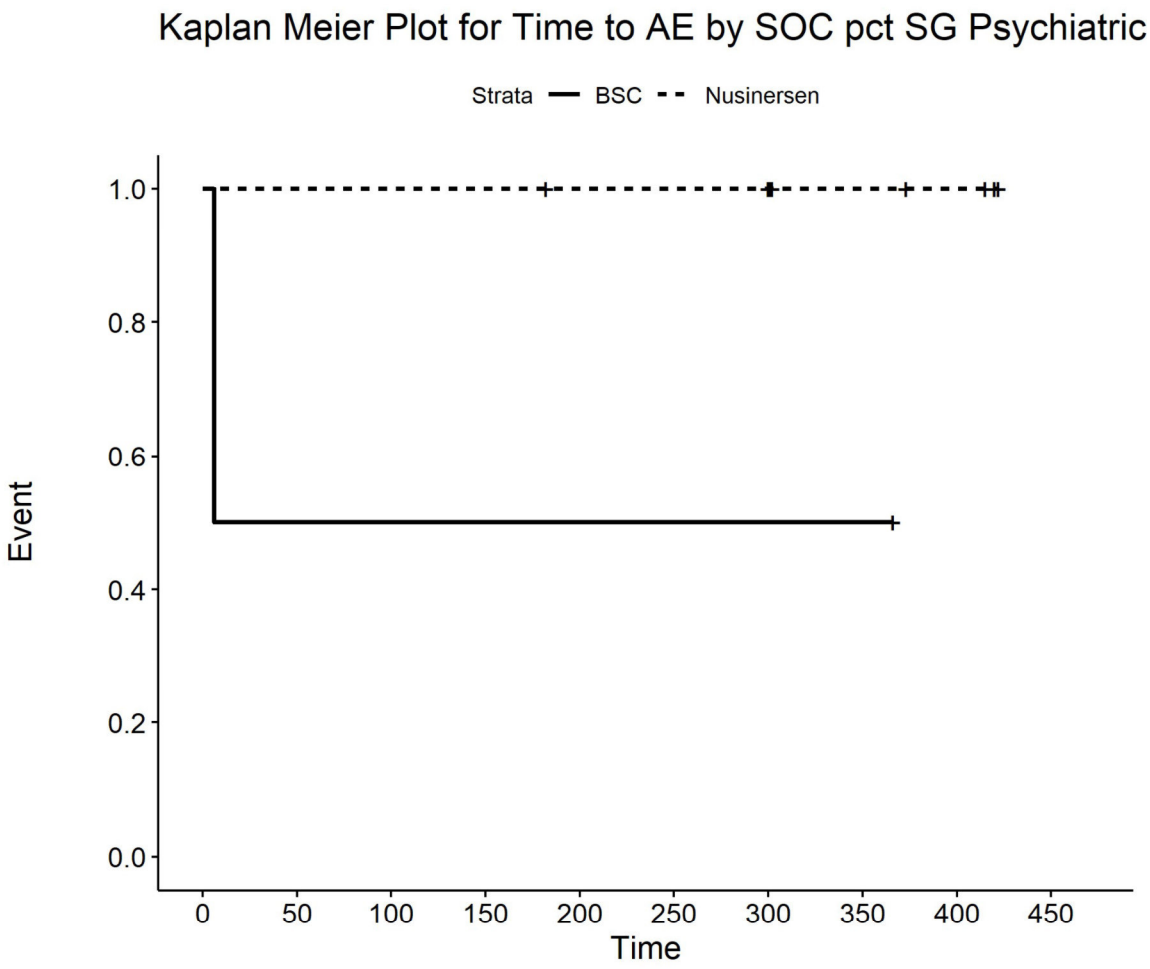
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



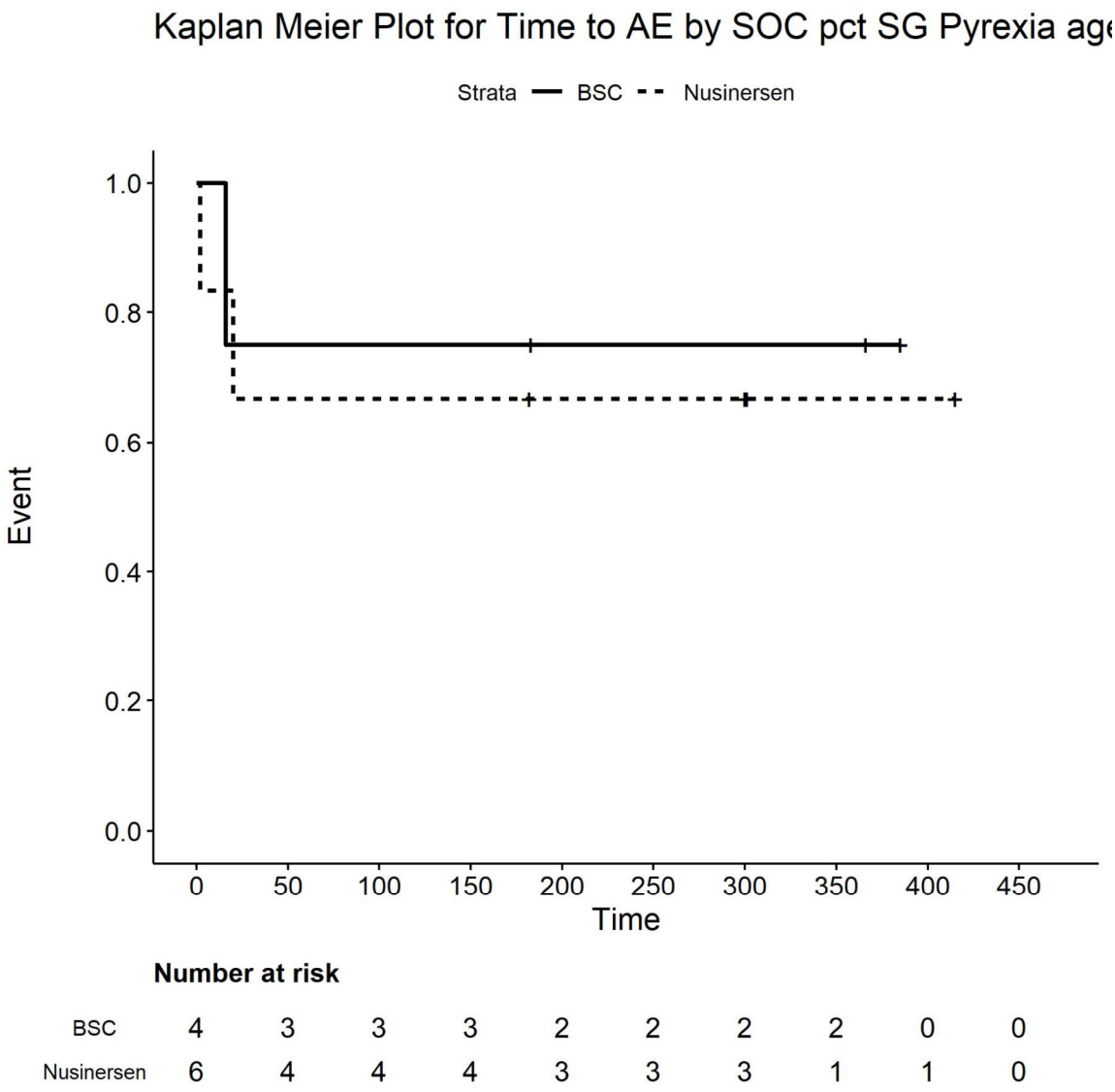
Number at risk

BSC	6	5	5	5	4	4	3	1	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



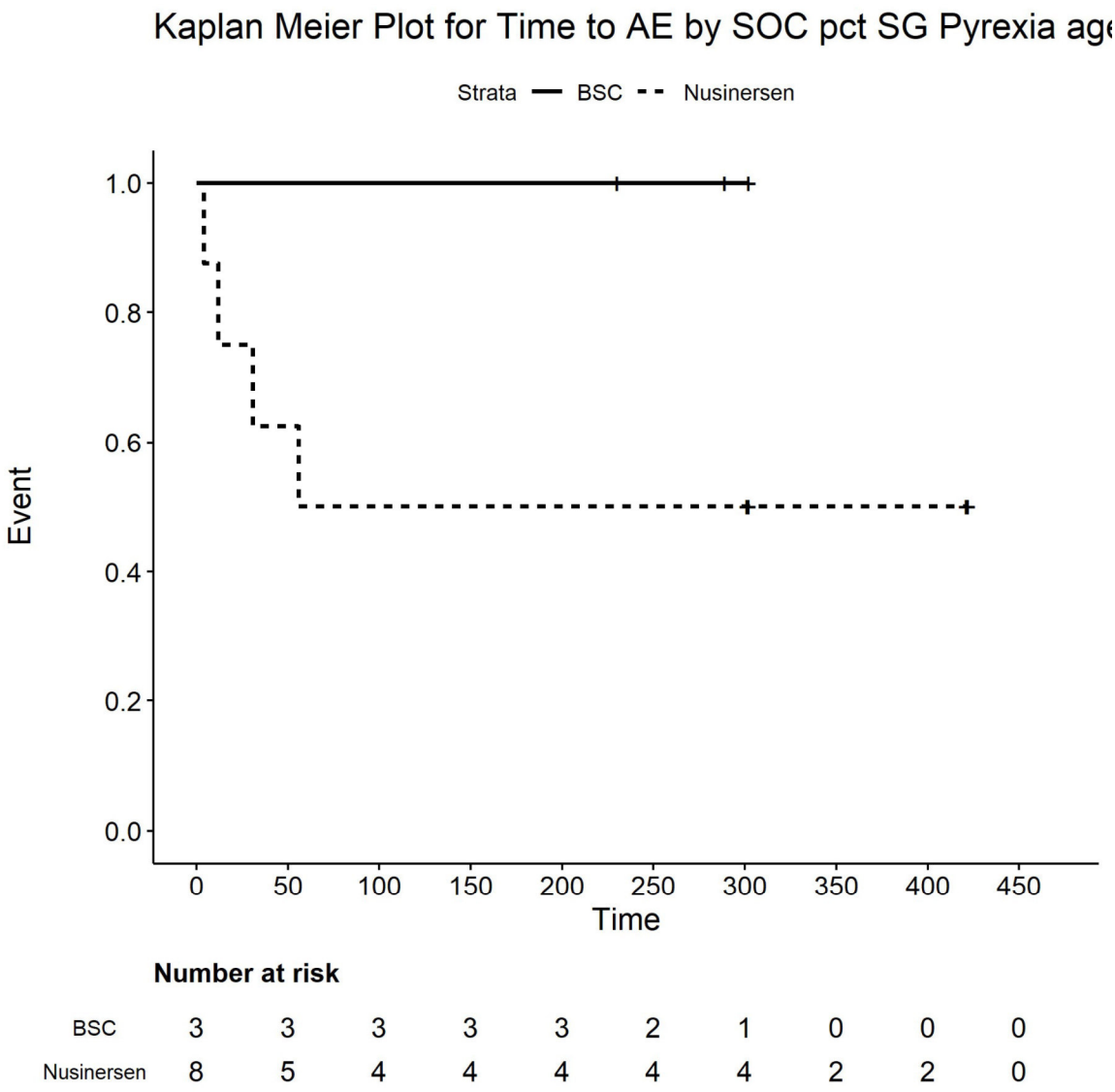
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



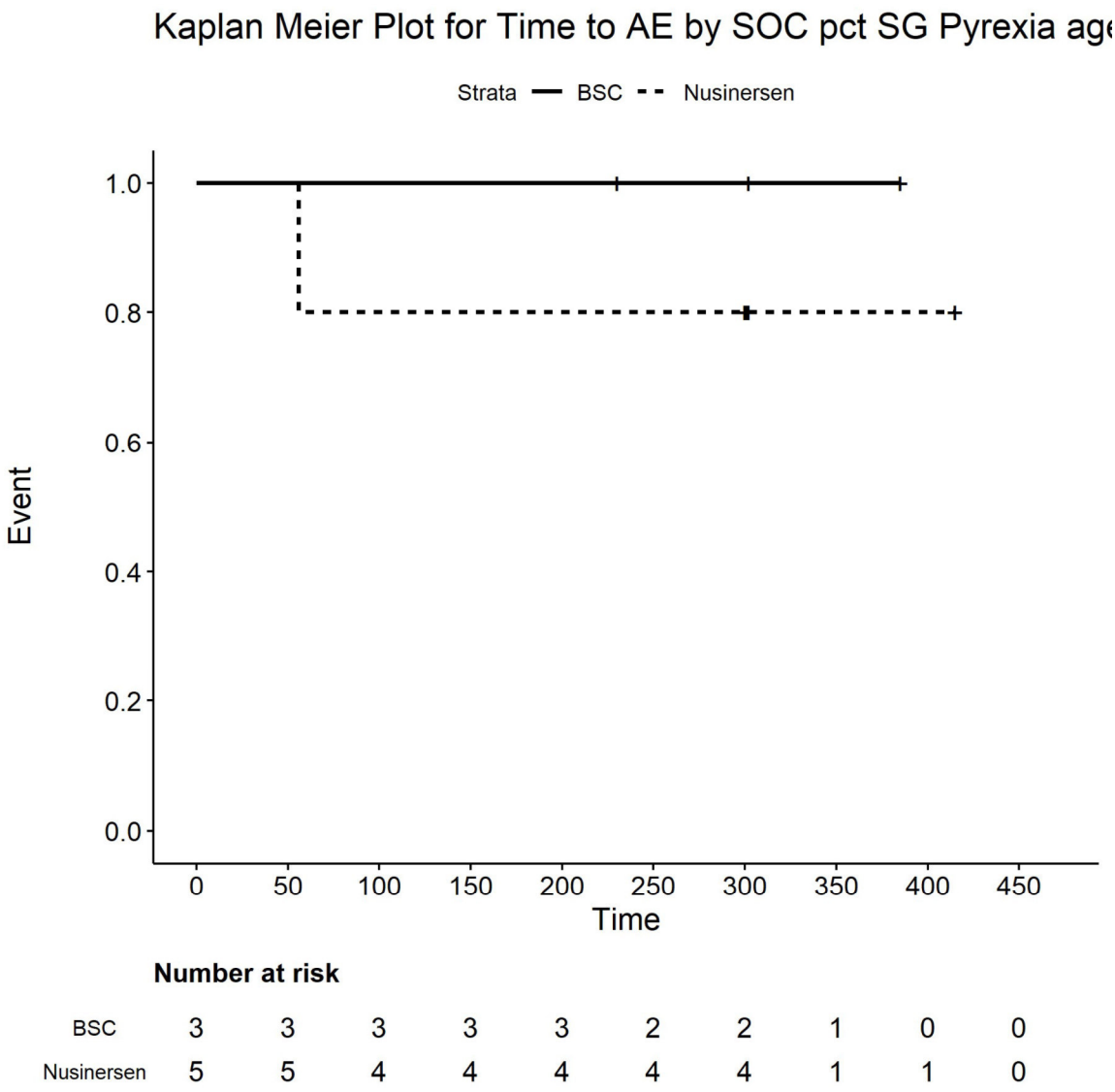
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	4	4	4	3	3	3	1	1	0



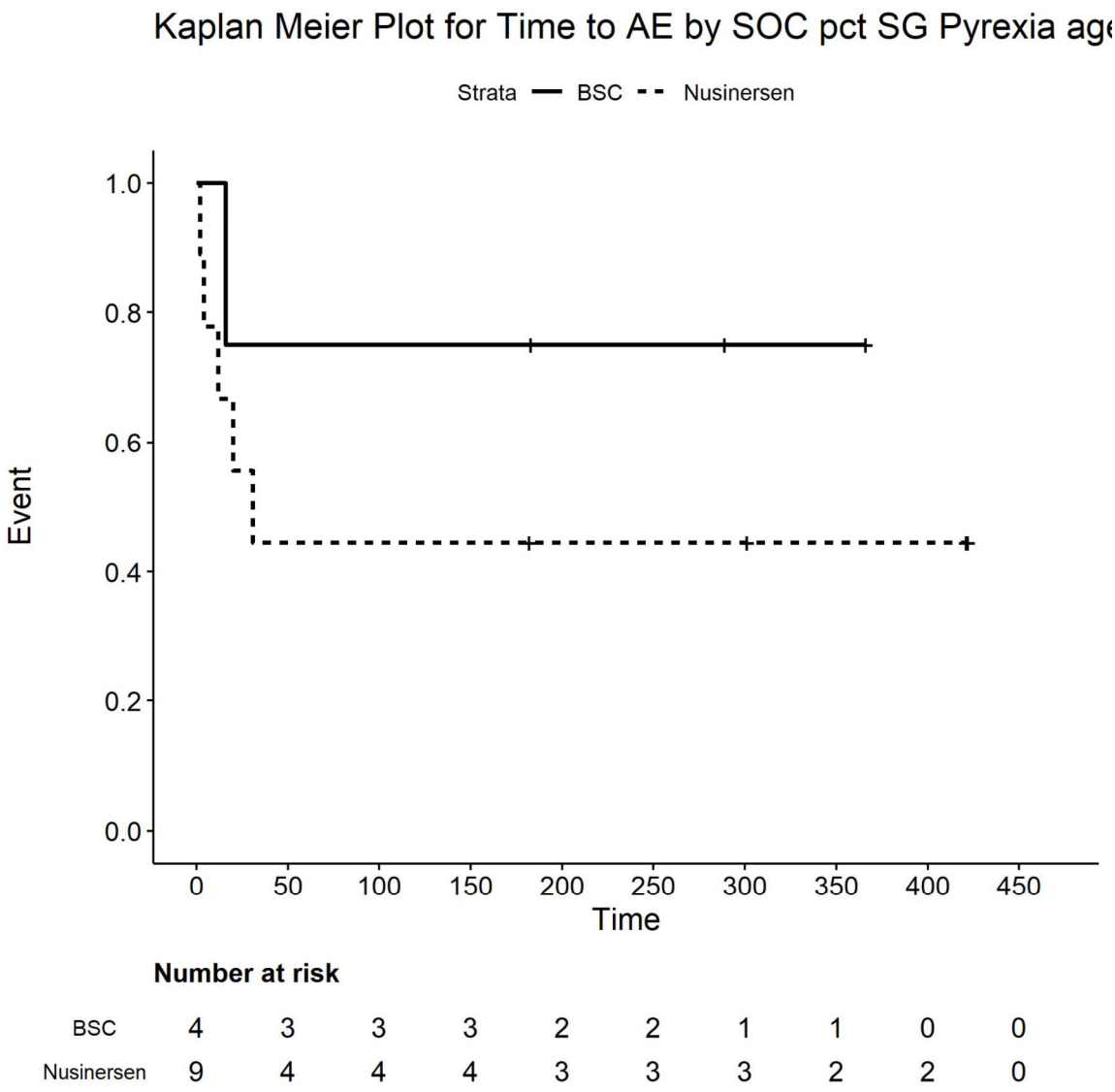
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	5	4	4	4	4	4	2	2	0



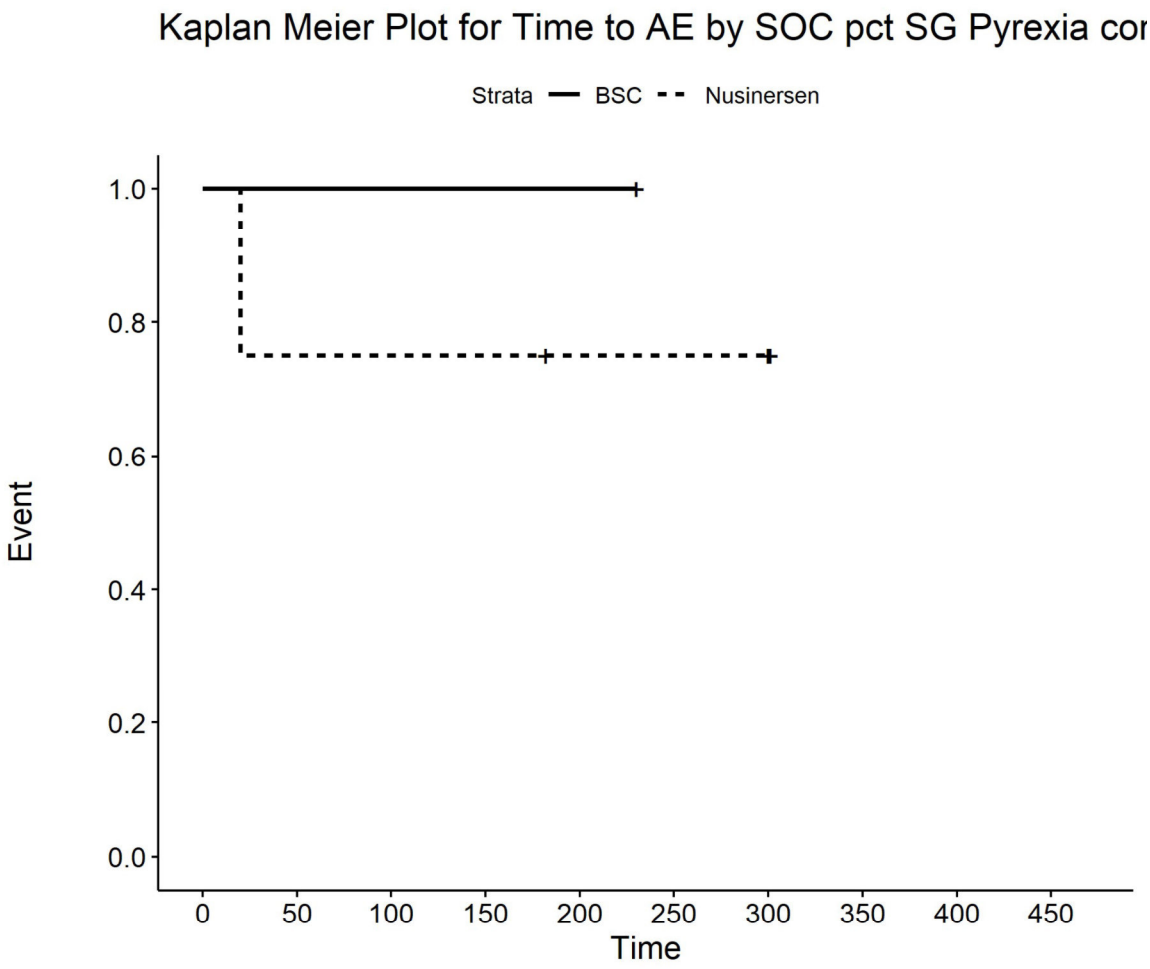
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	1	1	0



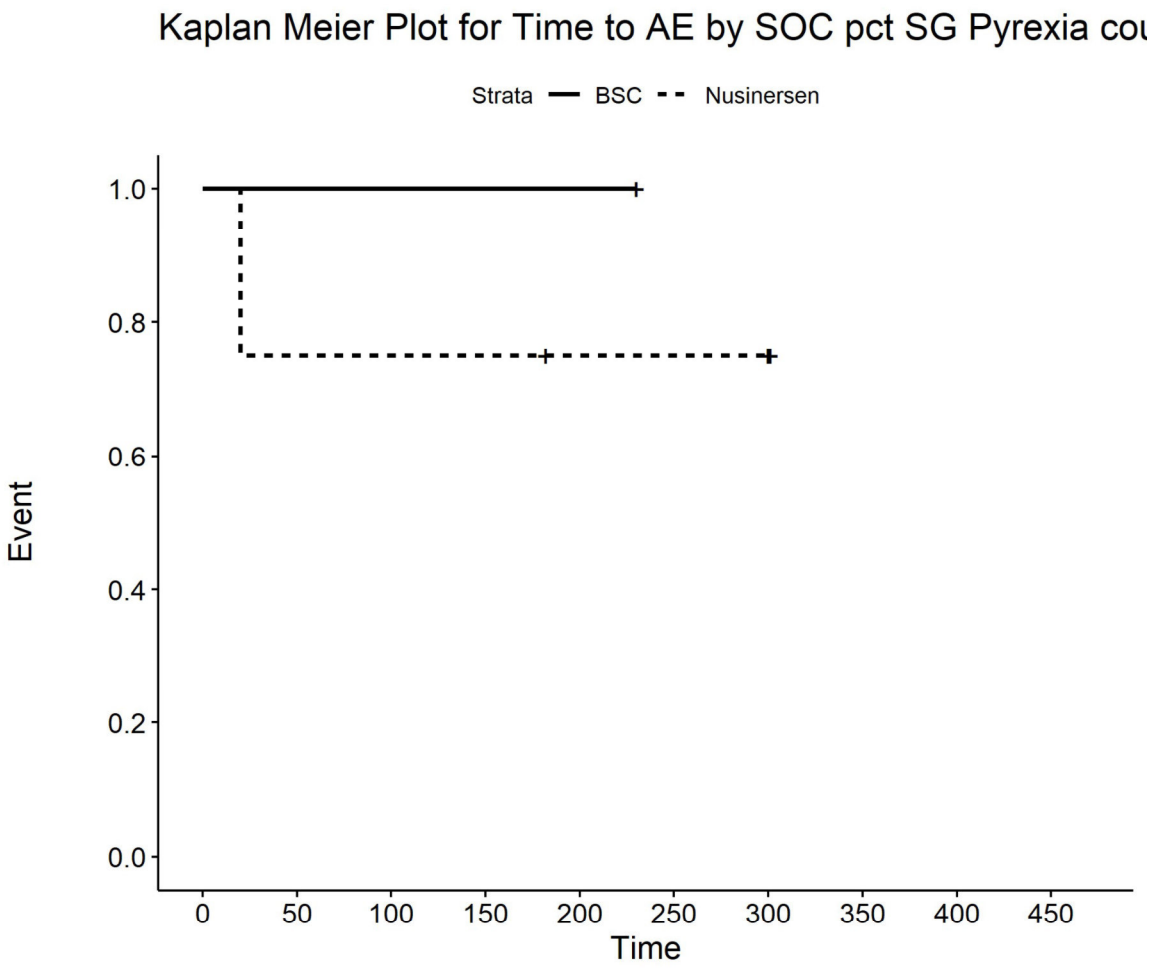
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	4	4	4	3	3	3	2	2	0



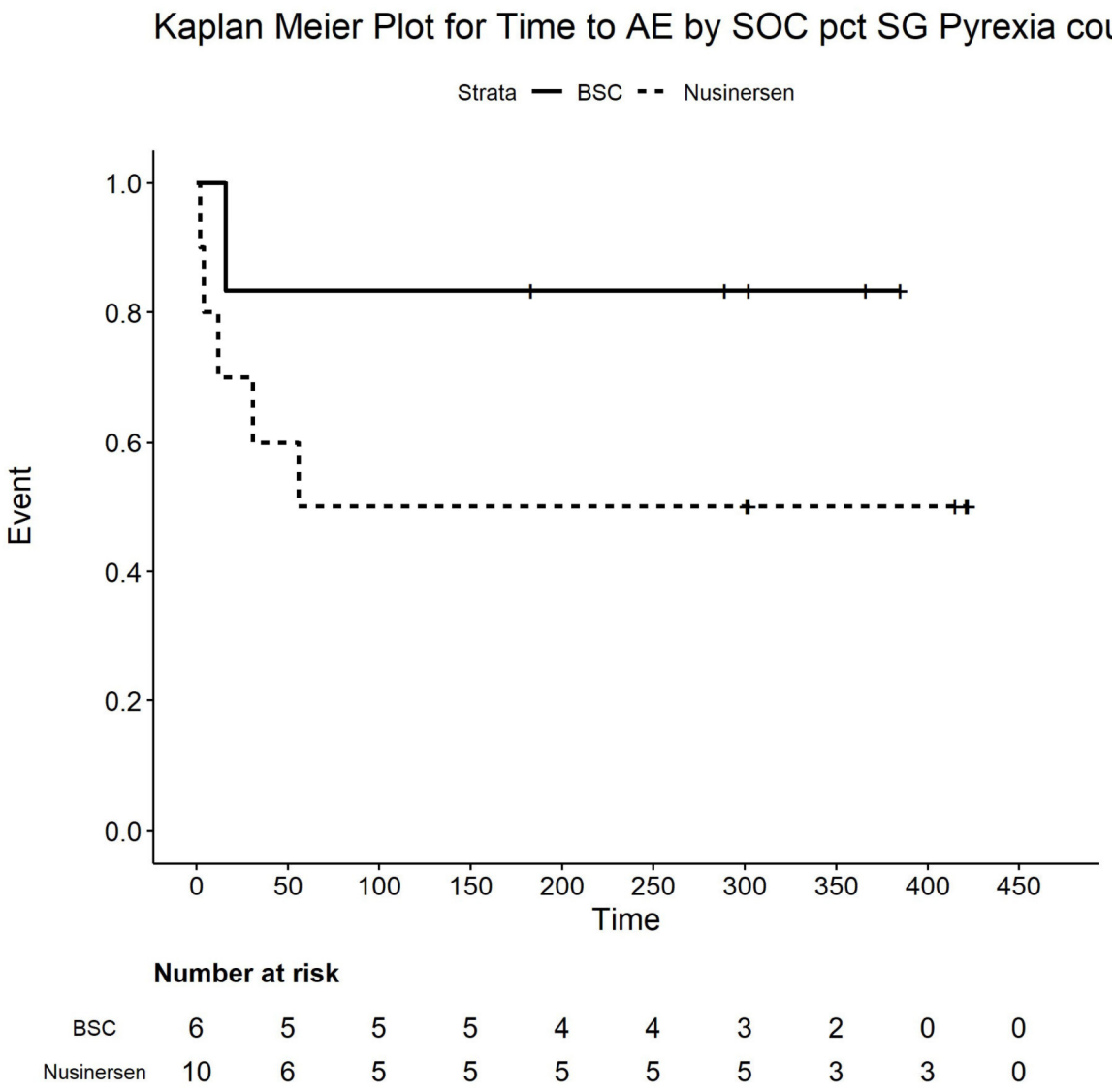
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



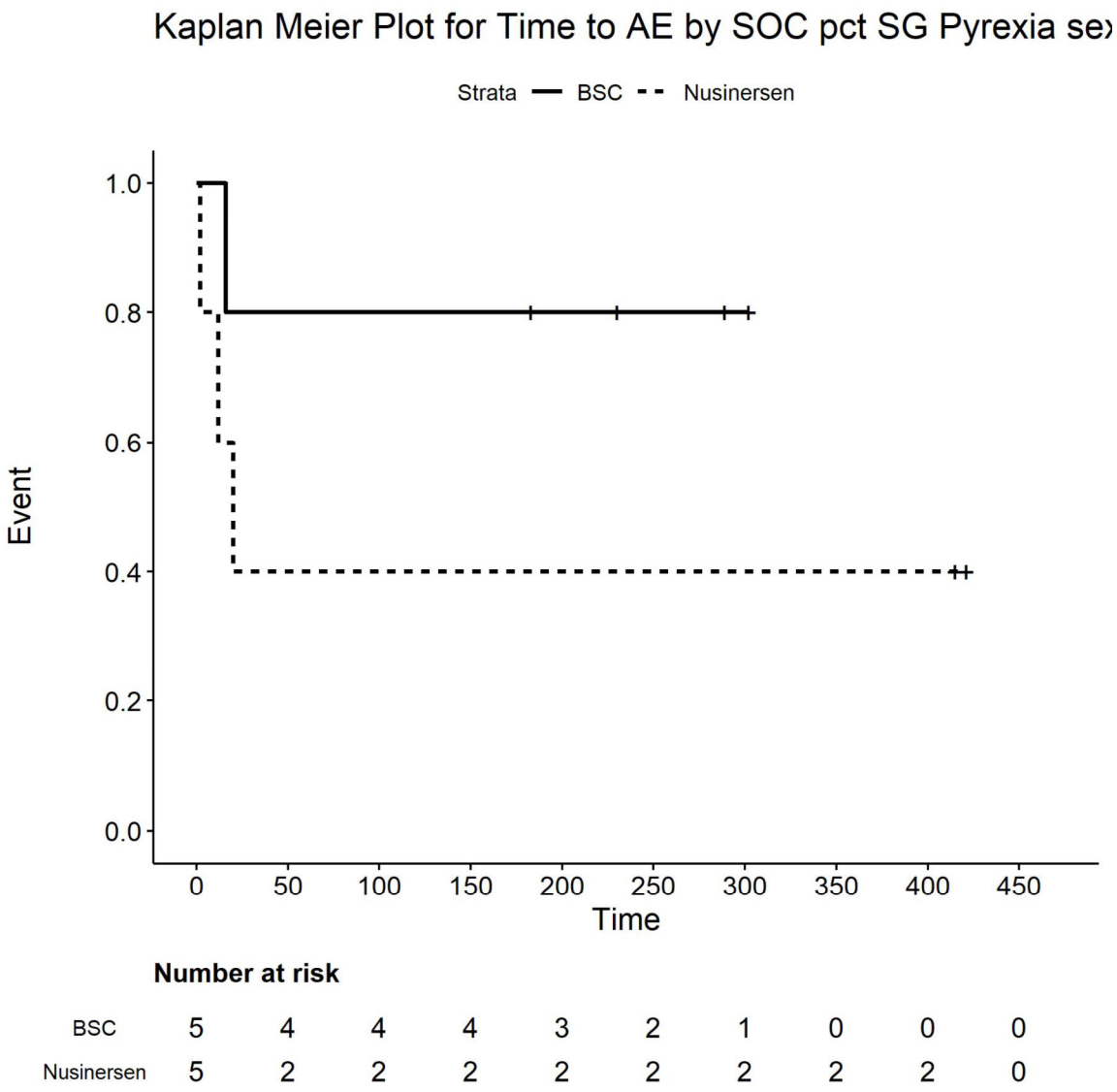
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



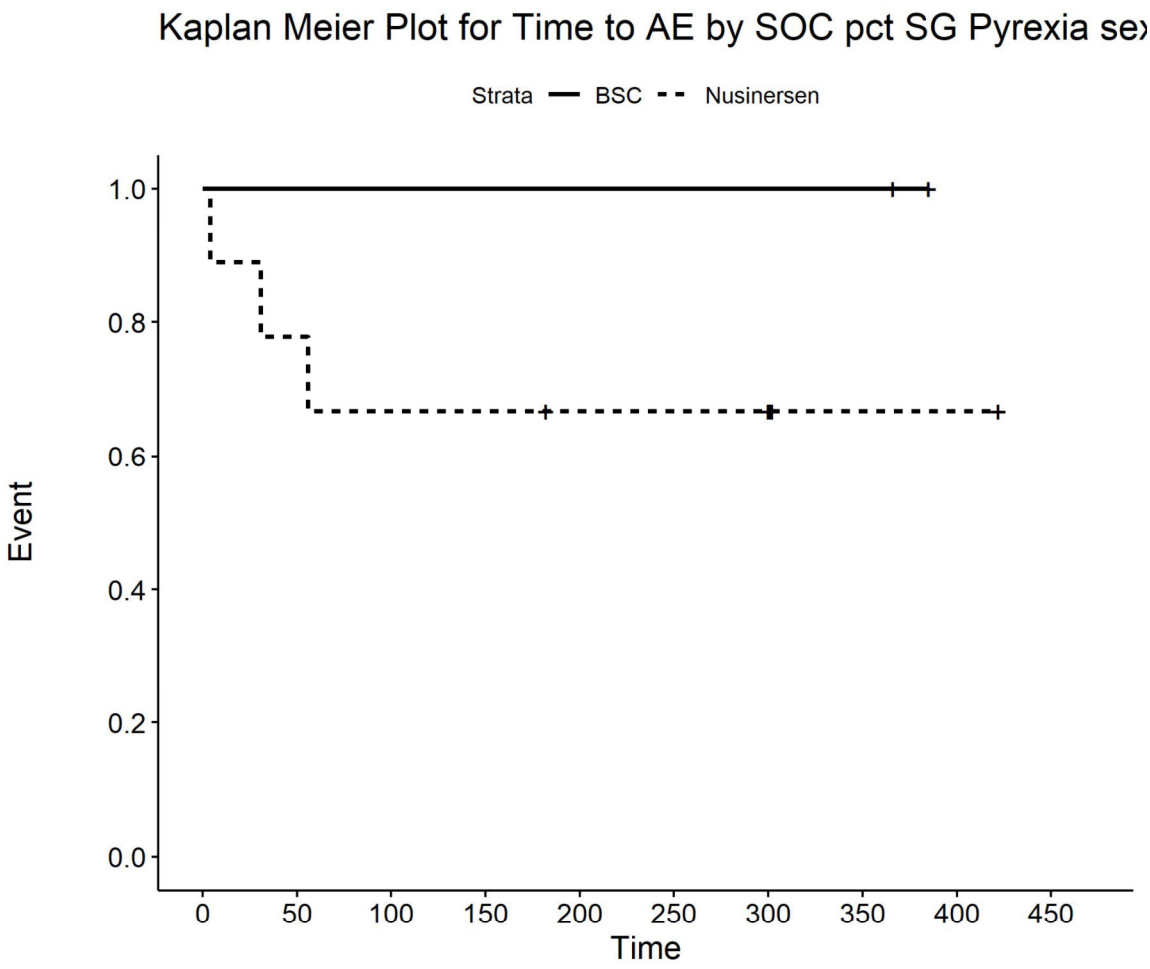
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	6	5	5	5	5	5	3	3	0



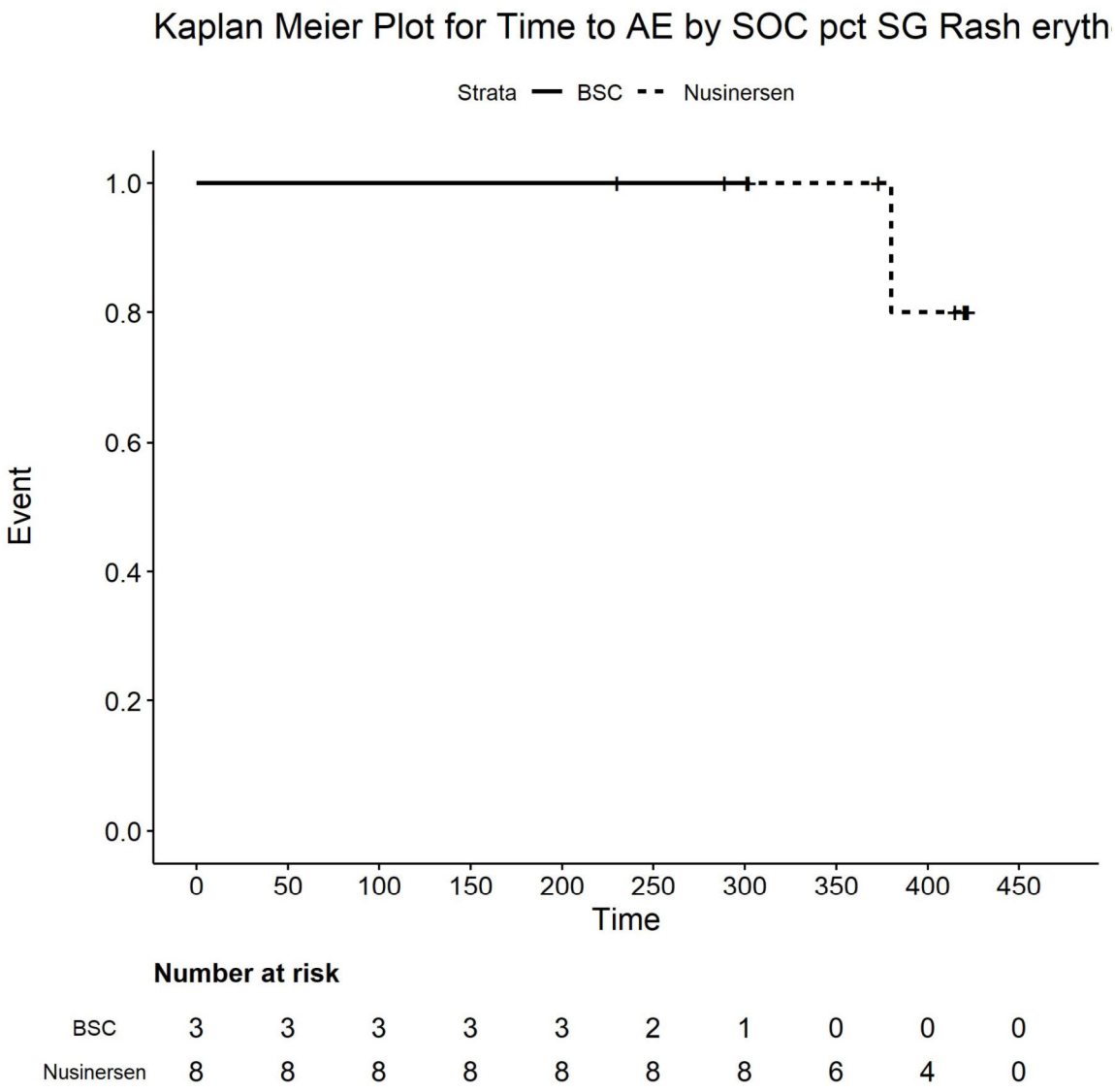
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	2	2	2	2	2	2	2	2	0



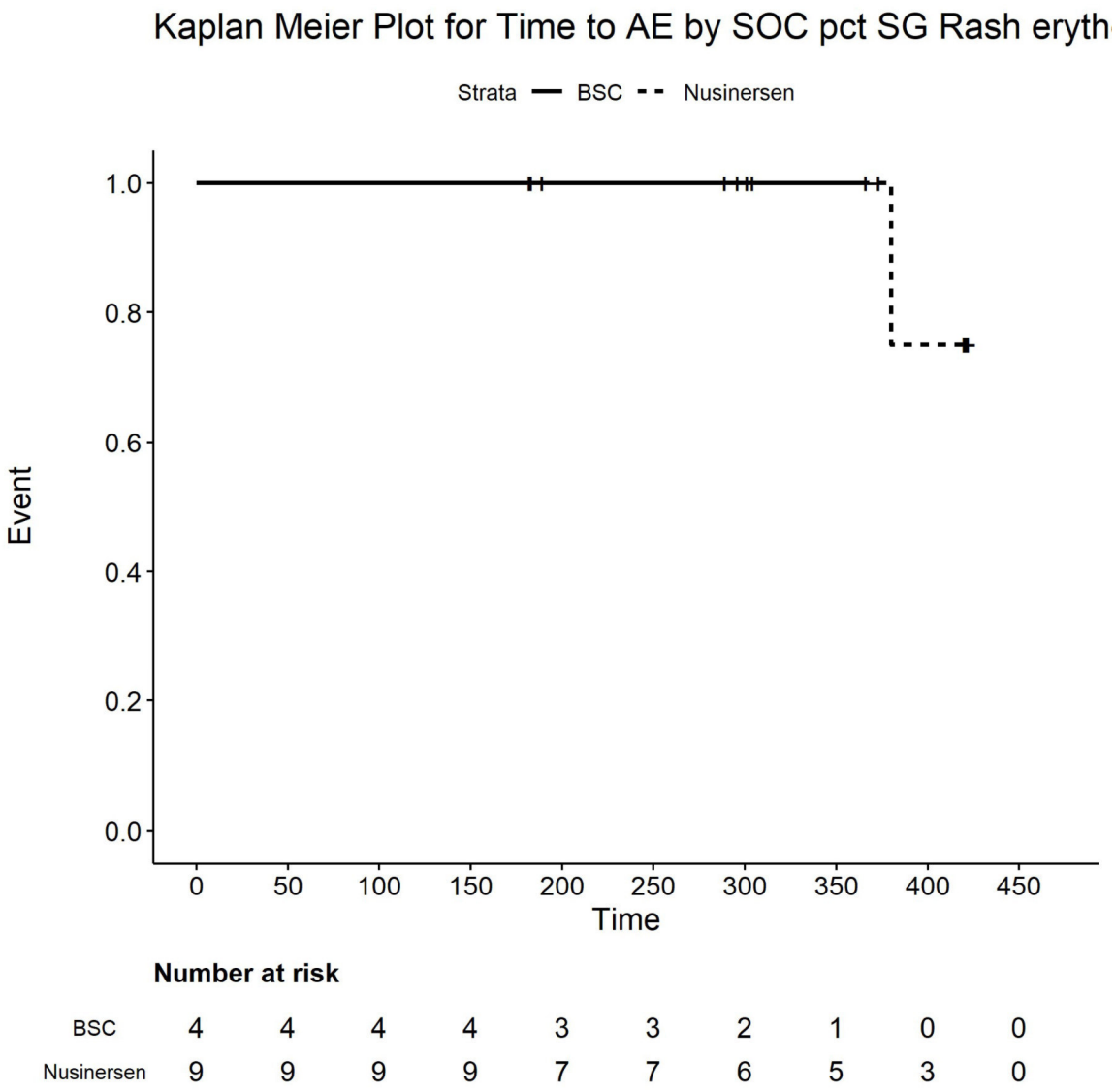
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	6	6	5	5	5	1	1	0



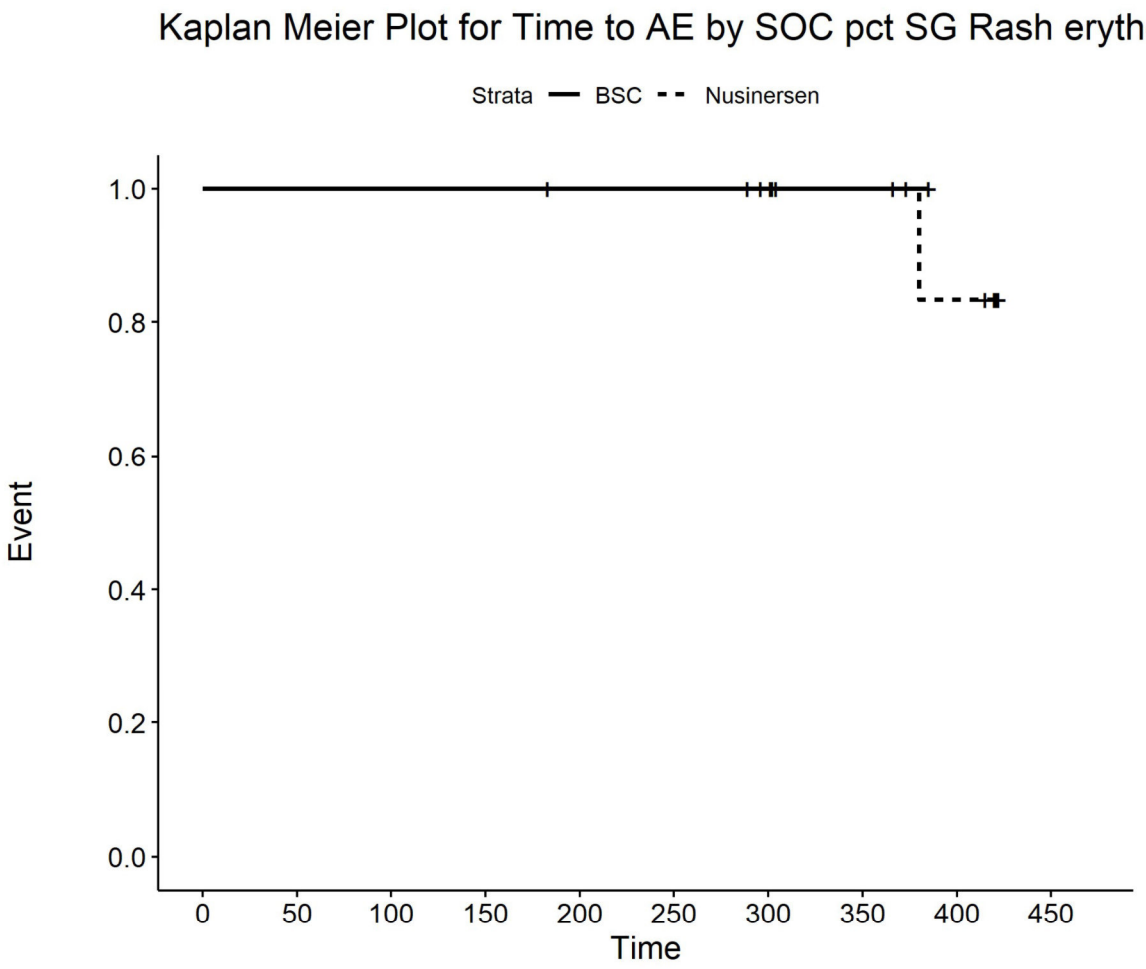
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	4	0



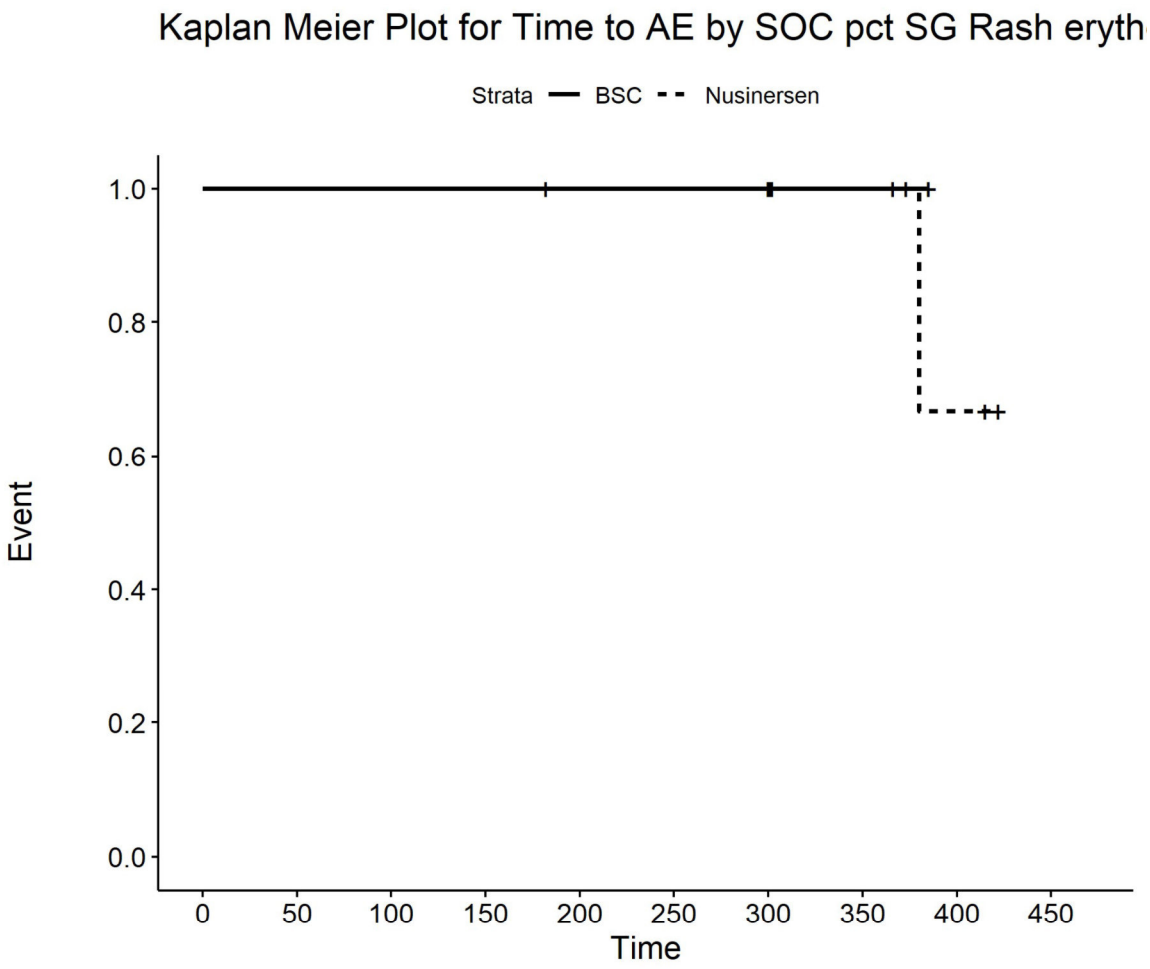
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	3	0



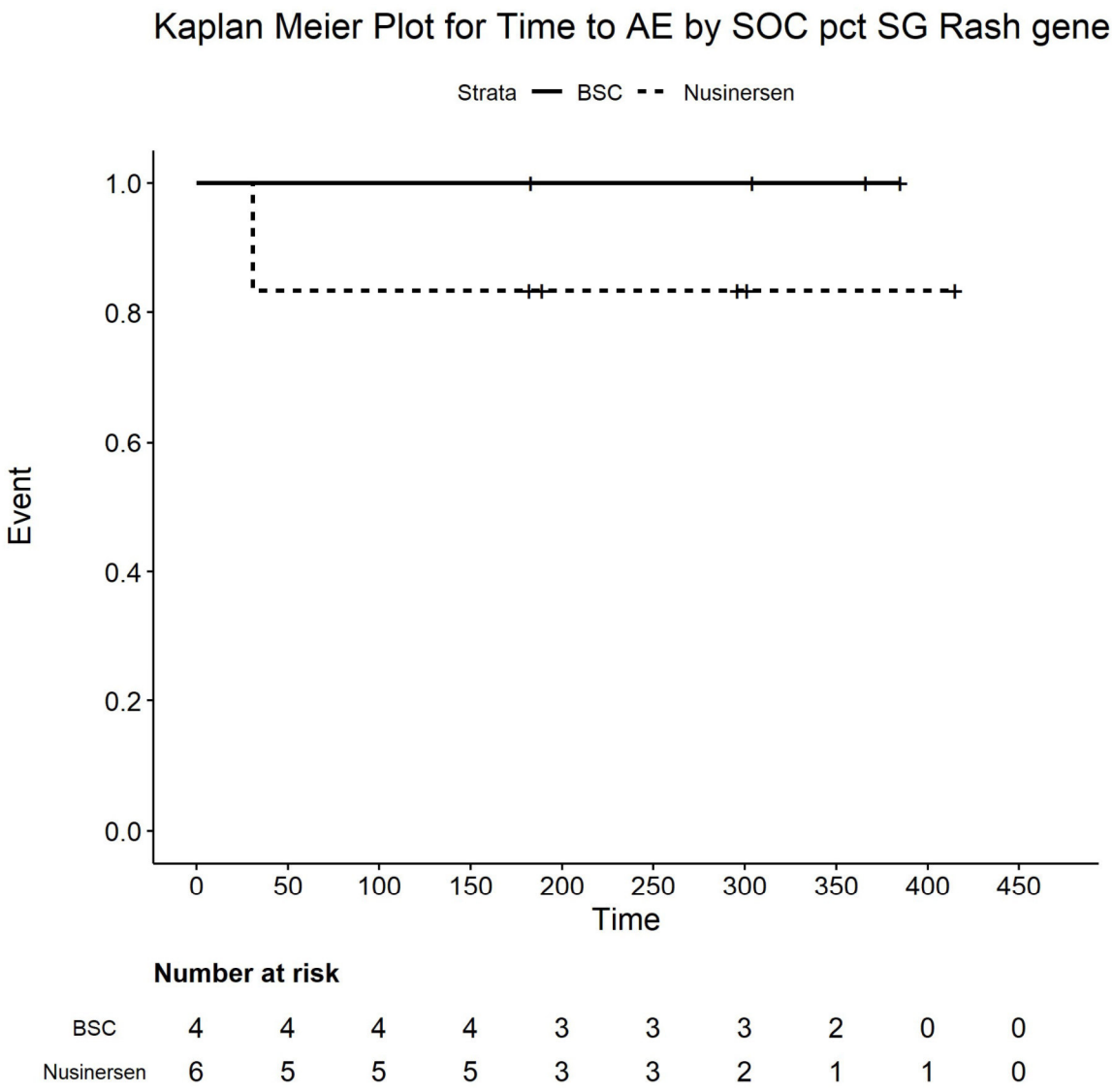
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	5	0



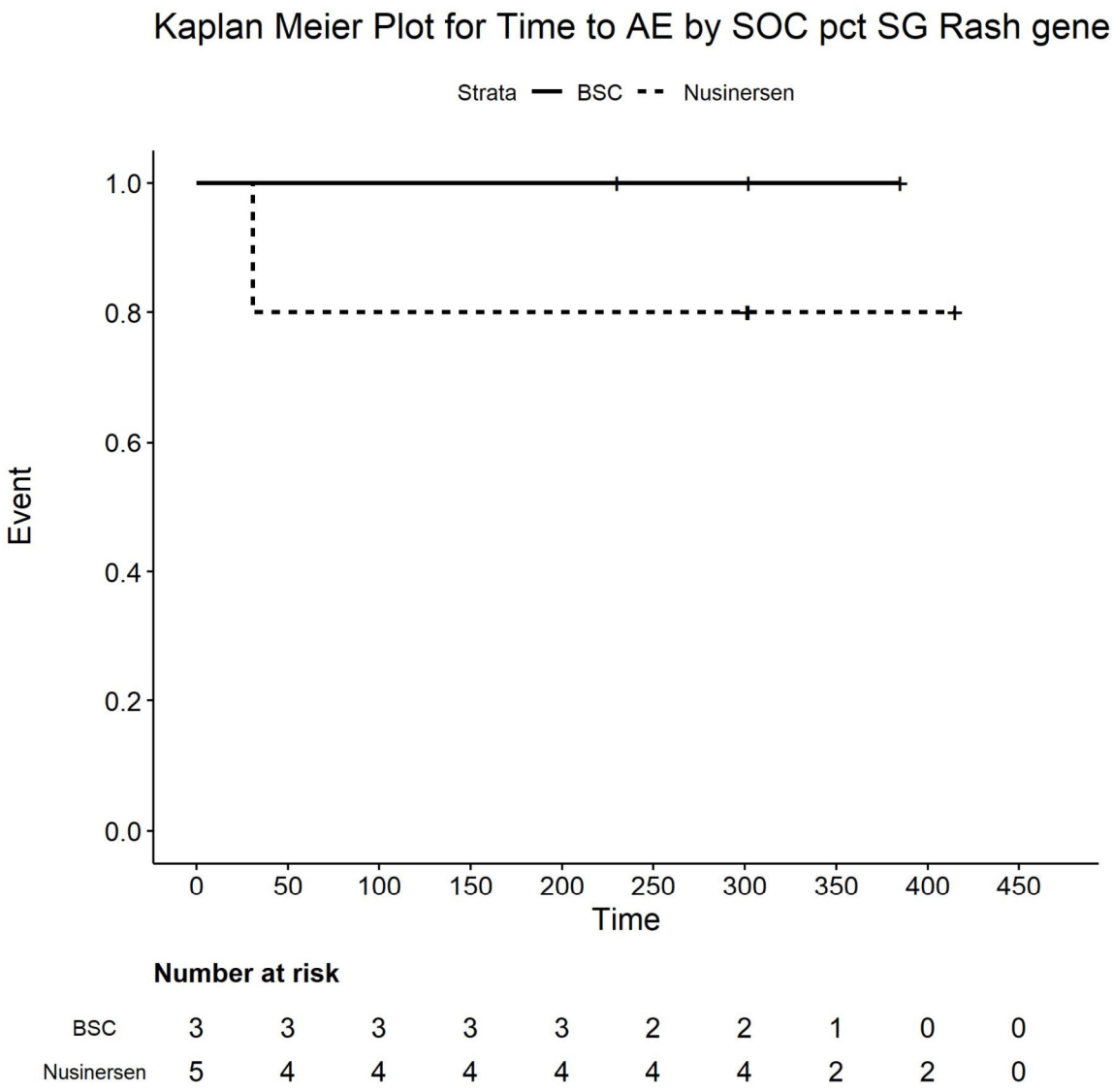
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	8	4	2	0



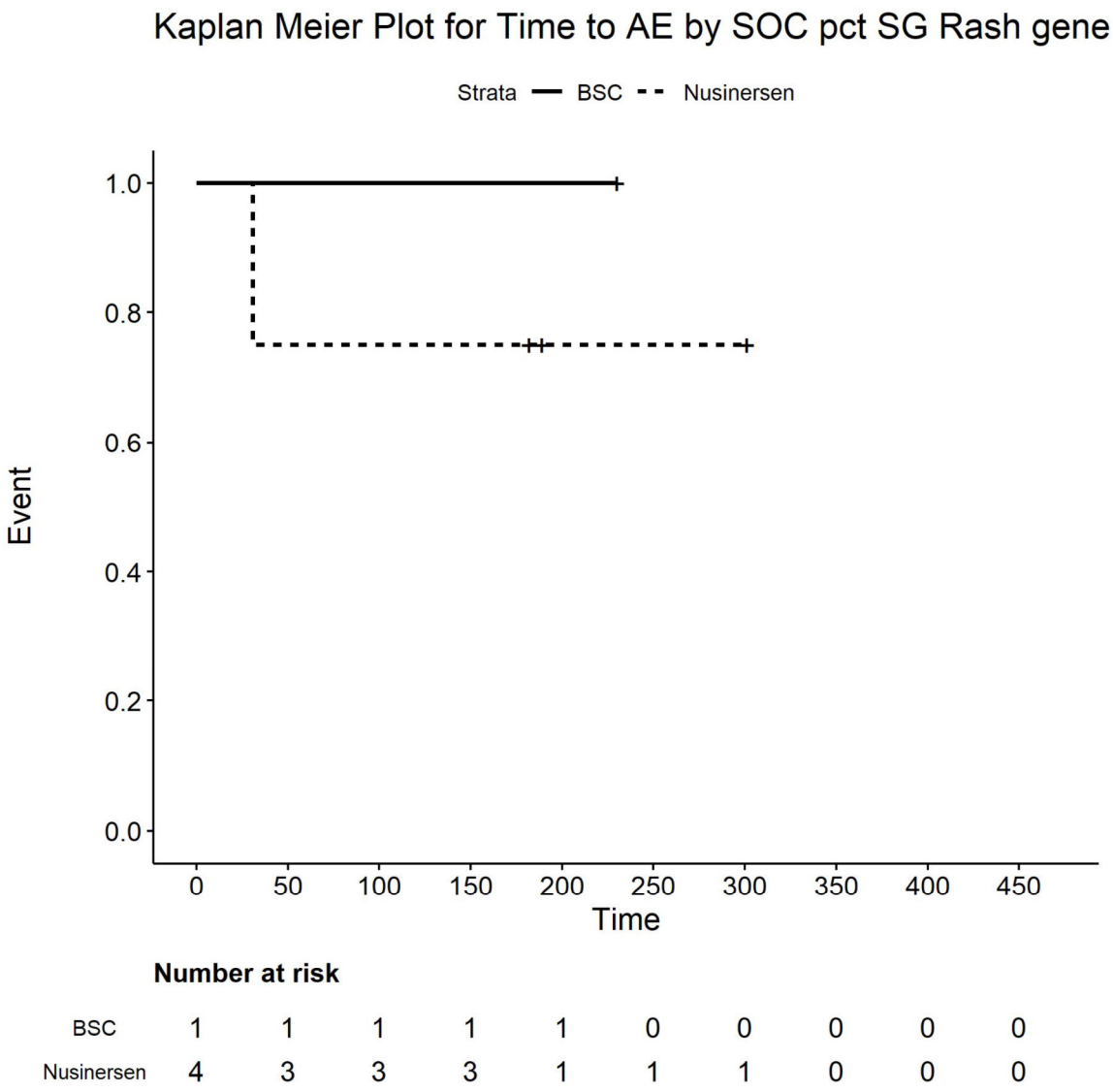
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	2	1	1	0



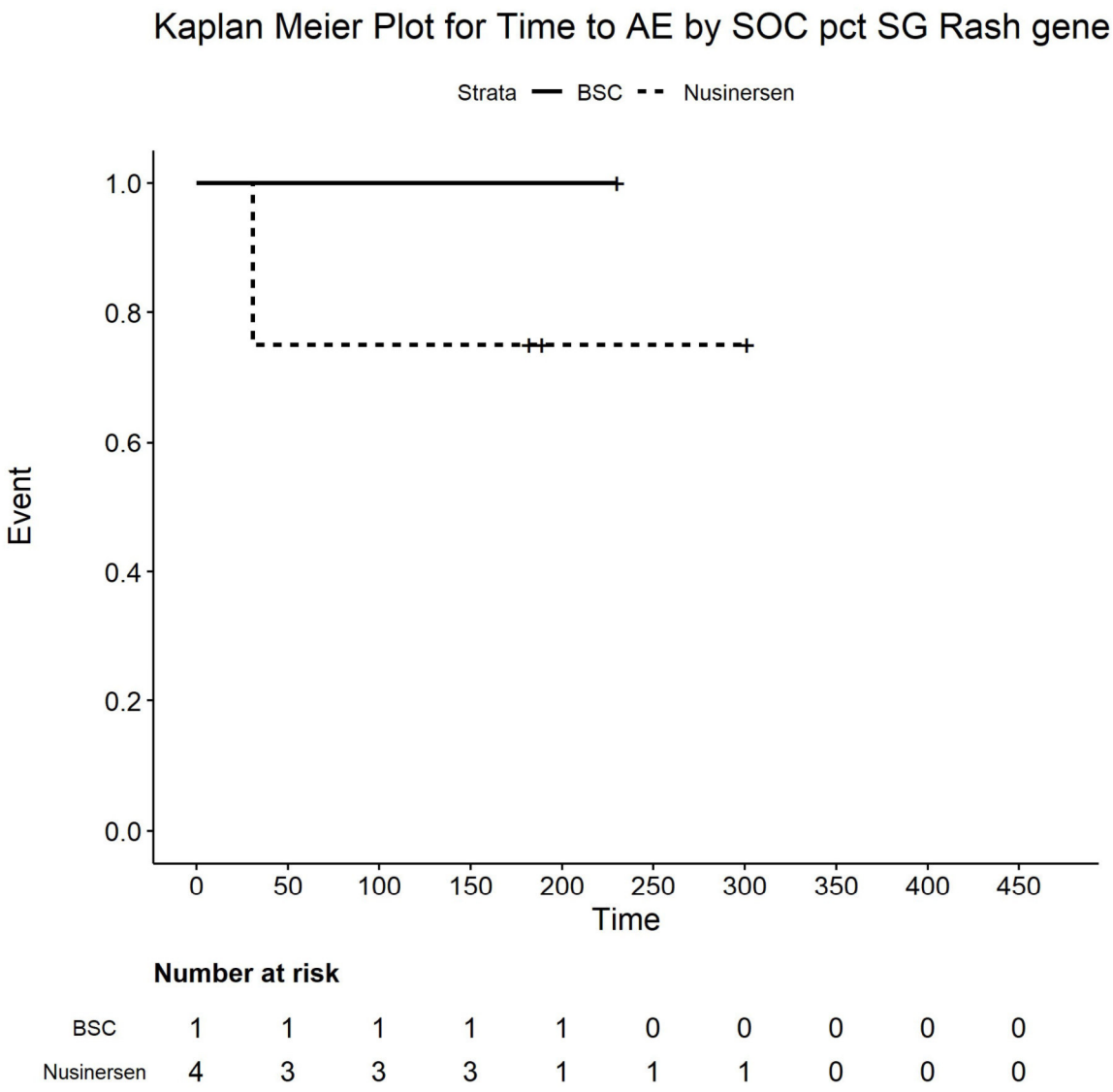
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



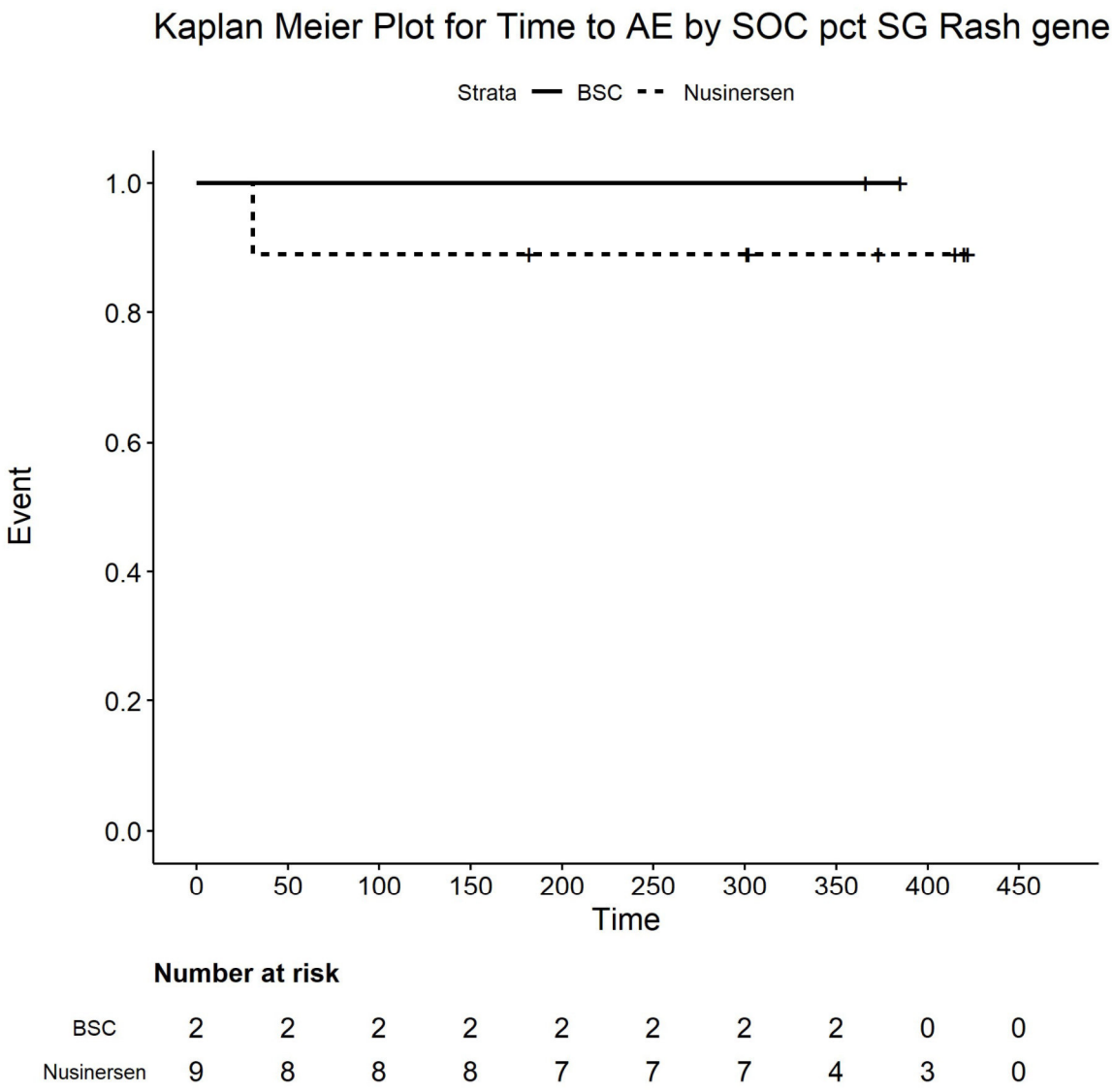
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



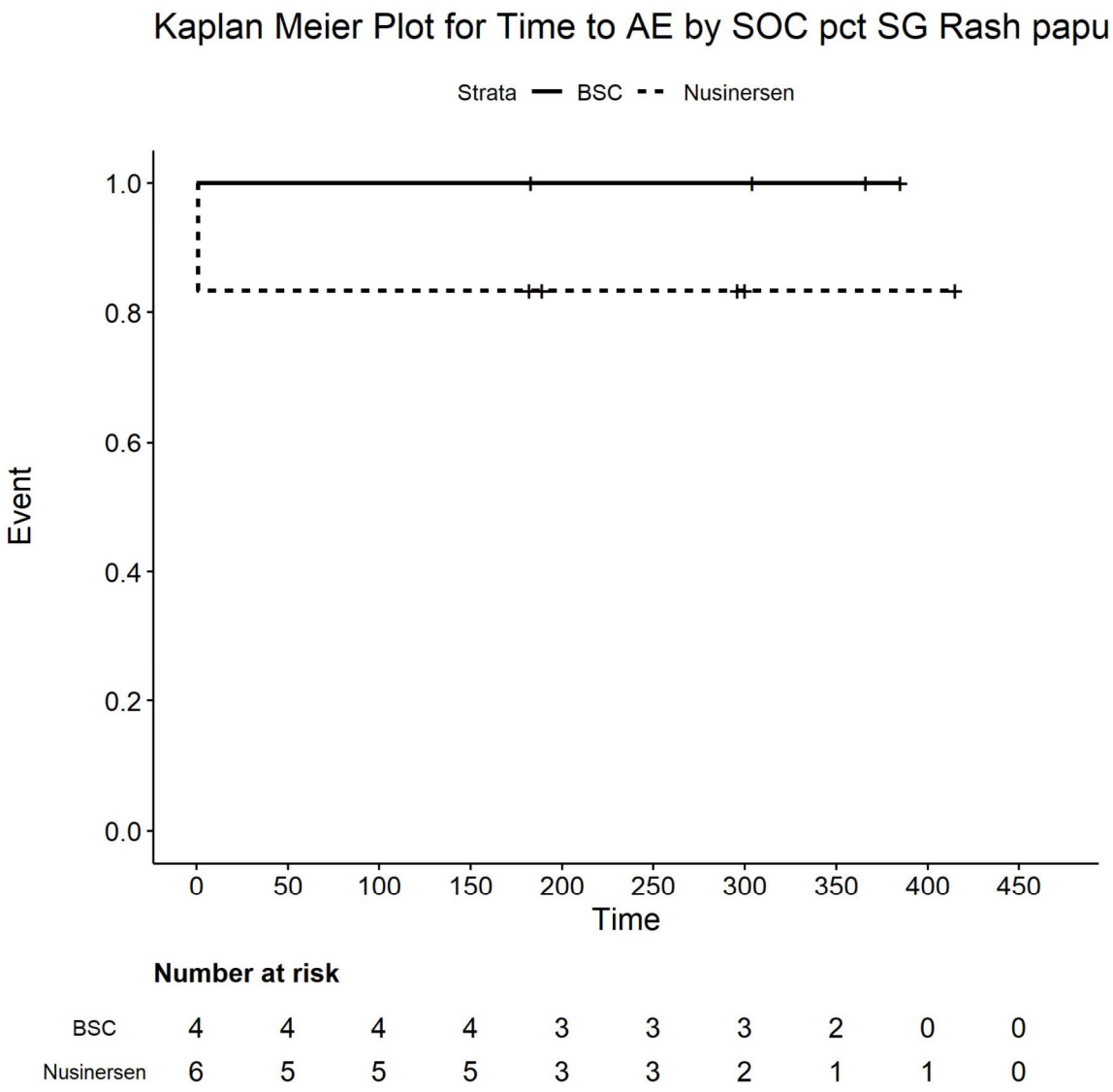
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



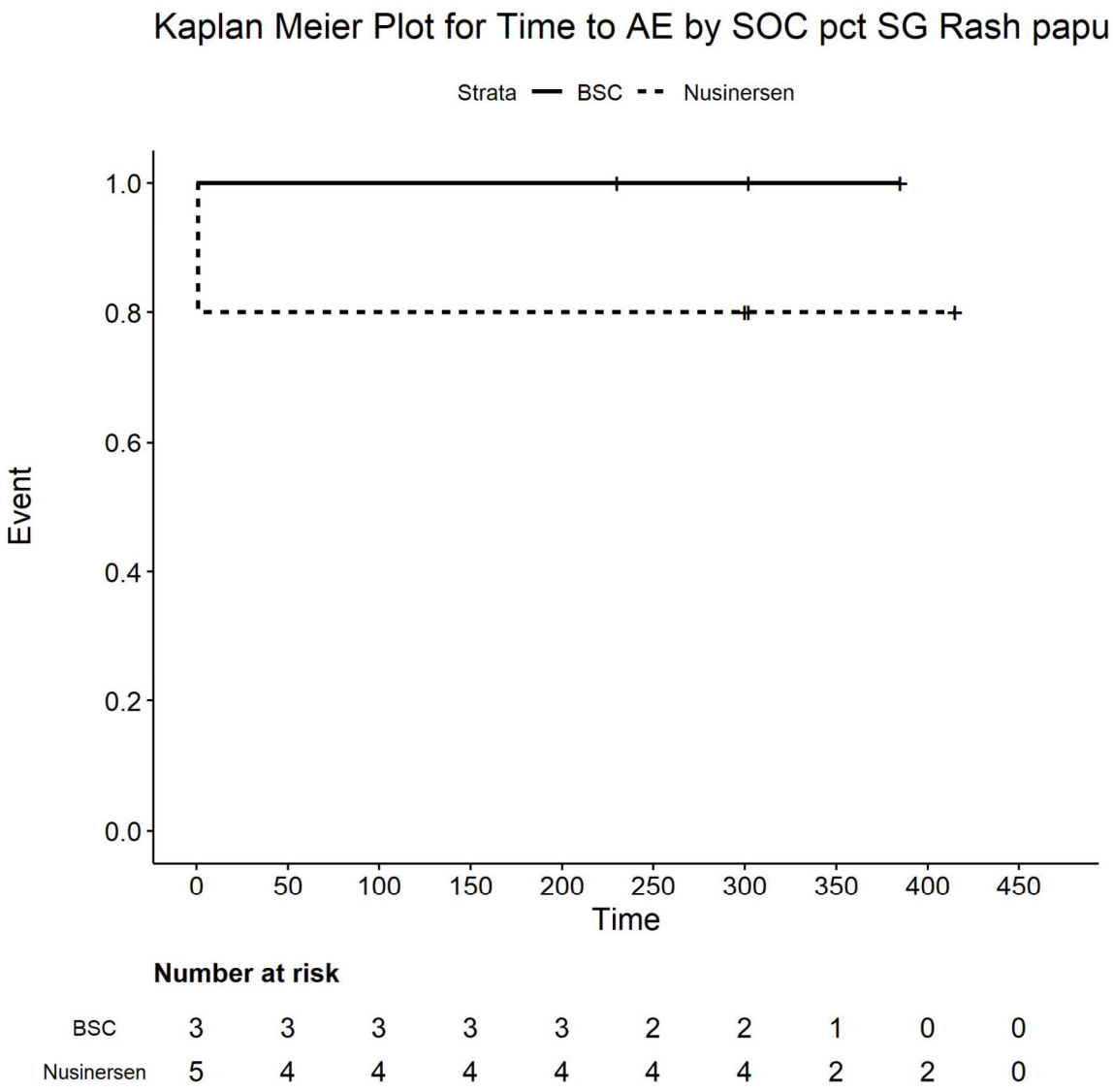
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



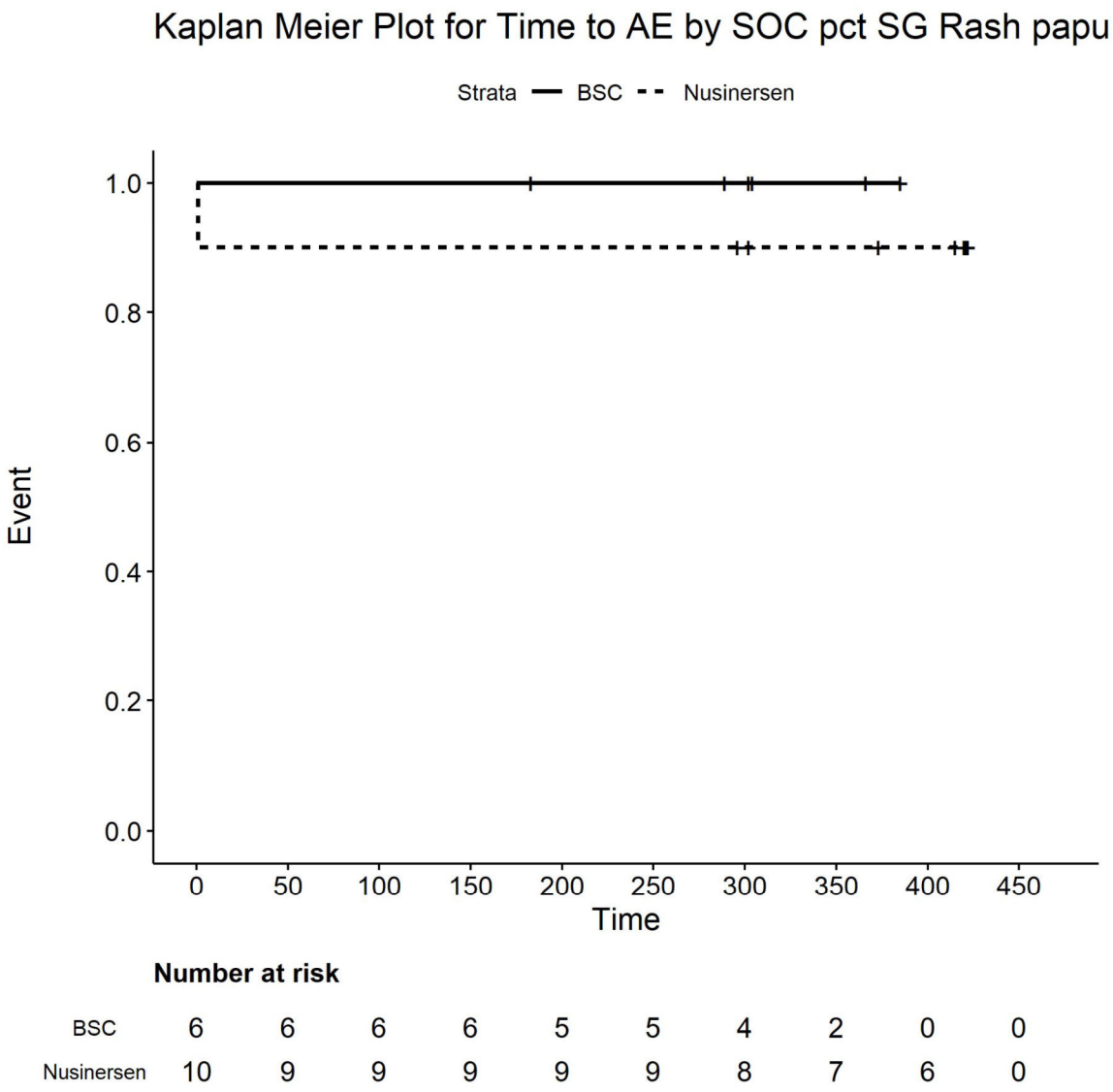
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	2	1	1	0



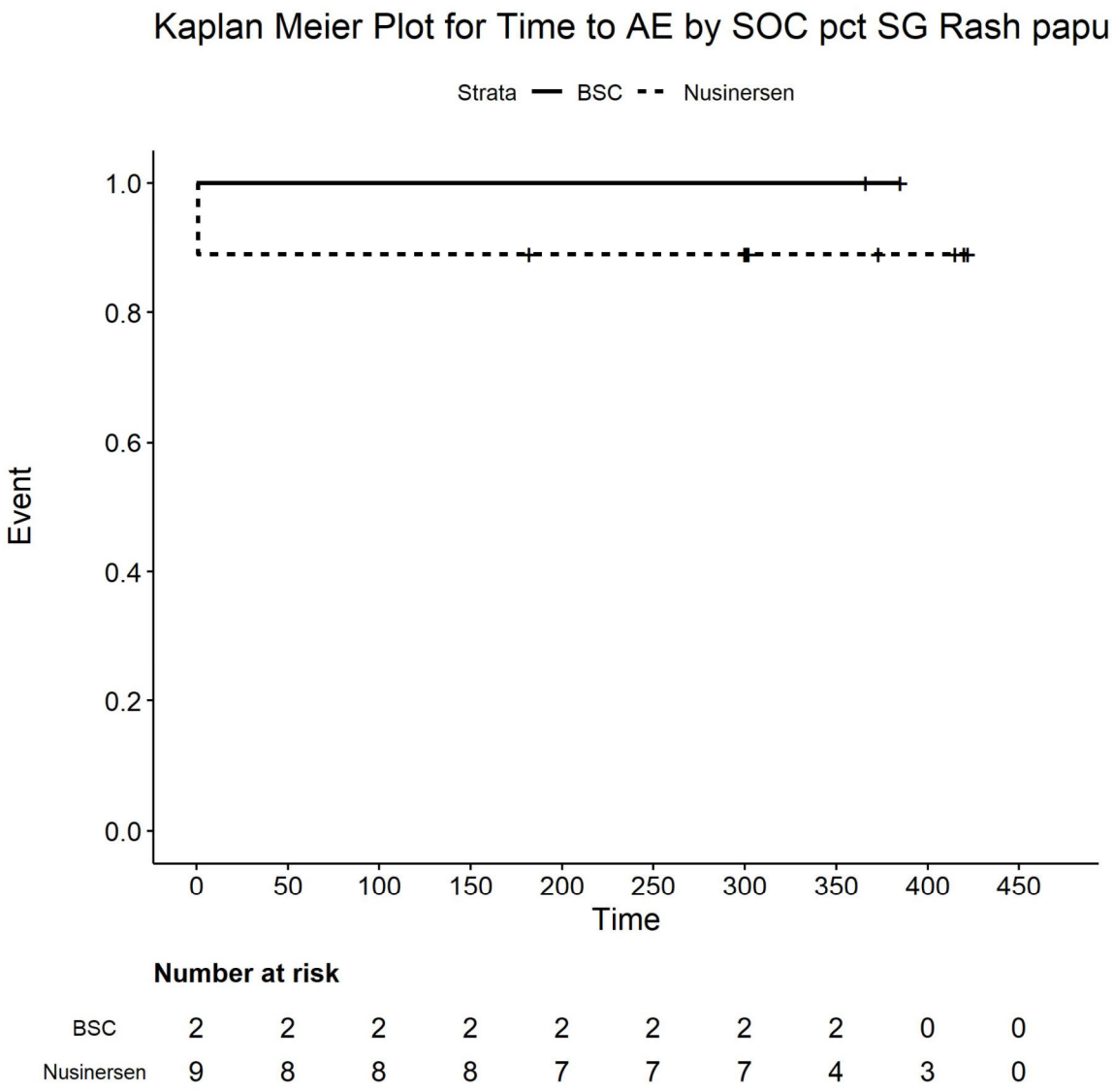
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



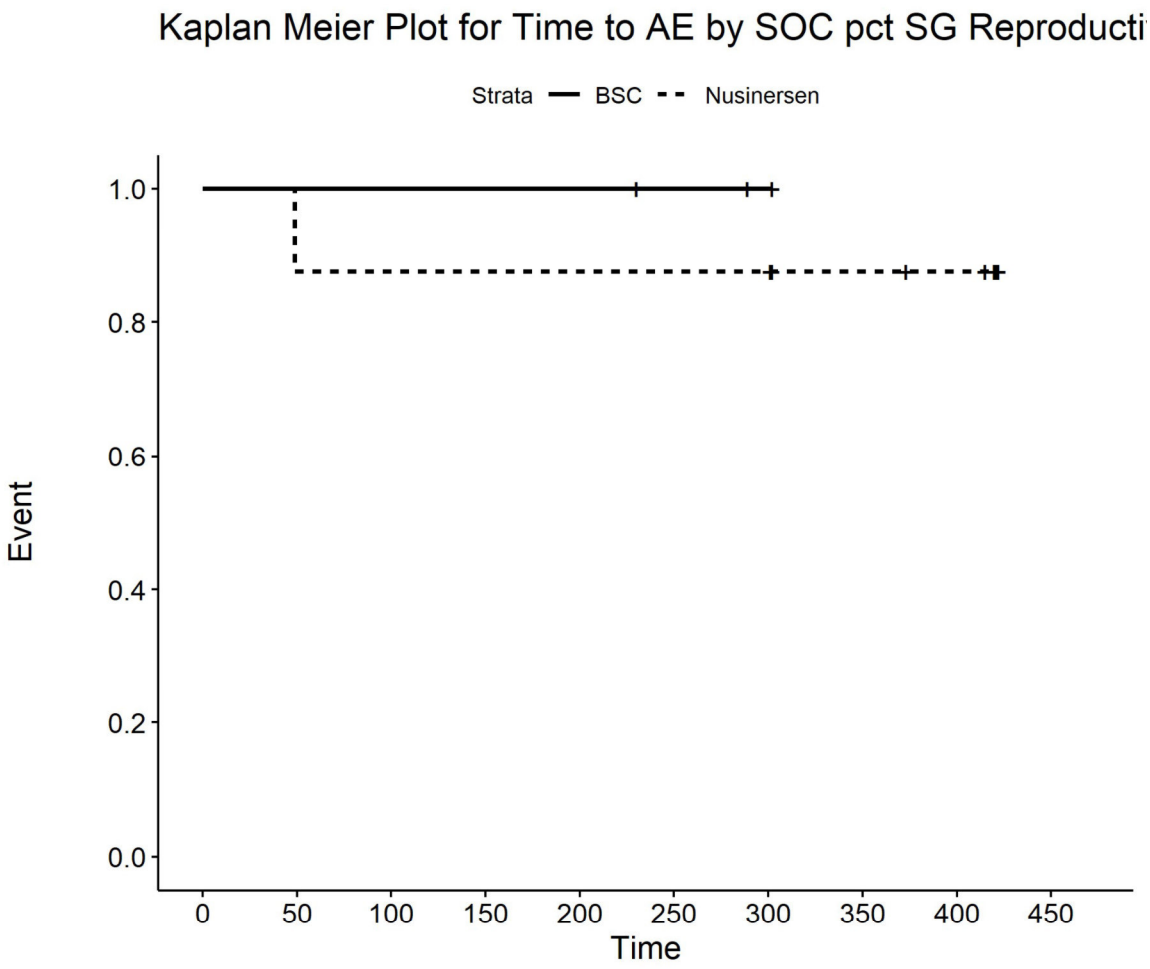
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	7	6	0



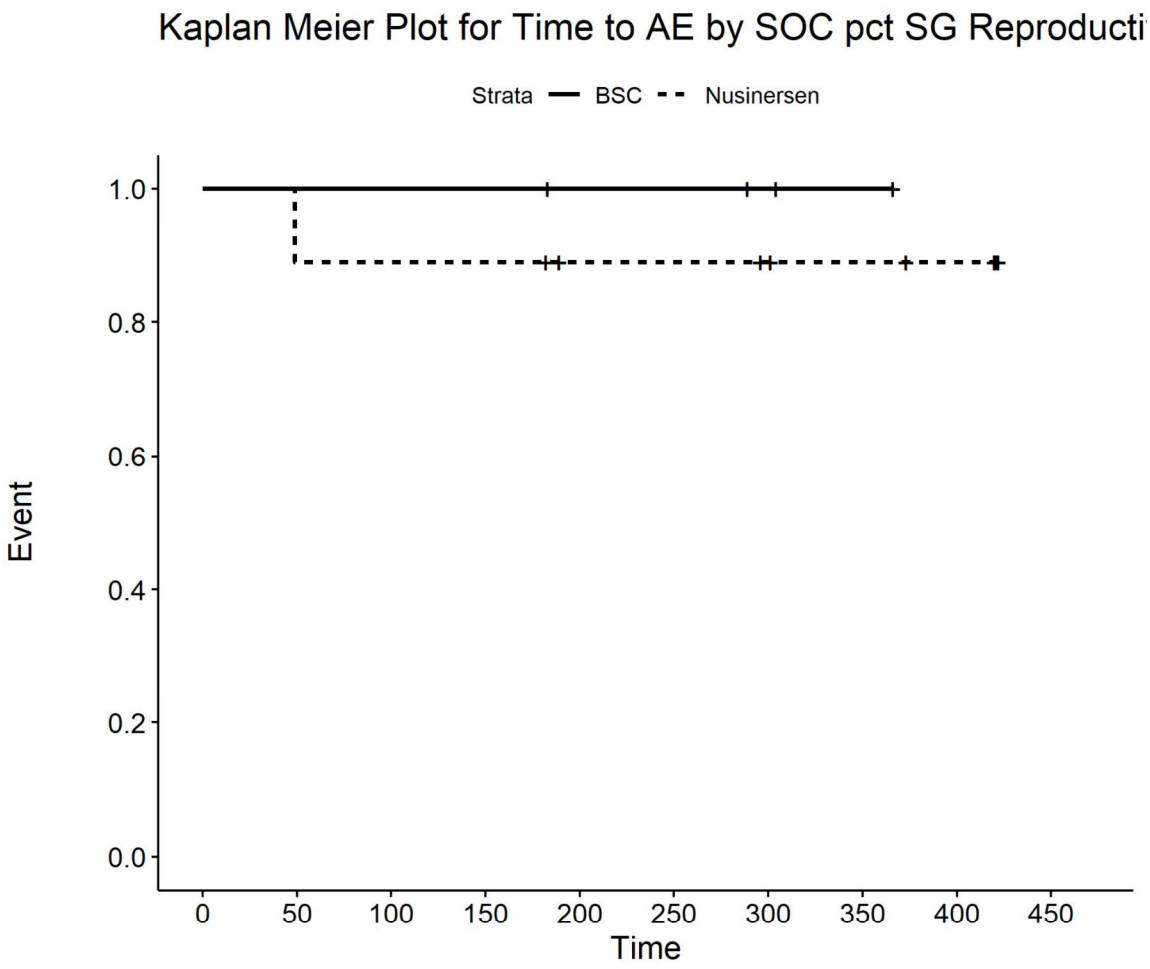
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



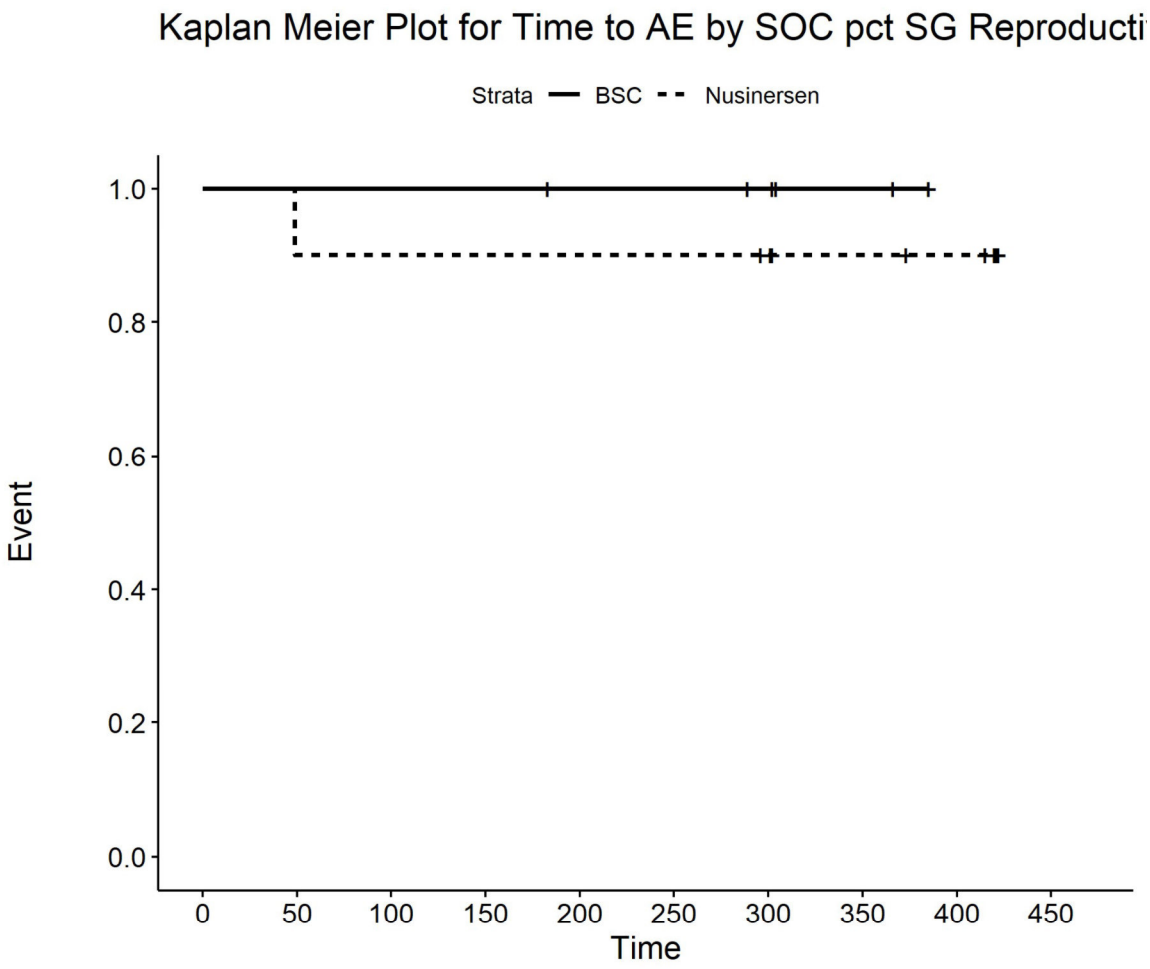
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



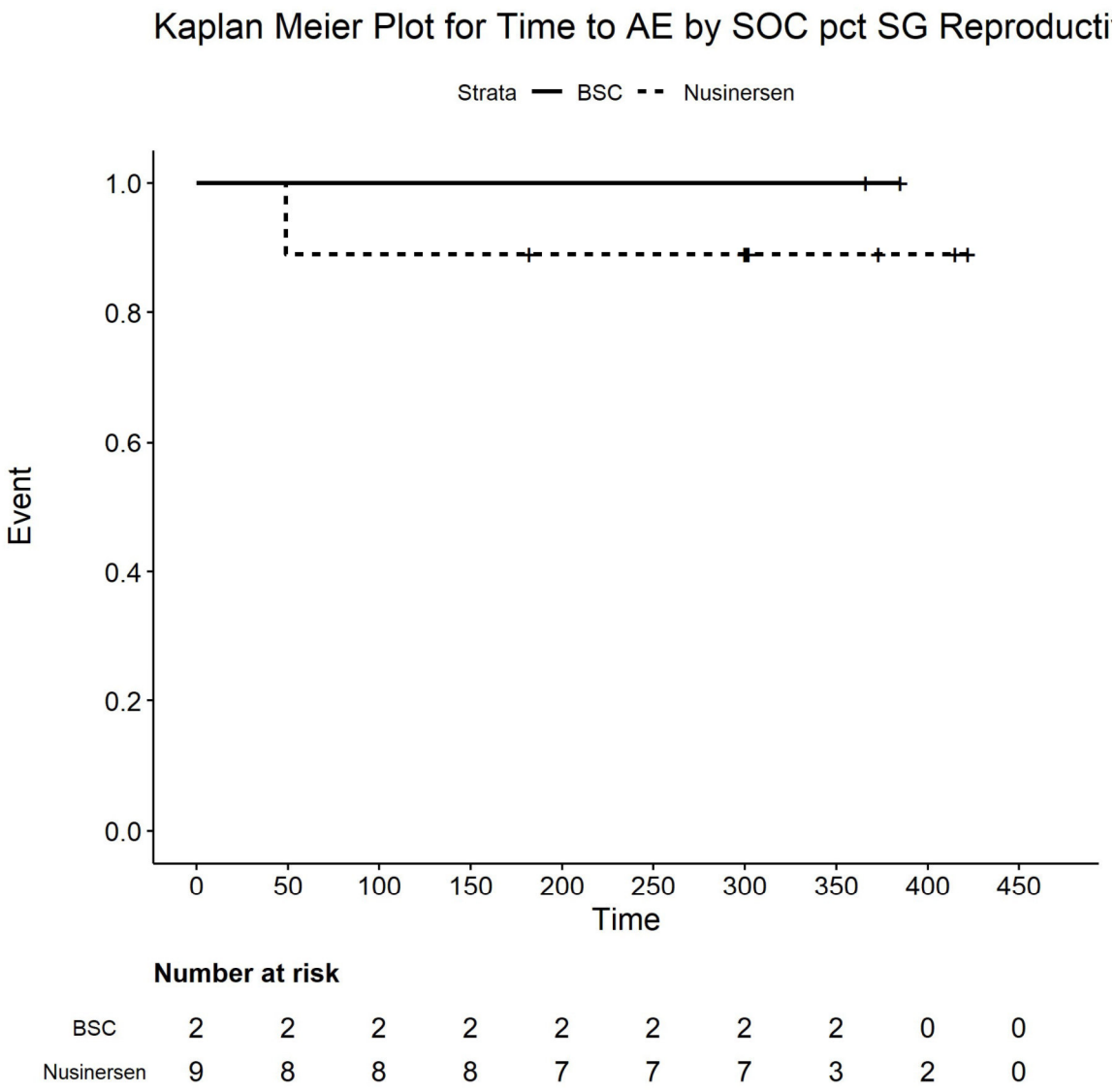
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



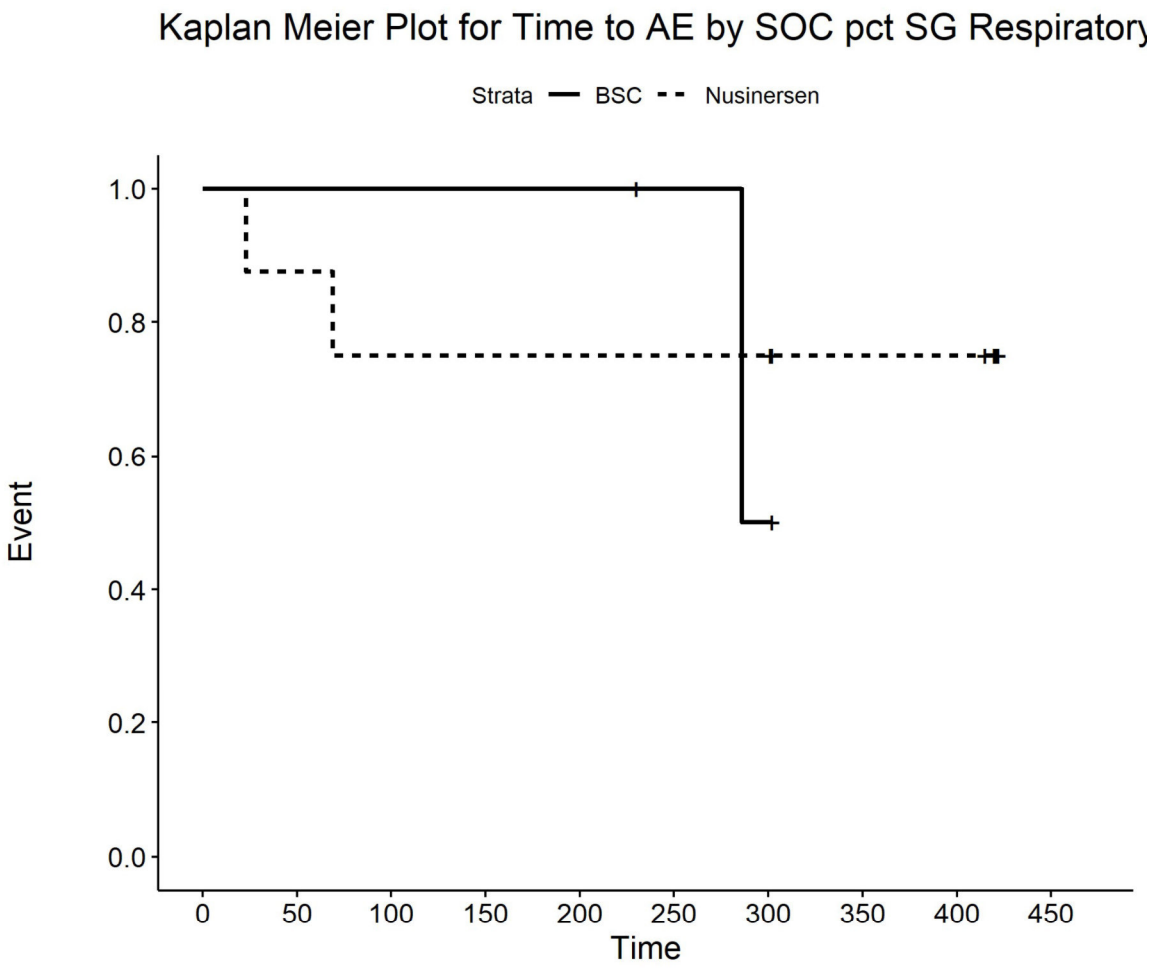
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



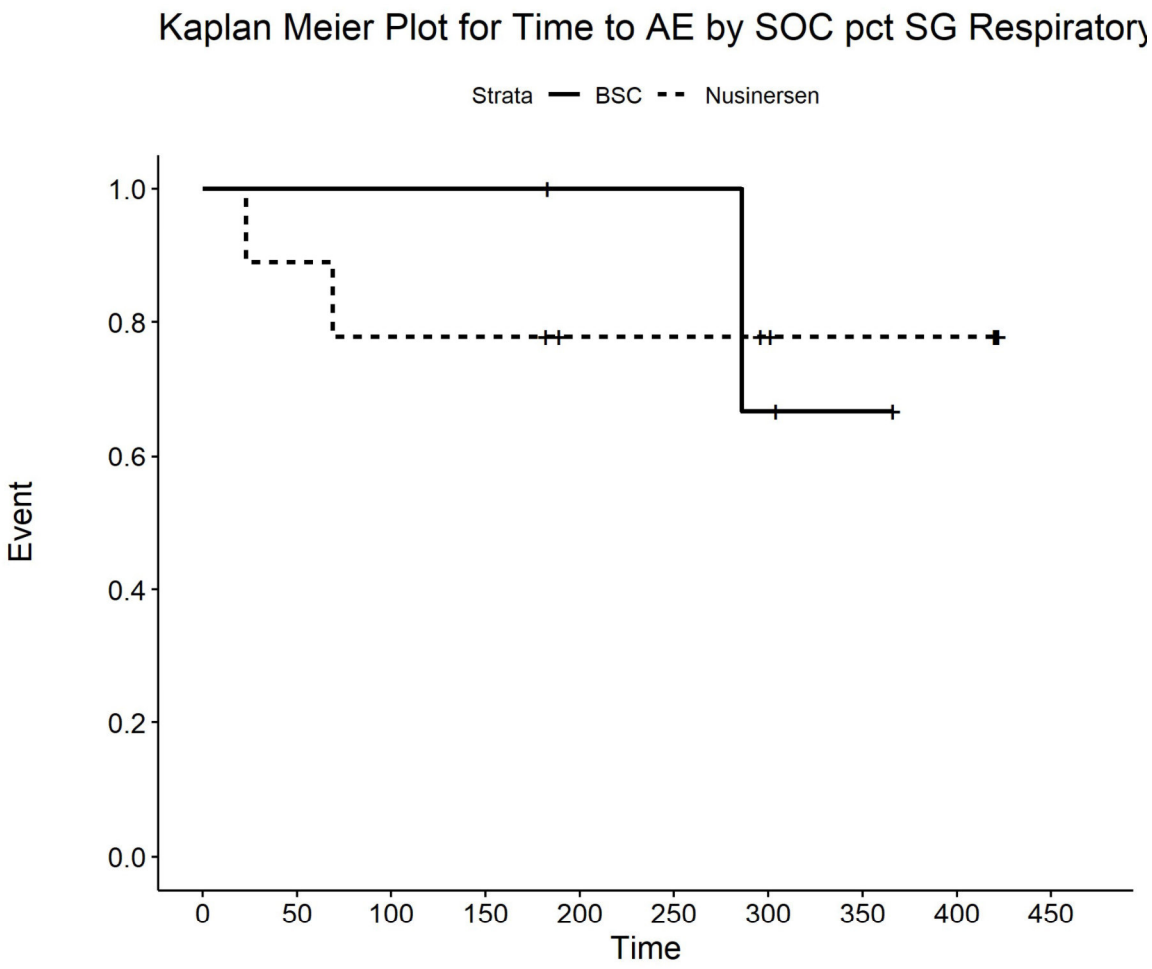
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	2	0



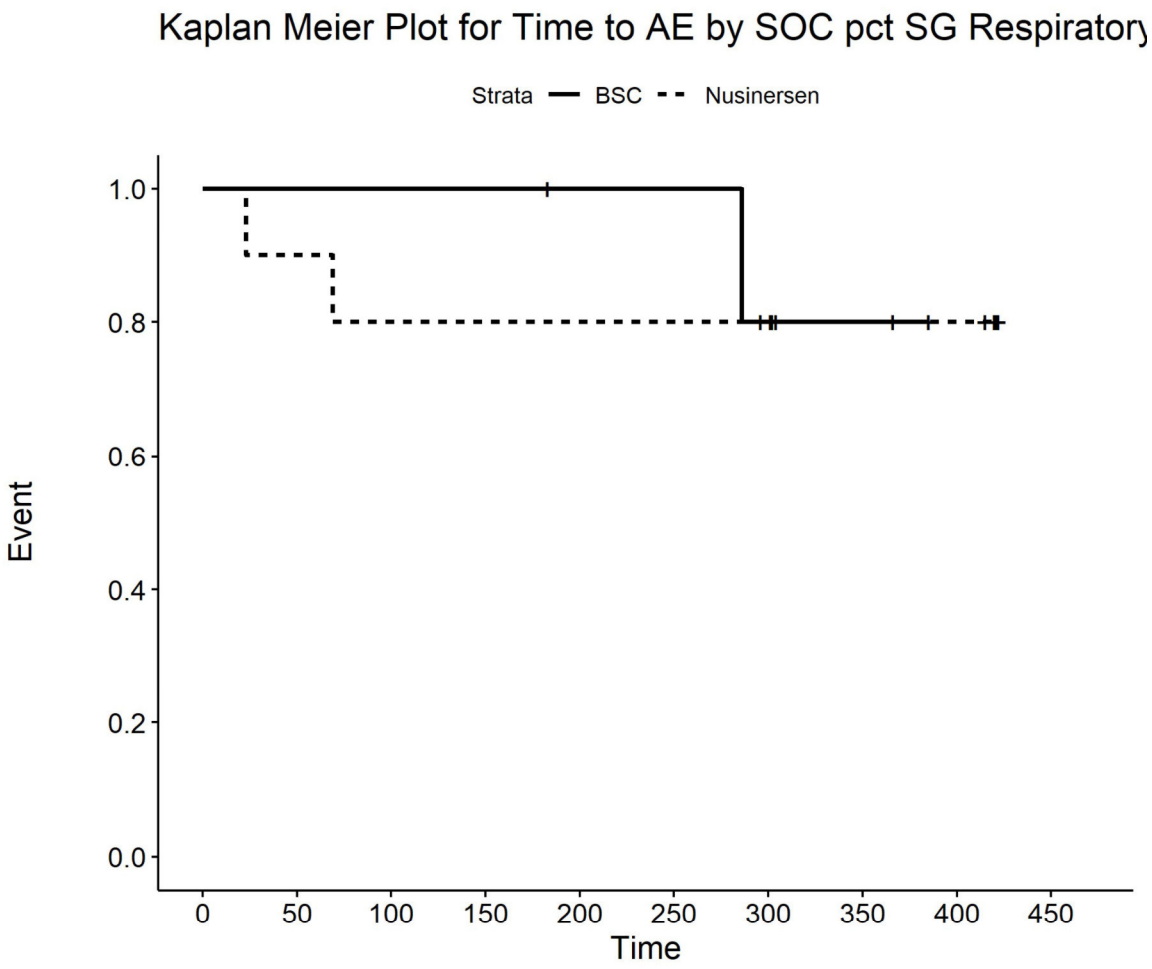
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	6	6	6	6	6	4	4	0



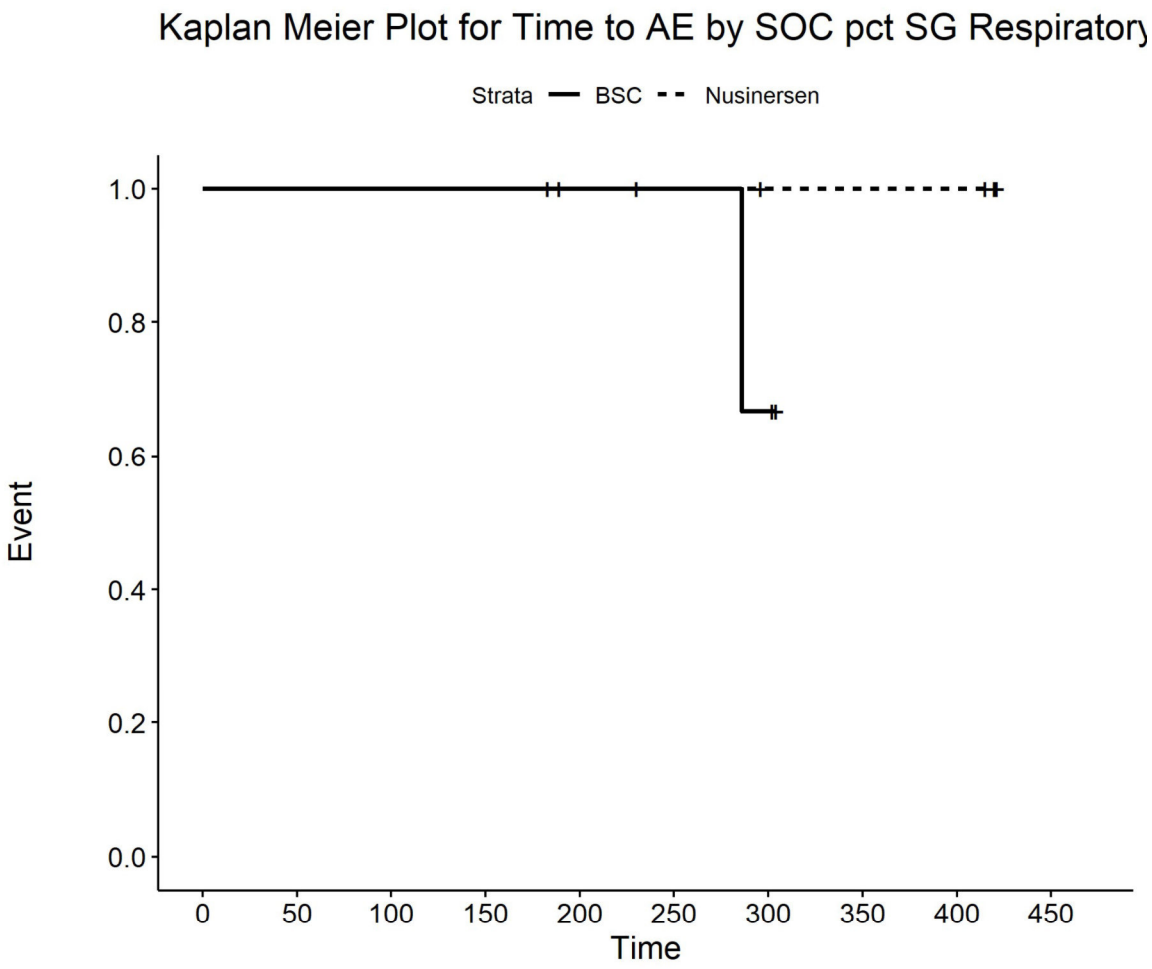
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	7	7	5	5	4	3	3	0



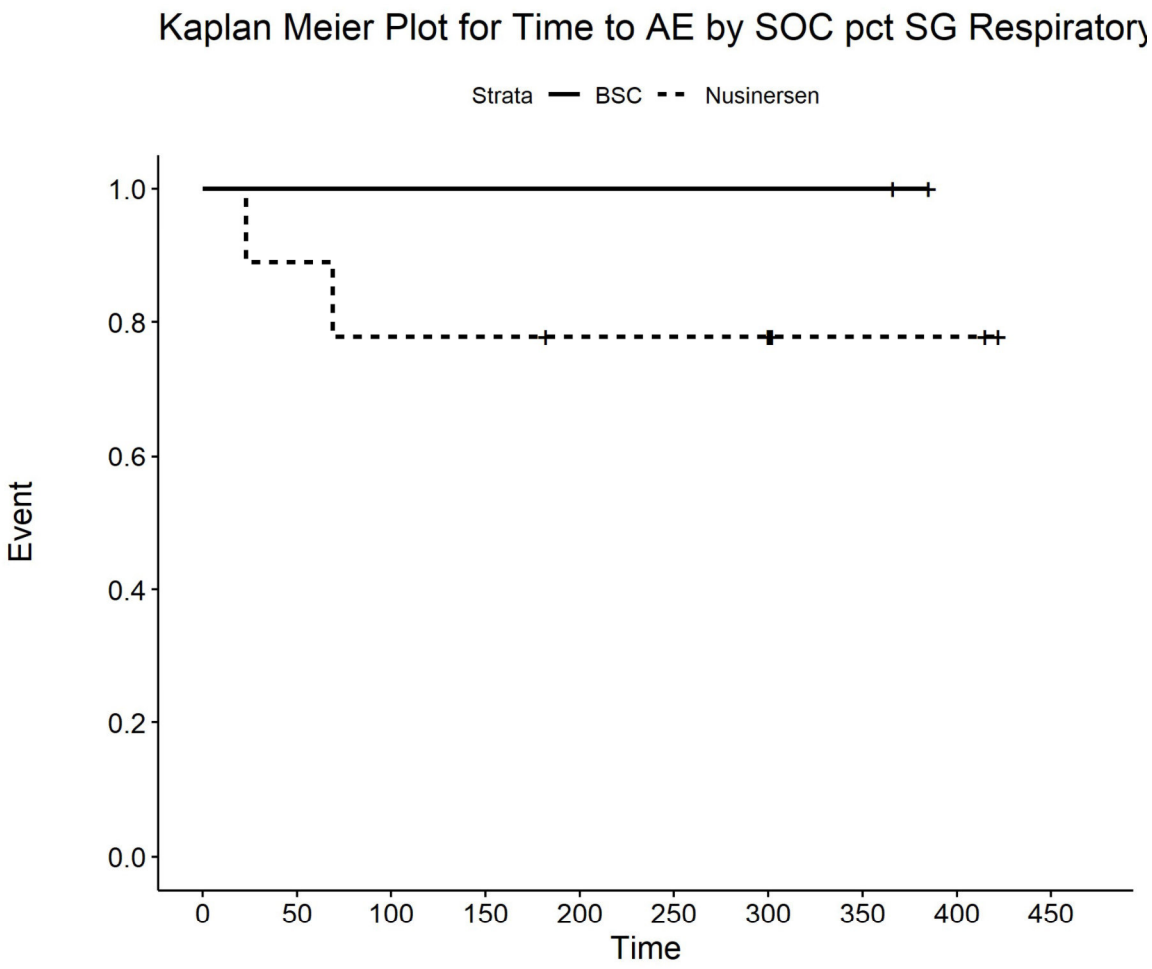
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	8	8	8	8	7	5	5	0



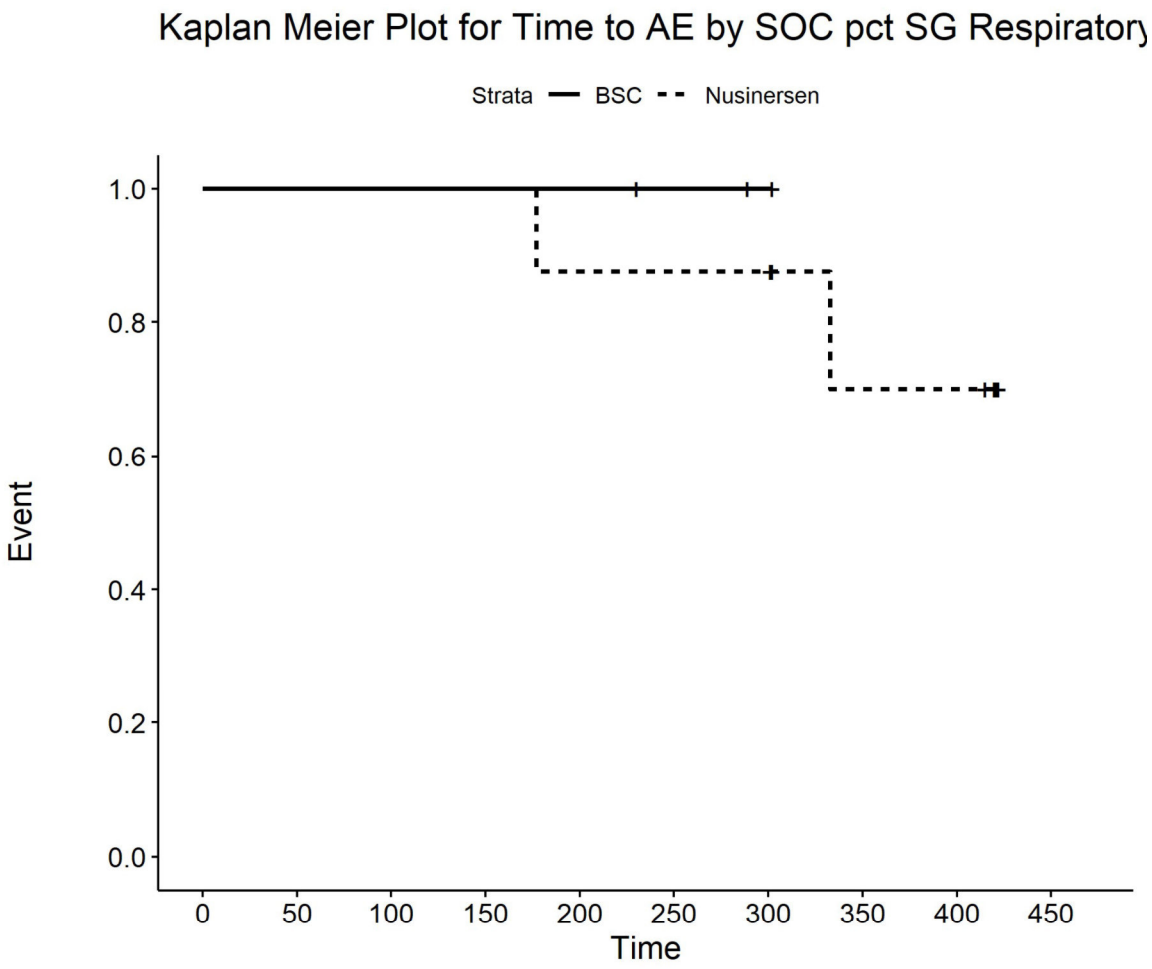
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



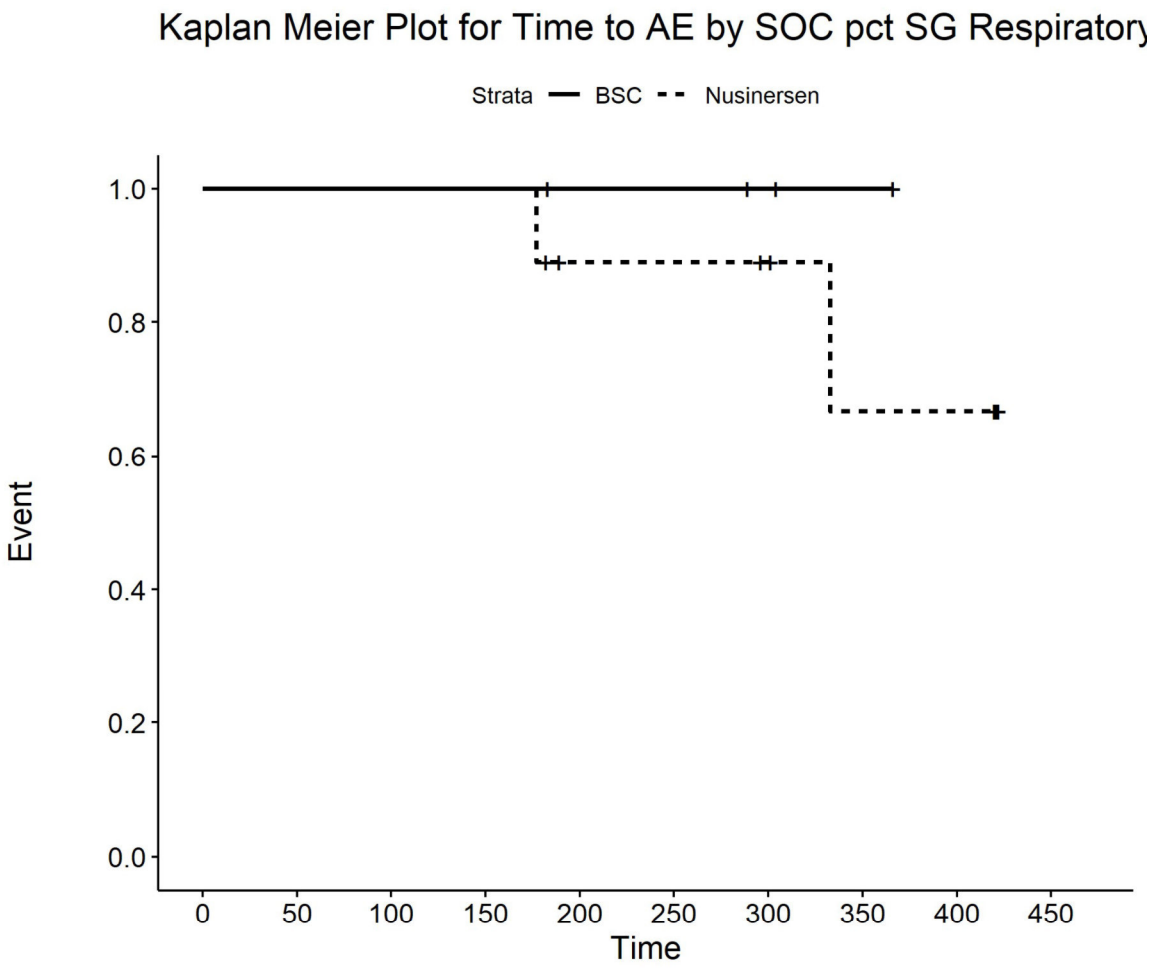
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	7	7	6	6	6	2	2	0



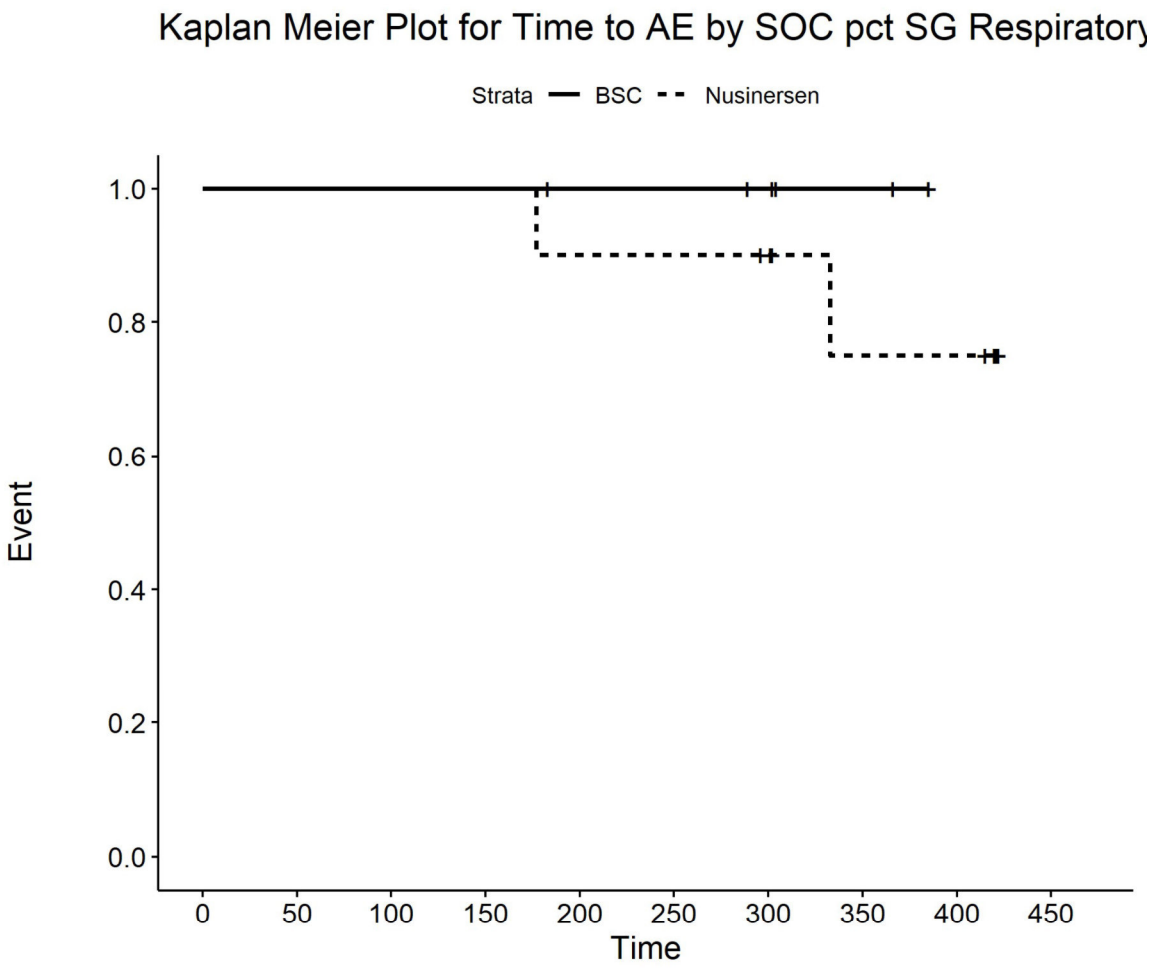
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	7	7	7	4	4	0



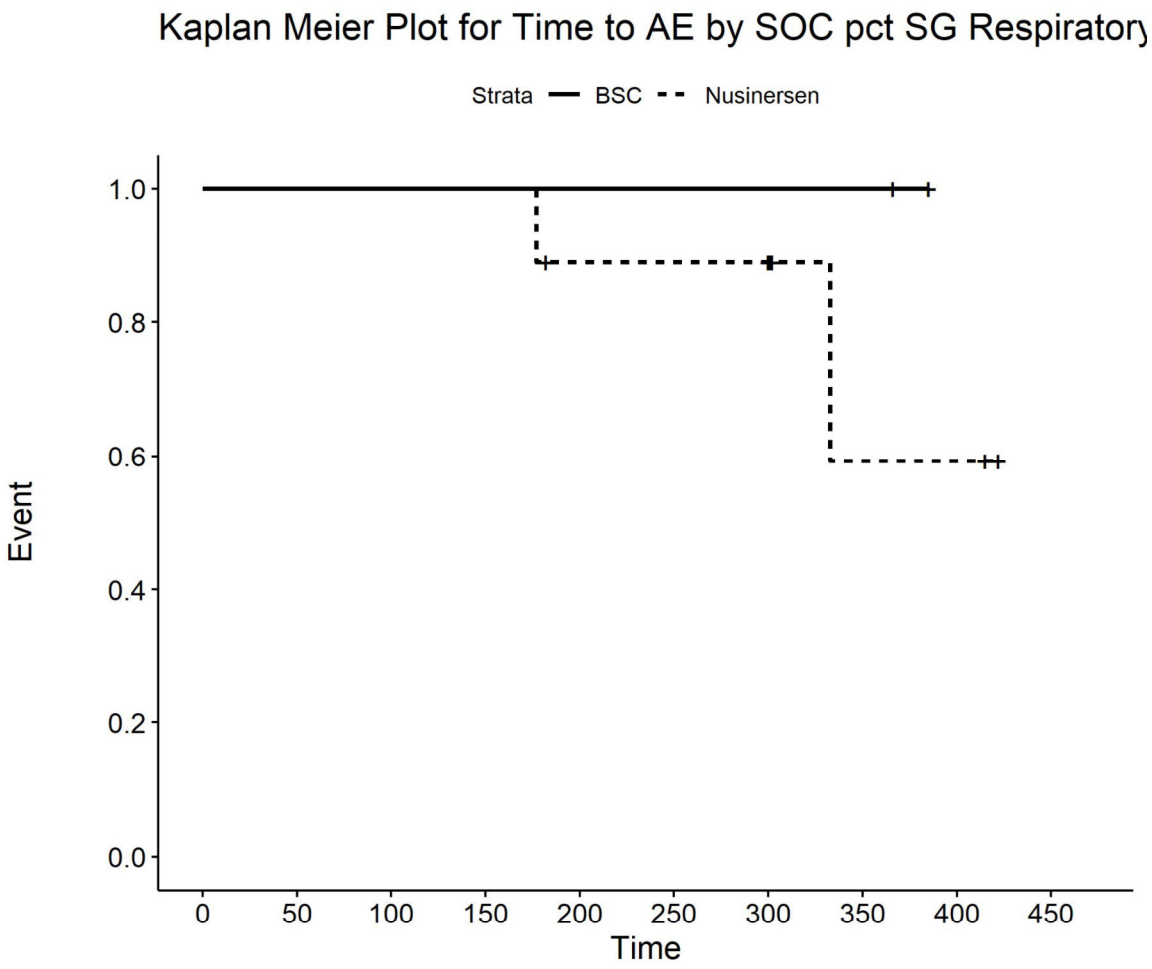
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	6	6	5	3	3	0



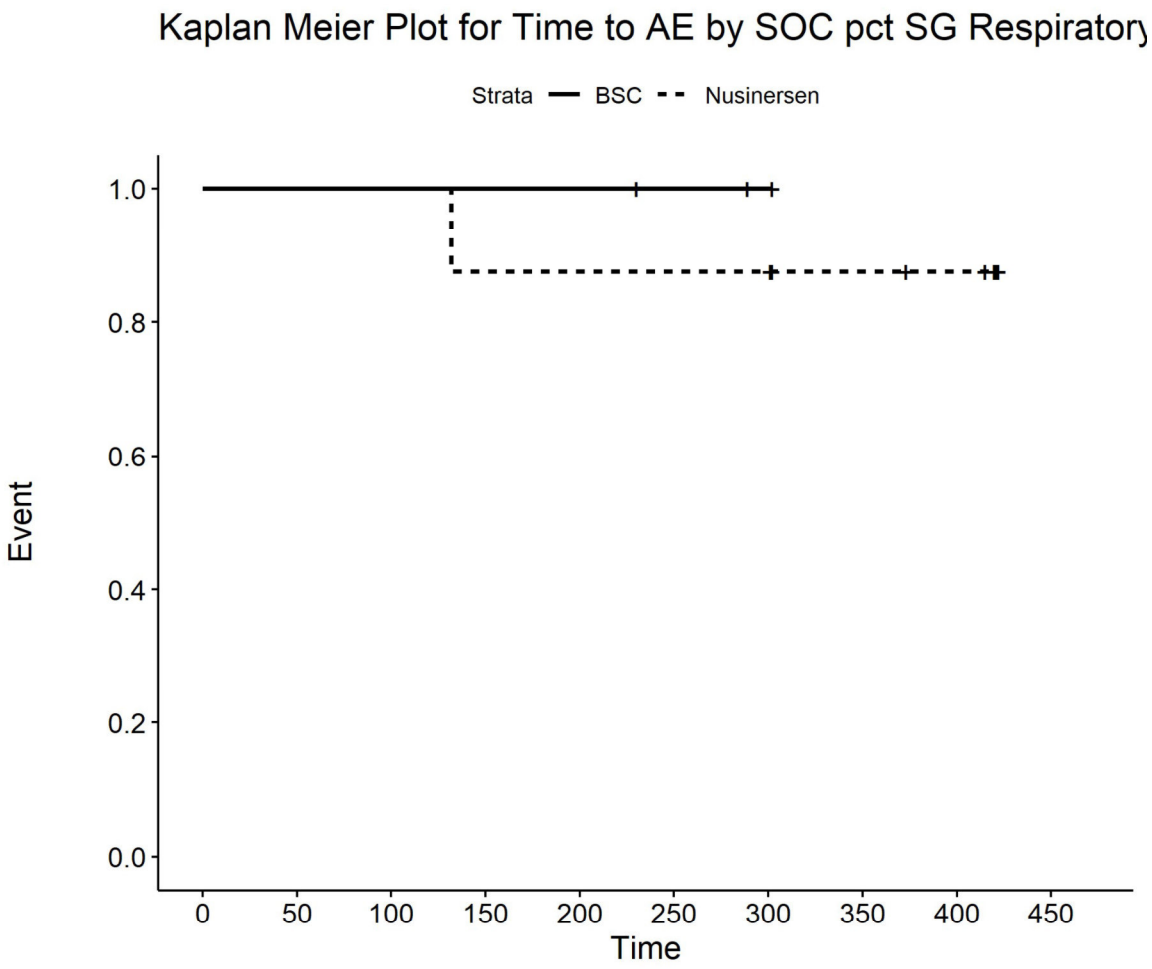
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	9	9	8	5	5	0



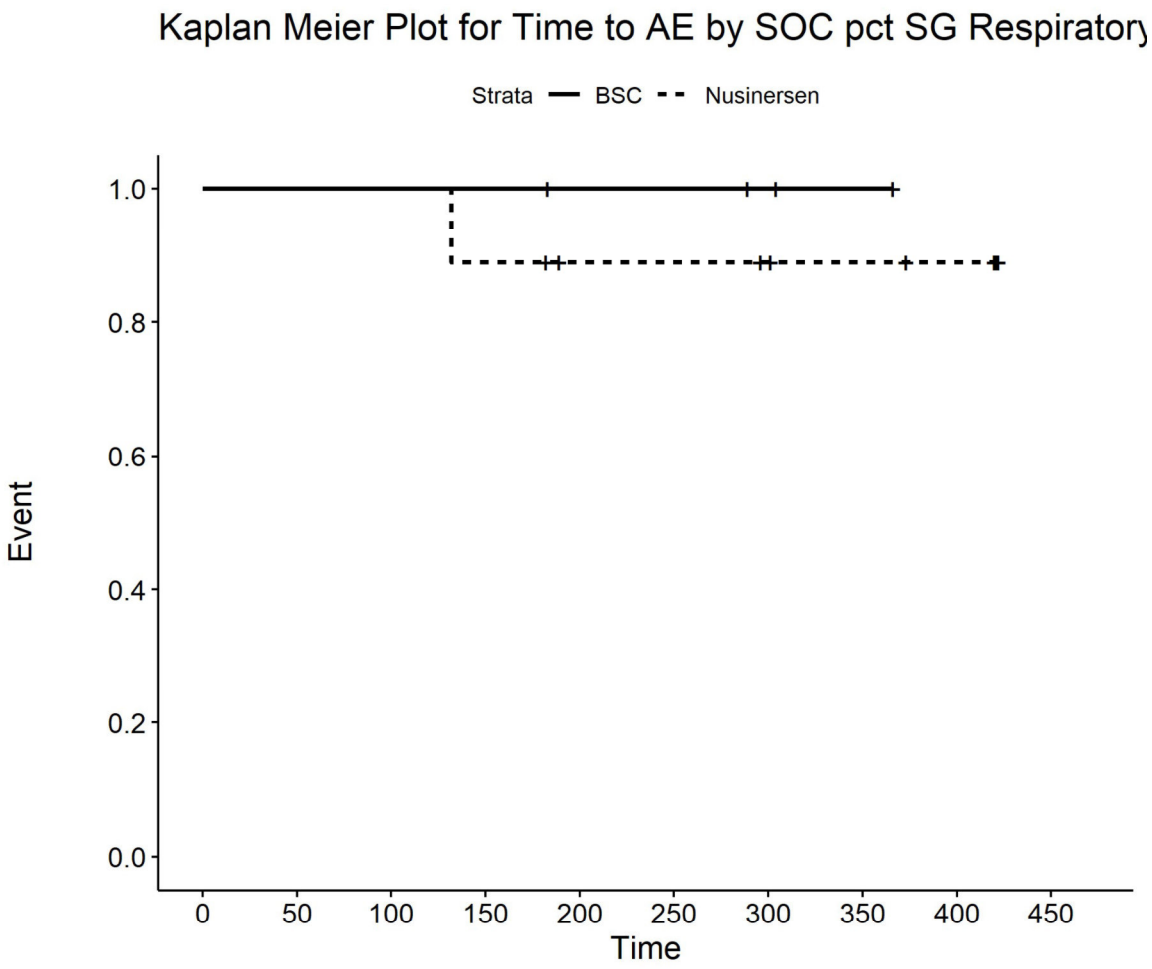
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	7	7	7	2	2	0



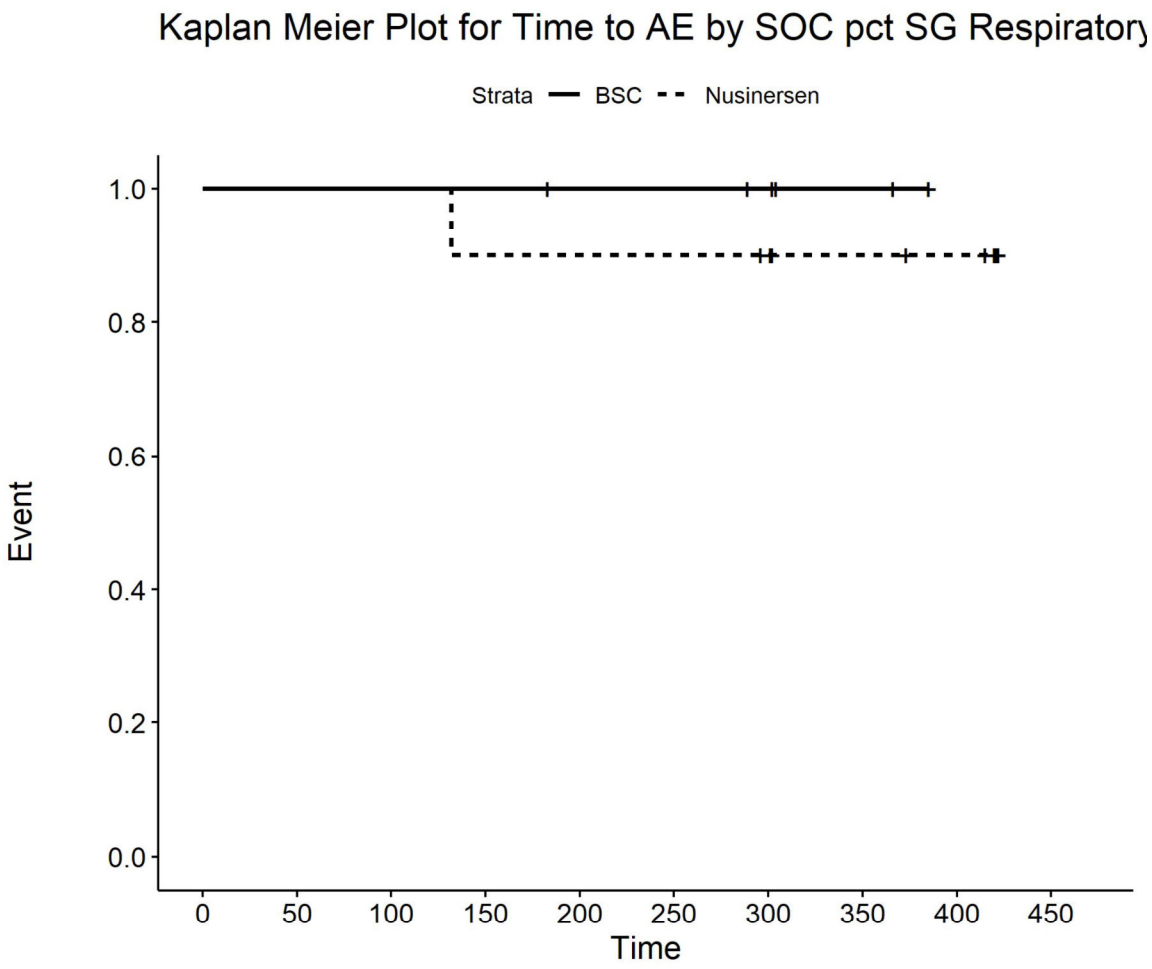
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



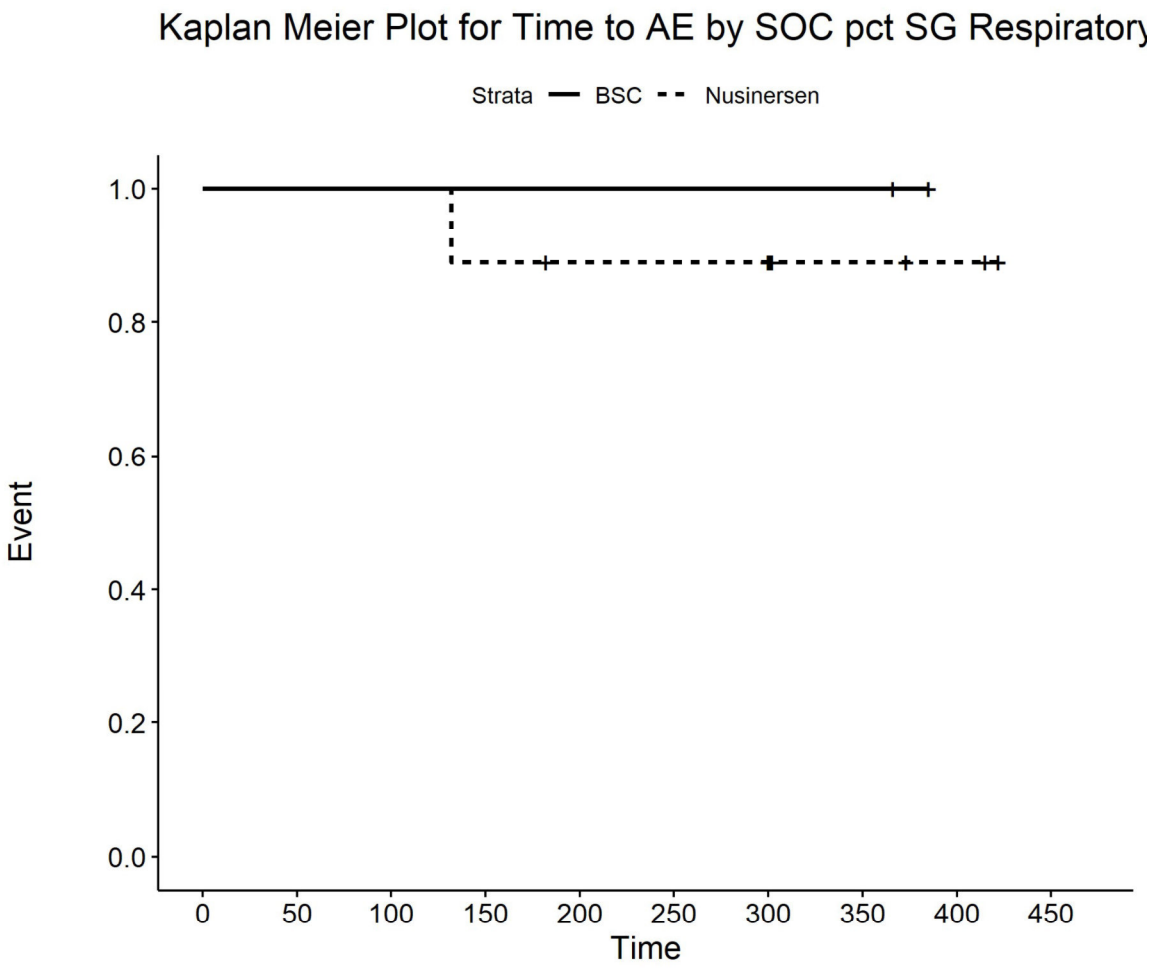
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



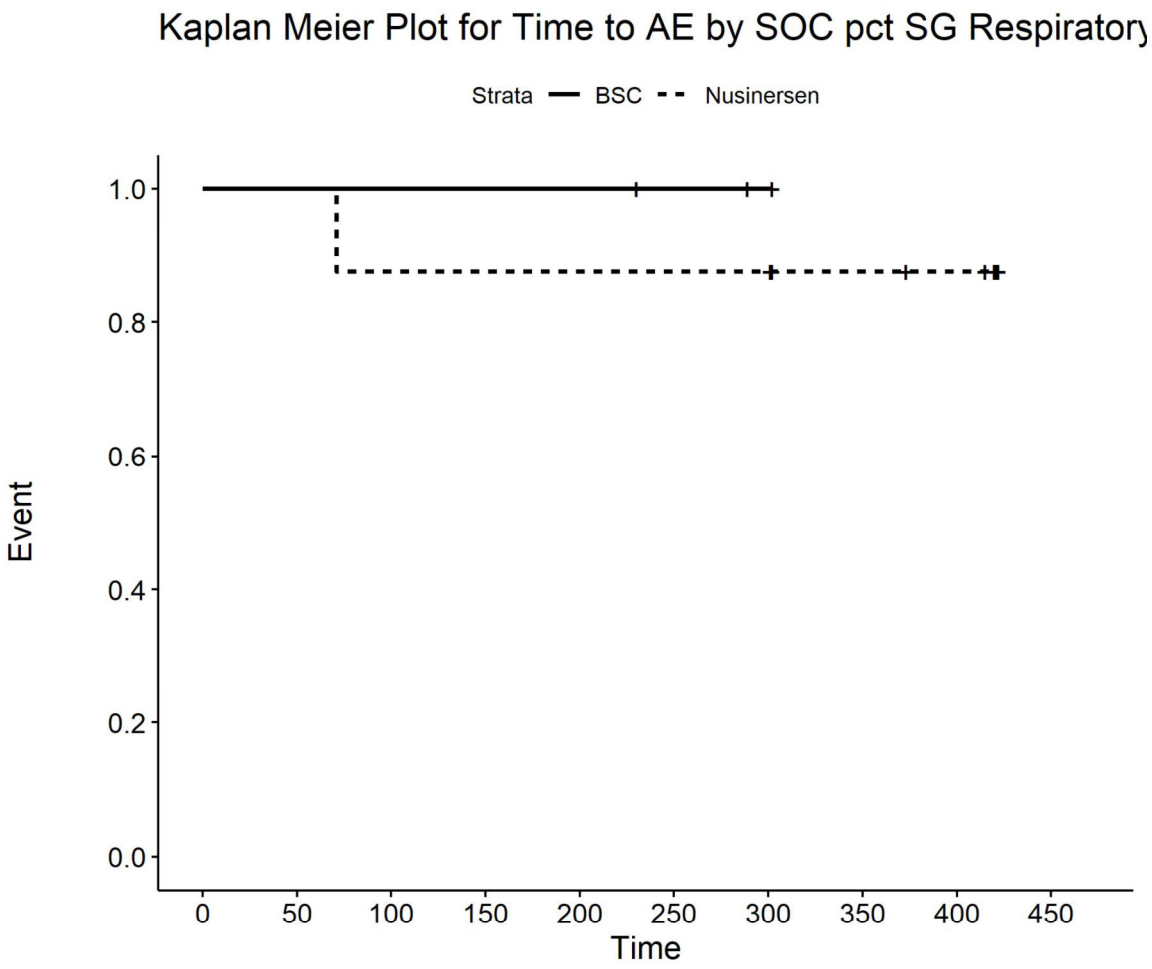
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



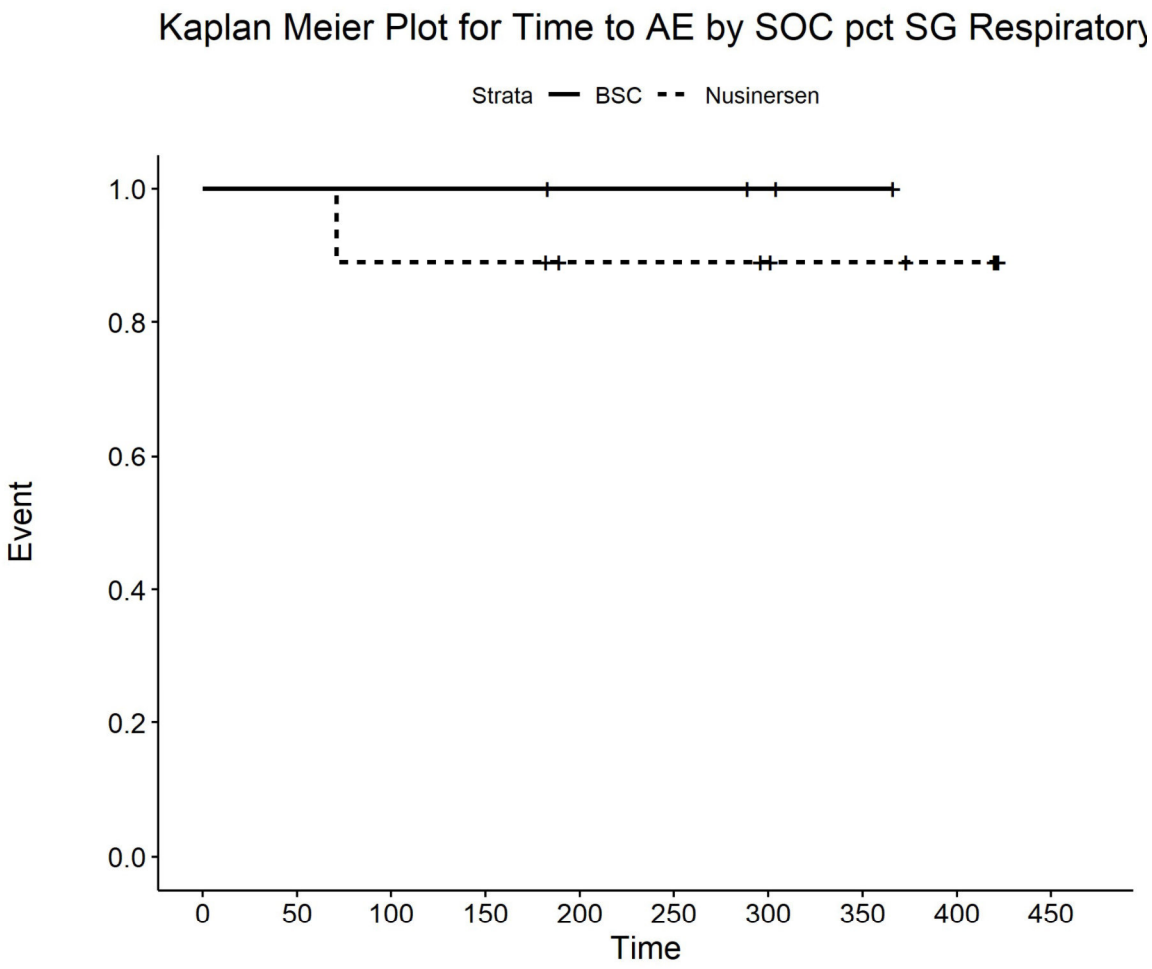
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



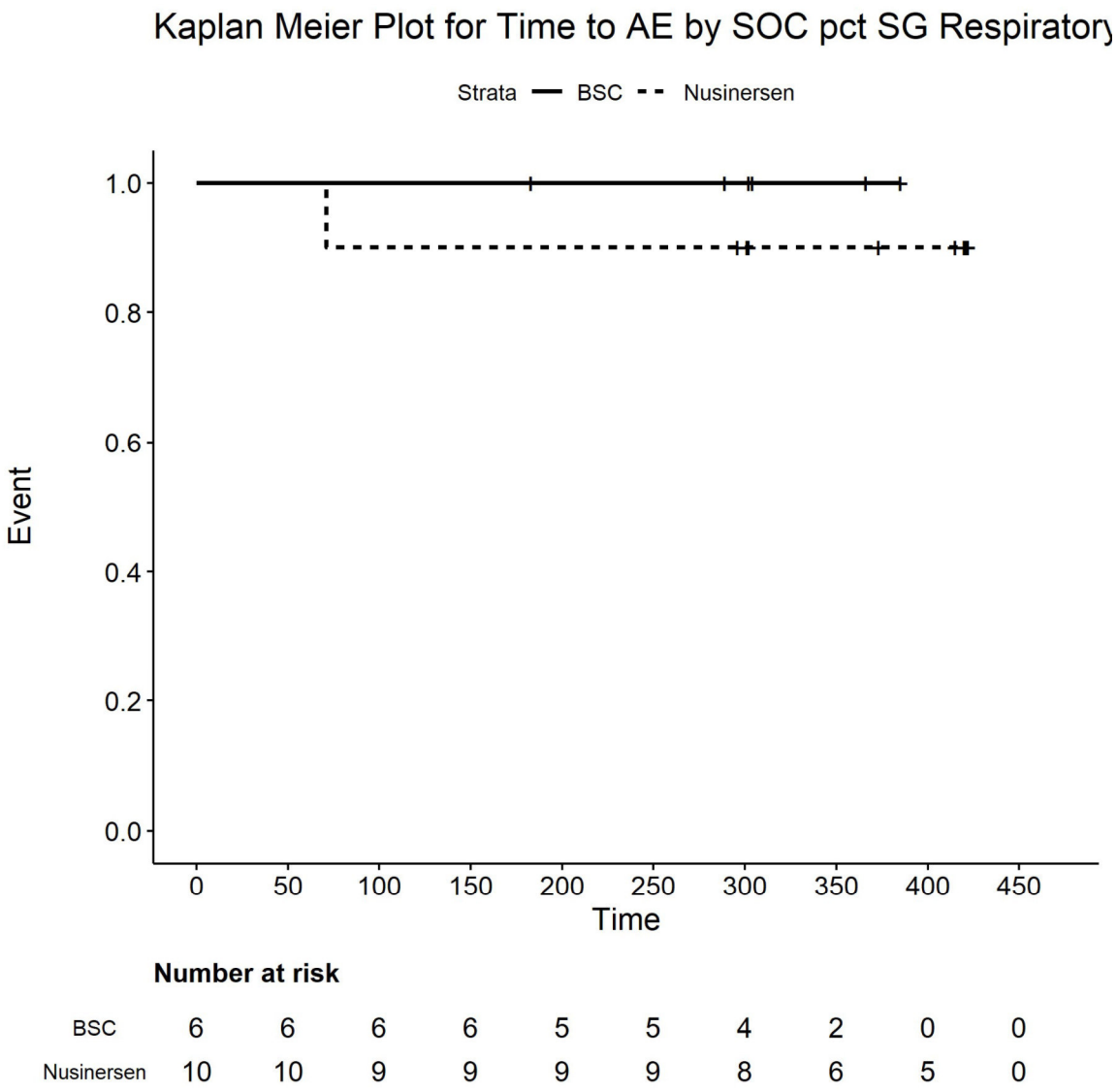
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	4	0



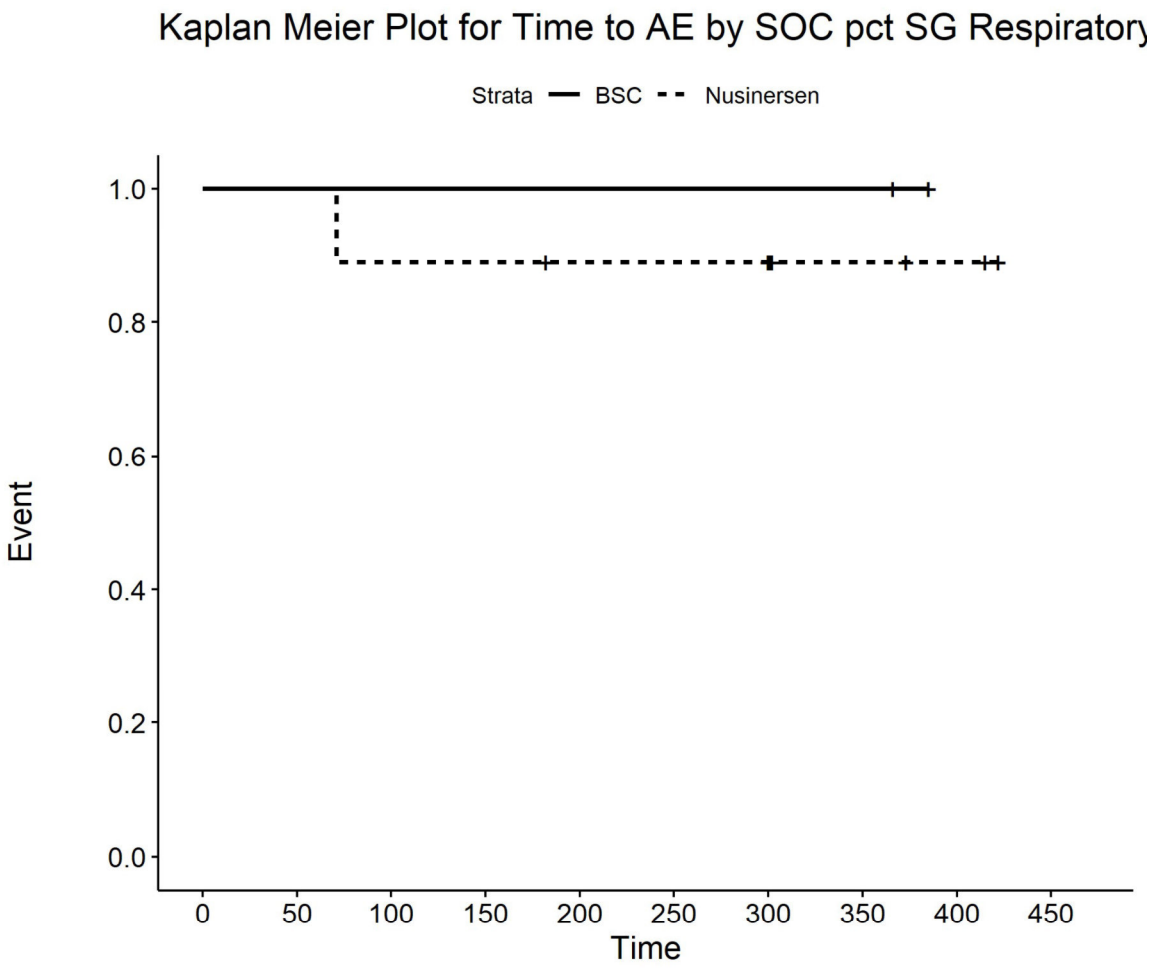
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



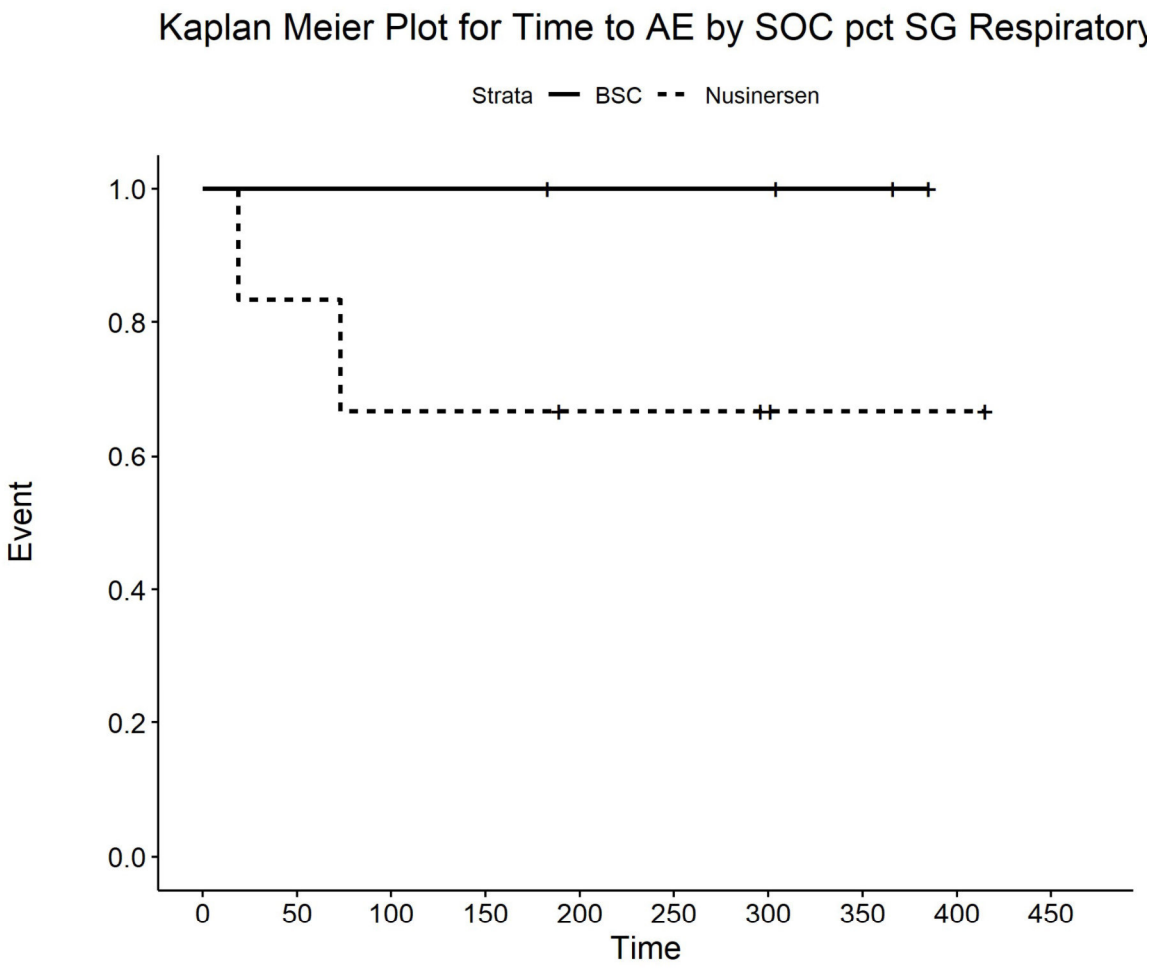
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



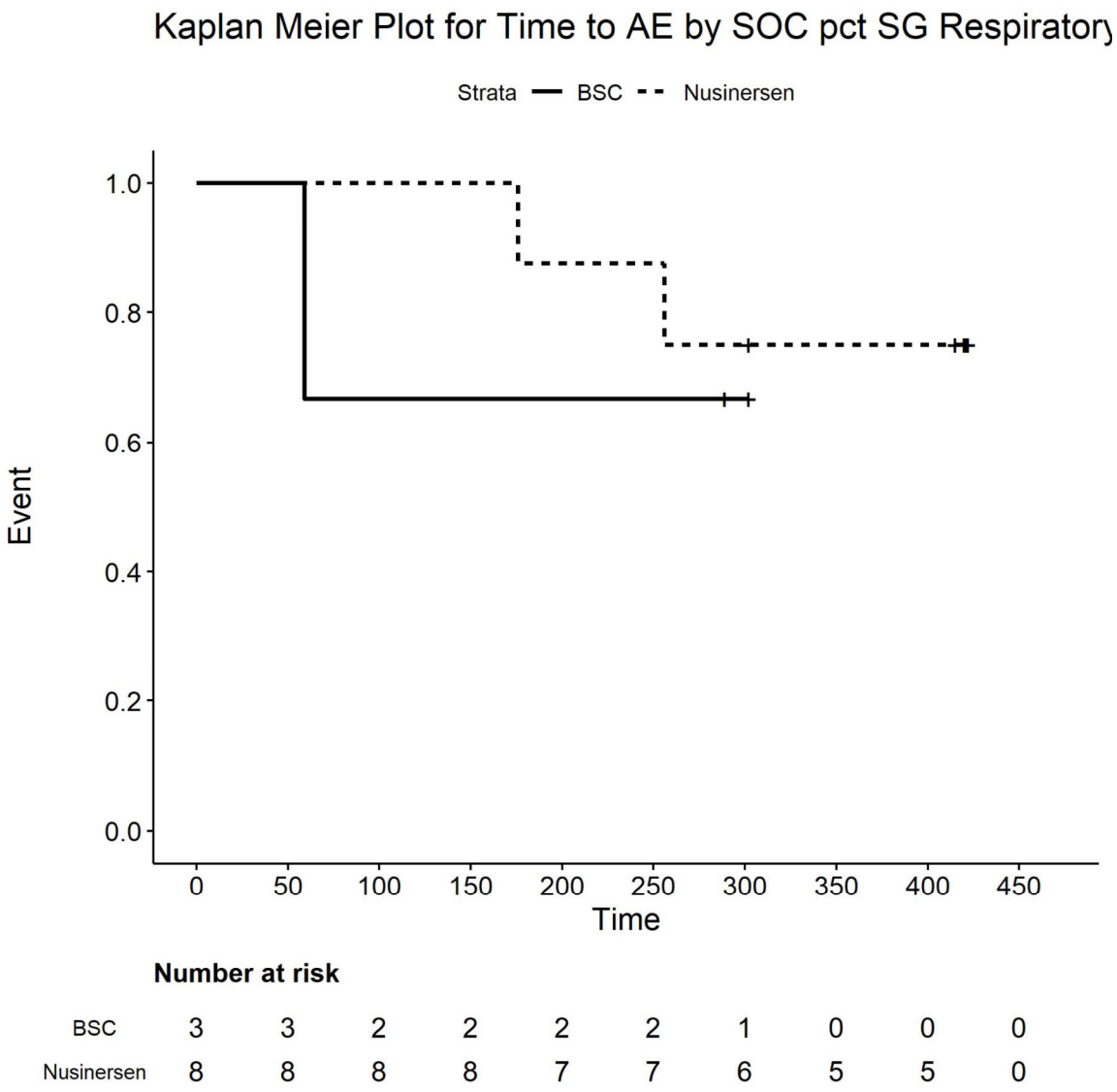
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	2	0



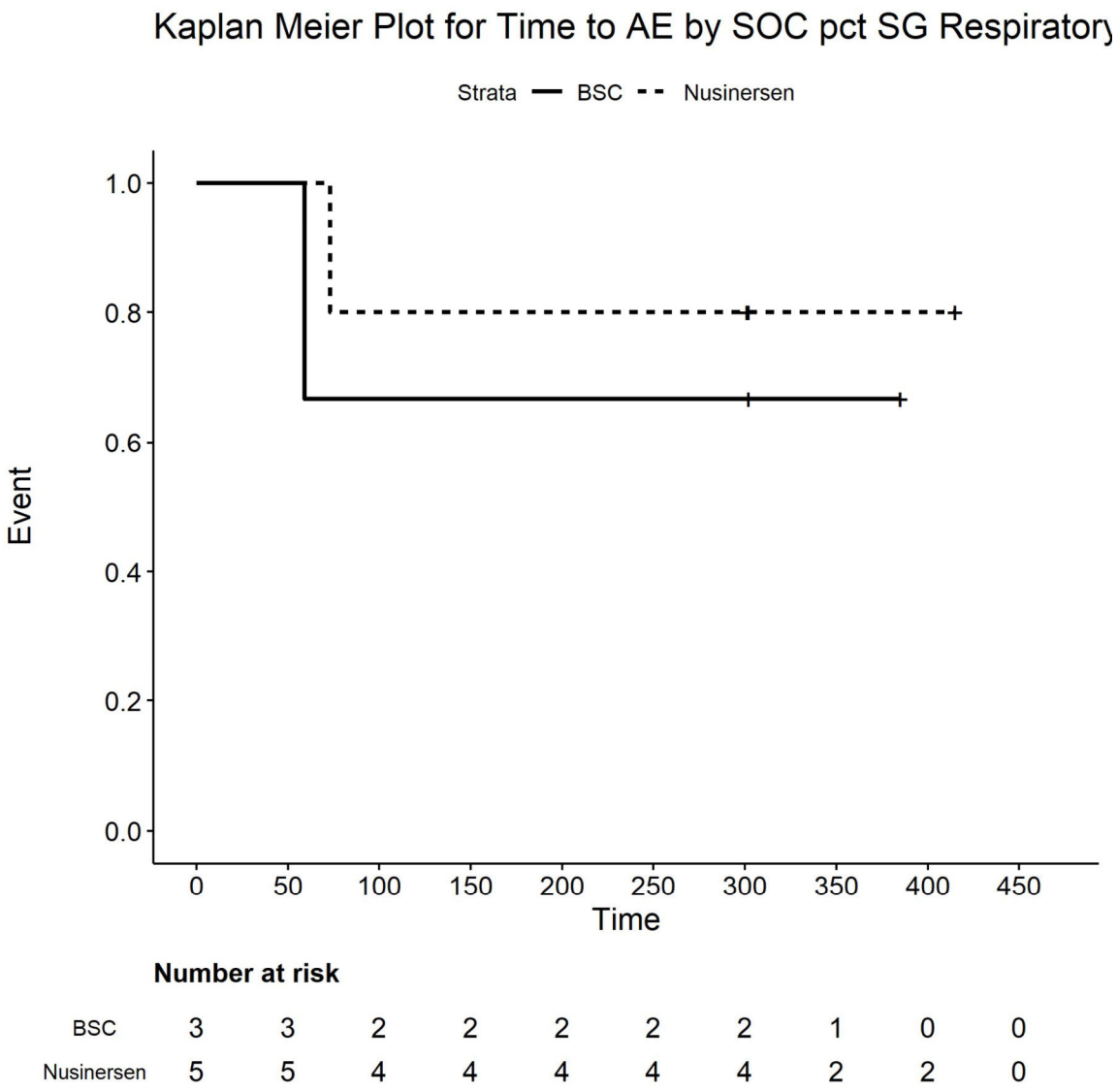
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	4	4	3	3	2	1	1	0



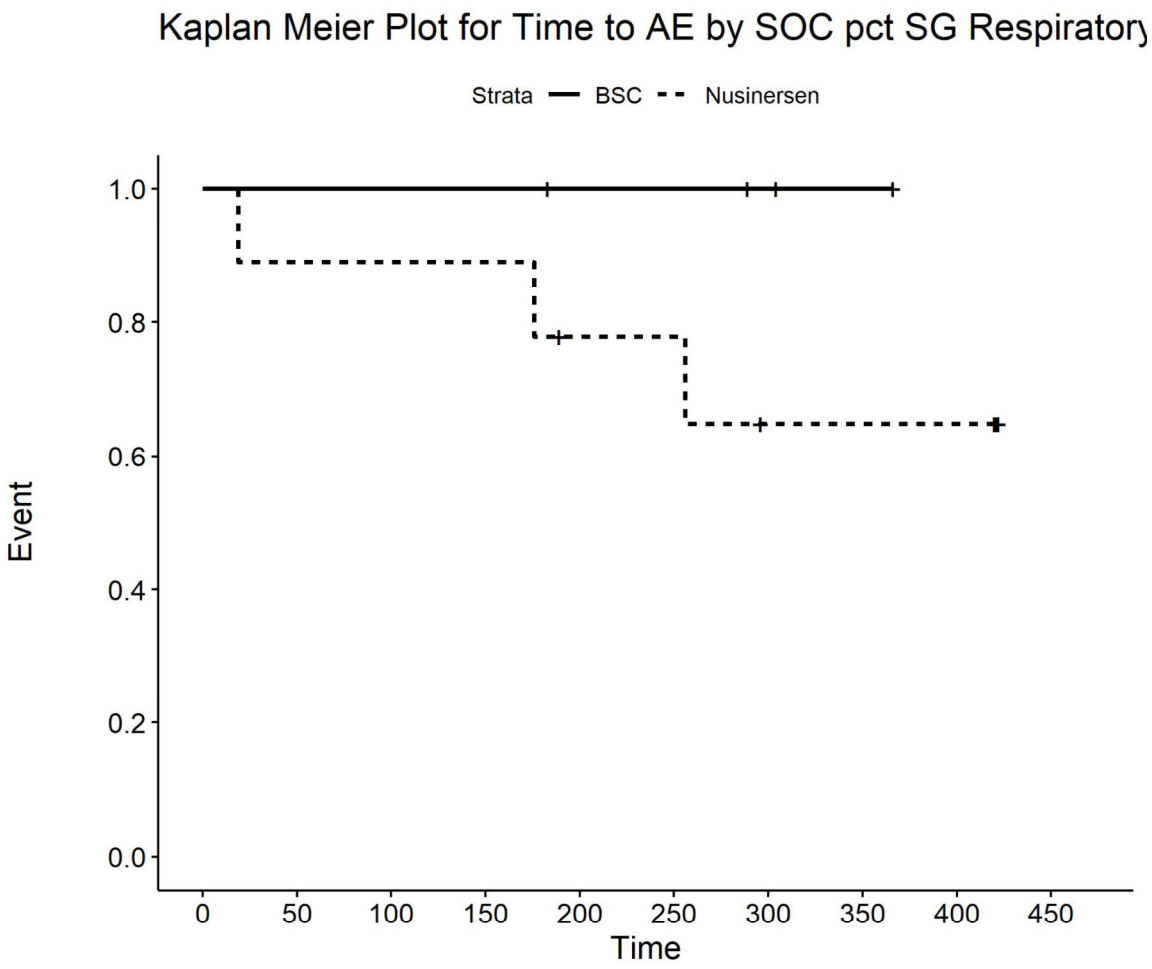
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	7	7	6	5	5	0



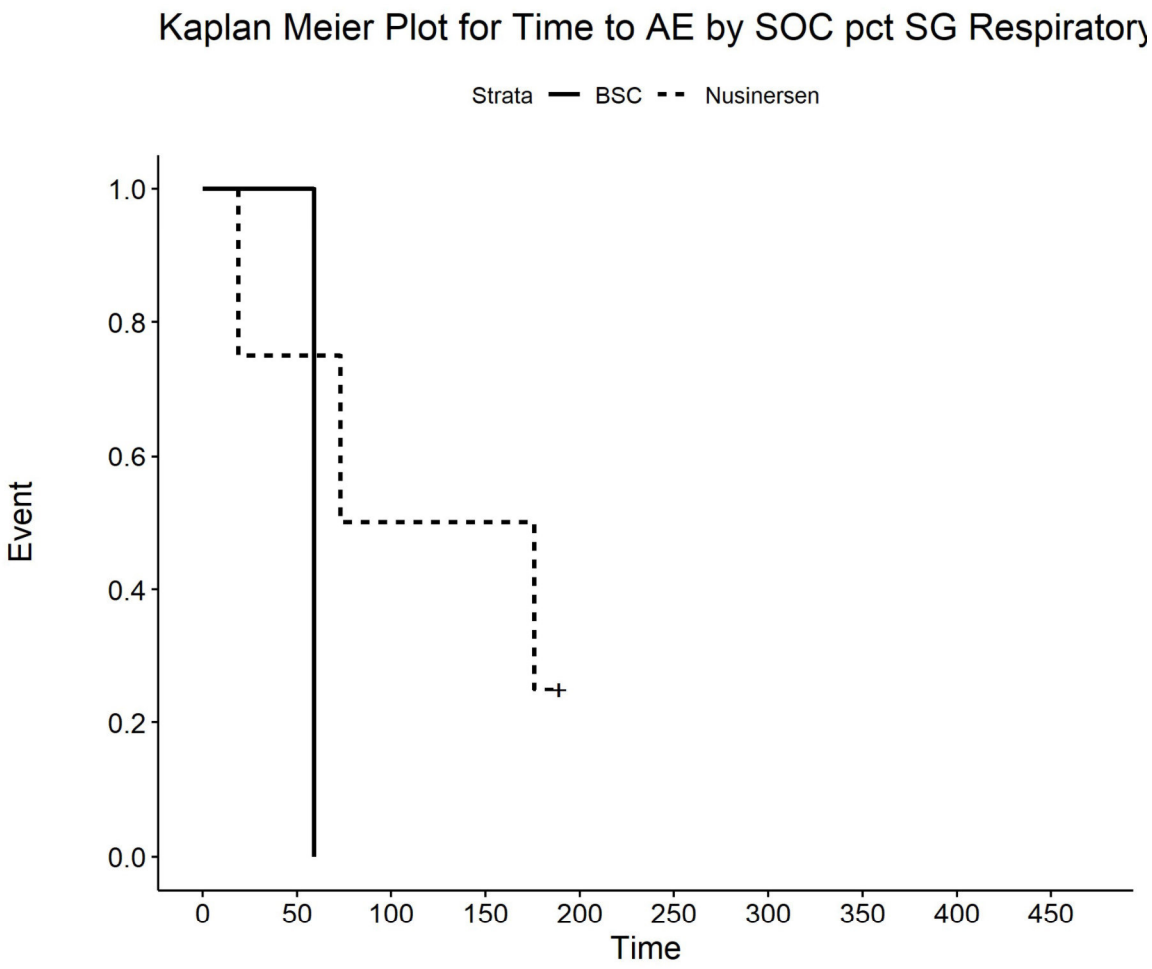
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



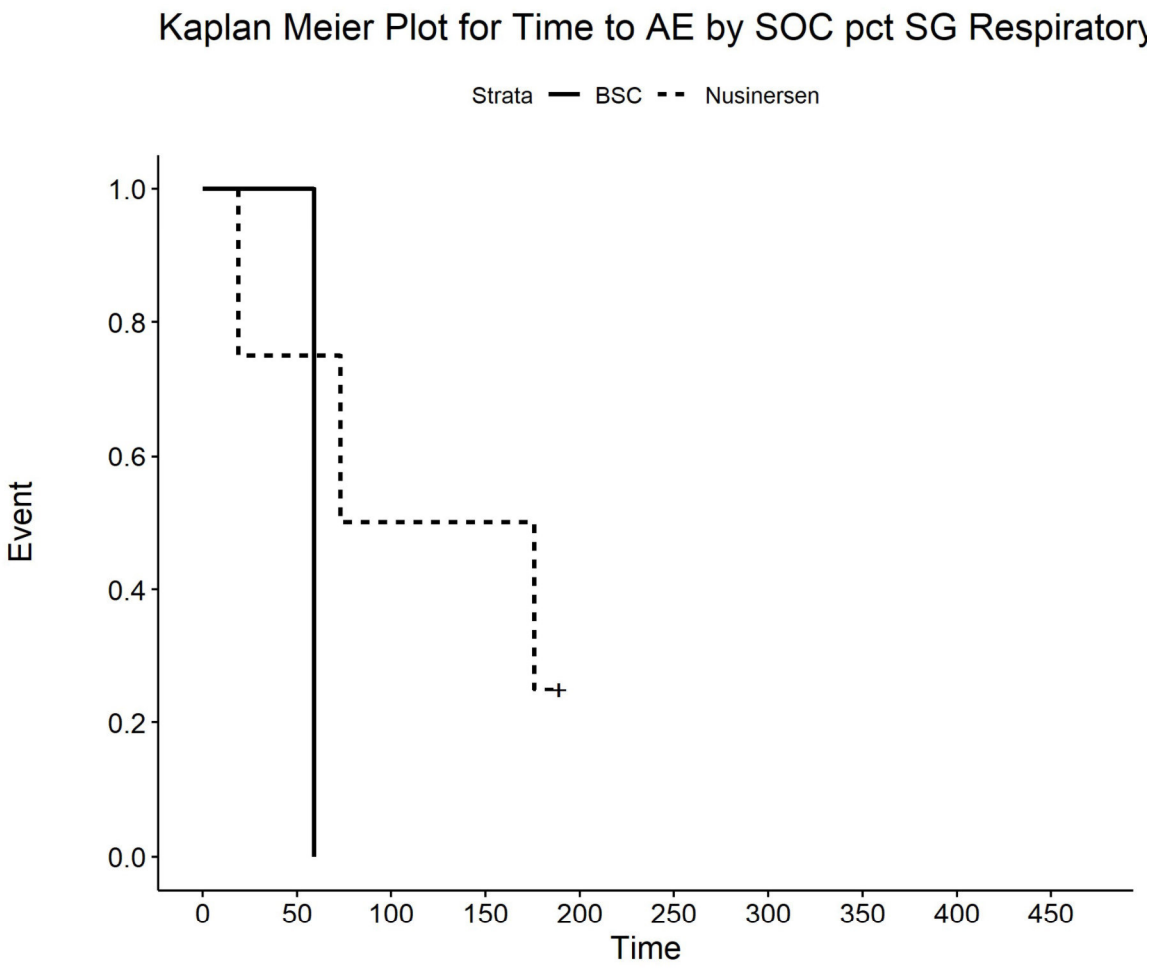
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	4	4	4	0



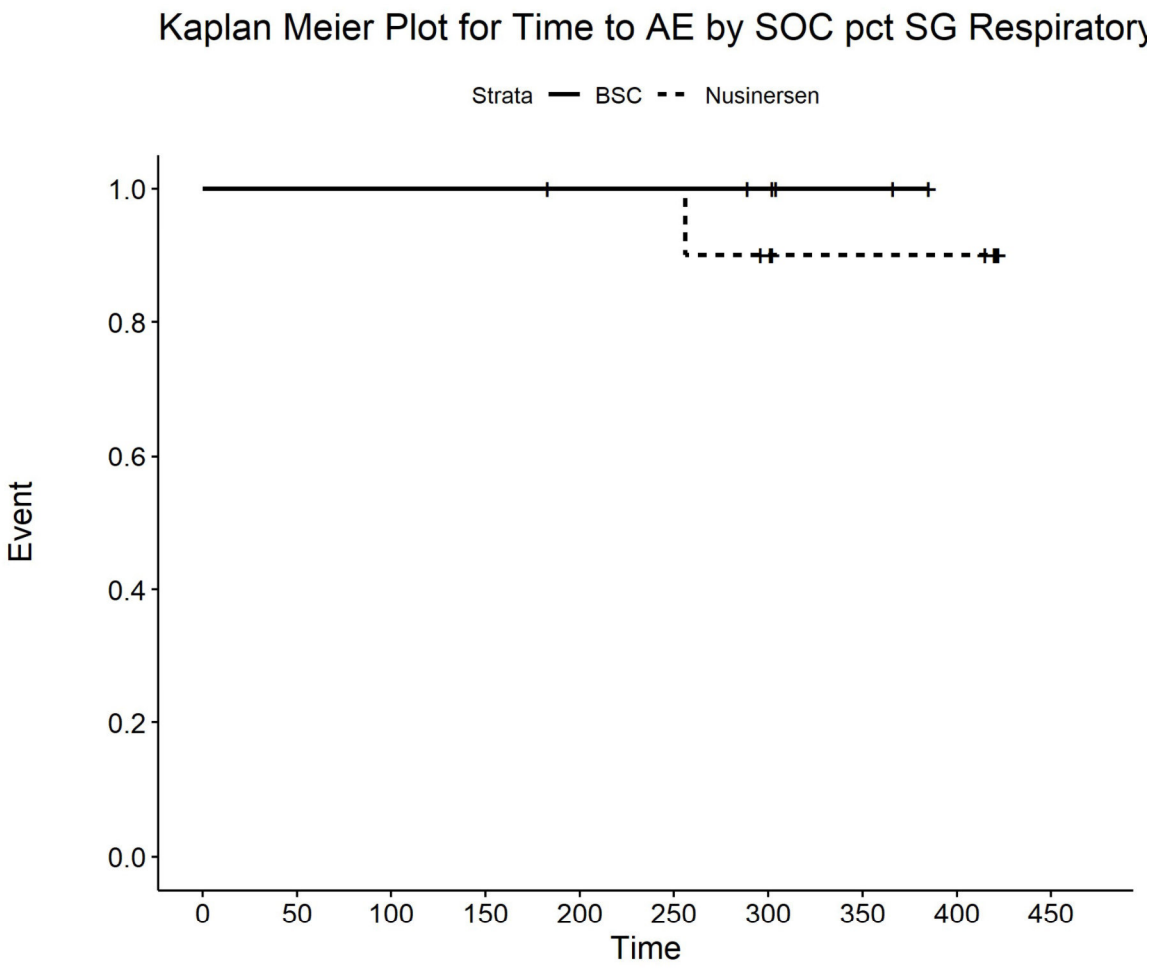
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	3	2	2	0	0	0	0	0	0



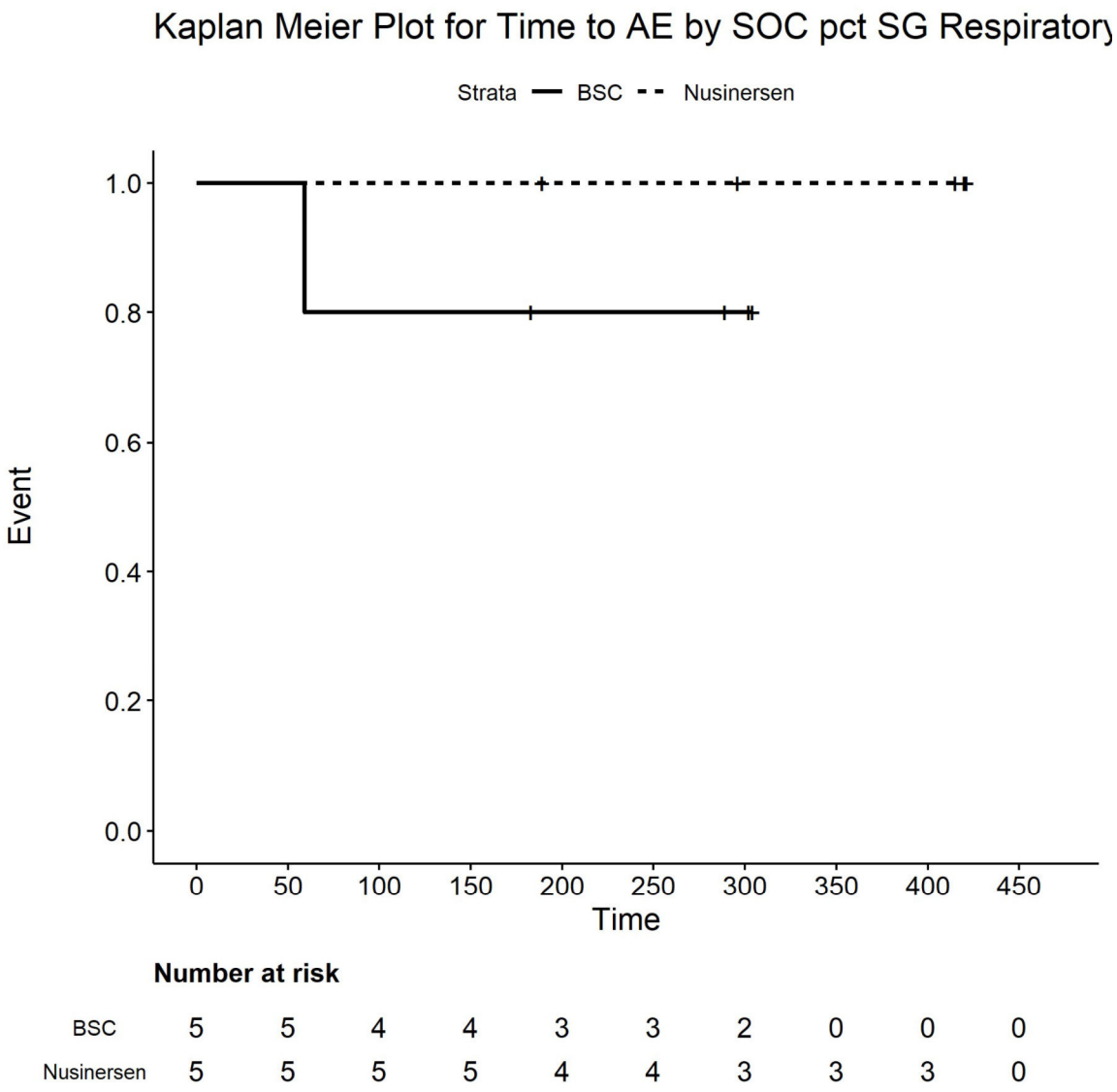
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	3	2	2	0	0	0	0	0	0



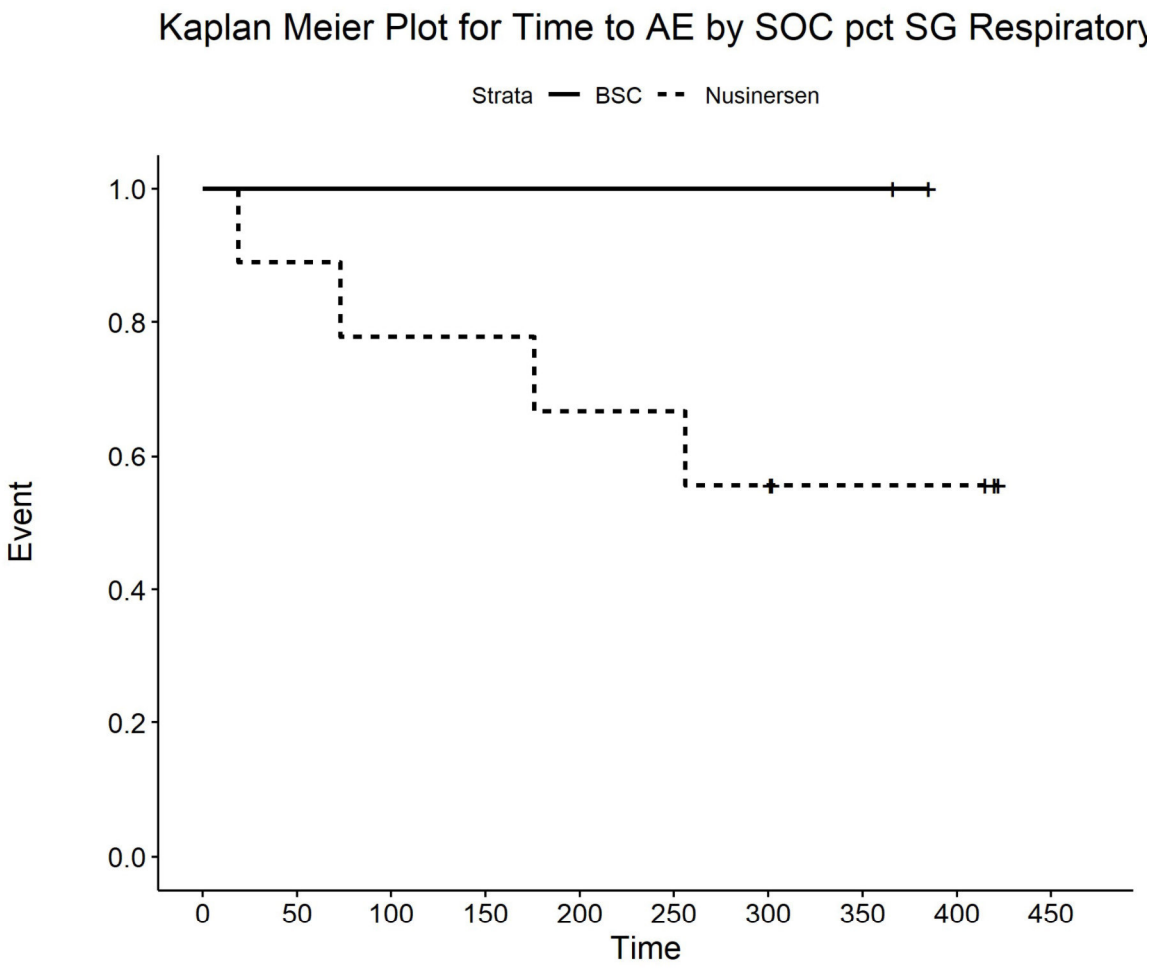
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	8	6	6	0



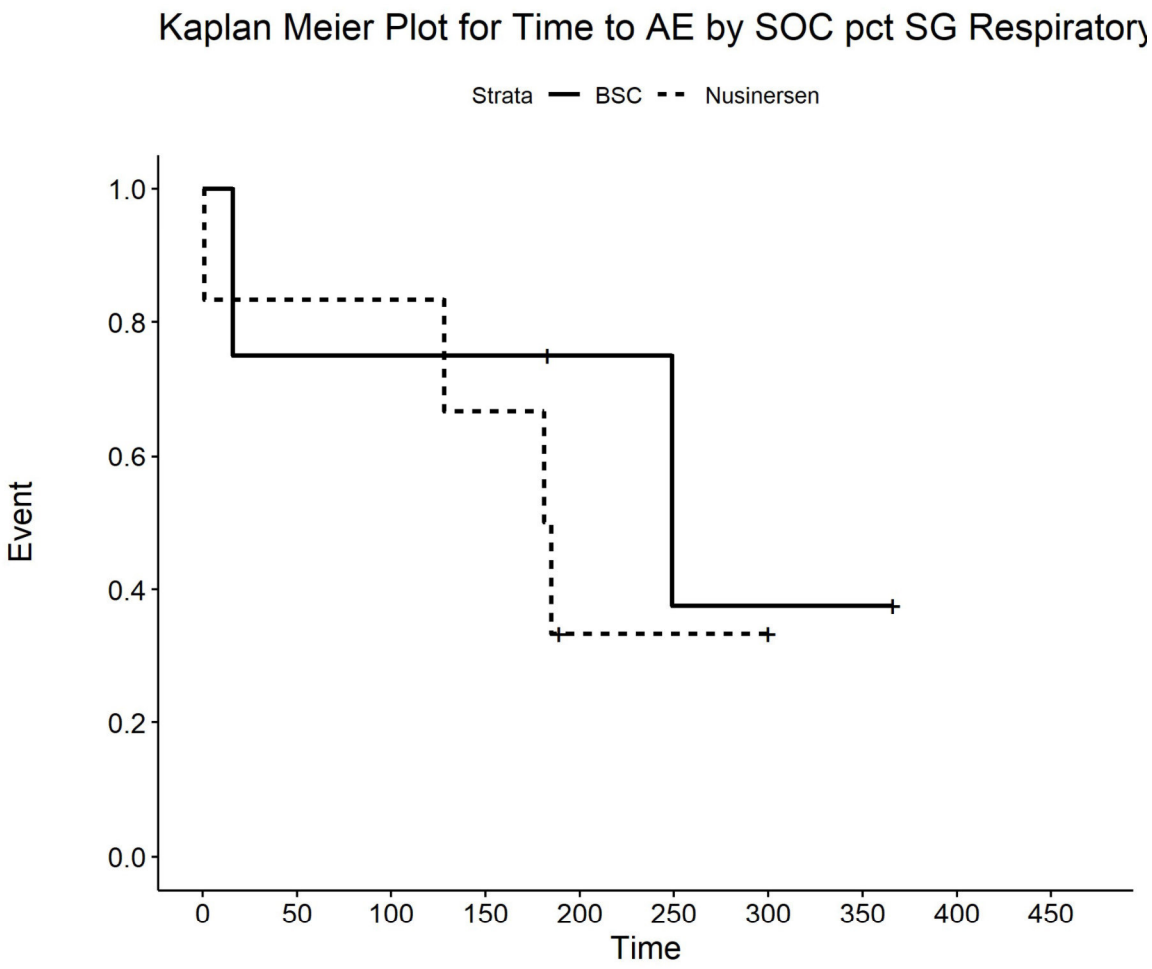
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



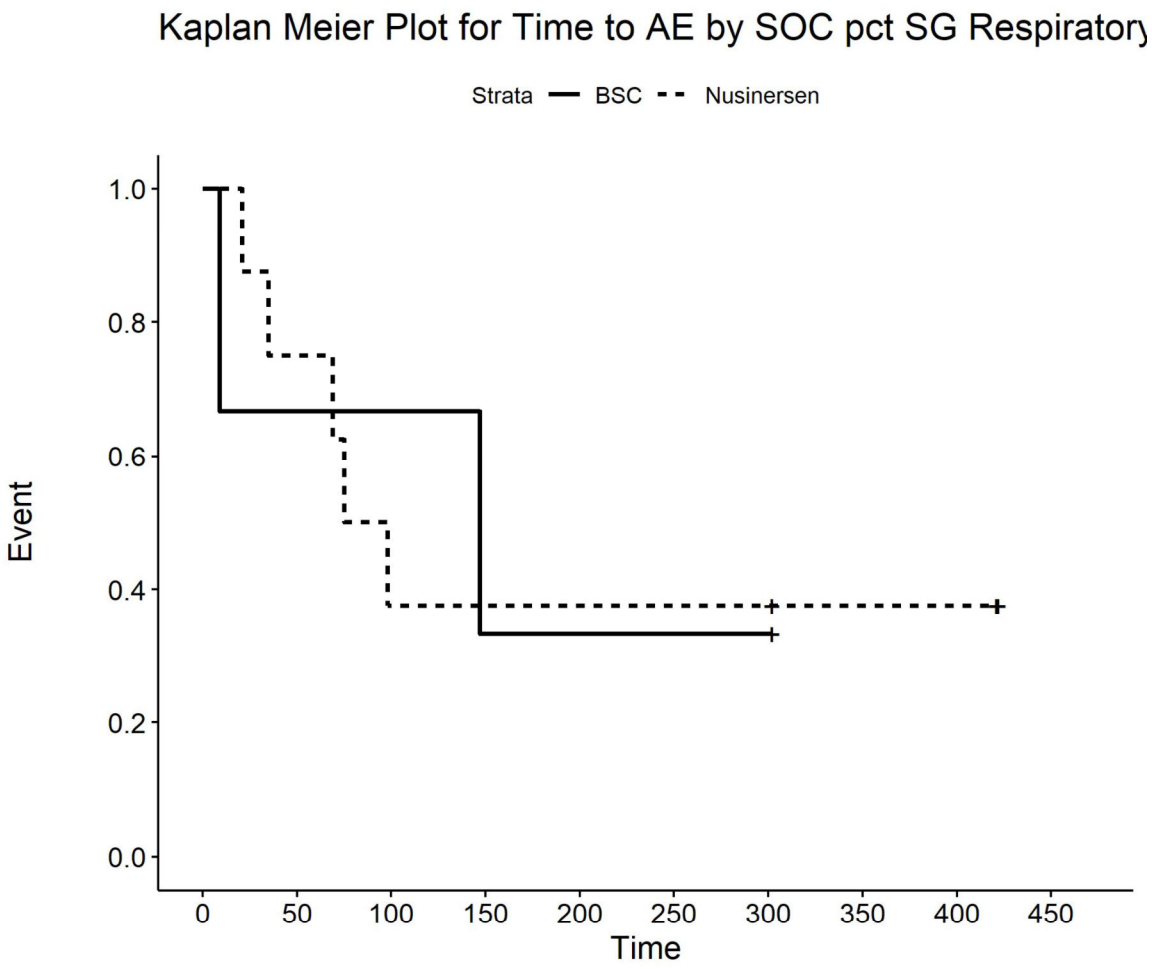
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	7	7	6	6	5	3	3	0



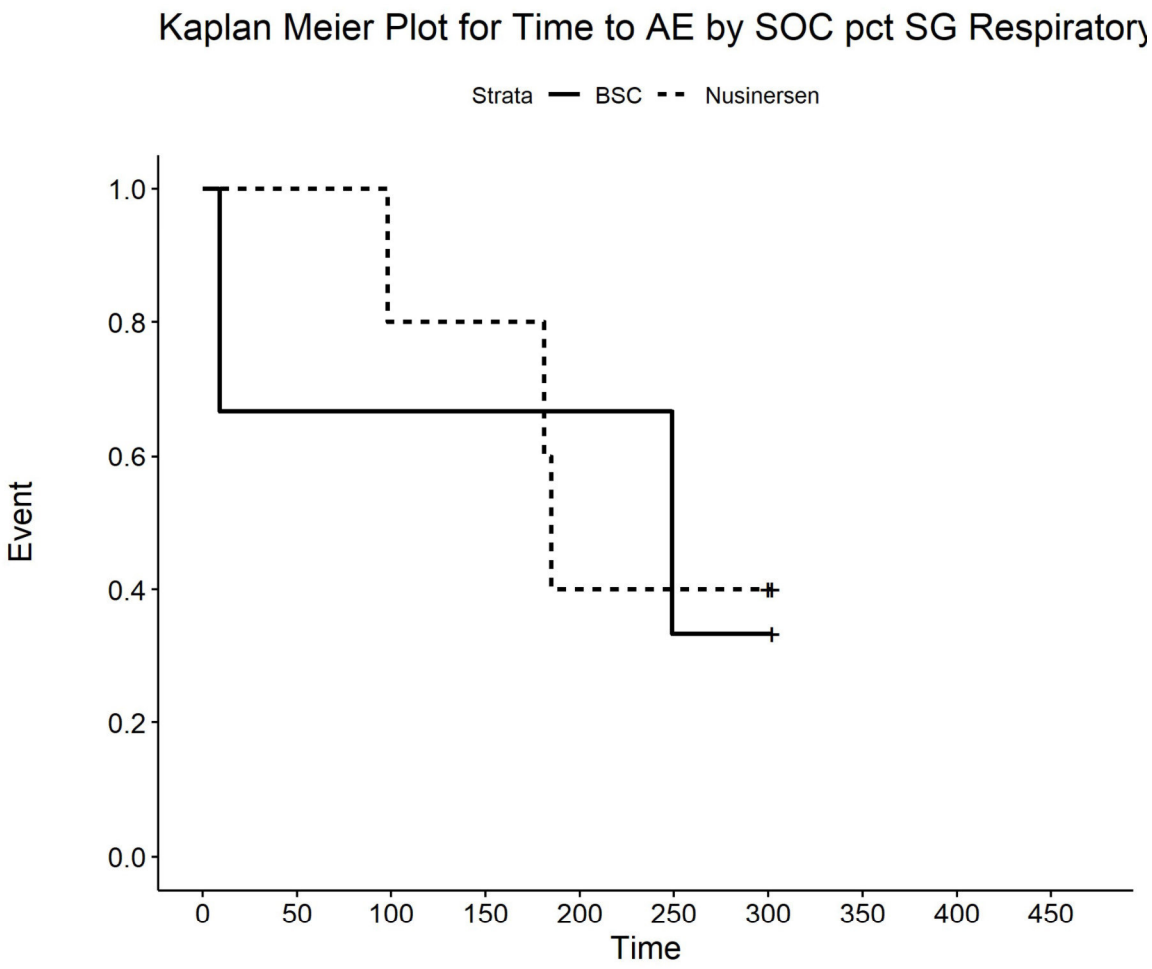
Number at risk

BSC	4	3	3	3	2	1	1	1	0	0
Nusinersen	6	5	5	4	1	1	1	0	0	0



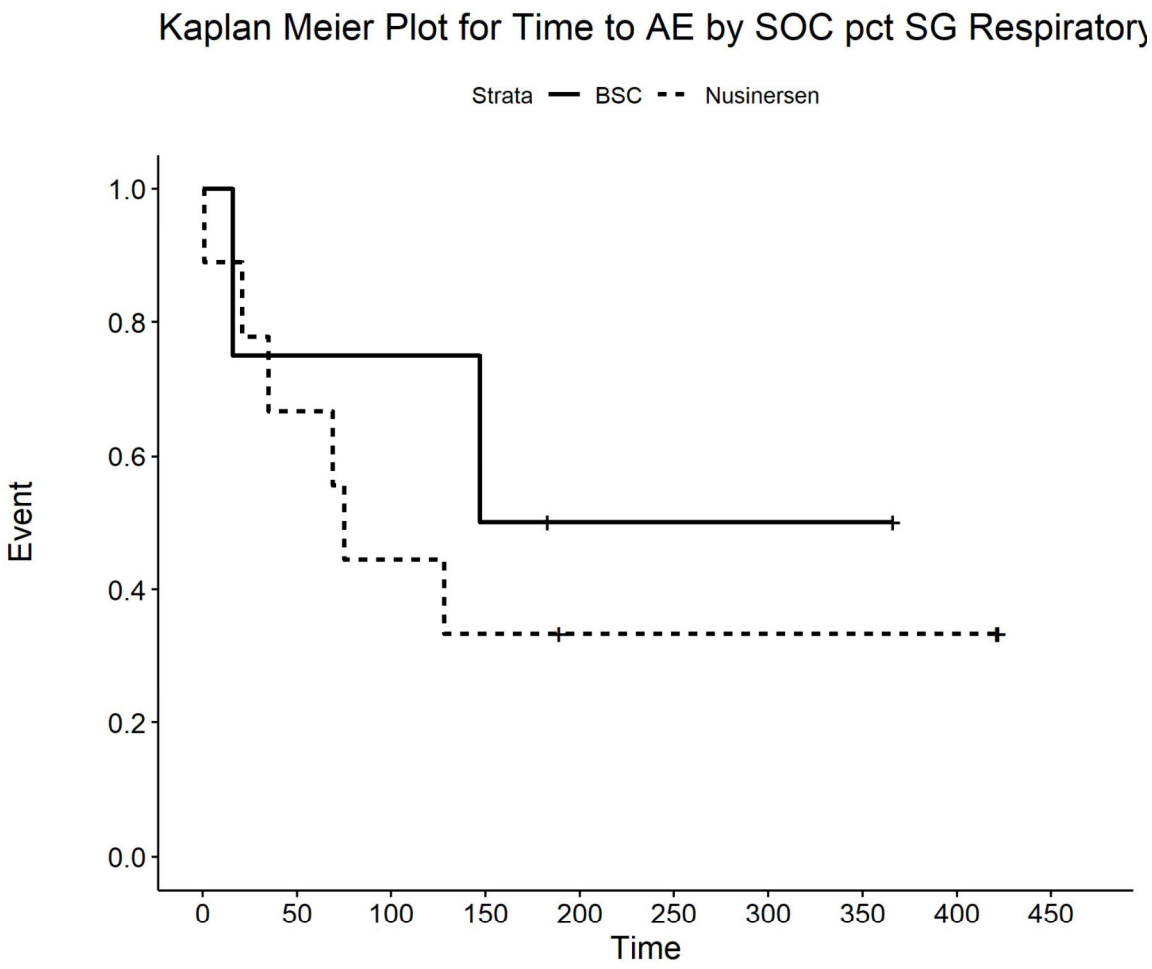
Number at risk

BSC	3	2	2	1	1	1	1	0	0	0
Nusinersen	8	6	3	3	3	3	3	2	2	0



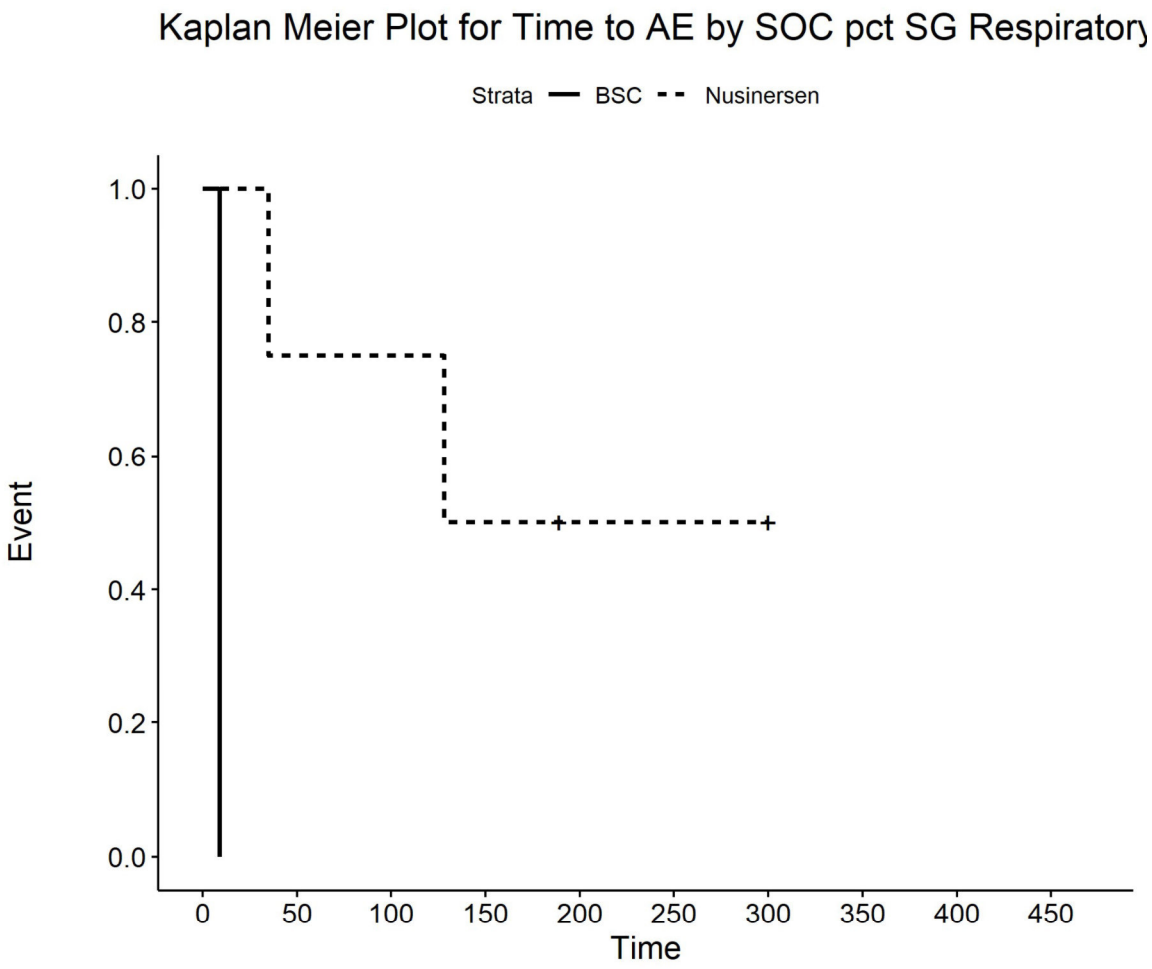
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	5	5	4	4	2	2	2	0	0	0



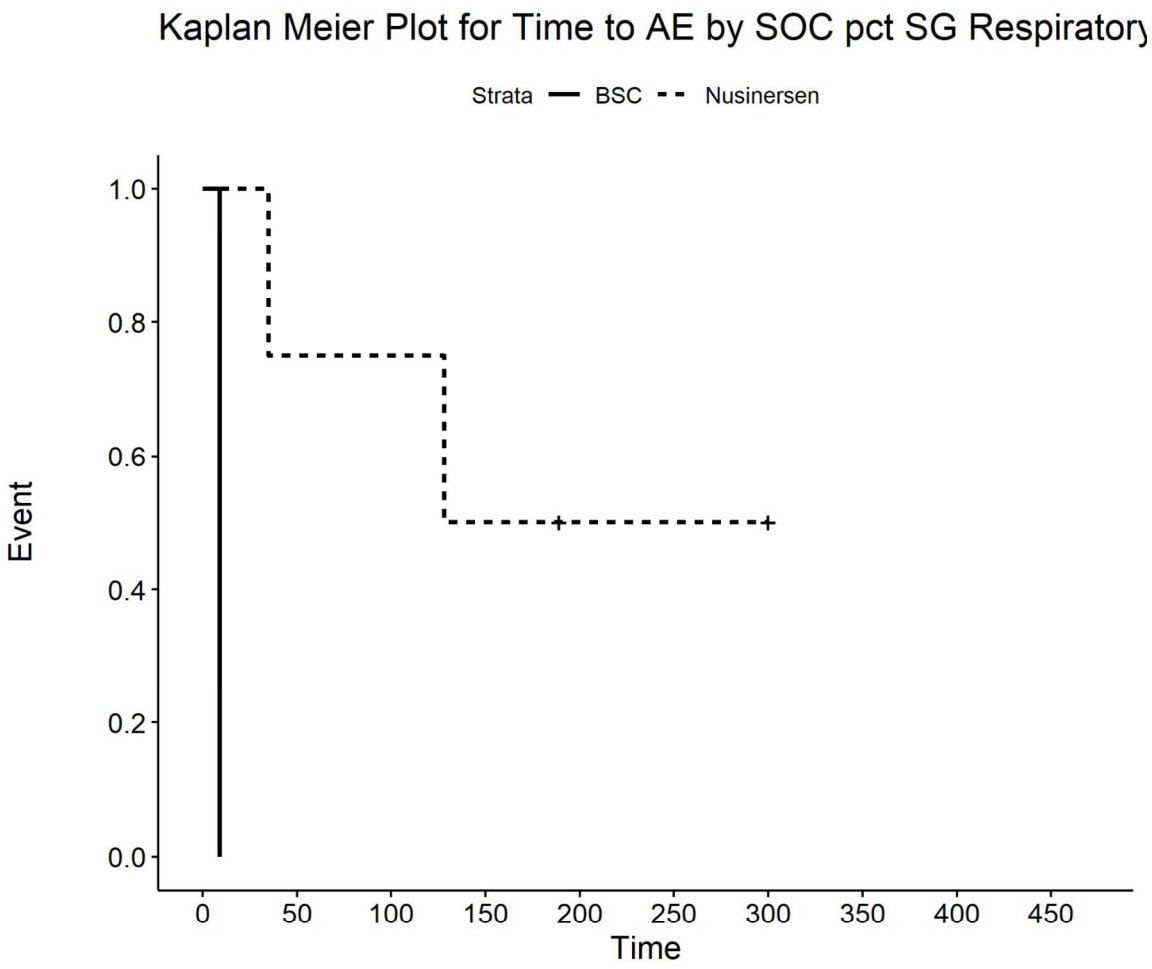
Number at risk

BSC	4	3	3	2	1	1	1	1	0	0
Nusinersen	9	6	4	3	2	2	2	2	2	0



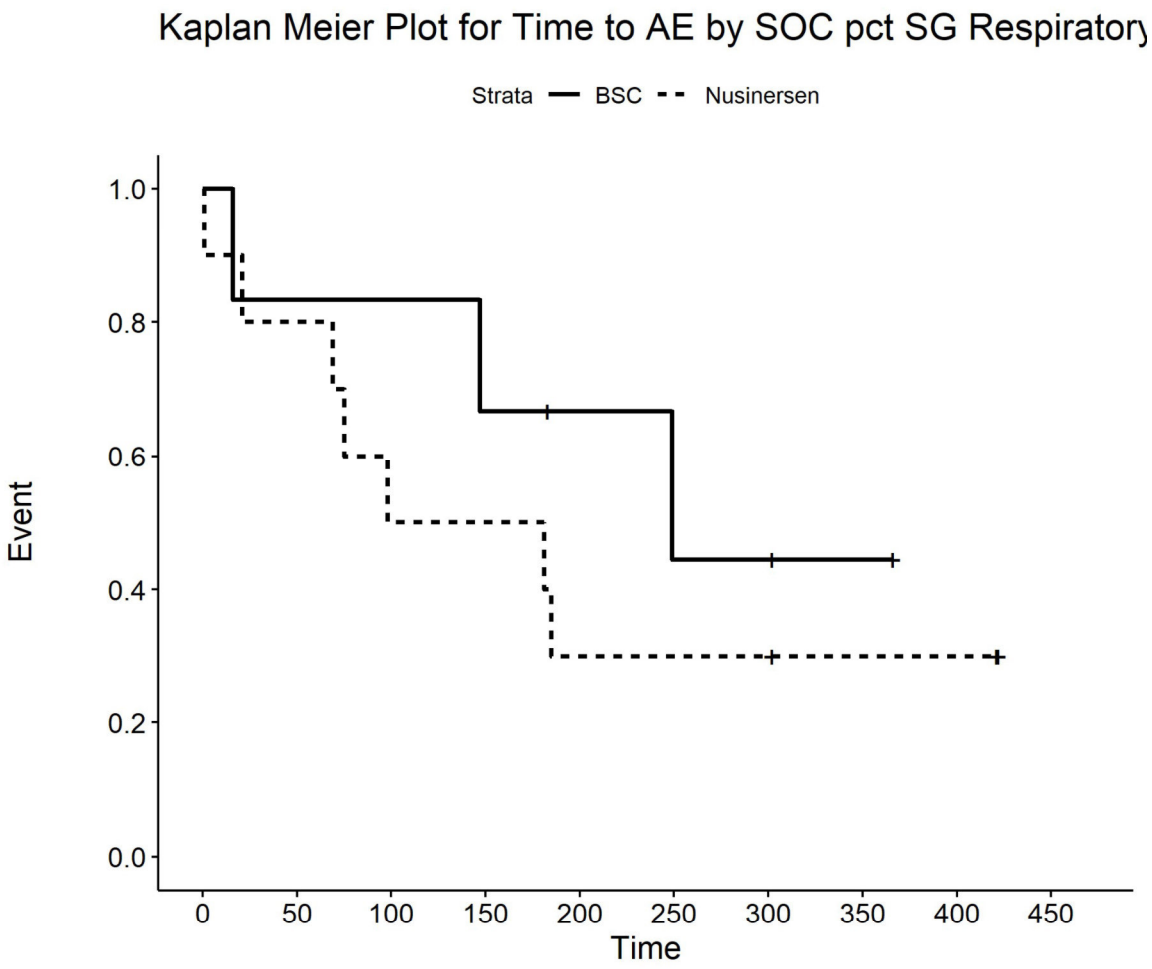
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



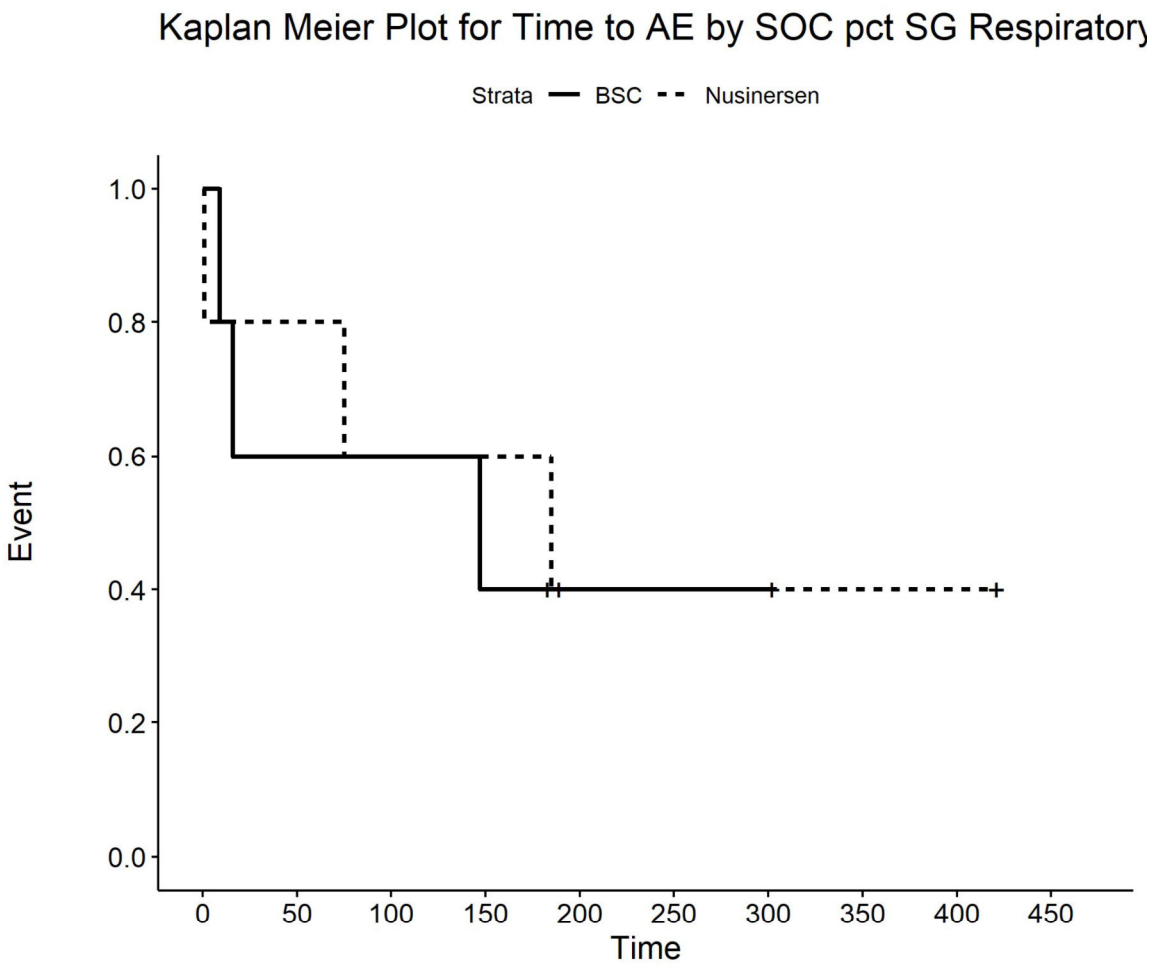
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



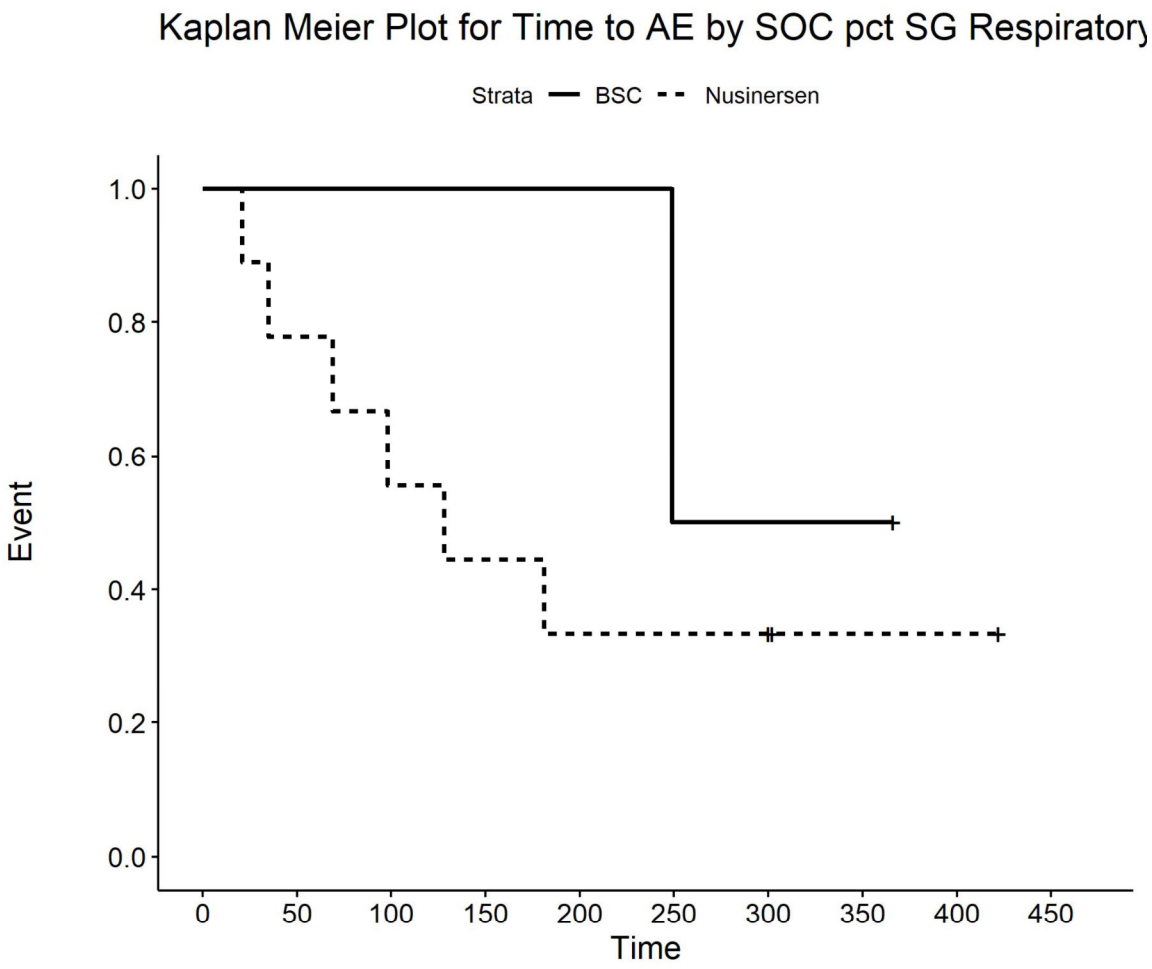
Number at risk

BSC	6	5	5	4	3	2	2	1	0	0
Nusinersen	10	8	5	5	3	3	3	2	2	0



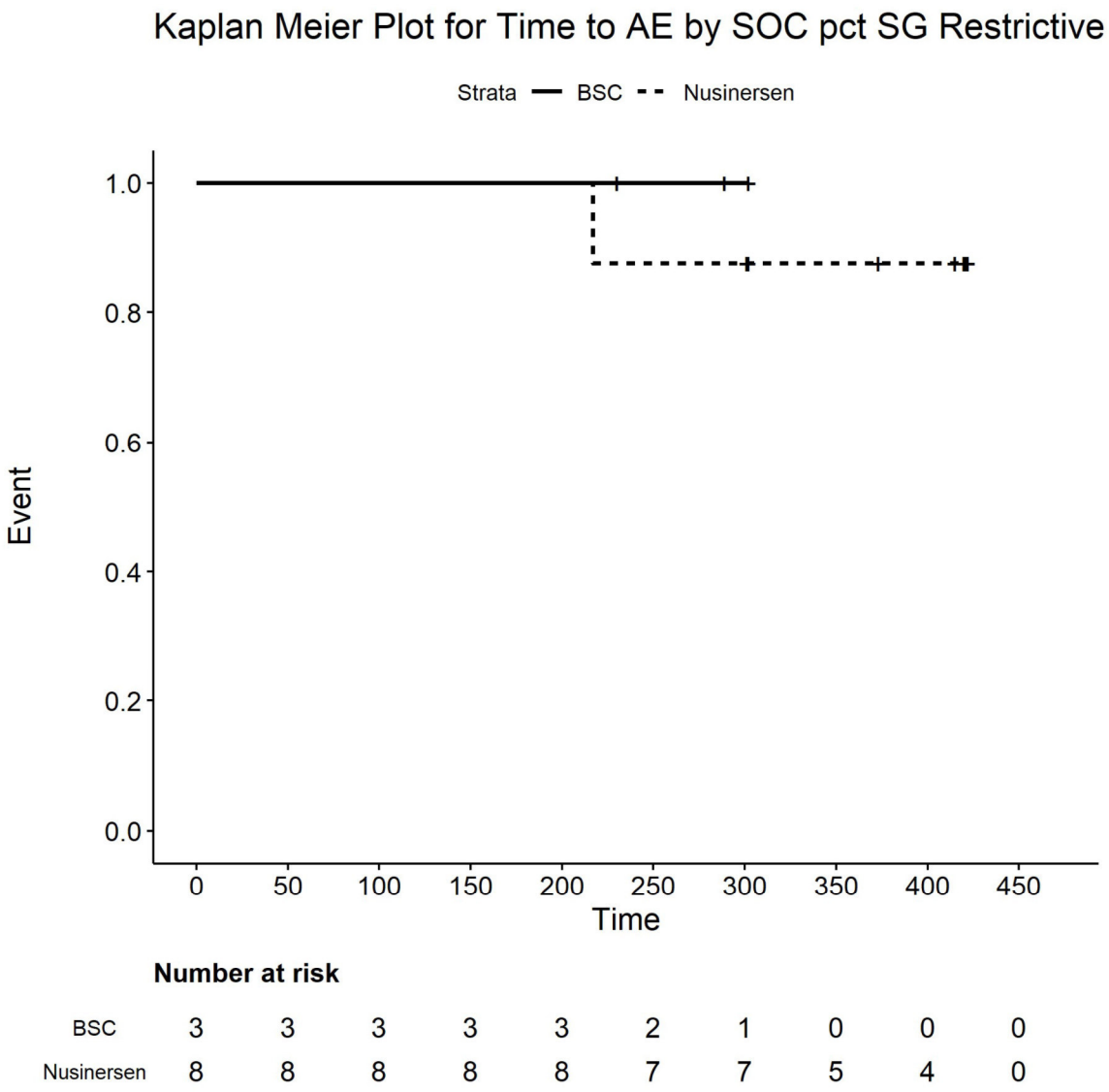
Number at risk

BSC	5	3	3	2	1	1	1	0	0	0
Nusinersen	5	4	3	3	1	1	1	1	1	0



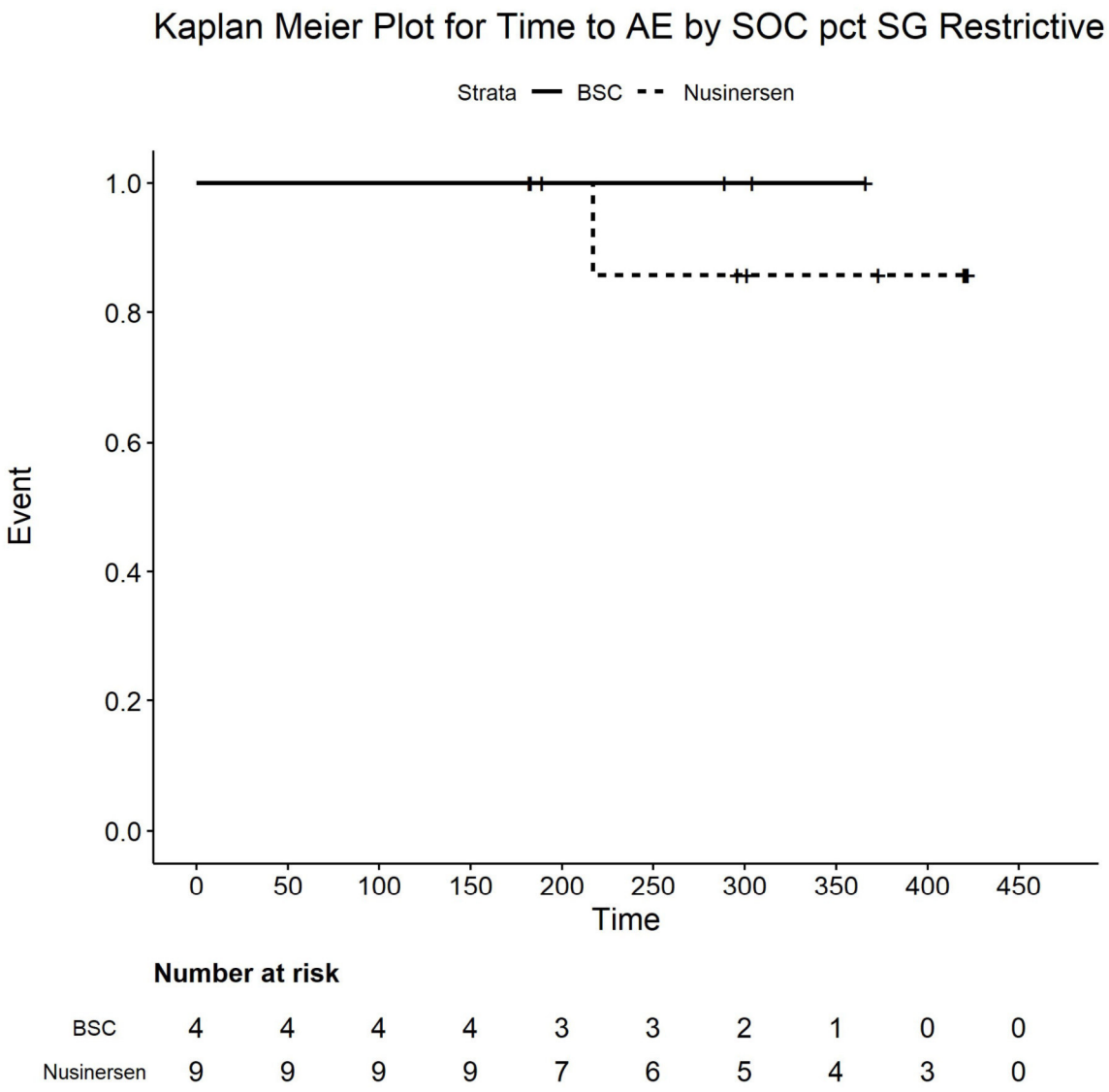
Number at risk

BSC	2	2	2	2	2	1	1	1	0	0
Nusinersen	9	7	5	4	3	3	3	1	1	0



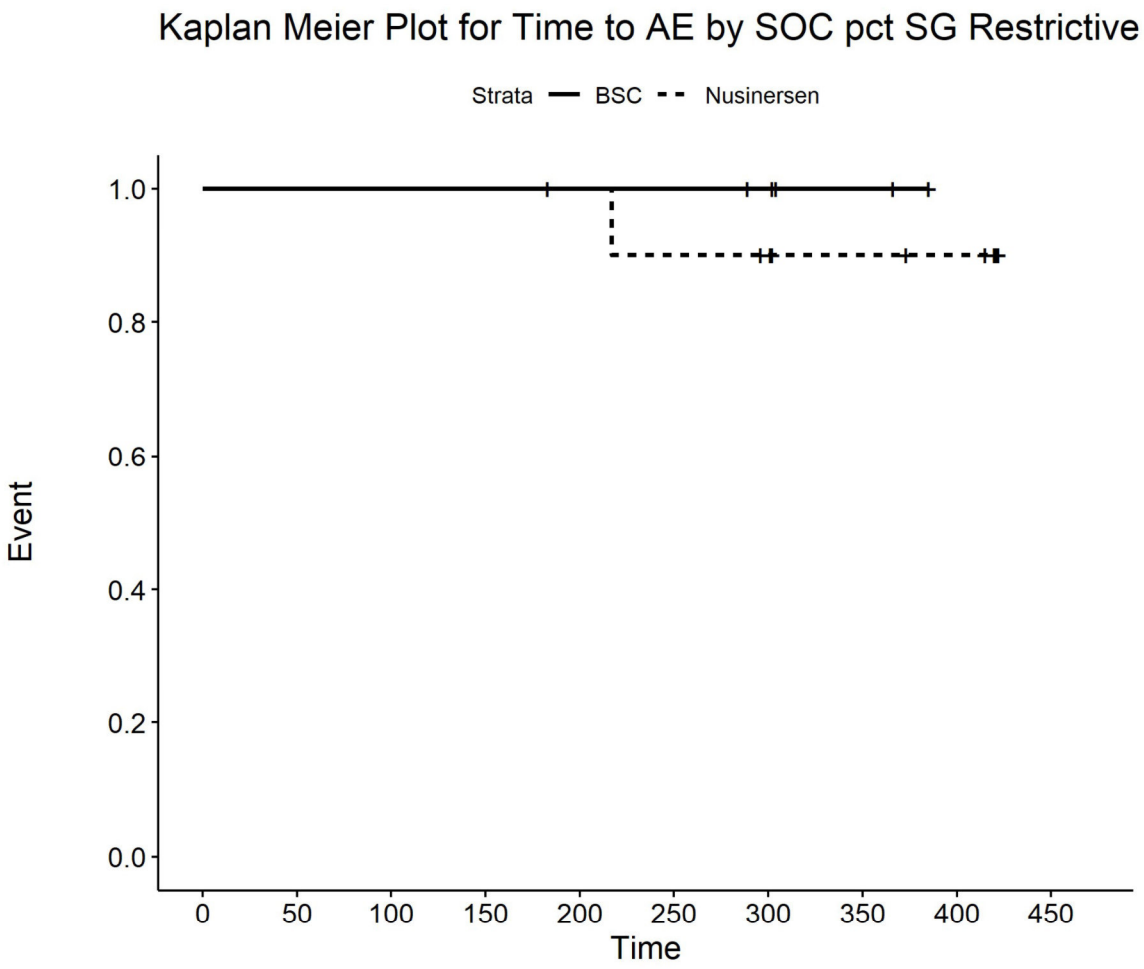
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



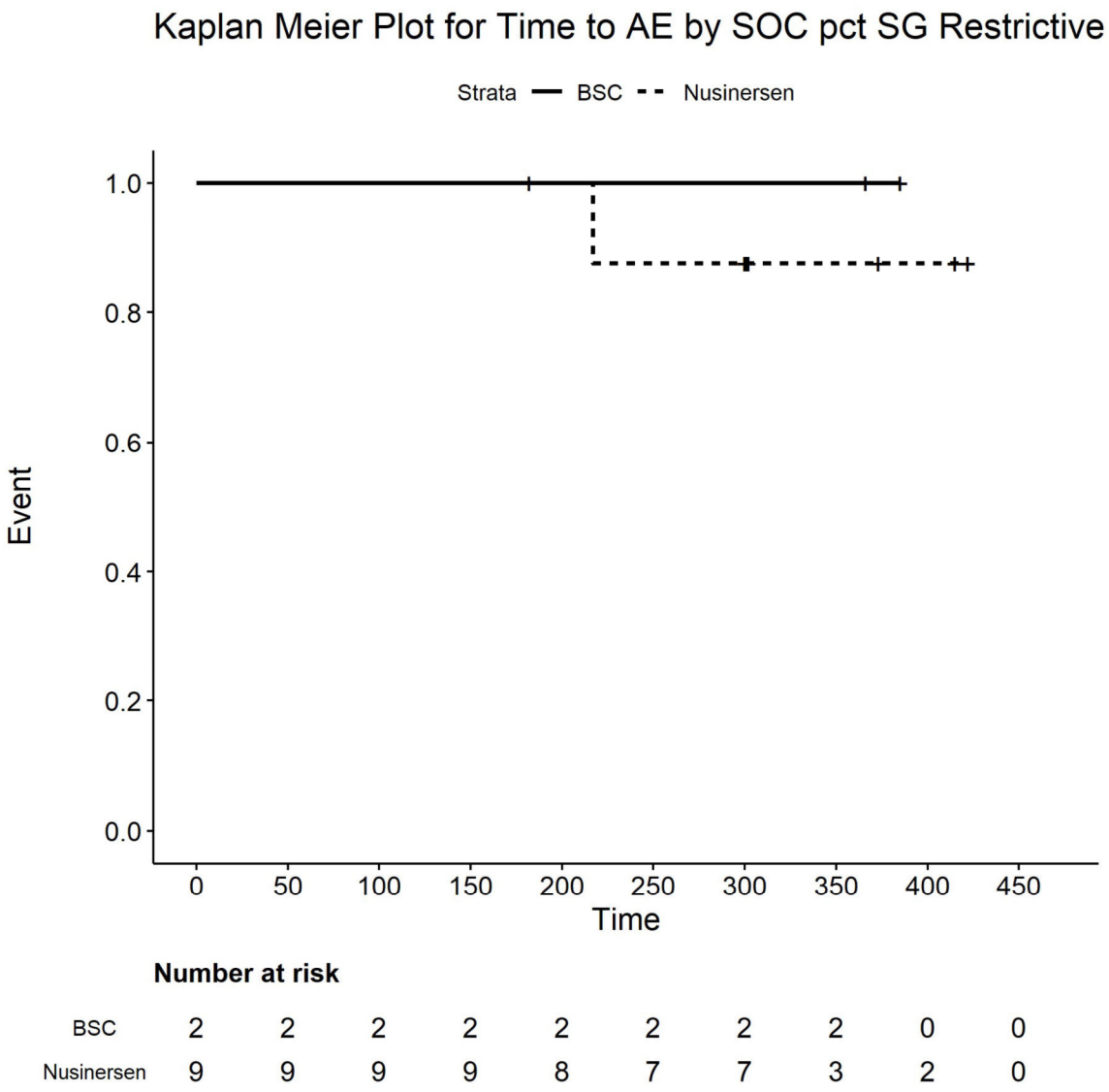
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



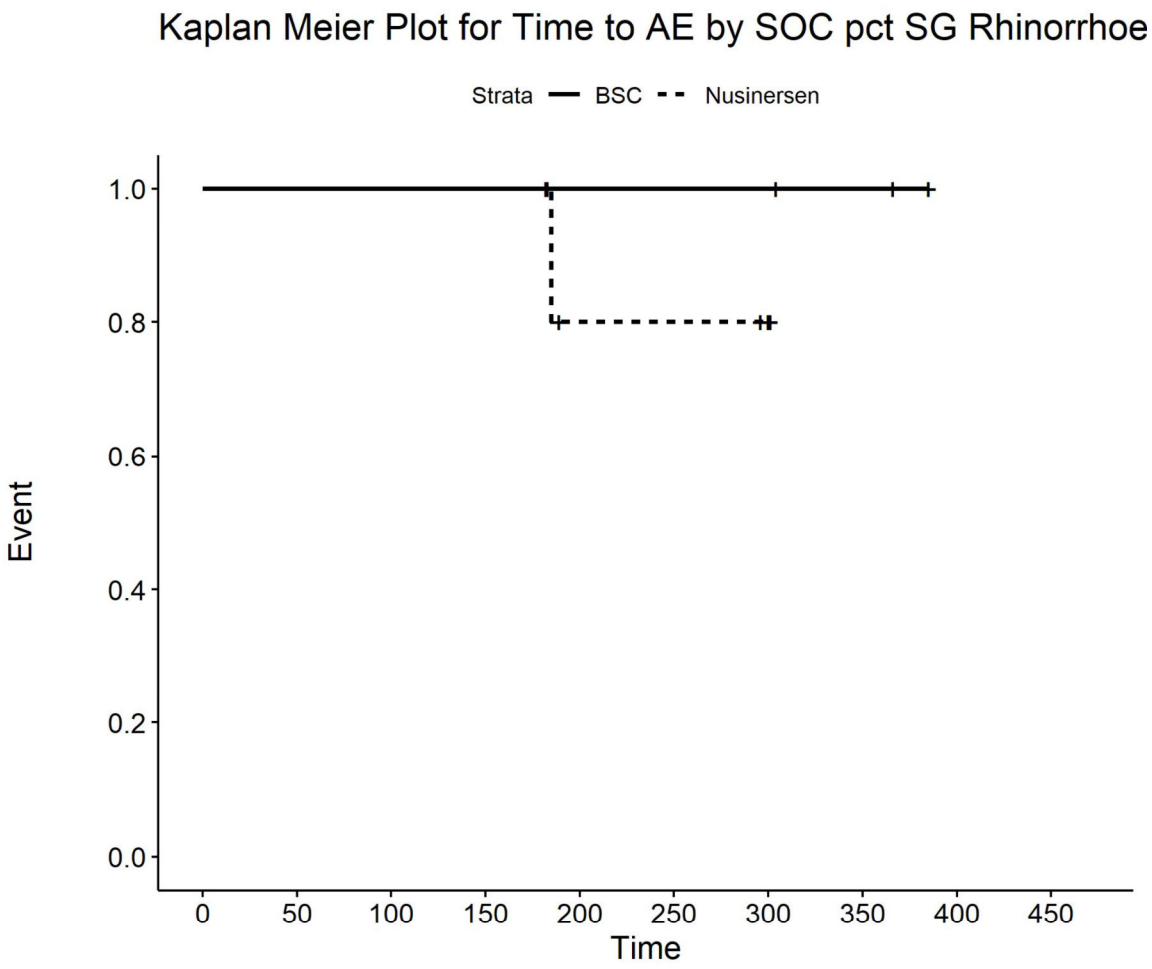
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



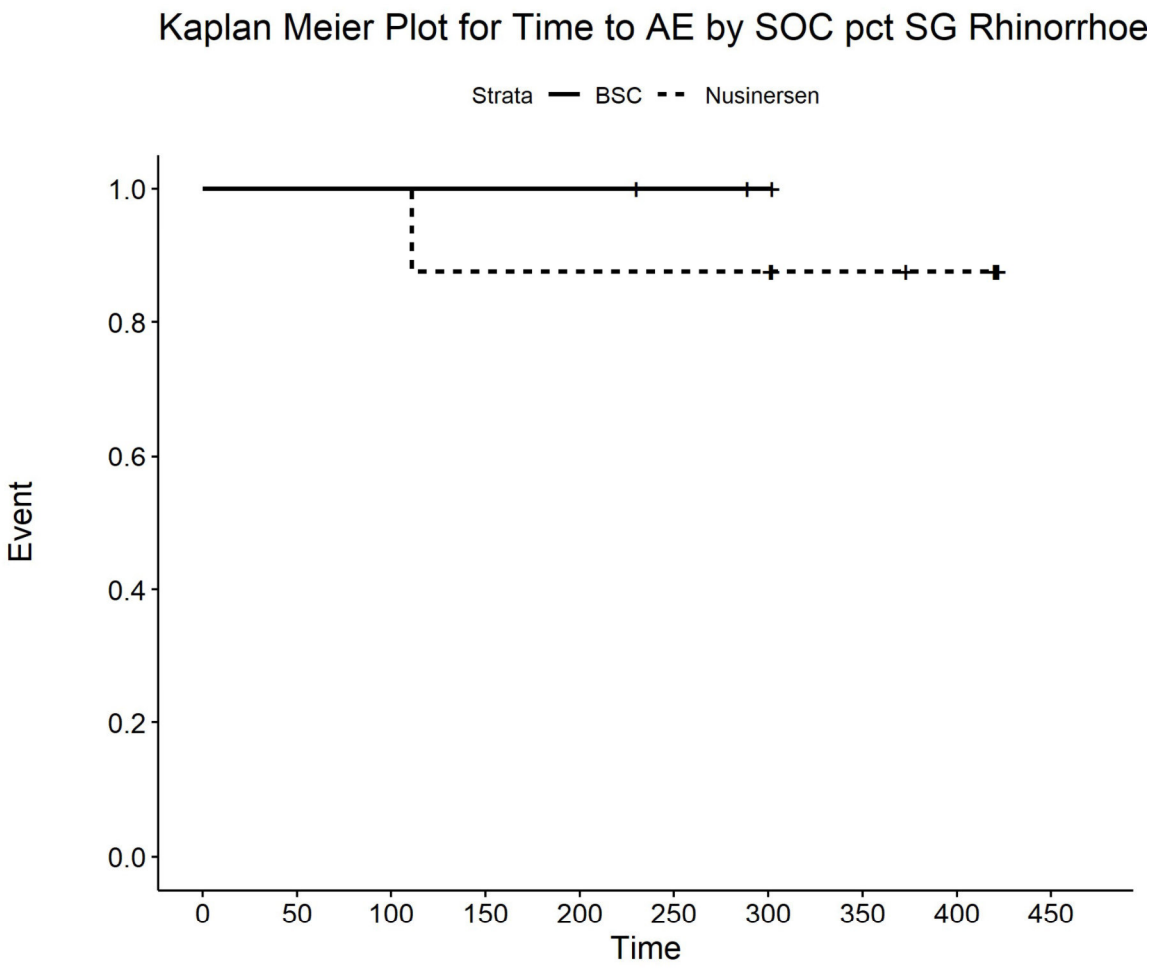
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	2	0



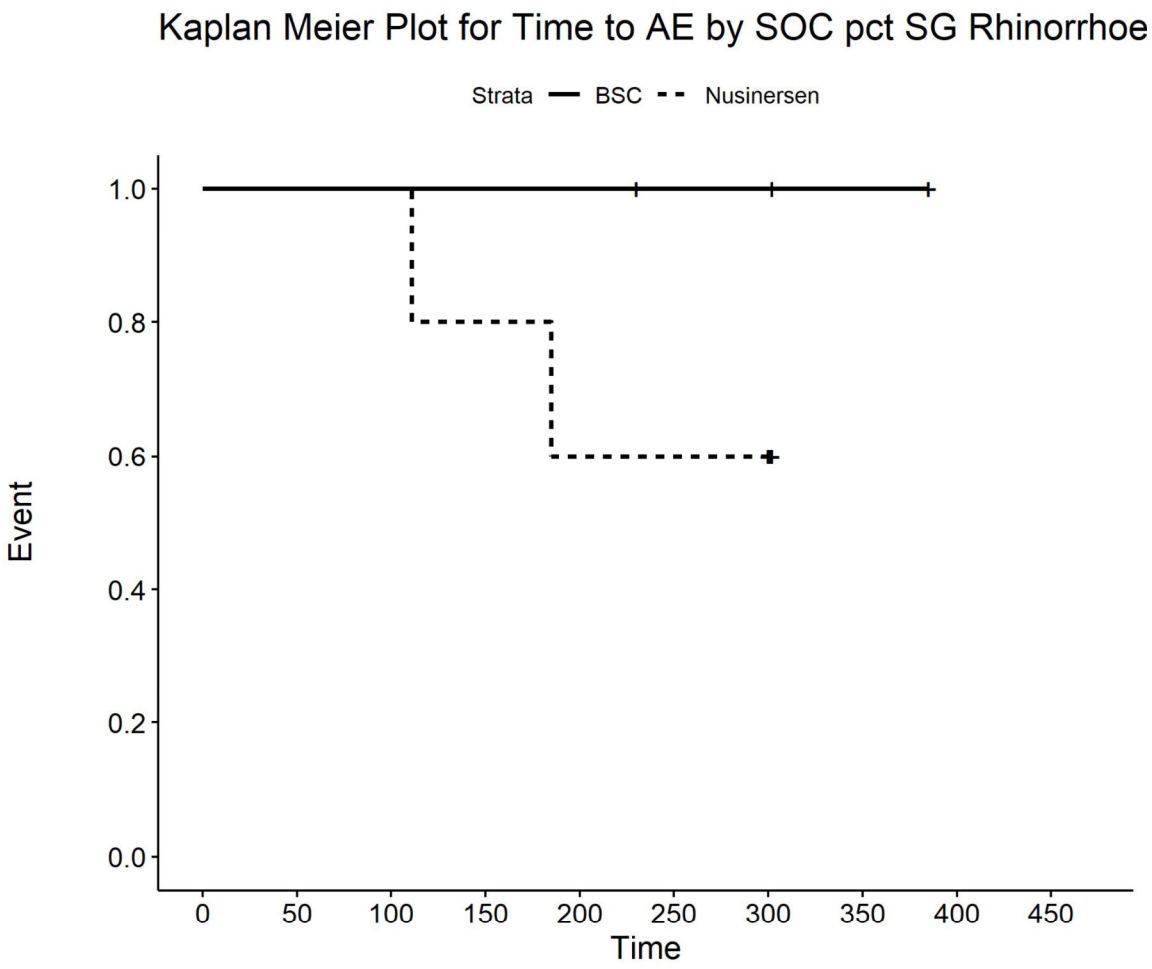
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	6	3	3	2	0	0	0



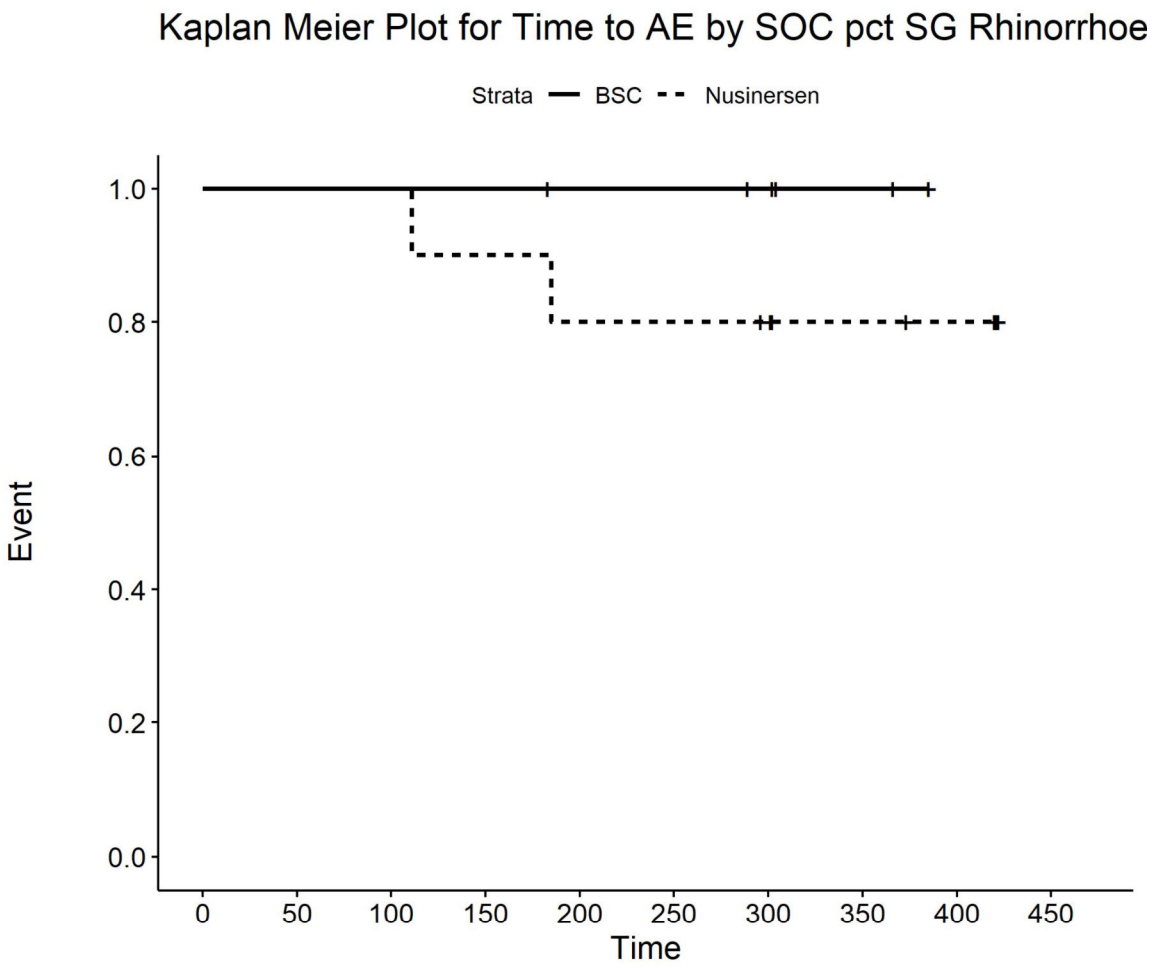
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



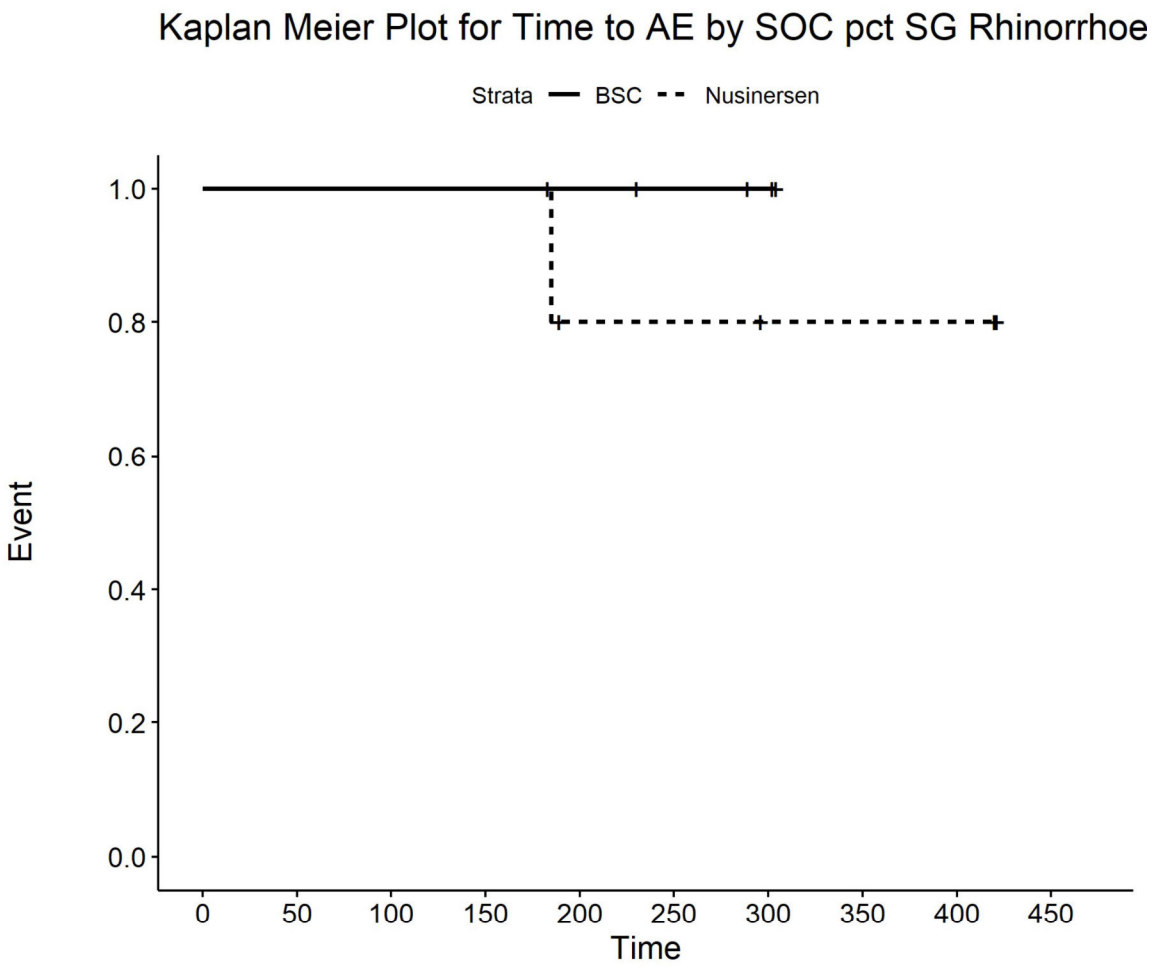
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	4	3	3	3	0	0	0



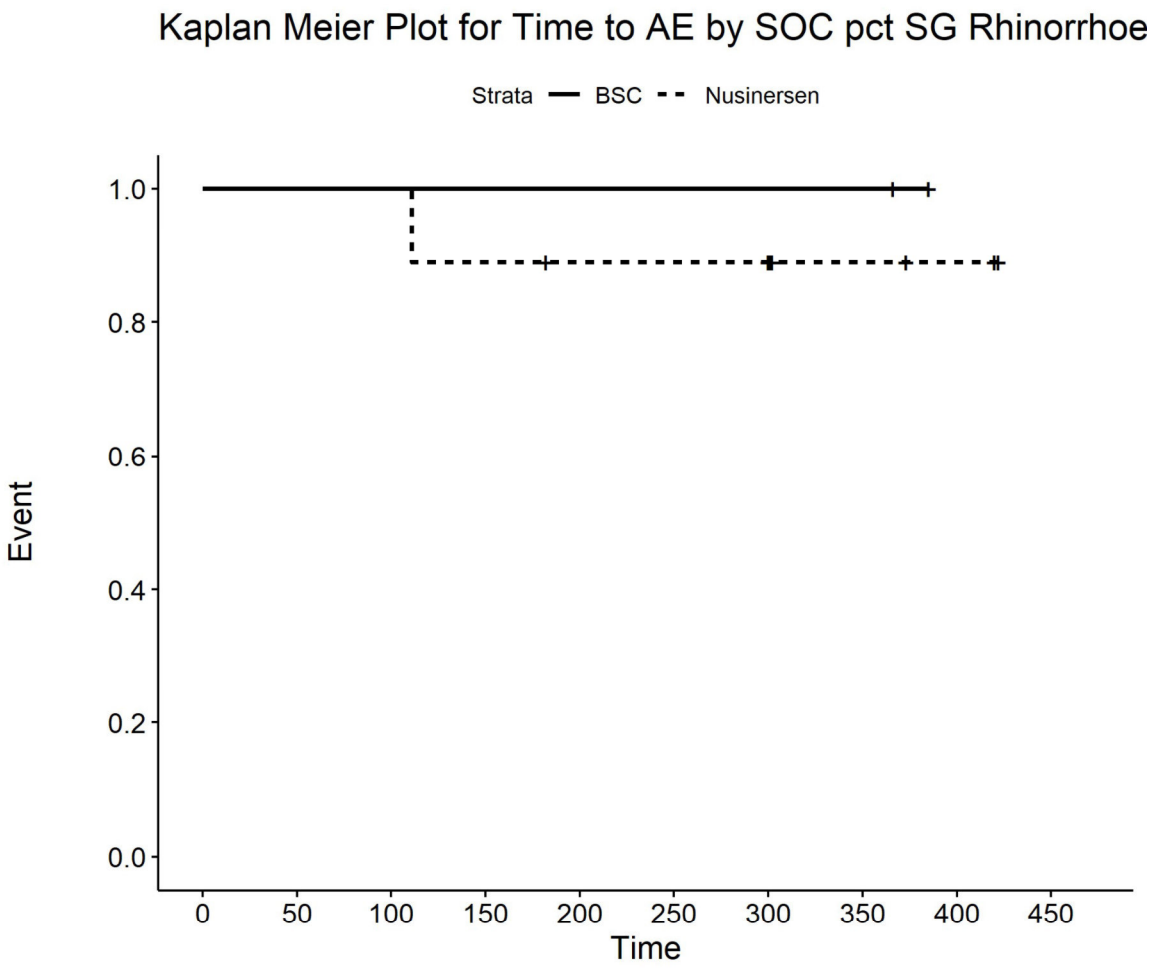
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	8	8	7	5	4	0



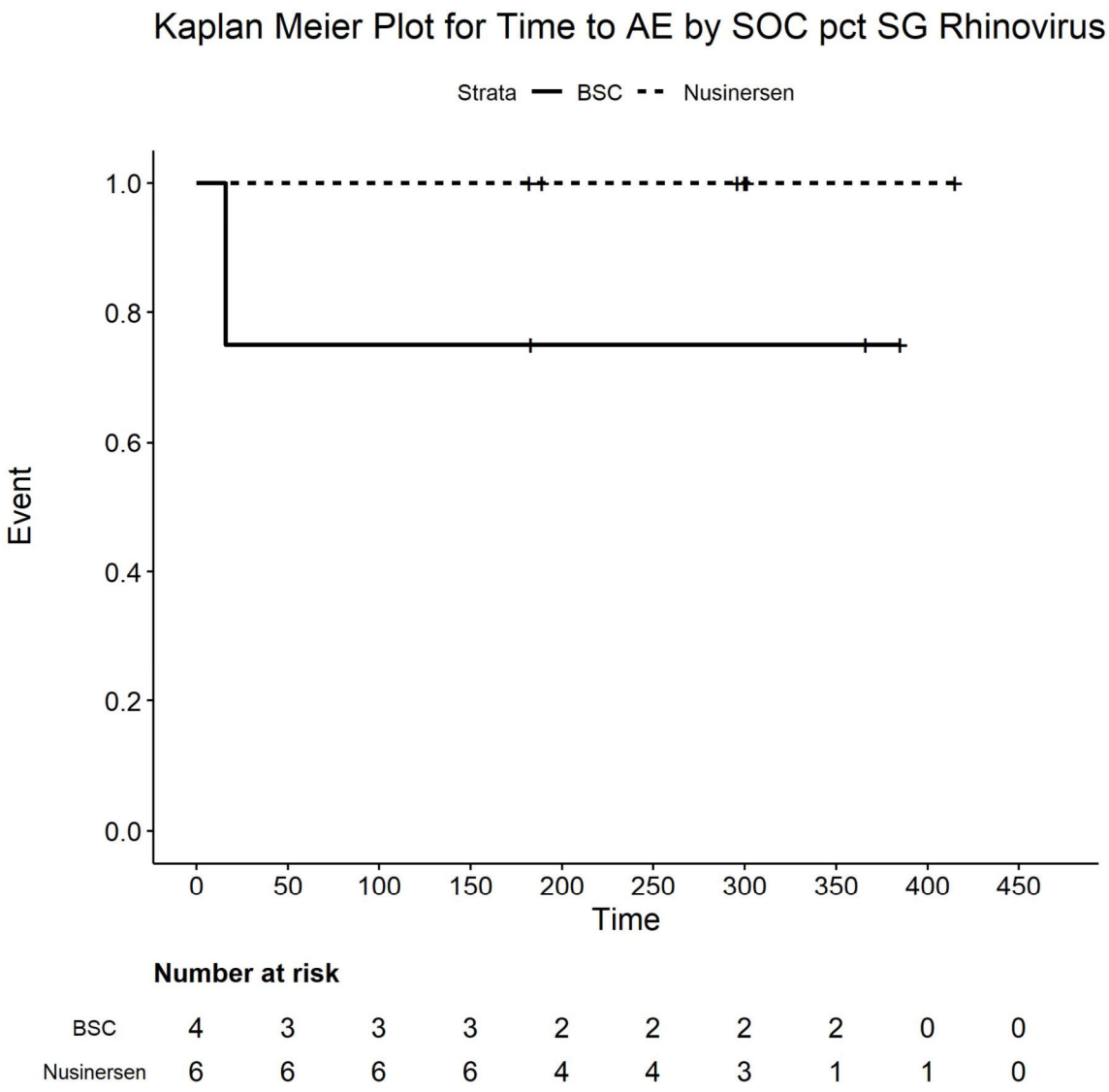
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	3	3	2	2	2	0



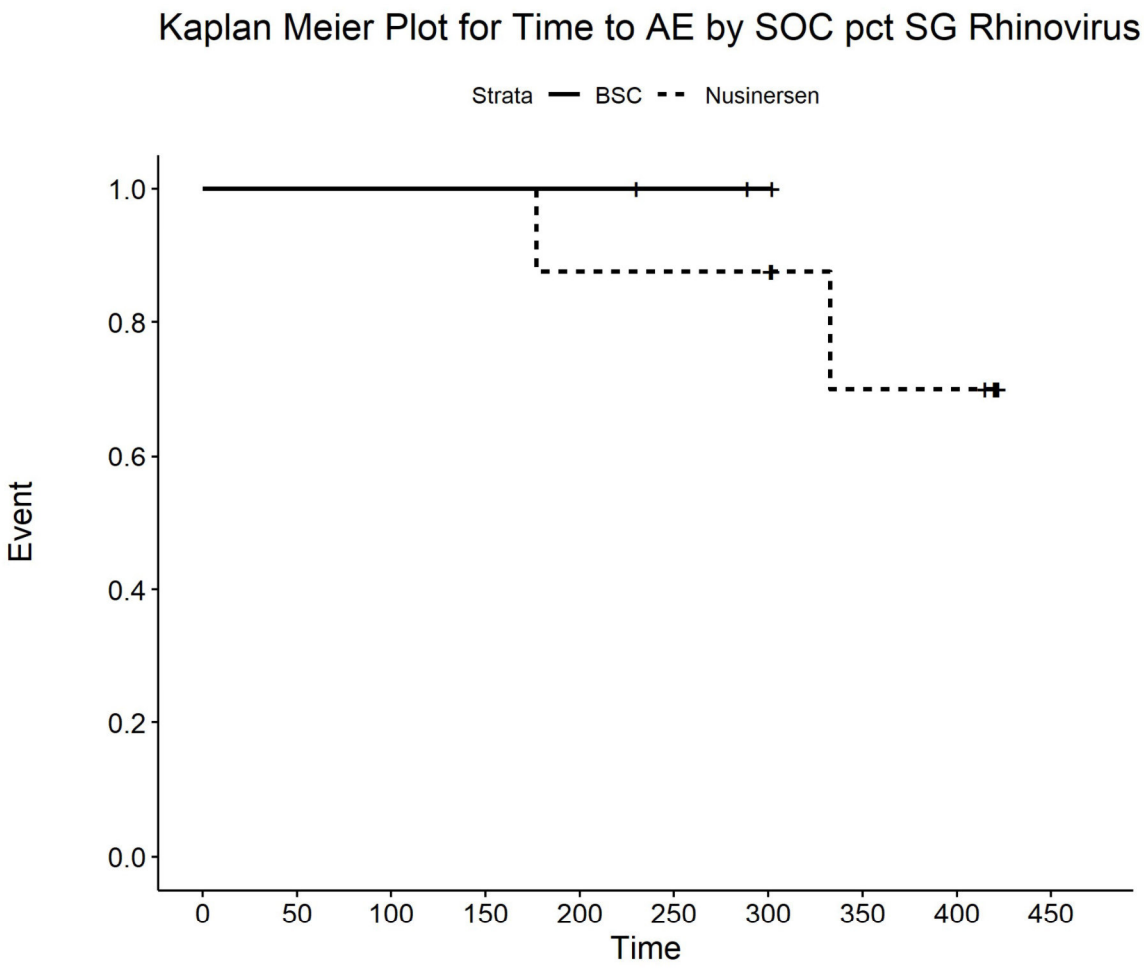
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



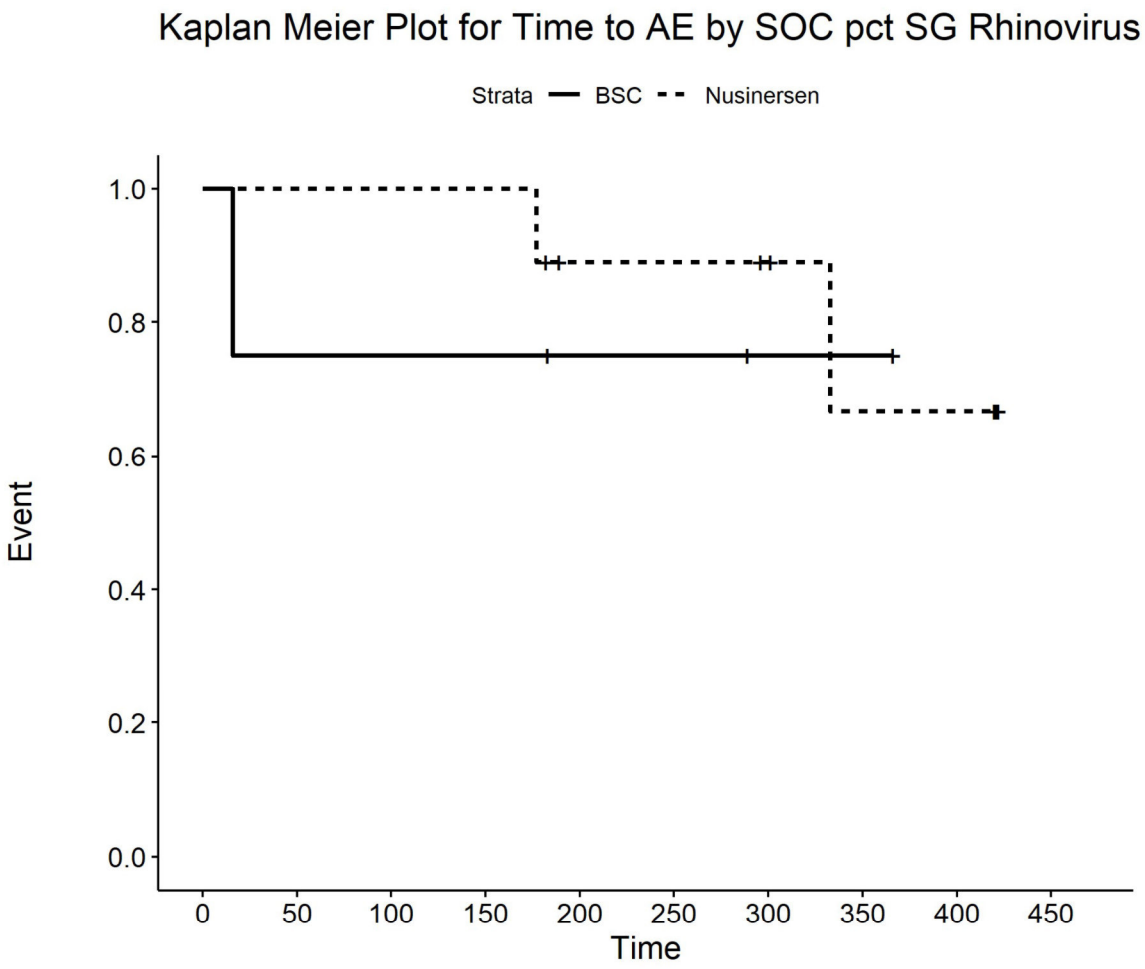
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



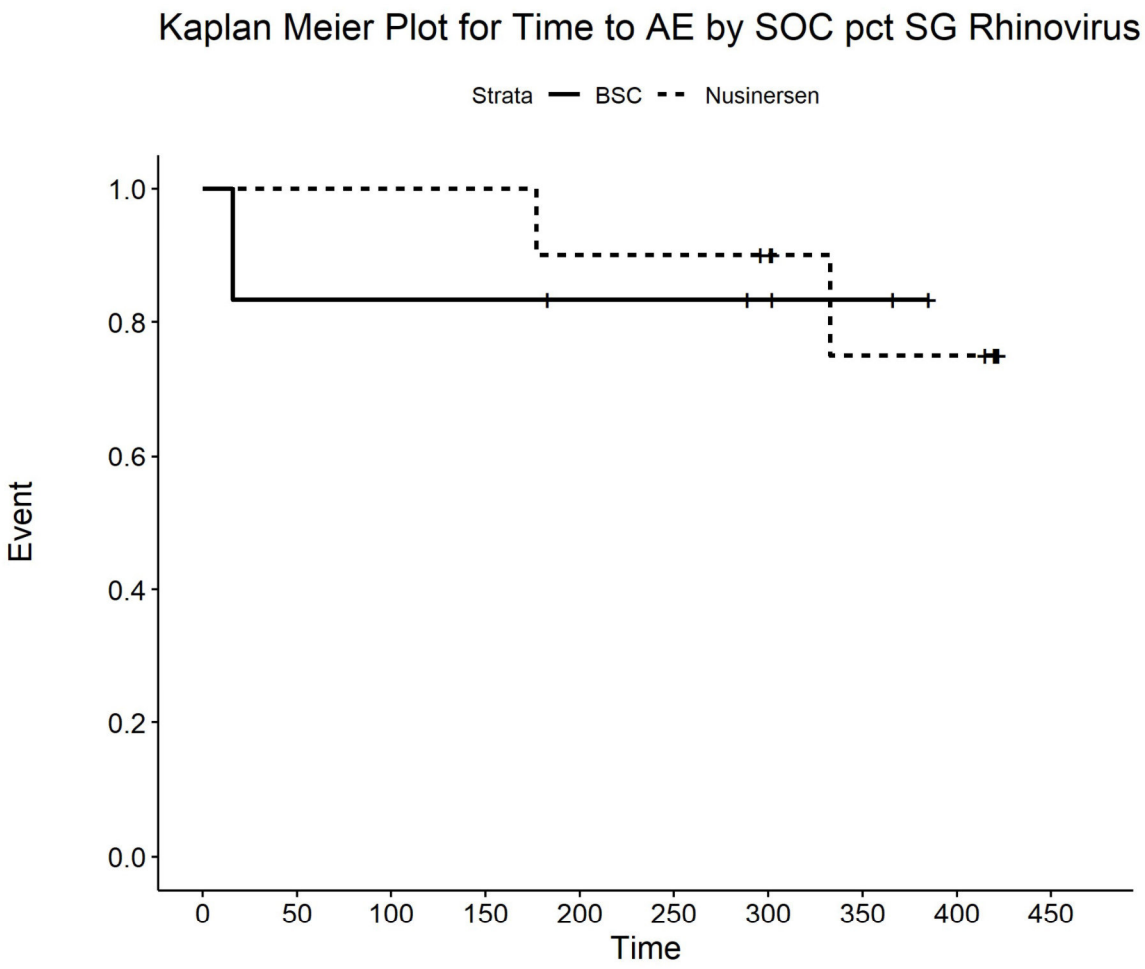
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	7	7	7	4	4	0



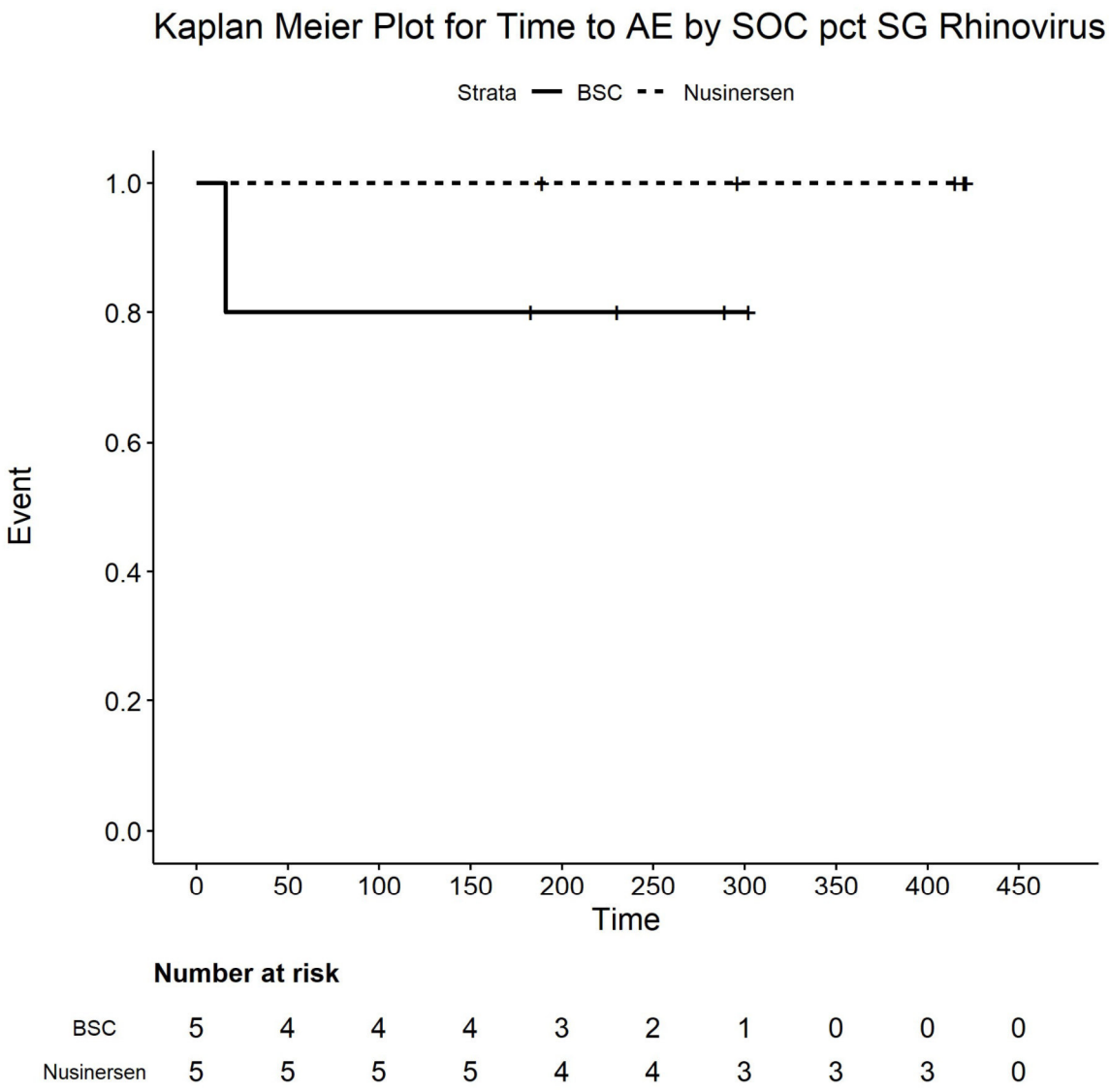
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	6	6	5	3	3	0



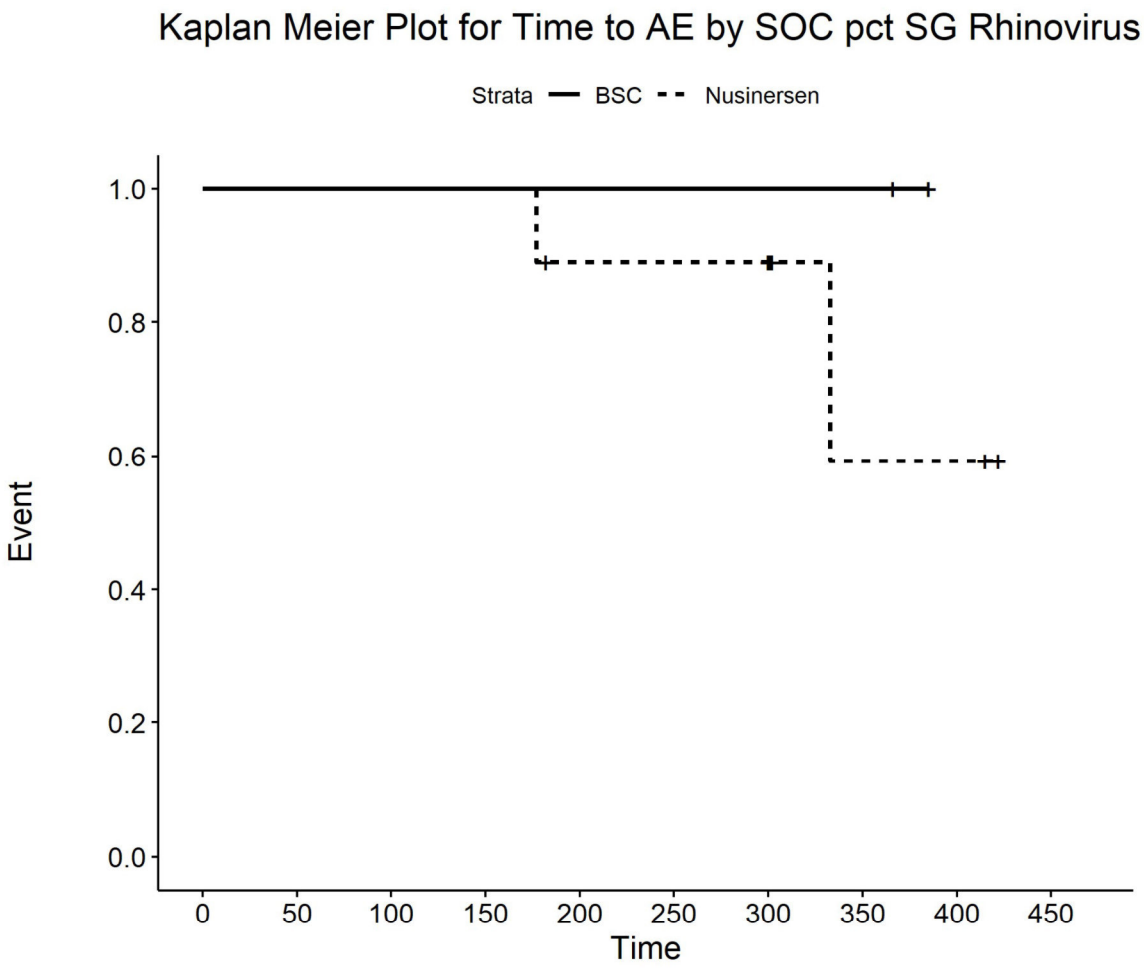
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	9	9	8	5	5	0



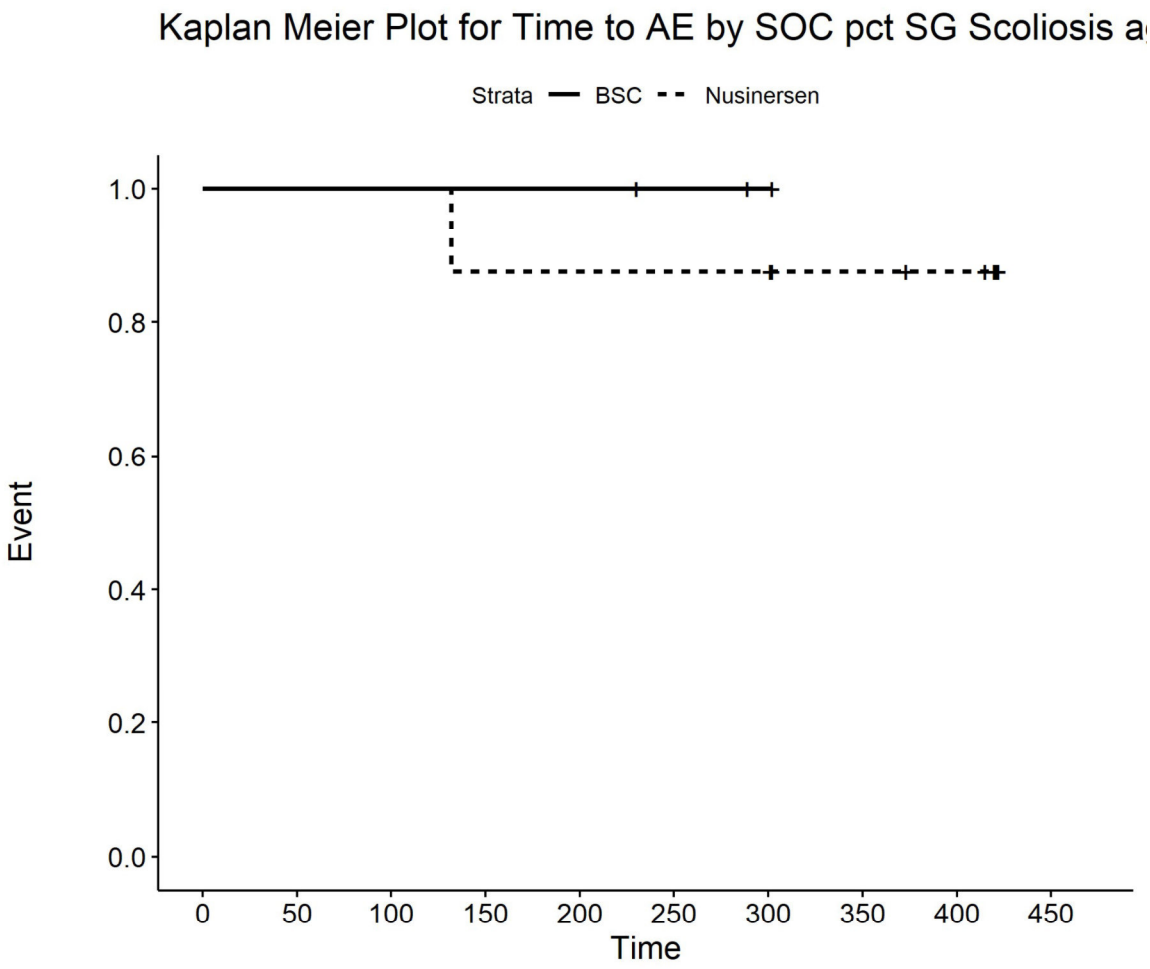
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



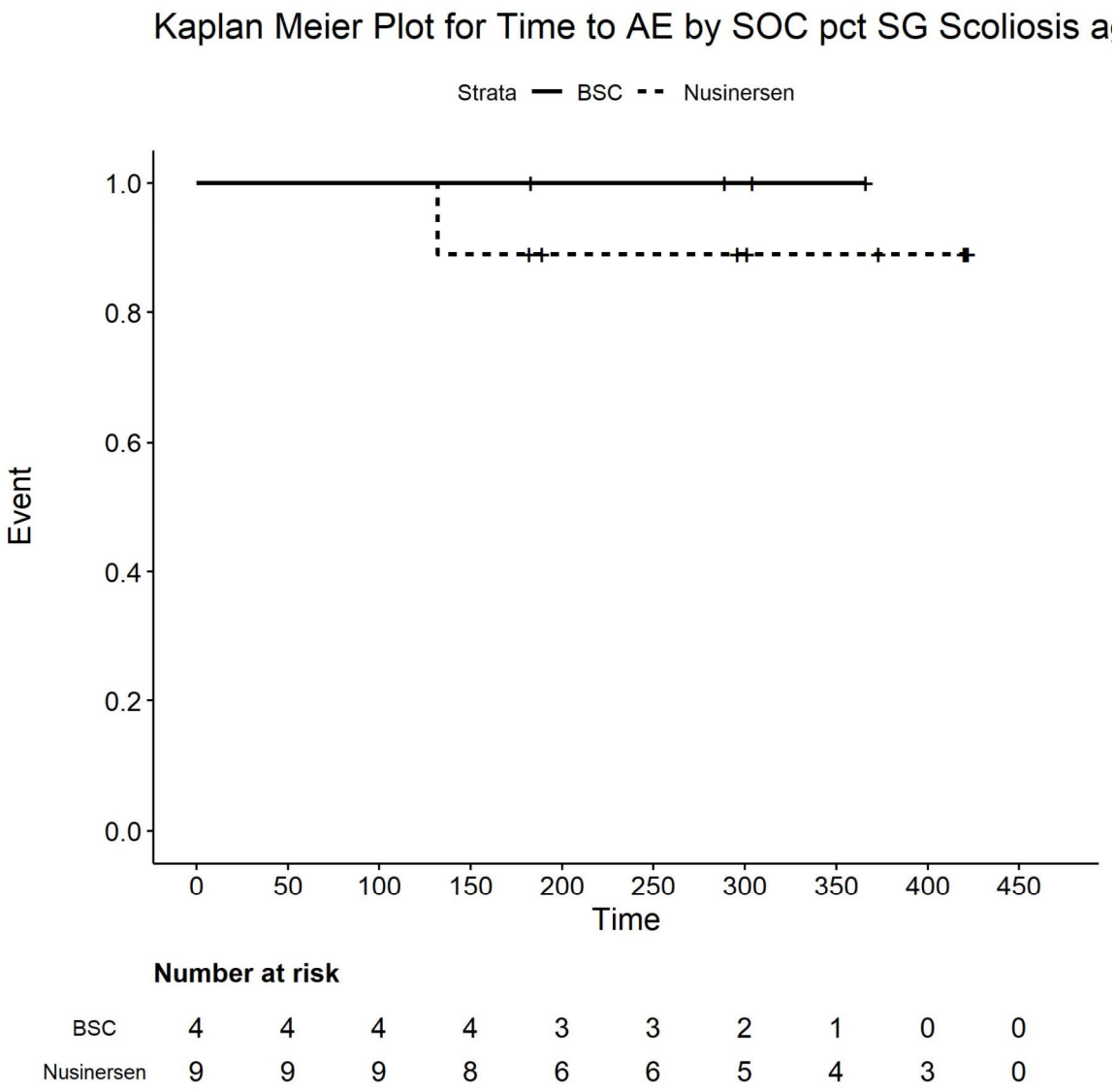
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	7	7	7	2	2	0



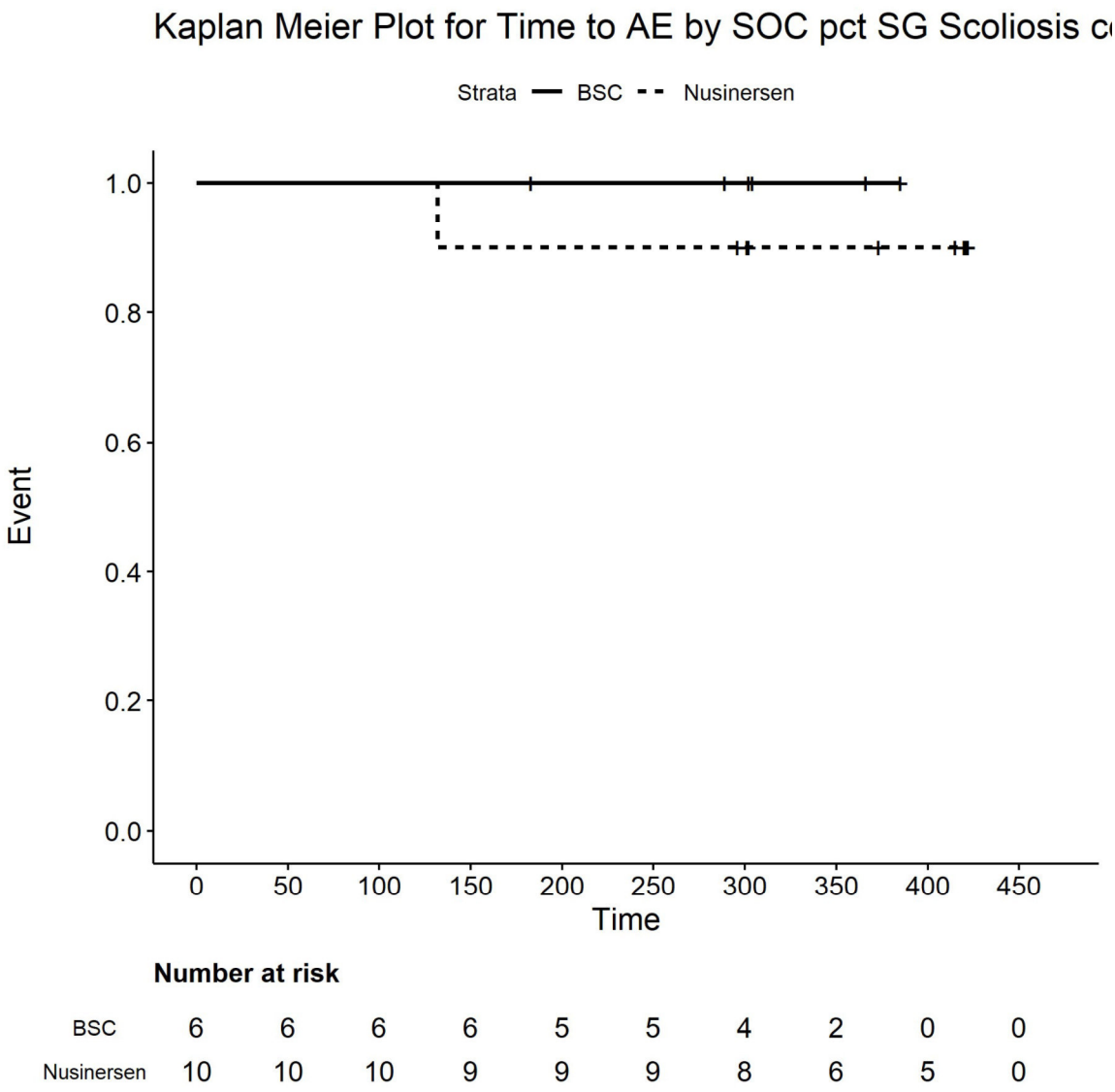
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



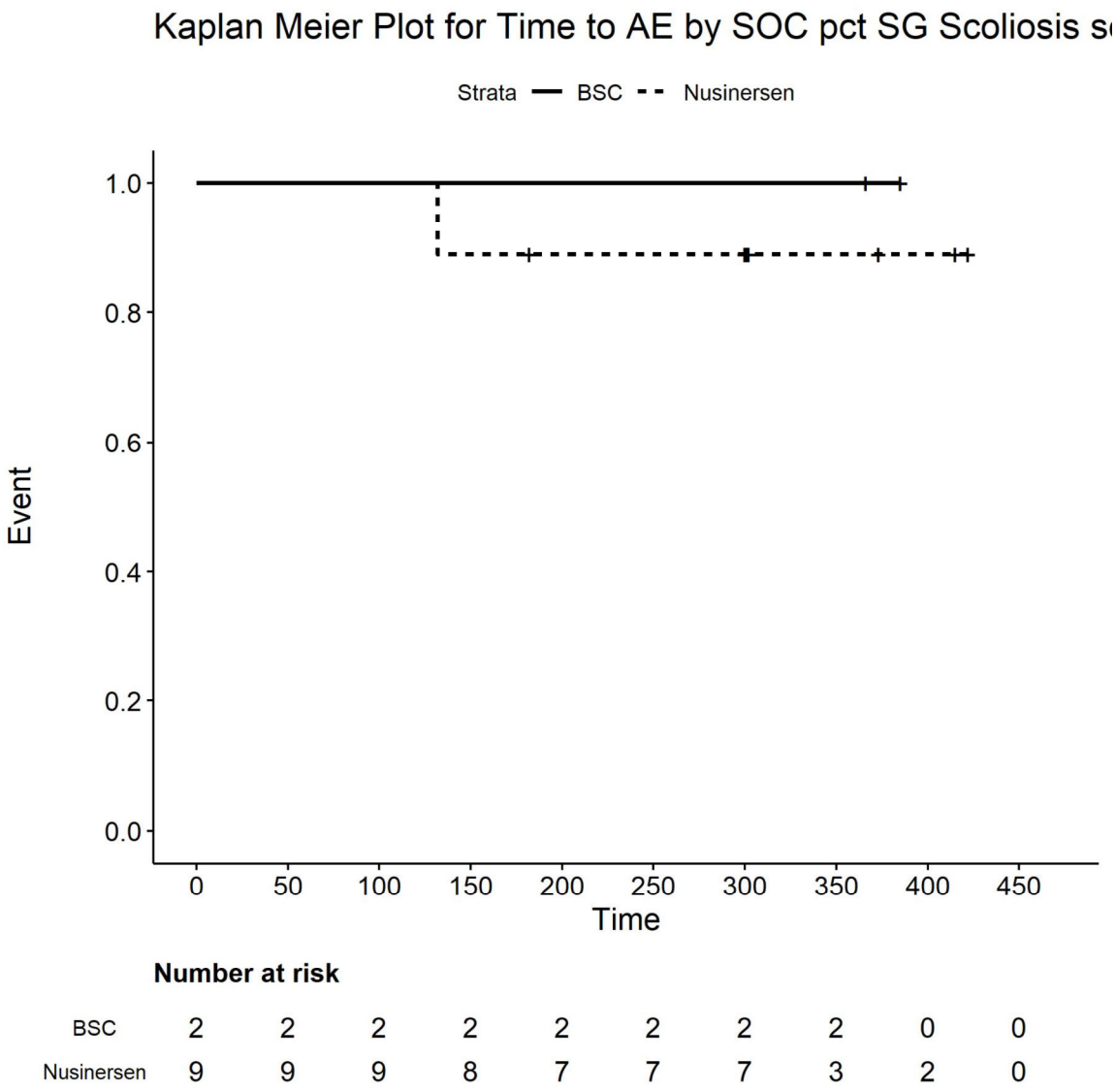
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



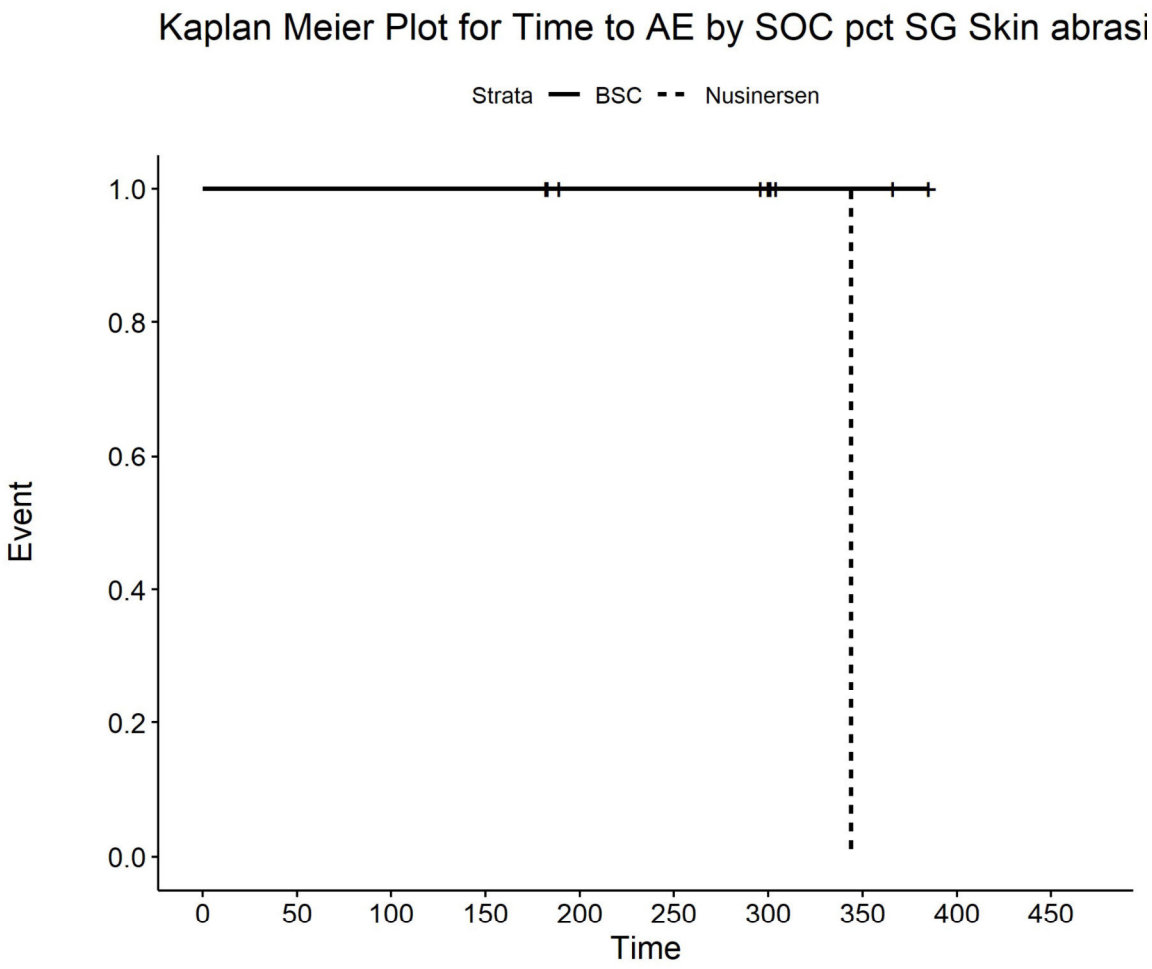
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



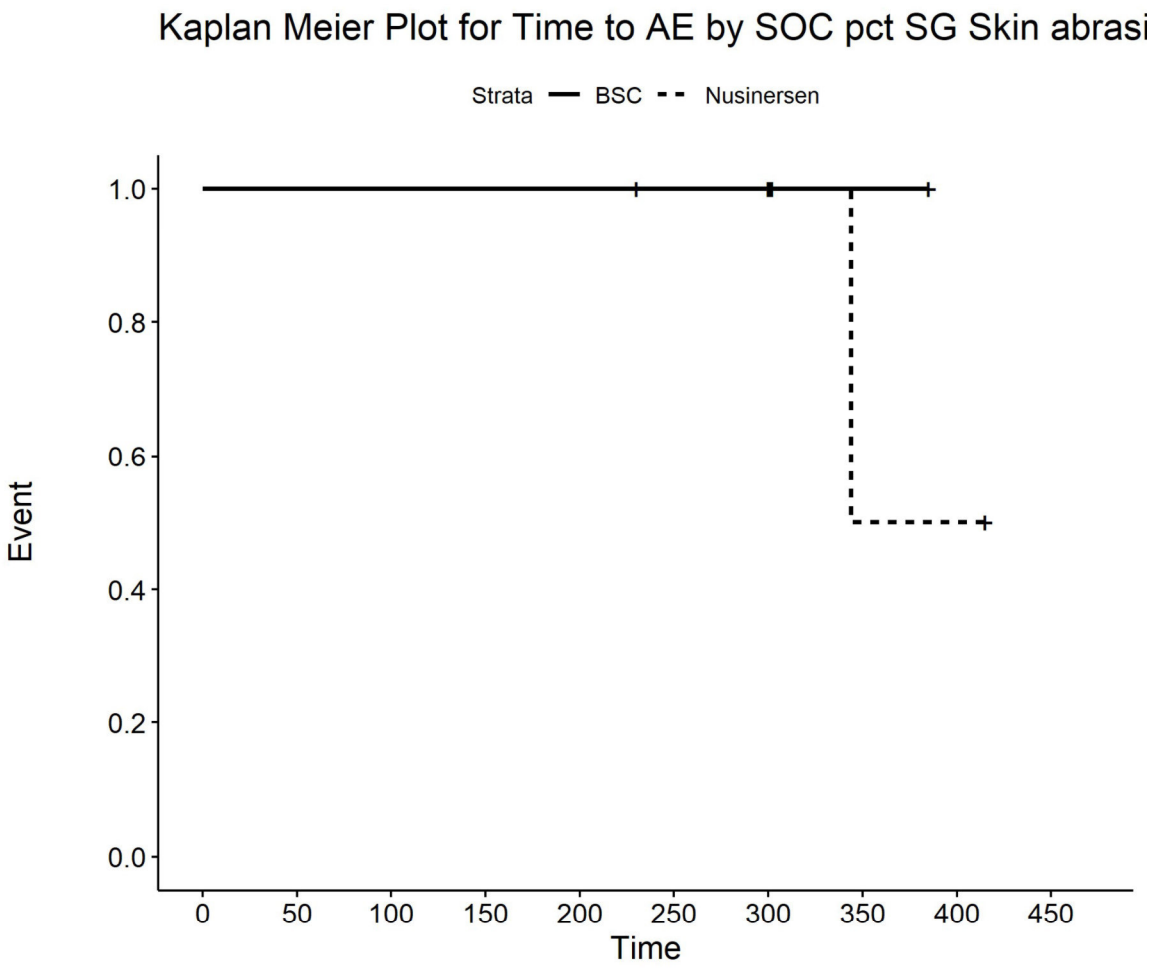
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



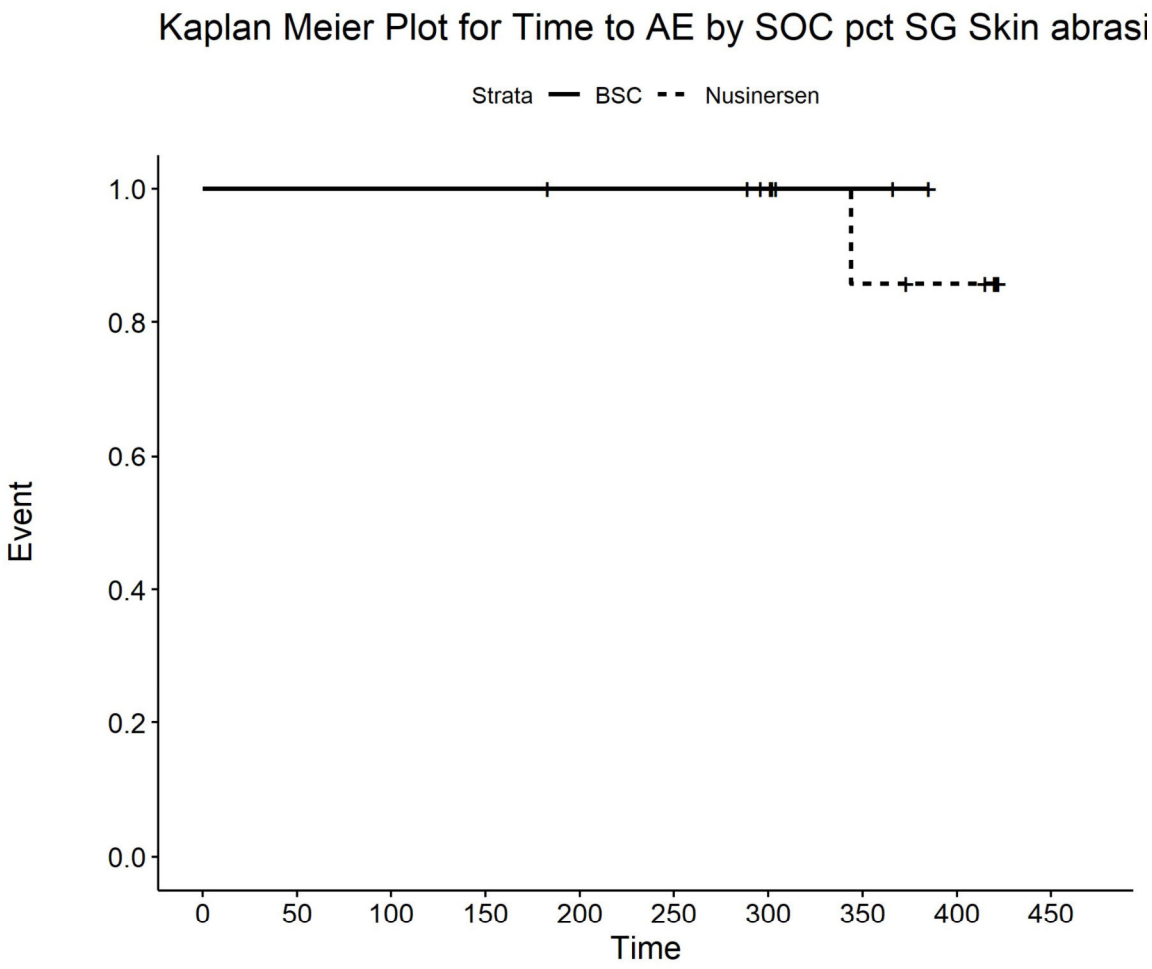
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	6	4	4	3	0	0	0



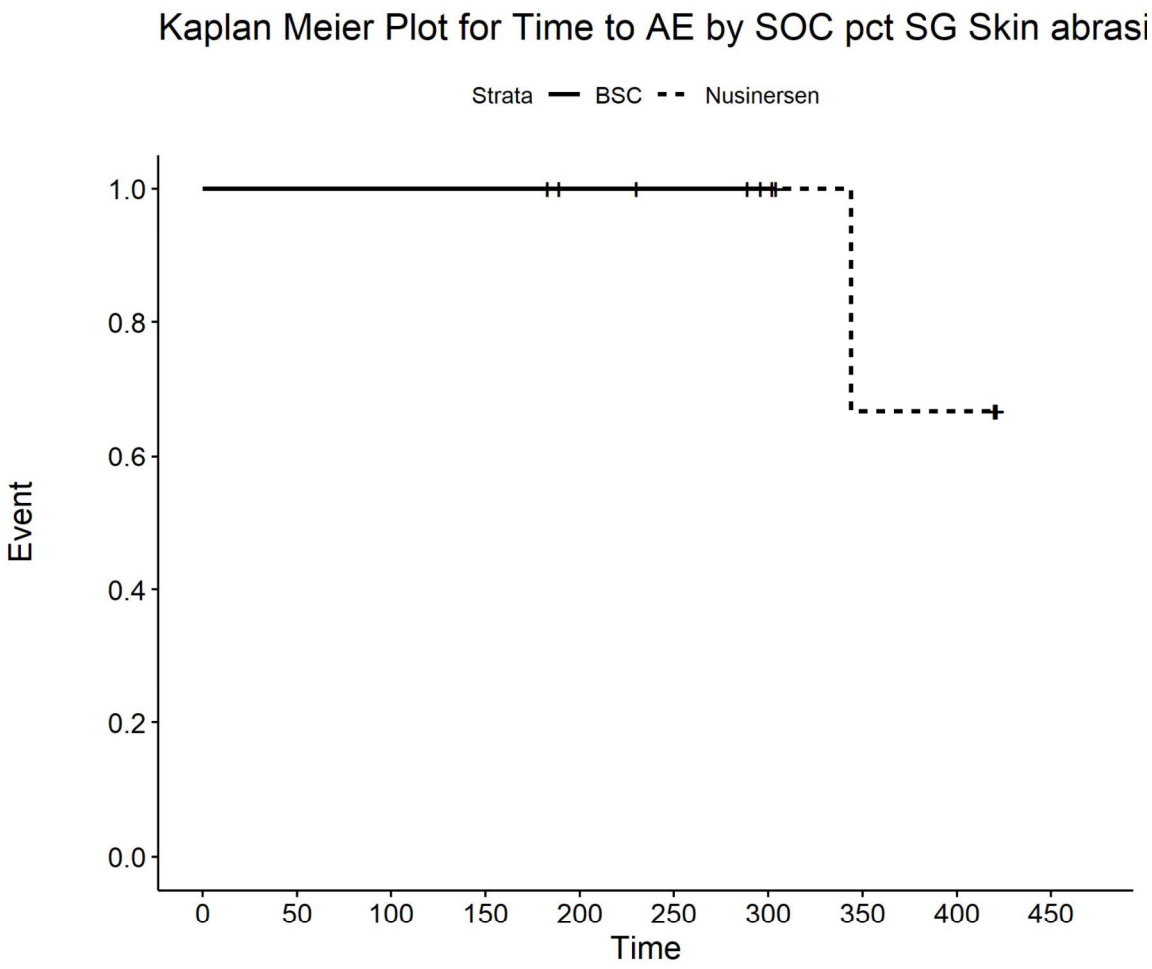
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	1	1	0



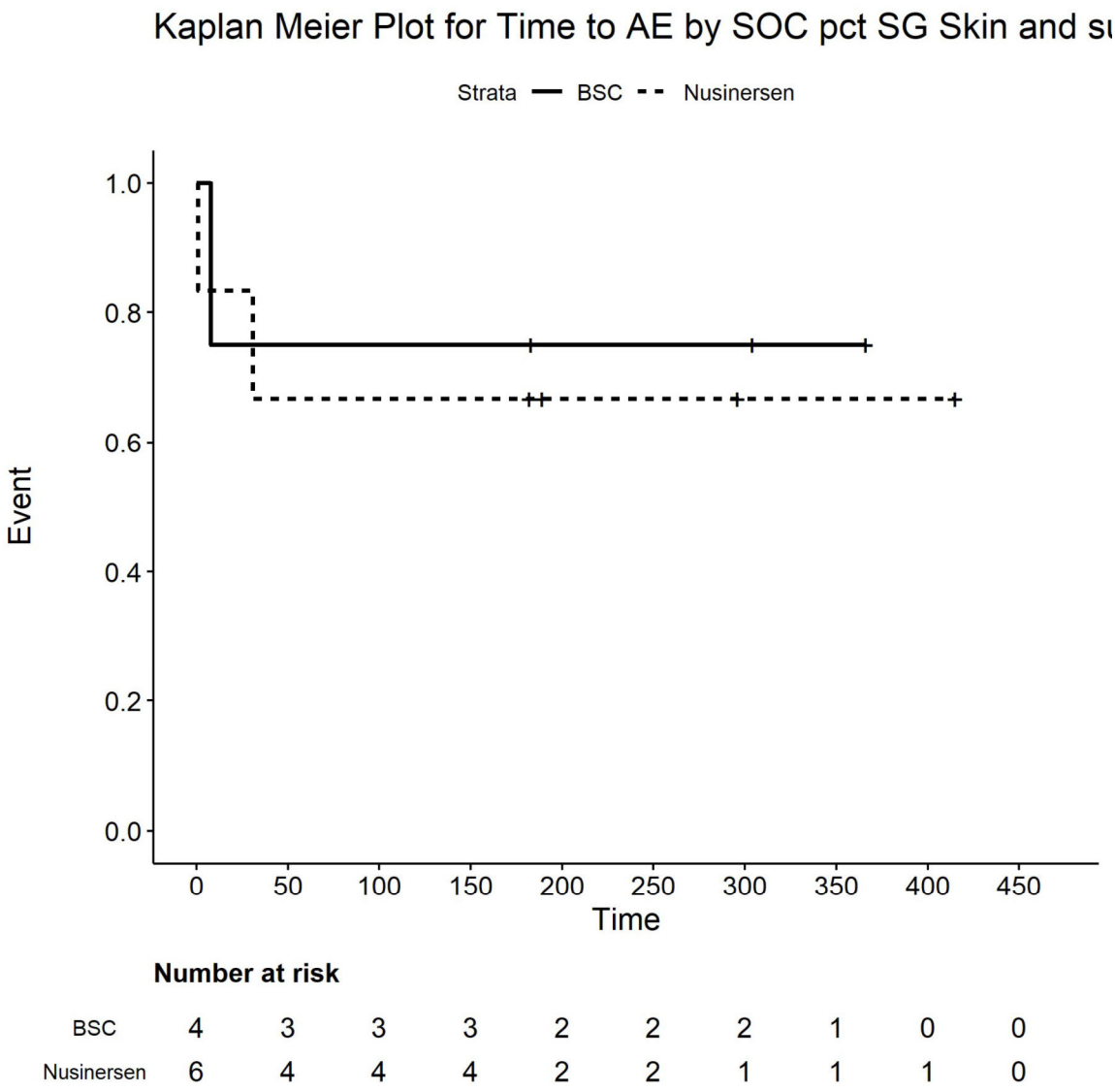
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	6	5	0



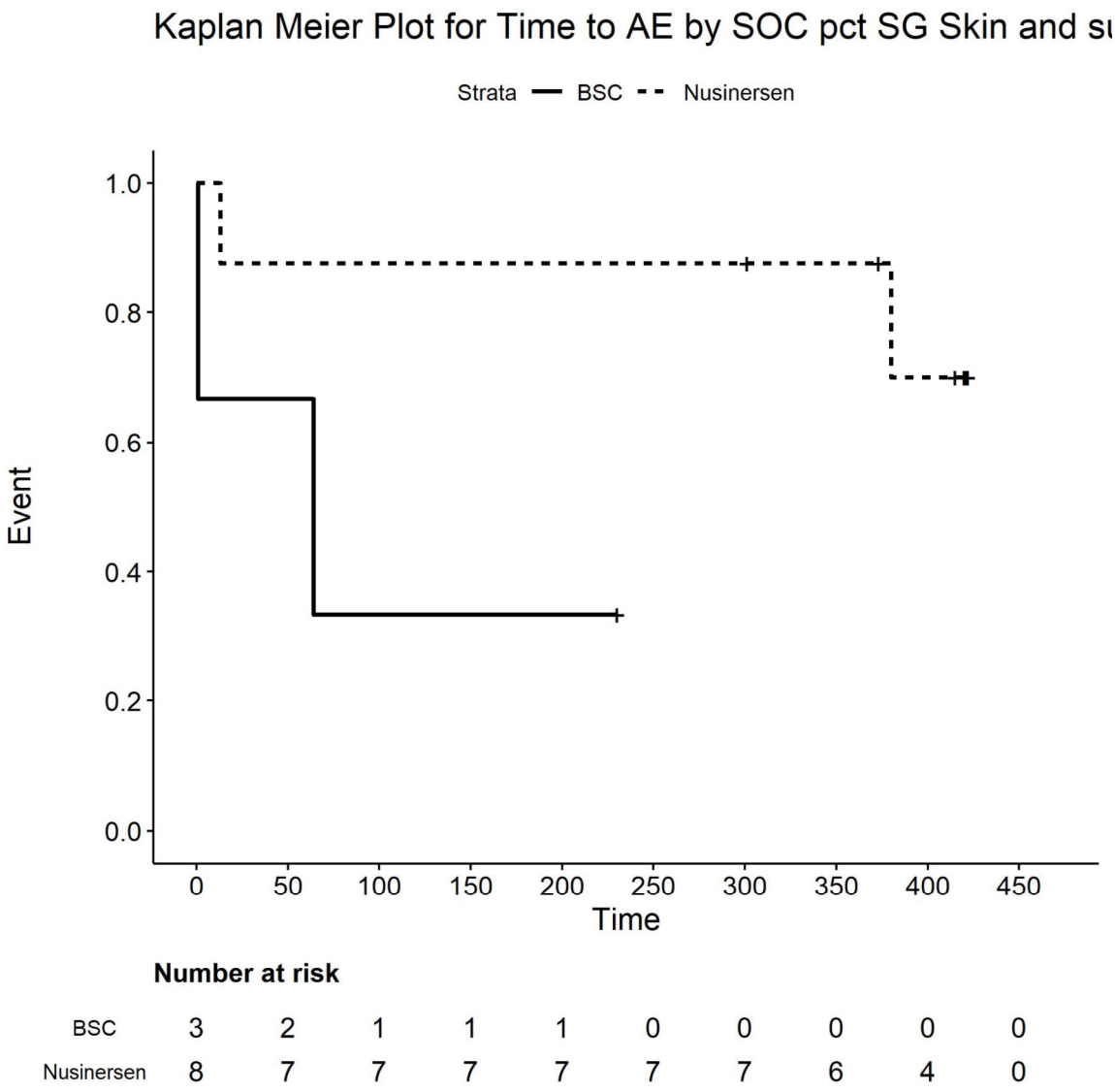
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	2	2	0



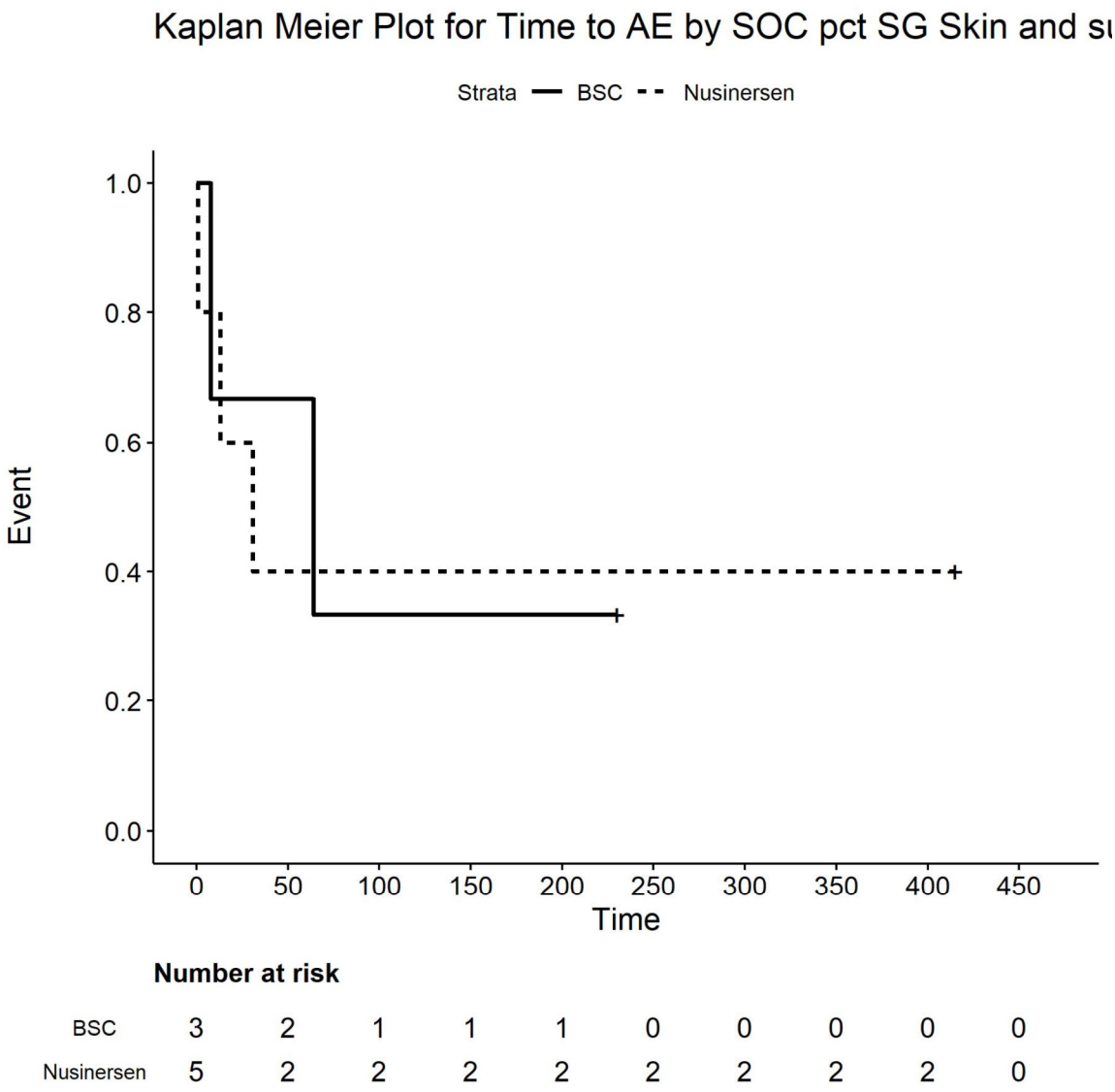
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	4	4	4	2	2	1	1	1	0



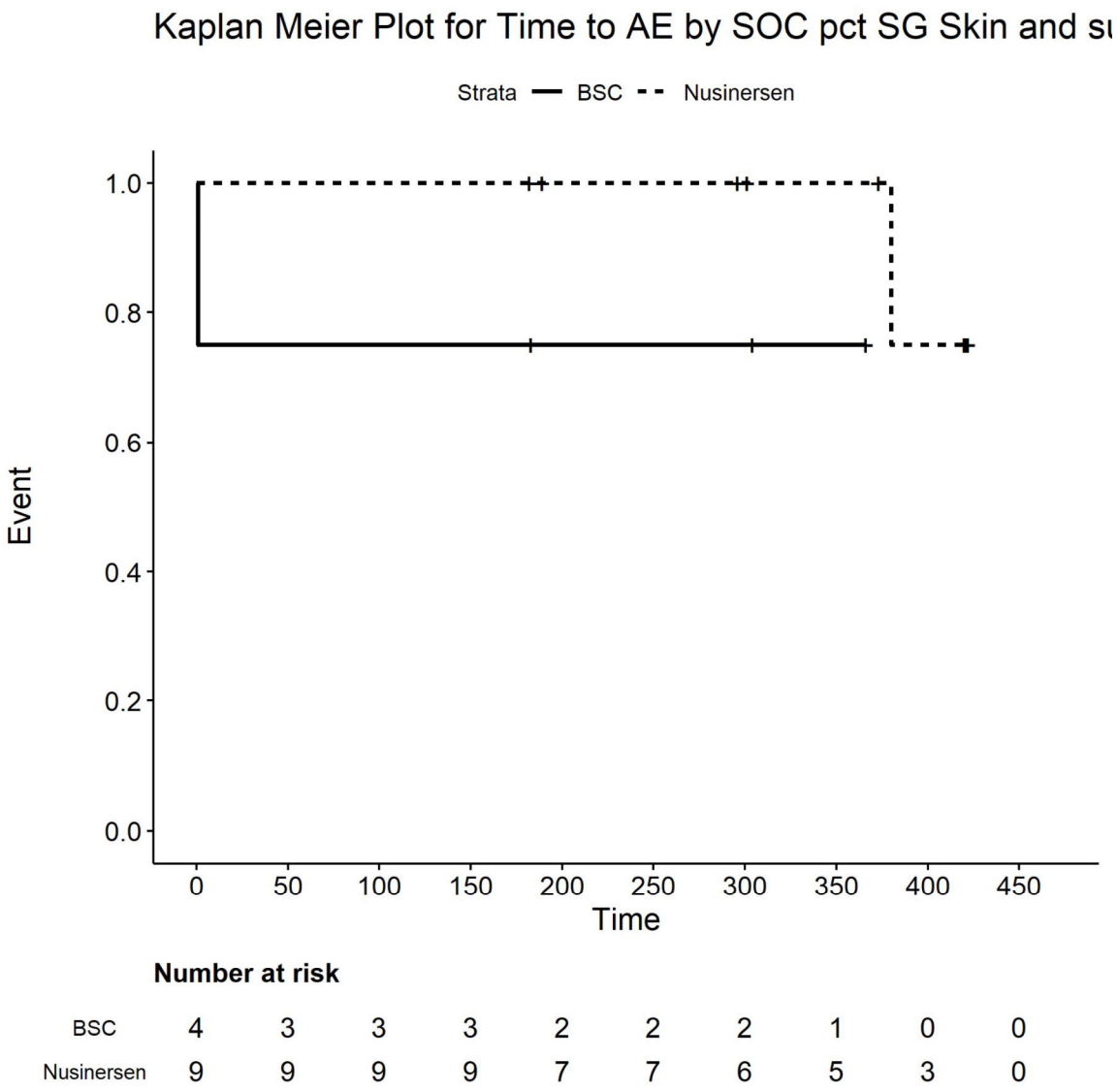
Number at risk

BSC	3	2	1	1	1	0	0	0	0	0
Nusinersen	8	7	7	7	7	7	7	6	4	0



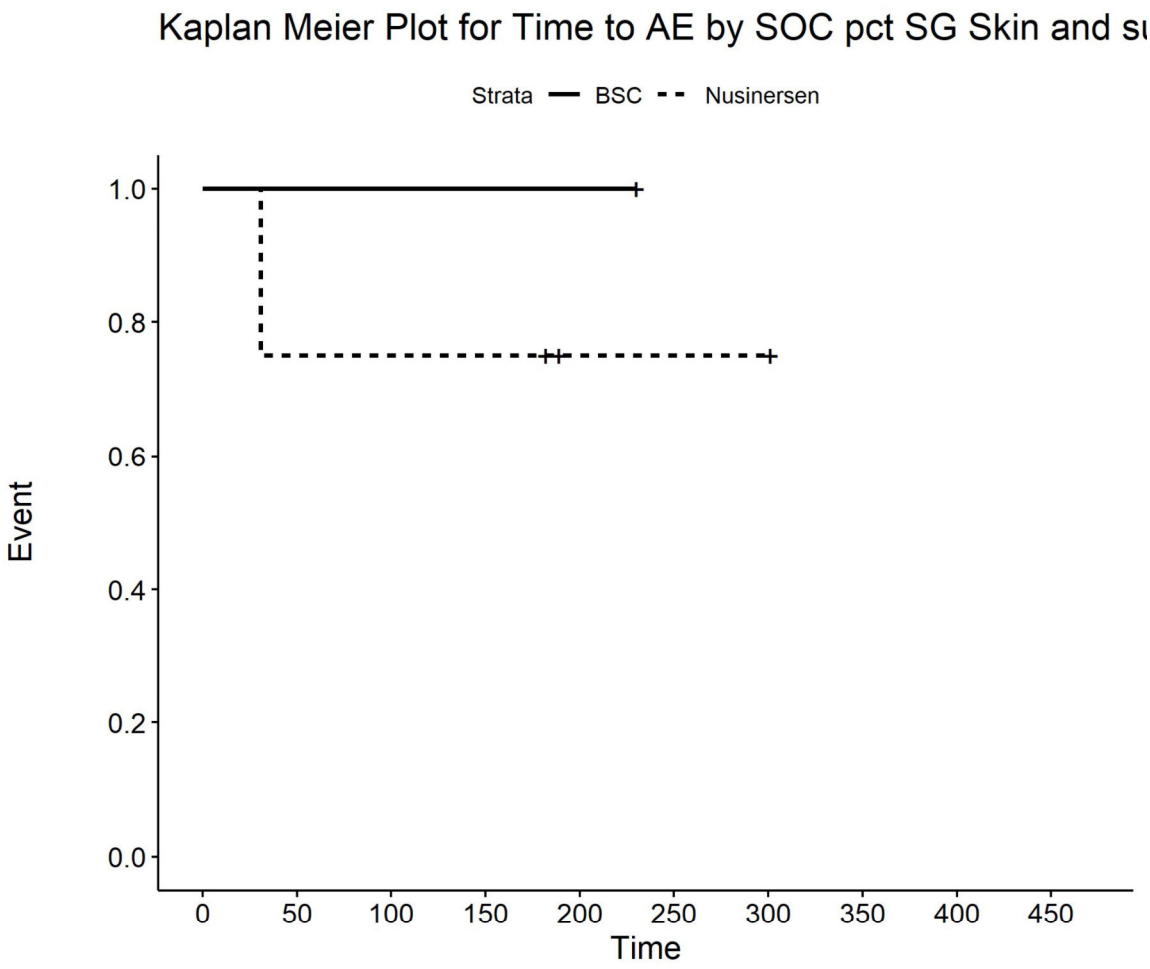
Number at risk

BSC	3	2	1	1	1	0	0	0	0	0
Nusinersen	5	2	2	2	2	2	2	2	2	0



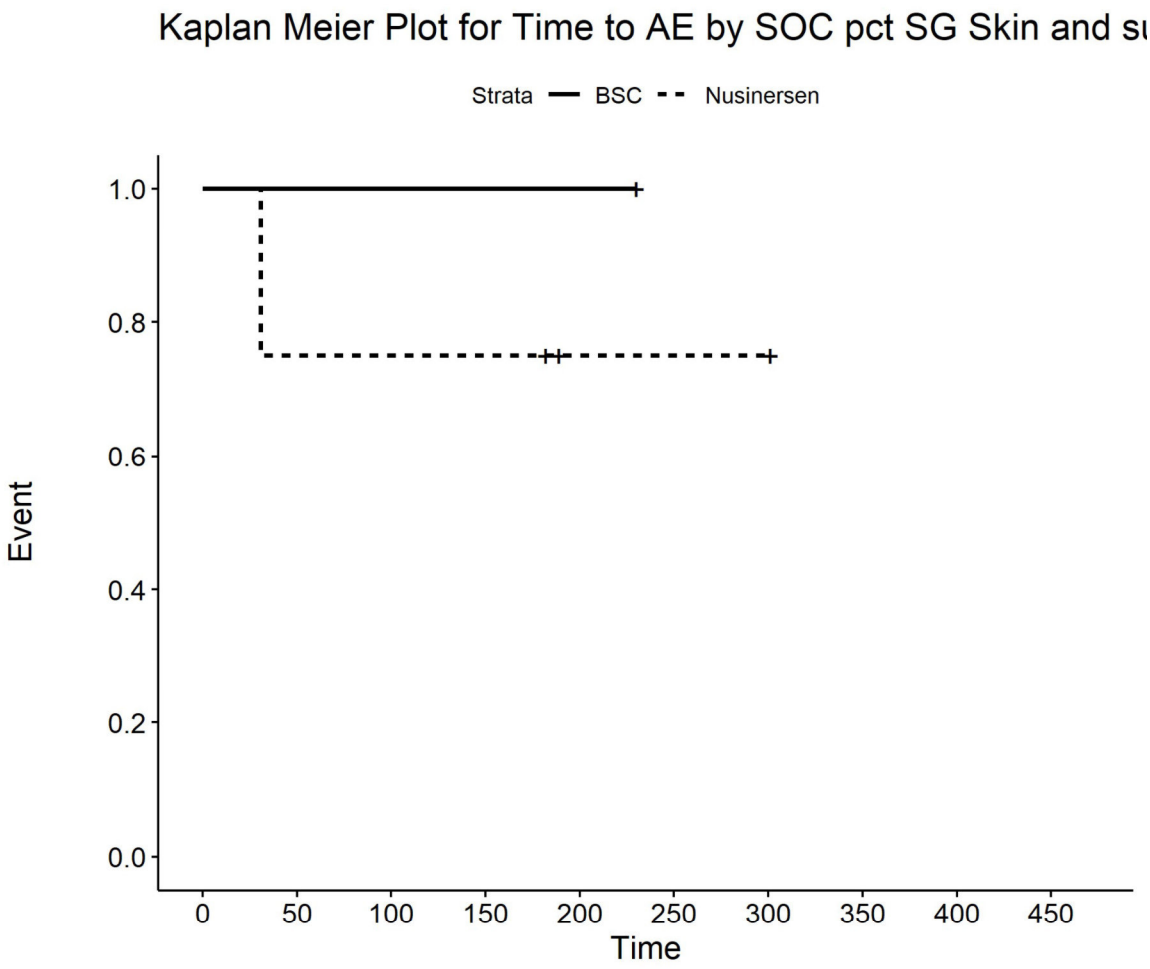
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	3	0



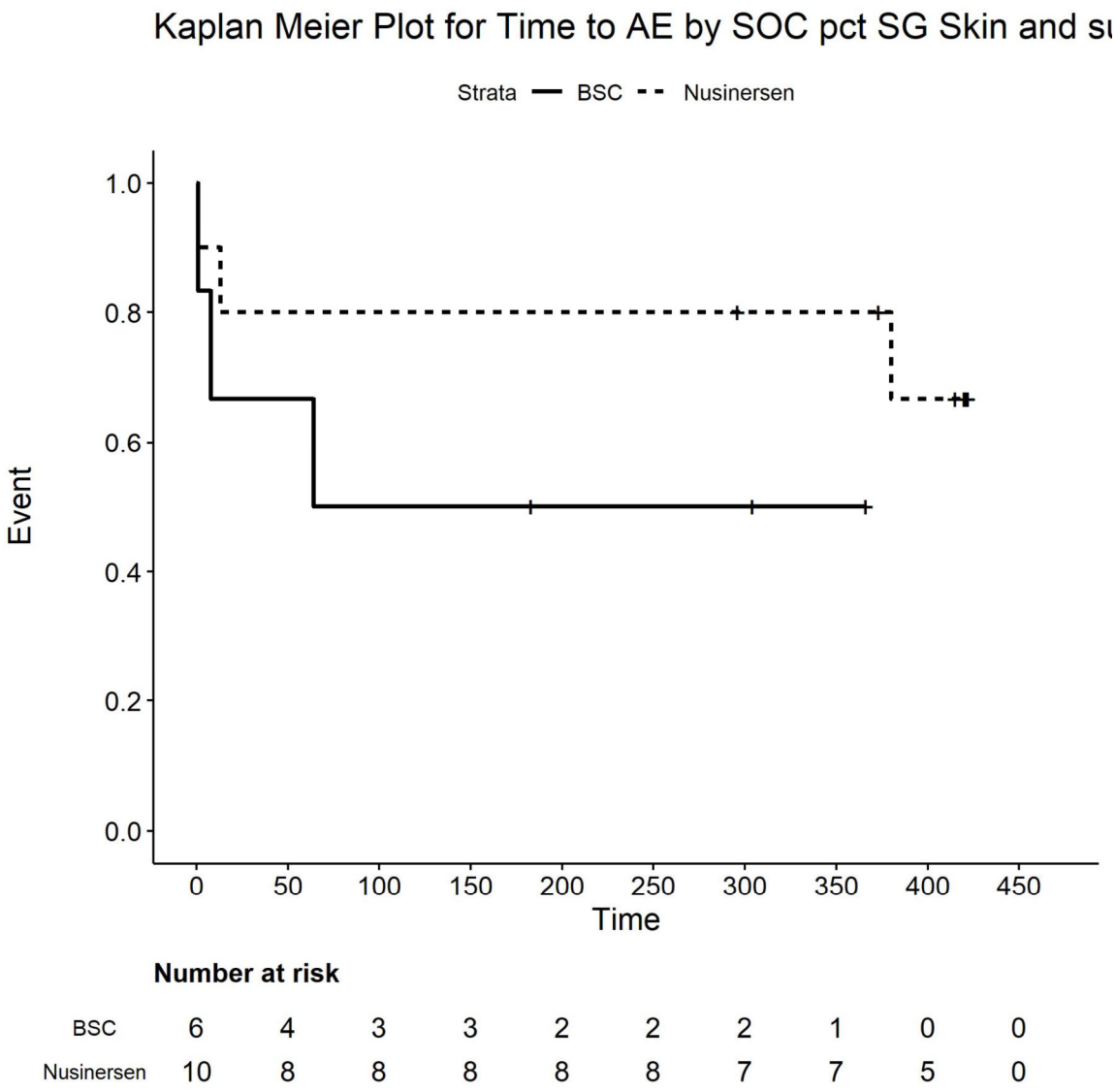
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



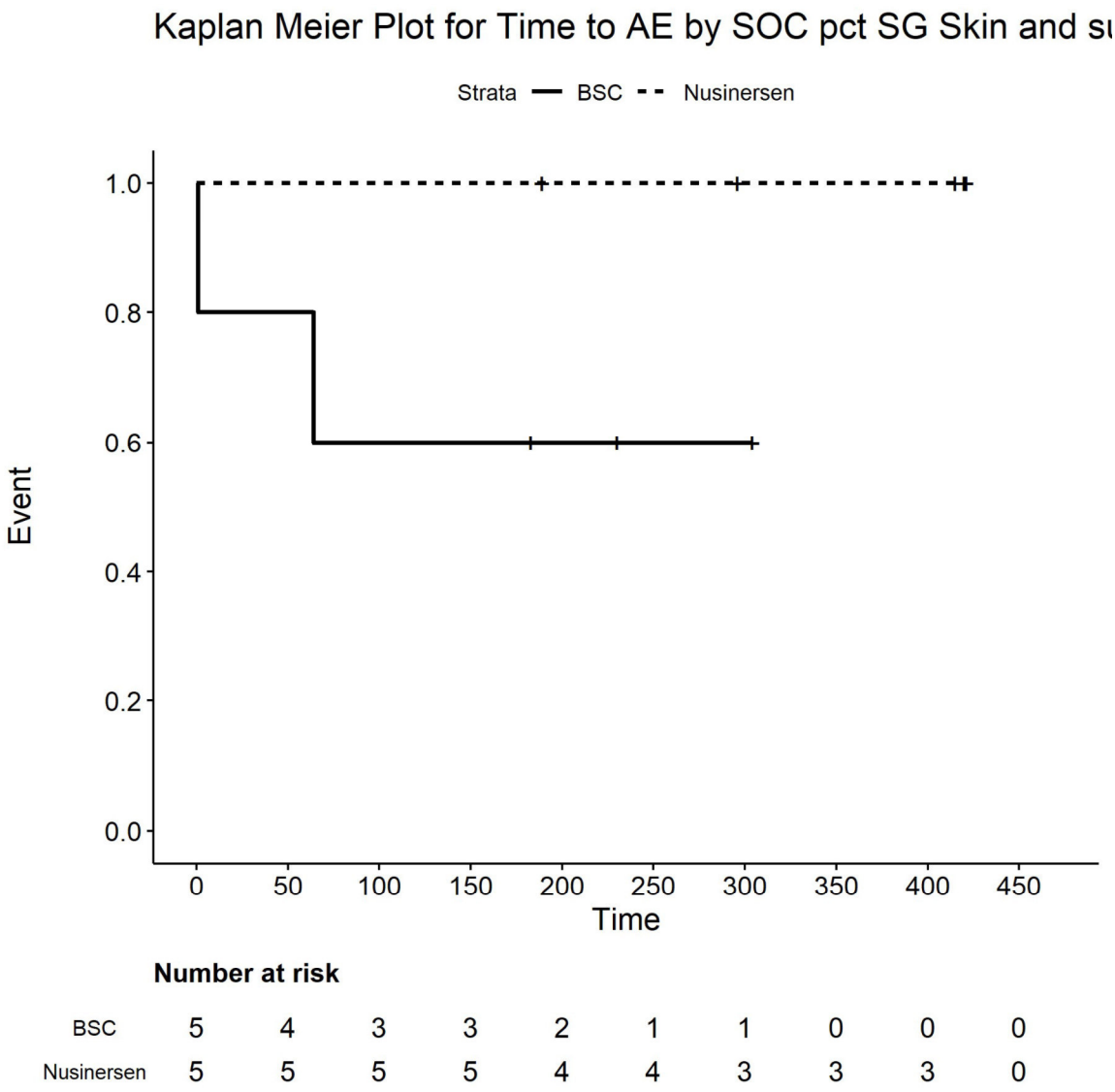
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



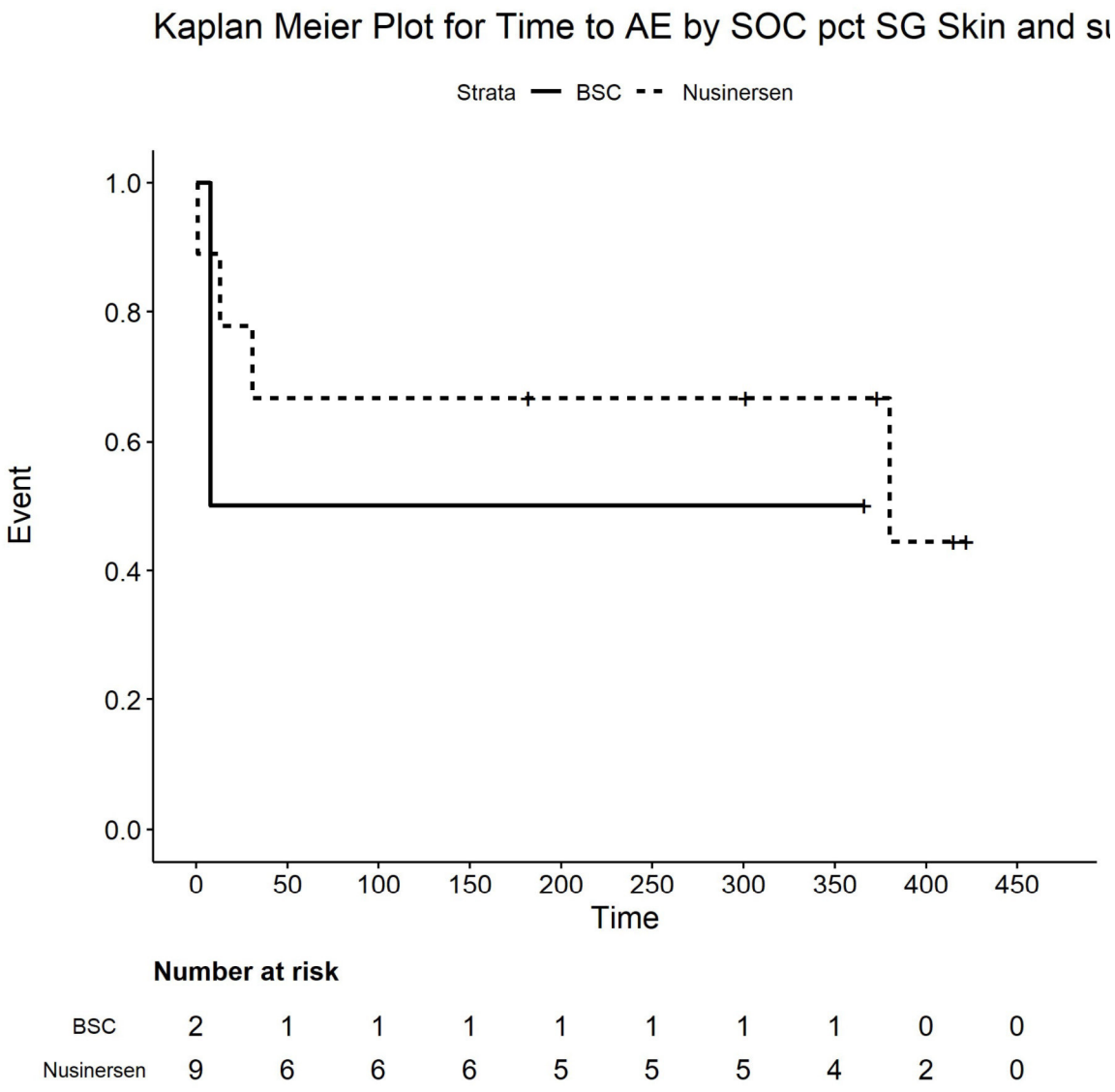
Number at risk

BSC	6	4	3	3	2	2	2	1	0	0
Nusinersen	10	8	8	8	8	8	7	7	5	0



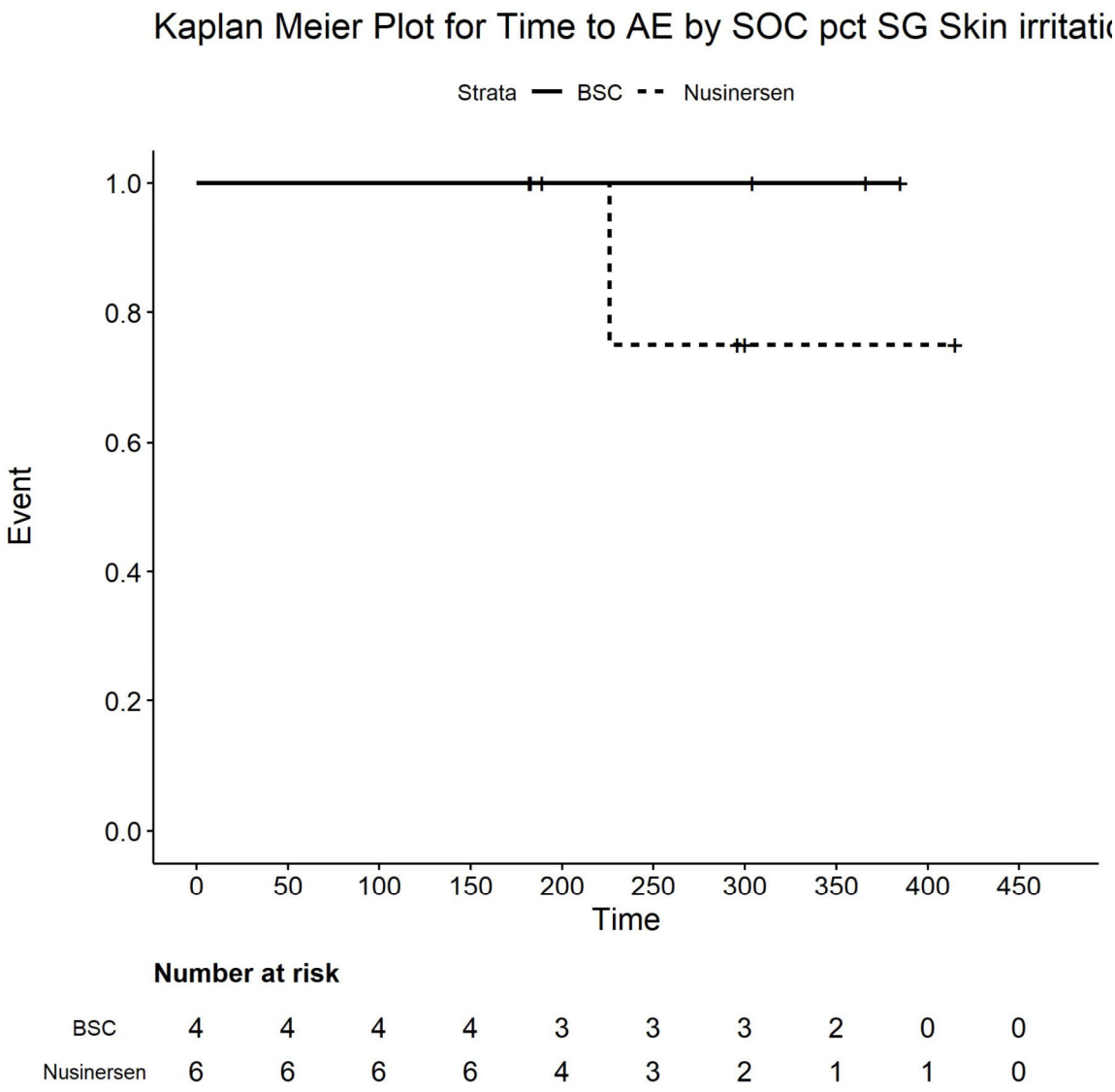
Number at risk

BSC	5	4	3	3	2	1	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



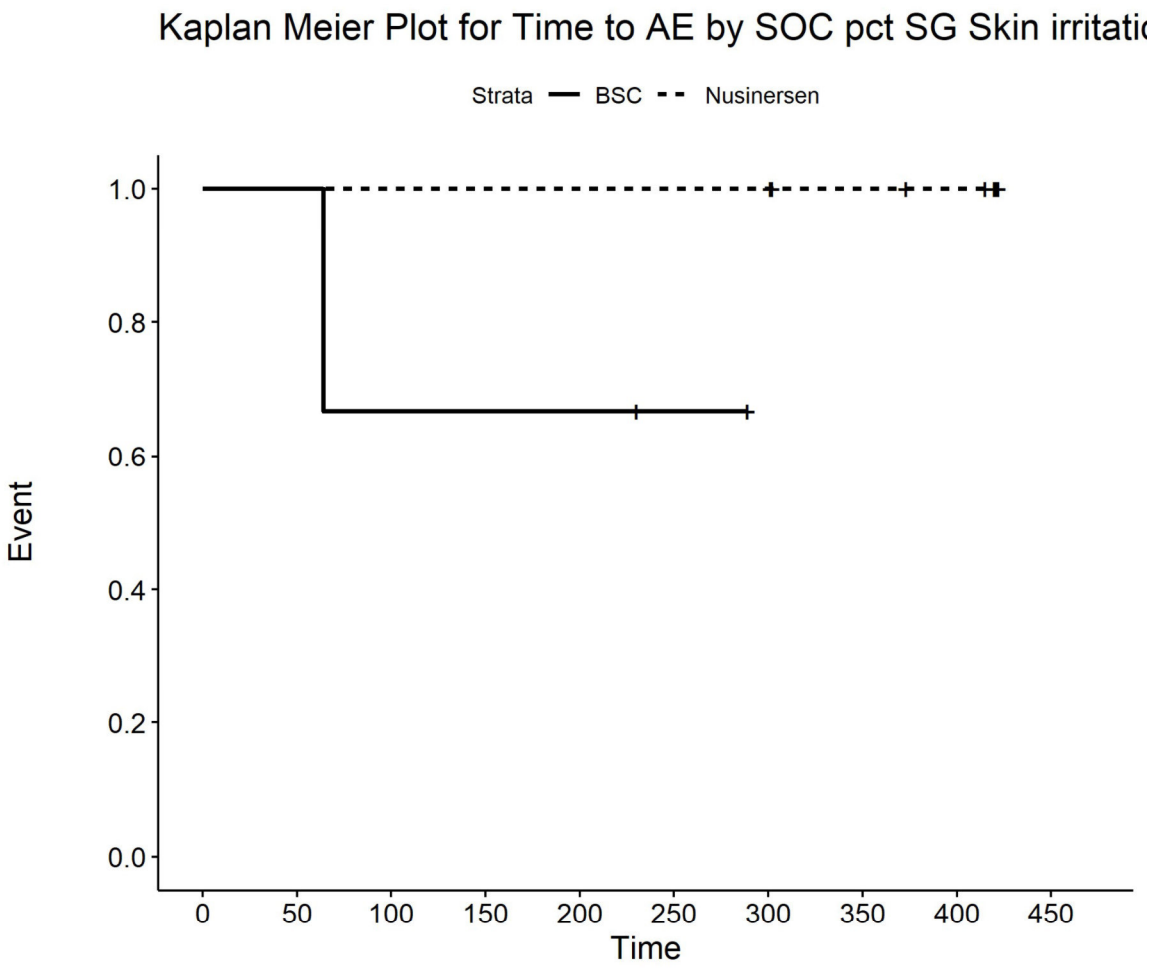
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	6	6	6	5	5	5	4	2	0



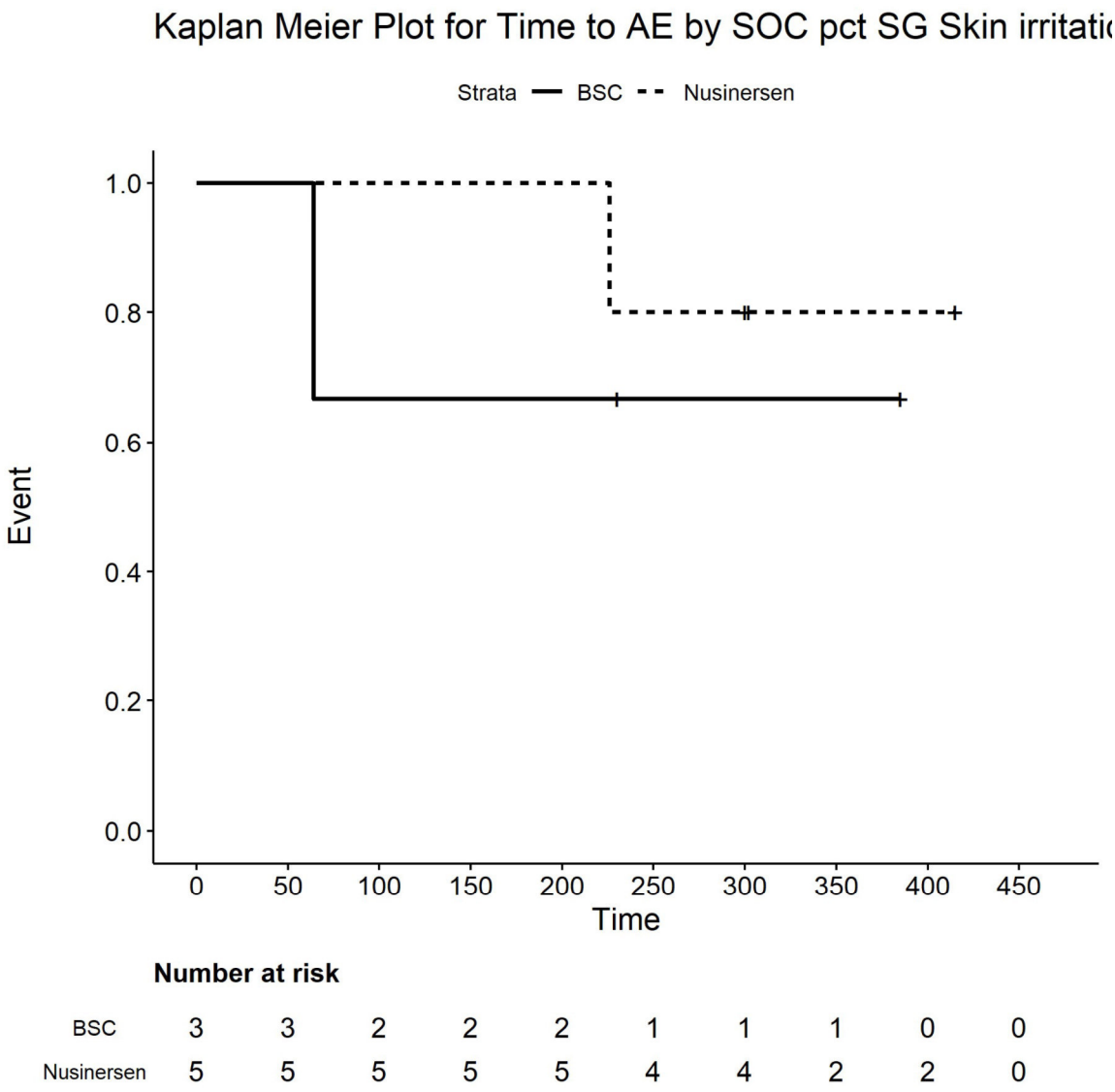
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	6	4	3	2	1	1	0



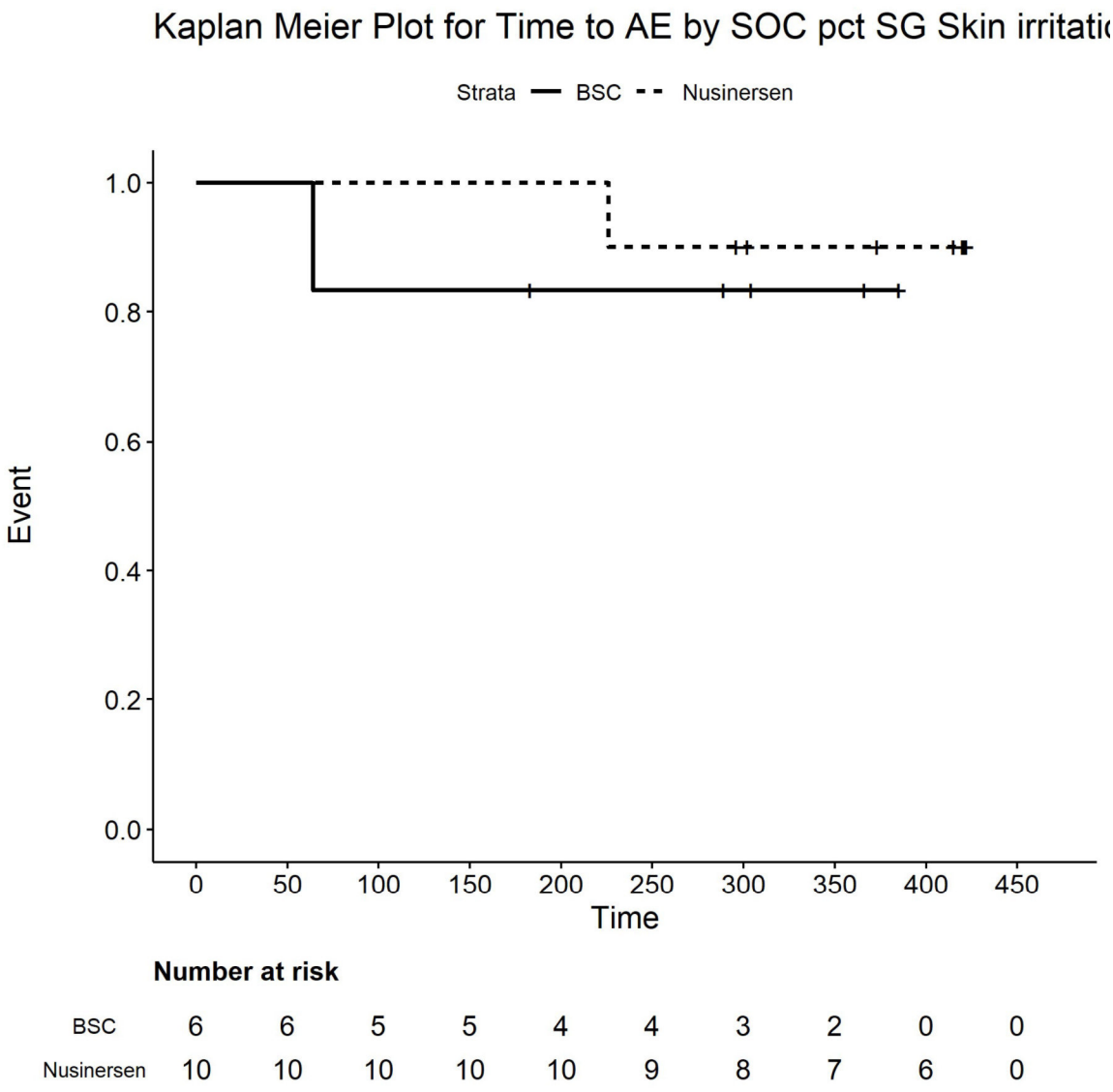
Number at risk

BSC	3	3	2	2	2	1	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



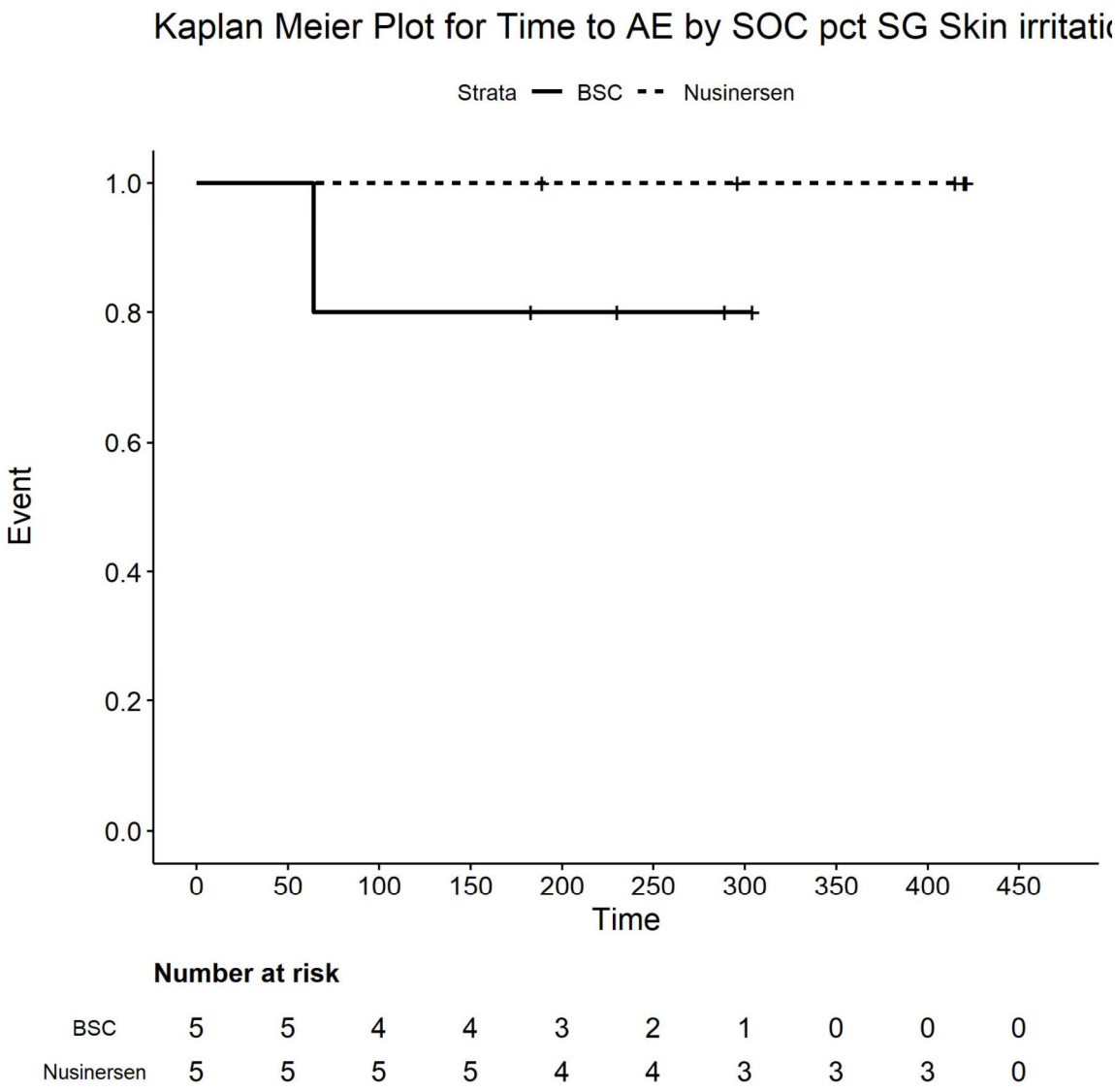
Number at risk

BSC	3	3	2	2	2	1	1	1	0	0
Nusinersen	5	5	5	5	5	4	4	2	2	0



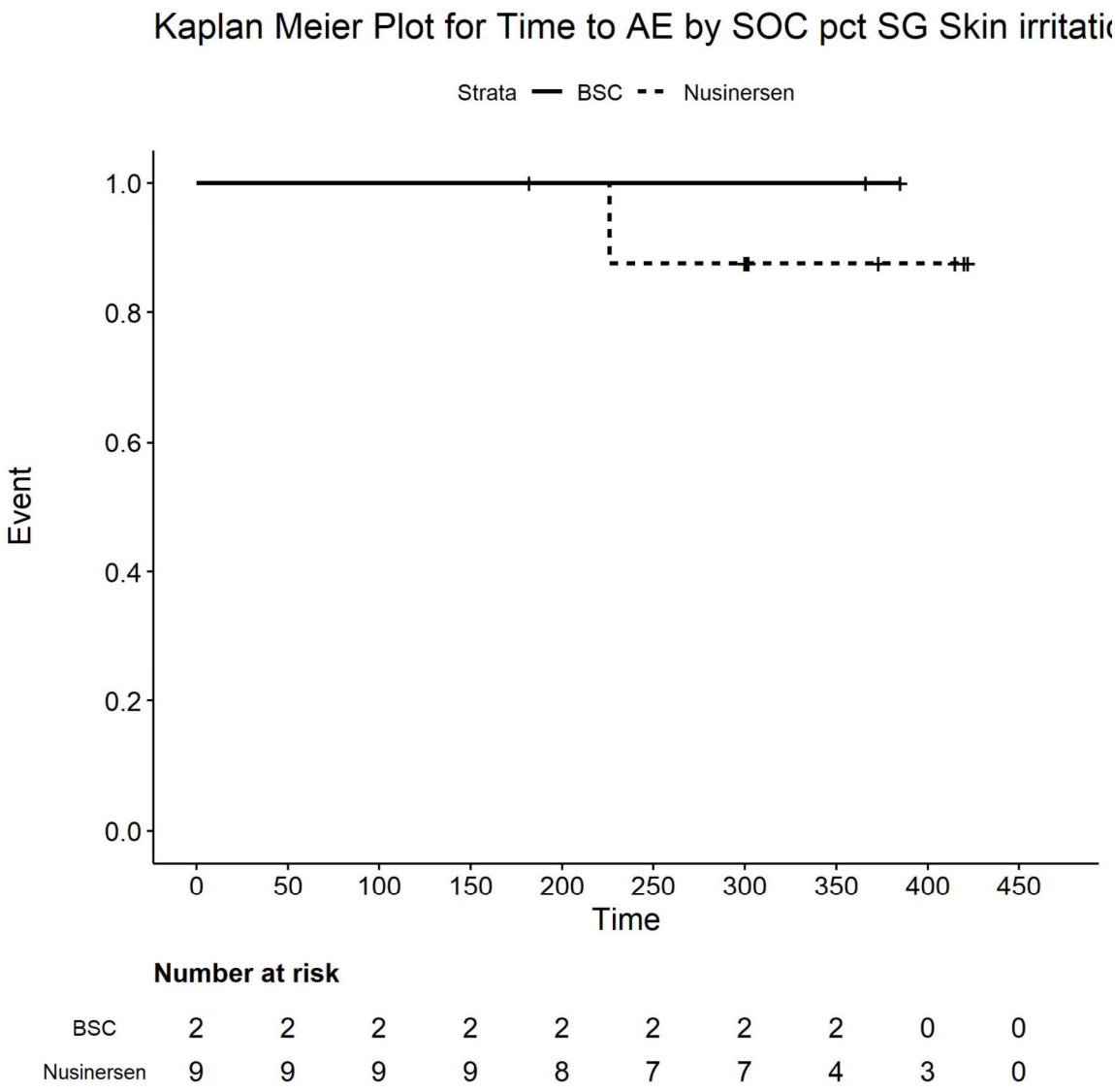
Number at risk

BSC	6	6	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	9	8	7	6	0



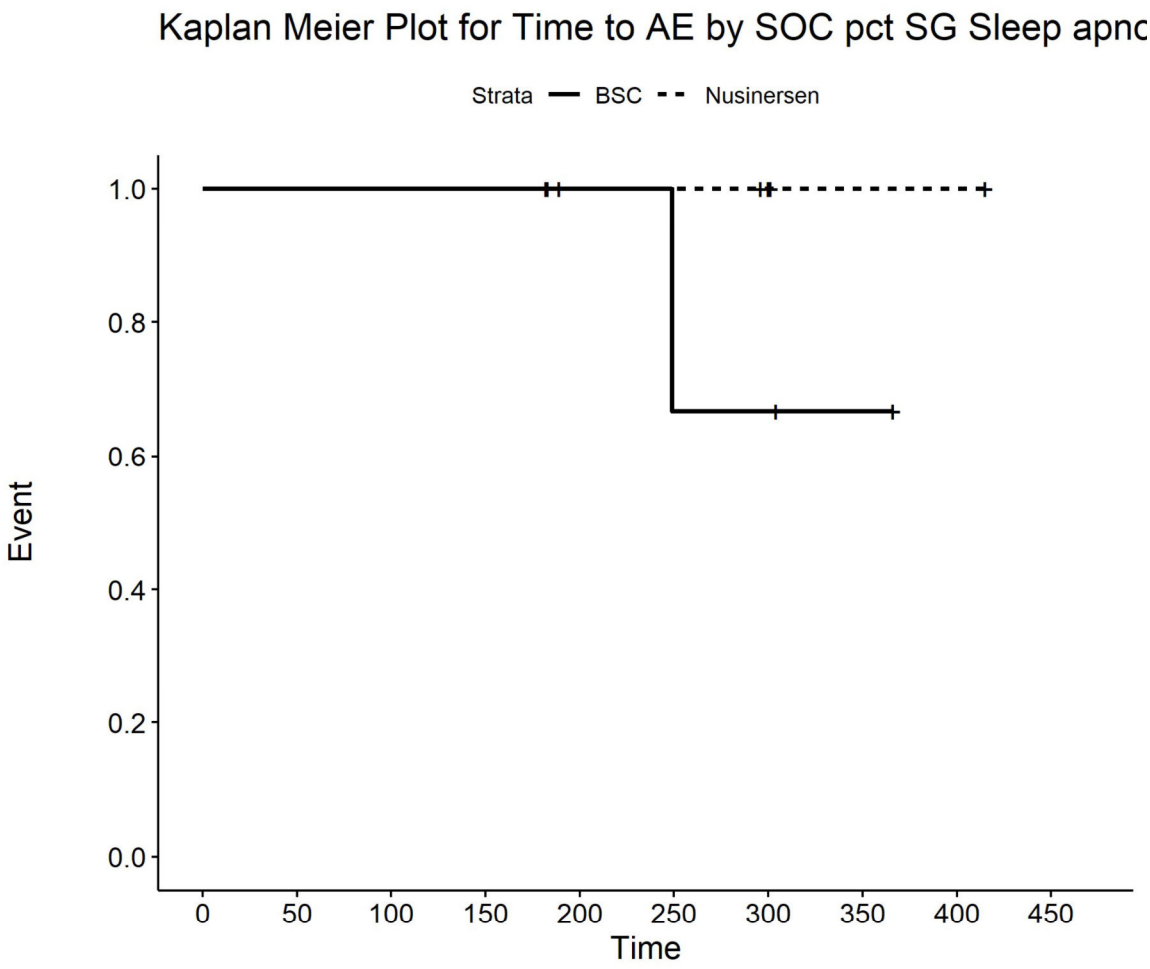
Number at risk

BSC	5	5	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



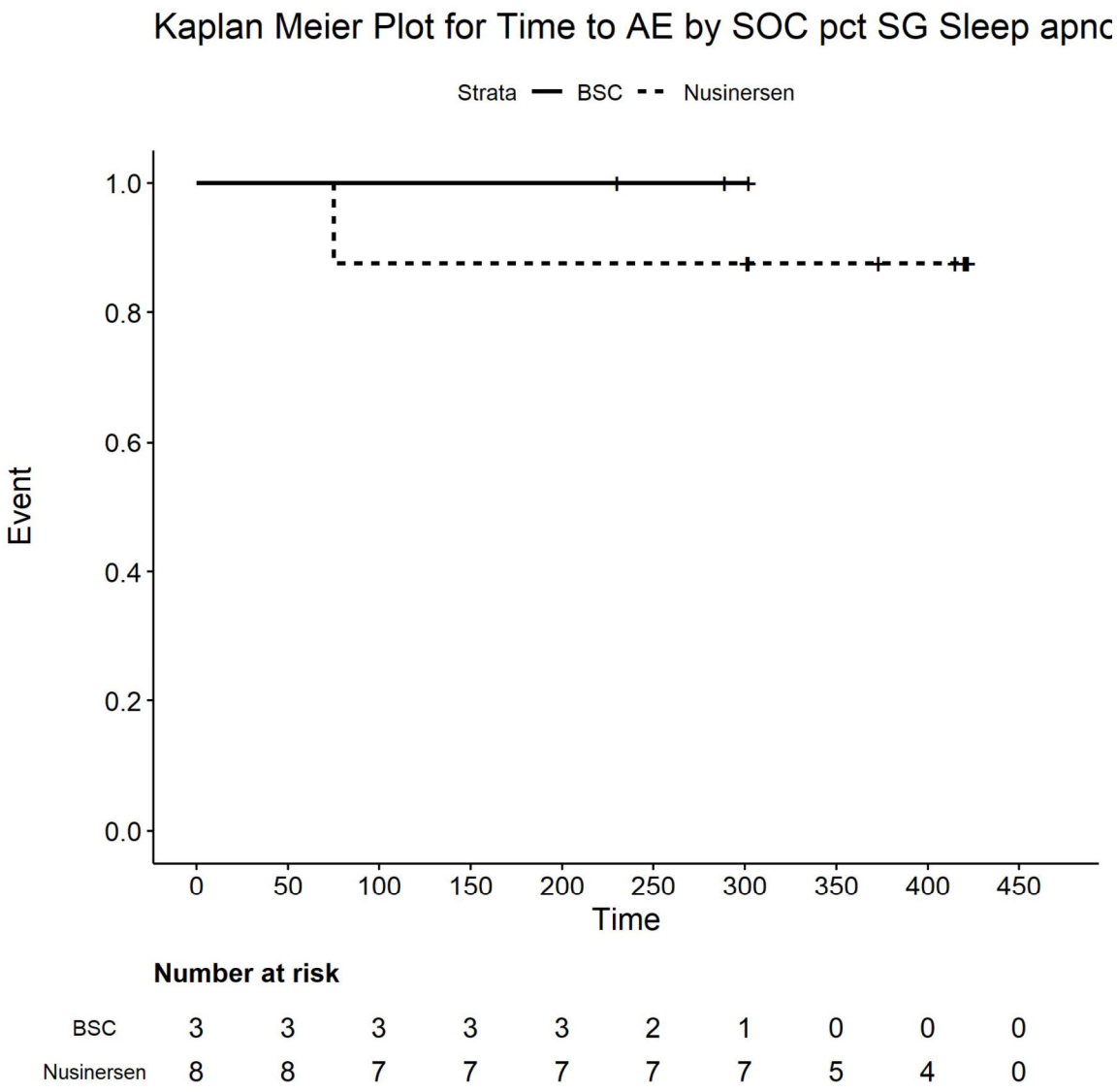
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	4	3	0



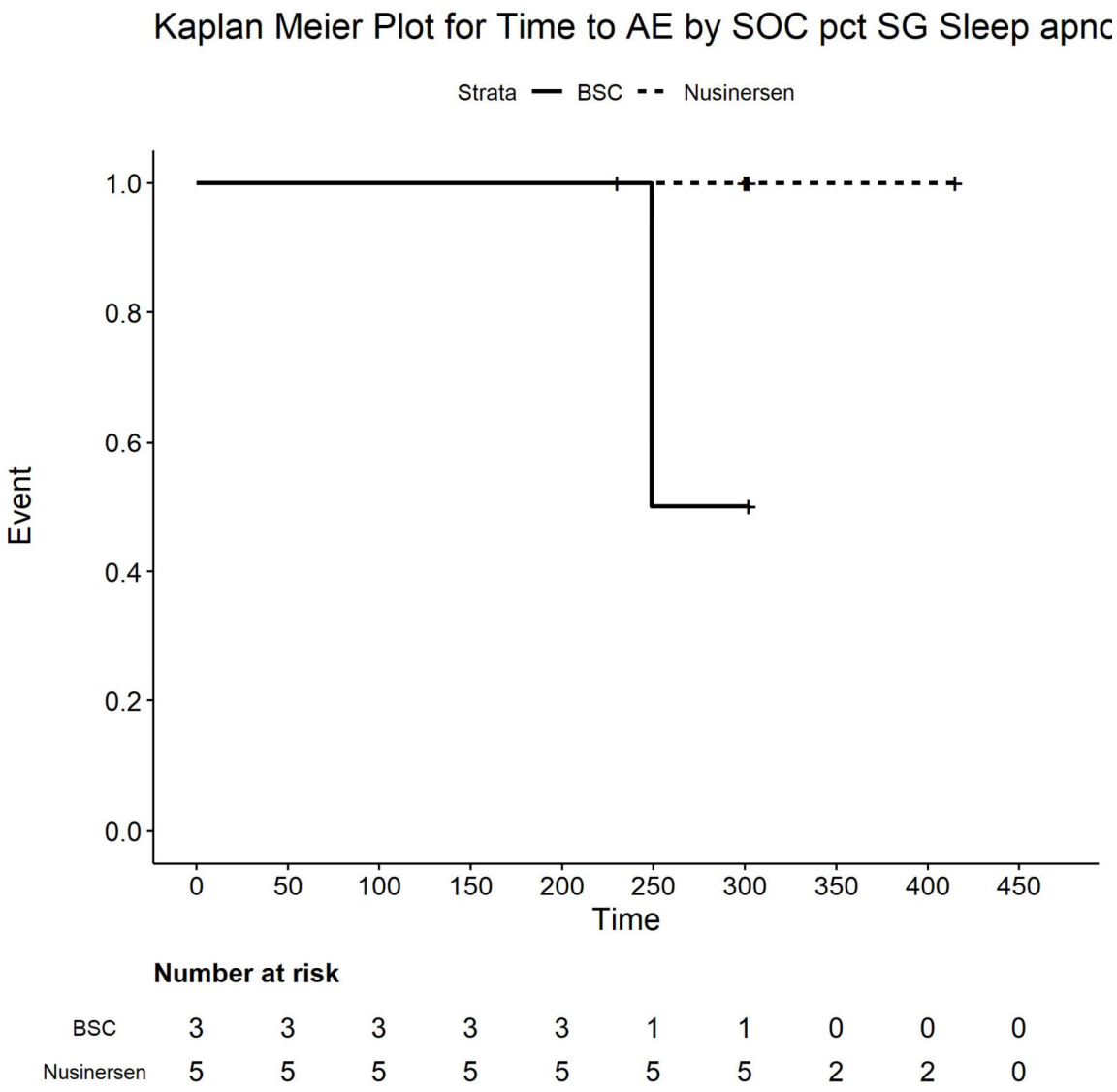
Number at risk

BSC	4	4	4	4	3	2	2	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



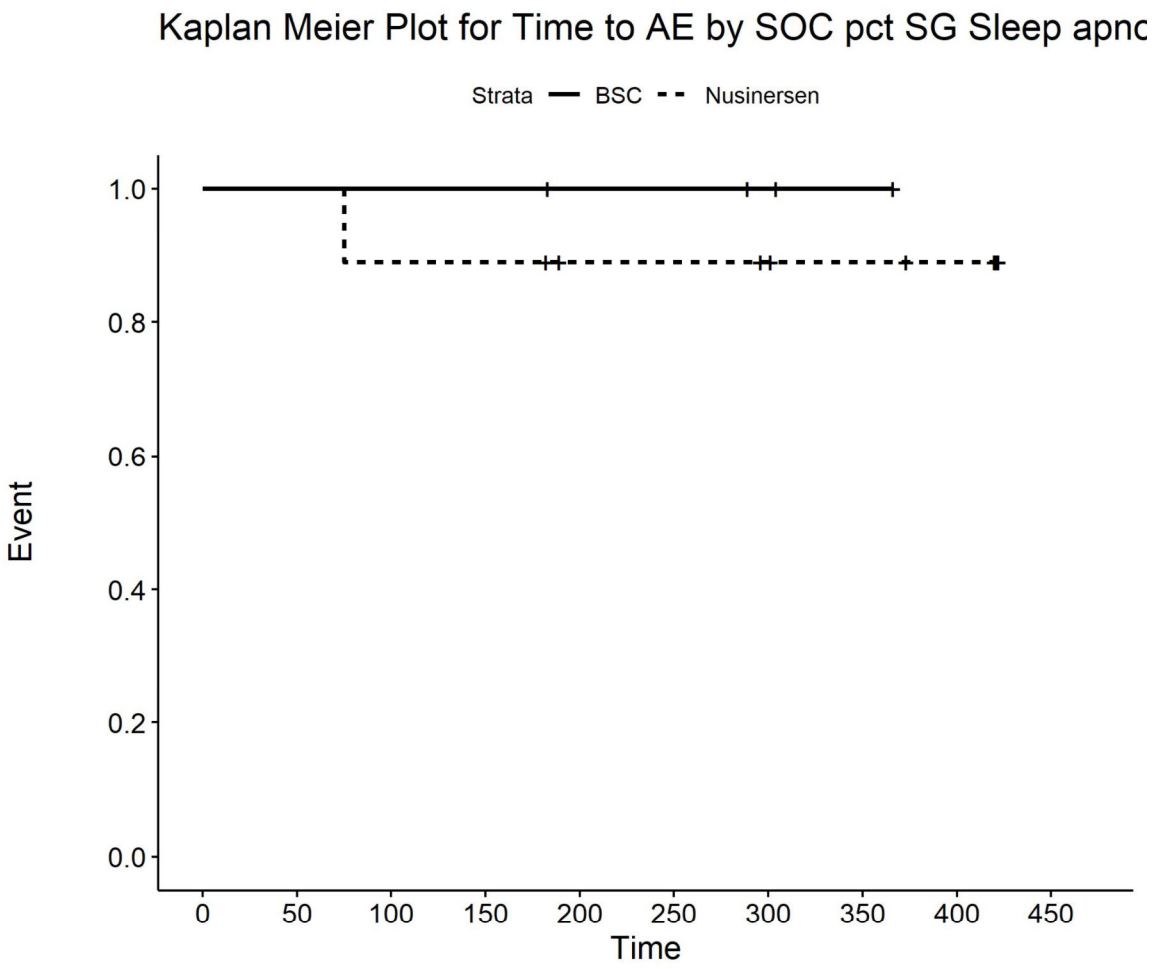
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	4	0



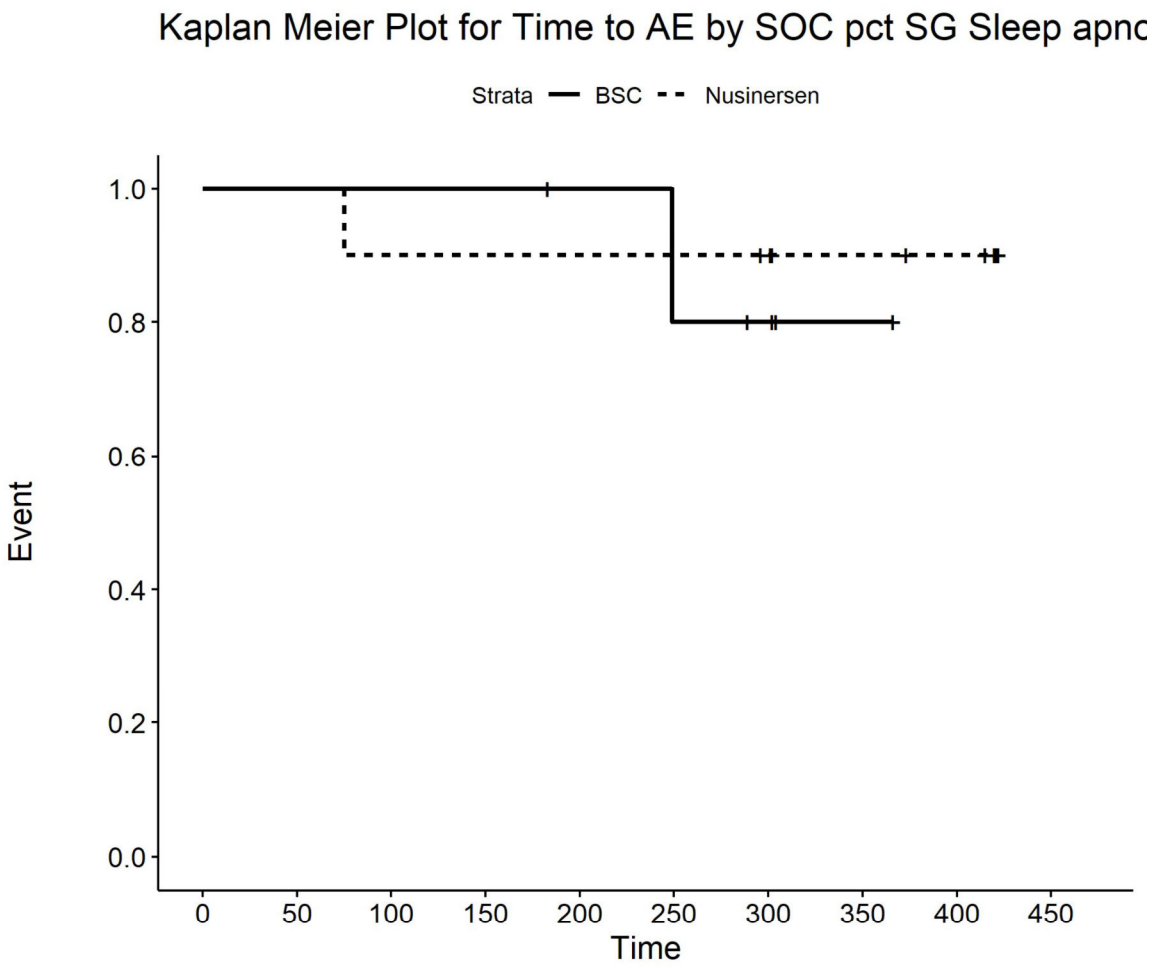
Number at risk

BSC	3	3	3	3	3	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



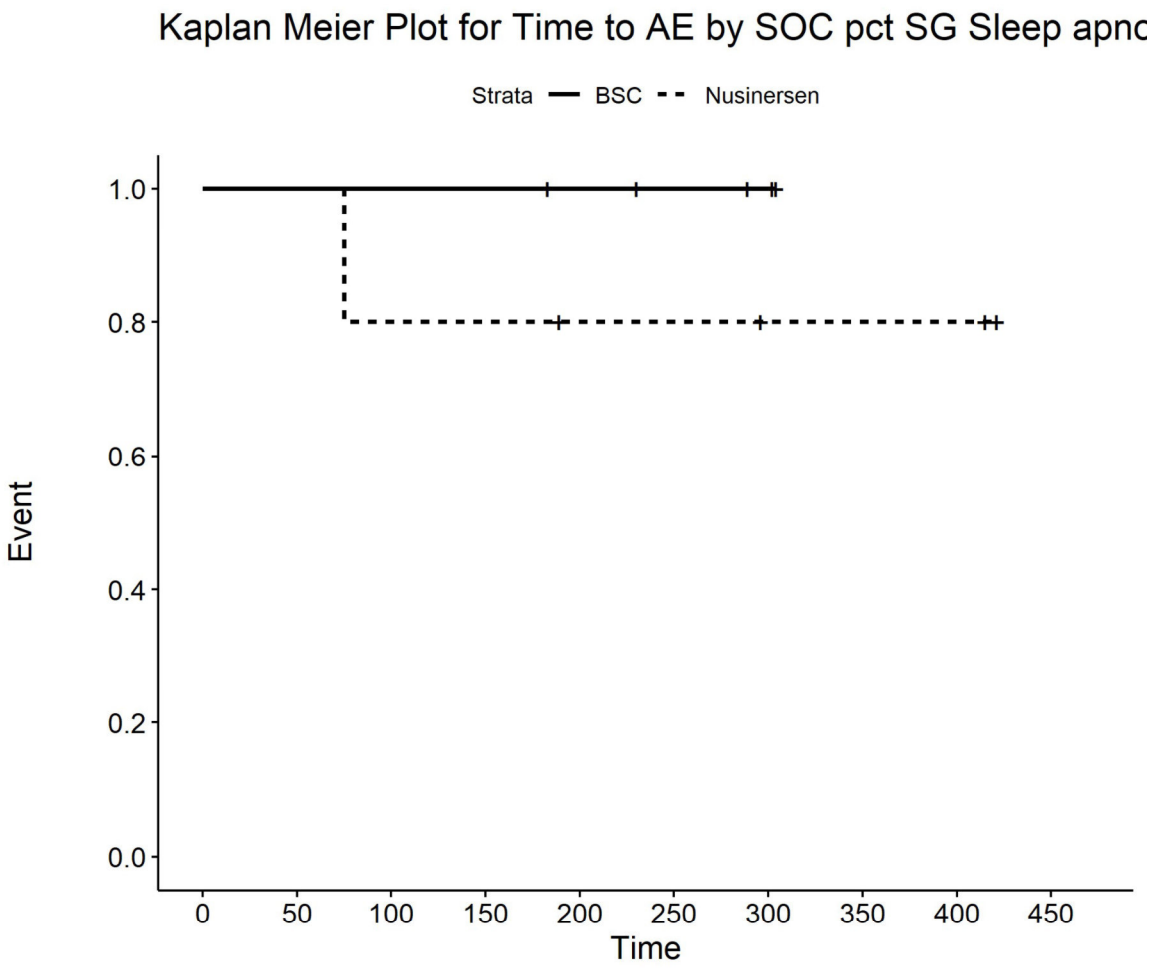
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



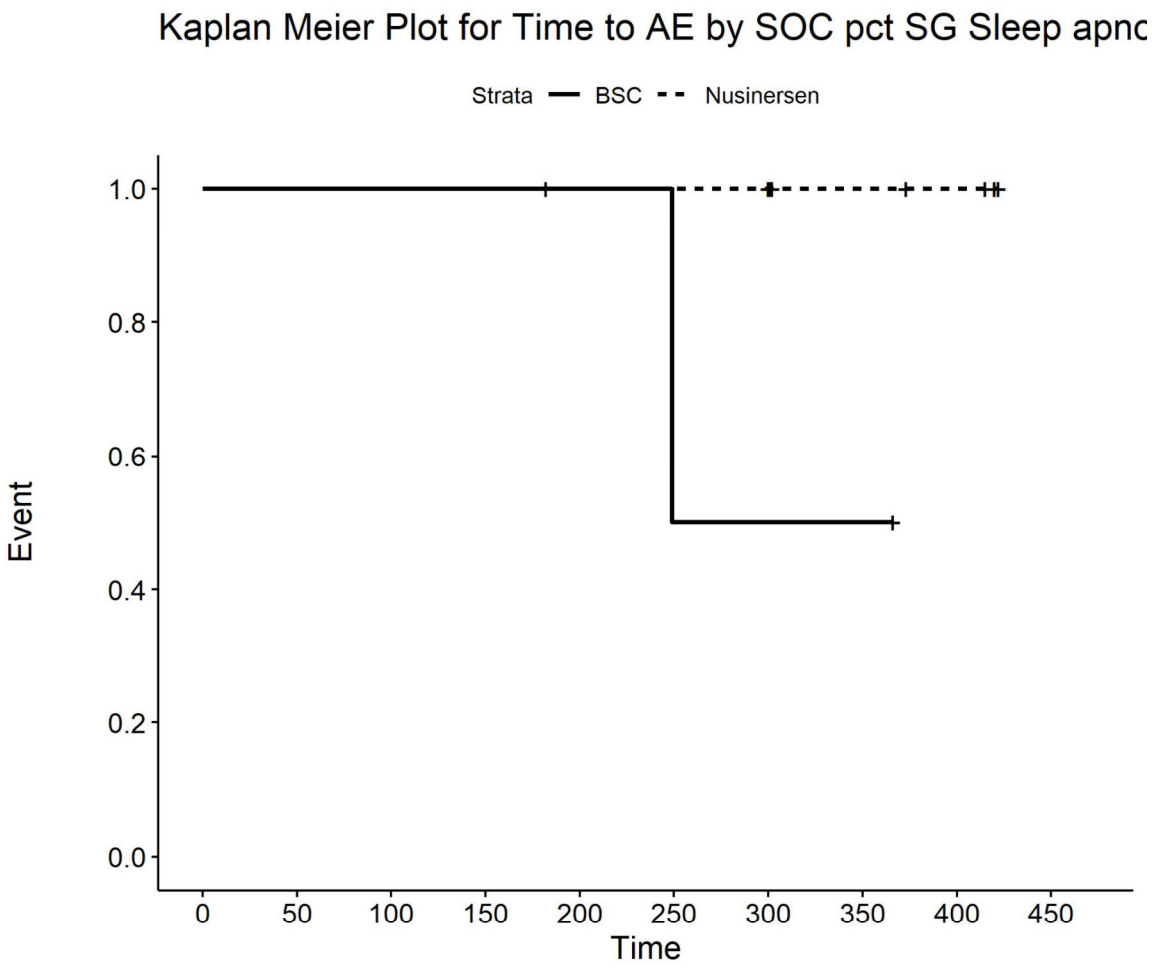
Number at risk

BSC	6	6	6	6	5	4	3	1	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



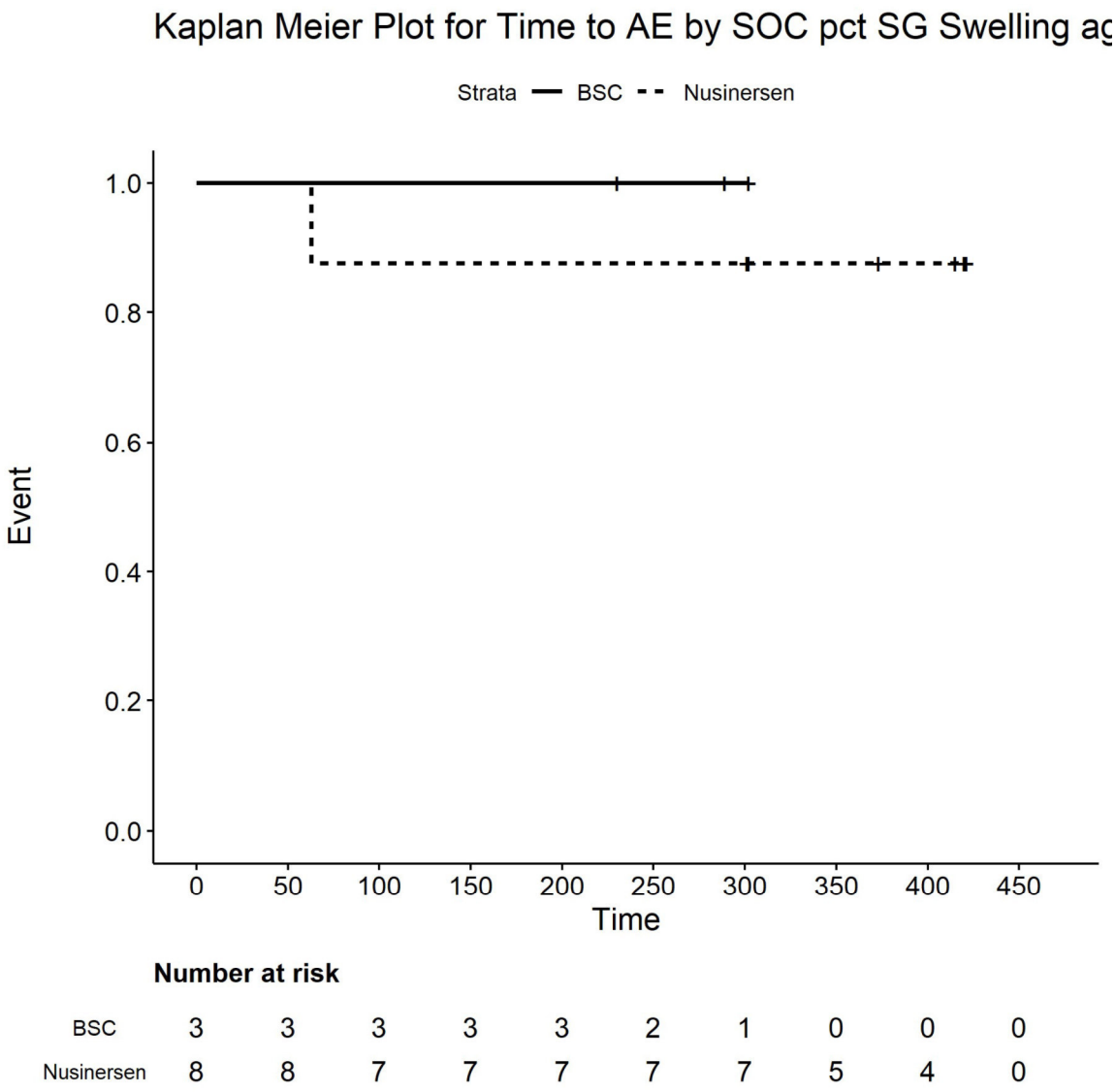
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	4	4	3	3	2	2	2	0



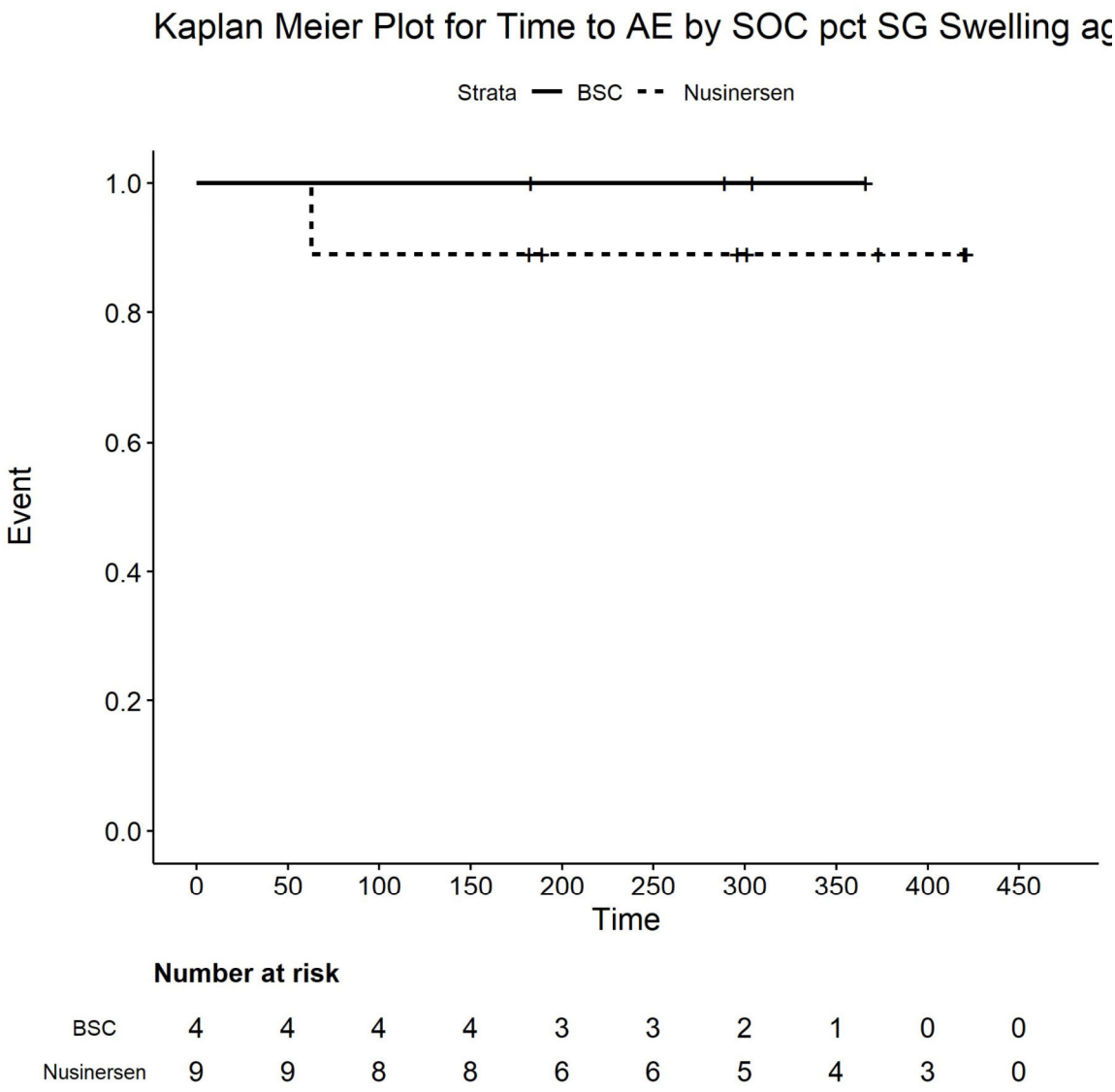
Number at risk

BSC	2	2	2	2	2	1	1	1	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



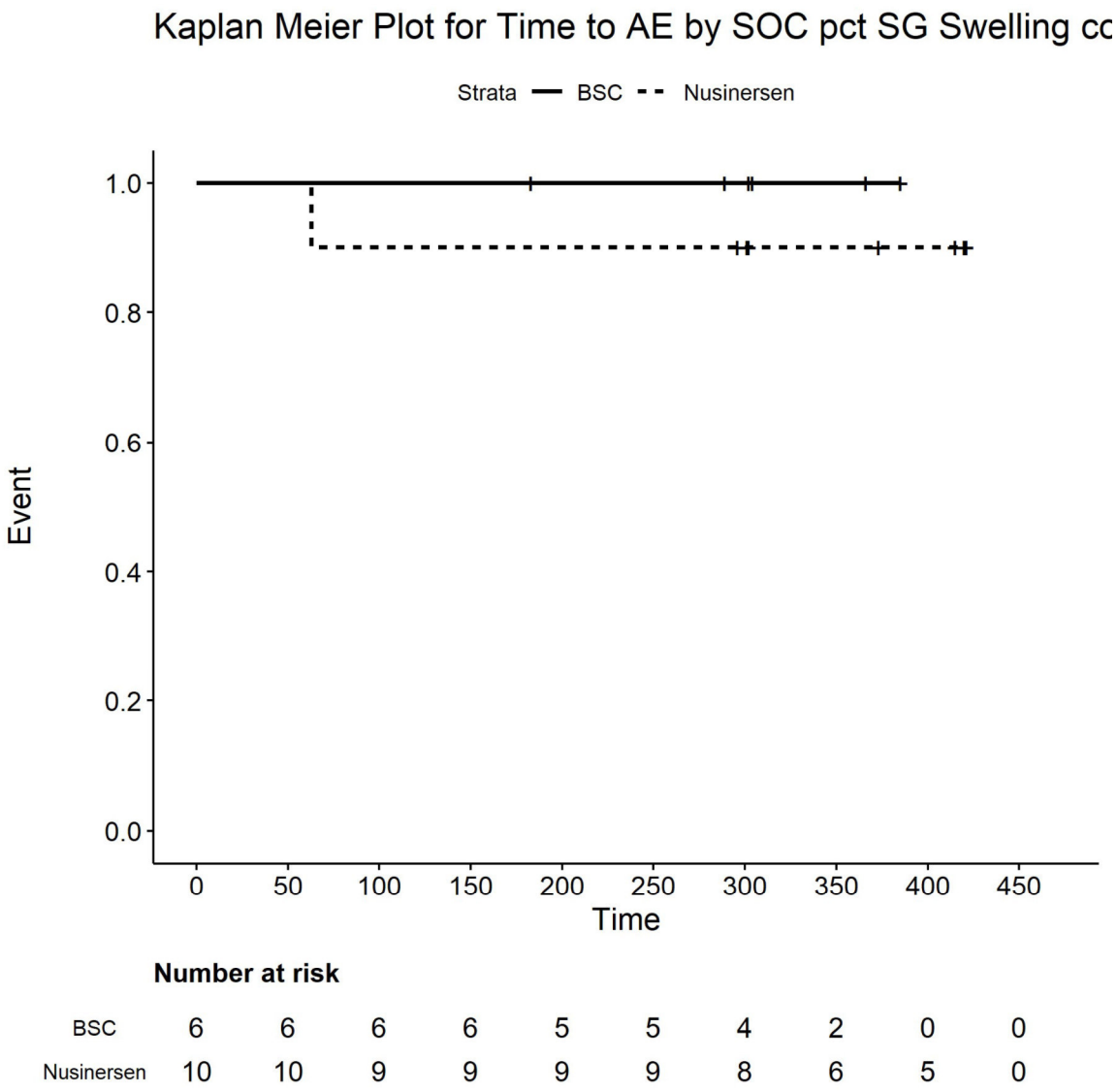
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	4	0



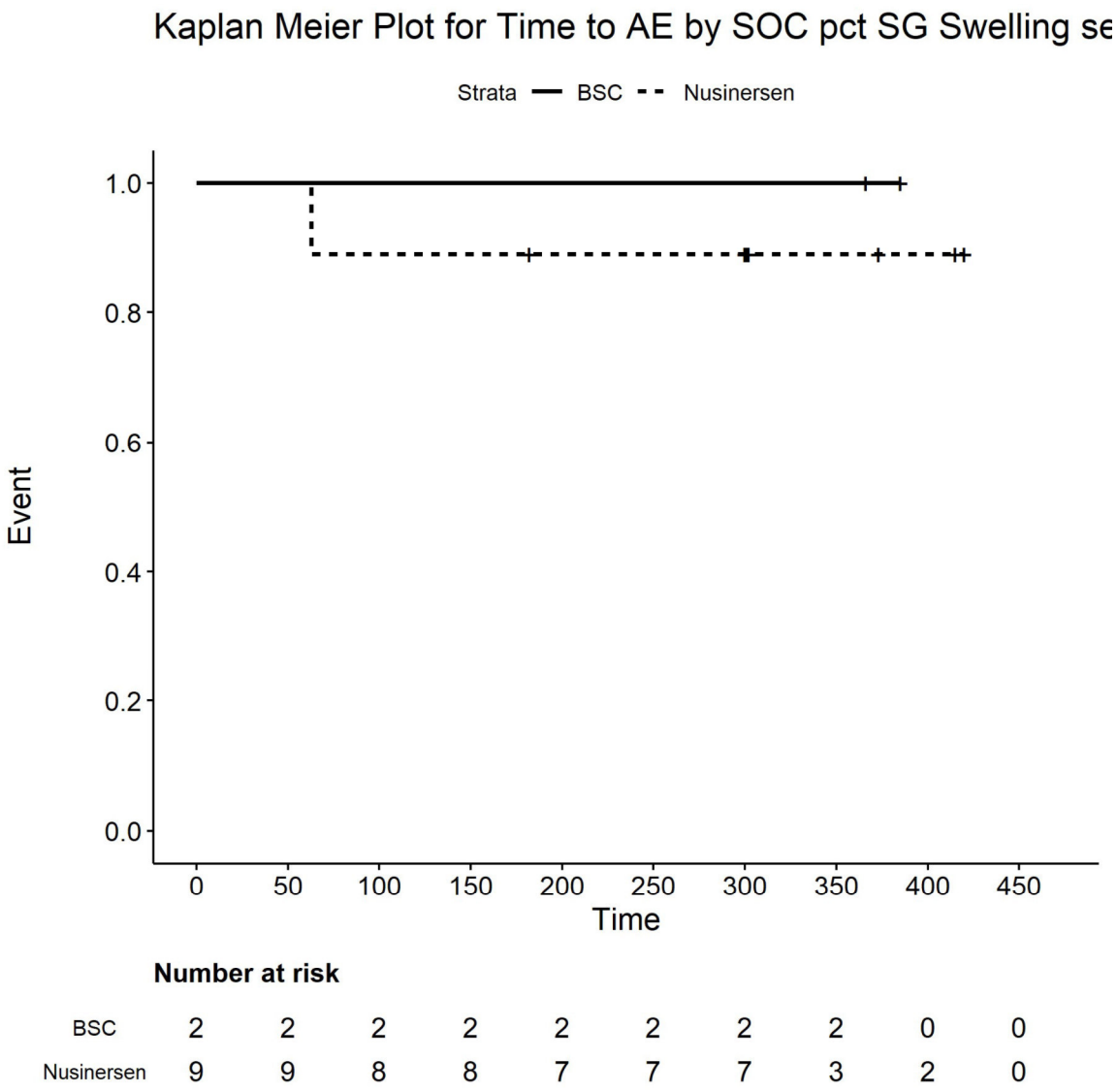
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



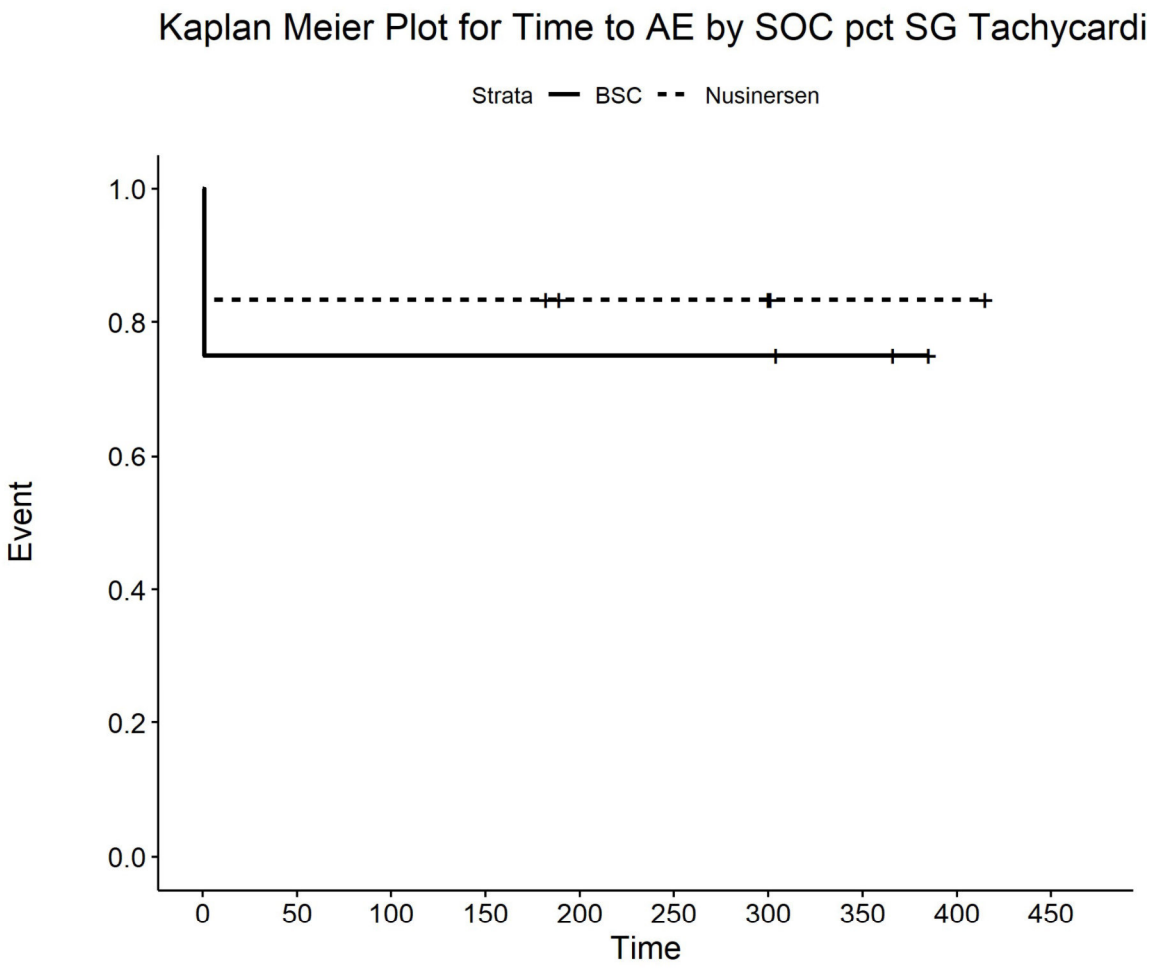
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



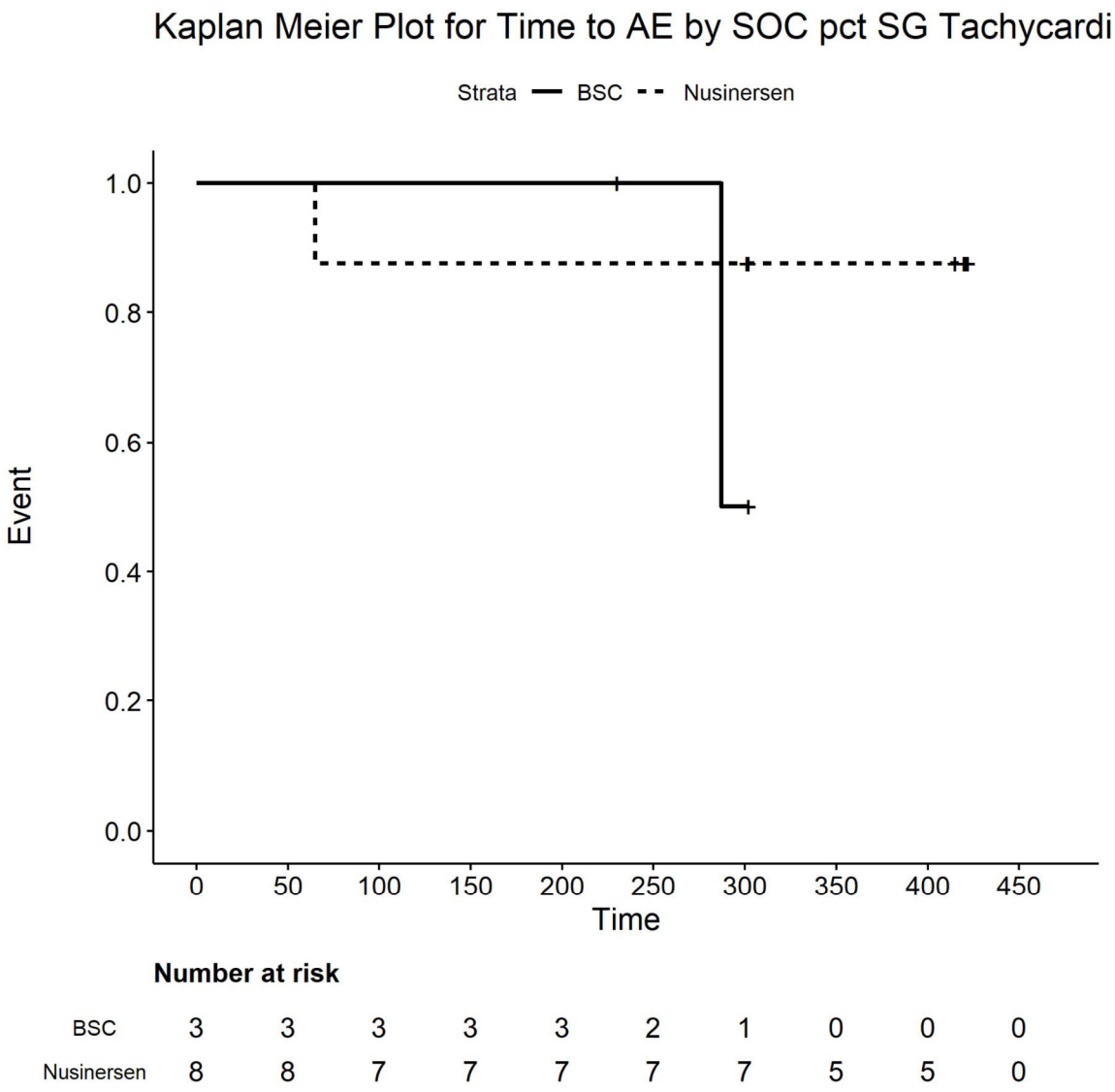
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	2	0



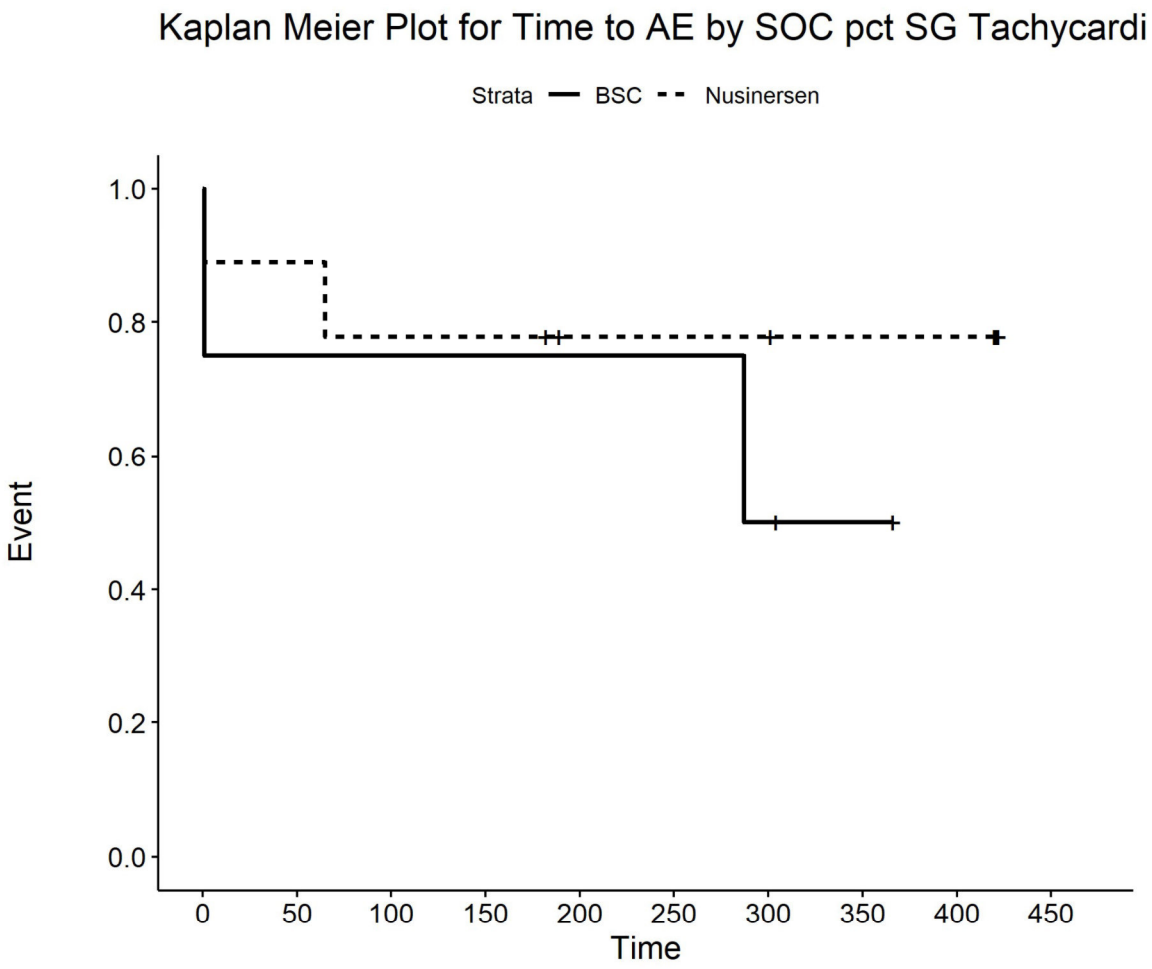
Number at risk

BSC	4	3	3	3	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	3	1	1	0



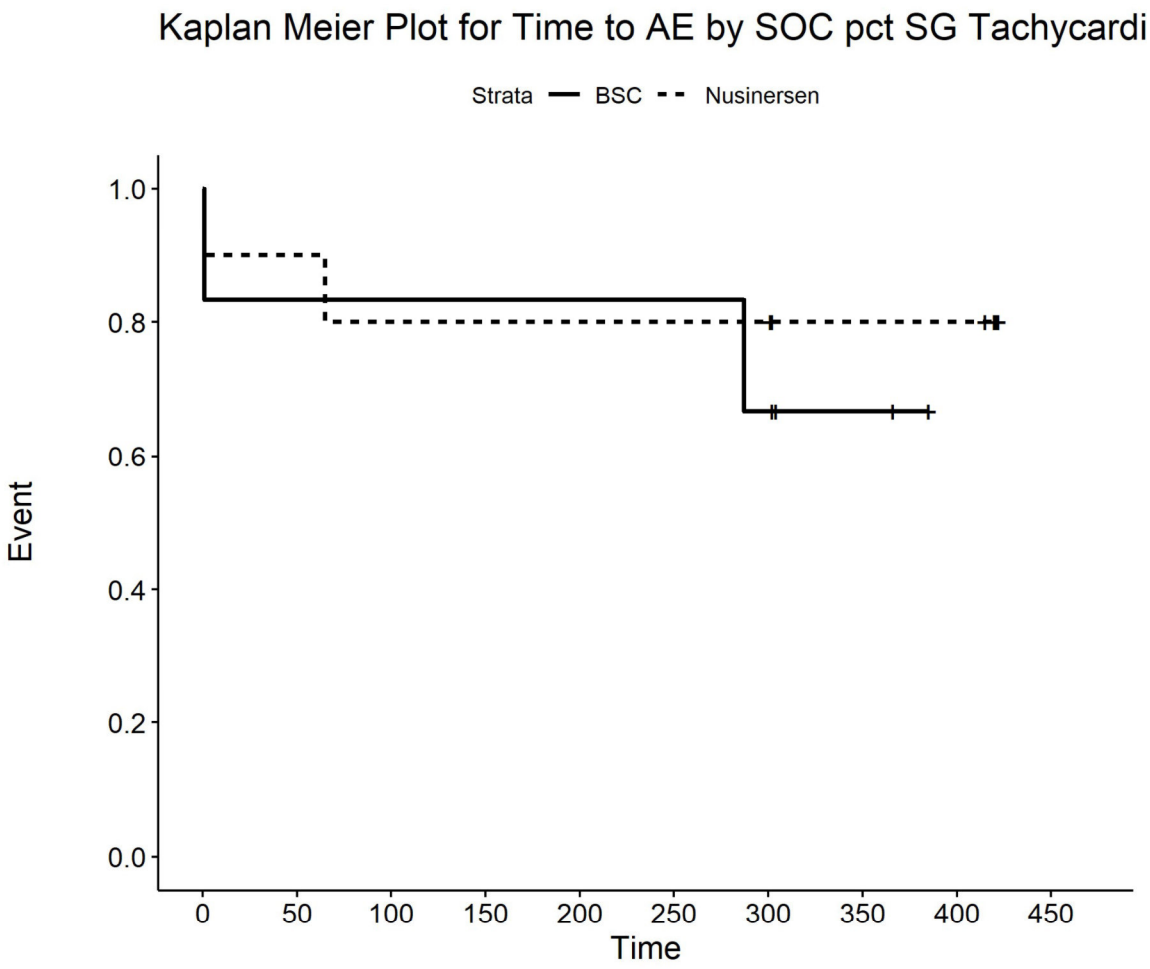
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	5	0



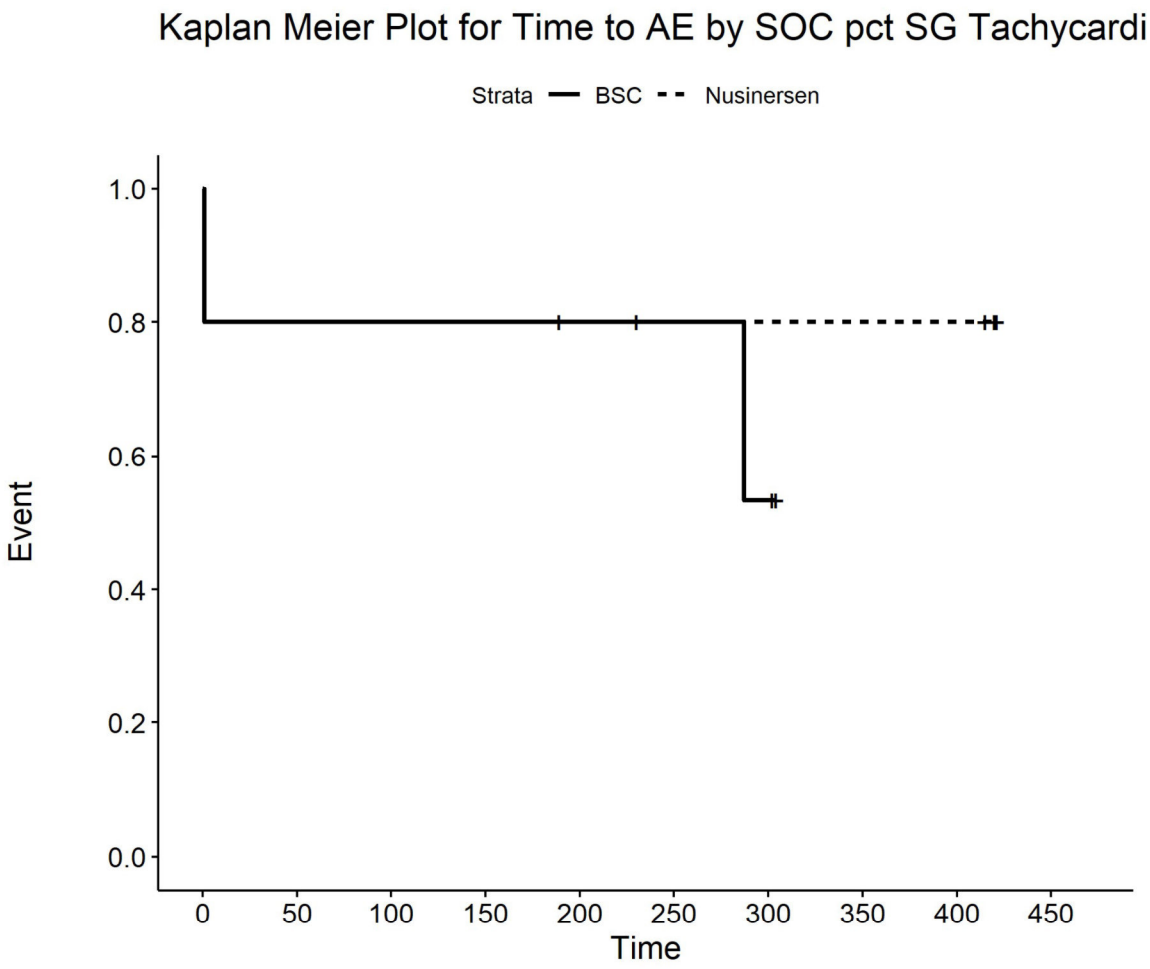
Number at risk

BSC	4	3	3	3	3	3	2	1	0	0
Nusinersen	9	8	7	7	5	5	5	4	4	0



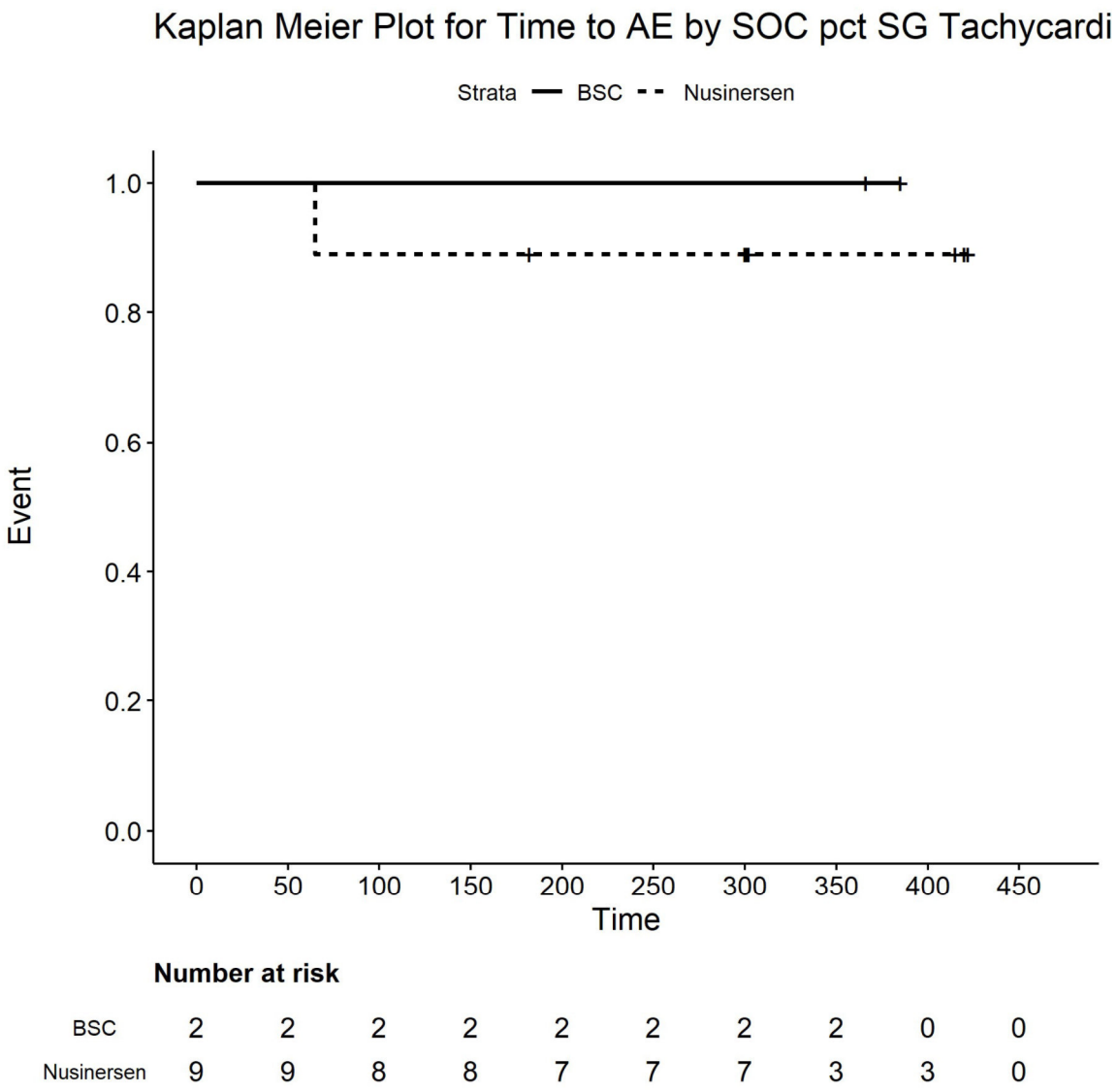
Number at risk

BSC	6	5	5	5	5	5	4	2	0	0
Nusinersen	10	9	8	8	8	8	8	6	6	0



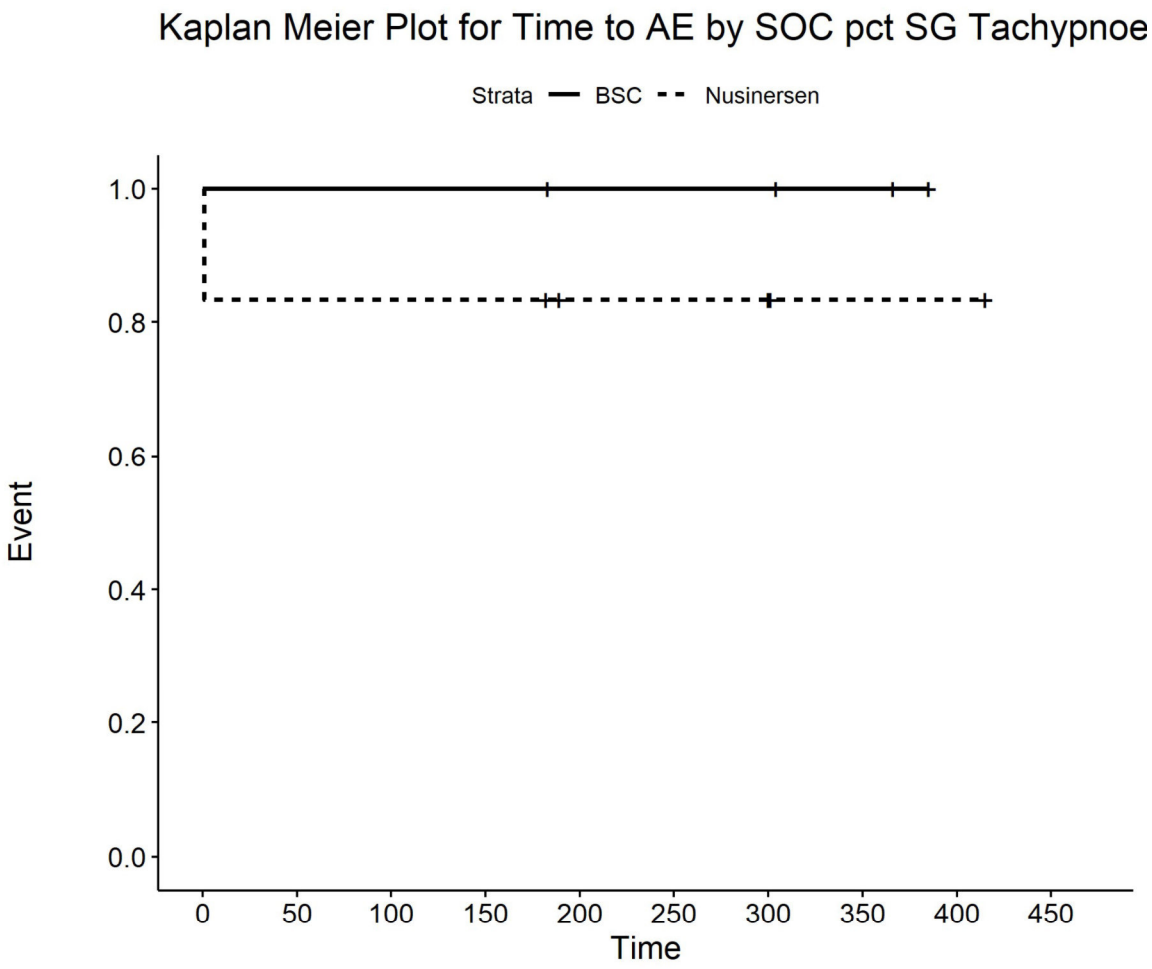
Number at risk

BSC	5	4	4	4	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	3	3	3	0



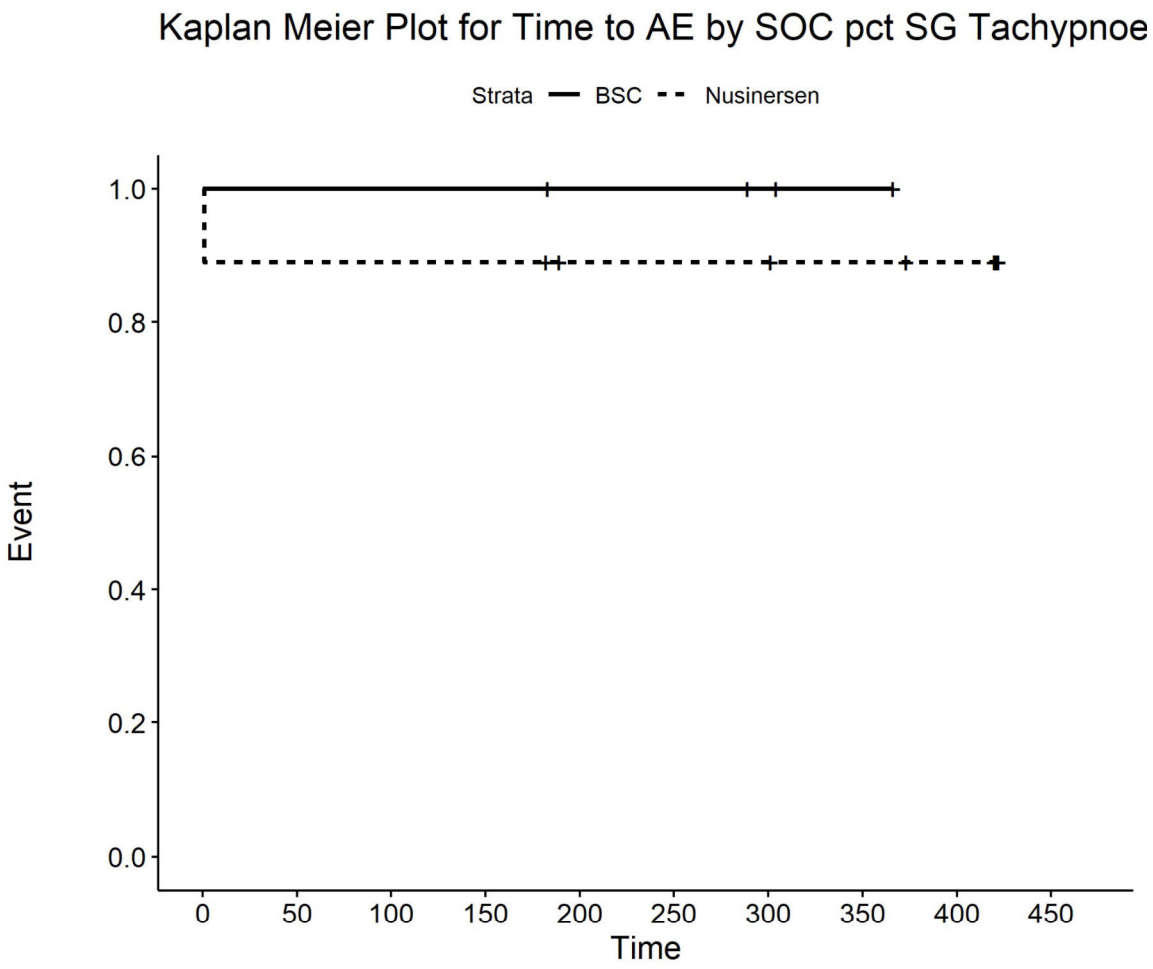
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	3	0



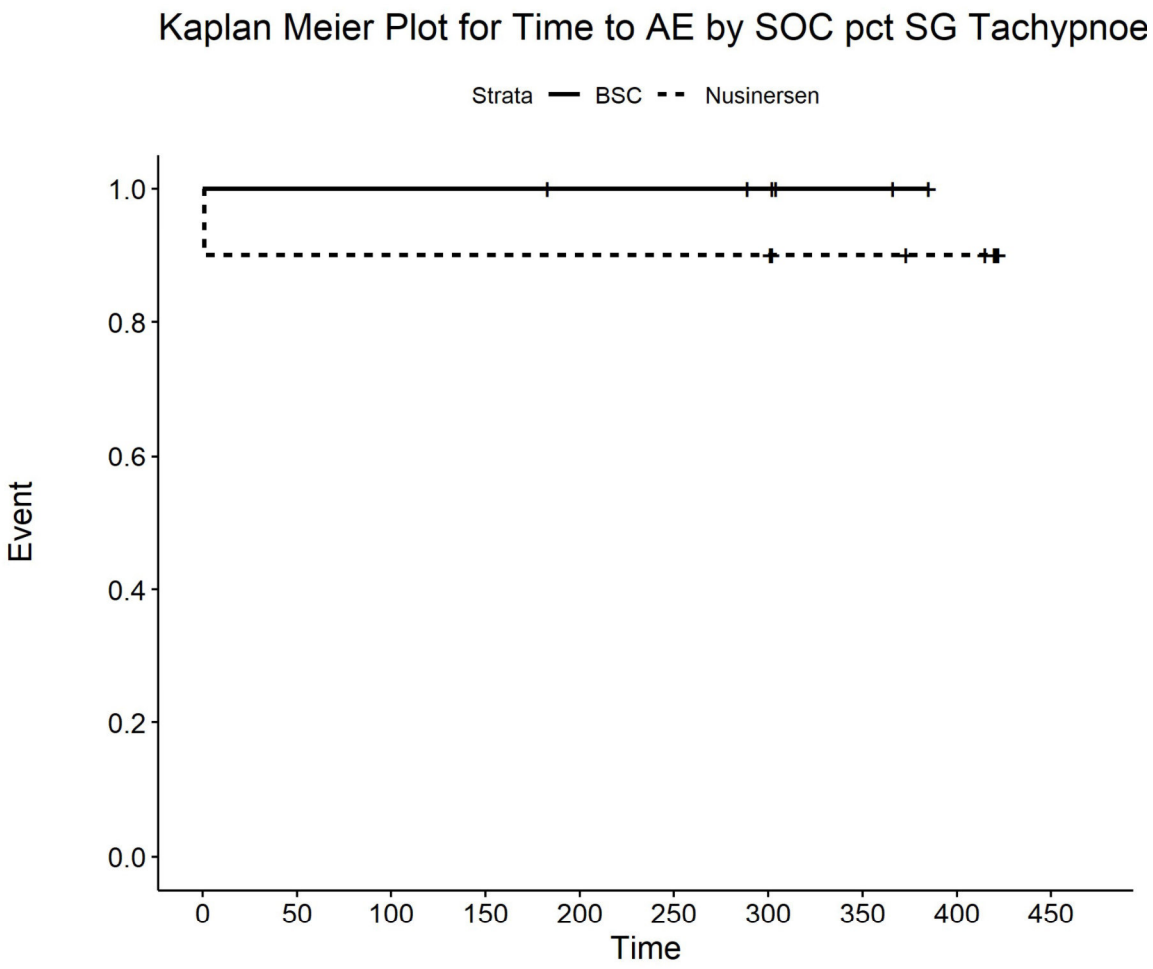
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	3	1	1	0



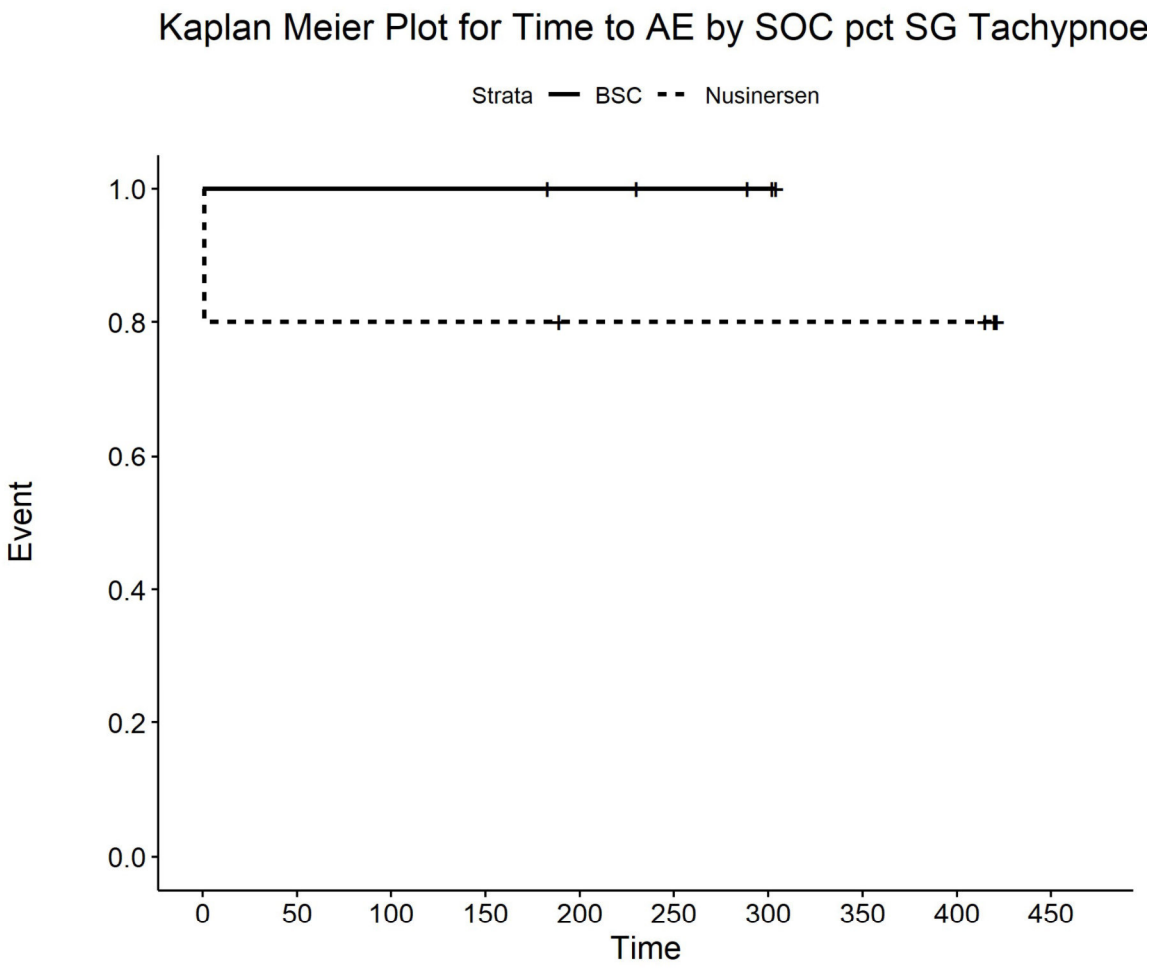
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	6	5	4	0



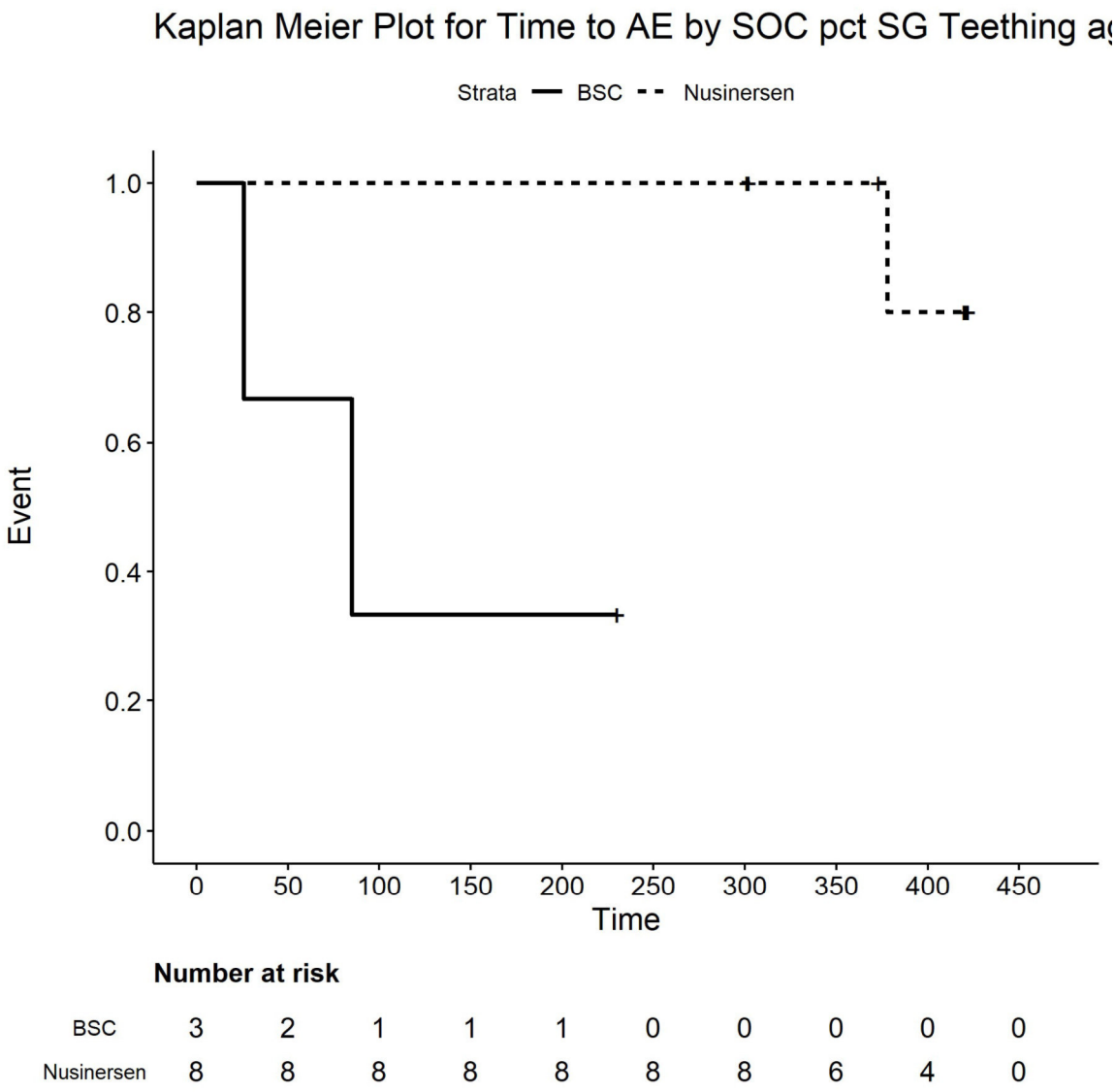
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	9	7	6	0



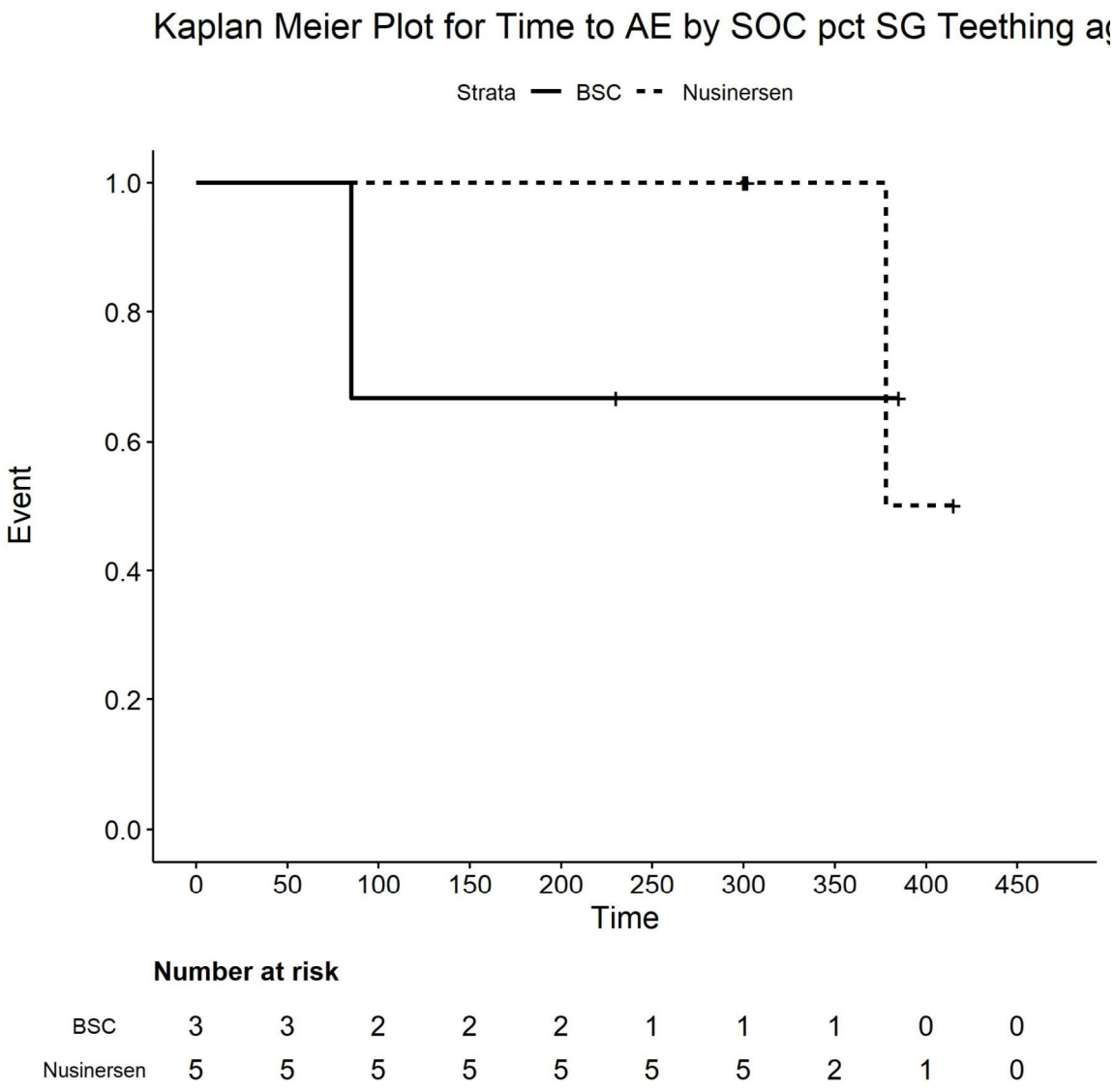
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	3	3	3	0



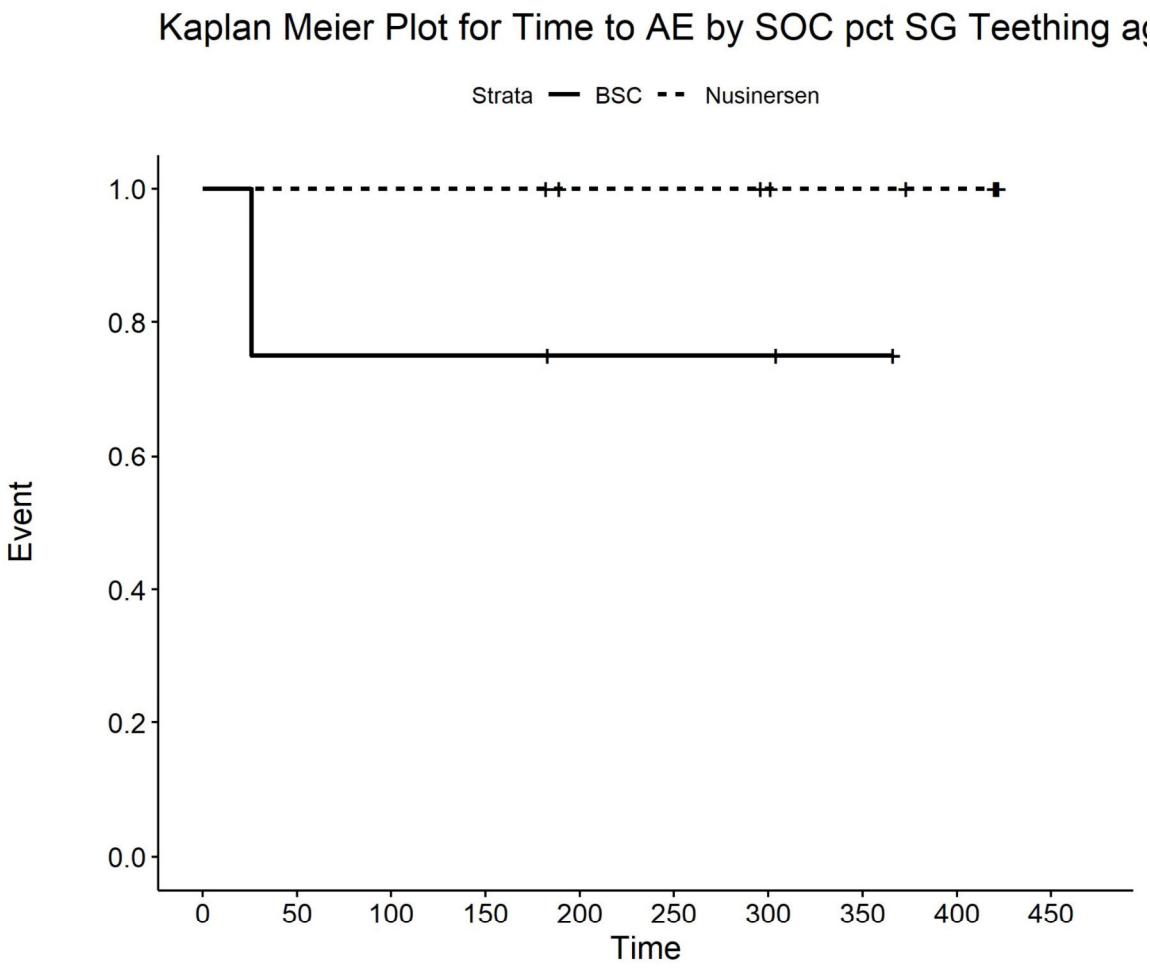
Number at risk

BSC	3	2	1	1	1	0	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	4	0



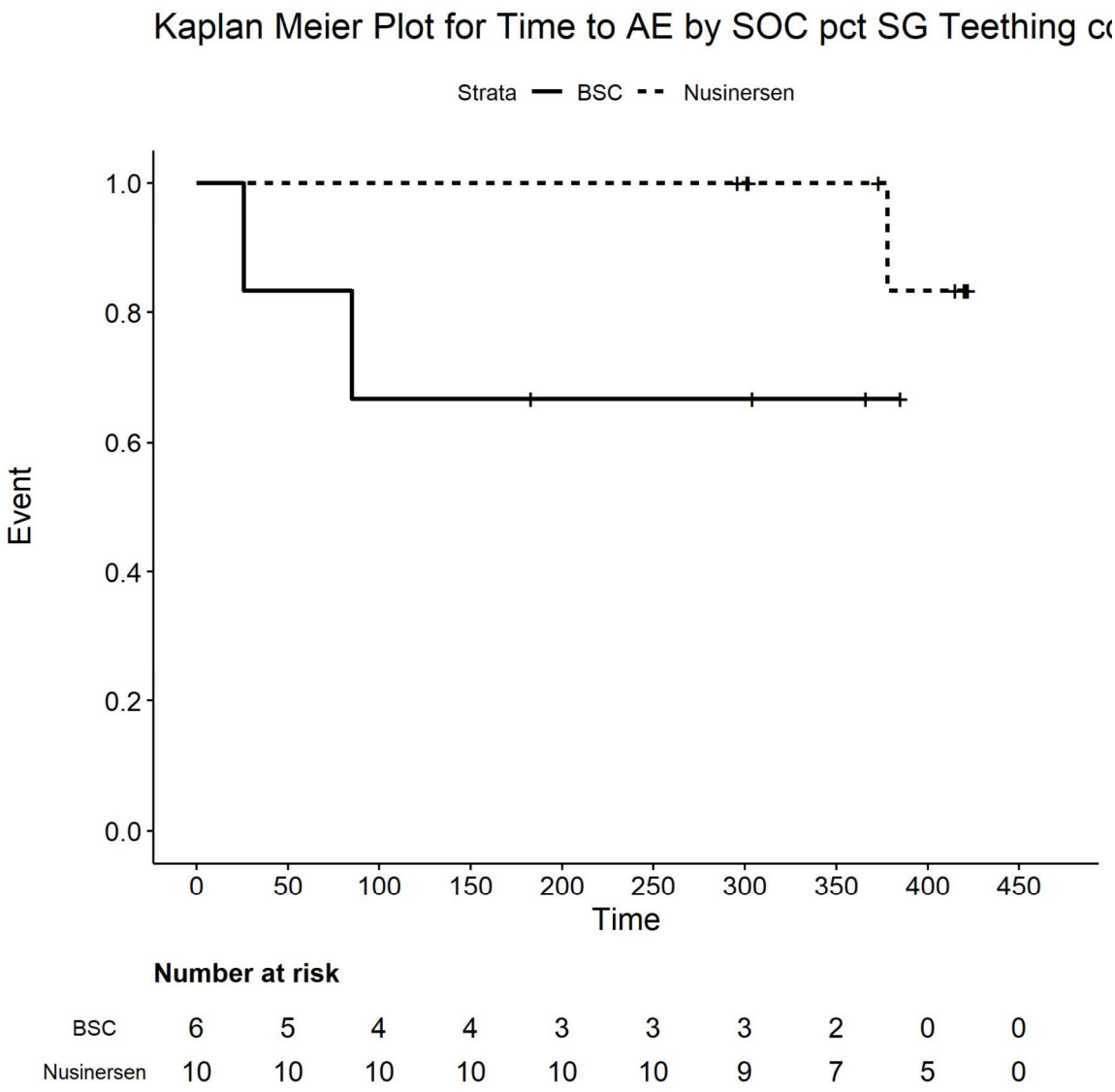
Number at risk

BSC	3	3	2	2	2	1	1	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	1	0



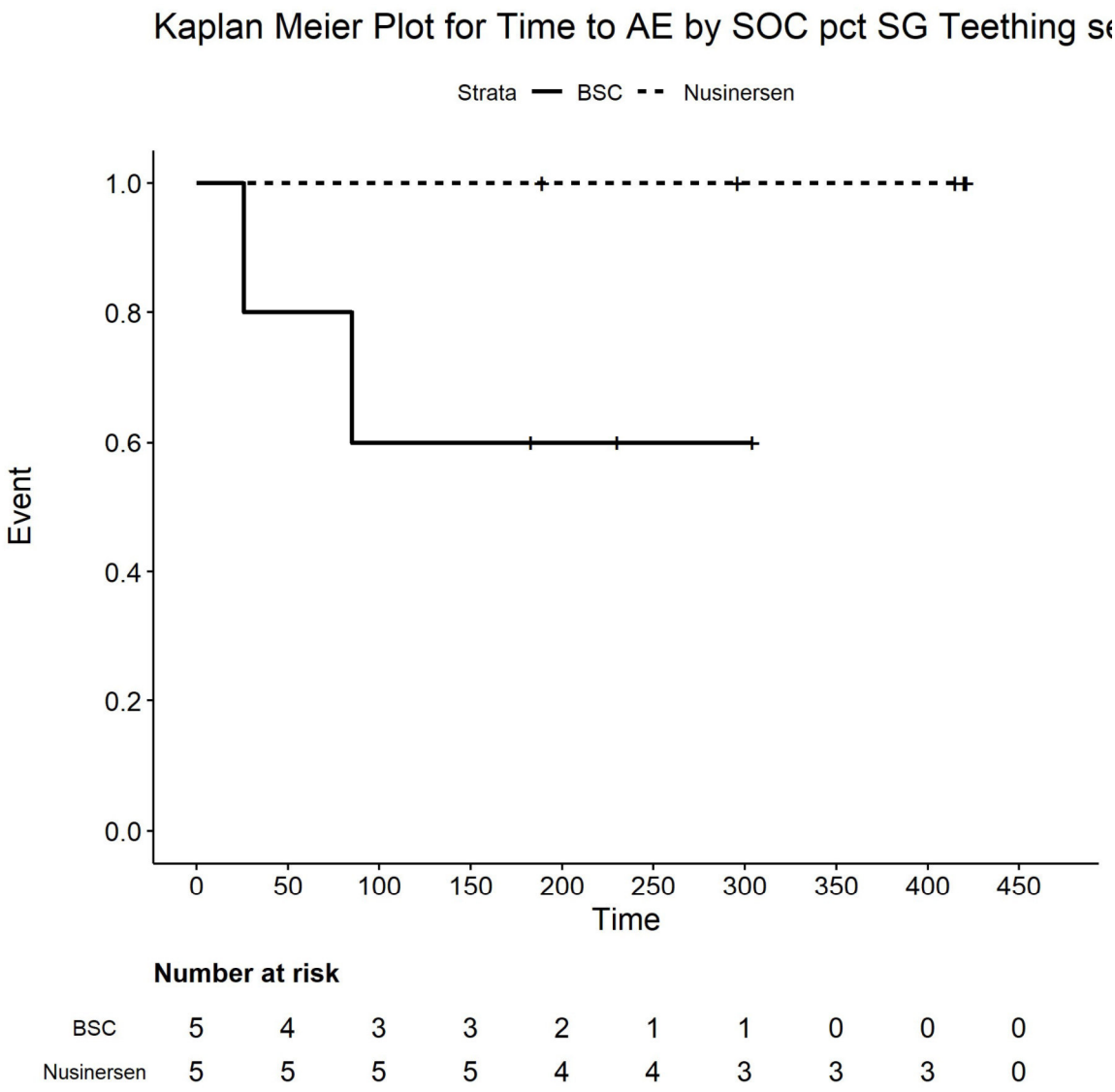
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



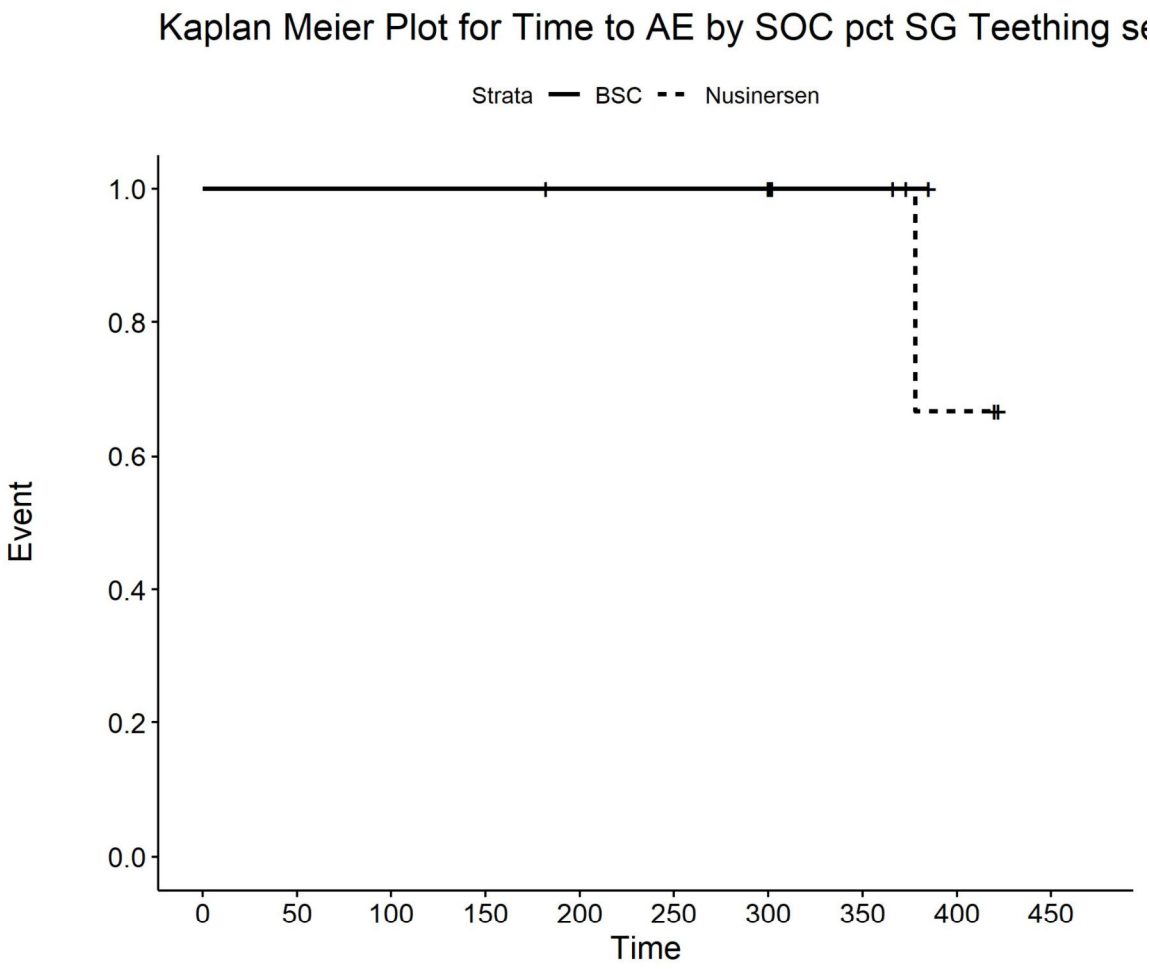
Number at risk

BSC	6	5	4	4	3	3	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	5	0



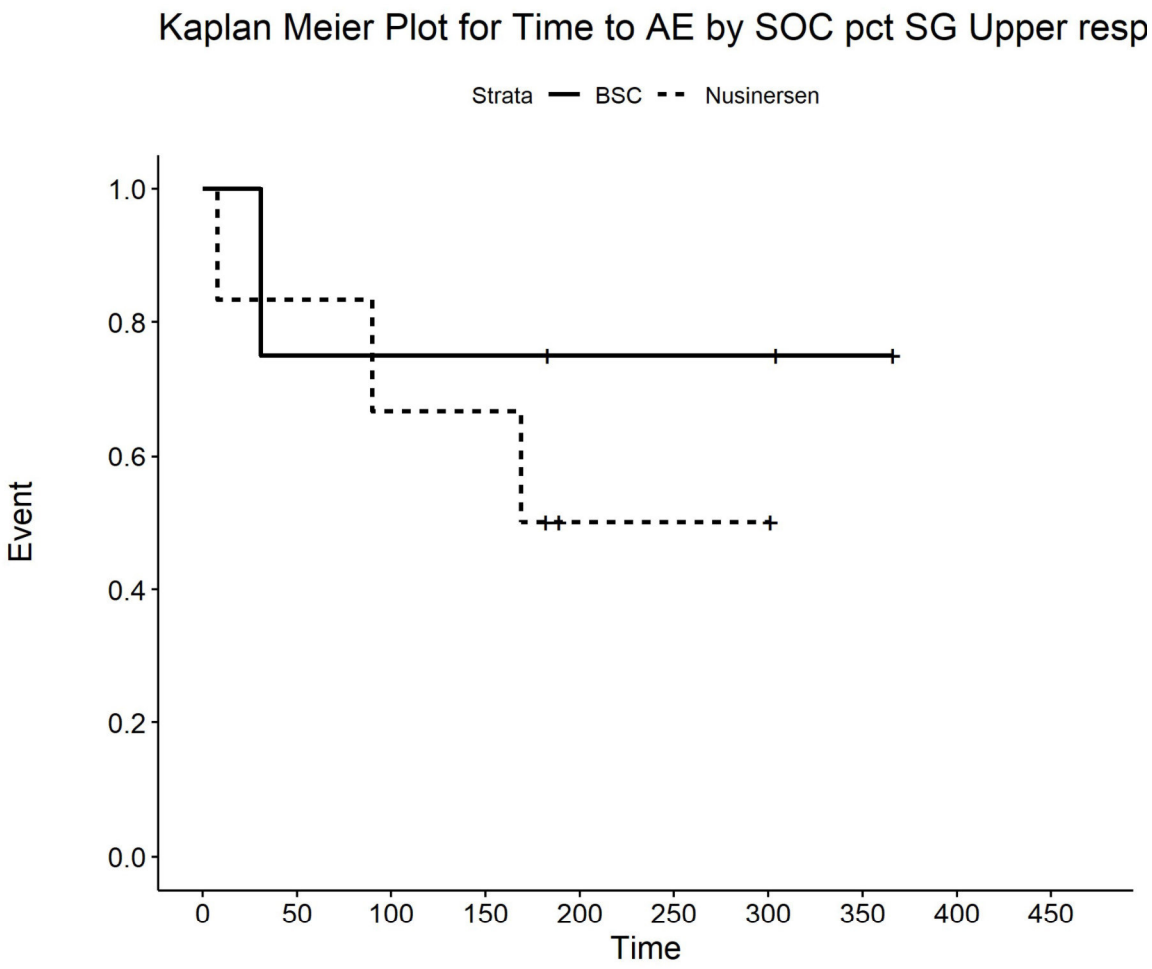
Number at risk

BSC	5	4	3	3	2	1	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



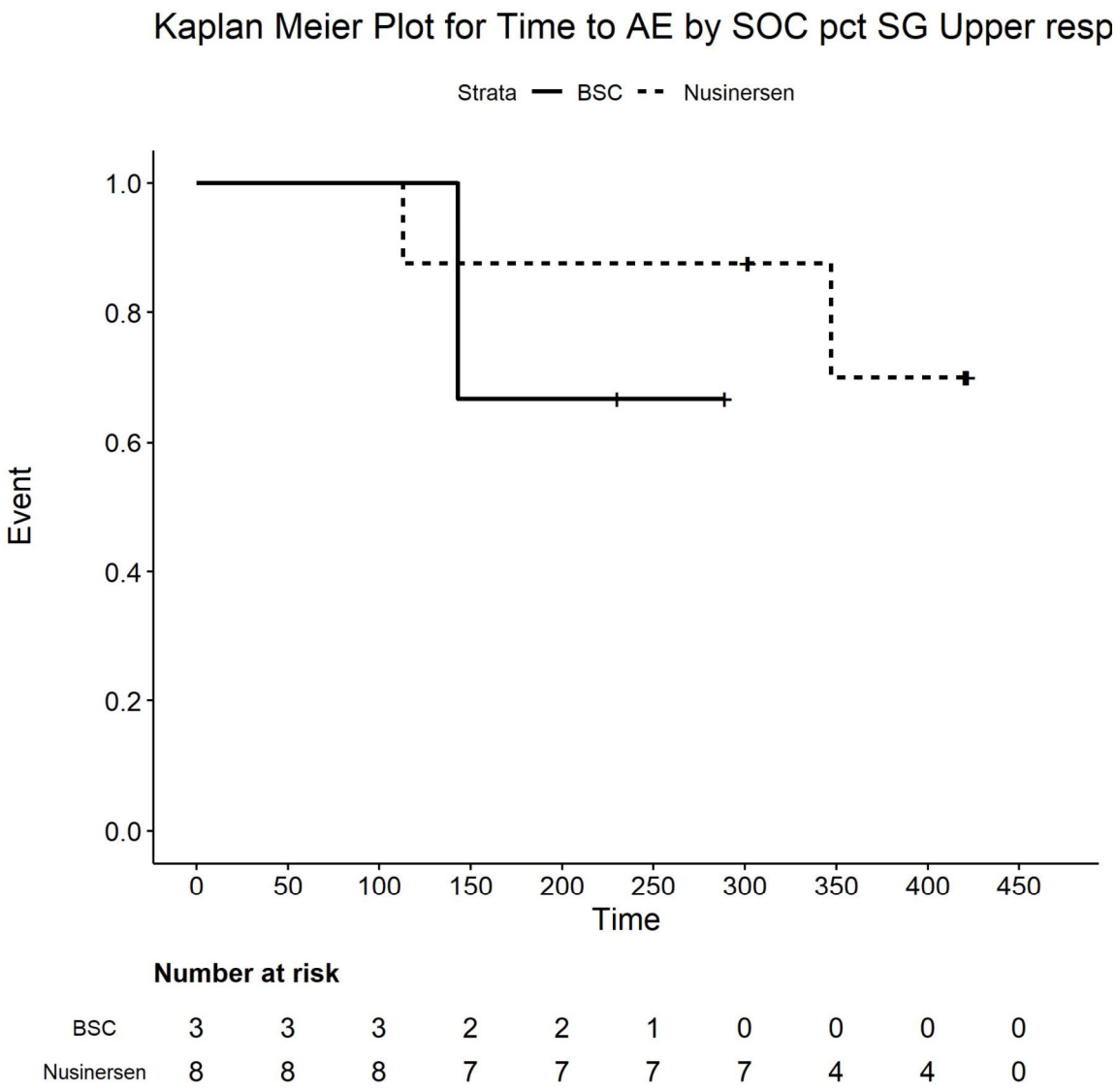
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	8	4	2	0



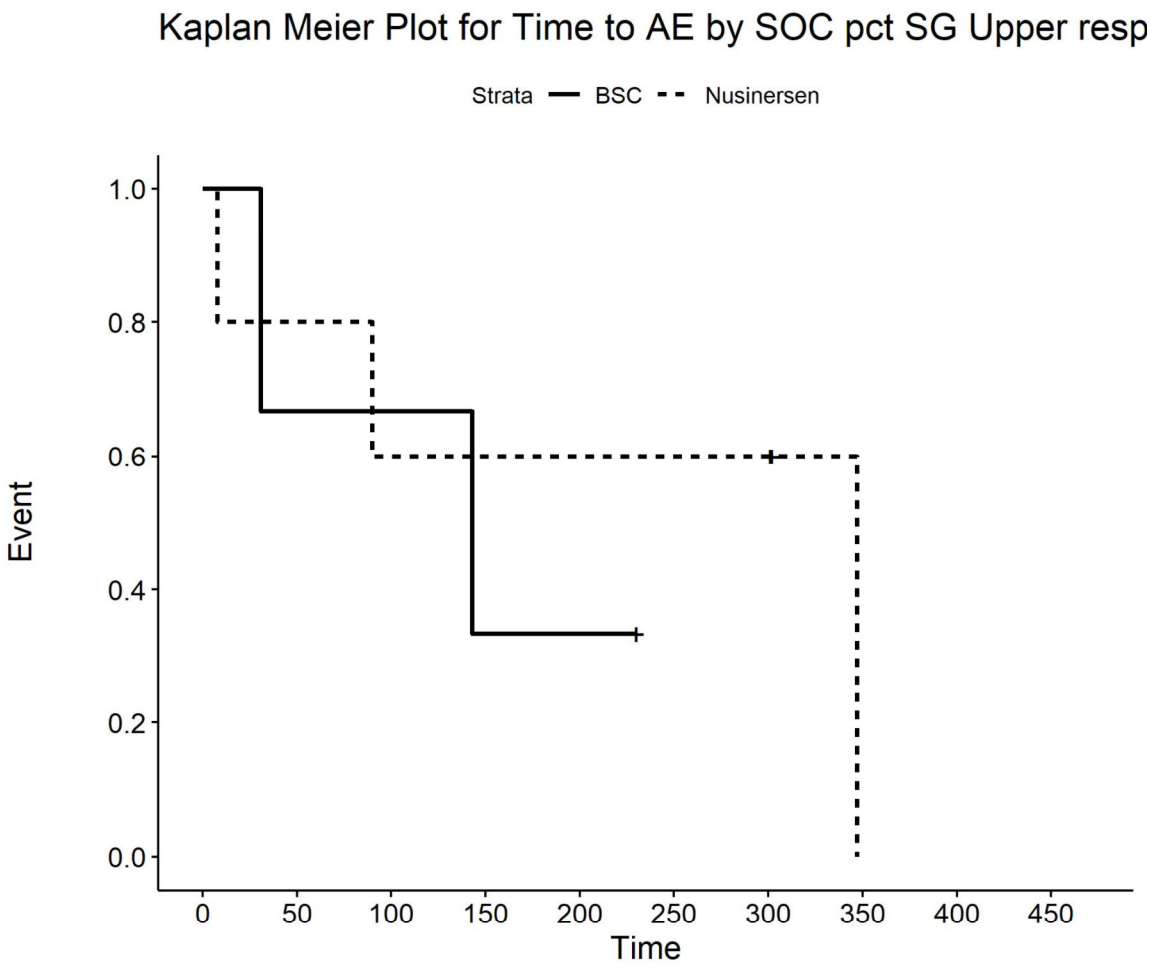
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	5	4	4	1	1	1	0	0	0



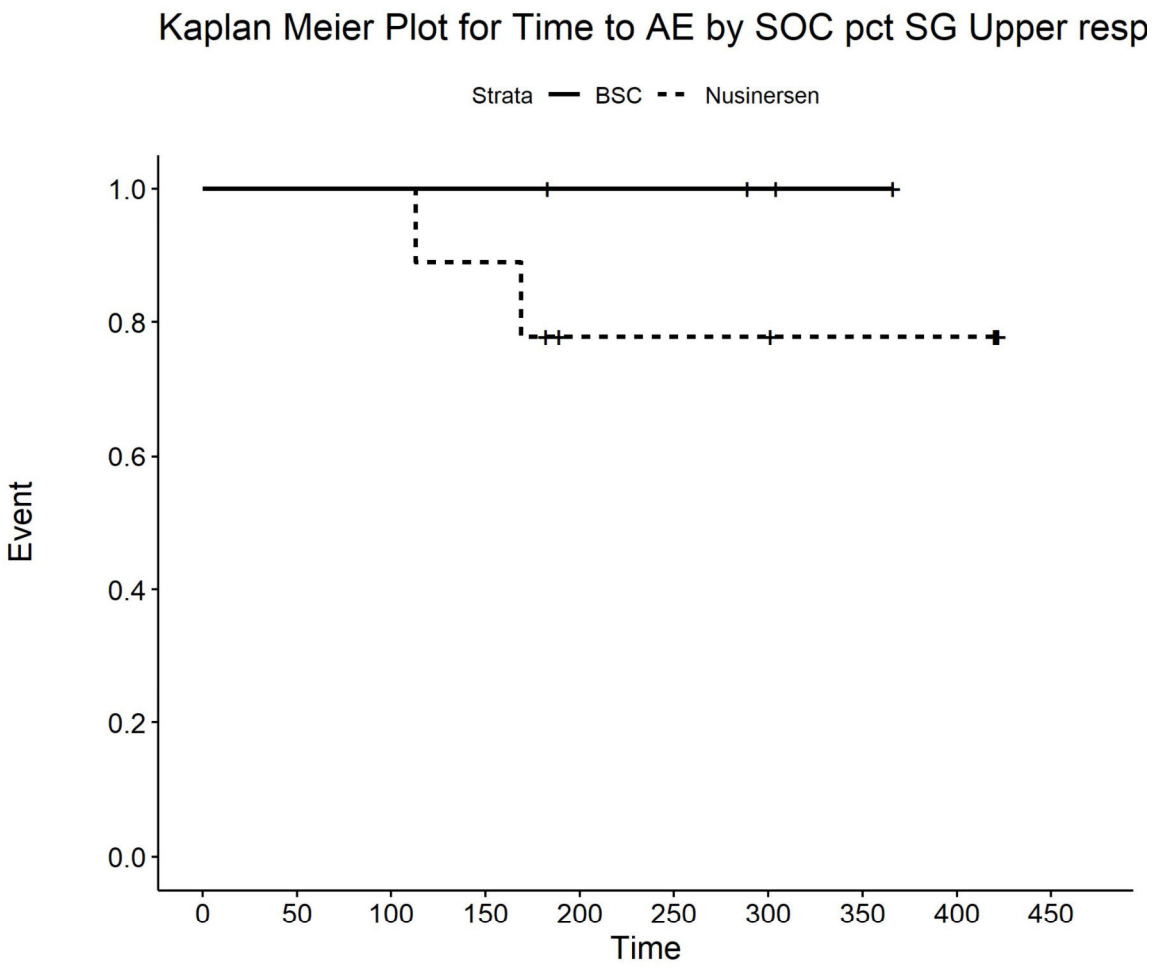
Number at risk

BSC	3	3	3	2	2	1	0	0	0	0
Nusinersen	8	8	8	7	7	7	7	4	4	0



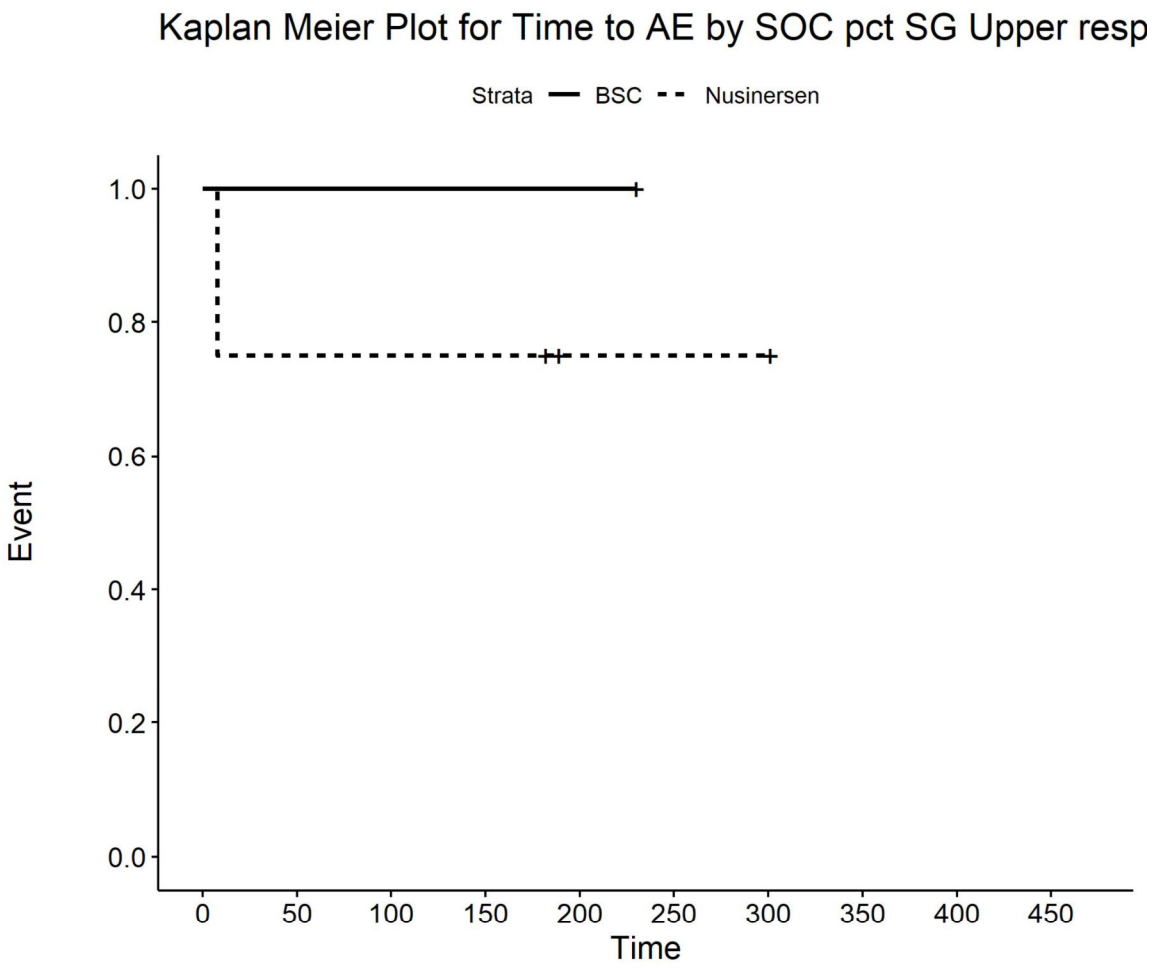
Number at risk

BSC	3	2	2	1	1	0	0	0	0	0
Nusinersen	5	4	3	3	3	3	3	0	0	0



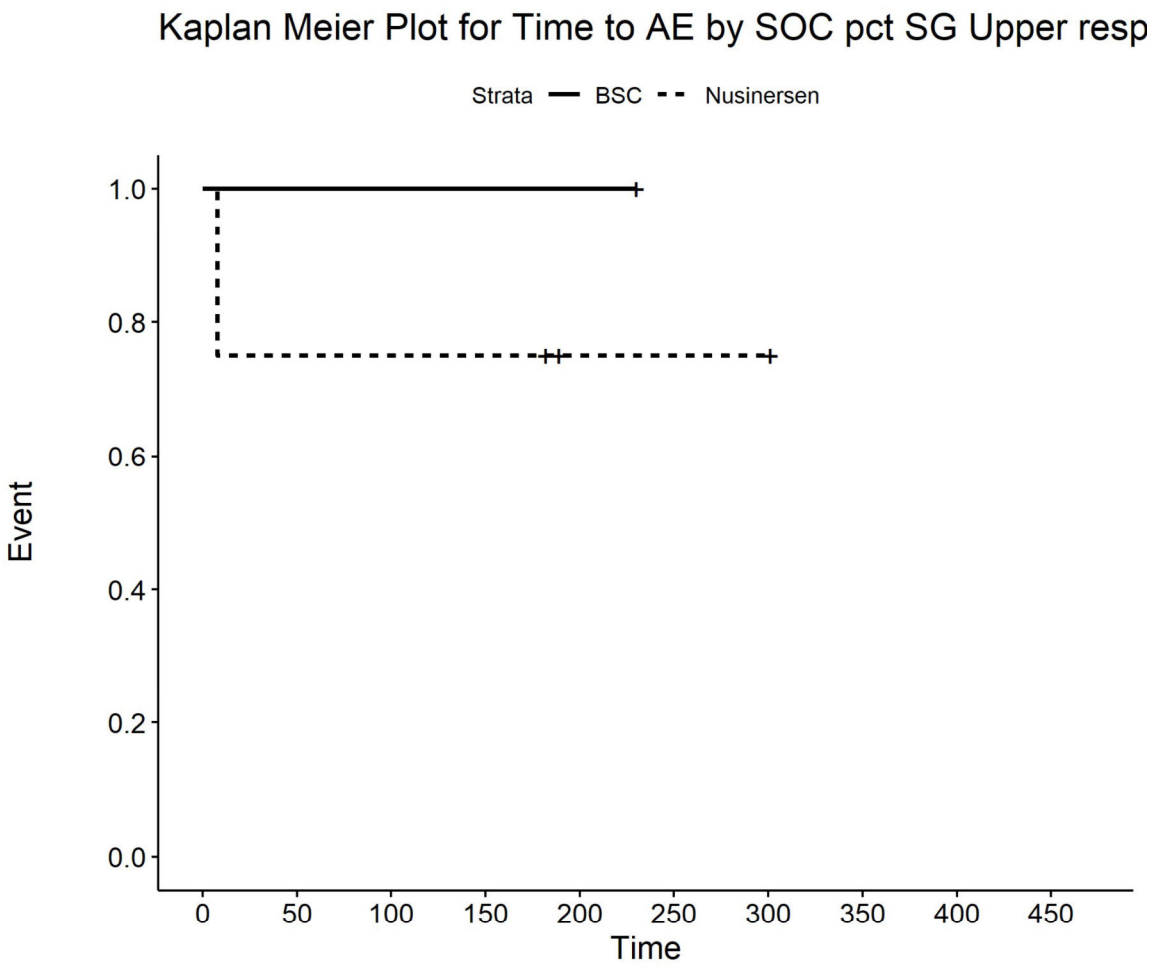
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	5	5	5	4	4	0



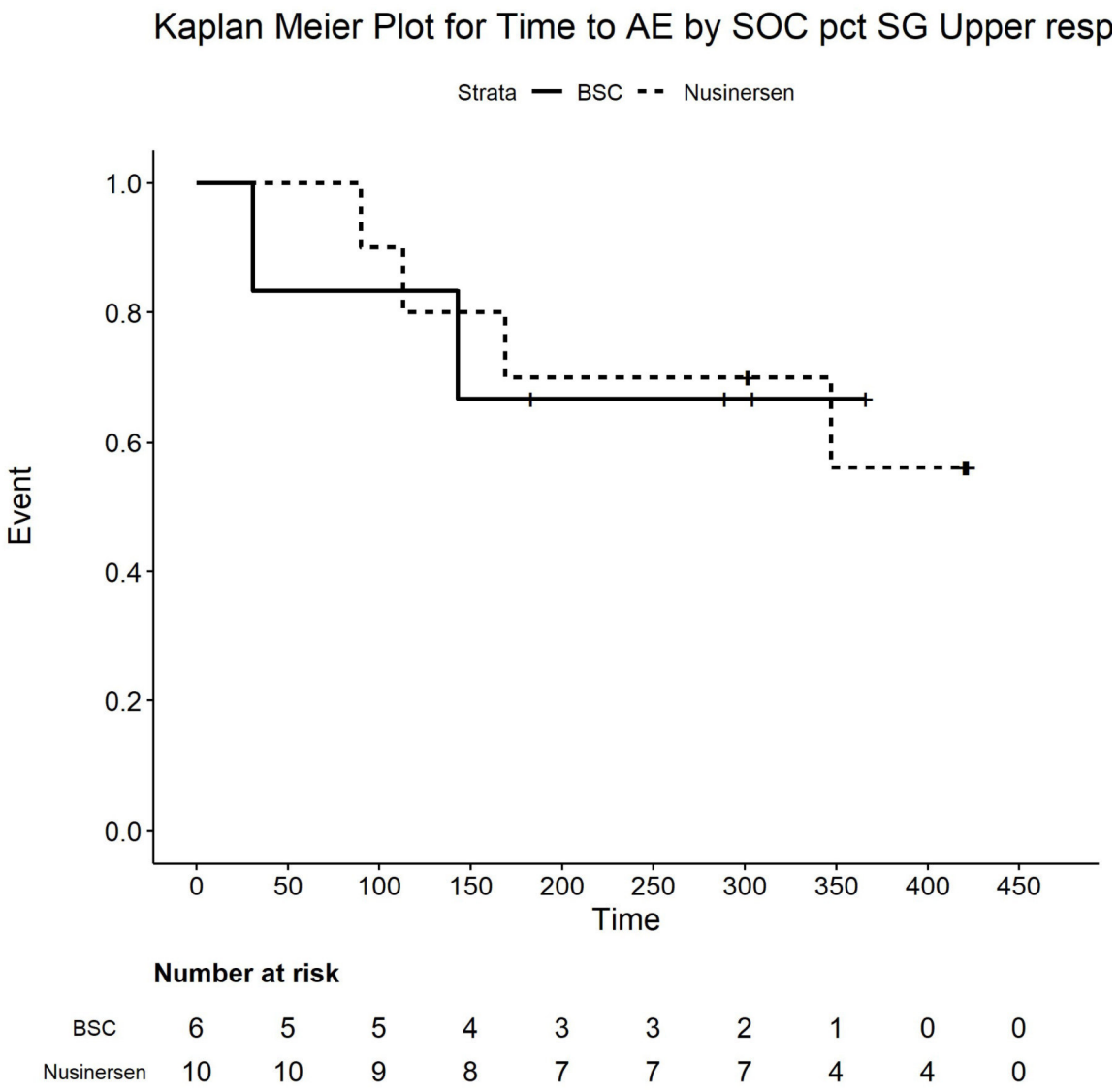
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



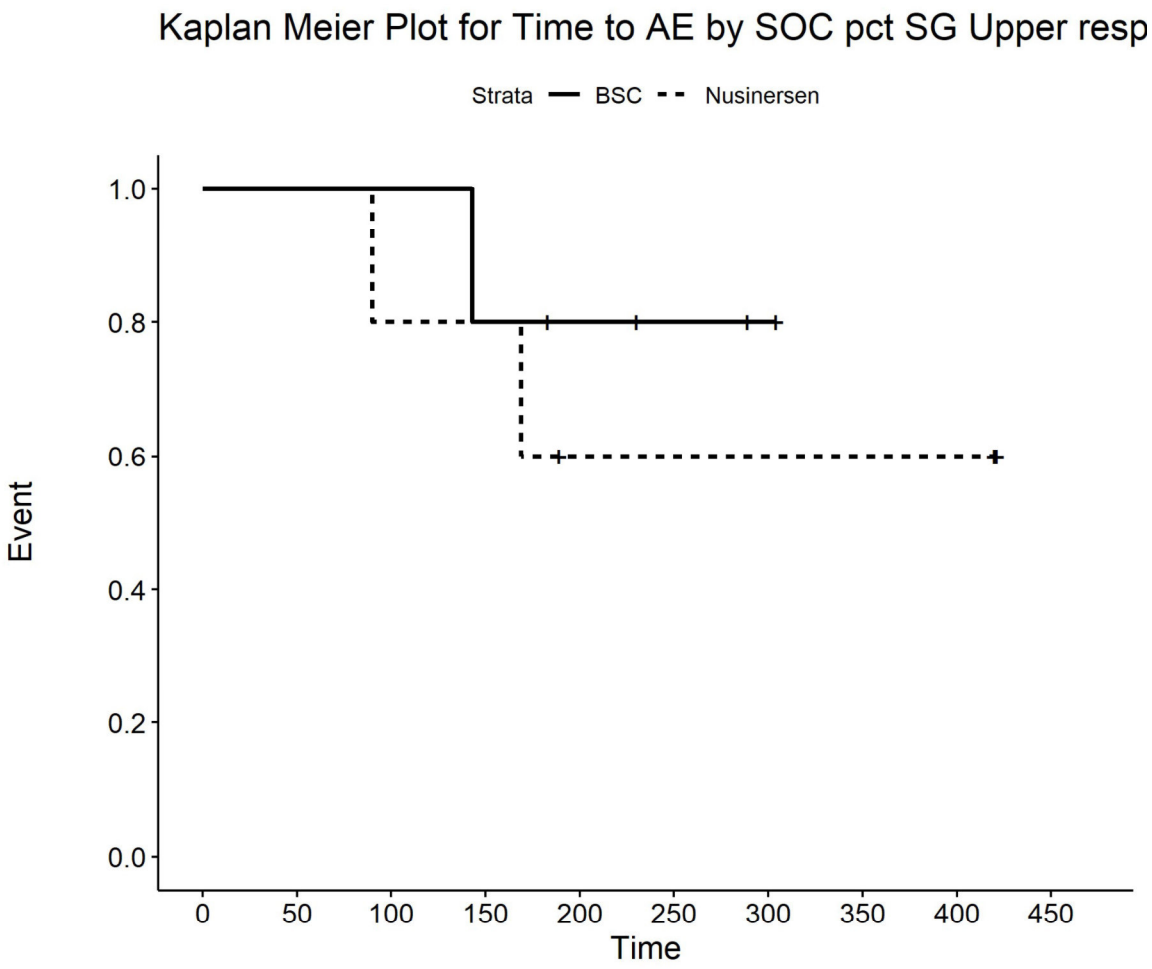
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



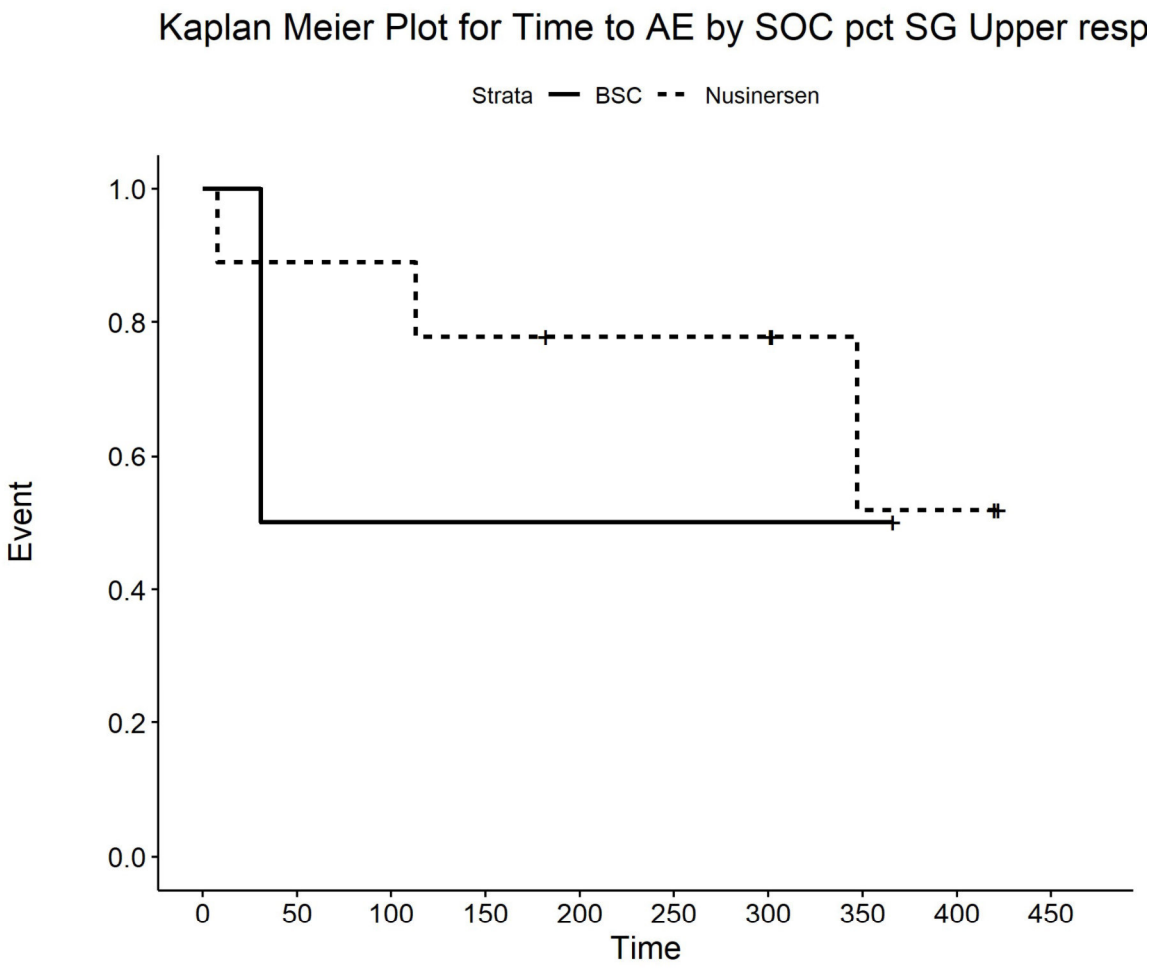
Number at risk

BSC	6	5	5	4	3	3	2	1	0	0
Nusinersen	10	10	9	8	7	7	7	4	4	0



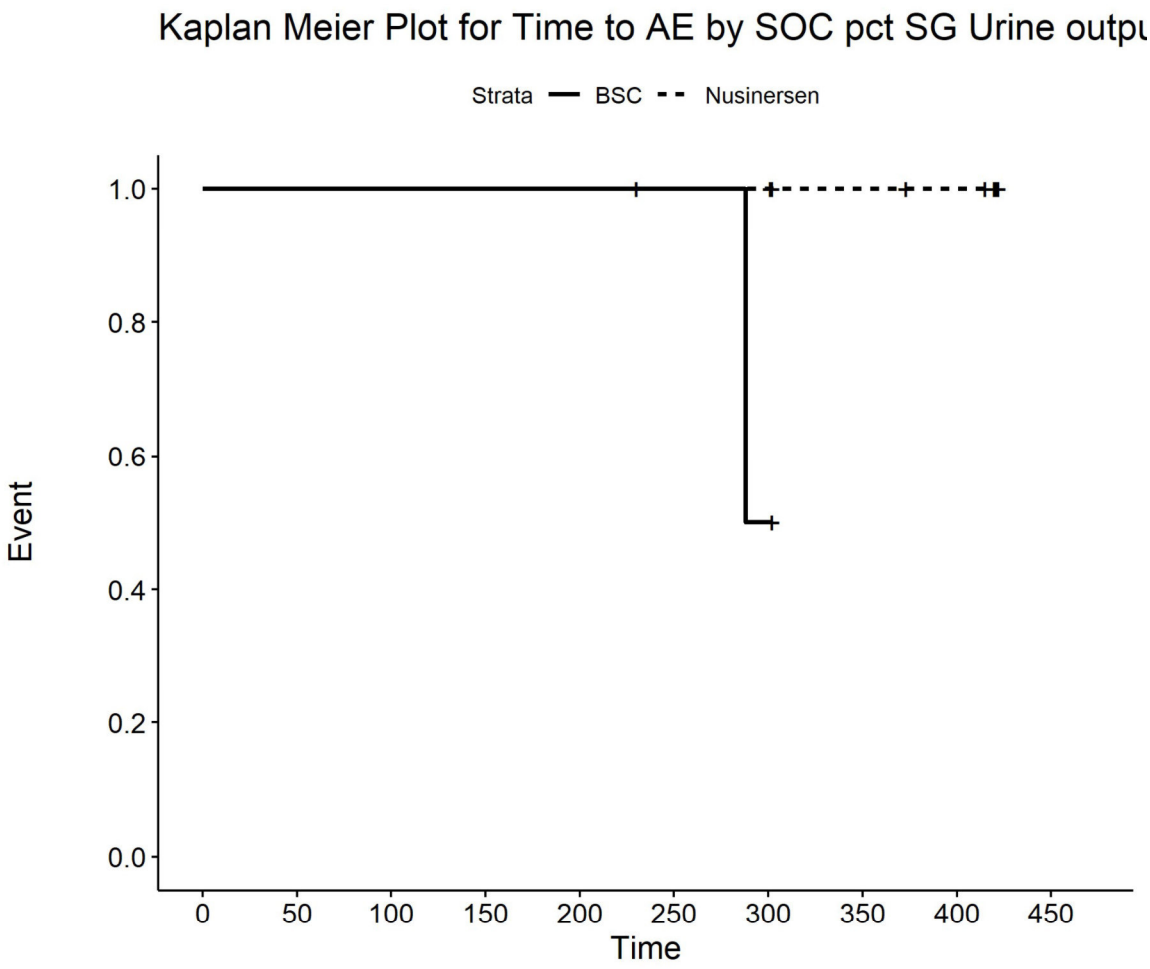
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	4	4	2	2	2	2	2	0



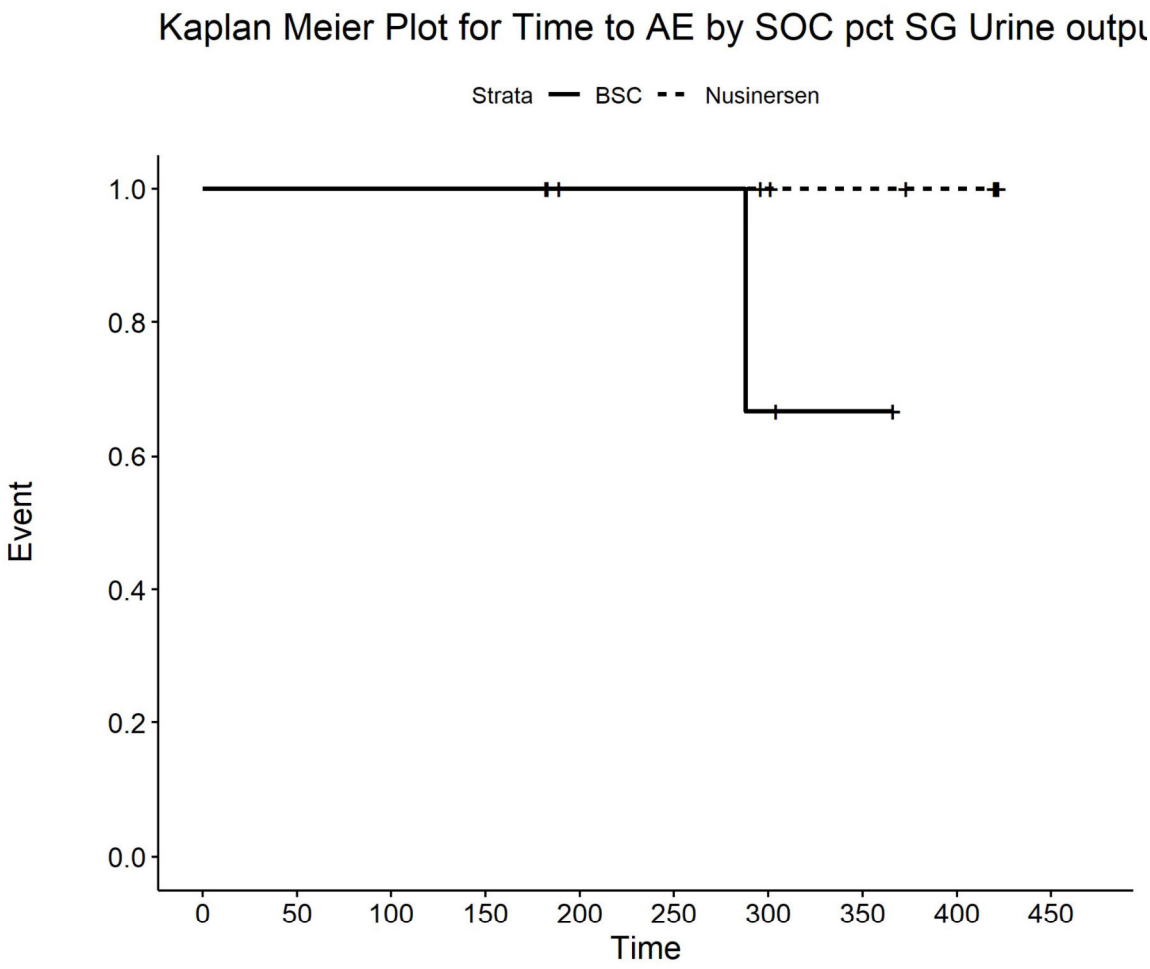
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	8	8	7	6	6	6	2	2	0



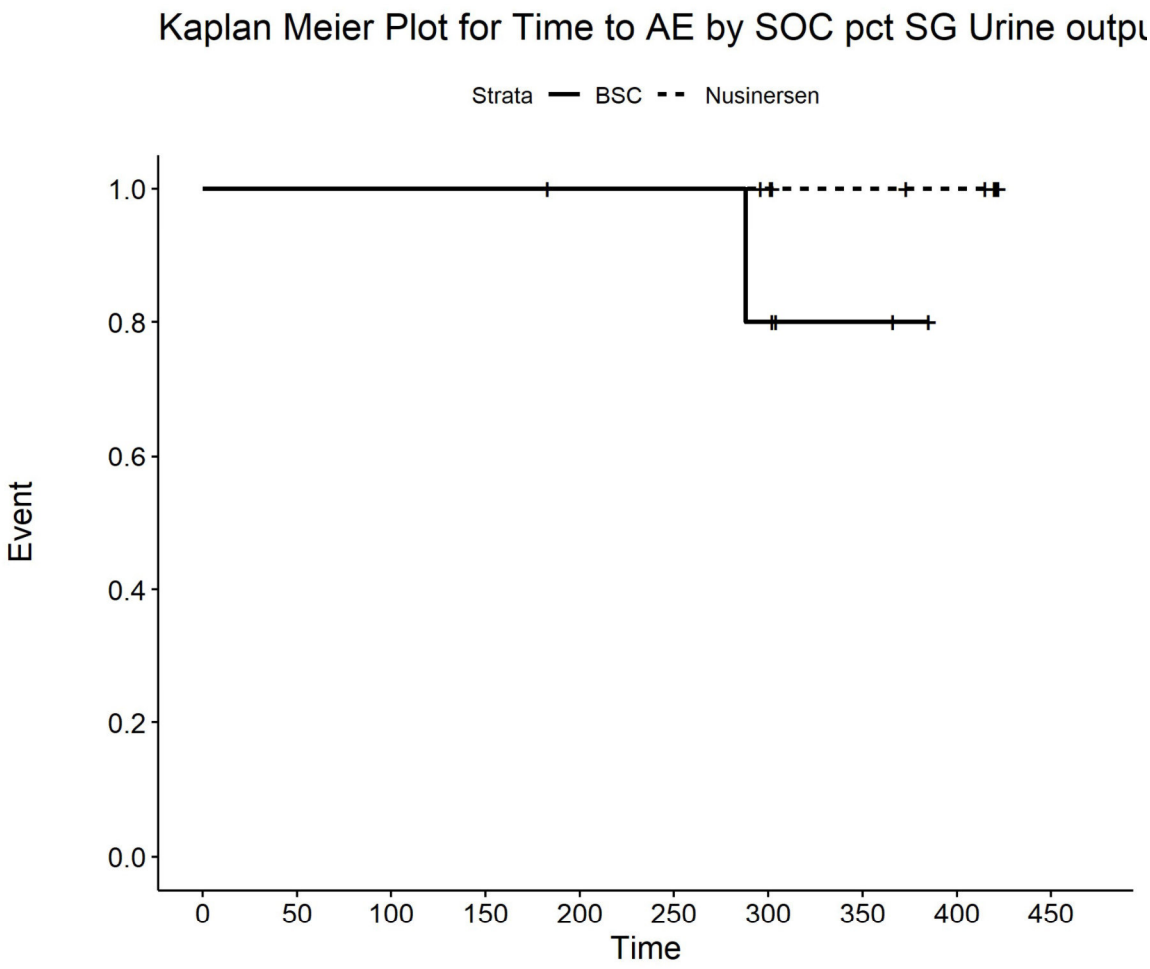
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



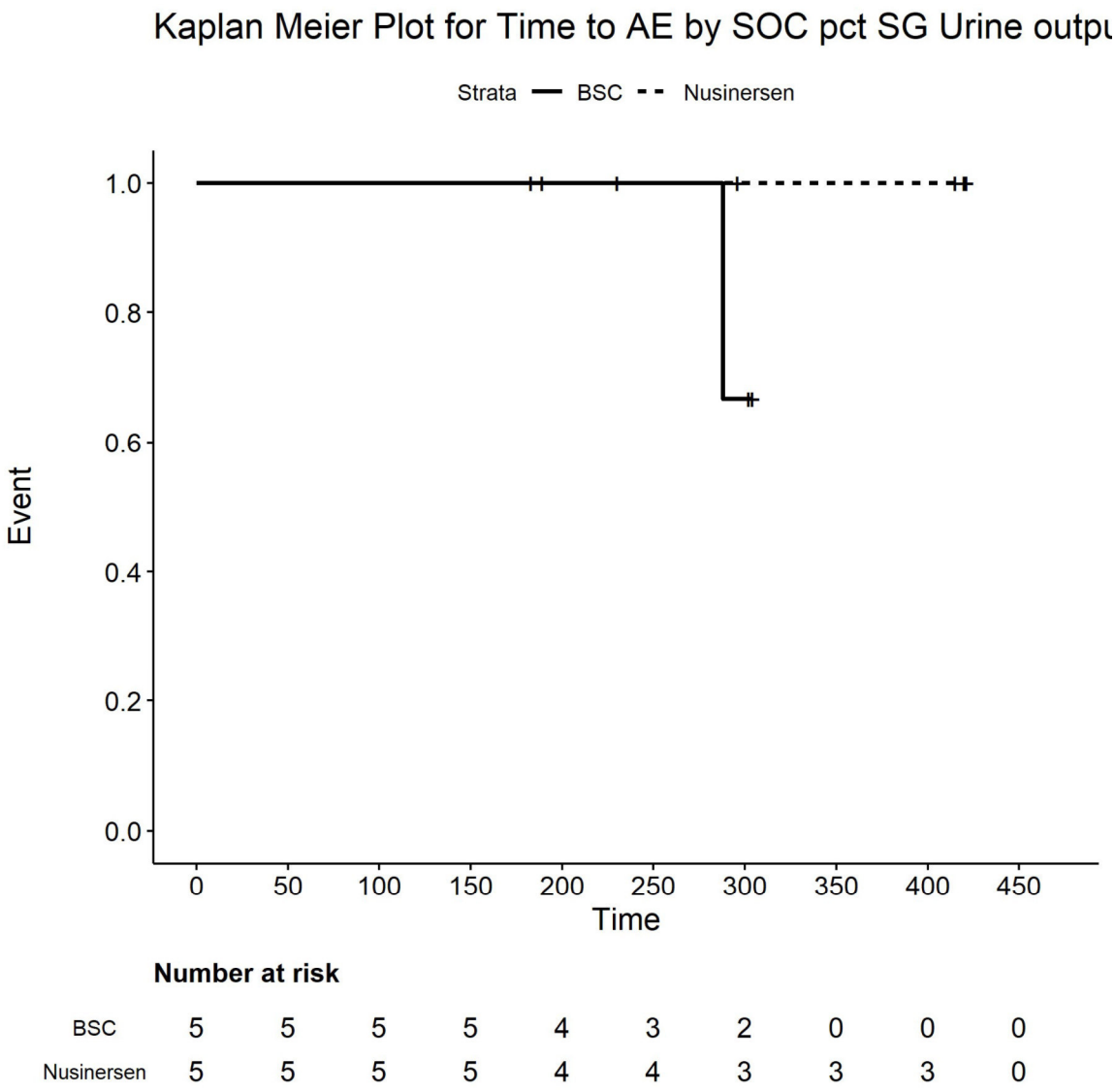
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



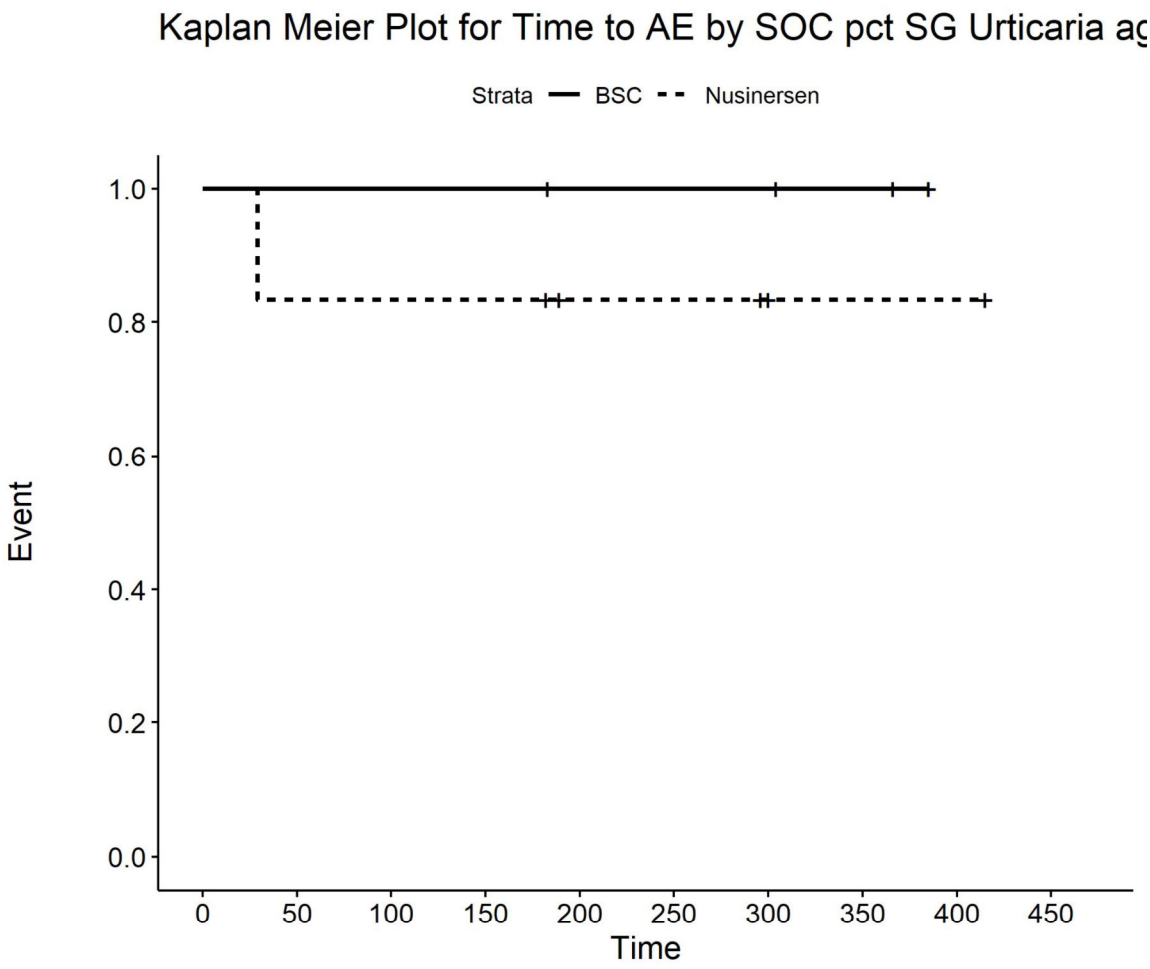
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



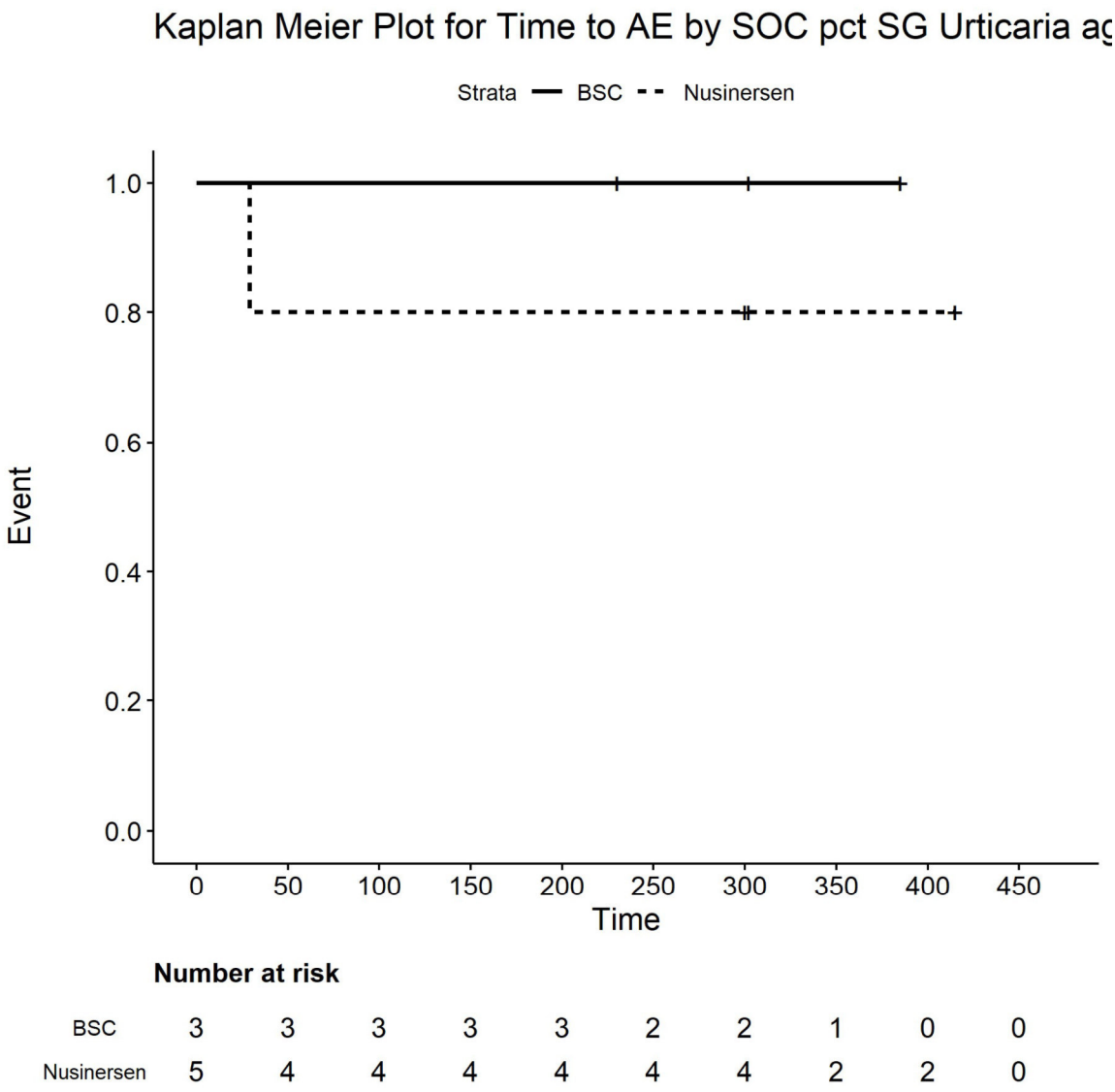
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



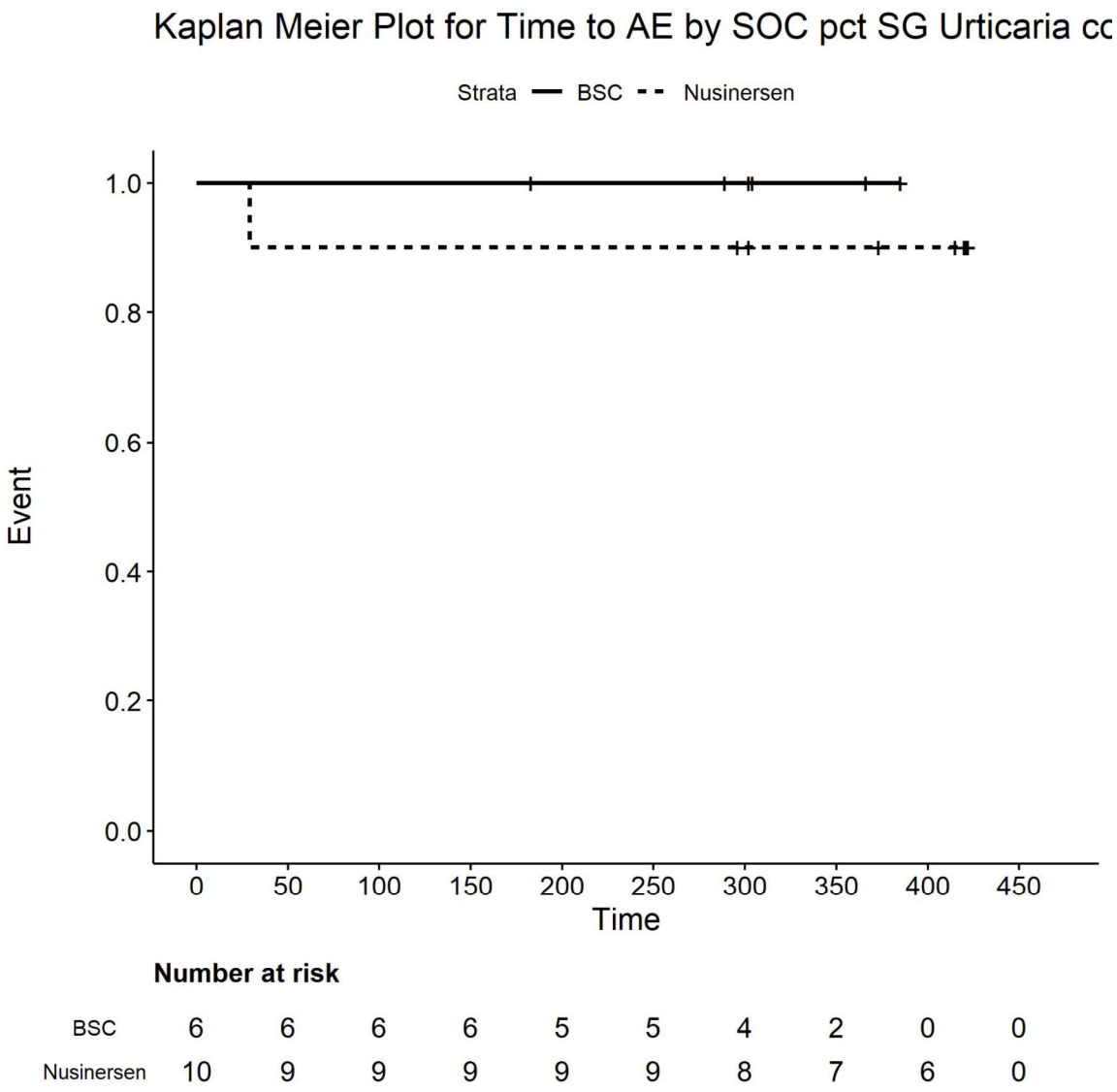
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	2	1	1	0



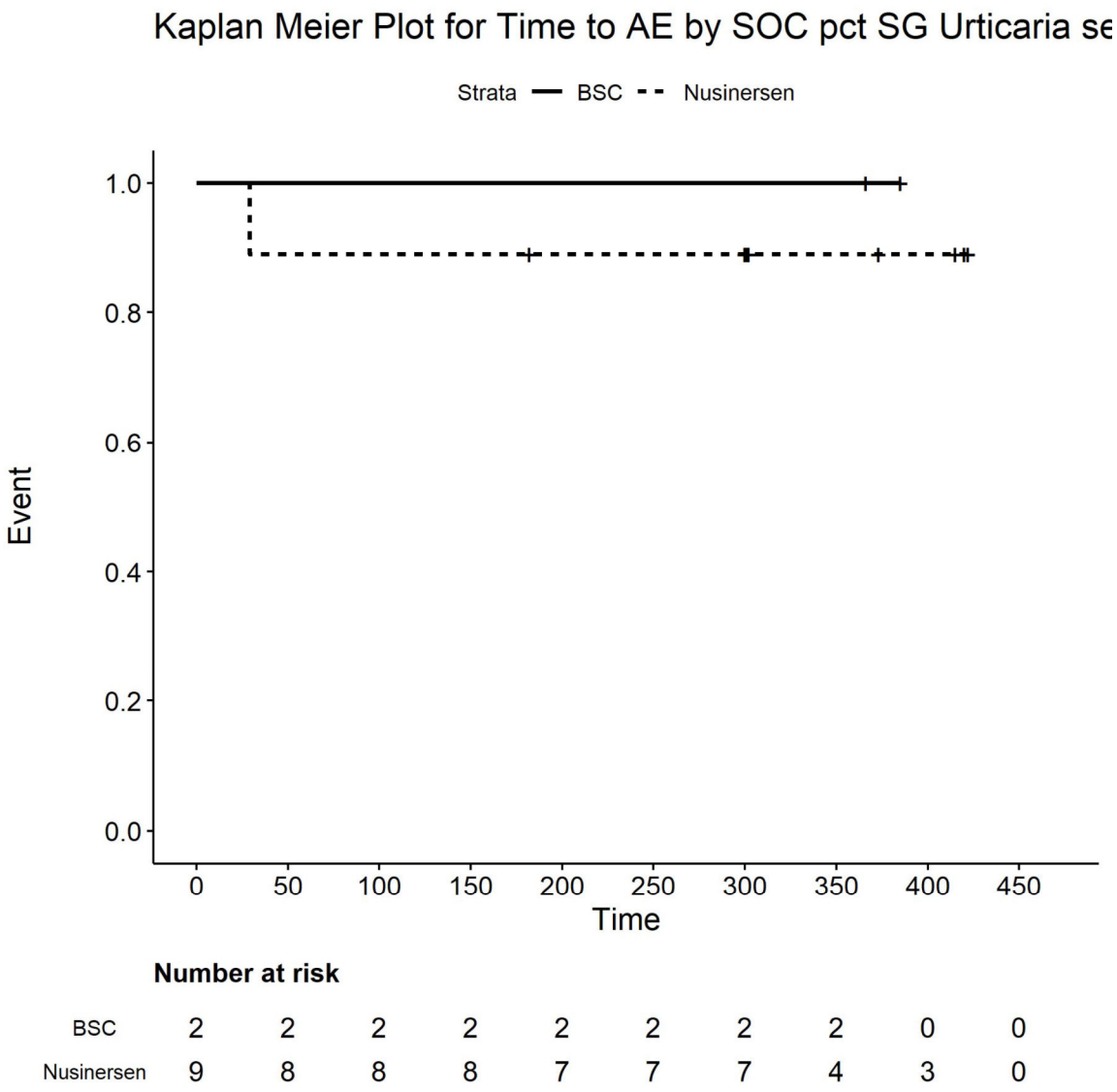
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



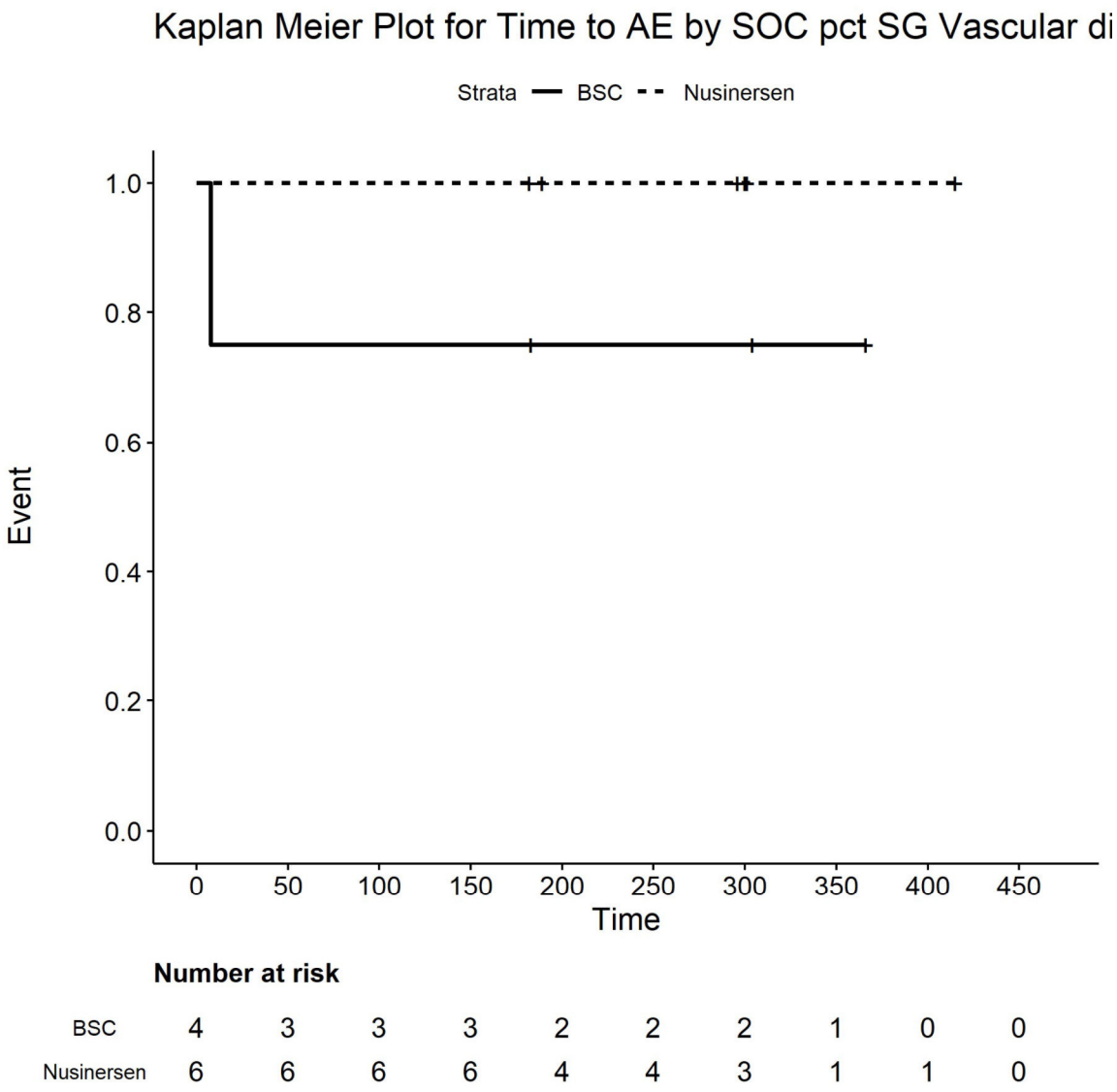
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	7	6	0



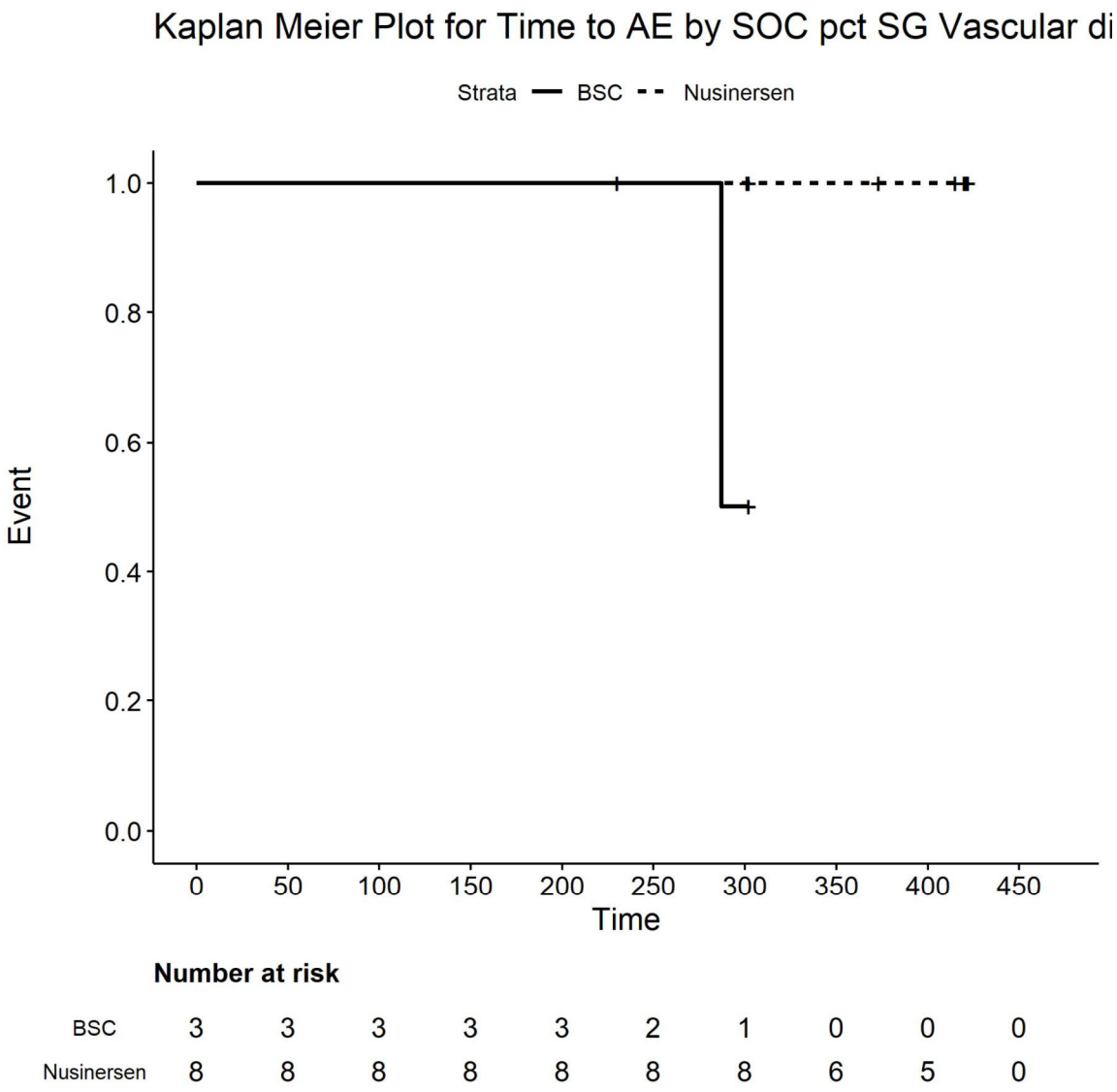
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



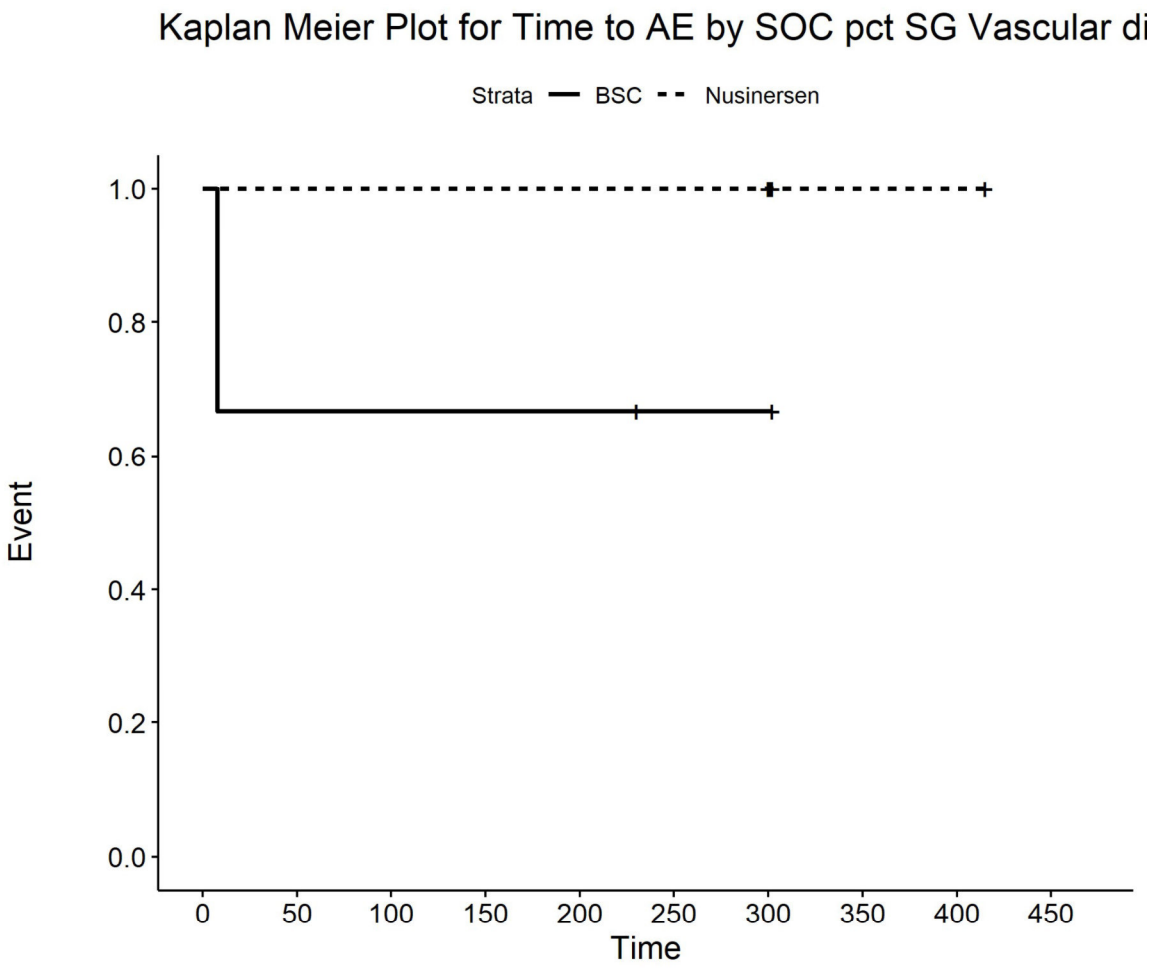
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



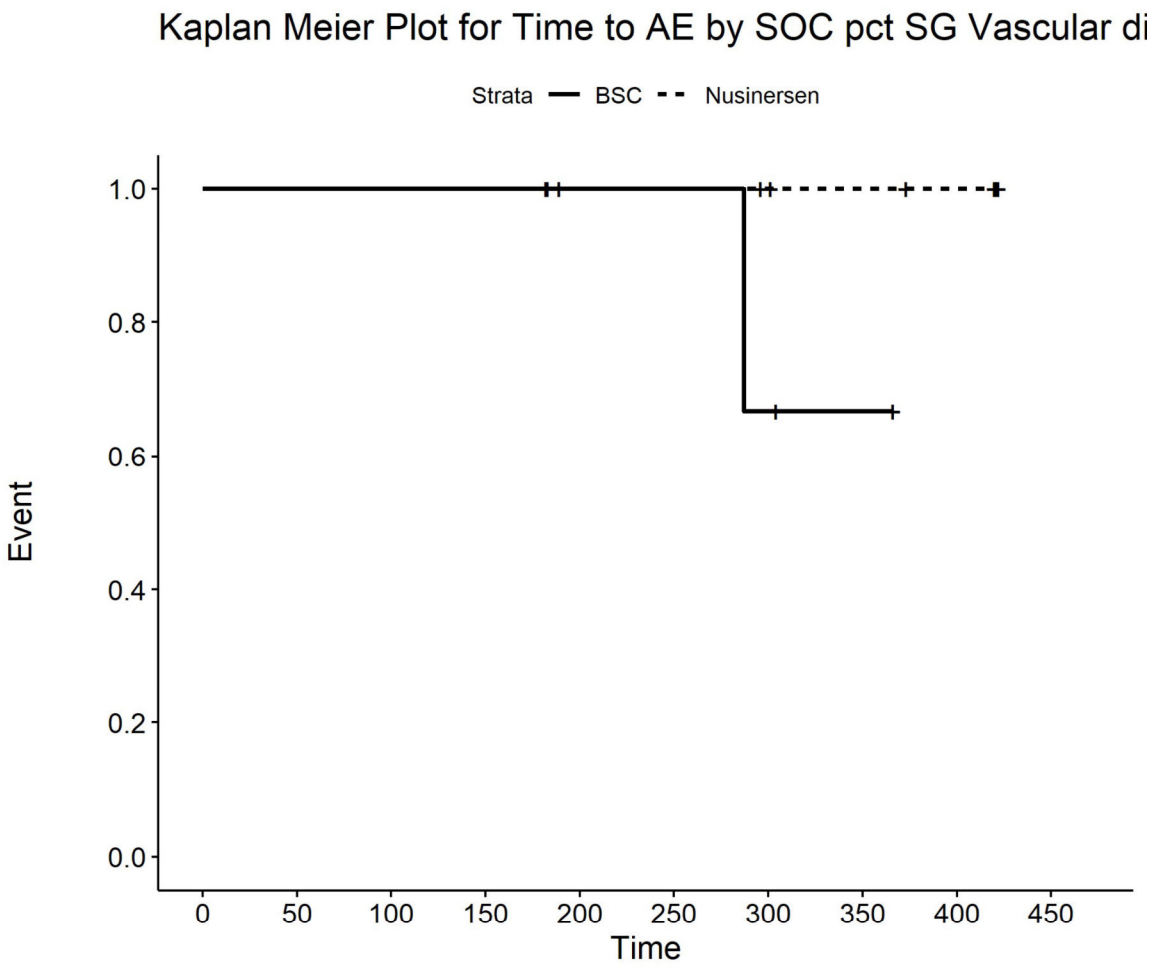
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



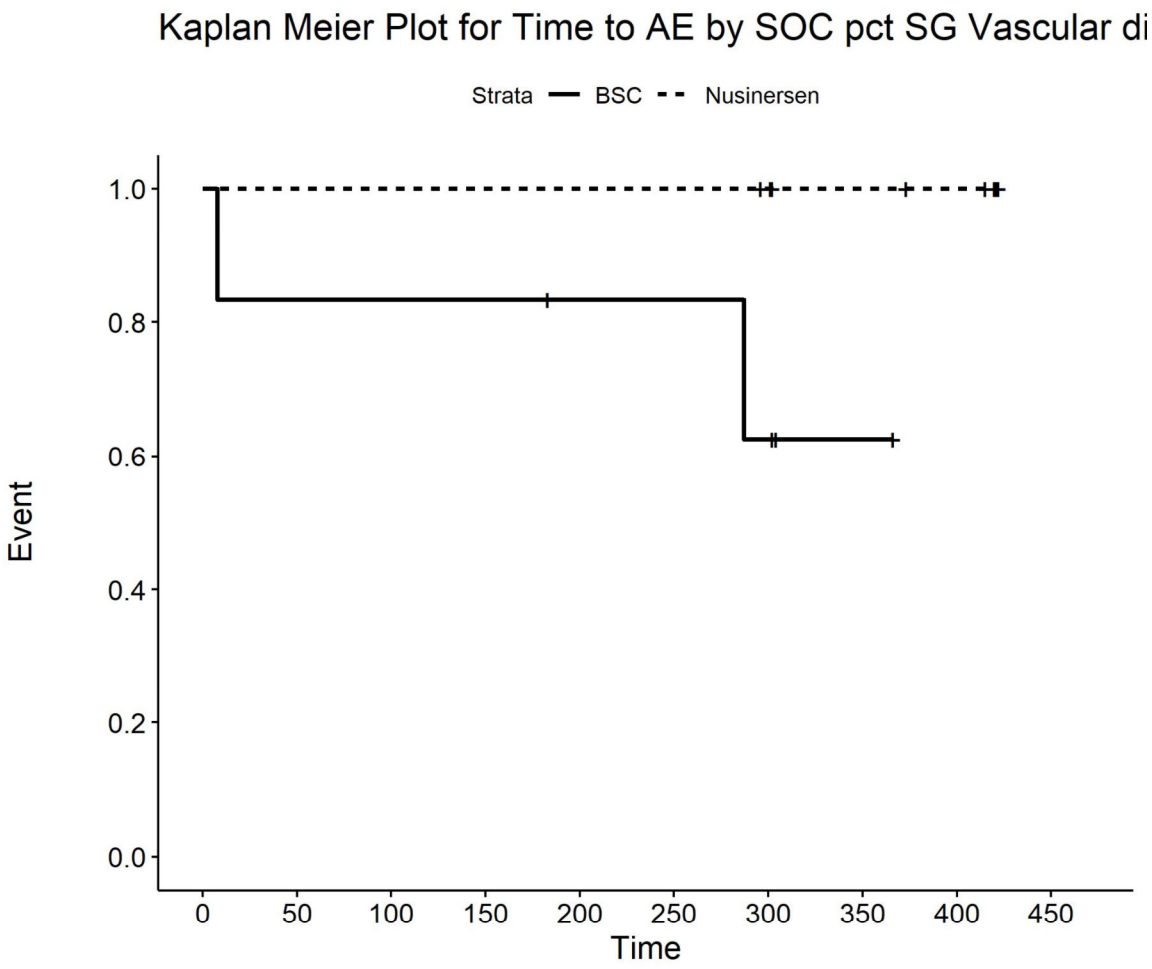
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



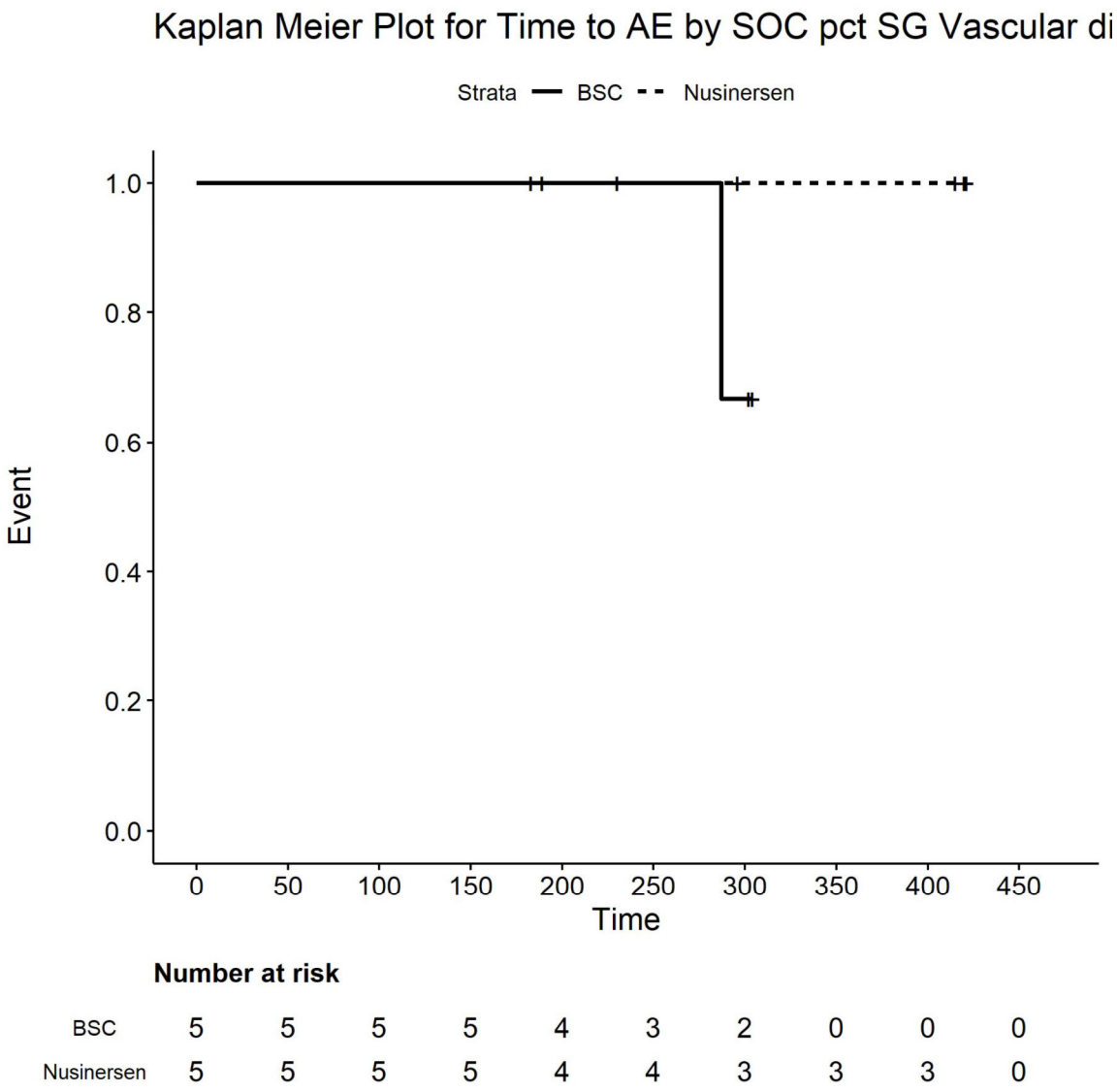
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



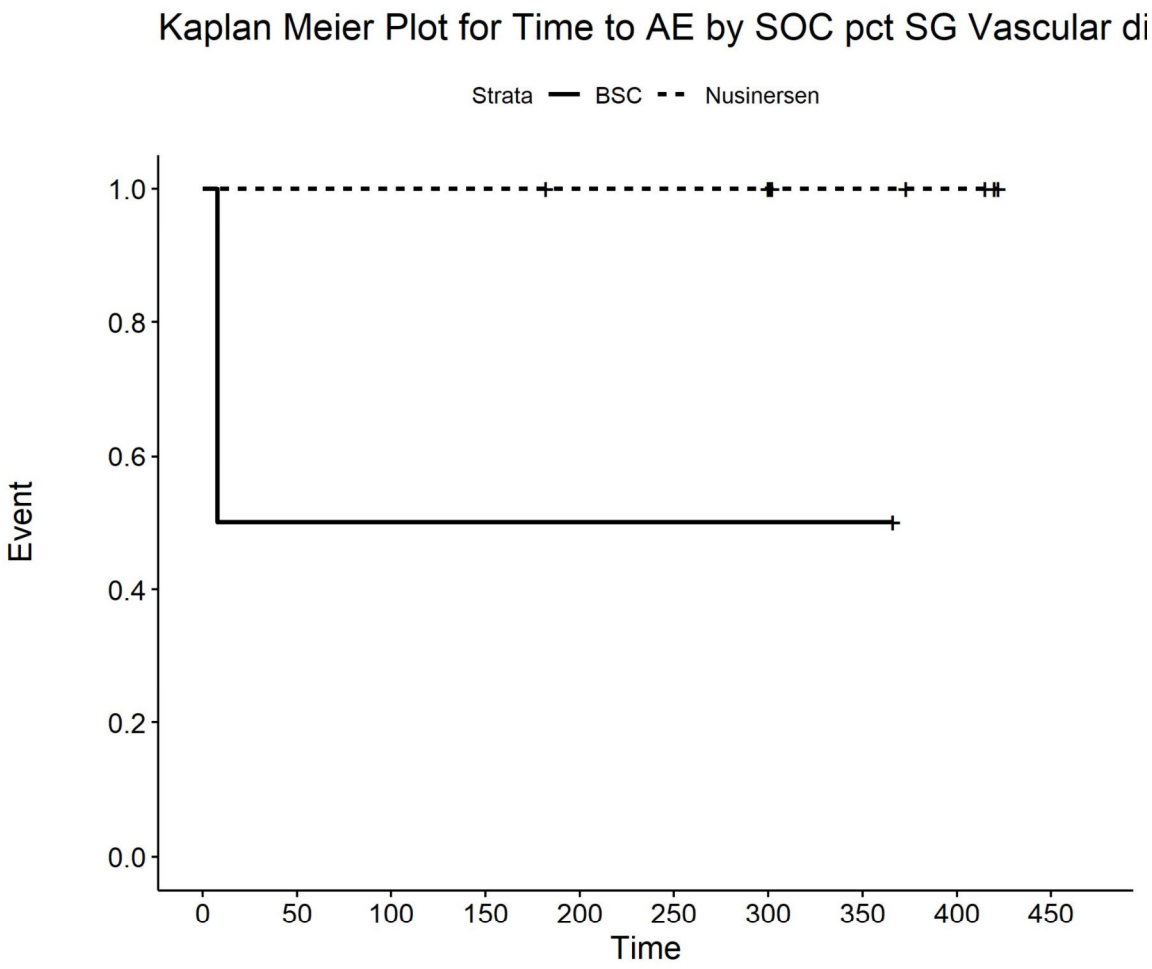
Number at risk

BSC	6	5	5	5	4	4	3	1	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



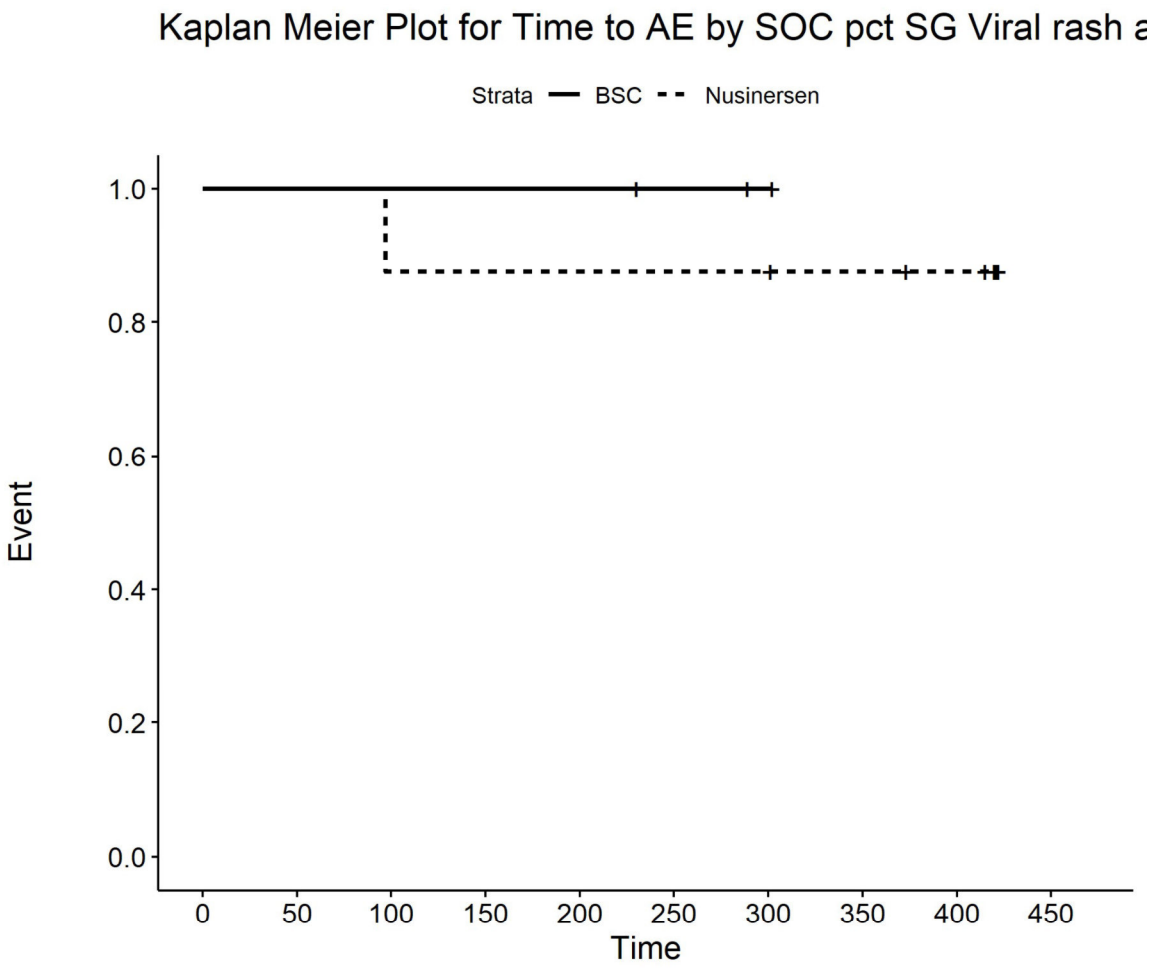
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



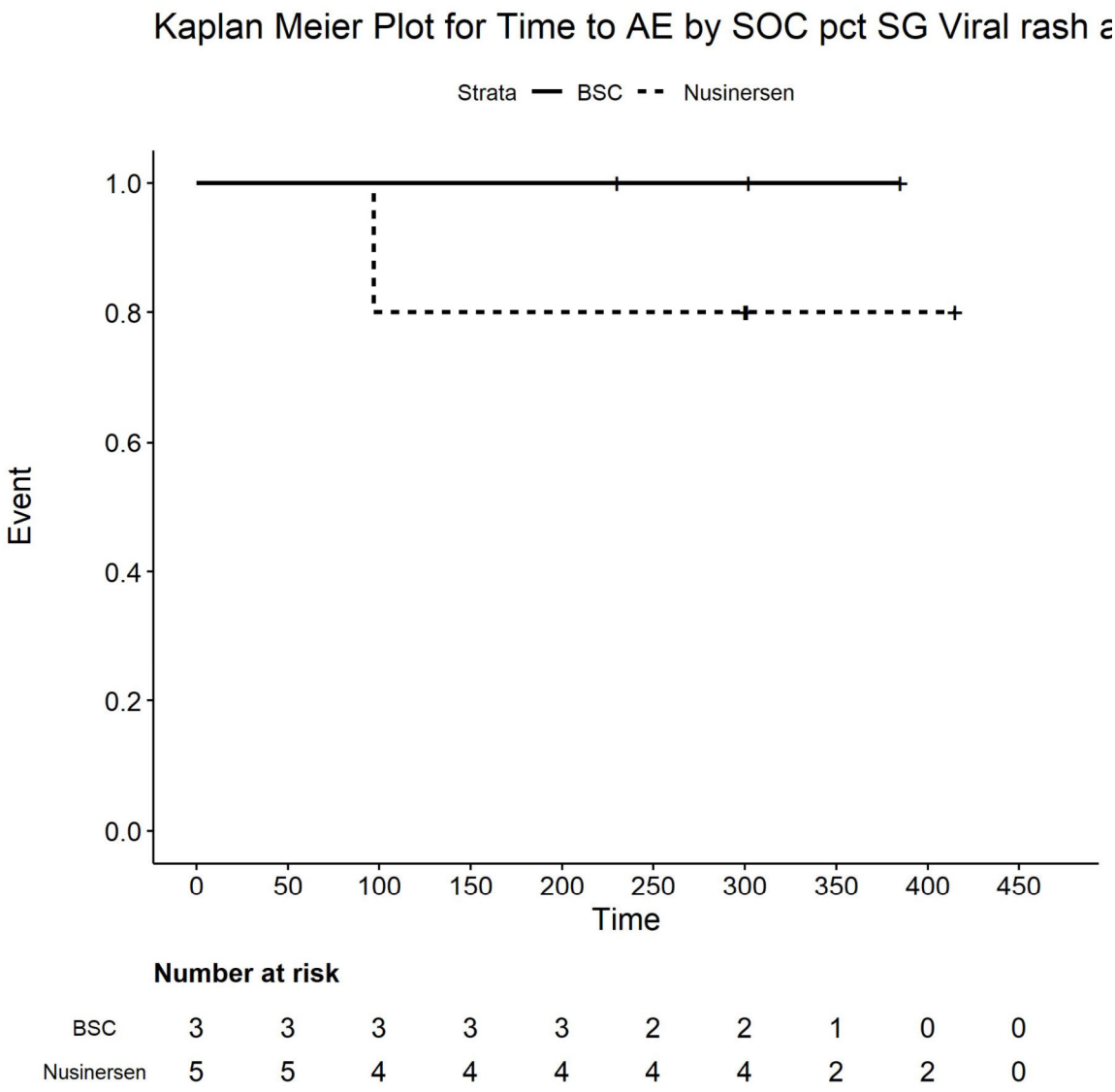
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



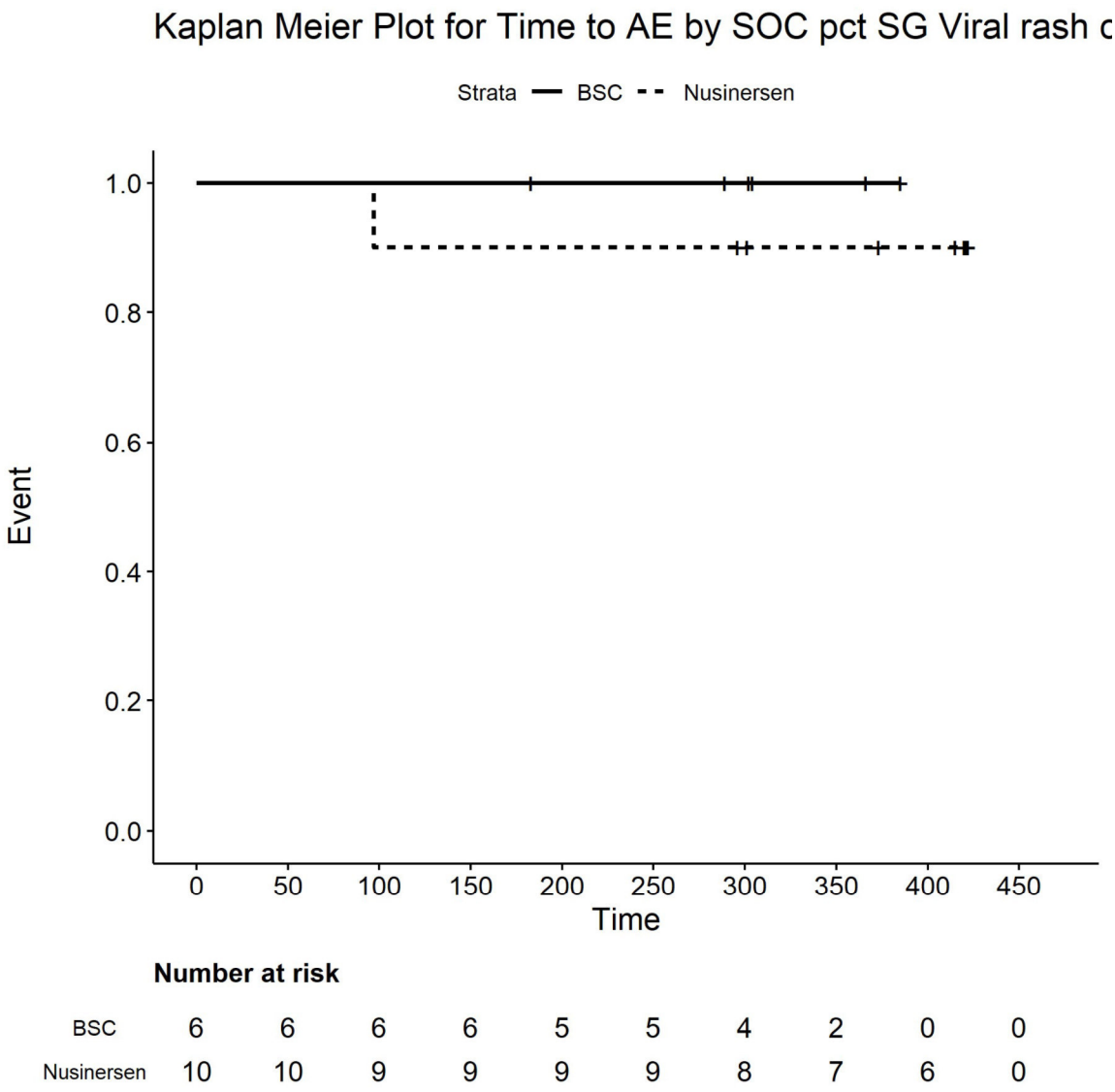
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	6	5	0



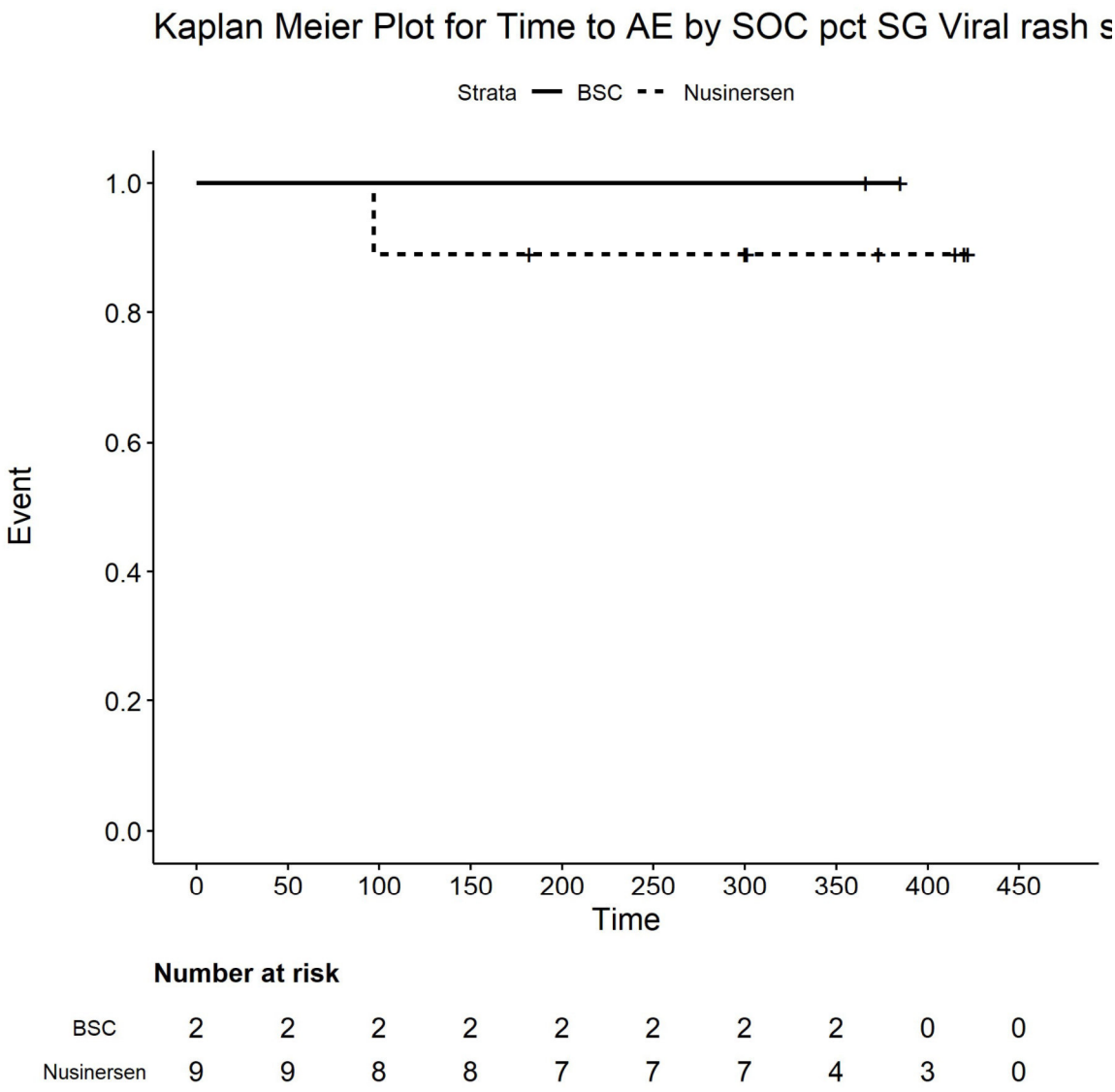
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



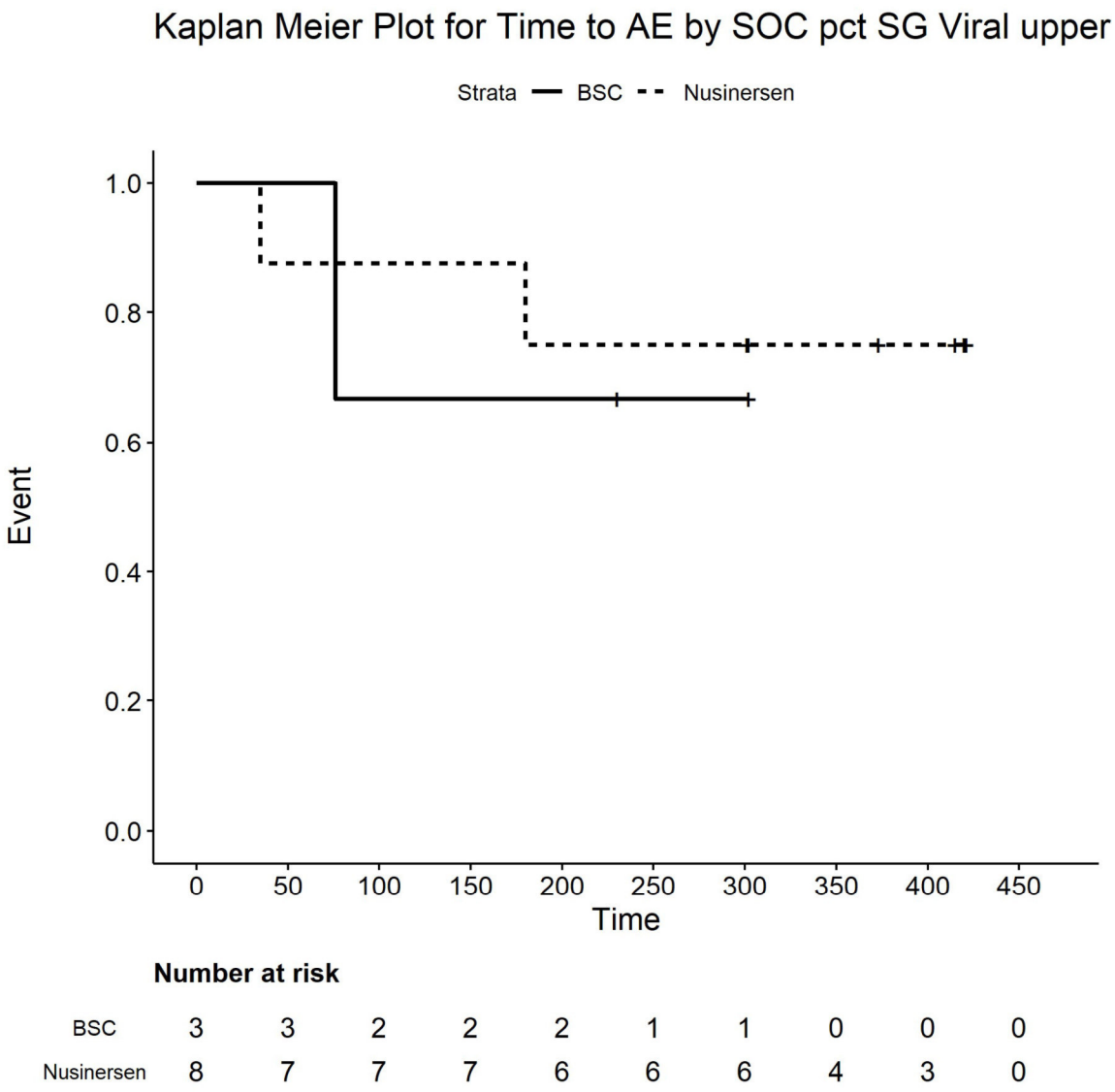
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



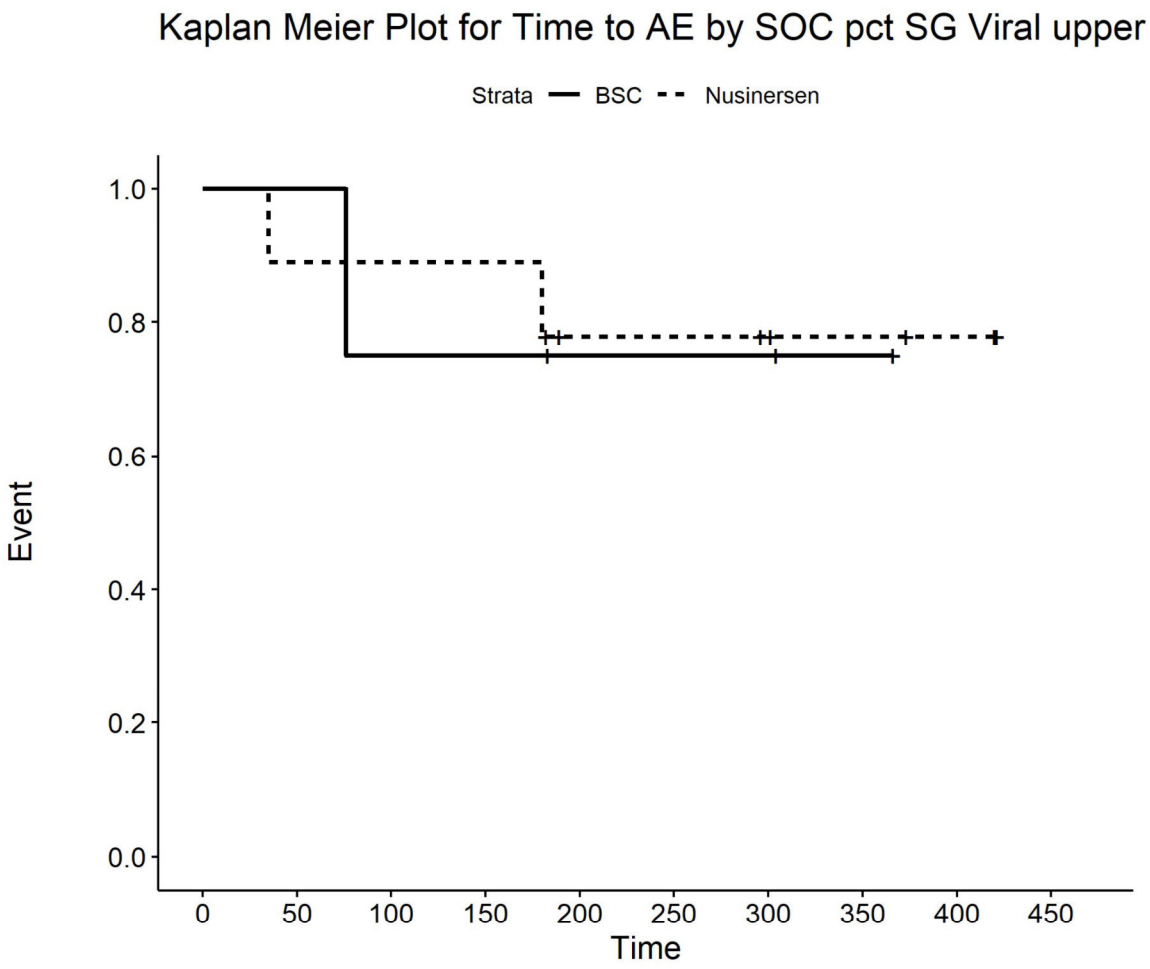
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



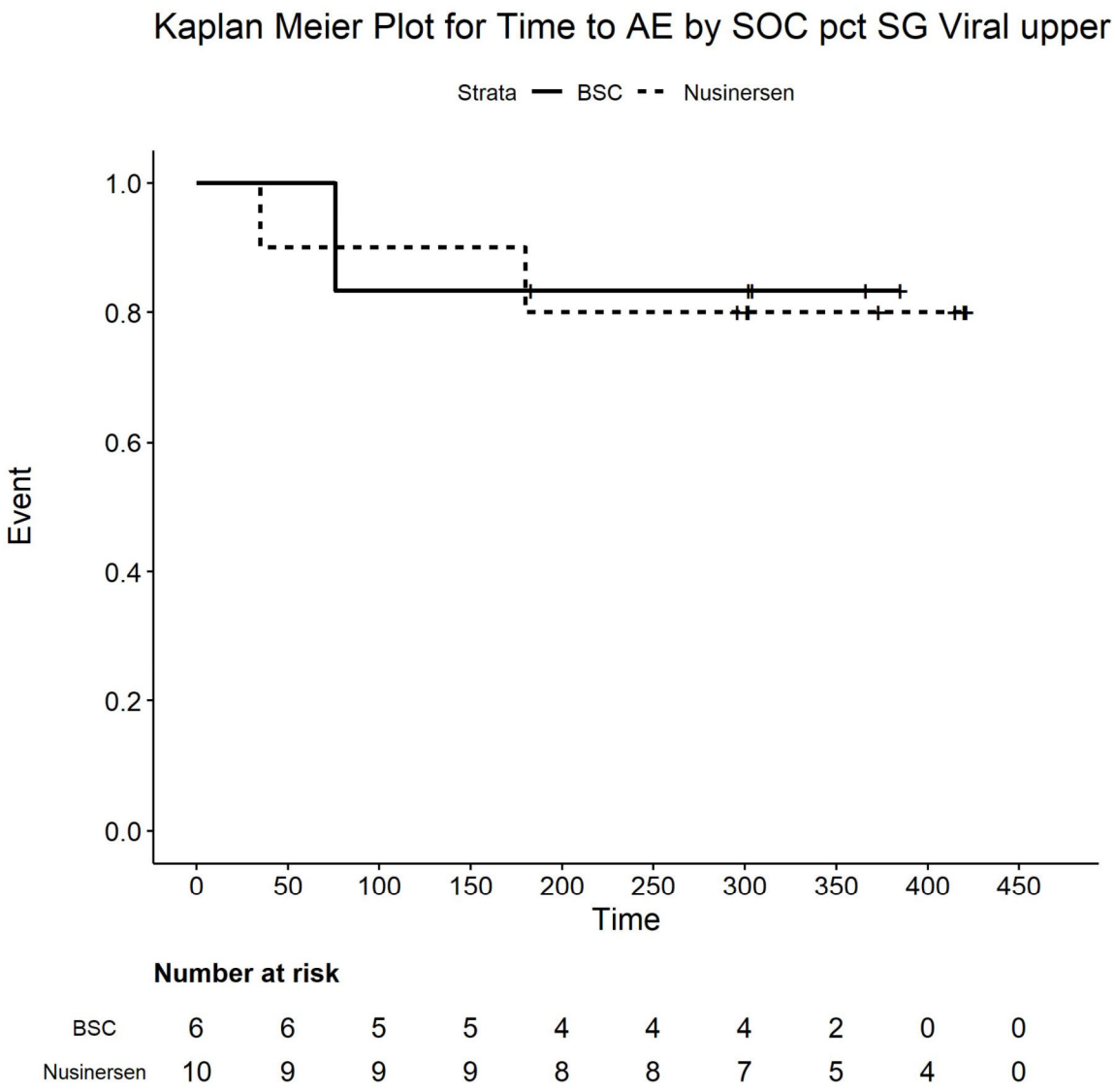
Number at risk

BSC	3	3	2	2	2	1	1	0	0	0
Nusinersen	8	7	7	7	6	6	6	4	3	0



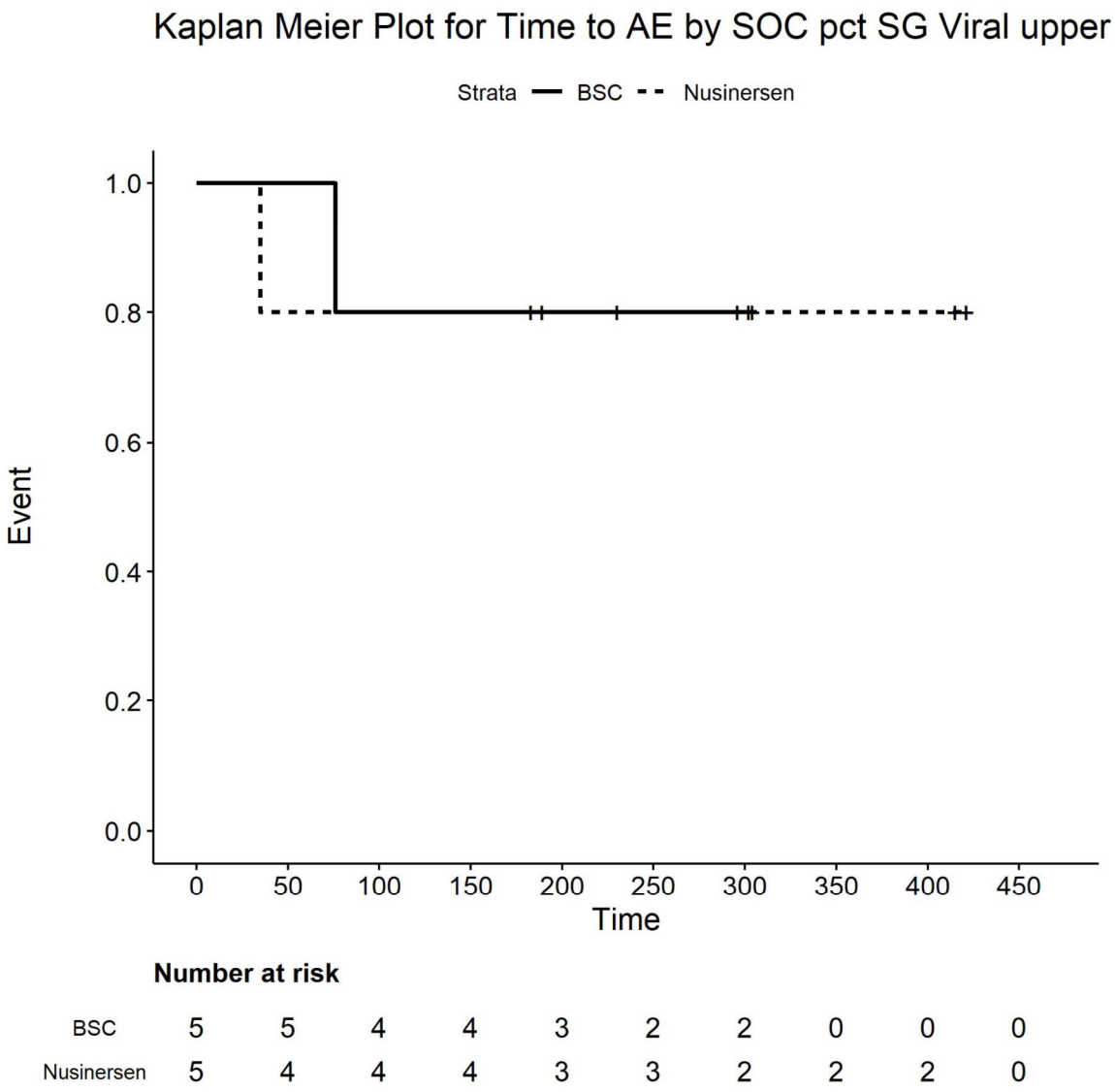
Number at risk

BSC	4	4	3	3	2	2	2	1	0	0
Nusinersen	9	8	8	8	5	5	4	3	2	0



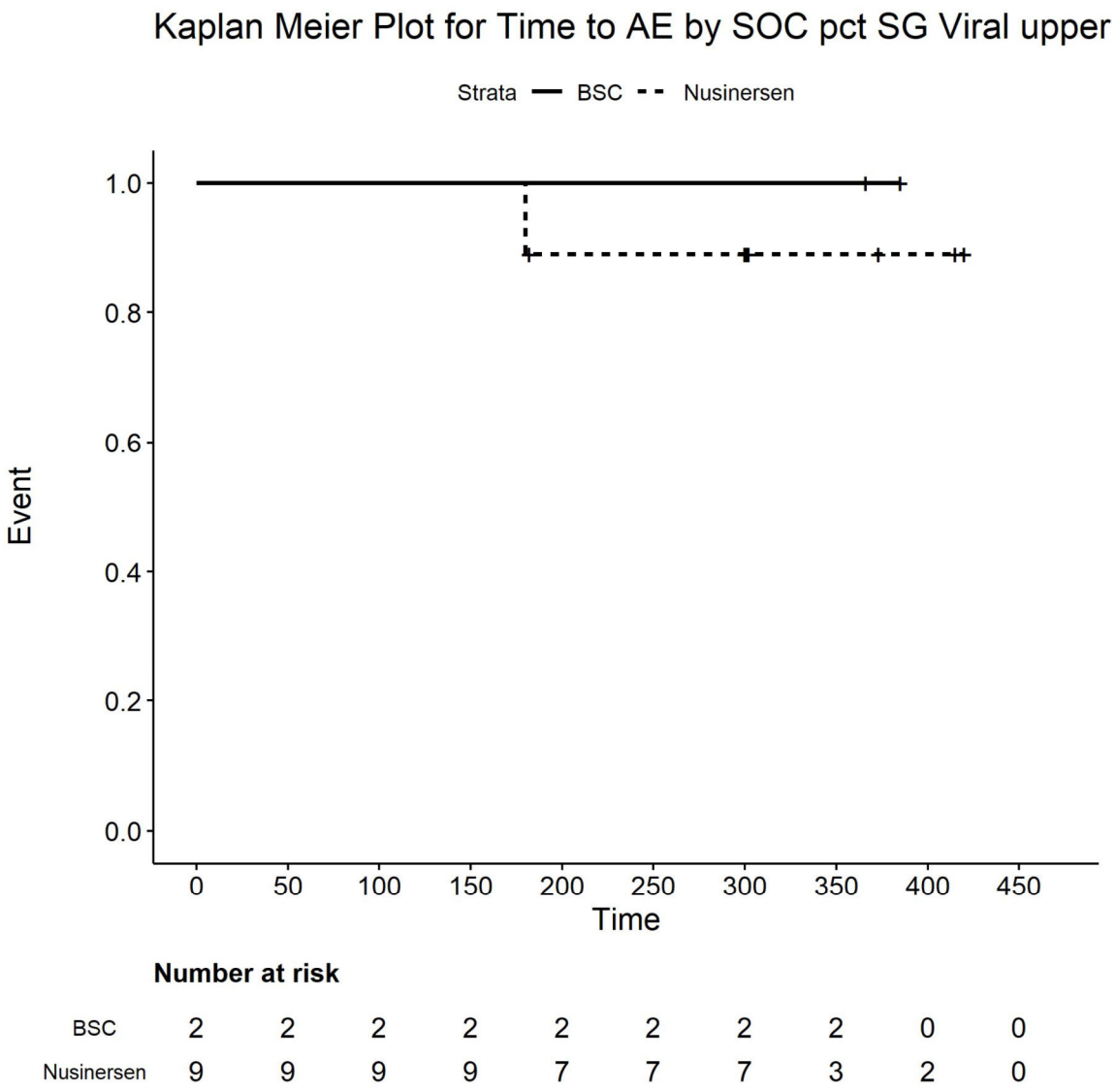
Number at risk

BSC	6	6	5	5	4	4	4	2	0	0
Nusinersen	10	9	9	9	8	8	7	5	4	0



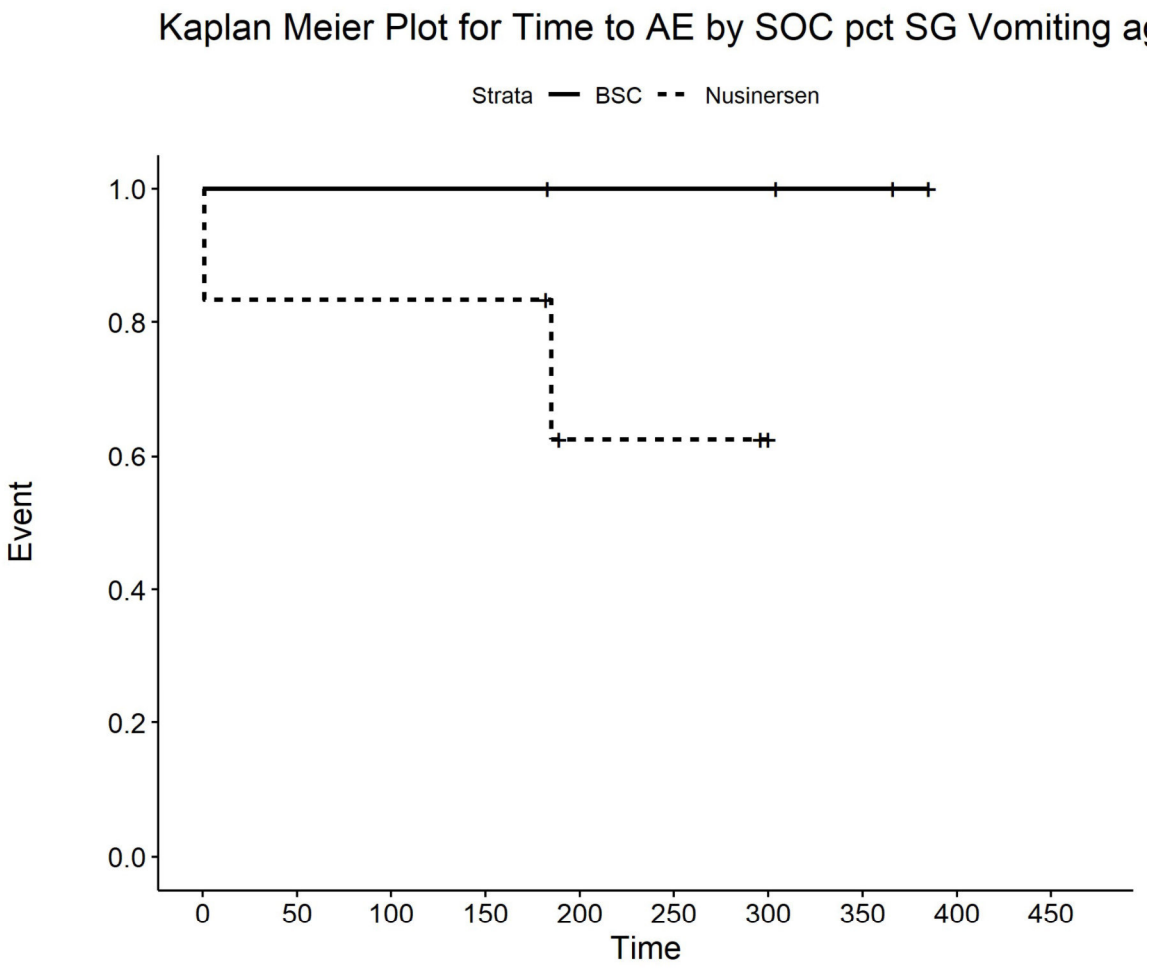
Number at risk

BSC	5	5	4	4	3	2	2	0	0	0
Nusinersen	5	4	4	4	3	3	2	2	2	0



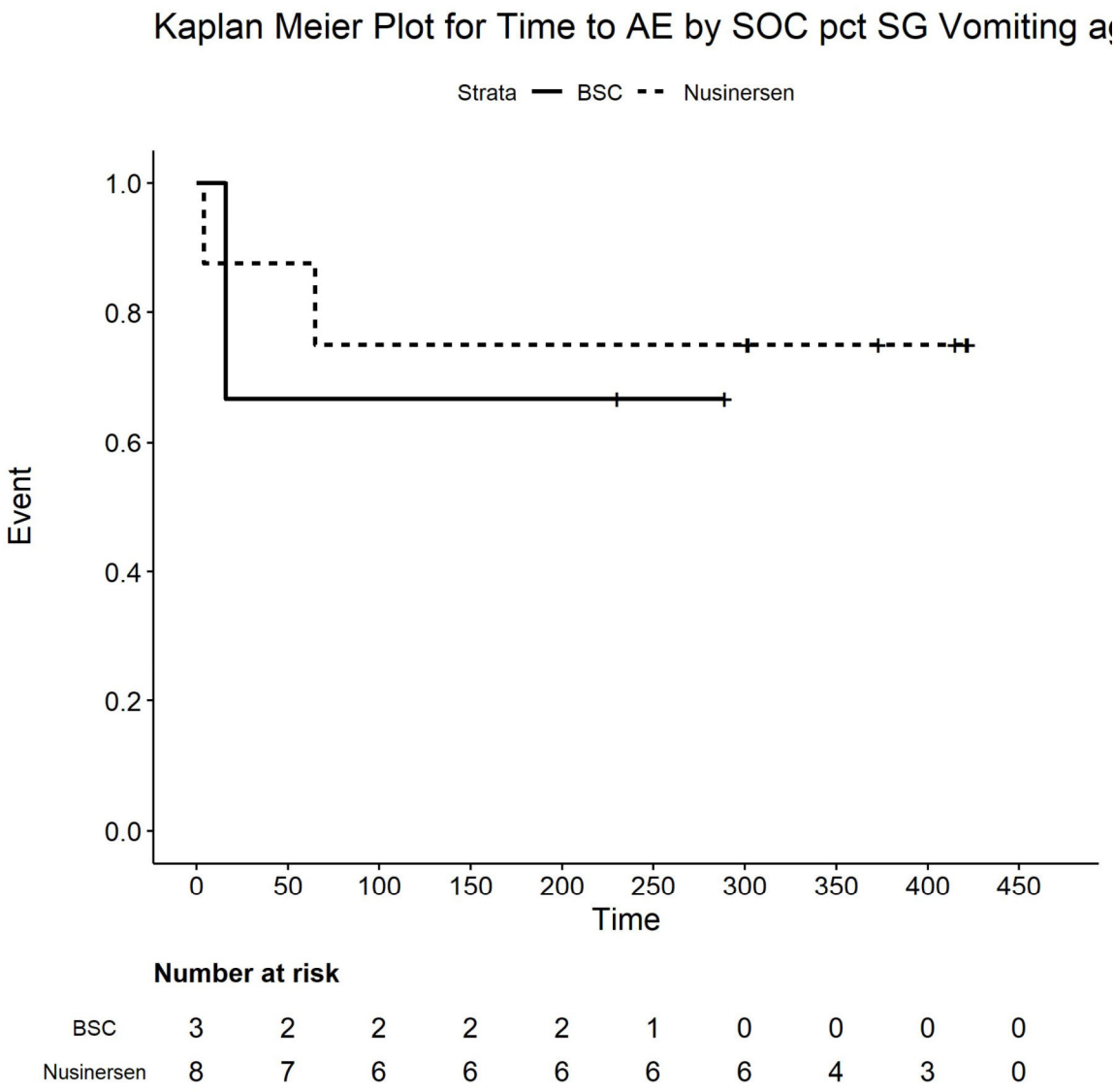
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	7	7	7	3	2	0



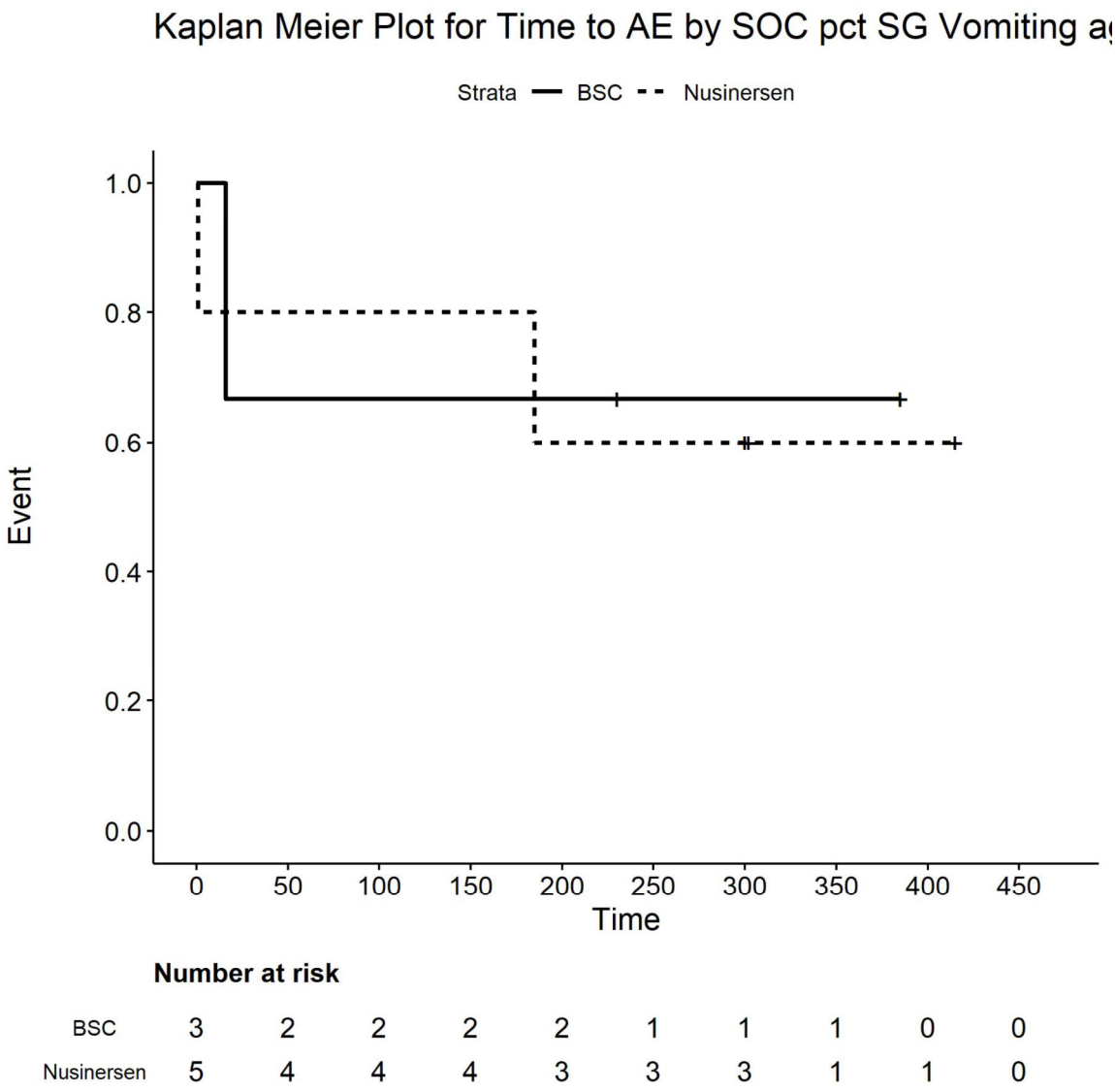
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	2	2	1	0	0	0



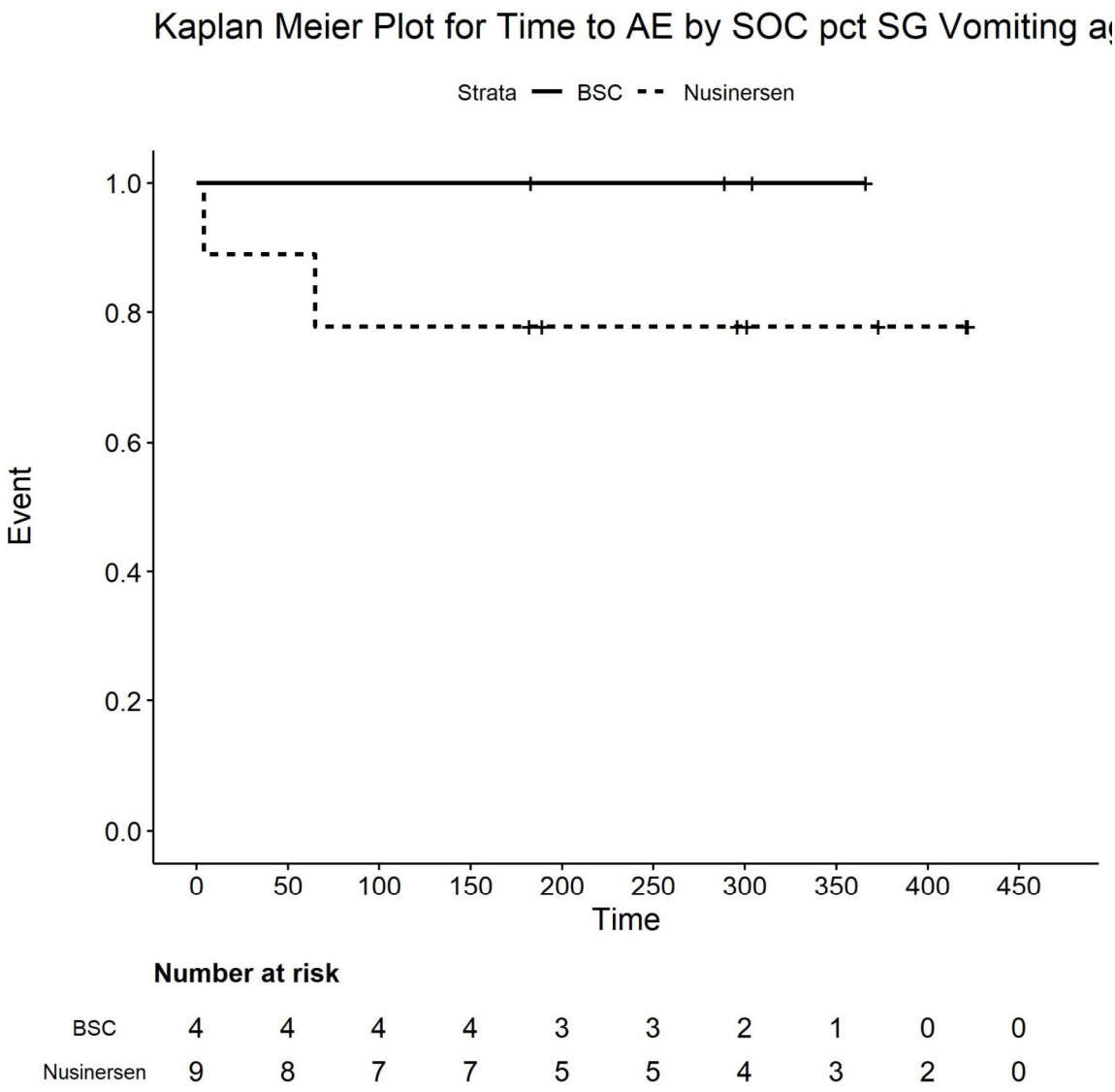
Number at risk

BSC	3	2	2	2	2	1	0	0	0	0
Nusinersen	8	7	6	6	6	6	6	4	3	0



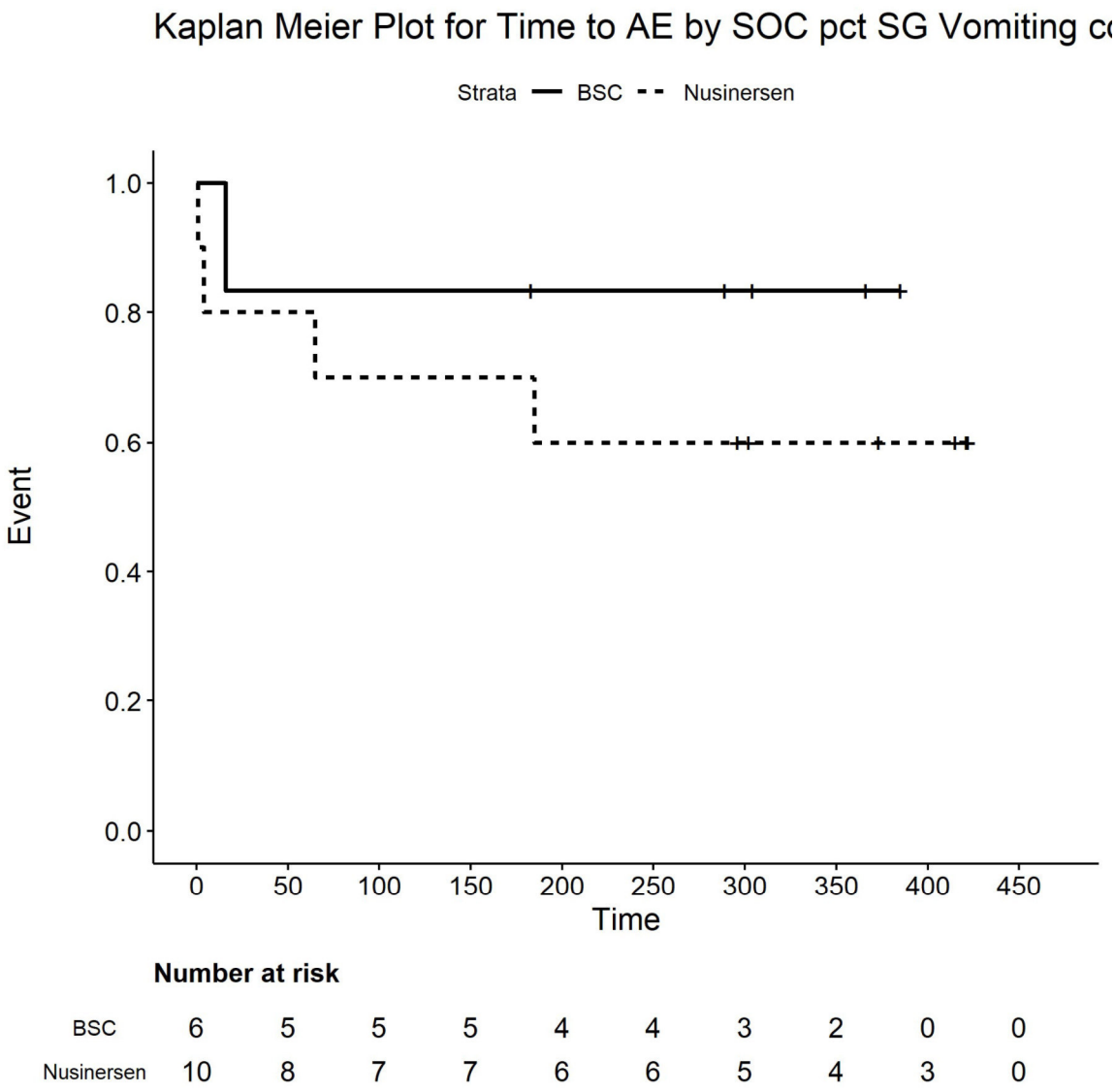
Number at risk

BSC	3	2	2	2	2	1	1	1	0	0
Nusinersen	5	4	4	4	3	3	3	1	1	0



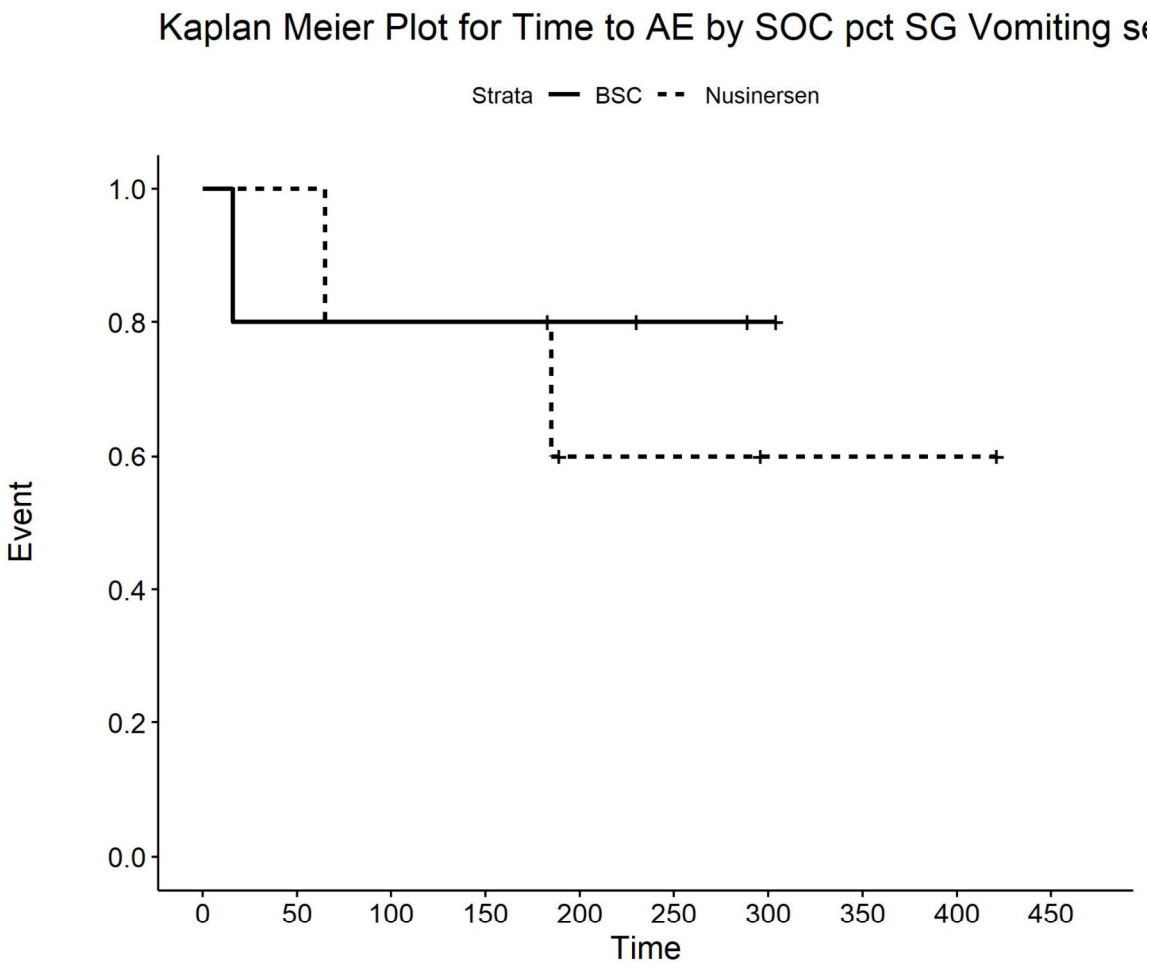
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	7	7	5	5	4	3	2	0



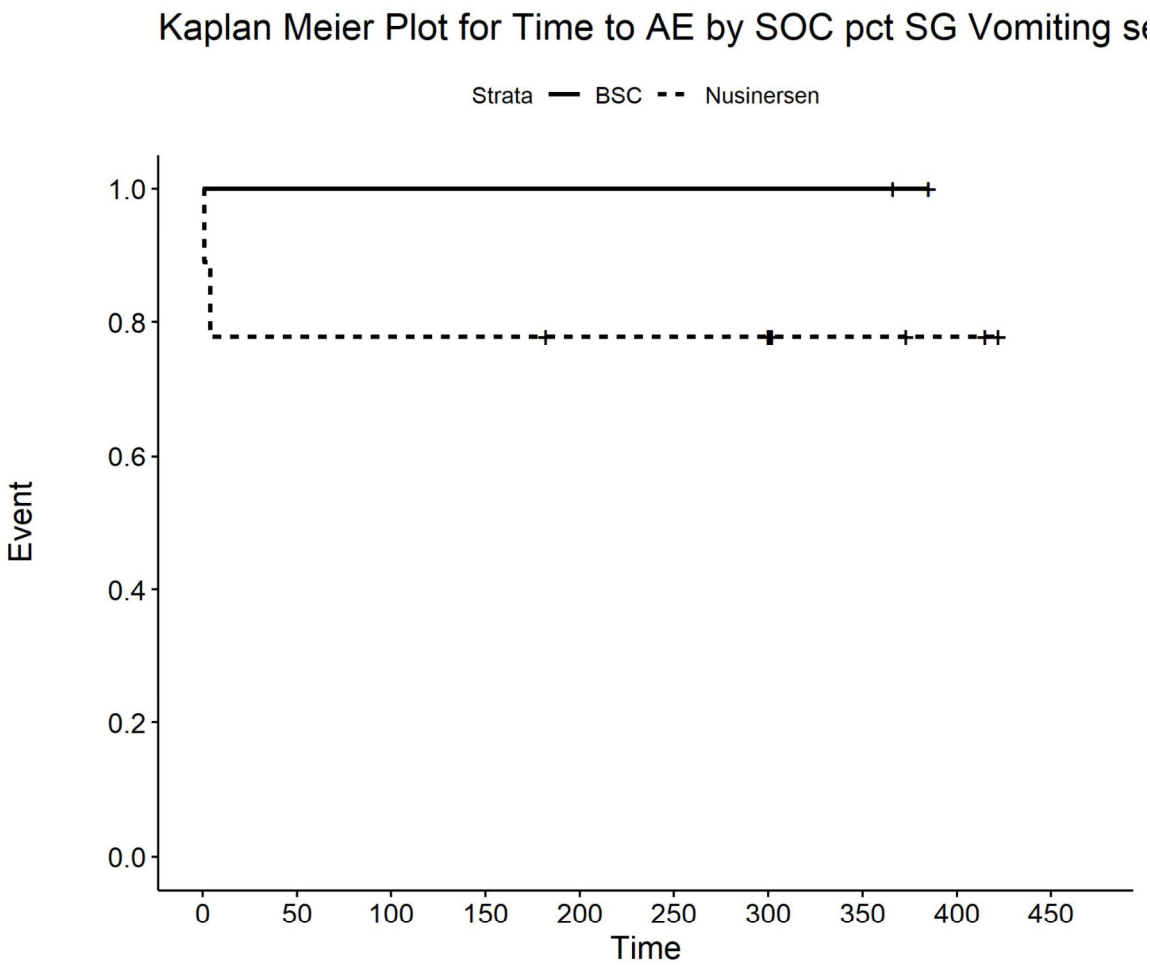
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	8	7	7	6	6	5	4	3	0



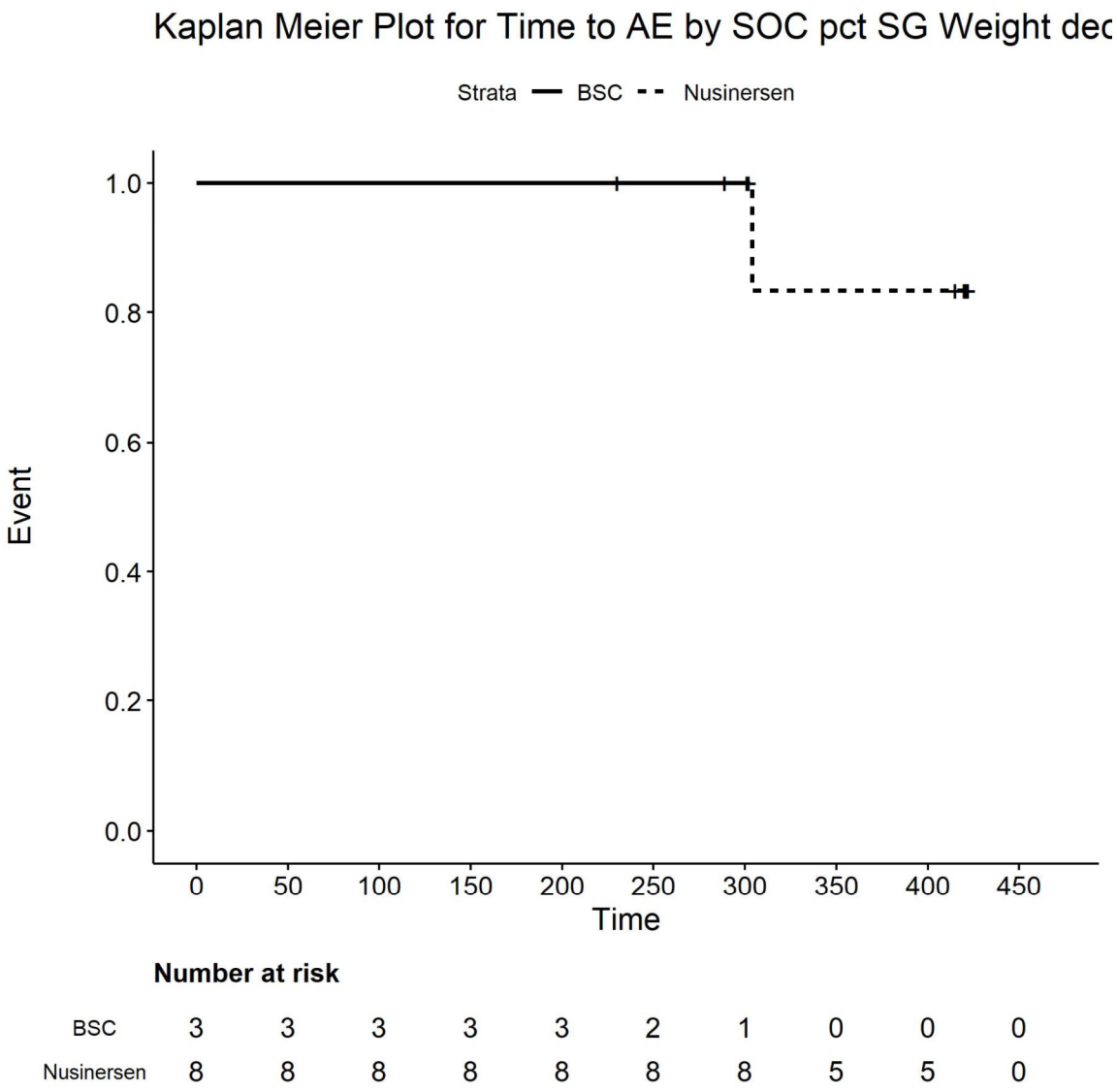
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	4	4	2	2	1	1	1	0



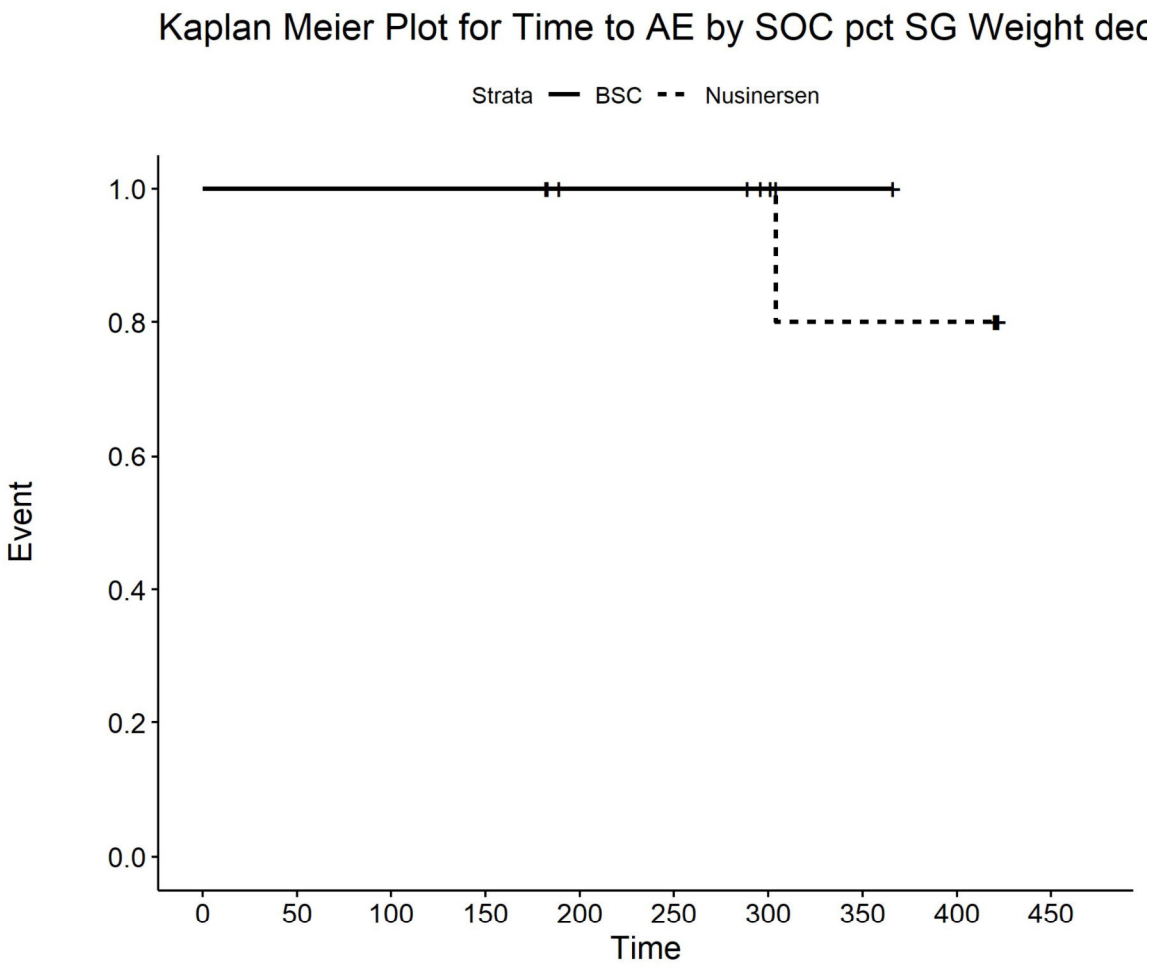
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	7	7	6	6	6	3	2	0



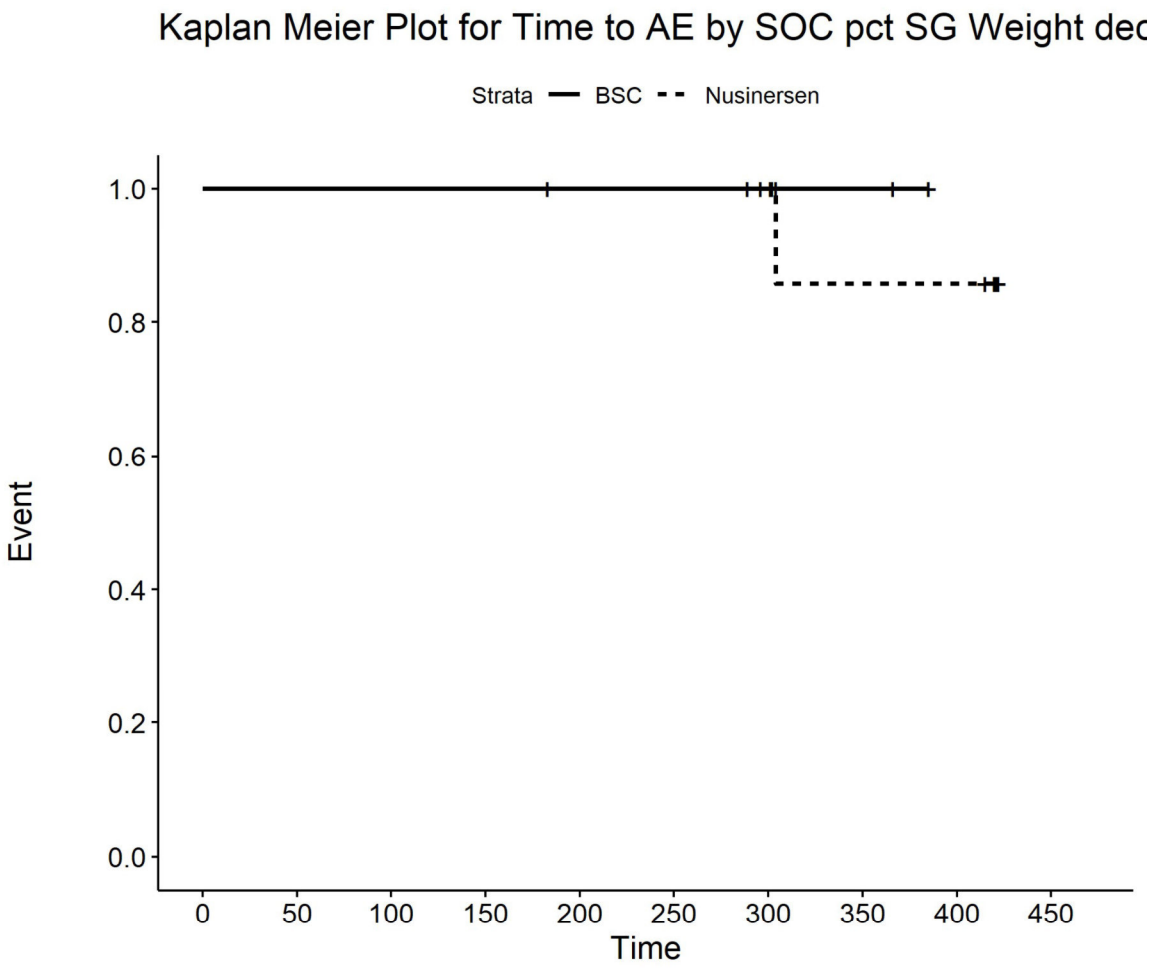
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	5	5	0



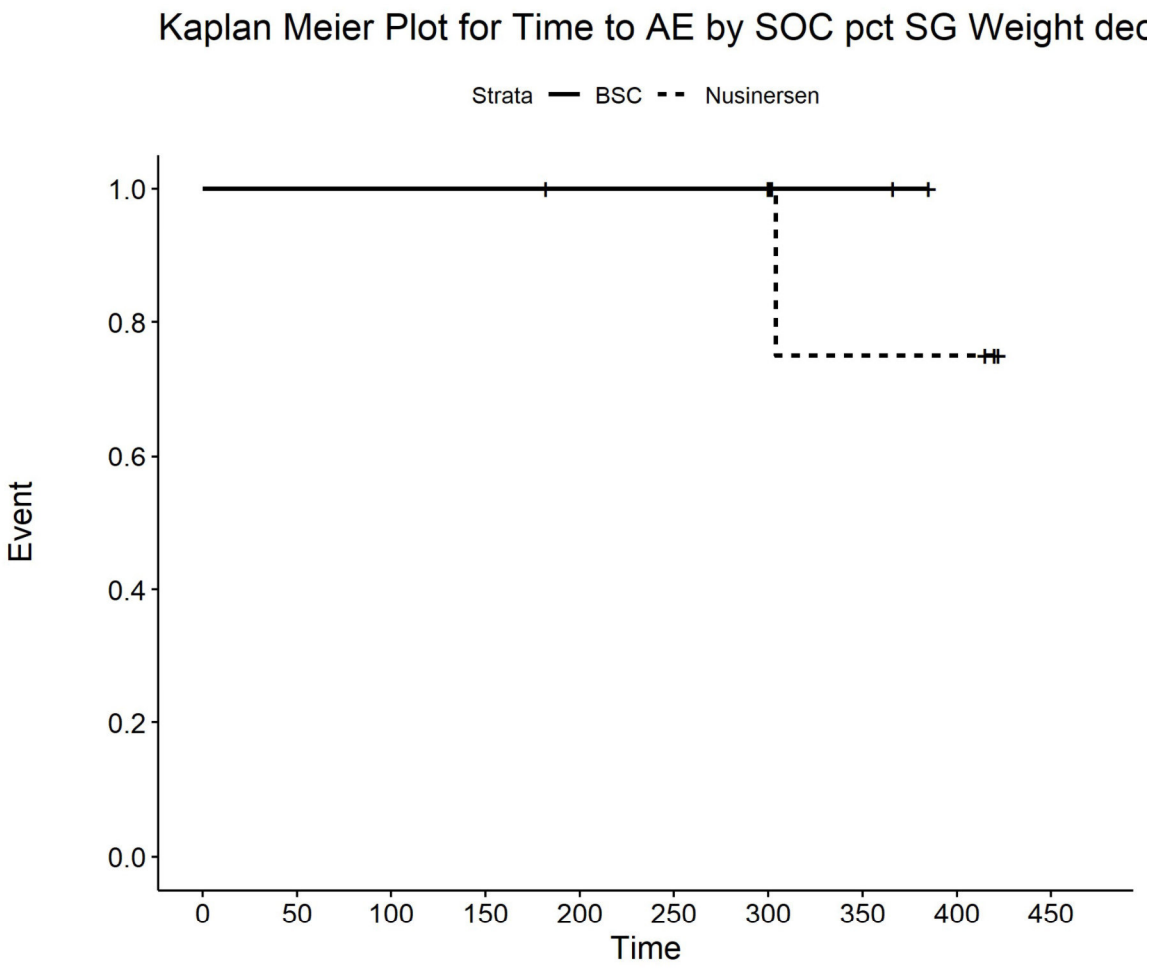
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	4	4	0



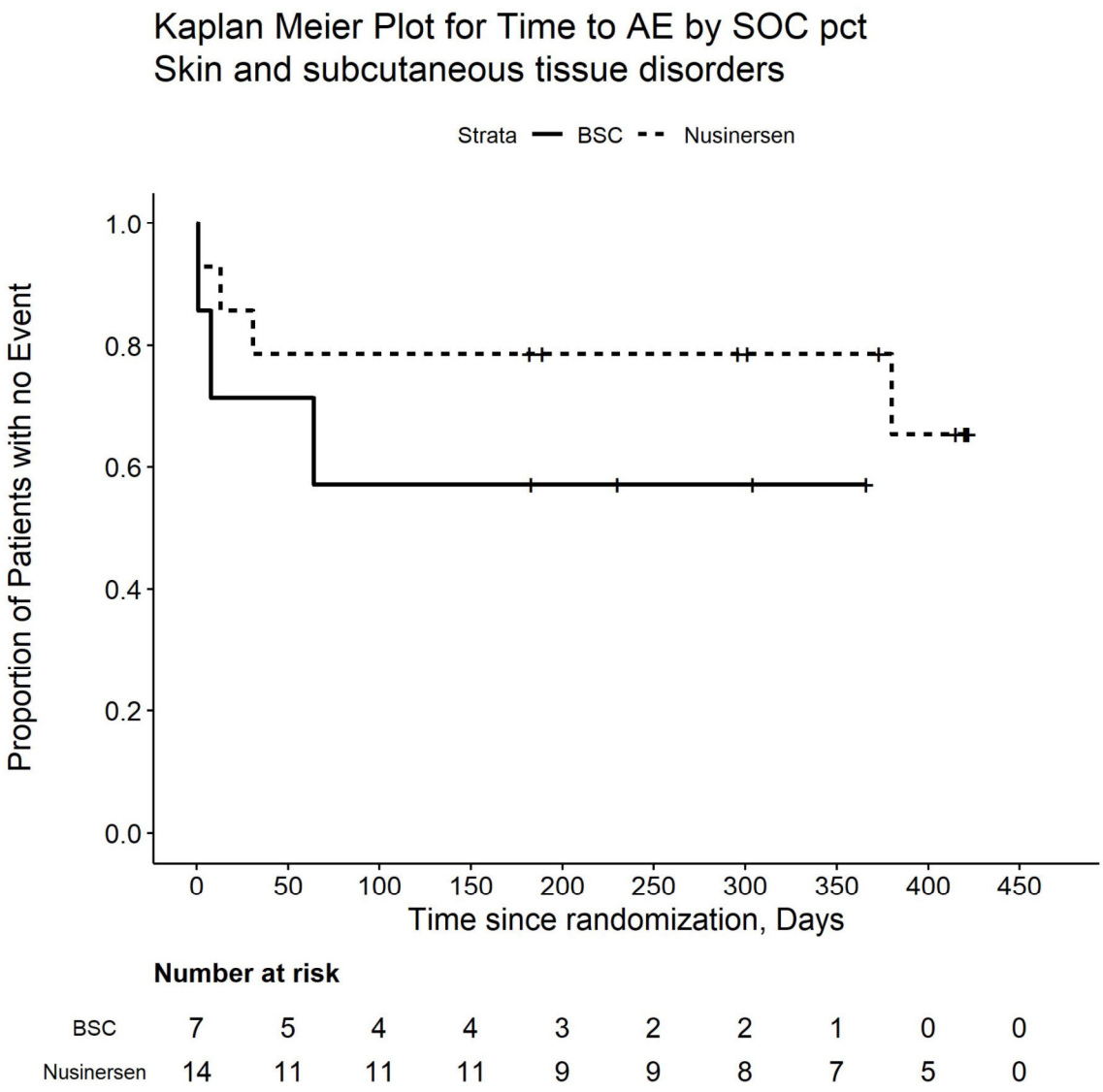
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	6	6	0



Number at risk

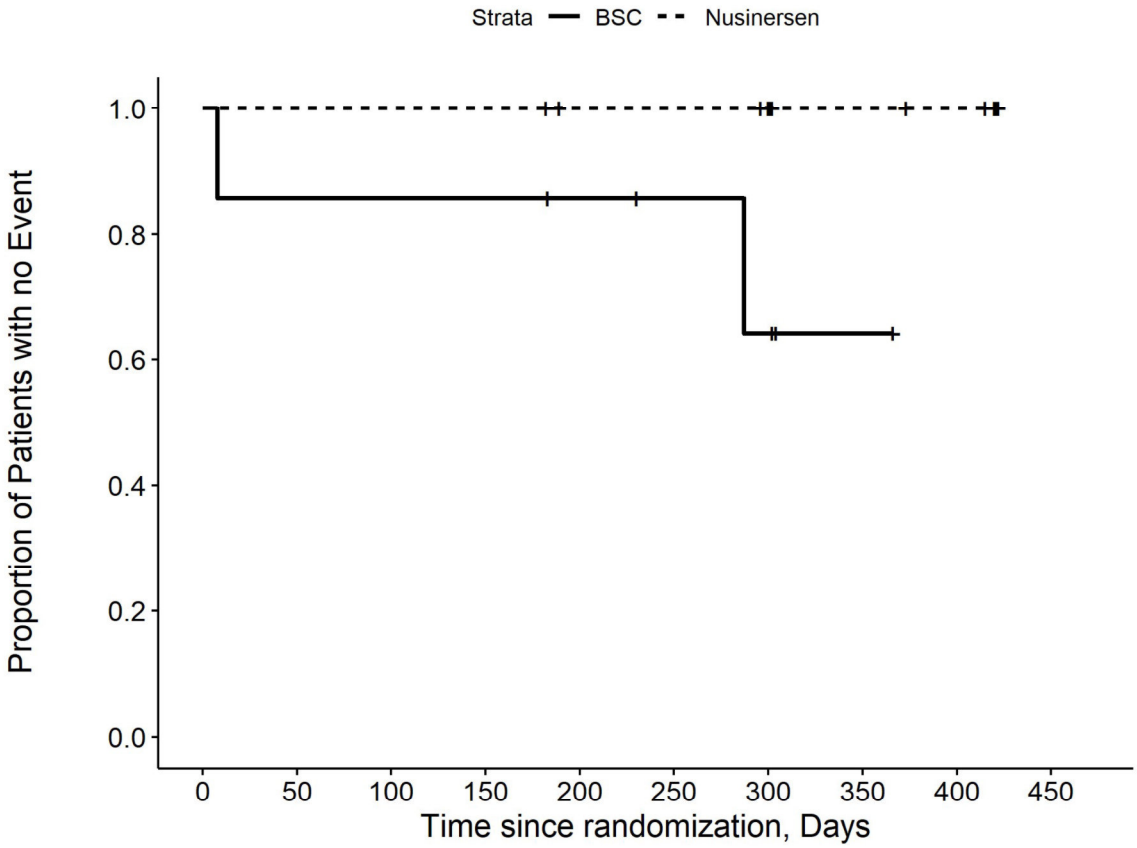
BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	8	3	3	0



Number at risk

BSC	7	5	4	4	3	2	2	1	0	0
Nusinersen	14	11	11	11	9	9	8	7	5	0

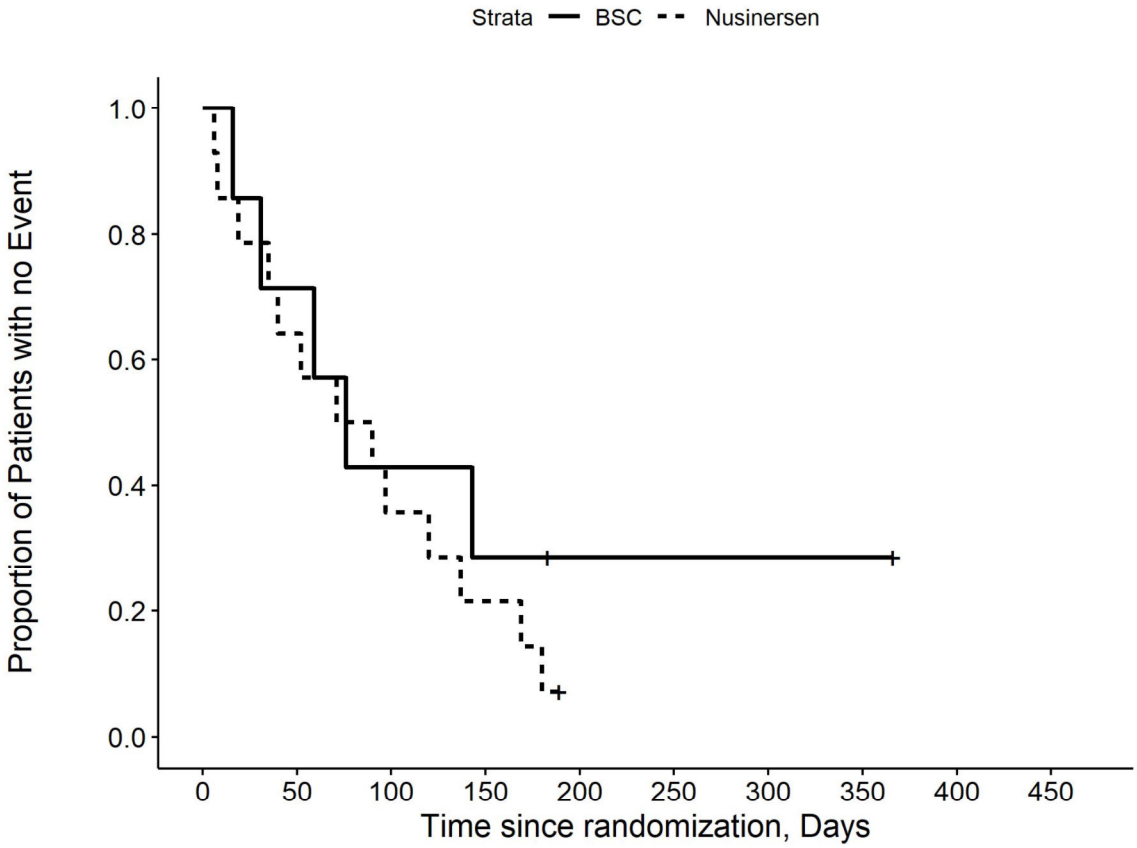
Kaplan Meier Plot for Time to AE by SOC pct
Vascular disorders



Number at risk

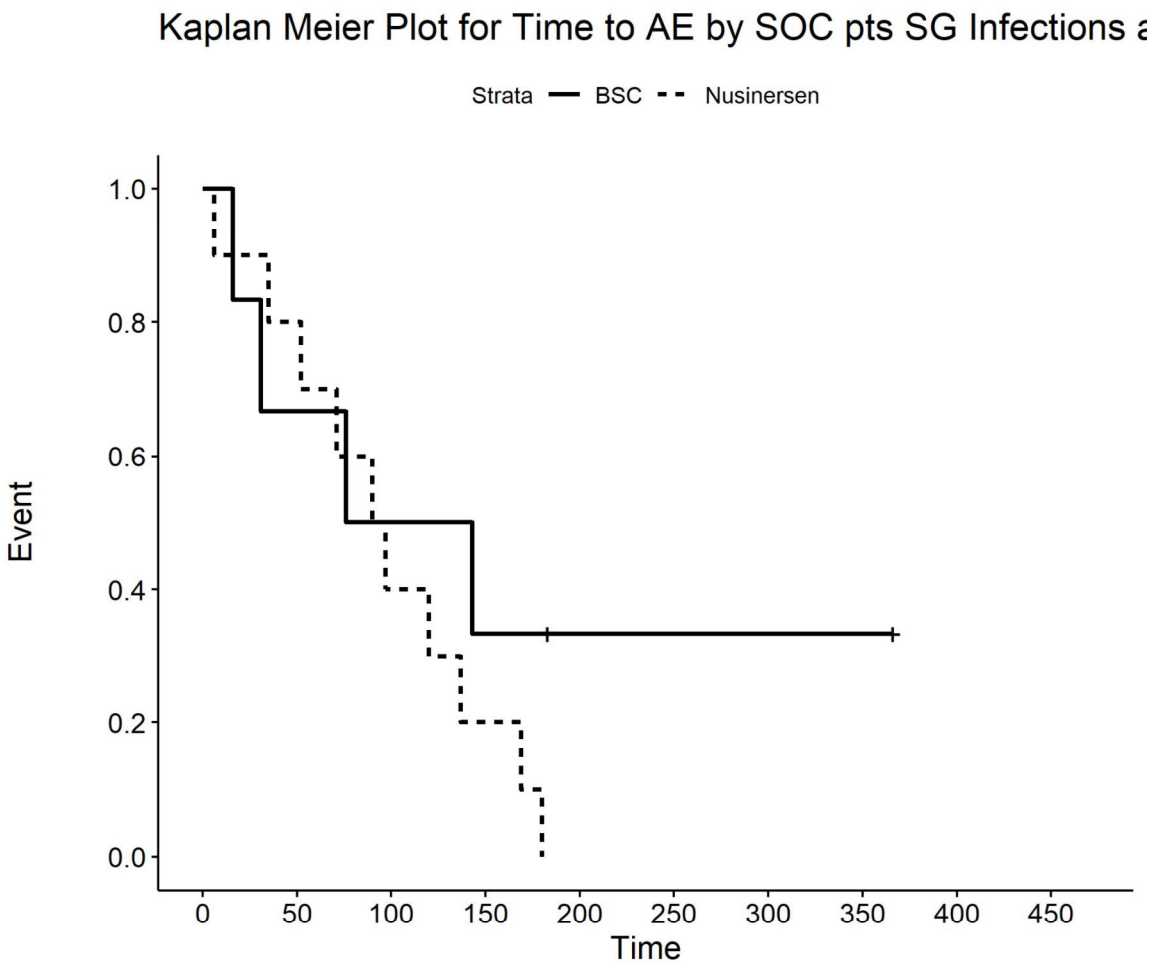
BSC	7	6	6	6	5	4	3	1	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for Time to AE by SOC pts
Infections and infestations



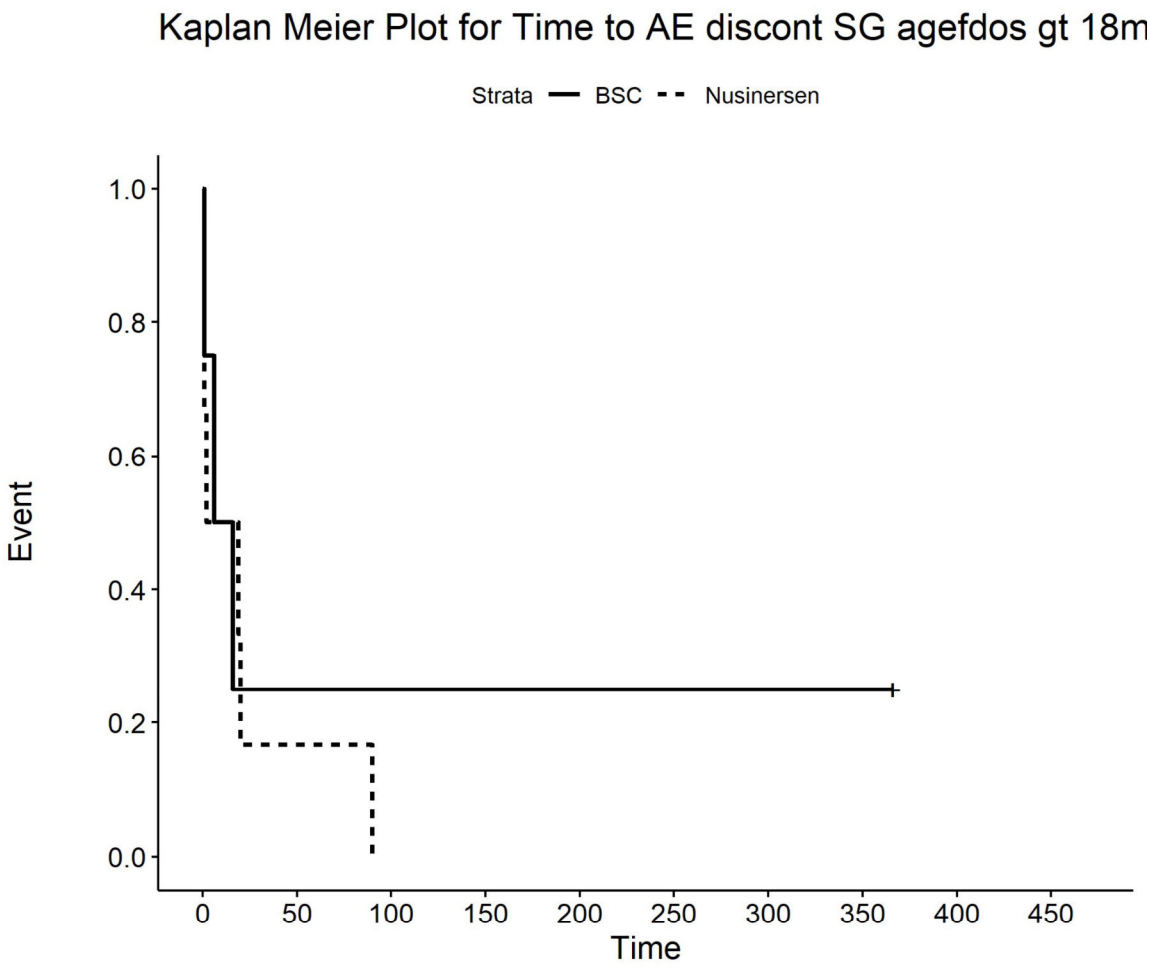
Number at risk

BSC	7	5	3	2	1	1	1	1	0	0
Nusinersen	14	9	5	3	0	0	0	0	0	0



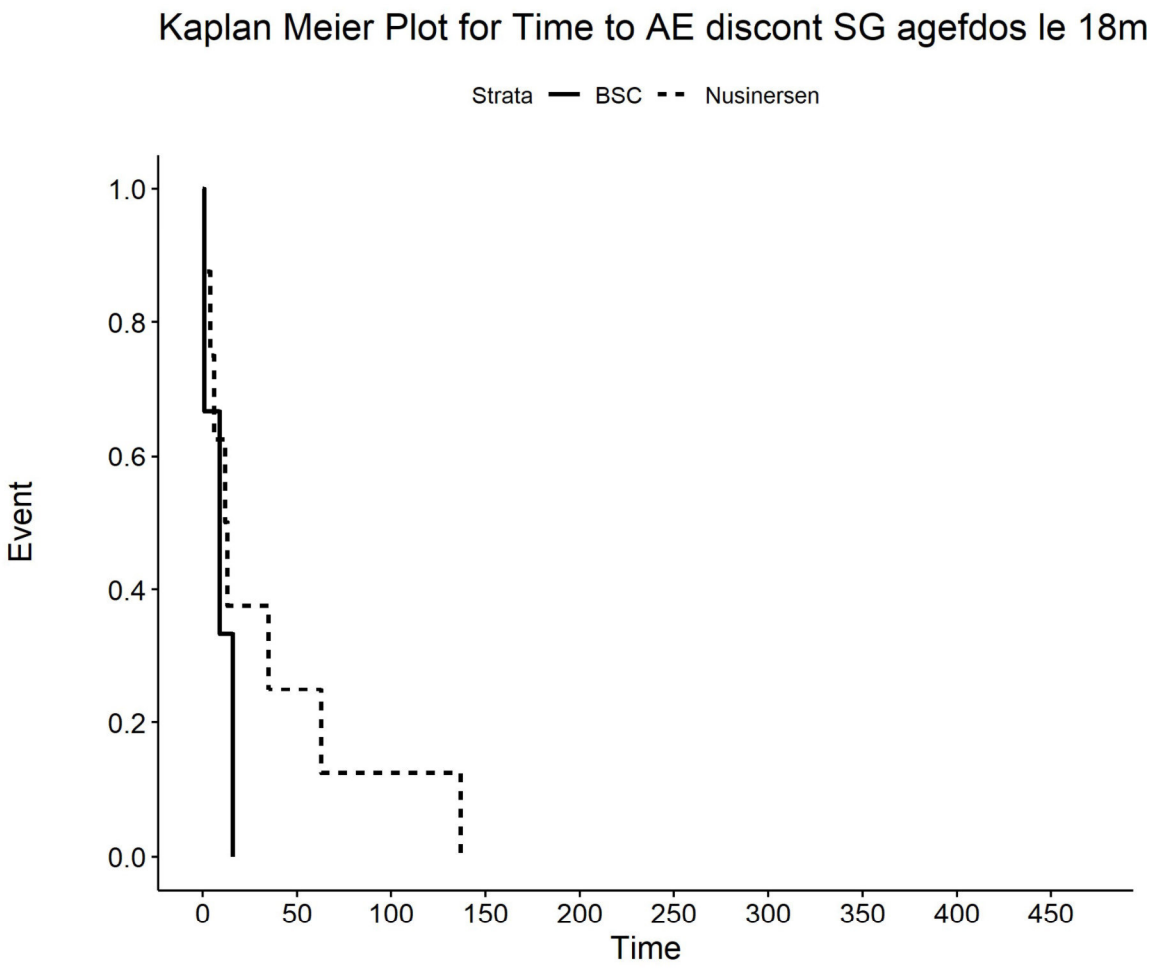
Number at risk

BSC	6	4	3	2	1	1	1	1	0	0
Nusinersen	10	8	4	2	0	0	0	0	0	0



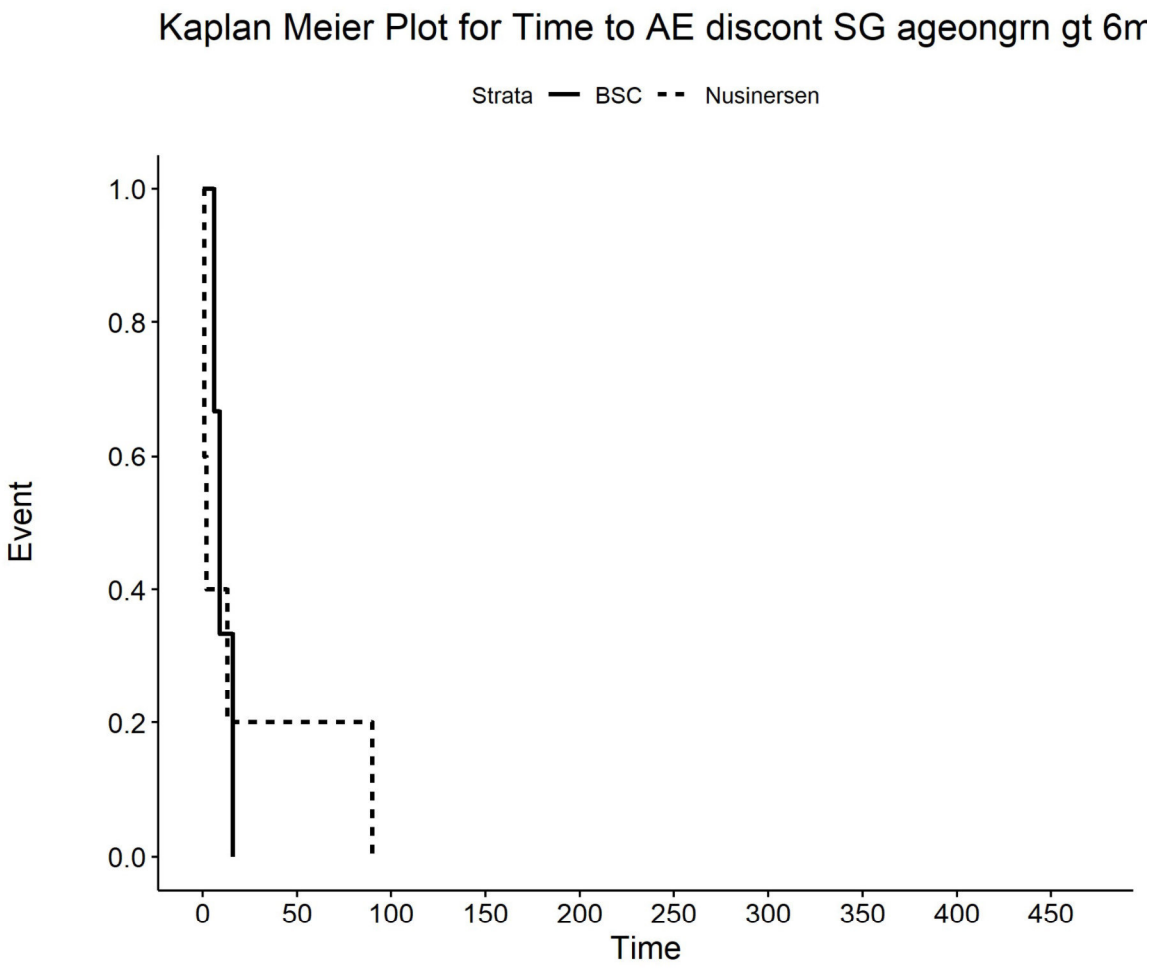
Number at risk

BSC	4	1	1	1	1	1	1	1	0	0
Nusinersen	6	1	0	0	0	0	0	0	0	0



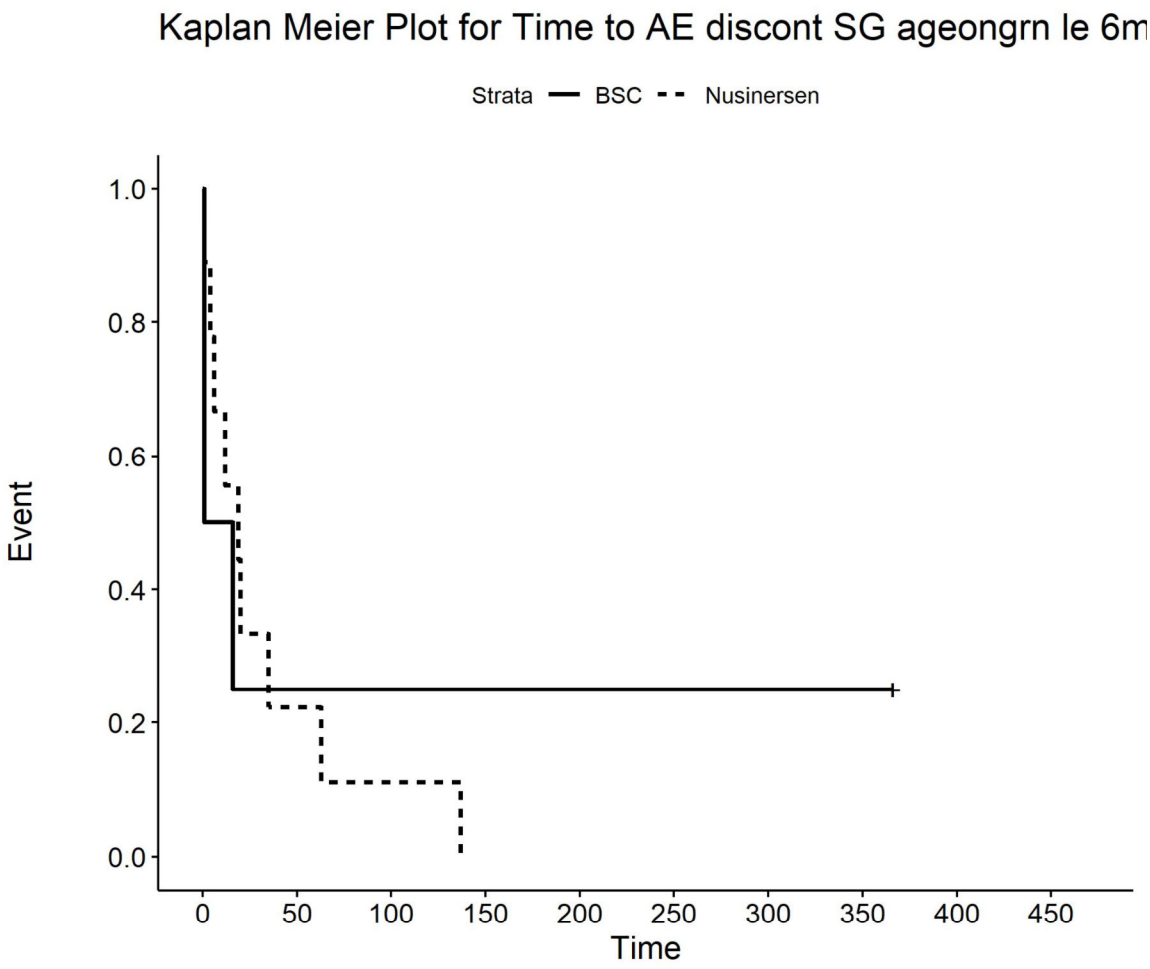
Number at risk

BSC	3	0	0	0	0	0	0	0	0	0
Nusinersen	8	2	1	0	0	0	0	0	0	0



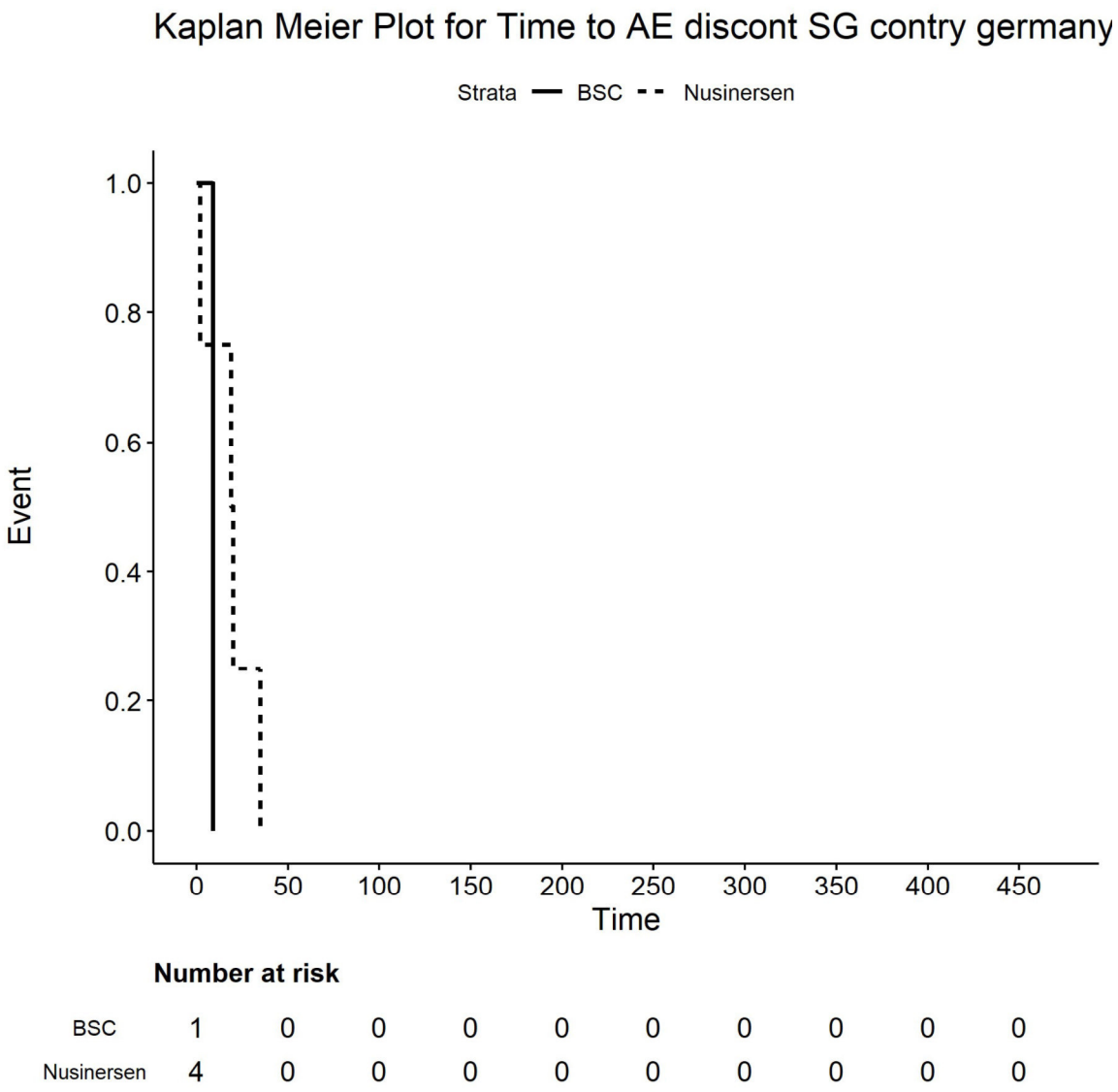
Number at risk

BSC	3	0	0	0	0	0	0	0	0	0
Nusinersen	5	1	0	0	0	0	0	0	0	0



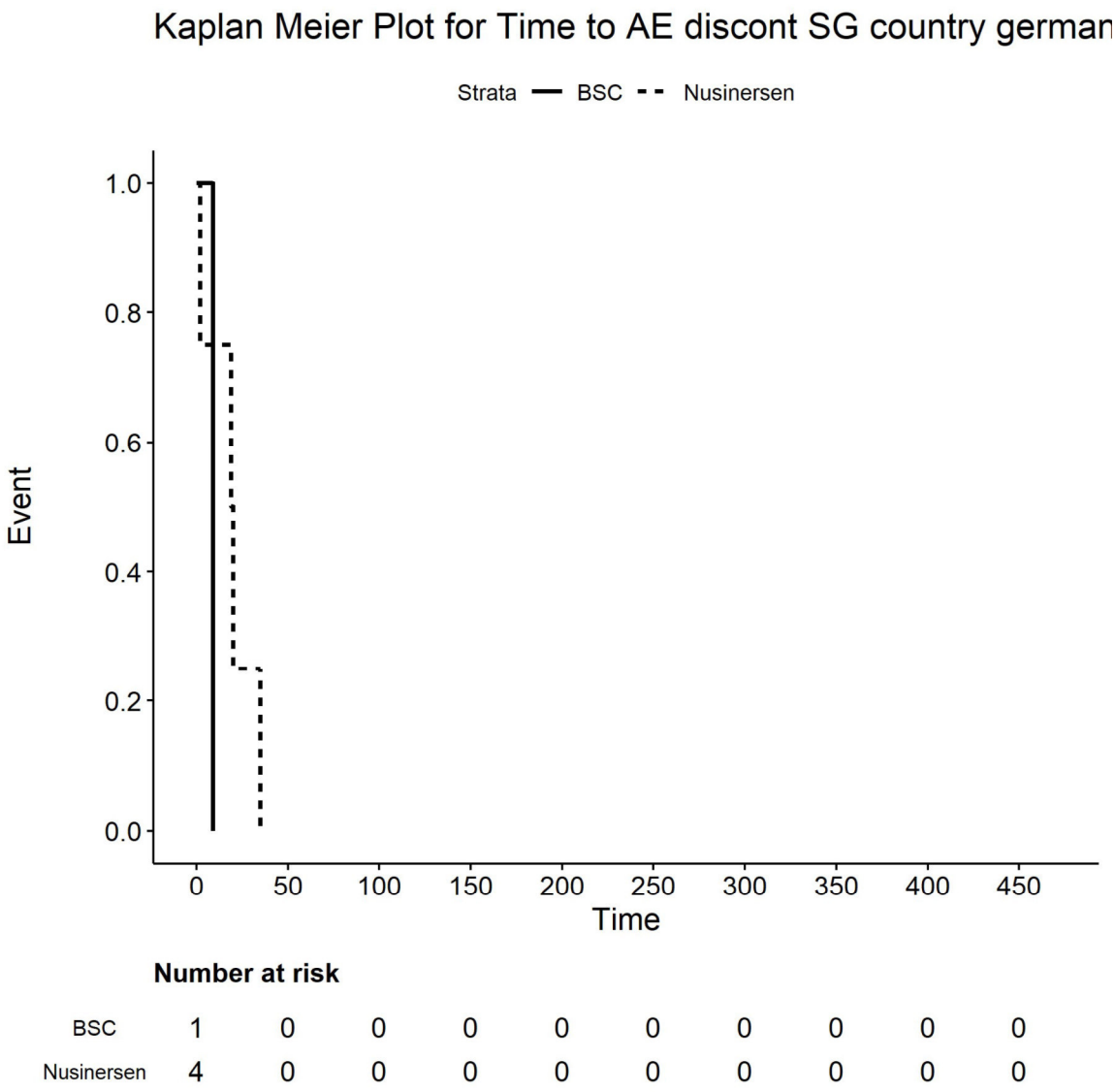
Number at risk

BSC	4	1	1	1	1	1	1	1	0	0
Nusinersen	9	2	1	0	0	0	0	0	0	0



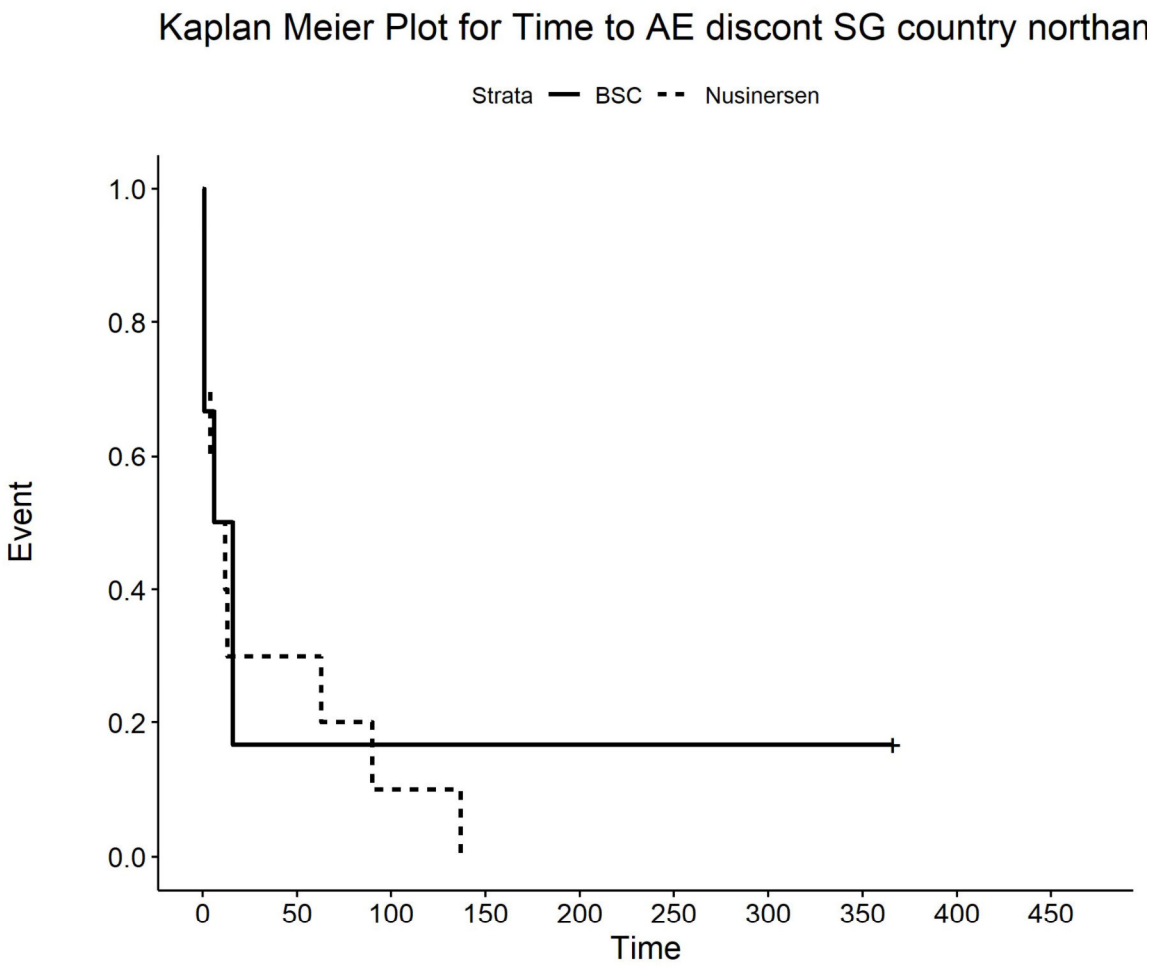
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	0	0	0	0	0	0	0	0	0



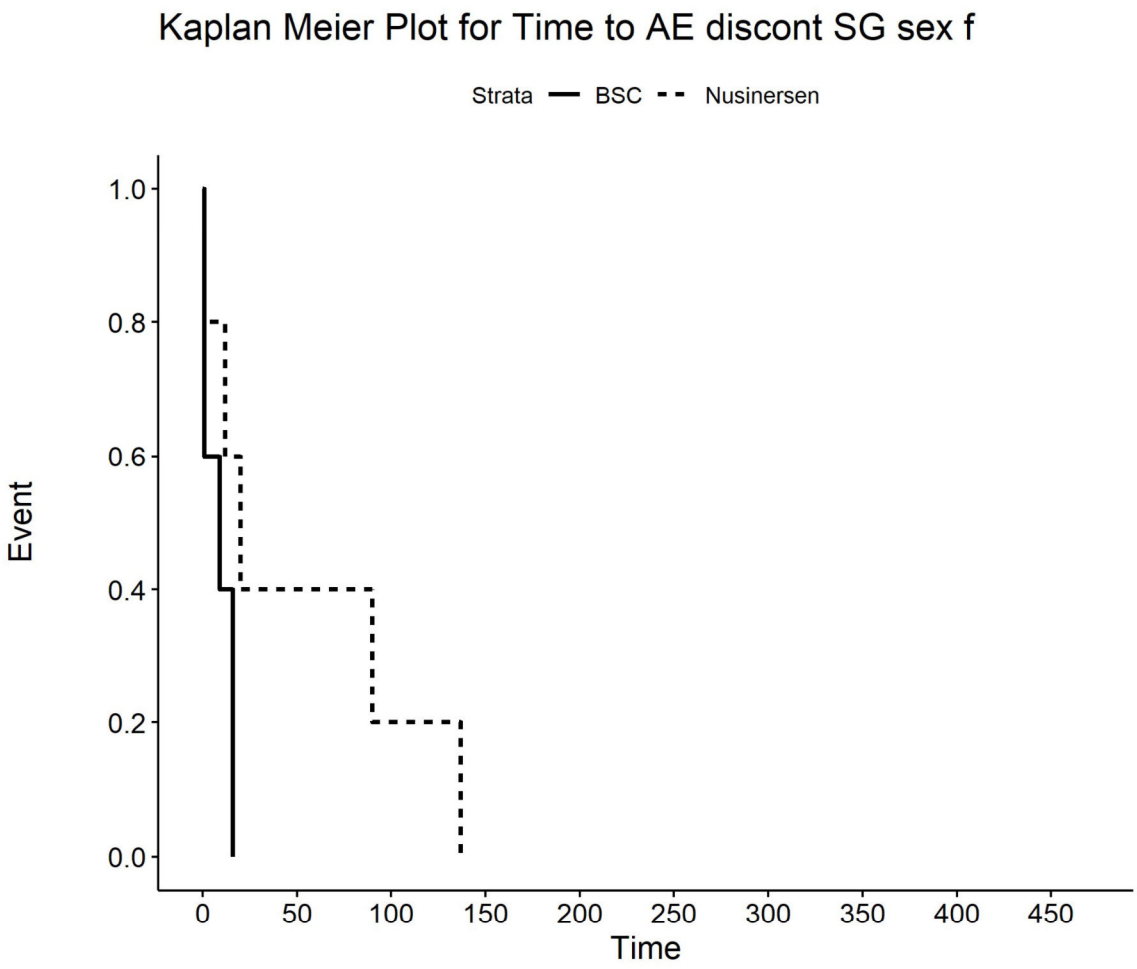
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	0	0	0	0	0	0	0	0	0



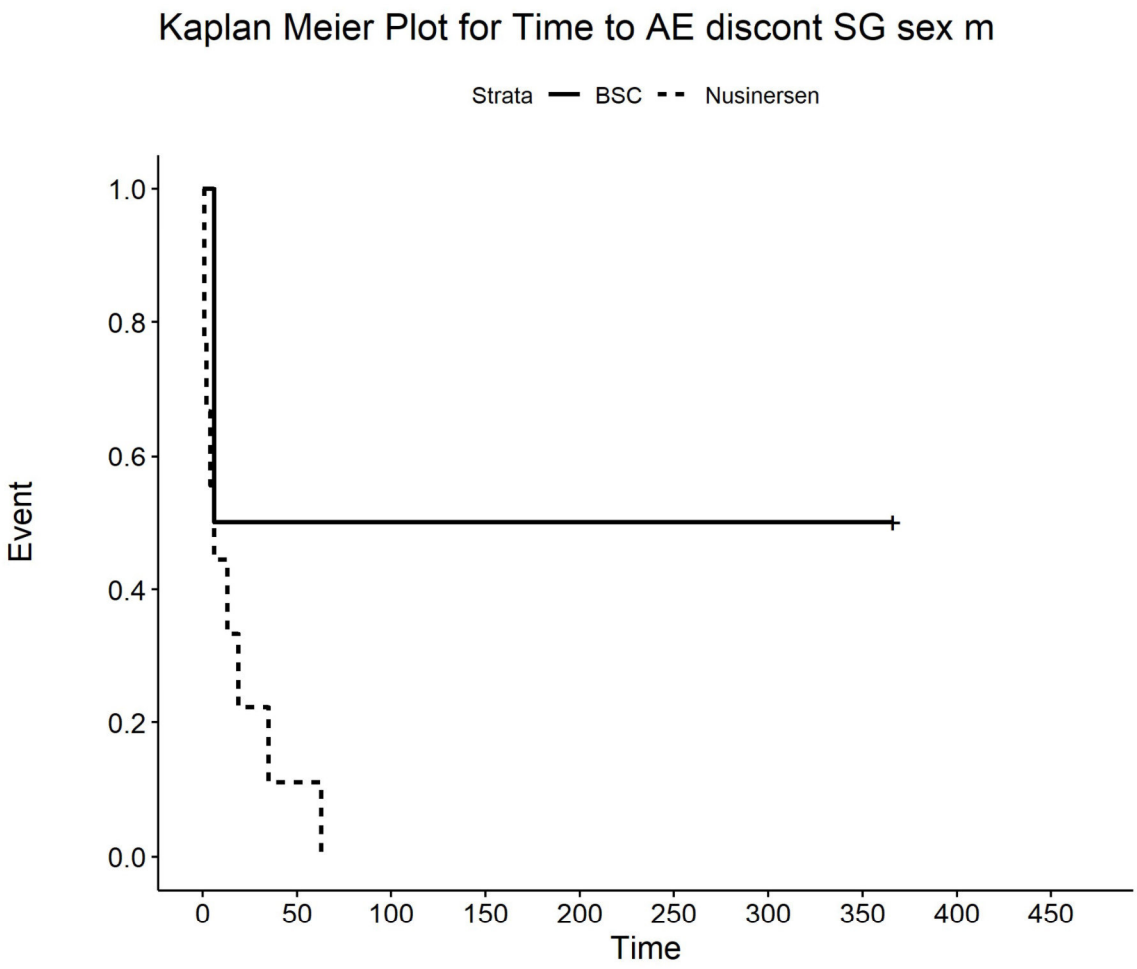
Number at risk

BSC	6	1	1	1	1	1	1	1	0	0
Nusinersen	10	3	1	0	0	0	0	0	0	0



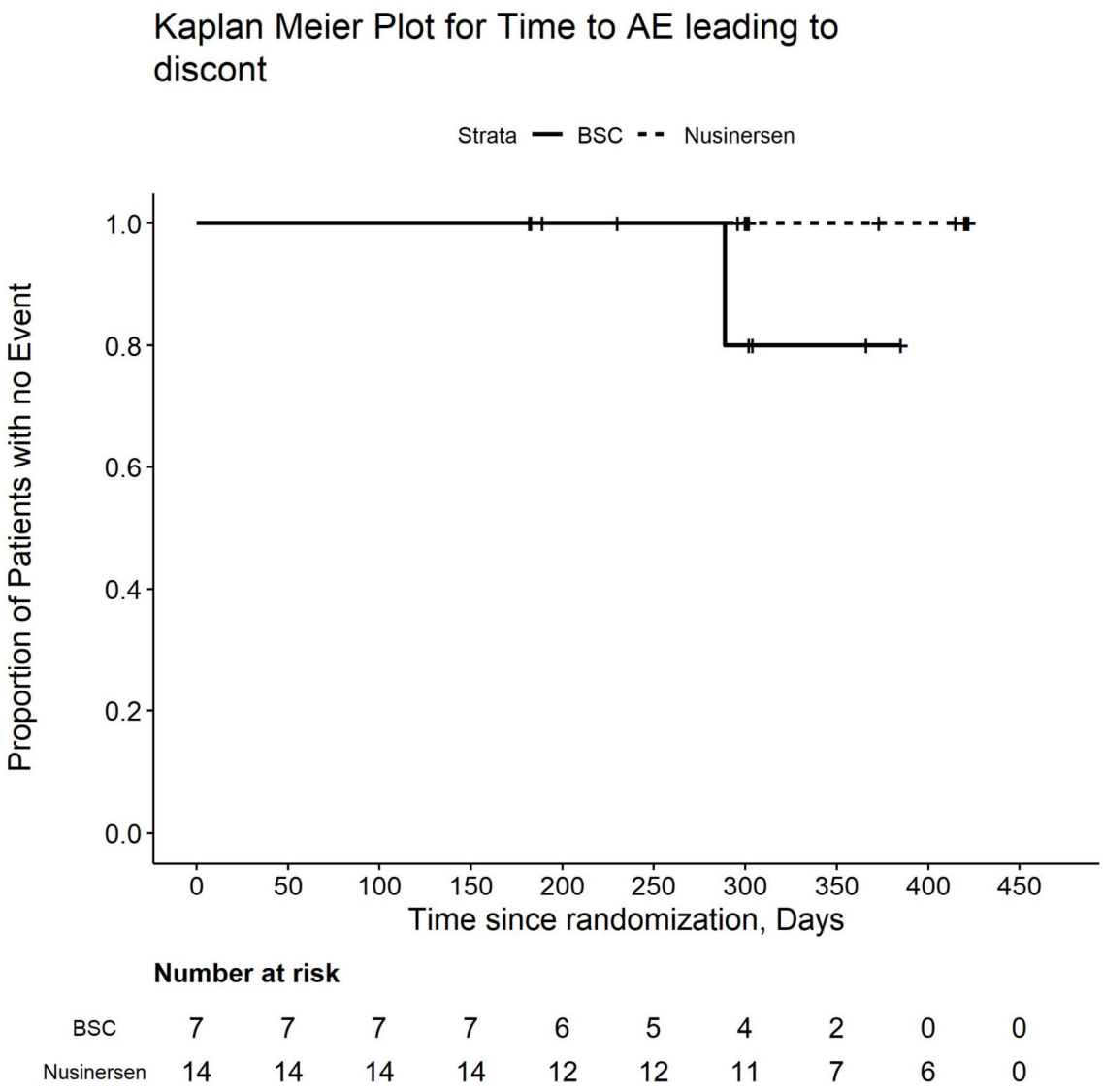
Number at risk

BSC	5	0	0	0	0	0	0	0	0	0
Nusinersen	5	2	1	0	0	0	0	0	0	0



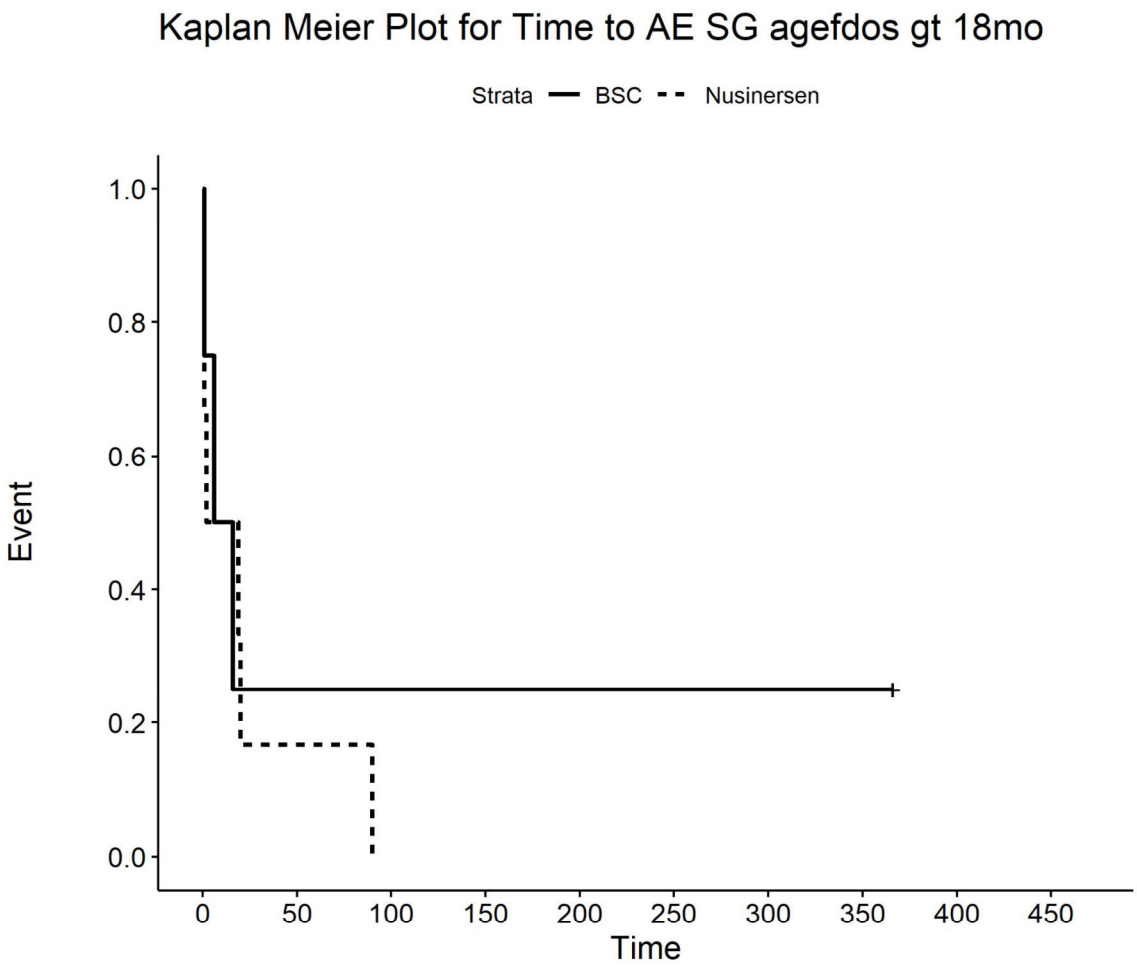
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	1	0	0	0	0	0	0	0	0



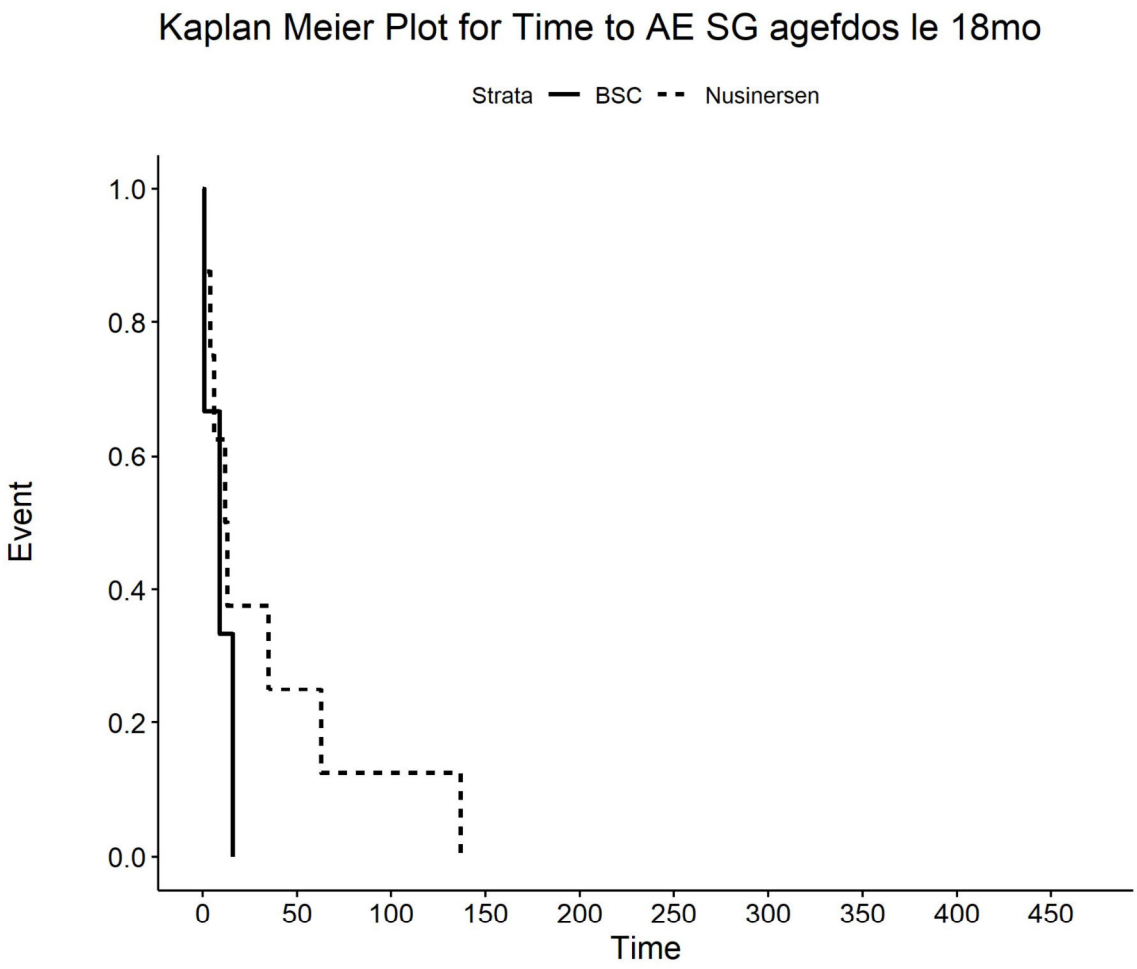
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



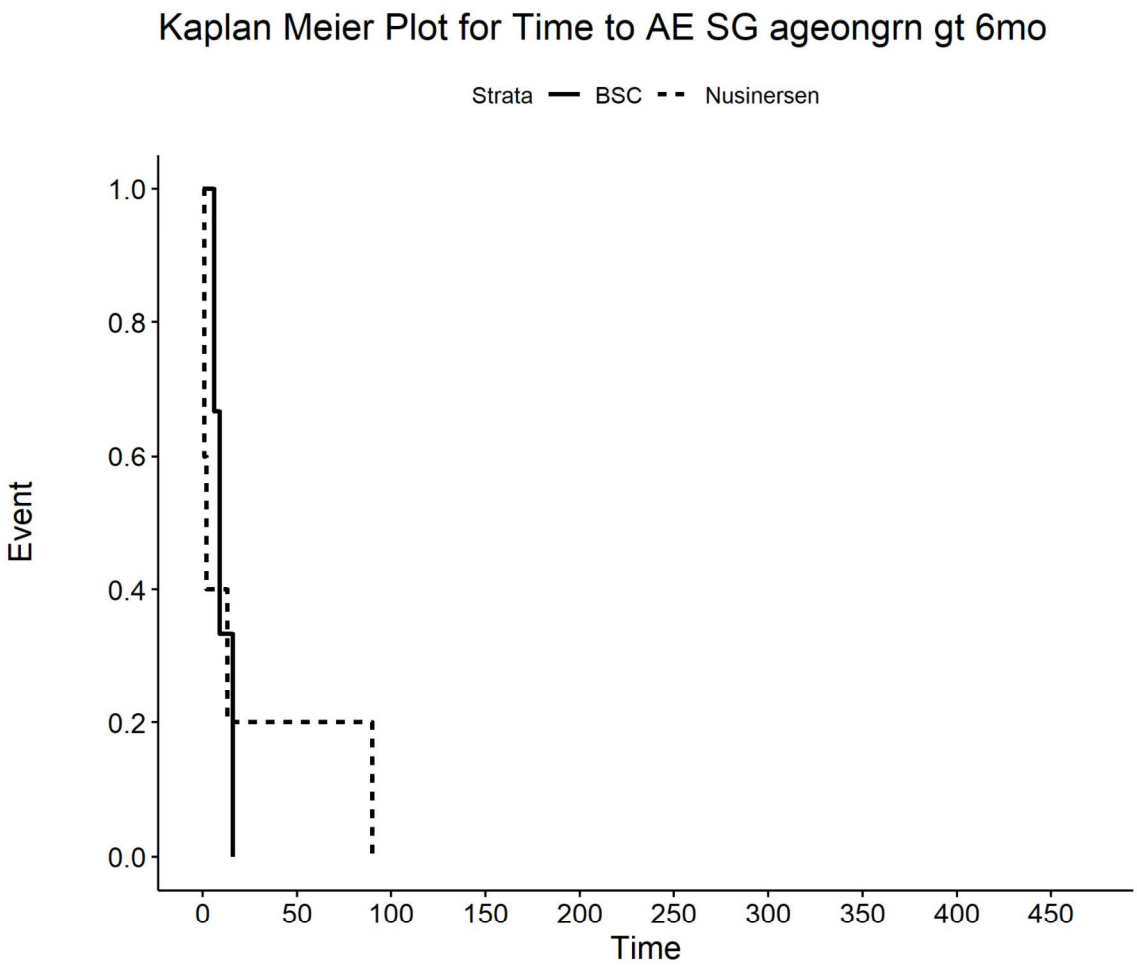
Number at risk

BSC	4	1	1	1	1	1	1	1	0	0
Nusinersen	6	1	0	0	0	0	0	0	0	0



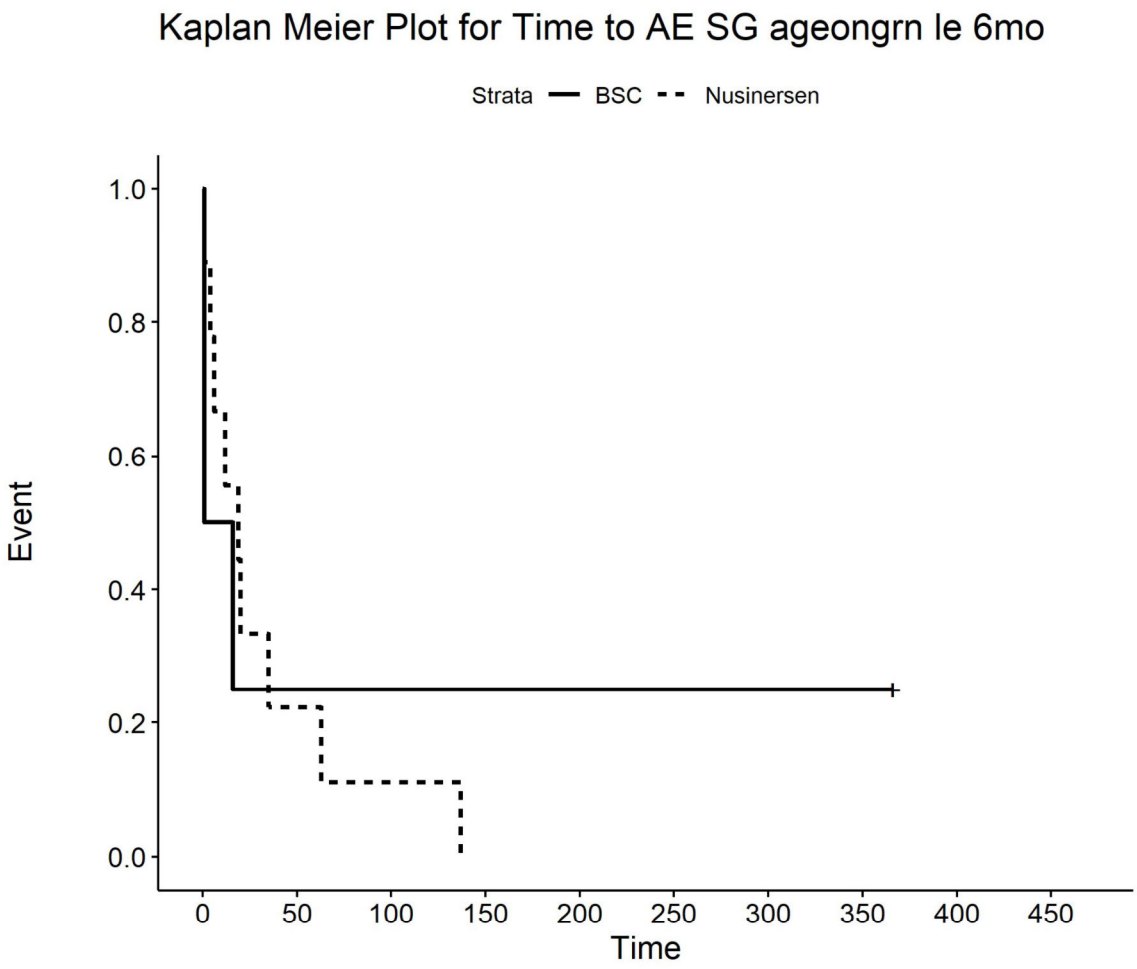
Number at risk

BSC	3	0	0	0	0	0	0	0	0	0
Nusinersen	8	2	1	0	0	0	0	0	0	0



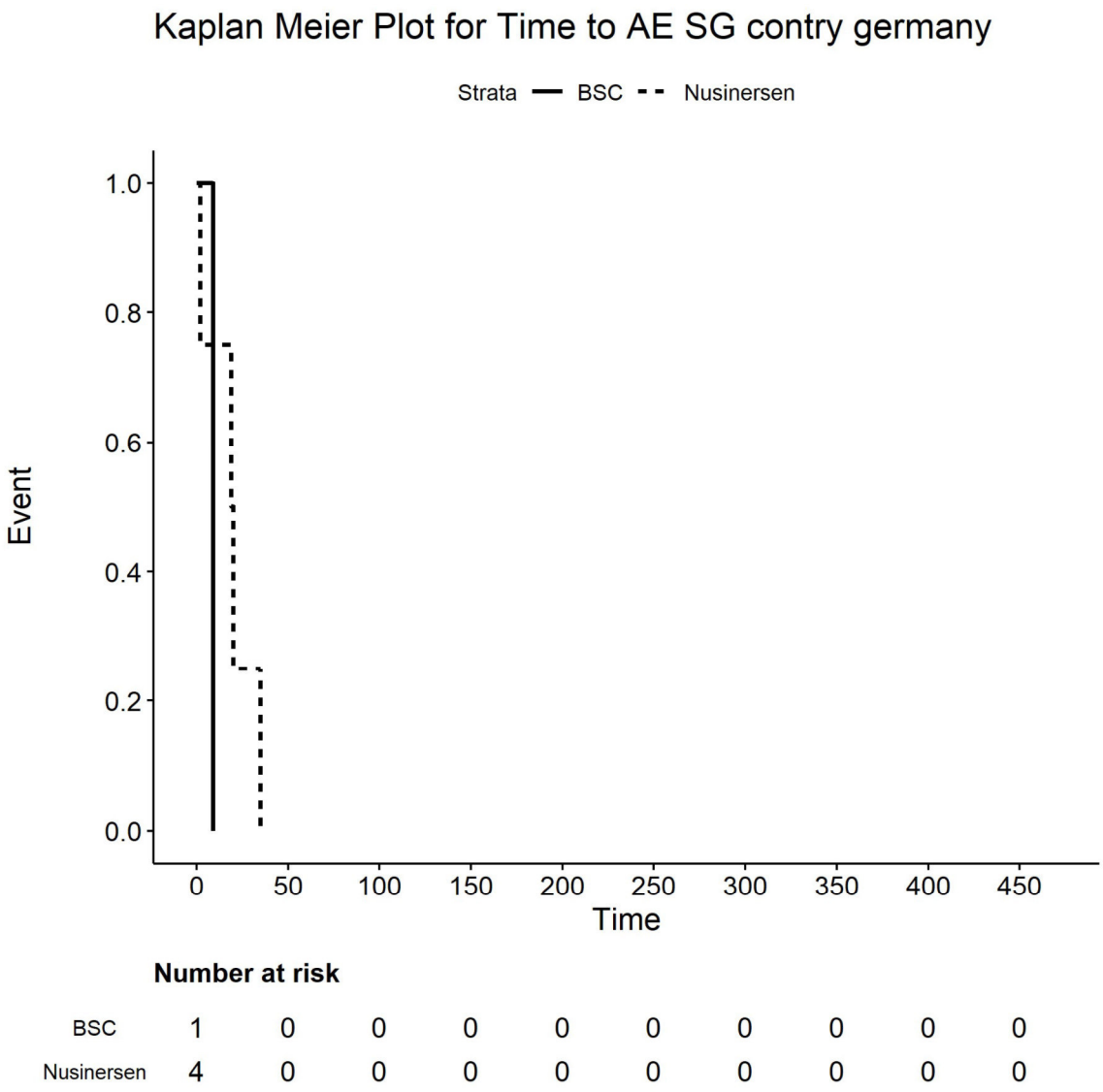
Number at risk

BSC	3	0	0	0	0	0	0	0	0	0
Nusinersen	5	1	0	0	0	0	0	0	0	0



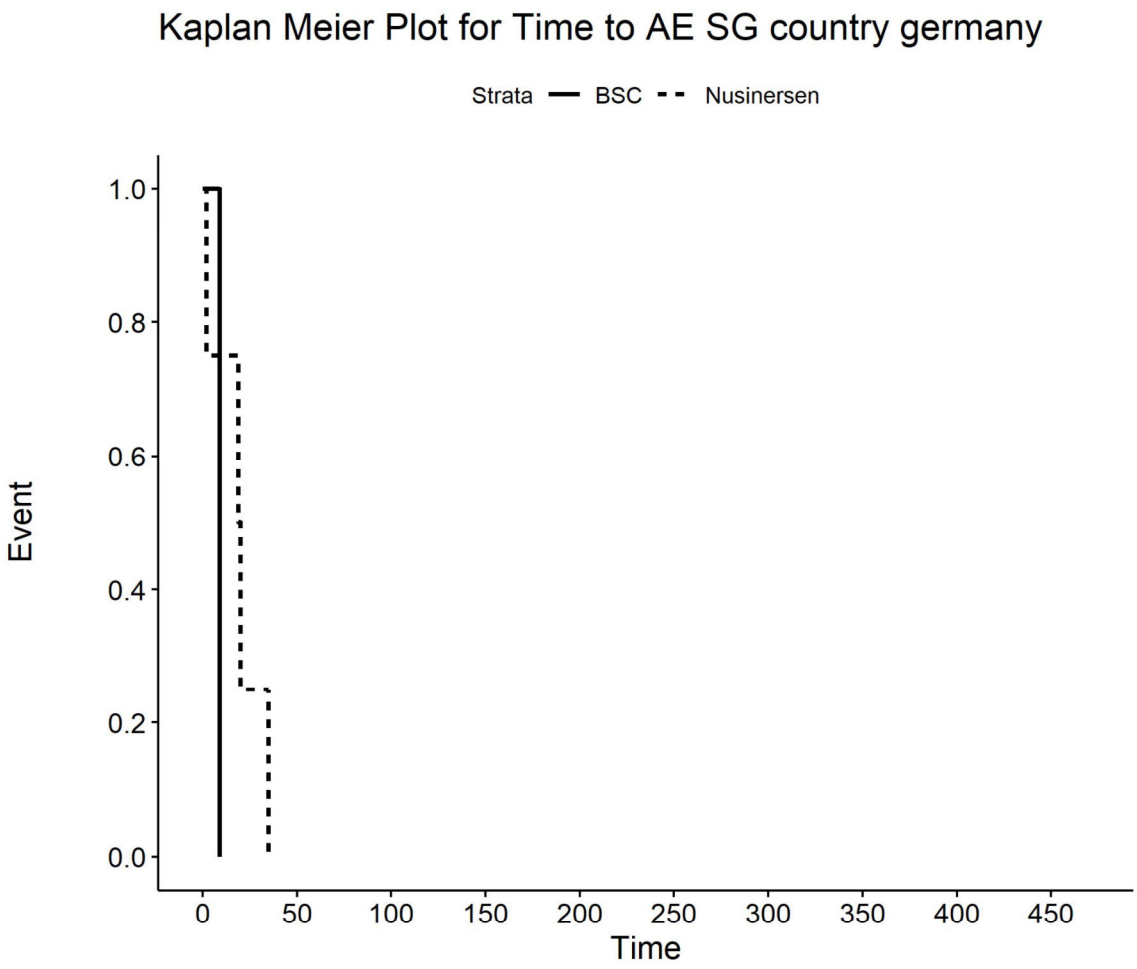
Number at risk

BSC	4	1	1	1	1	1	1	1	0	0
Nusinersen	9	2	1	0	0	0	0	0	0	0



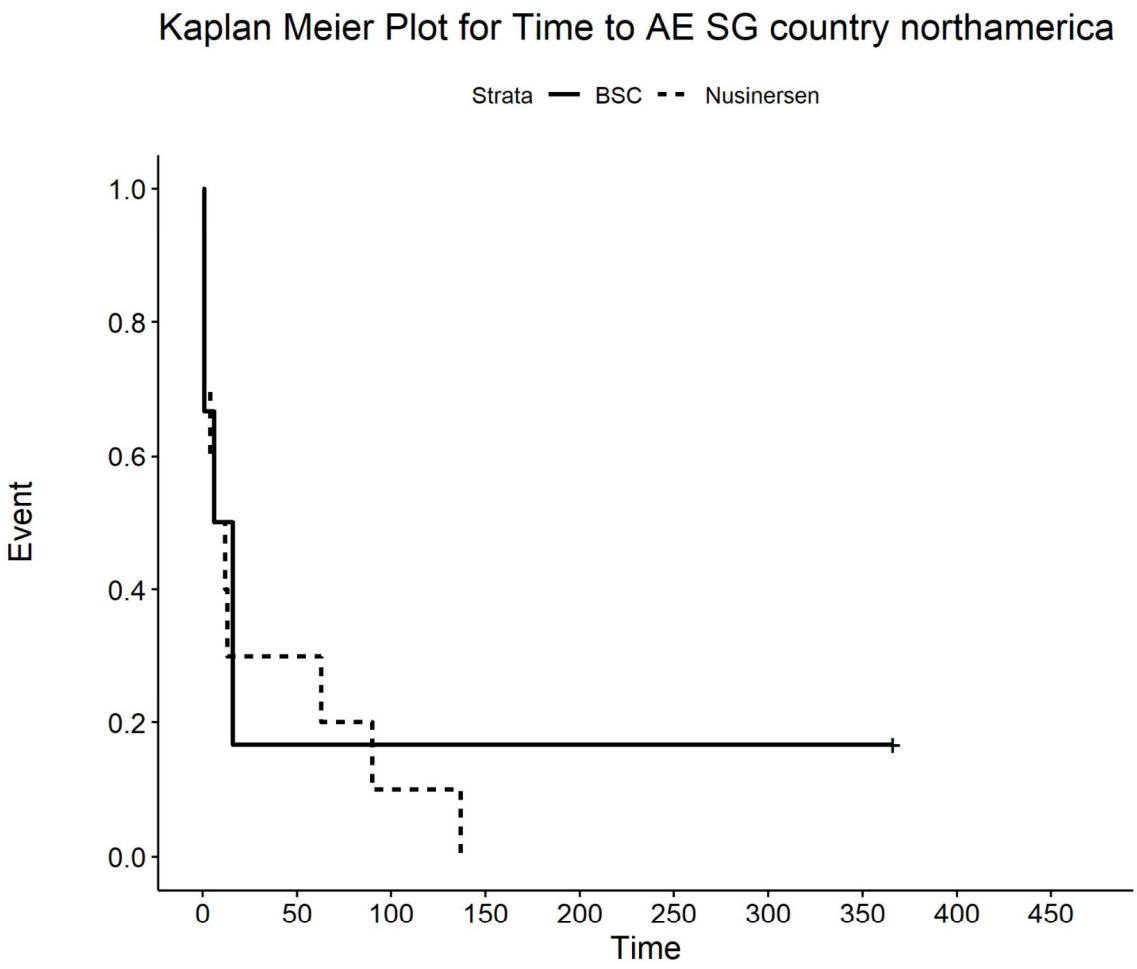
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	0	0	0	0	0	0	0	0	0



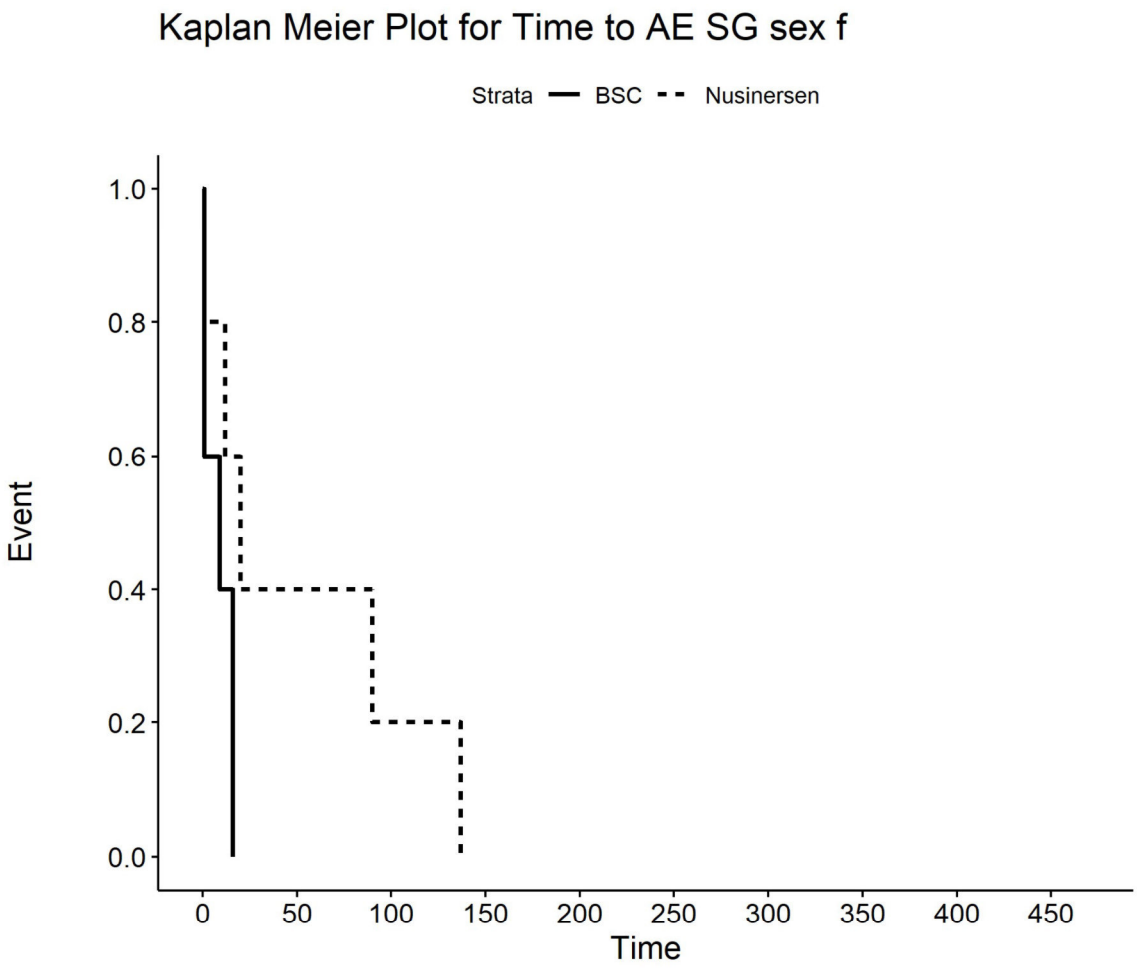
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	0	0	0	0	0	0	0	0	0



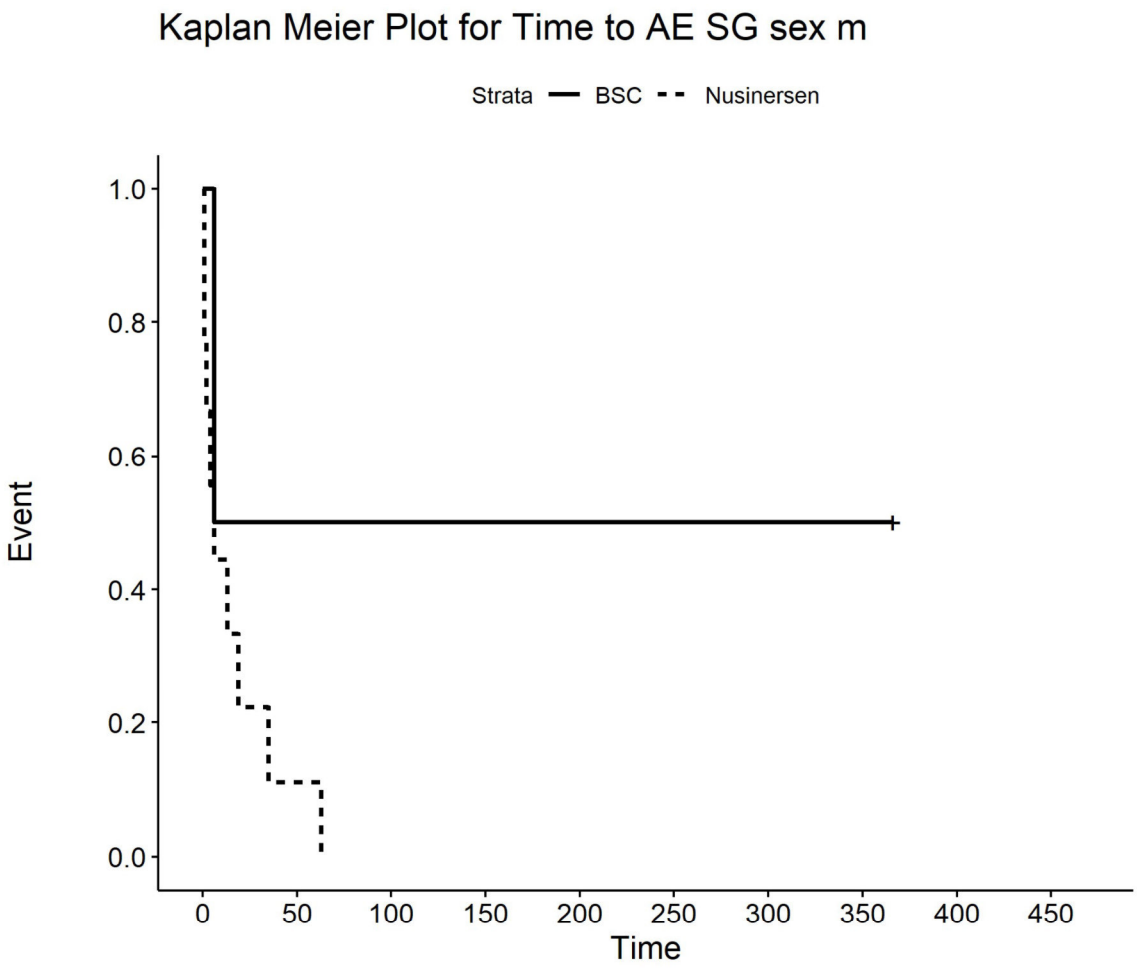
Number at risk

BSC	6	1	1	1	1	1	1	1	0	0
Nusinersen	10	3	1	0	0	0	0	0	0	0



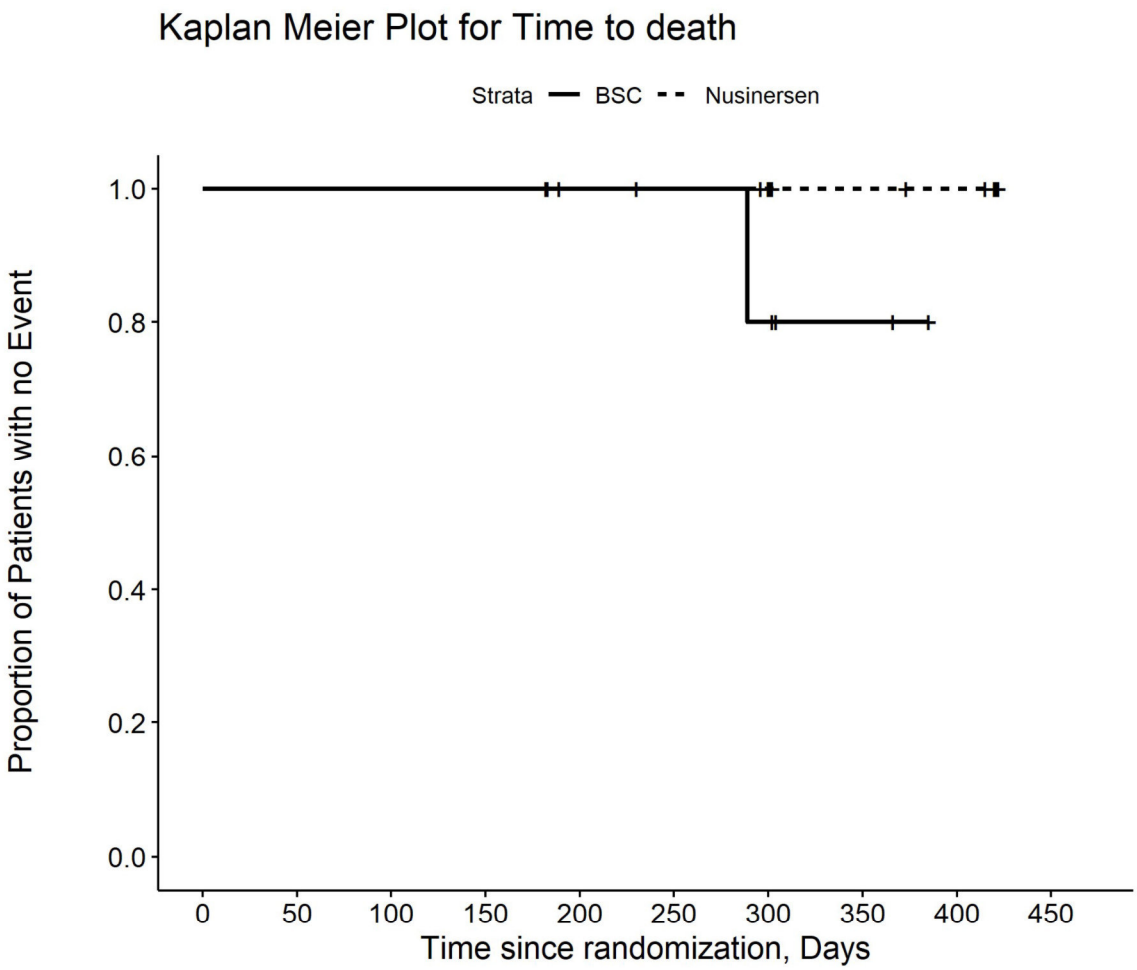
Number at risk

BSC	5	0	0	0	0	0	0	0	0	0
Nusinersen	5	2	1	0	0	0	0	0	0	0



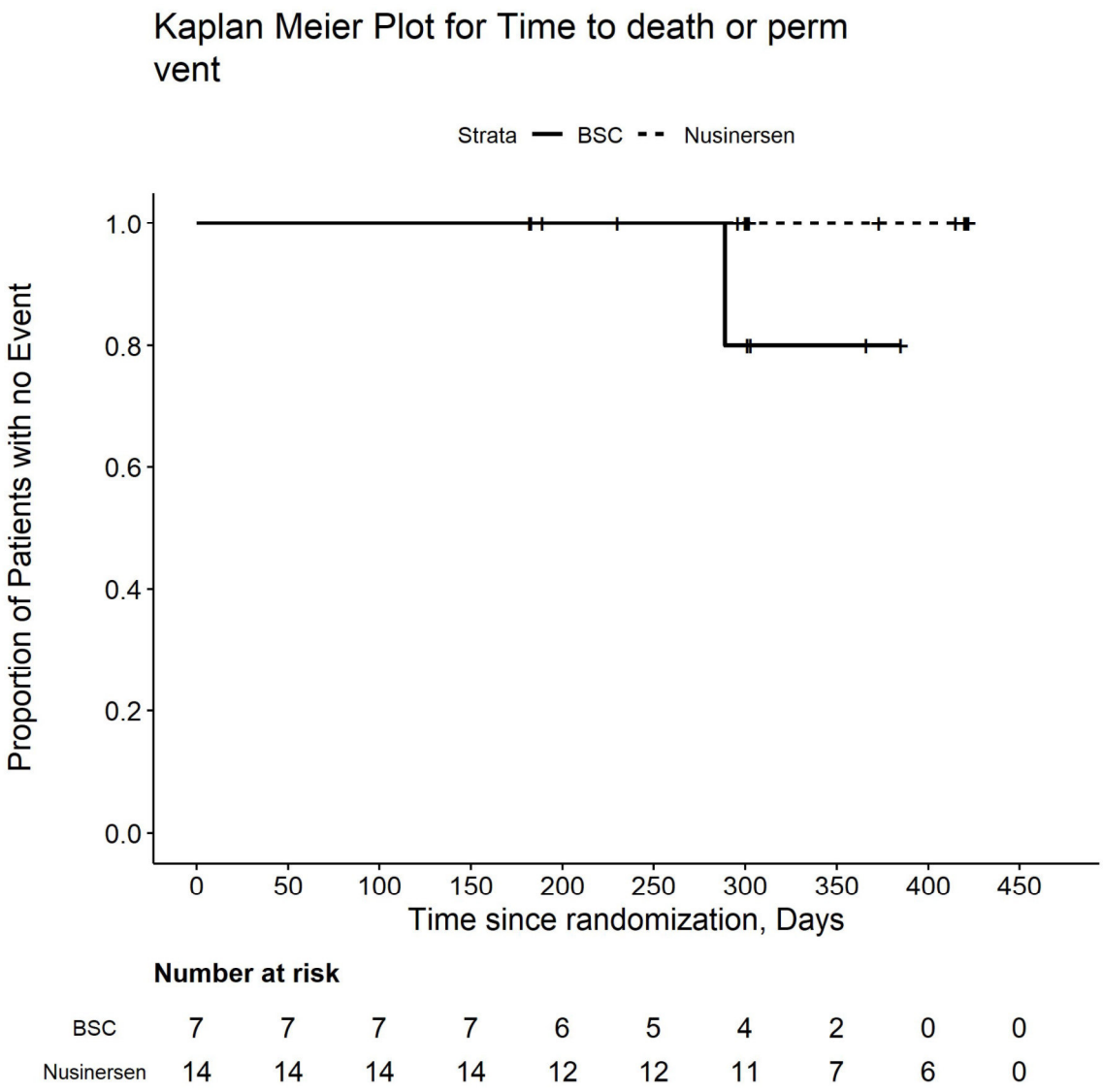
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	1	0	0	0	0	0	0	0	0



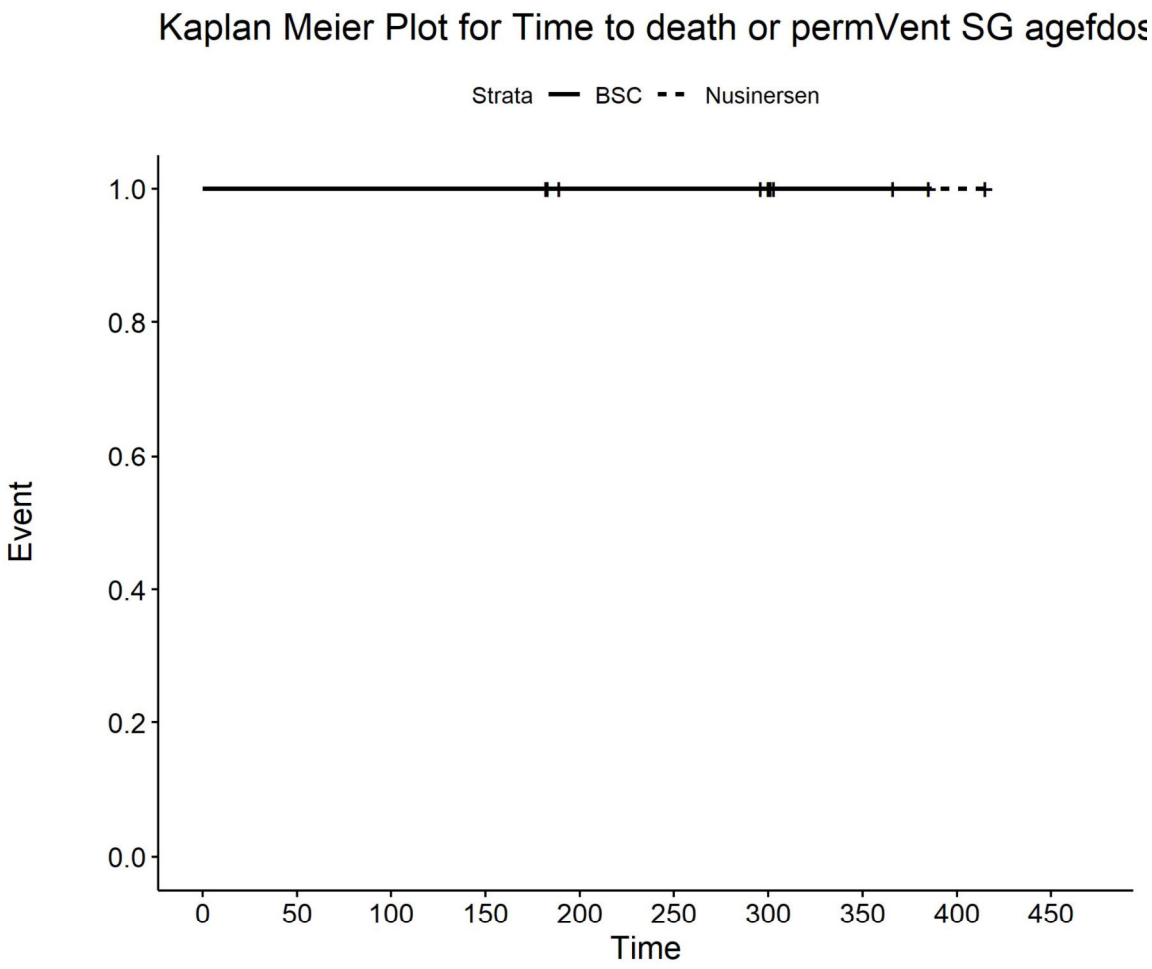
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



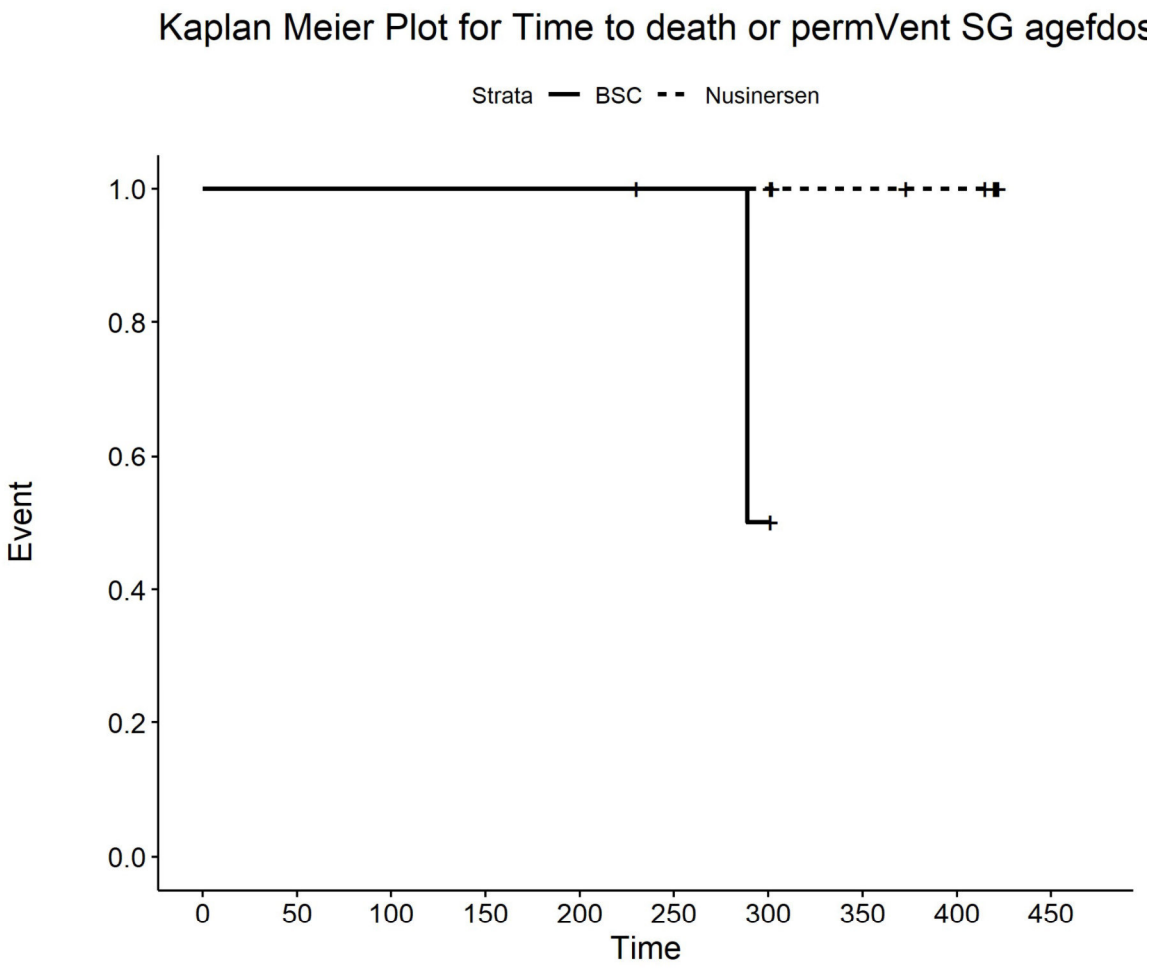
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



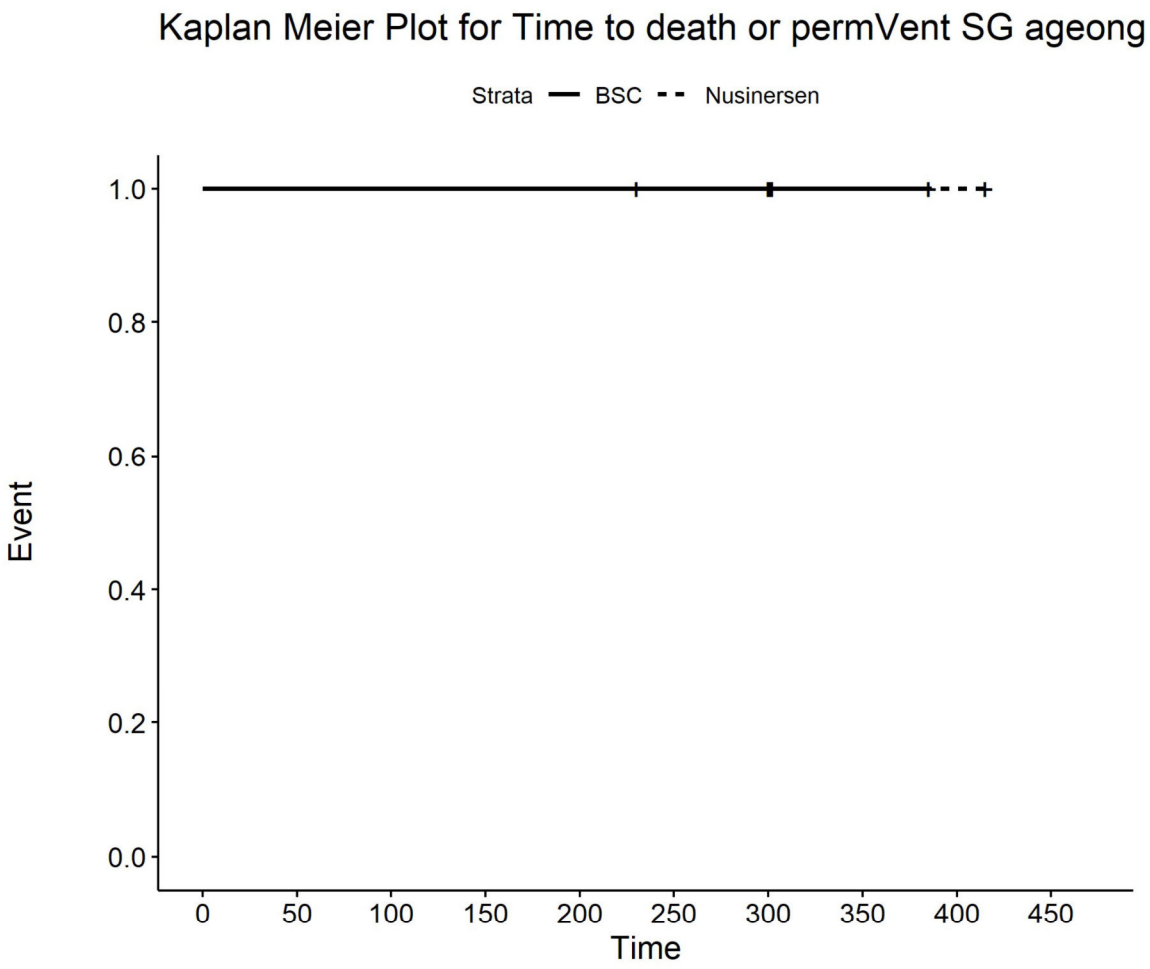
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



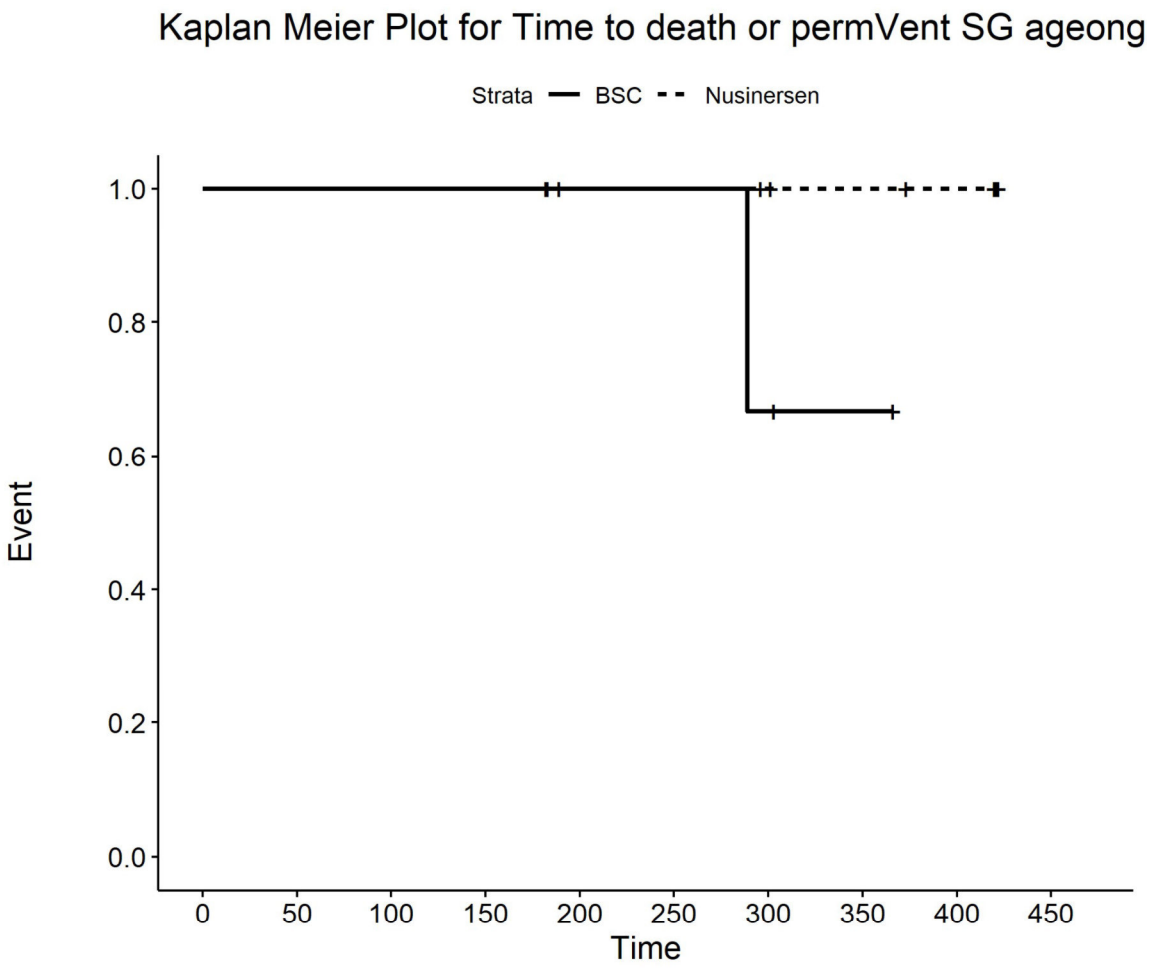
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



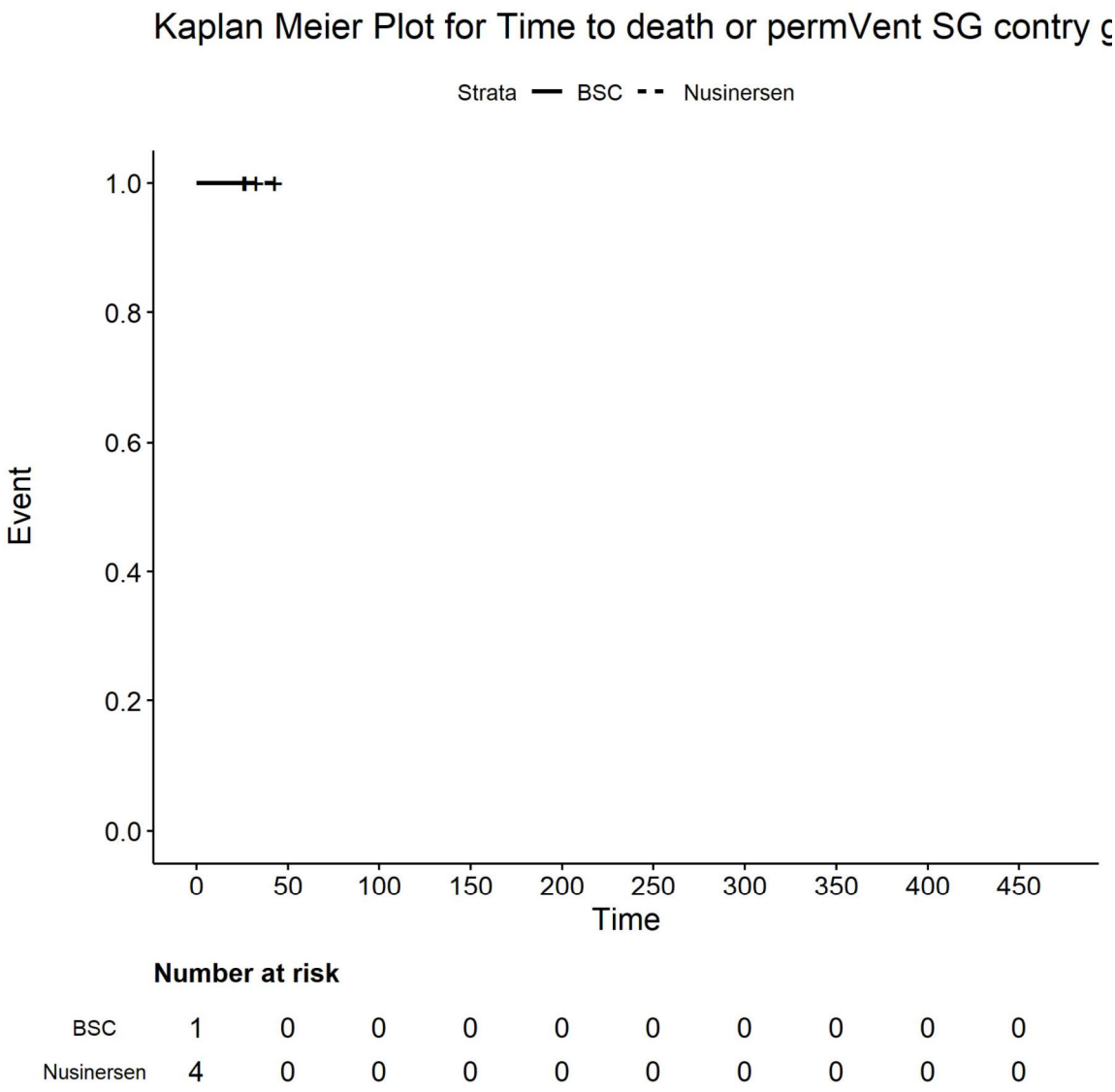
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



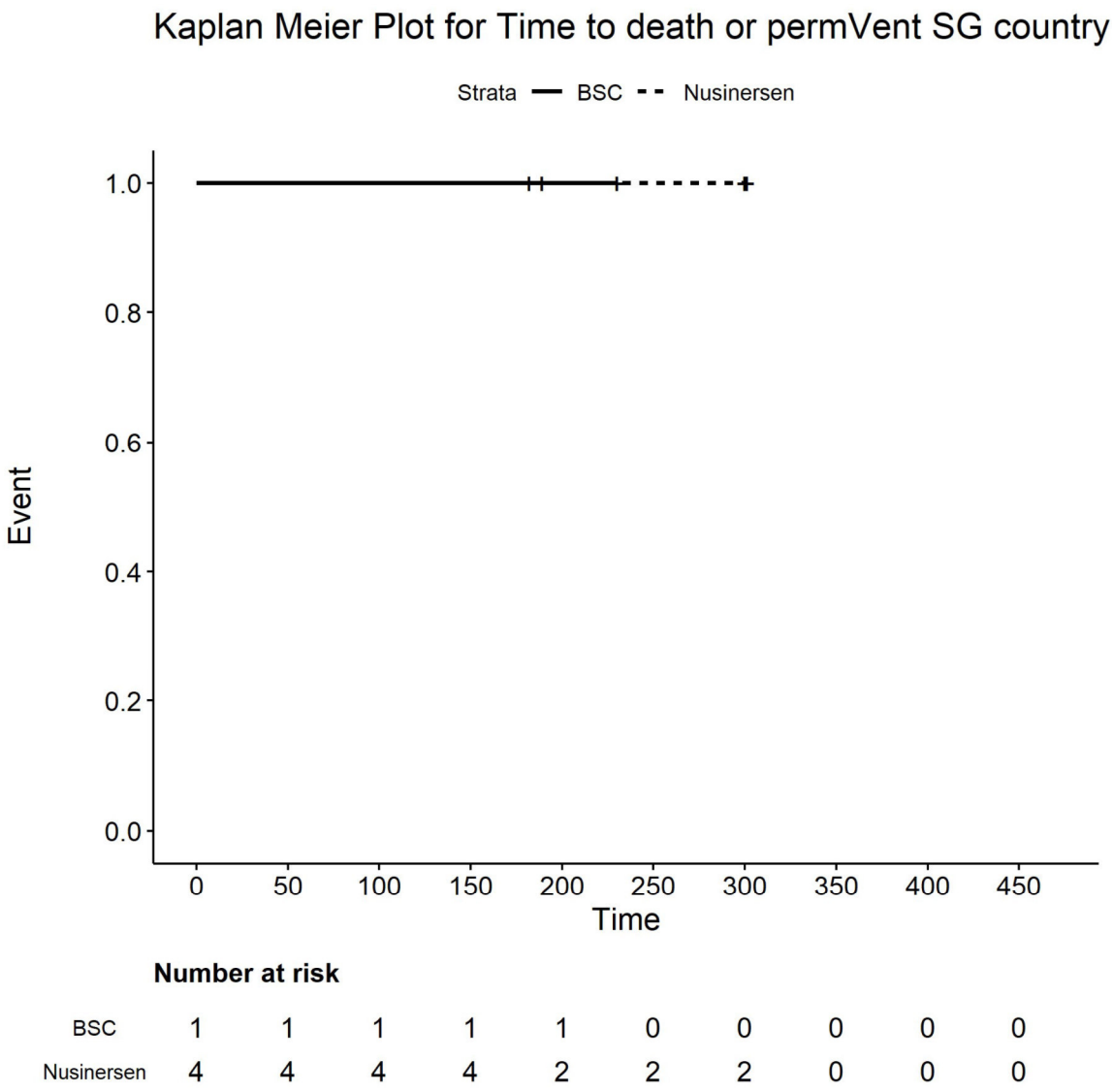
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



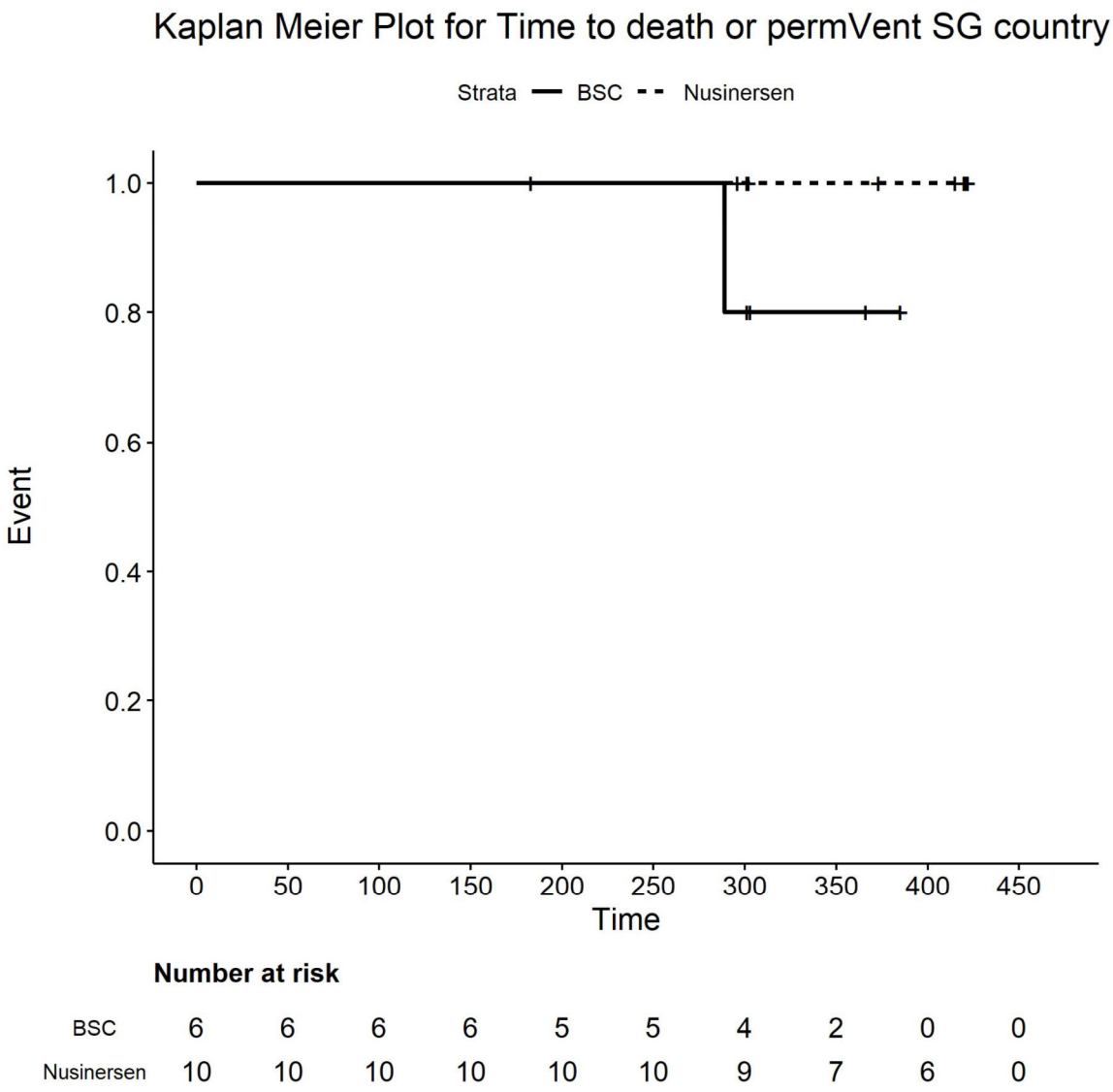
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	0	0	0	0	0	0	0	0	0



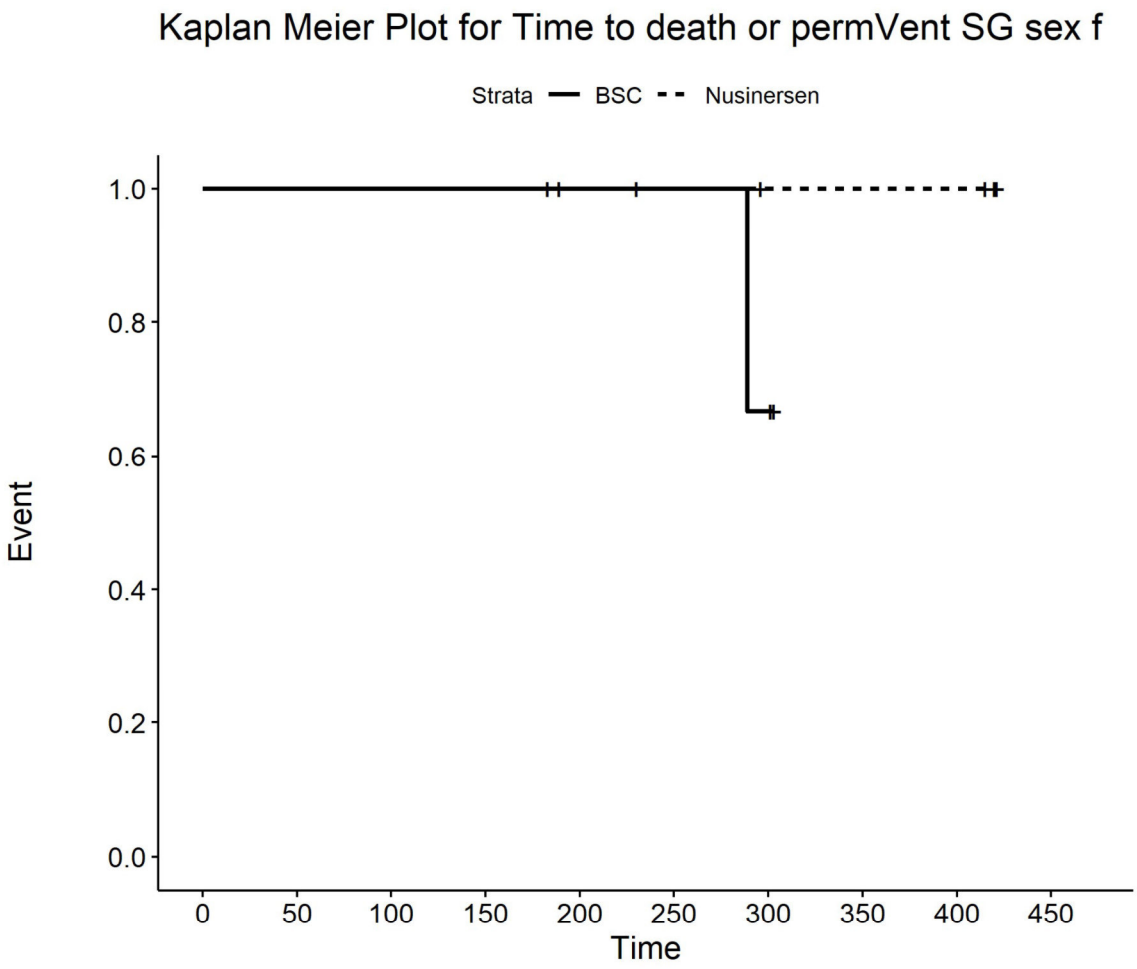
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



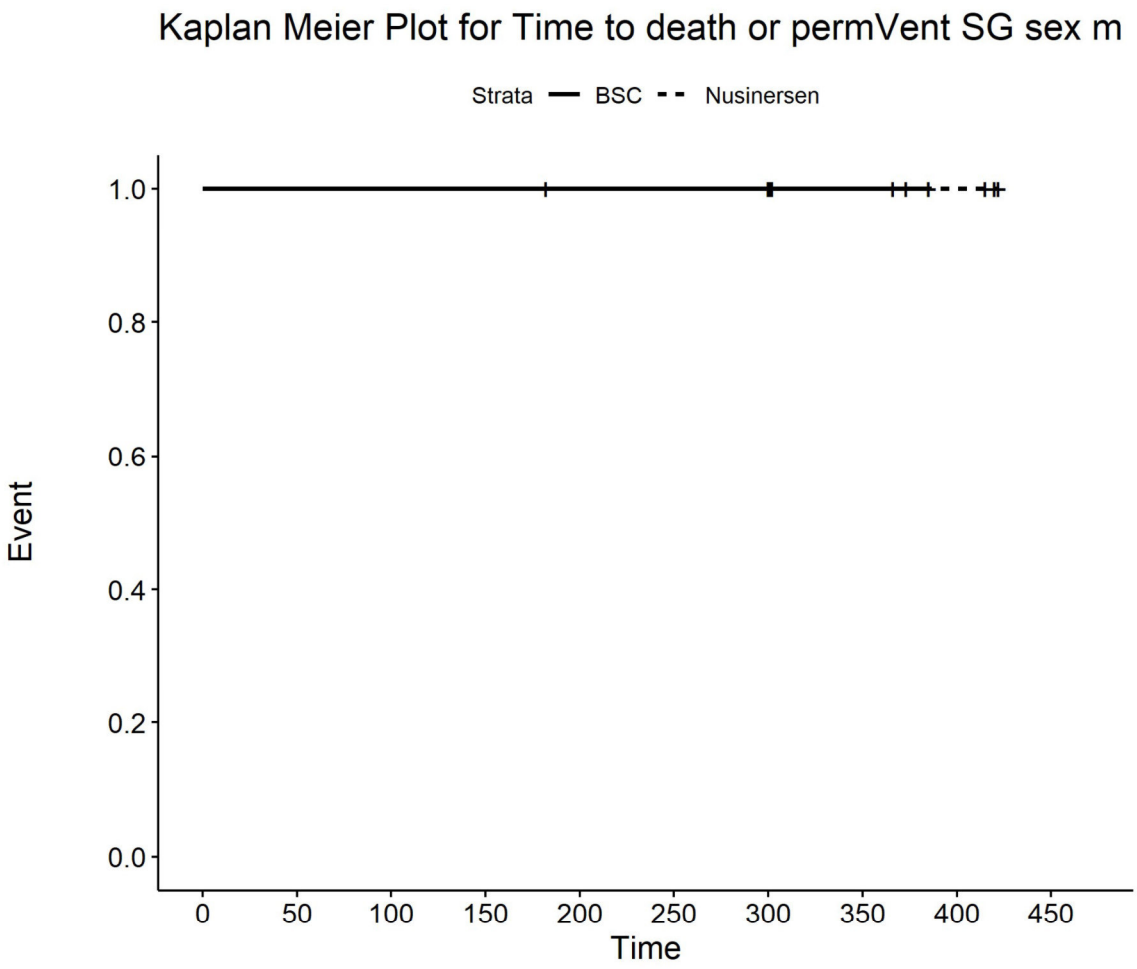
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



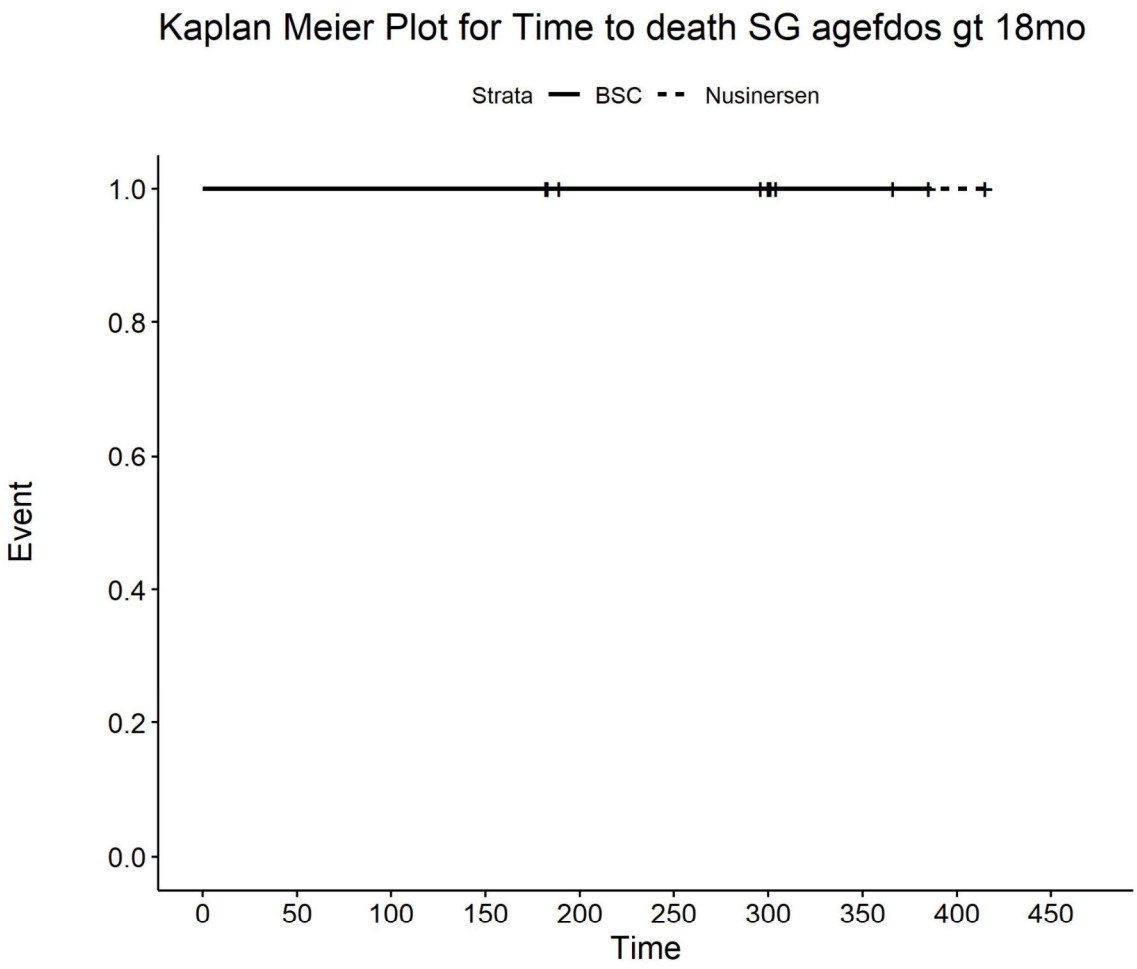
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



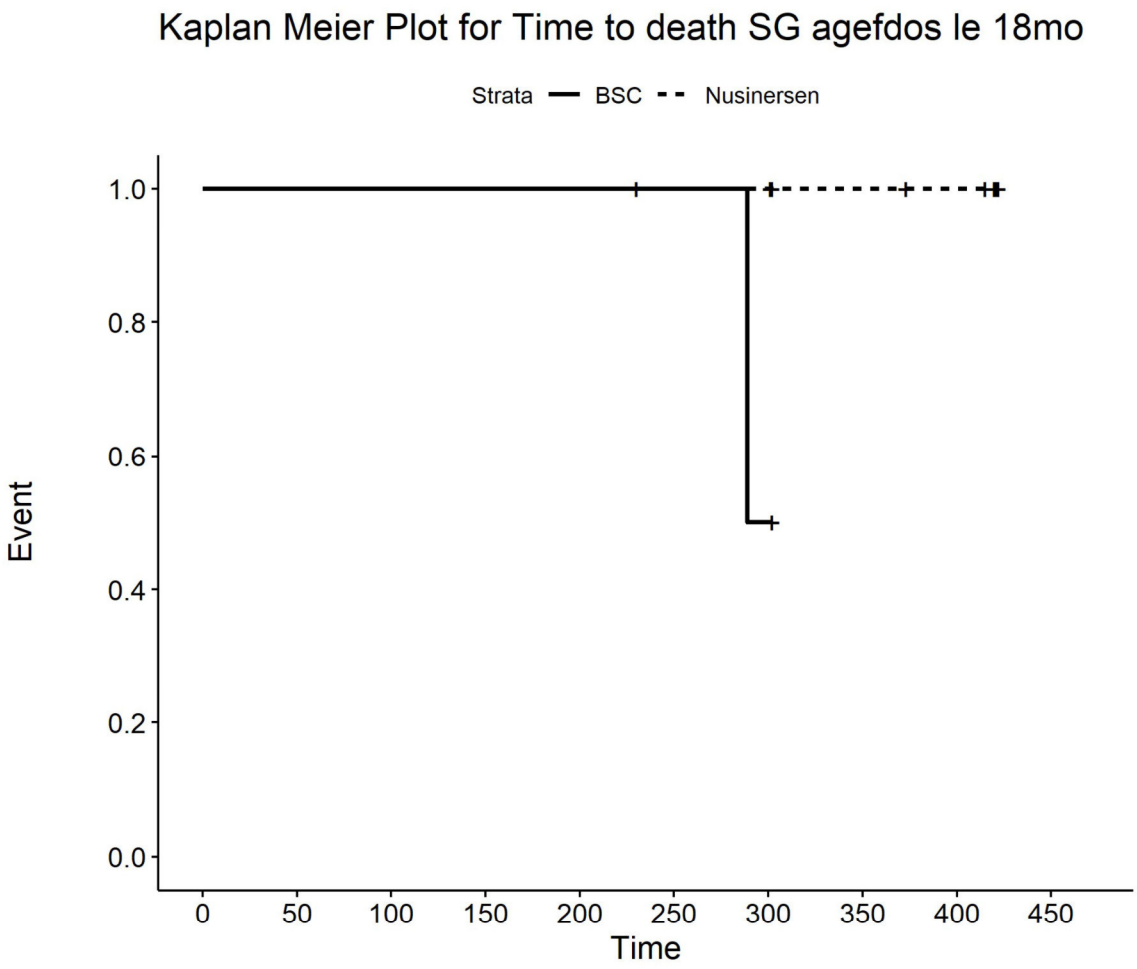
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



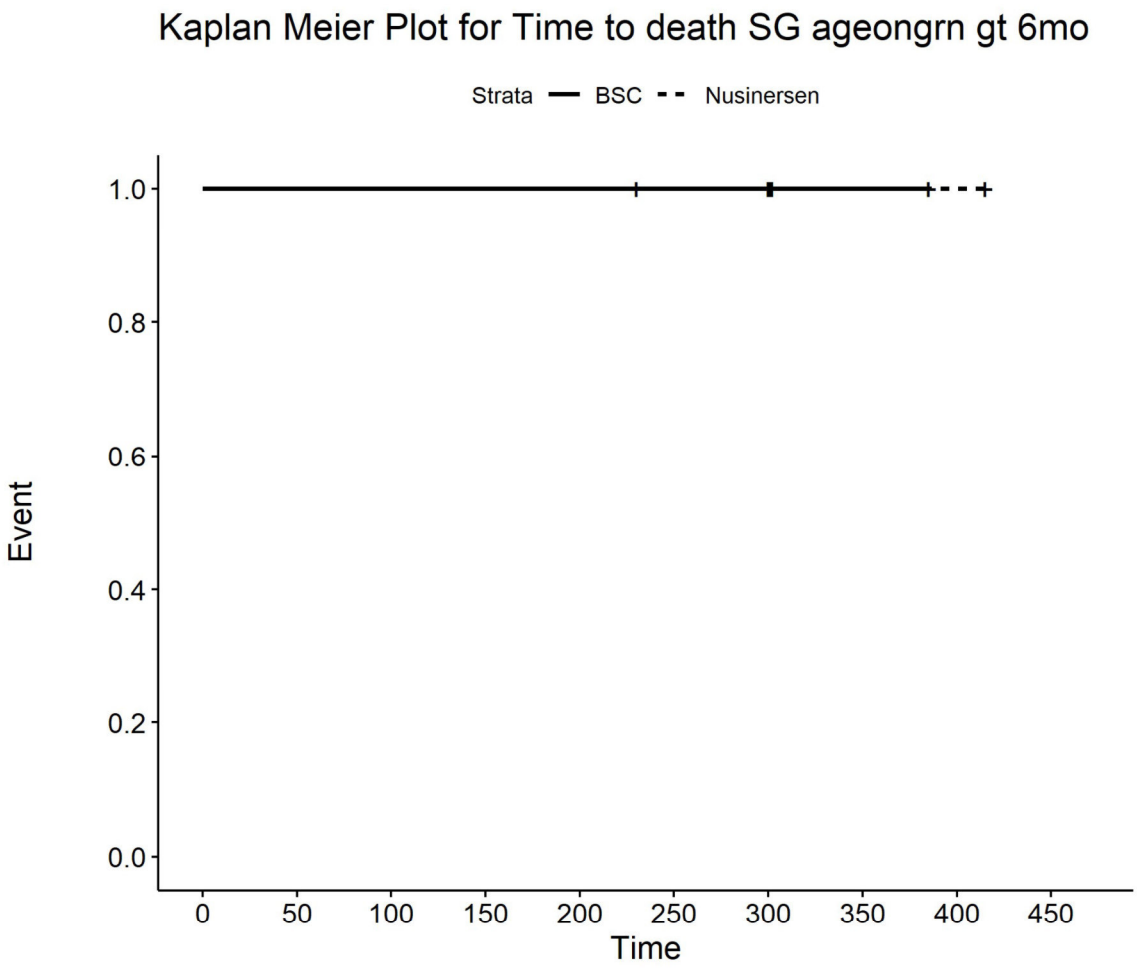
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



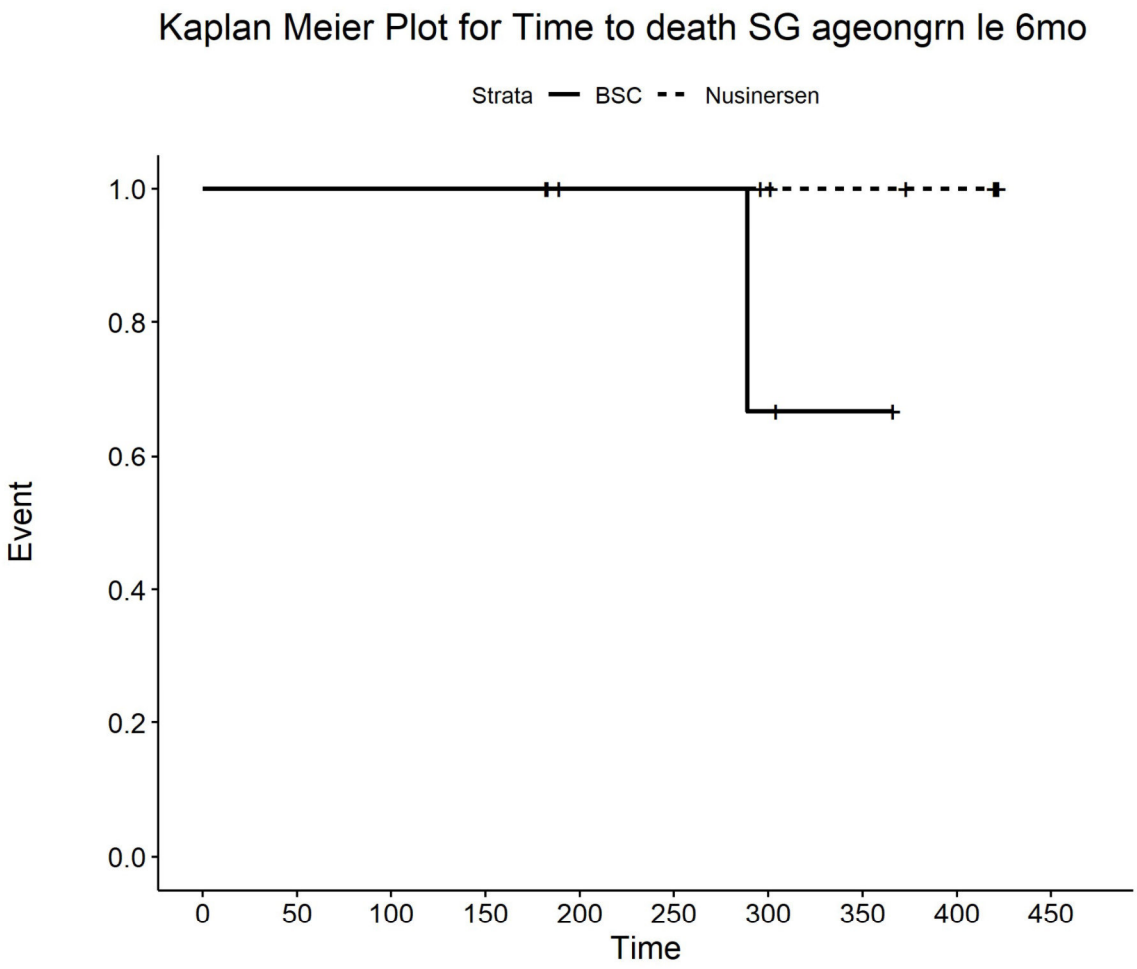
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



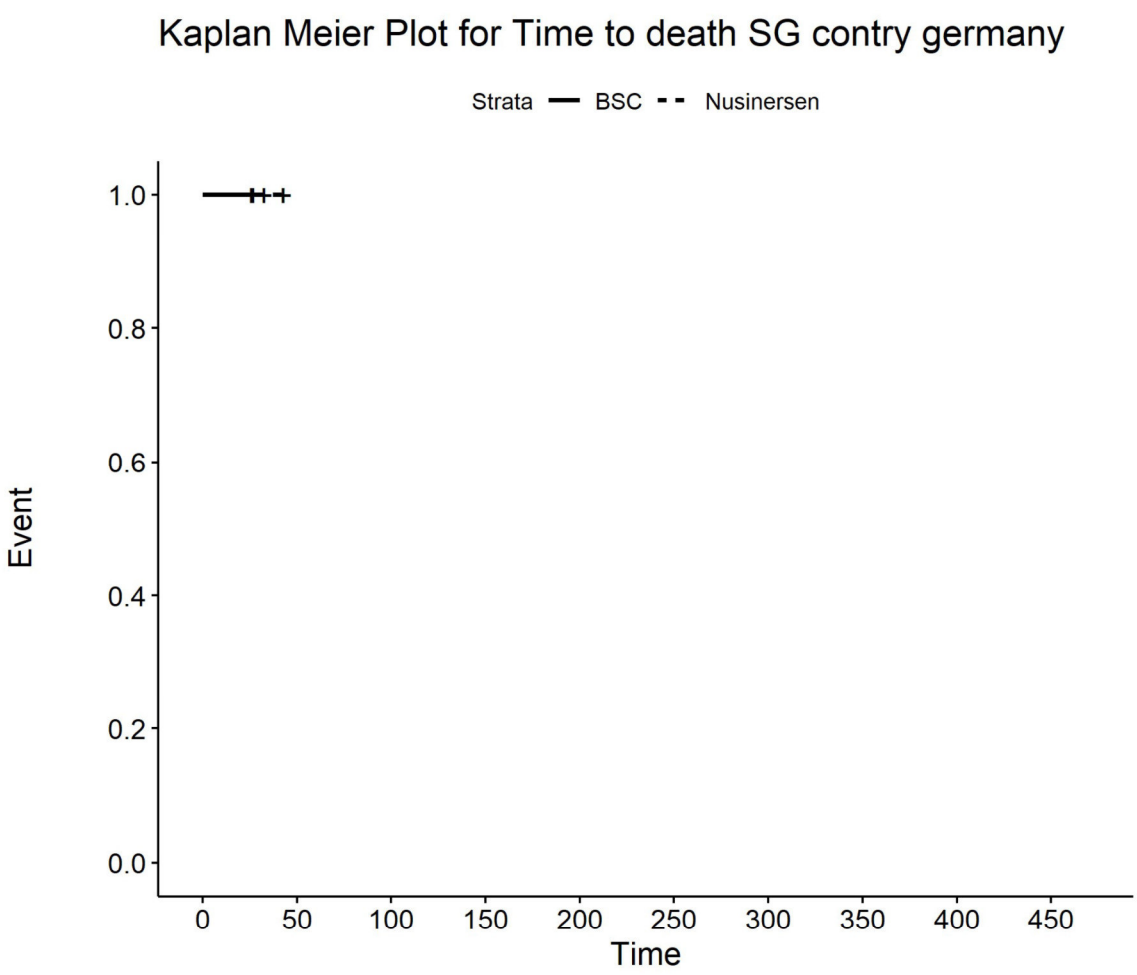
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



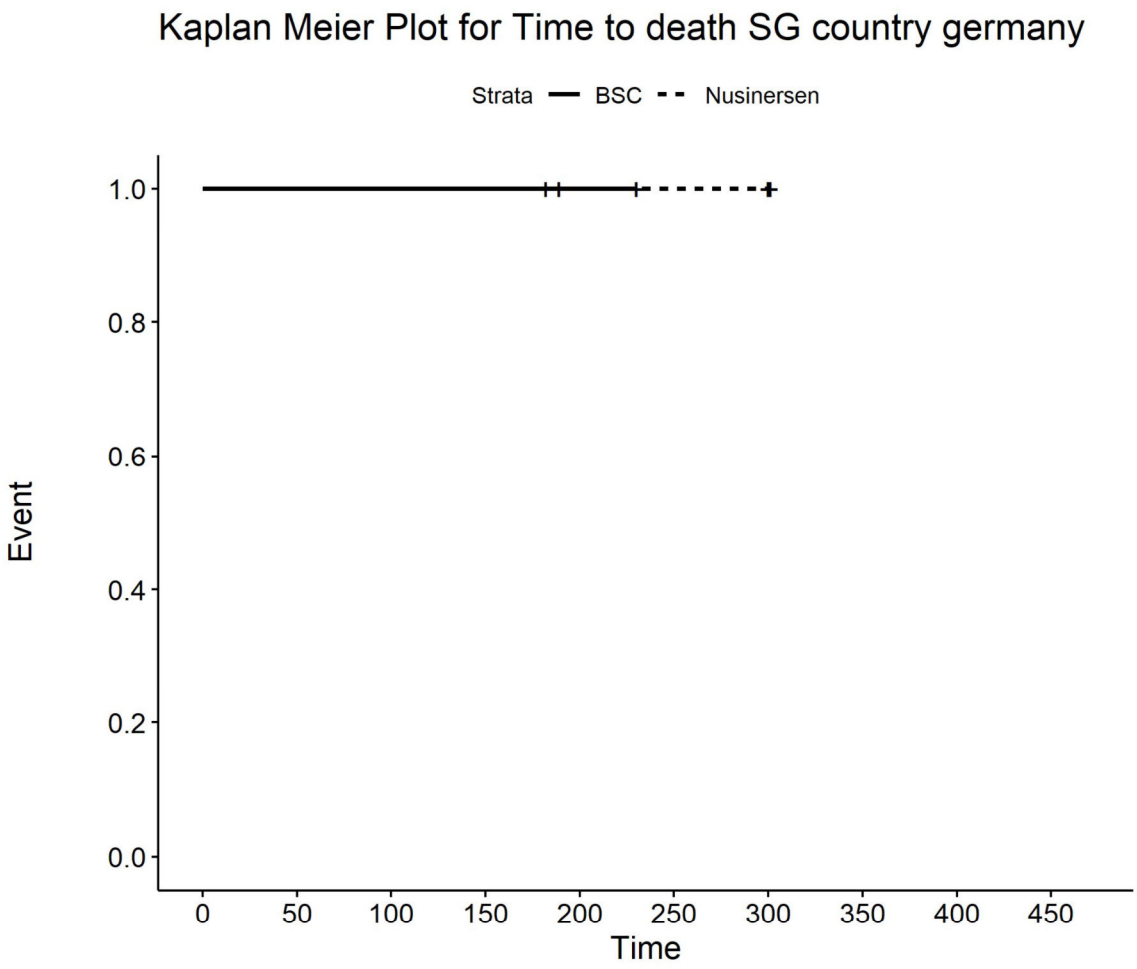
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



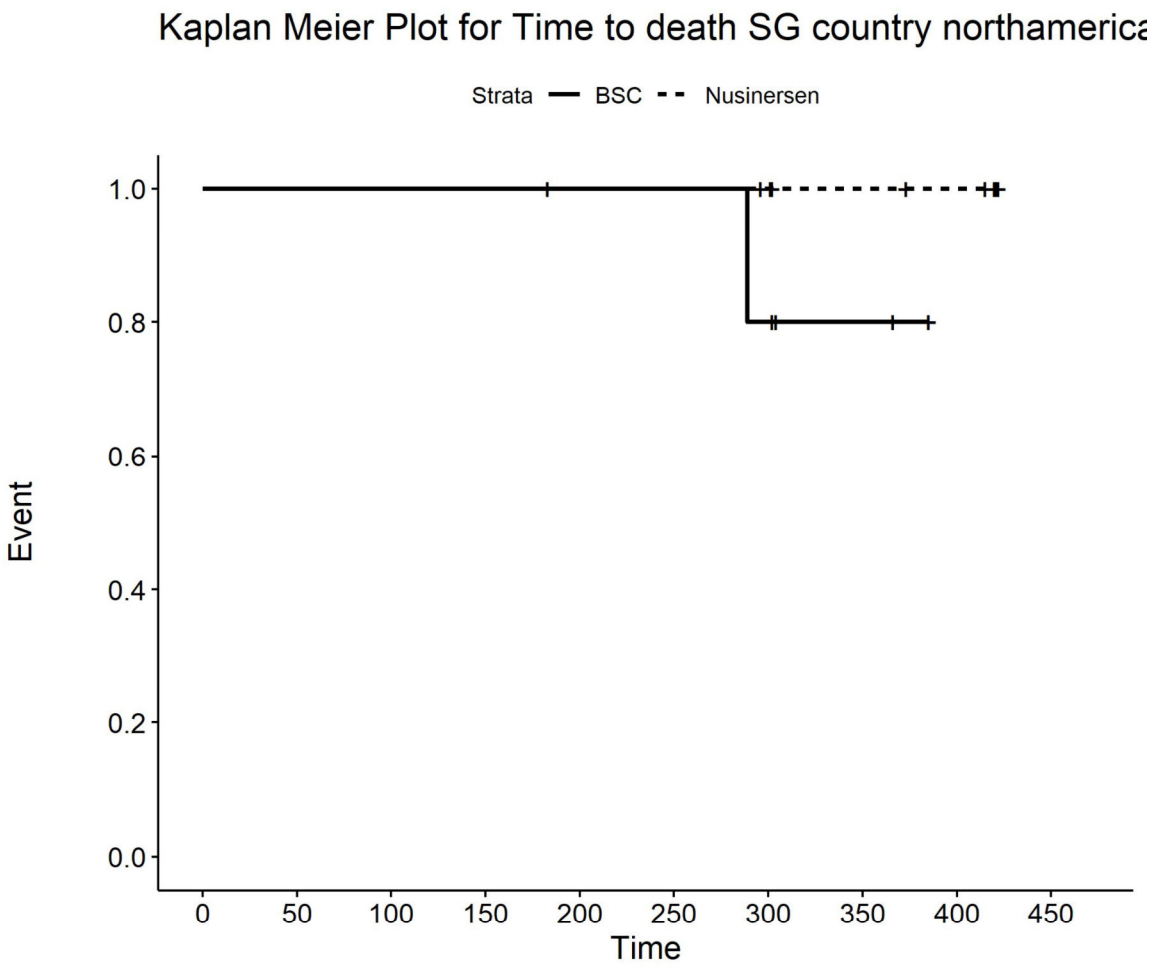
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	0	0	0	0	0	0	0	0	0



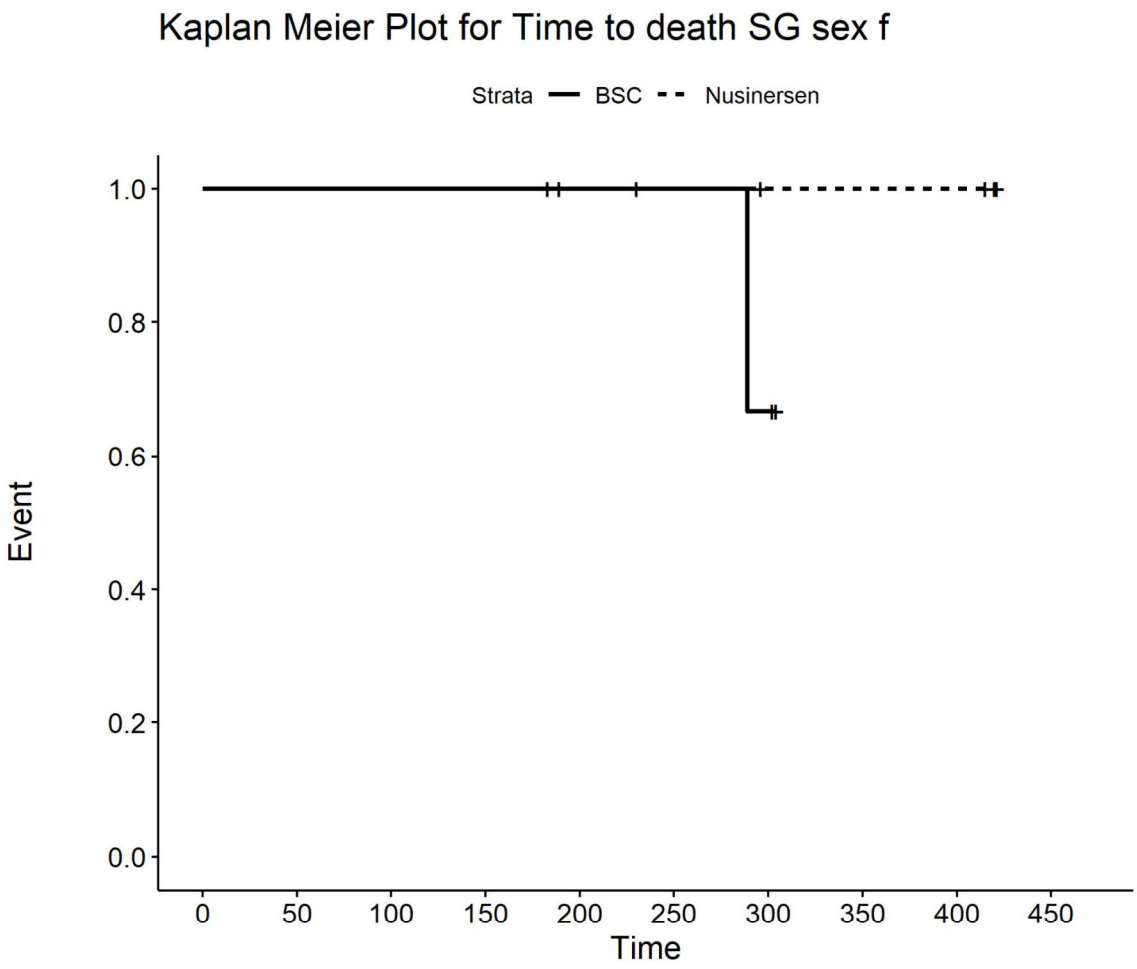
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



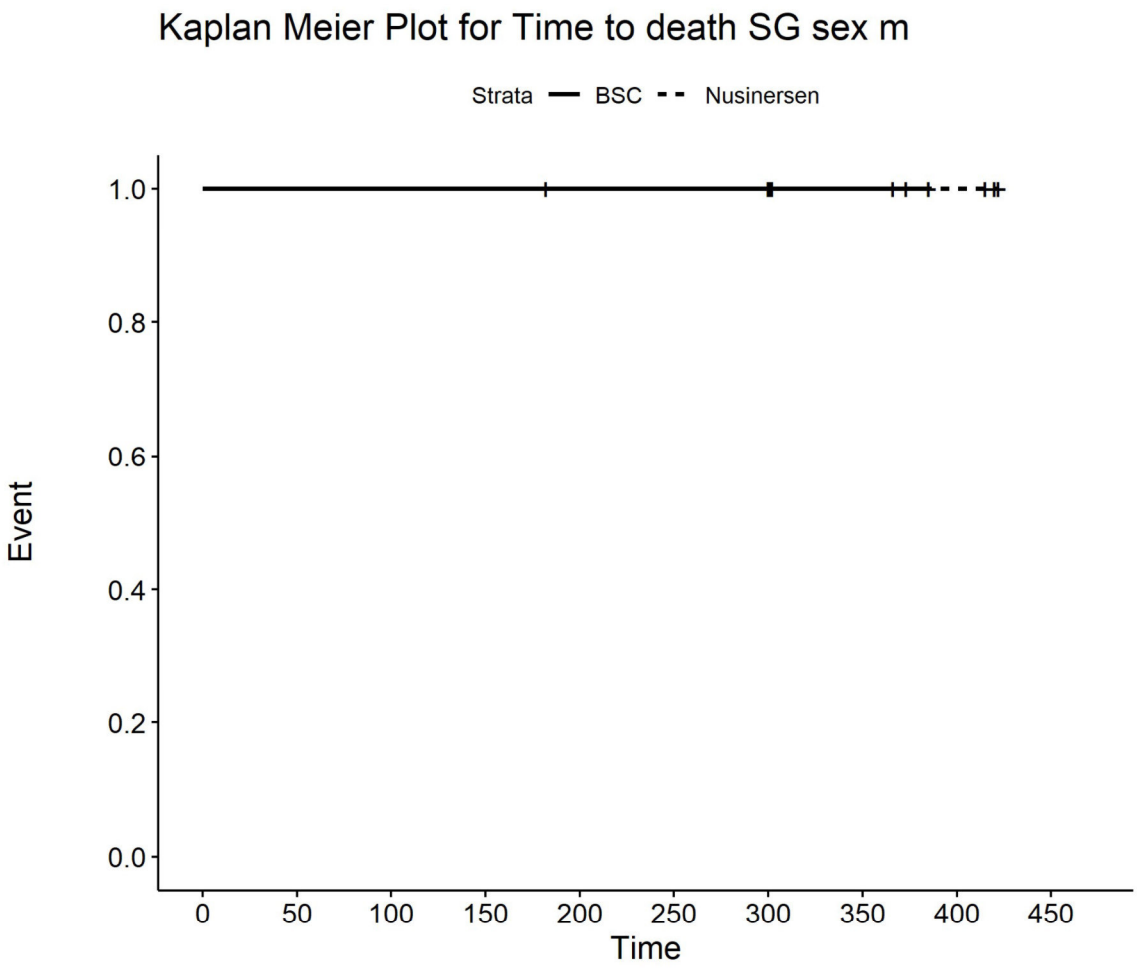
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



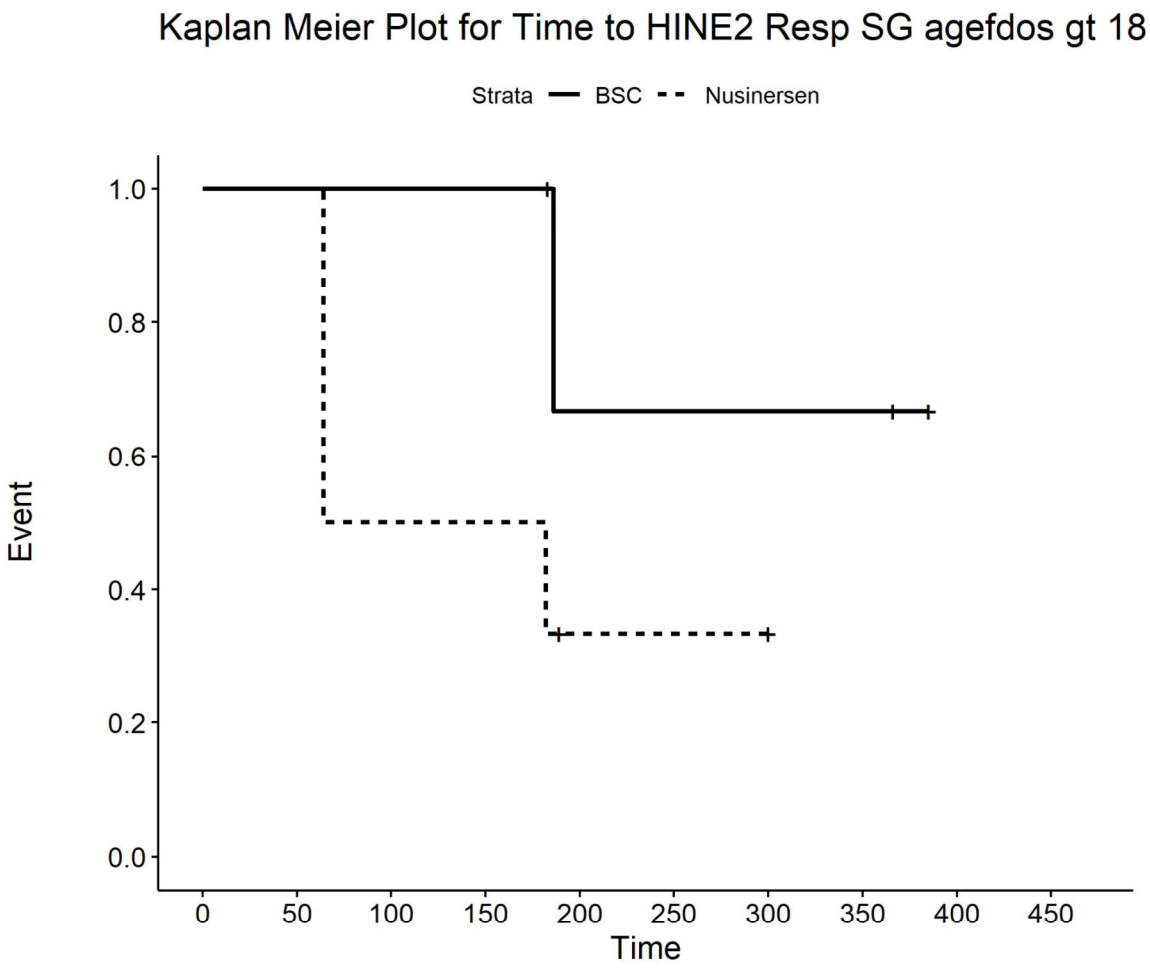
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



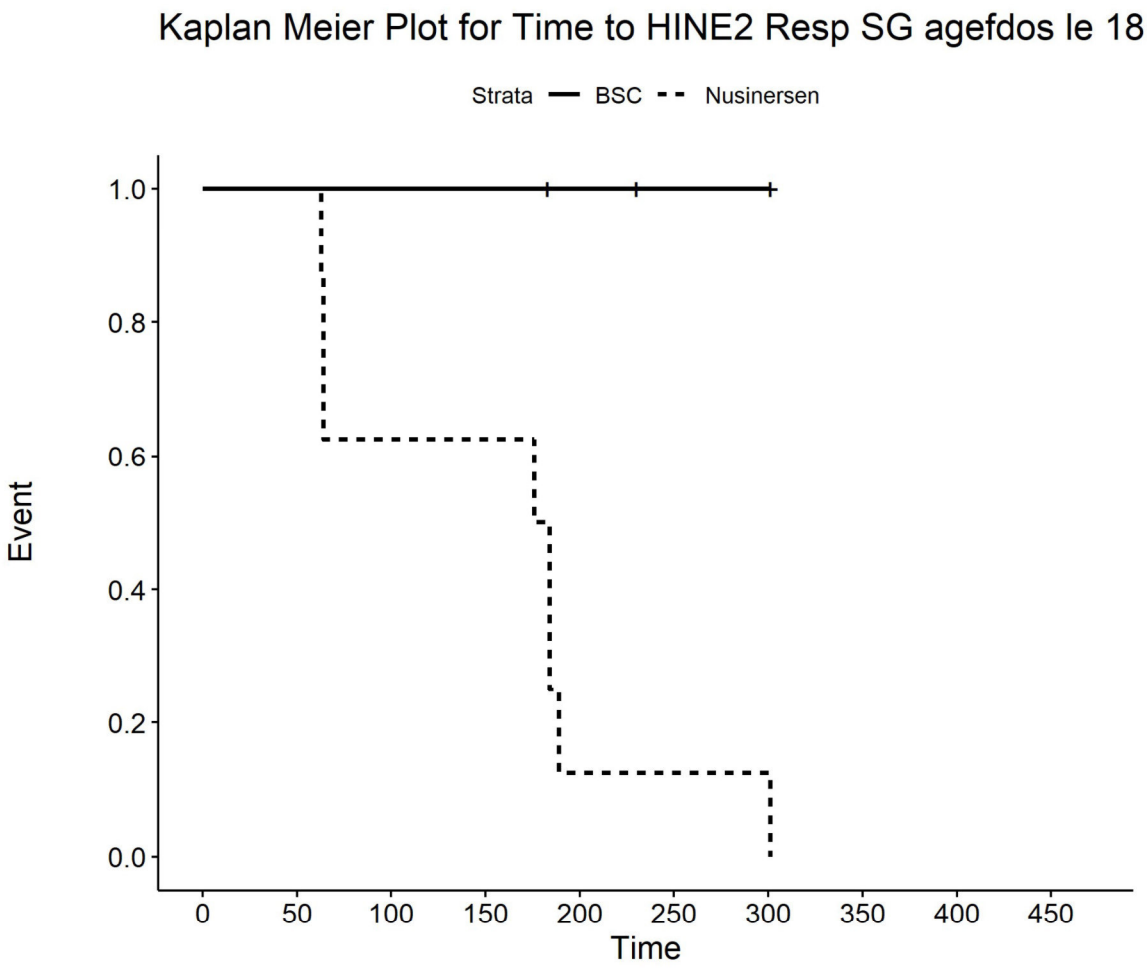
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



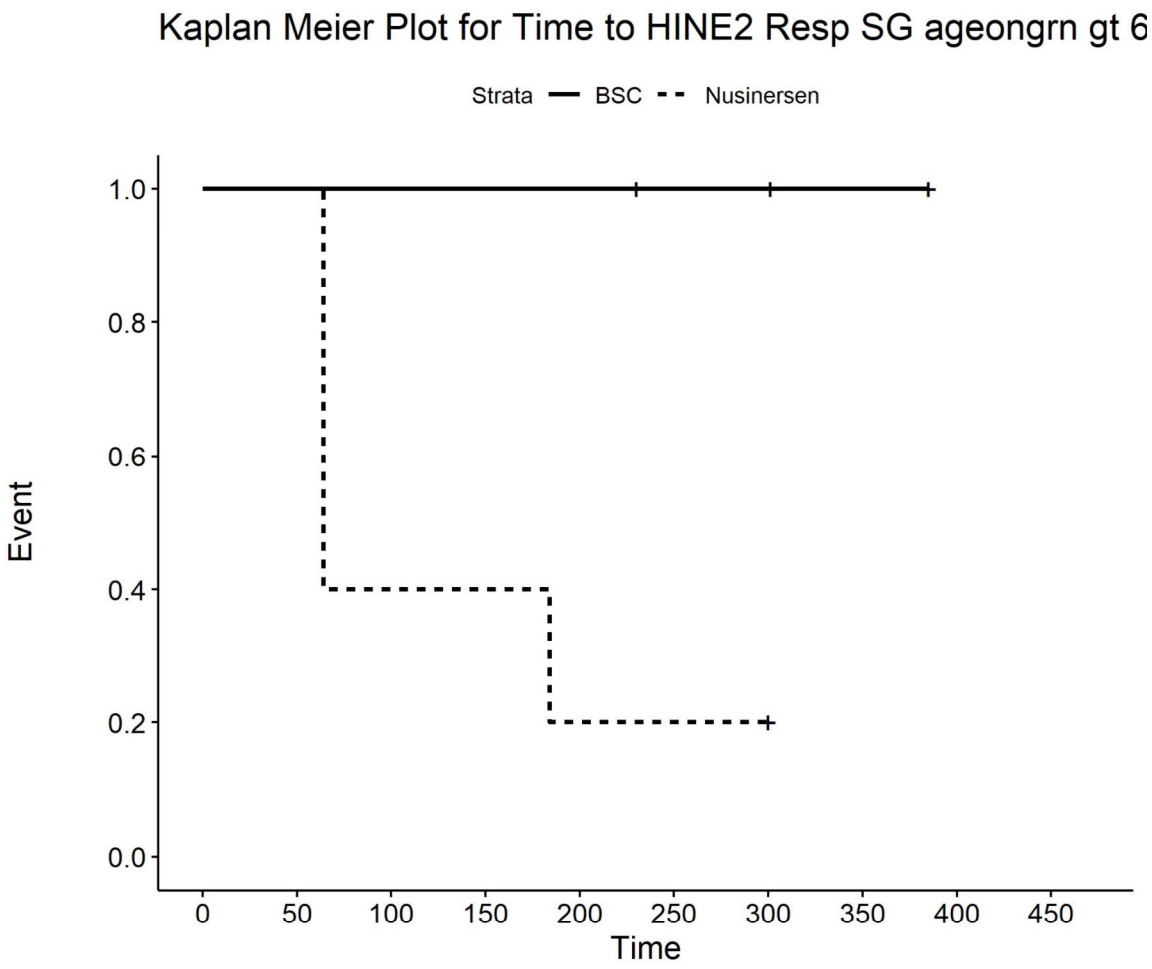
Number at risk

BSC	4	4	4	4	2	2	2	2	0	0
Nusinersen	6	6	3	3	1	1	1	0	0	0



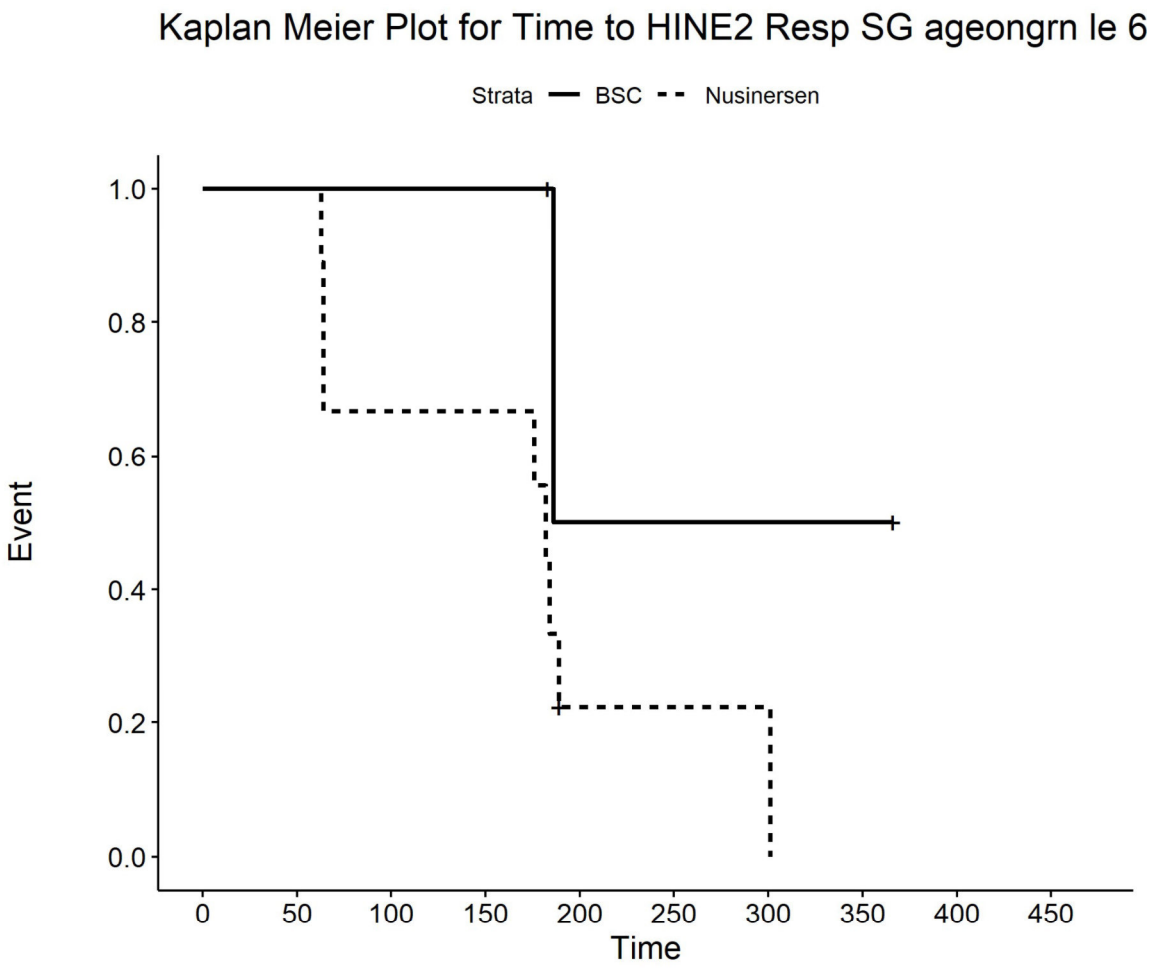
Number at risk

BSC	3	3	3	3	2	1	1	0	0	0
Nusinersen	8	8	5	5	1	1	1	0	0	0



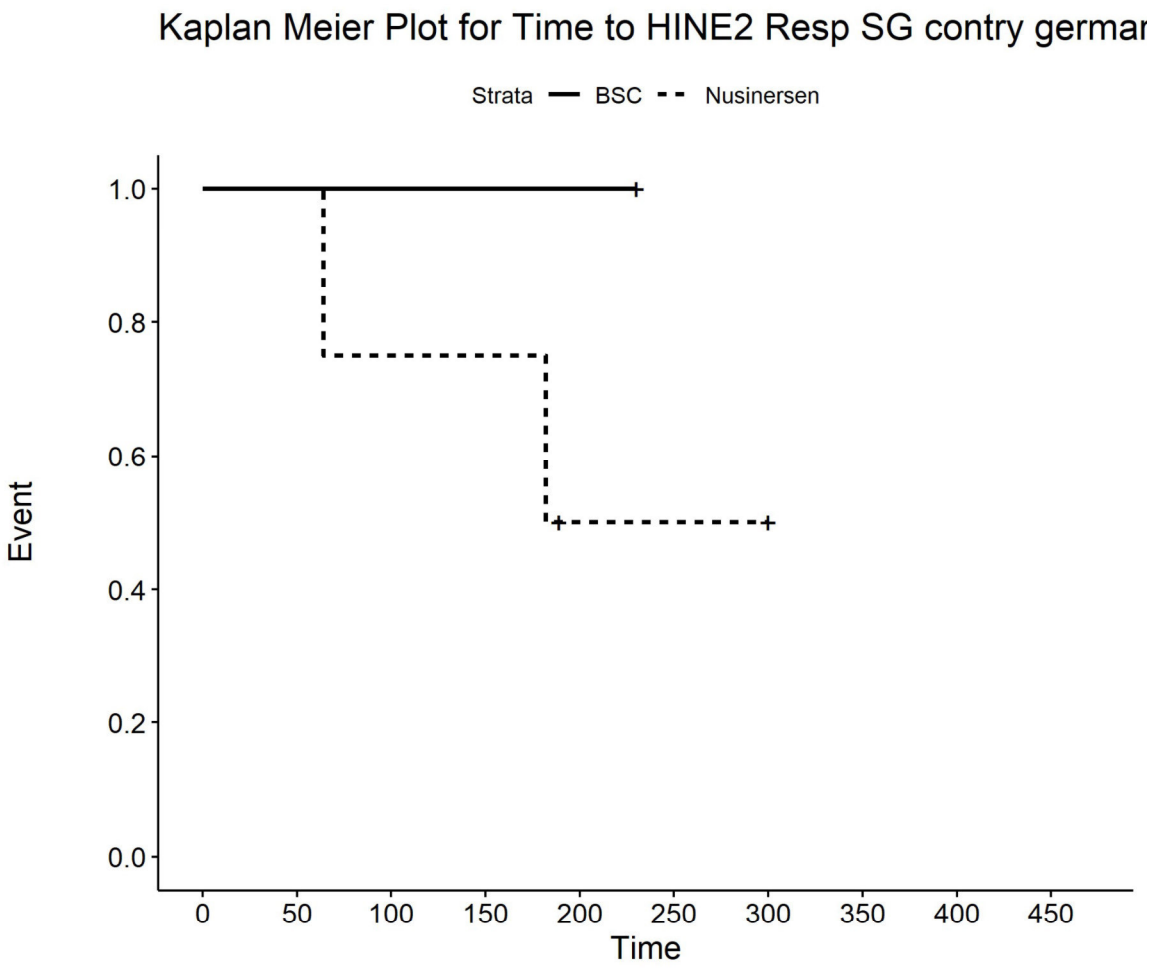
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	2	2	1	1	1	0	0	0



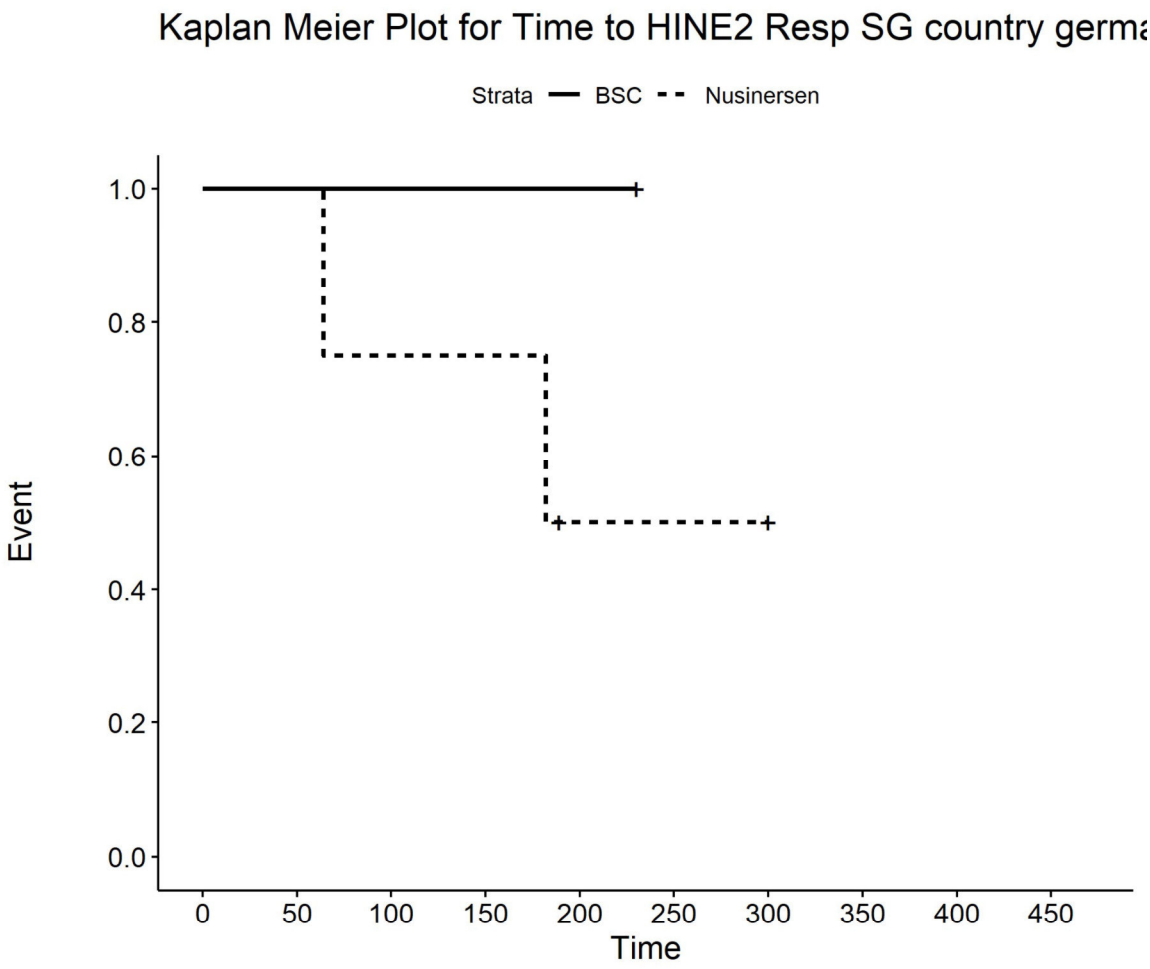
Number at risk

BSC	4	4	4	4	1	1	1	1	0	0
Nusinersen	9	9	6	6	1	1	1	0	0	0



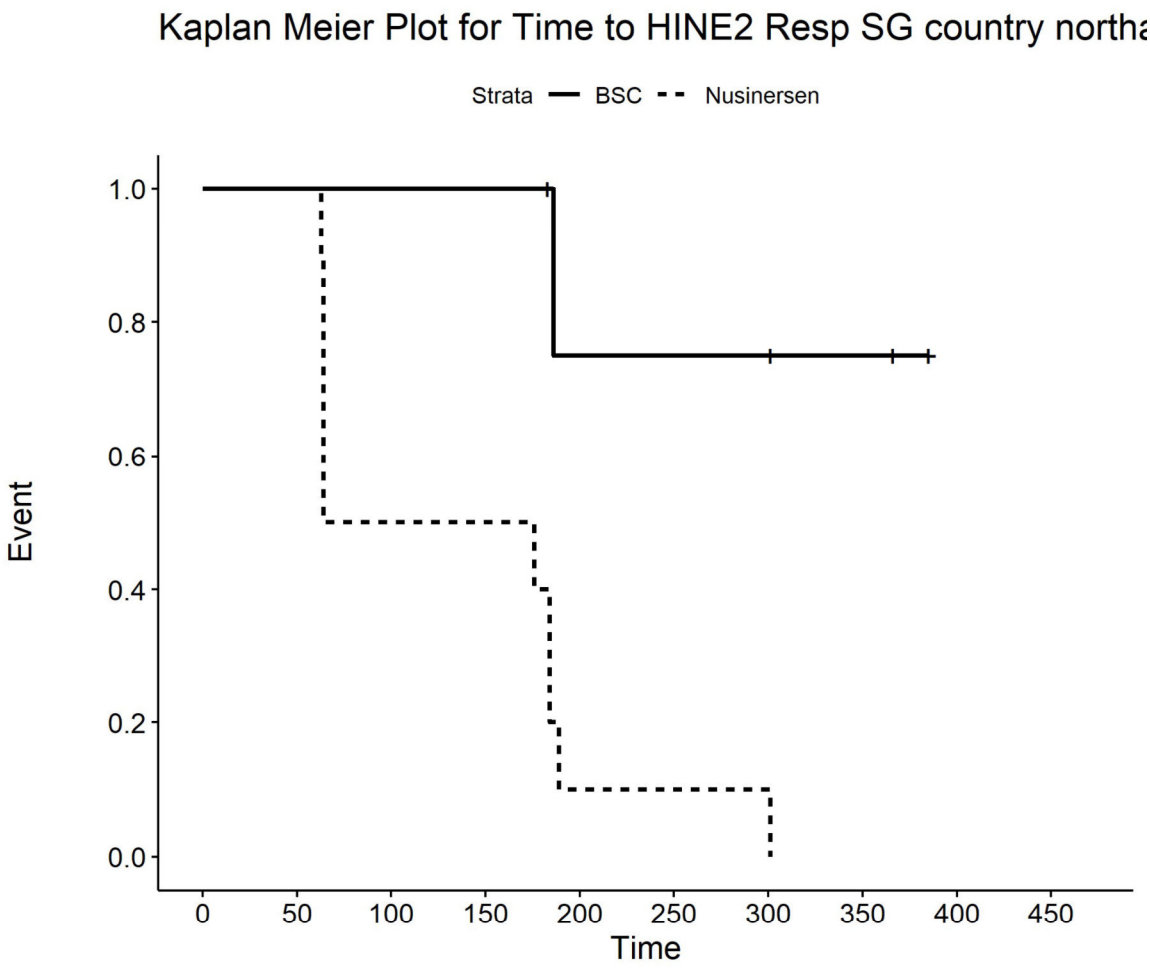
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



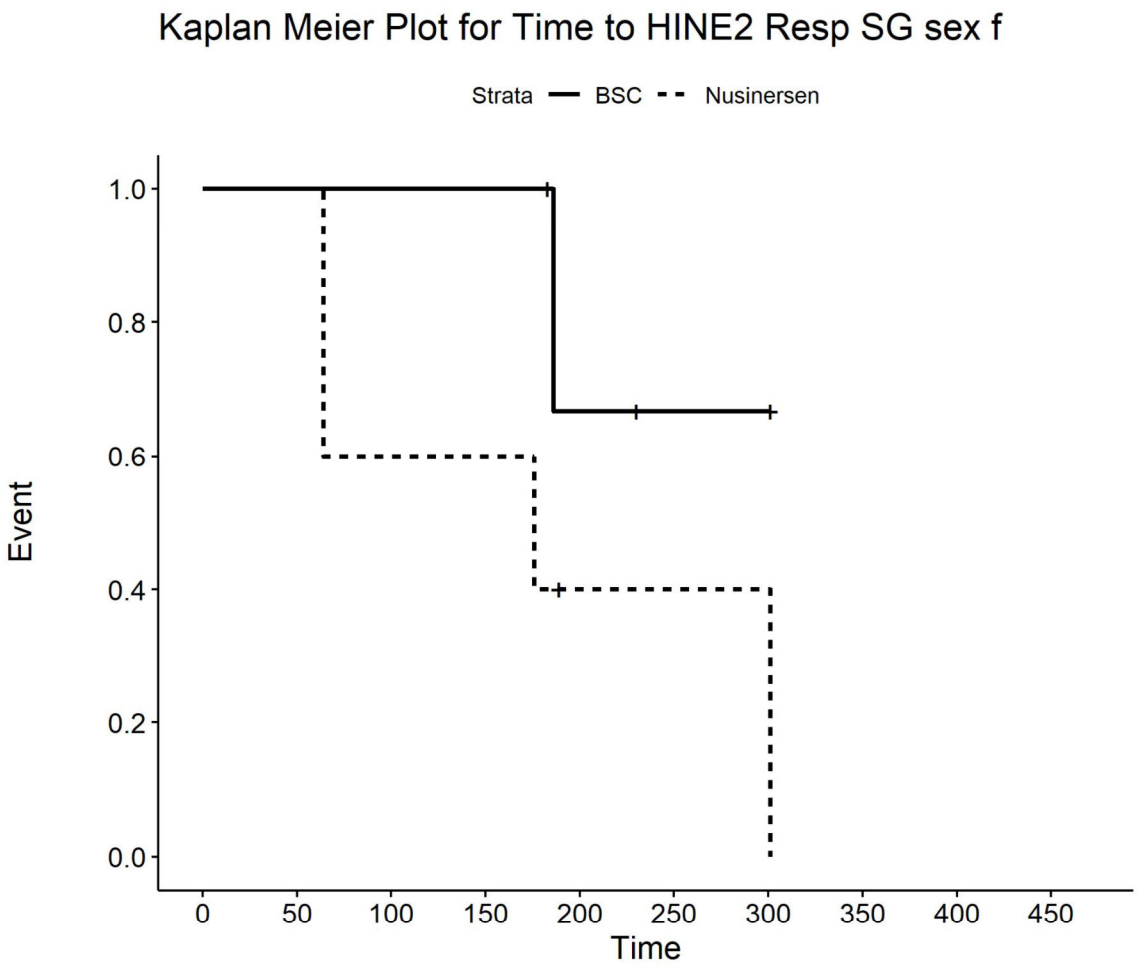
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



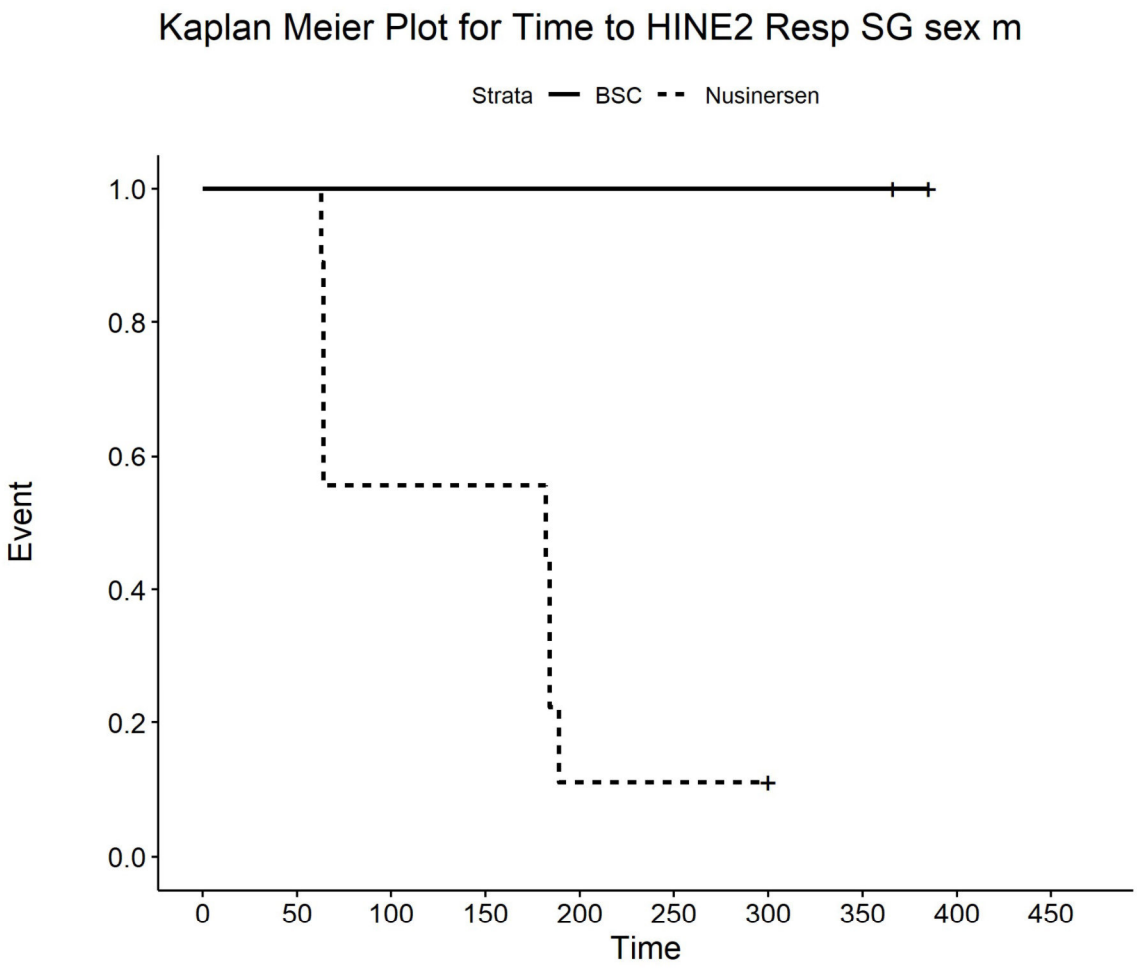
Number at risk

BSC	6	6	6	6	3	3	3	2	0	0
Nusinersen	10	10	5	5	1	1	1	0	0	0



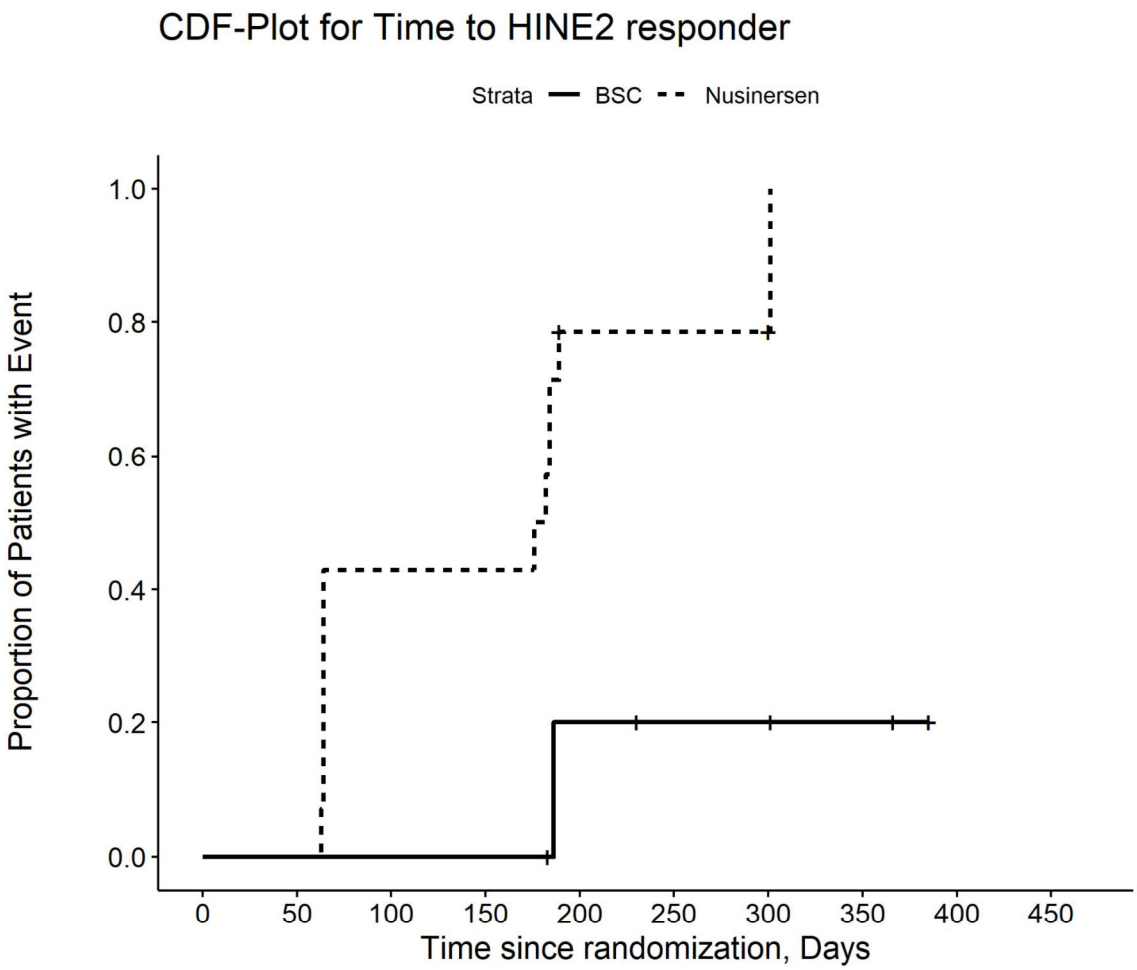
Number at risk

BSC	5	5	5	5	2	1	1	0	0	0
Nusinersen	5	5	3	3	1	1	1	0	0	0



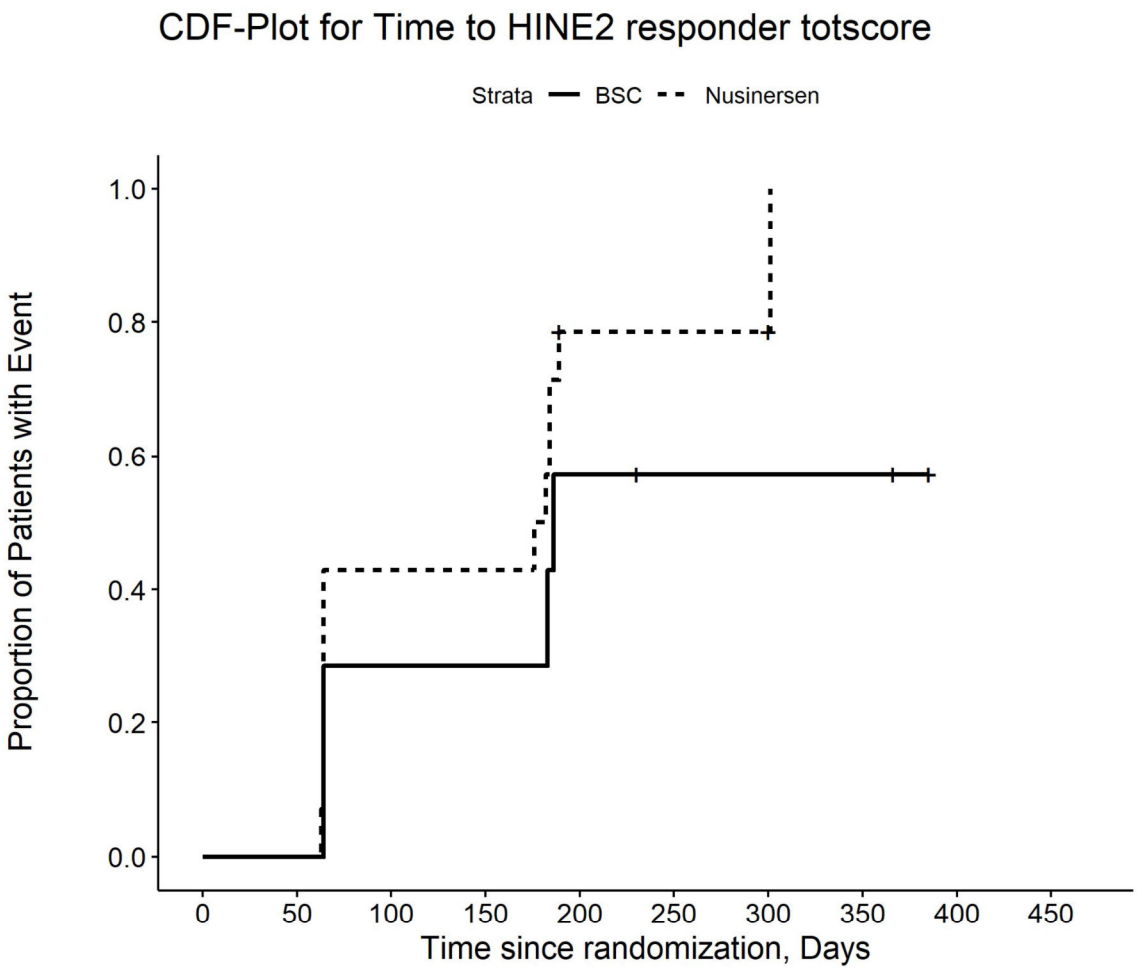
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	5	5	1	1	1	0	0	0



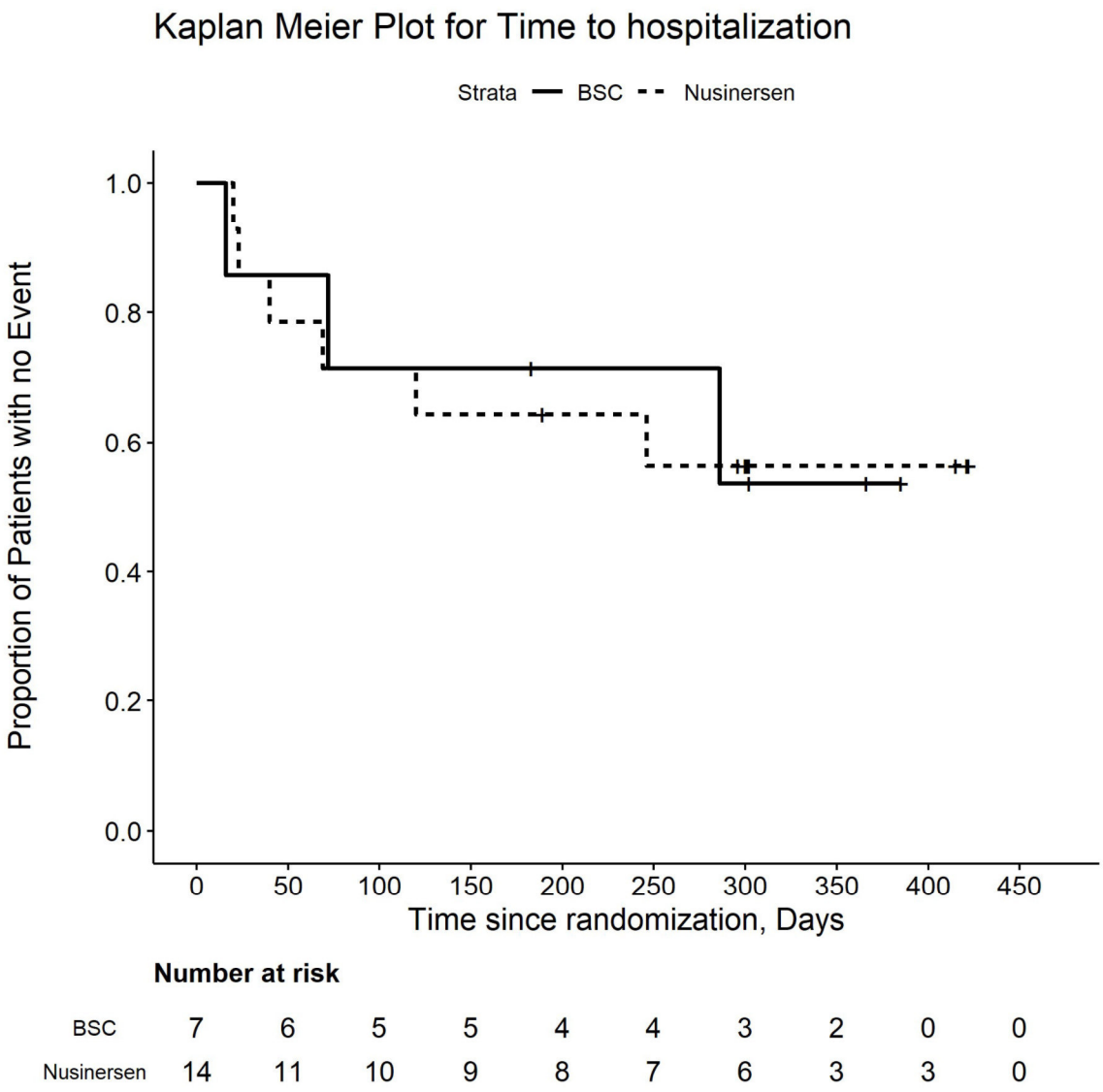
Number at risk

BSC	7	7	7	7	4	3	3	2	0	0
Nusinersen	14	14	8	8	2	2	2	0	0	0



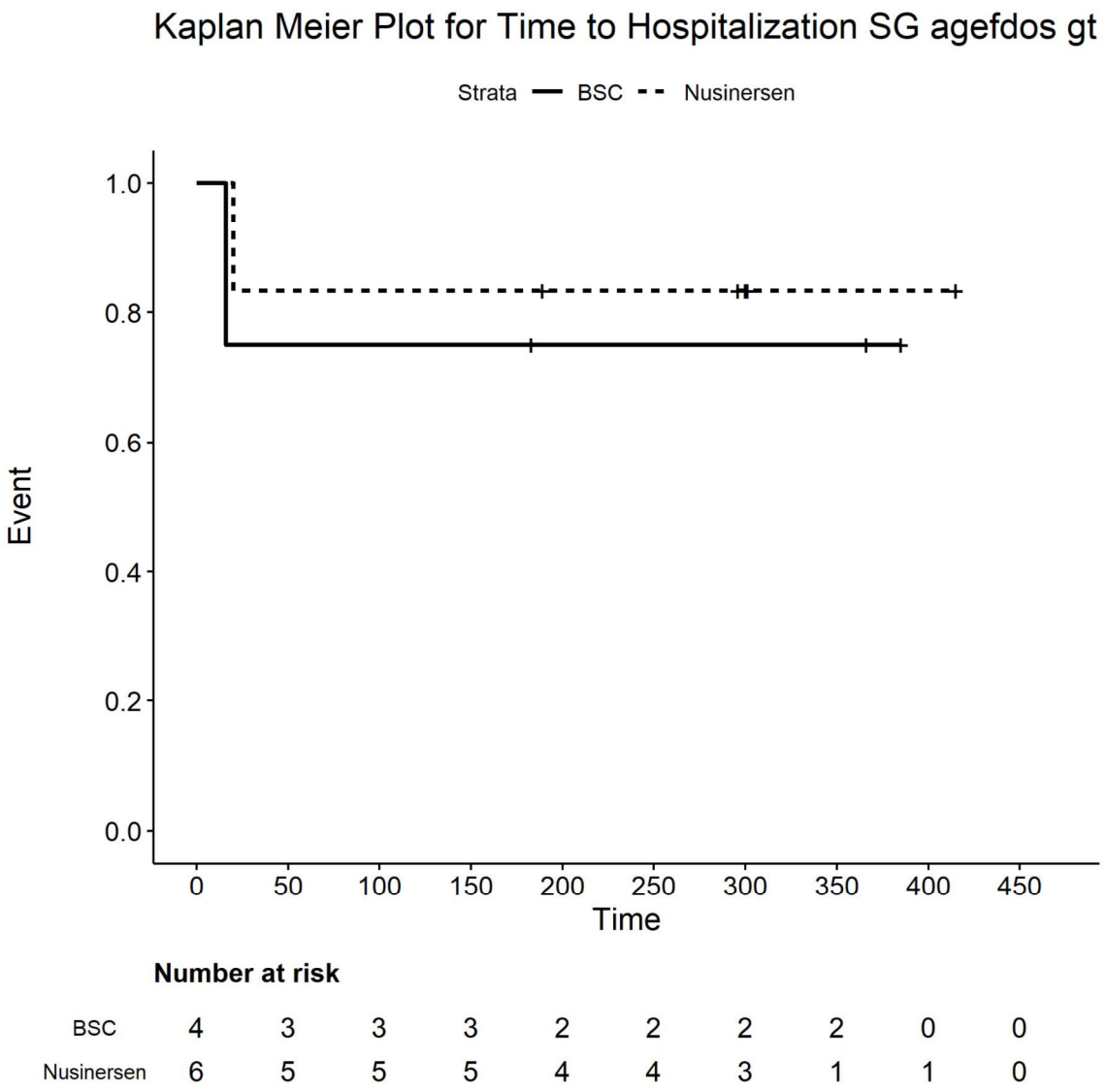
Number at risk

BSC	7	7	5	5	3	2	2	2	0	0
Nusinersen	14	14	8	8	2	2	2	0	0	0



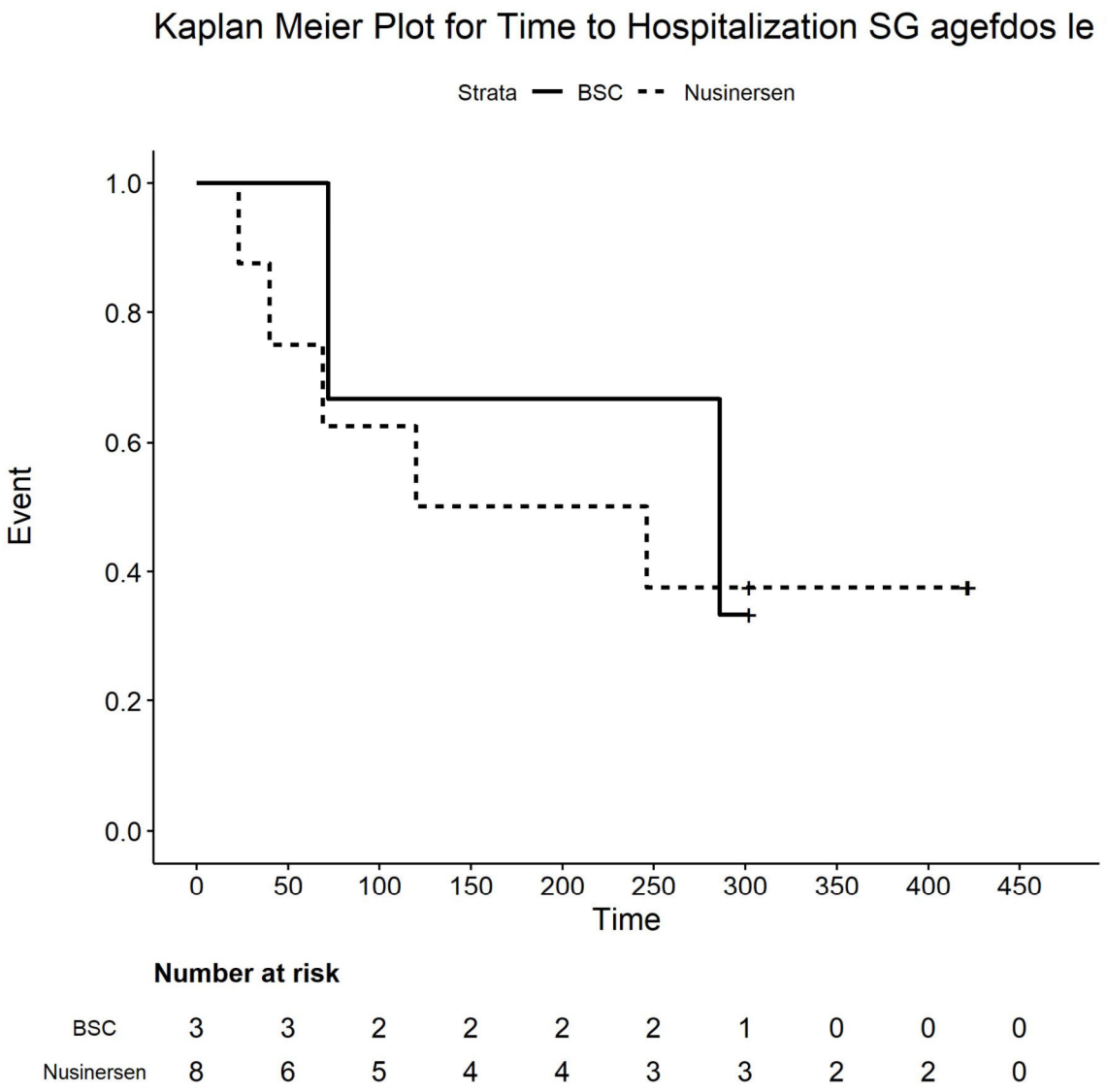
Number at risk

BSC	7	6	5	5	4	4	3	2	0	0
Nusinersen	14	11	10	9	8	7	6	3	3	0



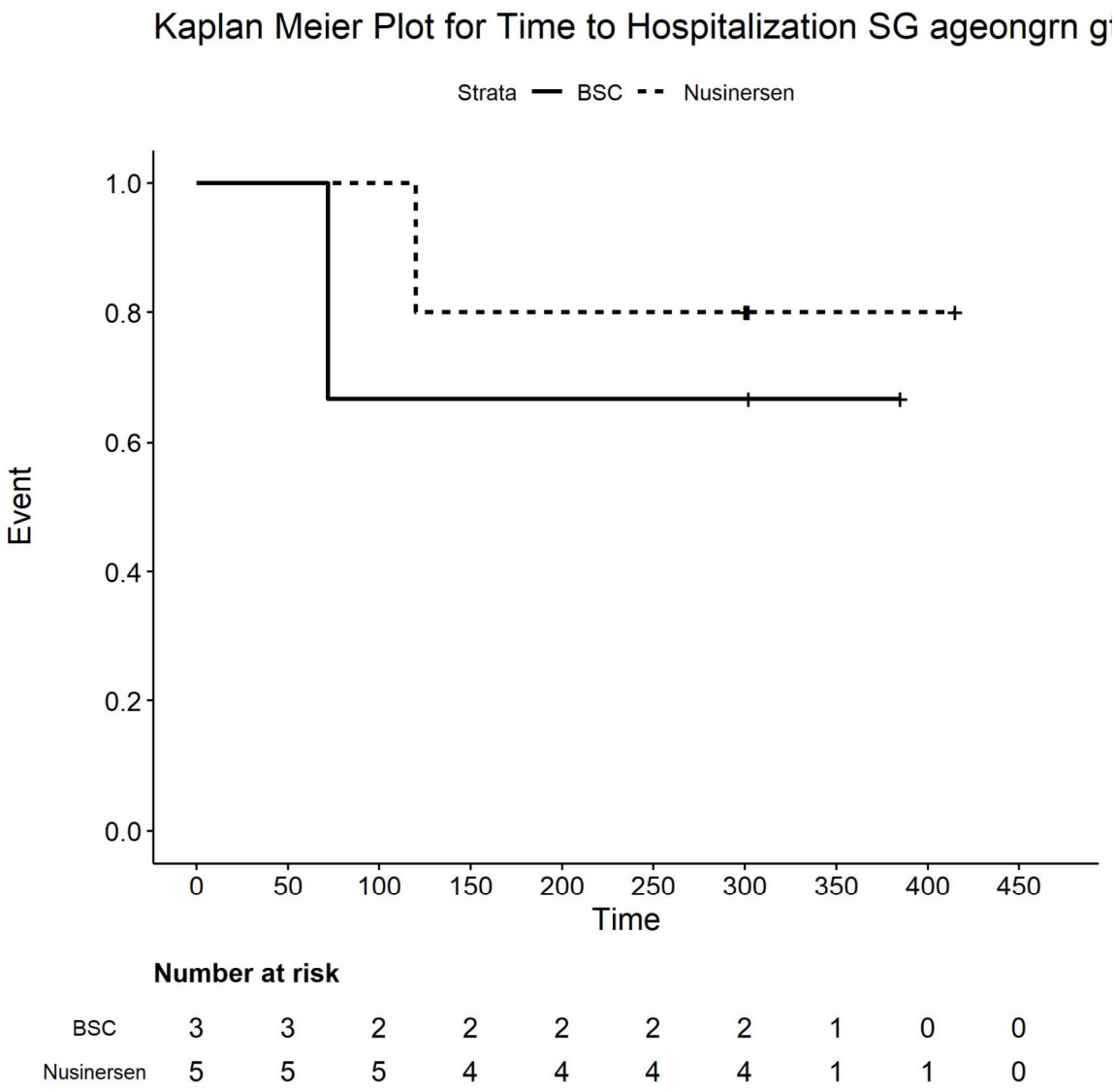
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	5	5	5	4	4	3	1	1	0



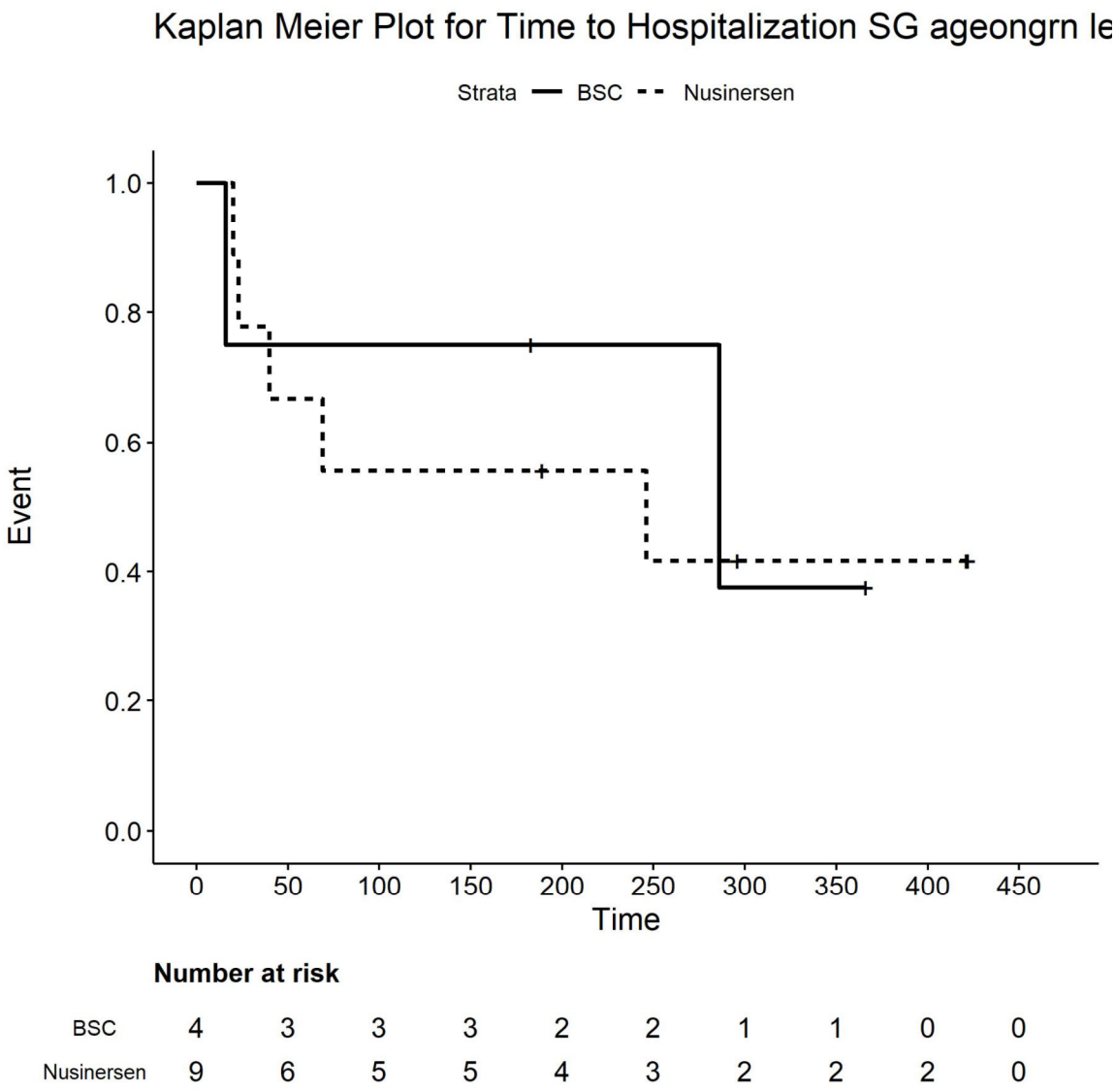
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	6	5	4	4	3	3	2	2	0



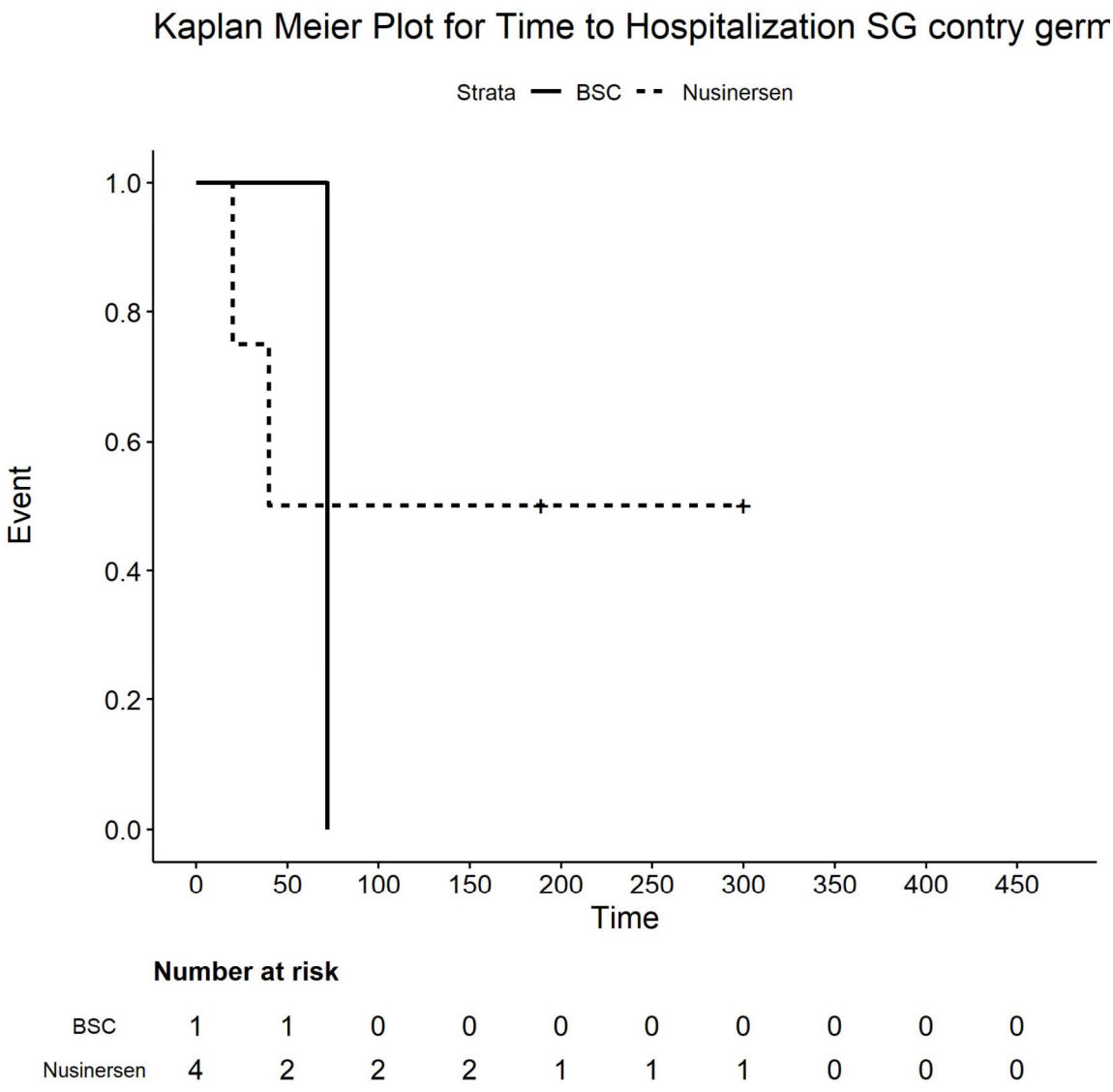
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	4	4	4	4	1	1	0



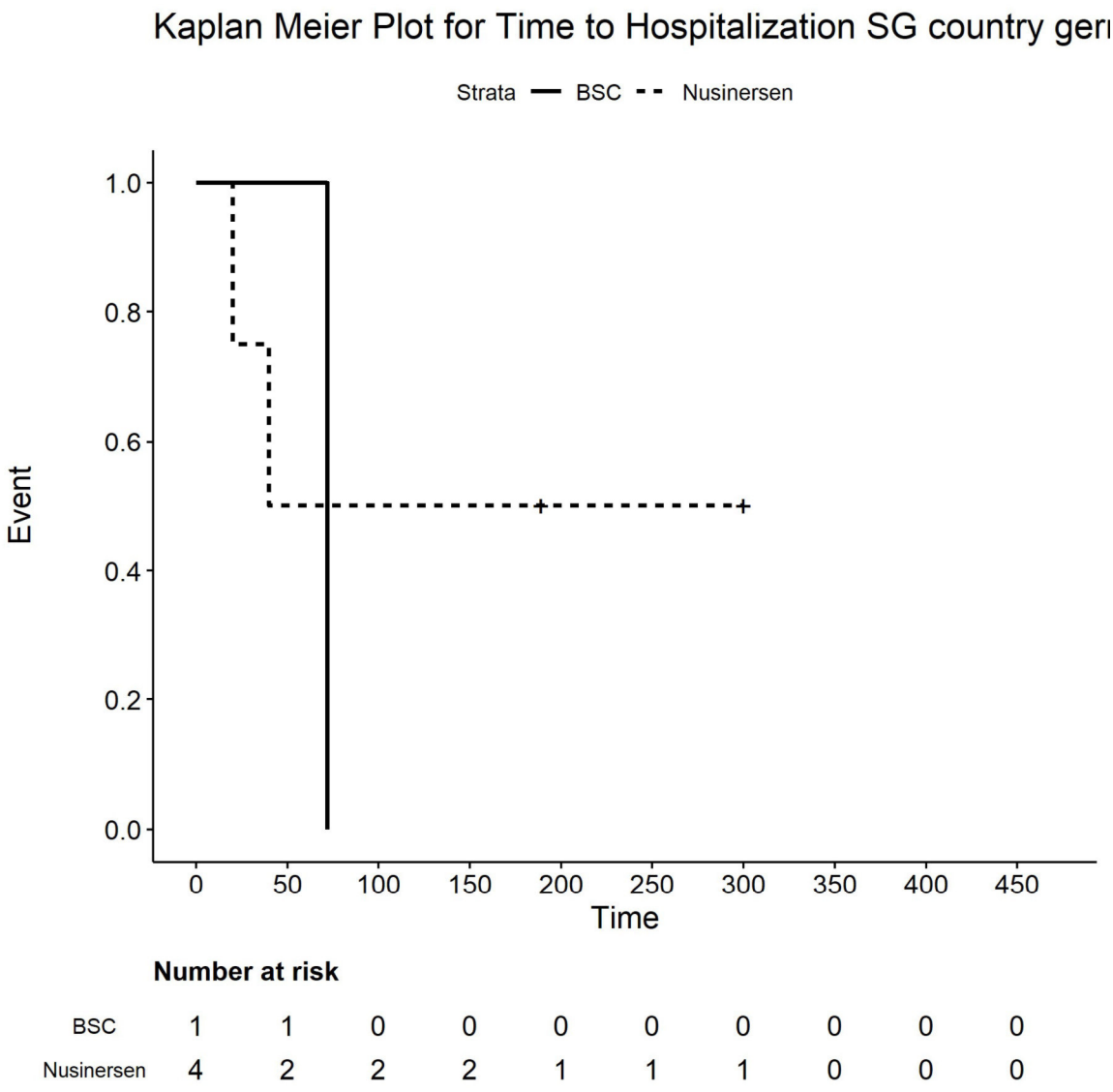
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	6	5	5	4	3	2	2	2	0



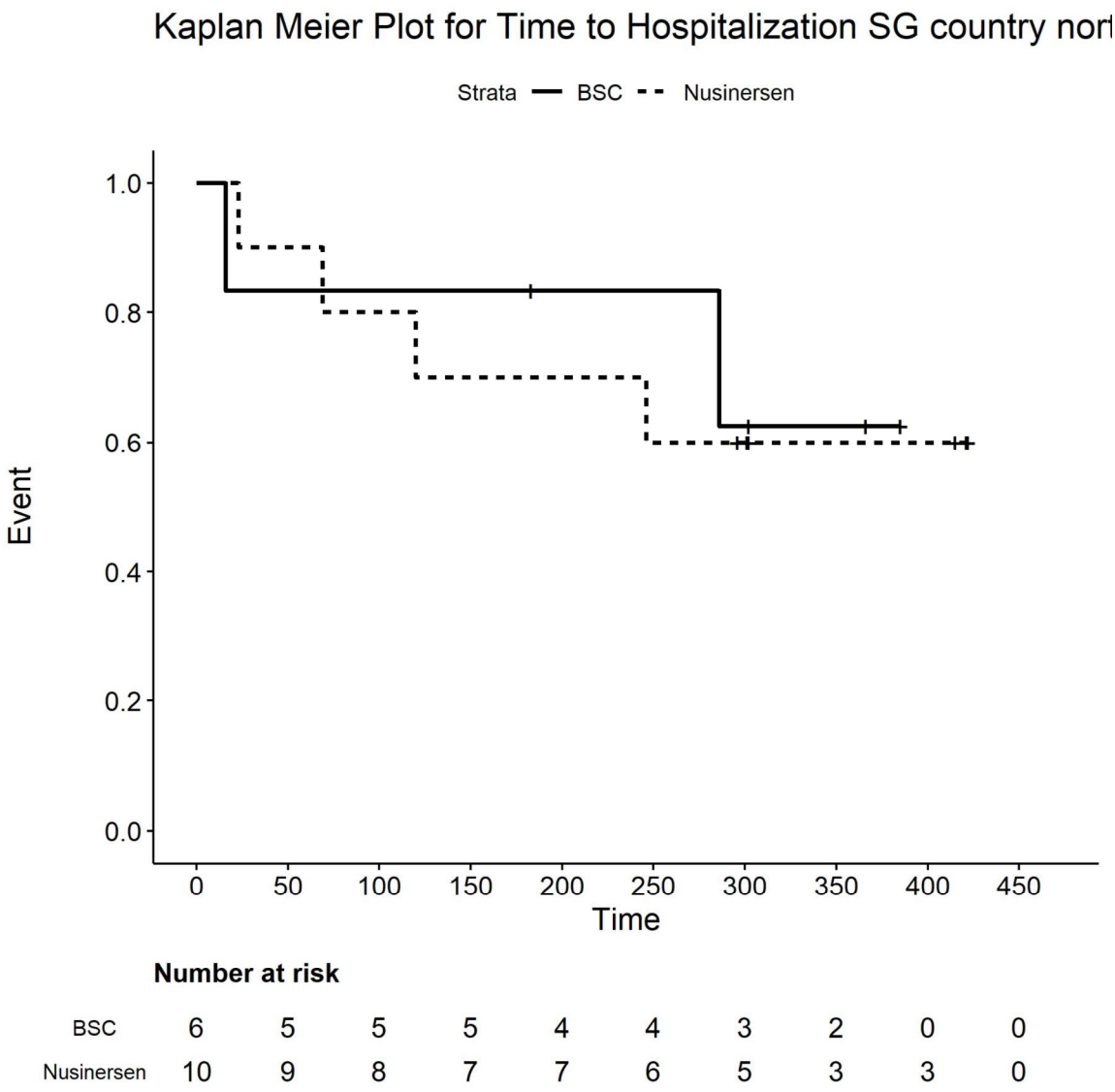
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	2	2	2	1	1	1	0	0	0



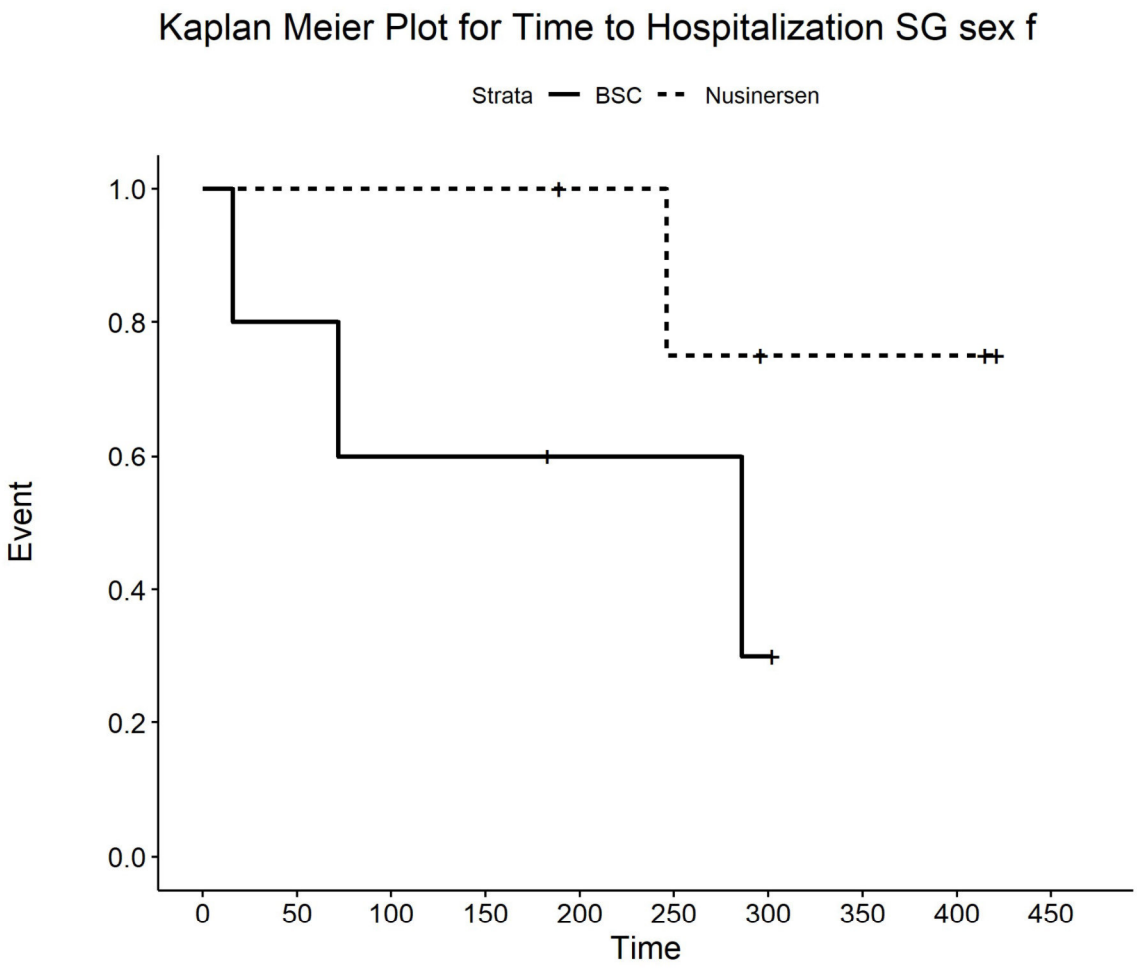
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	2	2	2	1	1	1	0	0	0



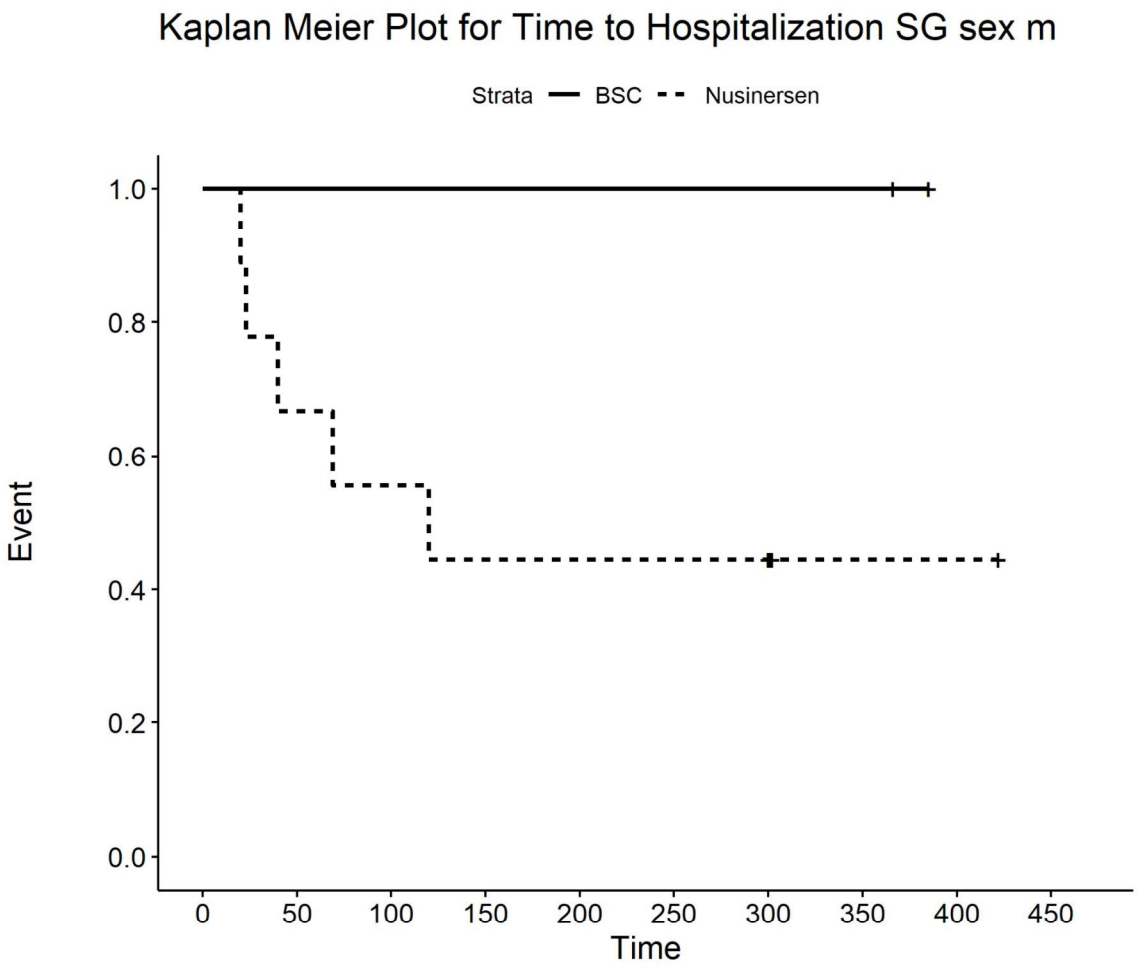
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	9	8	7	7	6	5	3	3	0



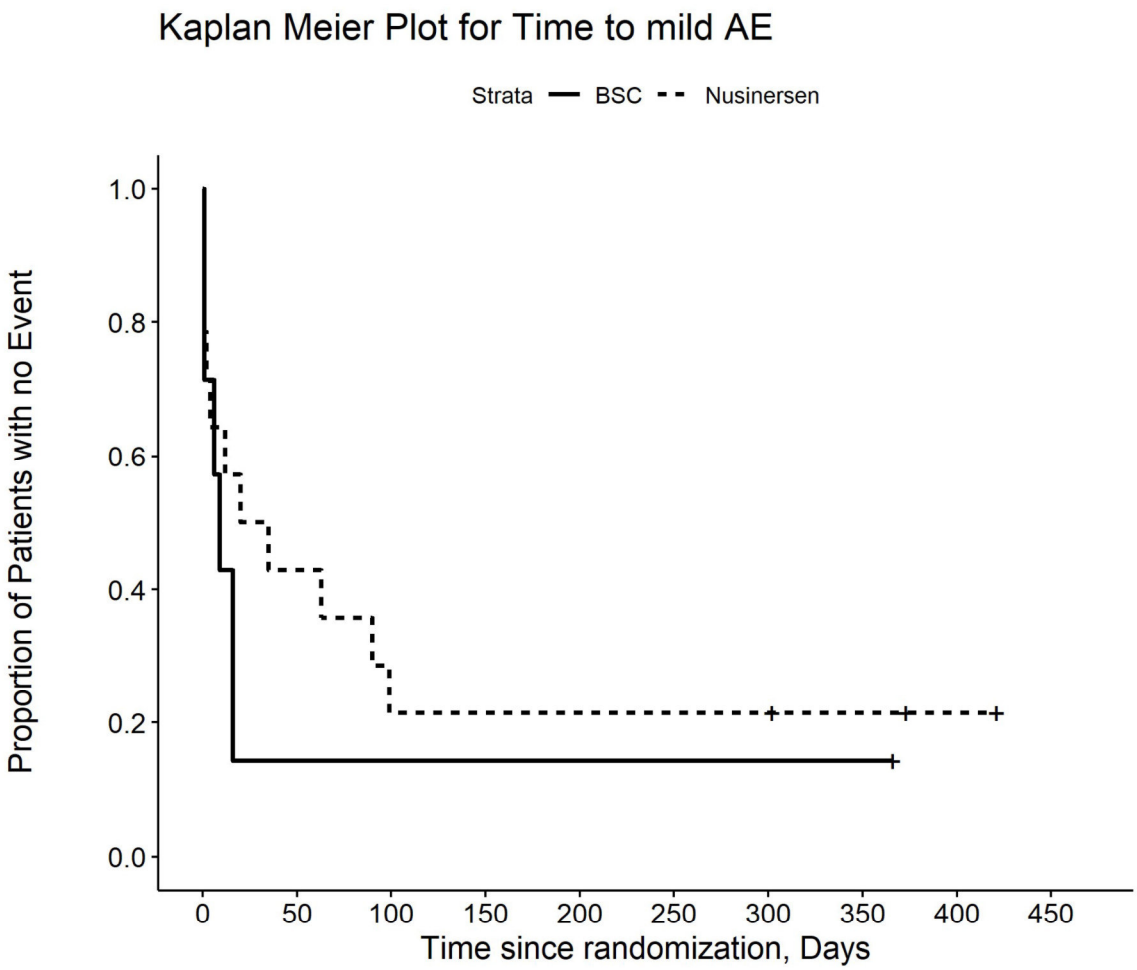
Number at risk

BSC	5	4	3	3	2	2	1	0	0	0
Nusinersen	5	5	5	5	4	3	2	2	2	0



Number at risk

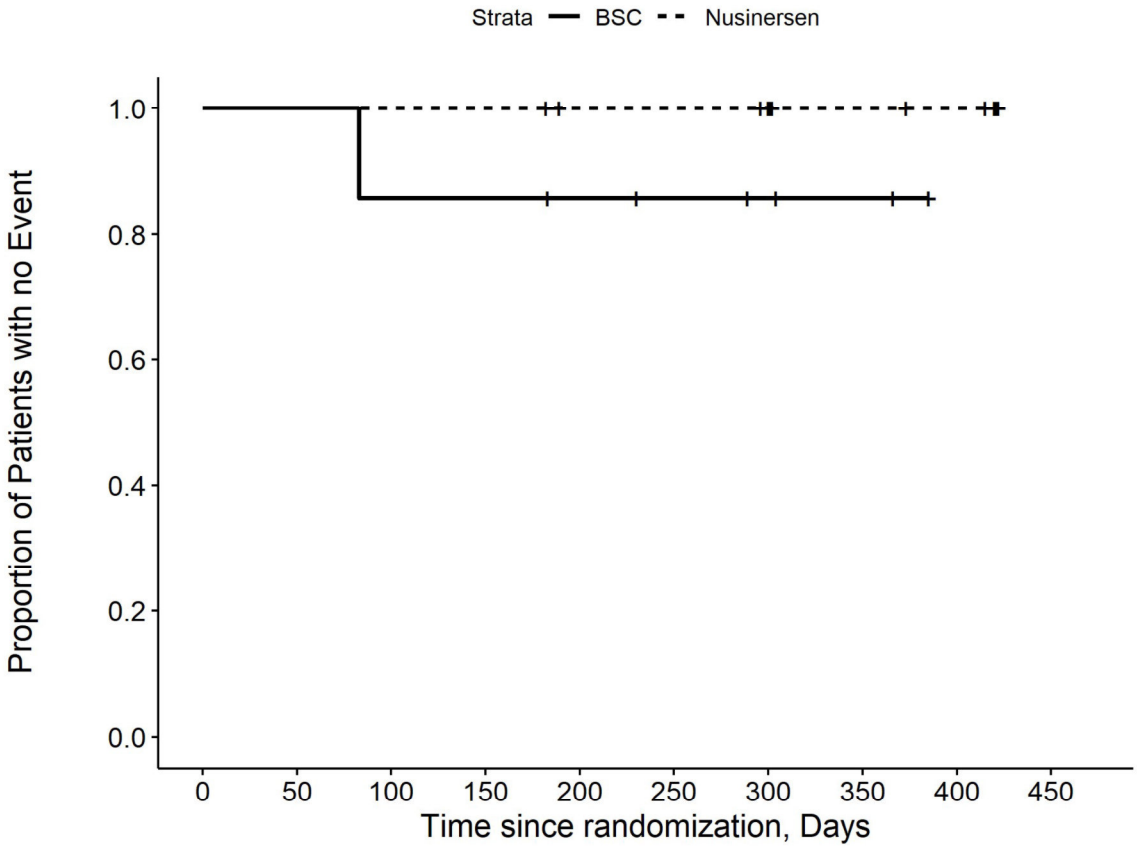
BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	6	5	4	4	4	4	1	1	0



Number at risk

BSC	7	1	1	1	1	1	1	1	0	0
Nusinersen	14	6	3	3	3	3	3	2	1	0

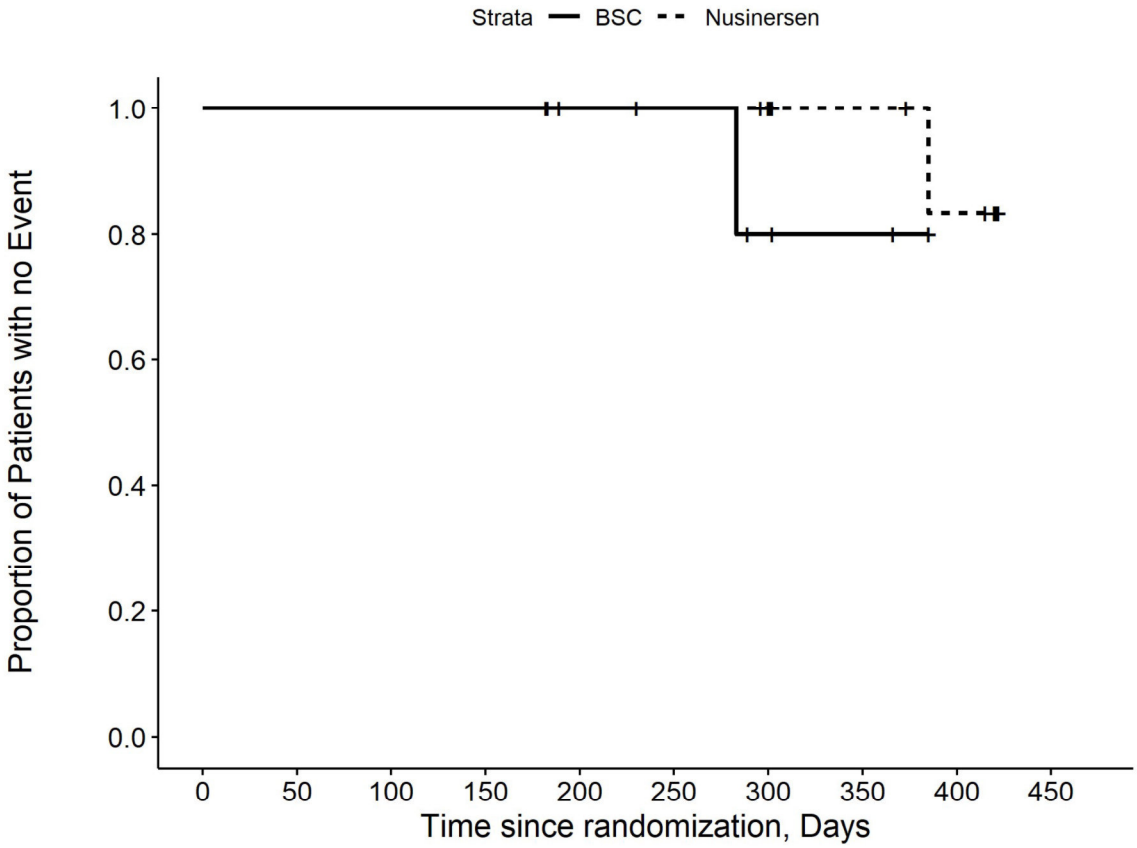
Kaplan Meier Plot for Time to mild AE by PT pct Aphthous ulcer



Number at risk

BSC	7	7	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

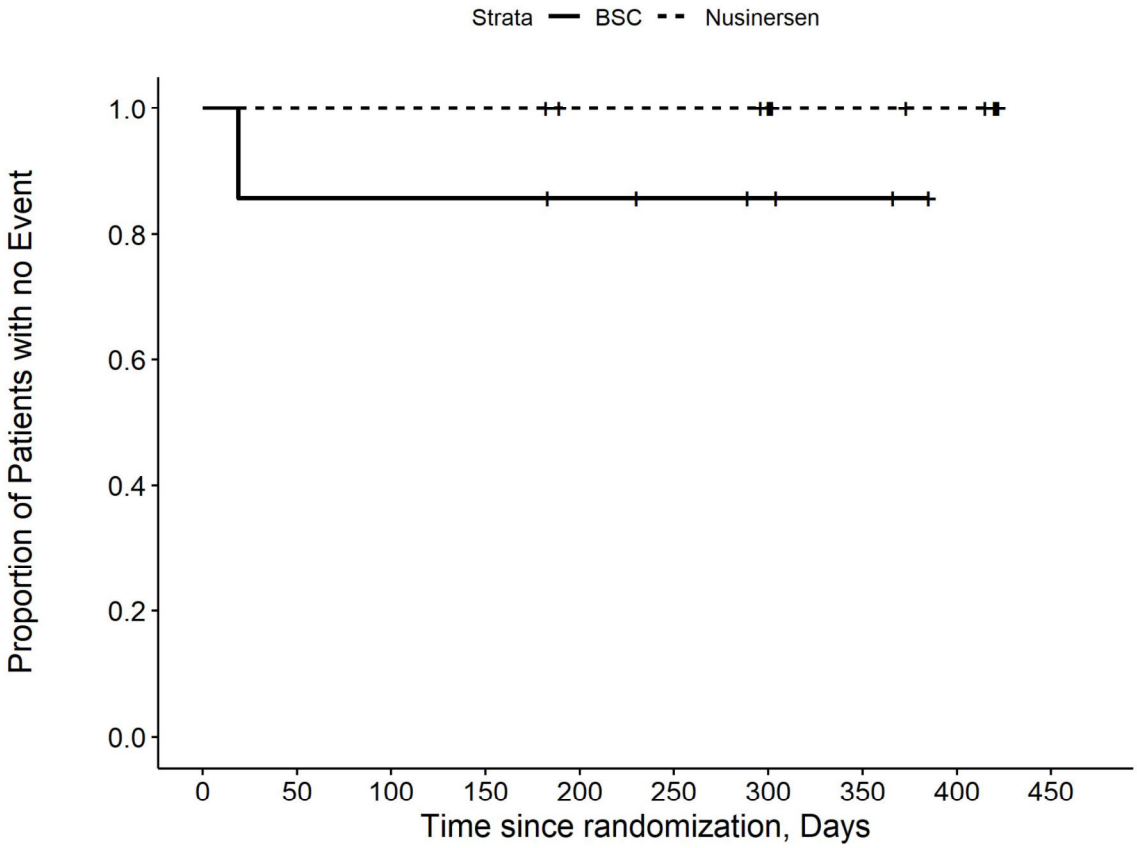
Kaplan Meier Plot for Time to mild AE by PT pct Constipation



Number at risk

BSC	7	7	7	7	6	5	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	5	0

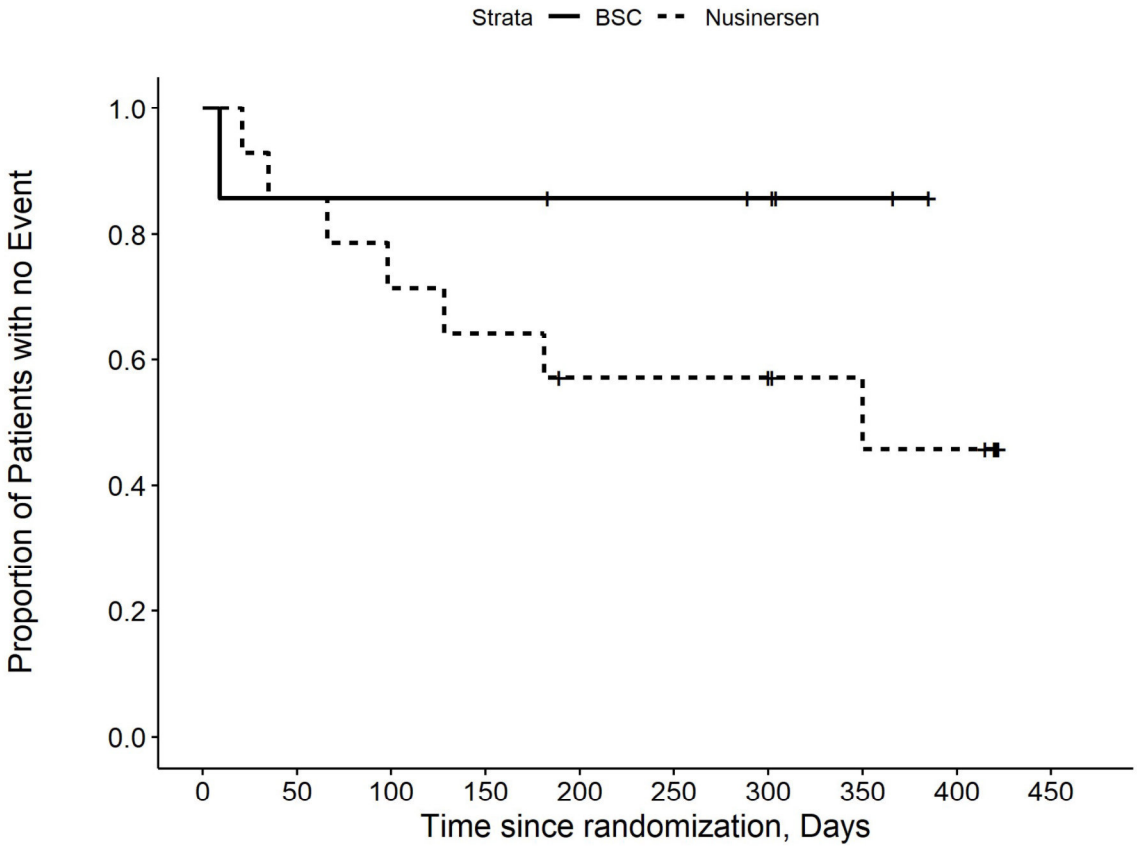
Kaplan Meier Plot for Time to mild AE by PT pct Contusion



Number at risk

BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

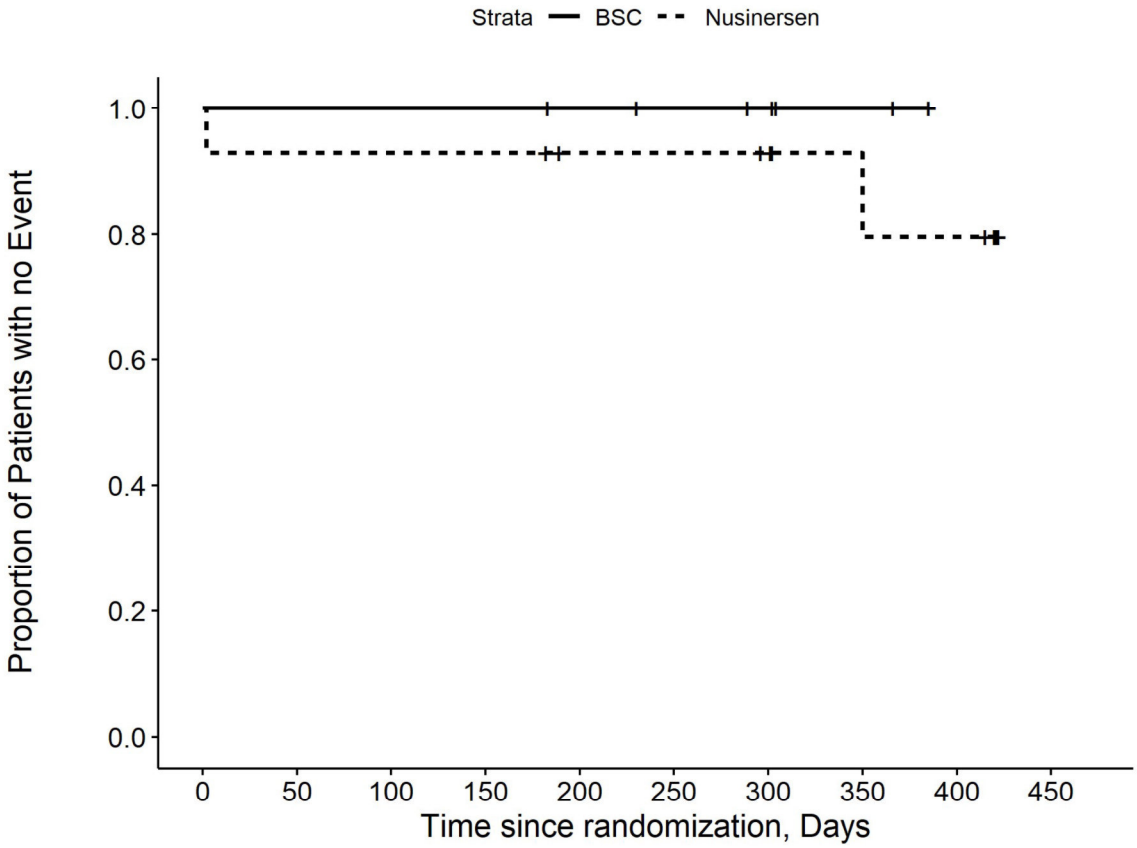
Kaplan Meier Plot for Time to mild AE by PT pct Cough



Number at risk

BSC	7	6	6	6	5	5	4	2	0	0
Nusinersen	14	12	10	9	7	7	7	5	4	0

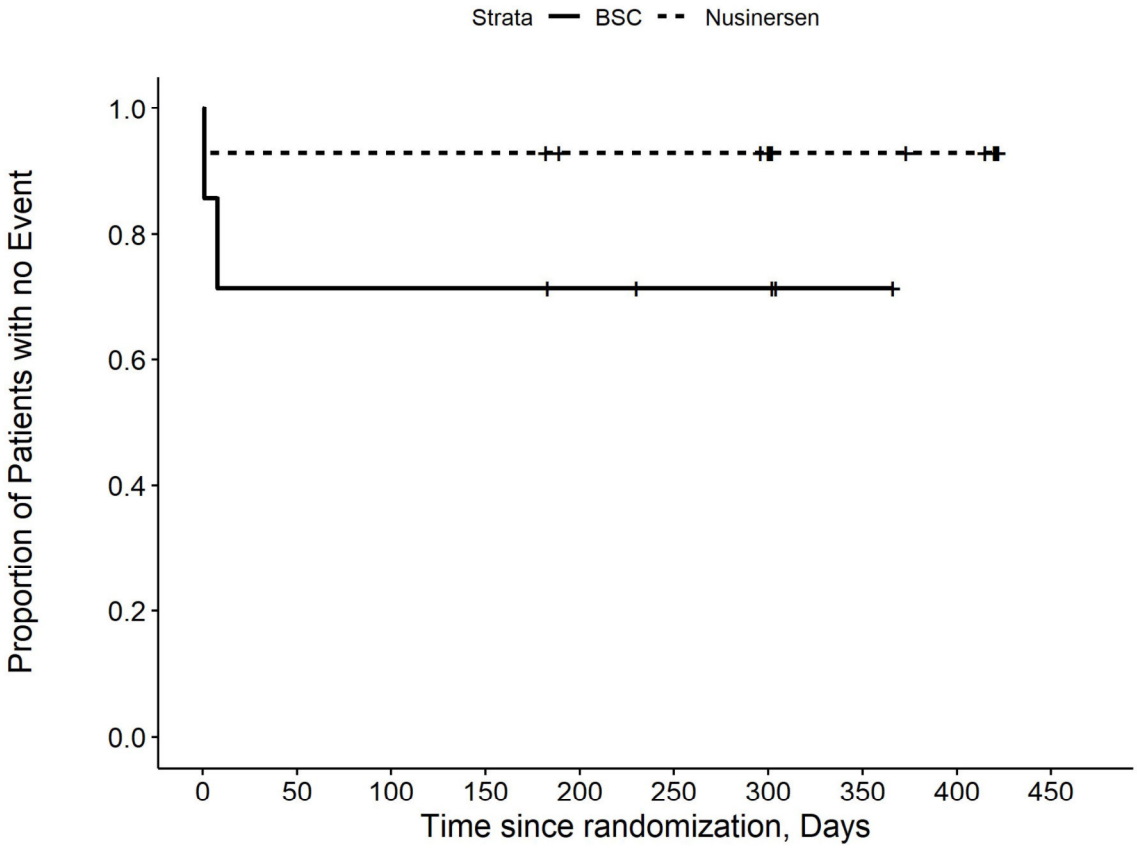
Kaplan Meier Plot for Time to mild AE by PT pct Diarrhoea



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	13	13	11	11	10	7	6	0

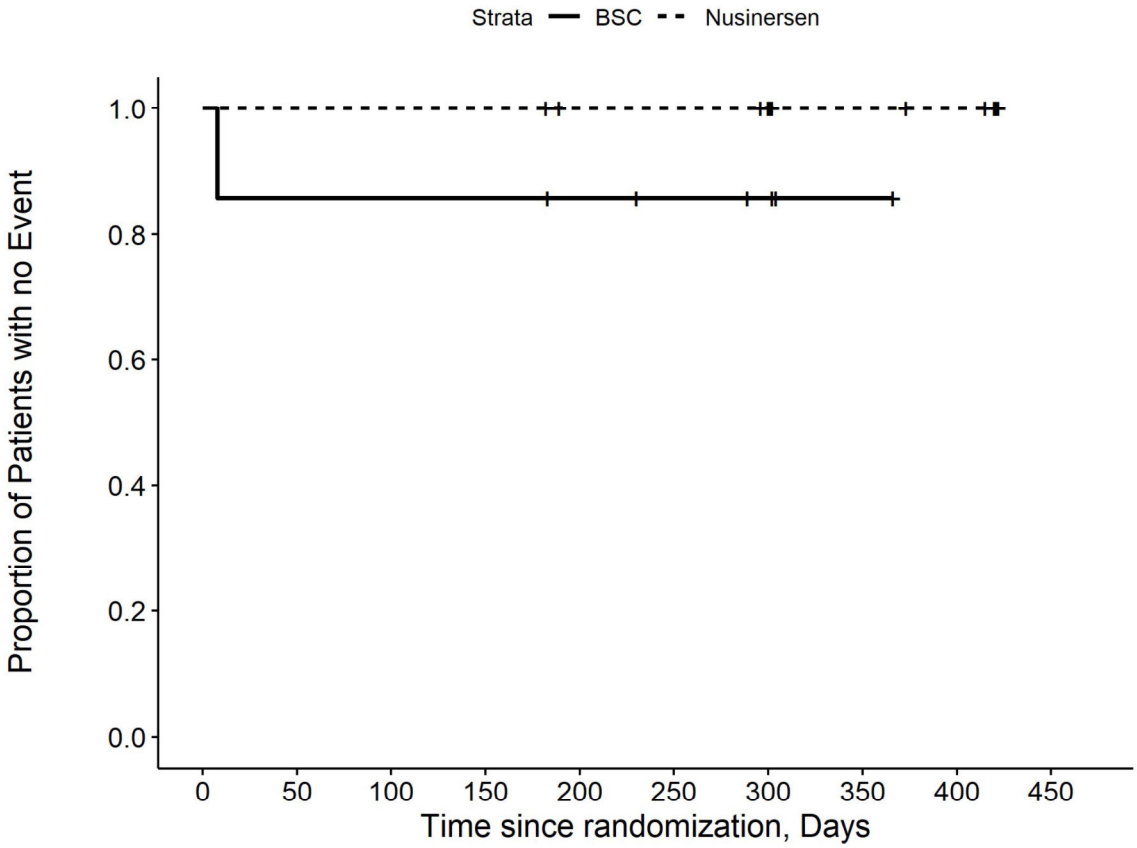
Kaplan Meier Plot for Time to mild AE by PT pct Erythema



Number at risk

BSC	7	5	5	5	4	3	3	1	0	0
Nusinersen	14	13	13	13	11	11	10	7	6	0

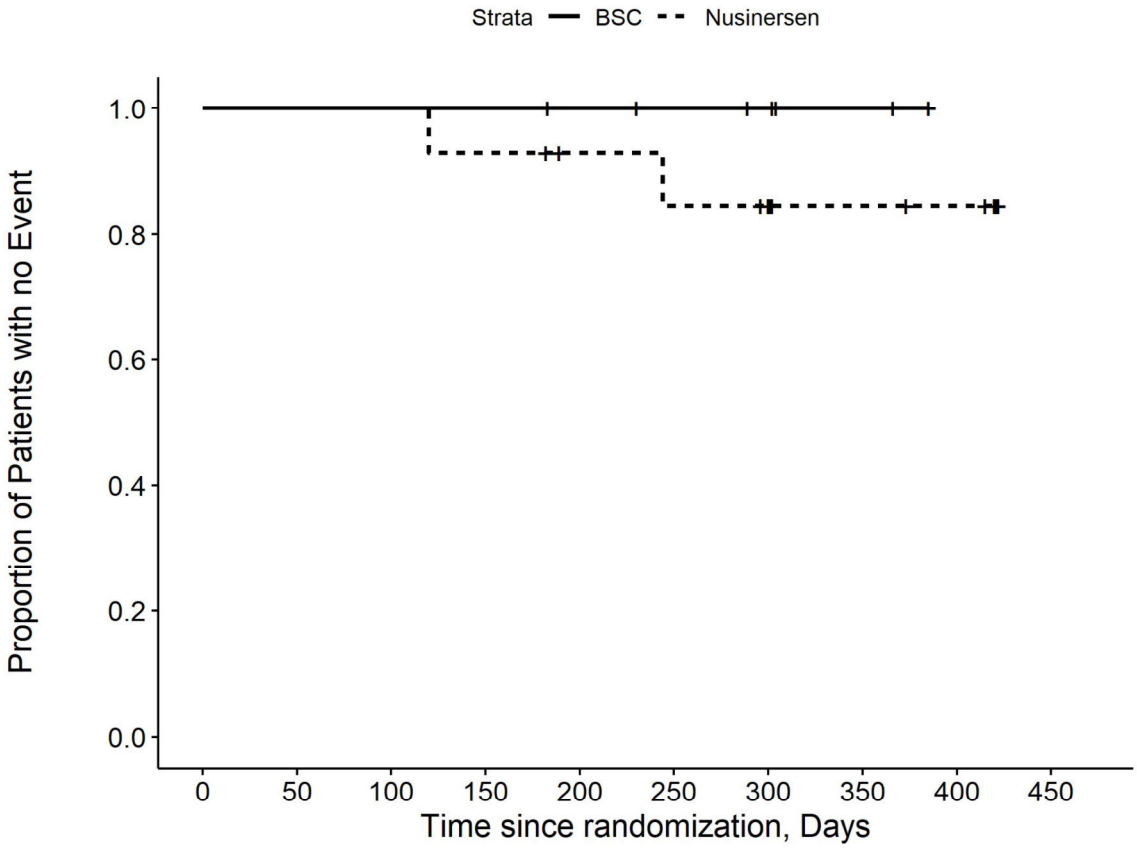
Kaplan Meier Plot for Time to mild AE by PT pct Flushing



Number at risk

BSC	7	6	6	6	5	4	3	1	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

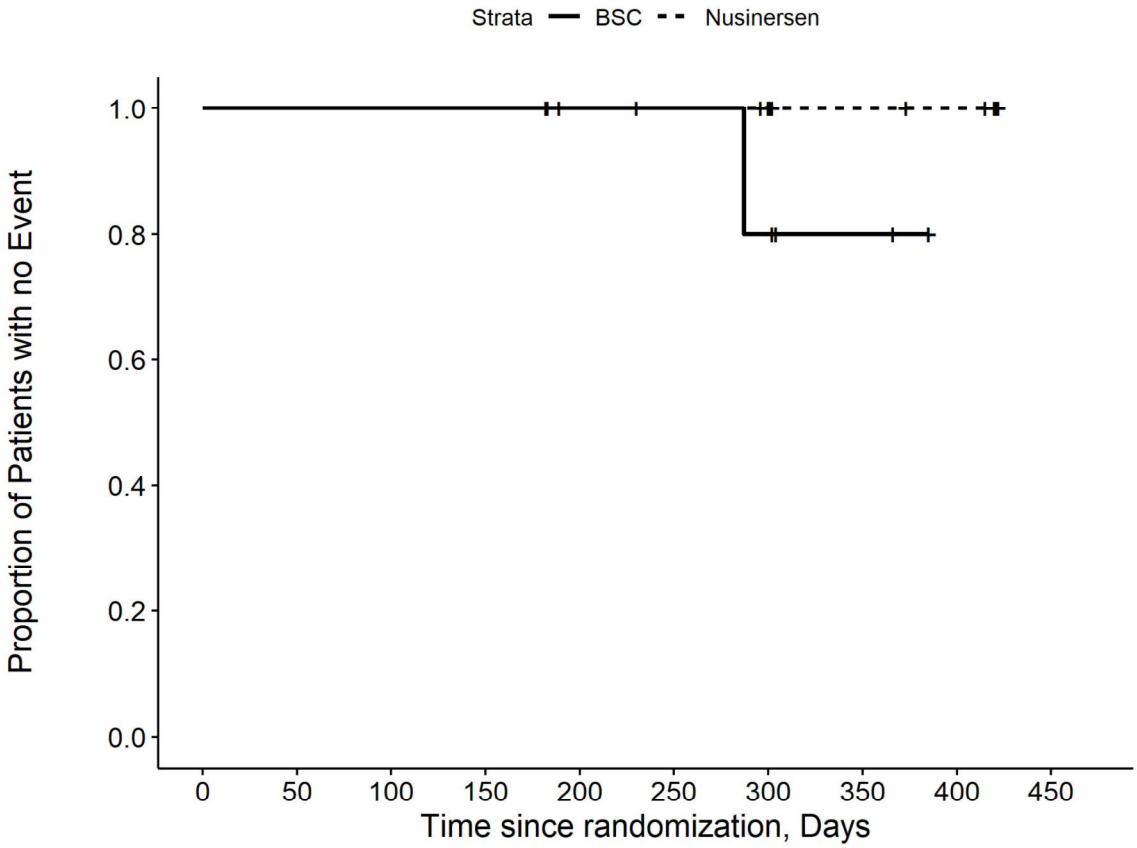
Kaplan Meier Plot for Time to mild AE by PT pct Gastroenteritis



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	11	10	9	6	5	0

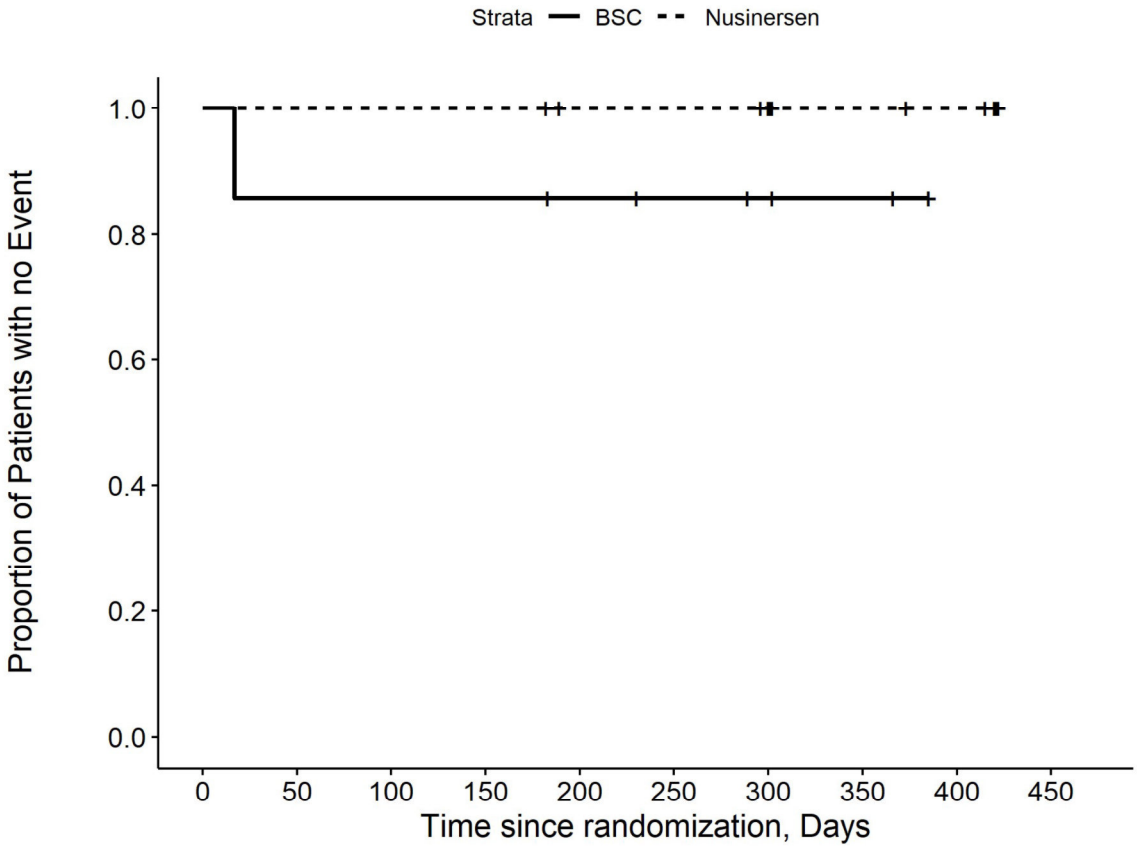
Kaplan Meier Plot for Time to mild AE by PT pct Hypertension



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

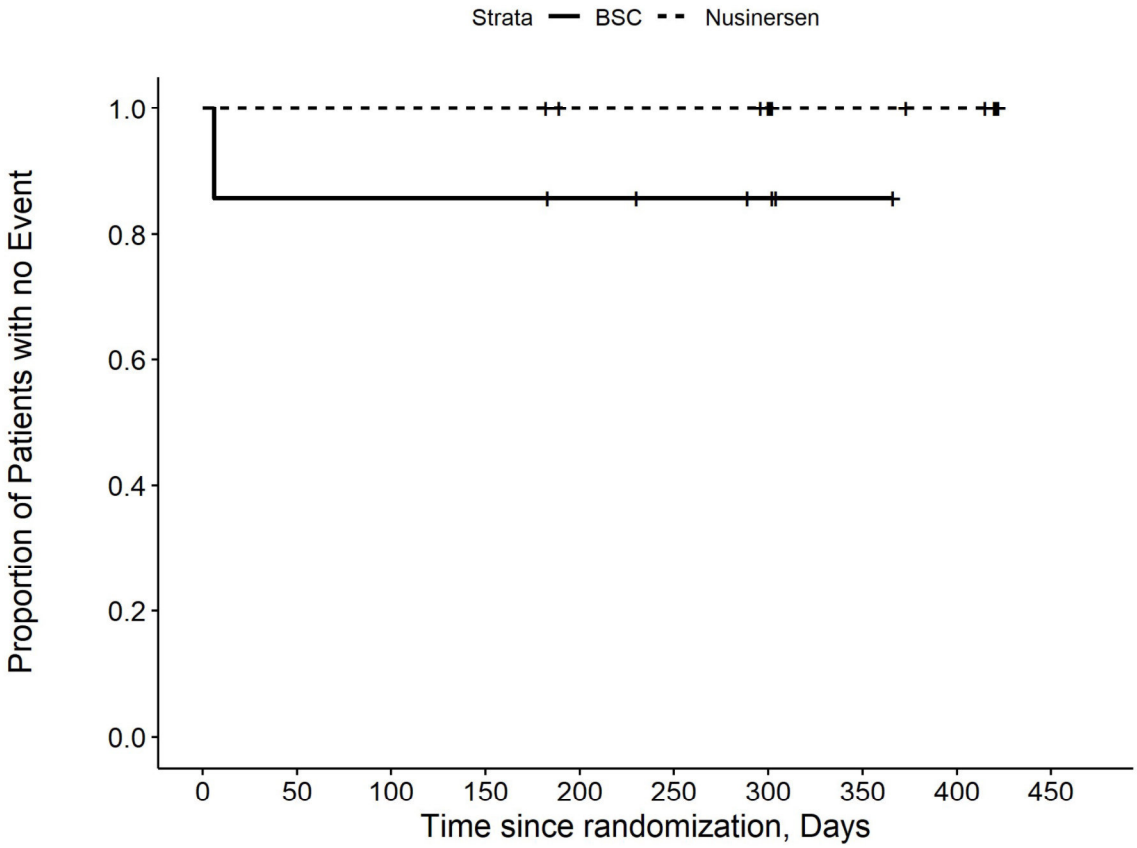
Kaplan Meier Plot for Time to mild AE by PT pct Hypokalaemia



Number at risk

BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

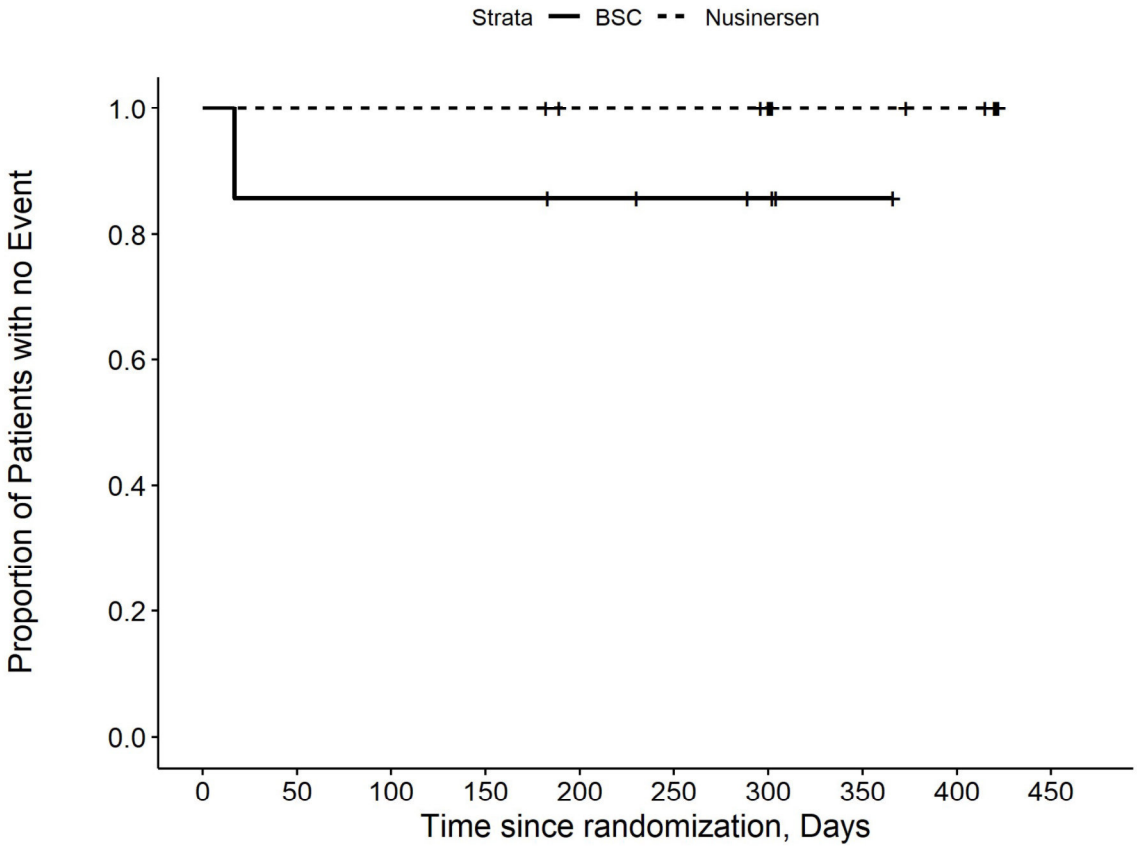
Kaplan Meier Plot for Time to mild AE by PT pct
Intermittent explosive disorder



Number at risk

BSC	7	6	6	6	5	4	3	1	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

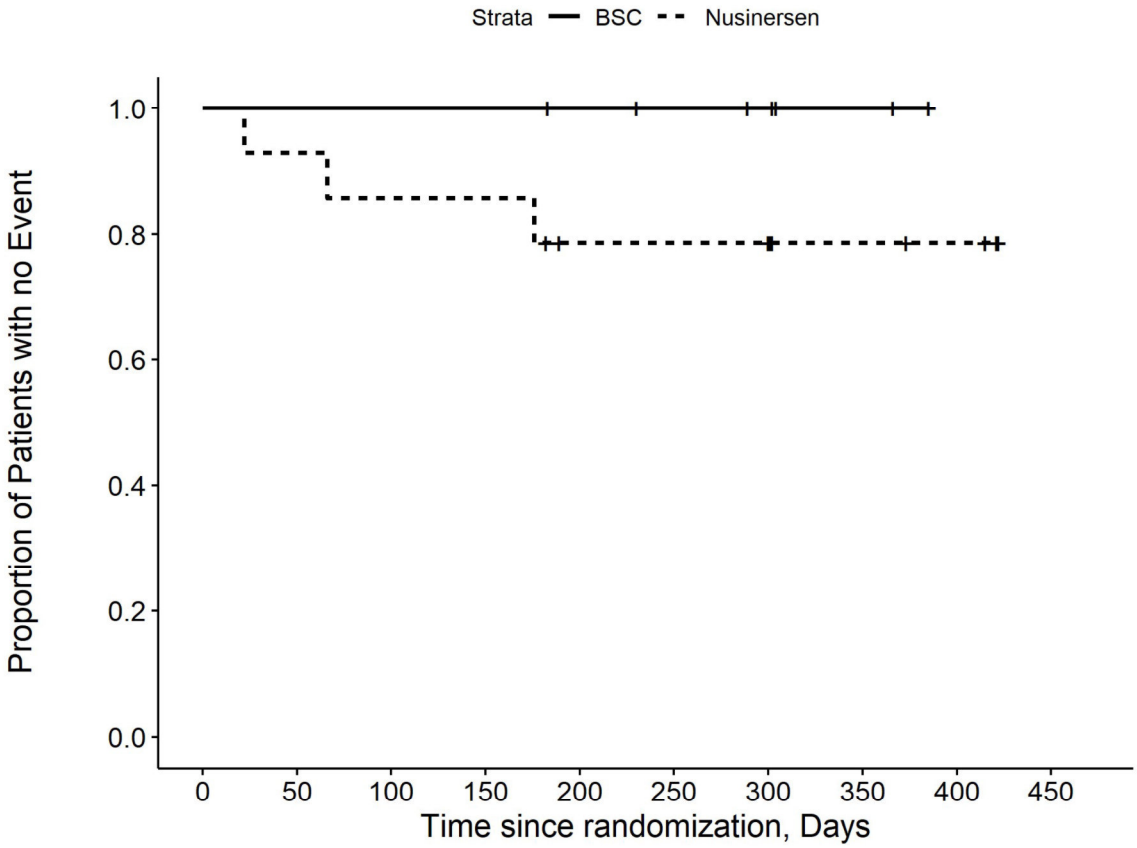
Kaplan Meier Plot for Time to mild AE by PT pct Irritability



Number at risk

BSC	7	6	6	6	5	4	3	1	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

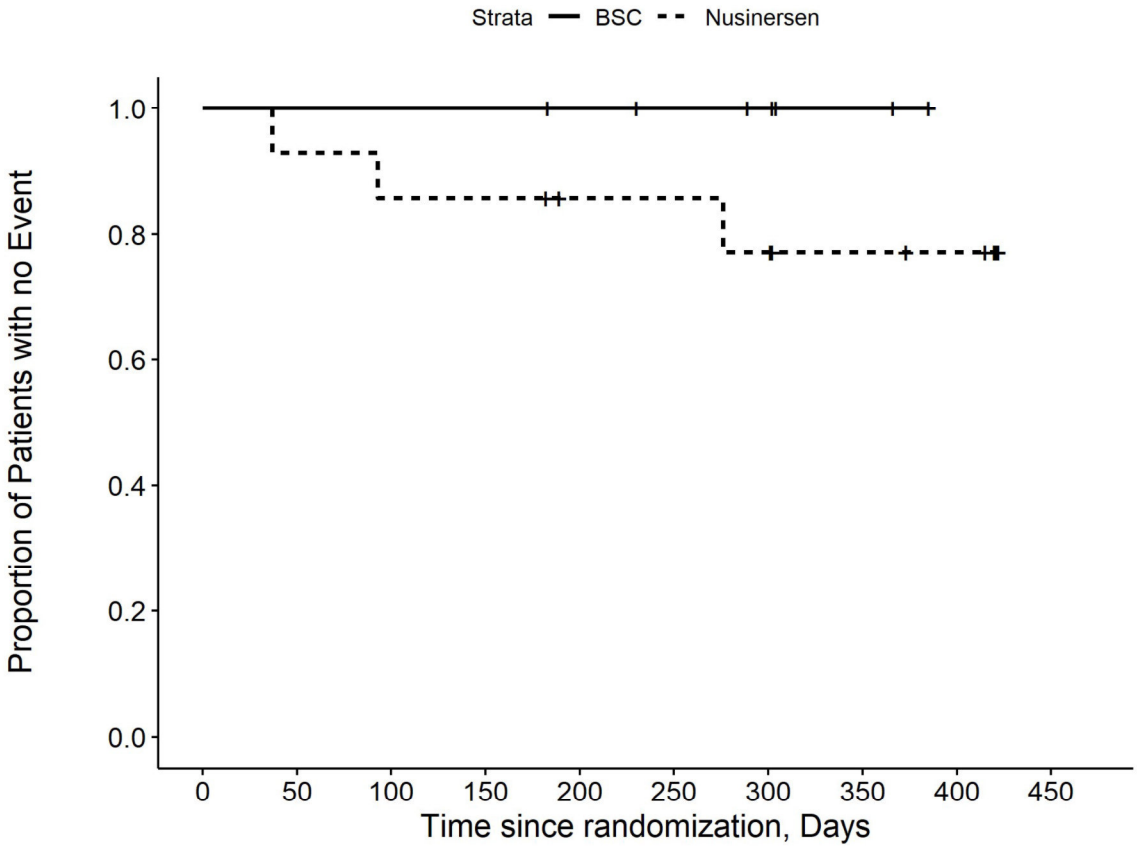
Kaplan Meier Plot for Time to mild AE by PT pct
Nasal congestion



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	12	12	9	9	9	5	4	0

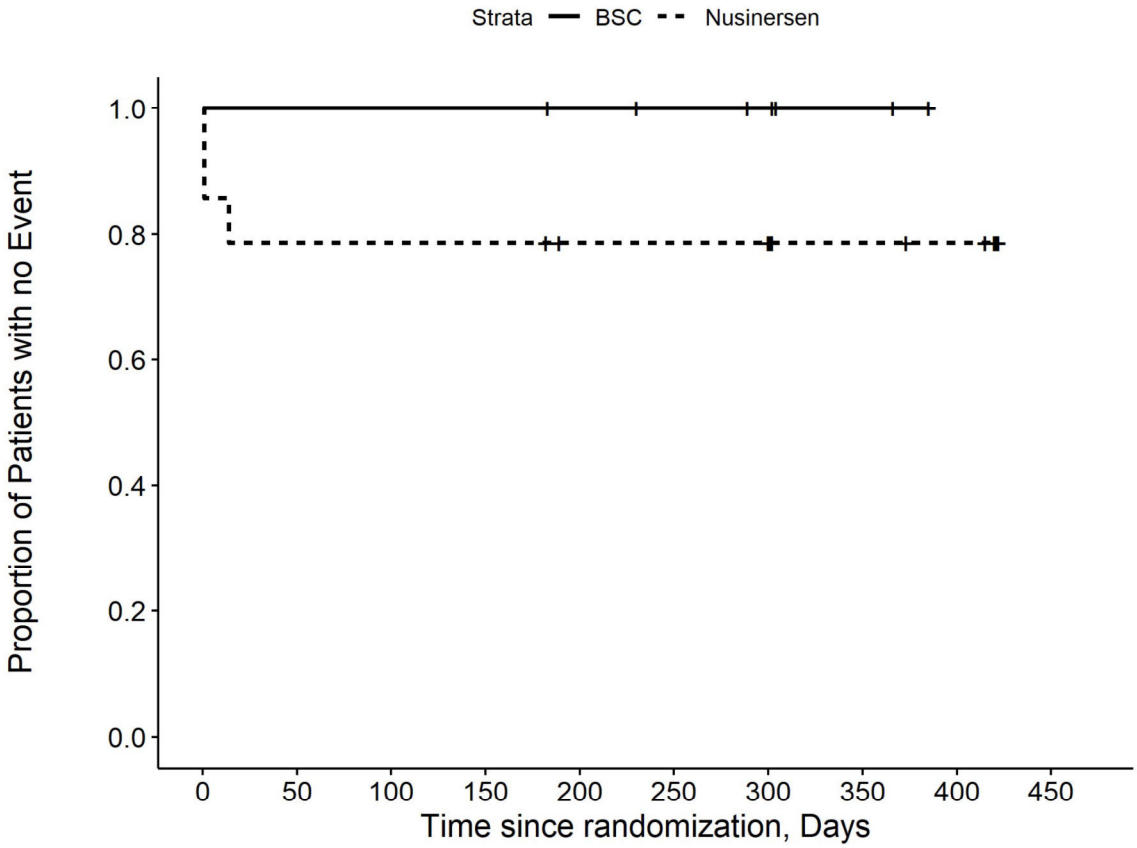
Kaplan Meier Plot for Time to mild AE by PT pct Pain in extremity



Number at risk

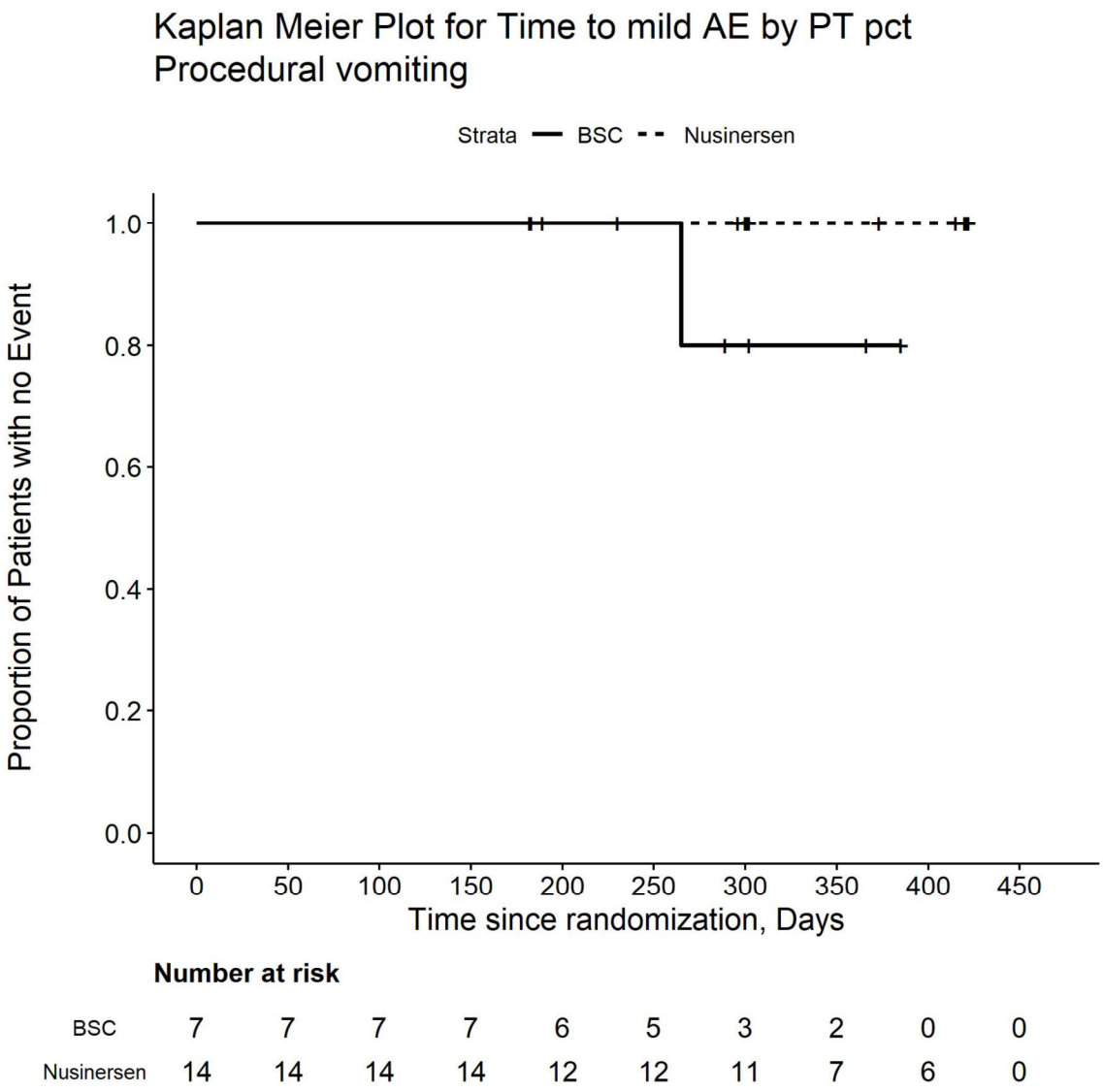
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	12	12	10	10	9	6	5	0

Kaplan Meier Plot for Time to mild AE by PT pct Procedural pain



Number at risk

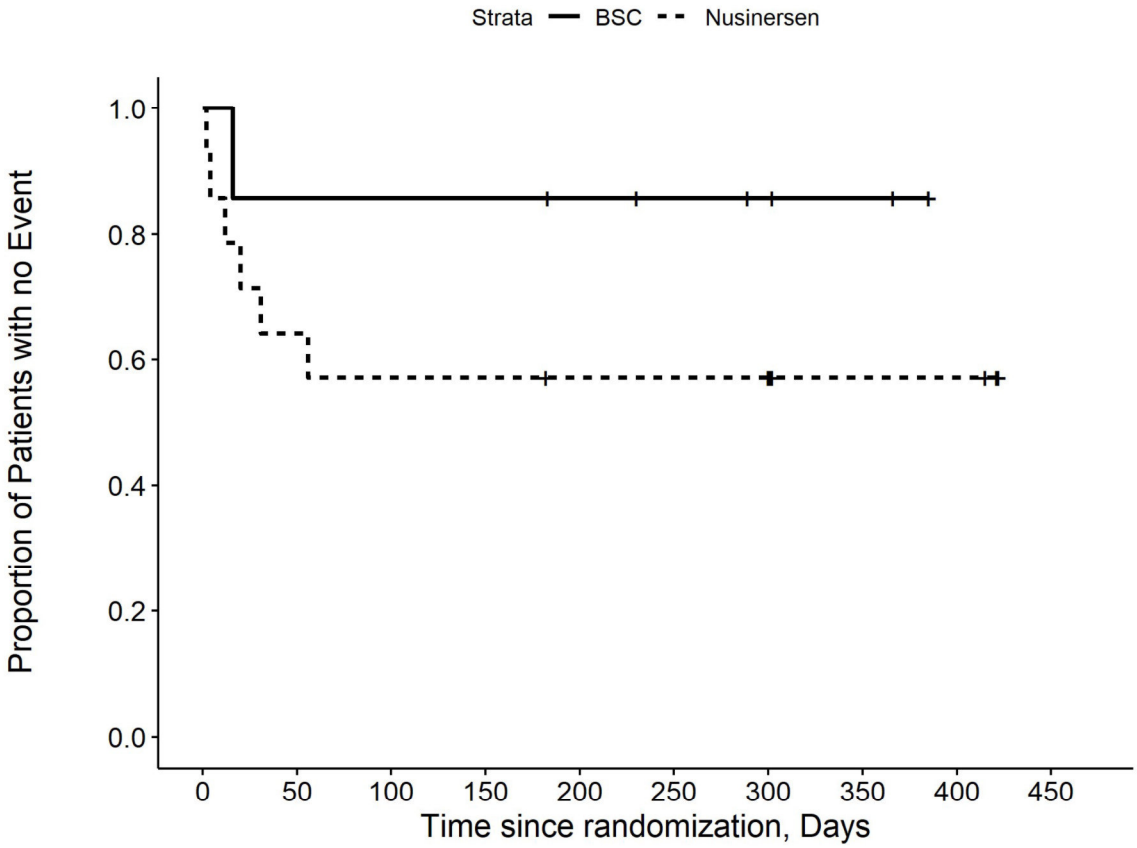
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	11	11	11	9	9	9	6	5	0



Number at risk

BSC	7	7	7	7	6	5	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

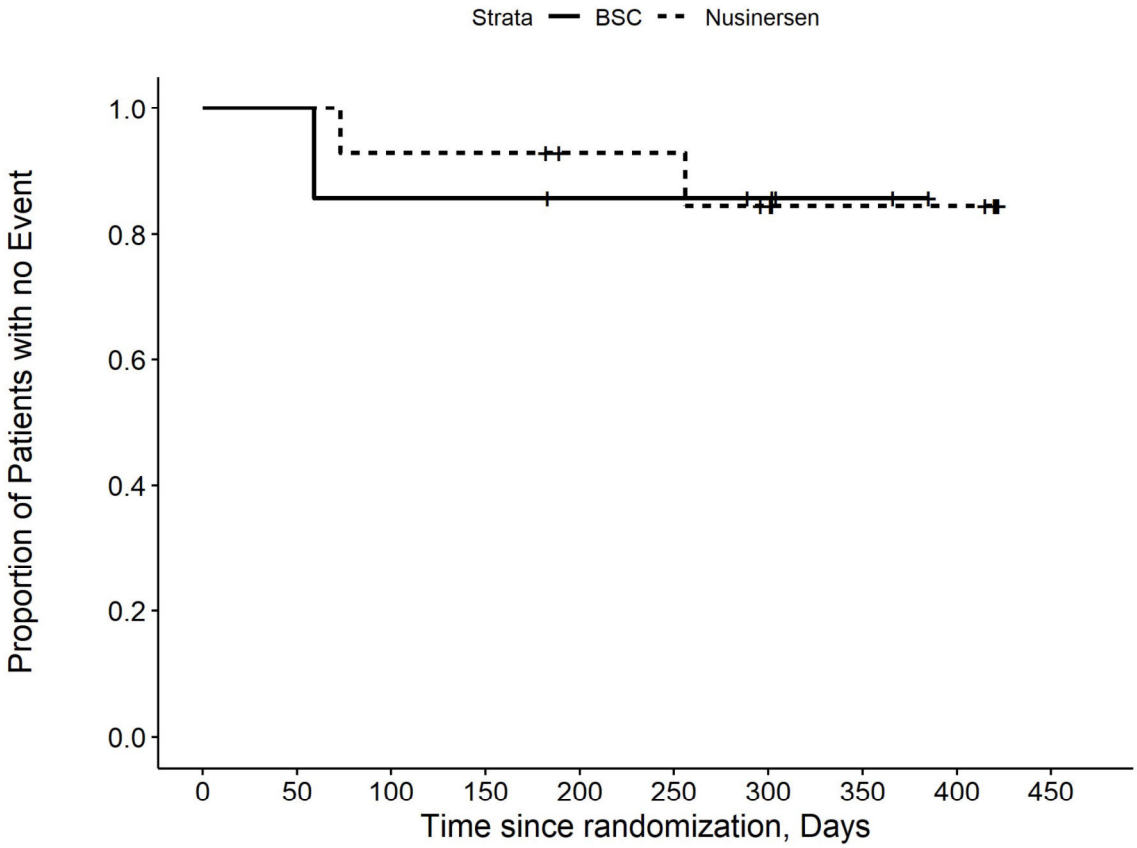
Kaplan Meier Plot for Time to mild AE by PT pct Pyrexia



Number at risk

BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	9	8	8	7	7	7	3	3	0

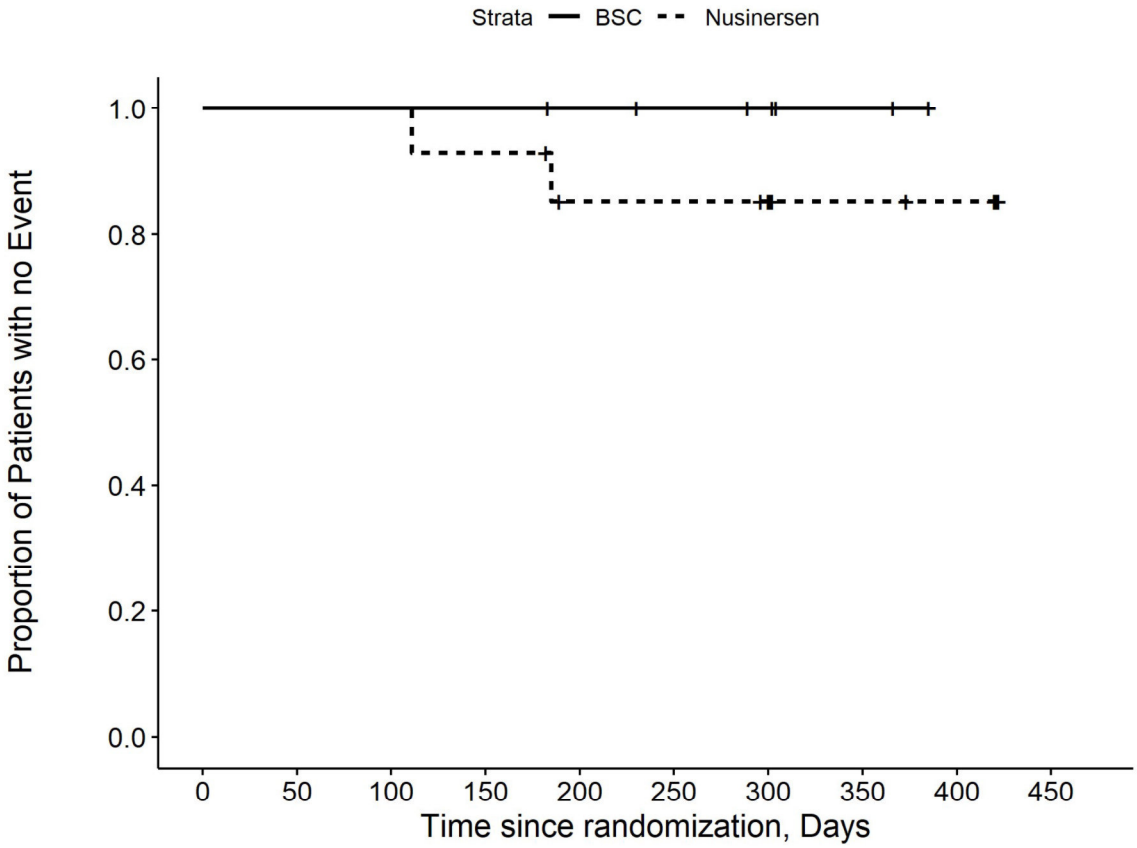
Kaplan Meier Plot for Time to mild AE by PT pct
Respiratory tract infection



Number at risk

BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	14	13	13	11	11	9	6	6	0

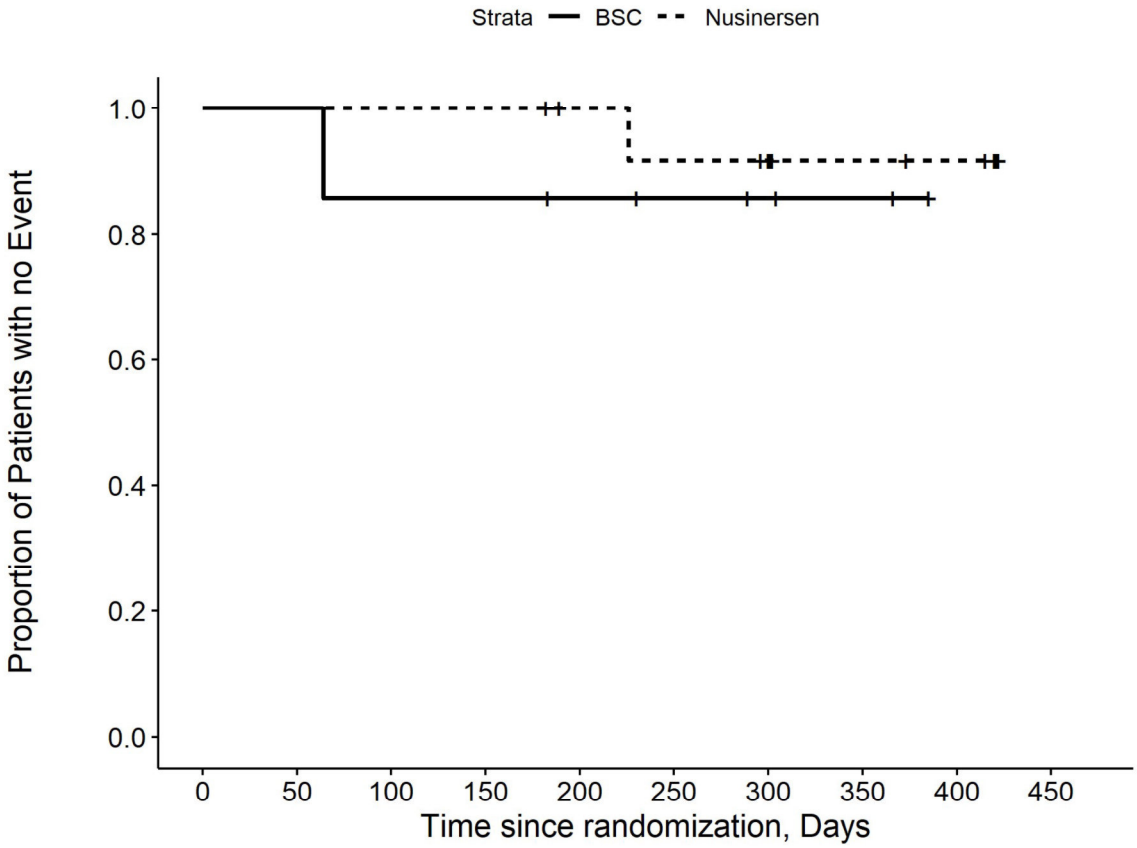
Kaplan Meier Plot for Time to mild AE by PT pct Rhinorrhoea



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	10	10	9	5	4	0

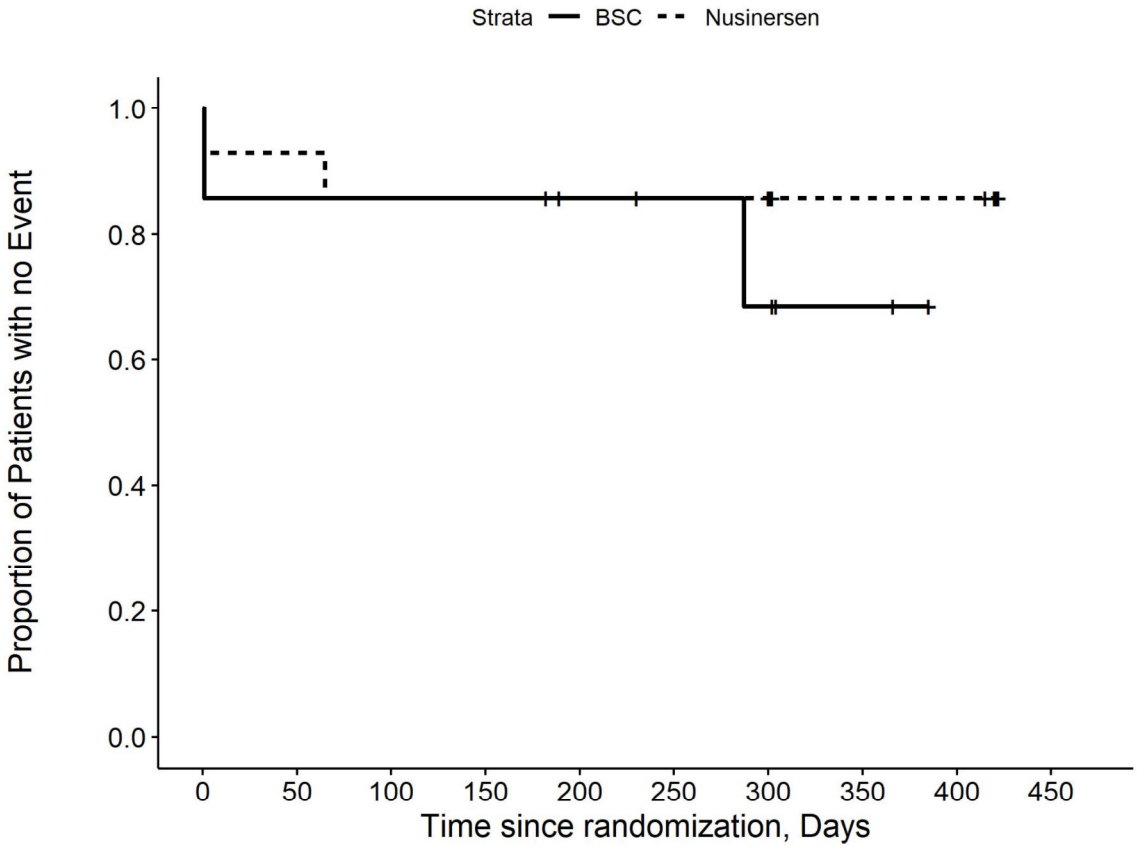
Kaplan Meier Plot for Time to mild AE by PT pct
Skin irritation



Number at risk

BSC	7	7	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	11	10	7	6	0

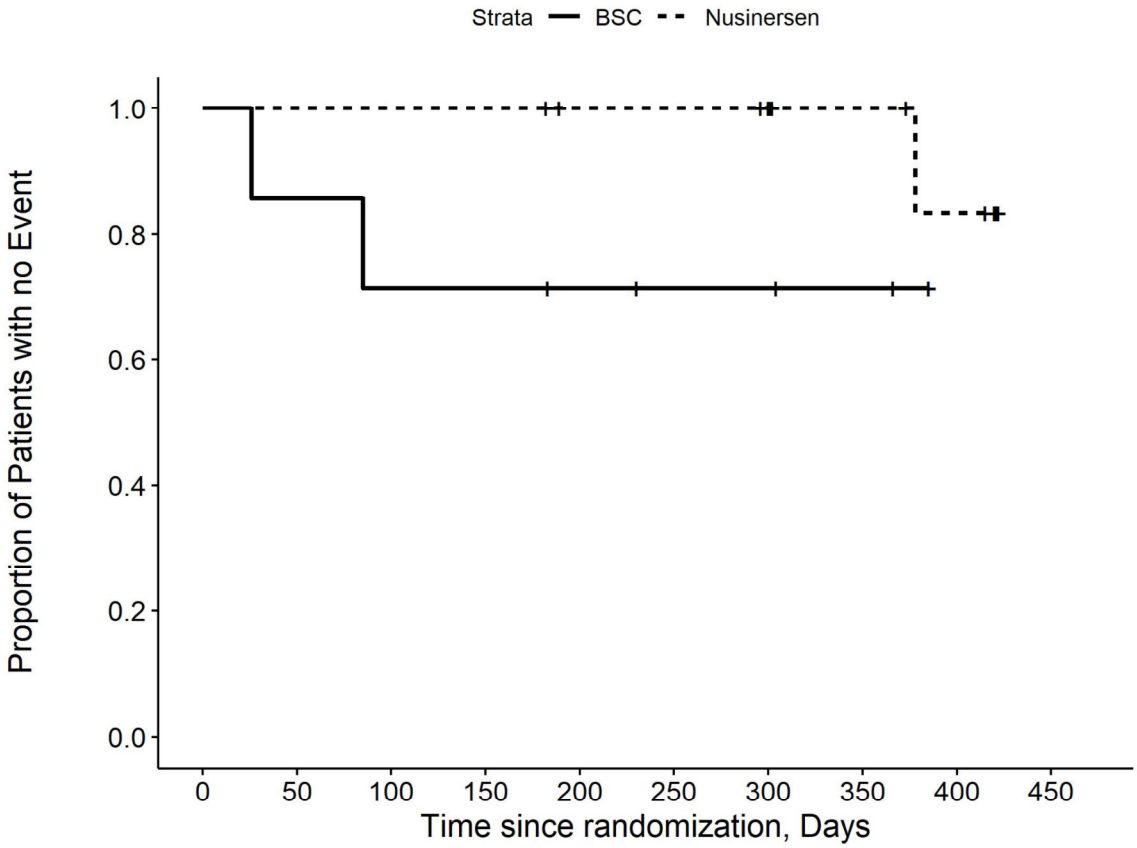
Kaplan Meier Plot for Time to mild AE by PT pct Tachycardia



Number at risk

BSC	7	6	6	6	6	5	4	2	0	0
Nusinersen	14	13	12	12	10	10	10	6	6	0

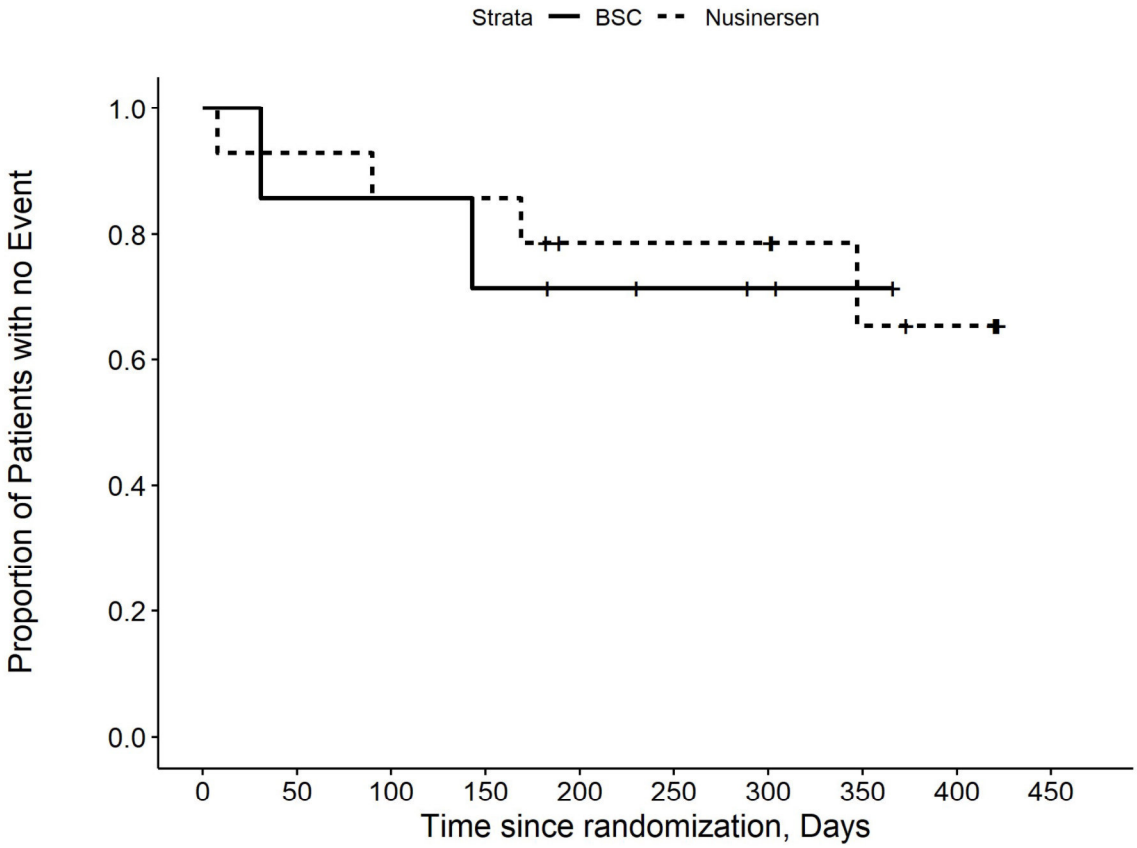
Kaplan Meier Plot for Time to mild AE by PT pct Teething



Number at risk

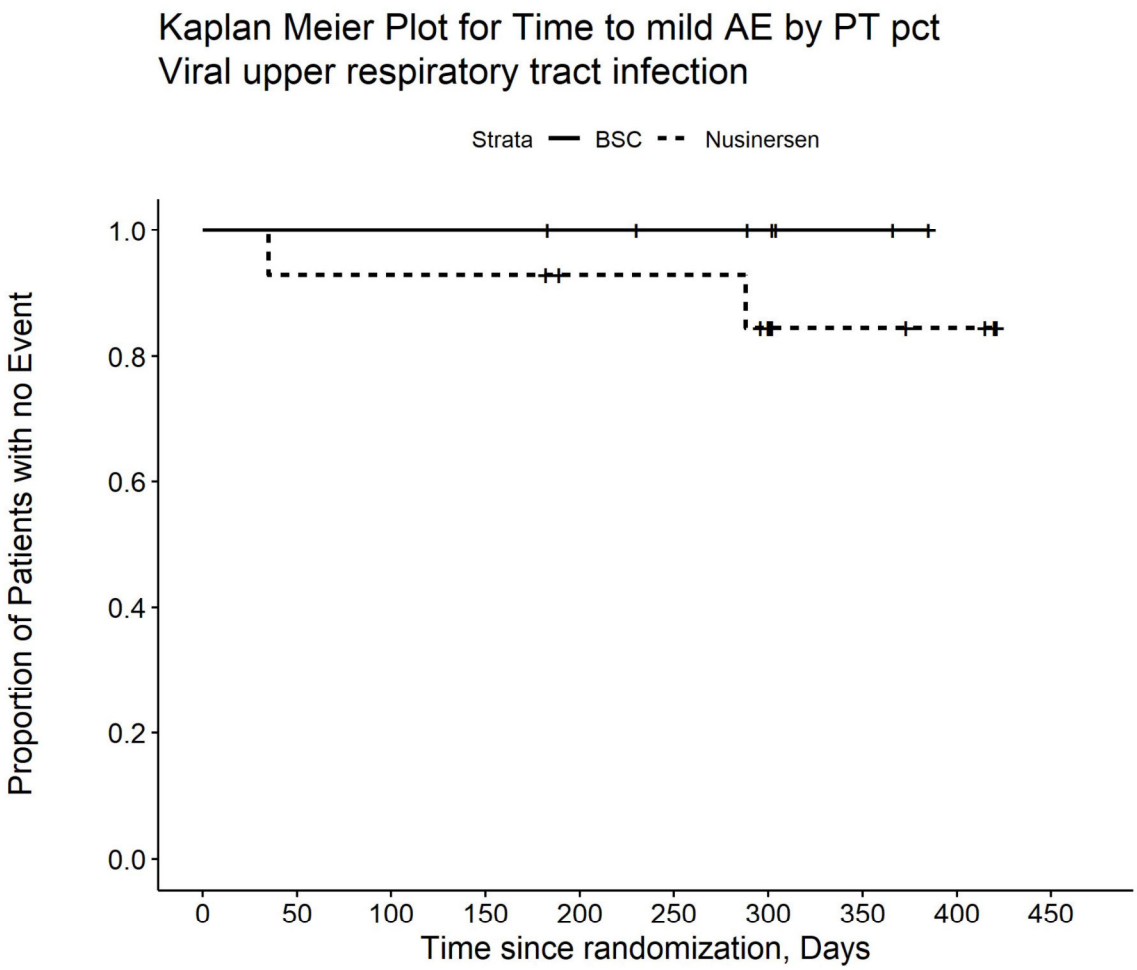
BSC	7	6	5	5	4	3	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	5	0

Kaplan Meier Plot for Time to mild AE by PT pct
Upper respiratory tract infection



Number at risk

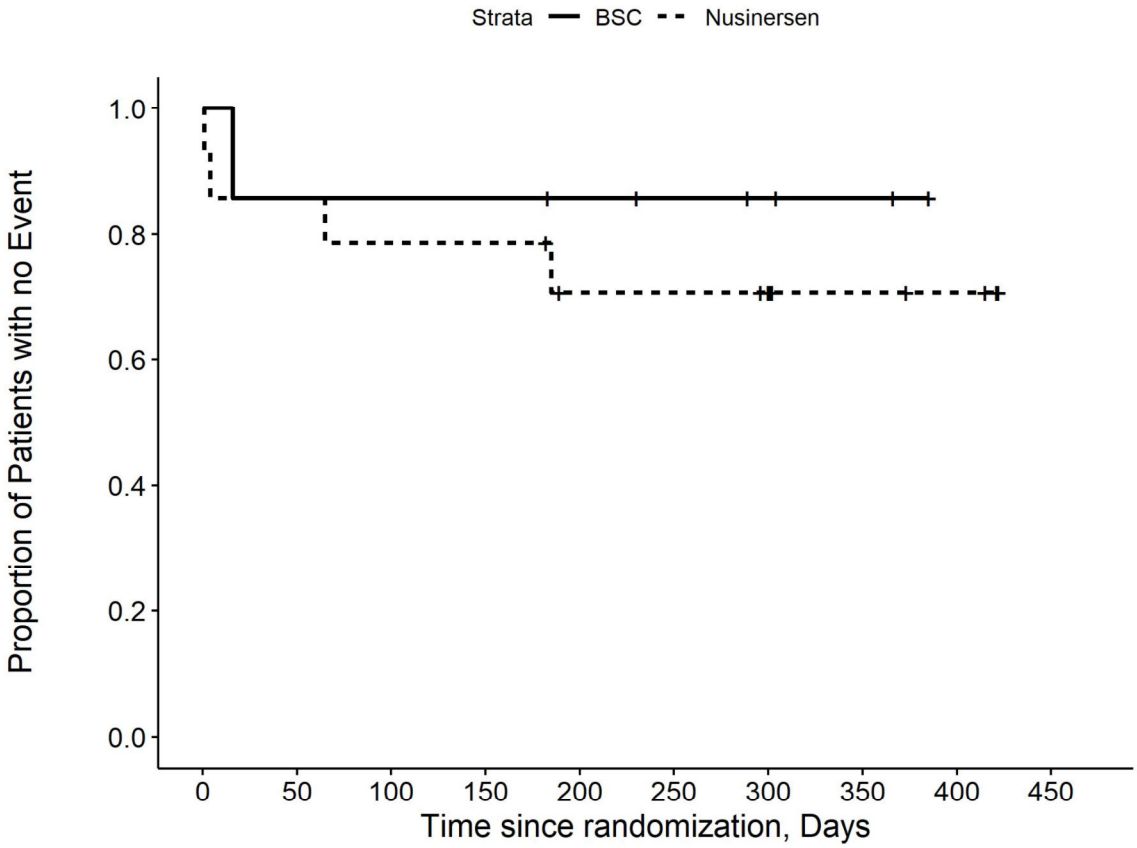
BSC	7	6	6	5	4	3	2	1	0	0
Nusinersen	14	13	12	12	9	9	9	5	4	0



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	13	13	11	11	9	5	4	0

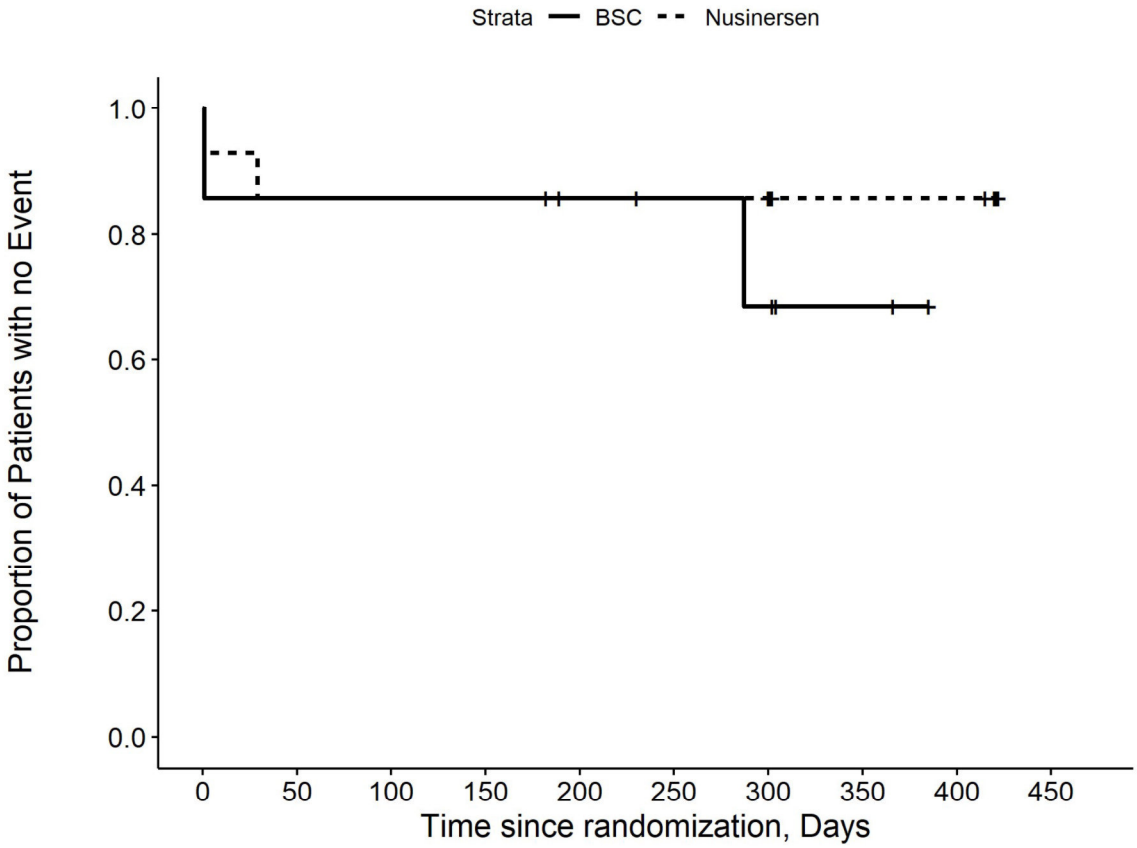
Kaplan Meier Plot for Time to mild AE by PT pct Vomiting



Number at risk

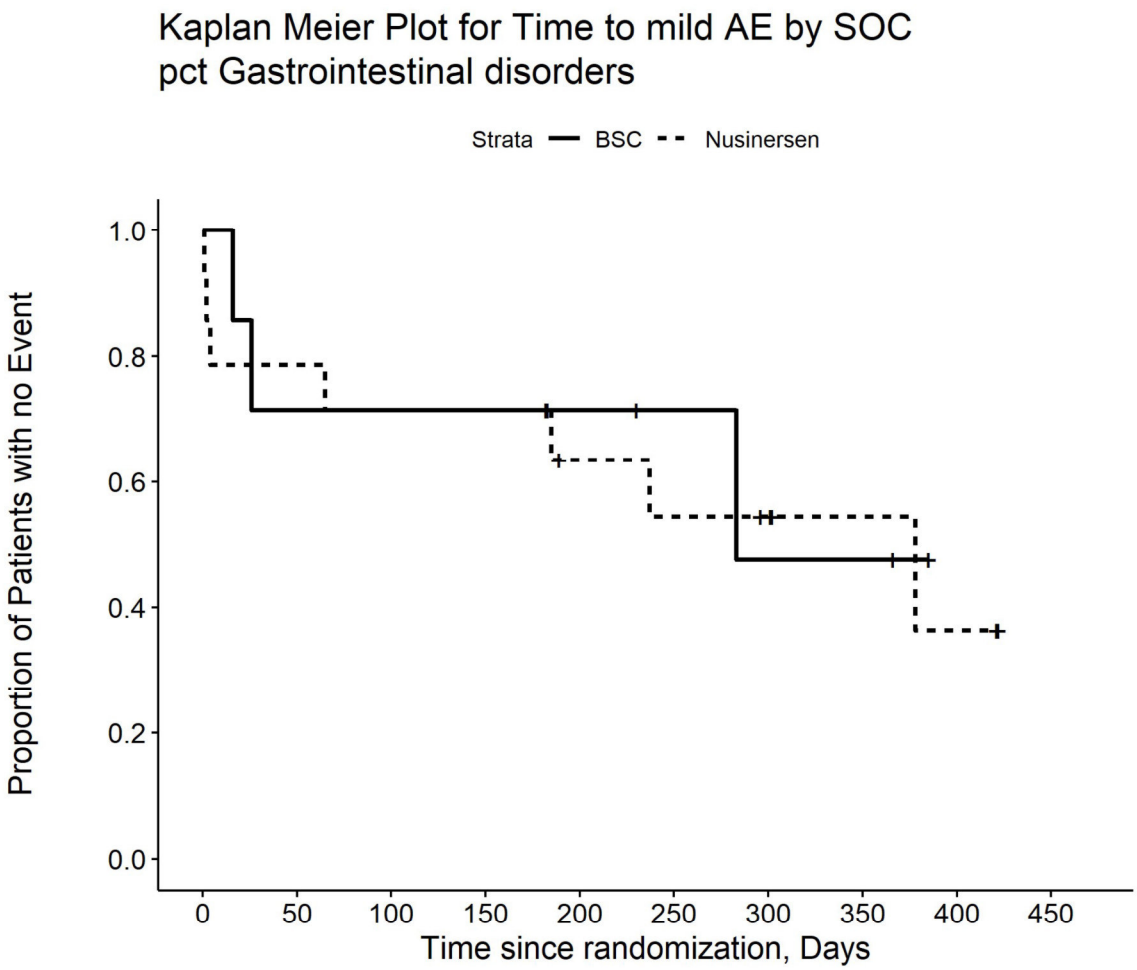
BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	12	11	11	8	8	7	4	3	0

Kaplan Meier Plot for Time to mild AE by SOC
pct Cardiac disorders



Number at risk

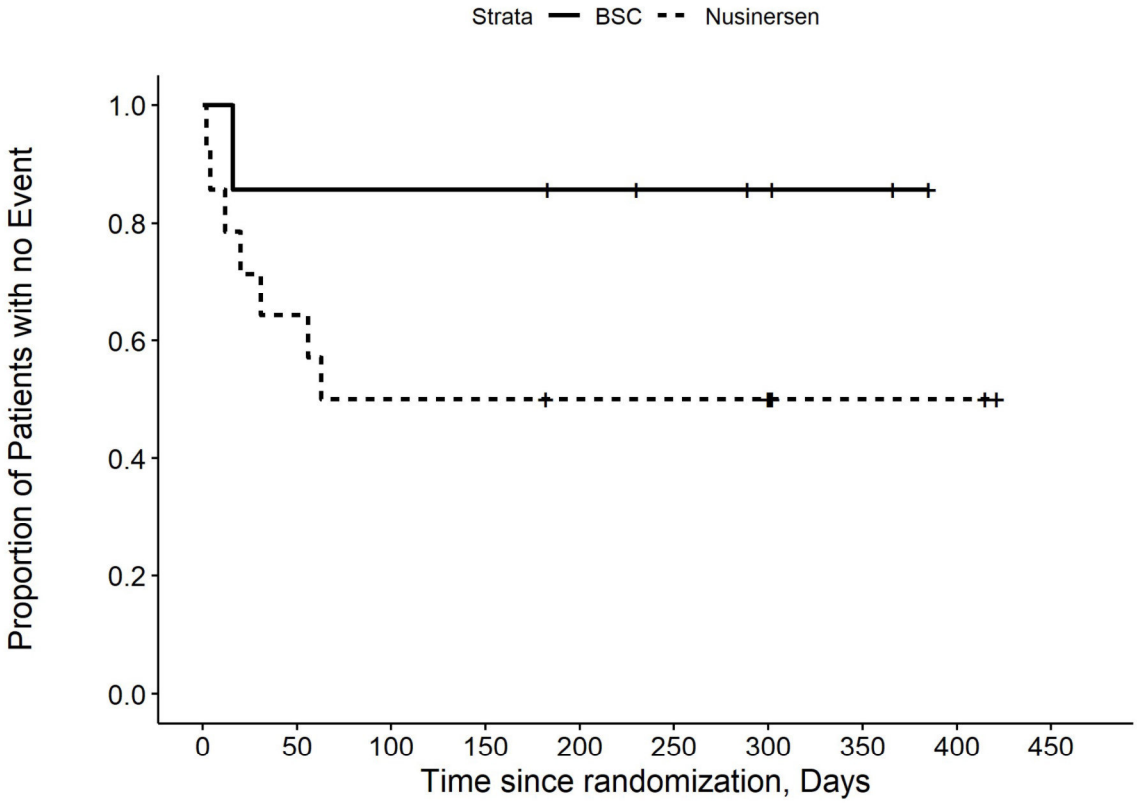
BSC	7	6	6	6	6	5	4	2	0	0
Nusinersen	14	12	12	12	10	10	10	6	6	0



Number at risk

BSC	7	5	5	5	4	3	2	2	0	0
Nusinersen	14	11	10	10	7	6	5	3	2	0

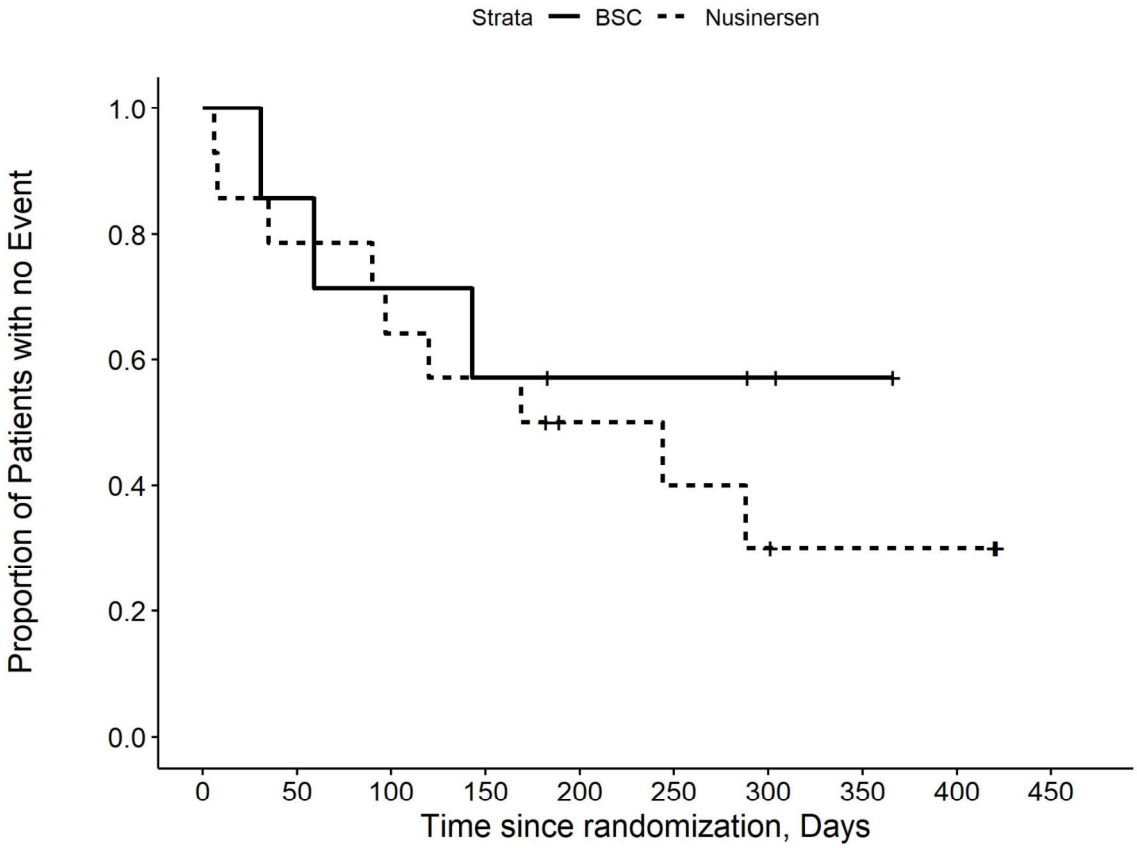
Kaplan Meier Plot for Time to mild AE by SOC pct General disorders and administration site conditions



Number at risk

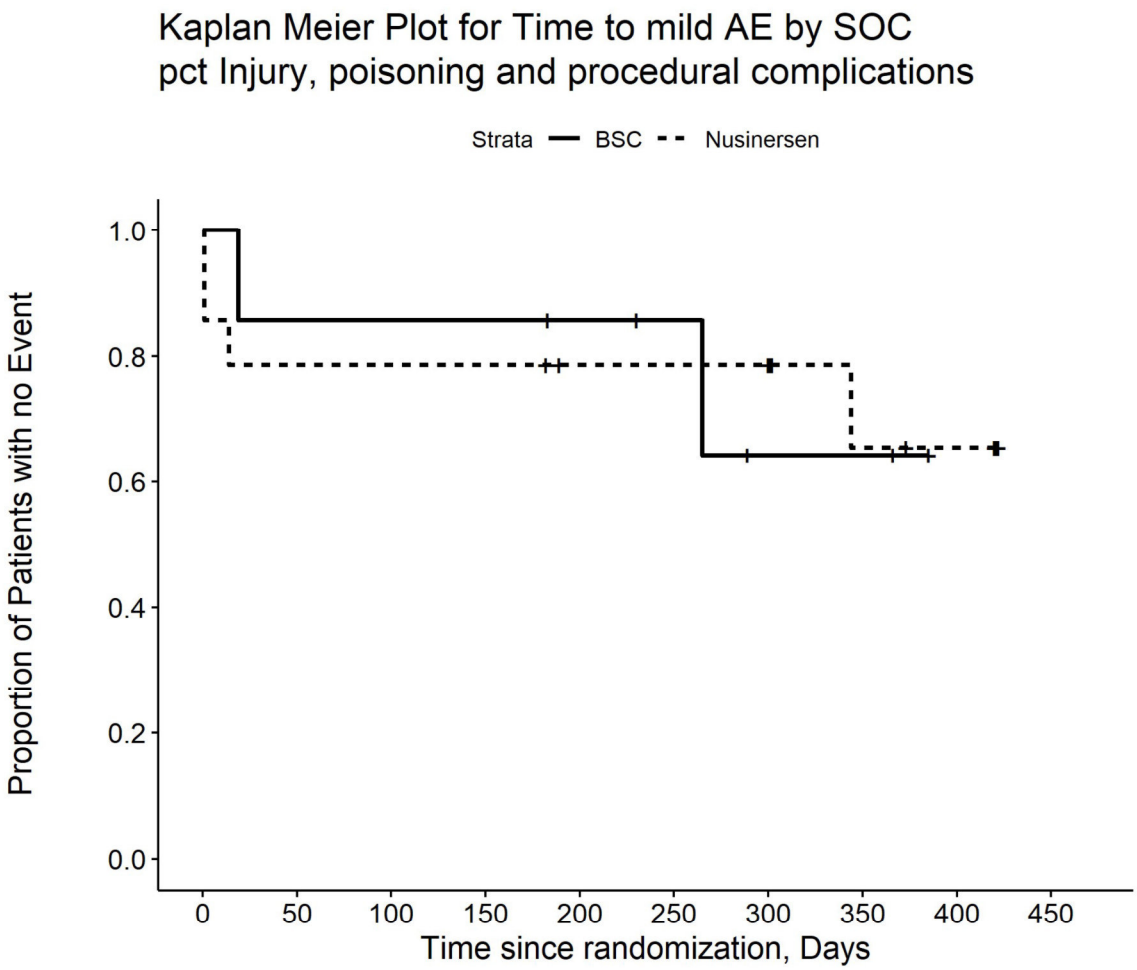
BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	9	7	7	6	6	6	2	2	0

Kaplan Meier Plot for Time to mild AE by SOC
pct Infections and infestations



Number at risk

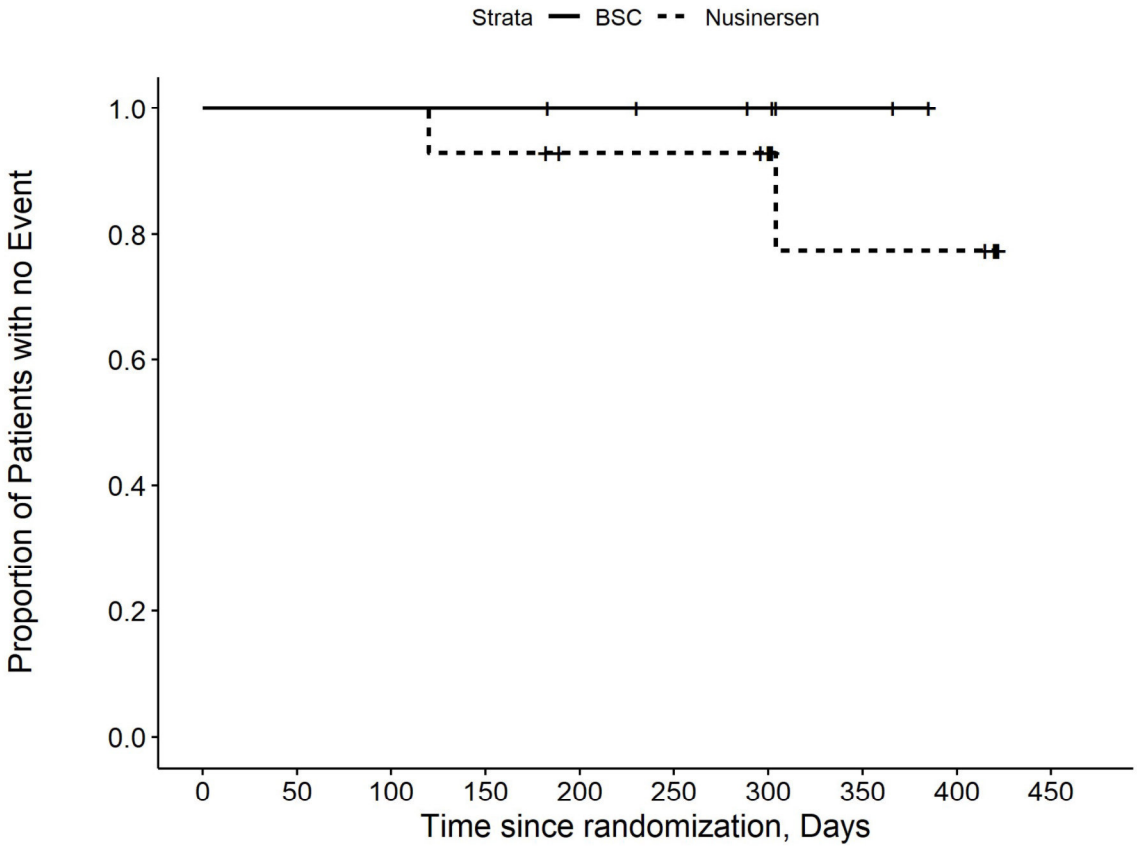
BSC	7	6	5	4	3	3	2	1	0	0
Nusinersen	14	11	9	8	5	4	3	2	2	0



Number at risk

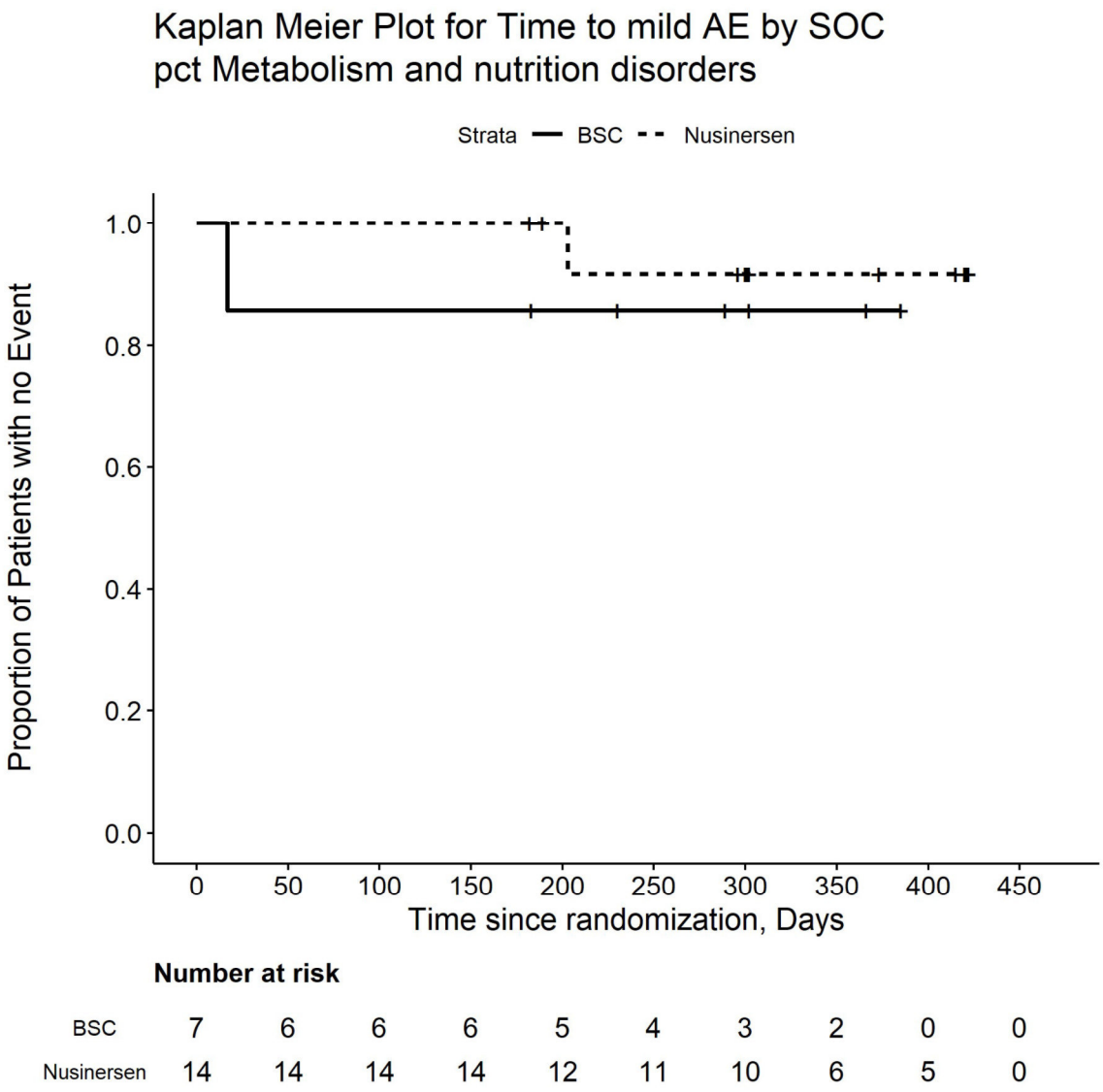
BSC	7	6	6	6	5	4	2	2	0	0
Nusinersen	14	11	11	11	9	9	9	5	4	0

Kaplan Meier Plot for Time to mild AE by SOC
pct Investigations



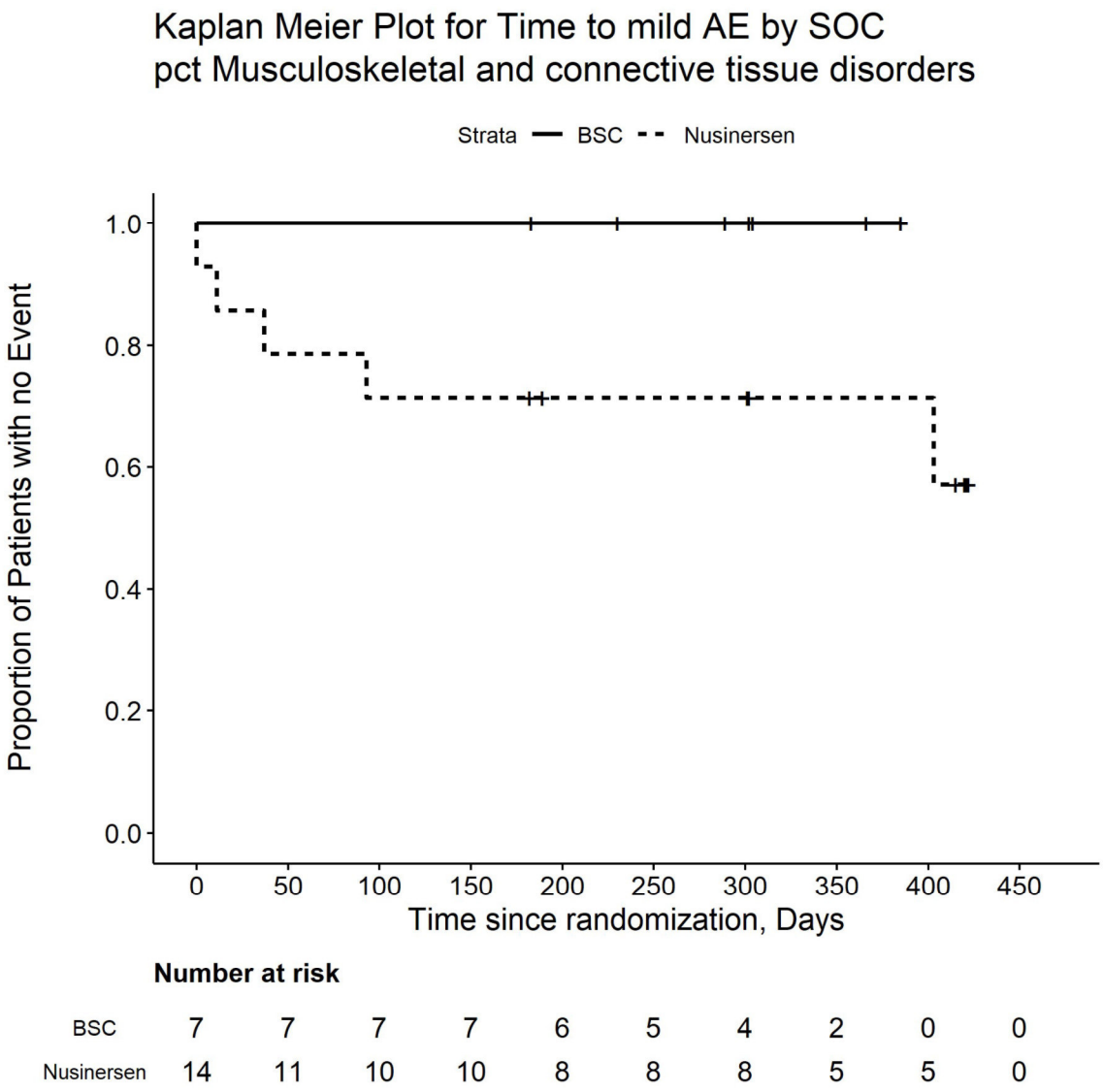
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	11	11	10	5	5	0



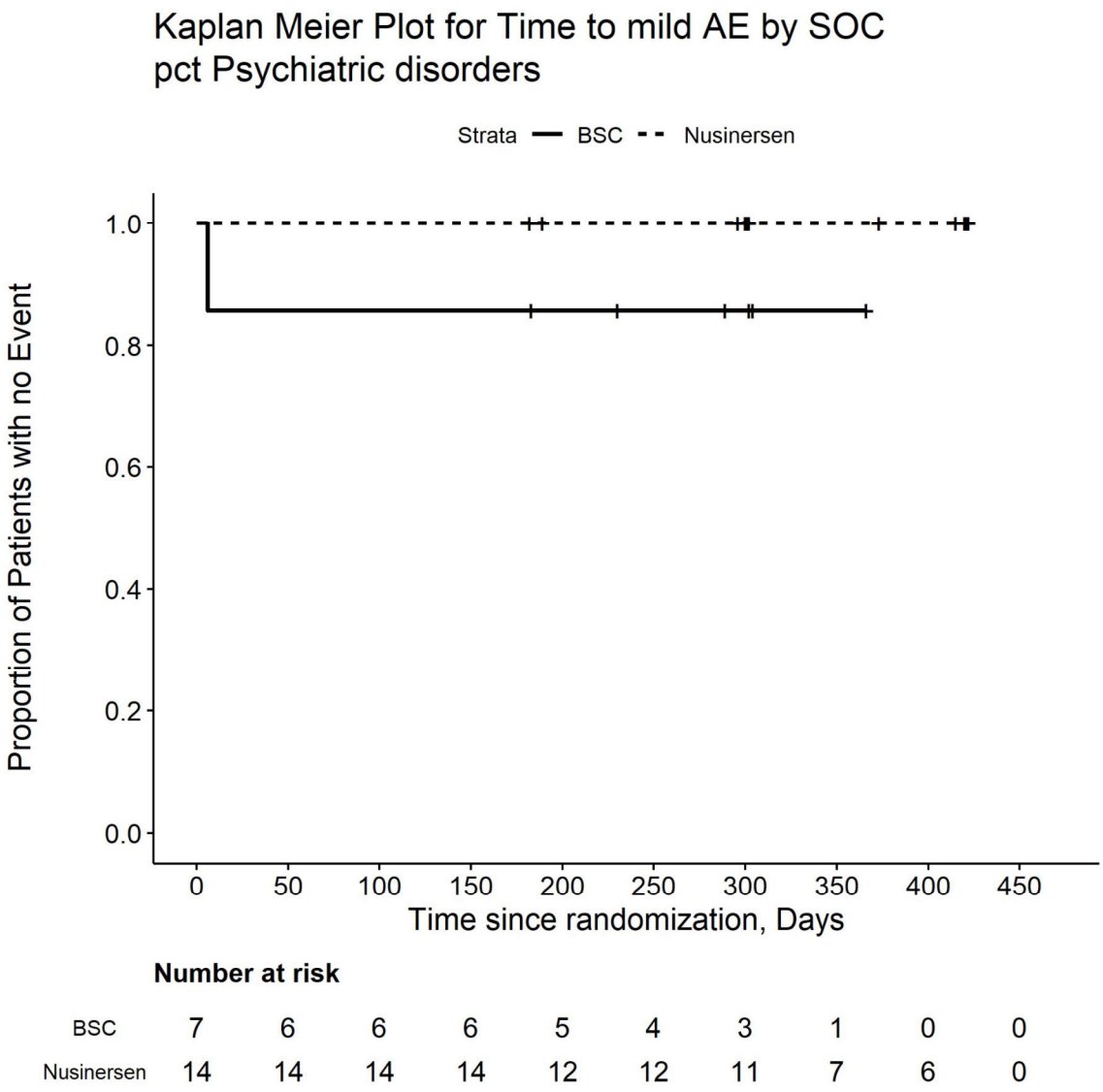
Number at risk

BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	11	10	6	5	0



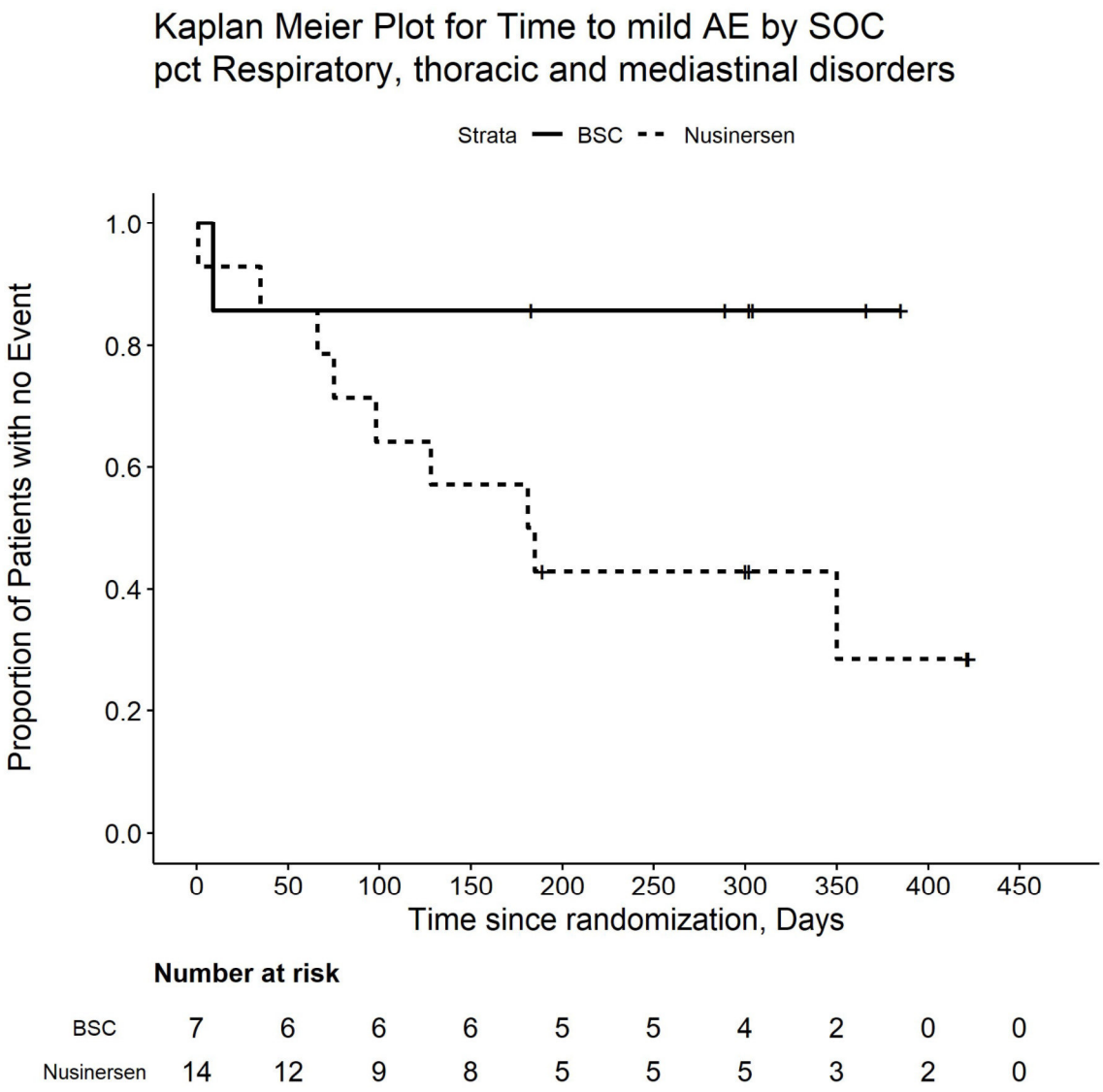
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	11	10	10	8	8	8	5	5	0



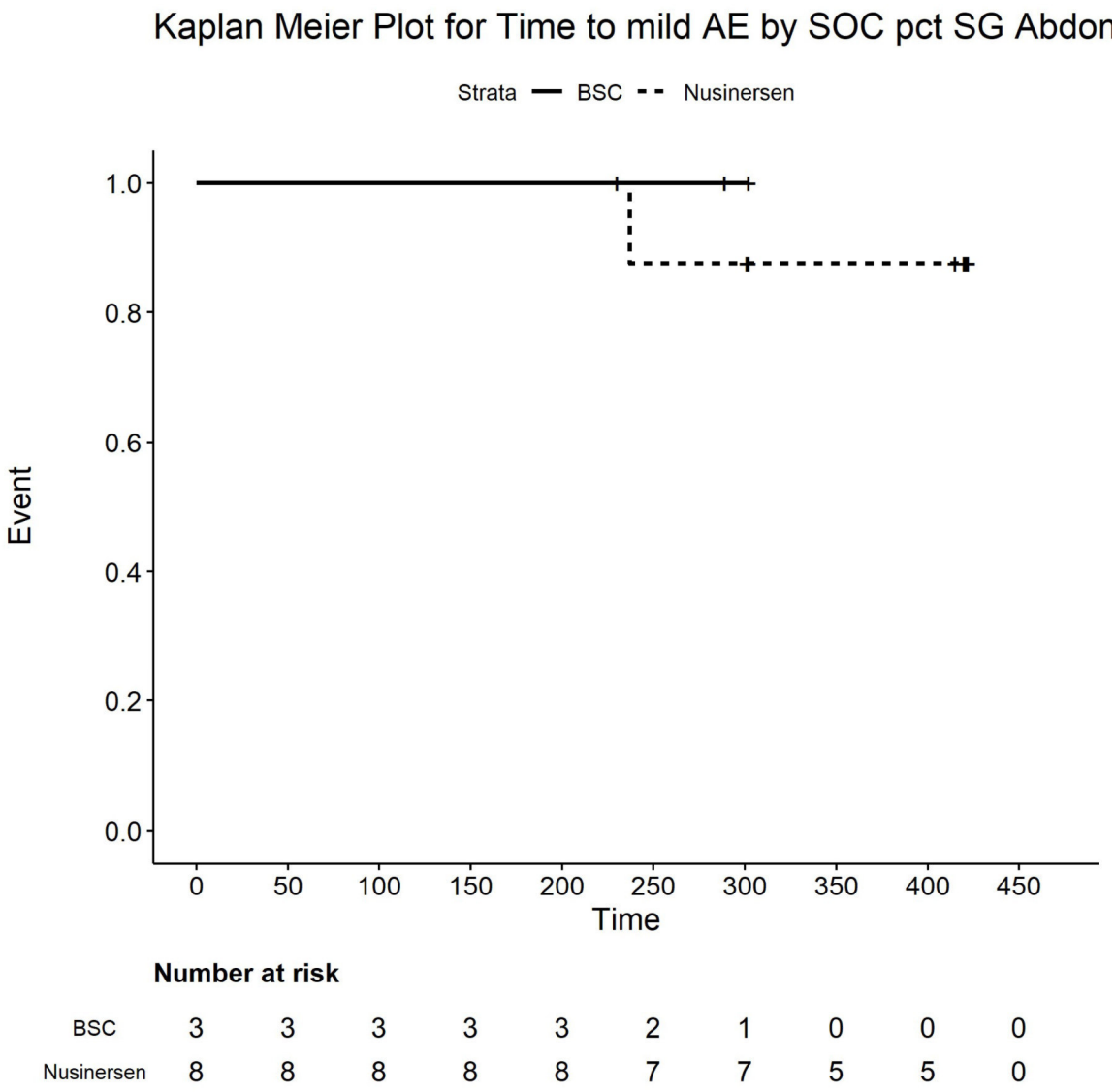
Number at risk

BSC	7	6	6	6	5	4	3	1	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



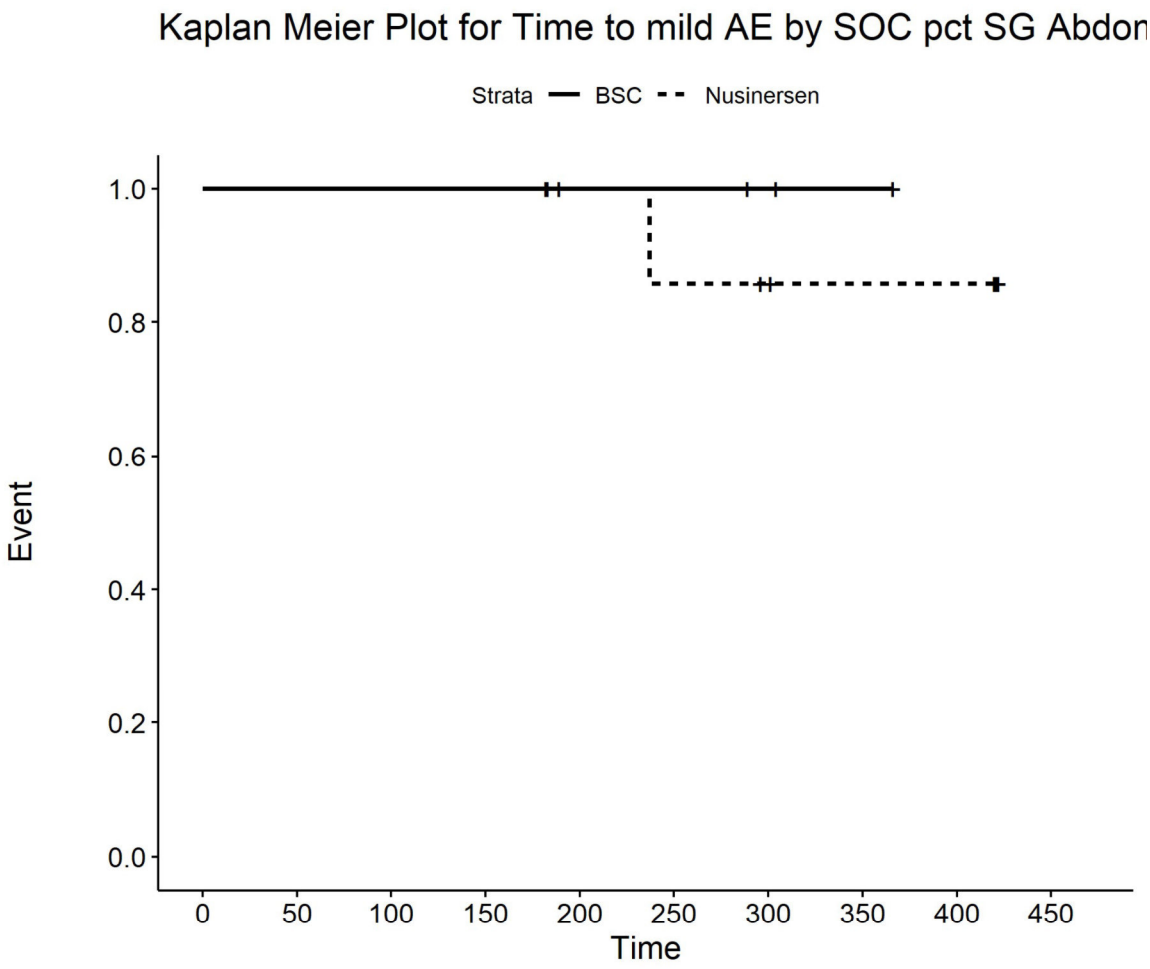
Number at risk

BSC	7	6	6	6	5	5	4	2	0	0
Nusinersen	14	12	9	8	5	5	5	3	2	0



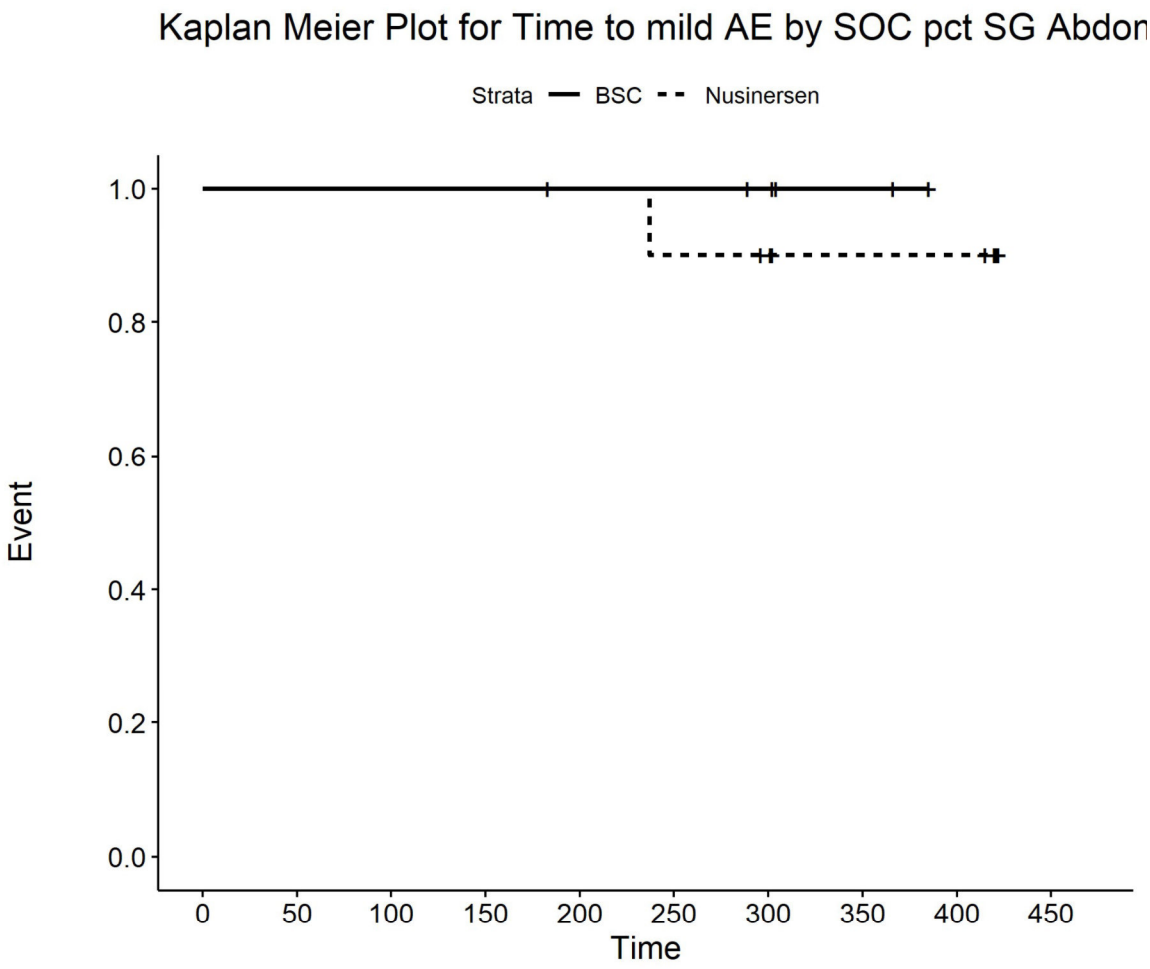
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	5	0



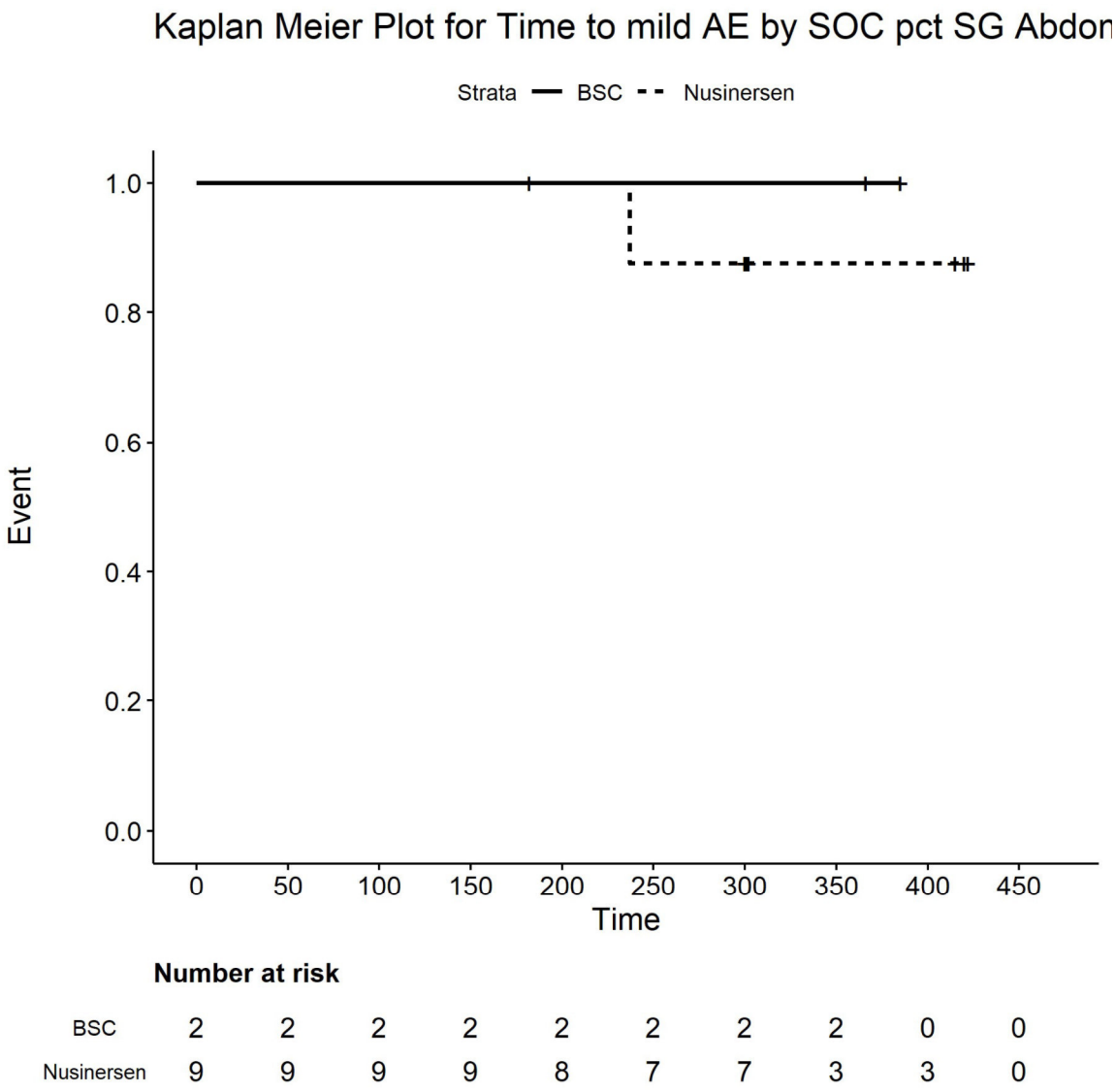
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	4	0



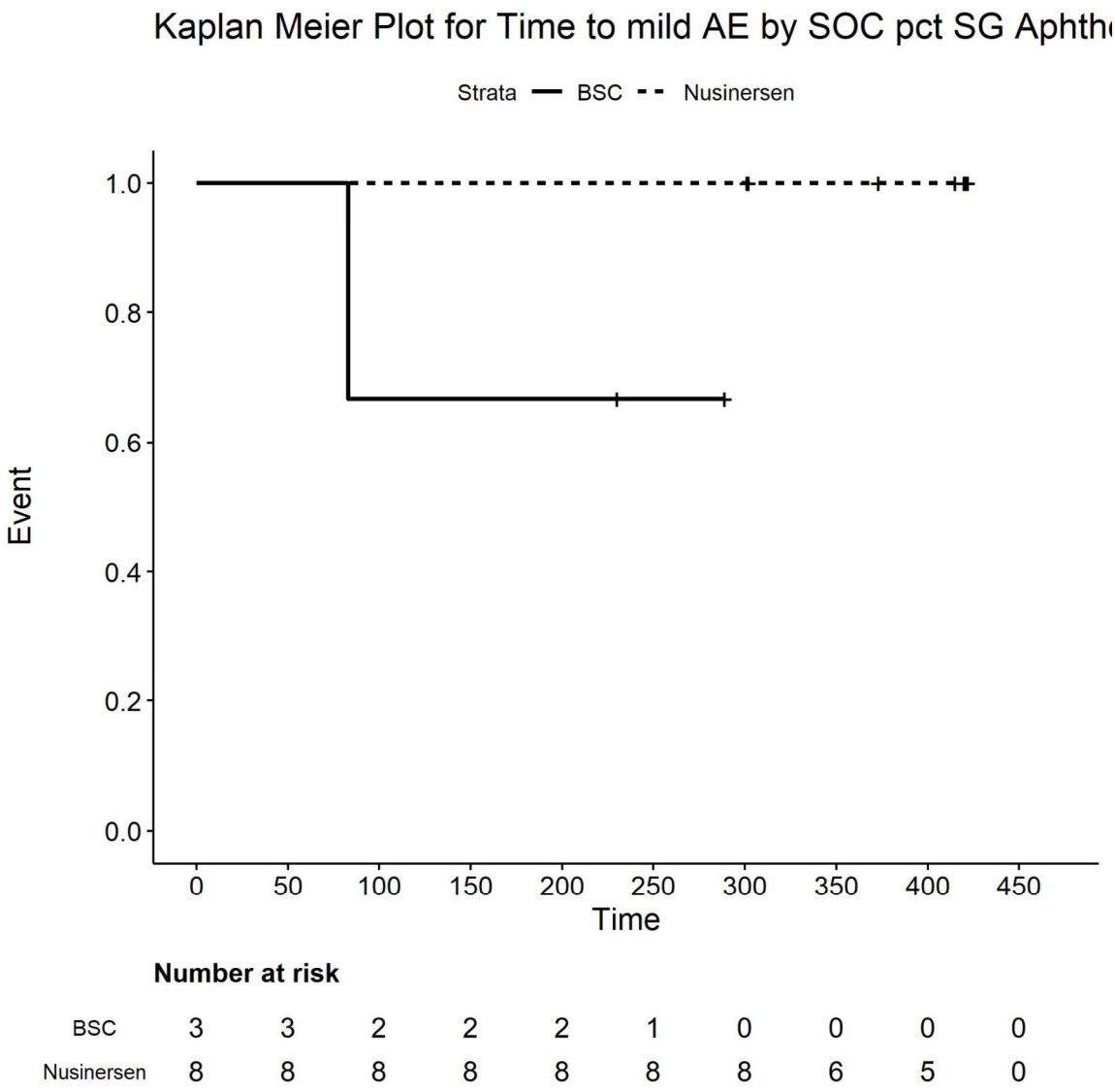
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	6	0



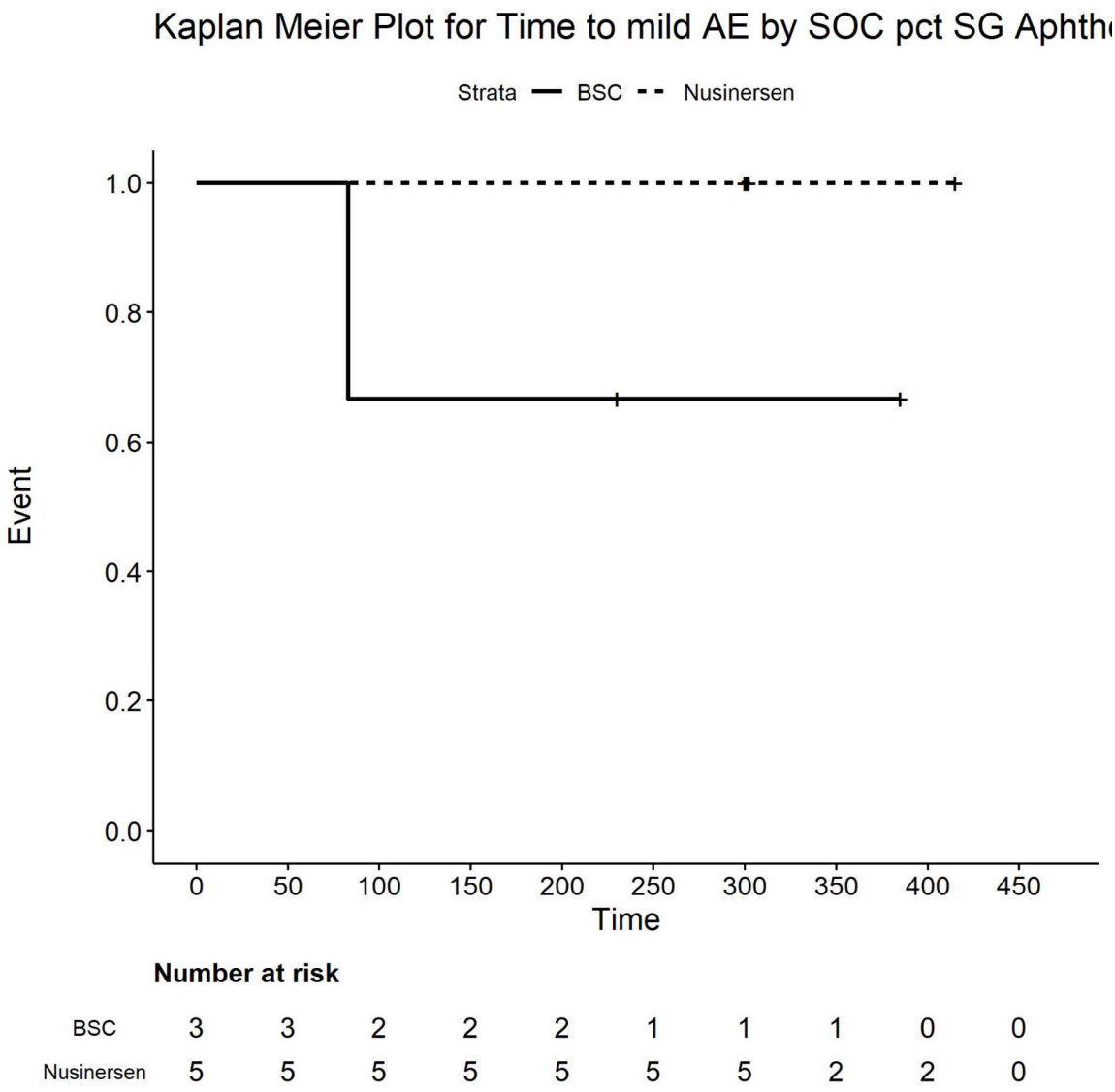
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	3	0



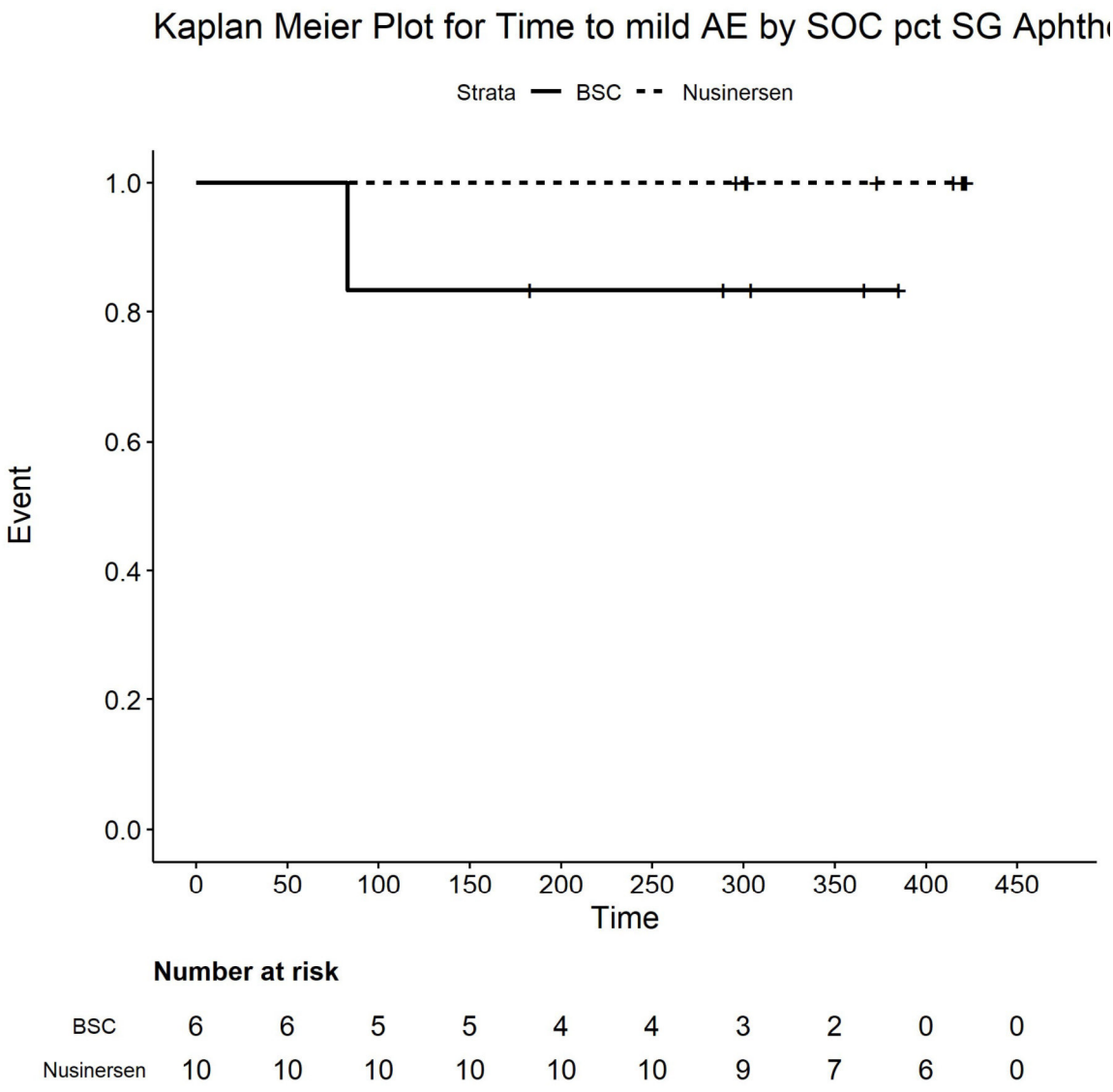
Number at risk

BSC	3	3	2	2	2	1	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



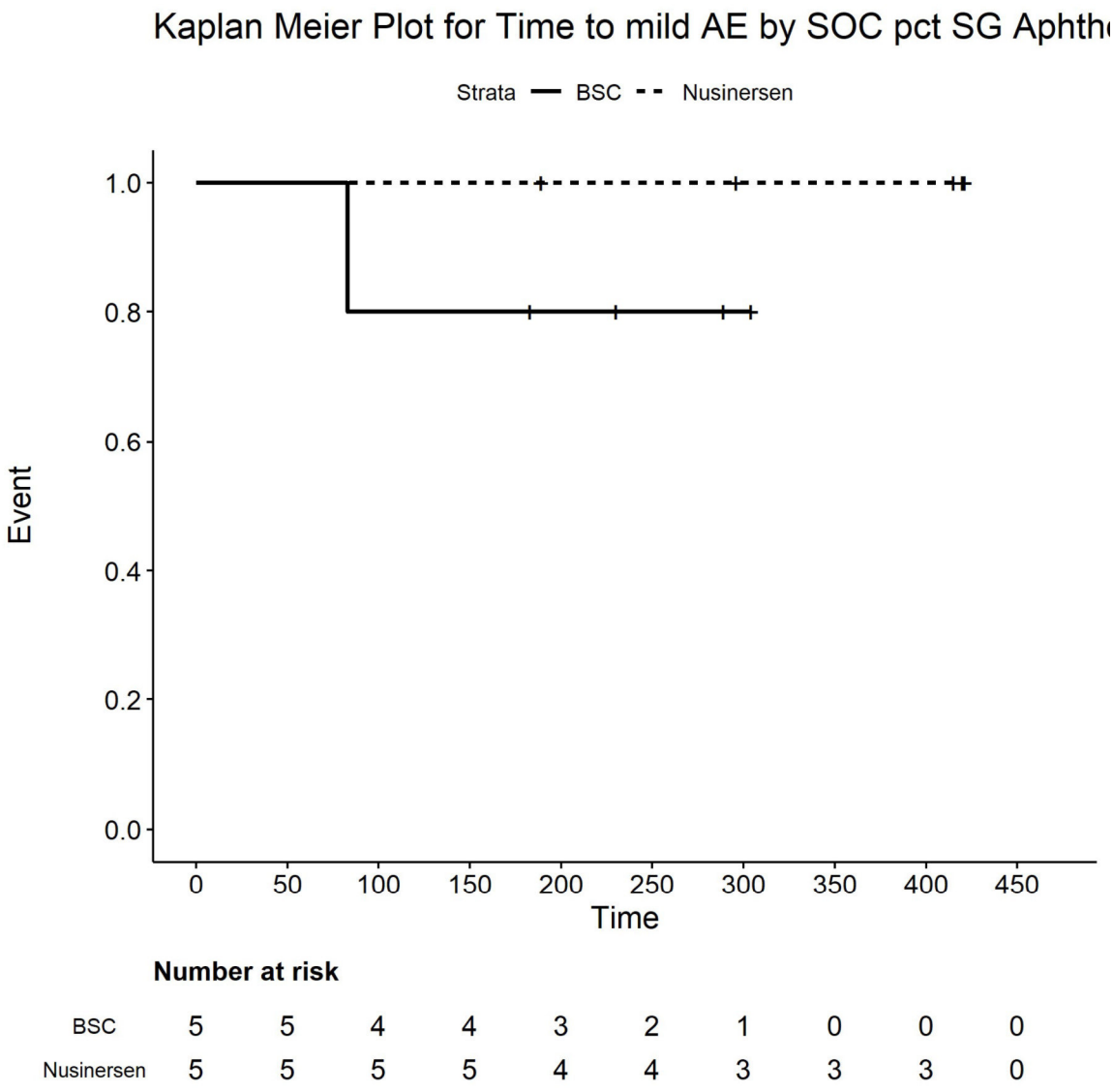
Number at risk

BSC	3	3	2	2	2	1	1	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



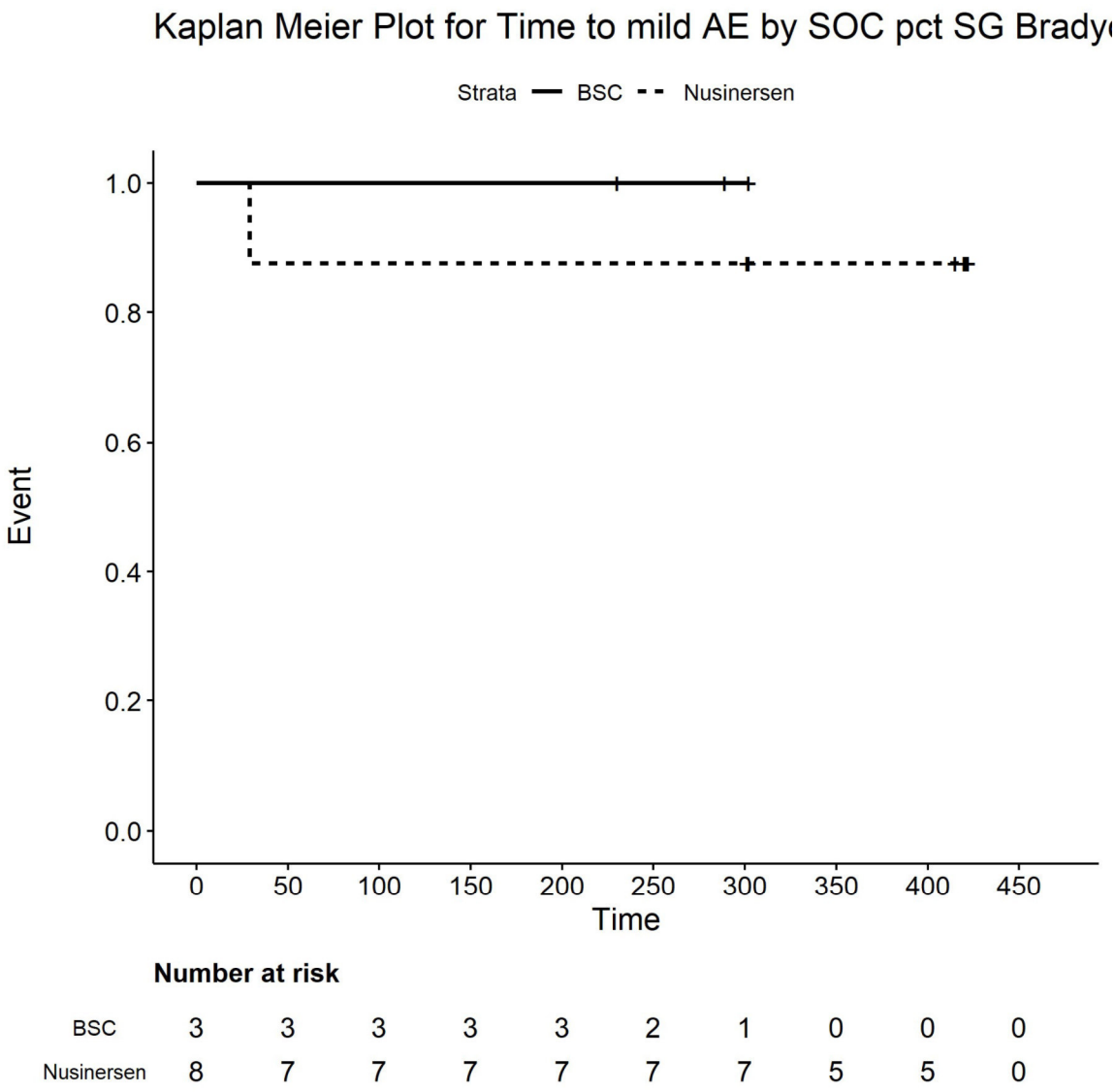
Number at risk

BSC	6	6	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



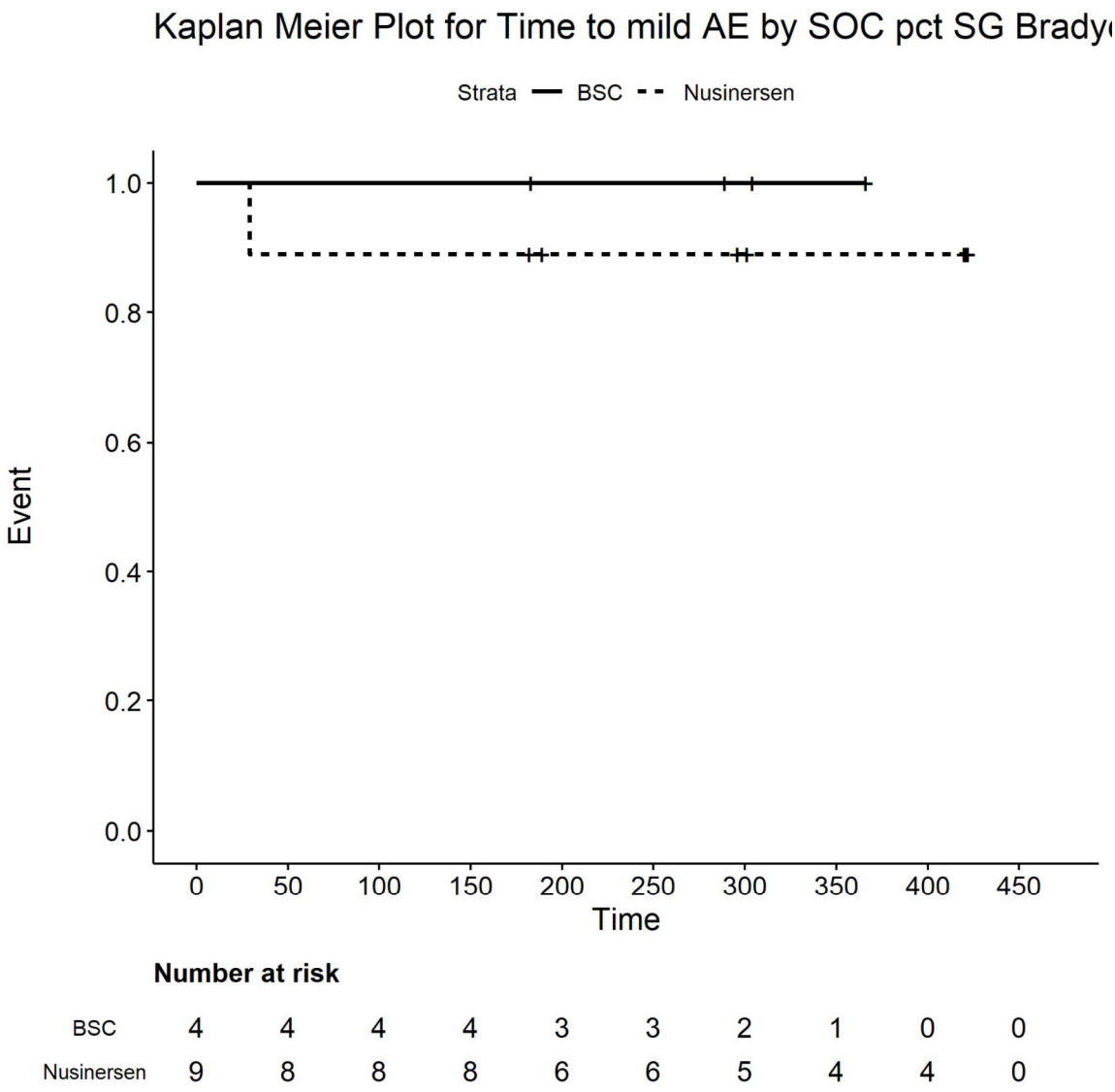
Number at risk

BSC	5	5	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



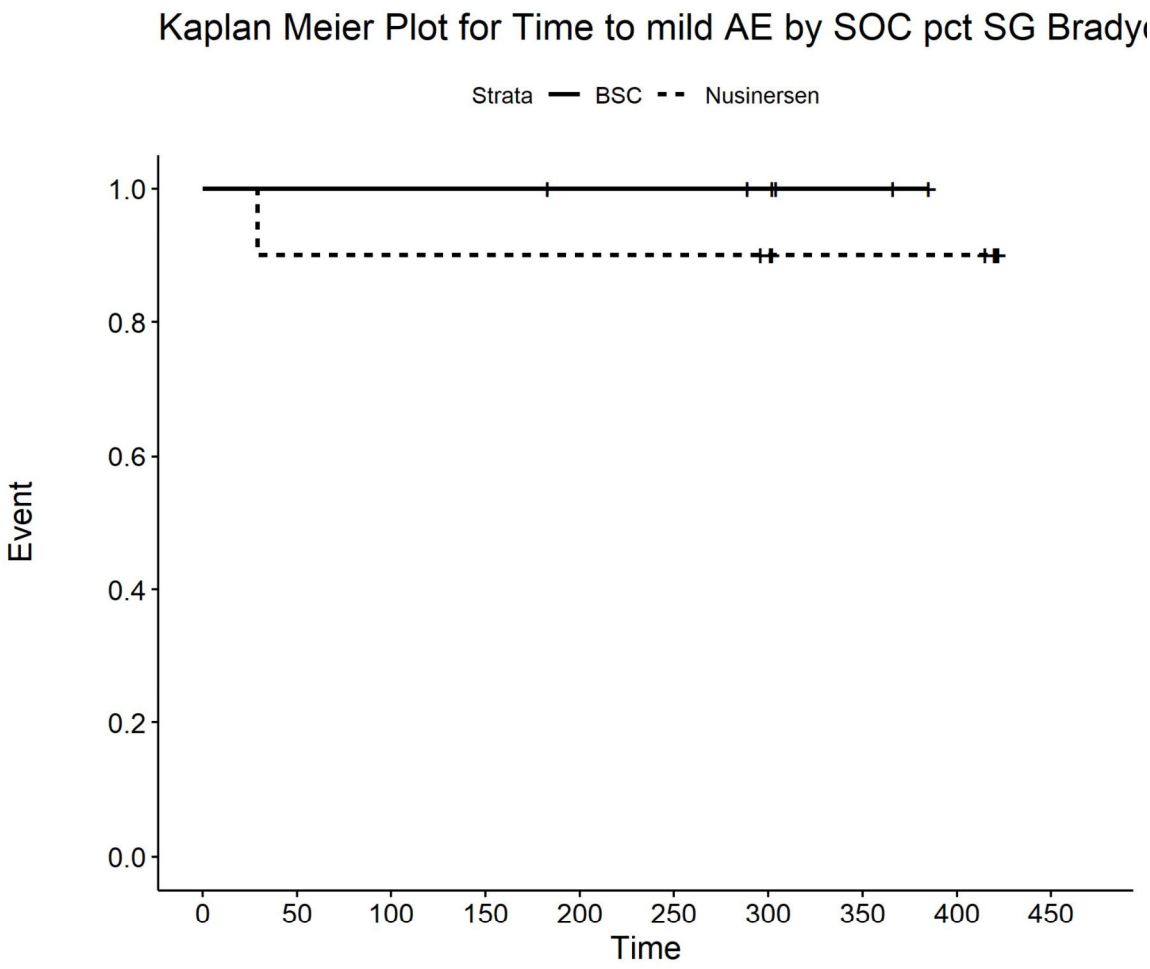
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	5	0



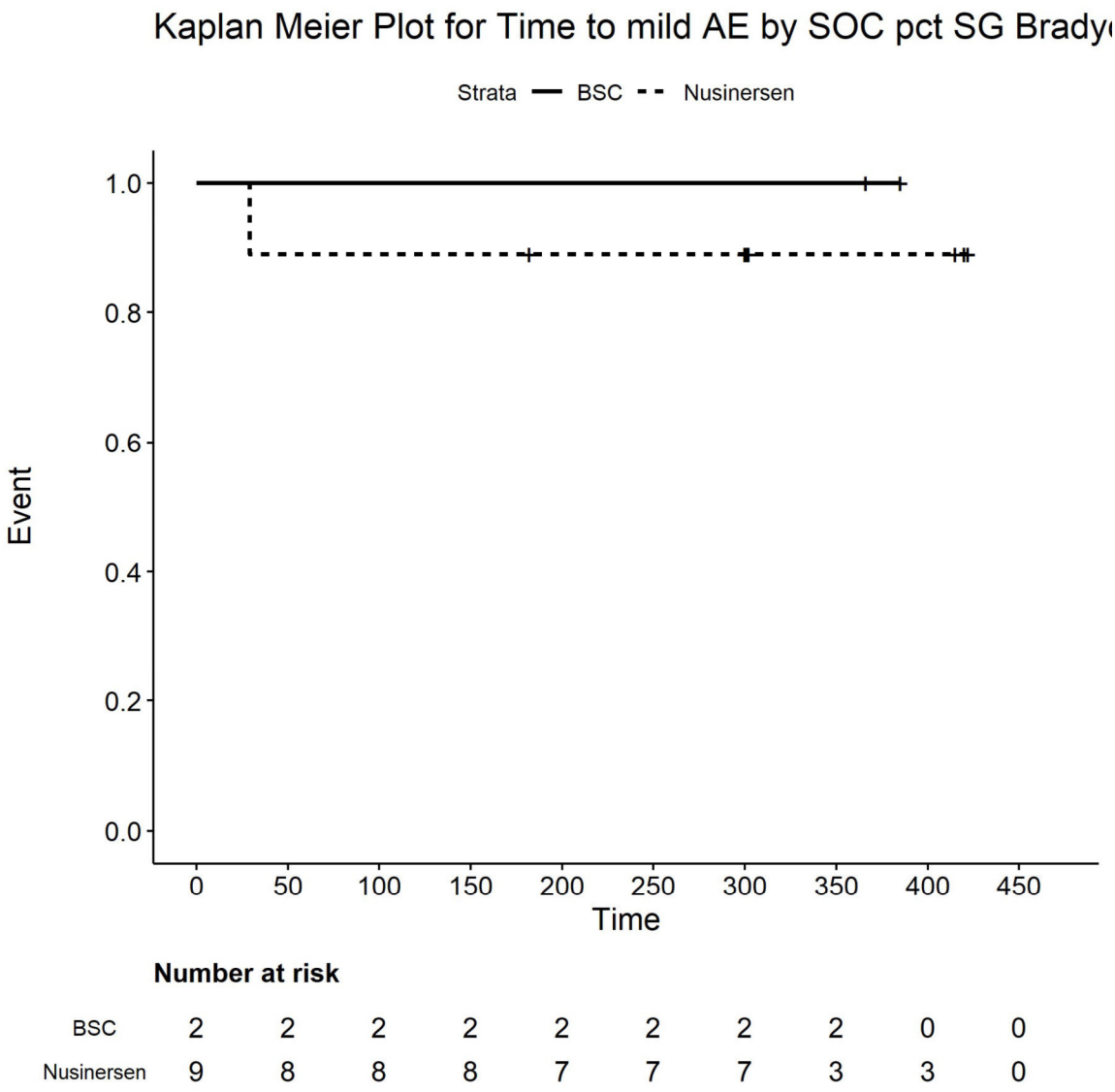
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	4	0



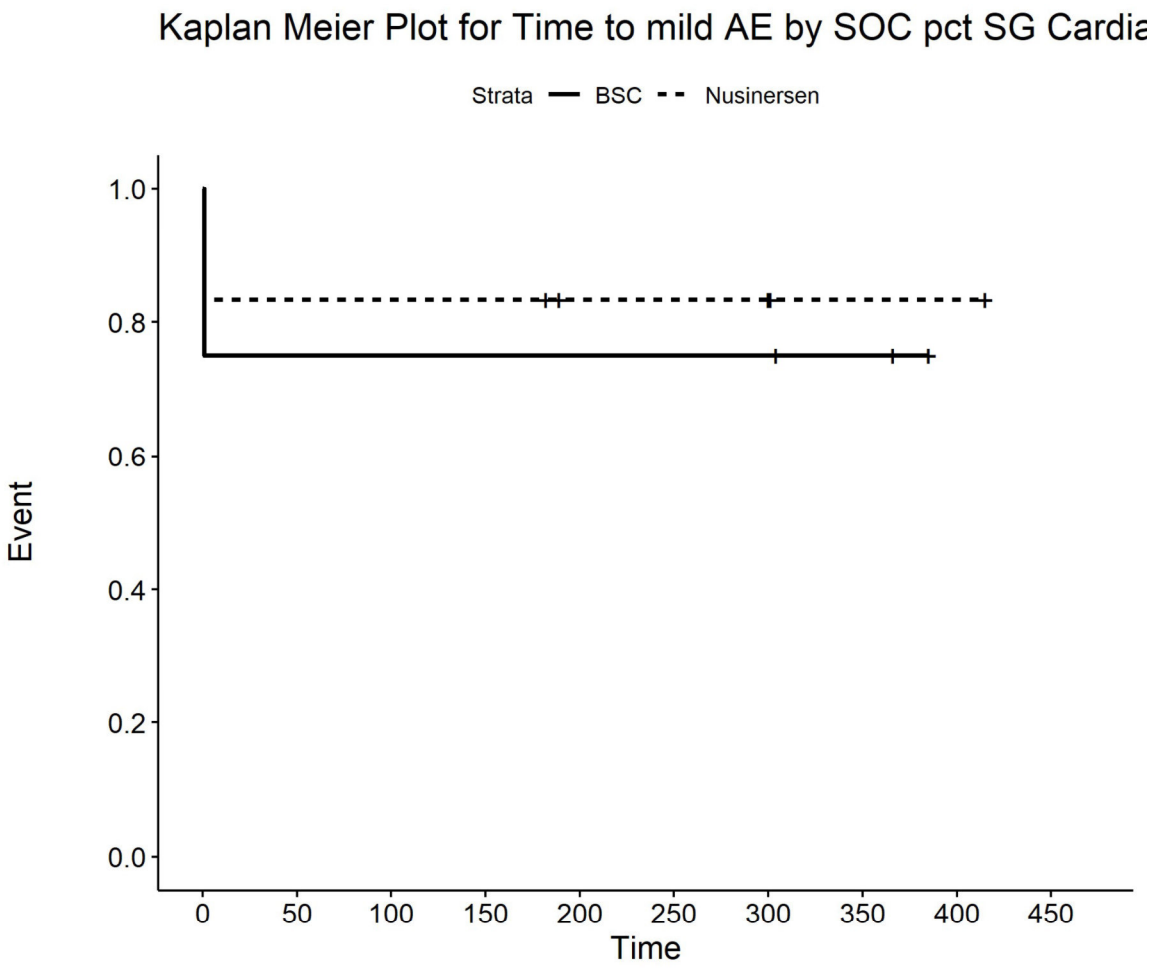
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	6	0



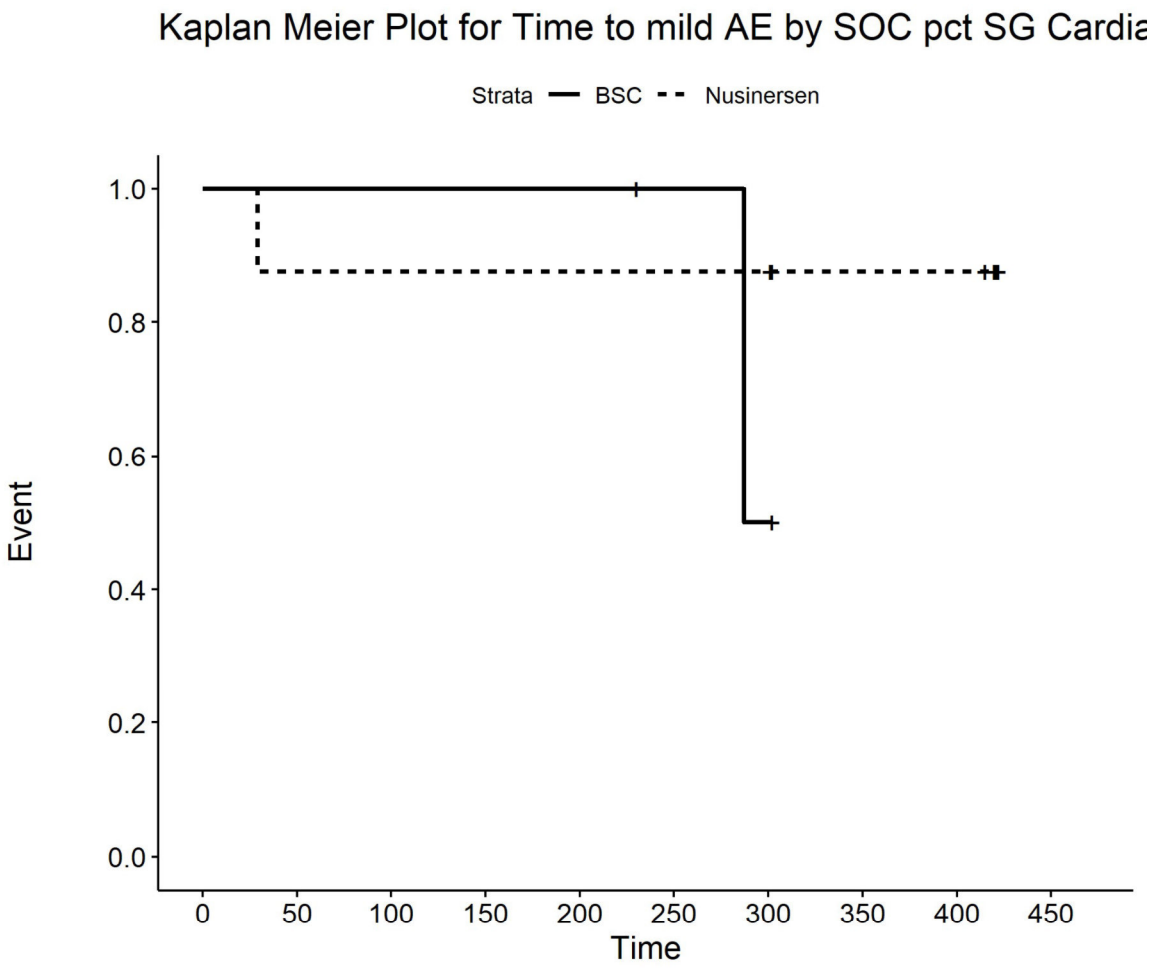
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	3	0



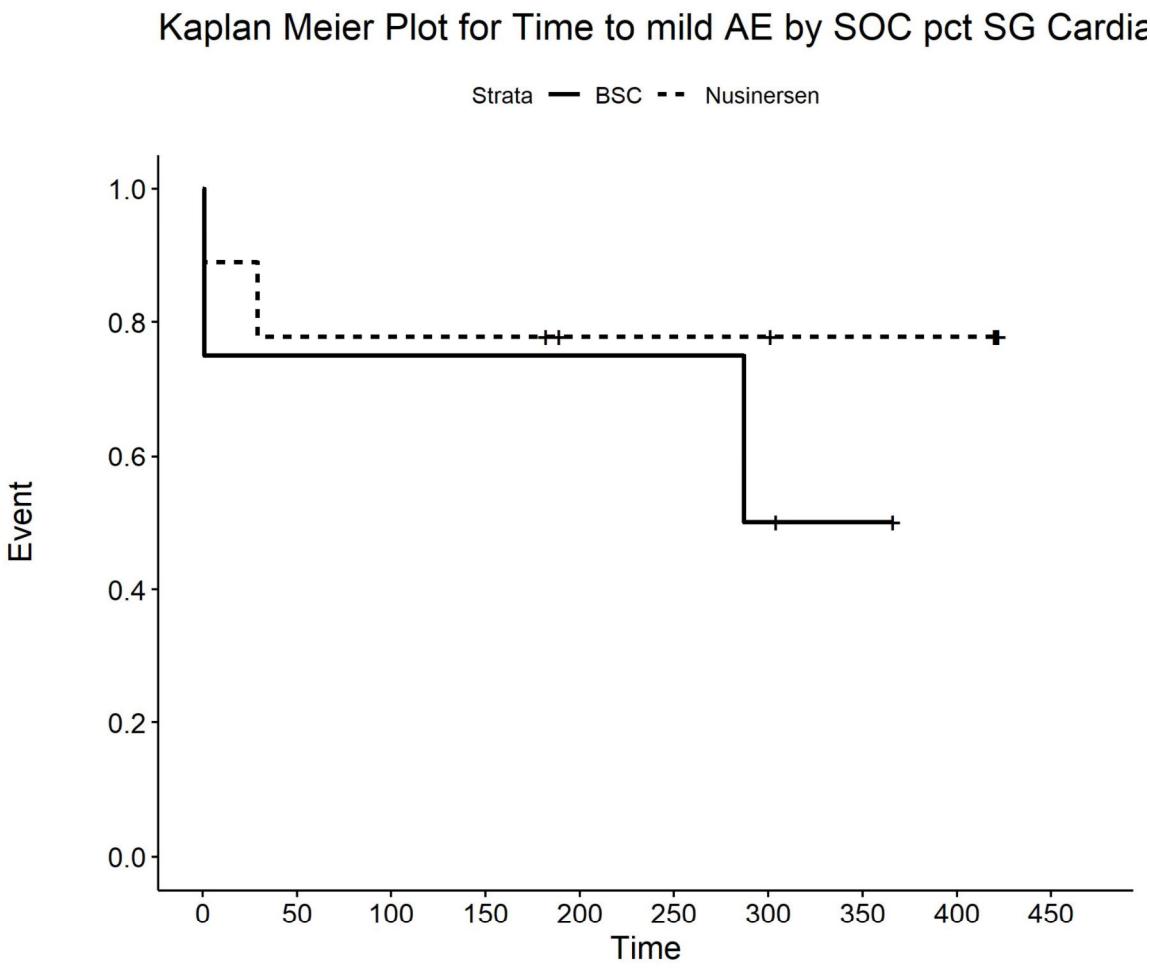
Number at risk

BSC	4	3	3	3	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	3	1	1	0



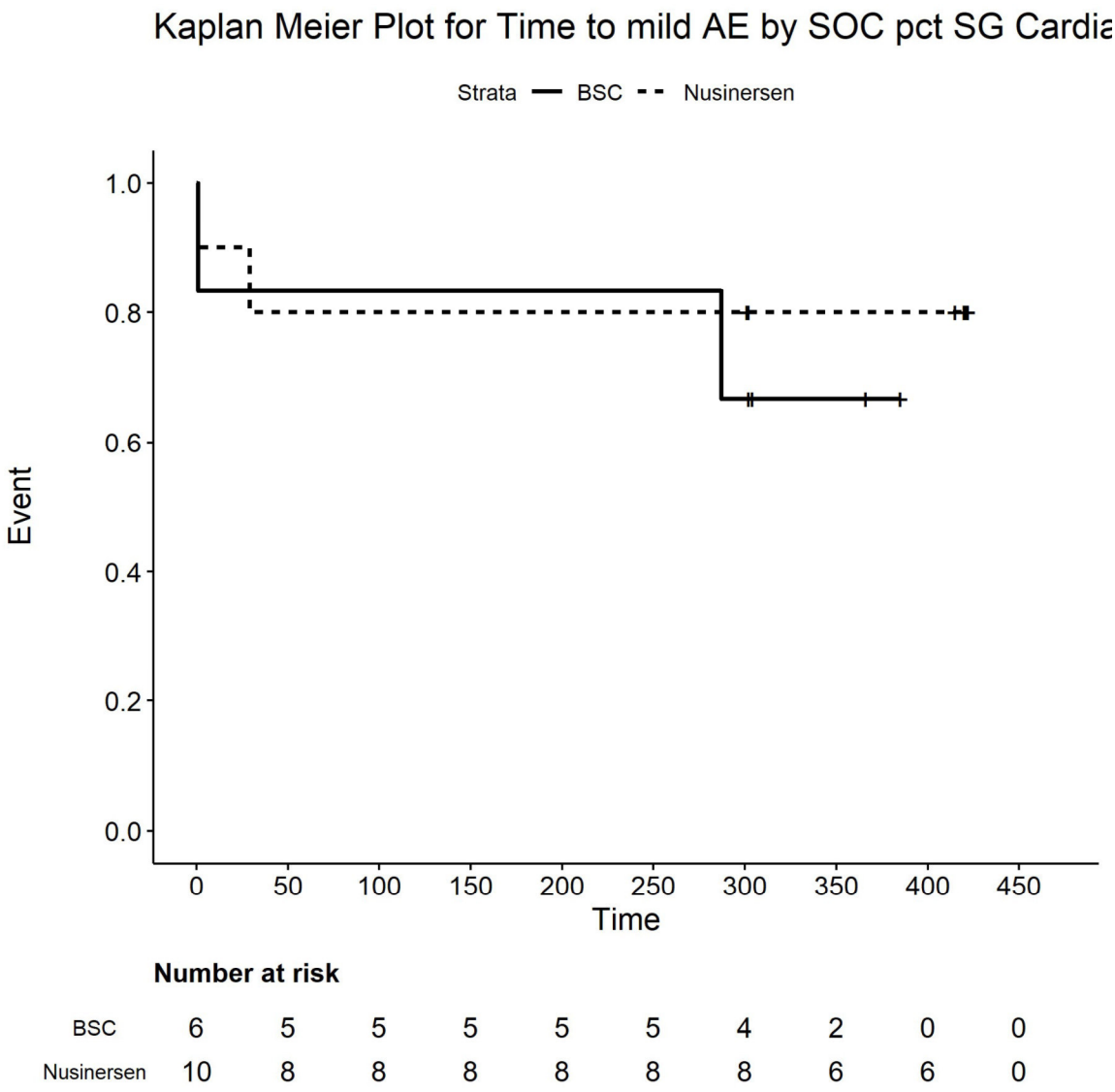
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	5	0



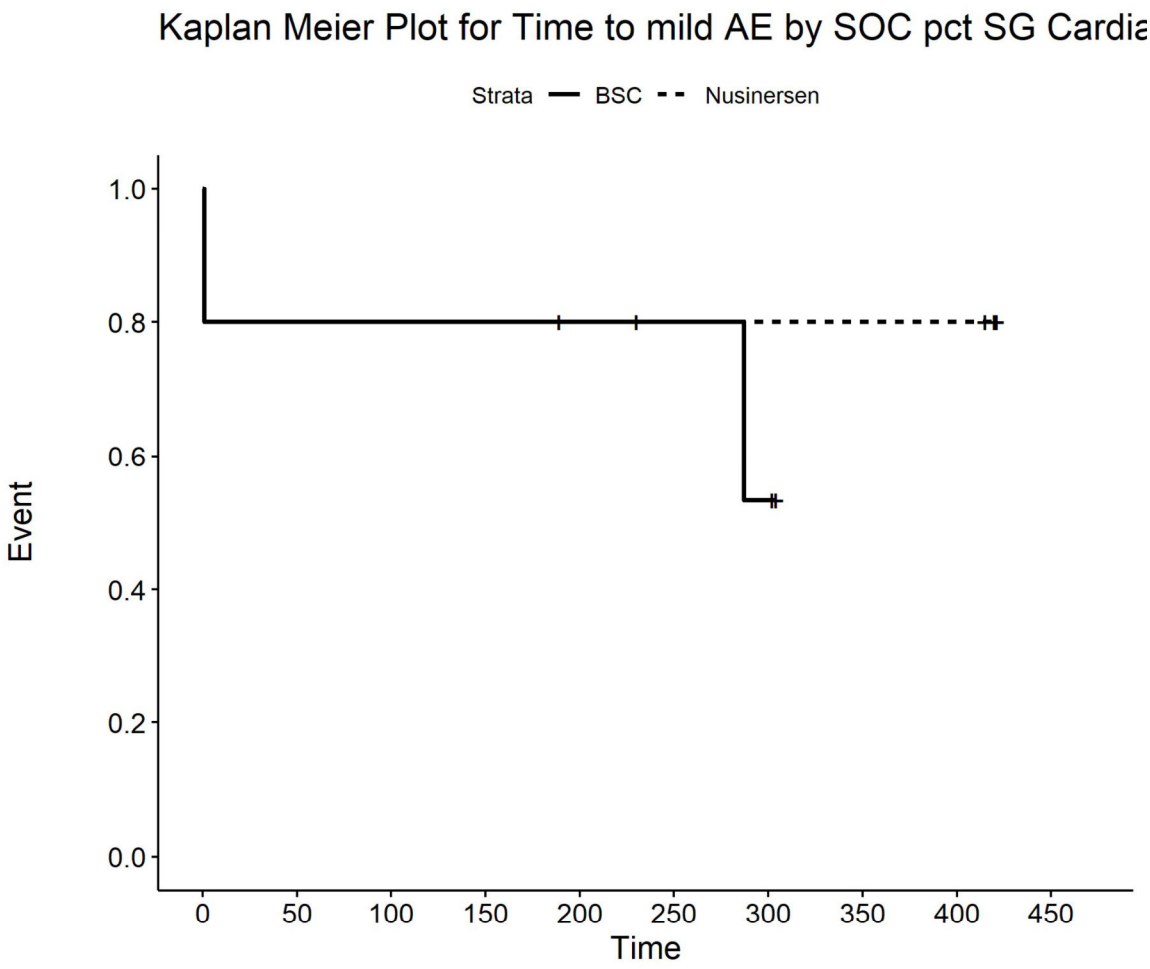
Number at risk

BSC	4	3	3	3	3	3	2	1	0	0
Nusinersen	9	7	7	7	5	5	5	4	4	0



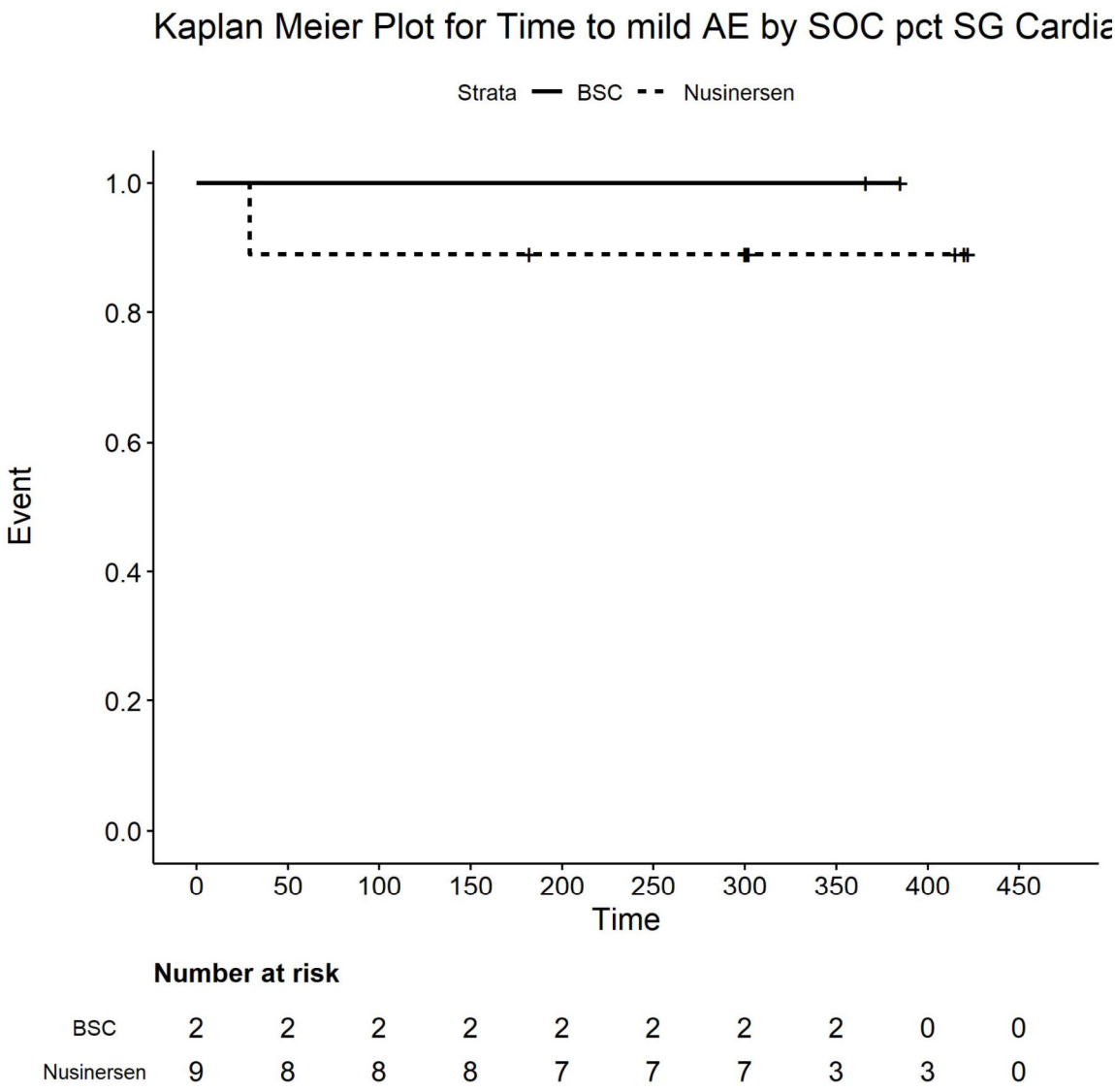
Number at risk

BSC	6	5	5	5	5	5	4	2	0	0
Nusinersen	10	8	8	8	8	8	8	6	6	0



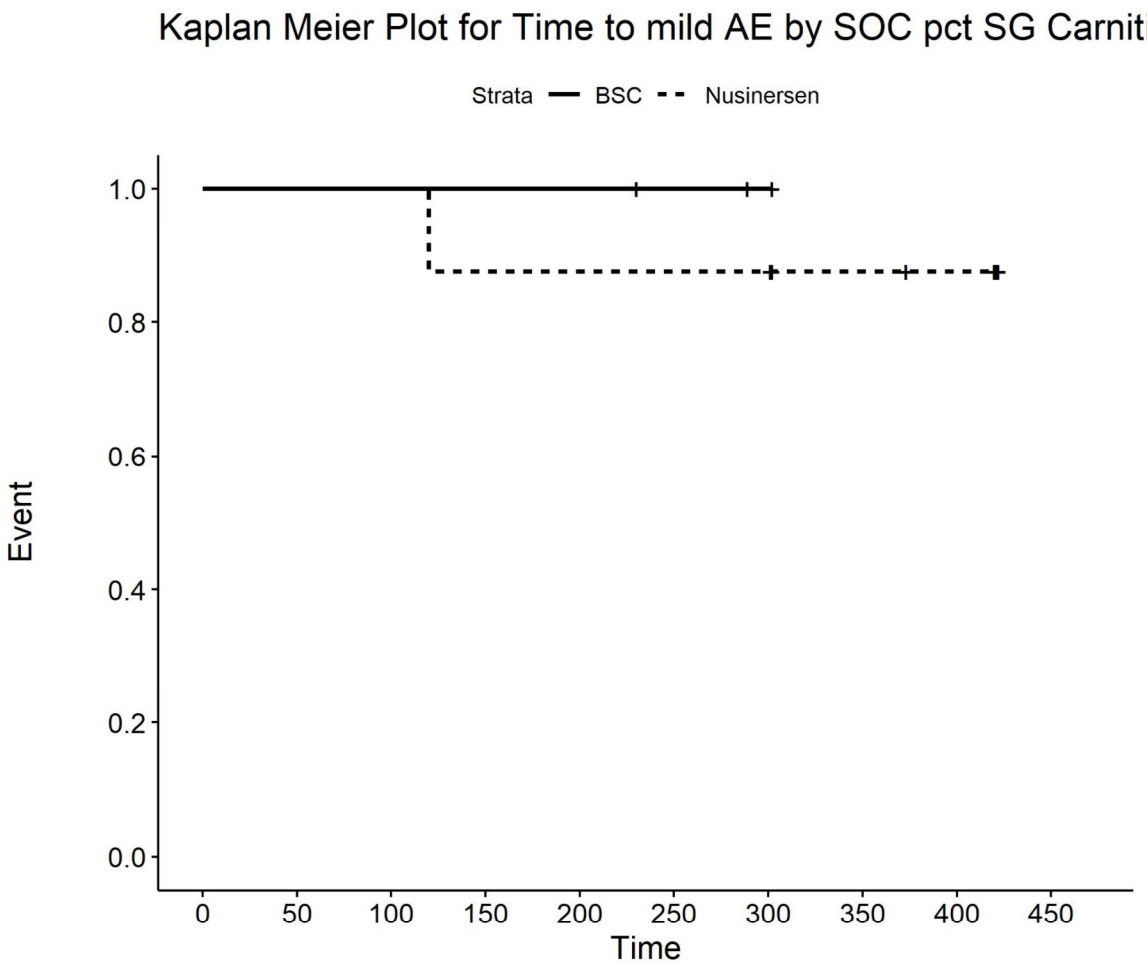
Number at risk

BSC	5	4	4	4	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	3	3	3	0



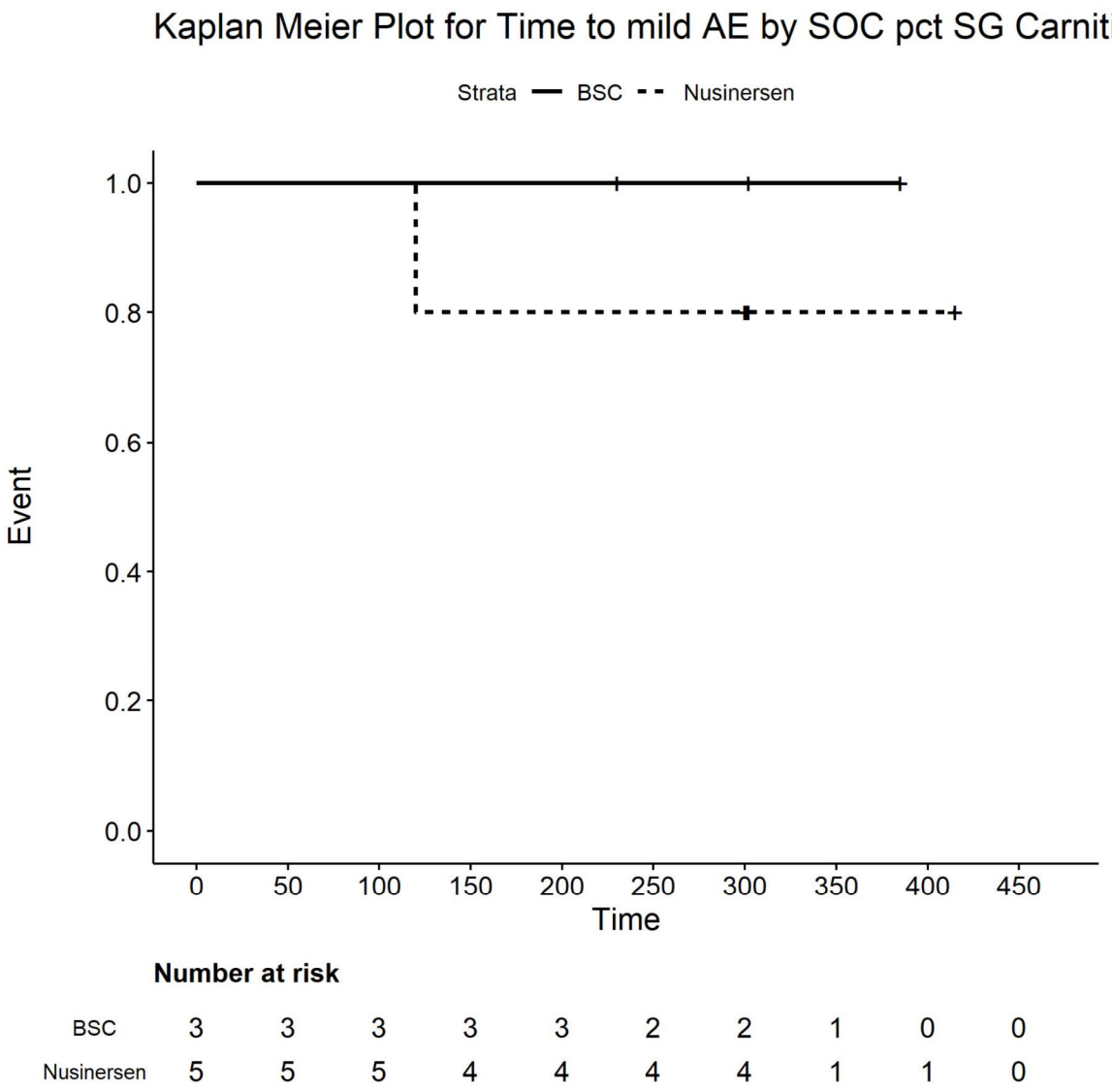
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	3	0



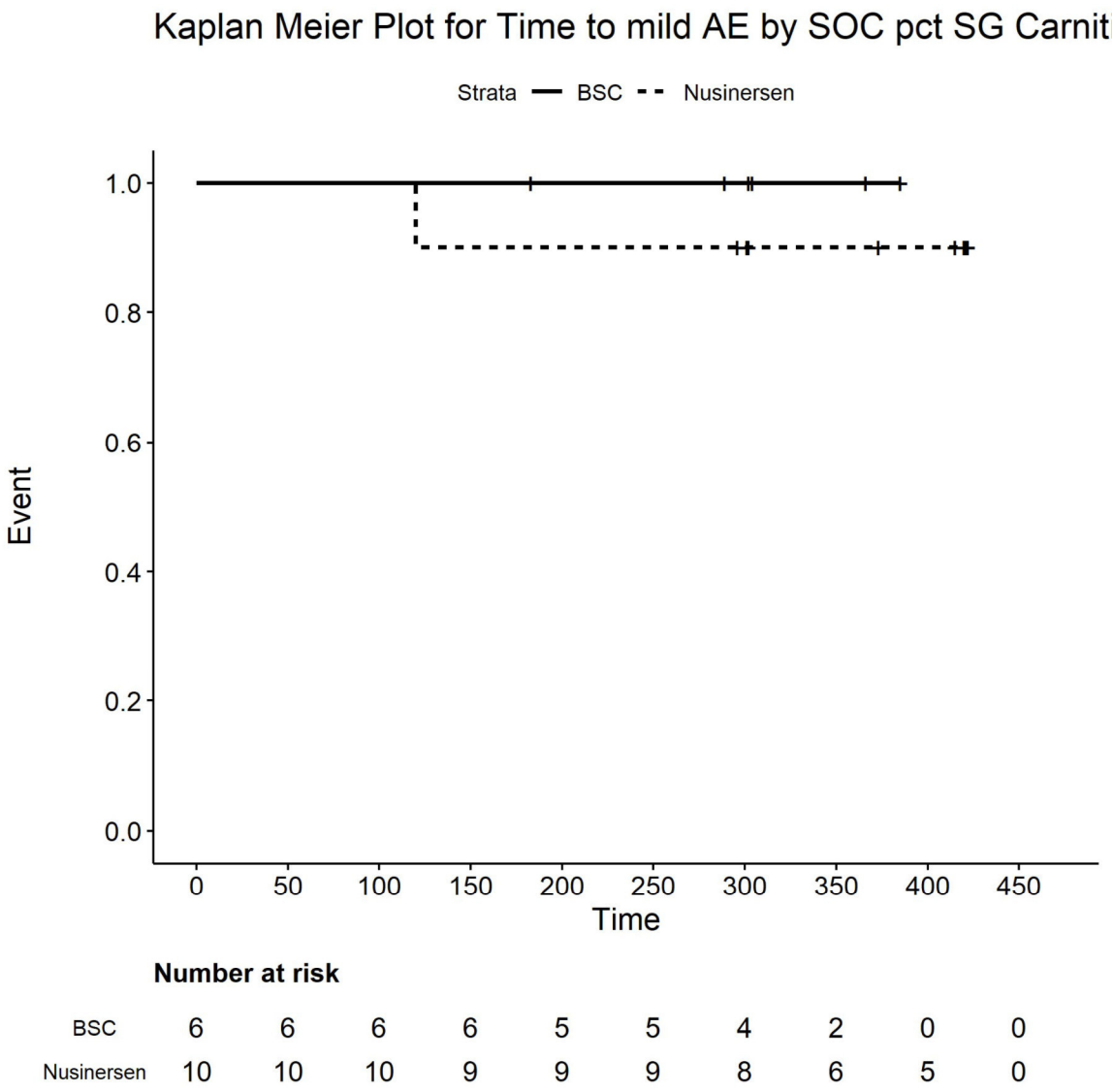
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



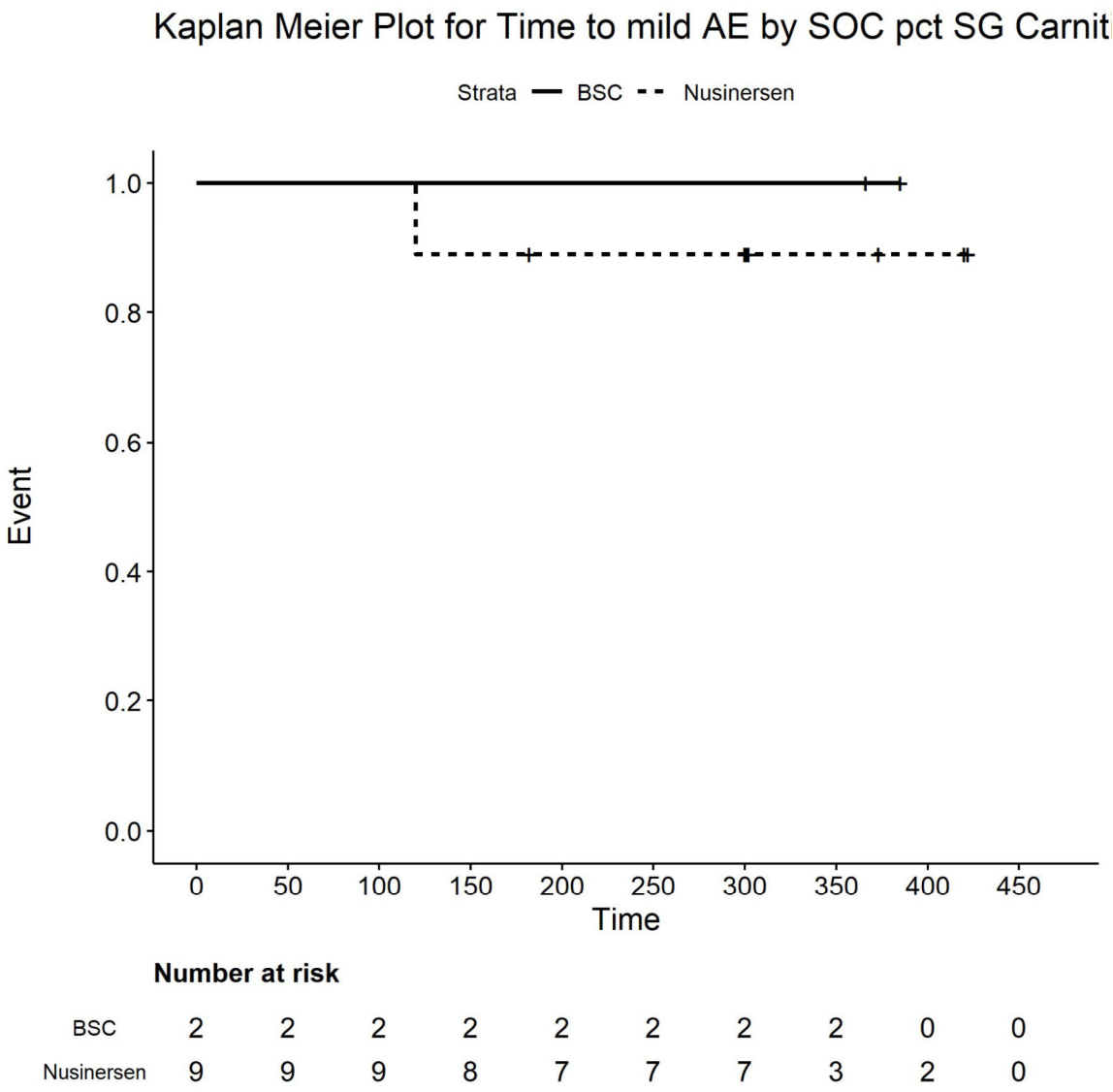
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	4	4	4	4	1	1	0



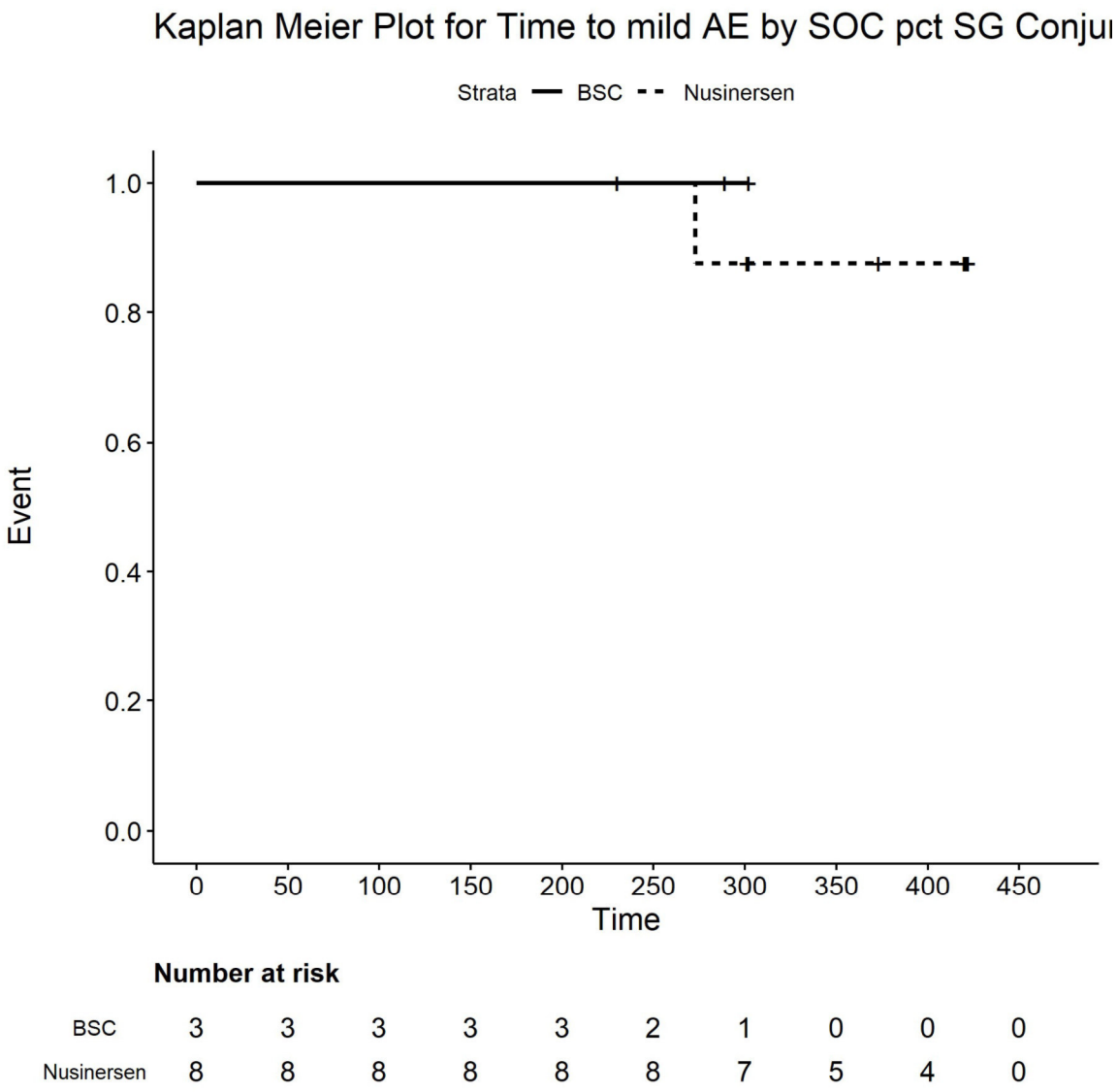
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



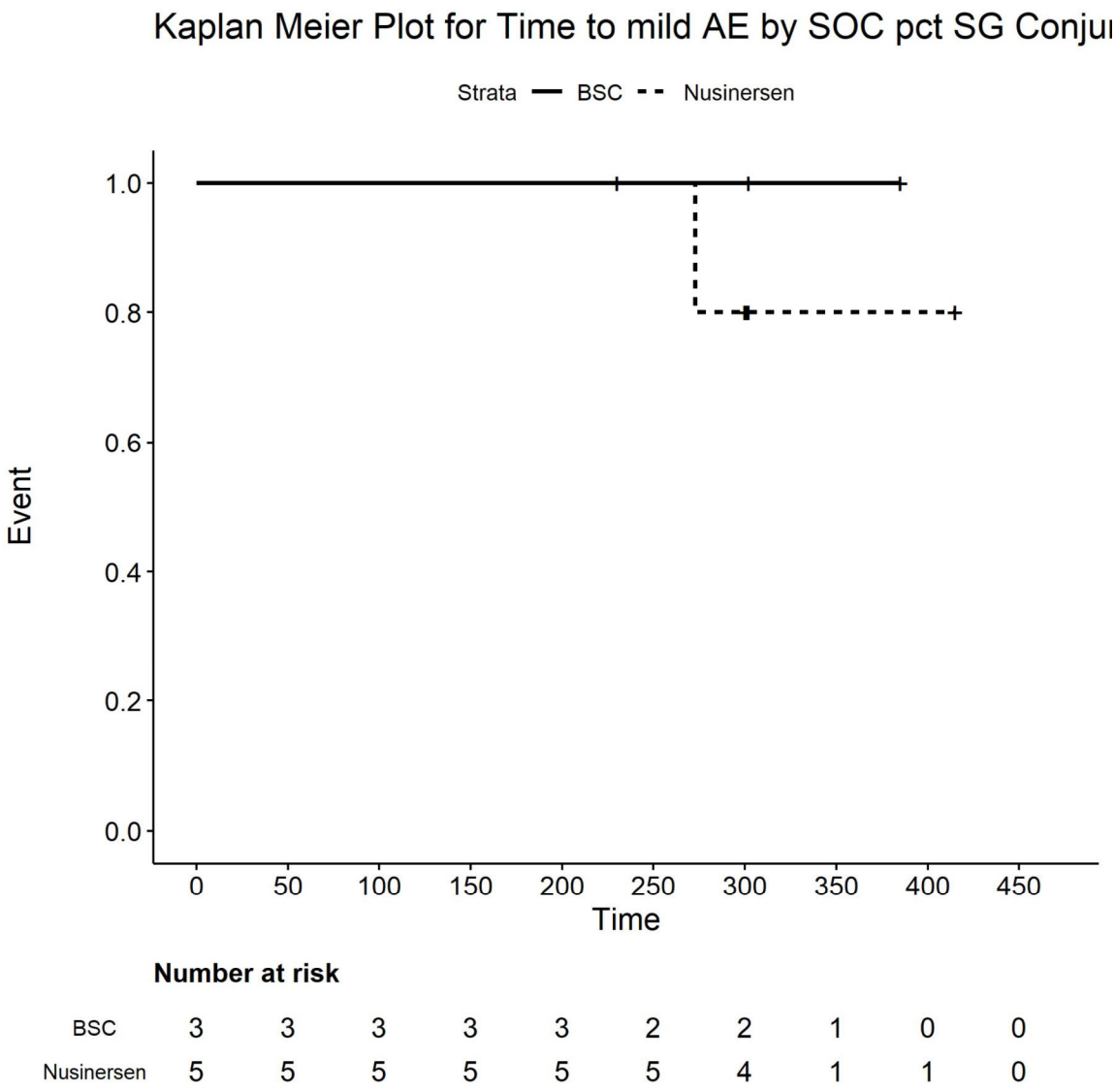
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



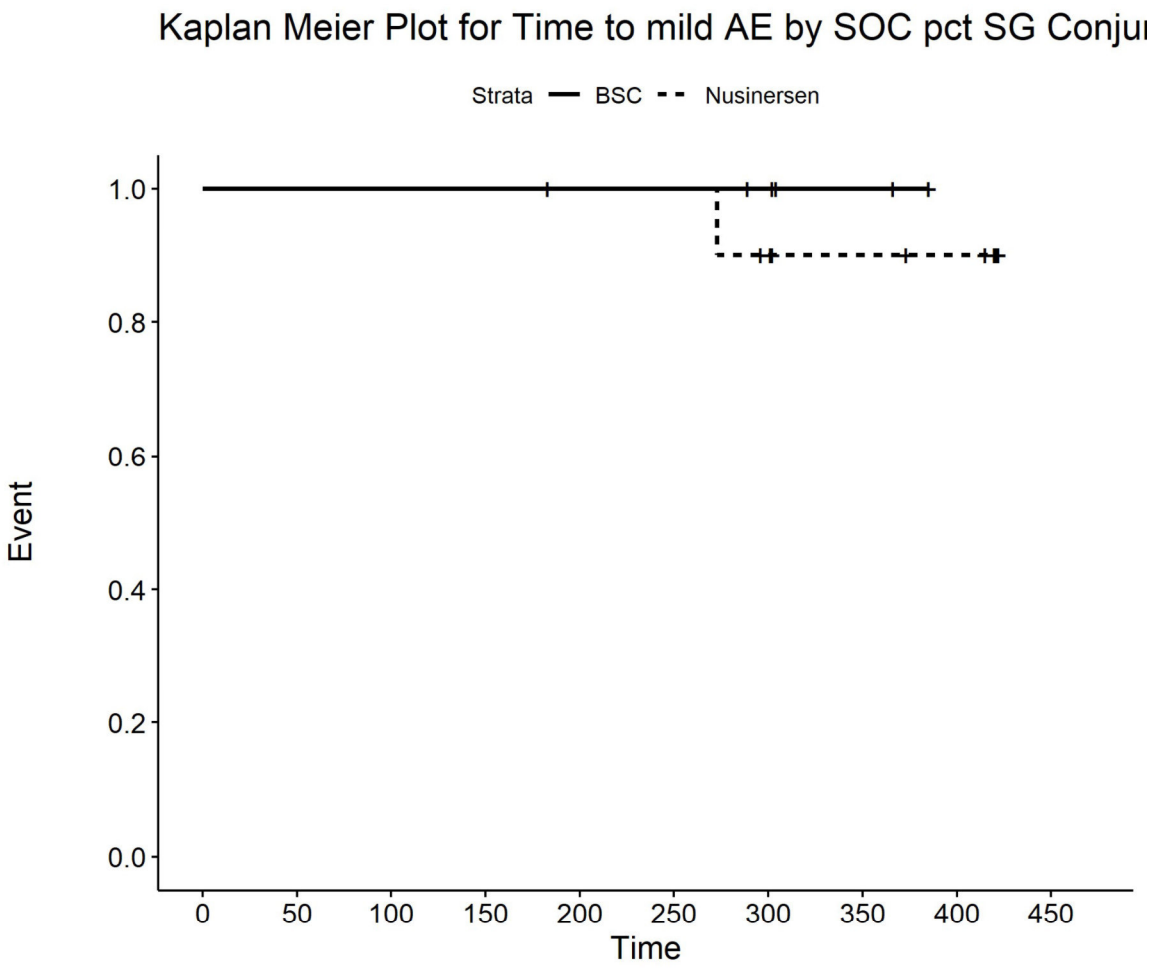
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	7	5	4	0



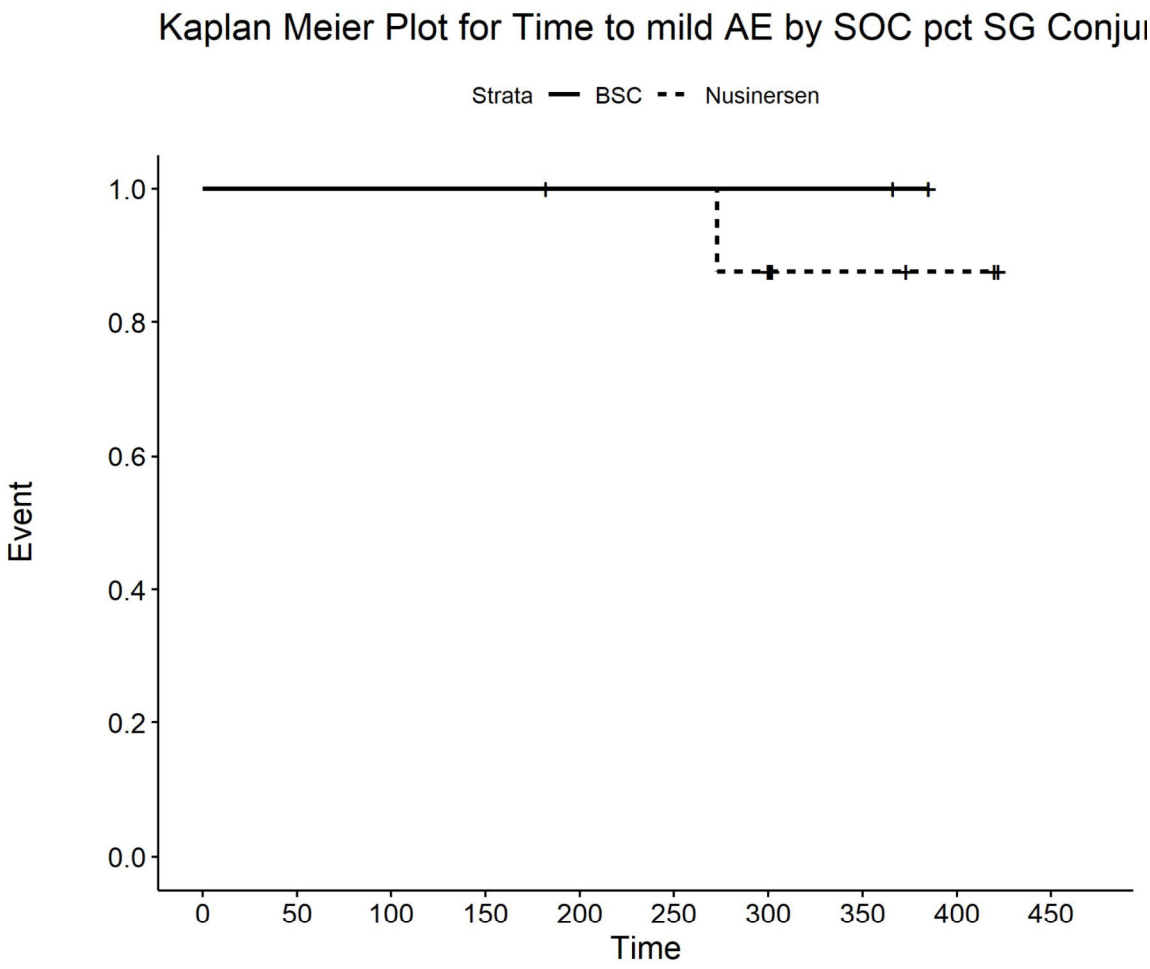
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	4	1	1	0



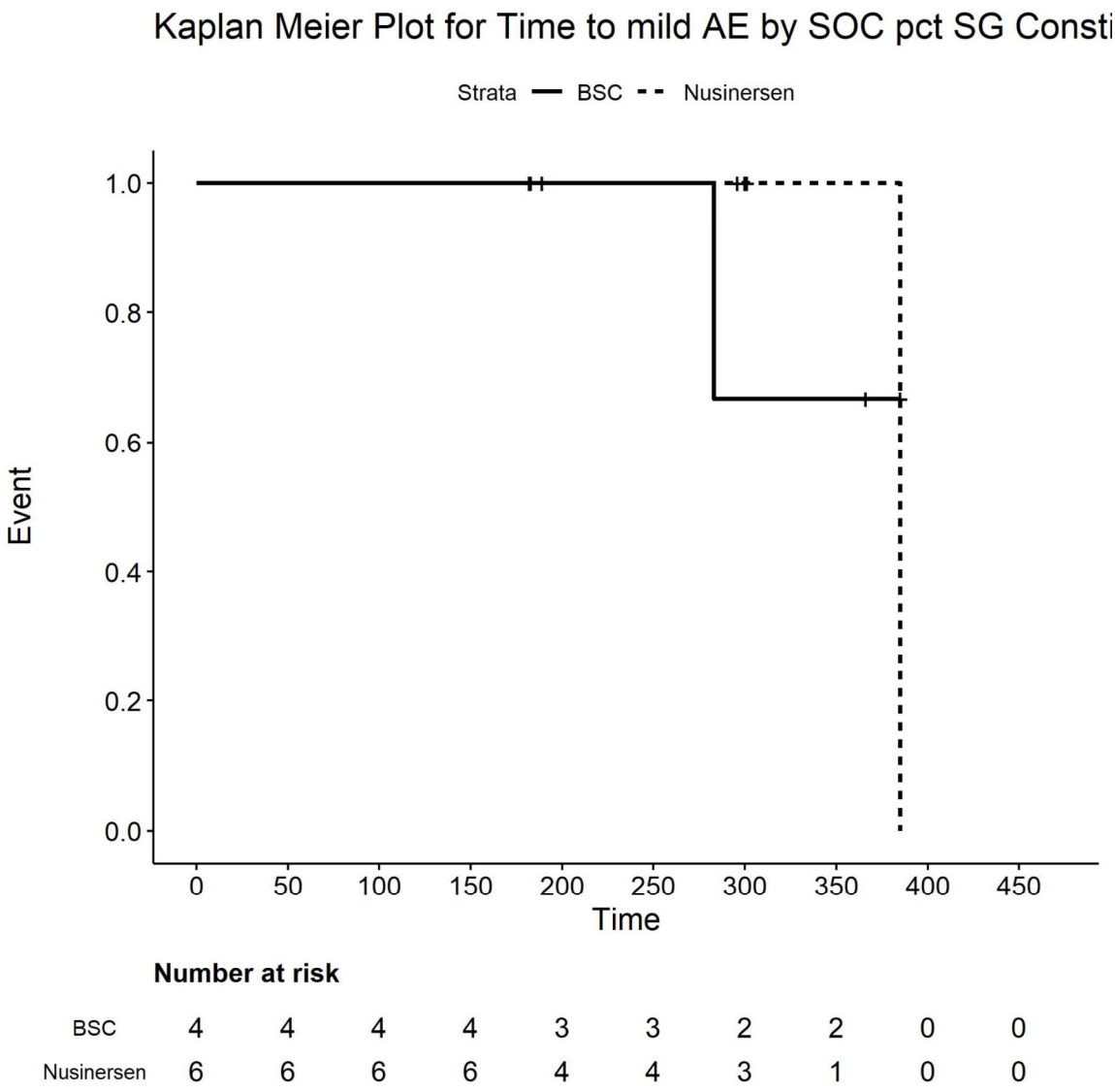
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	8	6	5	0



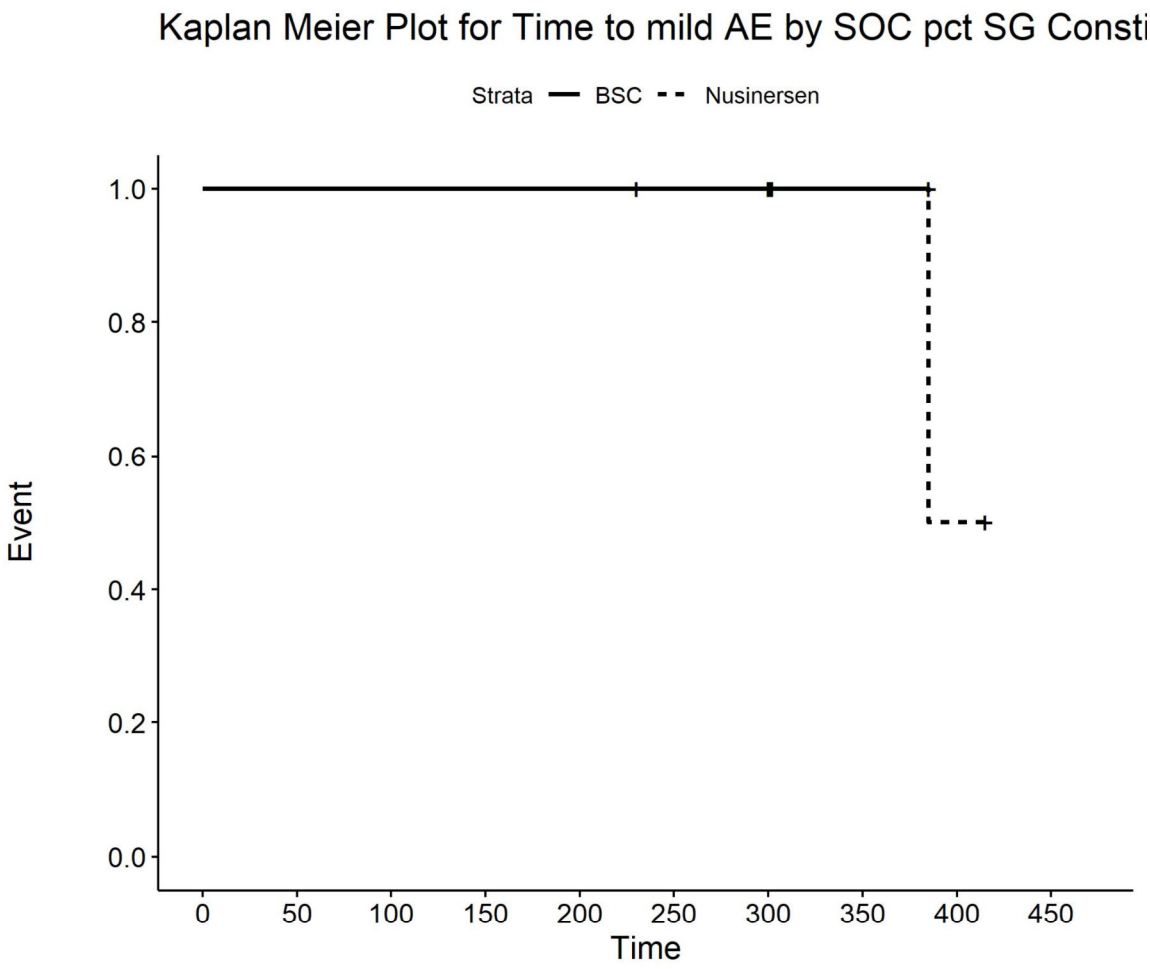
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	7	3	2	0



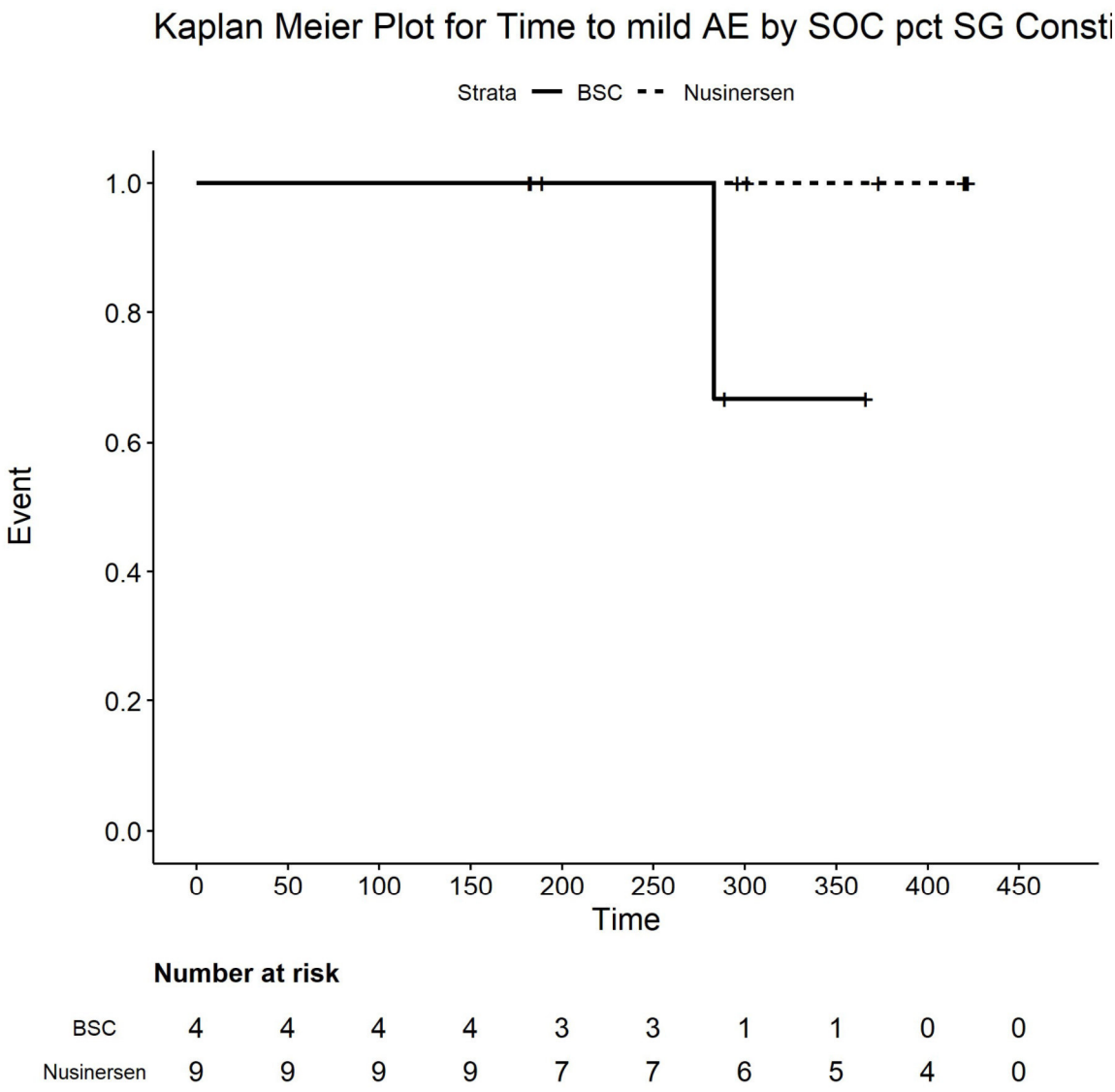
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	0	0



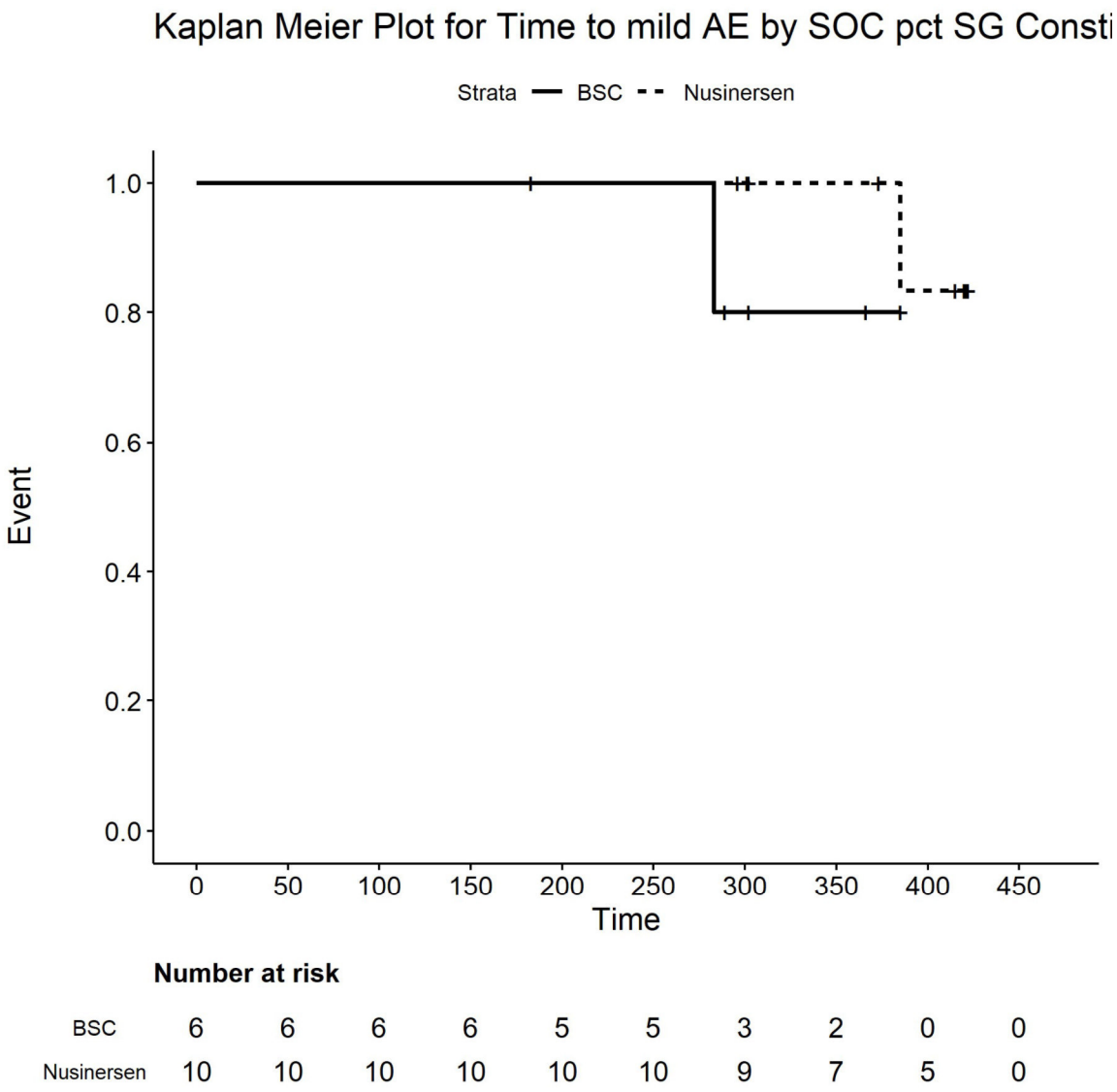
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	1	0



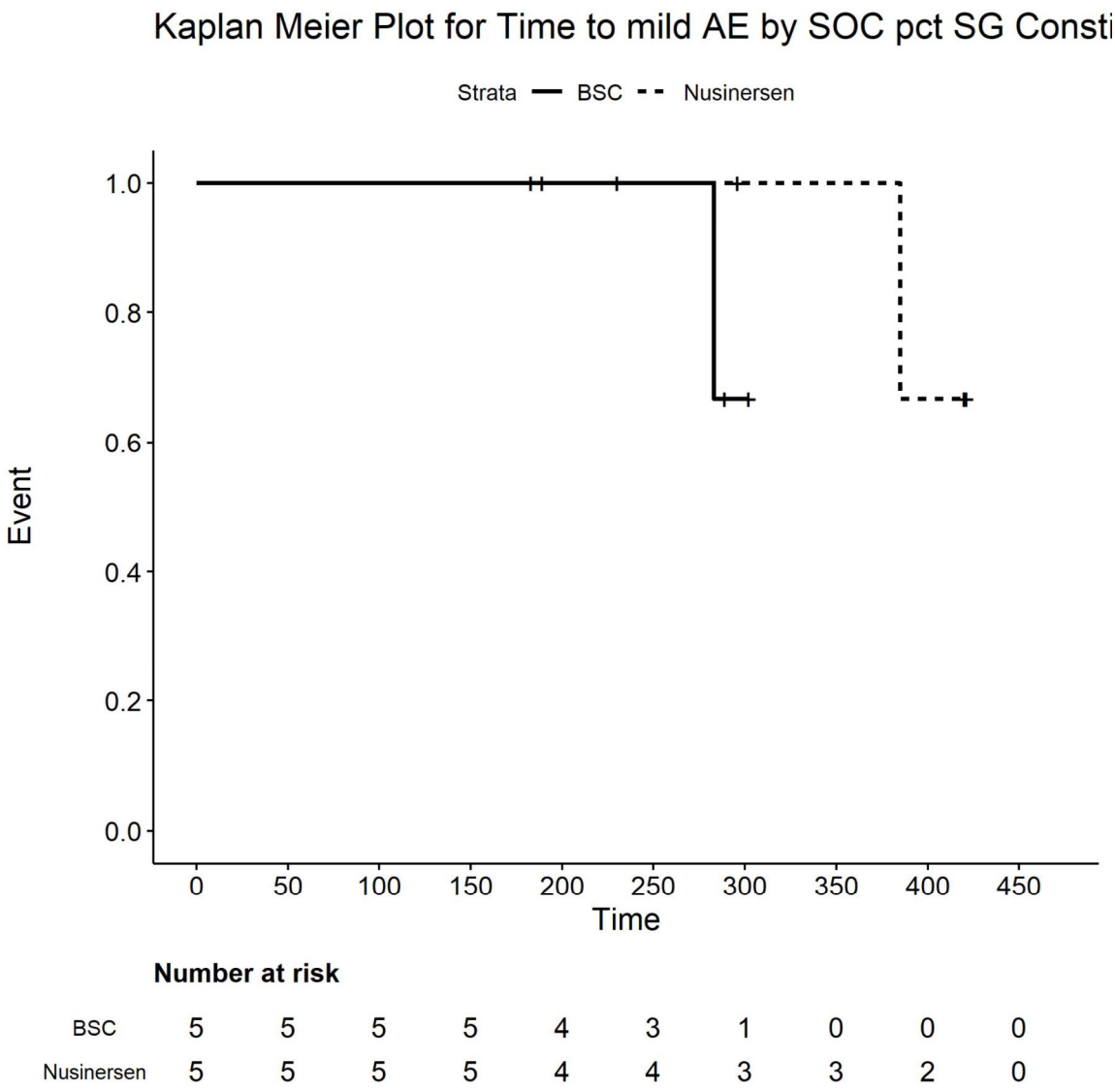
Number at risk

BSC	4	4	4	4	3	3	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



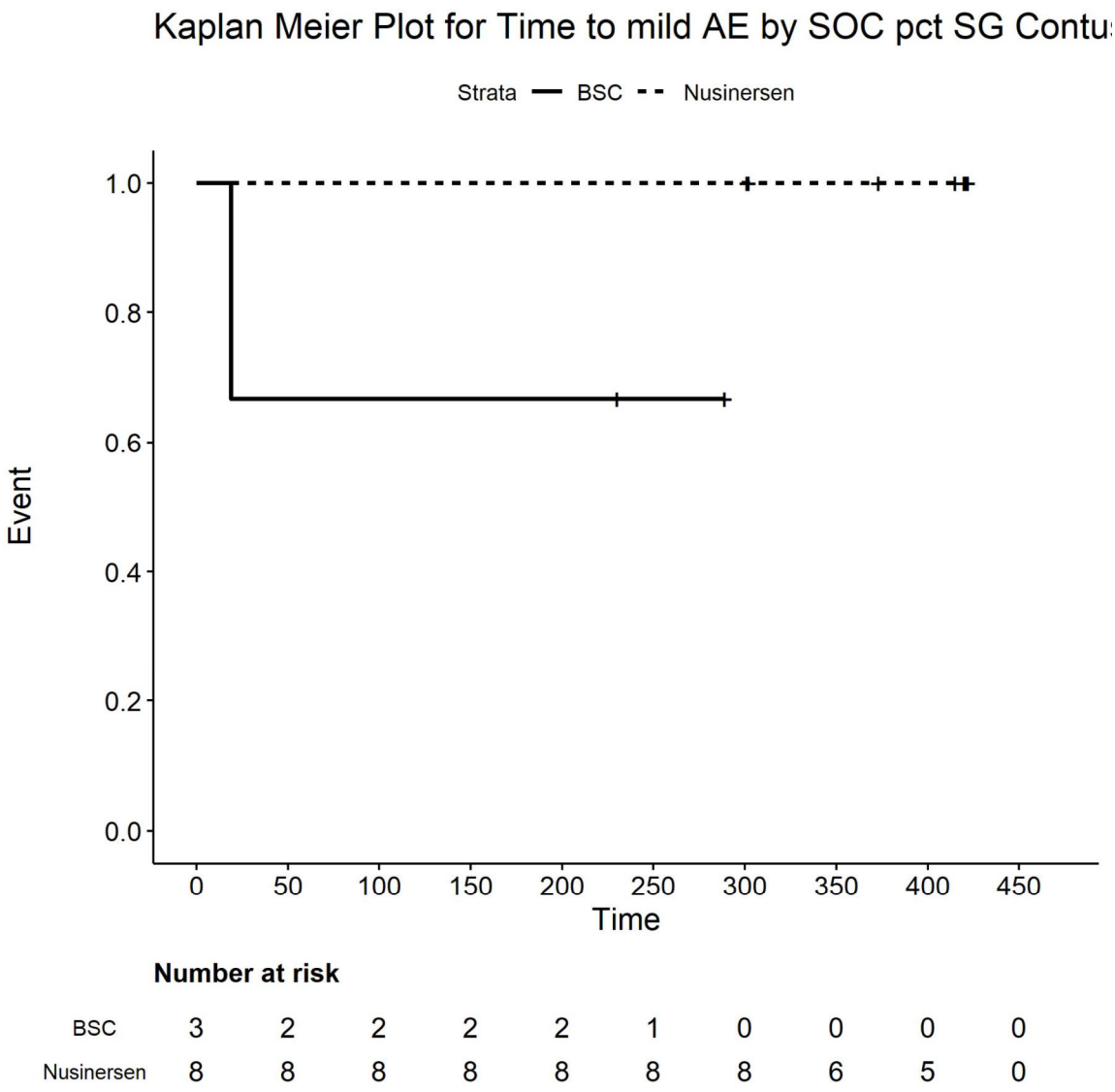
Number at risk

BSC	6	6	6	6	5	5	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	5	0



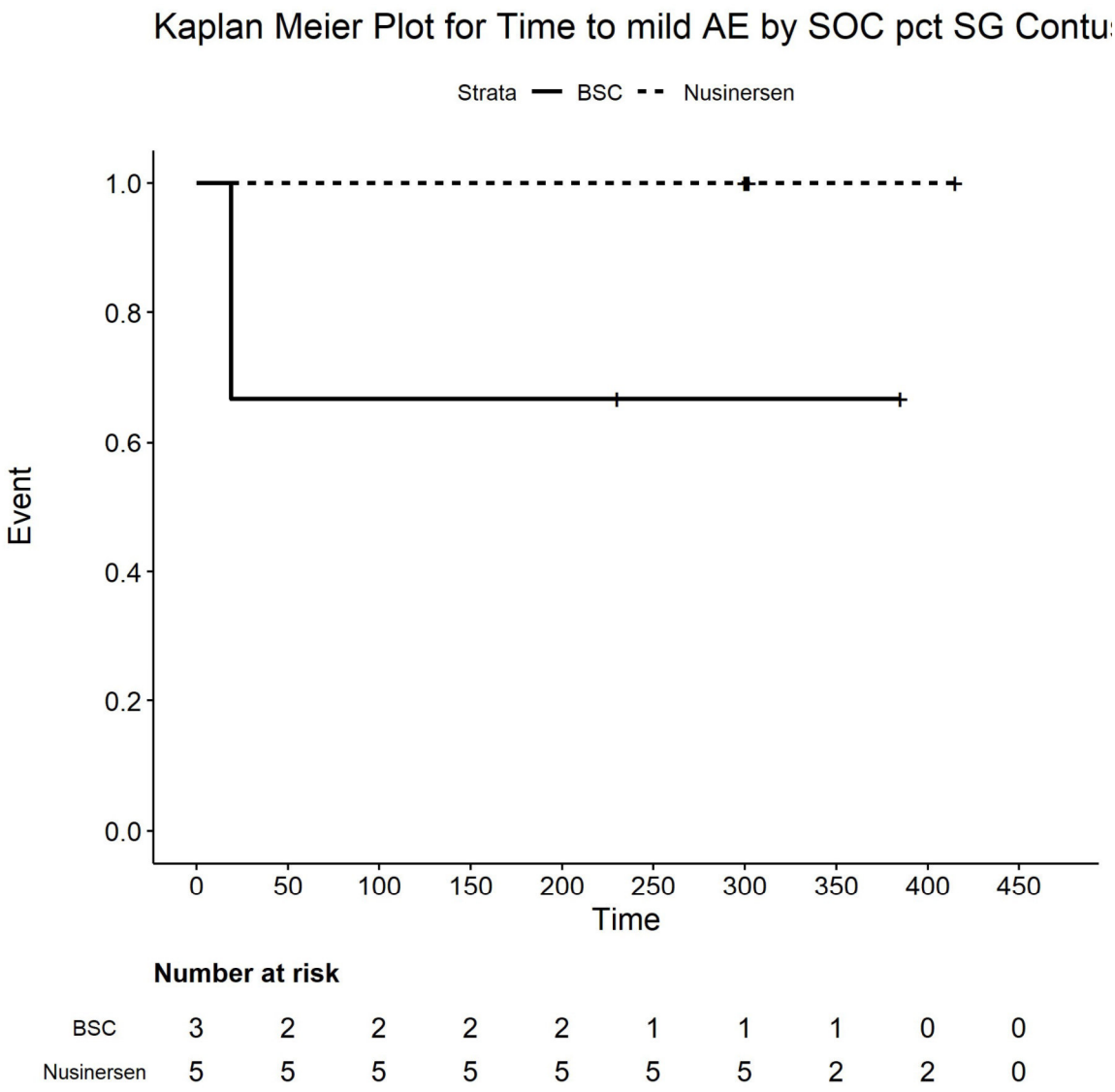
Number at risk

BSC	5	5	5	5	4	3	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	2	0



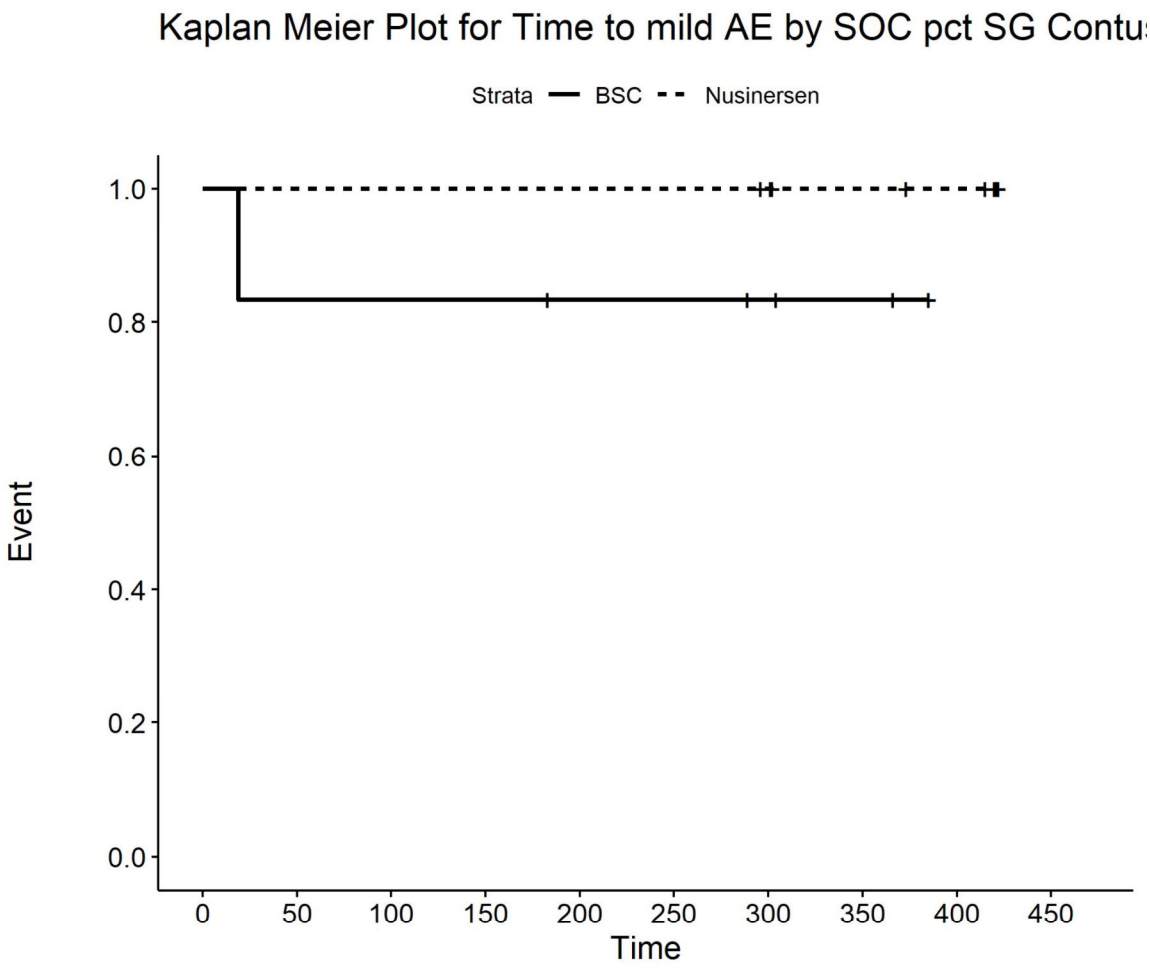
Number at risk

BSC	3	2	2	2	2	1	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



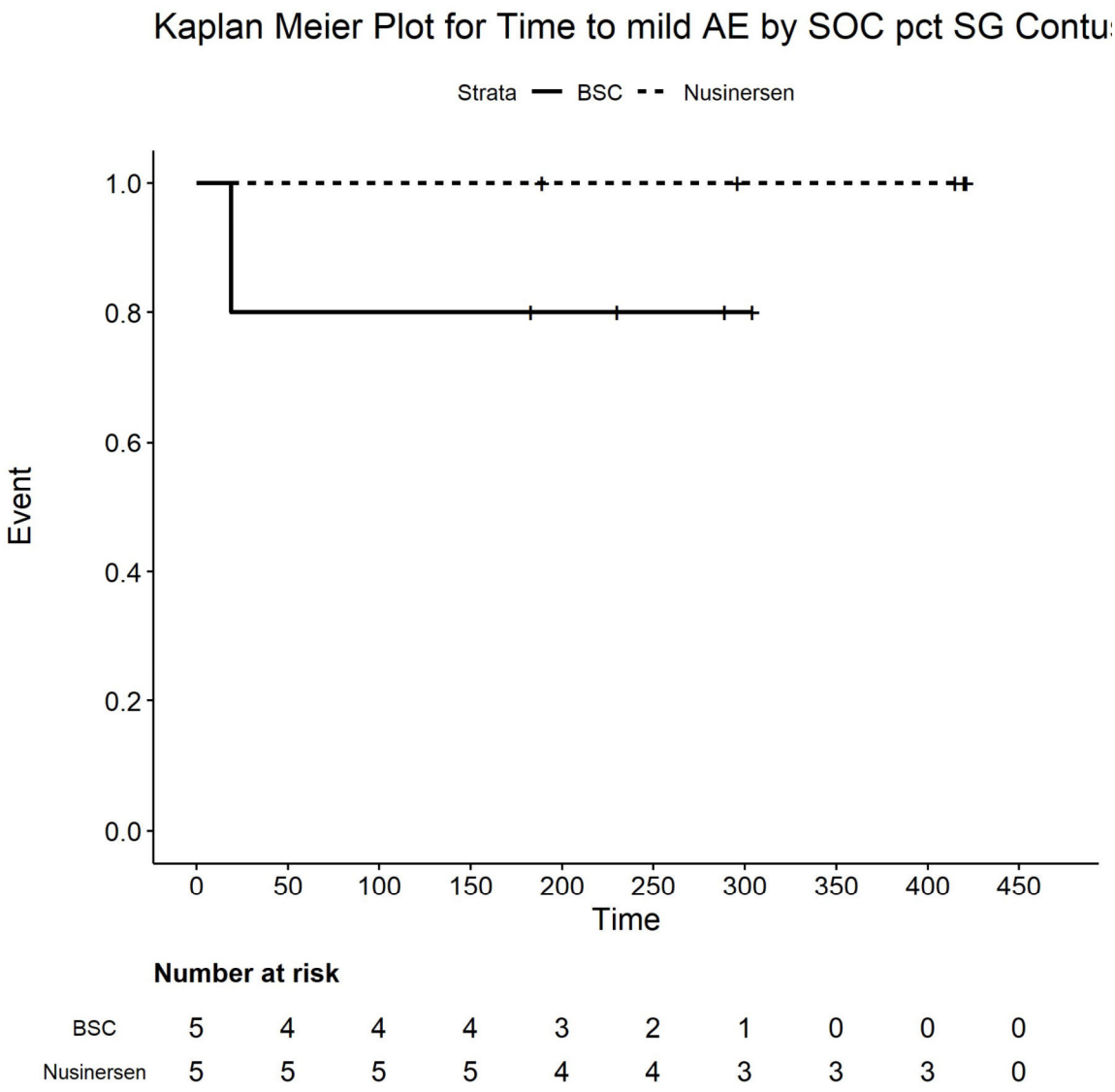
Number at risk

BSC	3	2	2	2	2	1	1	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



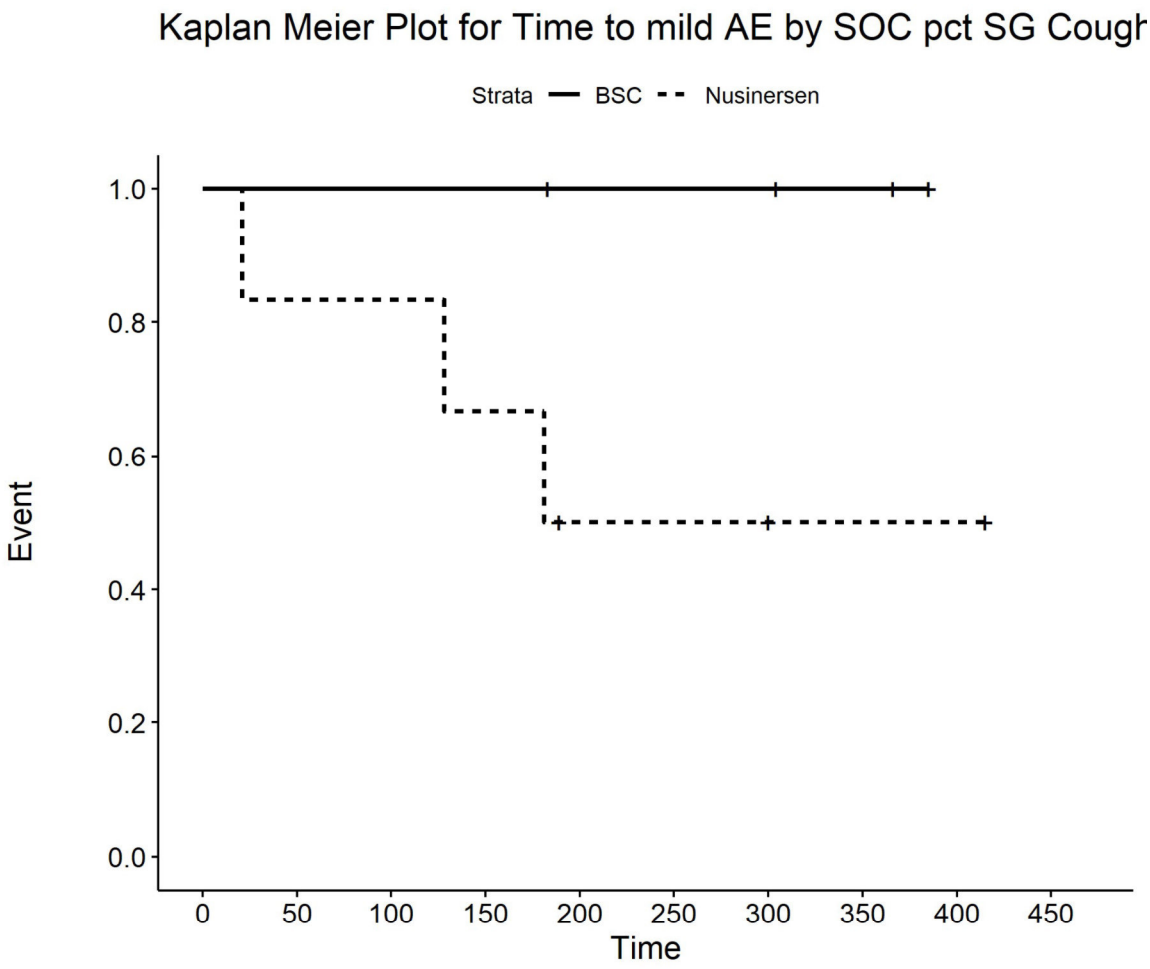
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



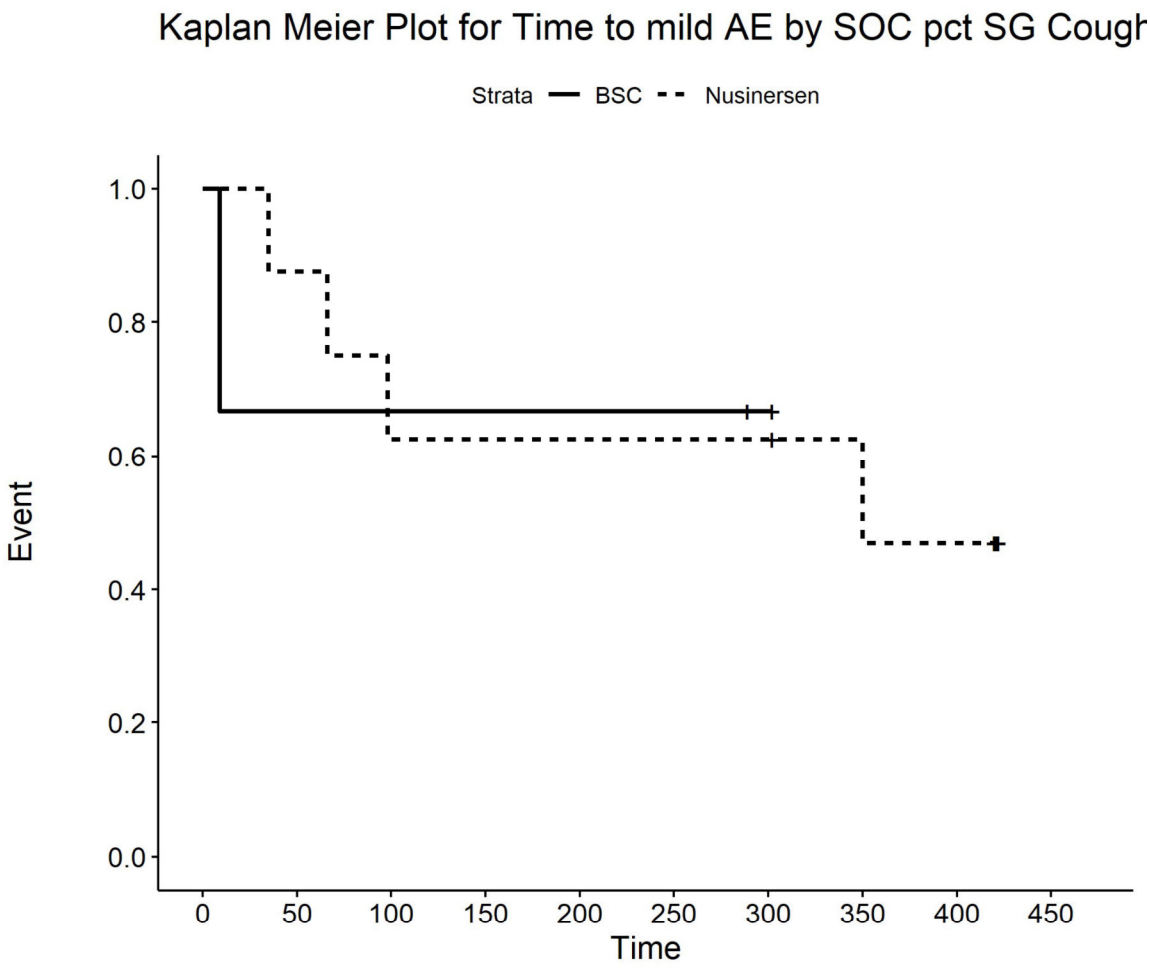
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



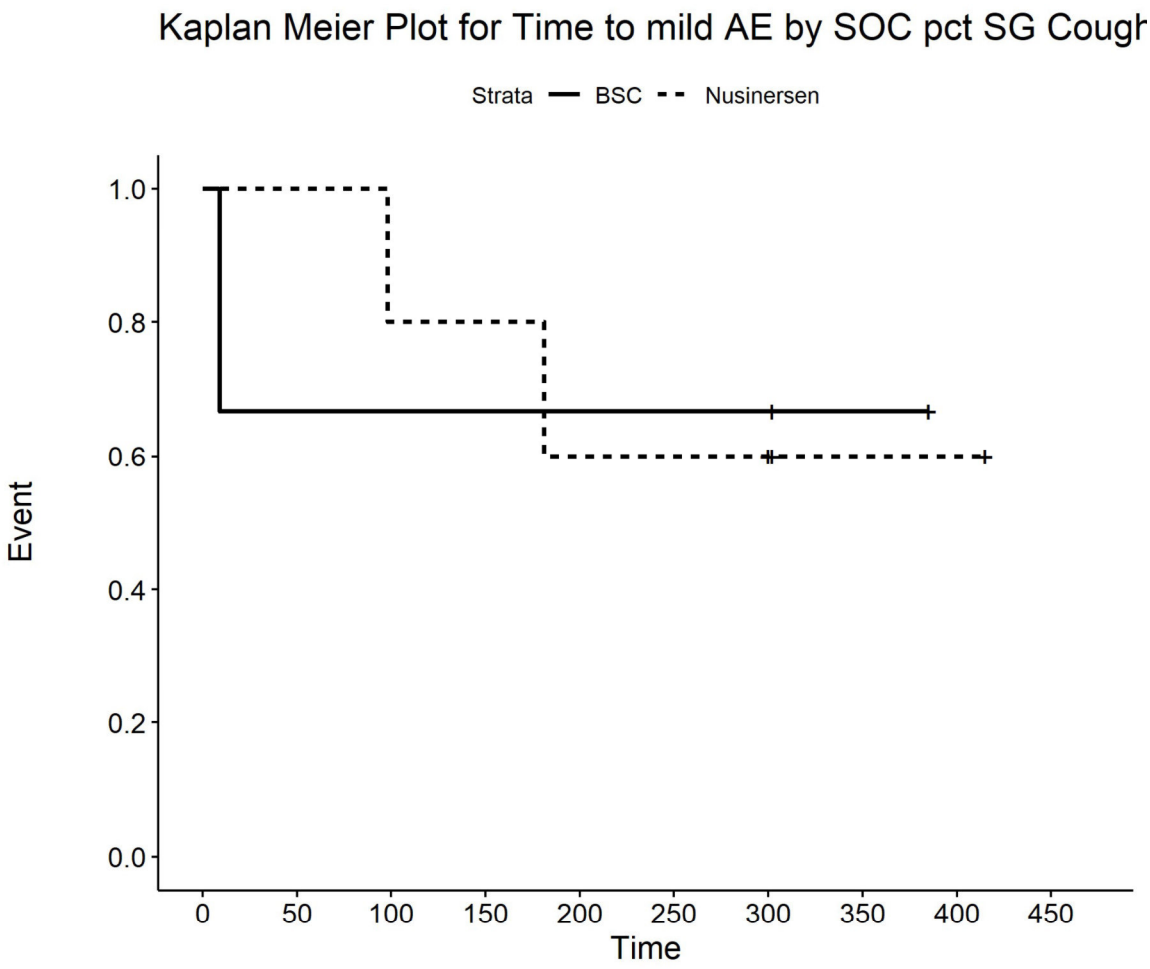
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	4	2	2	2	1	1	0



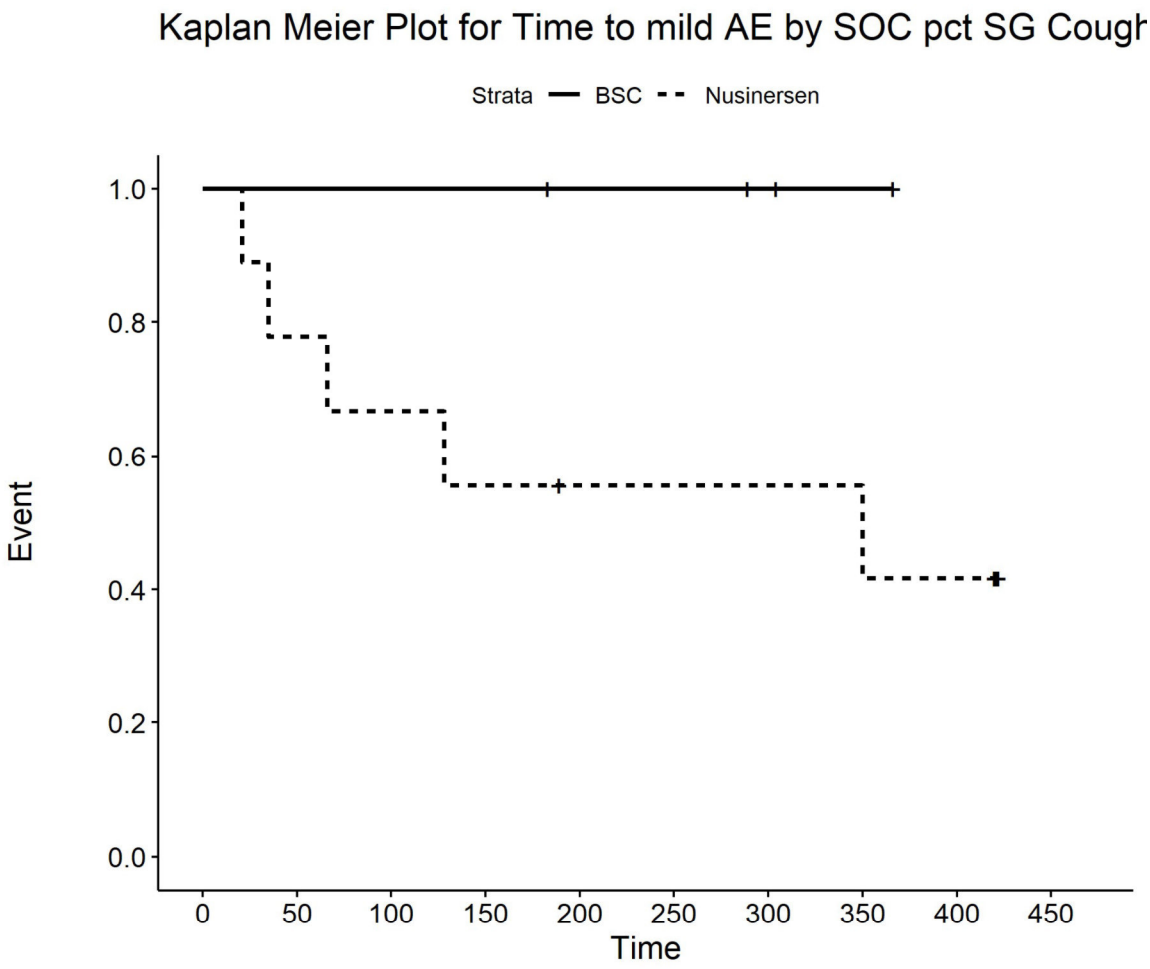
Number at risk

BSC	3	2	2	2	2	2	1	0	0	0
Nusinersen	8	7	5	5	5	5	5	4	3	0



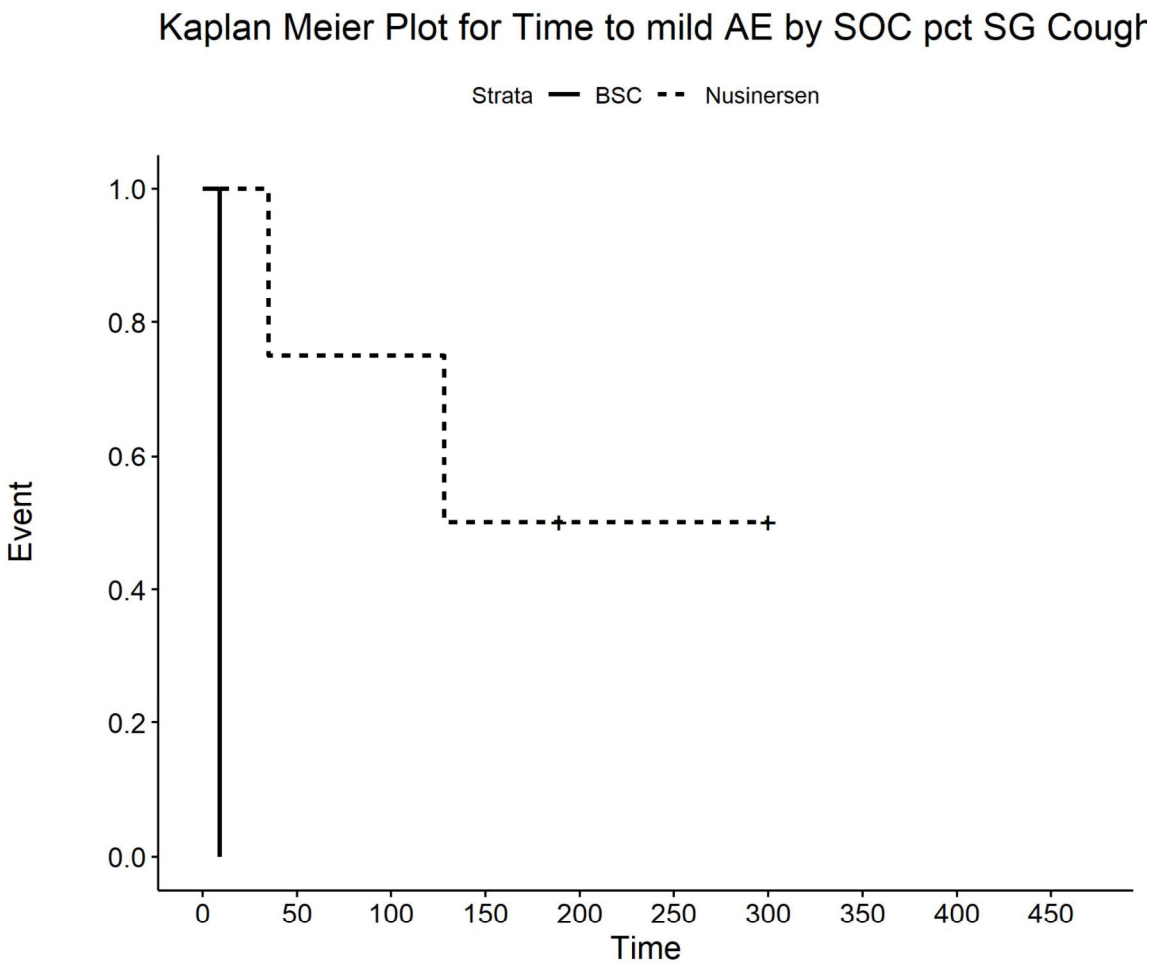
Number at risk

BSC	3	2	2	2	2	2	2	1	0	0
Nusinersen	5	5	4	4	3	3	3	1	1	0



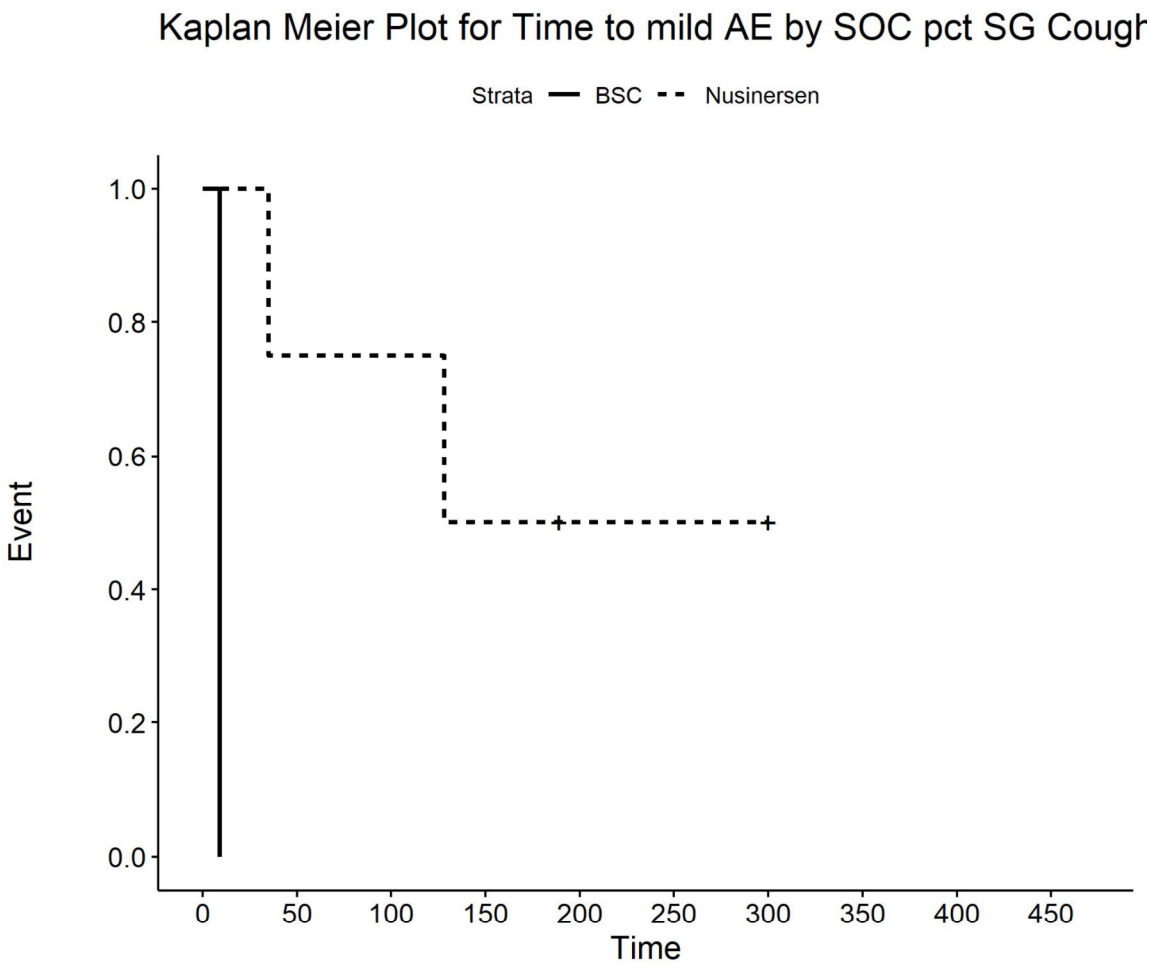
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	7	6	5	4	4	4	4	3	0



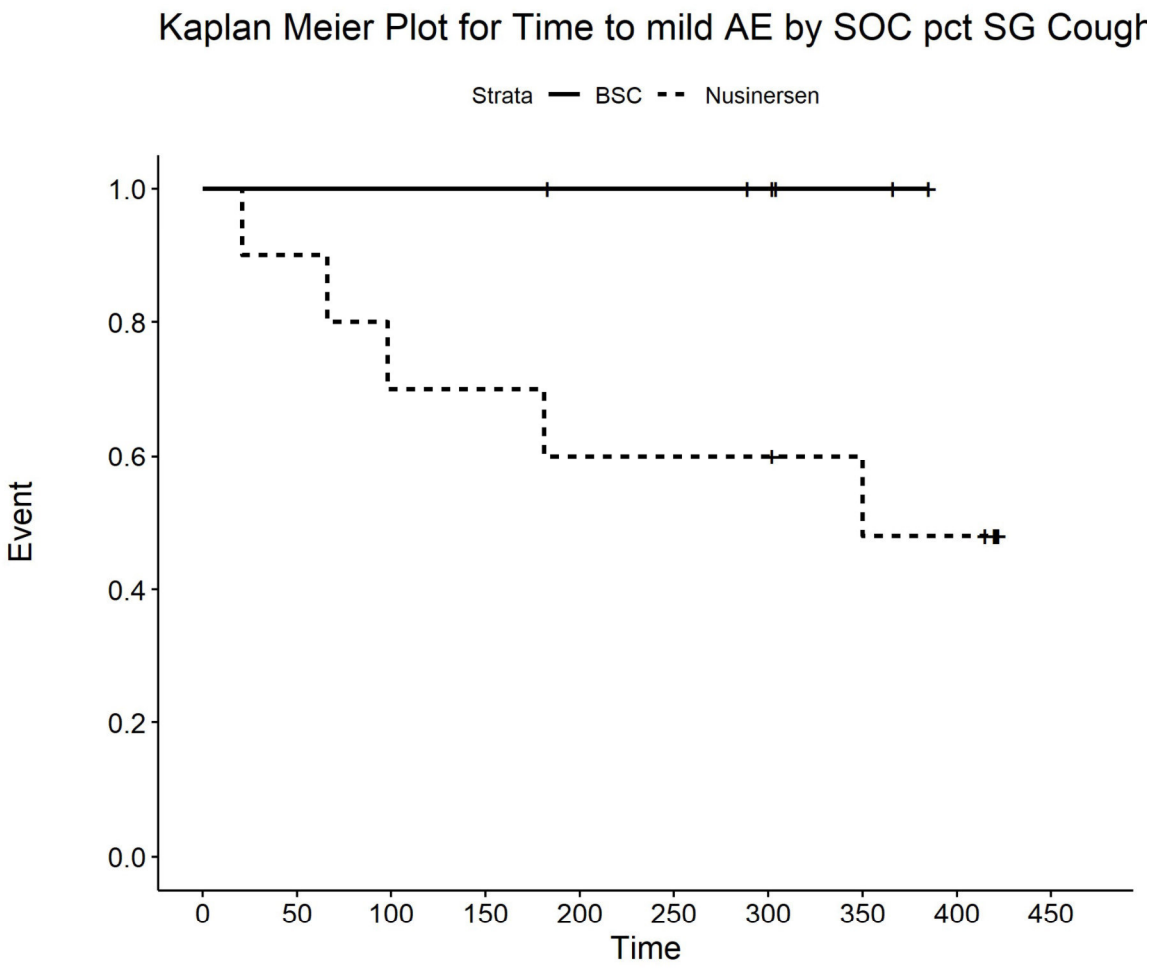
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



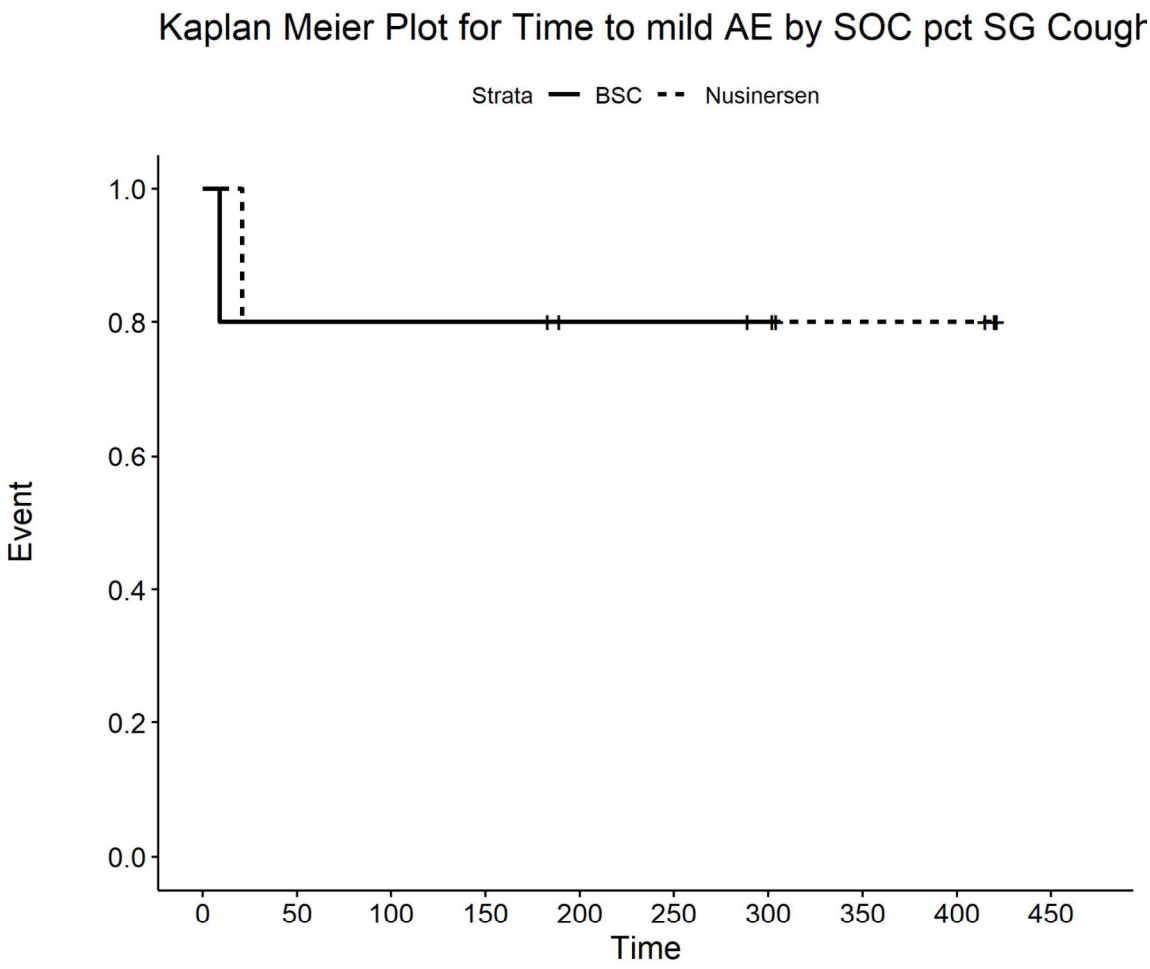
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



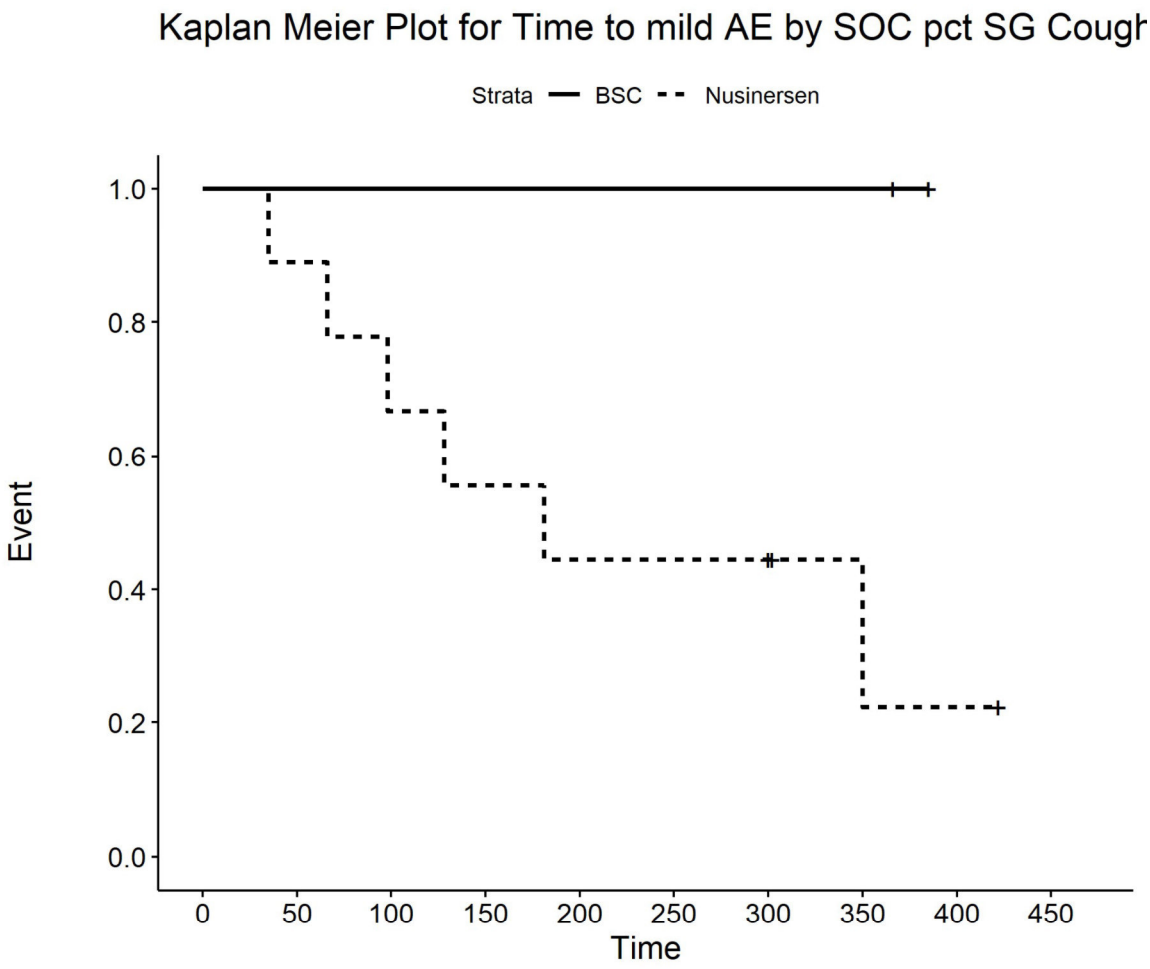
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	7	7	6	6	6	5	4	0



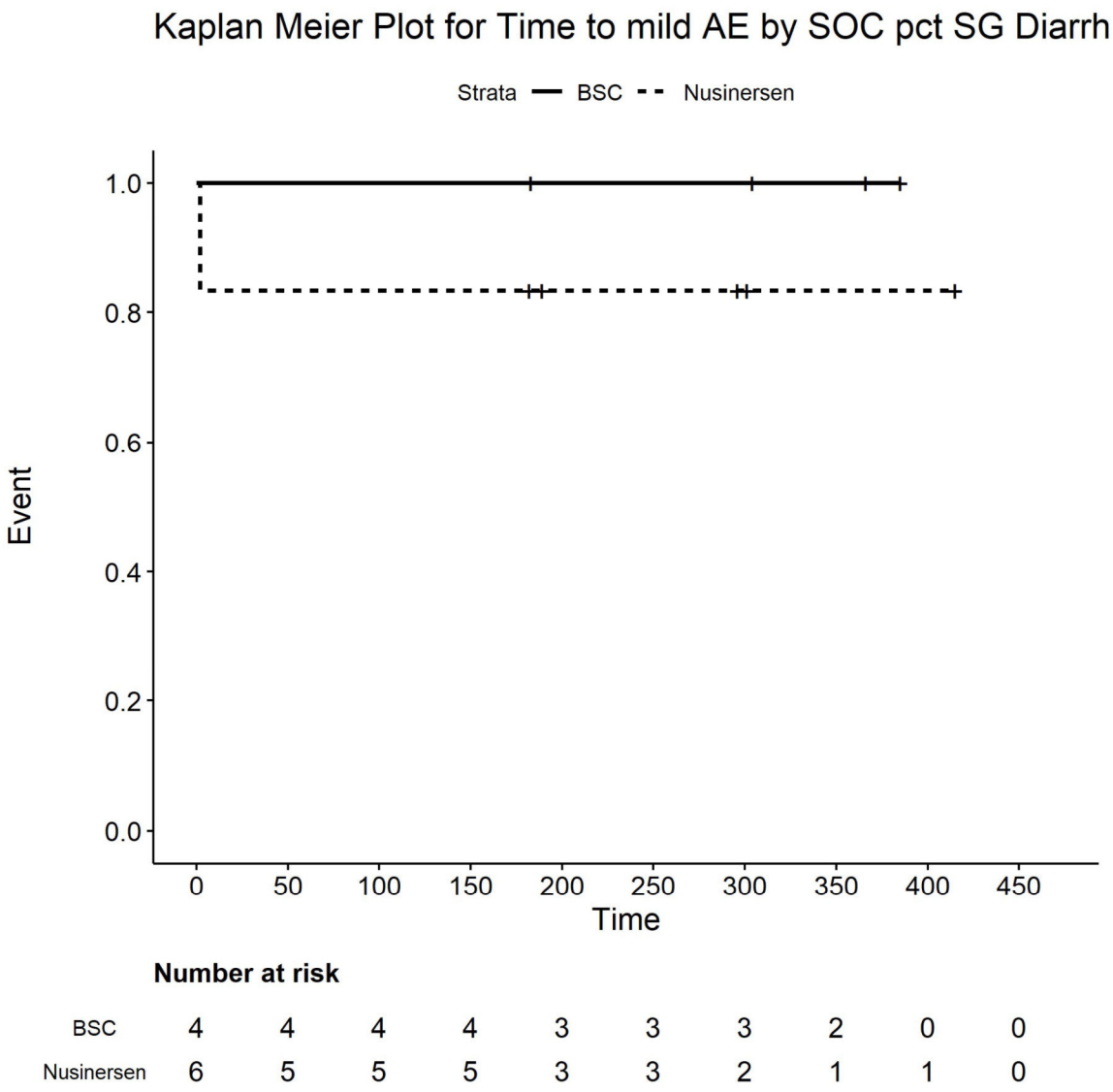
Number at risk

BSC	5	4	4	4	3	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	3	3	3	0



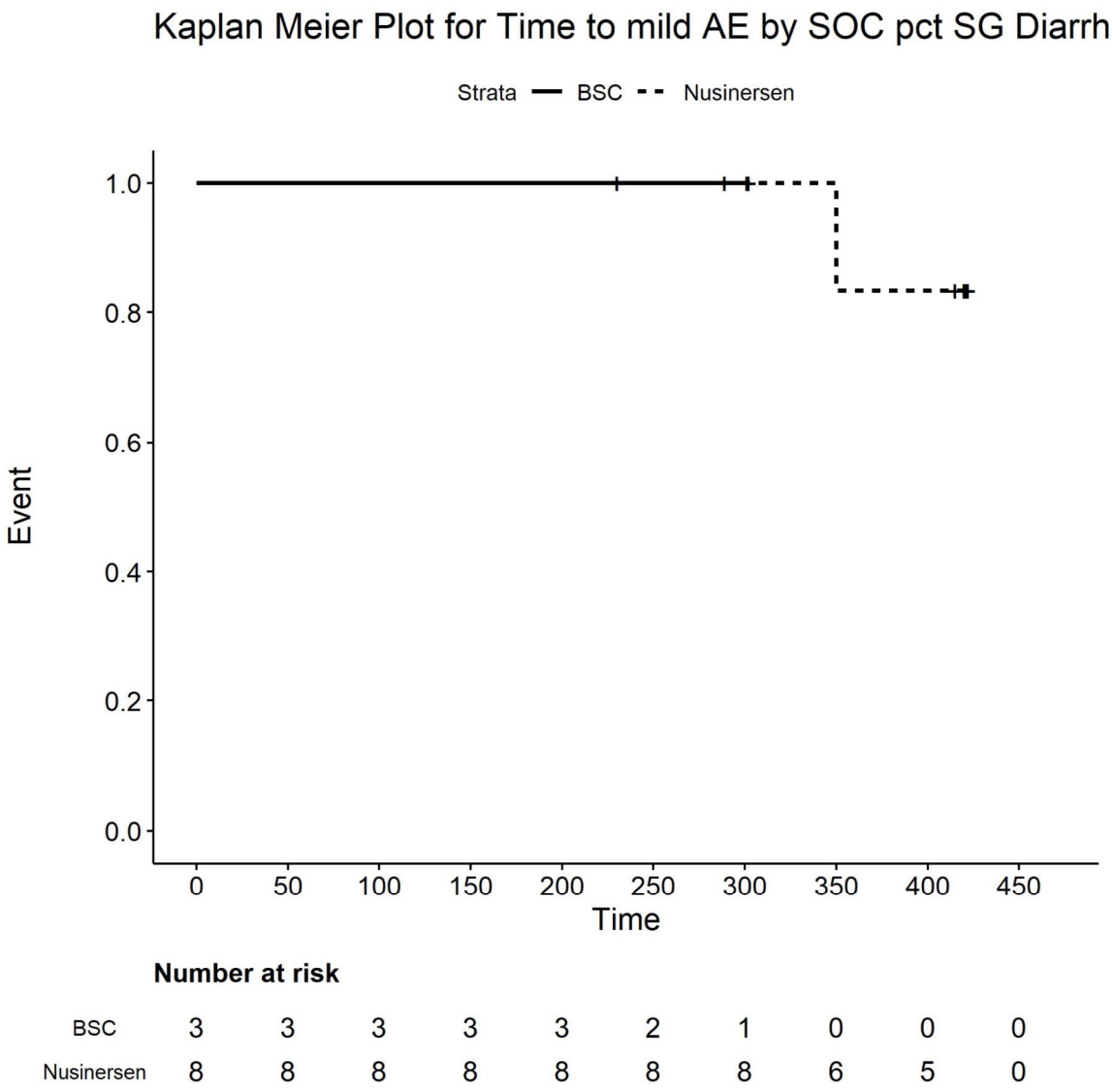
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	6	5	4	4	4	2	1	0



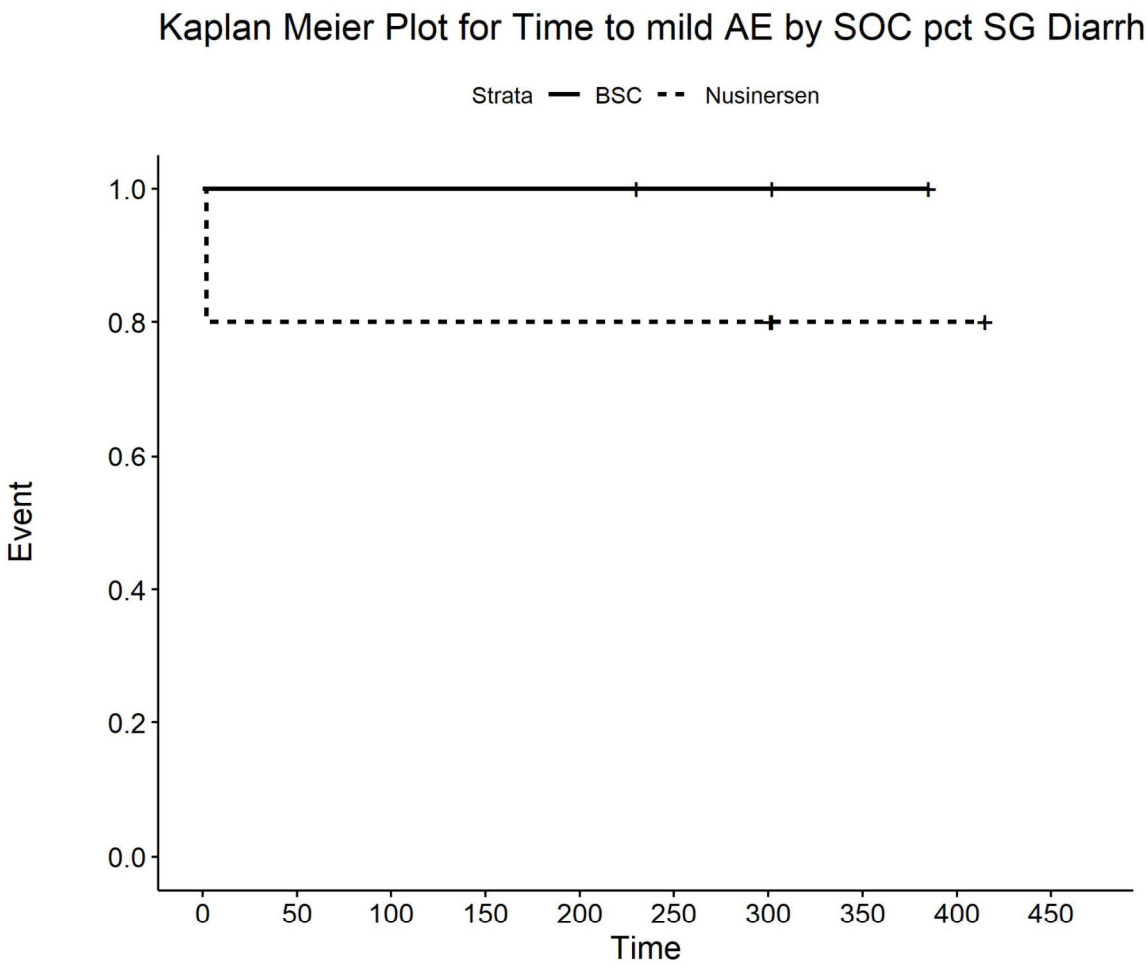
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	2	1	1	0



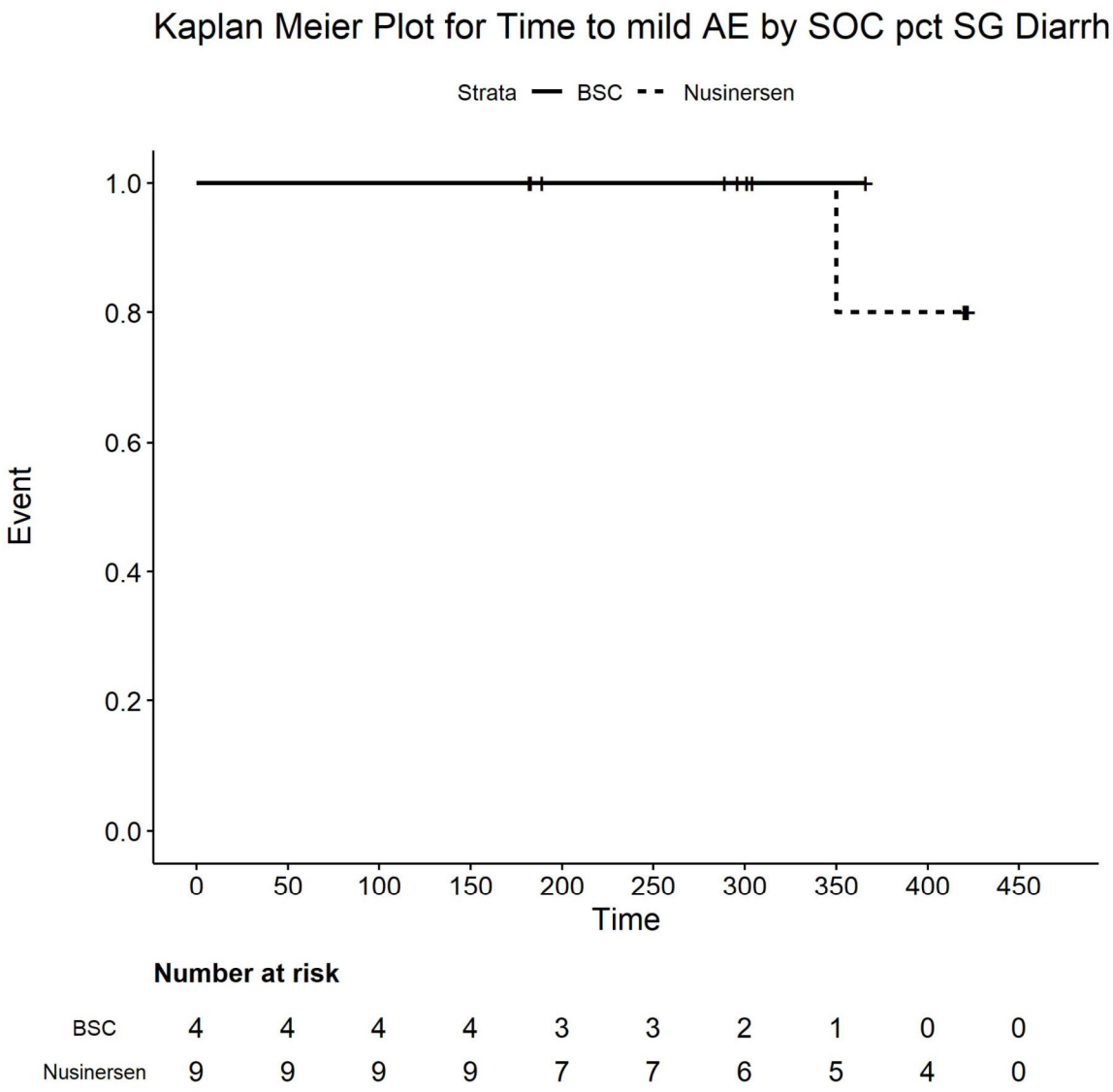
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



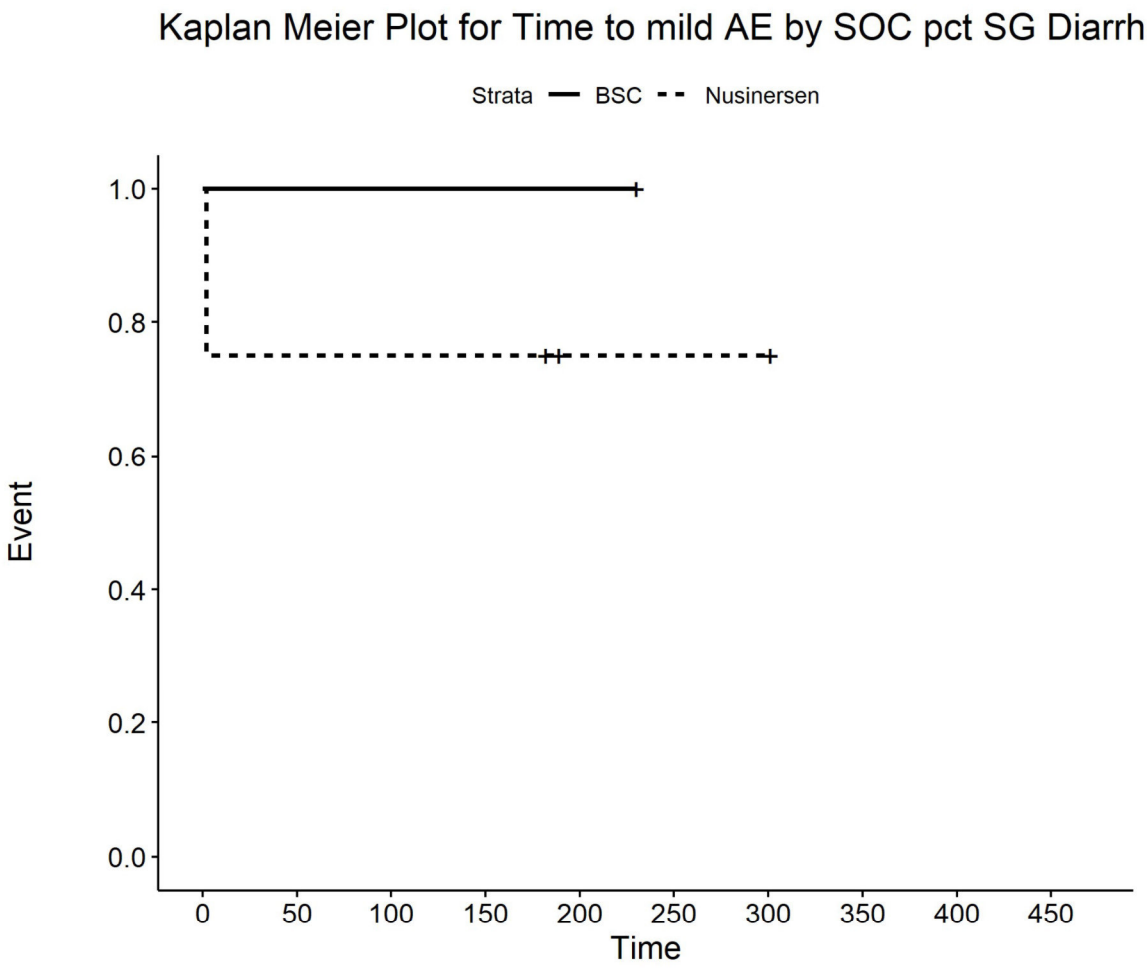
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



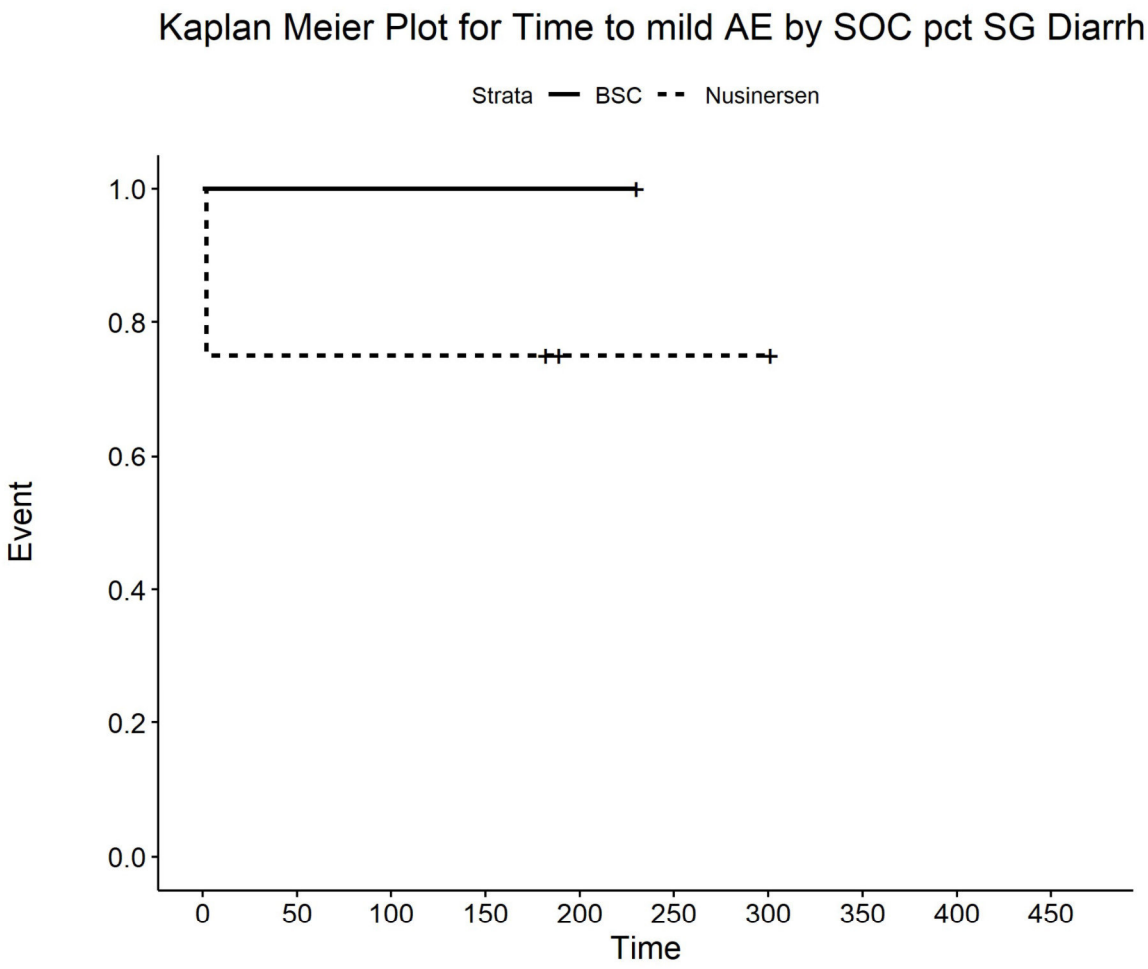
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



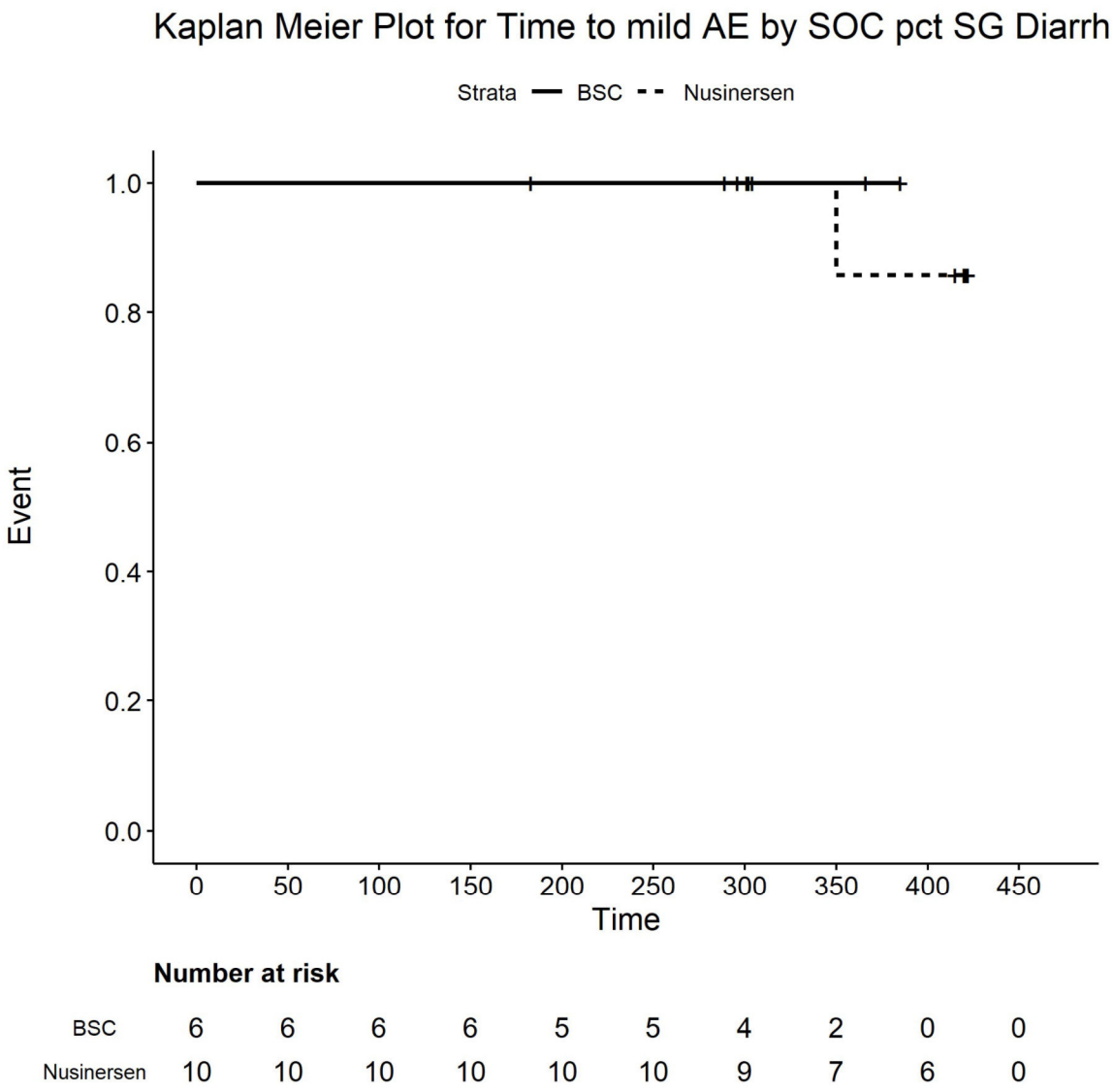
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



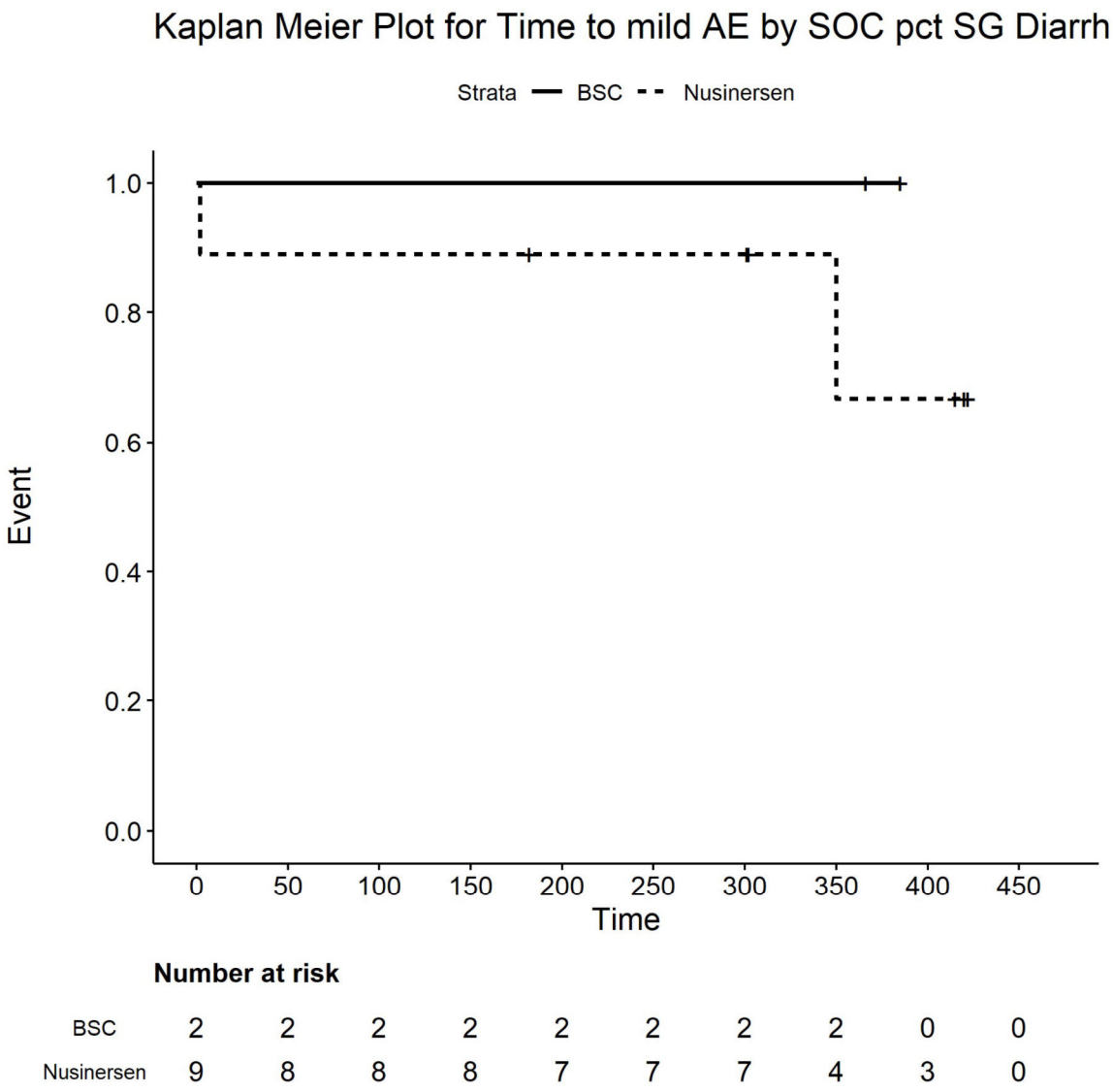
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



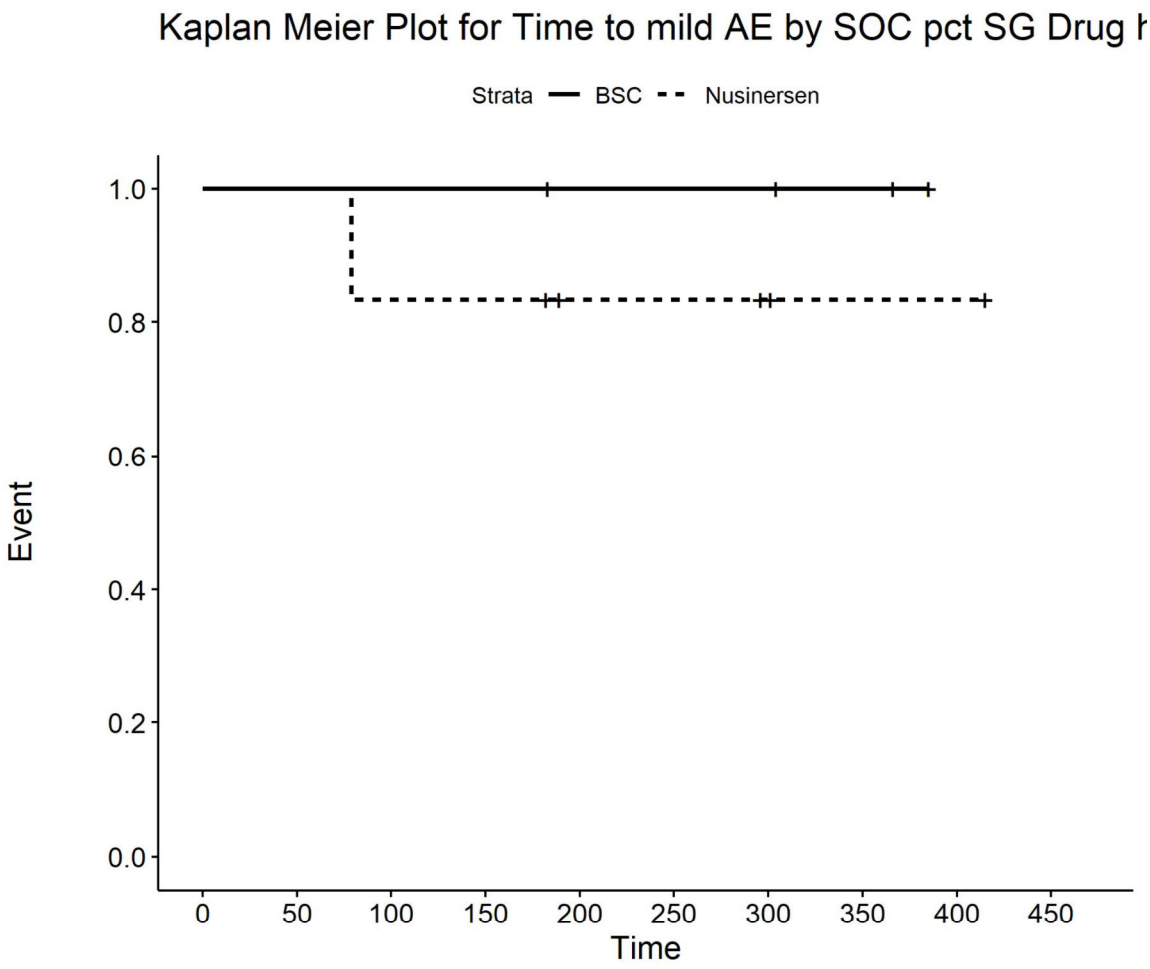
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



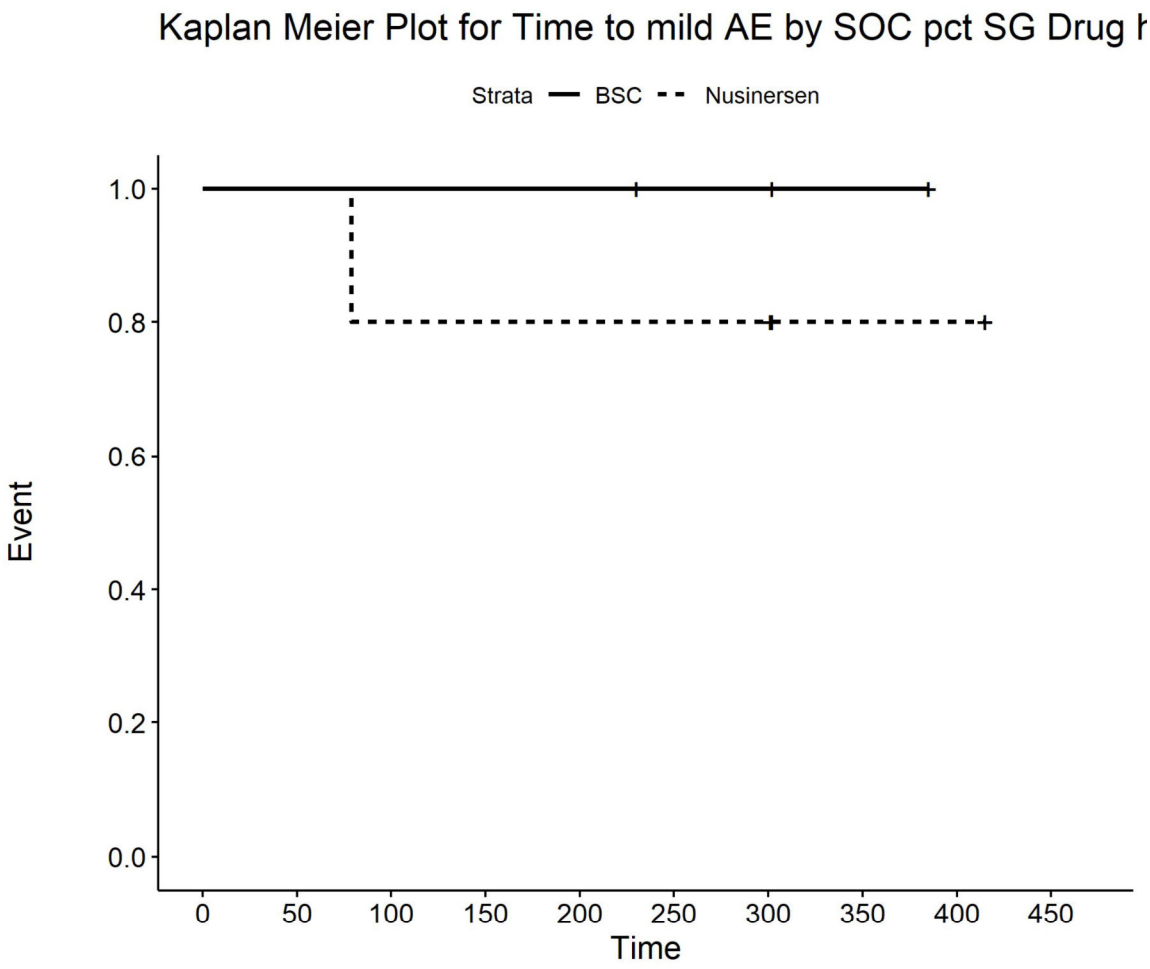
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



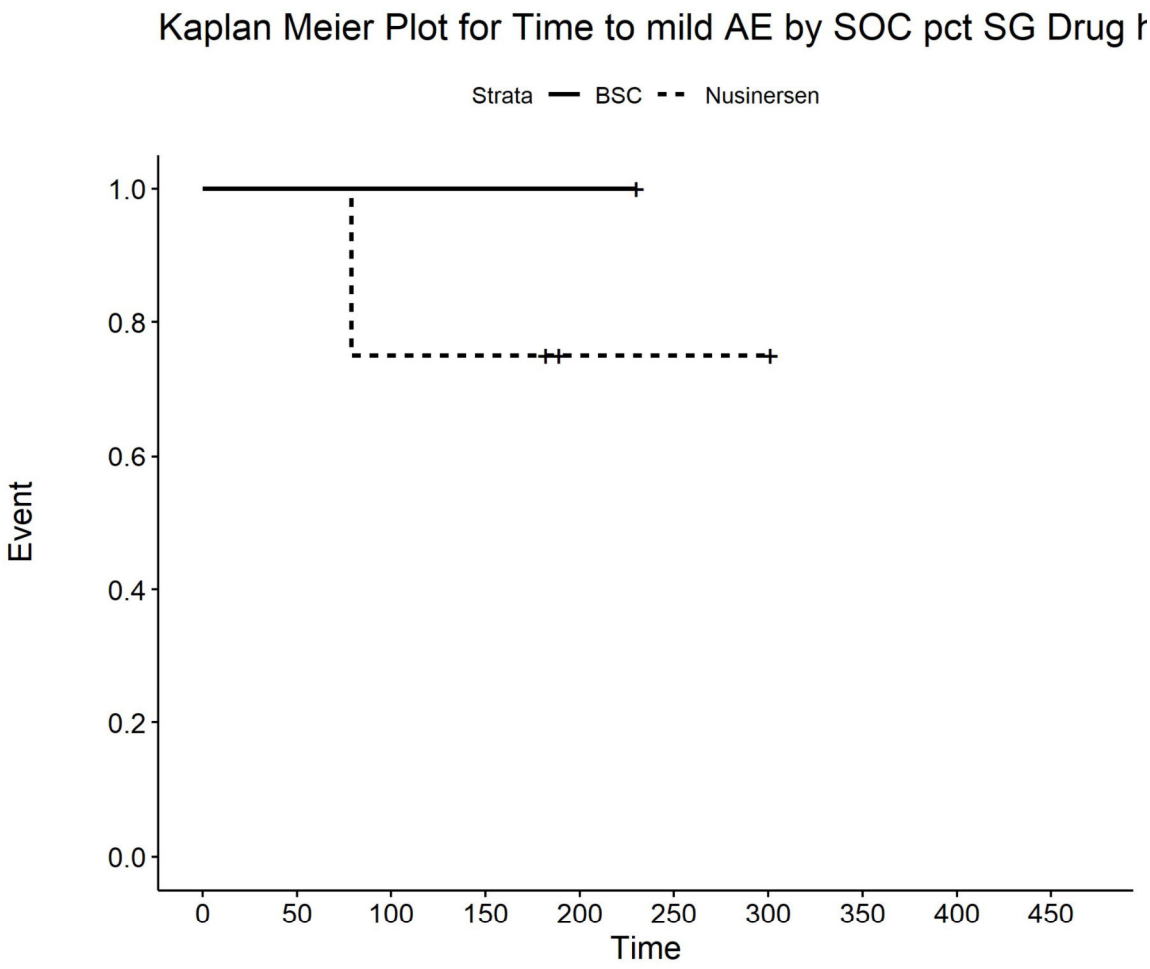
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



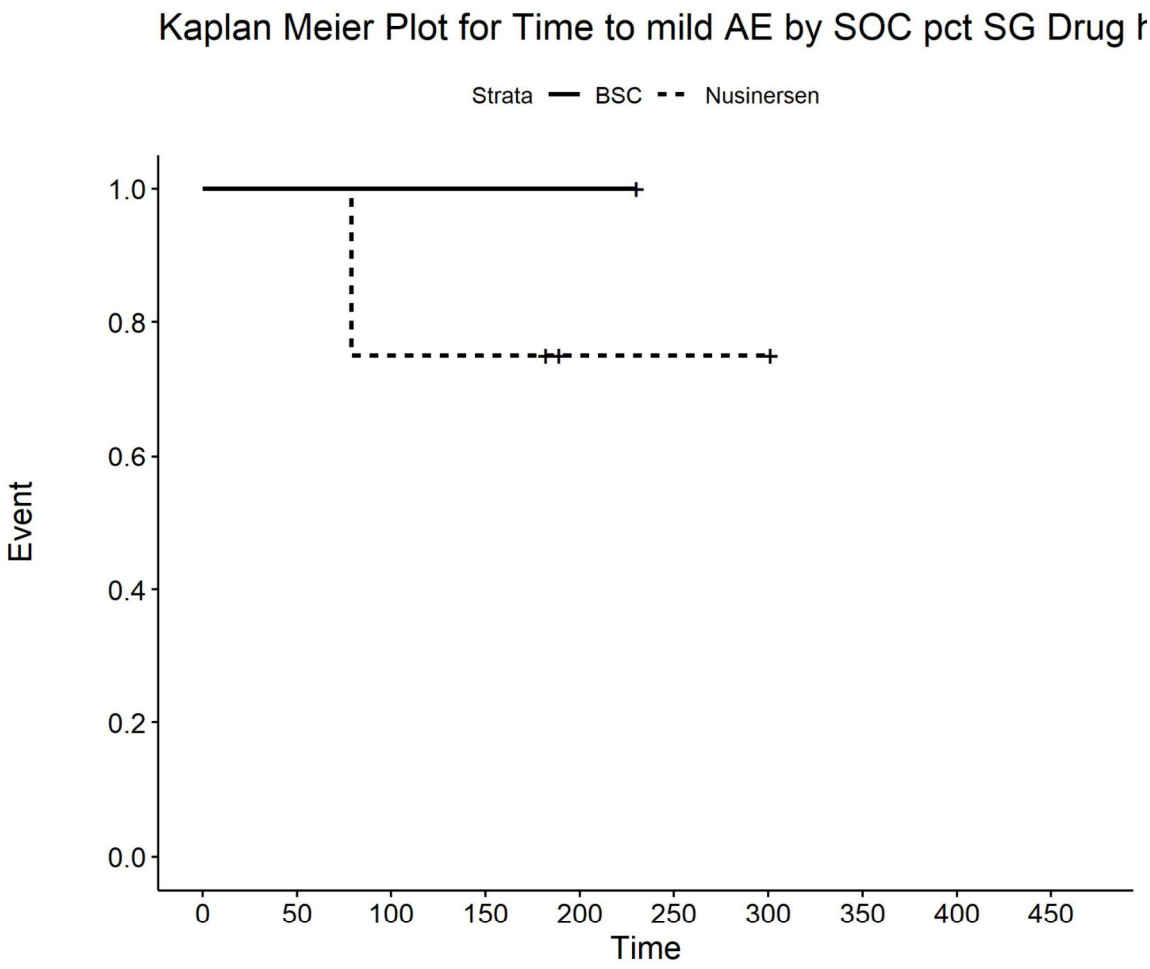
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



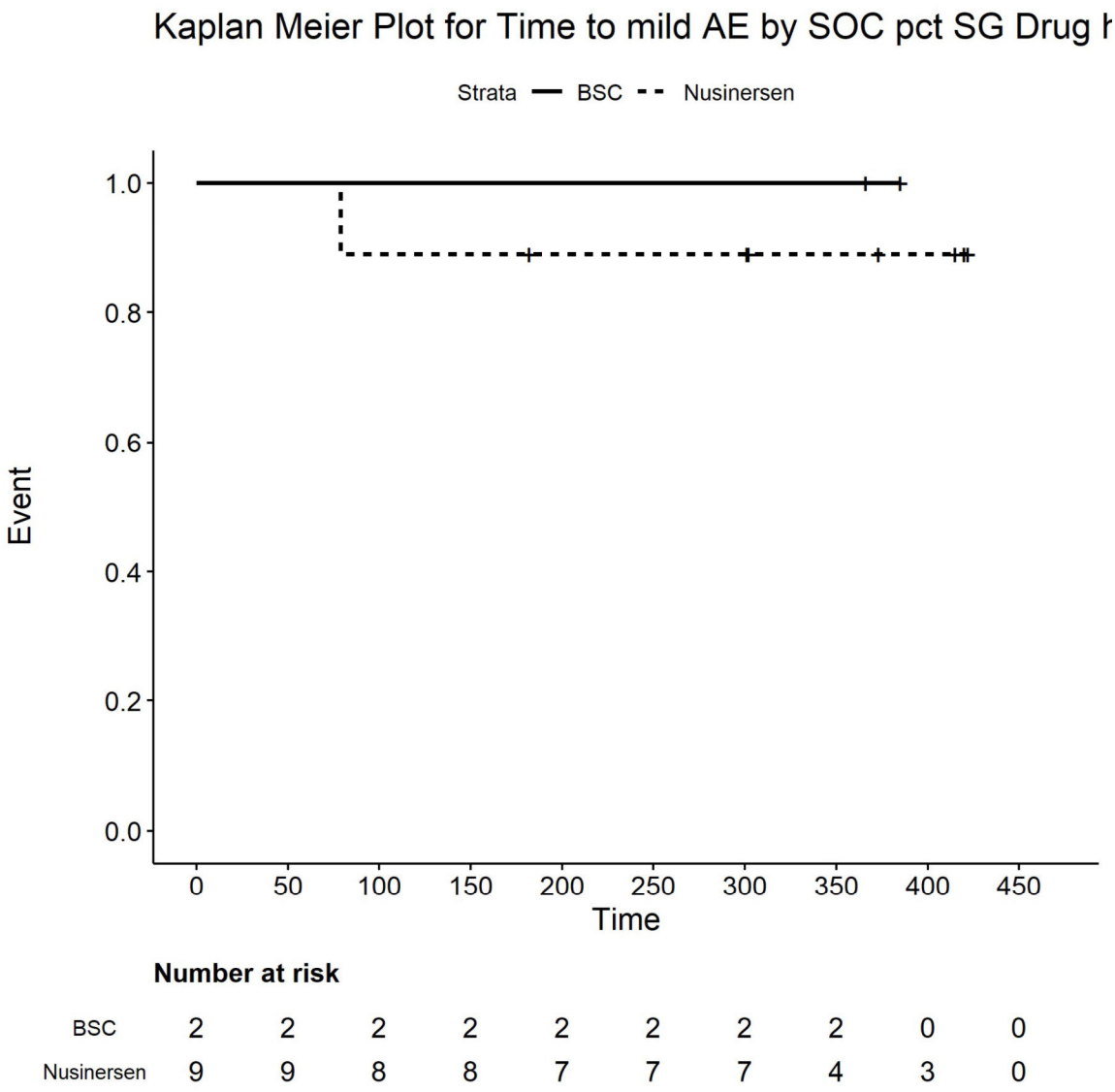
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



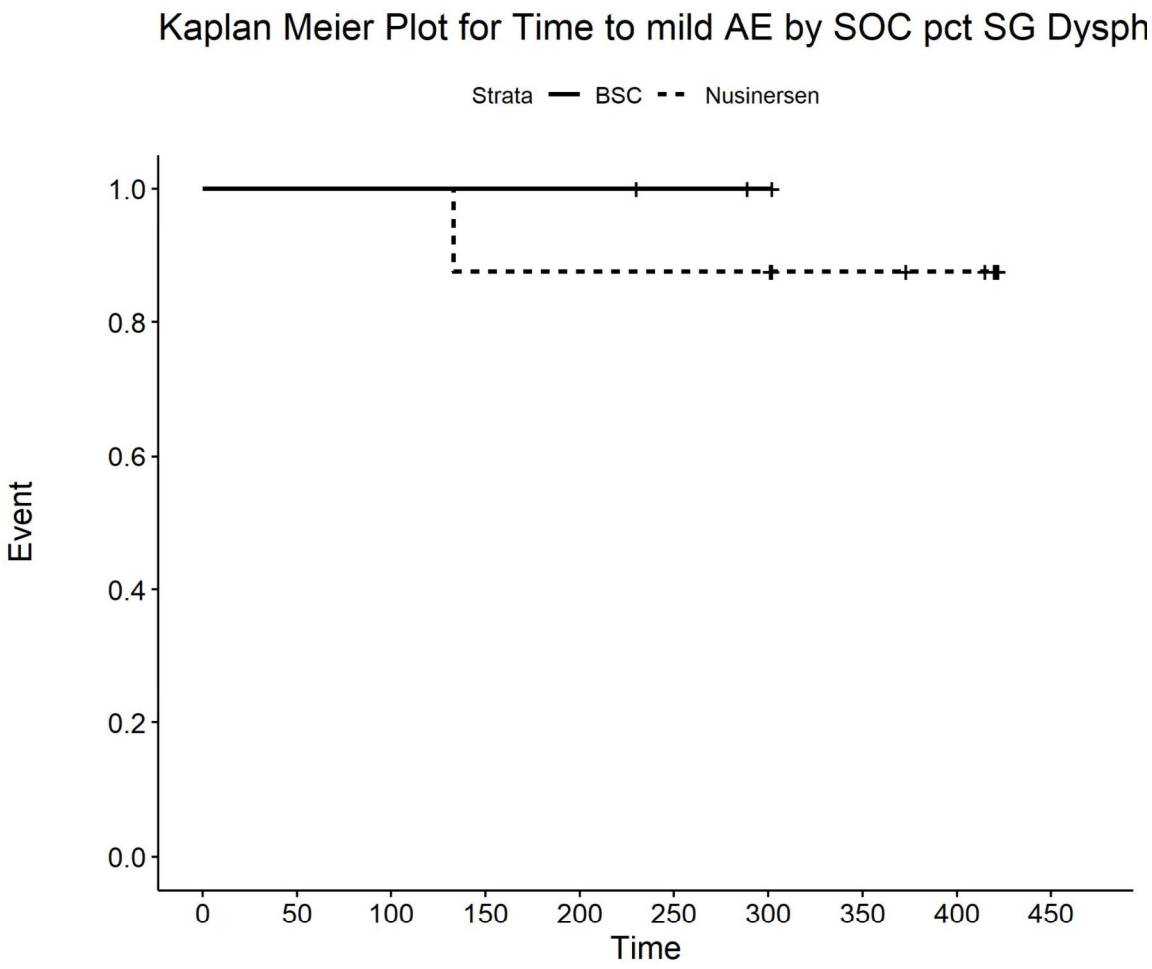
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



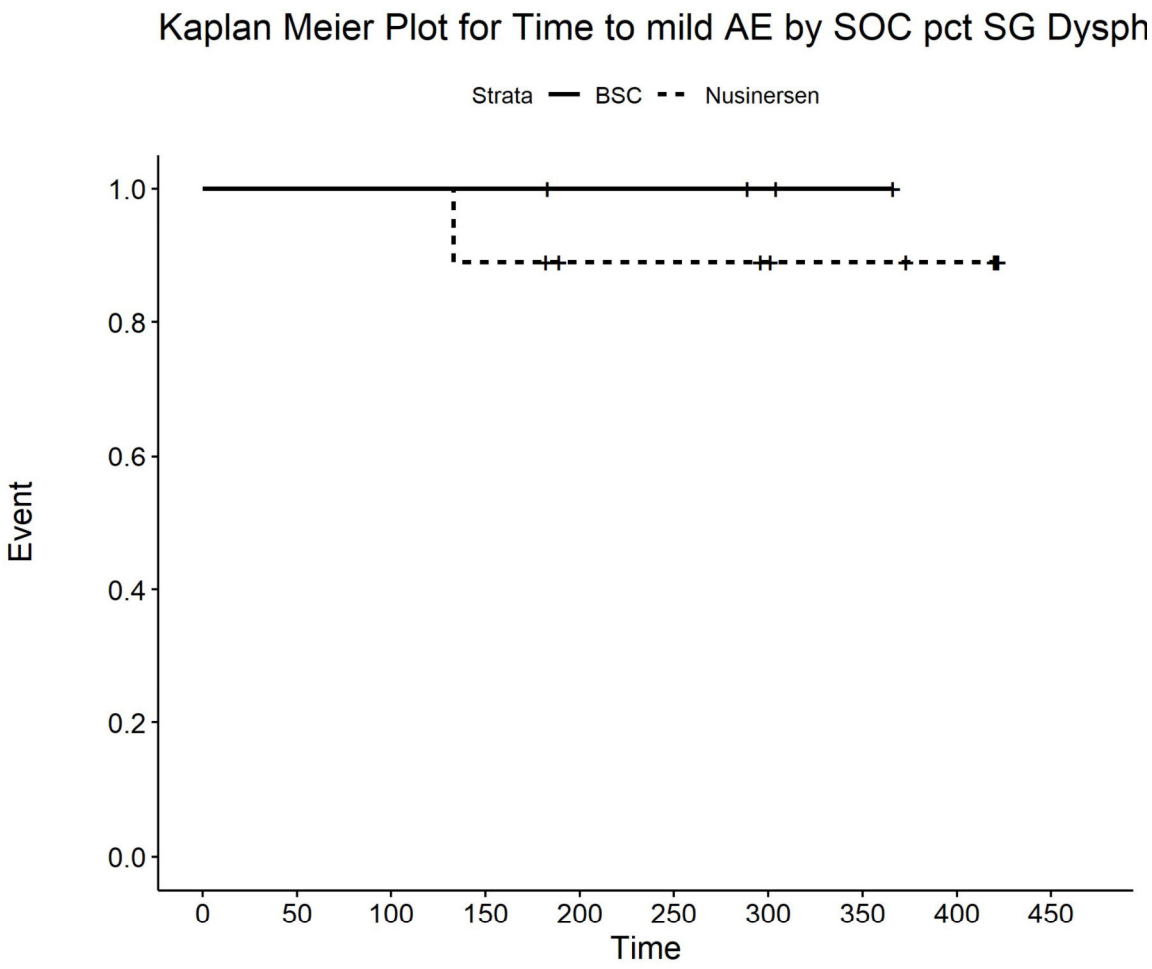
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



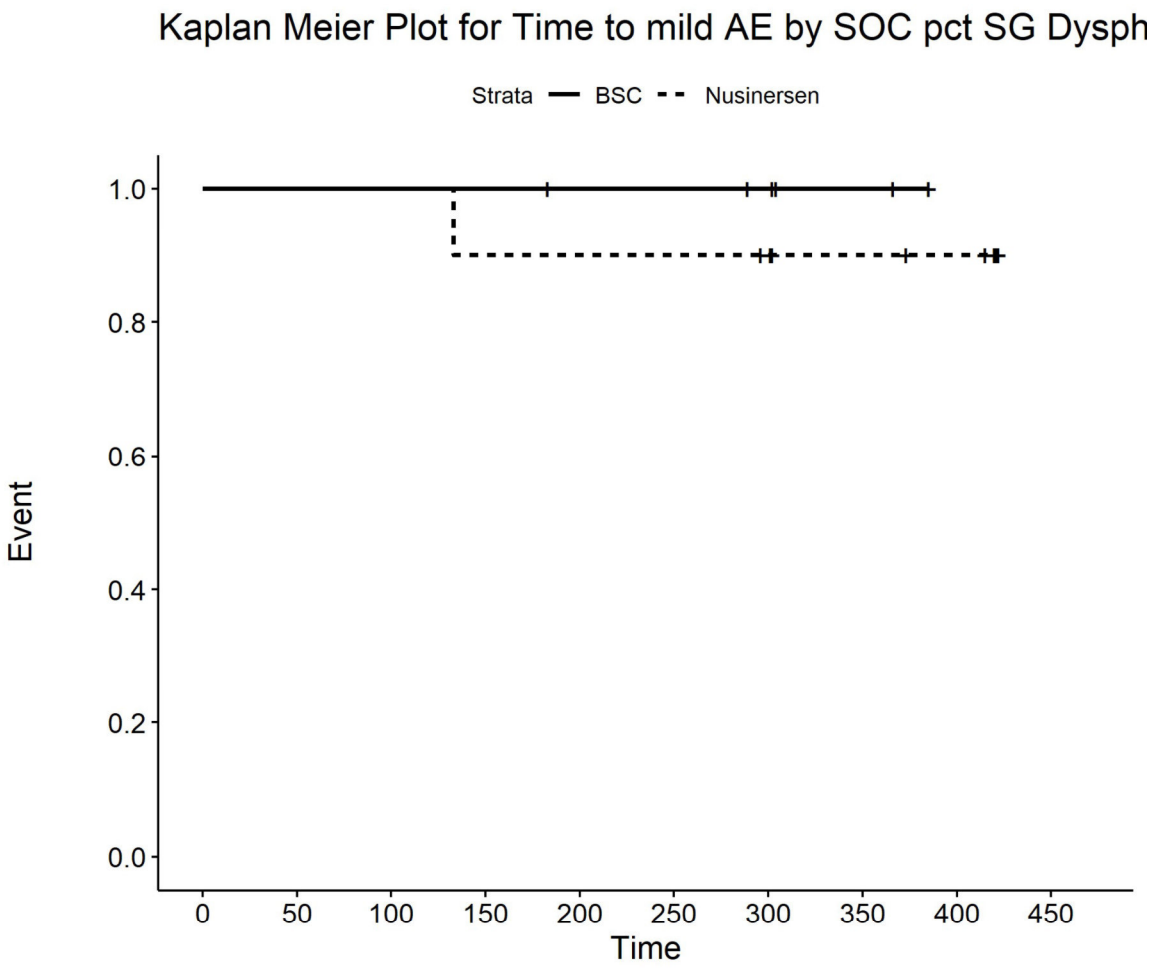
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



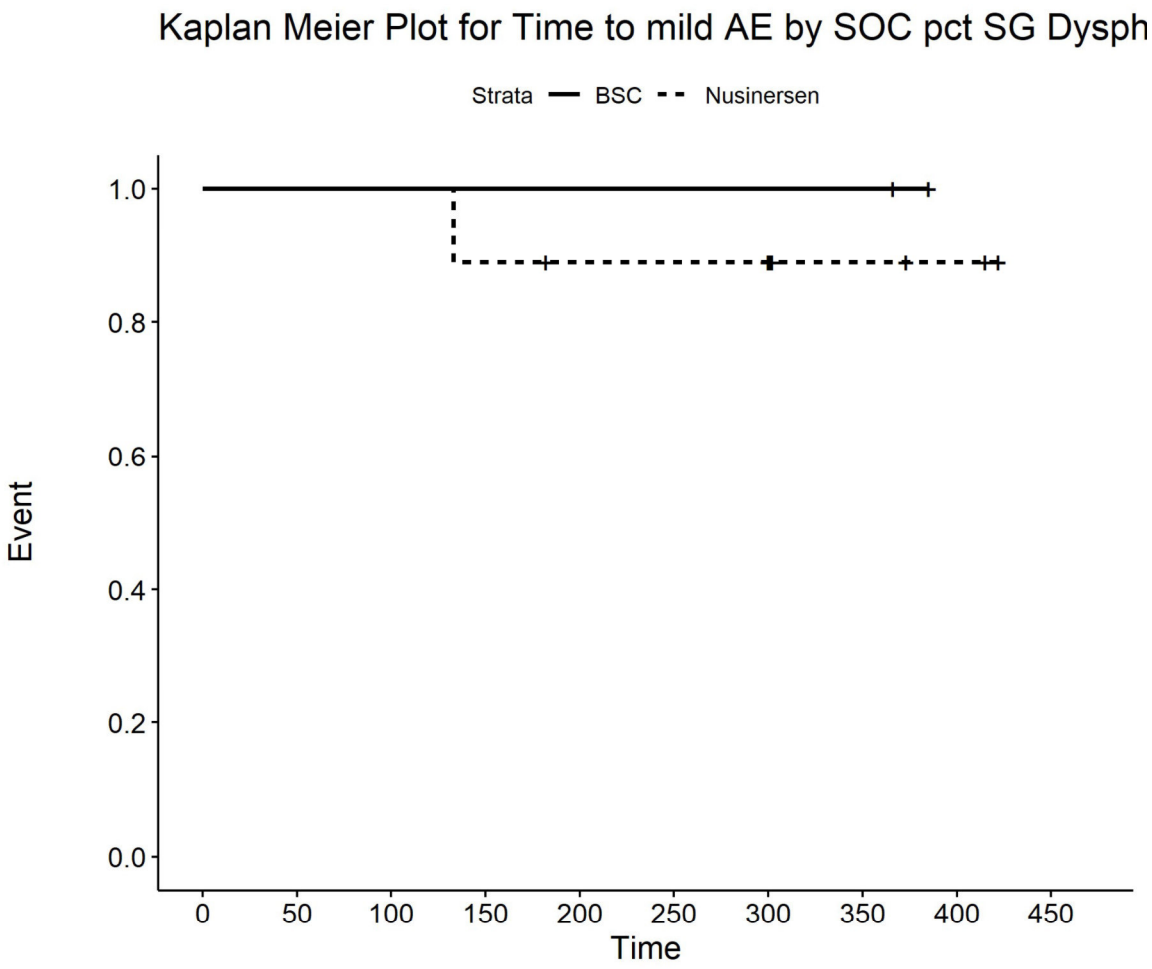
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



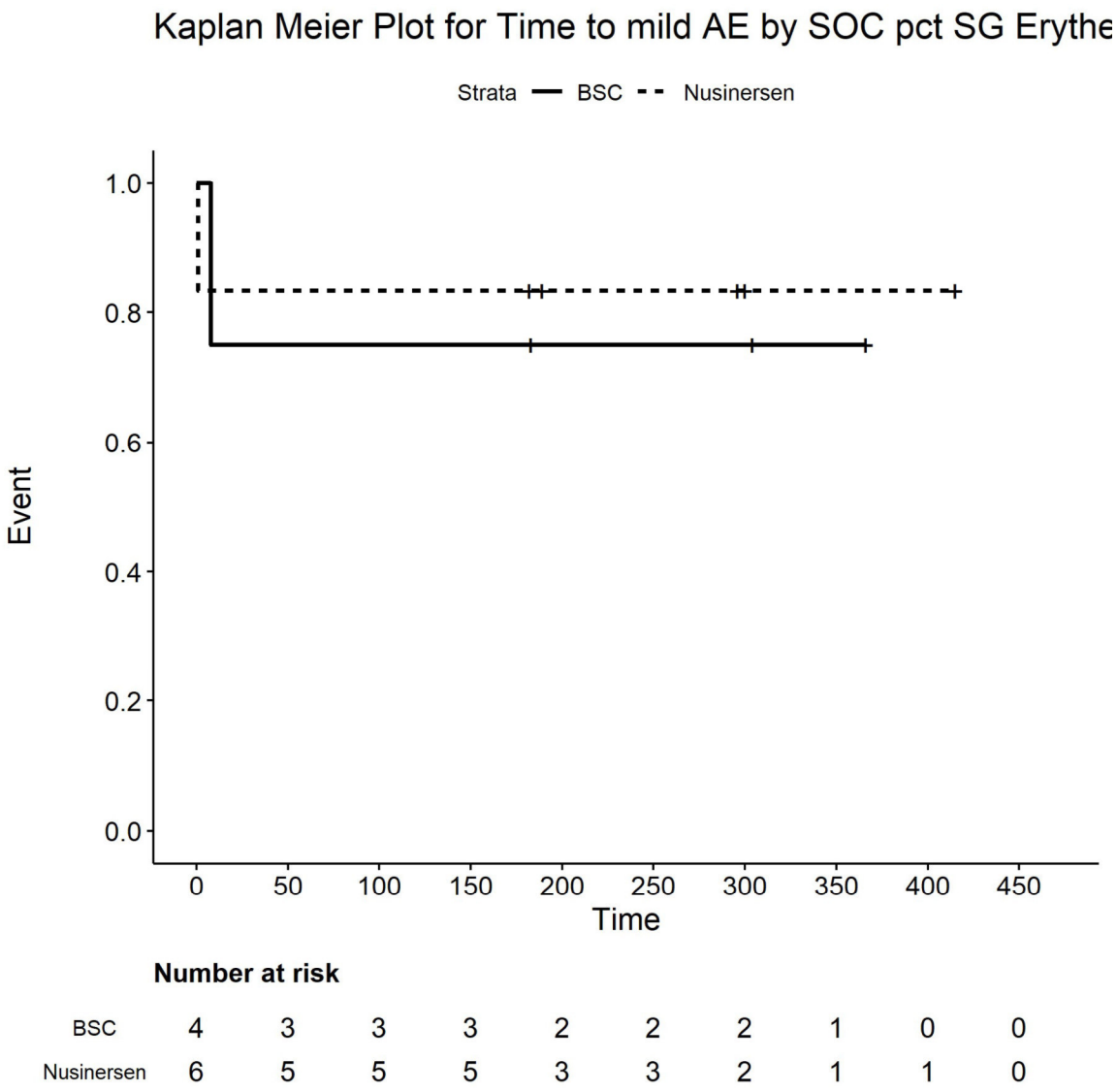
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



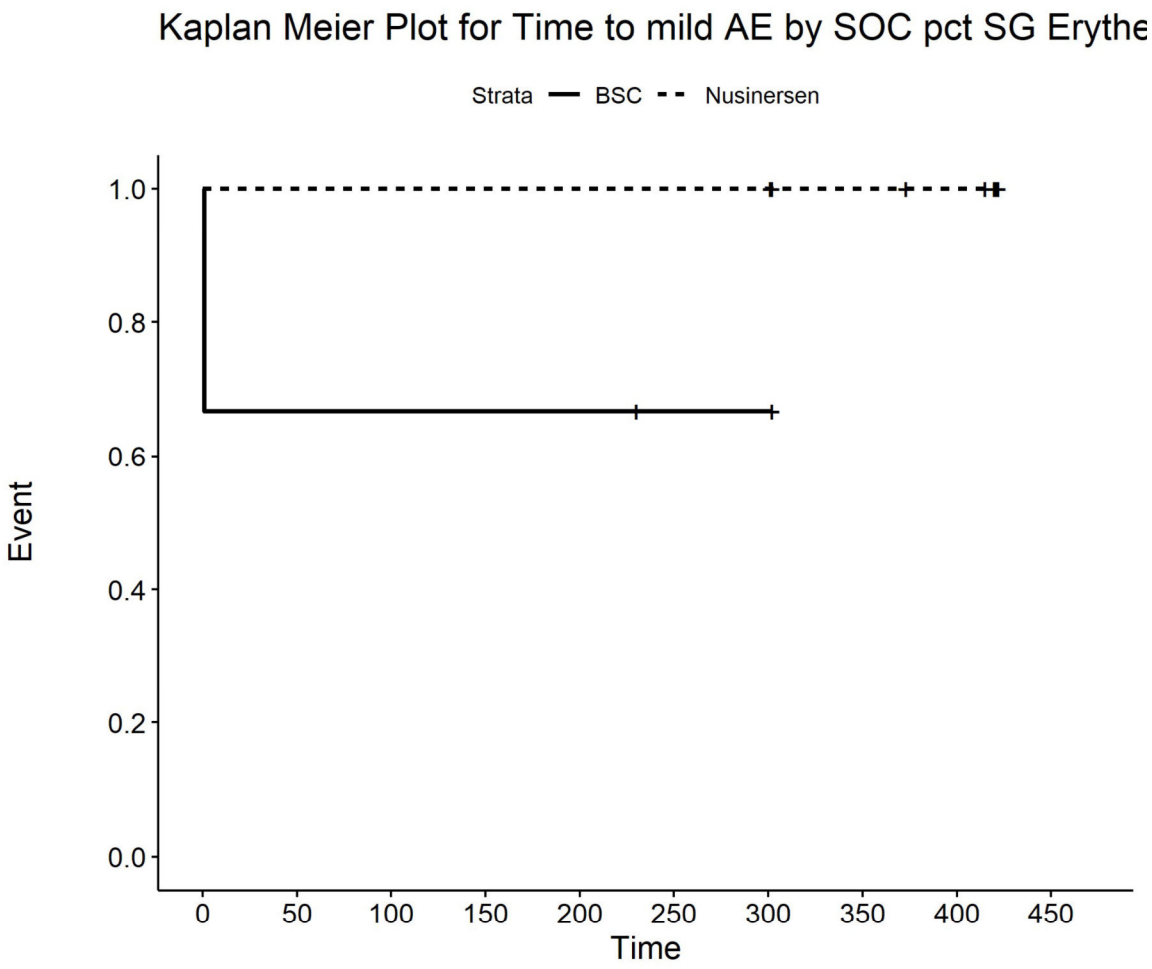
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



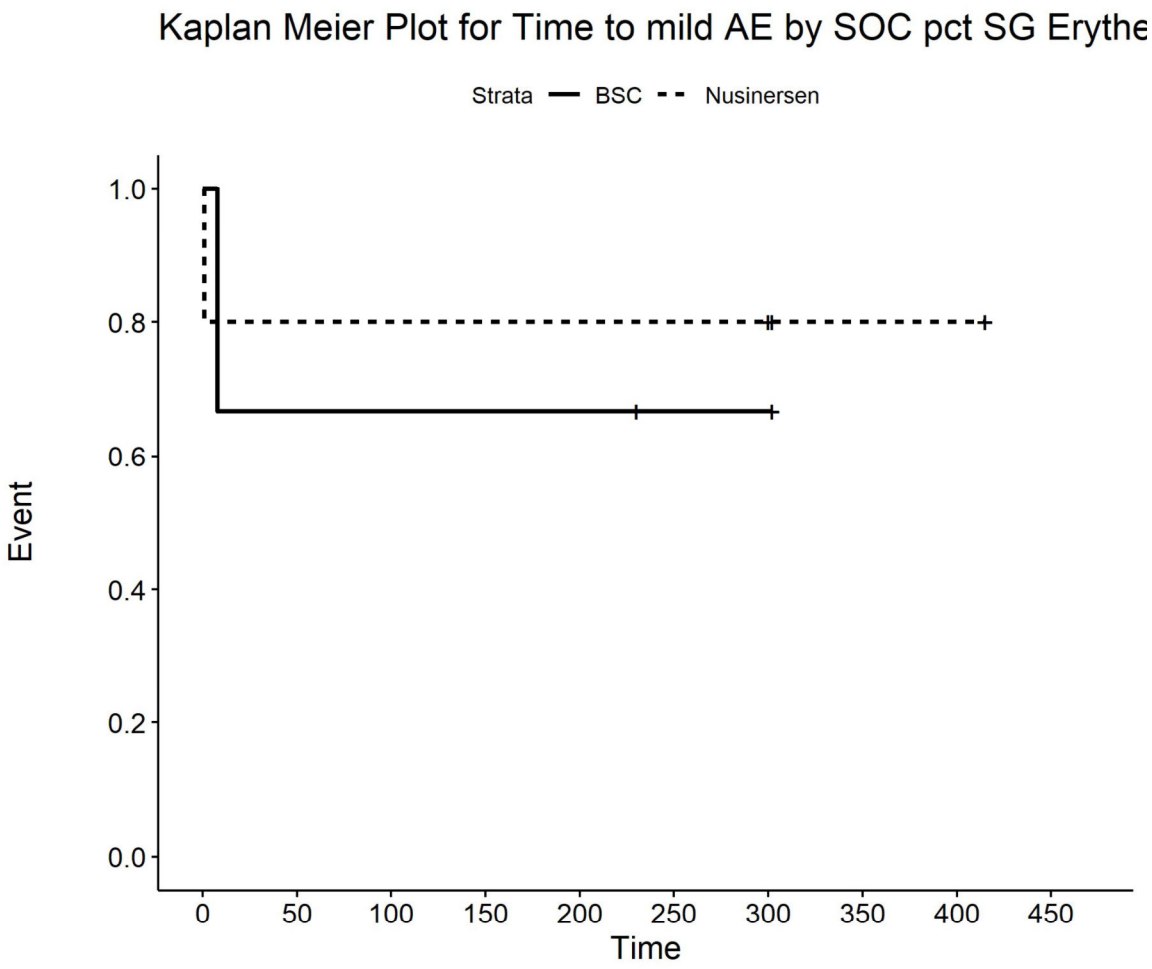
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	5	5	5	3	3	2	1	1	0



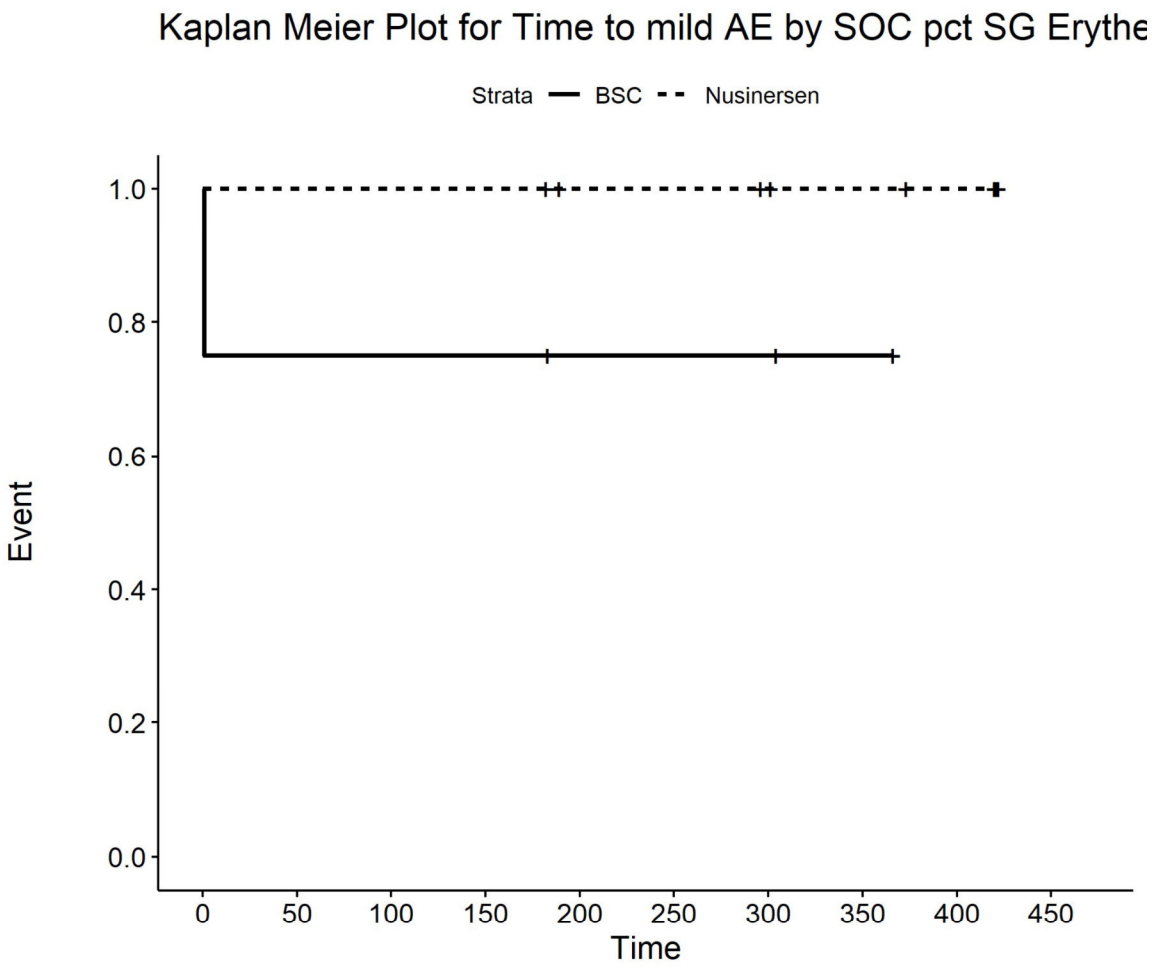
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



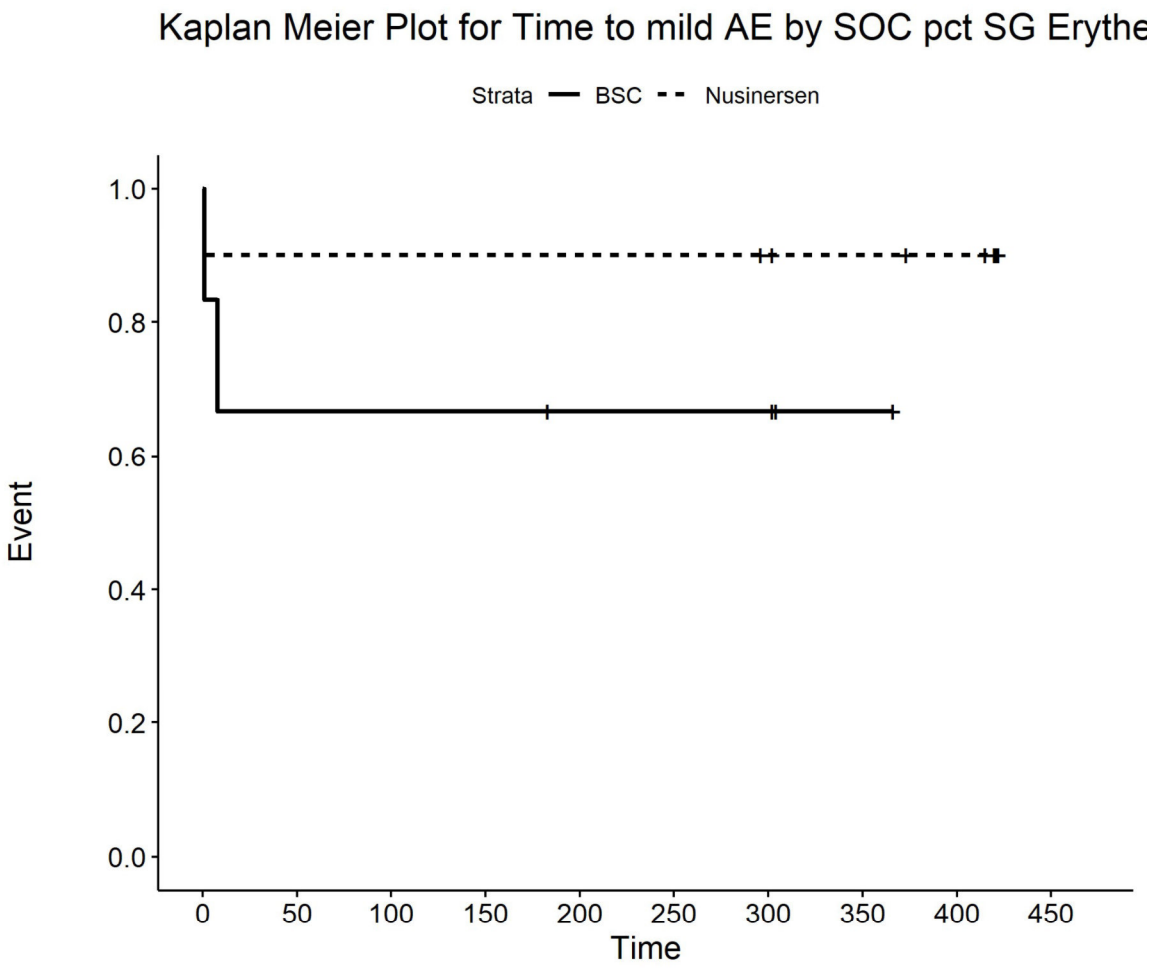
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



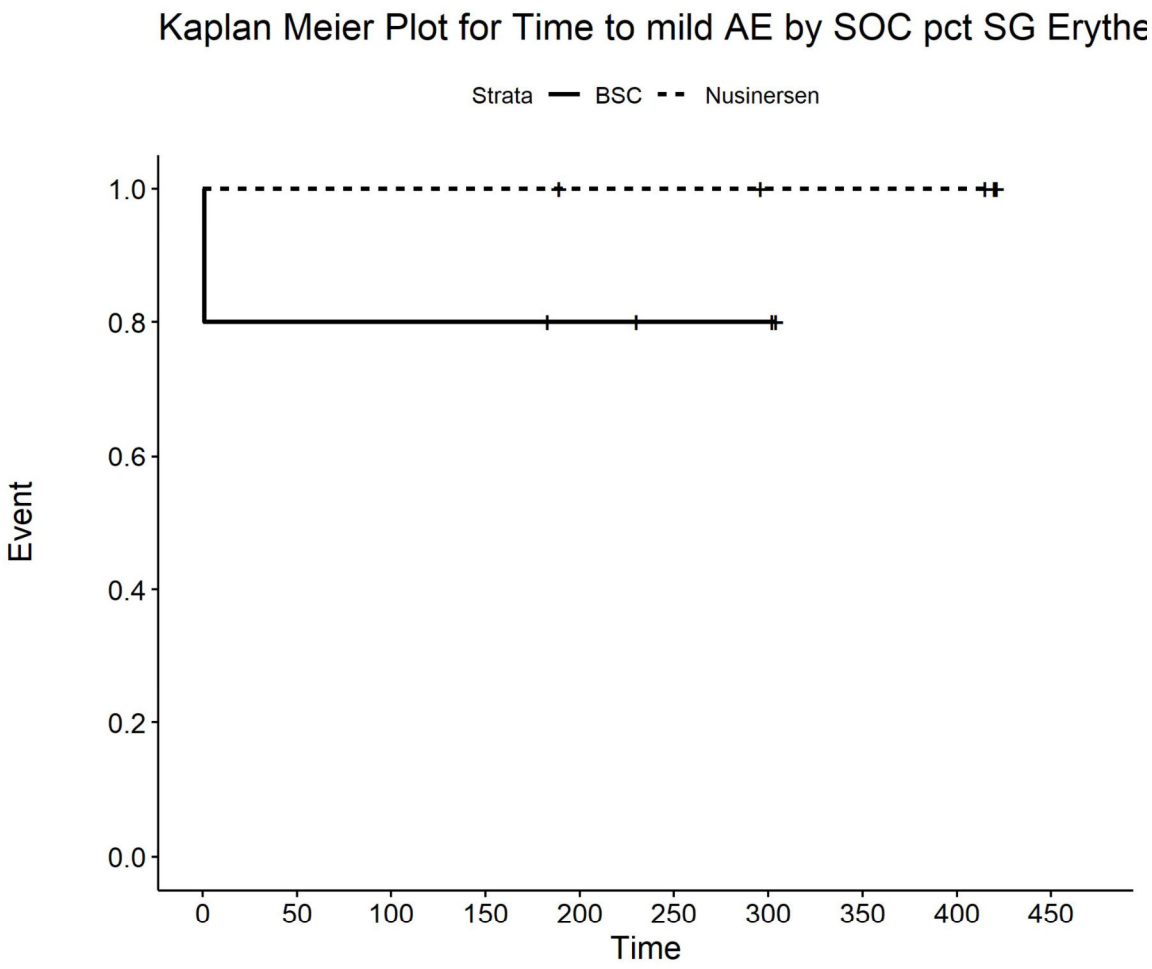
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



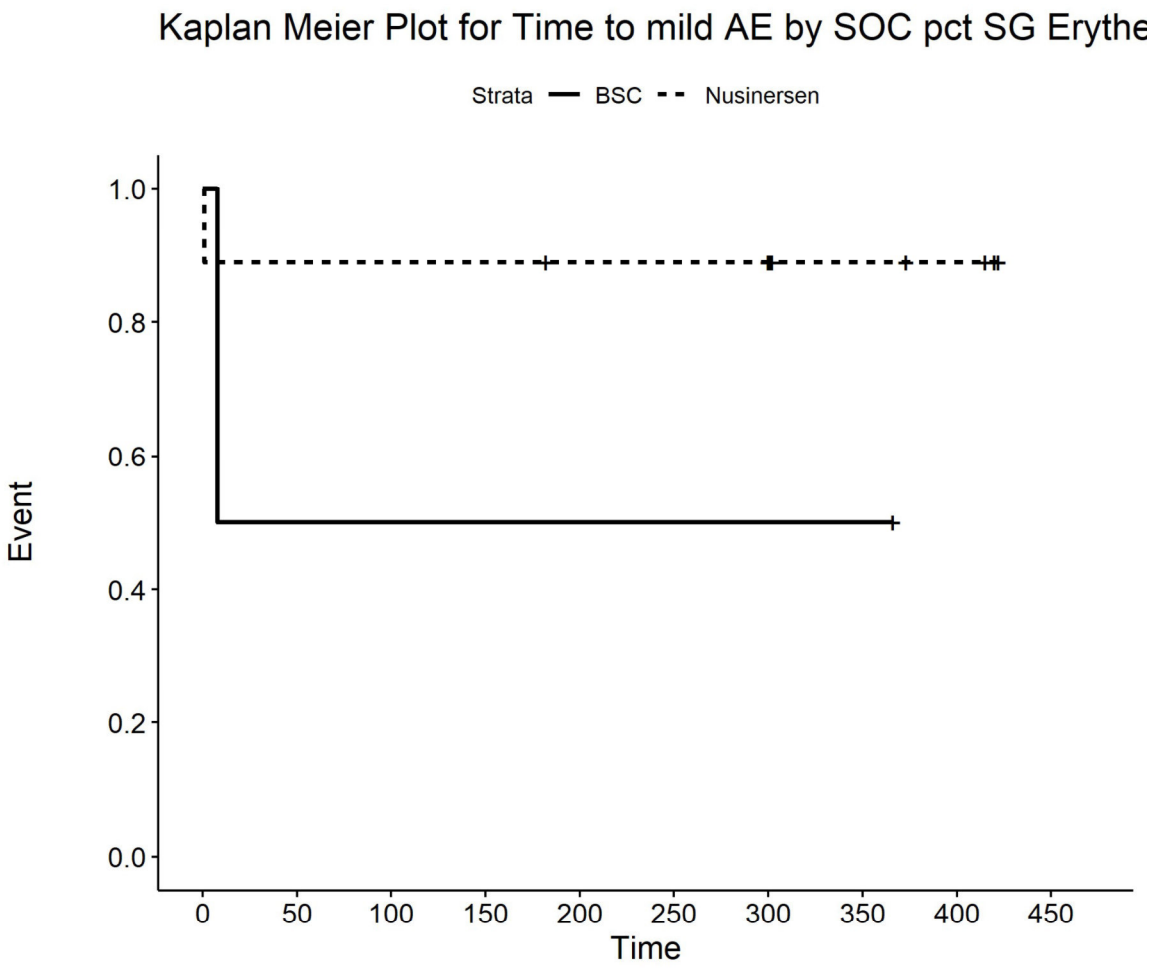
Number at risk

BSC	6	4	4	4	3	3	3	1	0	0
Nusinersen	10	9	9	9	9	9	8	7	6	0



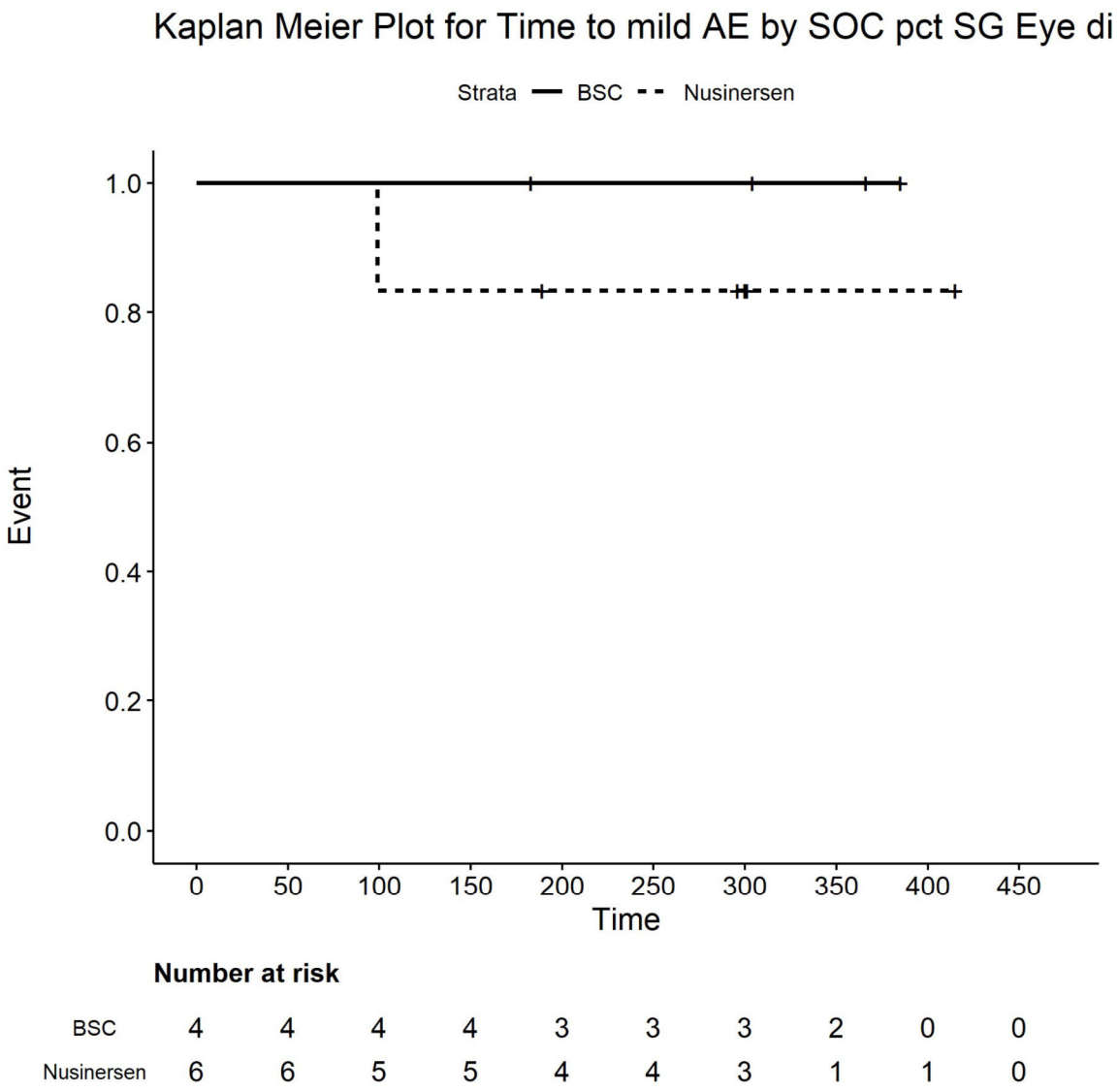
Number at risk

BSC	5	4	4	4	3	2	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



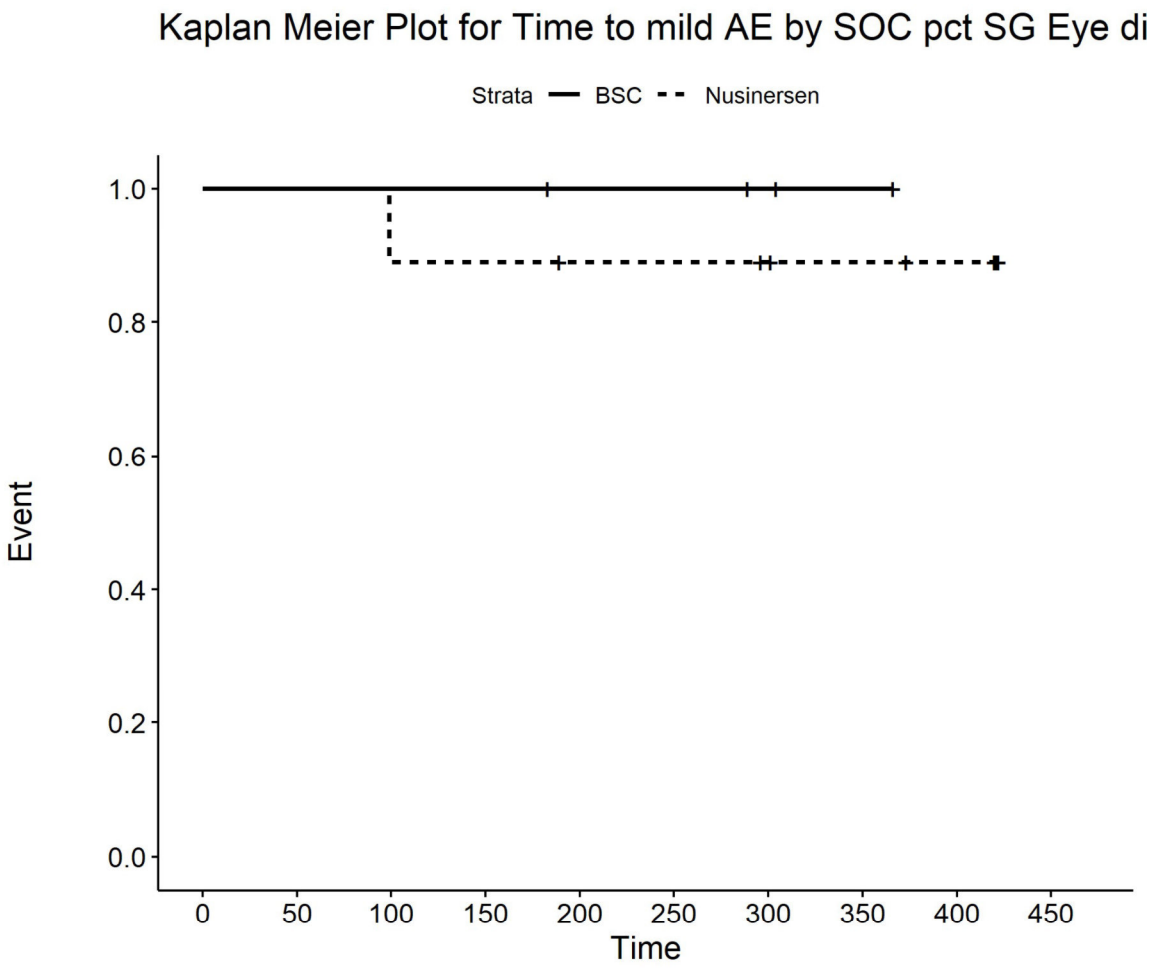
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



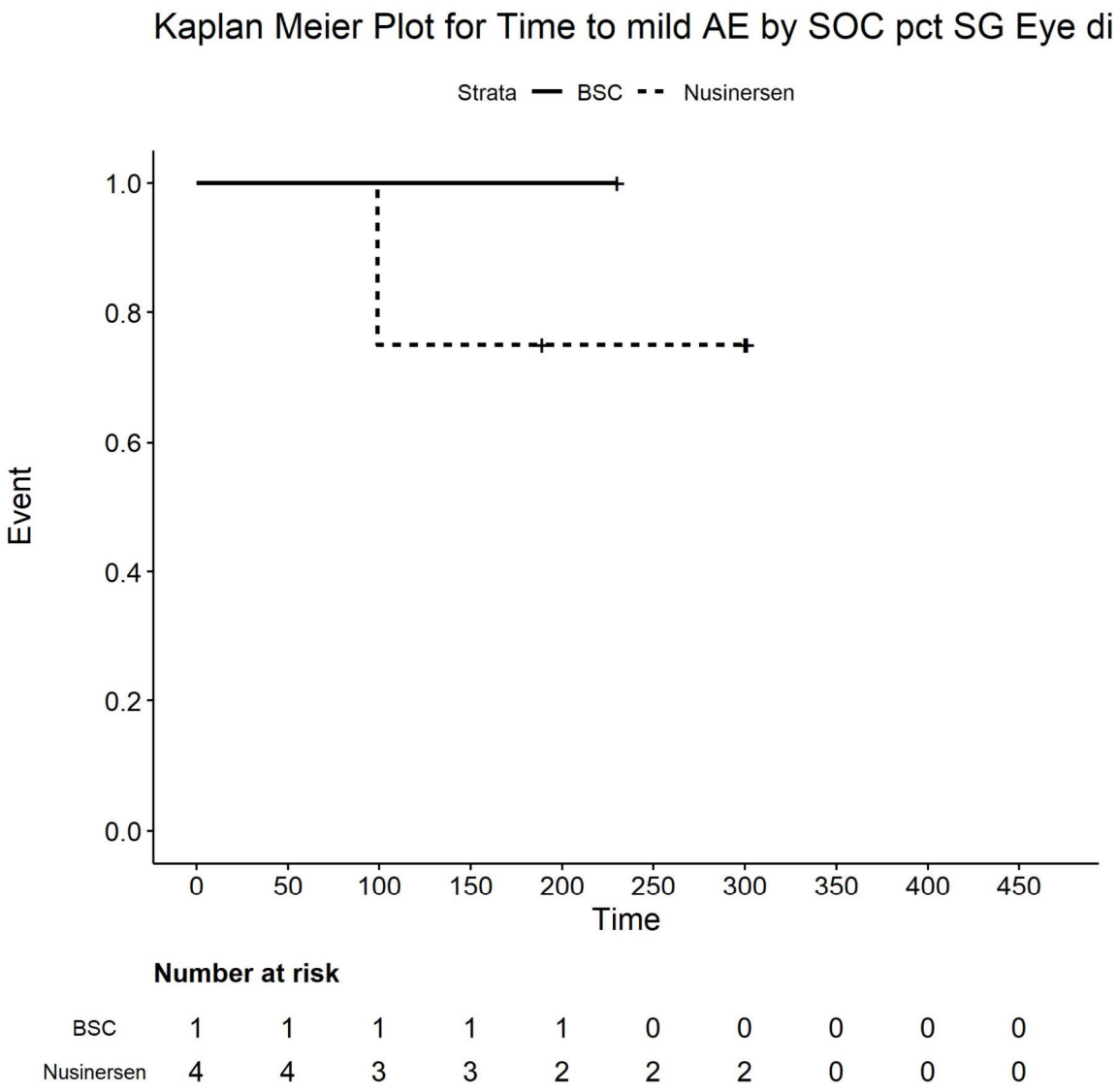
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	4	4	3	1	1	0



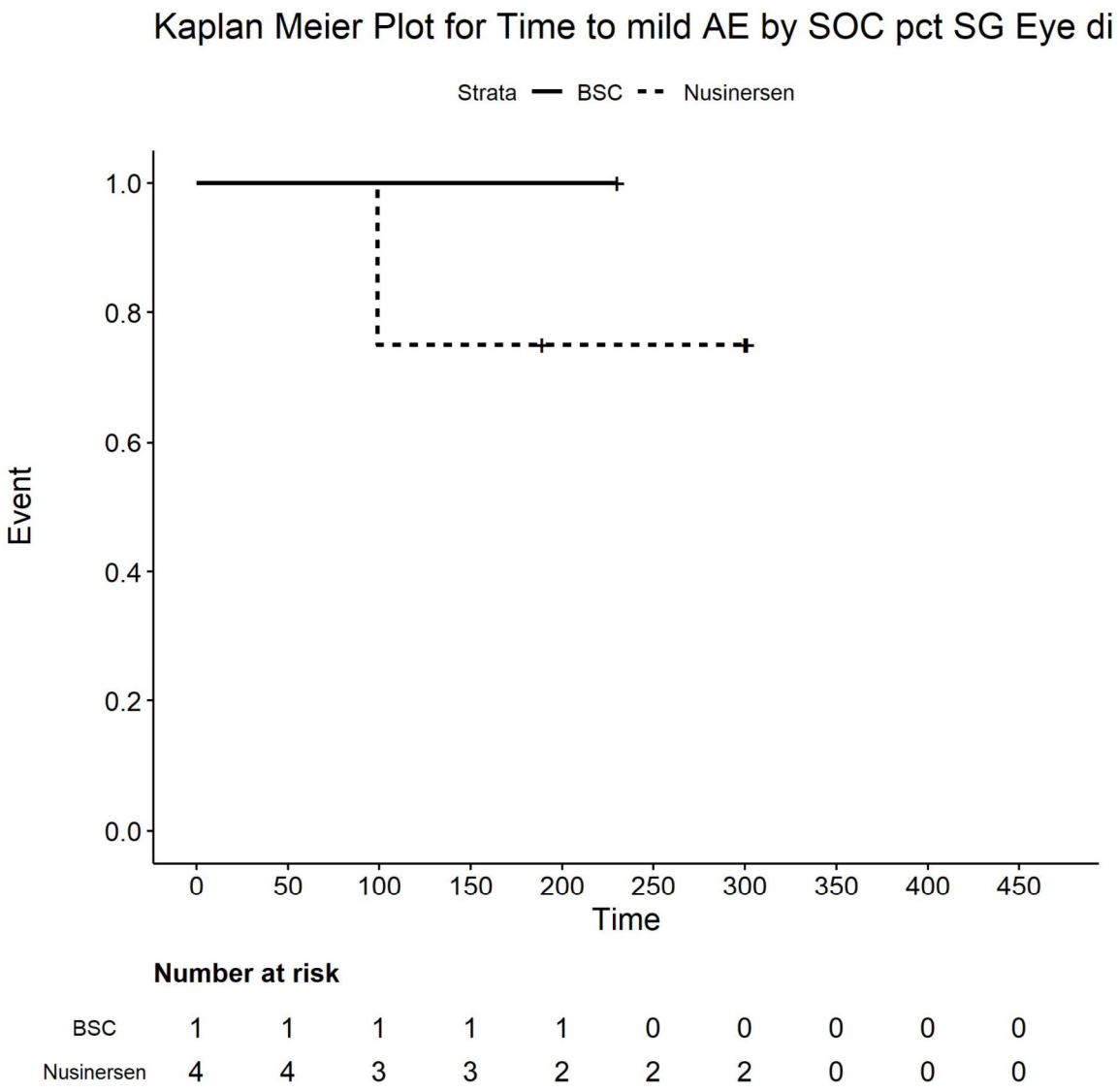
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	7	7	6	5	4	0



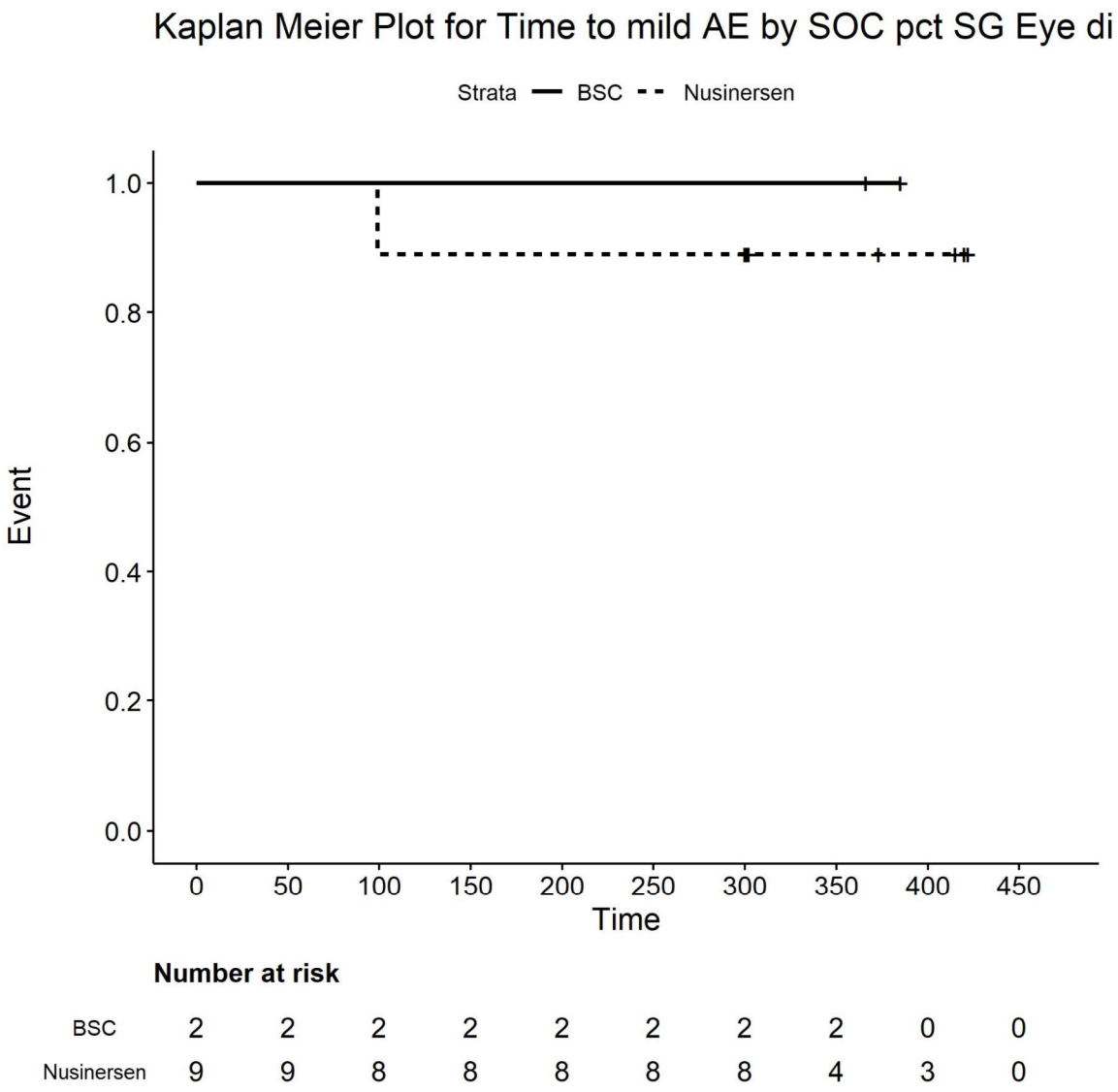
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	2	2	2	0	0	0



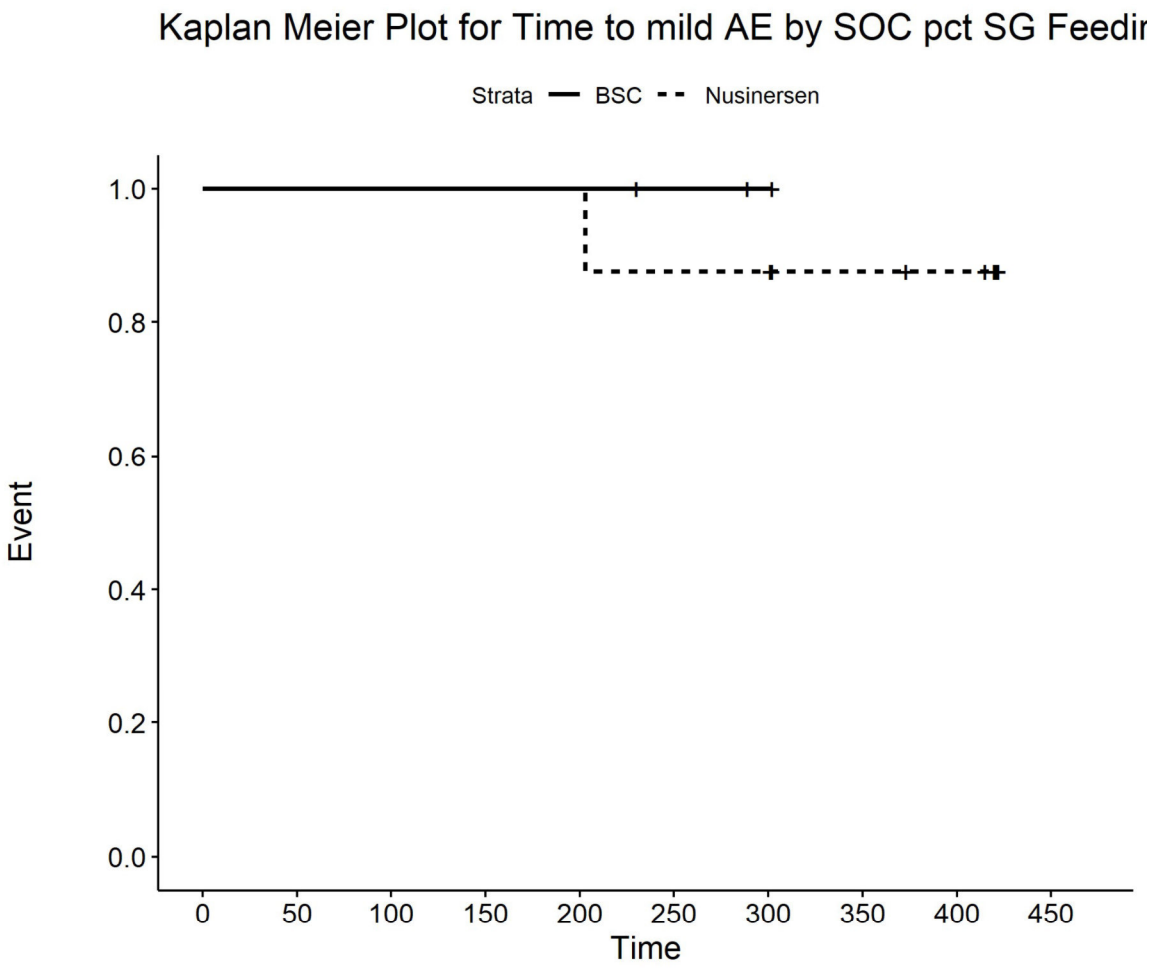
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	2	2	2	0	0	0



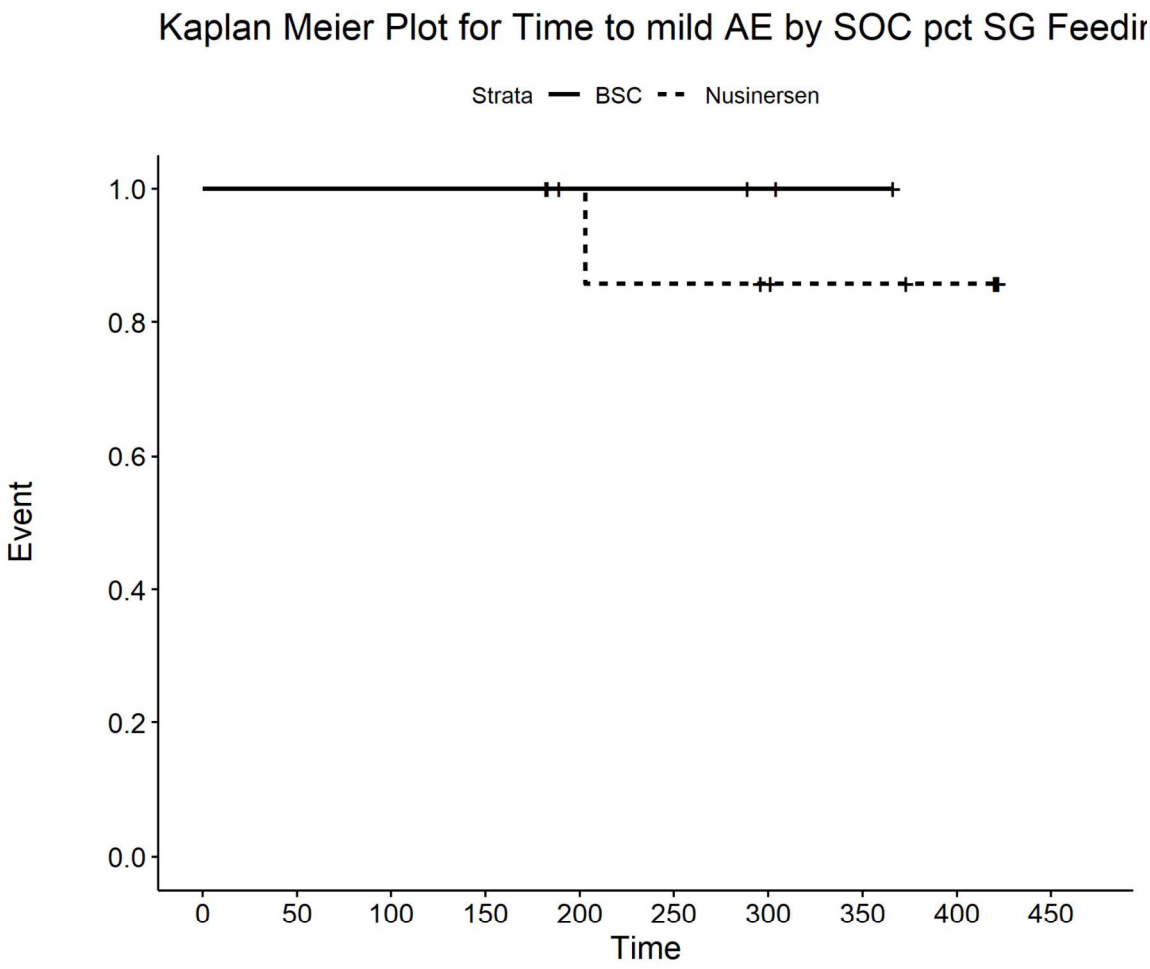
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	8	8	8	4	3	0



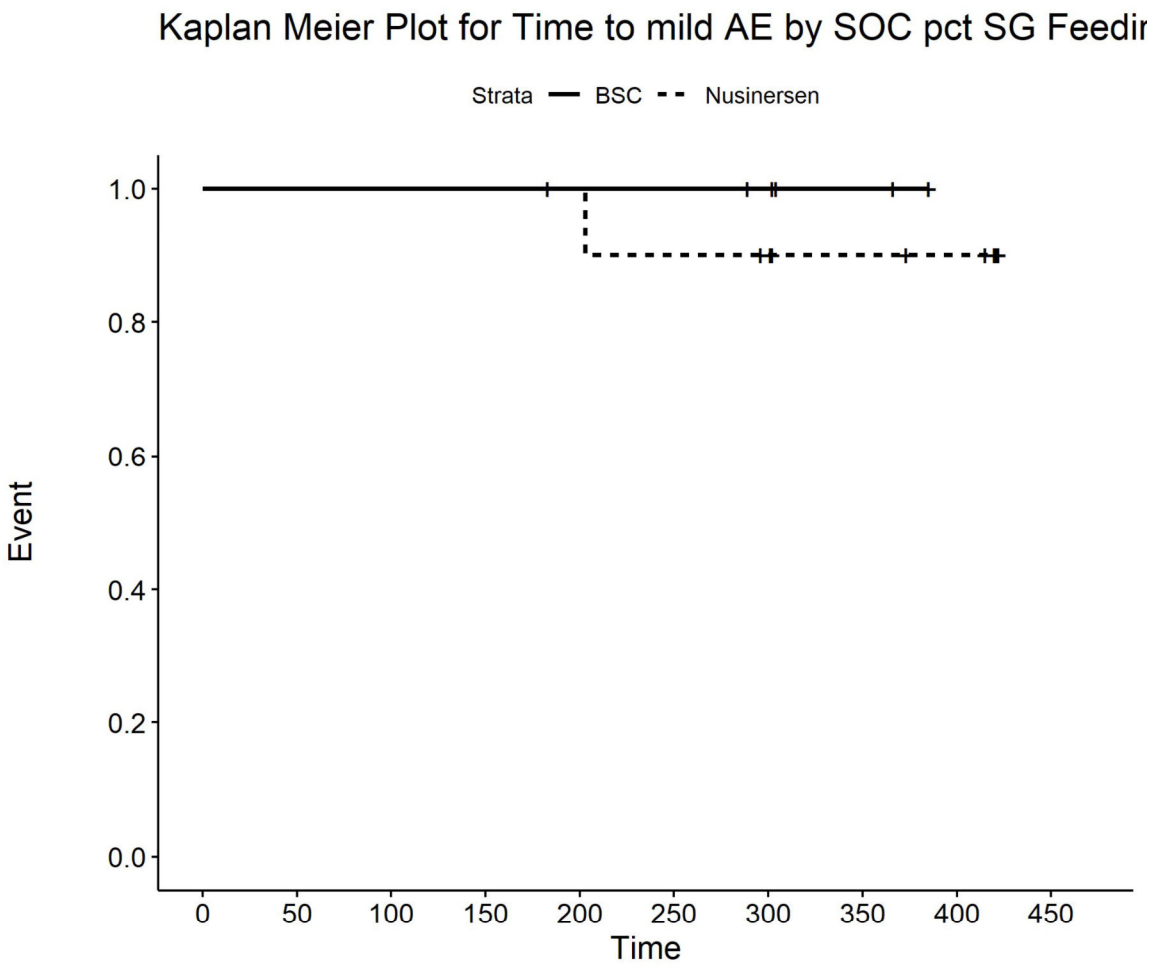
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



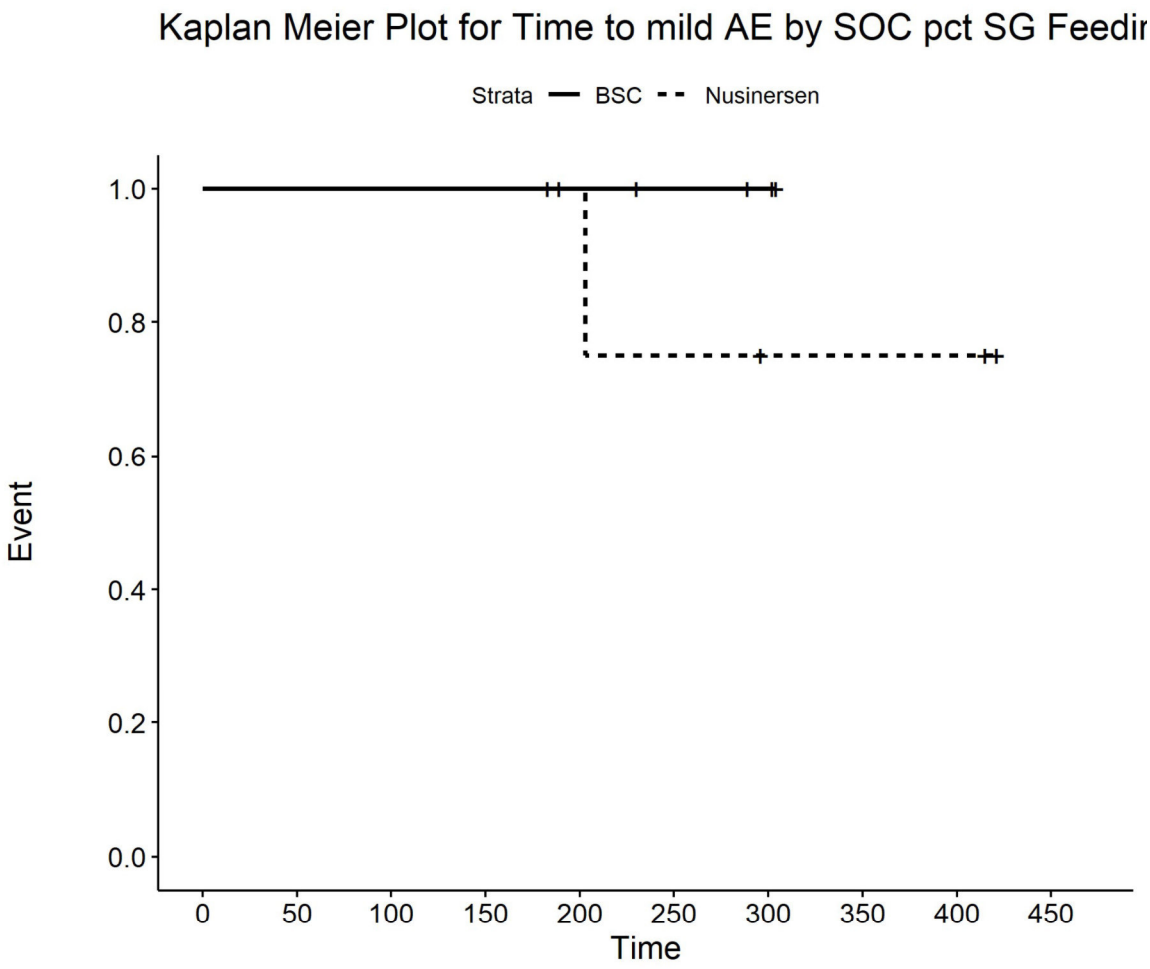
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



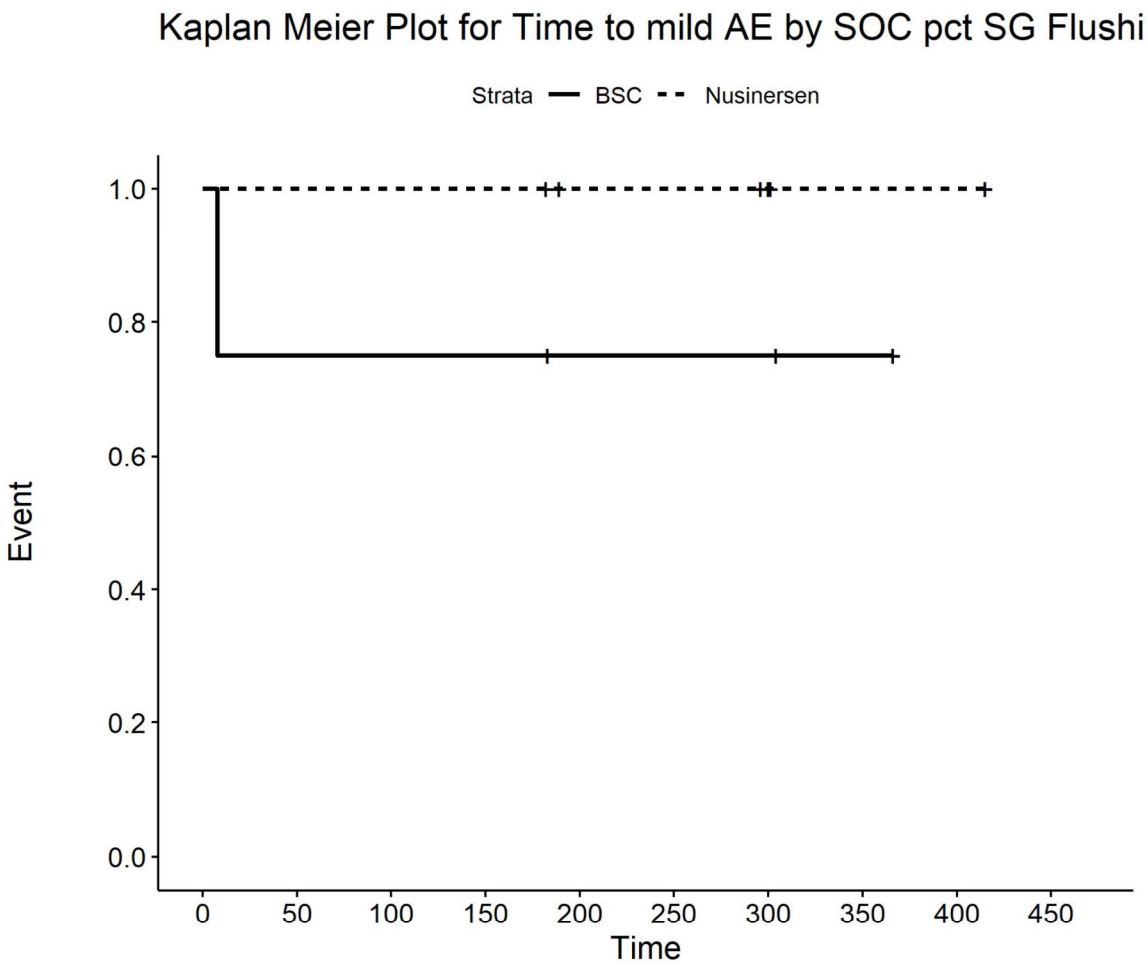
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



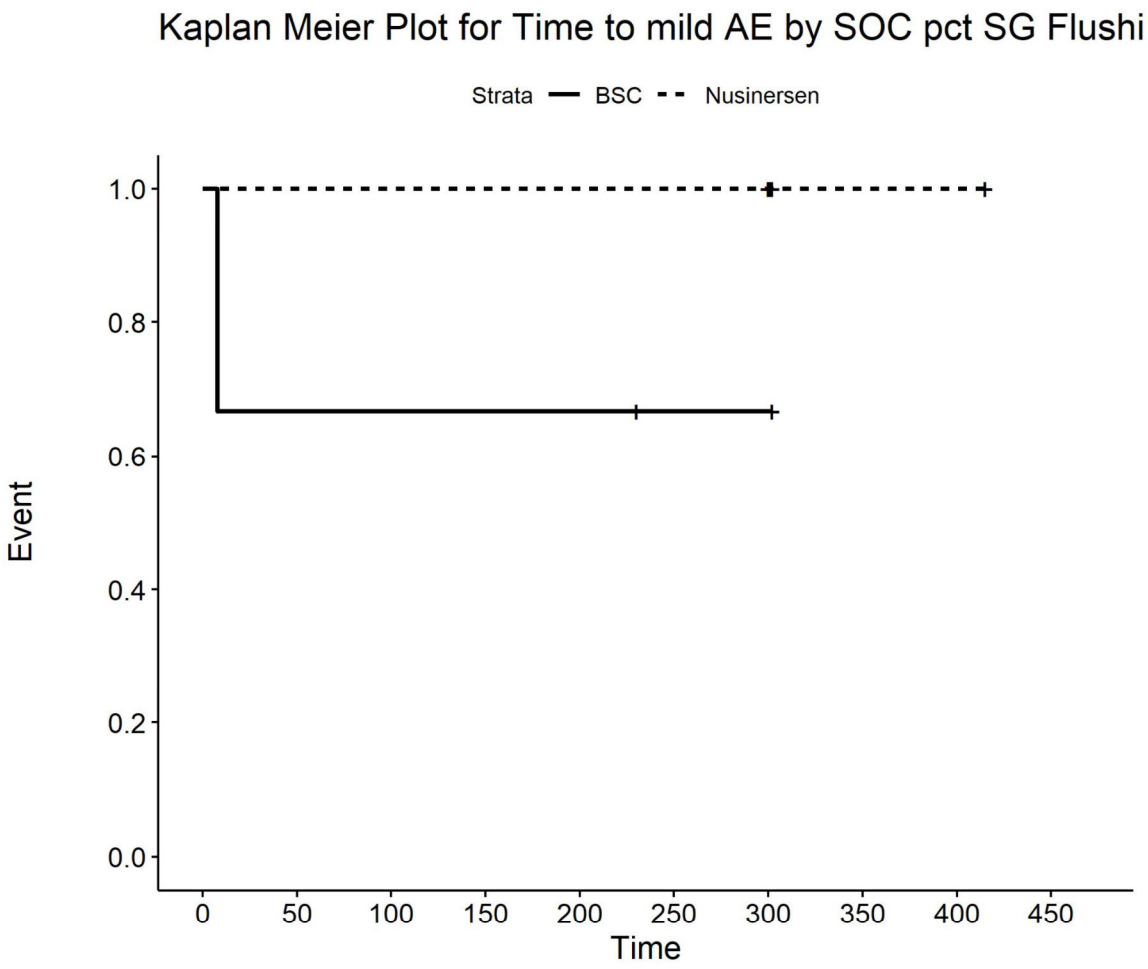
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	3	2	2	2	0



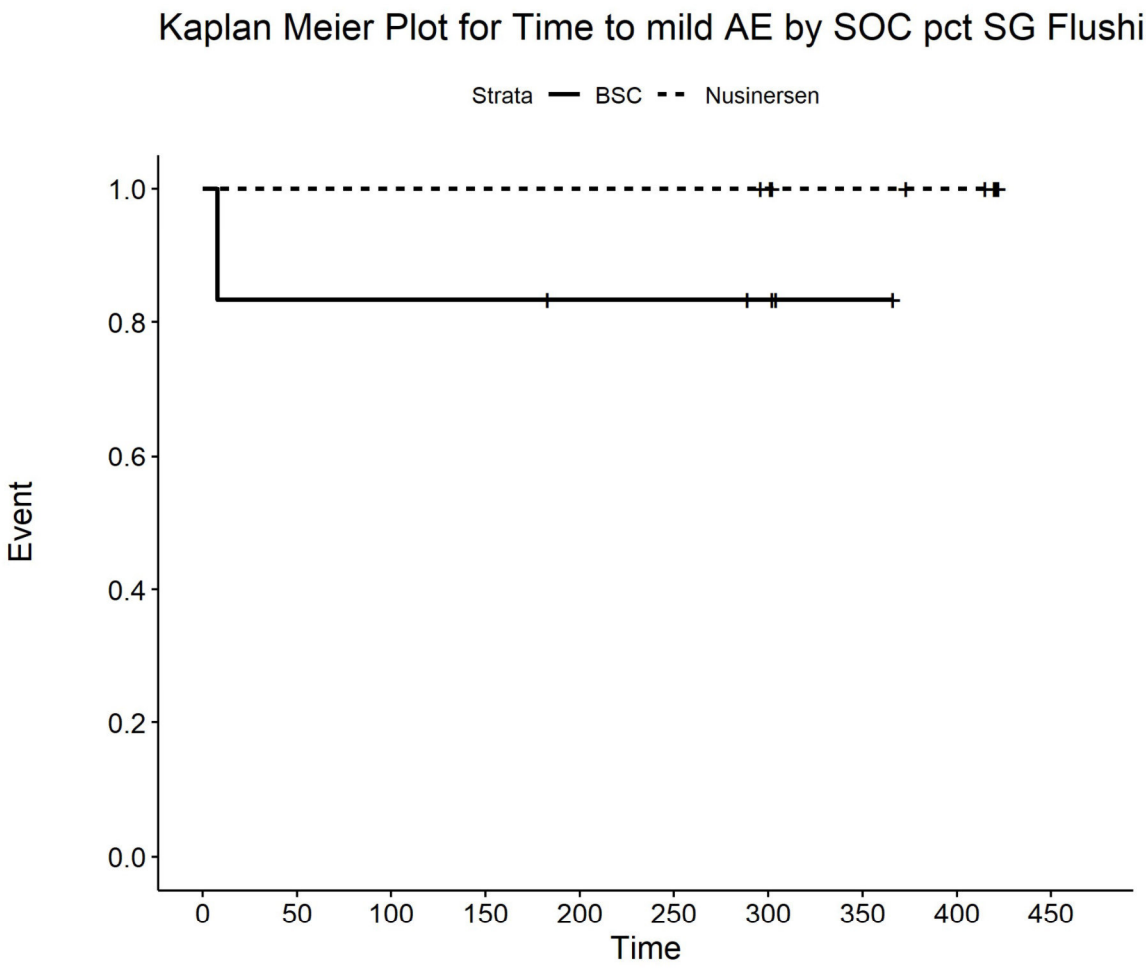
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



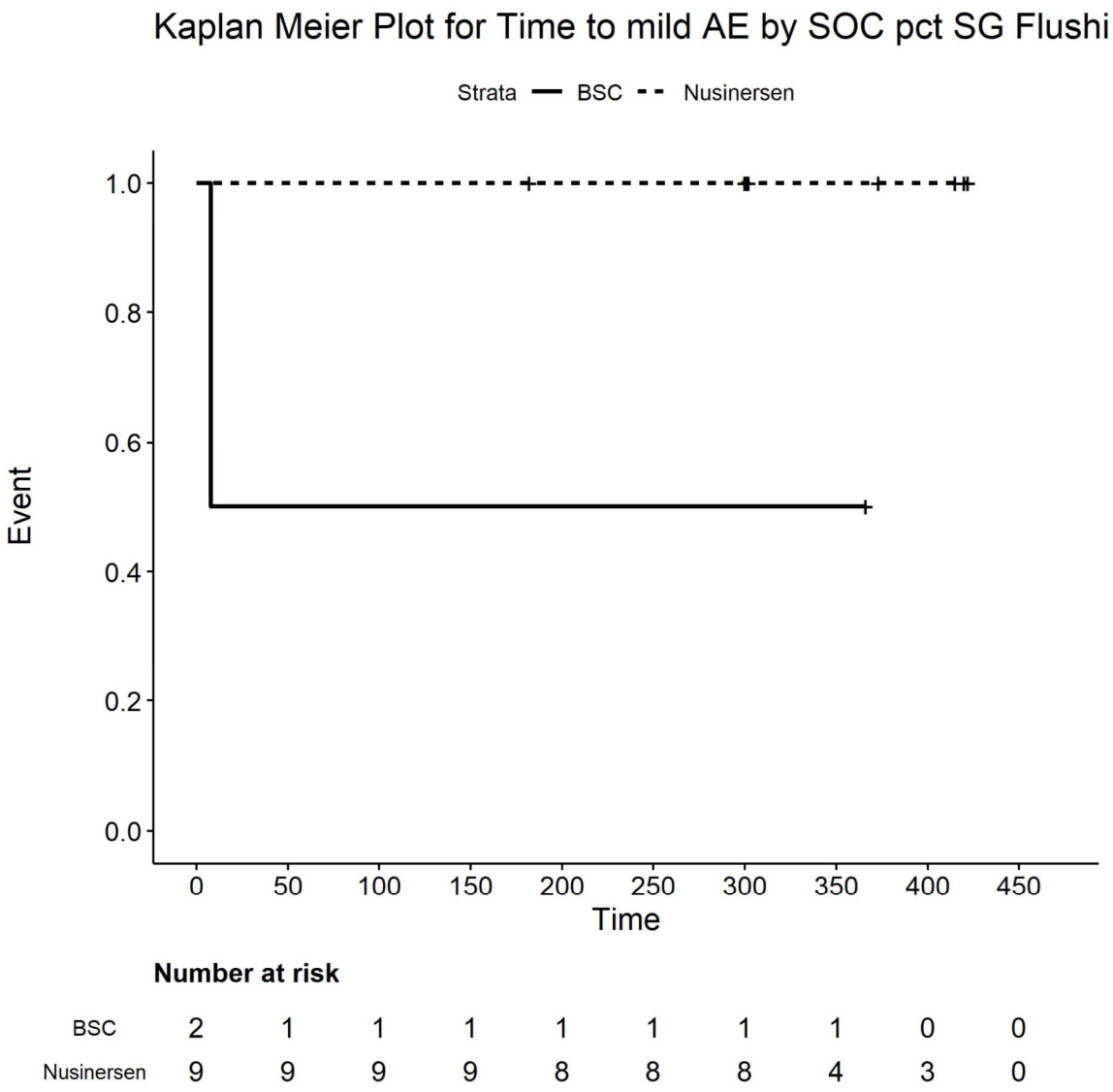
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



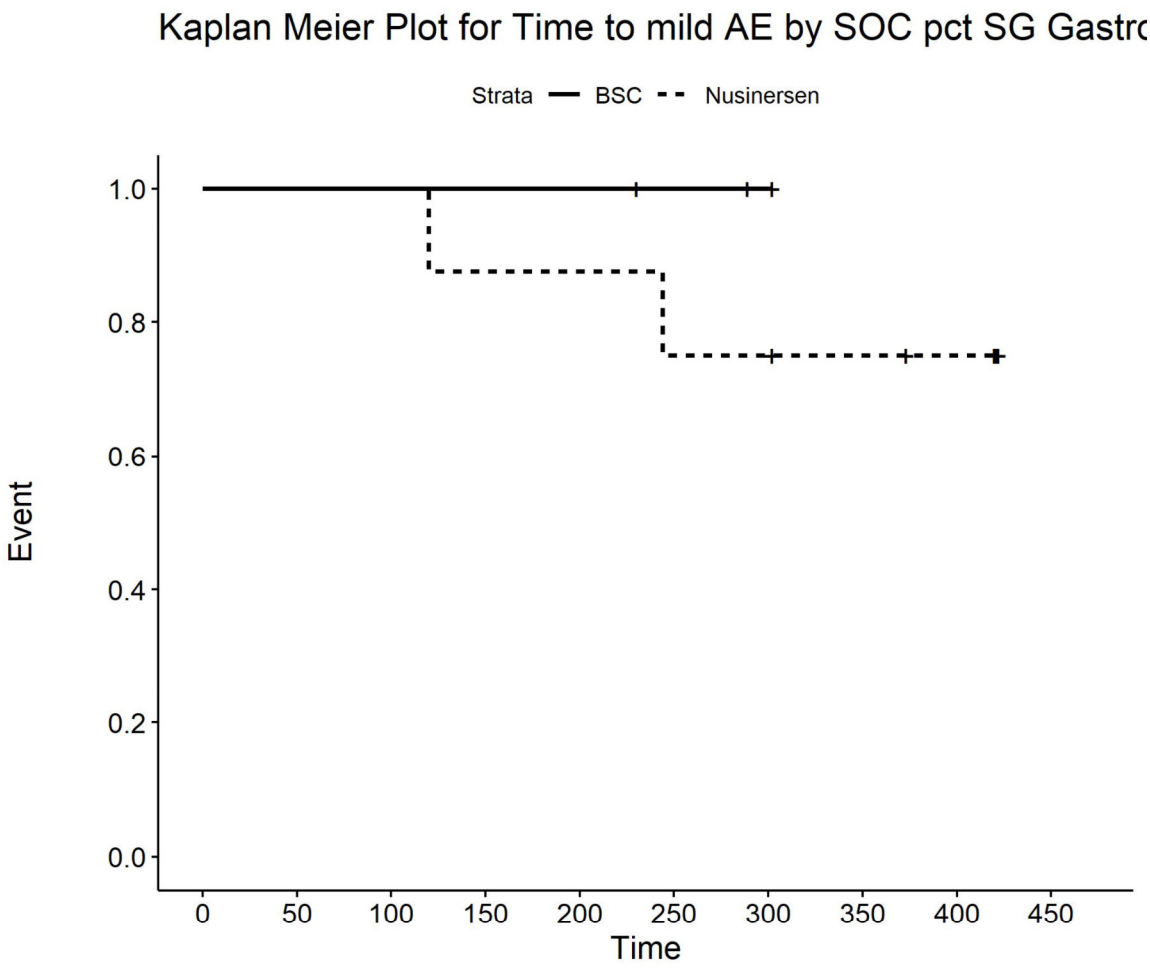
Number at risk

BSC	6	5	5	5	4	4	3	1	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



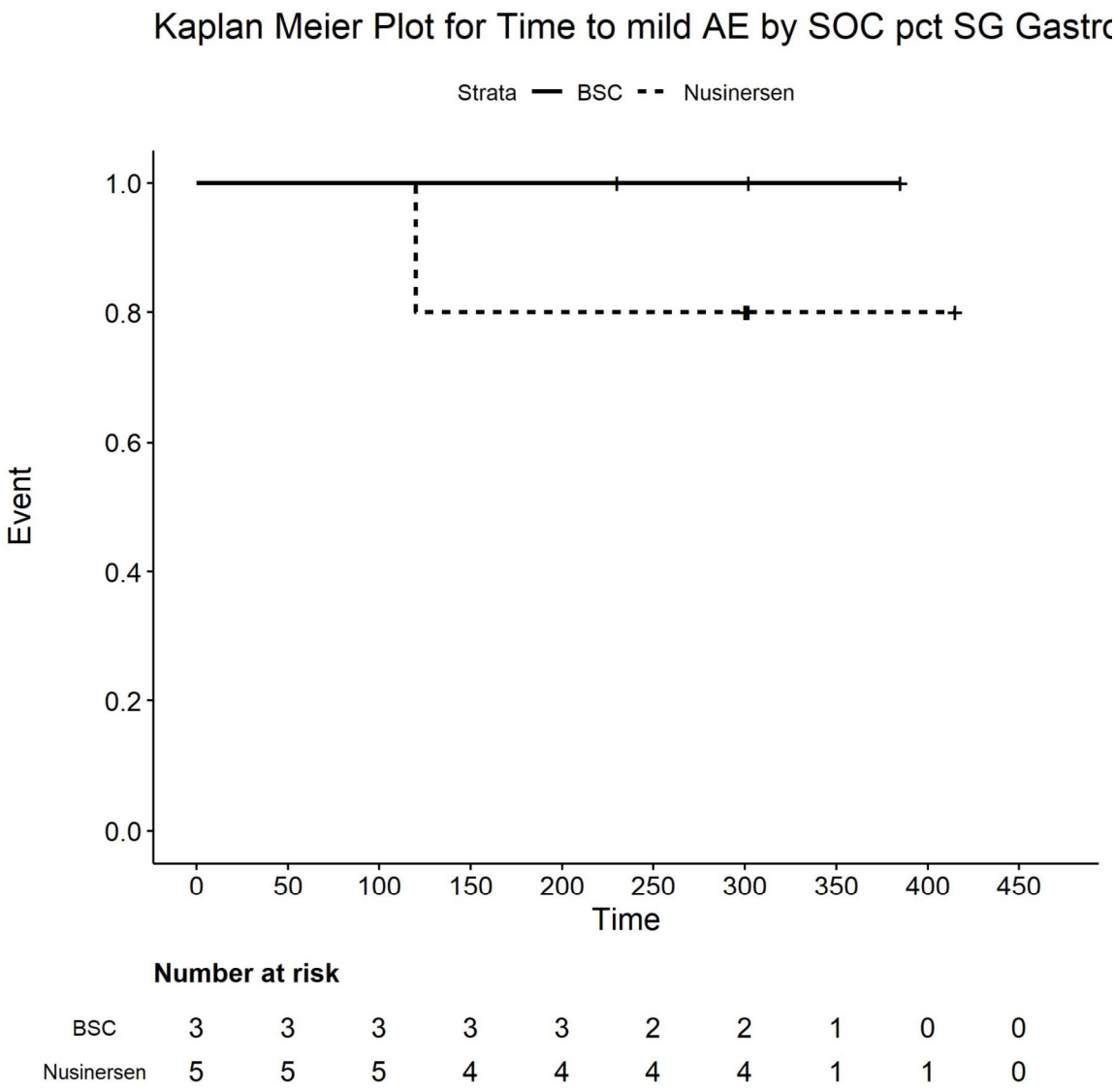
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



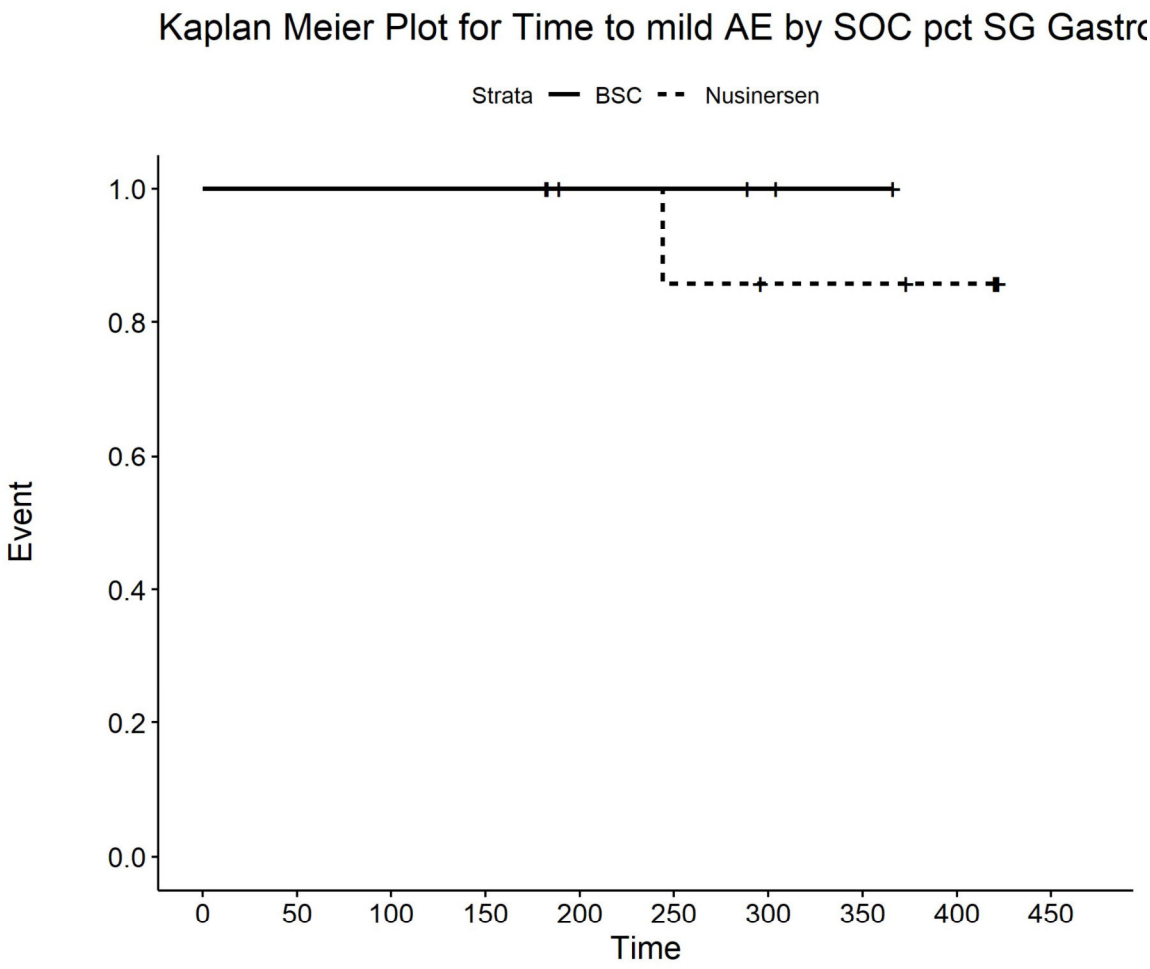
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	6	6	5	4	0



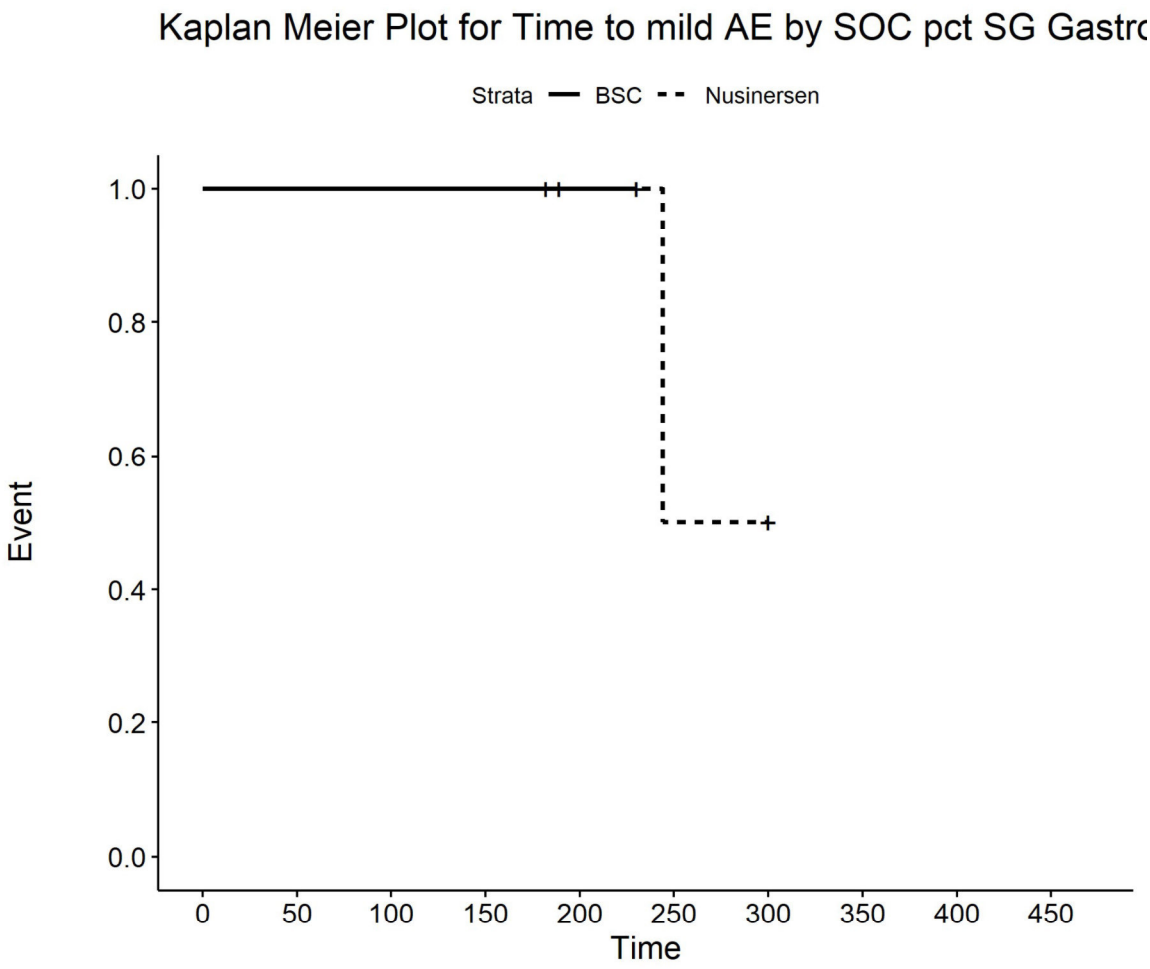
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	4	4	4	4	1	1	0



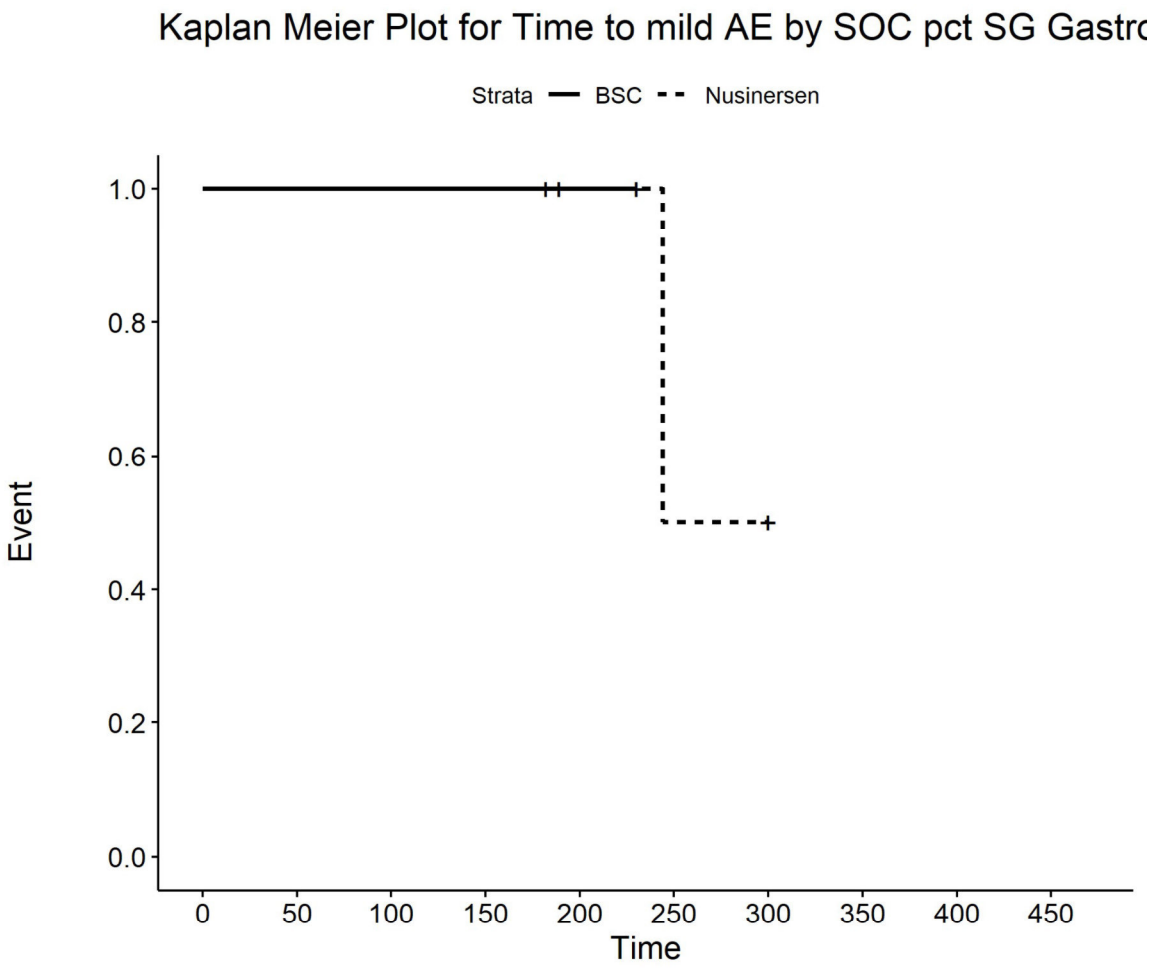
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	5	4	0



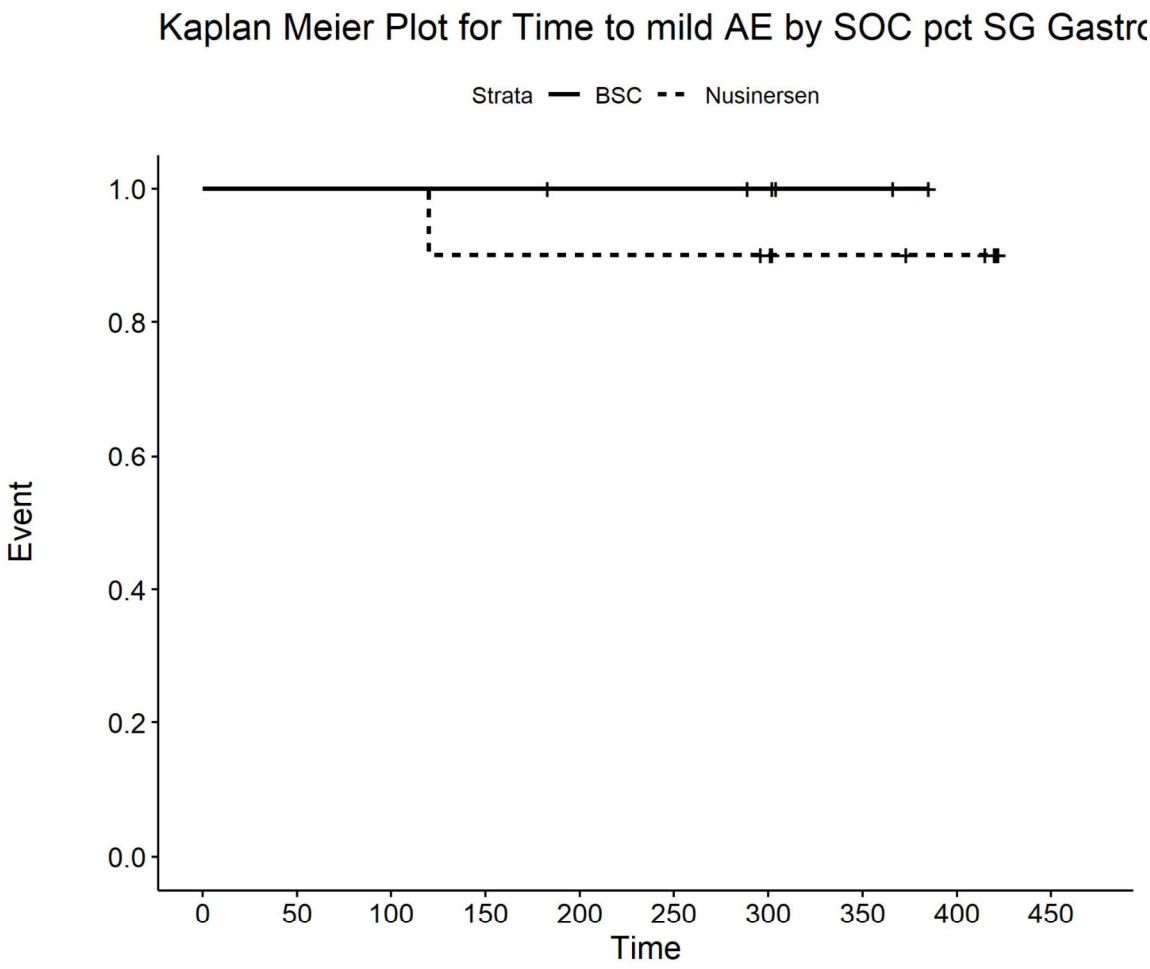
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	4	2	1	1	0	0	0



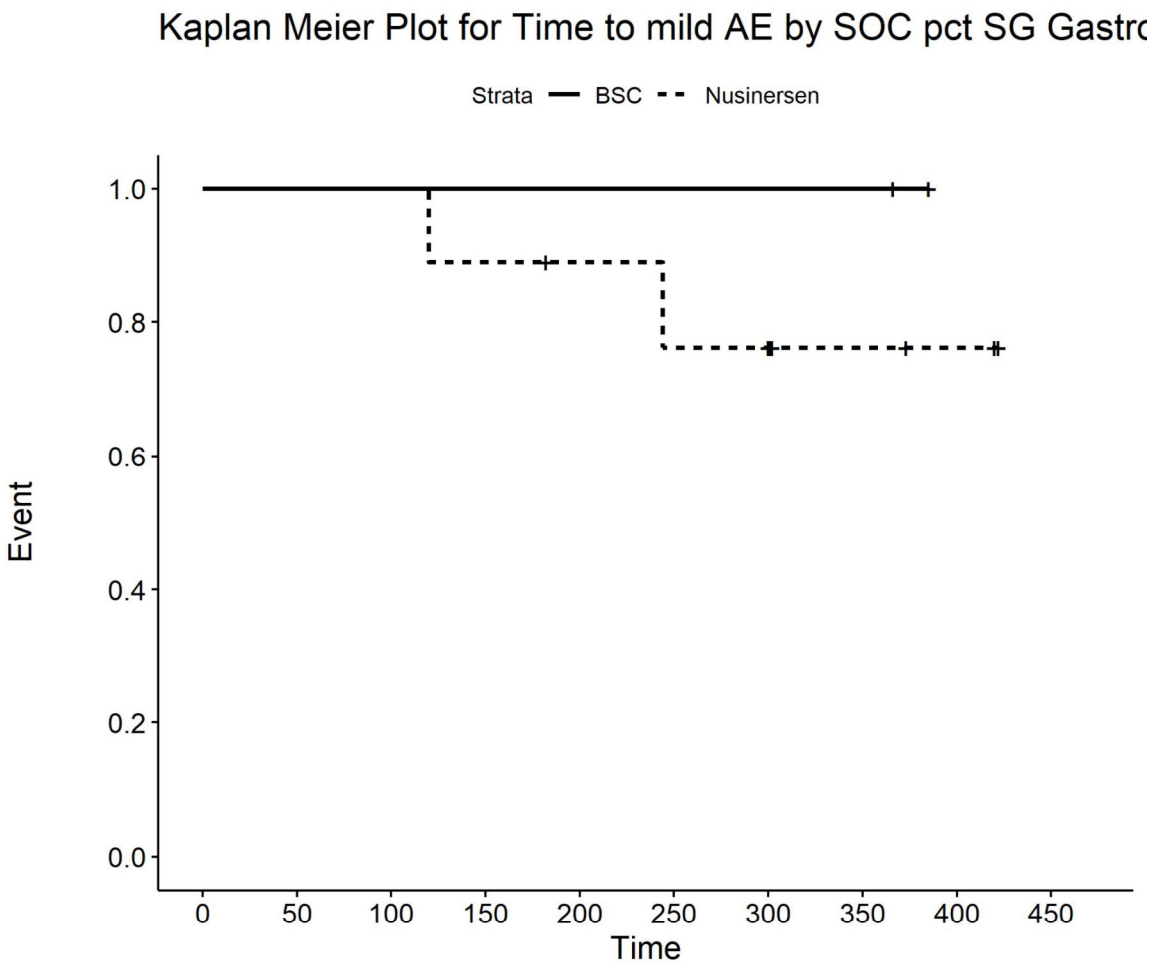
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	4	2	1	1	0	0	0



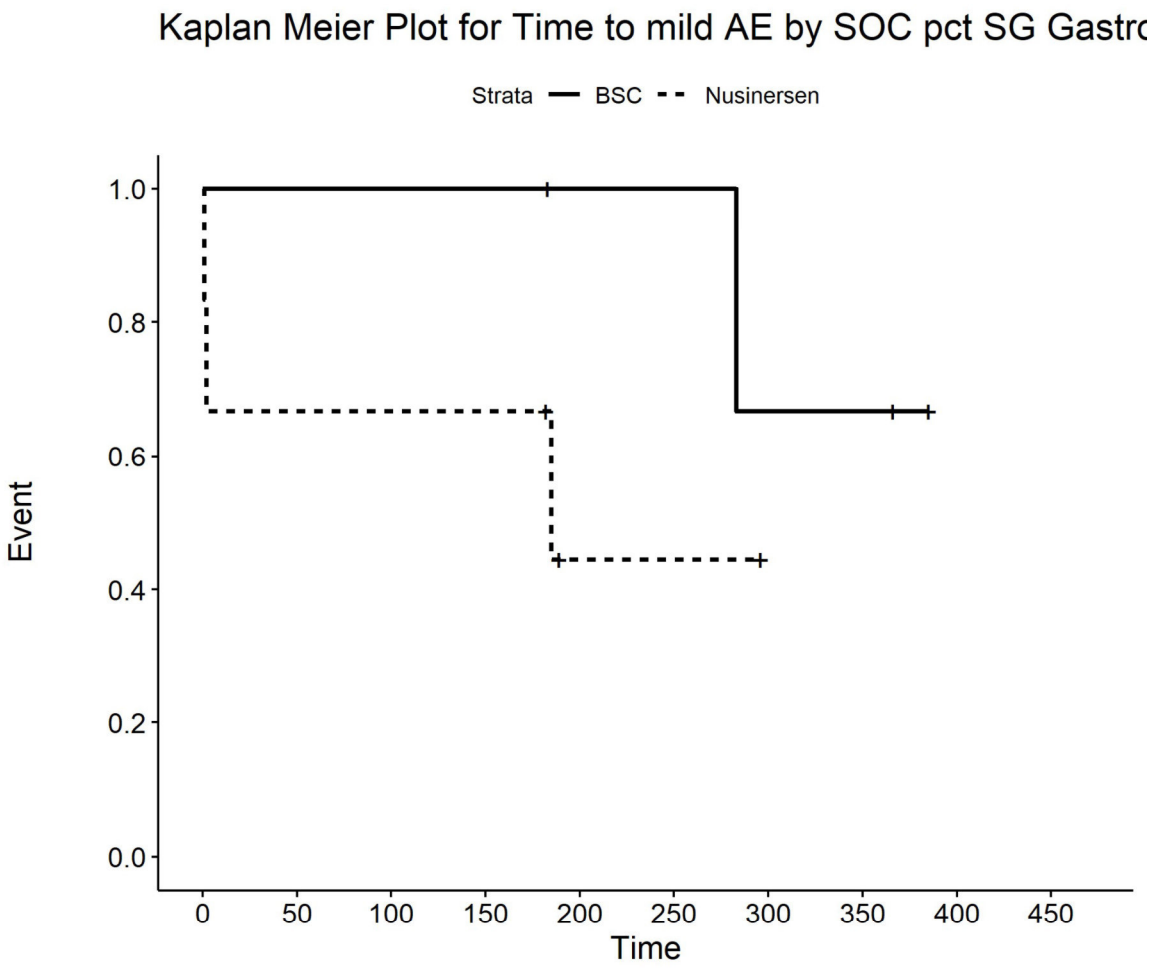
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



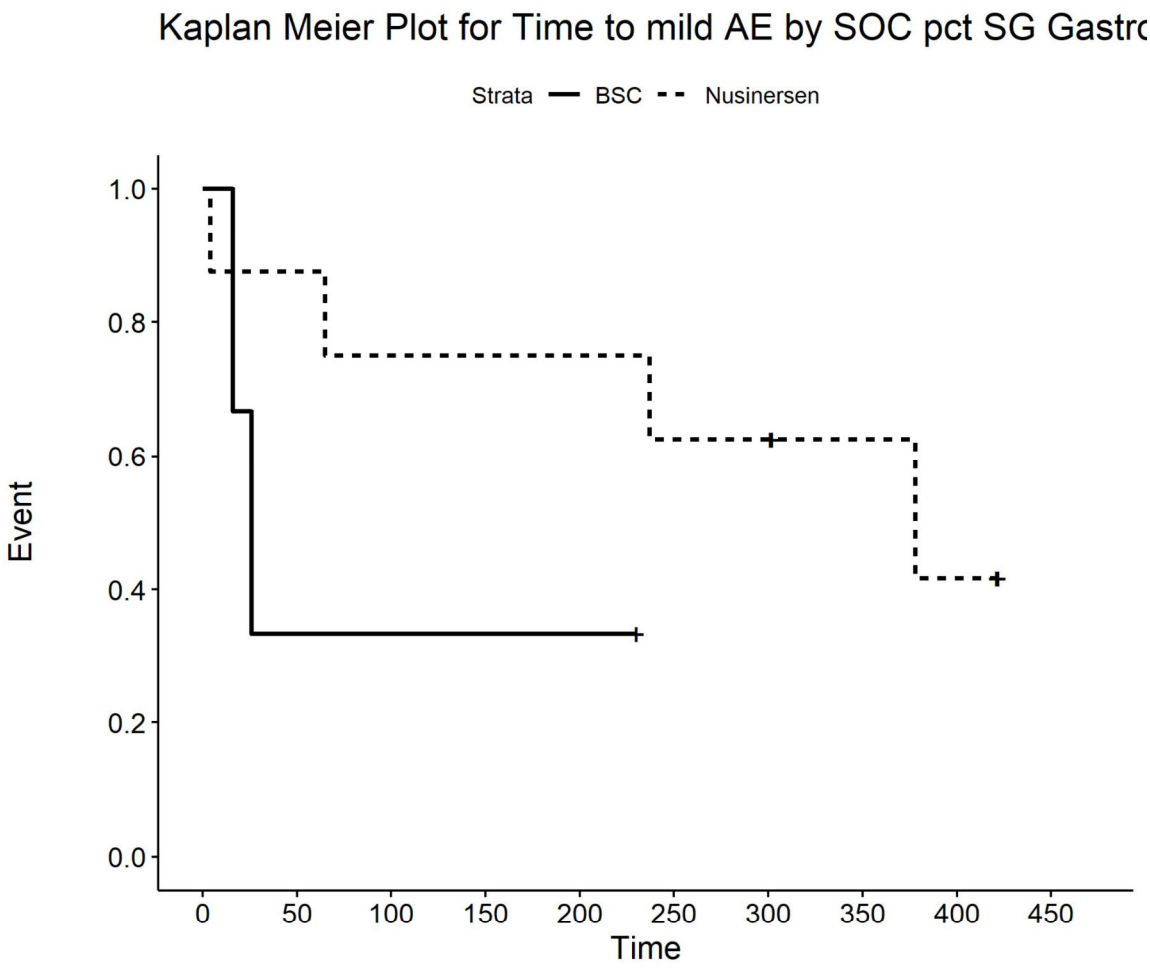
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	6	6	3	2	0



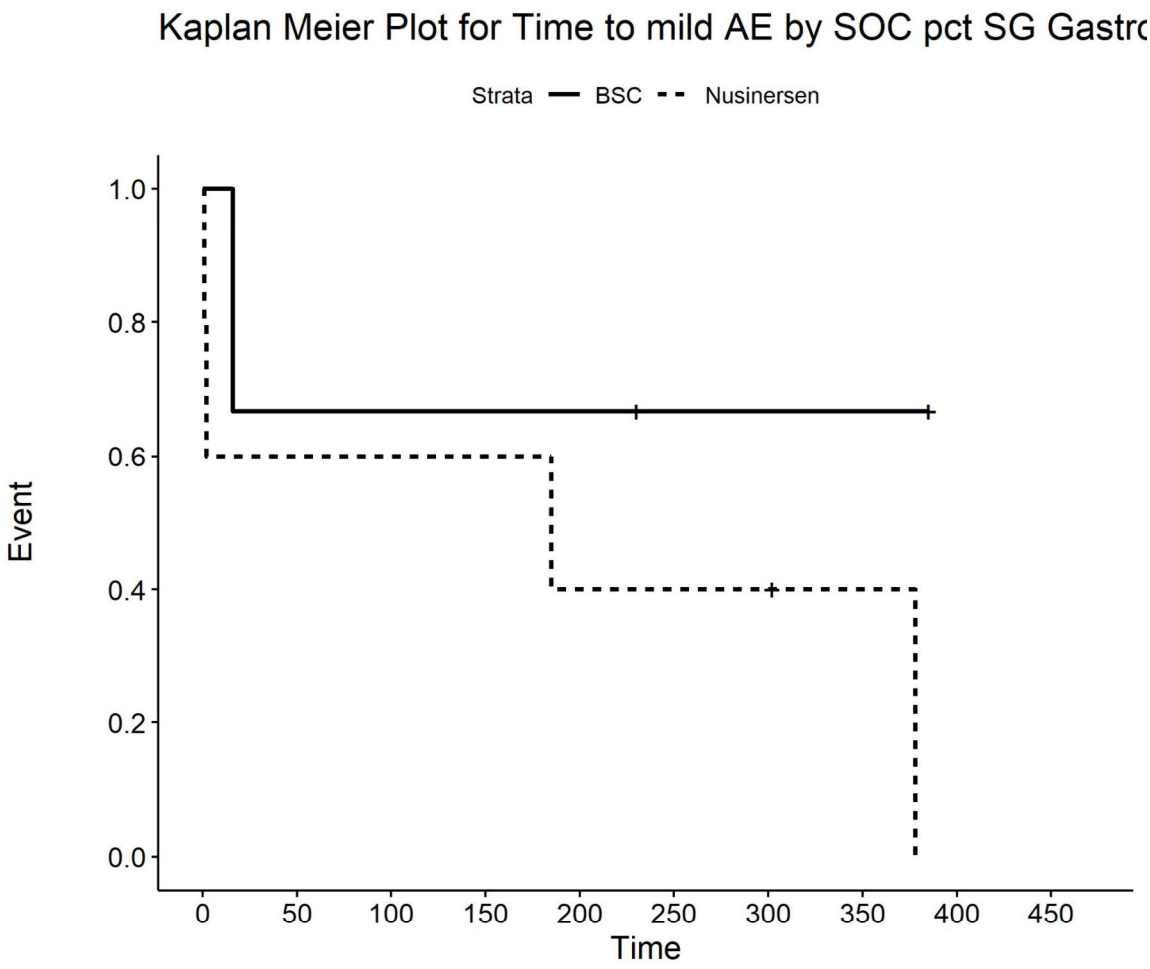
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	4	4	4	1	1	0	0	0	0



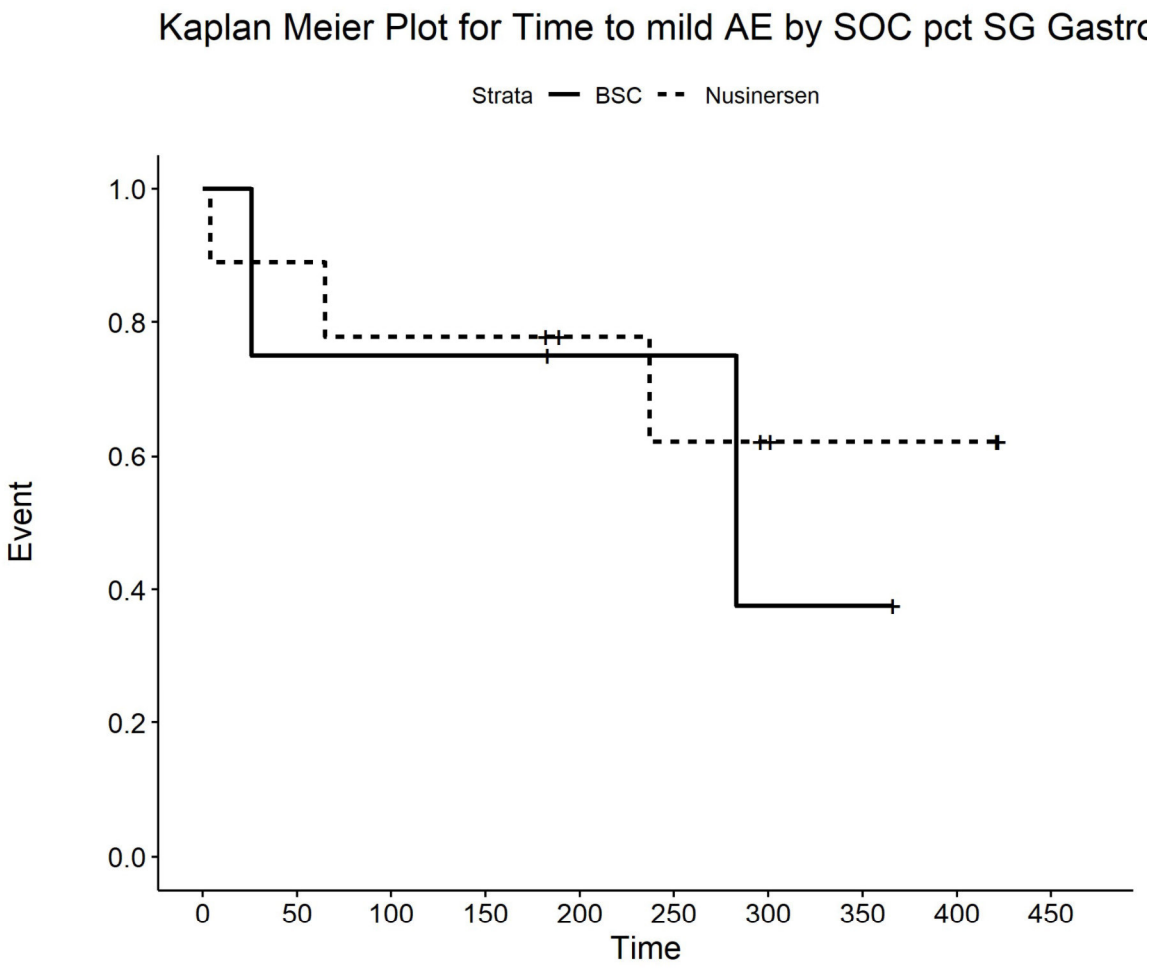
Number at risk

BSC	3	1	1	1	1	0	0	0	0	0
Nusinersen	8	7	6	6	6	5	5	3	2	0



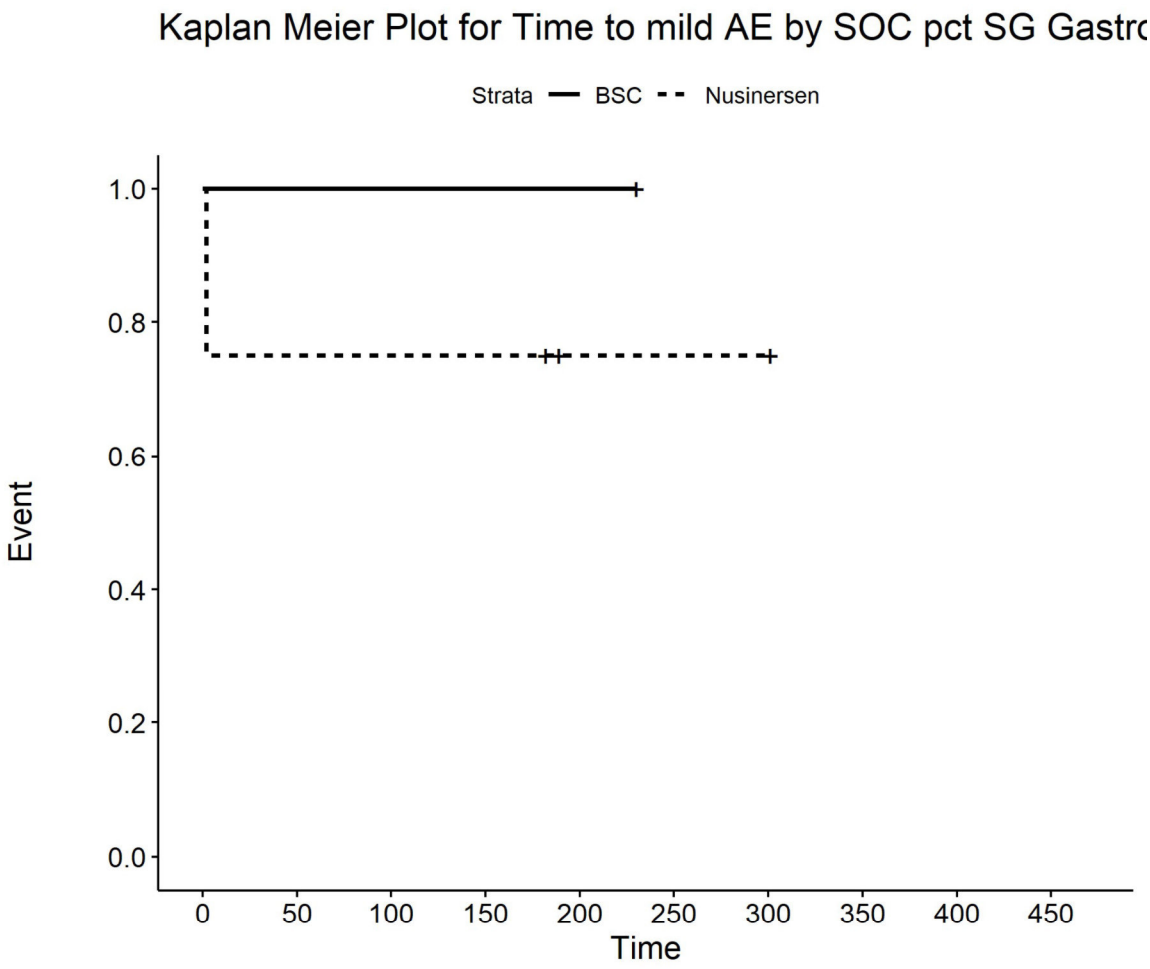
Number at risk

BSC	3	2	2	2	2	1	1	1	0	0
Nusinersen	5	3	3	3	2	2	2	1	0	0



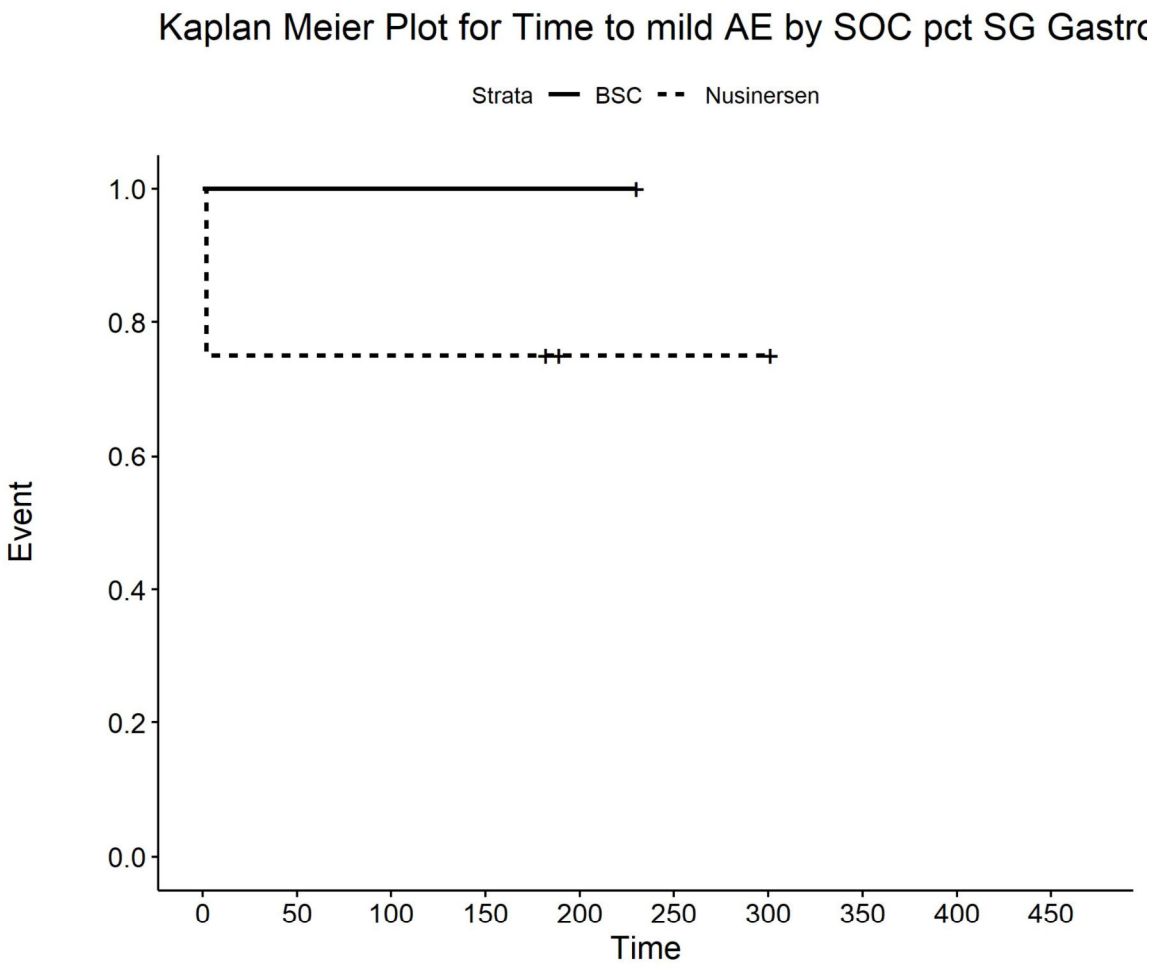
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	8	7	7	5	4	3	2	2	0



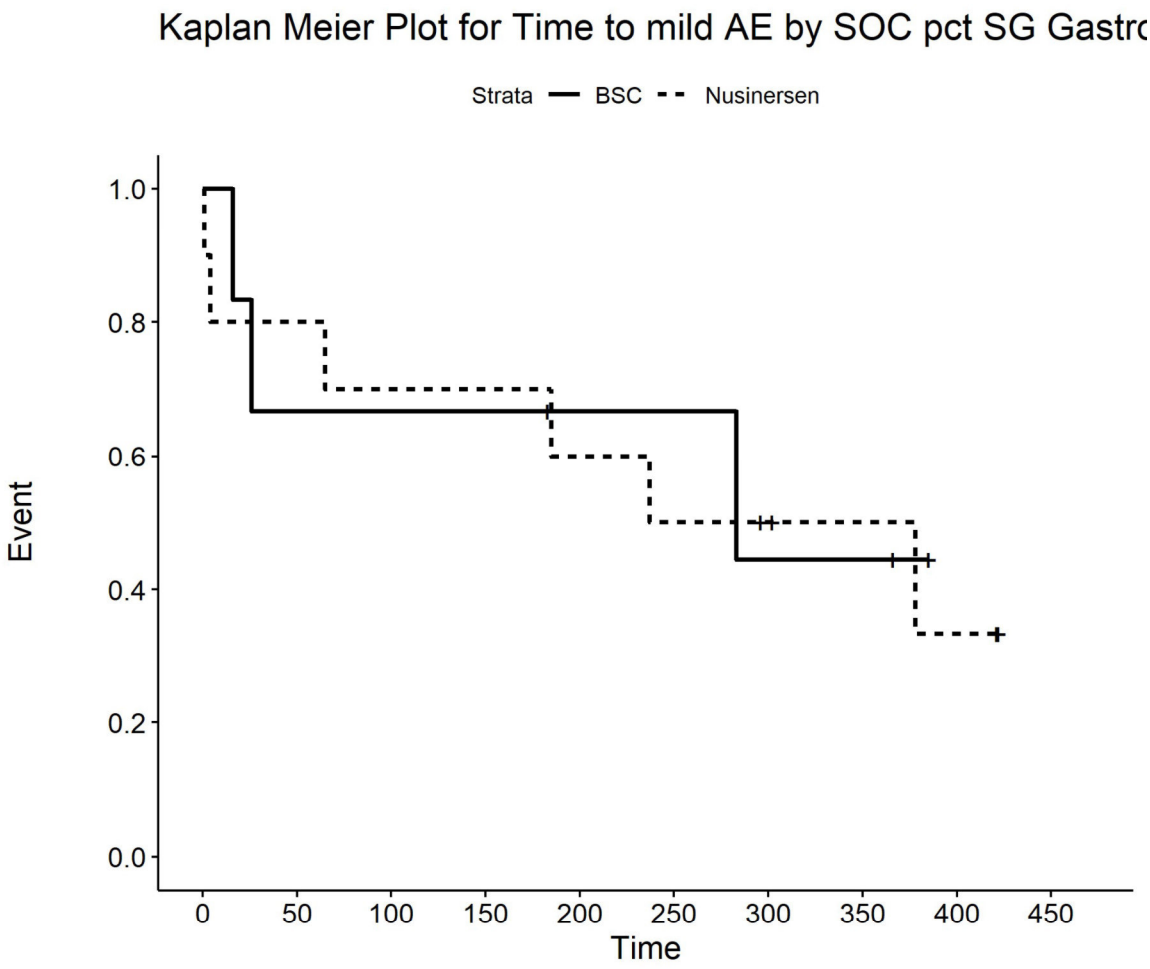
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



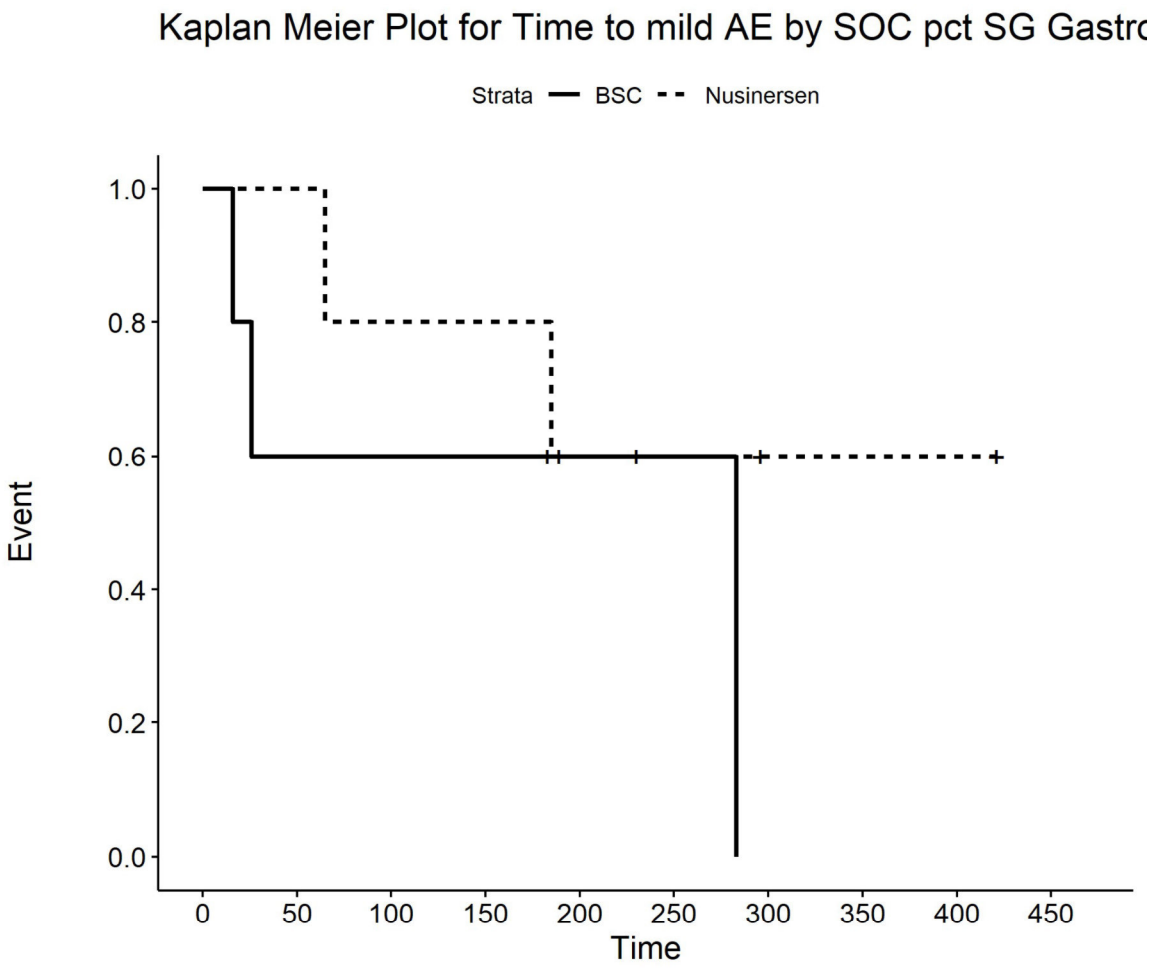
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



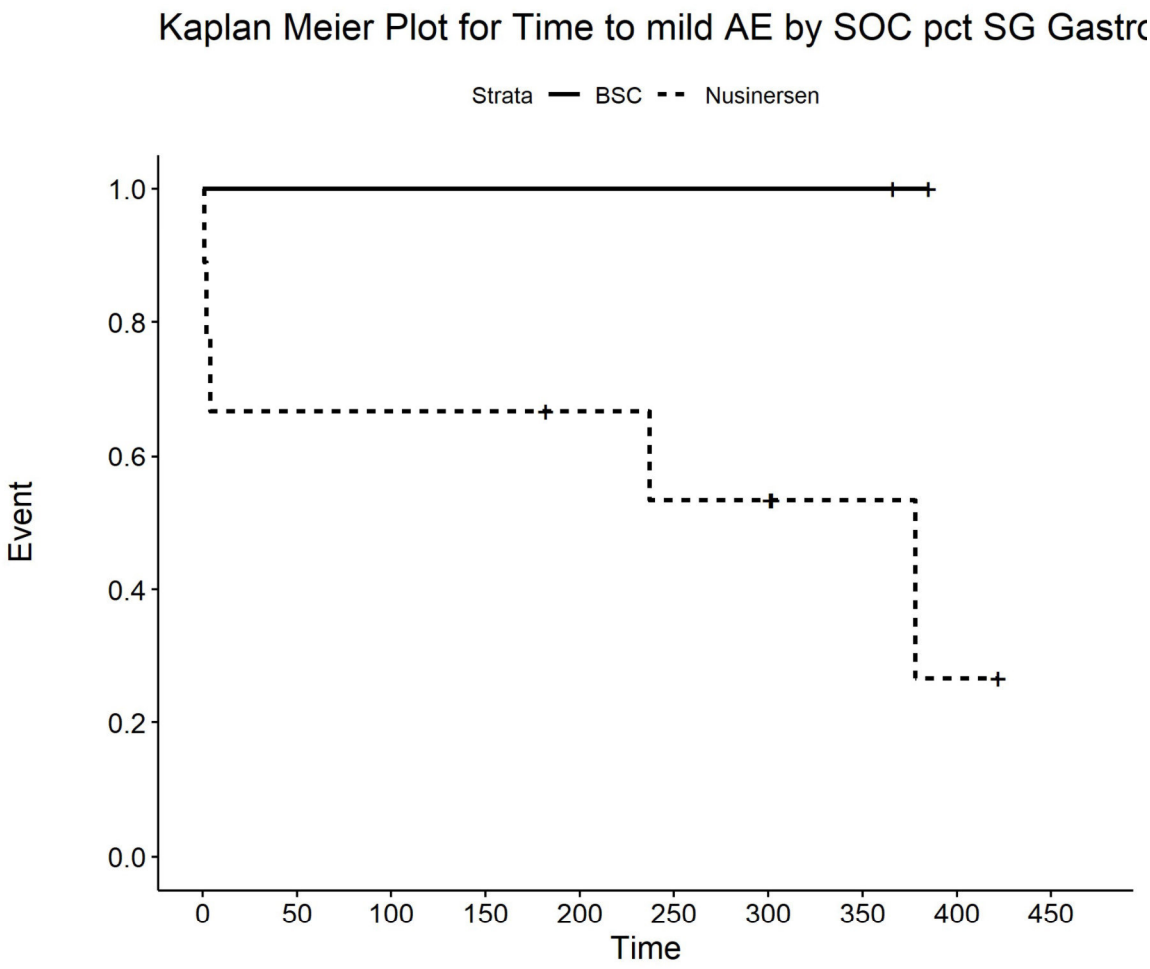
Number at risk

BSC	6	4	4	4	3	3	2	2	0	0
Nusinersen	10	8	7	7	6	5	4	3	2	0



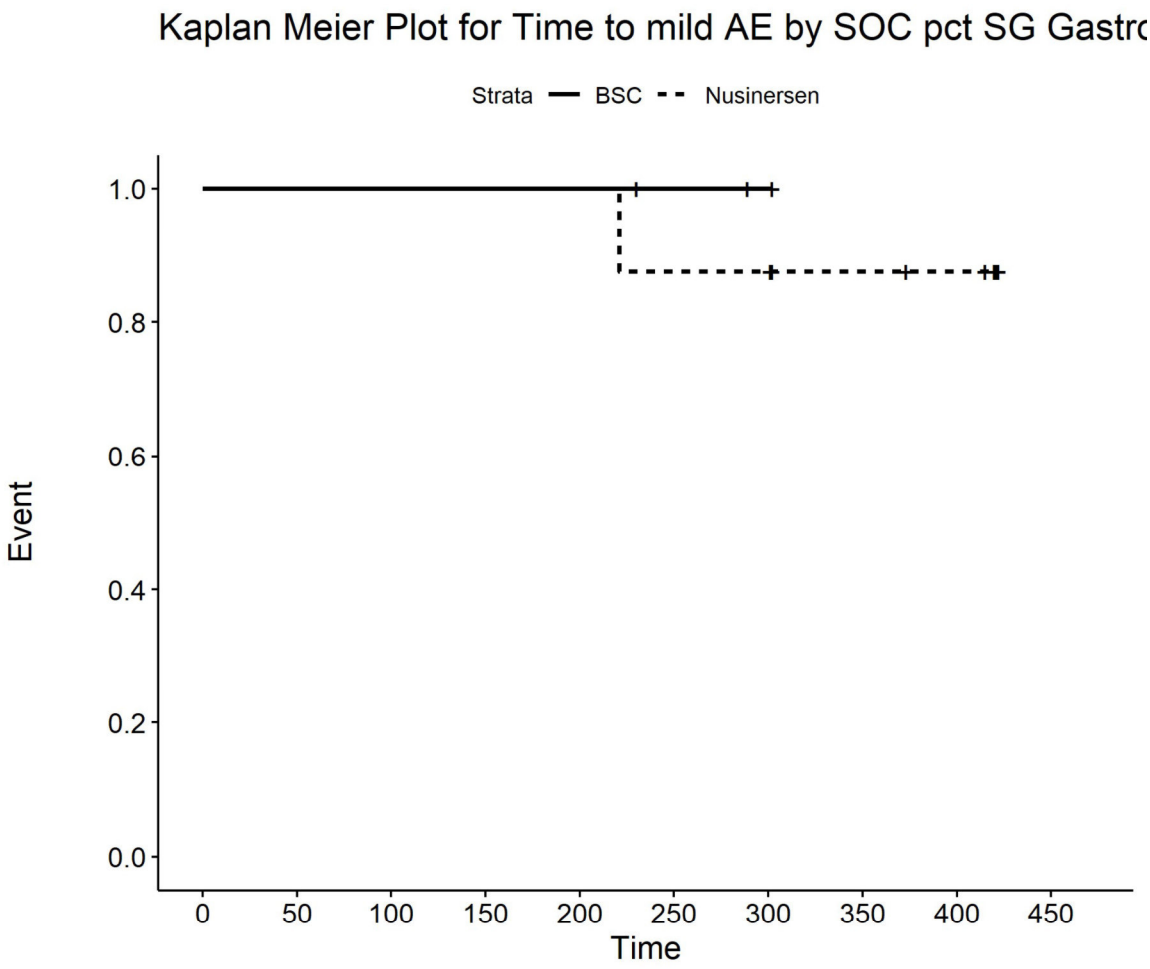
Number at risk

BSC	5	3	3	3	2	1	0	0	0	0
Nusinersen	5	5	4	4	2	2	1	1	1	0



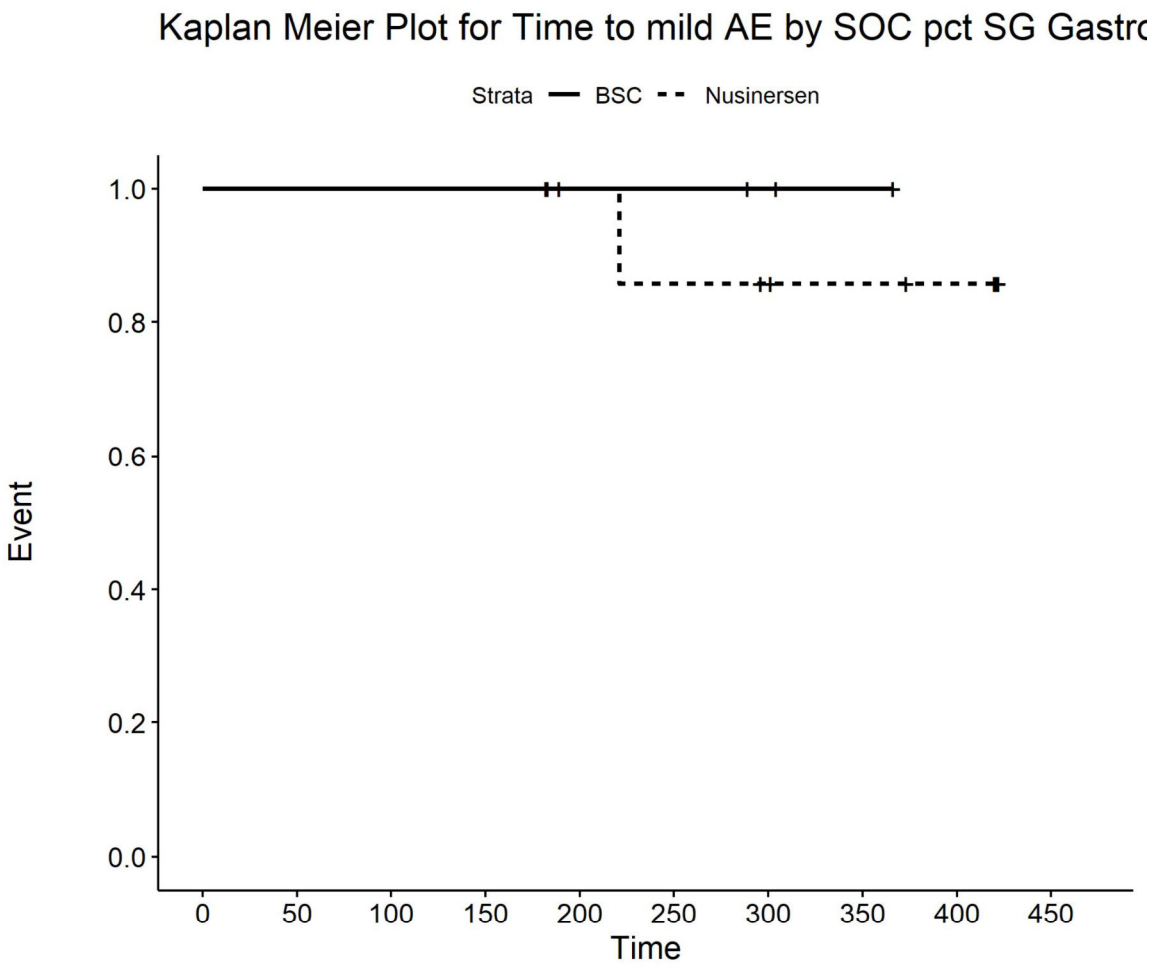
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	6	6	6	5	4	4	2	1	0



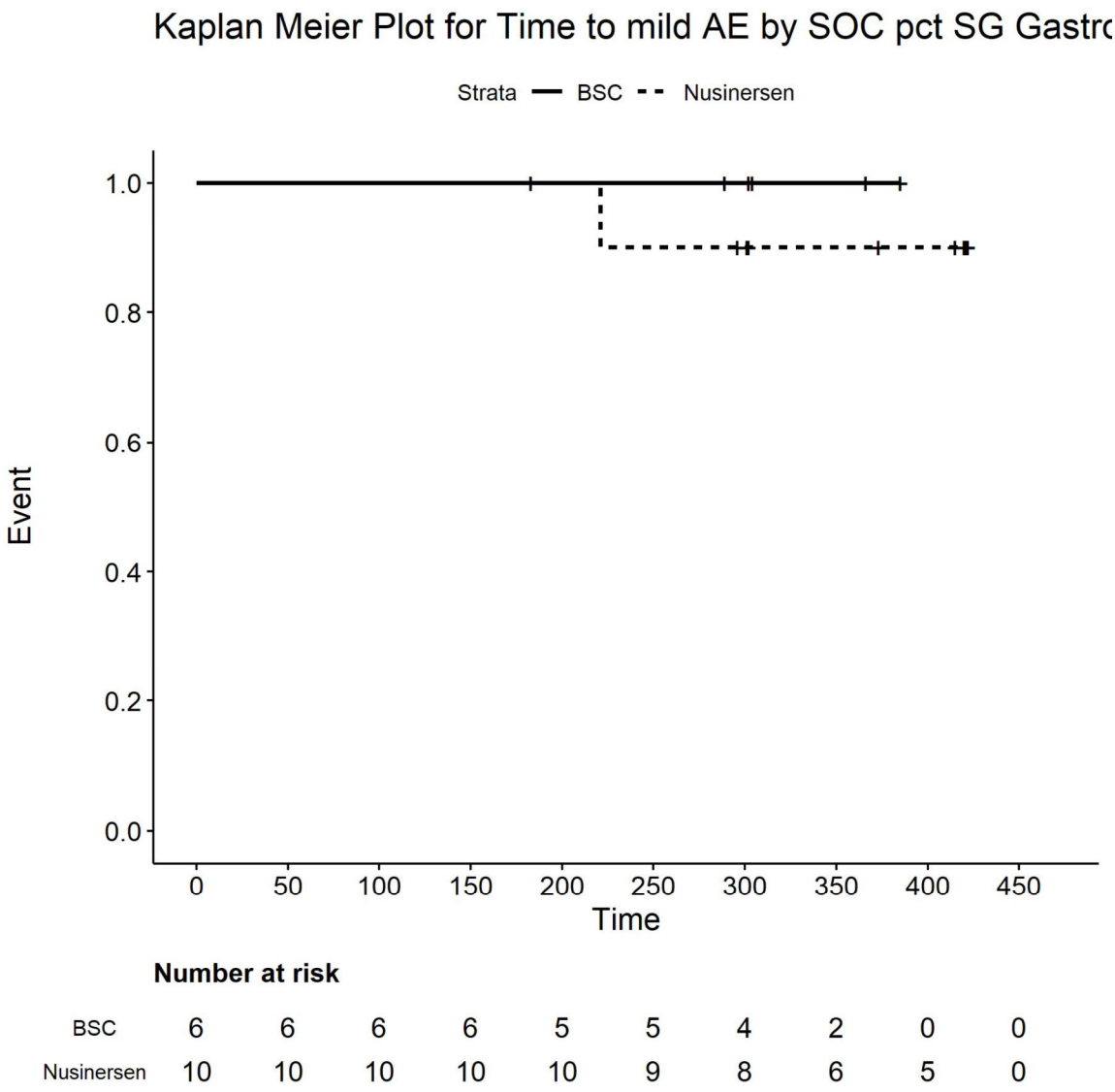
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



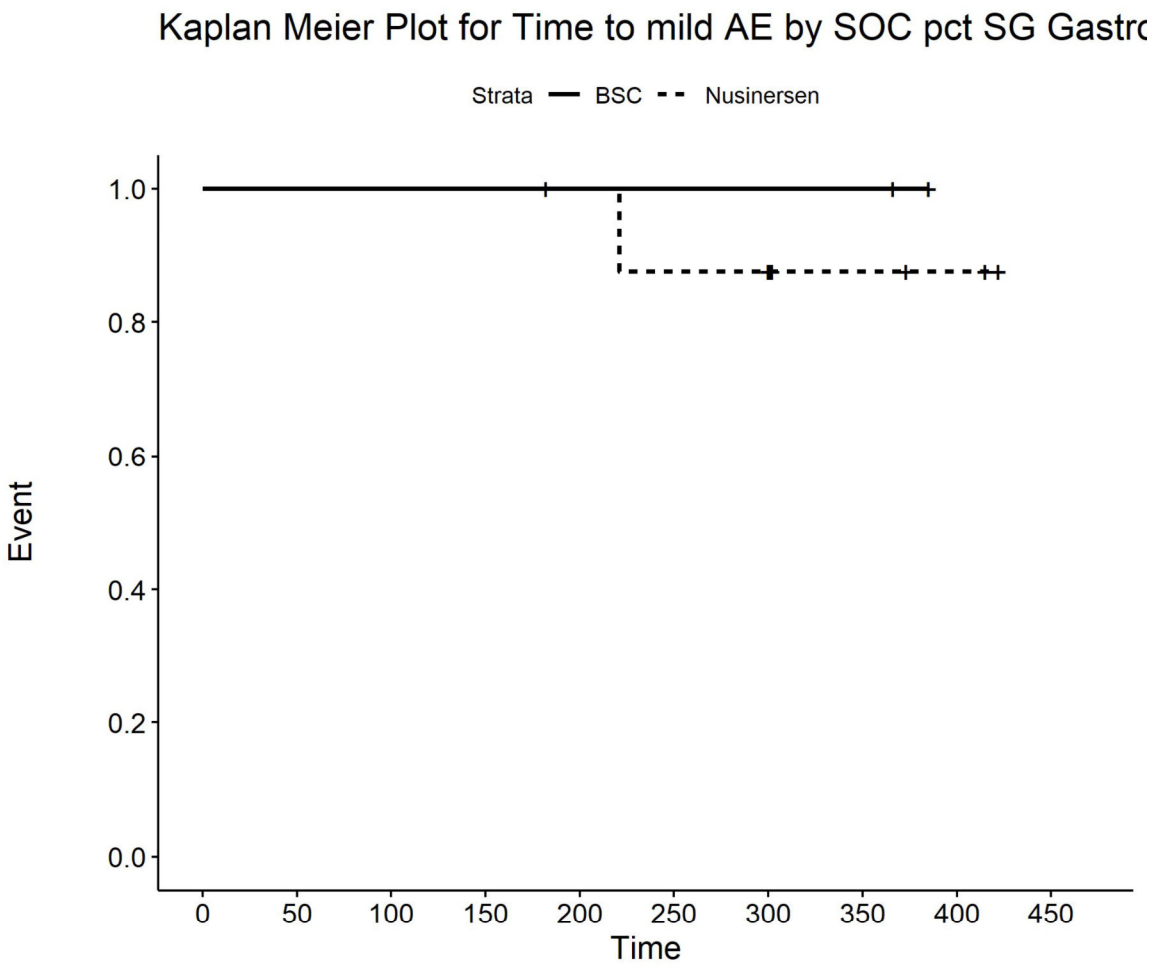
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



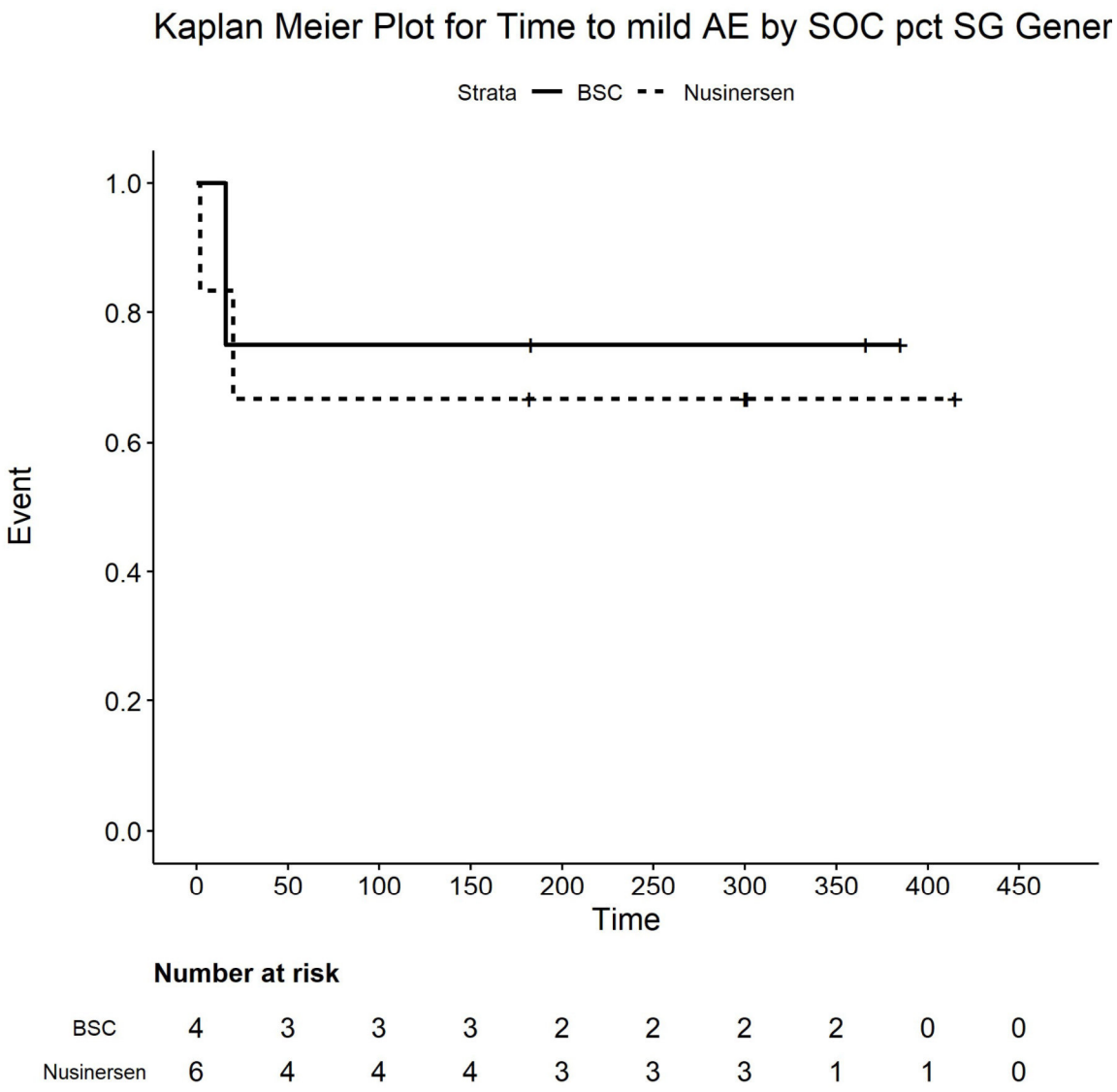
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



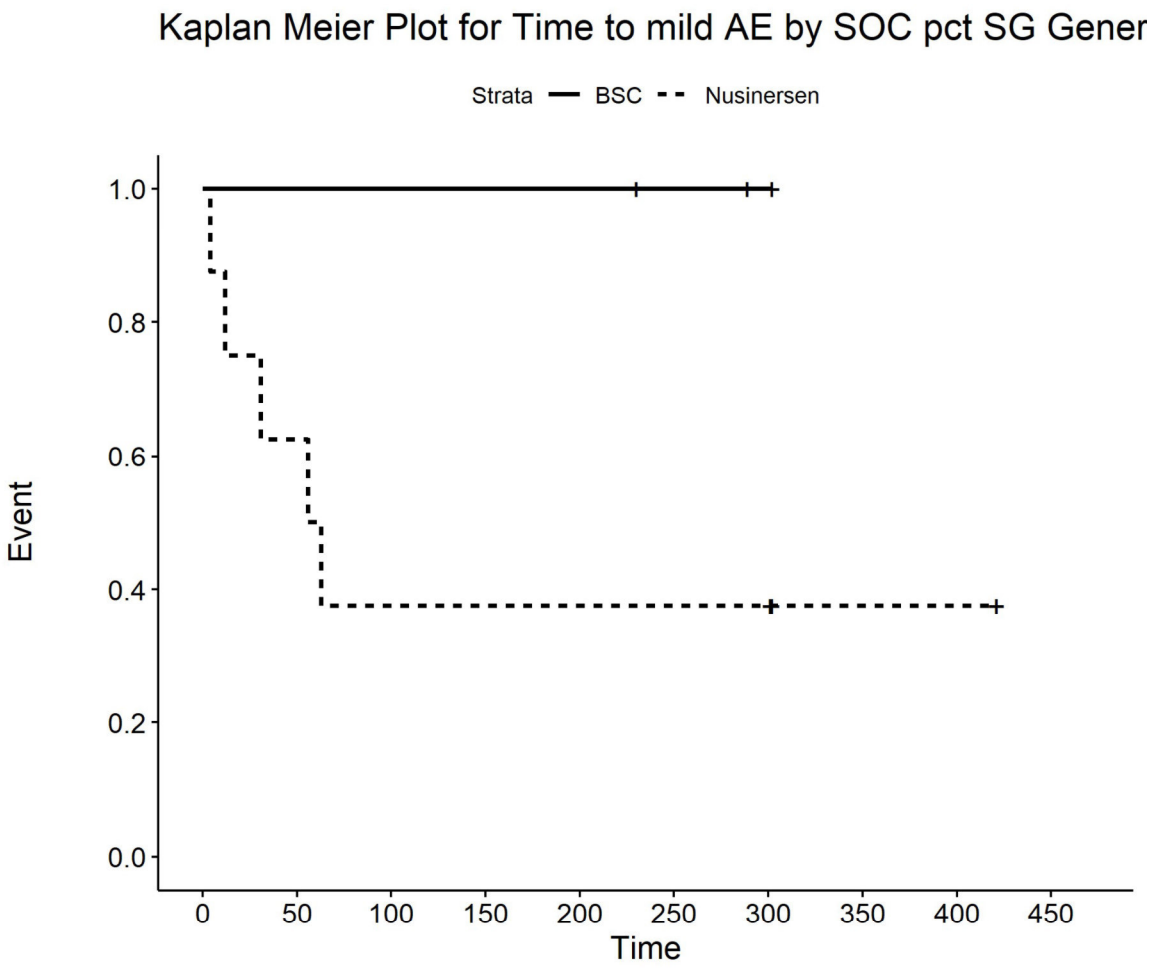
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	2	0



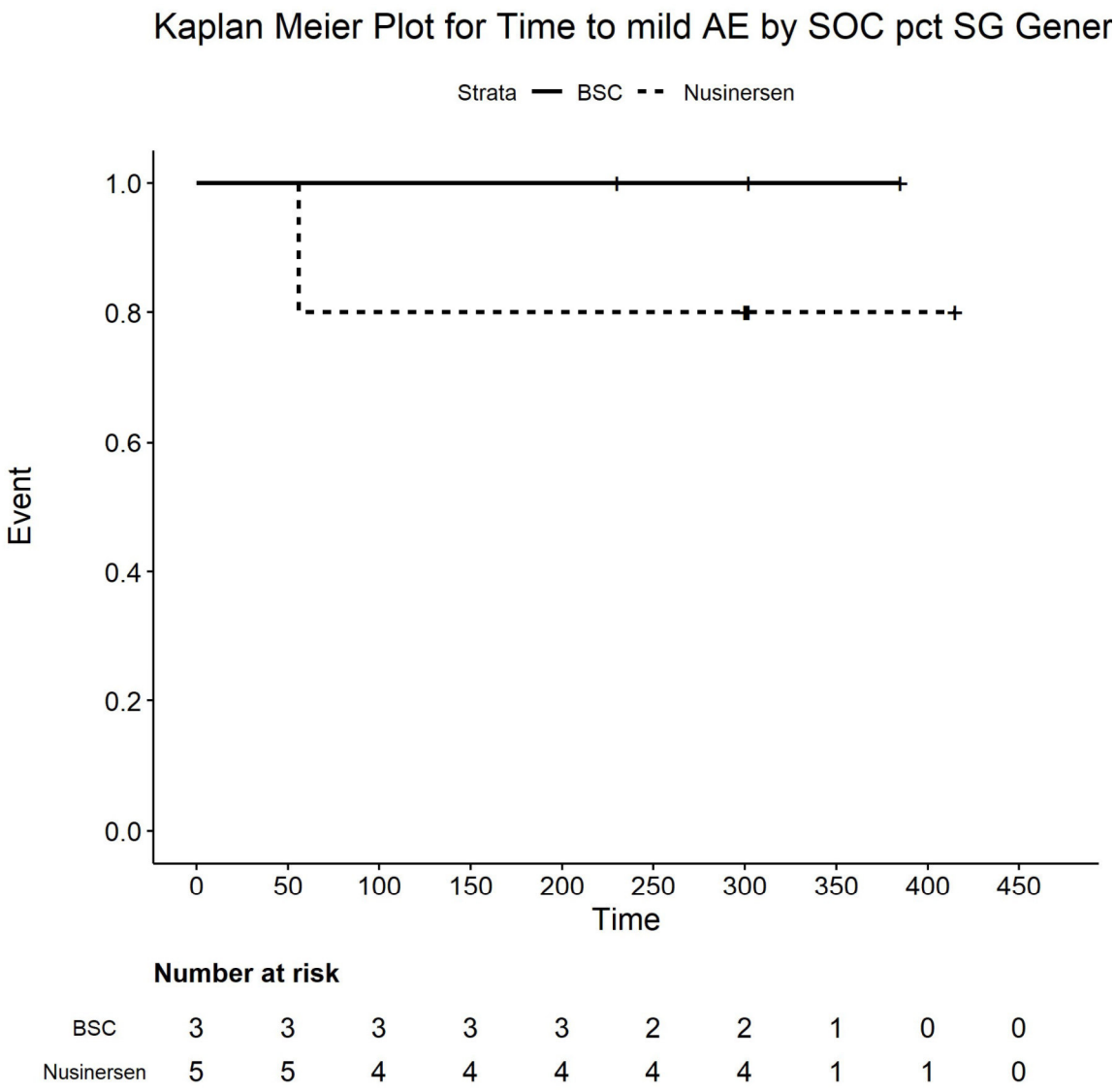
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	4	4	4	3	3	3	1	1	0



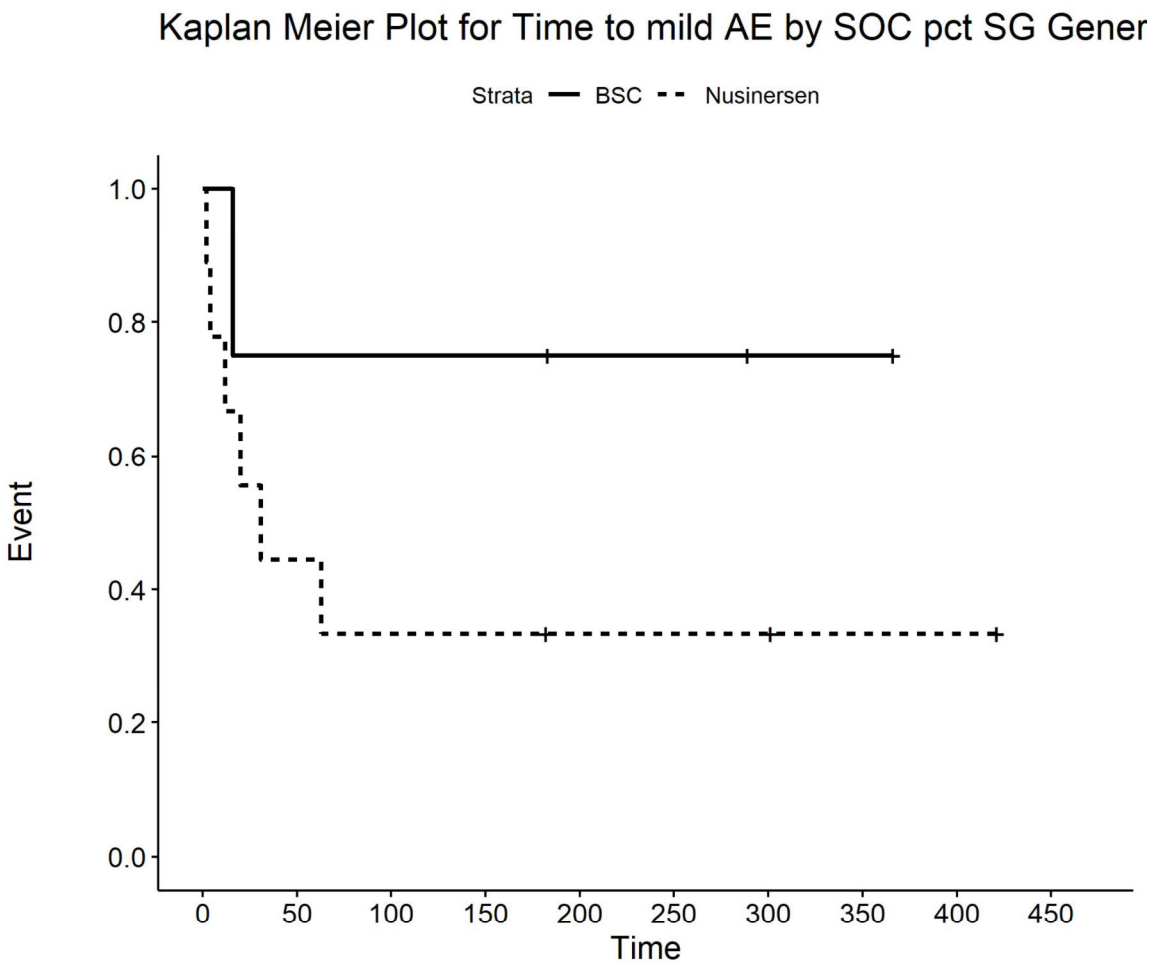
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	5	3	3	3	3	3	1	1	0



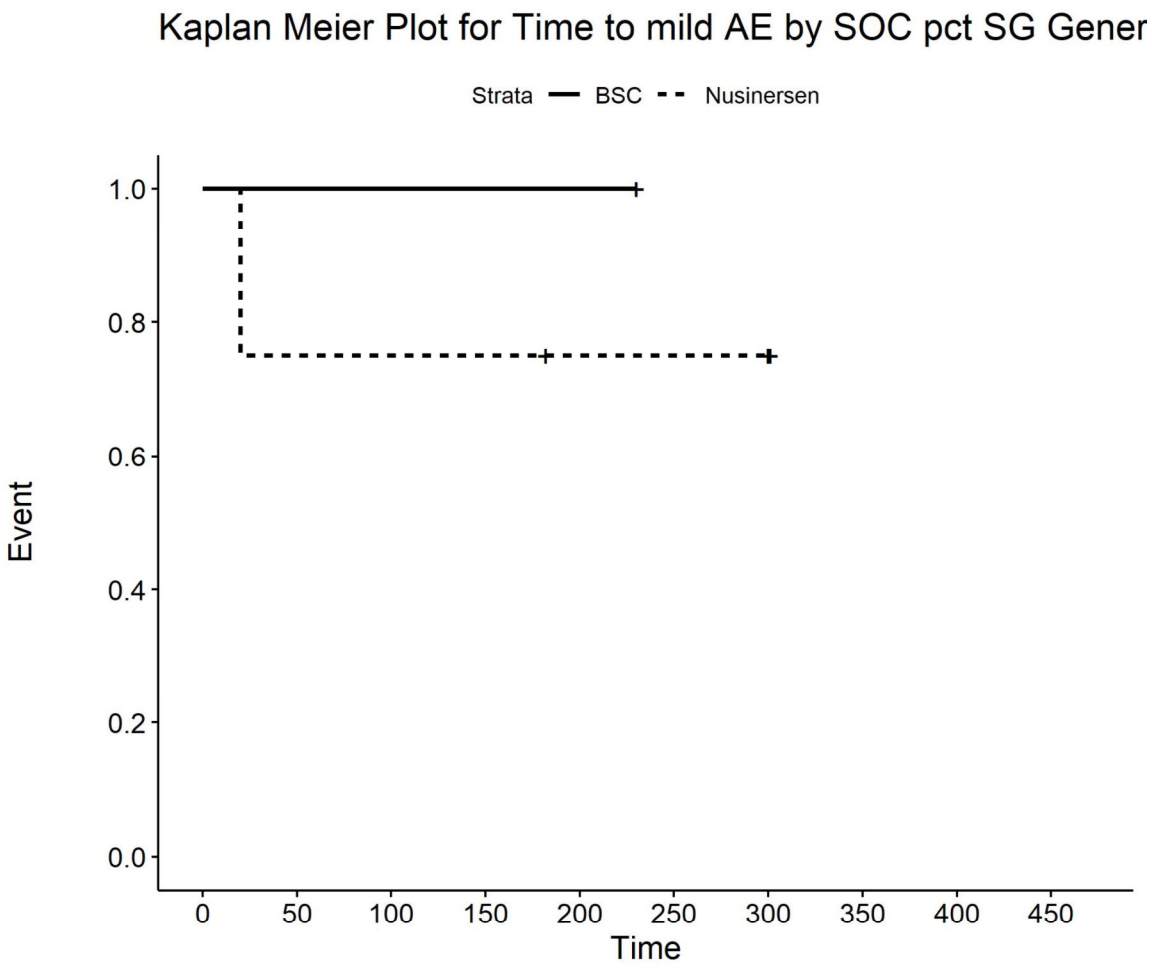
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	1	1	0



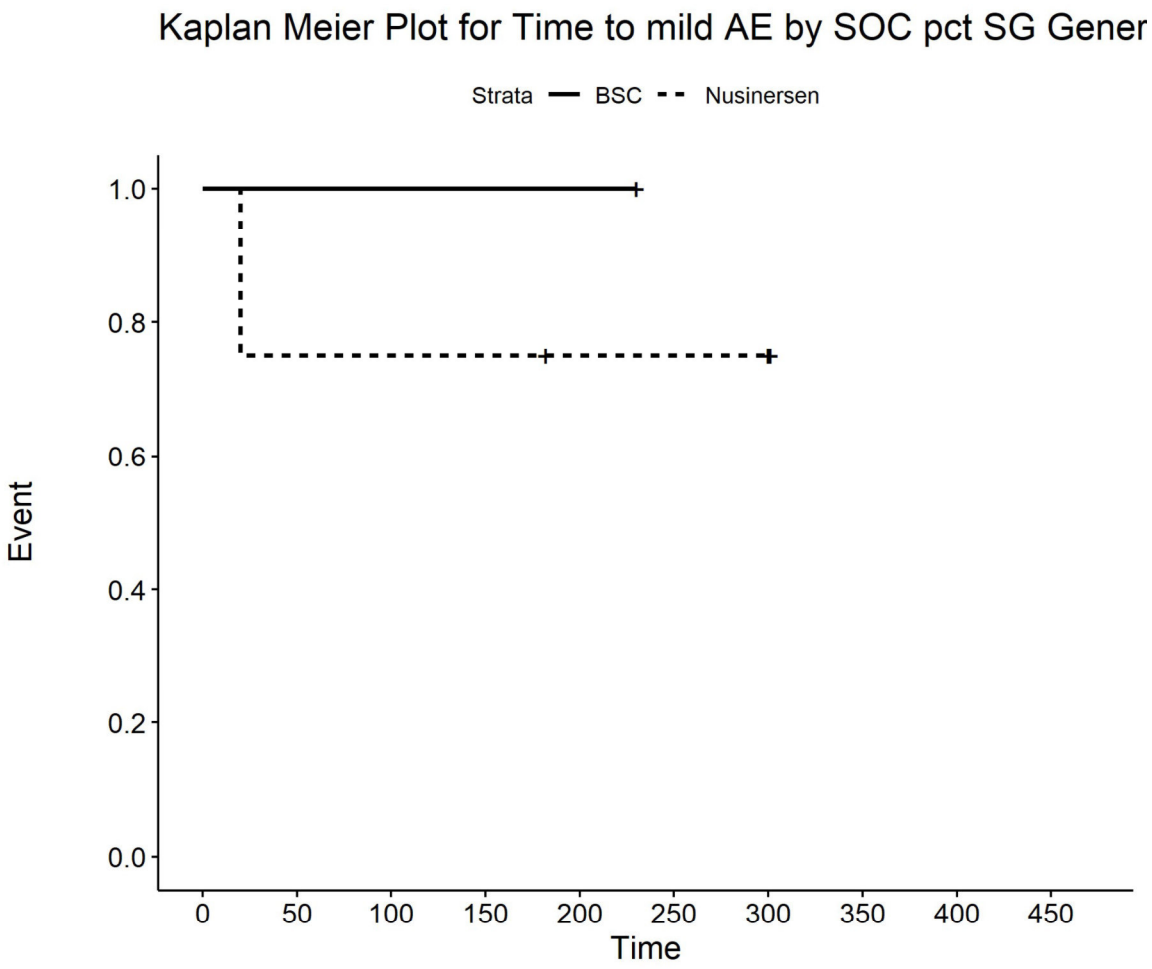
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	4	3	3	2	2	2	1	1	0



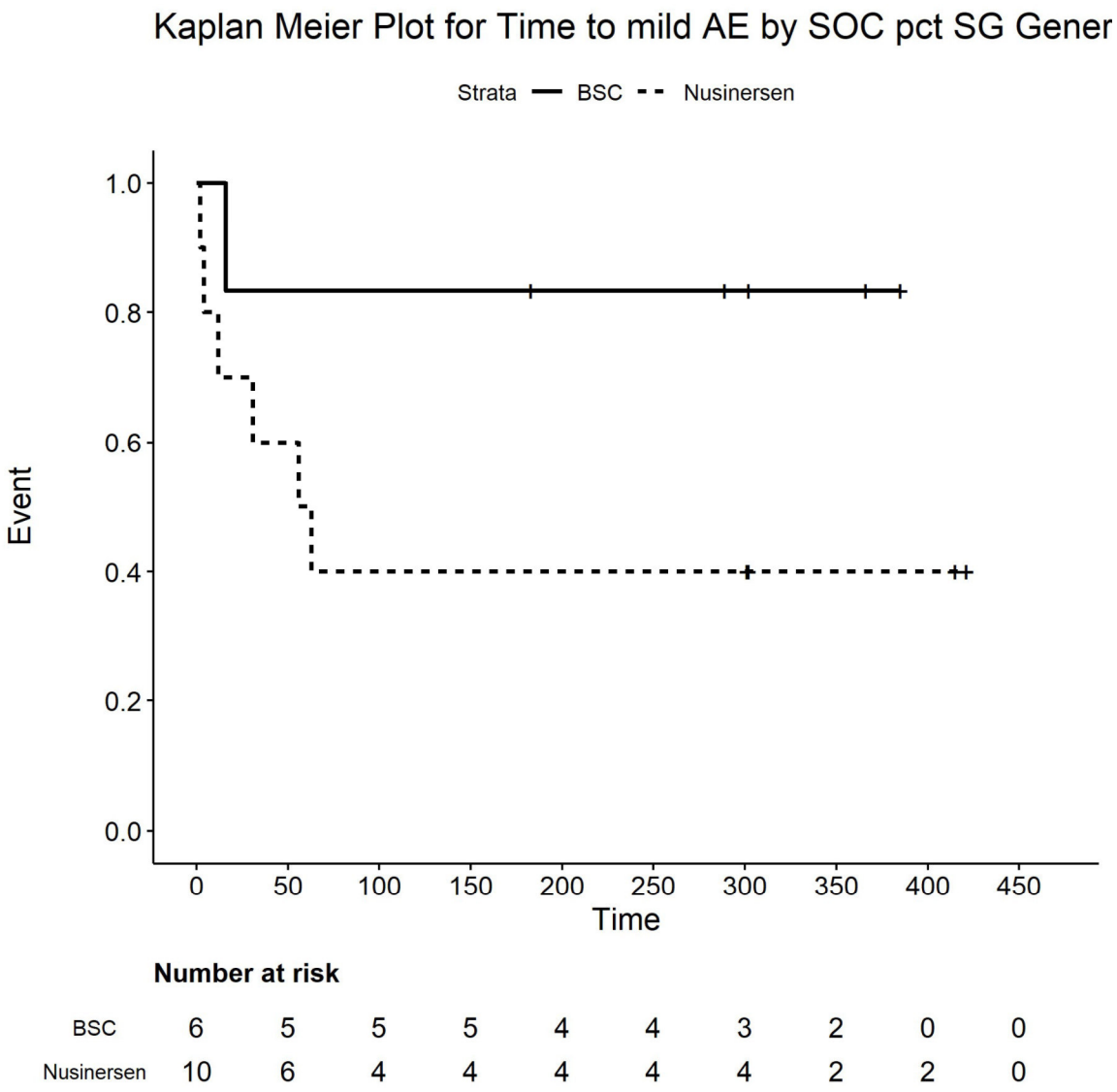
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



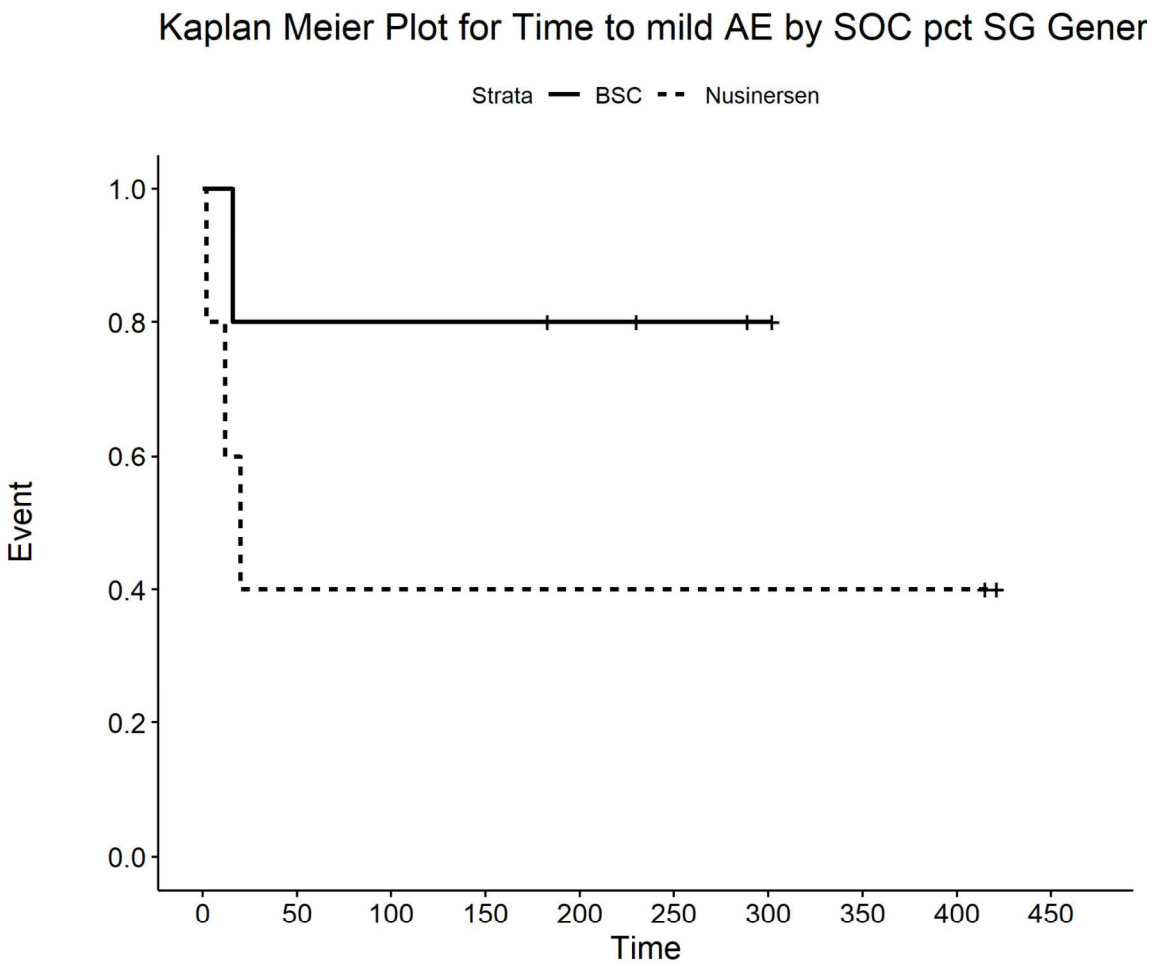
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



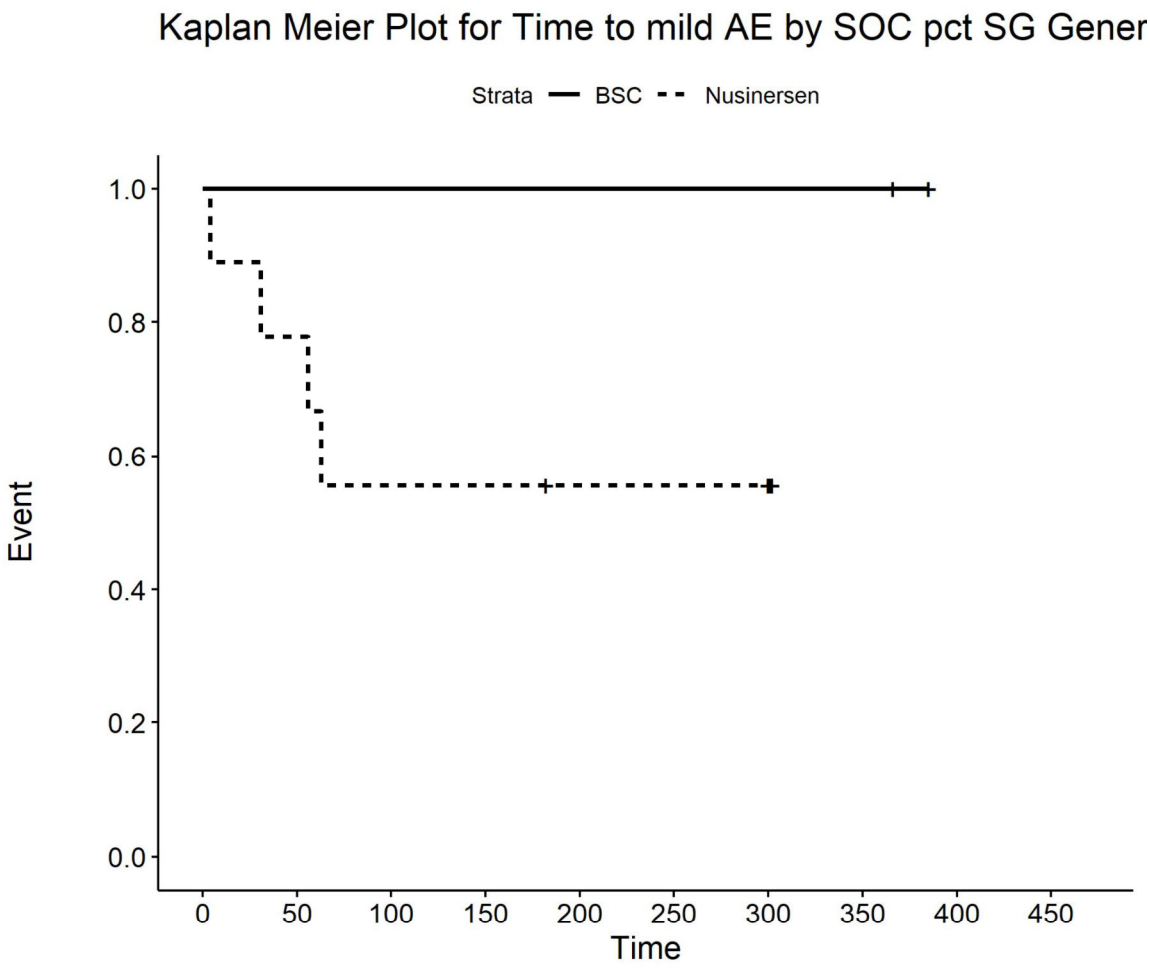
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	6	4	4	4	4	4	2	2	0



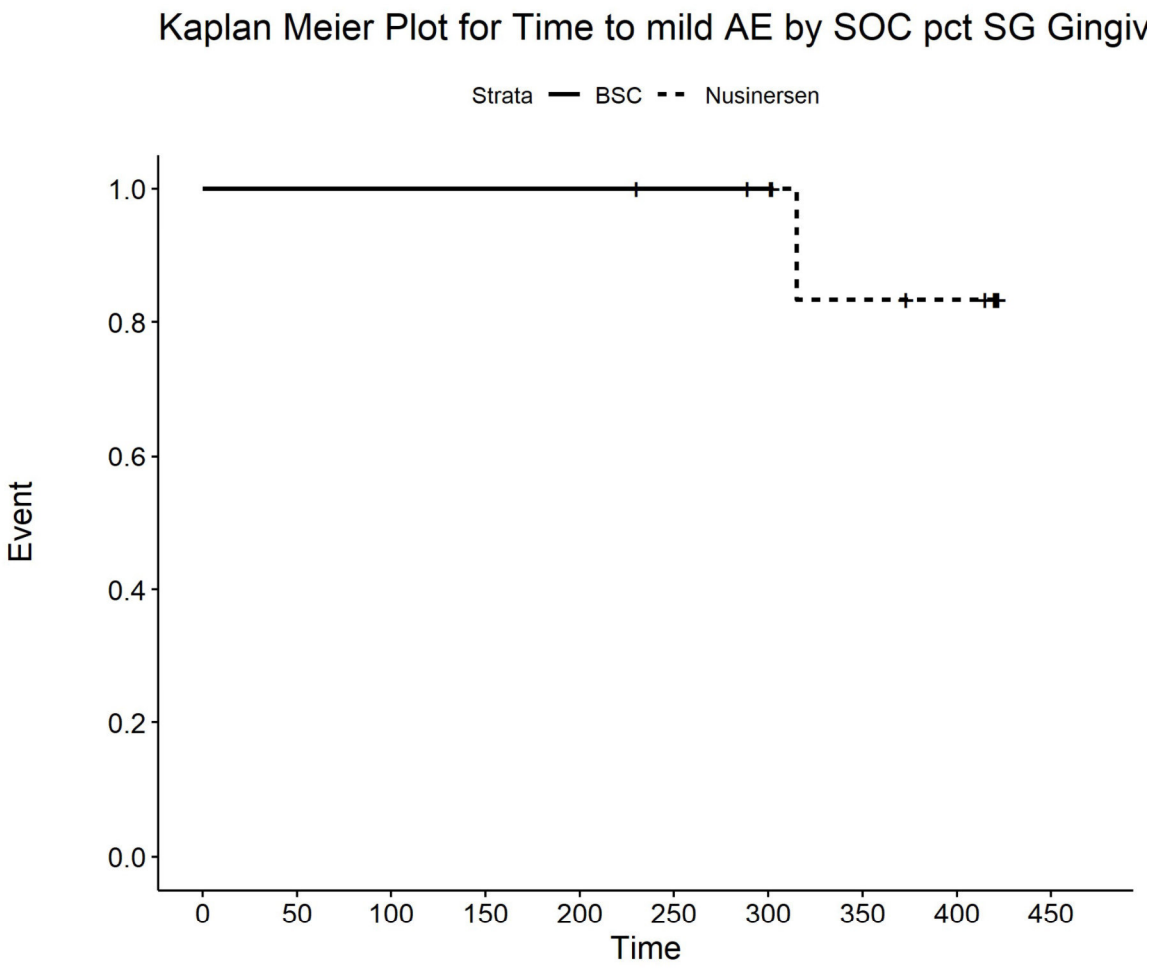
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	2	2	2	2	2	2	2	2	0



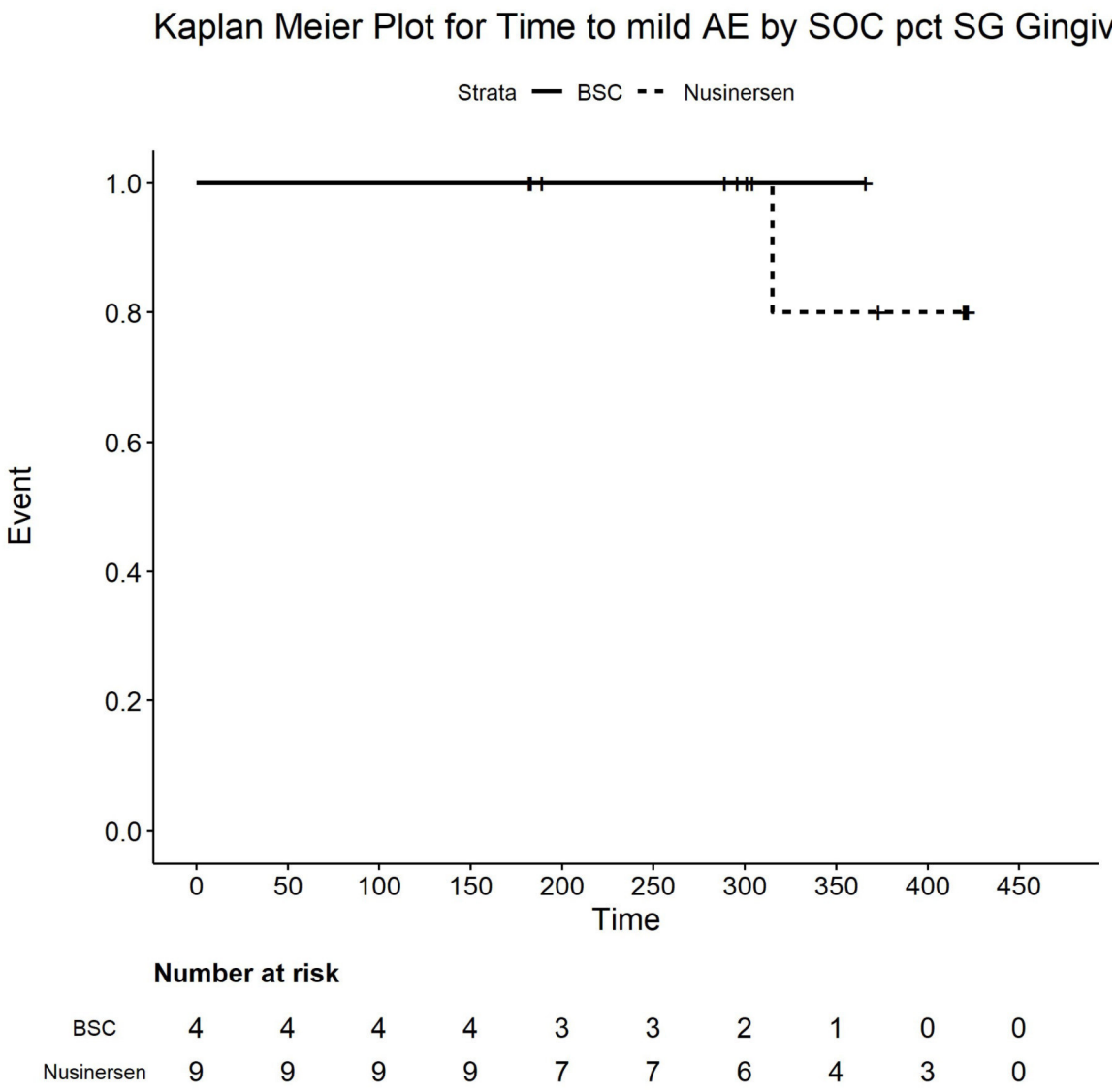
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	5	5	4	4	4	0	0	0



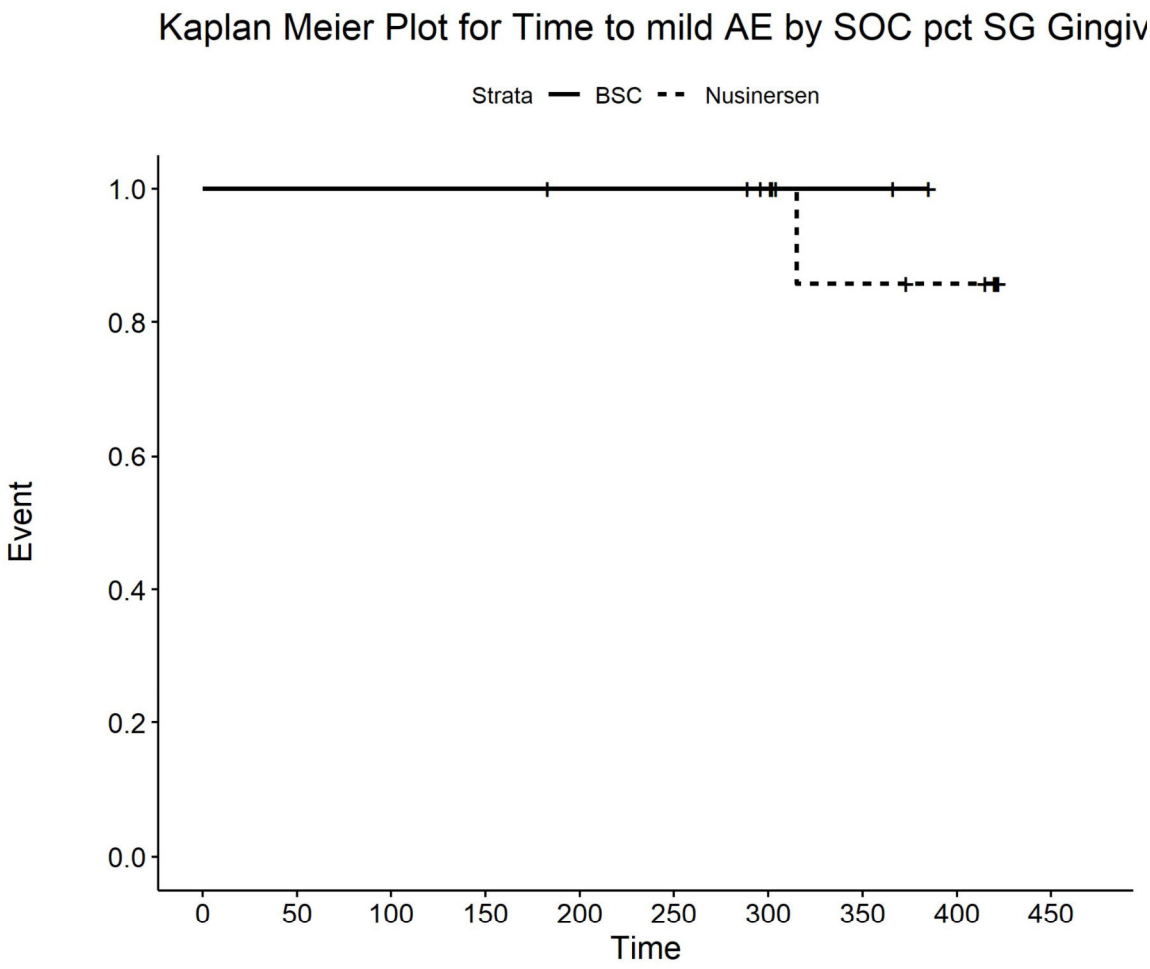
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	5	4	0



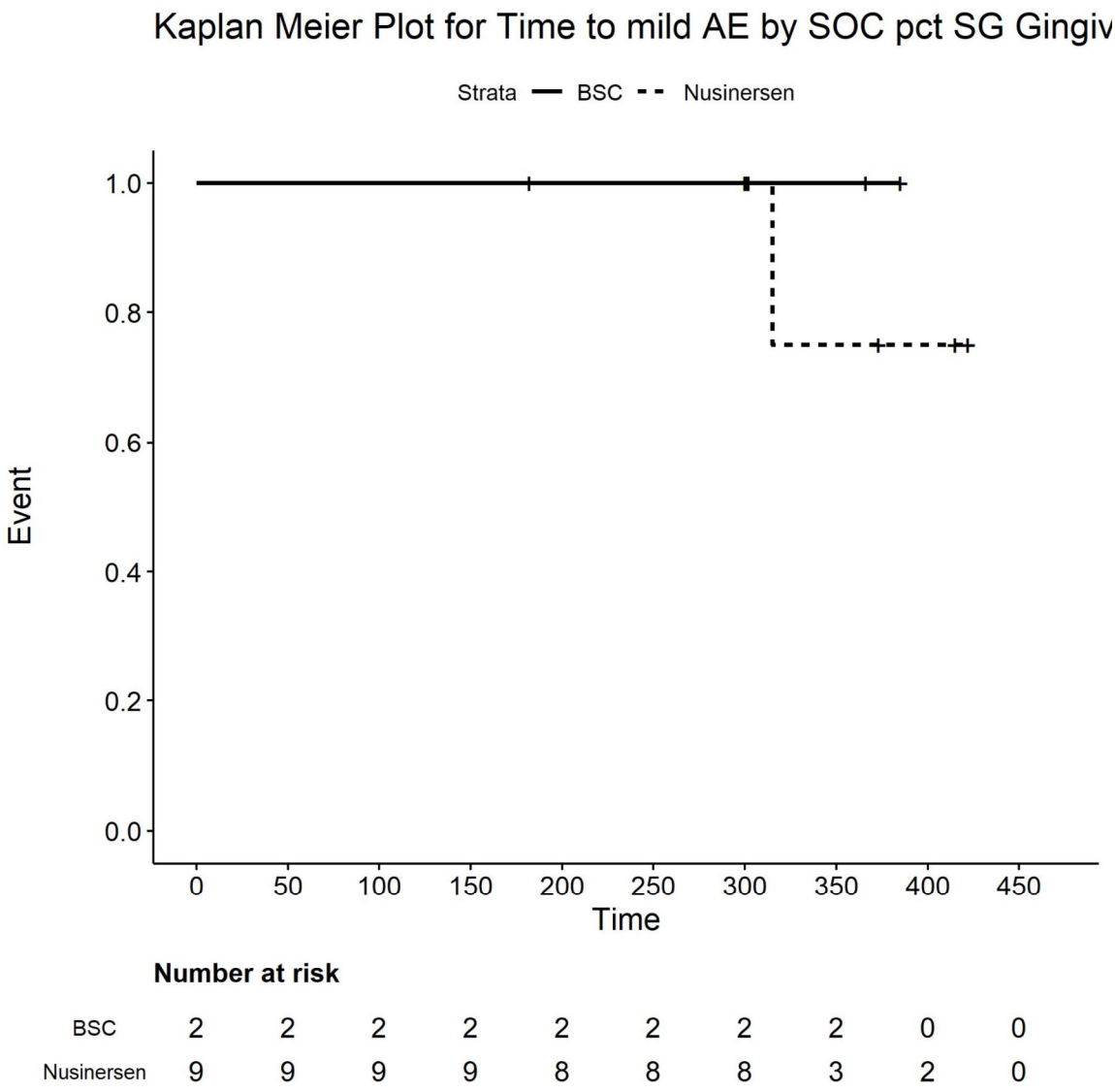
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	4	3	0



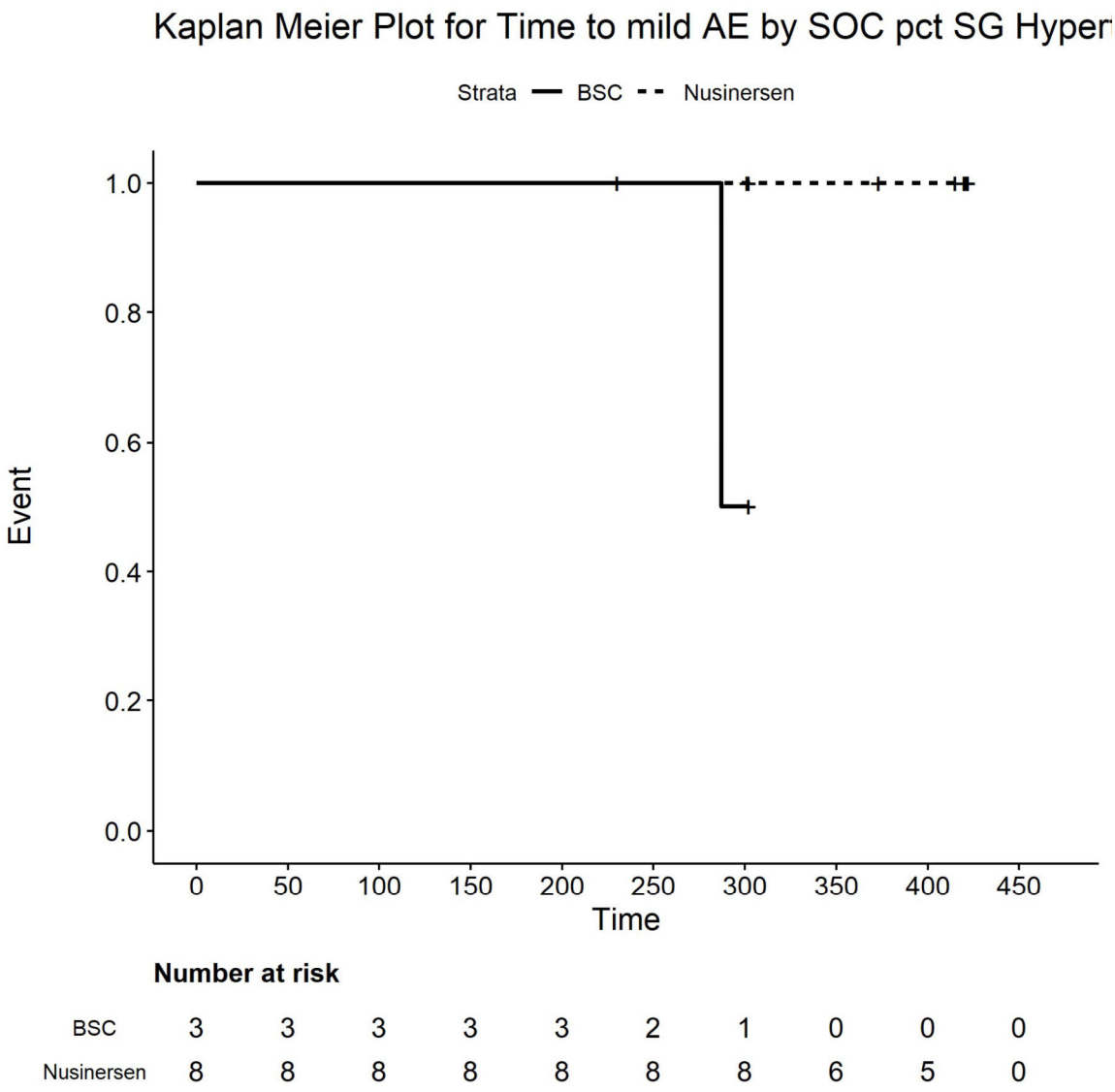
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	6	5	0



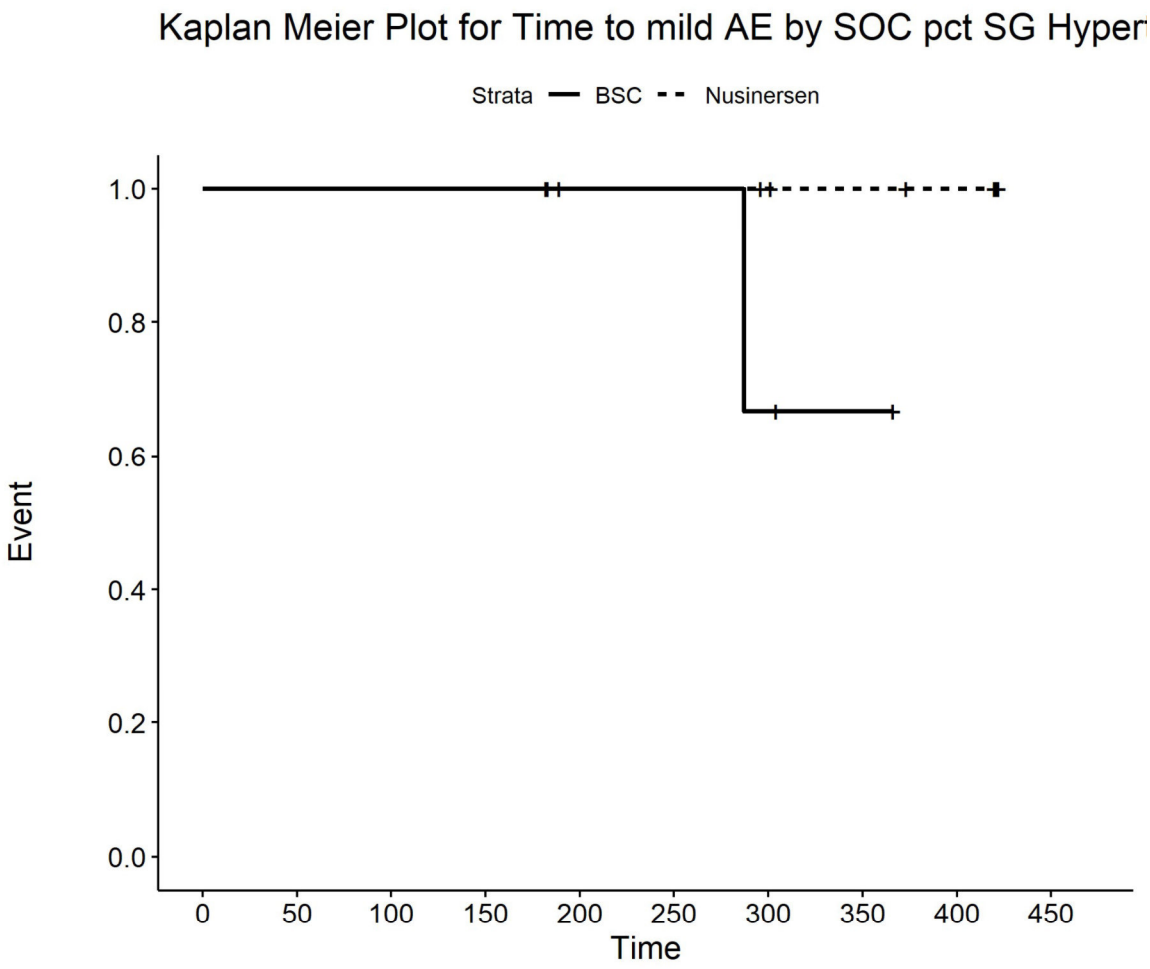
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	8	3	2	0



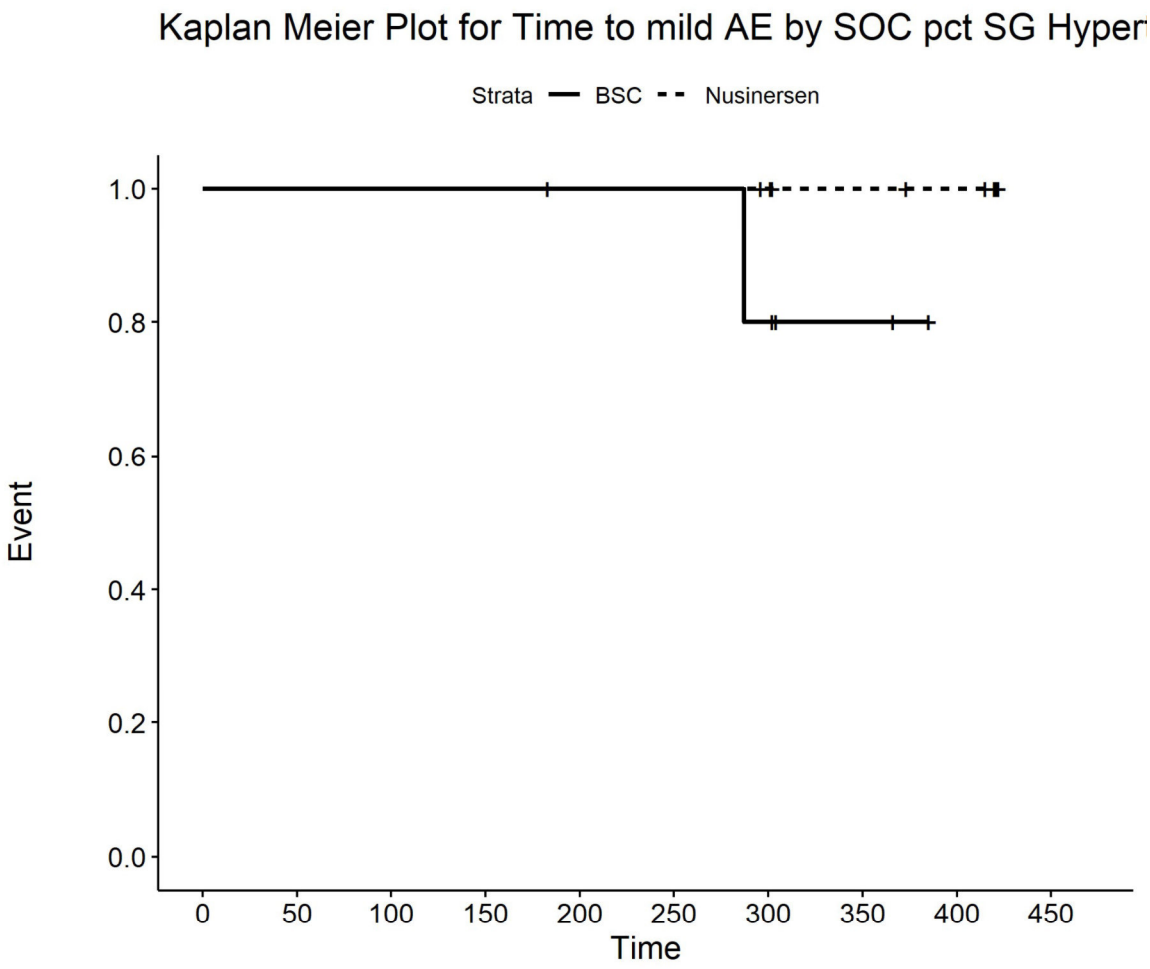
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



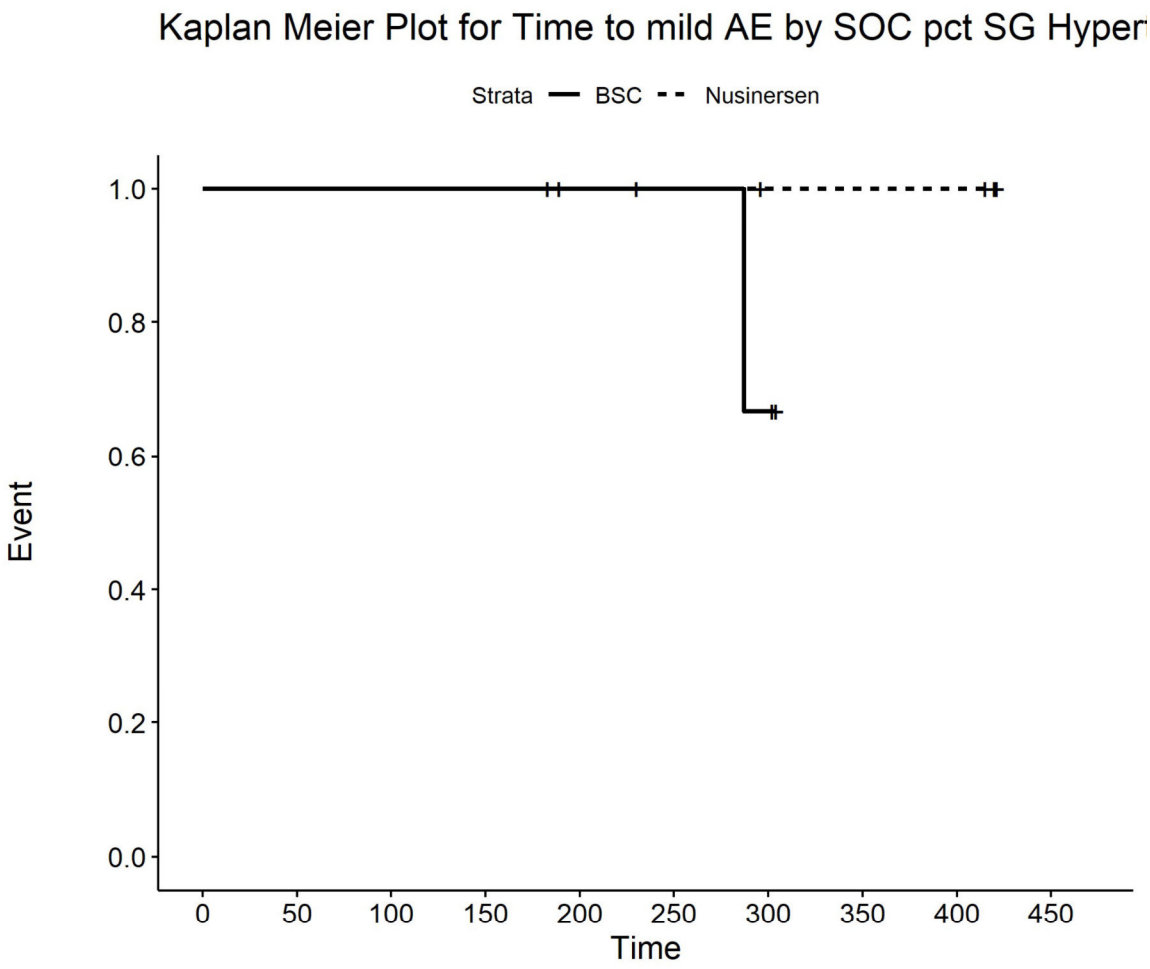
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



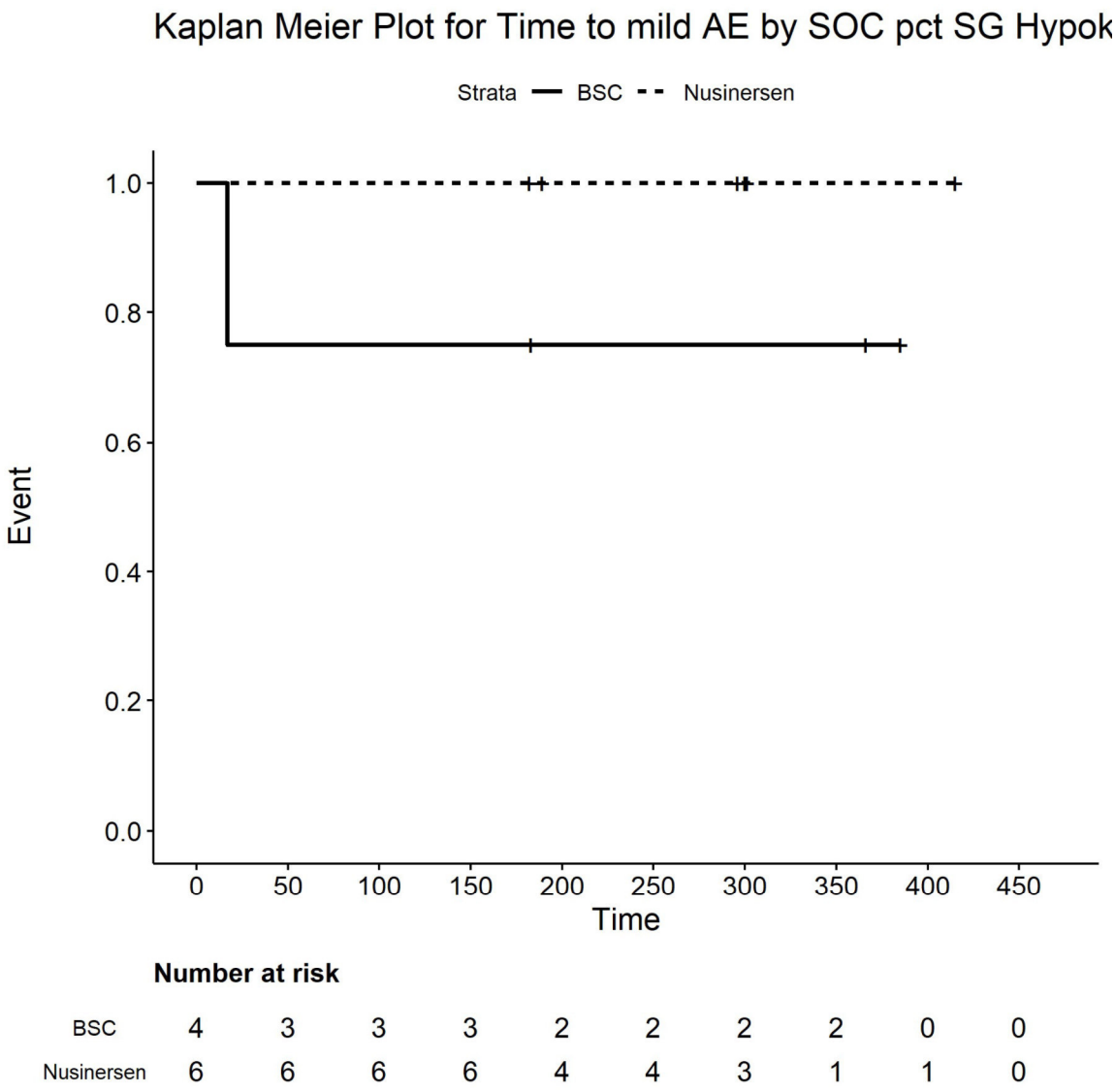
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



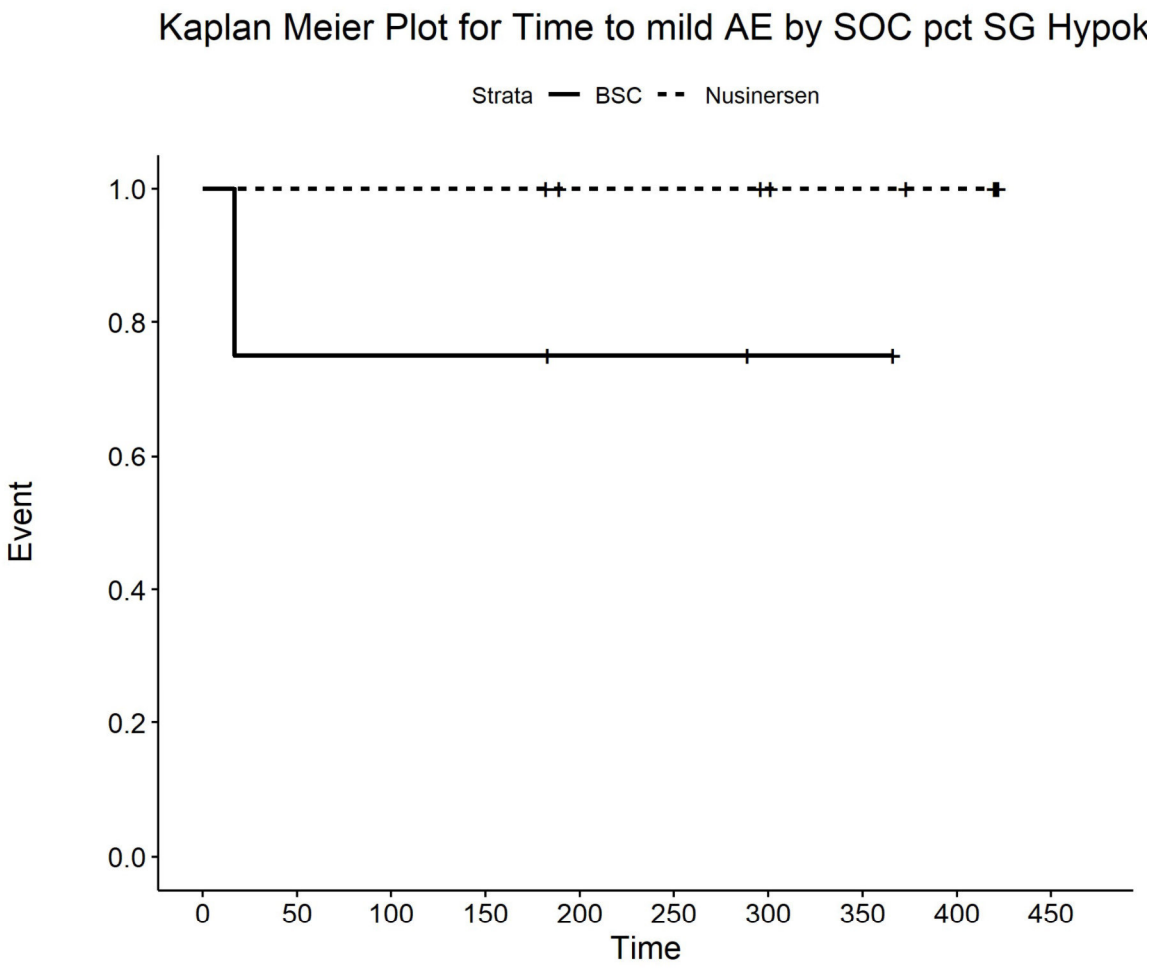
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



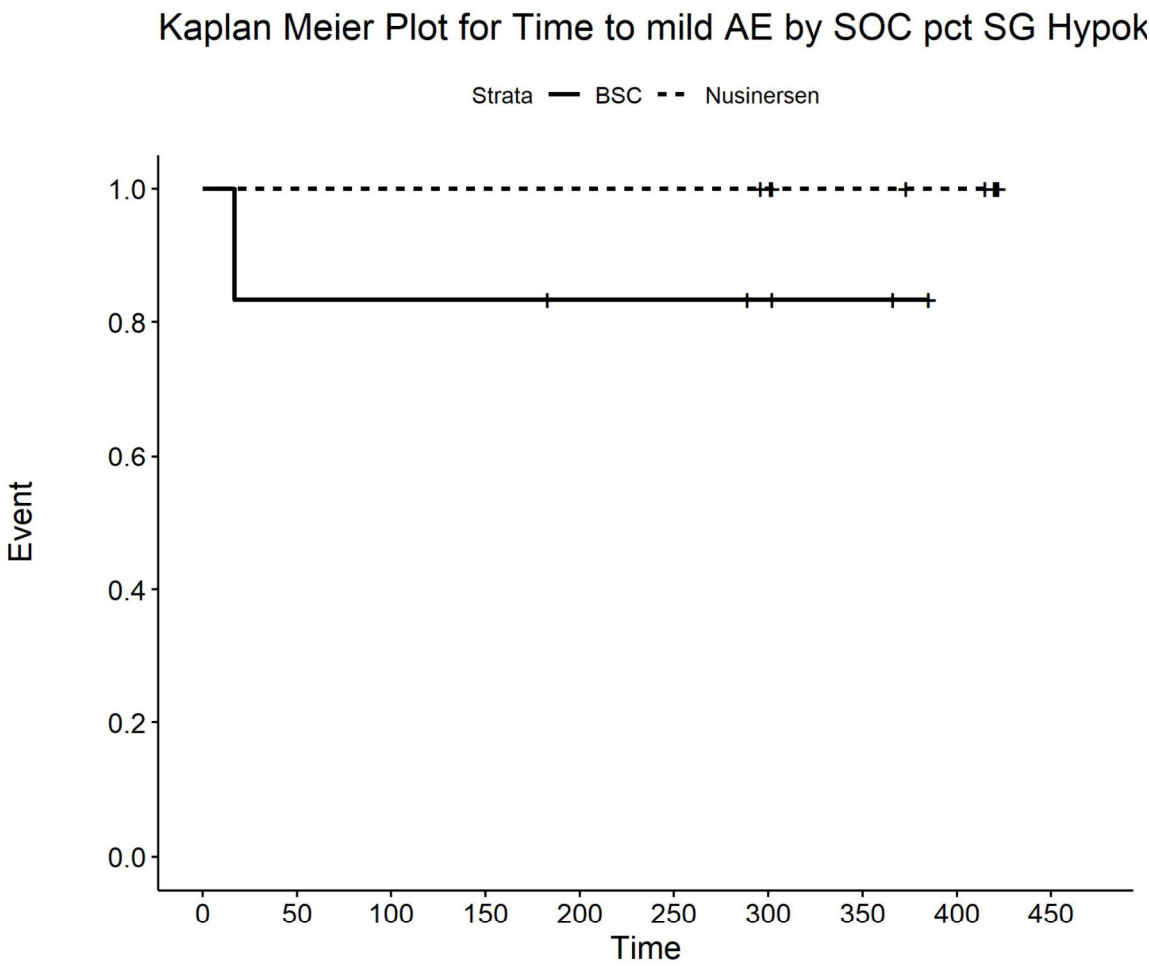
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



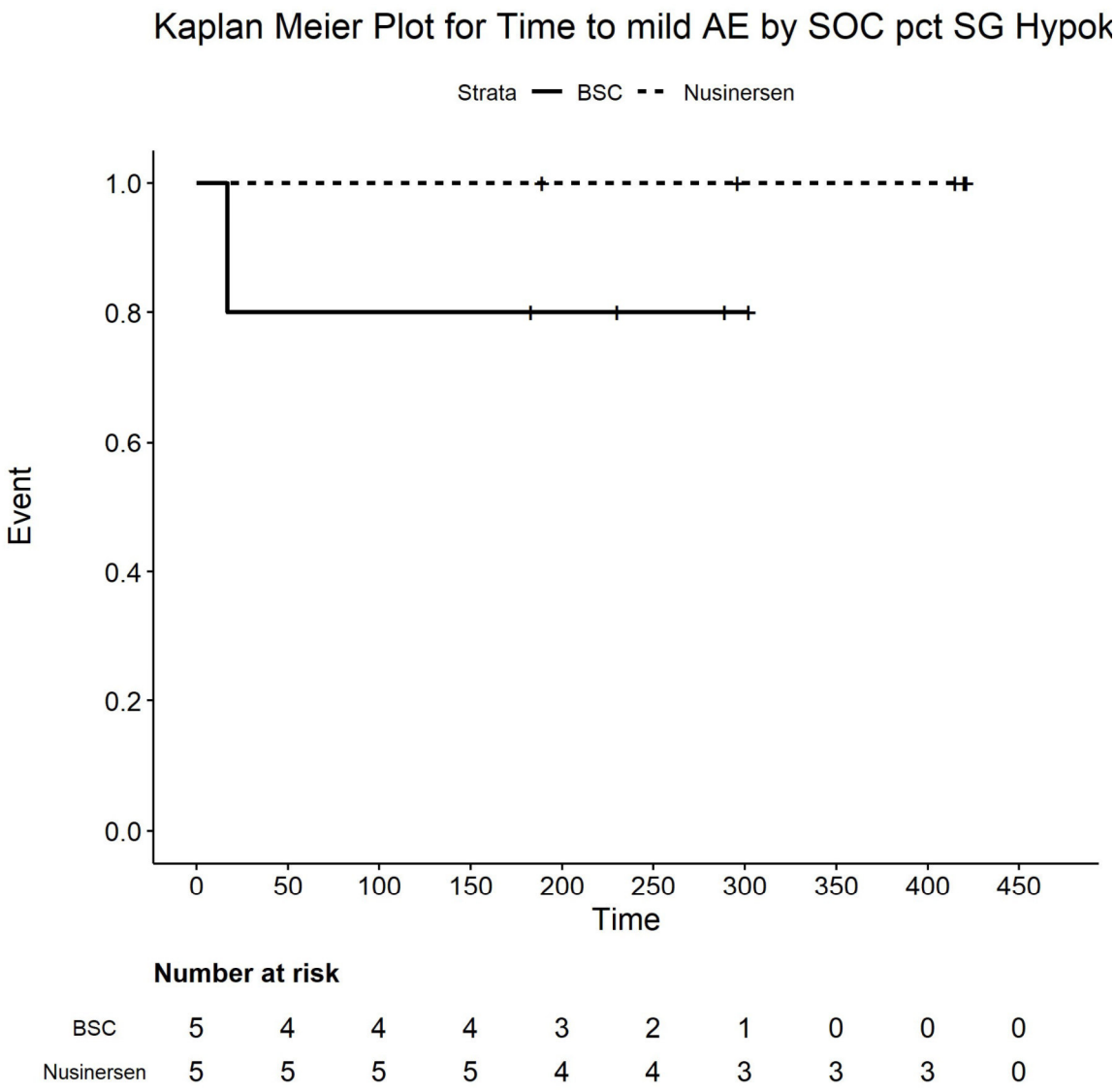
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



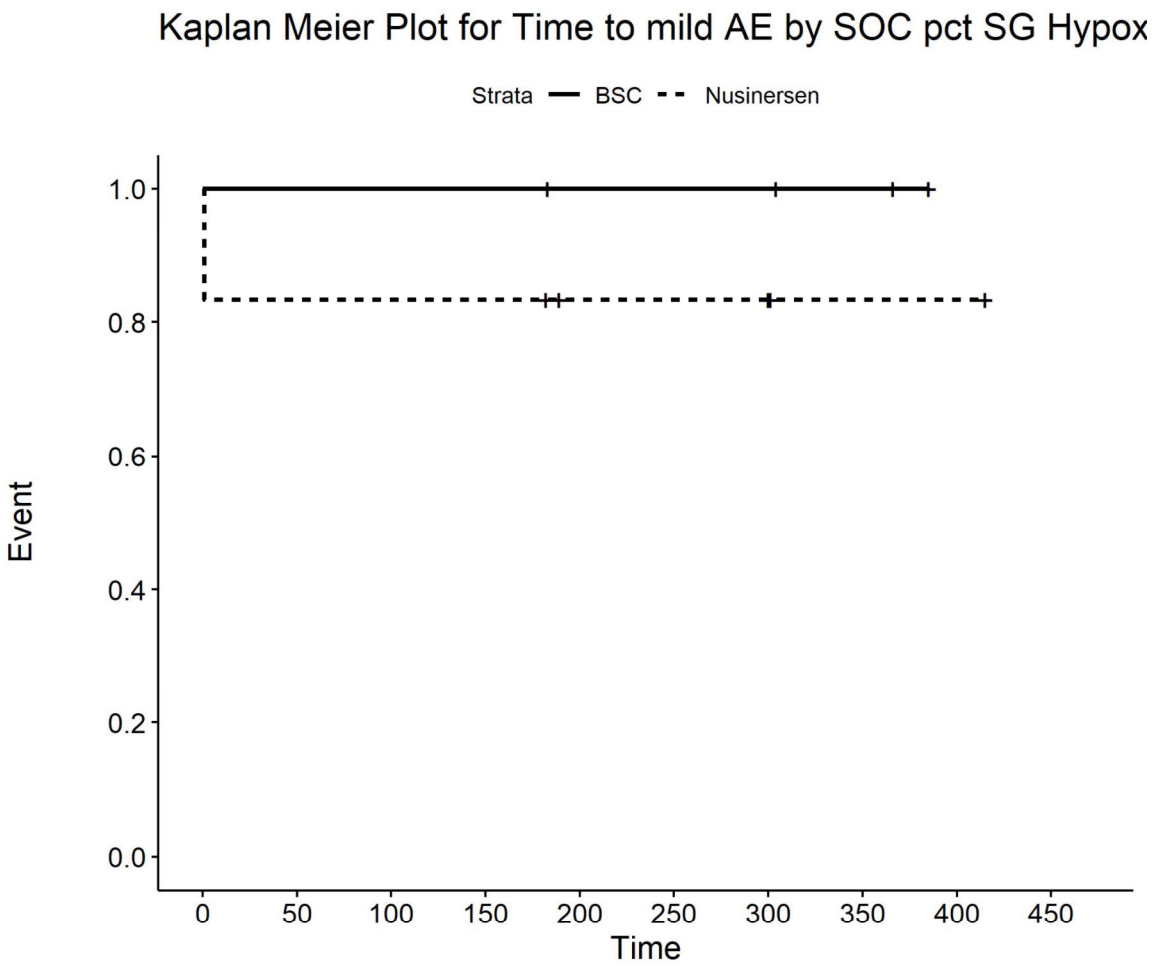
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



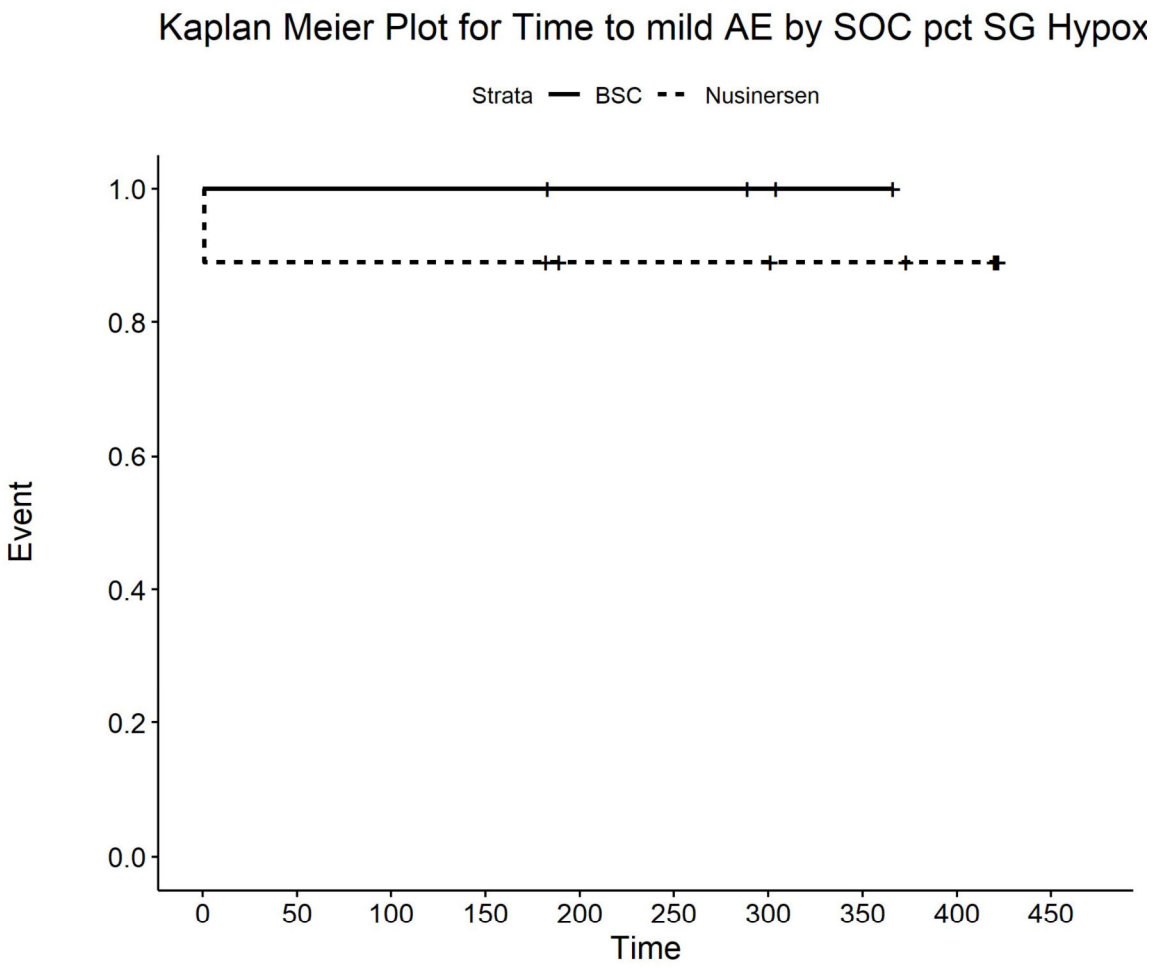
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



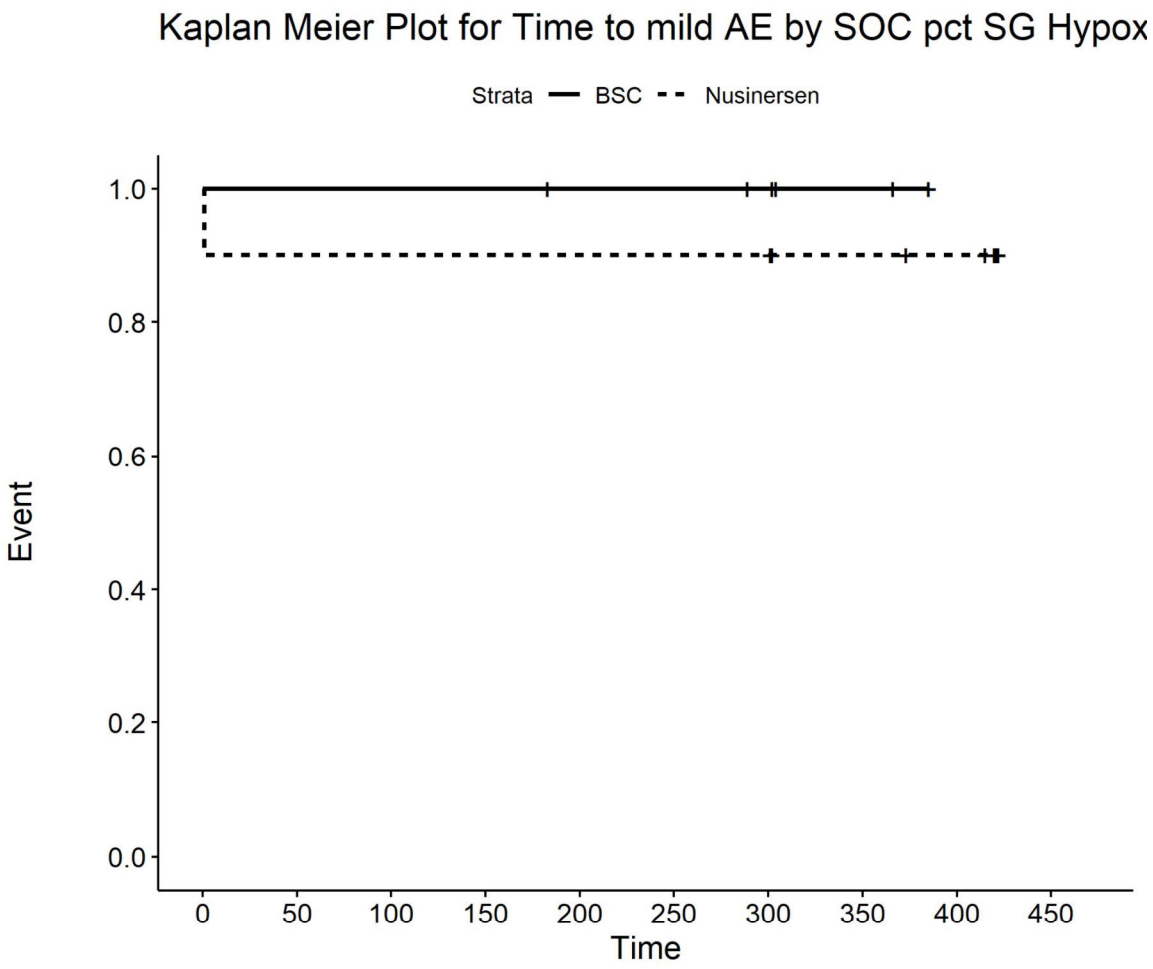
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	3	1	1	0



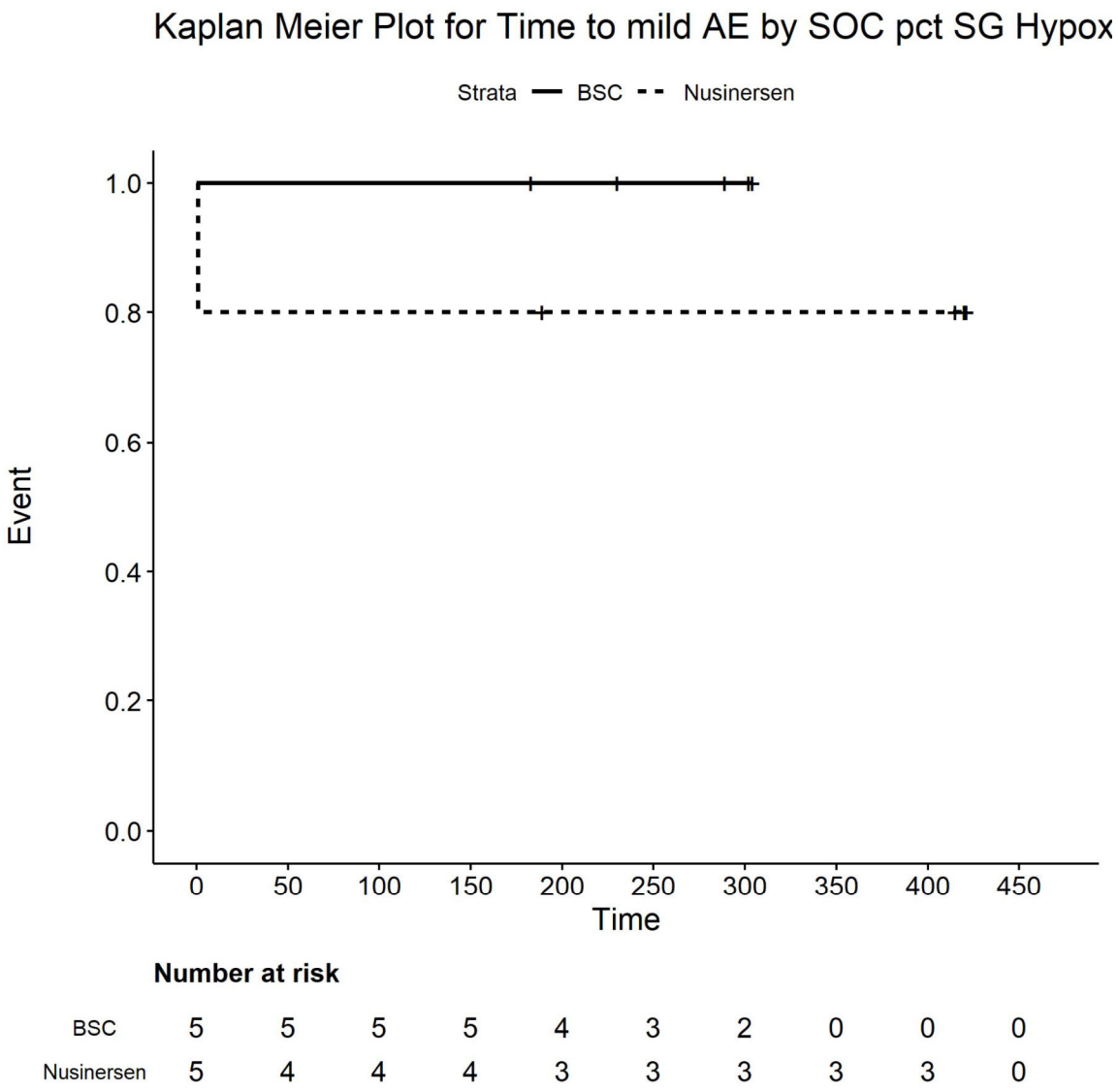
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	6	5	4	0



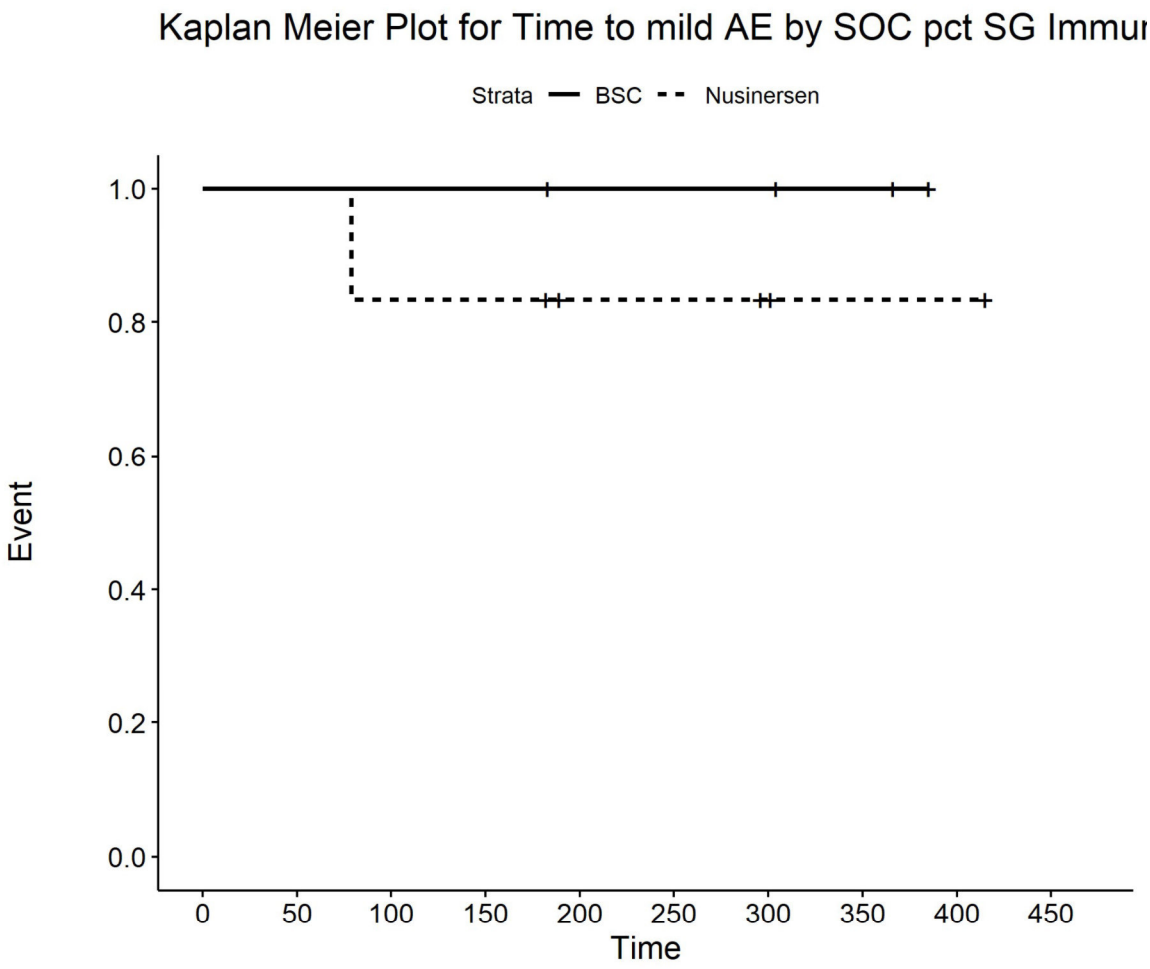
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	9	7	6	0



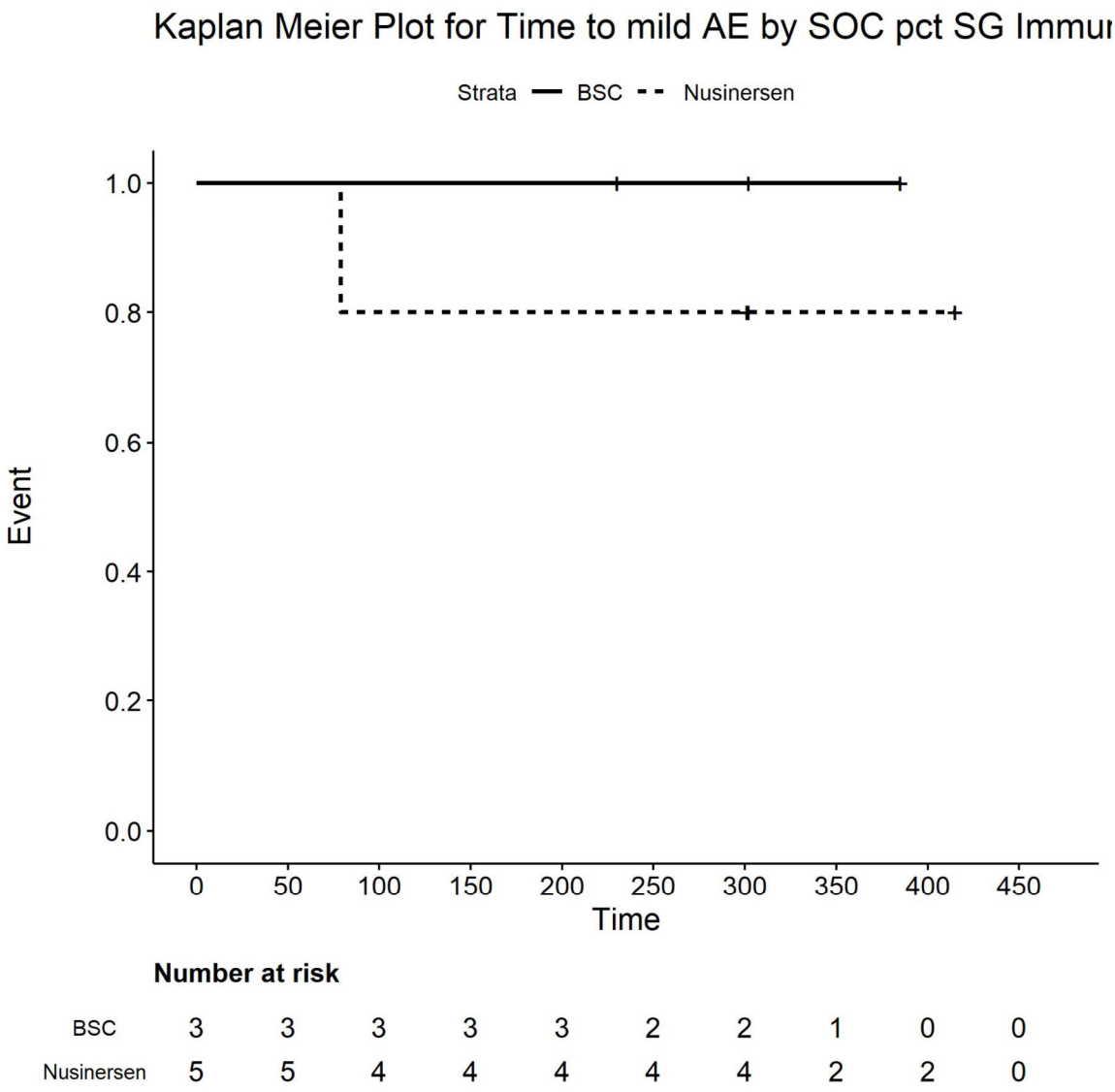
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	3	3	3	0



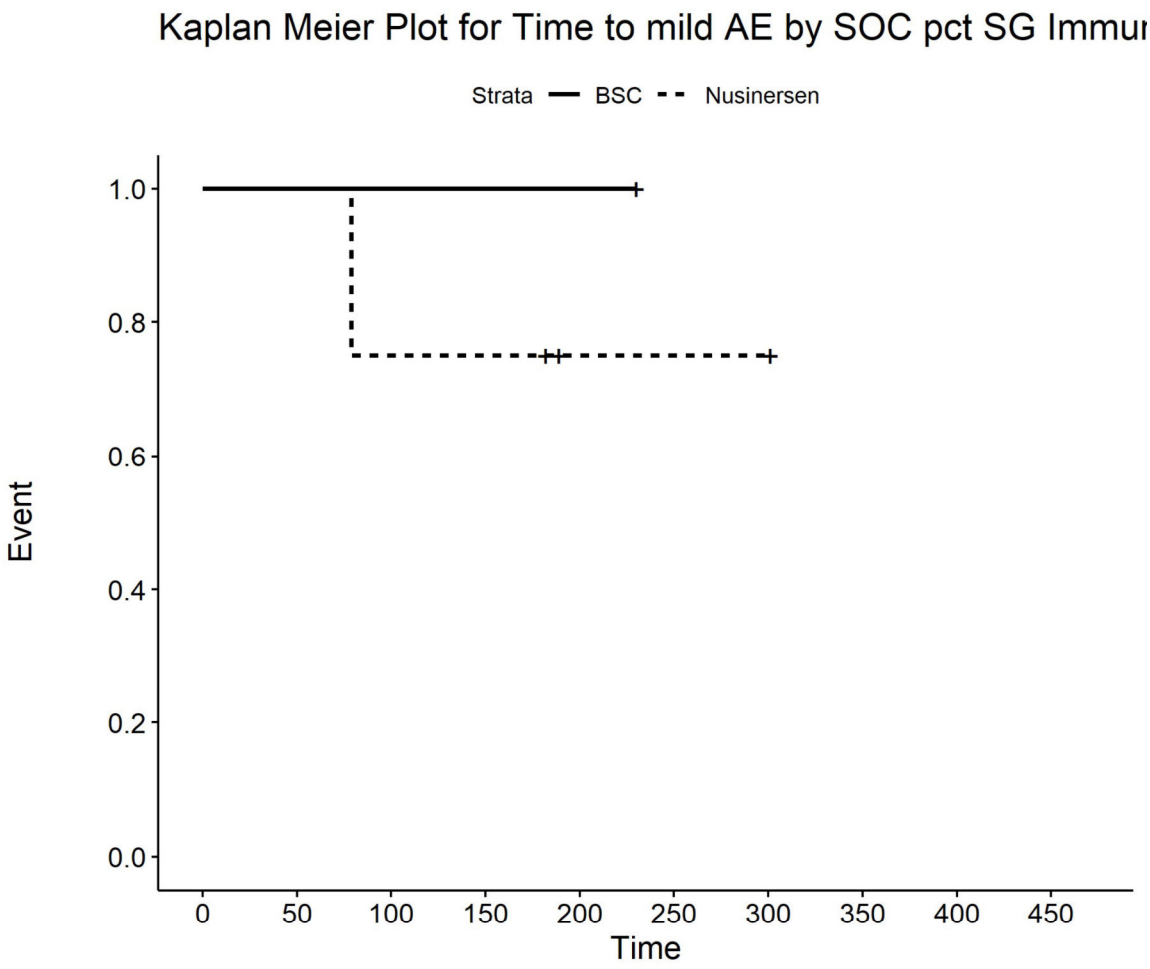
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



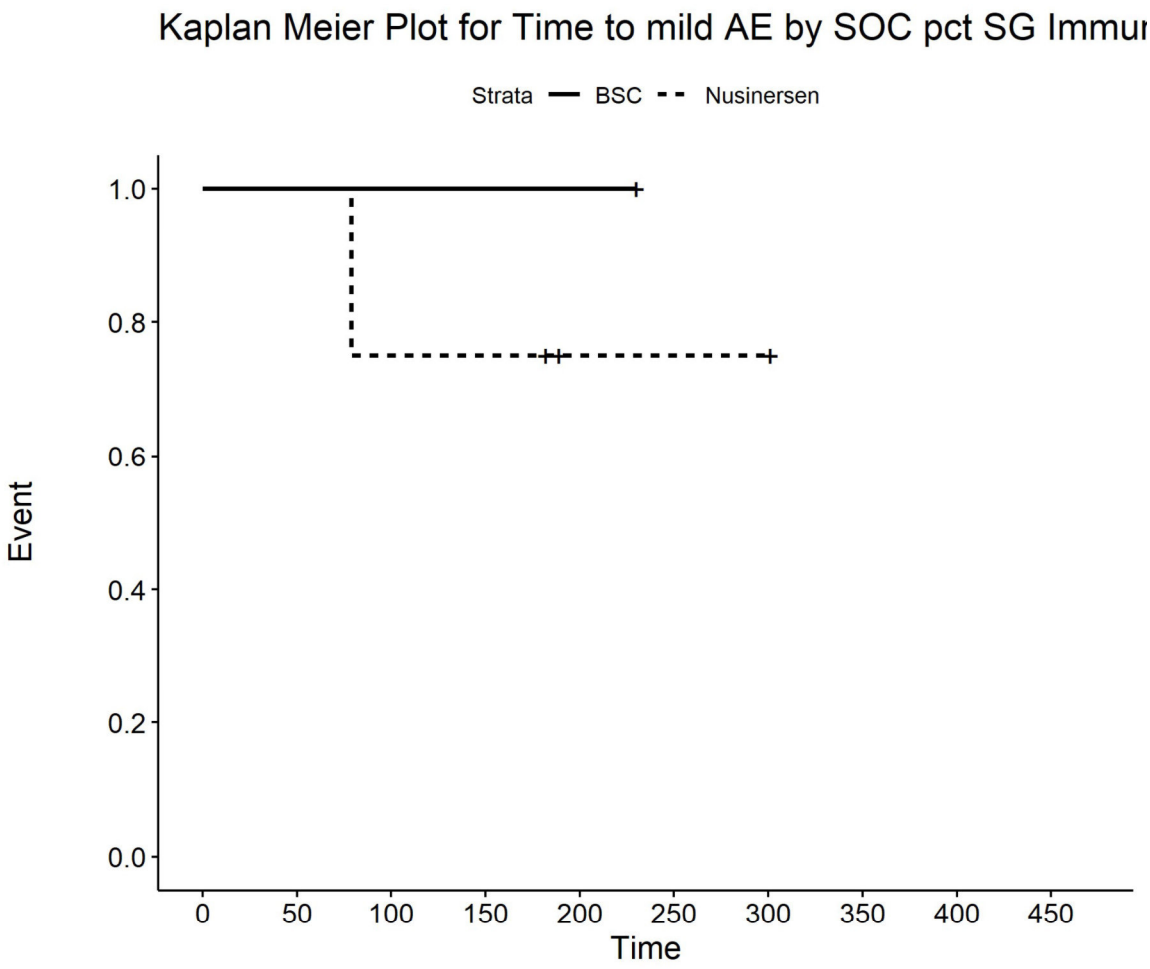
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



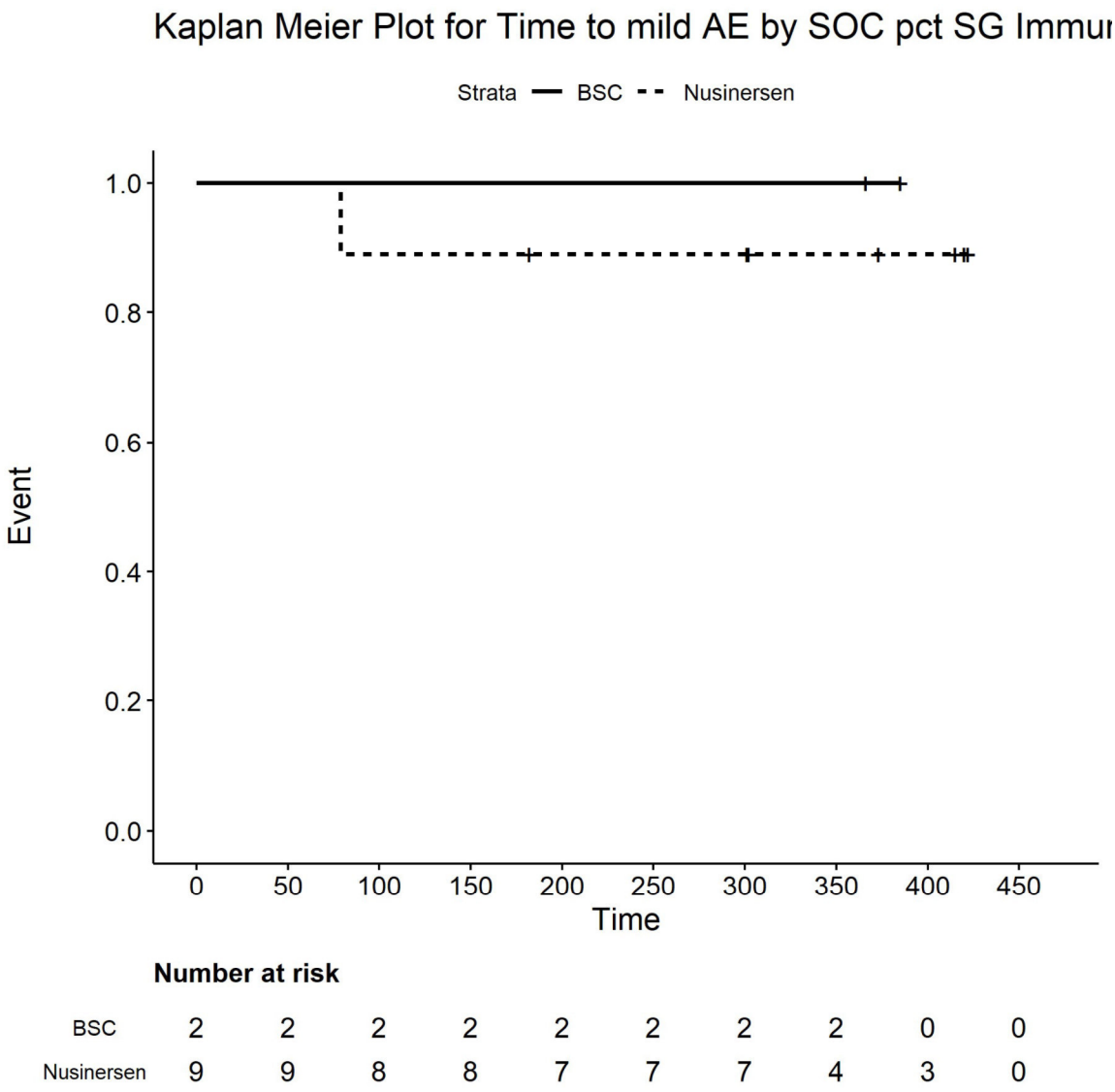
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



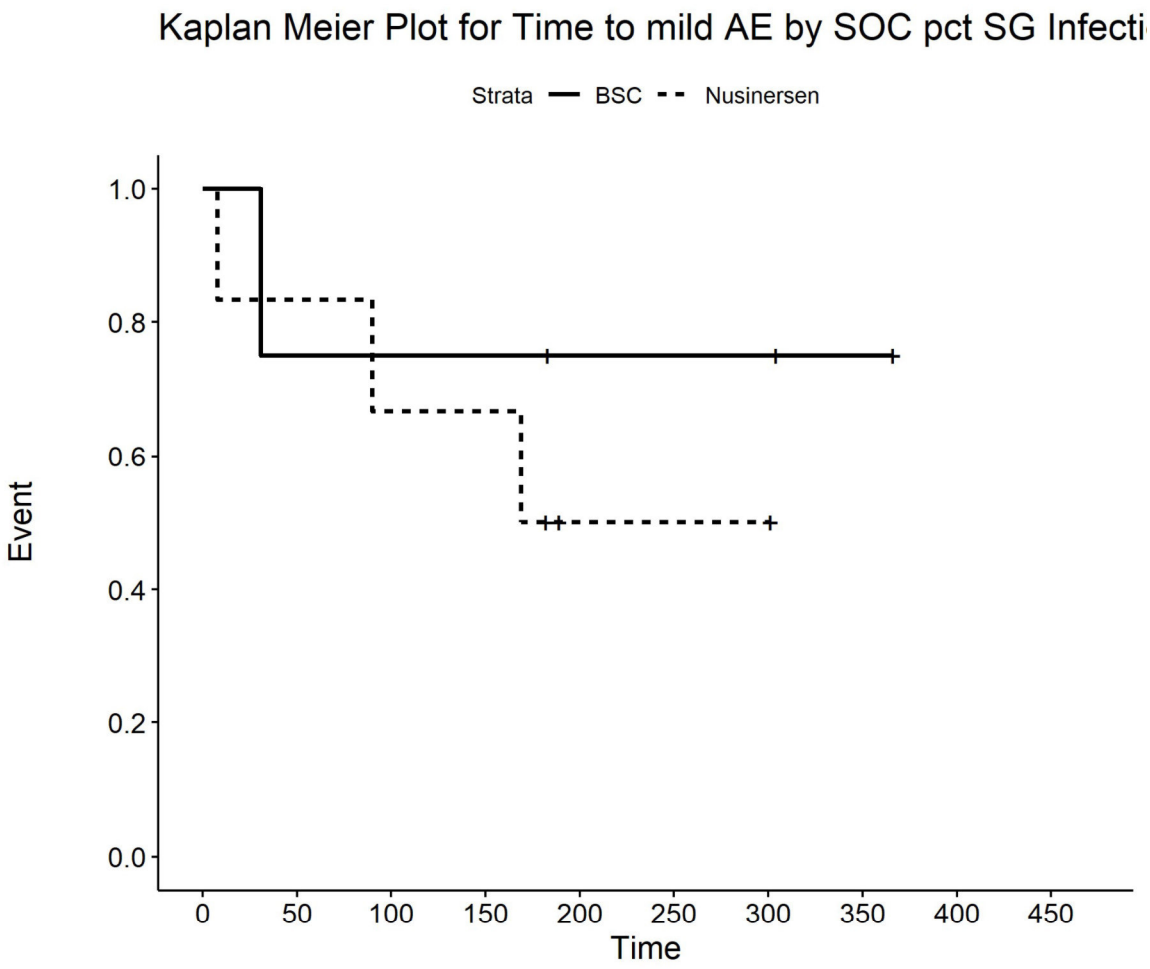
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



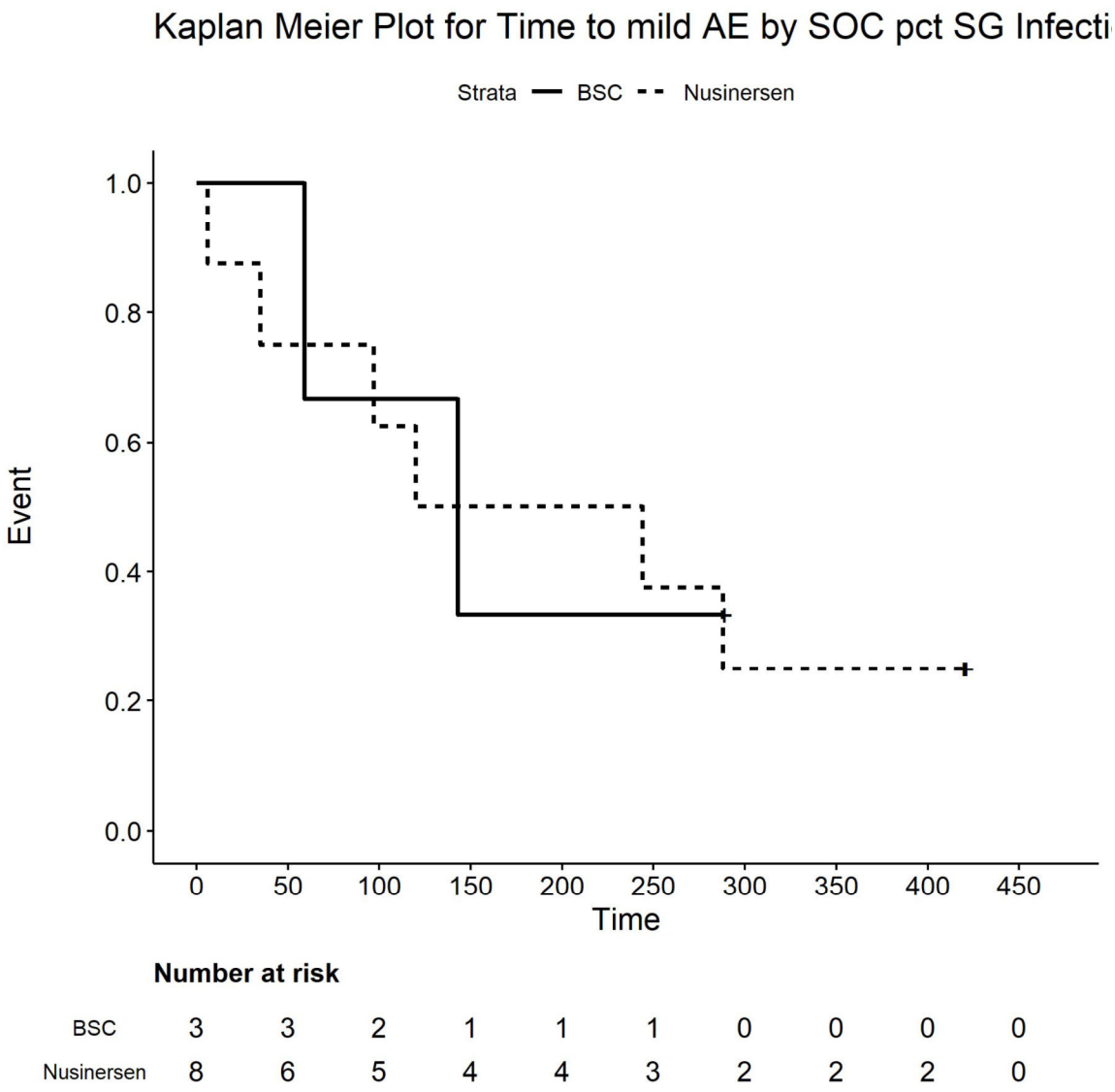
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



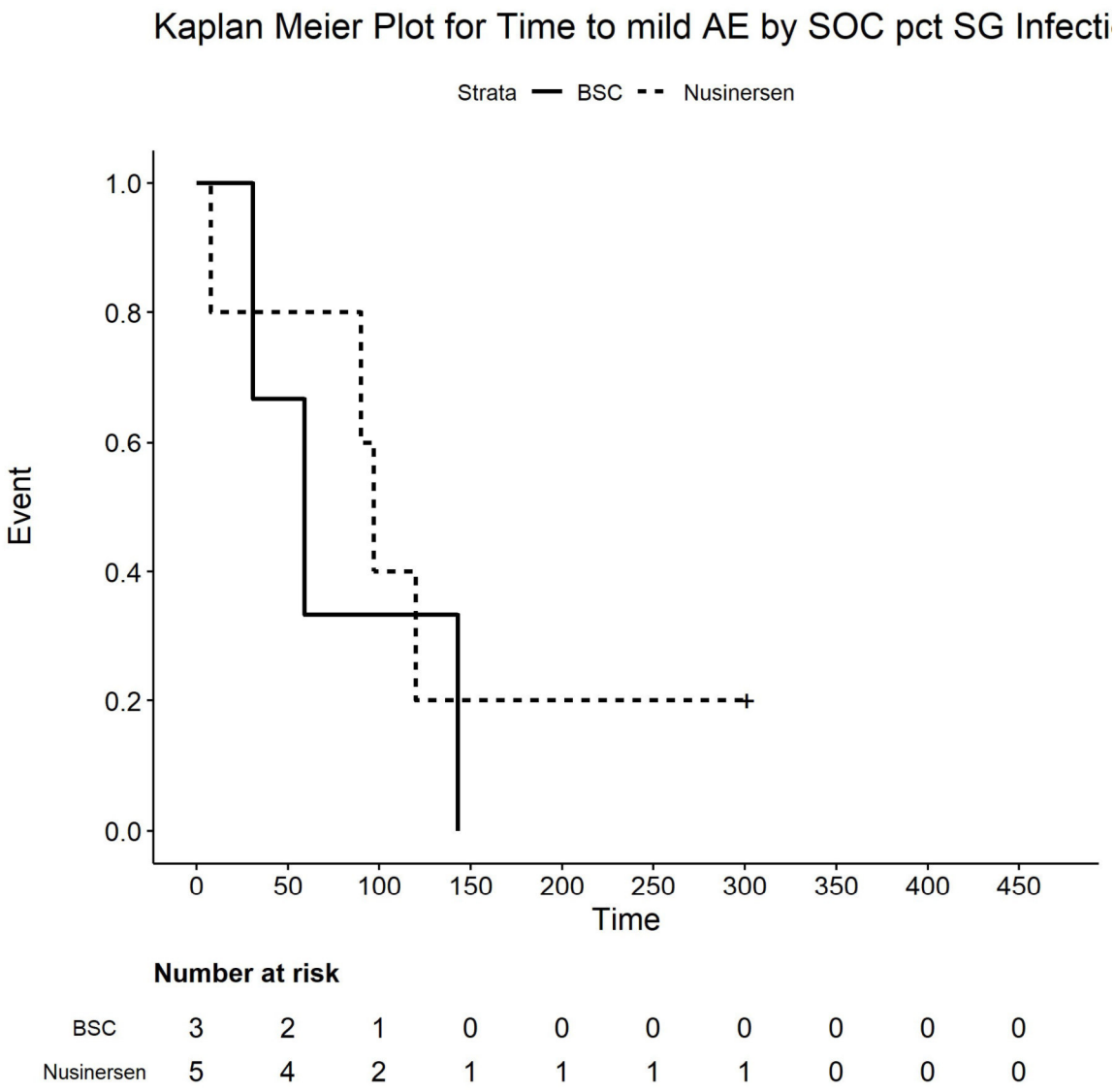
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	5	4	4	1	1	1	0	0	0



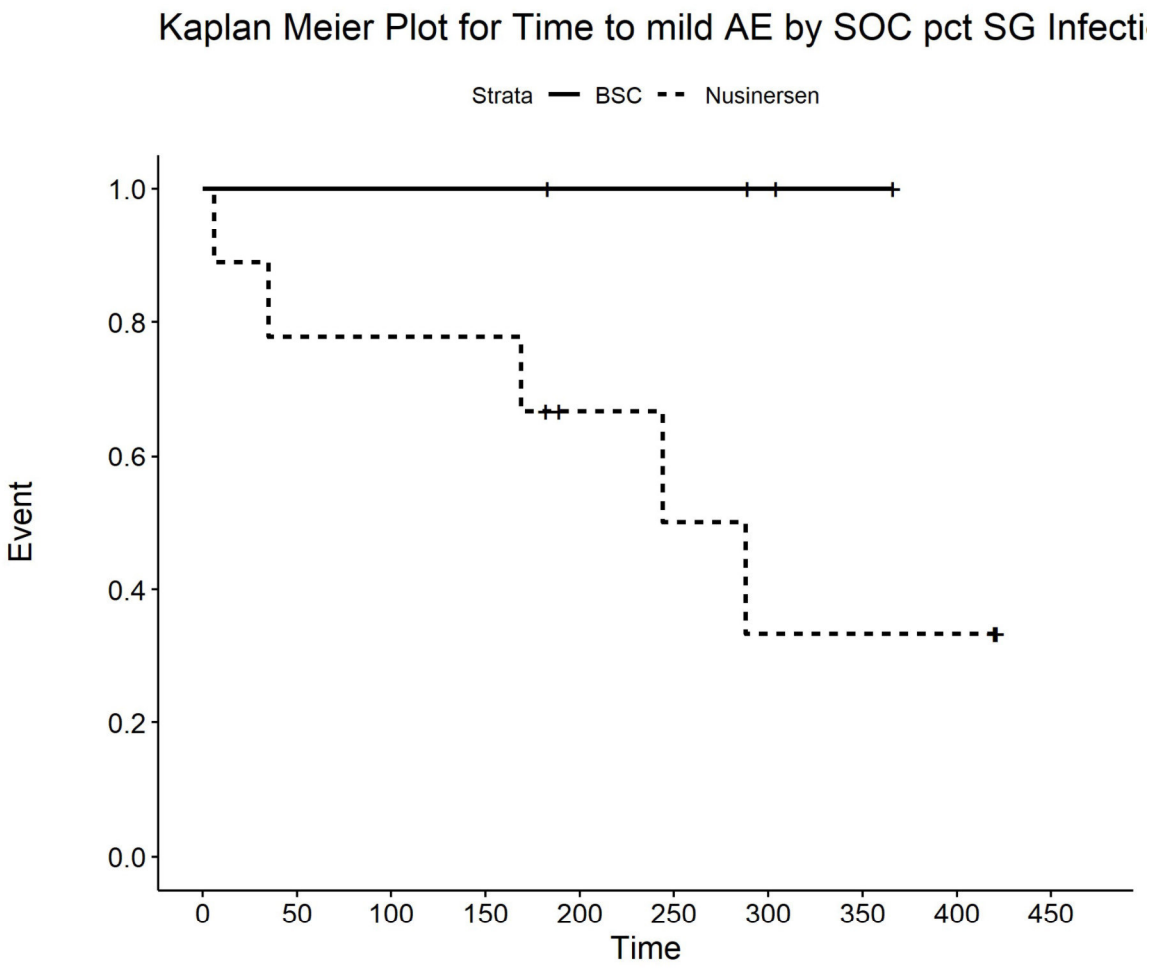
Number at risk

BSC	3	3	2	1	1	1	0	0	0	0
Nusinersen	8	6	5	4	4	3	2	2	2	0



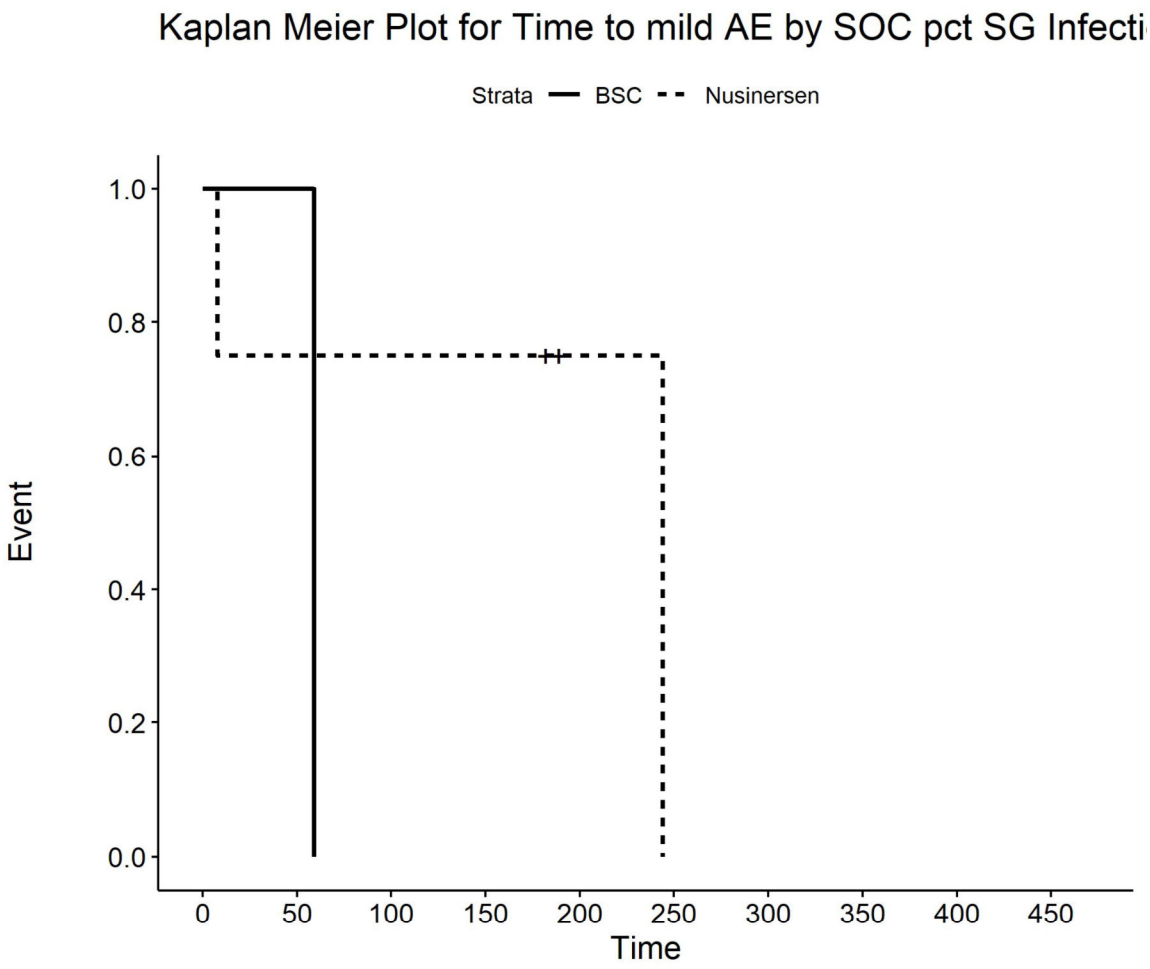
Number at risk

BSC	3	2	1	0	0	0	0	0	0	0
Nusinersen	5	4	2	1	1	1	1	0	0	0



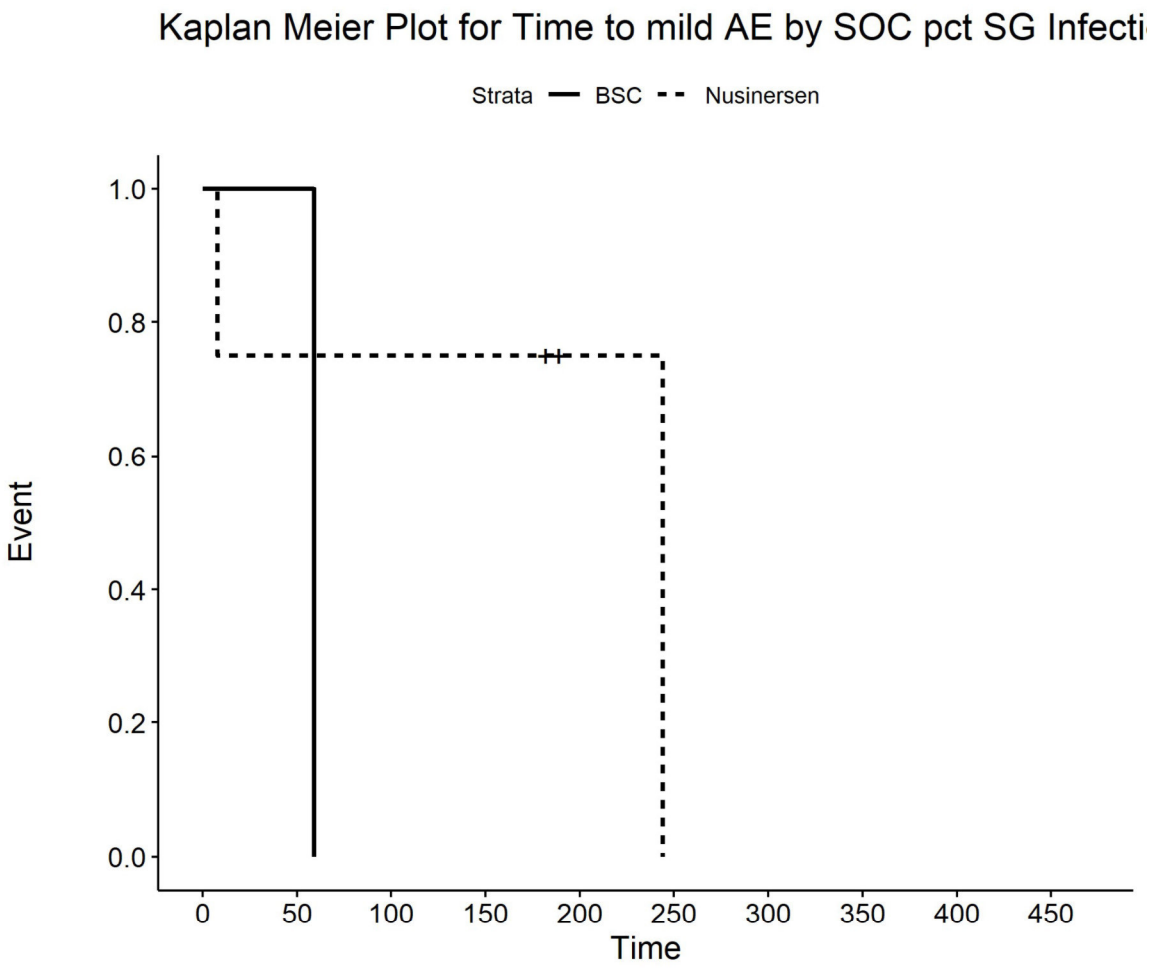
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	7	7	7	4	3	2	2	2	0



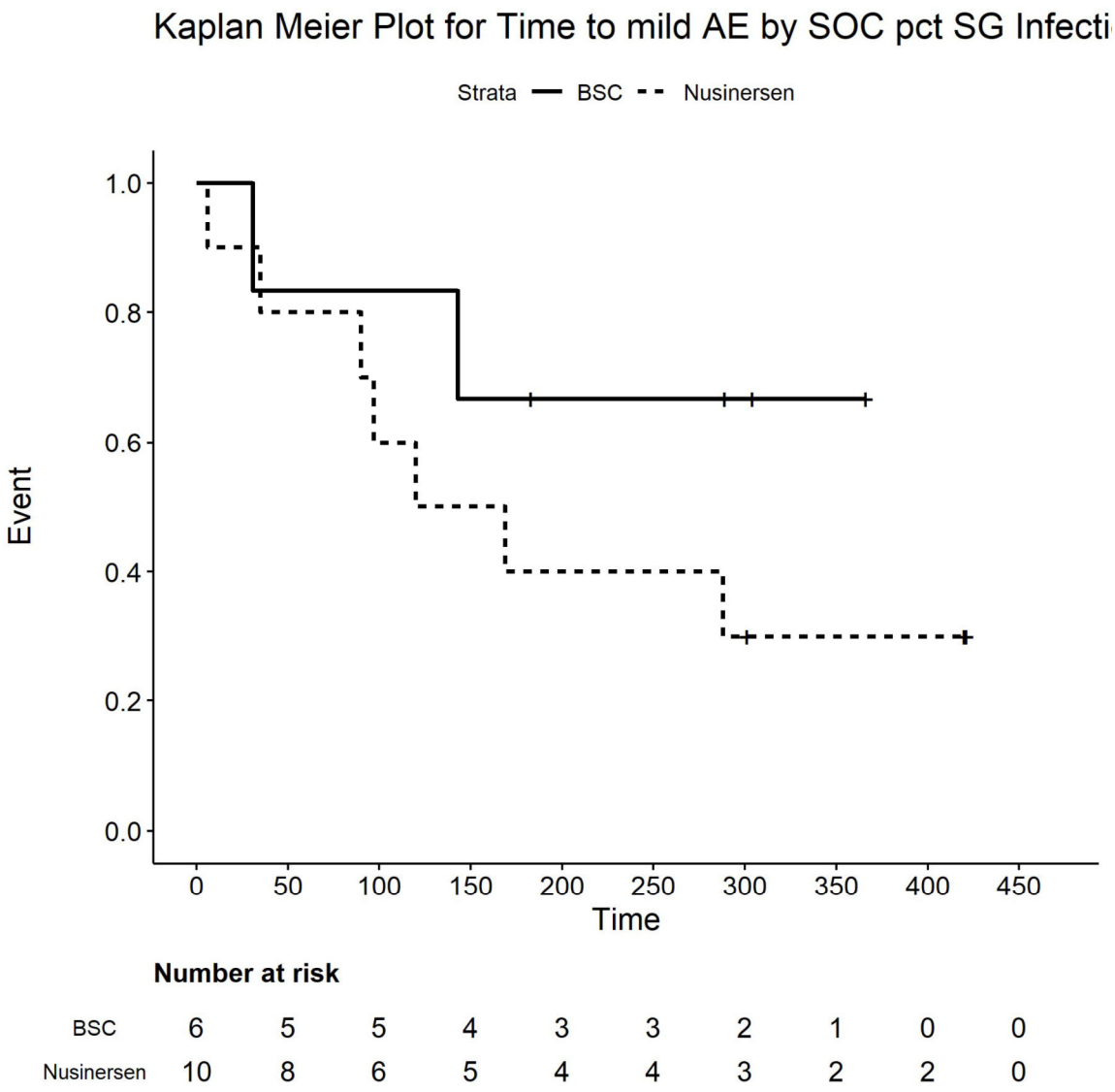
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	3	3	3	1	0	0	0	0	0



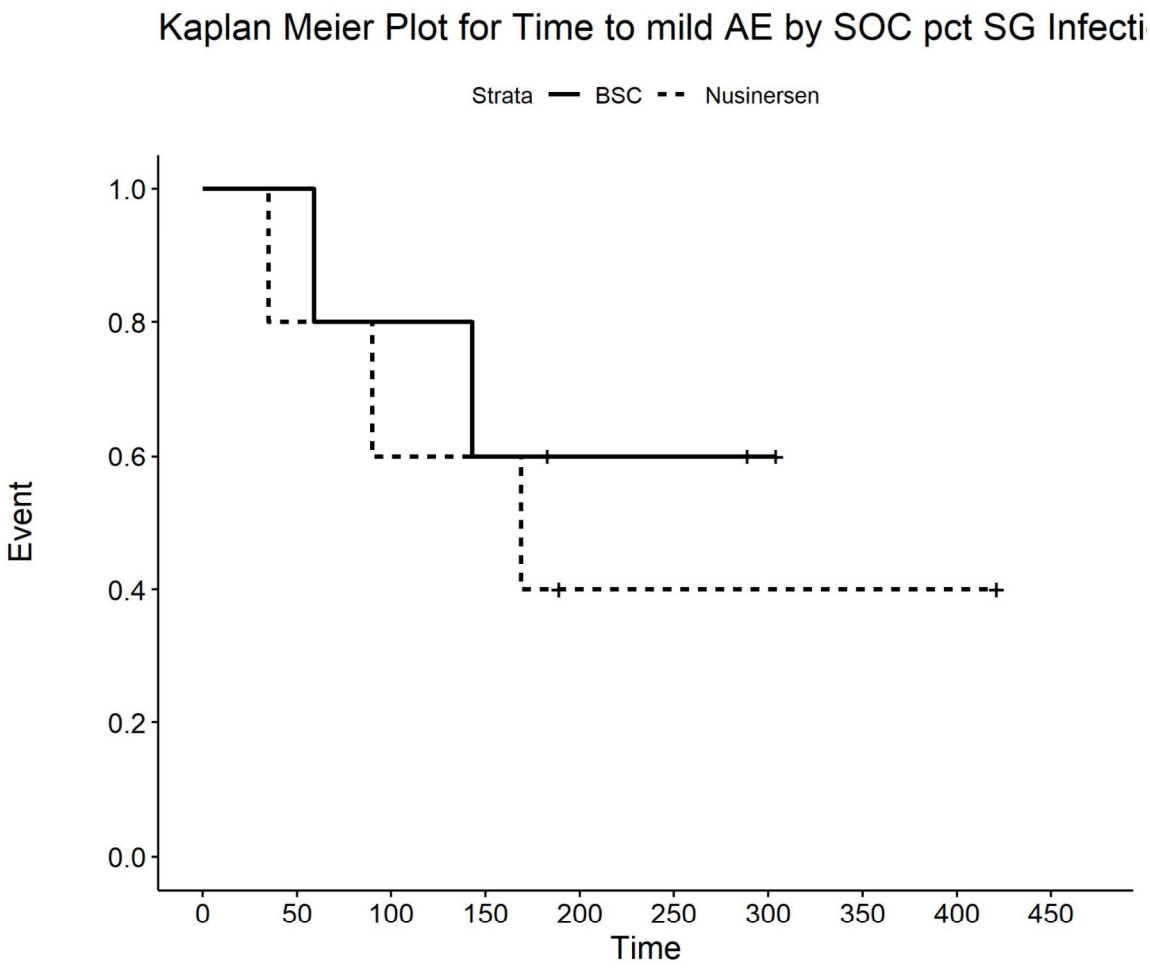
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	3	3	3	1	0	0	0	0	0



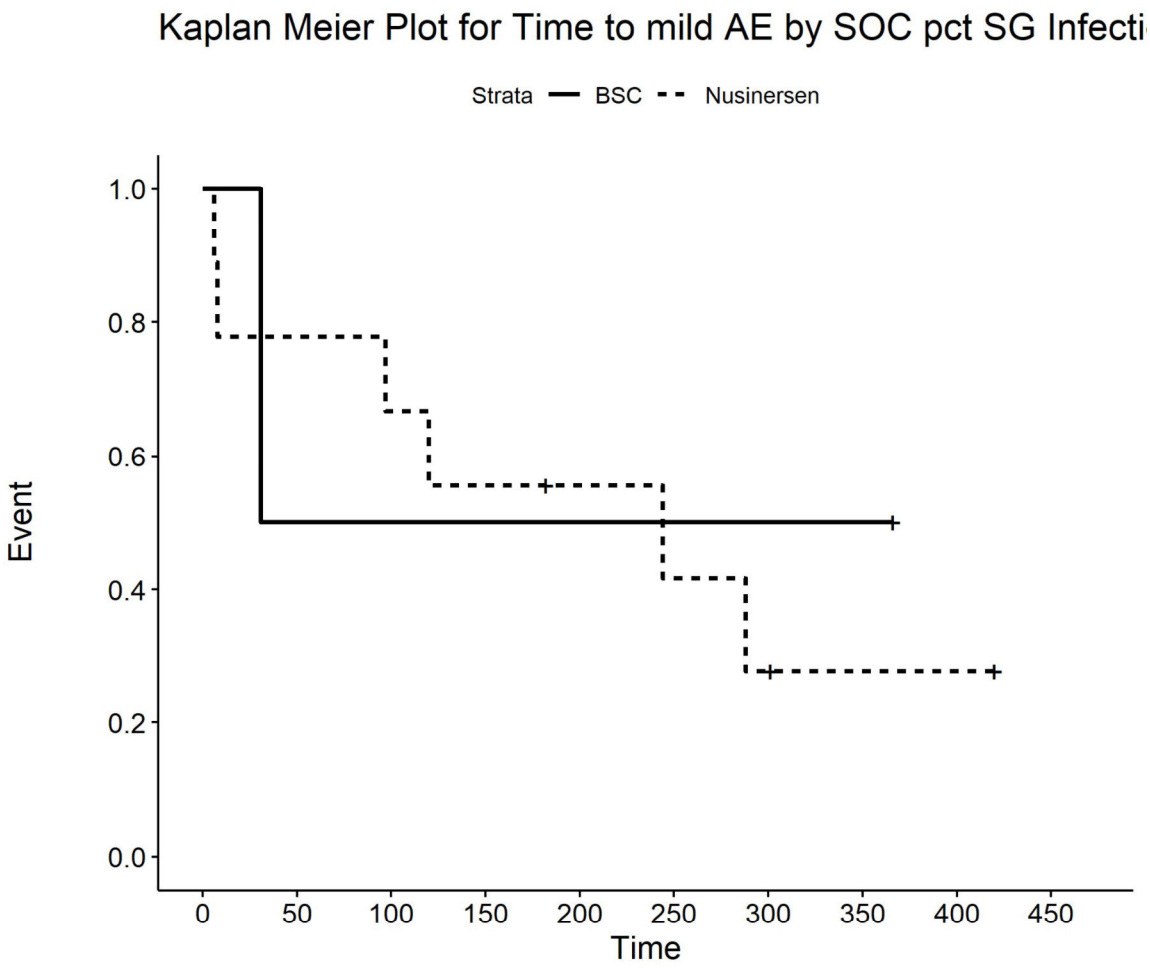
Number at risk

BSC	6	5	5	4	3	3	2	1	0	0
Nusinersen	10	8	6	5	4	4	3	2	2	0



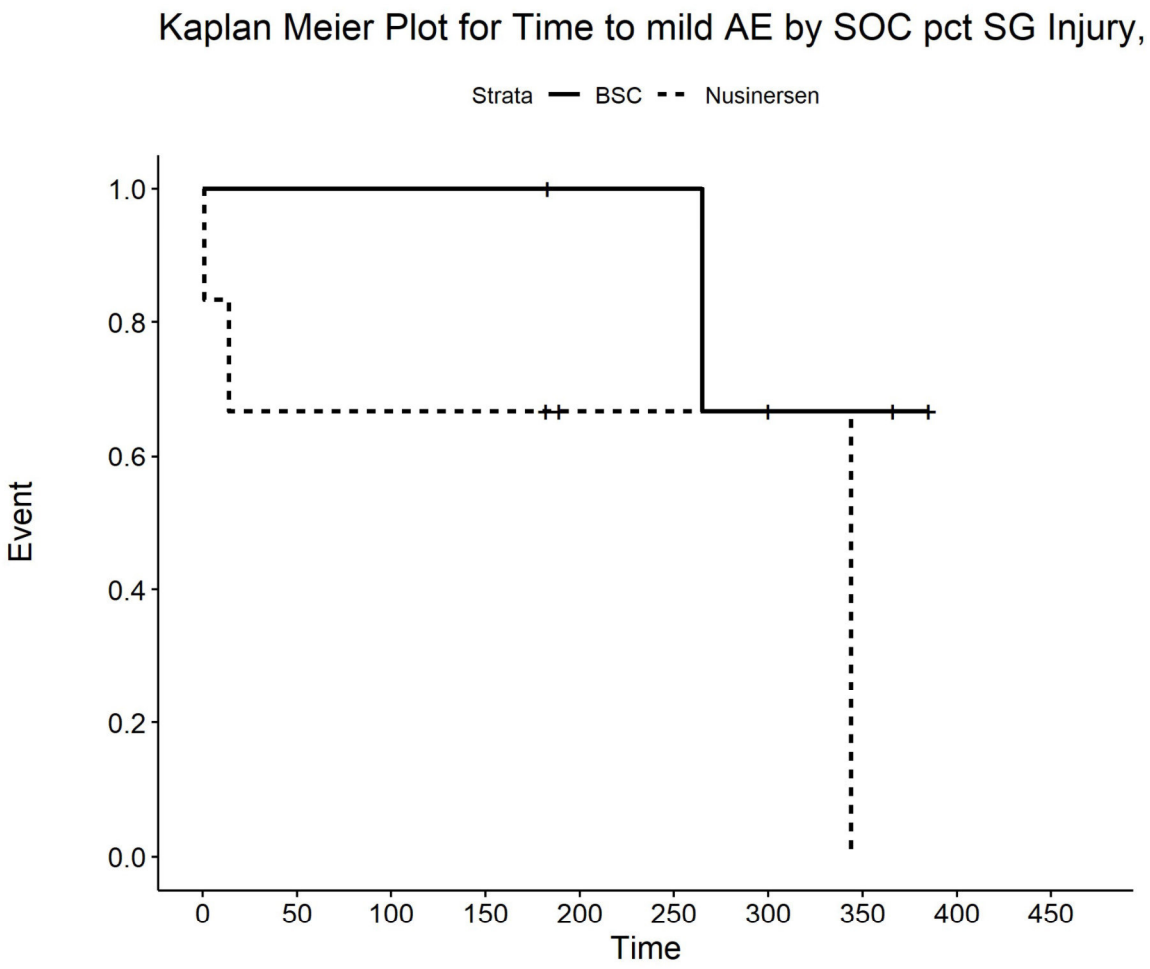
Number at risk

BSC	5	5	4	3	2	2	1	0	0	0
Nusinersen	5	4	3	3	1	1	1	1	1	0



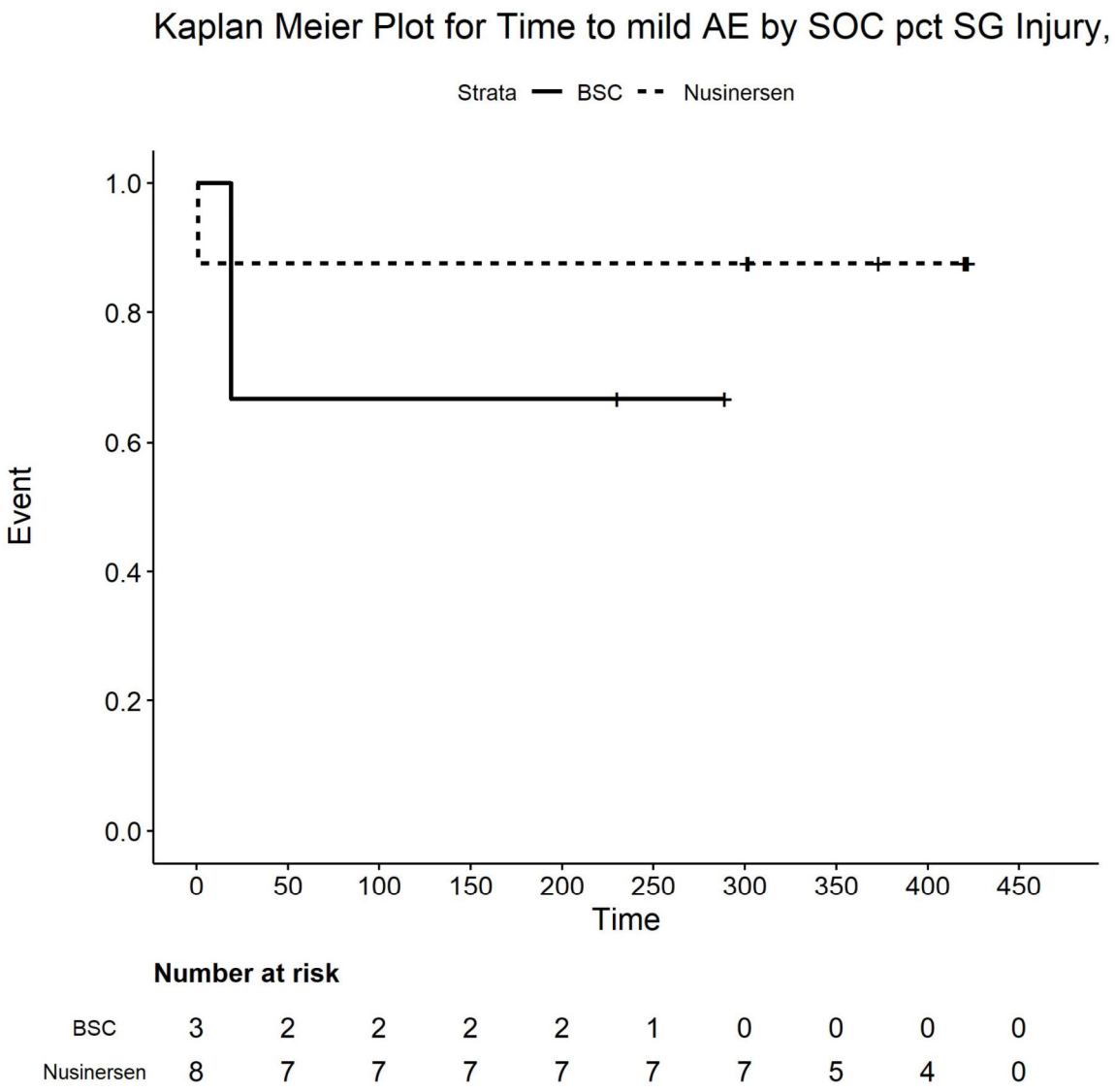
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	7	6	5	4	3	2	1	1	0



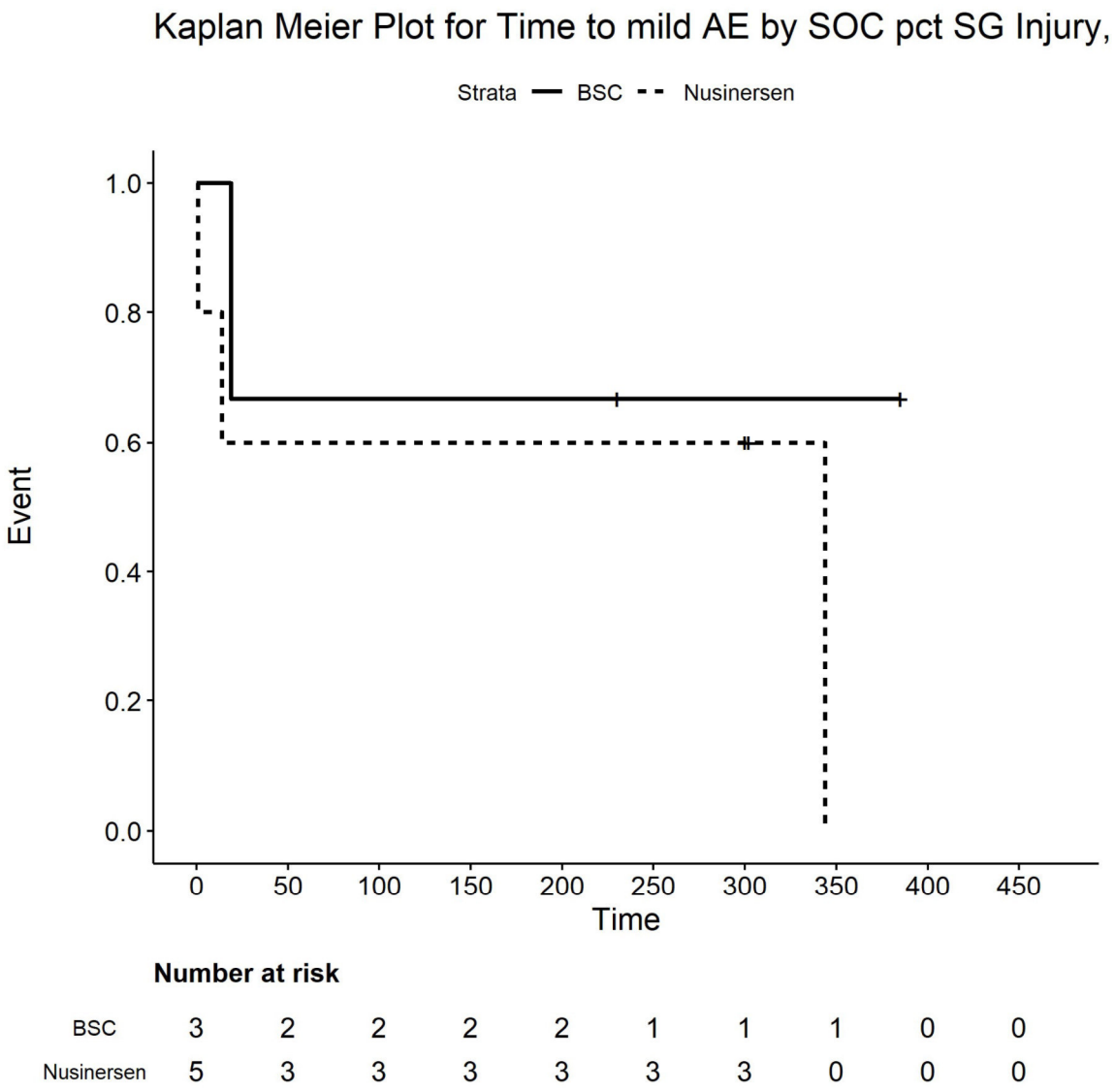
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	4	4	4	2	2	2	0	0	0



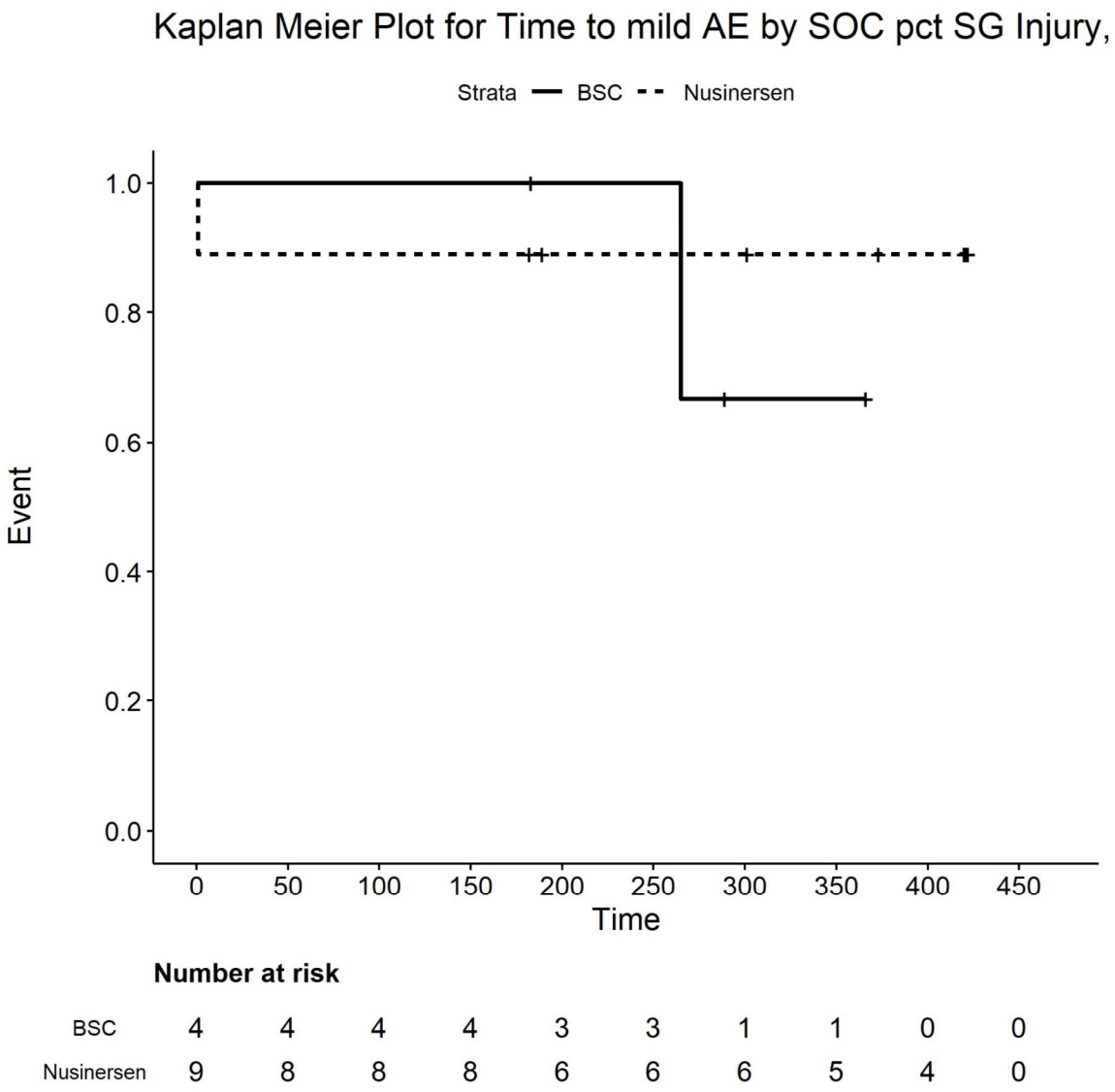
Number at risk

BSC	3	2	2	2	2	1	0	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



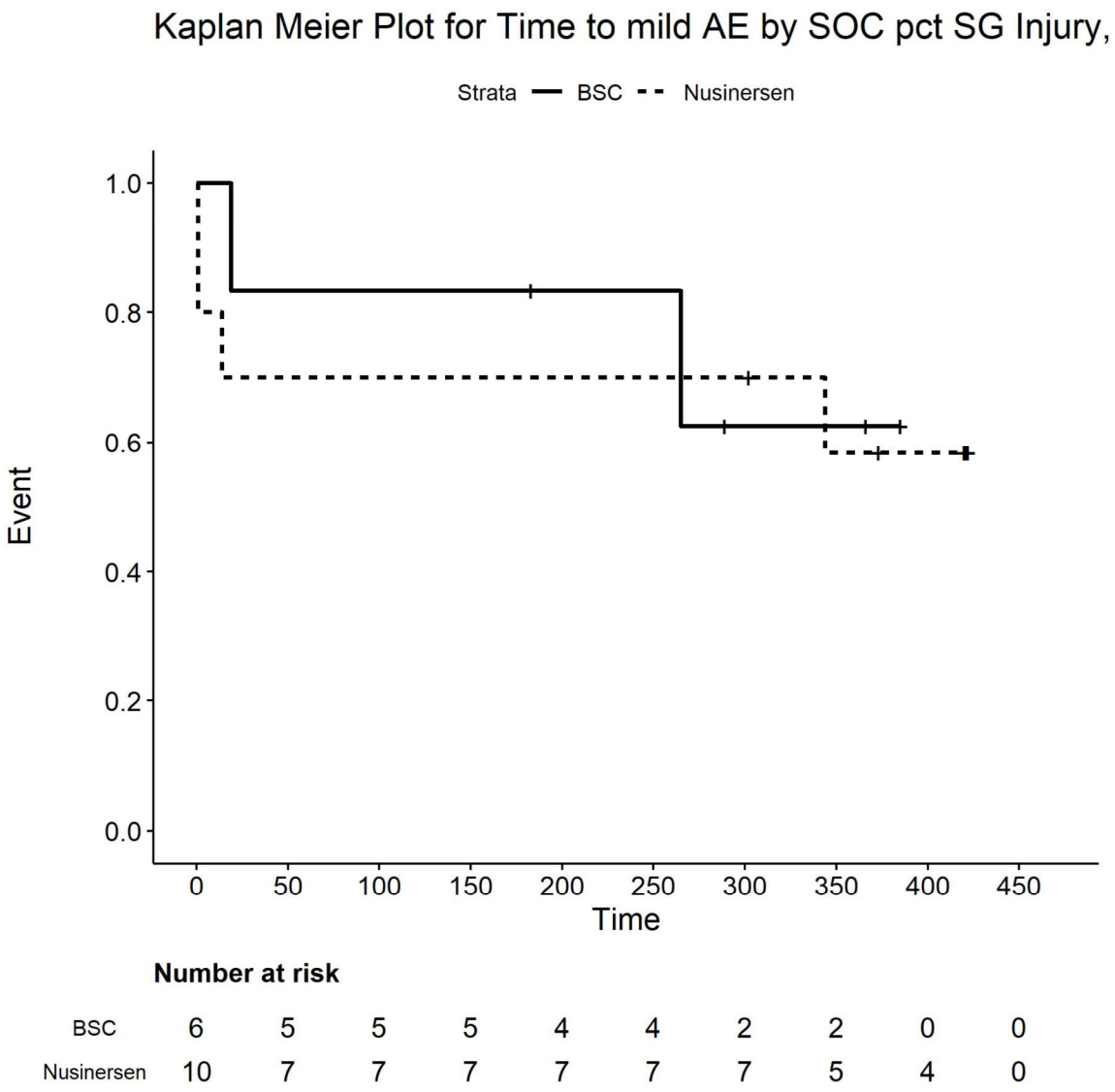
Number at risk

BSC	3	2	2	2	2	1	1	1	0	0
Nusinersen	5	3	3	3	3	3	3	0	0	0



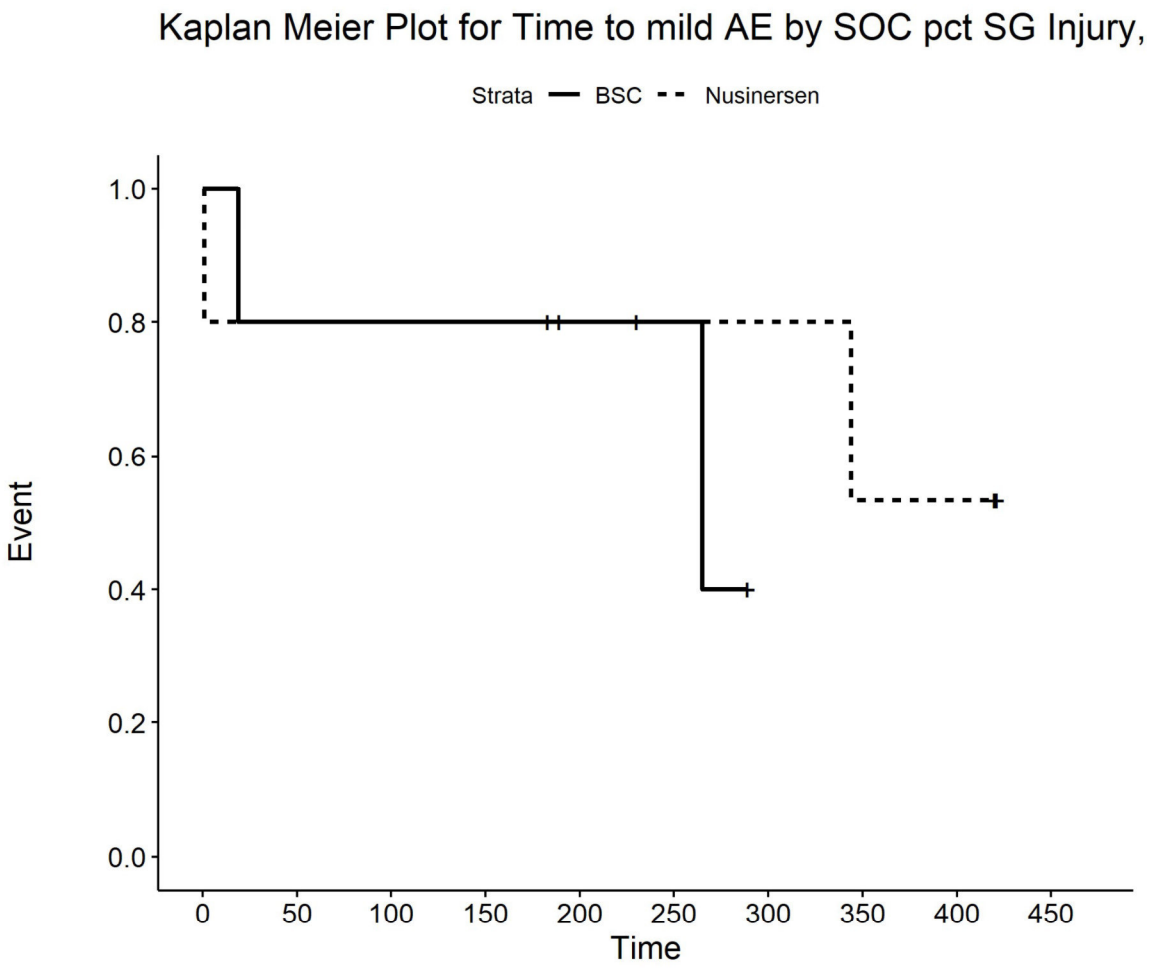
Number at risk

BSC	4	4	4	4	3	3	1	1	0	0
Nusinersen	9	8	8	8	6	6	6	5	4	0



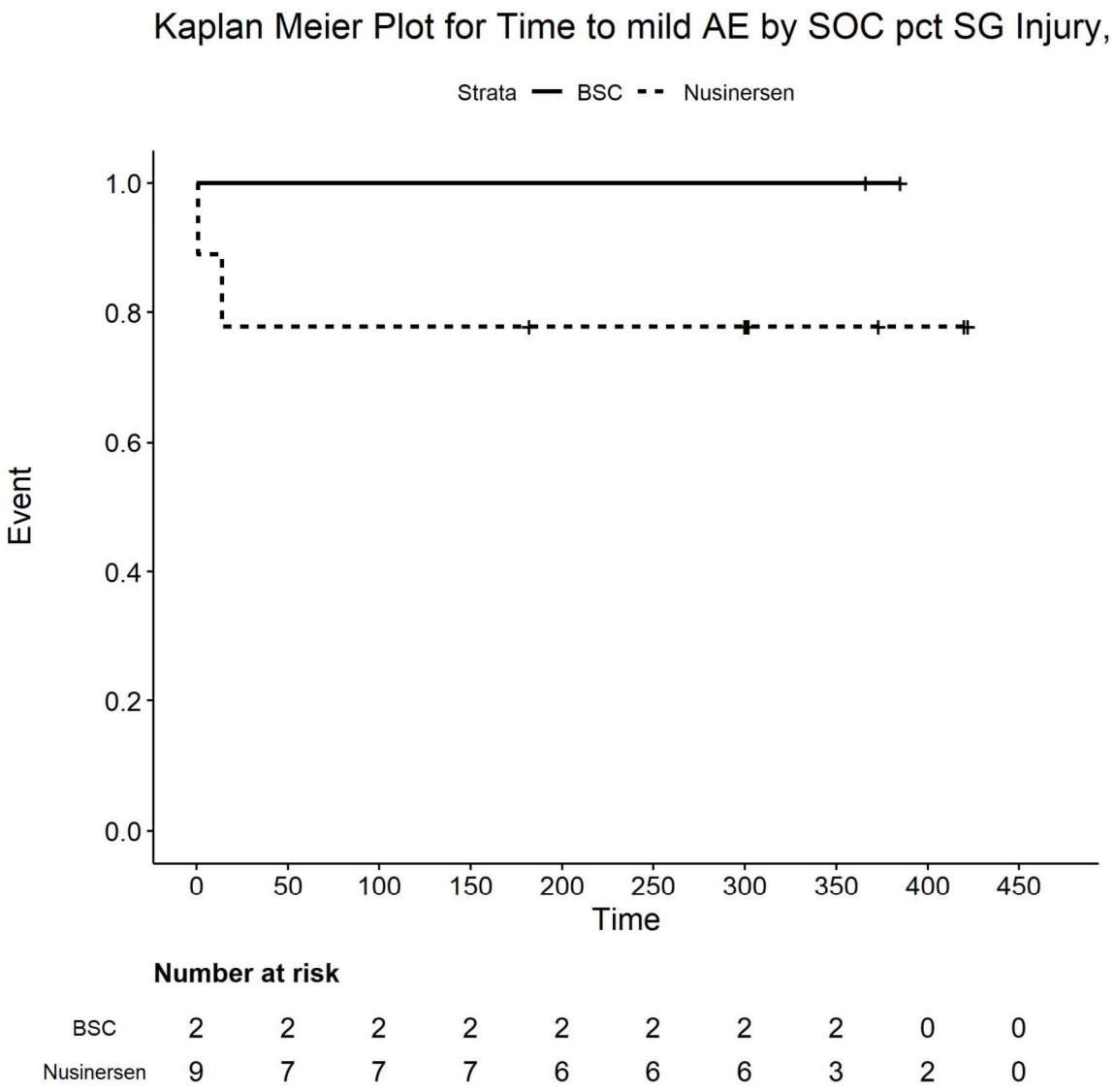
Number at risk

BSC	6	5	5	5	4	4	2	2	0	0
Nusinersen	10	7	7	7	7	7	7	5	4	0



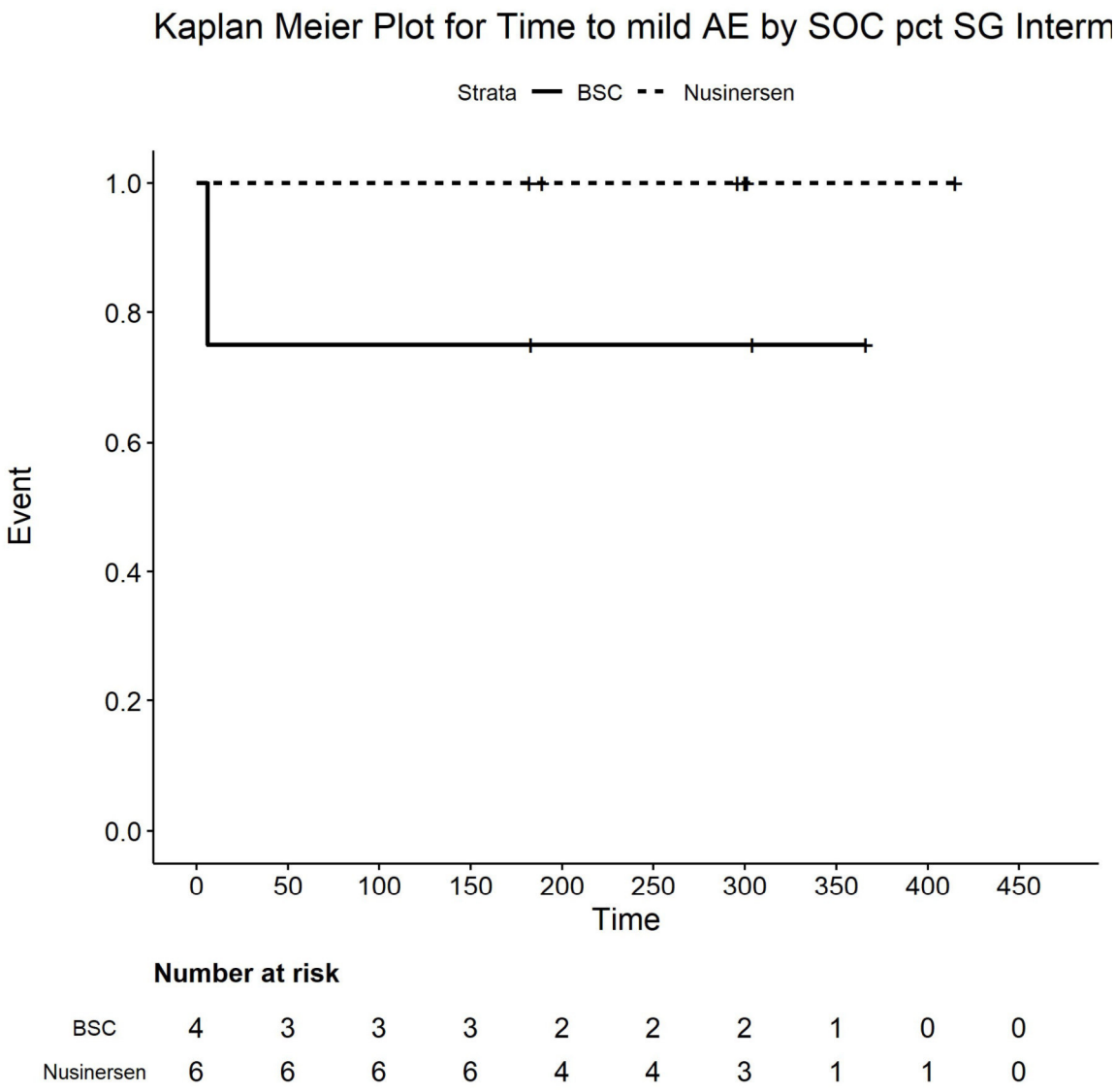
Number at risk

BSC	5	4	4	4	3	2	0	0	0	0
Nusinersen	5	4	4	4	3	3	3	2	2	0



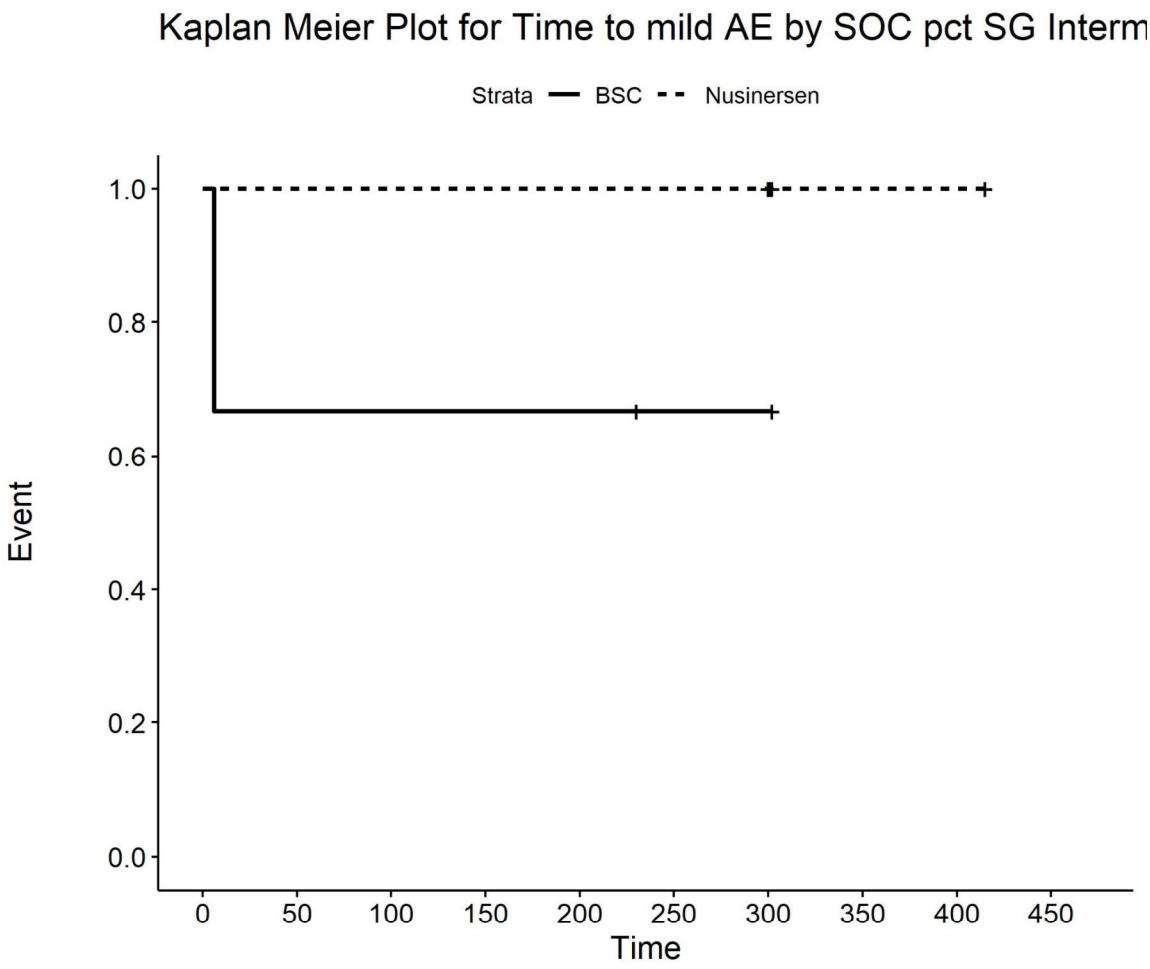
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	7	7	6	6	6	3	2	0



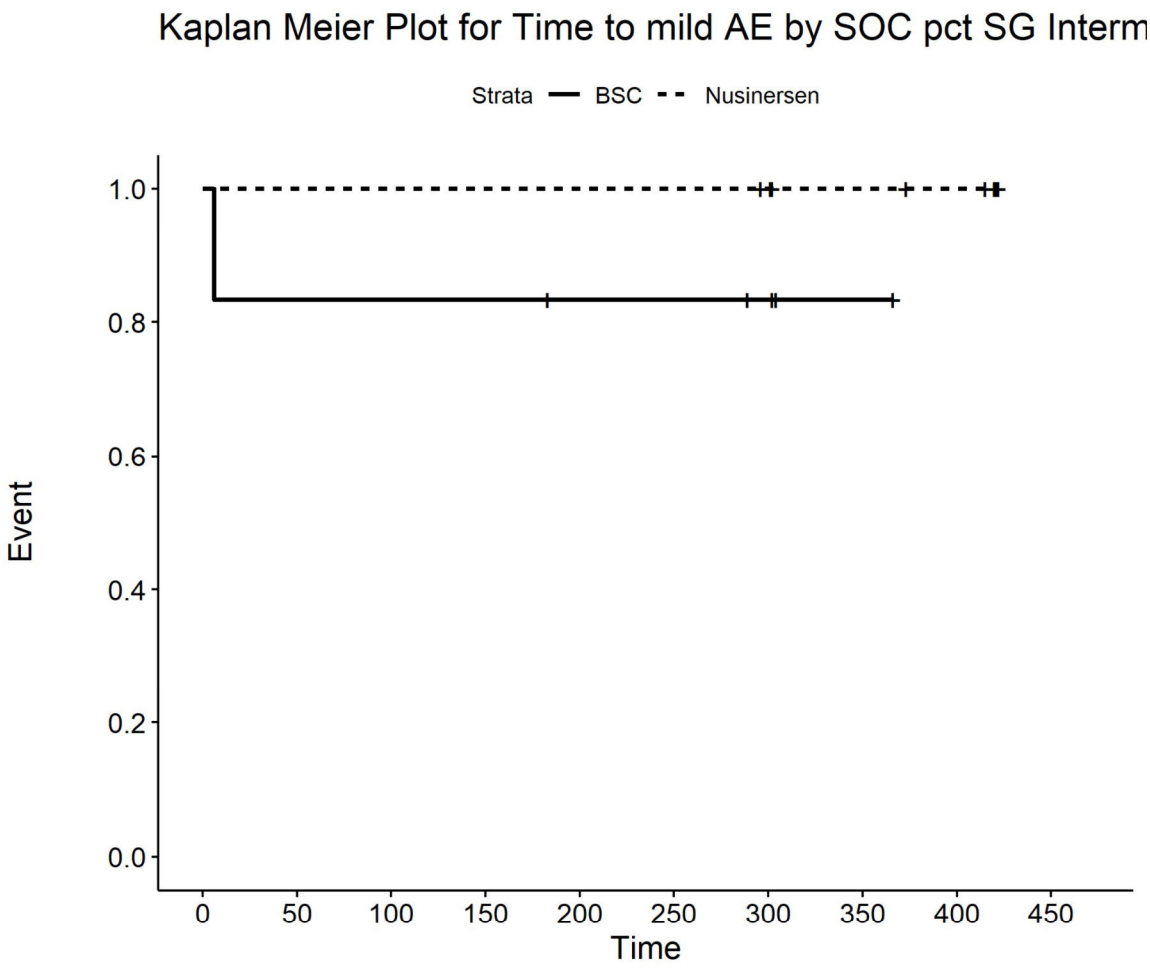
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



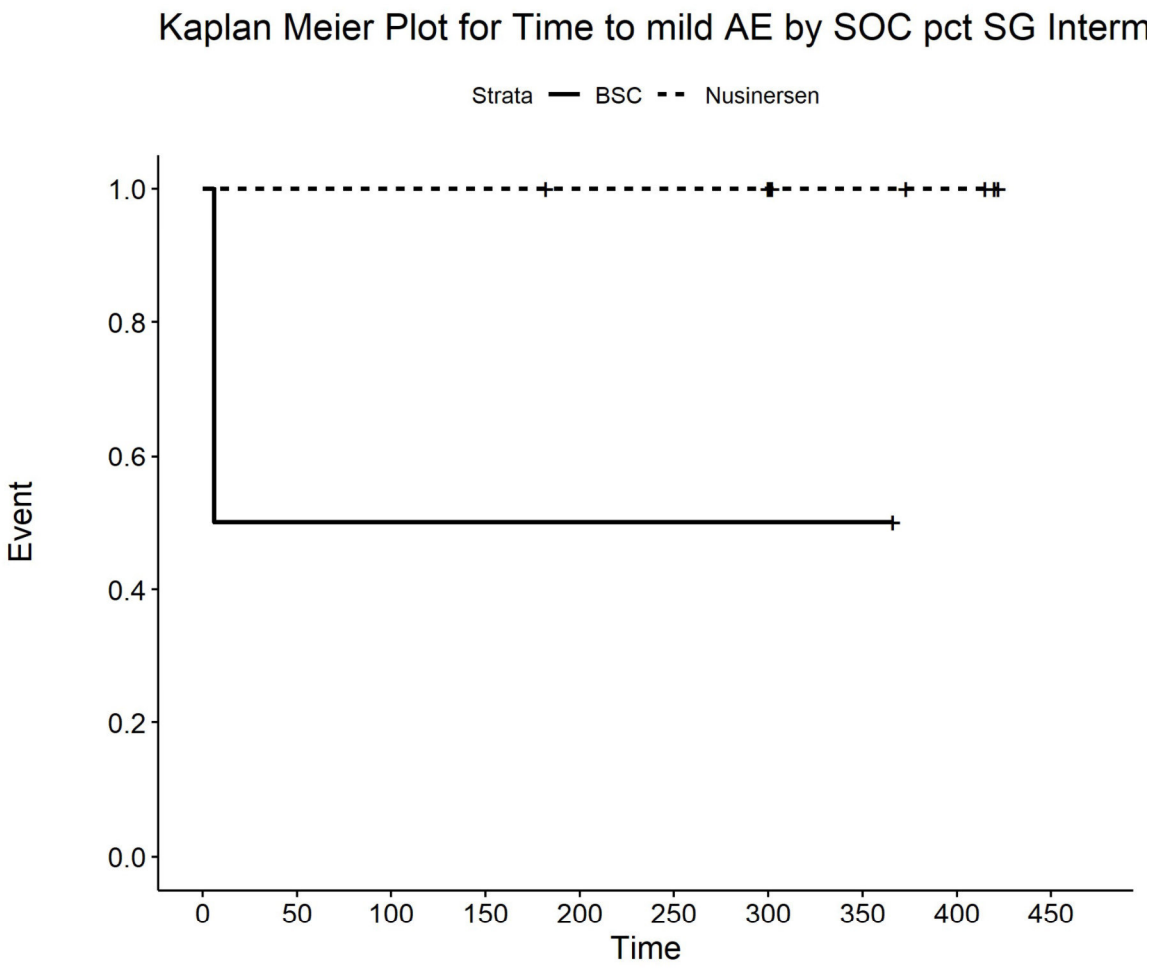
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



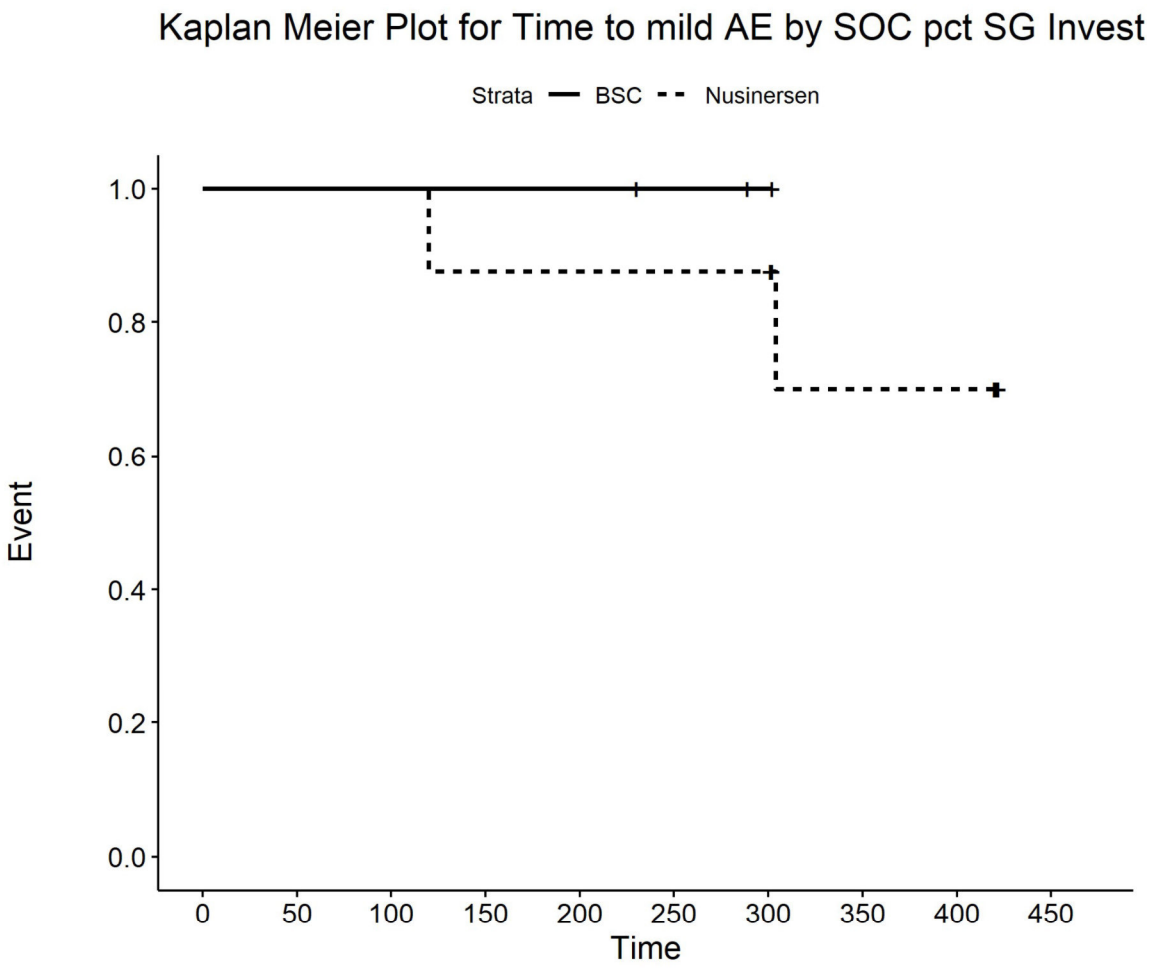
Number at risk

BSC	6	5	5	5	4	4	3	1	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



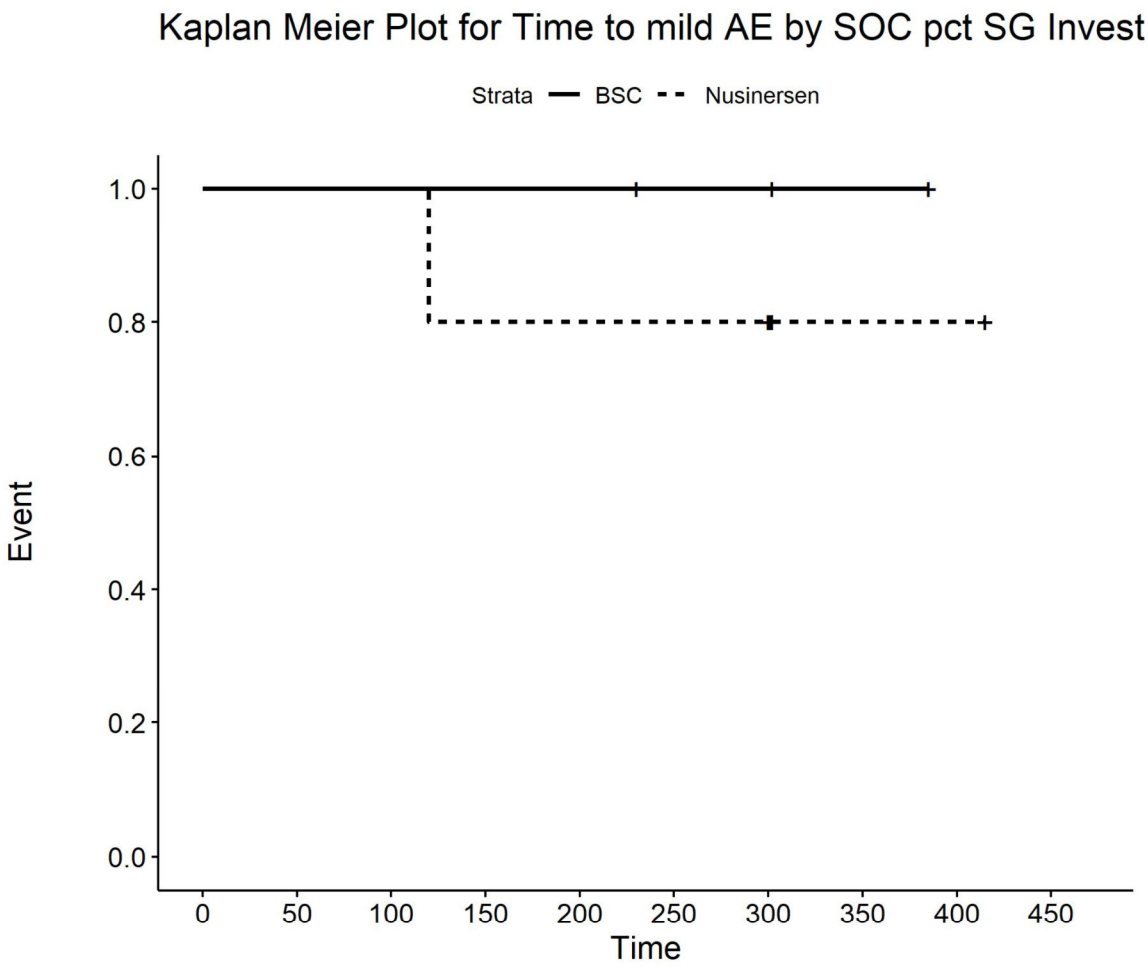
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



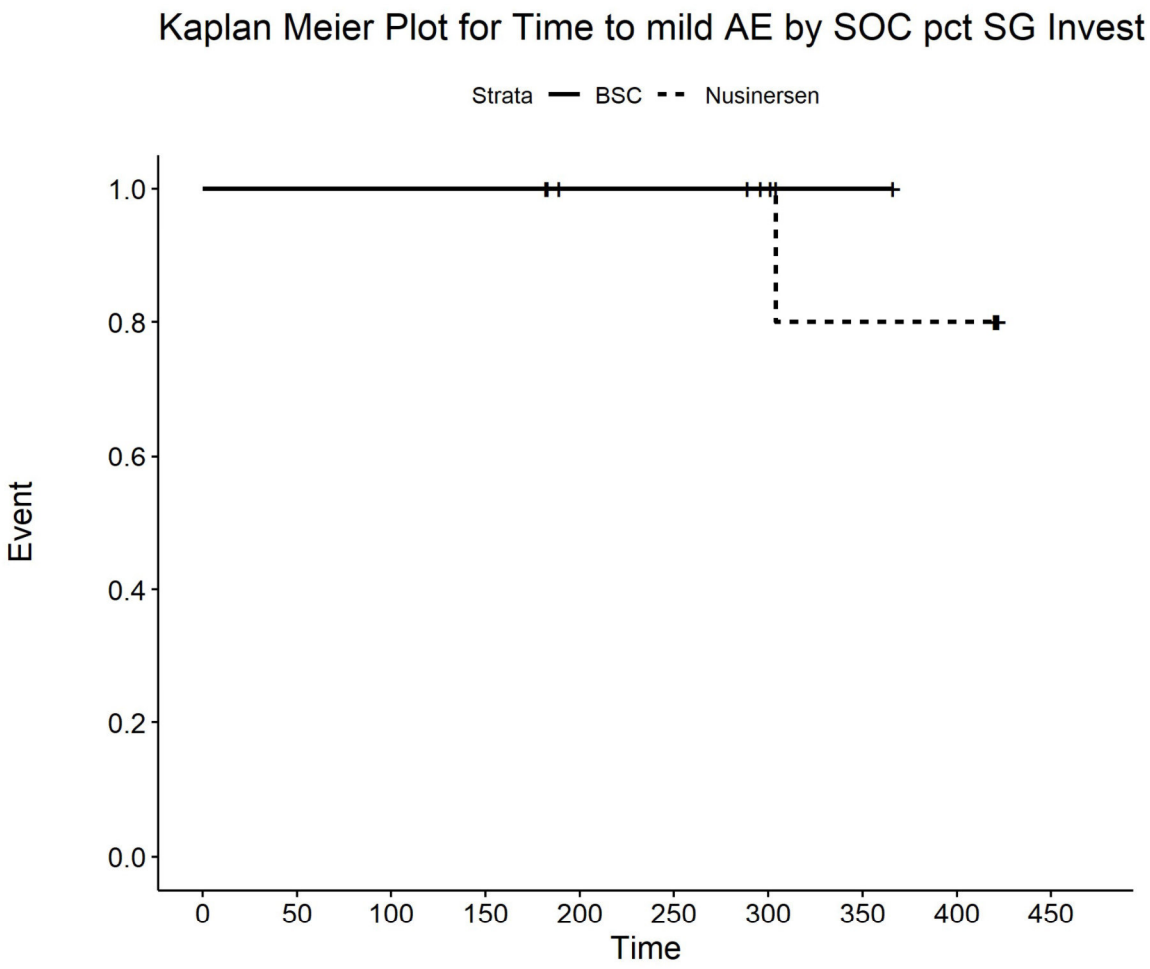
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	4	4	0



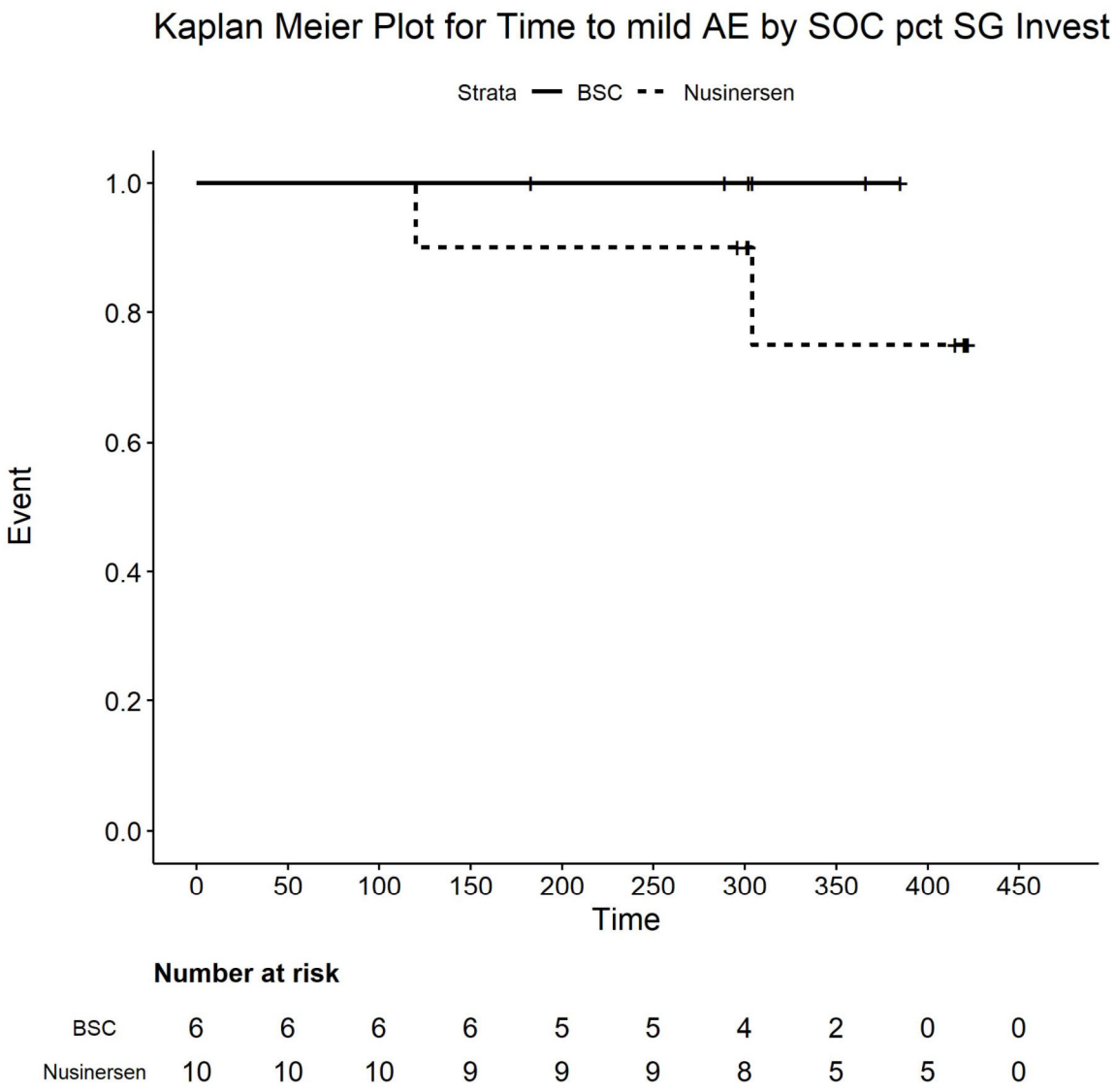
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	4	4	4	4	1	1	0



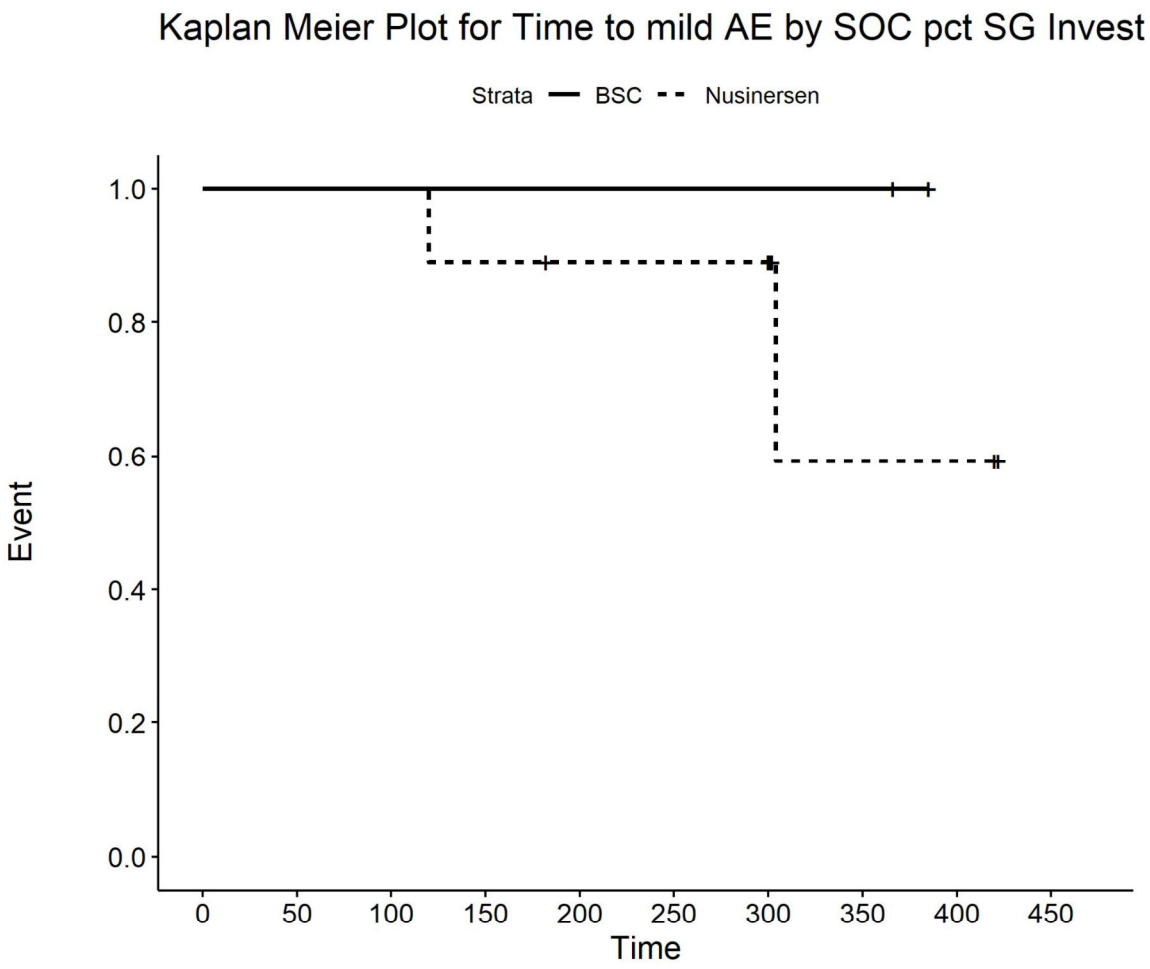
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	4	4	0



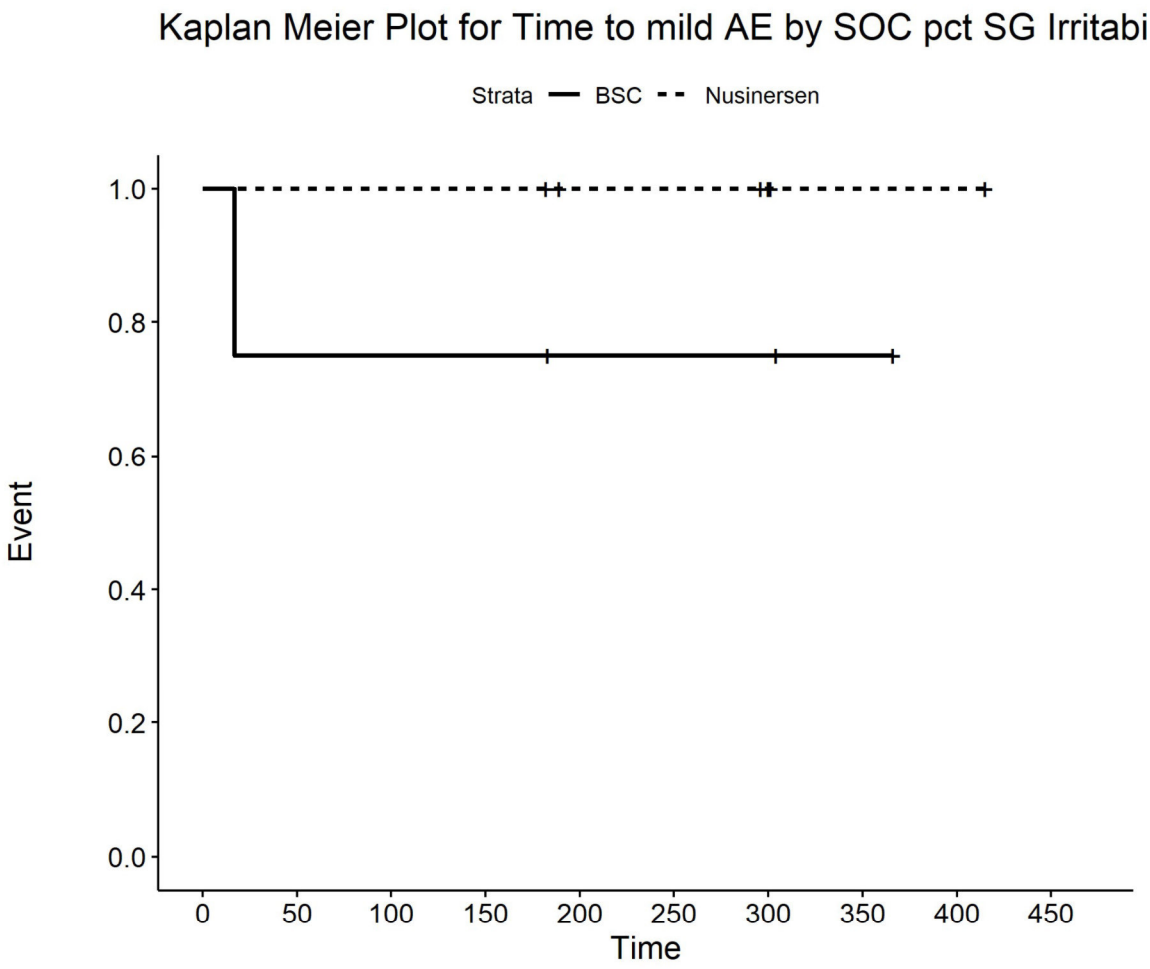
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	5	5	0



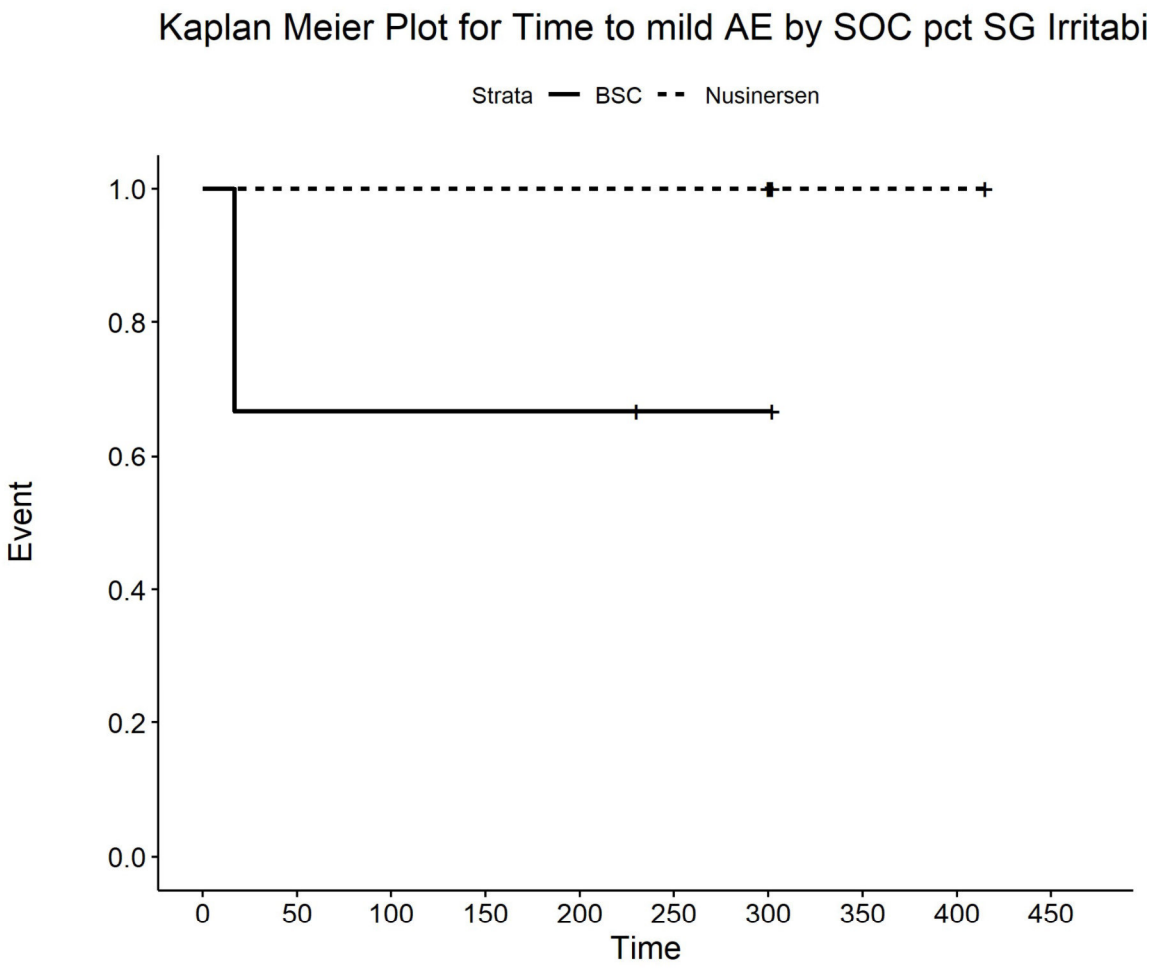
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	2	2	0



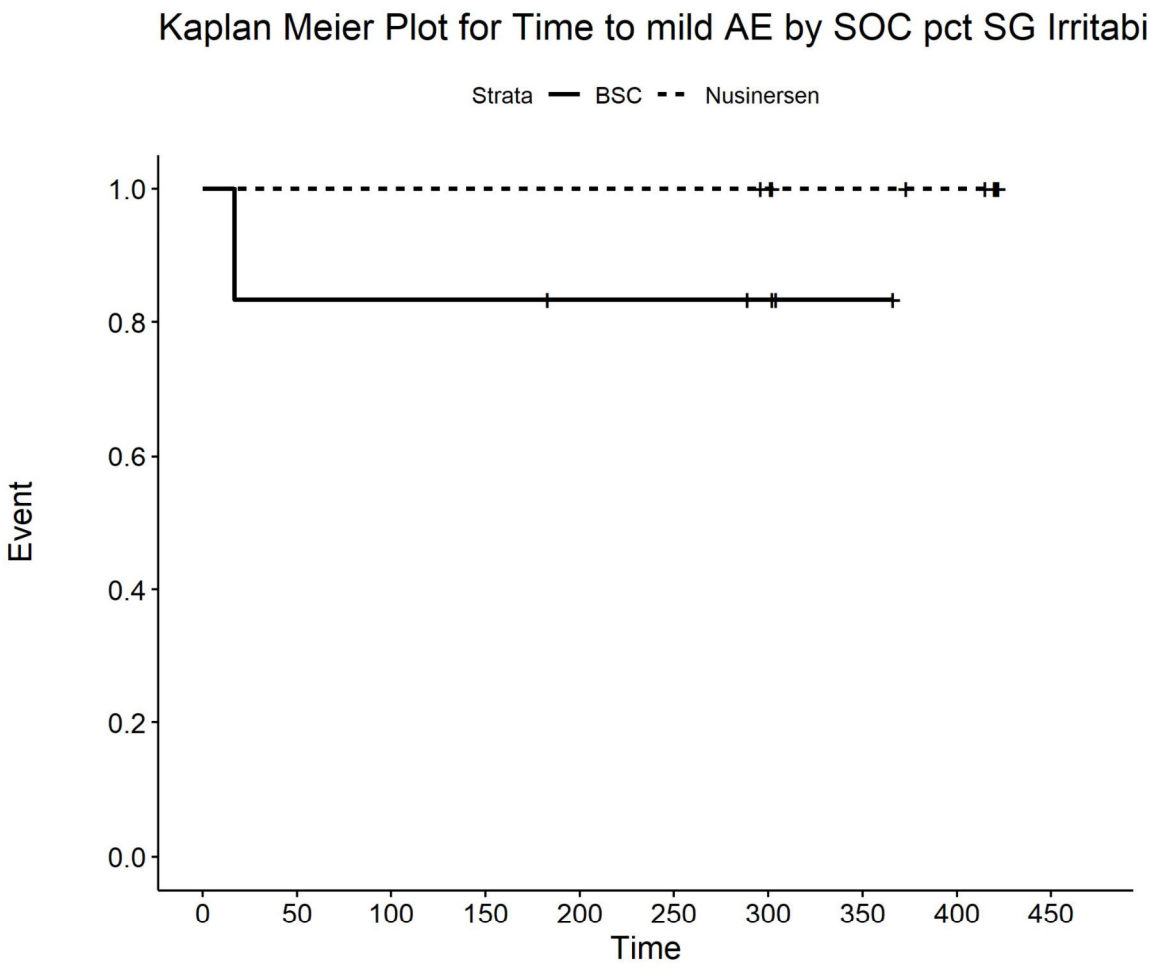
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



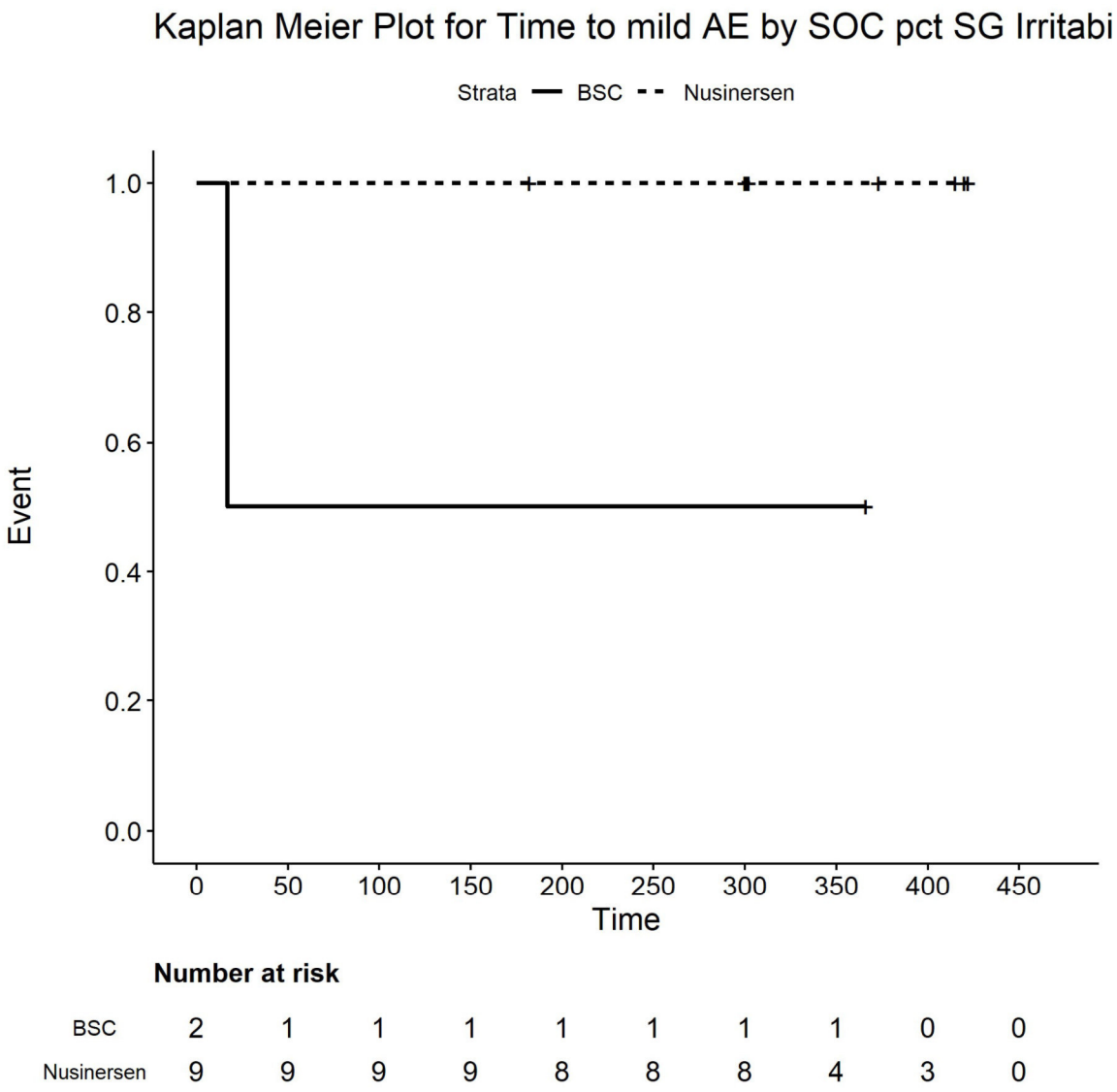
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



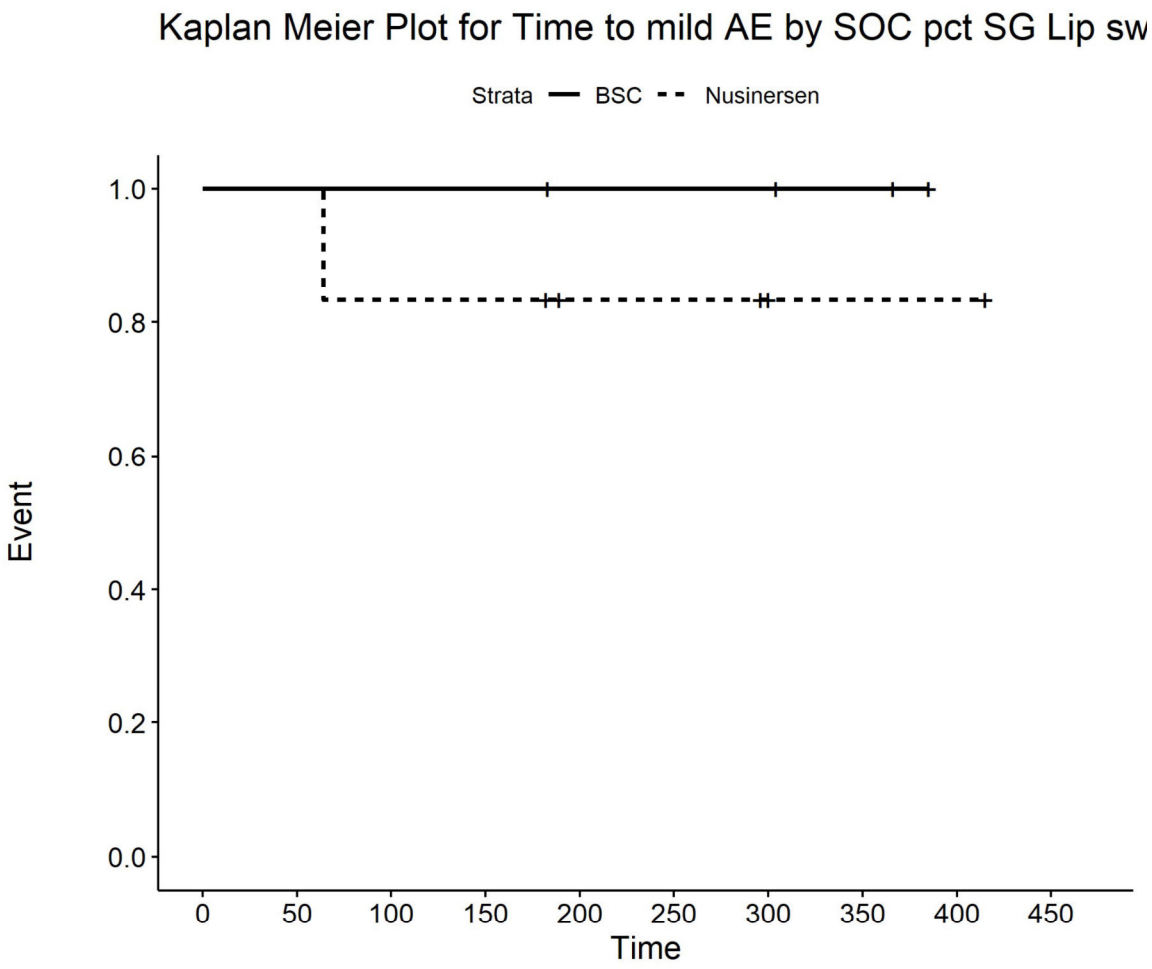
Number at risk

BSC	6	5	5	5	4	4	3	1	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



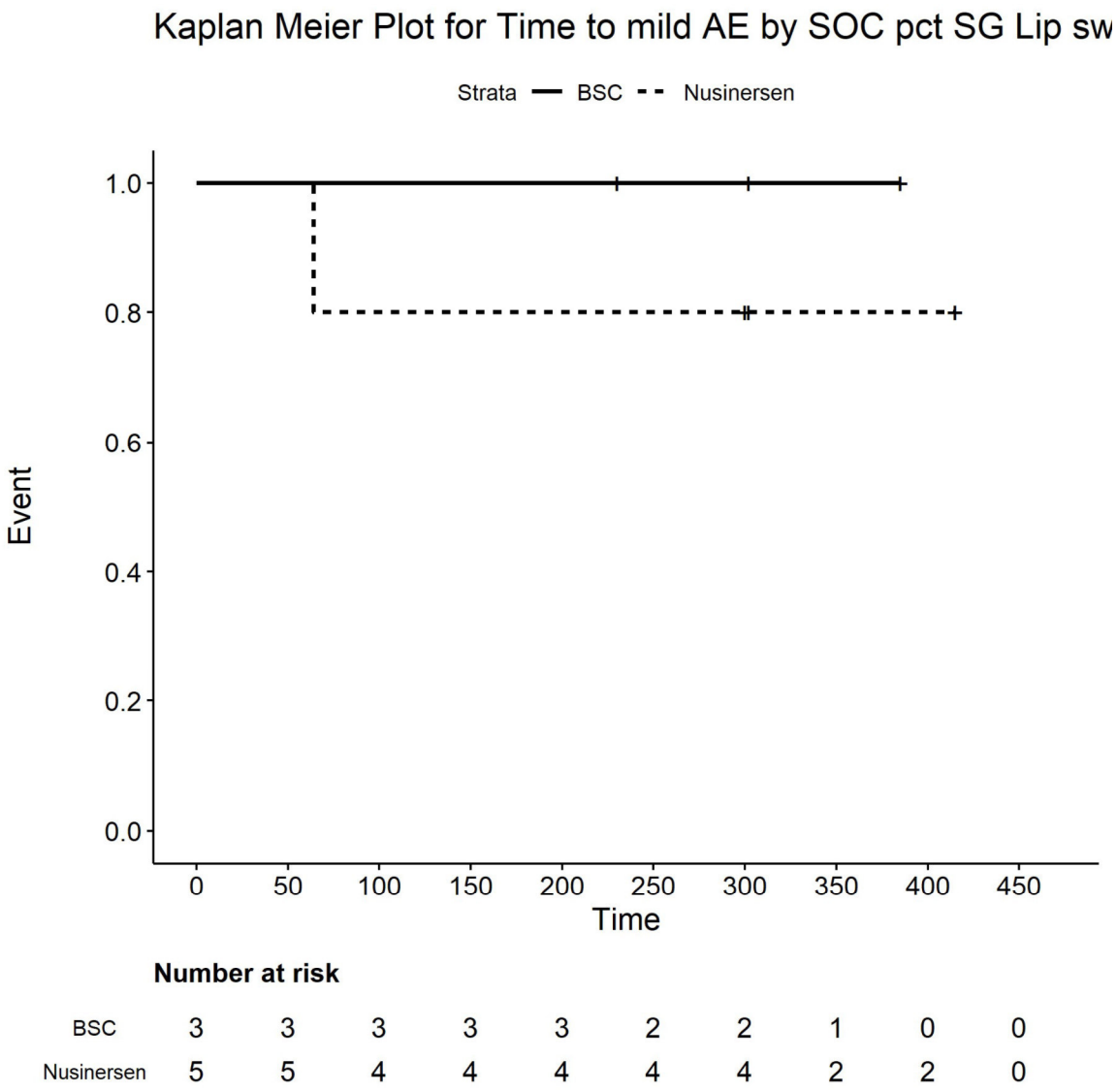
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



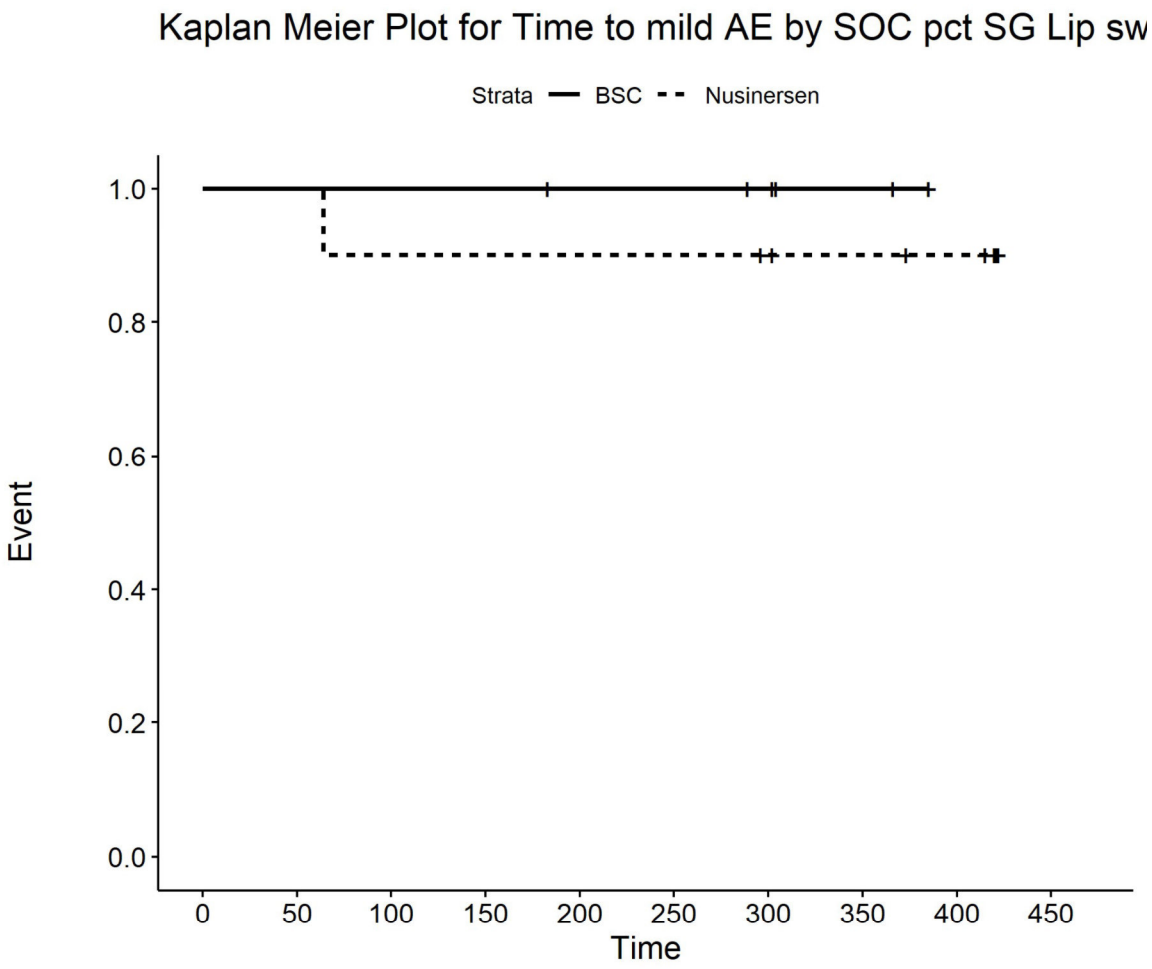
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



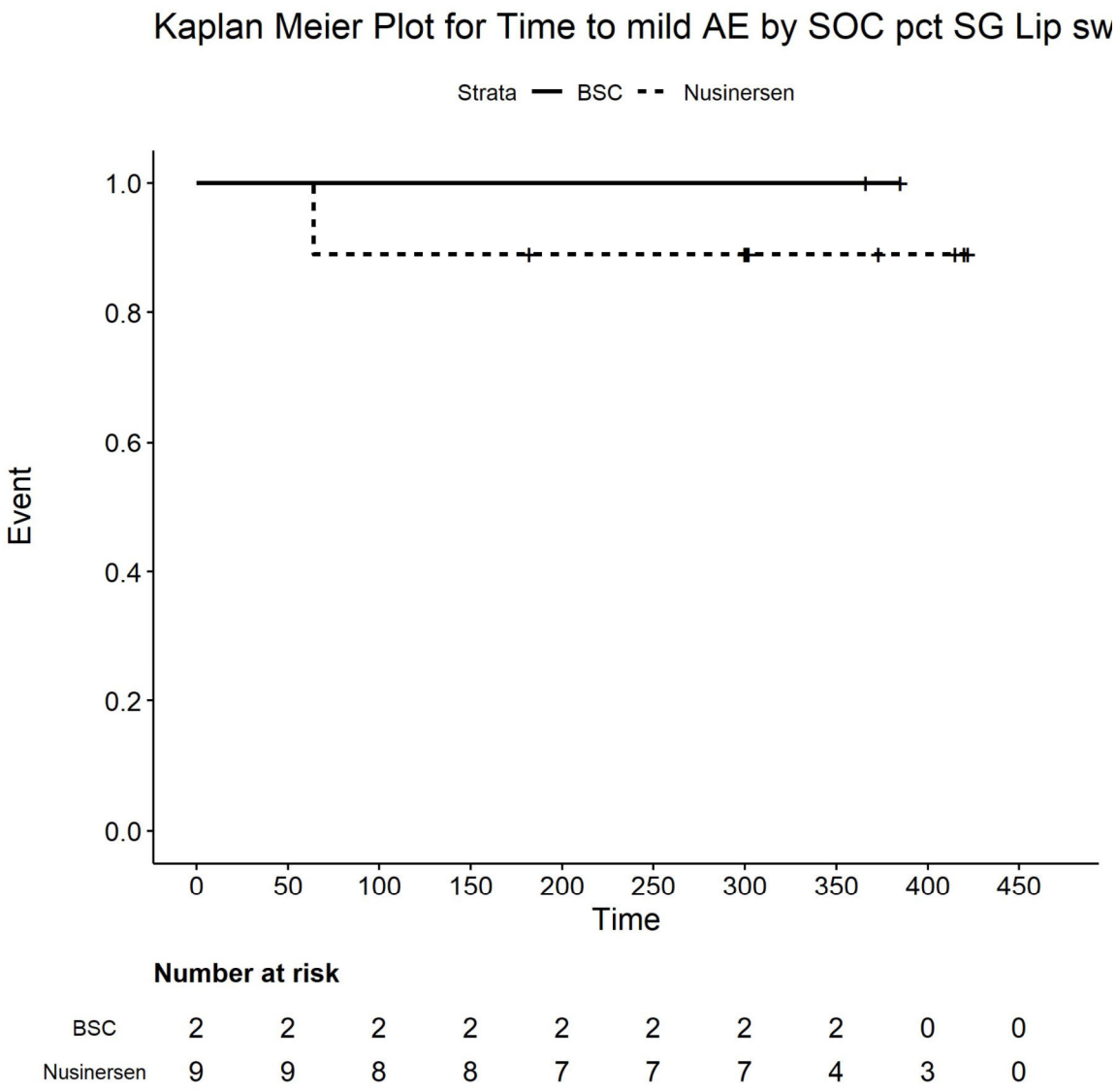
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



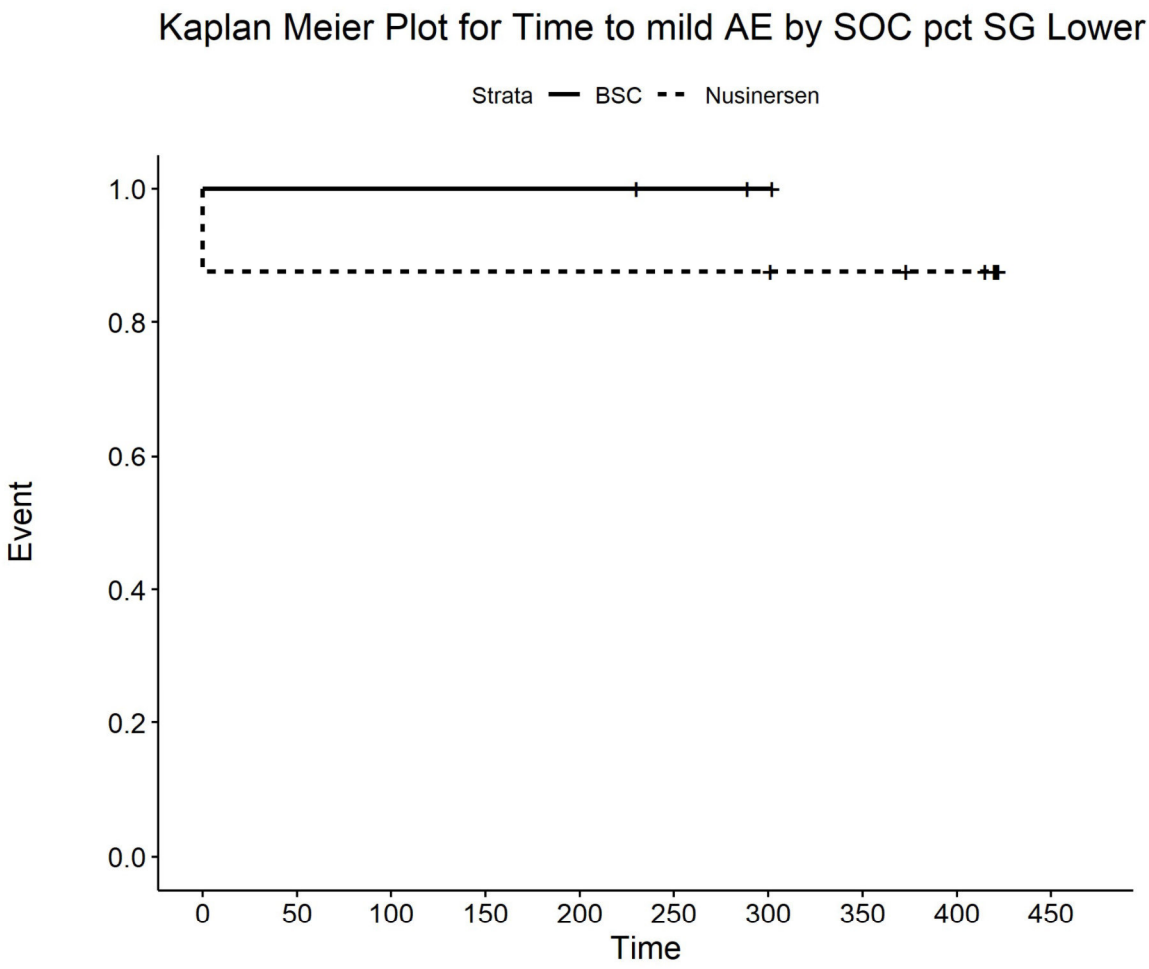
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



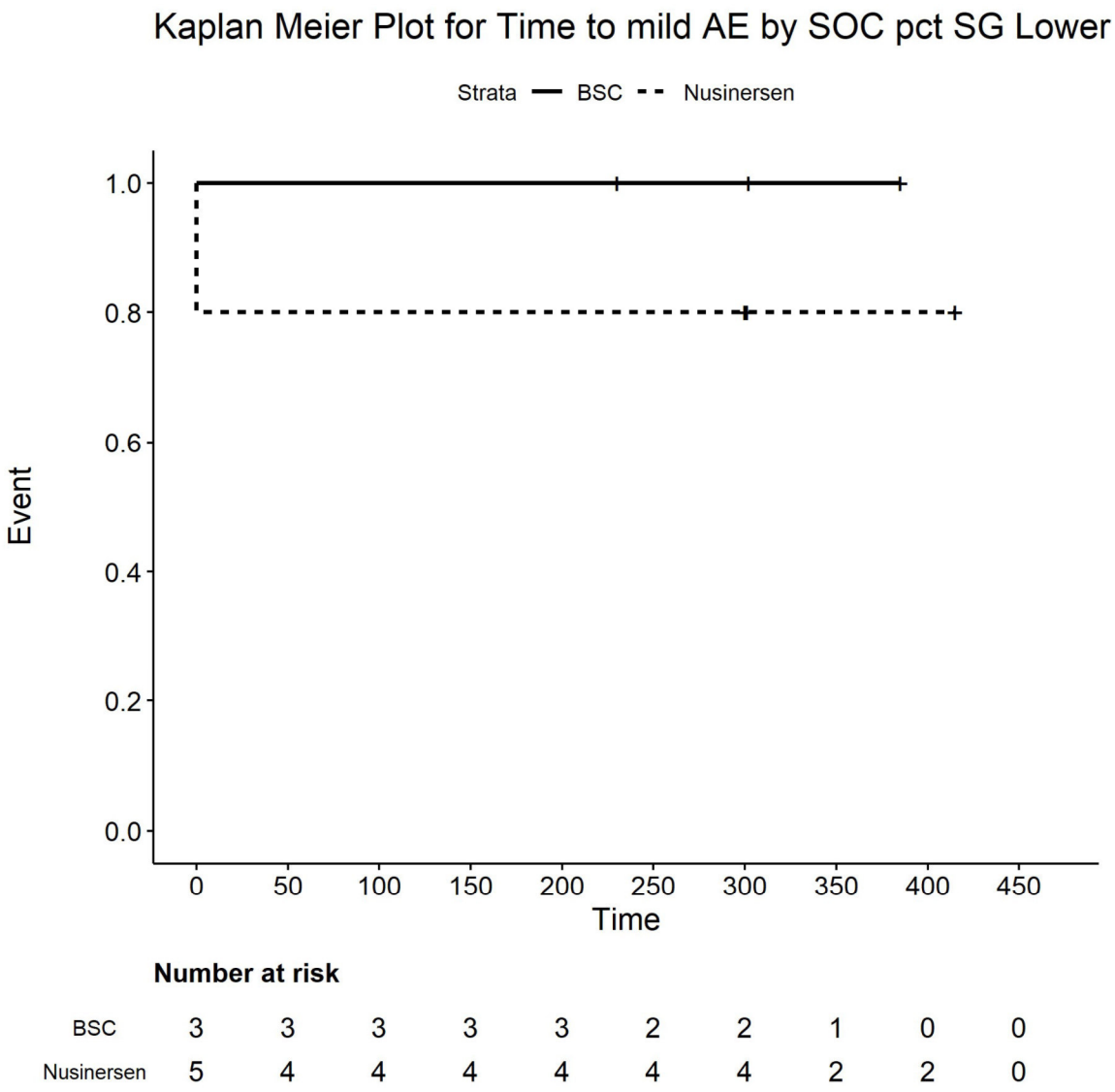
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



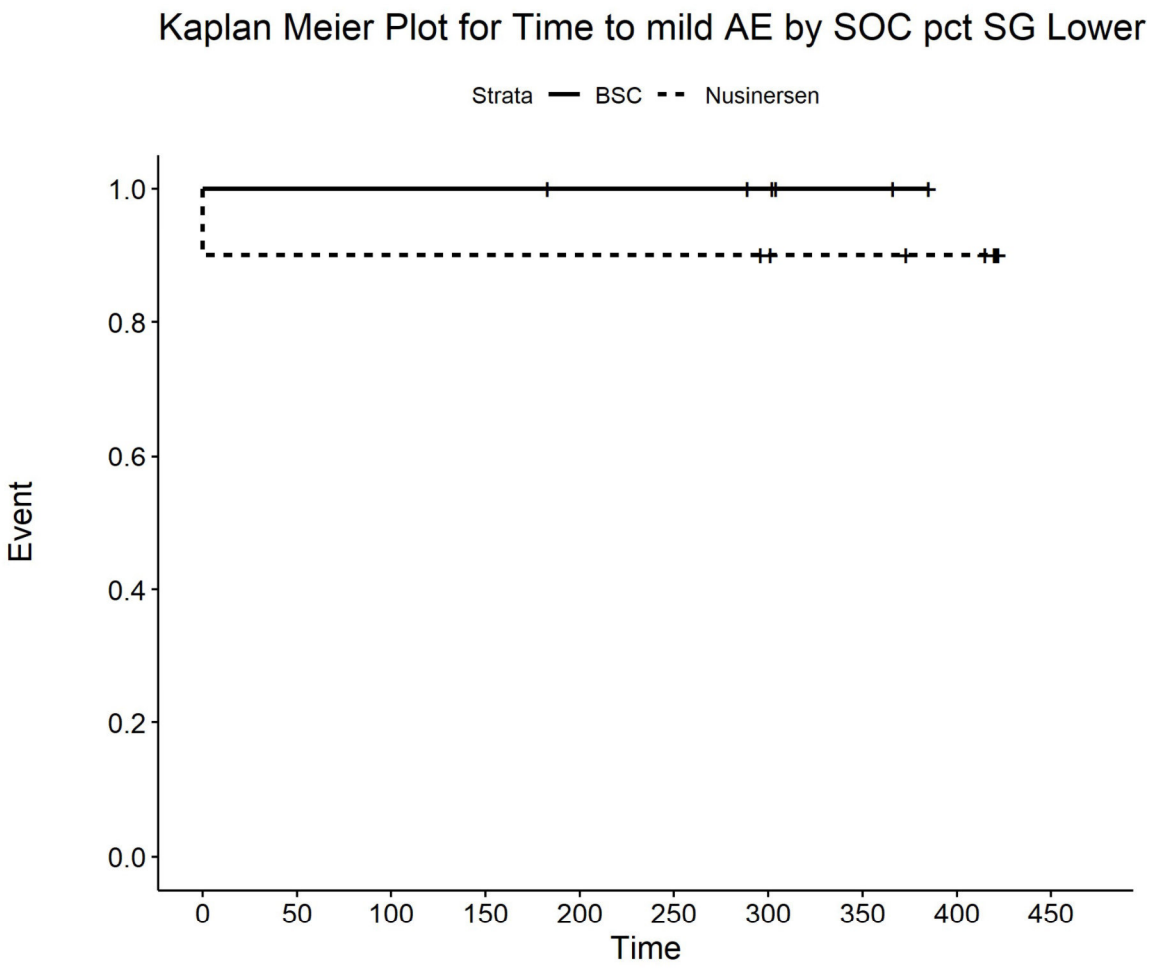
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	6	5	0



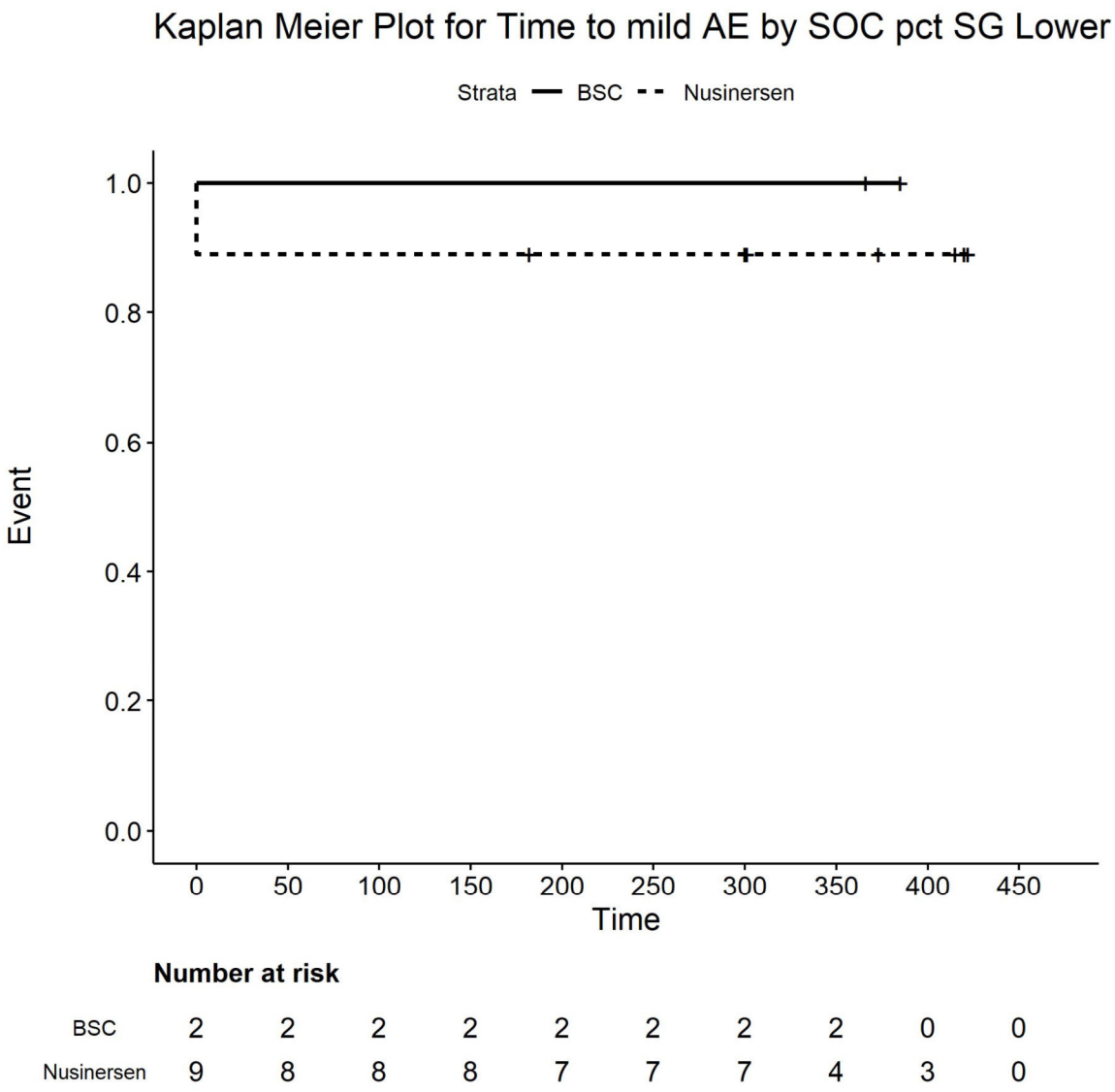
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



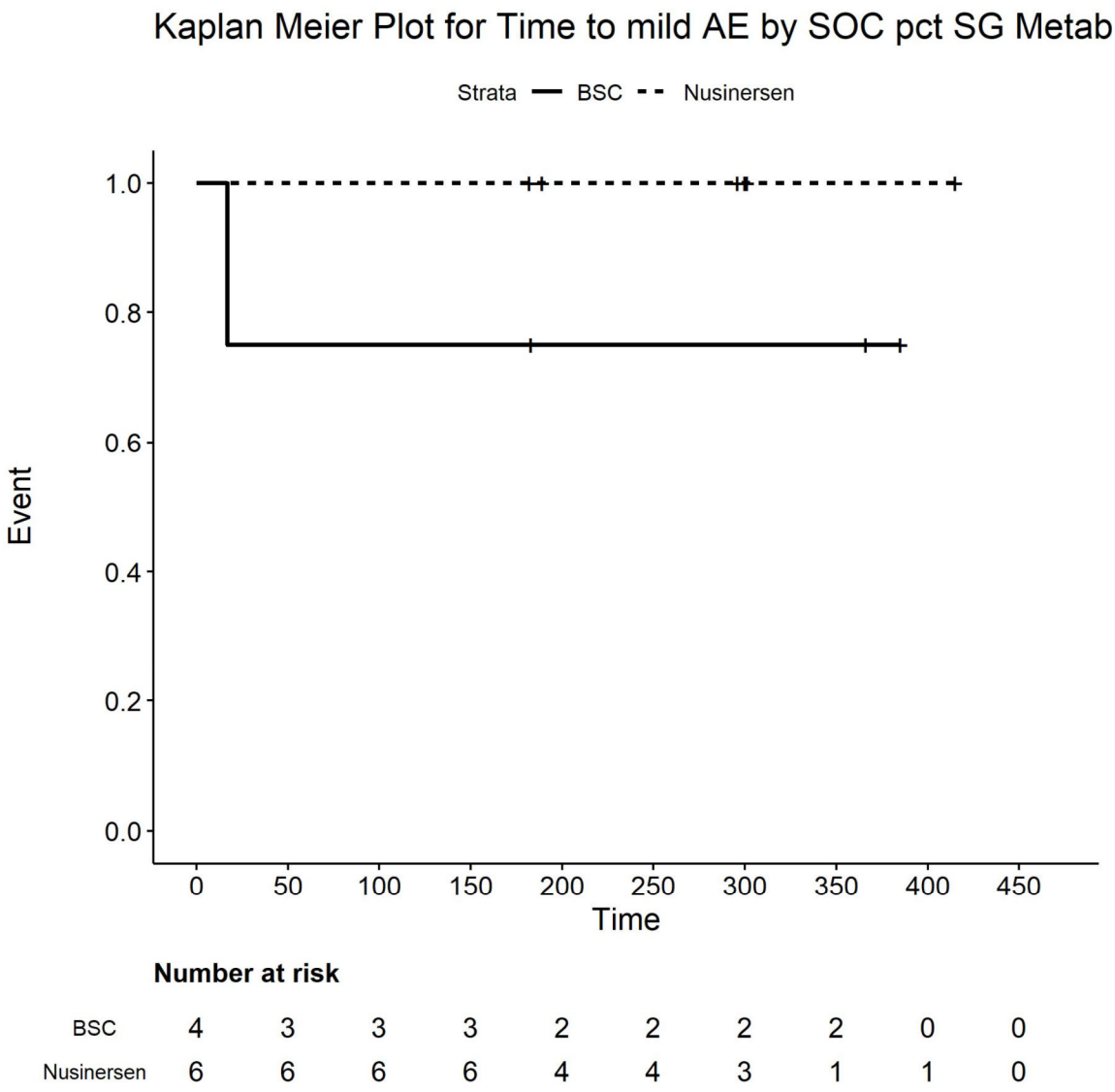
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	7	6	0



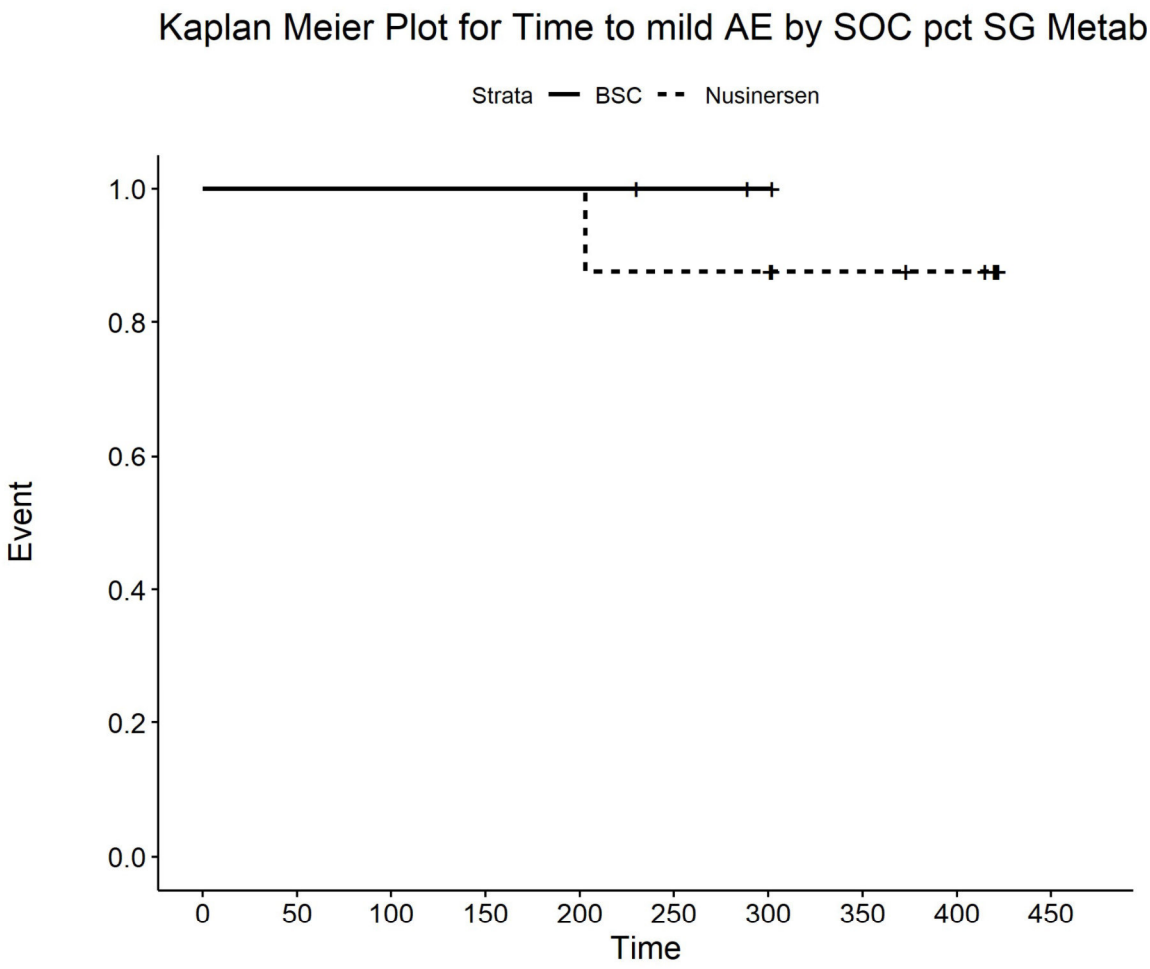
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



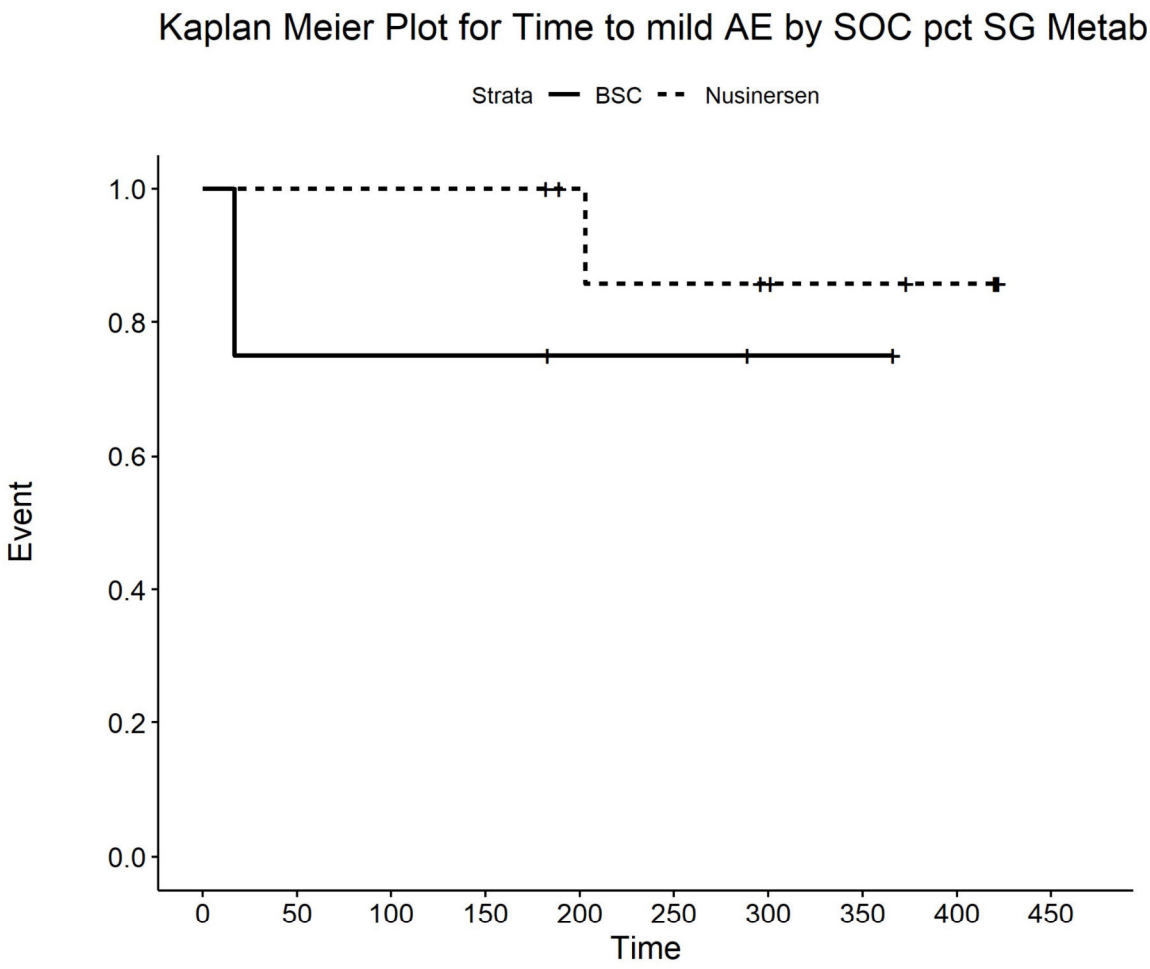
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



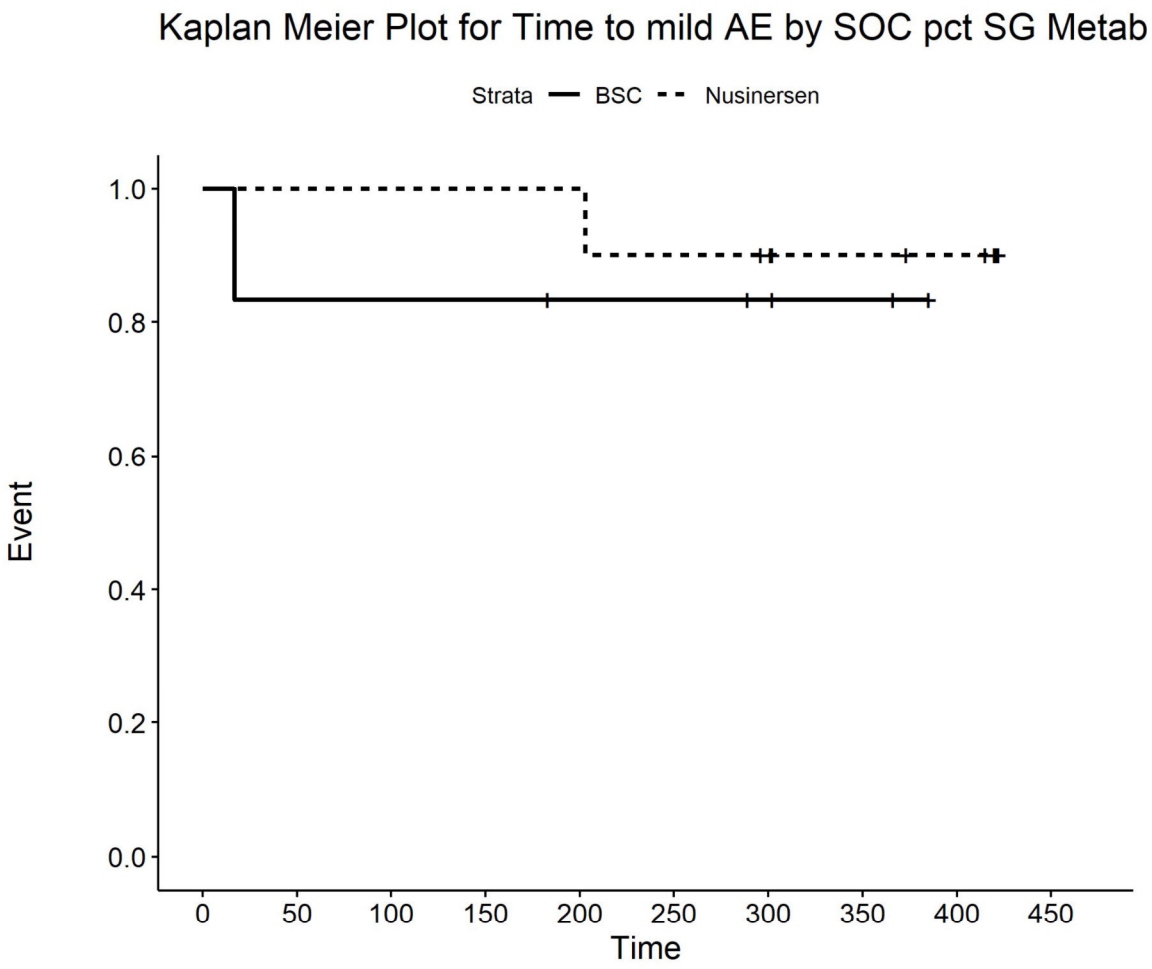
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



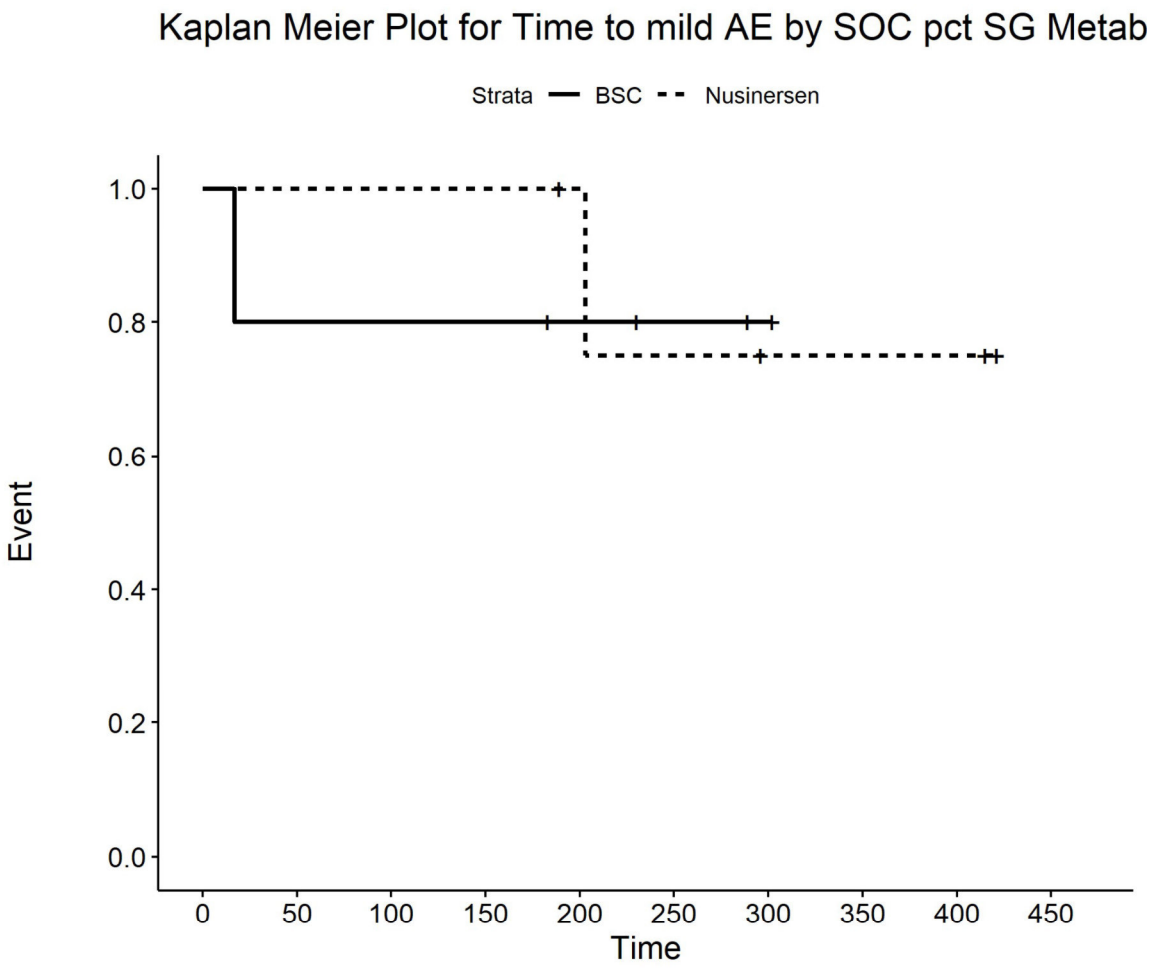
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



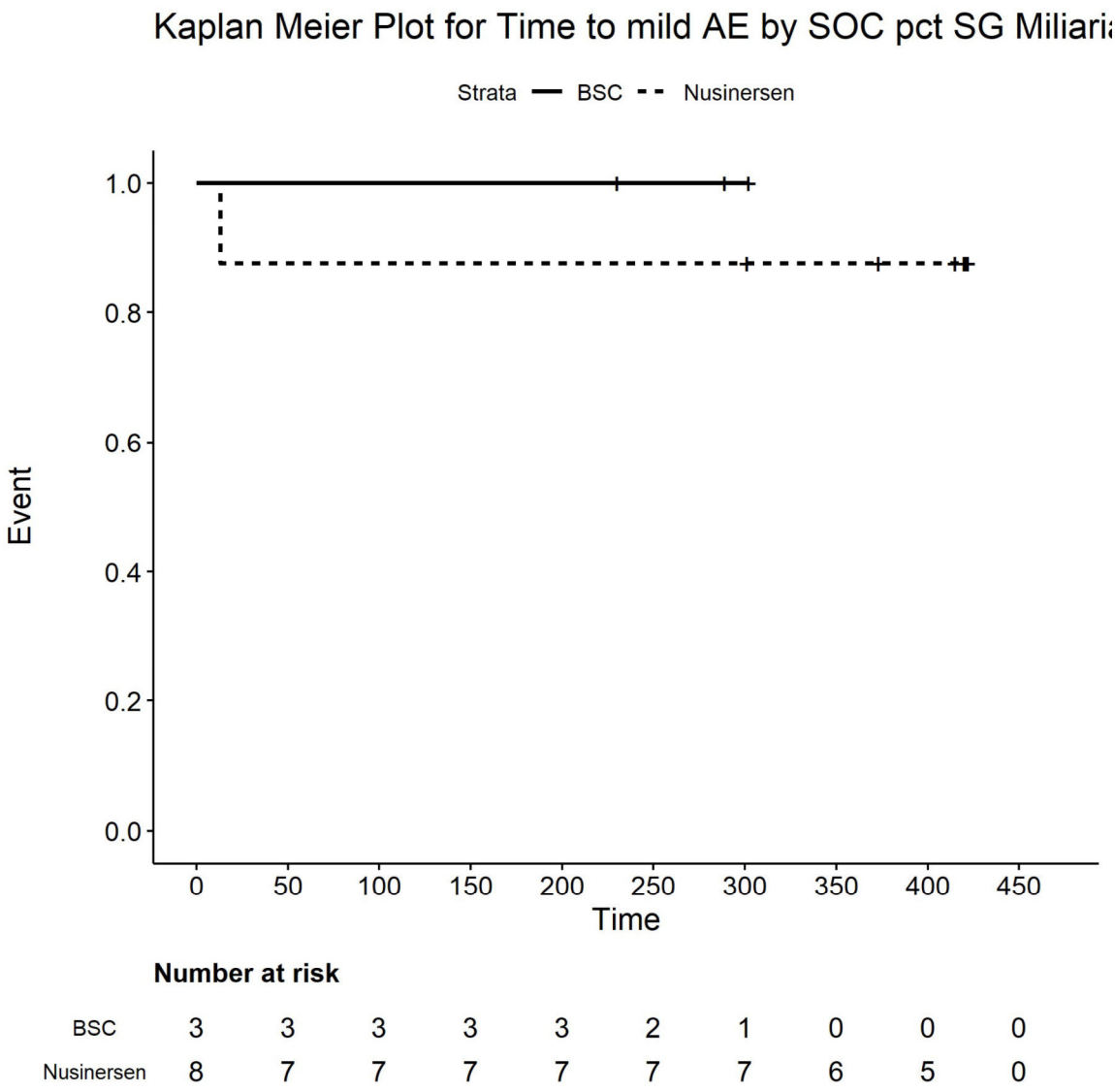
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



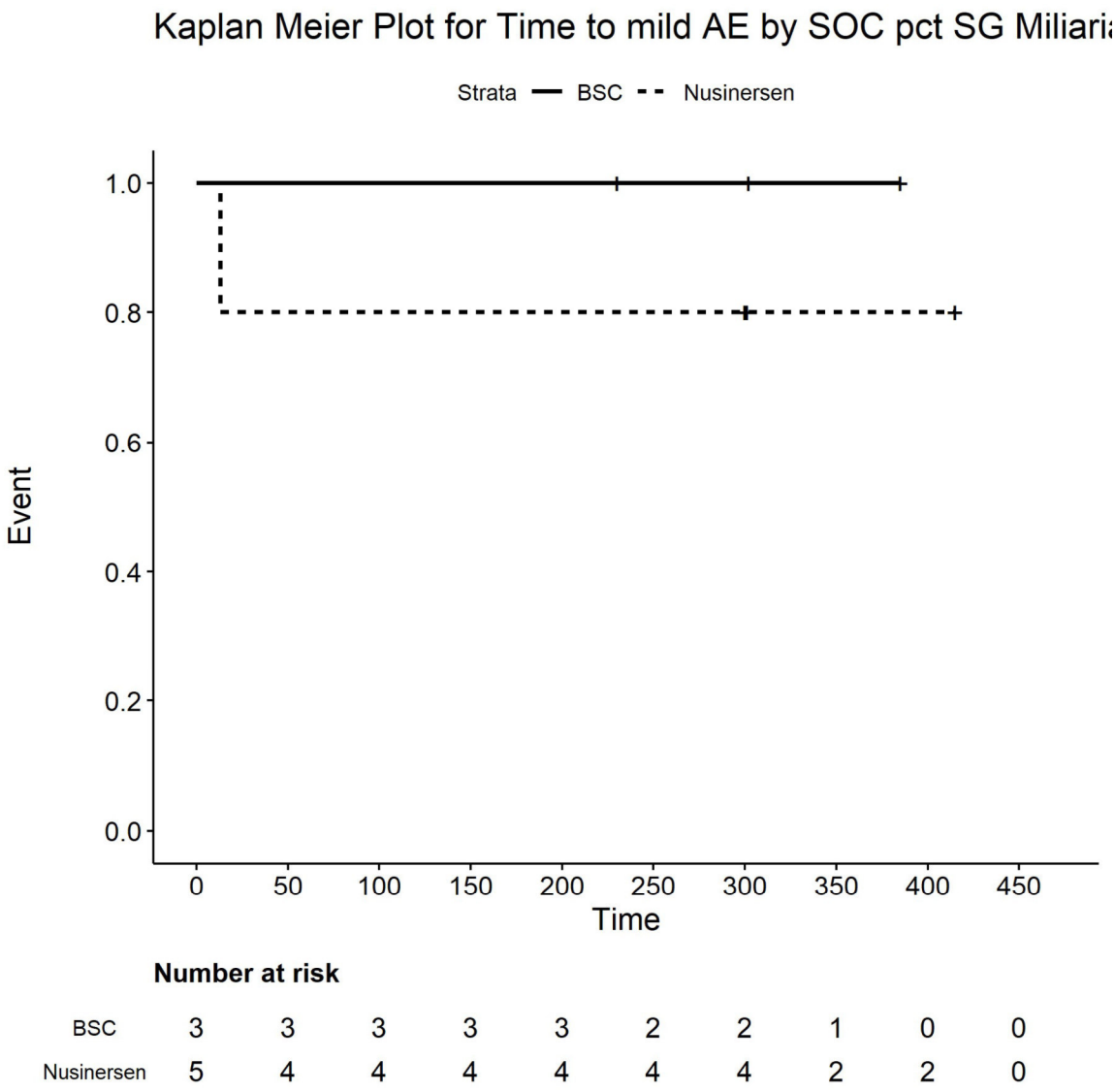
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	3	2	2	2	0



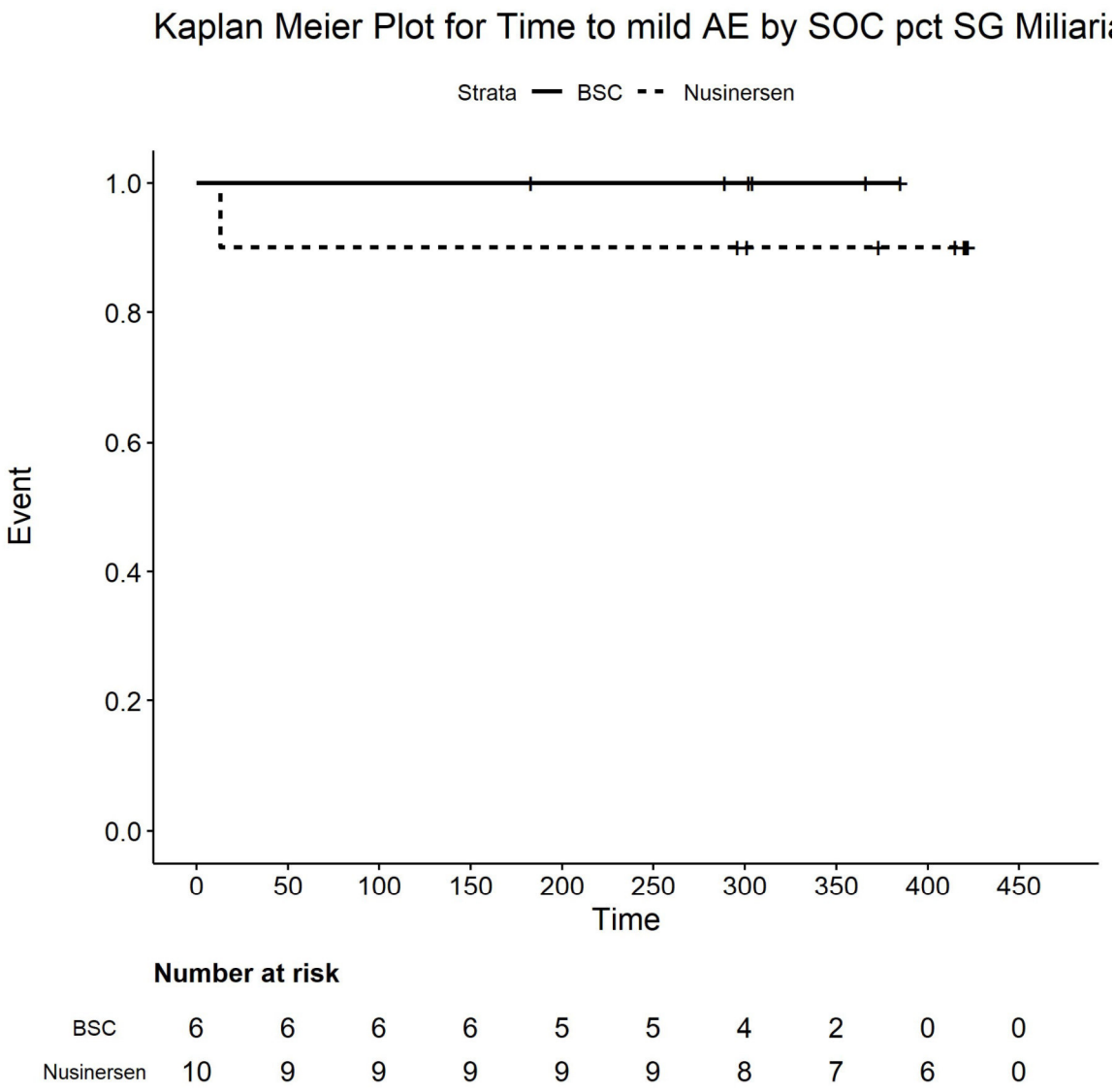
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	6	5	0



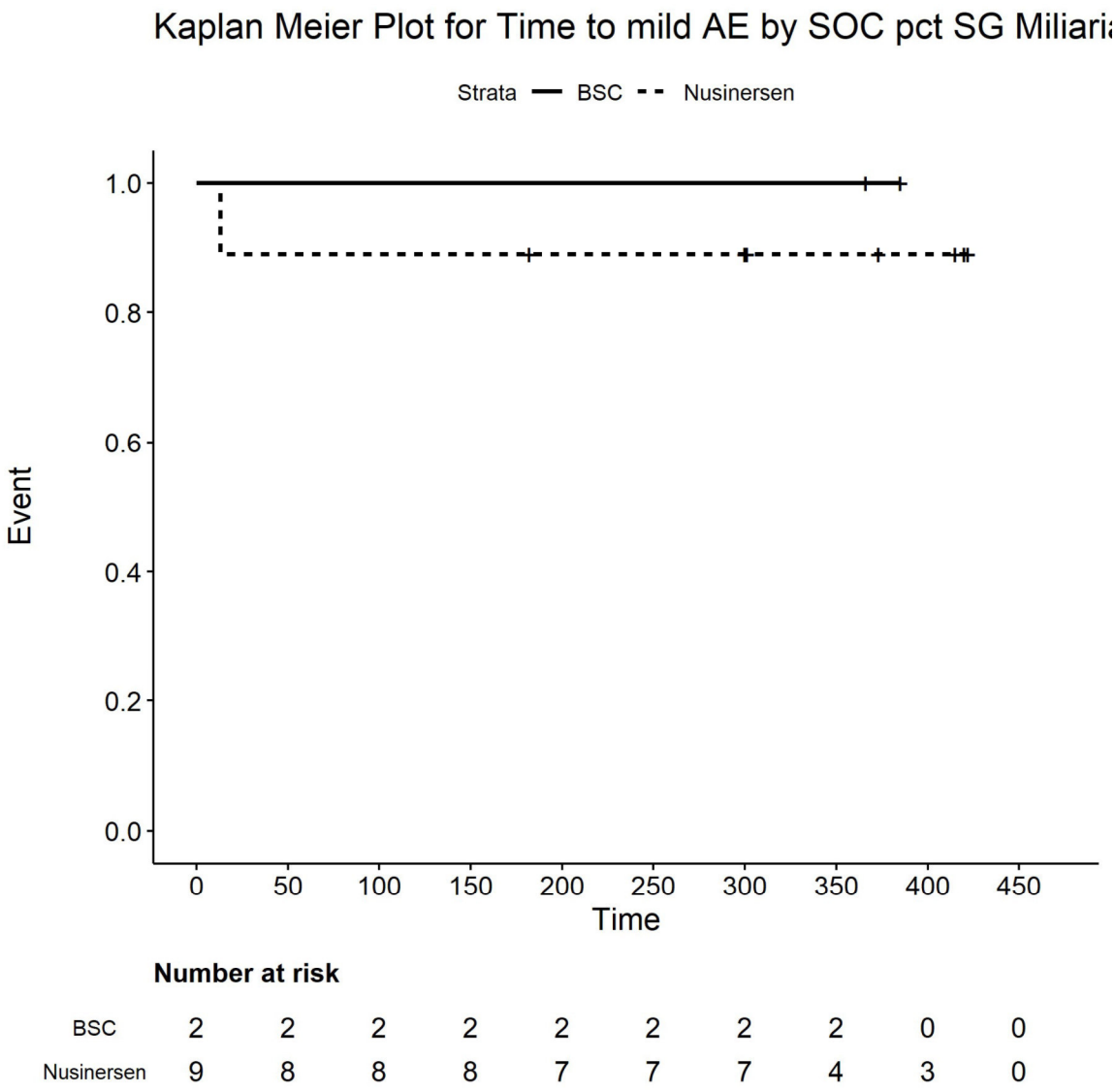
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



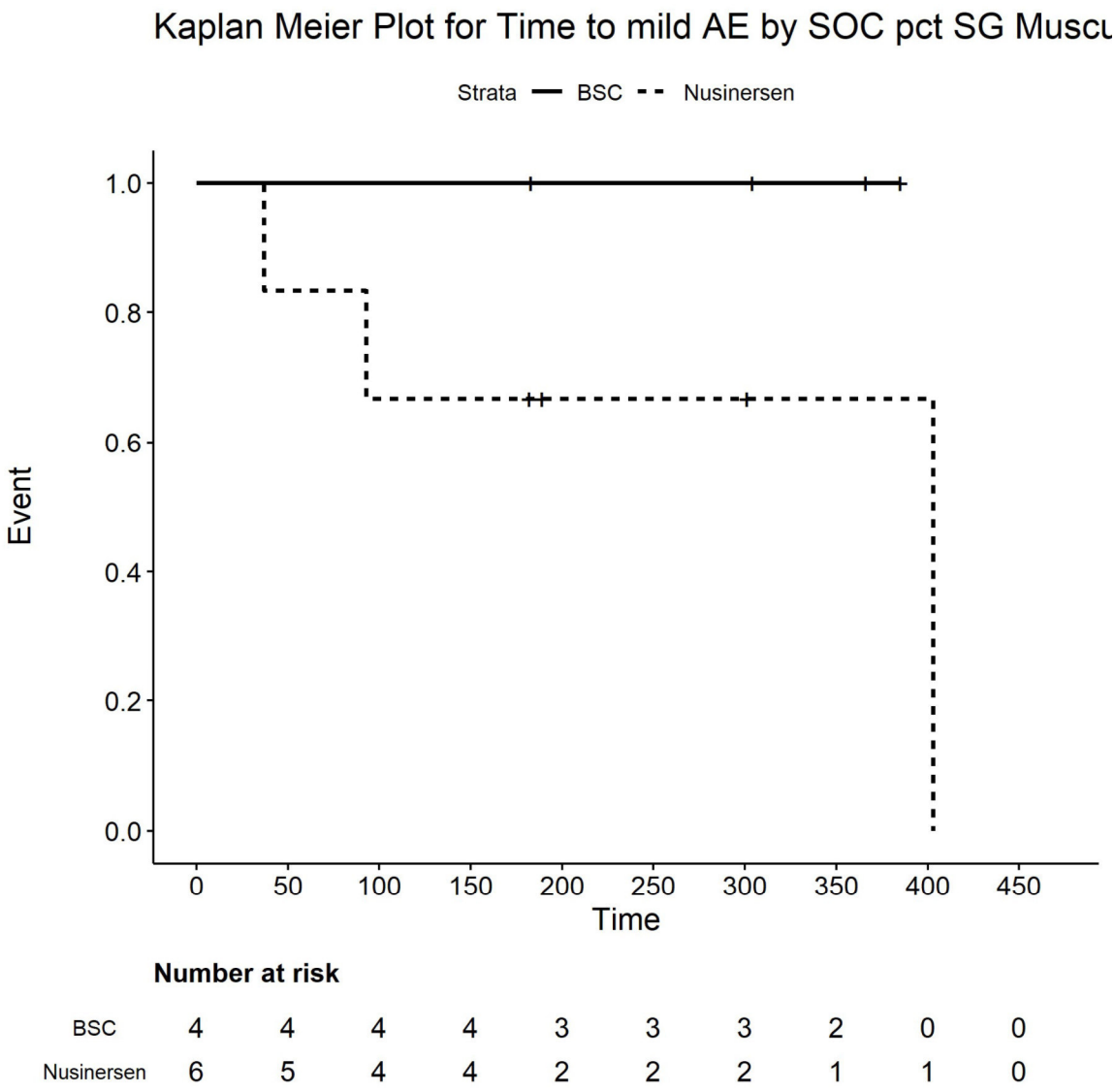
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	7	6	0



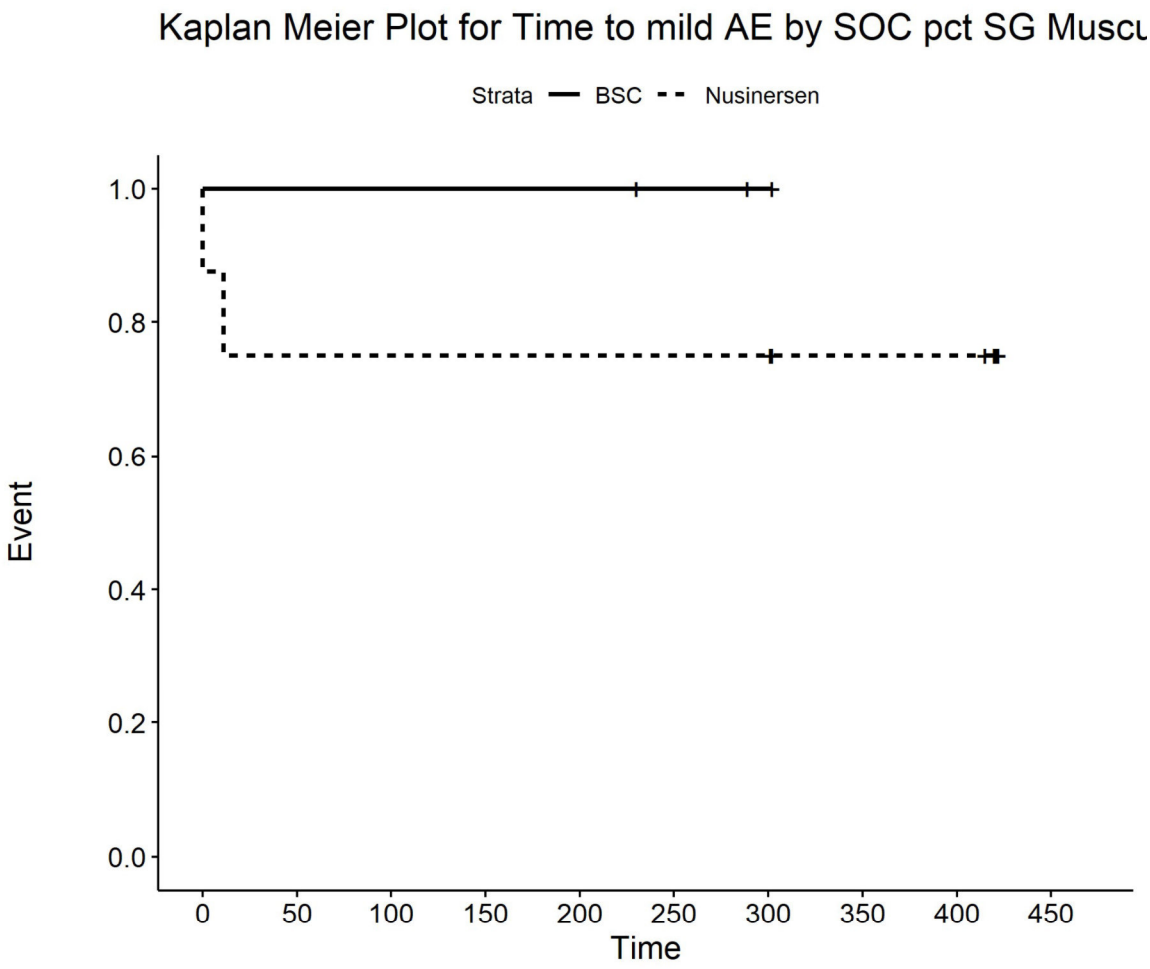
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



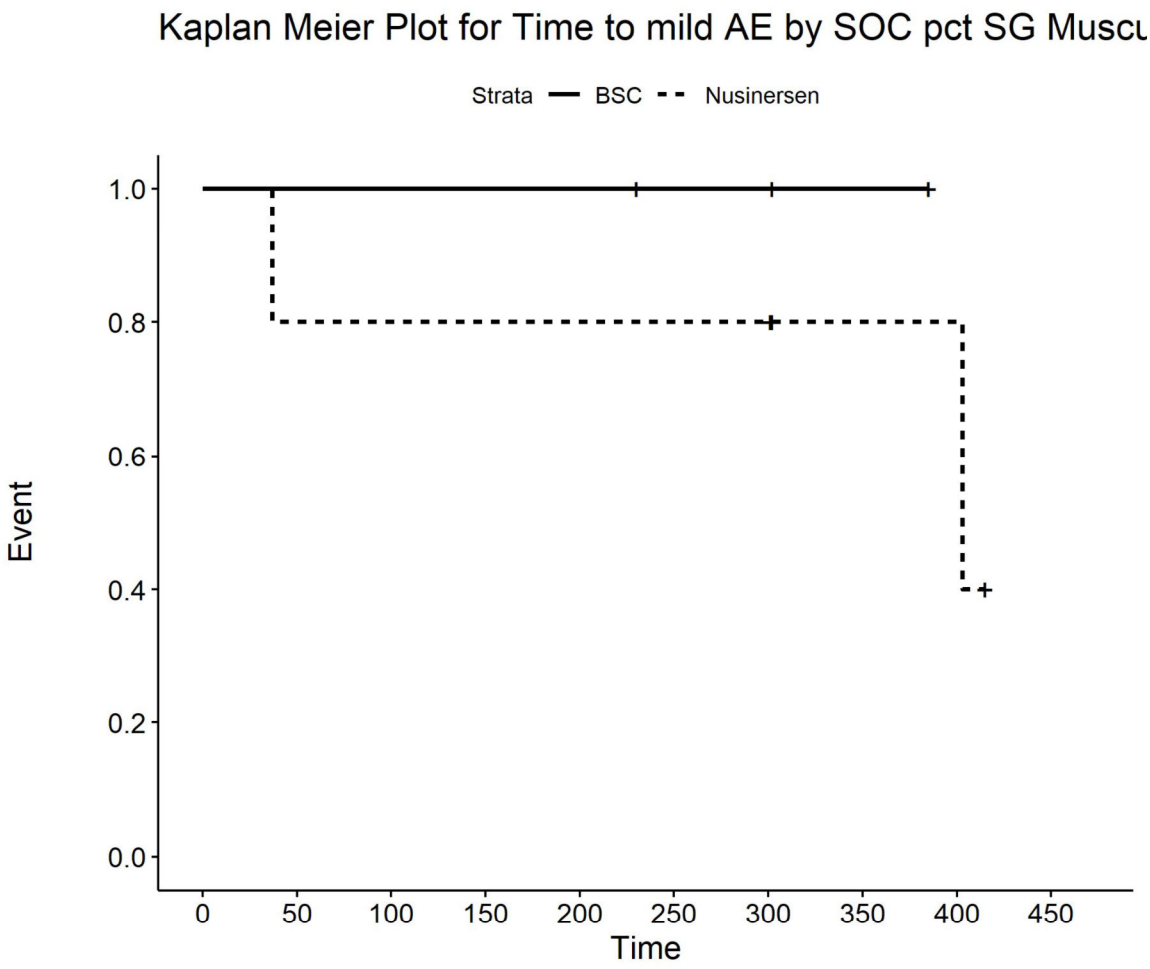
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	4	4	2	2	2	1	1	0



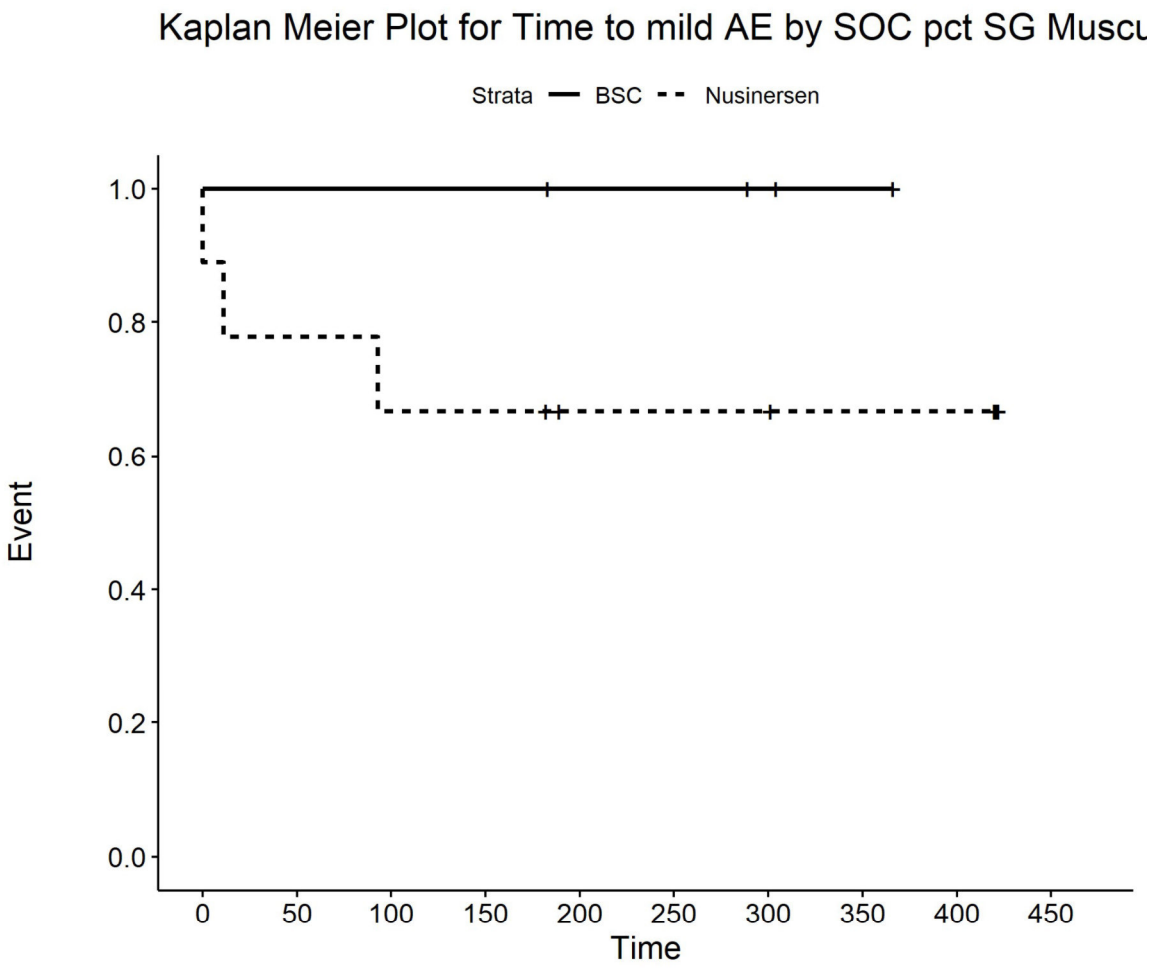
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	6	6	6	6	6	6	4	4	0



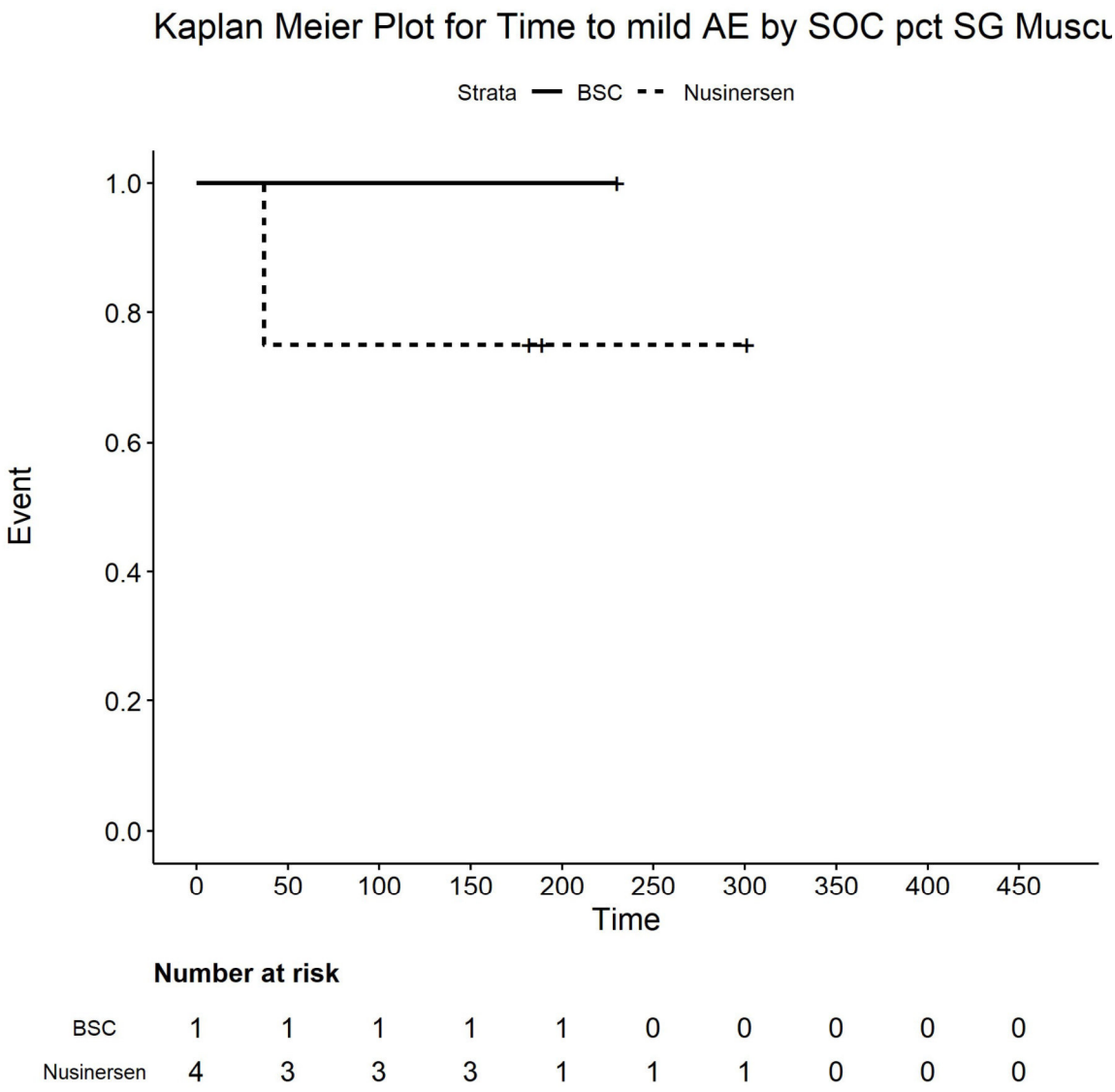
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



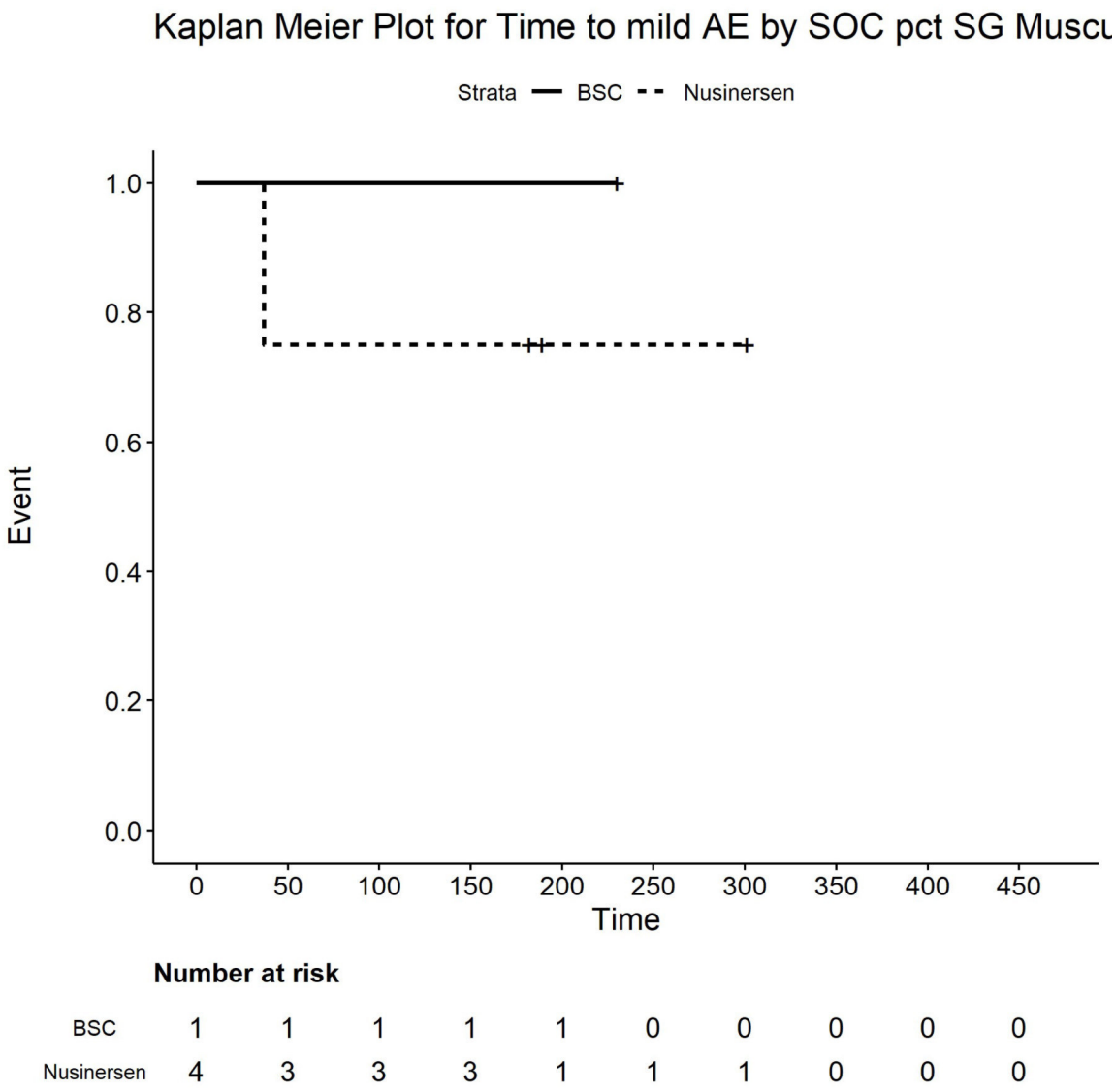
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	7	6	6	4	4	4	3	3	0



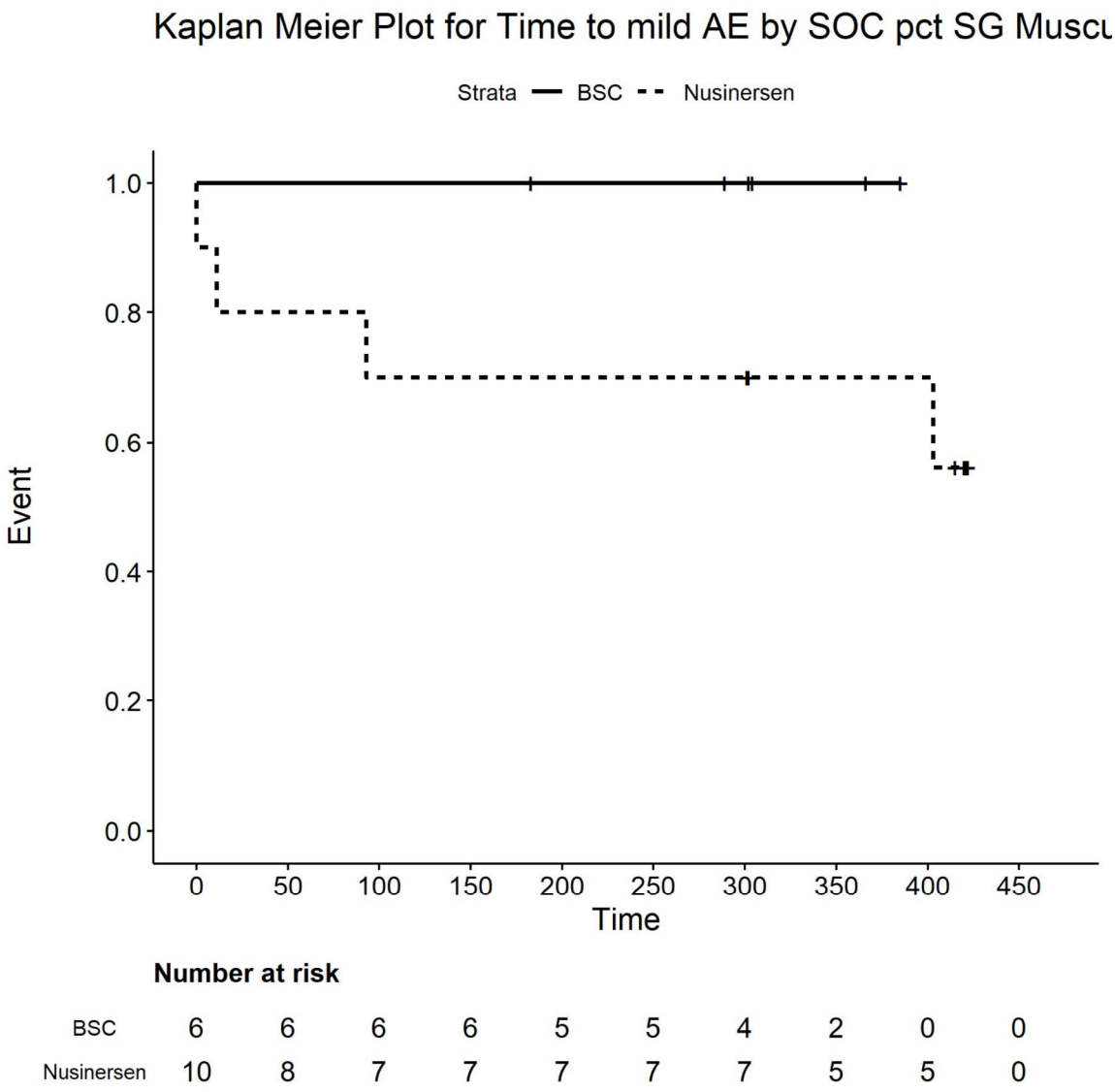
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



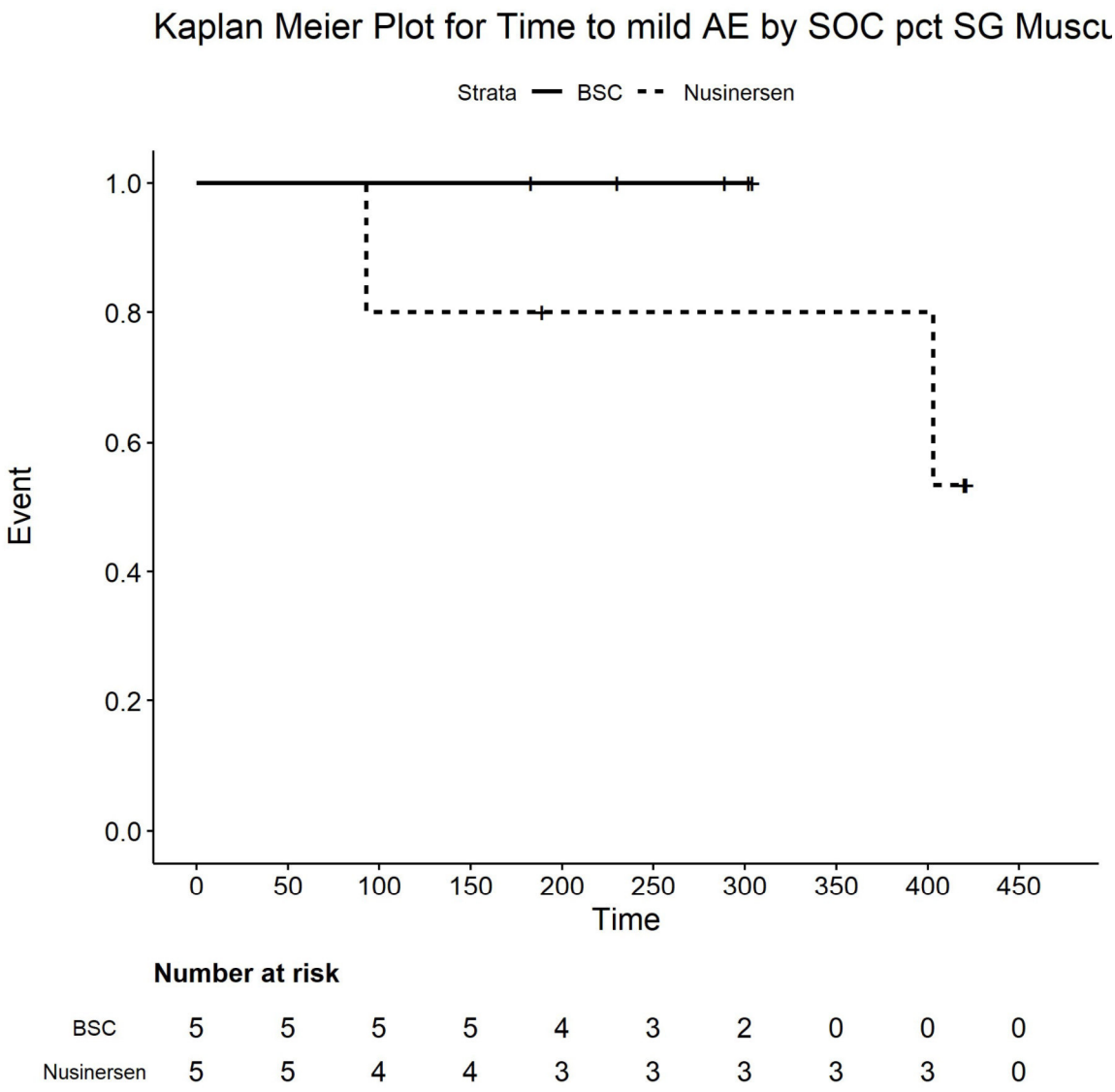
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



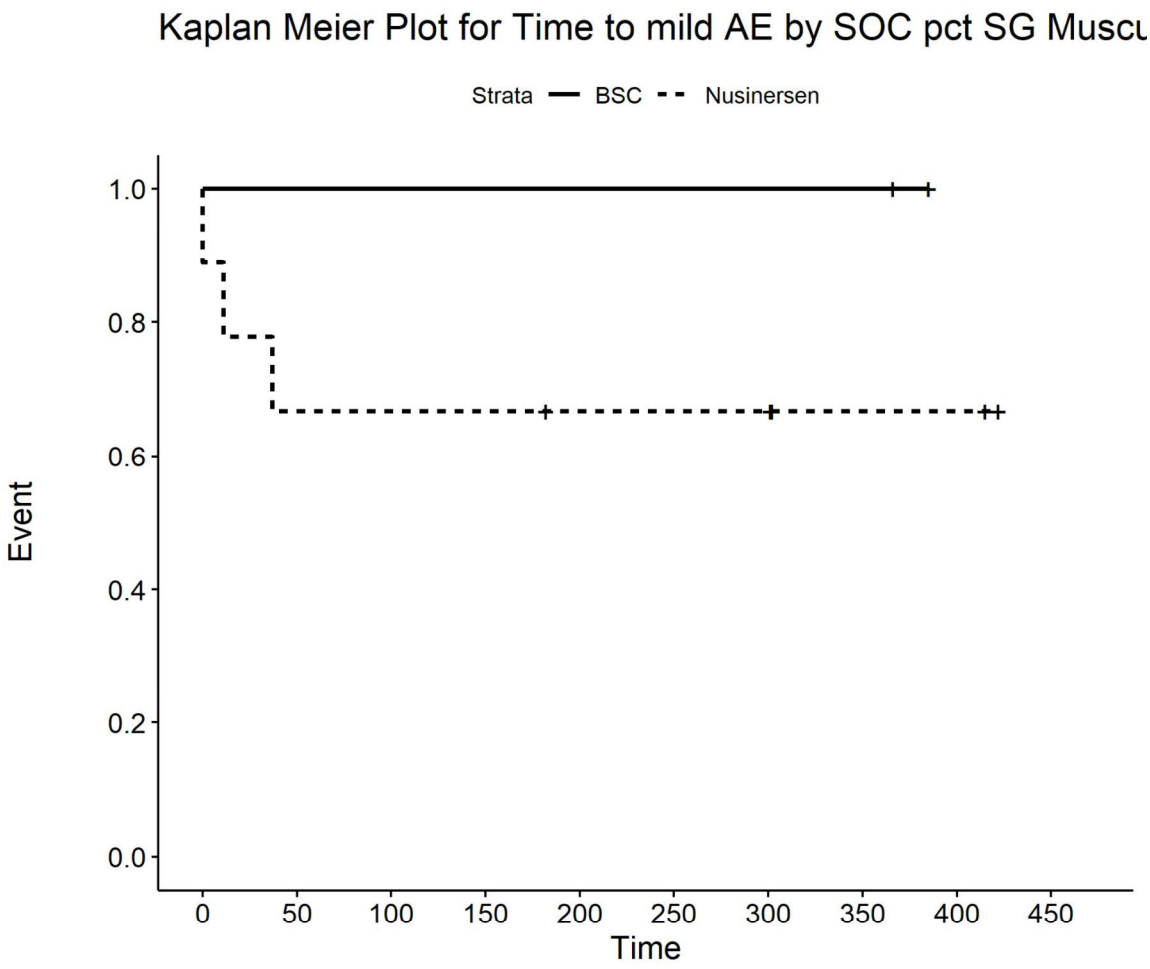
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	8	7	7	7	7	7	5	5	0



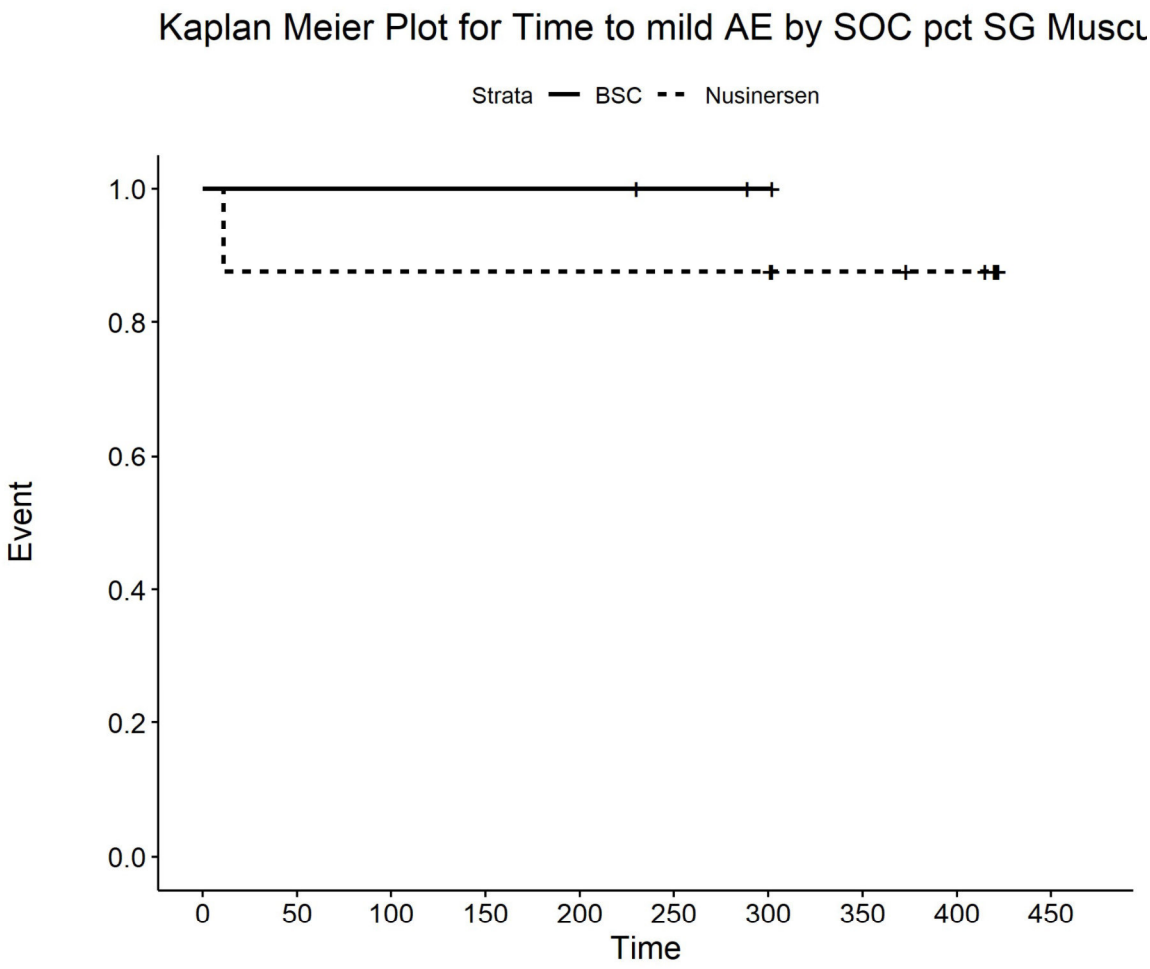
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	4	4	3	3	3	3	3	0



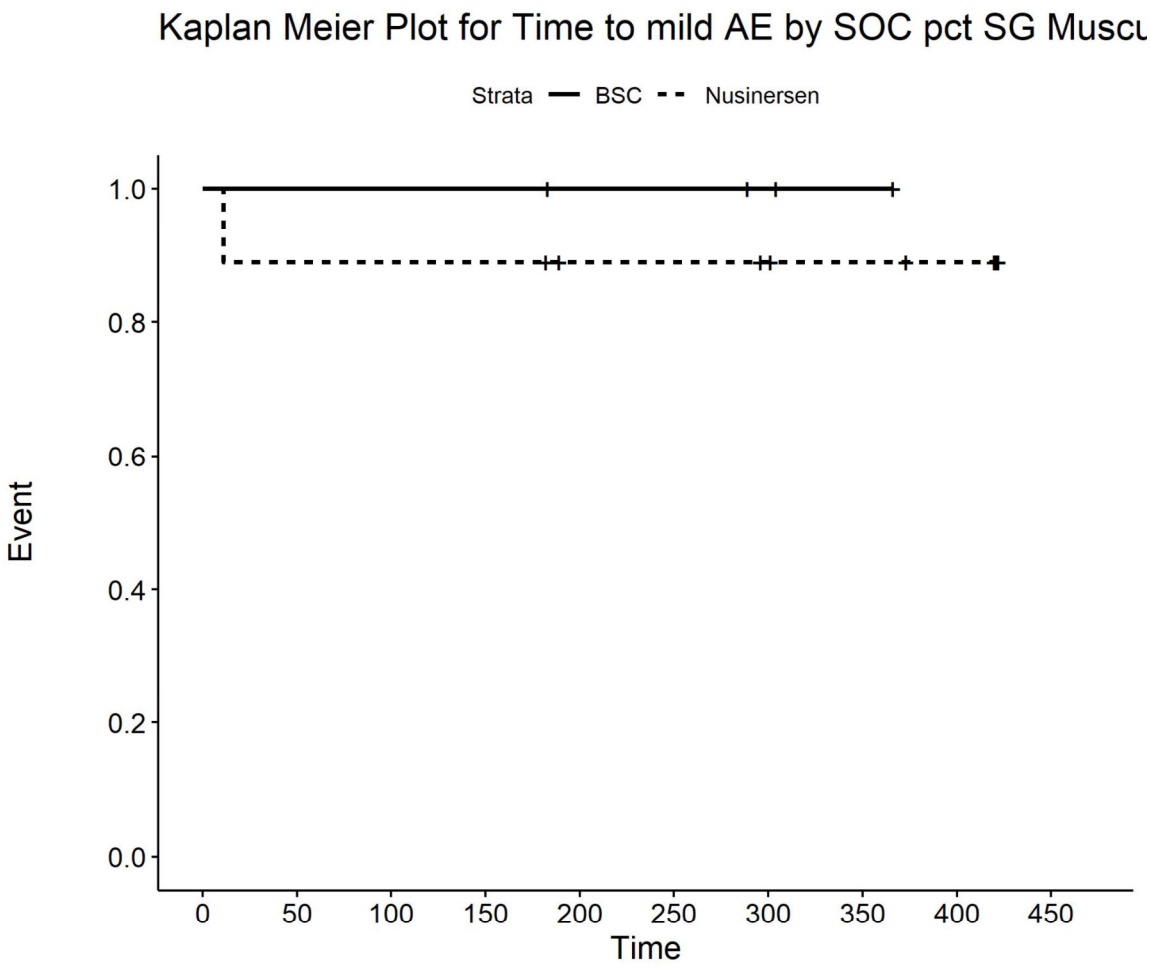
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	6	6	6	5	5	5	2	2	0



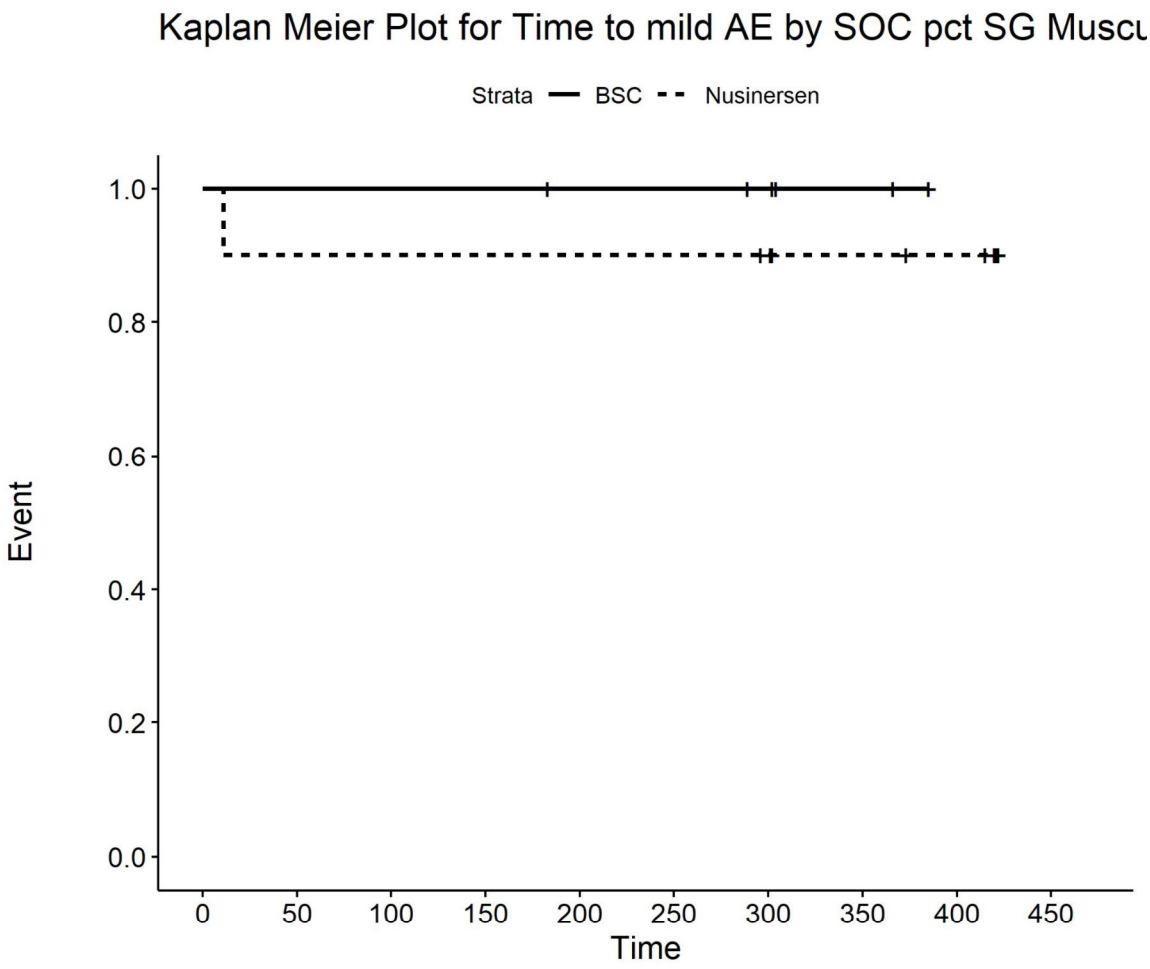
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



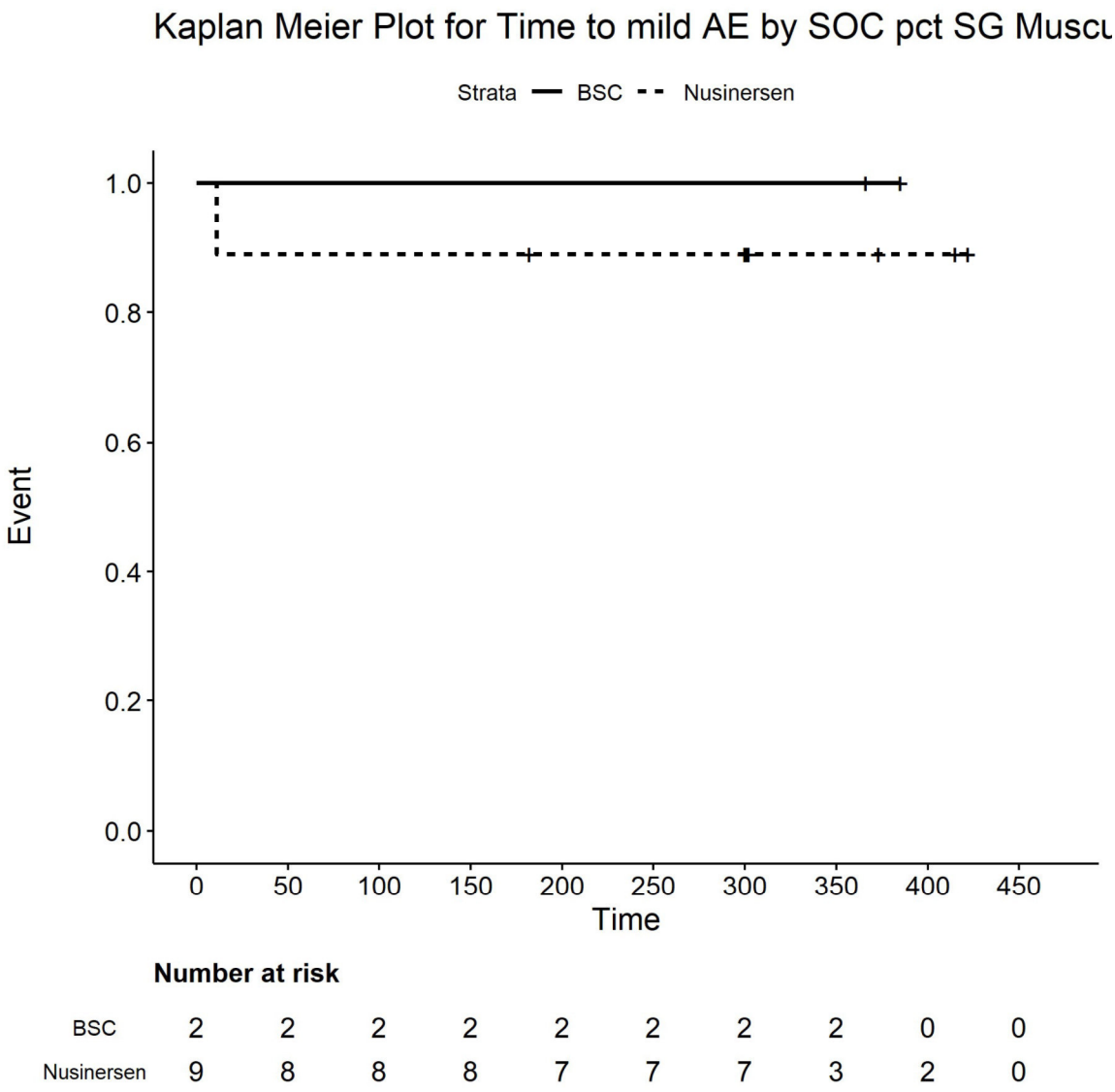
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



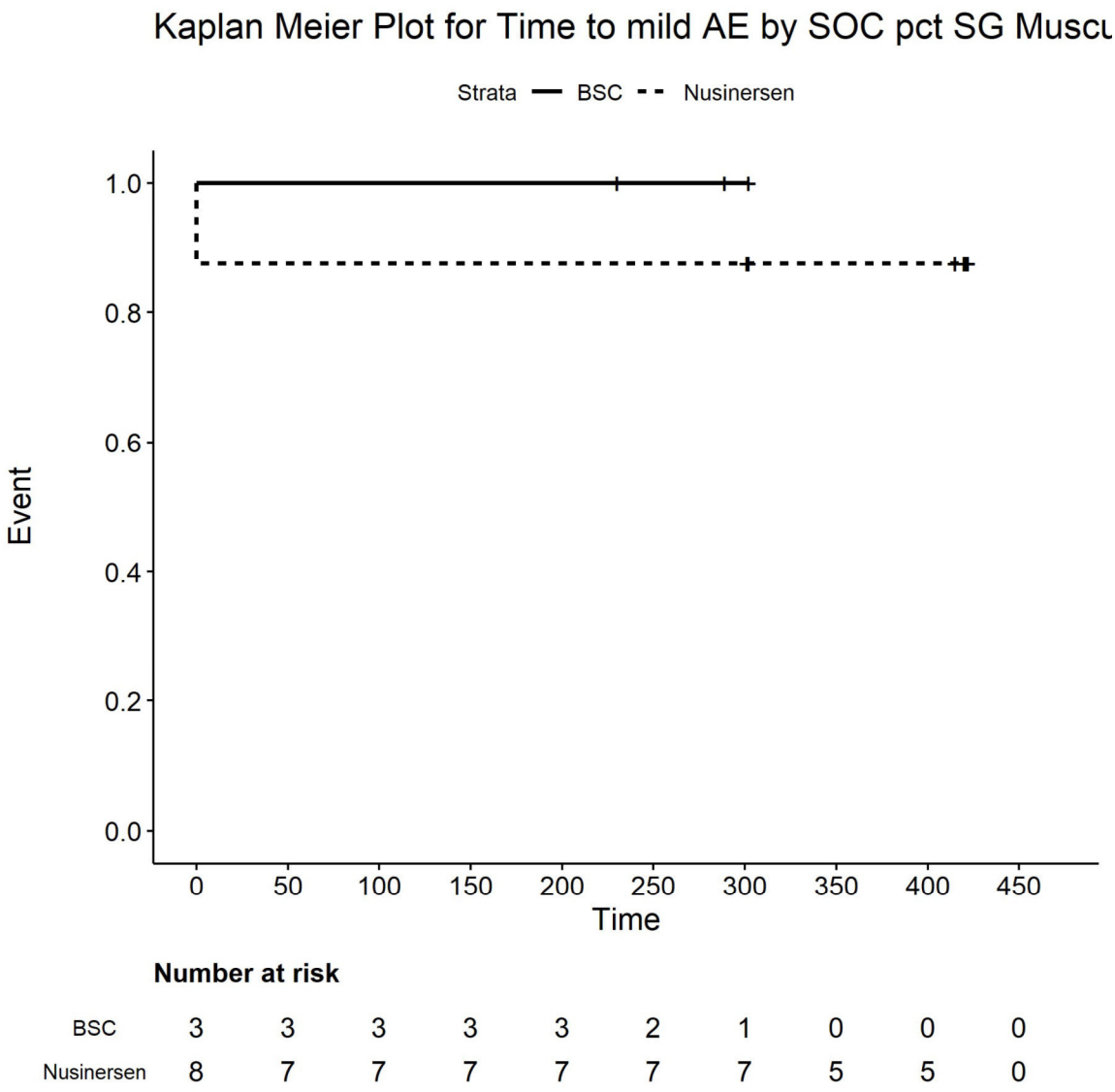
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



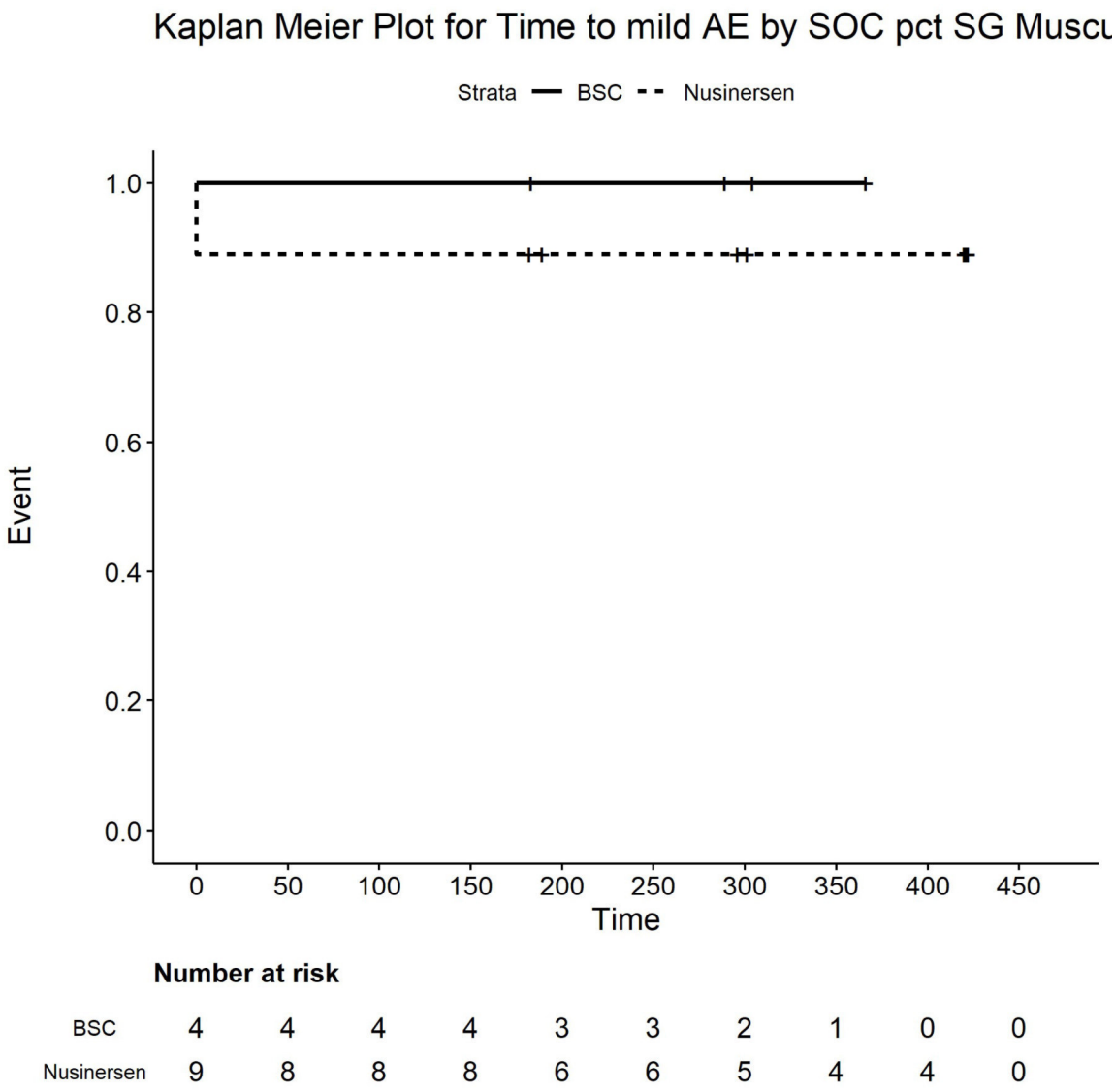
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	2	0



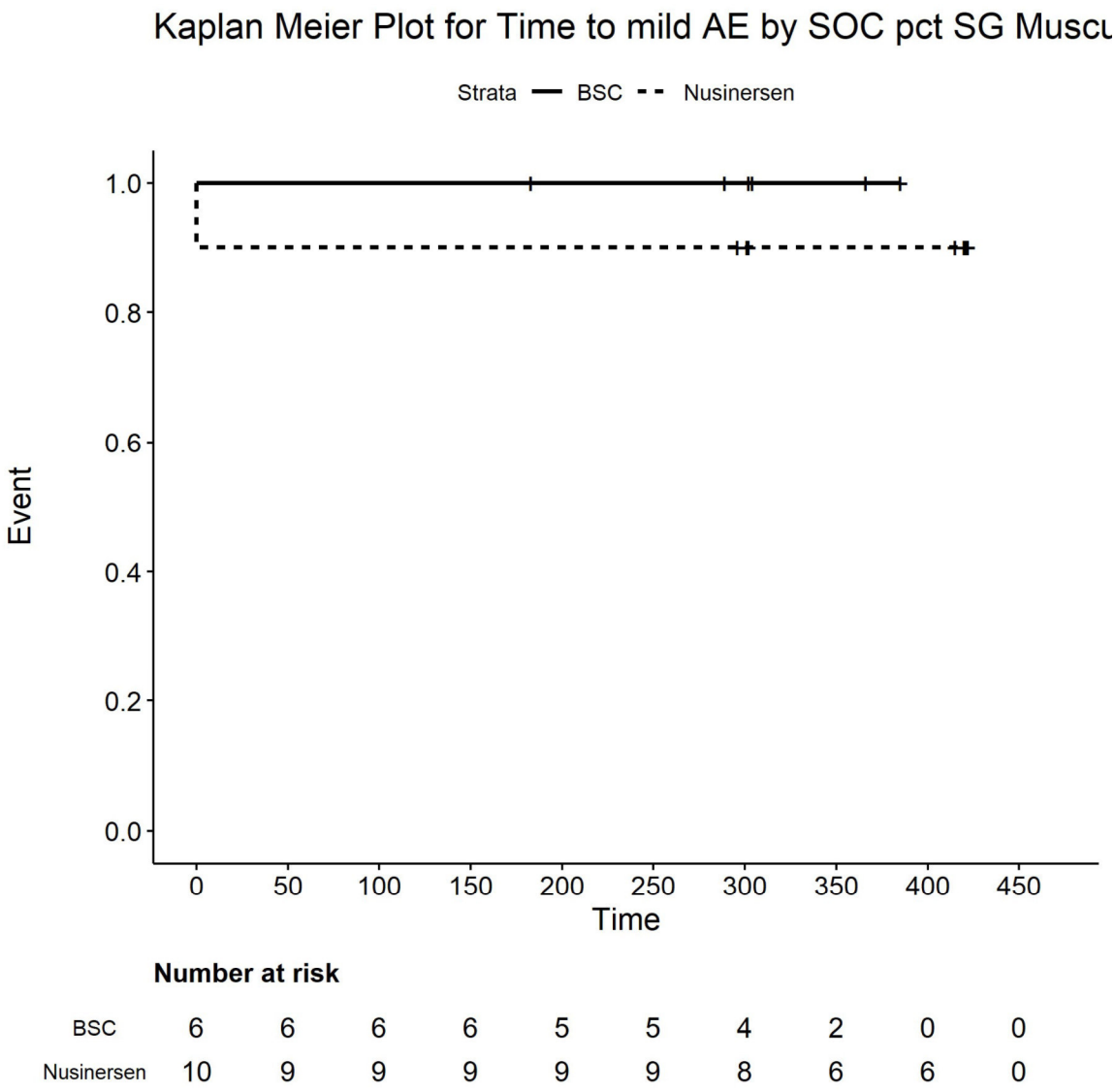
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	5	0



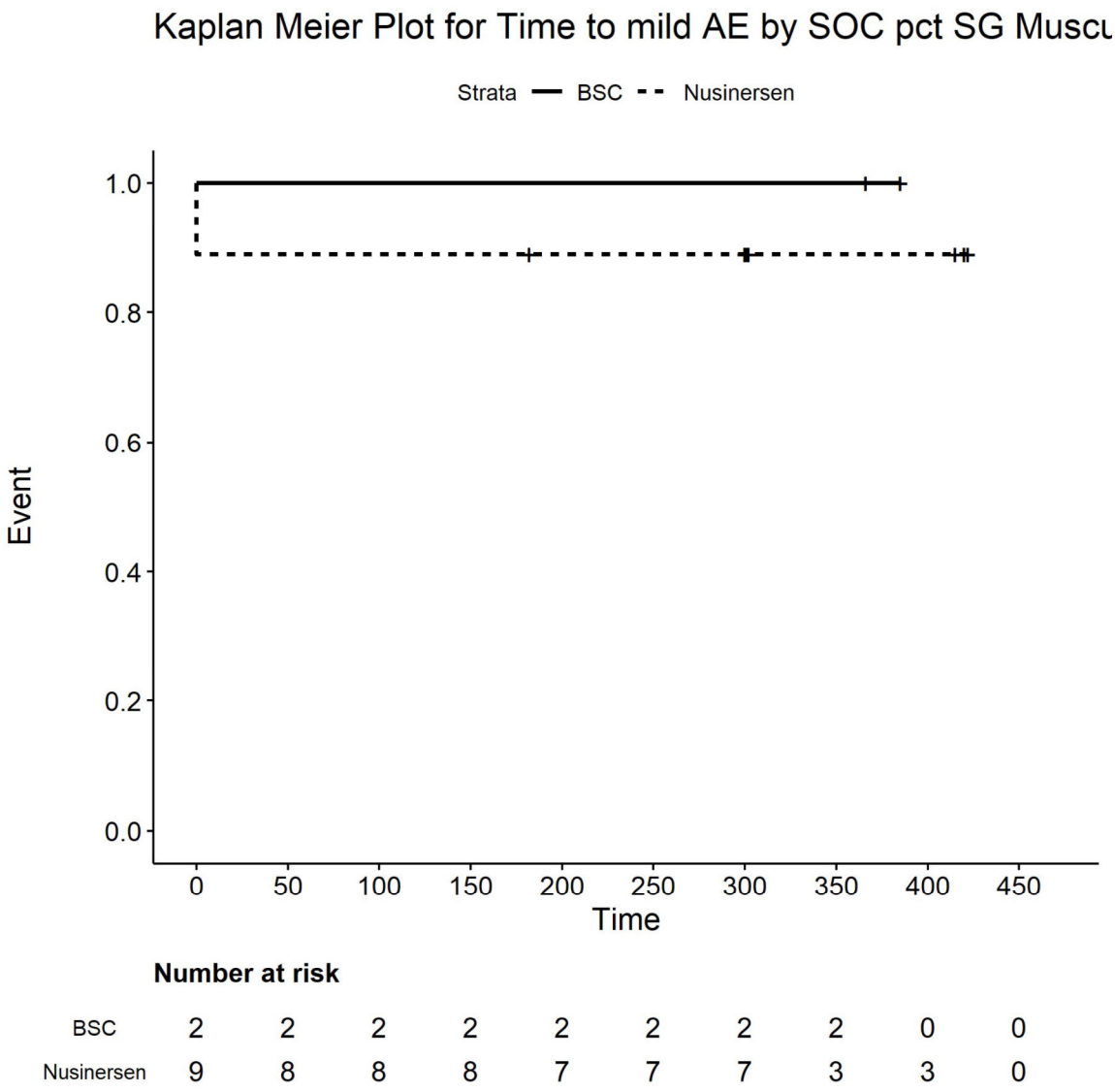
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	4	0



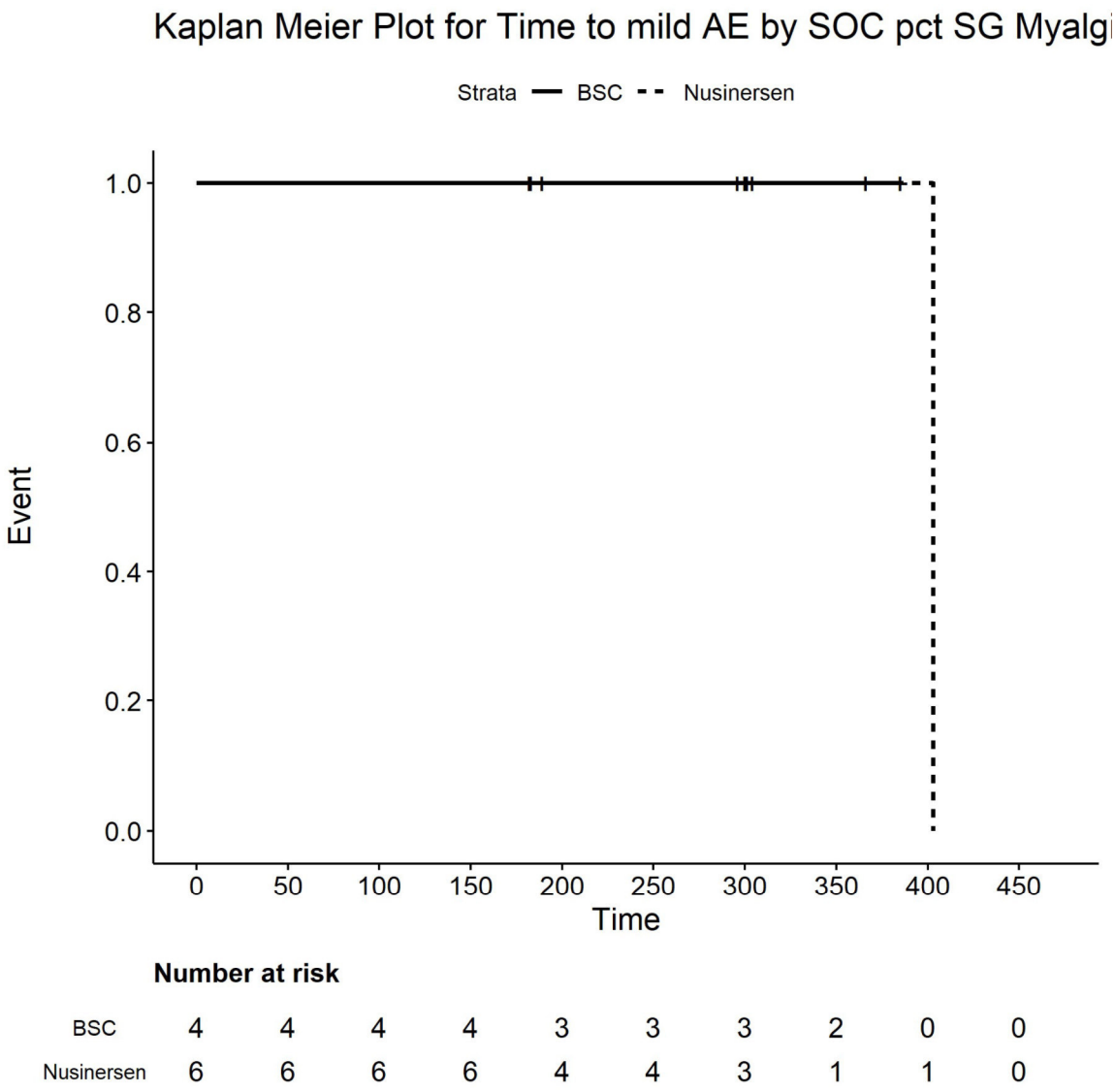
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	6	0



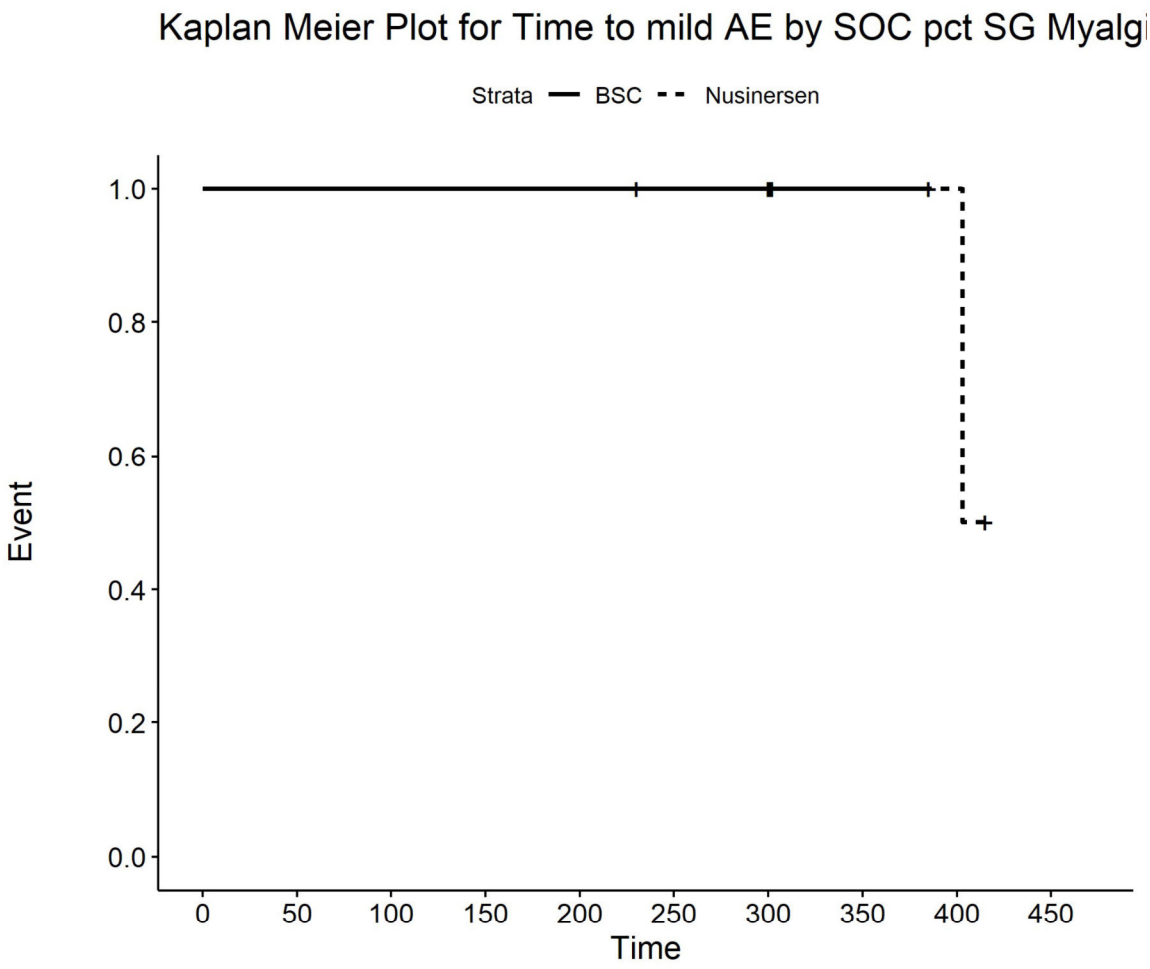
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	3	0



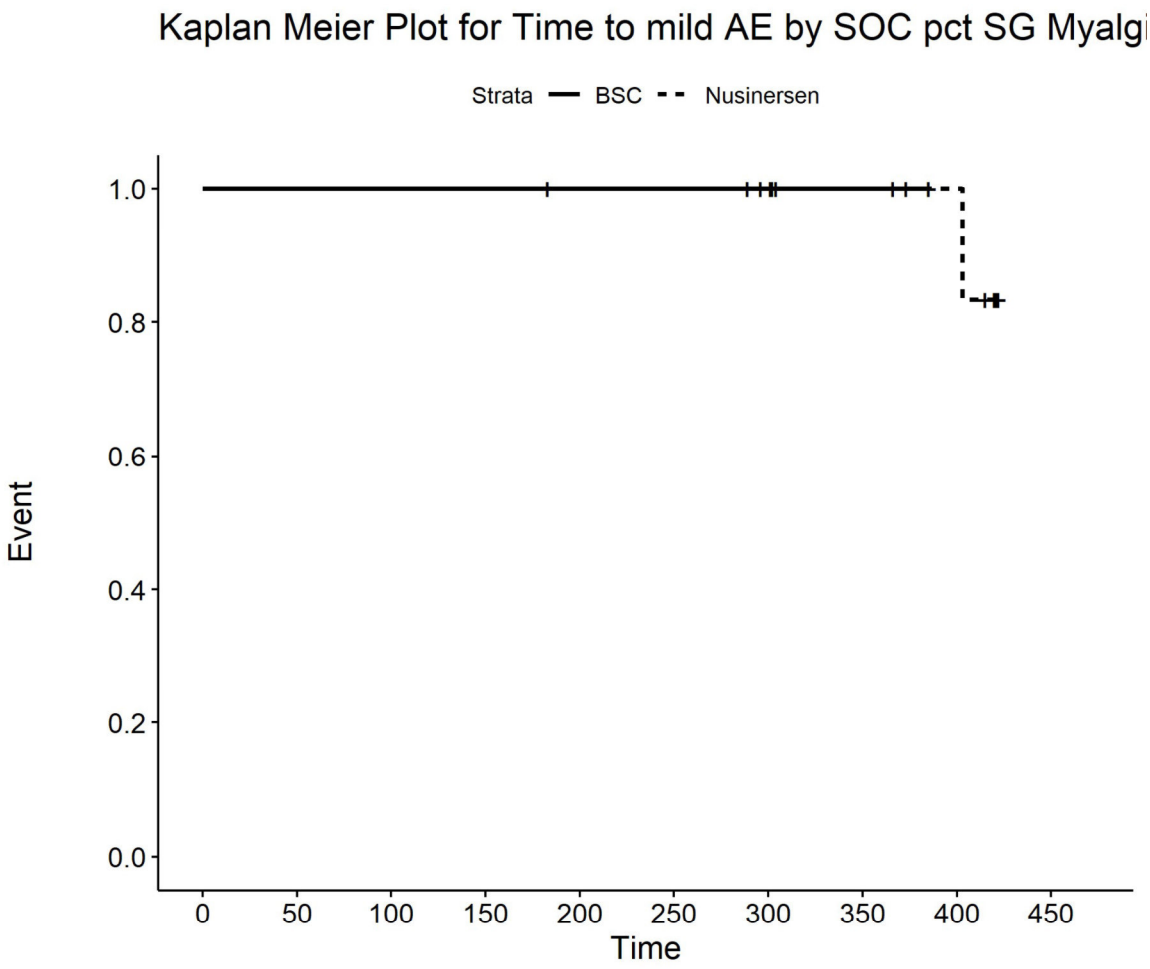
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



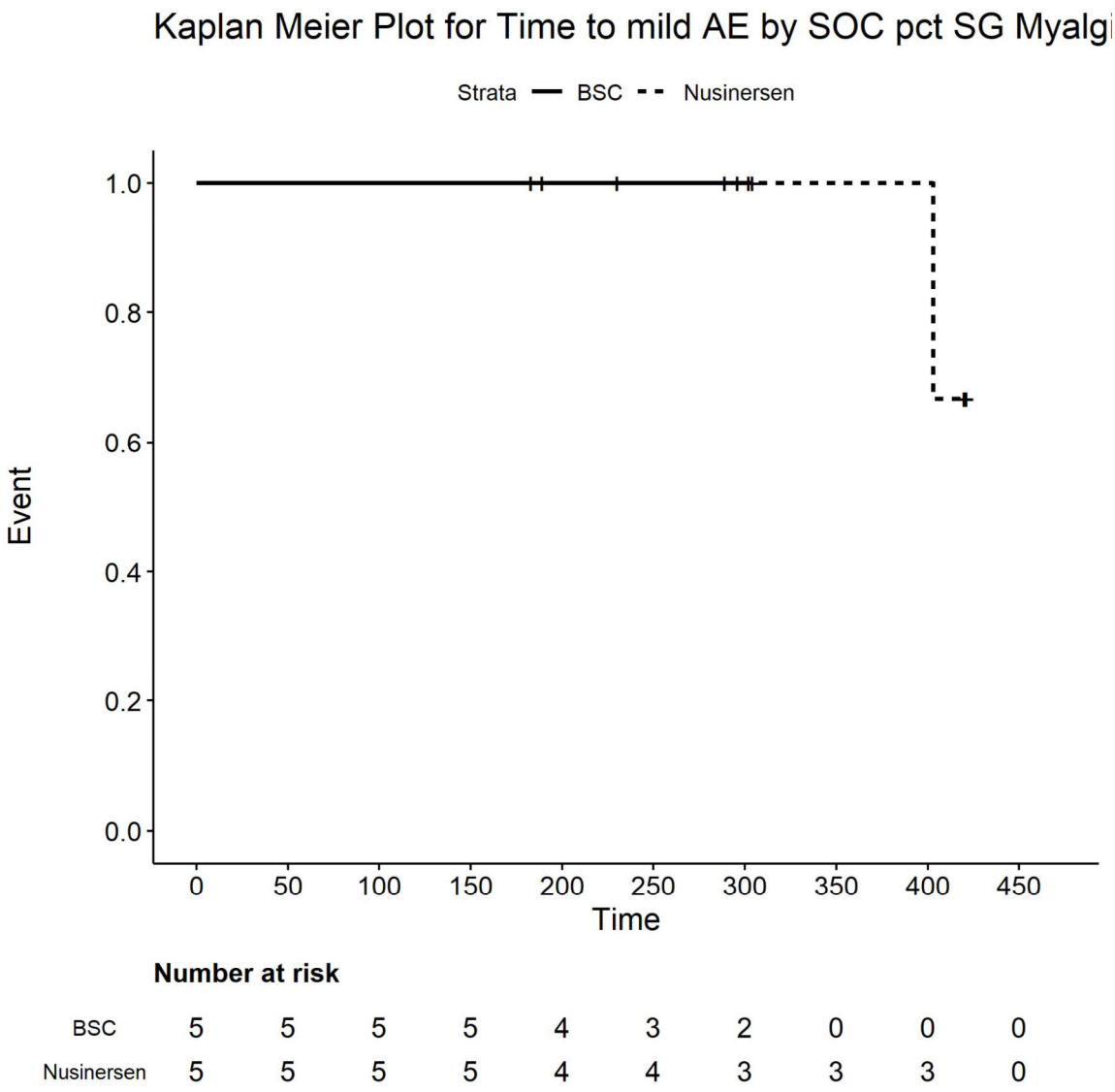
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



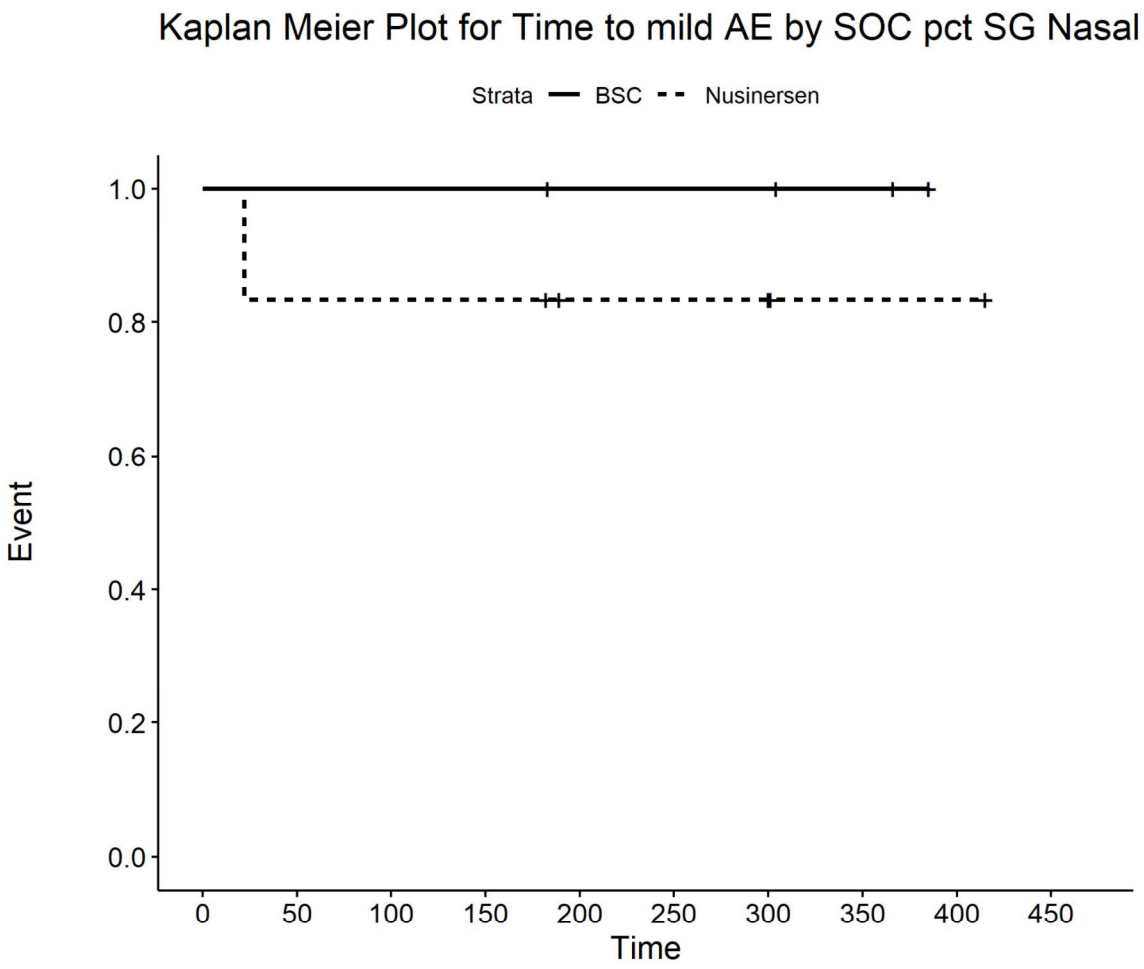
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



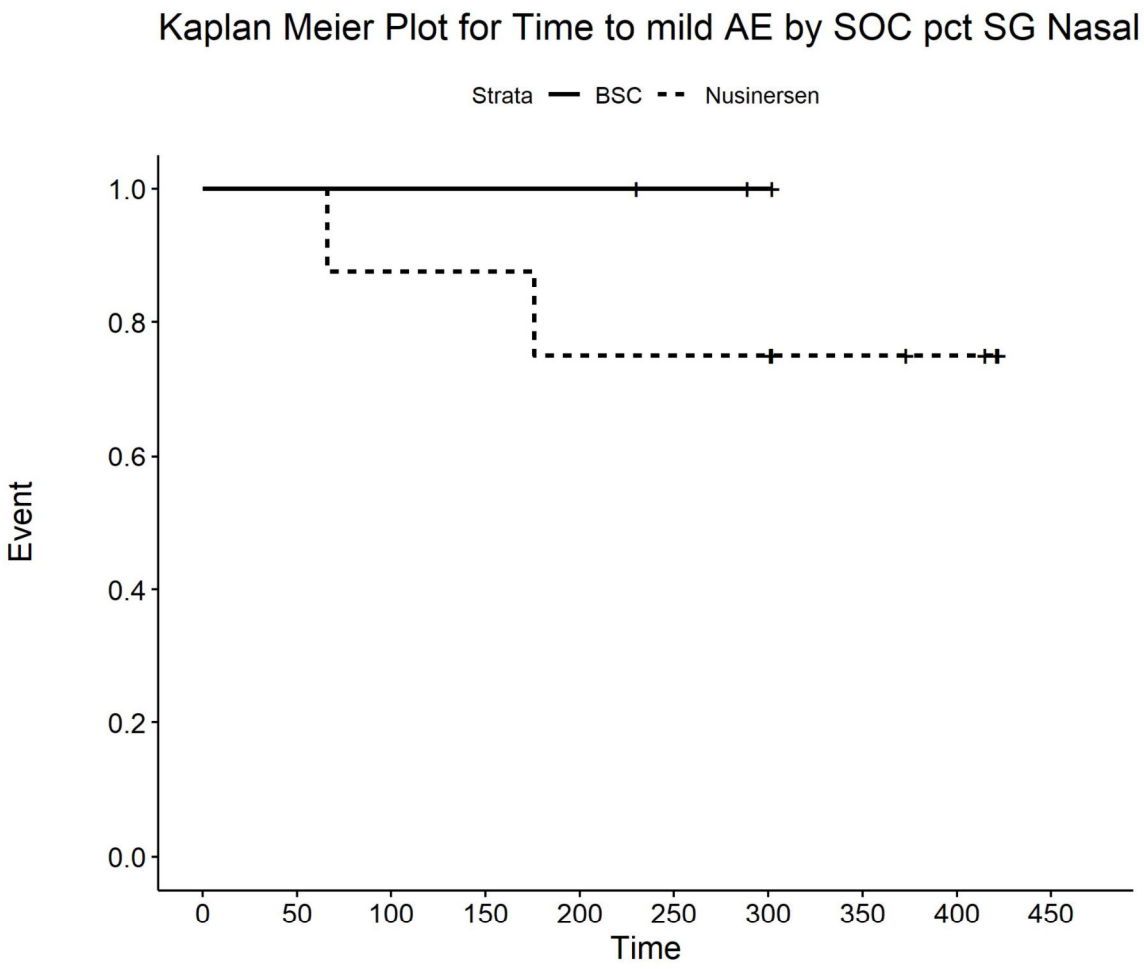
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



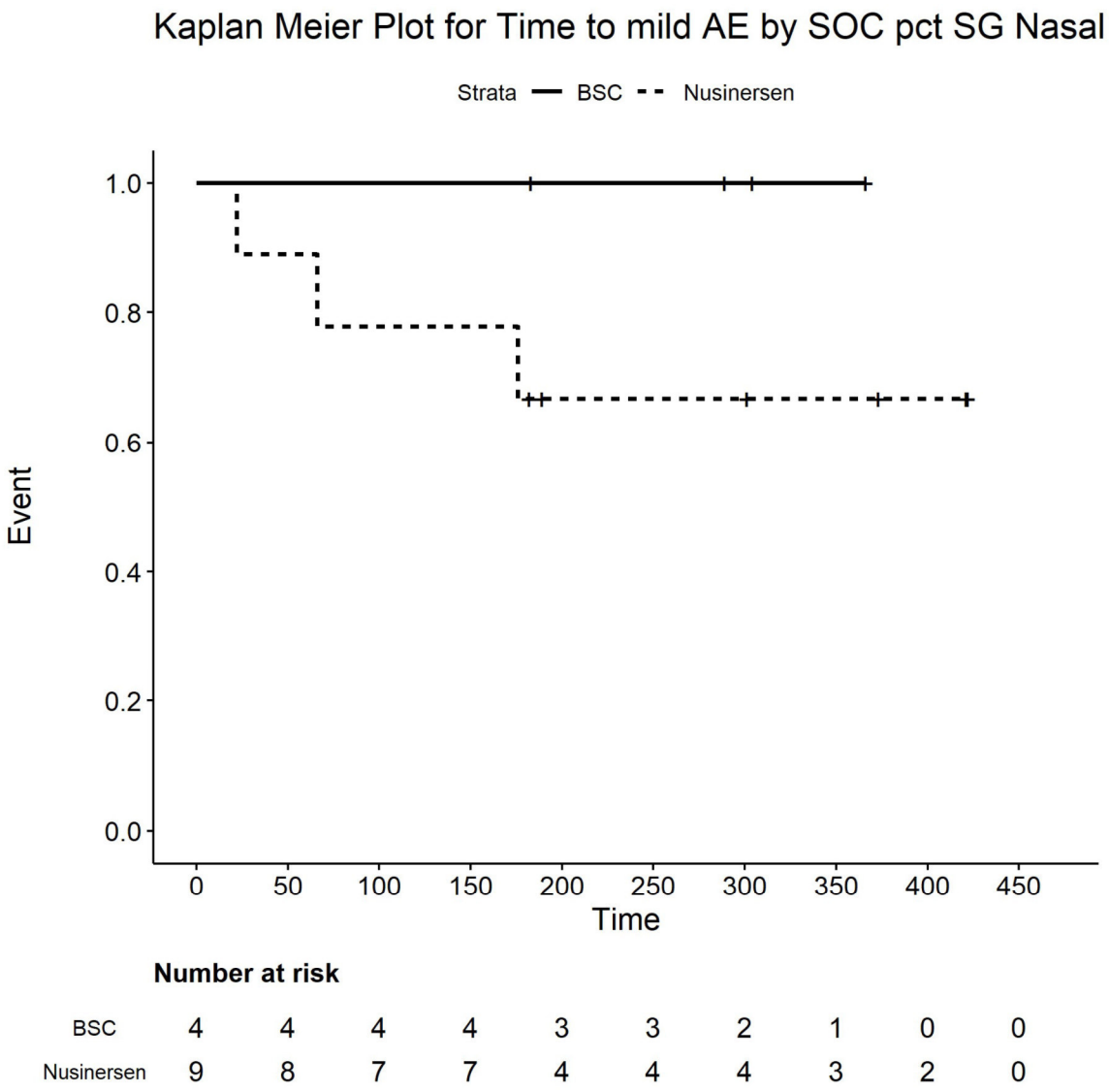
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	3	1	1	0



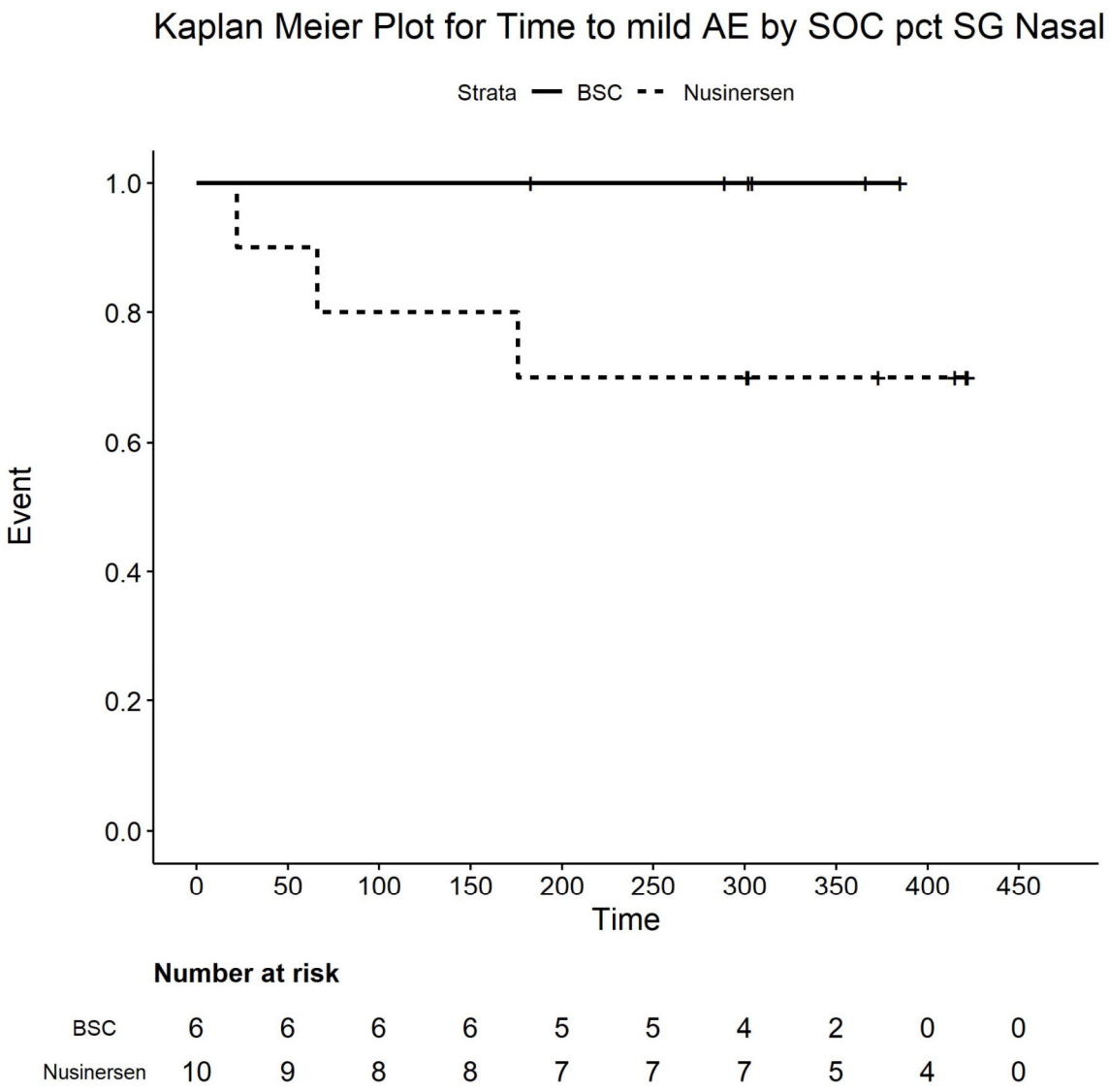
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	6	6	6	4	3	0



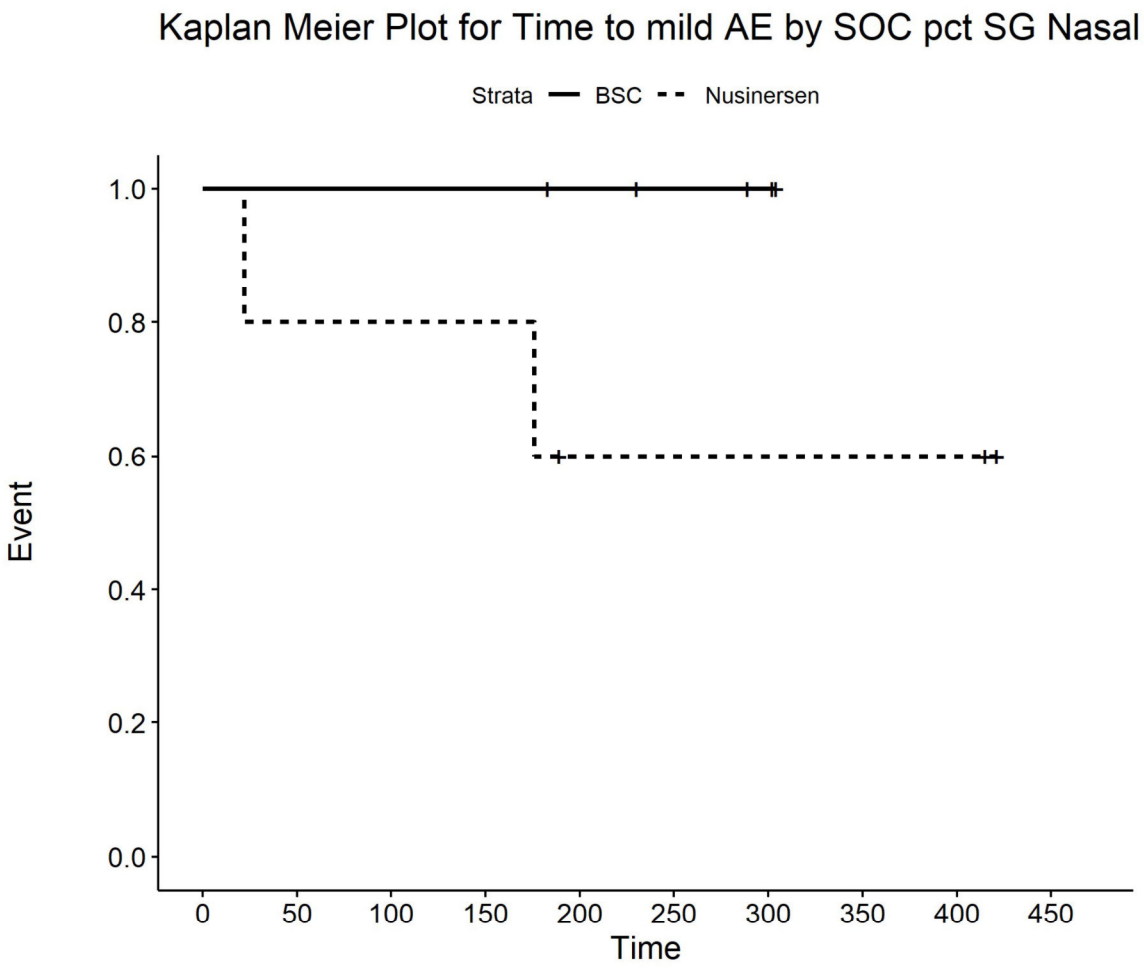
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	7	7	4	4	4	3	2	0



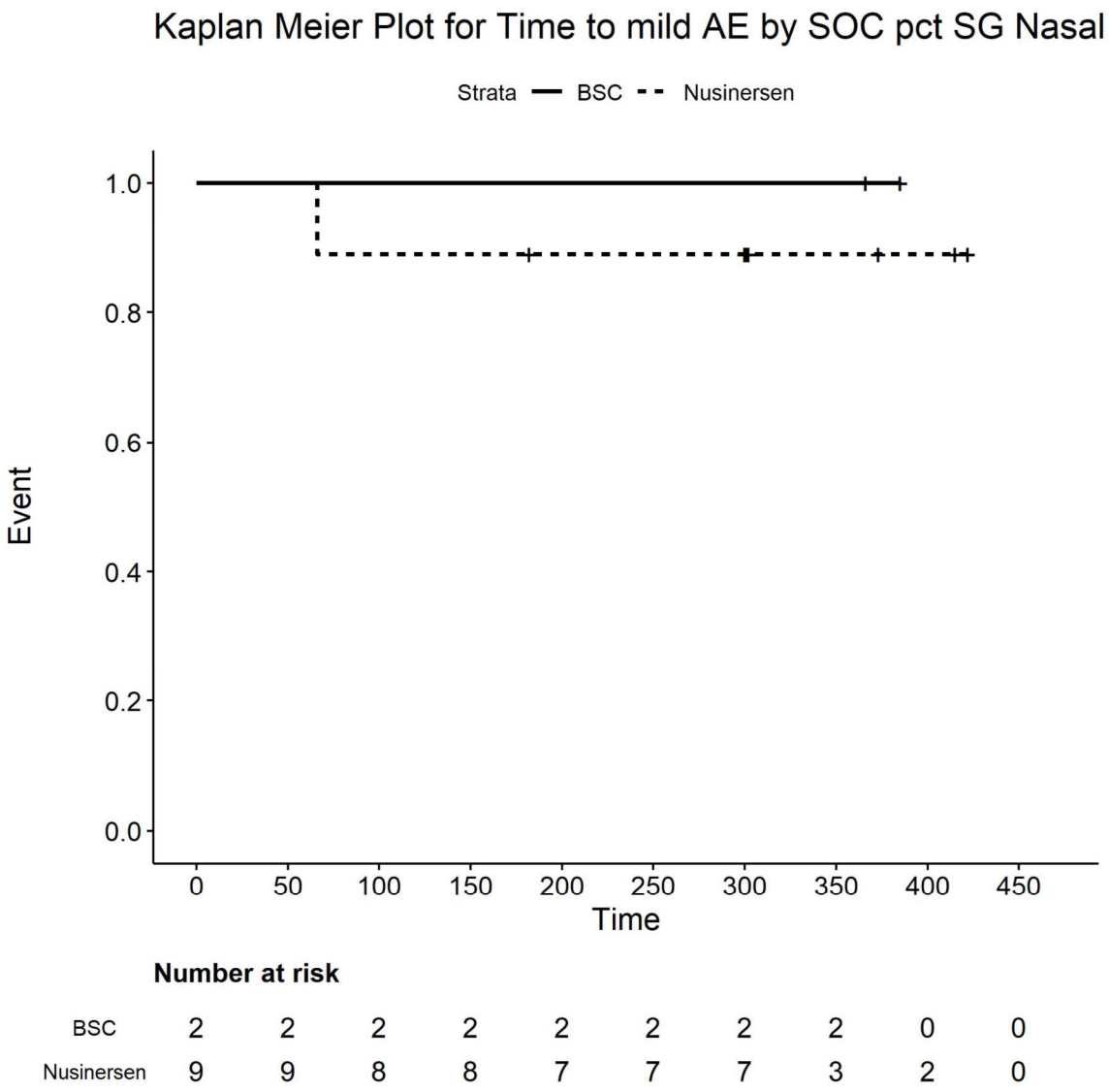
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	8	8	7	7	7	5	4	0



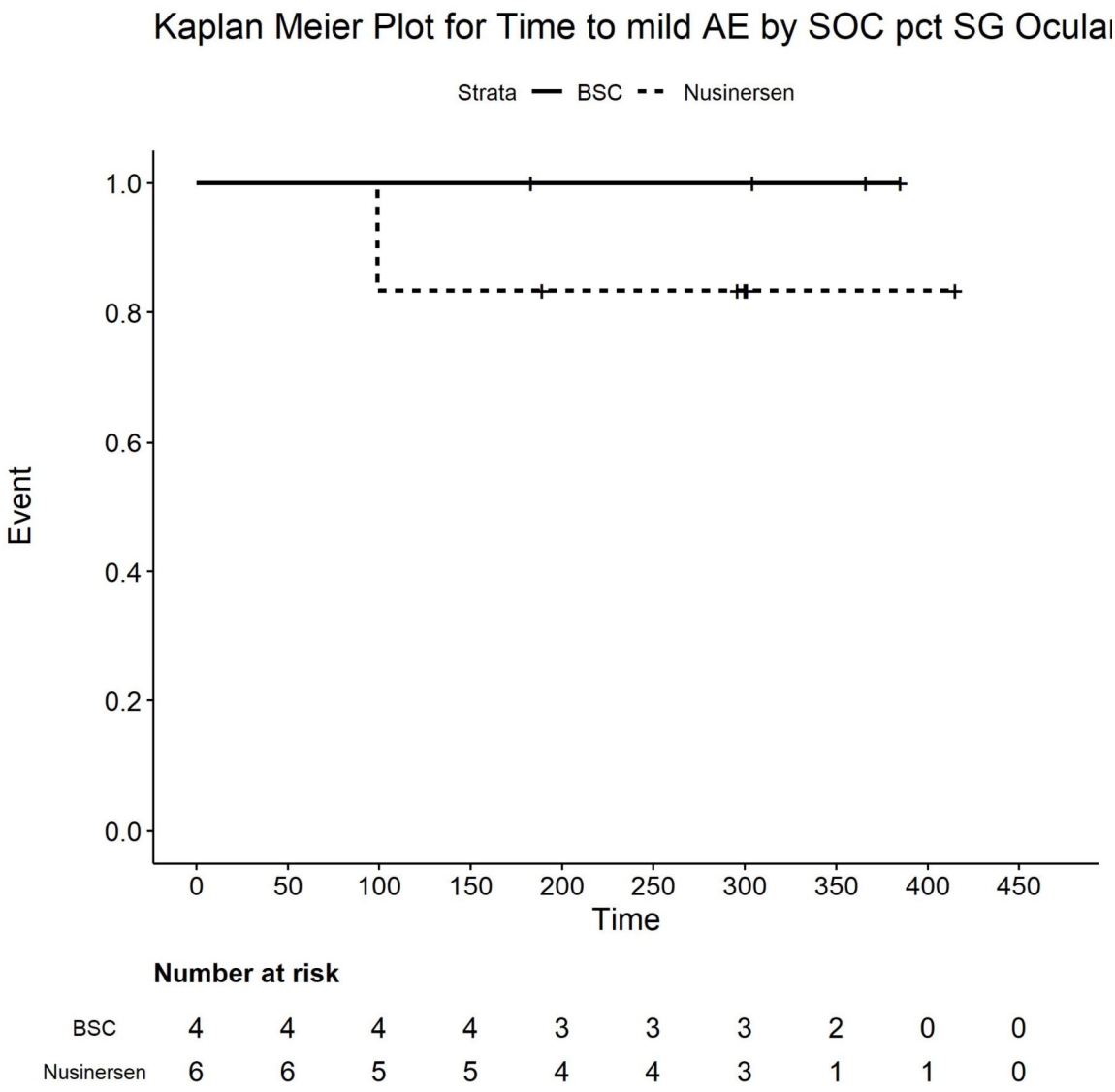
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	4	4	4	2	2	2	2	2	0



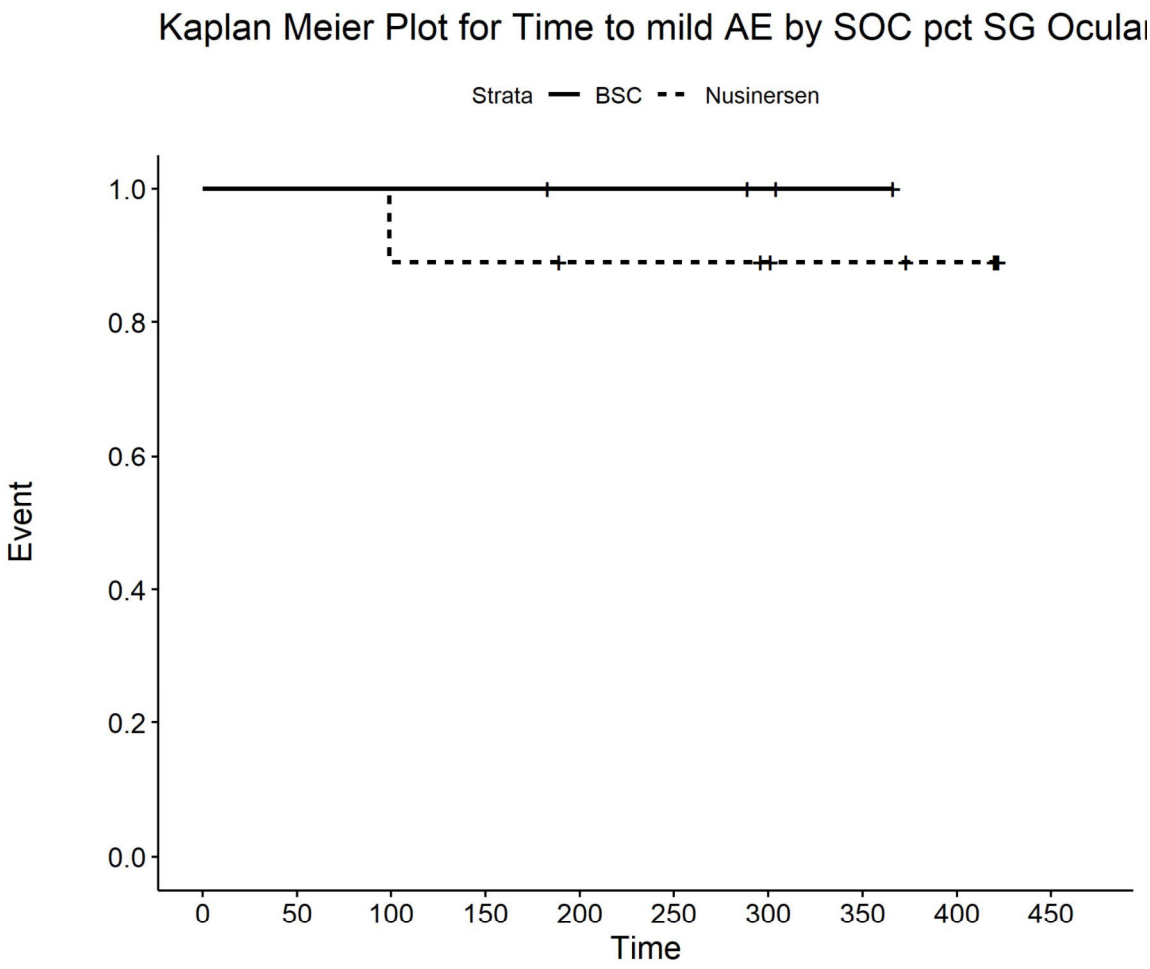
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	2	0



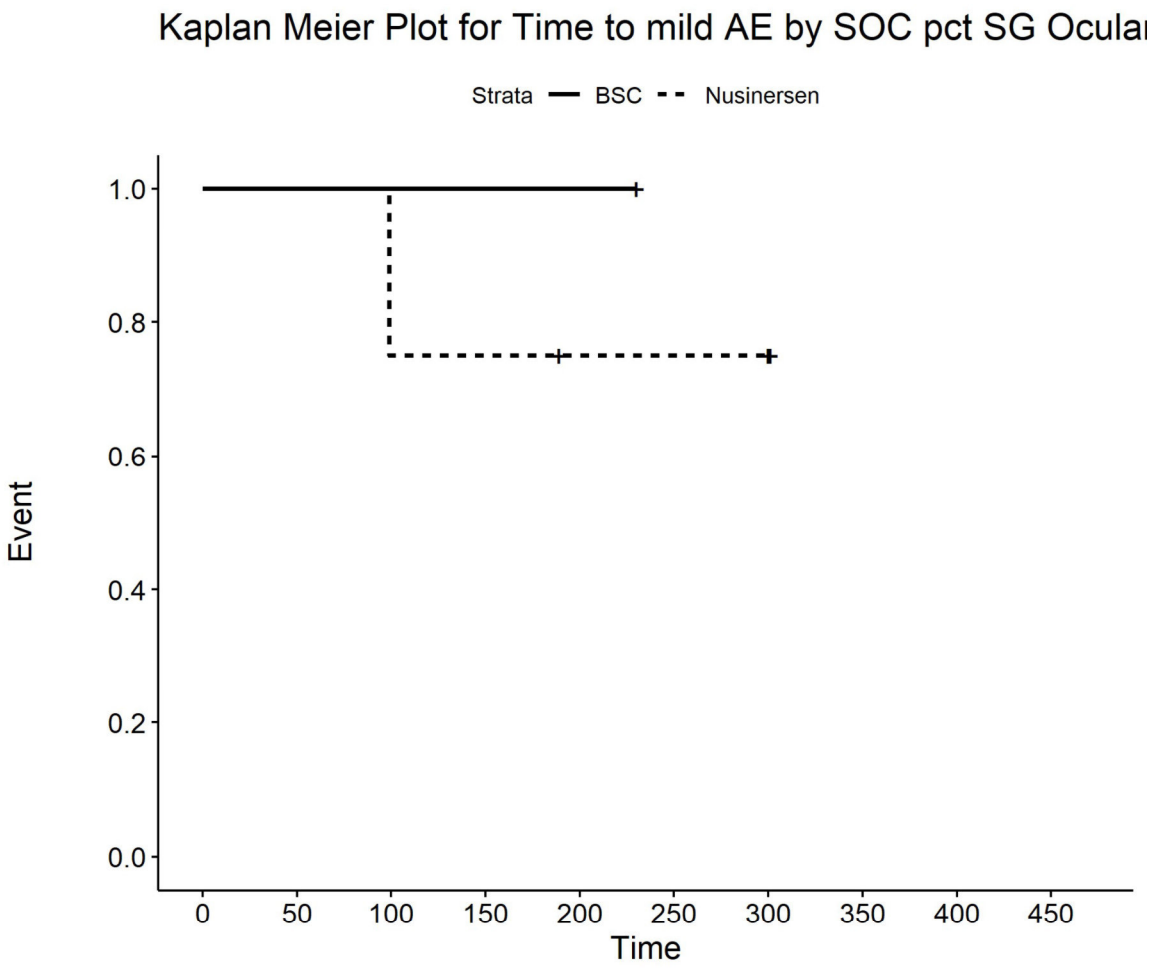
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	4	4	3	1	1	0



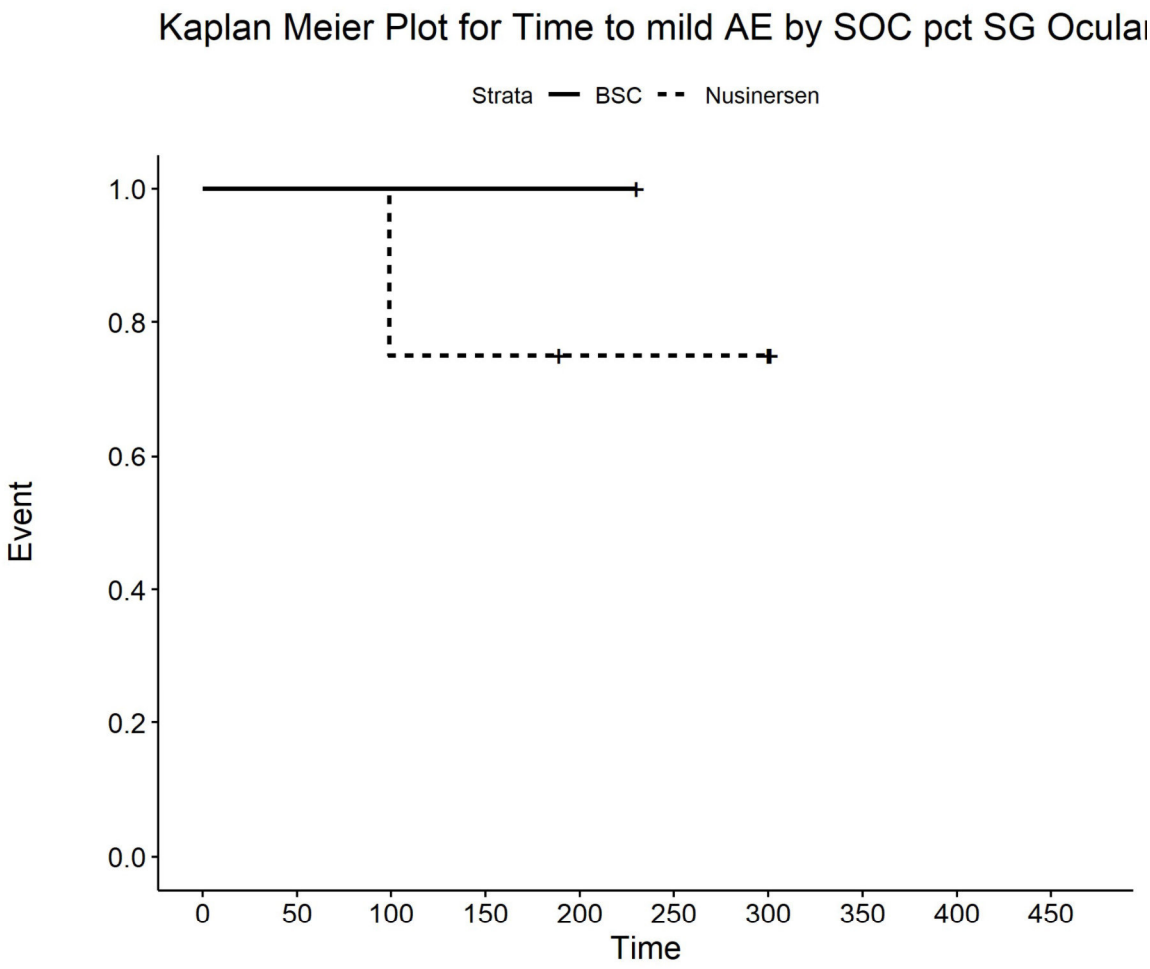
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	7	7	6	5	4	0



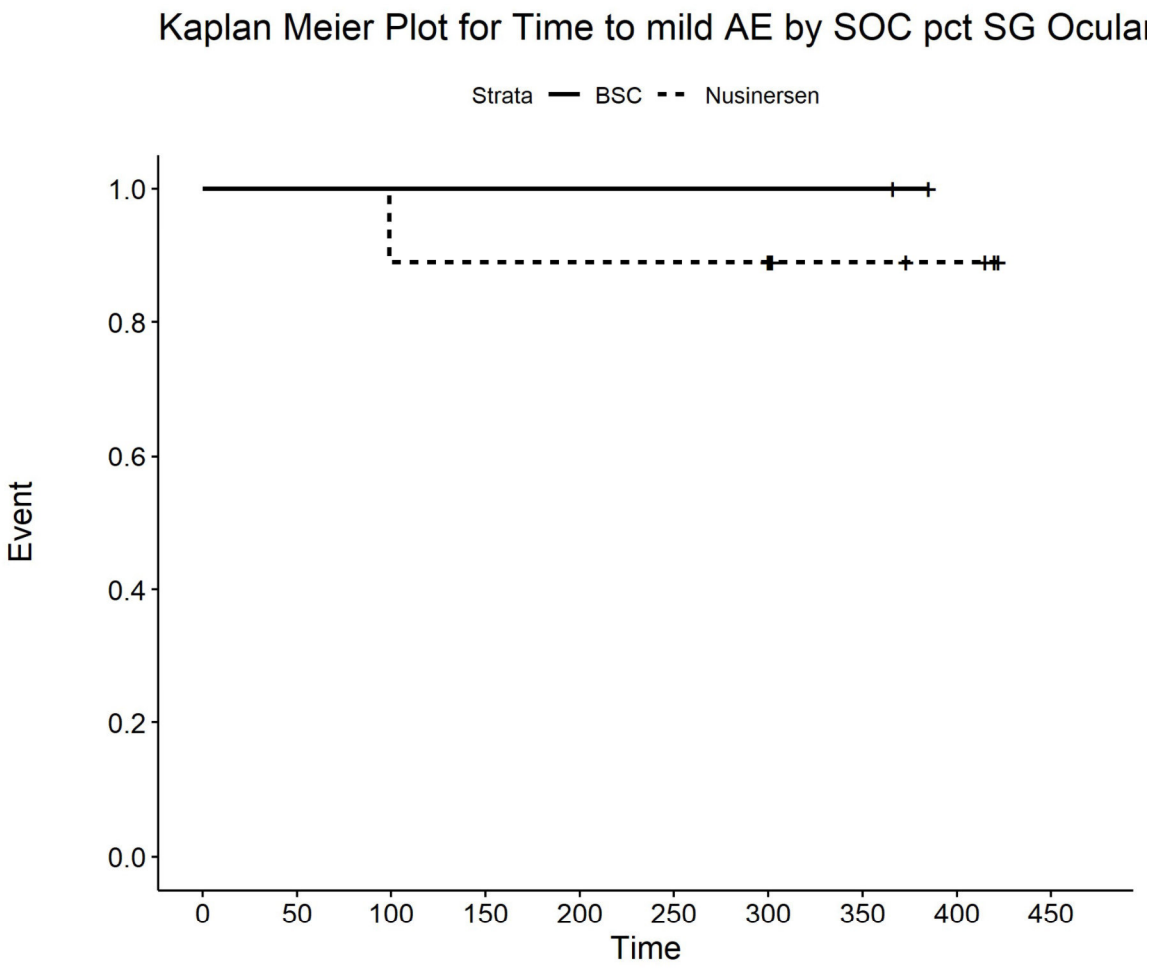
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	2	2	2	0	0	0



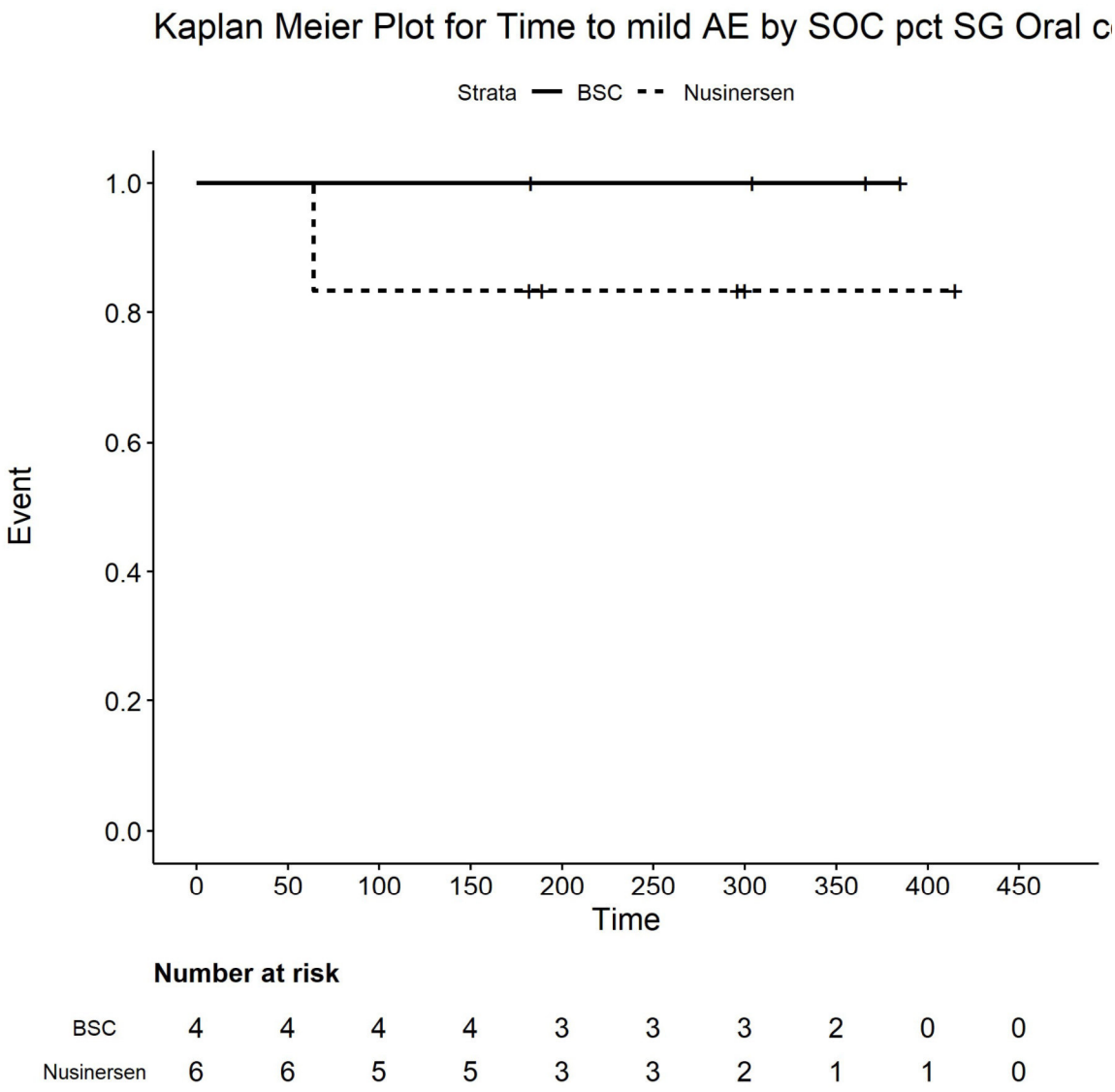
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	2	2	2	0	0	0



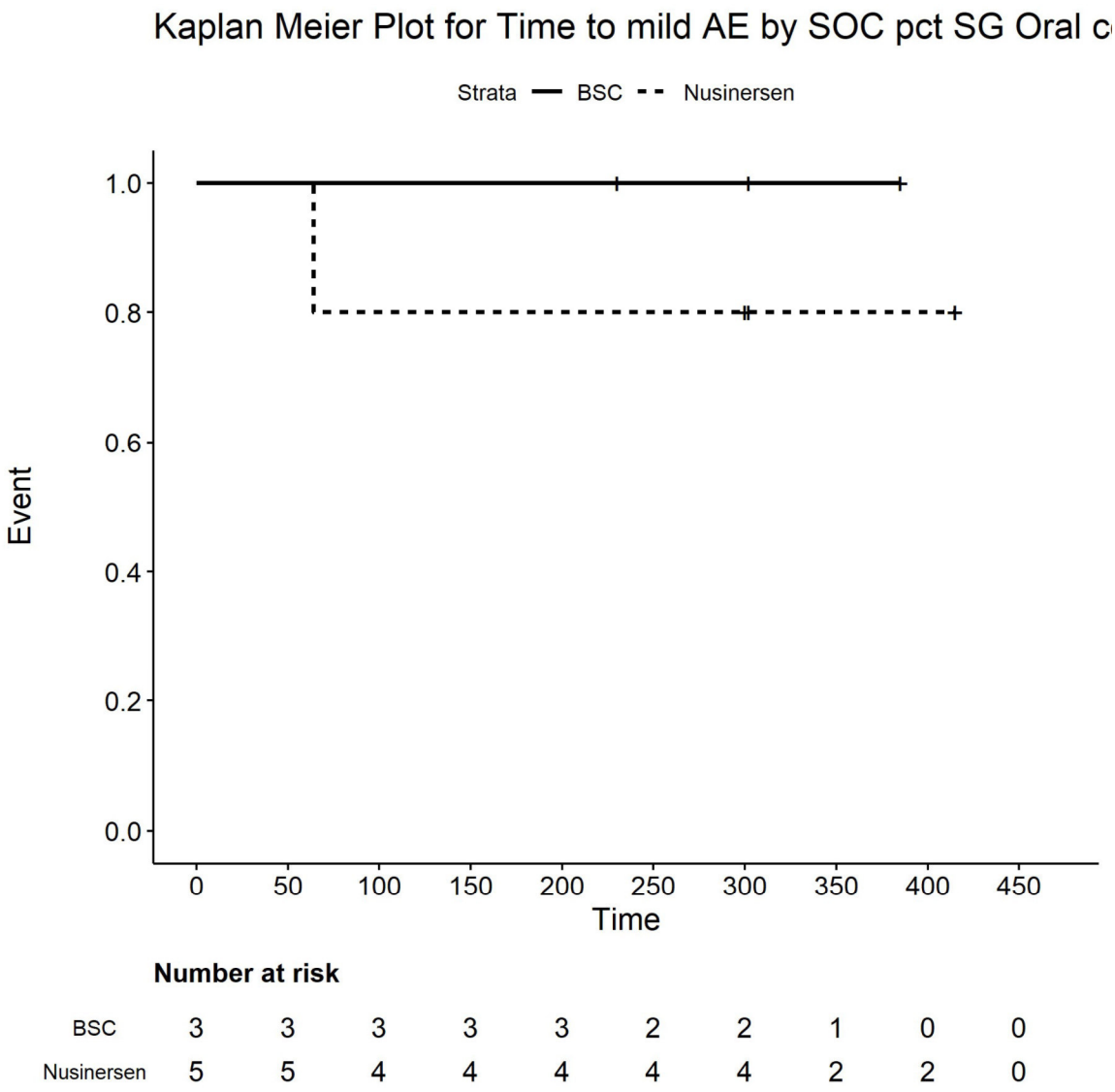
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	8	8	8	4	3	0



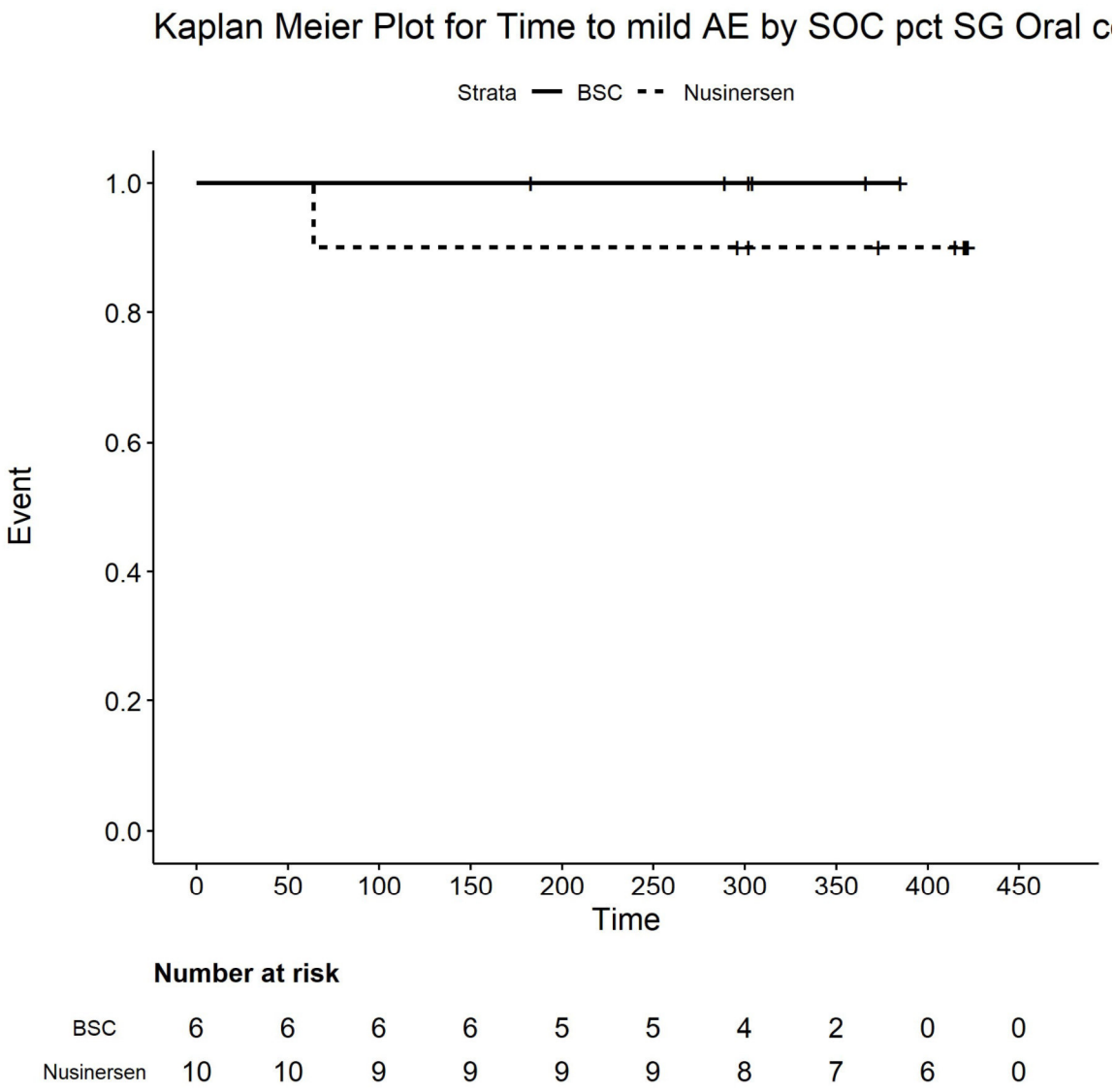
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



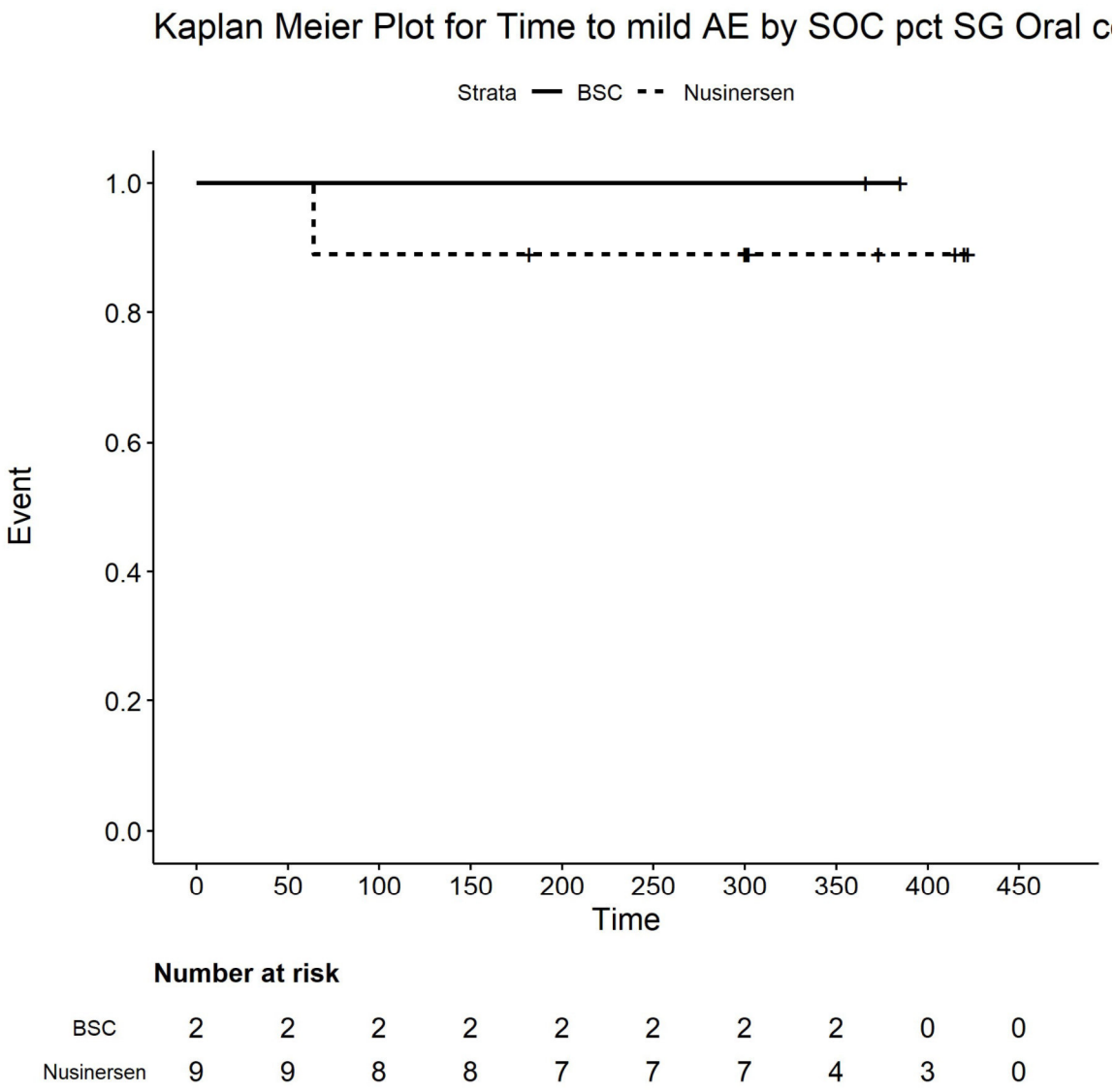
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



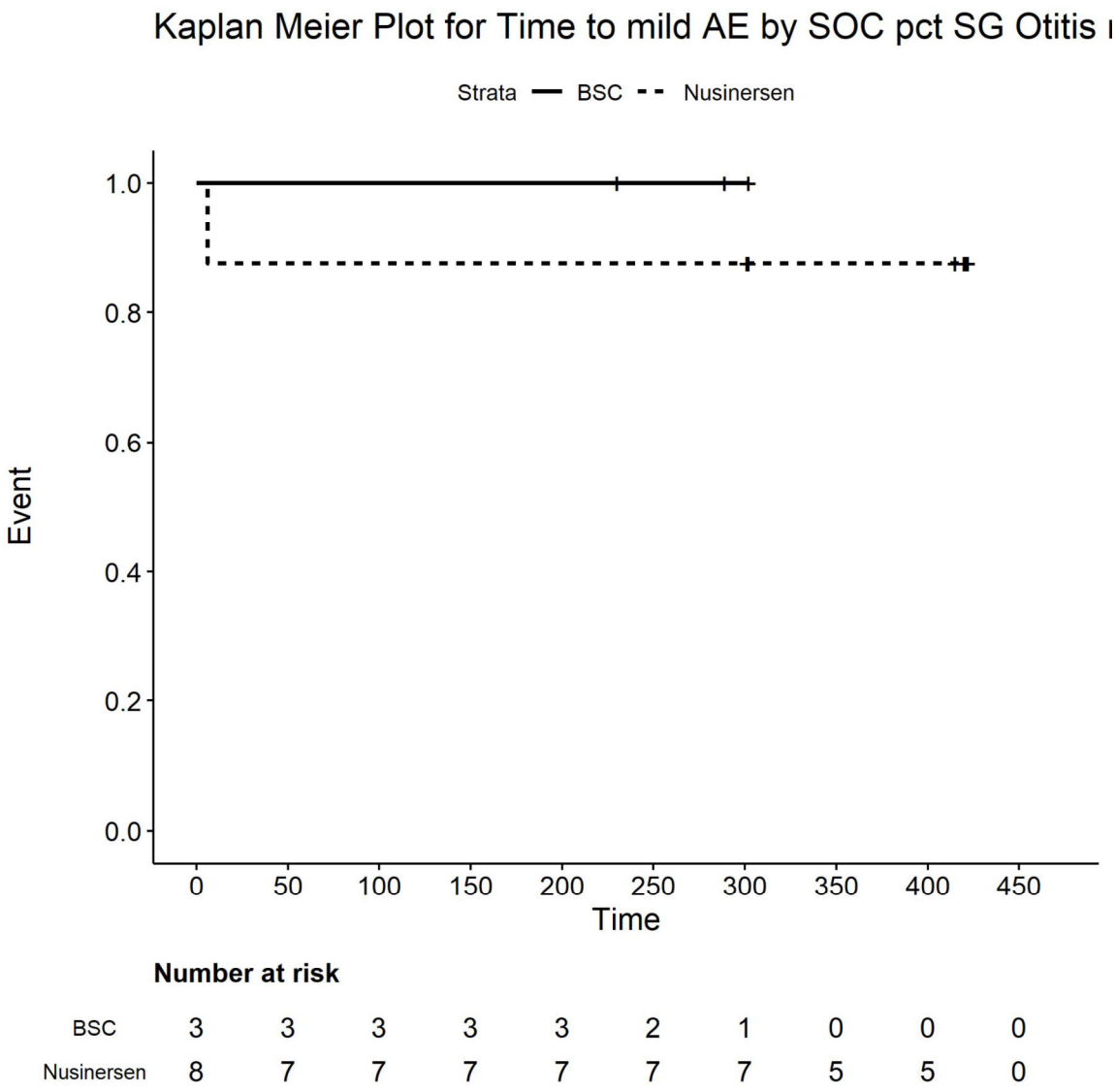
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



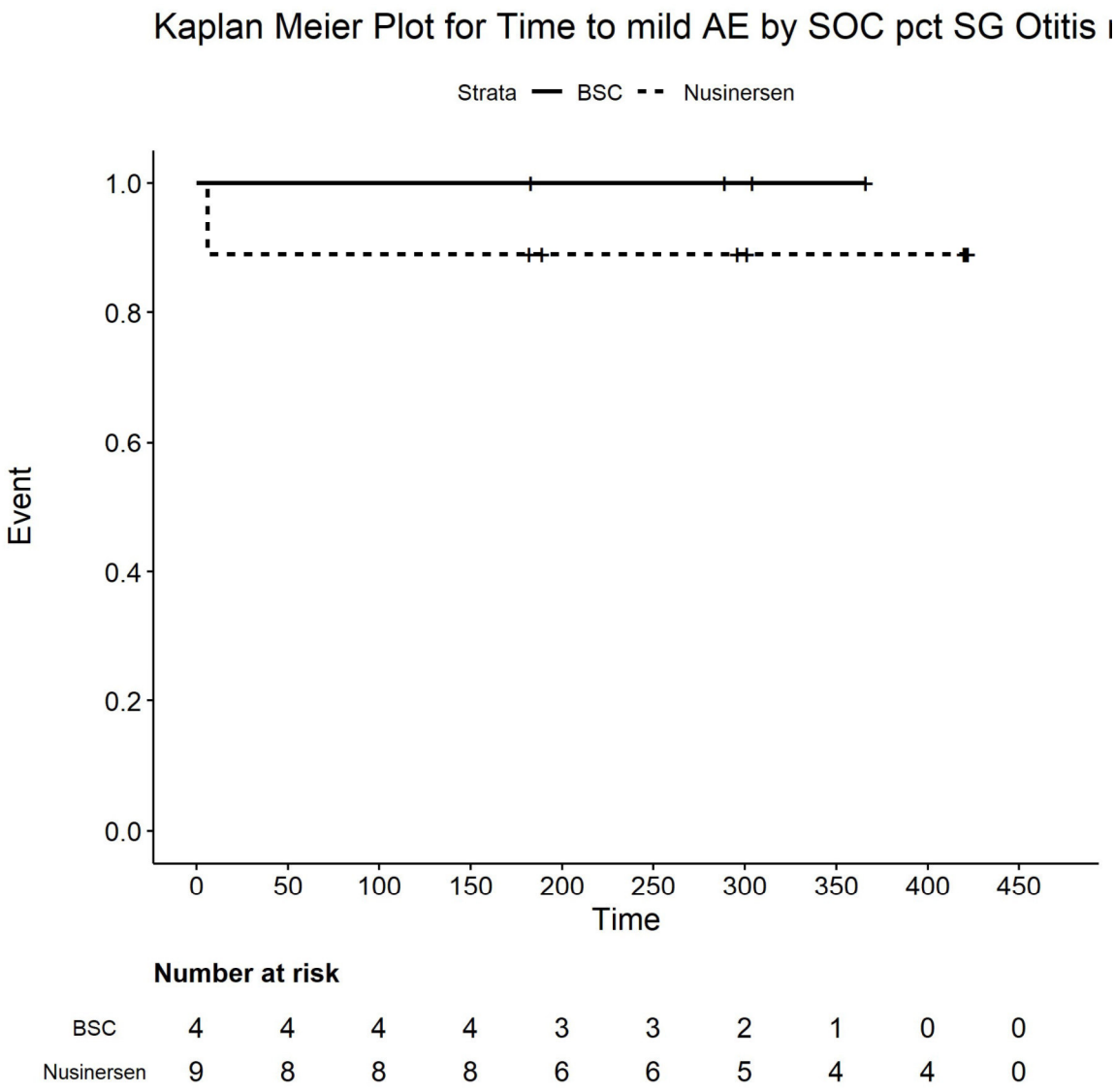
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



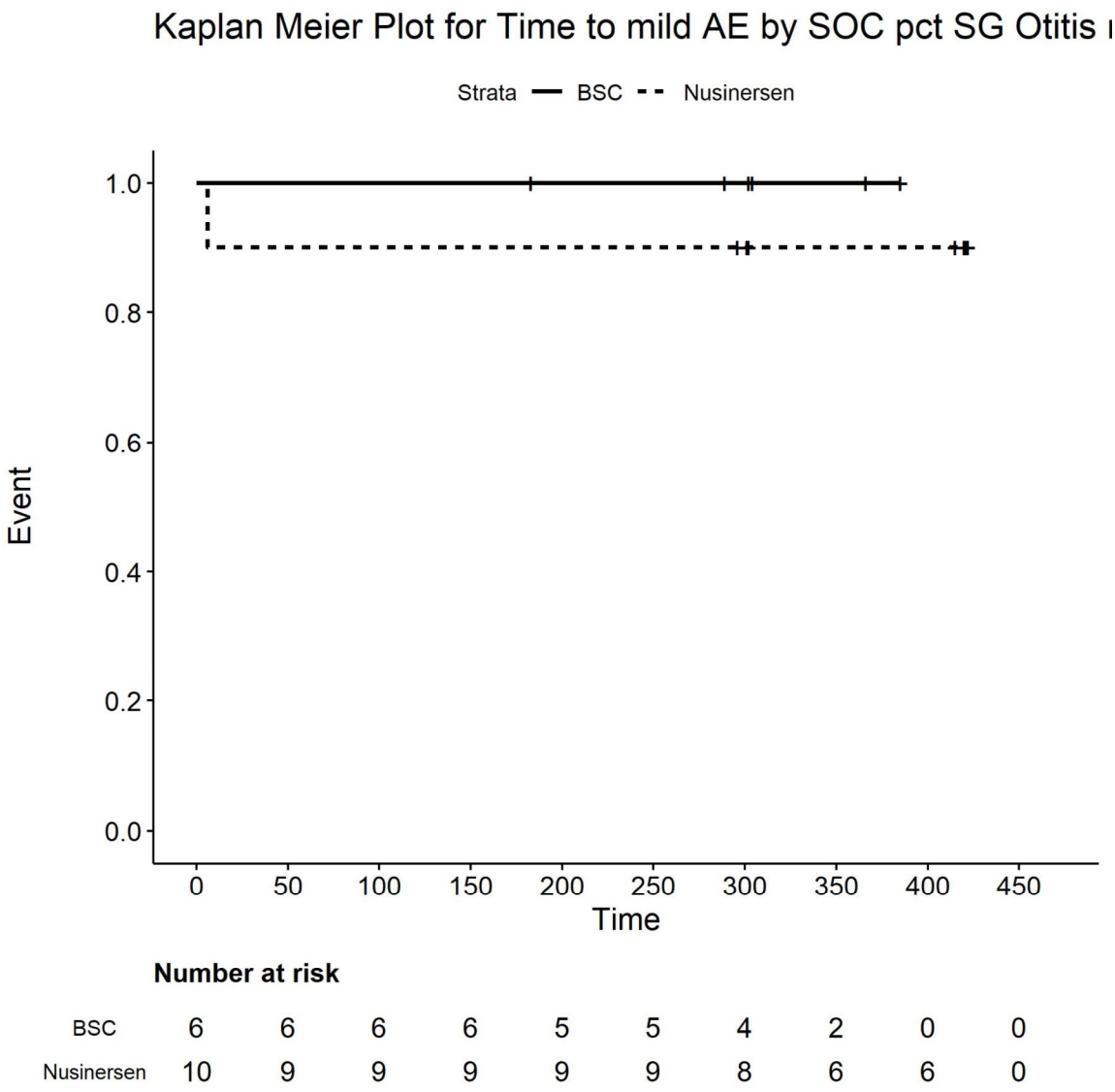
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	5	0



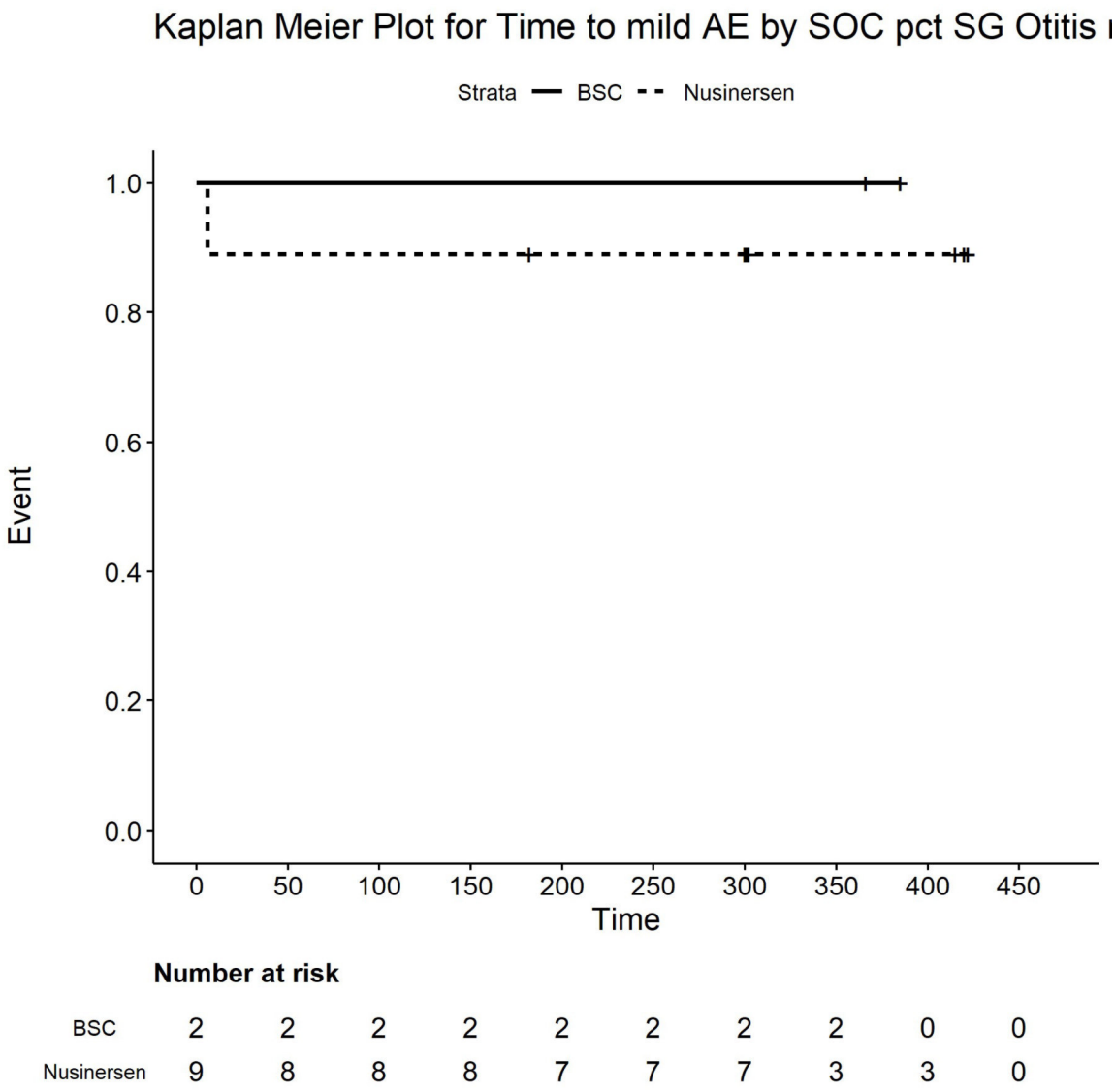
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	4	0



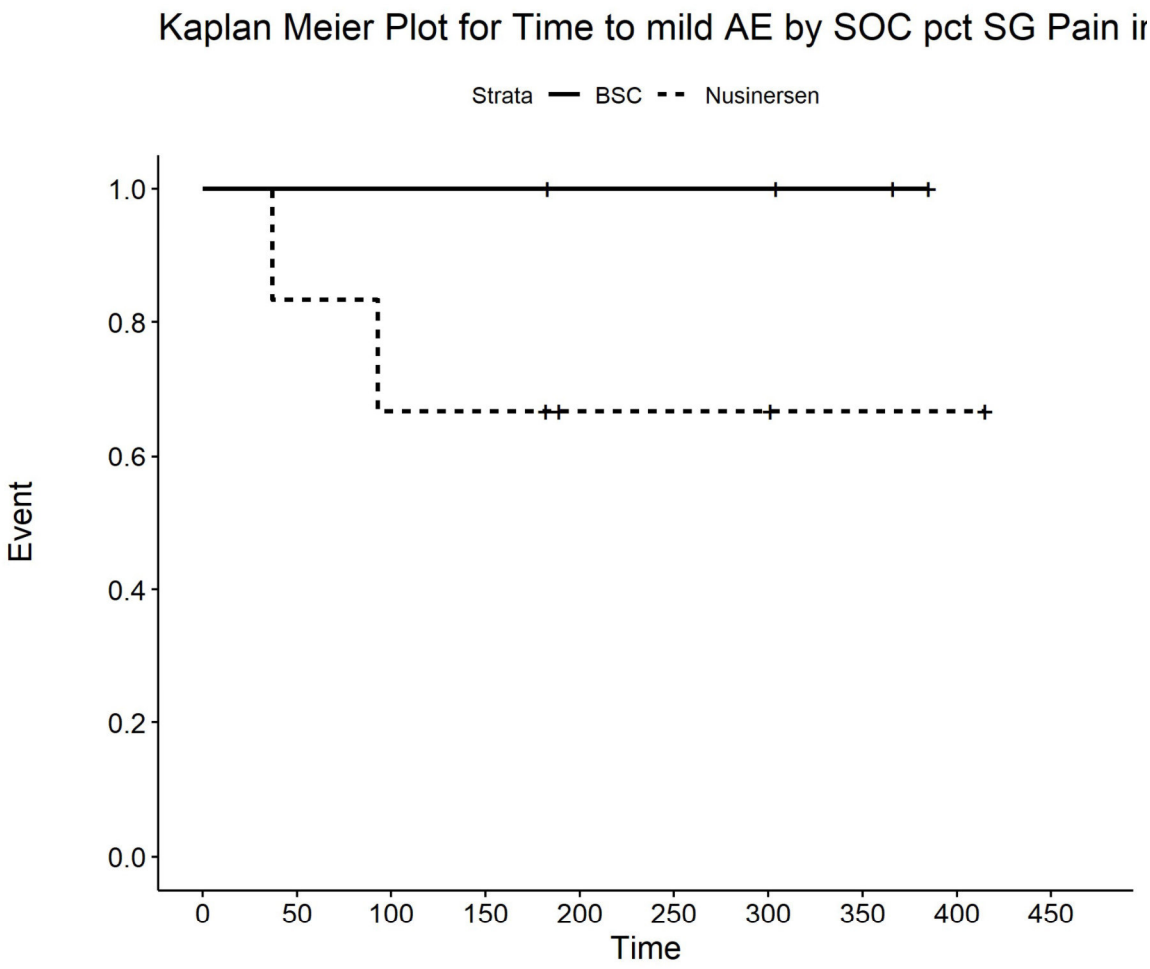
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	6	0



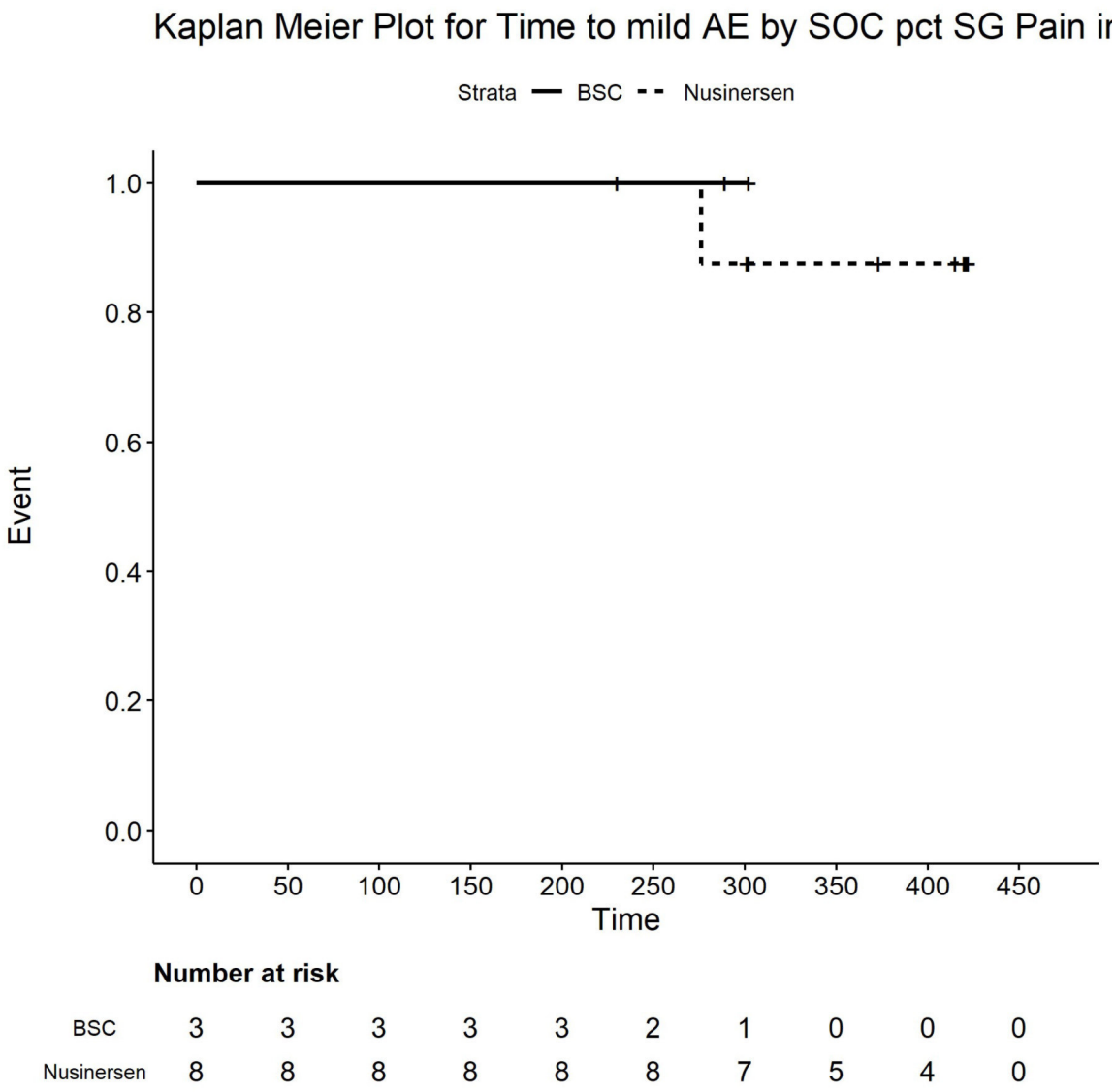
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	3	0



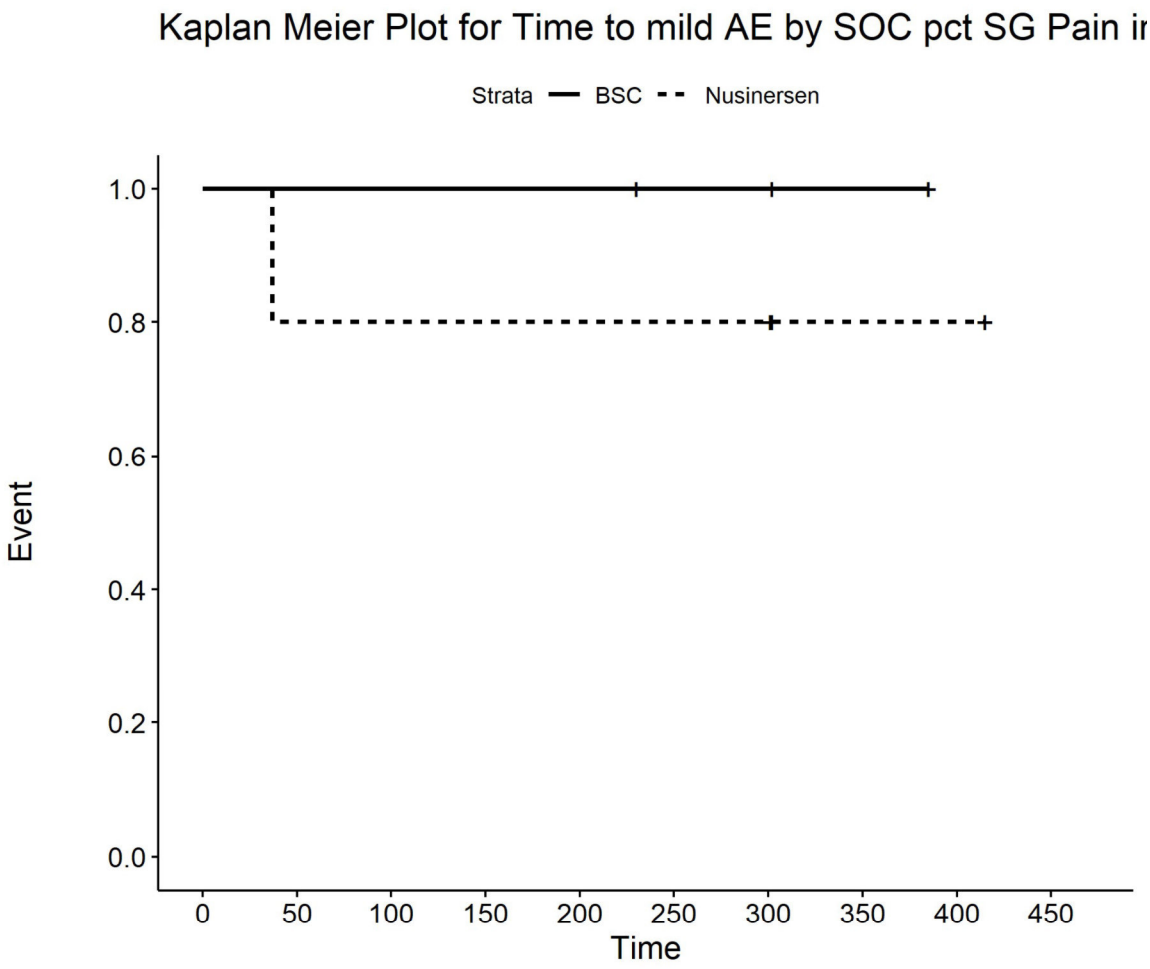
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	4	4	2	2	2	1	1	0



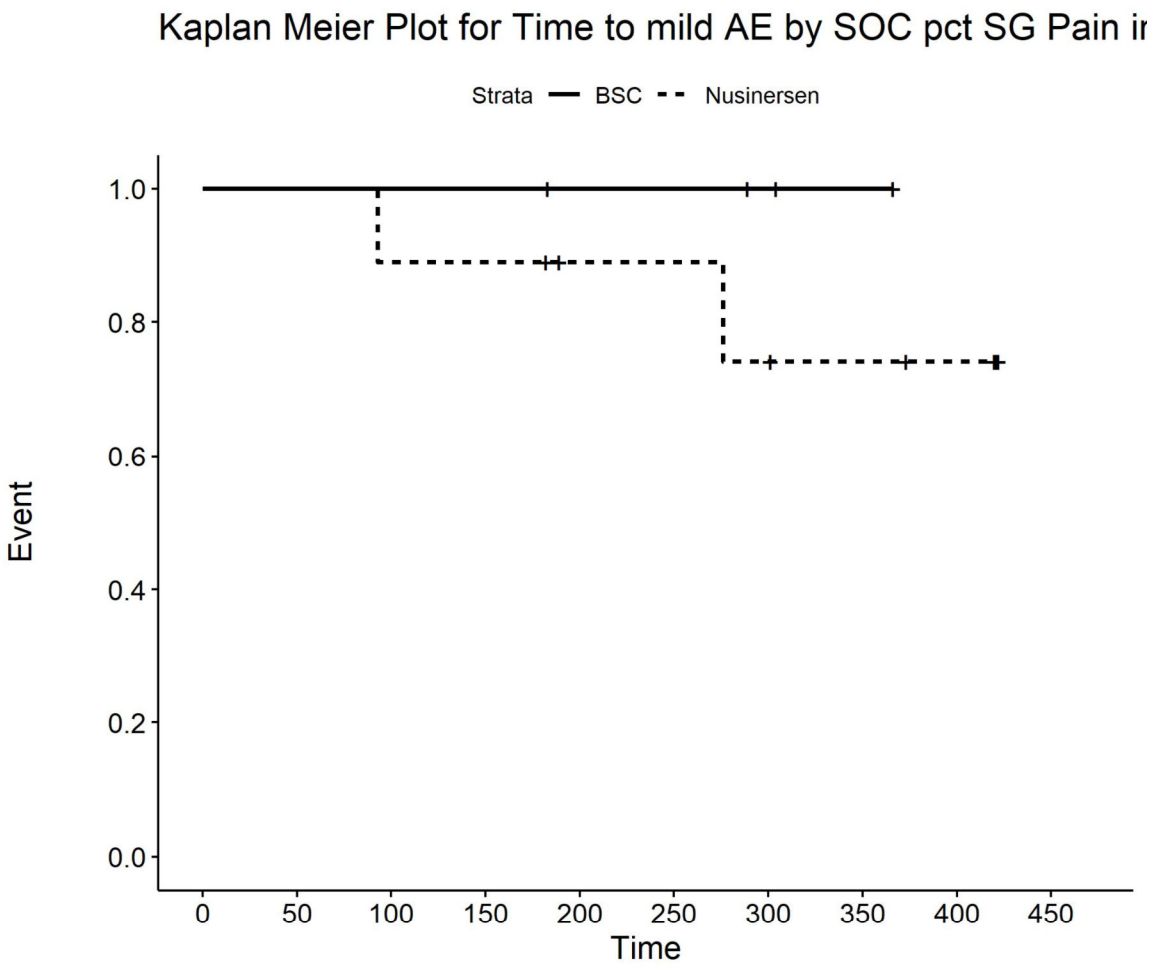
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	7	5	4	0



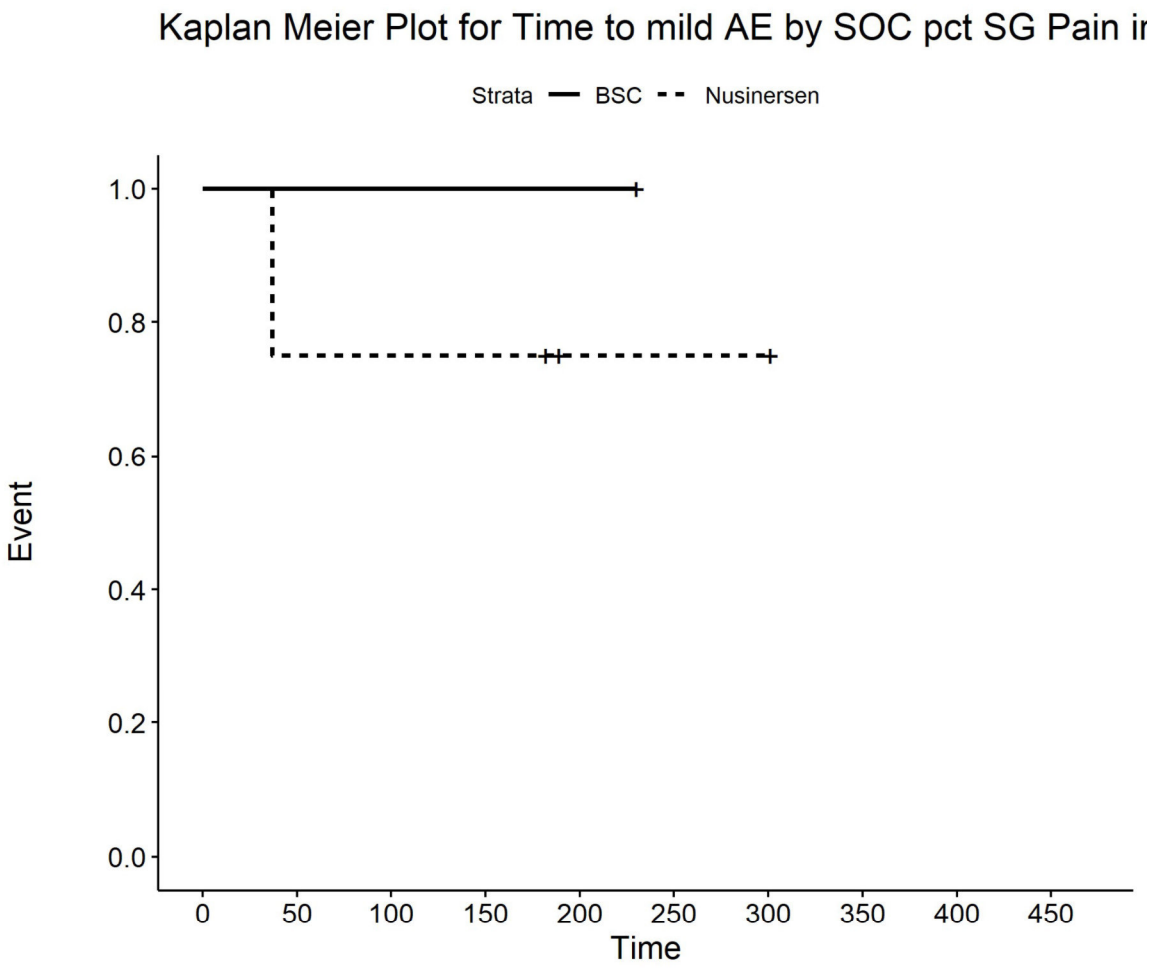
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



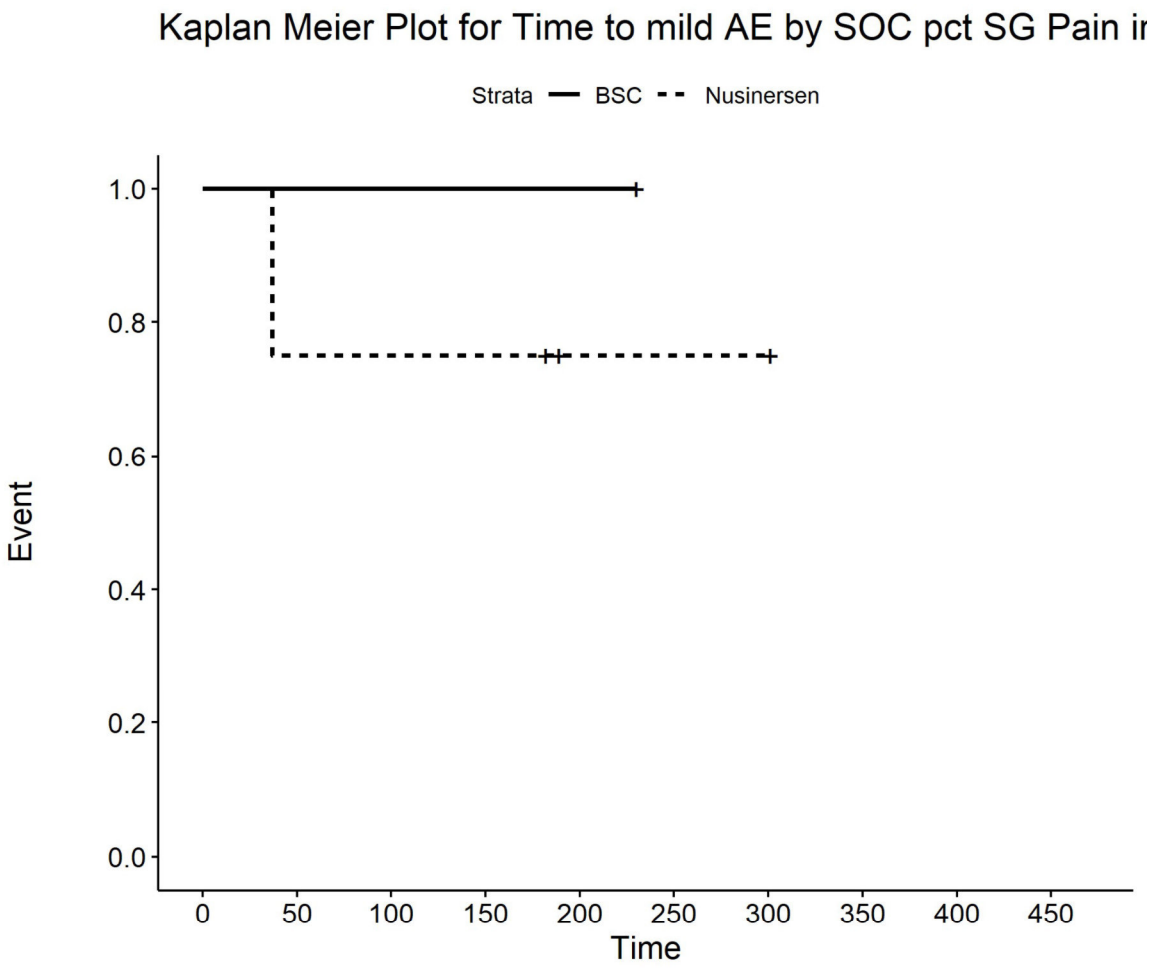
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



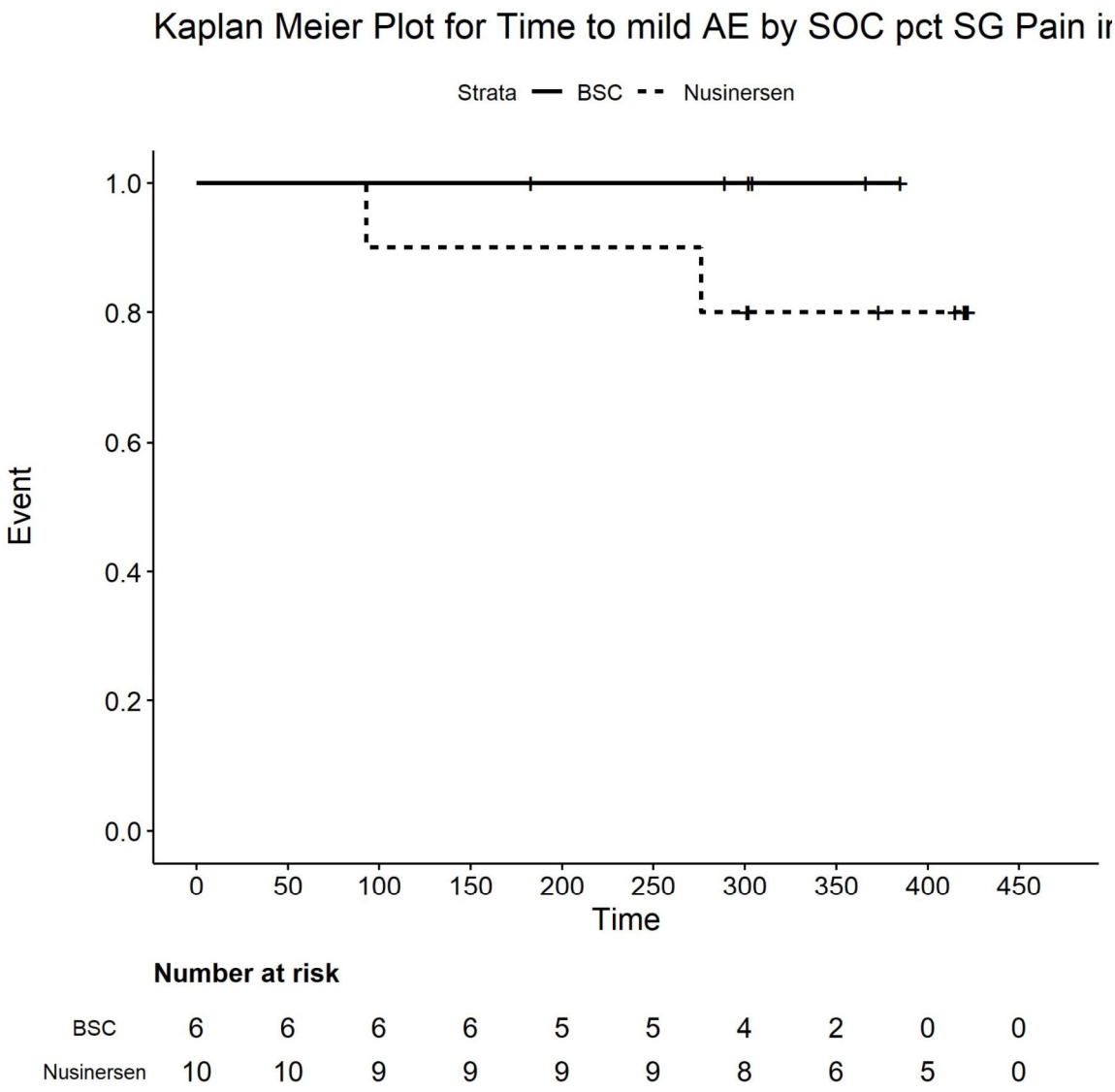
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



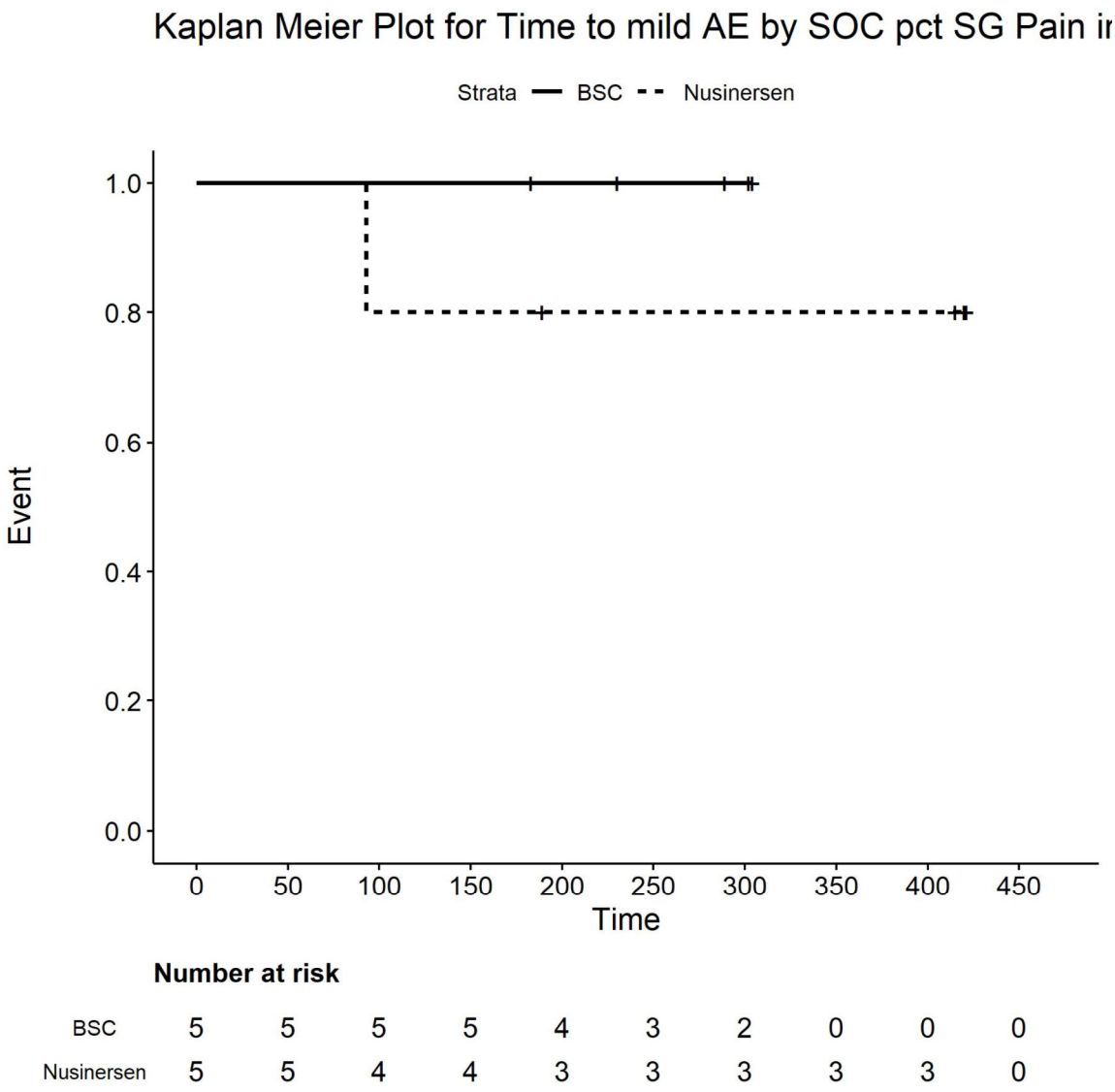
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



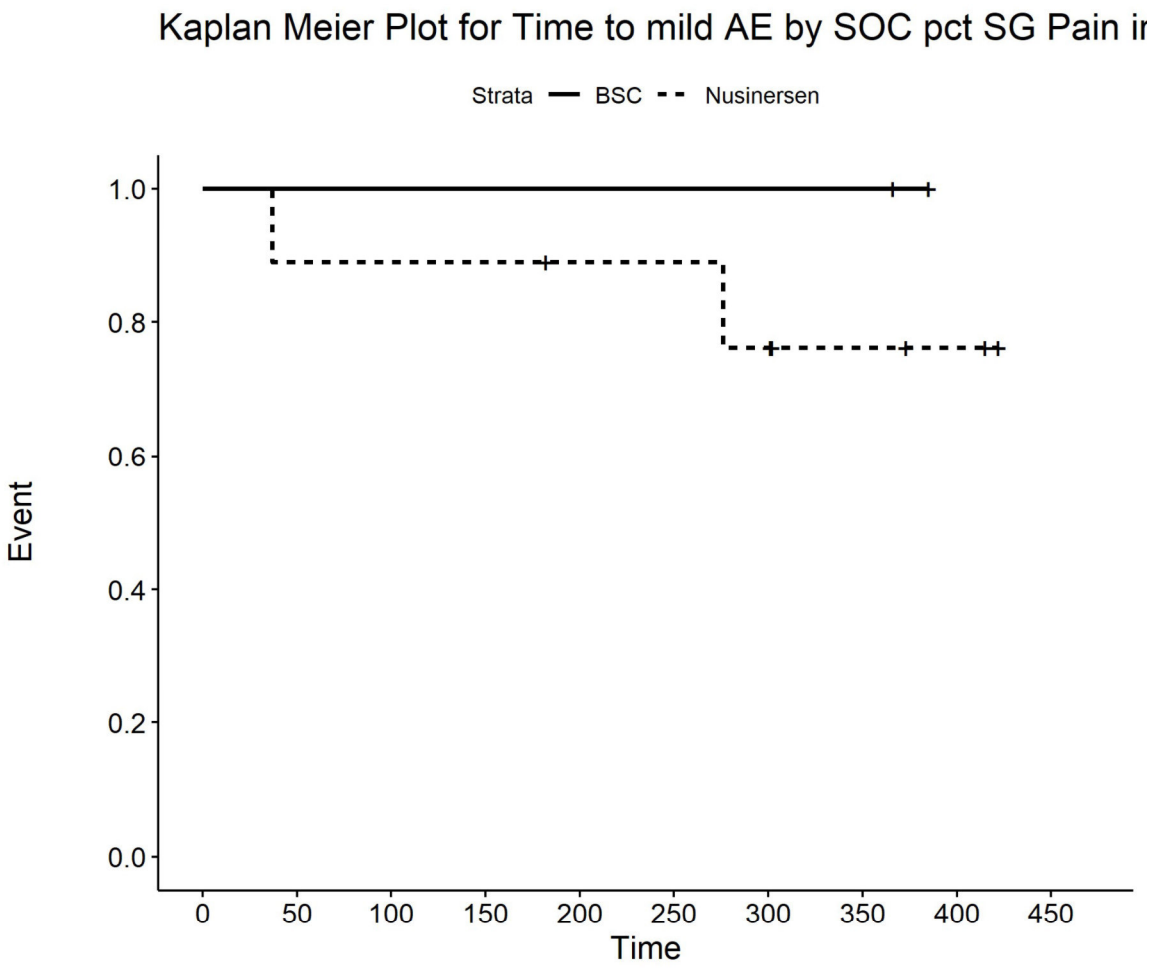
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



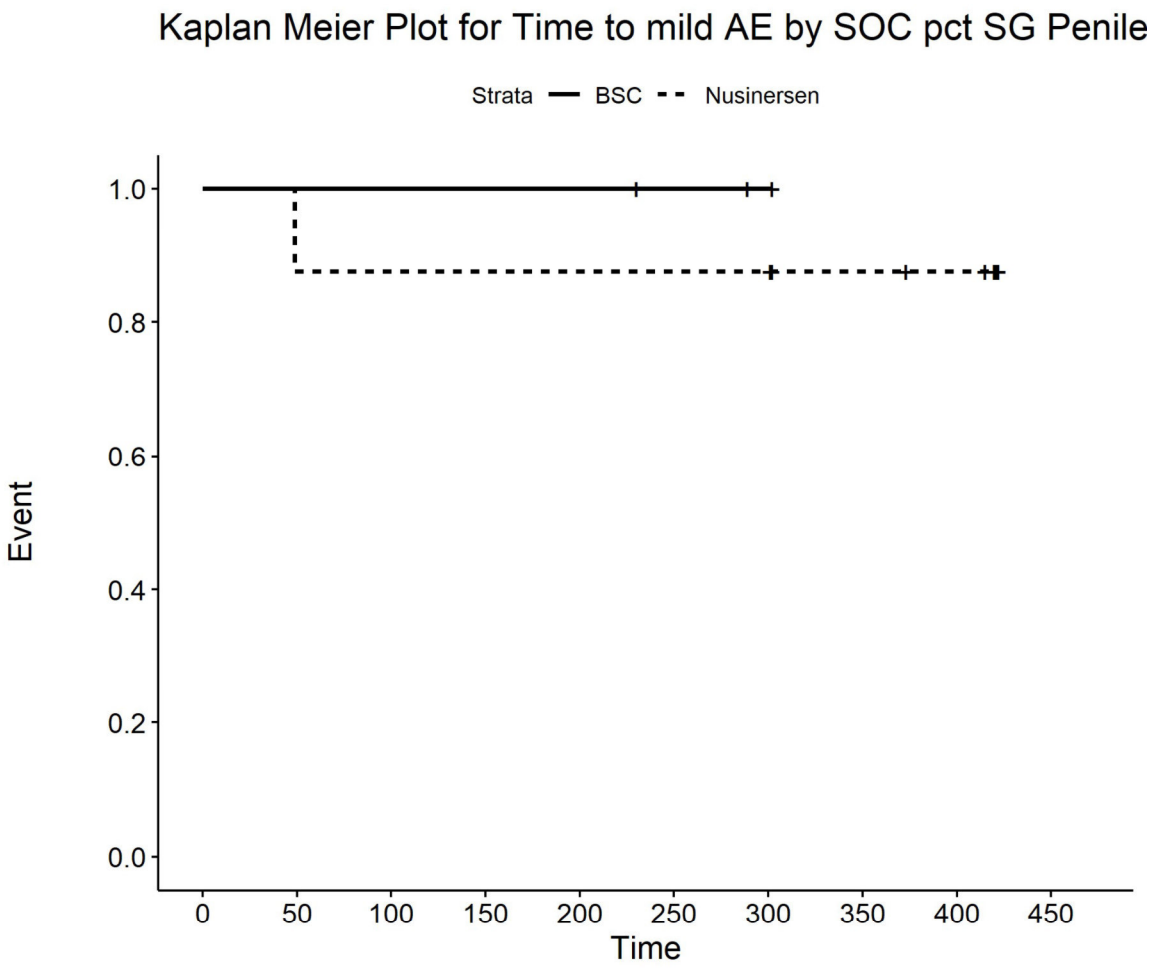
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	4	4	3	3	3	3	3	0



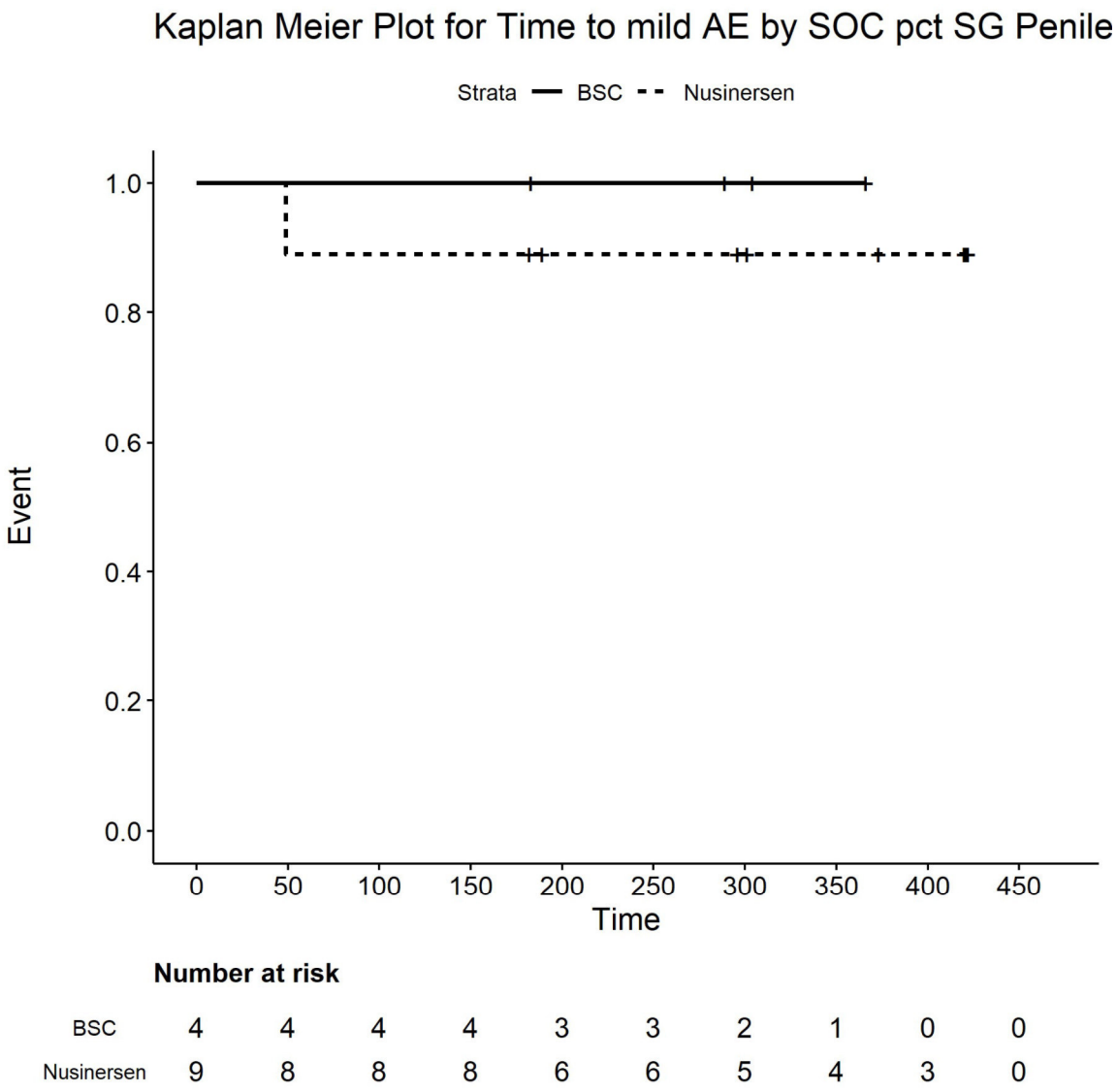
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	6	3	2	0



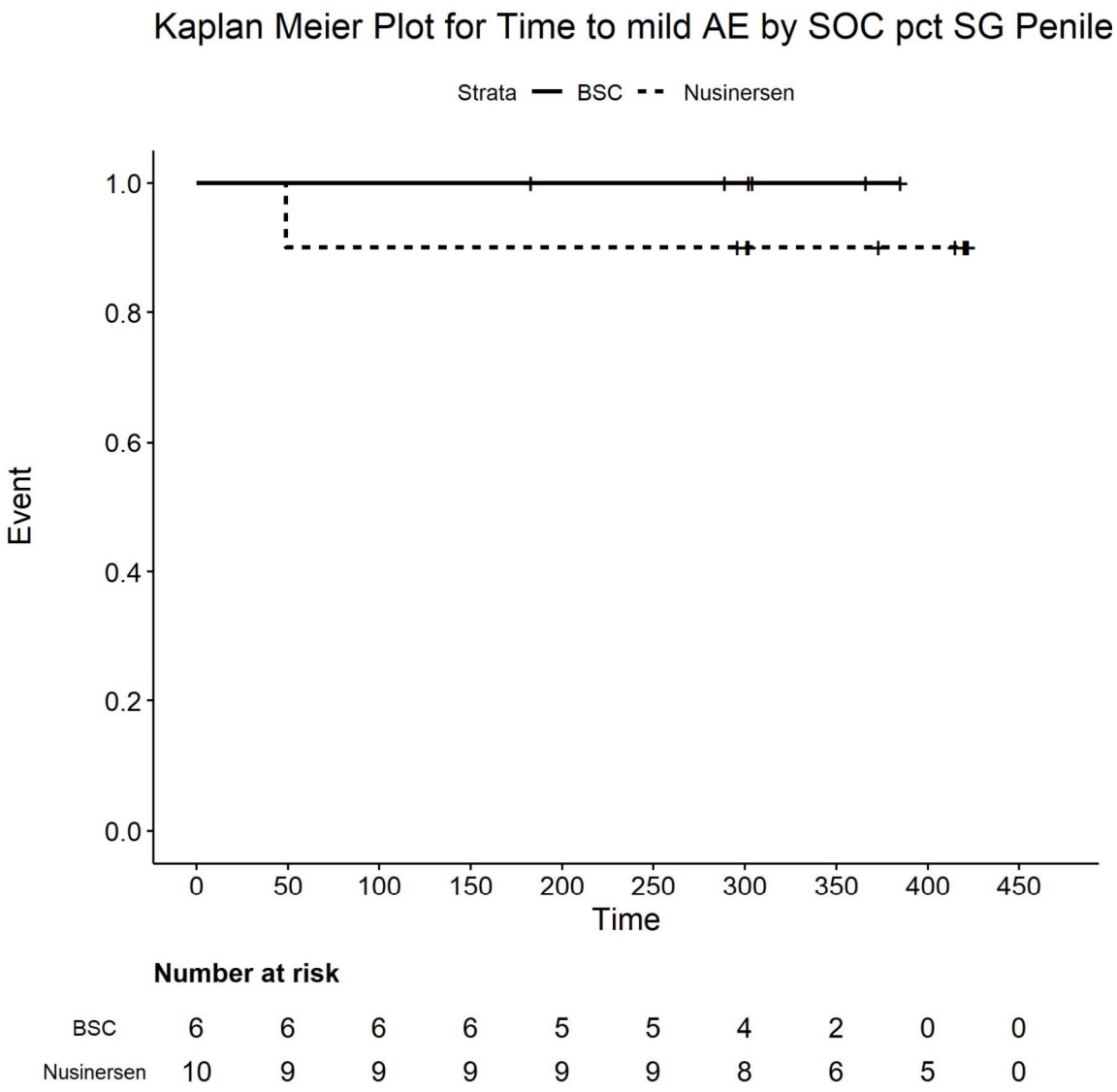
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



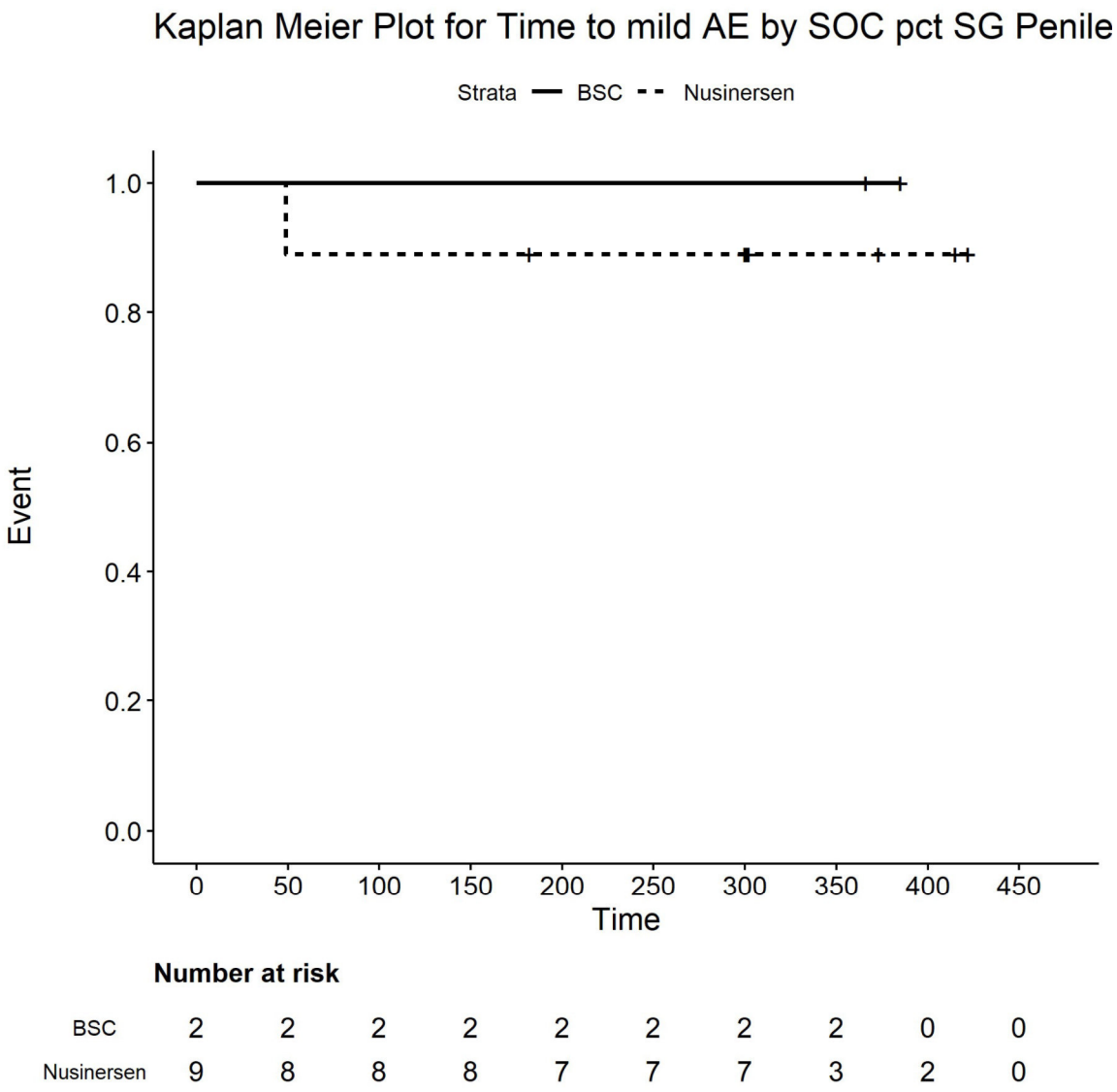
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



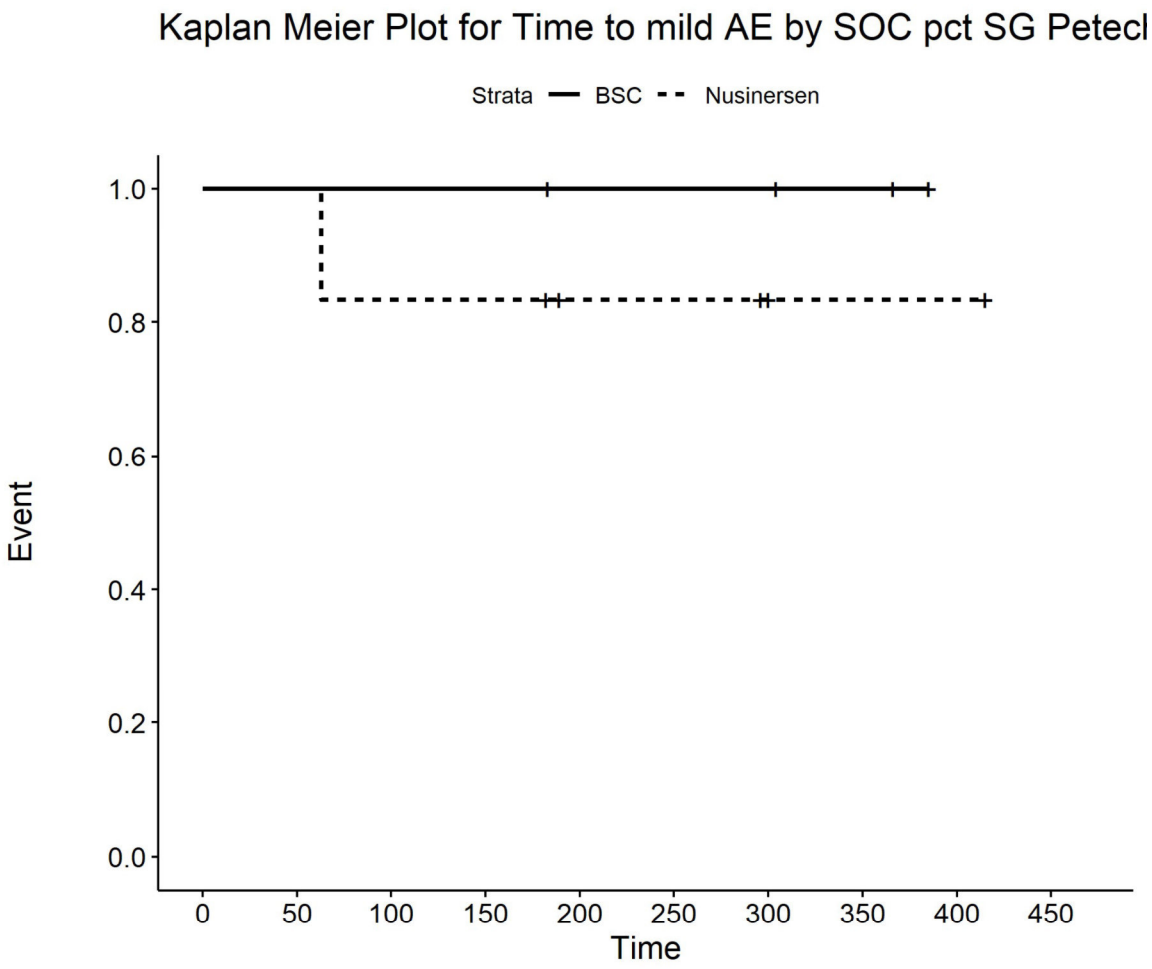
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



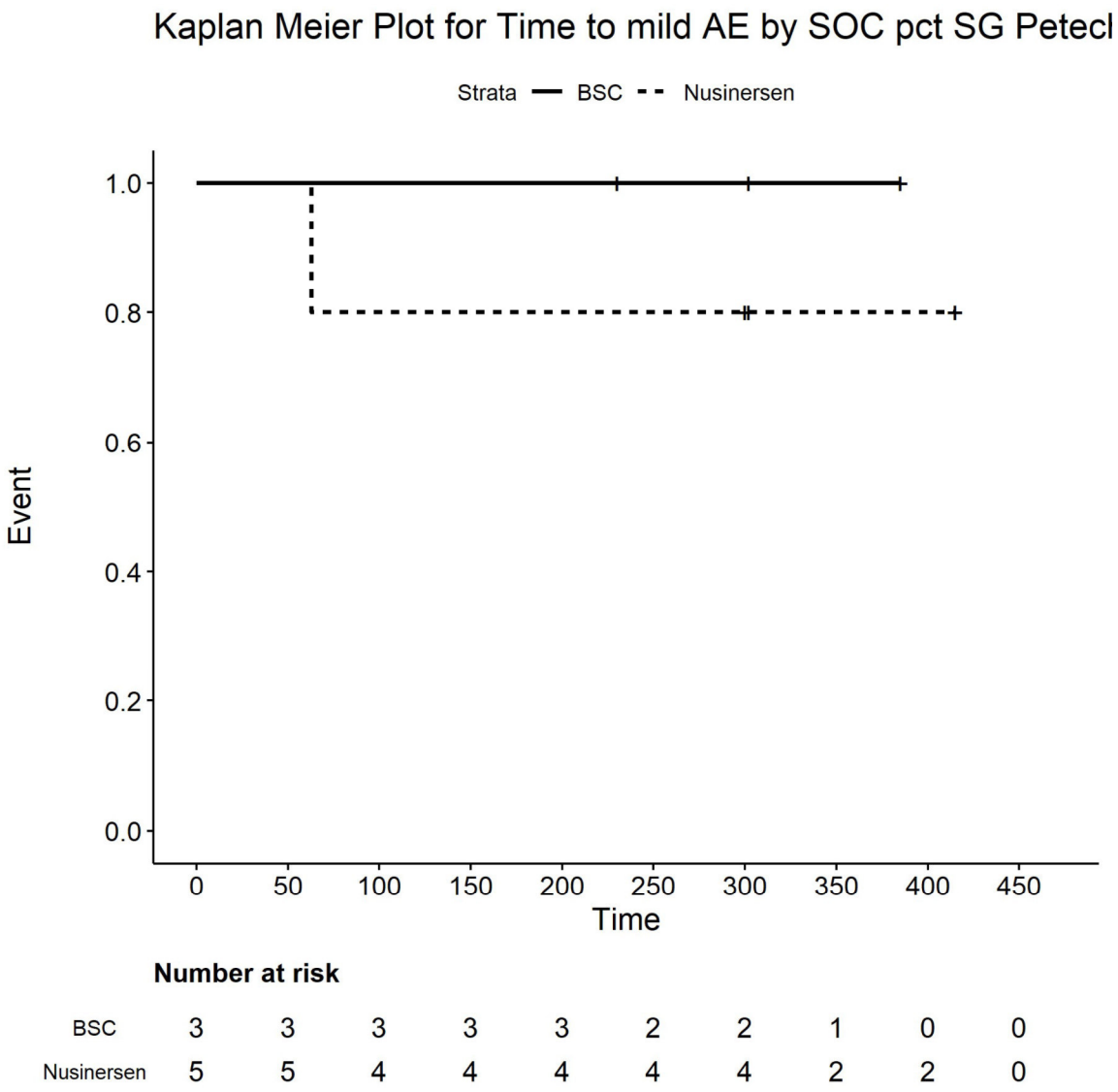
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	2	0



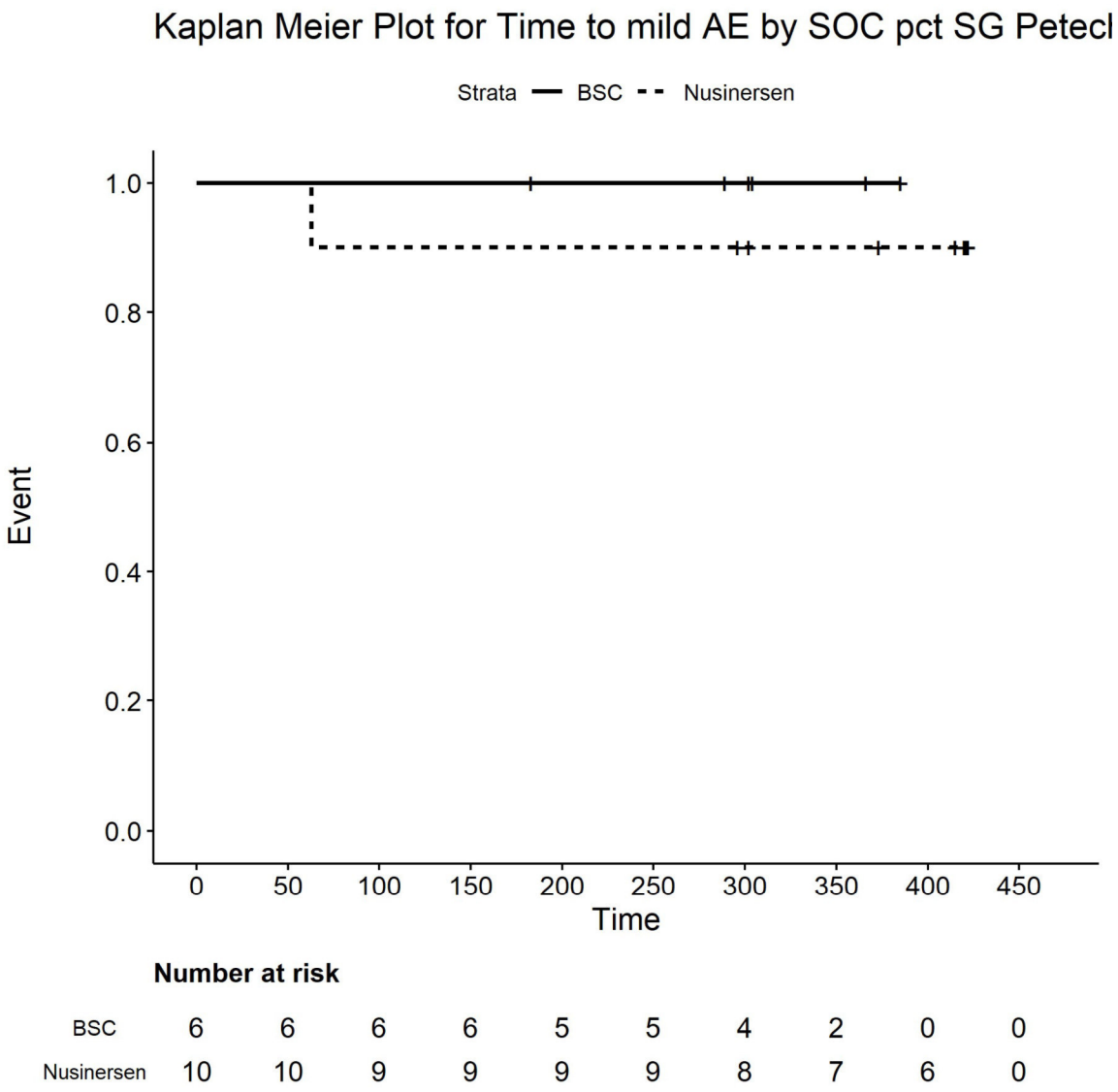
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



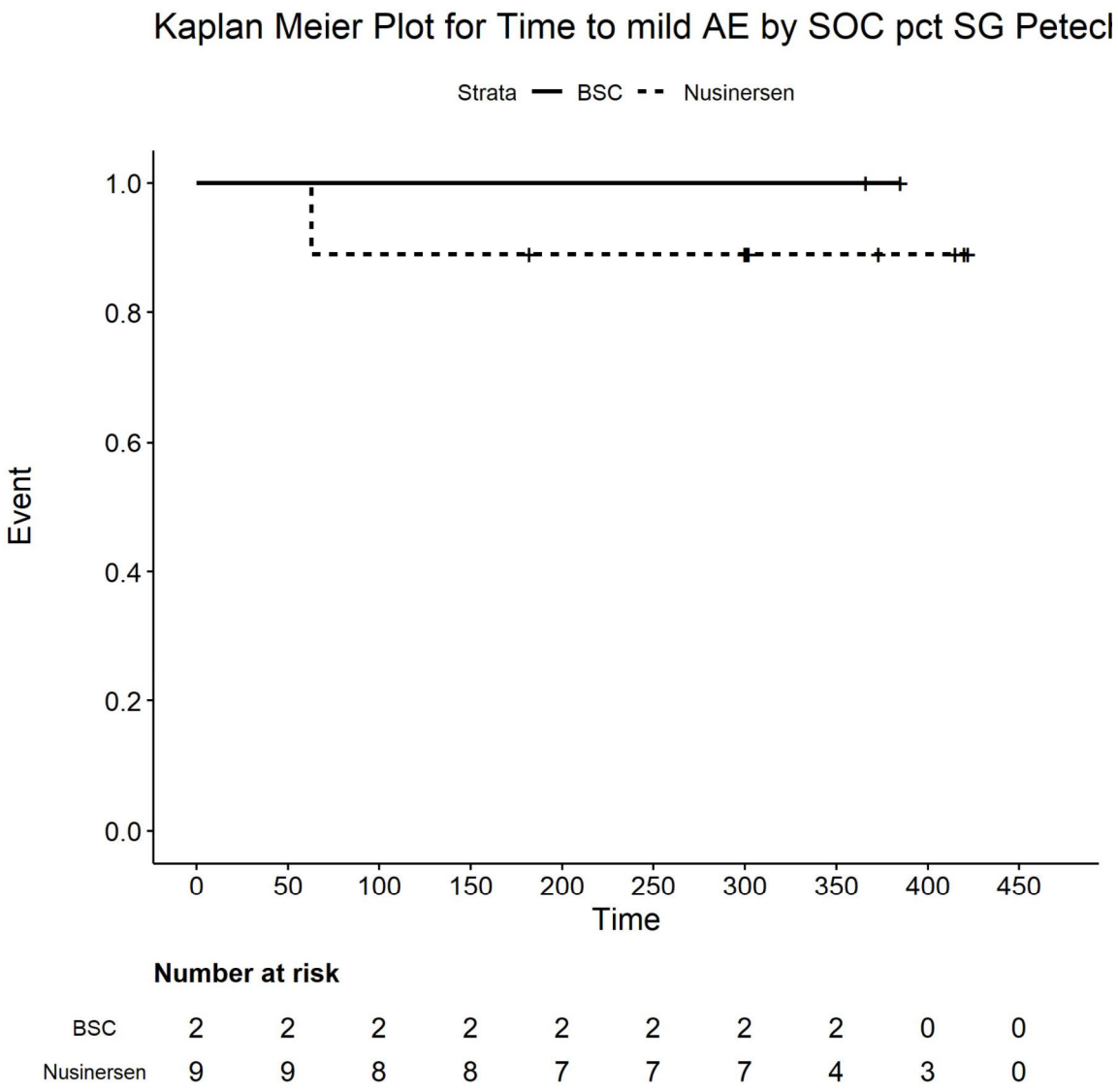
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



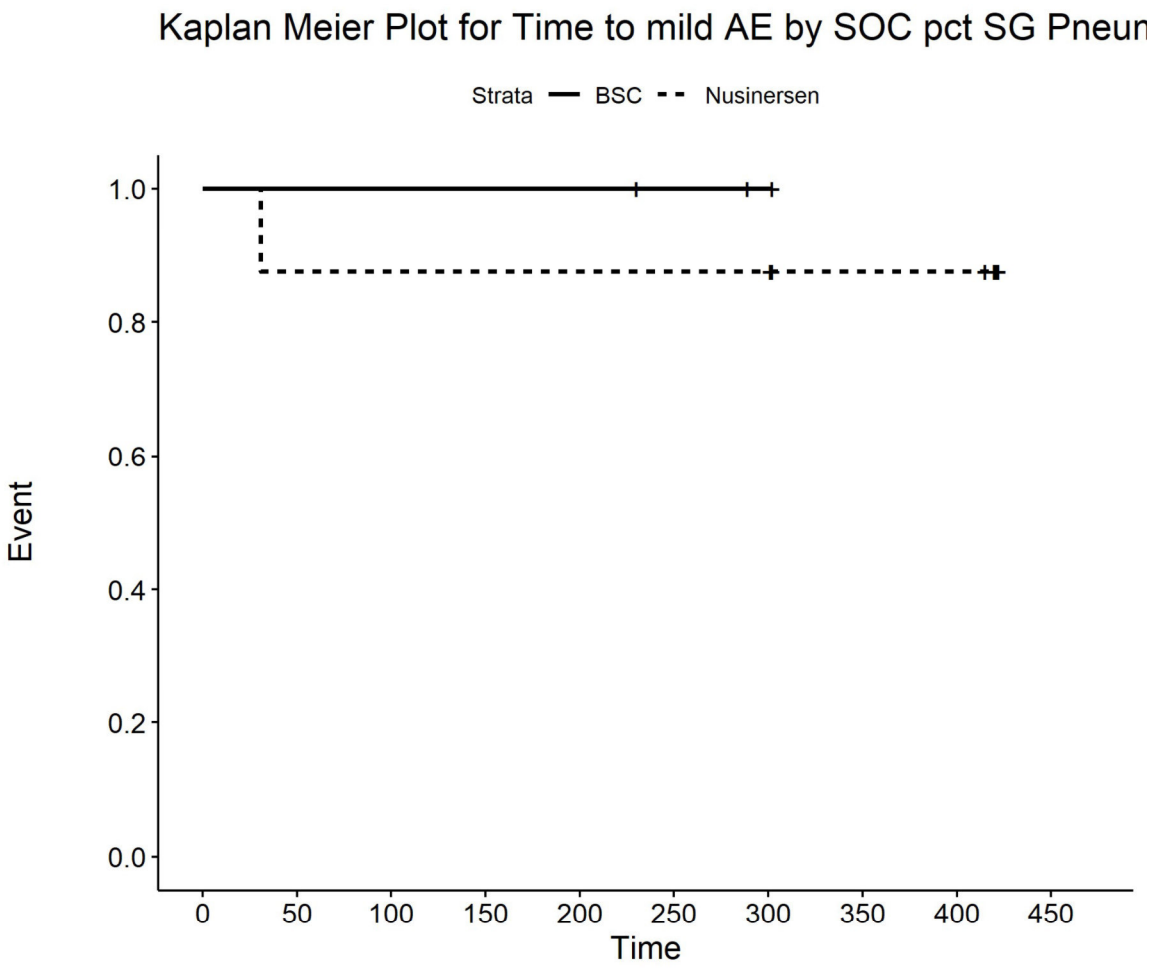
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



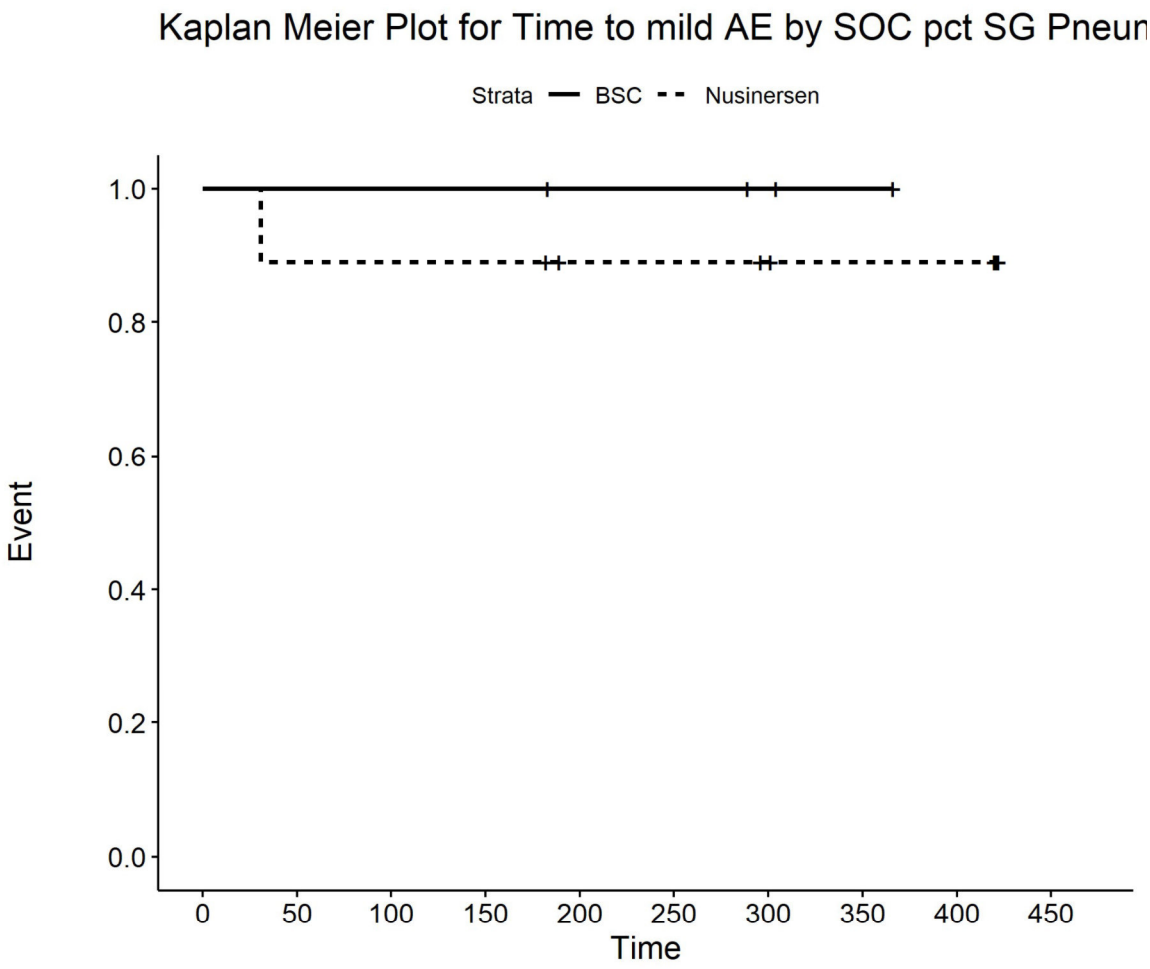
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



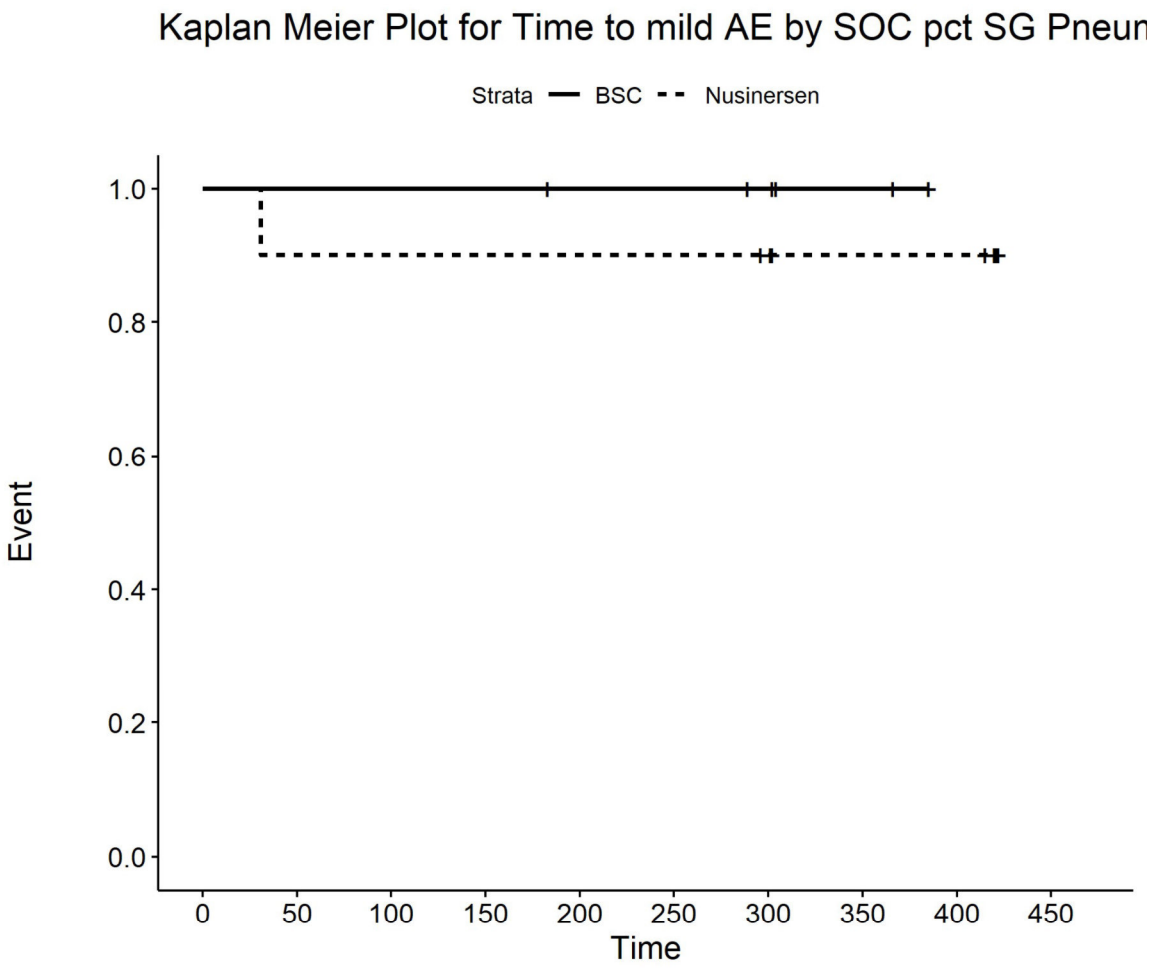
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	5	0



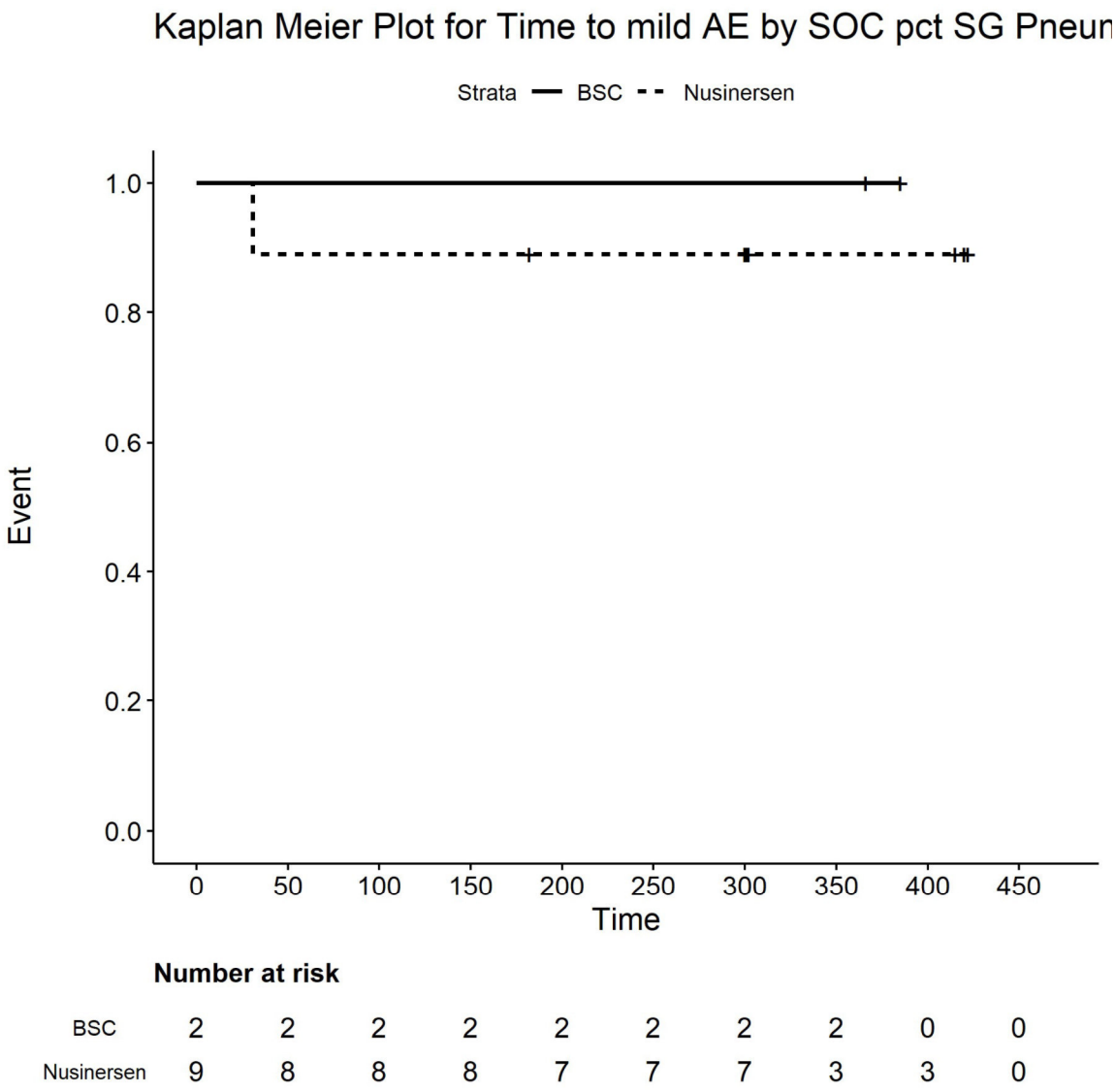
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	4	0



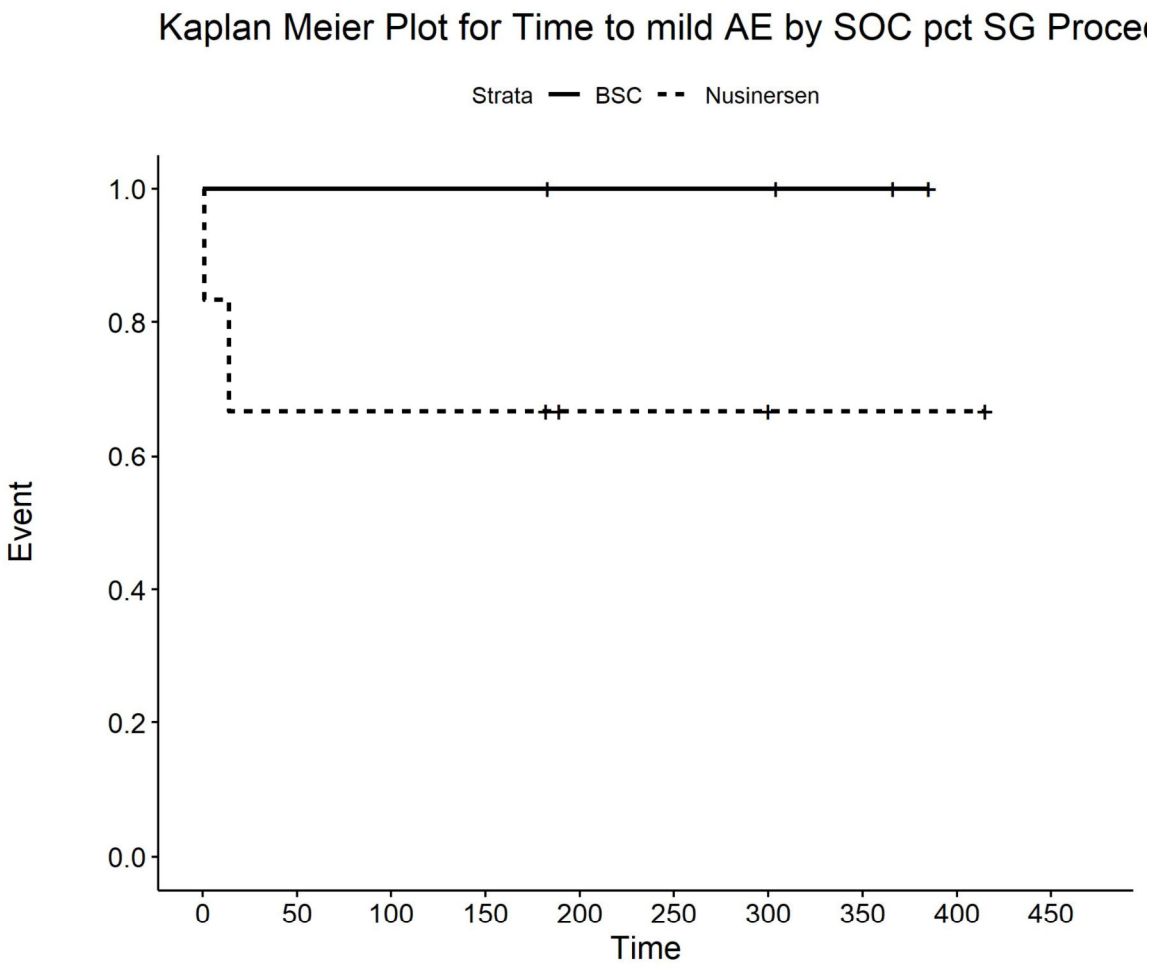
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	6	0



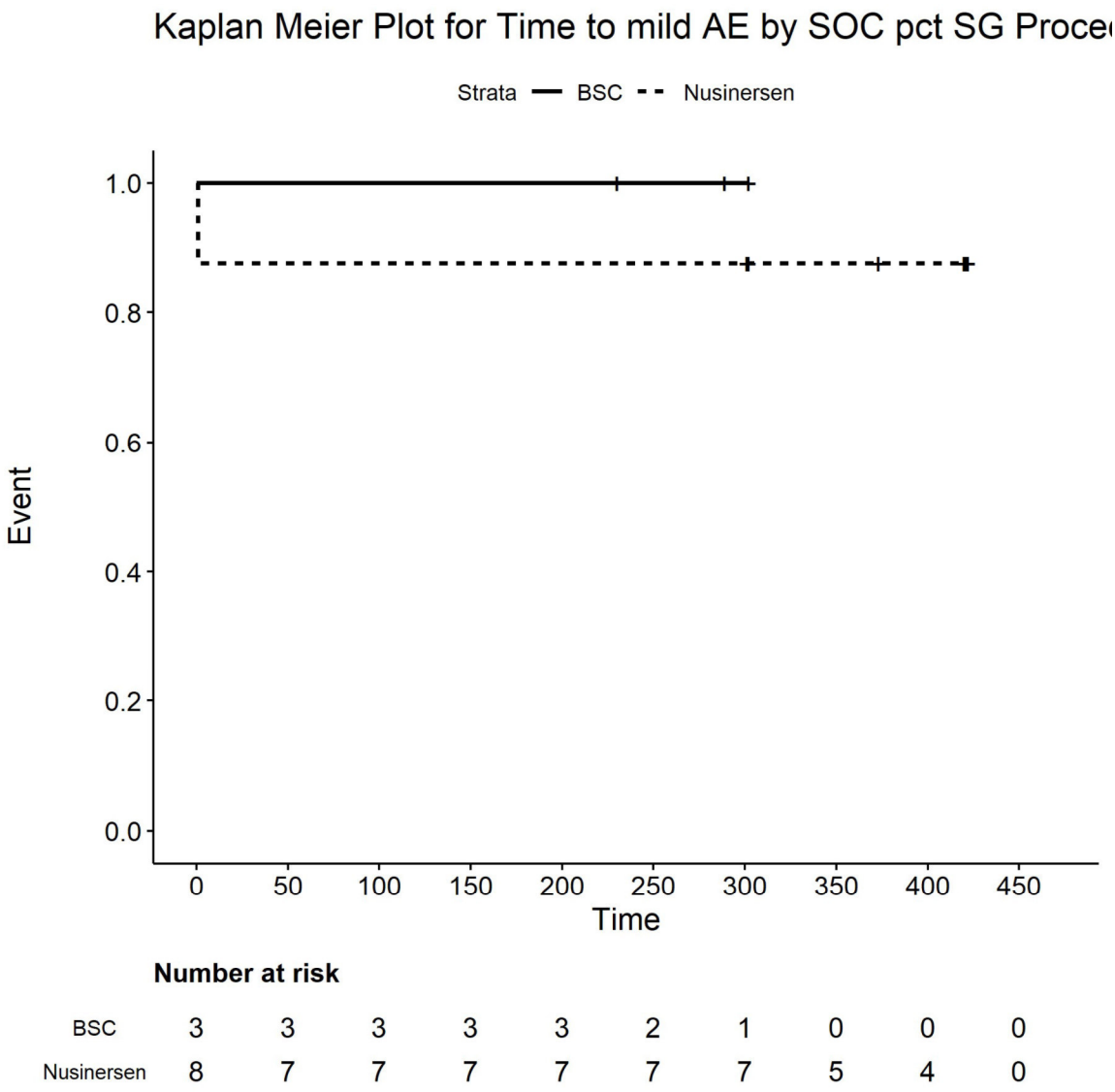
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	3	0



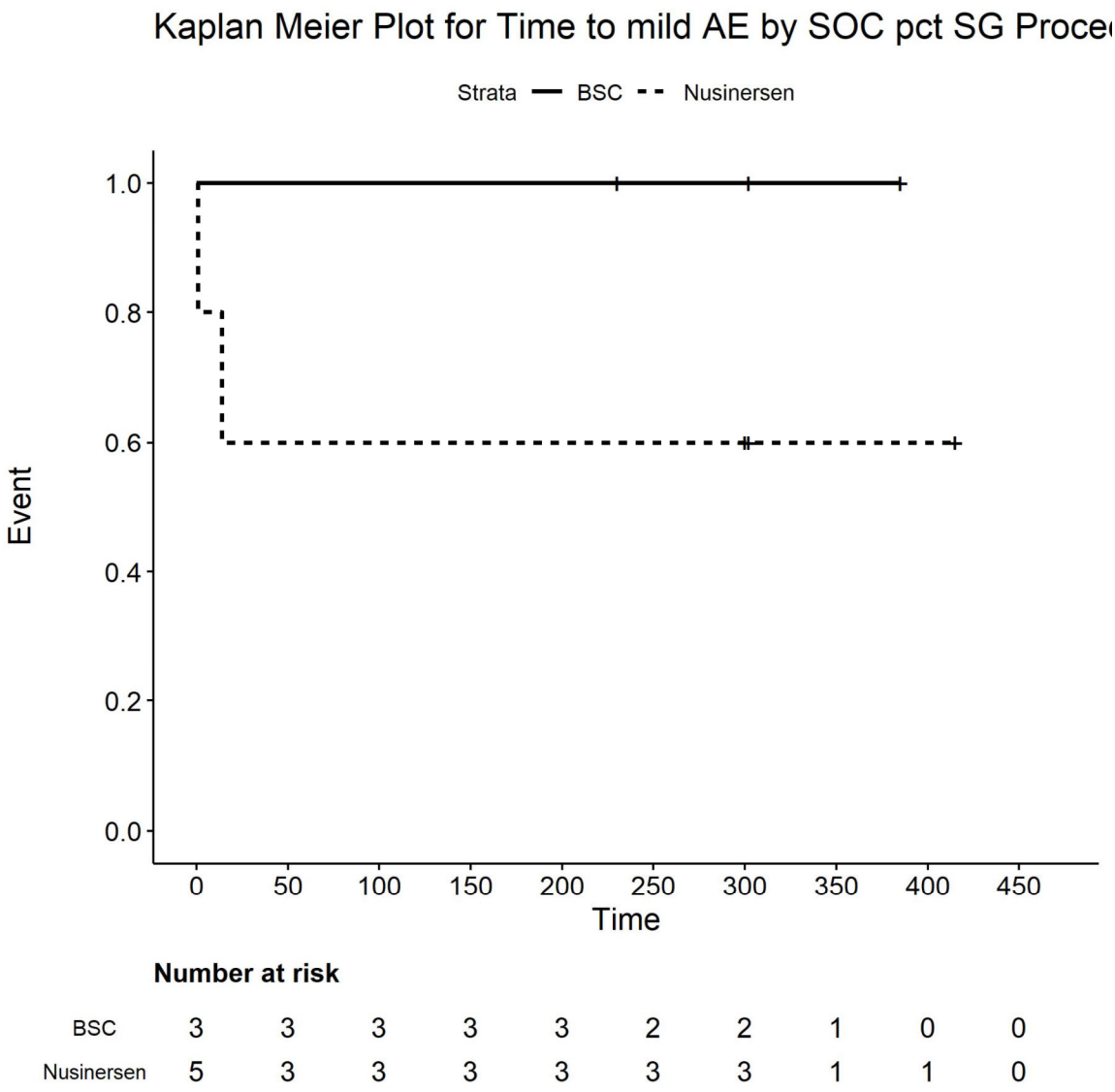
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	4	4	4	2	2	2	1	1	0



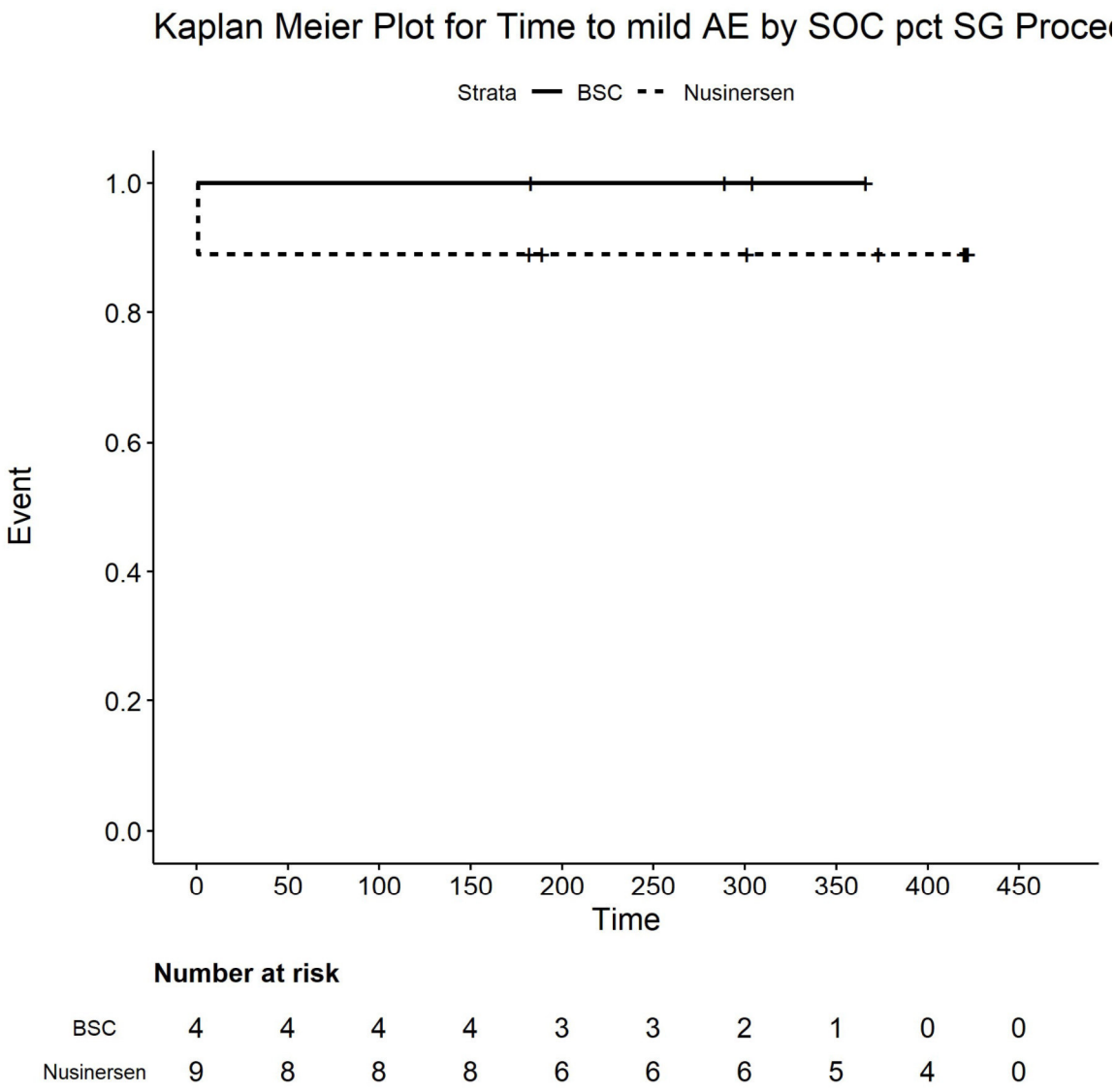
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



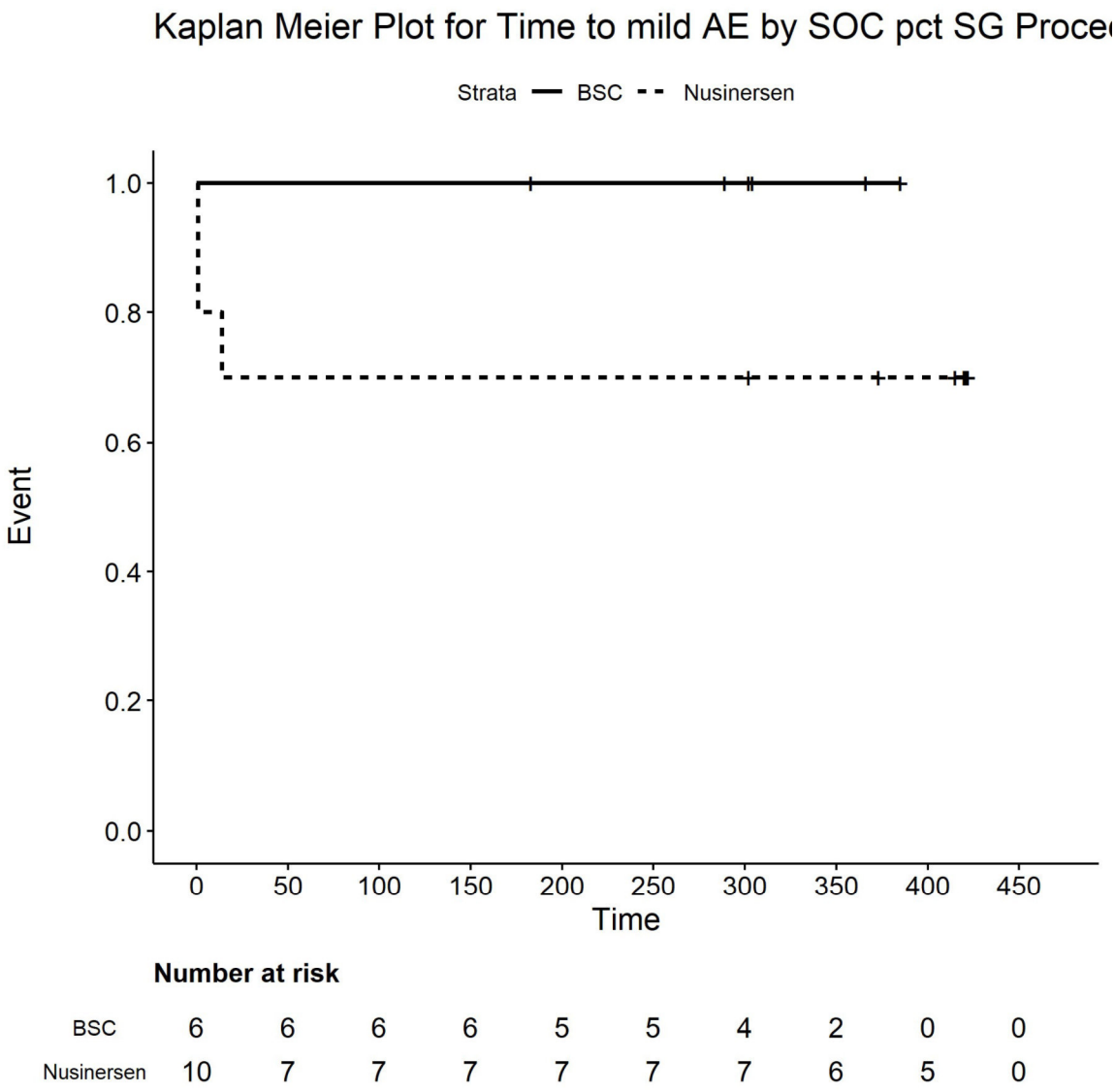
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	3	3	3	3	3	3	1	1	0



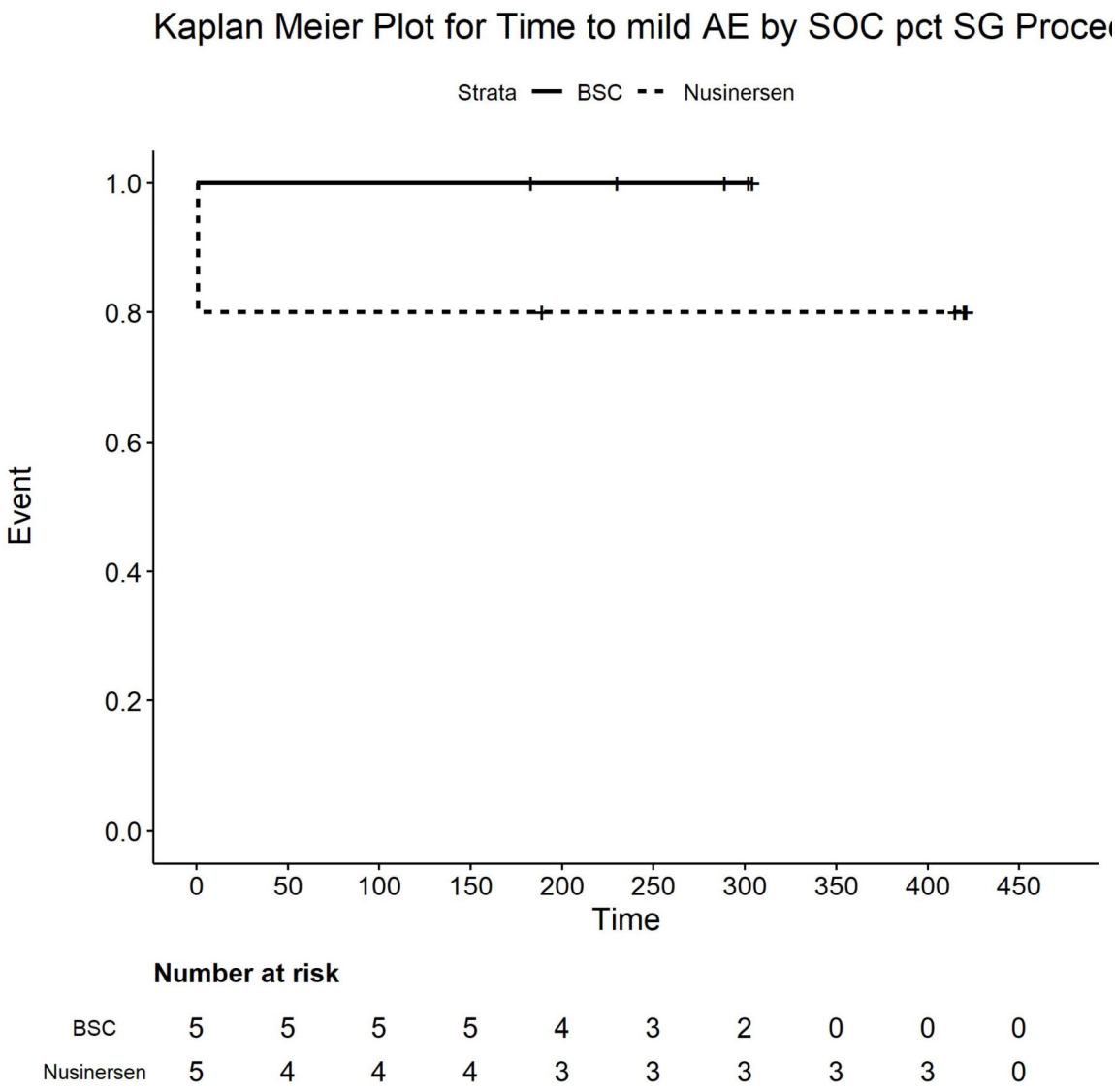
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	6	5	4	0



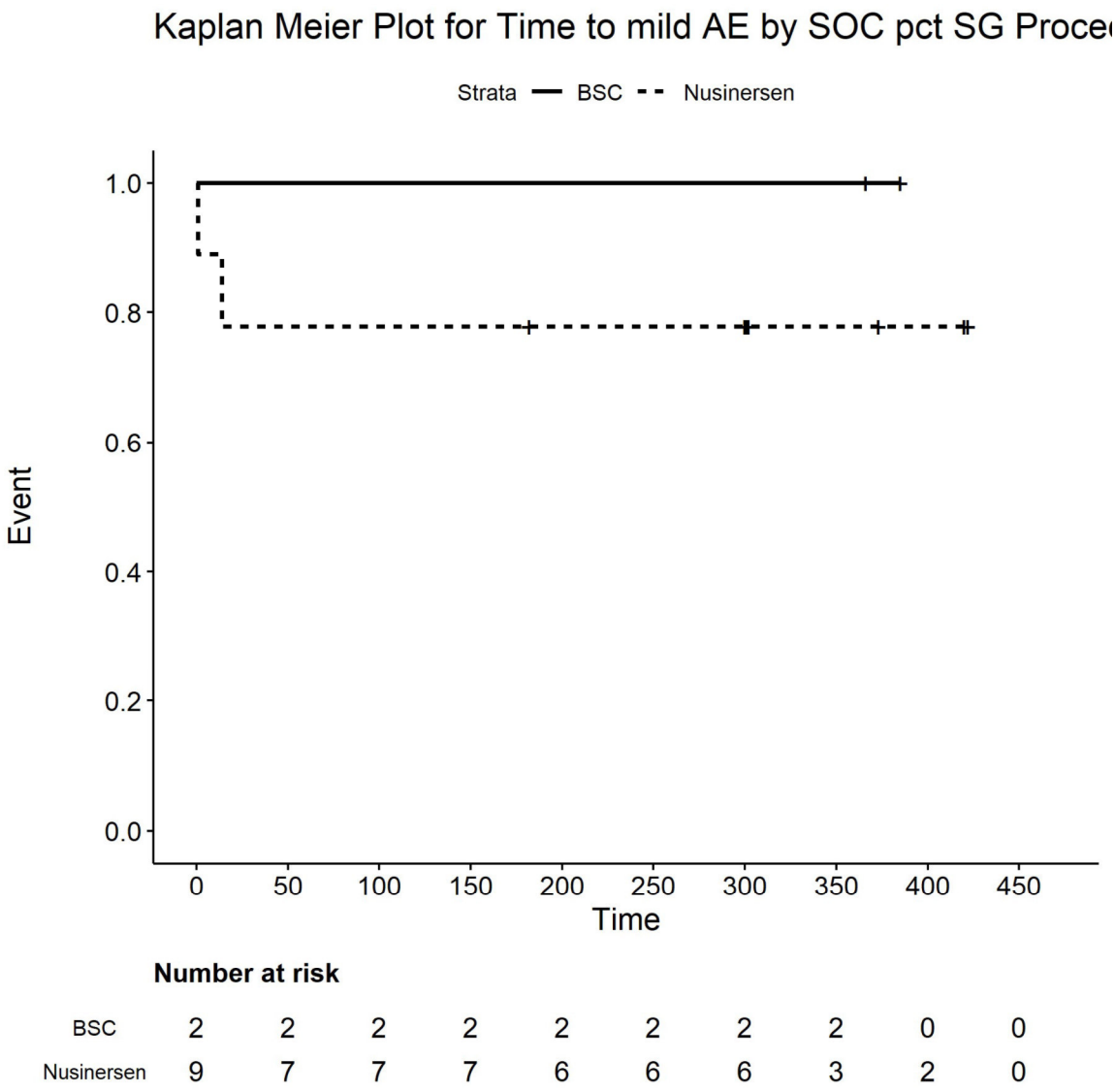
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	7	7	7	7	7	7	6	5	0



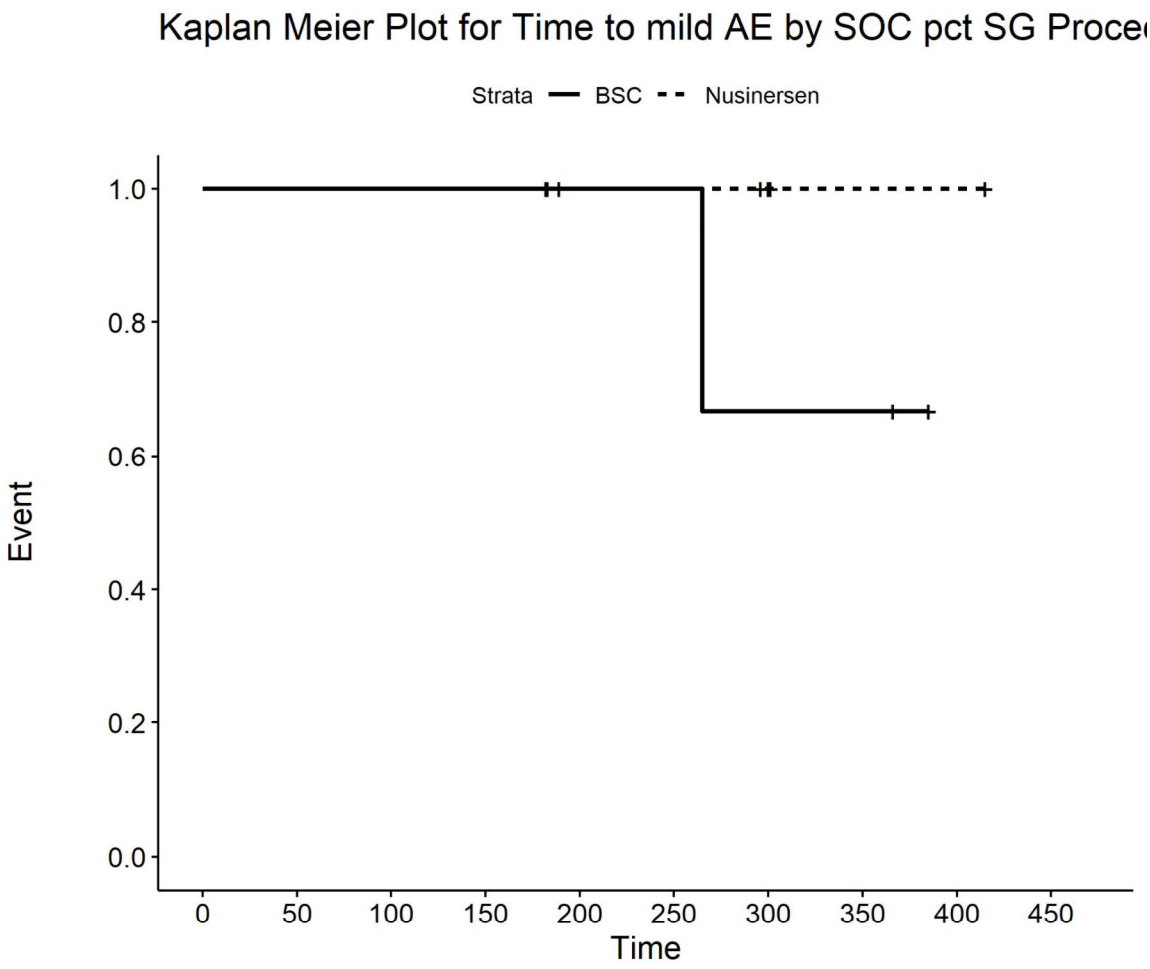
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	3	3	3	0



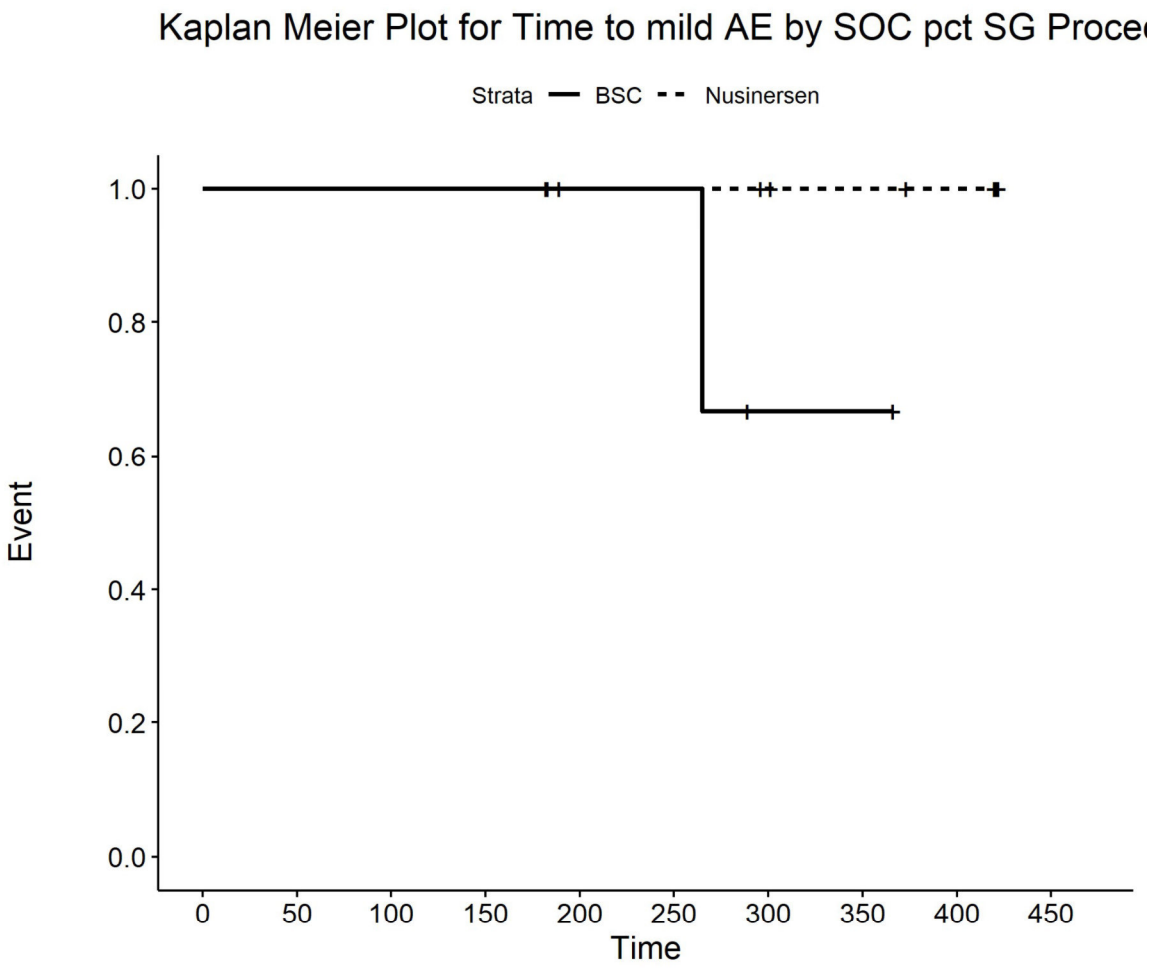
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	7	7	6	6	6	3	2	0



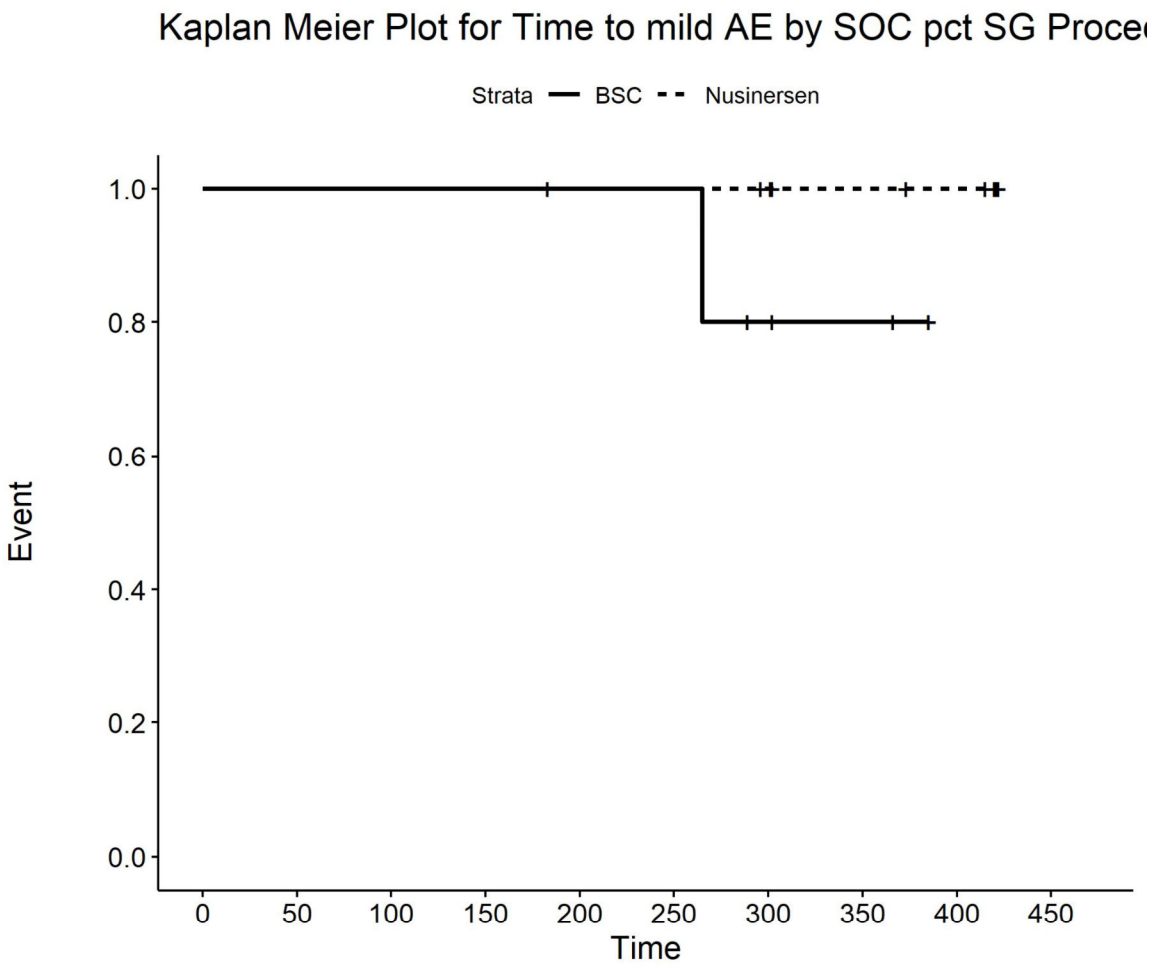
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



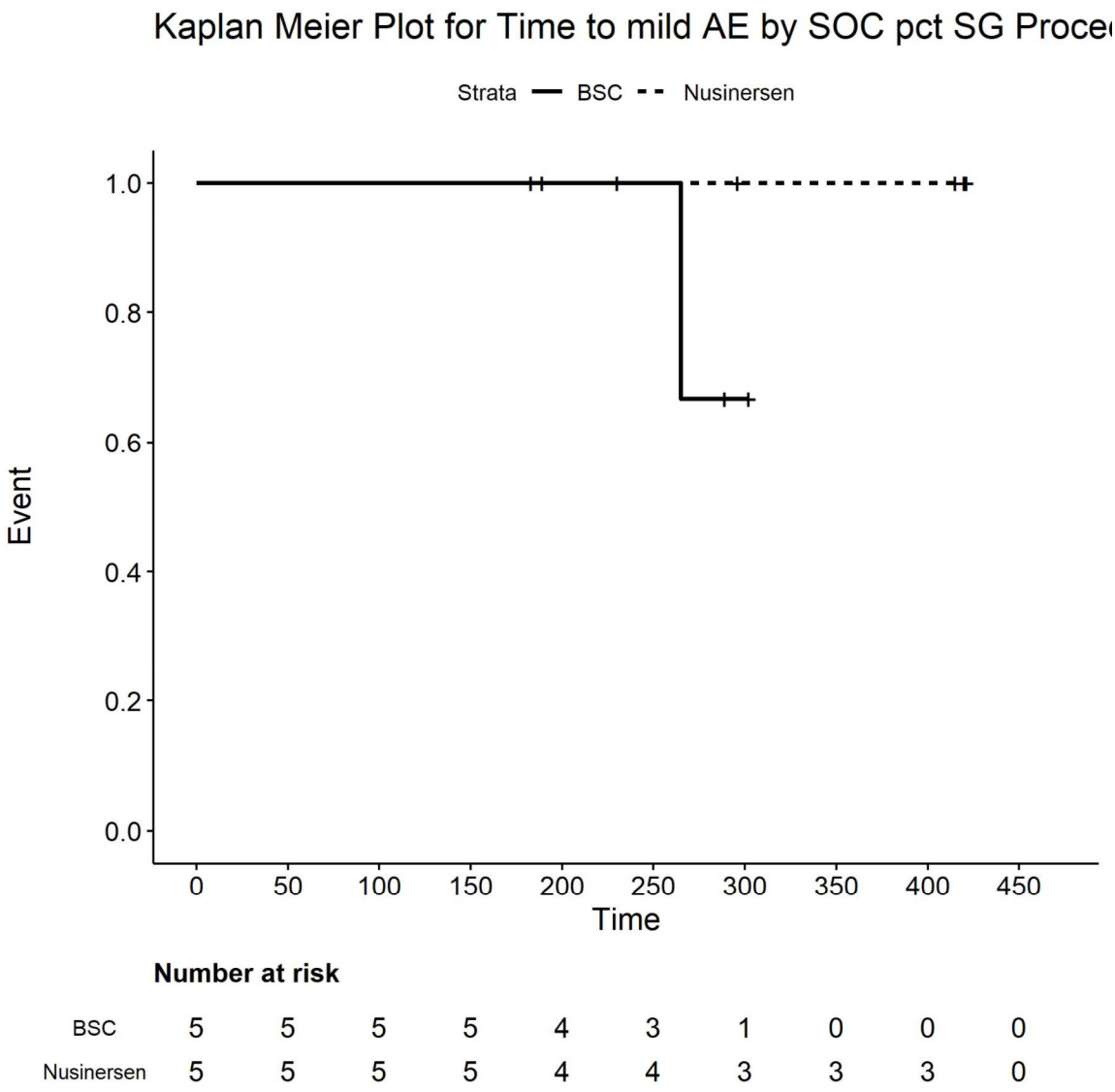
Number at risk

BSC	4	4	4	4	3	3	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



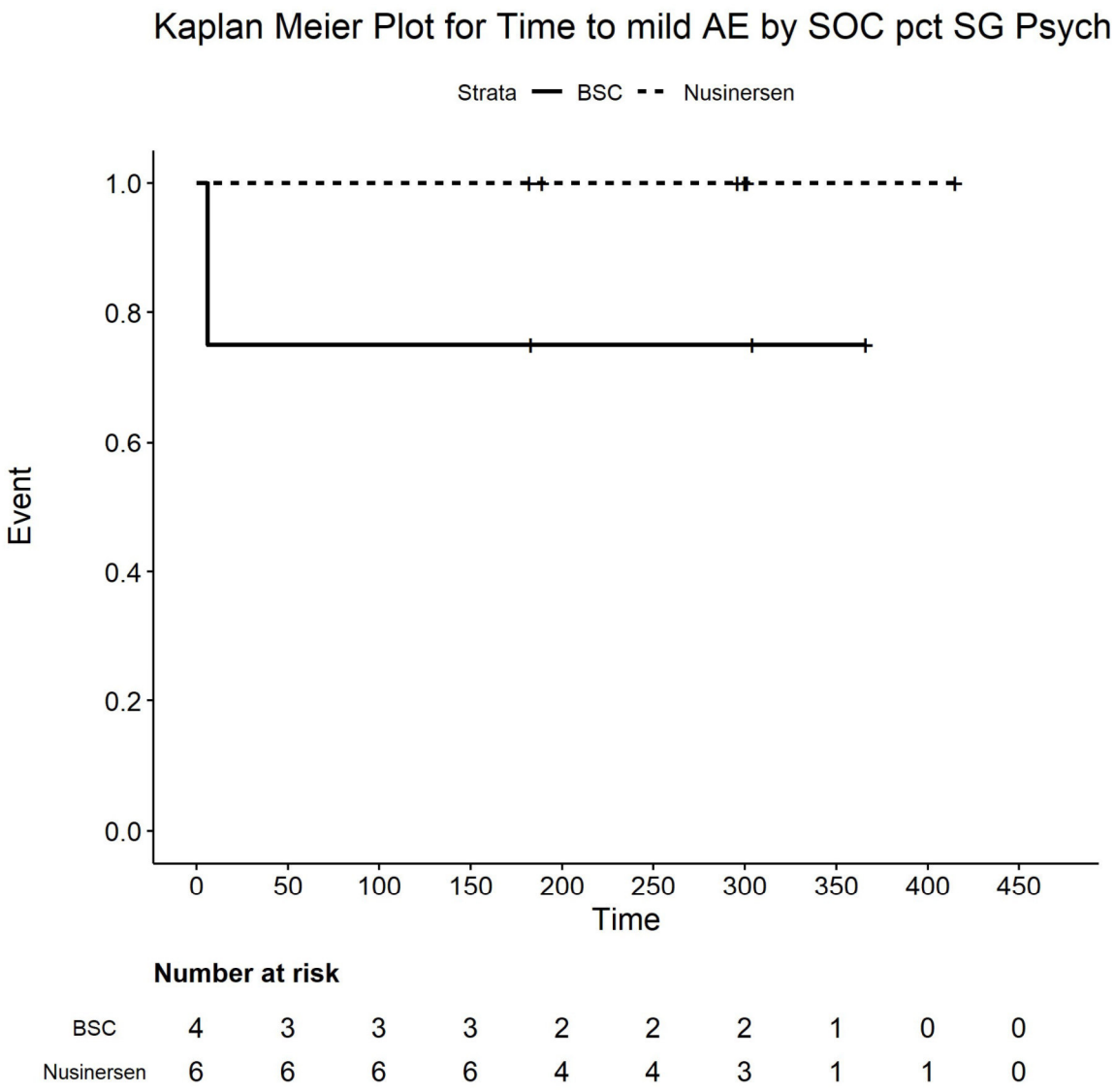
Number at risk

BSC	6	6	6	6	5	5	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



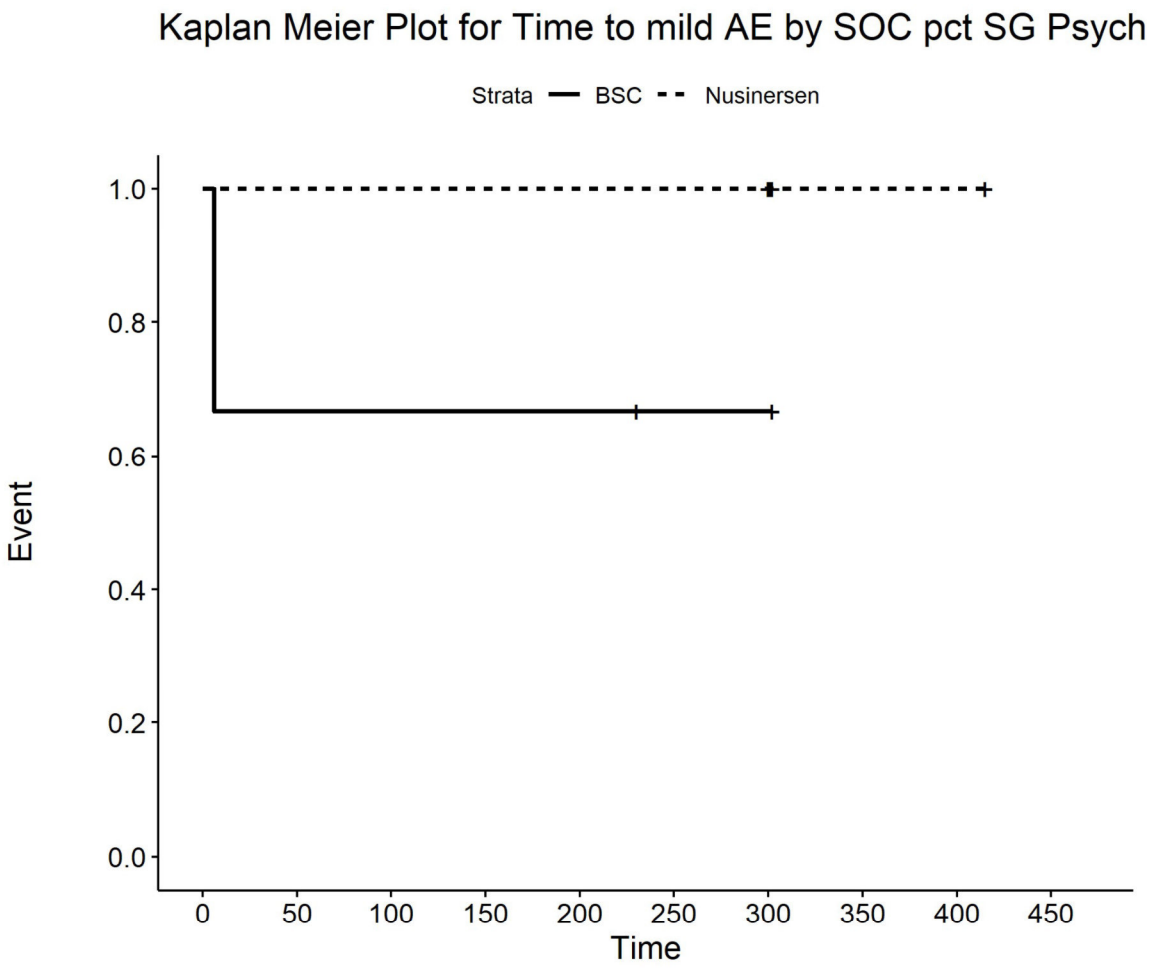
Number at risk

BSC	5	5	5	5	4	3	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



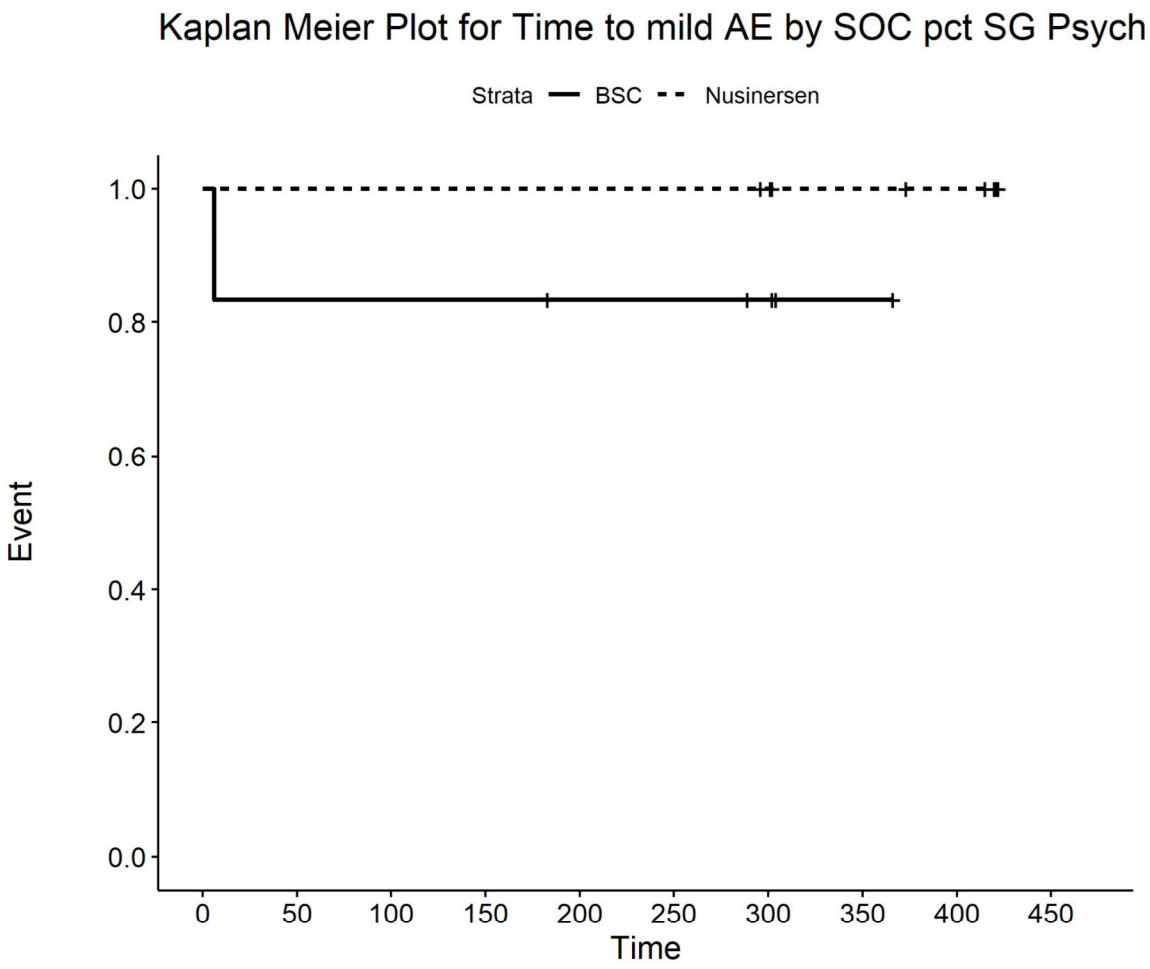
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



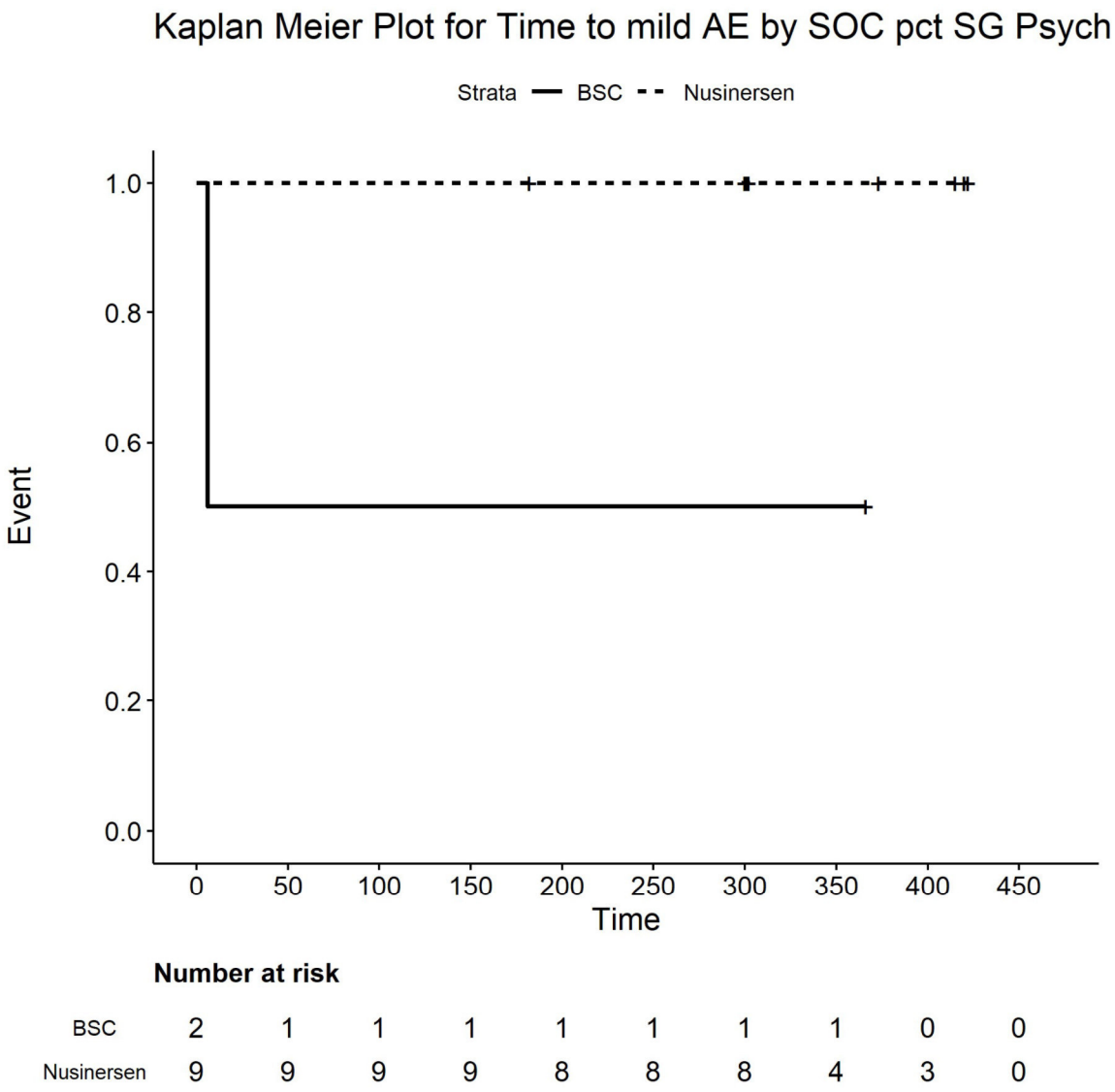
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



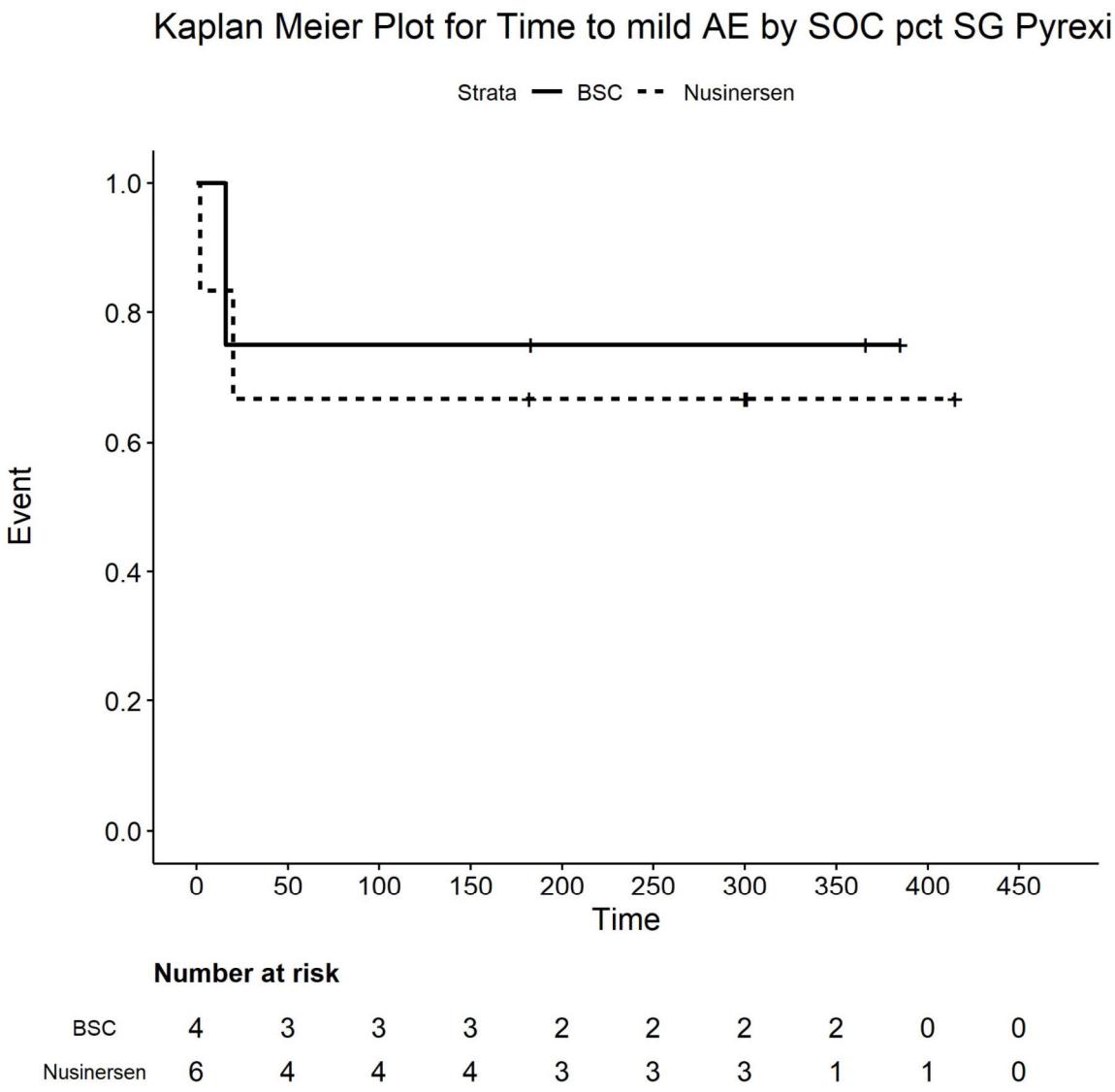
Number at risk

BSC	6	5	5	5	4	4	3	1	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



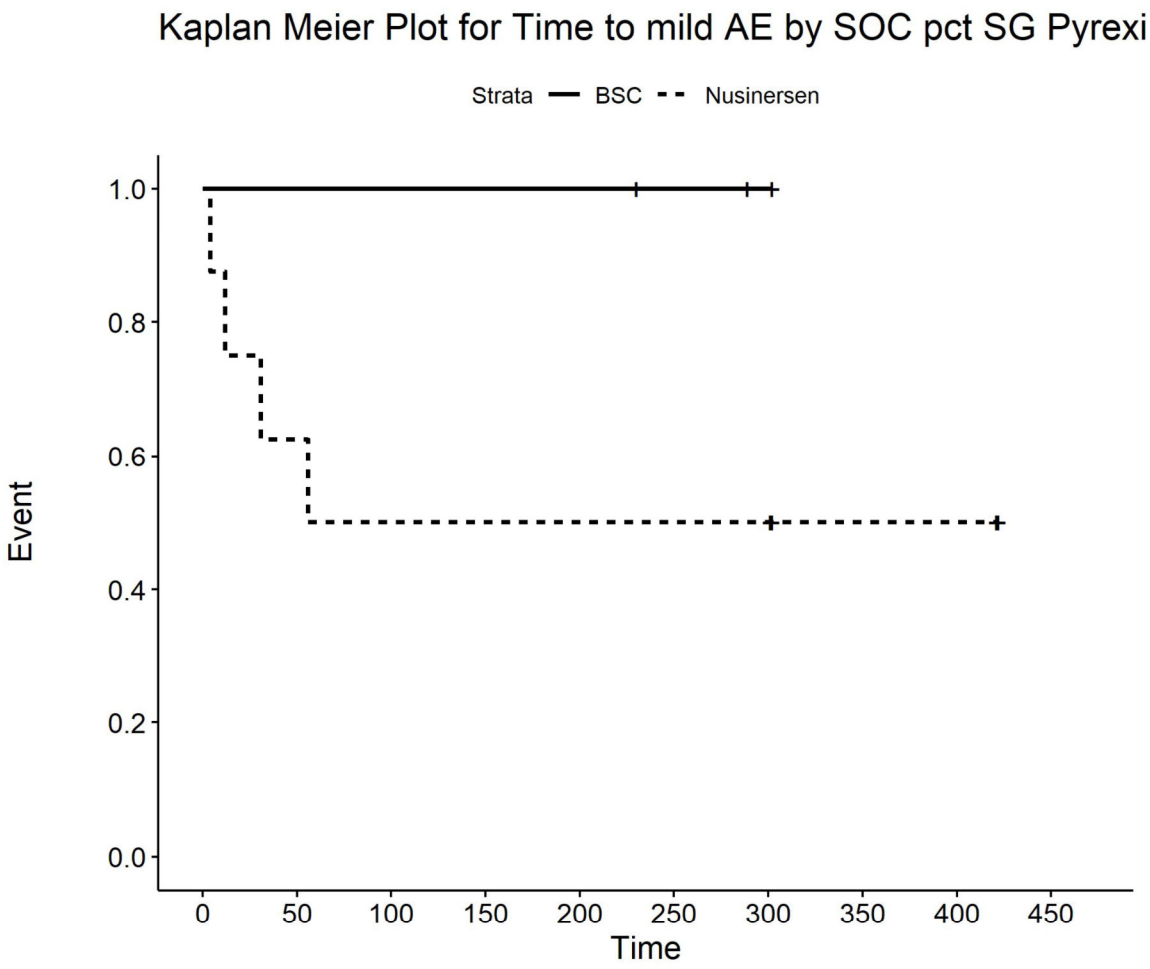
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



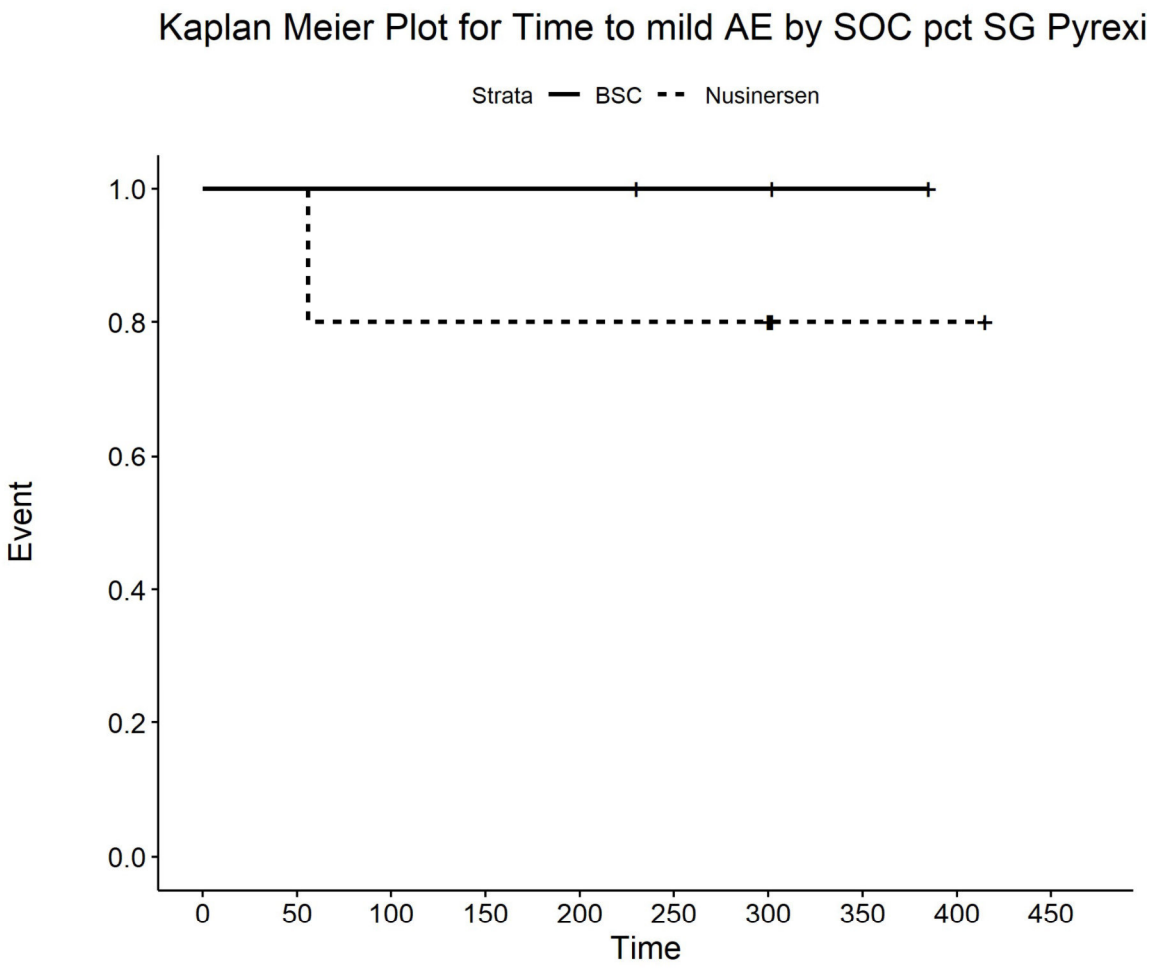
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	4	4	4	3	3	3	1	1	0



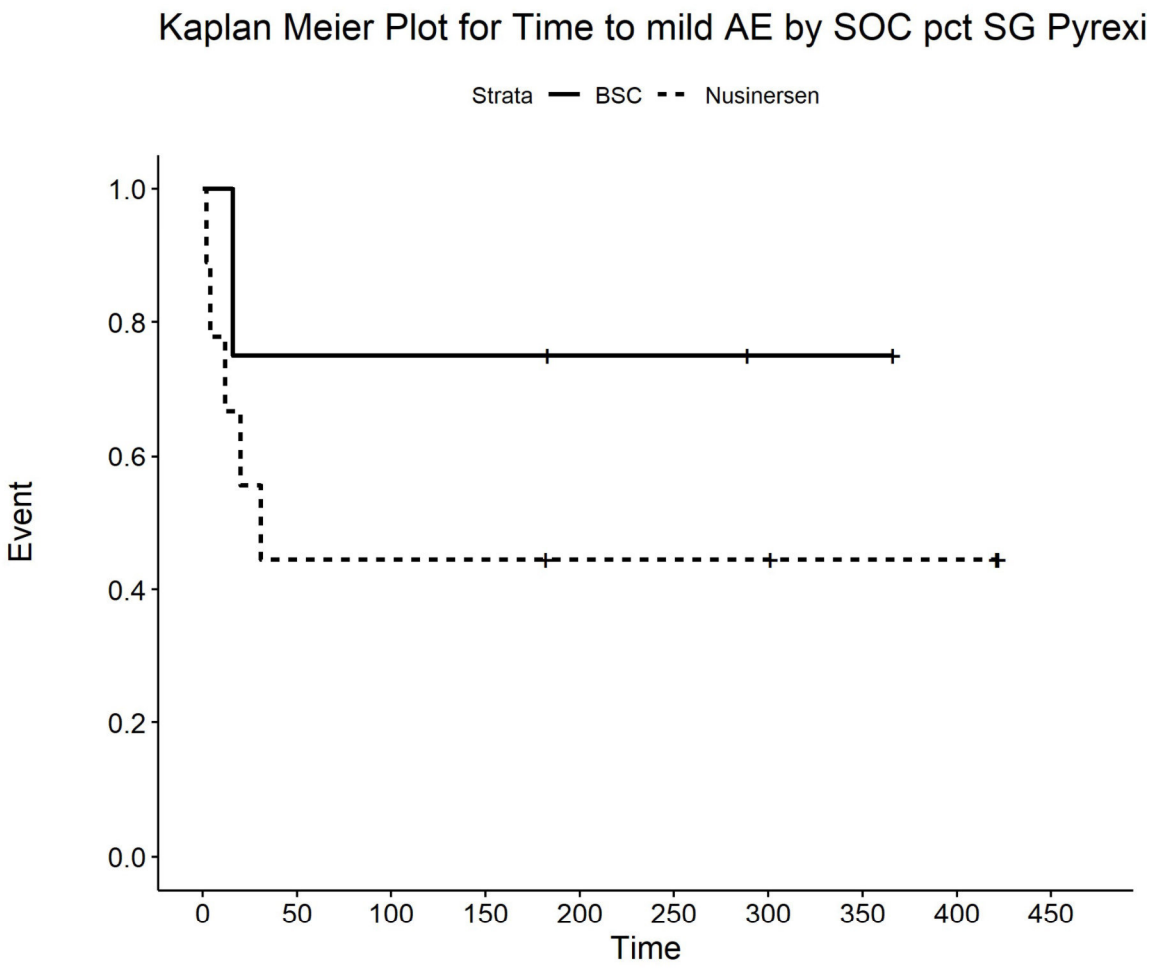
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	5	4	4	4	4	4	2	2	0



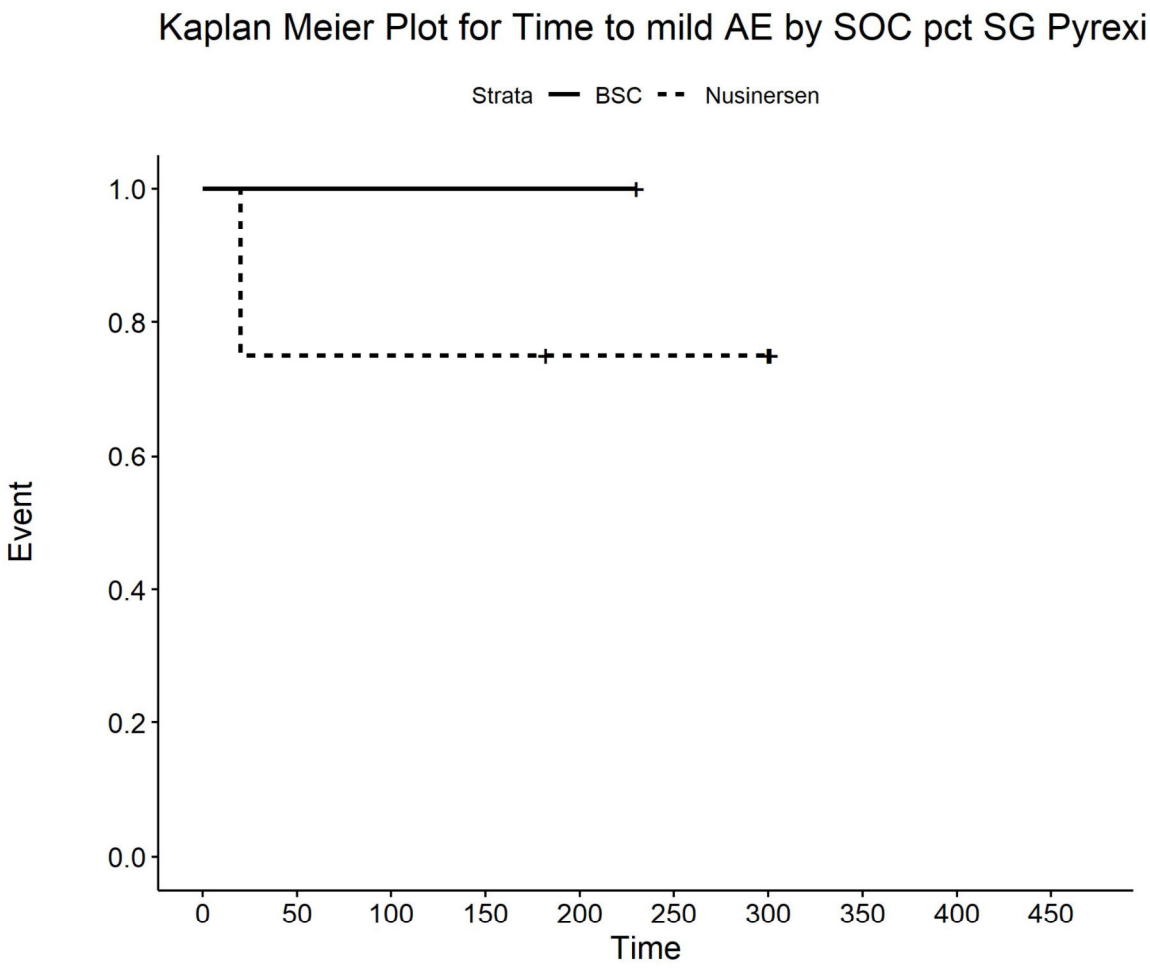
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	1	1	0



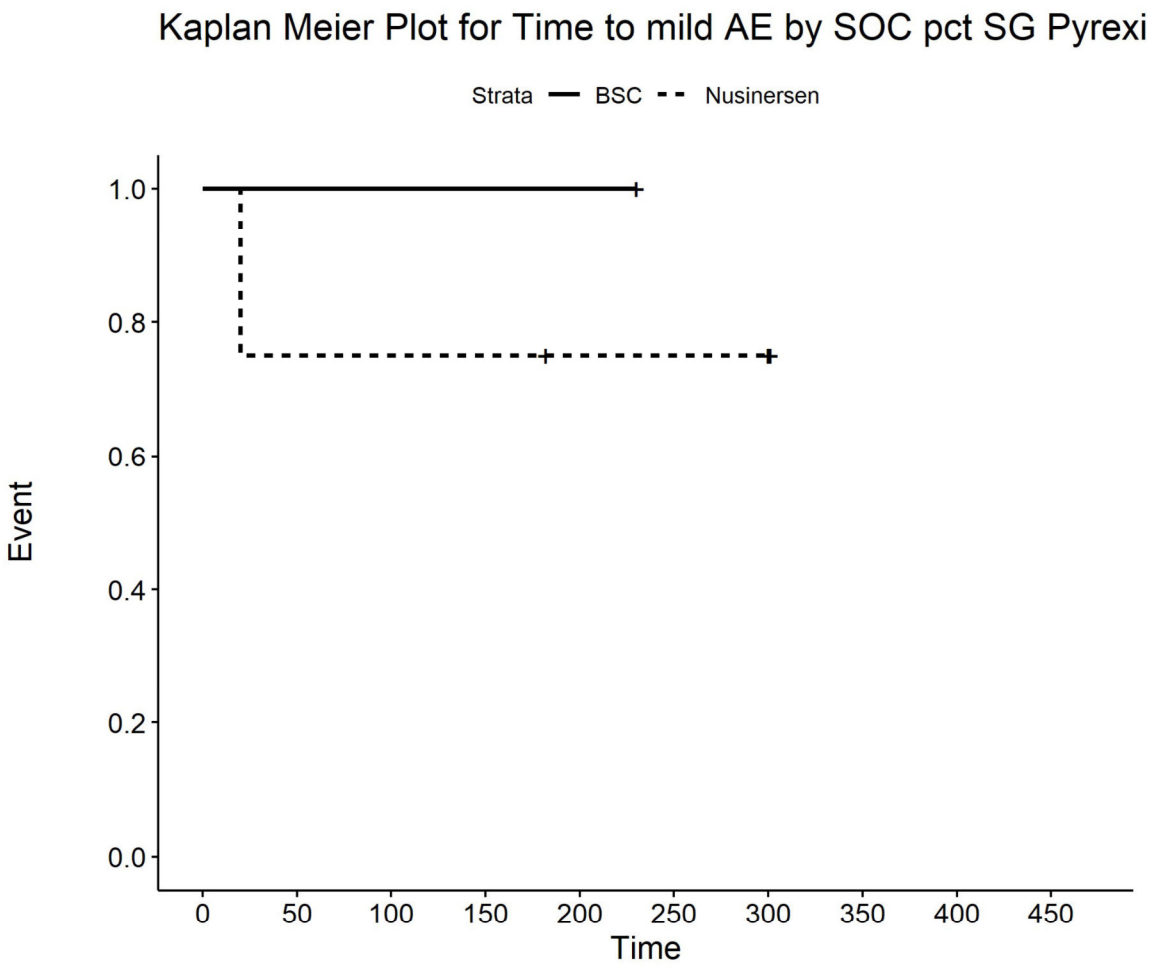
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	4	4	4	3	3	3	2	2	0



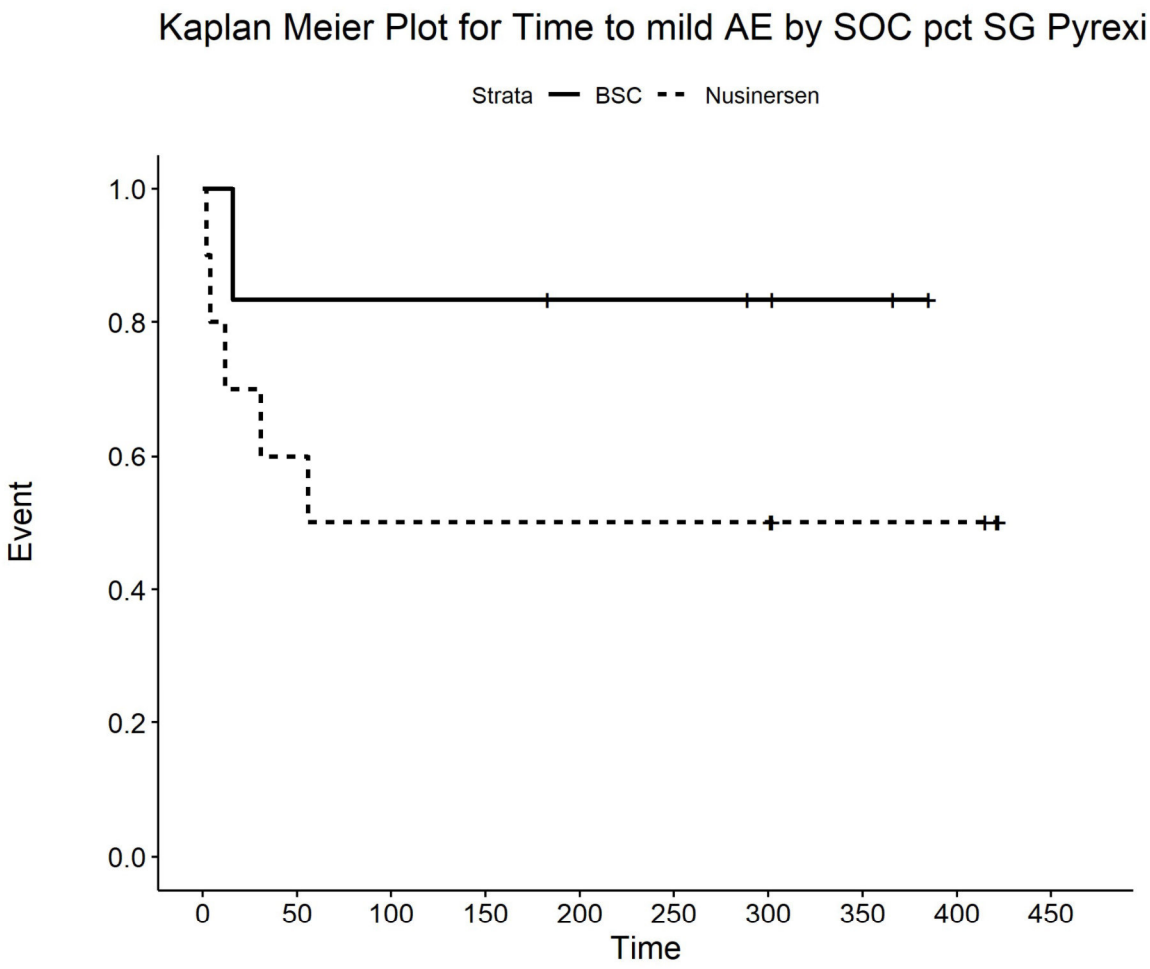
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



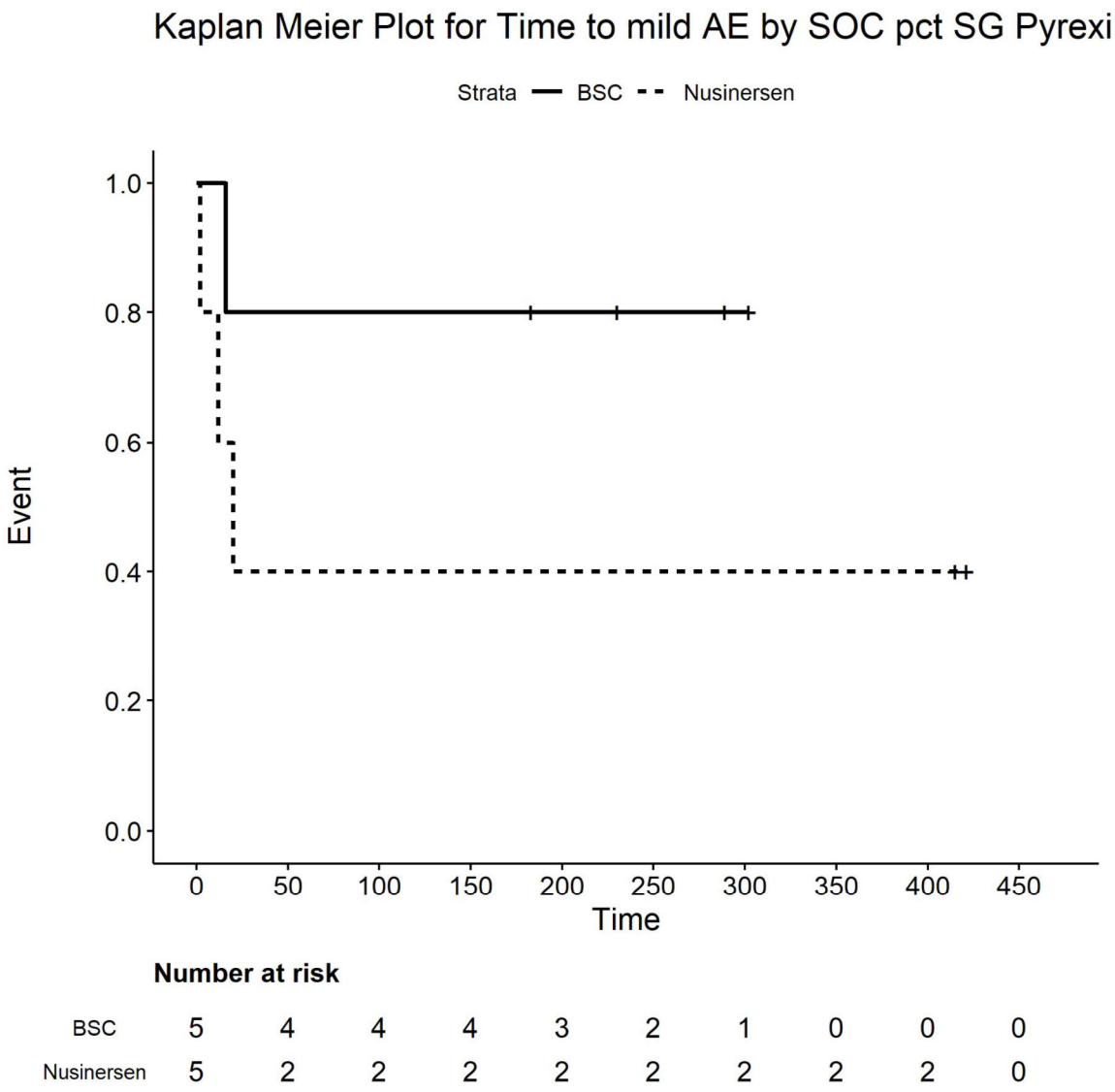
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



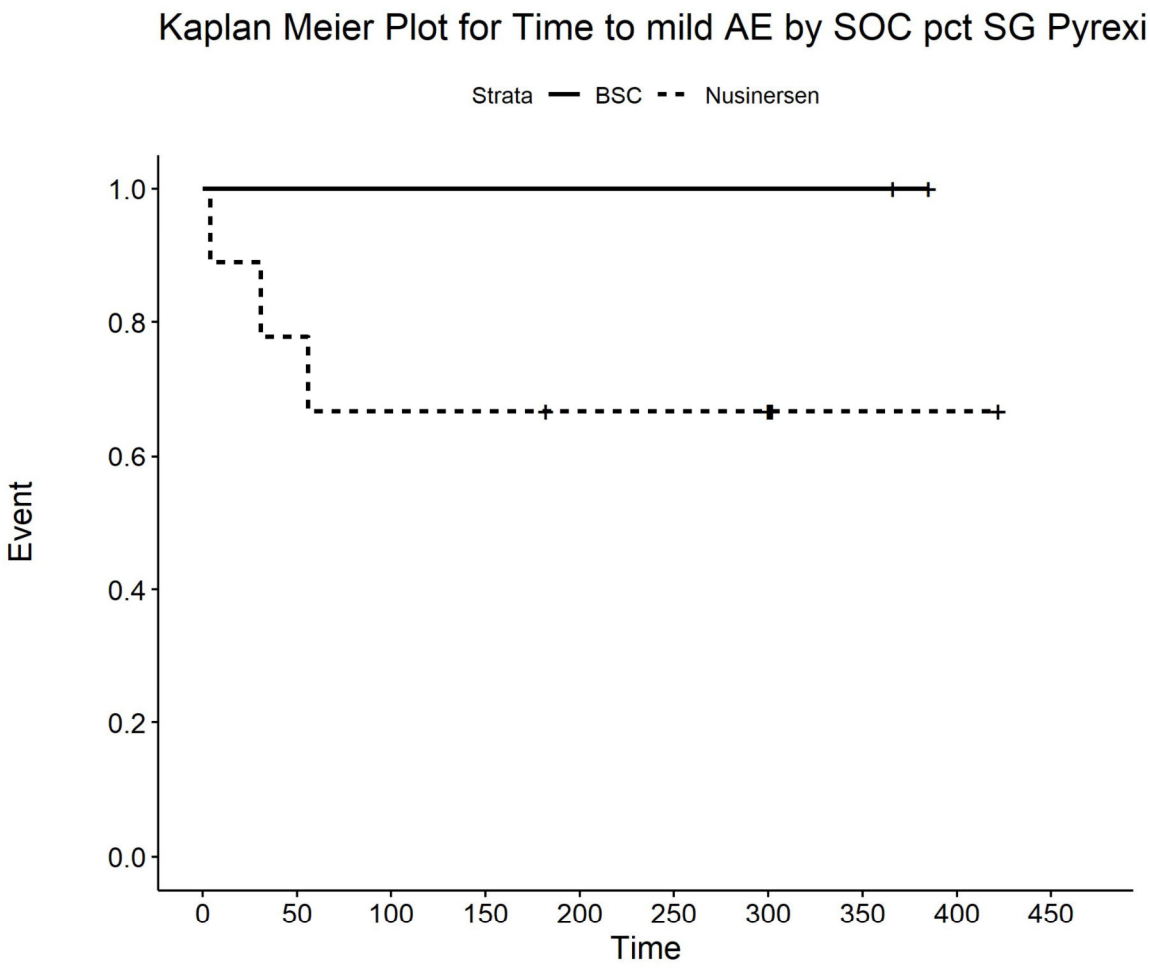
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	6	5	5	5	5	5	3	3	0



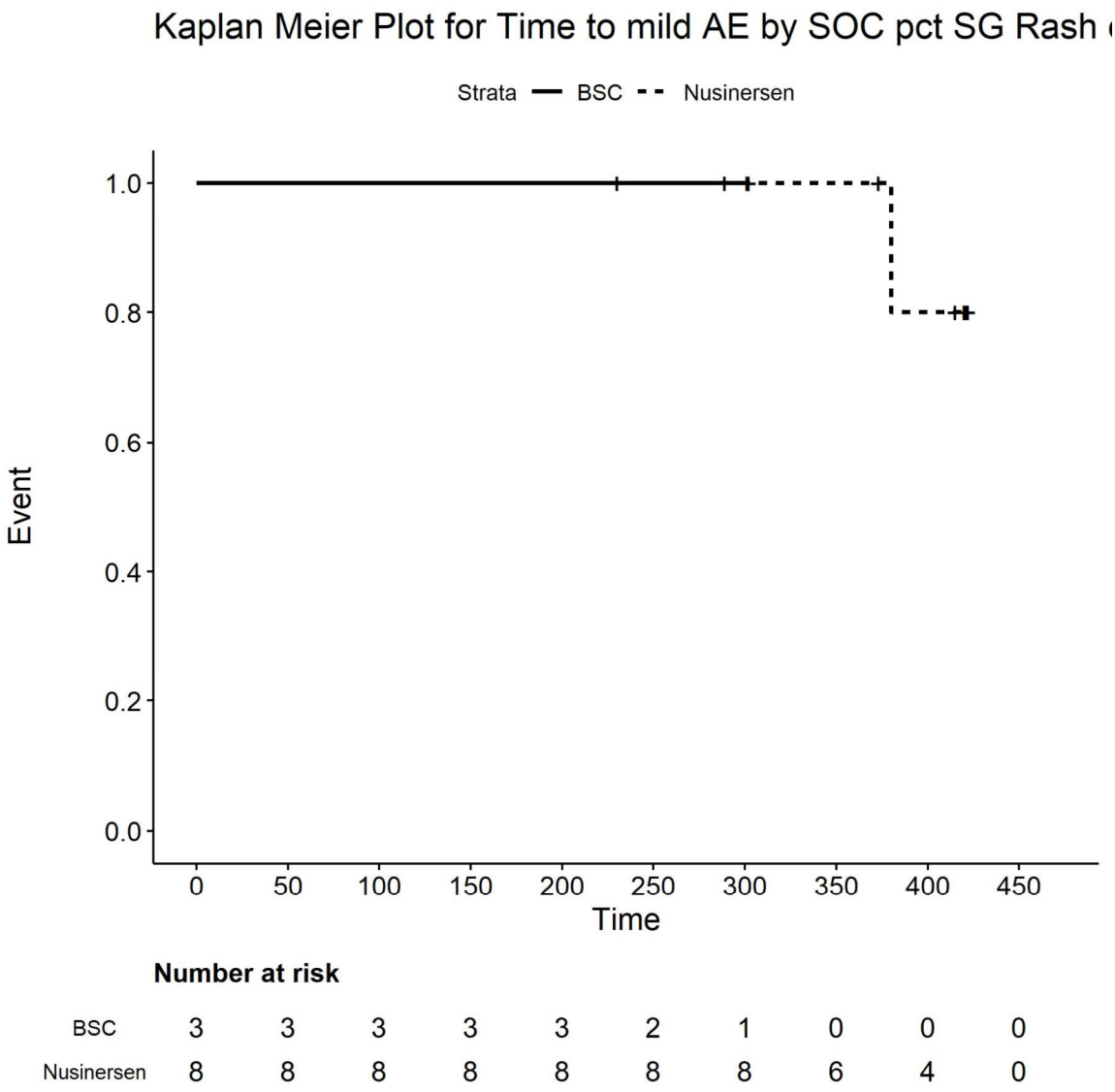
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	2	2	2	2	2	2	2	2	0



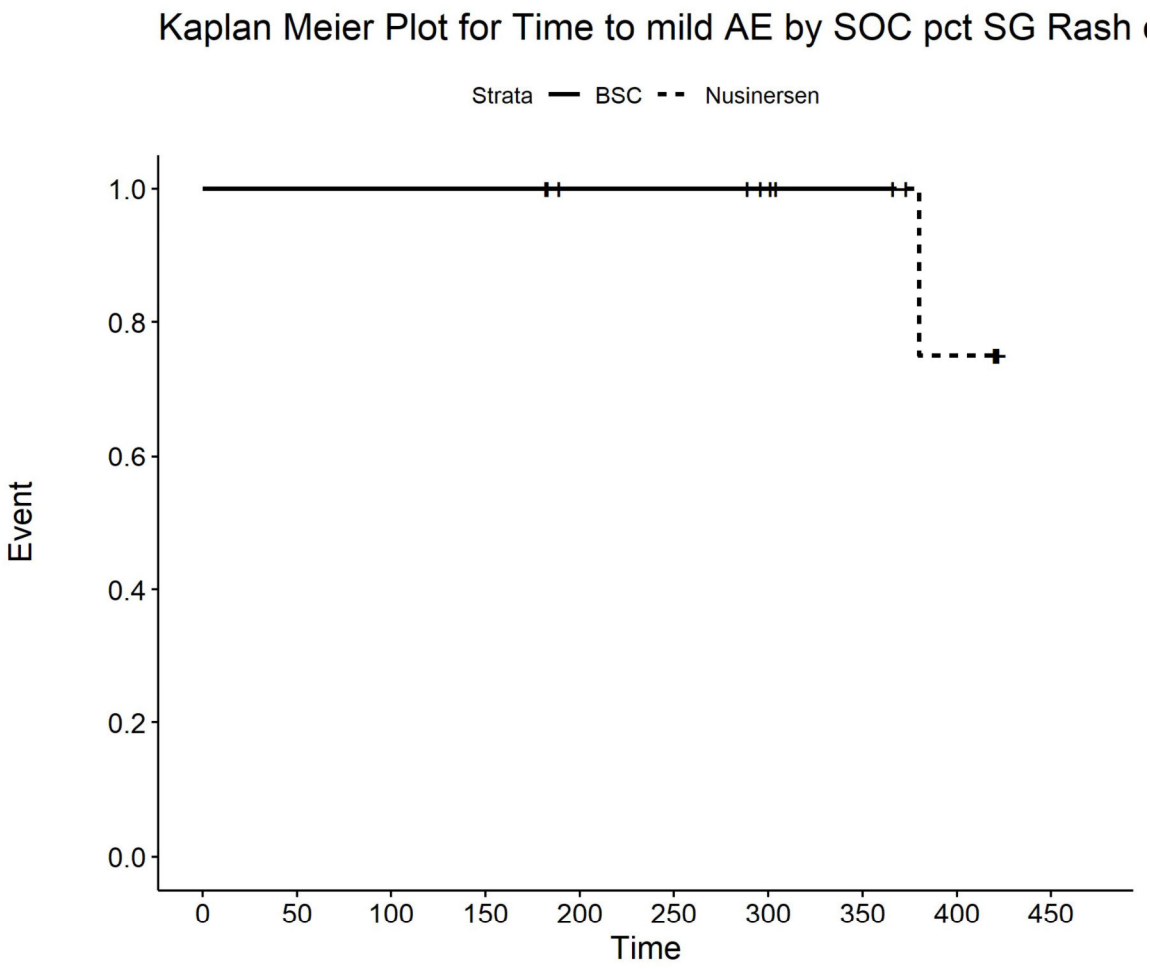
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	6	6	5	5	5	1	1	0



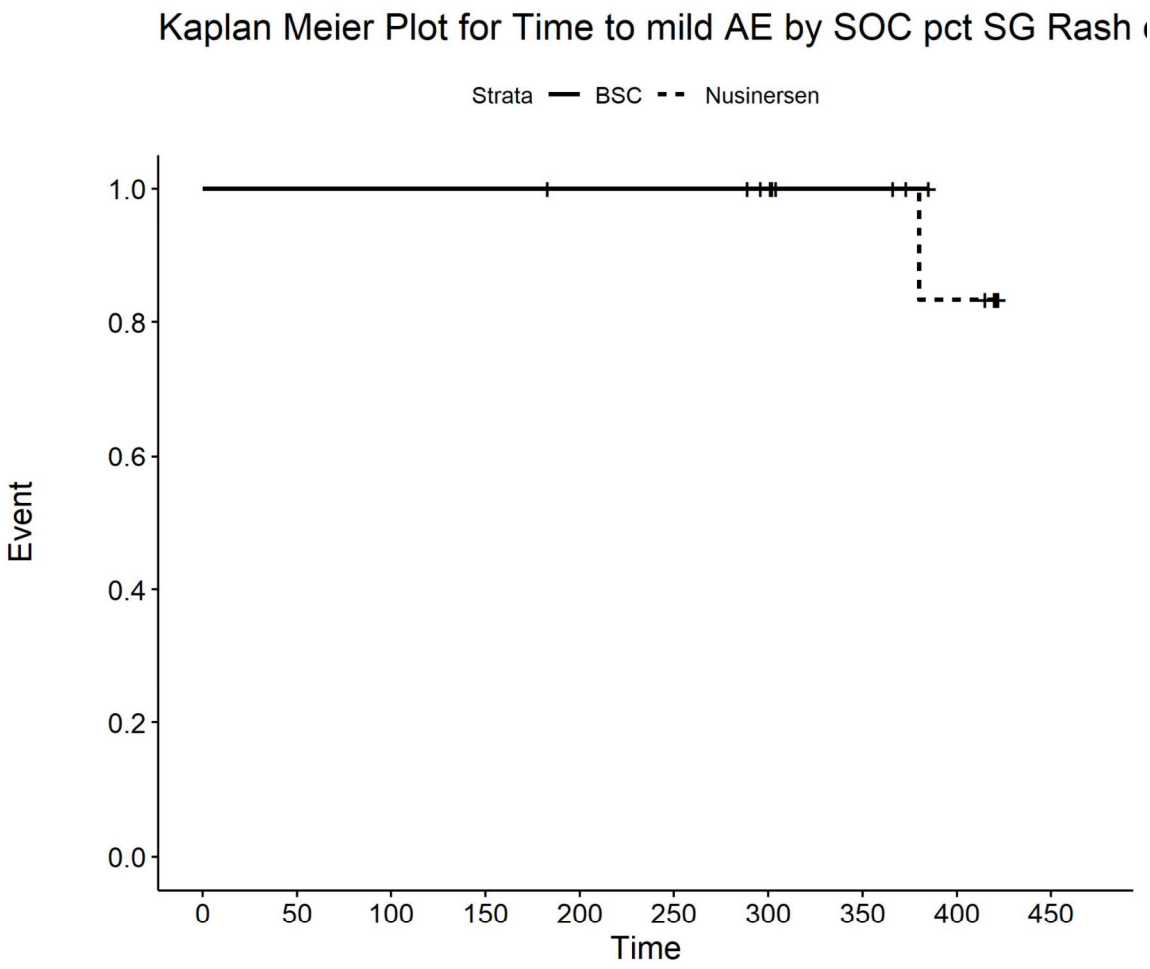
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	4	0



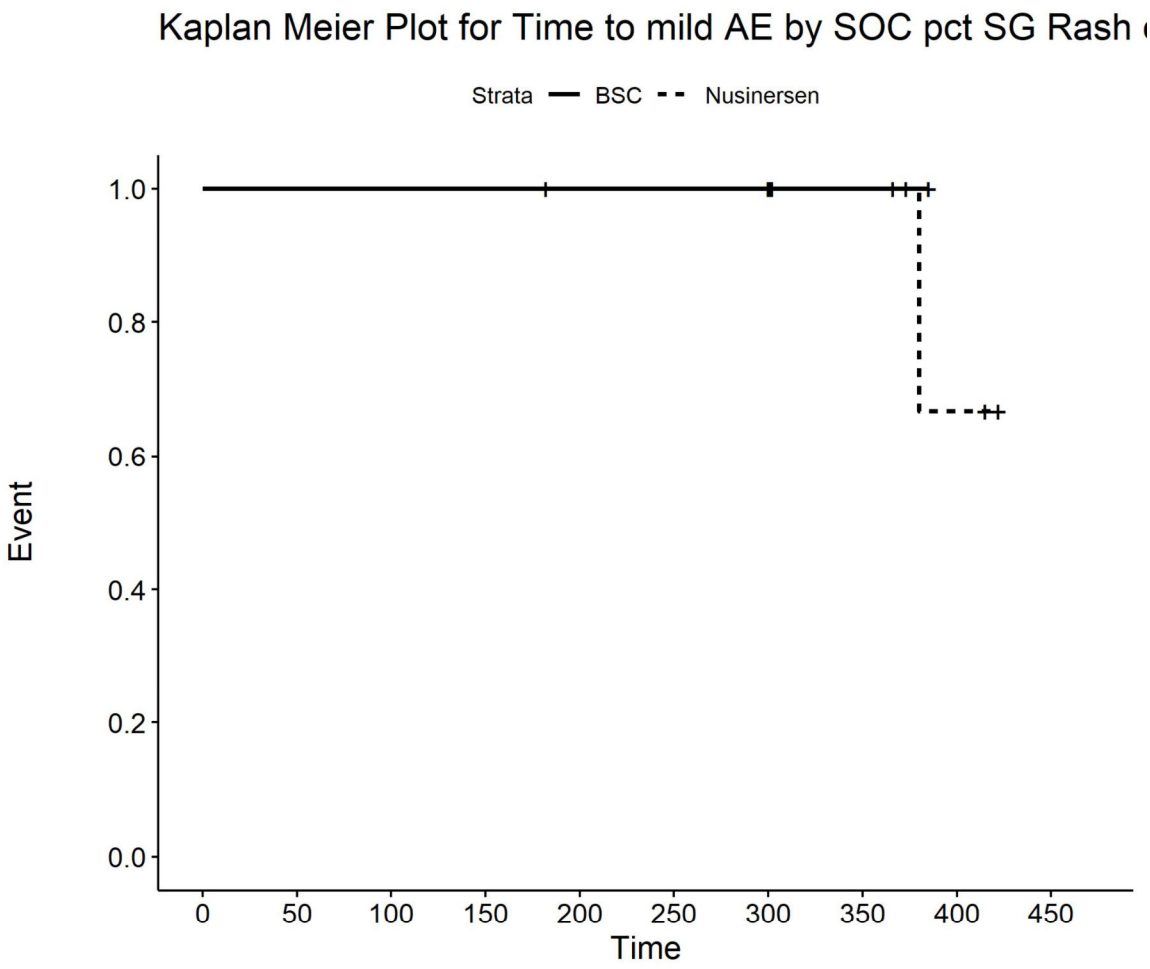
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	3	0



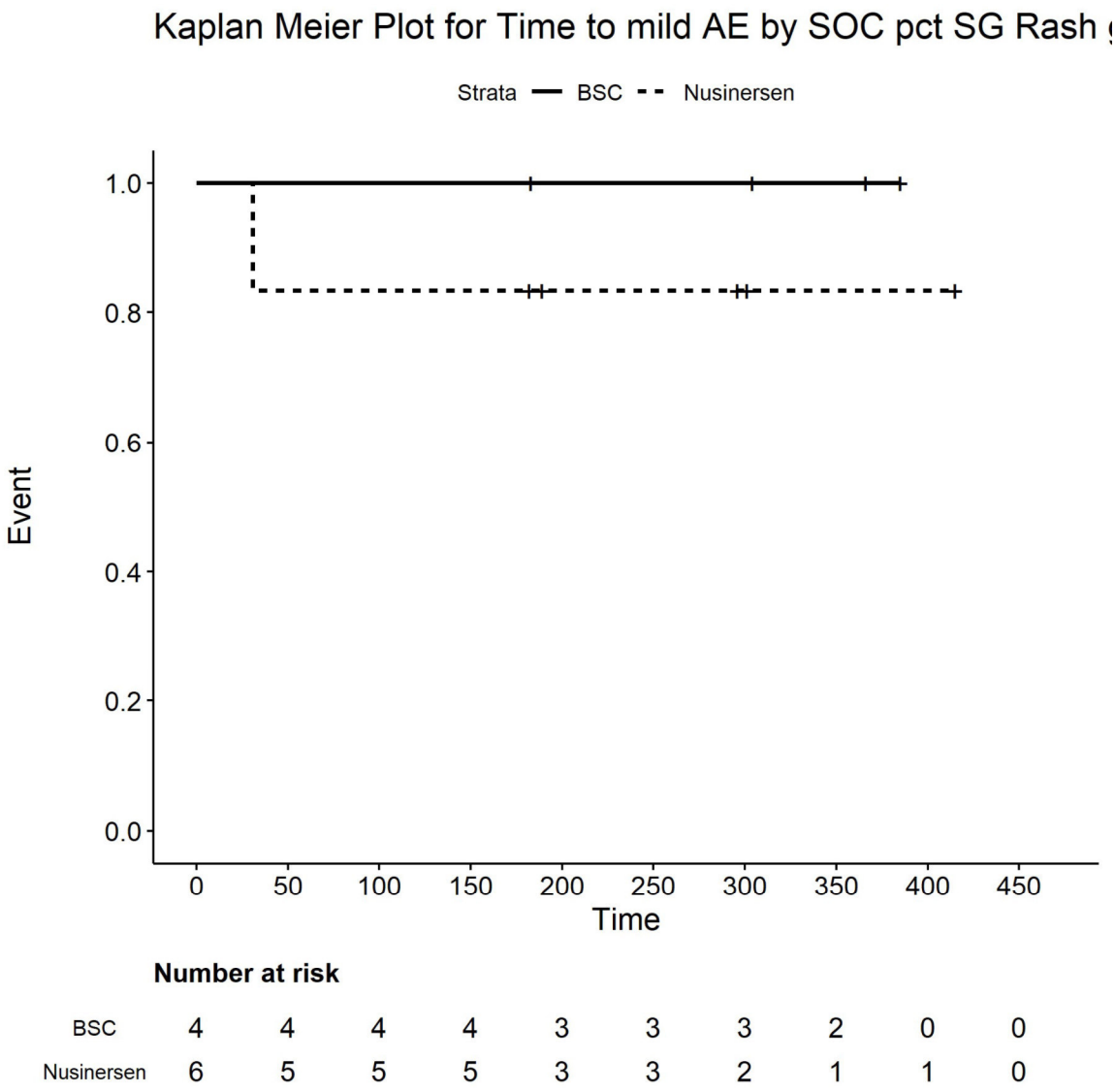
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	5	0



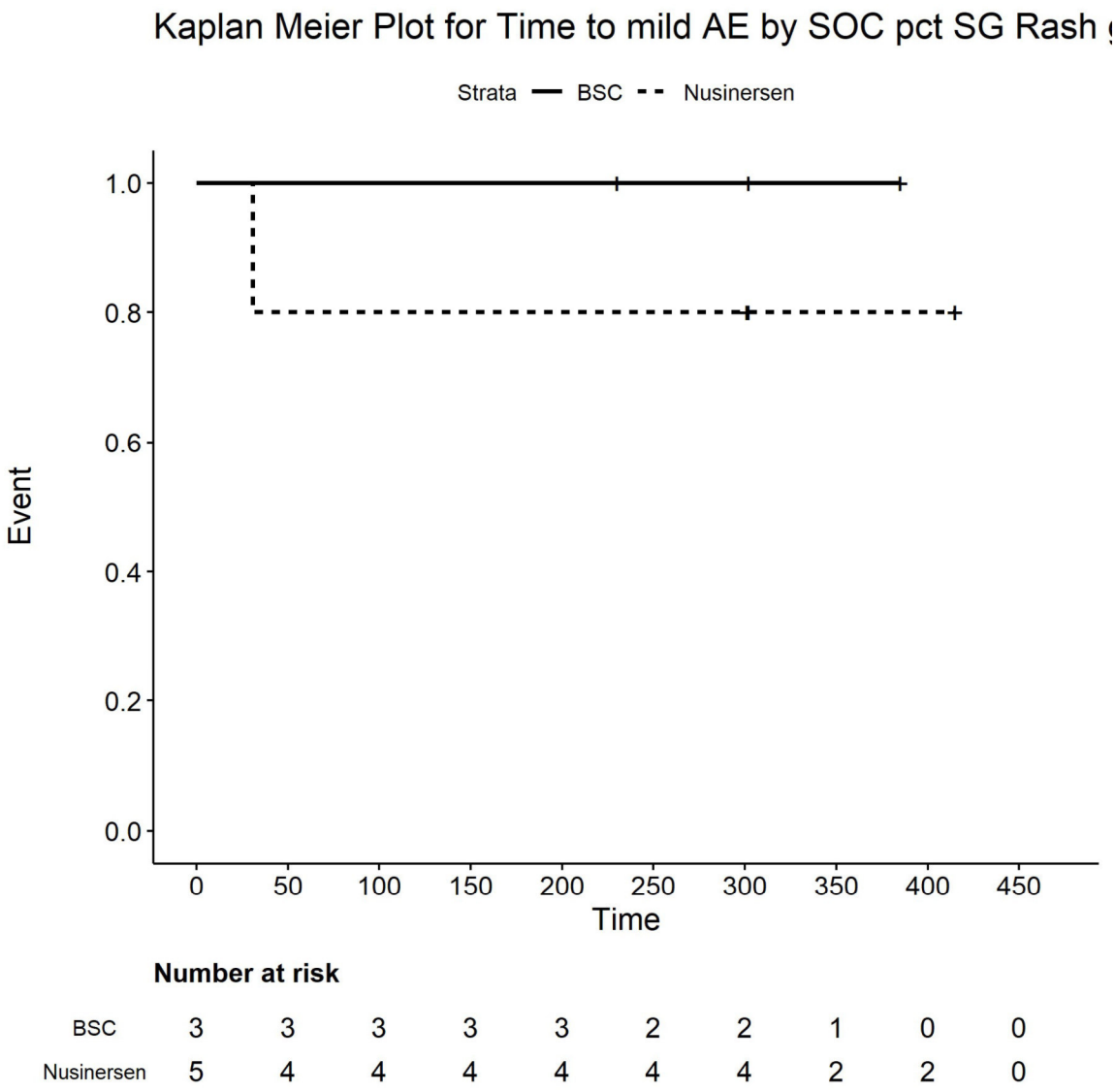
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	8	4	2	0



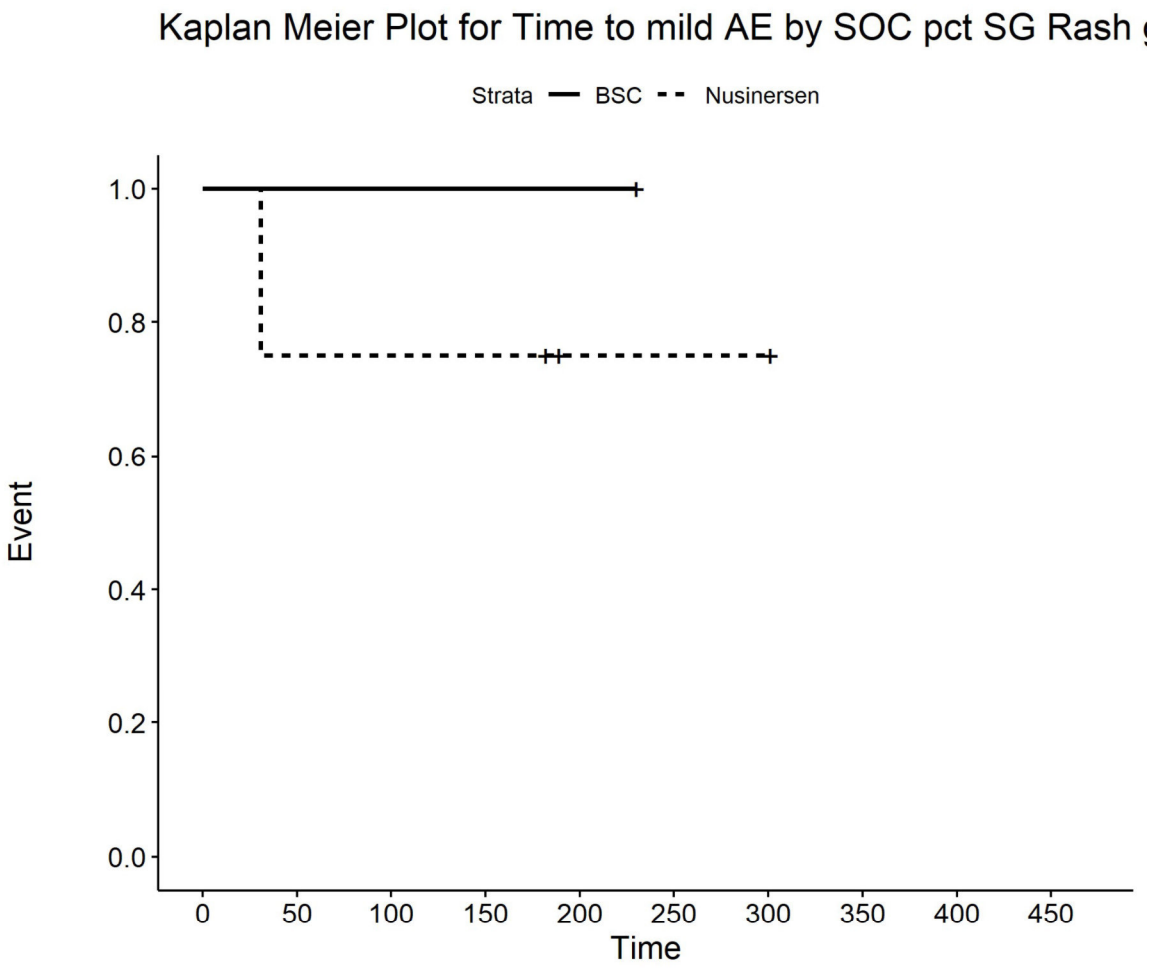
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	2	1	1	0



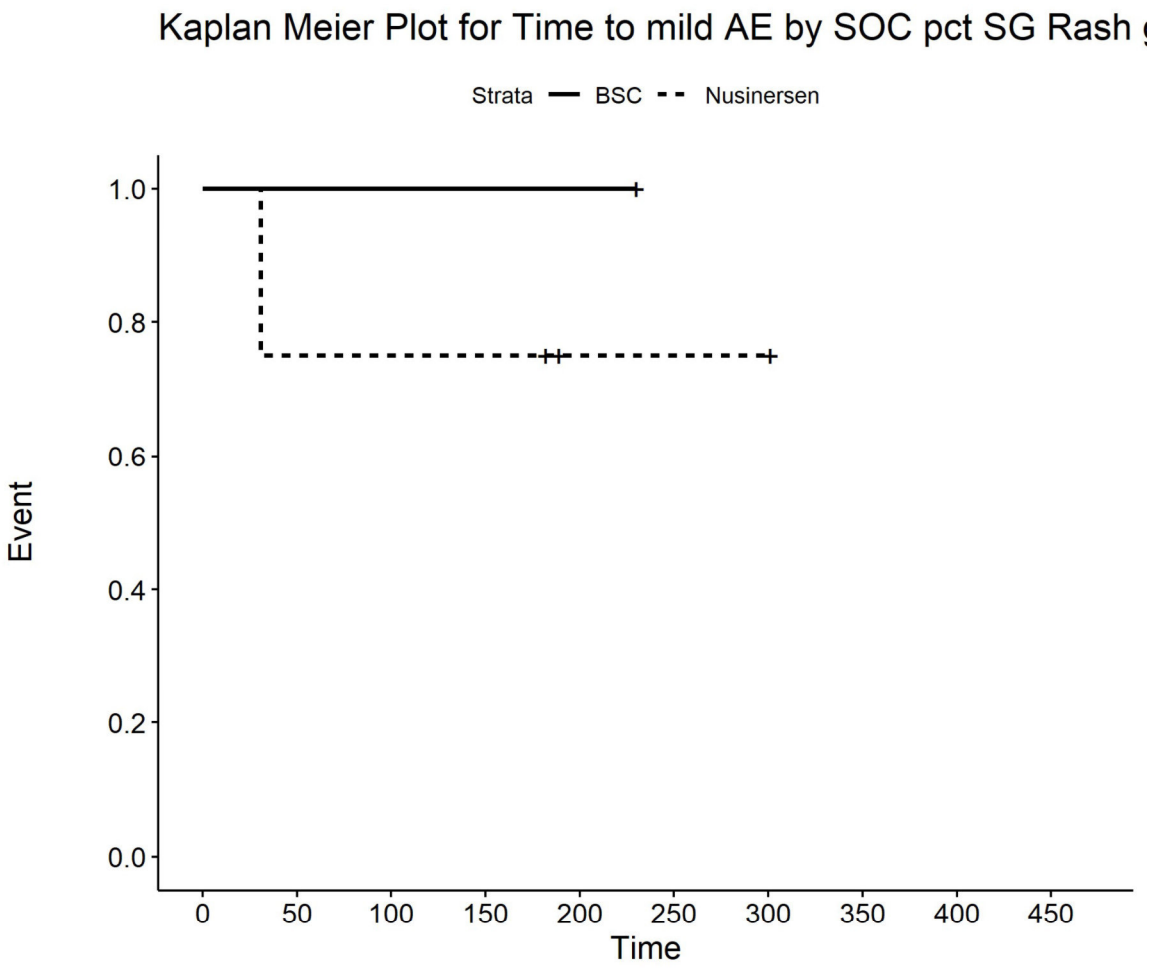
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



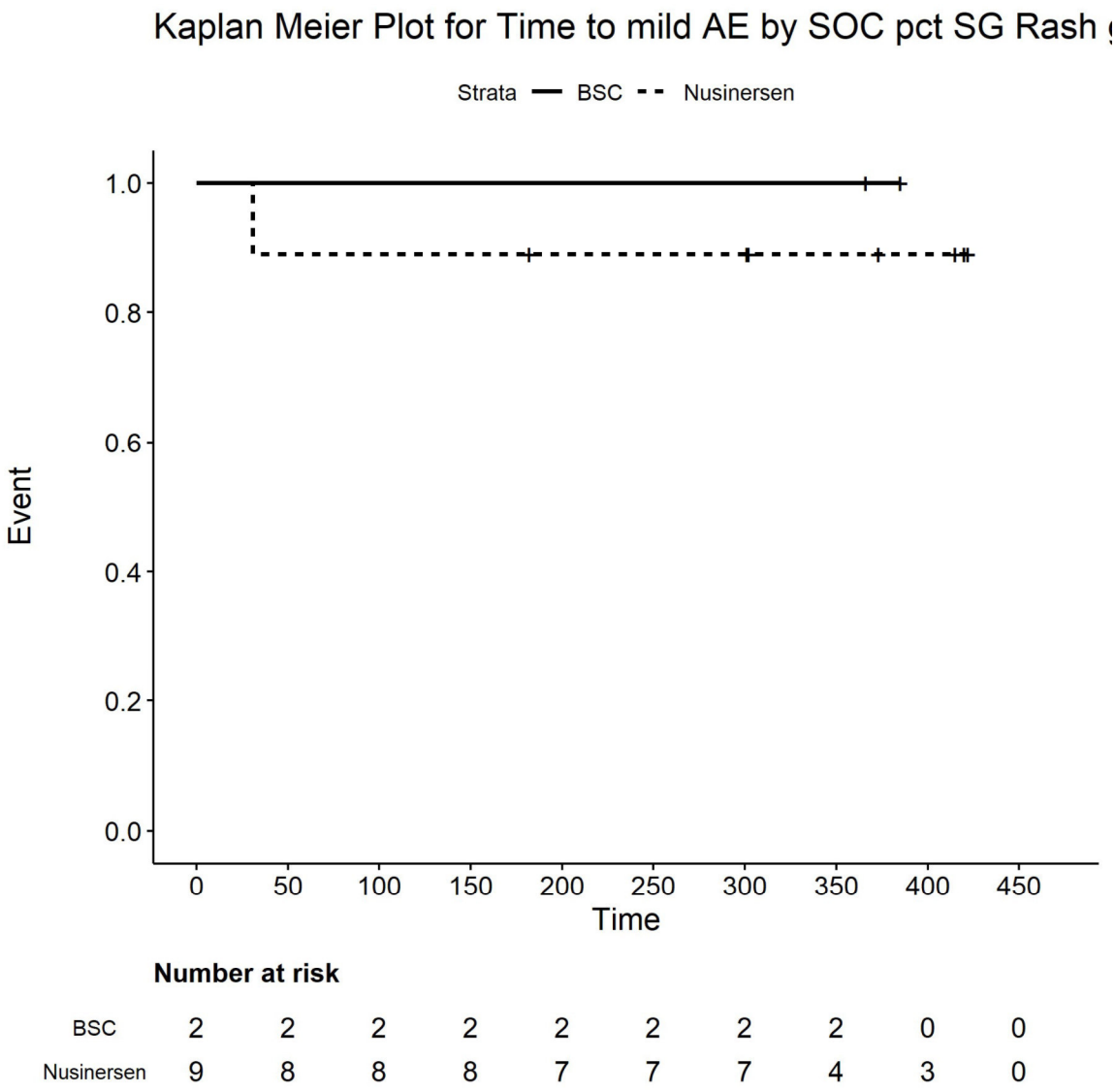
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



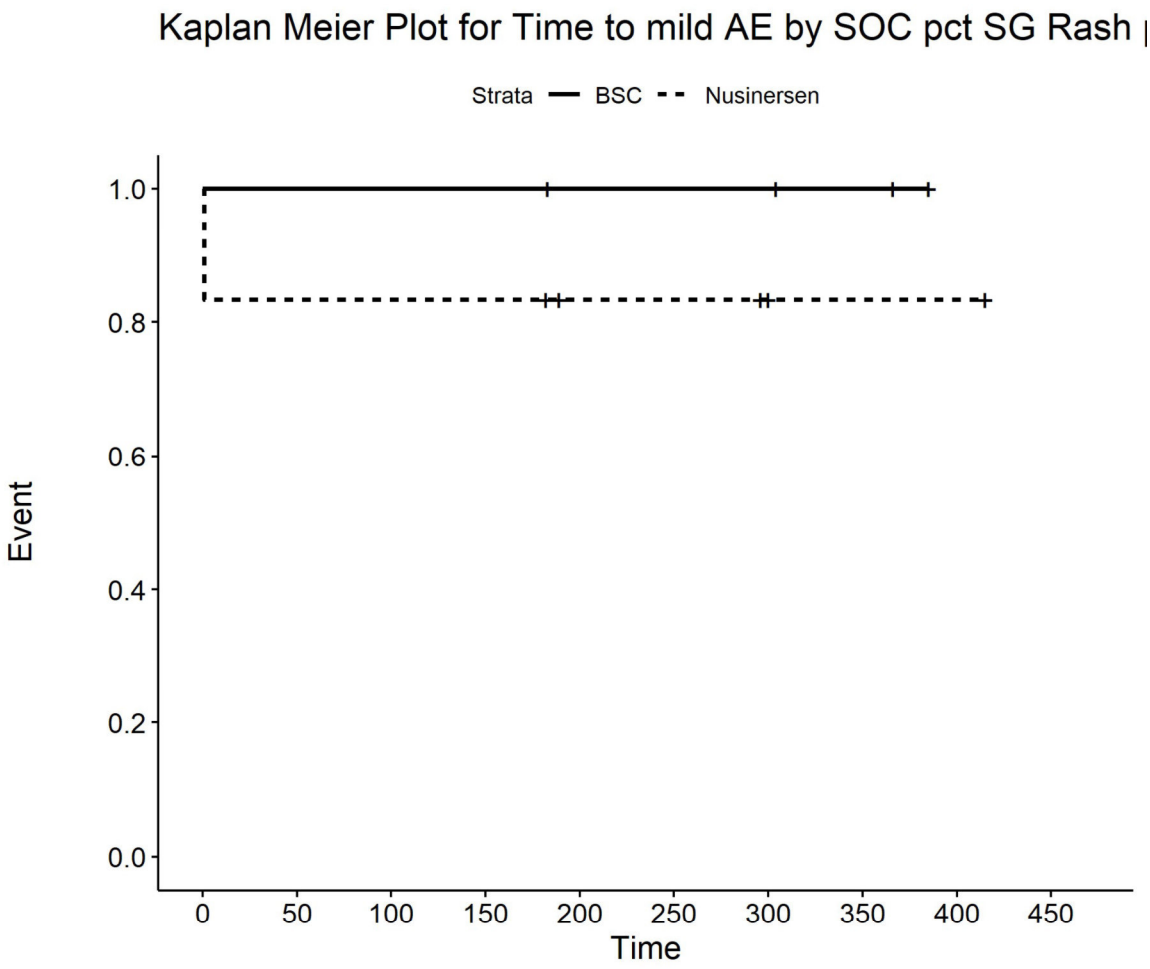
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



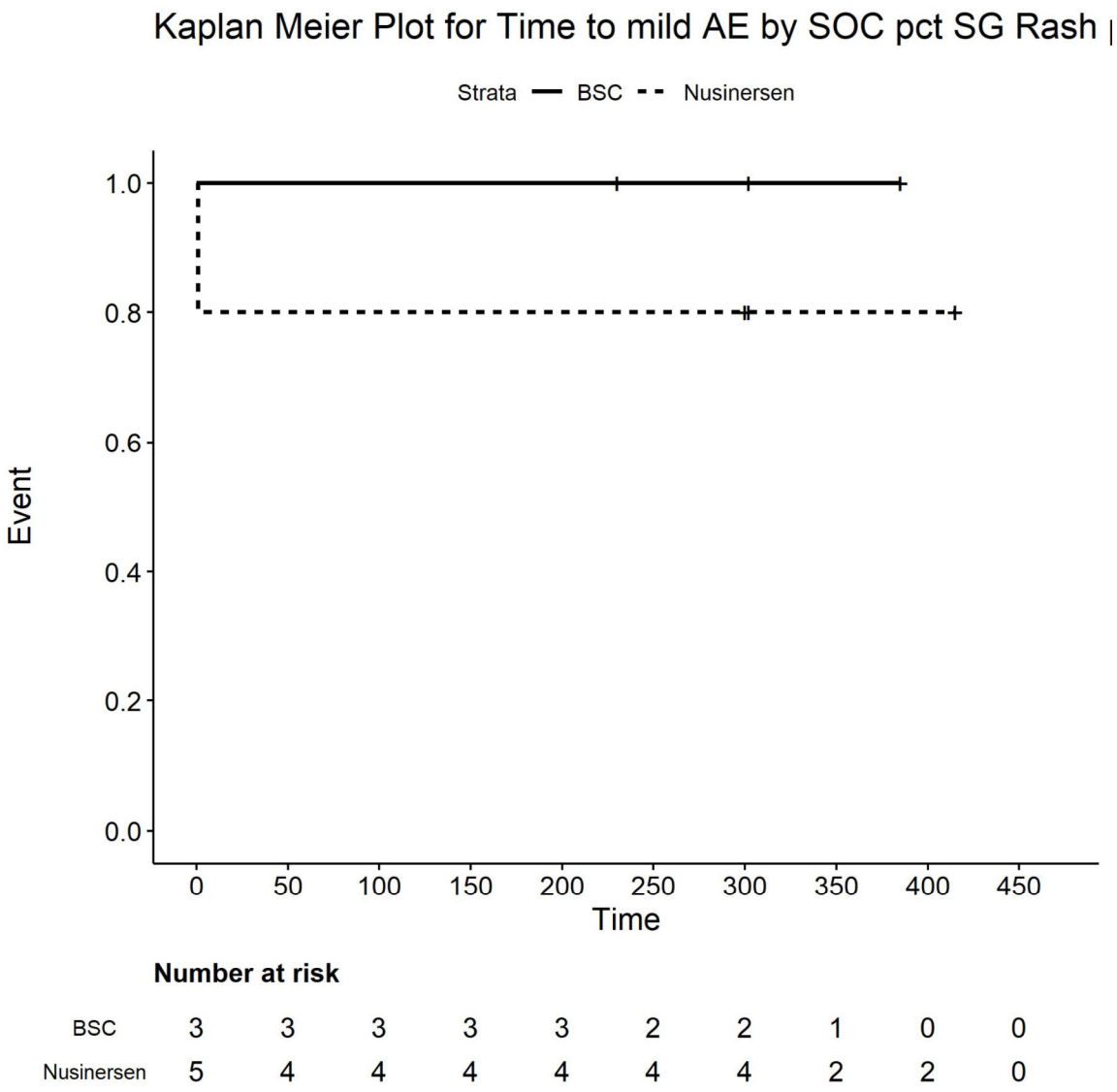
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



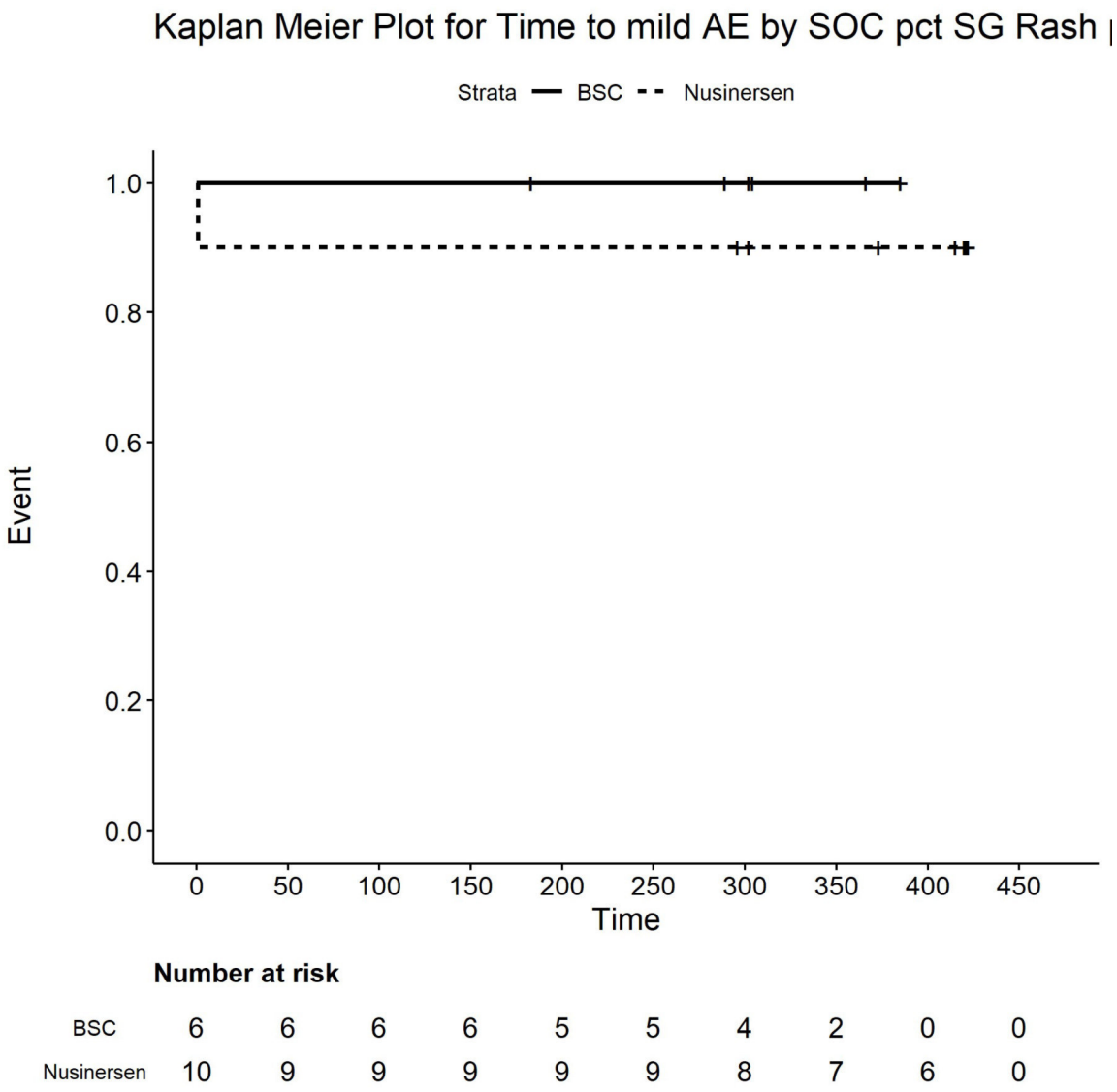
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	2	1	1	0



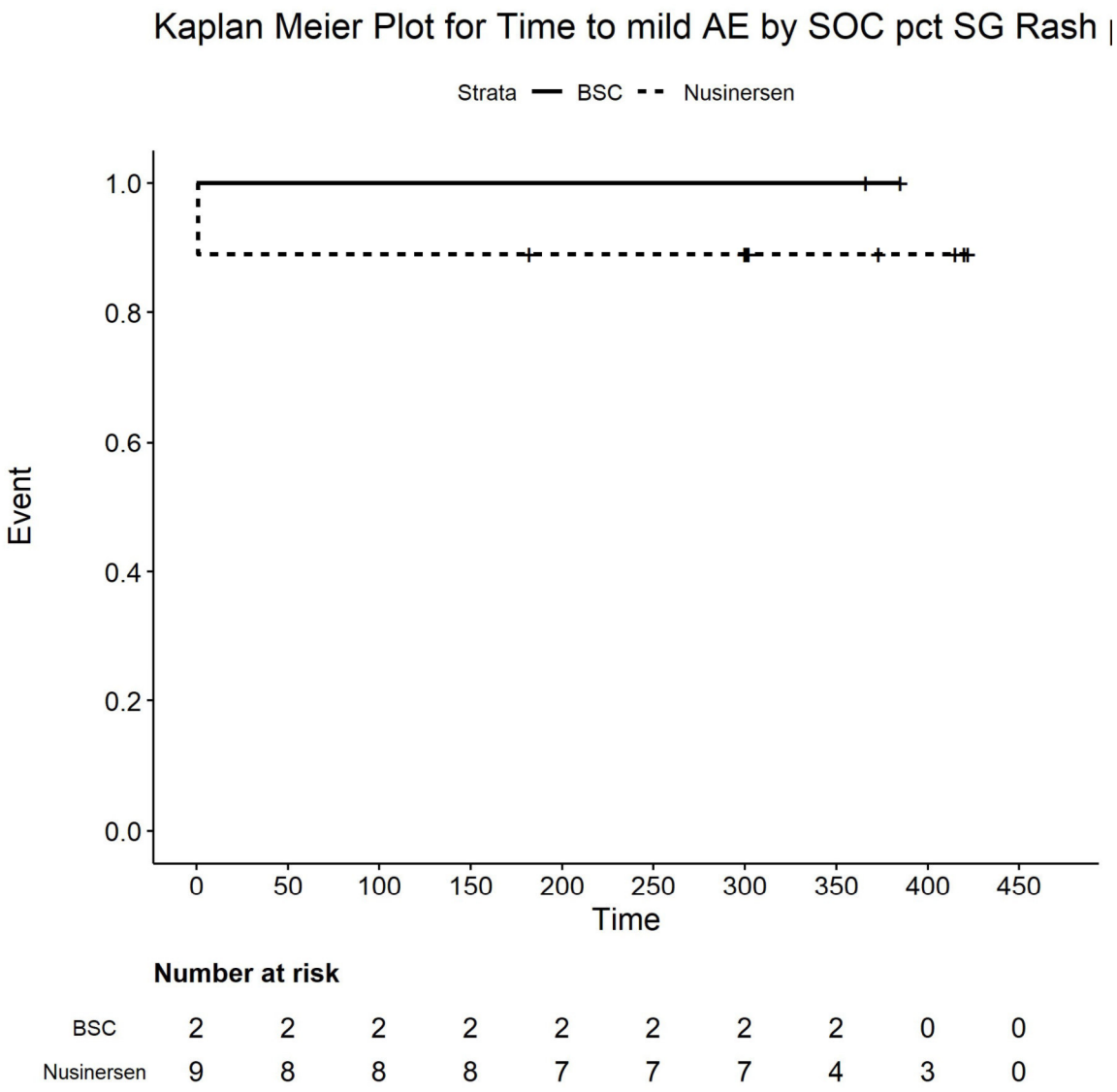
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



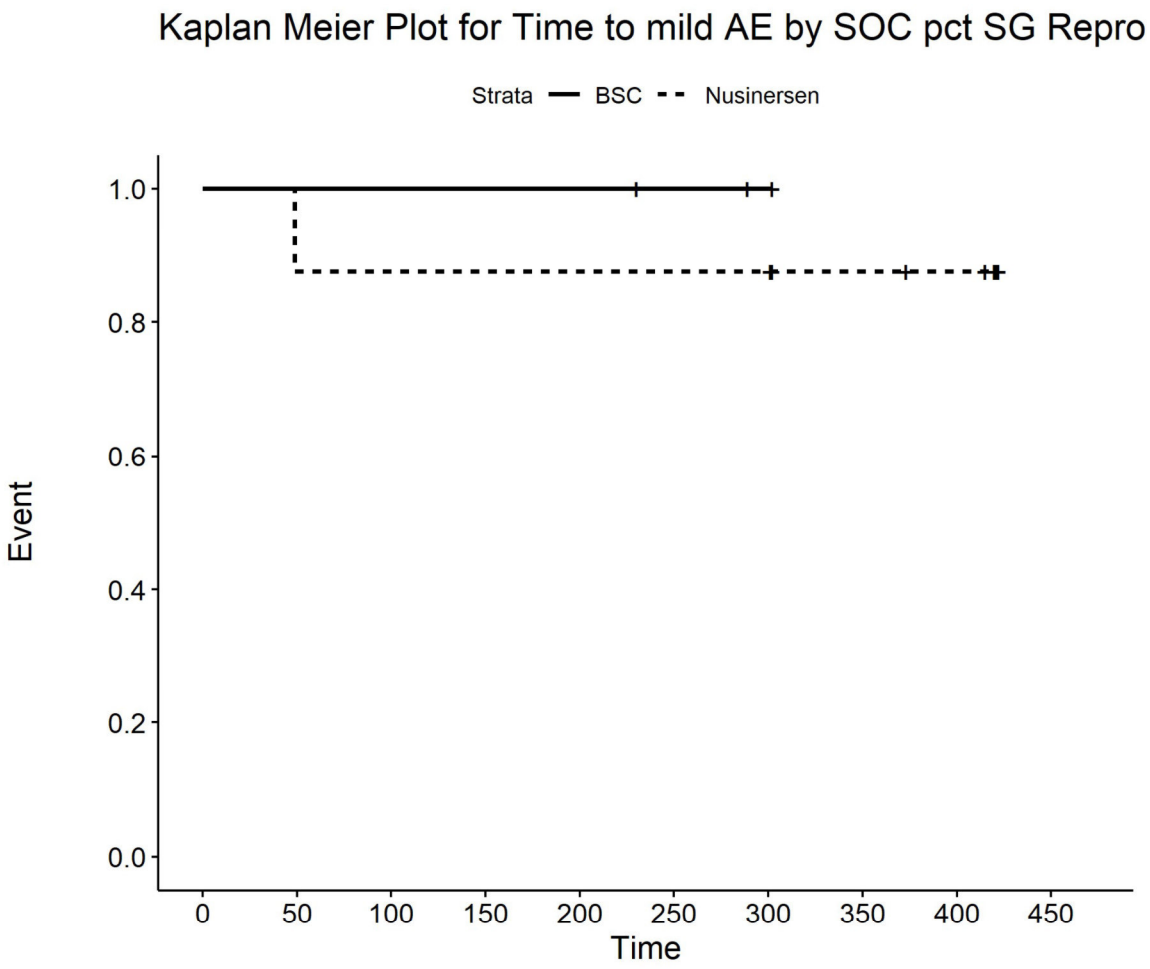
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	7	6	0



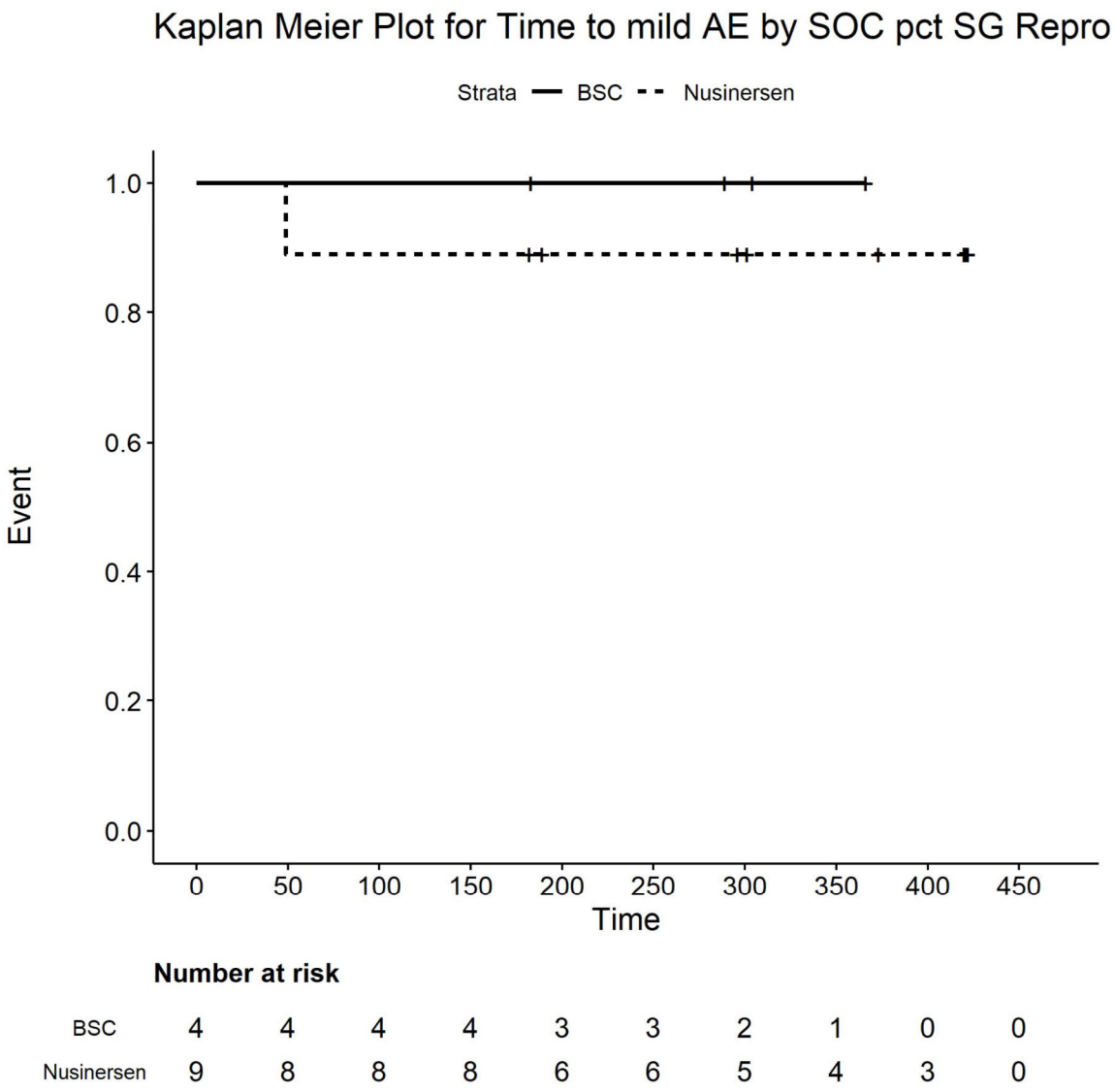
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



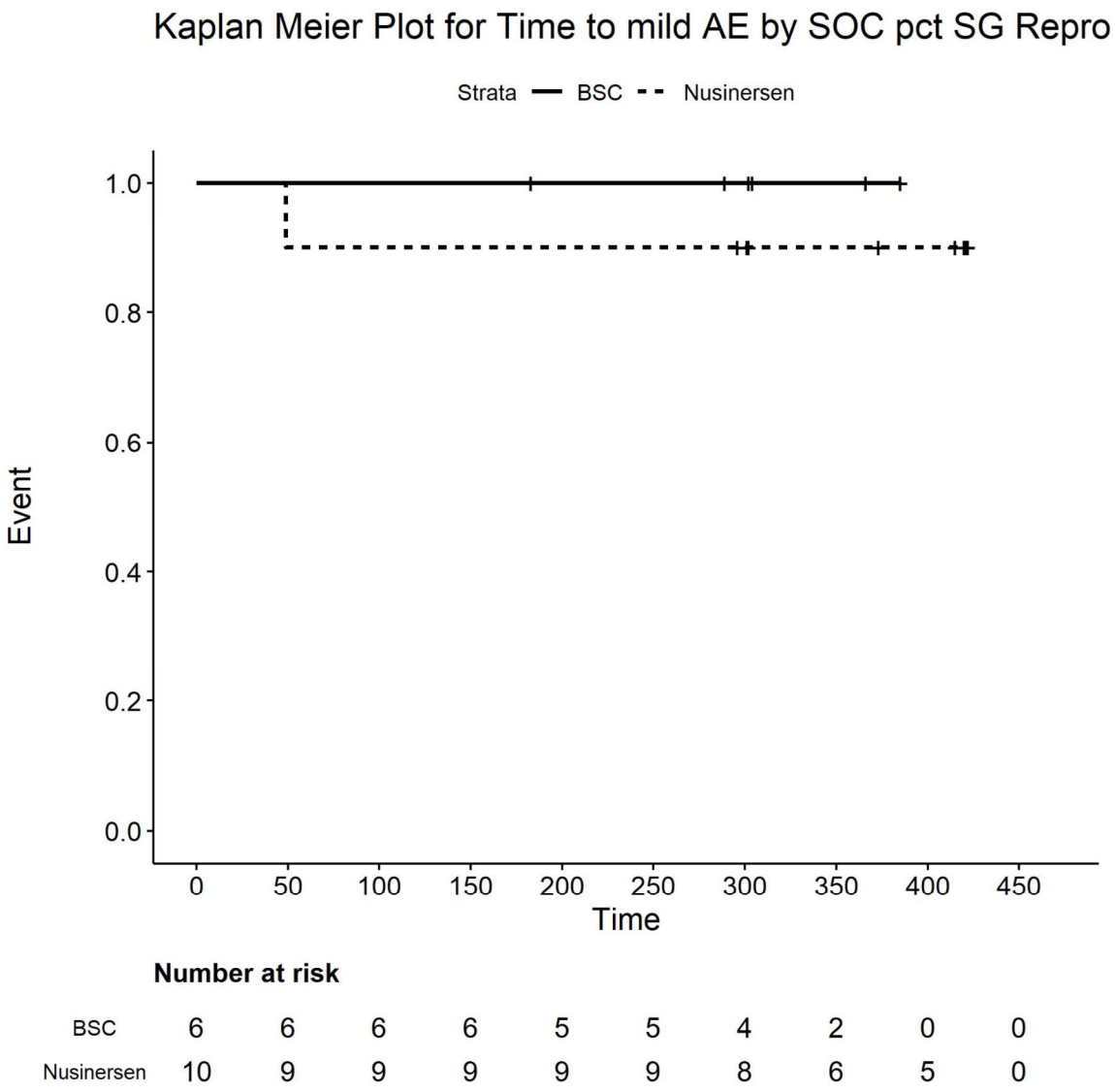
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



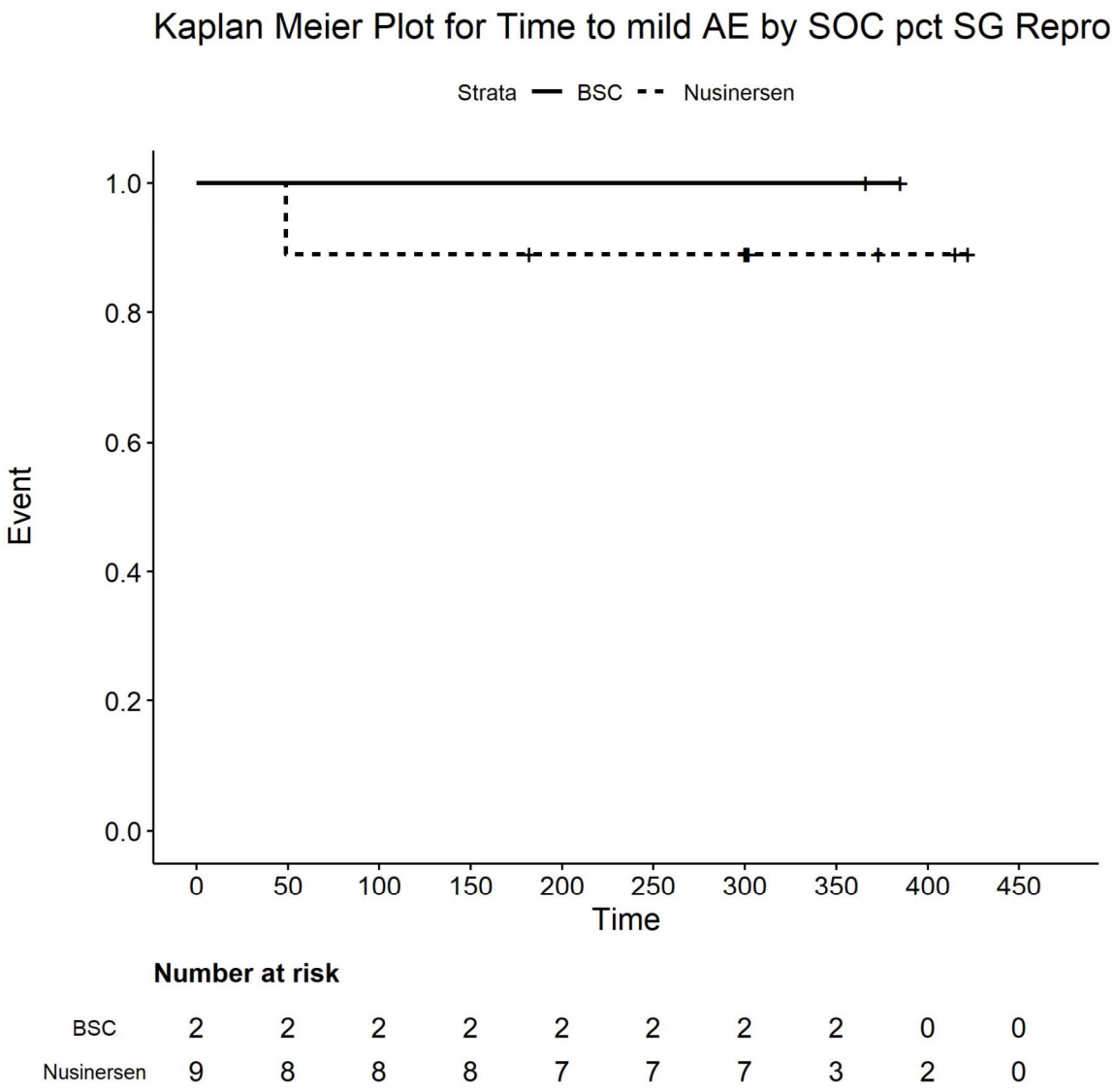
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



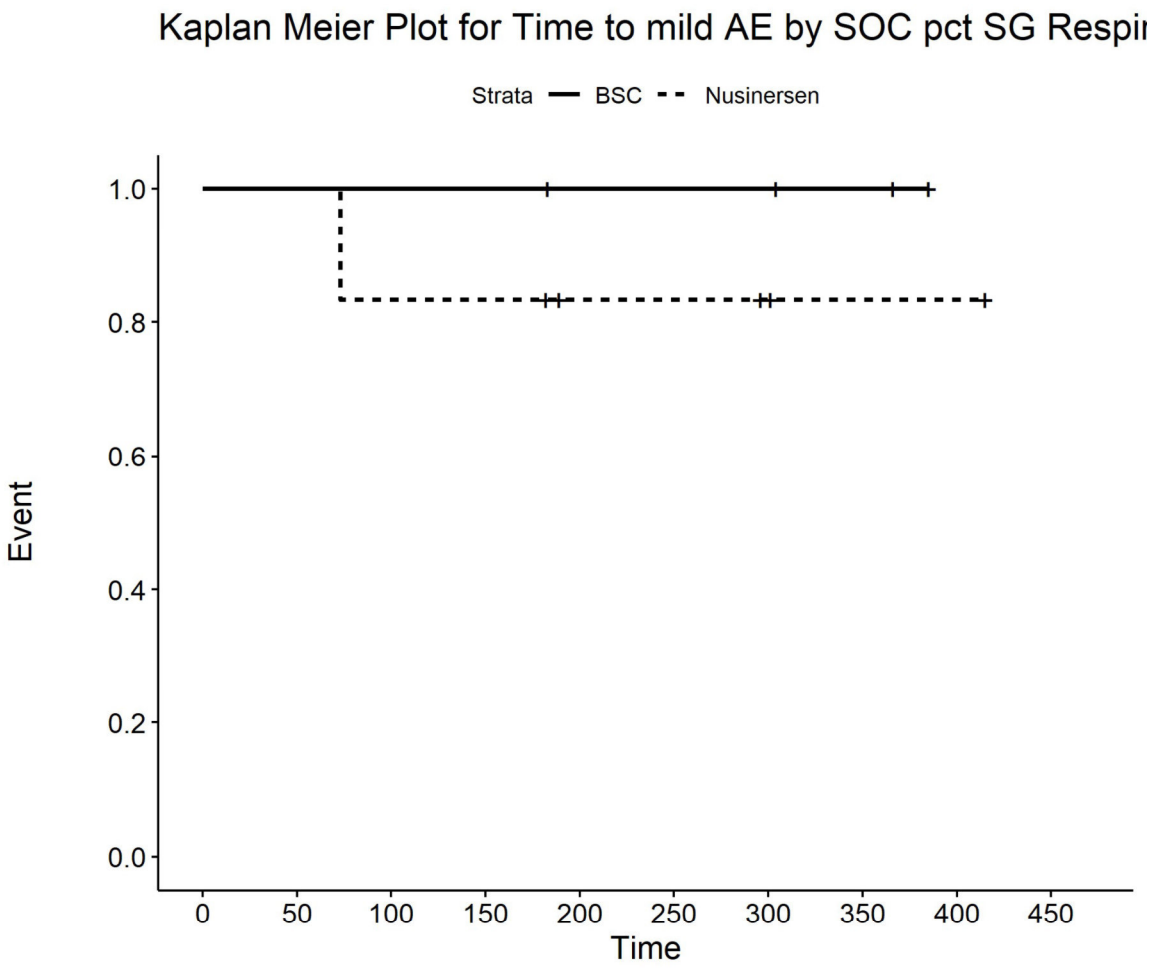
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



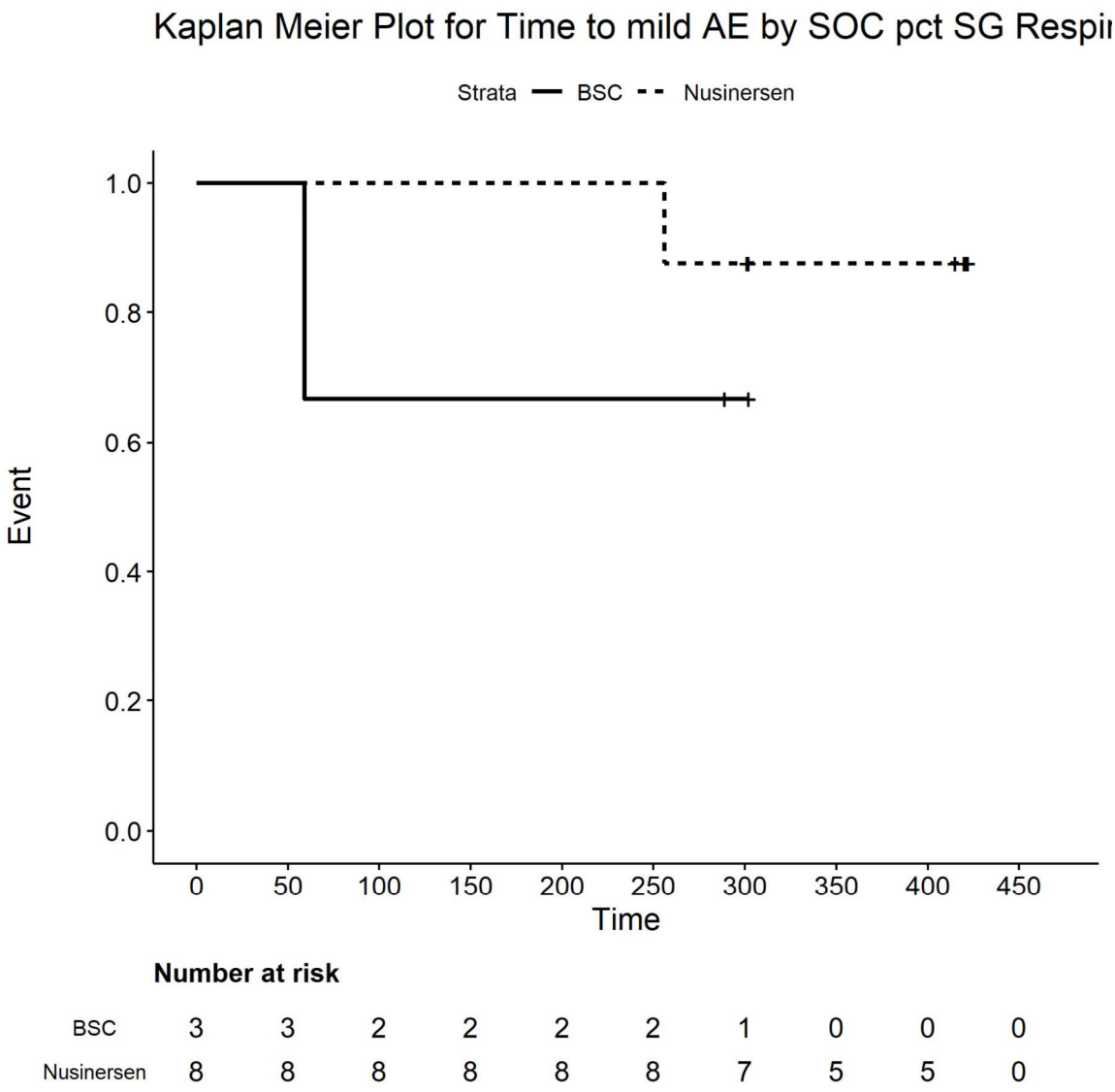
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	2	0



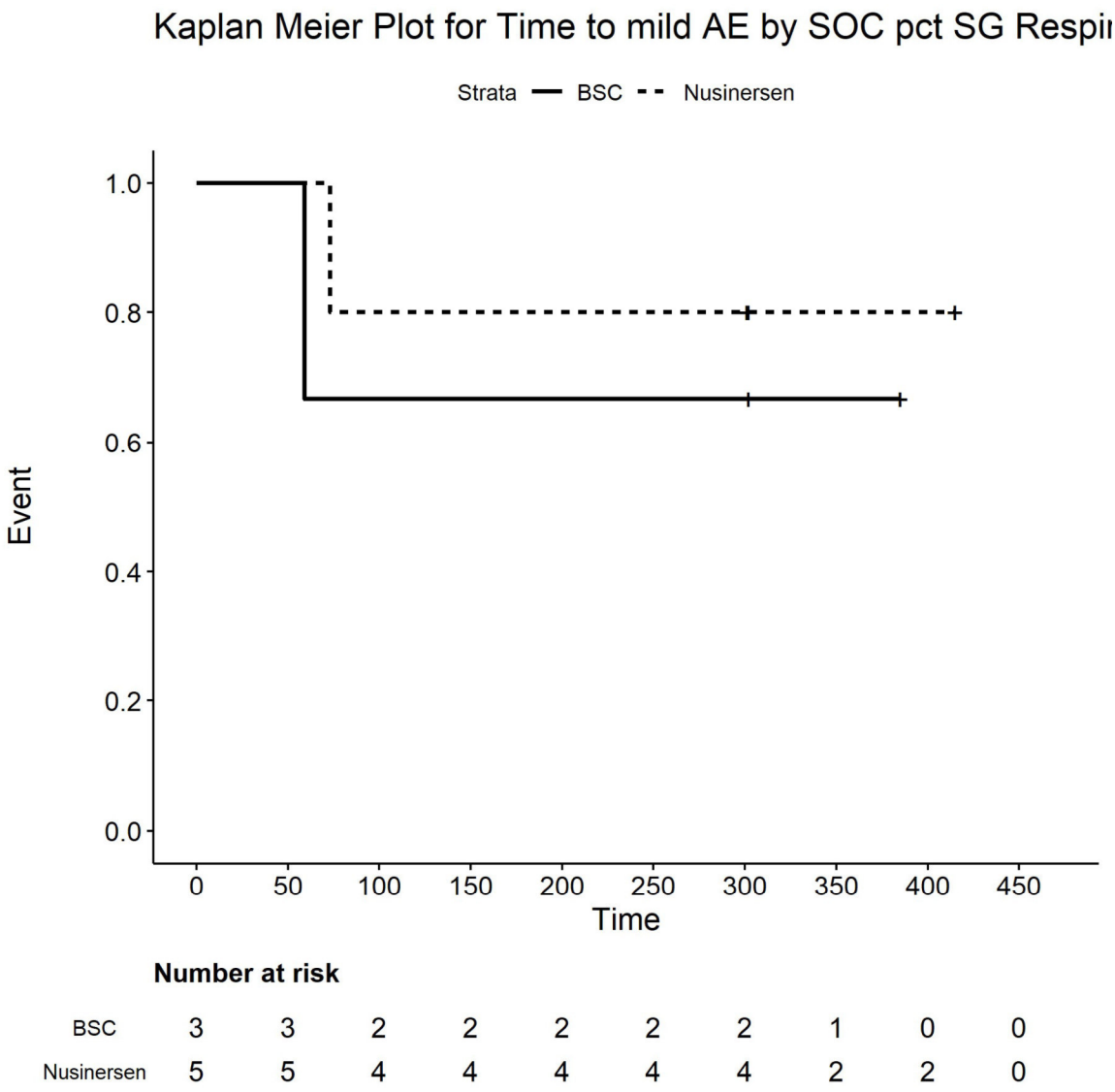
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



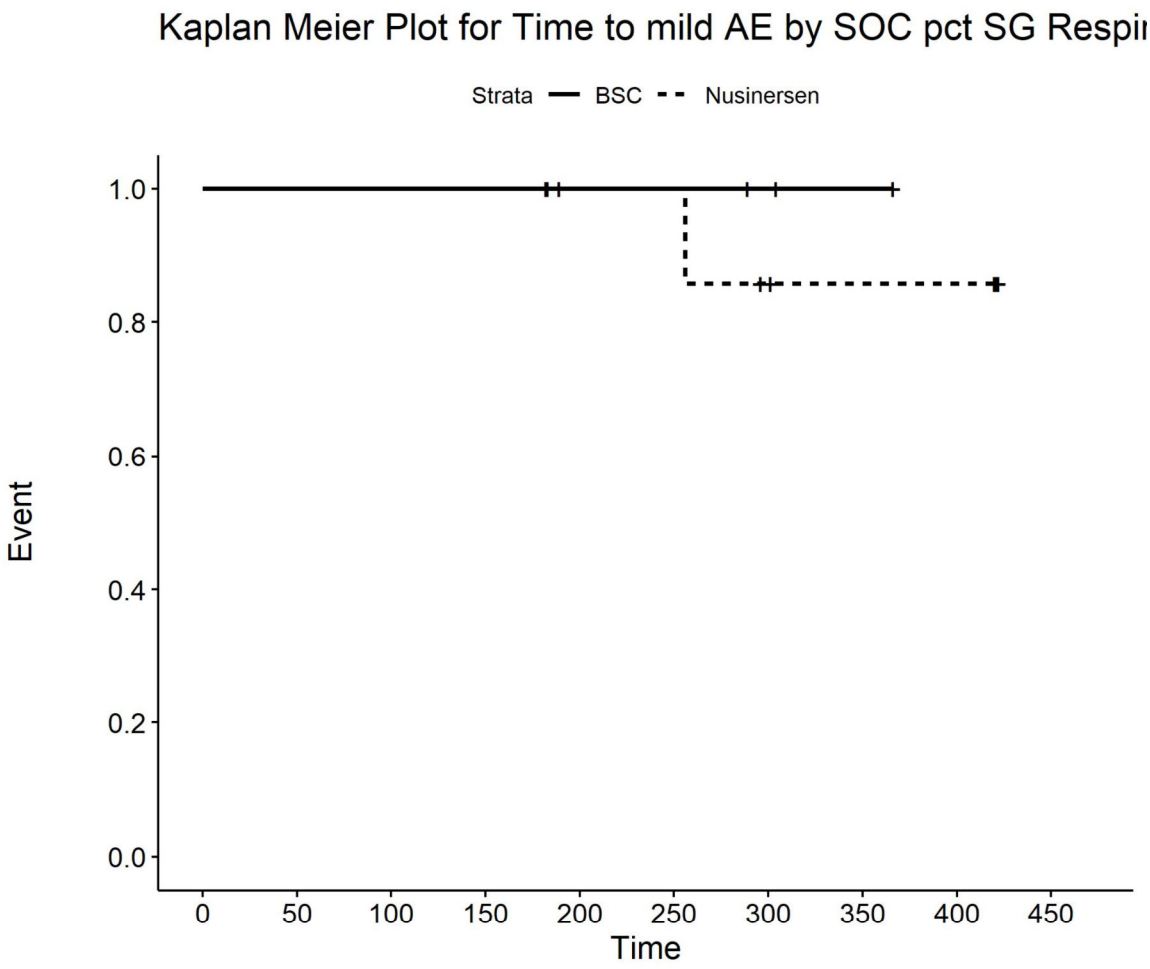
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	7	5	5	0



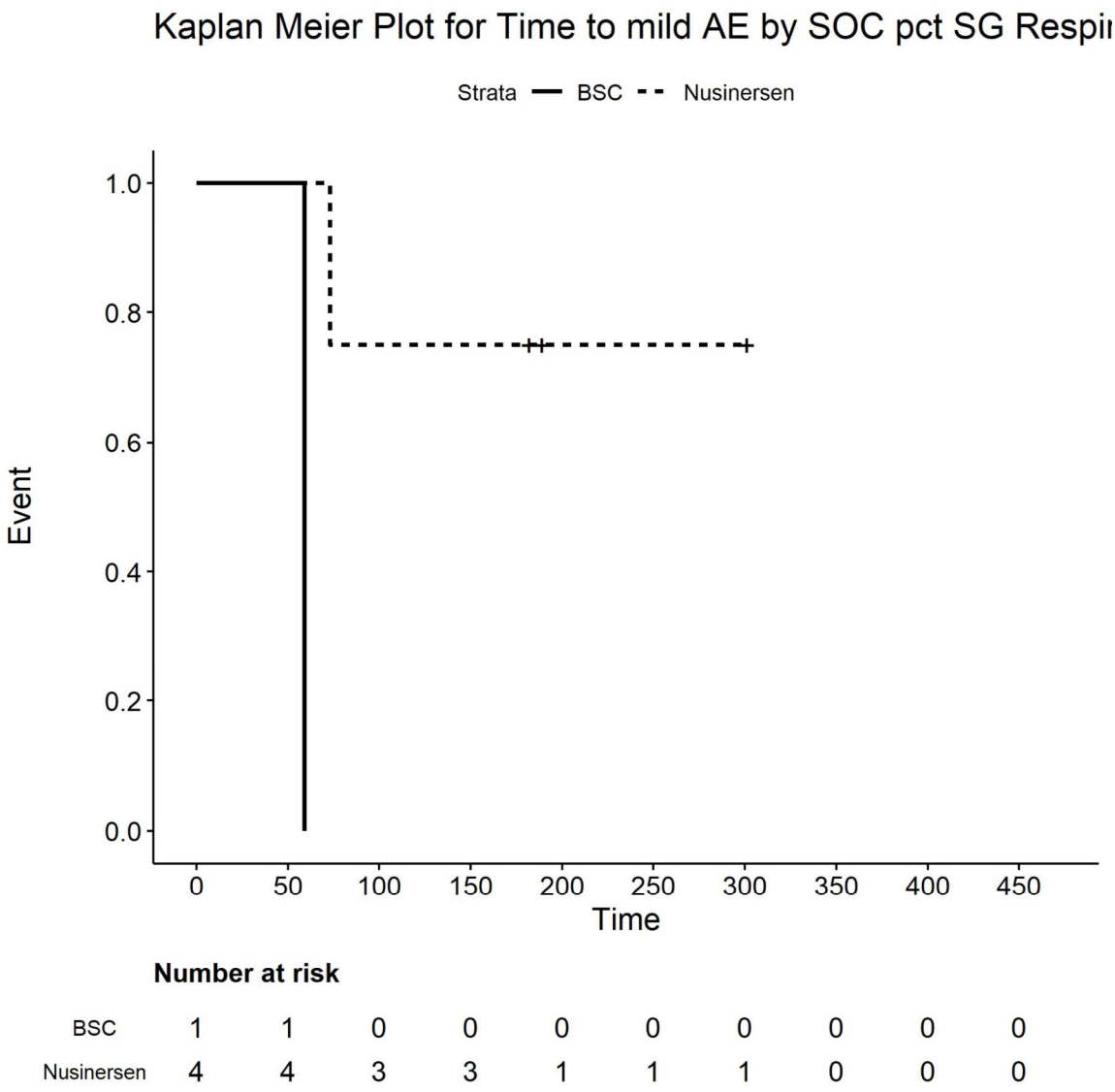
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



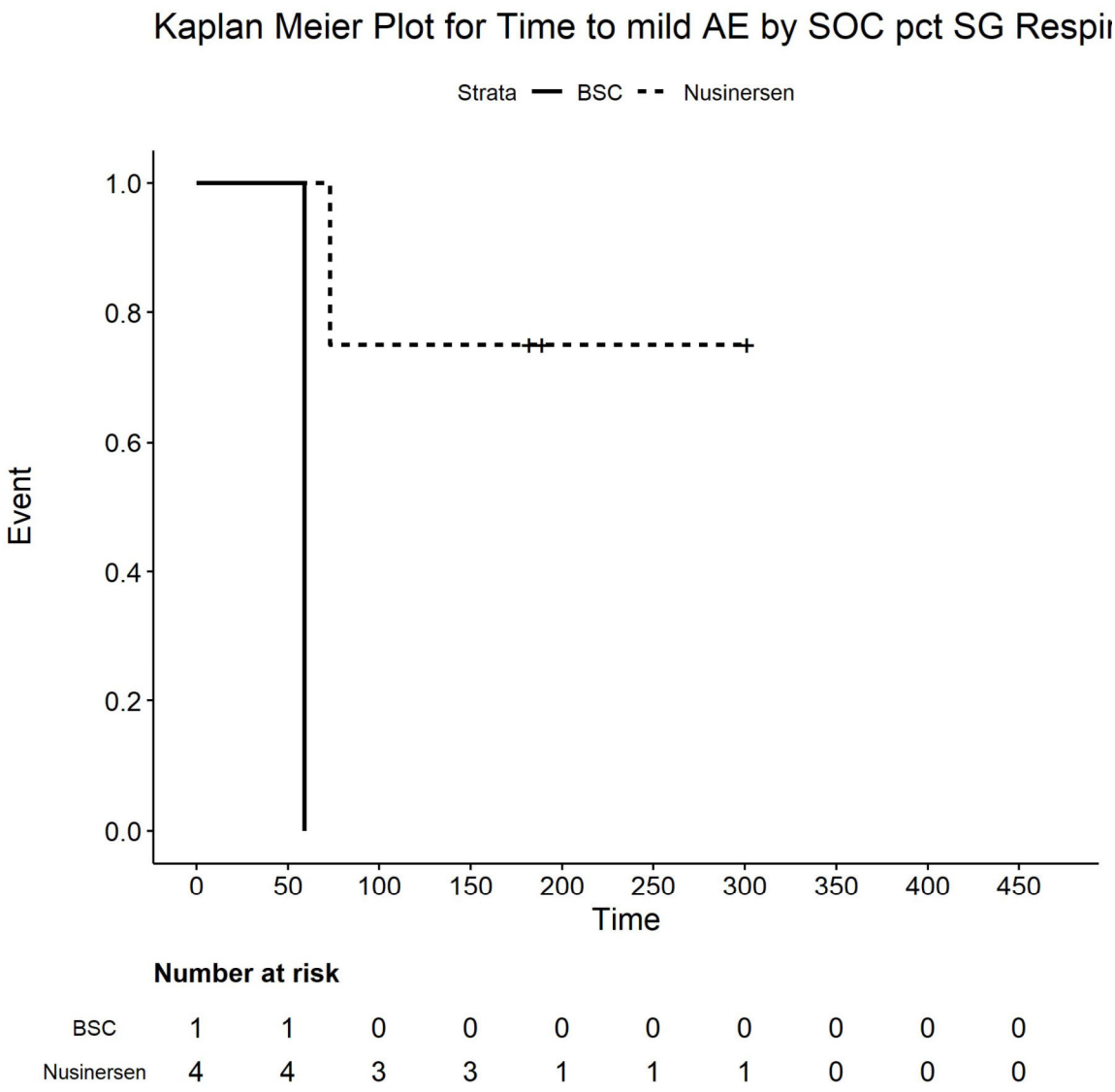
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	5	4	4	0



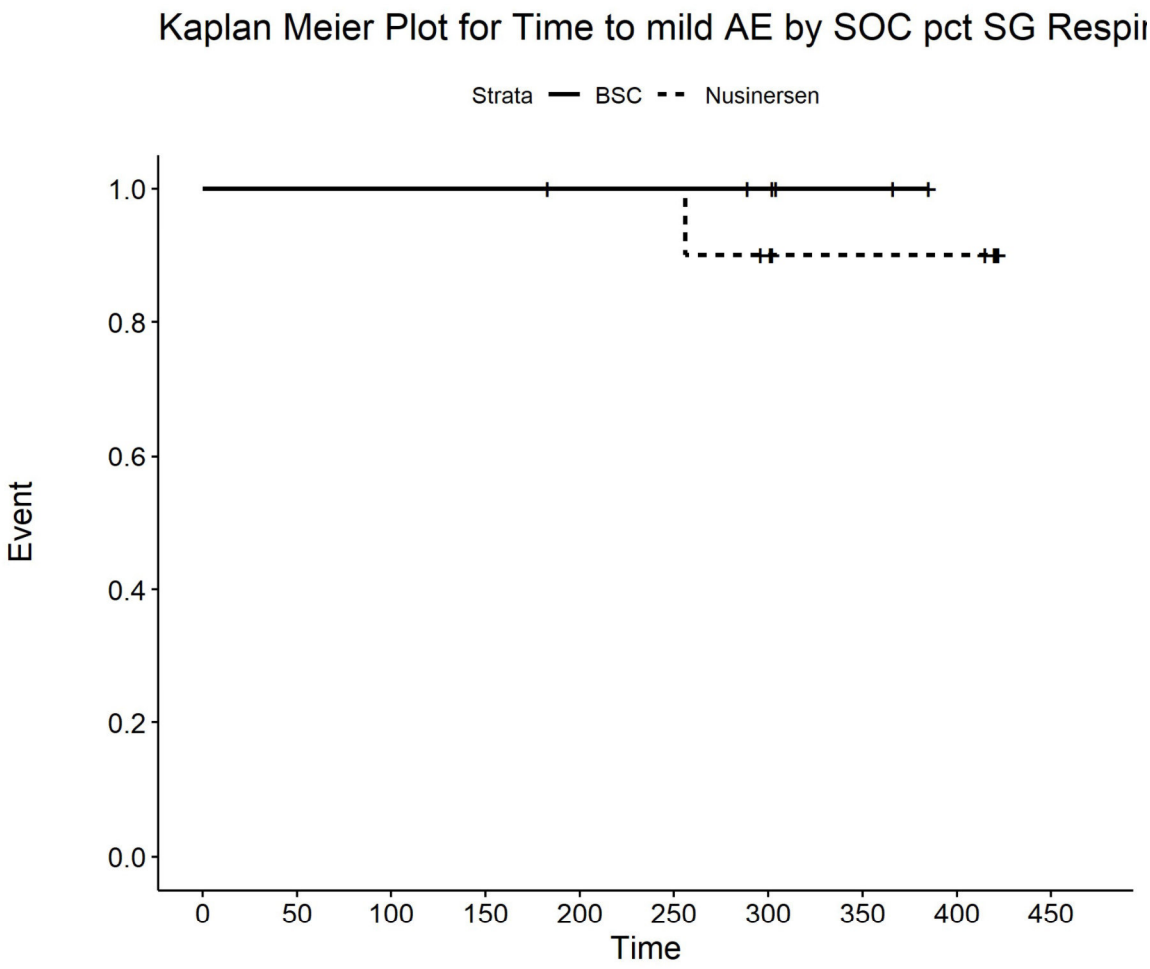
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



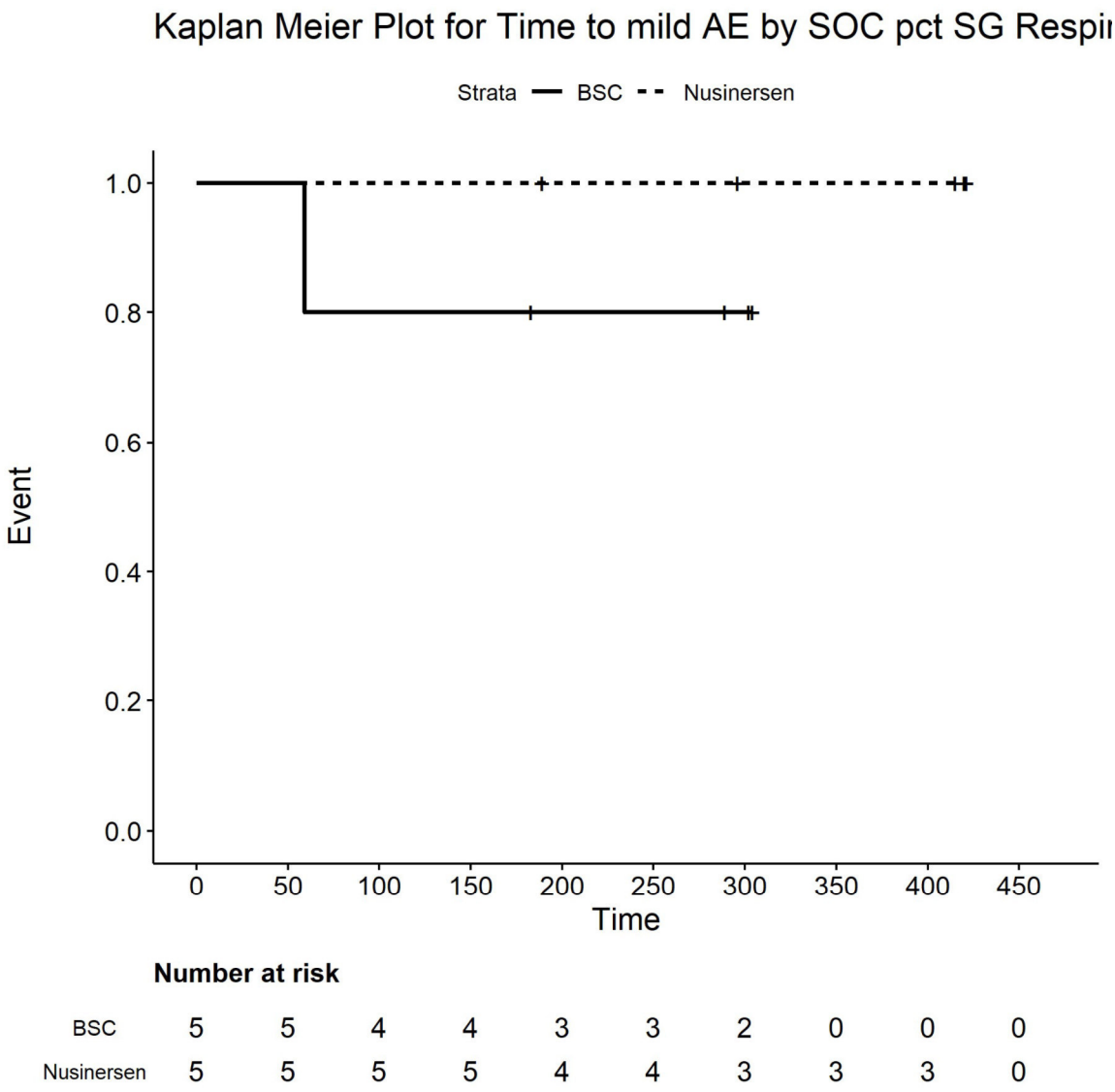
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



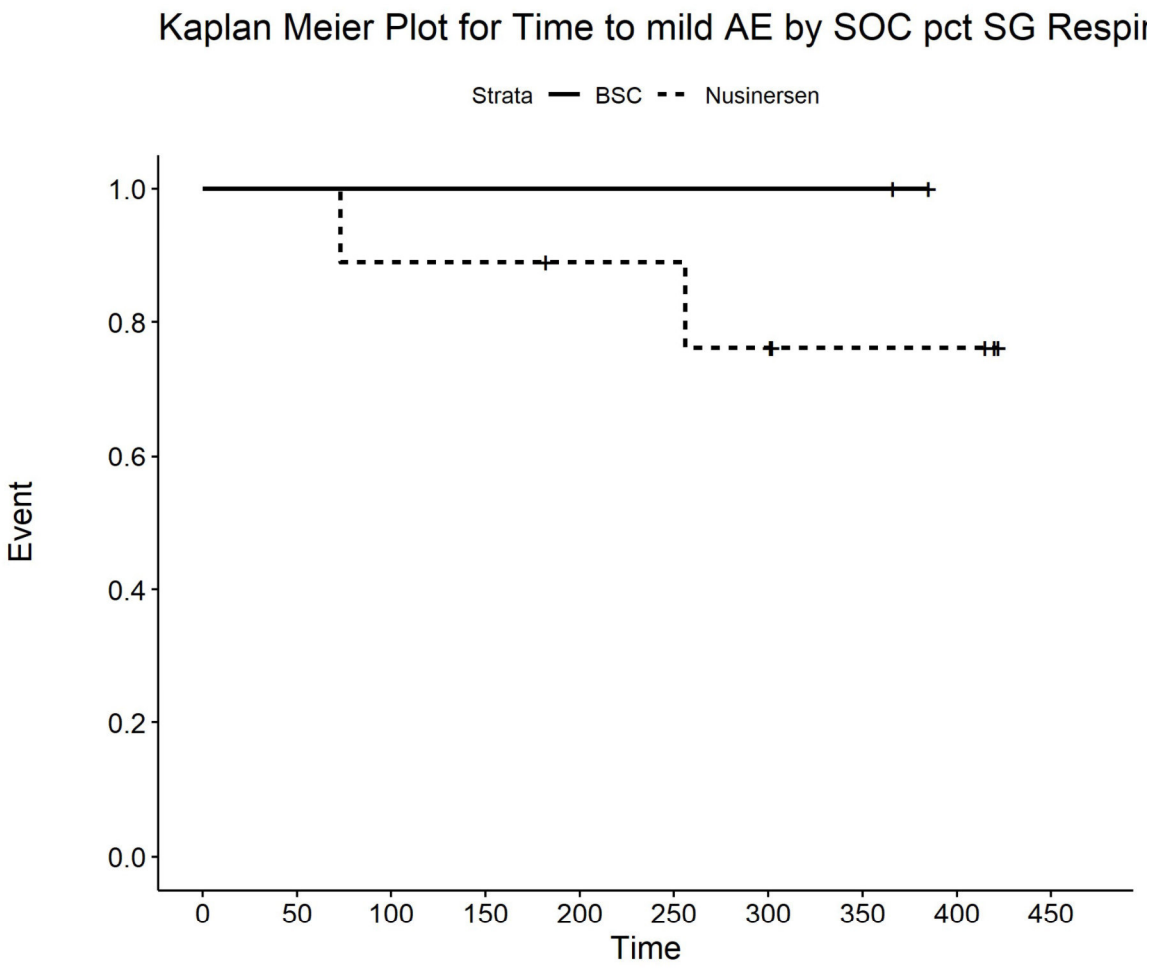
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	8	6	6	0



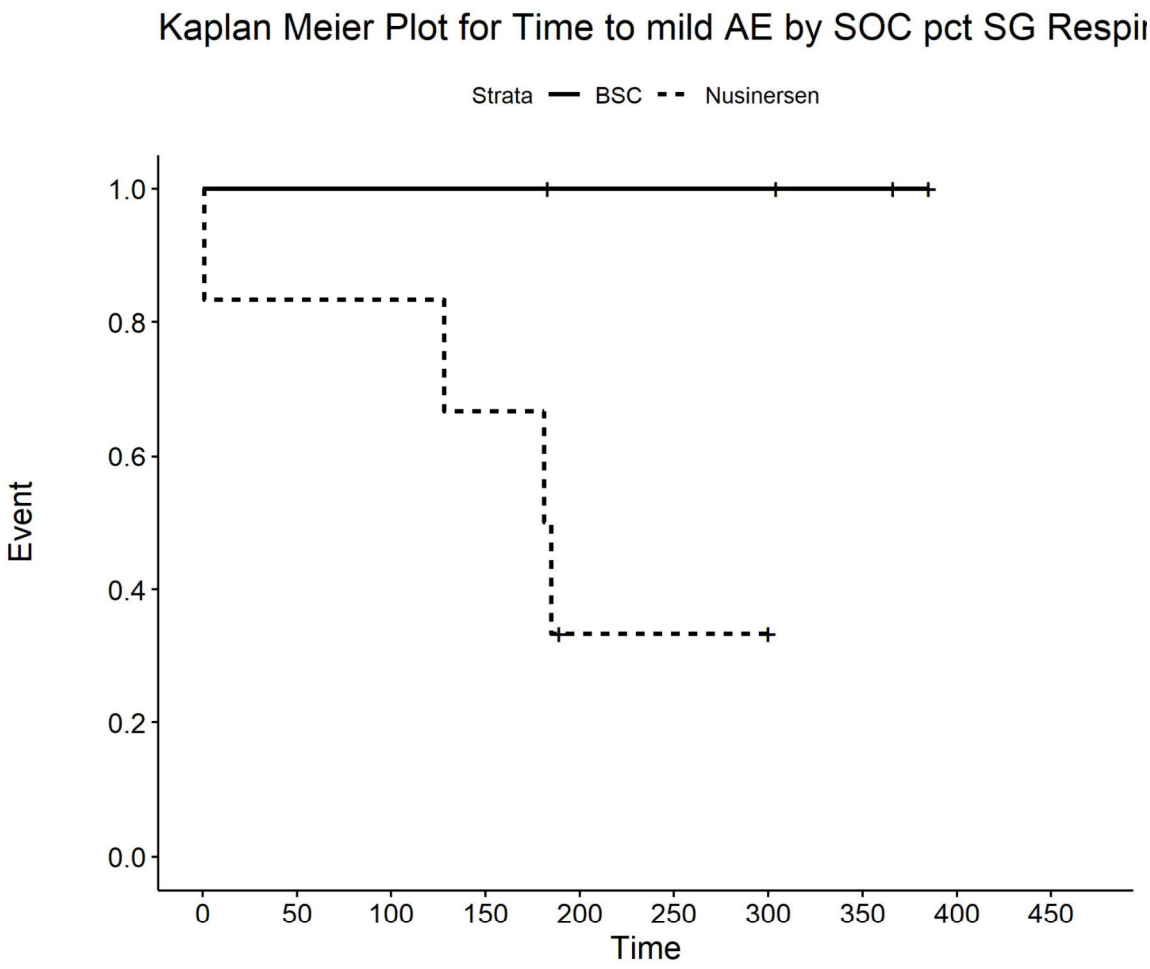
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



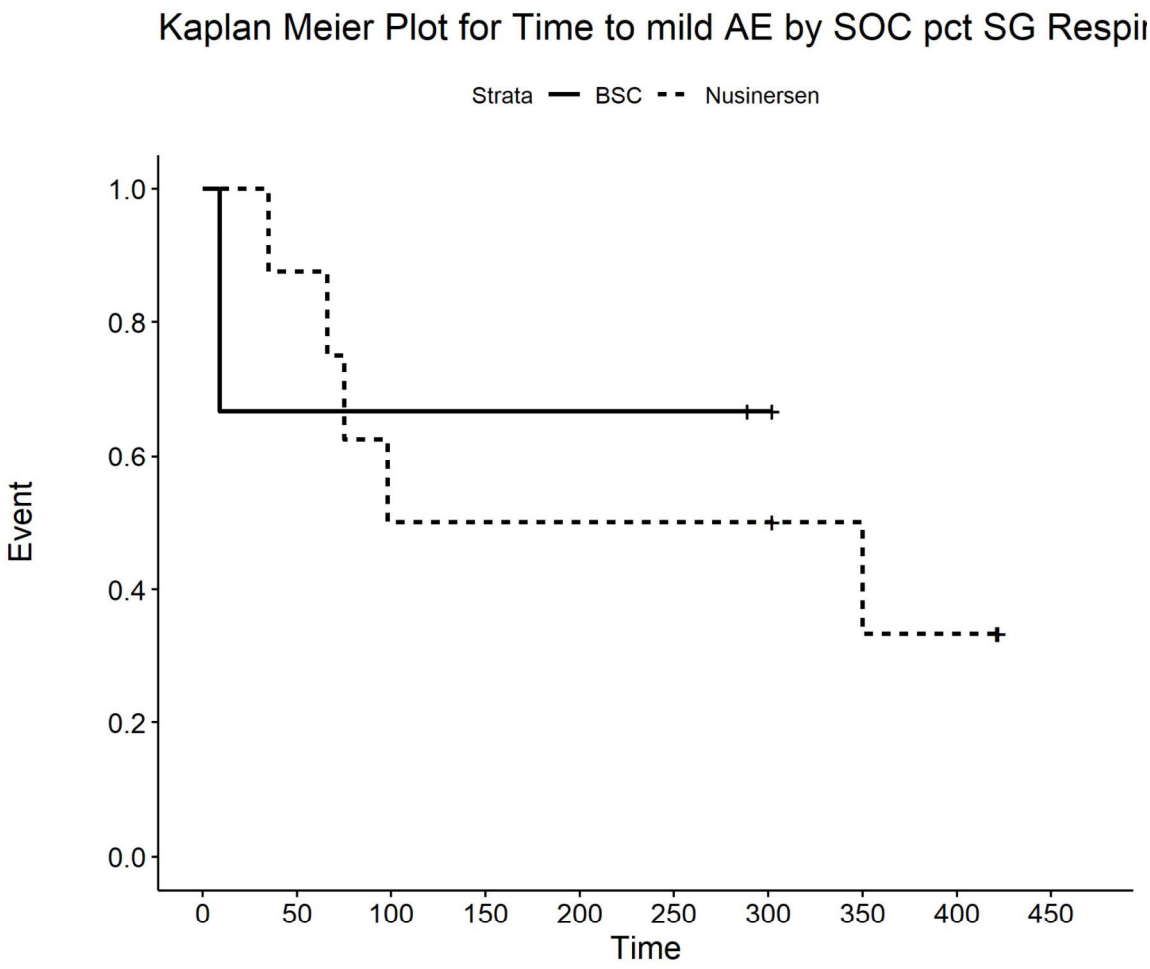
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	6	3	3	0



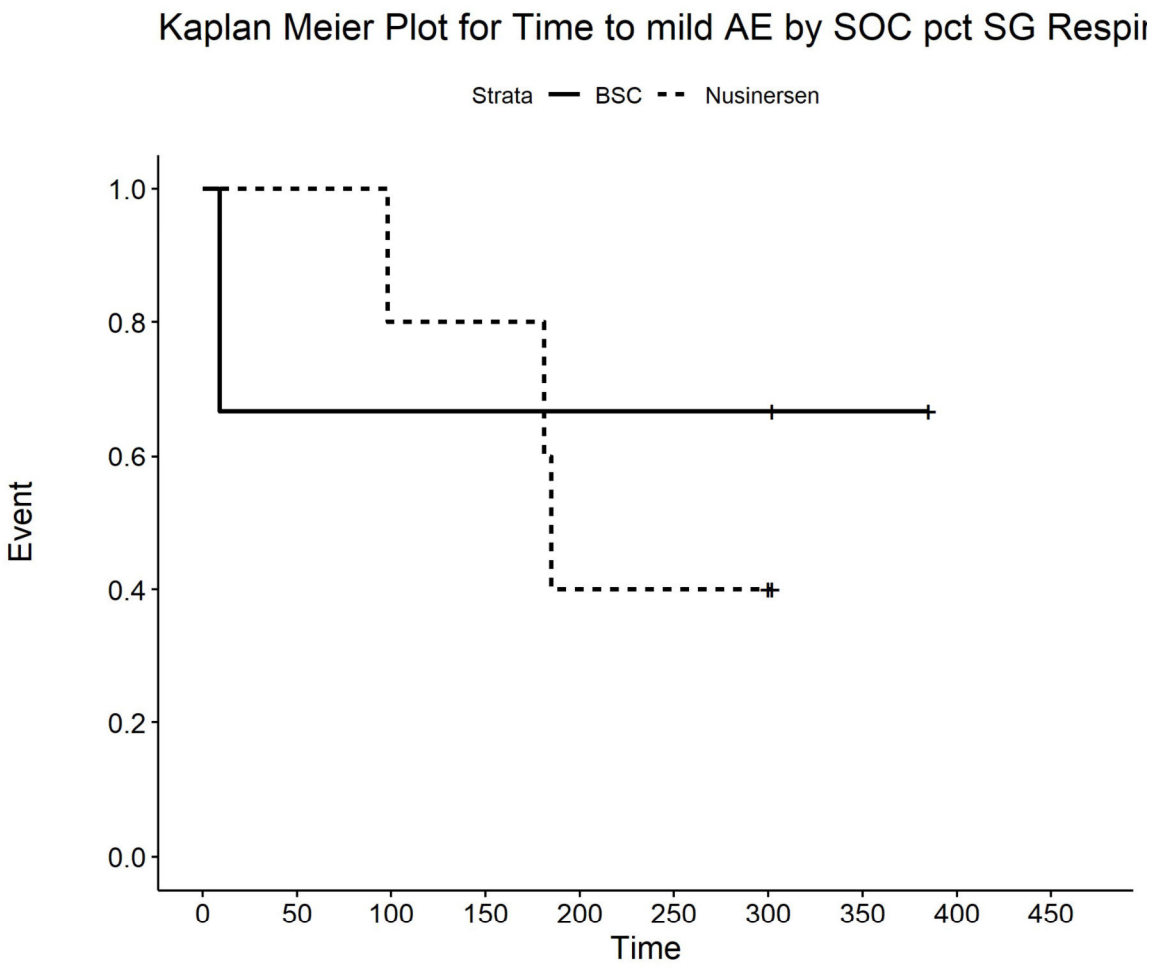
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	4	1	1	1	0	0	0



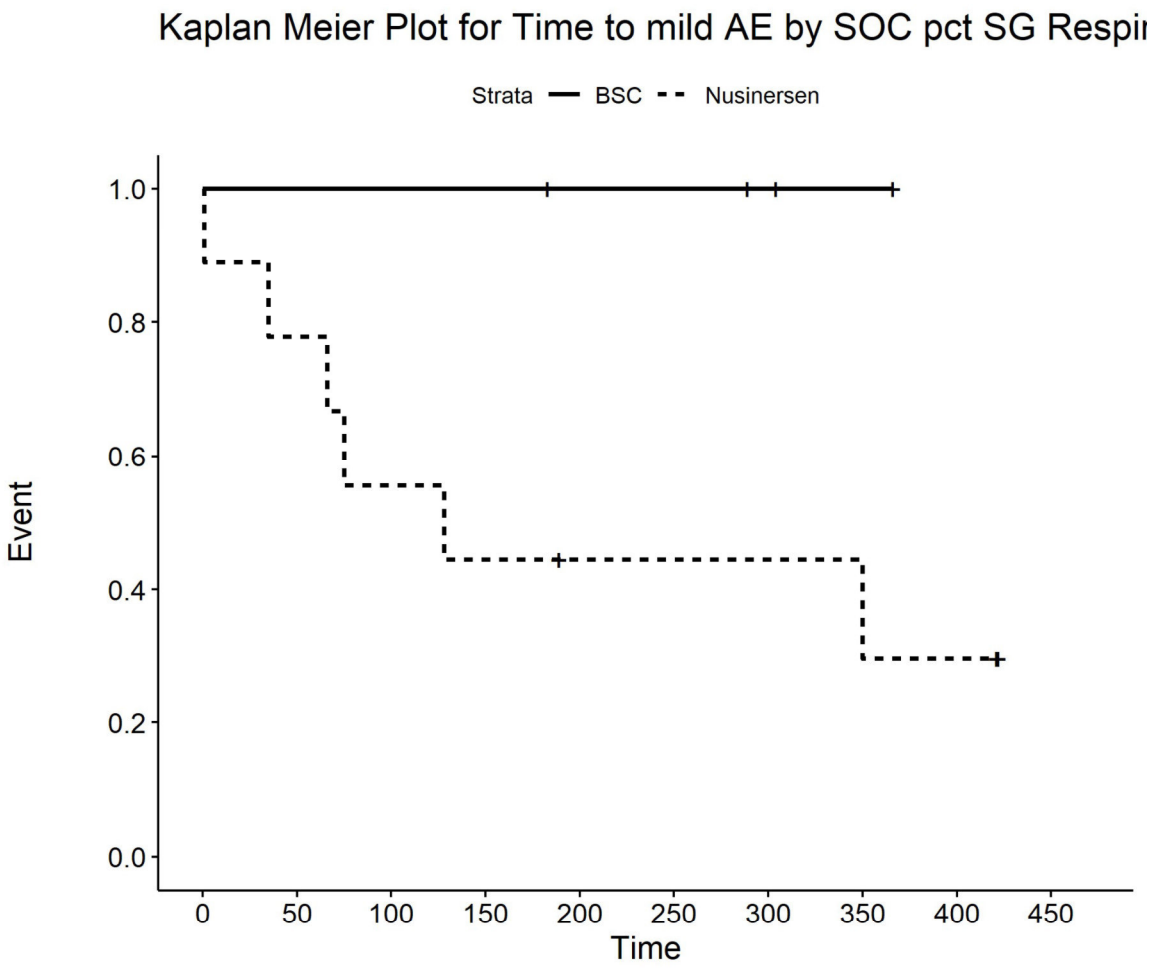
Number at risk

BSC	3	2	2	2	2	2	1	0	0	0
Nusinersen	8	7	4	4	4	4	4	3	2	0



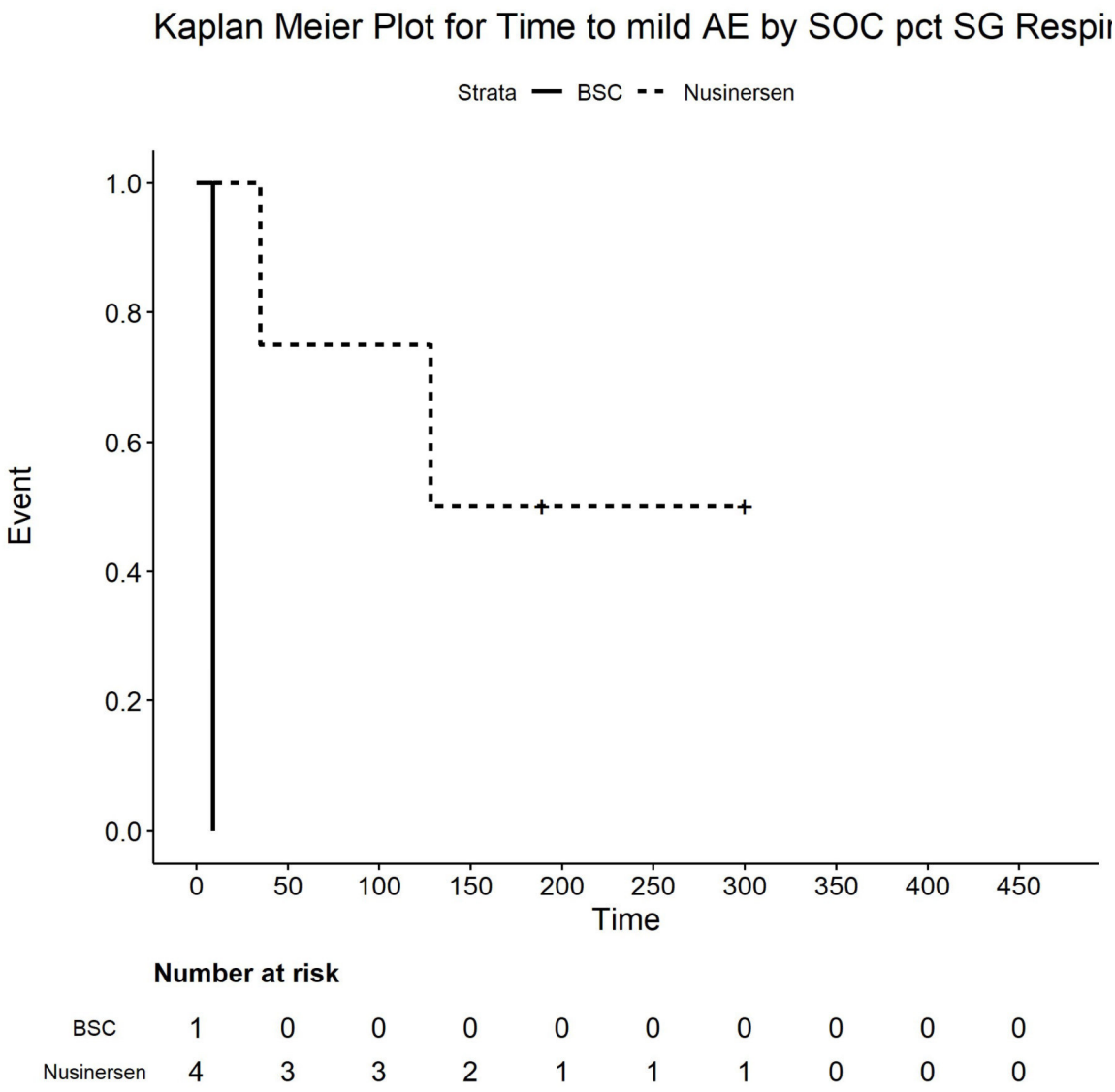
Number at risk

BSC	3	2	2	2	2	2	2	1	0	0
Nusinersen	5	5	4	4	2	2	2	0	0	0



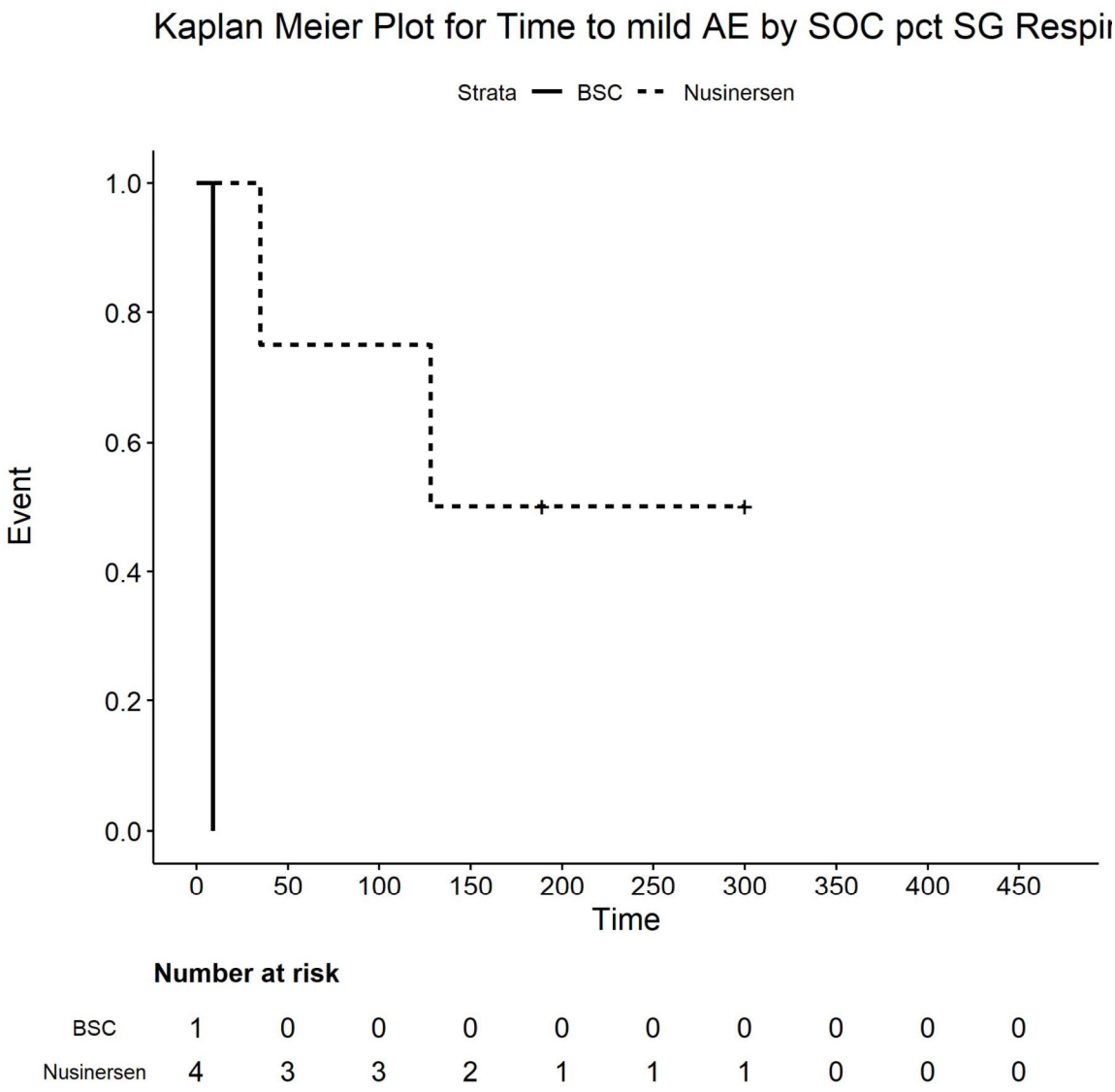
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	7	5	4	3	3	3	3	2	0



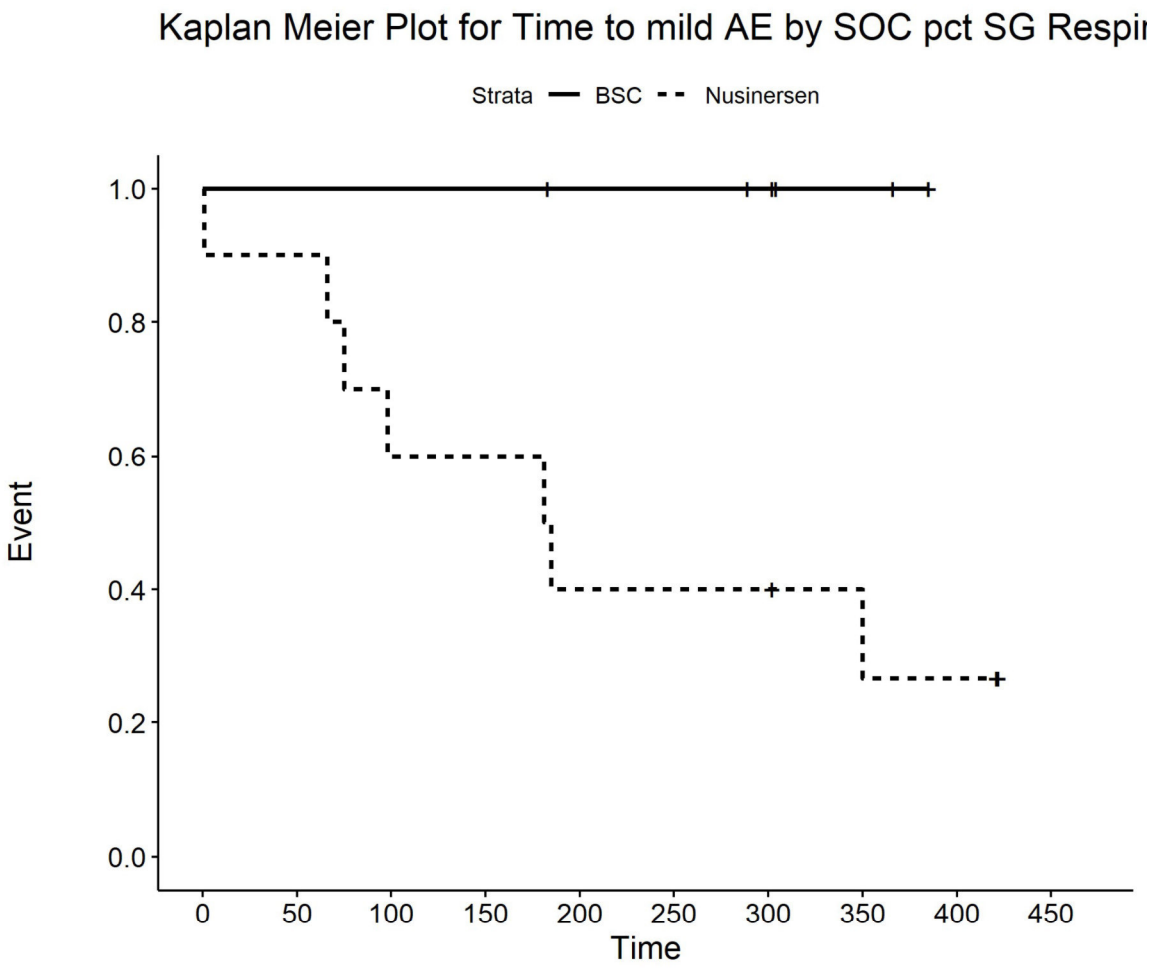
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



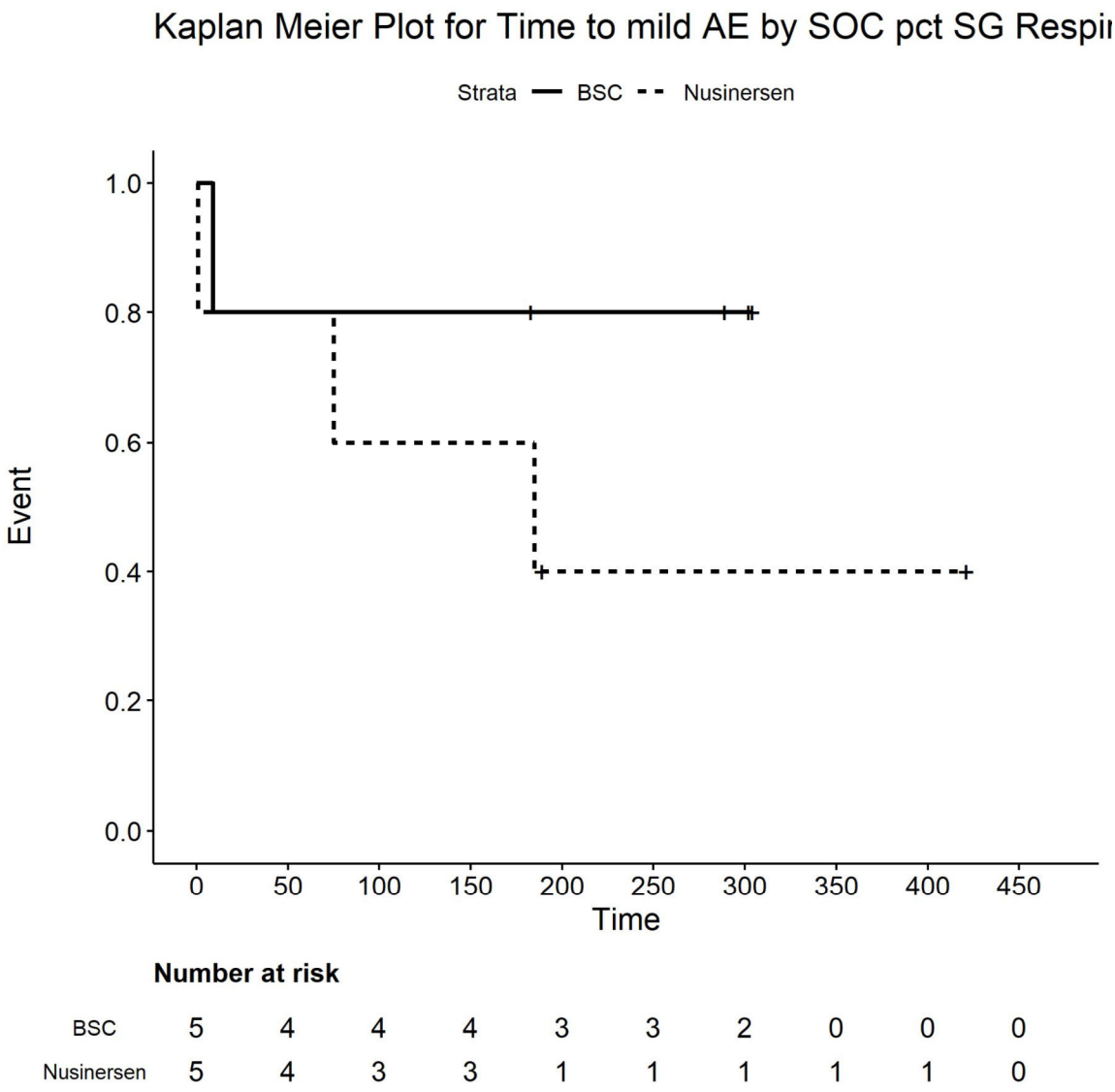
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



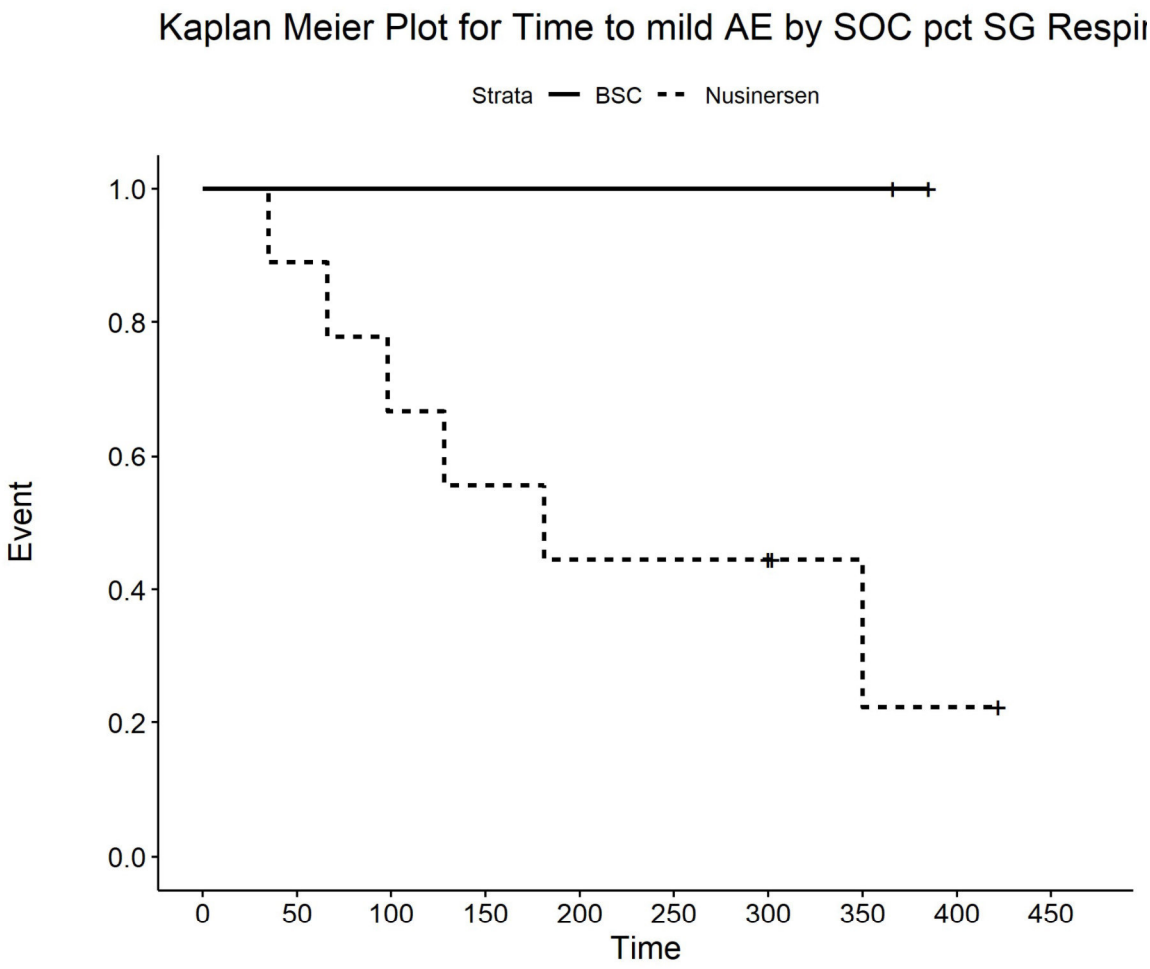
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	6	6	4	4	4	3	2	0



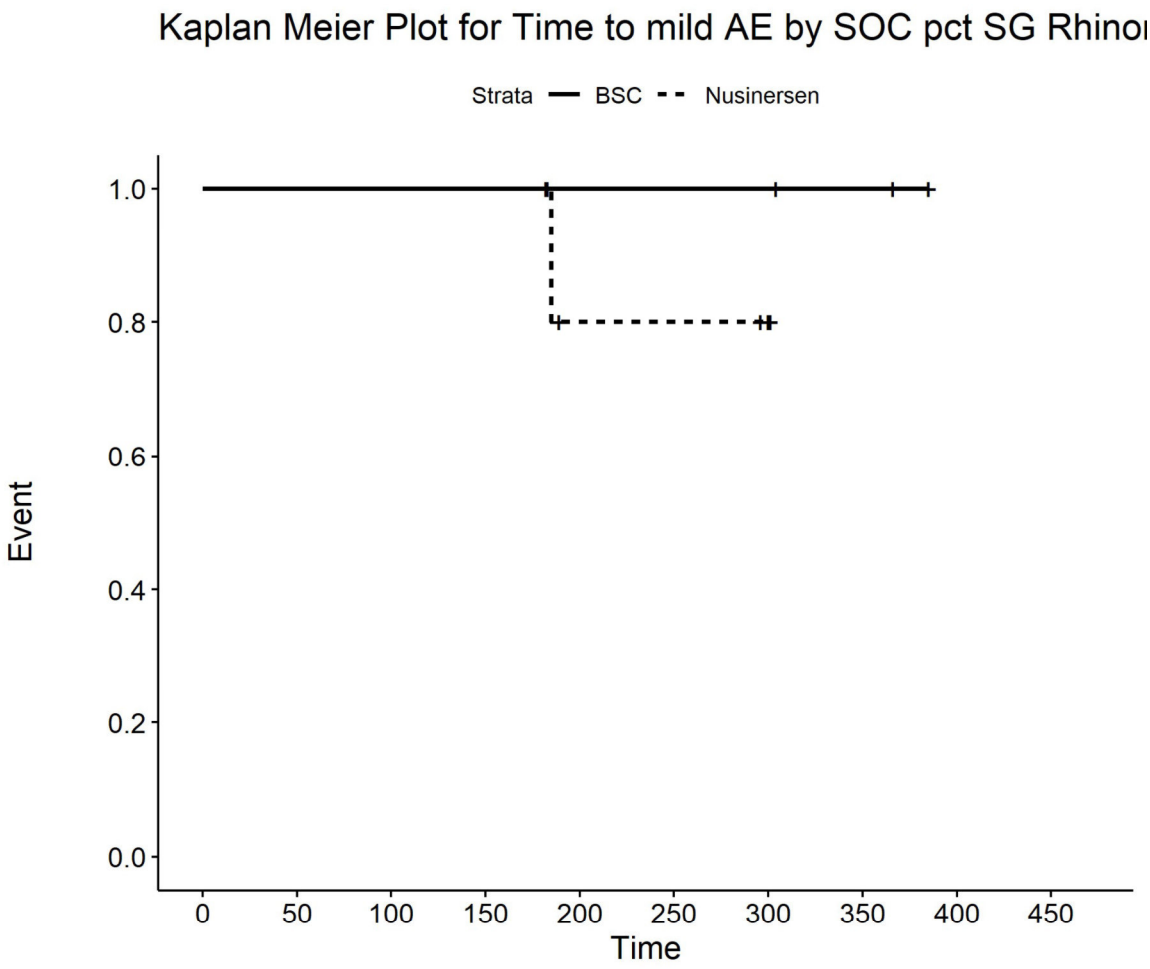
Number at risk

BSC	5	4	4	4	3	3	2	0	0	0
Nusinersen	5	4	3	3	1	1	1	1	1	0



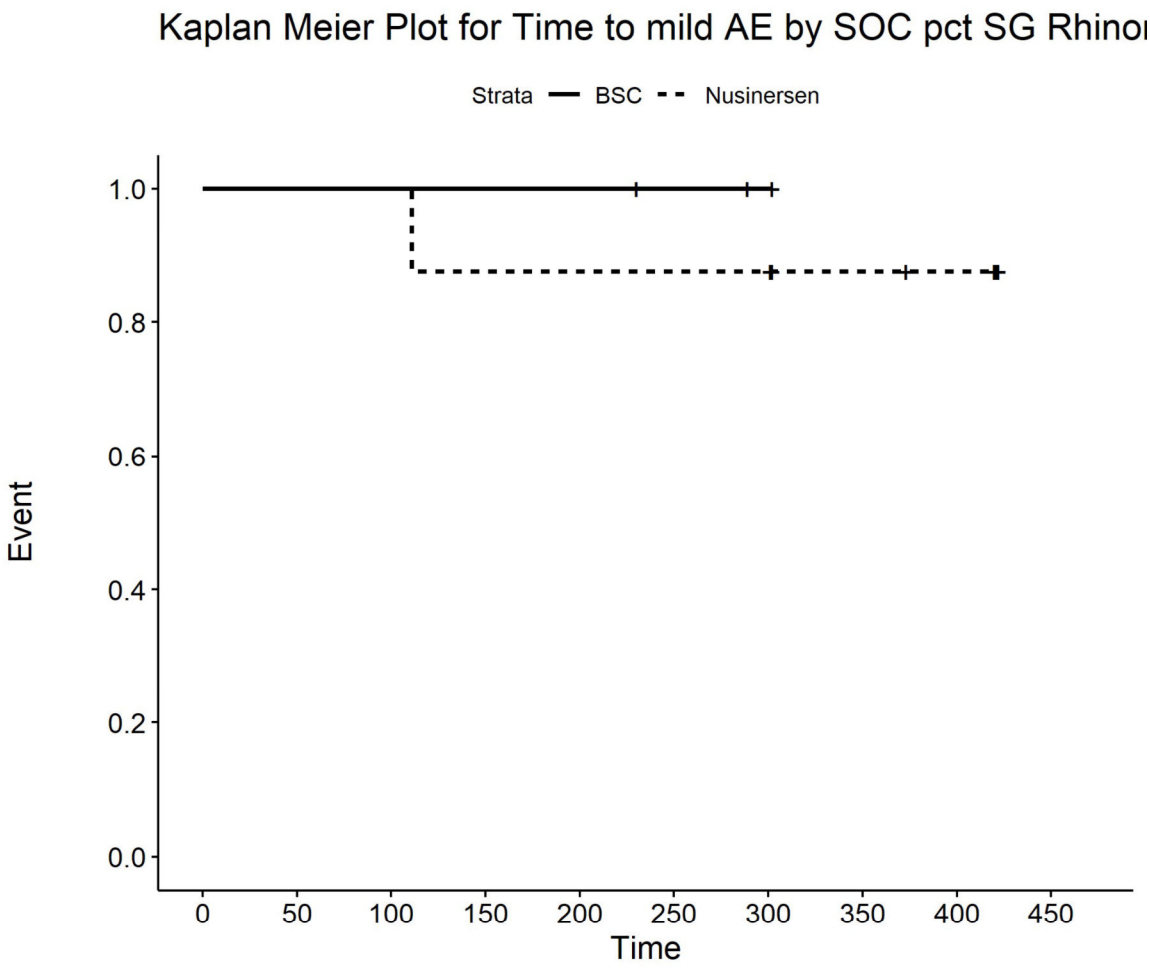
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	6	5	4	4	4	2	1	0



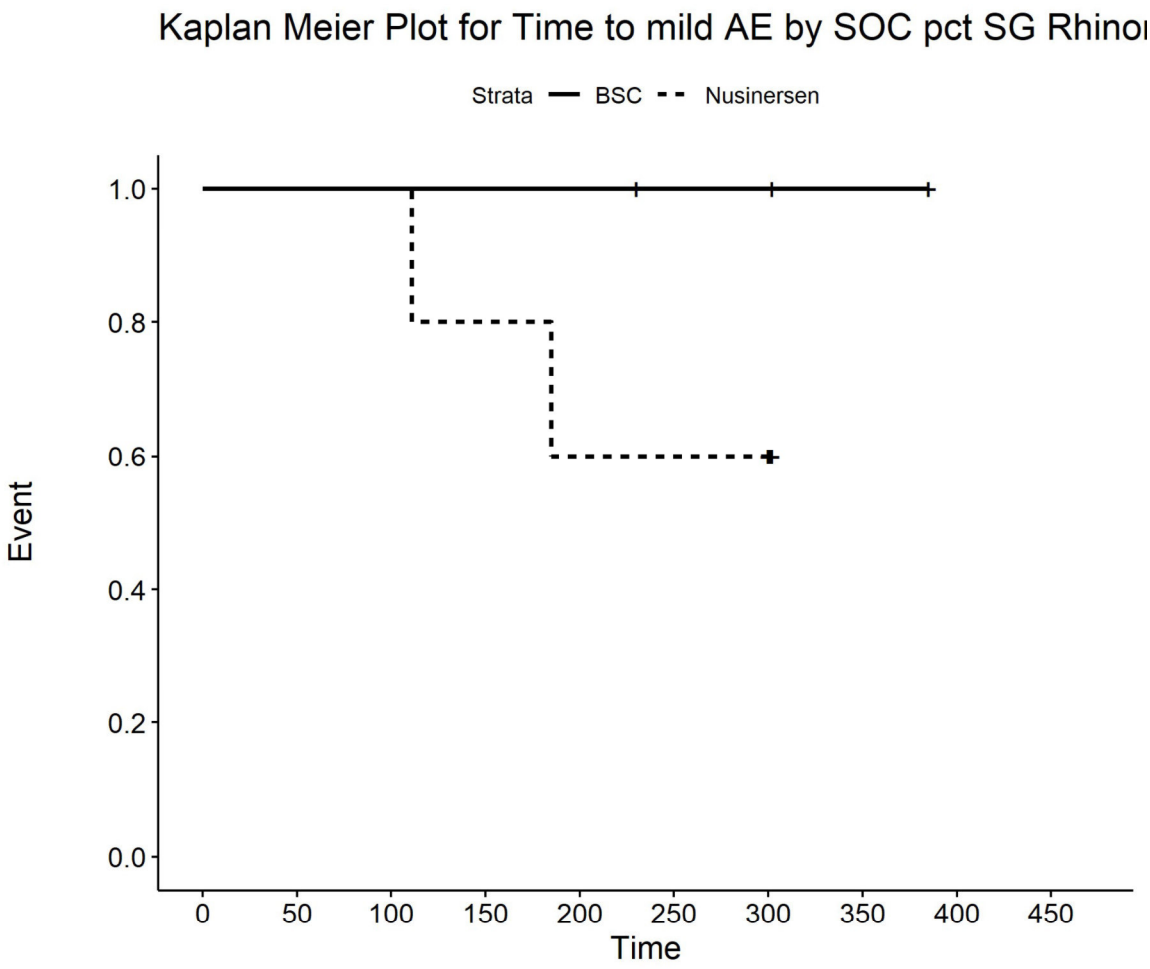
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	6	3	3	2	0	0	0



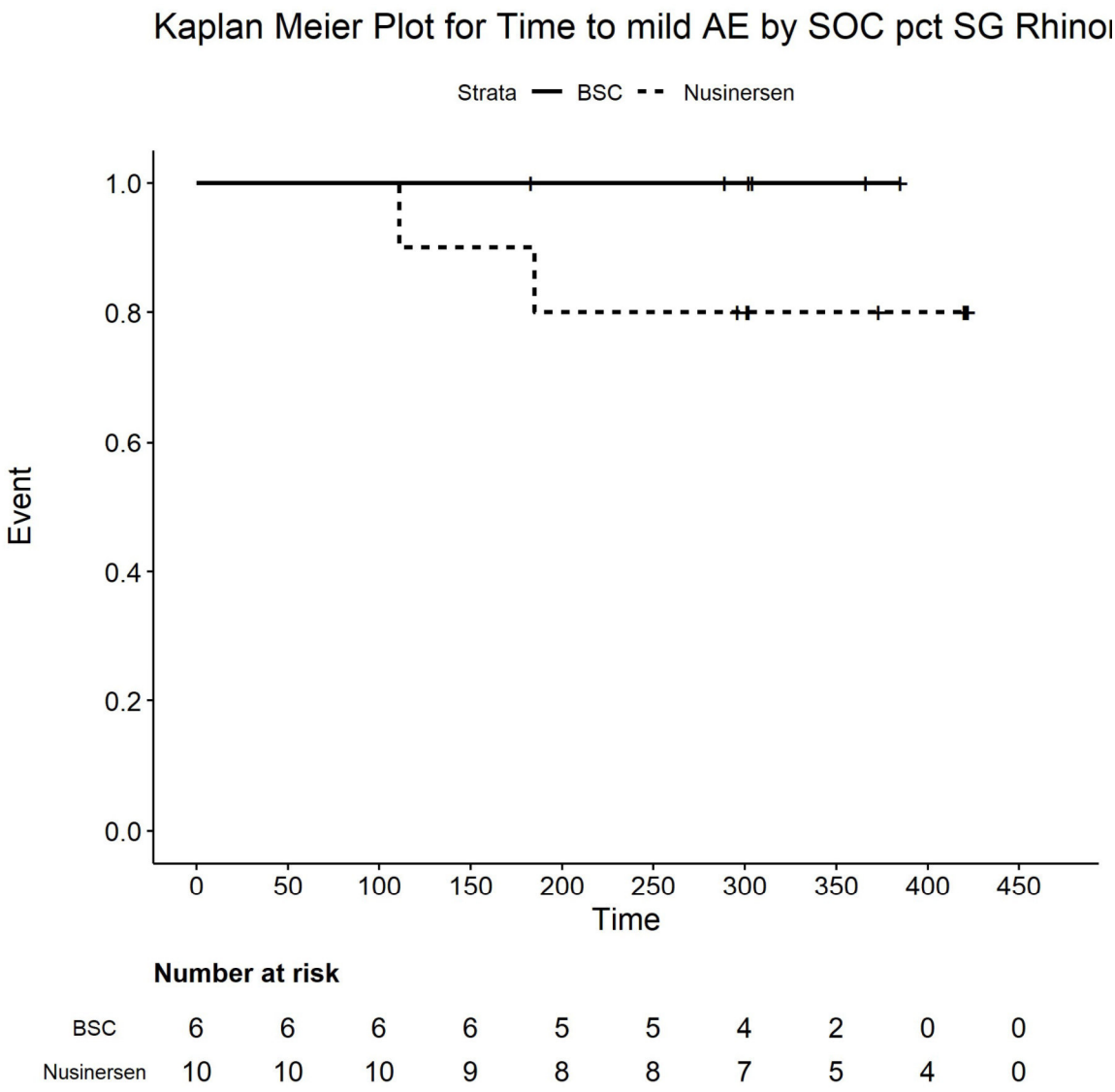
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



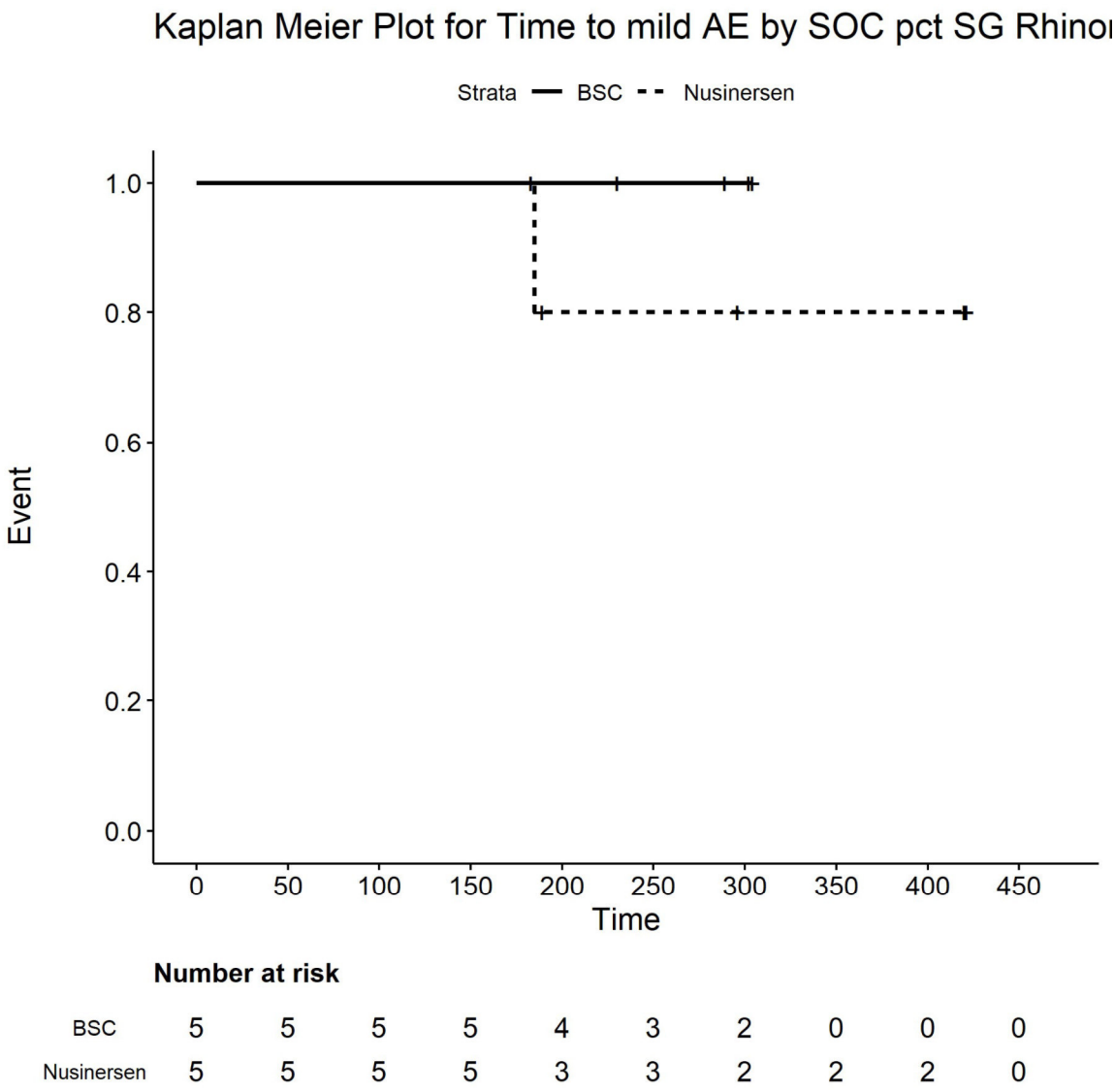
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	4	3	3	3	0	0	0



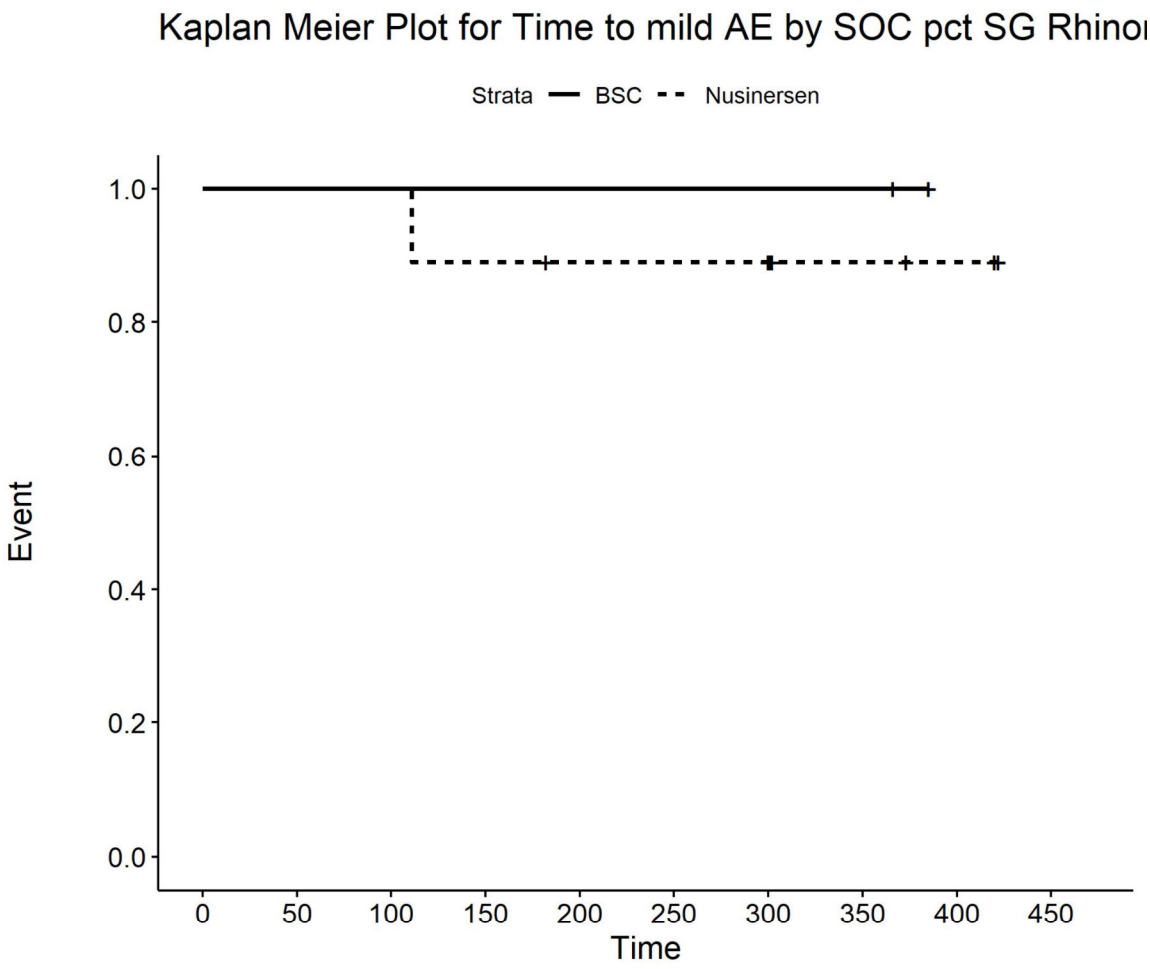
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	8	8	7	5	4	0



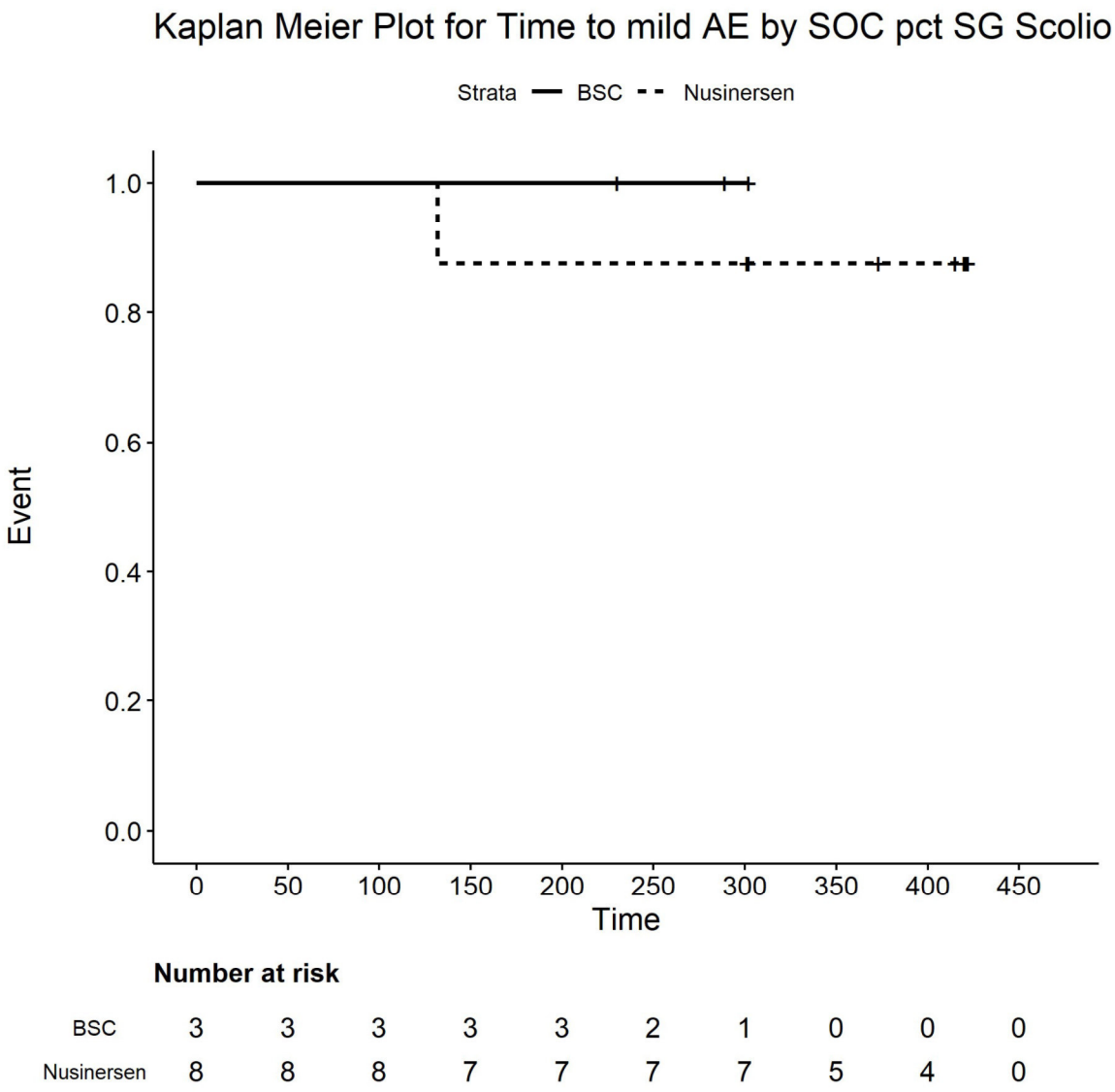
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	3	3	2	2	2	0



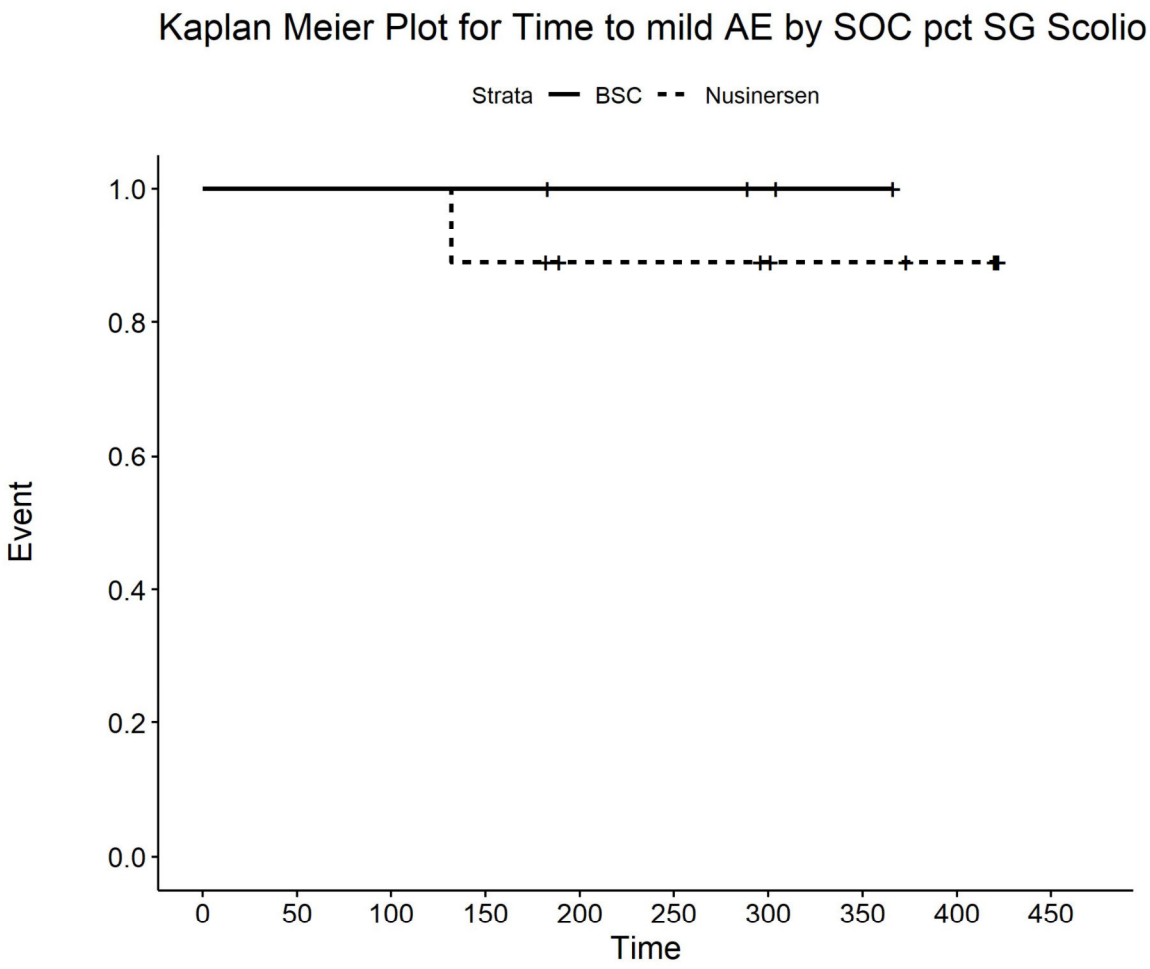
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



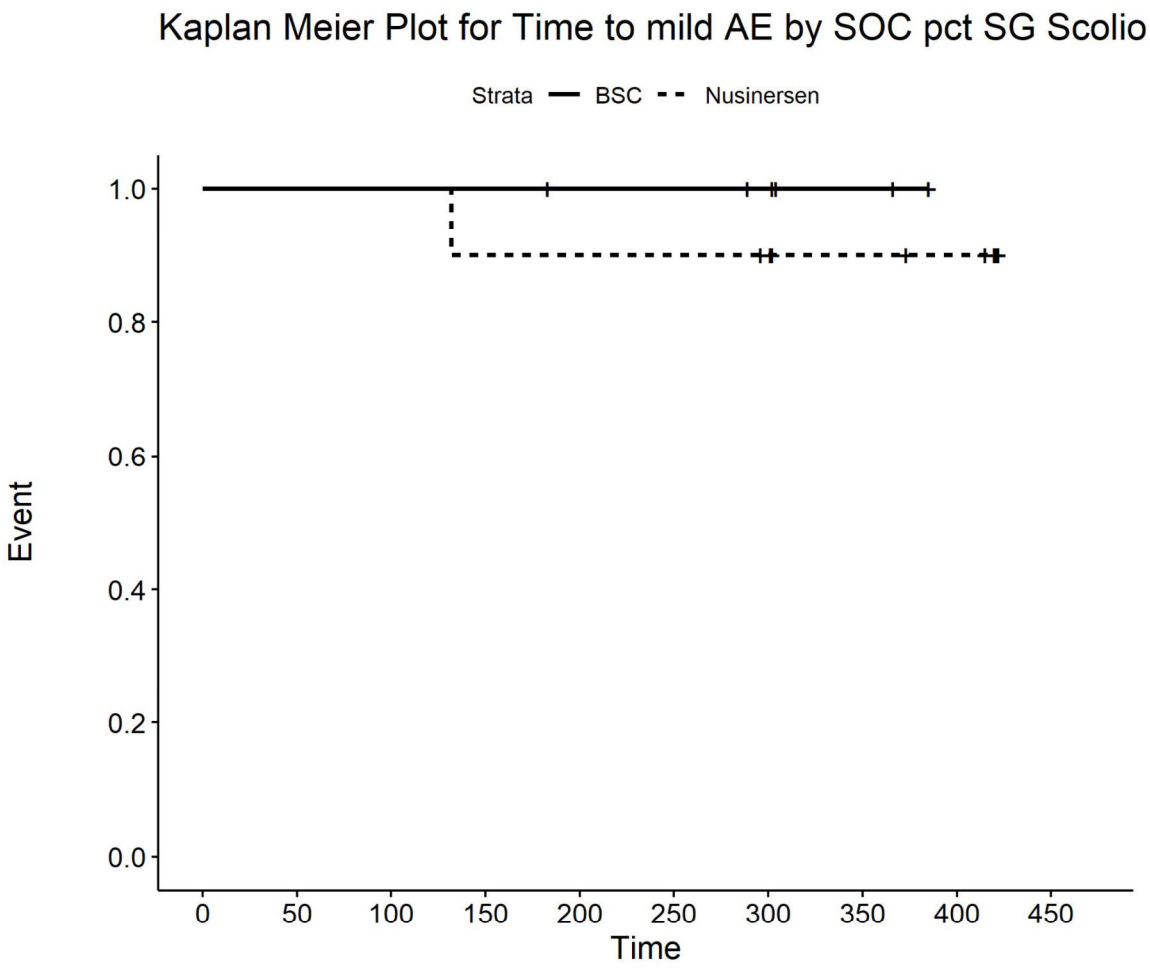
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



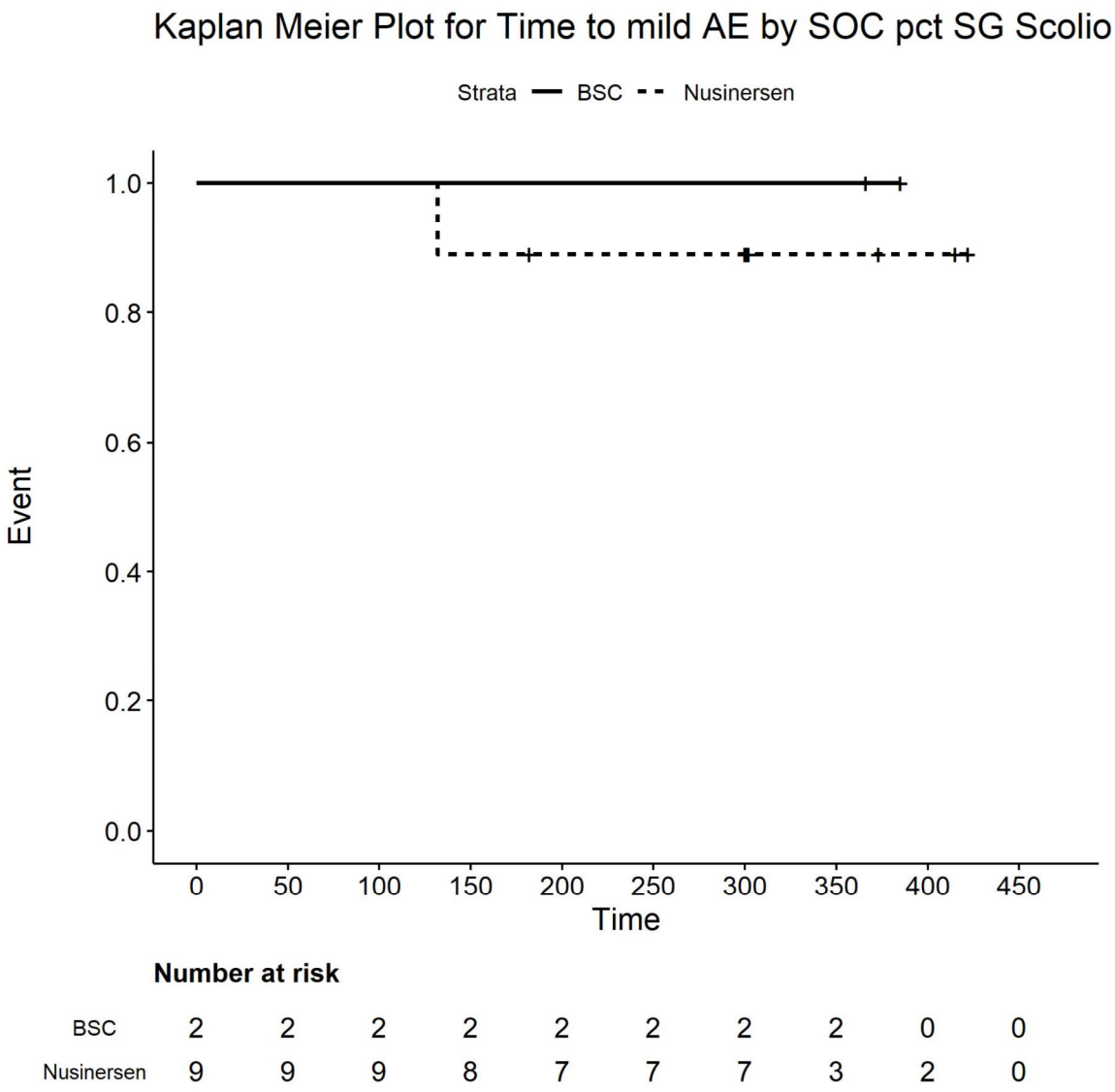
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



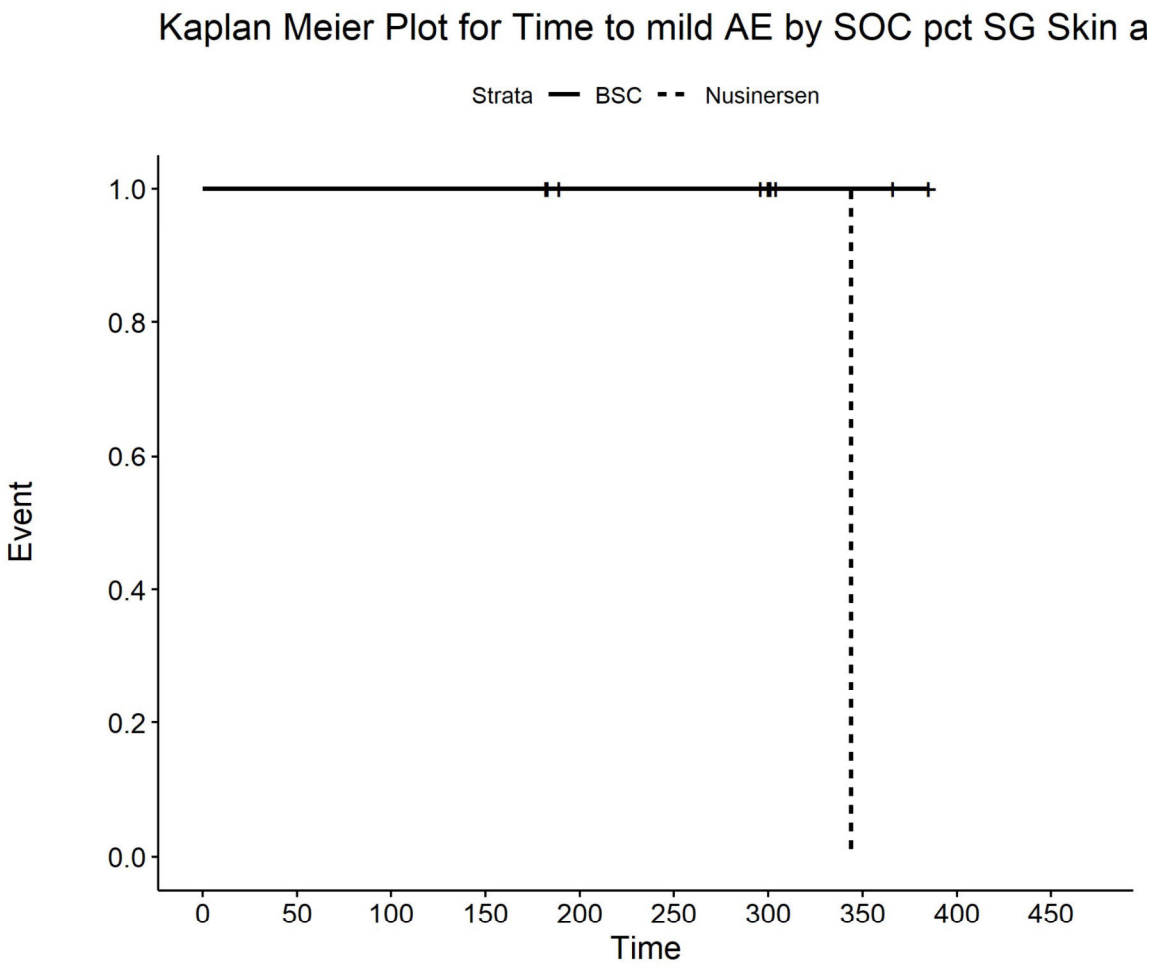
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



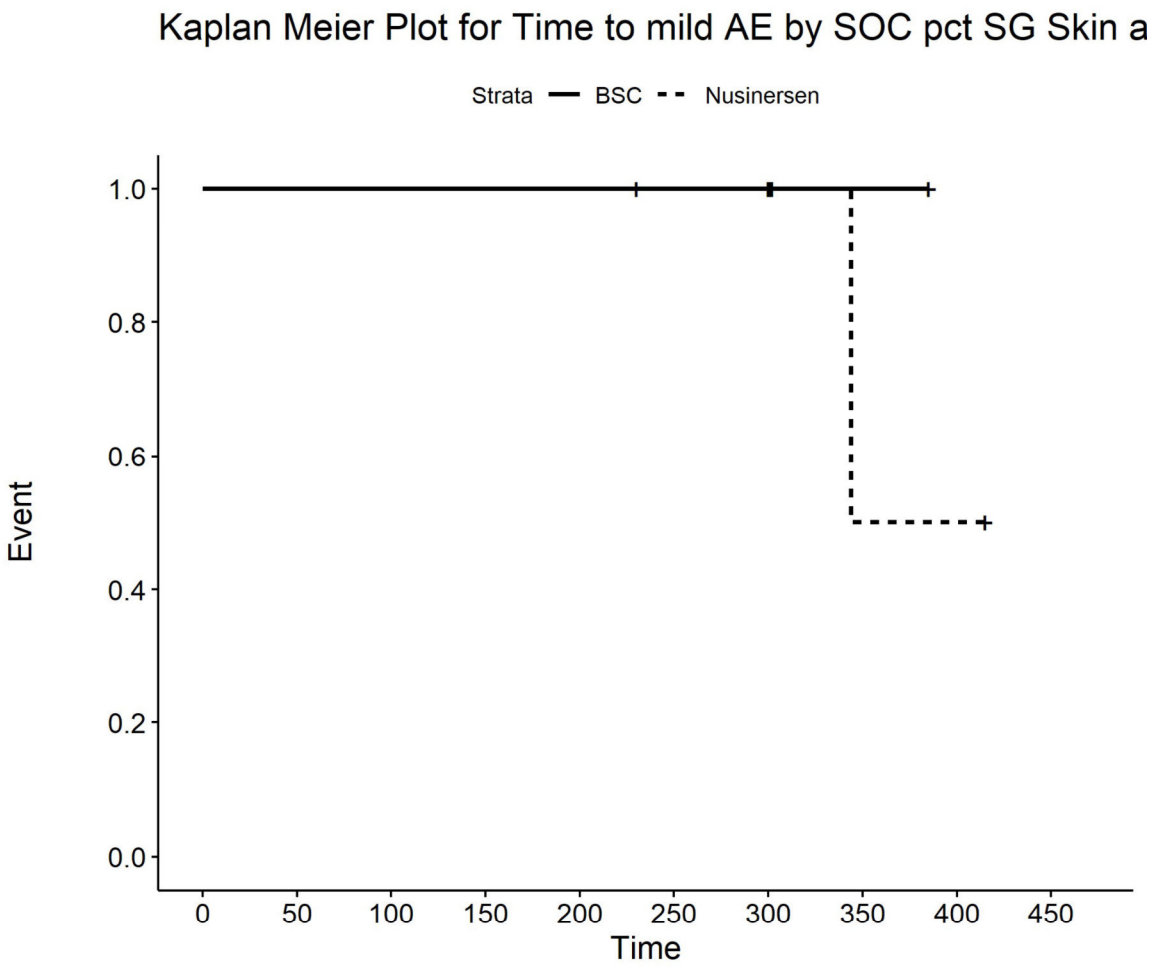
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



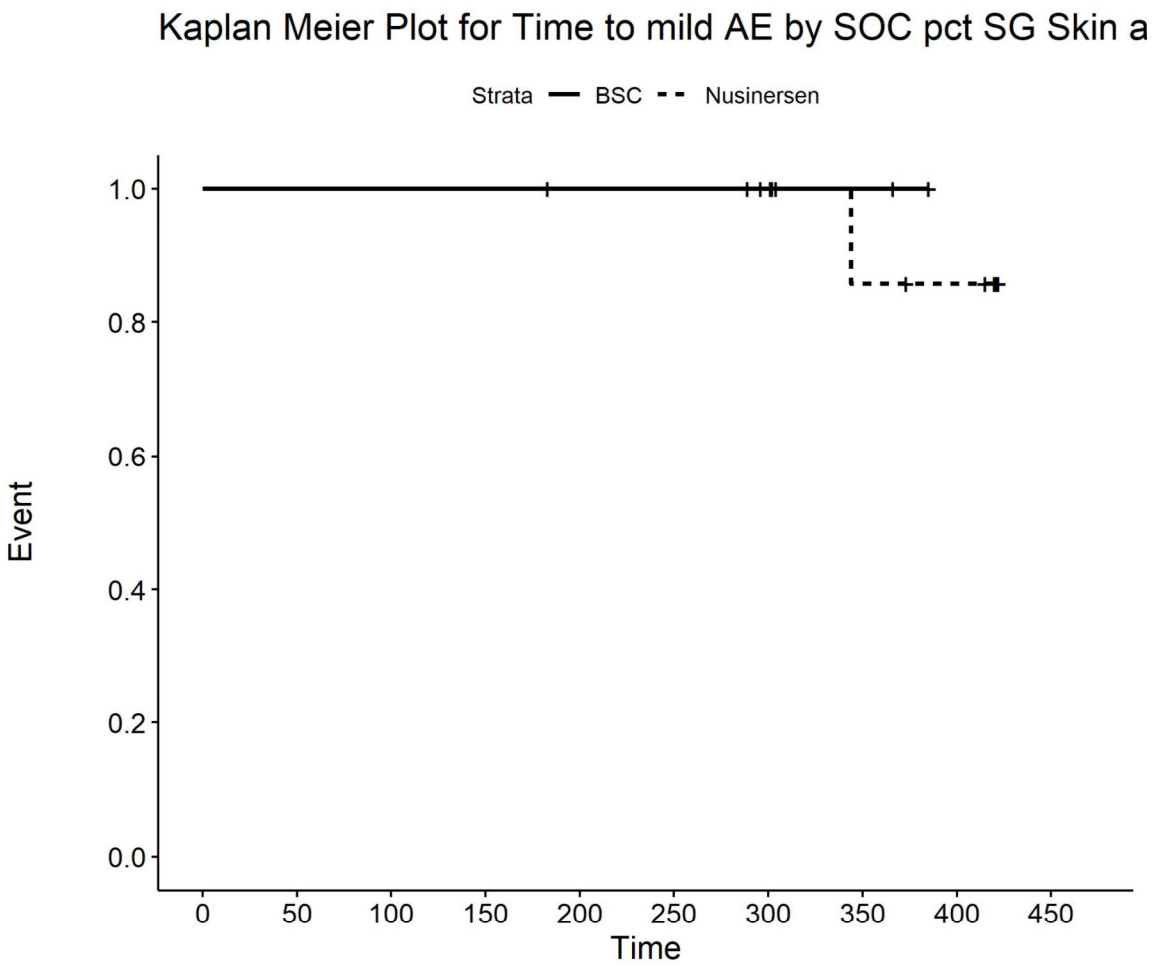
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	6	4	4	3	0	0	0



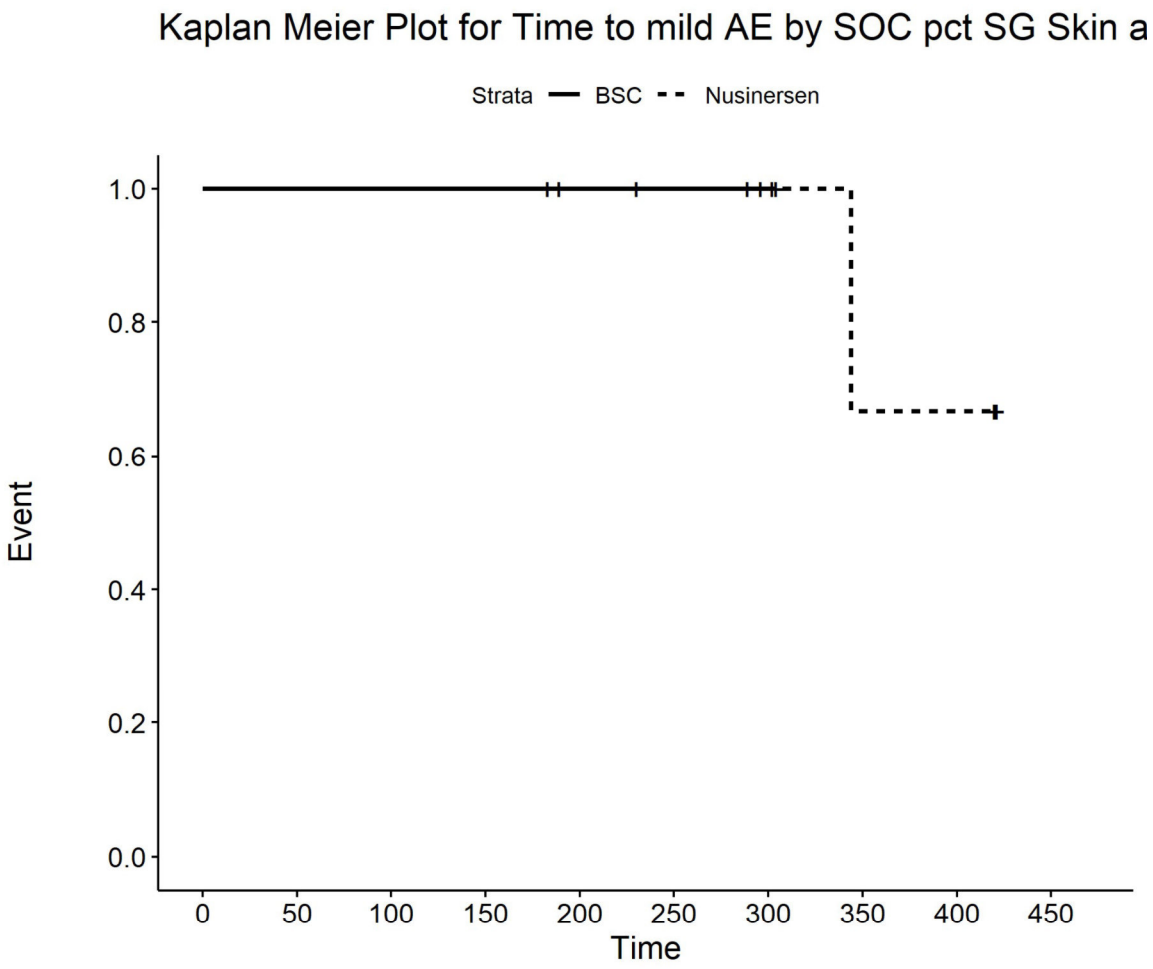
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	1	1	0



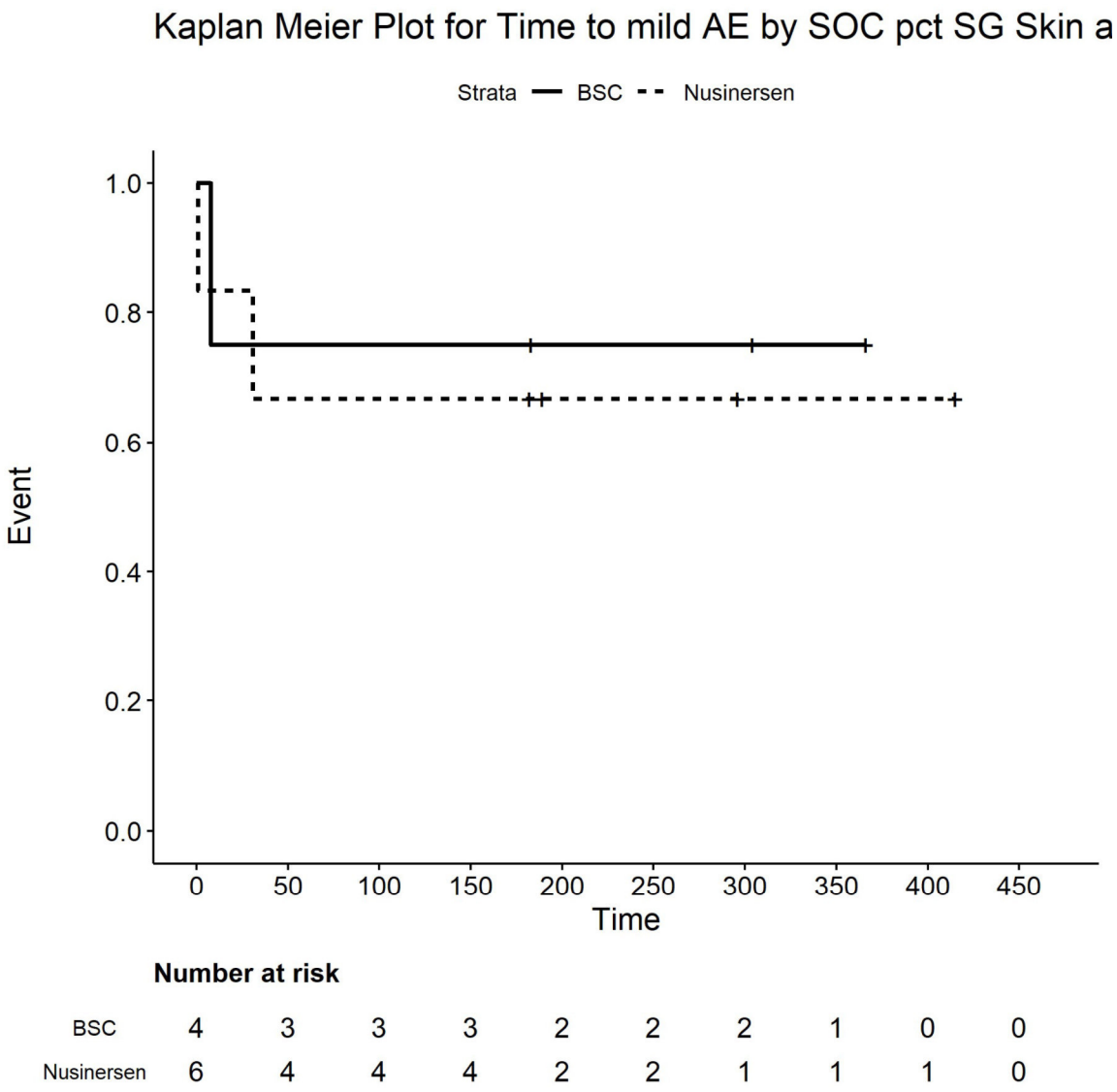
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	6	5	0



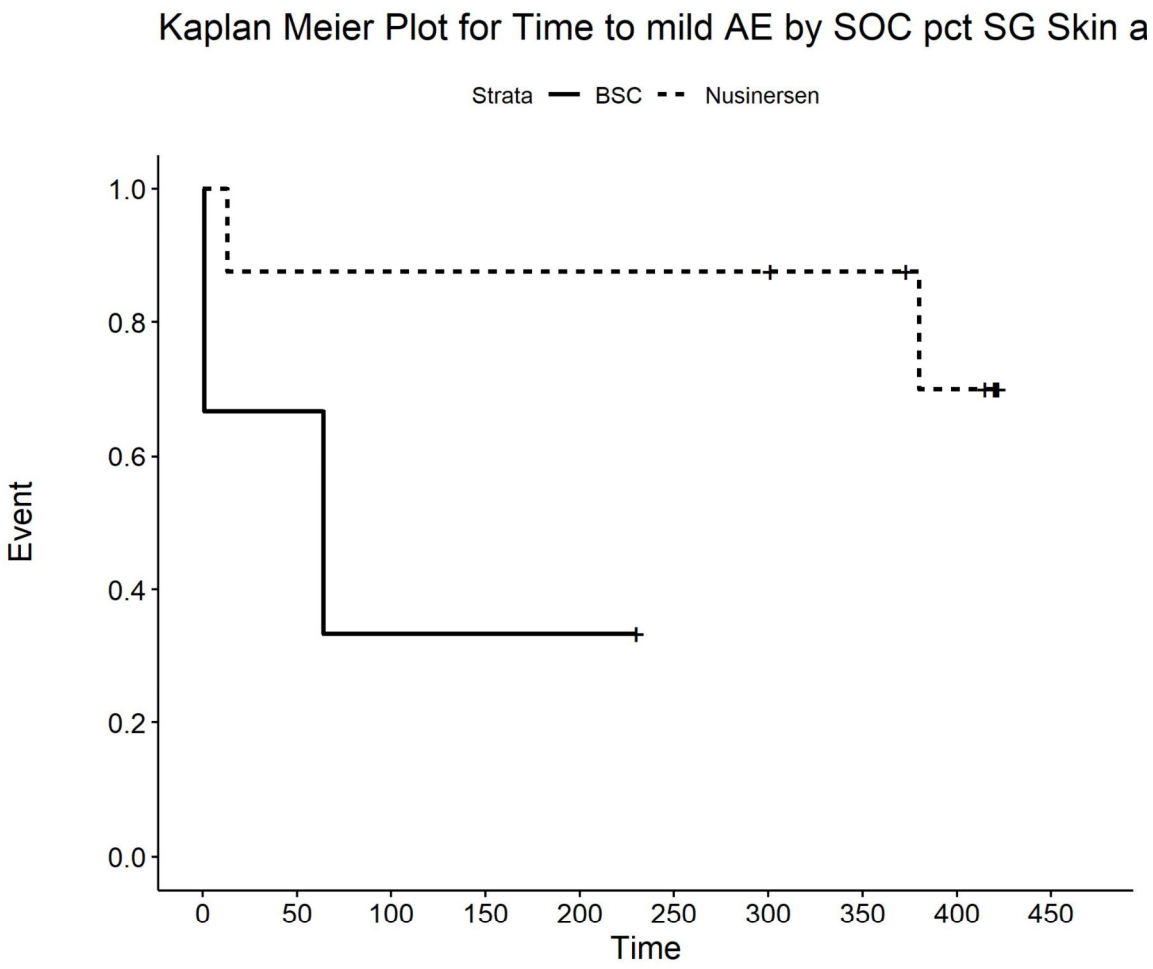
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	2	2	0



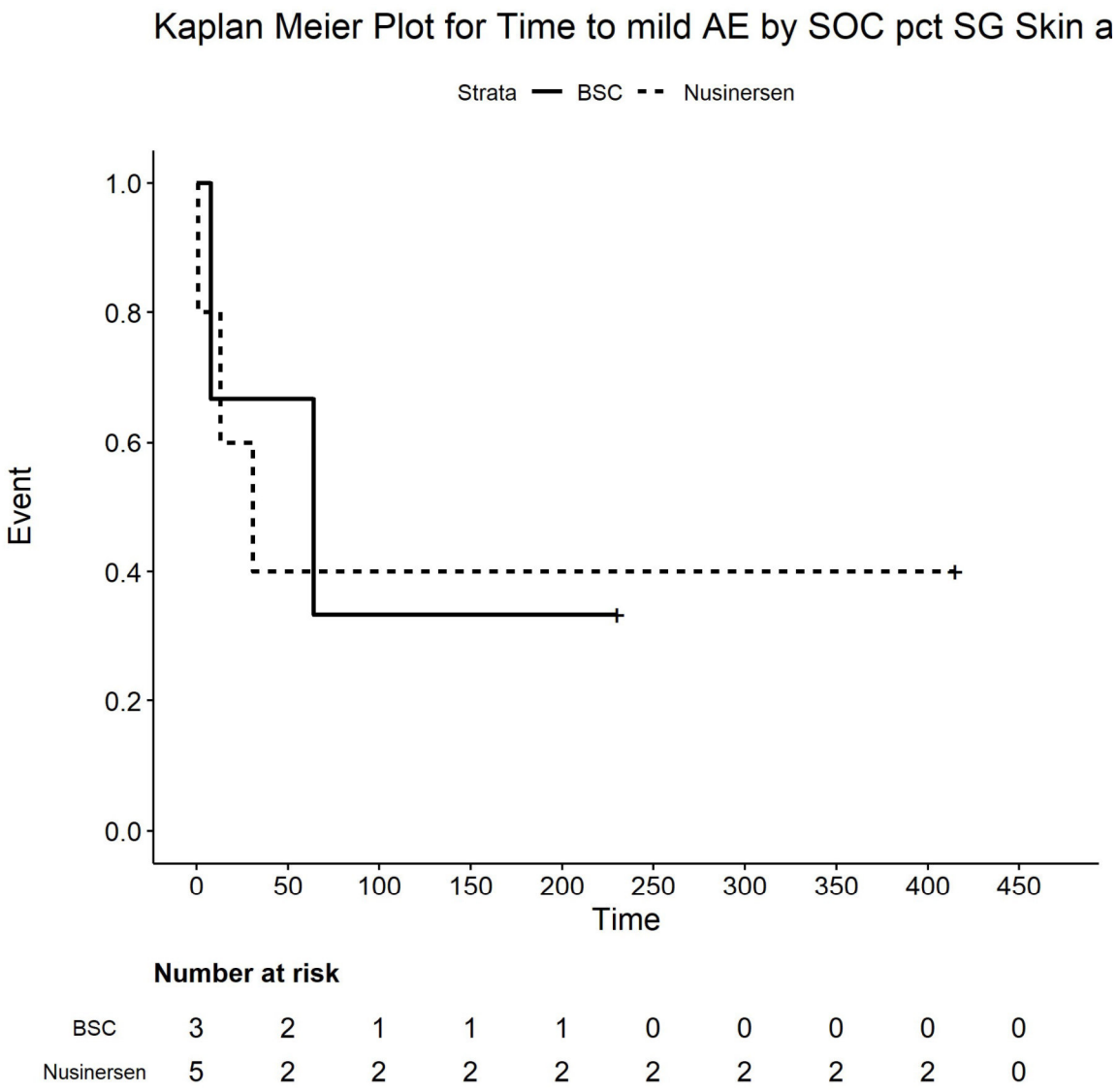
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	4	4	4	2	2	1	1	1	0



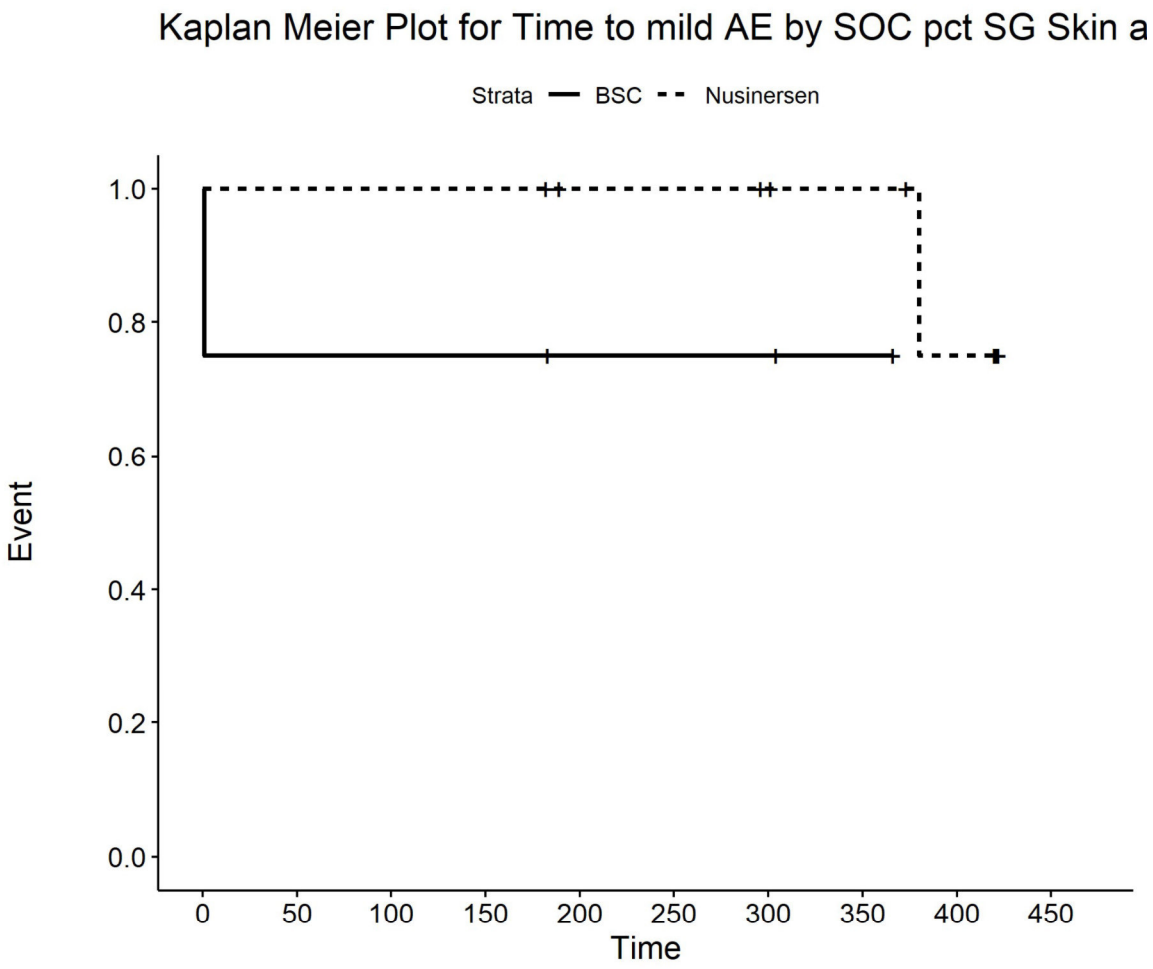
Number at risk

BSC	3	2	1	1	1	0	0	0	0	0
Nusinersen	8	7	7	7	7	7	7	6	4	0



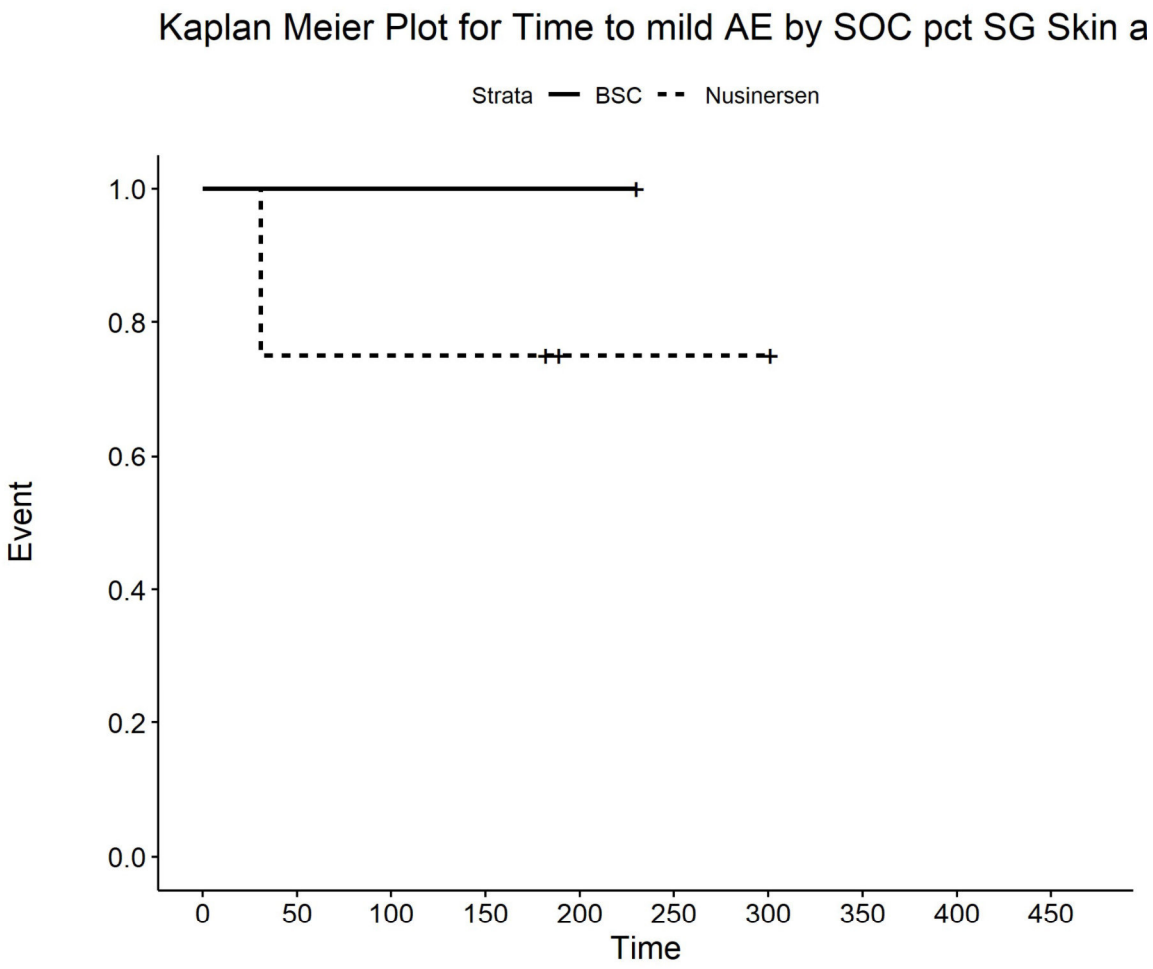
Number at risk

BSC	3	2	1	1	1	0	0	0	0	0
Nusinersen	5	2	2	2	2	2	2	2	2	0



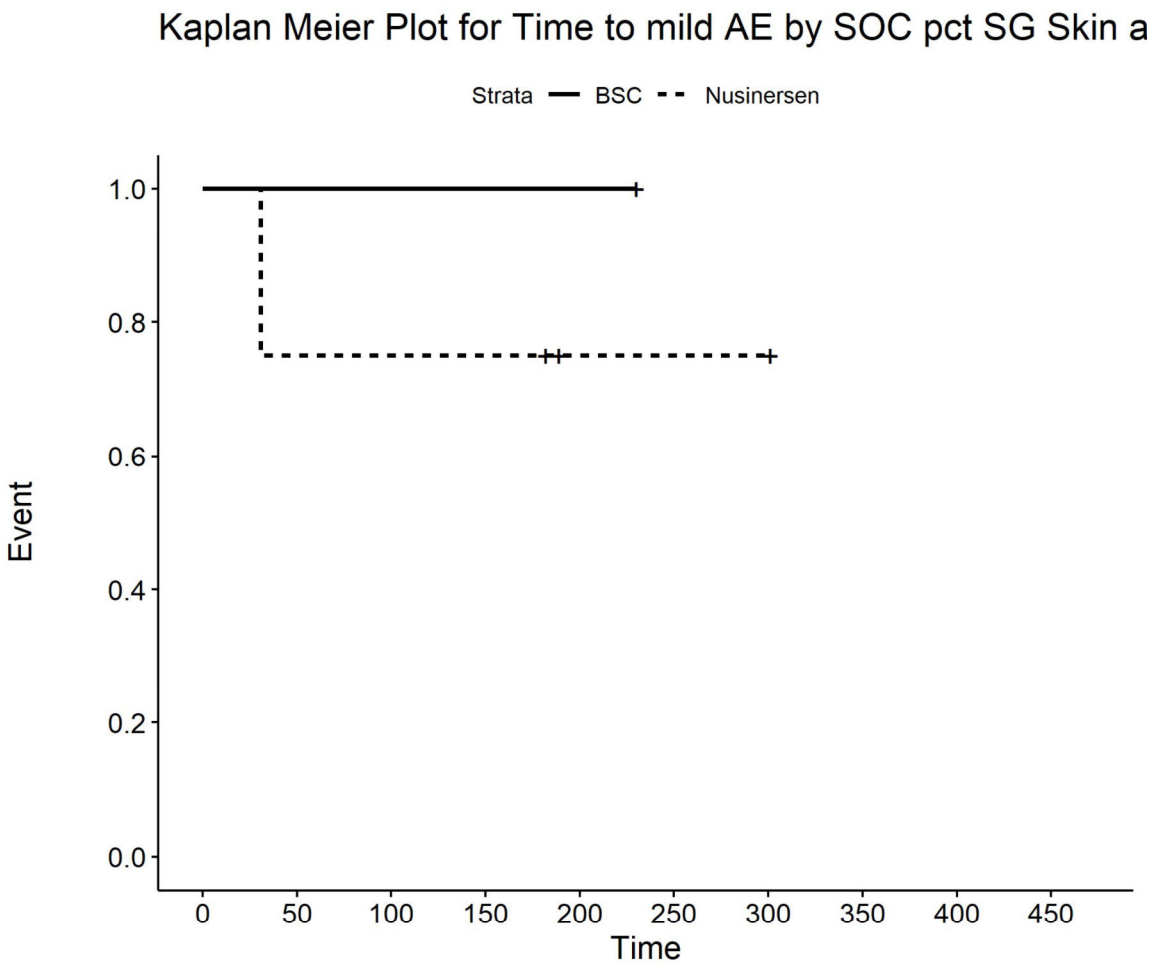
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	3	0



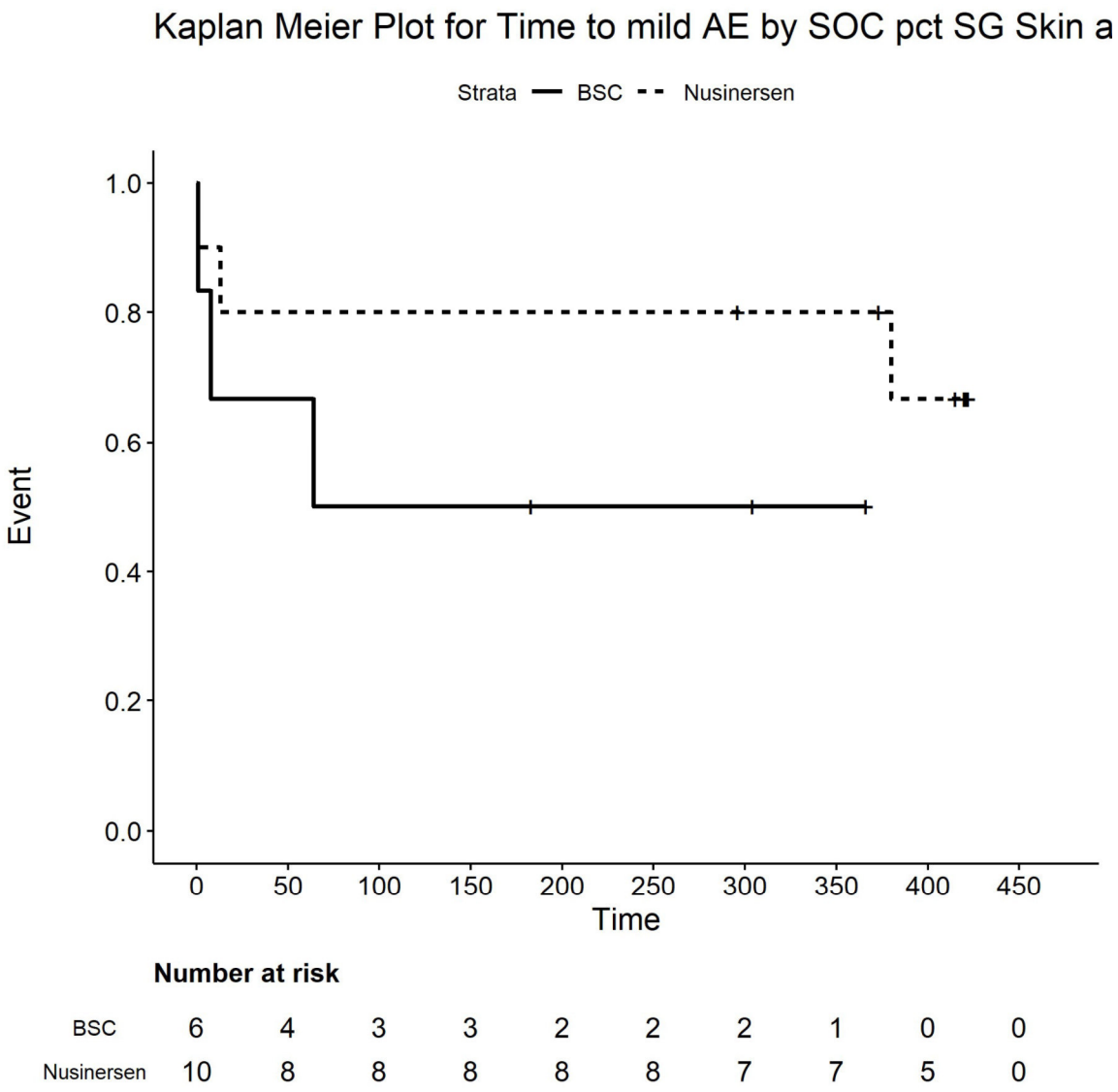
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



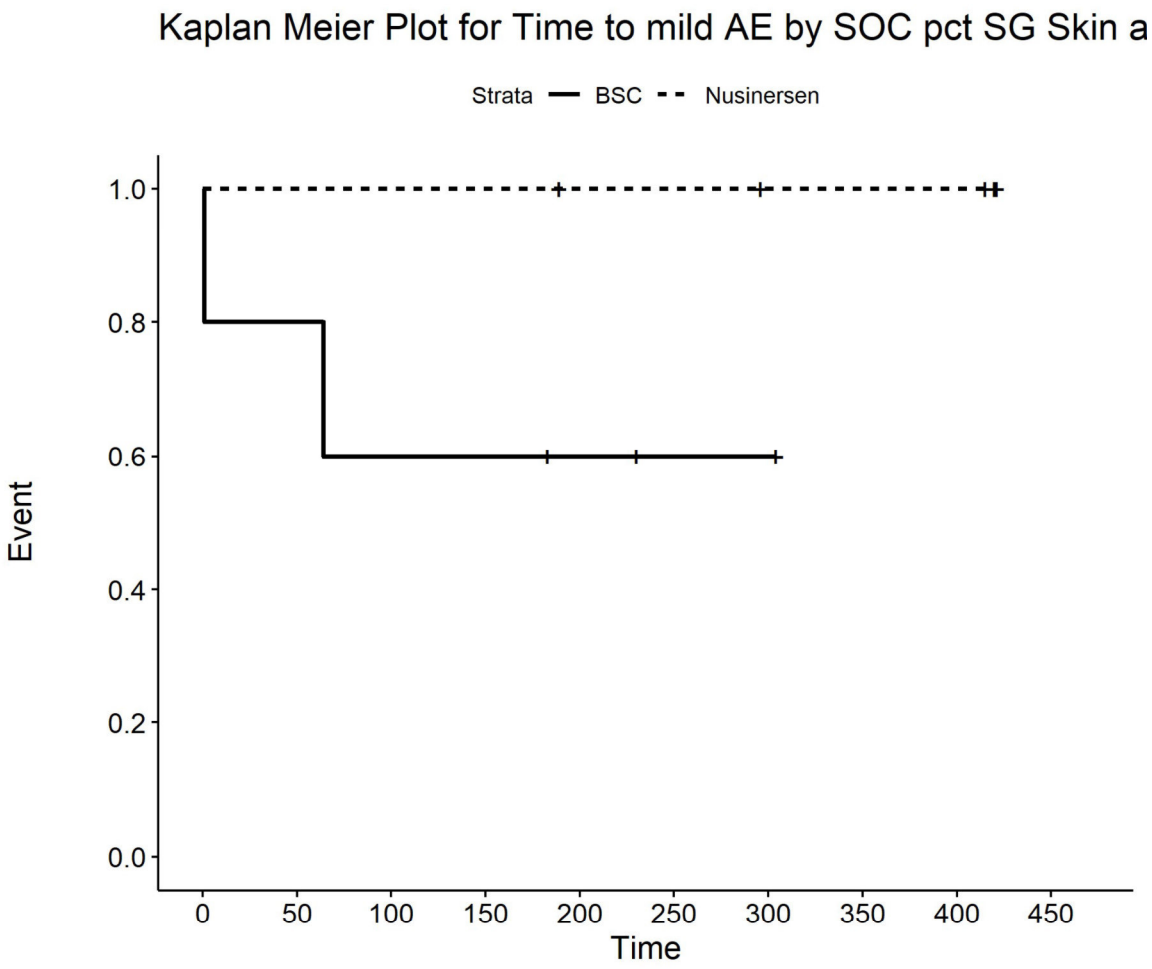
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



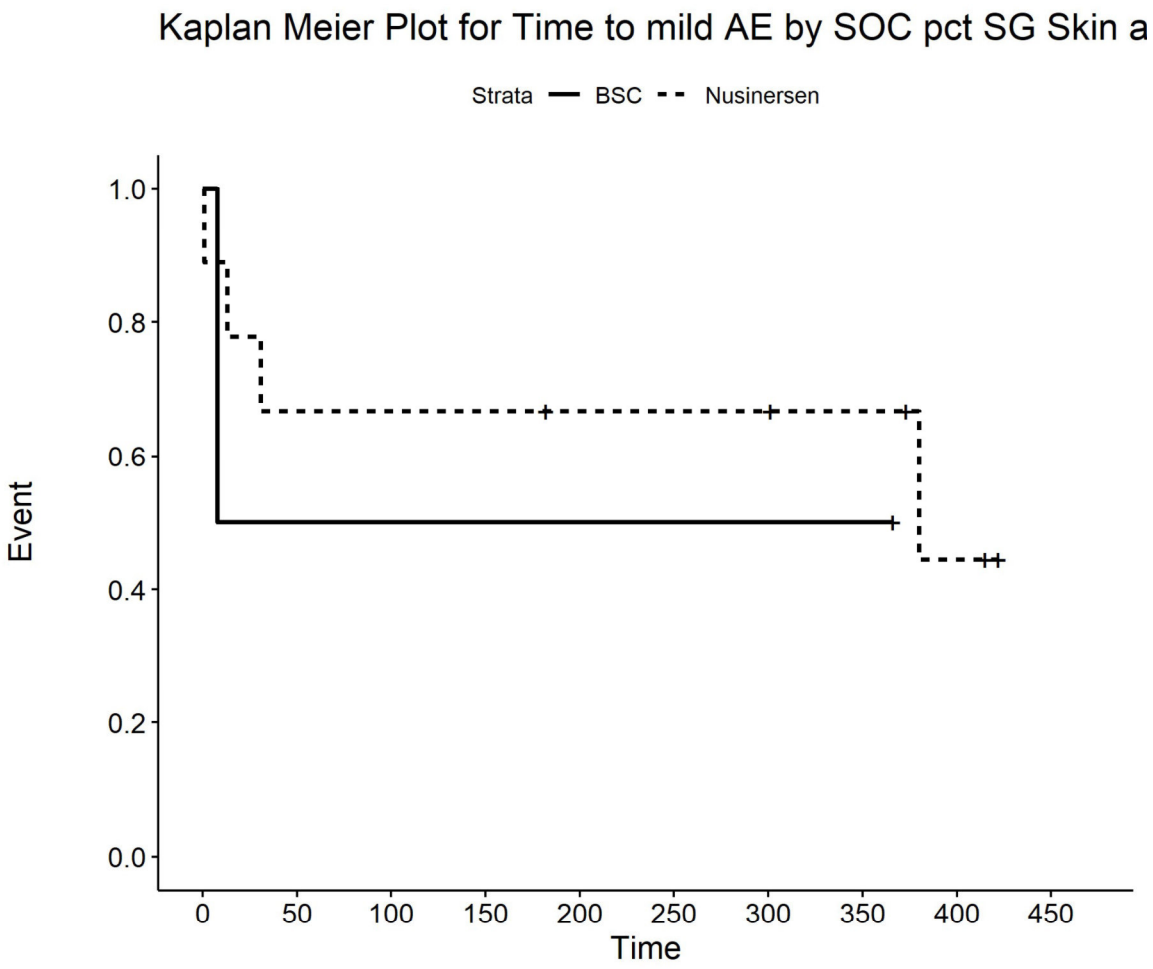
Number at risk

BSC	6	4	3	3	2	2	2	1	0	0
Nusinersen	10	8	8	8	8	8	7	7	5	0



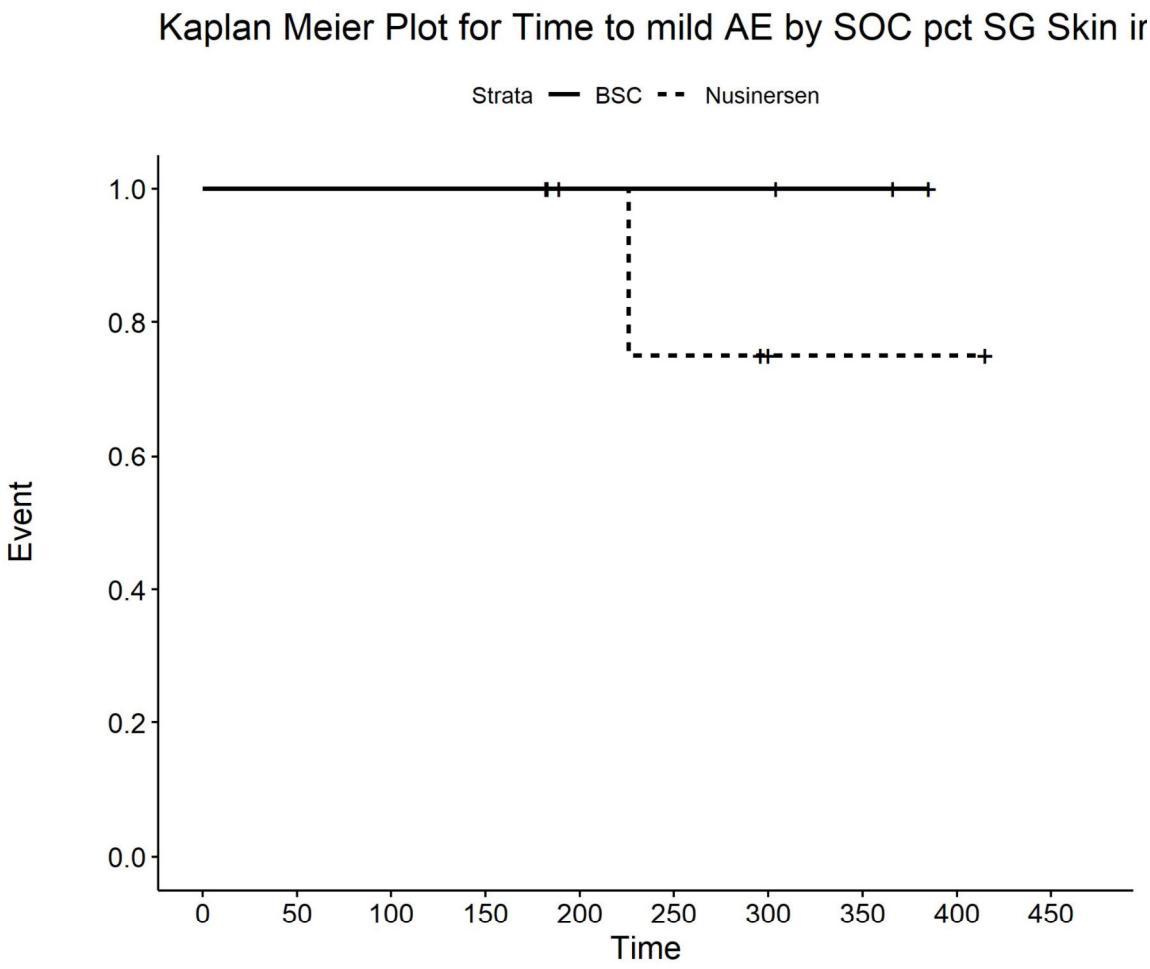
Number at risk

BSC	5	4	3	3	2	1	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



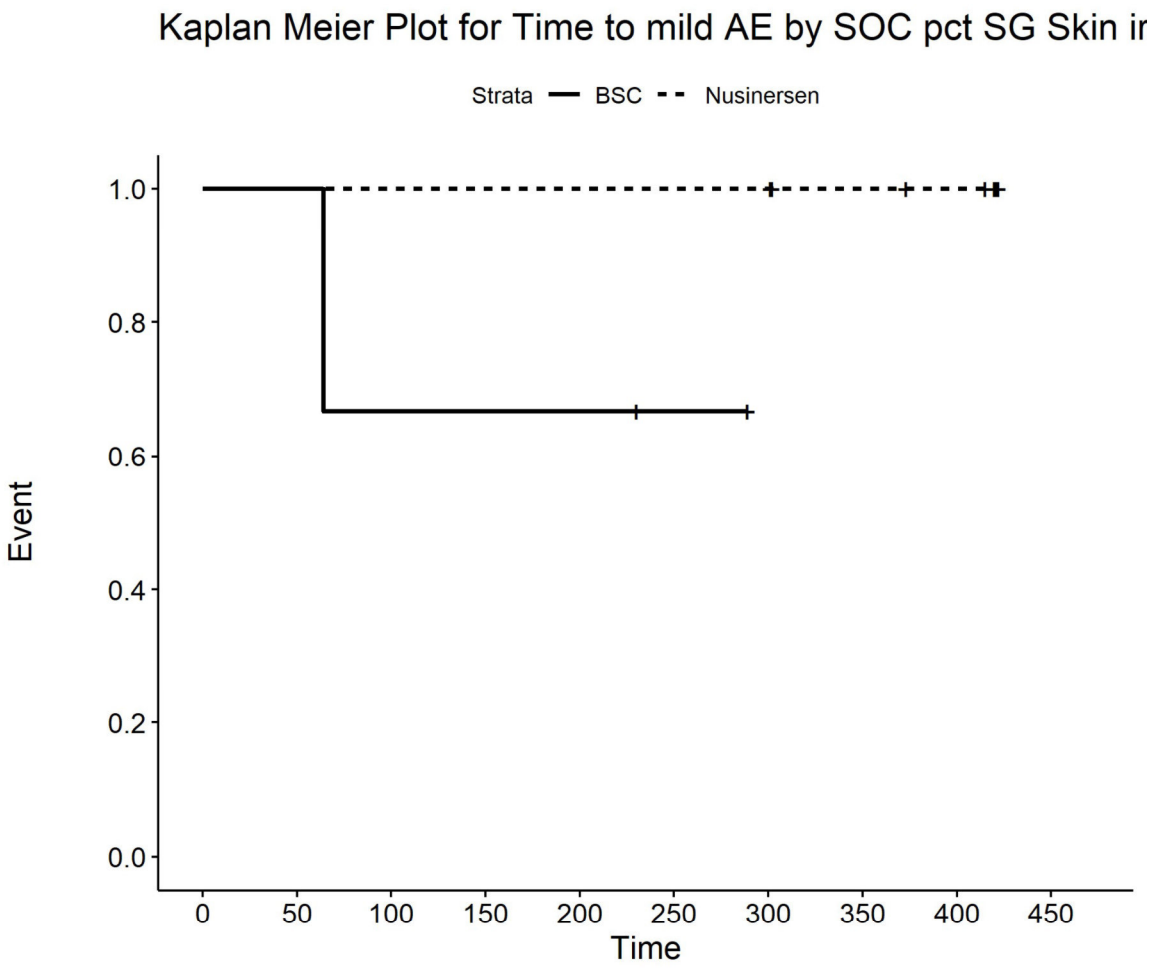
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	6	6	6	5	5	5	4	2	0



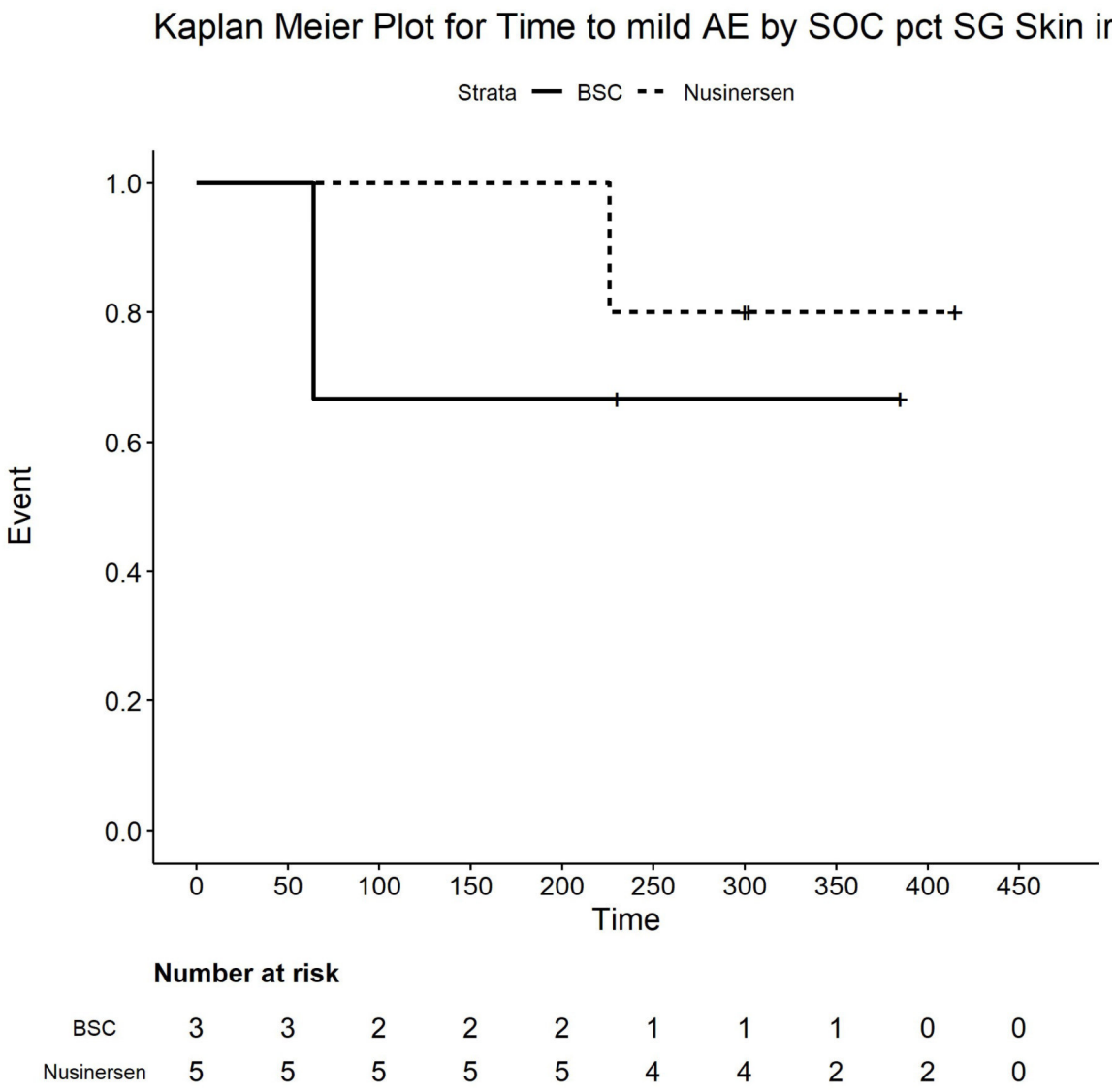
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	6	4	3	2	1	1	0



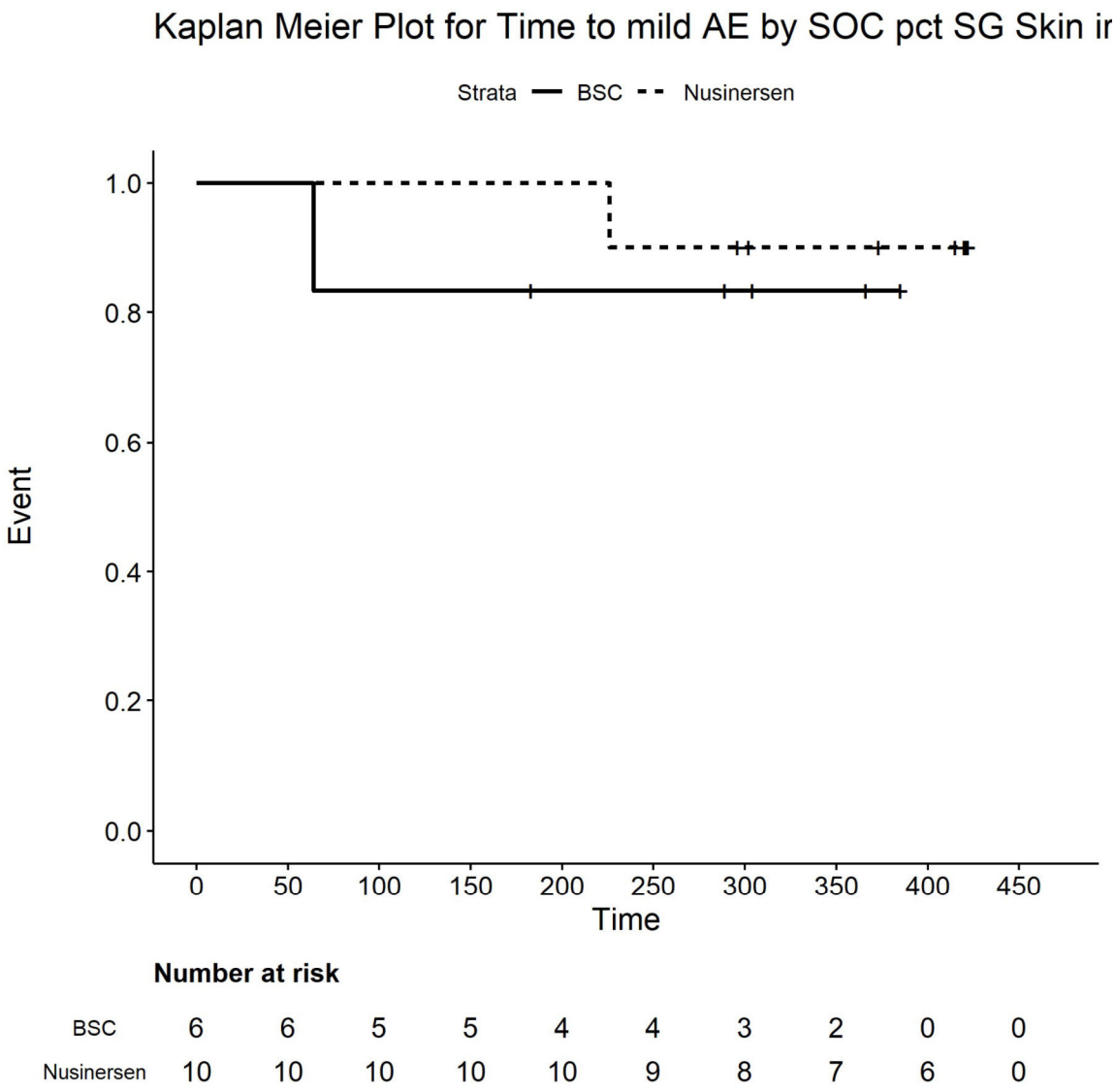
Number at risk

BSC	3	3	2	2	2	1	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



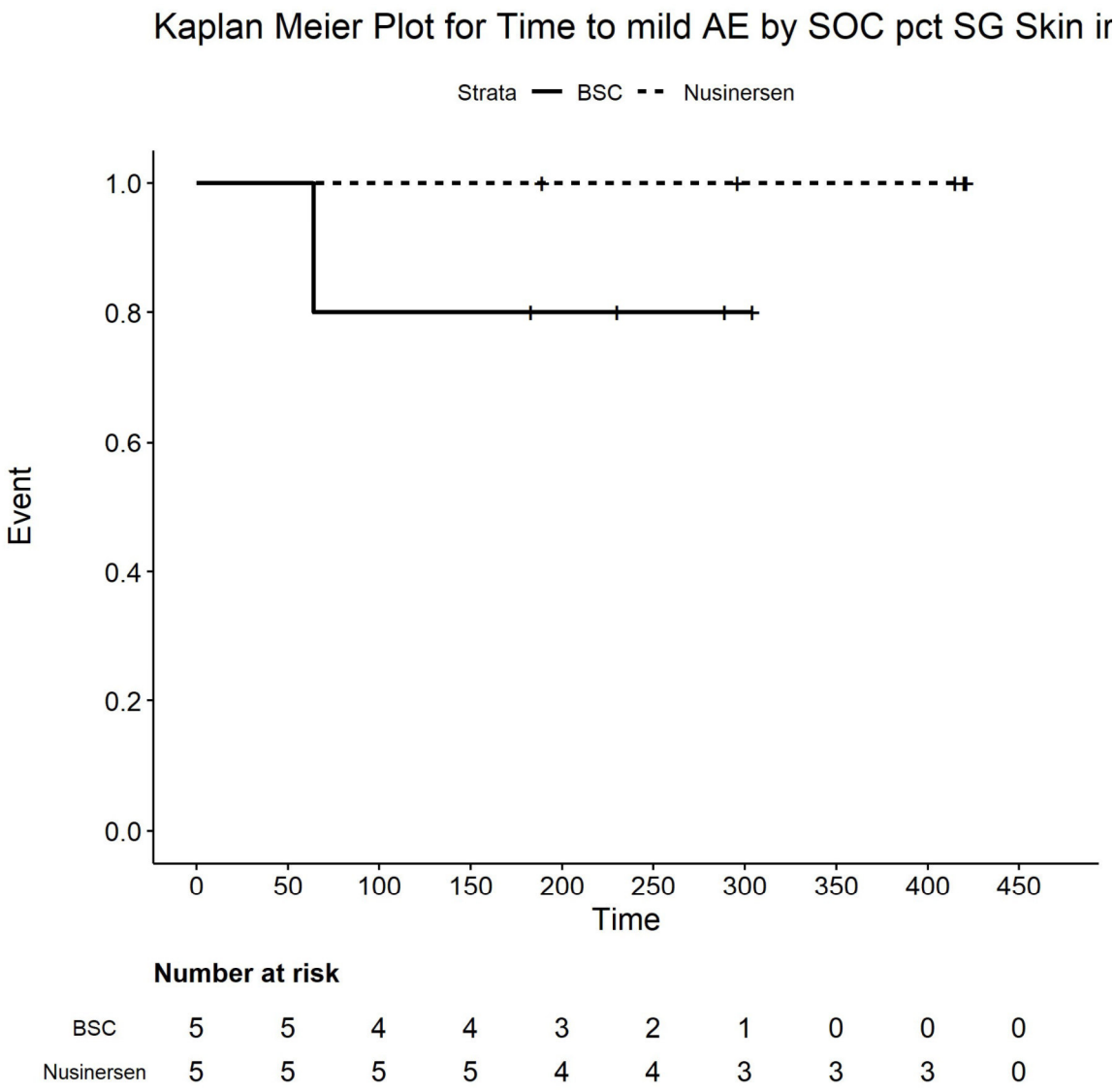
Number at risk

BSC	3	3	2	2	2	1	1	1	0	0
Nusinersen	5	5	5	5	5	4	4	2	2	0



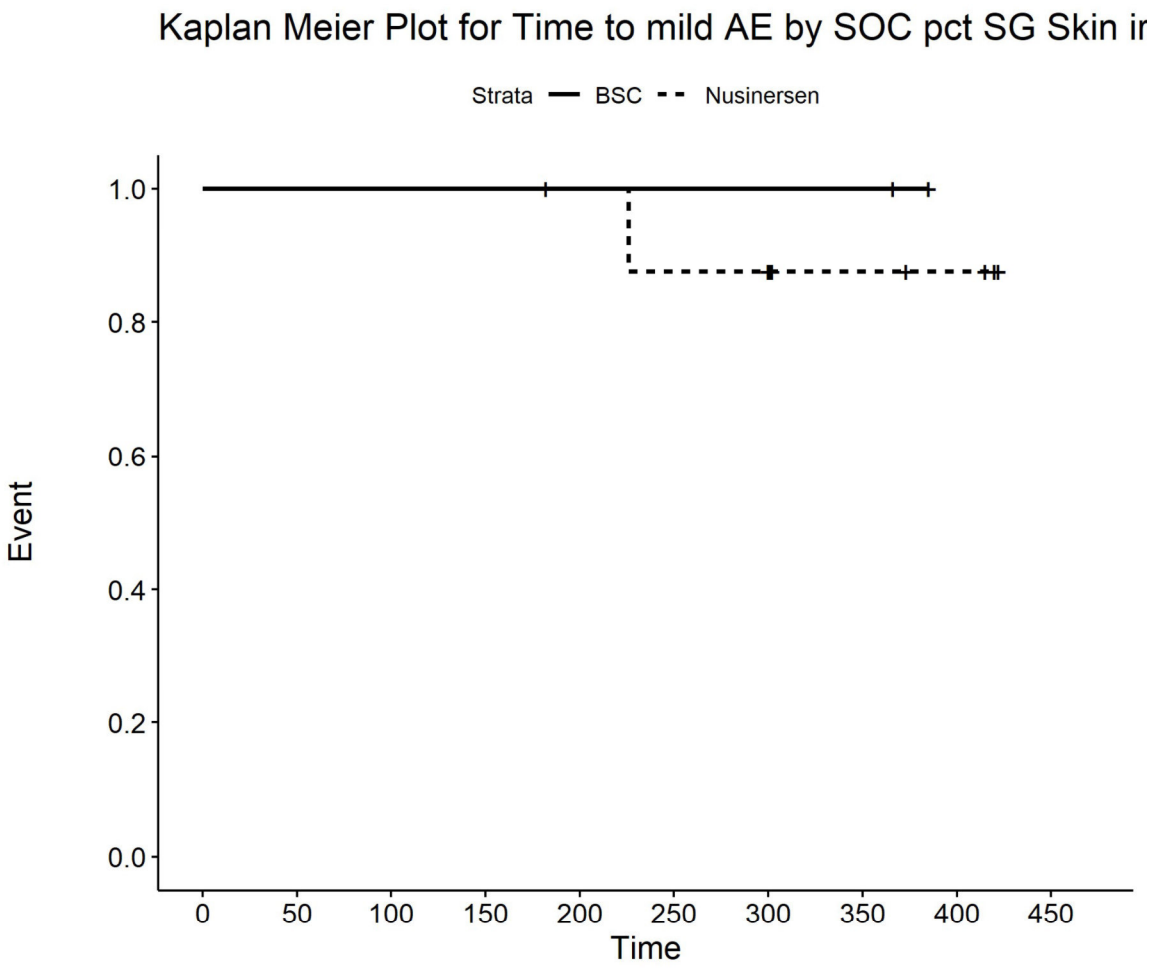
Number at risk

BSC	6	6	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	9	8	7	6	0



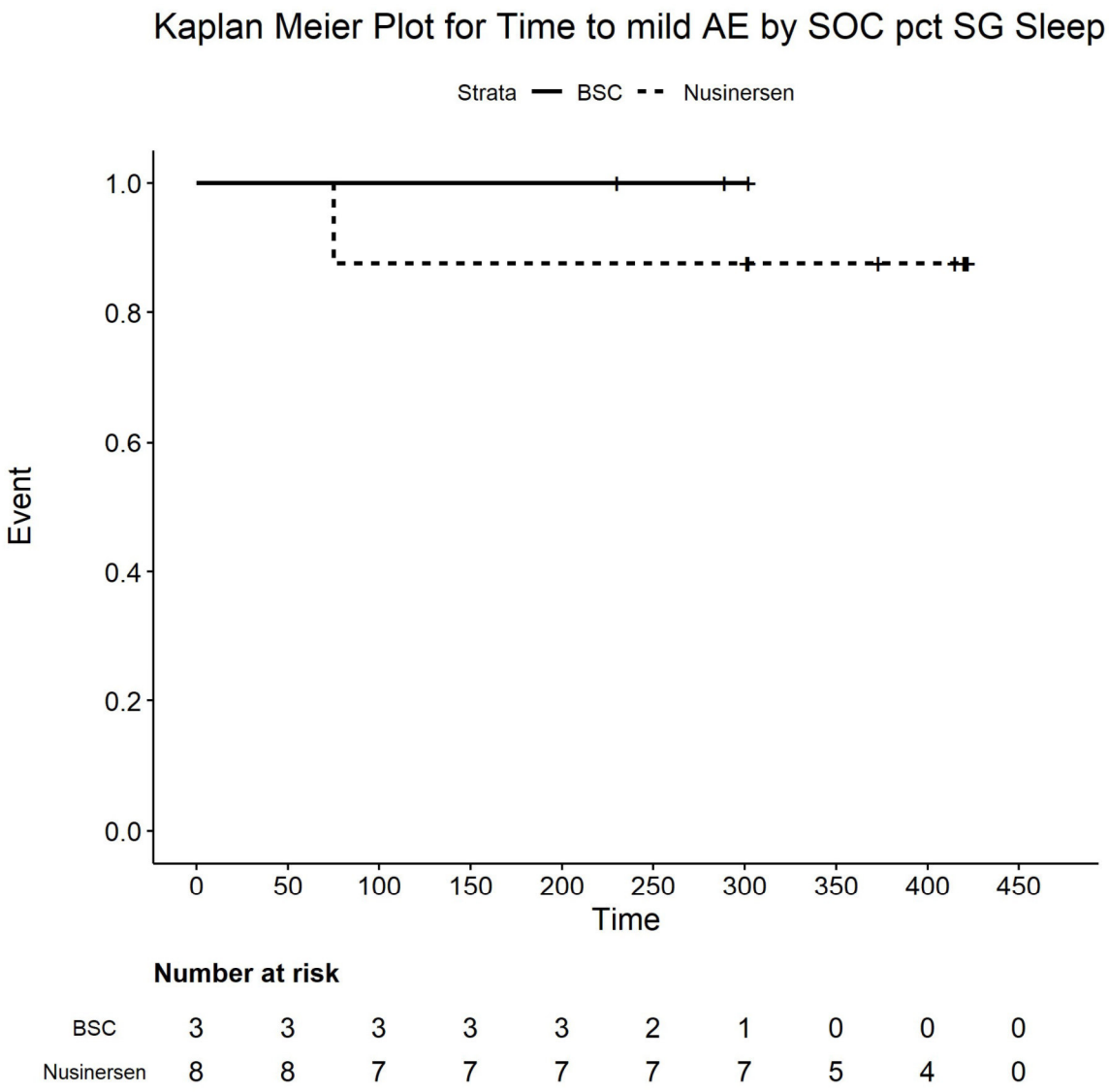
Number at risk

BSC	5	5	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



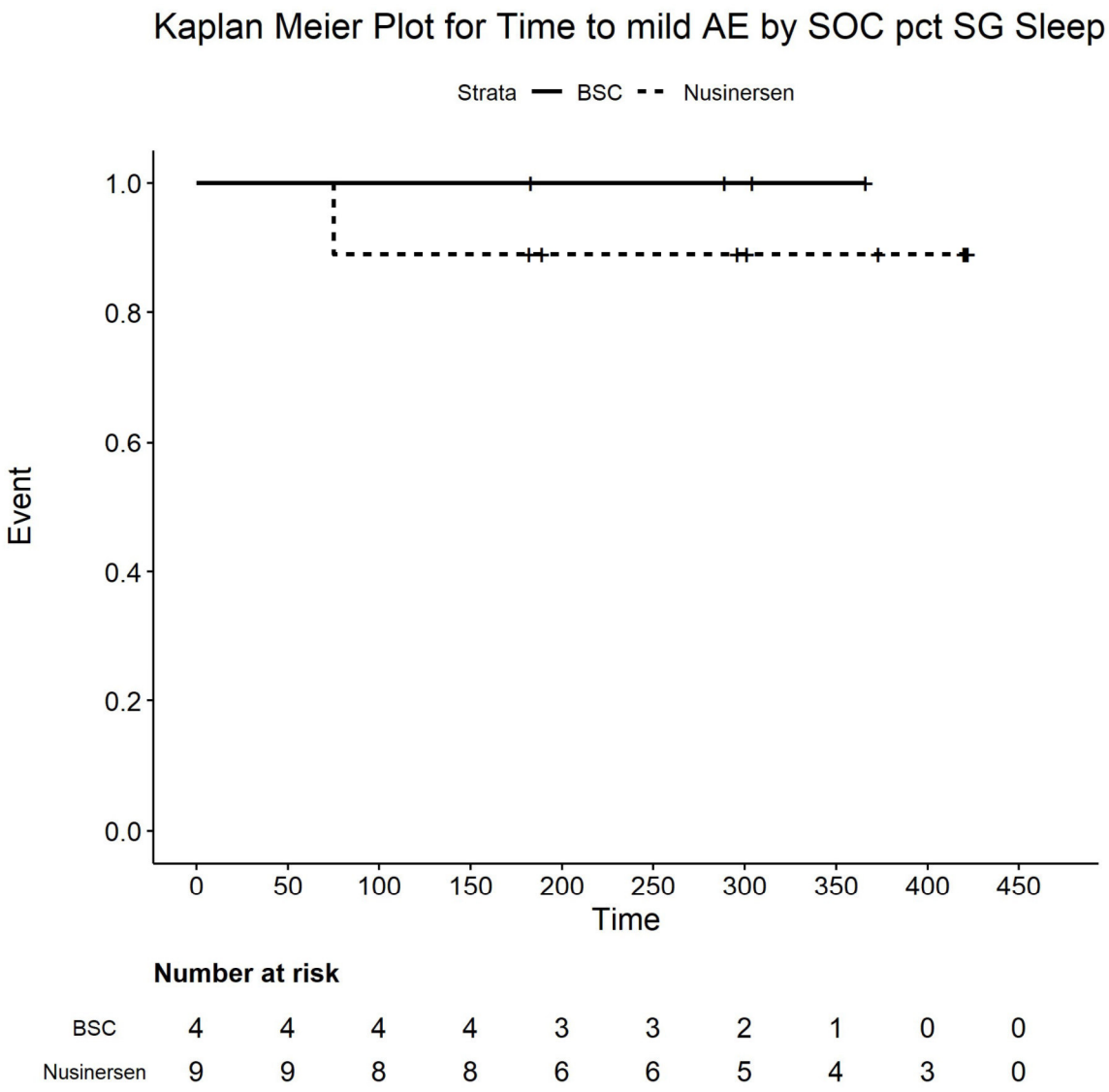
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	4	3	0



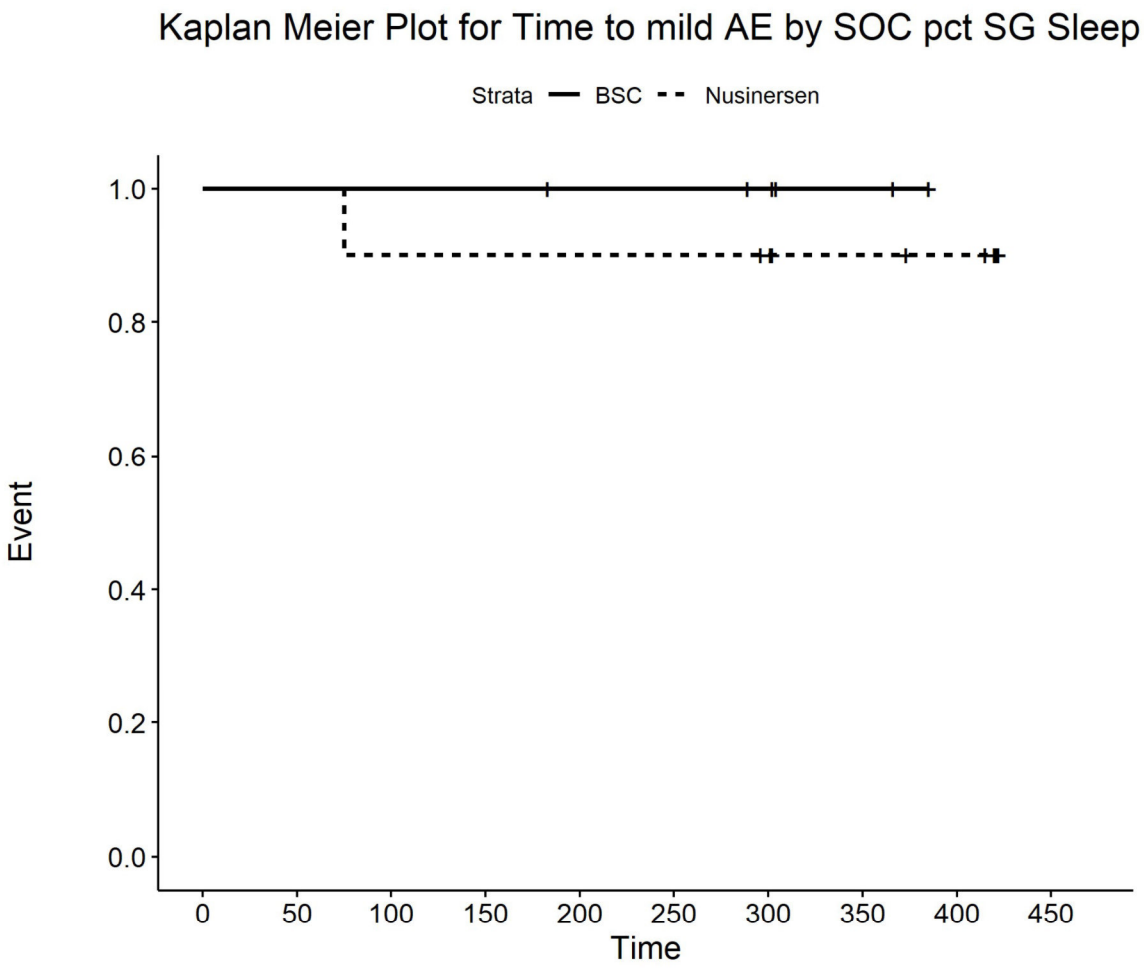
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	4	0



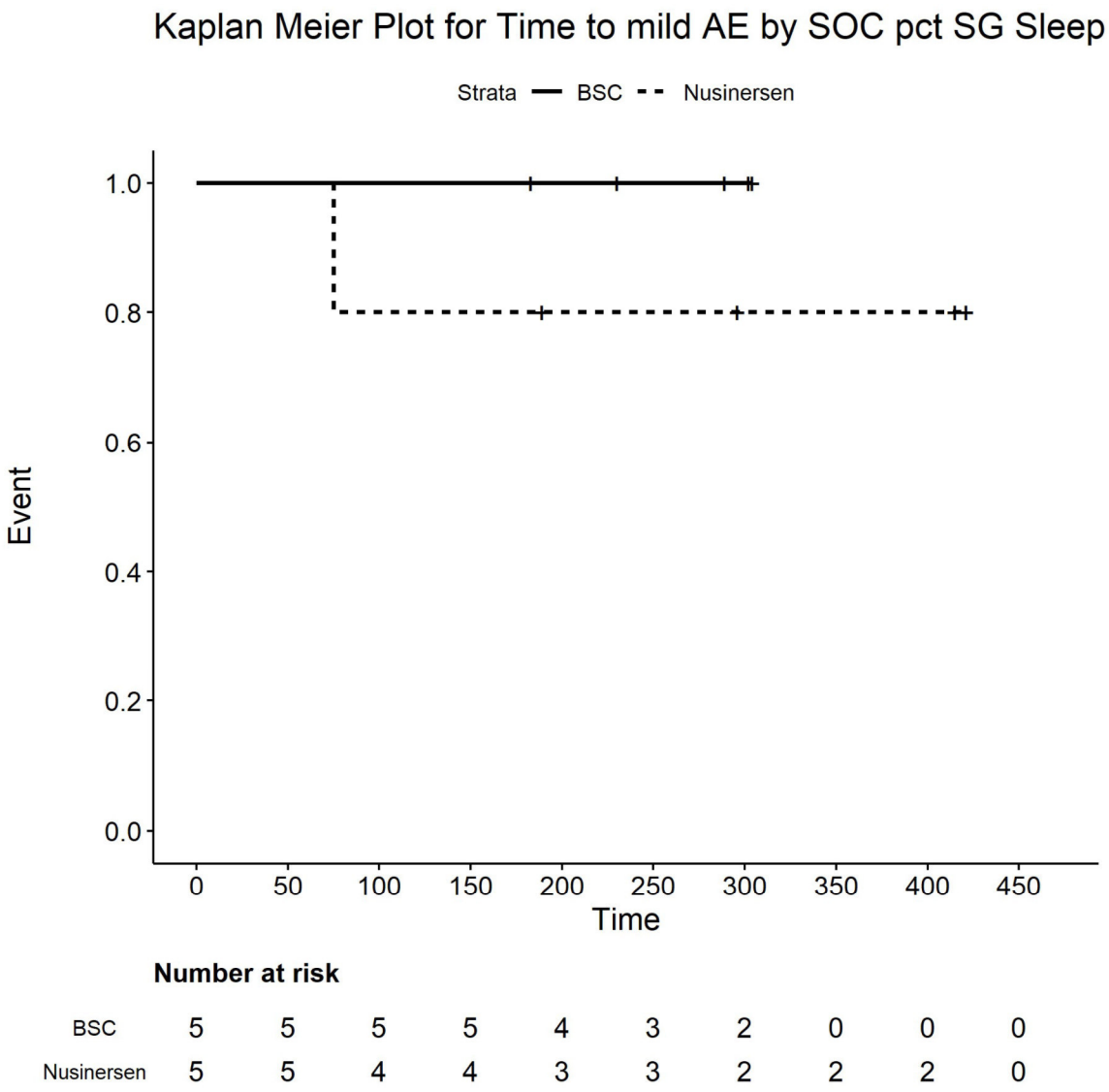
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



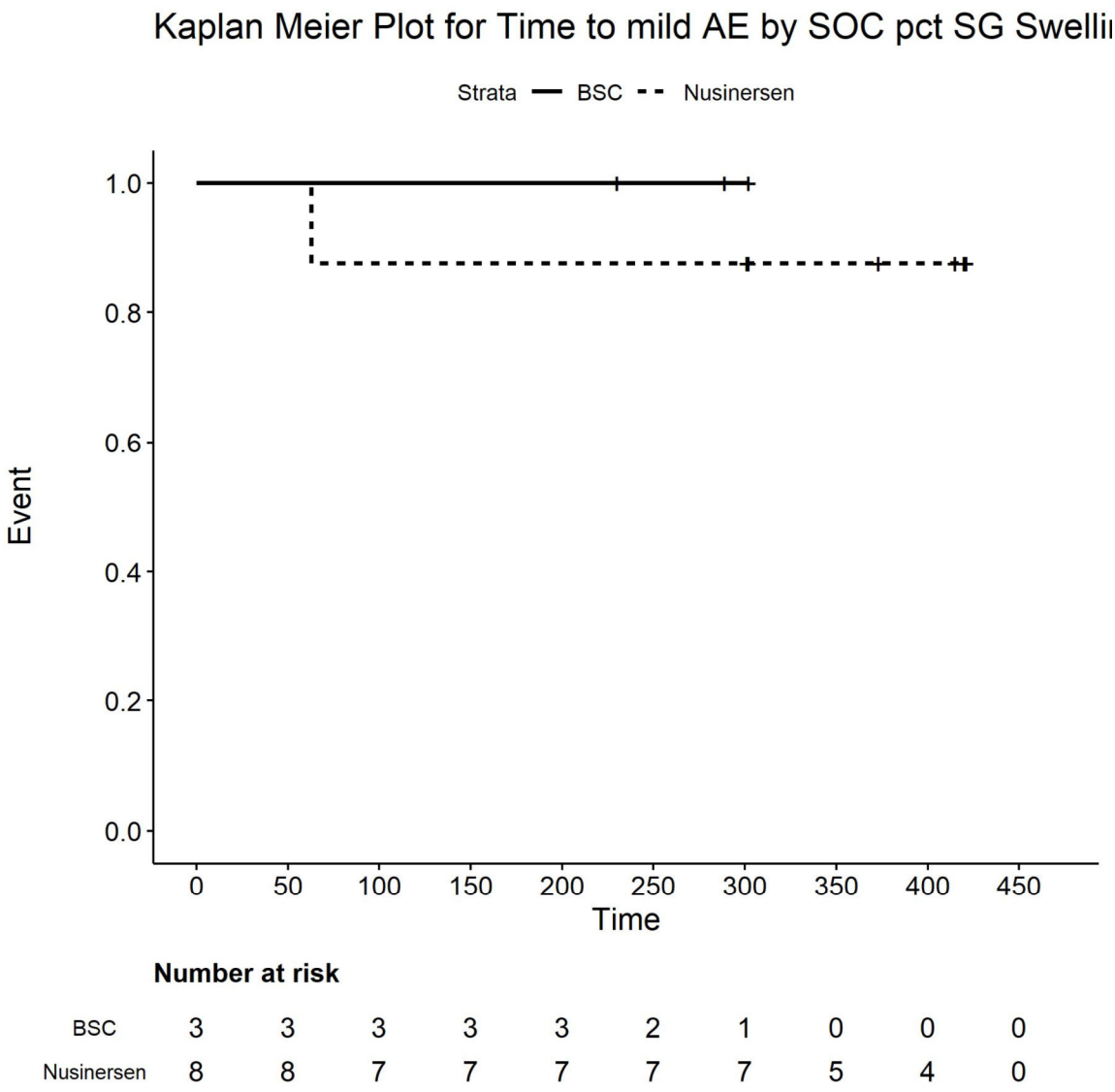
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



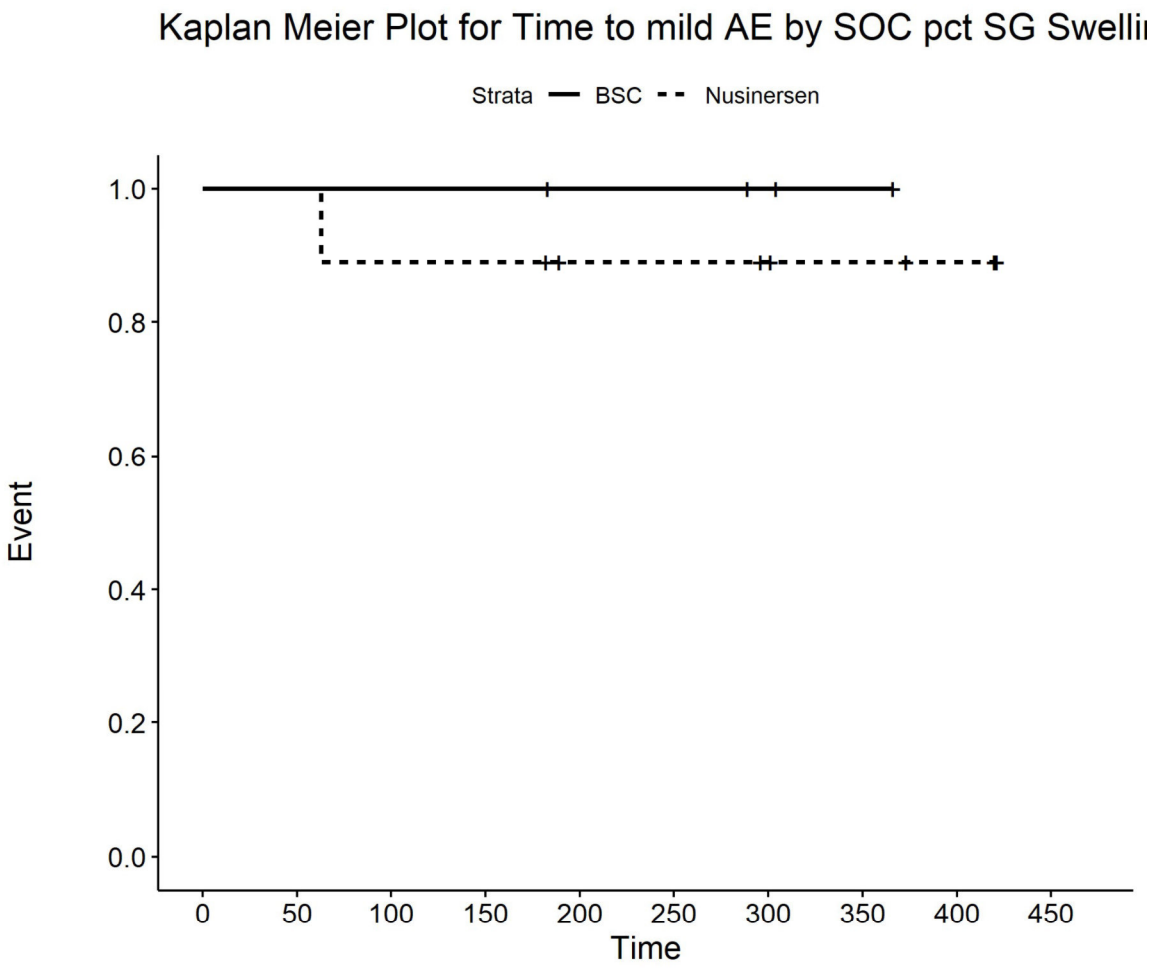
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	4	4	3	3	2	2	2	0



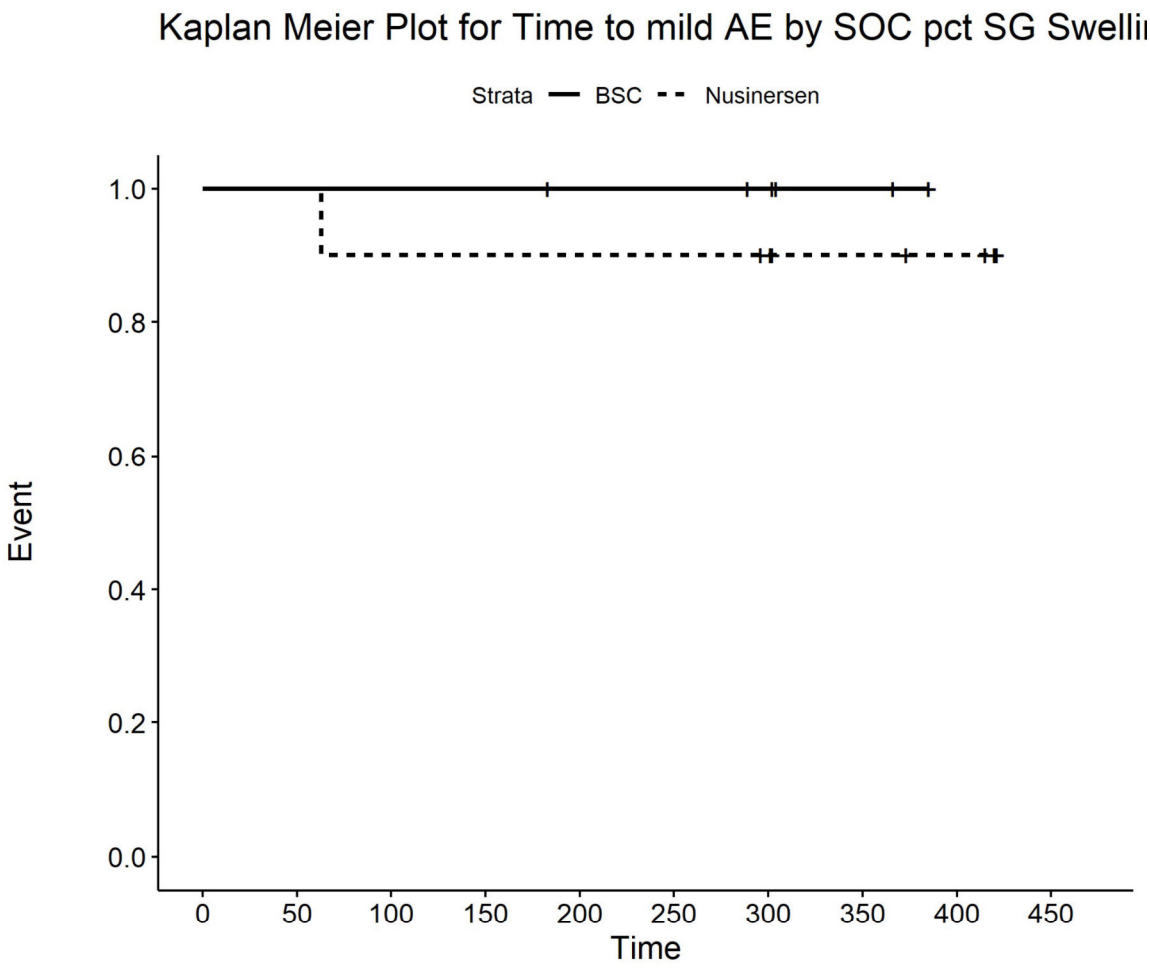
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	4	0



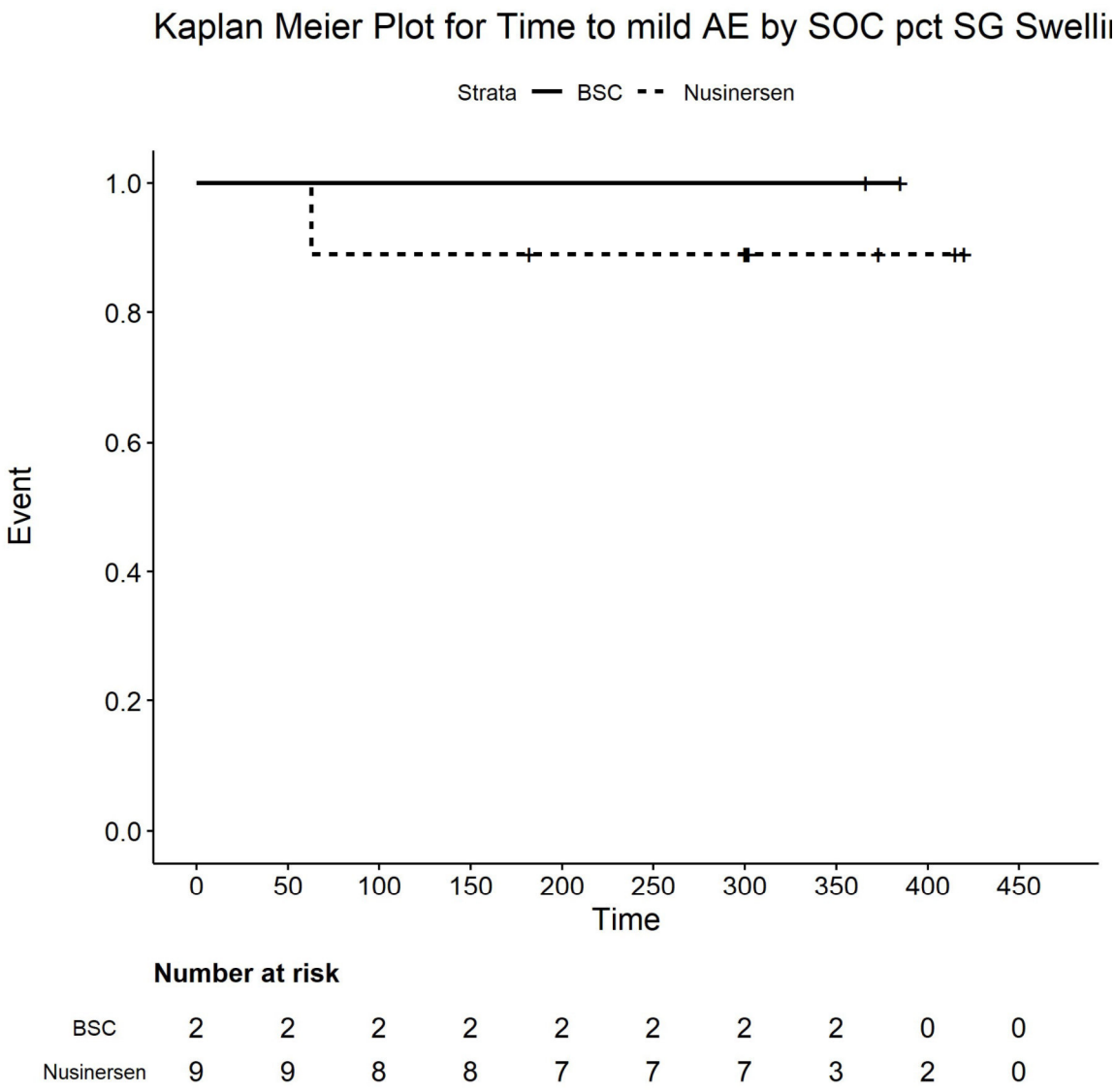
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



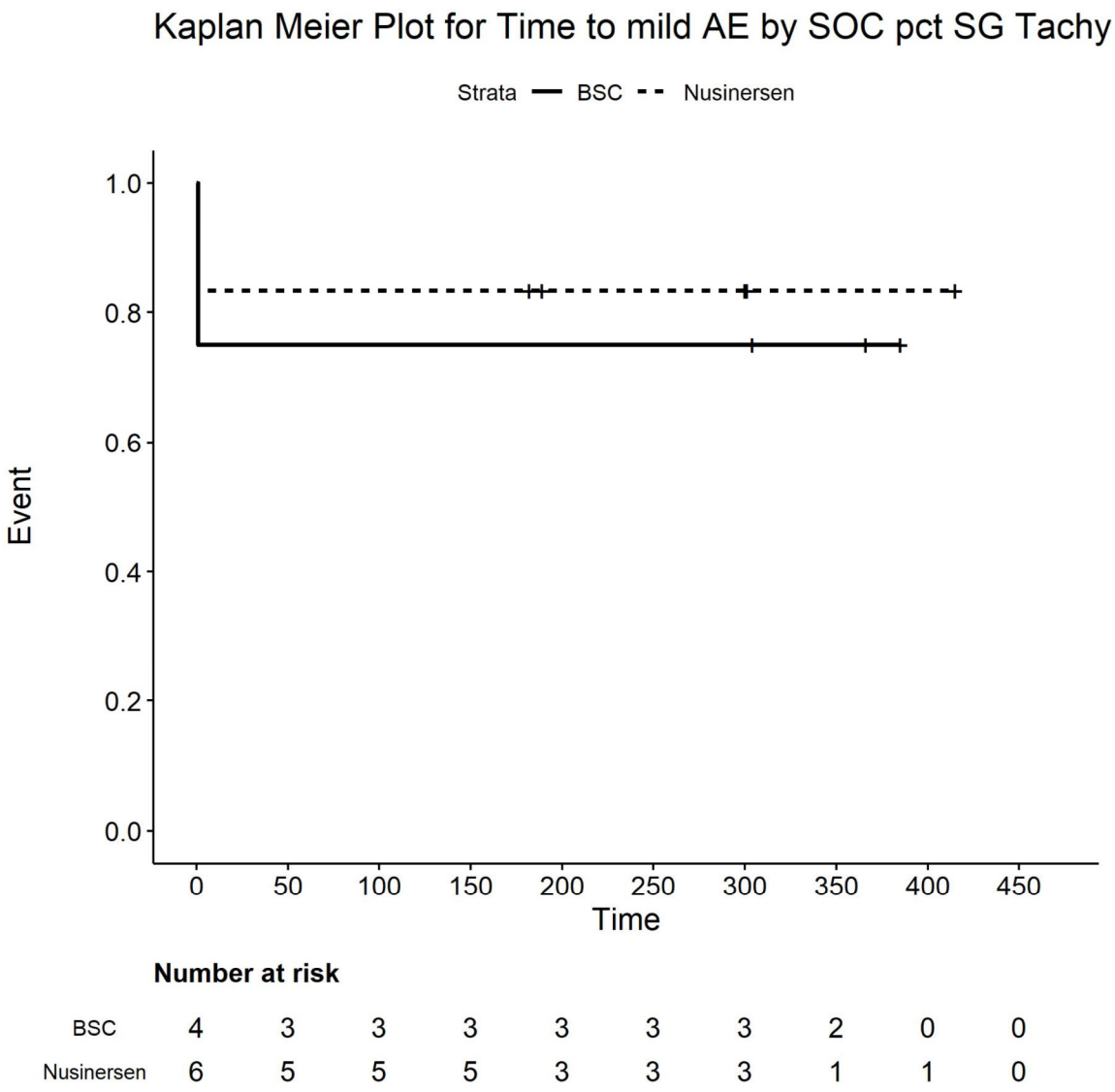
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



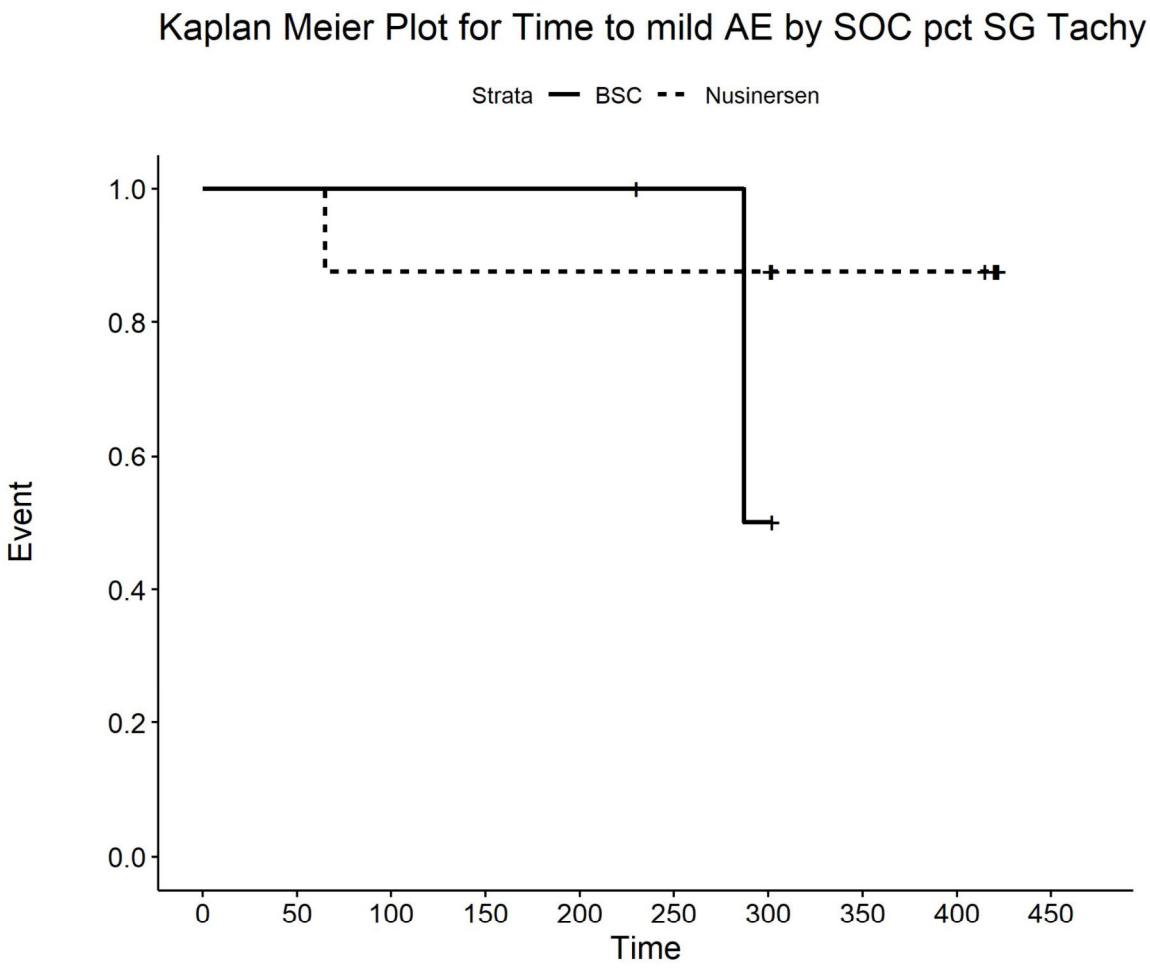
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	2	0



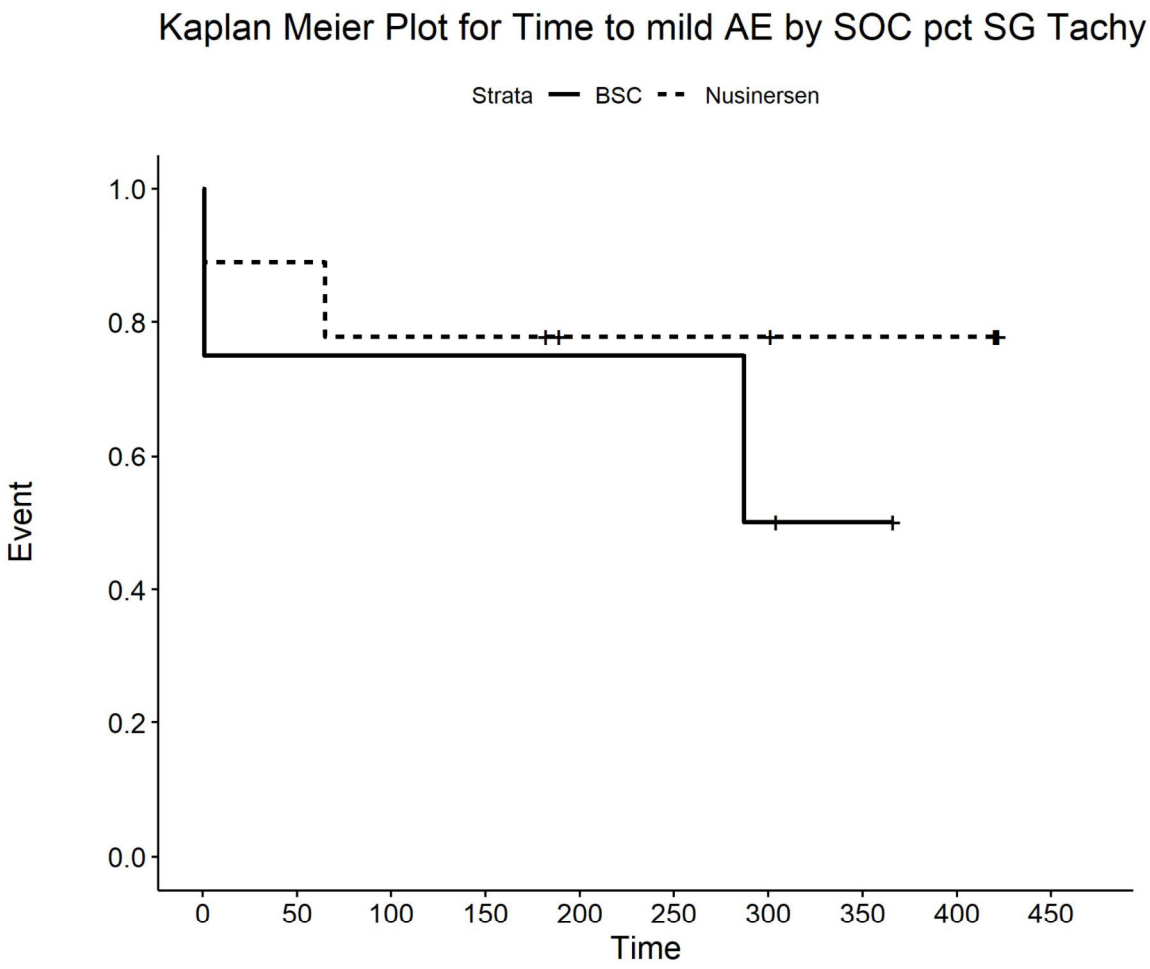
Number at risk

BSC	4	3	3	3	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	3	1	1	0



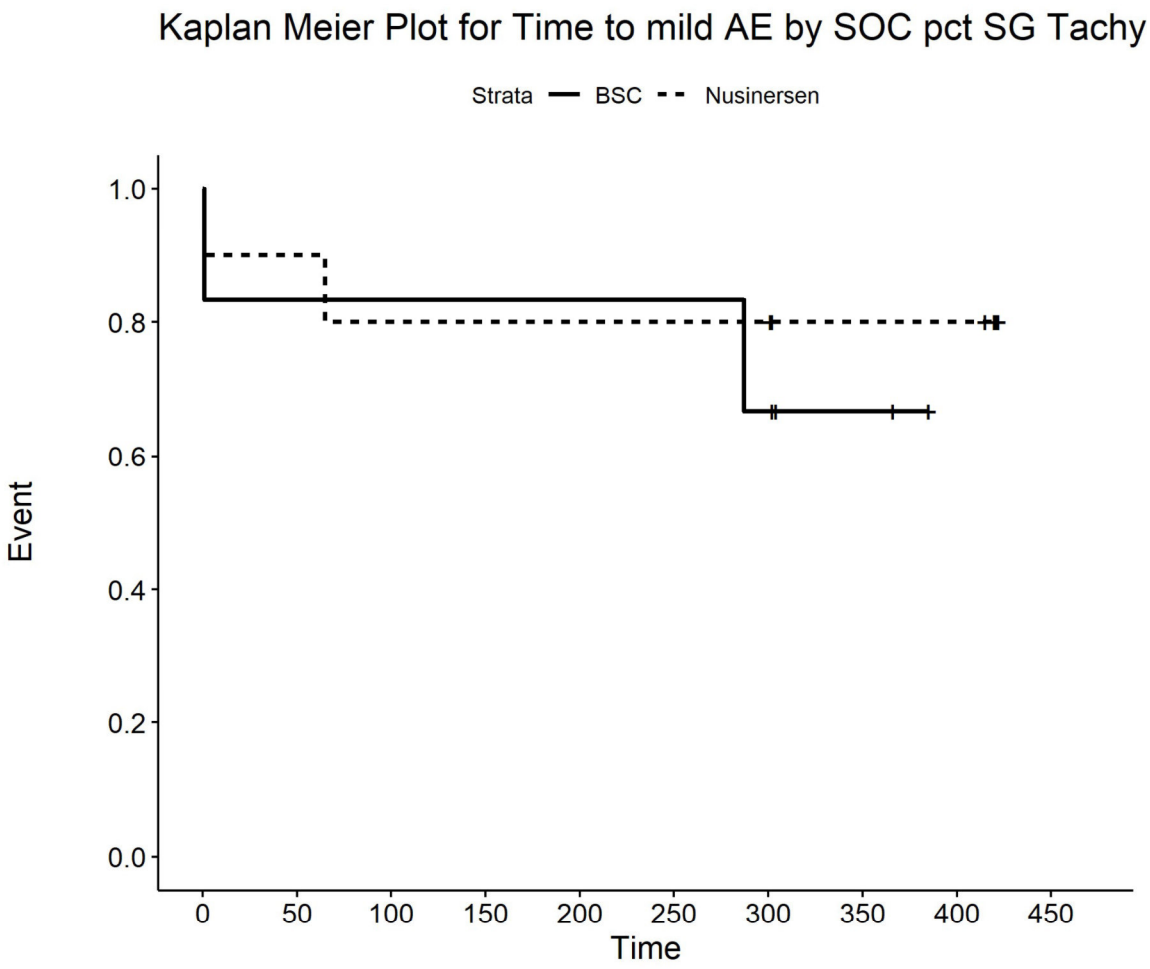
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	5	0



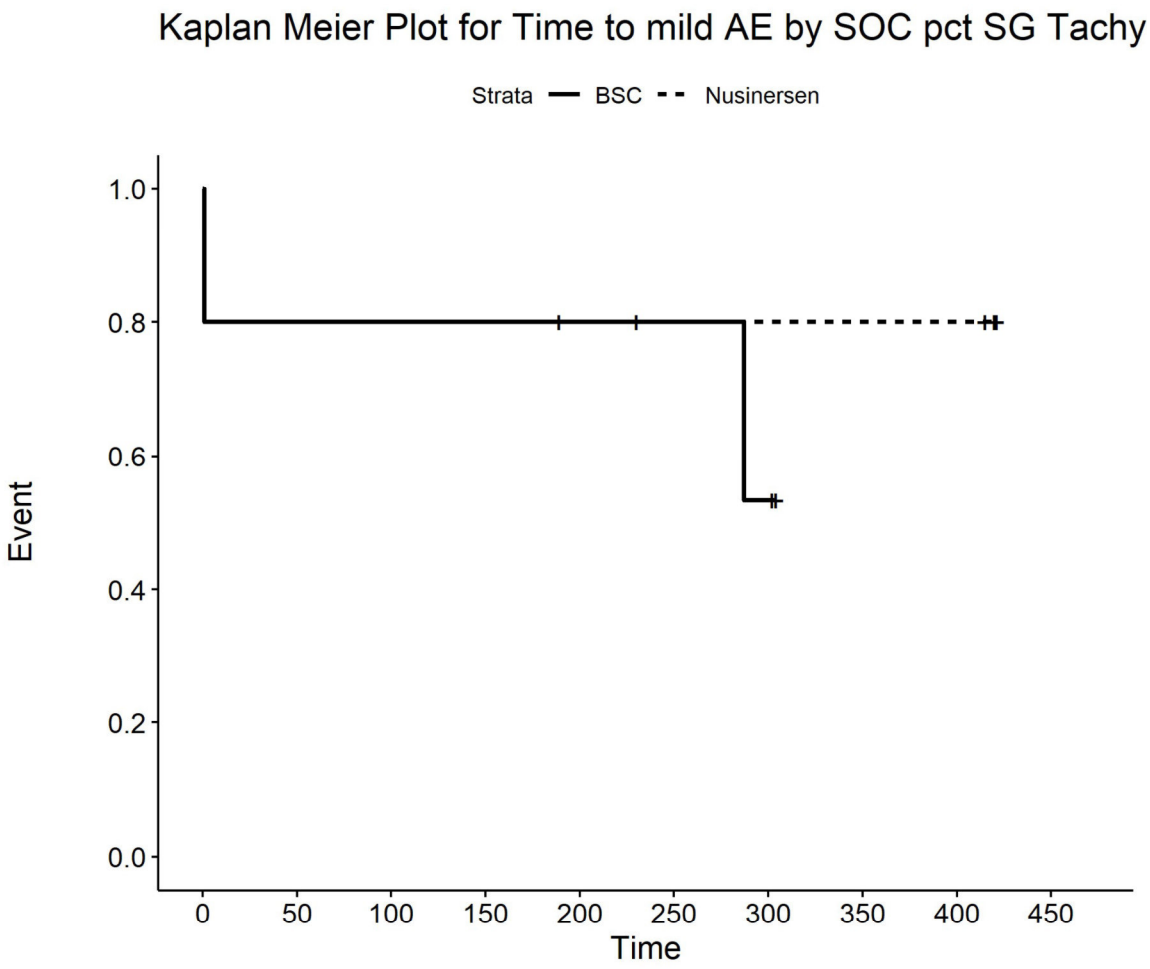
Number at risk

BSC	4	3	3	3	3	3	2	1	0	0
Nusinersen	9	8	7	7	5	5	5	4	4	0



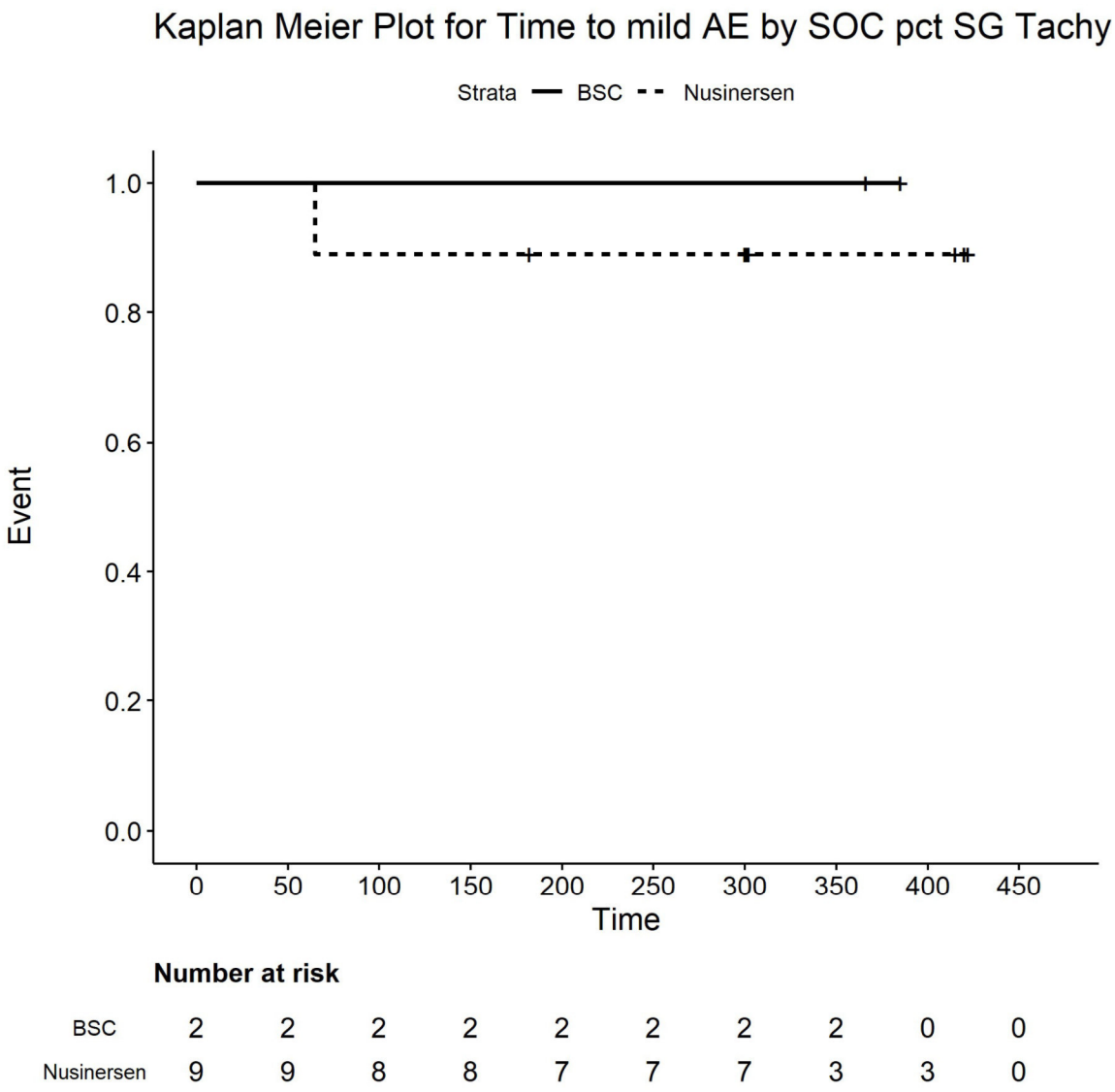
Number at risk

BSC	6	5	5	5	5	5	4	2	0	0
Nusinersen	10	9	8	8	8	8	8	6	6	0



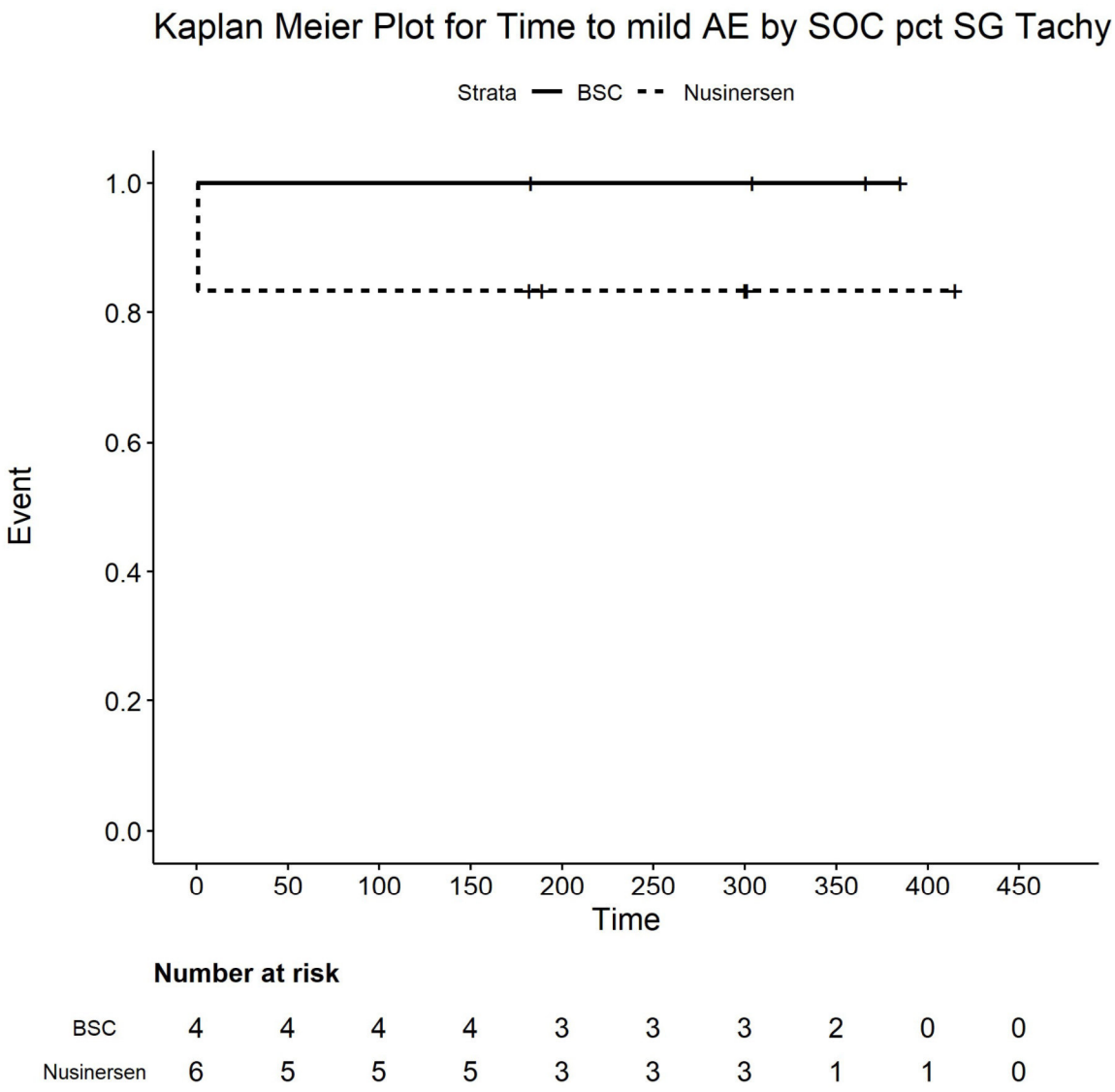
Number at risk

BSC	5	4	4	4	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	3	3	3	0



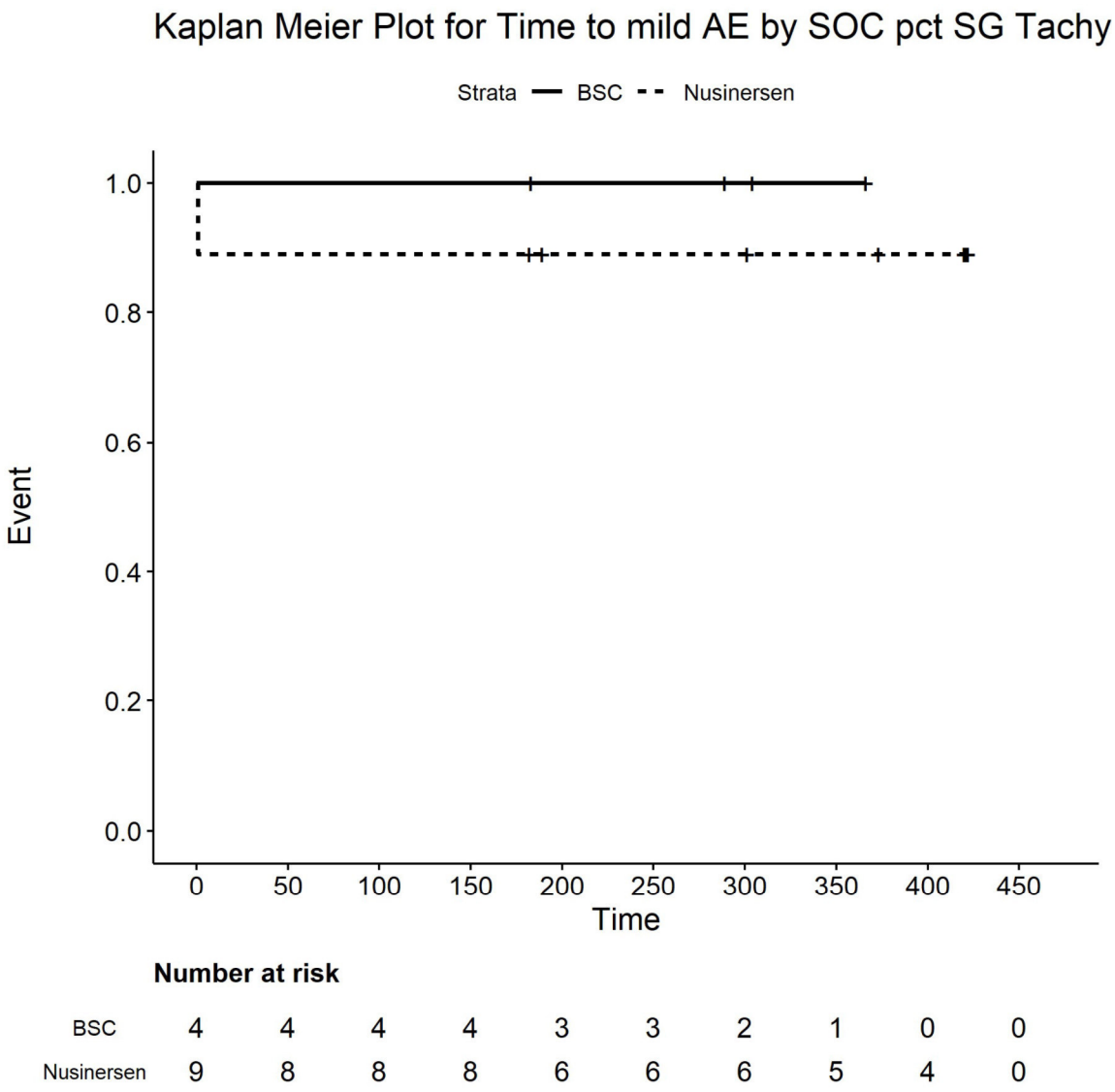
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	3	0



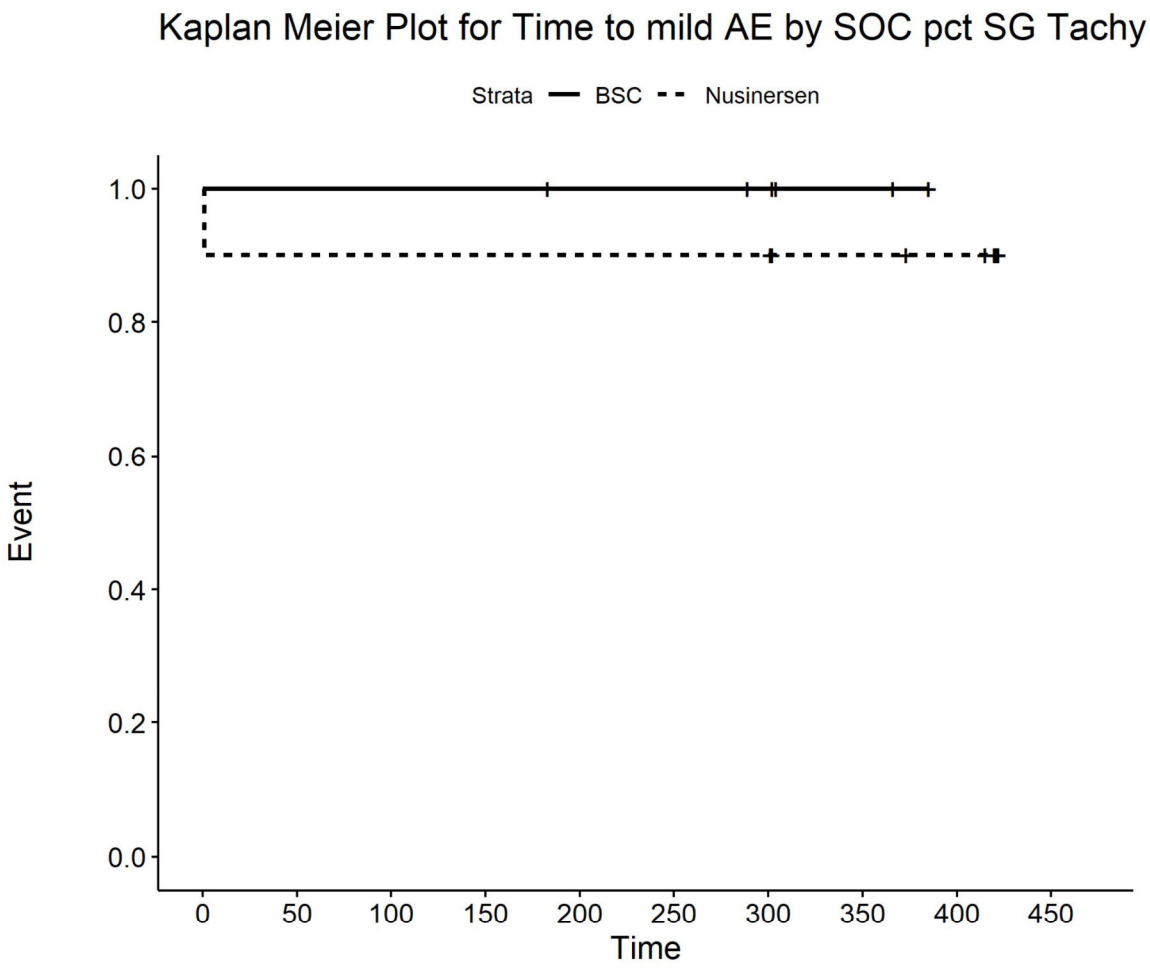
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	3	1	1	0



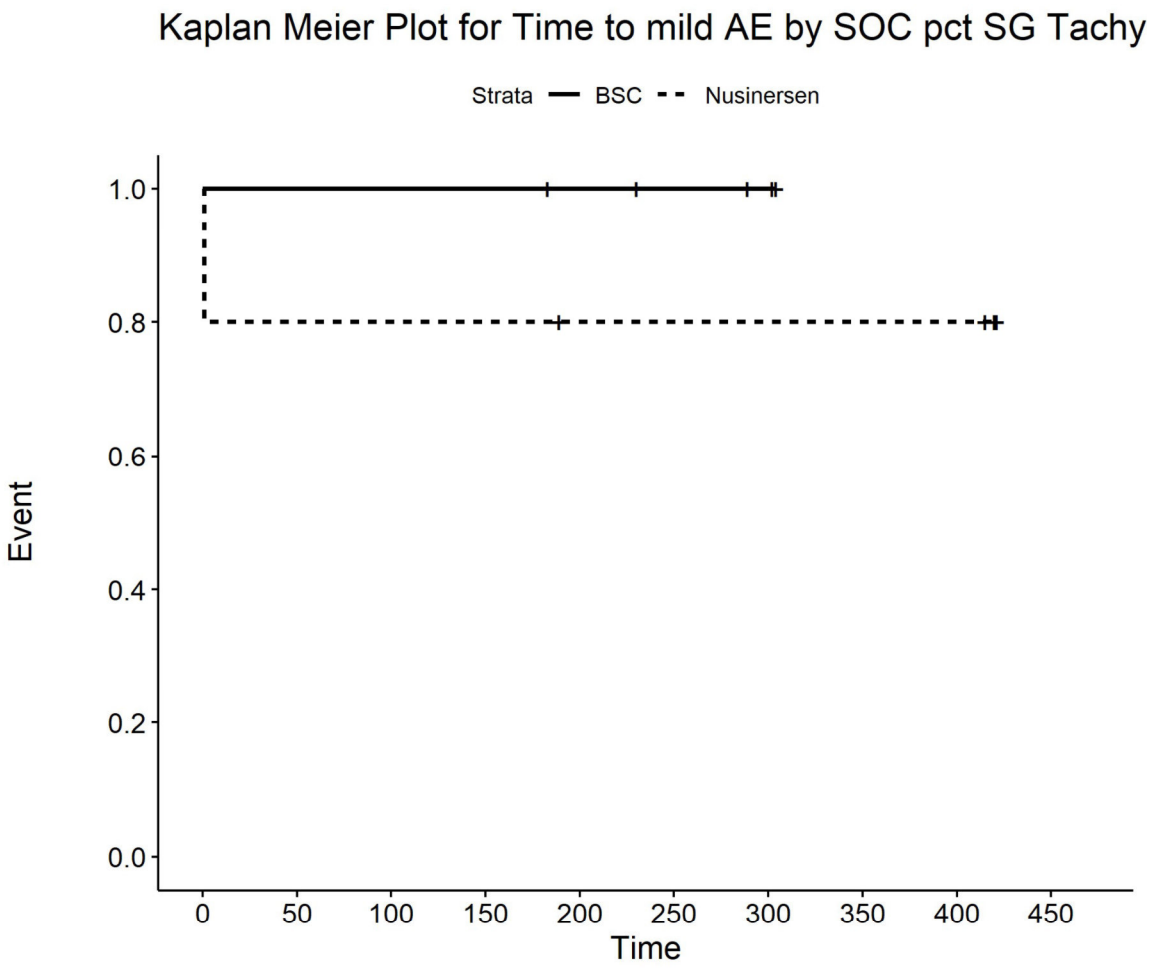
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	6	5	4	0



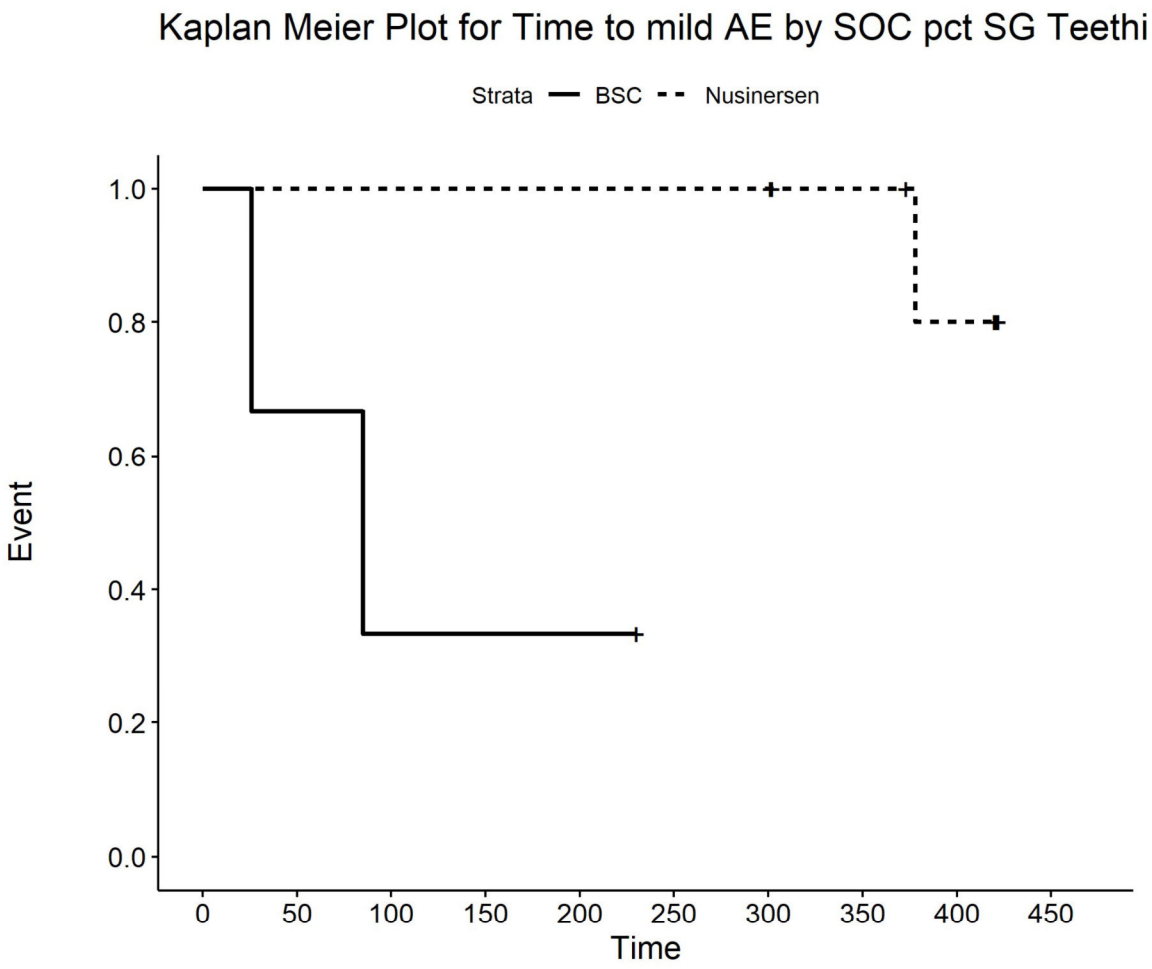
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	9	7	6	0



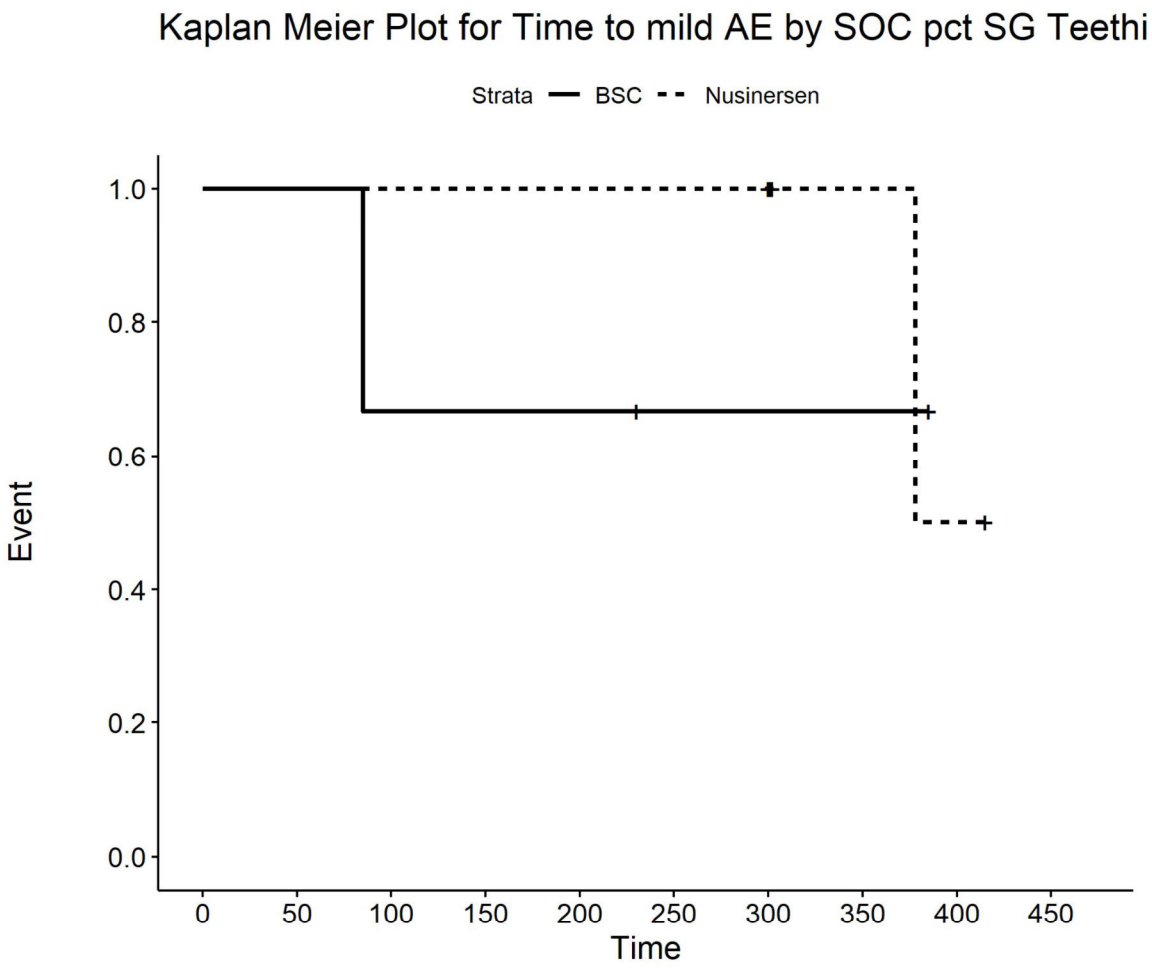
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	3	3	3	0



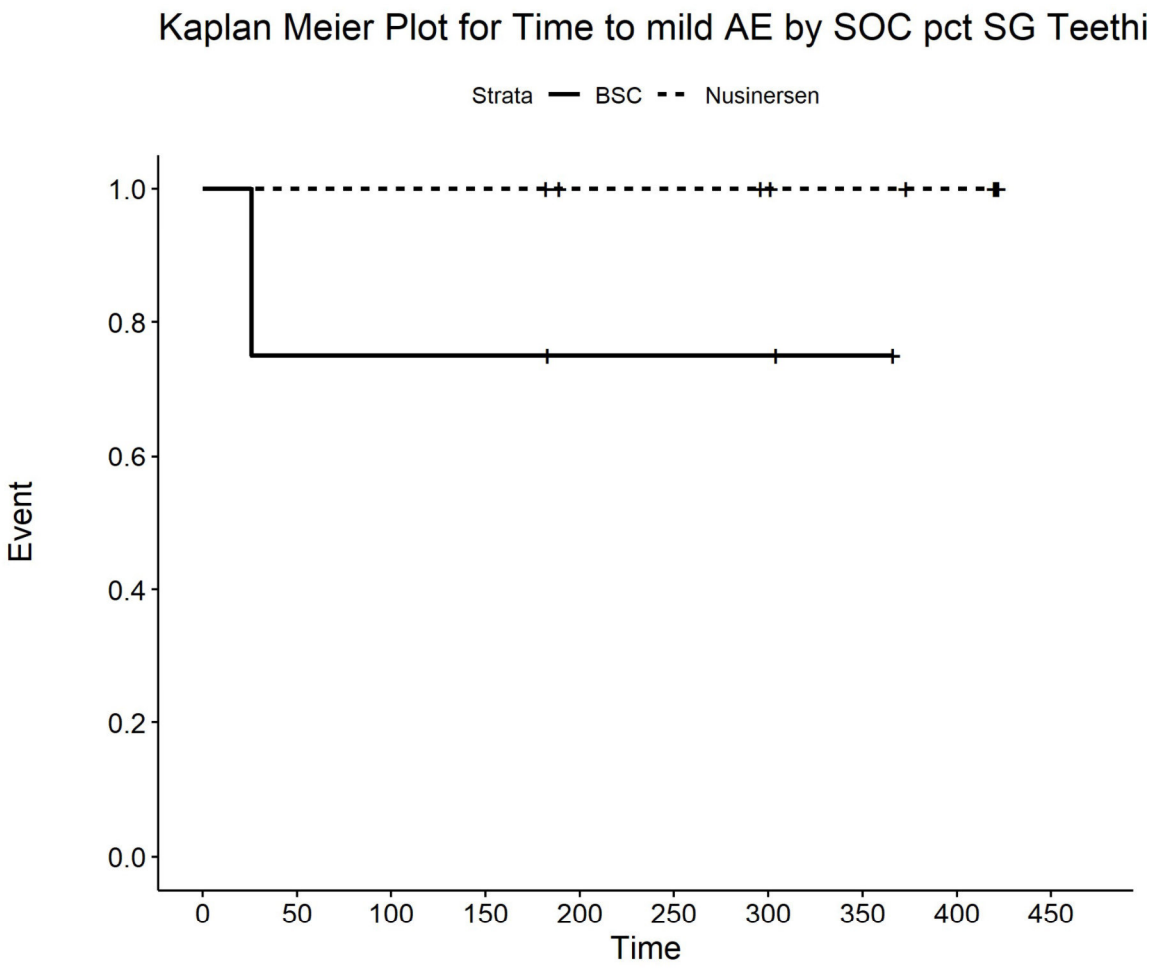
Number at risk

BSC	3	2	1	1	1	0	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	4	0



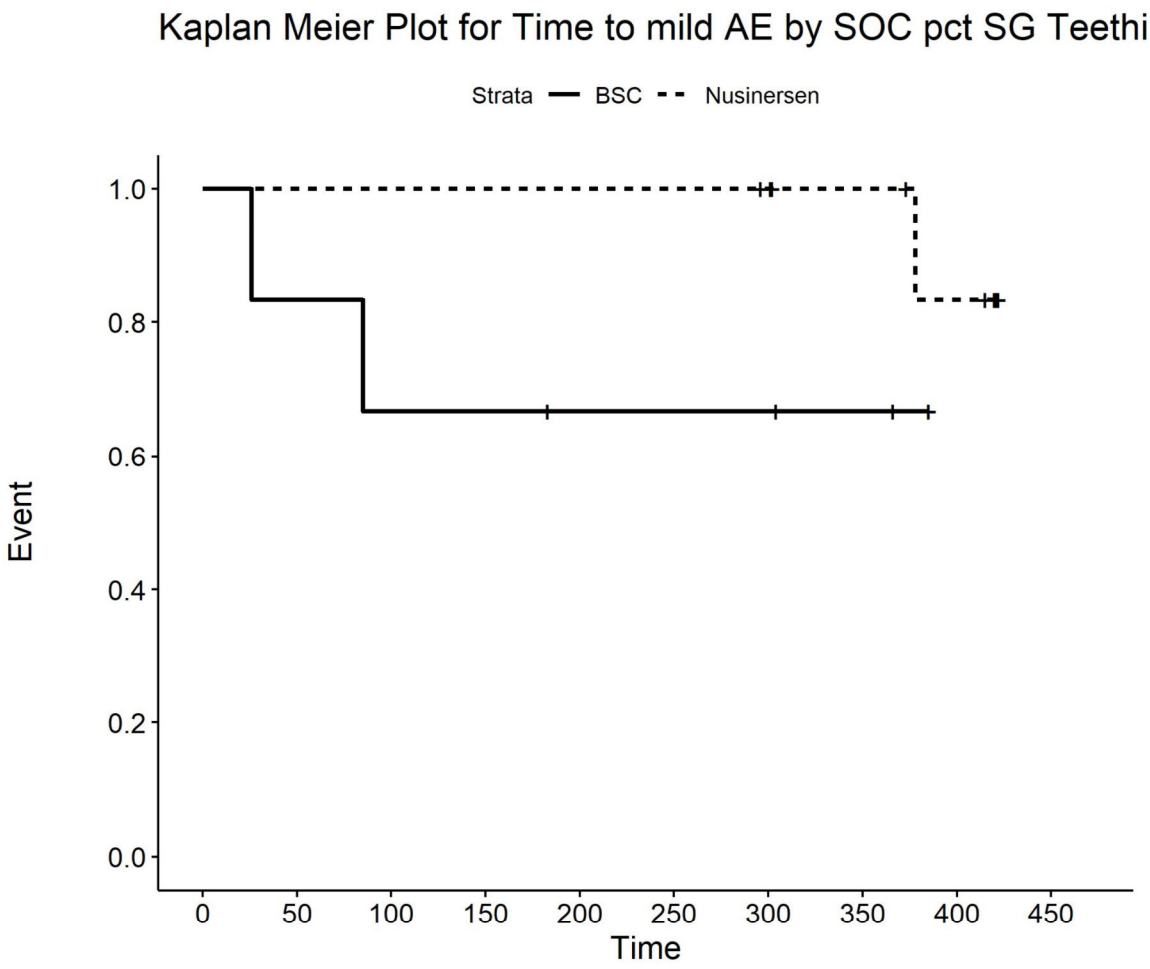
Number at risk

BSC	3	3	2	2	2	1	1	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	1	0



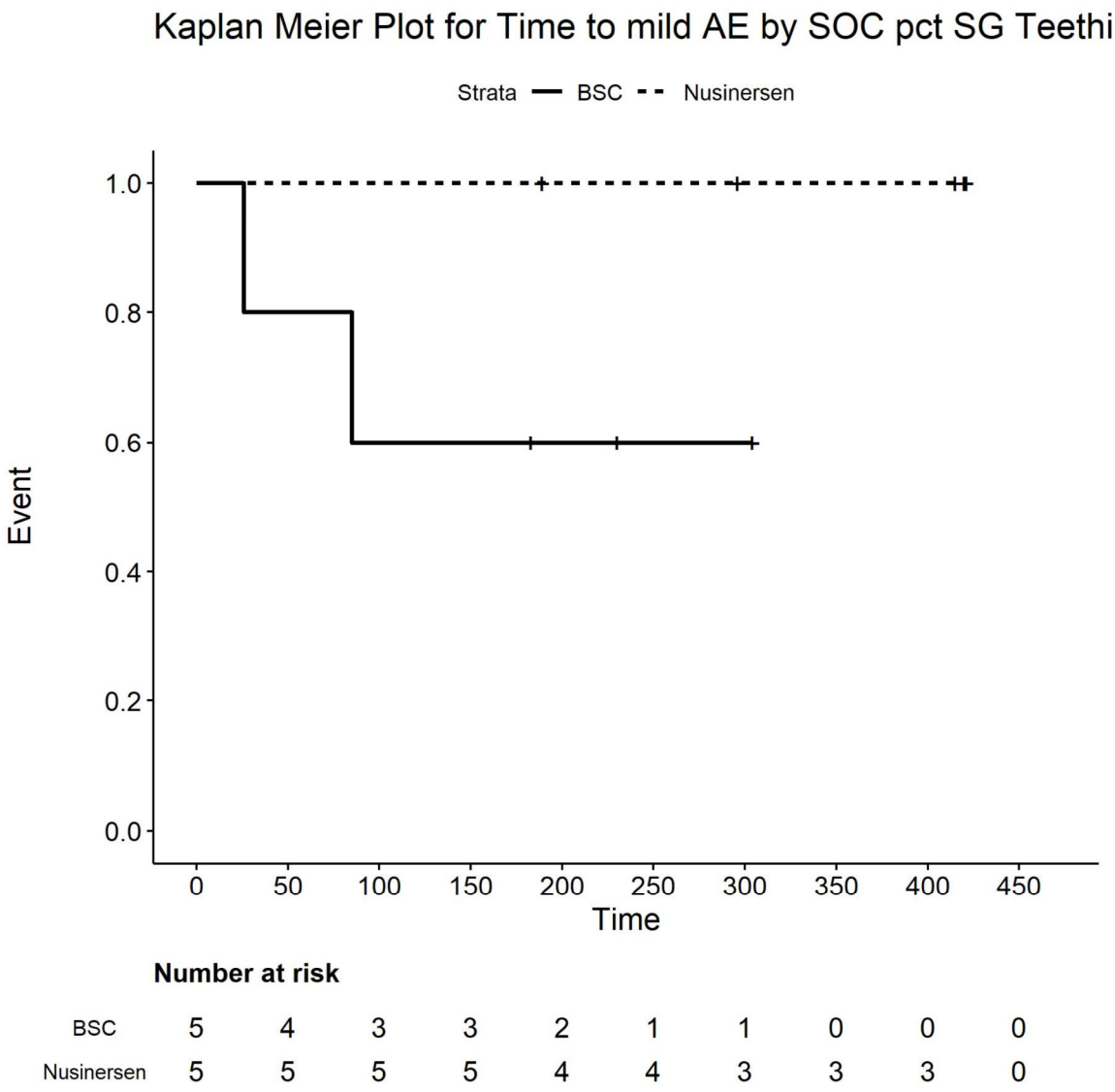
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



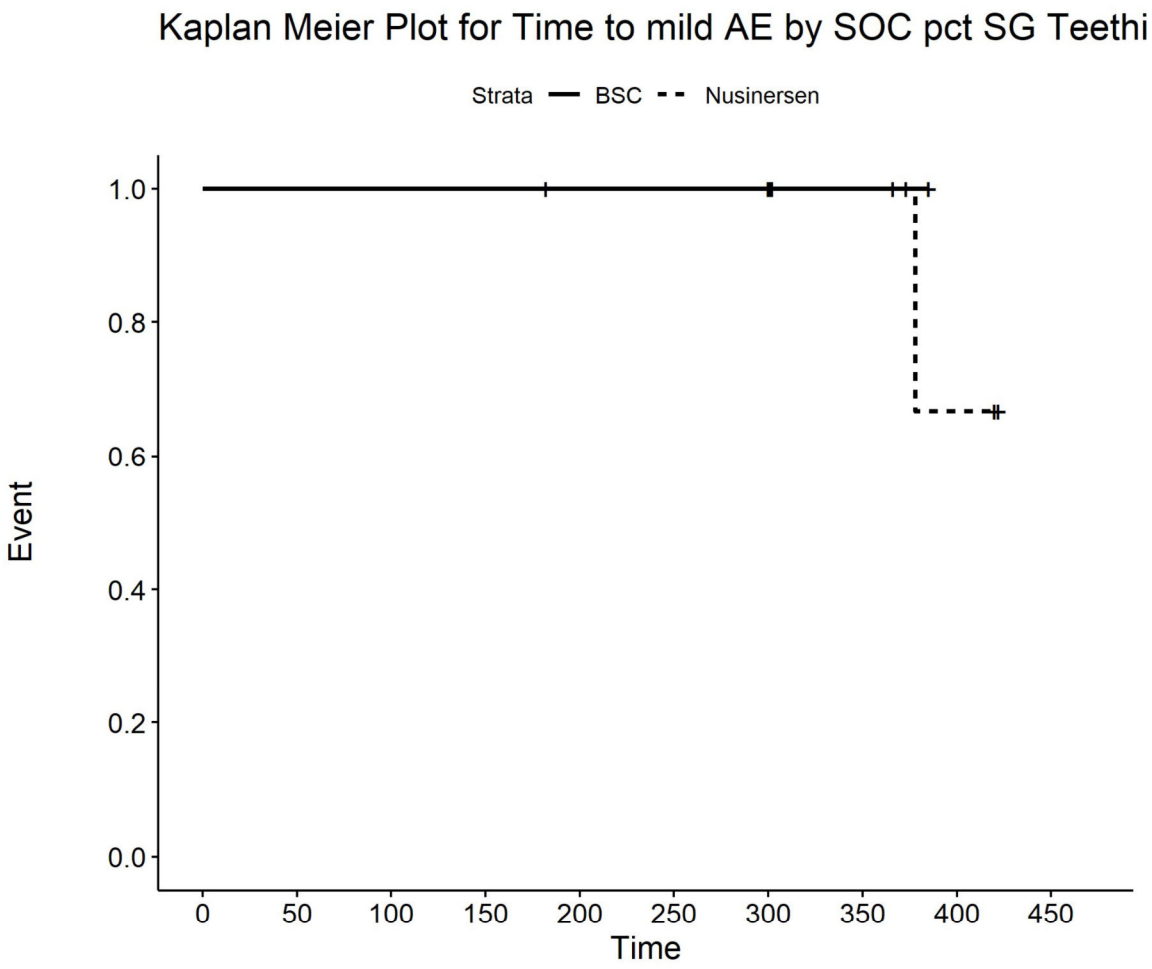
Number at risk

BSC	6	5	4	4	3	3	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	5	0



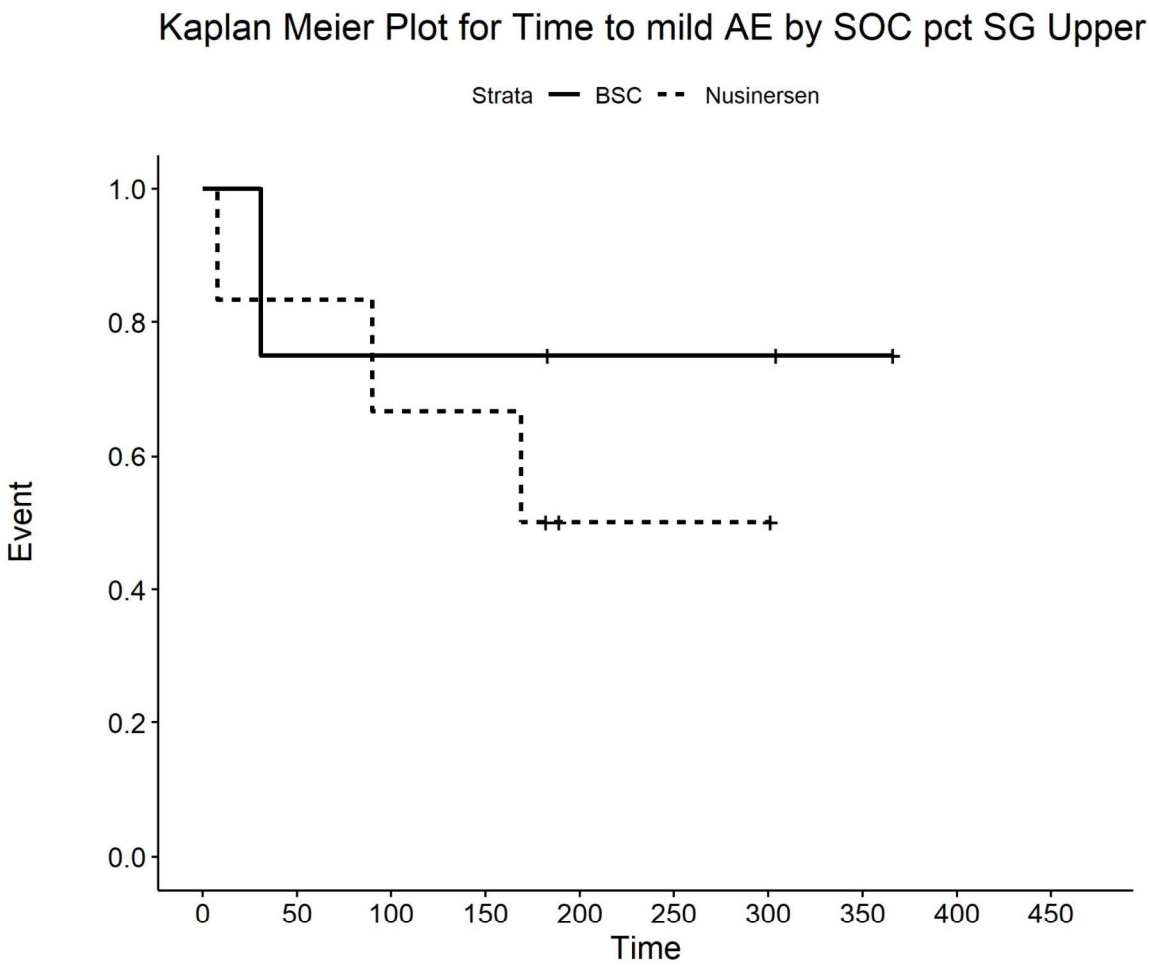
Number at risk

BSC	5	4	3	3	2	1	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



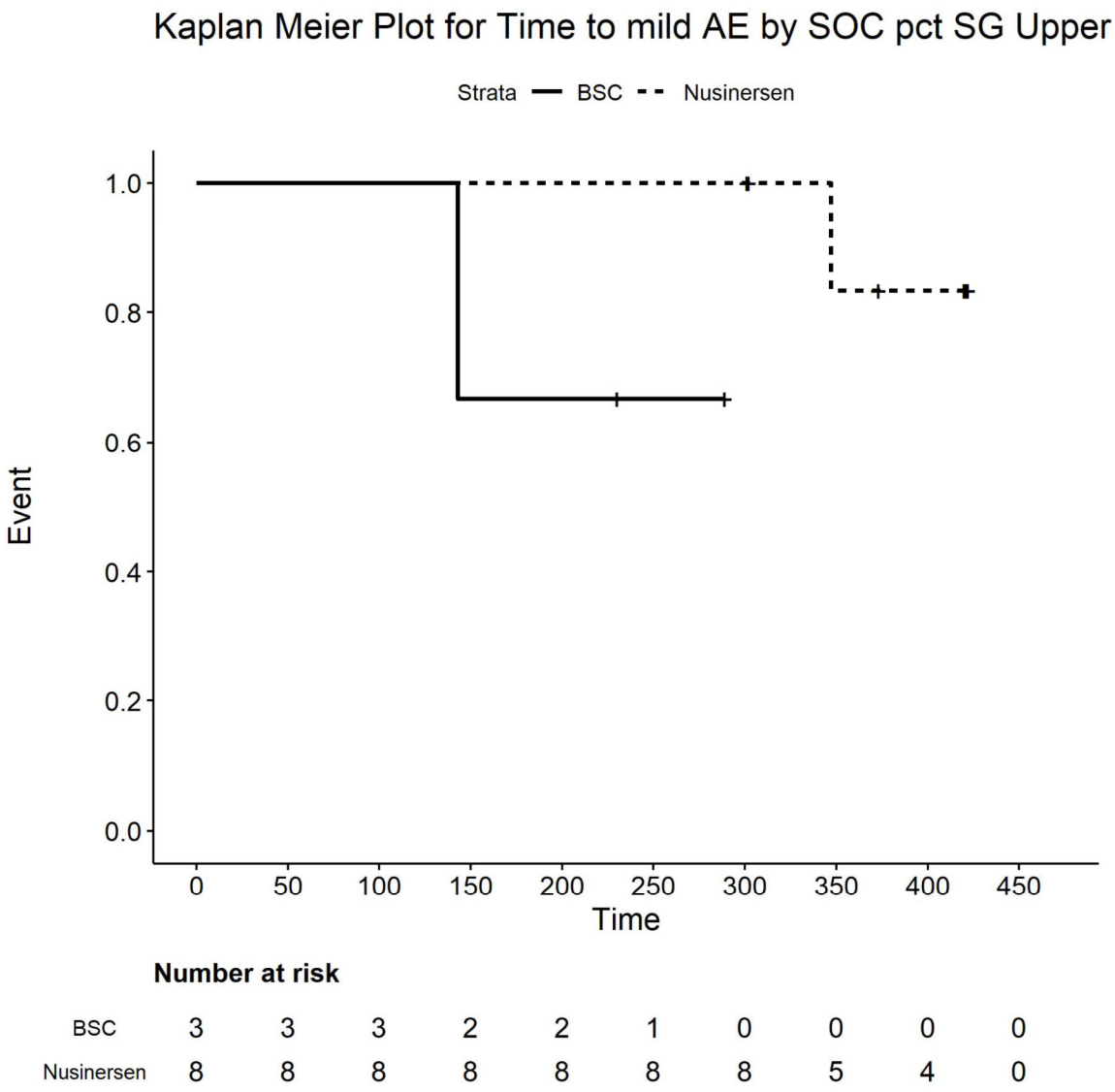
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	8	4	2	0



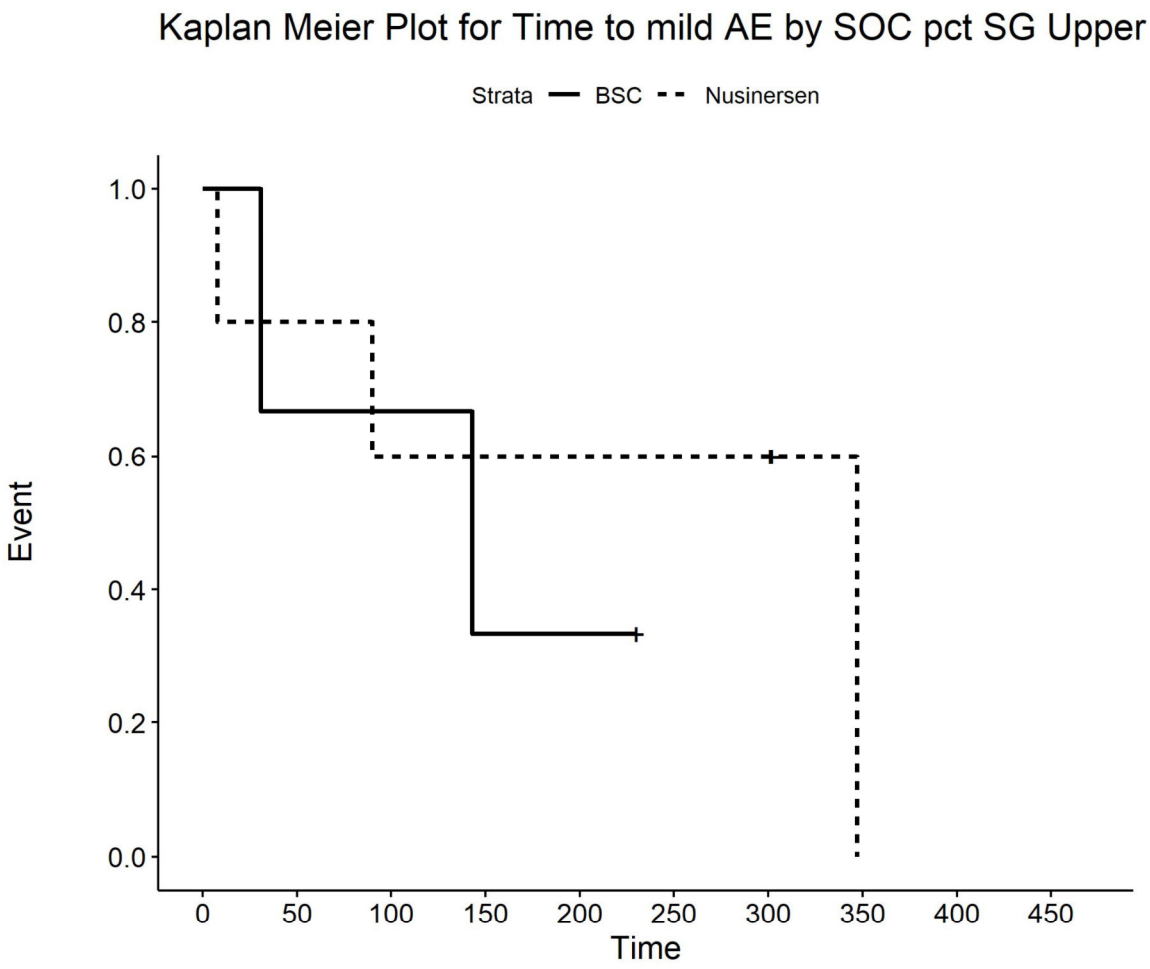
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	5	4	4	1	1	1	0	0	0



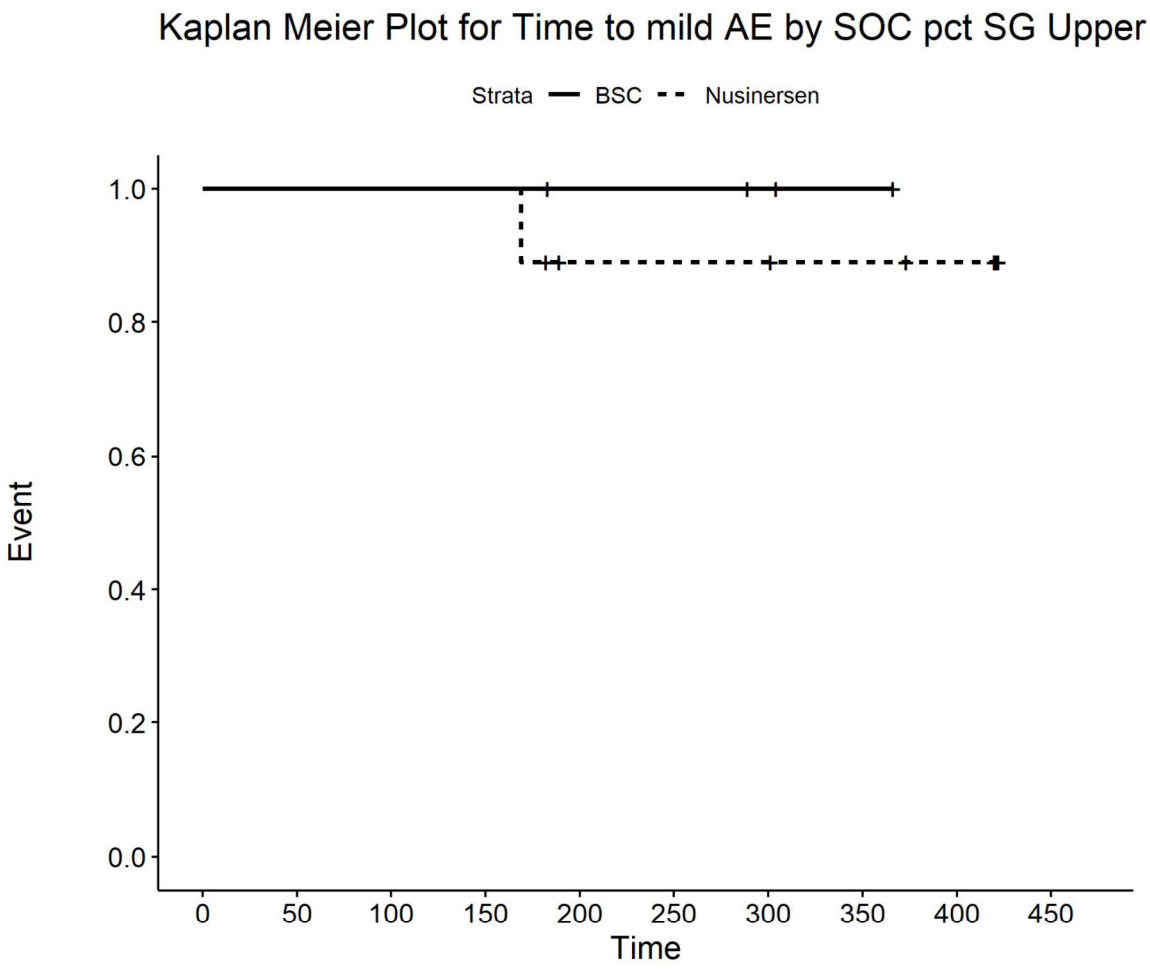
Number at risk

BSC	3	3	3	2	2	1	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	5	4	0



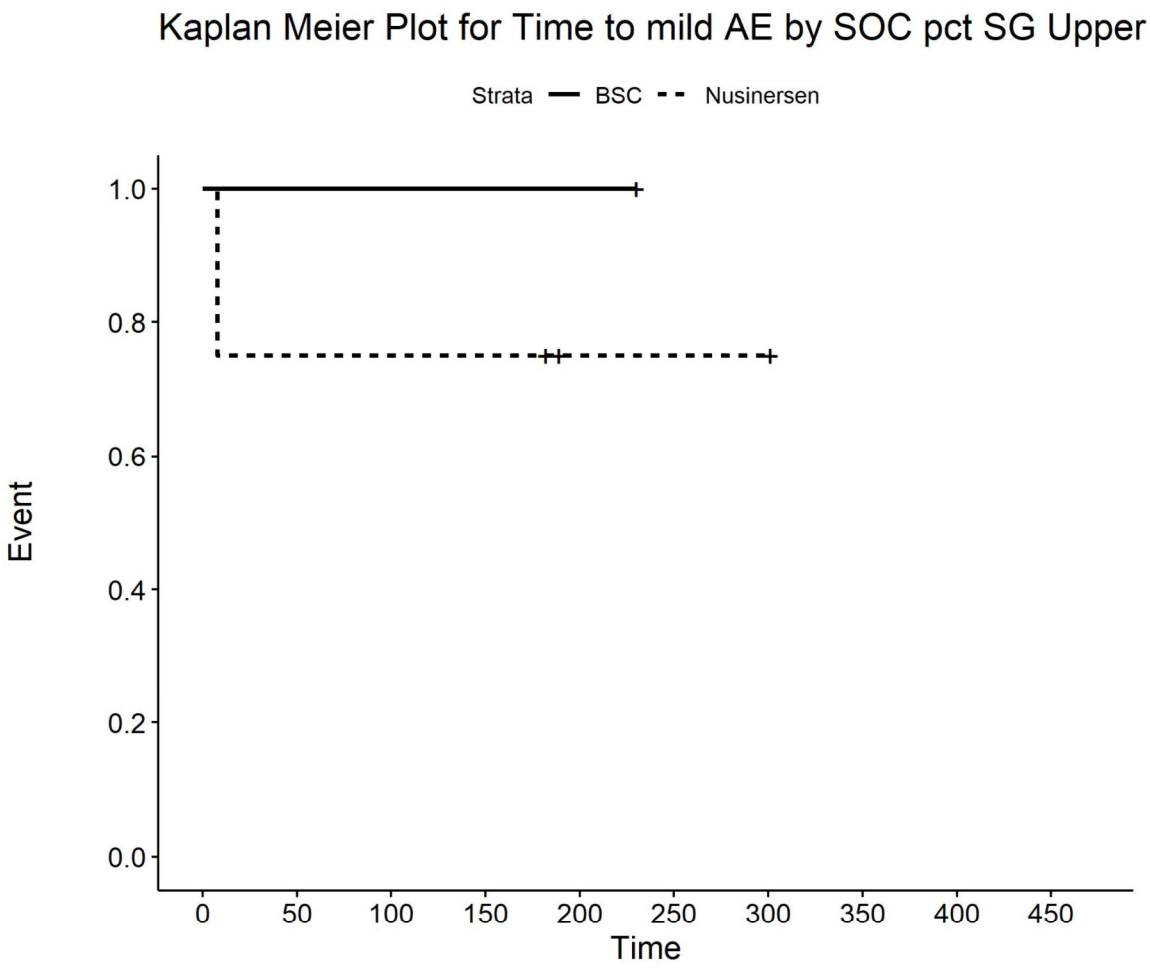
Number at risk

BSC	3	2	2	1	1	0	0	0	0	0
Nusinersen	5	4	3	3	3	3	3	0	0	0



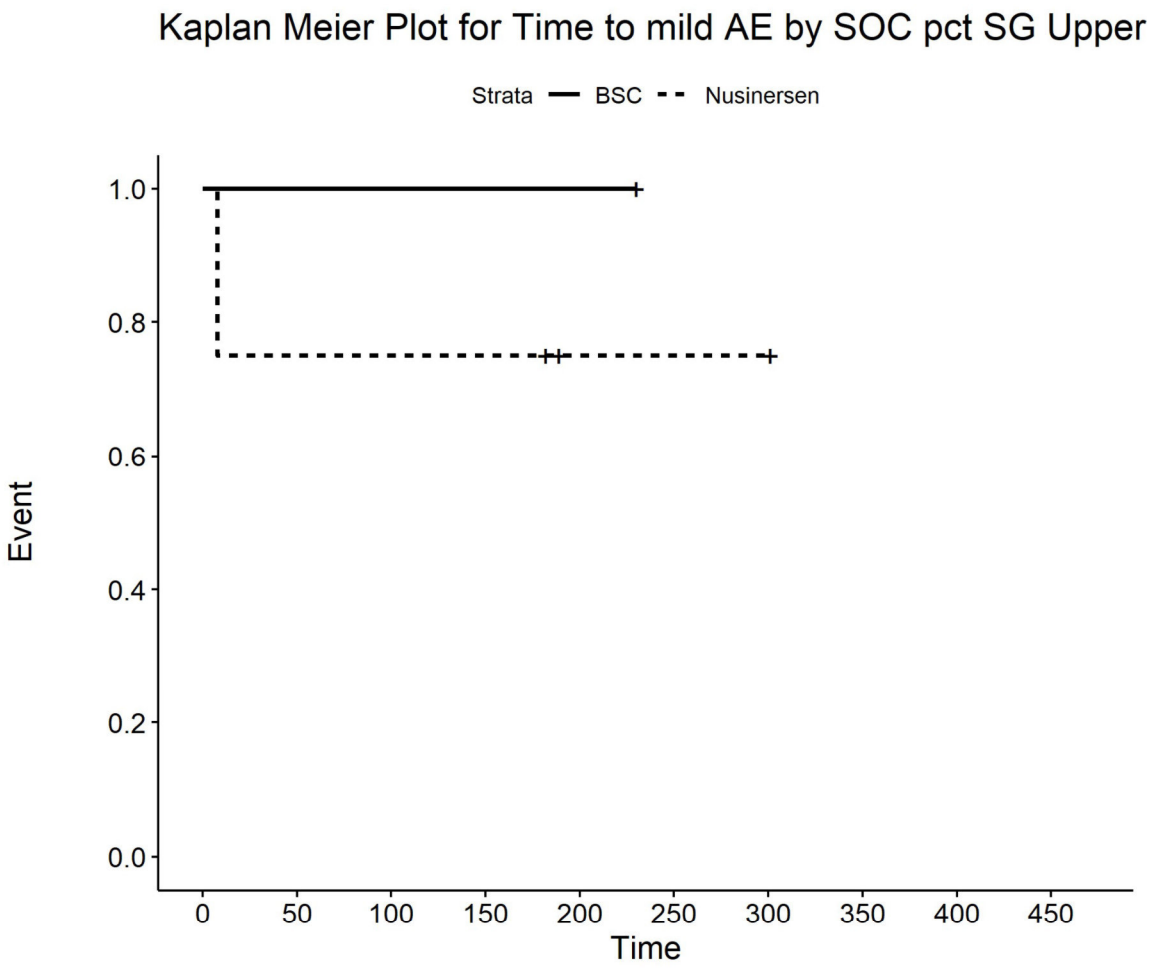
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	6	6	6	5	4	0



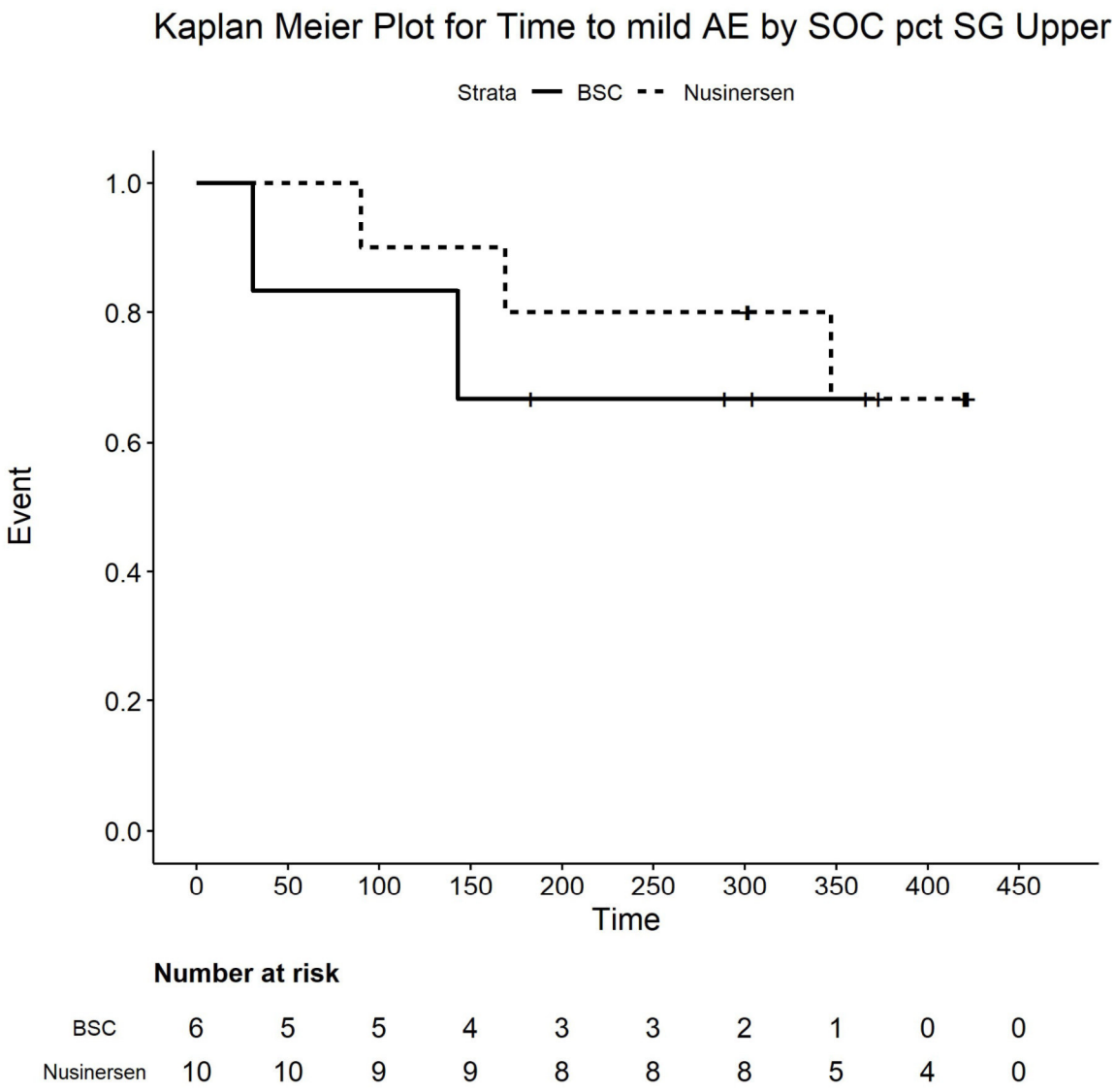
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



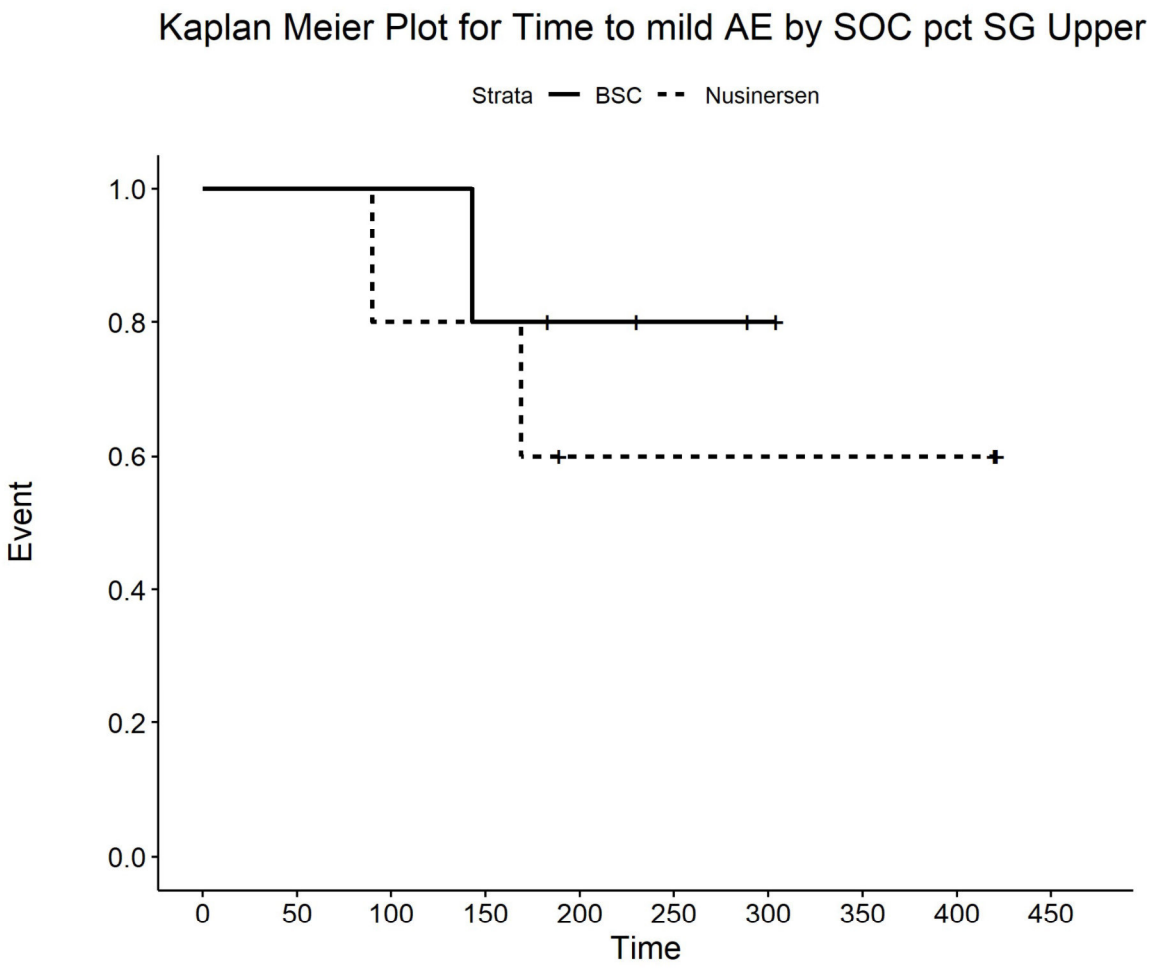
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



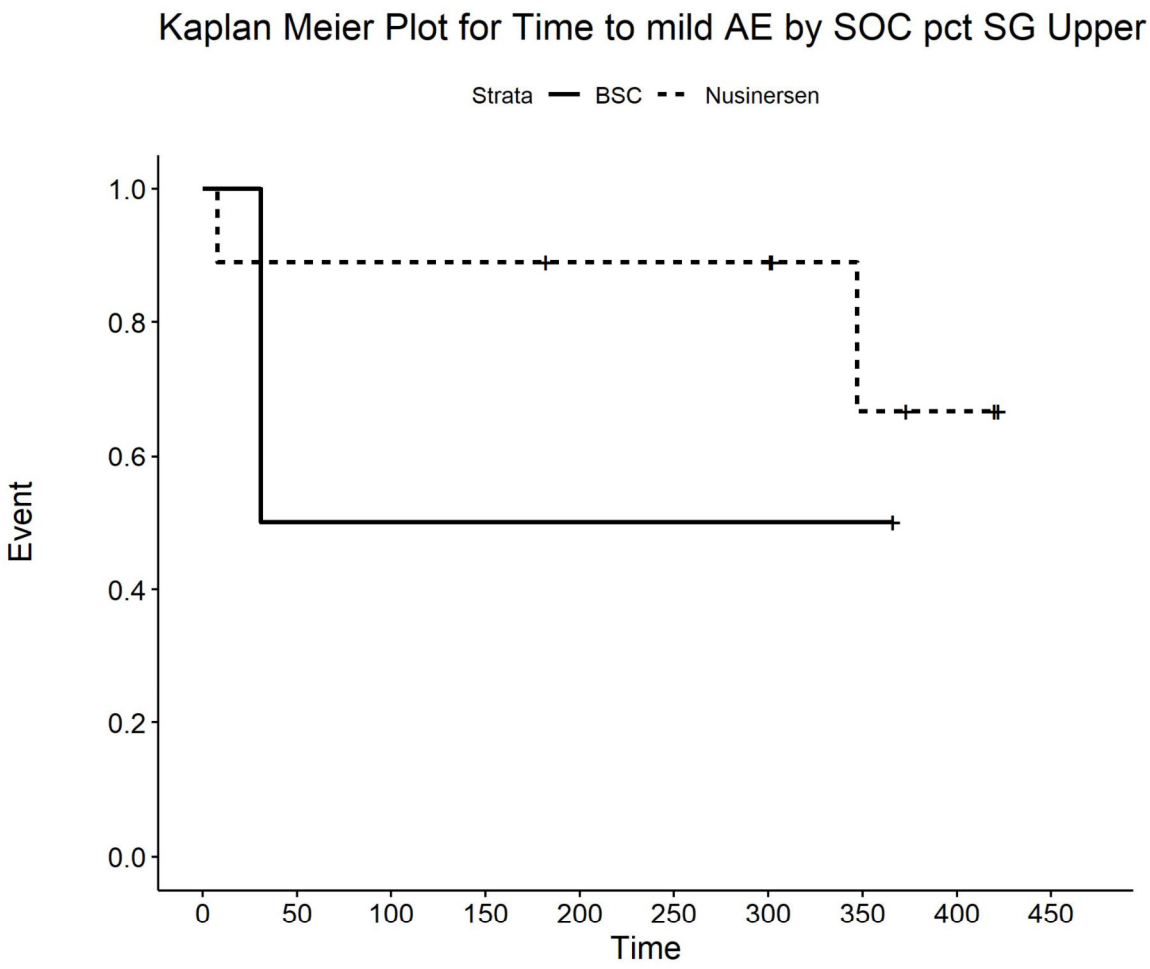
Number at risk

BSC	6	5	5	4	3	3	2	1	0	0
Nusinersen	10	10	9	9	8	8	8	5	4	0



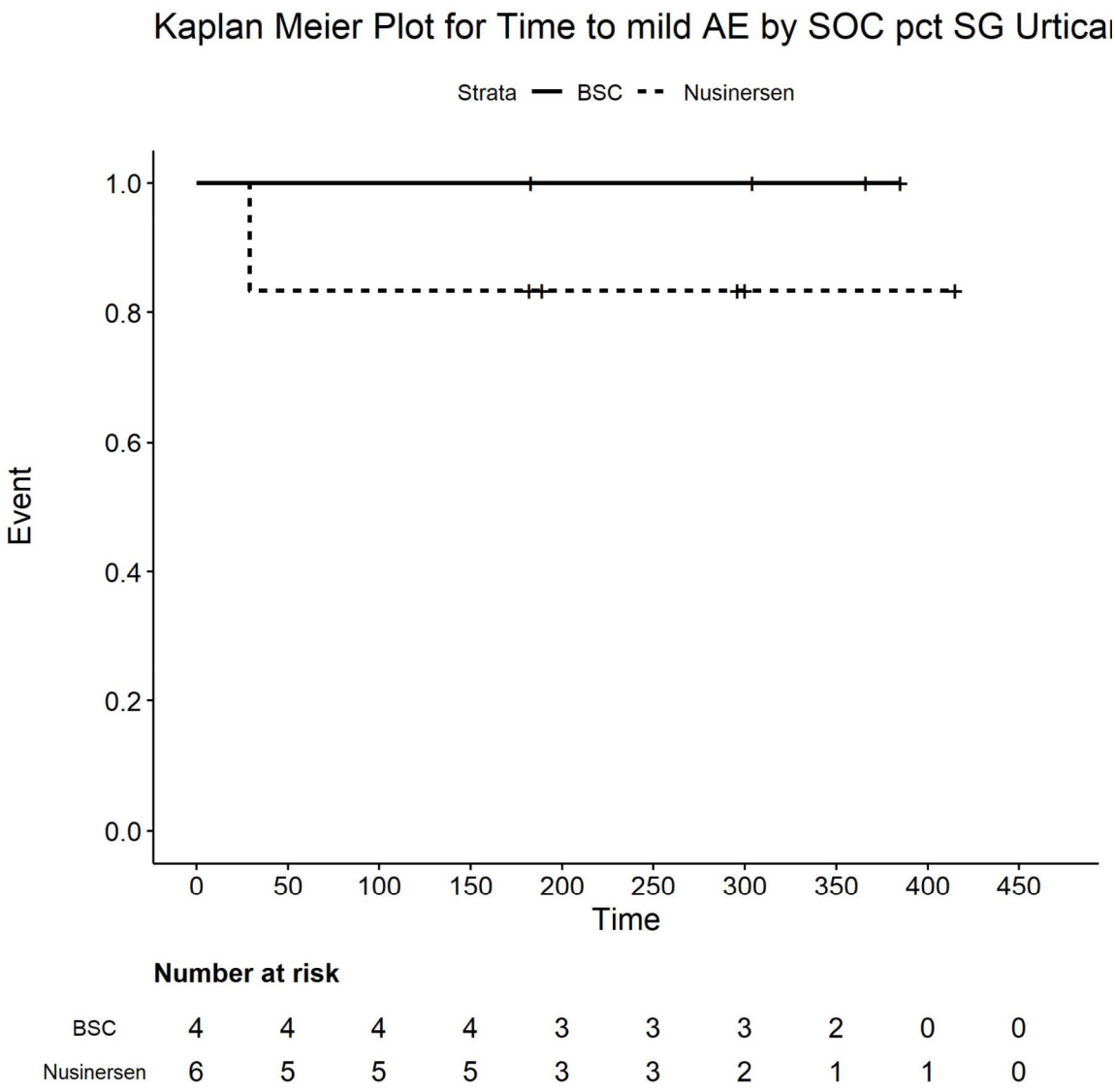
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	4	4	2	2	2	2	2	0



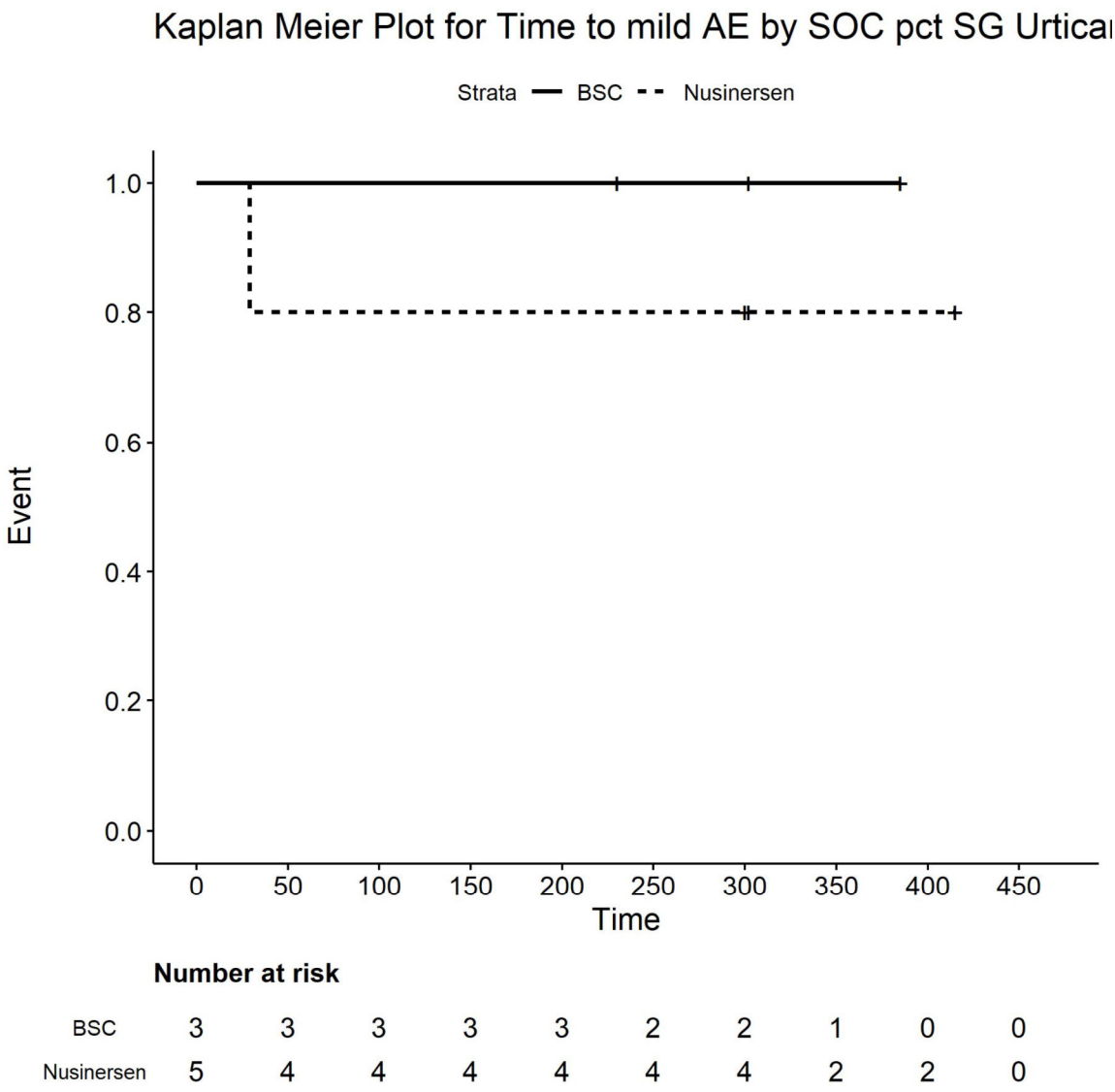
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	8	8	8	7	7	7	3	2	0



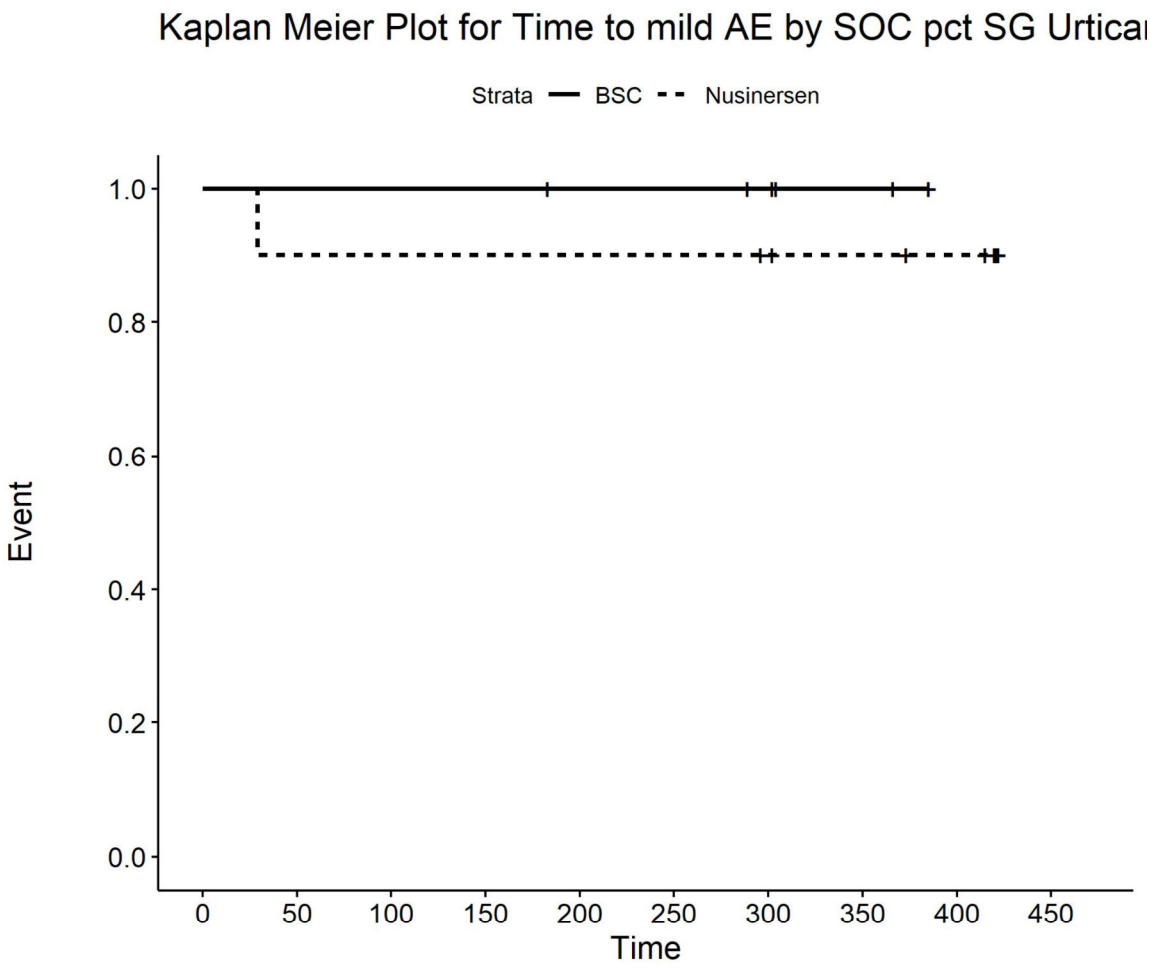
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	3	3	2	1	1	0



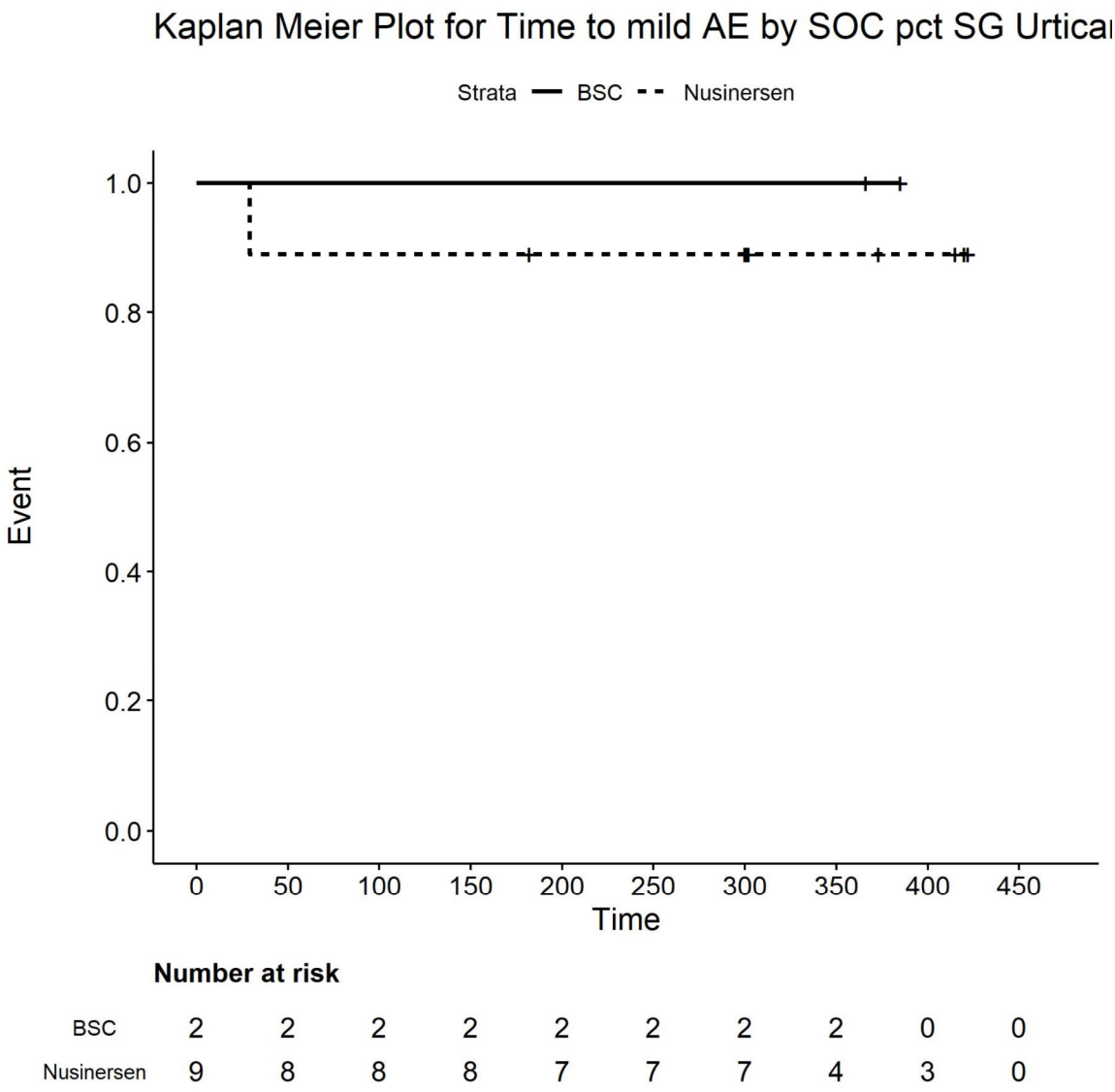
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



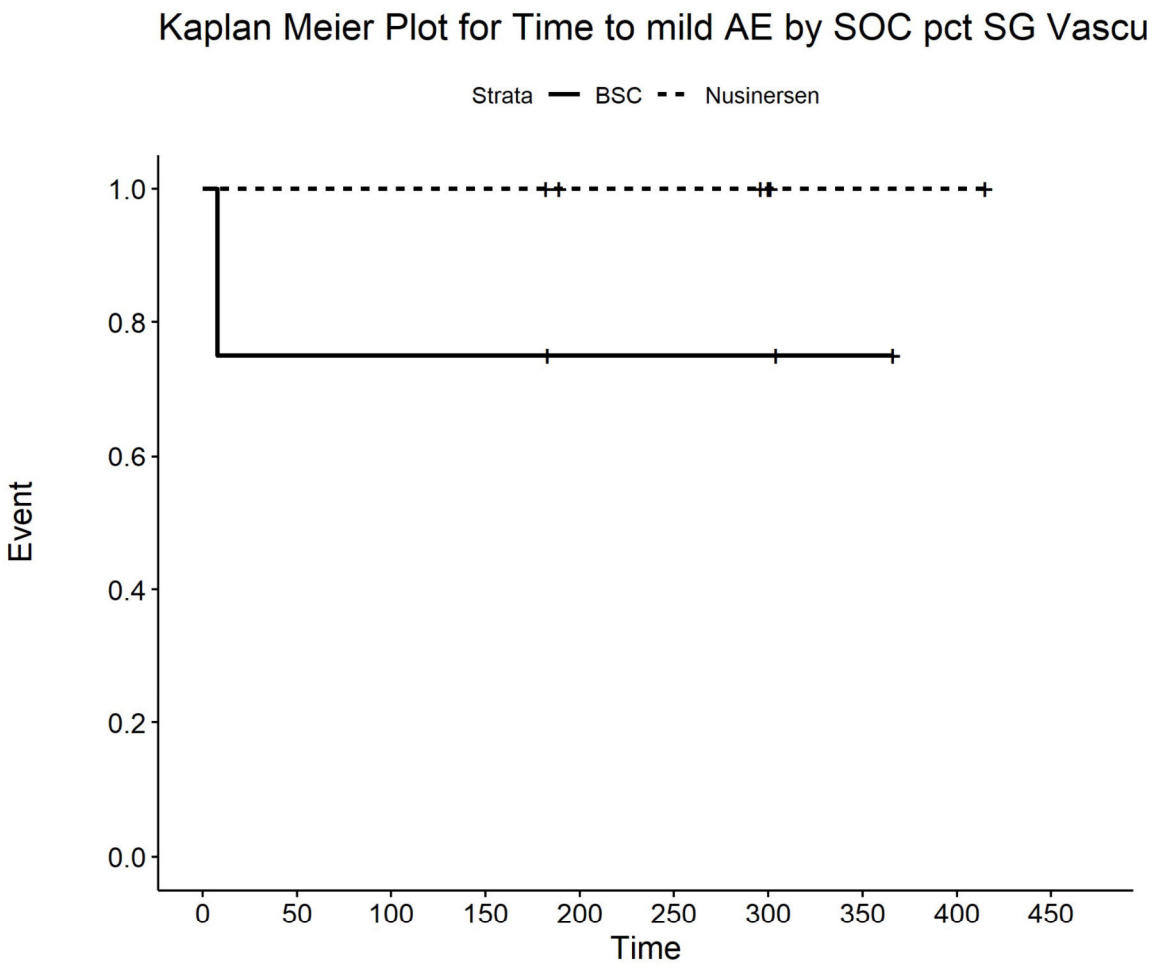
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	7	6	0



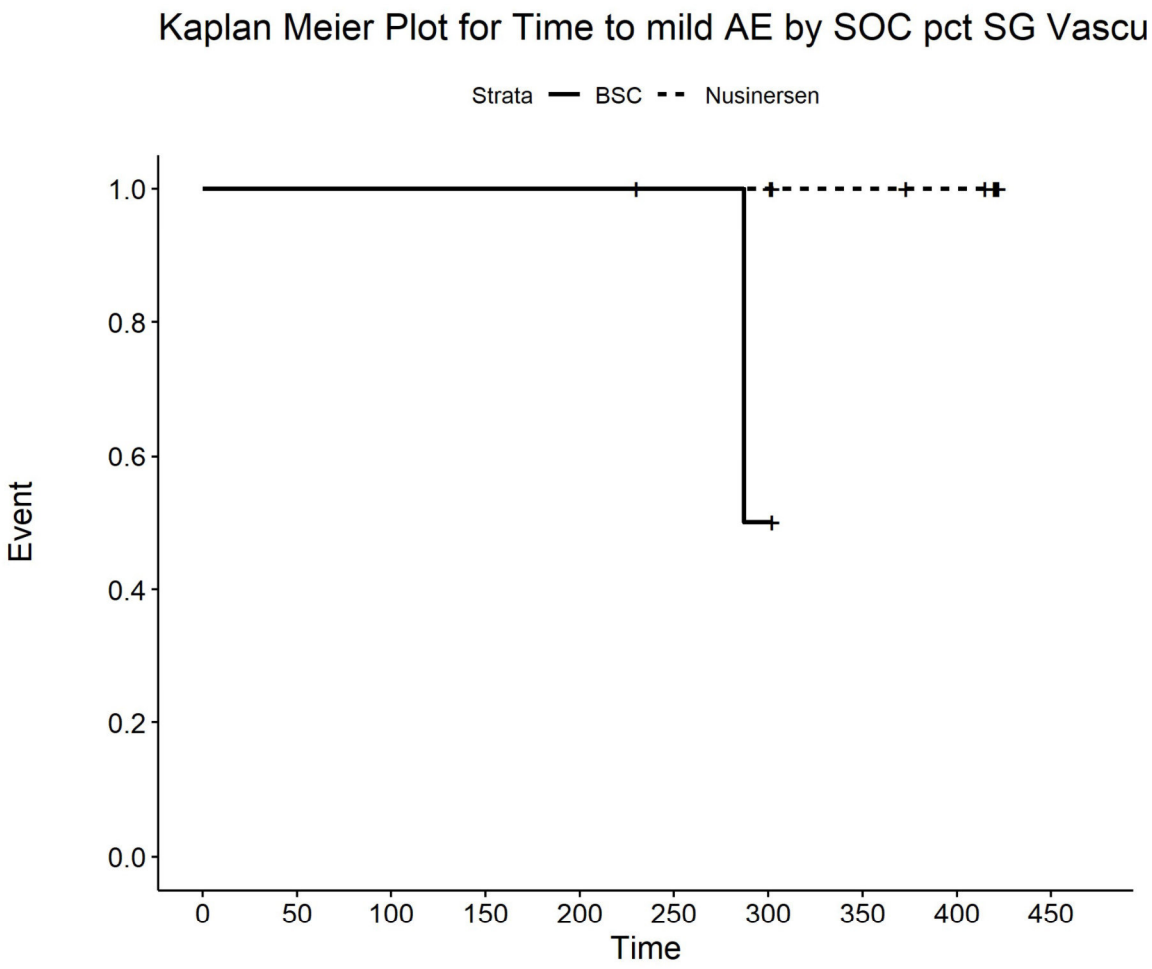
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



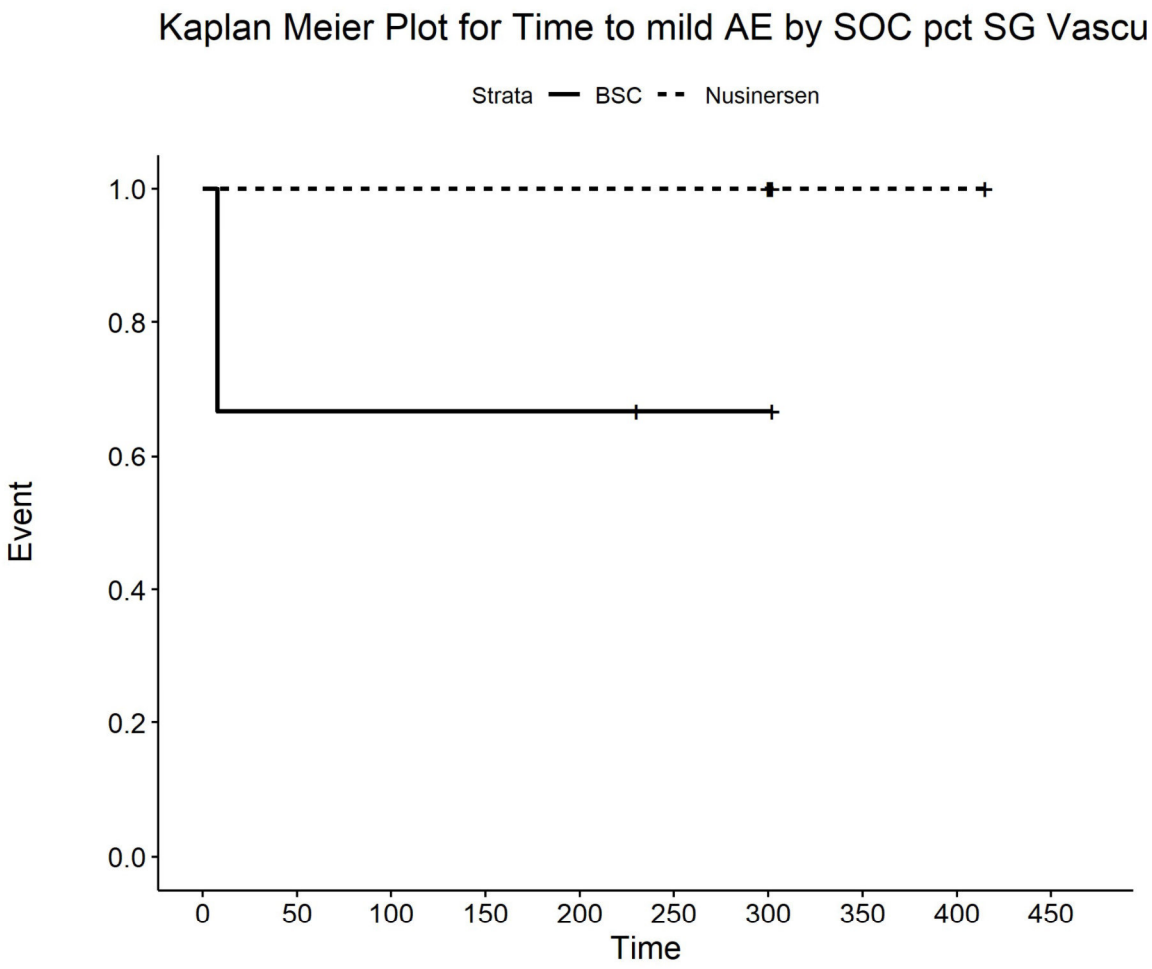
Number at risk

BSC	4	3	3	3	2	2	2	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



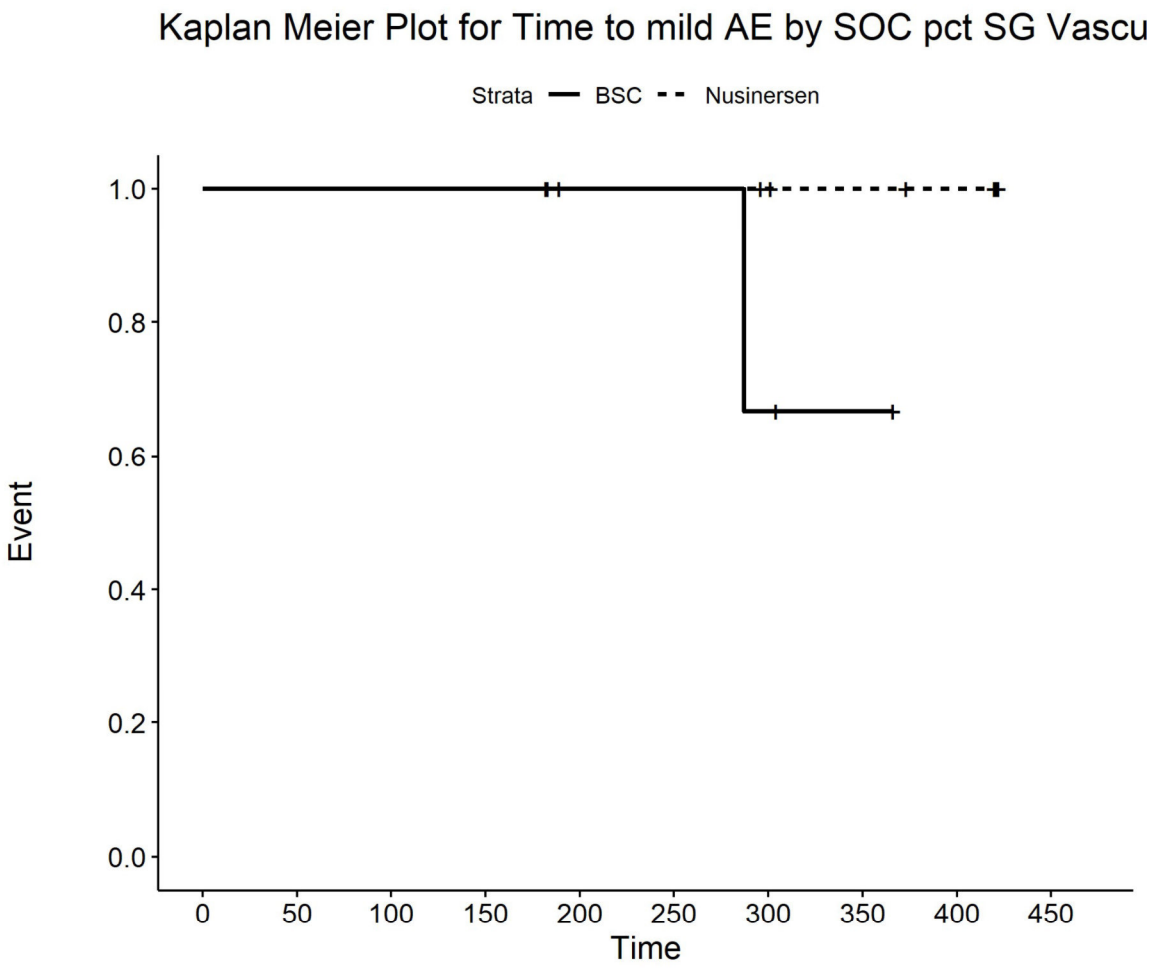
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



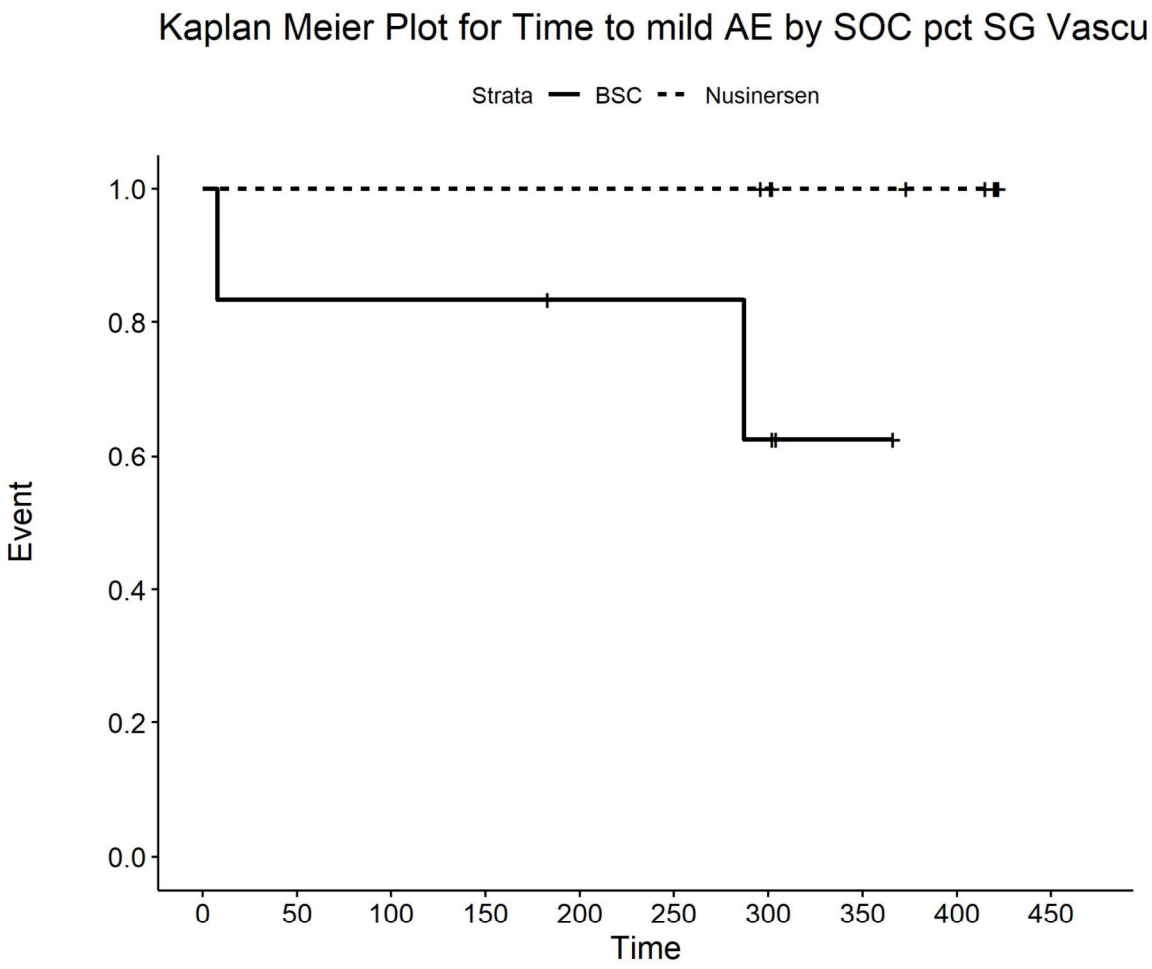
Number at risk

BSC	3	2	2	2	2	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



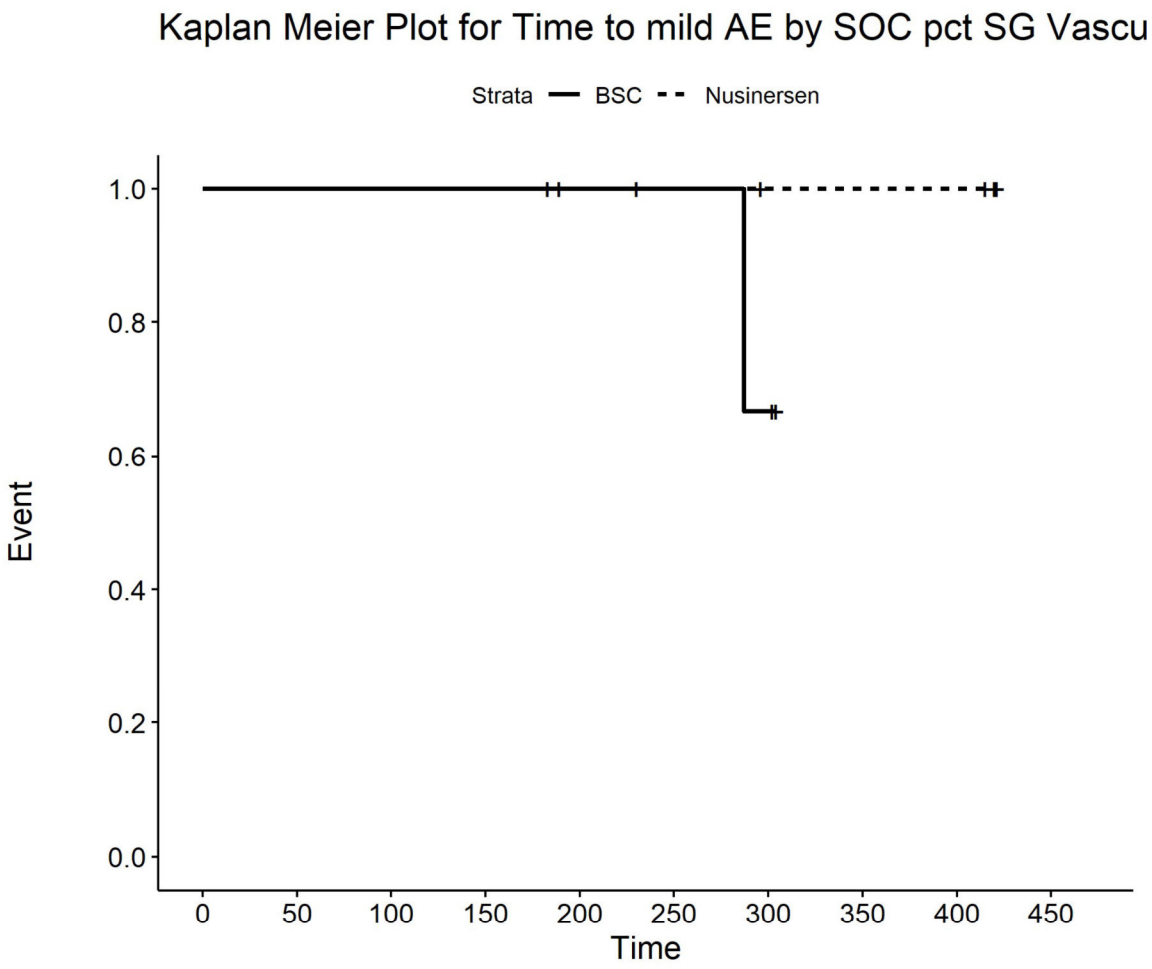
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



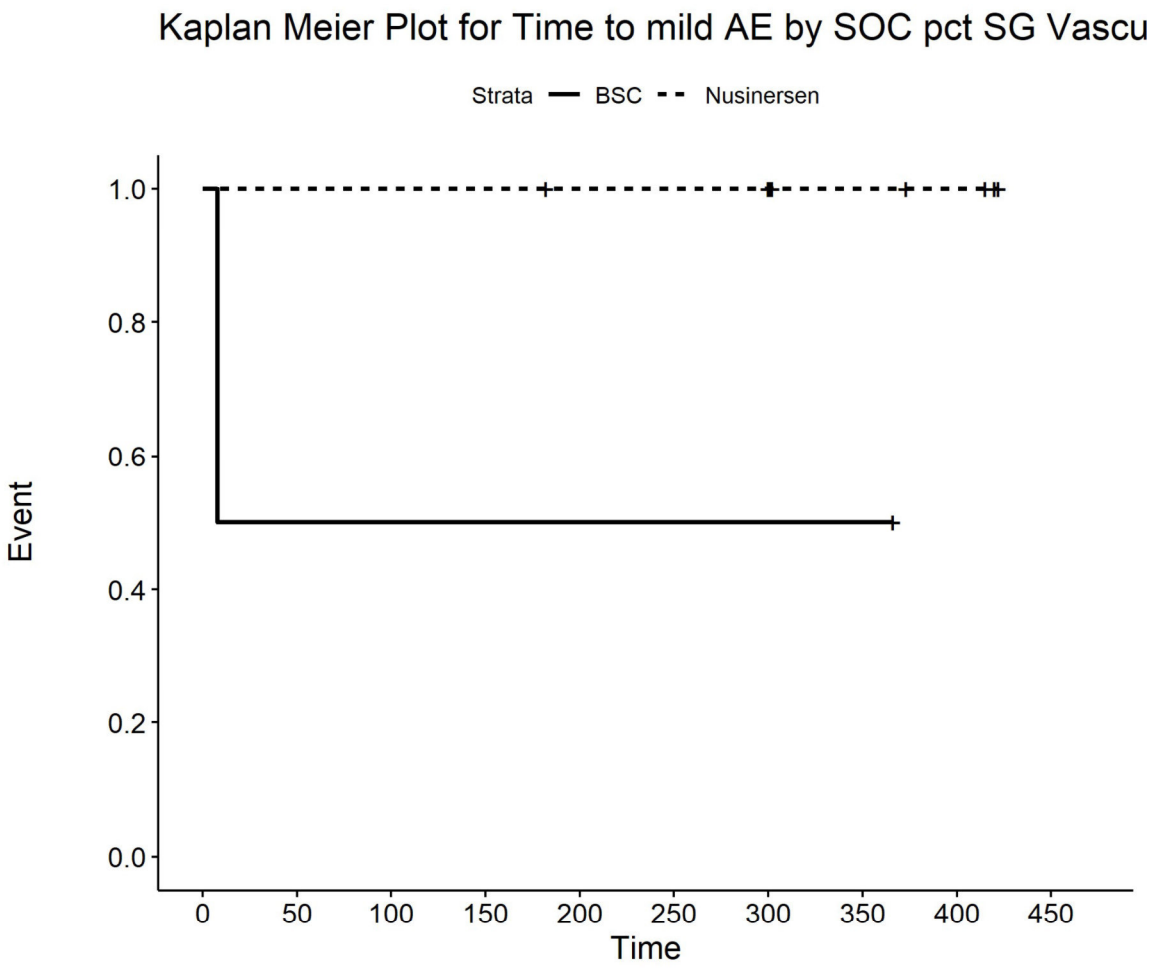
Number at risk

BSC	6	5	5	5	4	4	3	1	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



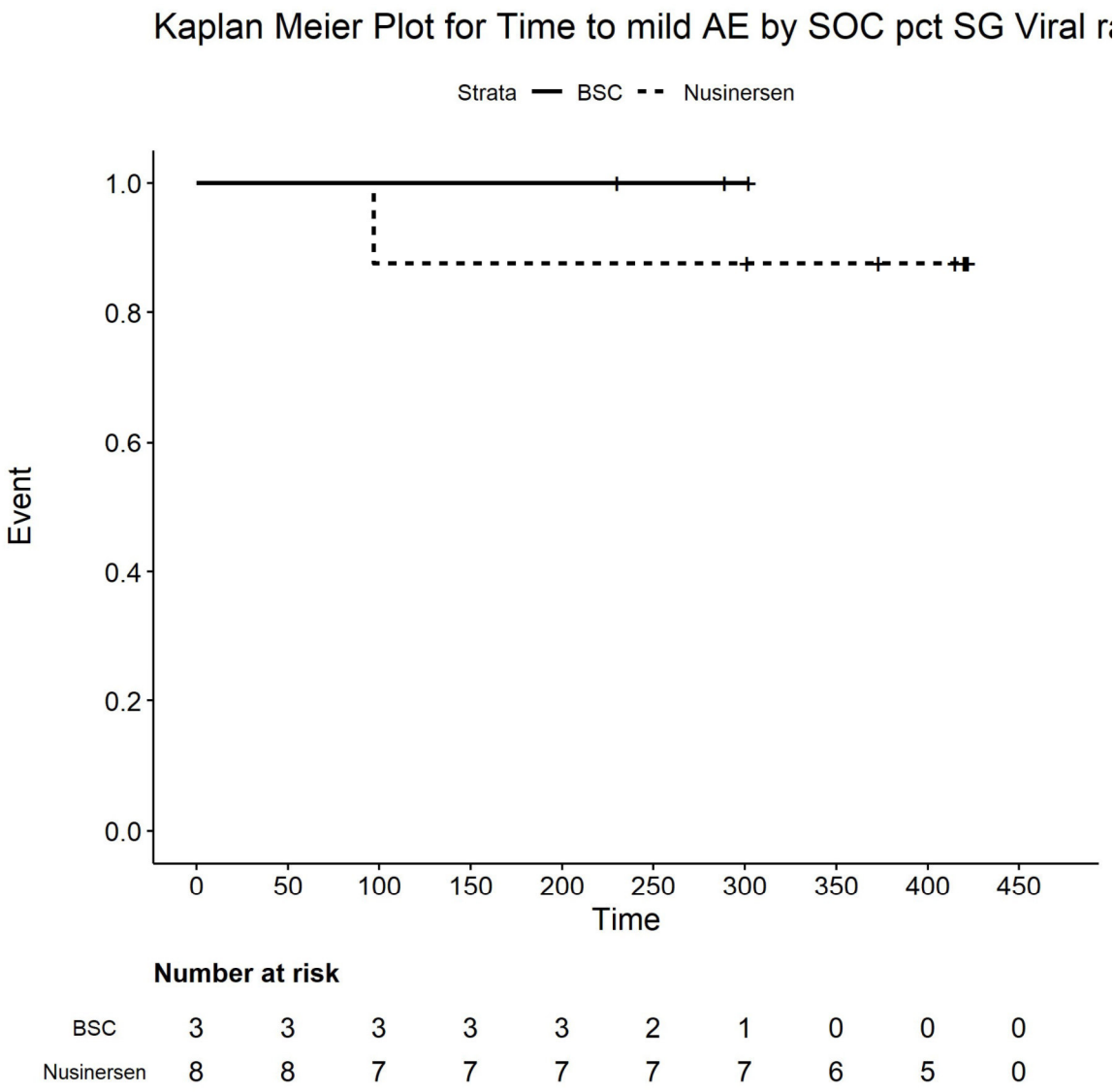
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



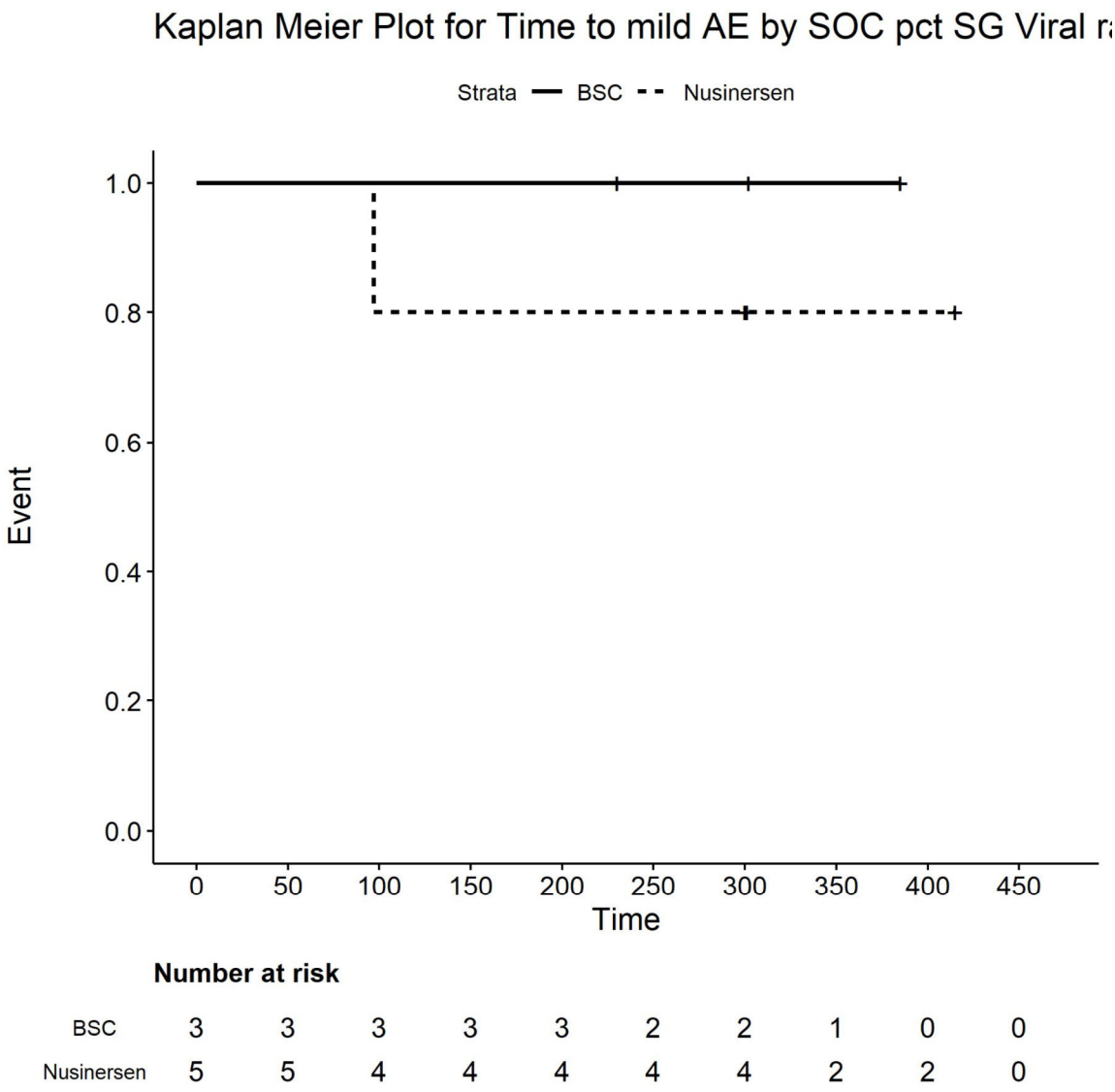
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



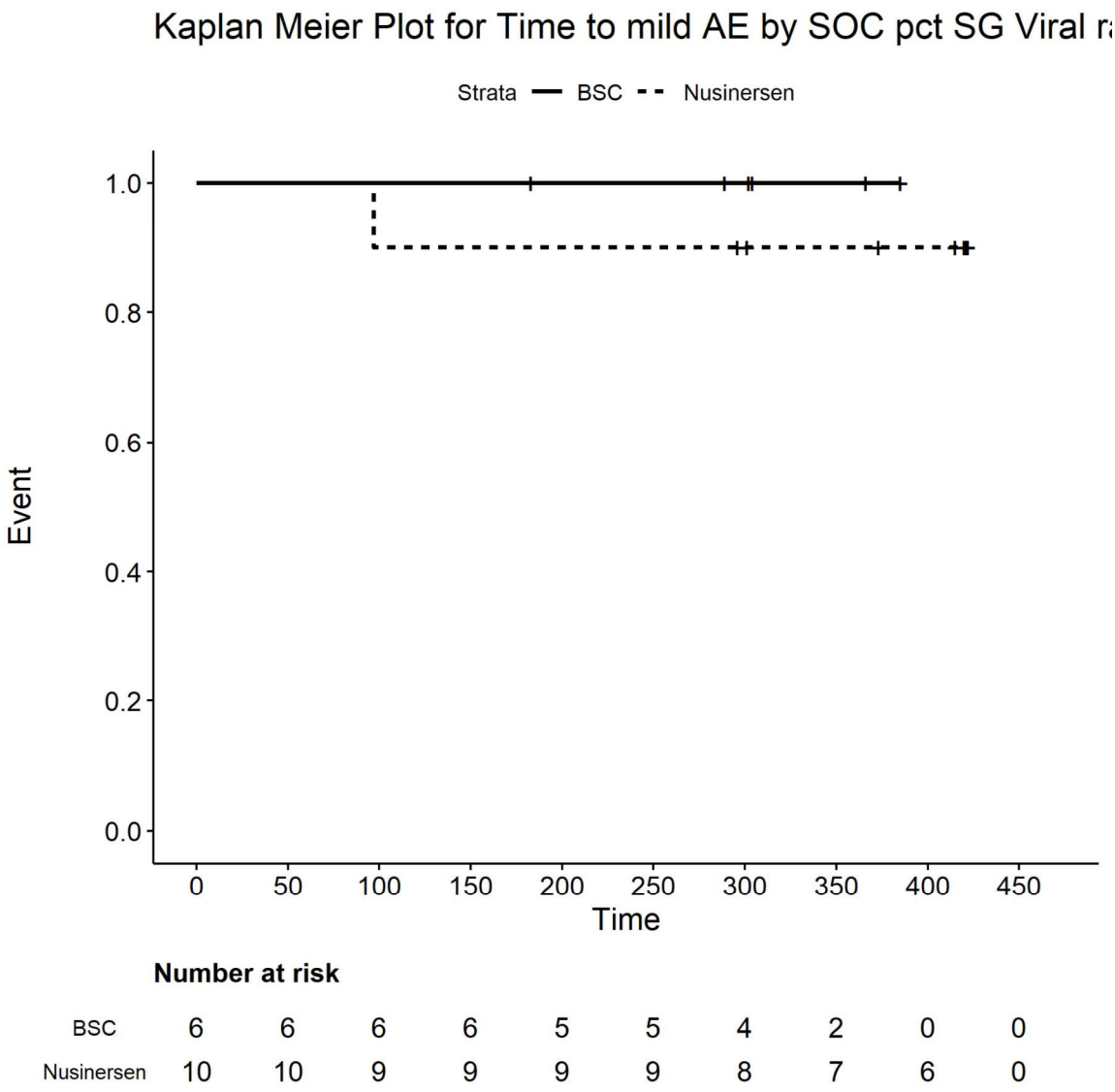
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	6	5	0



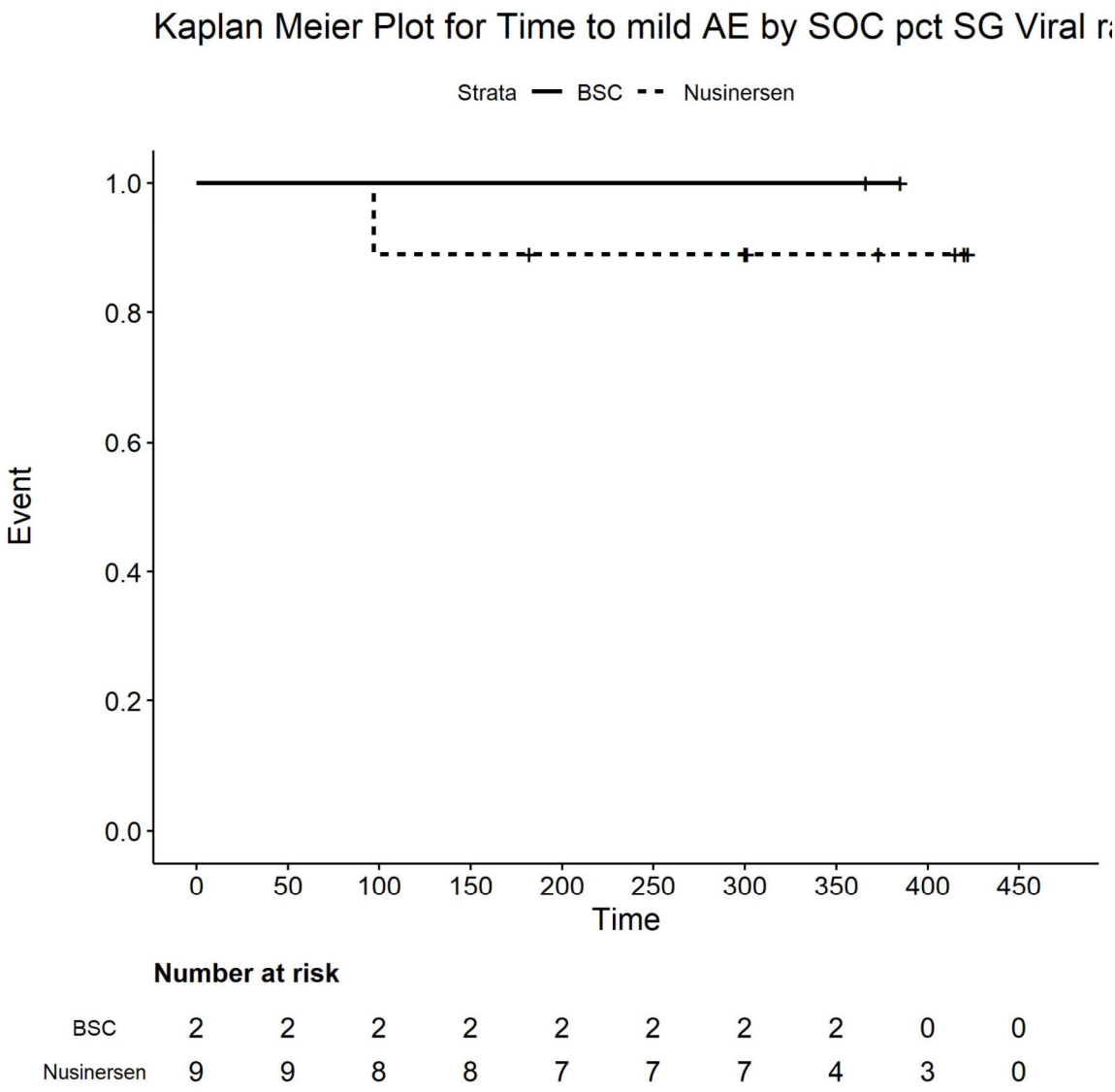
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



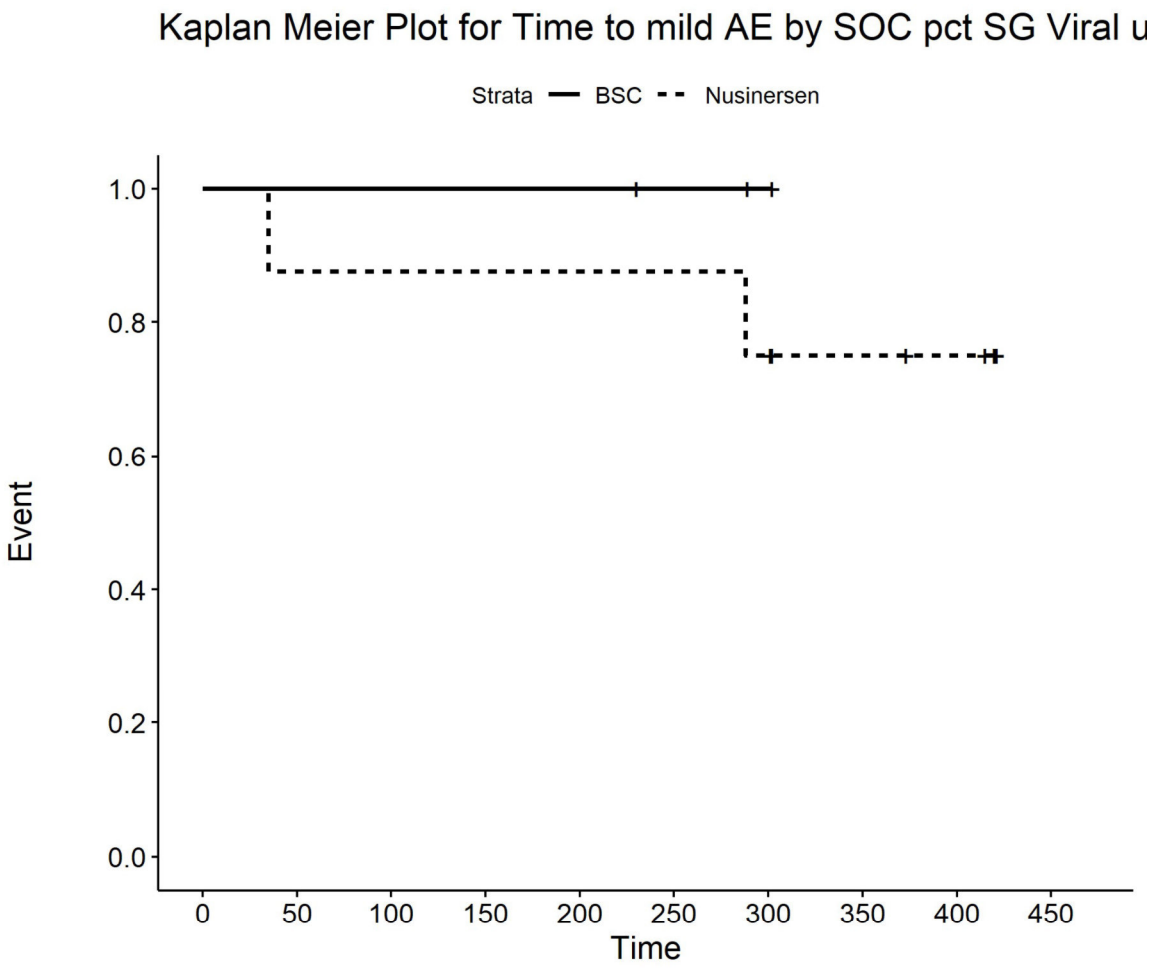
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



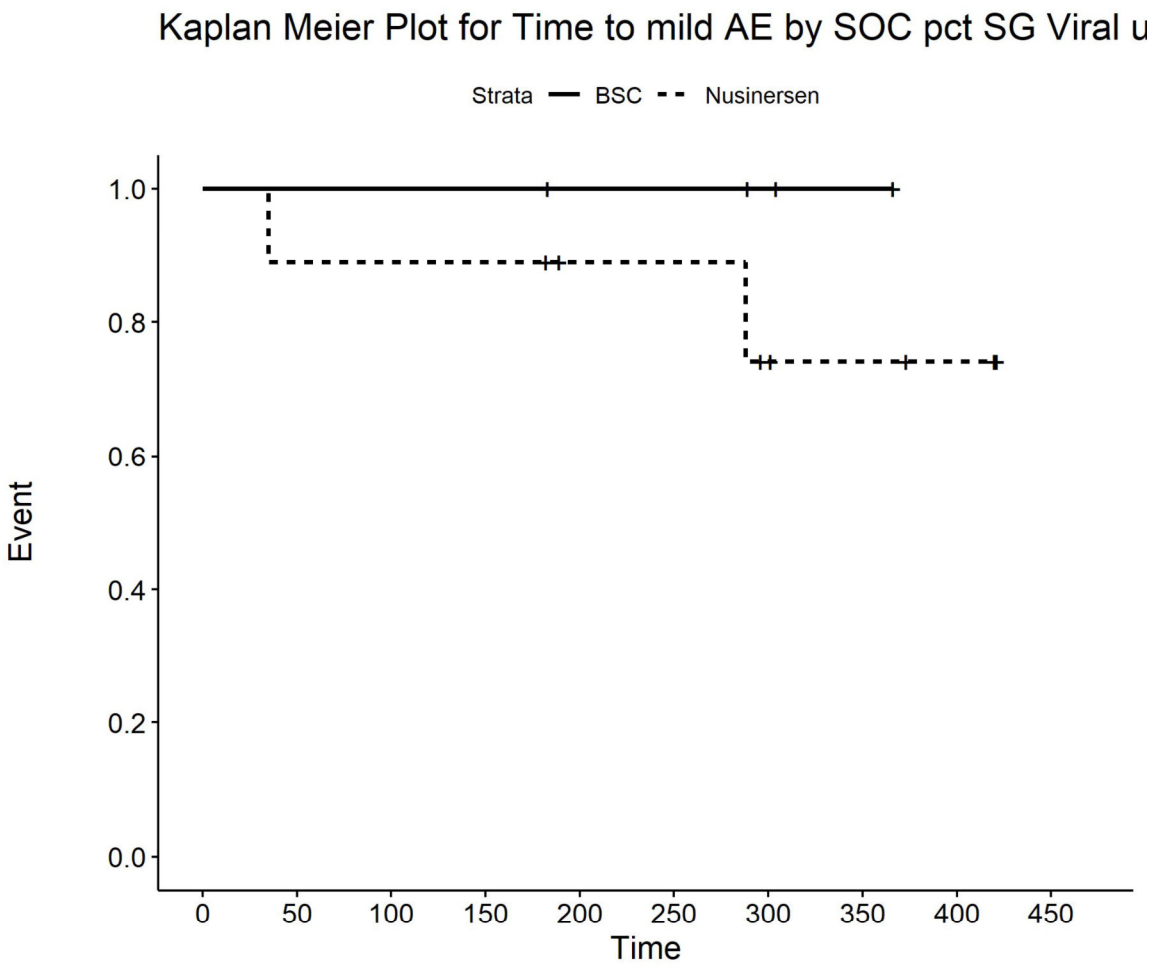
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



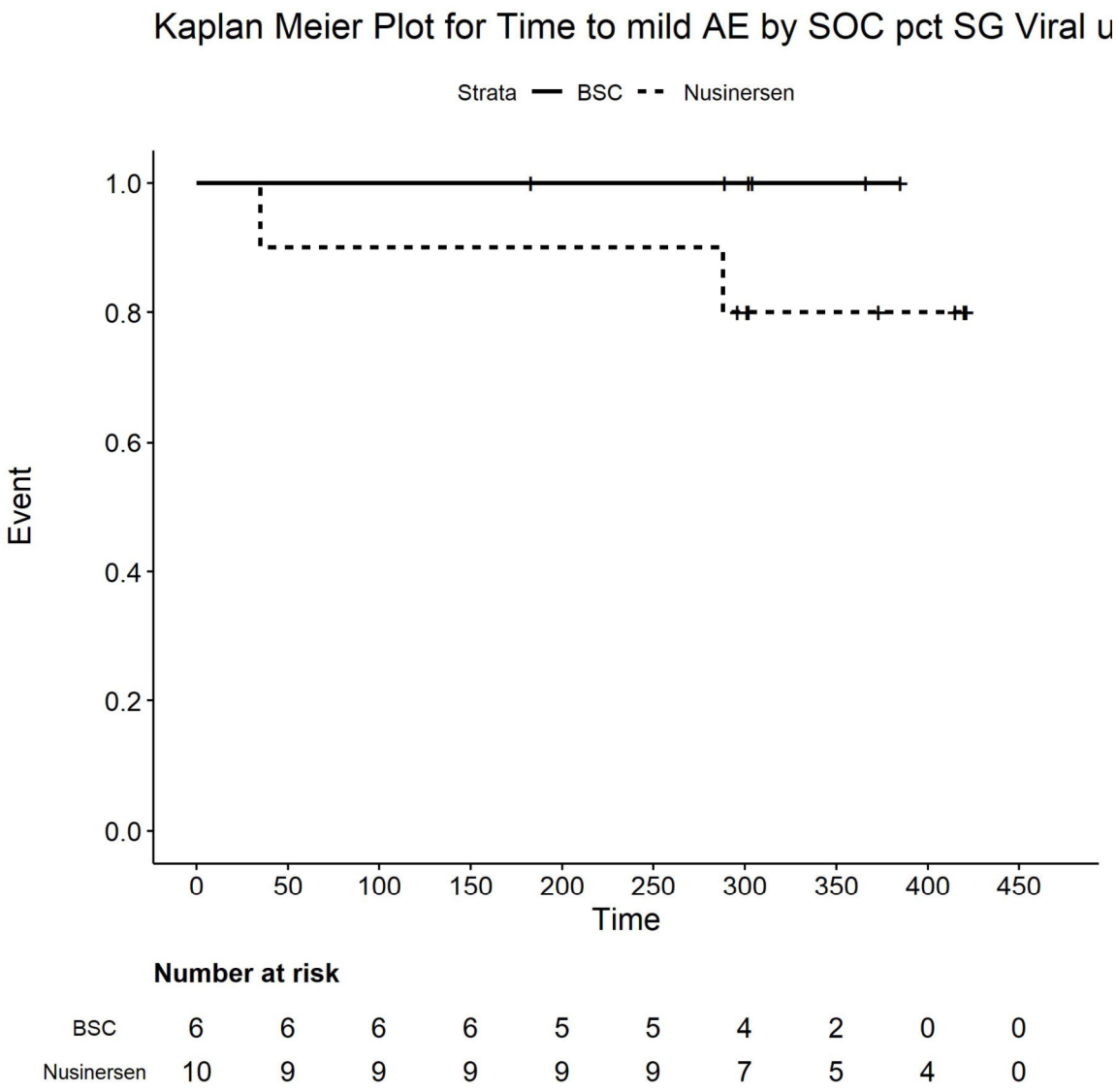
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	6	4	3	0



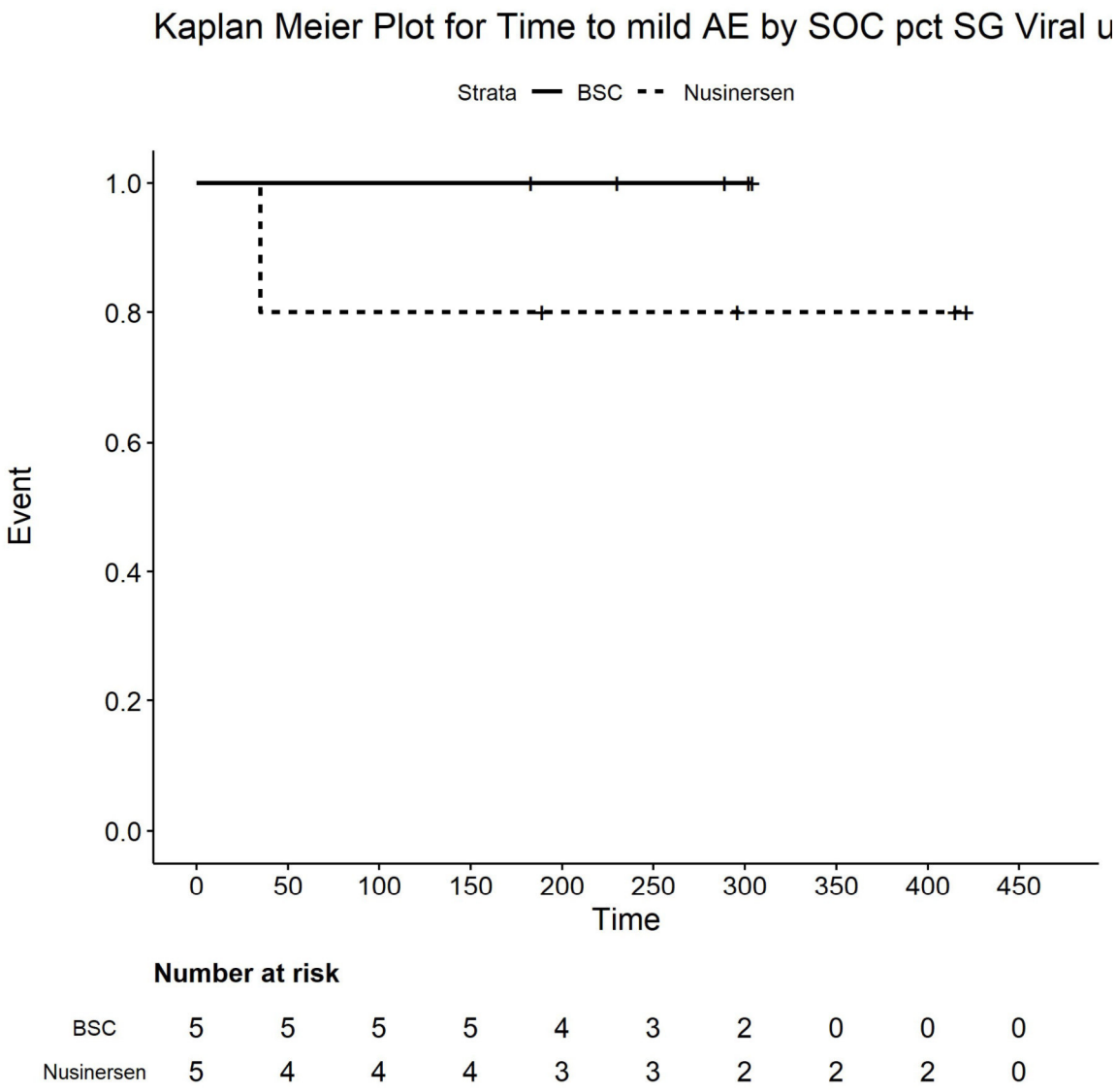
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	4	3	2	0



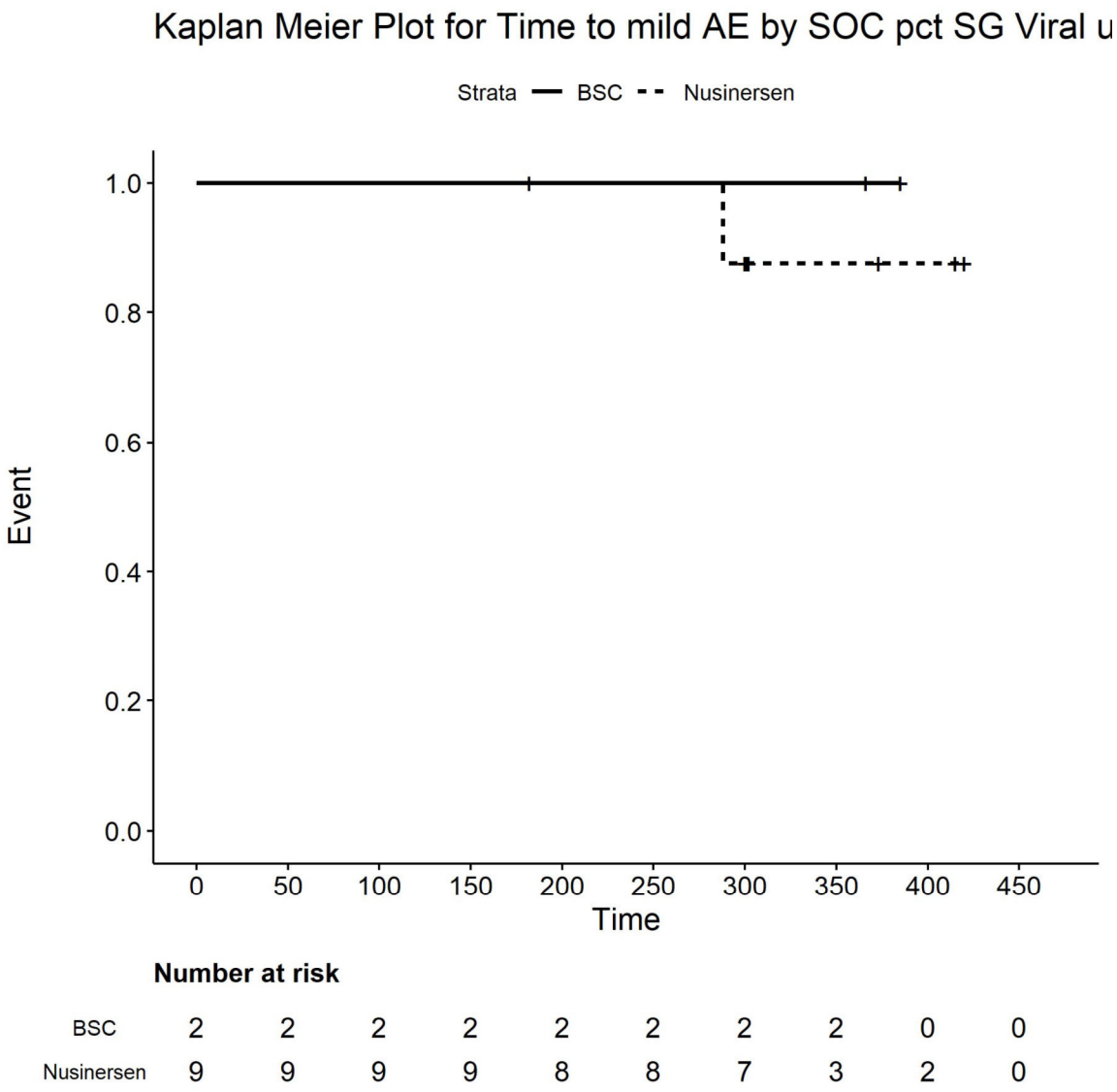
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	7	5	4	0



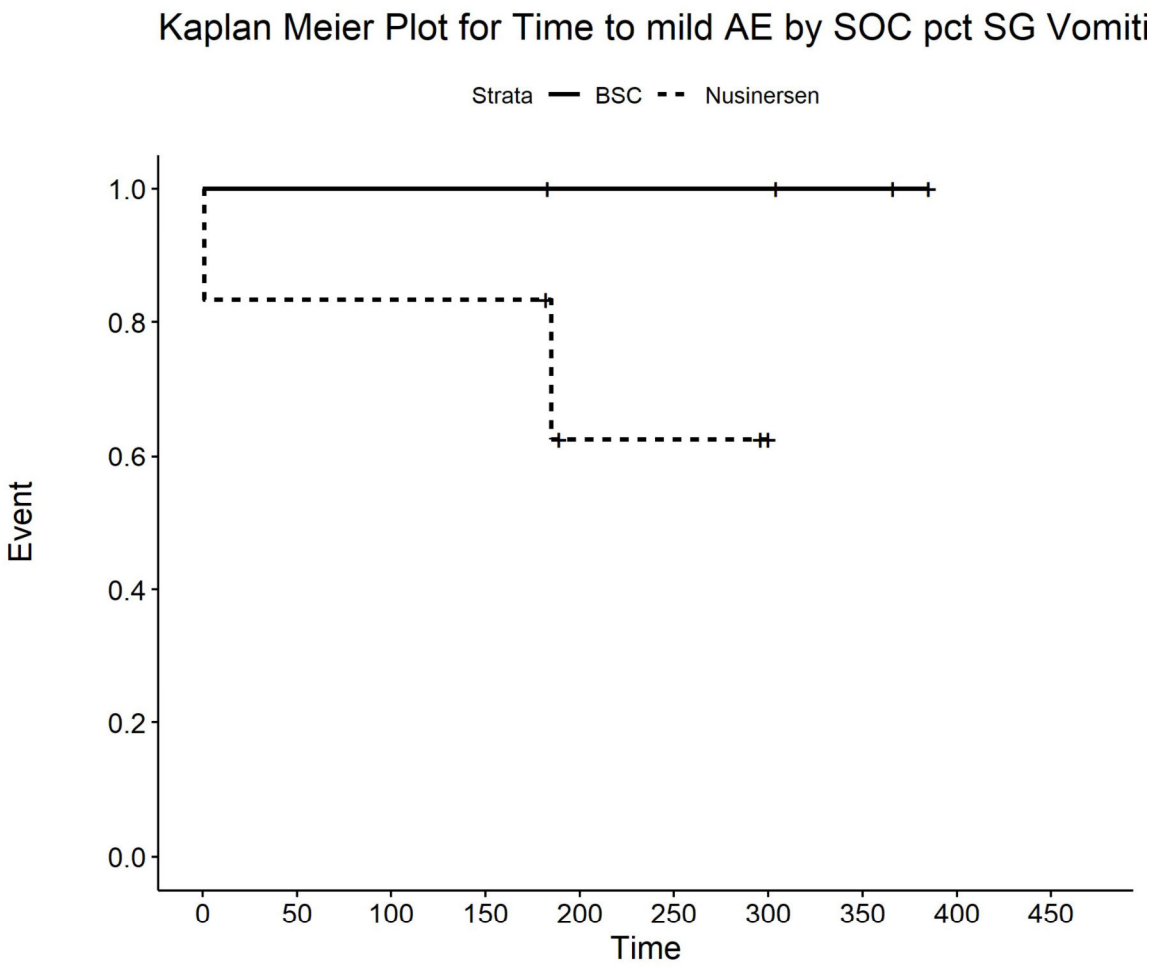
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	2	2	2	0



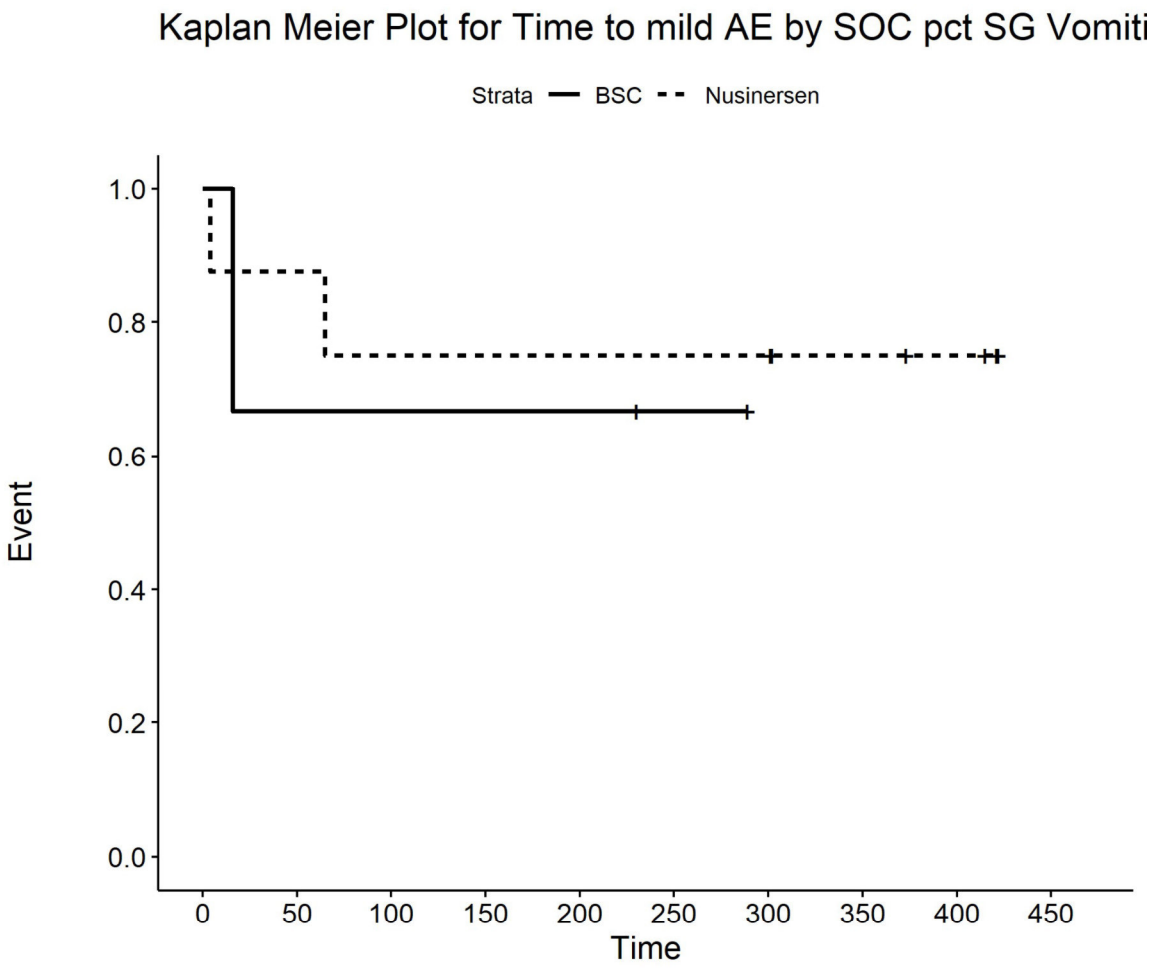
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	7	3	2	0



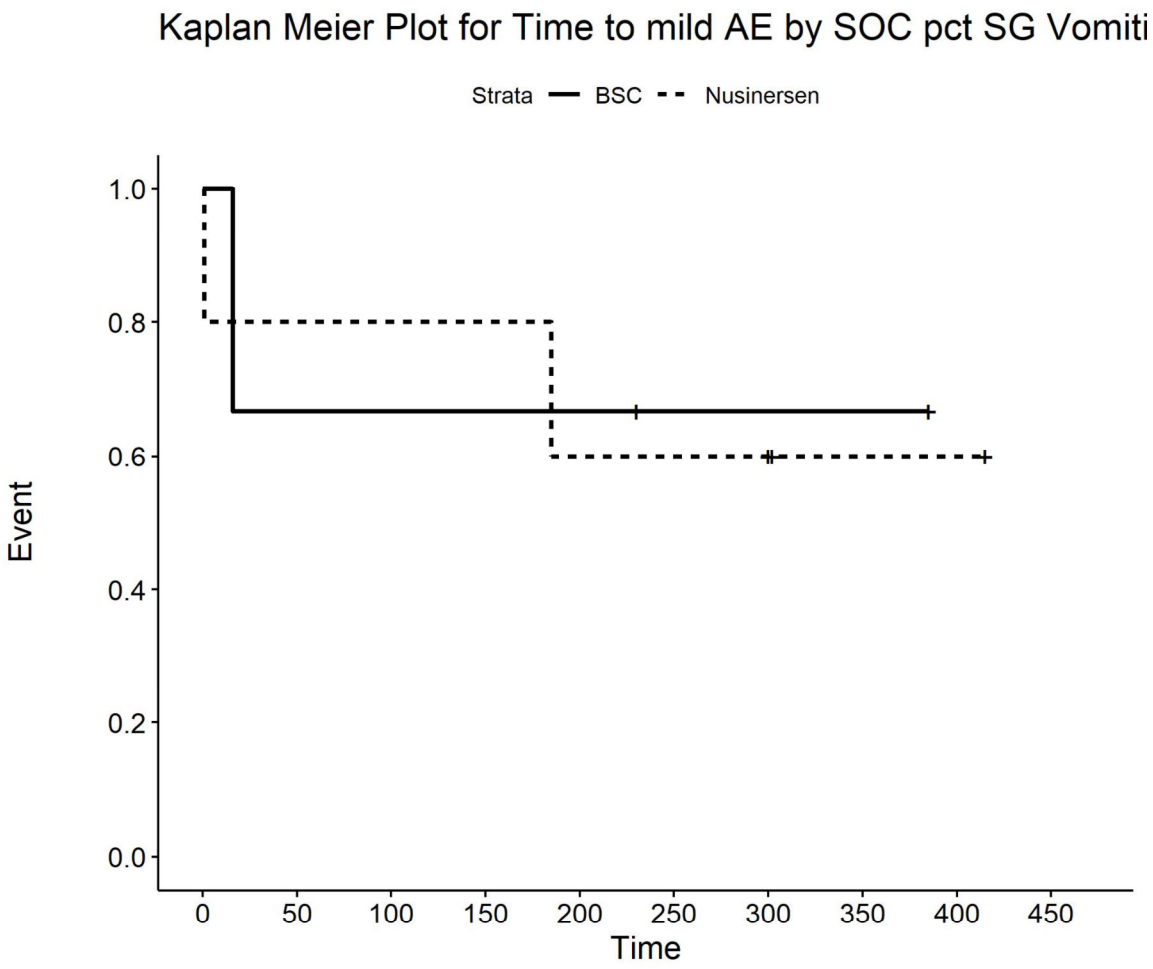
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	2	2	1	0	0	0



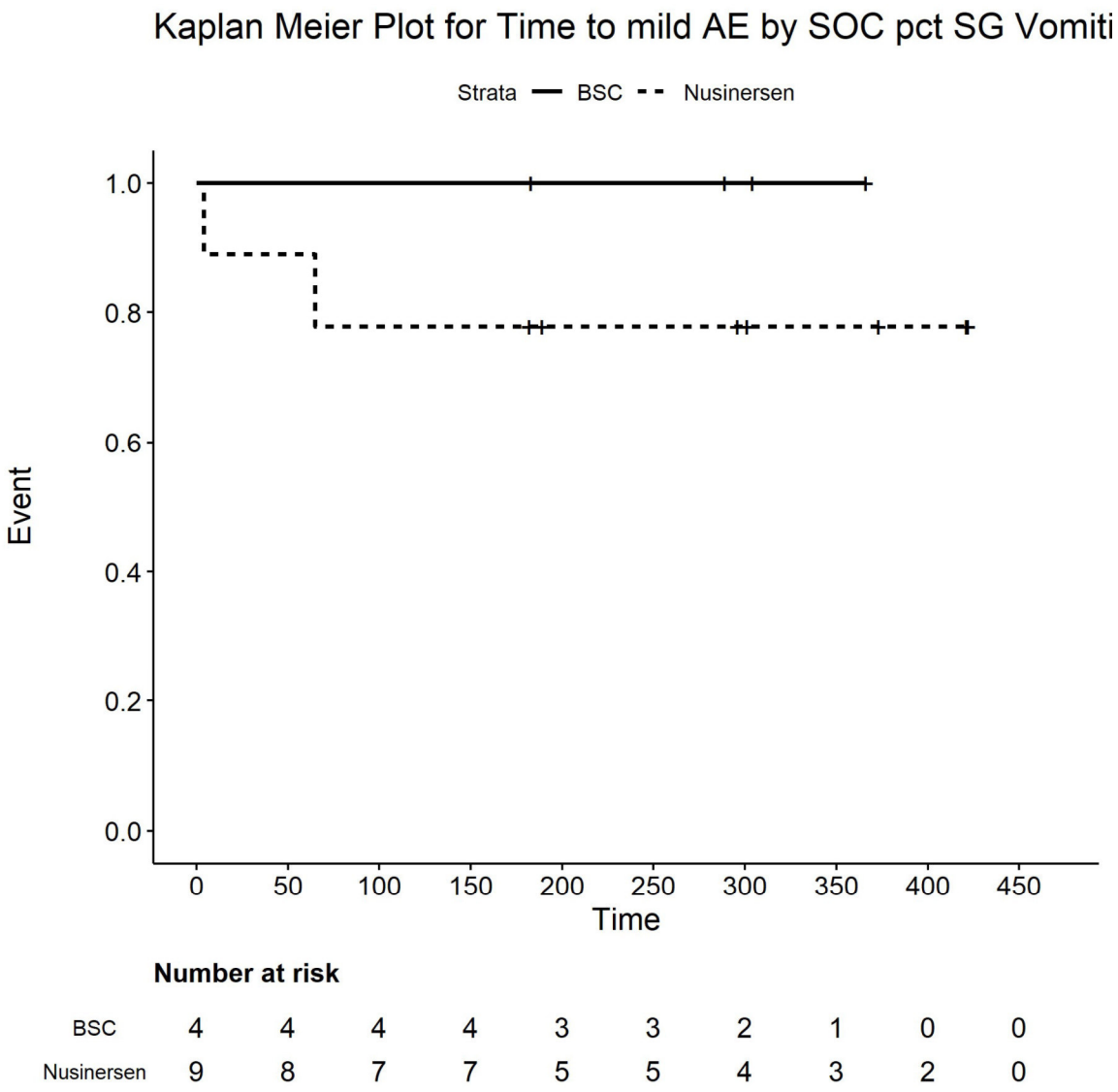
Number at risk

BSC	3	2	2	2	2	1	0	0	0	0
Nusinersen	8	7	6	6	6	6	6	4	3	0



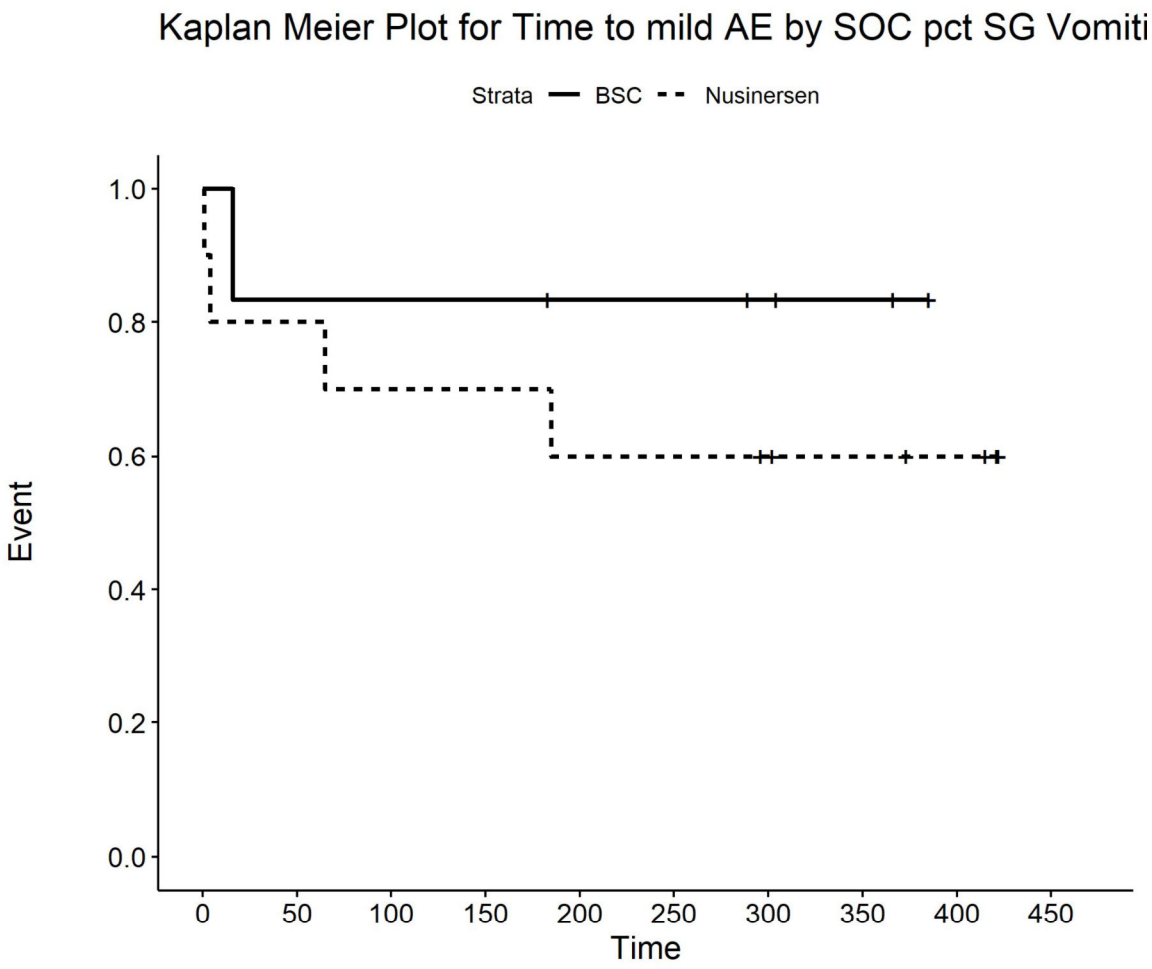
Number at risk

BSC	3	2	2	2	2	1	1	1	0	0
Nusinersen	5	4	4	4	3	3	3	1	1	0



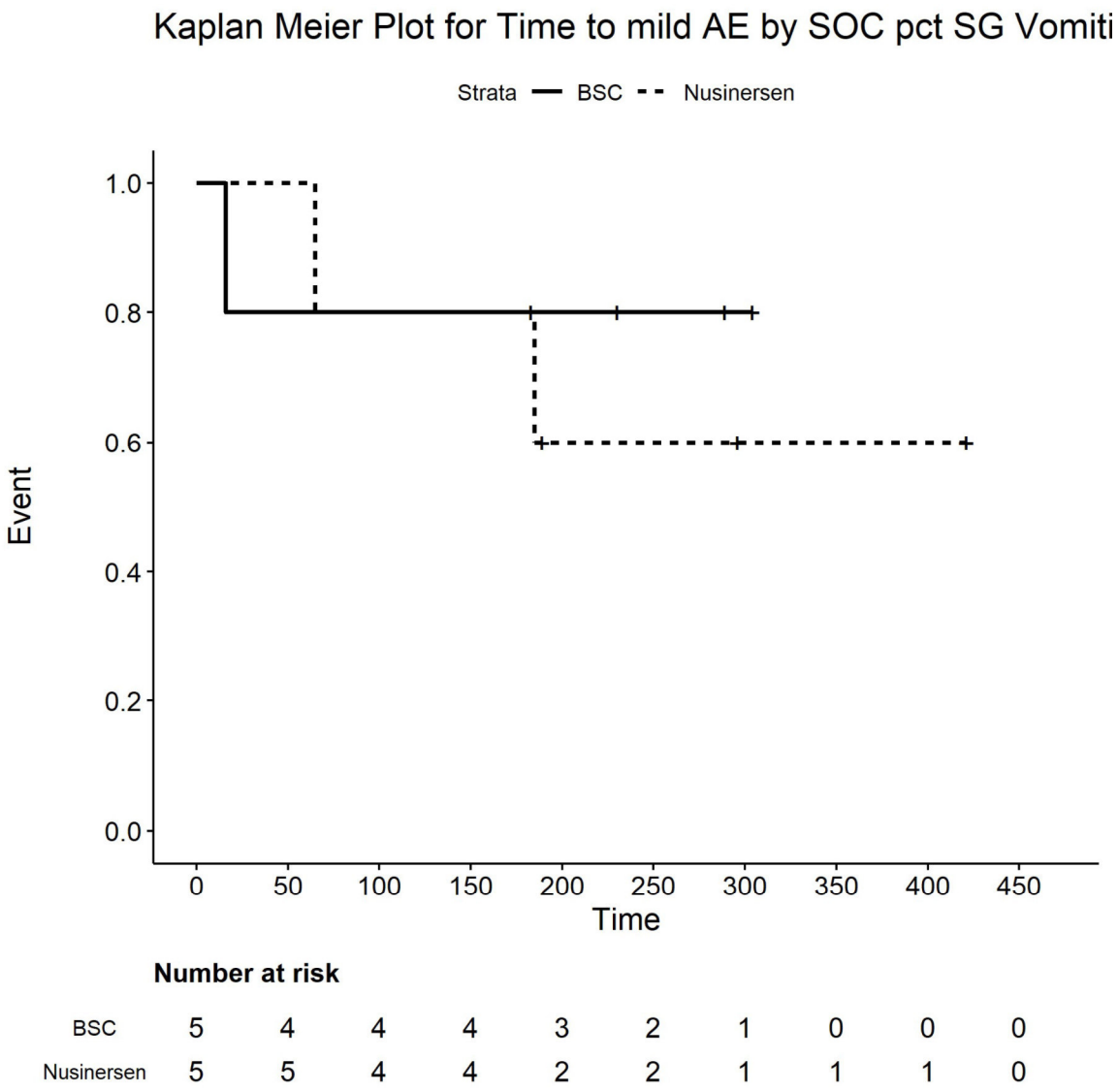
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	7	7	5	5	4	3	2	0



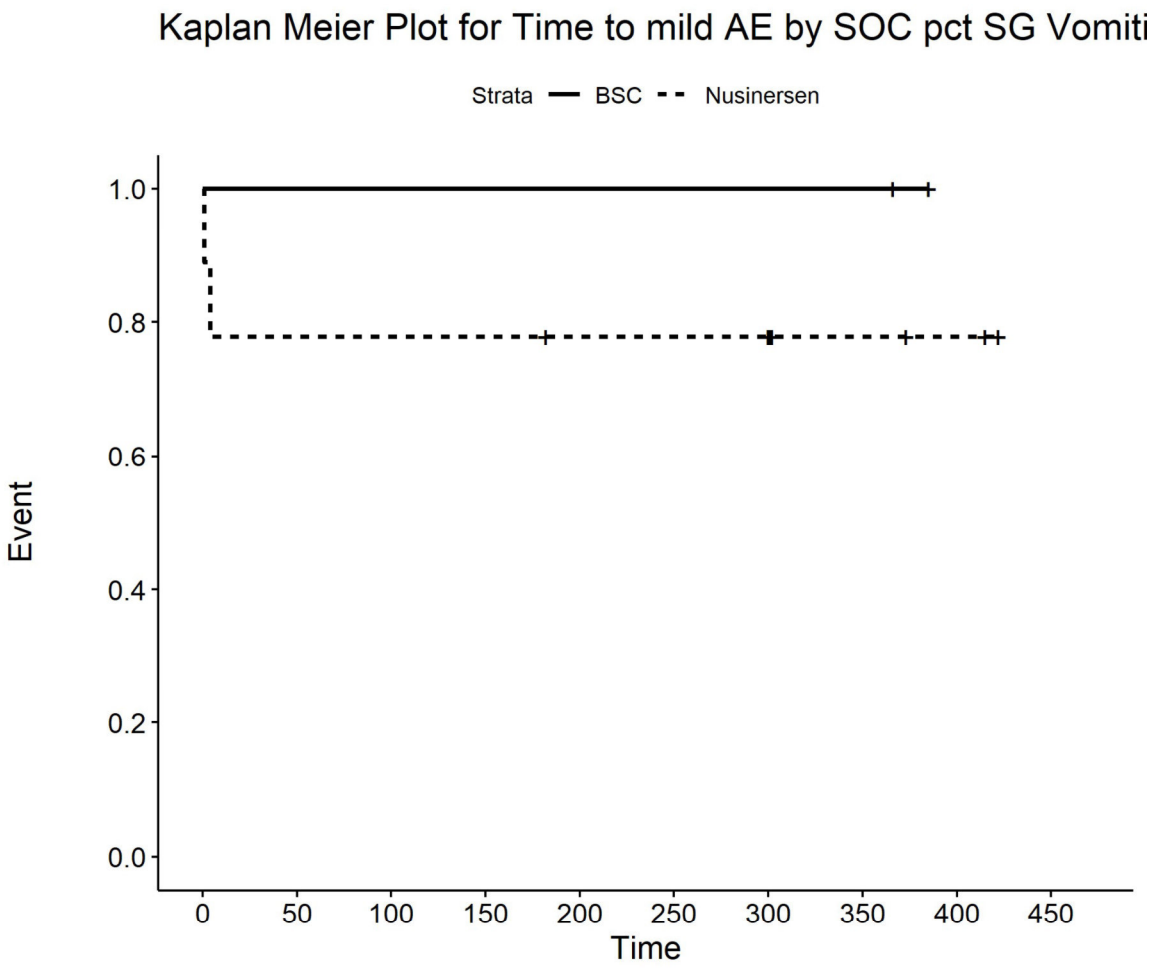
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	8	7	7	6	6	5	4	3	0



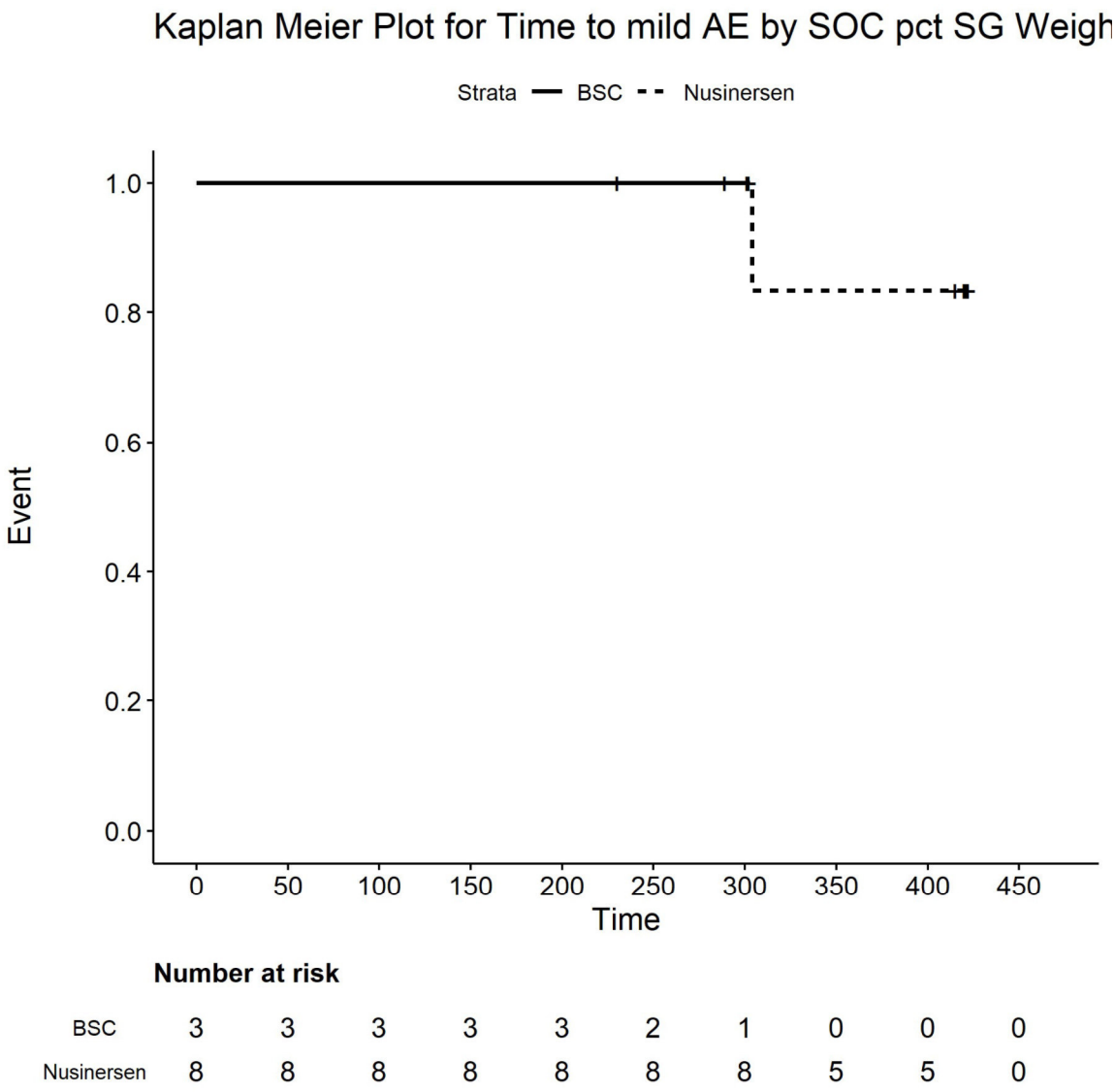
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	4	4	2	2	1	1	1	0



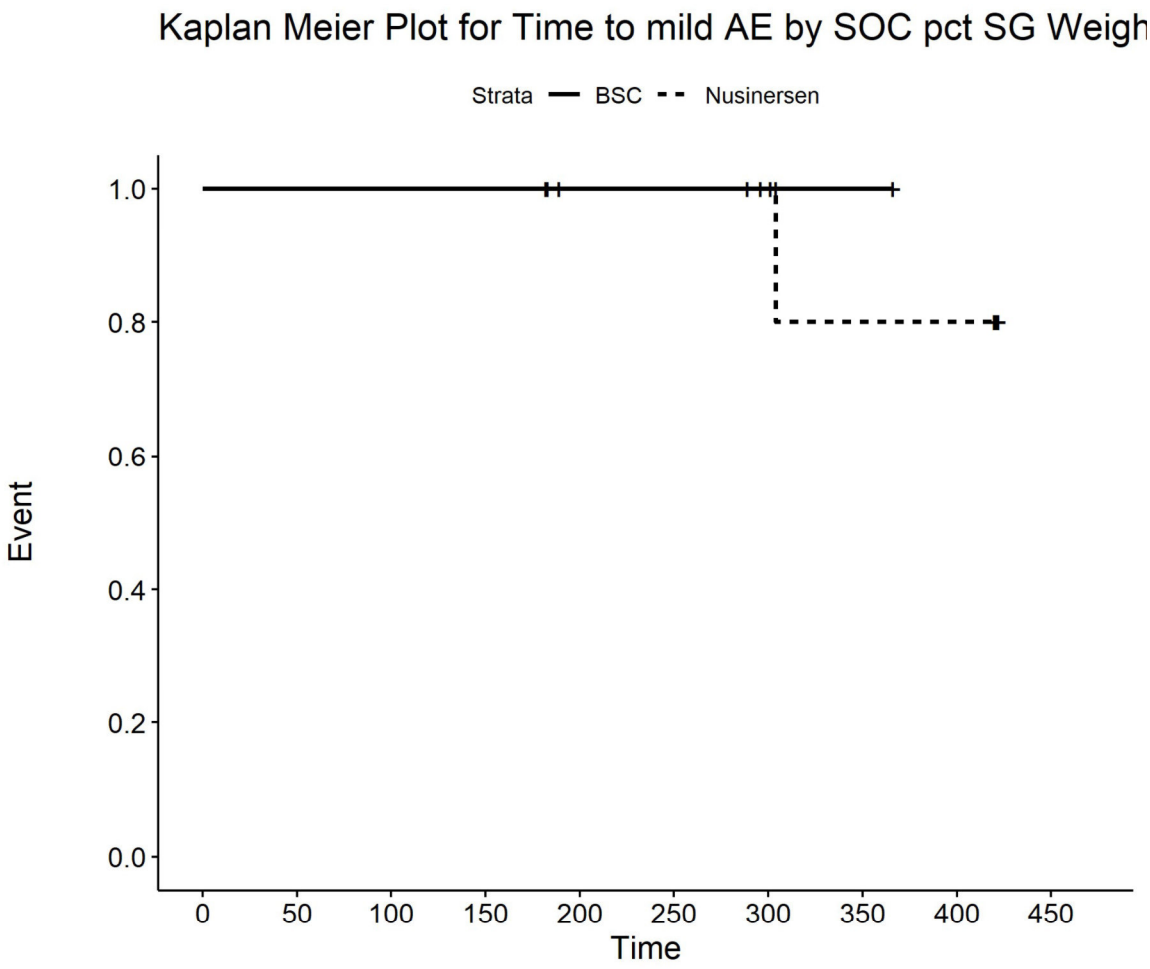
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	7	7	6	6	6	3	2	0



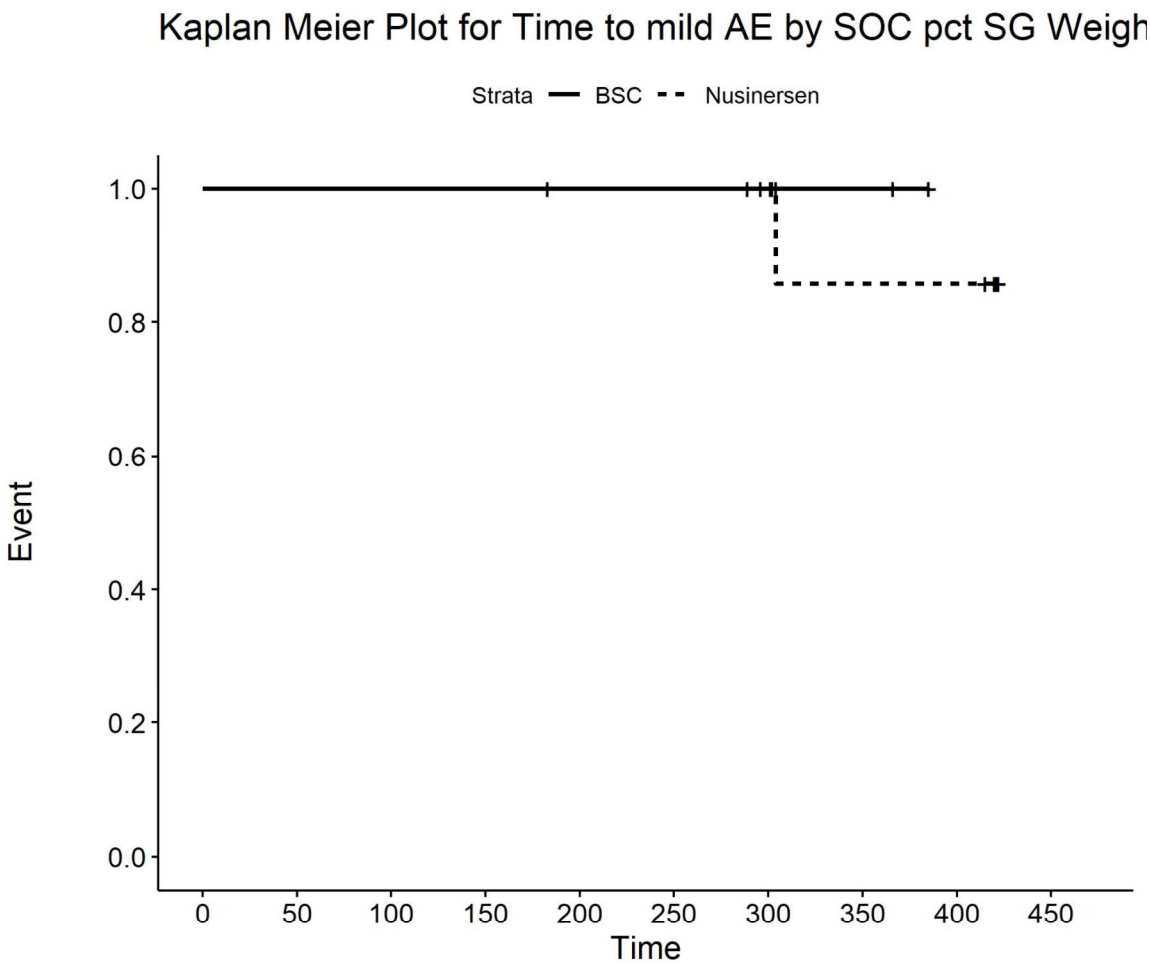
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	5	5	0



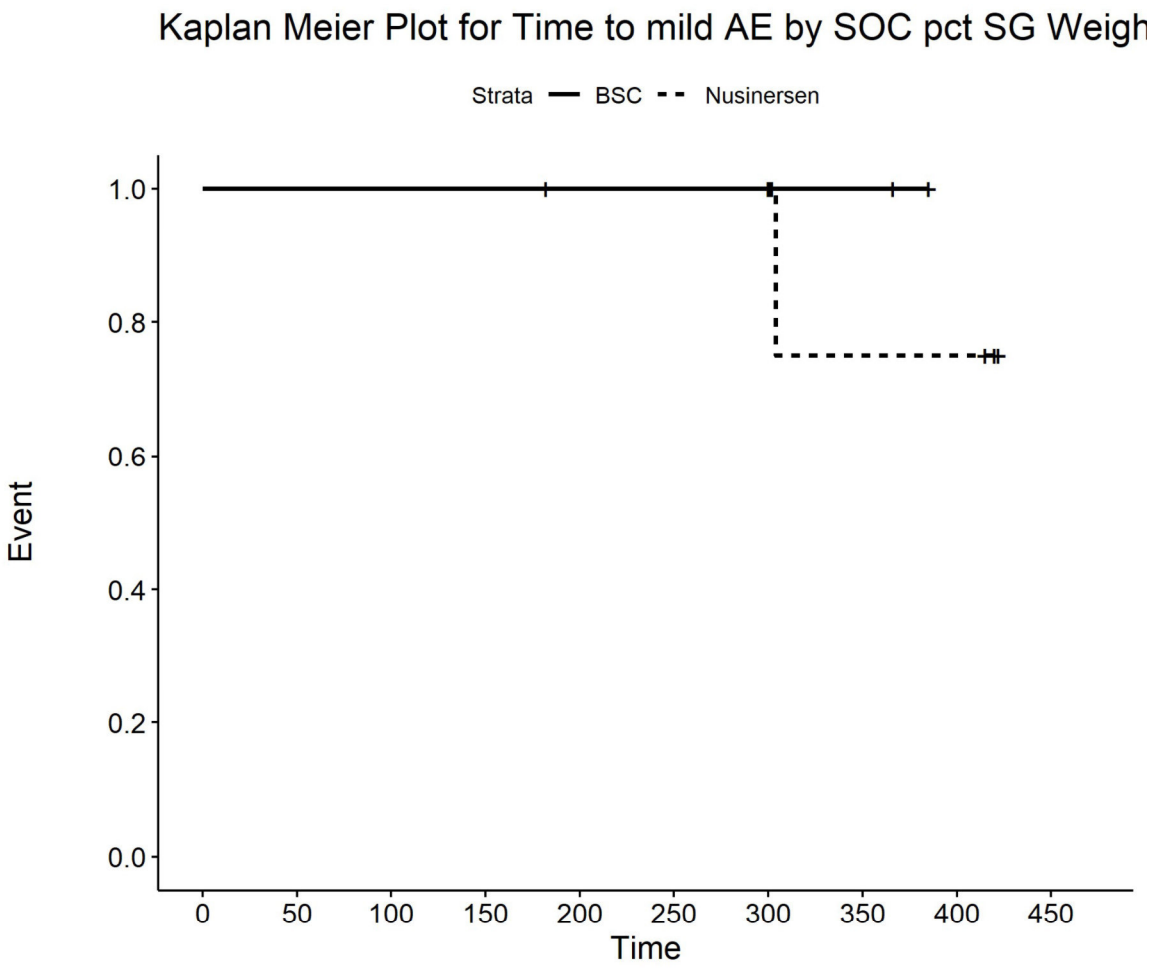
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	4	4	0



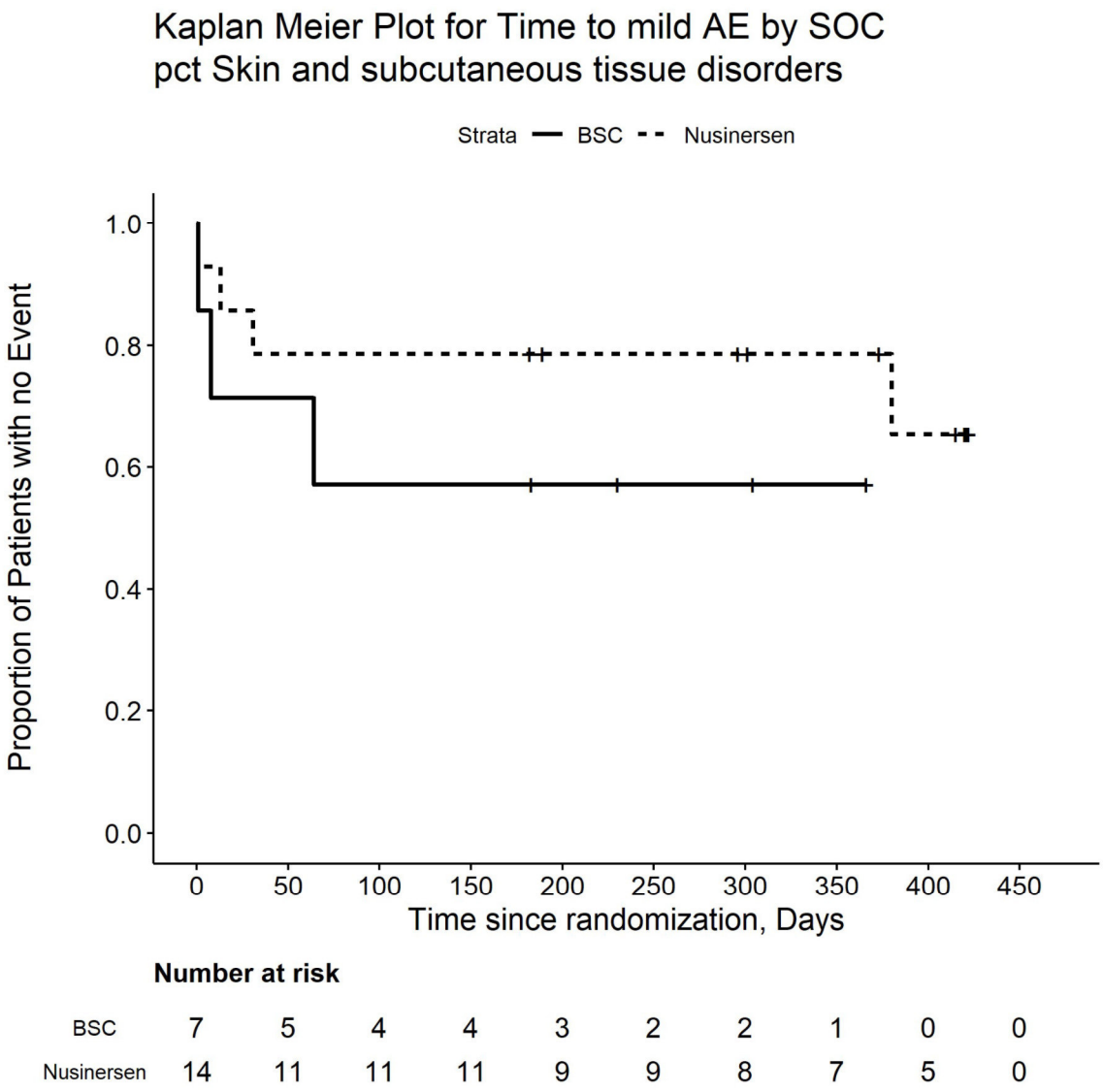
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	6	6	0



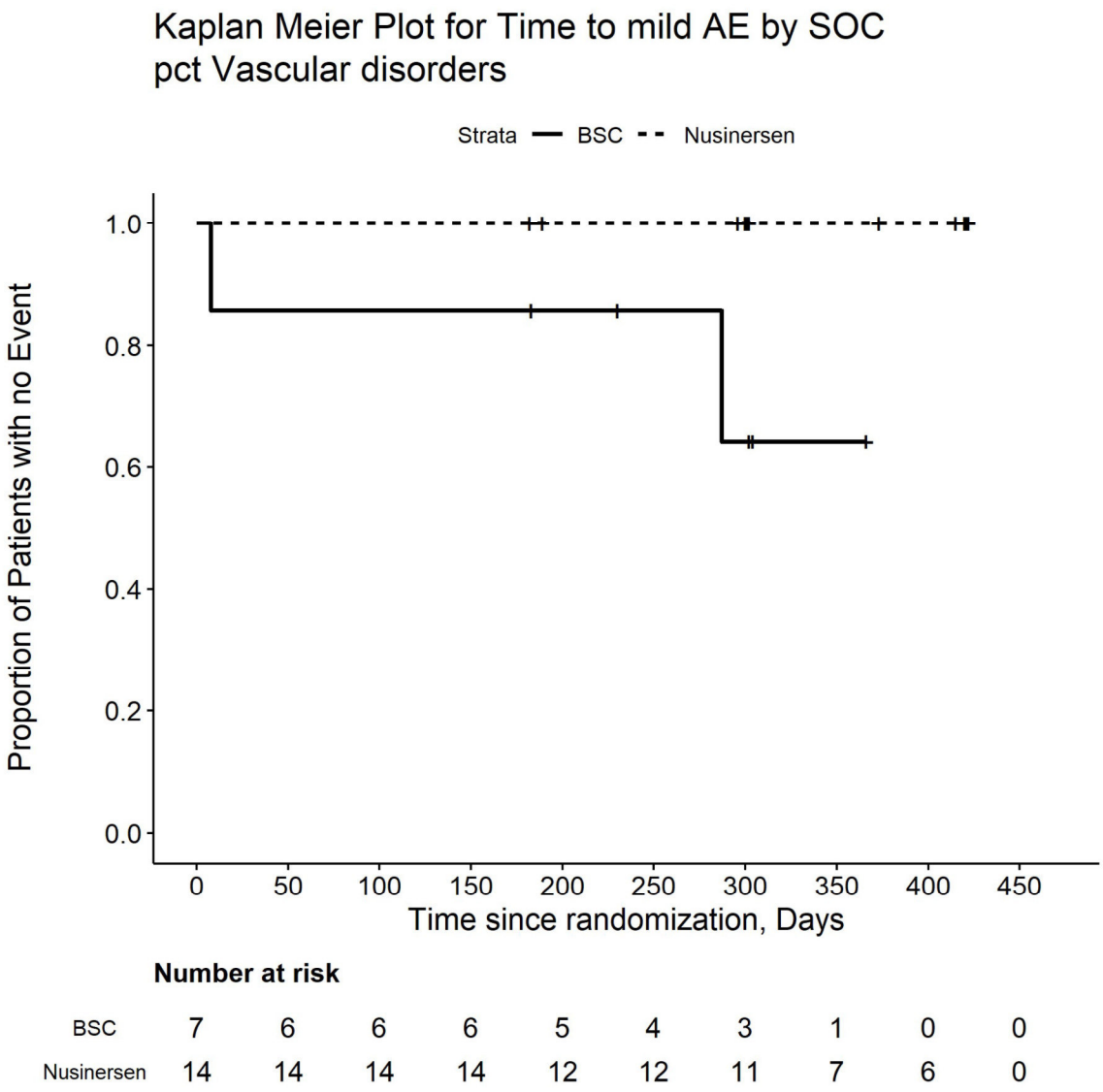
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	8	3	3	0



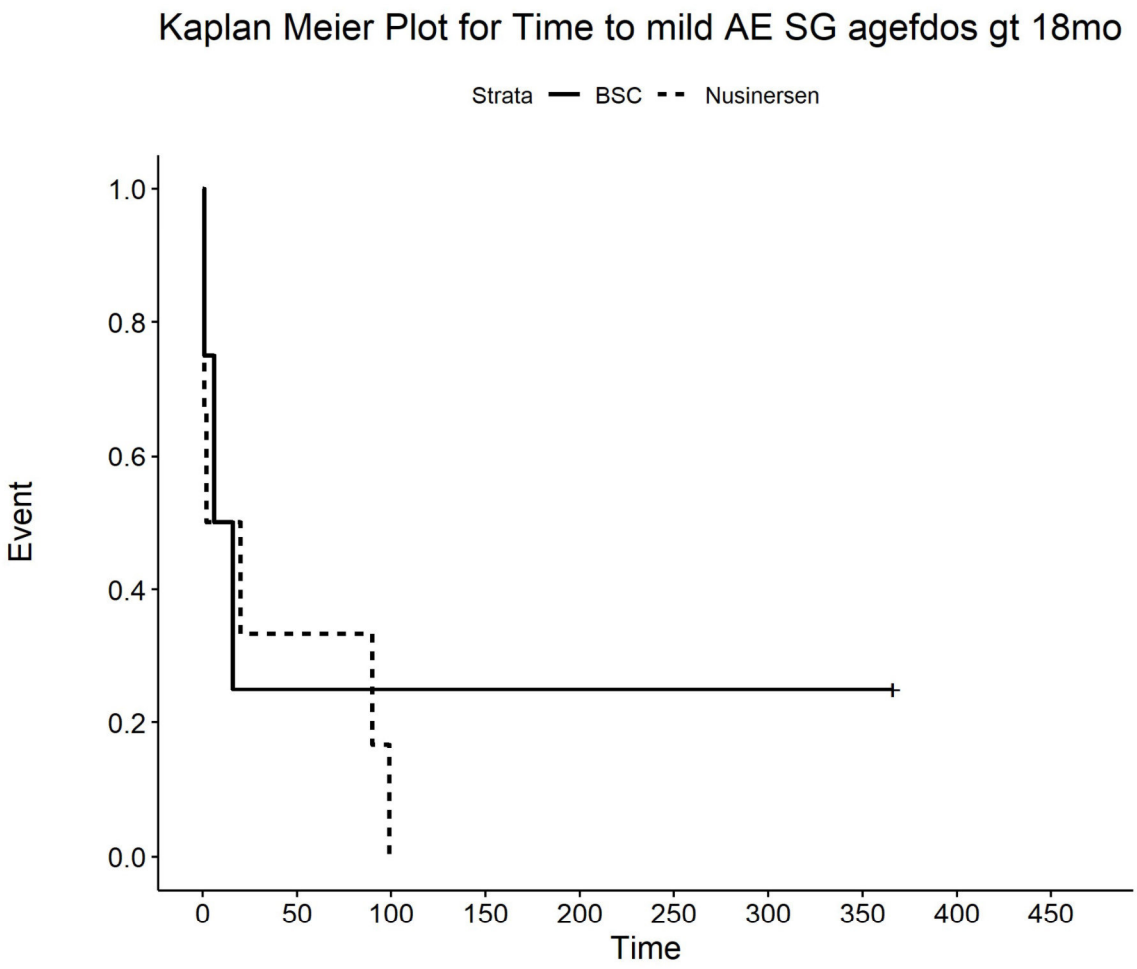
Number at risk

BSC	7	5	4	4	3	2	2	1	0	0
Nusinersen	14	11	11	11	9	9	8	7	5	0



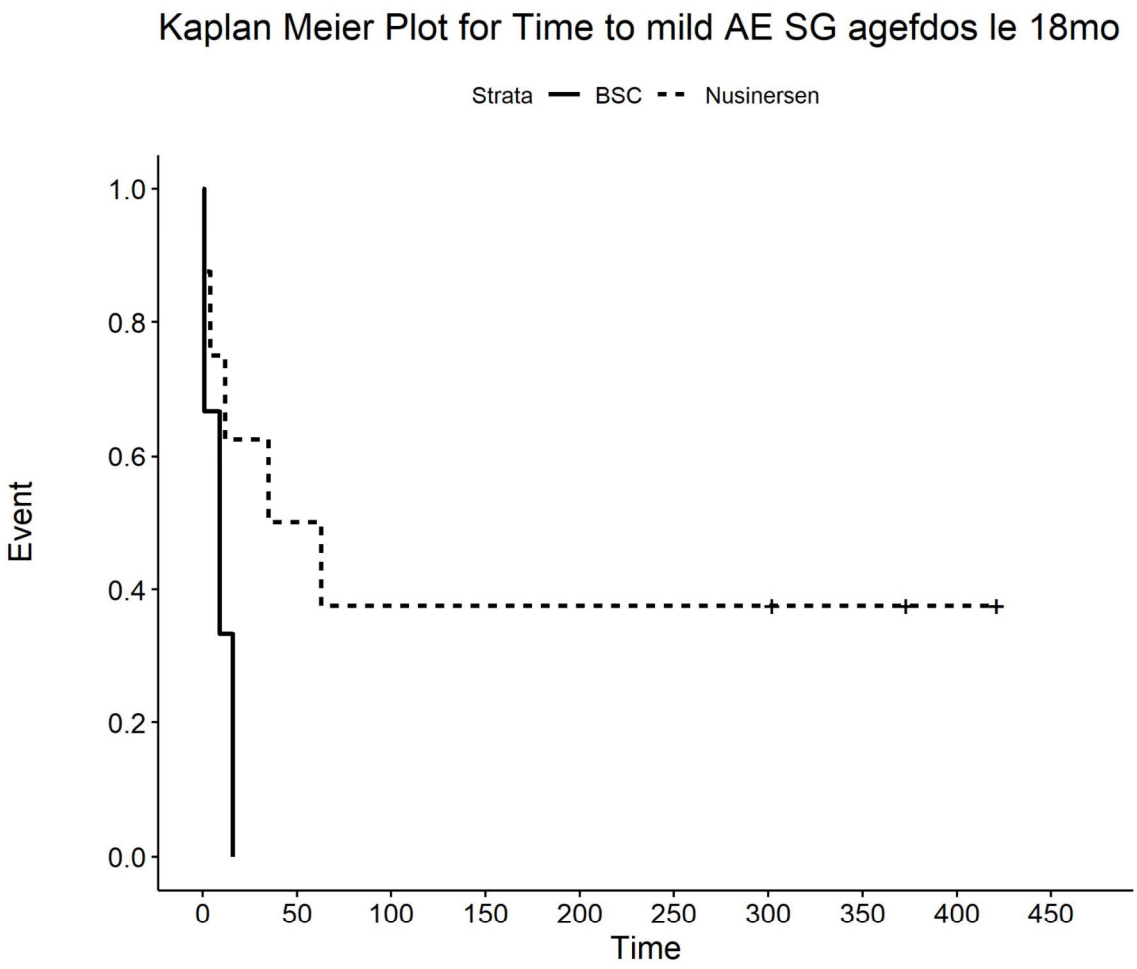
Number at risk

BSC	7	6	6	6	5	4	3	1	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



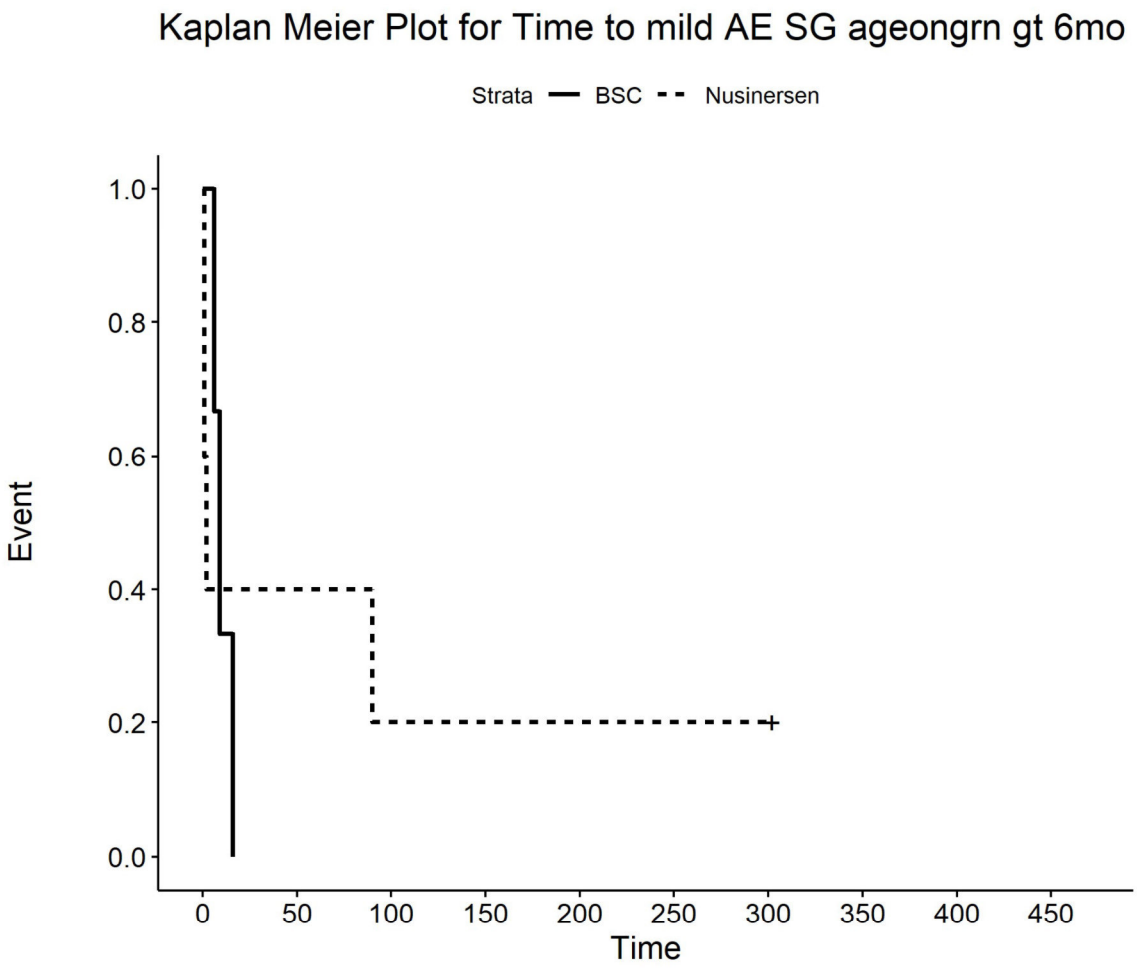
Number at risk

BSC	4	1	1	1	1	1	1	1	0	0
Nusinersen	6	2	0	0	0	0	0	0	0	0



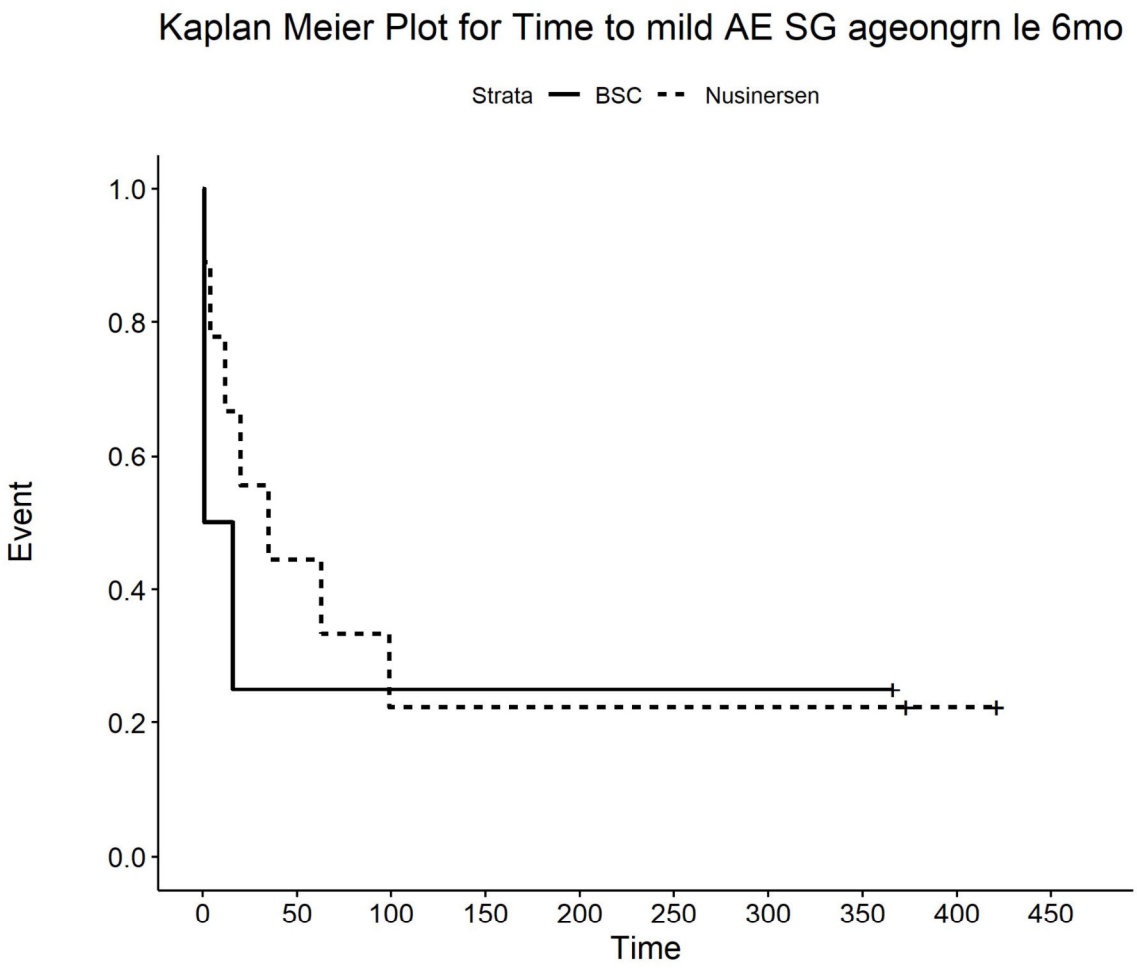
Number at risk

BSC	3	0	0	0	0	0	0	0	0	0
Nusinersen	8	4	3	3	3	3	3	2	1	0



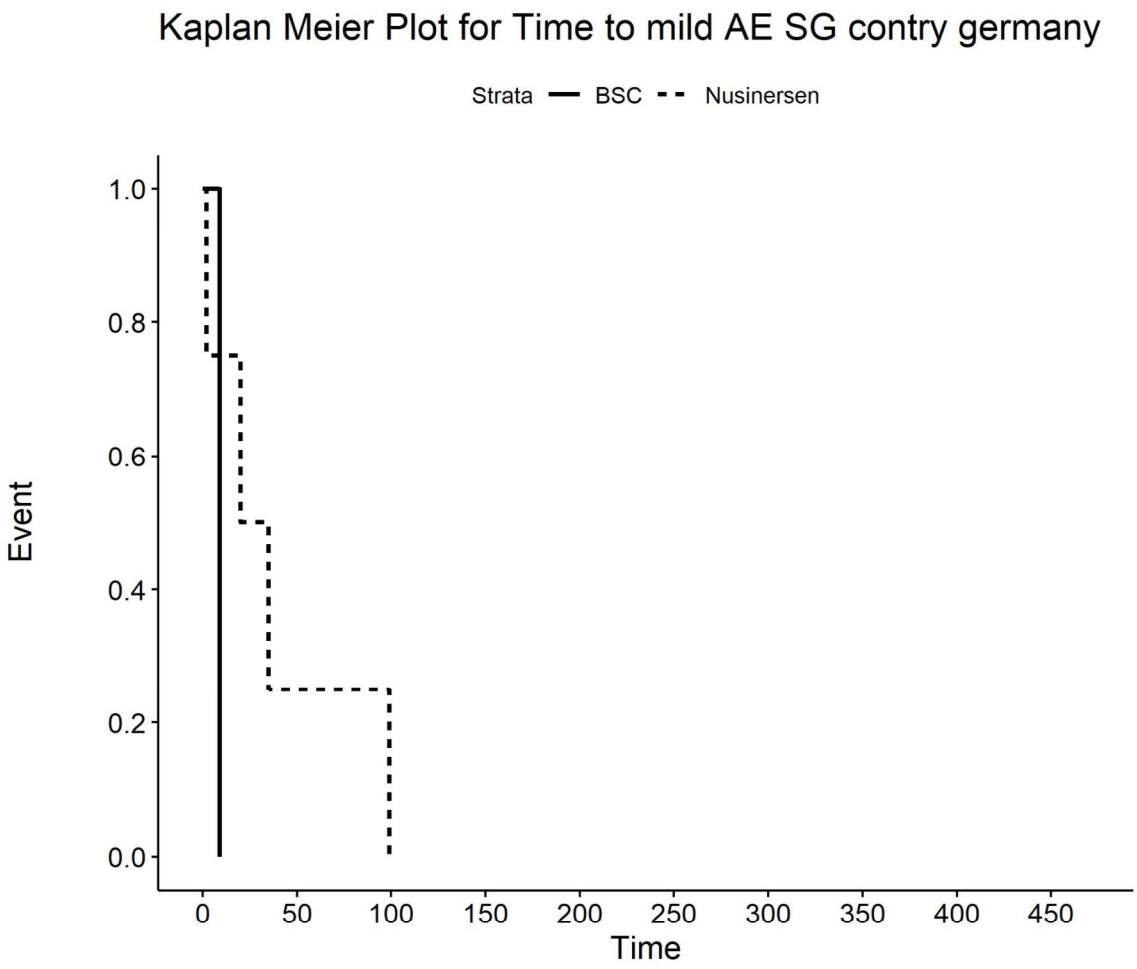
Number at risk

BSC	3	0	0	0	0	0	0	0	0	0
Nusinersen	5	2	1	1	1	1	1	0	0	0



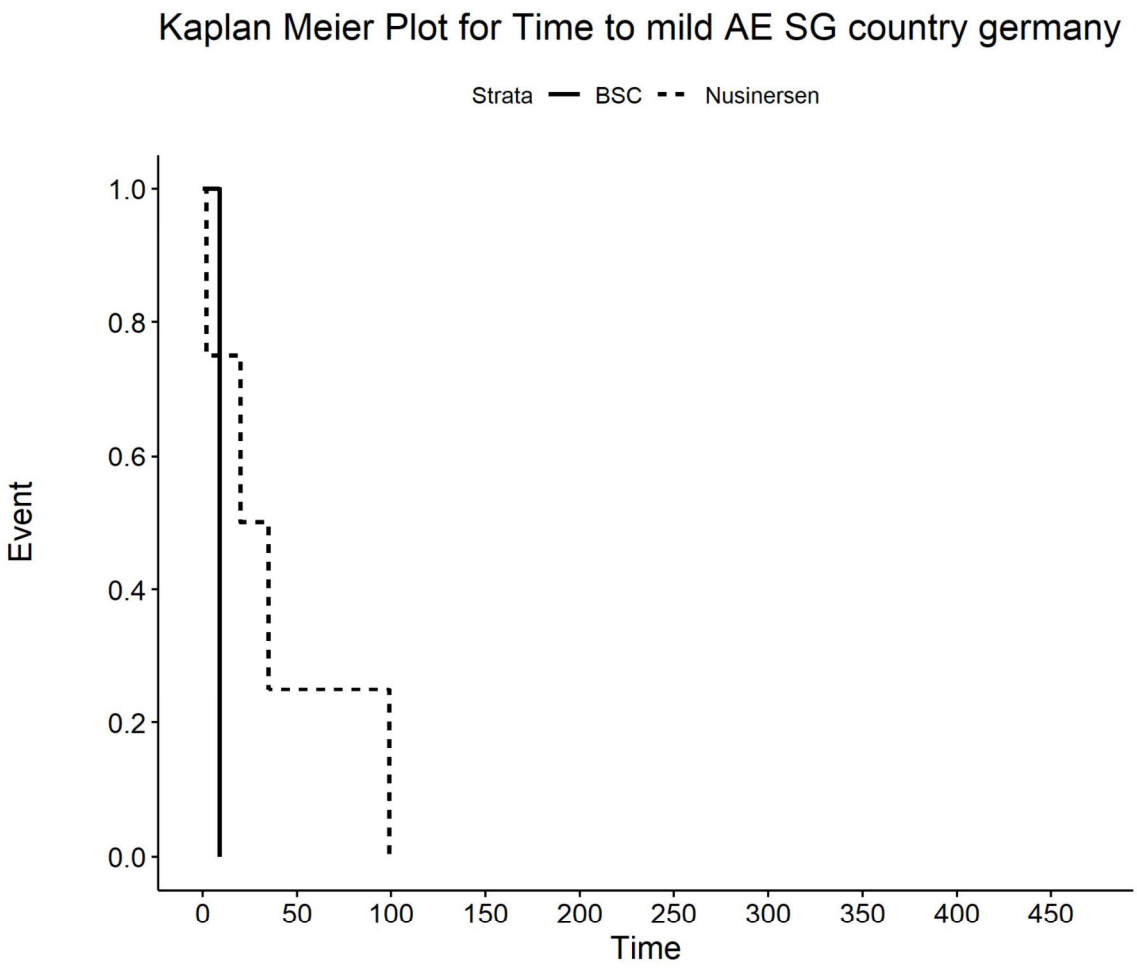
Number at risk

BSC	4	1	1	1	1	1	1	1	0	0
Nusinersen	9	4	2	2	2	2	2	2	1	0



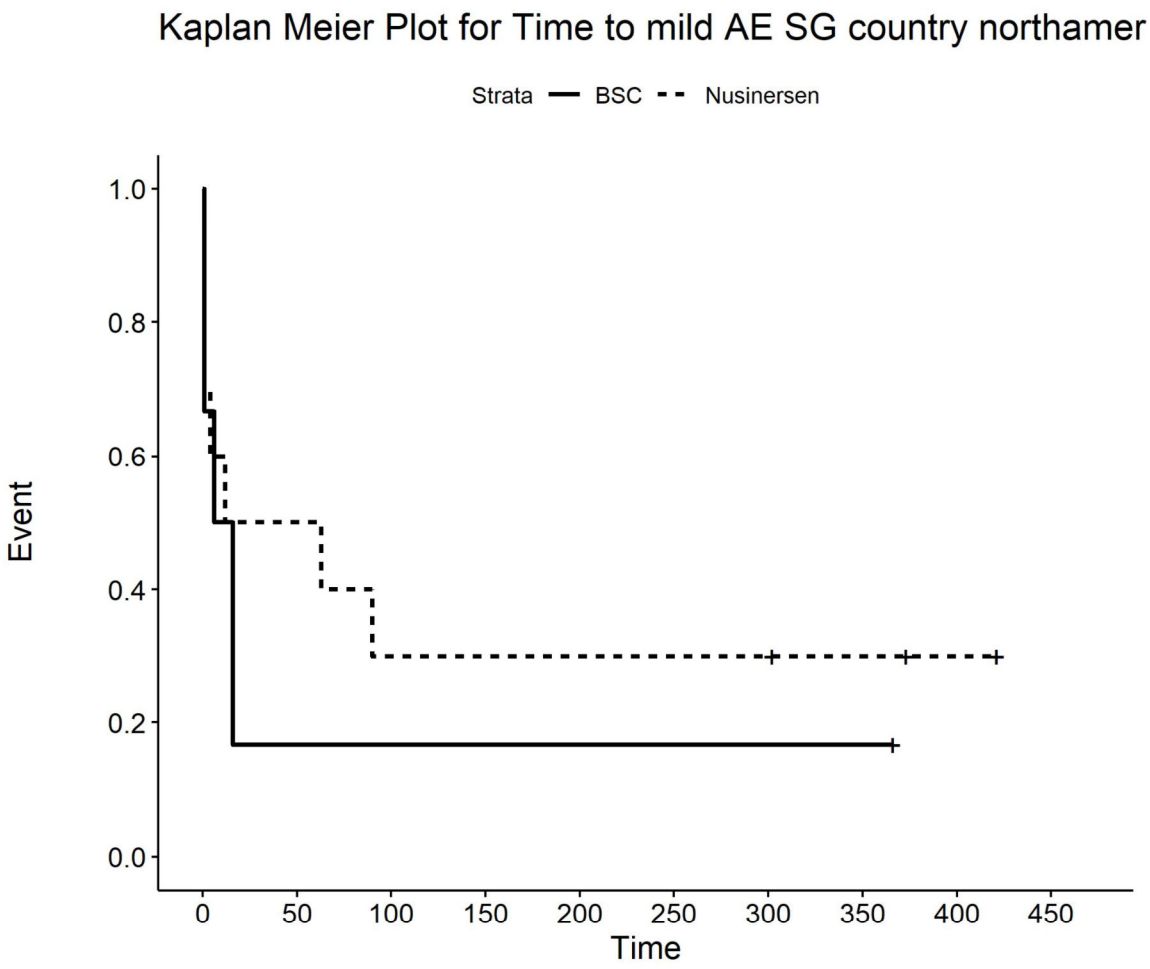
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	1	0	0	0	0	0	0	0	0



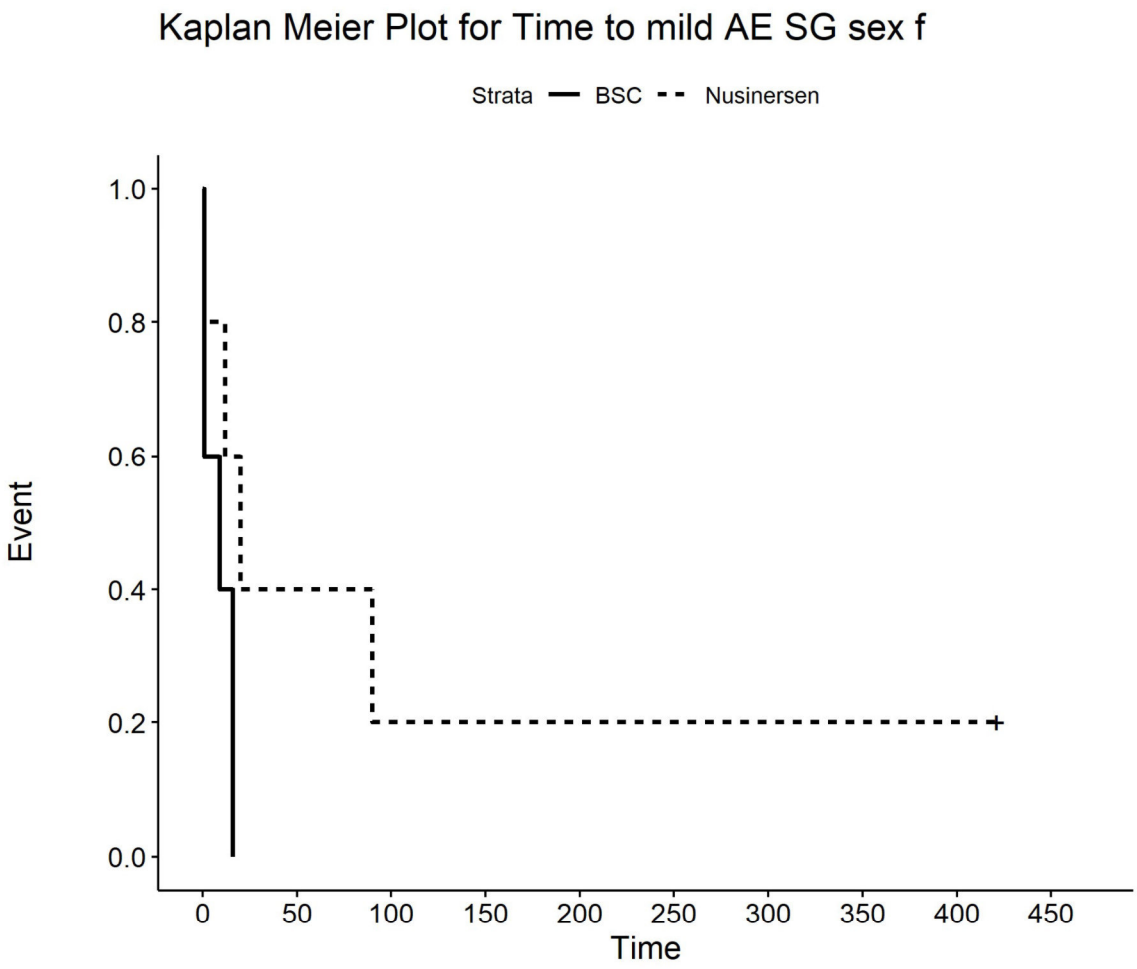
Number at risk

BSC	1	0	0	0	0	0	0	0	0	0
Nusinersen	4	1	0	0	0	0	0	0	0	0



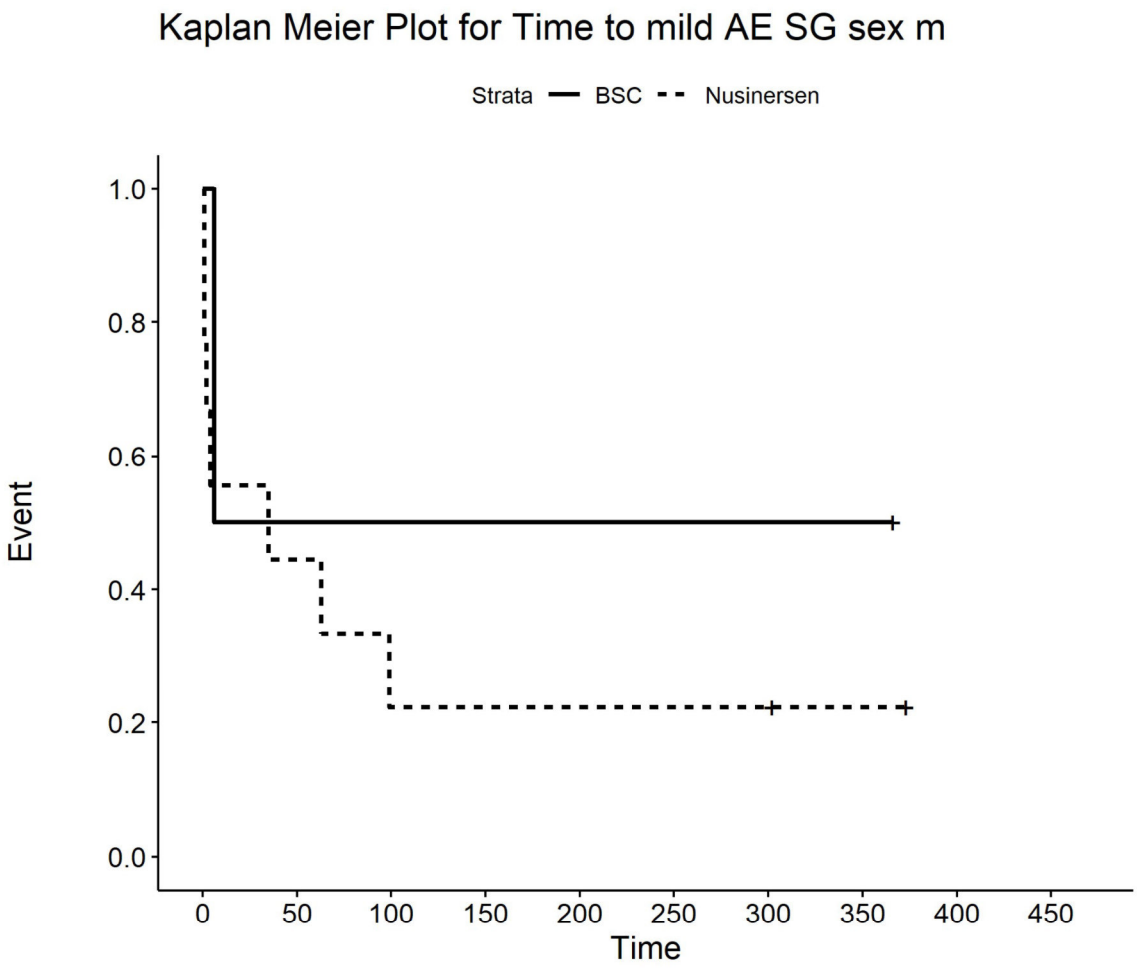
Number at risk

BSC	6	1	1	1	1	1	1	1	0	0
Nusinersen	10	5	3	3	3	3	3	2	1	0



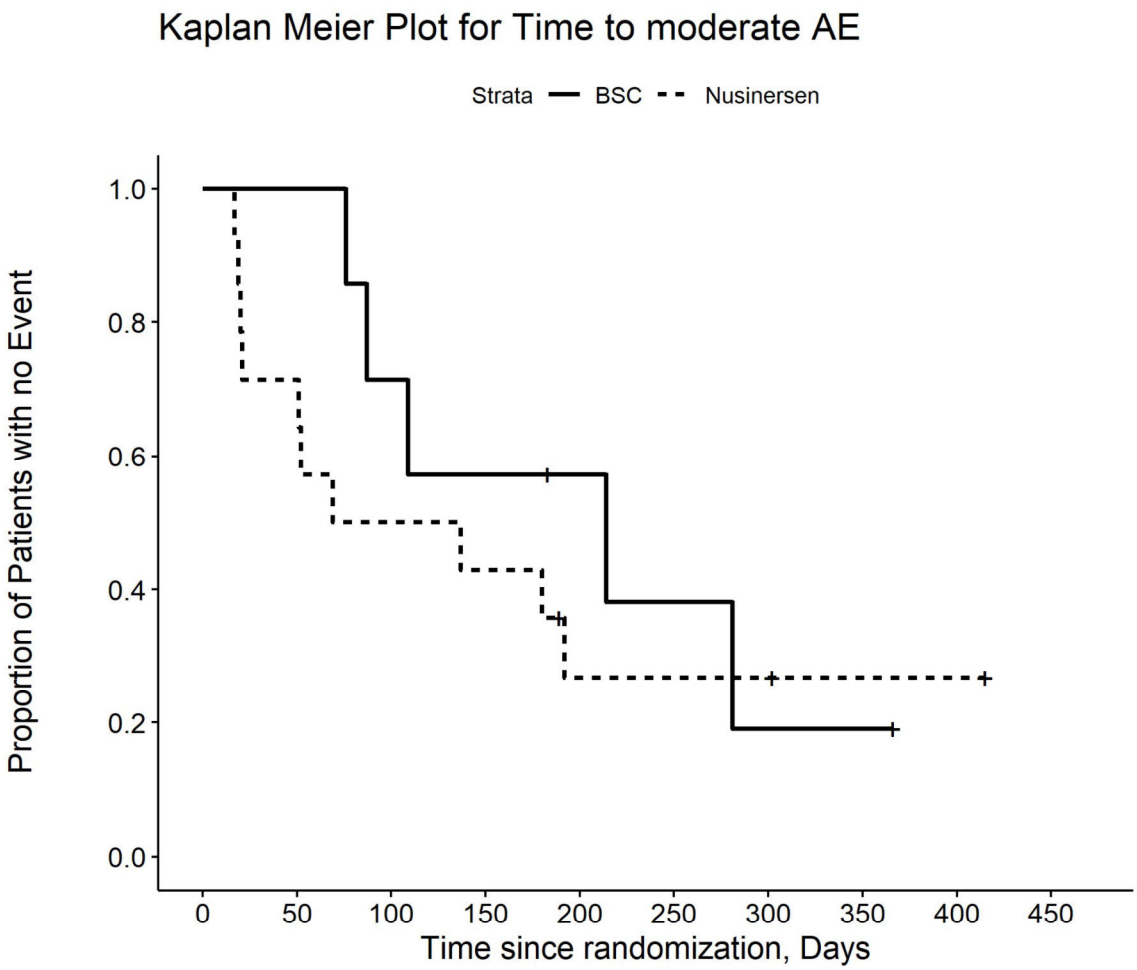
Number at risk

BSC	5	0	0	0	0	0	0	0	0	0
Nusinersen	5	2	1	1	1	1	1	1	1	0



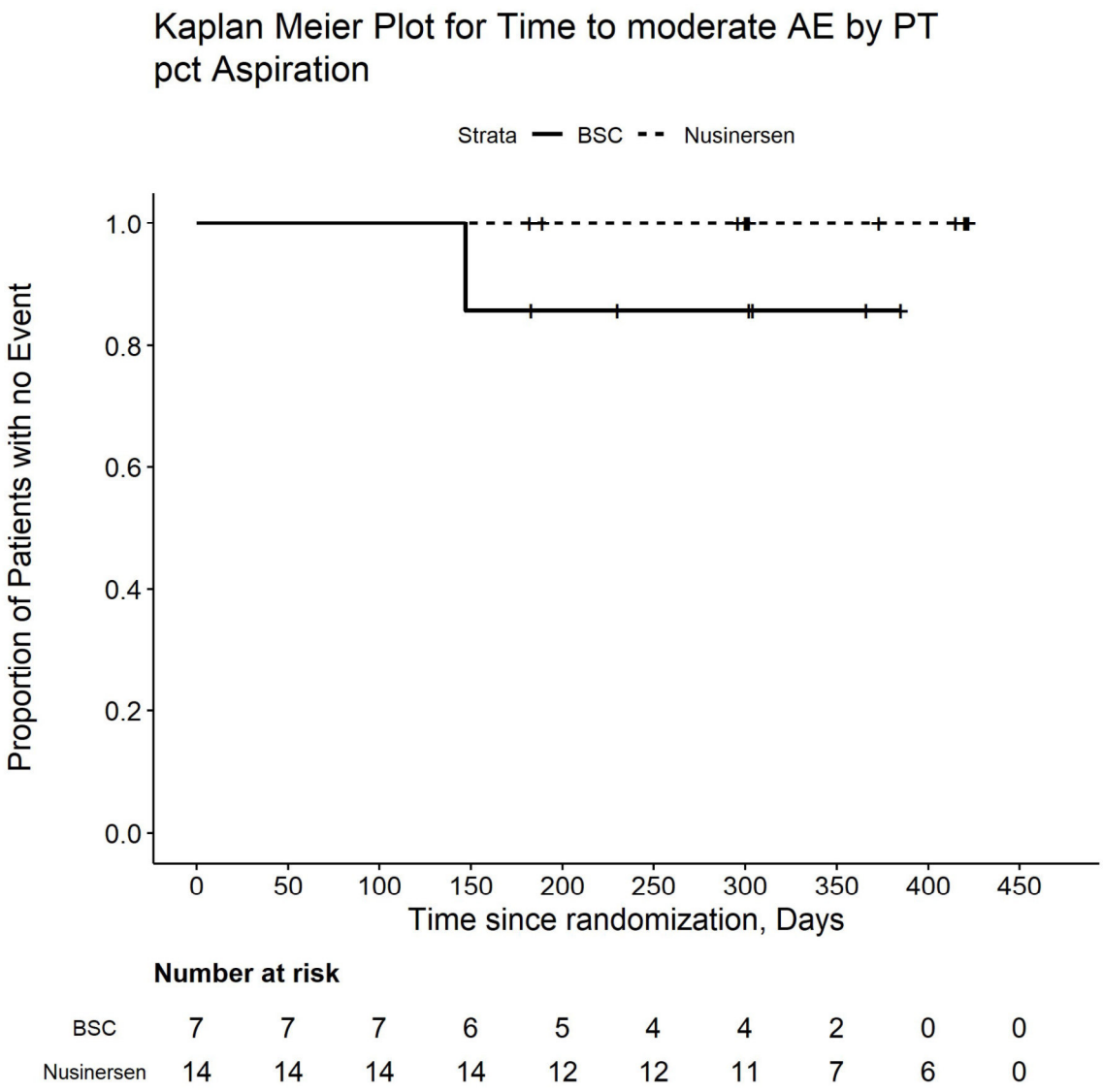
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	4	2	2	2	2	2	1	0	0



Number at risk

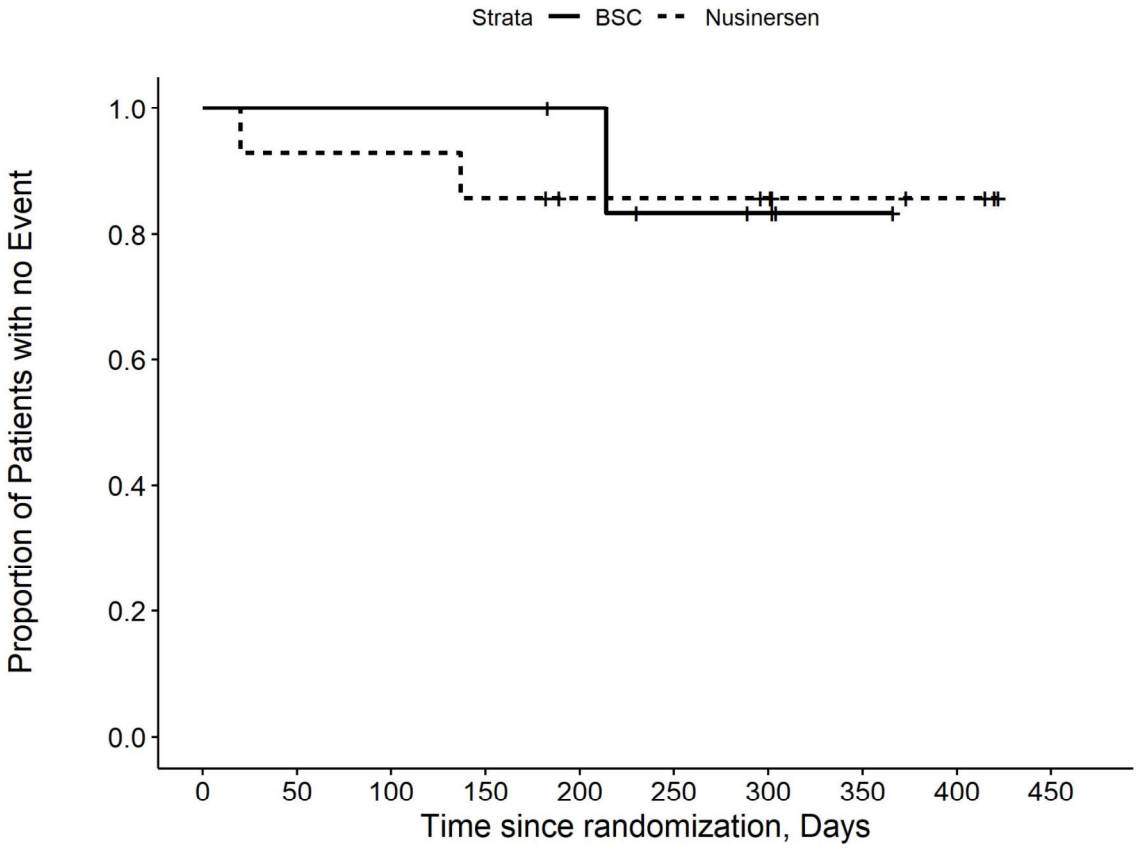
BSC	7	7	5	4	3	2	1	1	0	0
Nusinersen	14	10	7	6	3	3	3	2	2	0



Number at risk

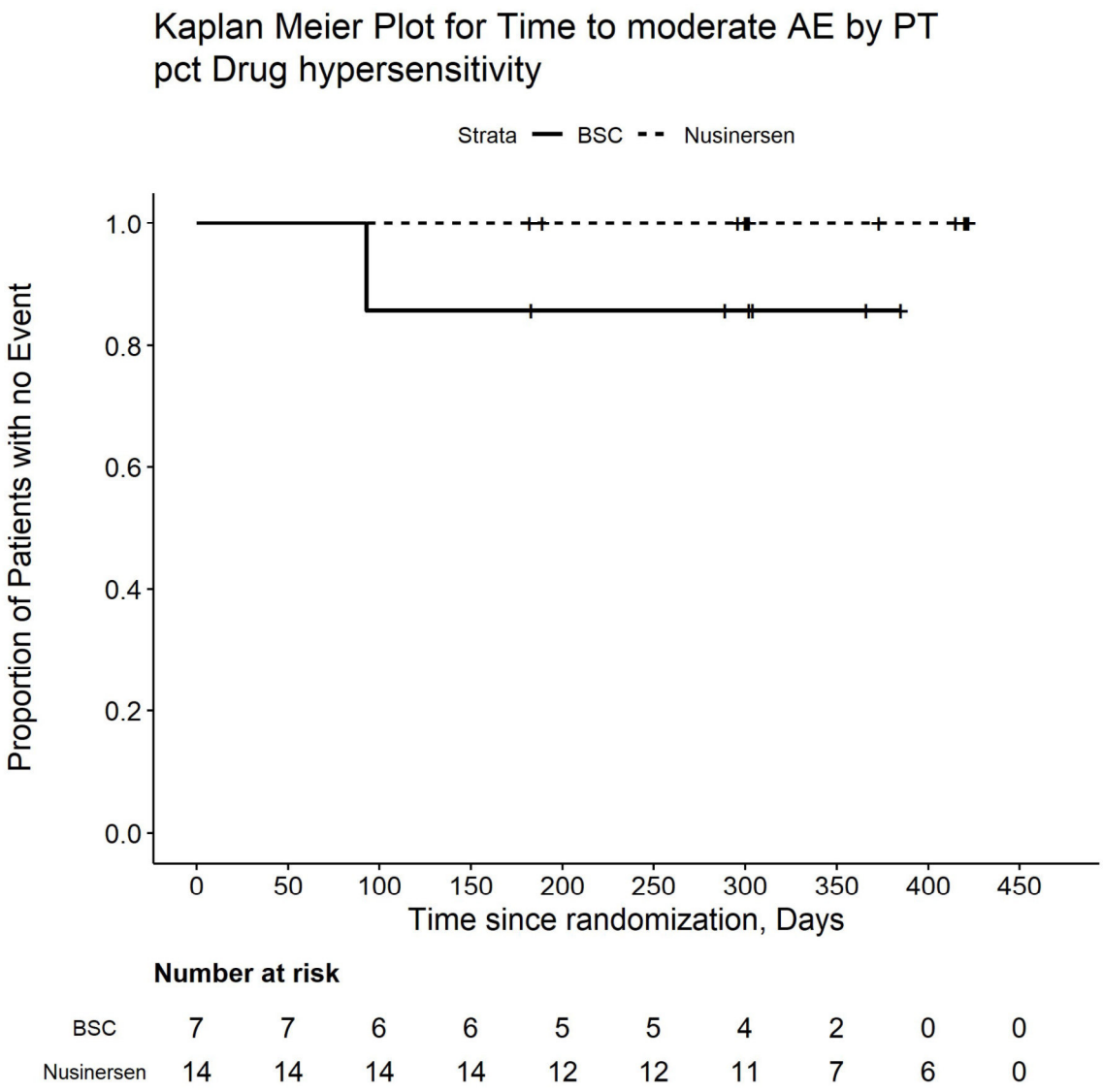
BSC	7	7	7	6	5	4	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

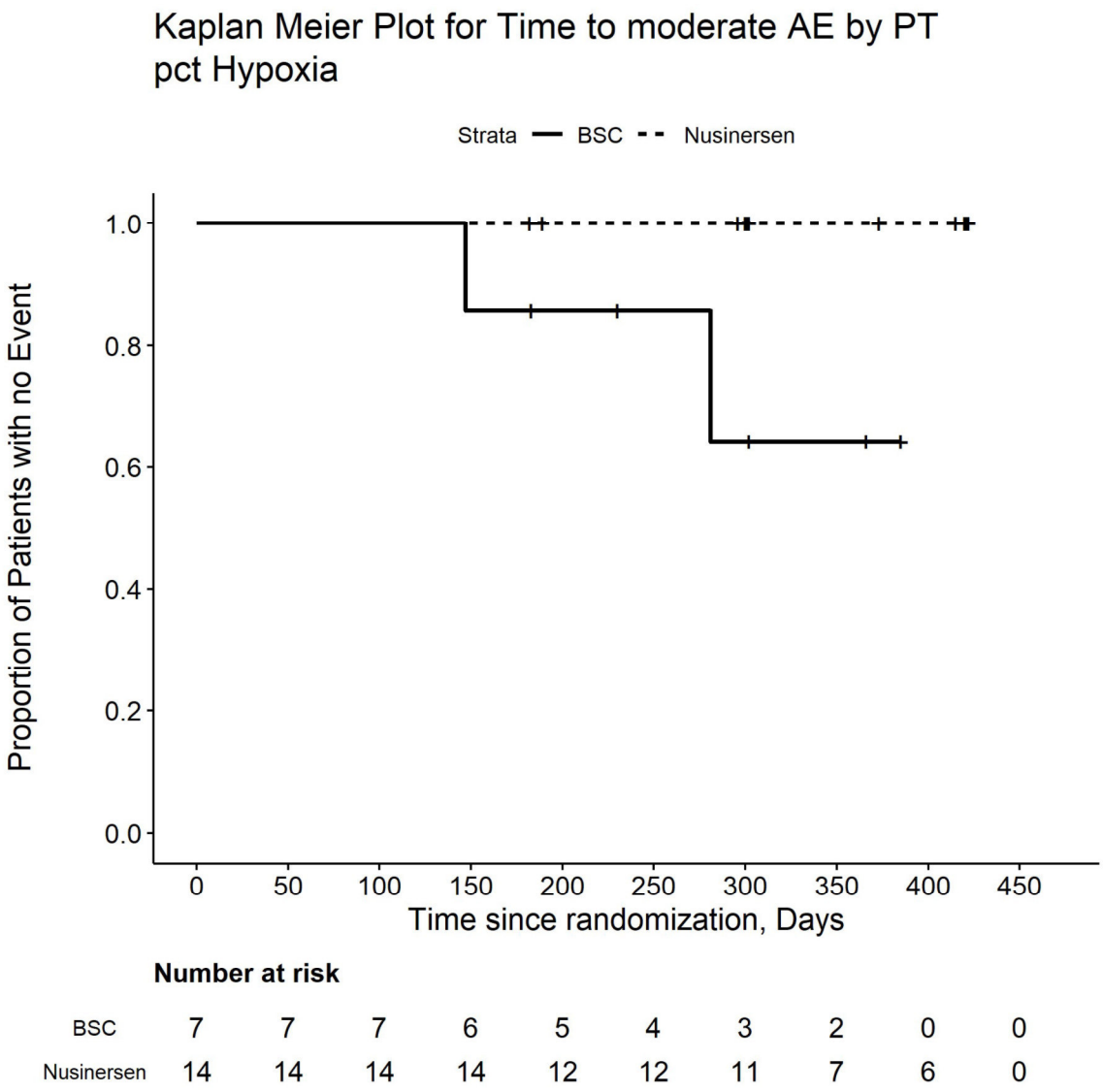
Kaplan Meier Plot for Time to moderate AE by PT
pct Bronchitis



Number at risk

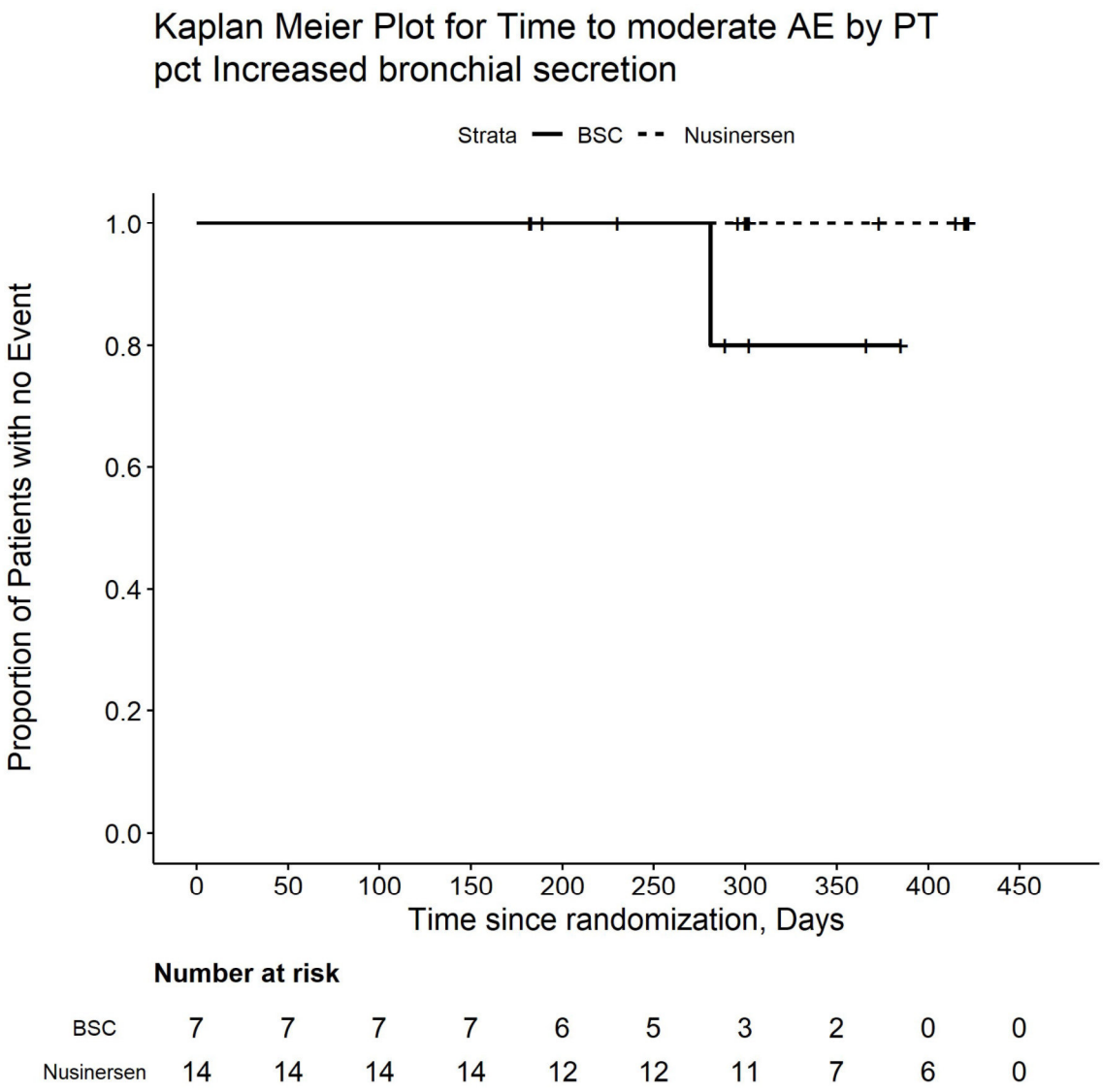
BSC	7	7	7	7	6	4	3	1	0	0
Nusinersen	14	13	13	12	10	10	9	6	5	0


Kaplan Meier Plot for Time to moderate AE by PT
pct Drug hypersensitivity
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0 50 100 150 200 250 300 350 400 450
Time since randomization, Days
Number at risk
BSC 7 7 6 6 5 5 4 2 0 0
Nusinersen 14 14 14 14 12 12 11 7 6 0



Number at risk

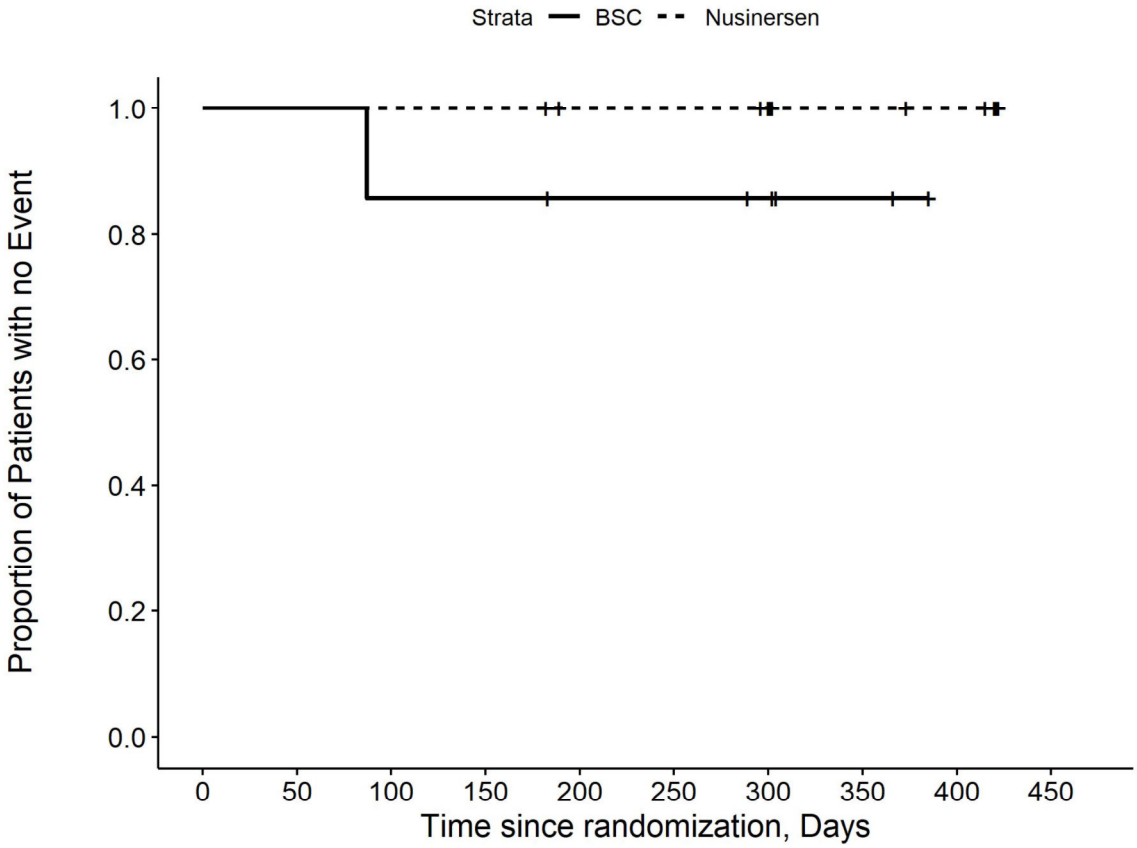
BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

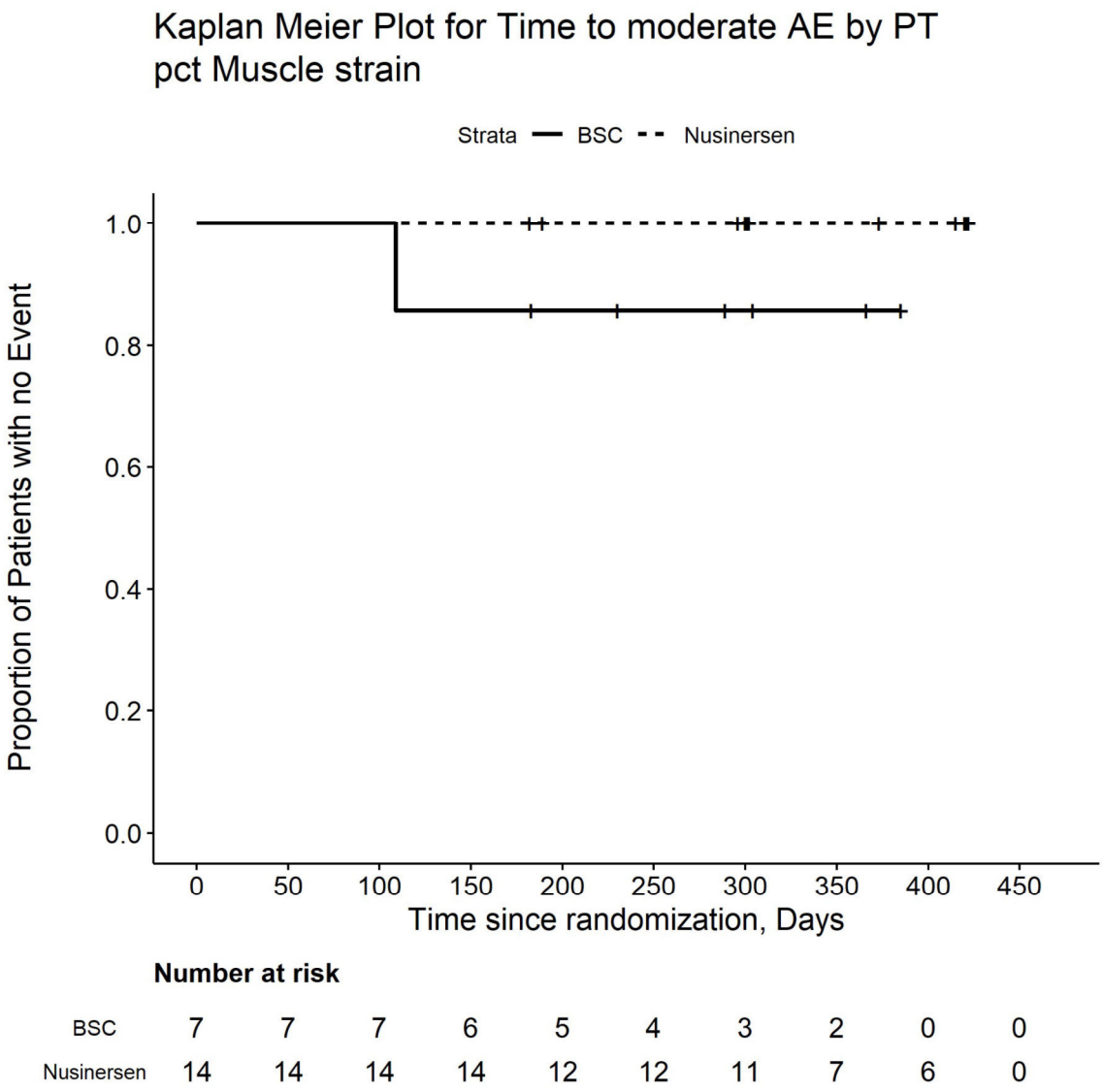
BSC	7	7	7	7	6	5	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for Time to moderate AE by PT
pct Larynx irritation



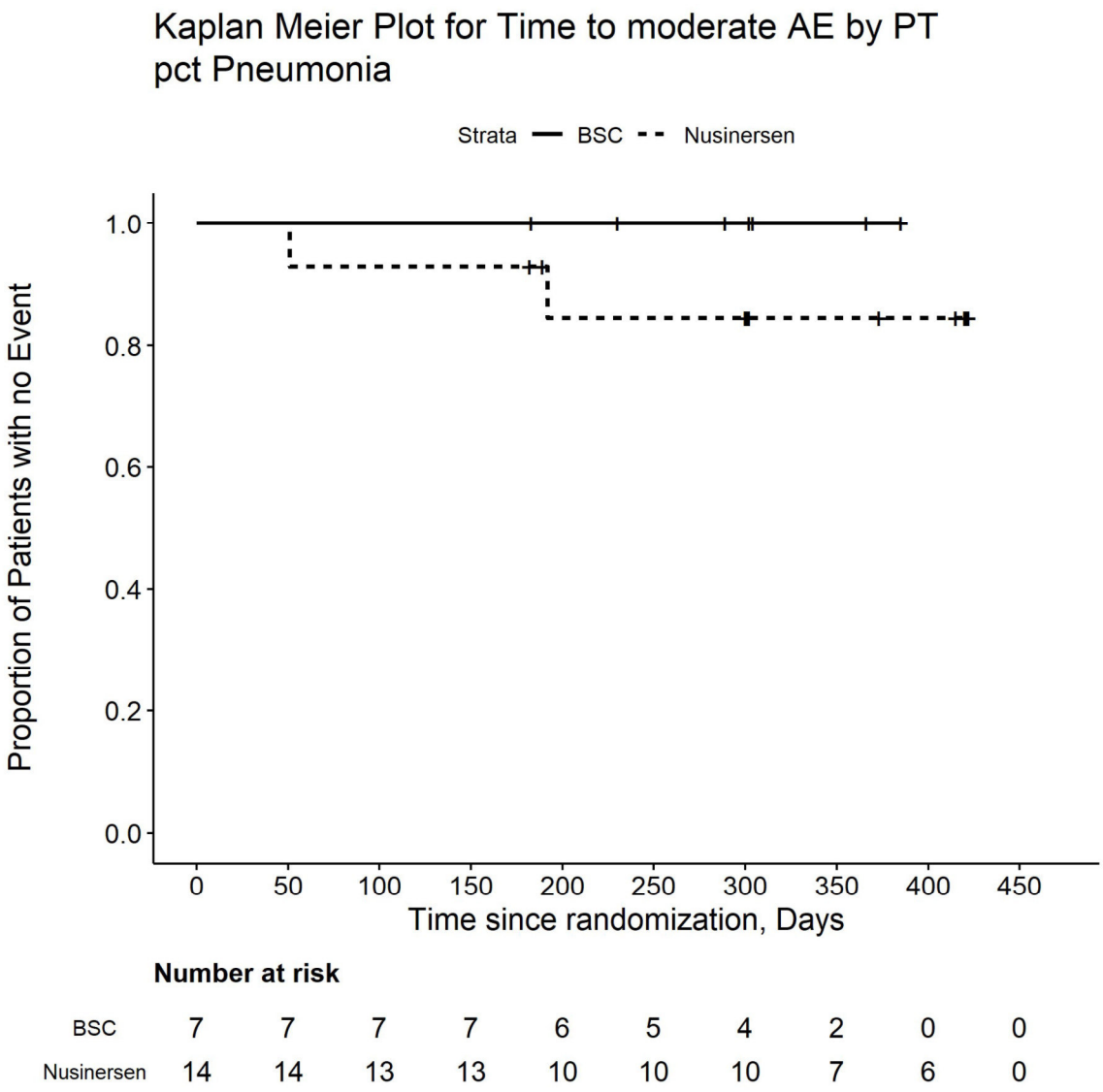
Number at risk

BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



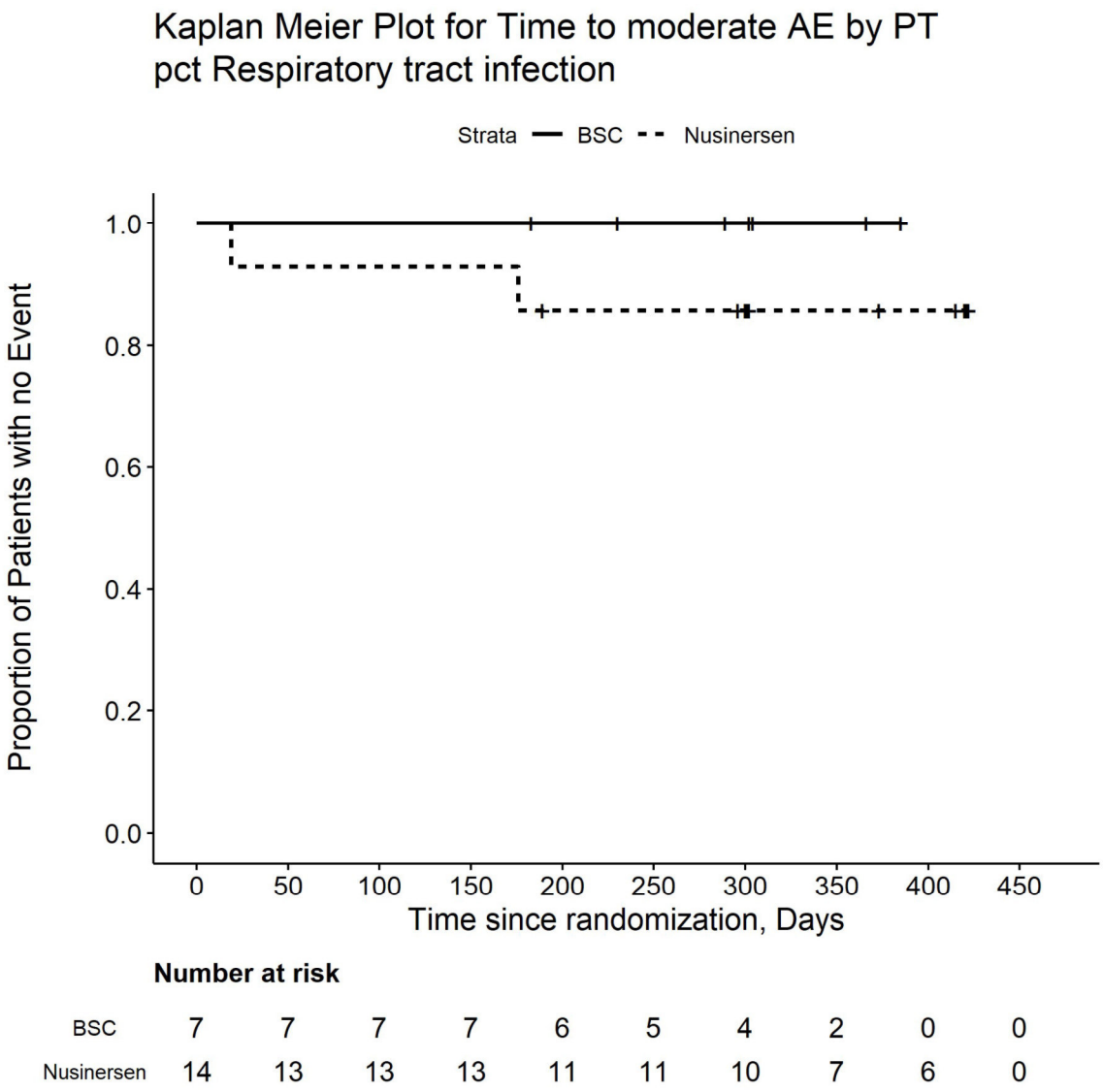
Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



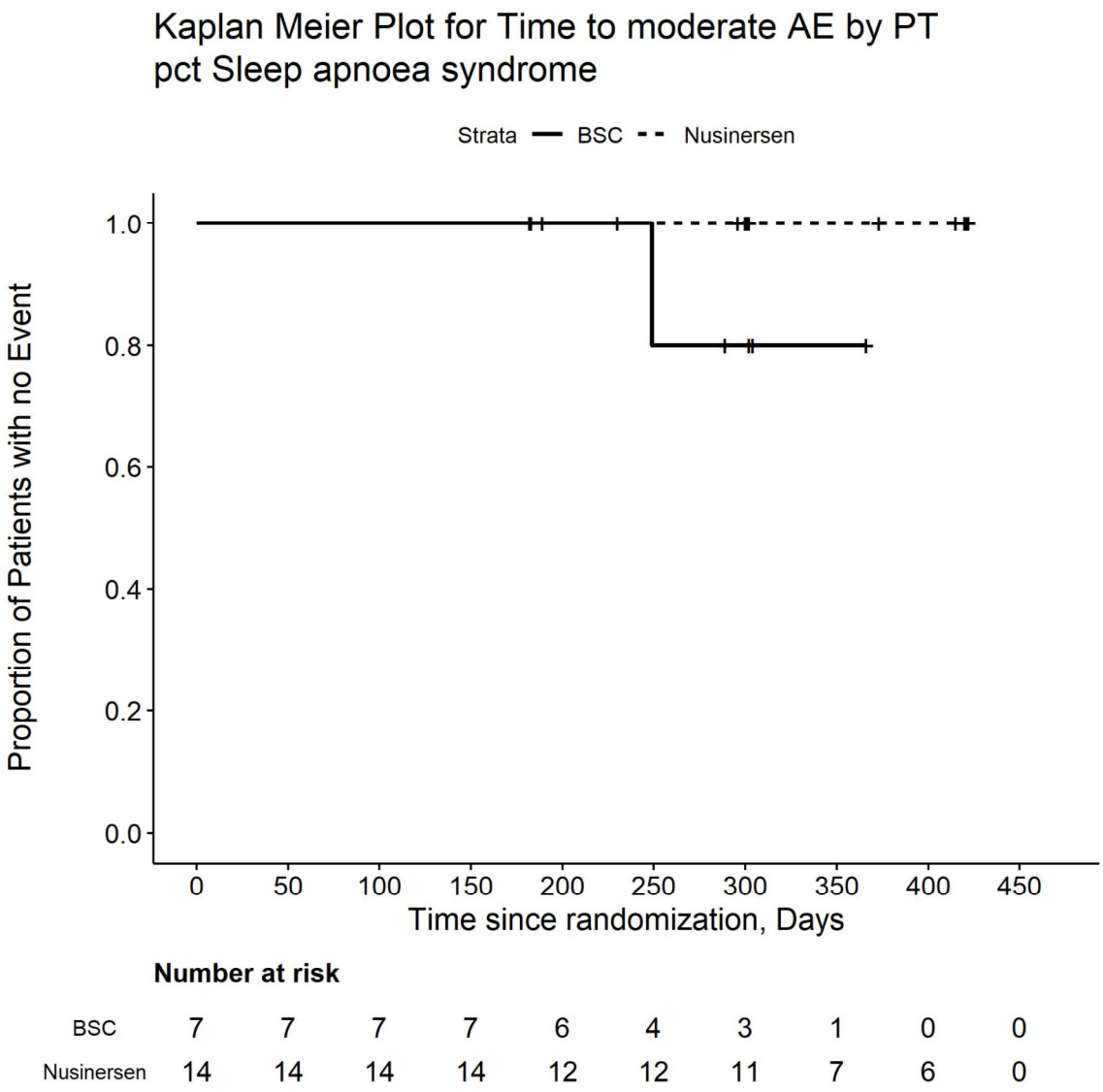
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	13	13	10	10	10	7	6	0



Number at risk

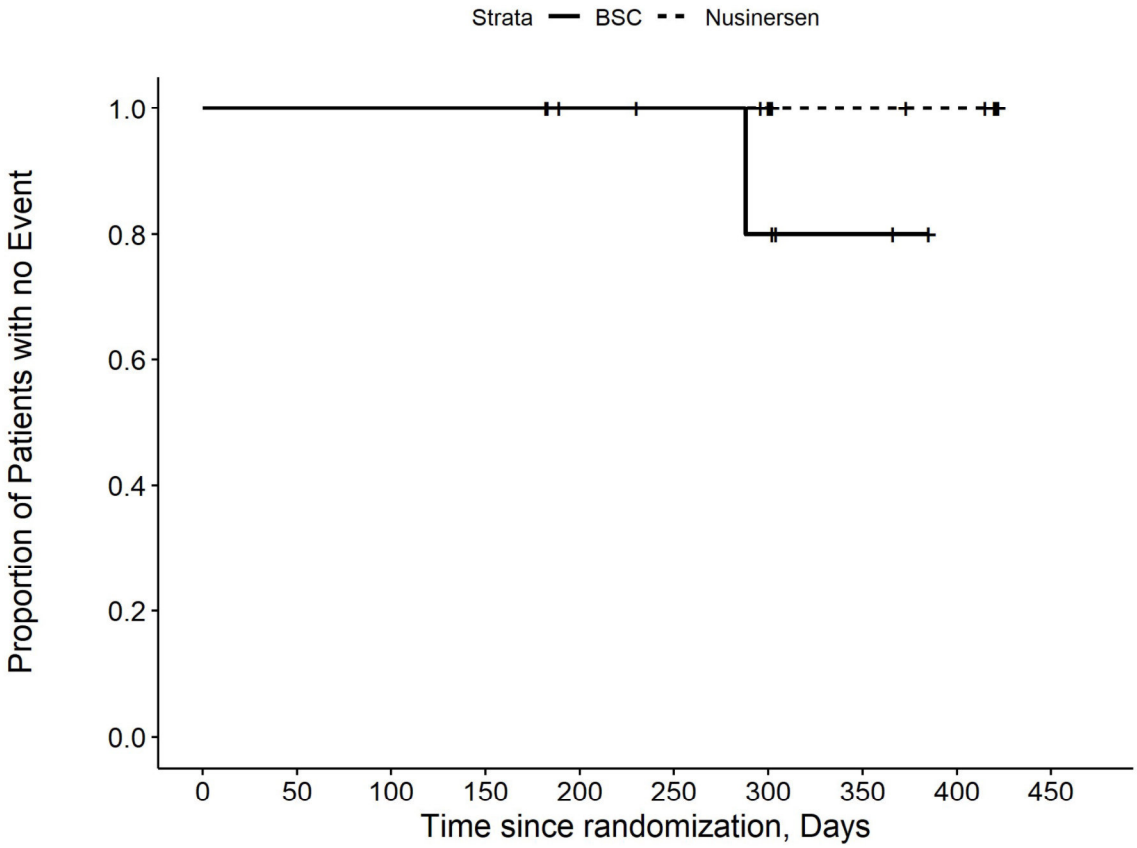
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	13	13	11	11	10	7	6	0



Number at risk

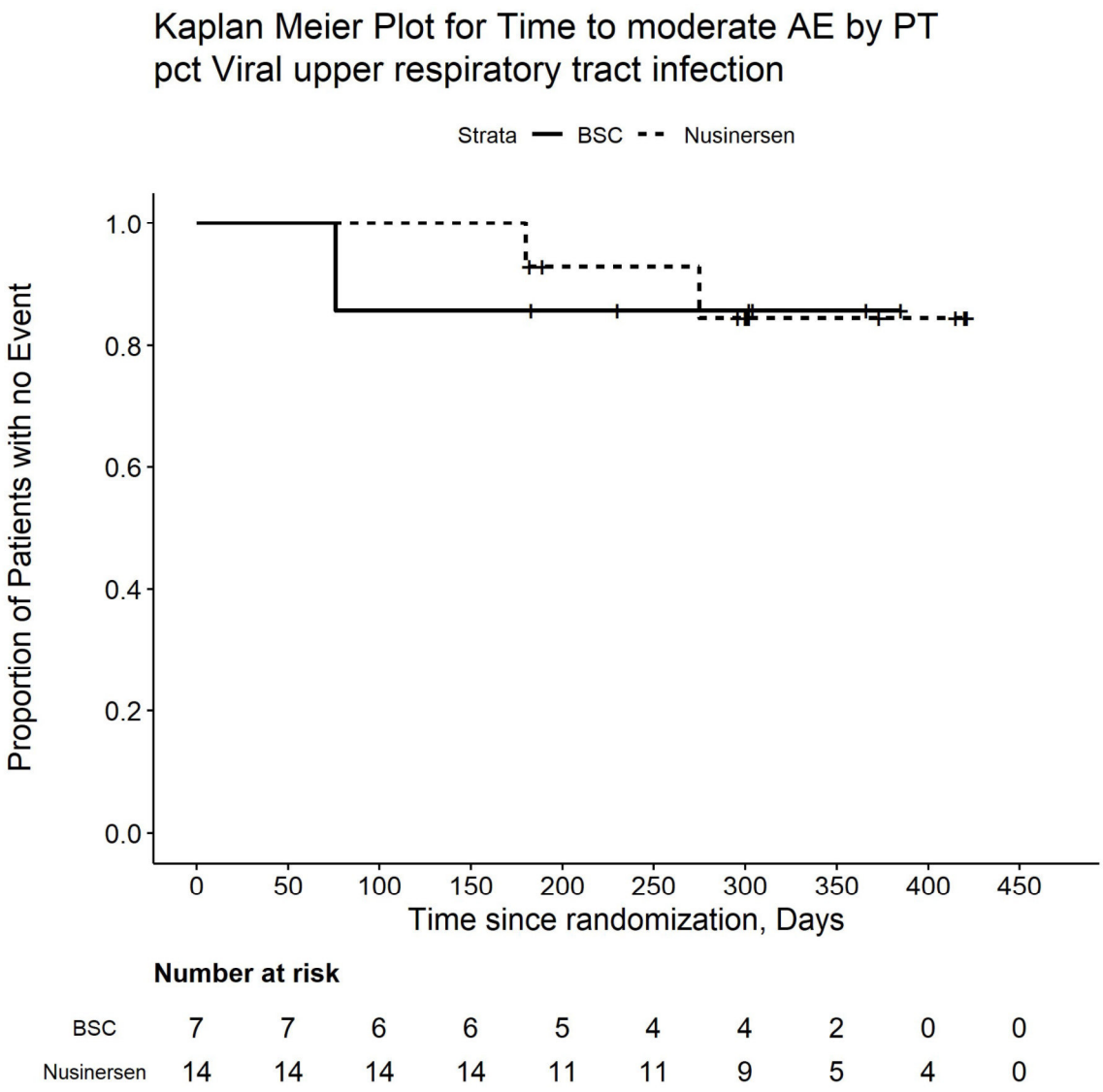
BSC	7	7	7	7	6	4	3	1	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for Time to moderate AE by PT
pct Urine output increased



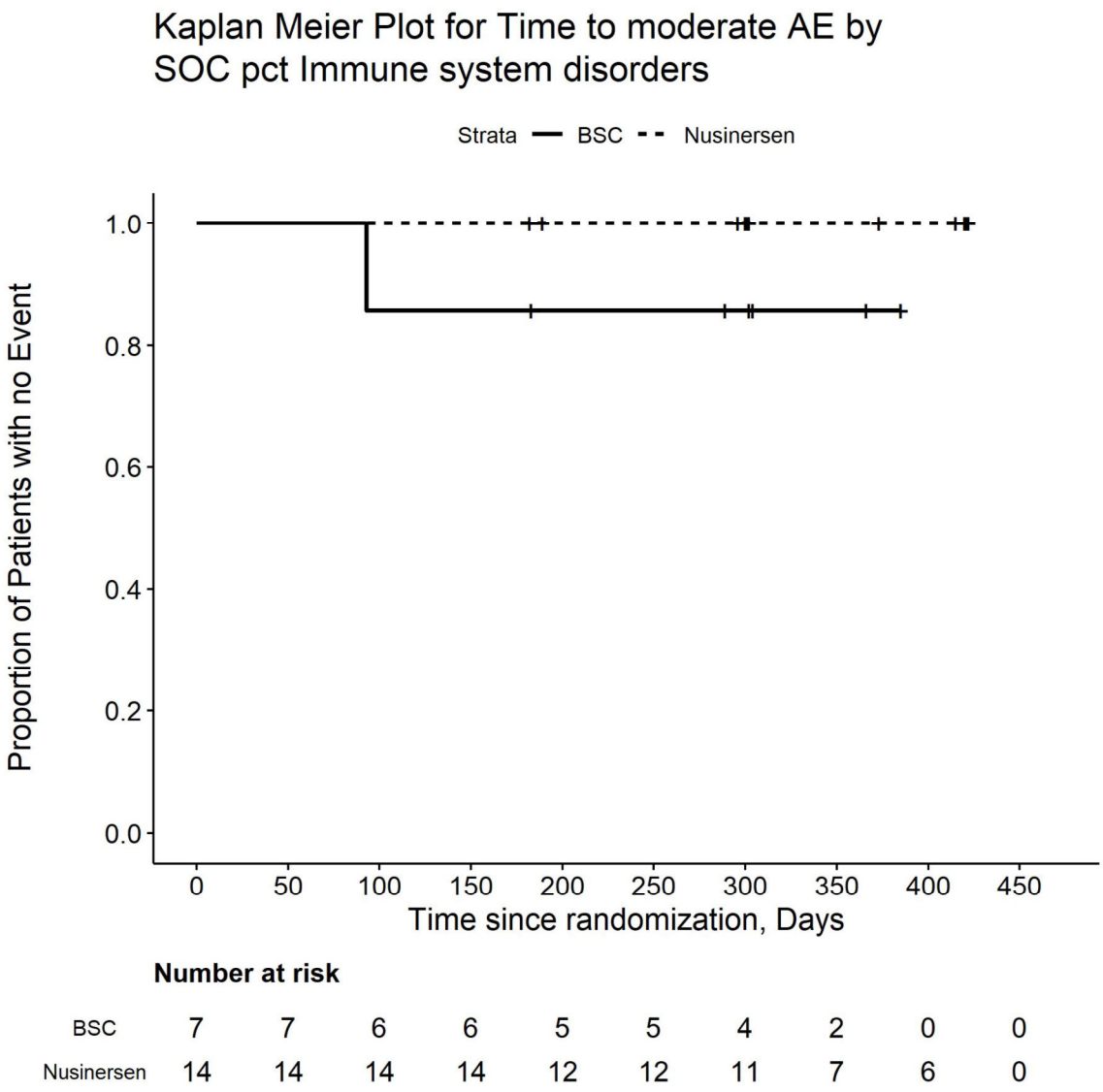
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



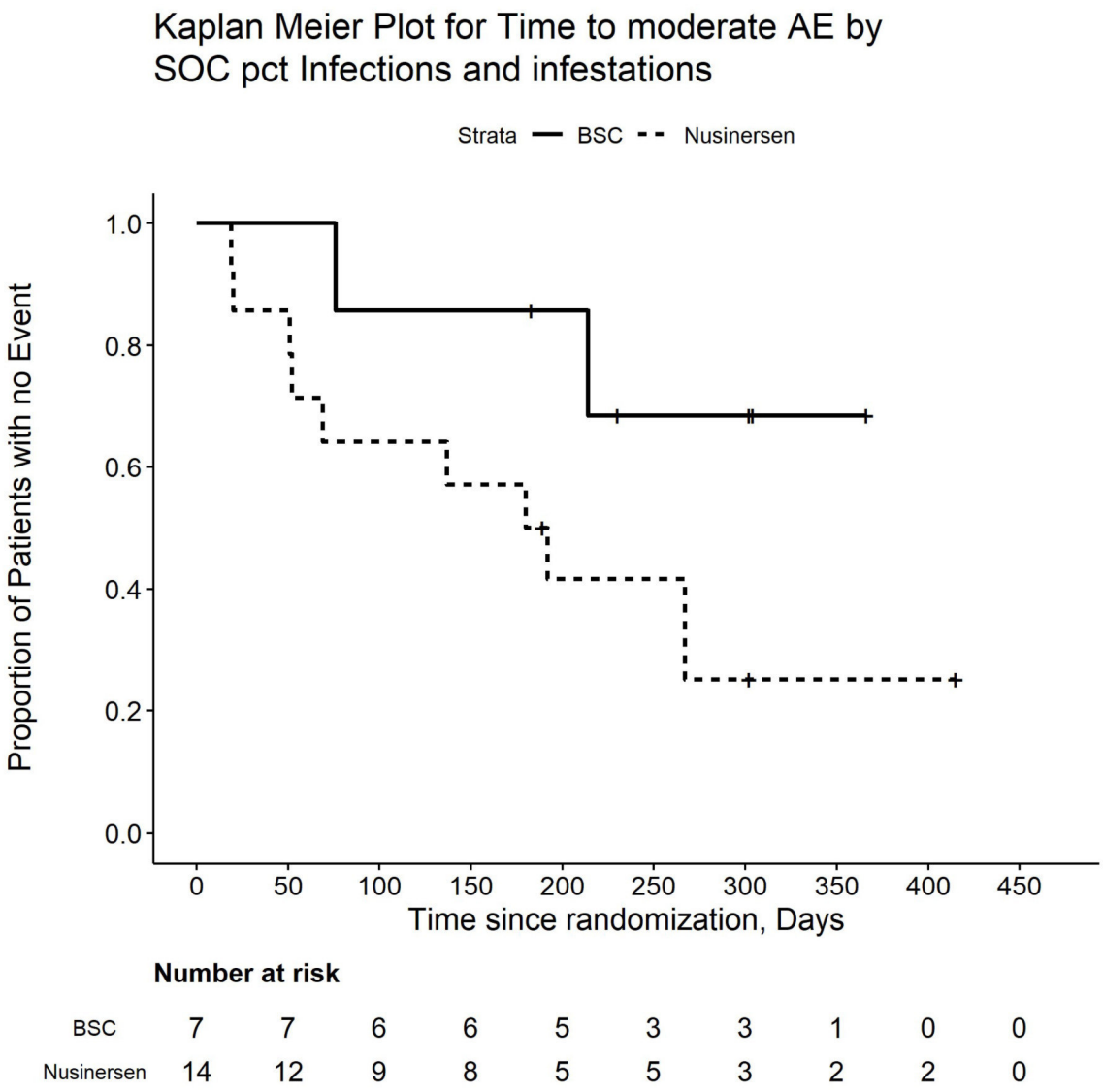
Number at risk

BSC	7	7	6	6	5	4	4	2	0	0
Nusinersen	14	14	14	14	11	11	9	5	4	0



Number at risk

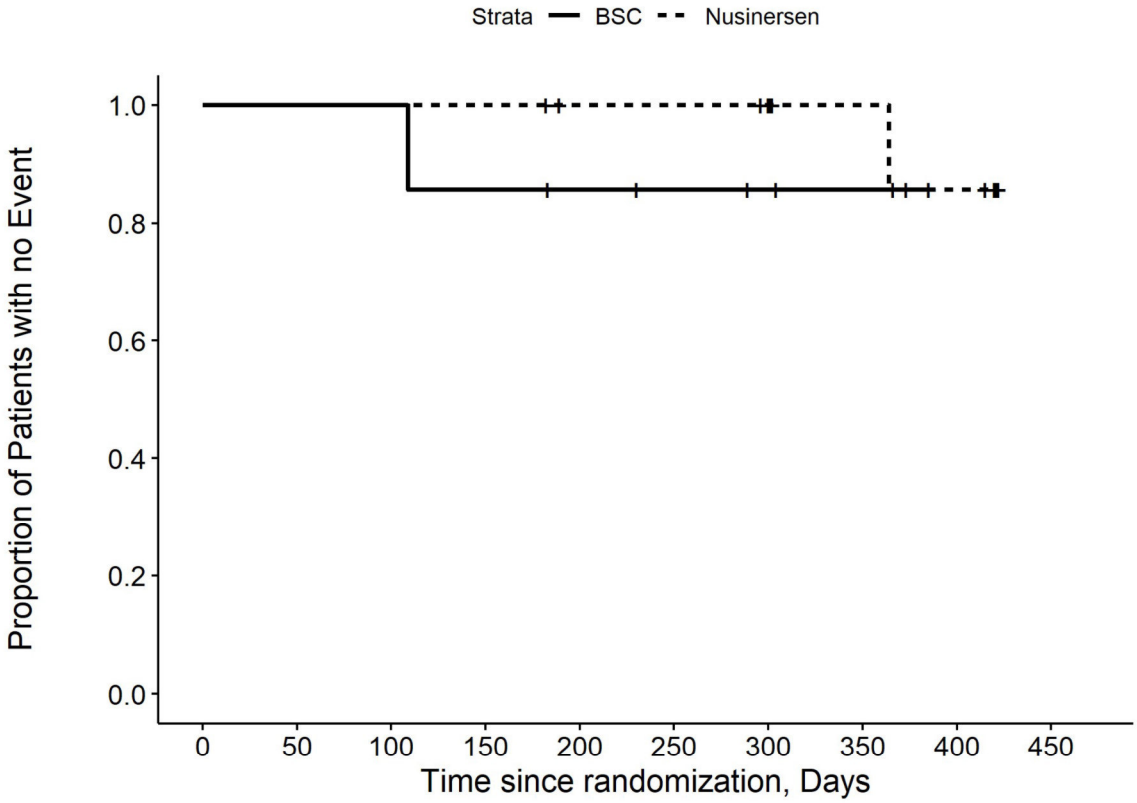
BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

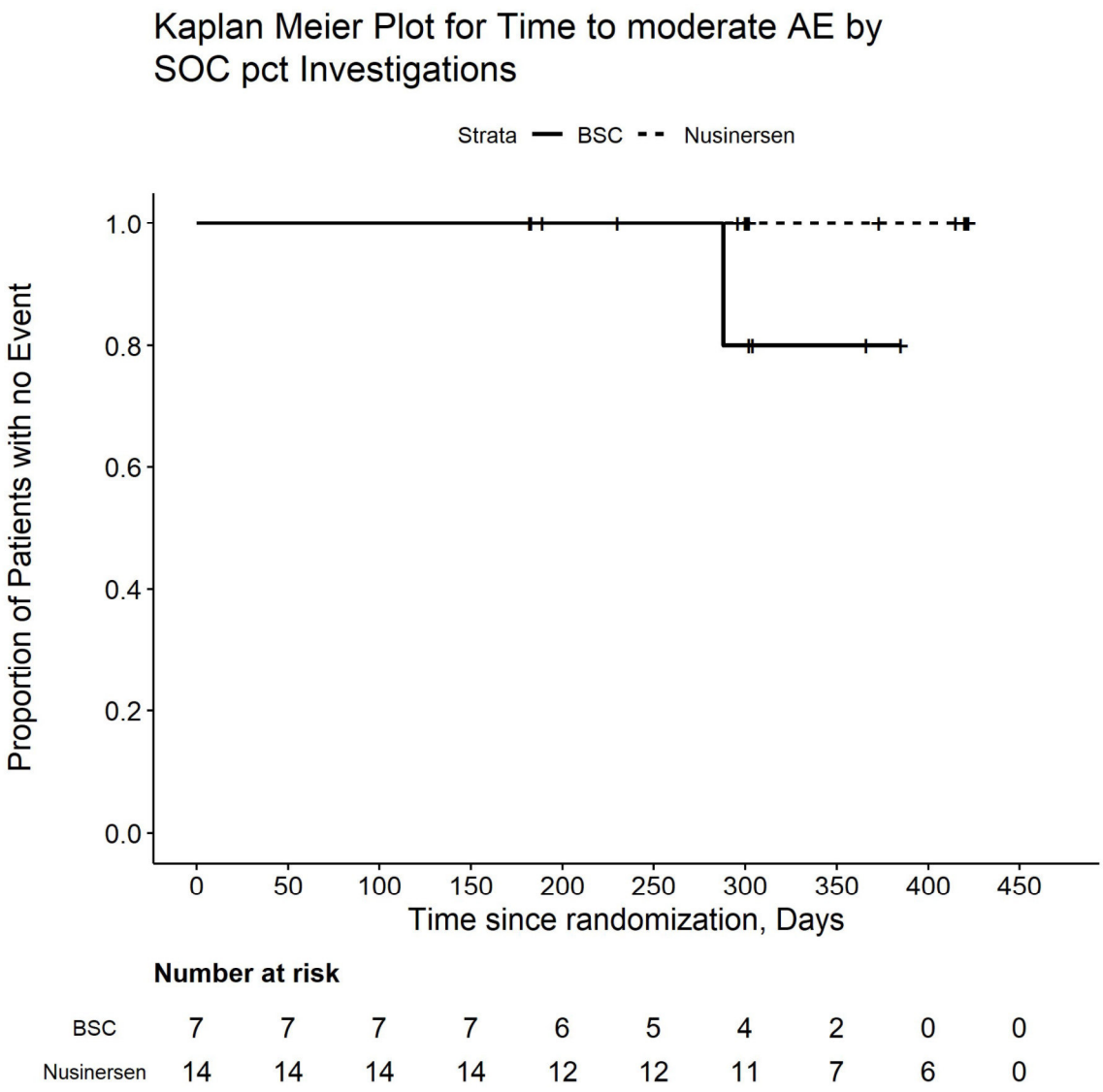
BSC	7	7	6	6	5	3	3	1	0	0
Nusinersen	14	12	9	8	5	5	3	2	2	0

Kaplan Meier Plot for Time to moderate AE by SOC pct Injury, poisoning and procedural complications



Number at risk

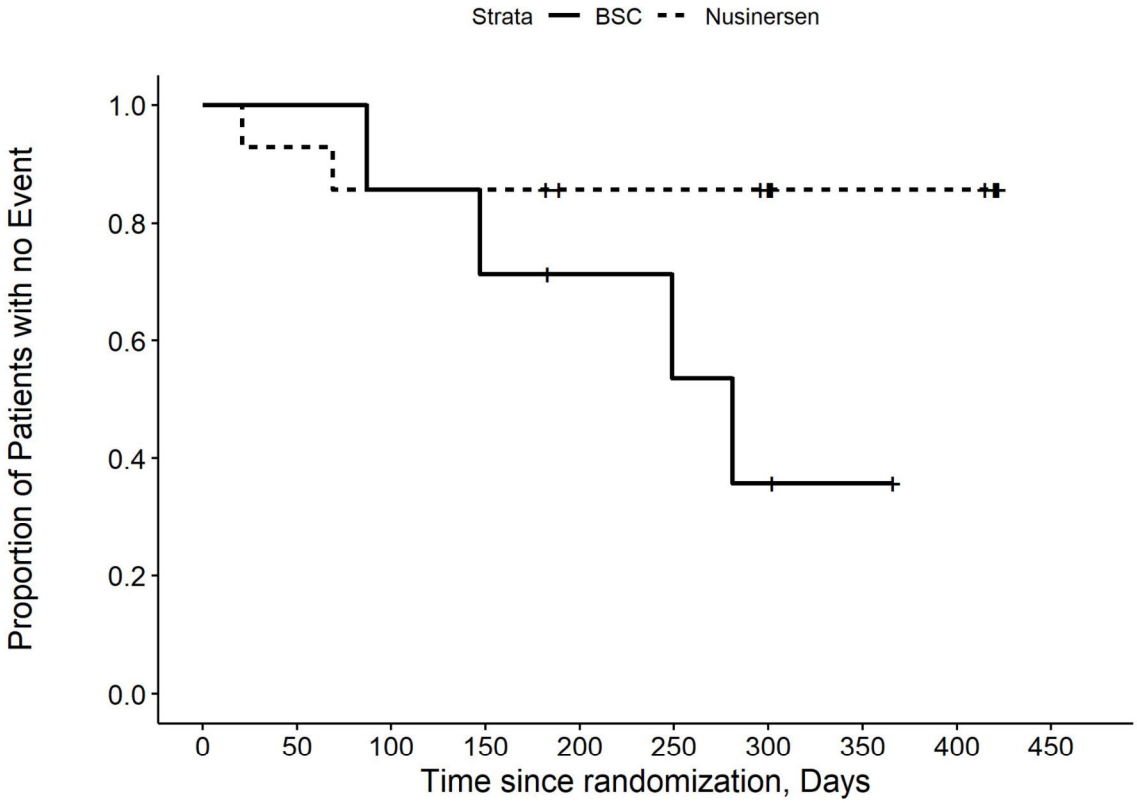
BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	5	0



Number at risk

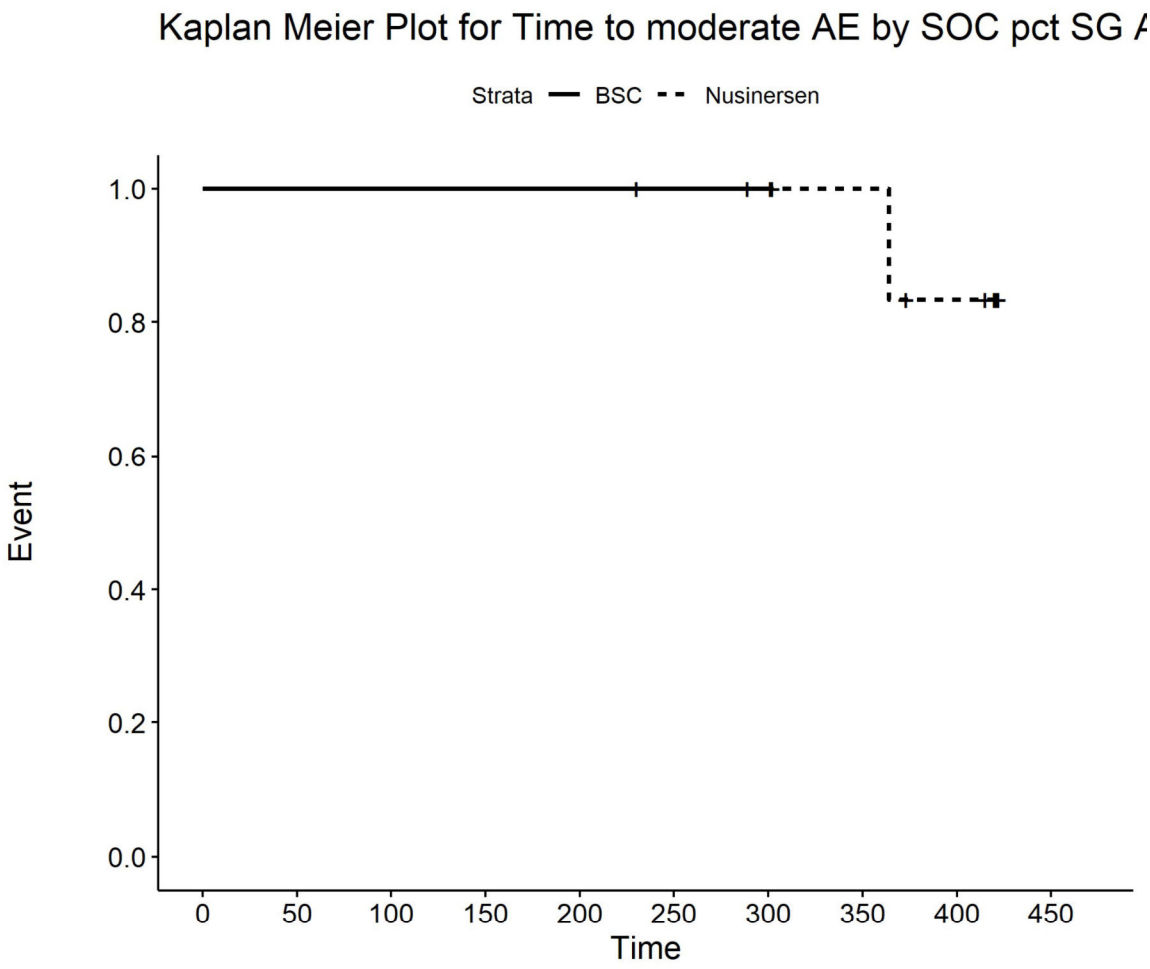
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for Time to moderate AE by SOC pct Respiratory, thoracic and mediastinal disorders



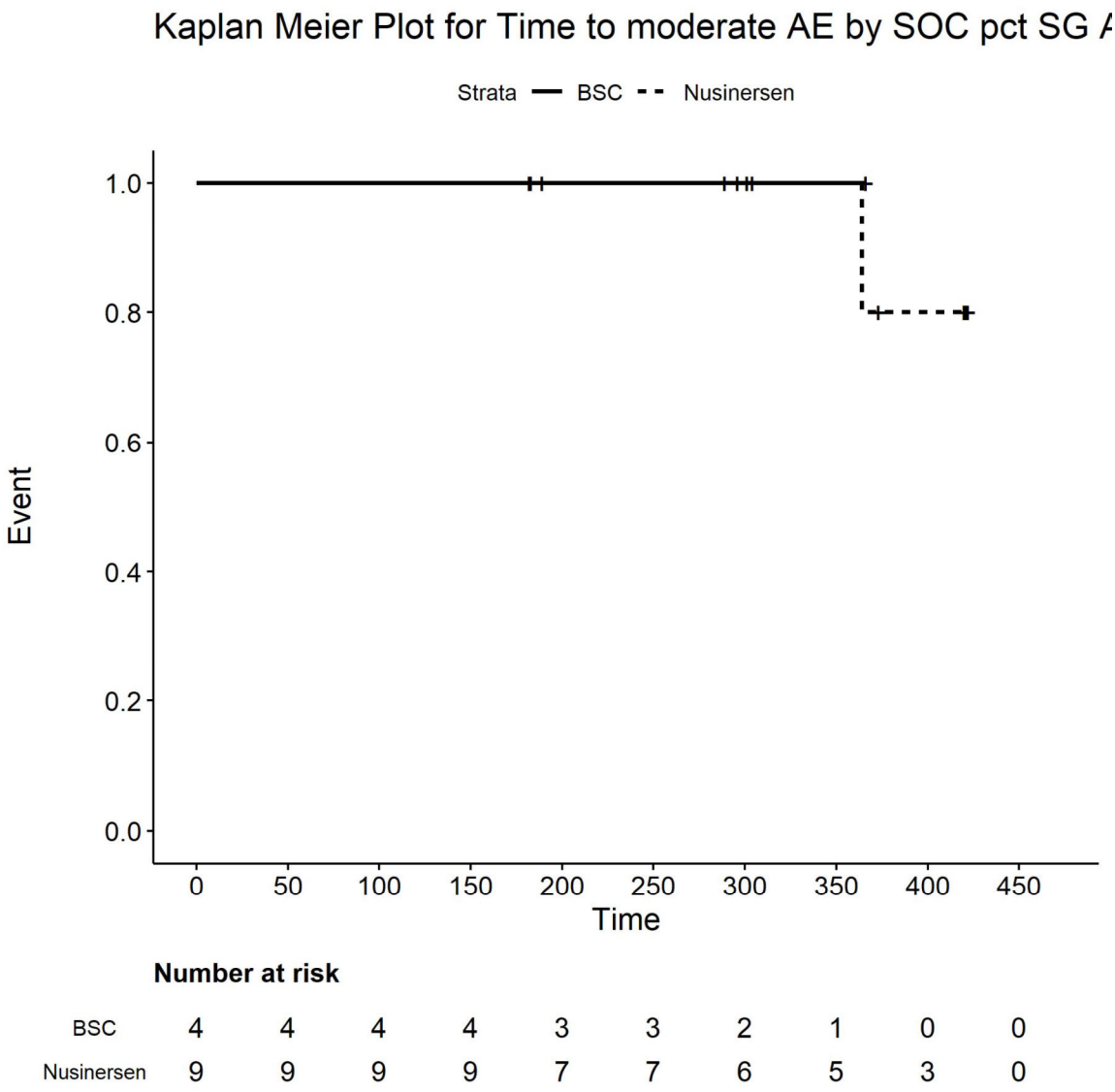
Number at risk

BSC	7	7	6	5	4	3	2	1	0	0
Nusinersen	14	13	12	12	10	10	9	5	5	0



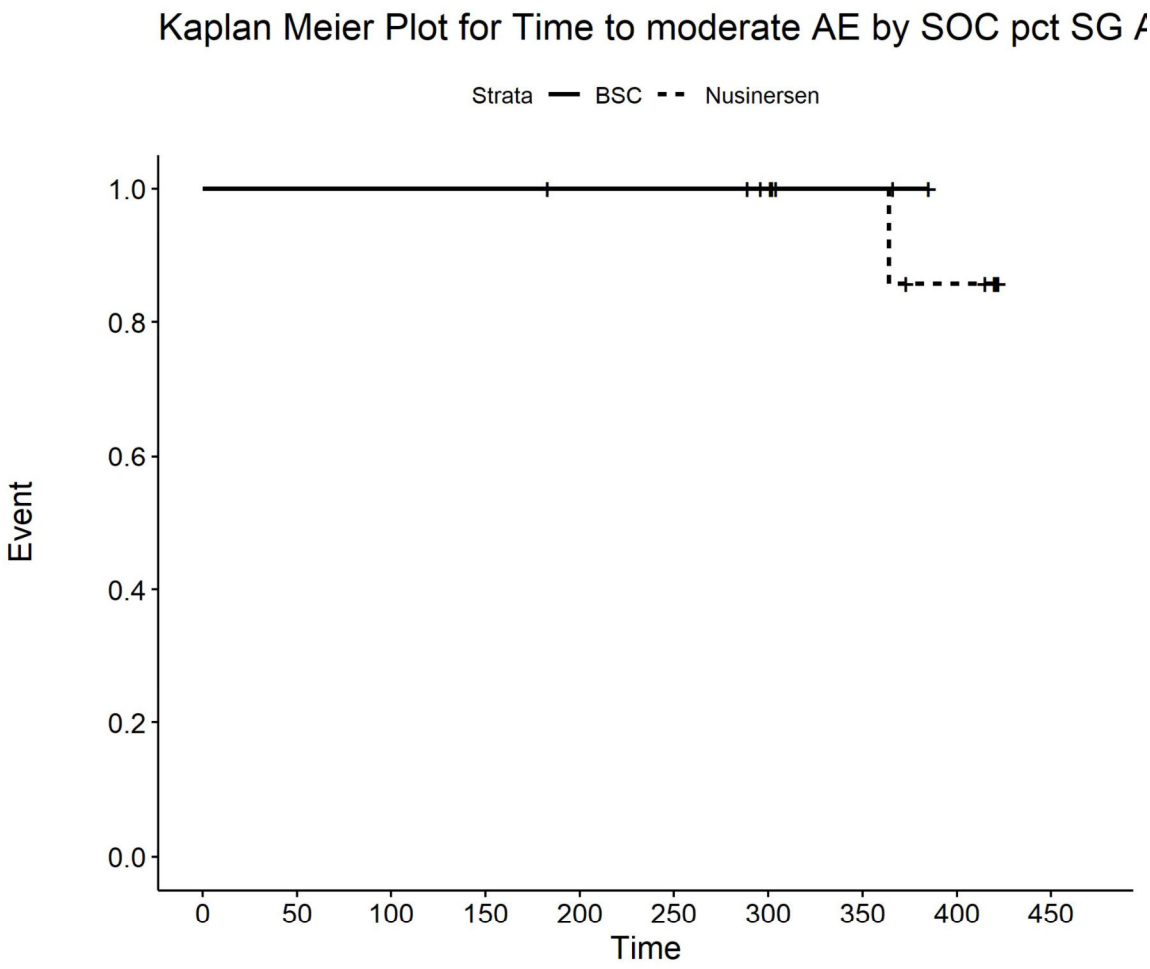
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	4	0



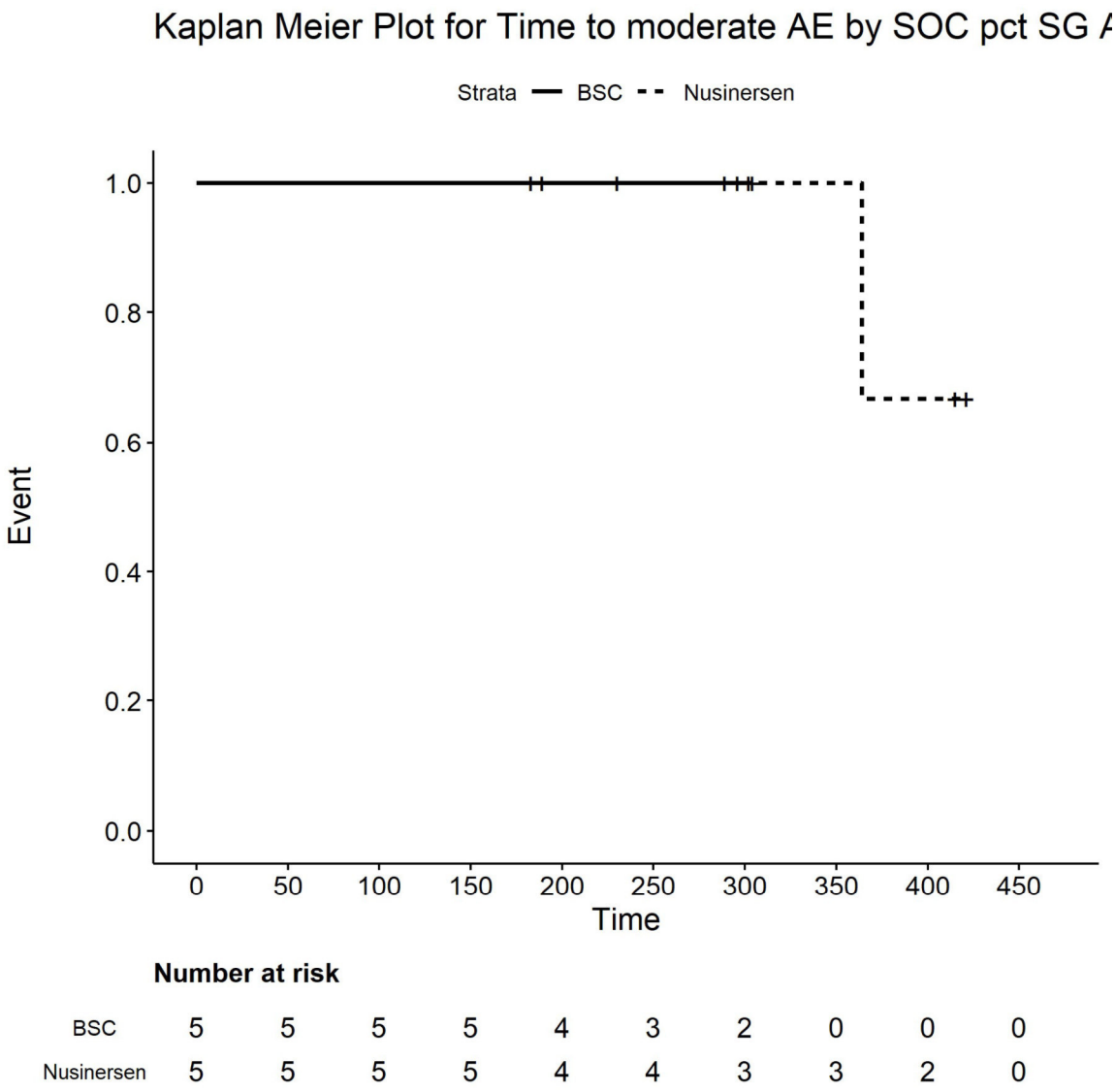
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	3	0



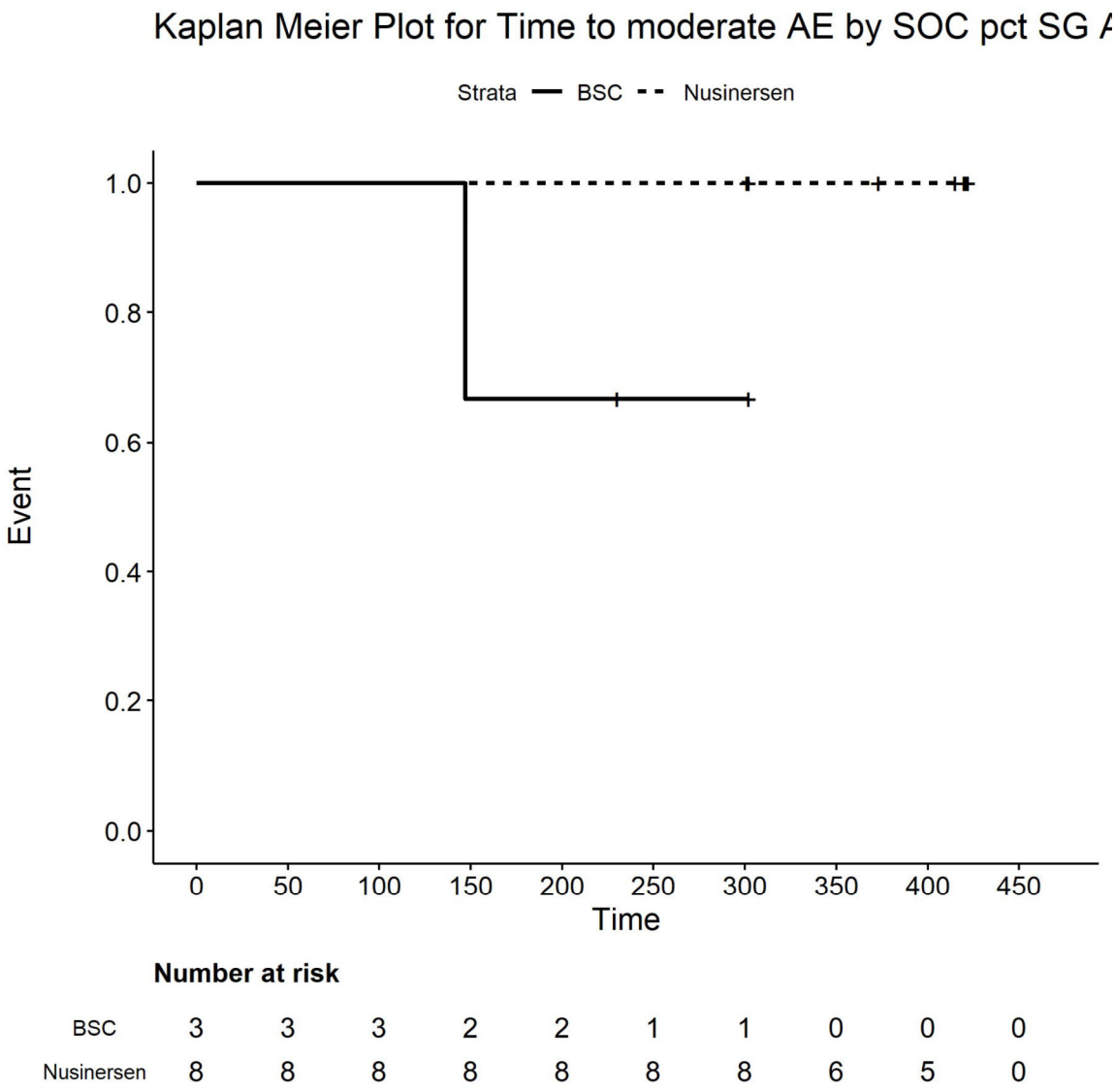
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	5	0



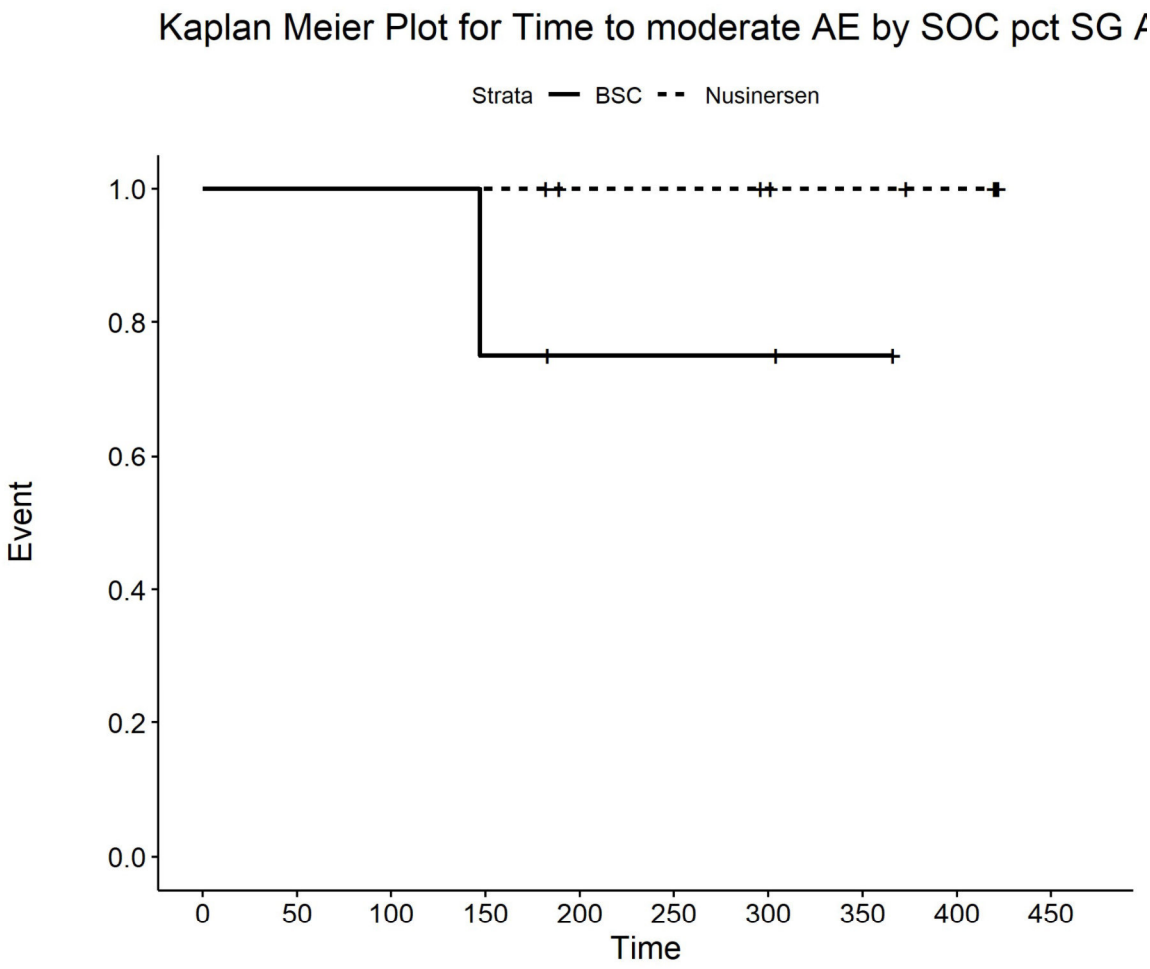
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	2	0



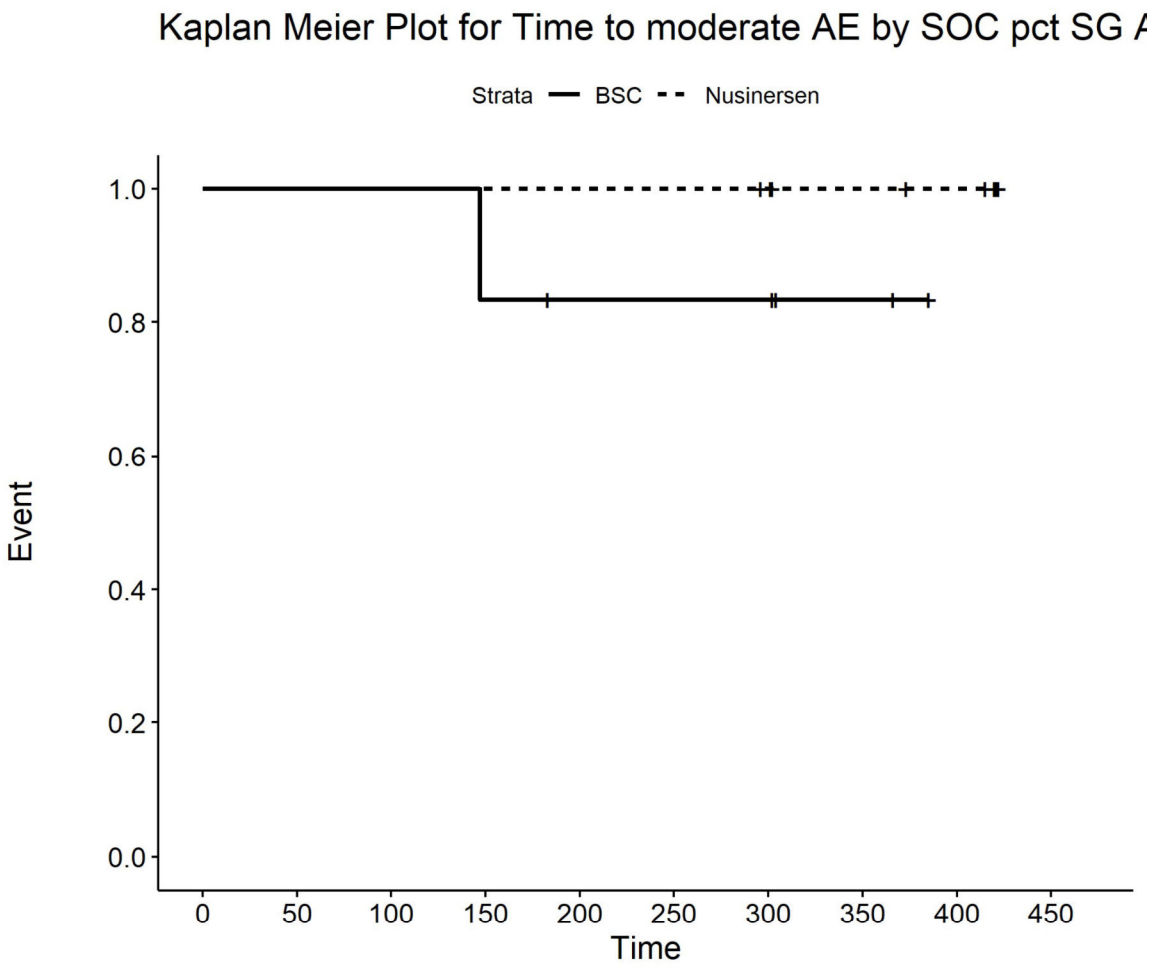
Number at risk

BSC	3	3	3	2	2	1	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



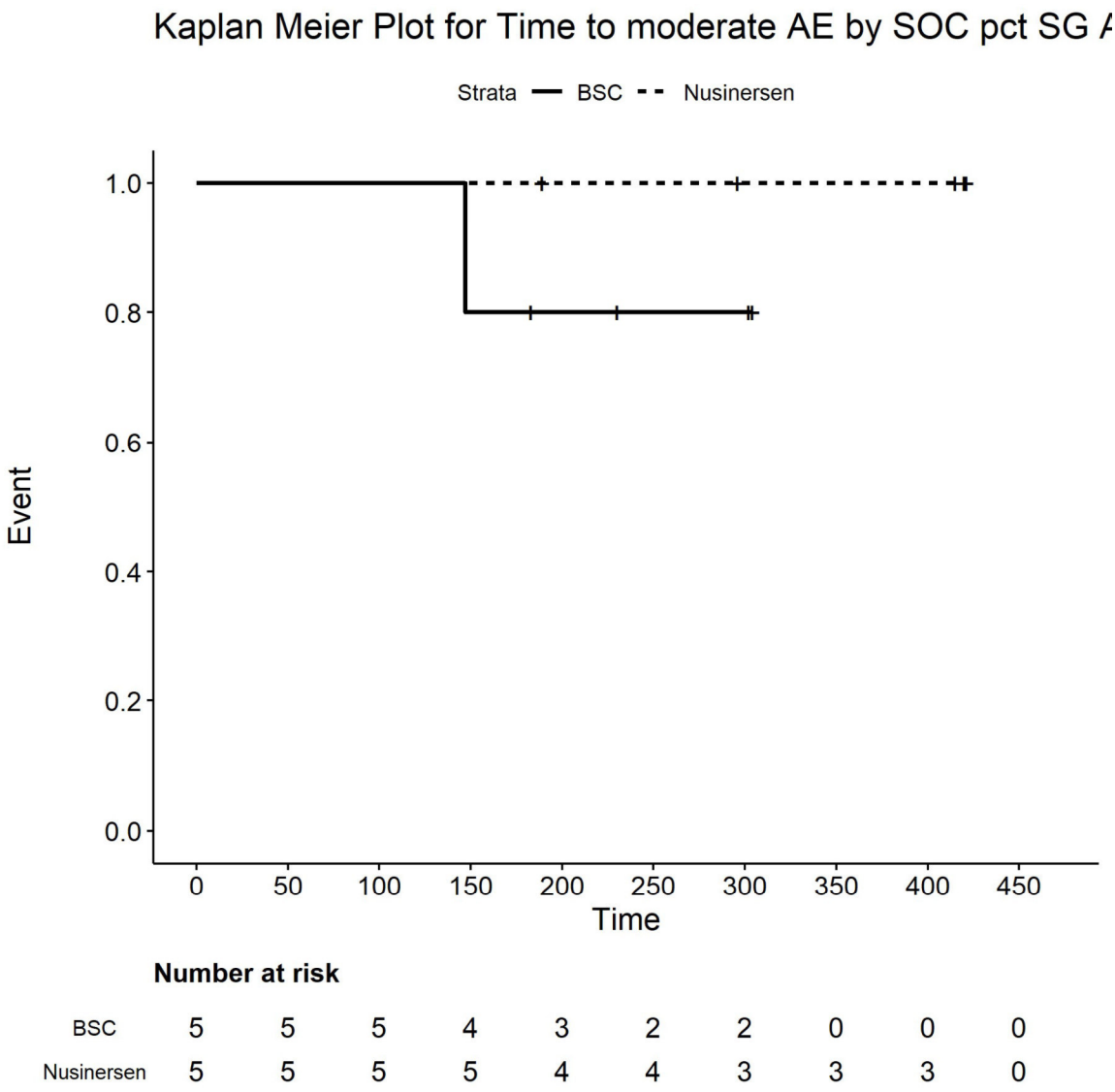
Number at risk

BSC	4	4	4	3	2	2	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



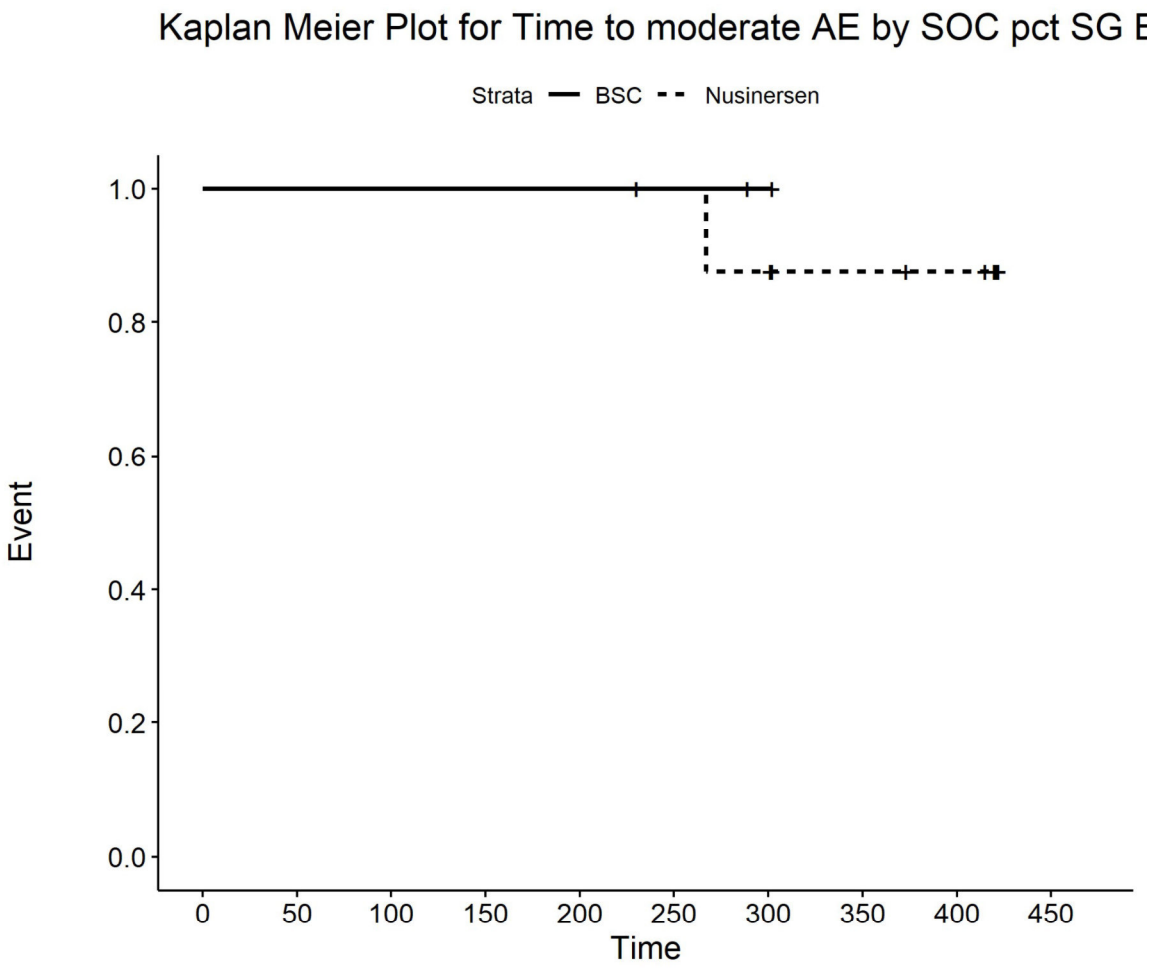
Number at risk

BSC	6	6	6	5	4	4	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



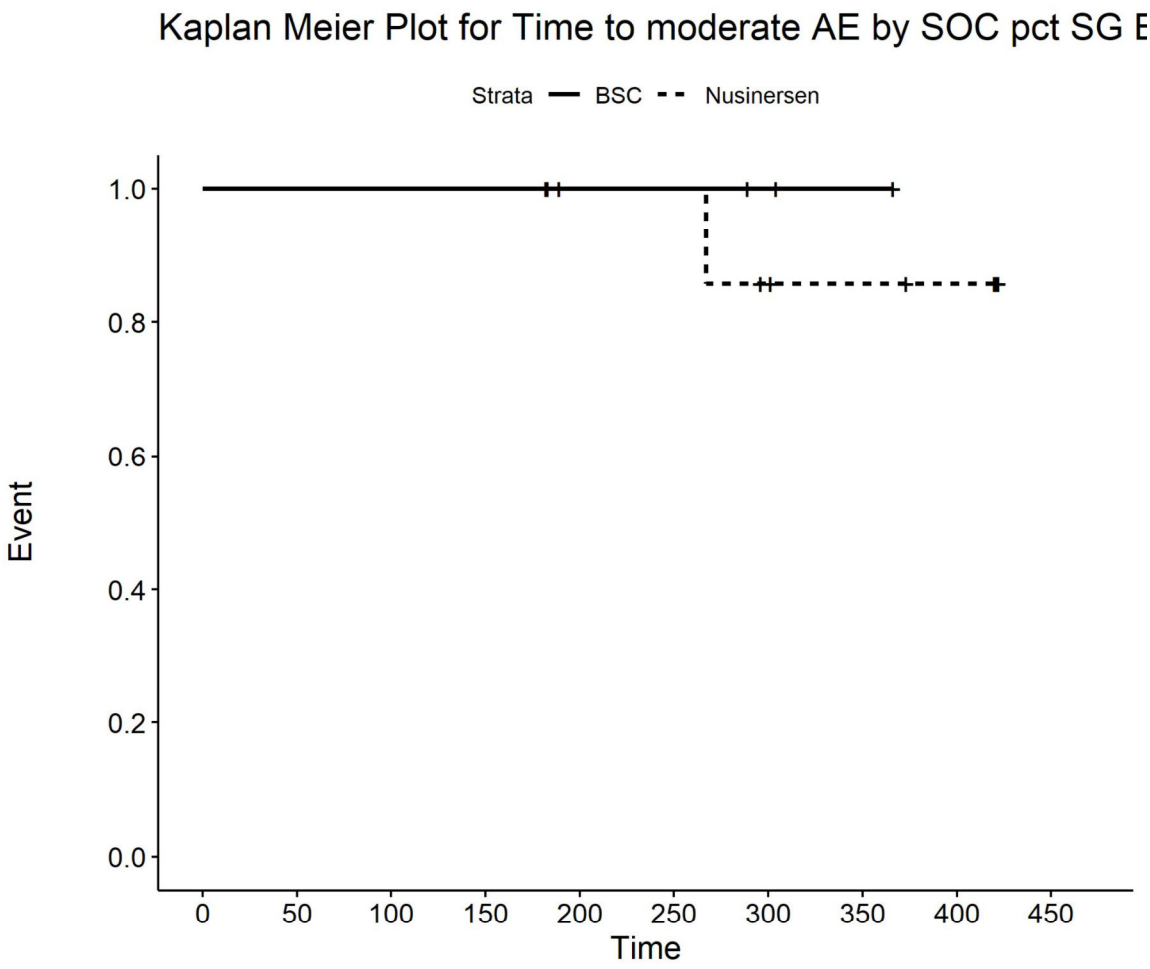
Number at risk

BSC	5	5	5	4	3	2	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



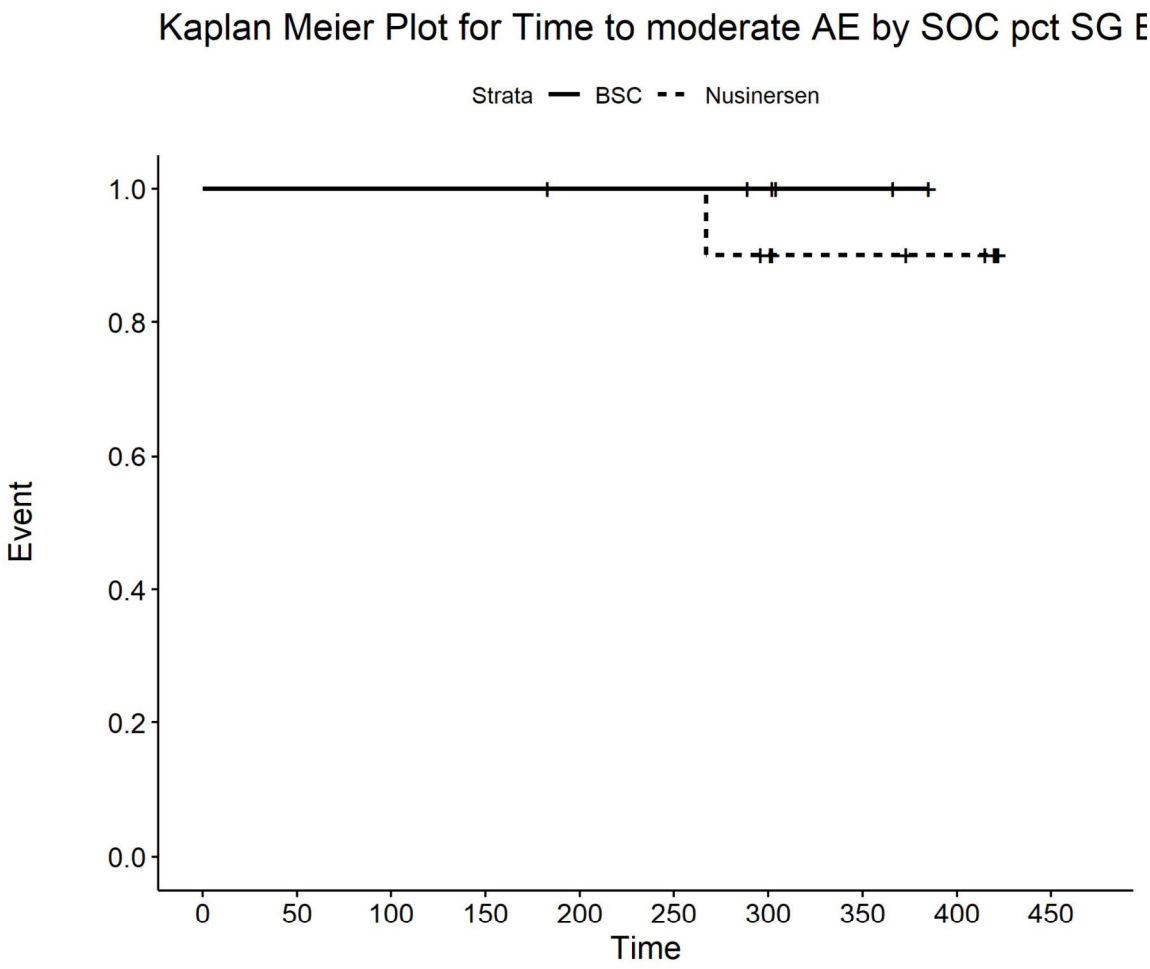
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	7	5	4	0



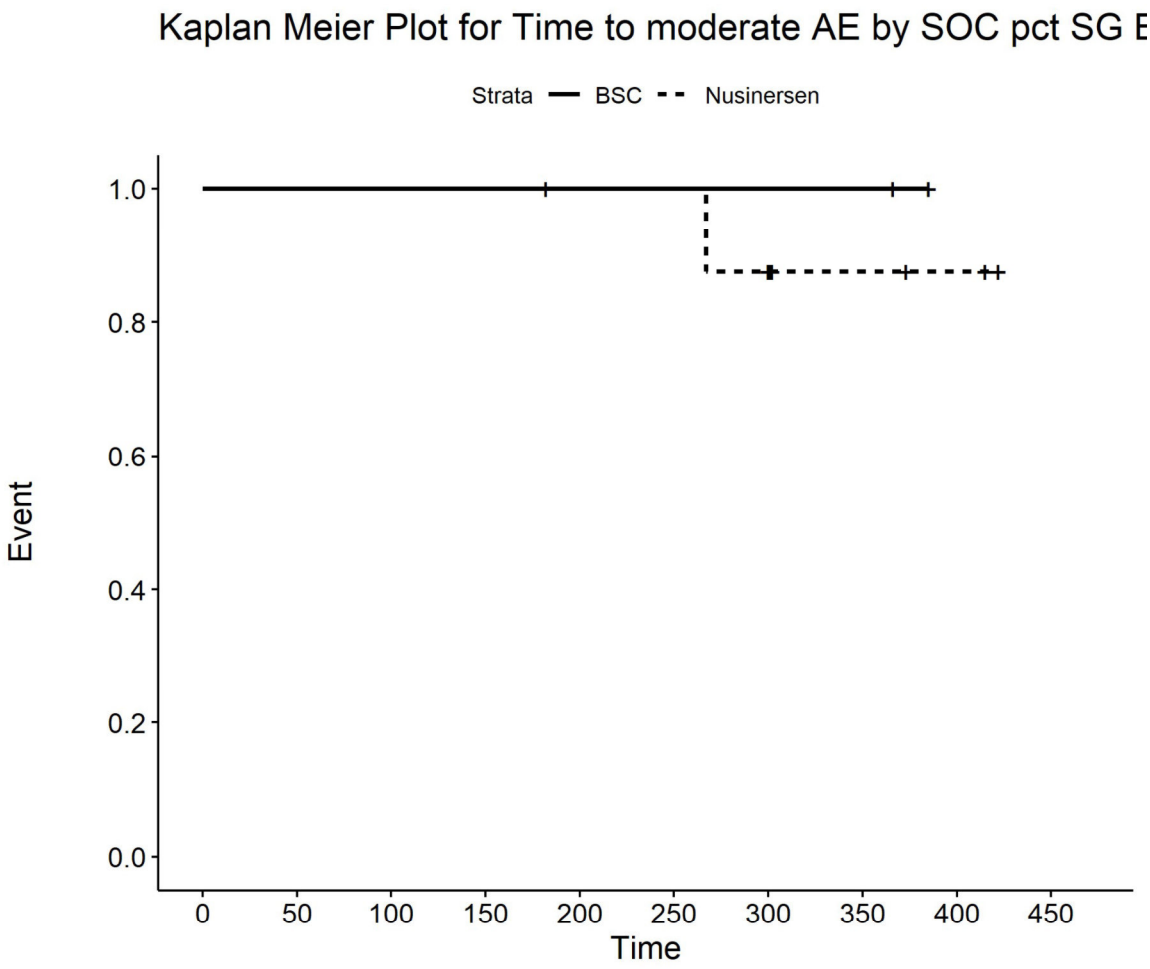
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	5	4	3	0



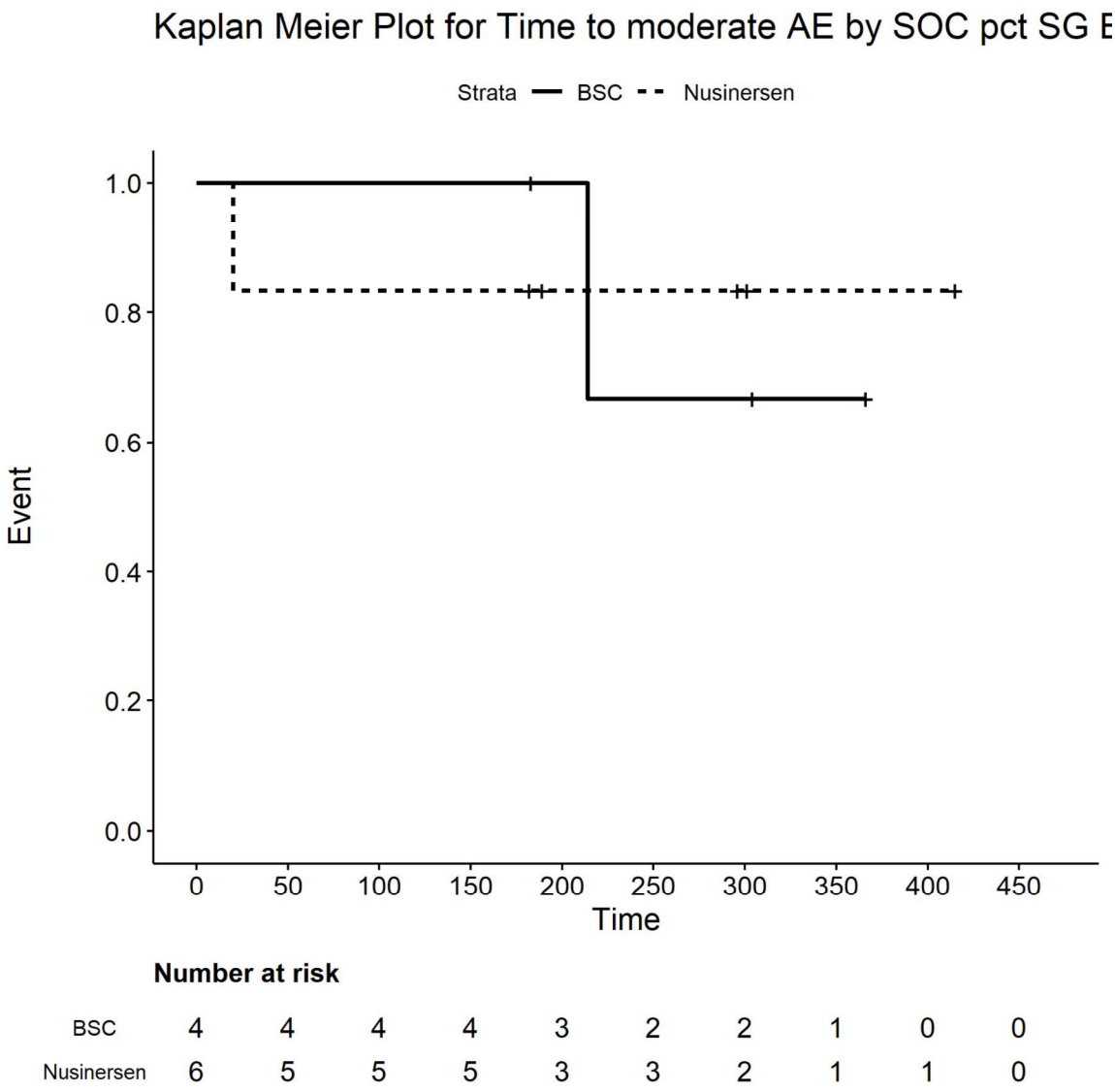
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	8	6	5	0



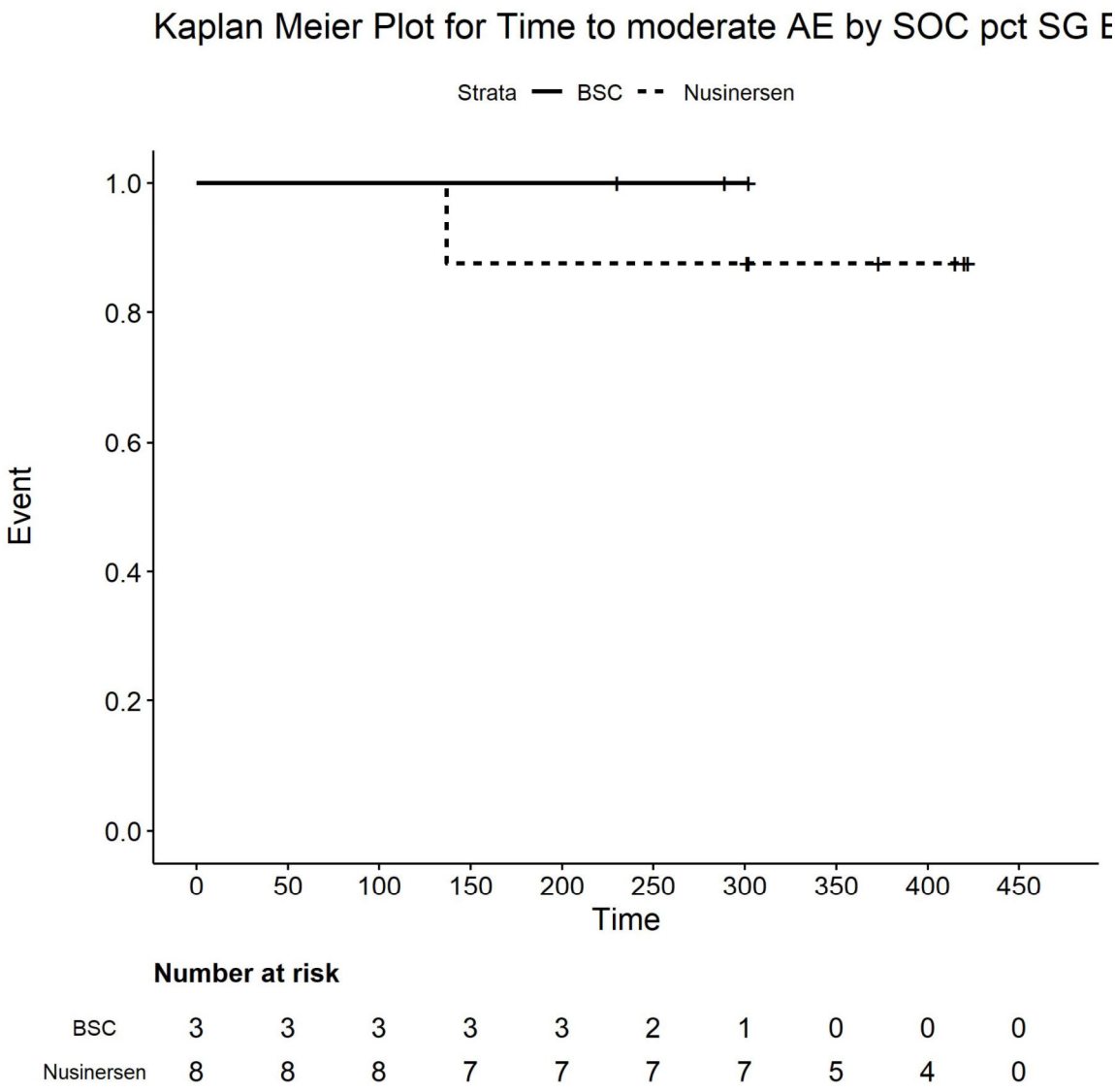
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	7	3	2	0



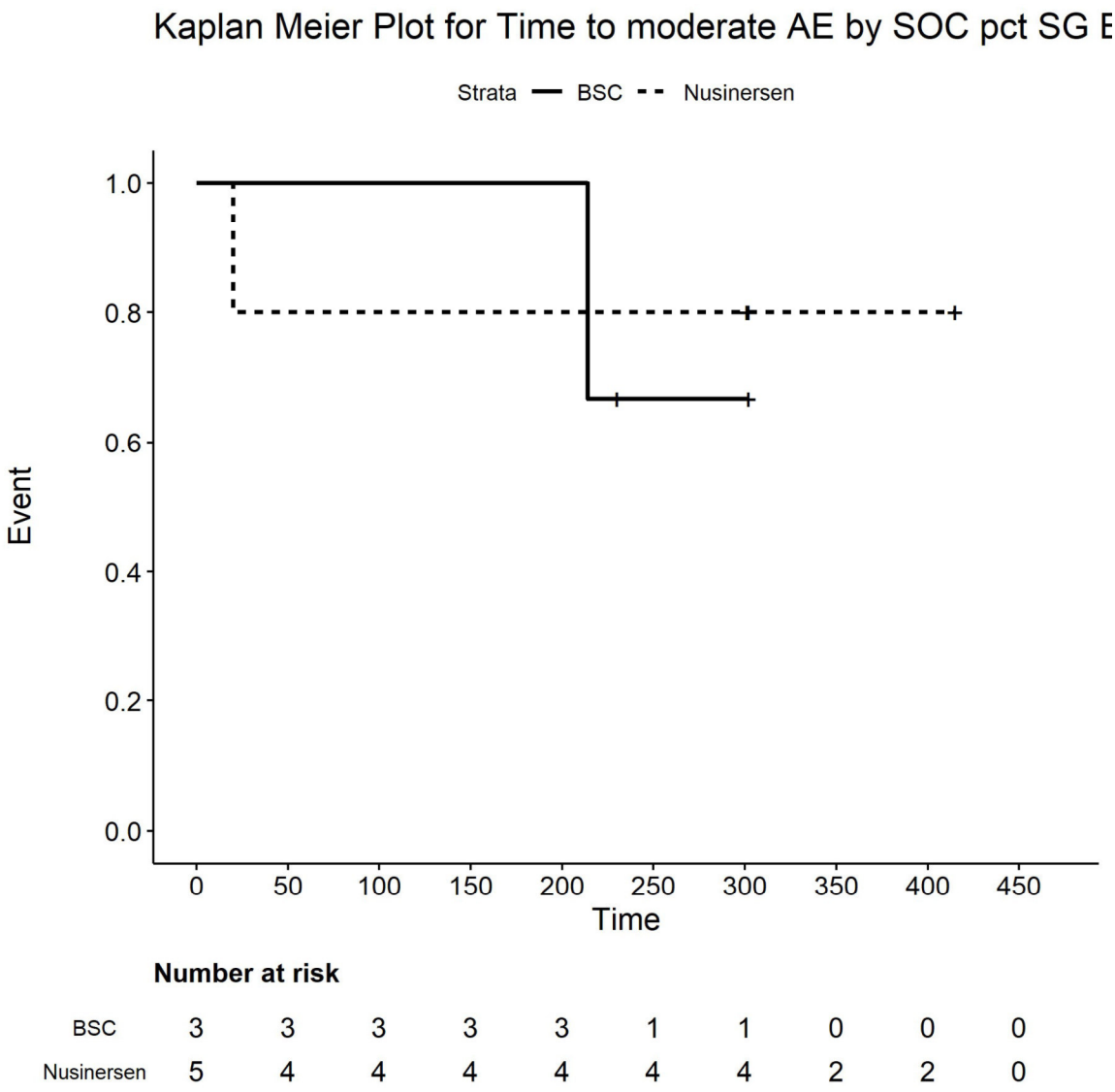
Number at risk

BSC	4	4	4	4	3	2	2	1	0	0
Nusinersen	6	5	5	5	3	3	2	1	1	0



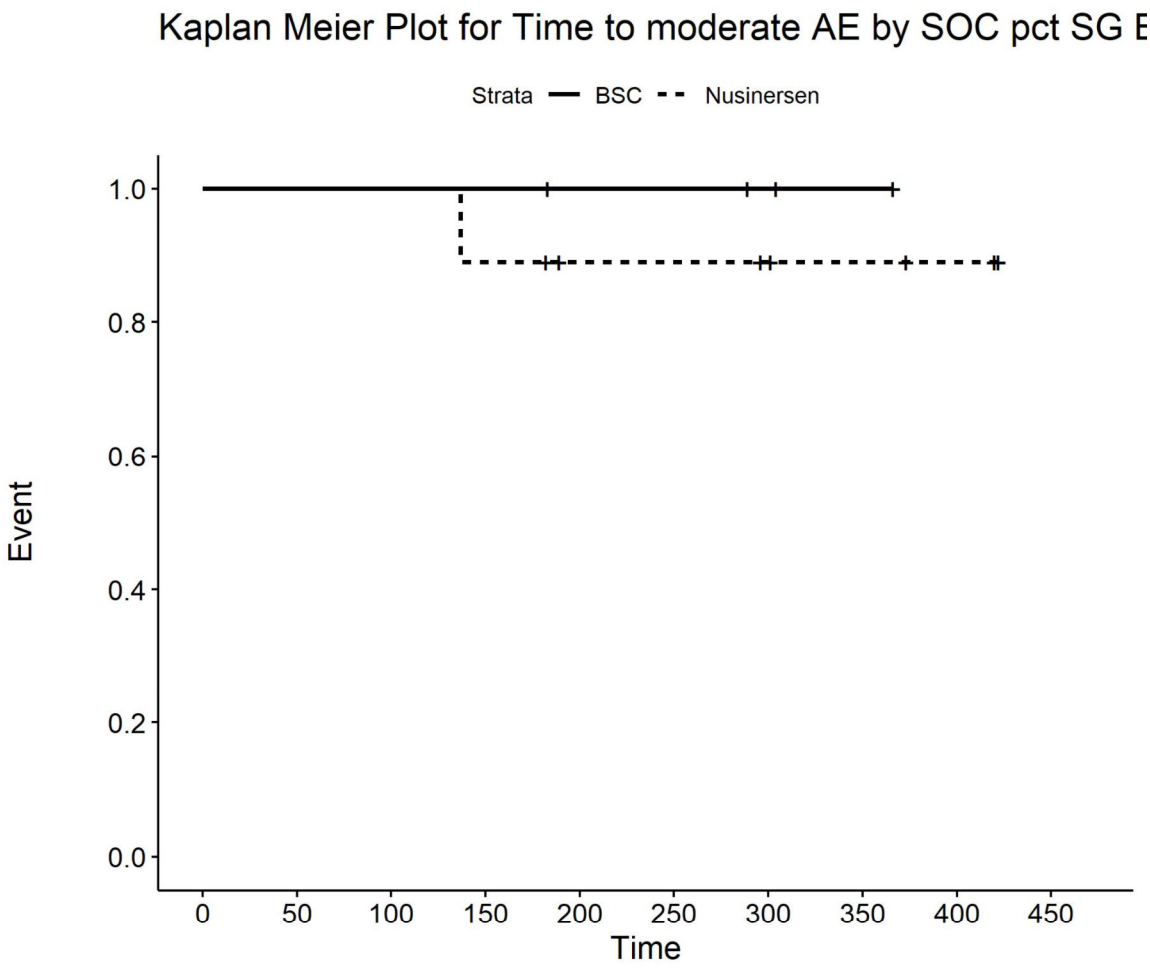
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



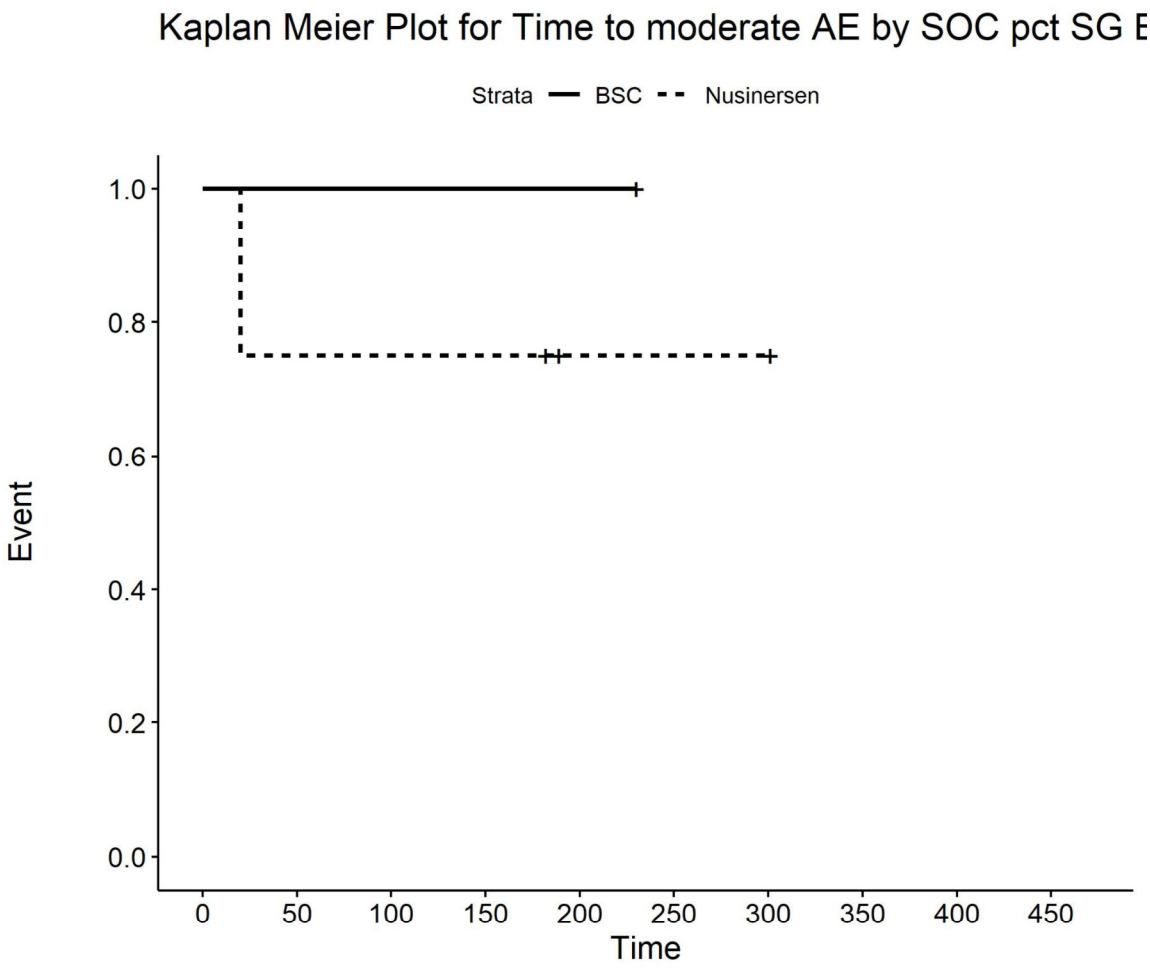
Number at risk

BSC	3	3	3	3	3	1	1	0	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



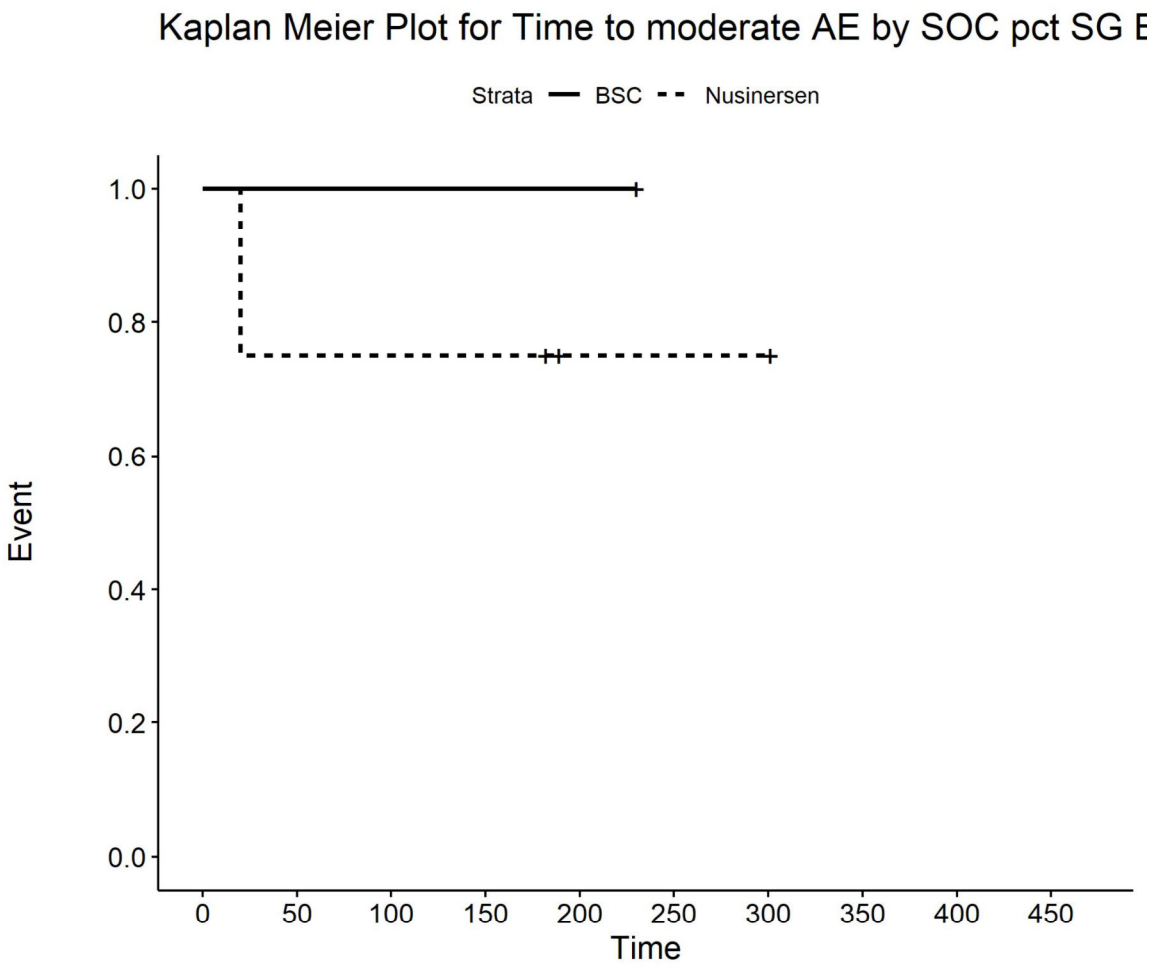
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



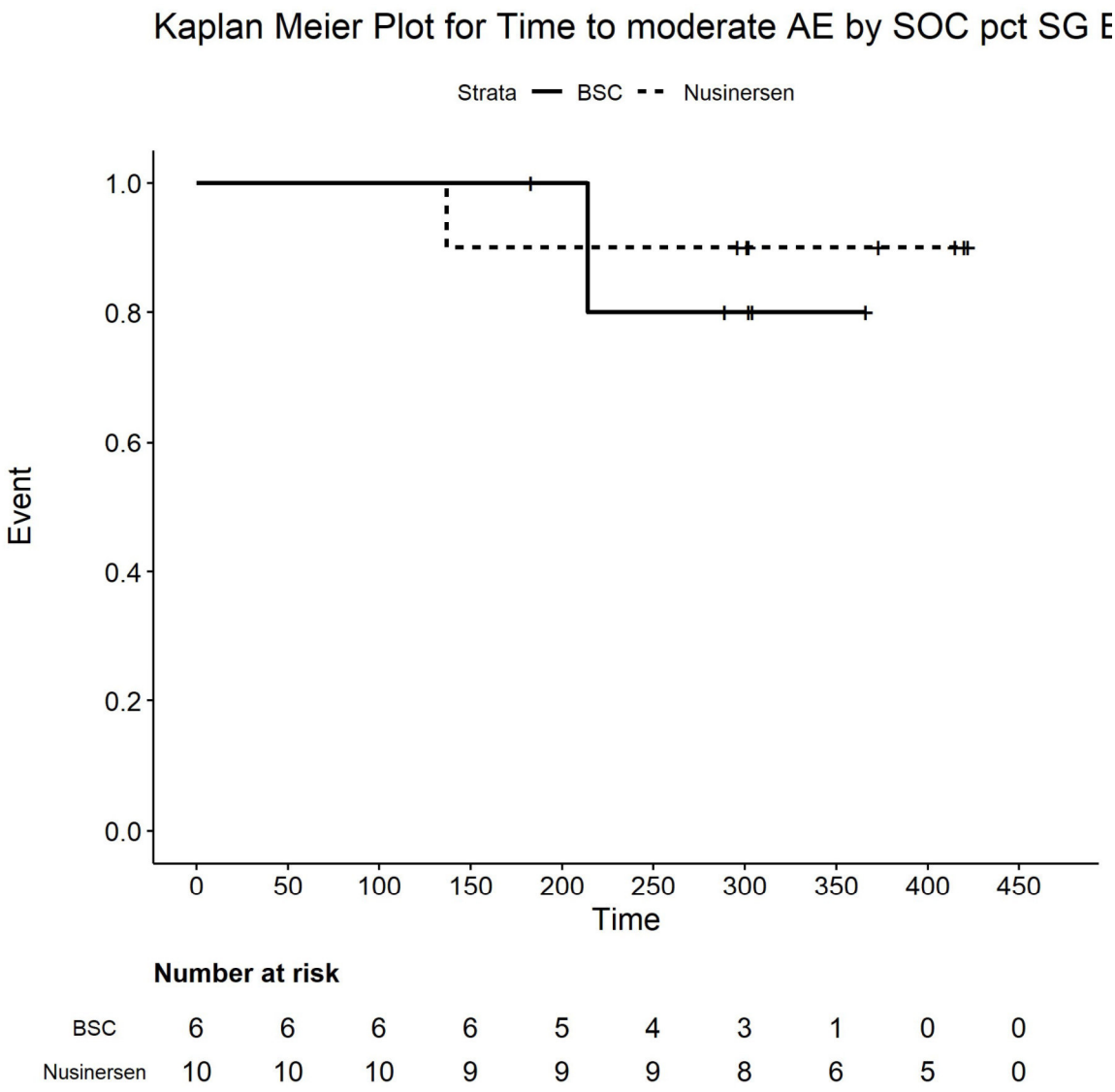
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



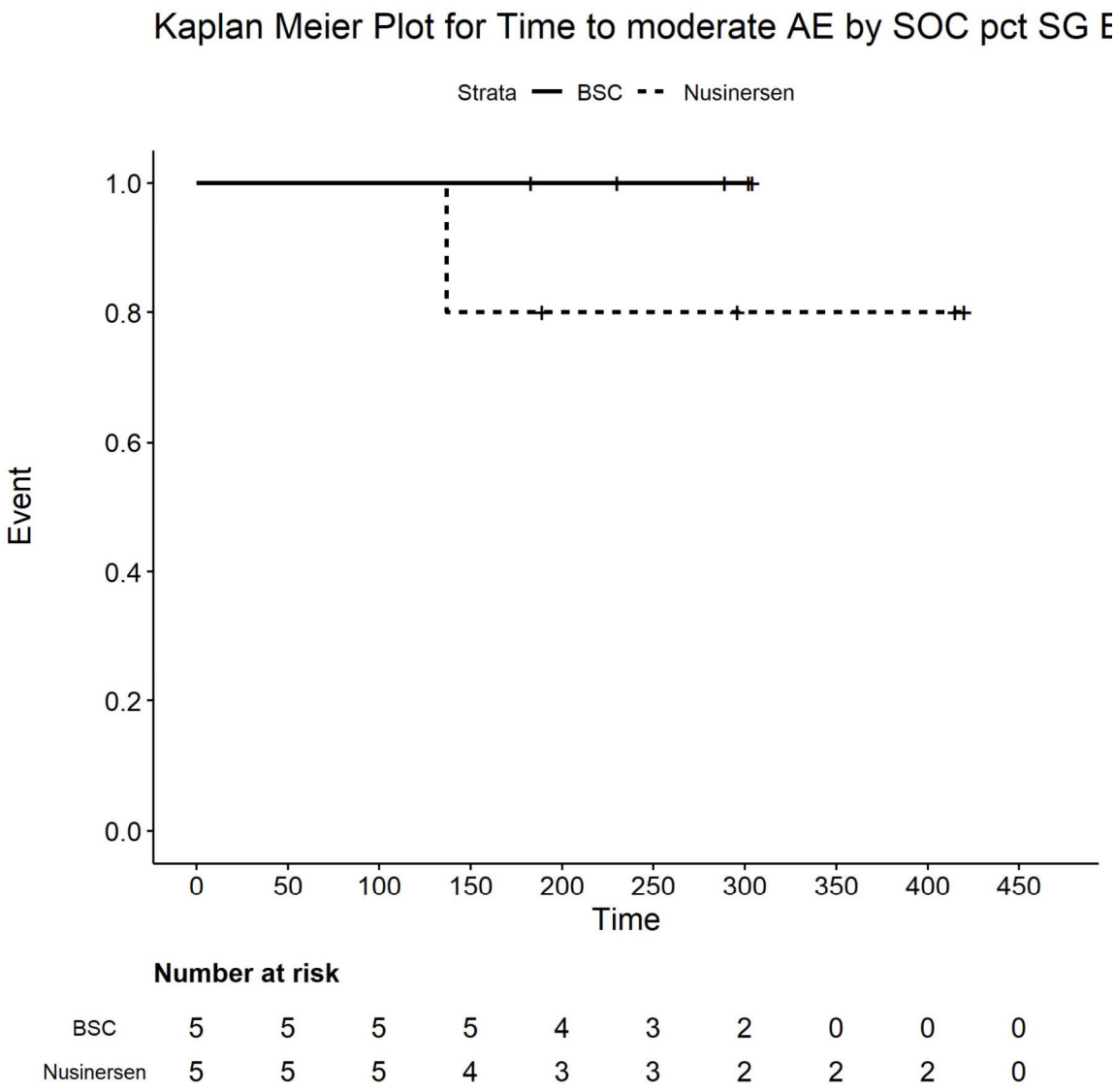
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



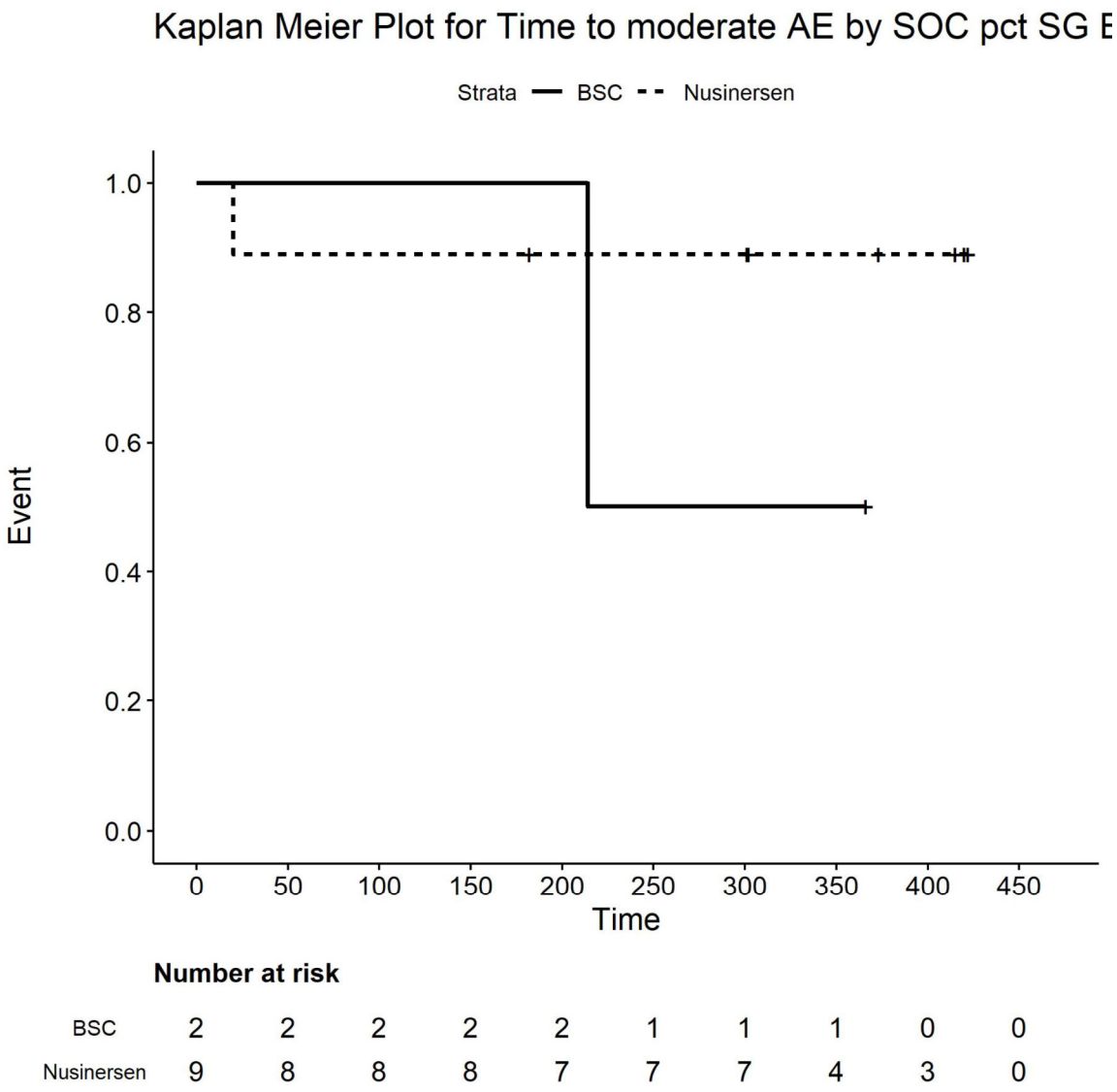
Number at risk

BSC	6	6	6	6	5	4	3	1	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



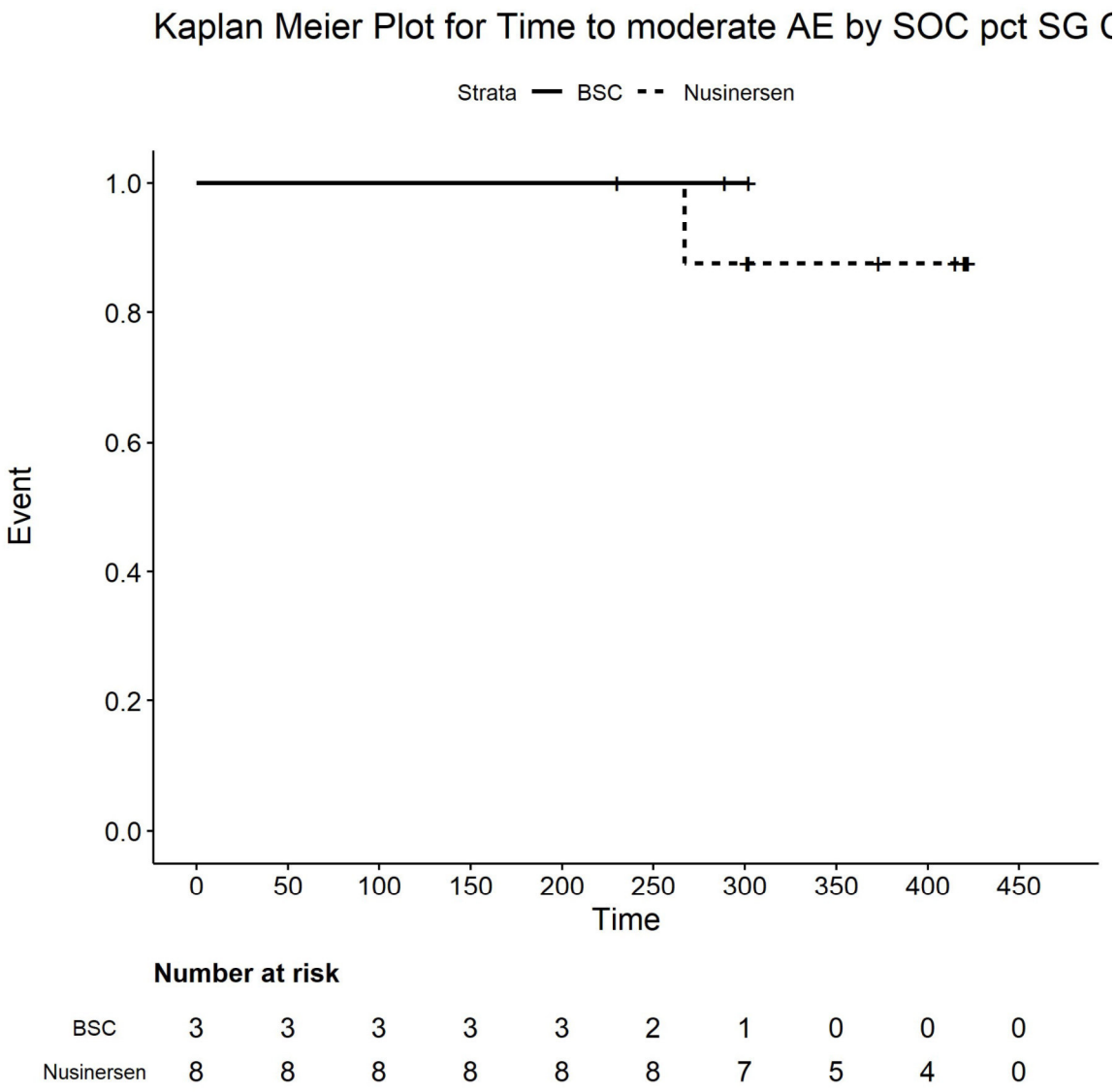
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	4	3	3	2	2	2	0



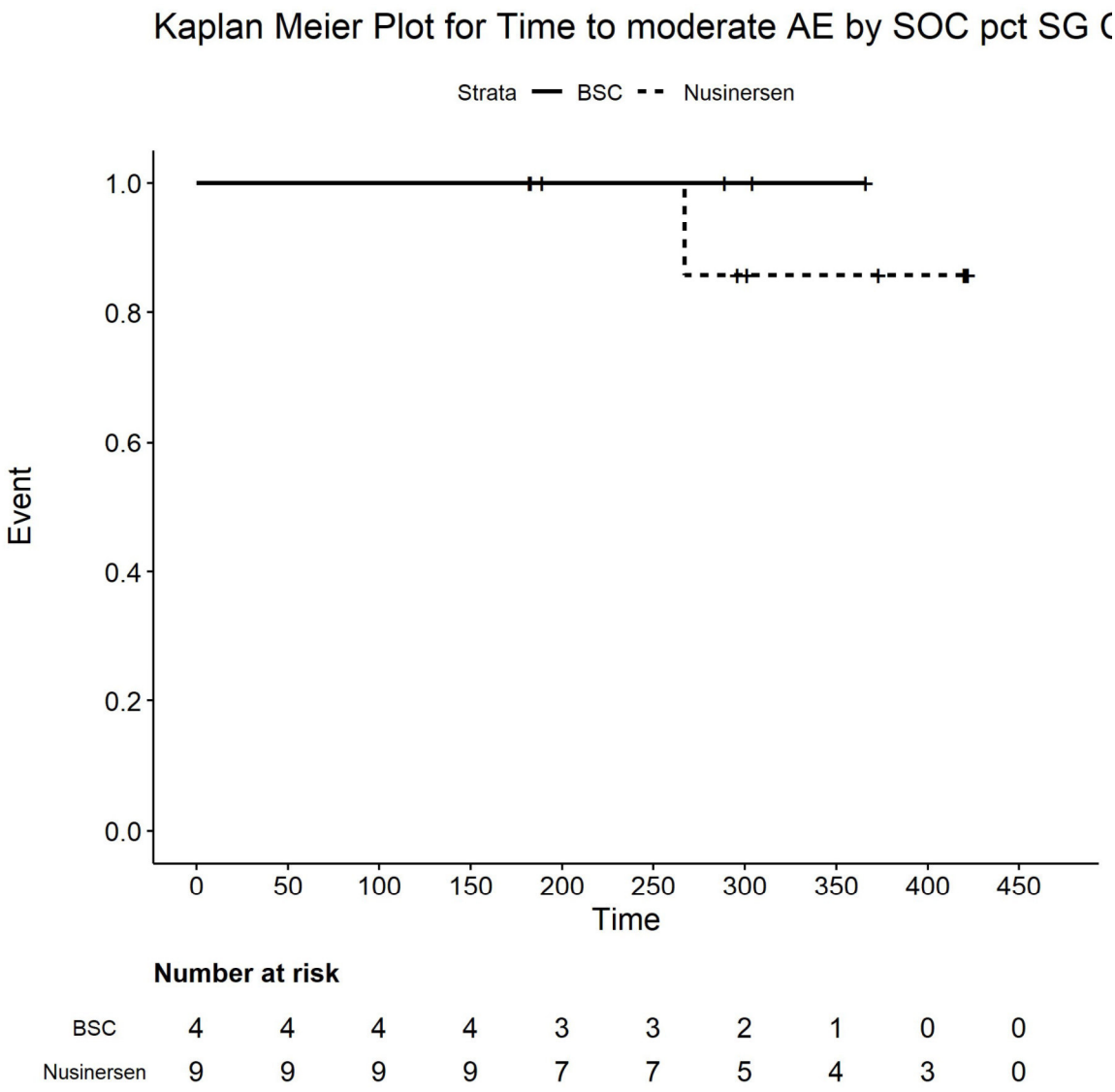
Number at risk

BSC	2	2	2	2	2	1	1	1	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



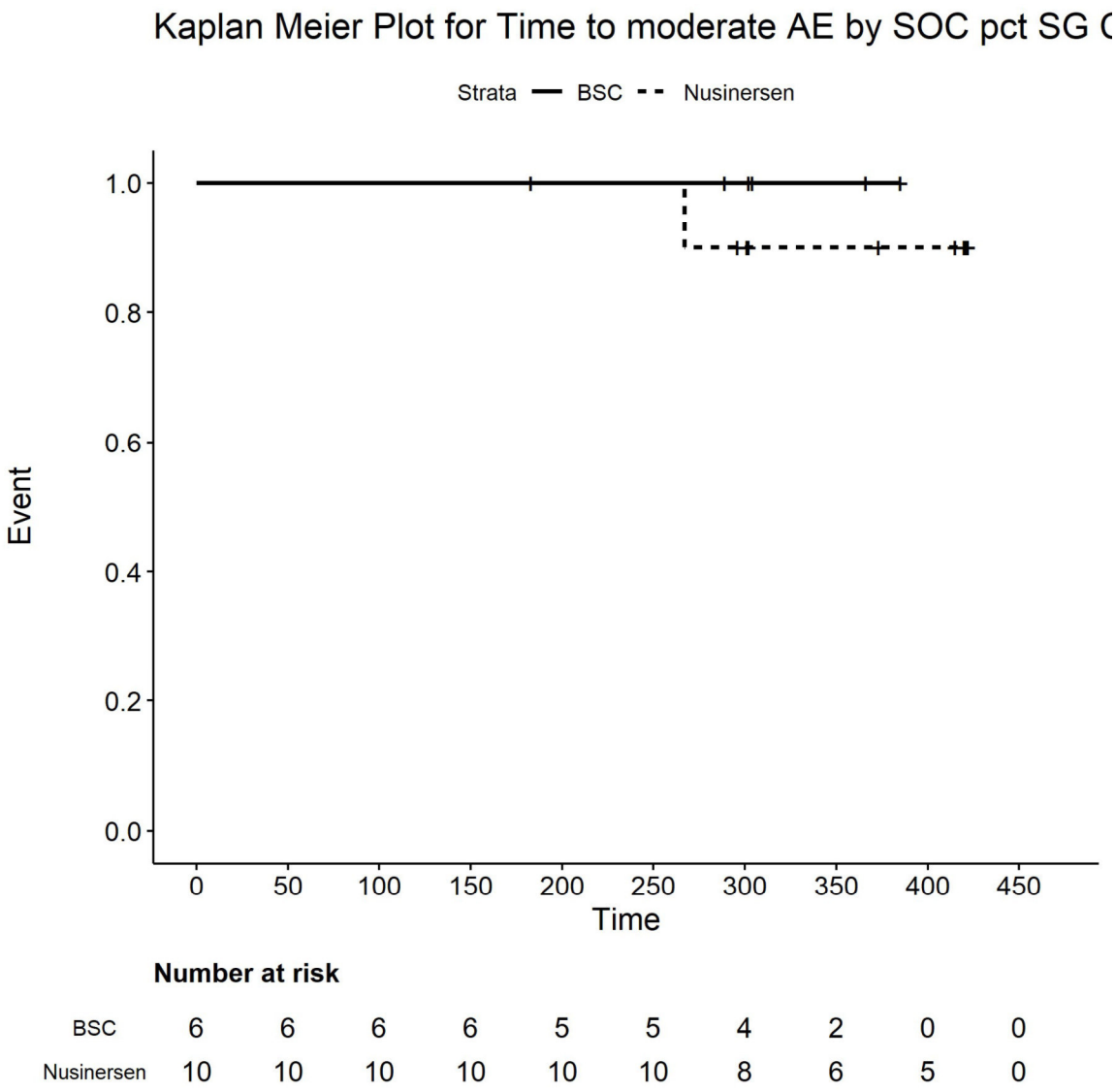
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	7	5	4	0



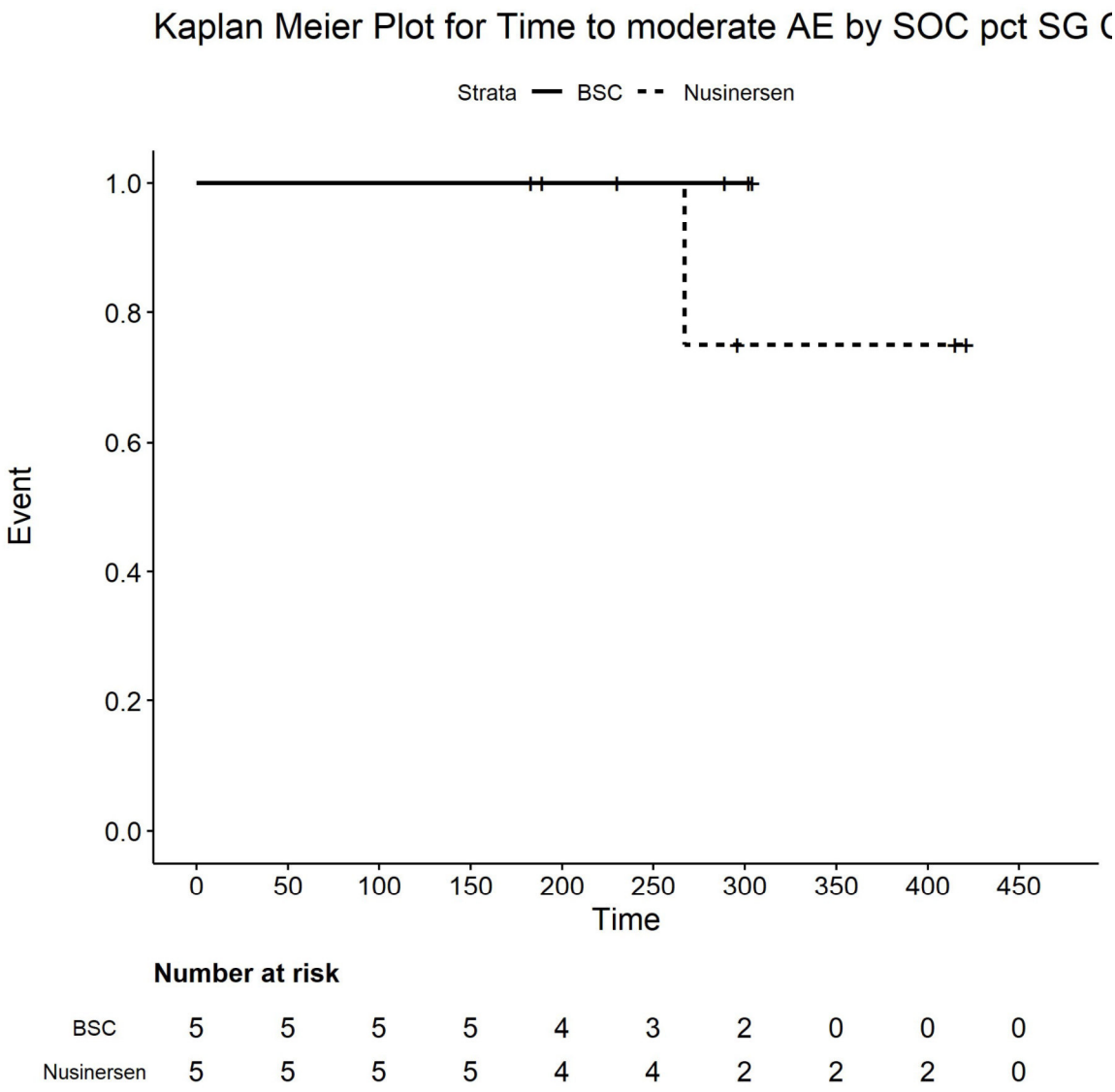
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	5	4	3	0



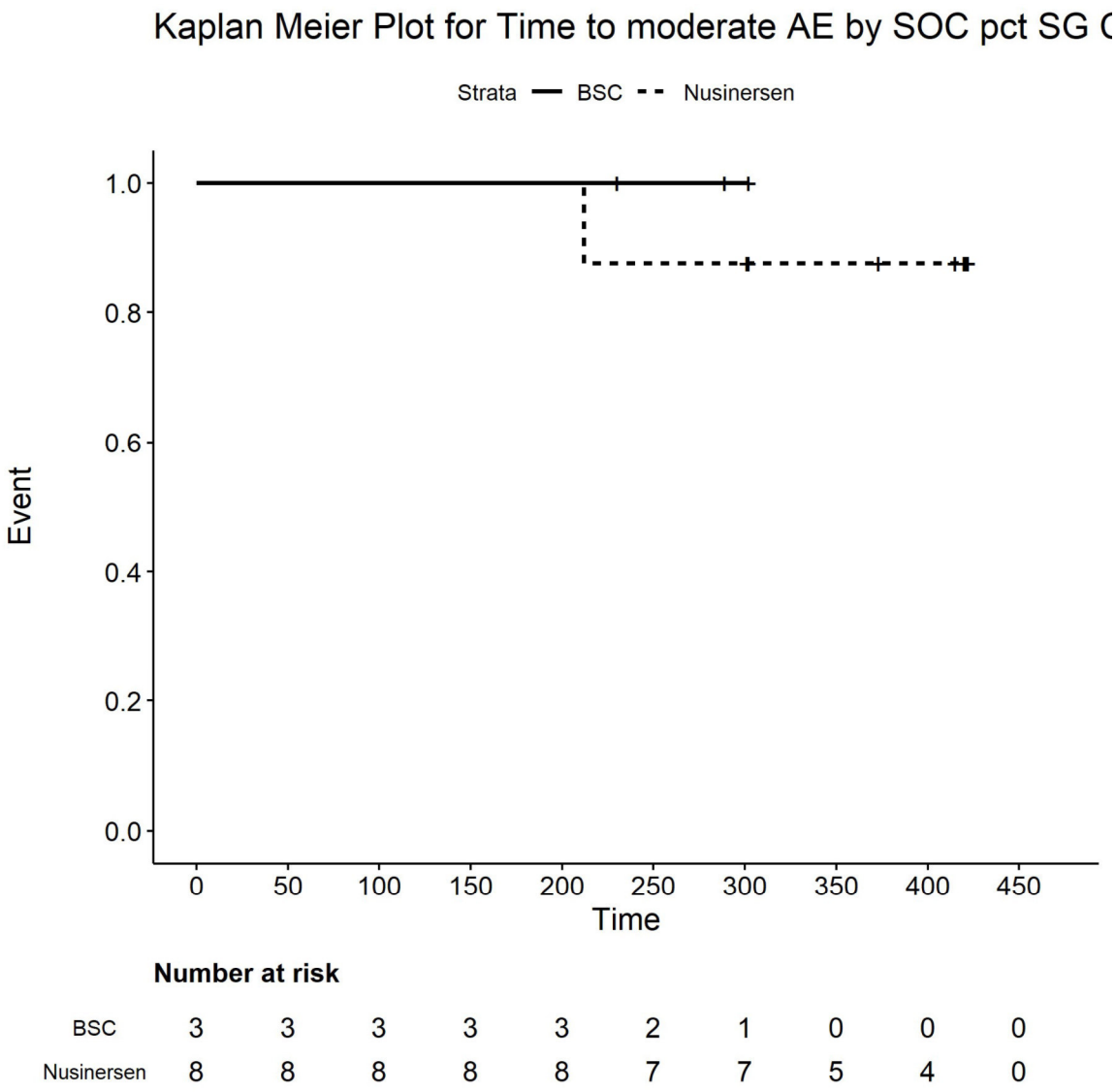
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	8	6	5	0



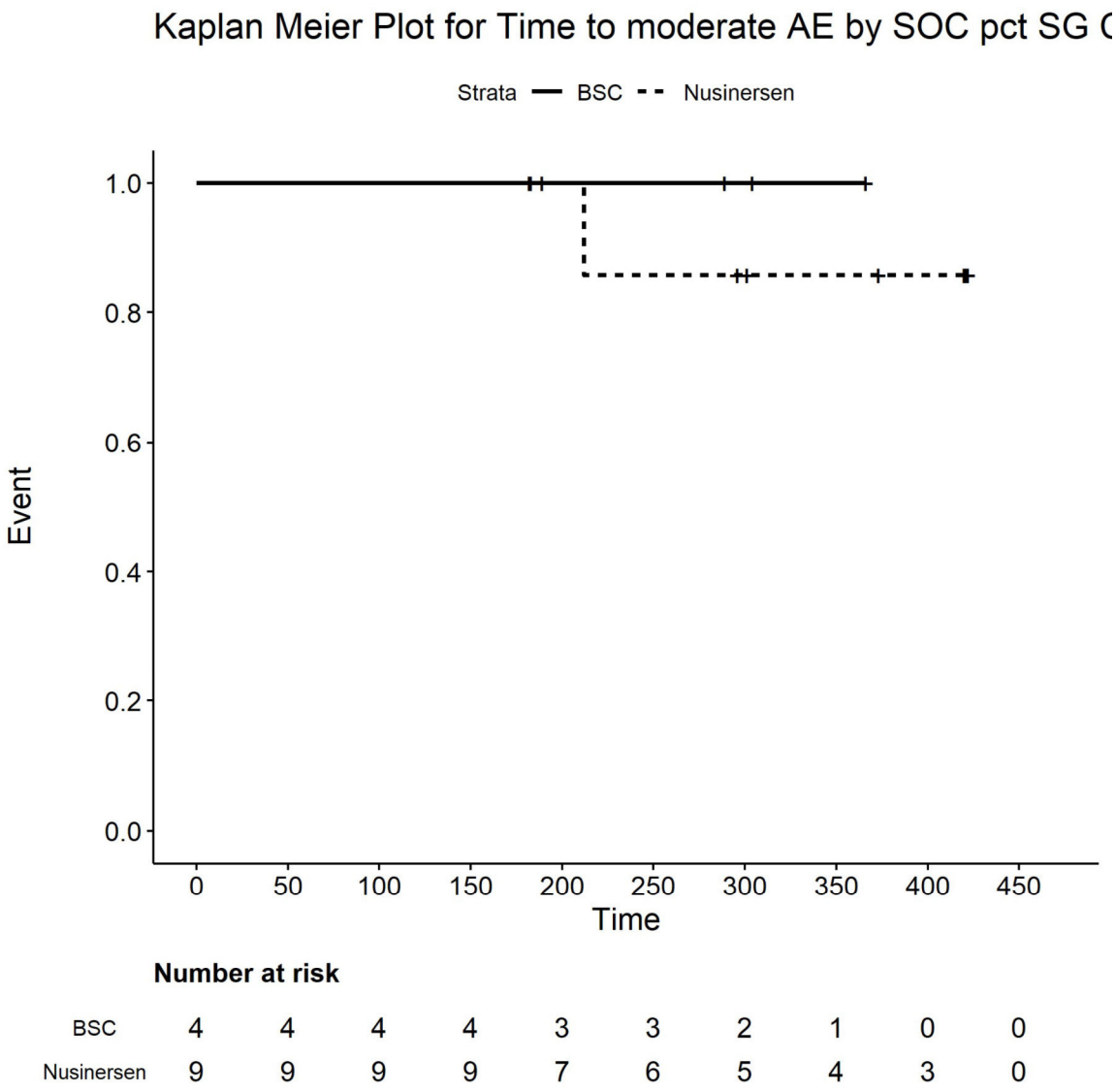
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	2	2	2	0



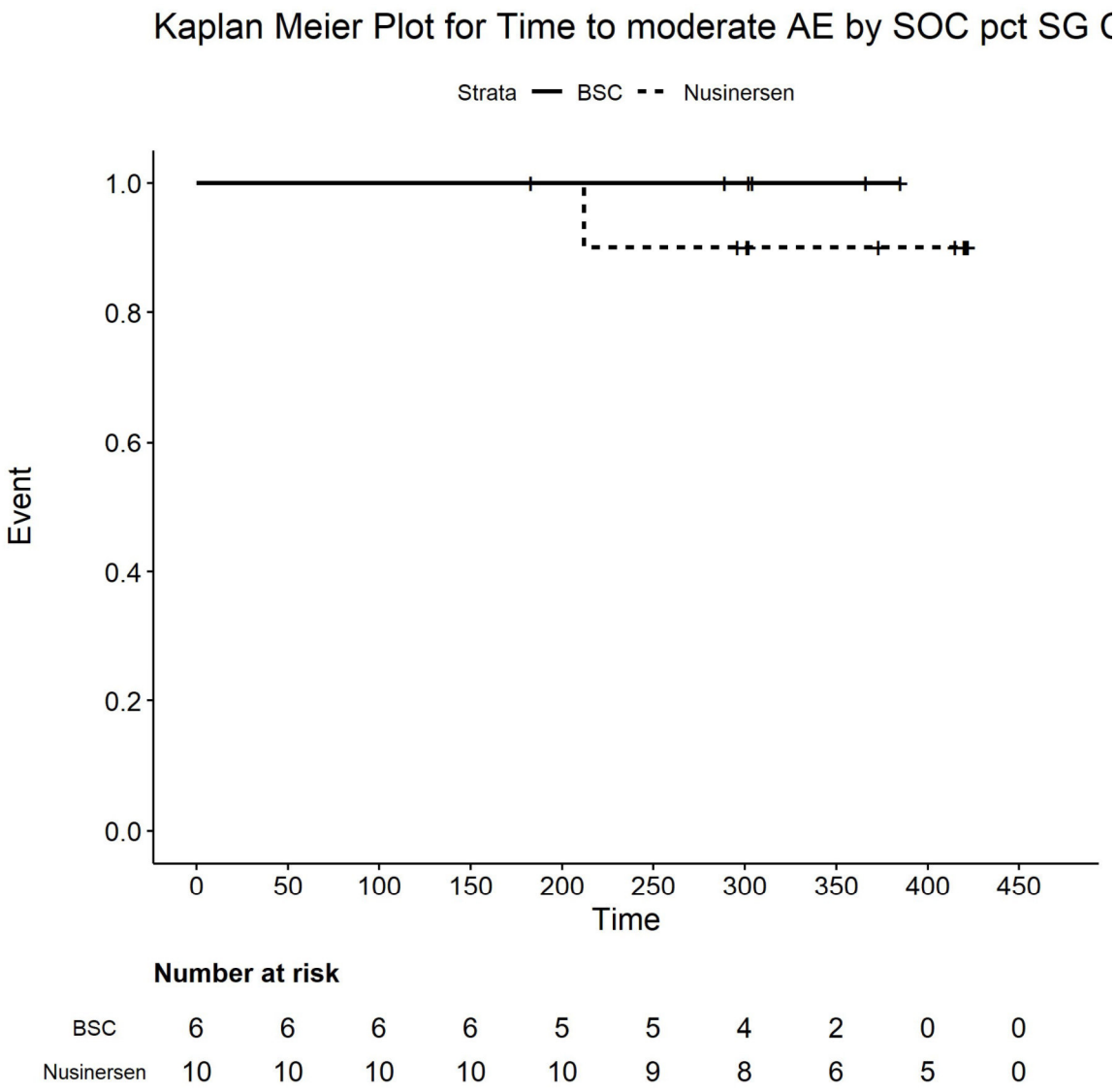
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



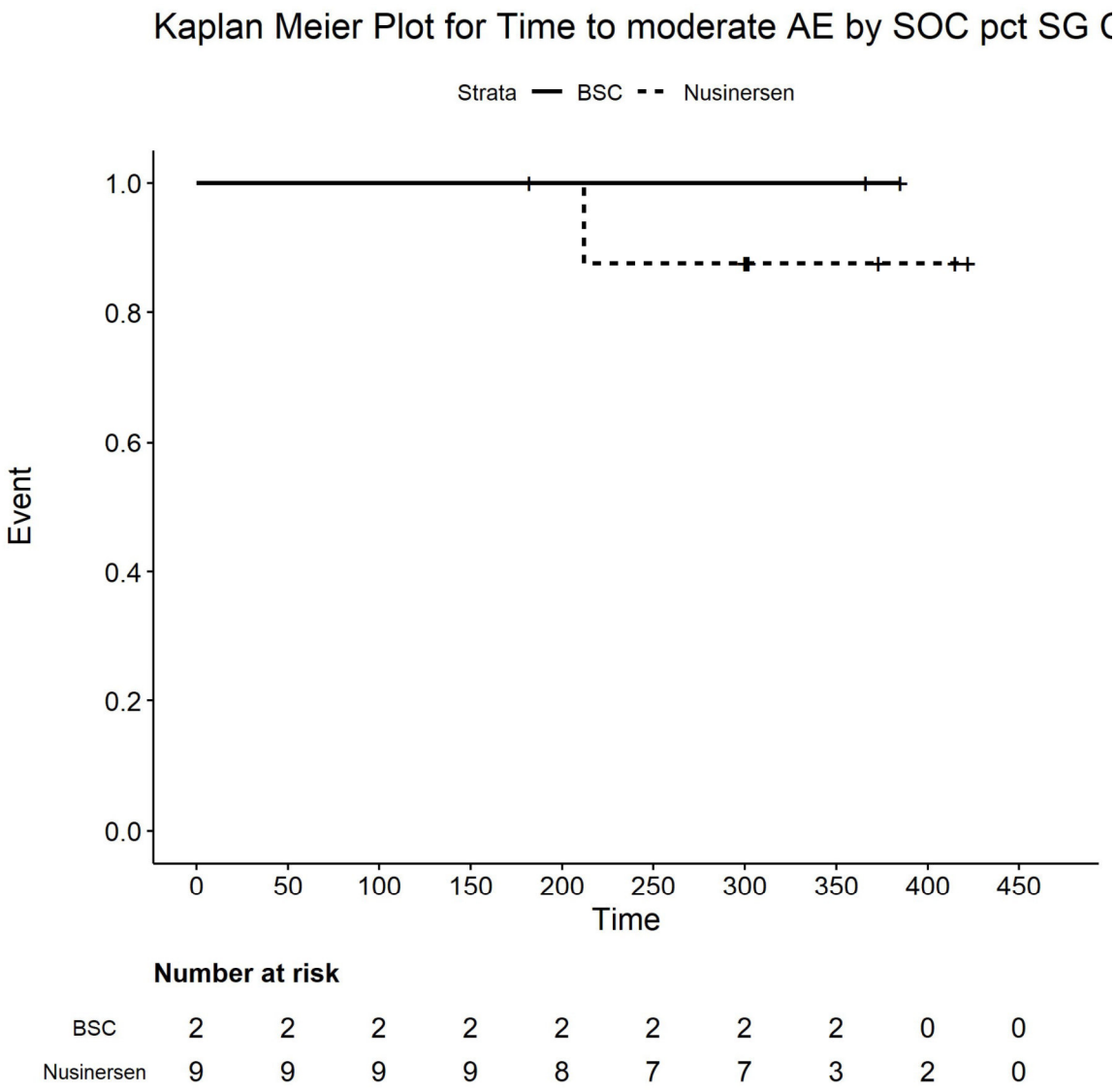
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



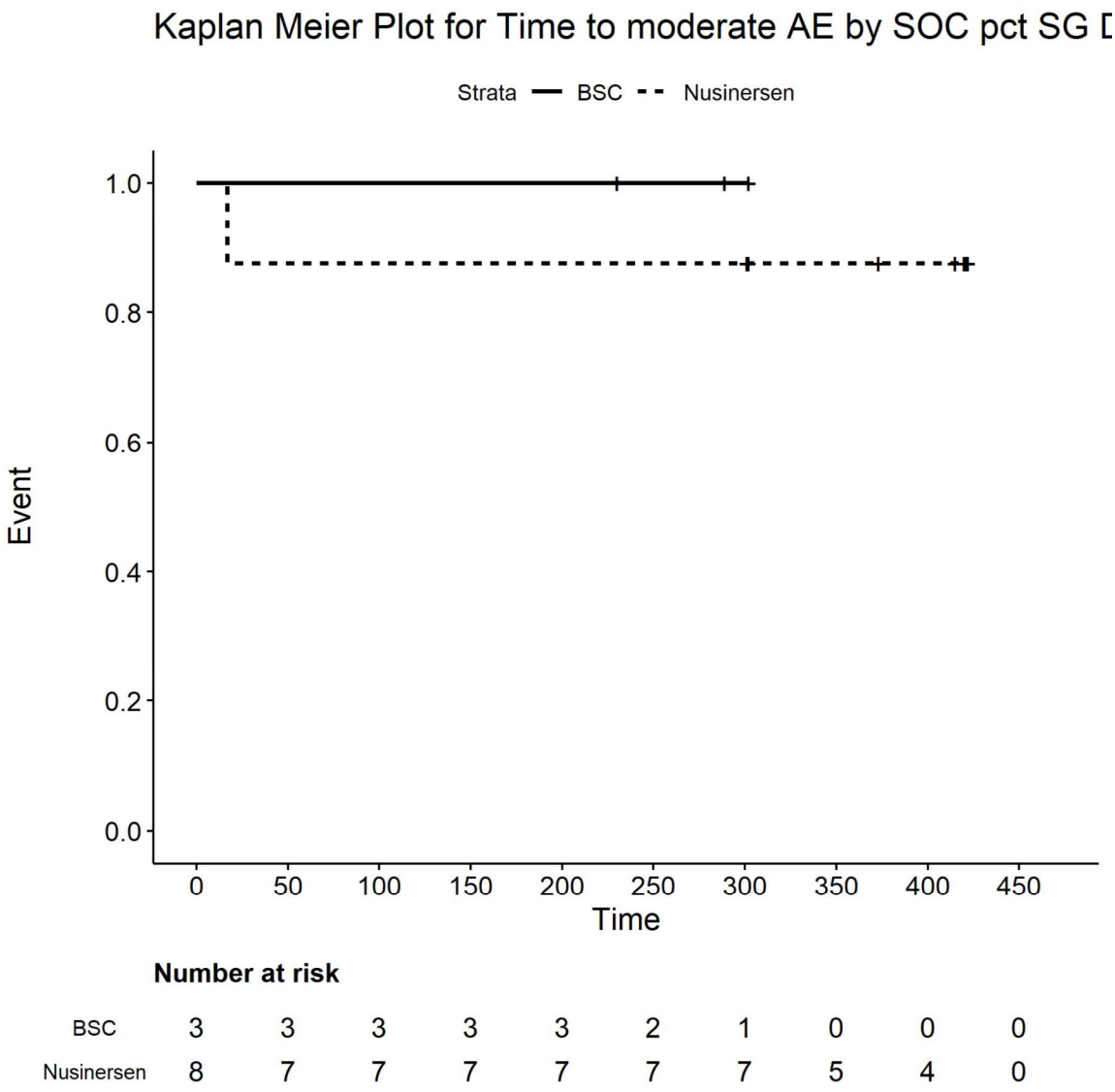
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



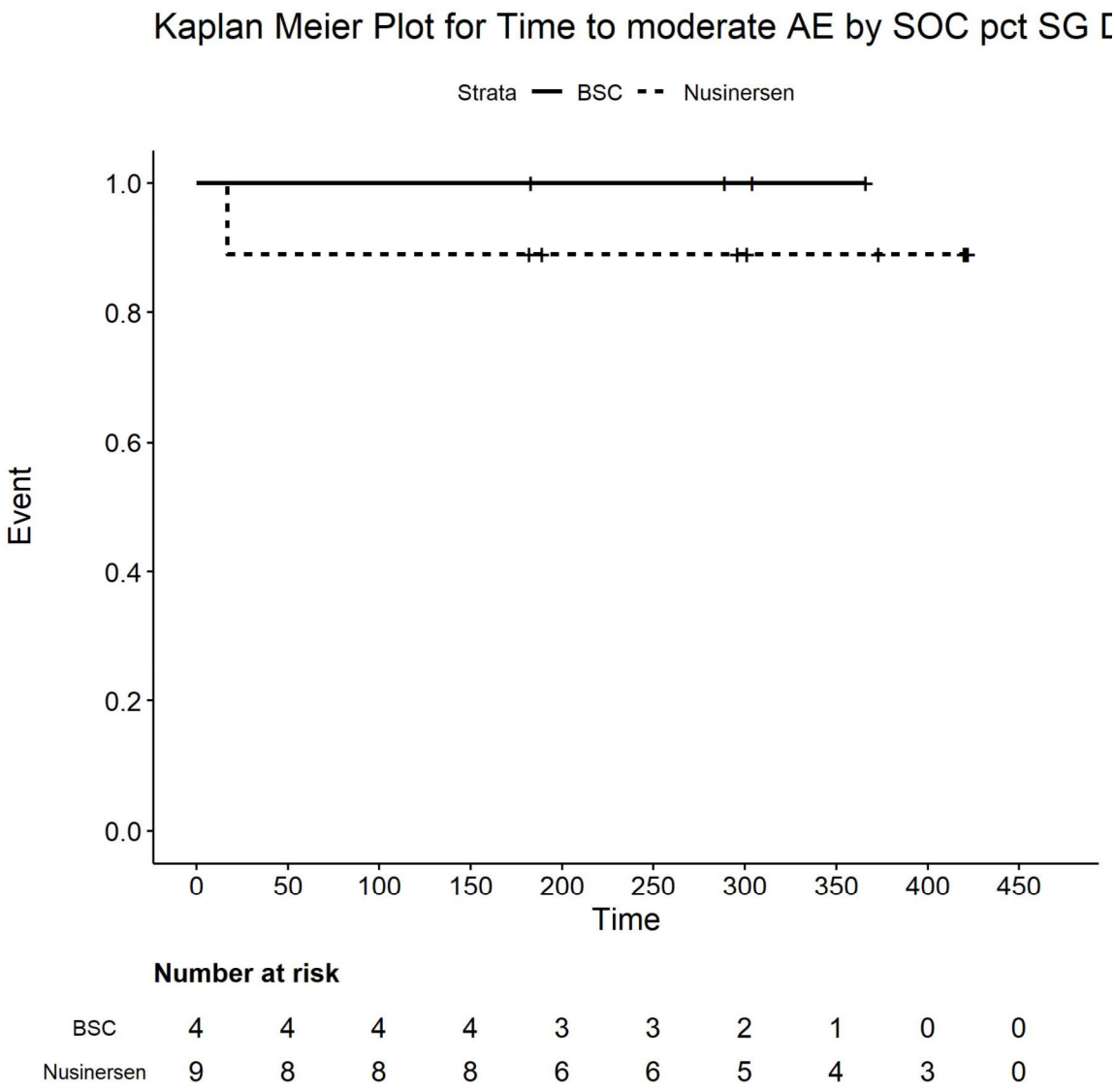
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	2	0



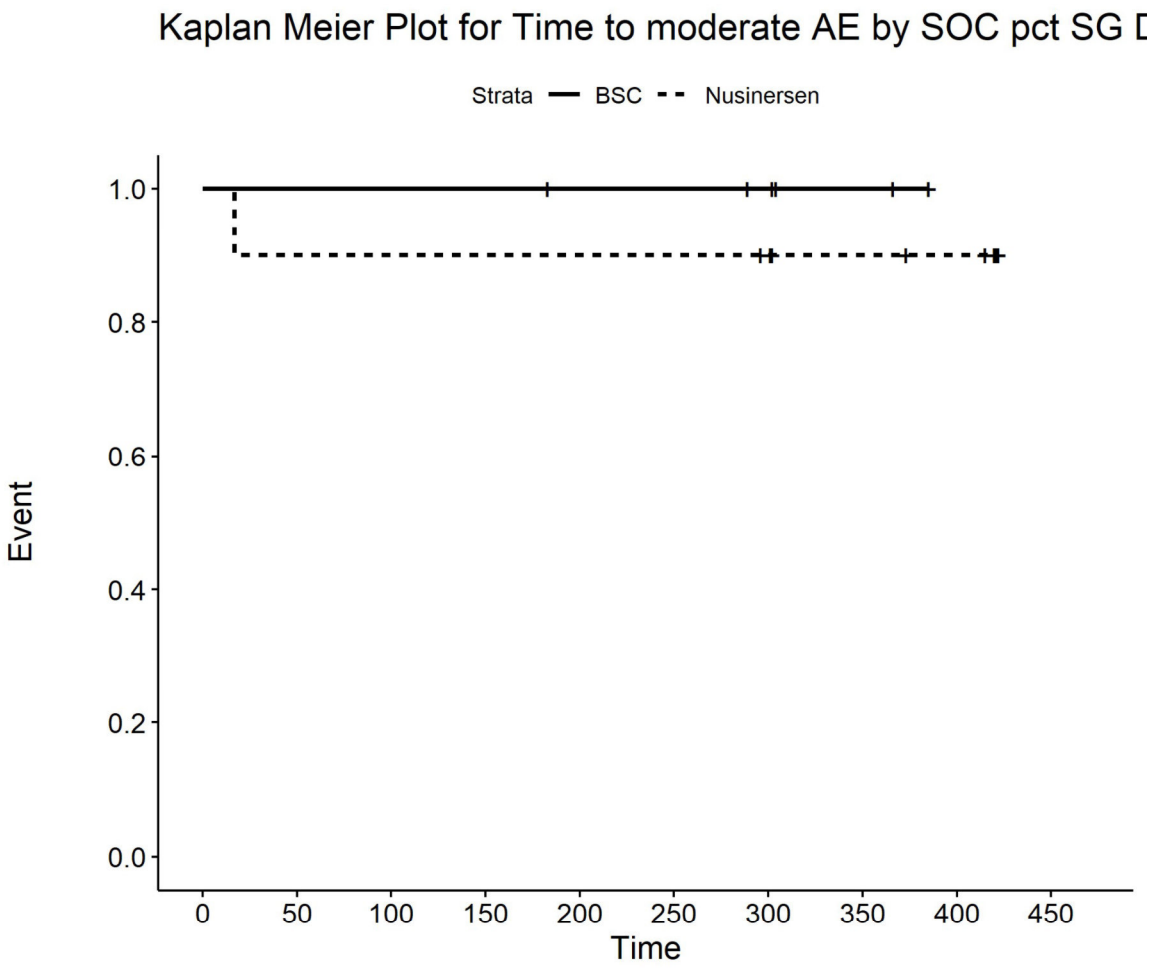
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



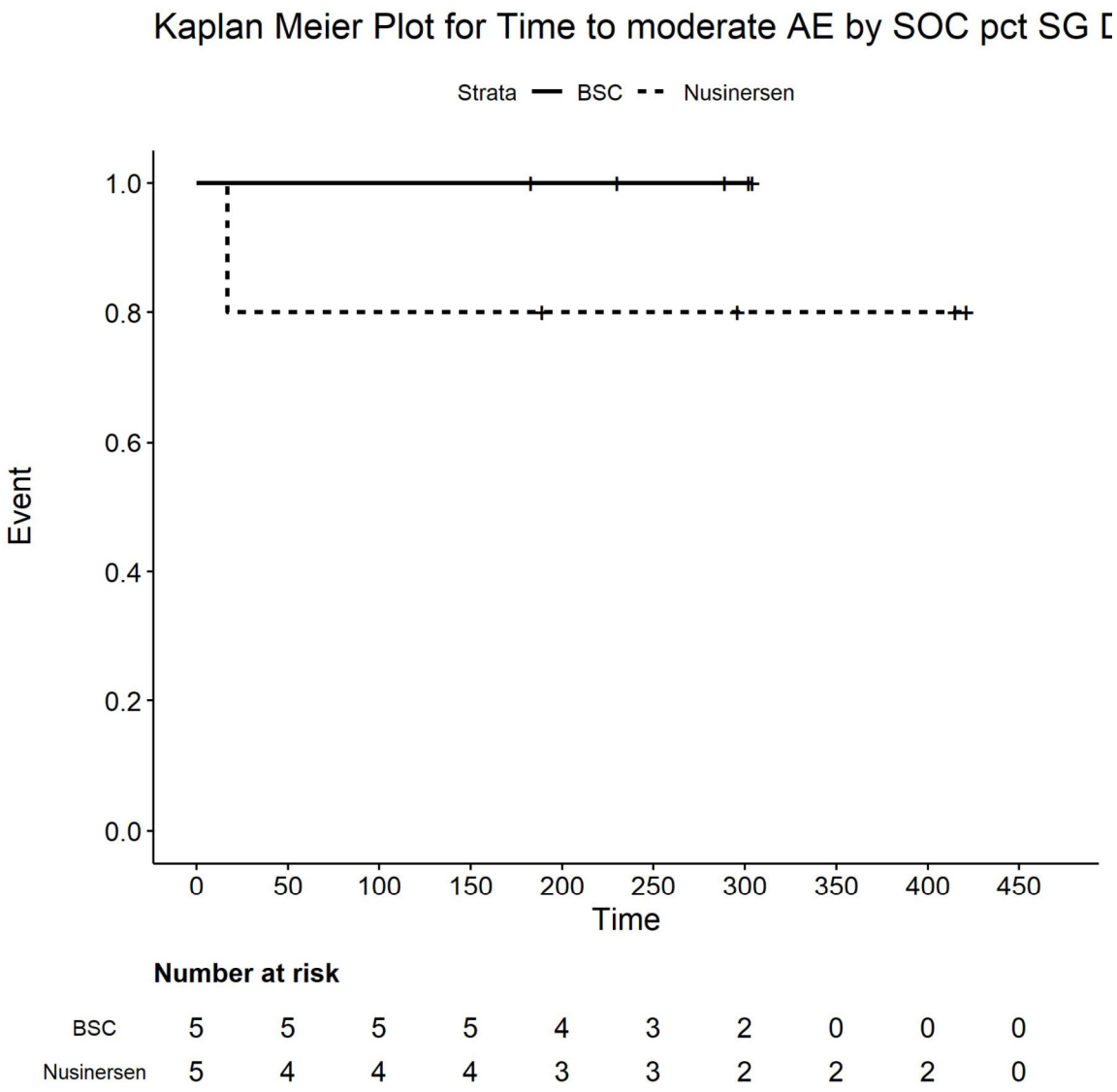
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



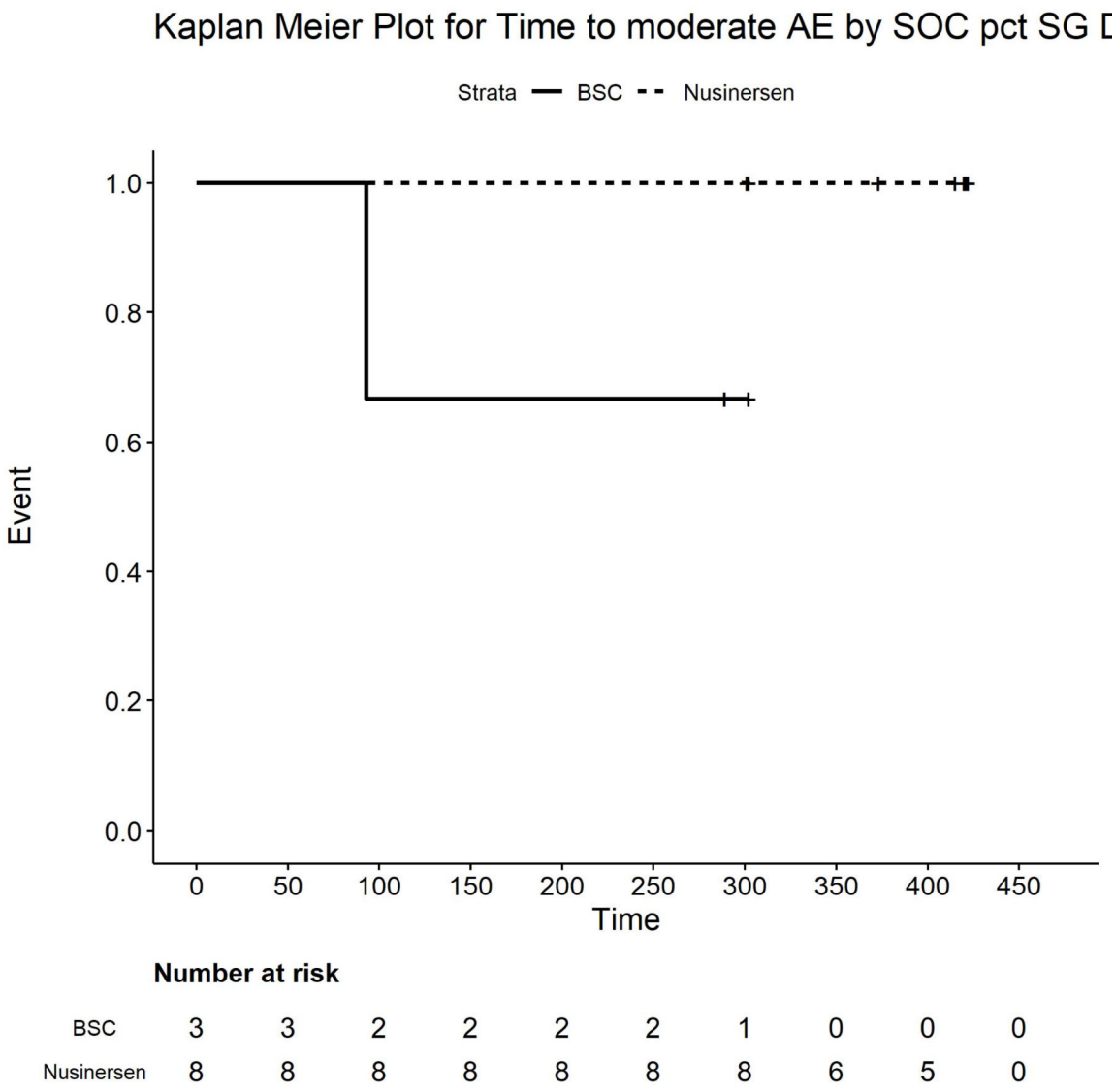
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



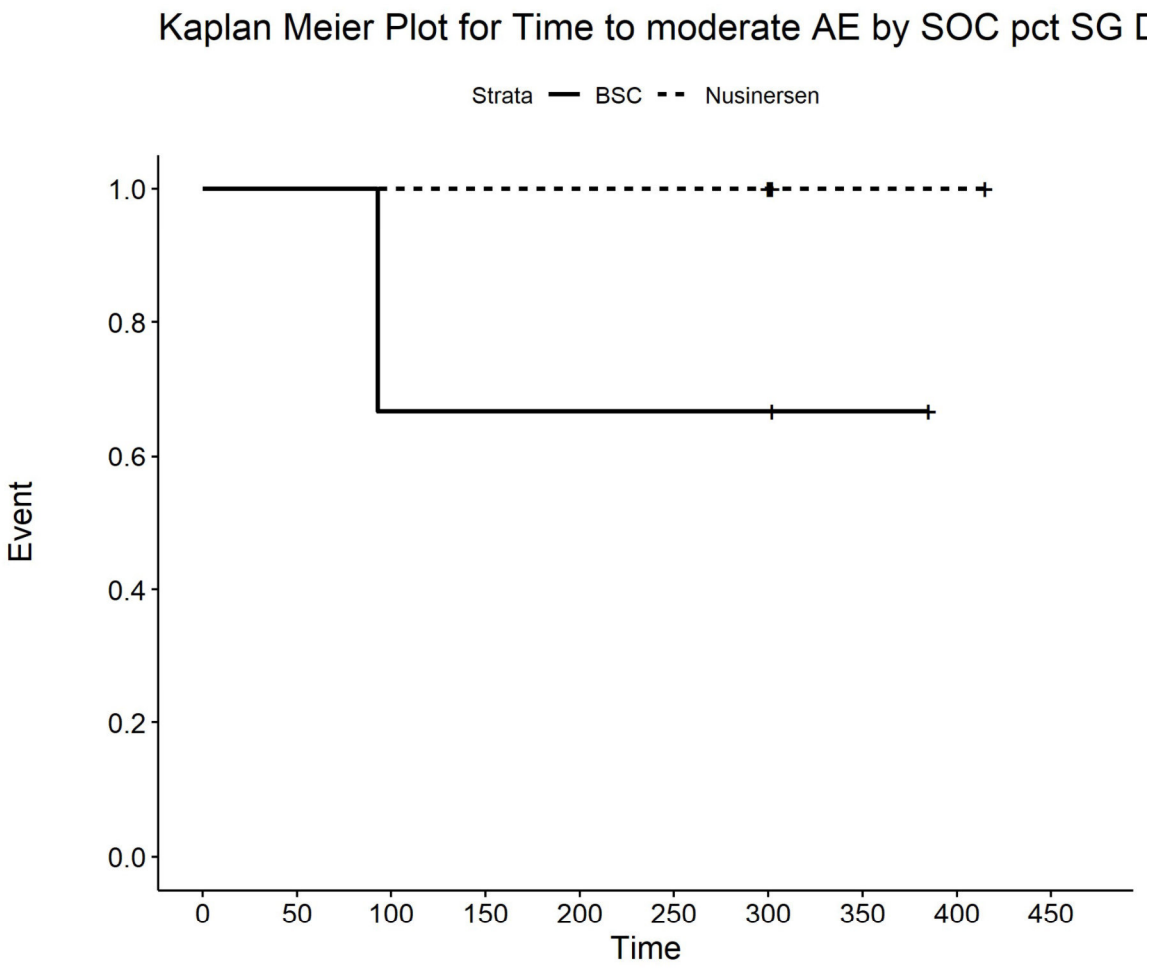
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	2	2	2	0



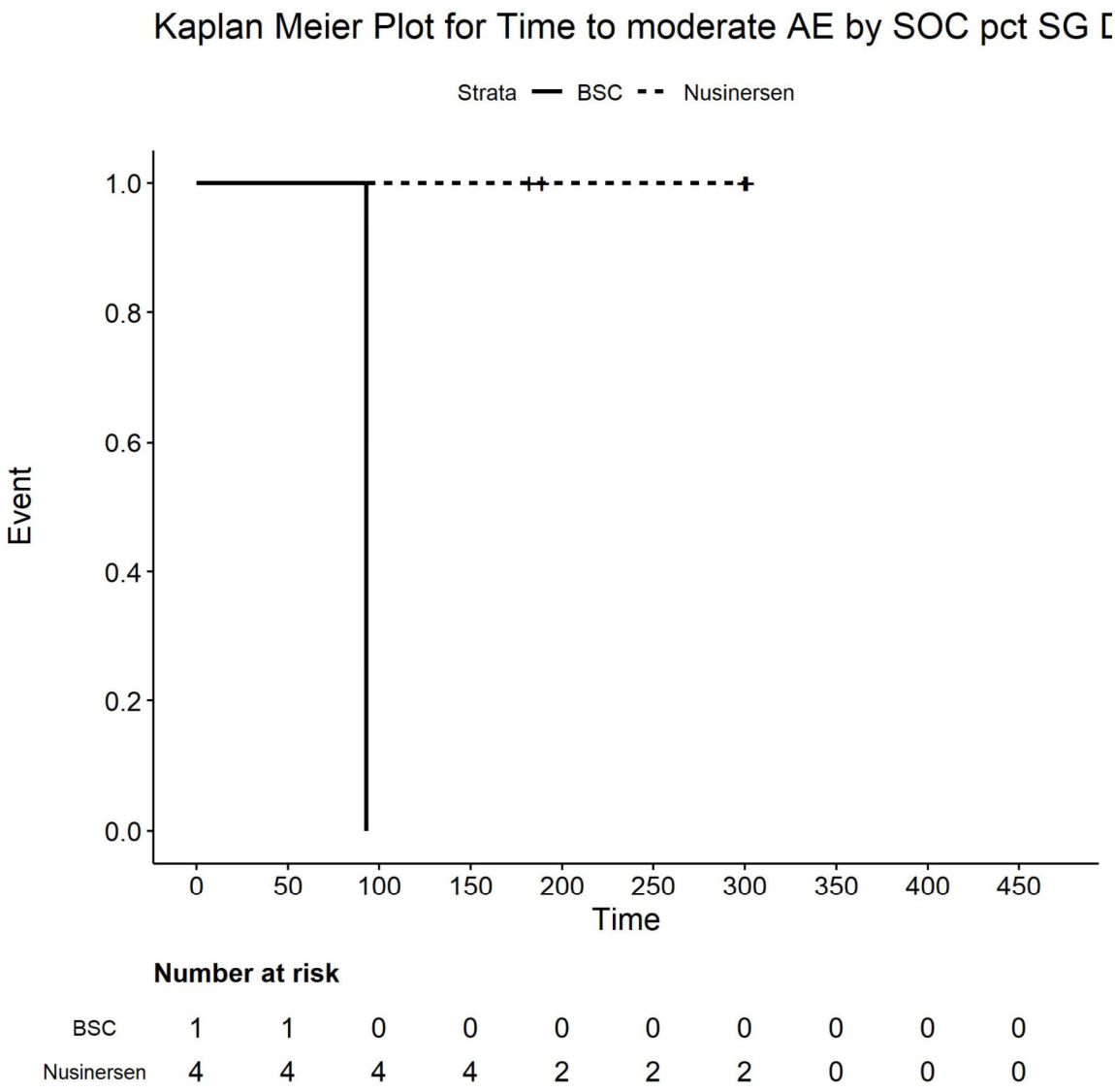
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



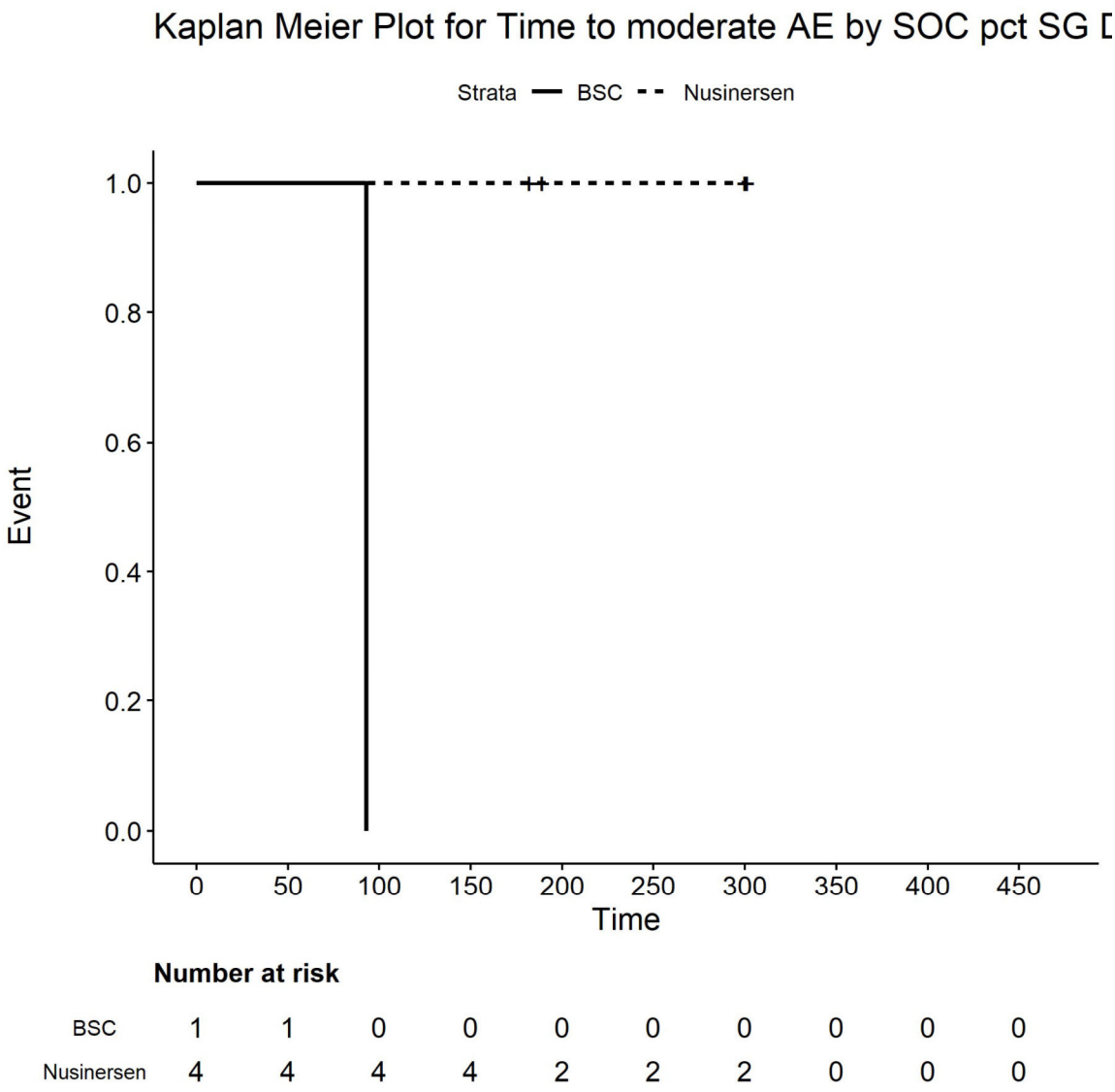
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



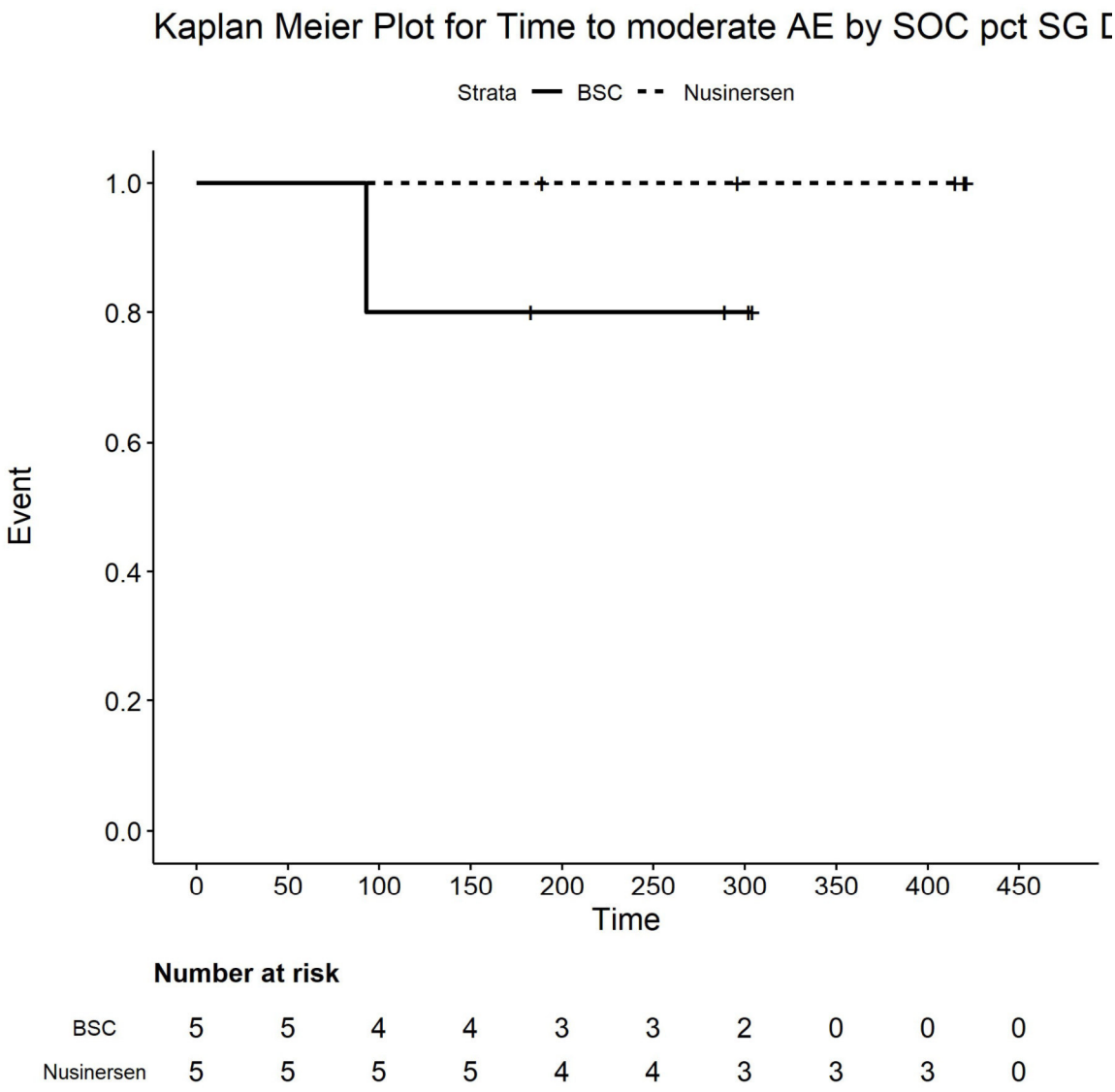
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



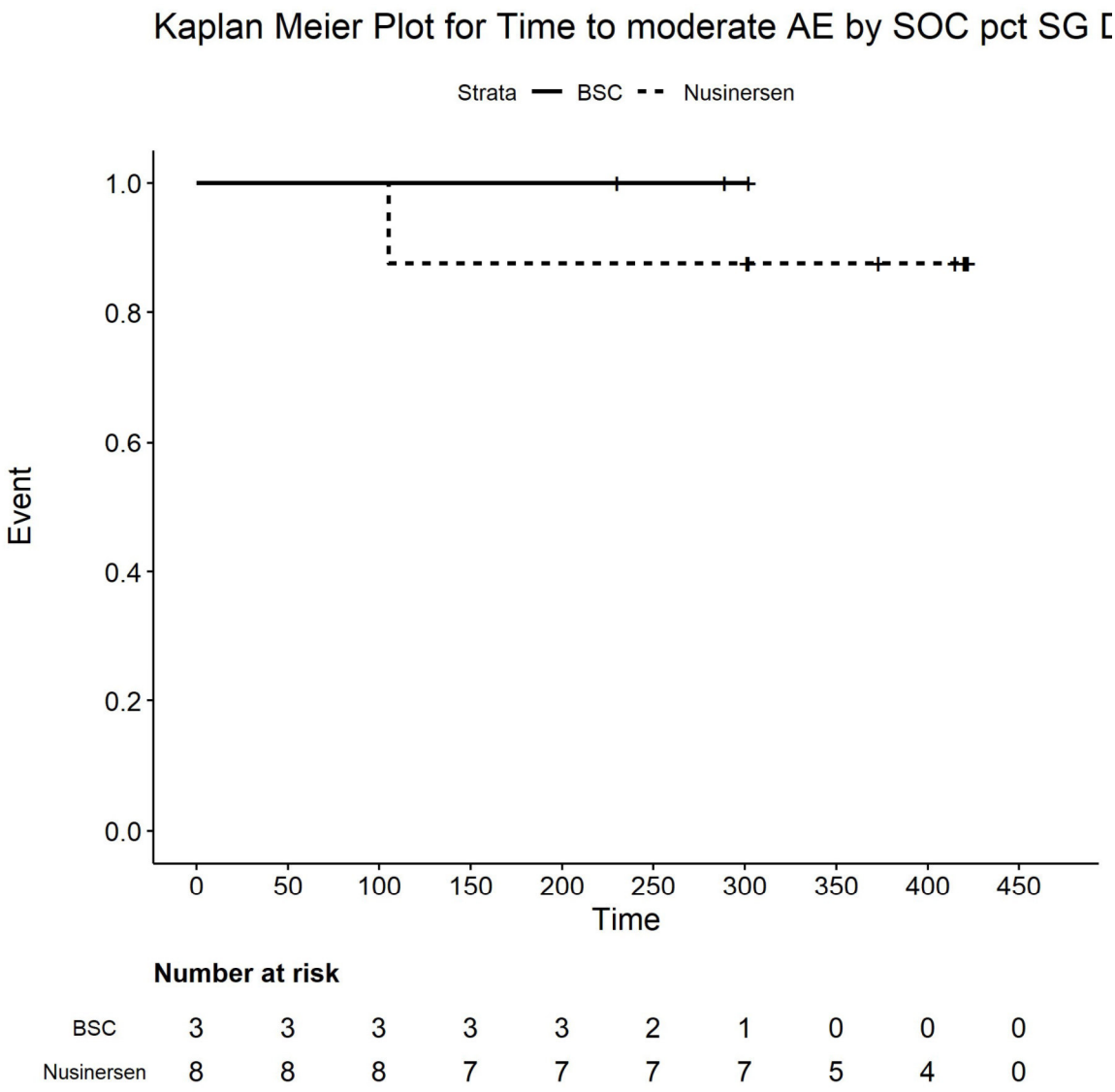
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



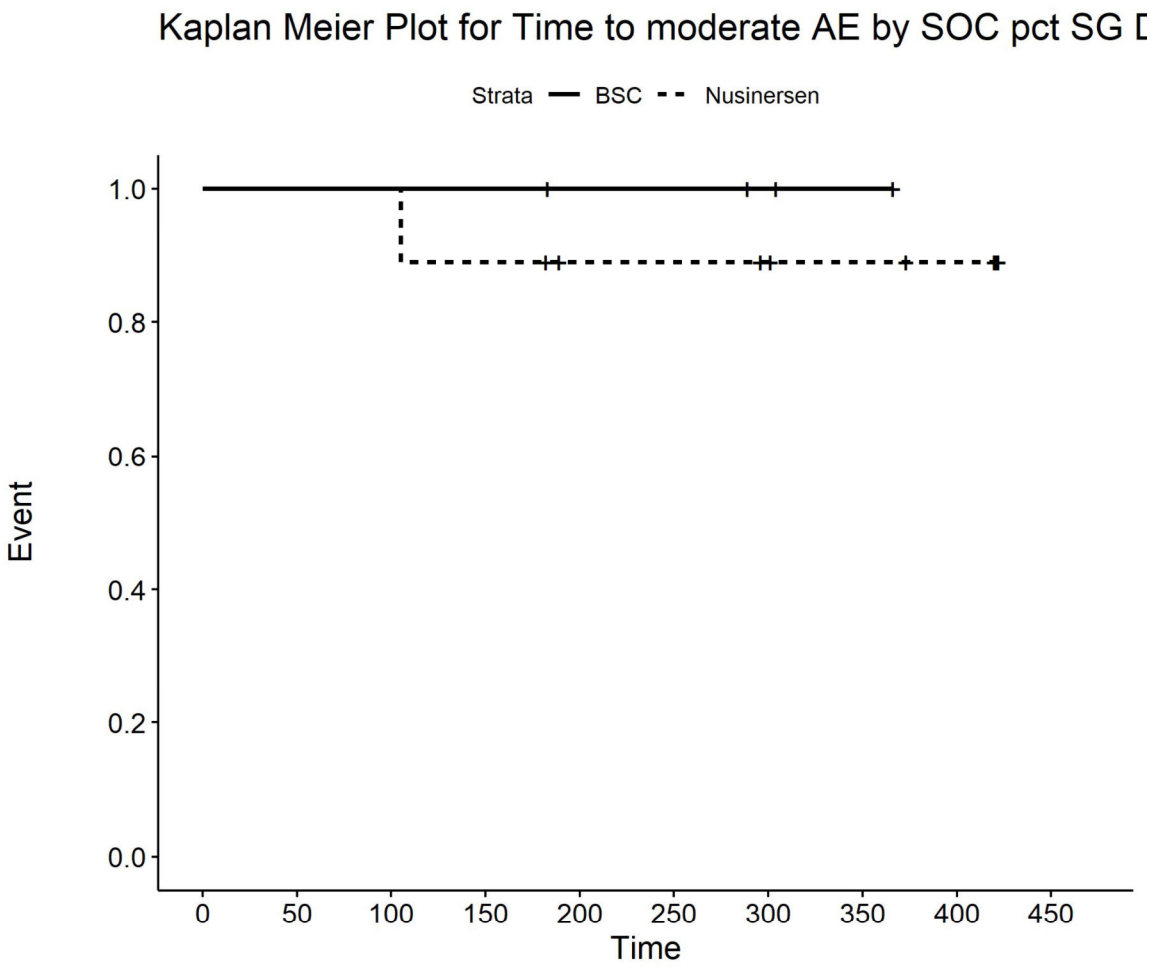
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



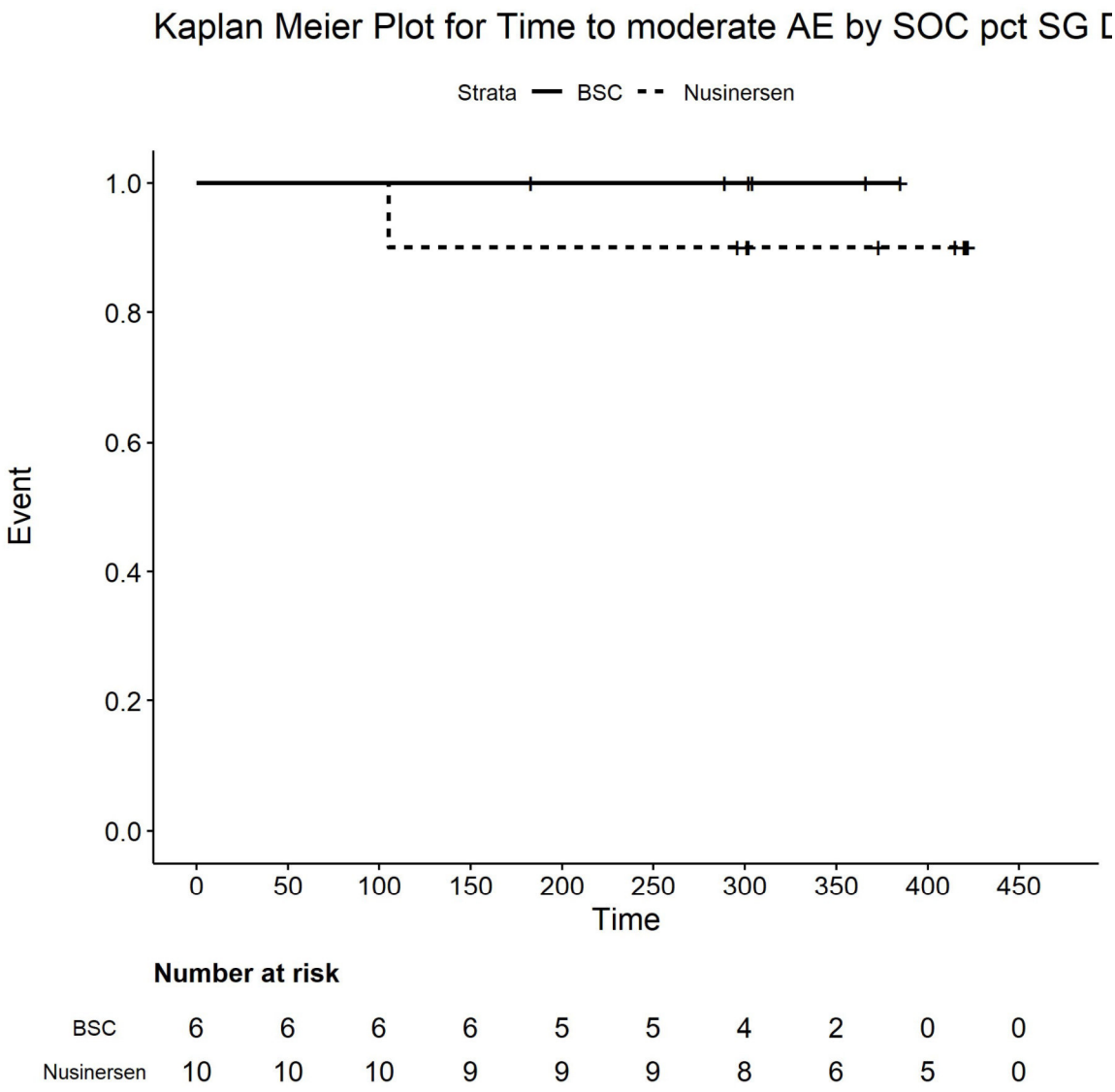
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



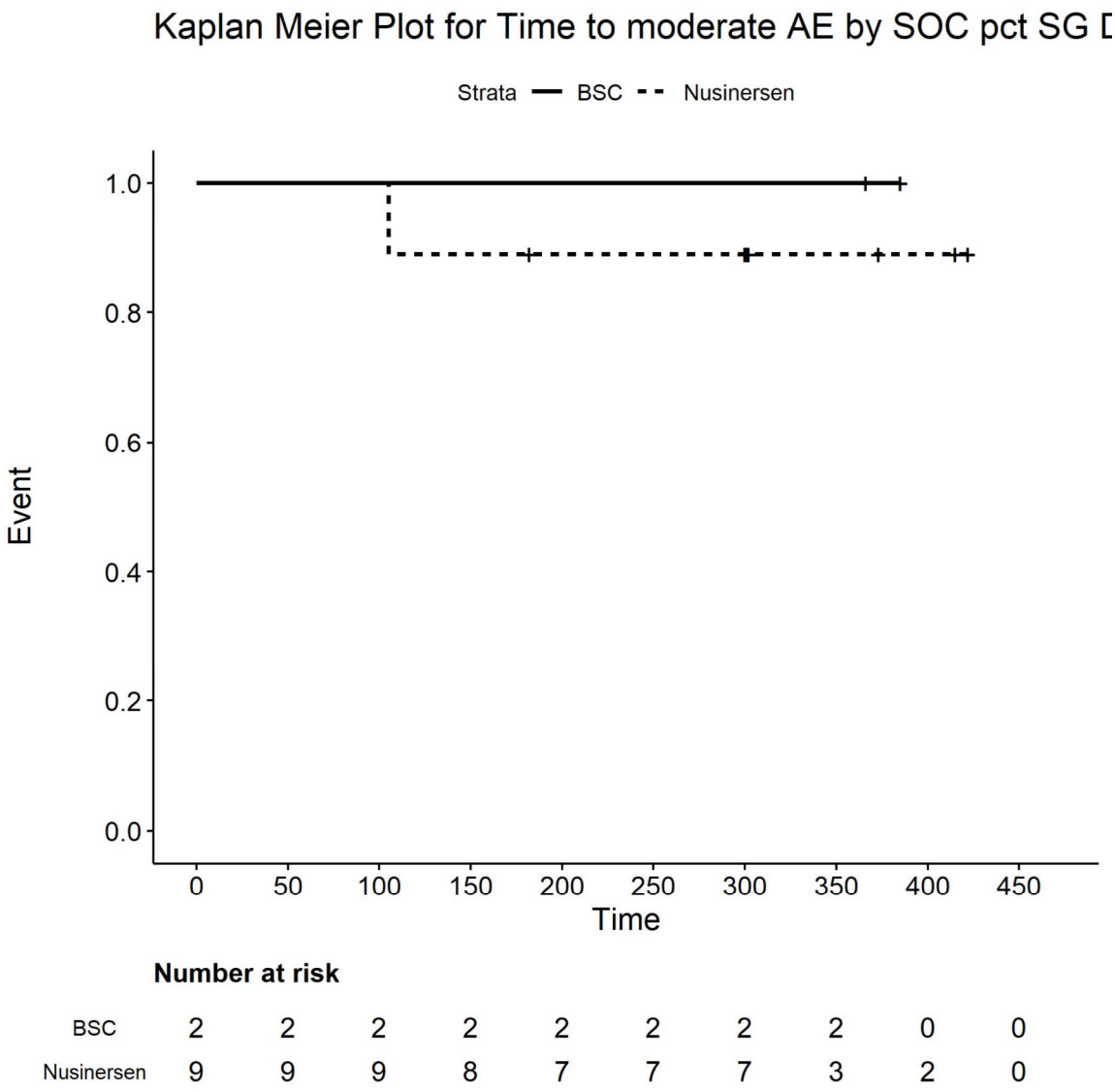
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



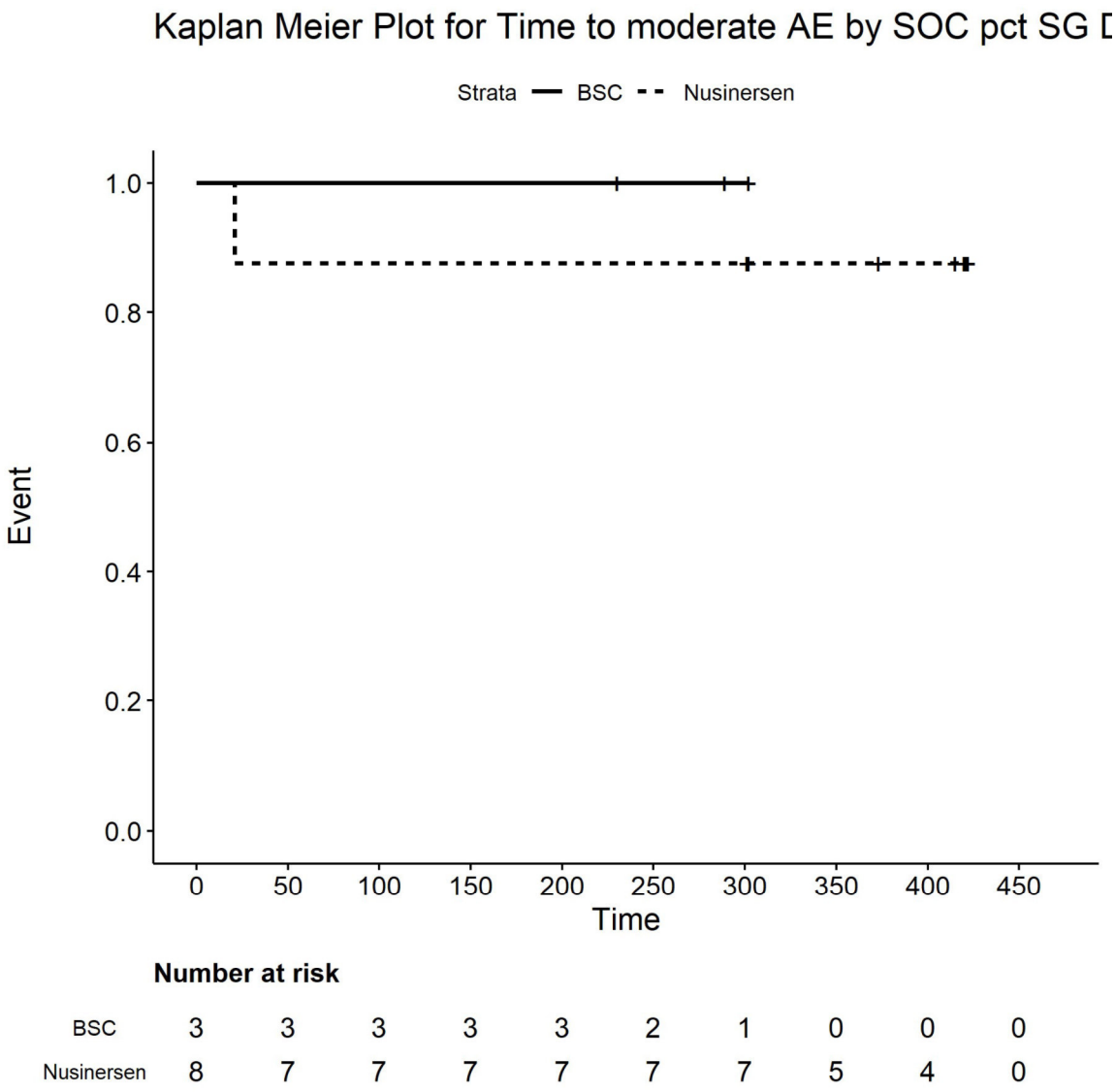
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



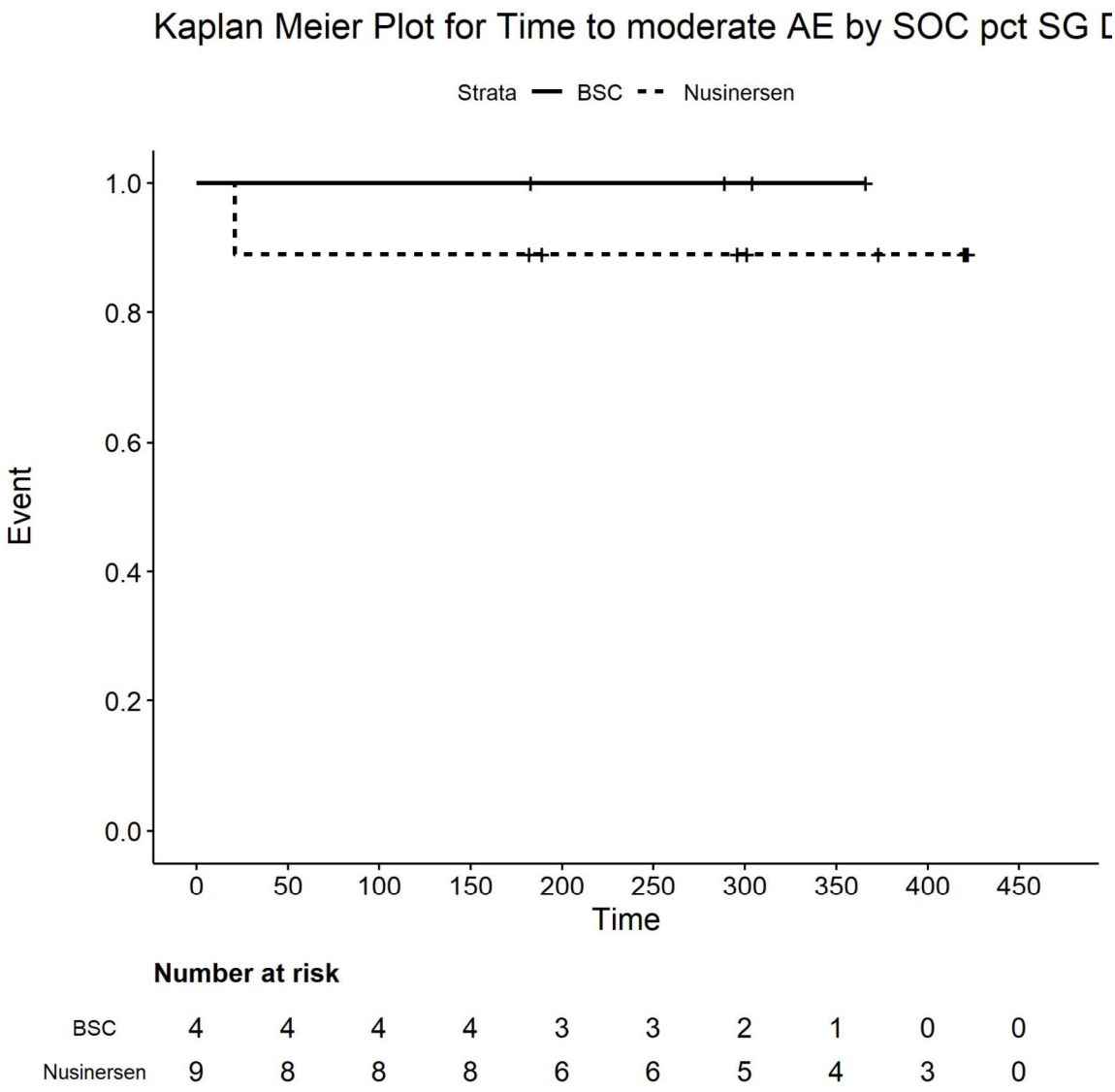
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



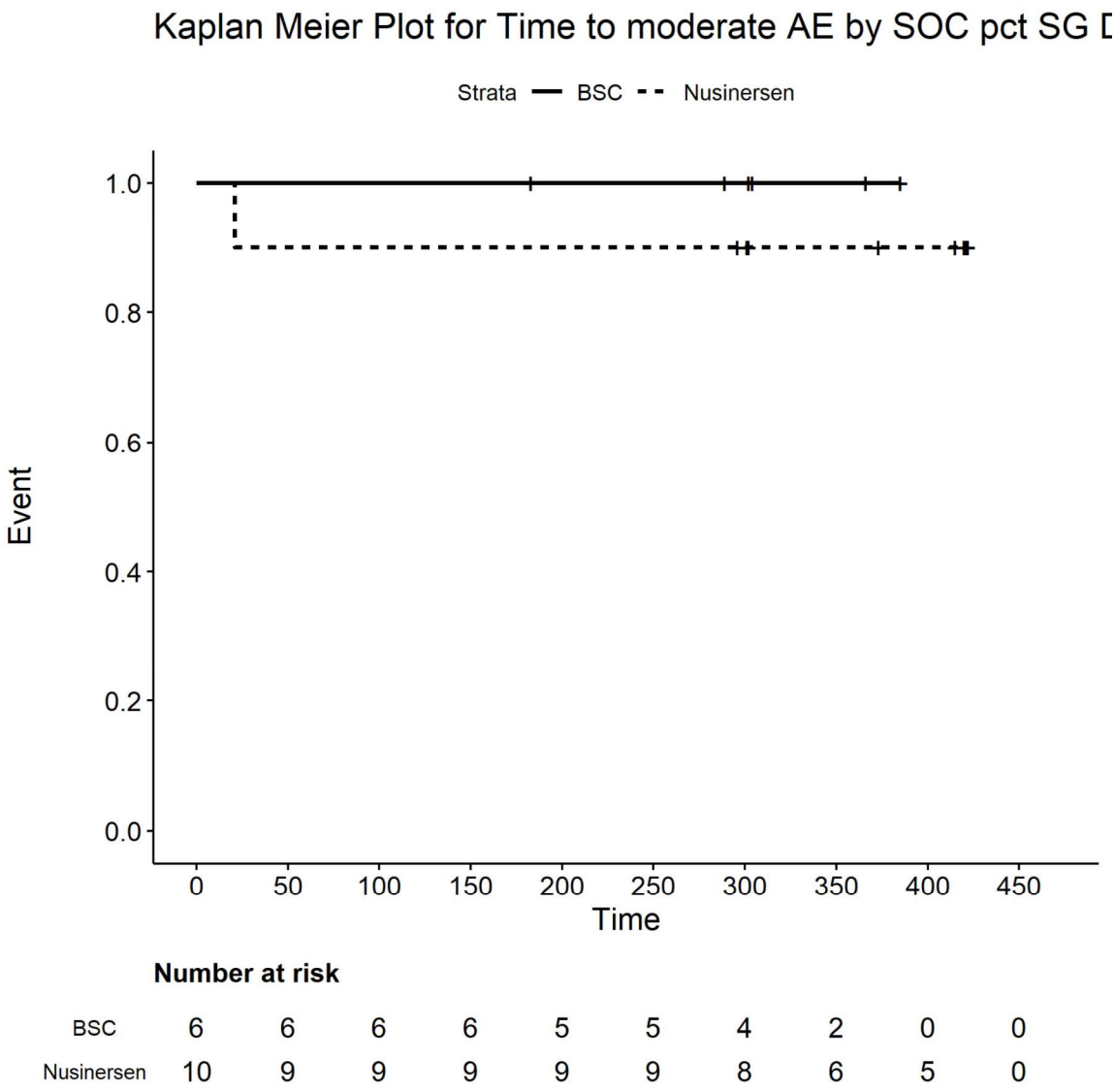
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



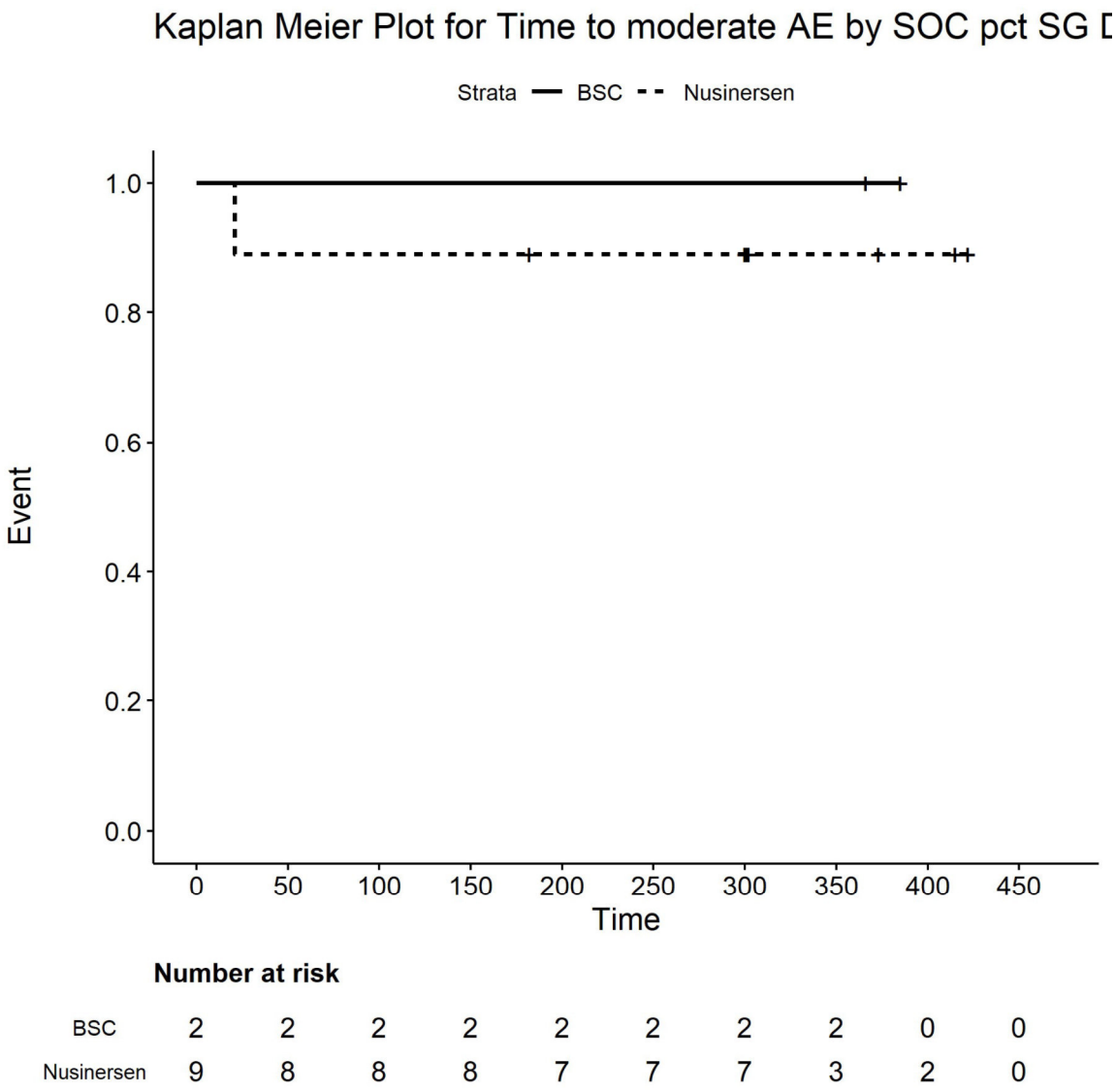
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



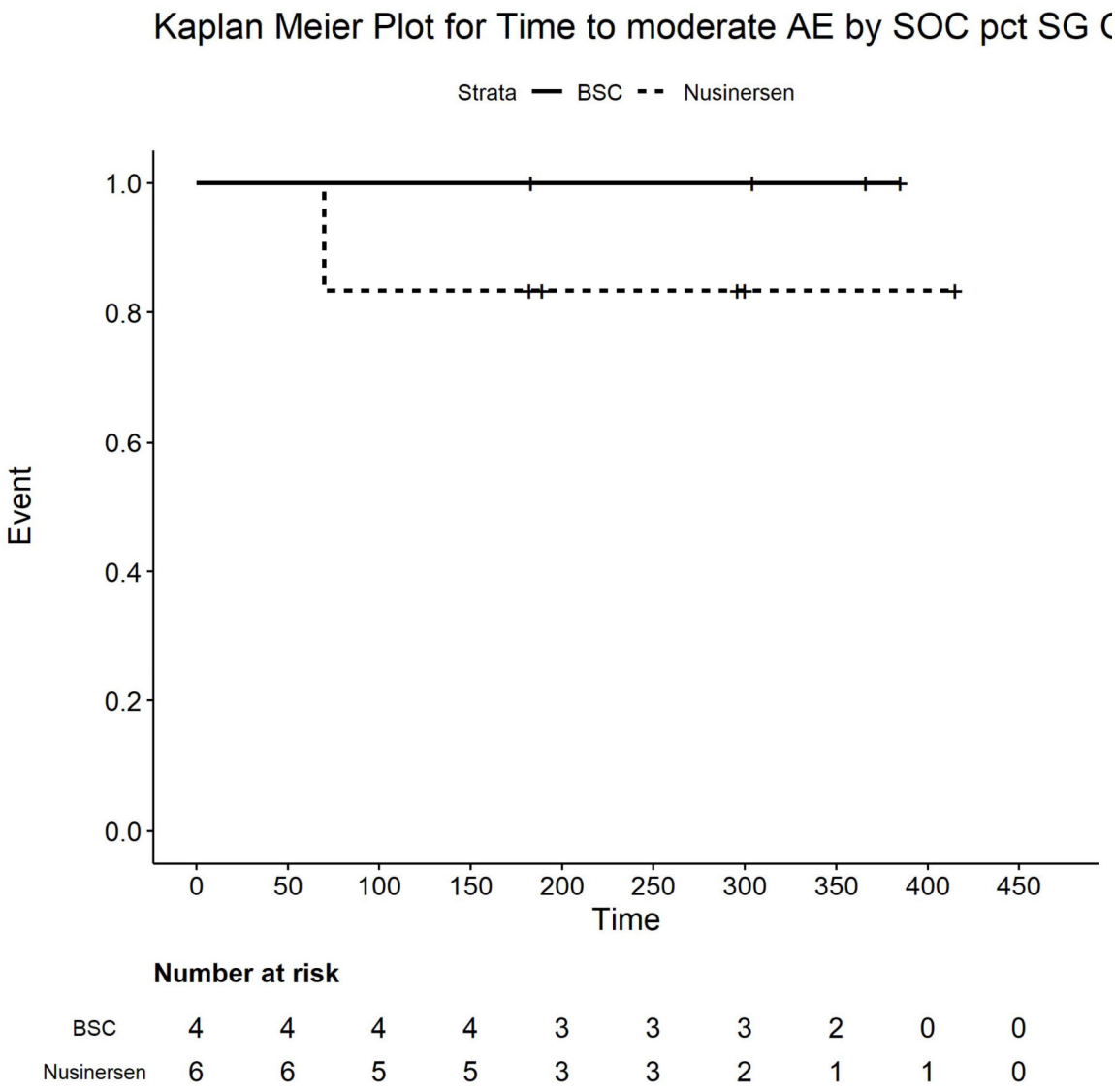
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



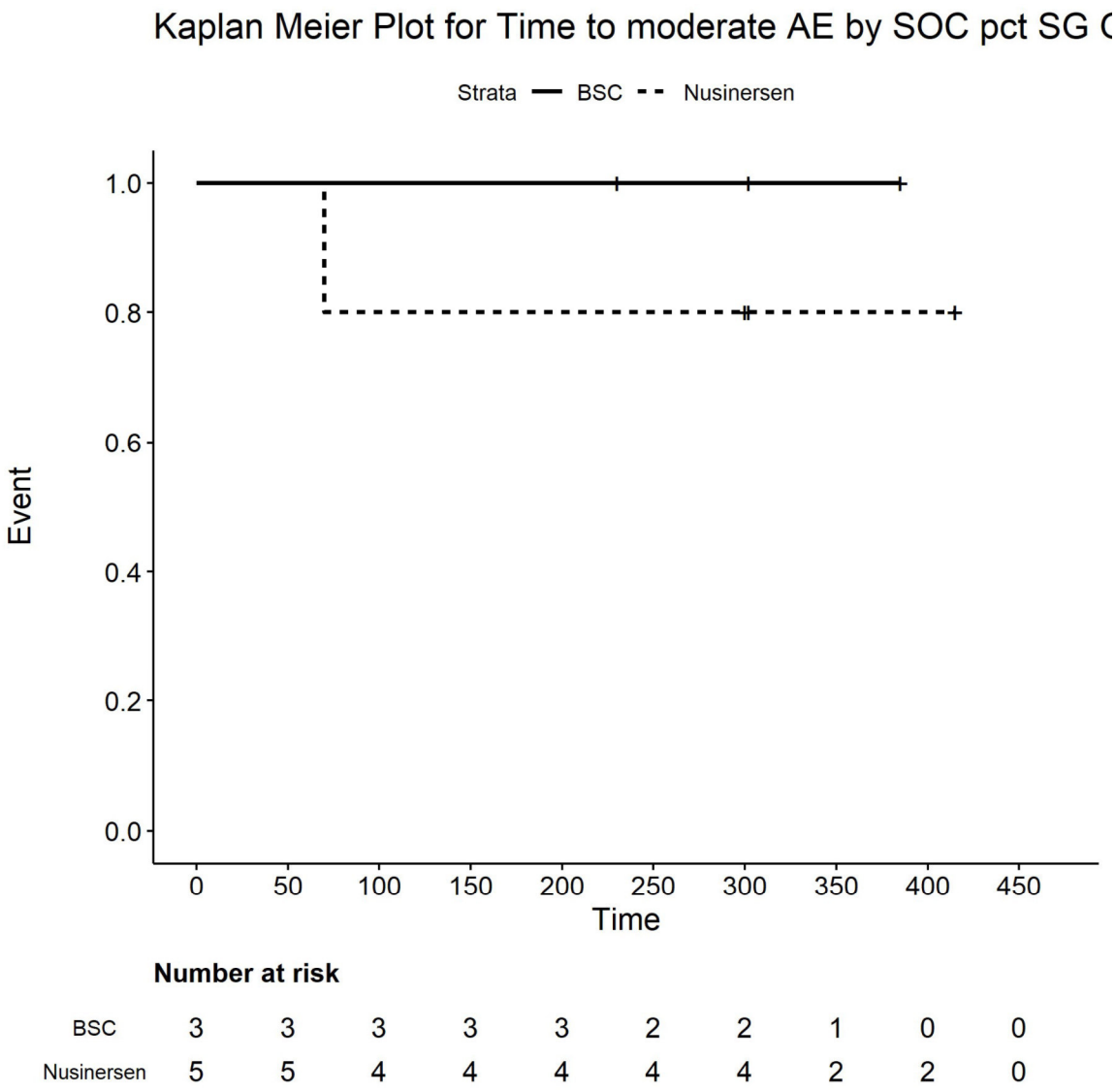
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	2	0



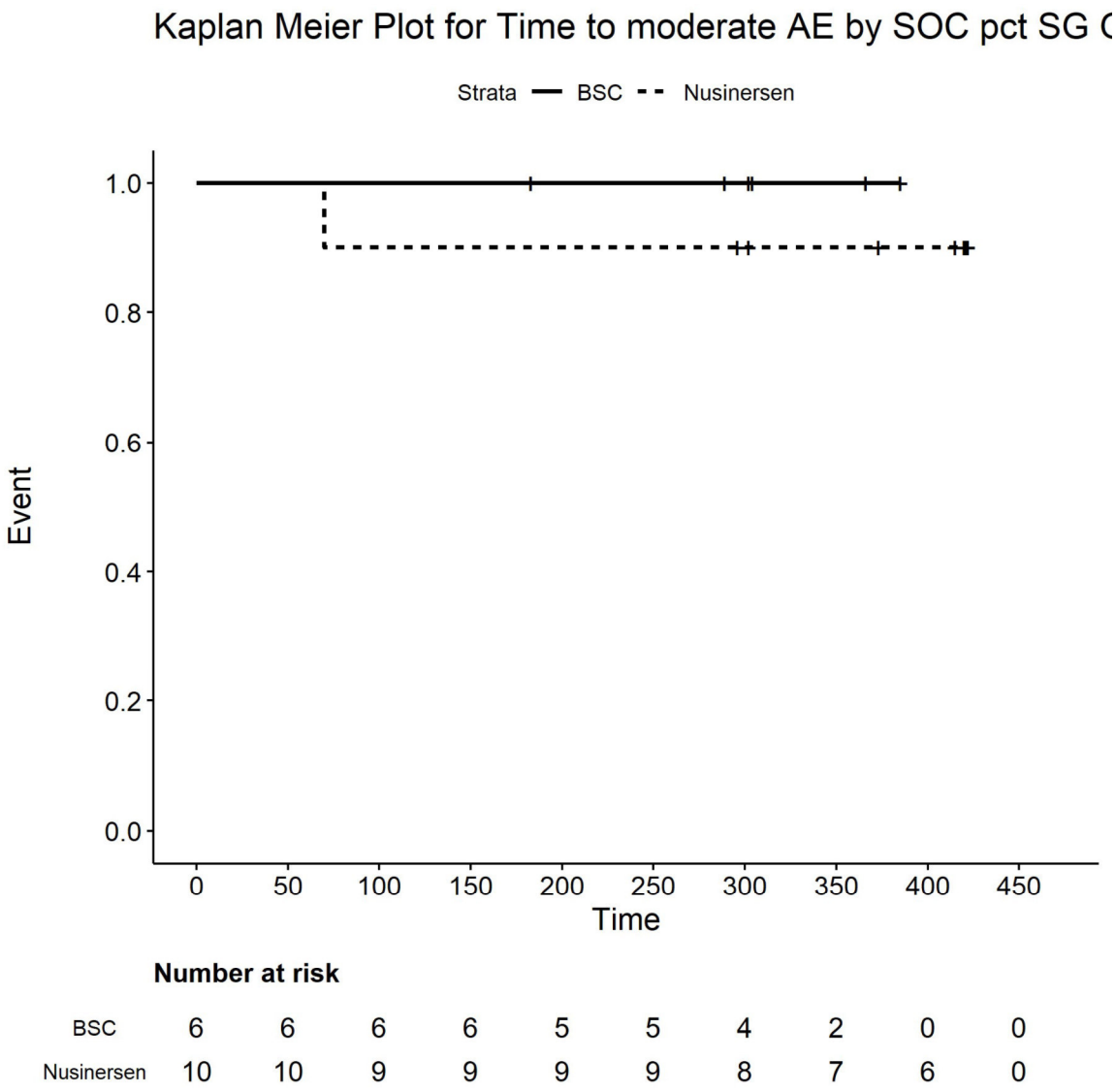
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



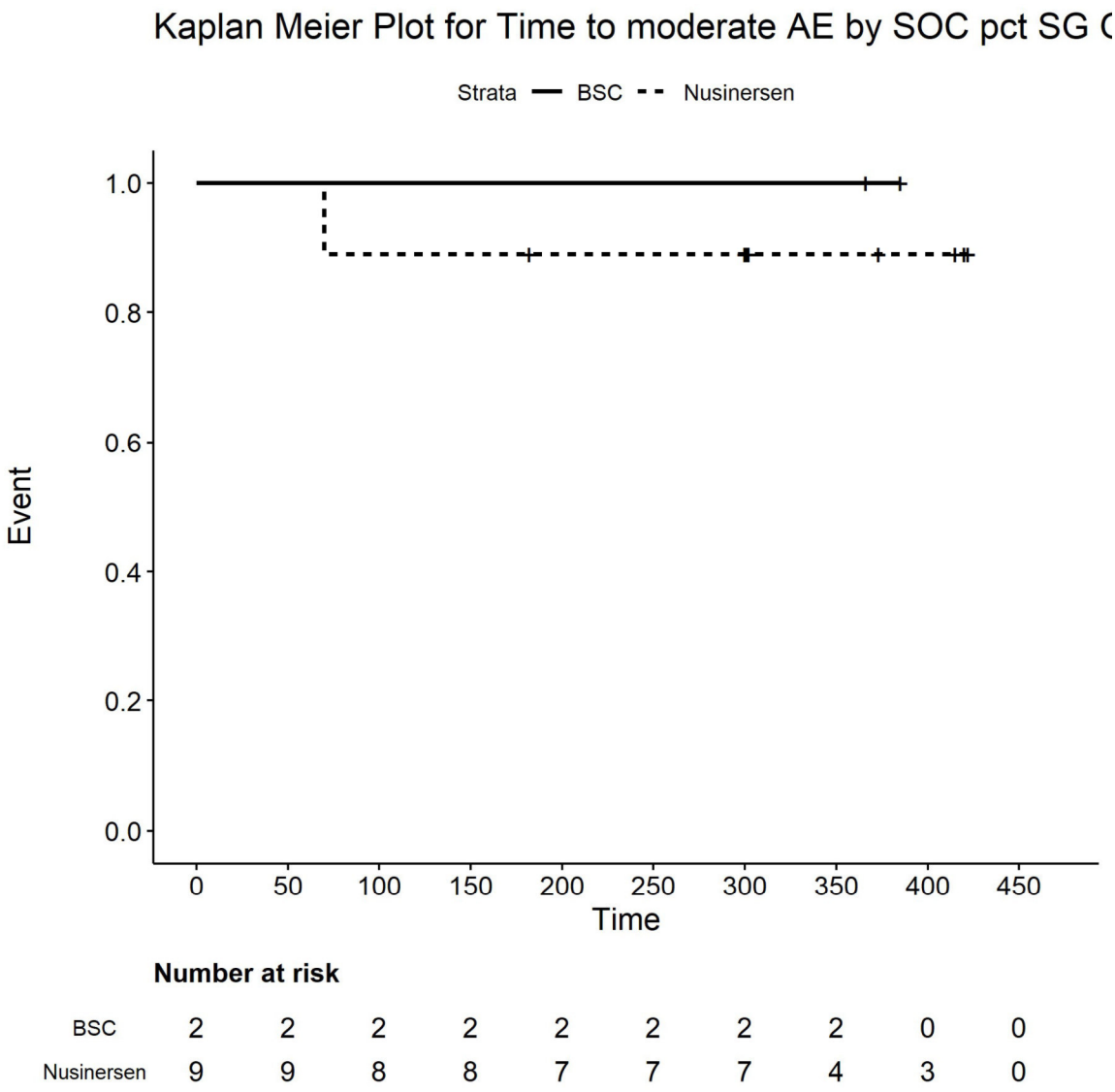
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



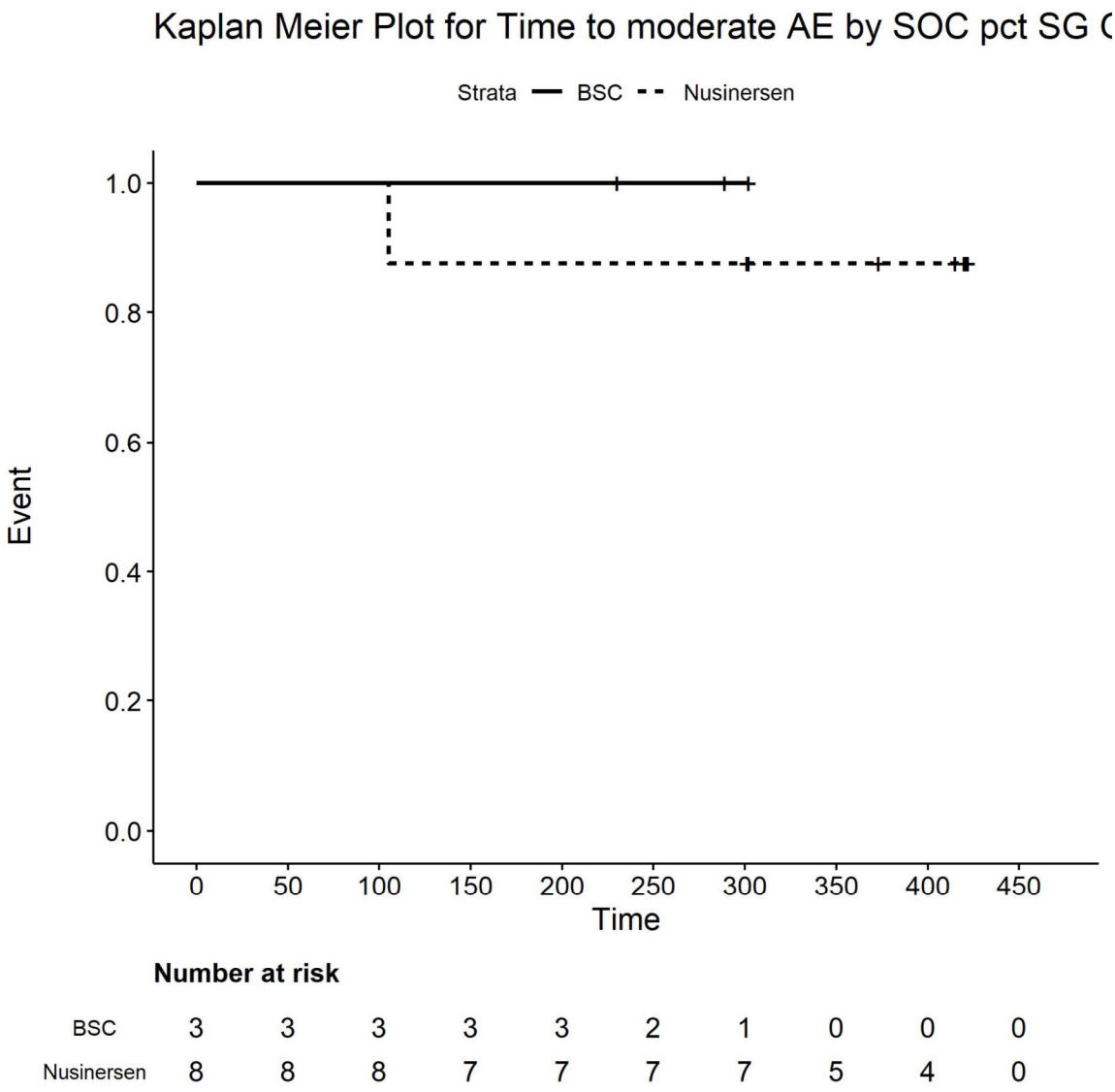
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



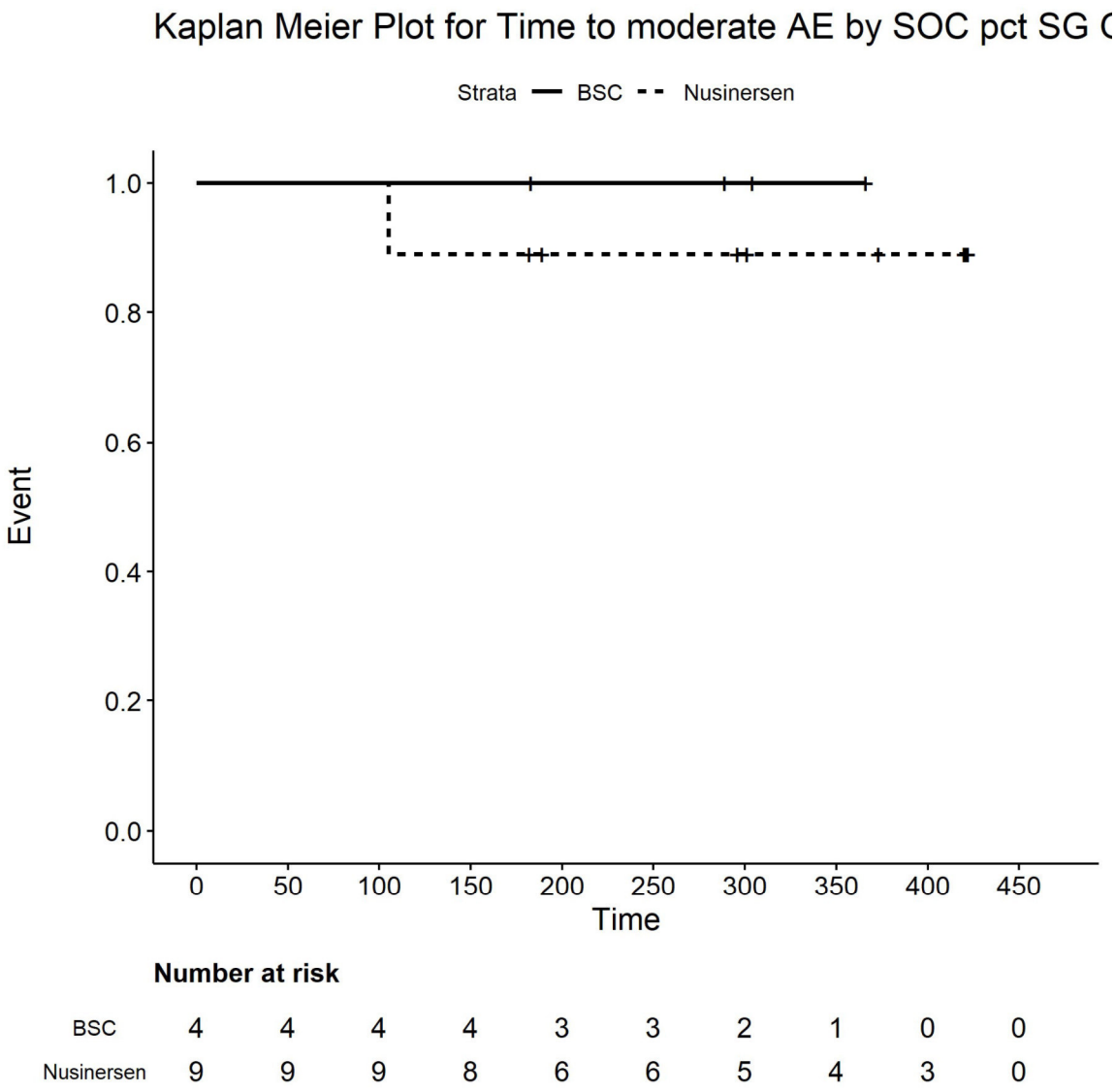
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



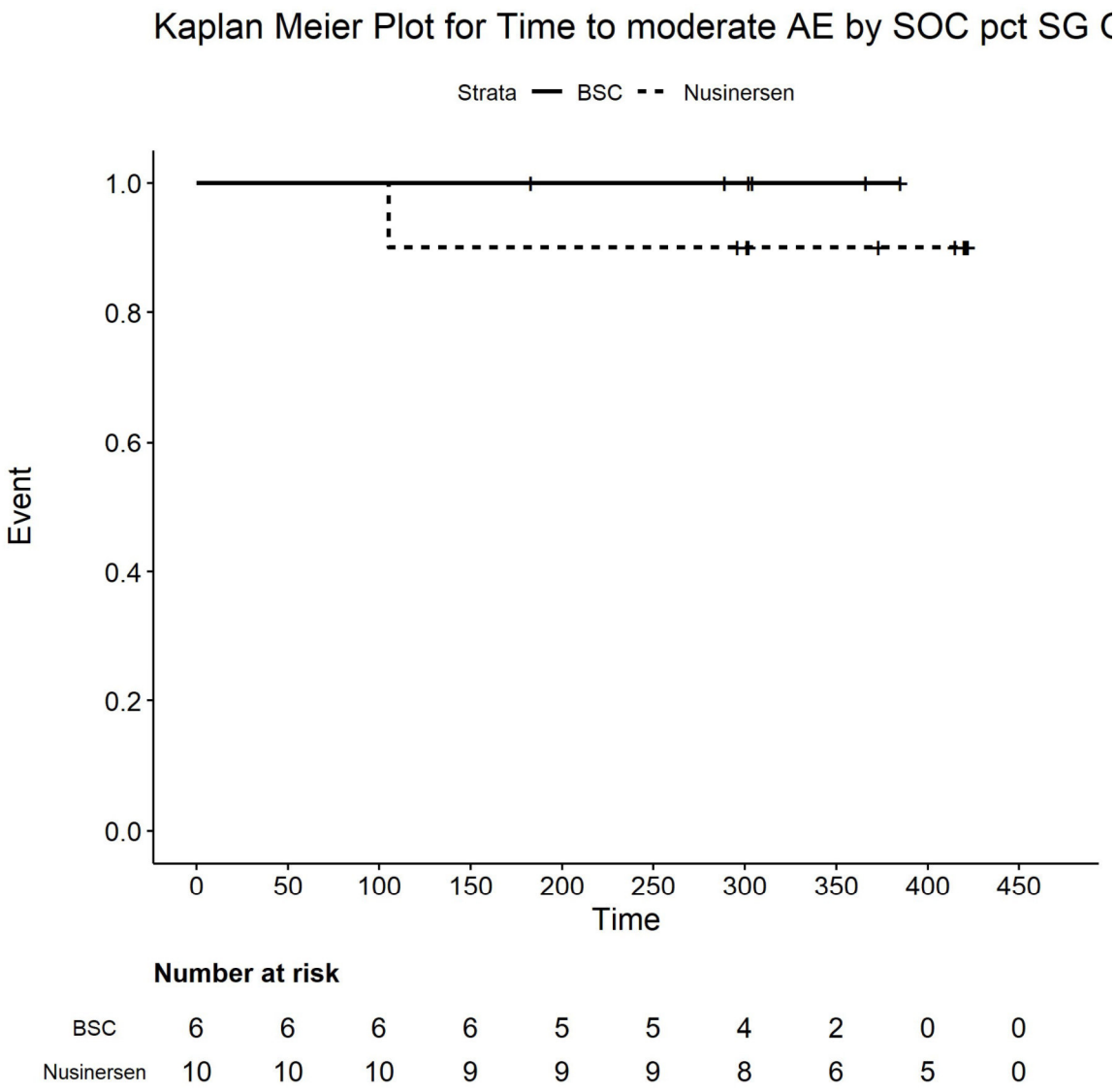
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



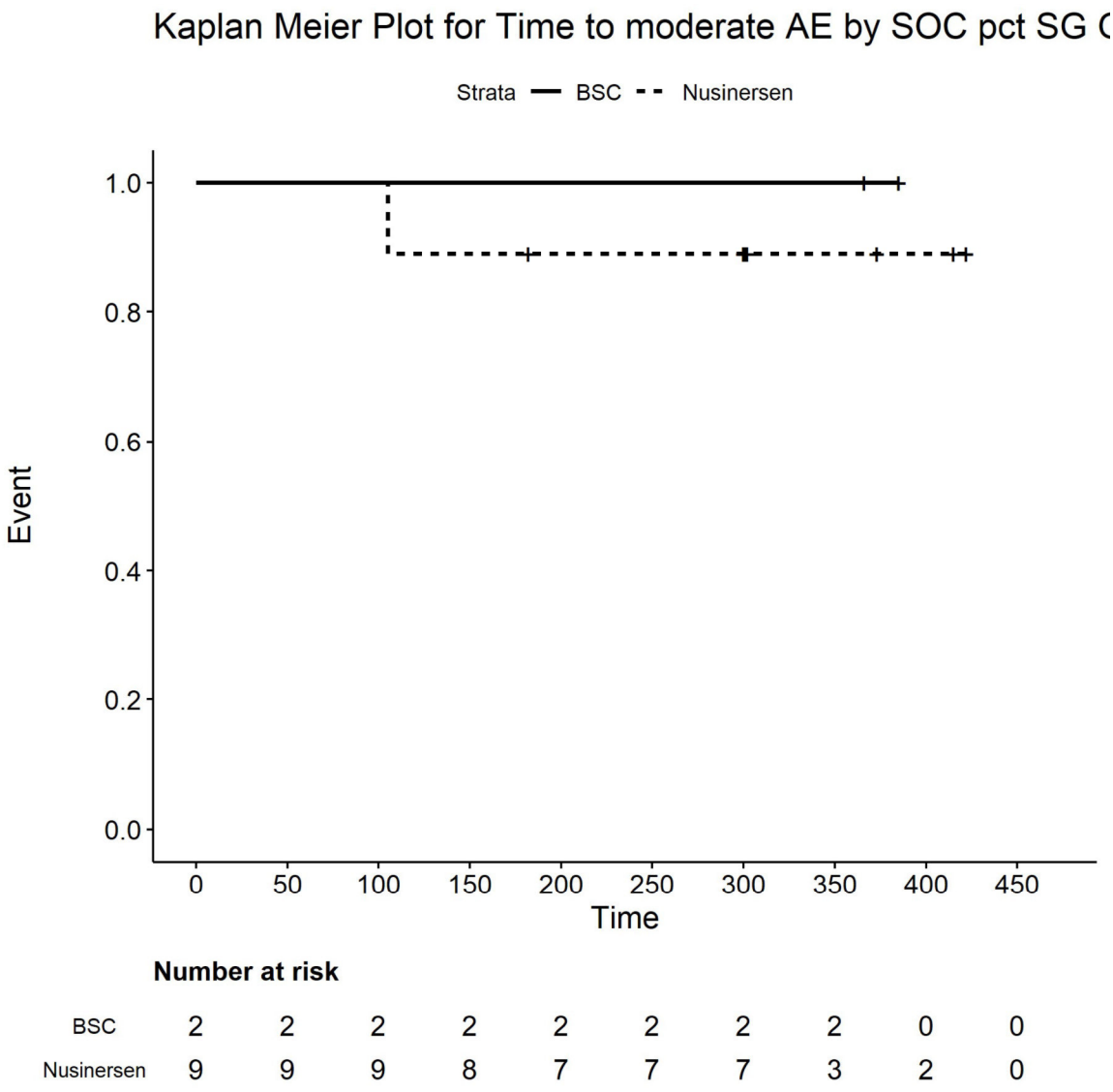
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



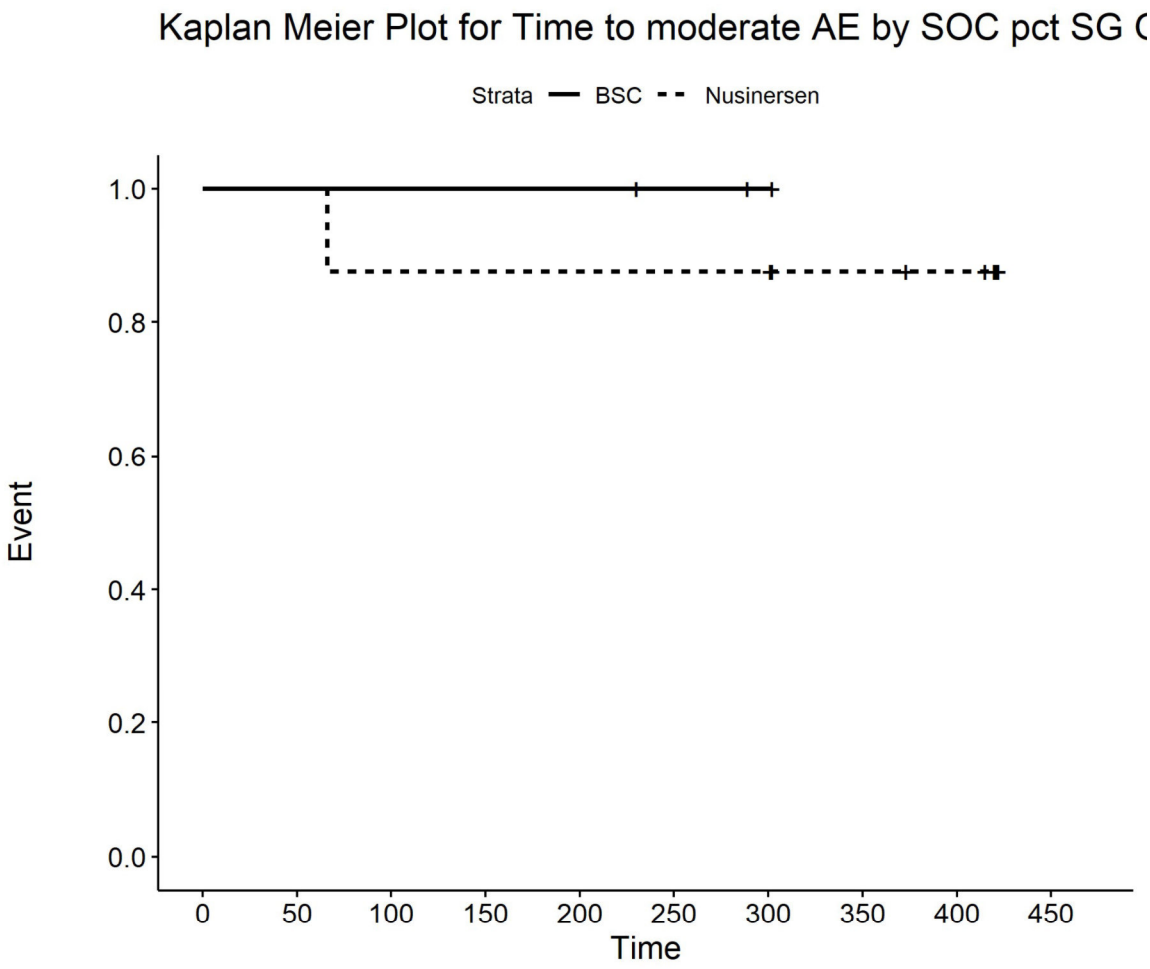
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



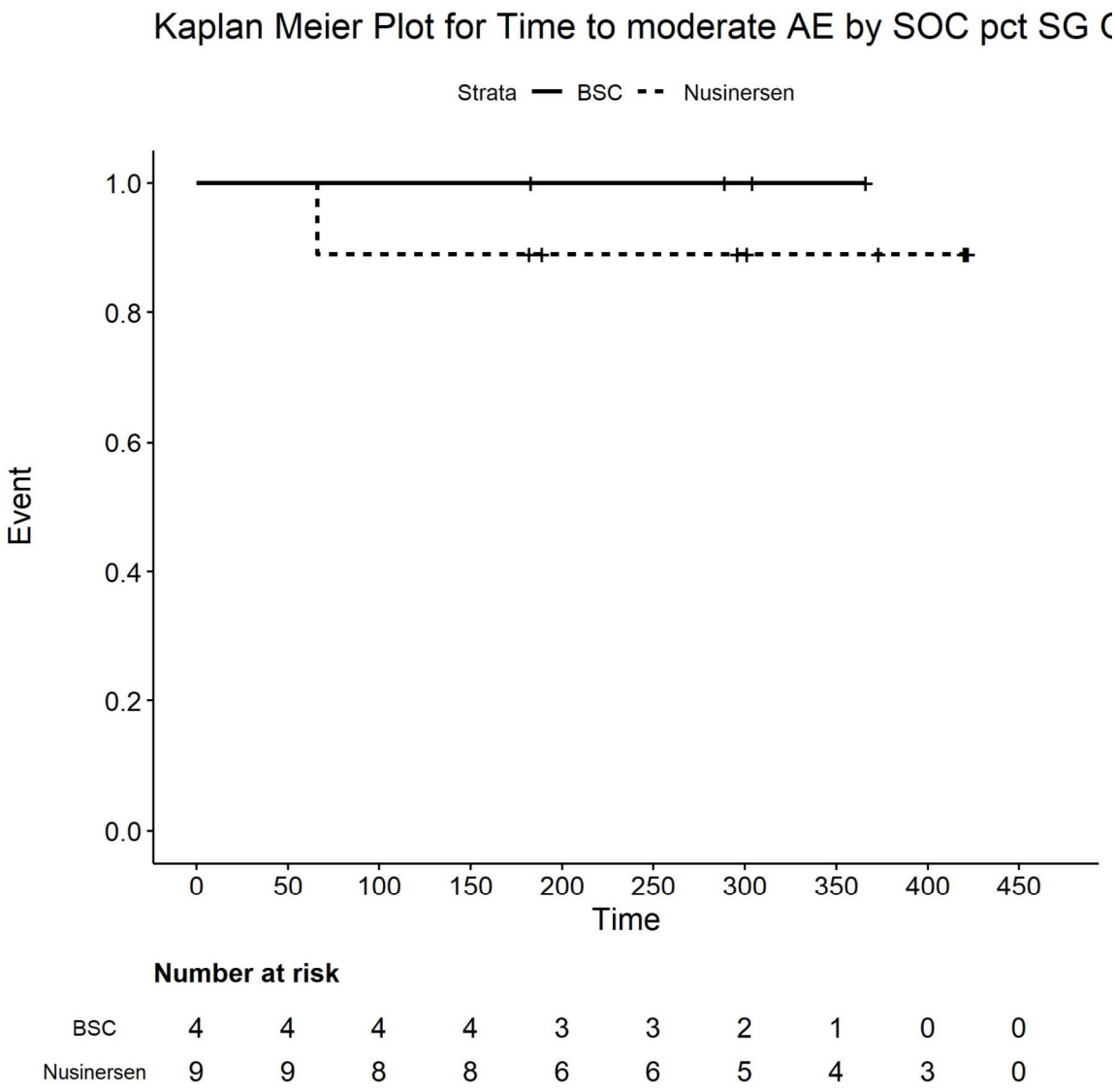
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



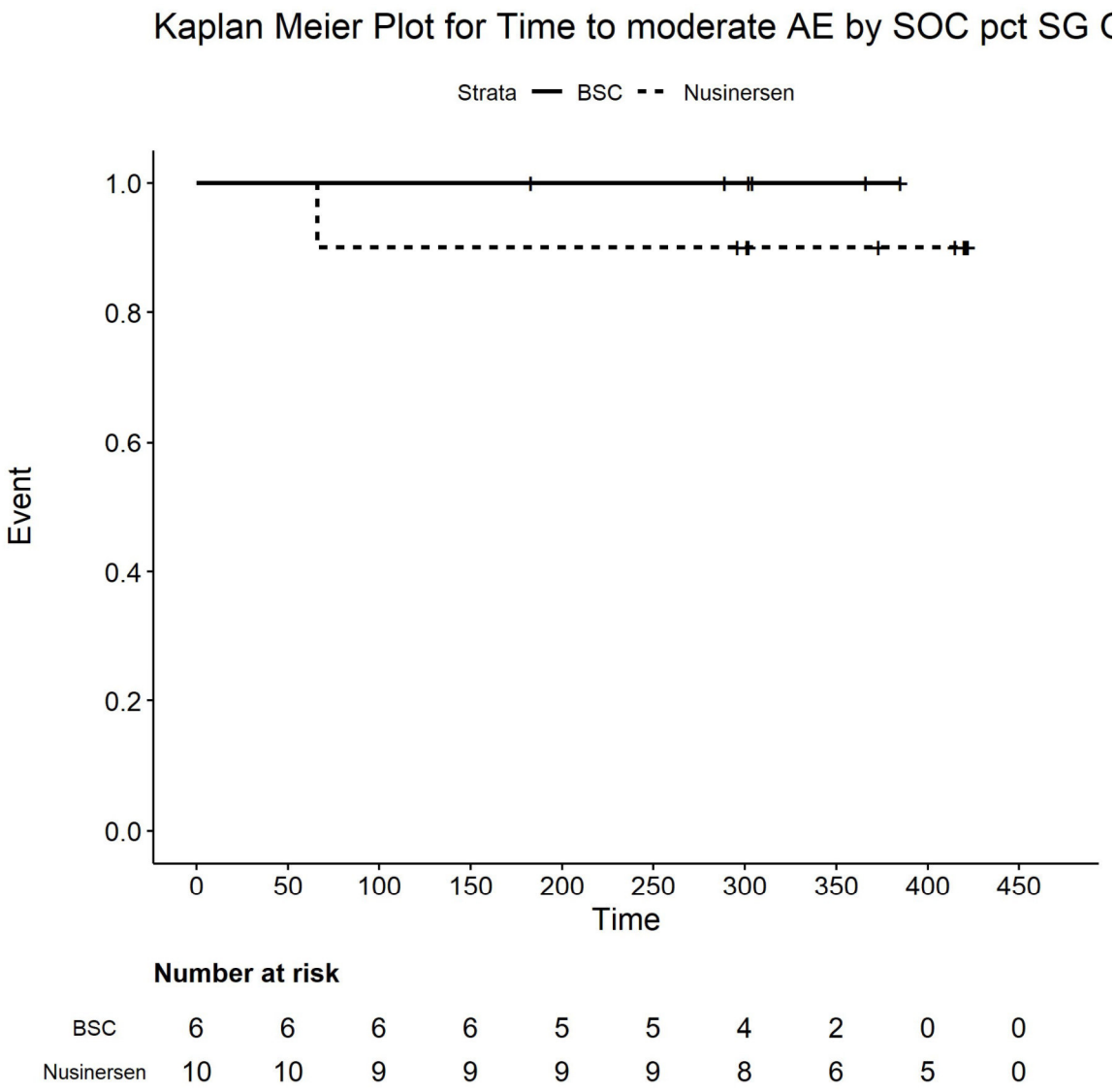
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	4	0



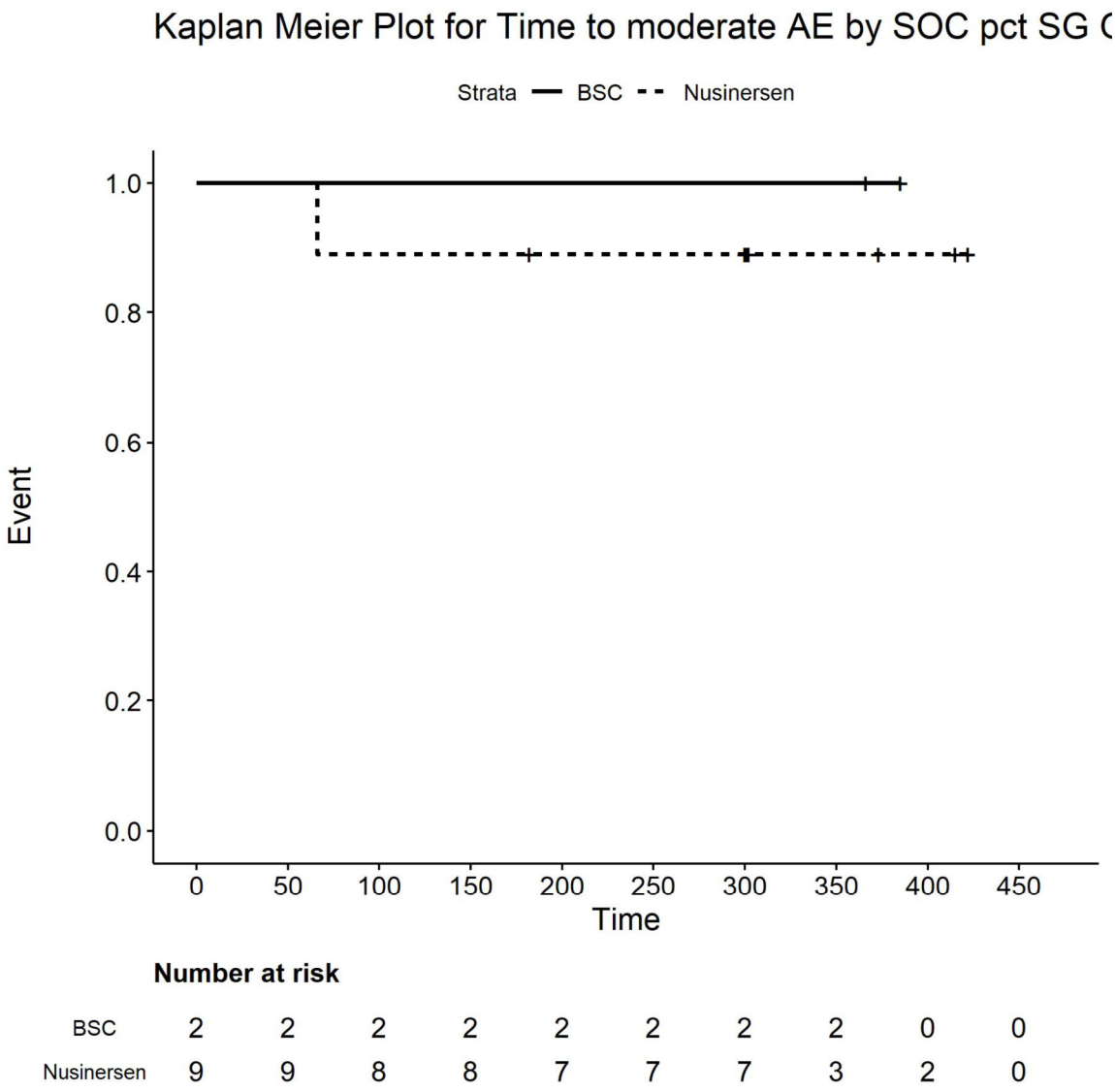
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



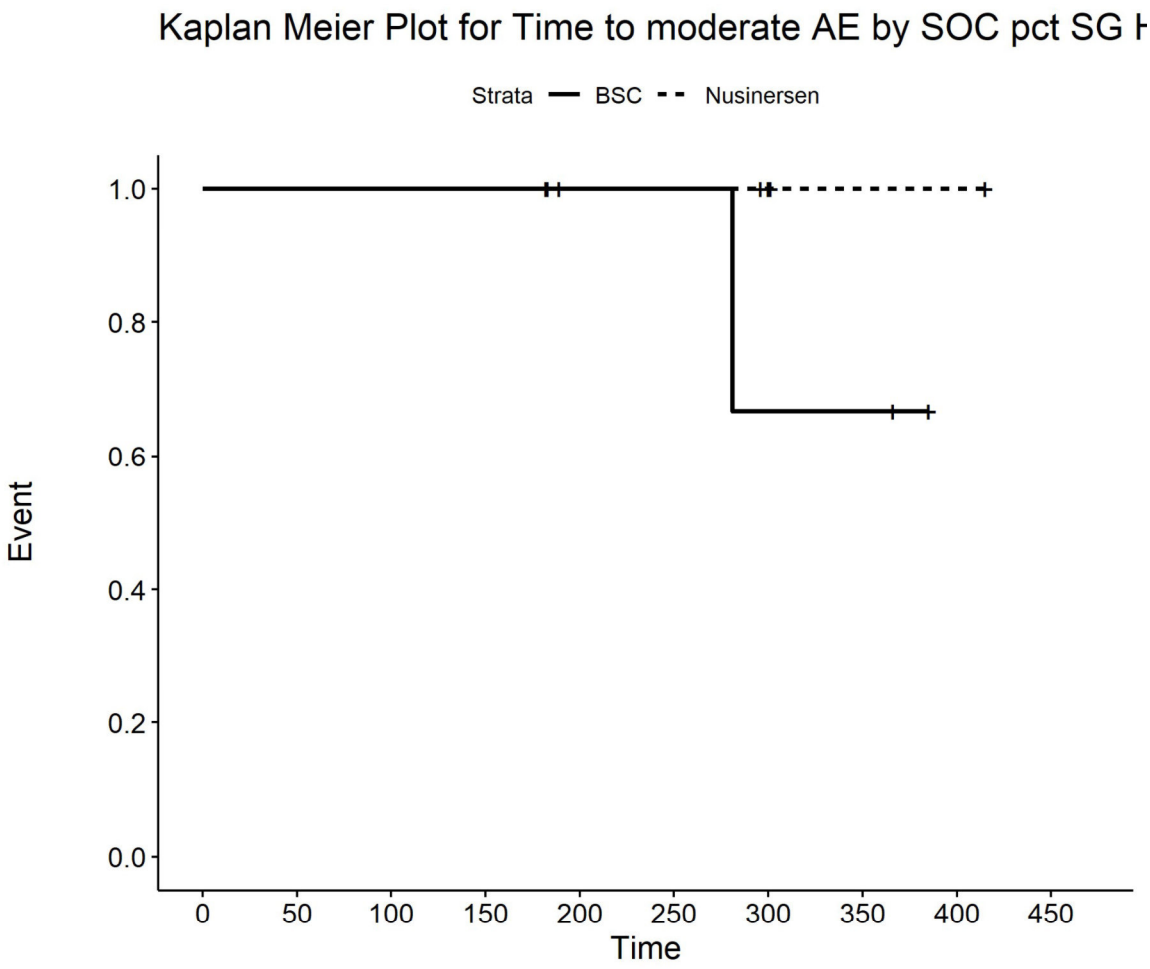
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



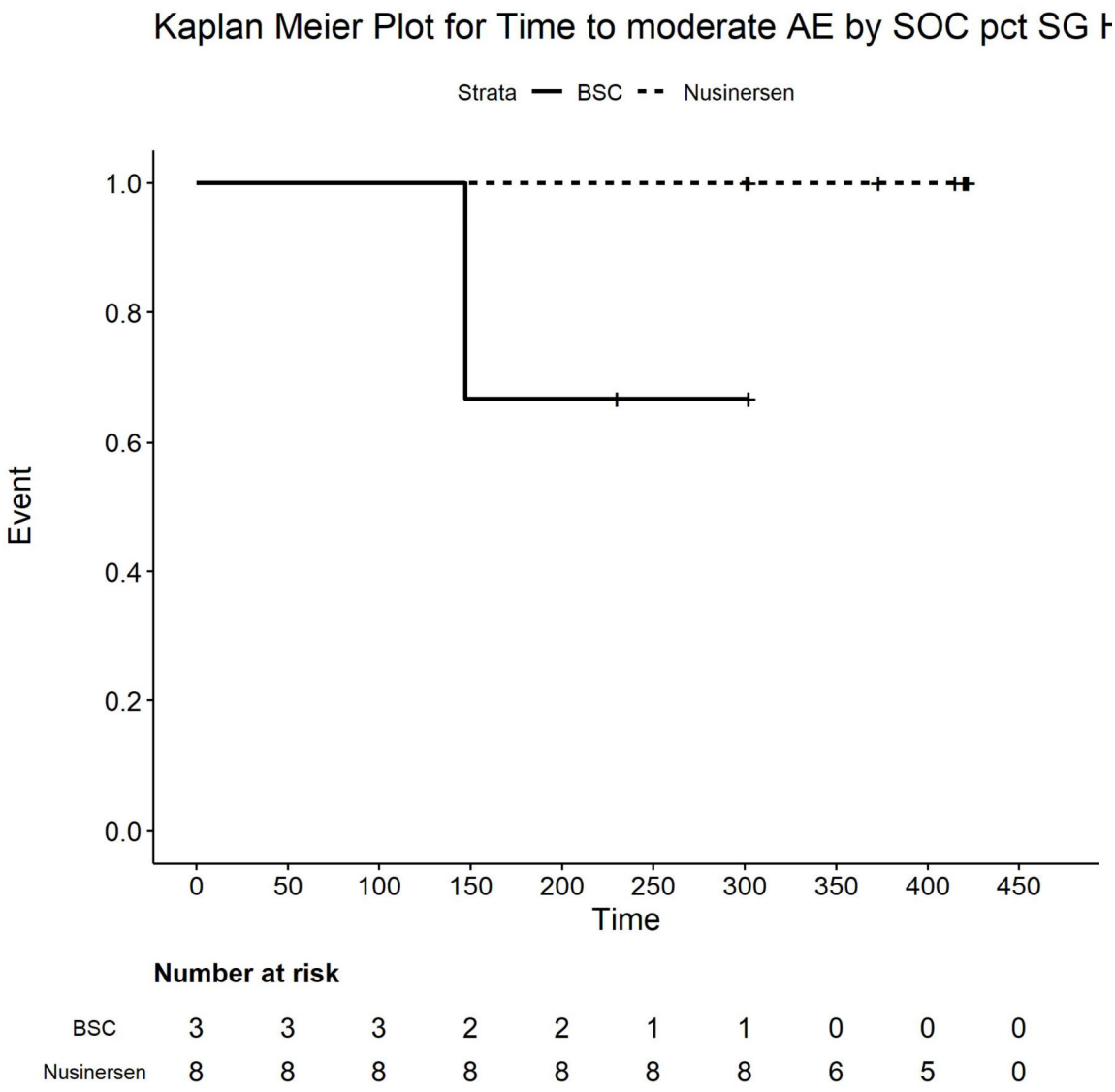
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	2	0



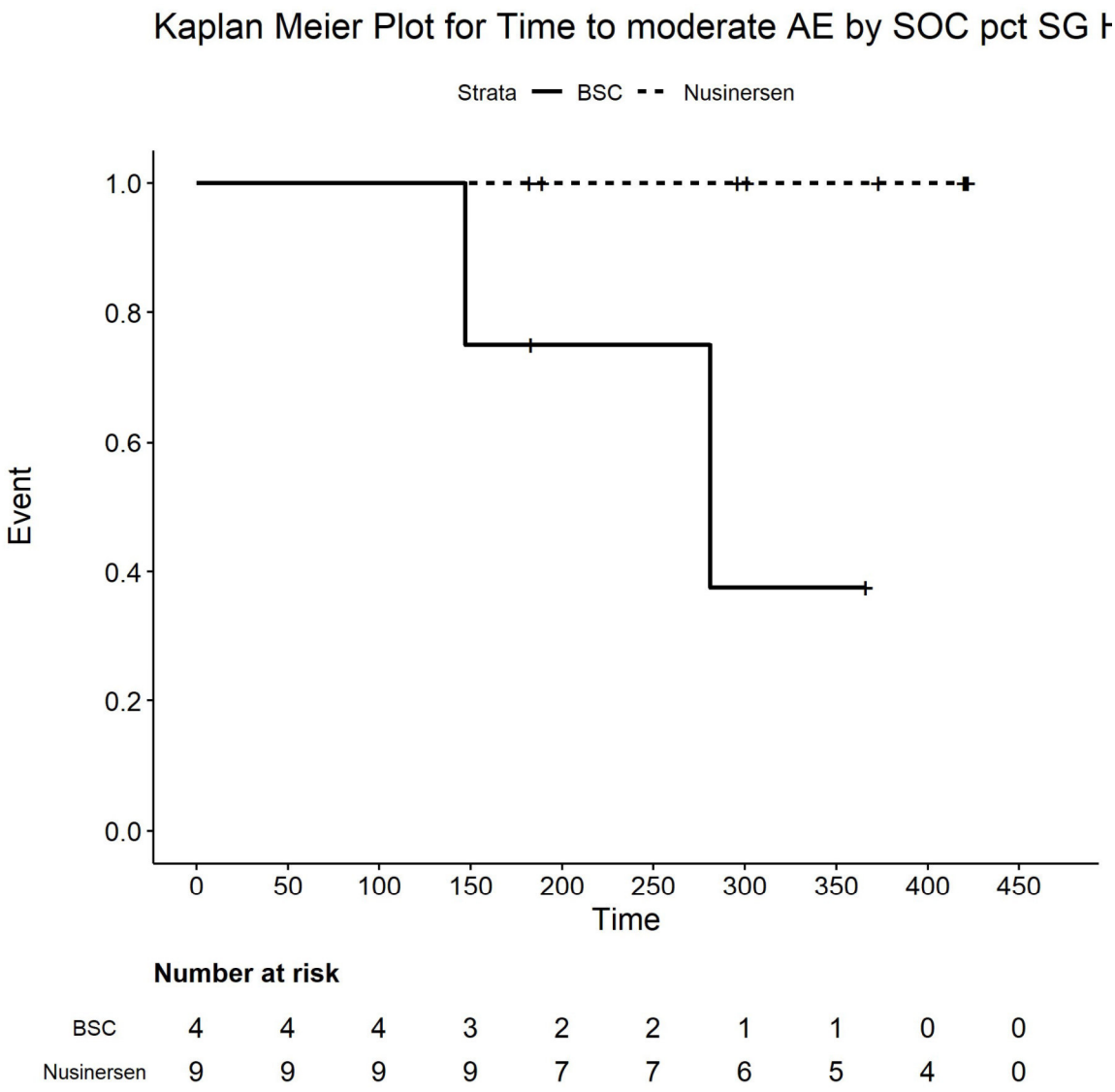
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



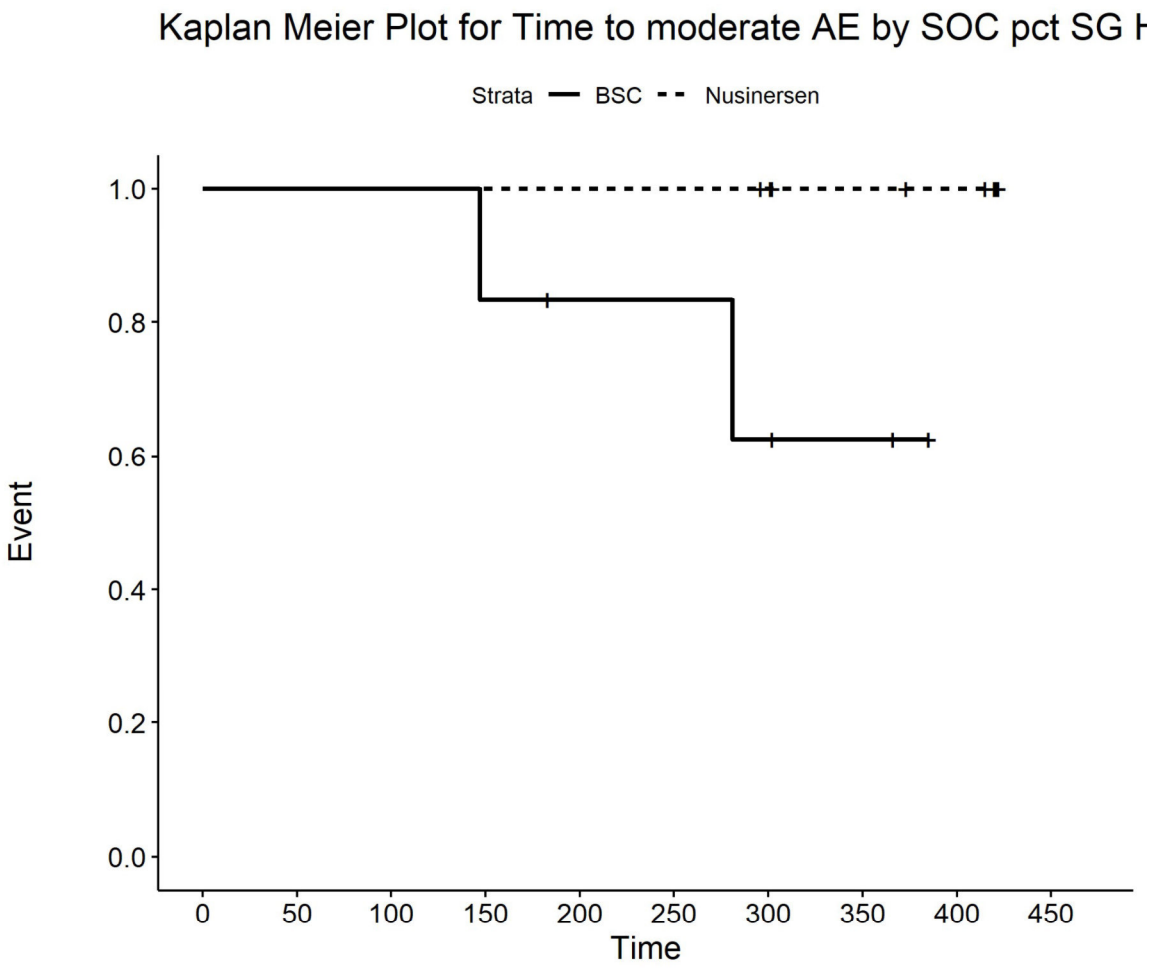
Number at risk

BSC	3	3	3	2	2	1	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



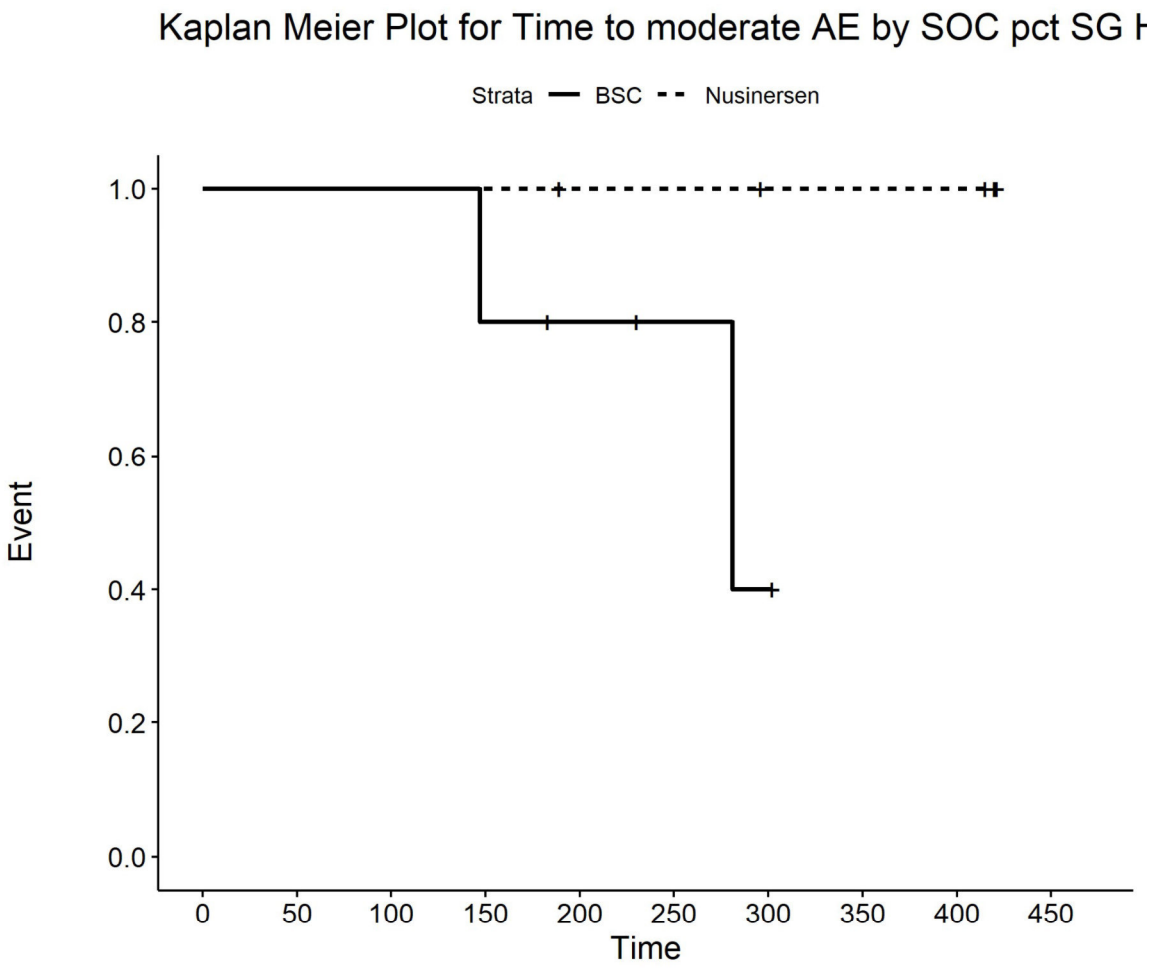
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



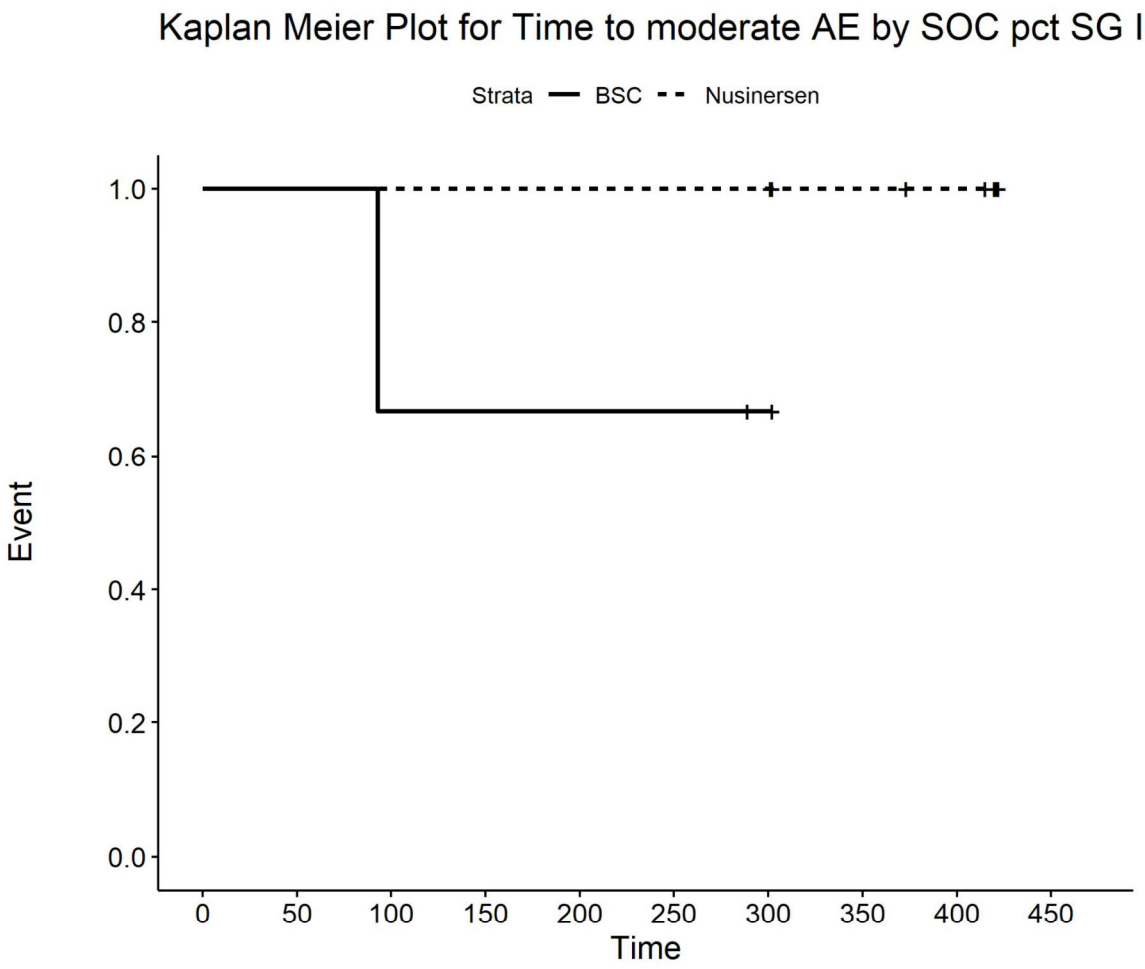
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



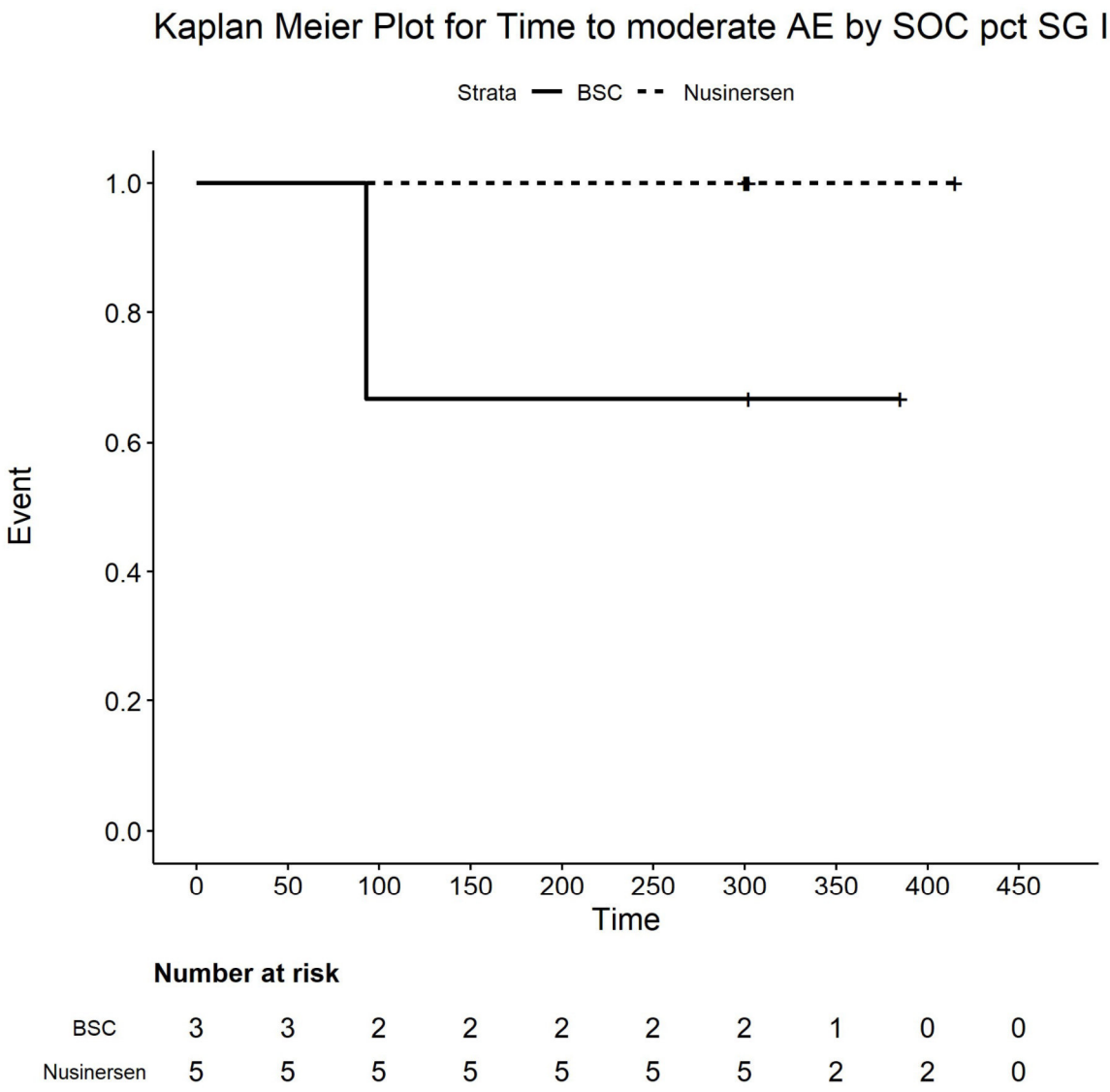
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



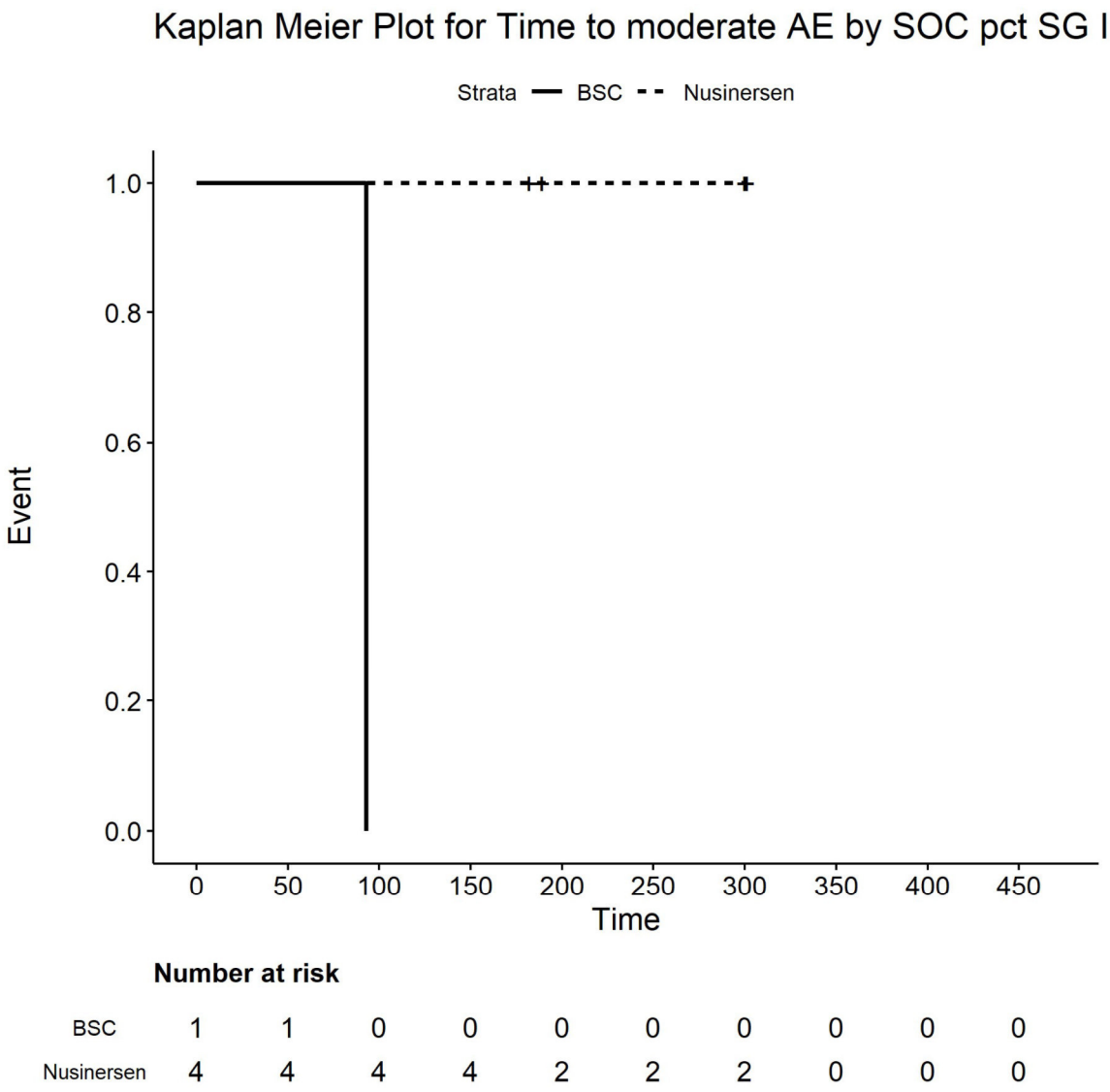
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



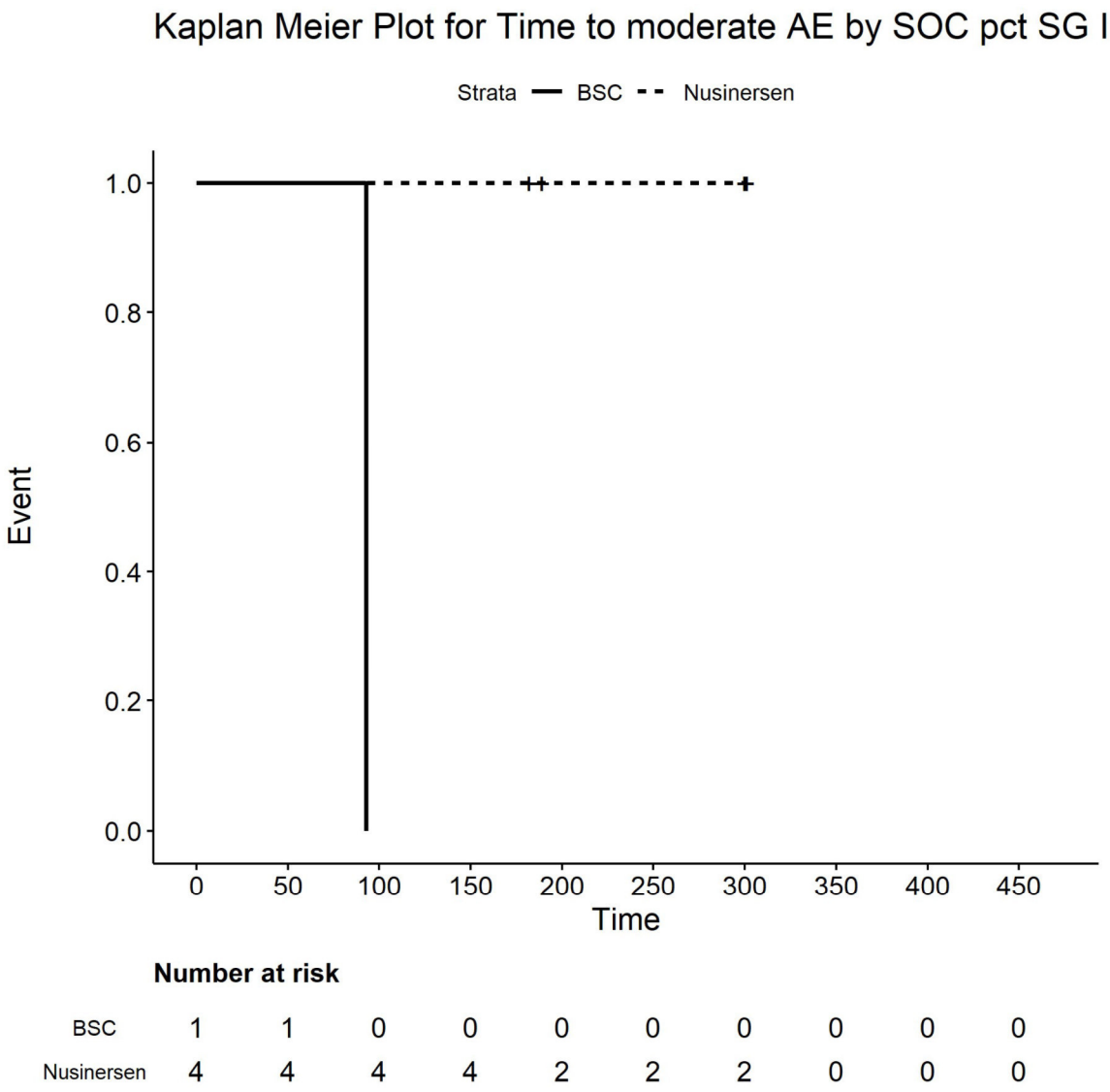
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



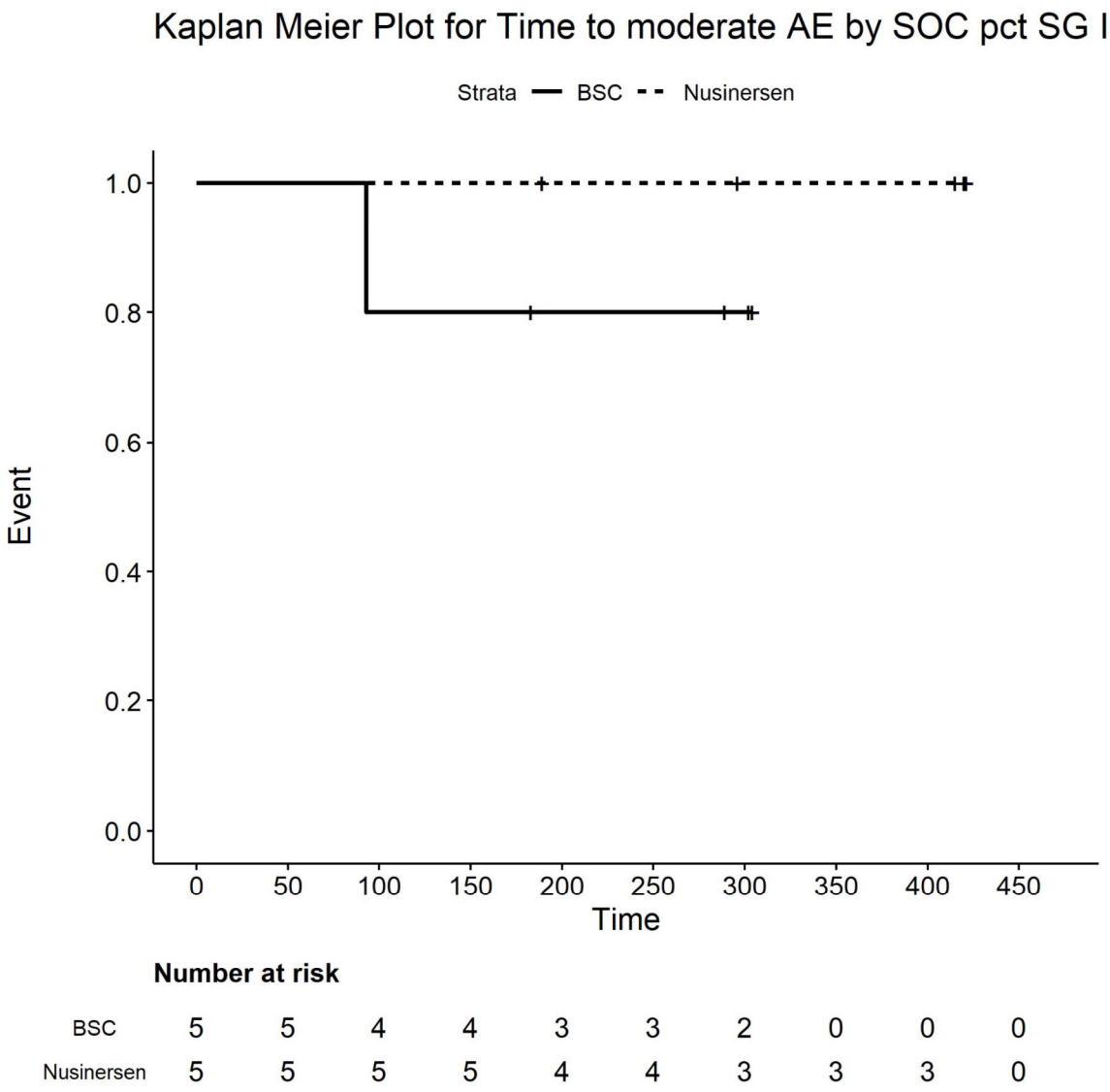
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



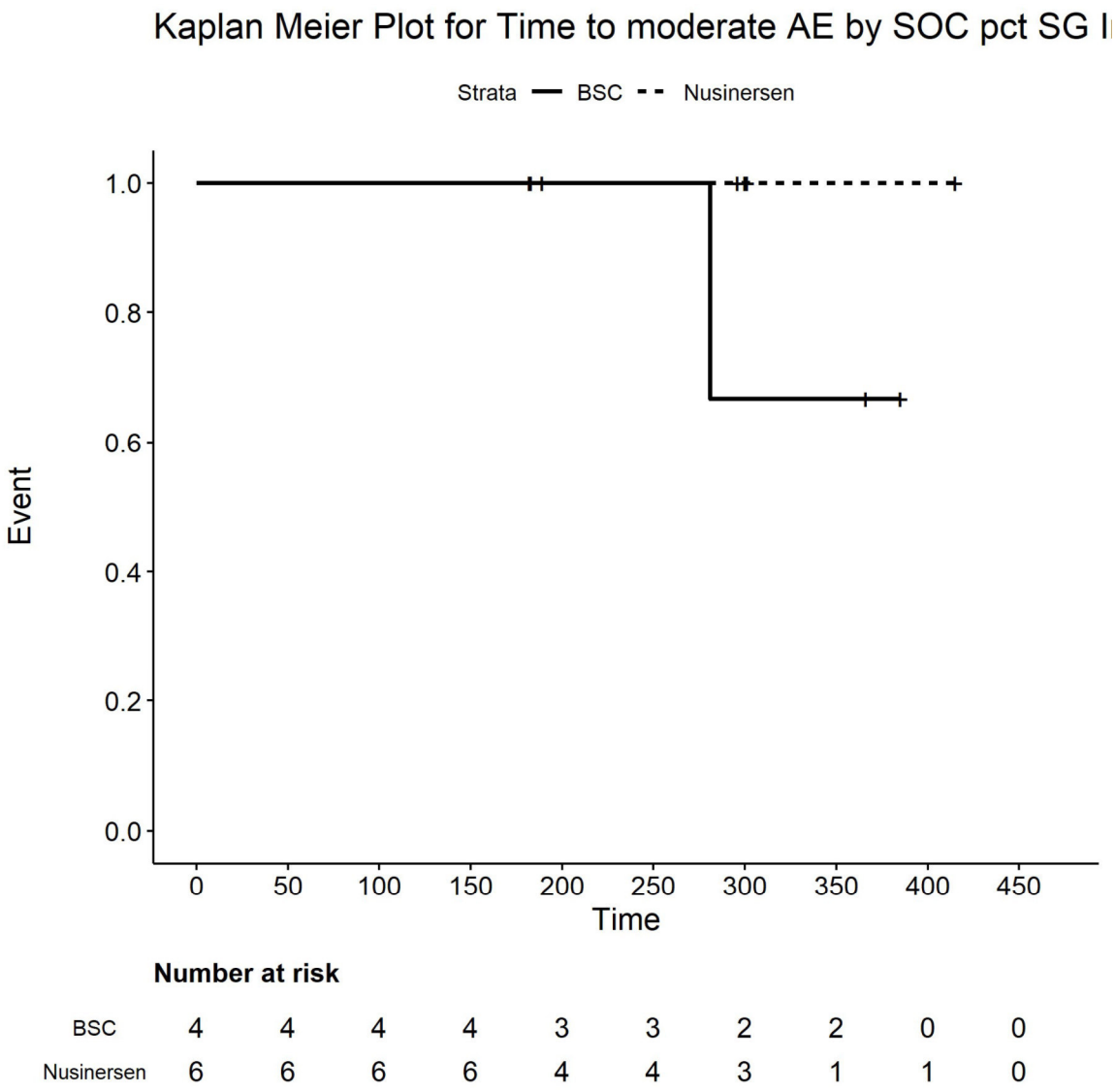
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



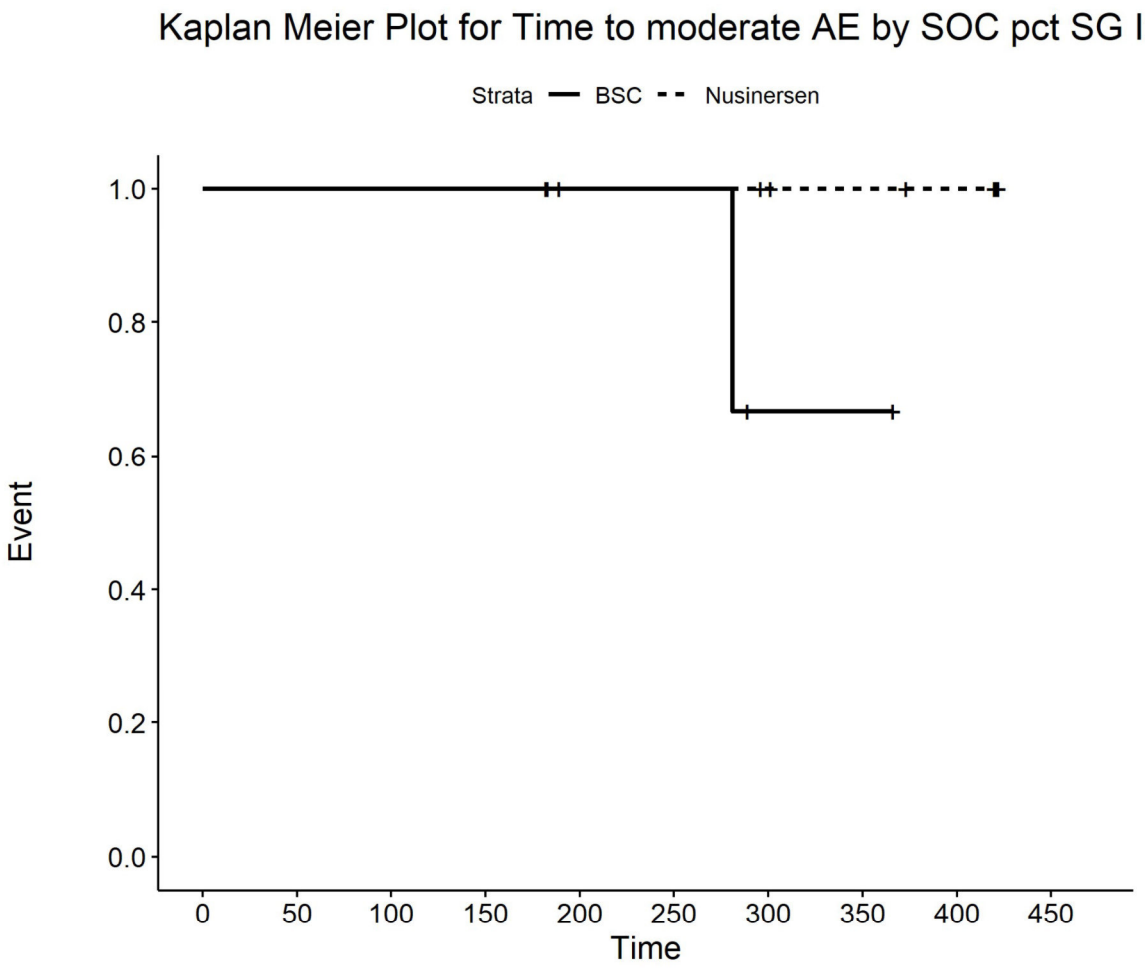
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



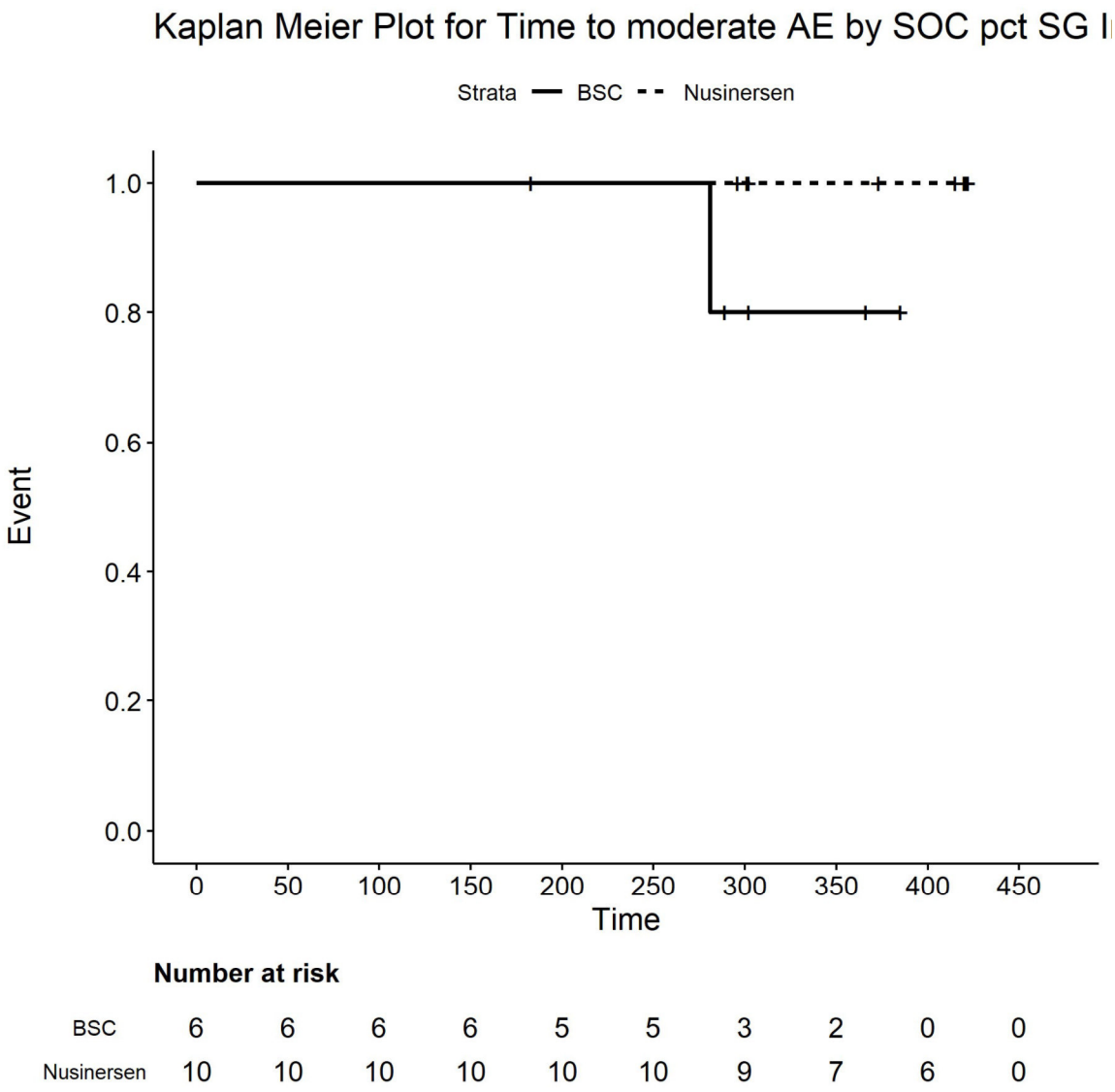
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



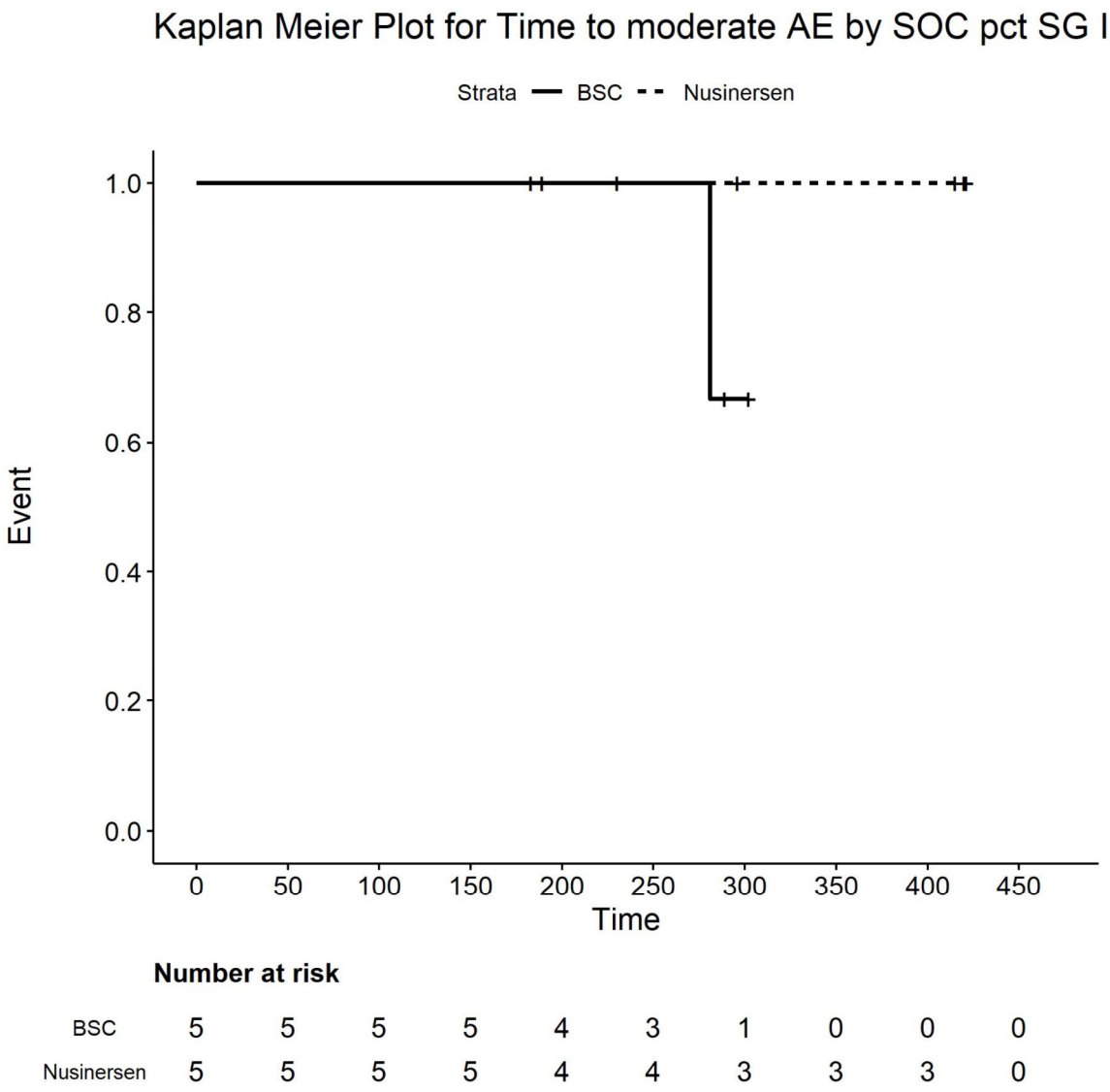
Number at risk

BSC	4	4	4	4	3	3	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



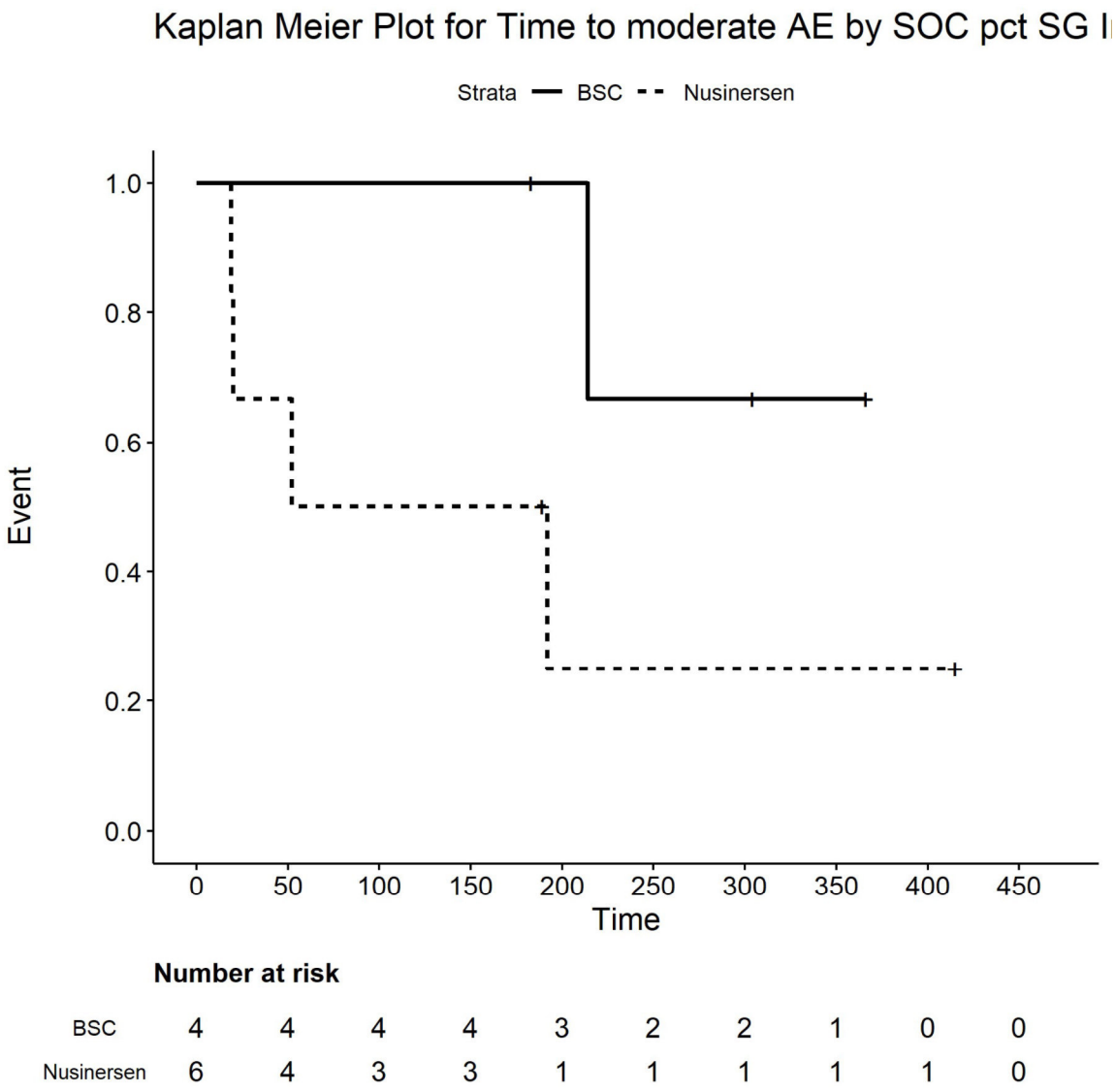
Number at risk

BSC	6	6	6	6	5	5	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



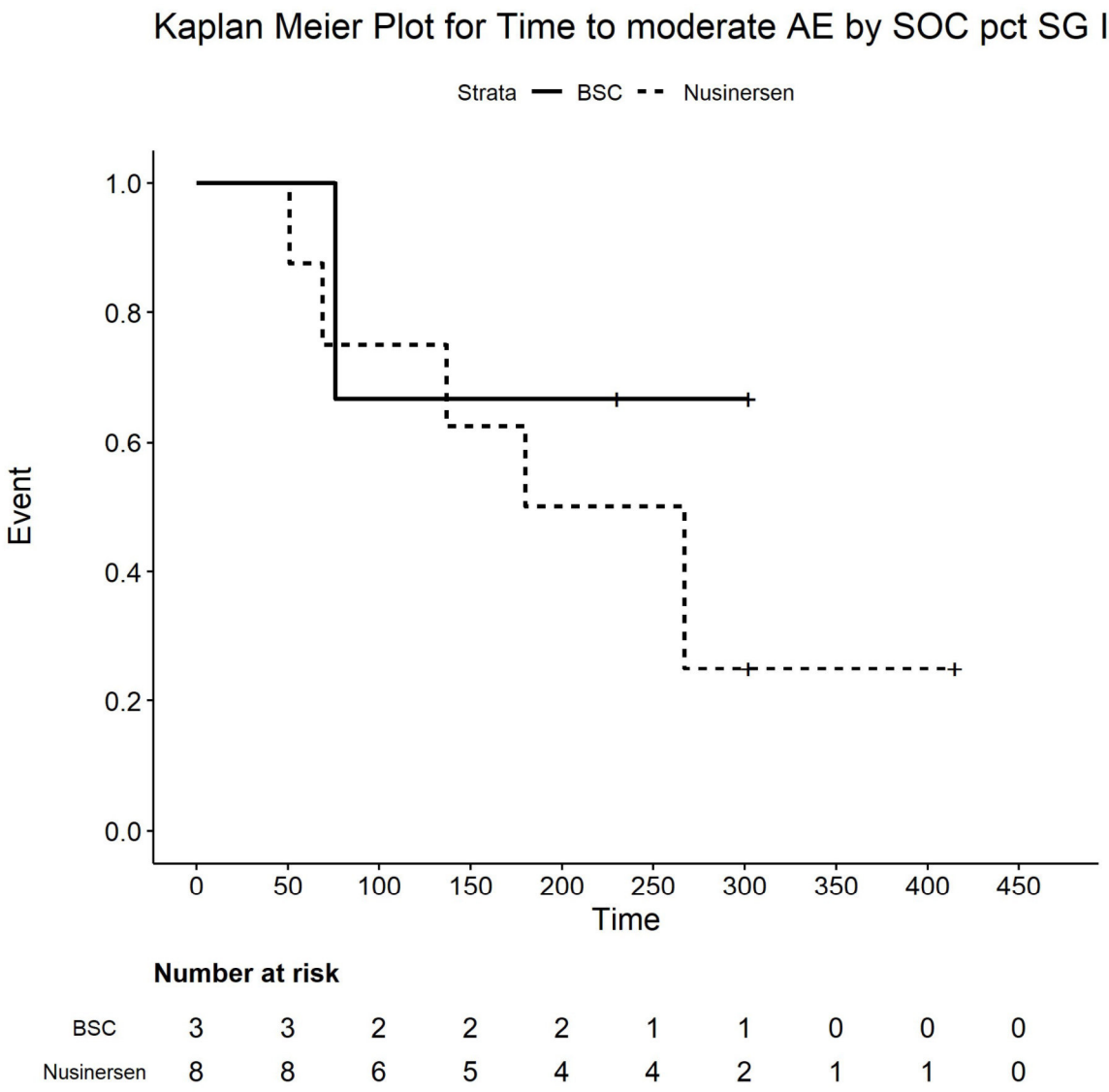
Number at risk

BSC	5	5	5	5	4	3	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



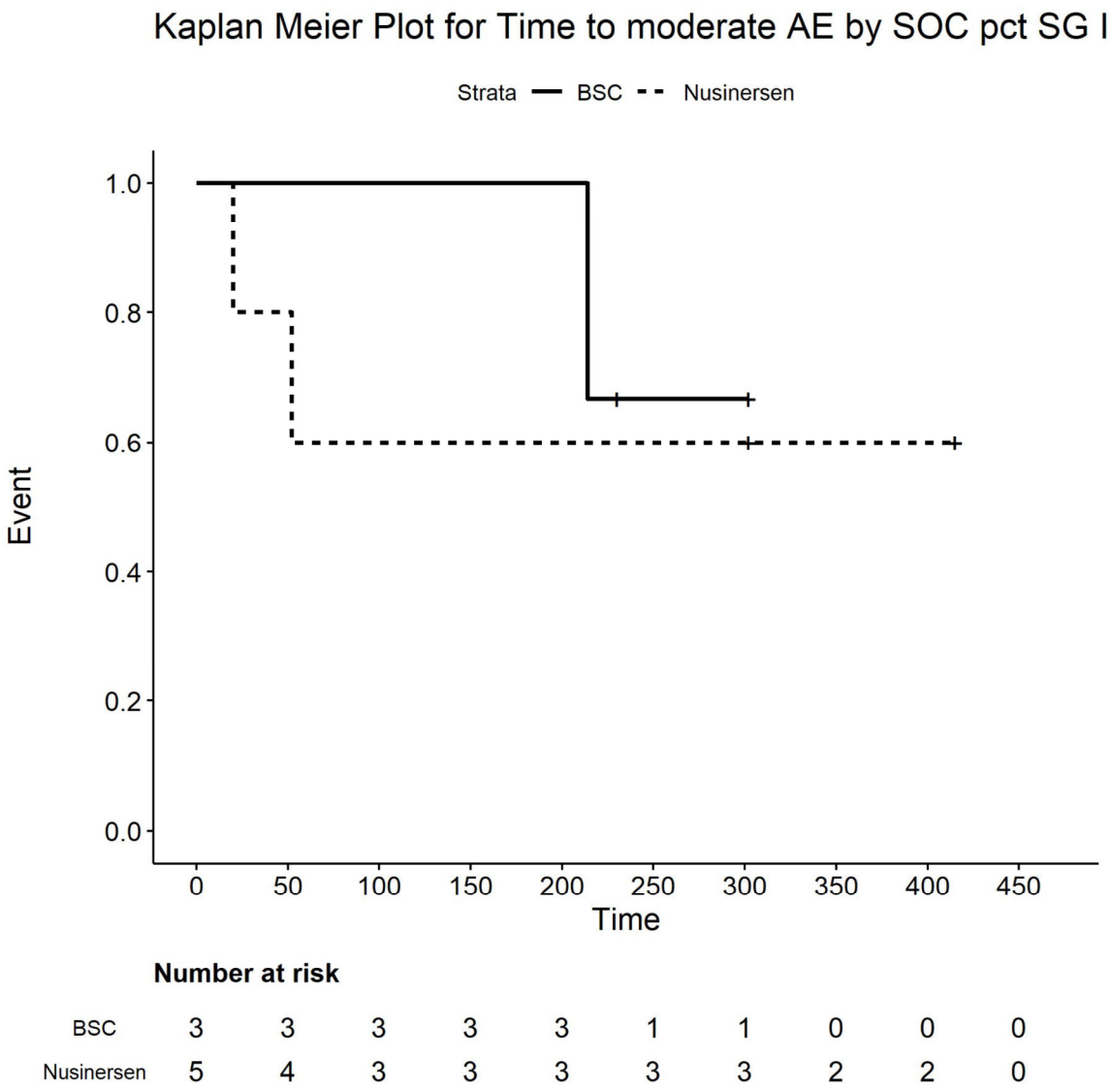
Number at risk

BSC	4	4	4	4	3	2	2	1	0	0
Nusinersen	6	4	3	3	1	1	1	1	1	0



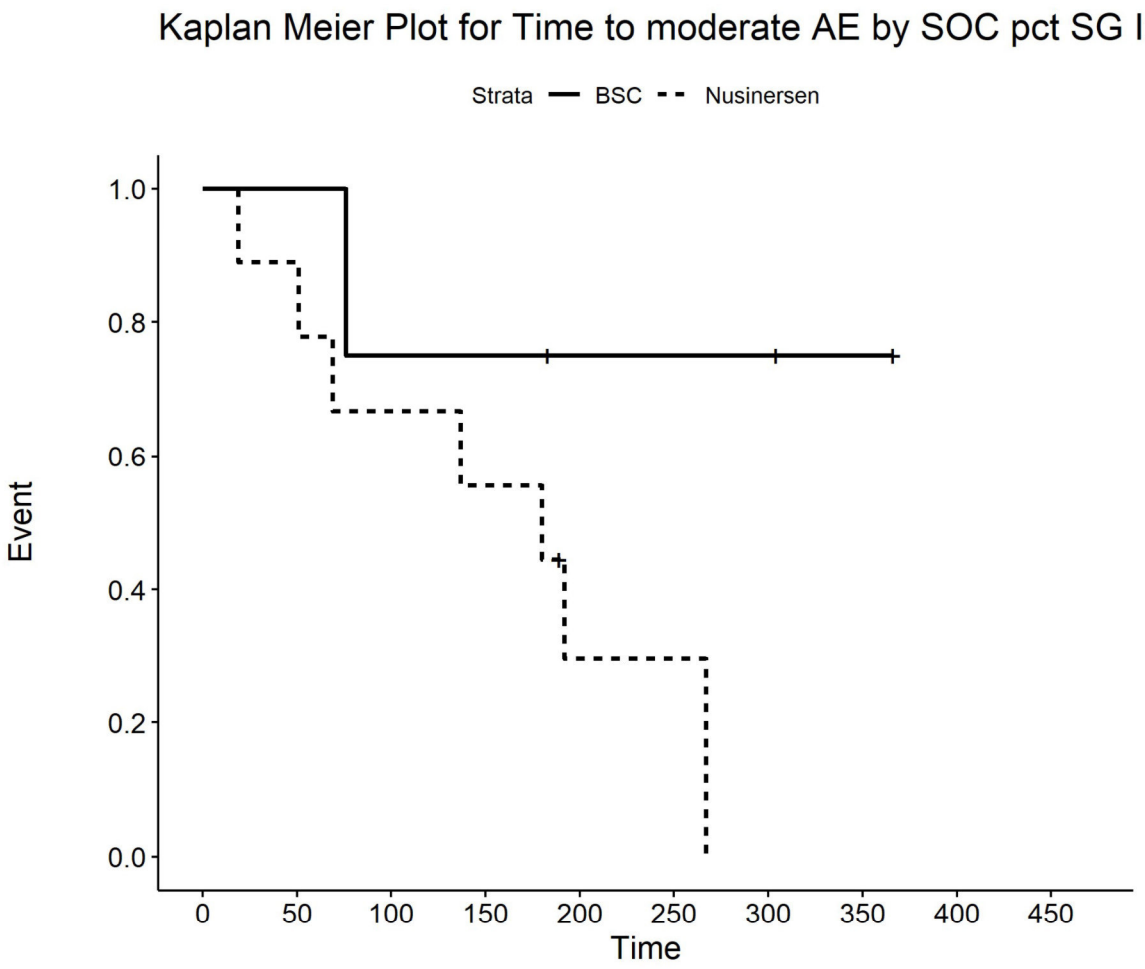
Number at risk

BSC	3	3	2	2	2	1	1	0	0	0
Nusinersen	8	8	6	5	4	4	2	1	1	0



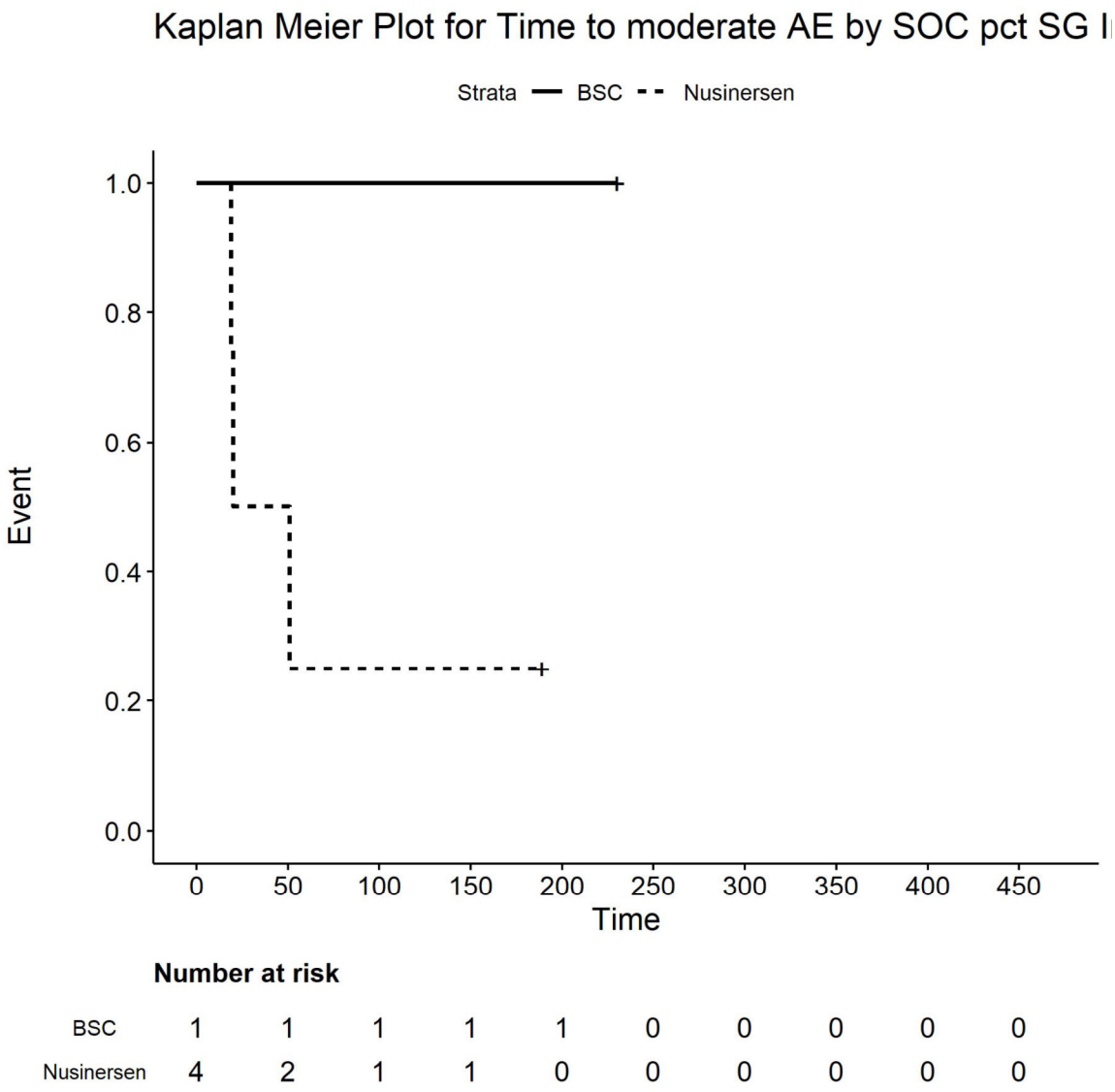
Number at risk

BSC	3	3	3	3	3	1	1	0	0	0
Nusinersen	5	4	3	3	3	3	3	2	2	0



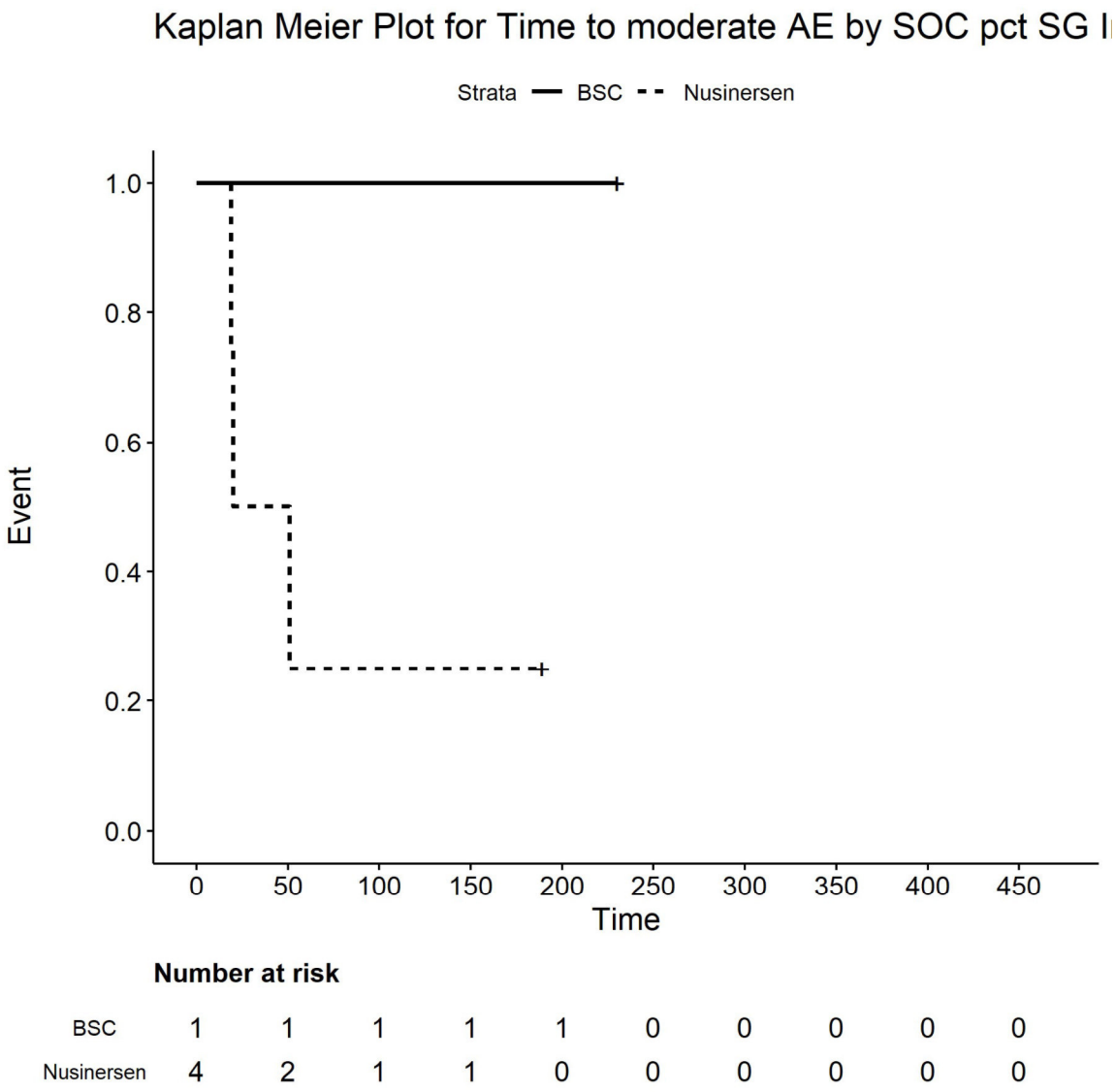
Number at risk

BSC	4	4	3	3	2	2	2	1	0	0
Nusinersen	9	8	6	5	2	2	0	0	0	0



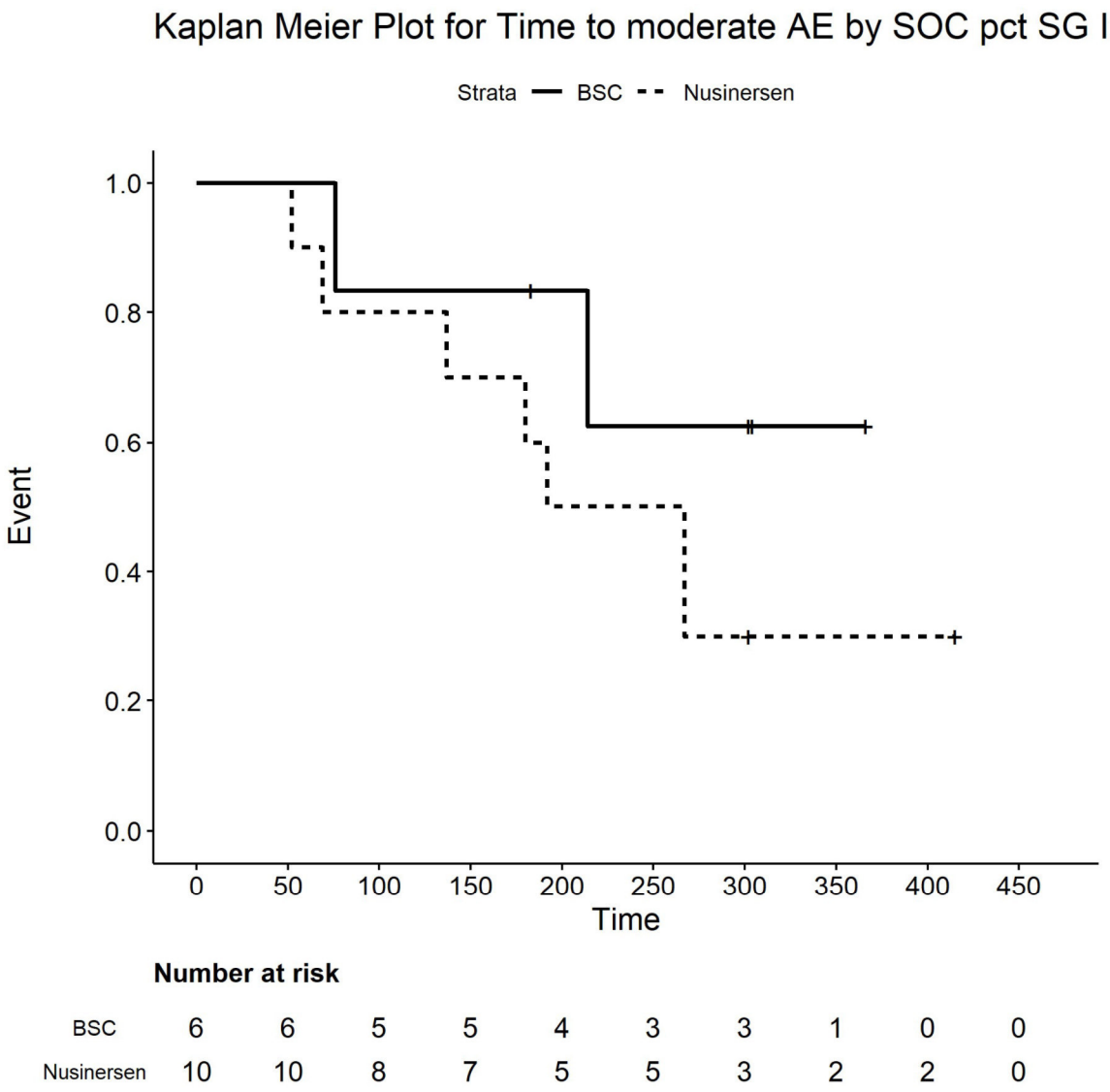
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	2	1	1	0	0	0	0	0	0



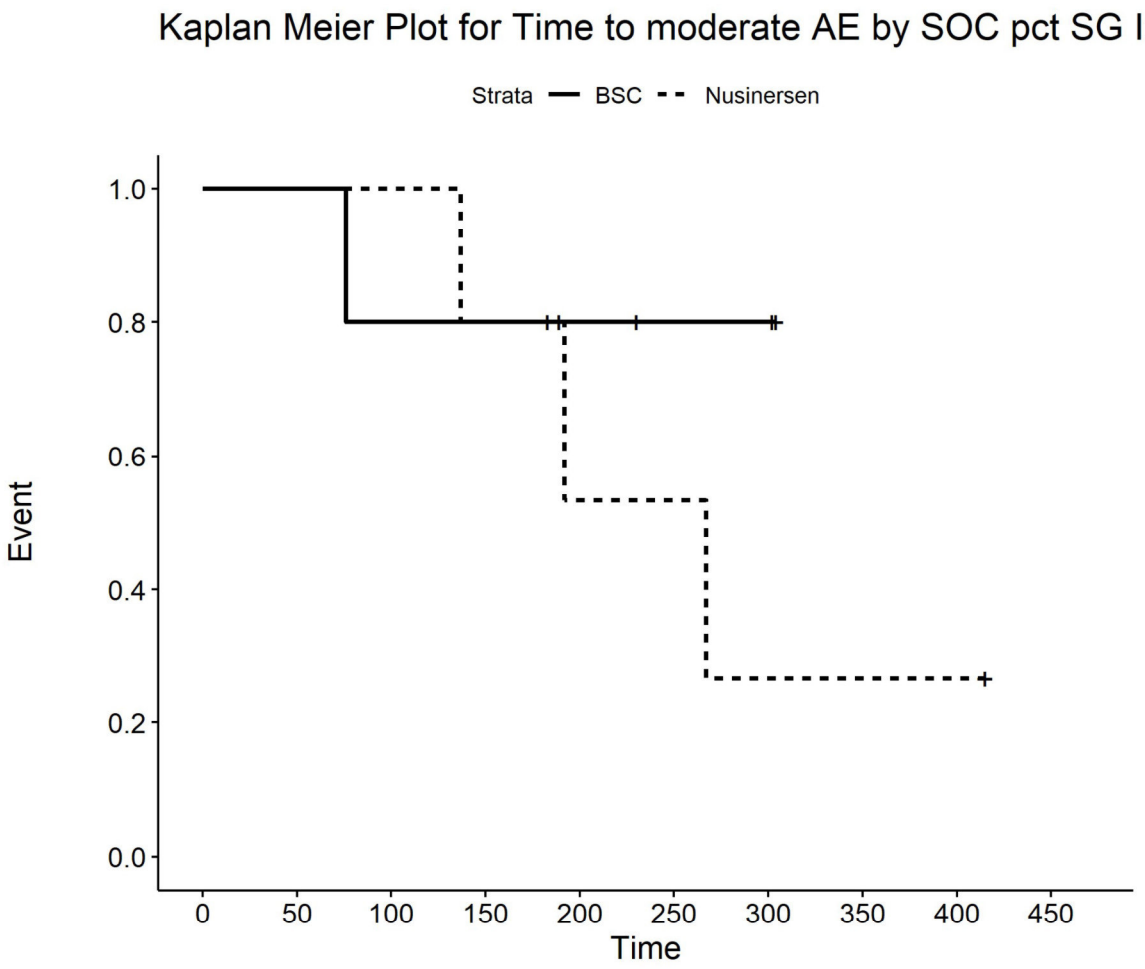
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	2	1	1	0	0	0	0	0	0



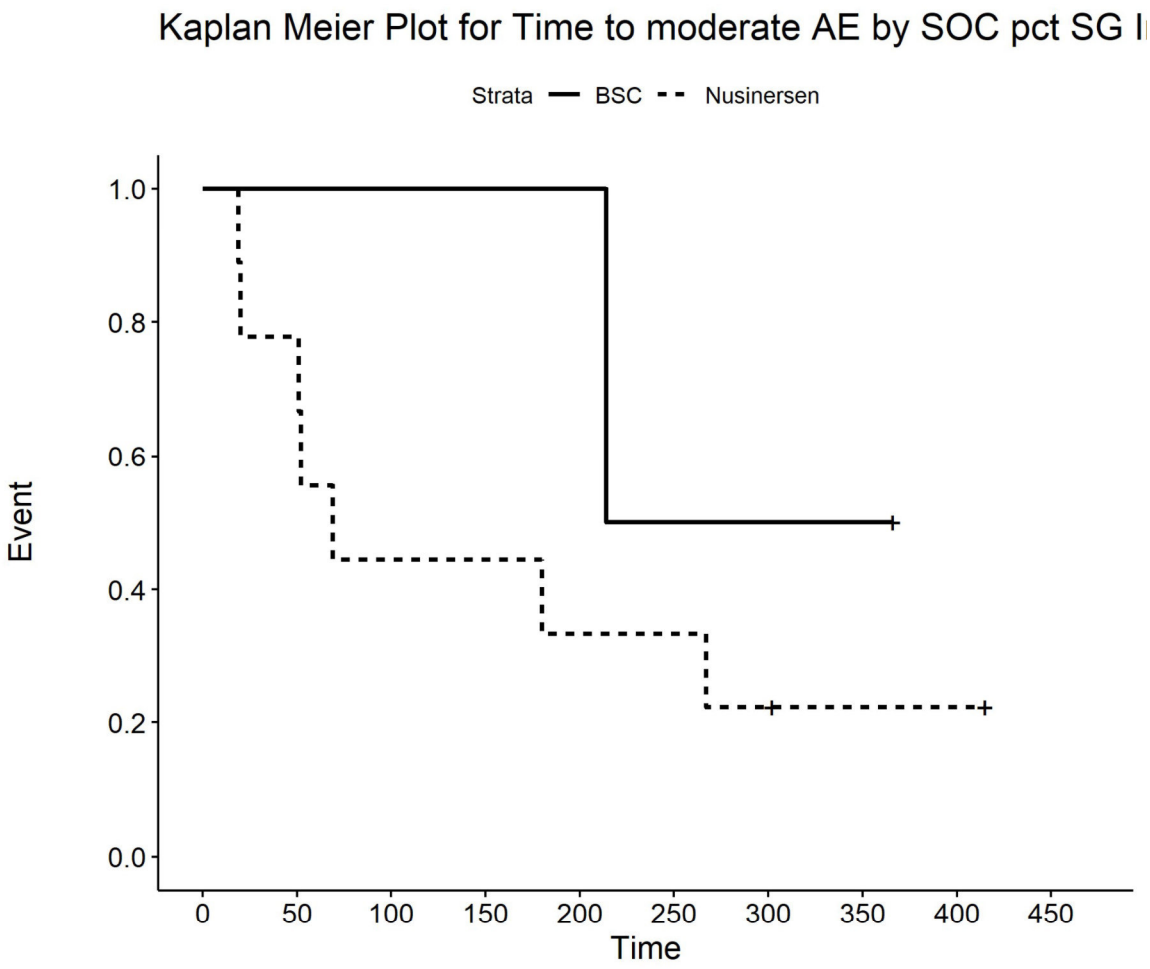
Number at risk

BSC	6	6	5	5	4	3	3	1	0	0
Nusinersen	10	10	8	7	5	5	3	2	2	0



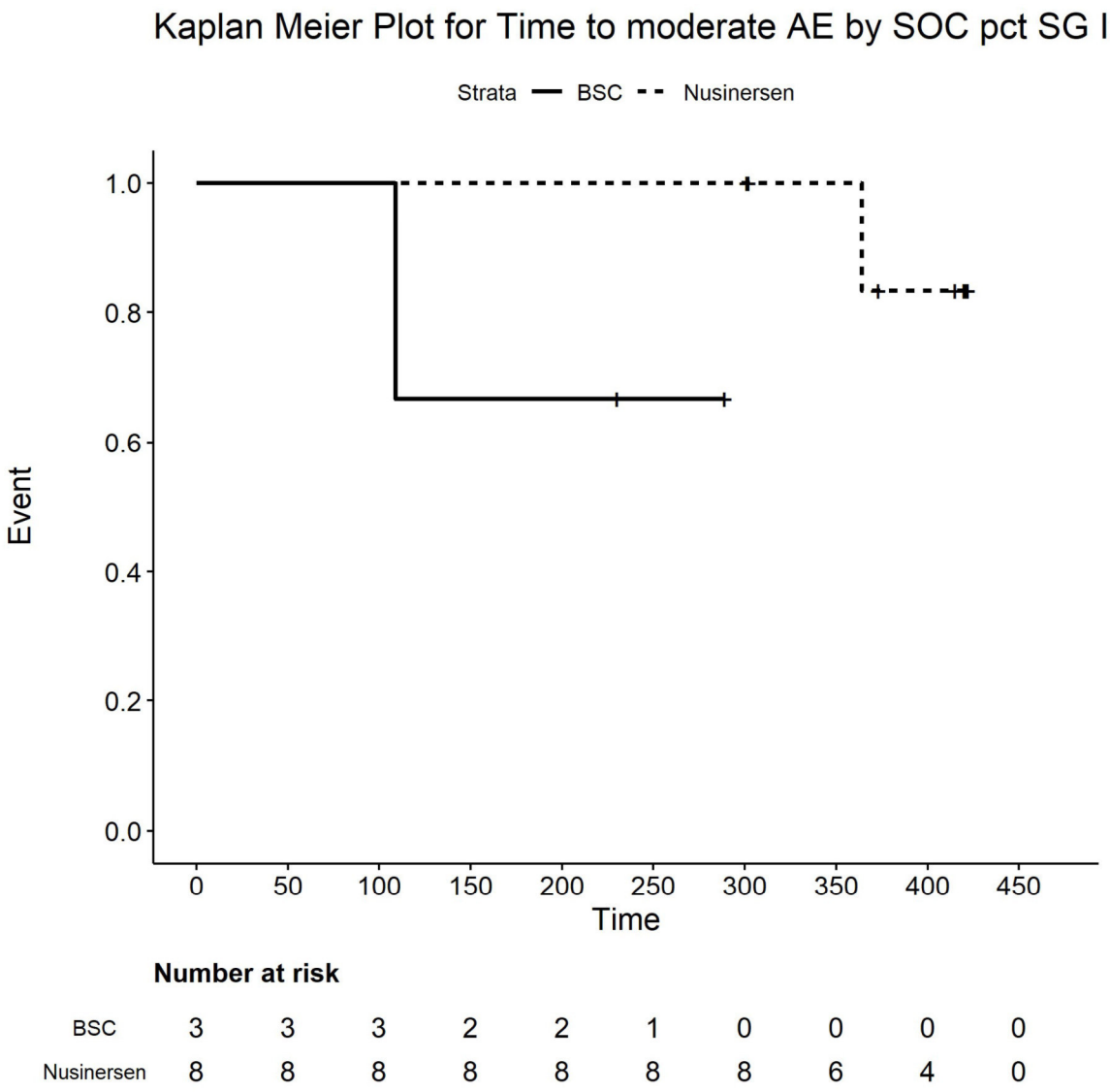
Number at risk

BSC	5	5	4	4	3	2	2	0	0	0
Nusinersen	5	5	5	4	2	2	1	1	1	0



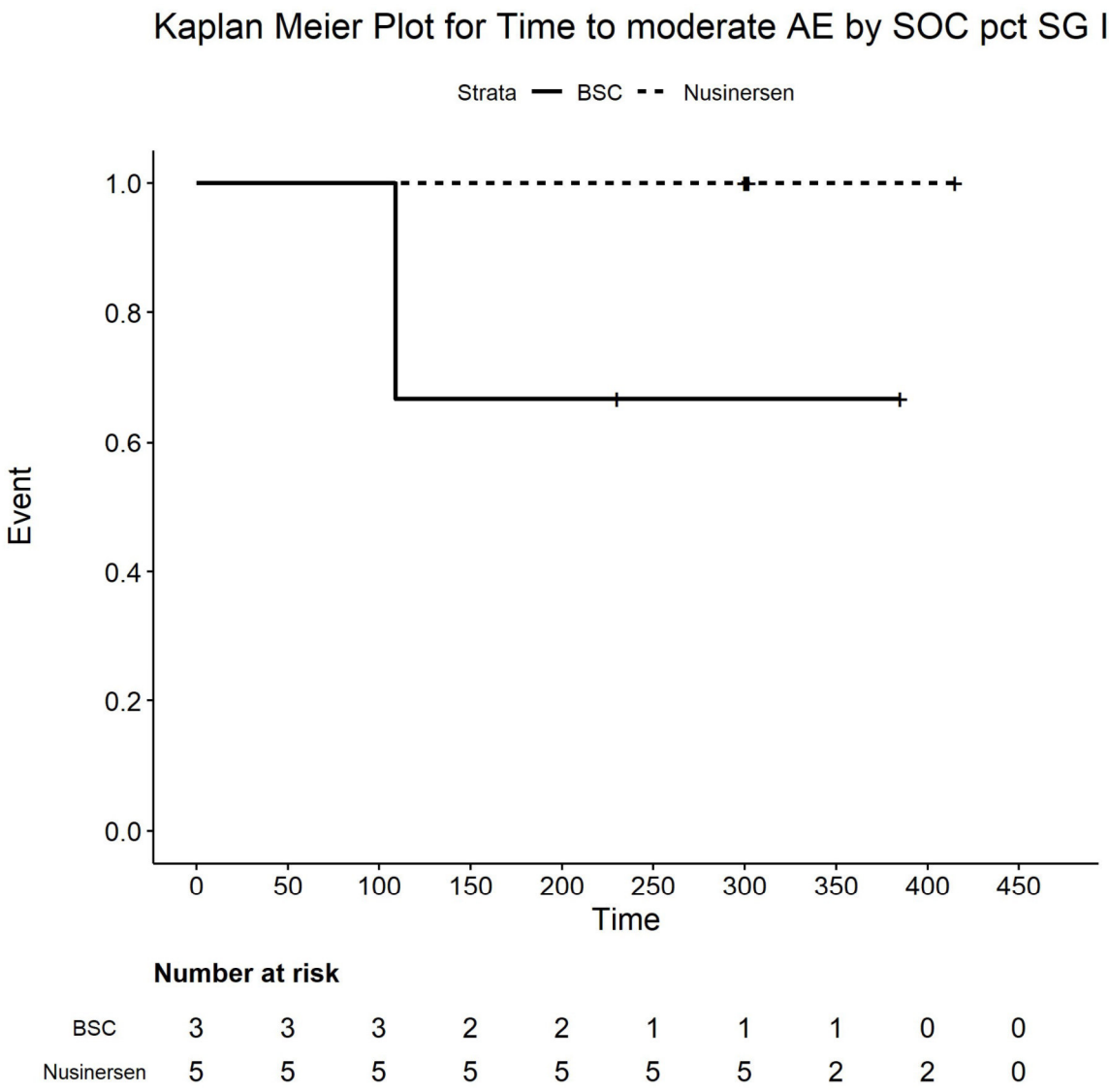
Number at risk

BSC	2	2	2	2	2	1	1	1	0	0
Nusinersen	9	7	4	4	3	3	2	1	1	0



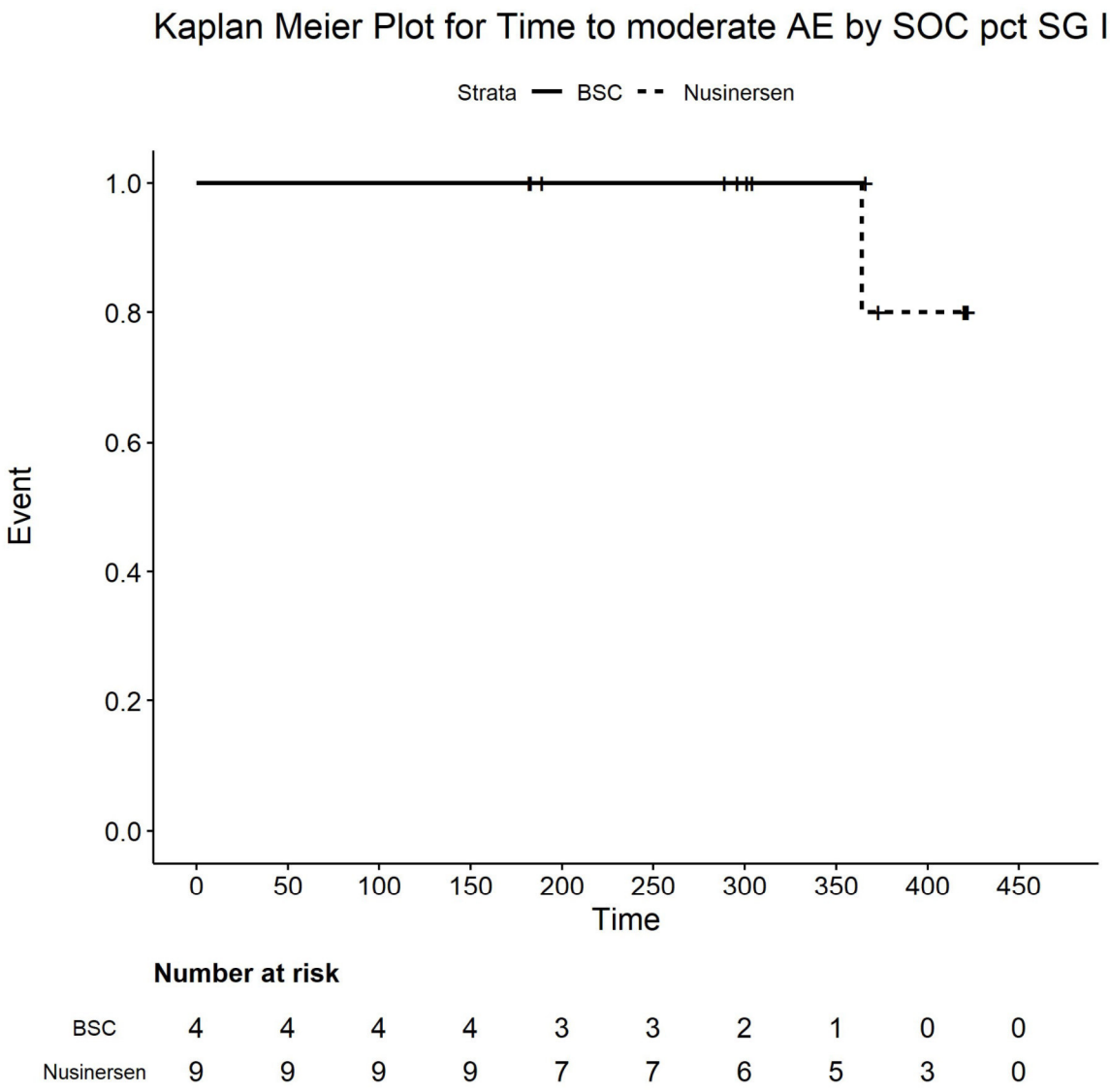
Number at risk

BSC	3	3	3	2	2	1	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	4	0



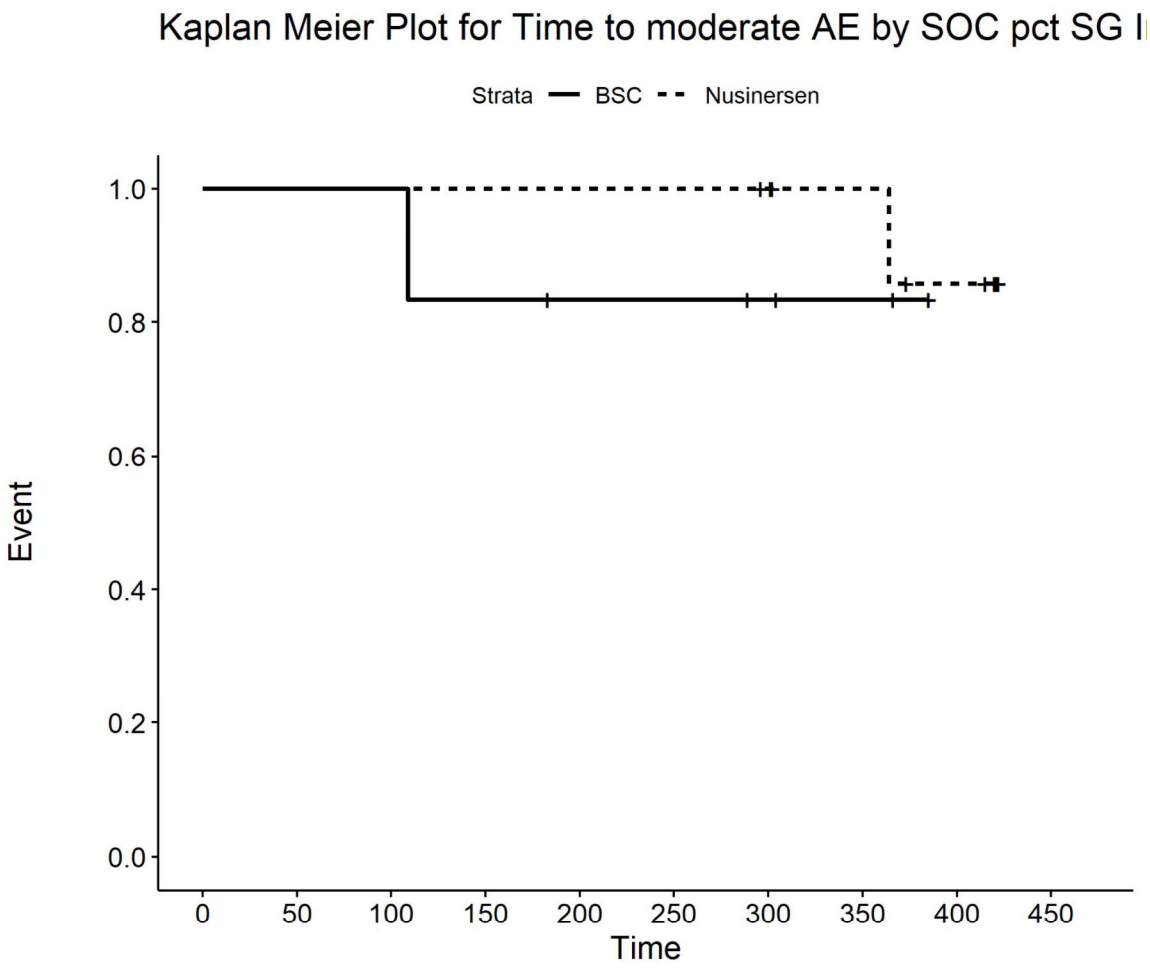
Number at risk

BSC	3	3	3	2	2	1	1	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



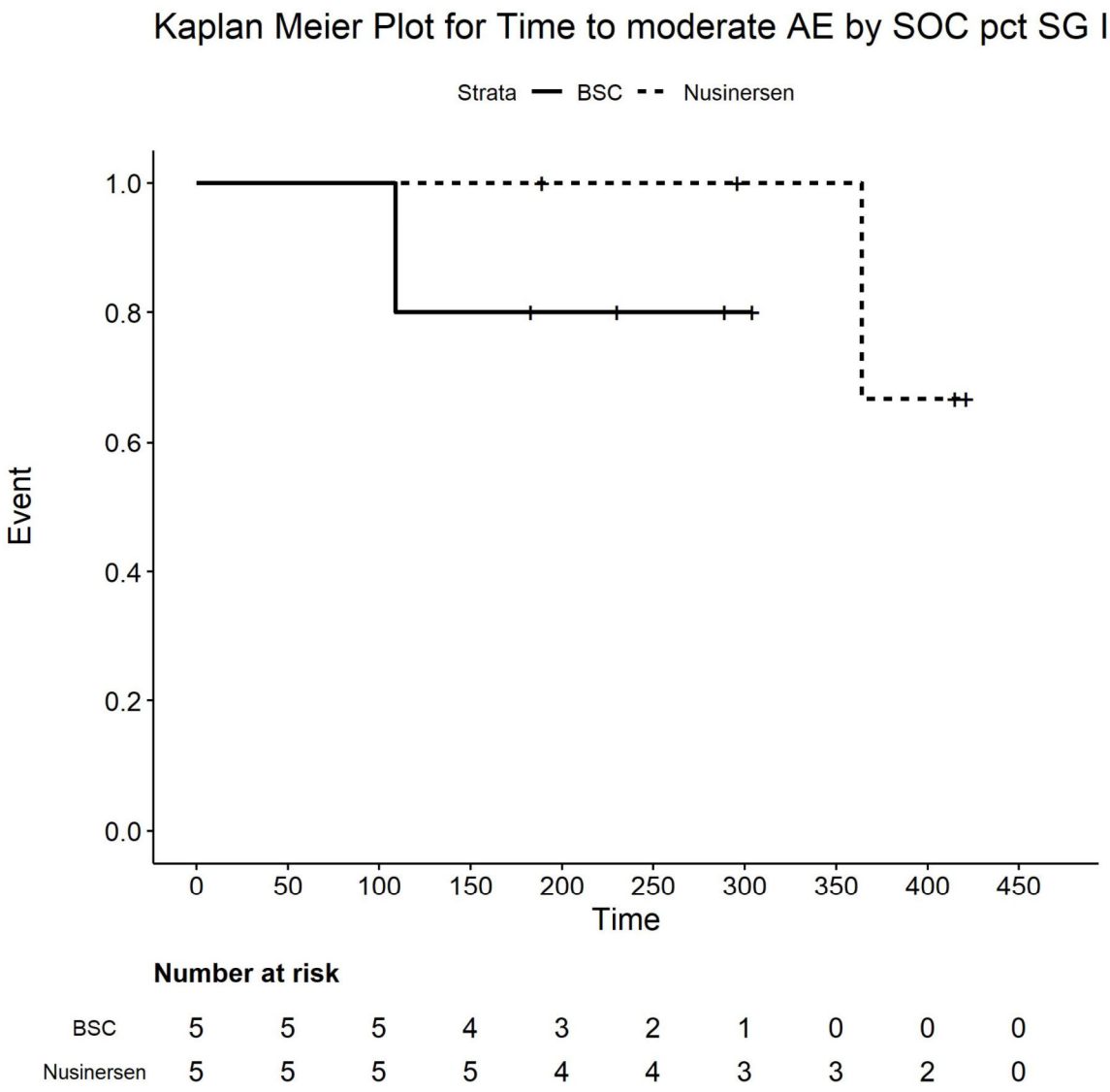
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	3	0



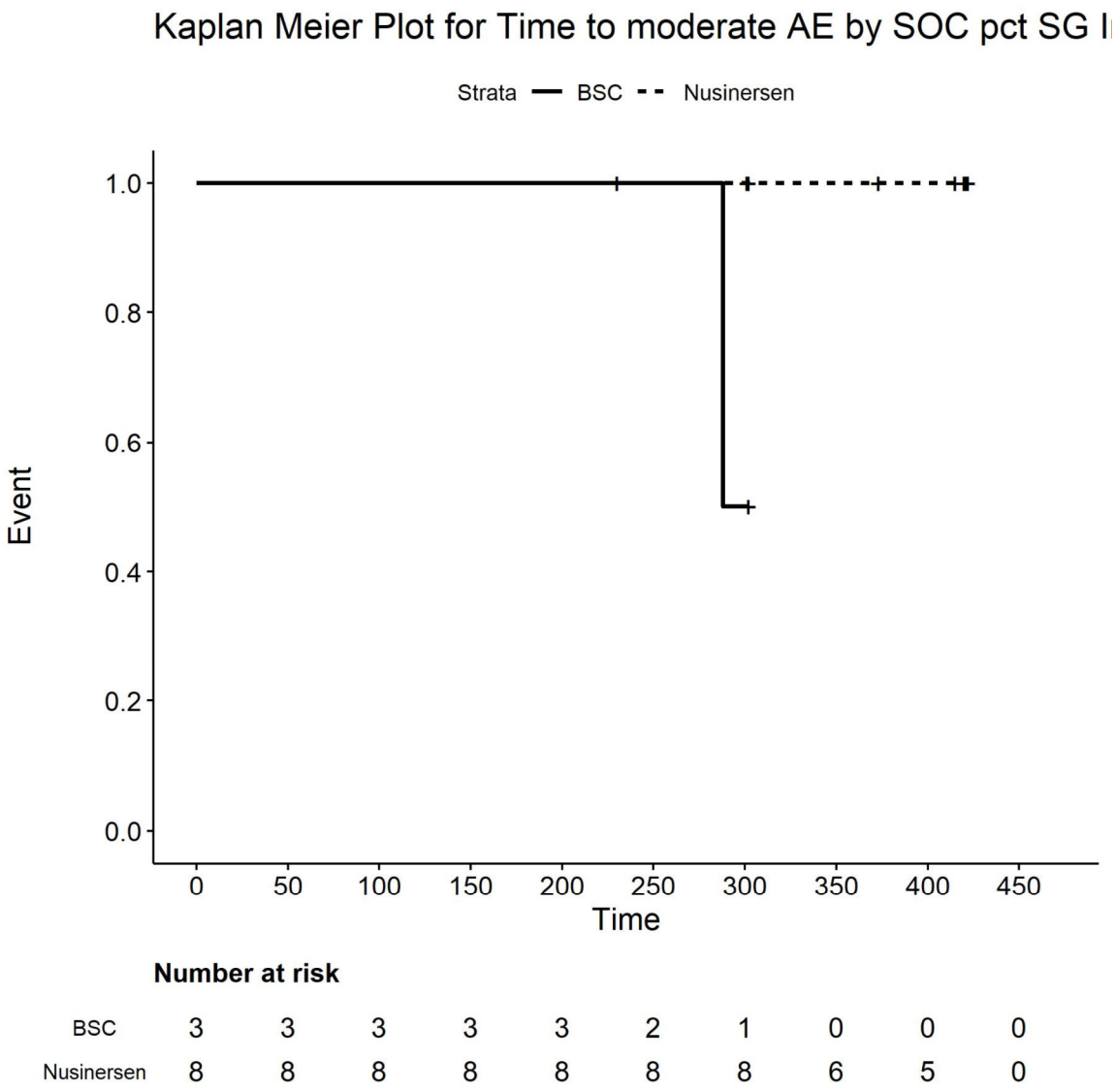
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	5	0



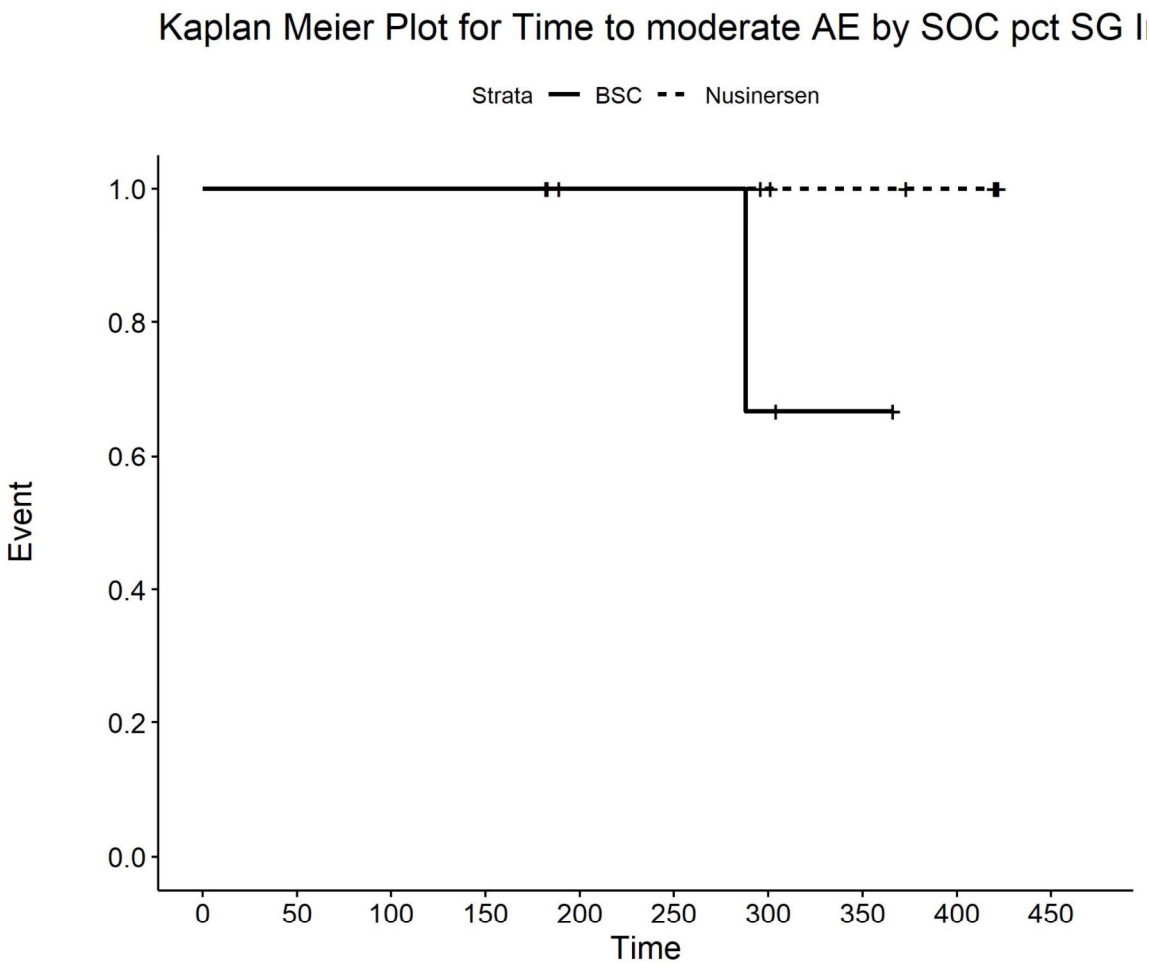
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	2	0



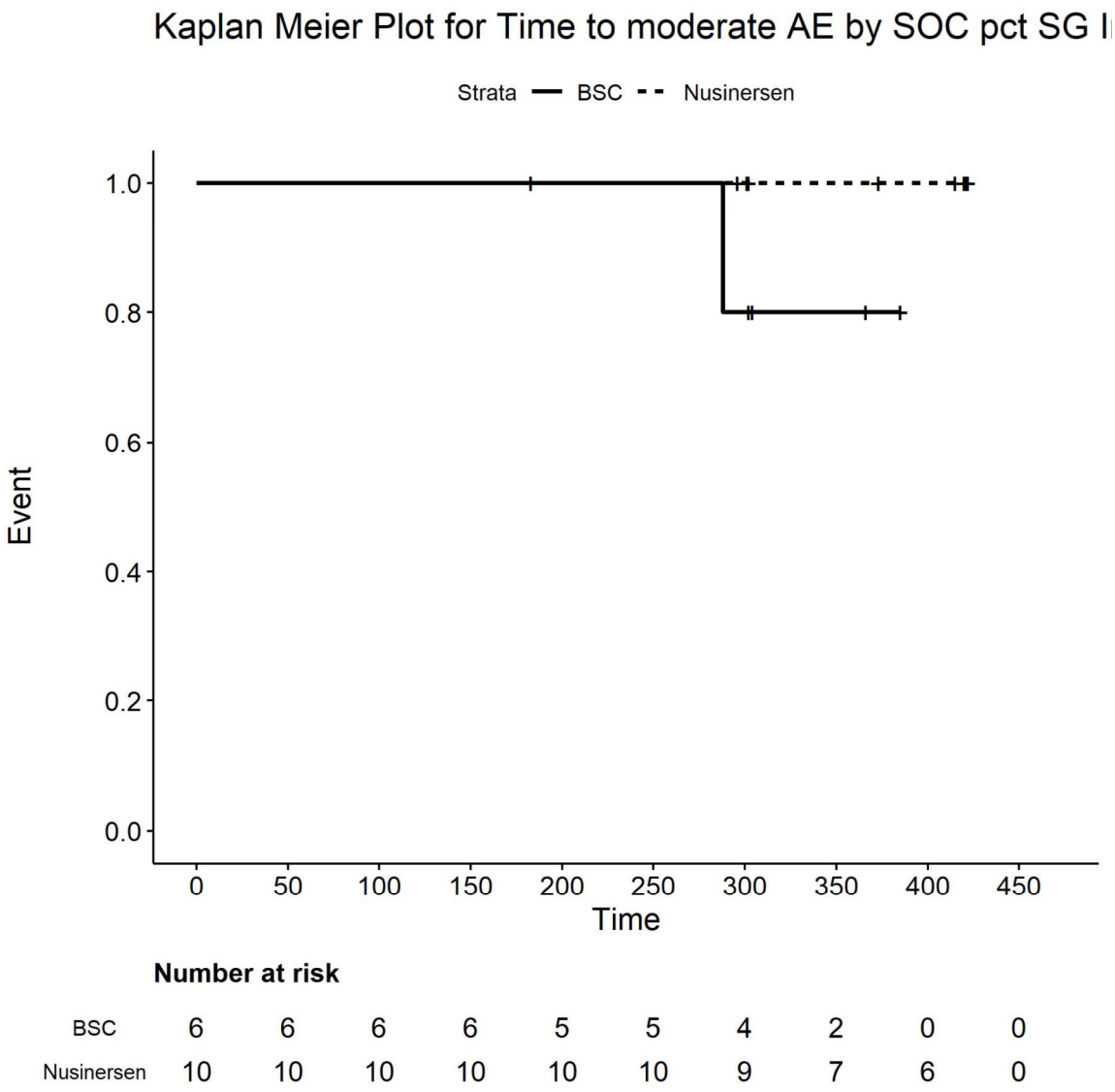
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



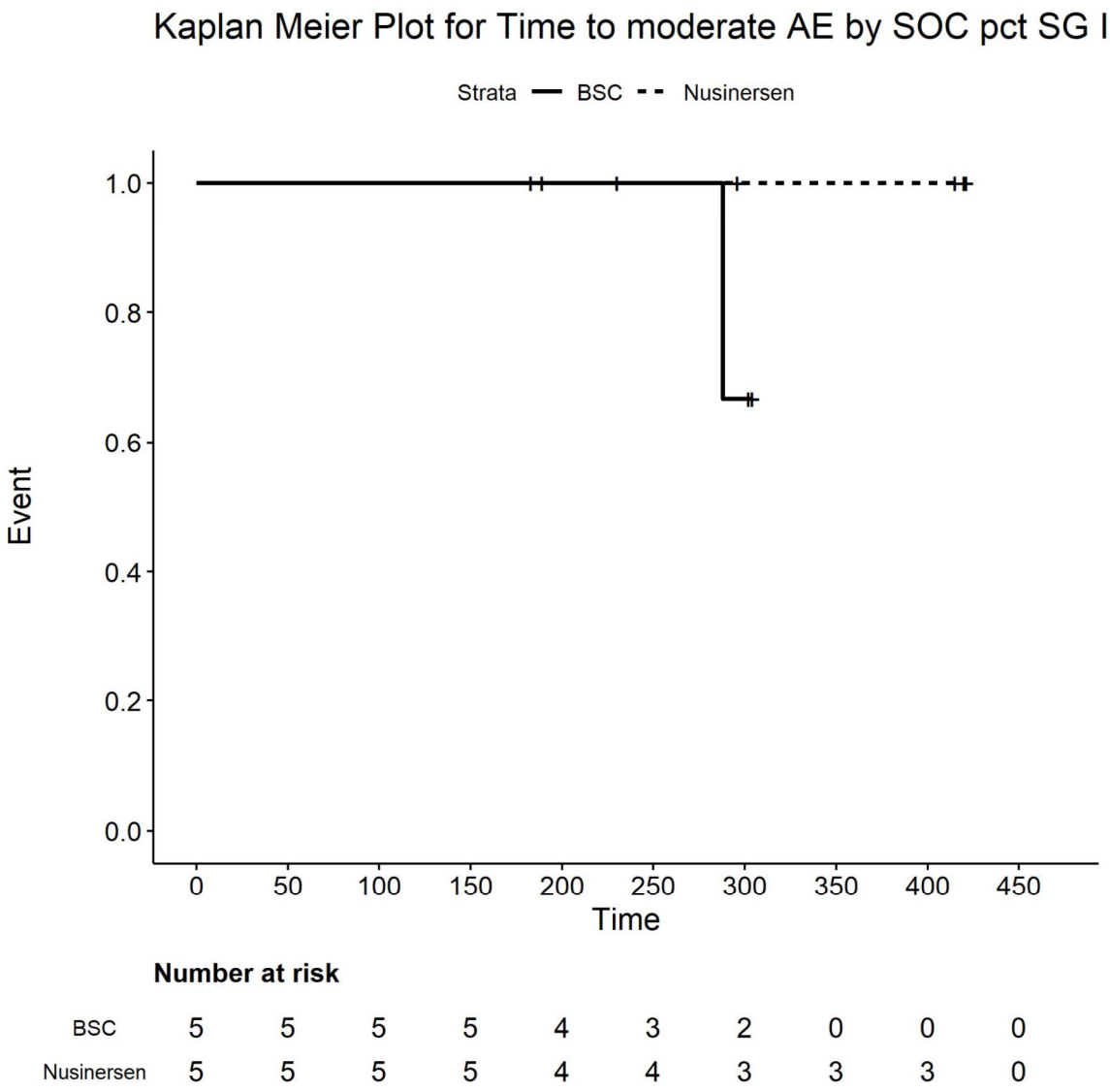
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



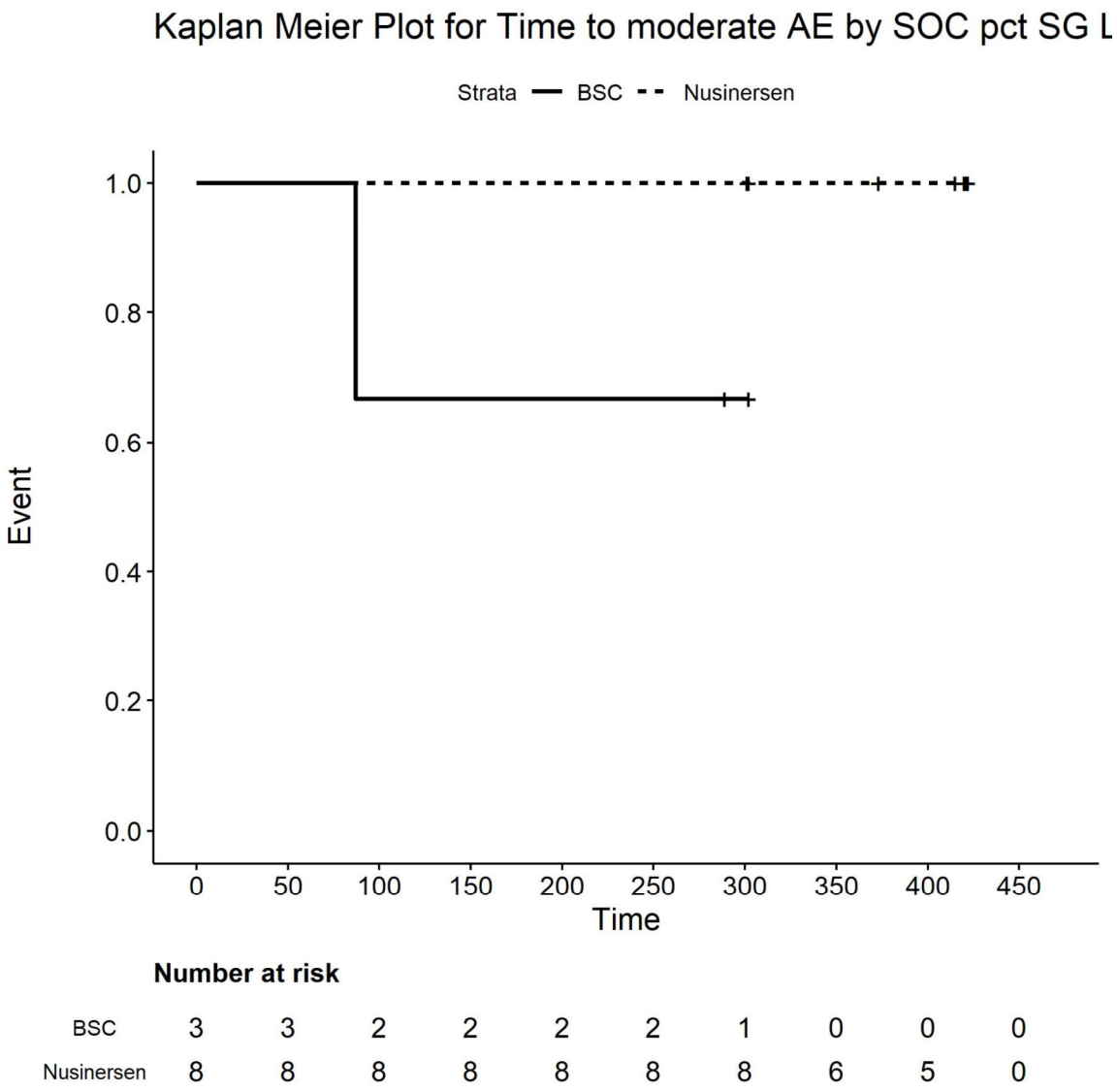
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



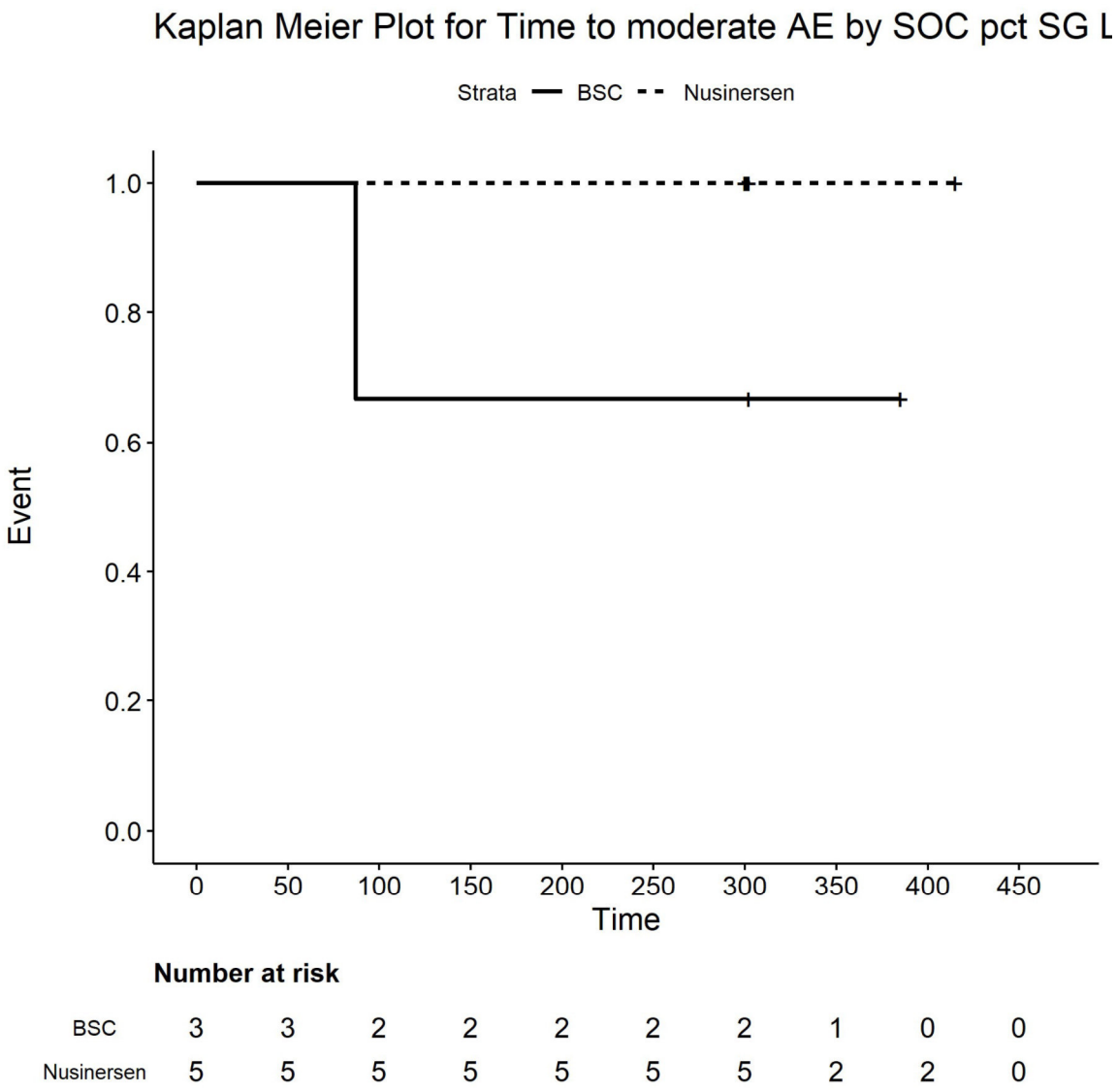
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



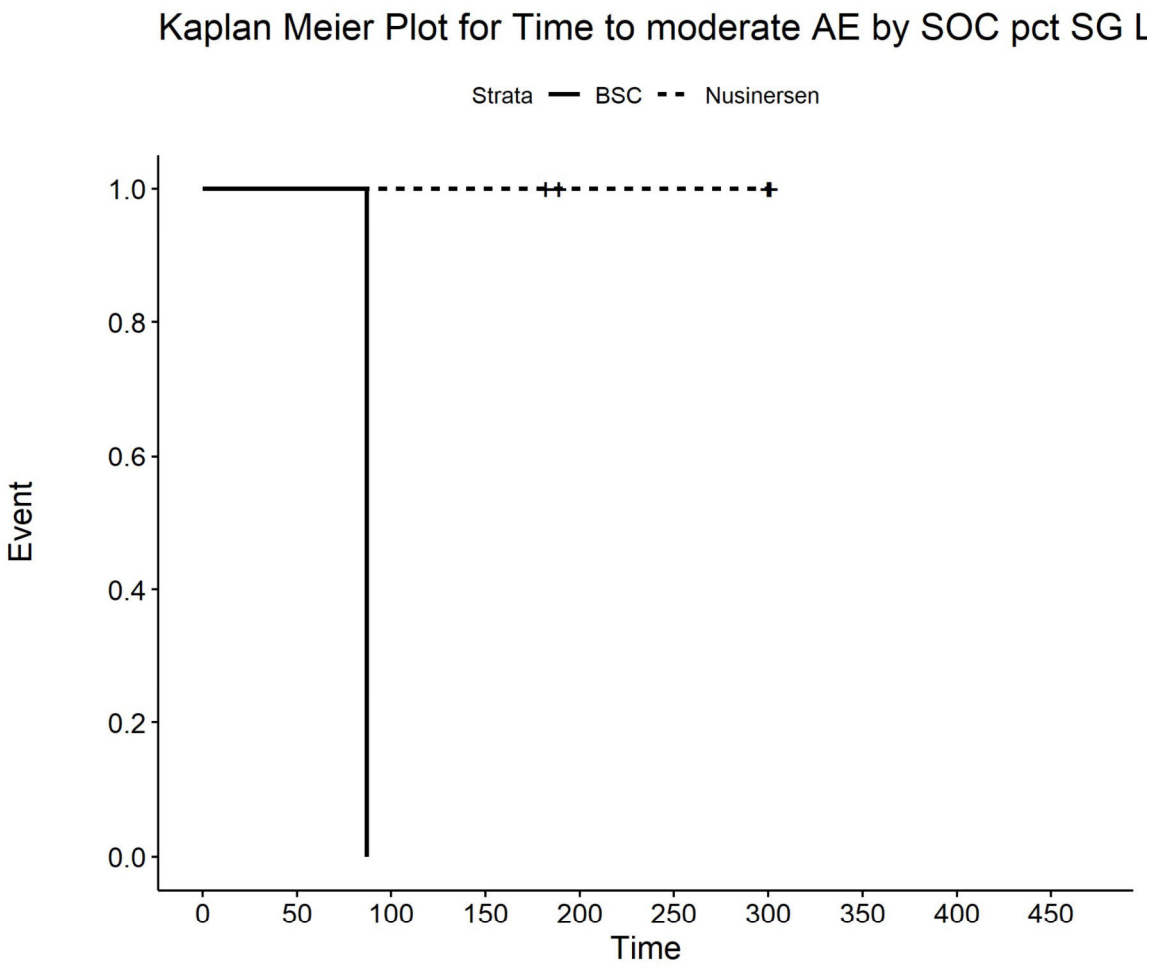
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



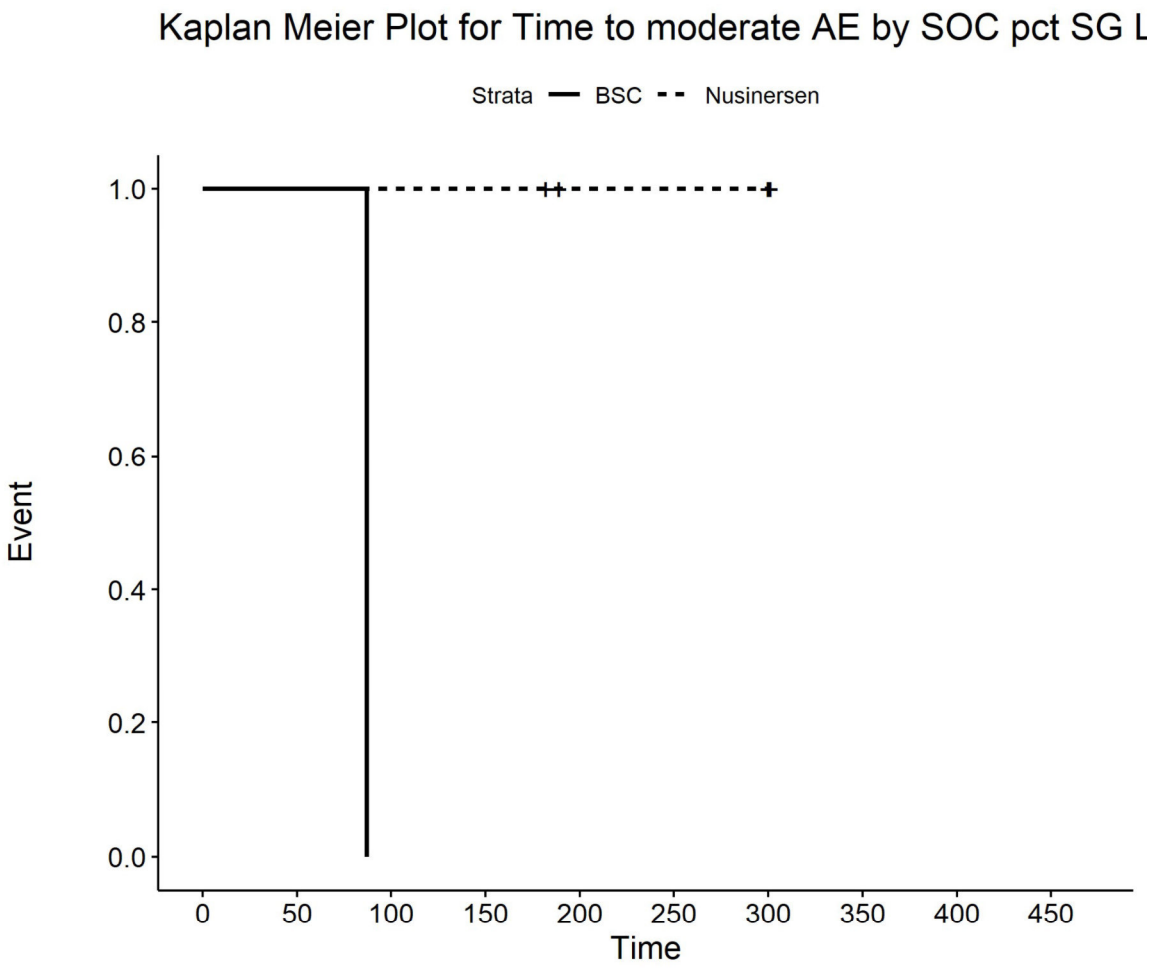
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



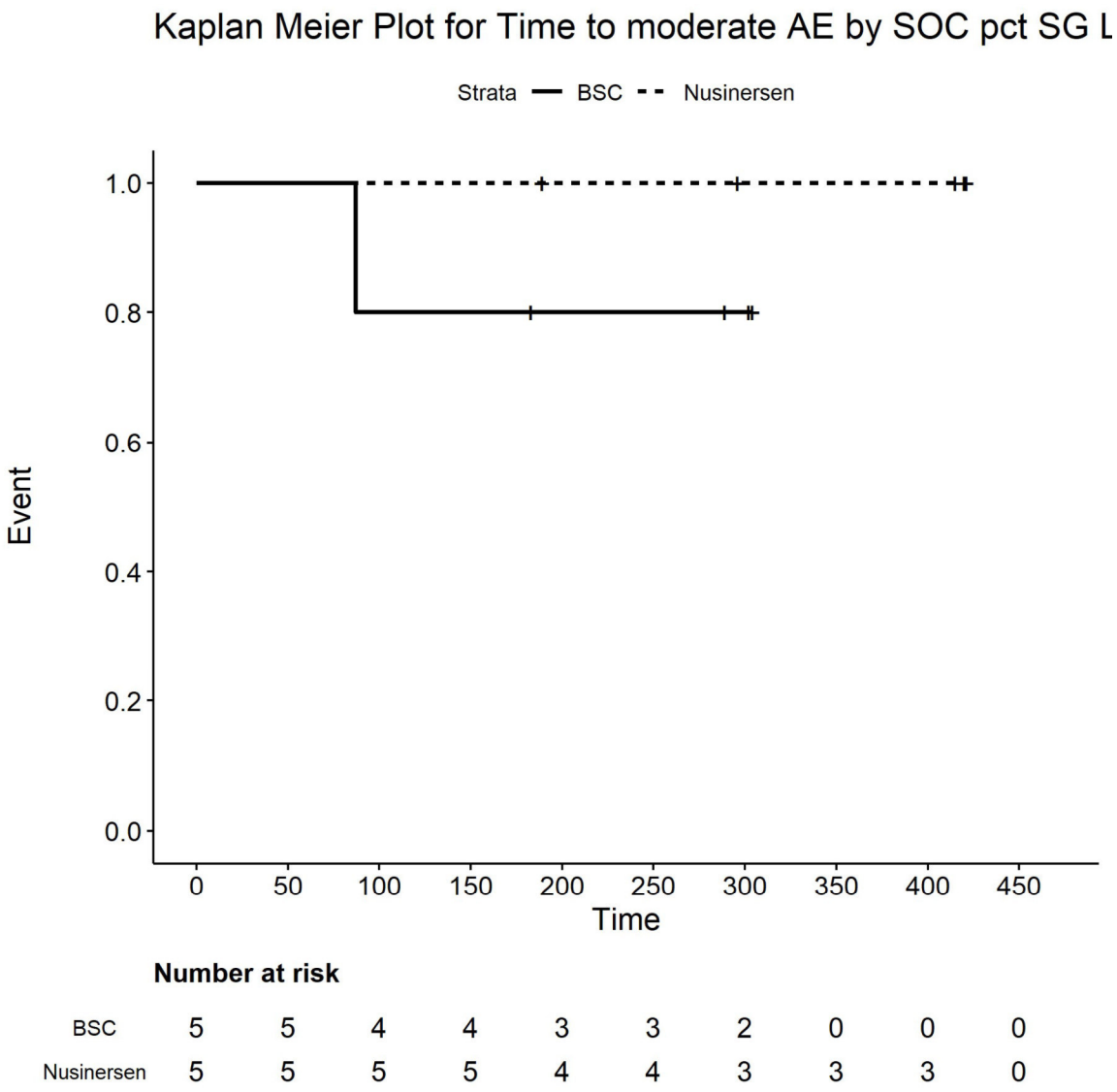
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



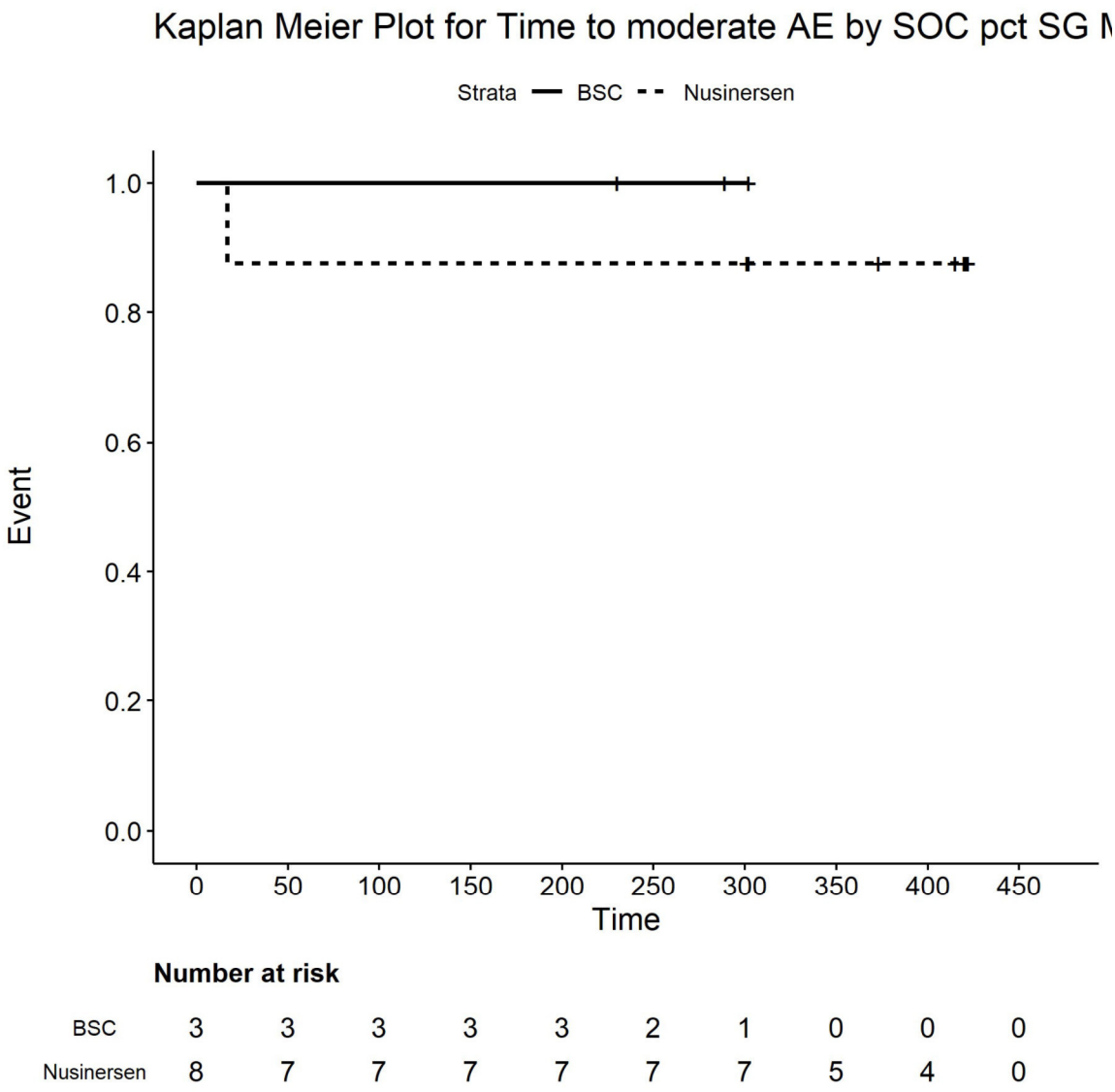
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



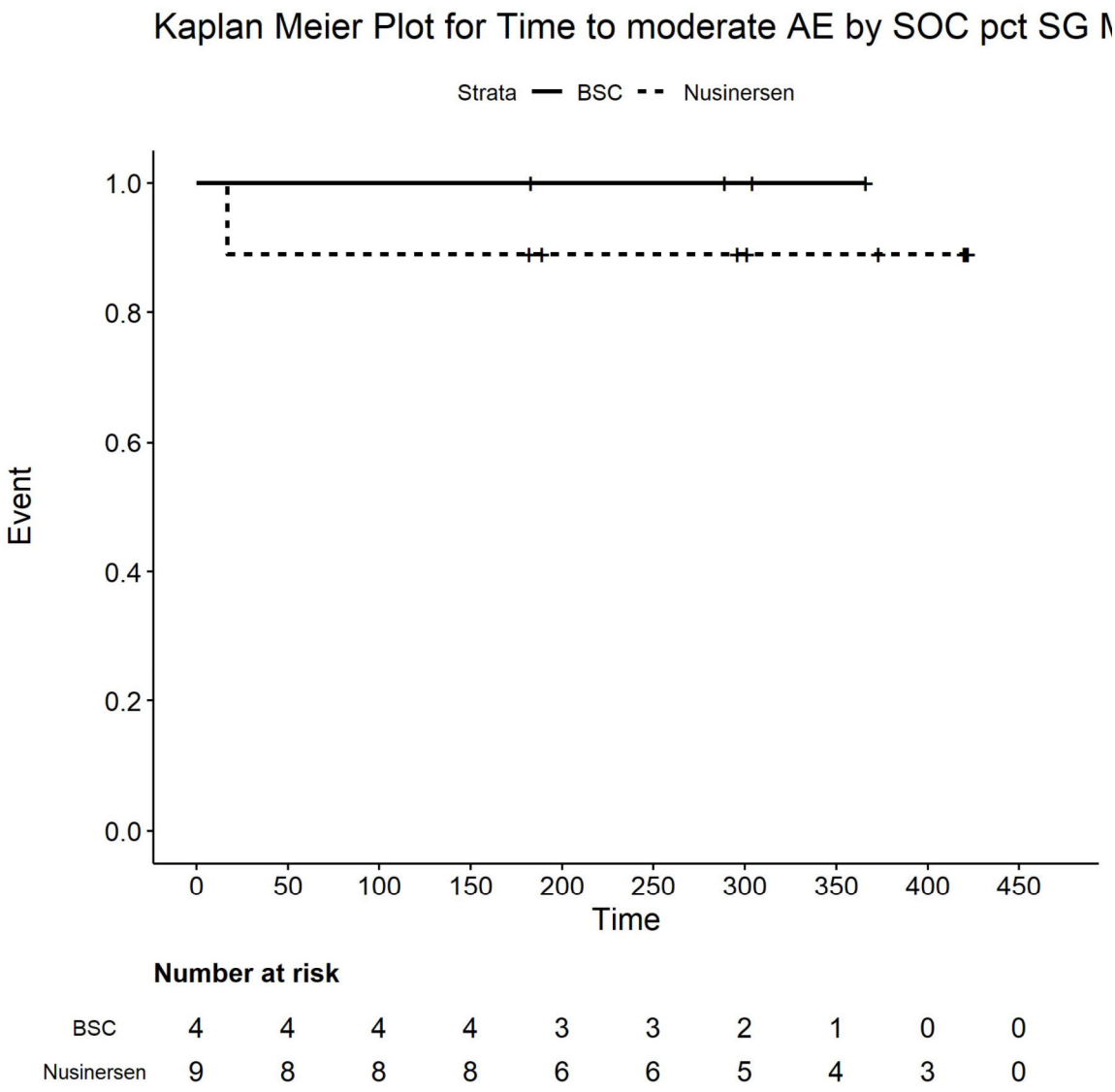
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



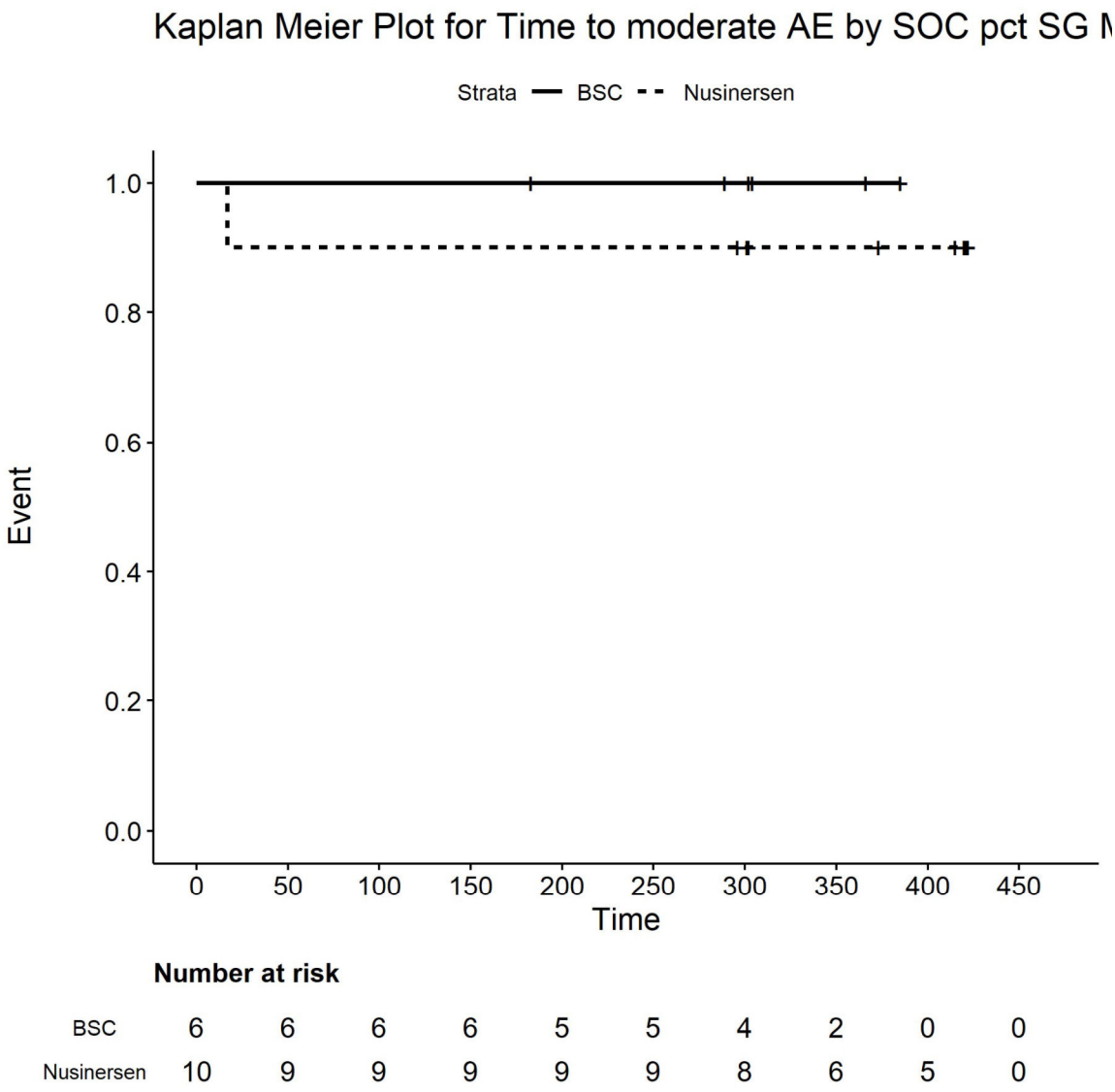
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



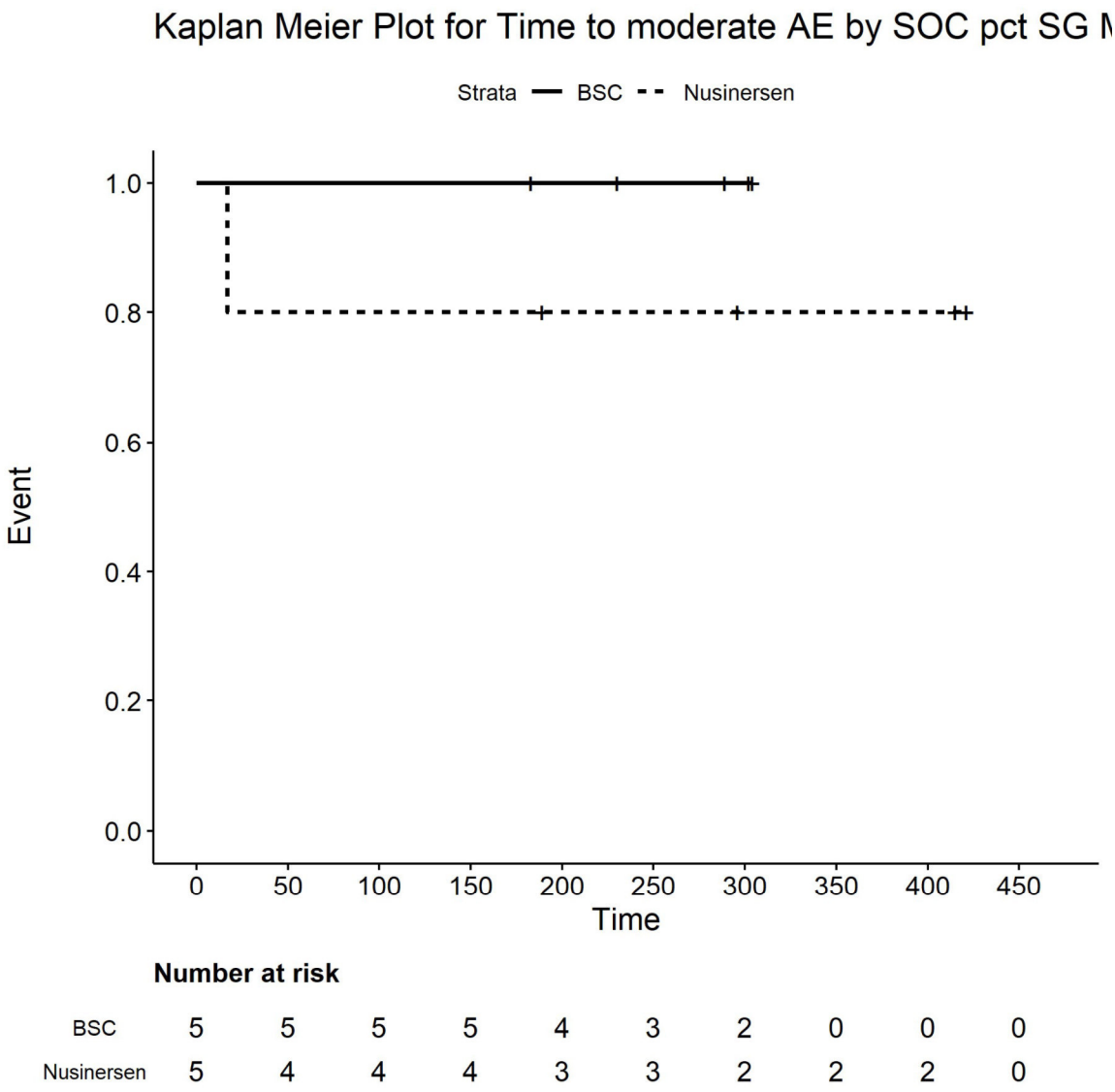
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



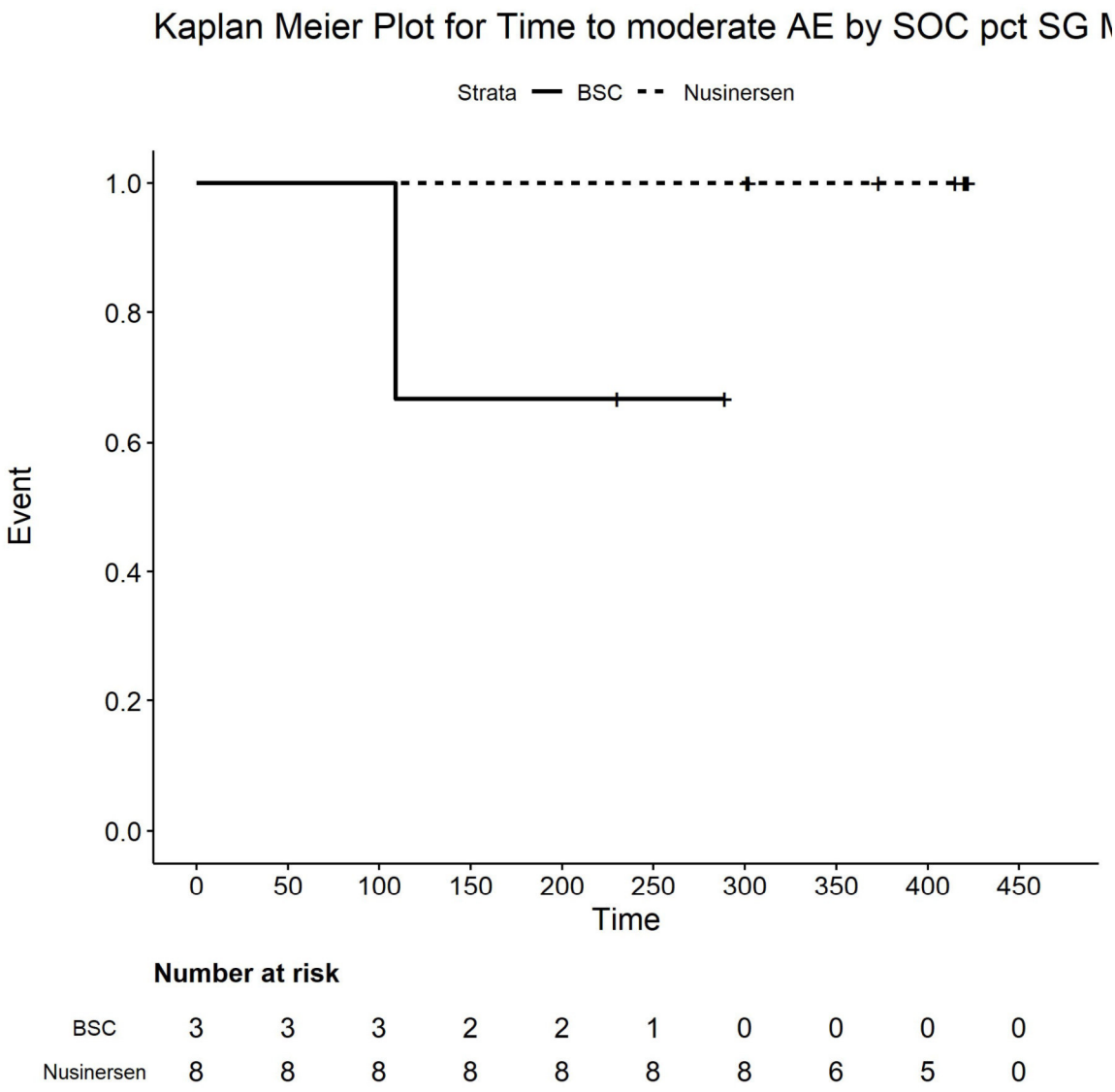
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



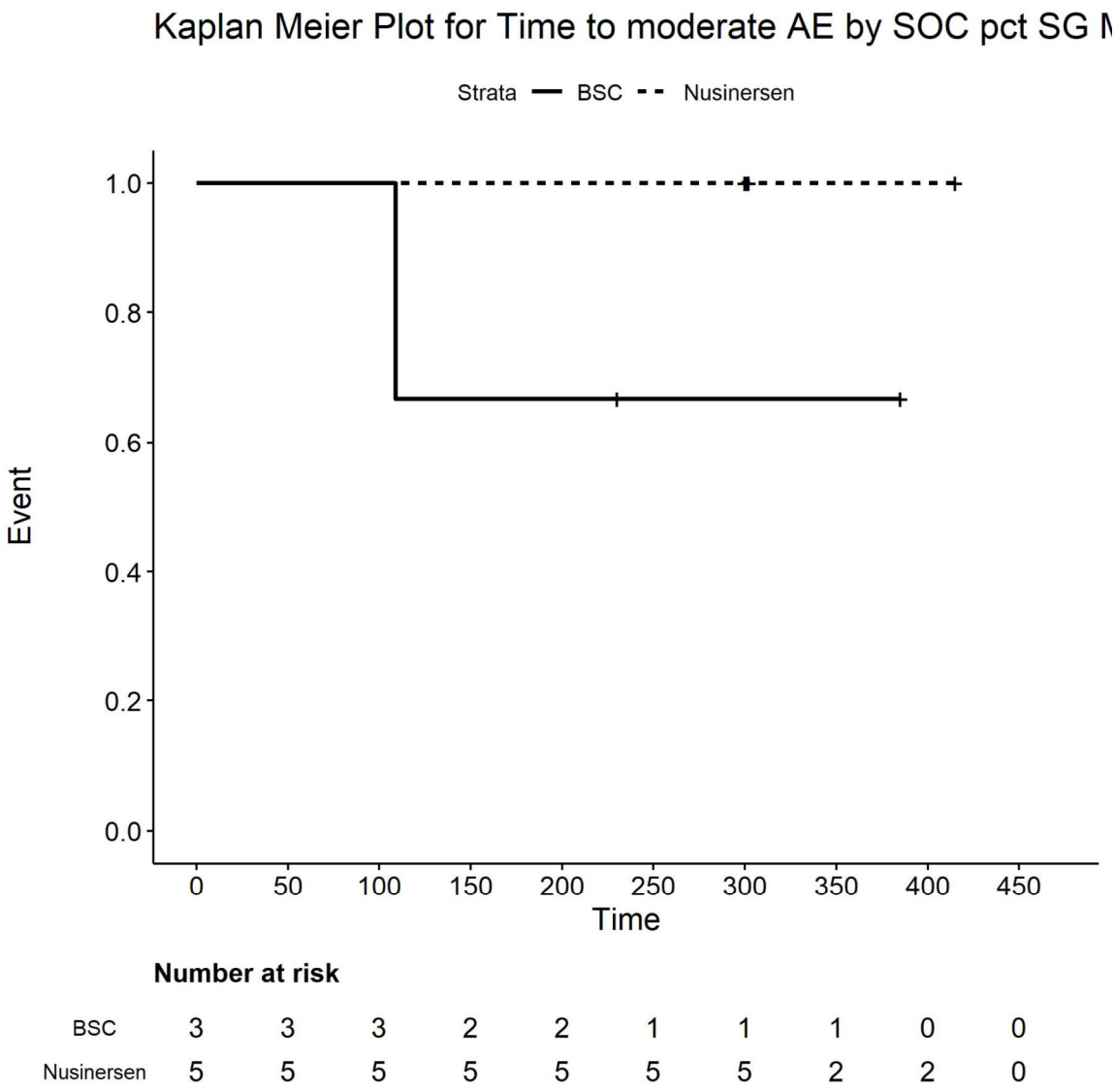
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	2	2	2	0



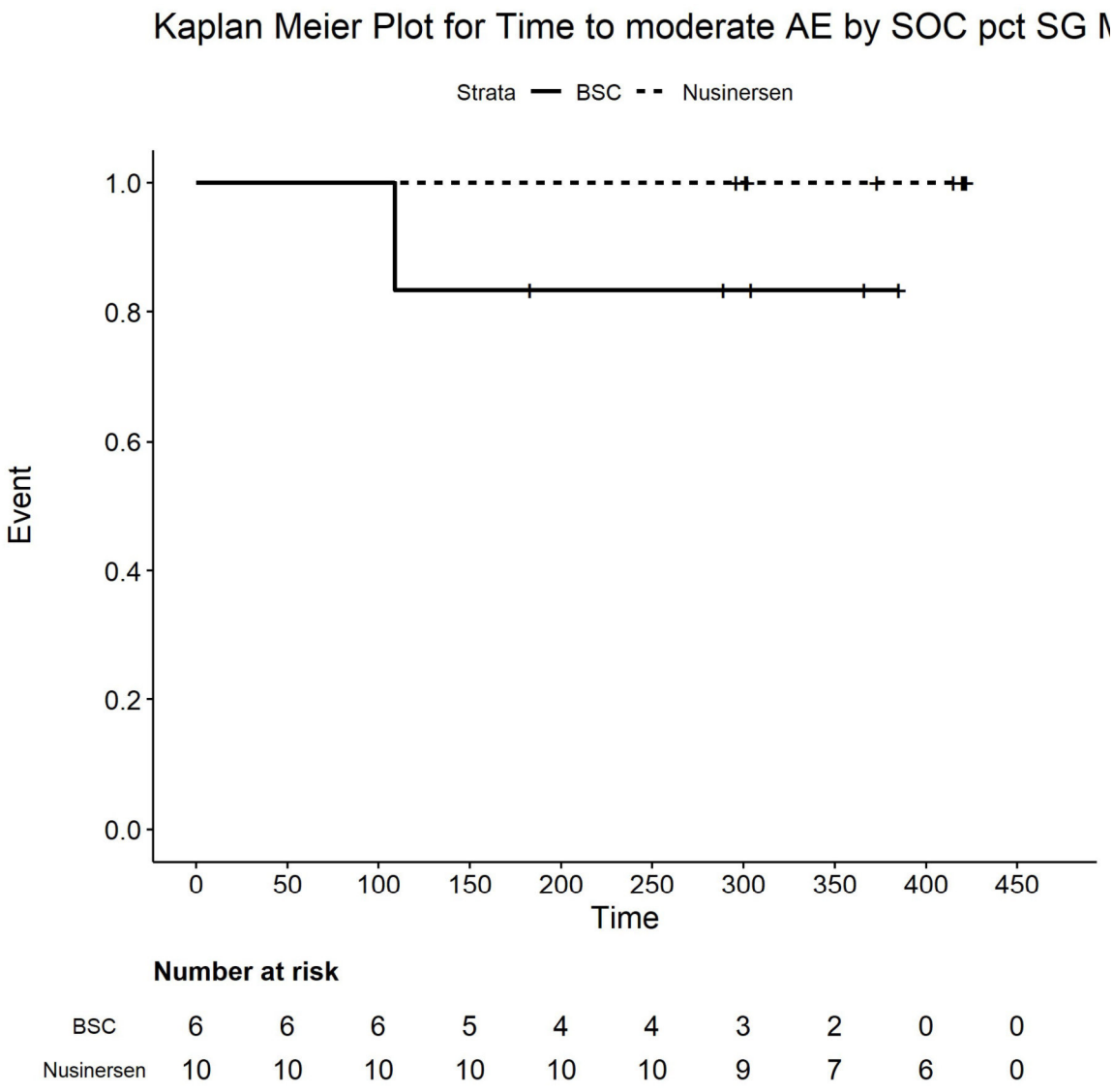
Number at risk

BSC	3	3	3	2	2	1	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



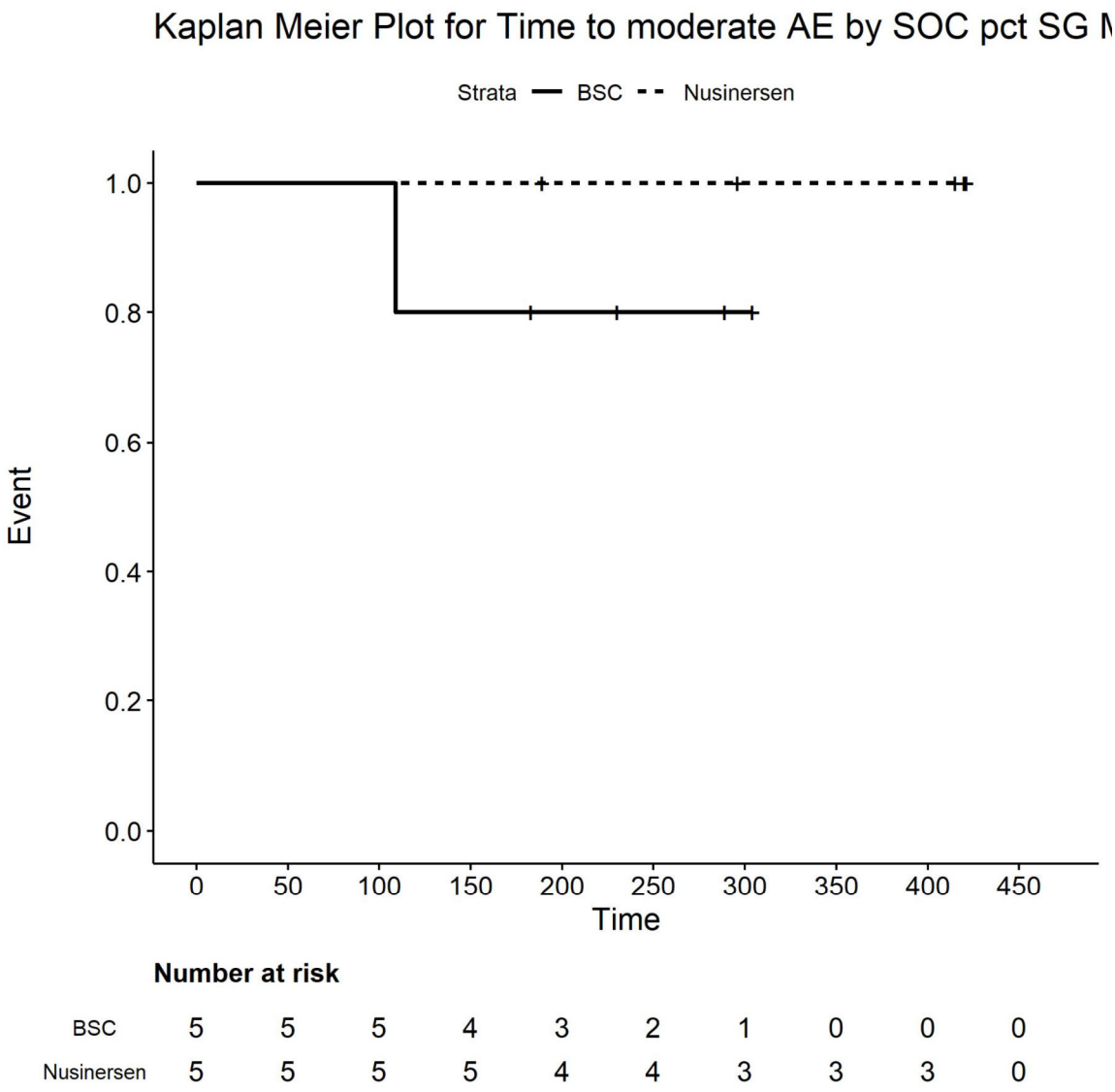
Number at risk

BSC	3	3	3	2	2	1	1	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



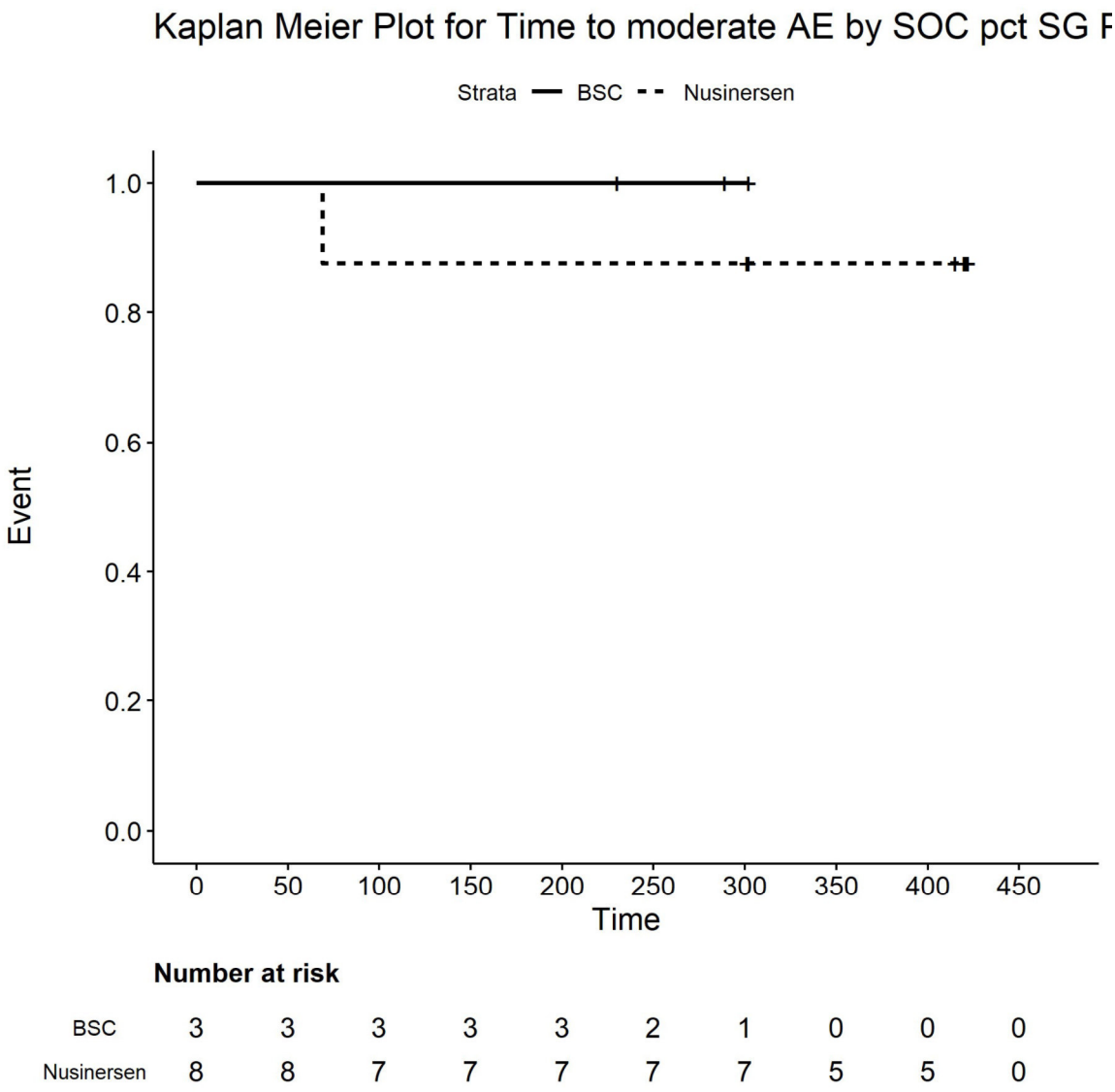
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



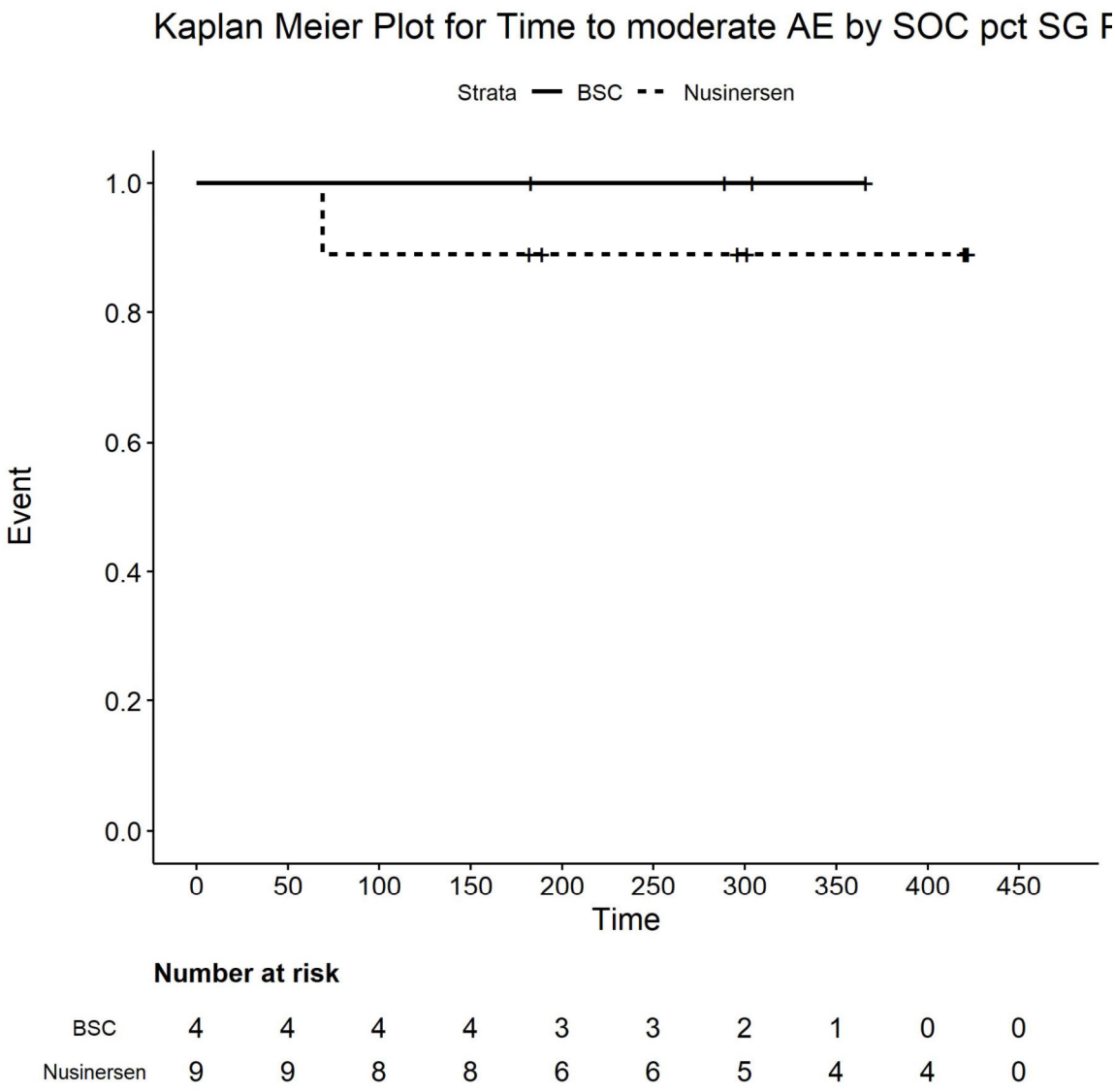
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



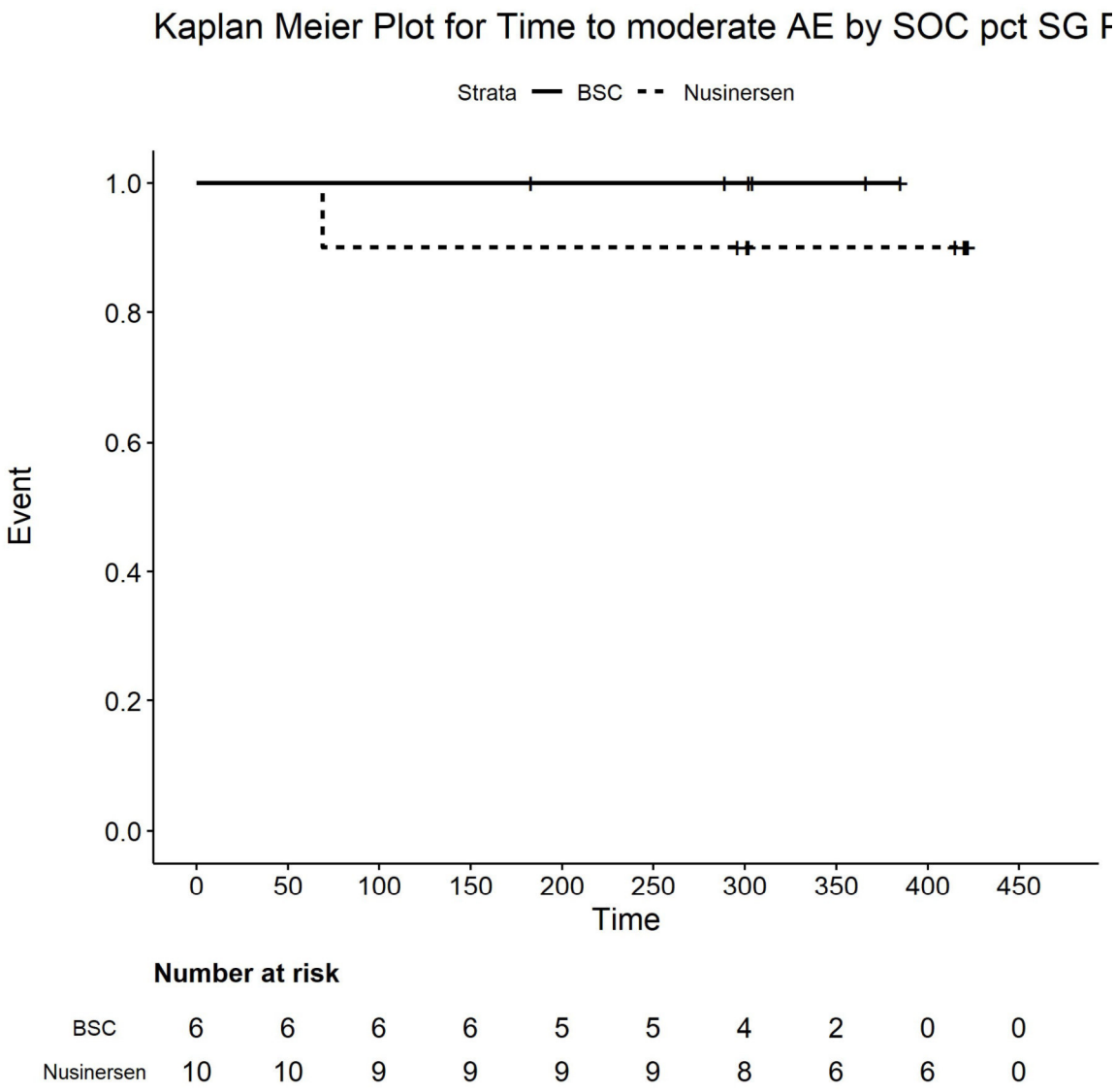
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	5	0



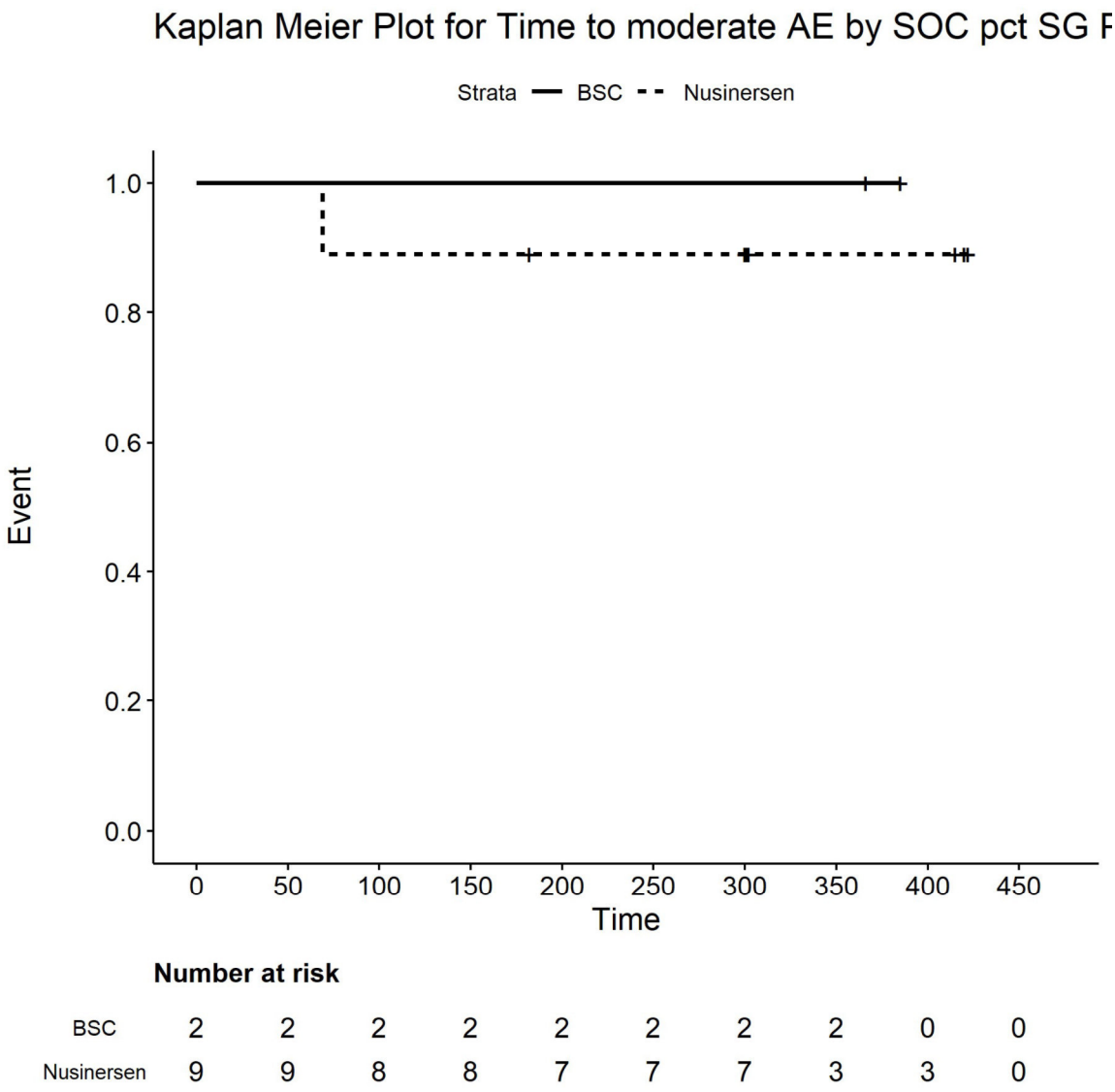
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	4	0



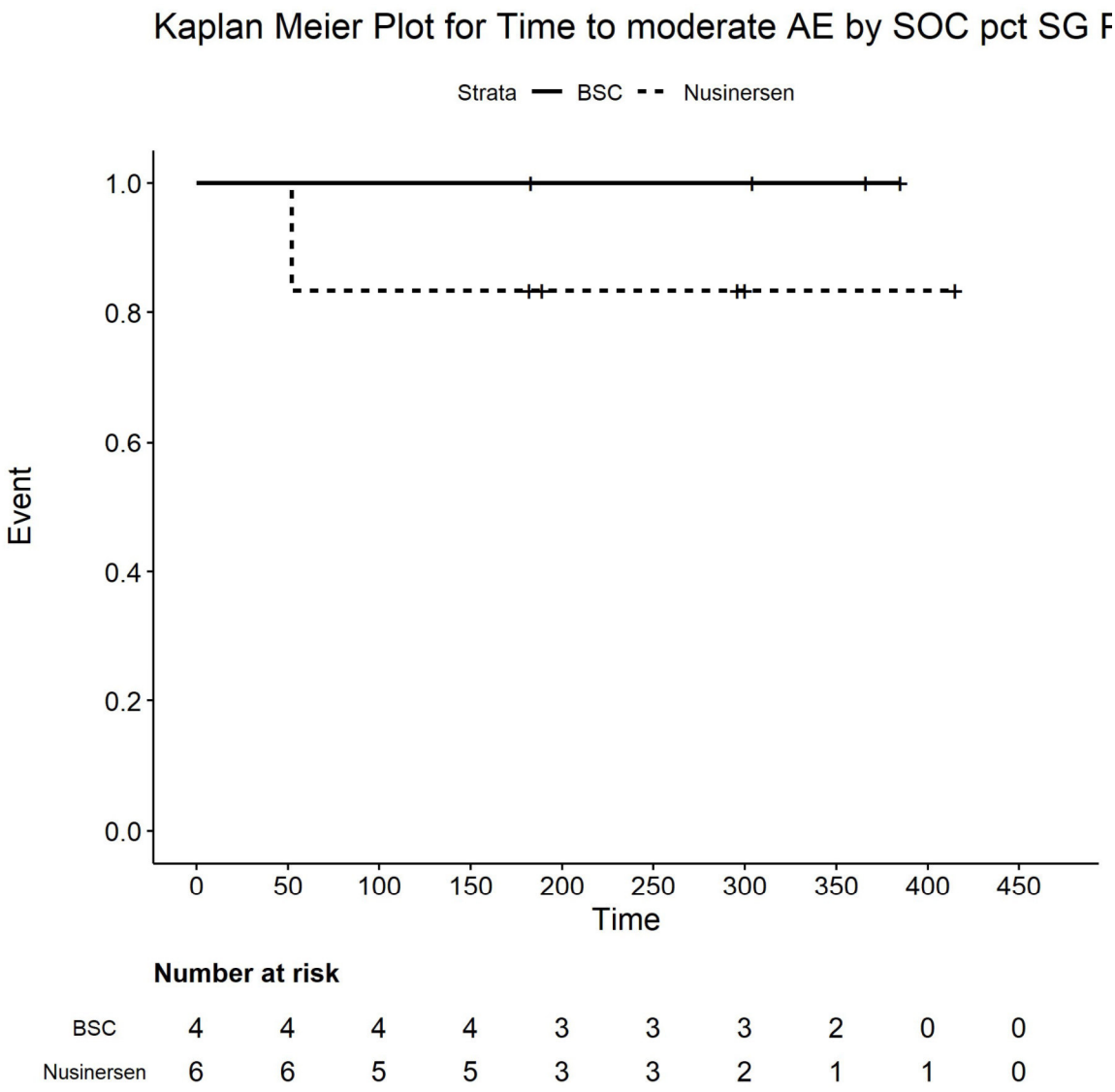
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	6	0



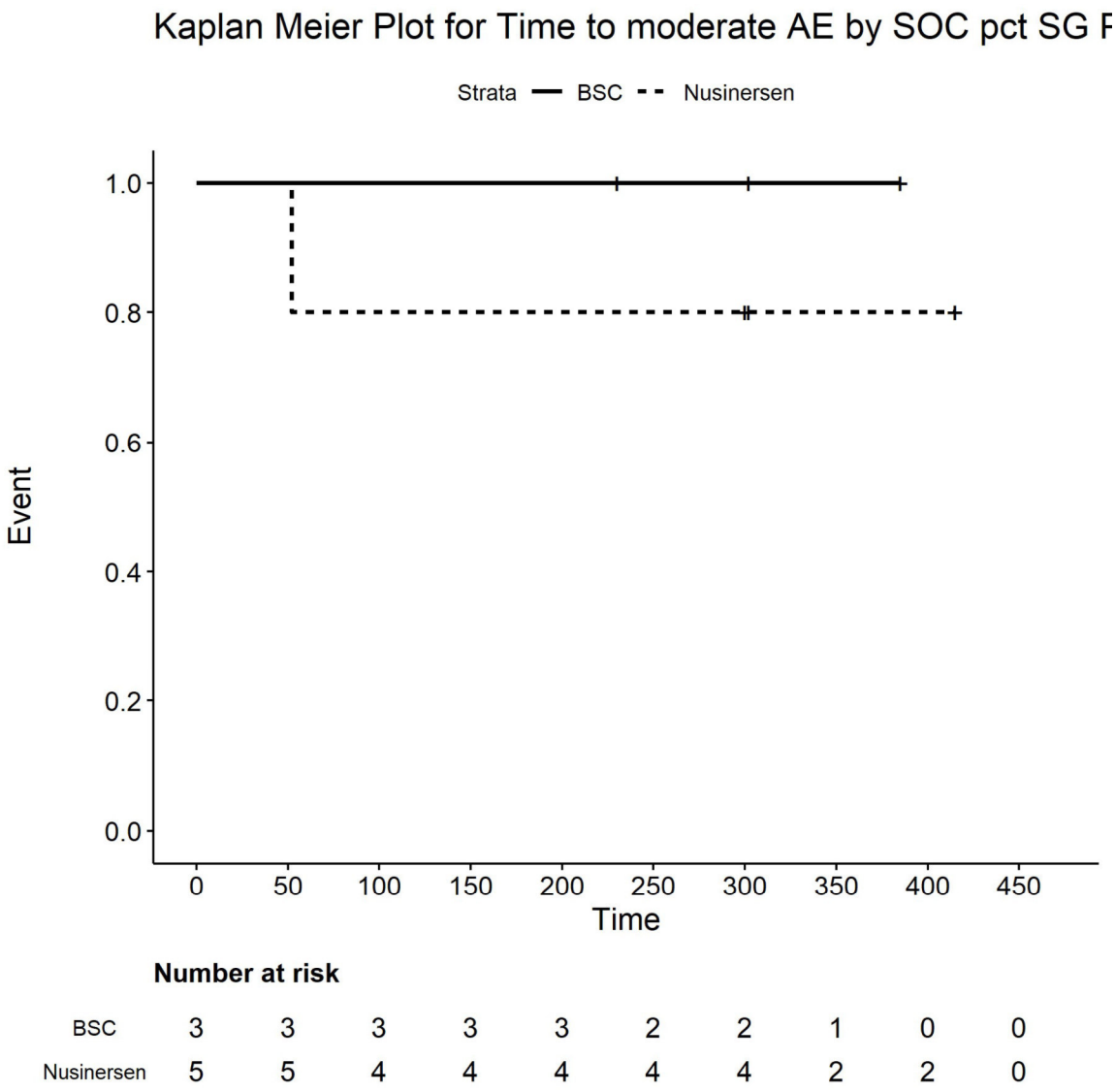
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	3	0



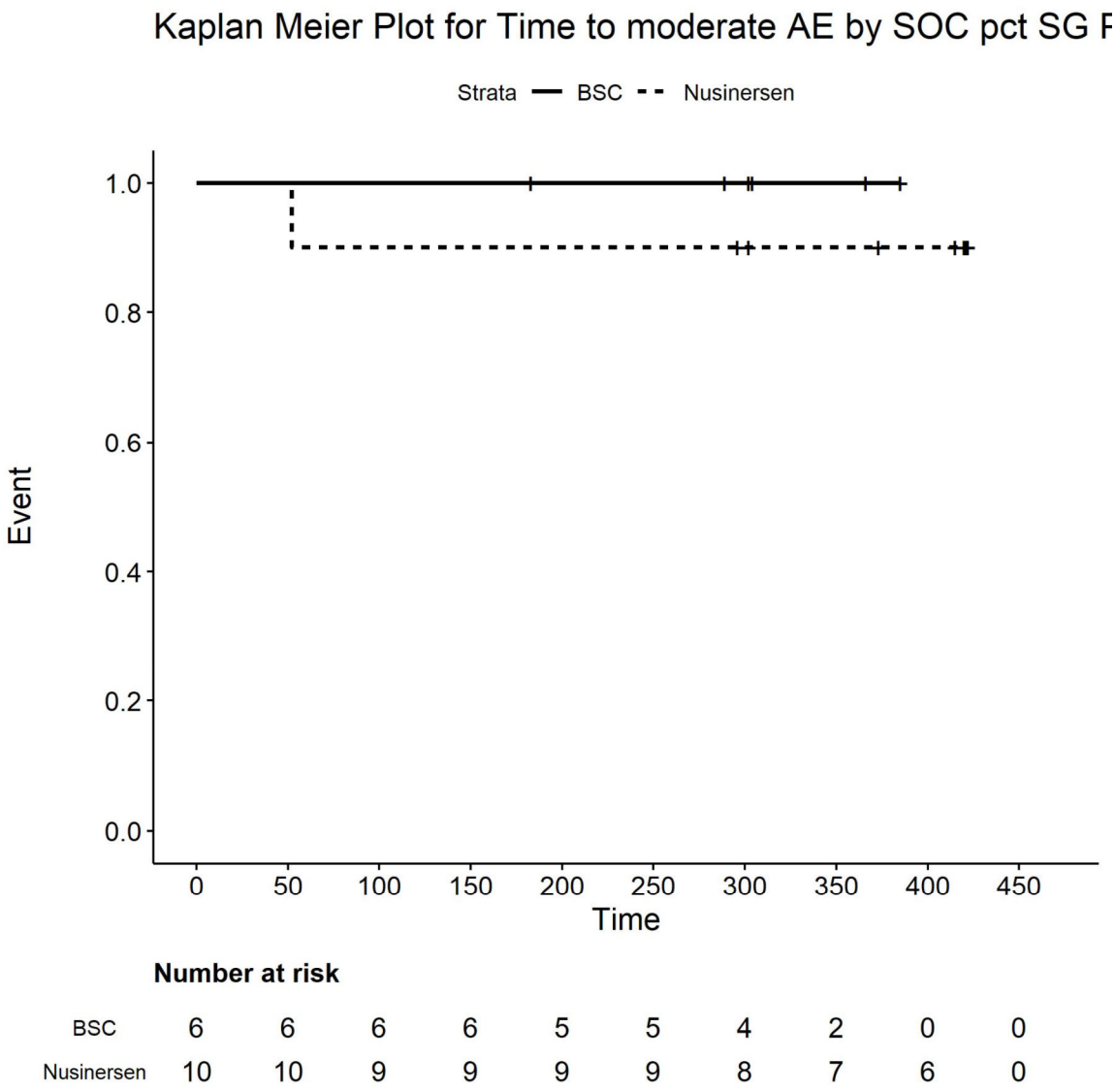
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



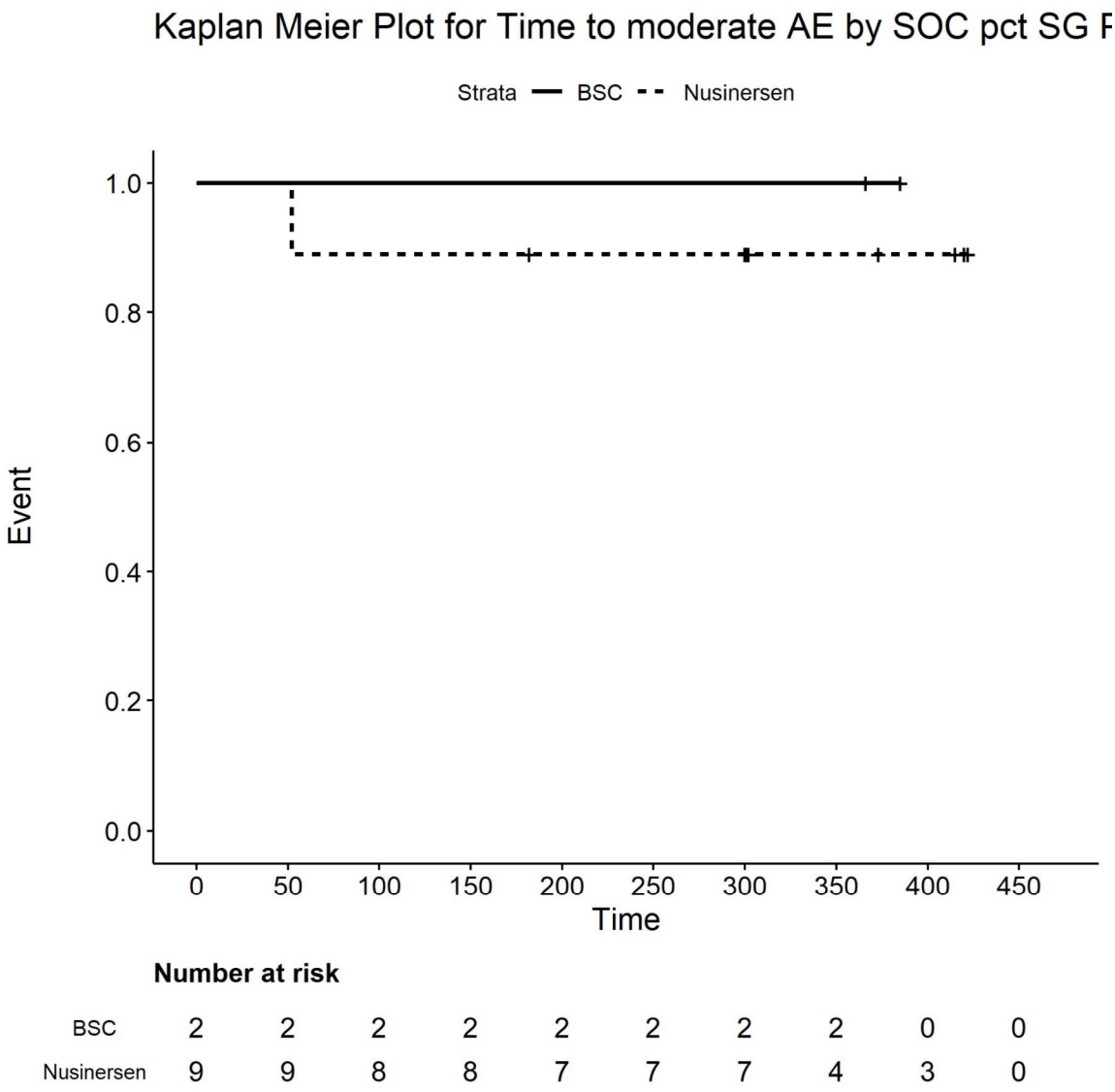
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



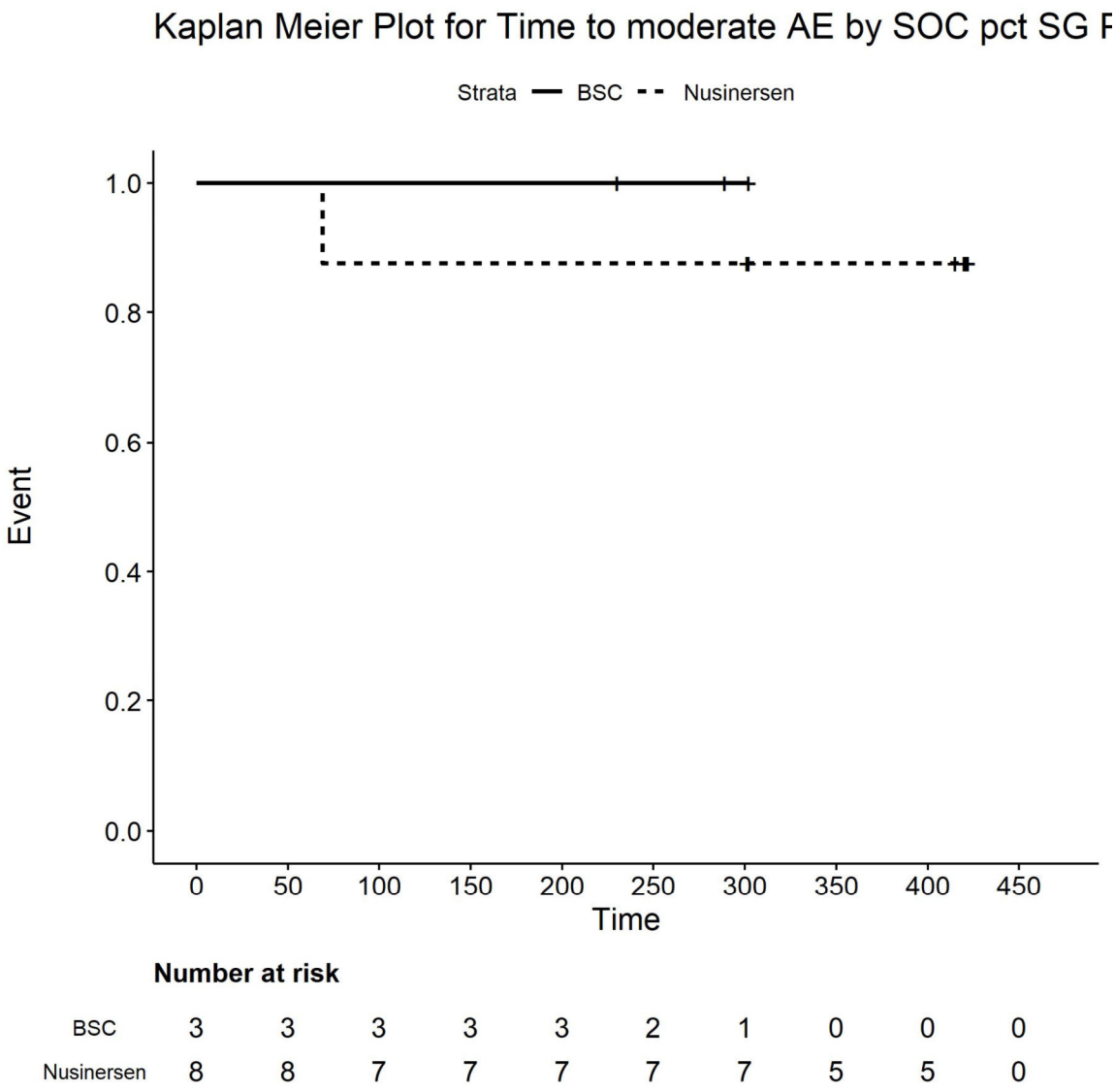
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



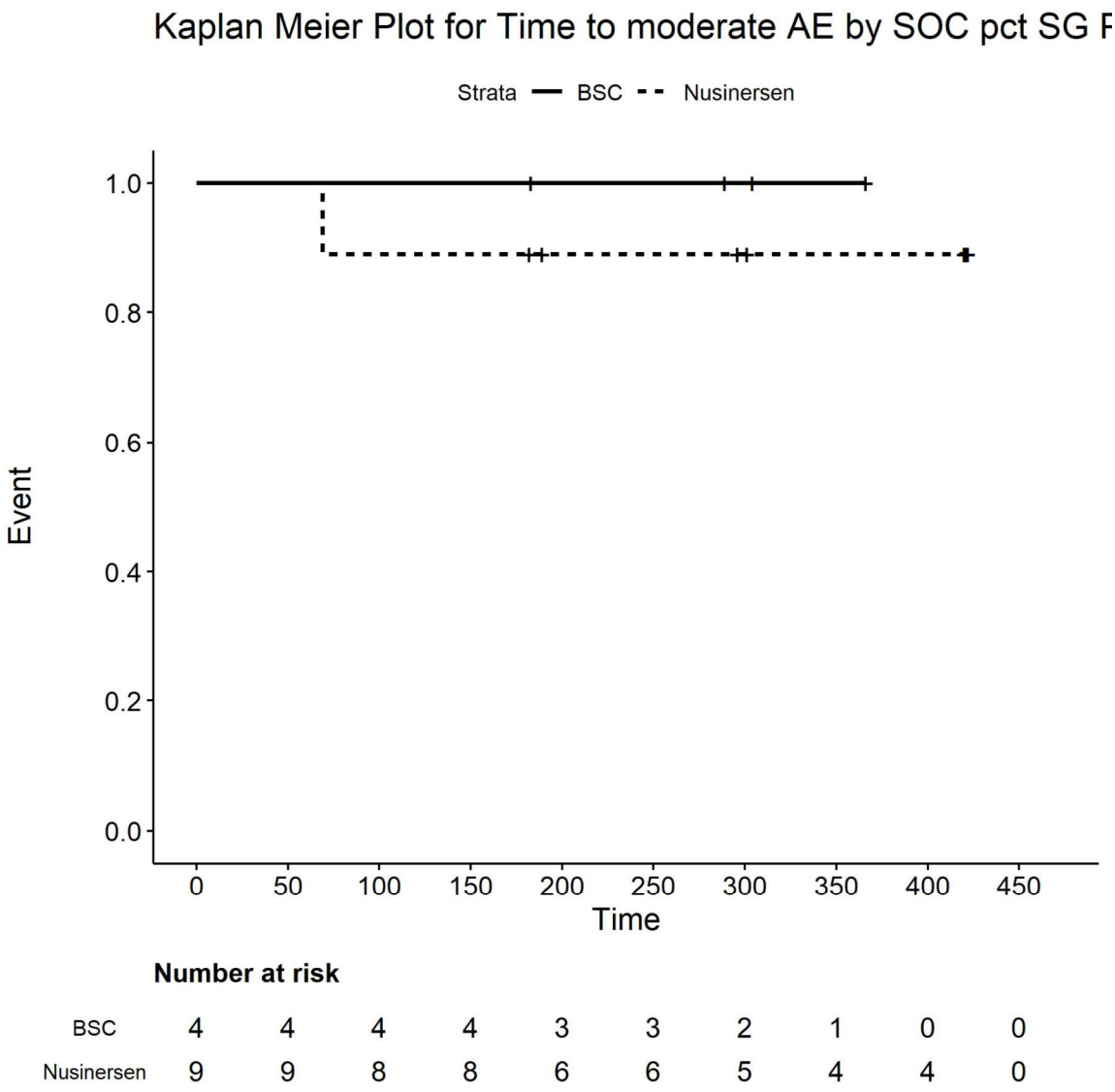
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



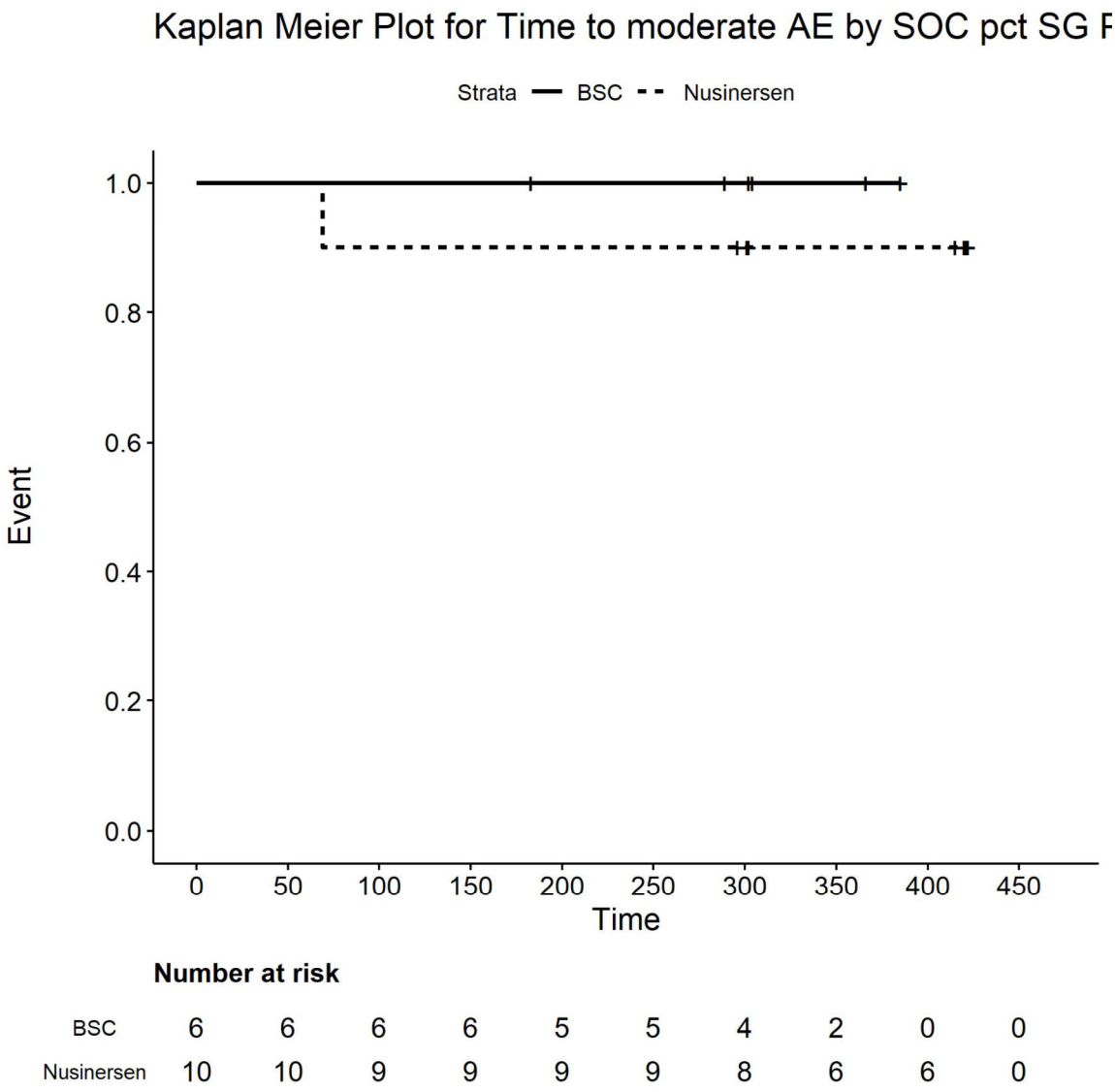
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	5	0



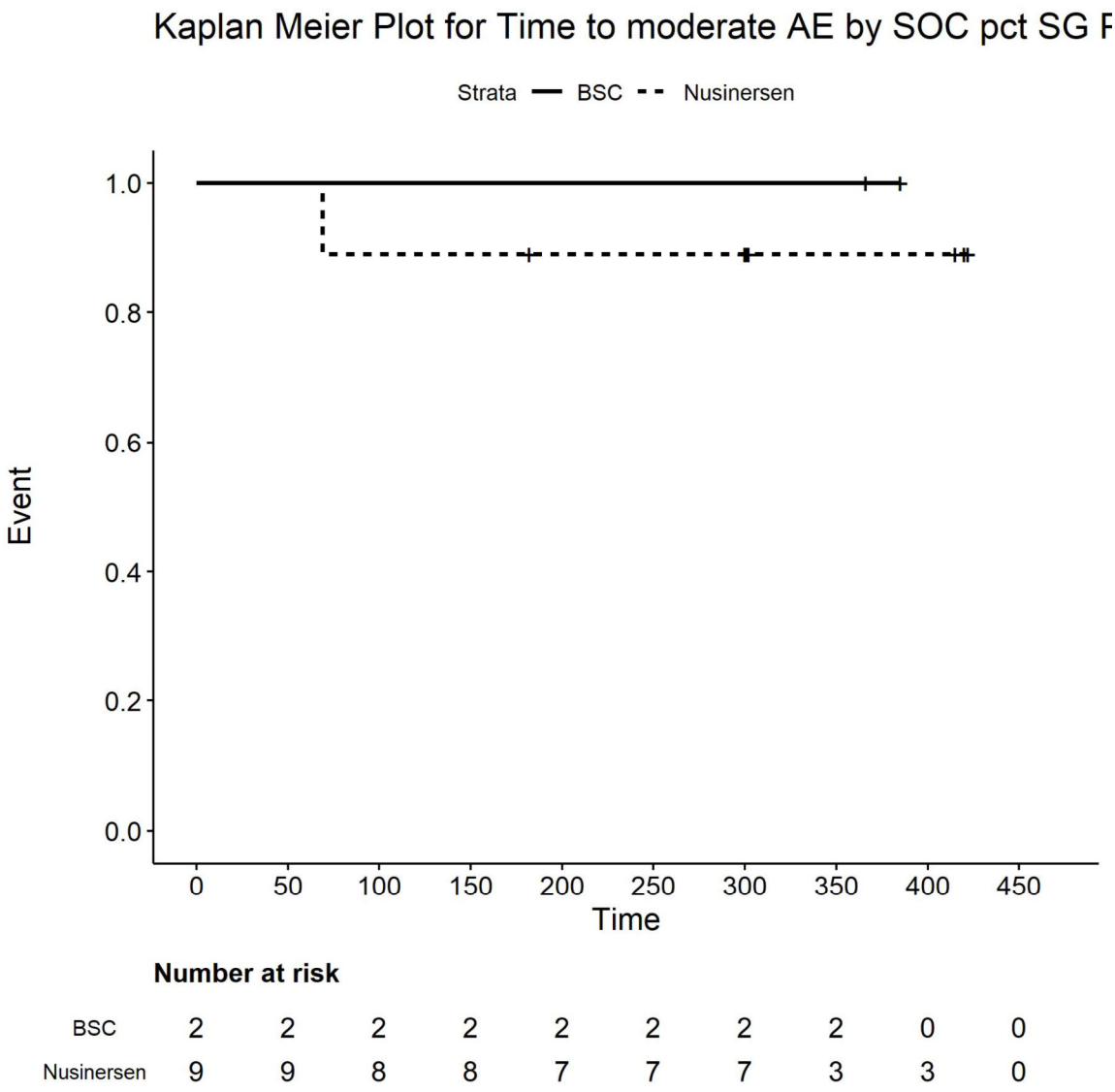
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	4	0



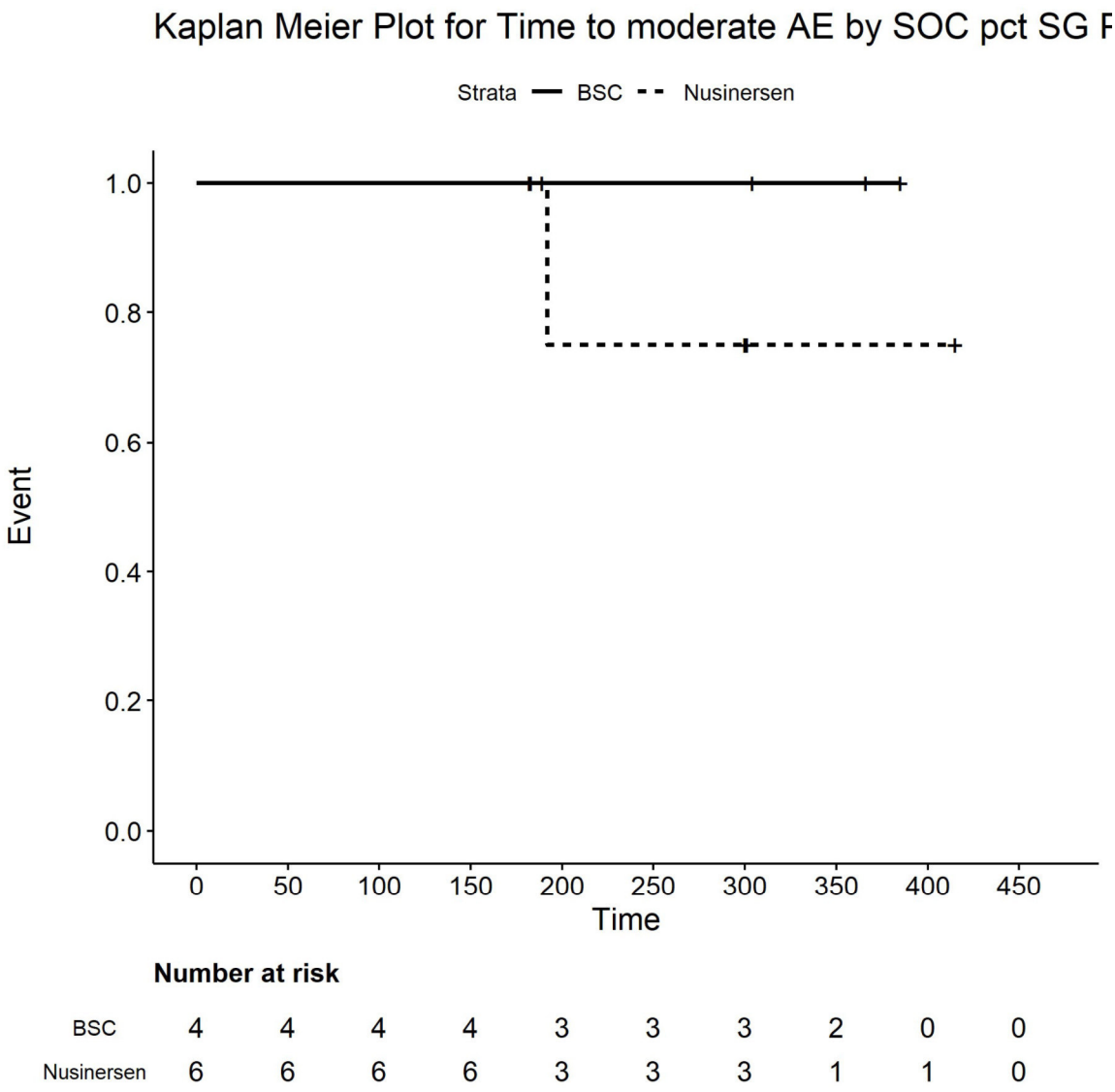
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	6	0



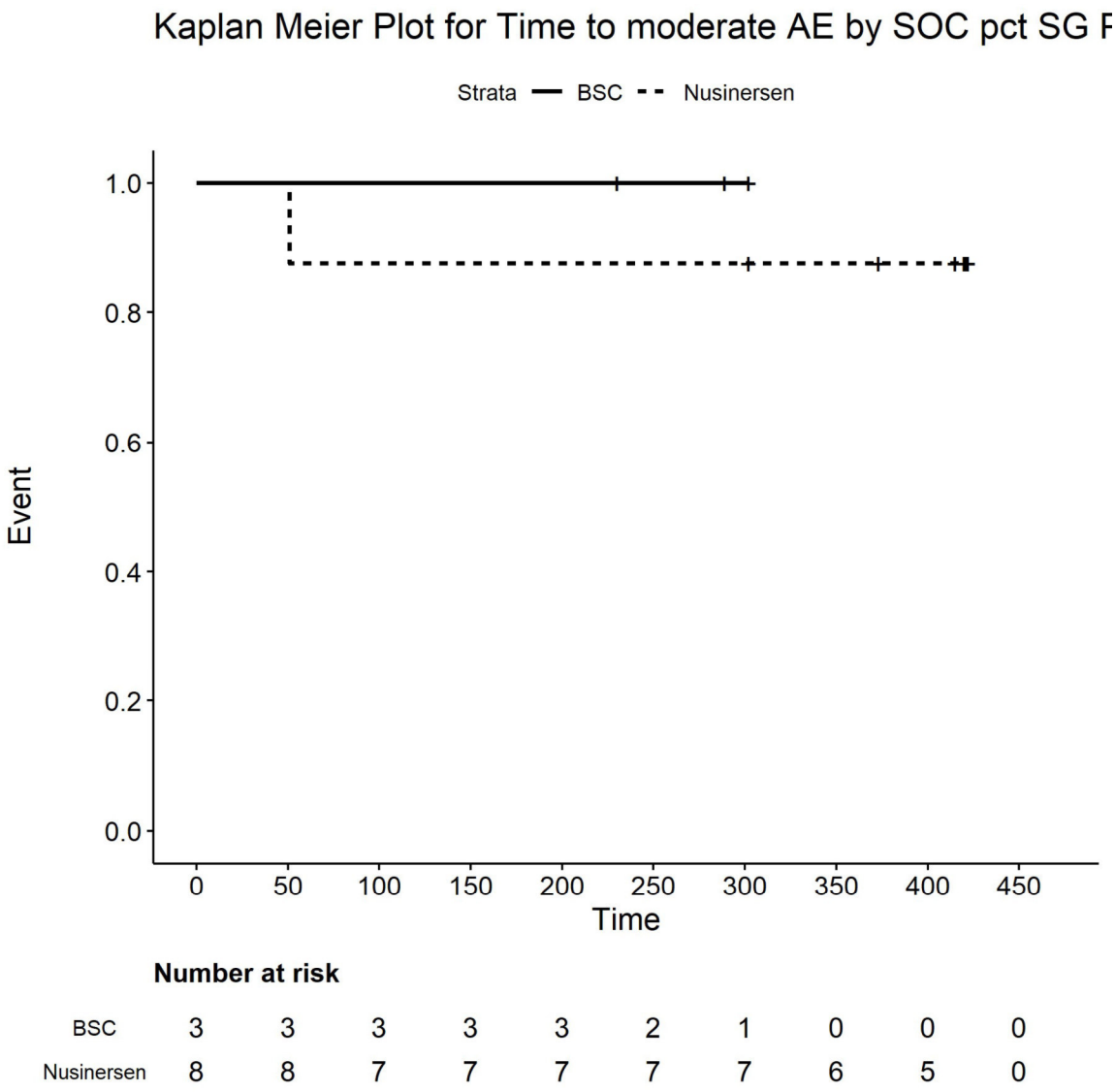
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	3	0



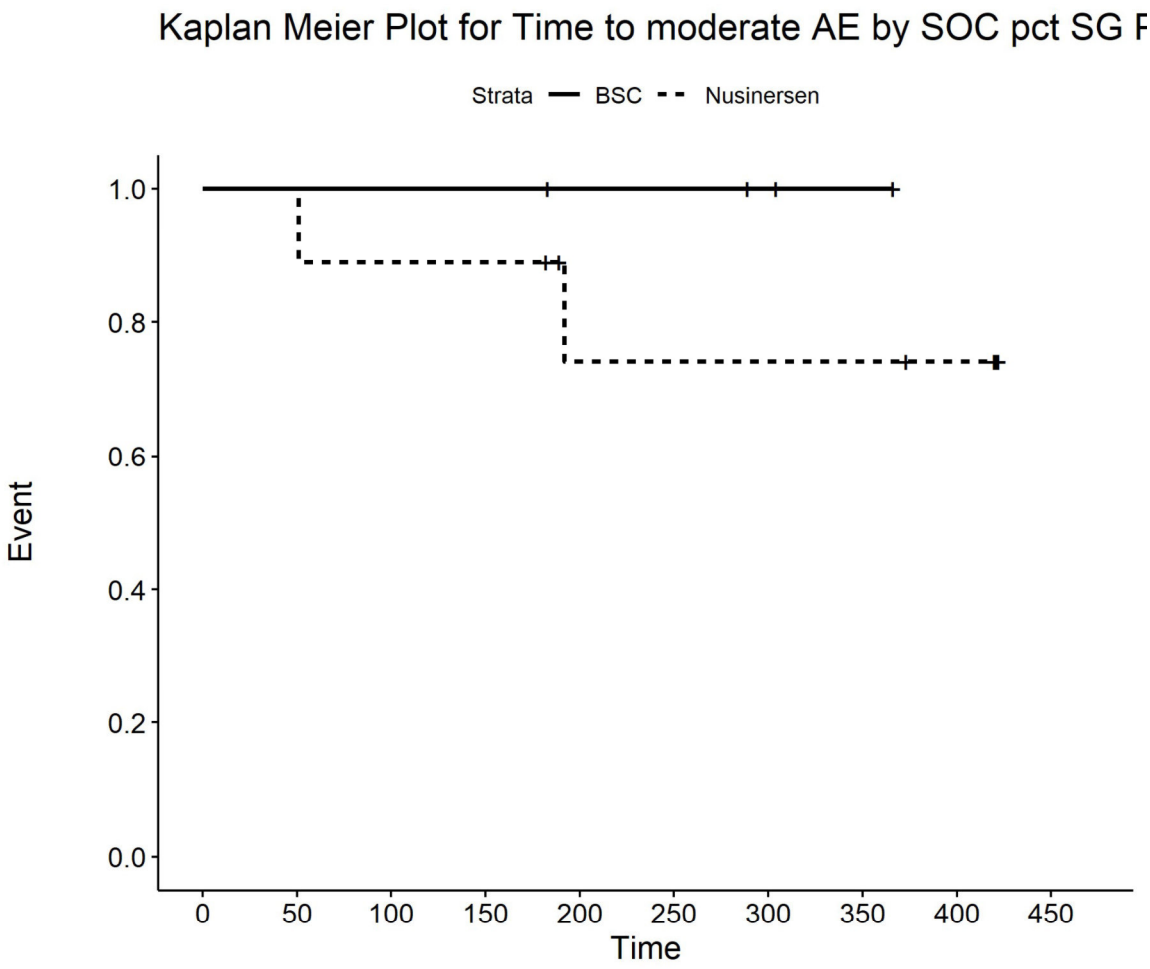
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	6	3	3	3	1	1	0



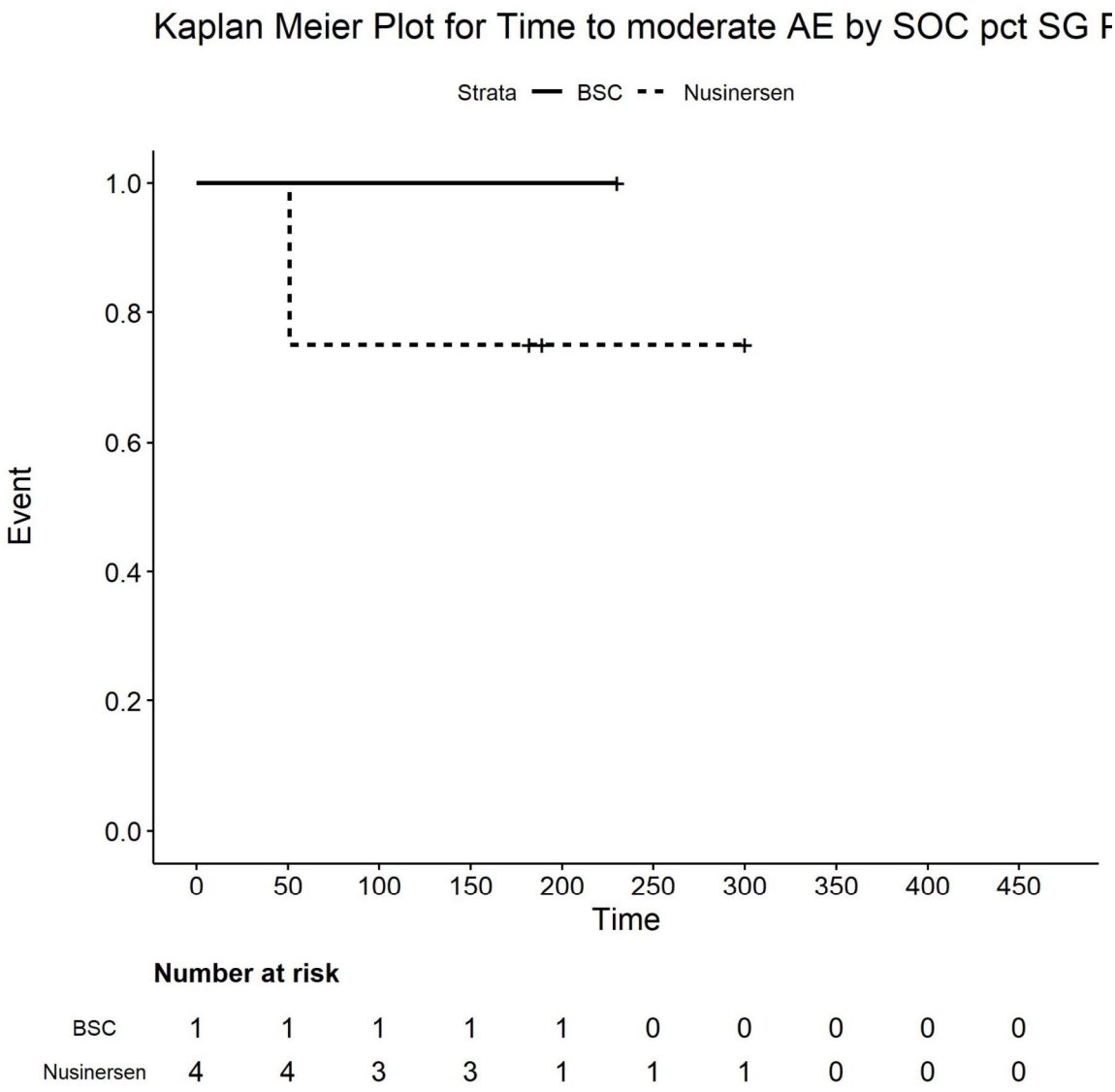
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	6	5	0



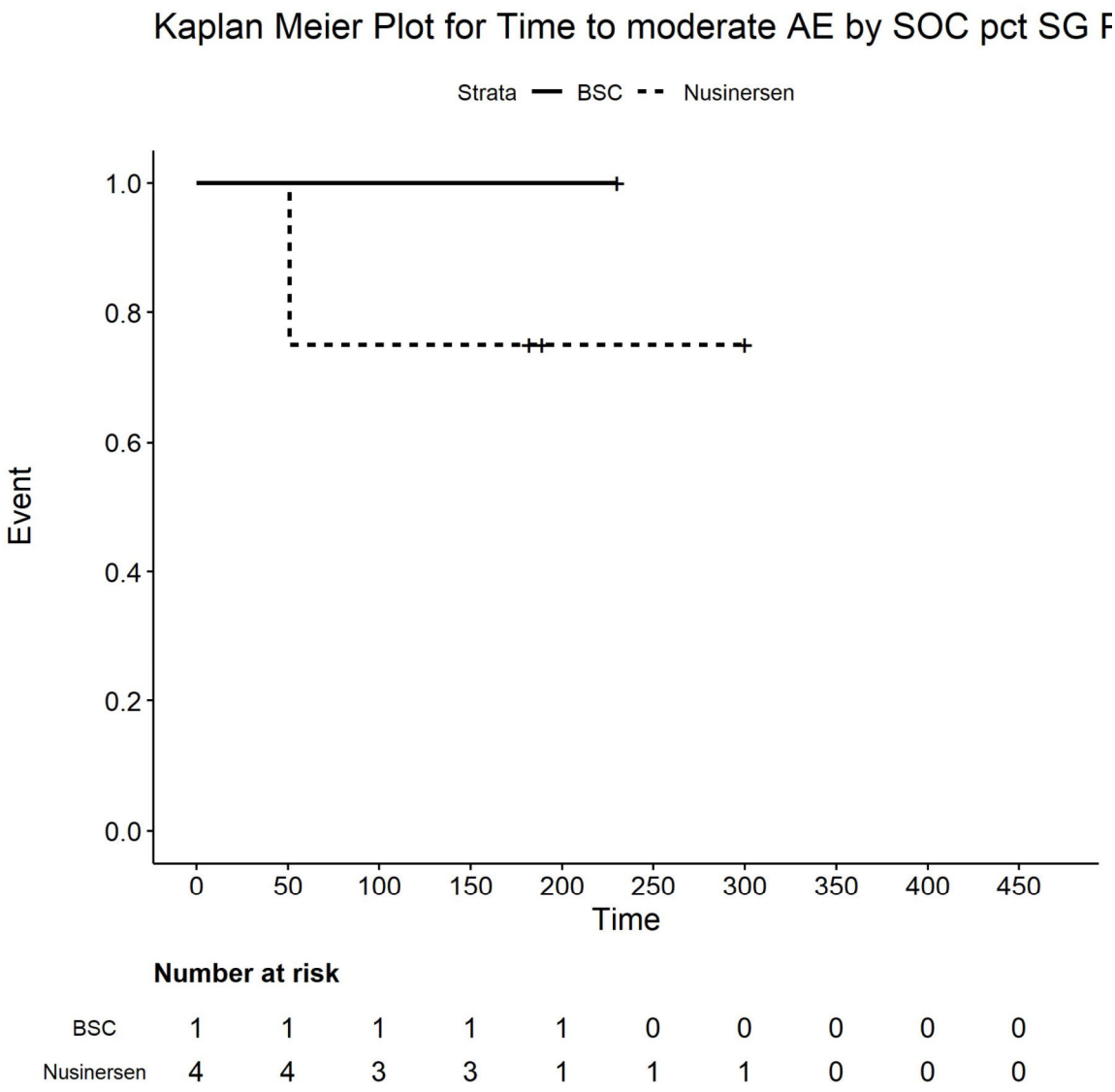
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	5	5	5	5	4	0



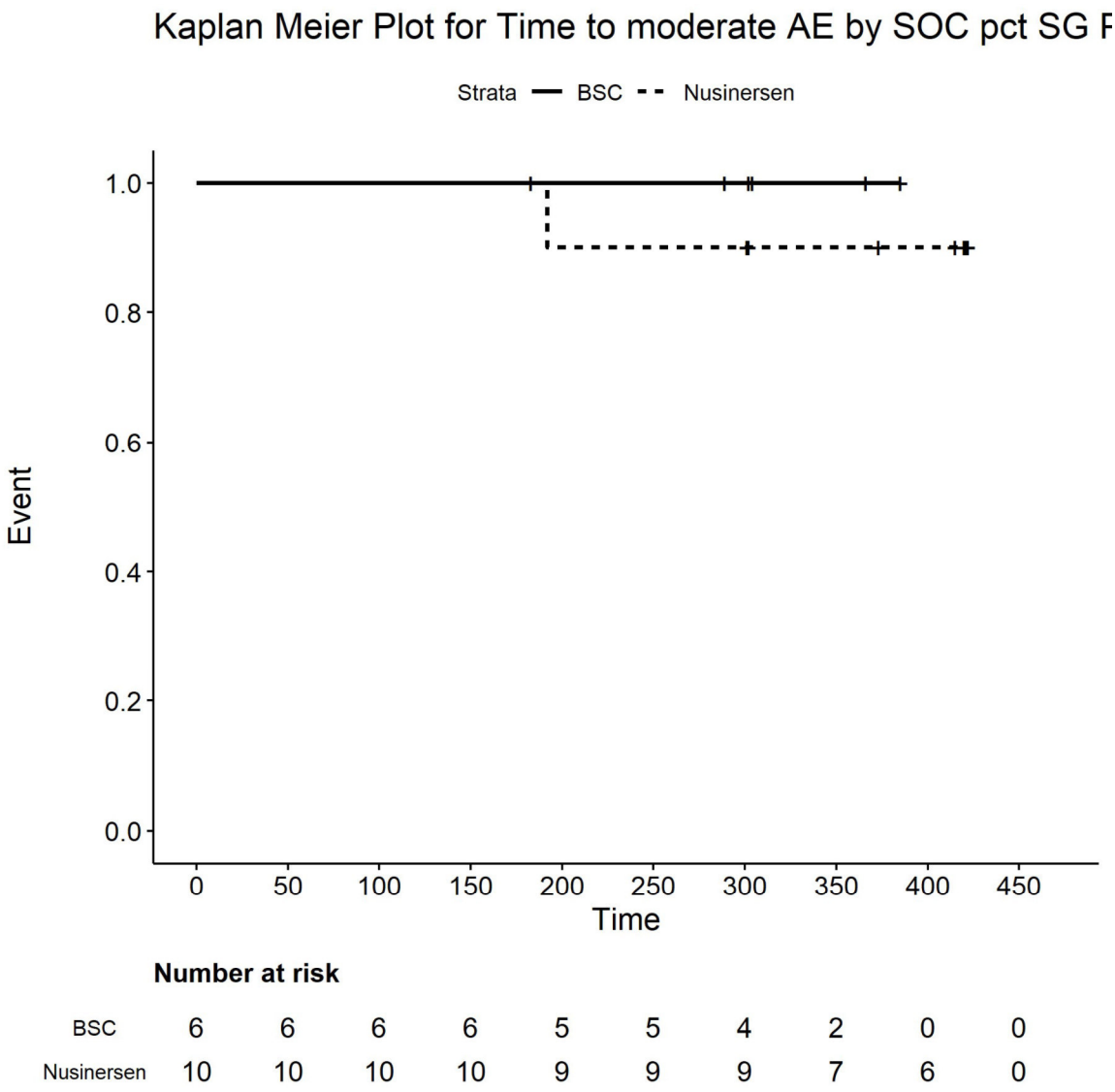
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



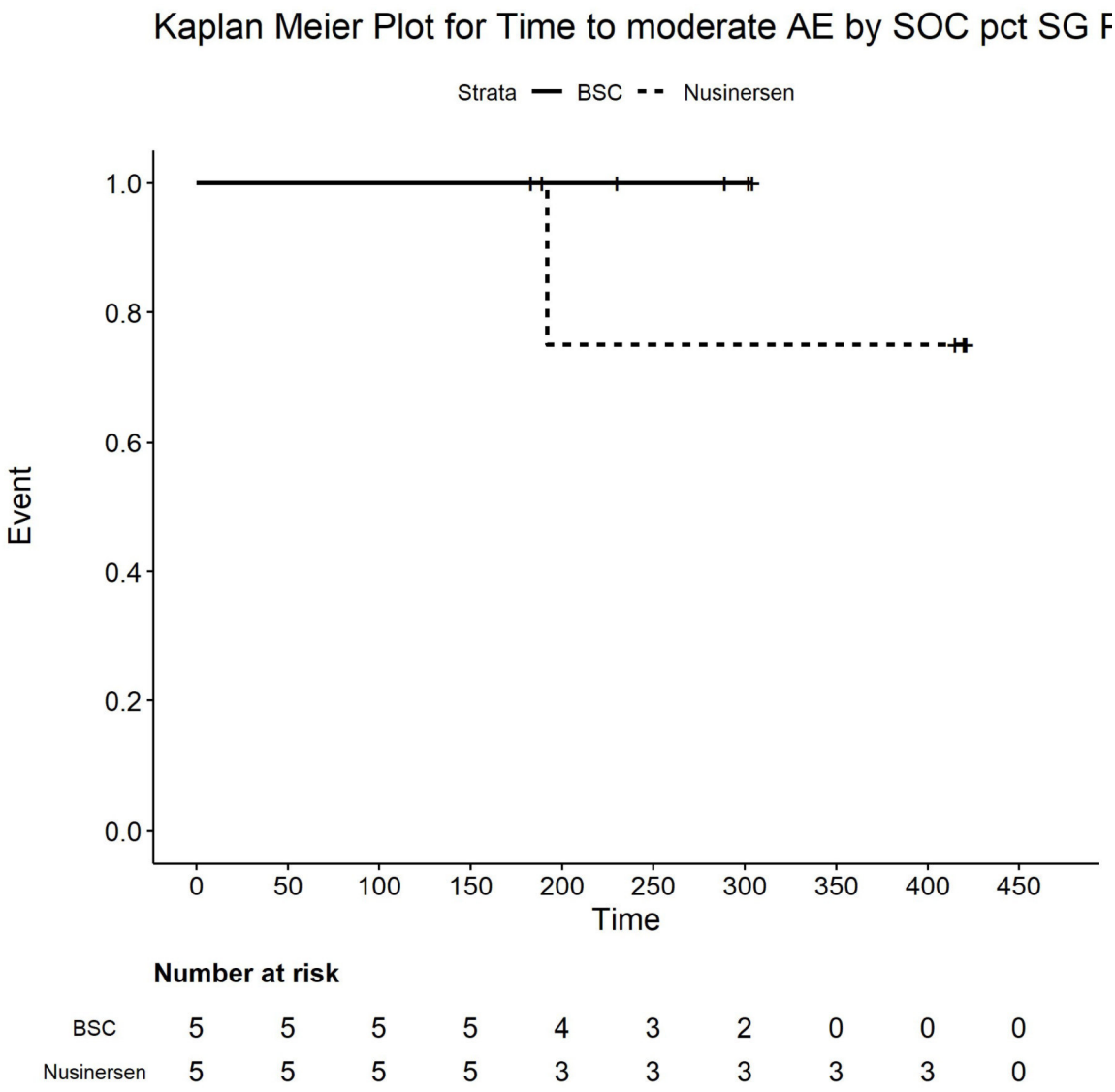
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	3	3	1	1	1	0	0	0



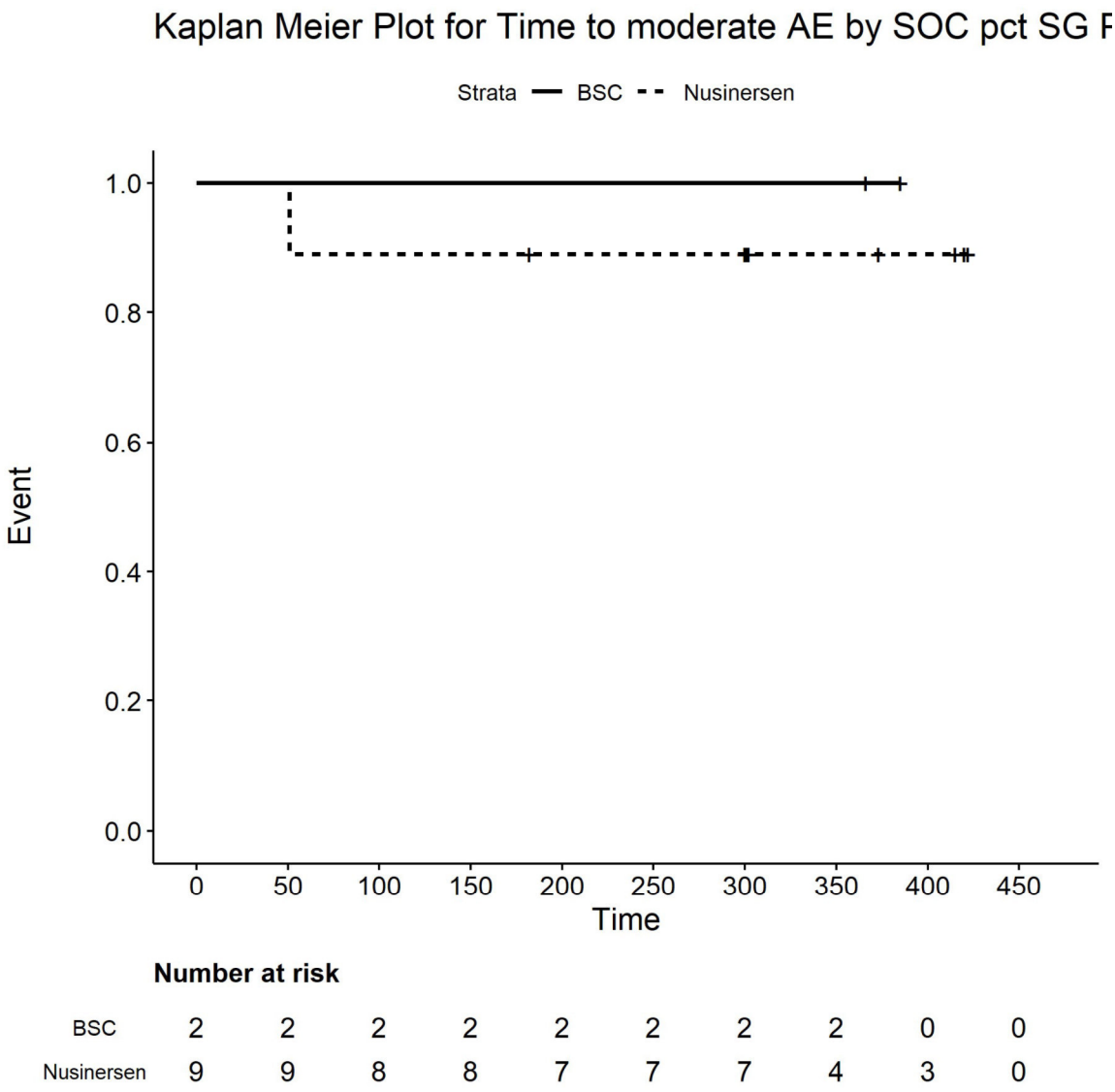
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	9	9	9	7	6	0



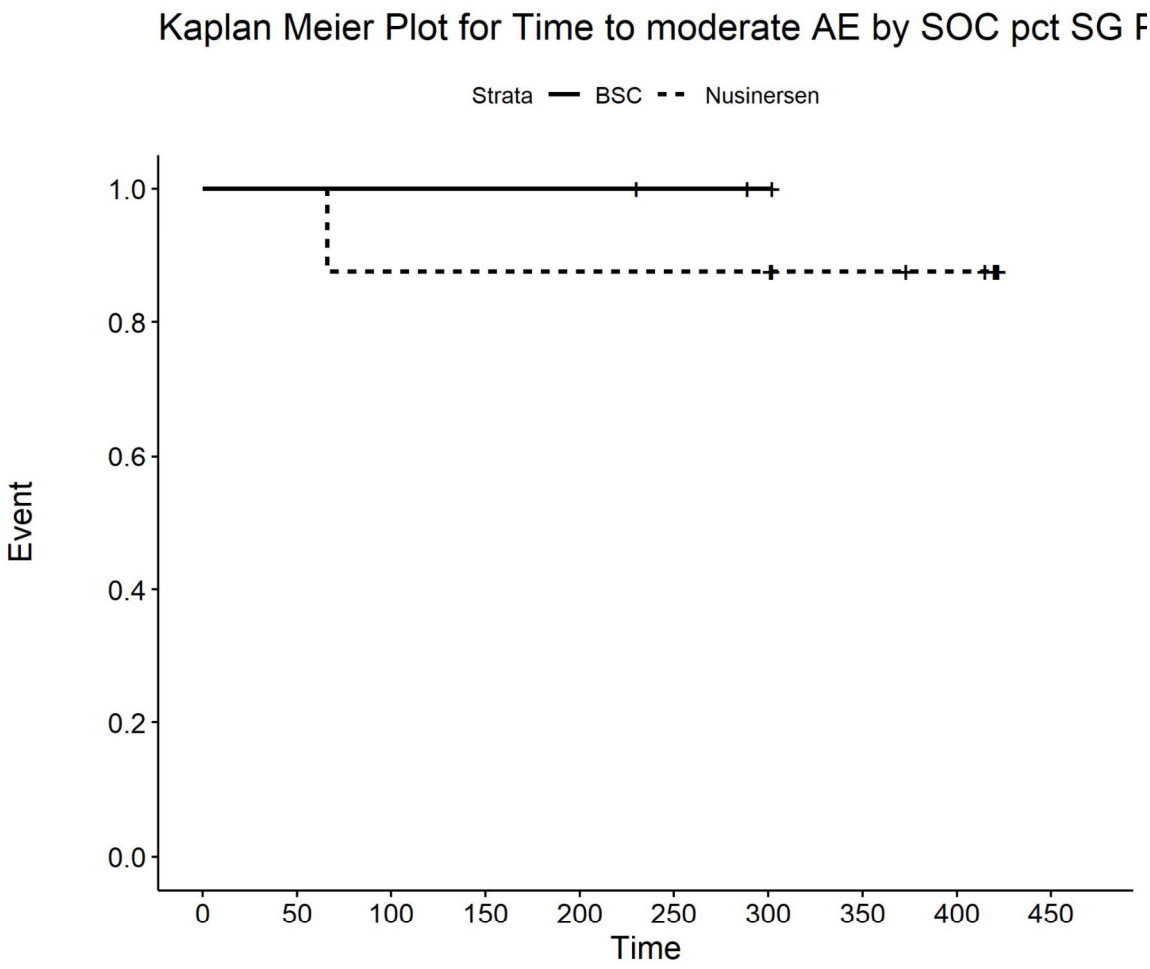
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	3	3	3	3	3	0



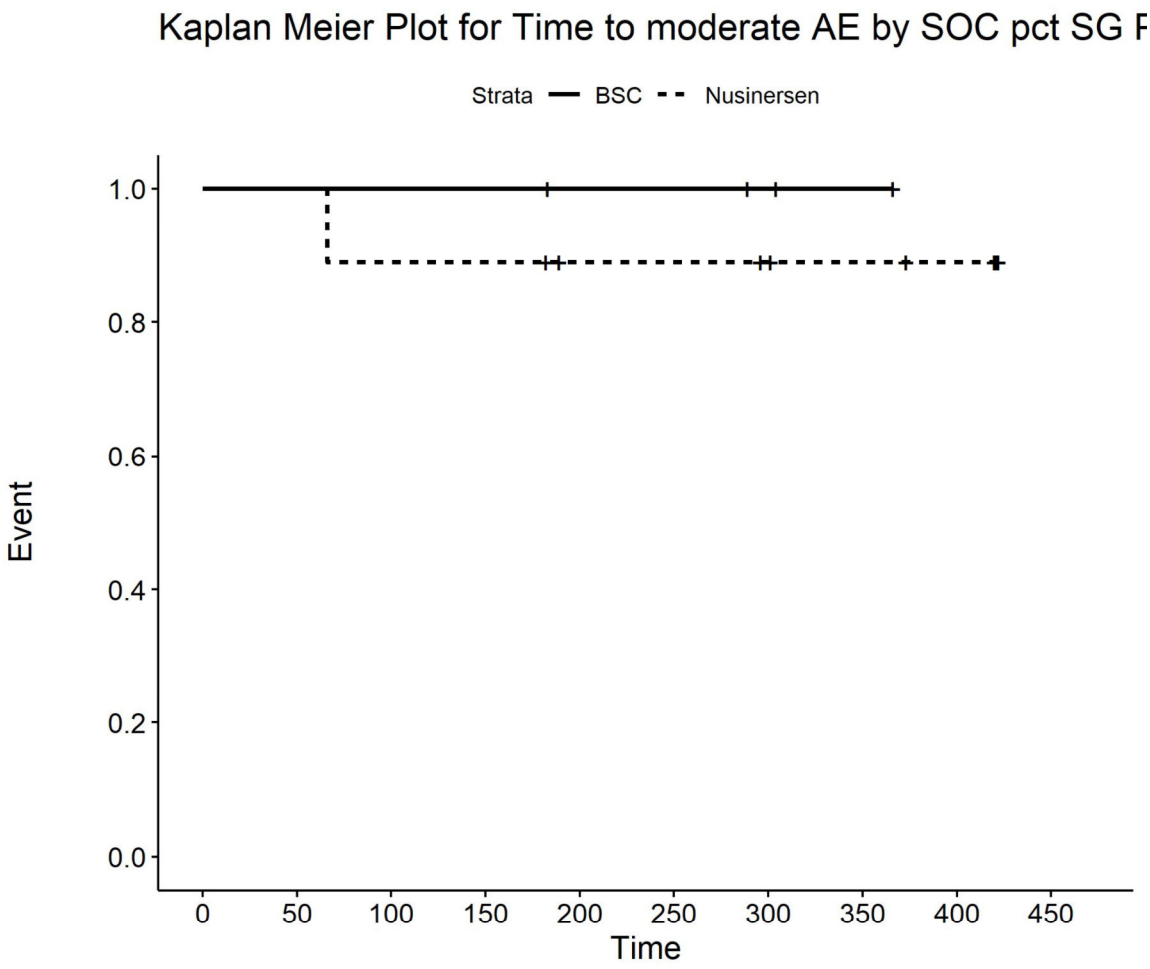
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



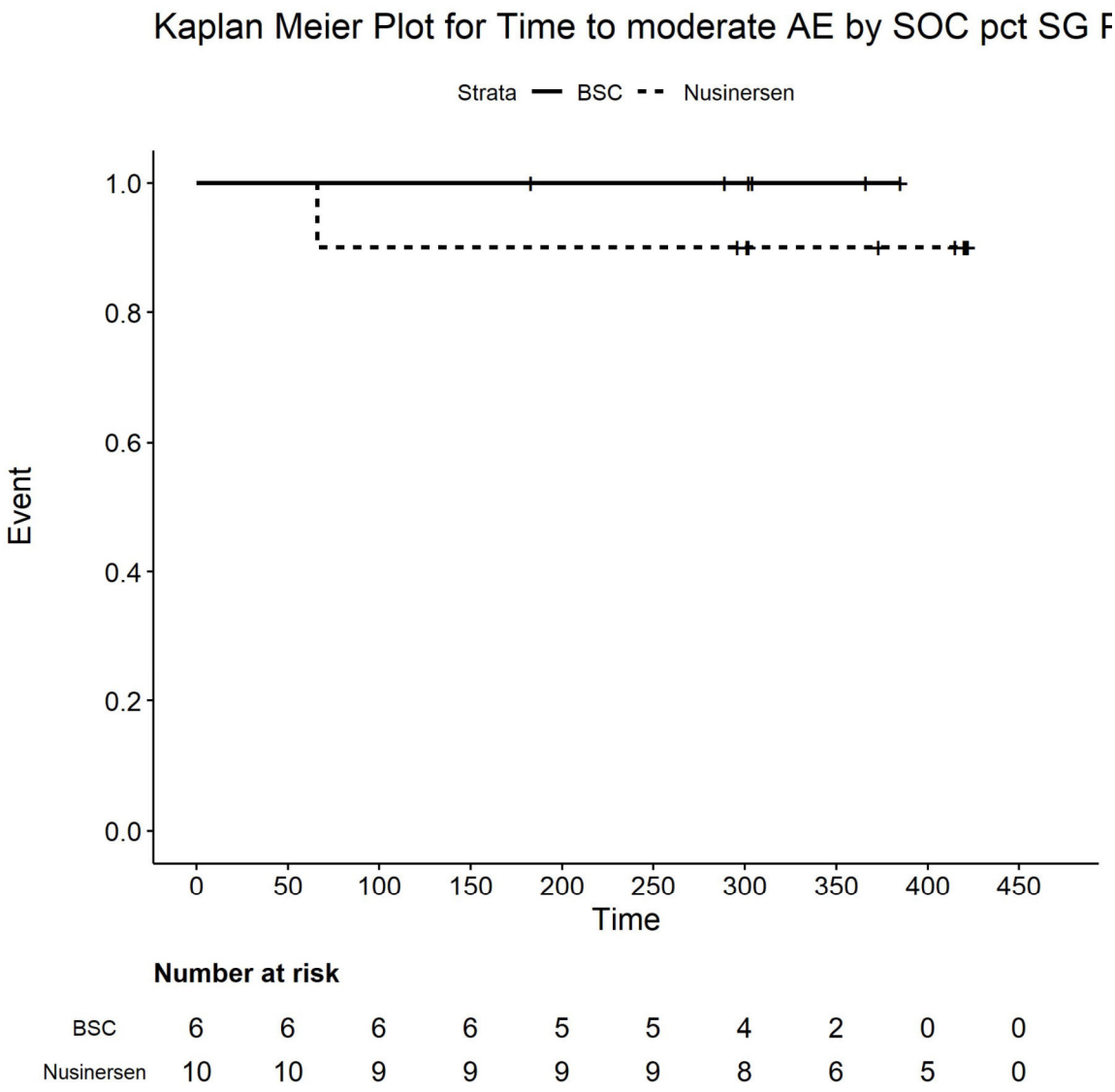
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	4	0



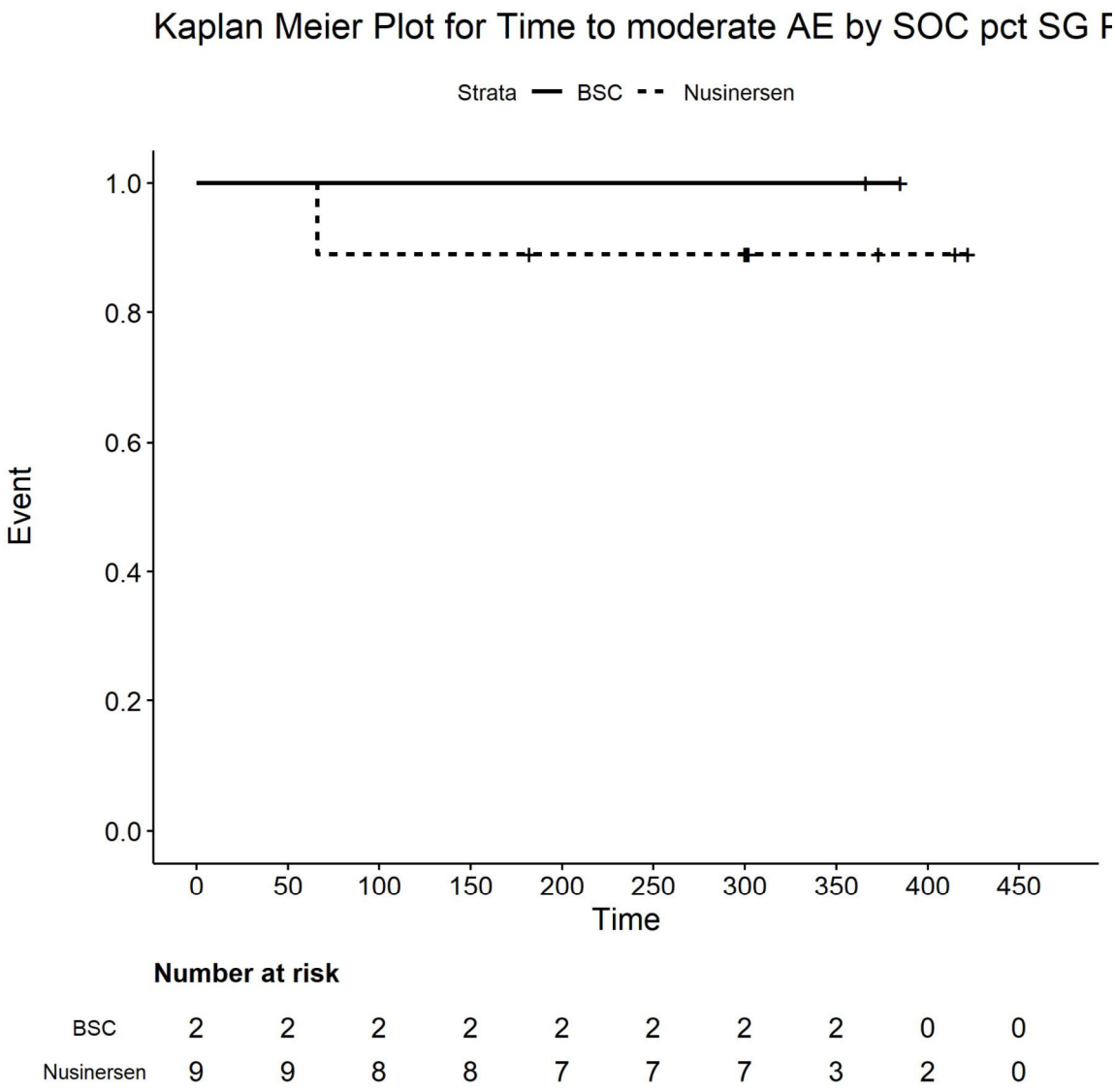
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



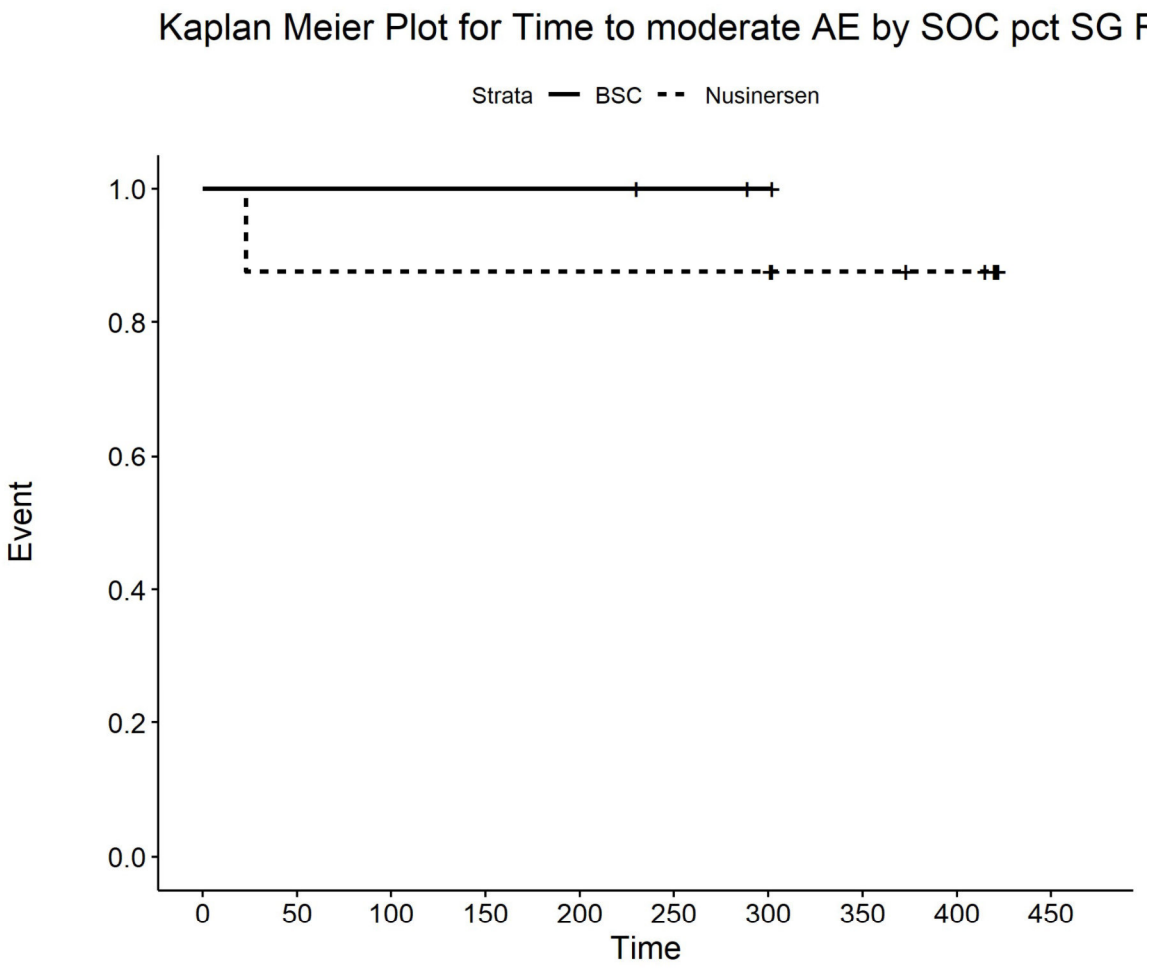
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



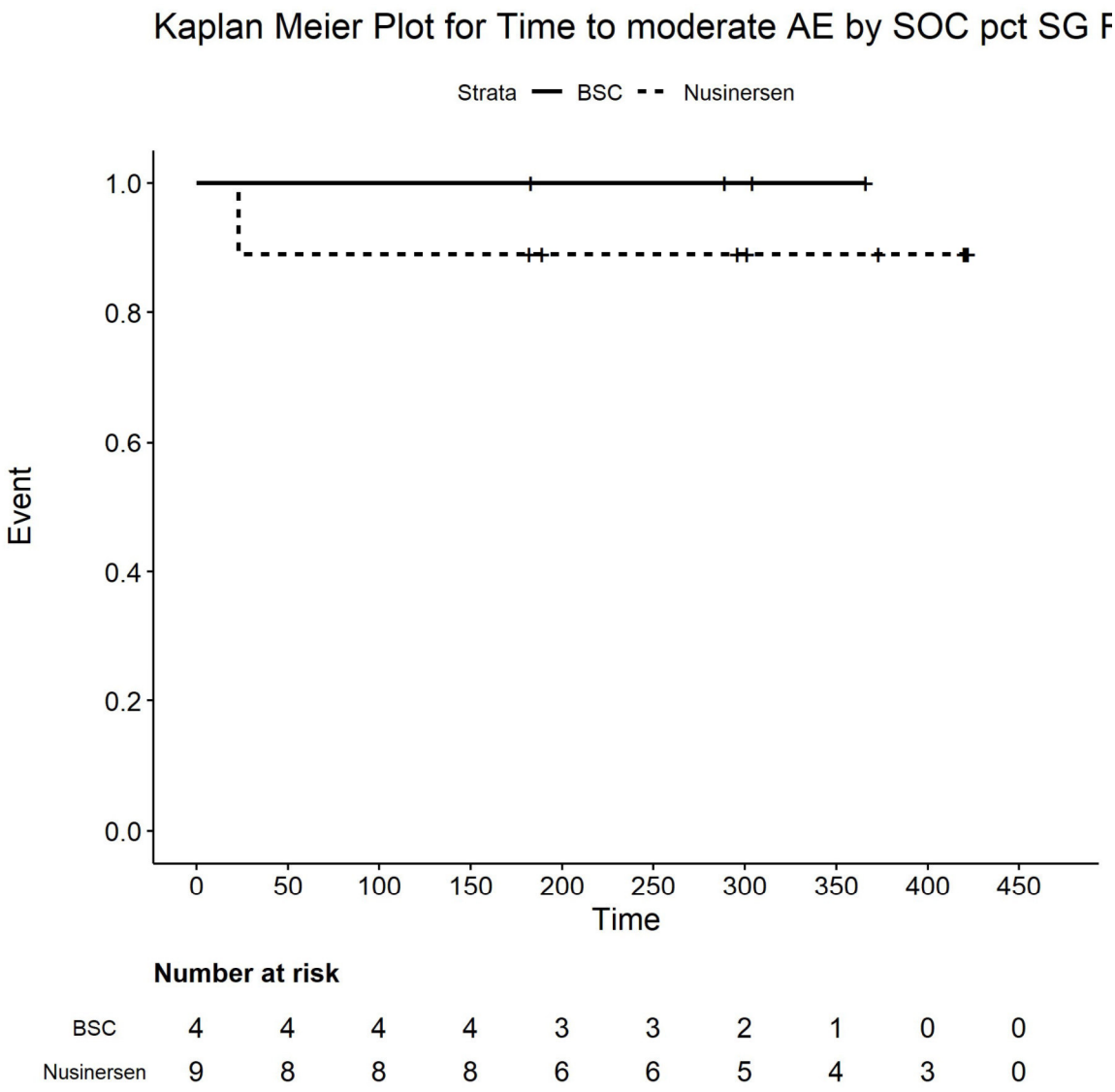
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	2	0



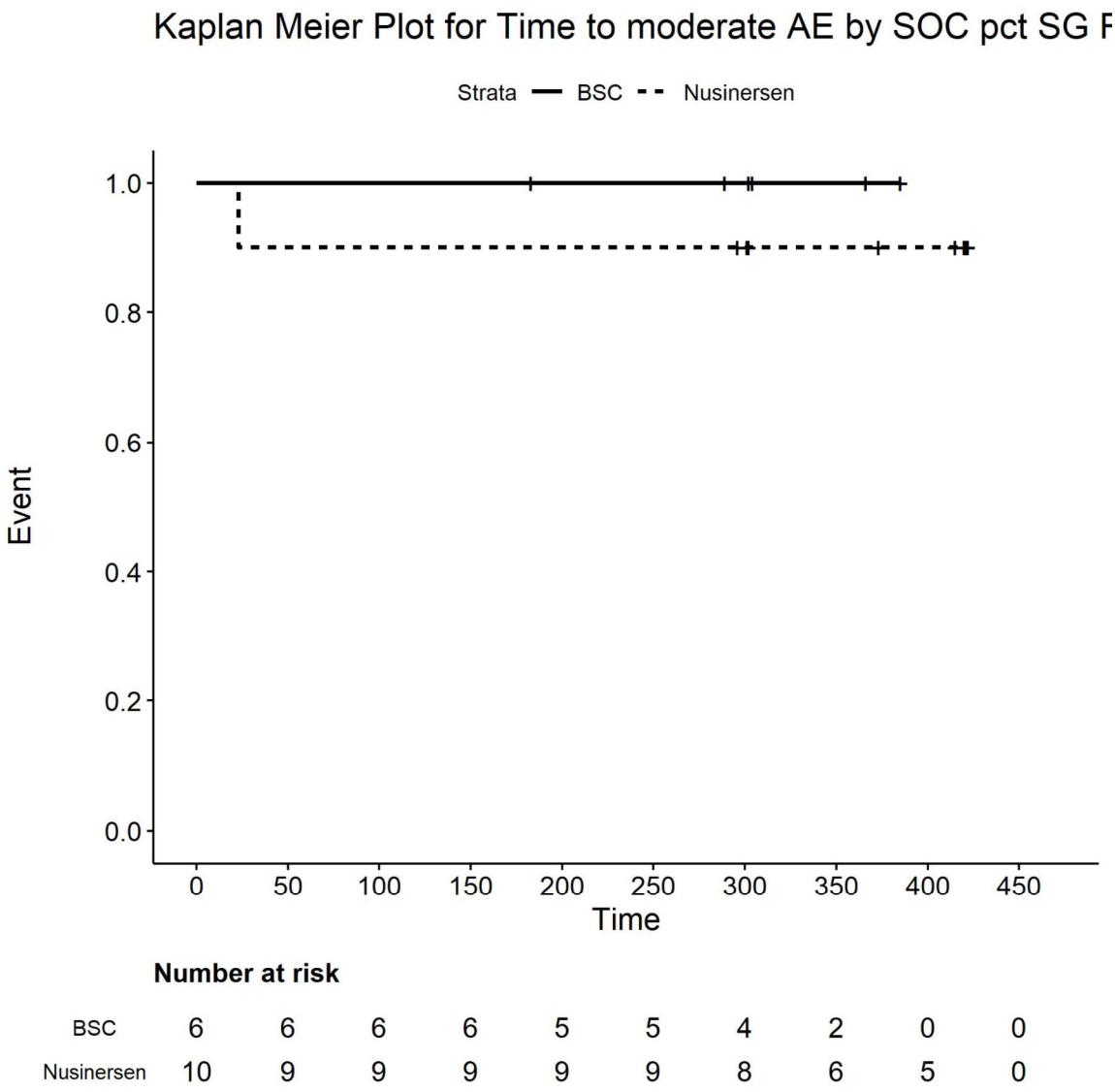
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



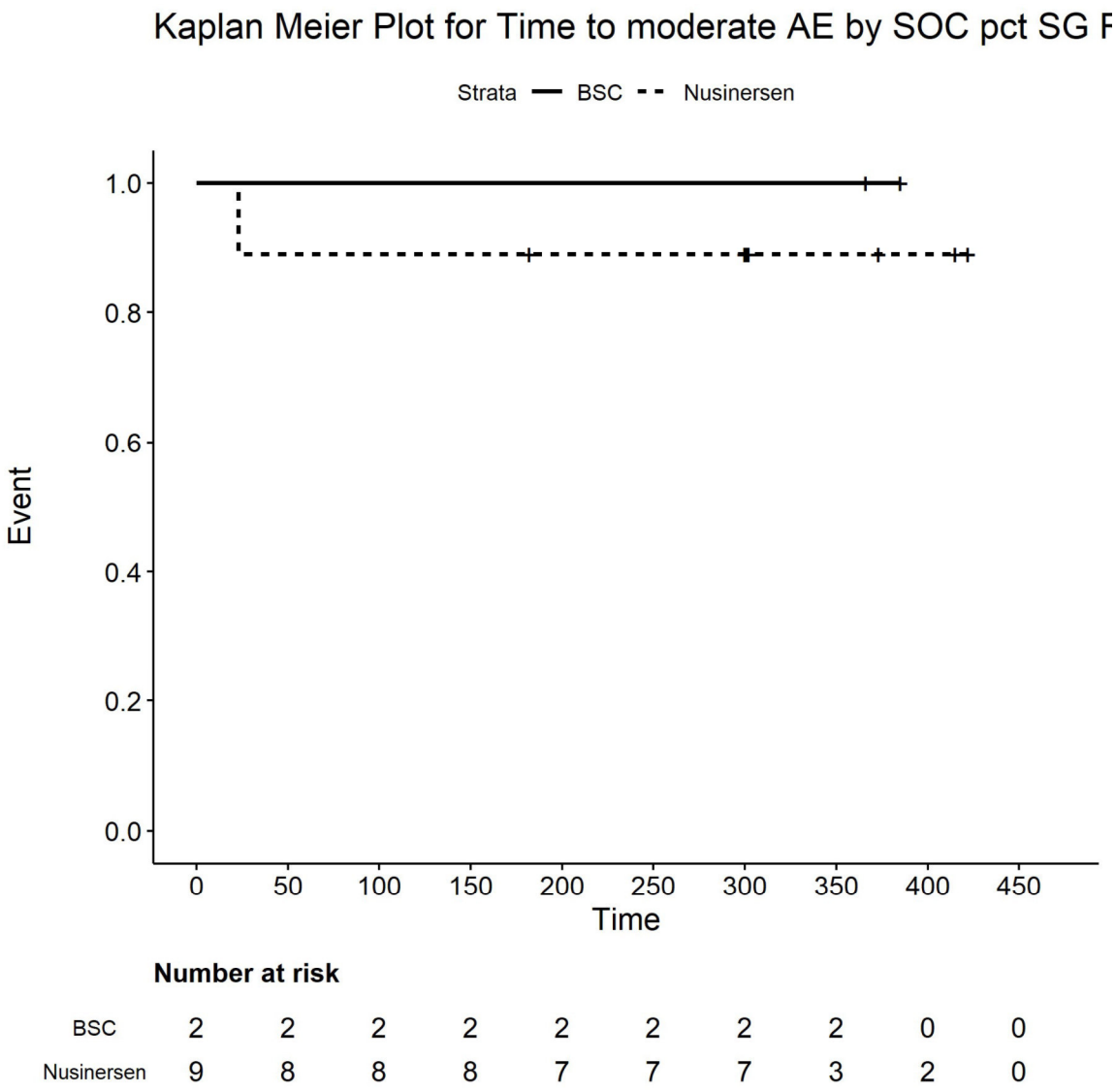
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



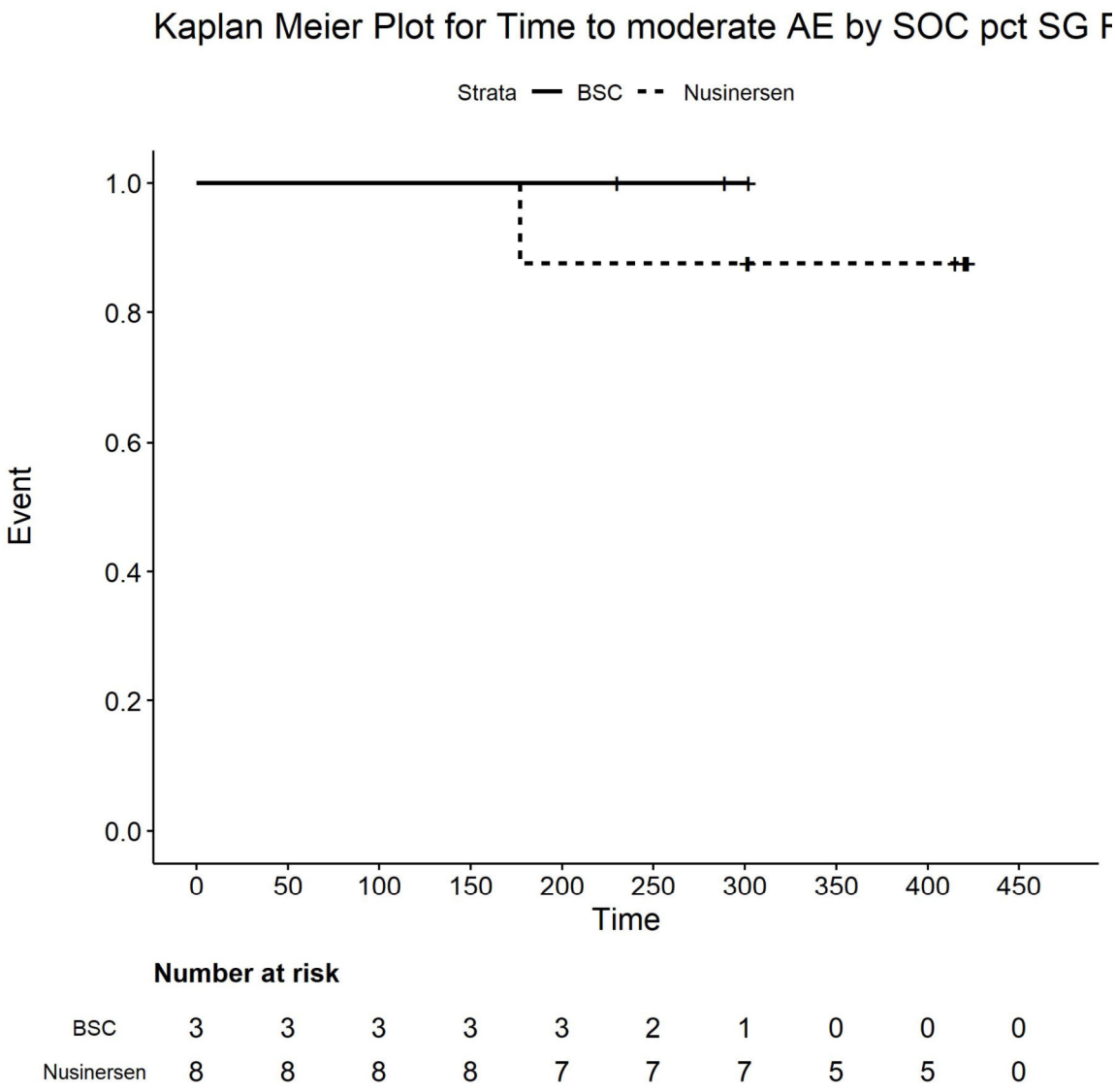
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



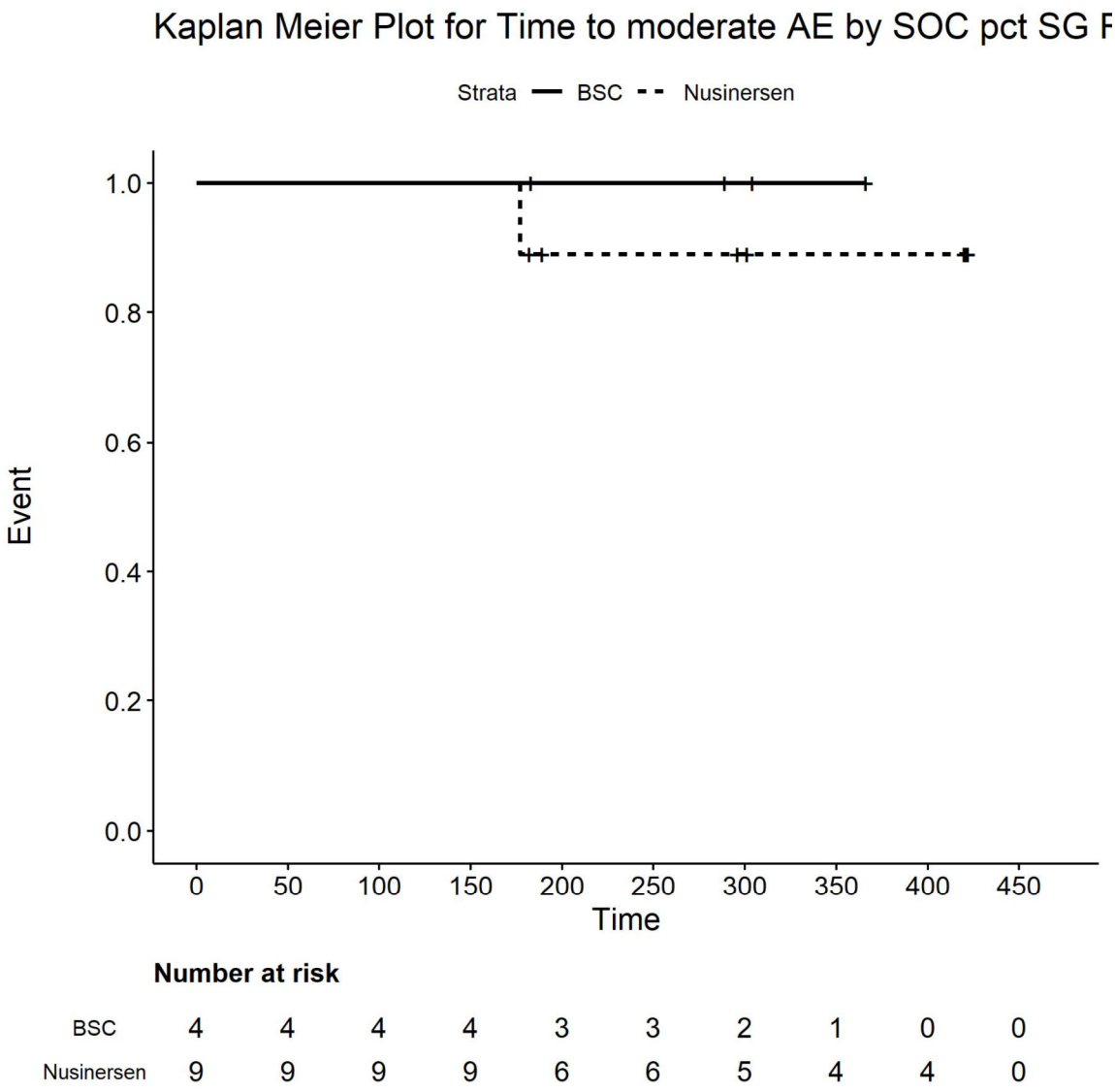
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	2	0



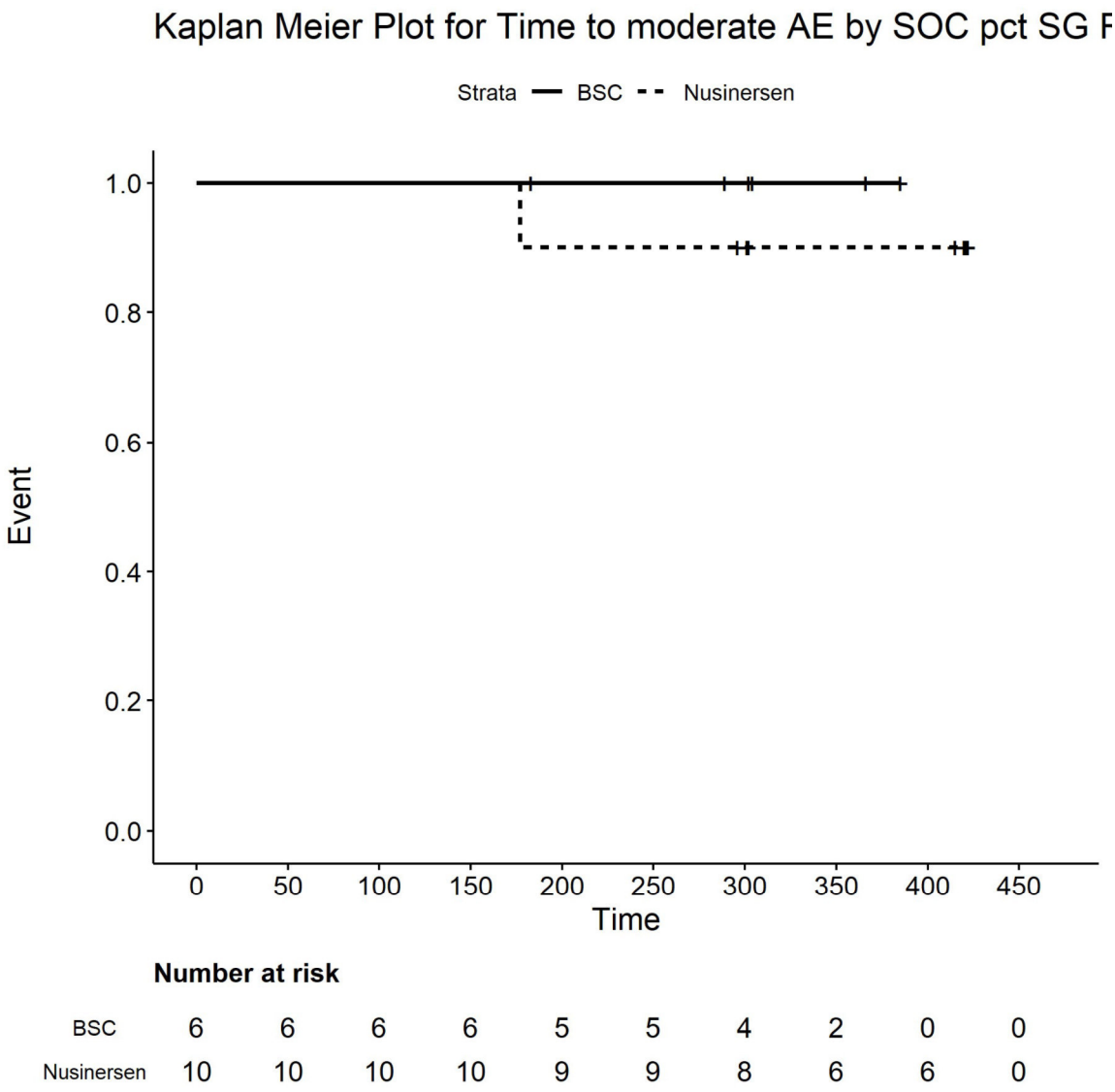
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	7	7	7	5	5	0



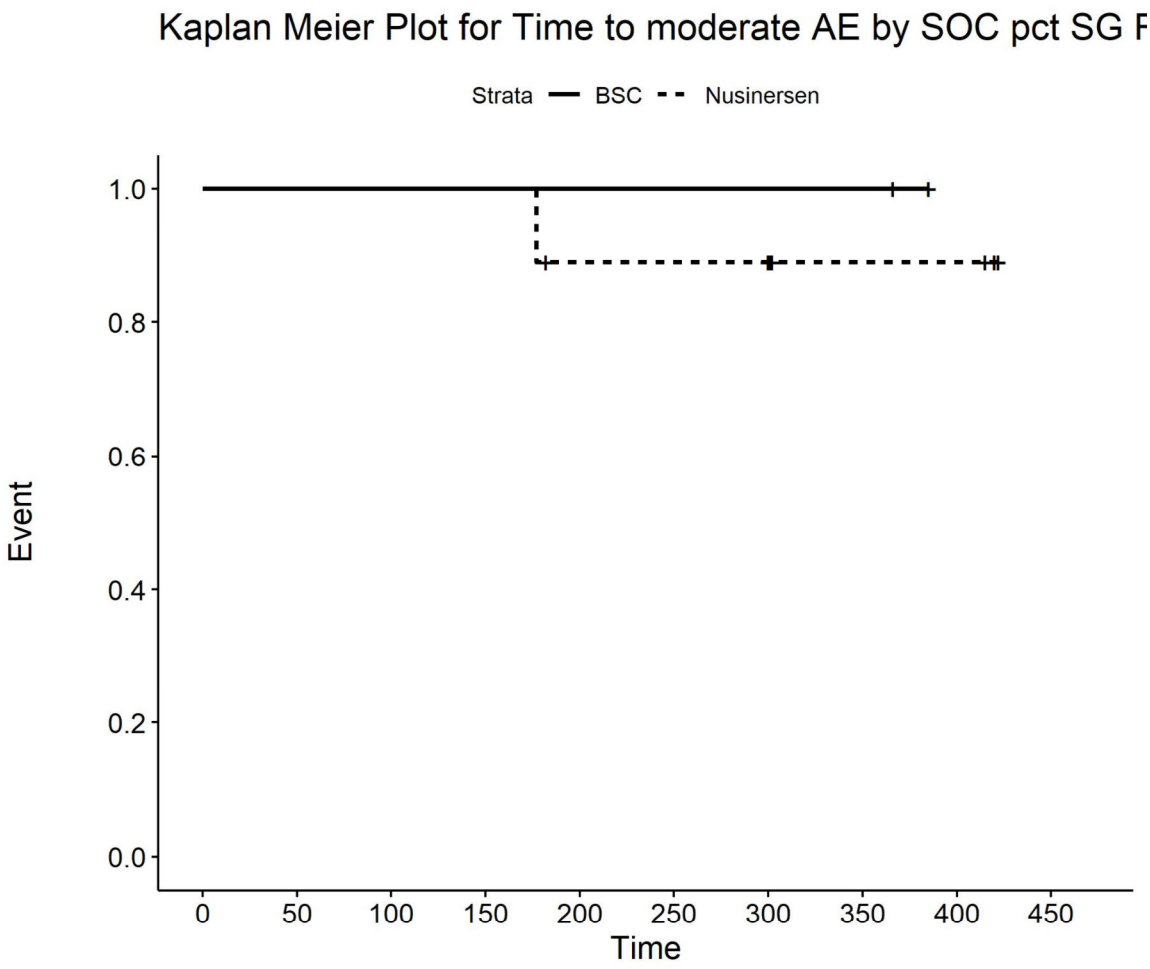
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	6	6	5	4	4	0



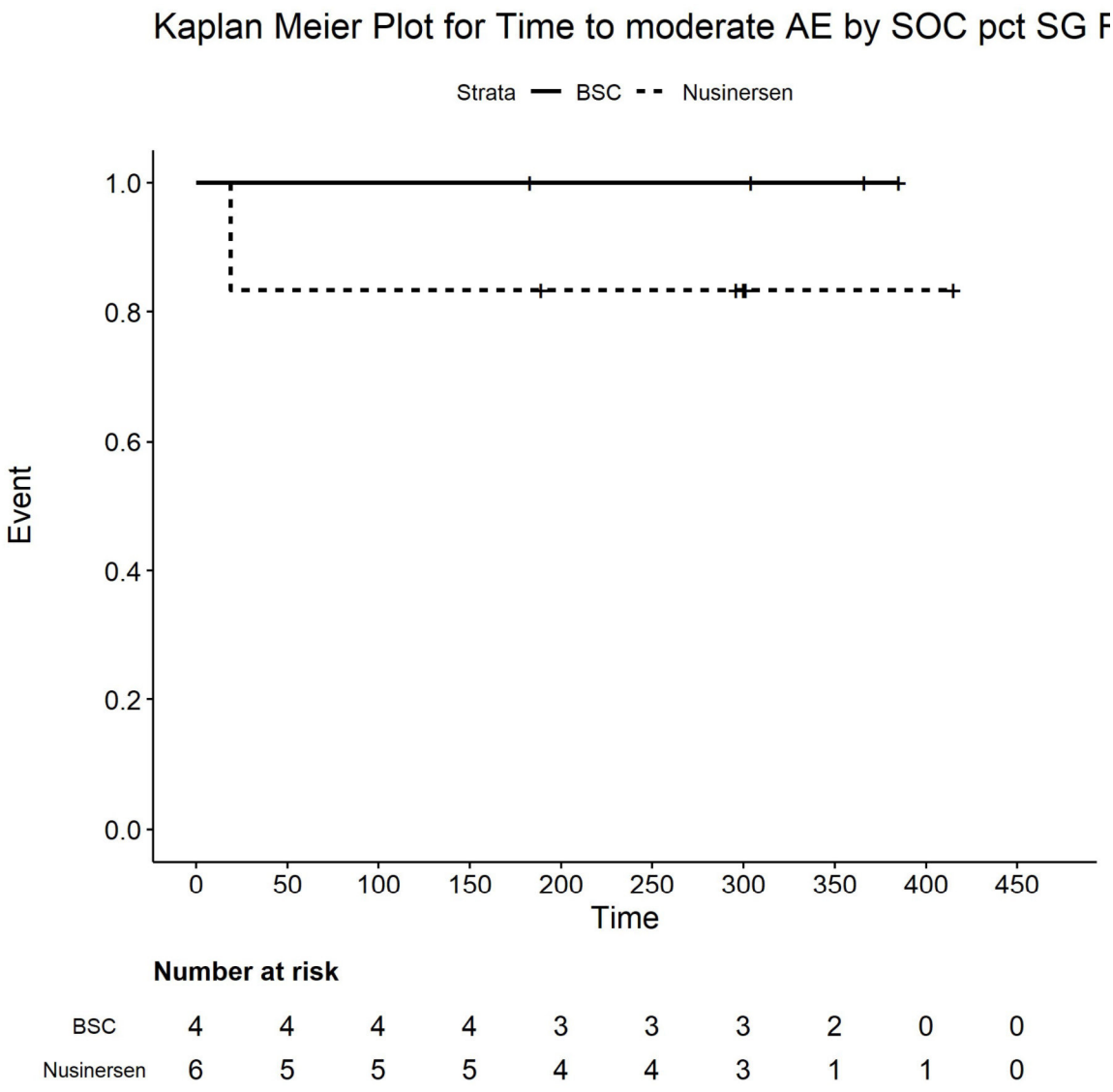
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	9	9	8	6	6	0



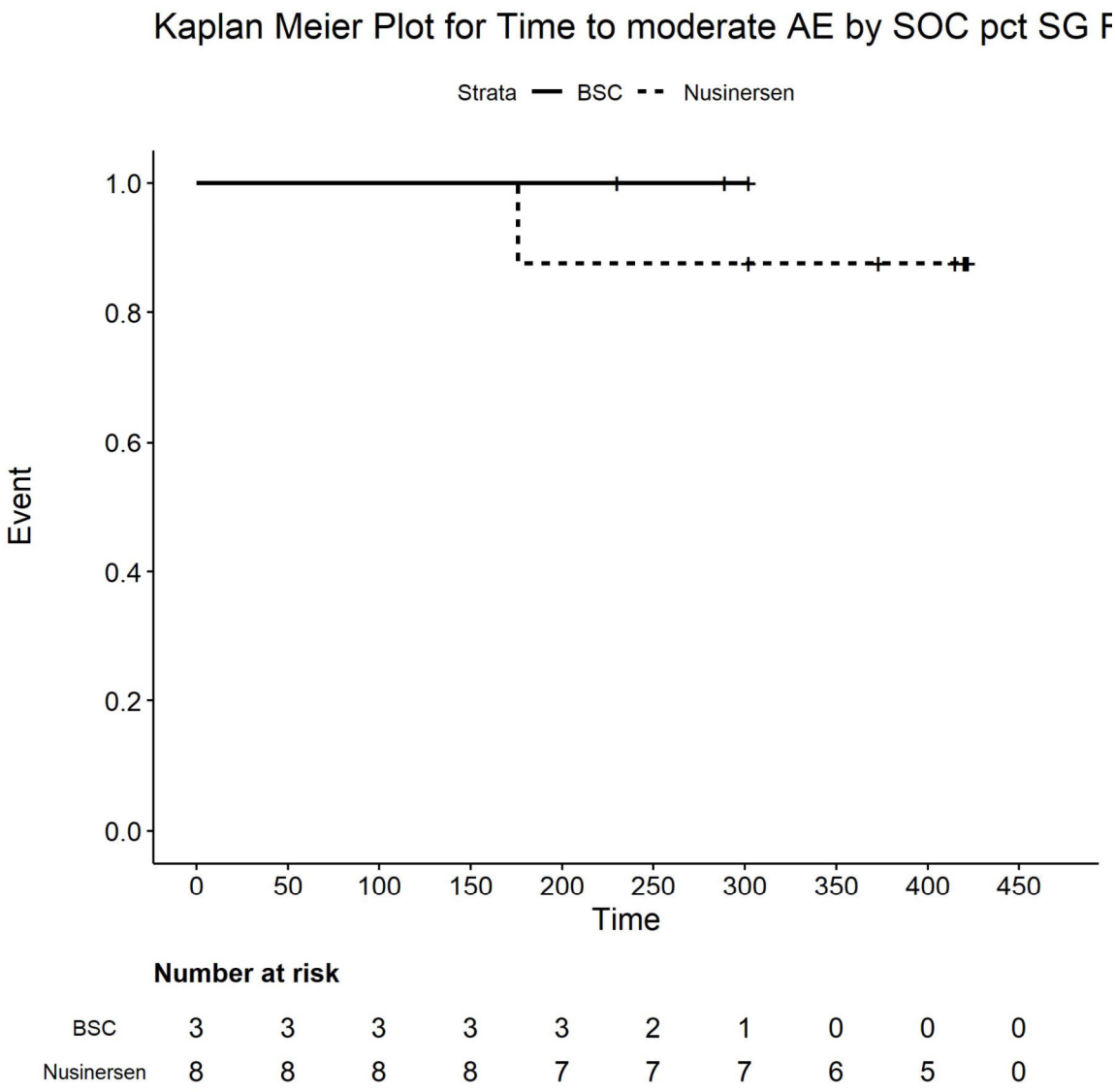
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	7	7	7	3	3	0



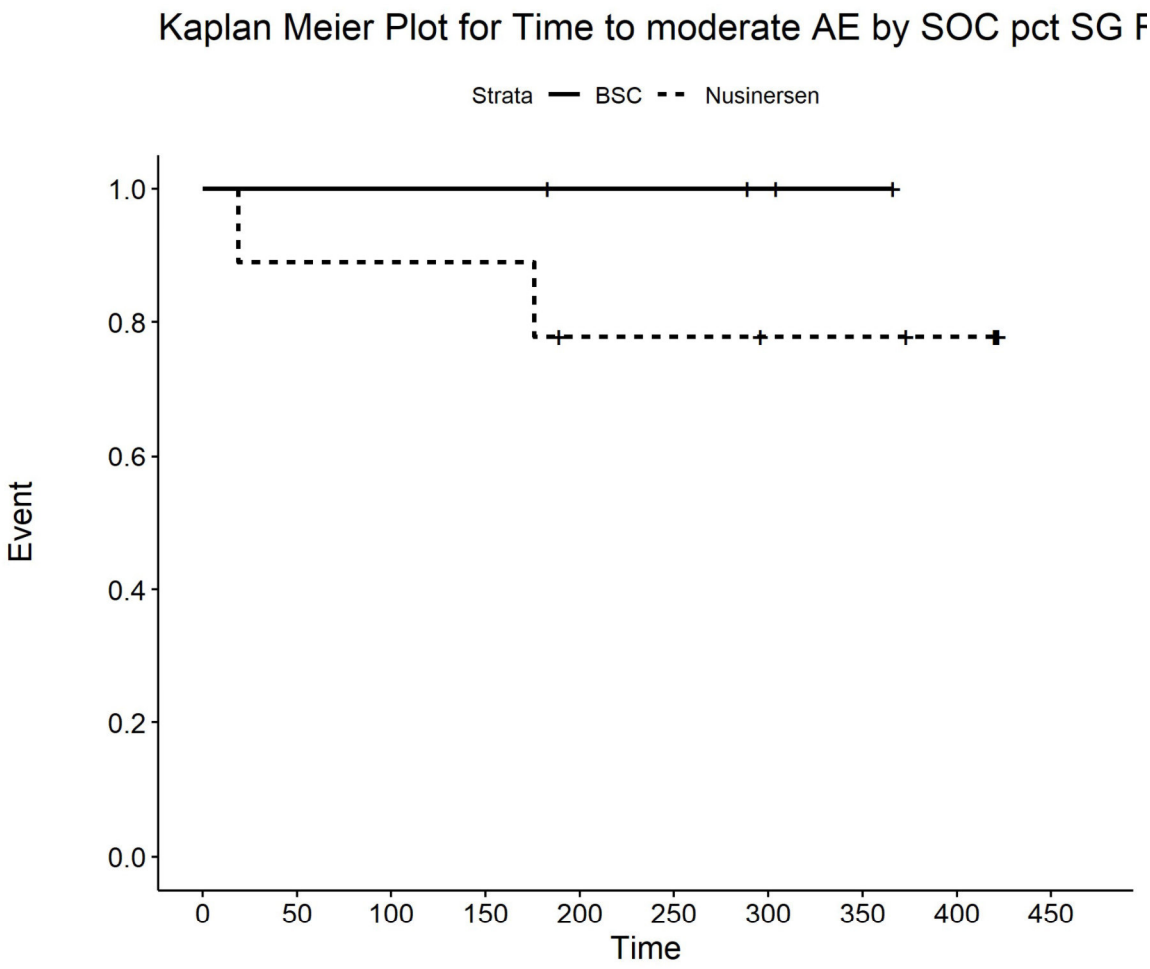
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	4	4	3	1	1	0



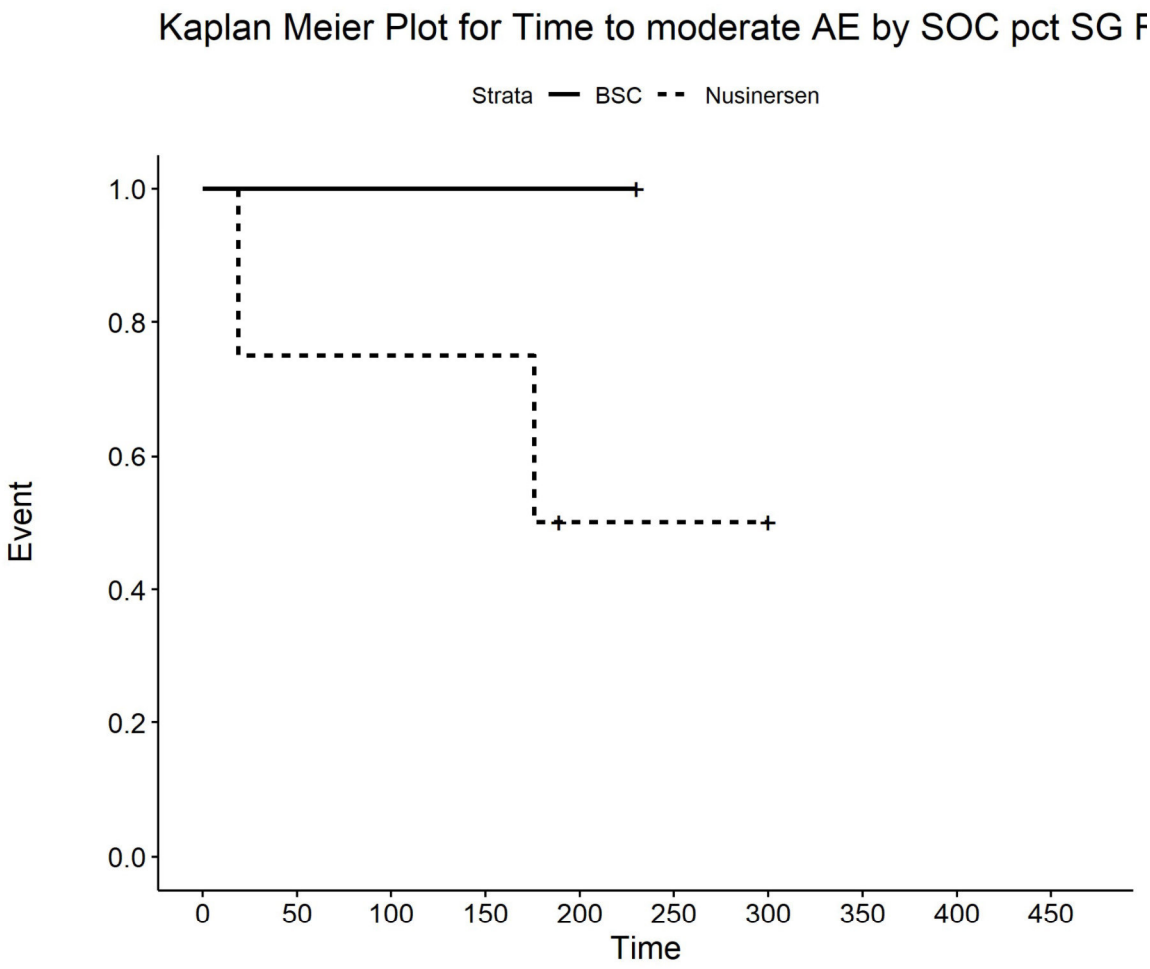
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	7	7	7	6	5	0



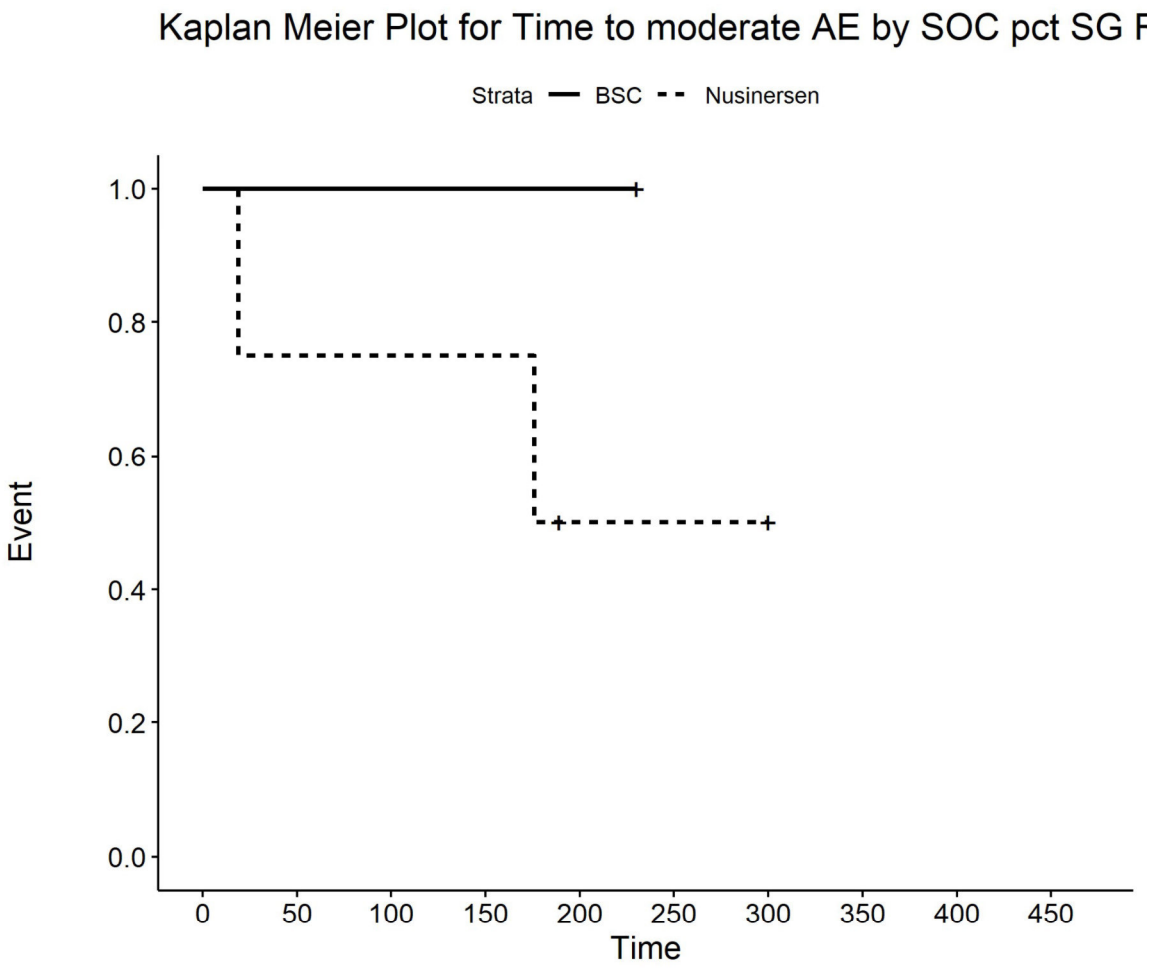
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	5	4	0



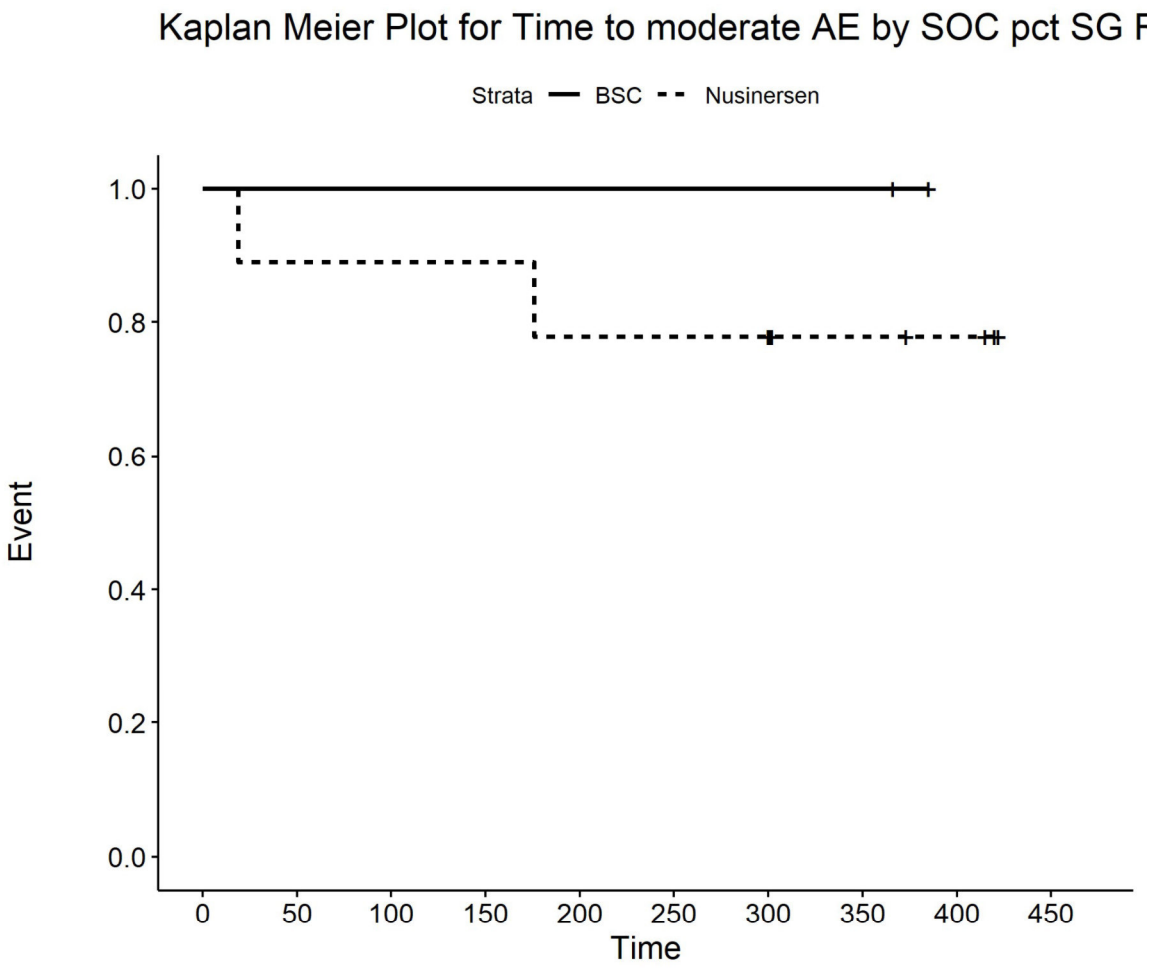
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



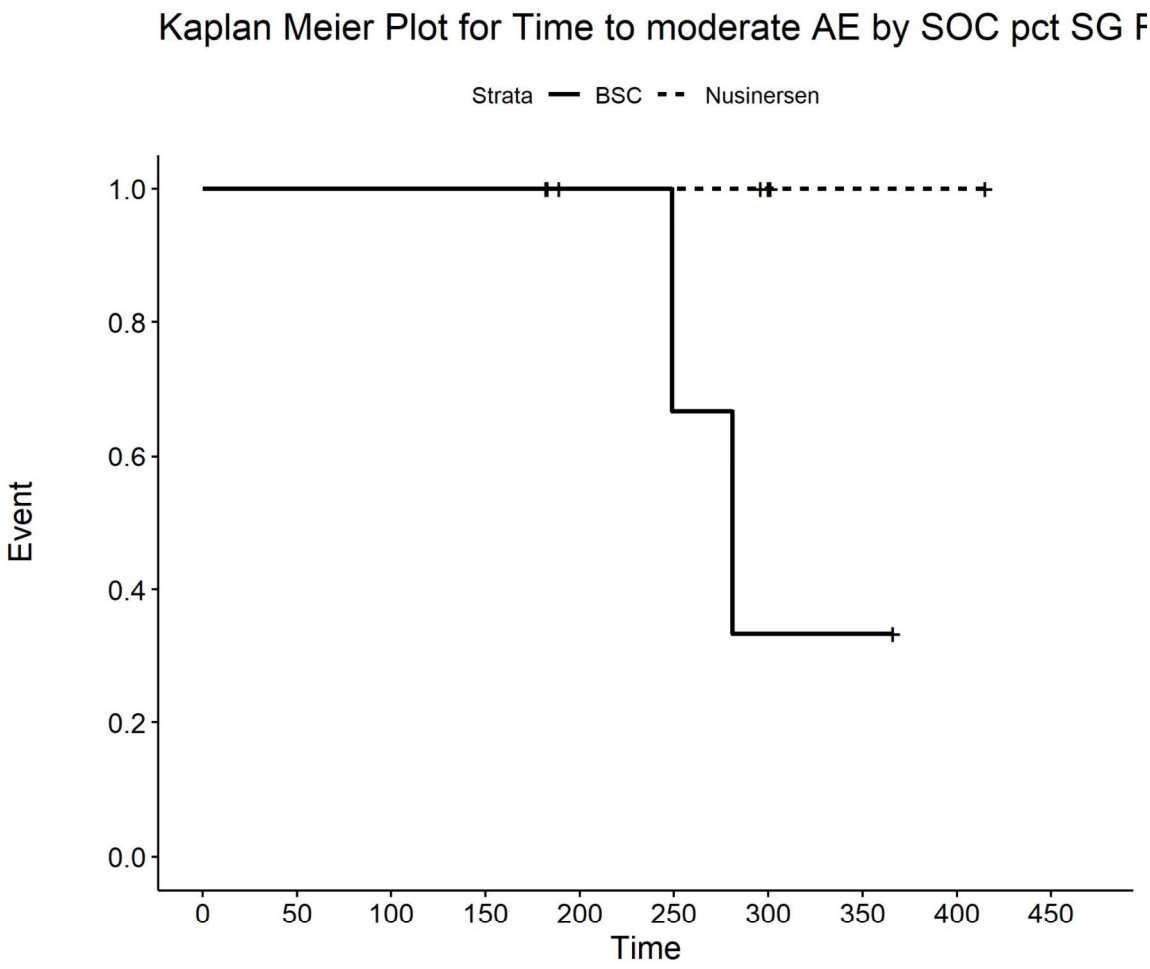
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



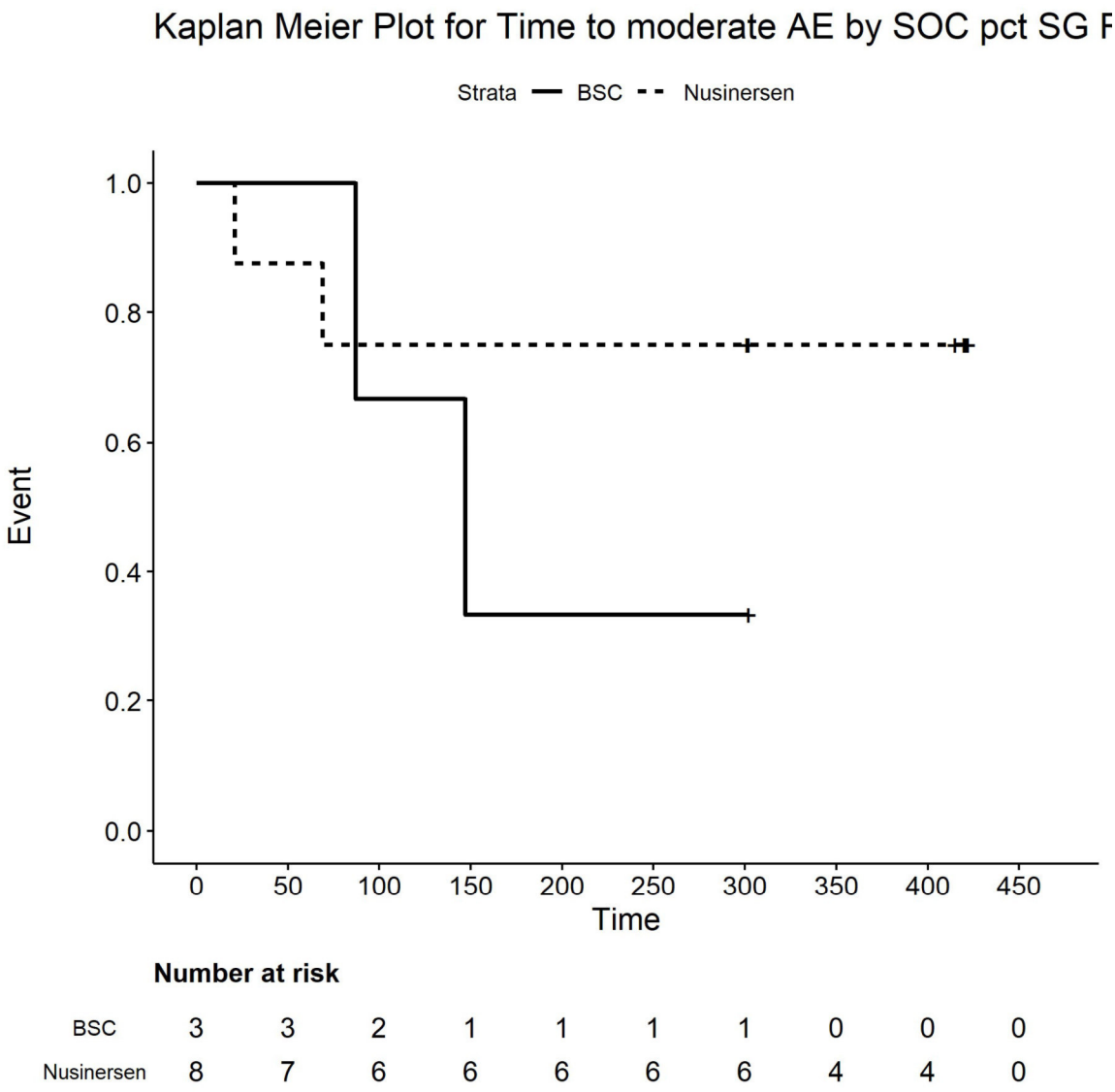
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



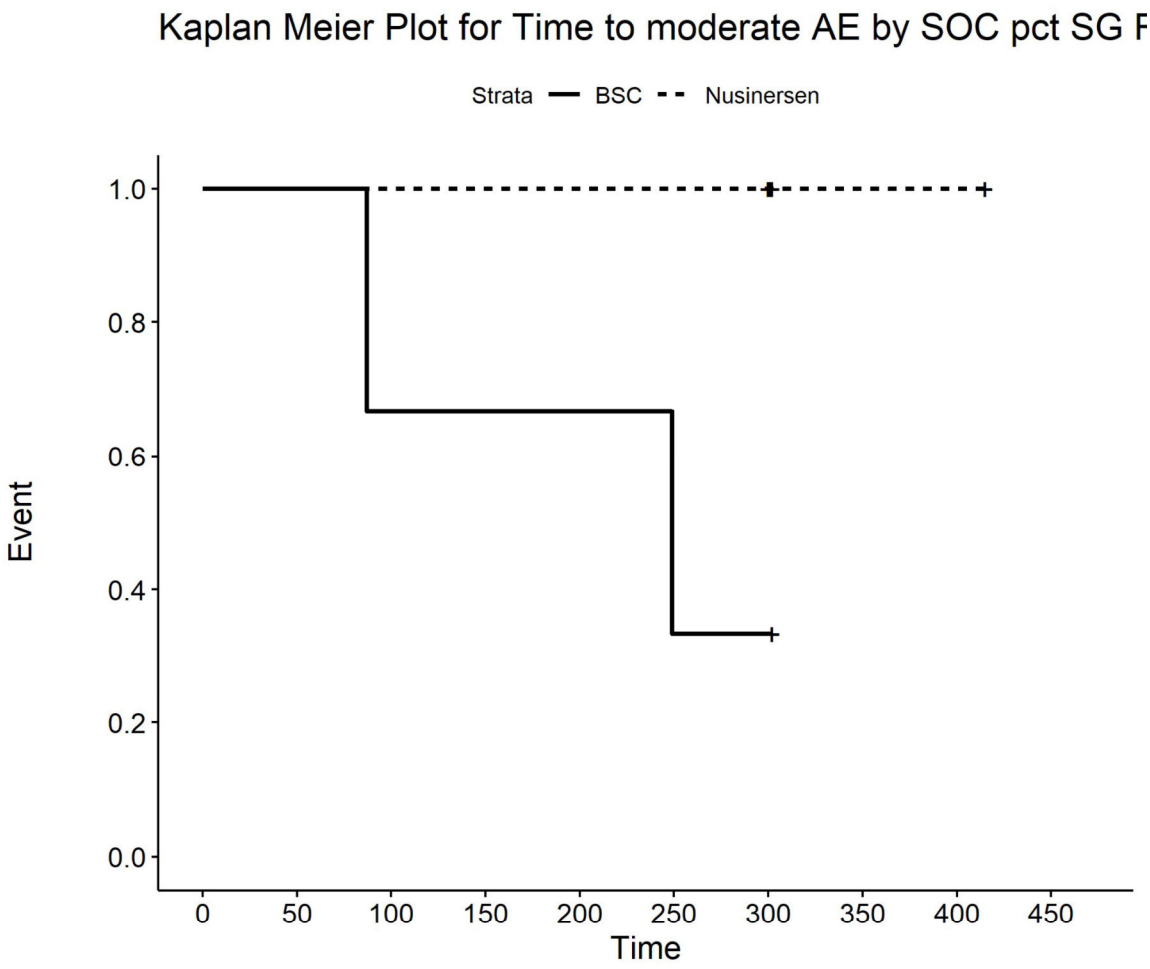
Number at risk

BSC	4	4	4	4	3	2	1	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



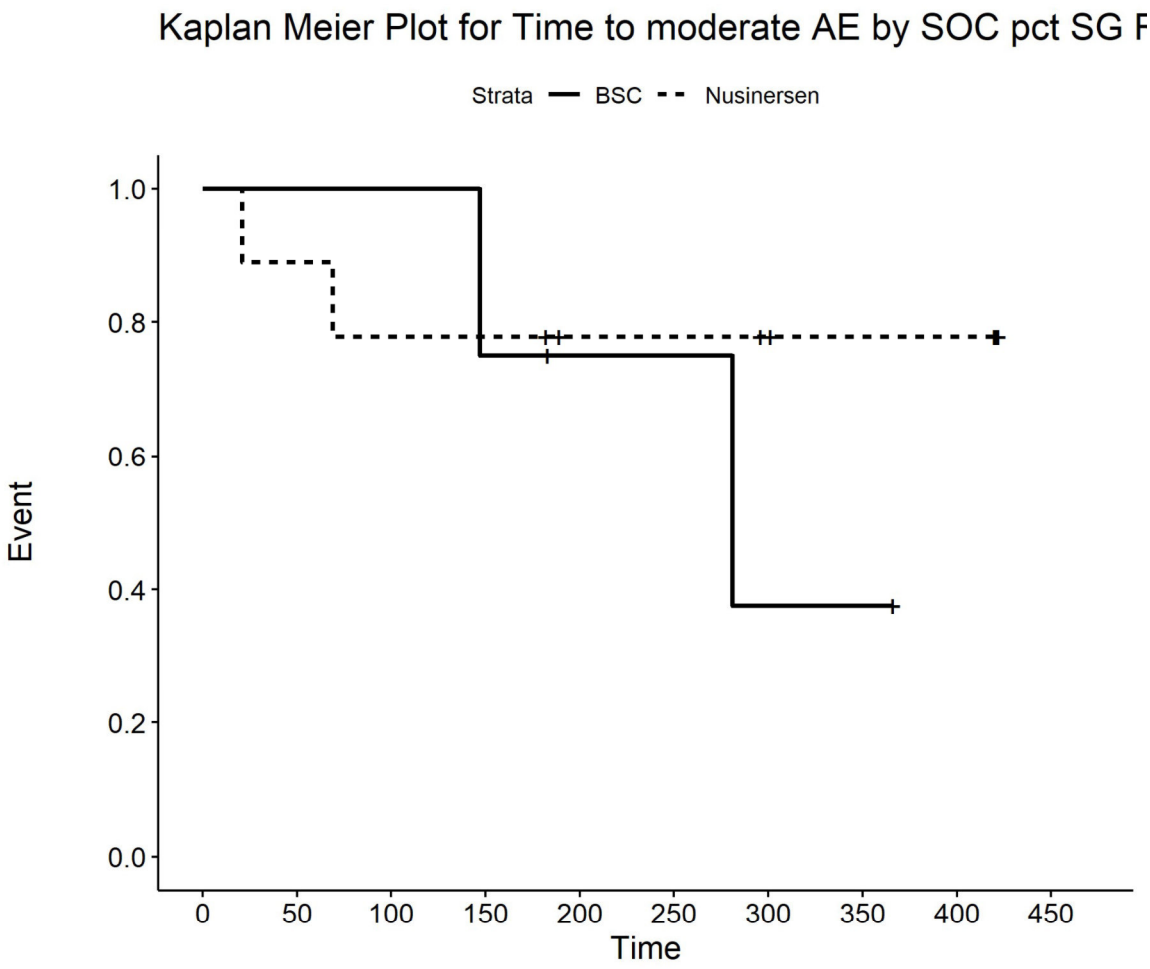
Number at risk

BSC	3	3	2	1	1	1	1	0	0	0
Nusinersen	8	7	6	6	6	6	6	4	4	0



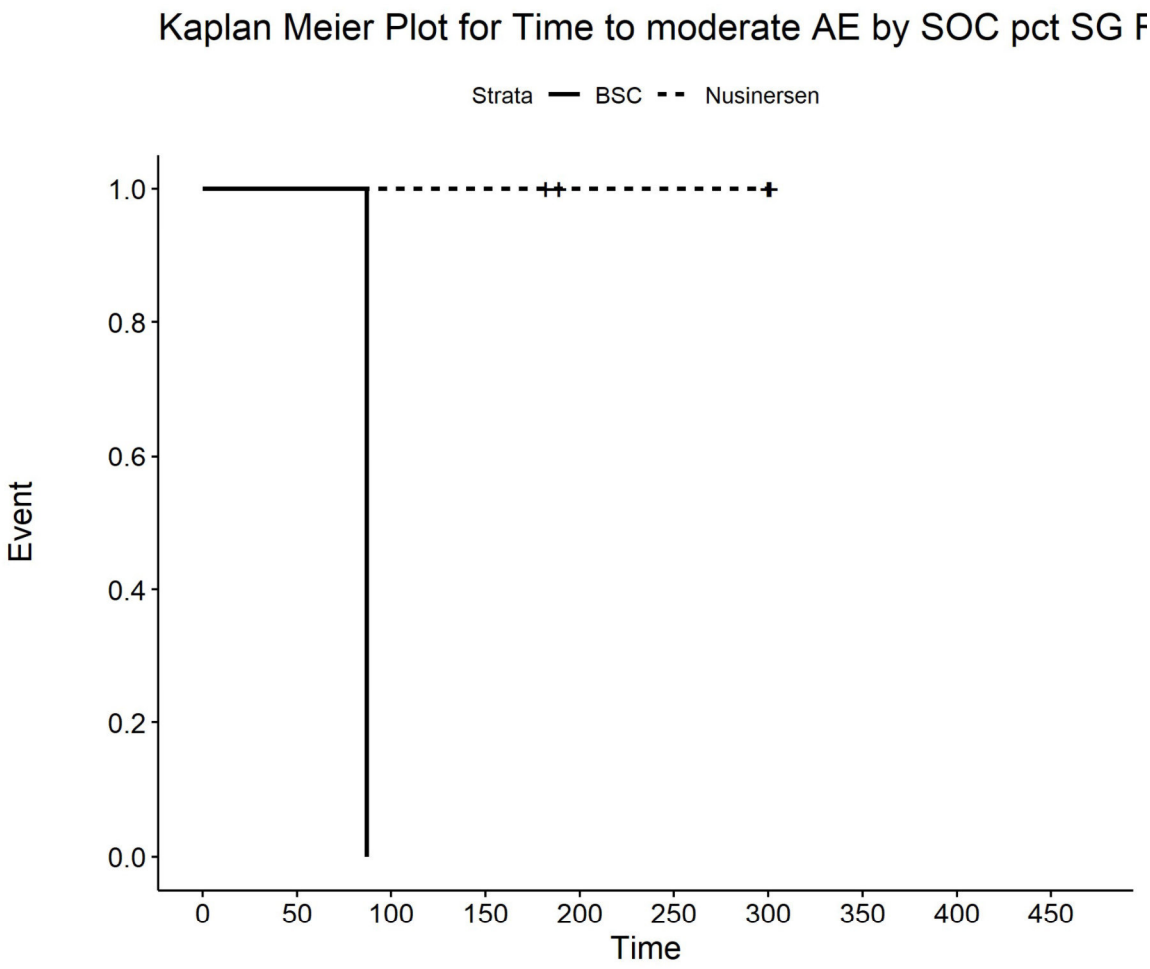
Number at risk

BSC	3	3	2	2	2	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



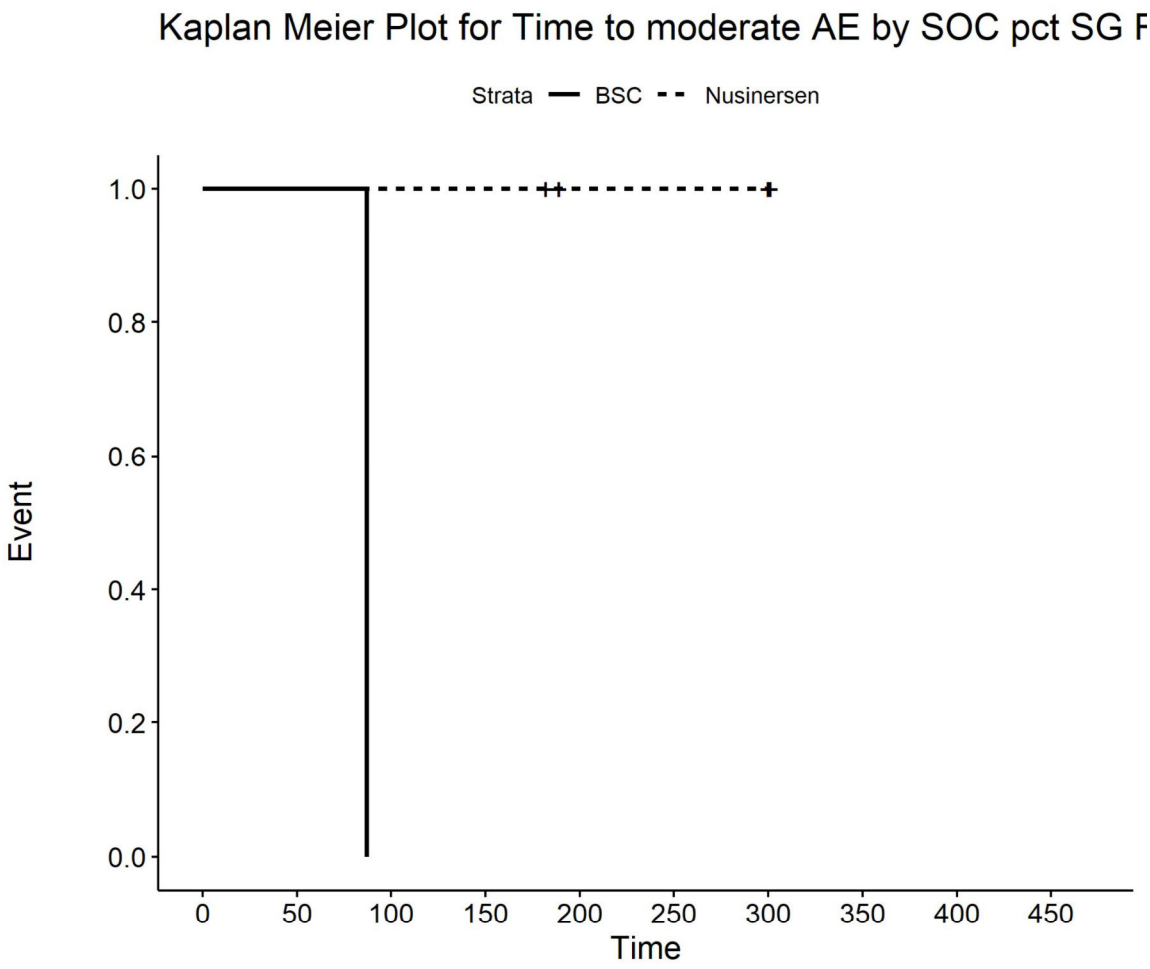
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	8	7	7	5	5	4	3	3	0



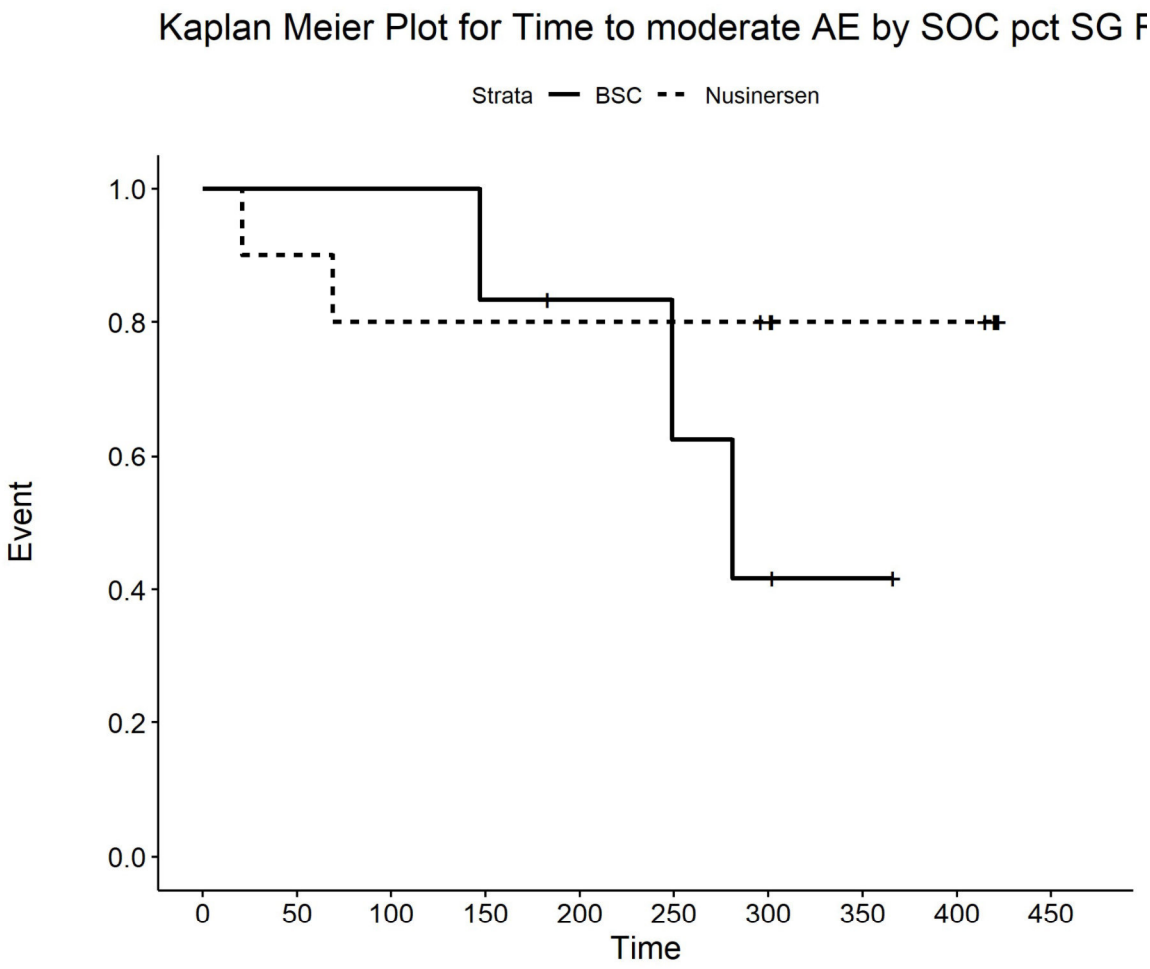
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



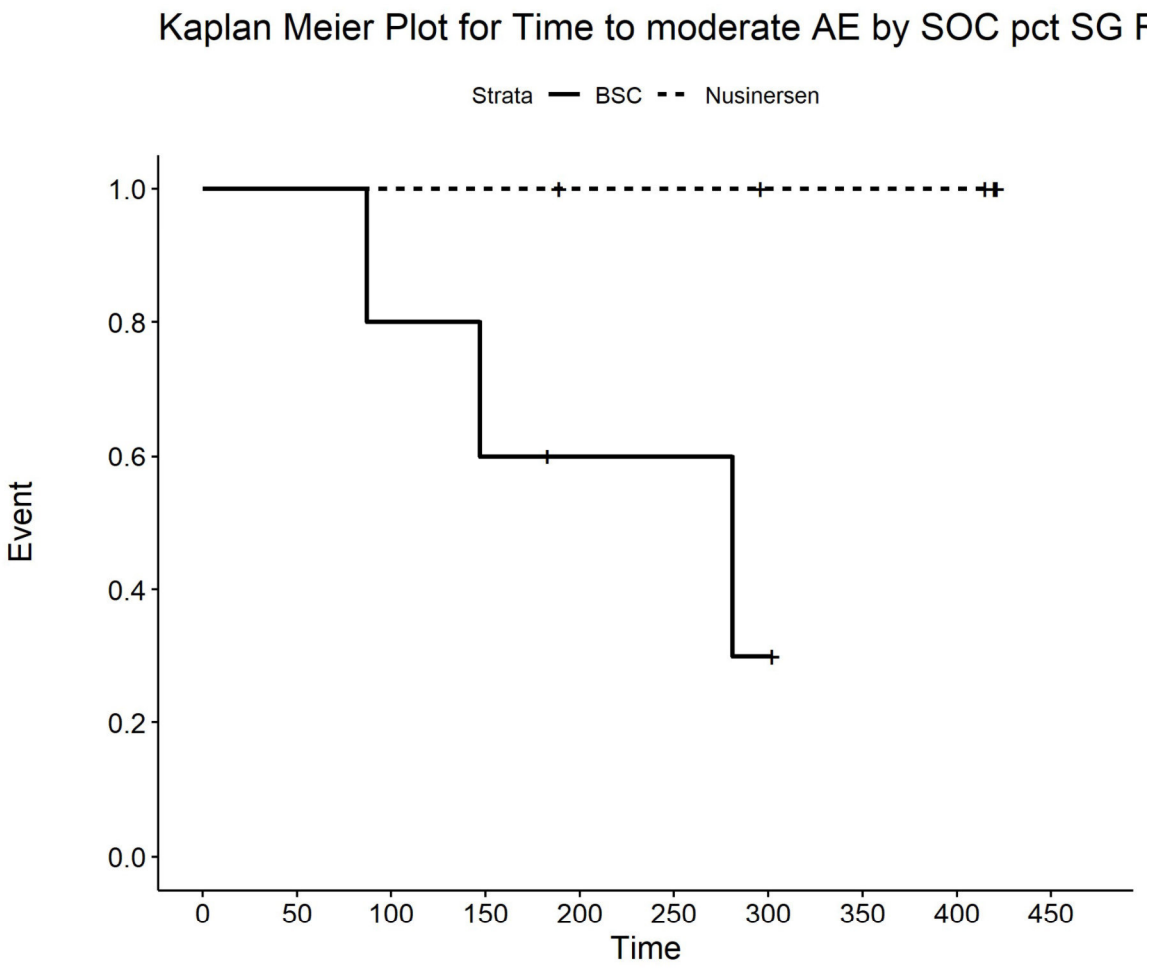
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



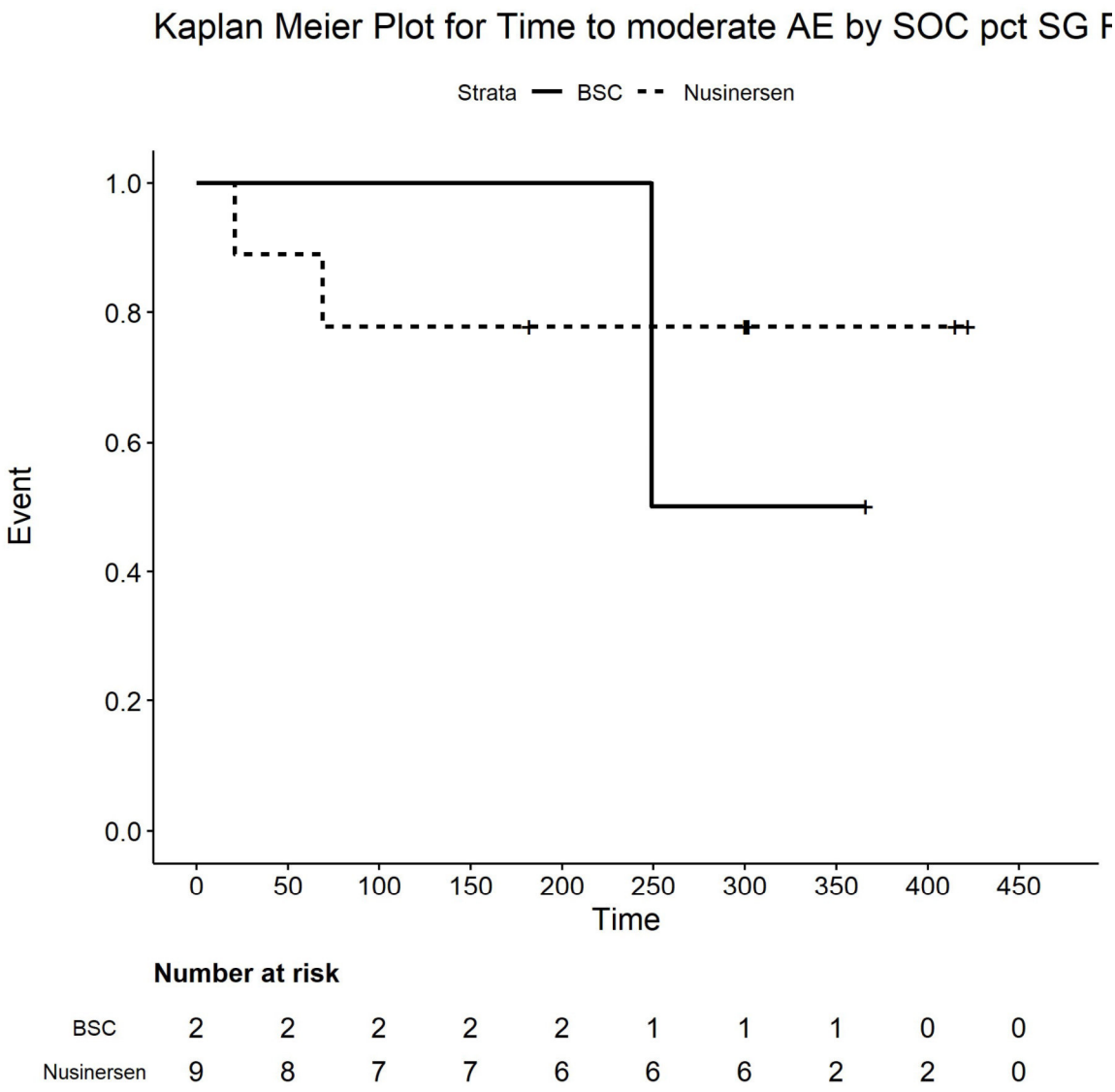
Number at risk

BSC	6	6	6	5	4	3	2	1	0	0
Nusinersen	10	9	8	8	8	8	7	5	5	0



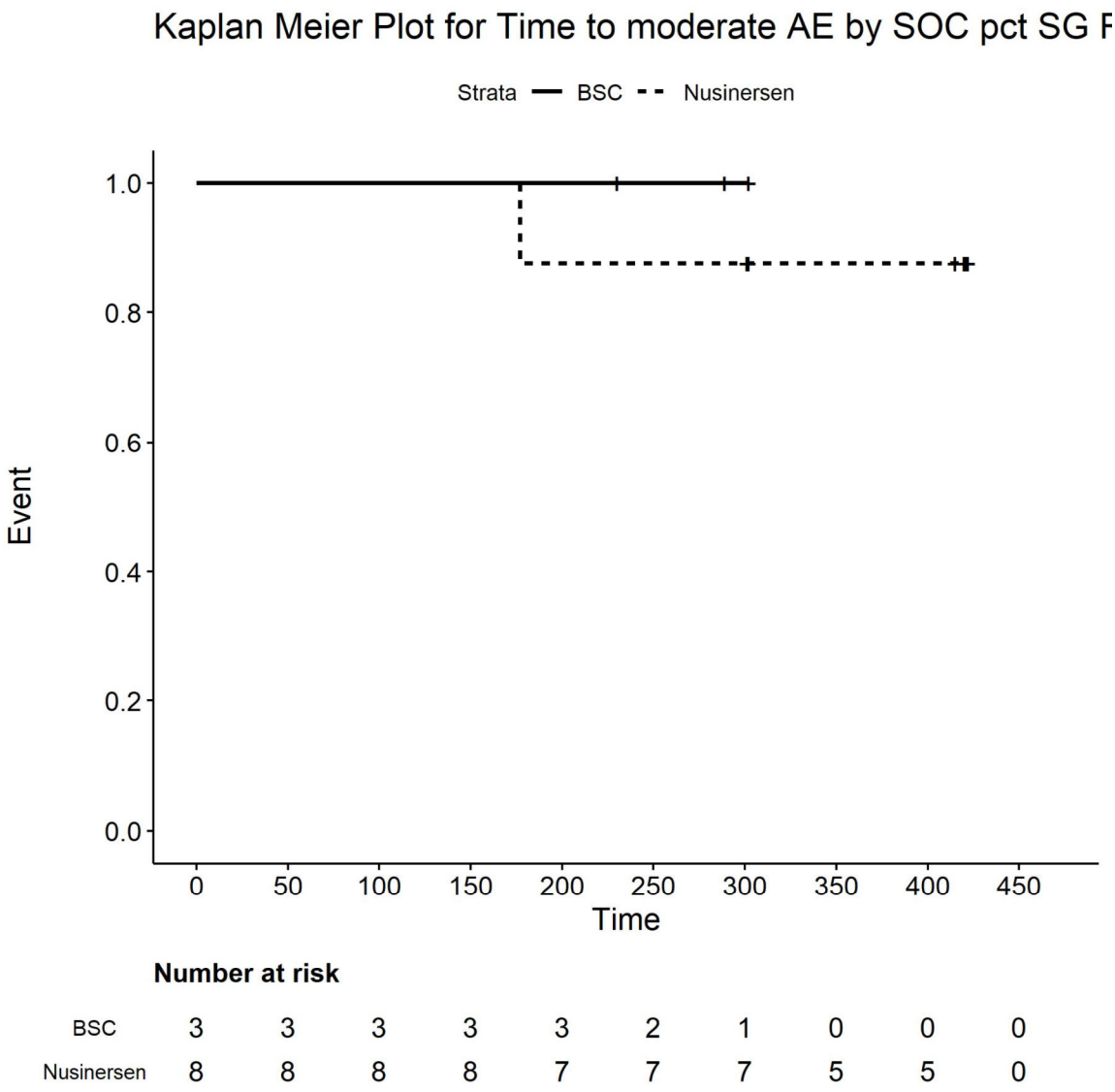
Number at risk

BSC	5	5	4	3	2	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



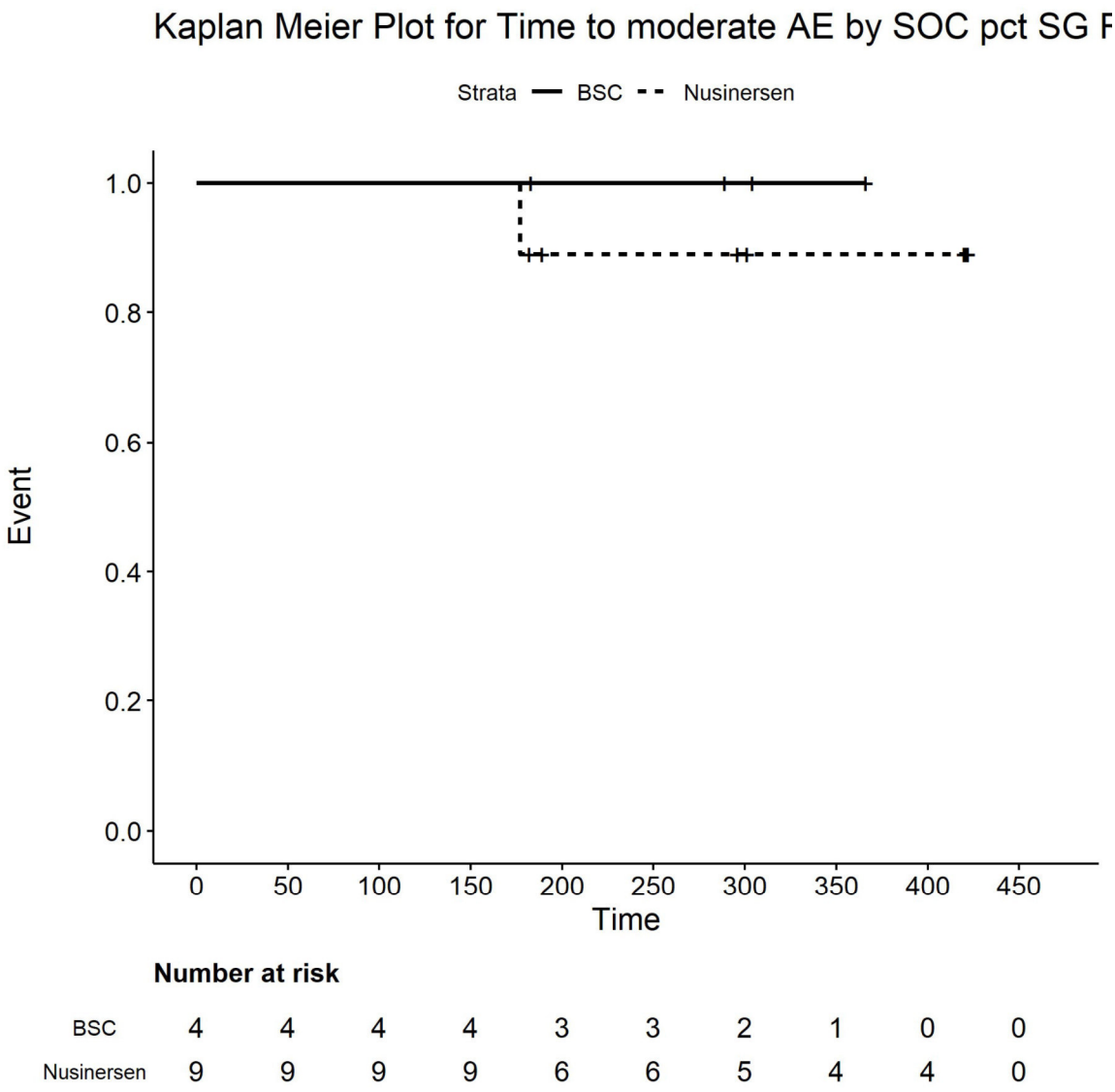
Number at risk

BSC	2	2	2	2	2	1	1	1	0	0
Nusinersen	9	8	7	7	6	6	6	2	2	0



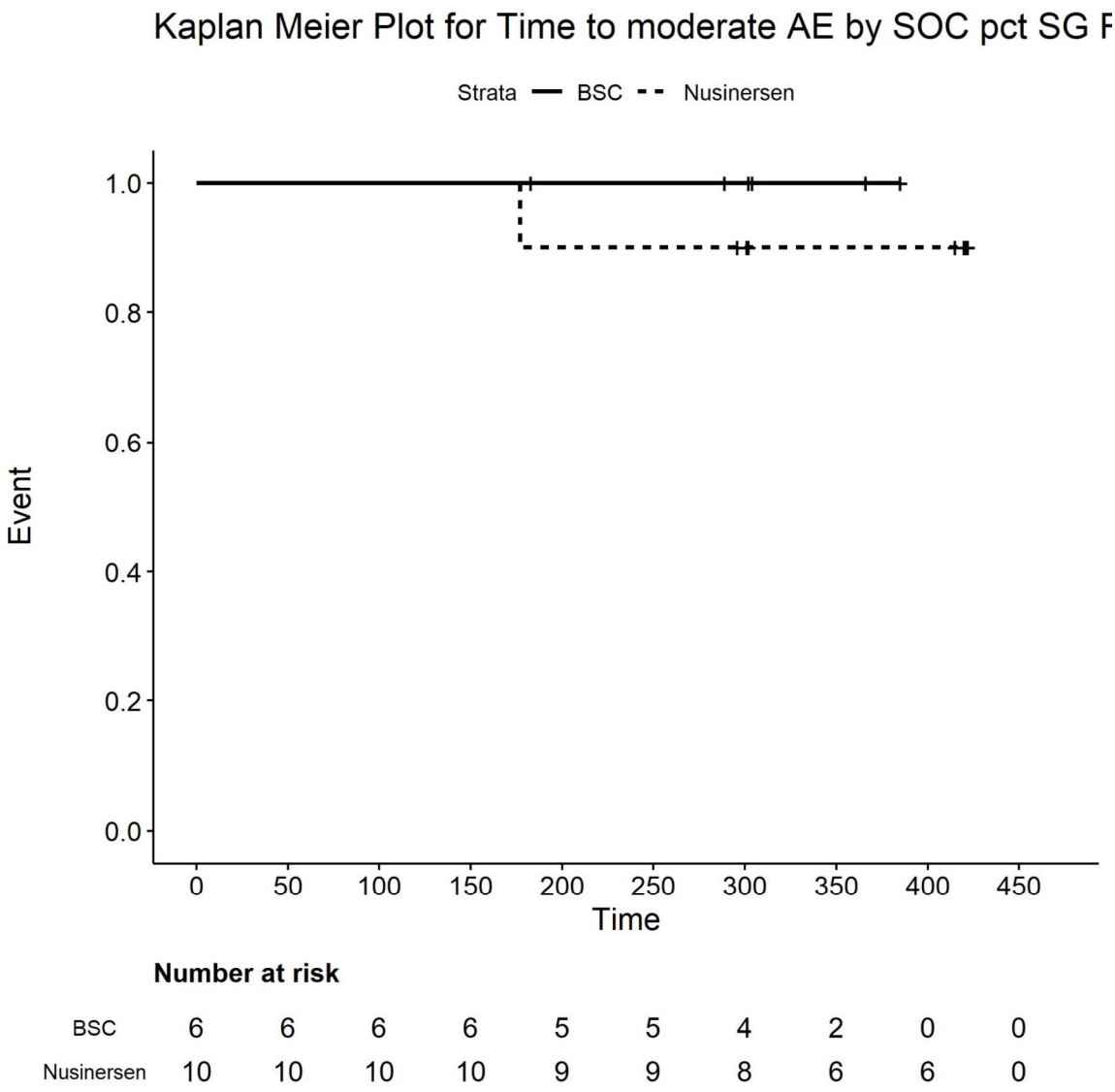
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	7	7	7	5	5	0



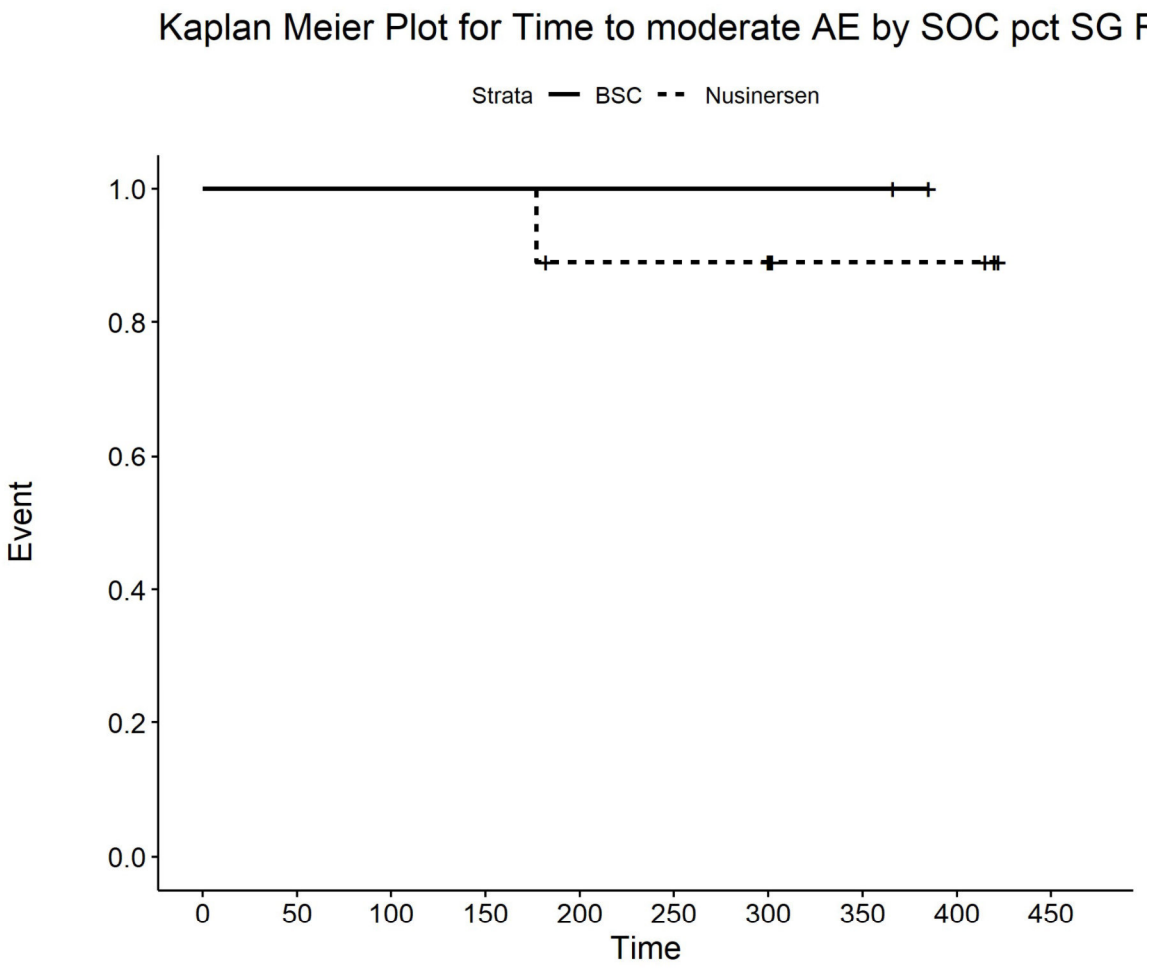
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	6	6	5	4	4	0



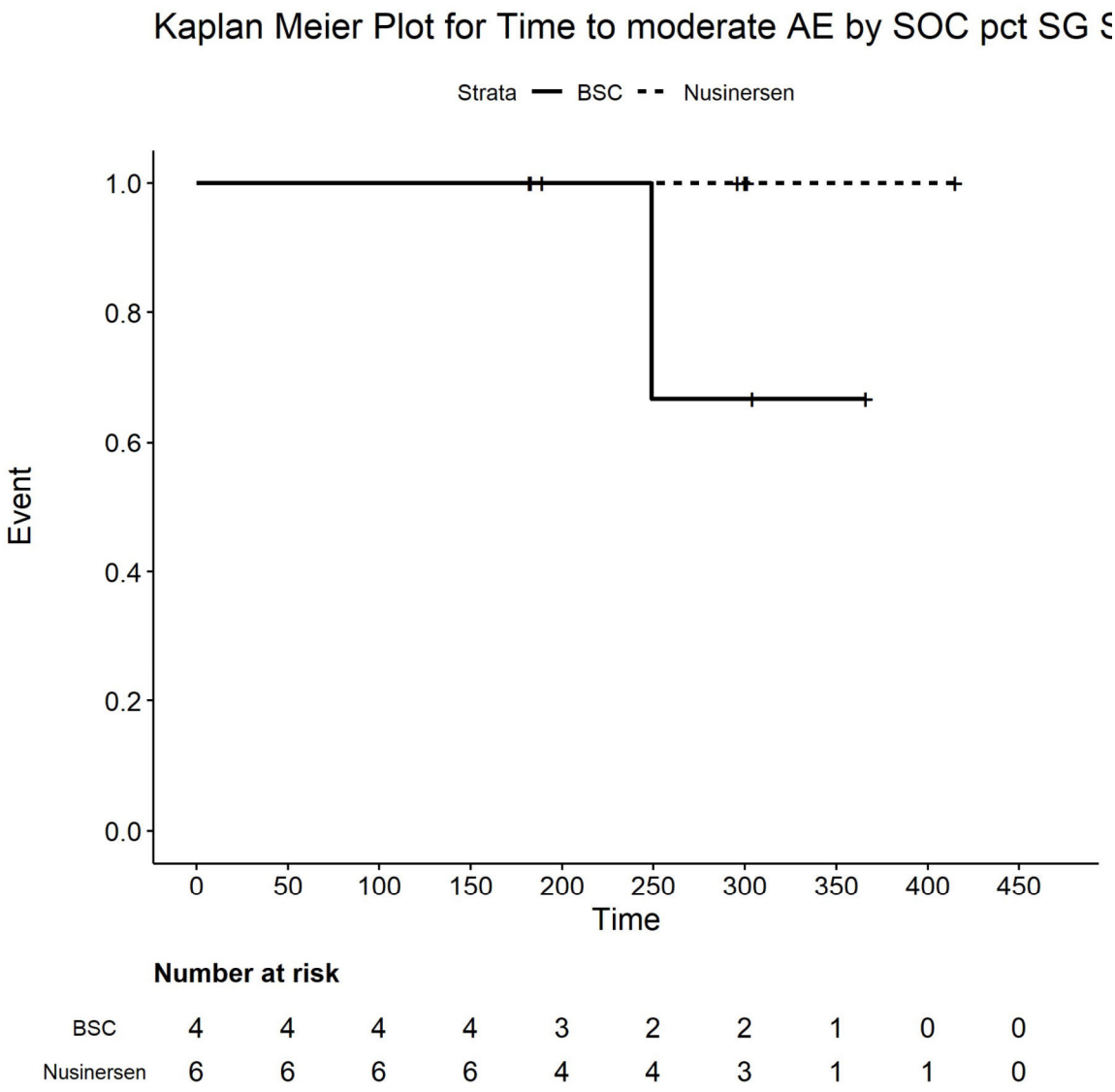
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	9	9	8	6	6	0



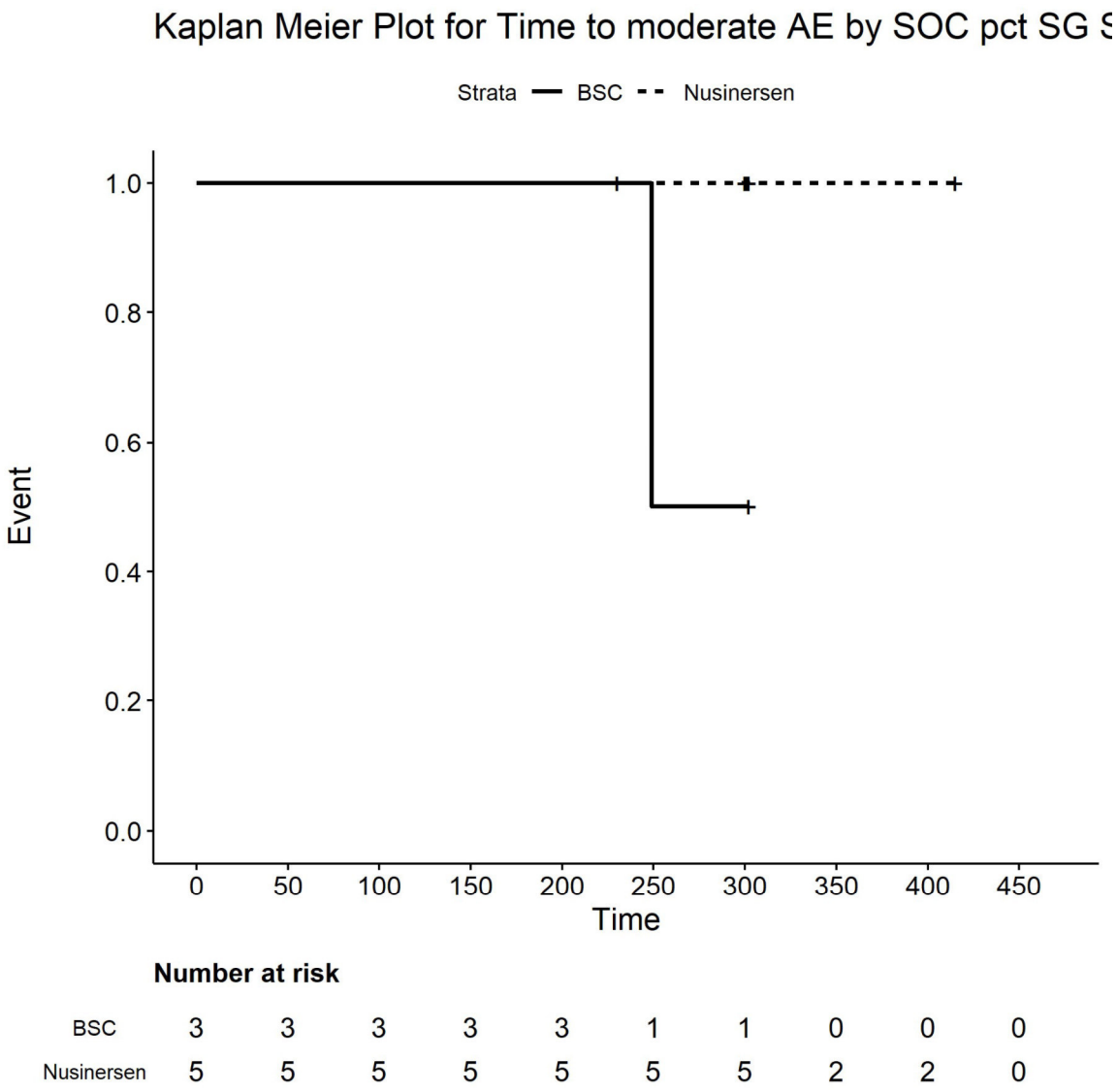
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	7	7	7	3	3	0



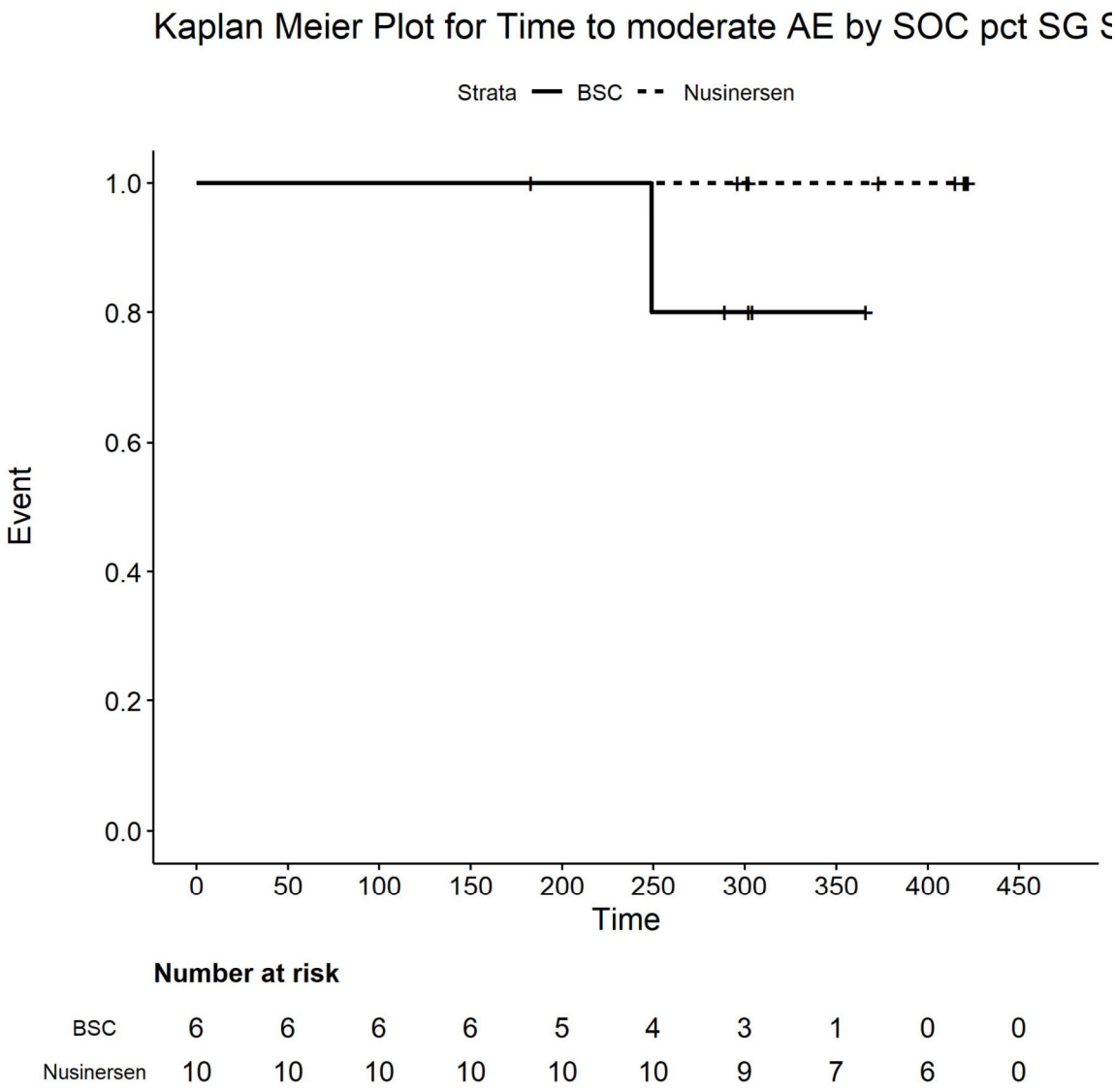
Number at risk

BSC	4	4	4	4	3	2	2	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



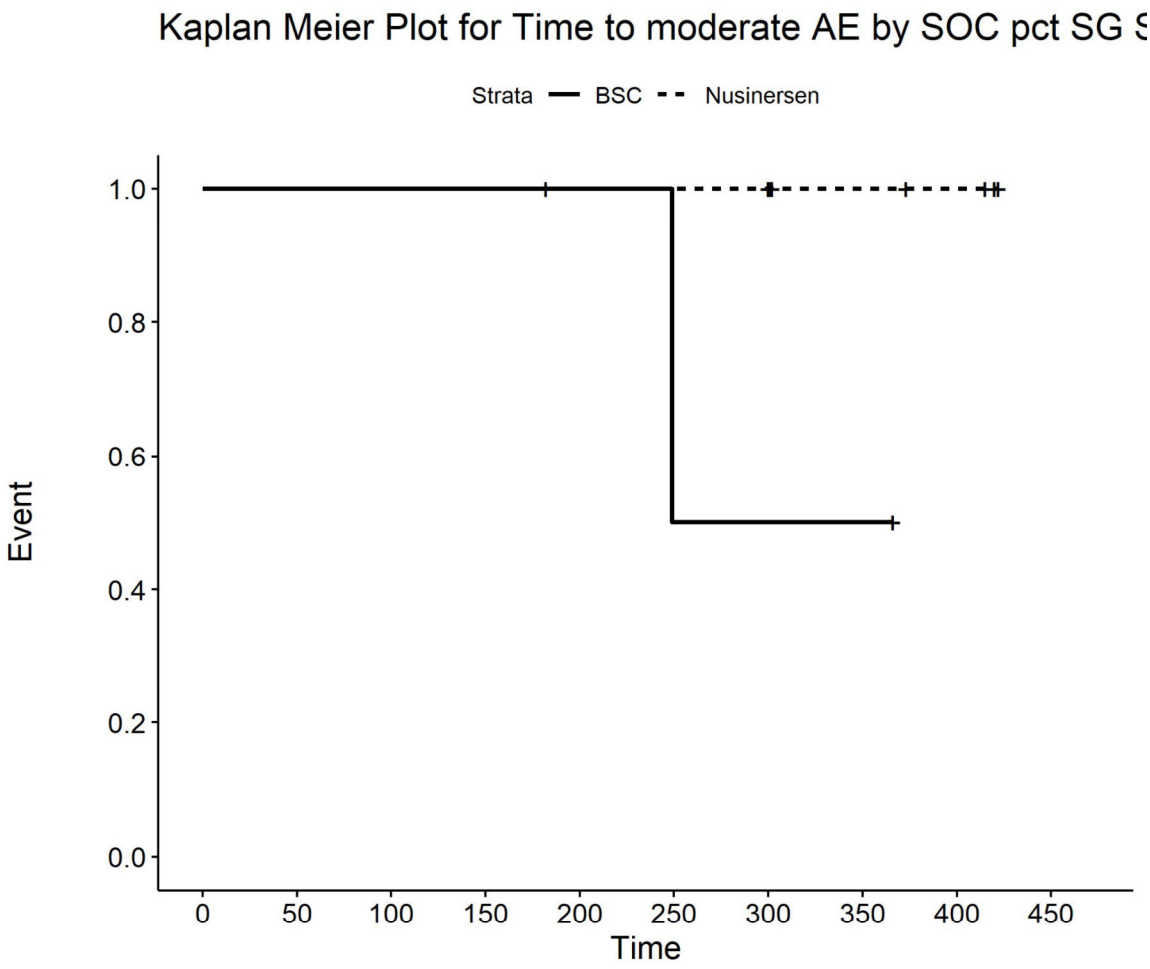
Number at risk

BSC	3	3	3	3	3	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



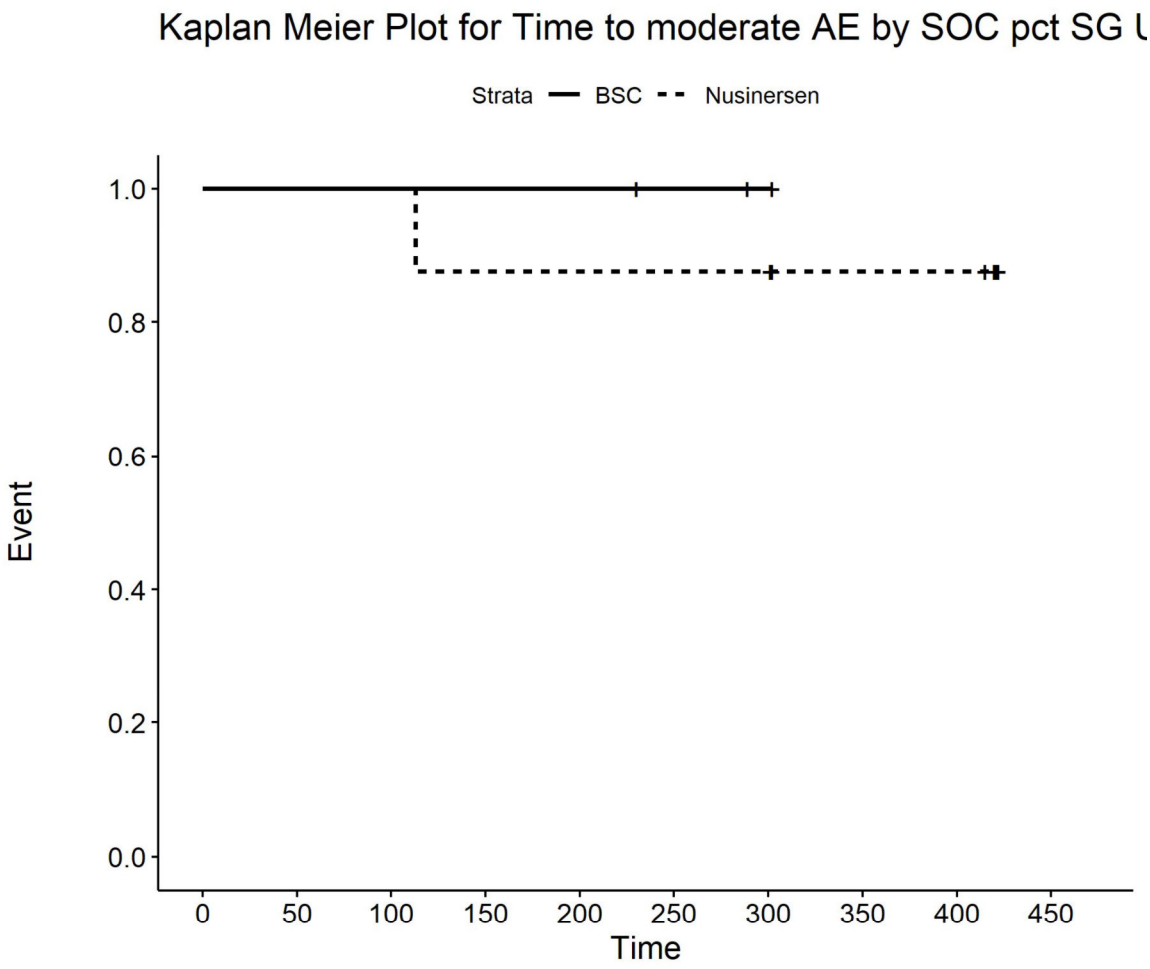
Number at risk

BSC	6	6	6	6	5	4	3	1	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



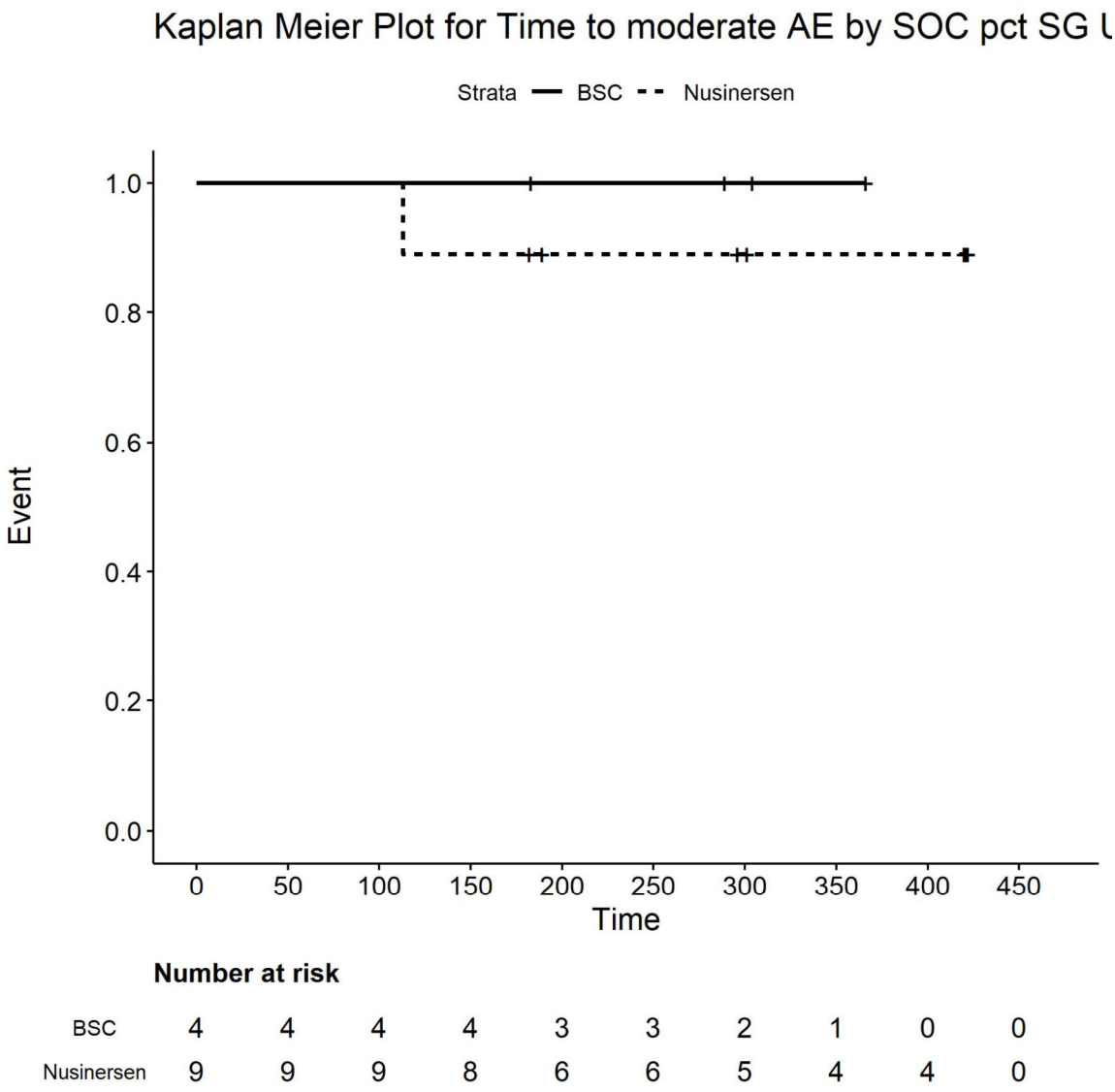
Number at risk

BSC	2	2	2	2	2	1	1	1	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



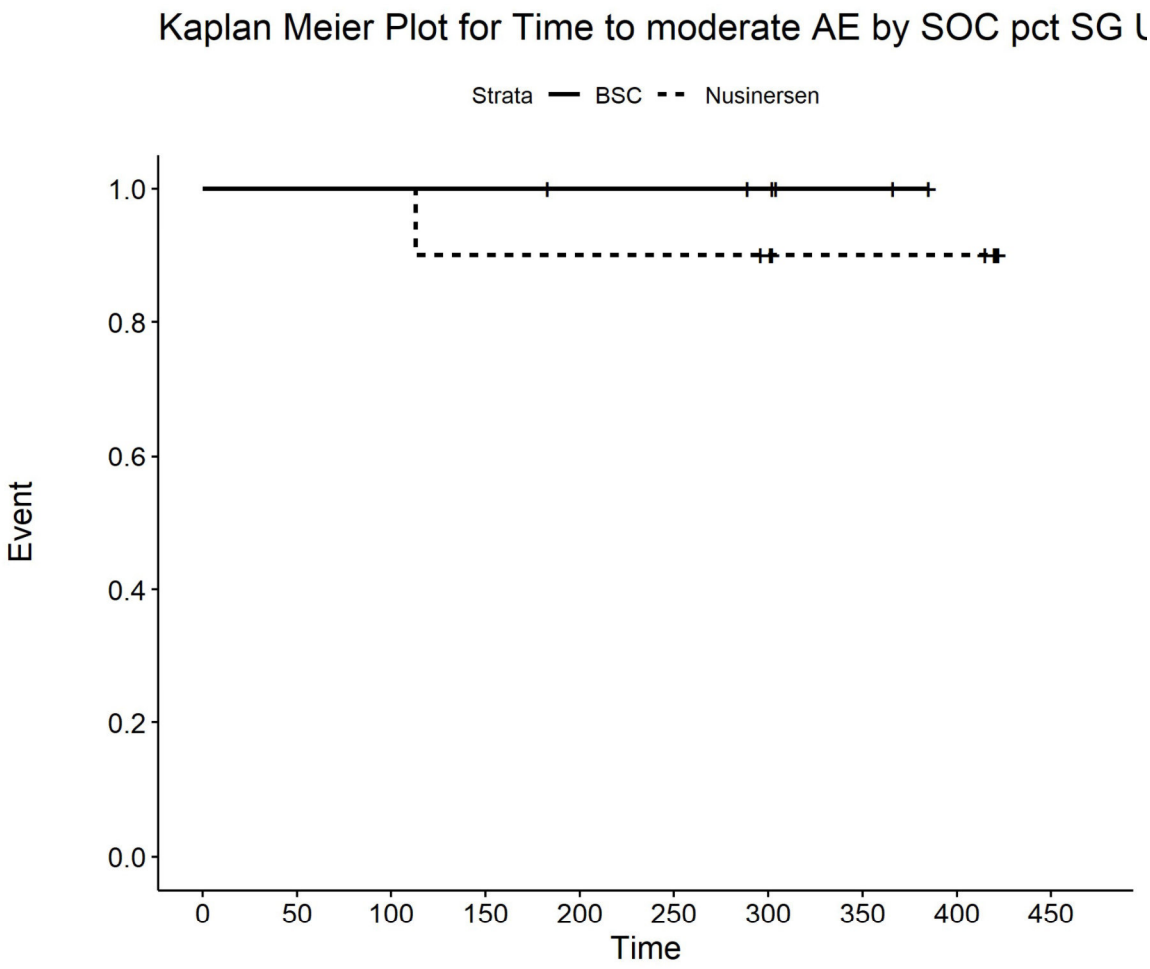
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	5	0



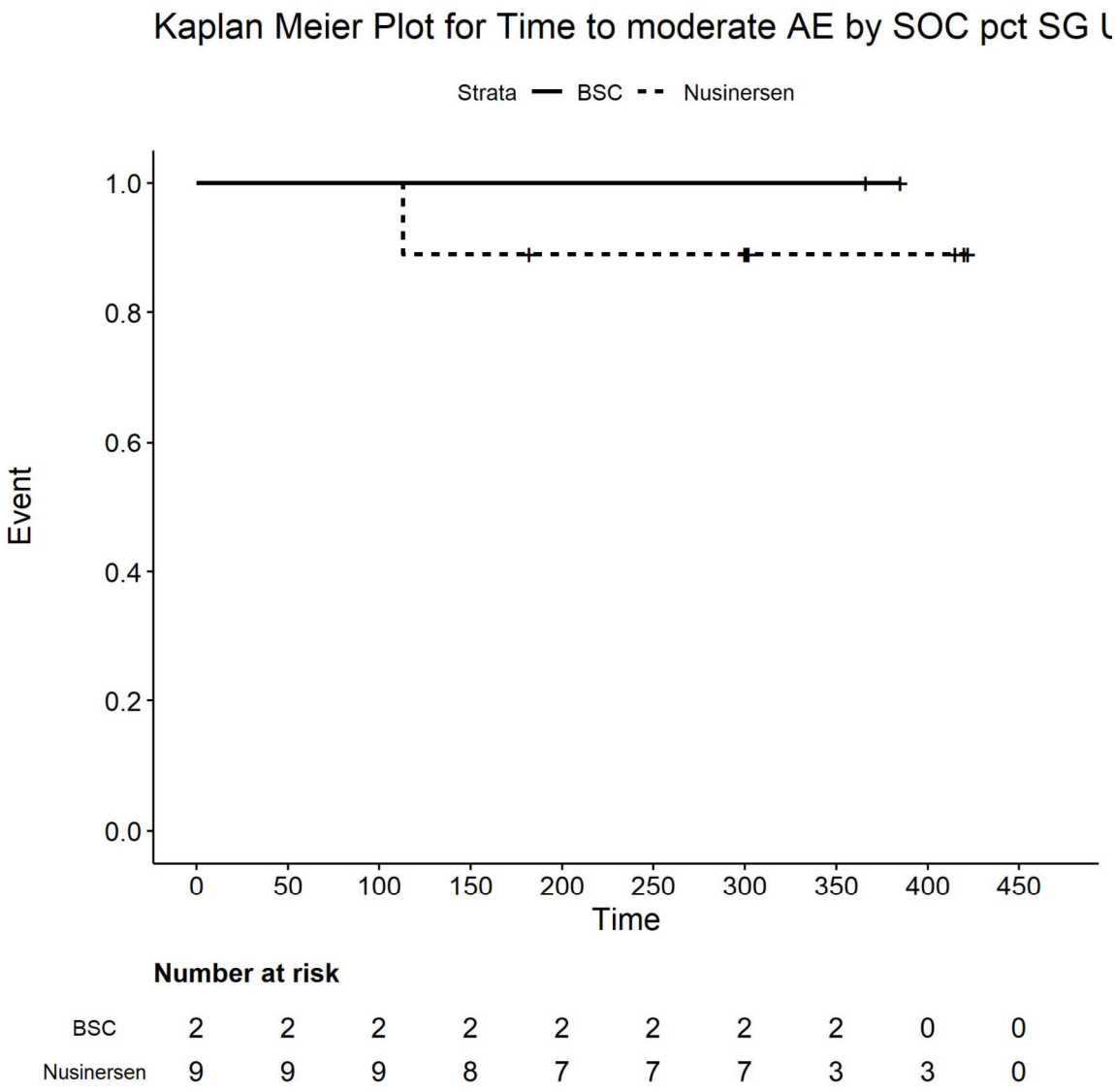
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	4	0



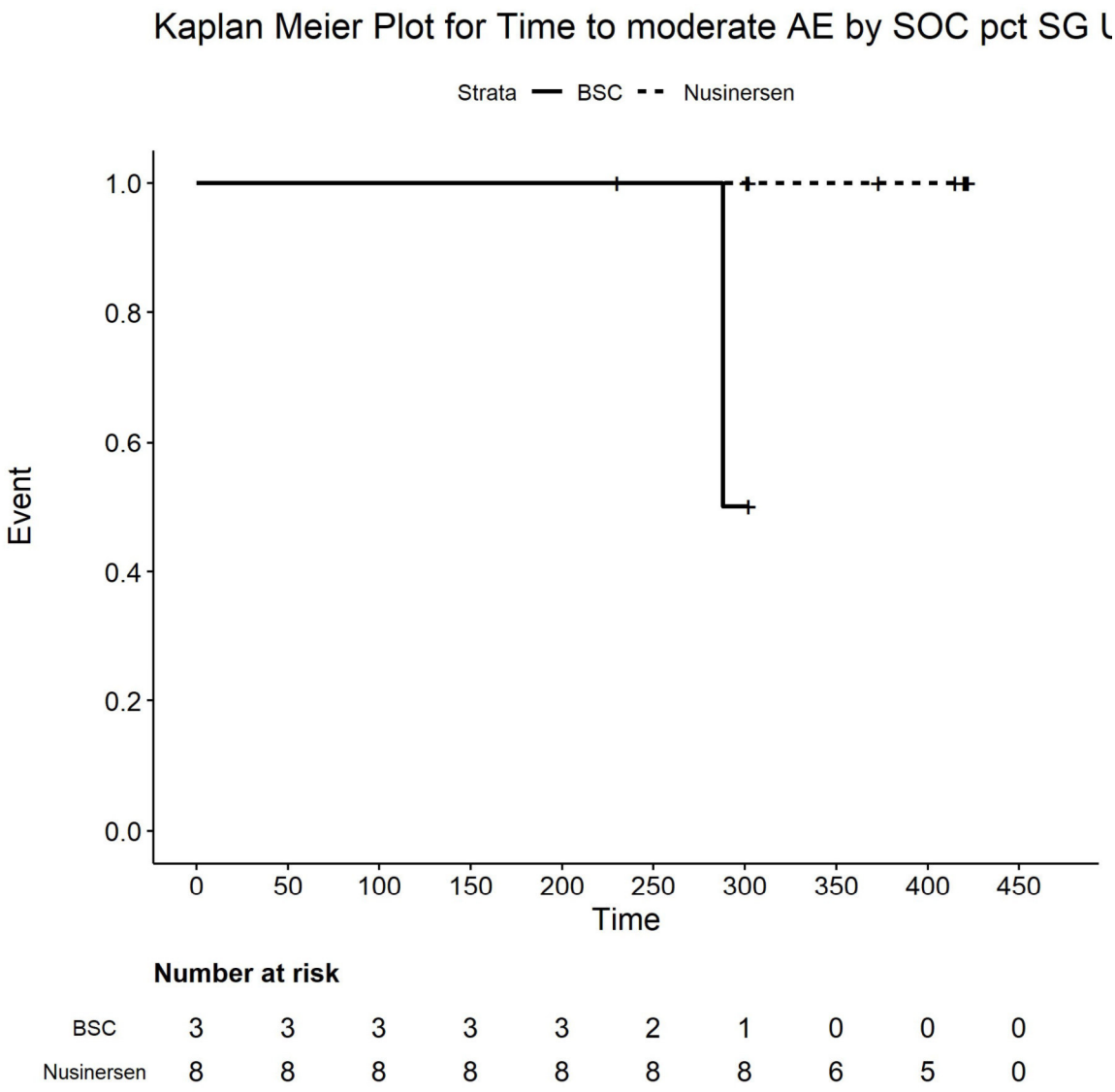
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	6	0



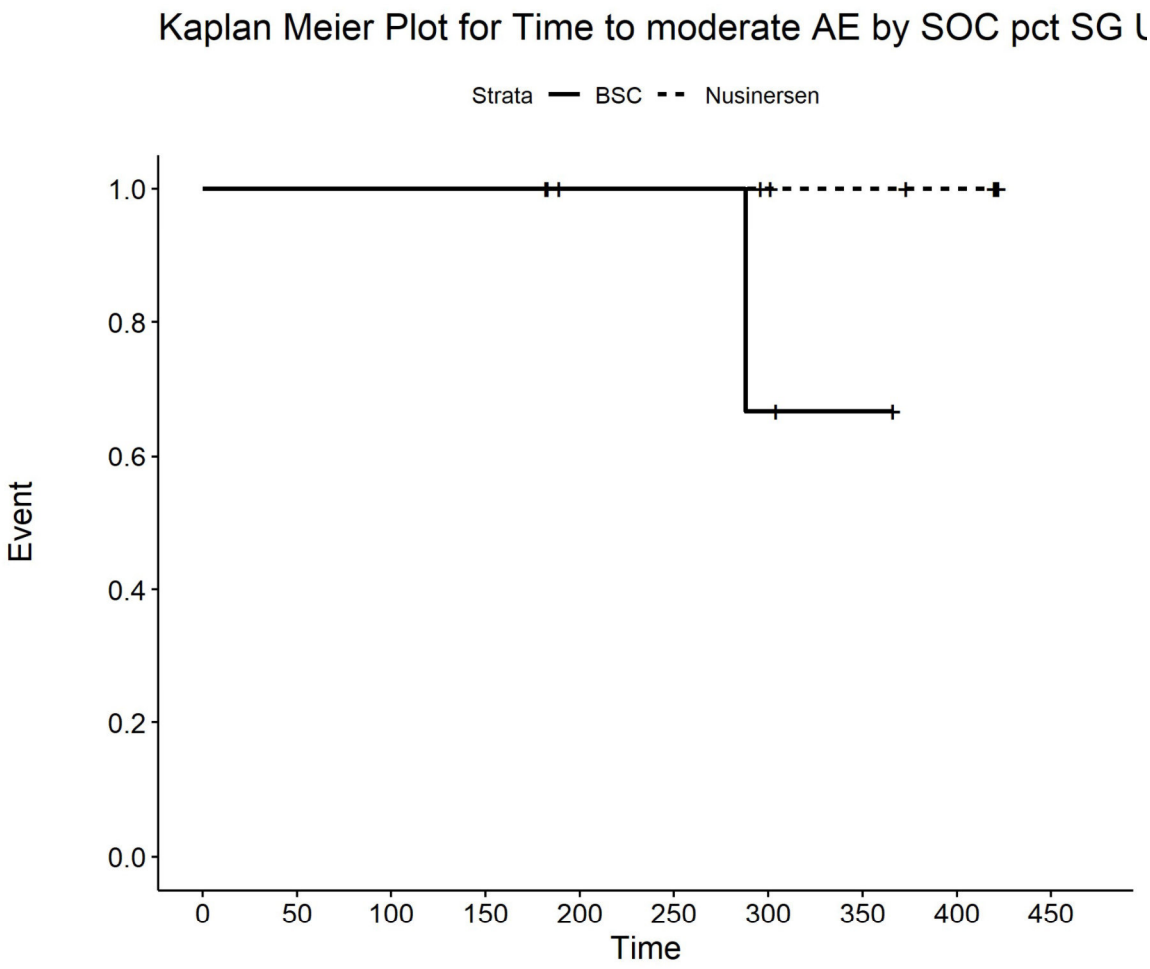
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	3	0



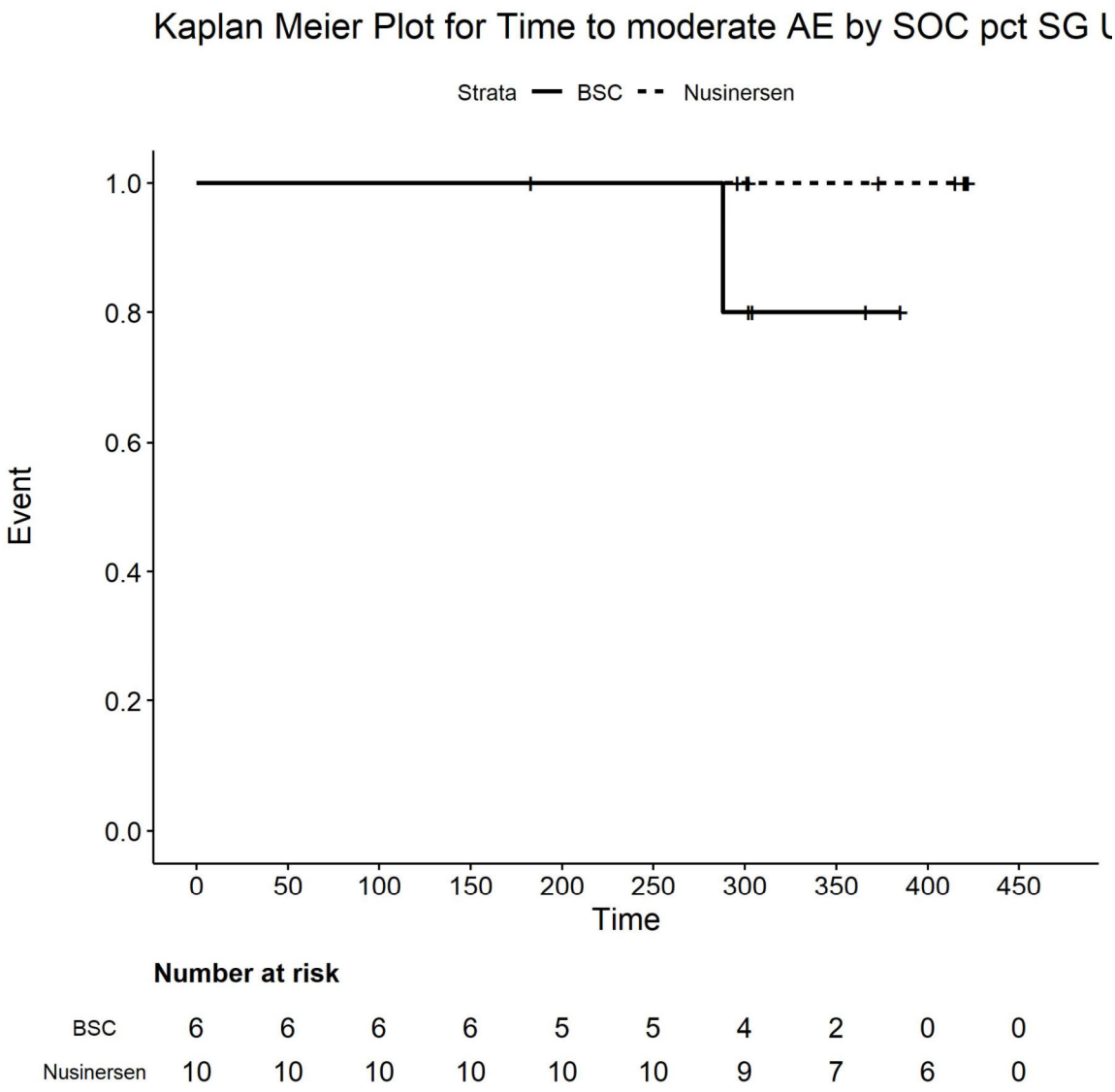
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



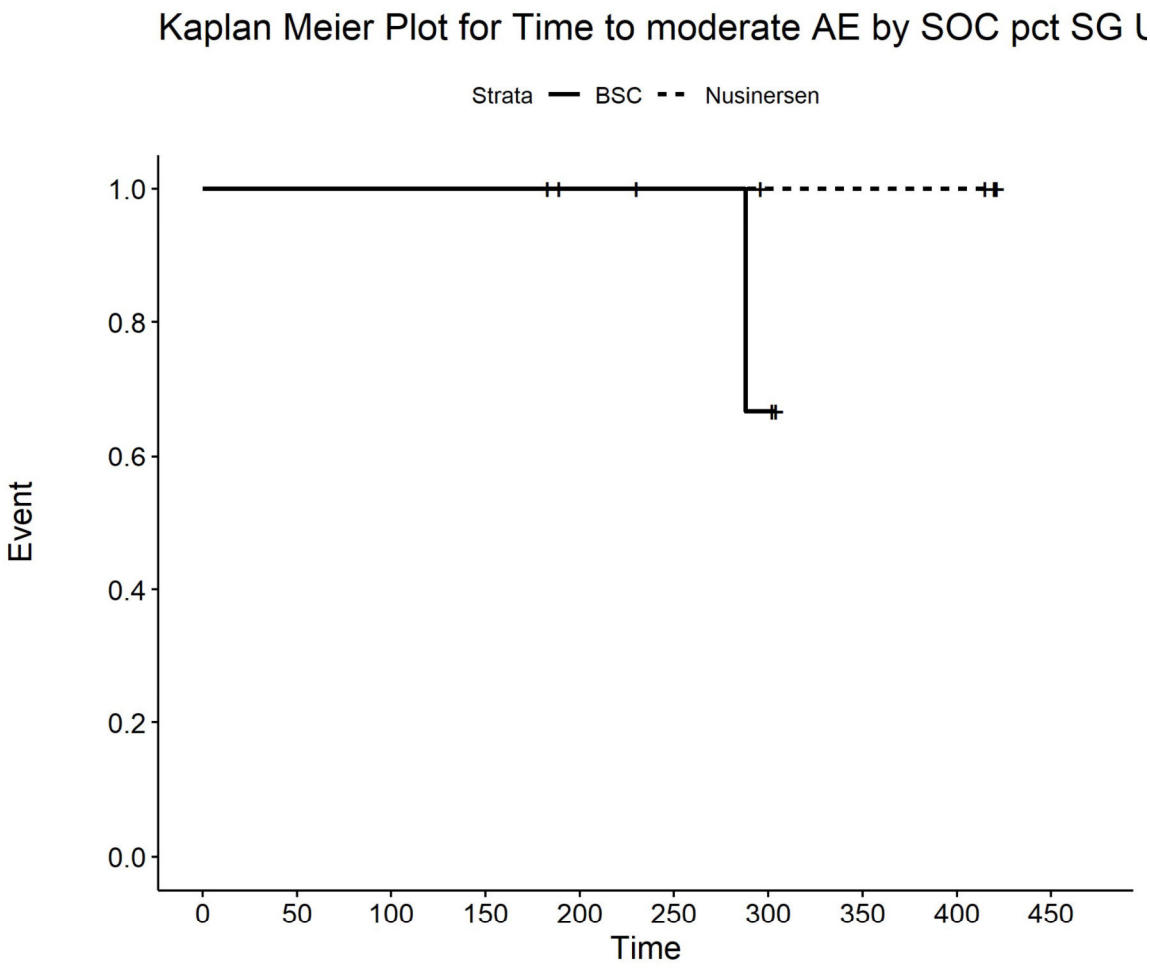
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



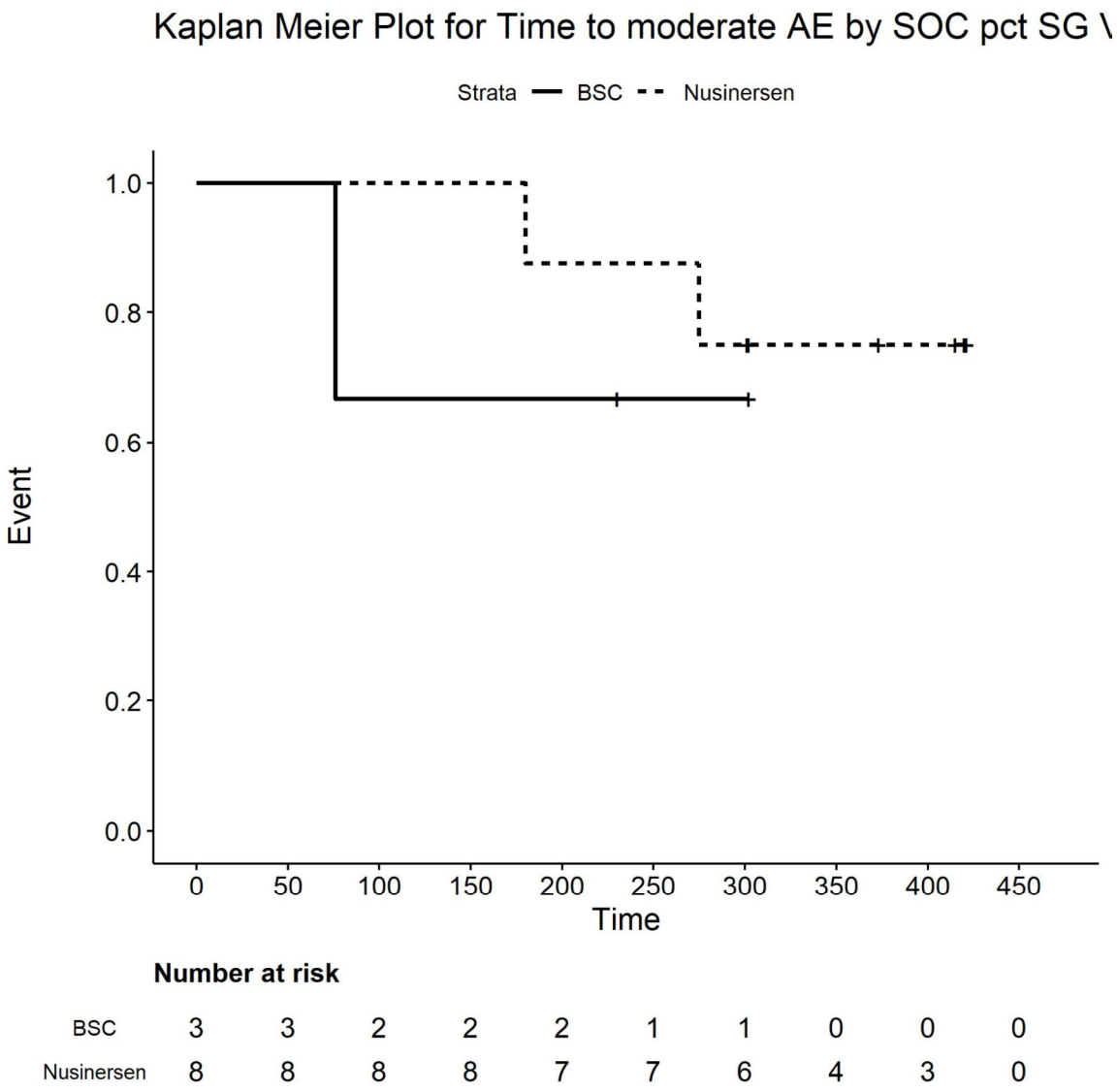
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



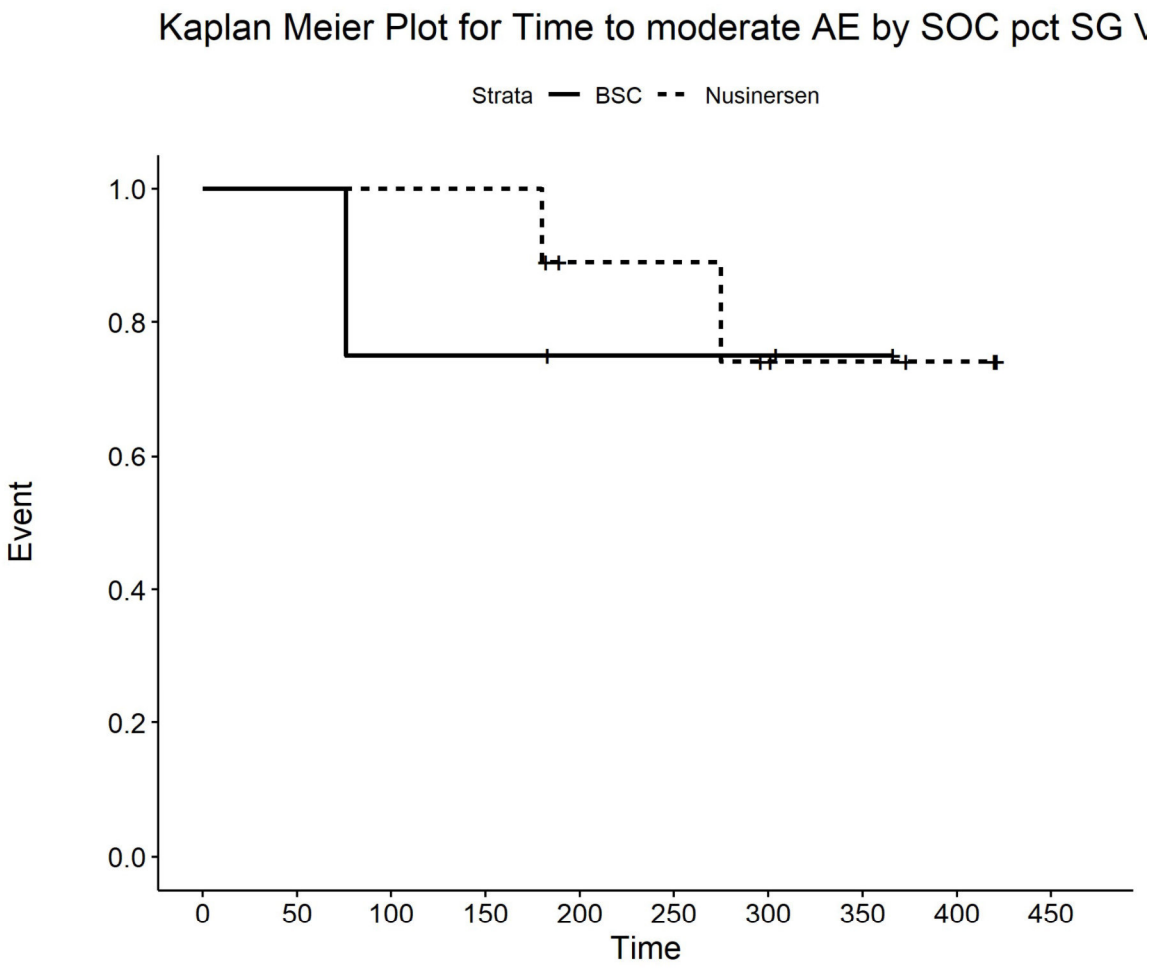
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



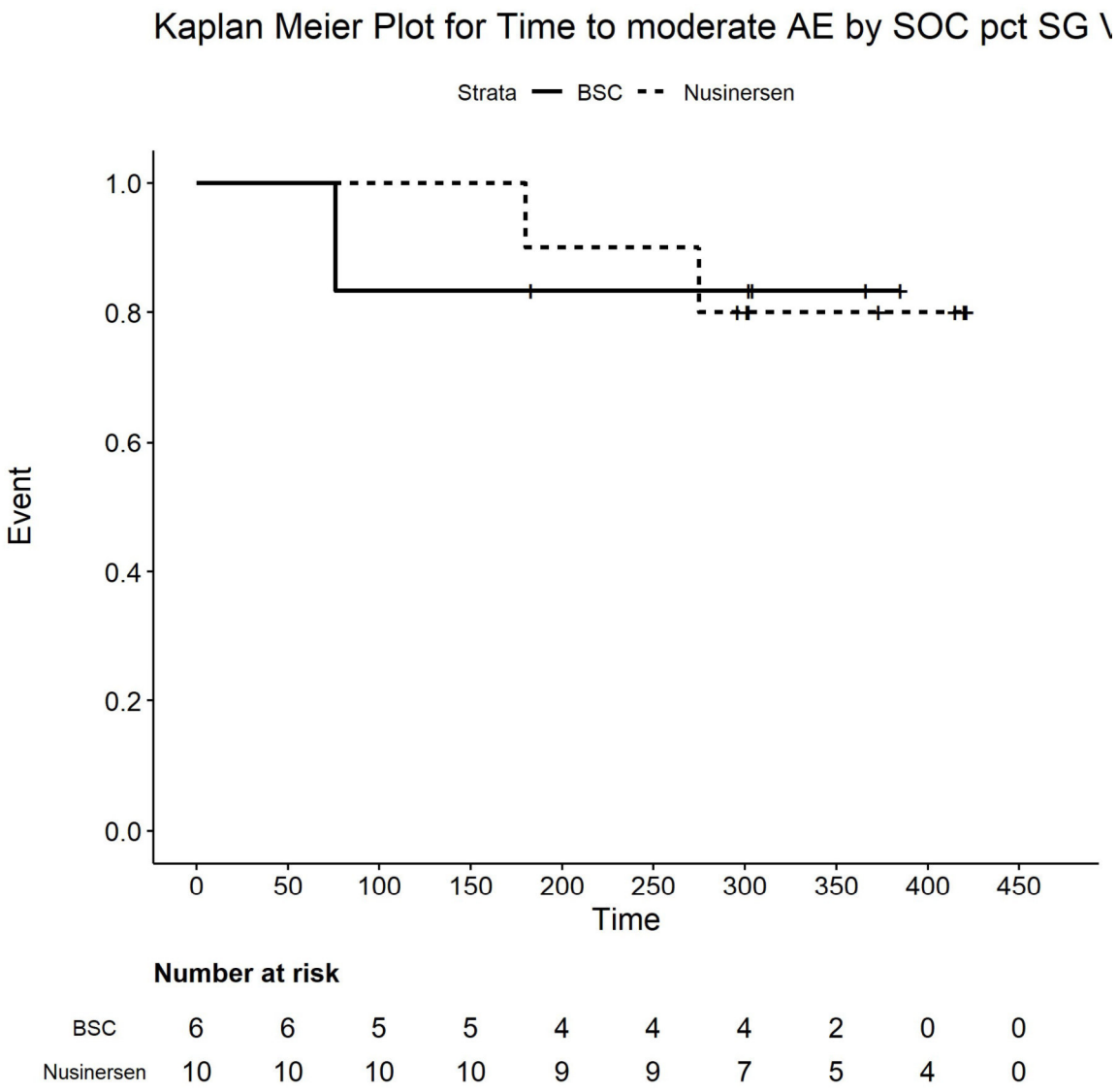
Number at risk

BSC	3	3	2	2	2	1	1	0	0	0
Nusinersen	8	8	8	8	7	7	6	4	3	0



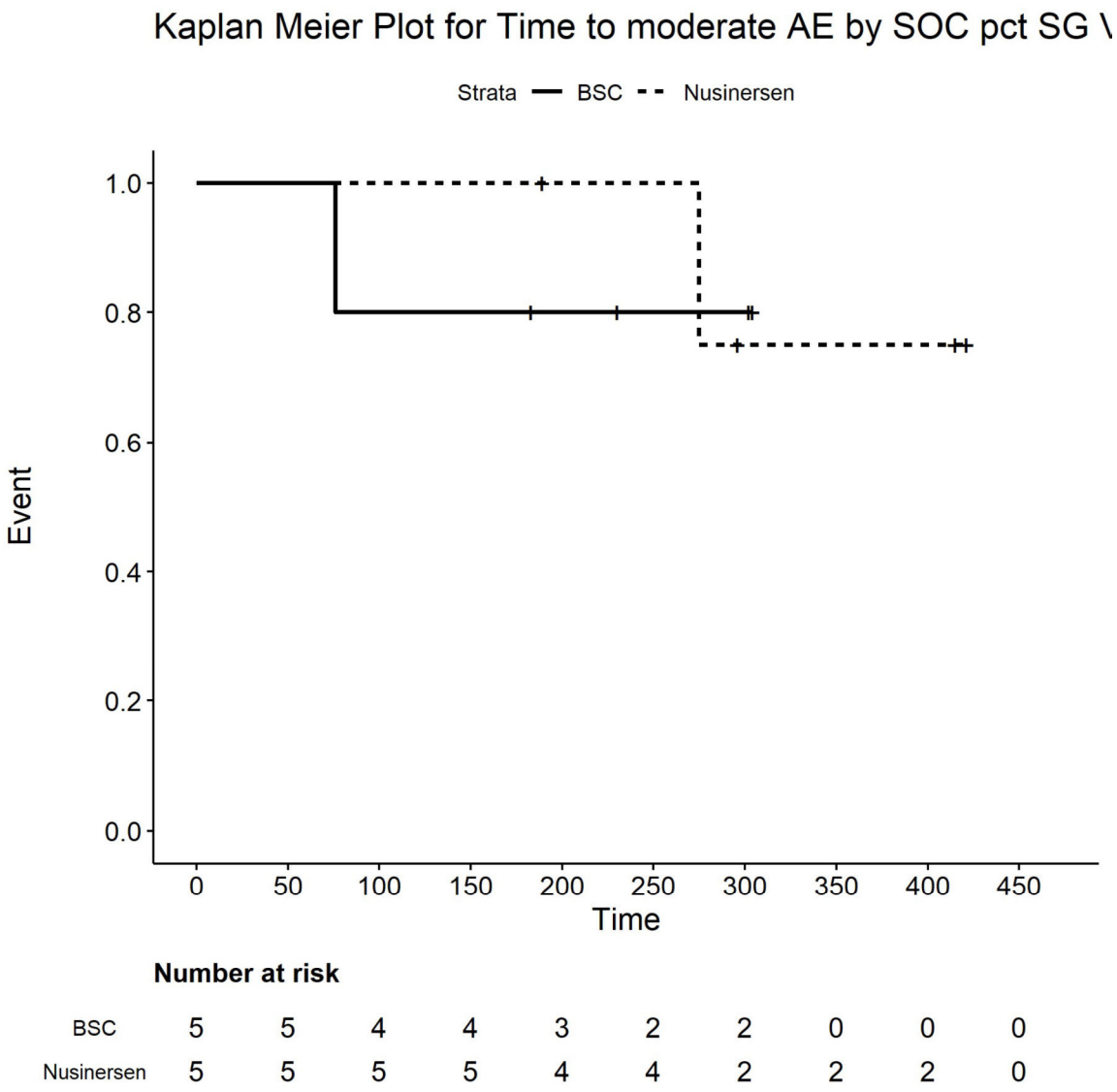
Number at risk

BSC	4	4	3	3	2	2	2	1	0	0
Nusinersen	9	9	9	9	6	6	4	3	2	0



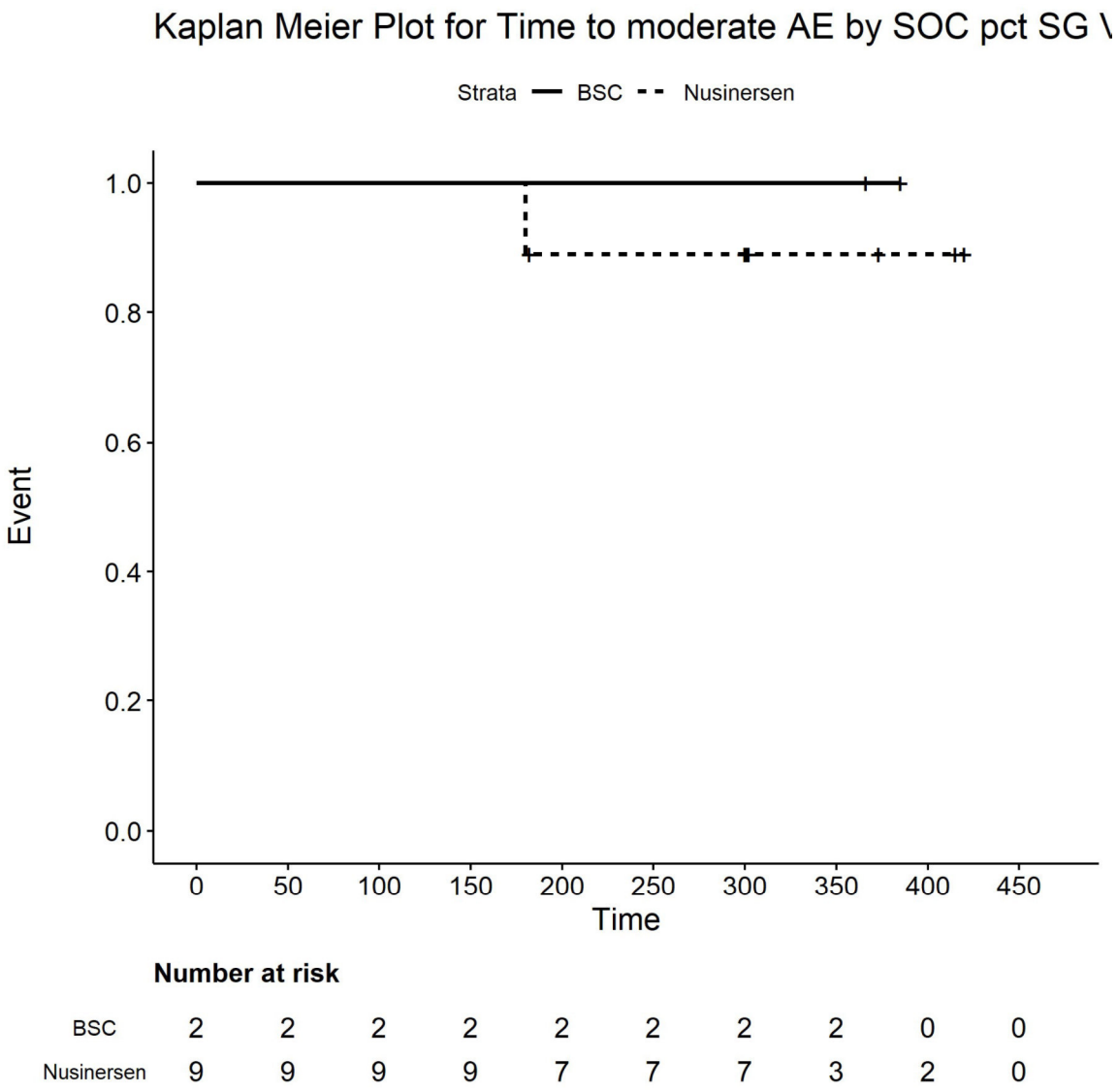
Number at risk

BSC	6	6	5	5	4	4	4	2	0	0
Nusinersen	10	10	10	10	9	9	7	5	4	0



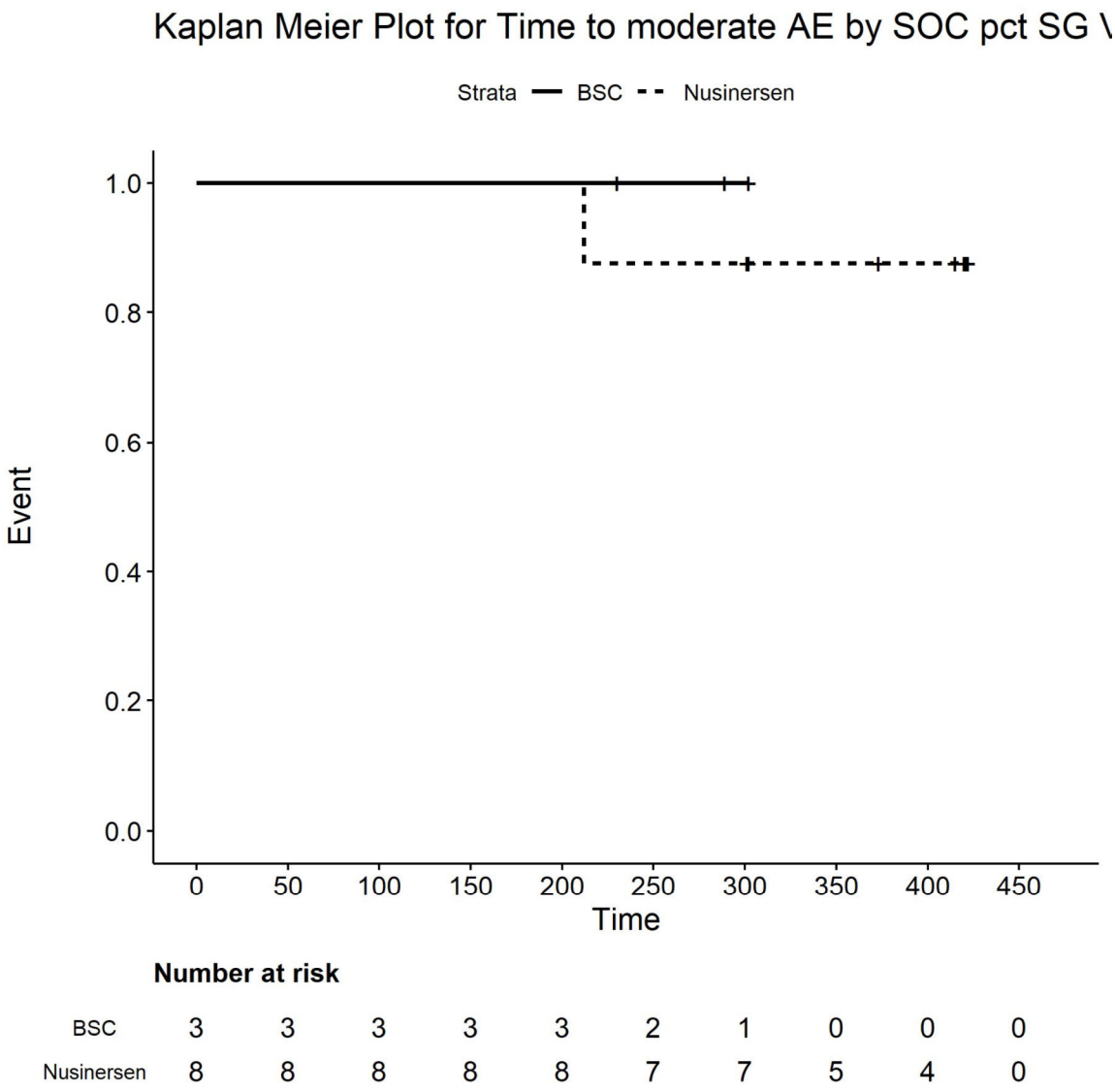
Number at risk

BSC	5	5	4	4	3	2	2	0	0	0
Nusinersen	5	5	5	5	4	4	2	2	2	0



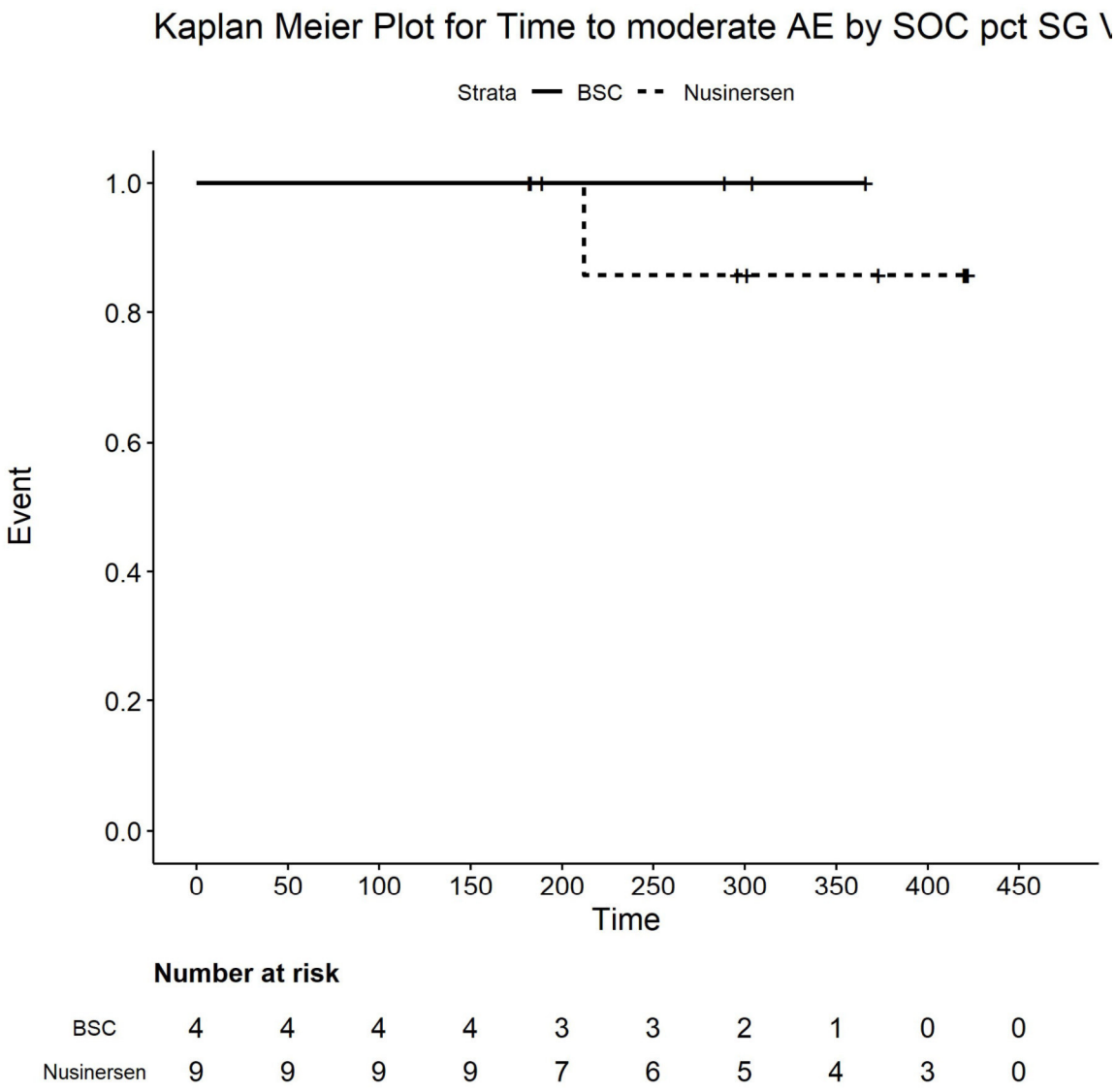
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	7	7	7	3	2	0



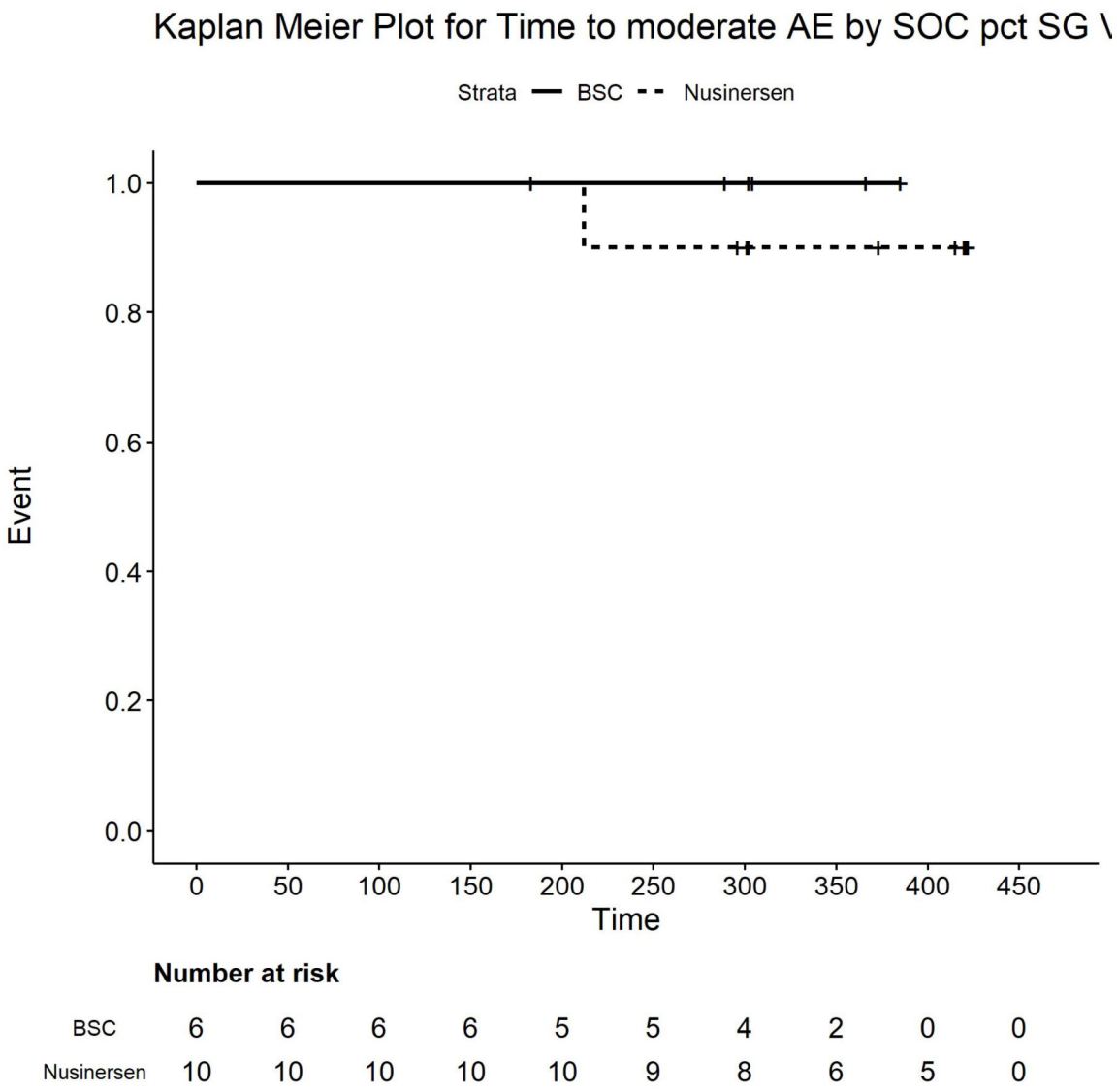
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



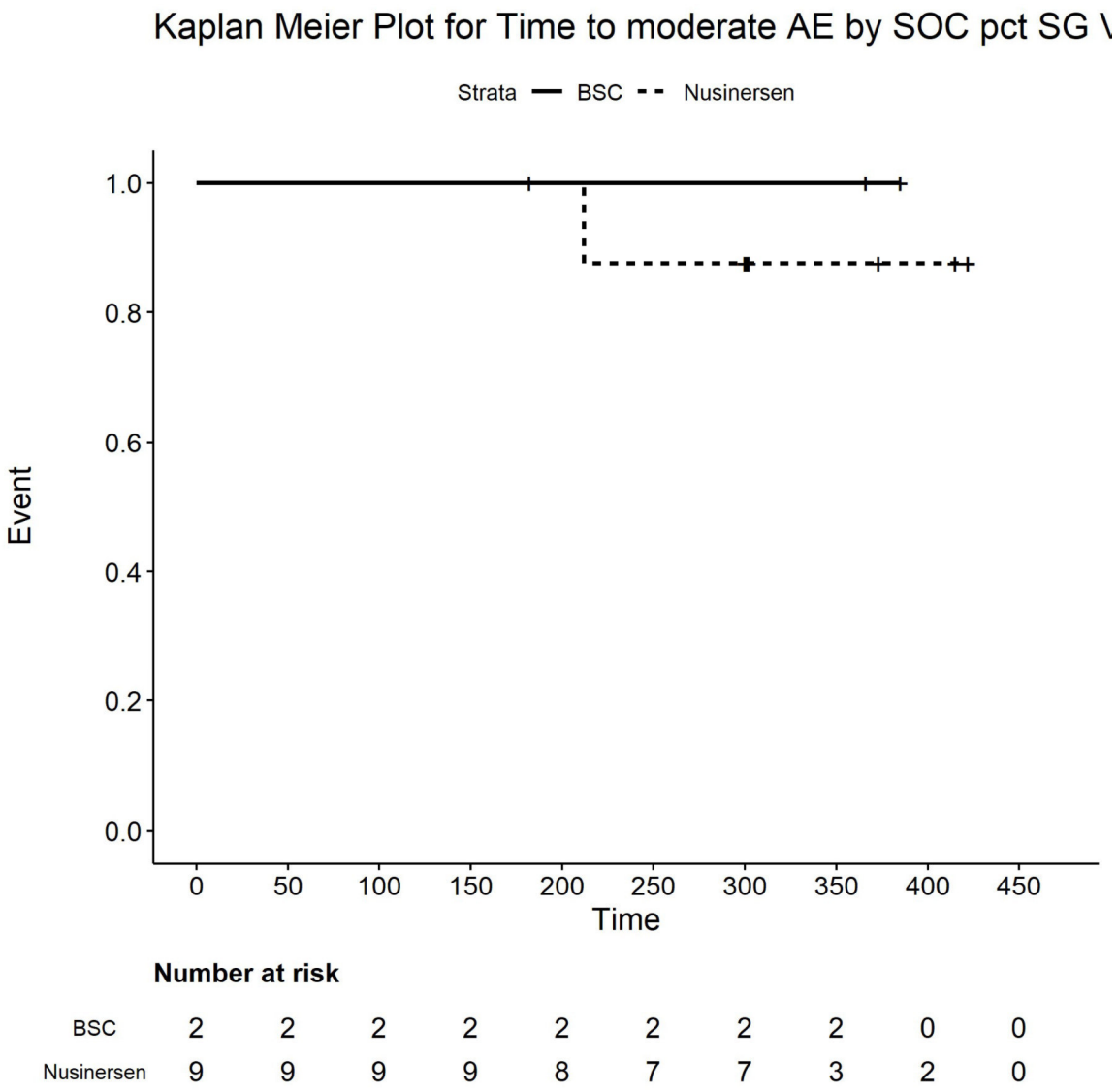
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



Number at risk

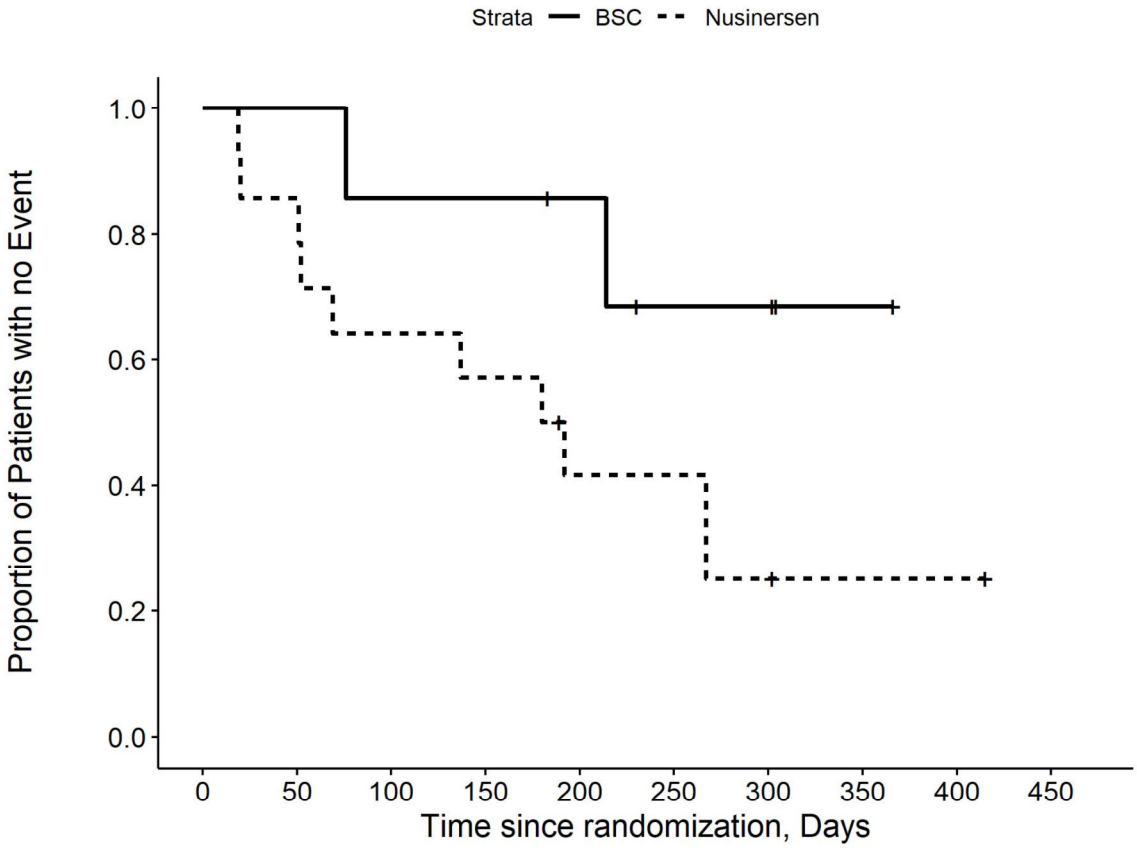
BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



Number at risk

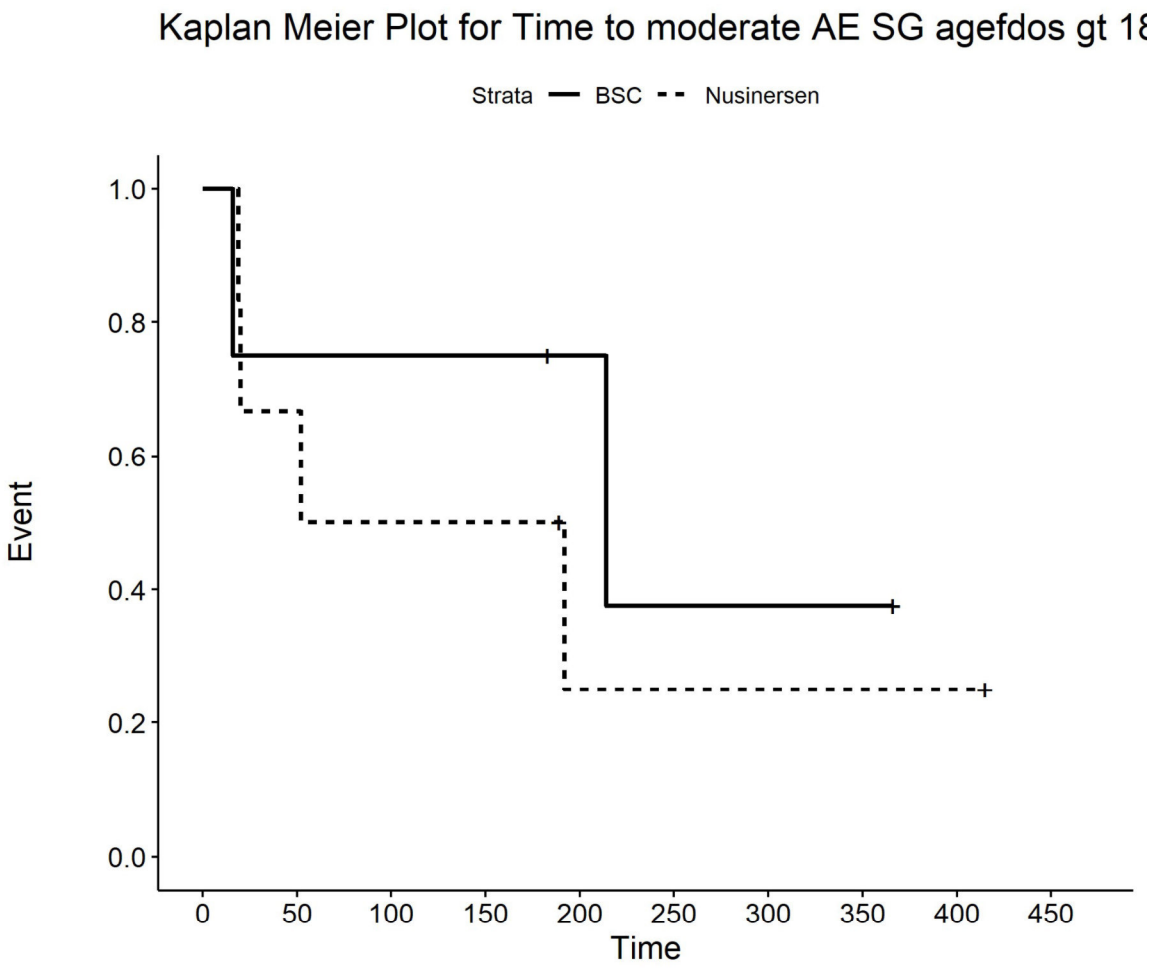
BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	2	0

Kaplan Meier Plot for Time to moderate AE by SOC pts Infections and infestations



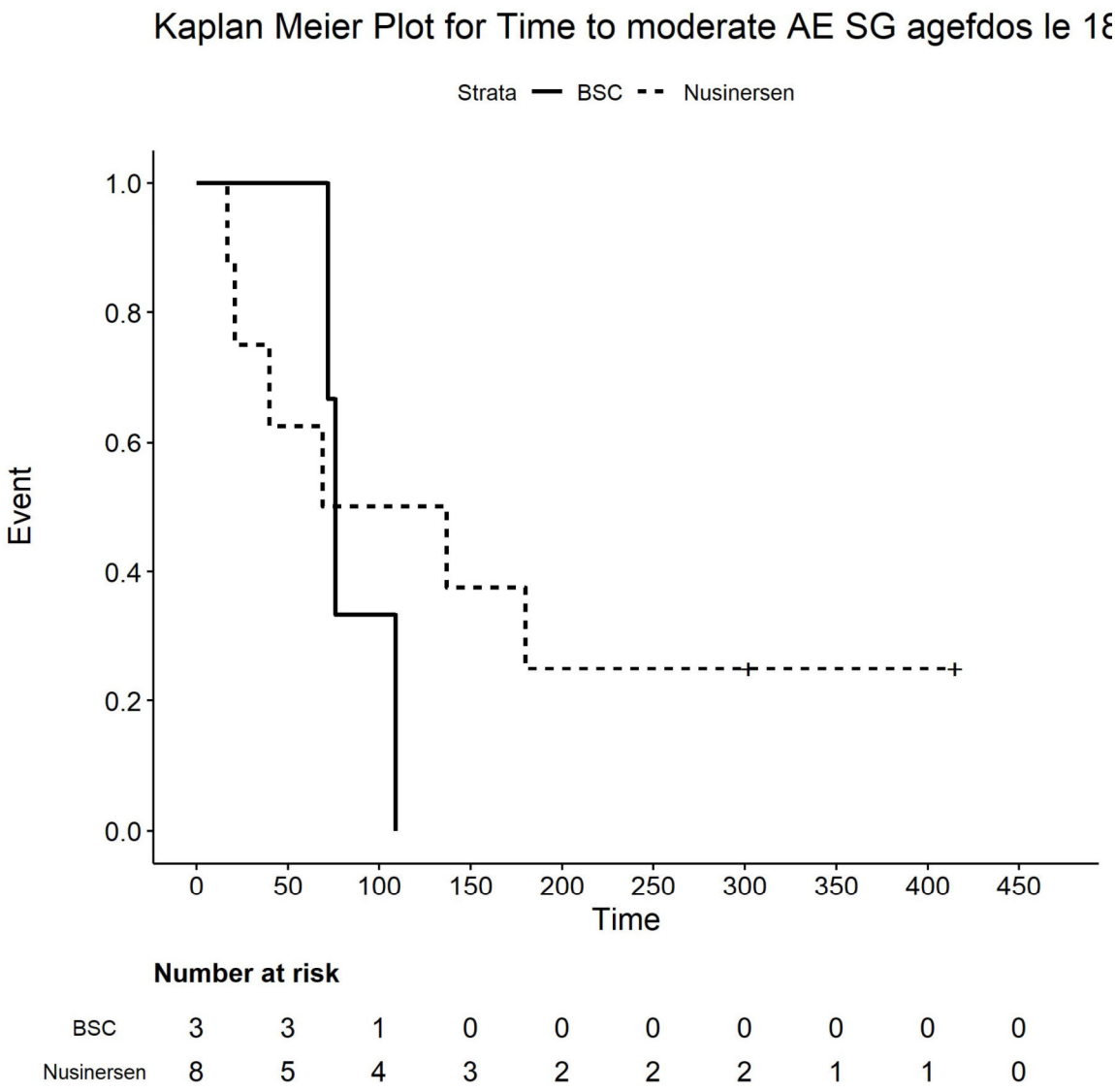
Number at risk

BSC	7	7	6	6	5	3	3	1	0	0
Nusinersen	14	12	9	8	5	5	3	2	2	0



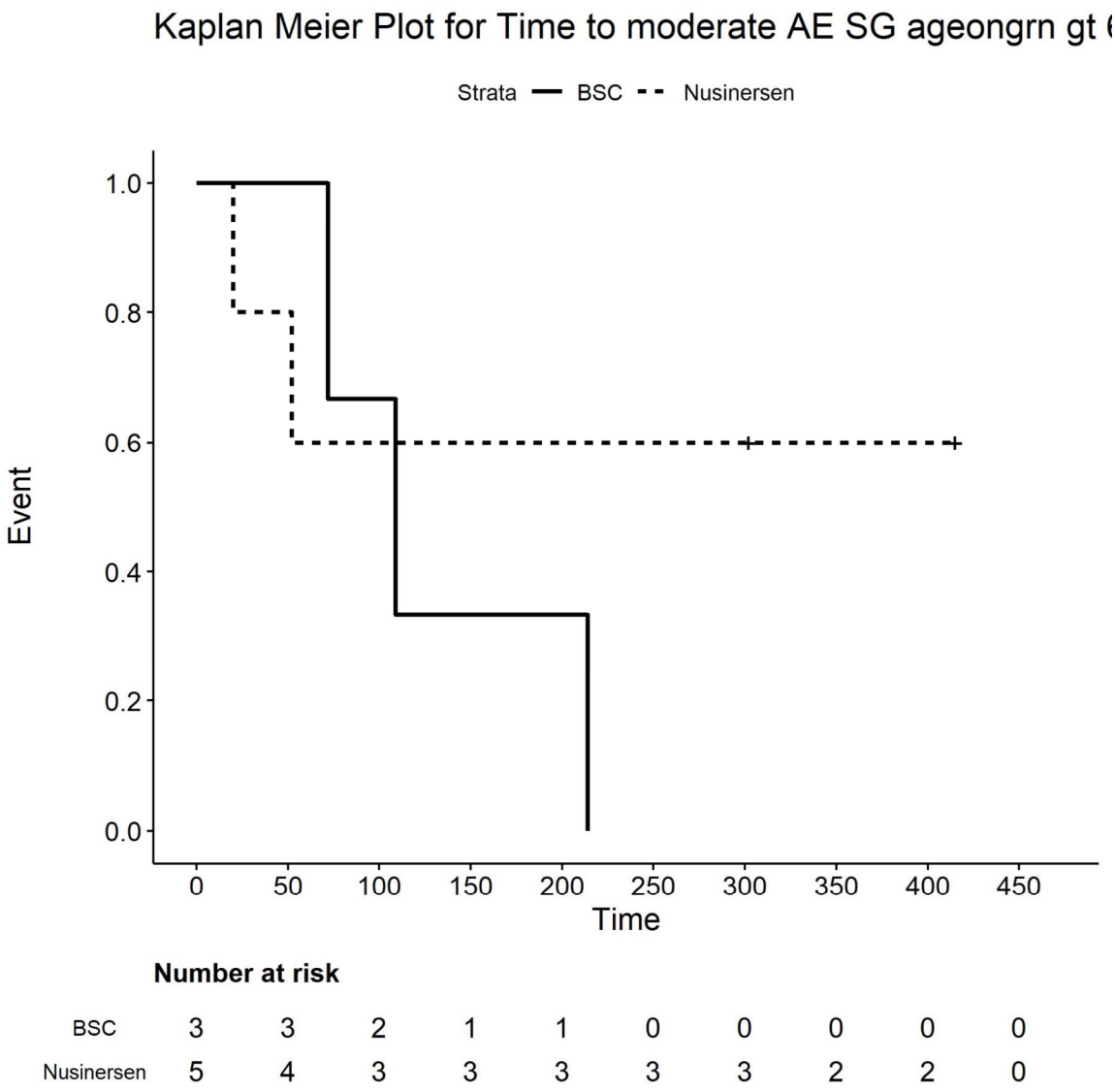
Number at risk

BSC	4	3	3	3	2	1	1	1	0	0
Nusinersen	6	4	3	3	1	1	1	1	1	0



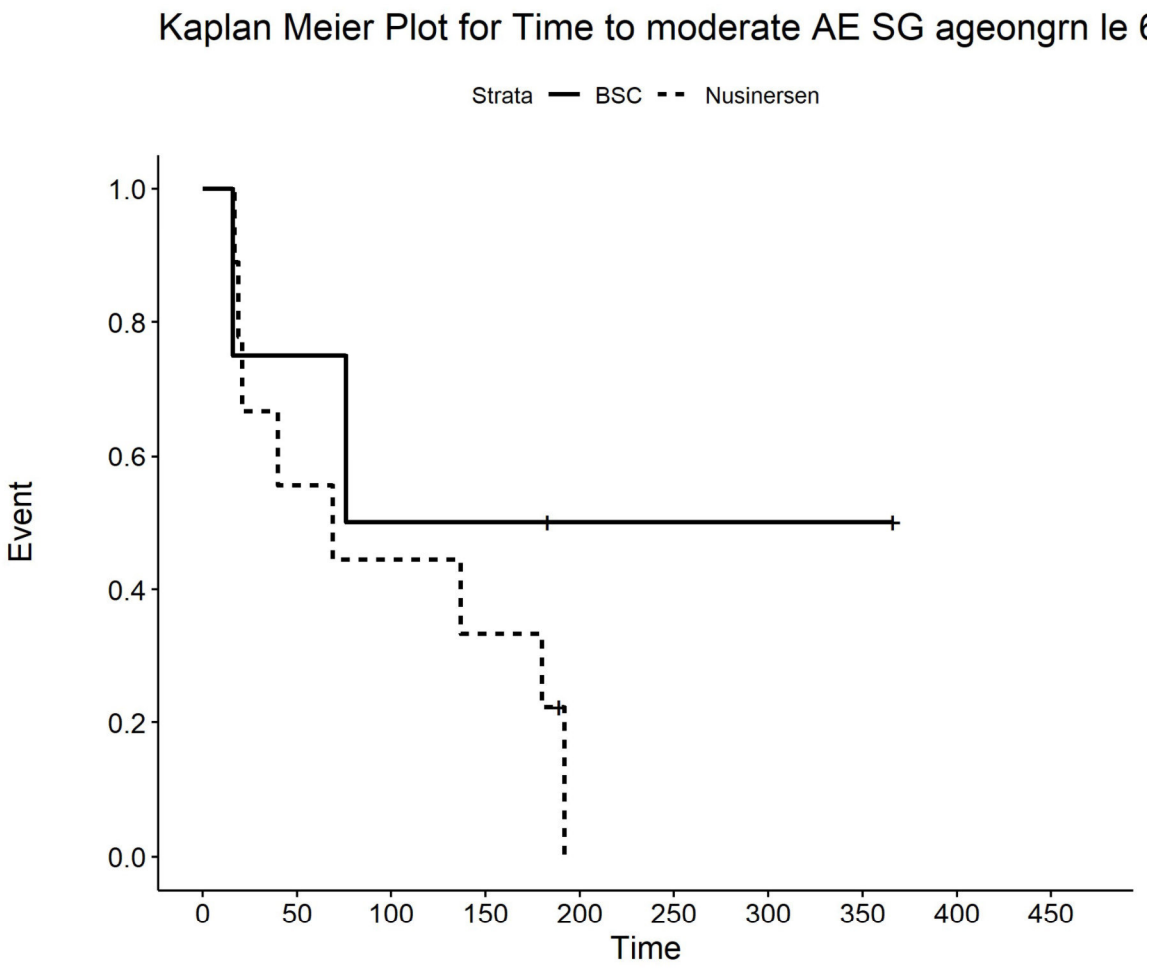
Number at risk

BSC	3	3	1	0	0	0	0	0	0	0
Nusinersen	8	5	4	3	2	2	2	1	1	0



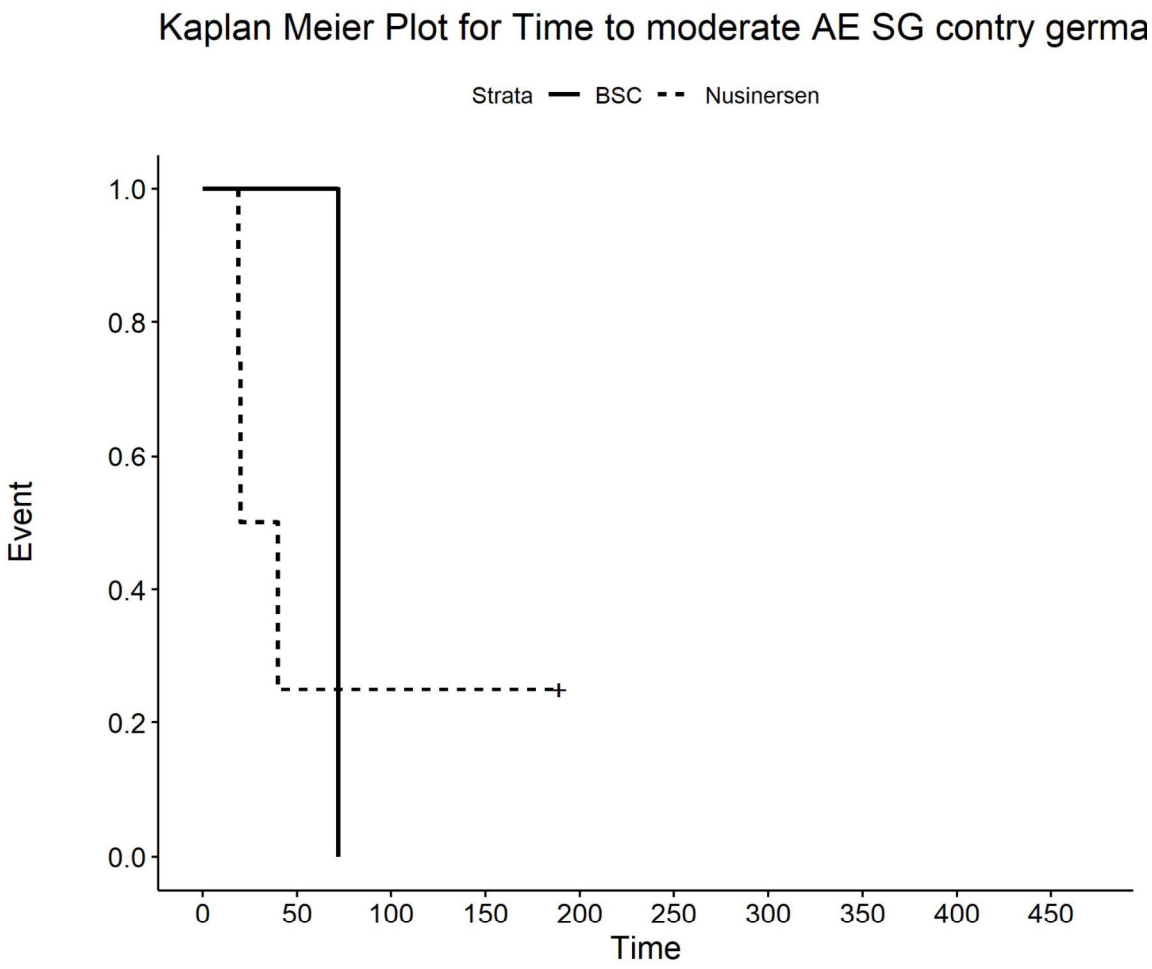
Number at risk

BSC	3	3	2	1	1	0	0	0	0	0
Nusinersen	5	4	3	3	3	3	3	2	2	0



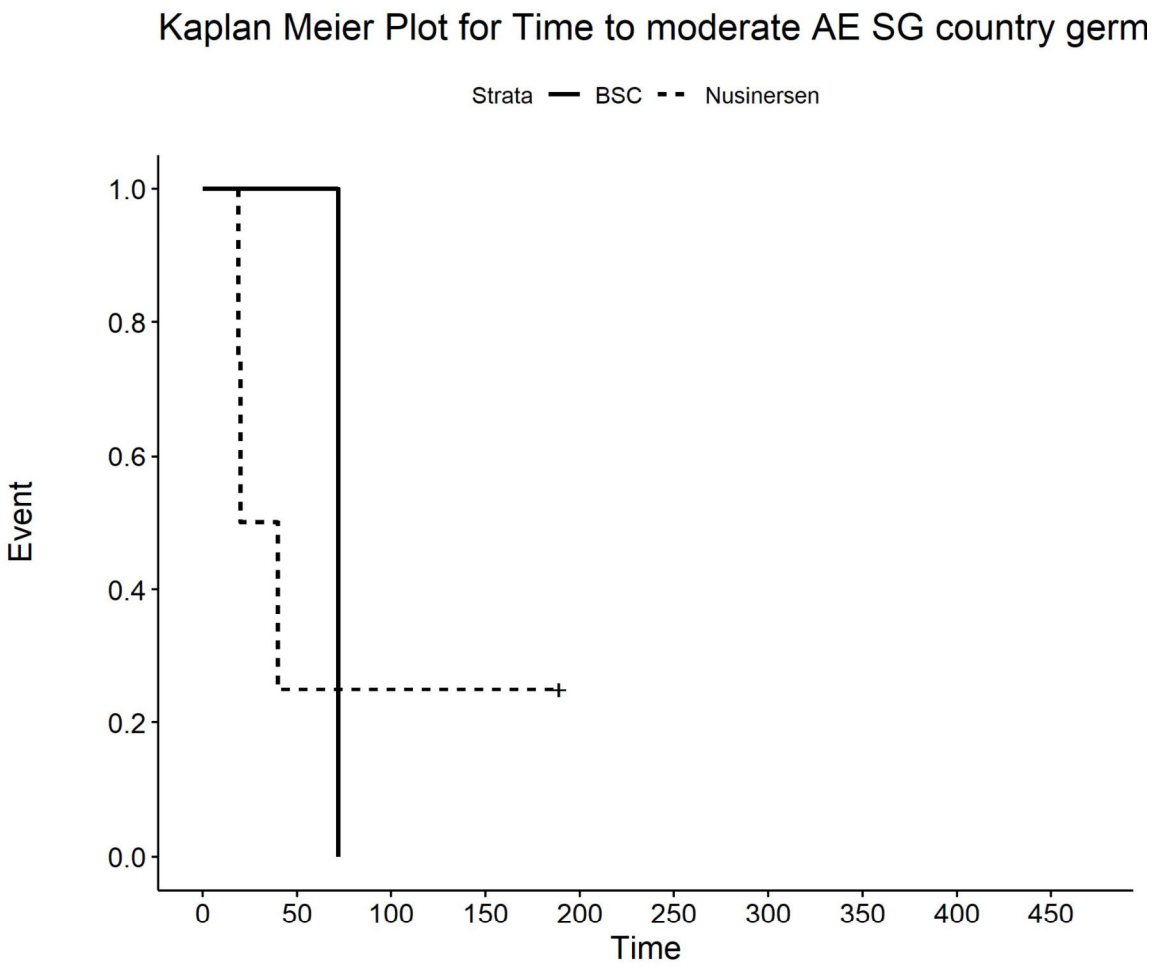
Number at risk

BSC	4	3	2	2	1	1	1	1	0	0
Nusinersen	9	5	4	3	0	0	0	0	0	0



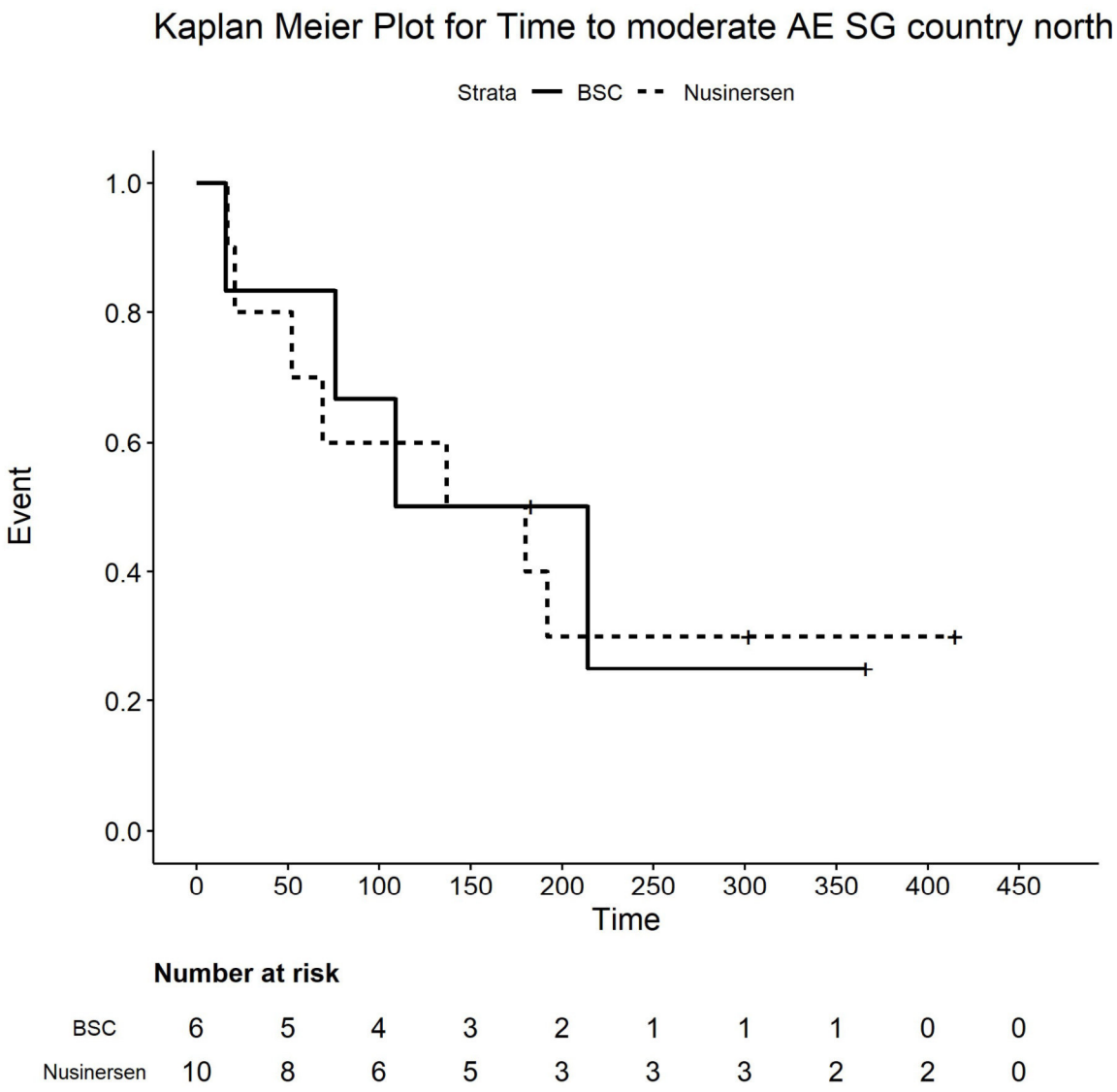
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	1	1	1	0	0	0	0	0	0



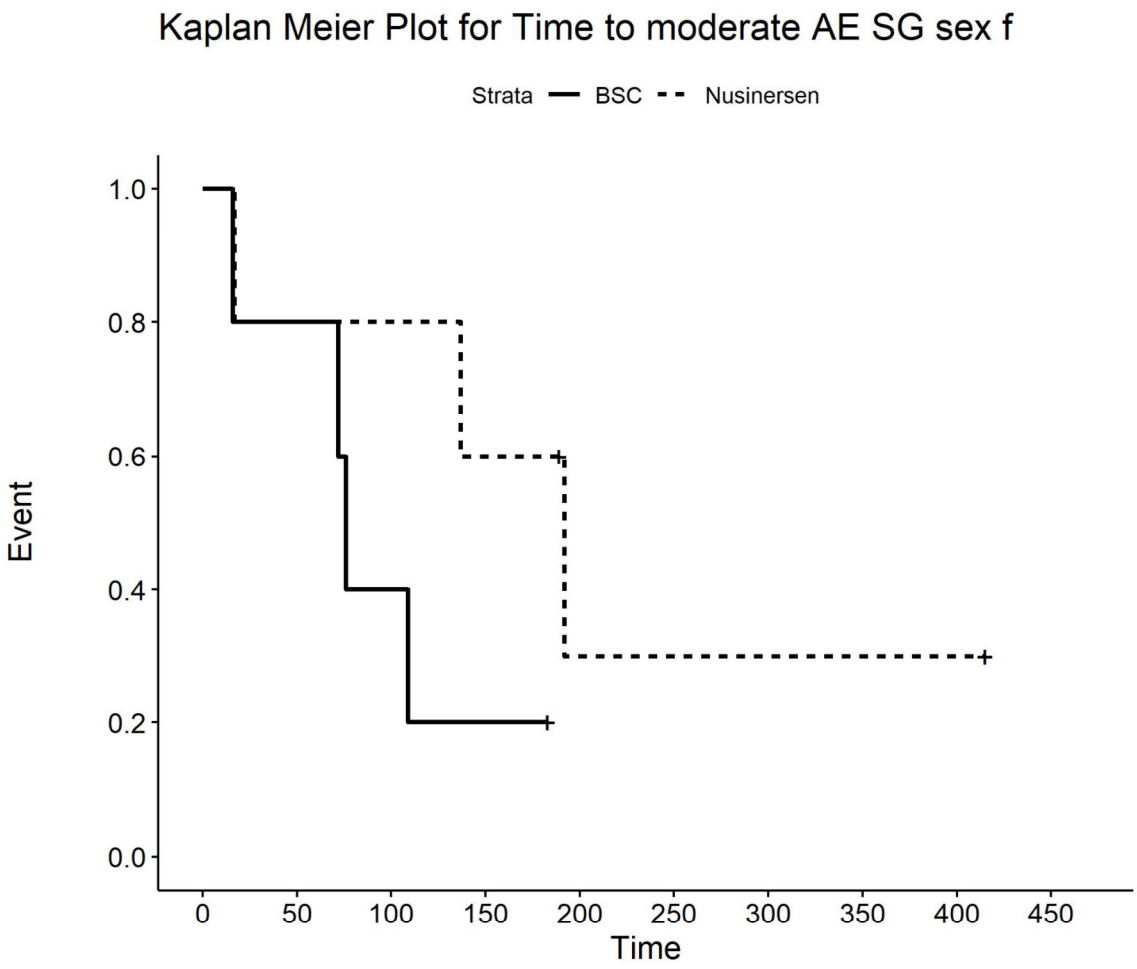
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	1	1	1	0	0	0	0	0	0



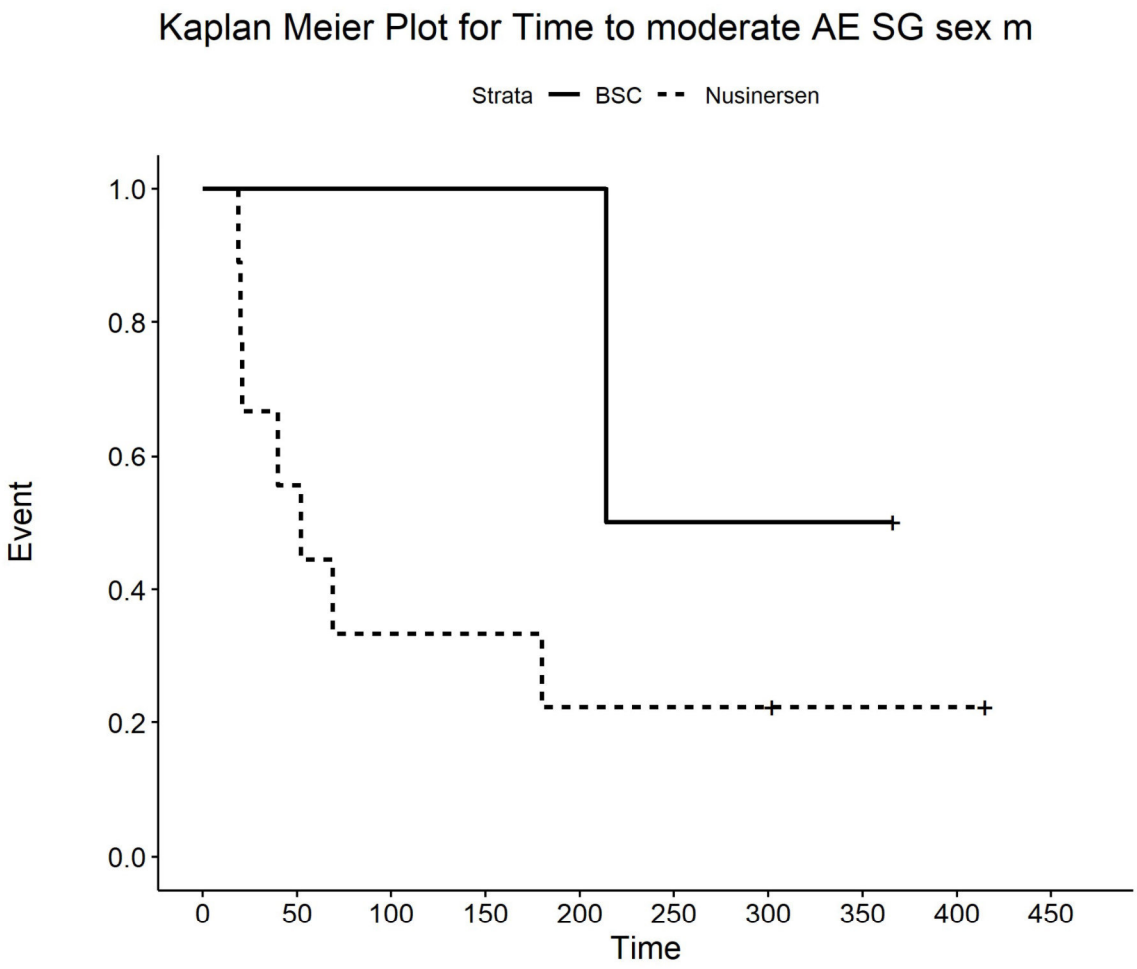
Number at risk

BSC	6	5	4	3	2	1	1	1	0	0
Nusinersen	10	8	6	5	3	3	3	2	2	0



Number at risk

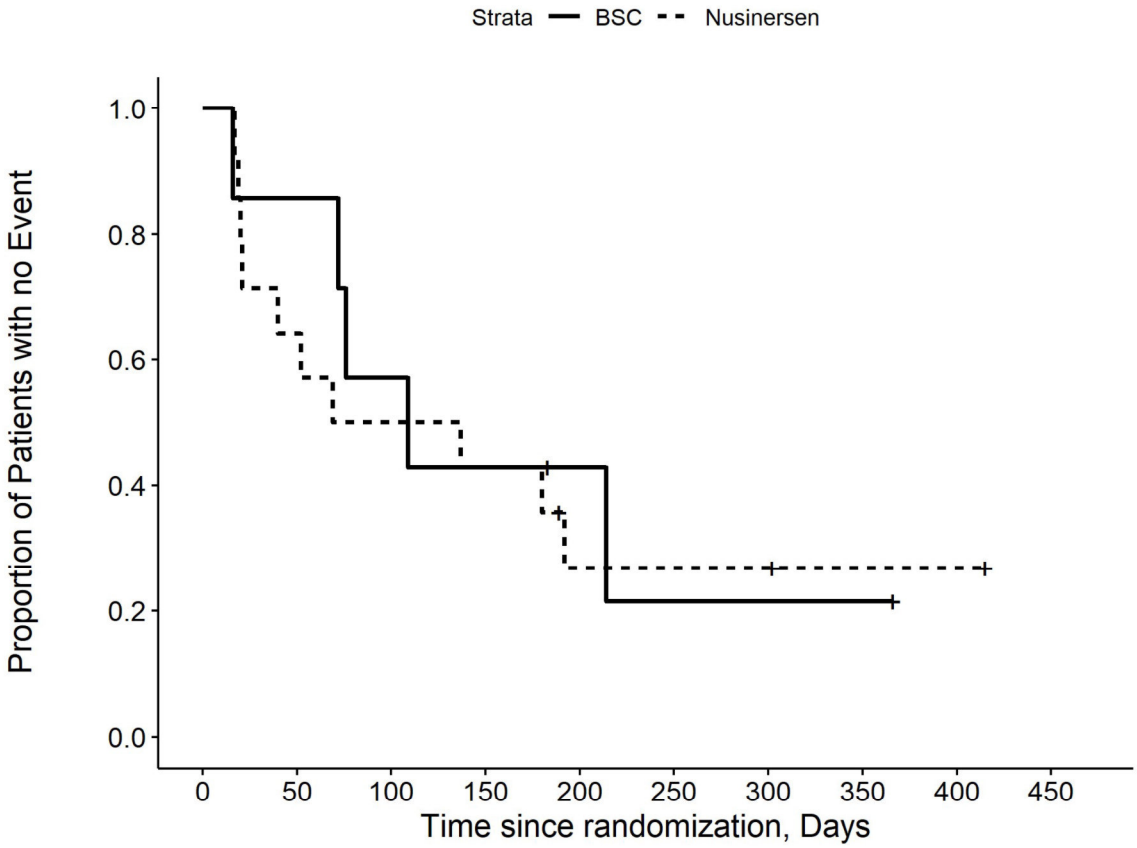
BSC	5	4	2	1	0	0	0	0	0	0
Nusinersen	5	4	4	3	1	1	1	1	1	0



Number at risk

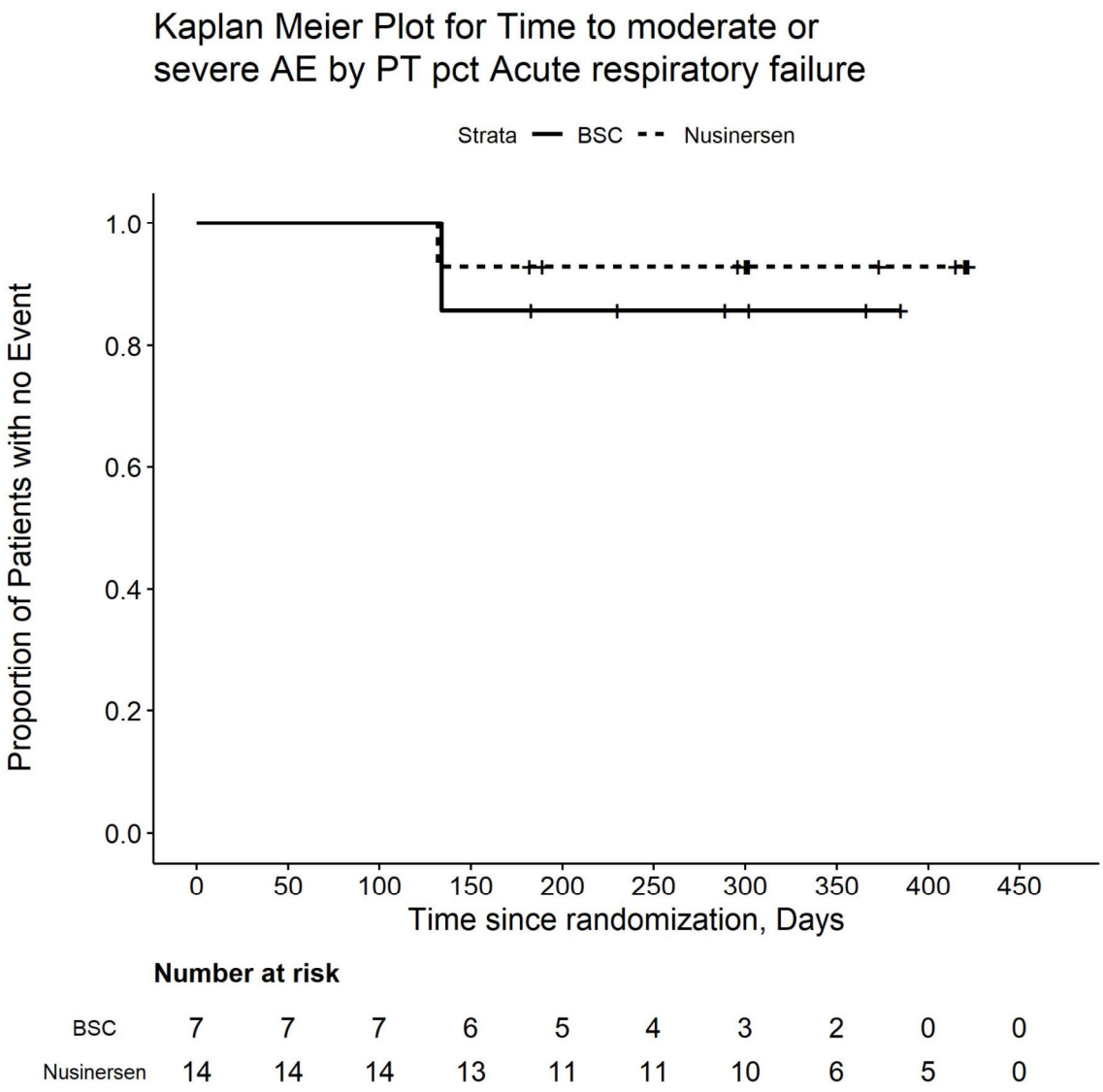
BSC	2	2	2	2	2	1	1	1	0	0
Nusinersen	9	5	3	3	2	2	2	1	1	0

Kaplan Meier Plot for Time to moderate or severe AE



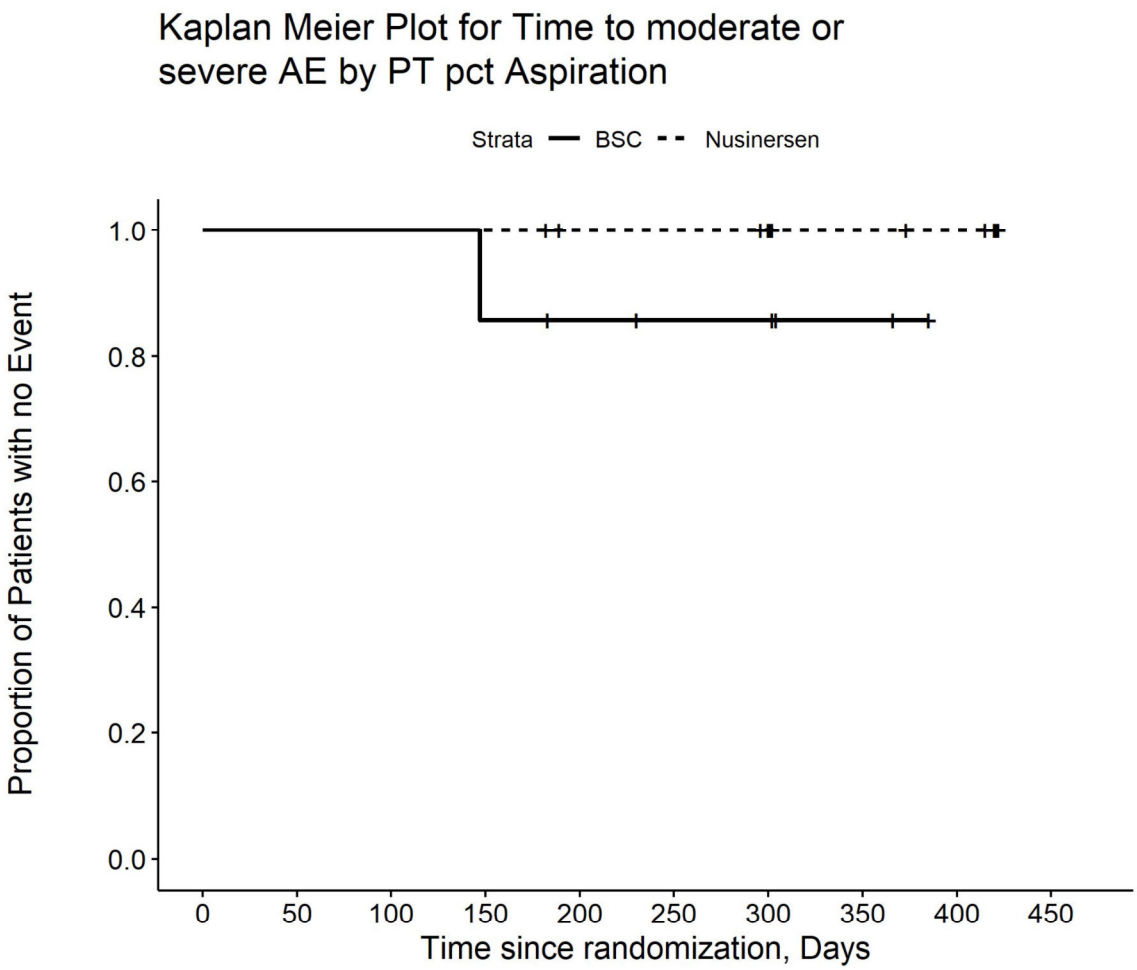
Number at risk

BSC	7	6	4	3	2	1	1	1	0	0
Nusinersen	14	9	7	6	3	3	3	2	2	0



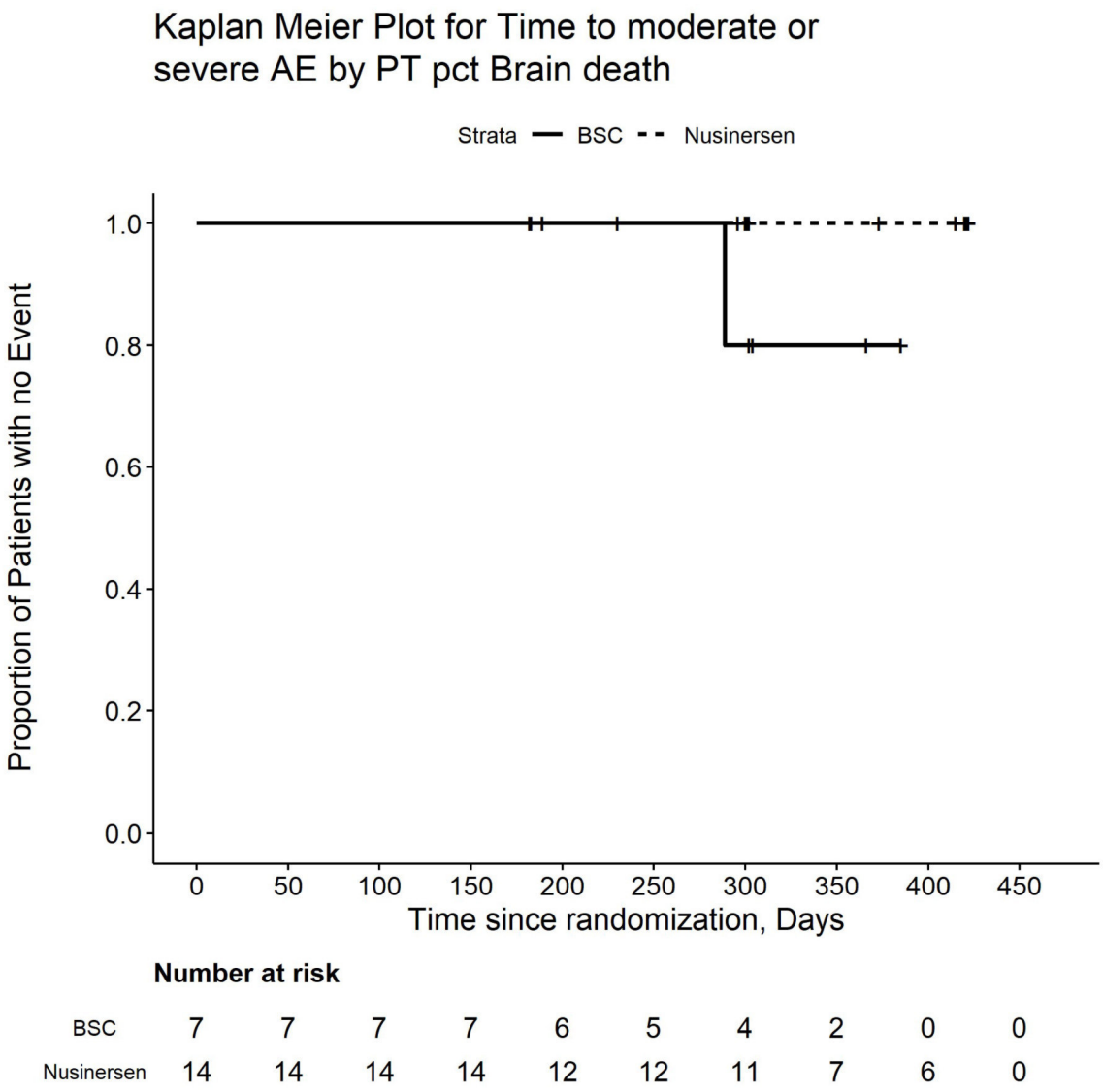
Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	13	11	11	10	6	5	0



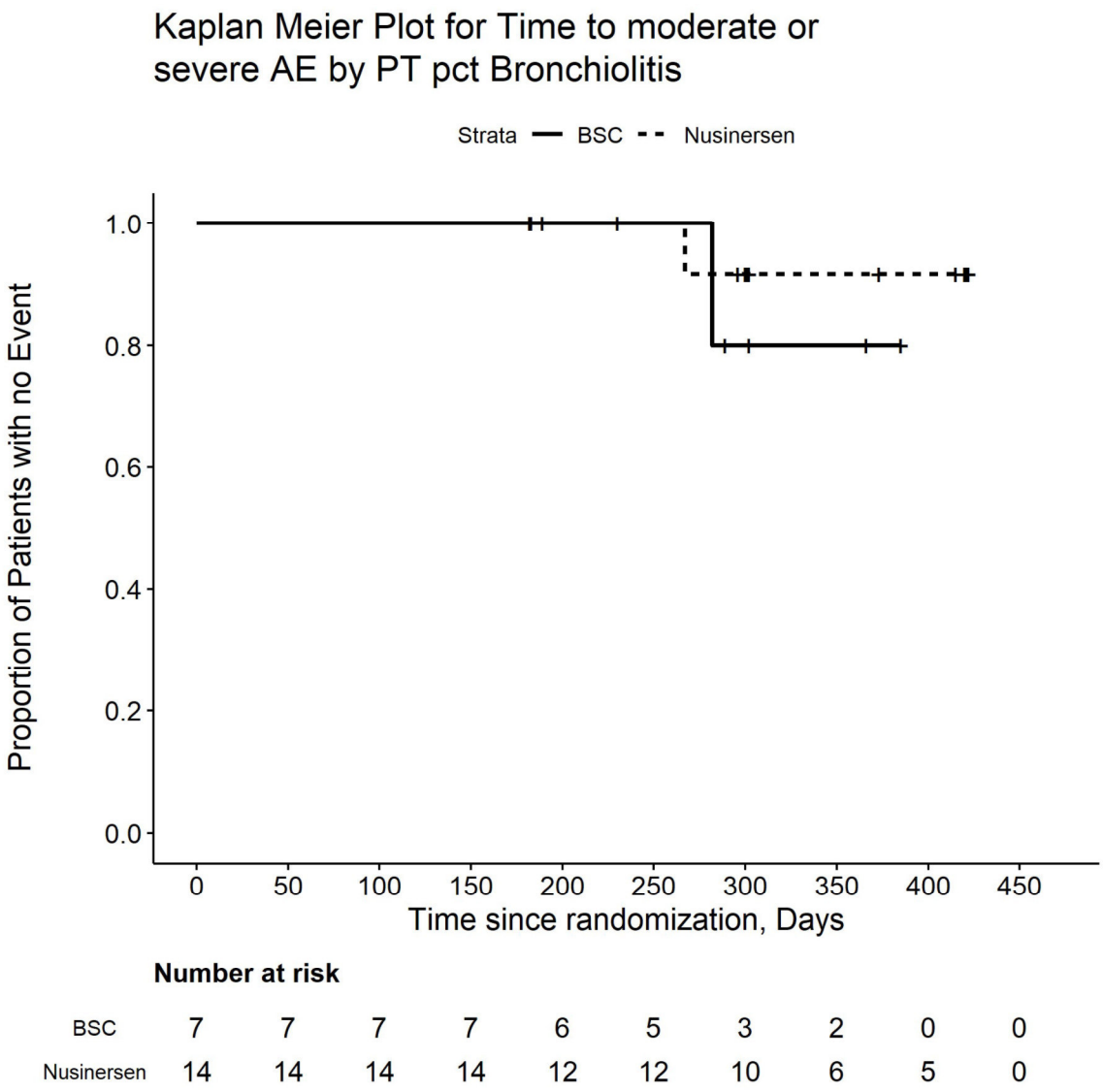
Number at risk

BSC	7	7	7	6	5	4	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



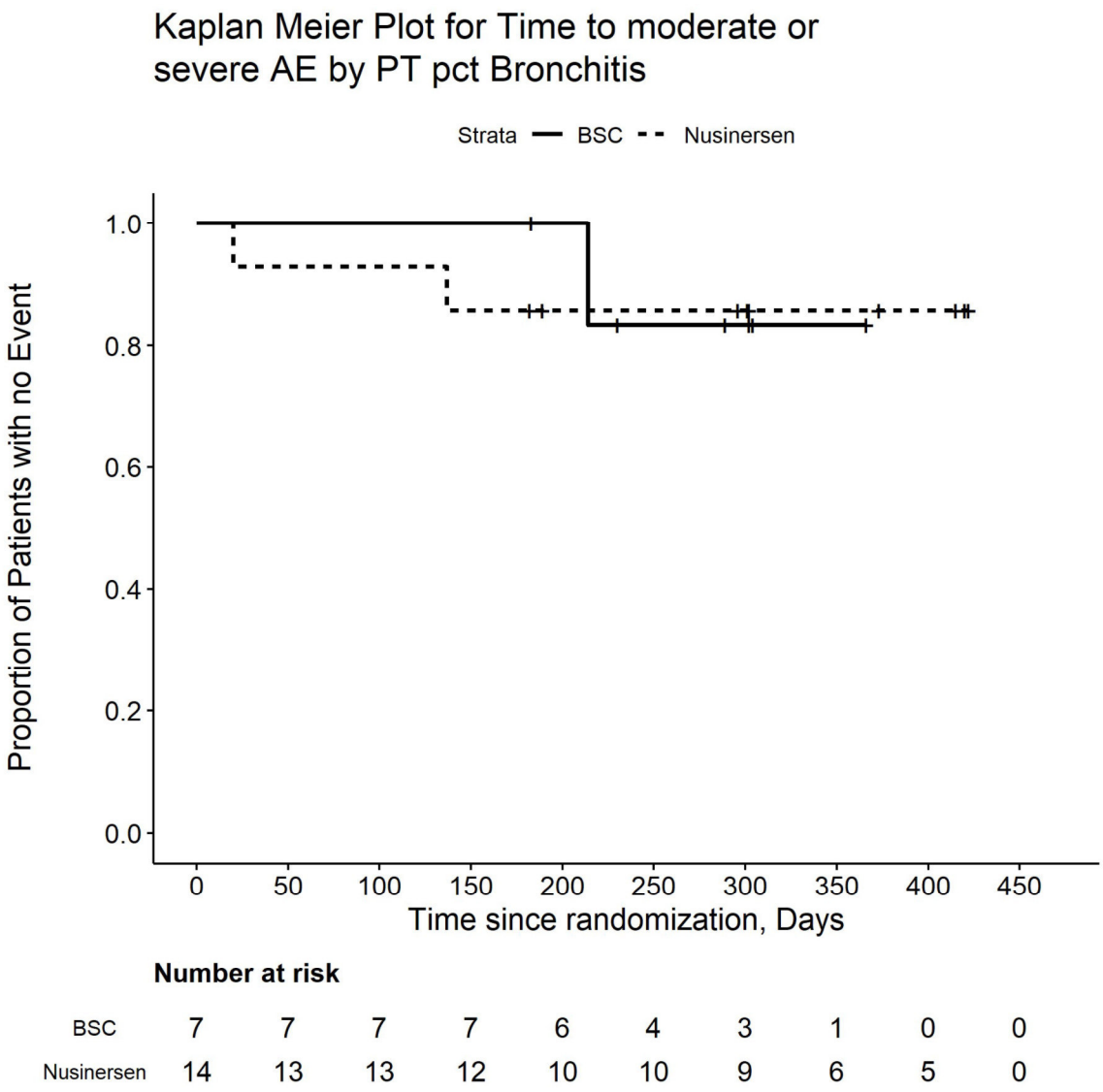
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

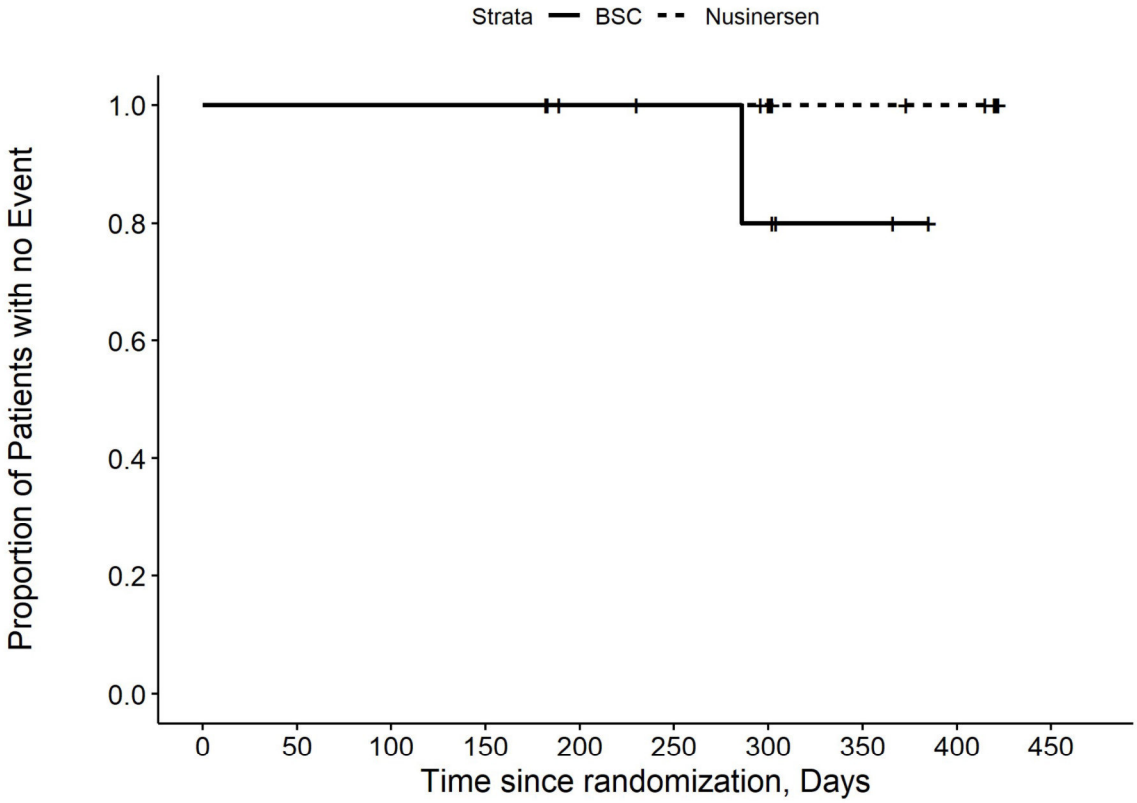
BSC	7	7	7	7	6	5	3	2	0	0
Nusinersen	14	14	14	14	12	12	10	6	5	0



Number at risk

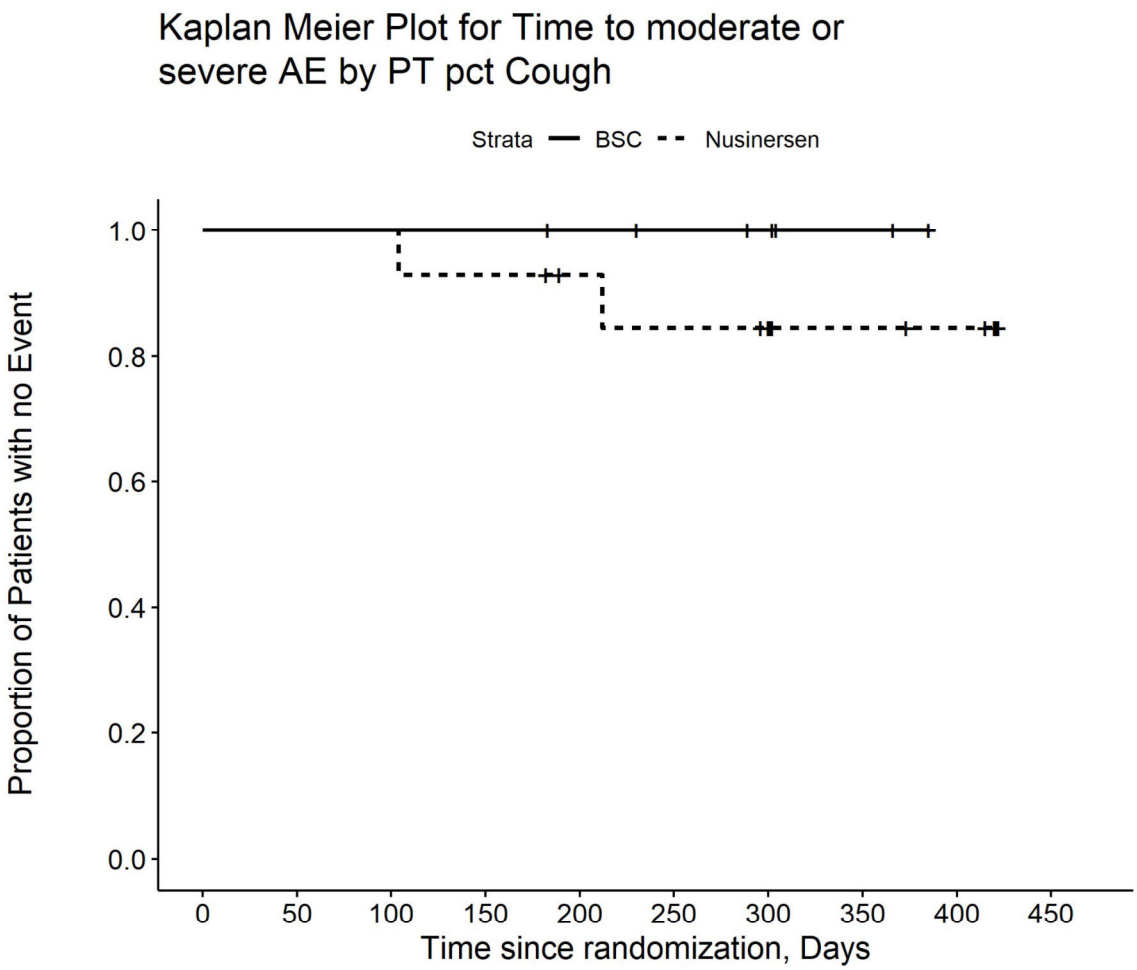
BSC	7	7	7	7	6	4	3	1	0	0
Nusinersen	14	13	13	12	10	10	9	6	5	0

Kaplan Meier Plot for
Time to moderate or
severe AE by PT pct Cardio : respiratory arrest



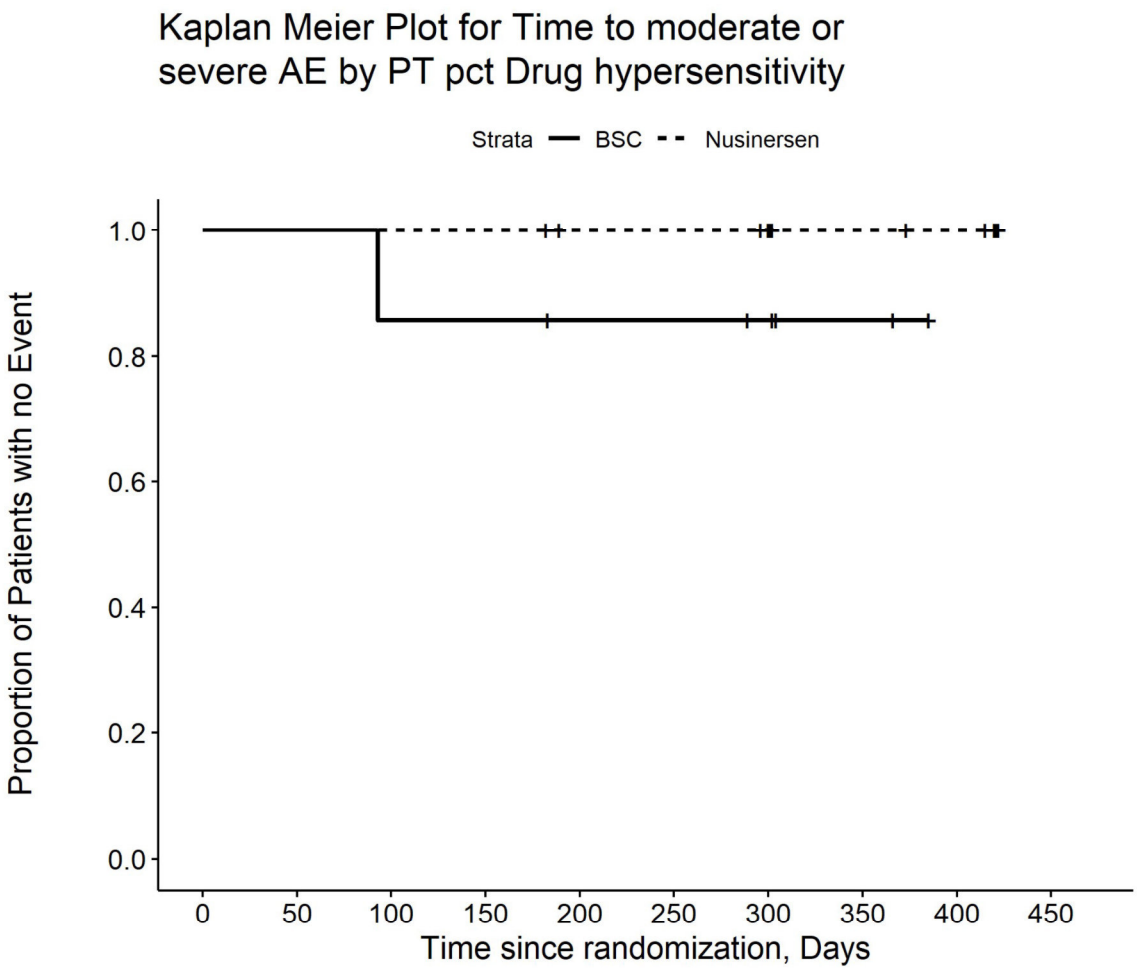
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



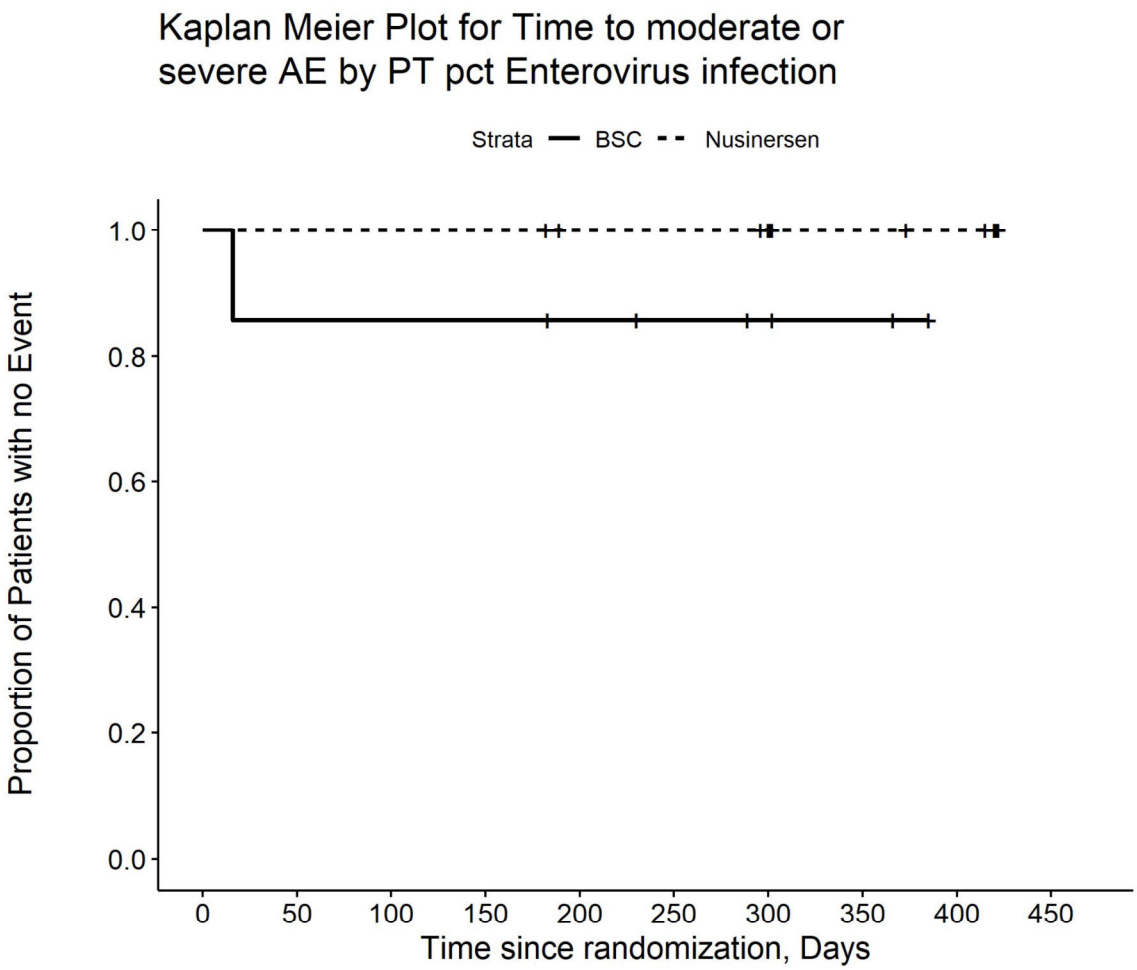
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	11	10	9	6	5	0



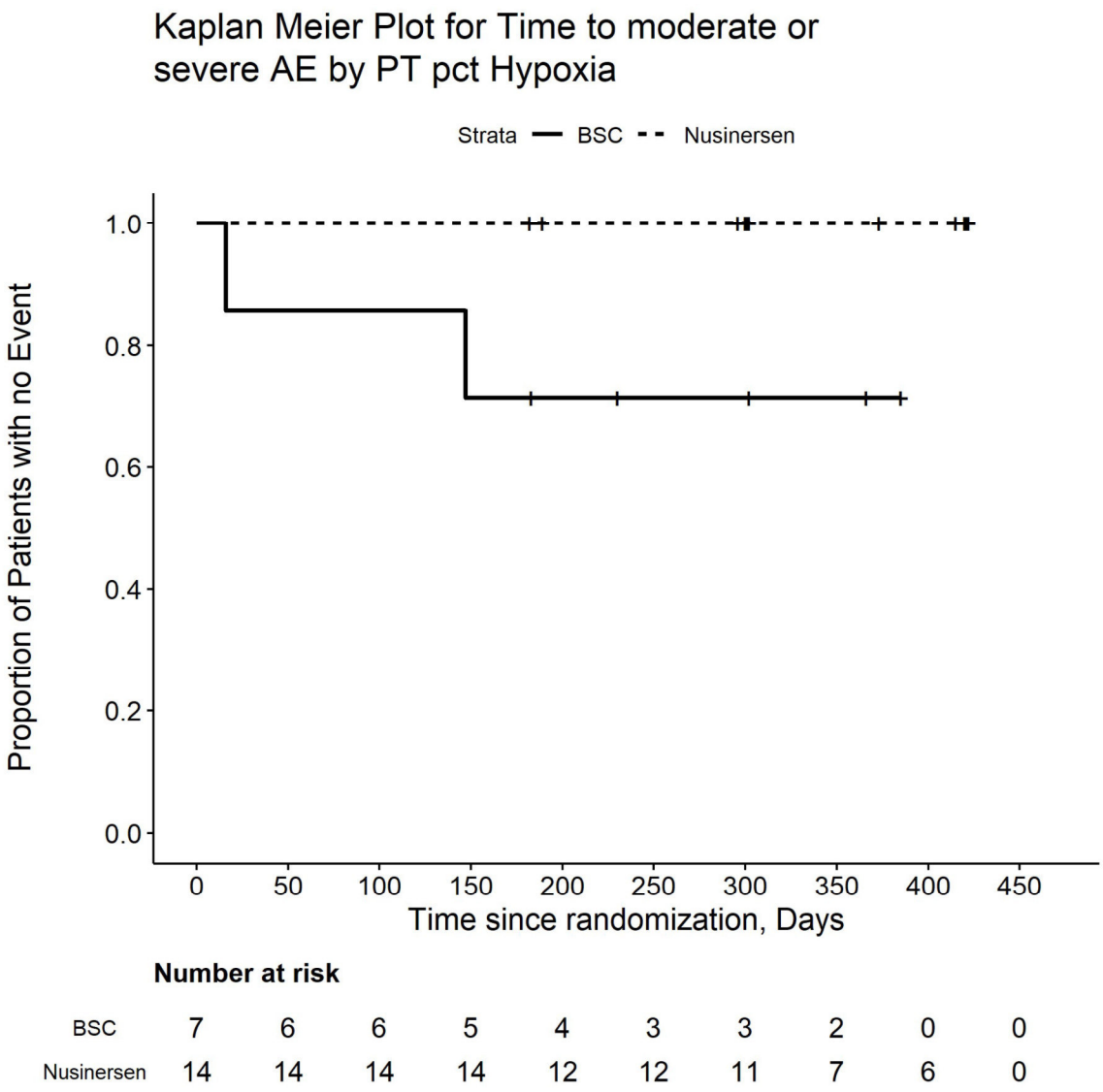
Number at risk

BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

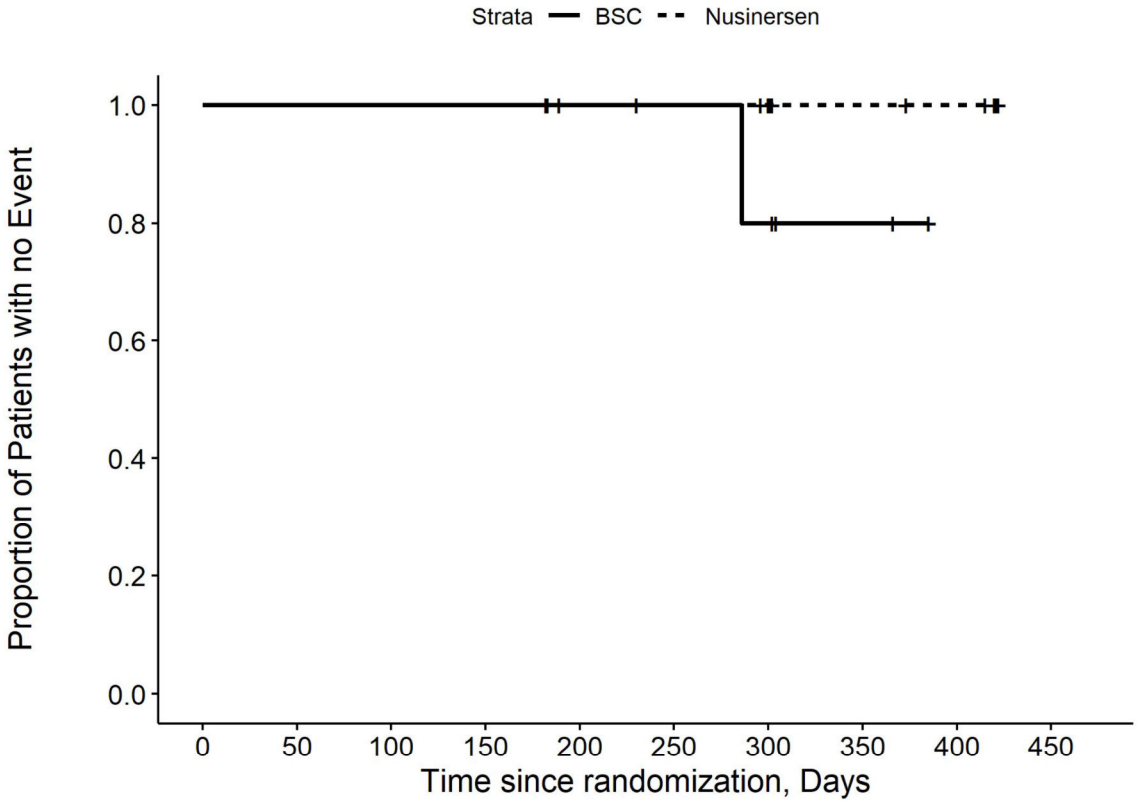
BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

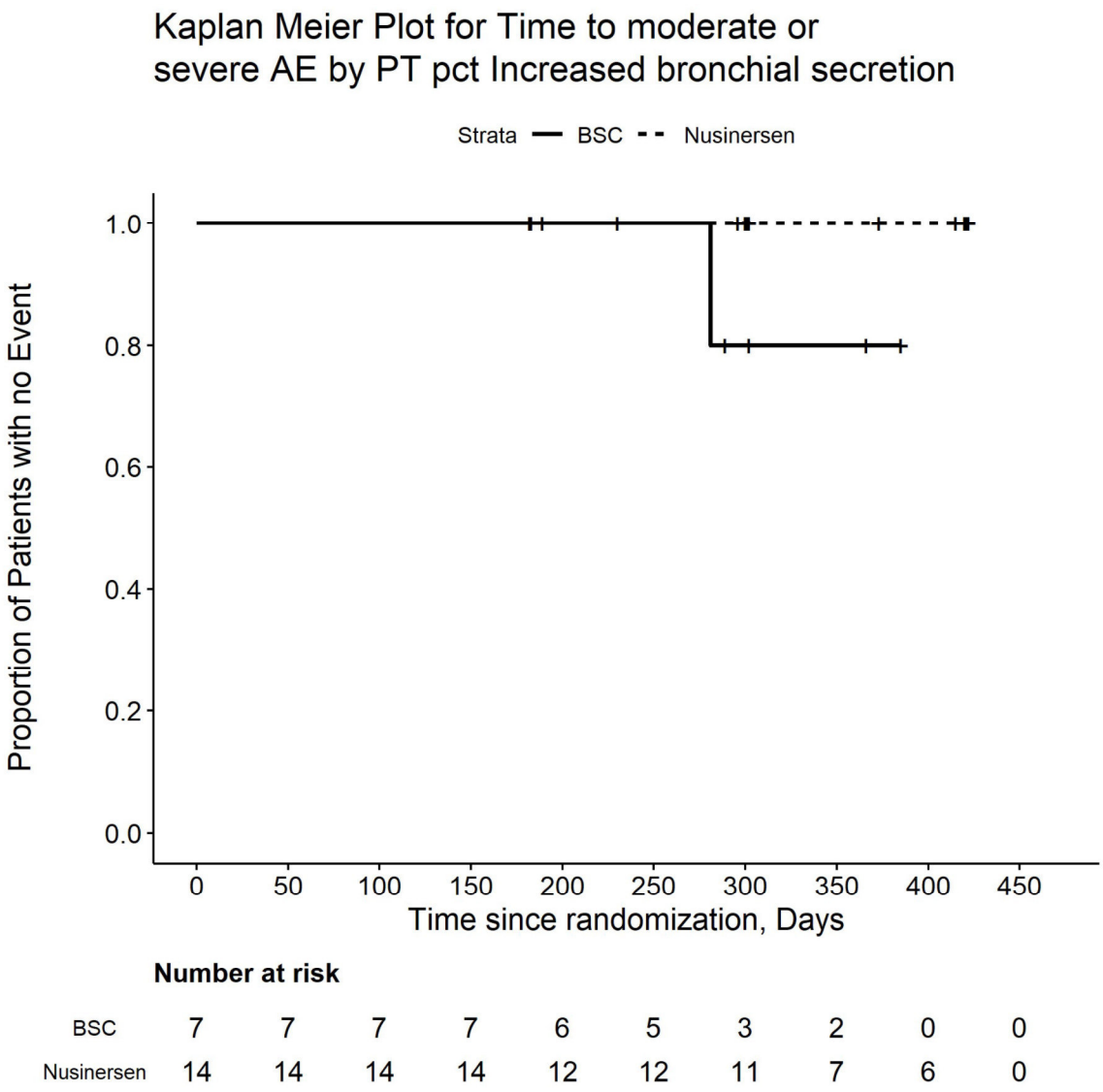
BSC	7	6	6	5	4	3	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for
Time to moderate or
severe AE by PT pct Hypoxic : ischaemic encephalopathy



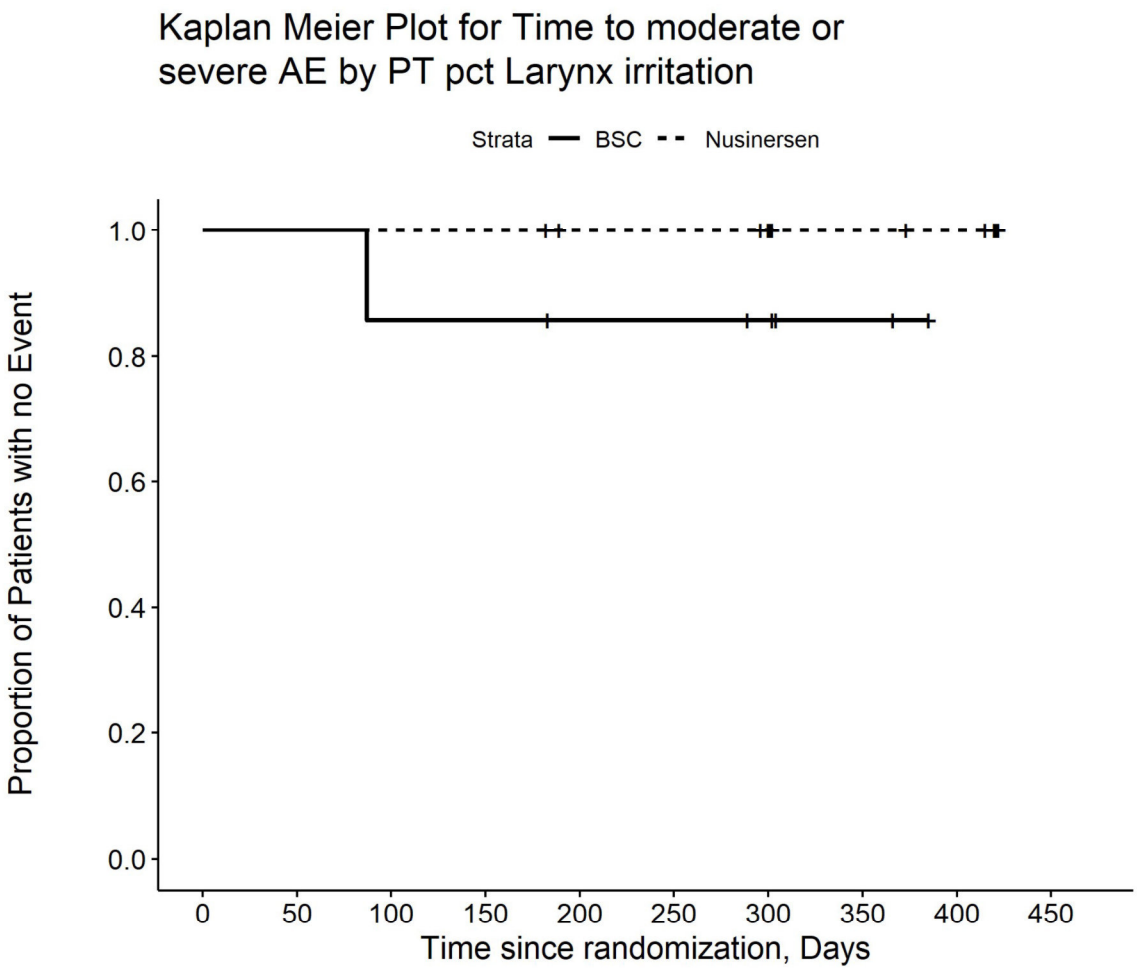
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



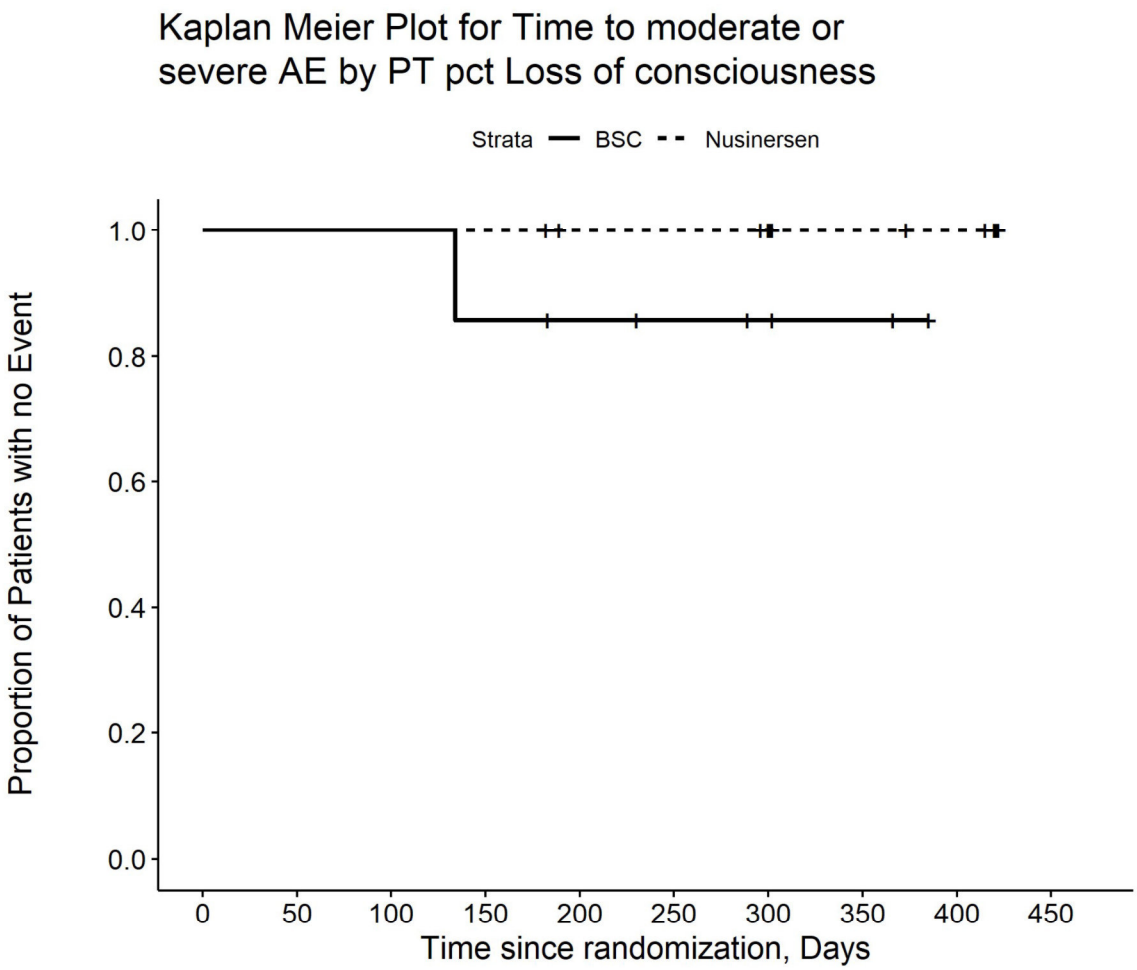
Number at risk

BSC	7	7	7	7	6	5	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



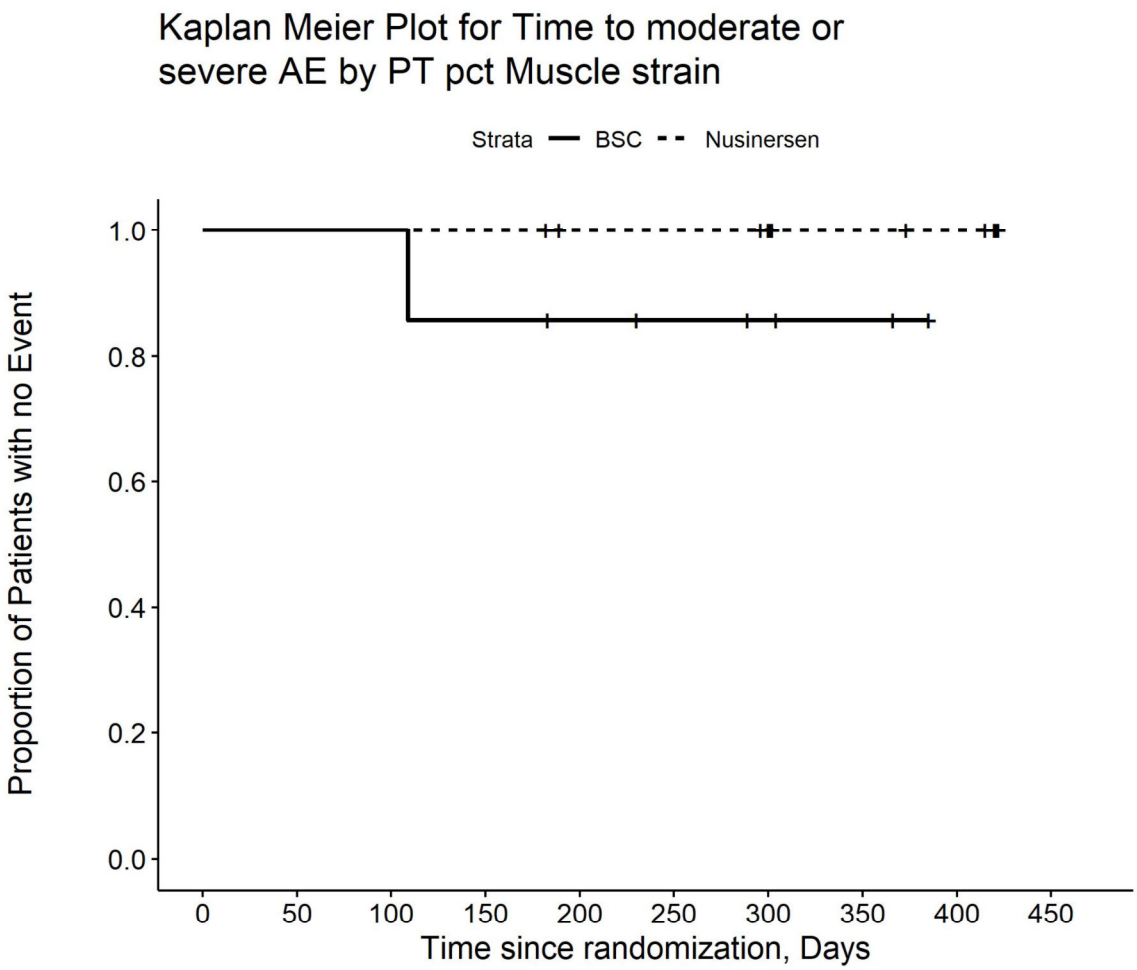
Number at risk

BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



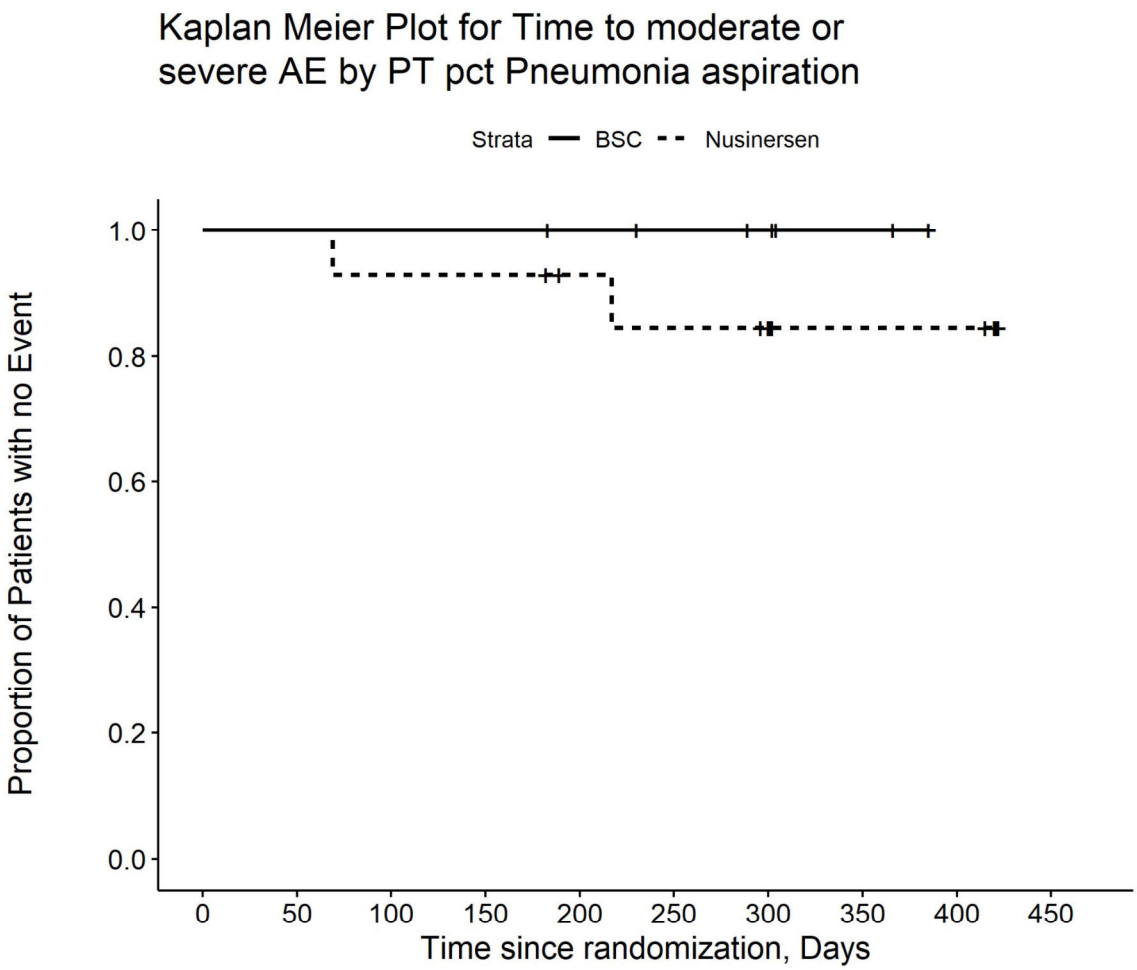
Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



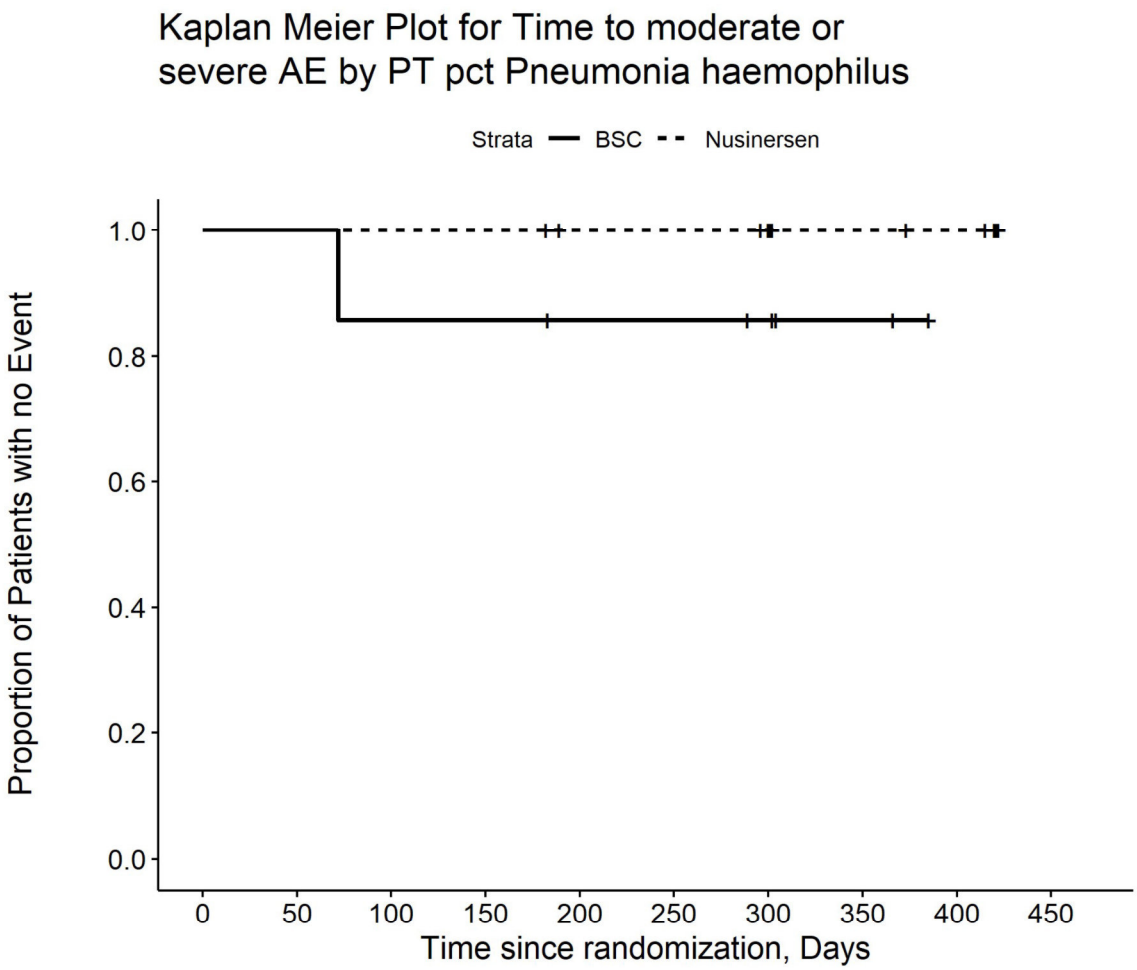
Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



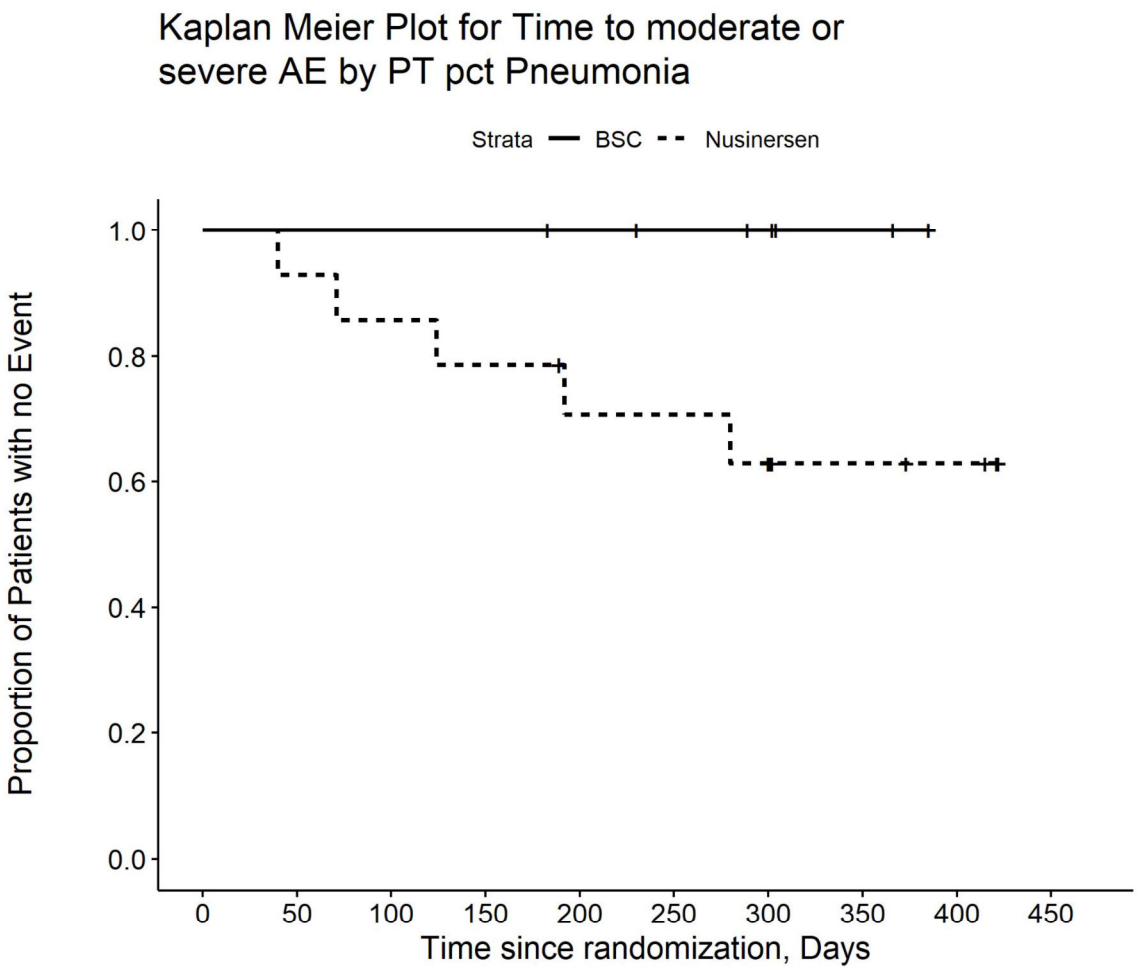
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	13	13	11	10	9	5	5	0



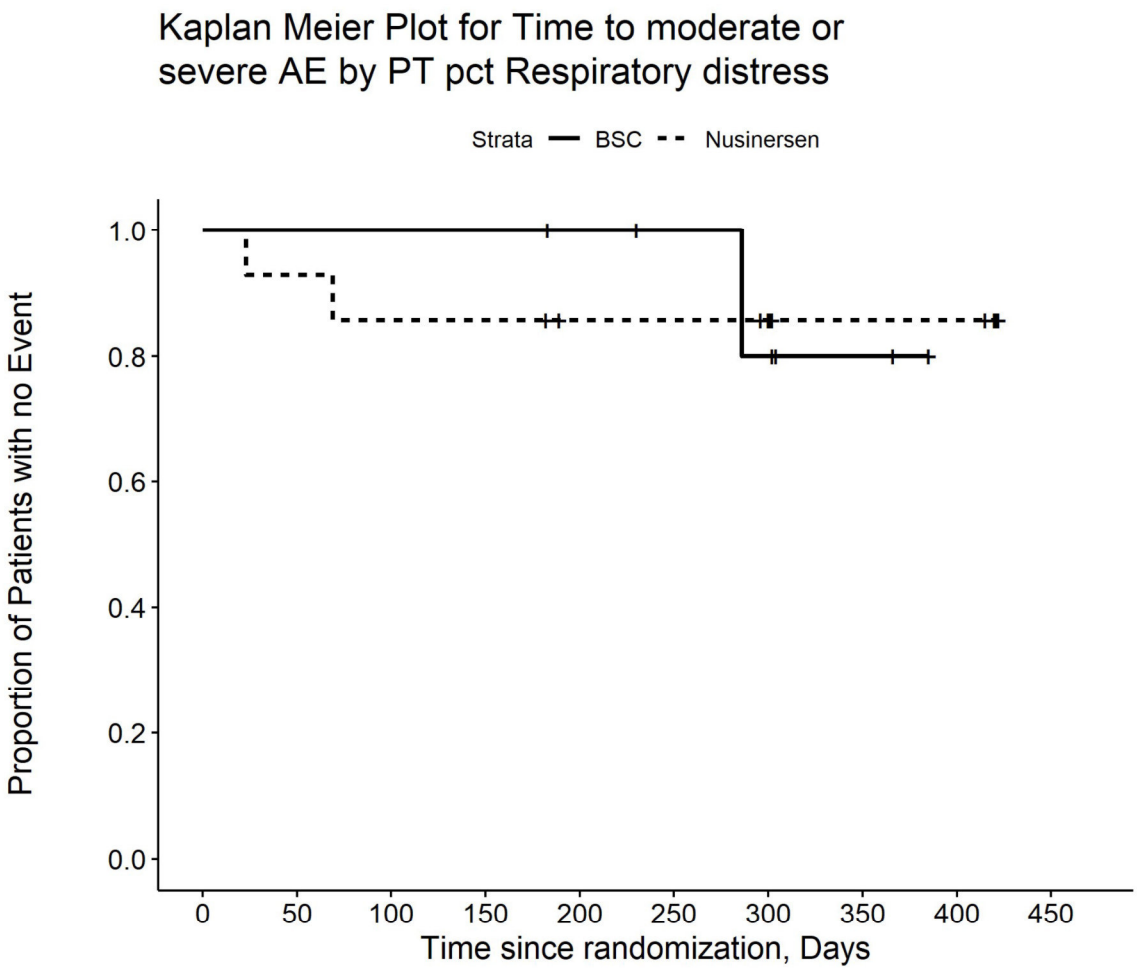
Number at risk

BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



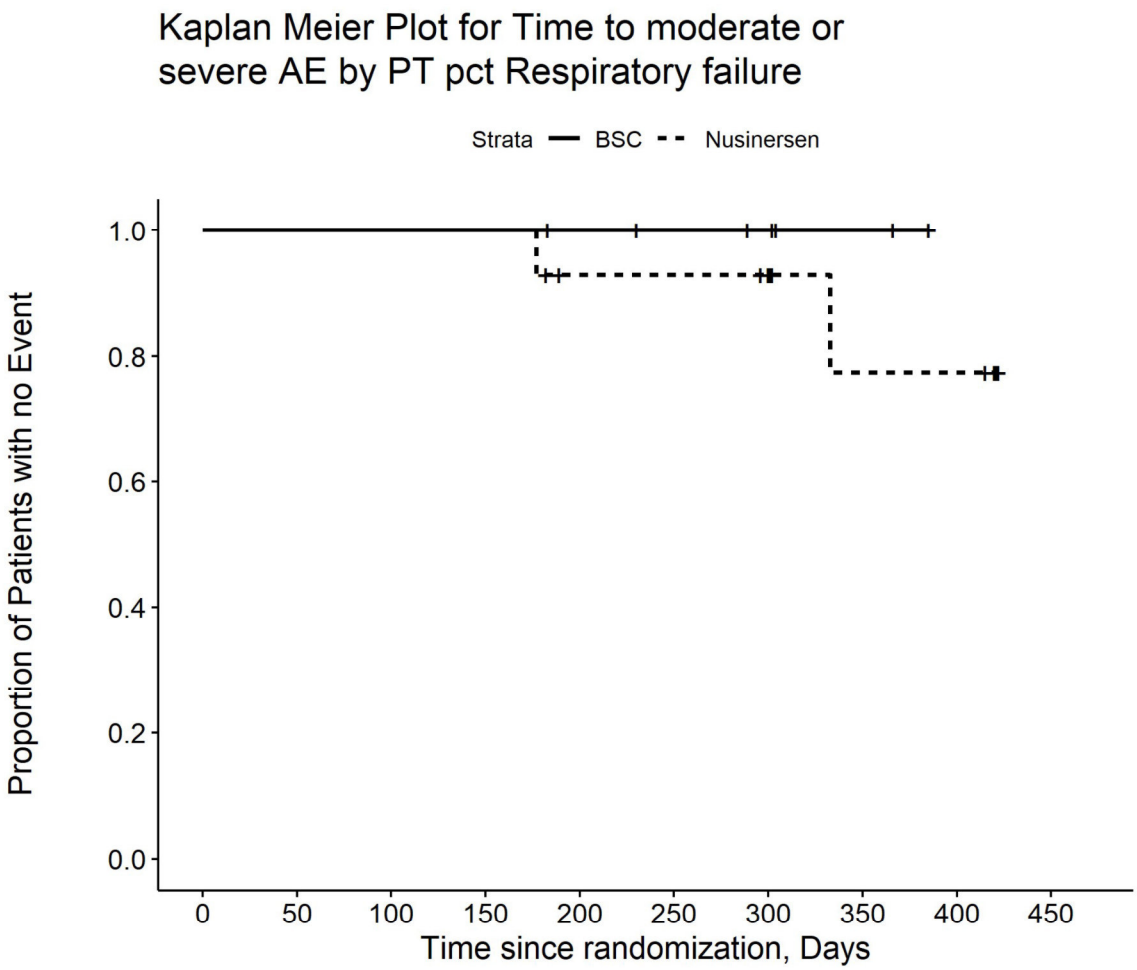
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	12	11	9	9	8	5	4	0



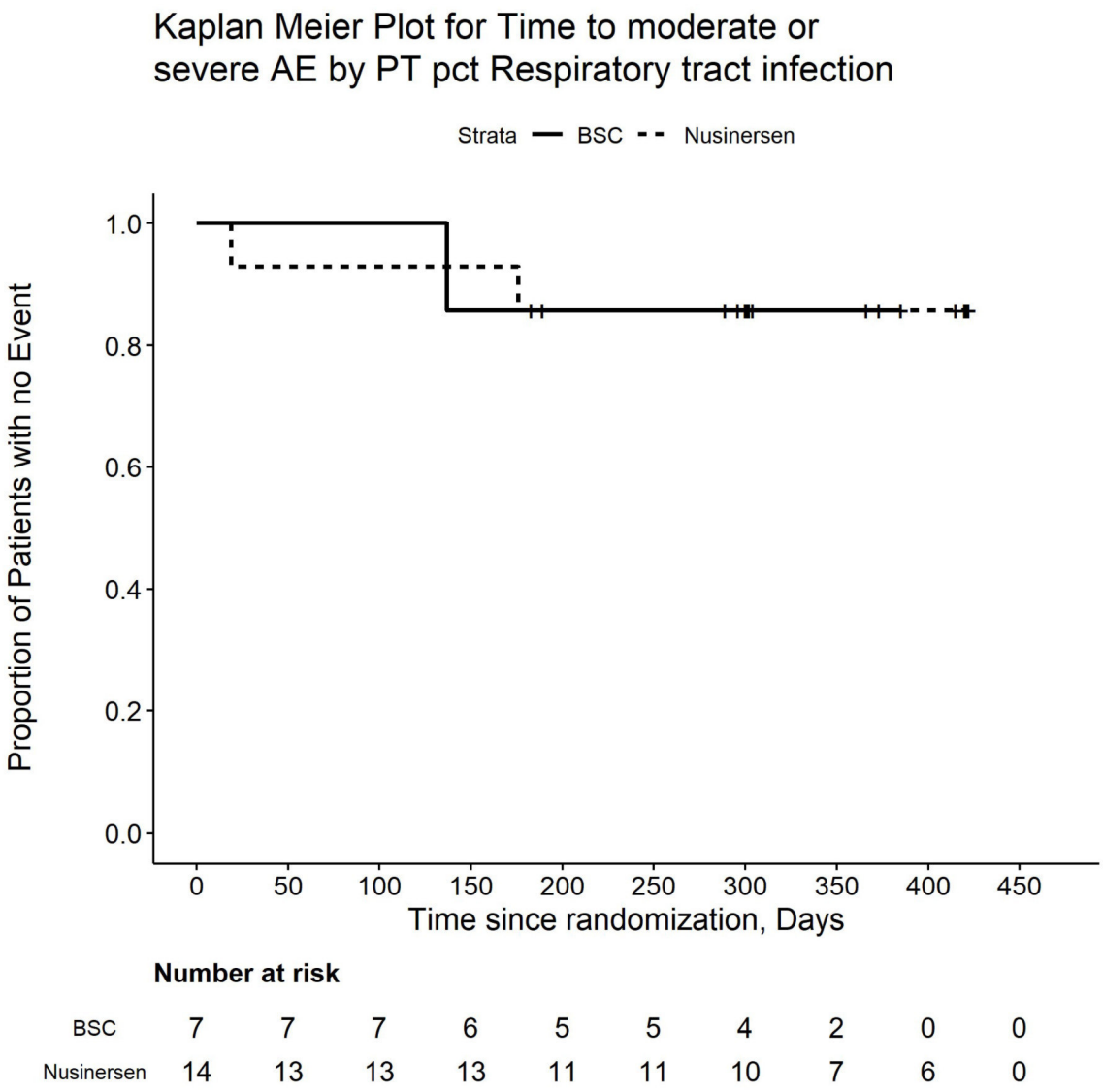
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	12	12	10	10	9	5	5	0



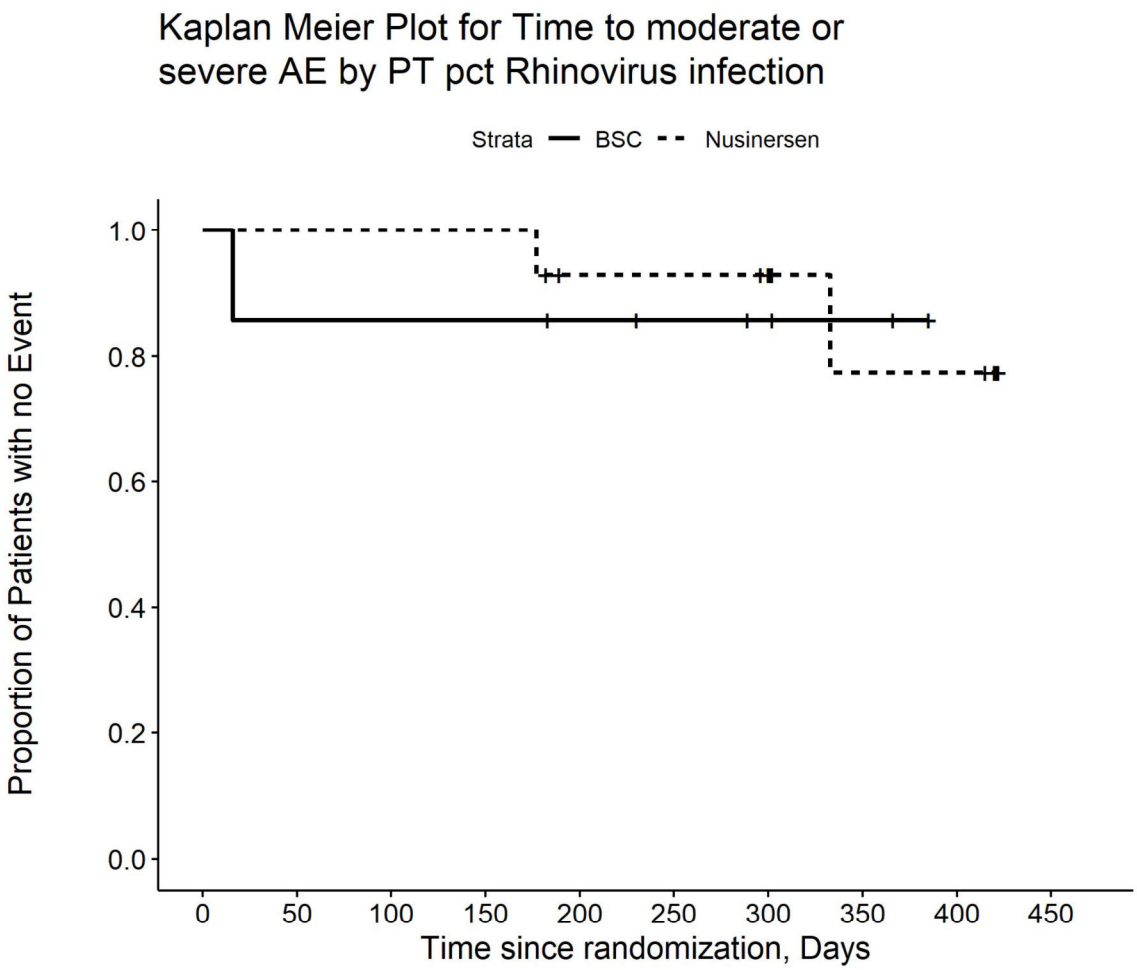
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	11	11	10	5	5	0



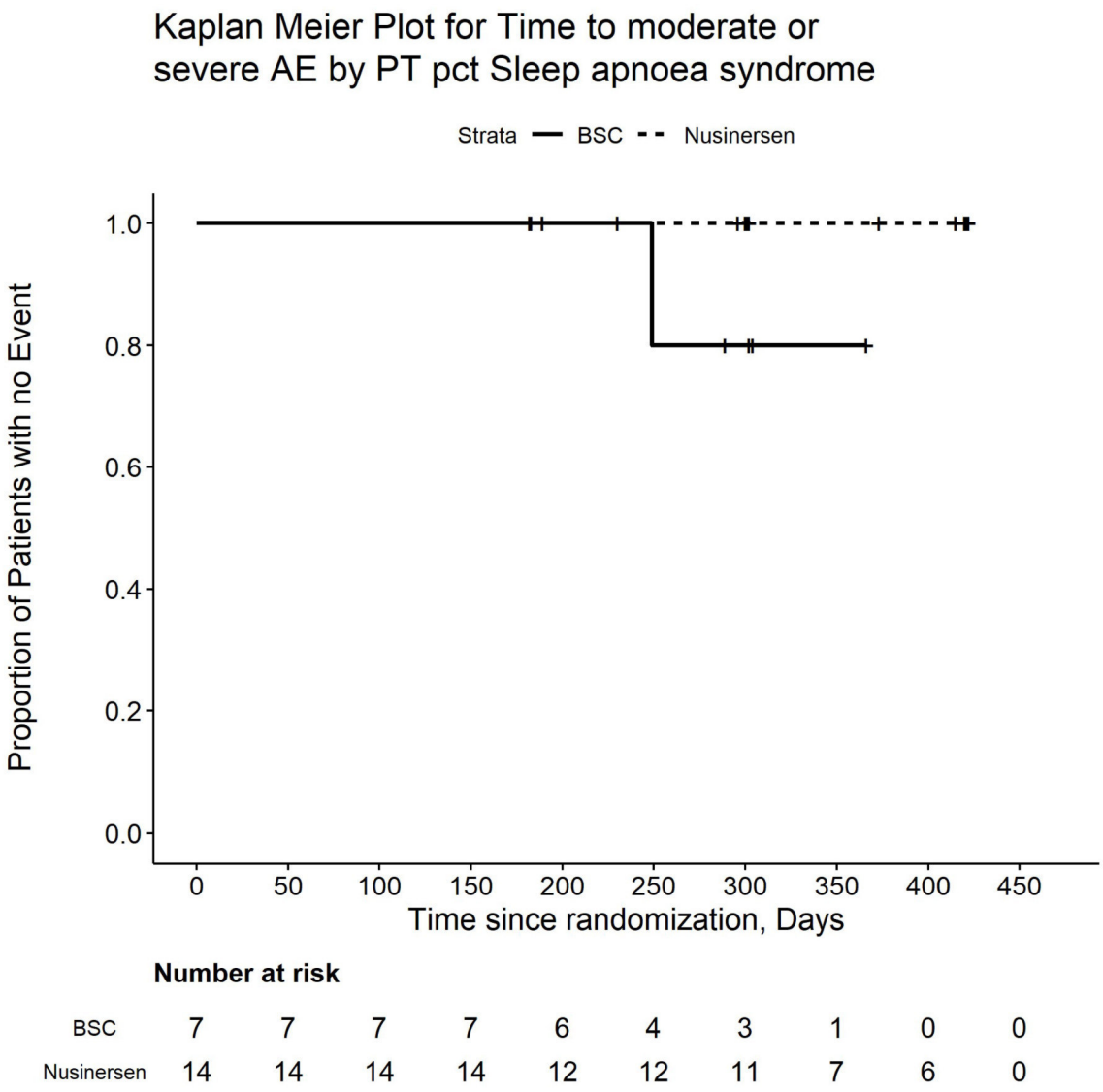
Number at risk

BSC	7	7	7	6	5	5	4	2	0	0
Nusinersen	14	13	13	13	11	11	10	7	6	0



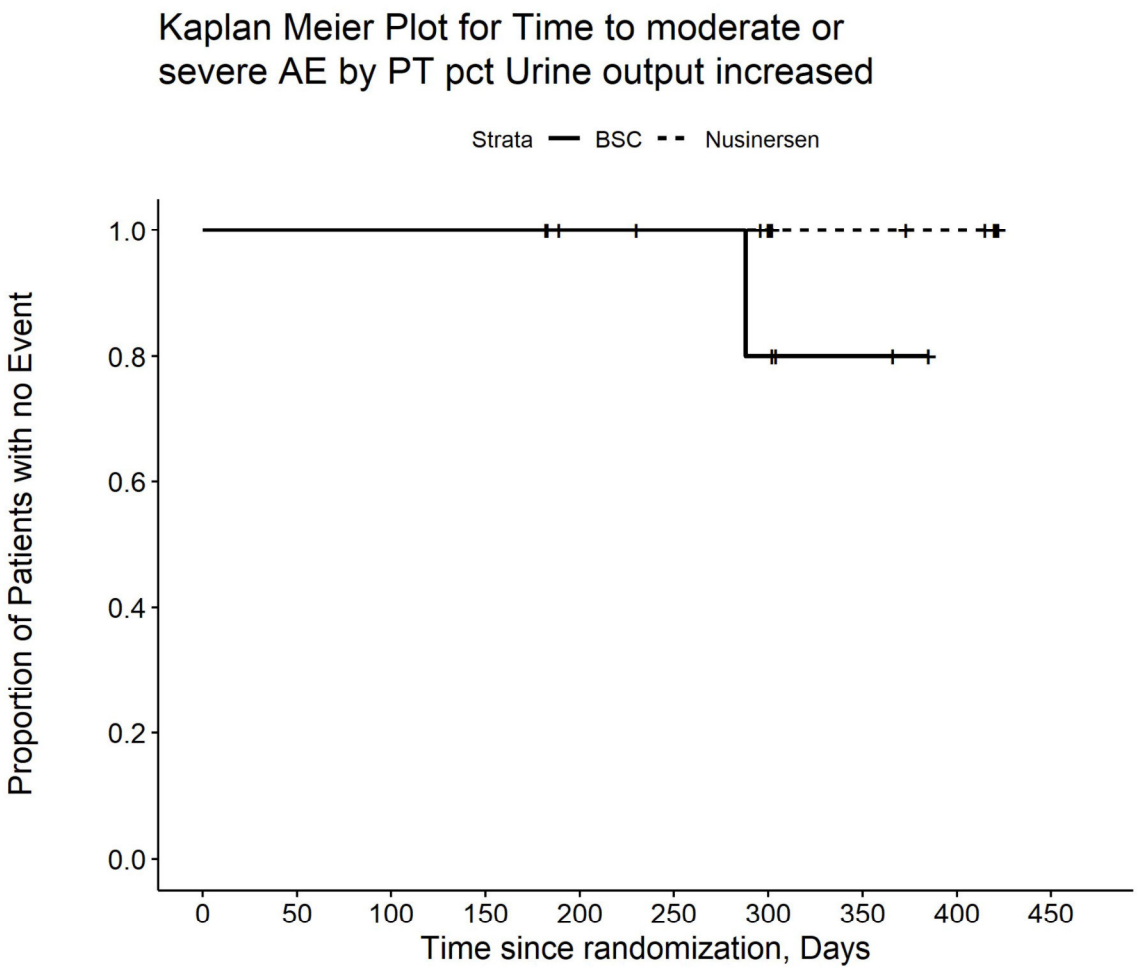
Number at risk

BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	11	11	10	5	5	0



Number at risk

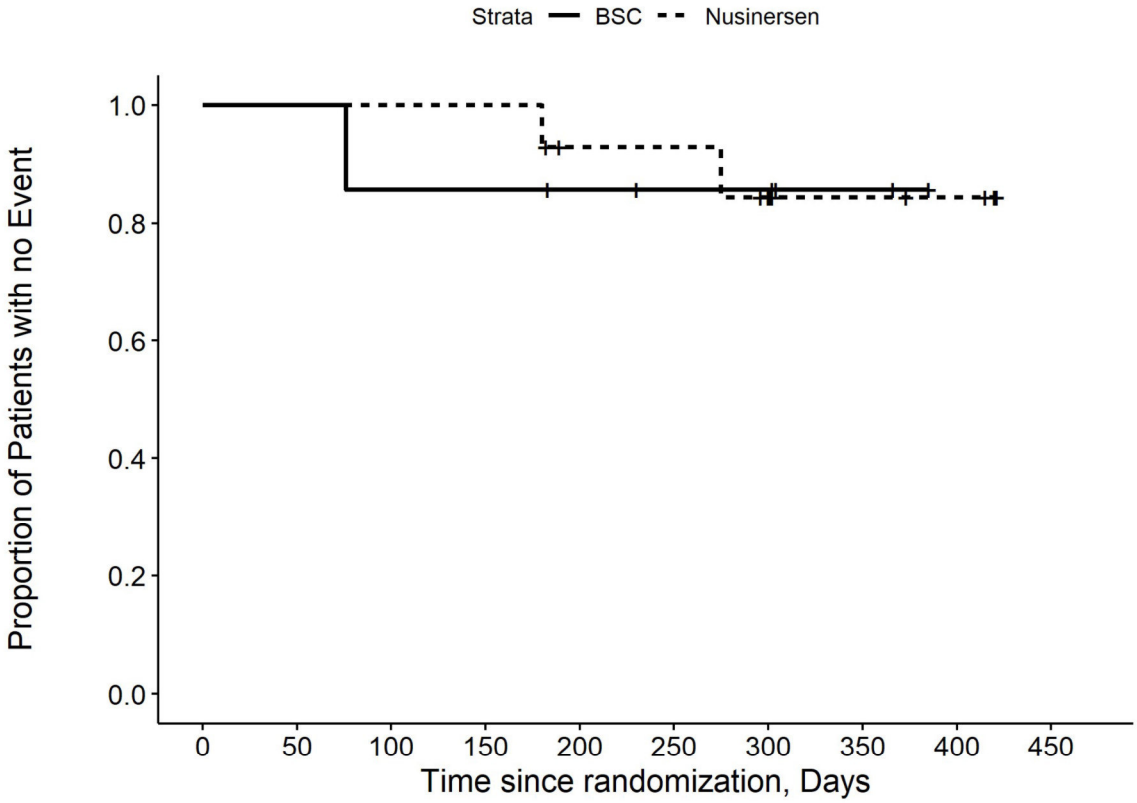
BSC	7	7	7	7	6	4	3	1	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

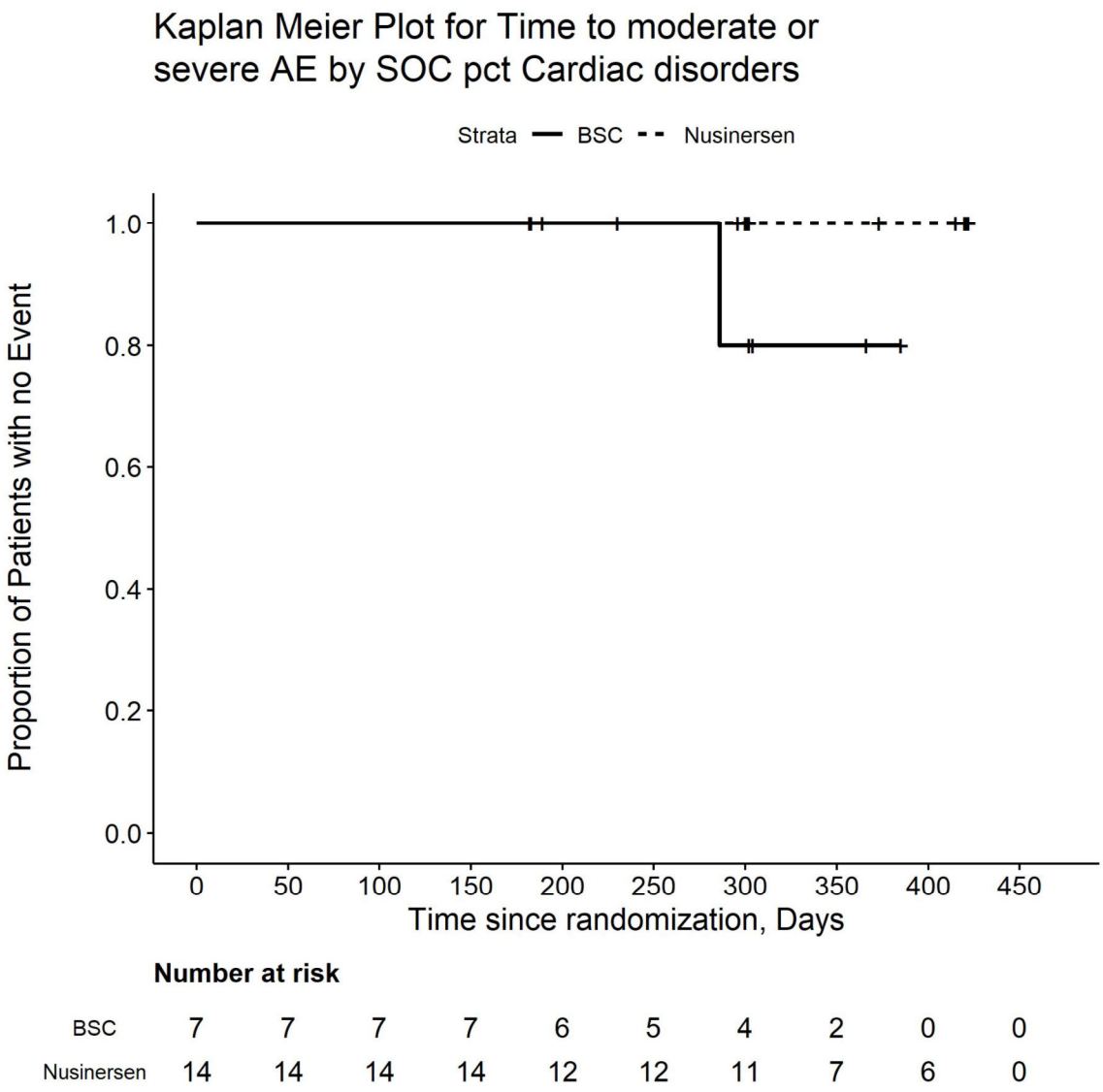
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for Time to moderate or severe AE by PT pct Viral upper respiratory tract infection



Number at risk

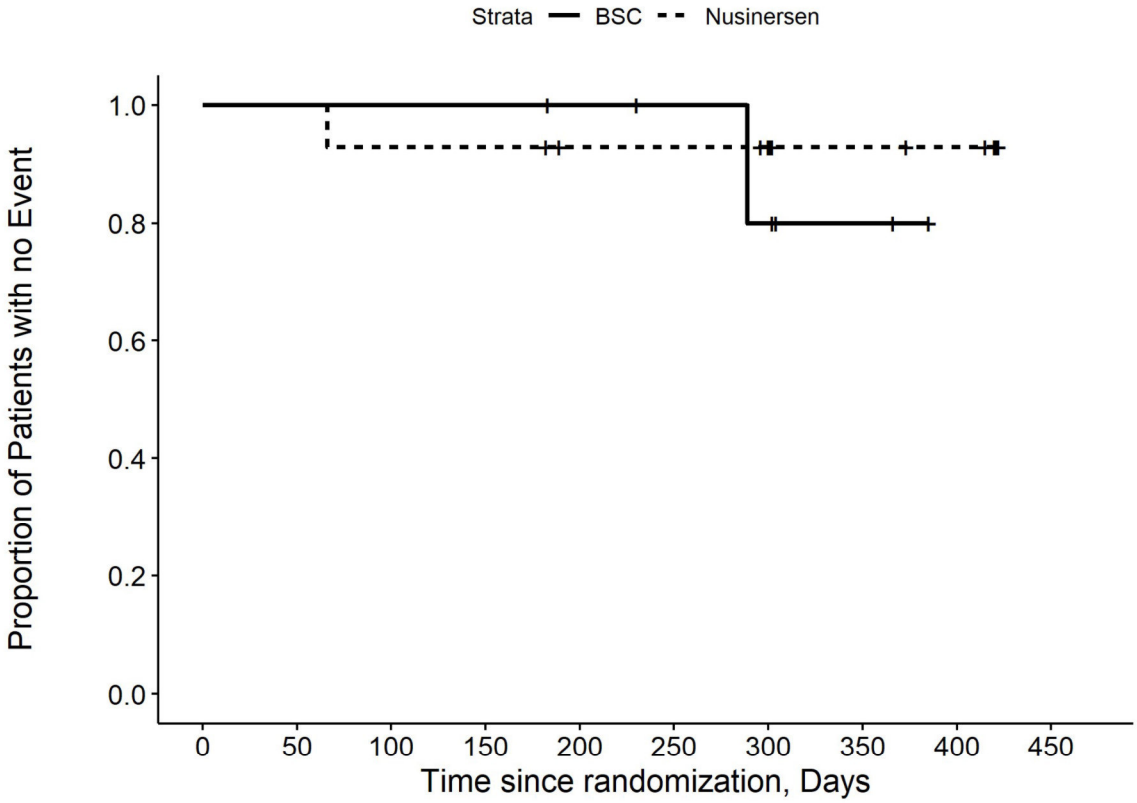
BSC	7	7	6	6	5	4	4	2	0	0
Nusinersen	14	14	14	14	11	11	9	5	4	0



Number at risk

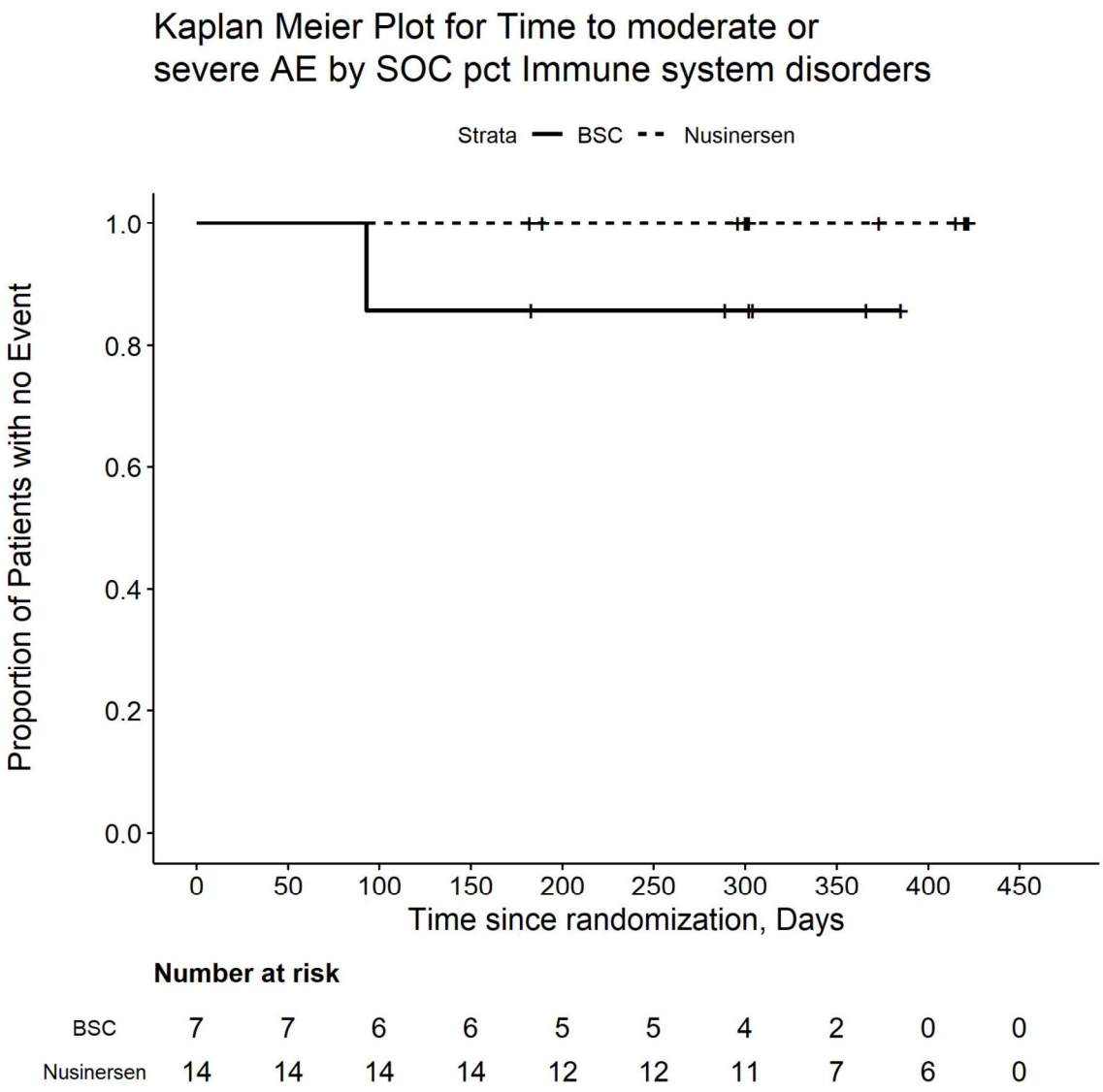
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for Time to moderate or severe AE by SOC pct General disorders and administration site conditions



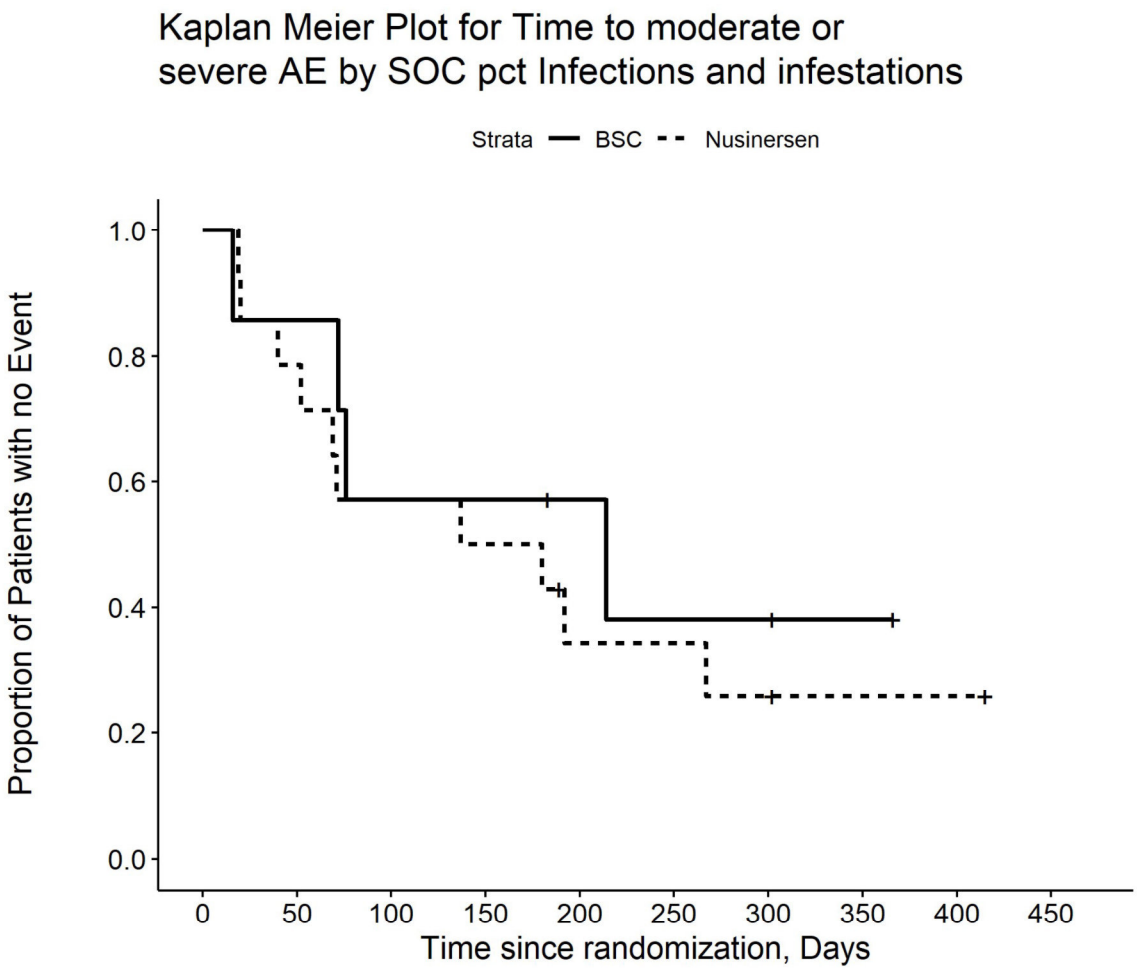
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	13	13	11	11	10	6	5	0



Number at risk

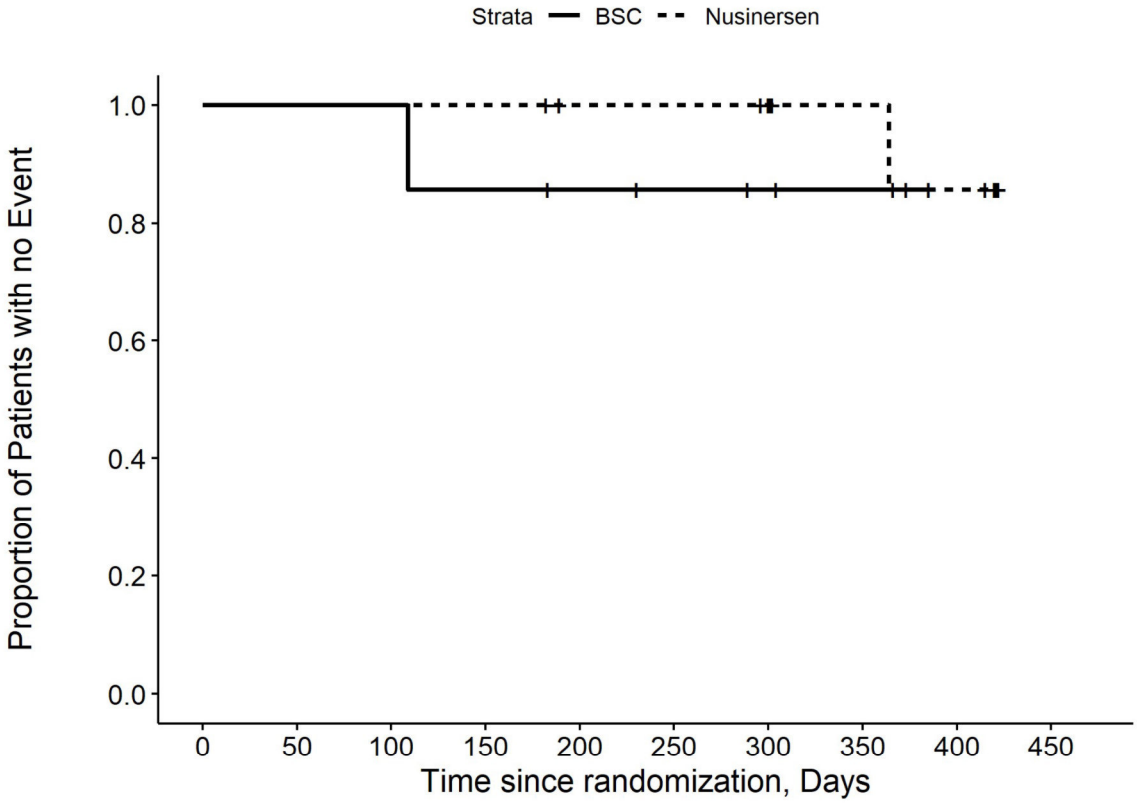
BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

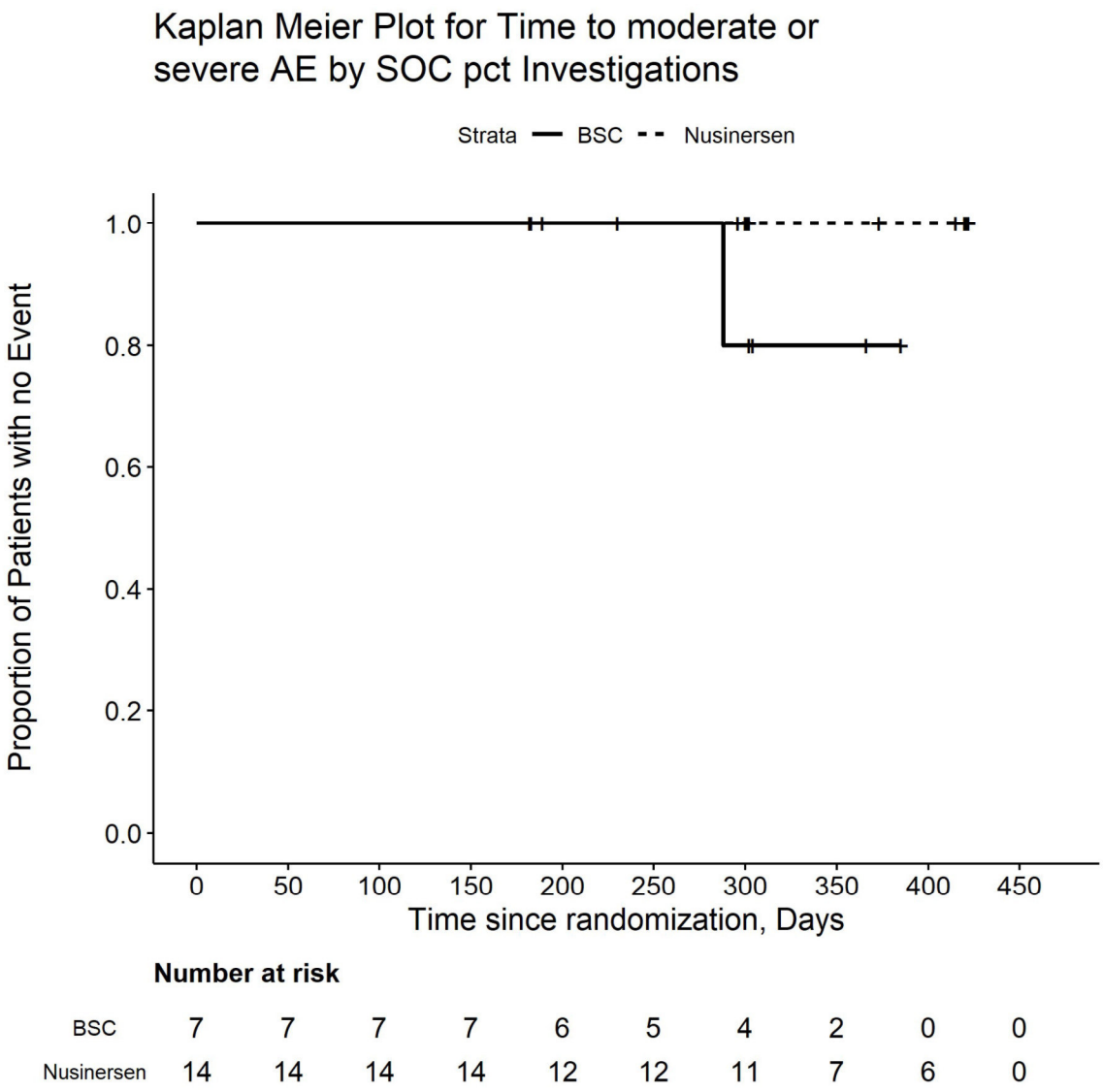
BSC	7	6	4	4	3	2	2	1	0	0
Nusinersen	14	11	8	7	4	4	3	2	2	0

Kaplan Meier Plot for Time to moderate or severe AE by SOC pct Injury, poisoning and procedural complications



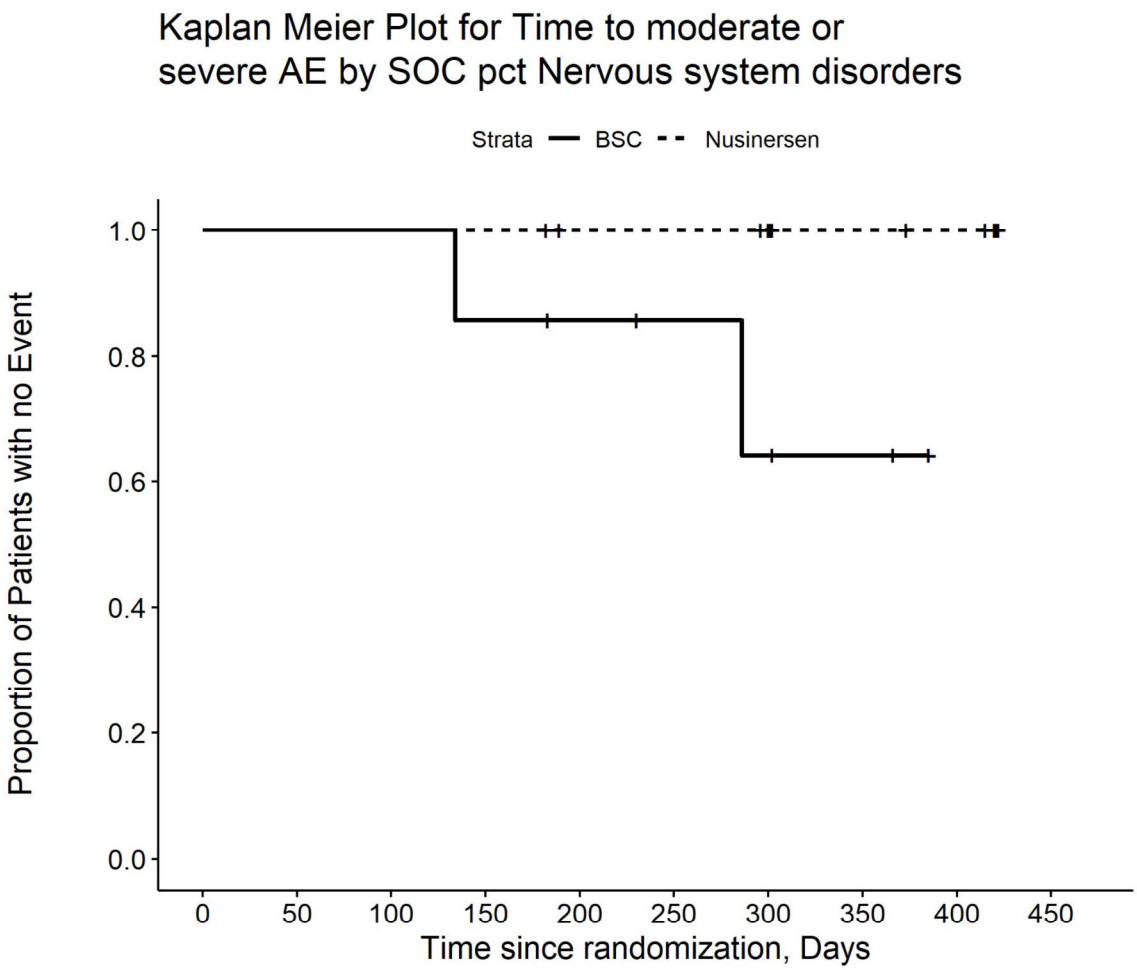
Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	5	0



Number at risk

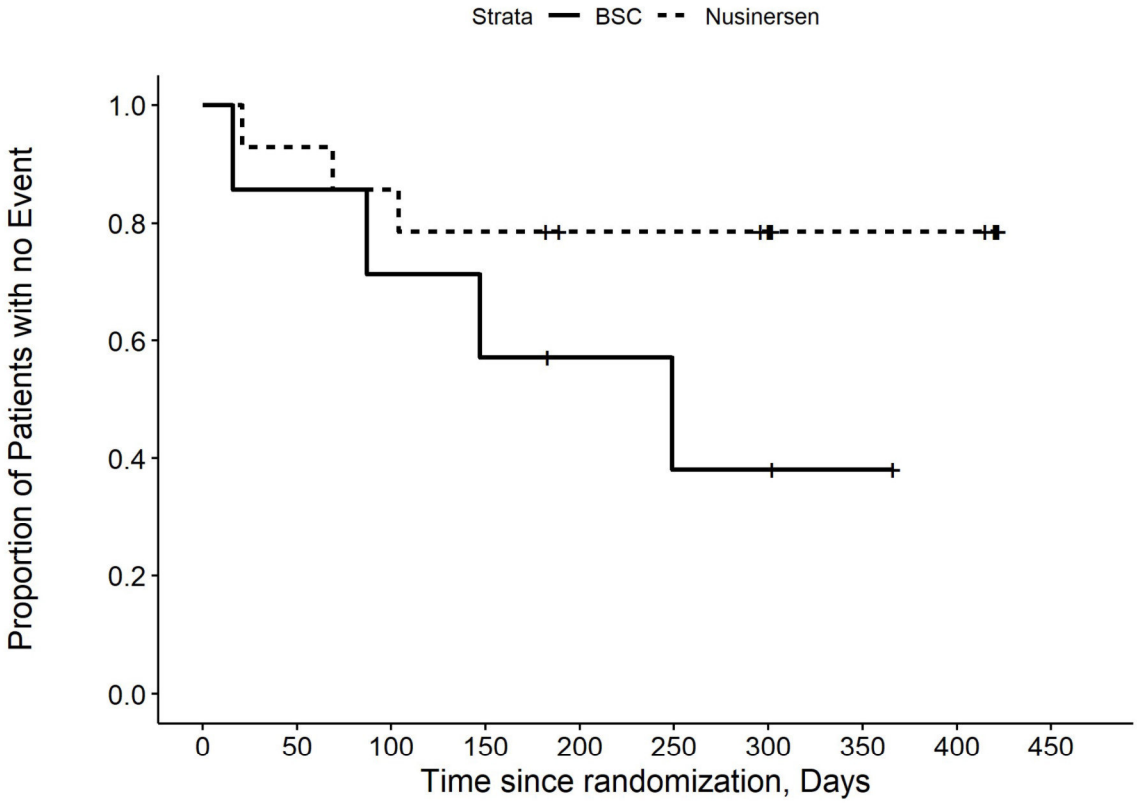
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

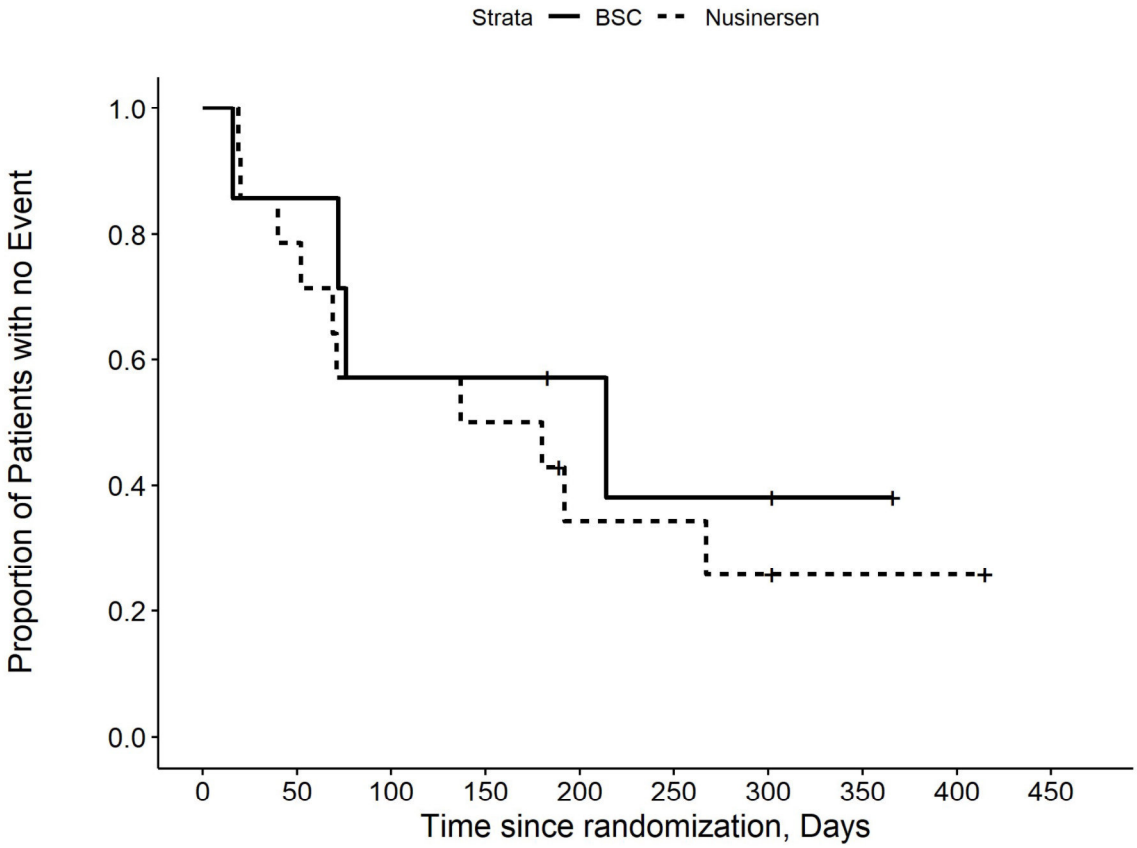
Kaplan Meier Plot for Time to moderate or severe AE by SOC pct Respiratory, thoracic and mediastinal disorders



Number at risk

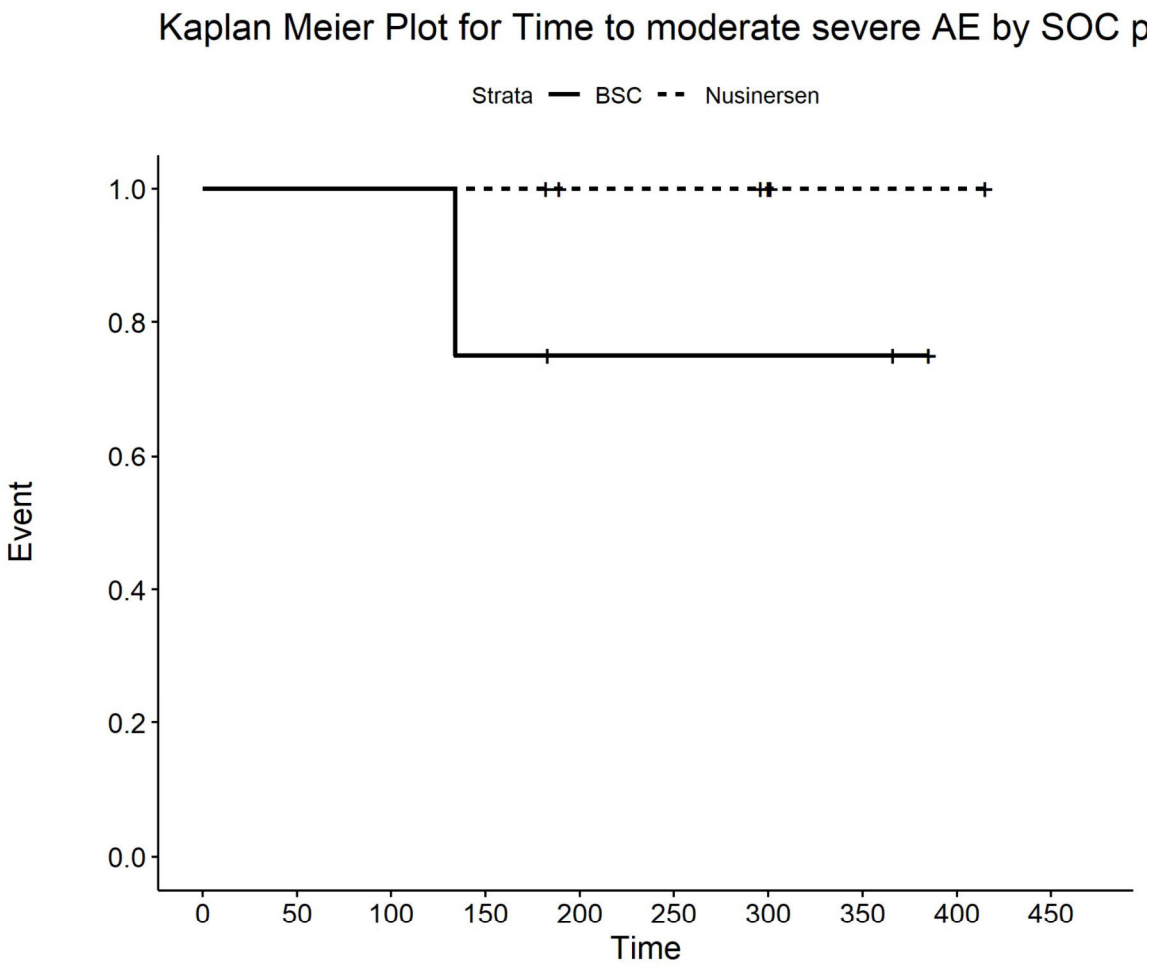
BSC	7	6	5	4	3	2	2	1	0	0
Nusinersen	14	13	12	11	9	9	8	5	5	0

Kaplan Meier Plot for Time to moderate or severe AE by SOC pts Infections and infestations



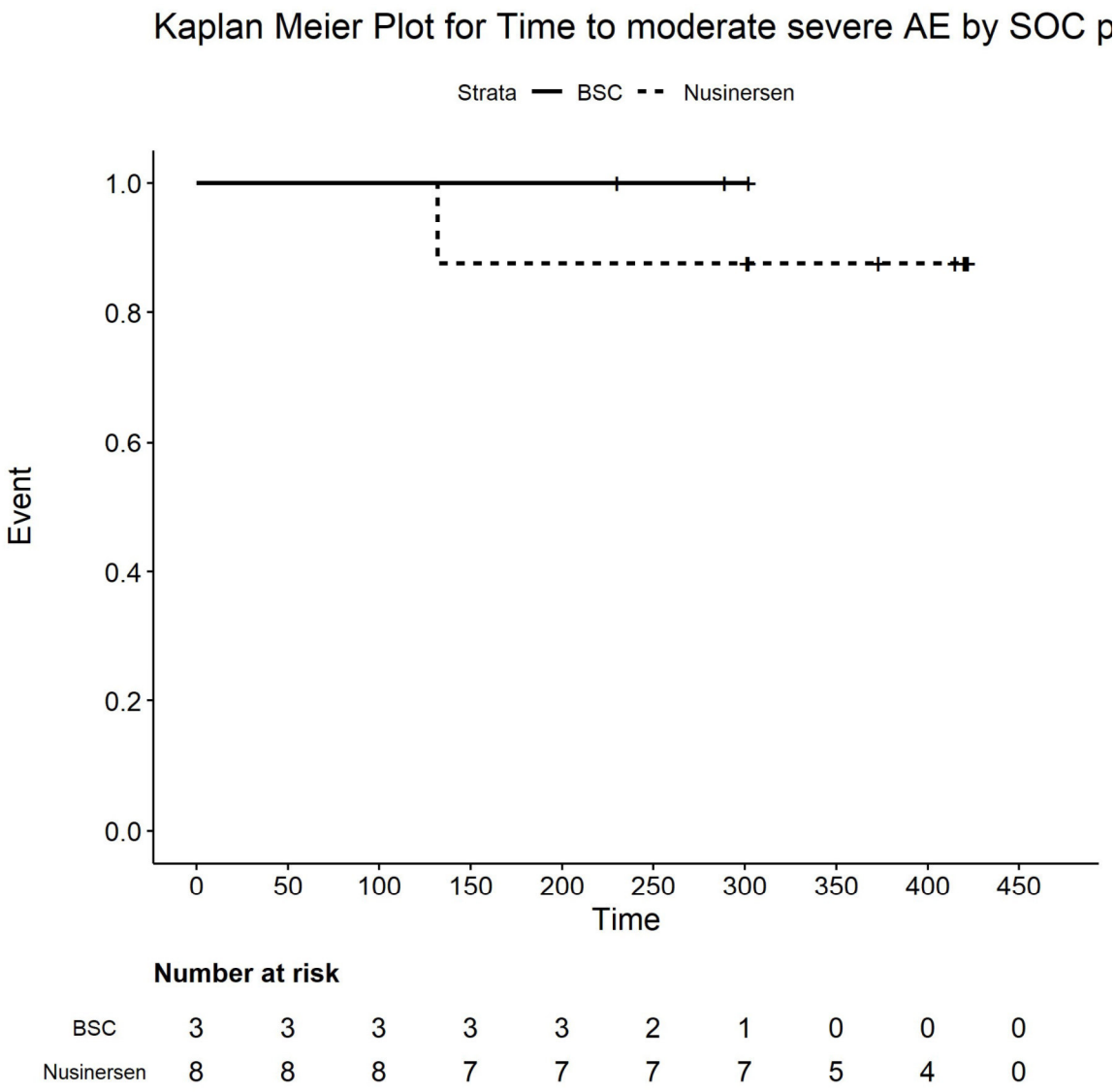
Number at risk

BSC	7	6	4	4	3	2	2	1	0	0
Nusinersen	14	11	8	7	4	4	3	2	2	0



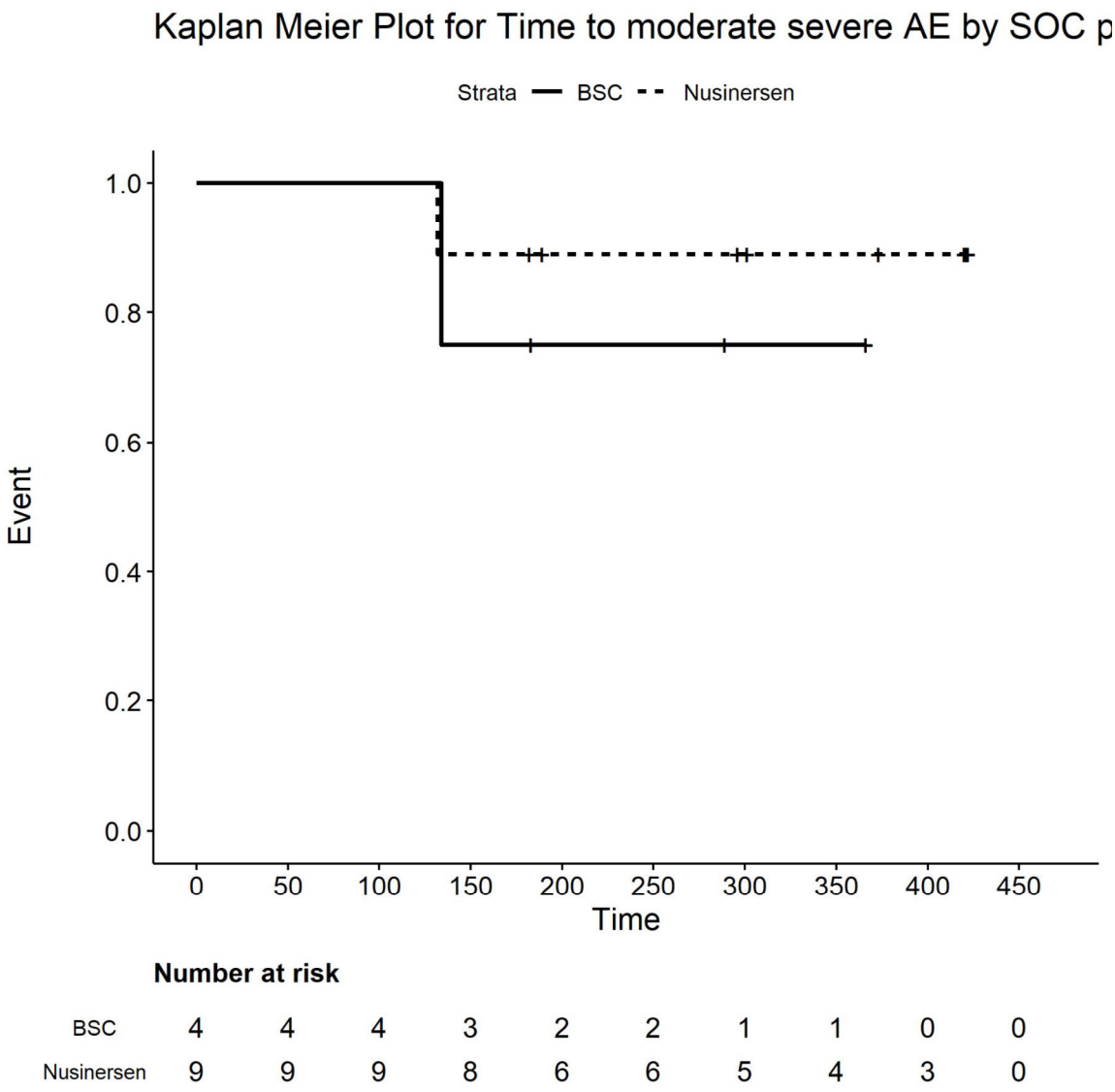
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



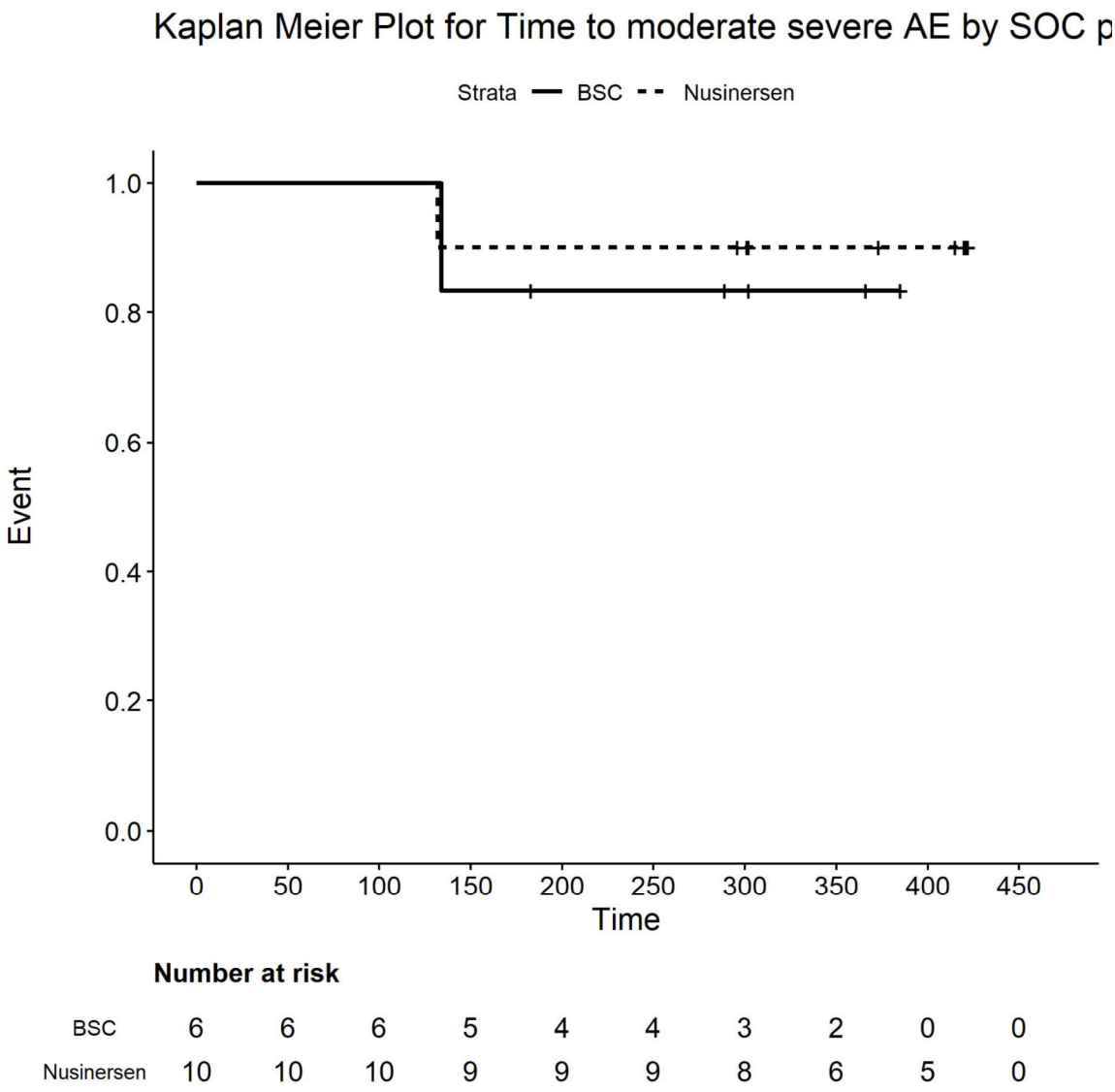
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



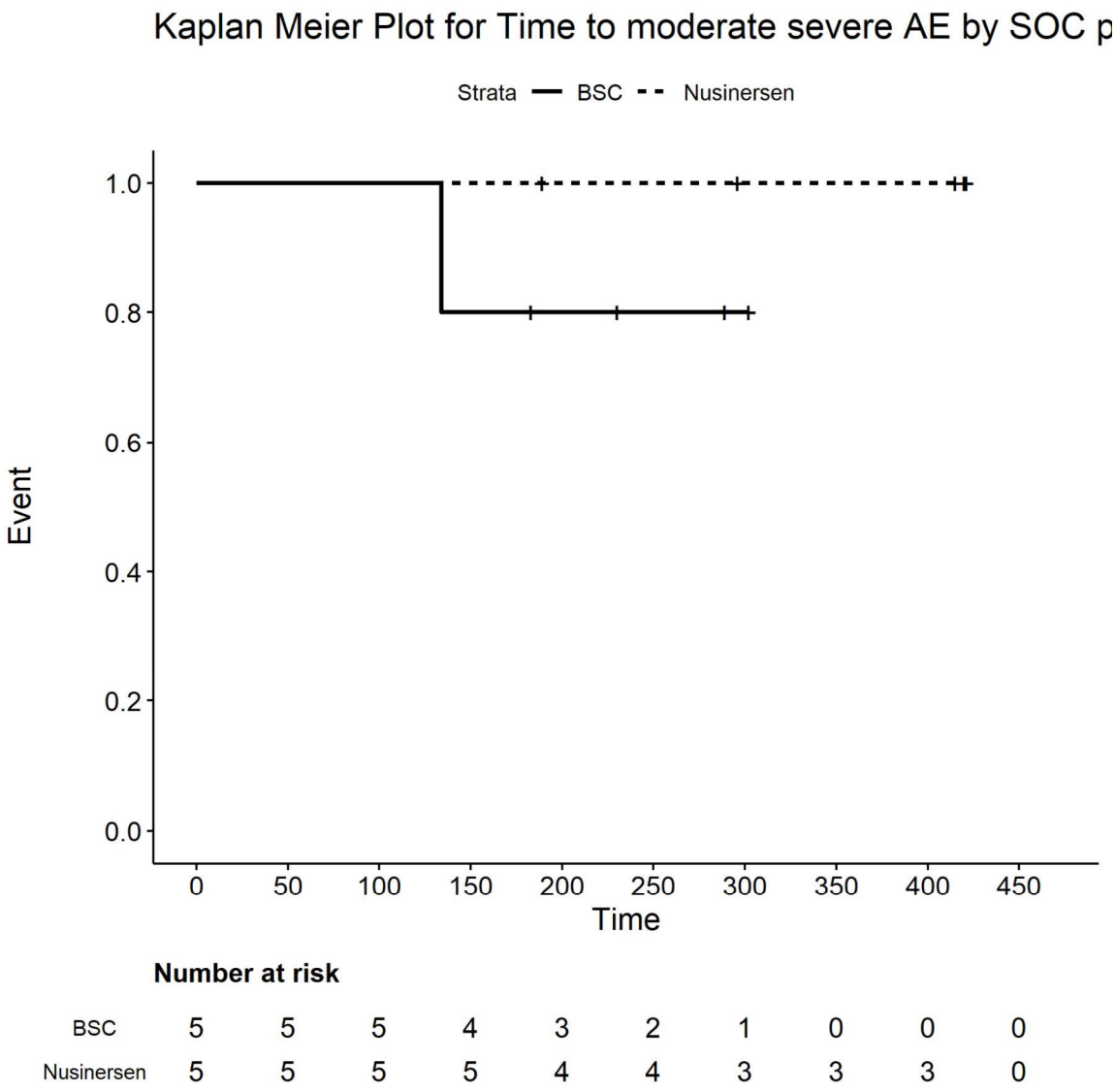
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



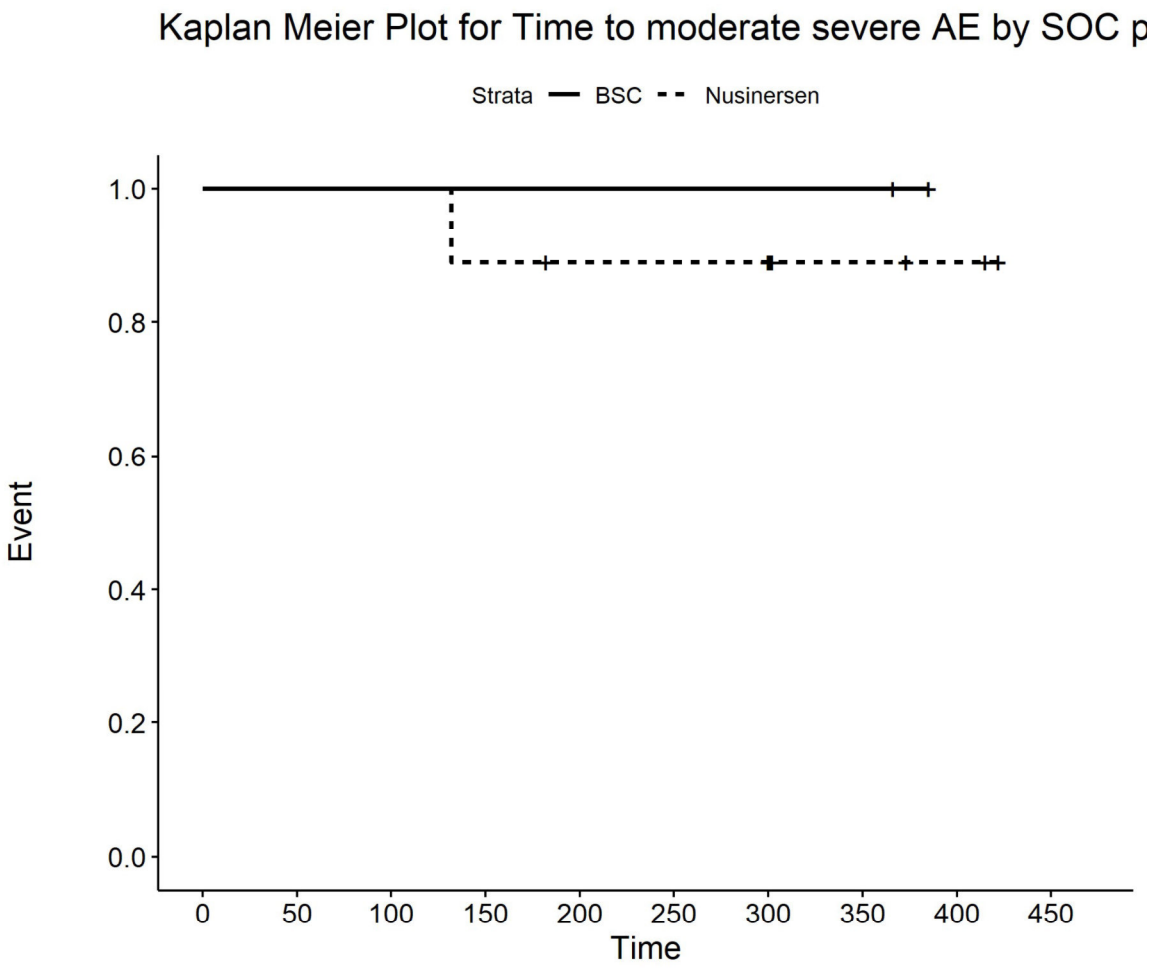
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



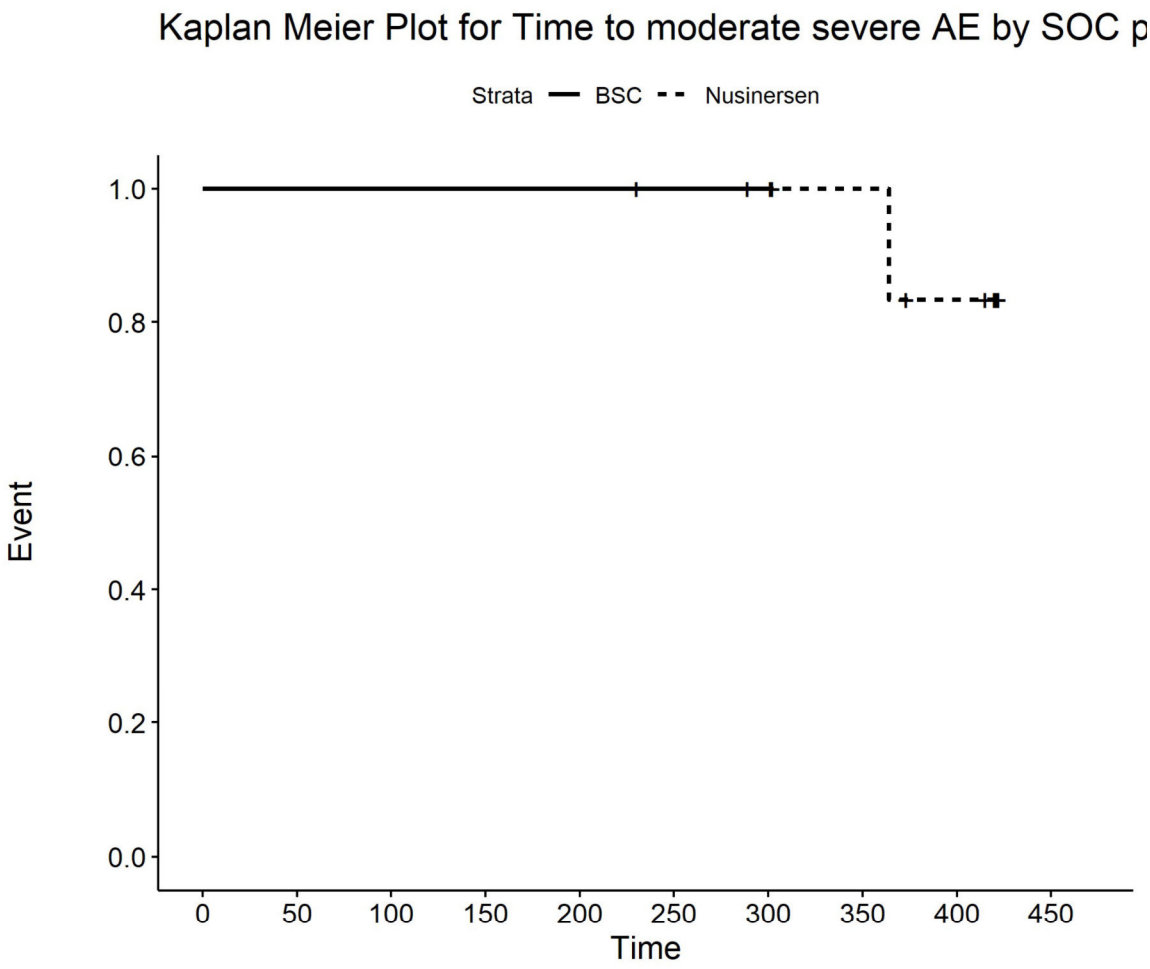
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



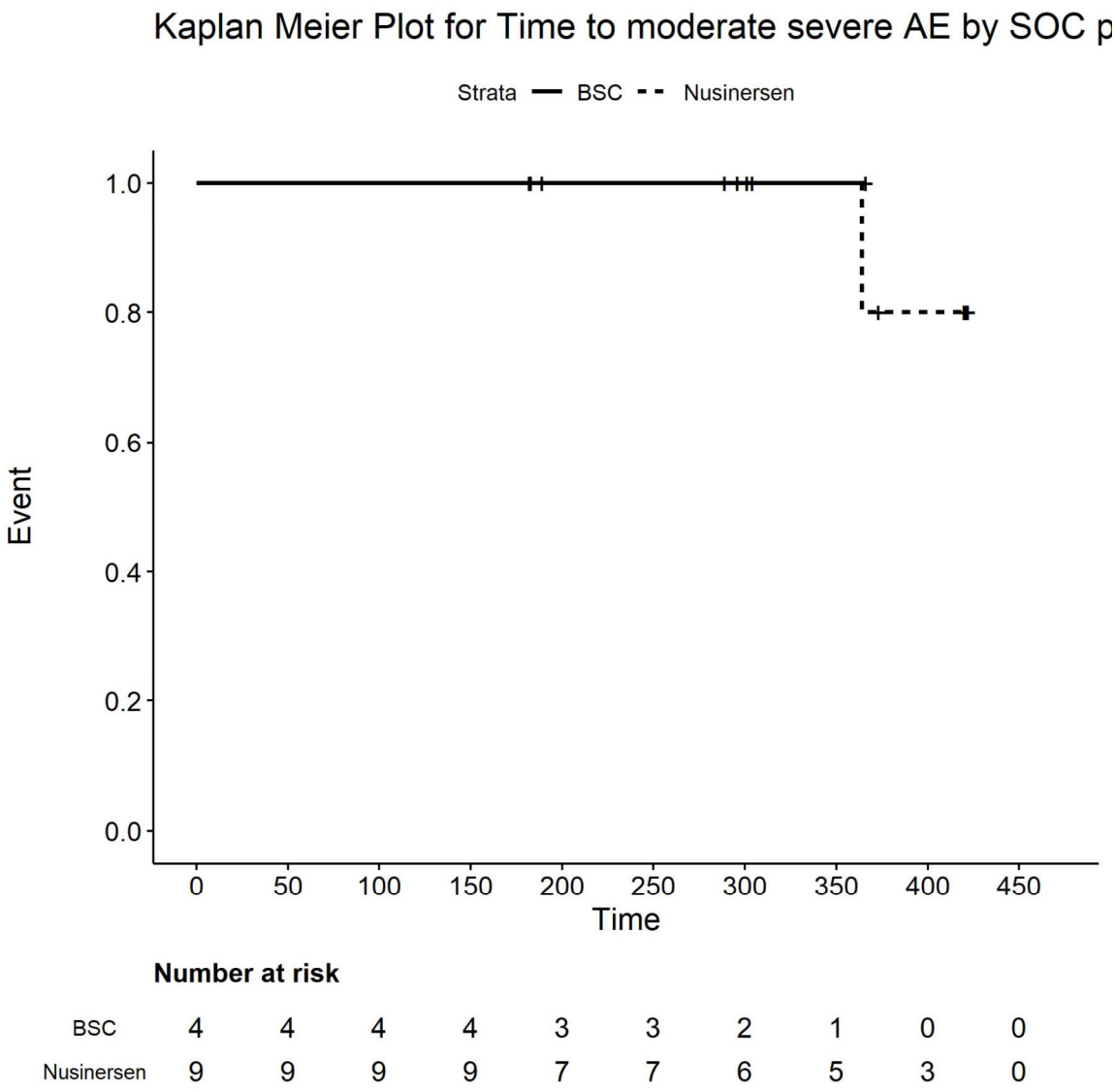
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



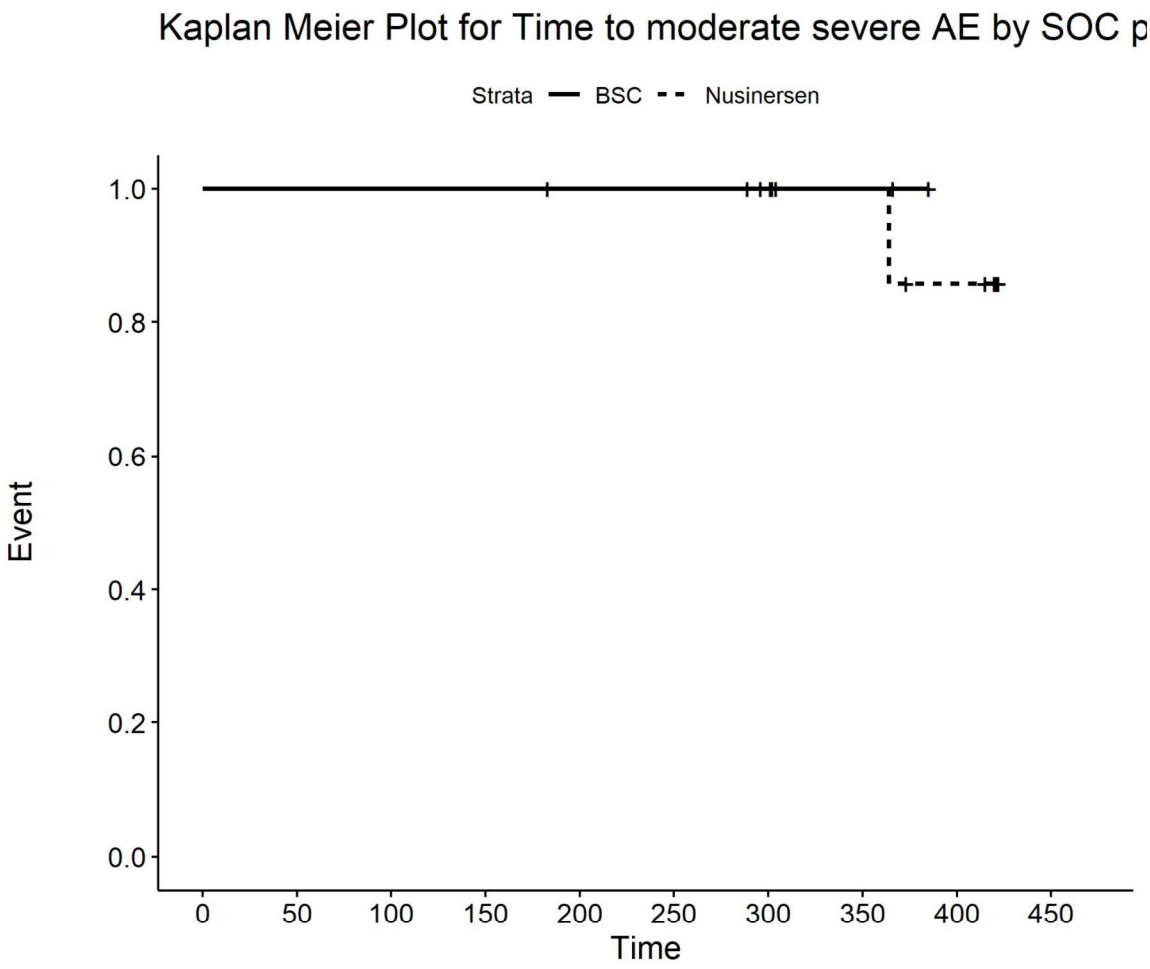
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	4	0



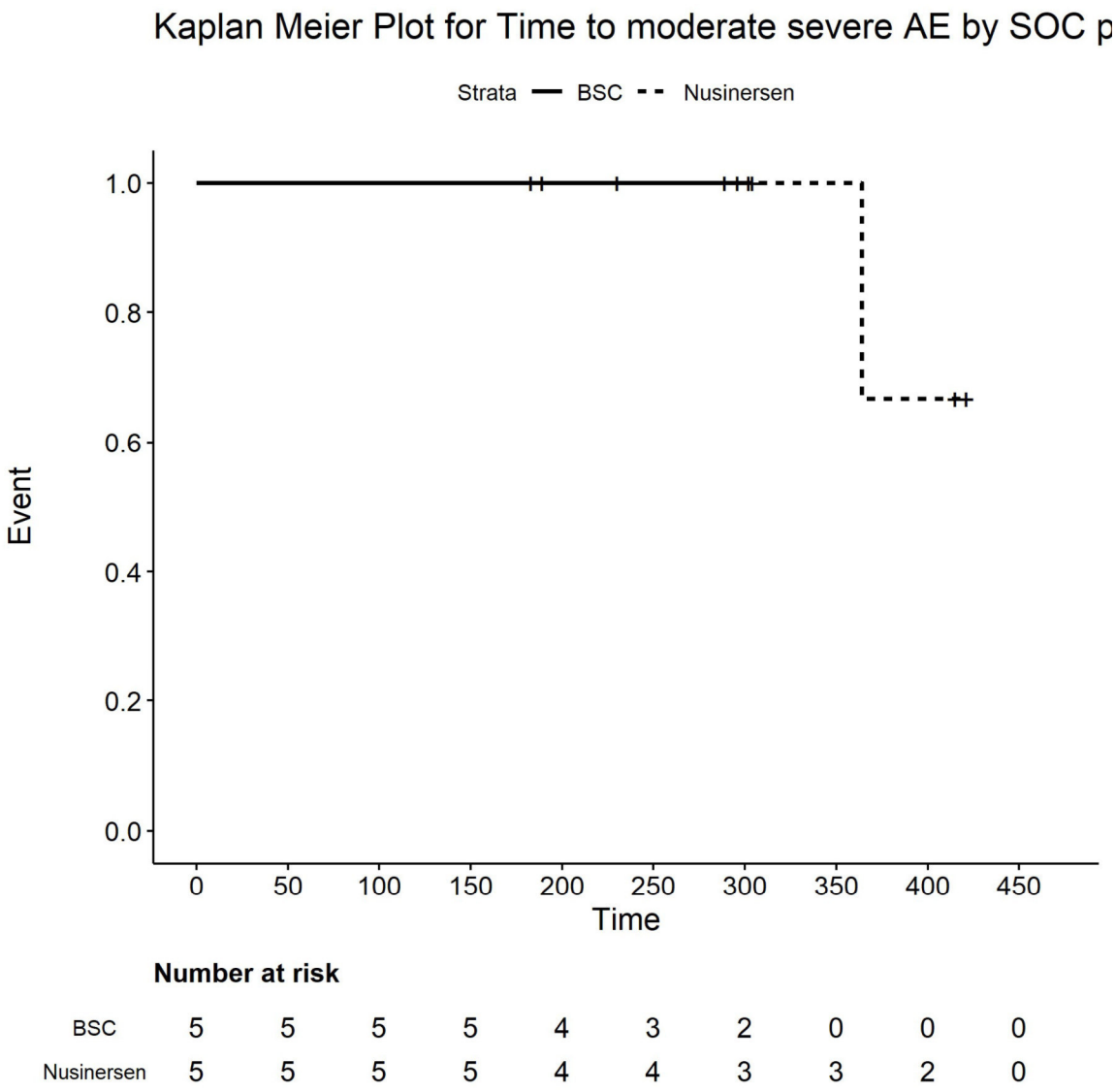
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	3	0



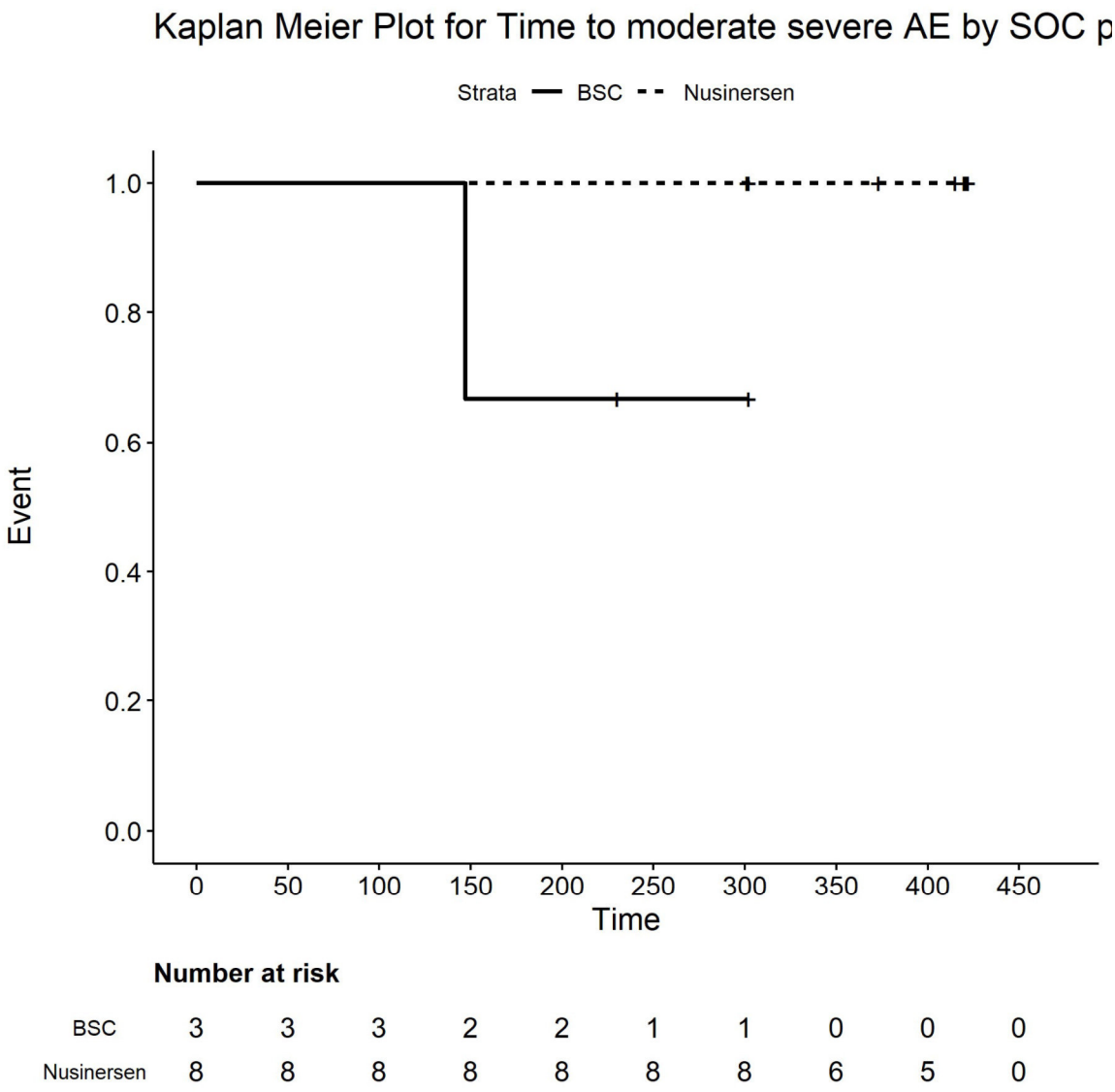
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	5	0



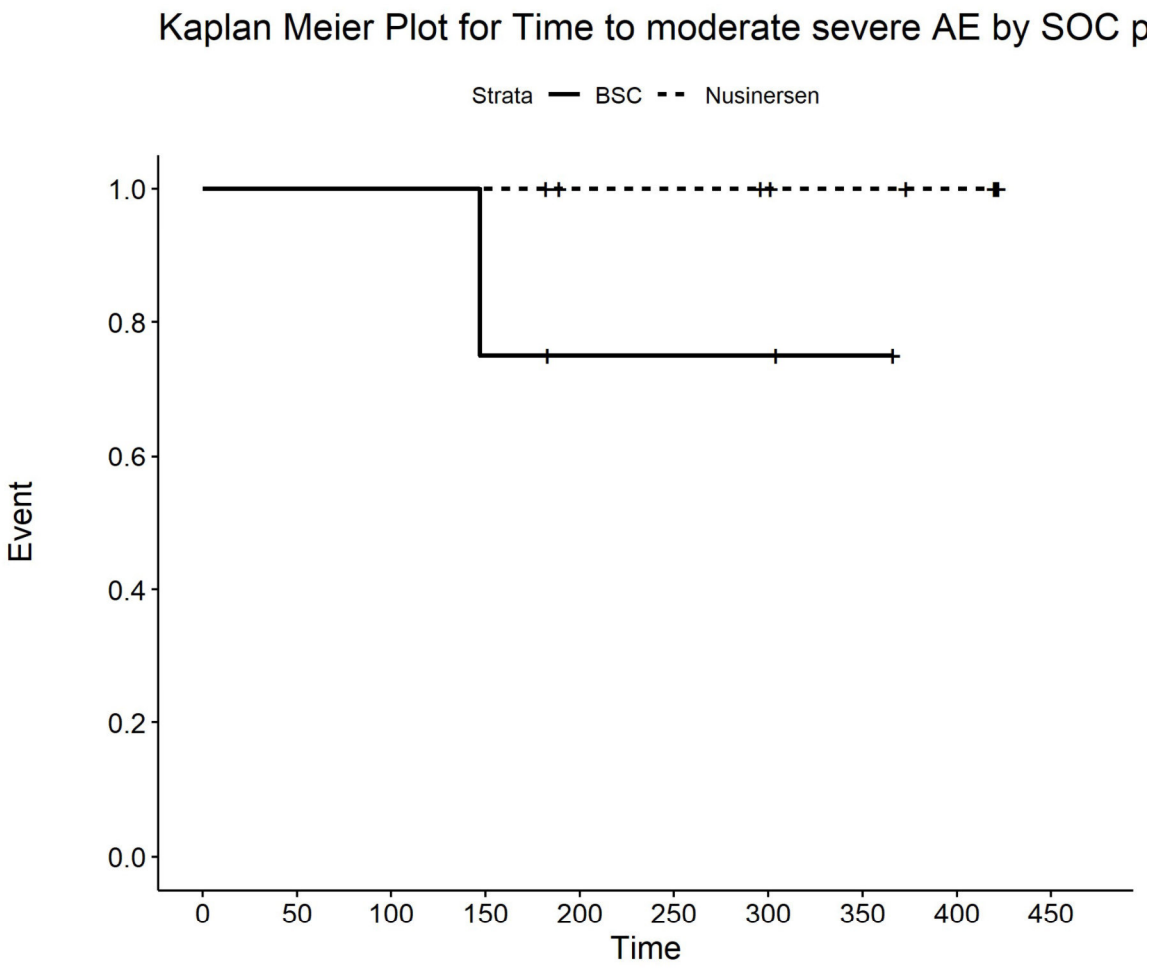
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	2	0



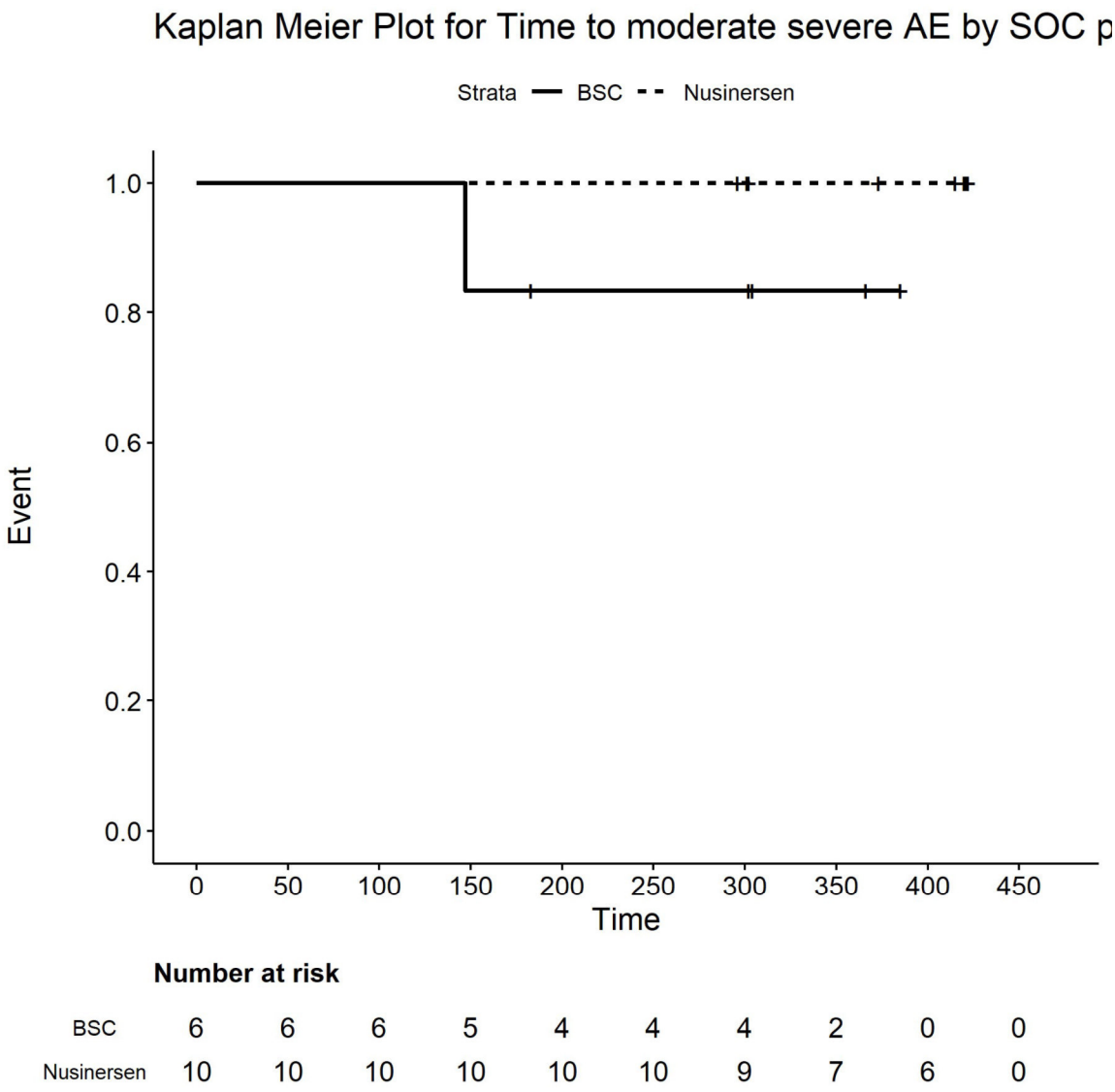
Number at risk

BSC	3	3	3	2	2	1	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



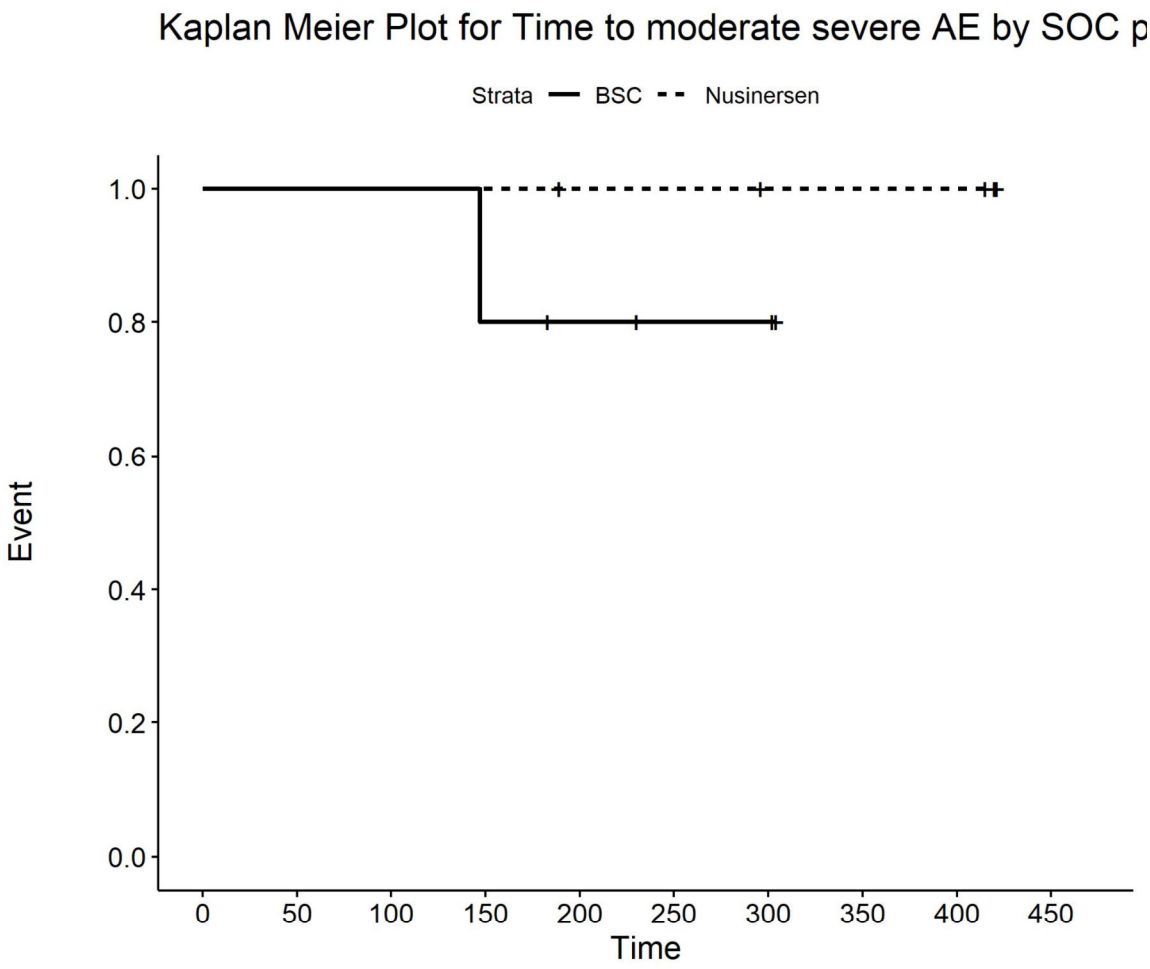
Number at risk

BSC	4	4	4	3	2	2	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



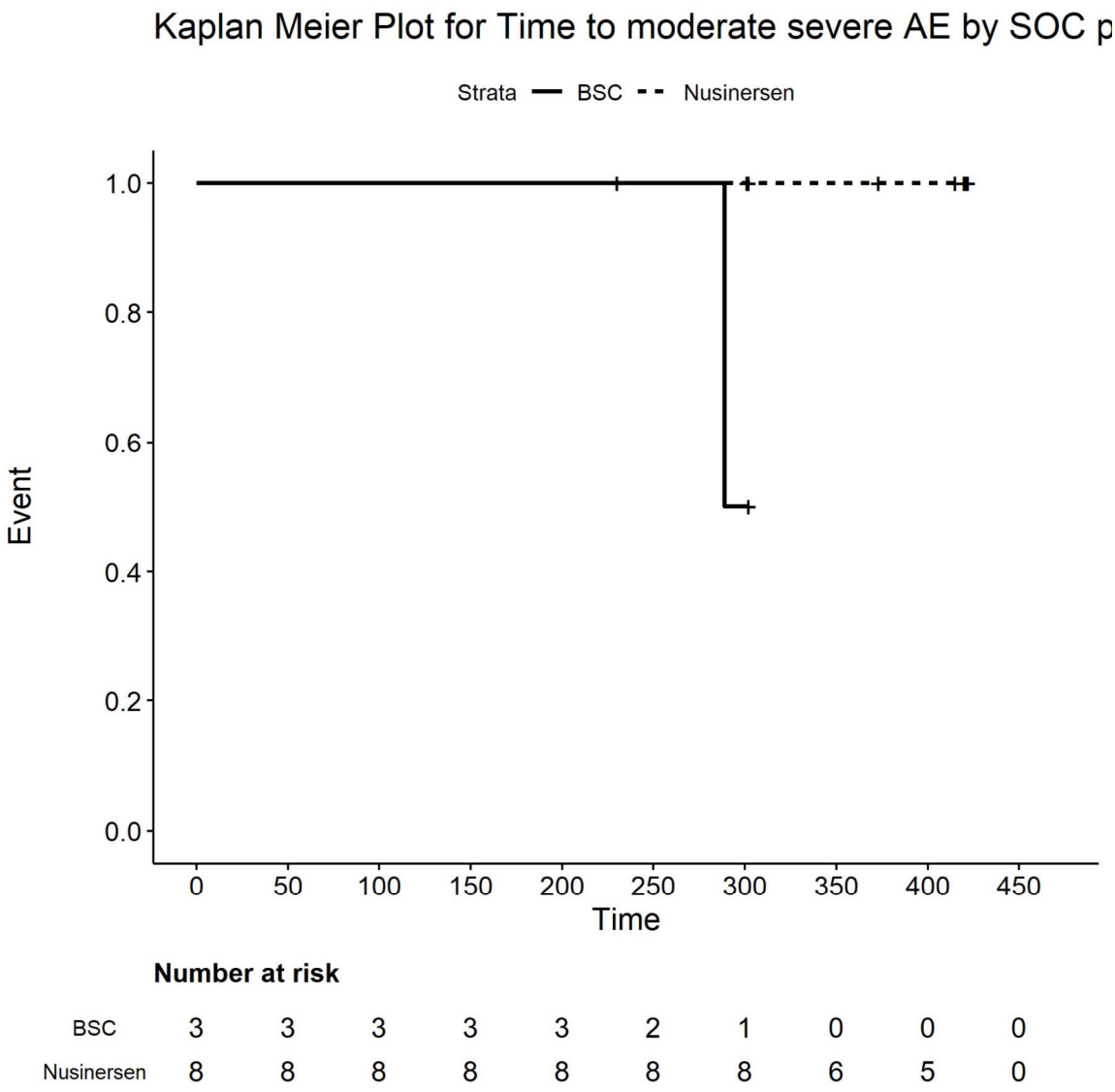
Number at risk

BSC	6	6	6	5	4	4	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



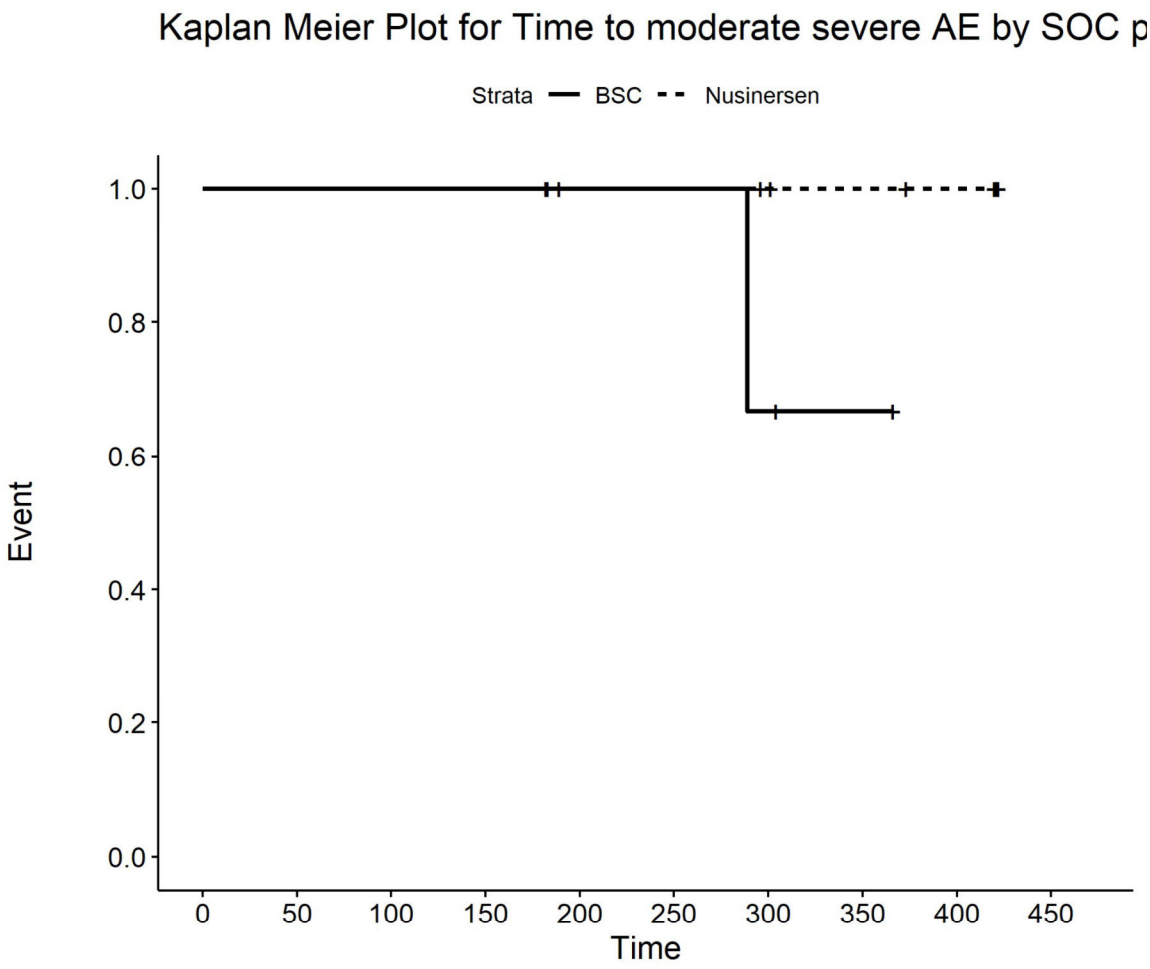
Number at risk

BSC	5	5	5	4	3	2	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



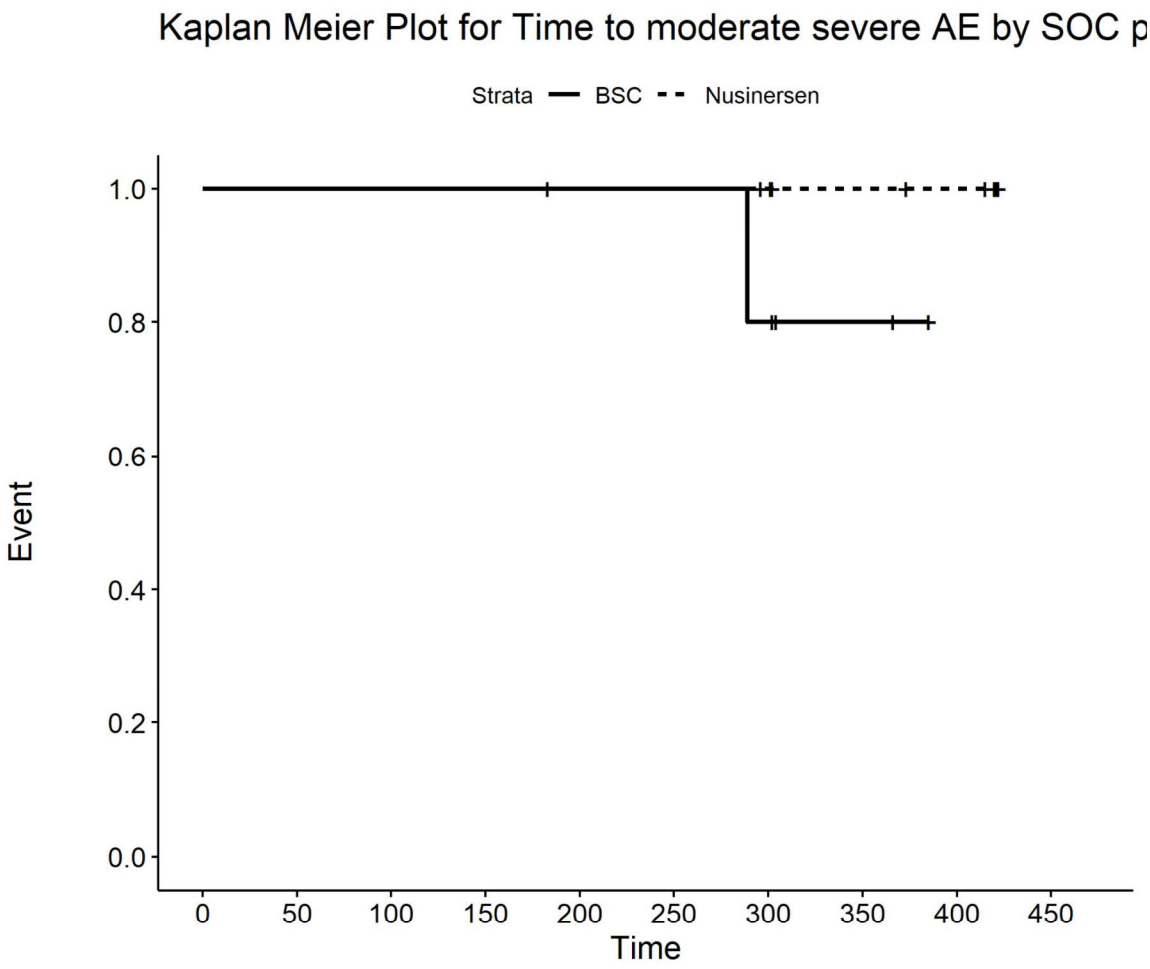
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



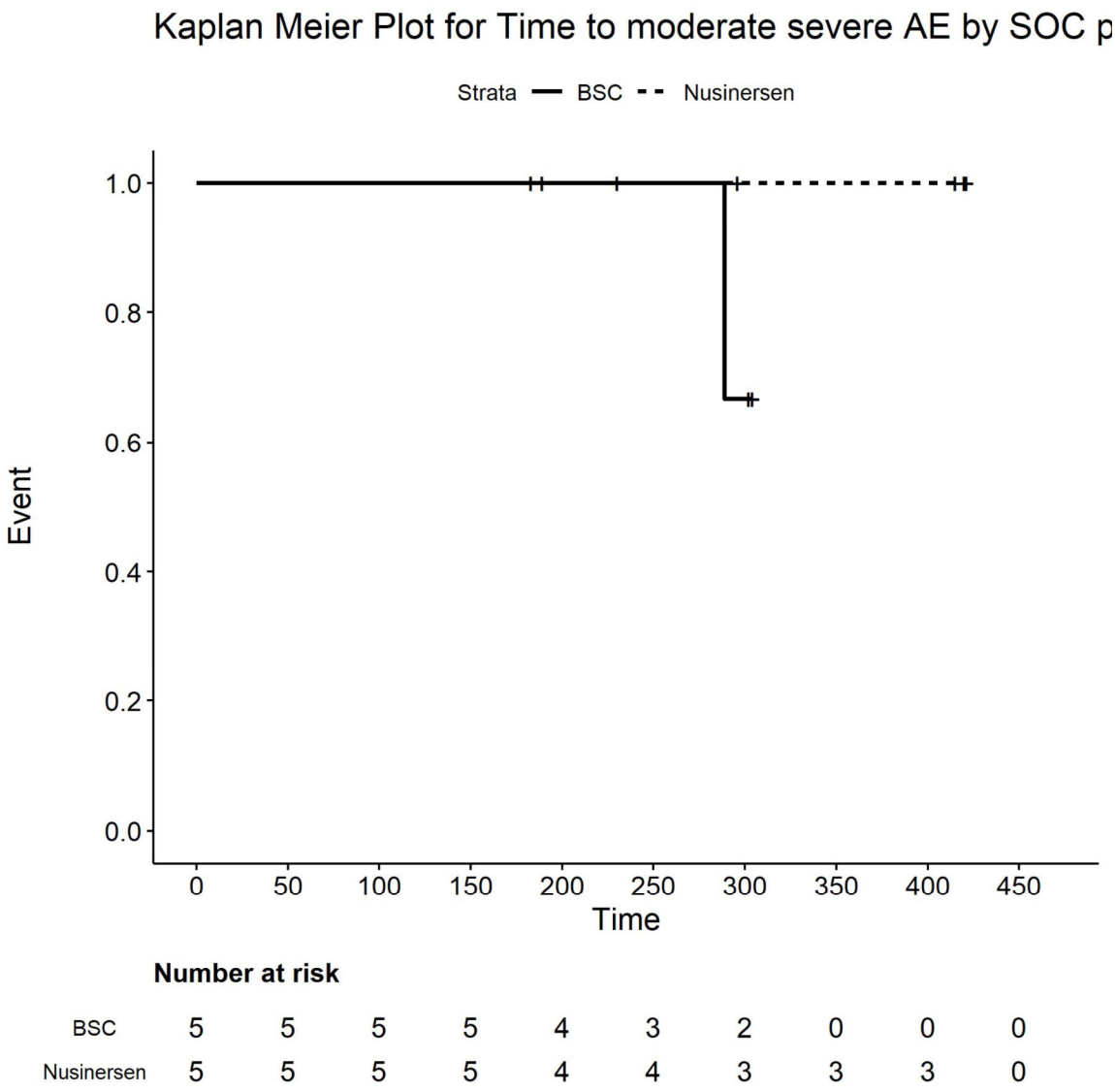
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



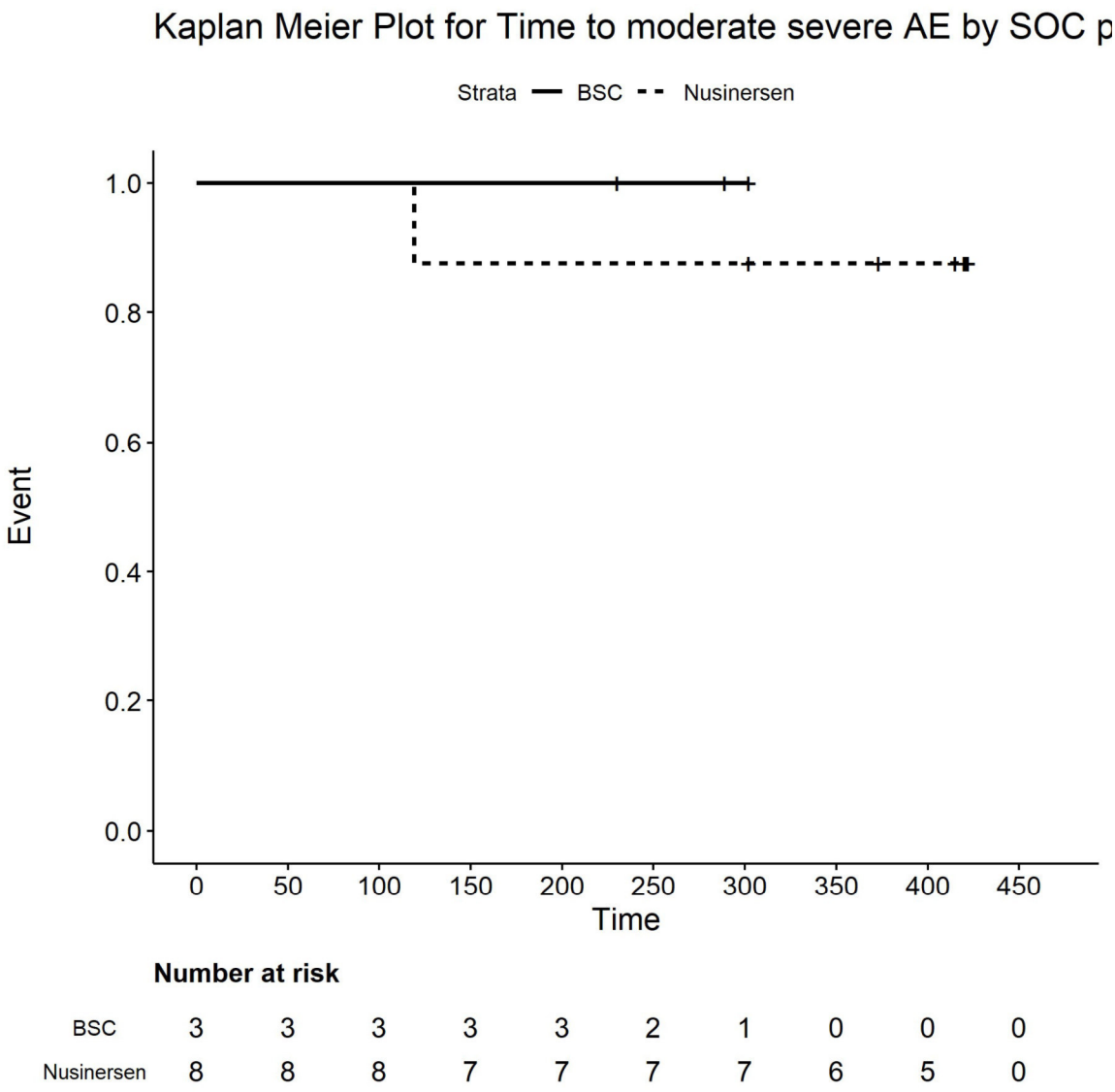
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



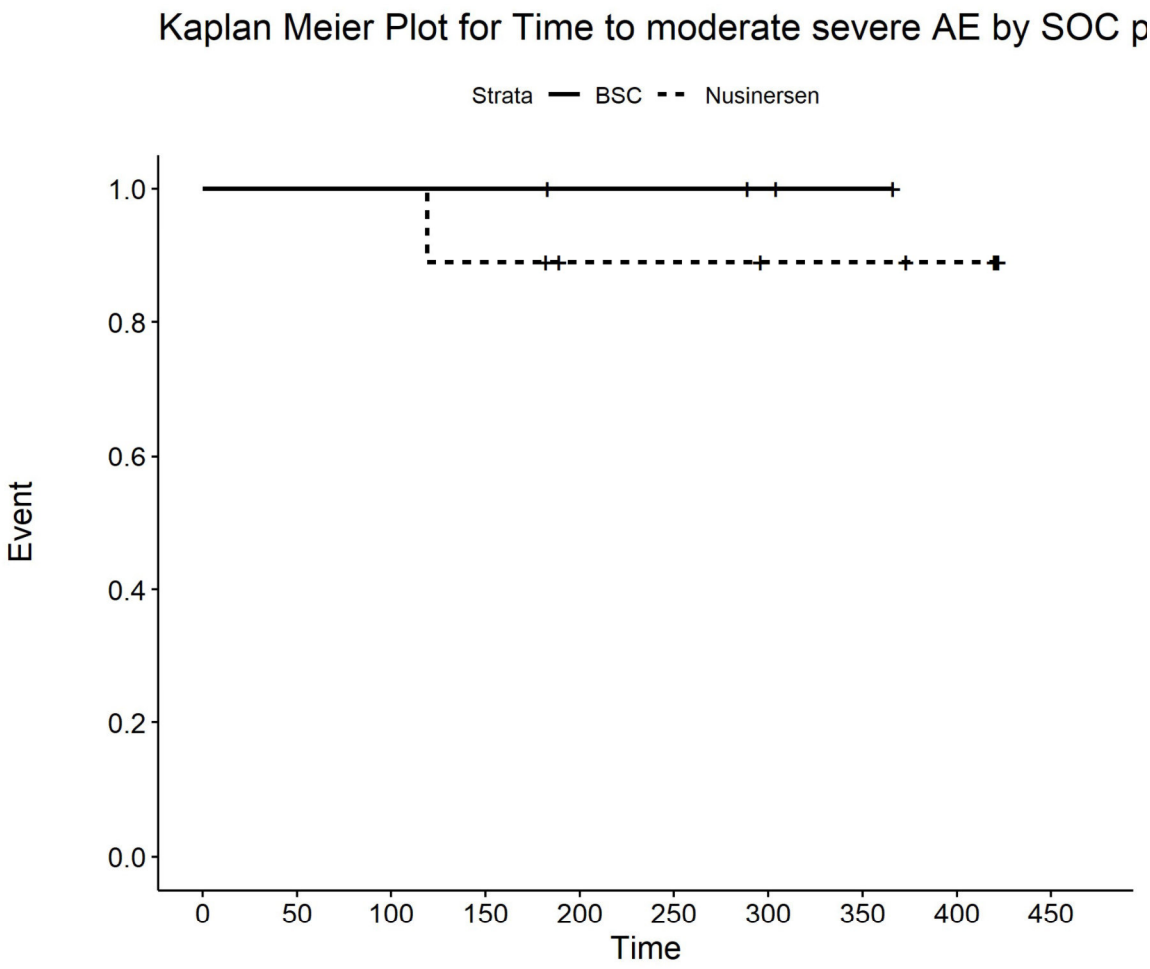
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



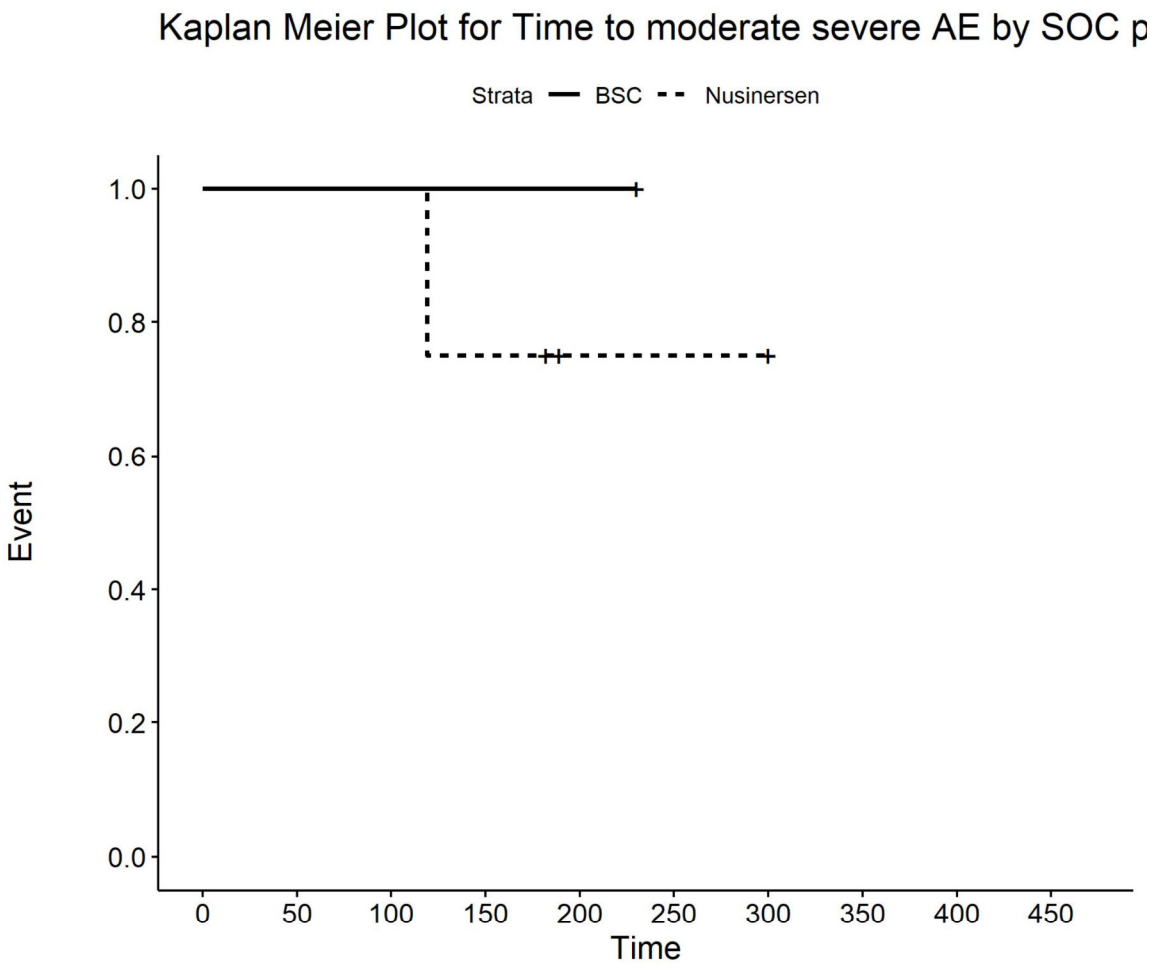
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	6	5	0



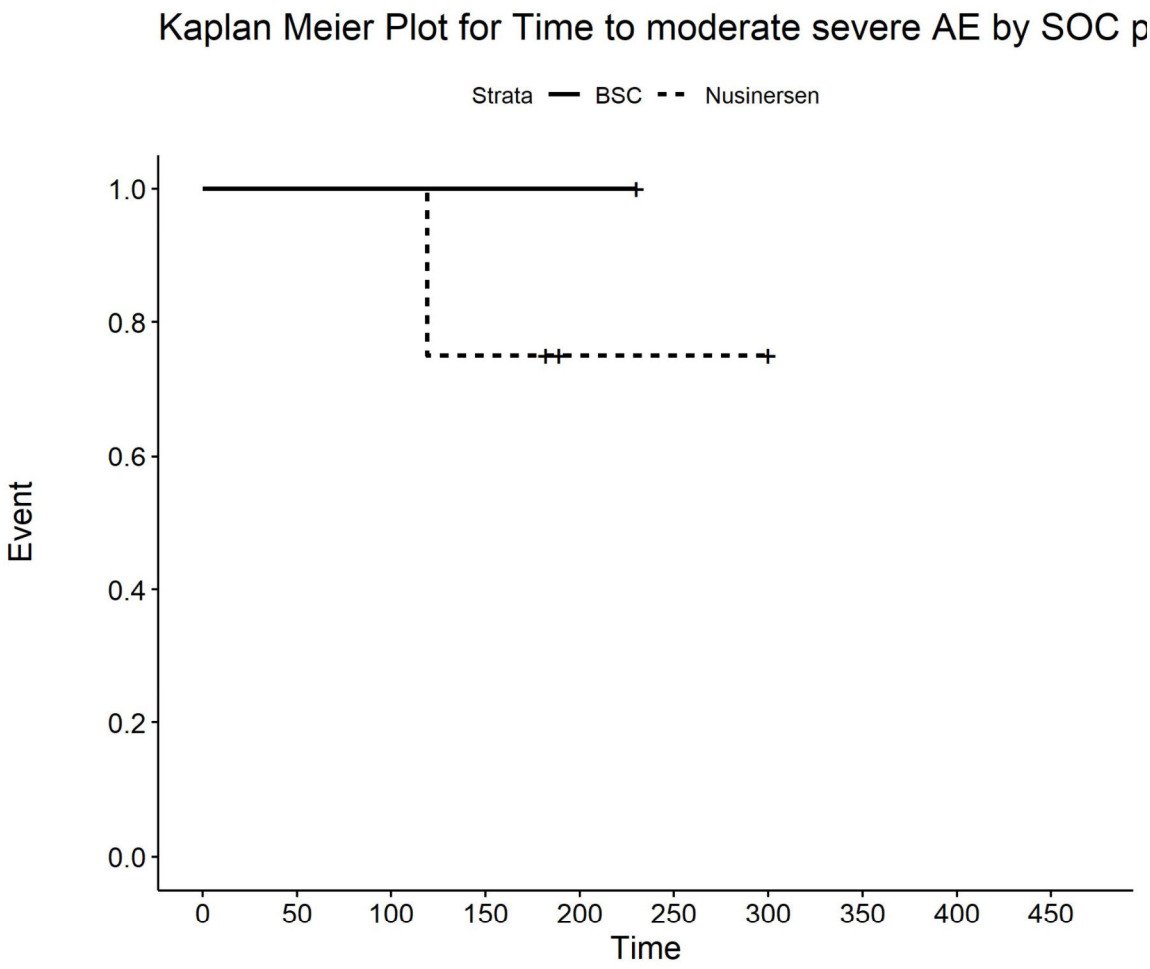
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	5	4	0



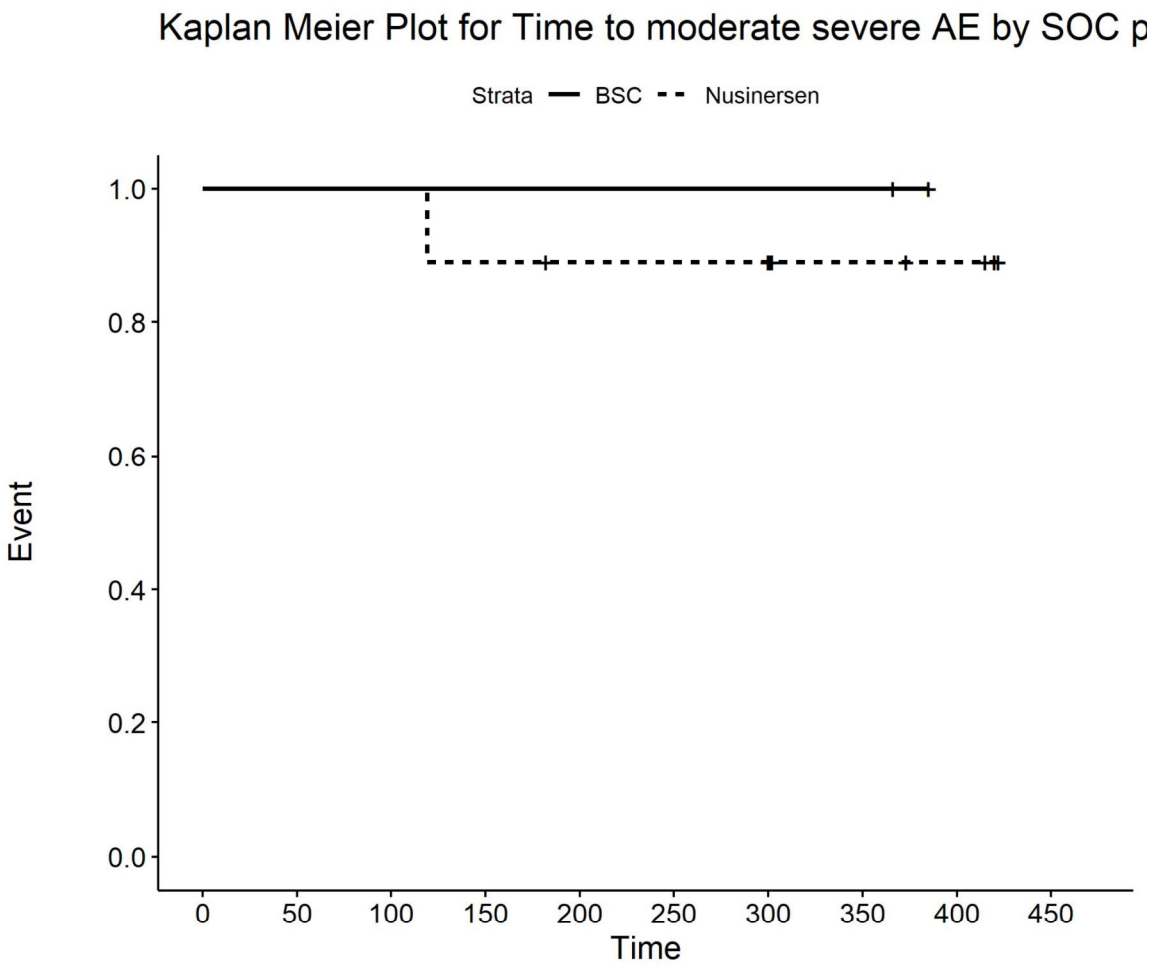
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



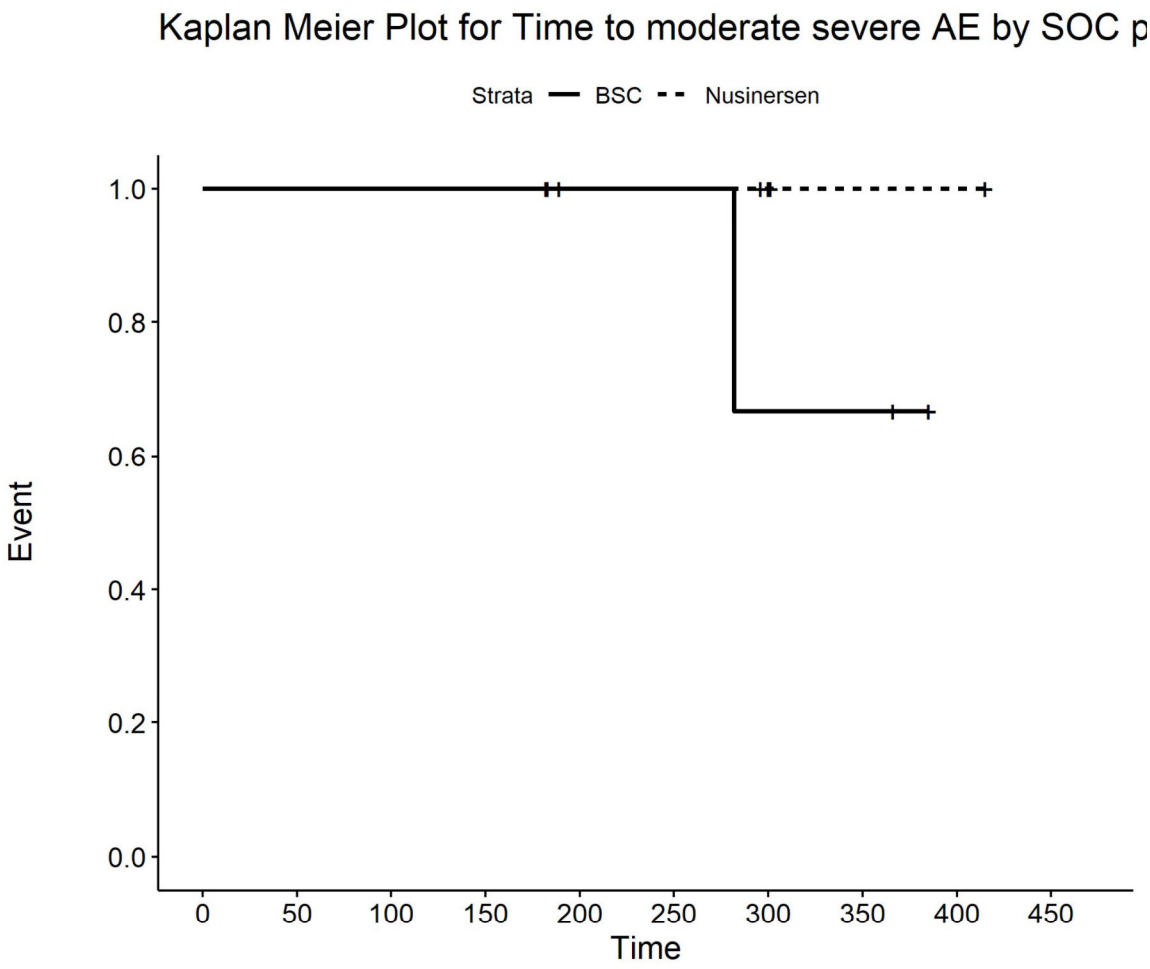
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



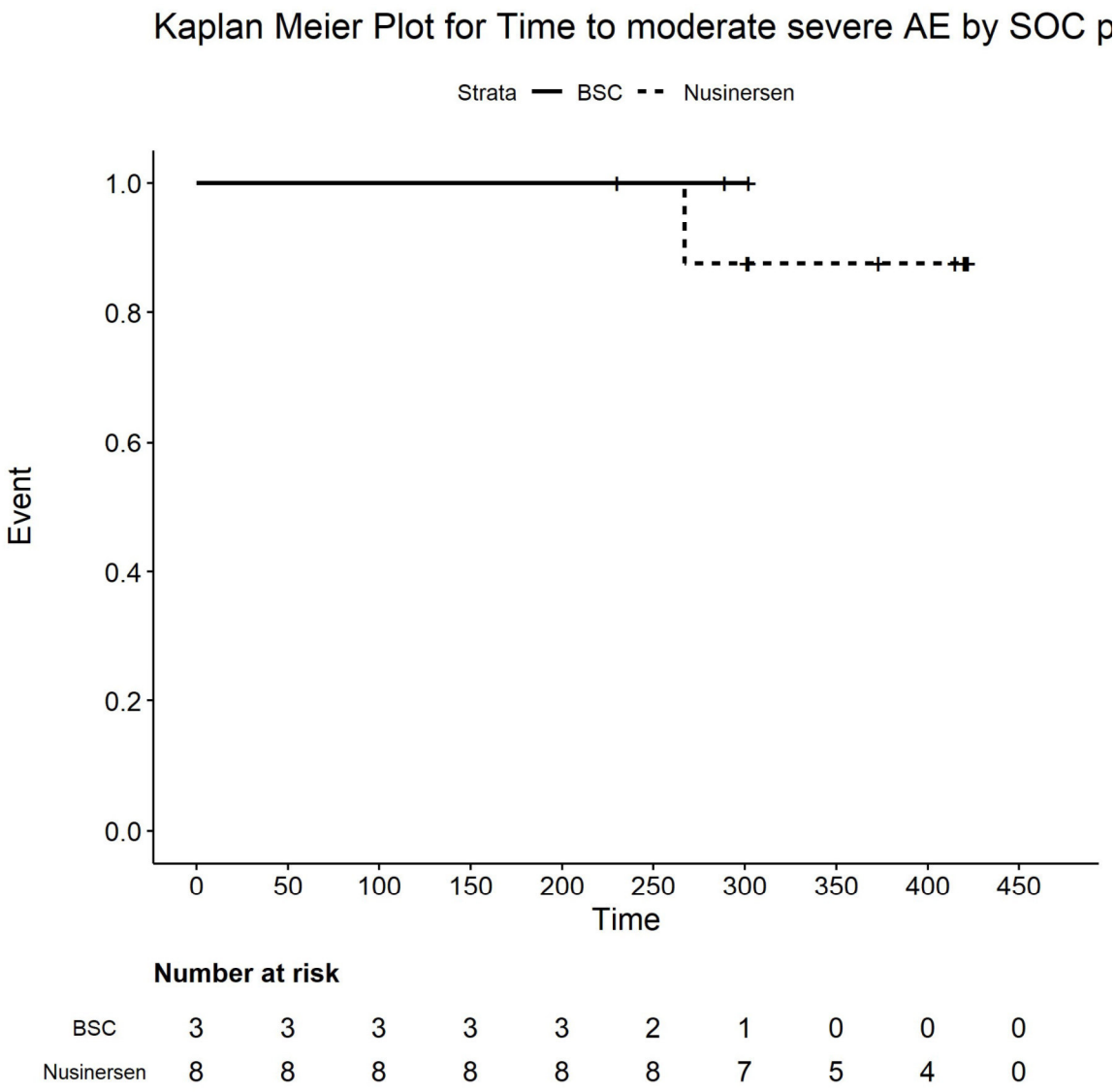
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	4	3	0



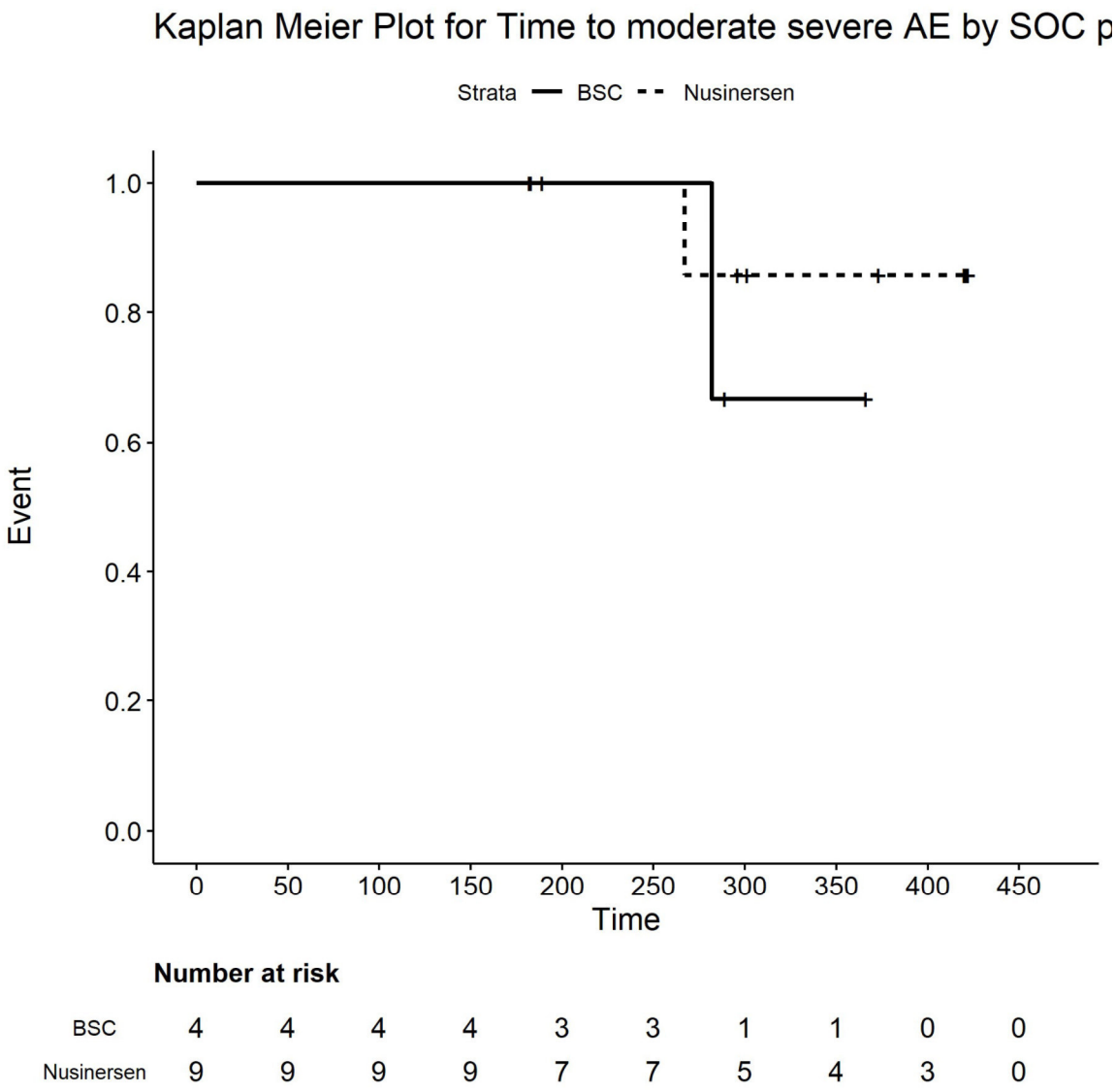
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



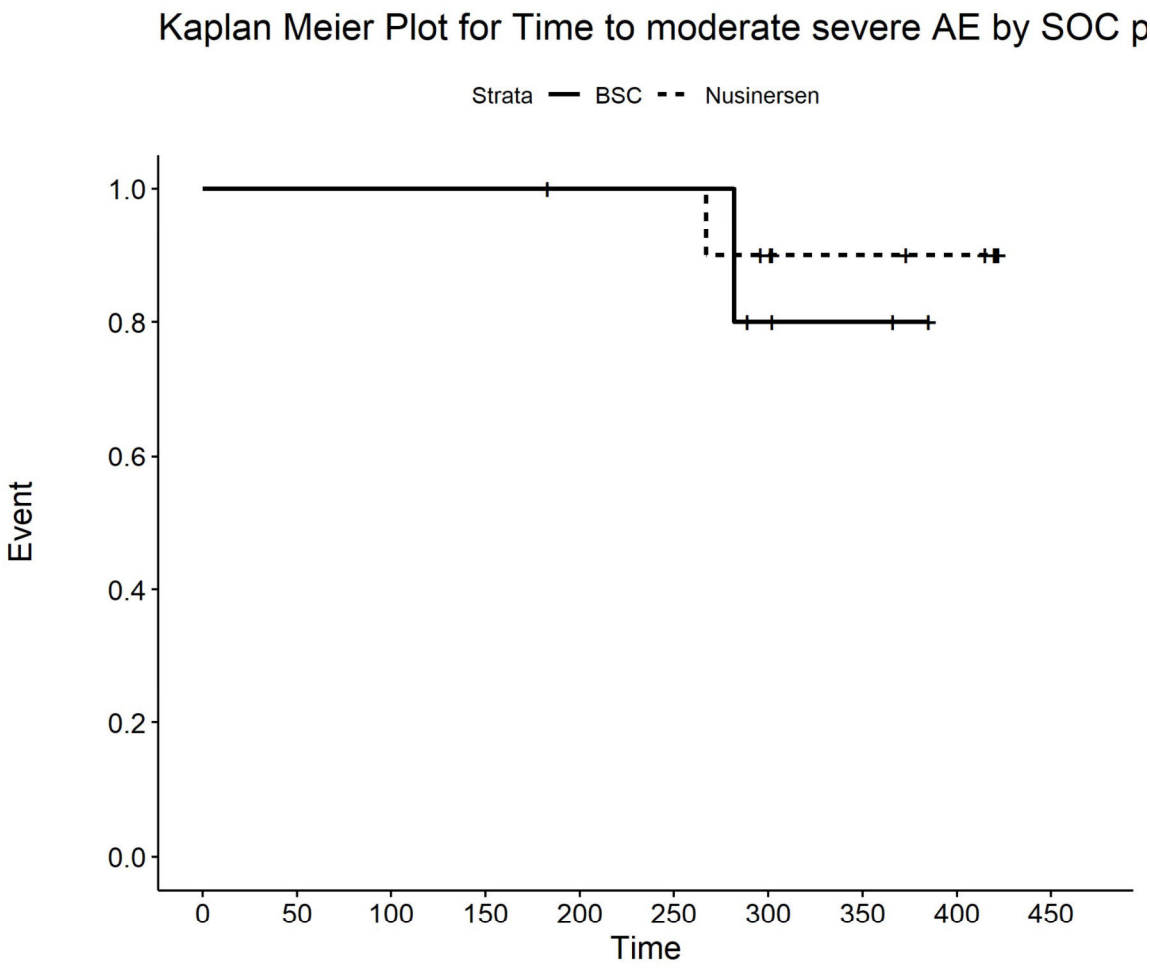
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	7	5	4	0



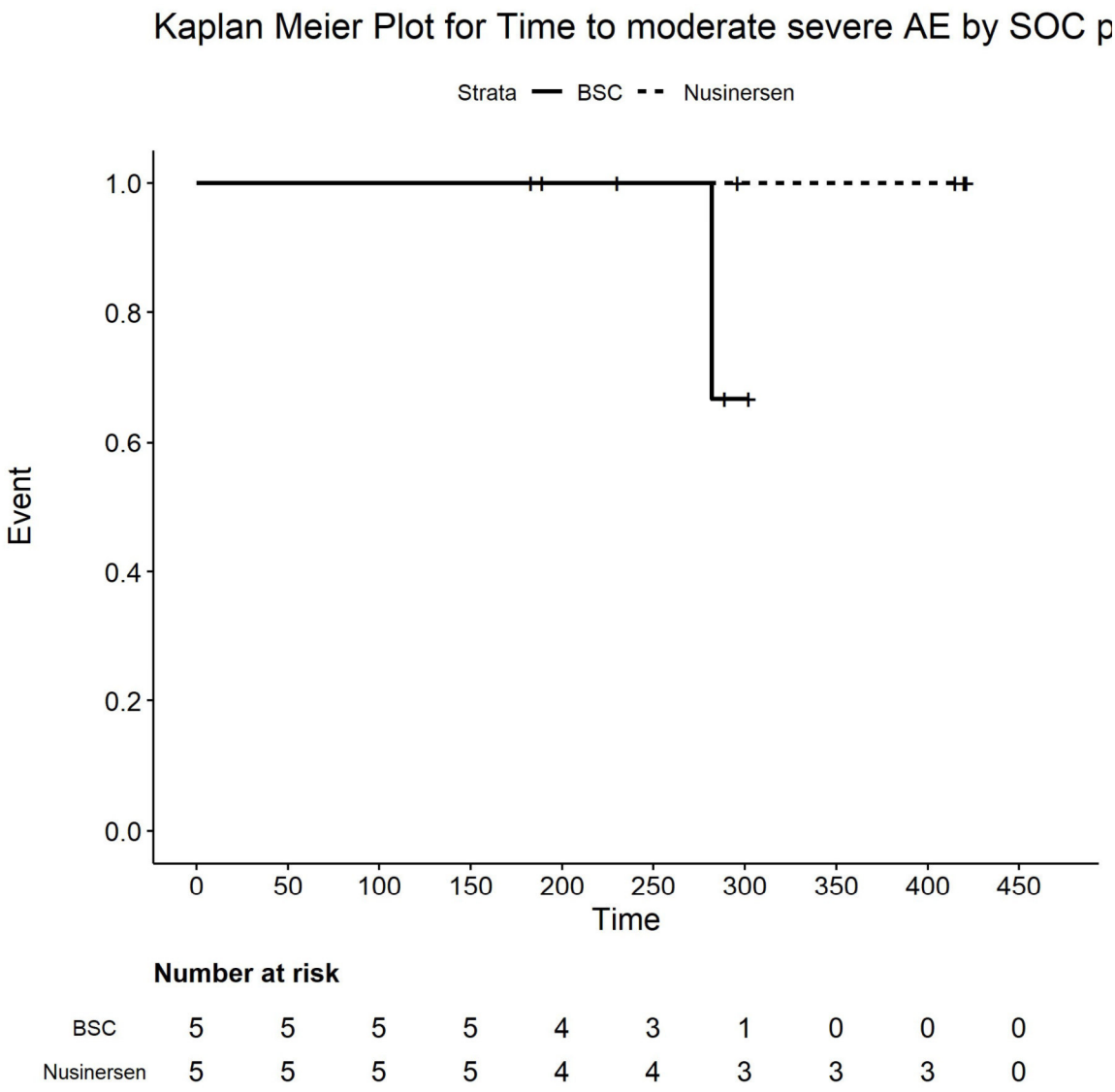
Number at risk

BSC	4	4	4	4	3	3	1	1	0	0
Nusinersen	9	9	9	9	7	7	5	4	3	0



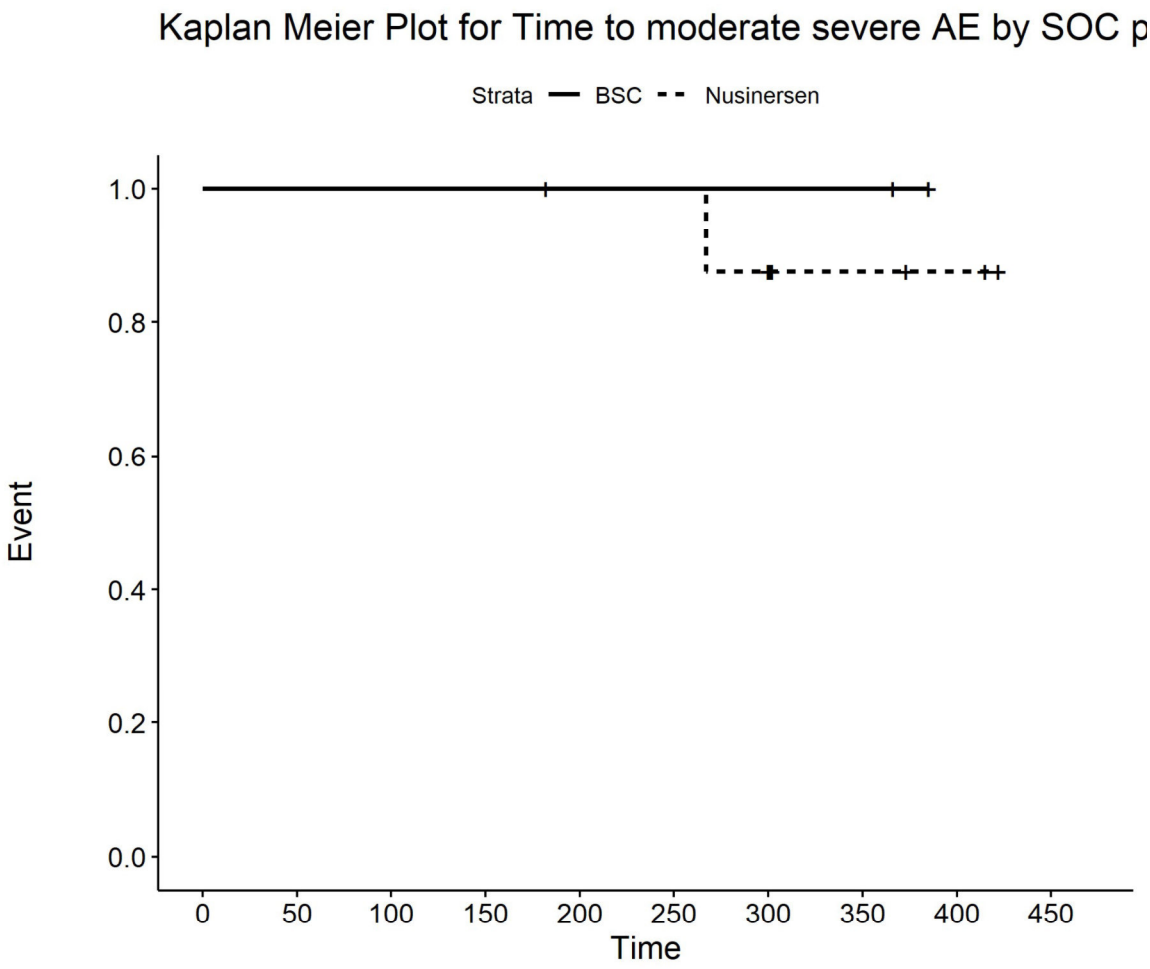
Number at risk

BSC	6	6	6	6	5	5	3	2	0	0
Nusinersen	10	10	10	10	10	10	8	6	5	0



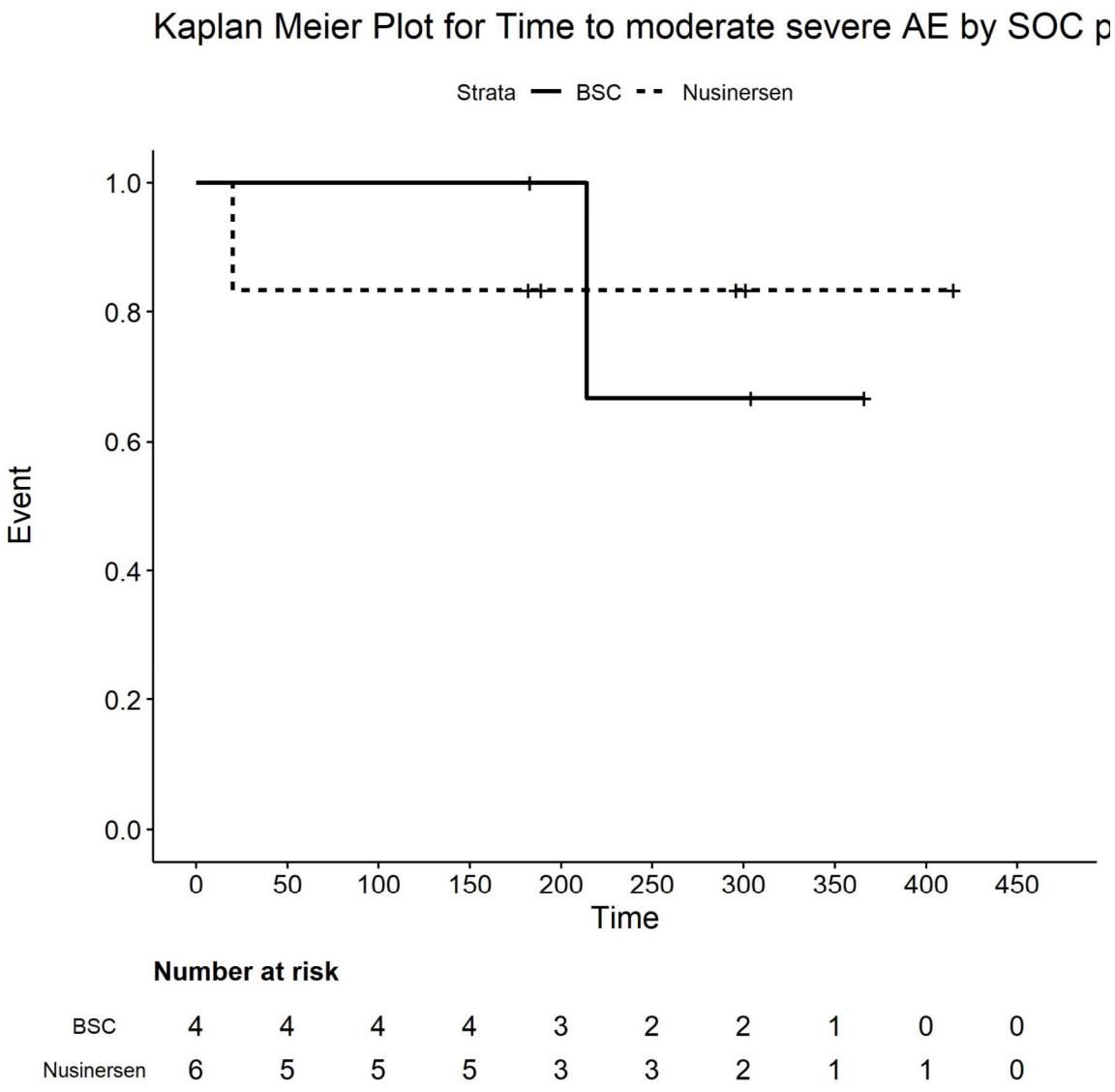
Number at risk

BSC	5	5	5	5	4	3	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



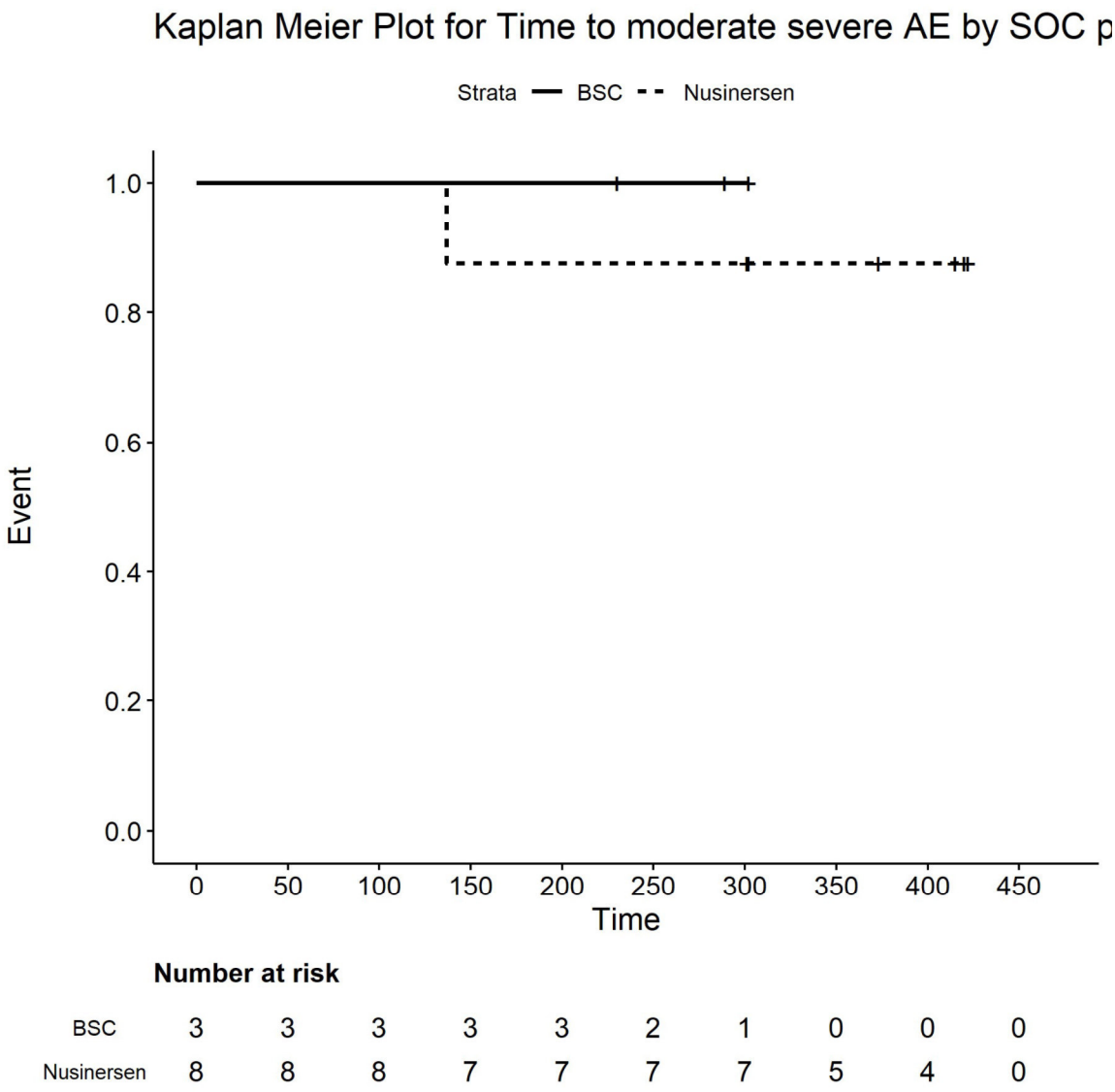
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	7	3	2	0



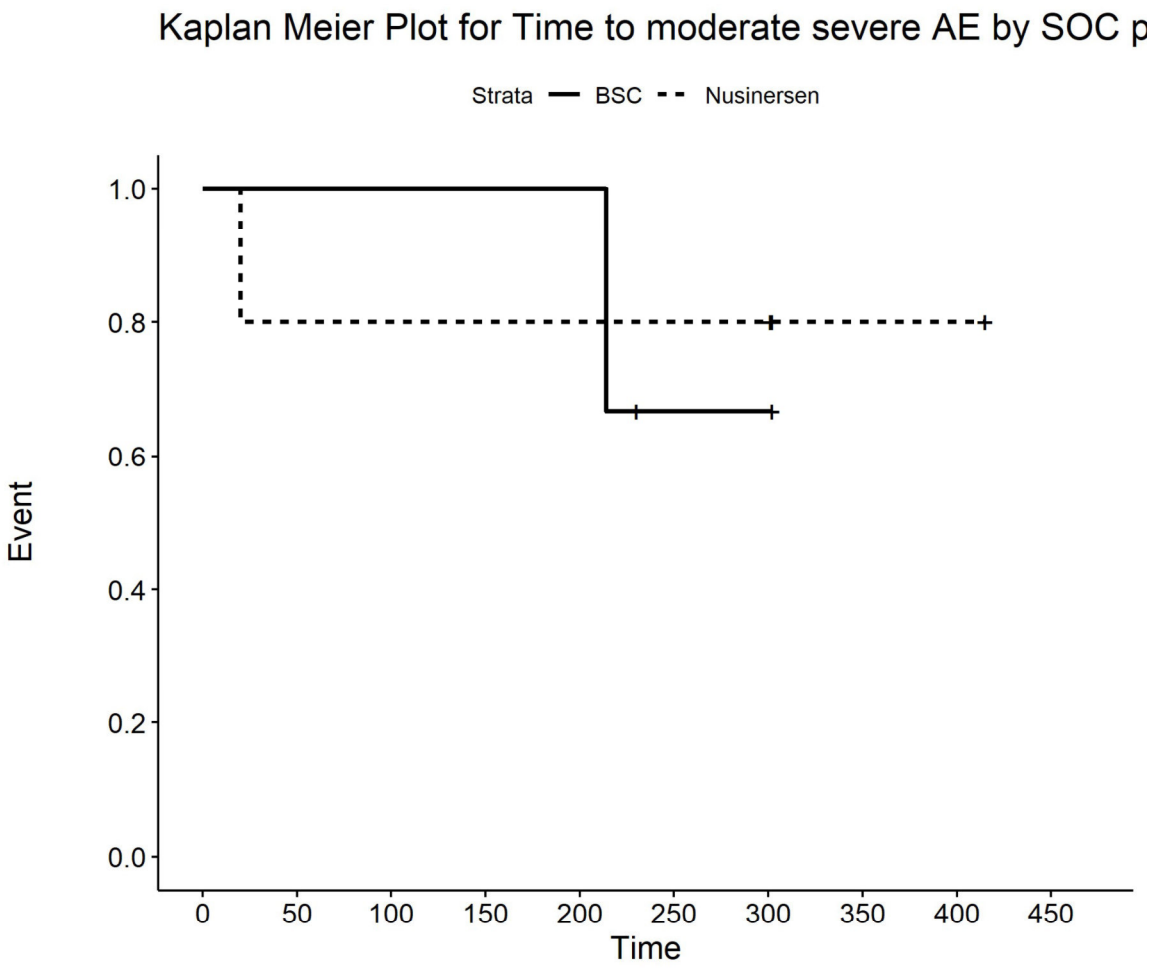
Number at risk

BSC	4	4	4	4	3	2	2	1	0	0
Nusinersen	6	5	5	5	3	3	2	1	1	0



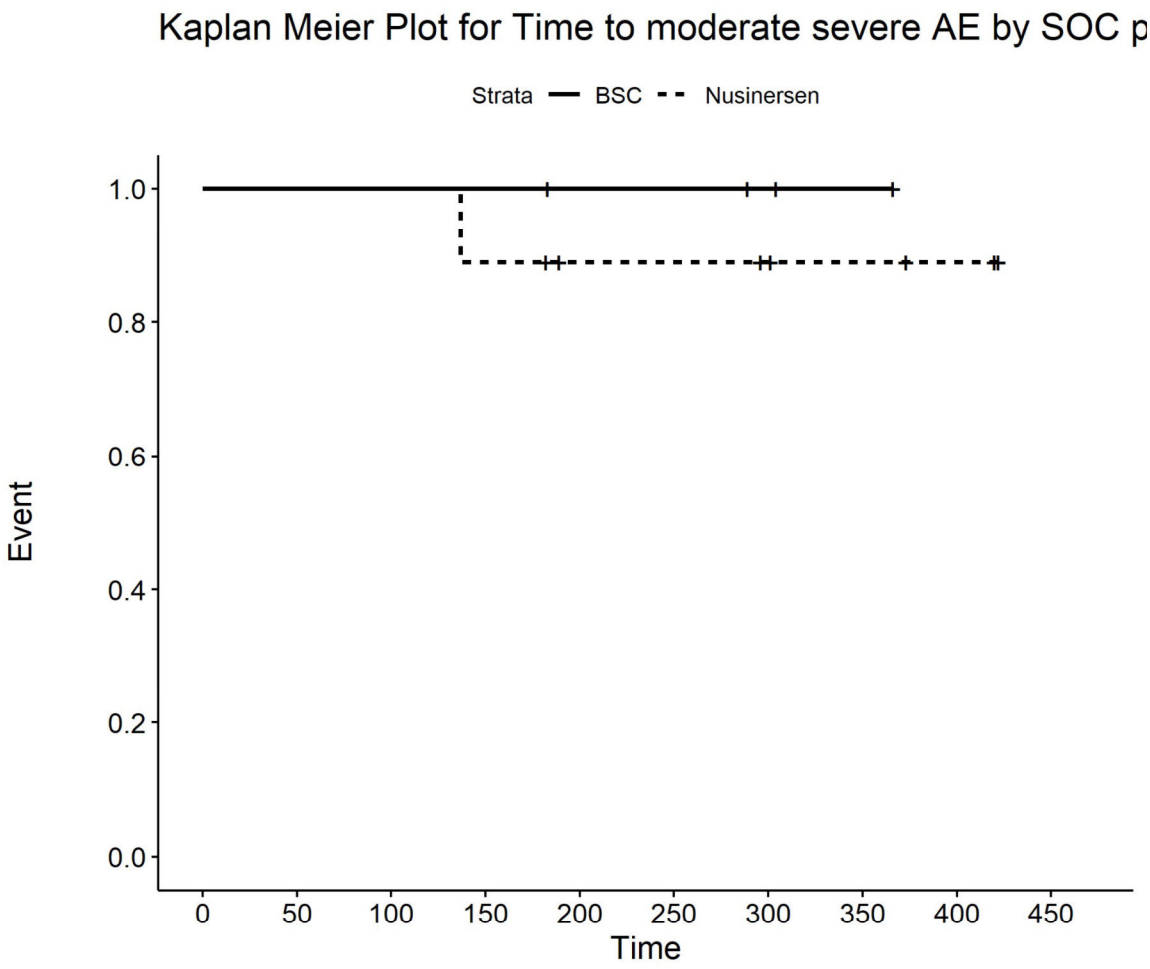
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



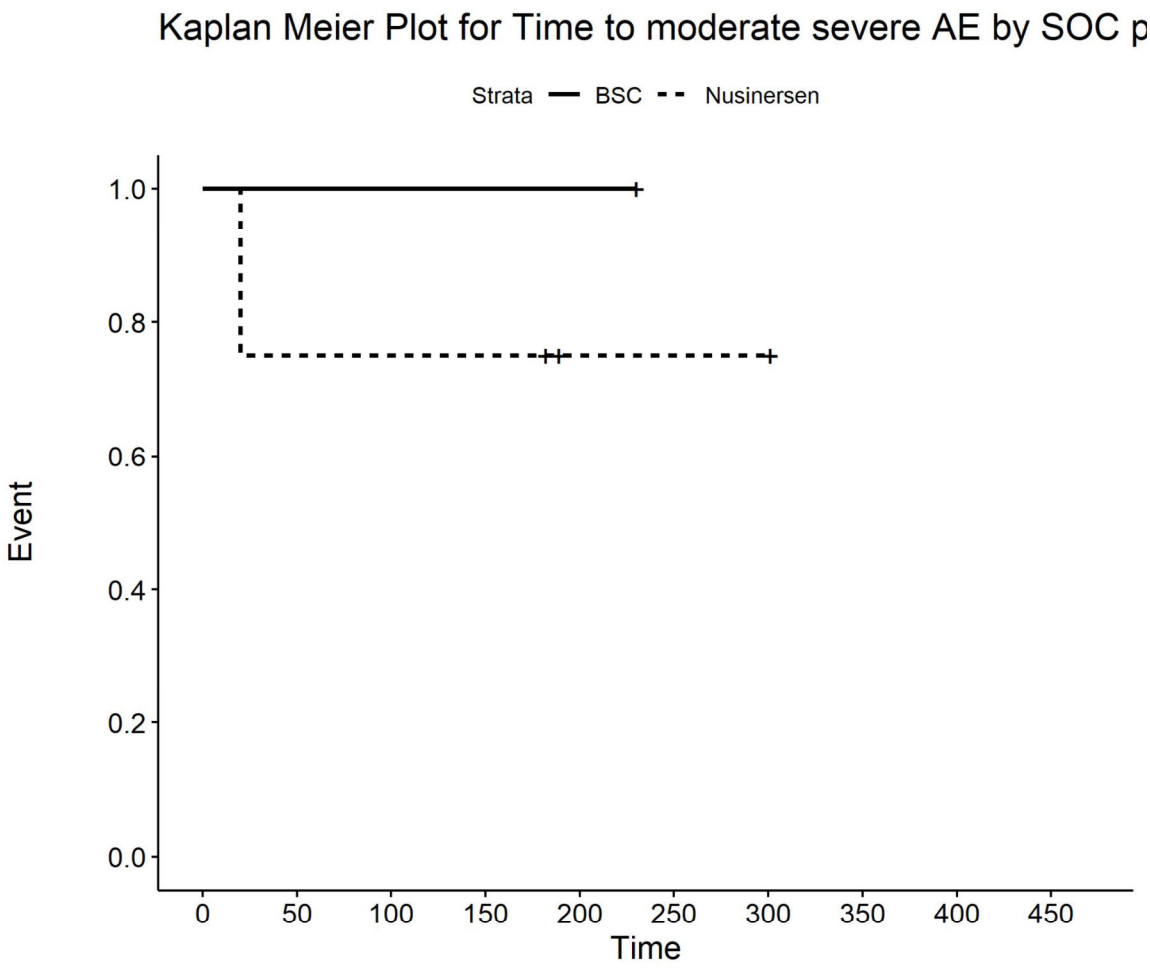
Number at risk

BSC	3	3	3	3	3	1	1	0	0	0
Nusinersen	5	4	4	4	4	4	4	2	2	0



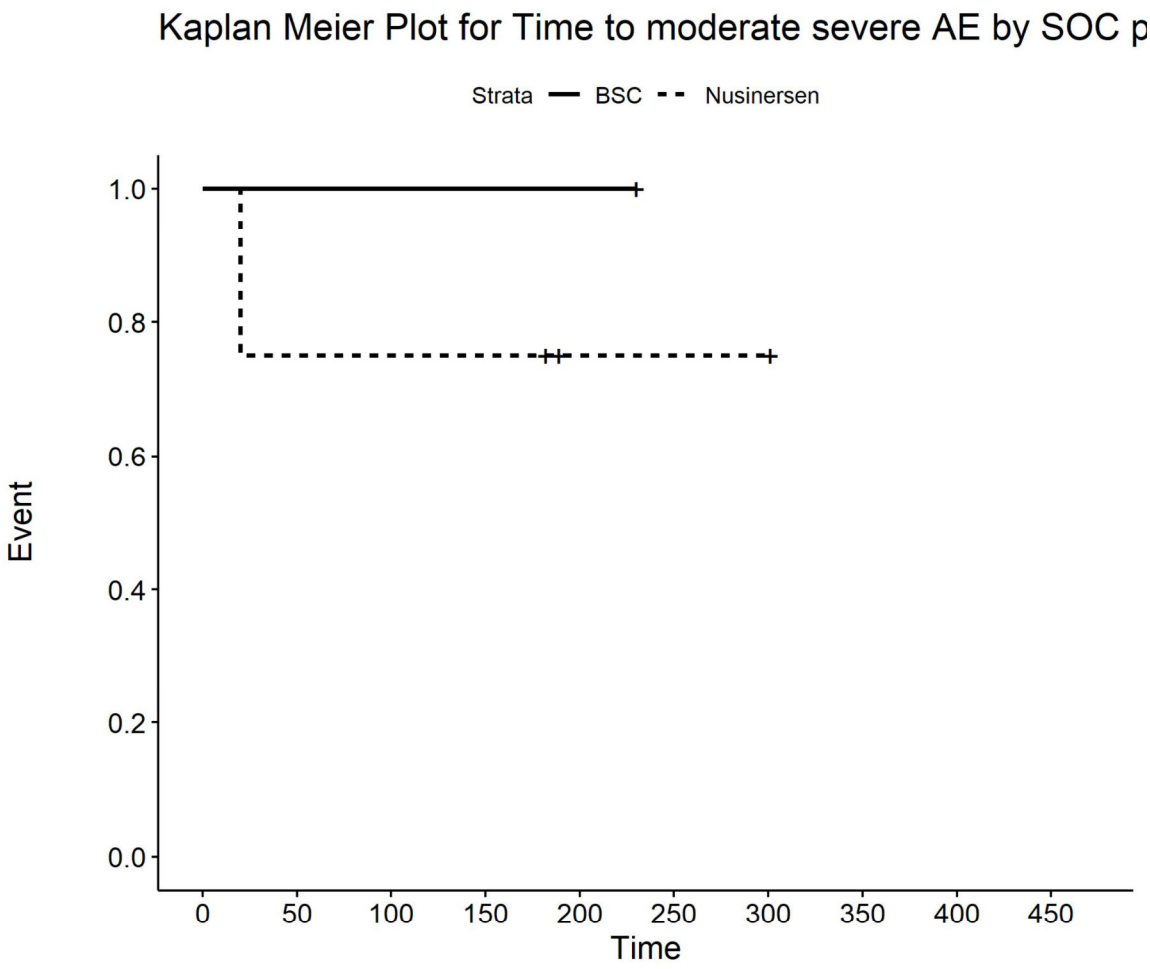
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



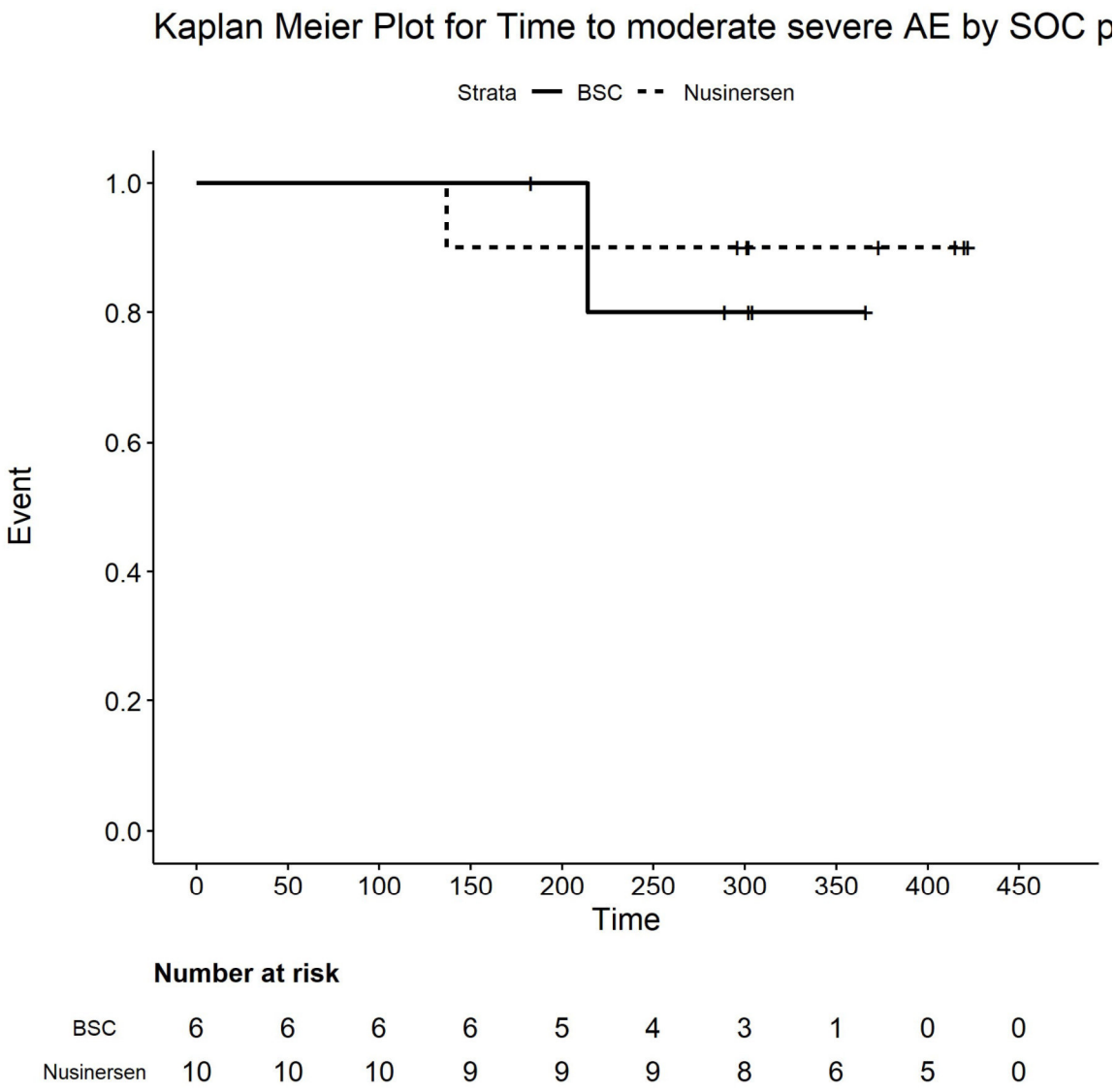
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



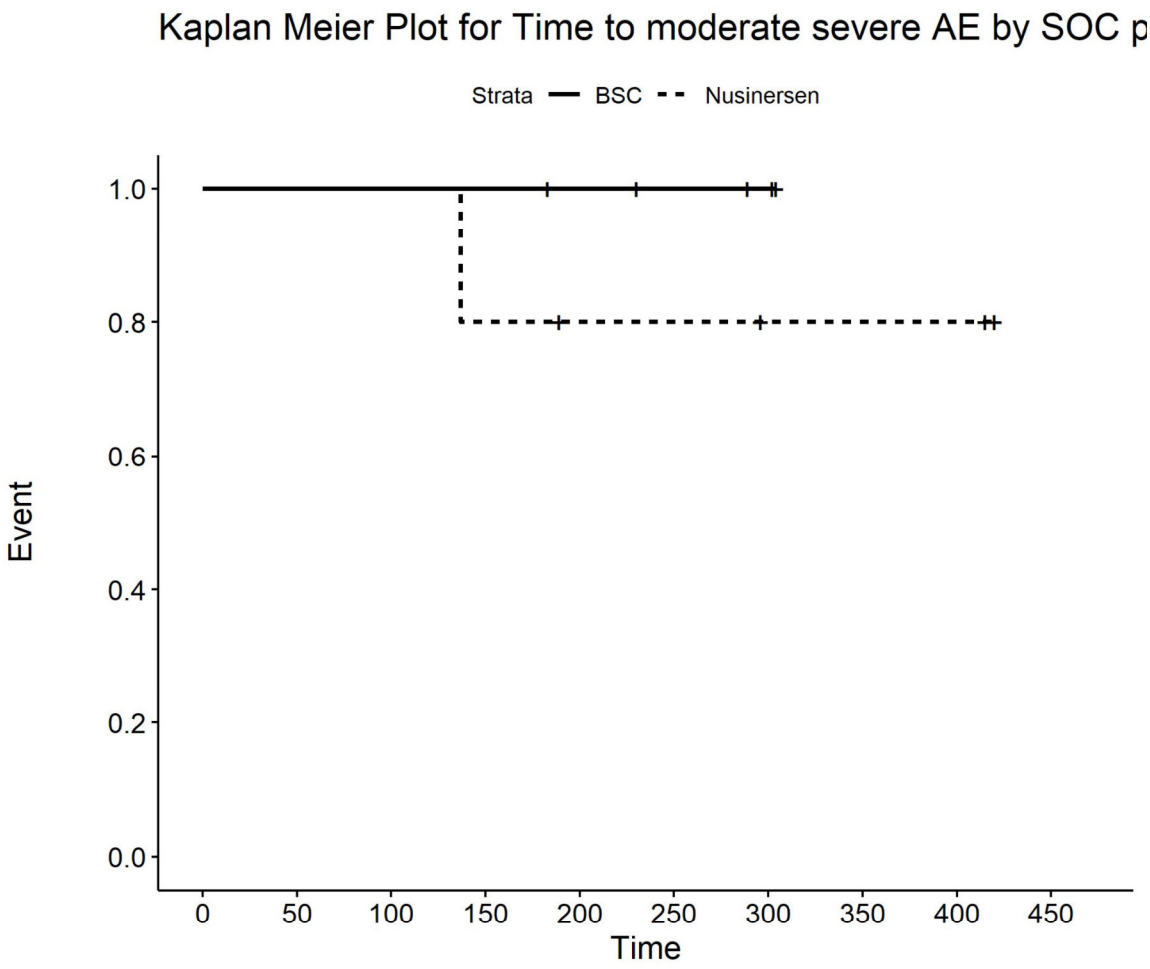
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



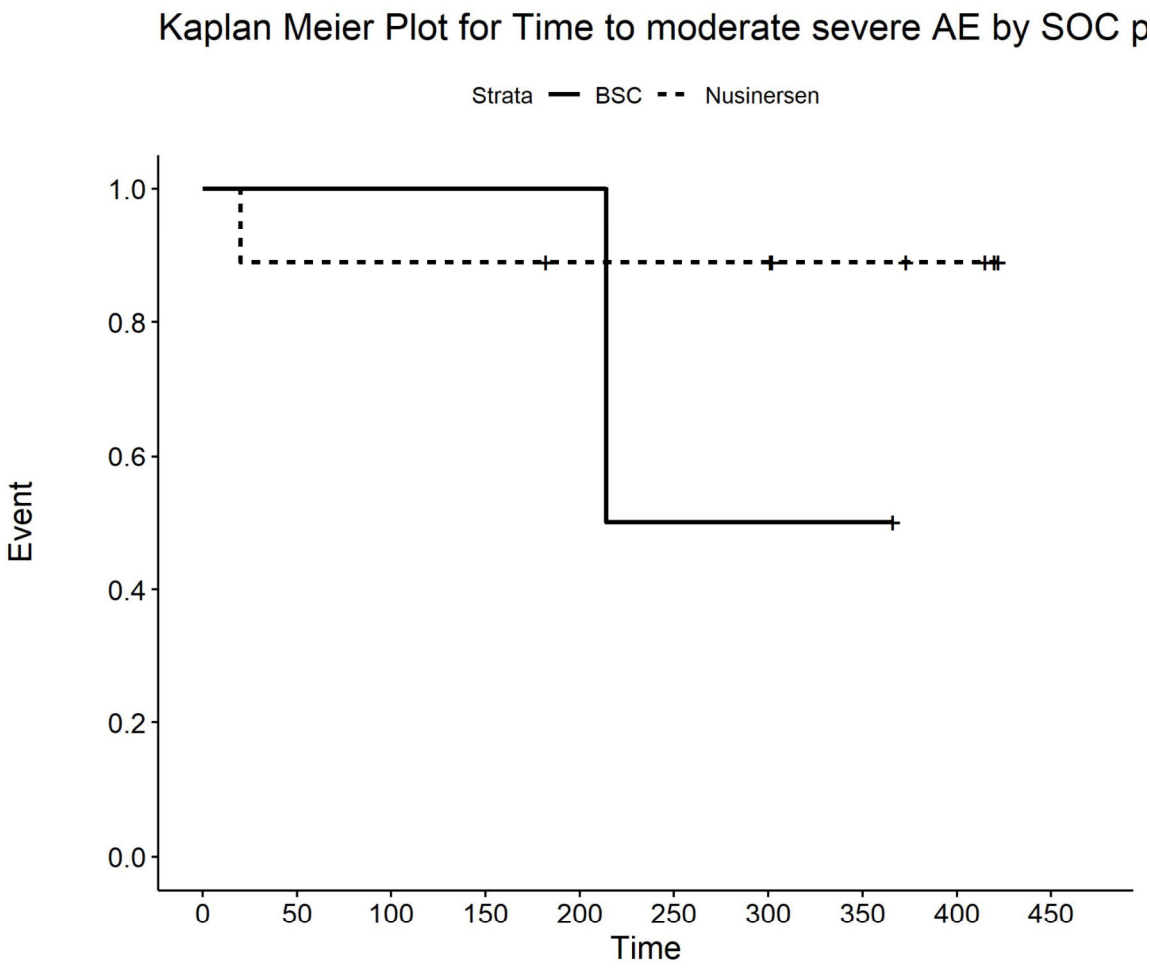
Number at risk

BSC	6	6	6	6	5	4	3	1	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



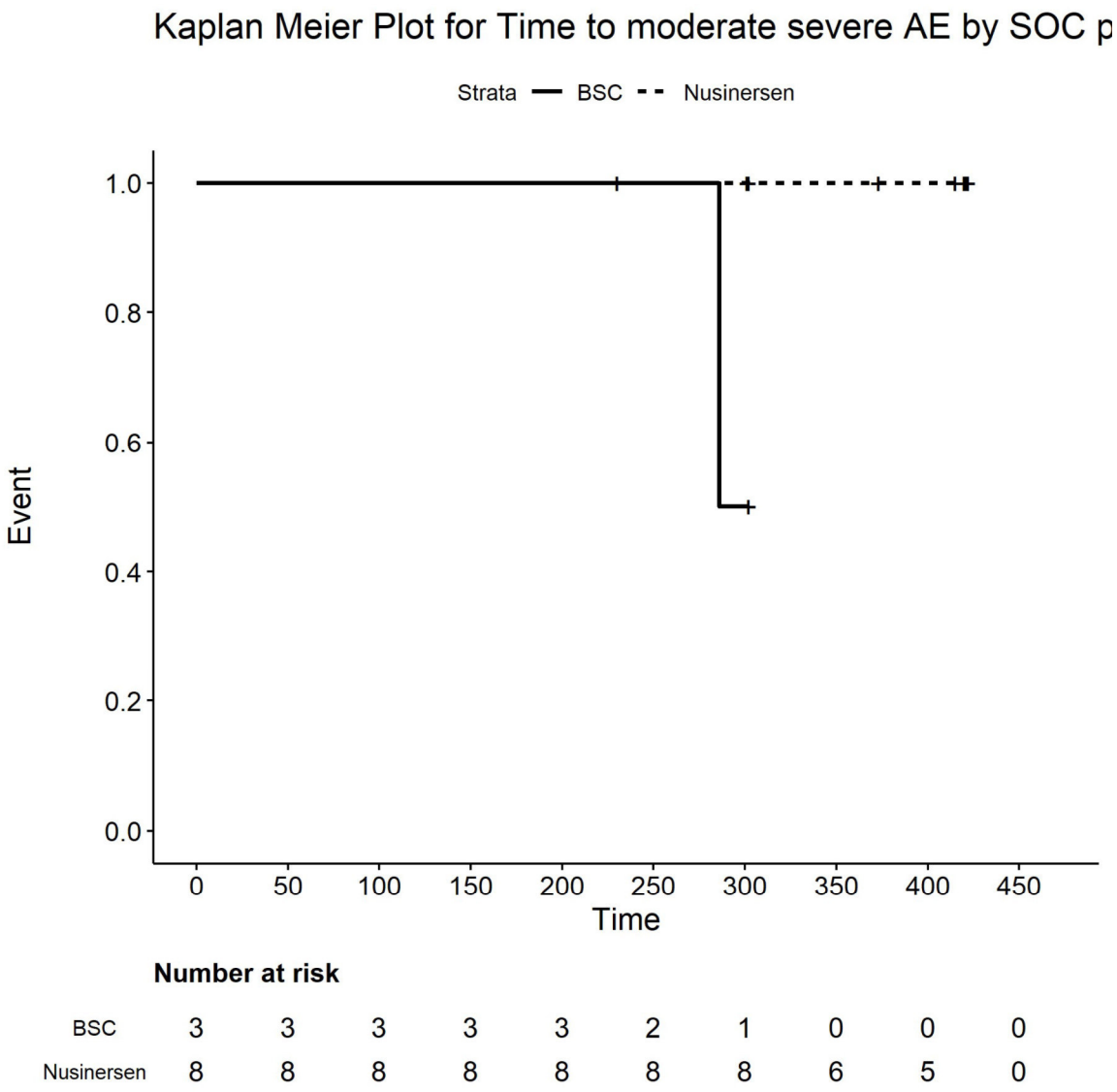
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	4	3	3	2	2	2	0



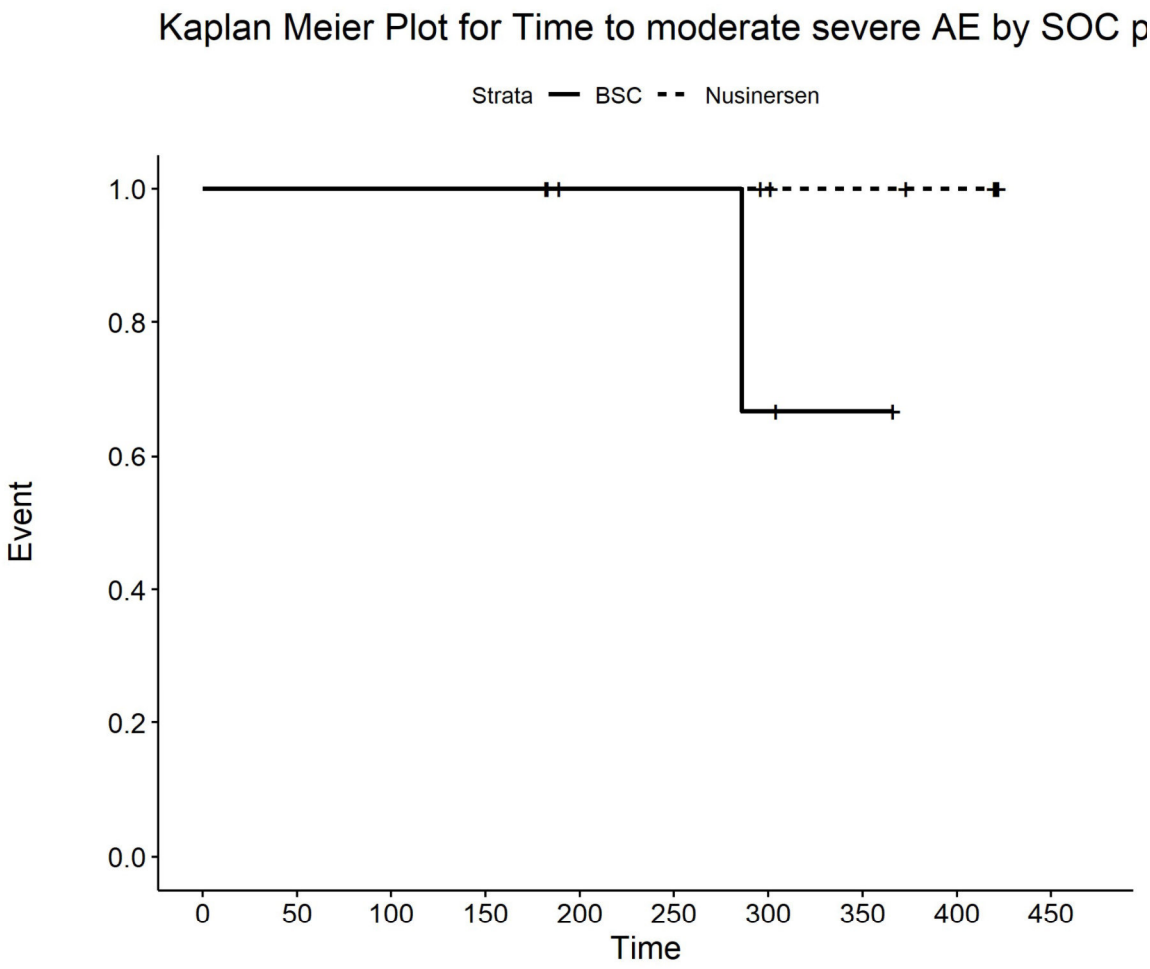
Number at risk

BSC	2	2	2	2	2	1	1	1	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



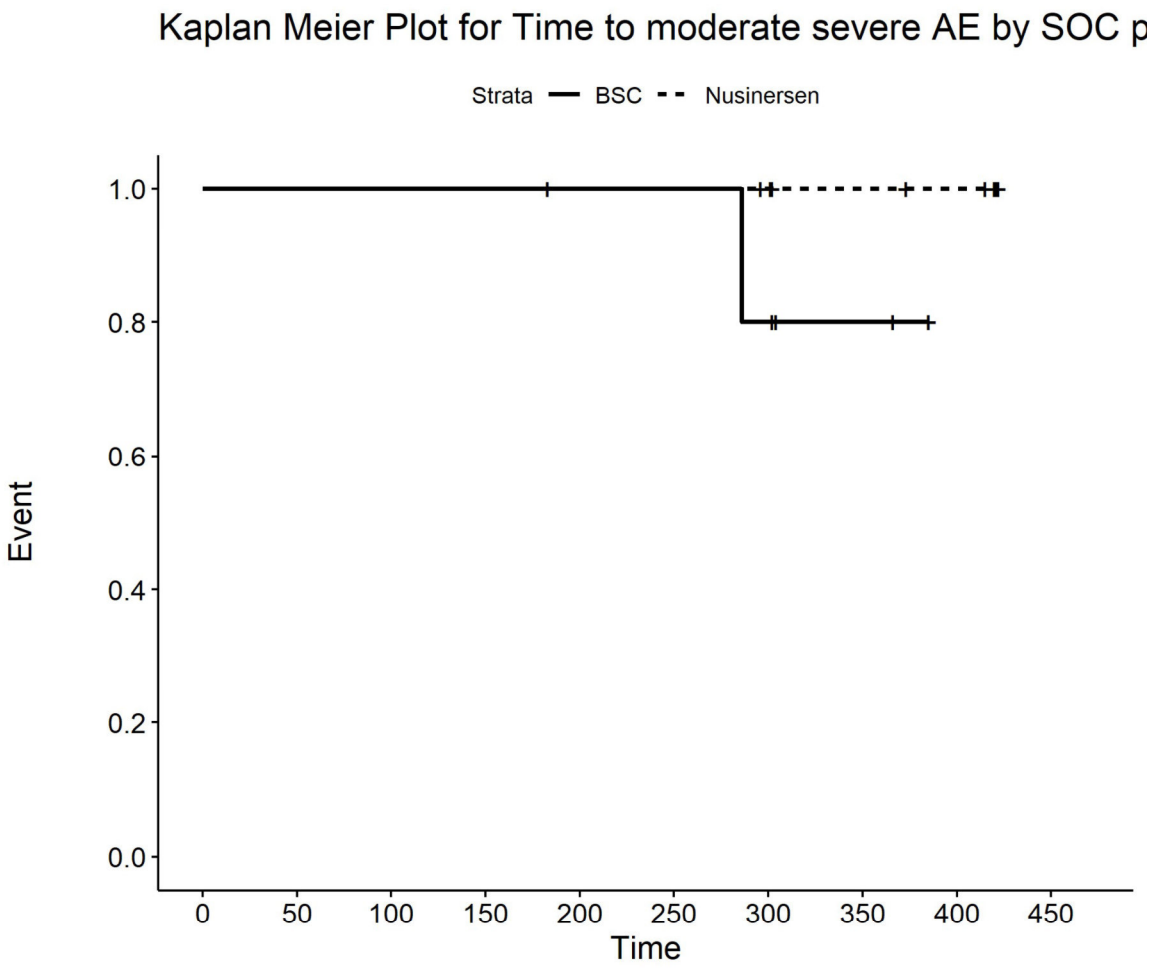
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



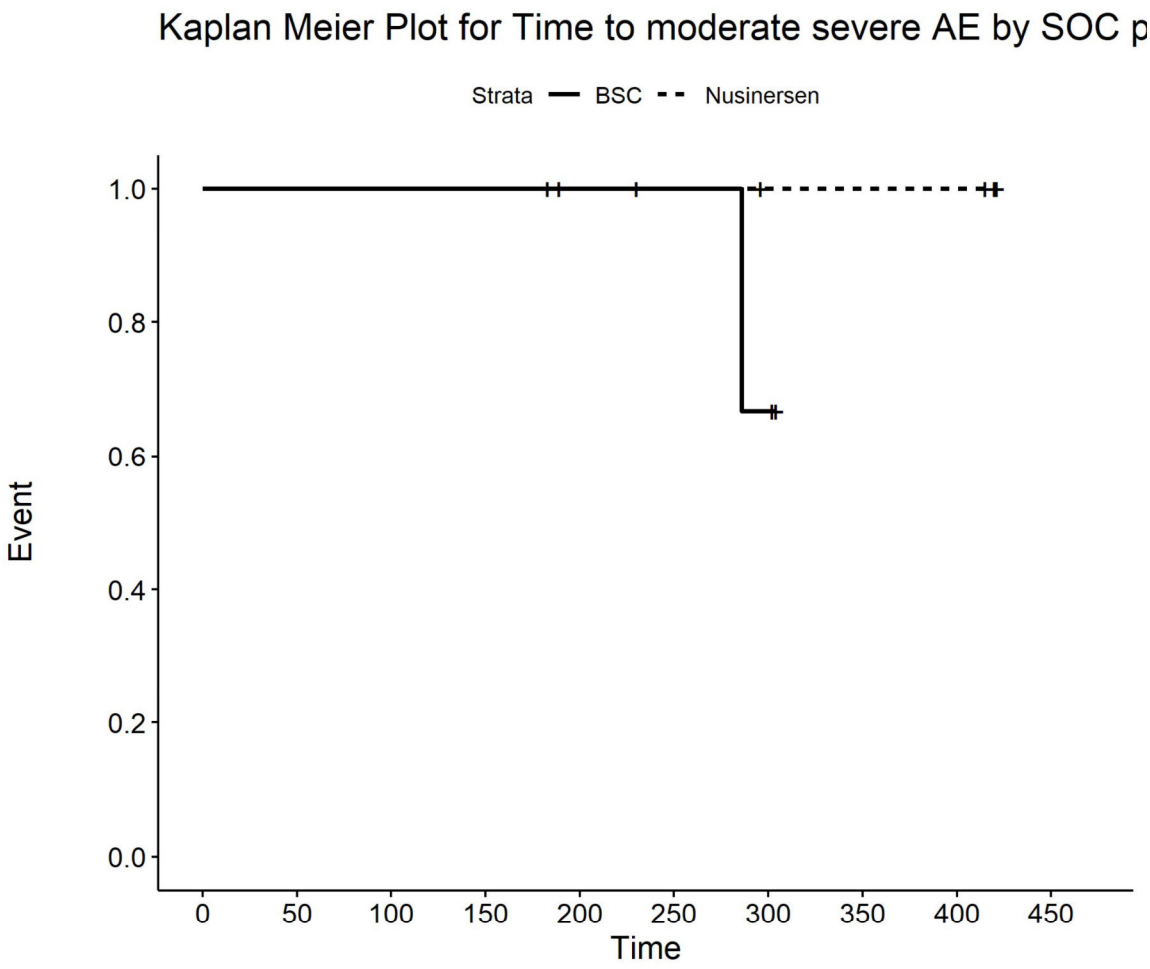
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



Number at risk

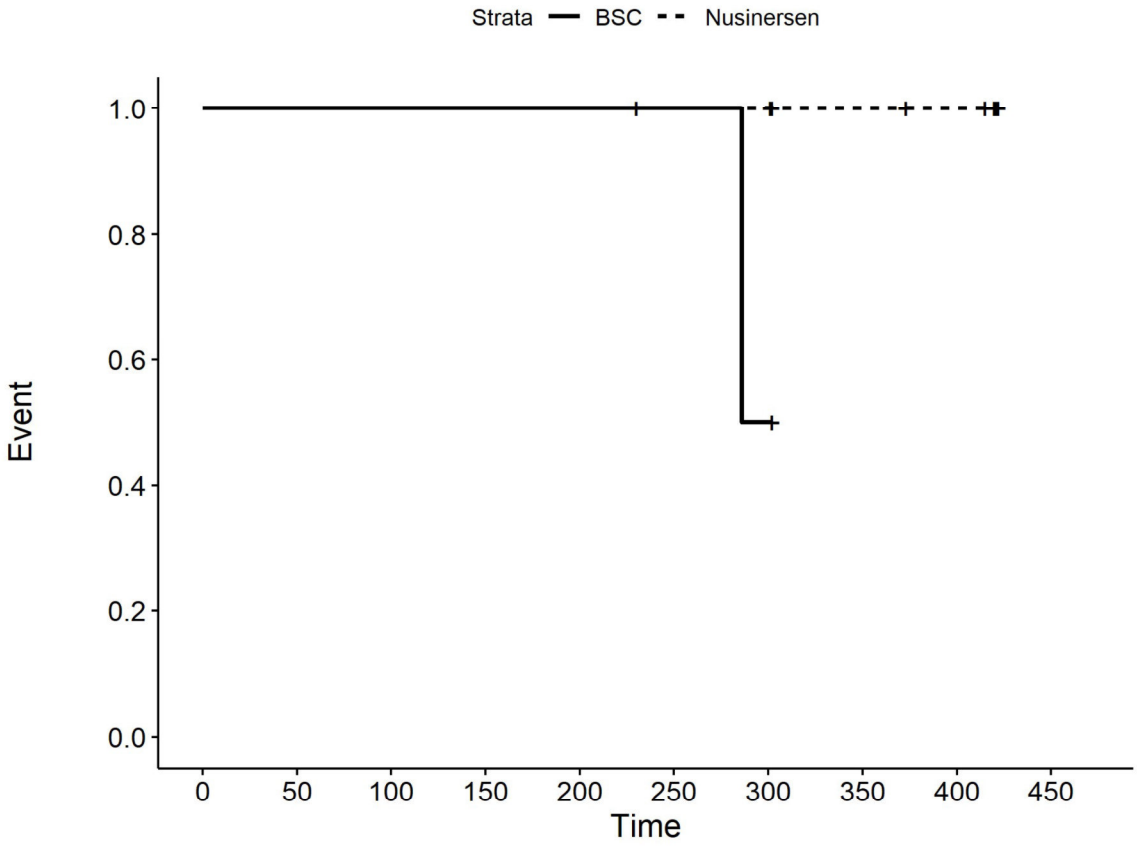
BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0

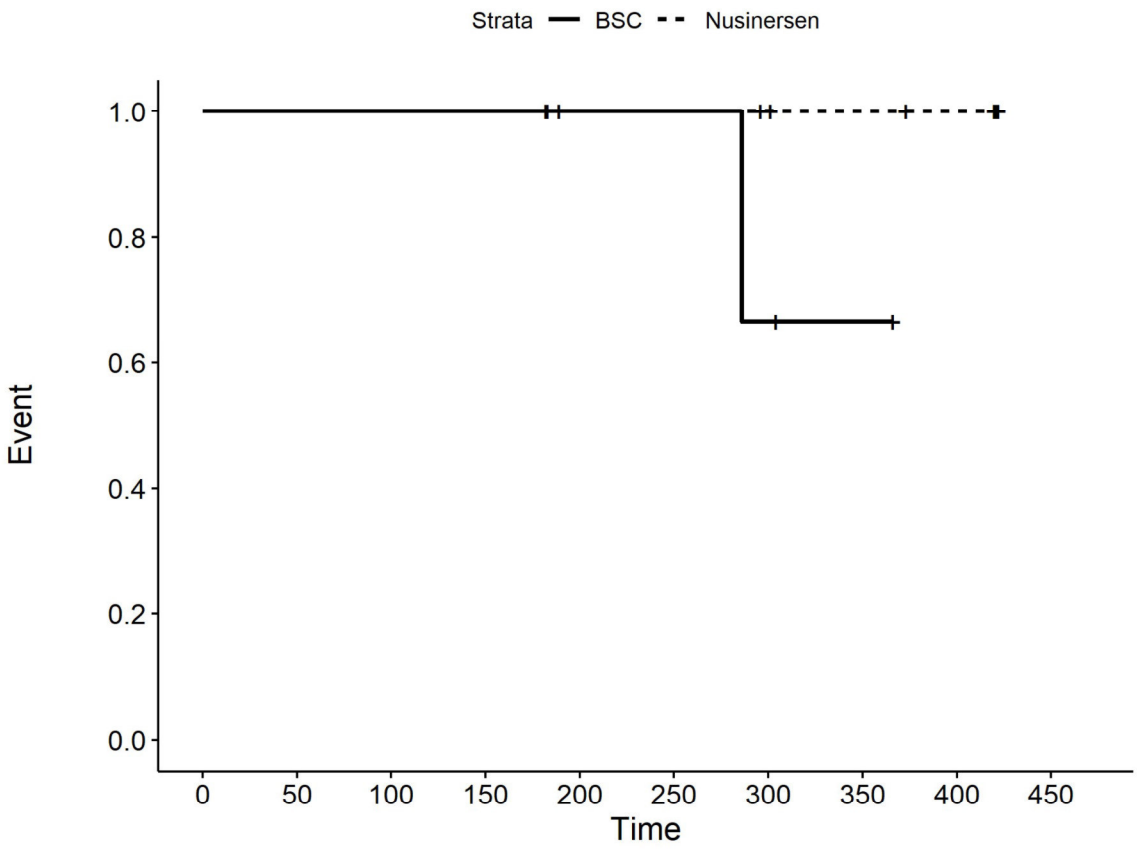
Kaplan Meier Plot for
Time to moderate severe AE by SOC pct SG Cardio : respira



Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0

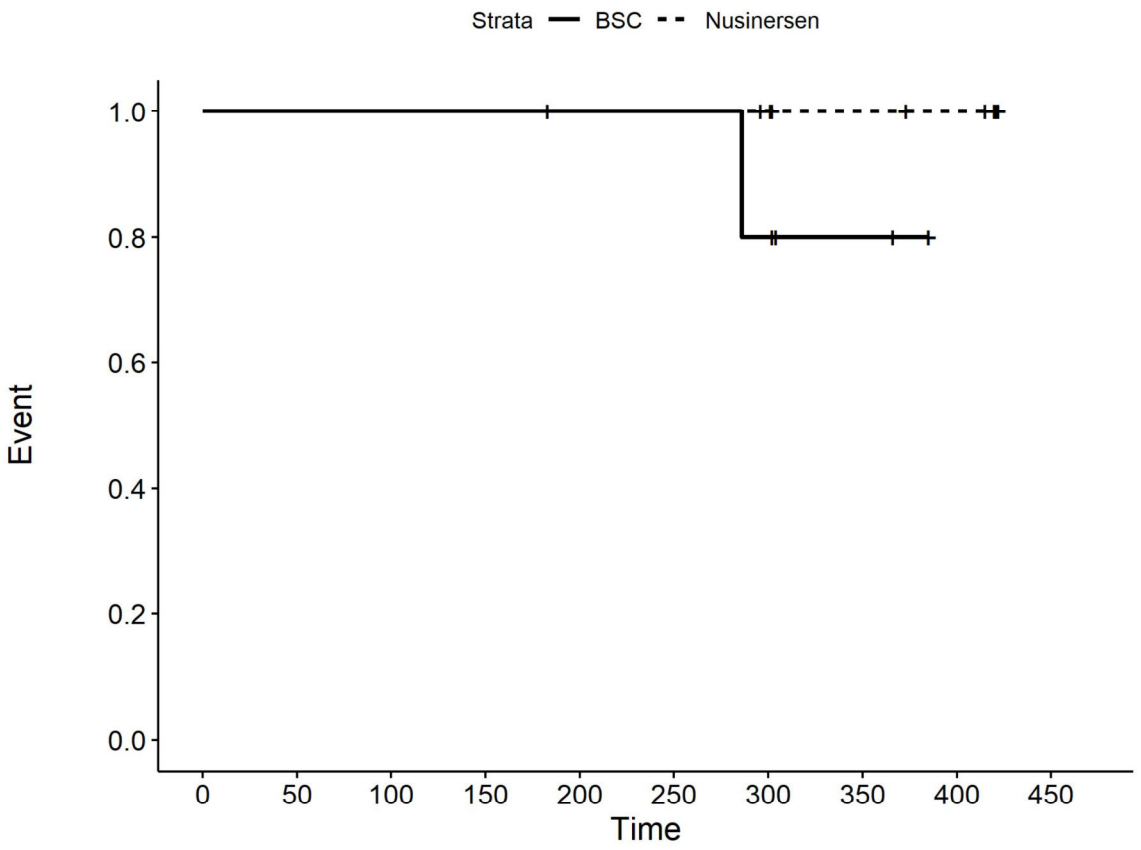
Kaplan Meier Plot for
Time to moderate severe AE by SOC pct SG Cardio : respira



Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0

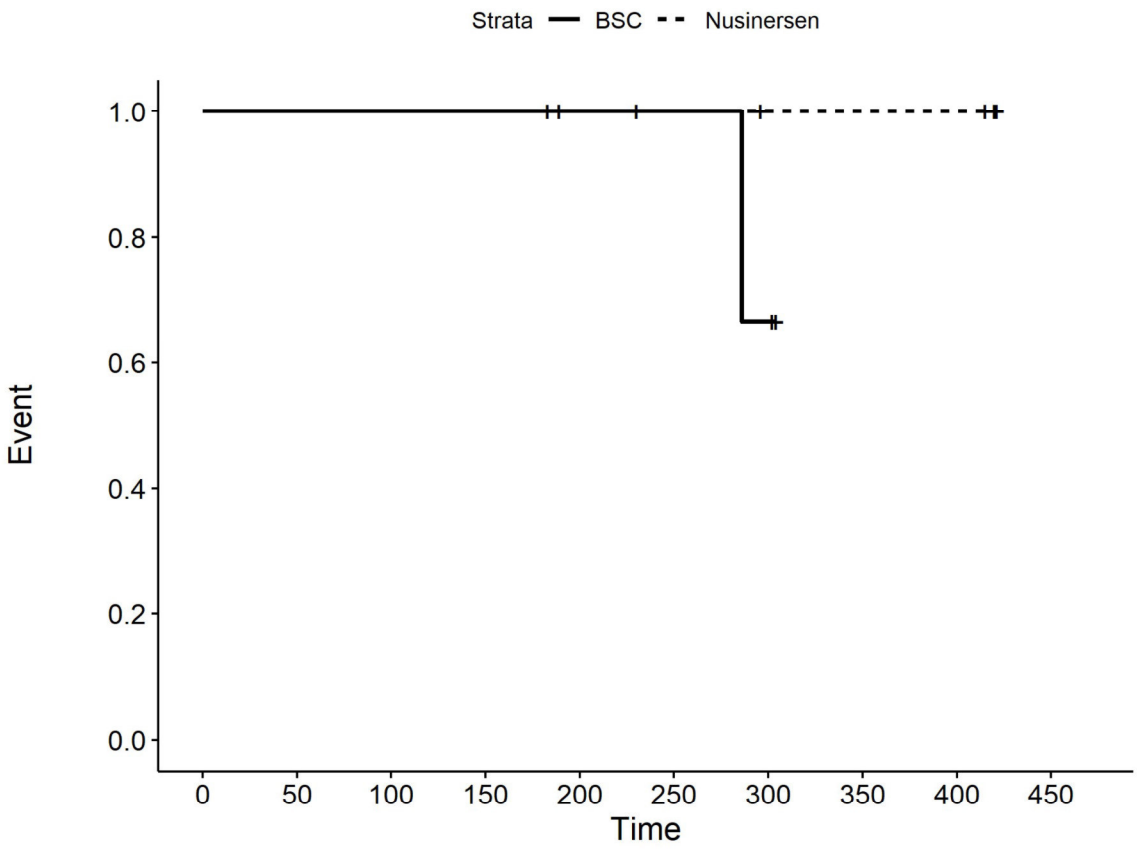
Kaplan Meier Plot for
Time to moderate severe AE by SOC pct SG Cardio : respira



Number at risk

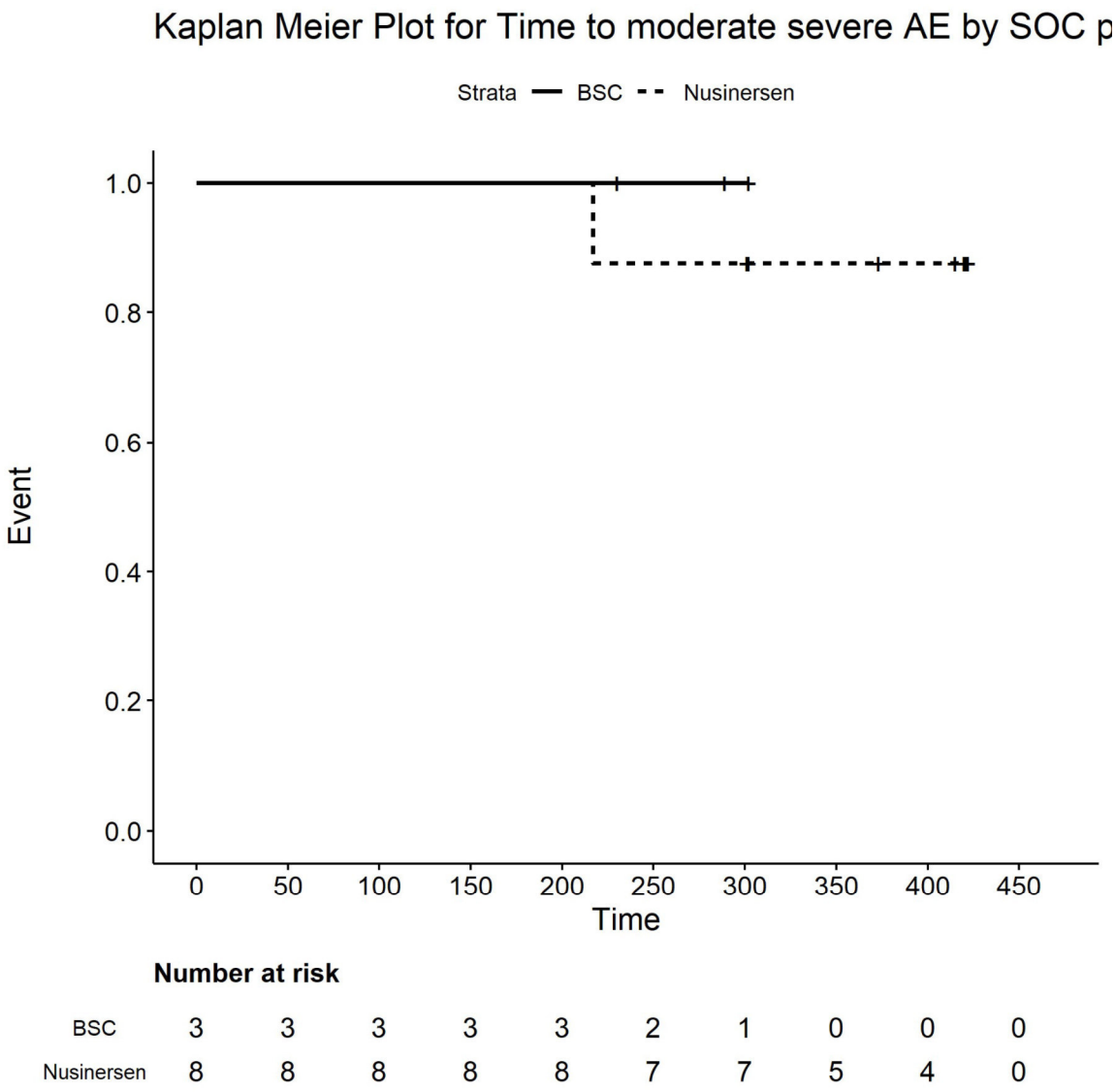
BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0

Kaplan Meier Plot for
Time to moderate severe AE by SOC pct SG Cardio : respira



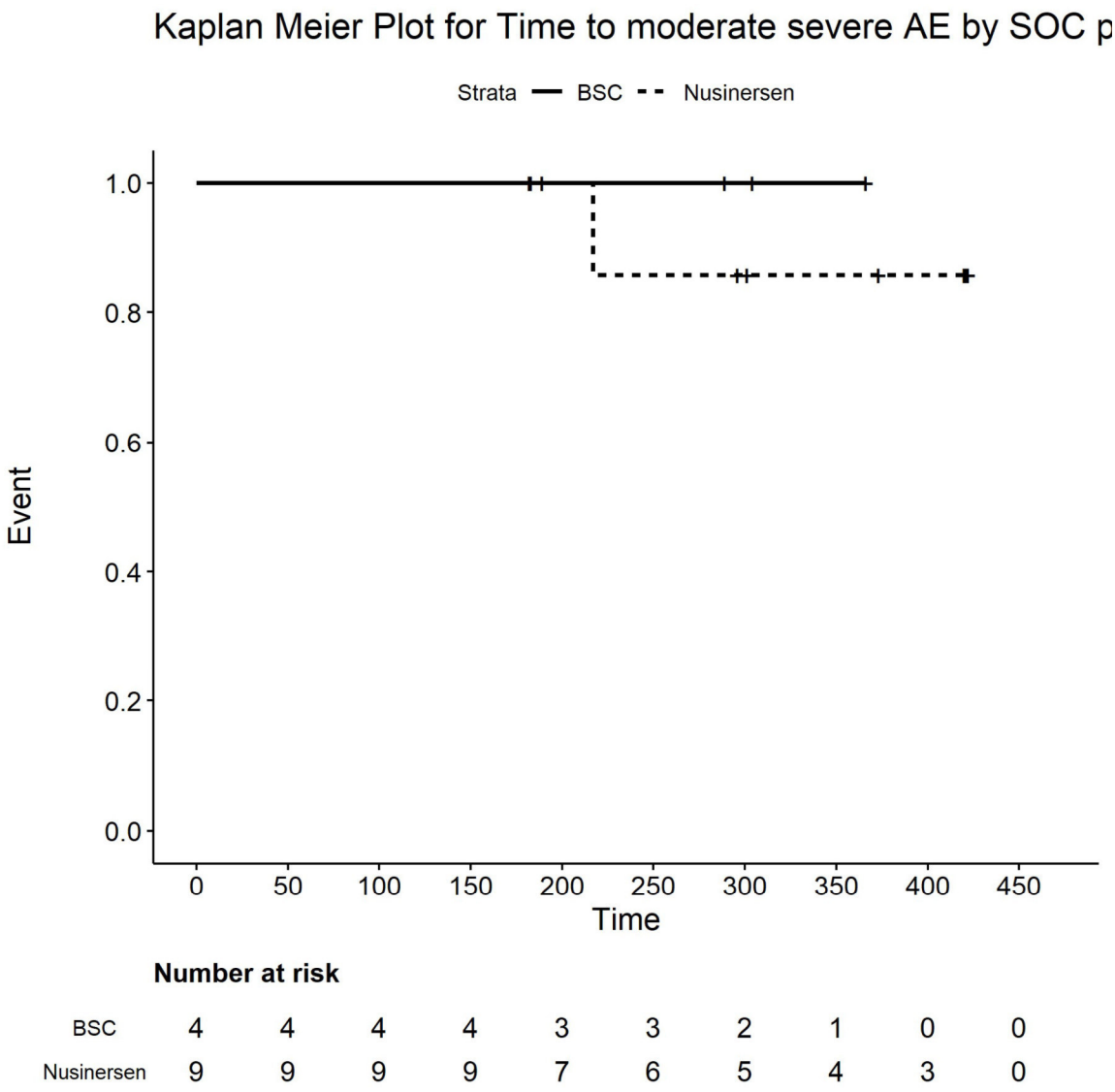
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



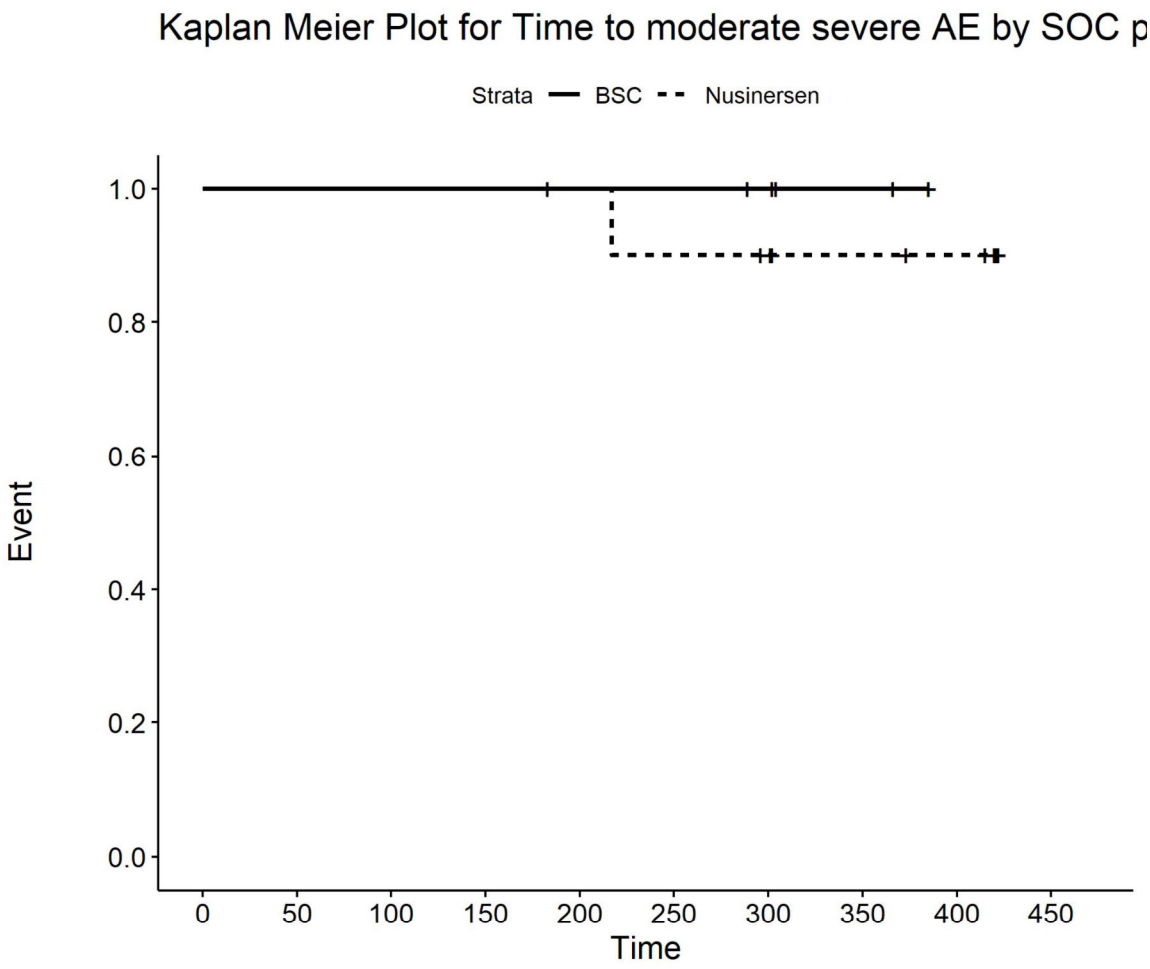
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



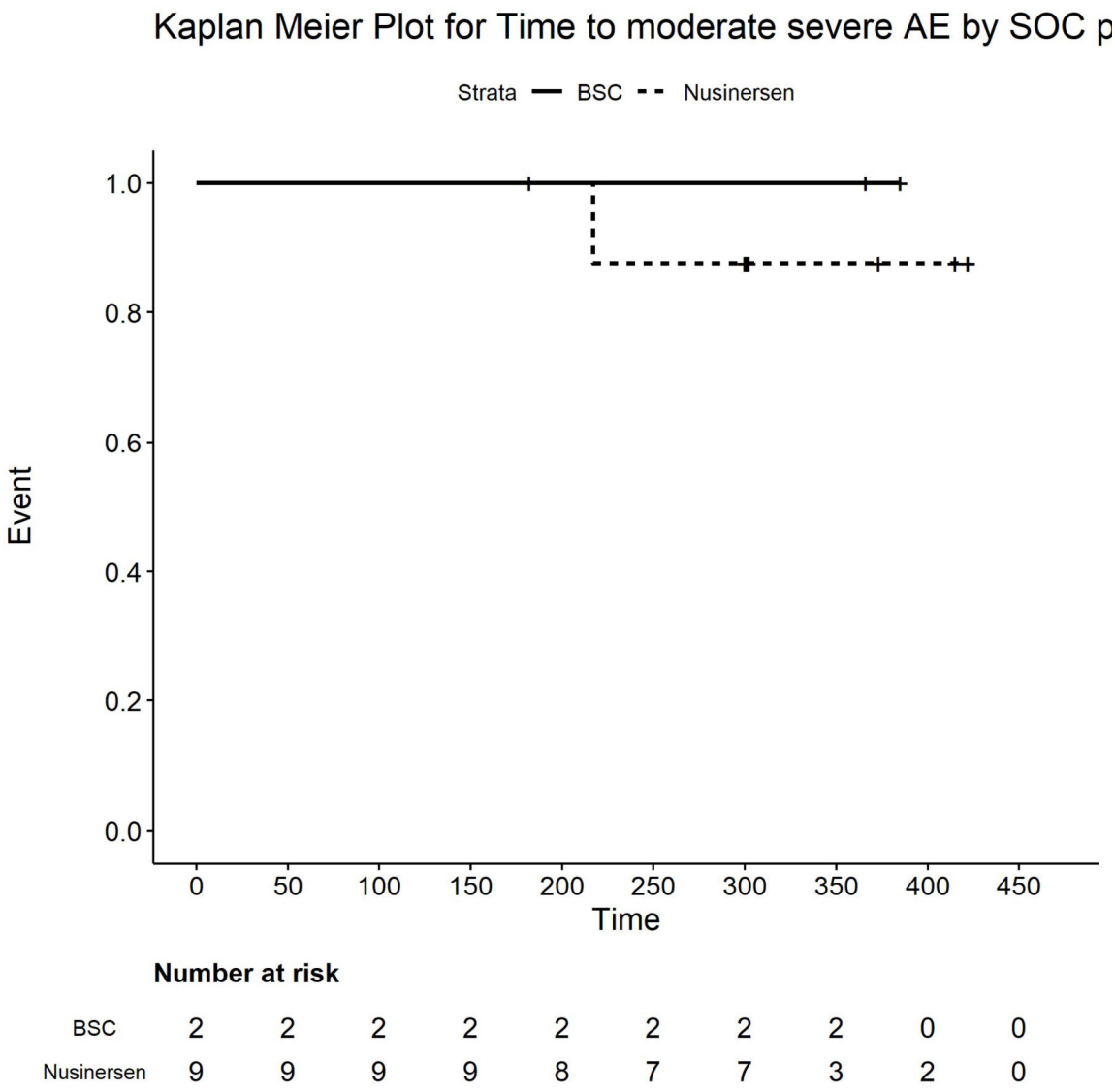
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



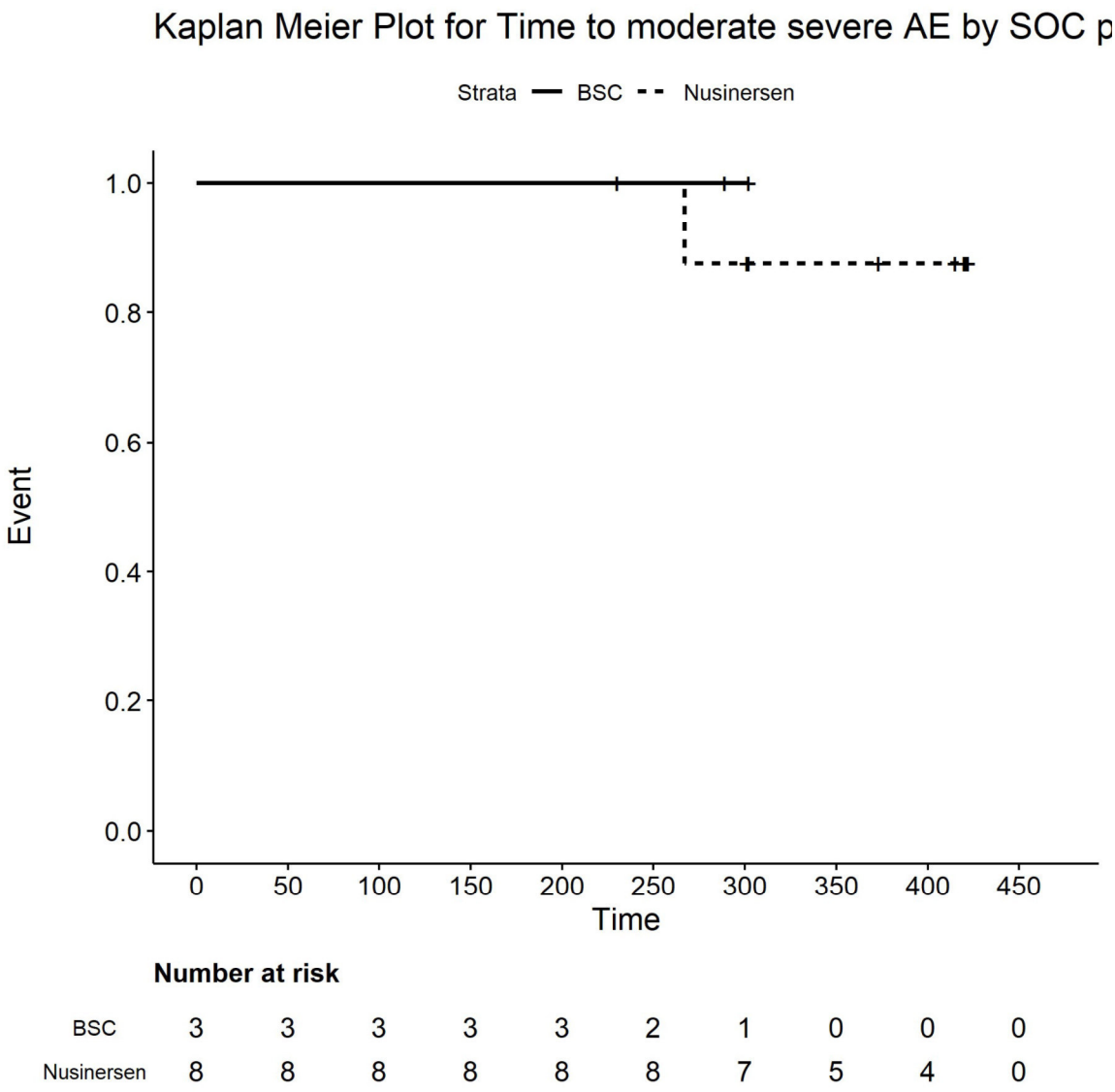
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



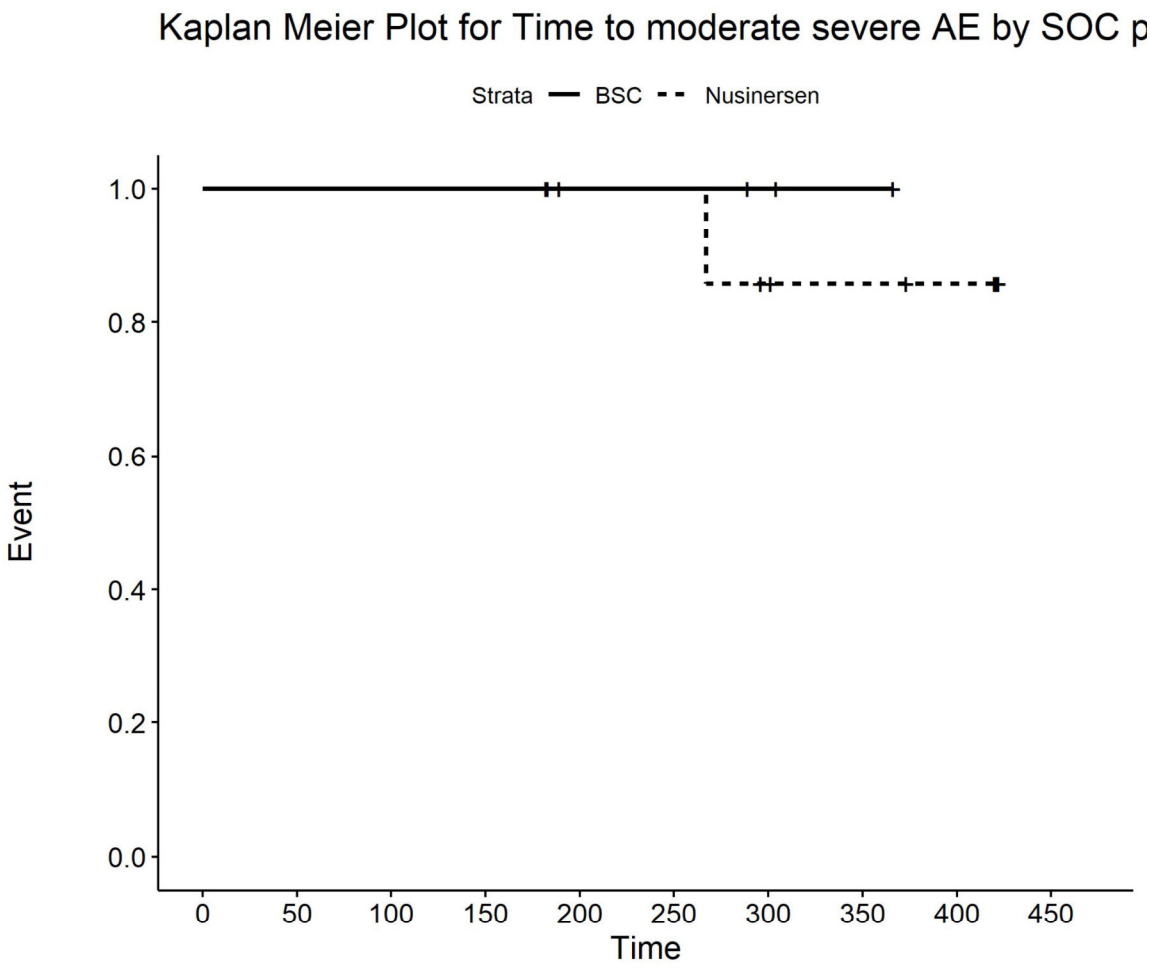
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	2	0



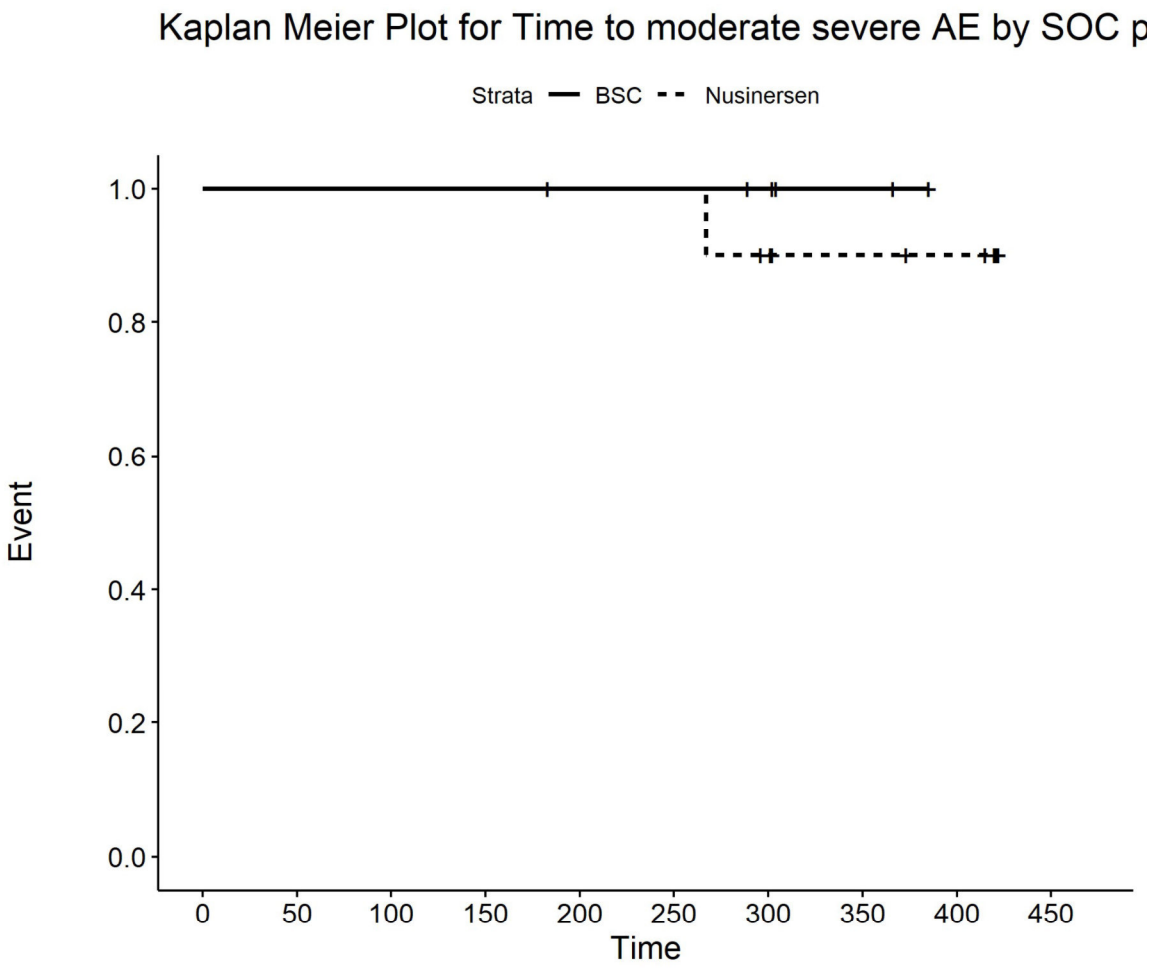
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	7	5	4	0



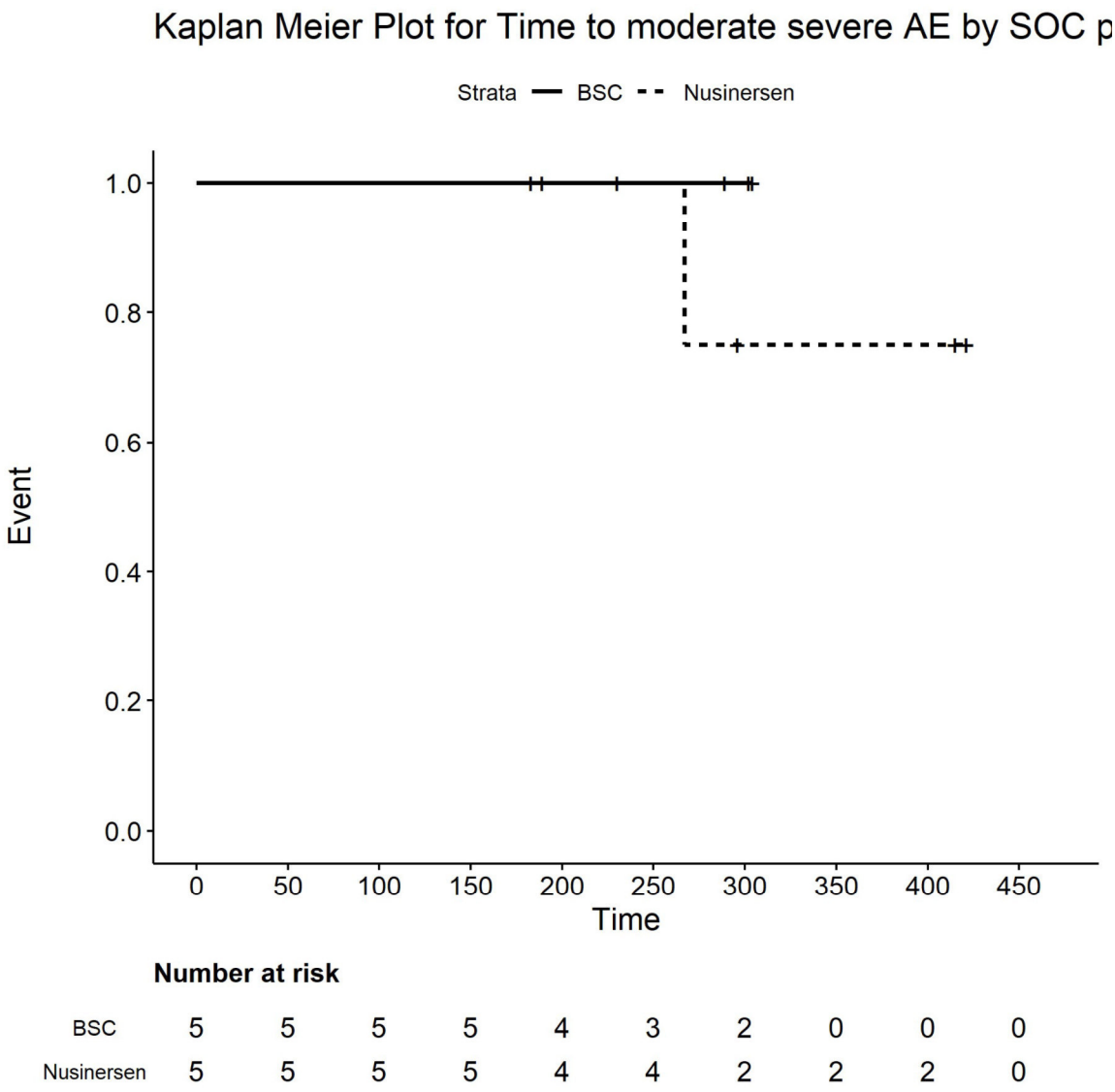
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	5	4	3	0



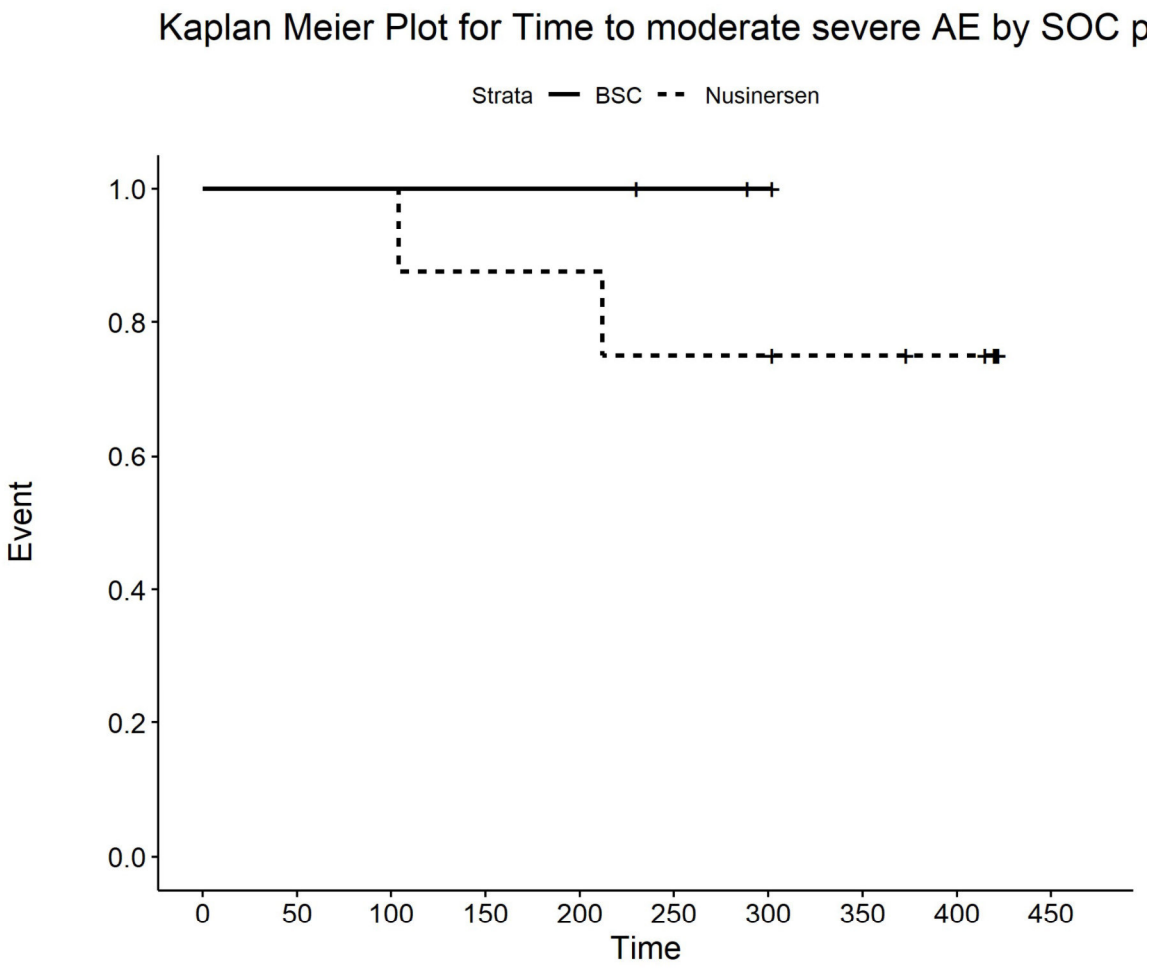
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	8	6	5	0



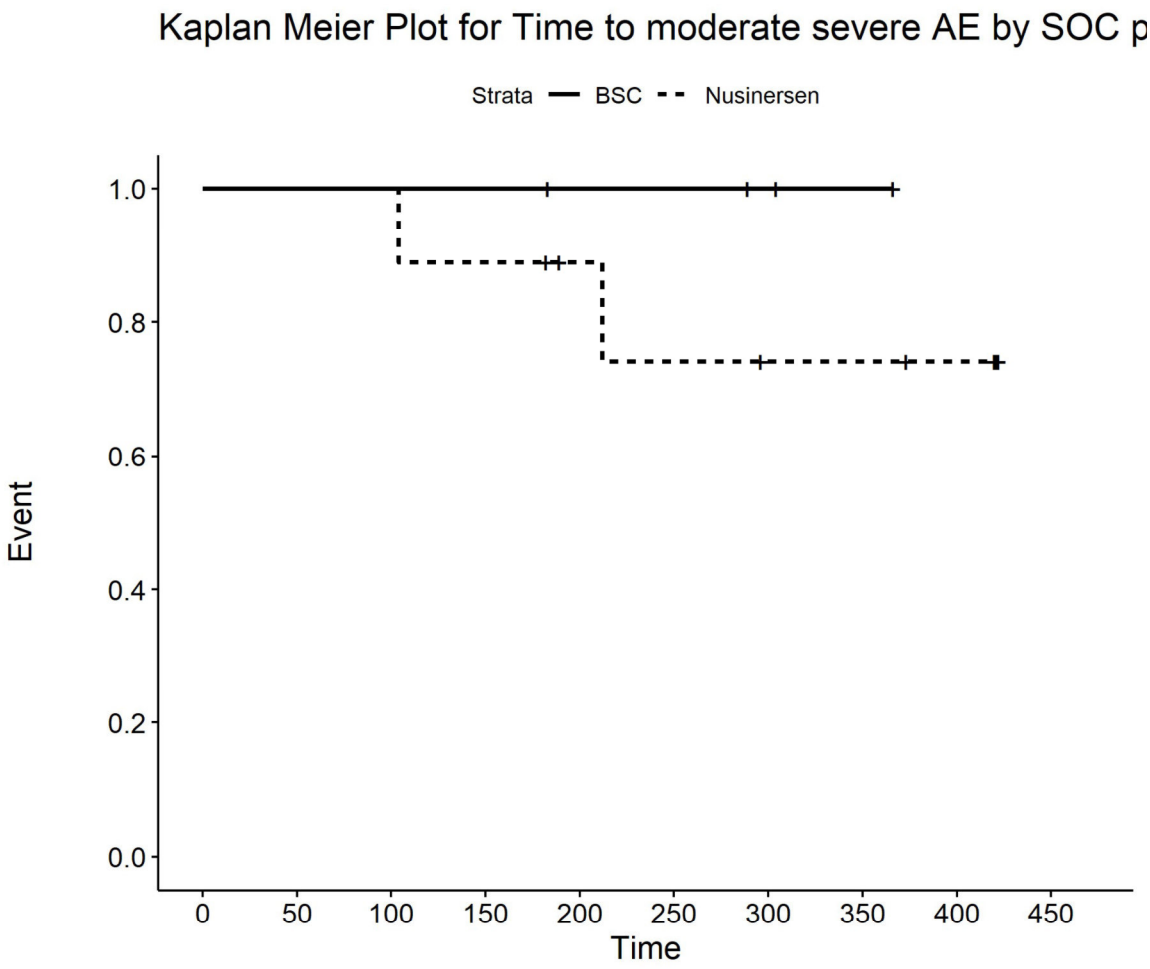
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	2	2	2	0



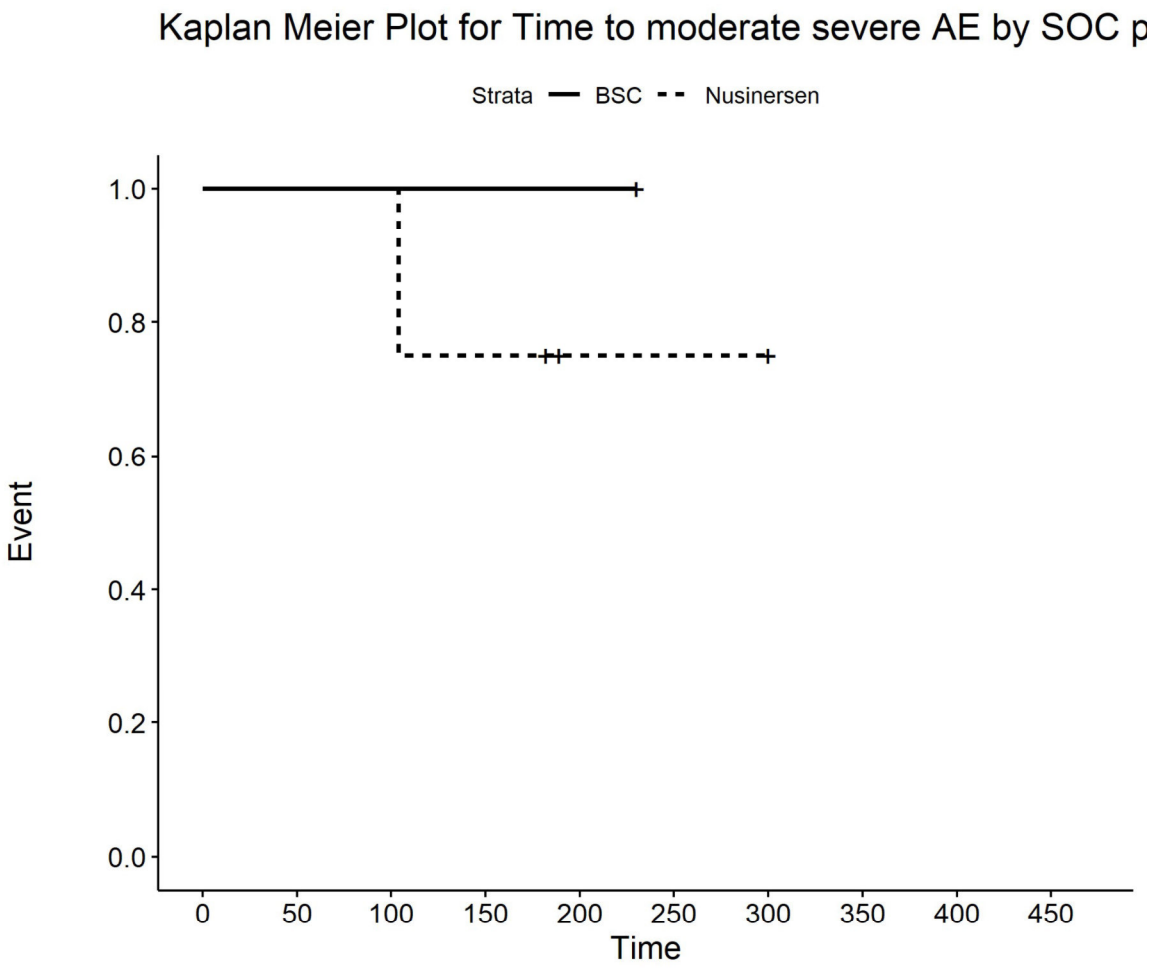
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	6	6	5	4	0



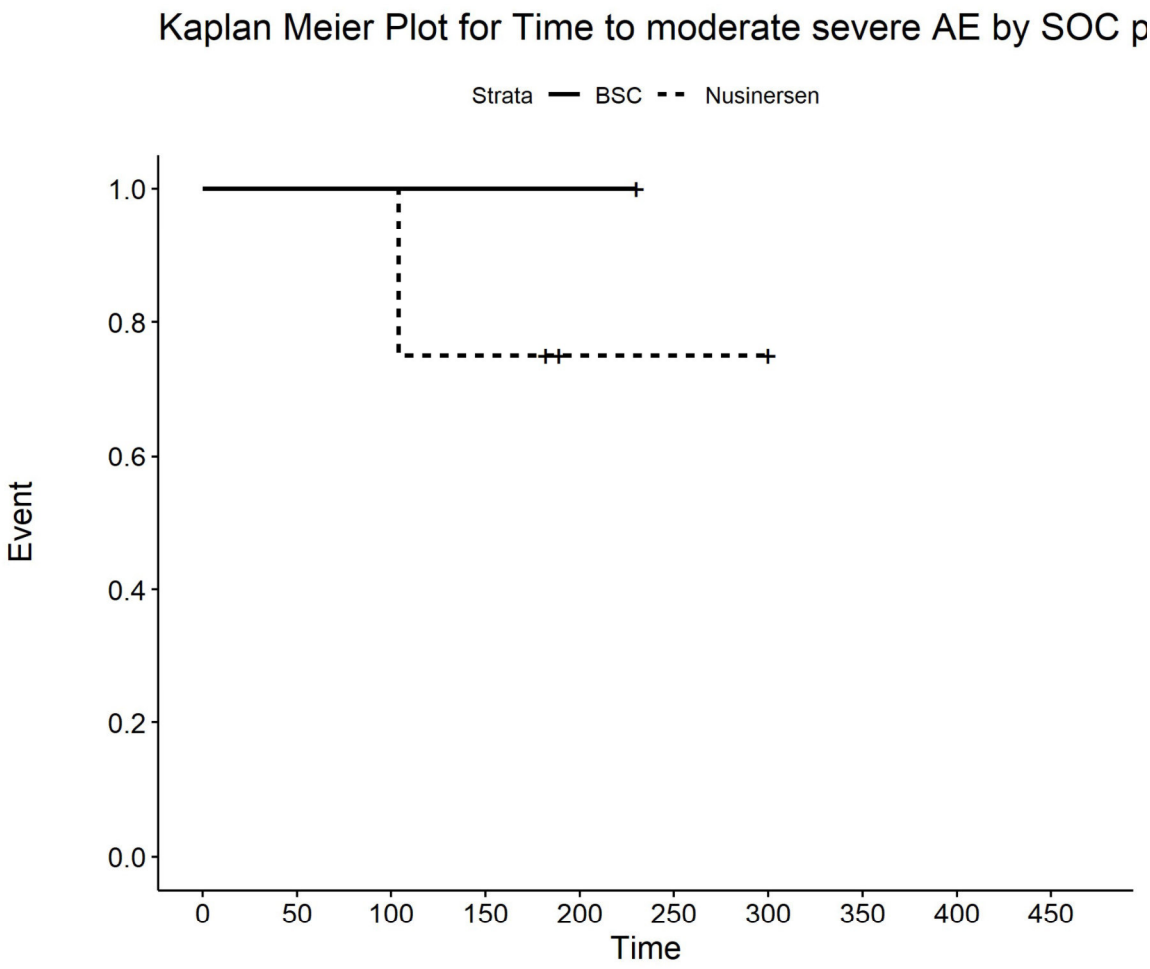
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	5	4	4	3	0



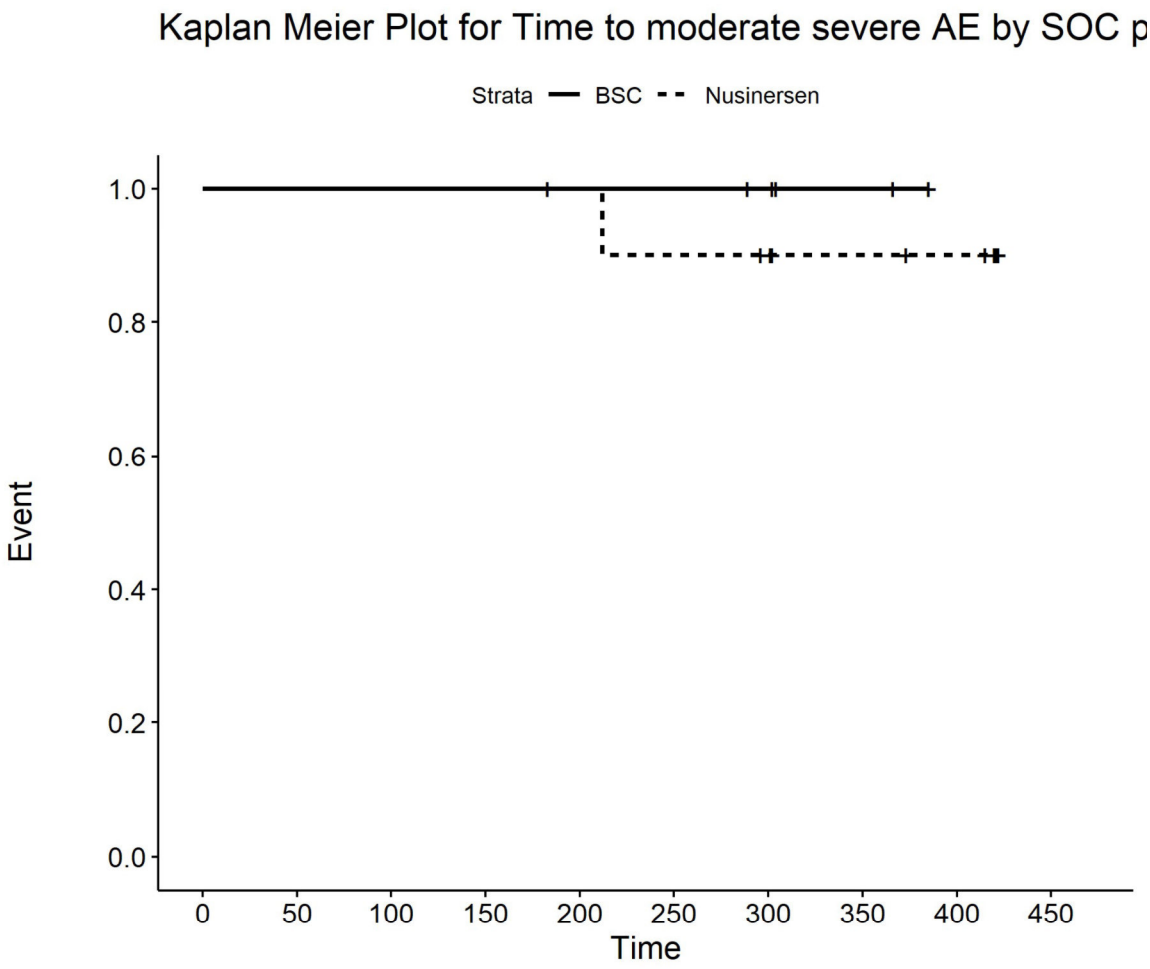
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



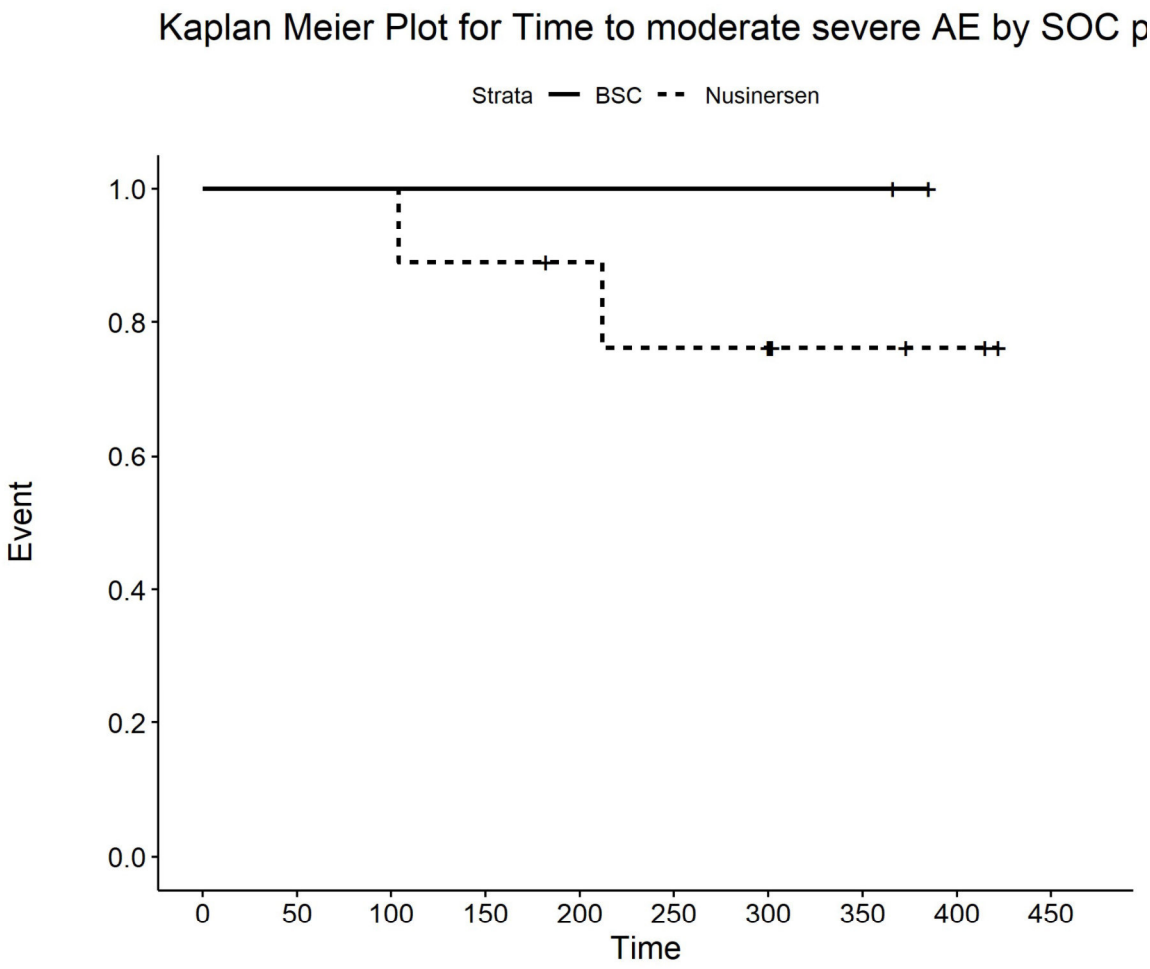
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



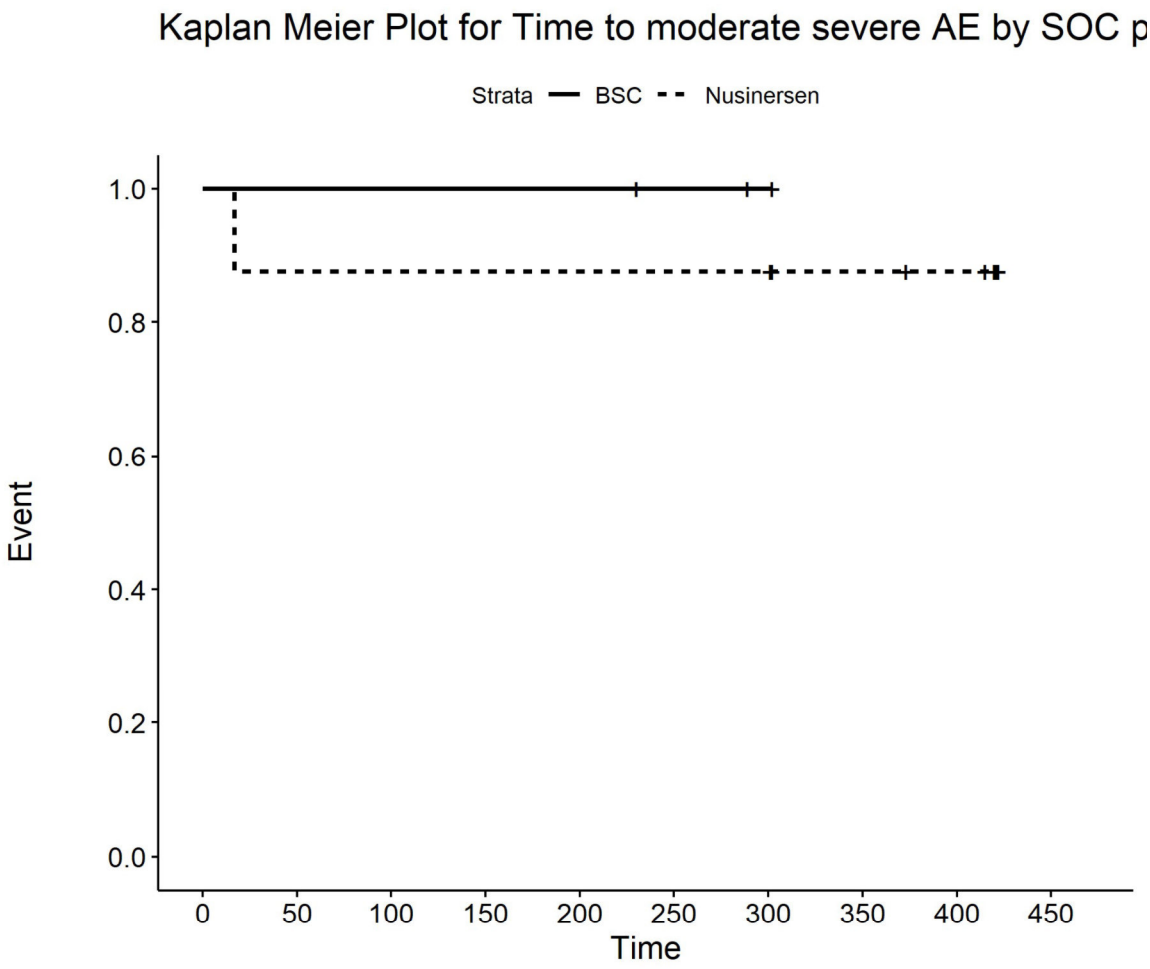
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



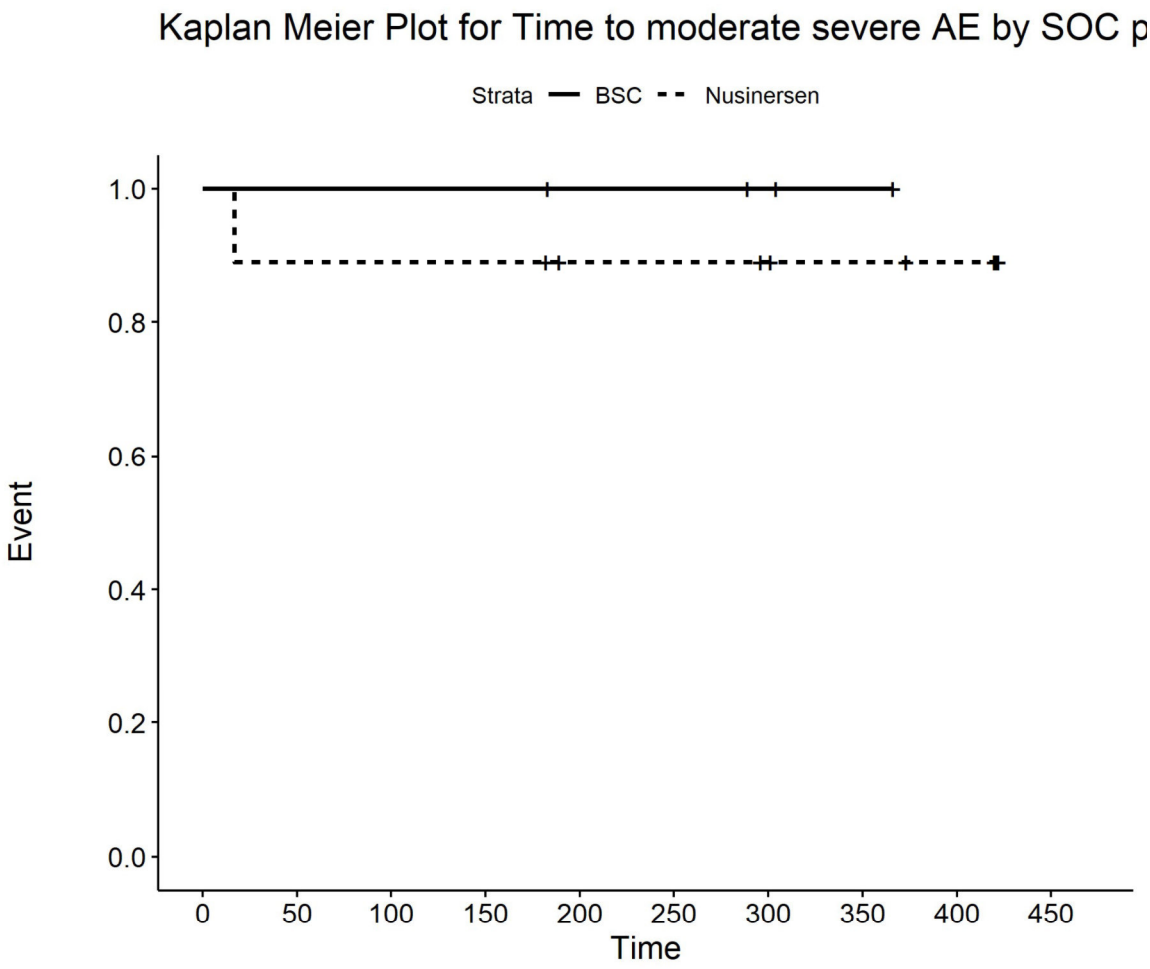
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	6	6	3	2	0



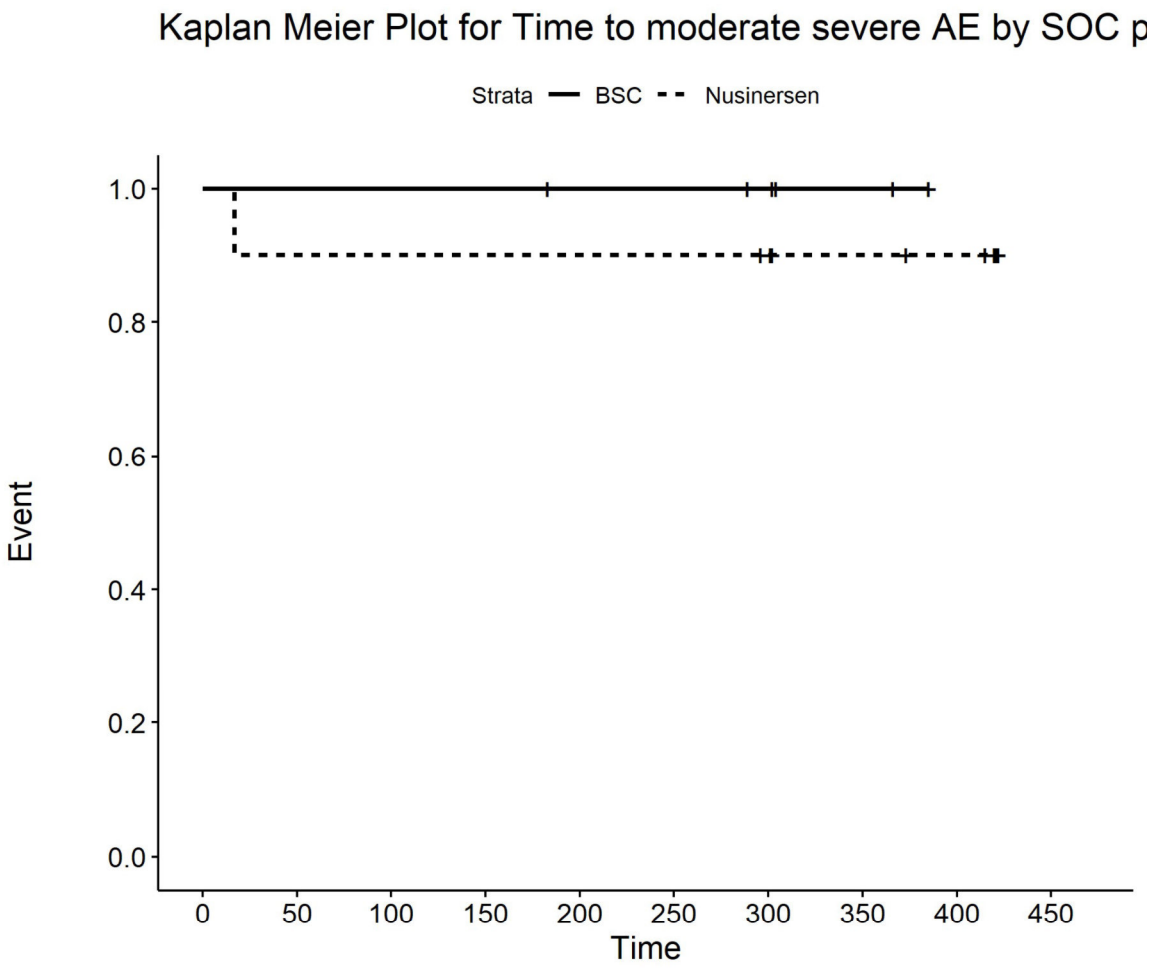
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



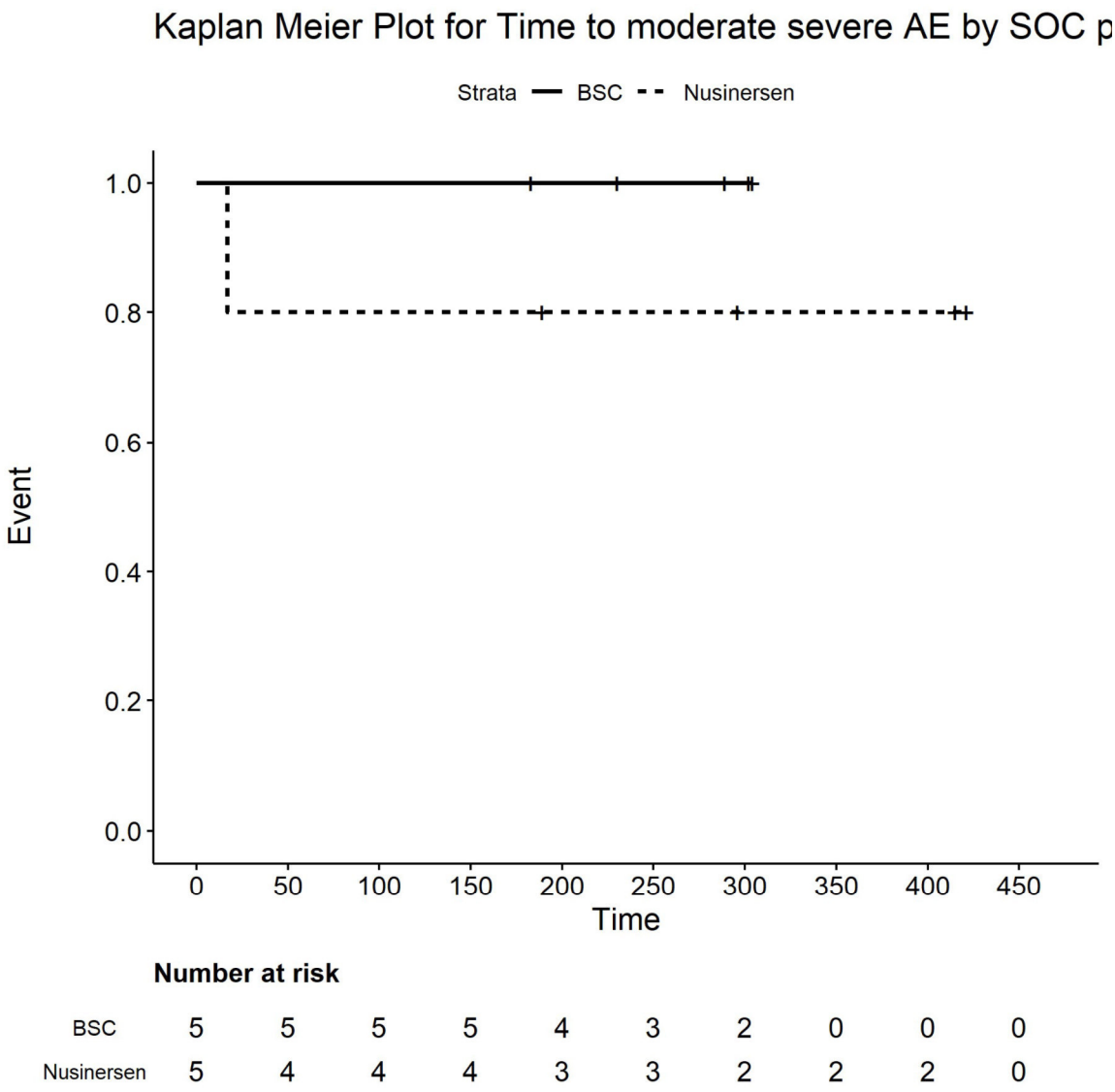
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



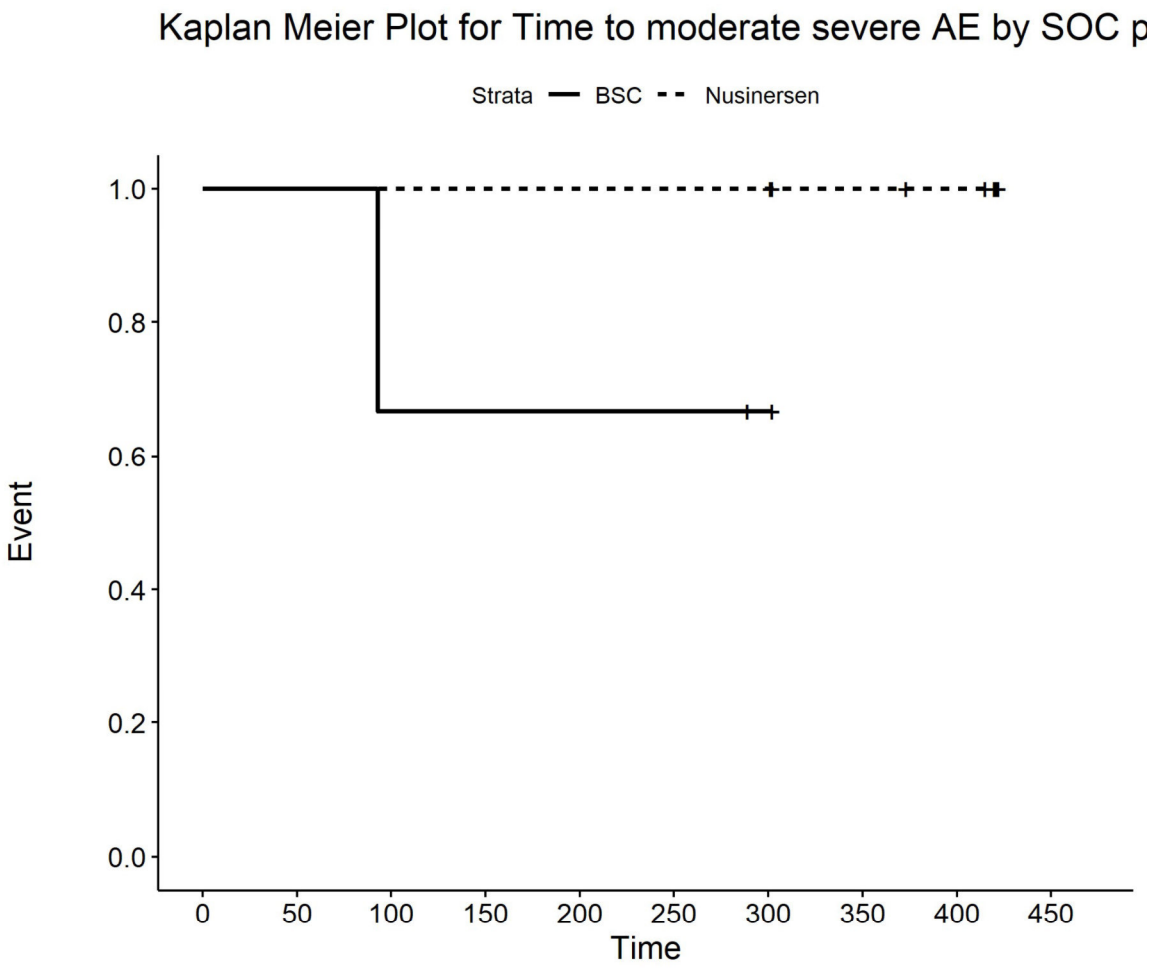
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



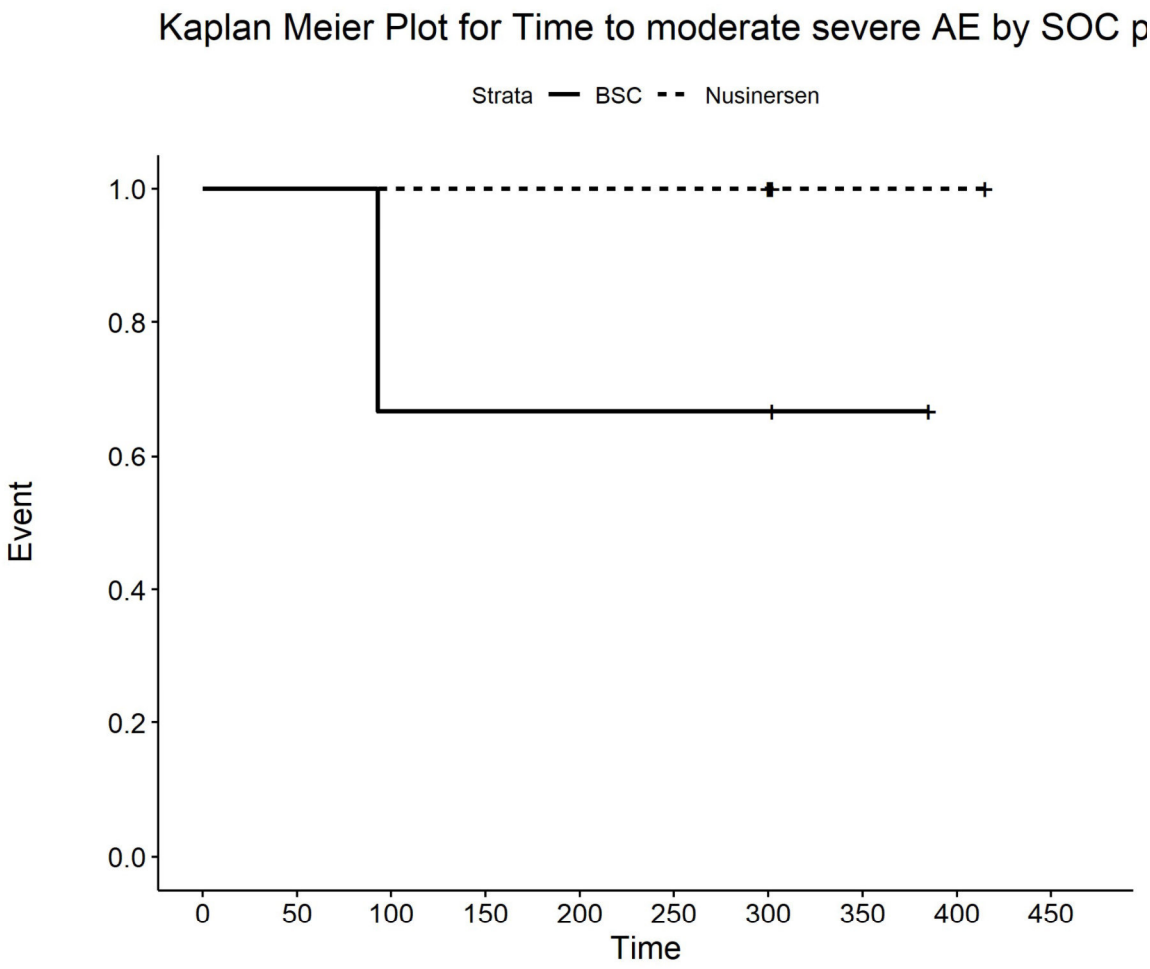
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	2	2	2	0



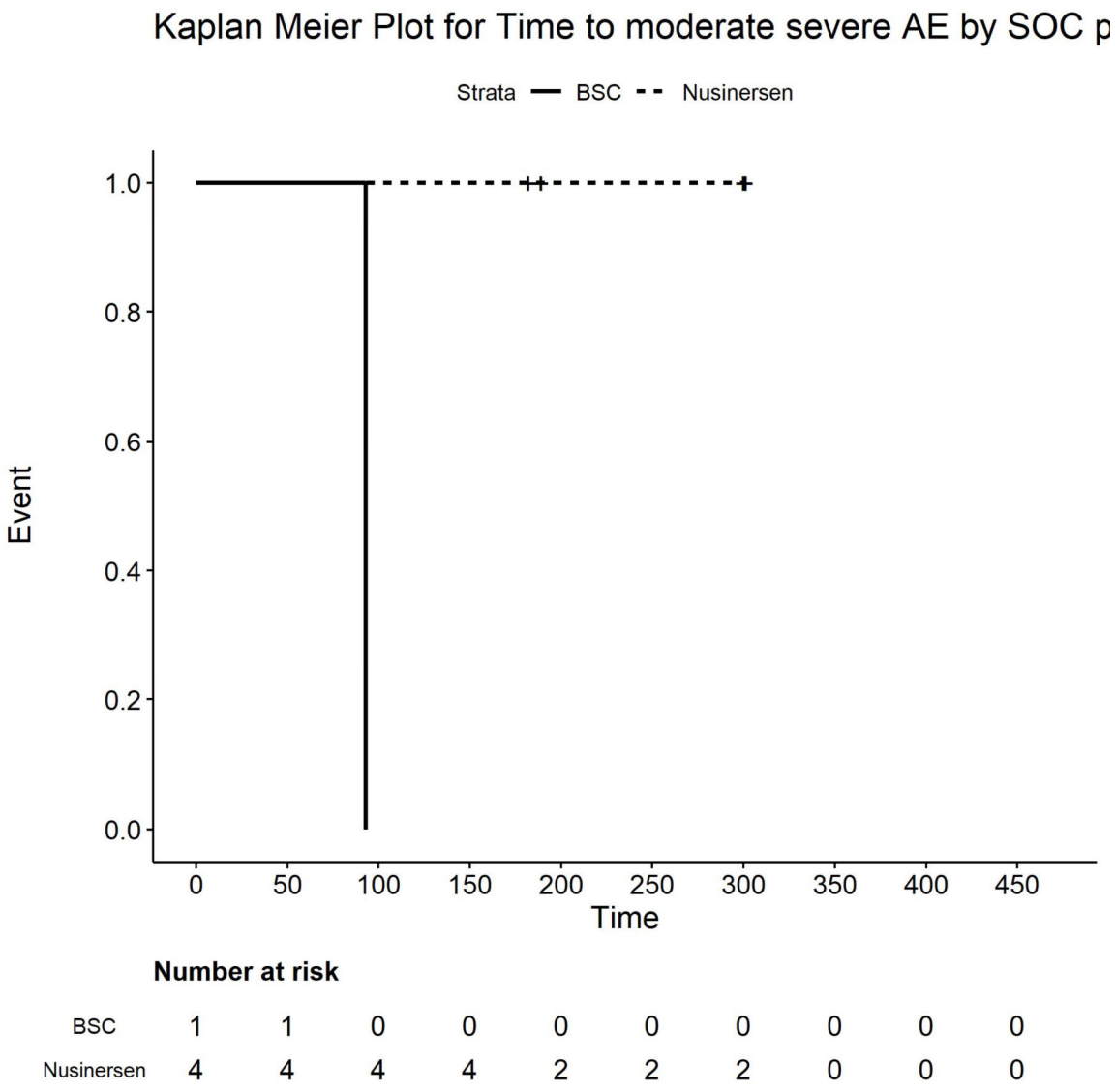
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



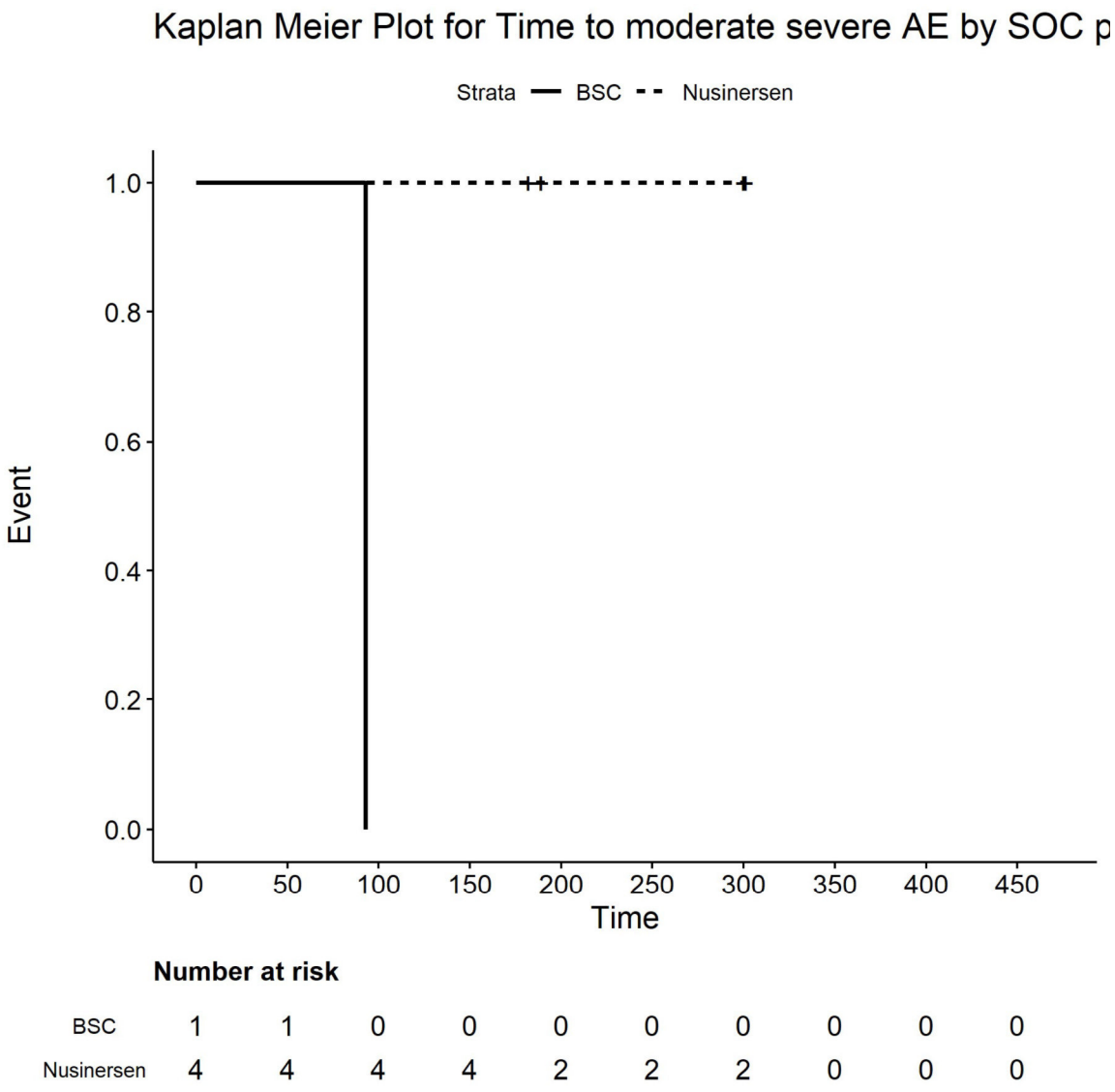
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



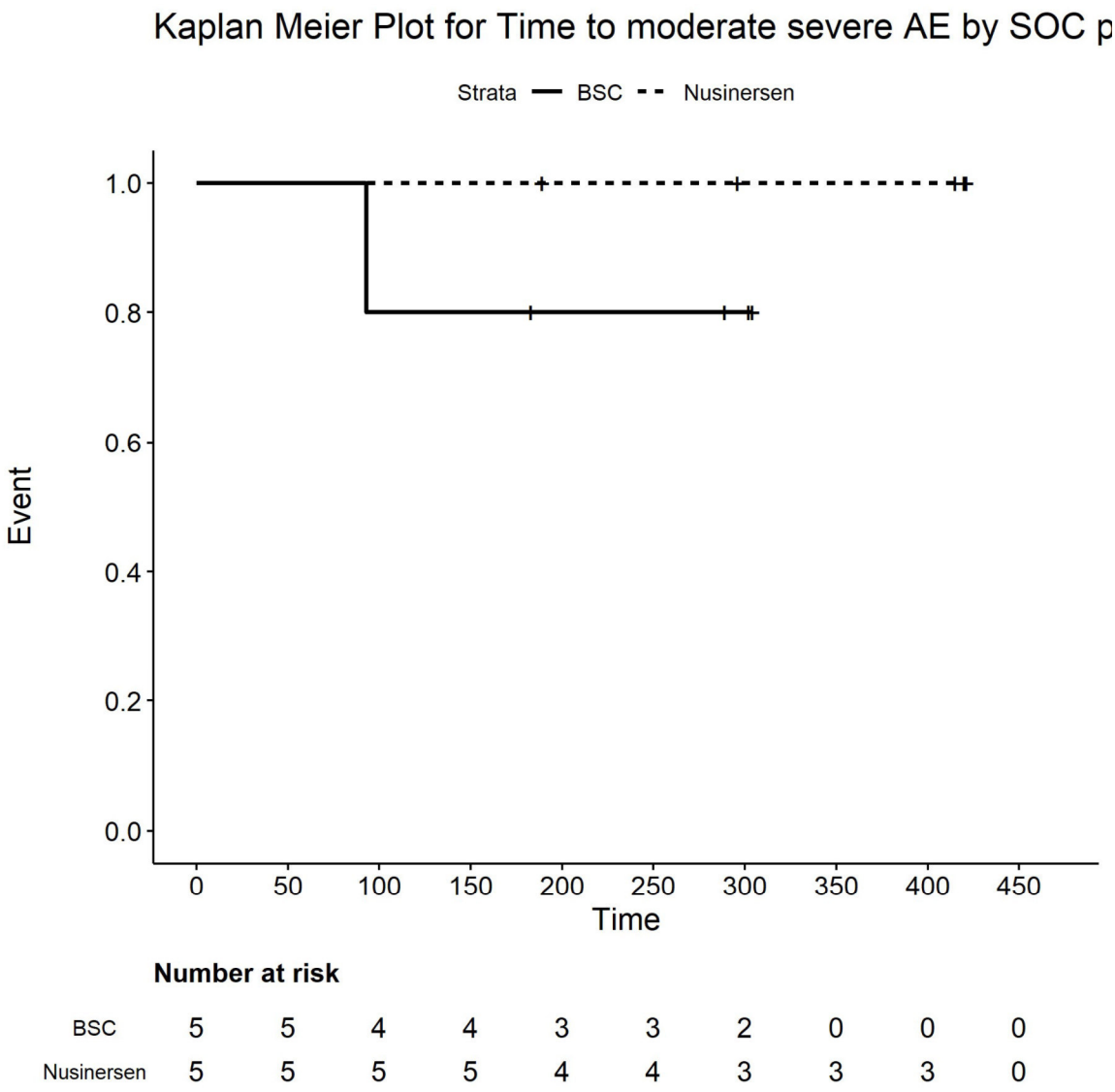
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



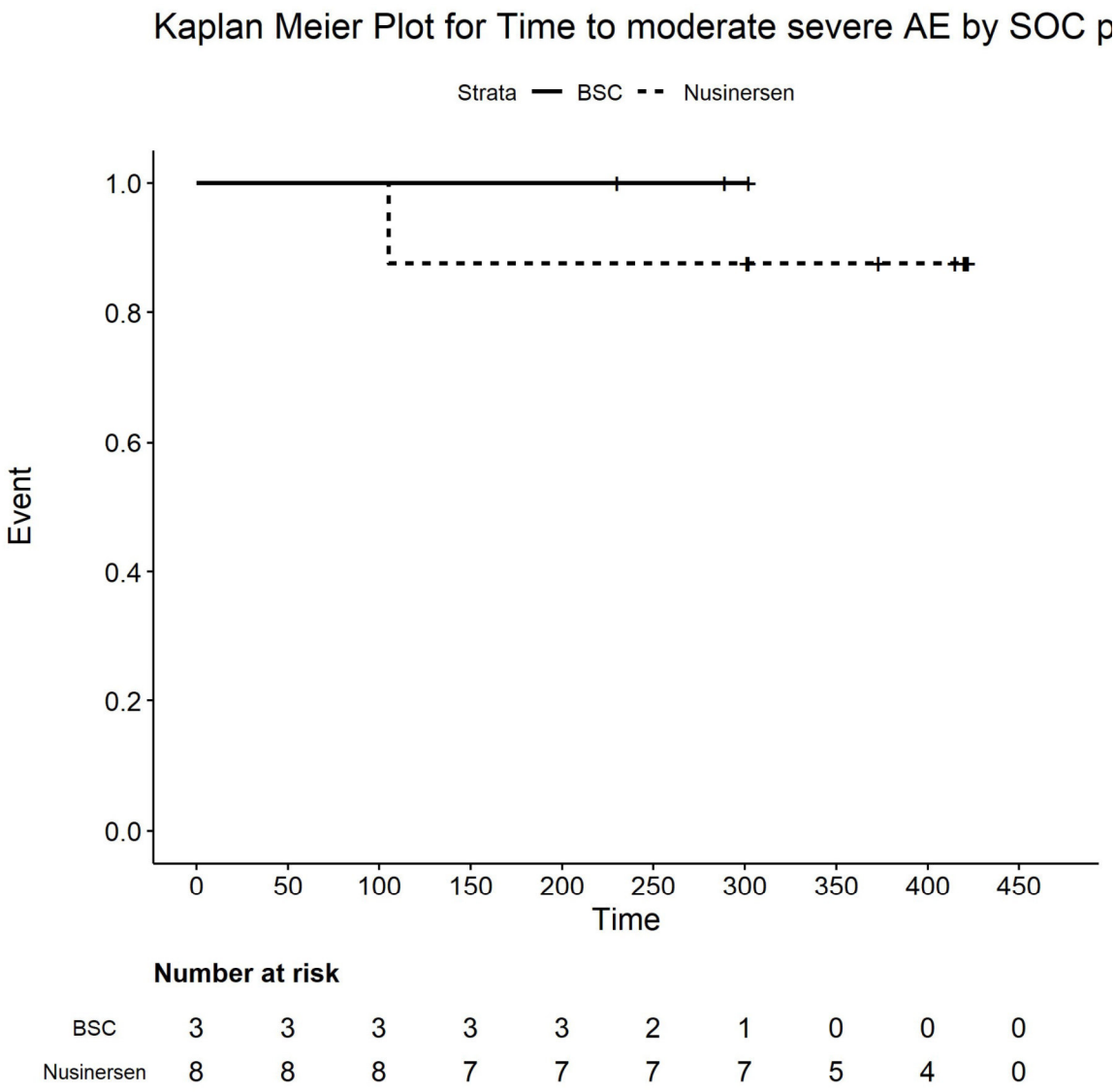
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



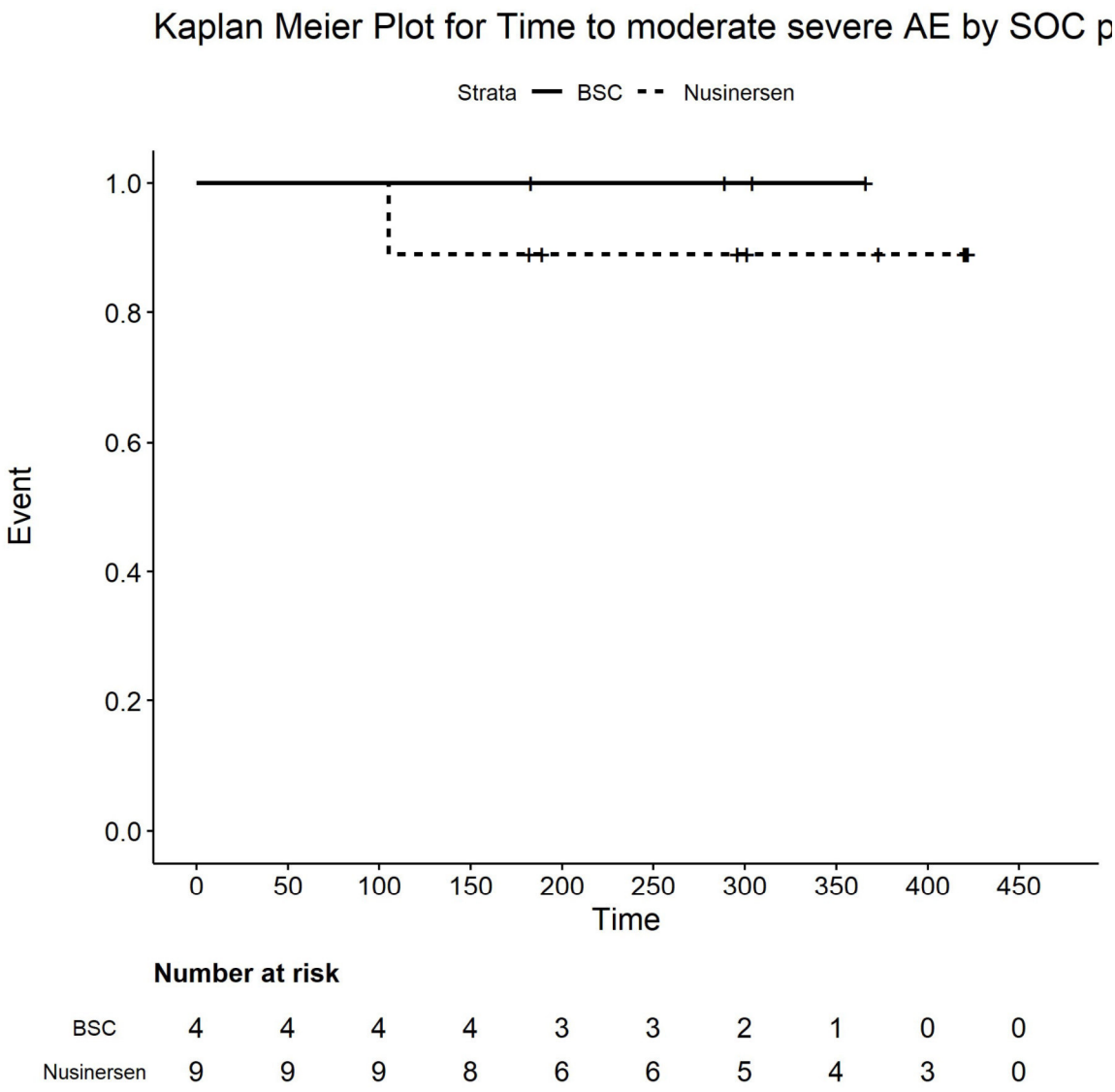
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



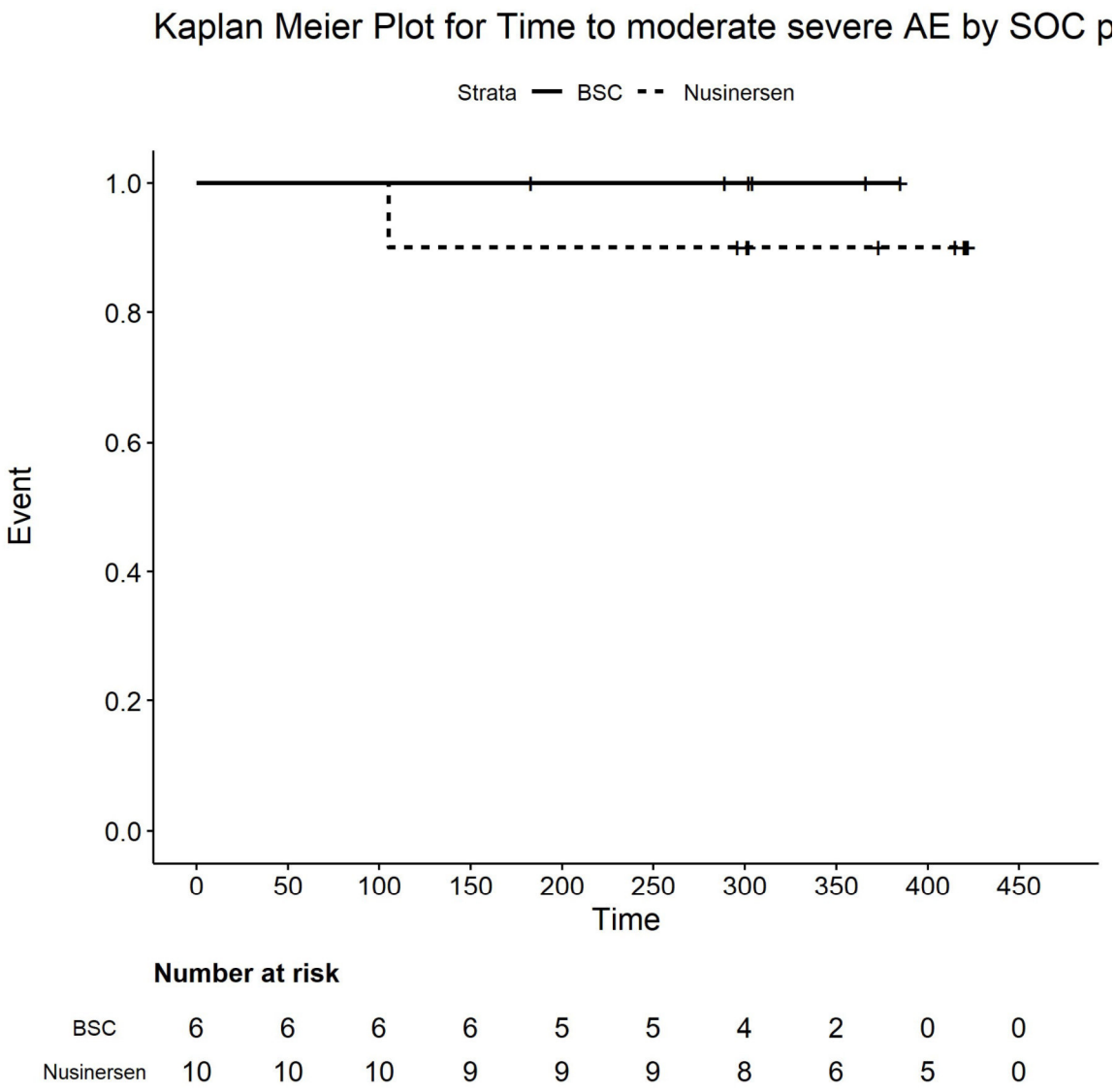
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



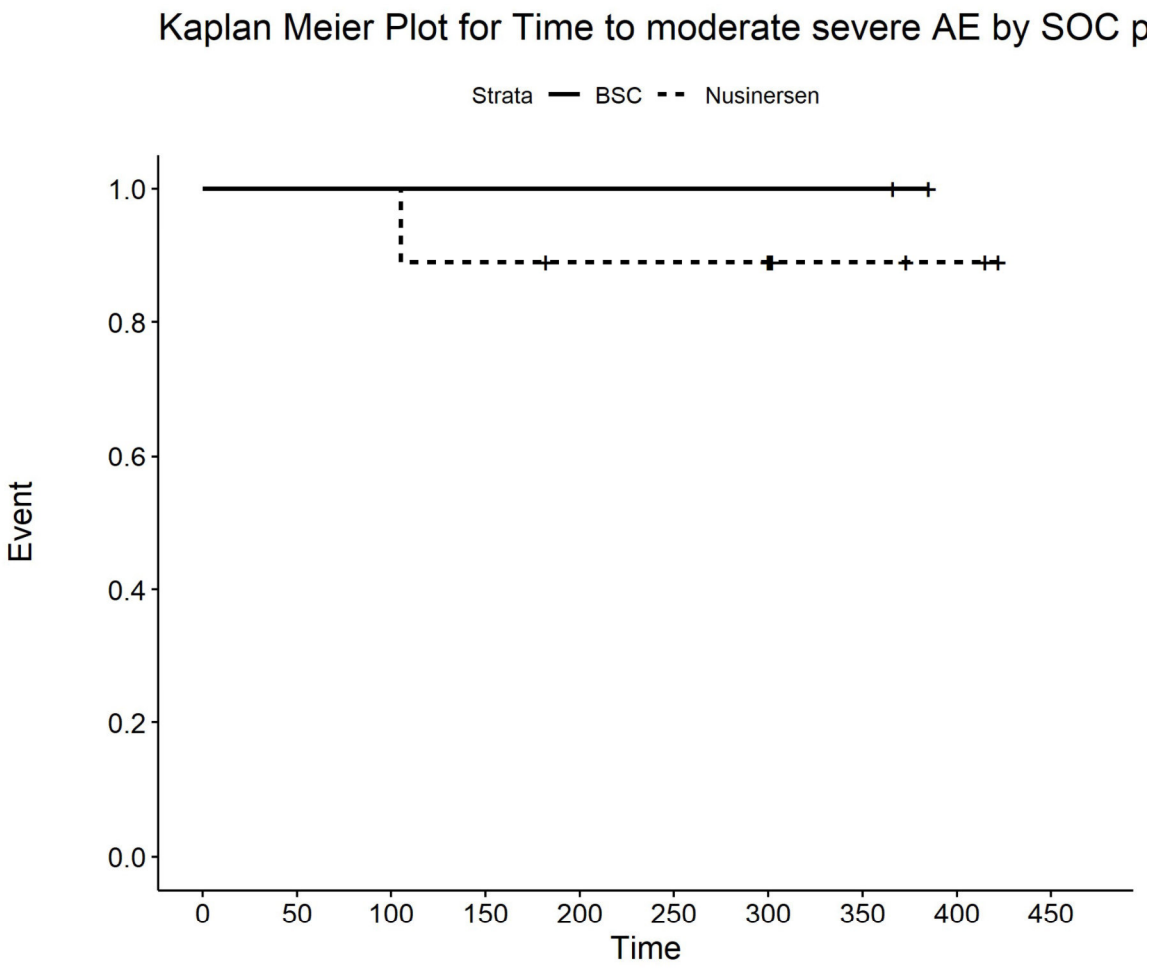
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



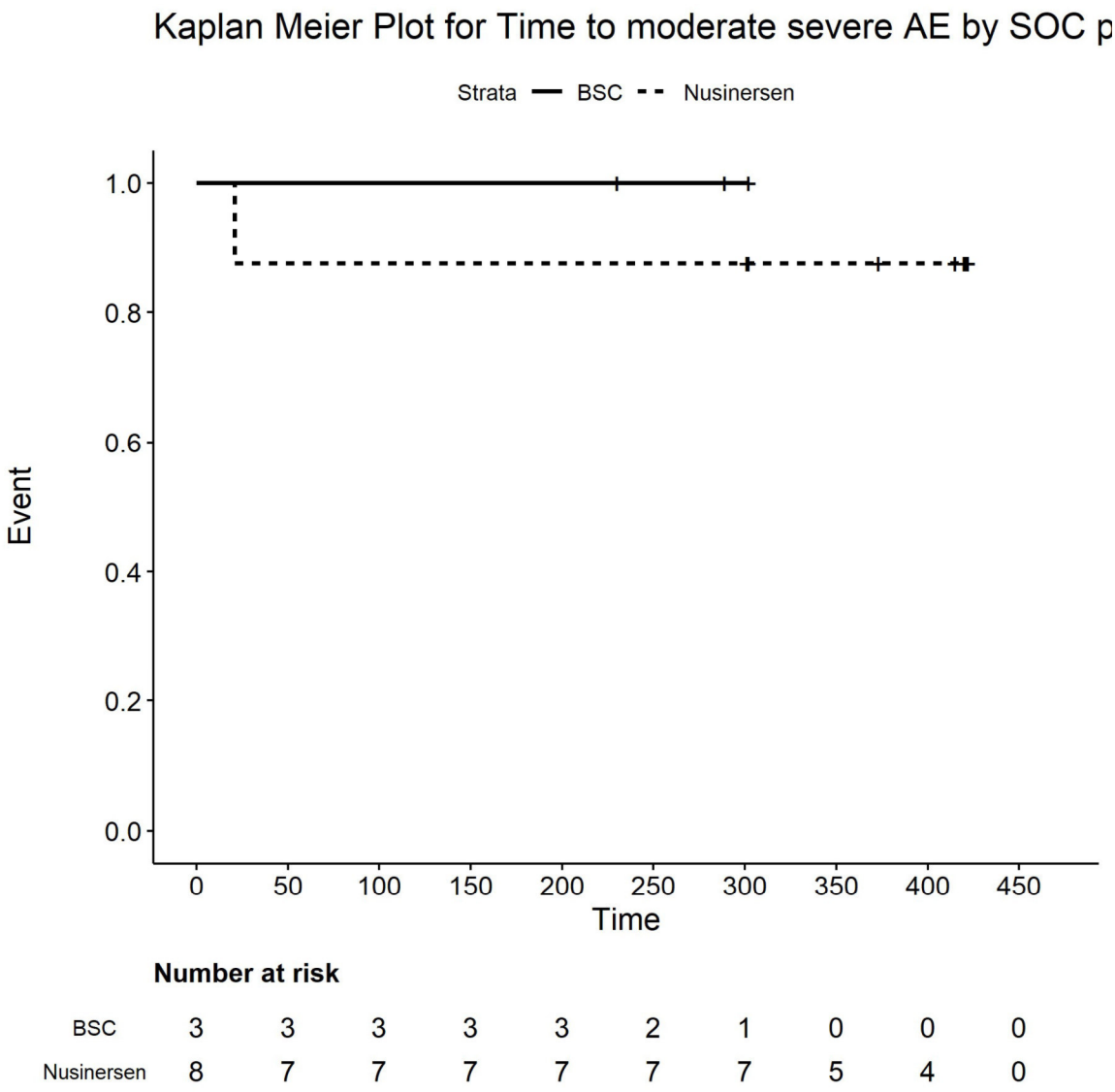
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



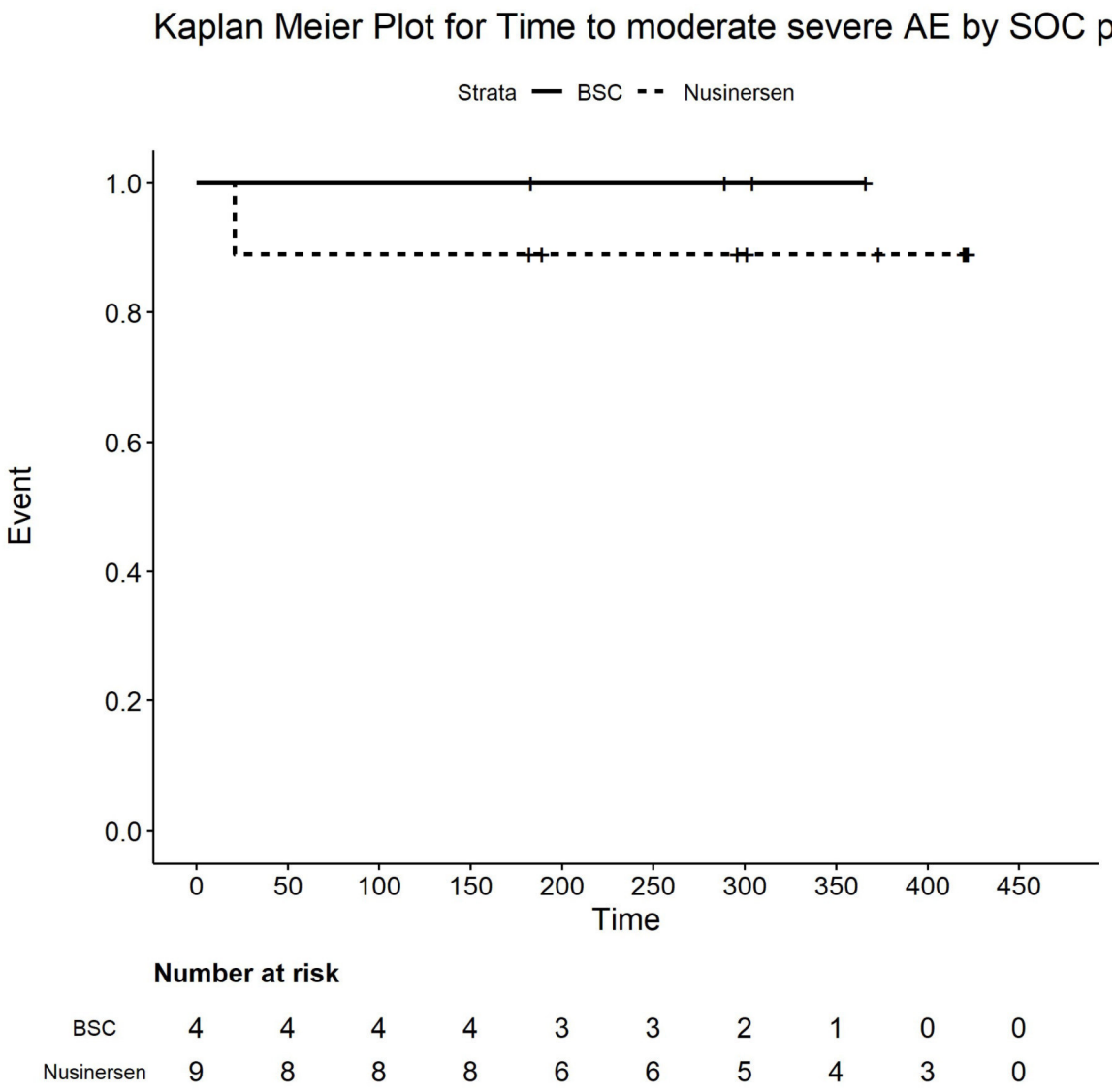
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



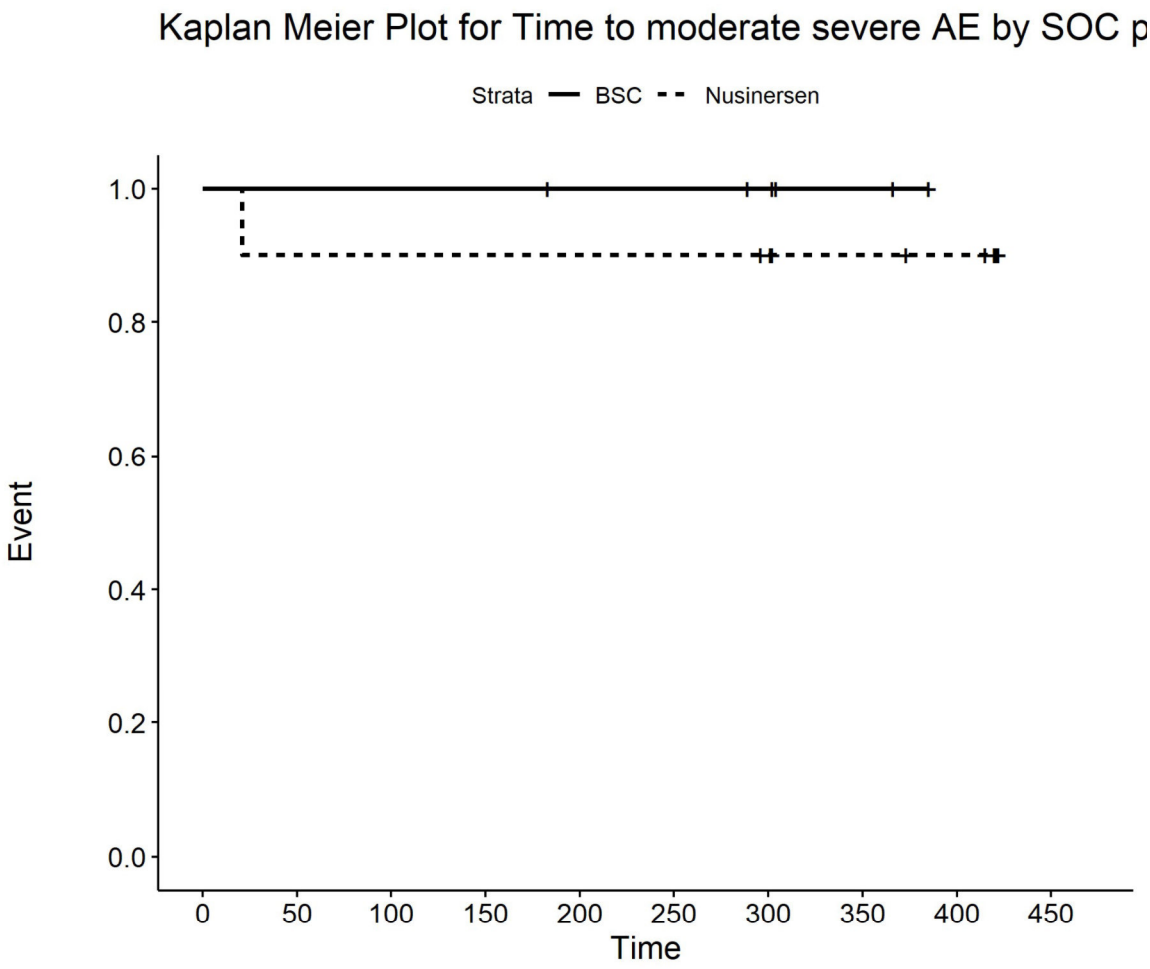
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



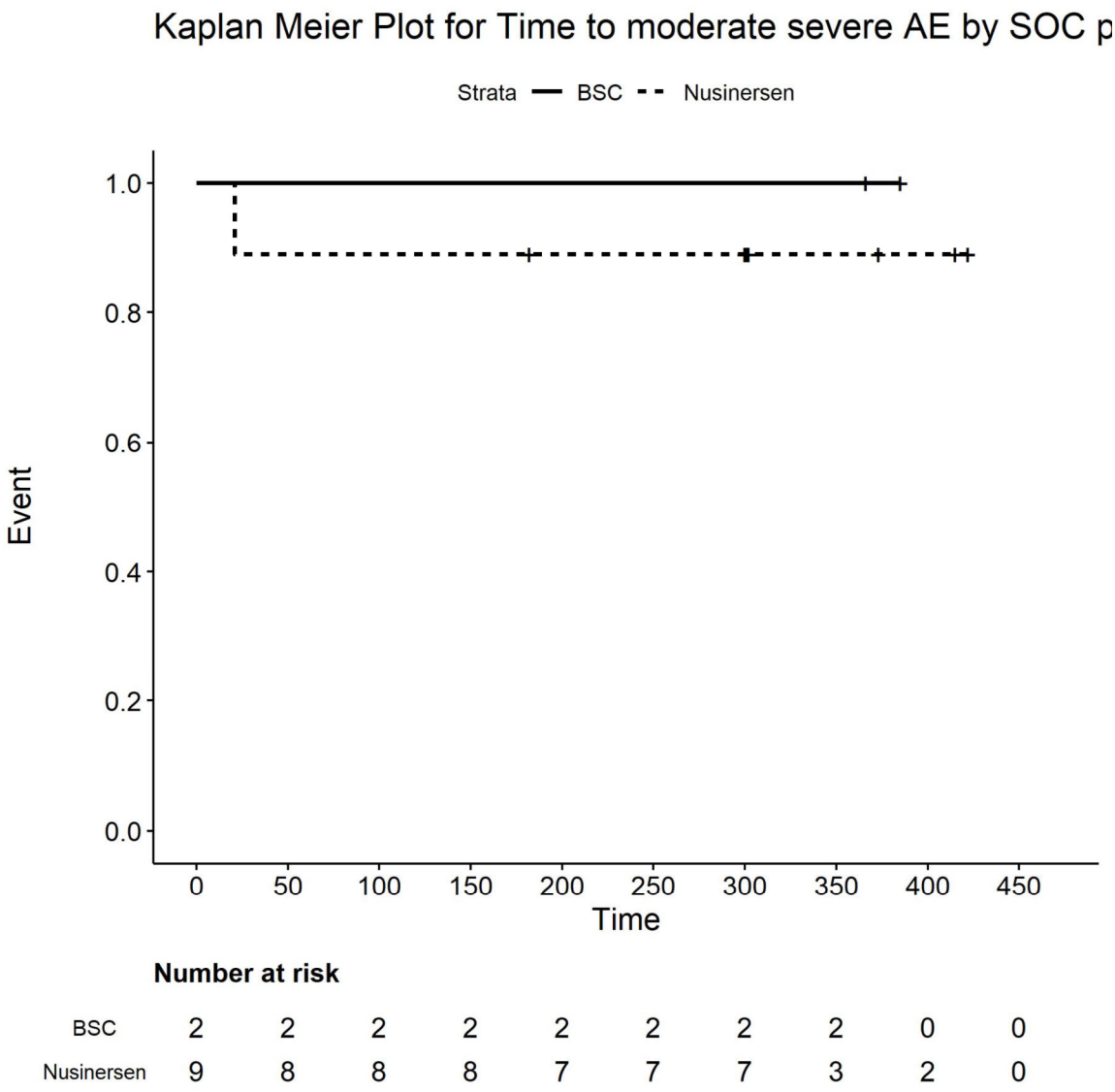
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



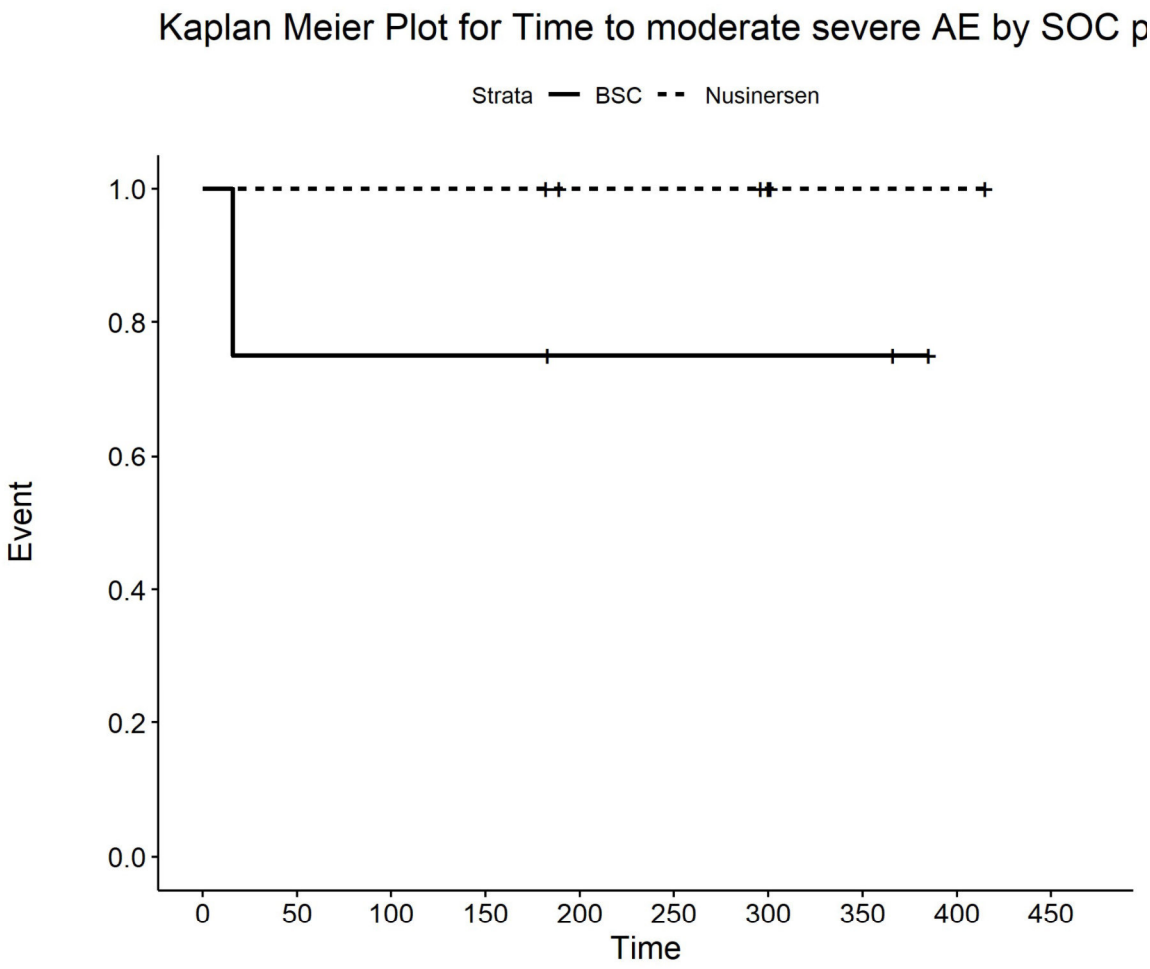
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



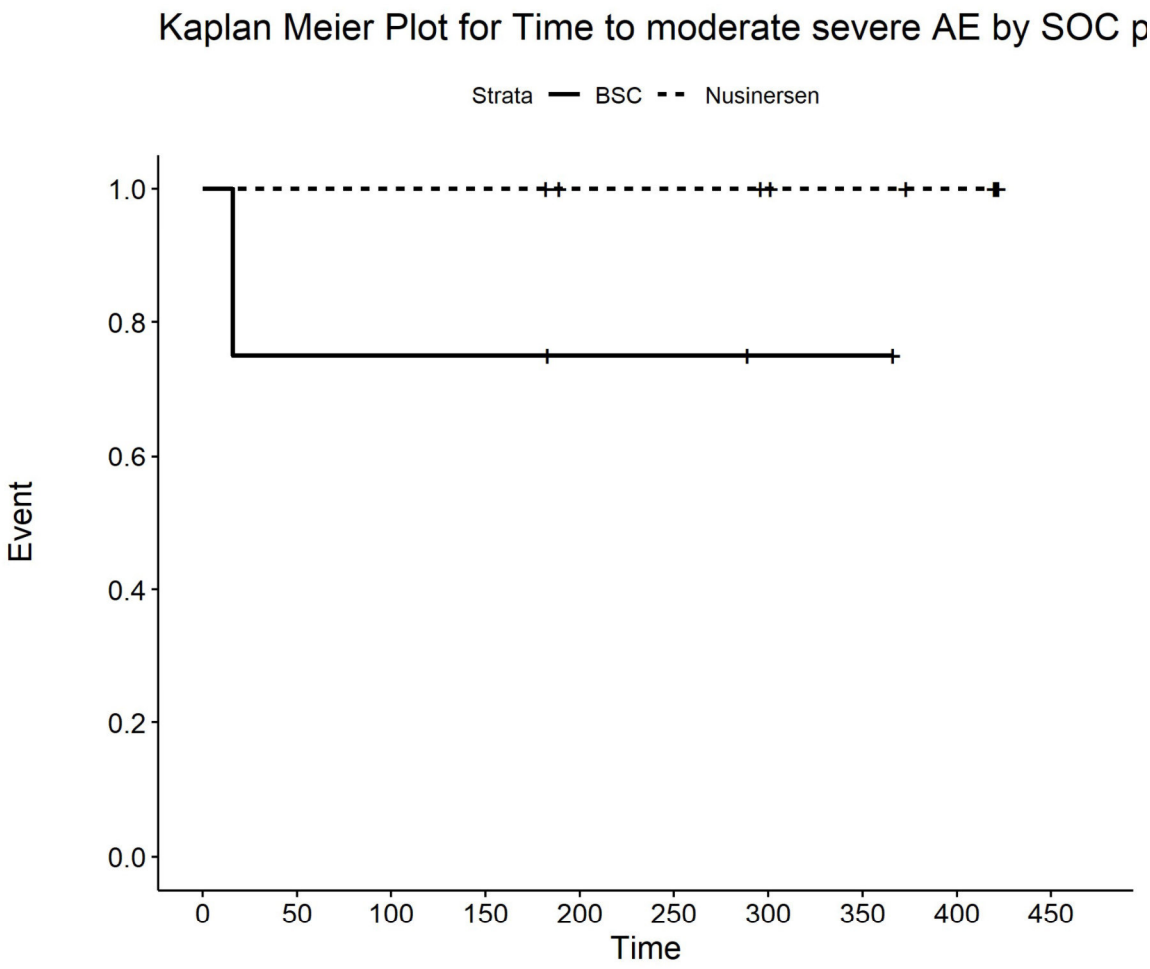
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	3	2	0



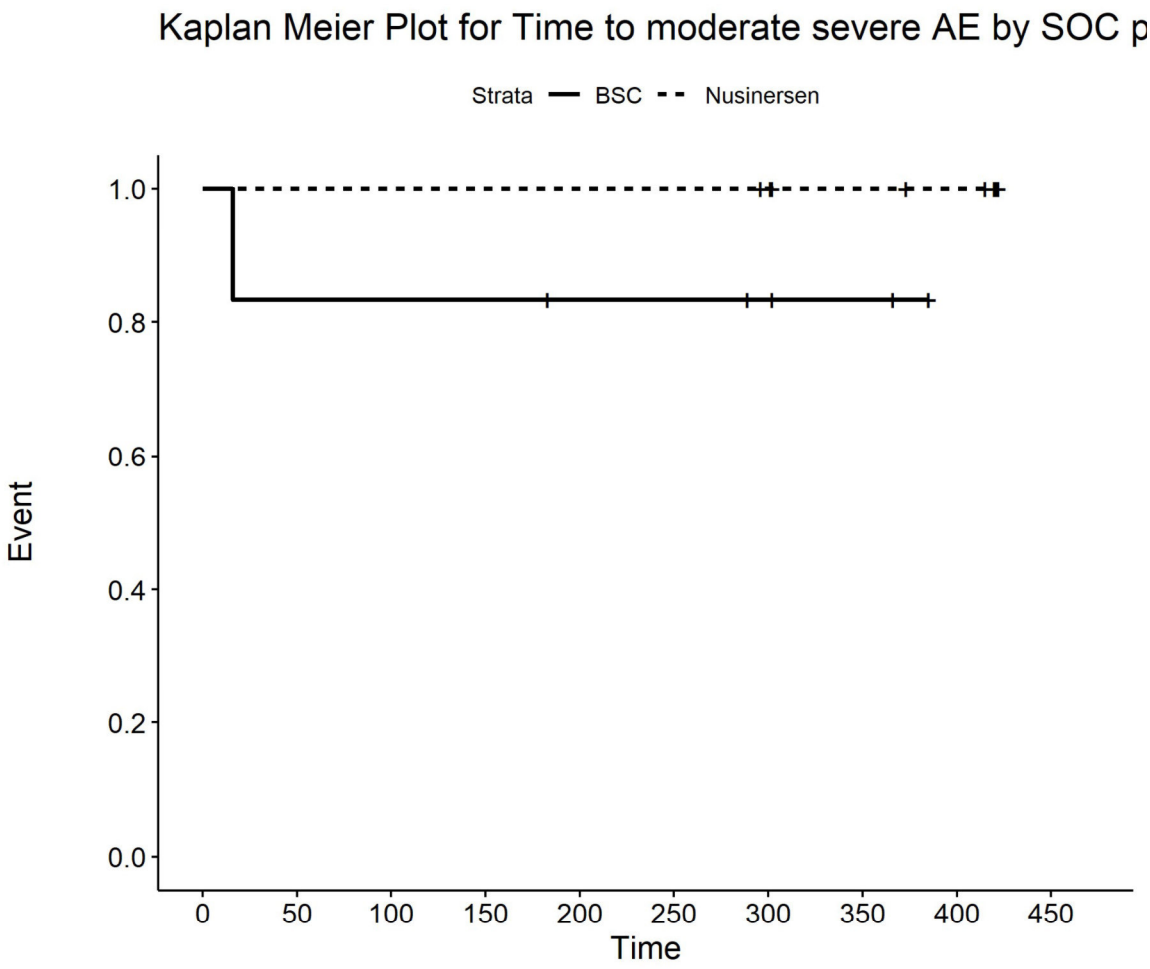
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



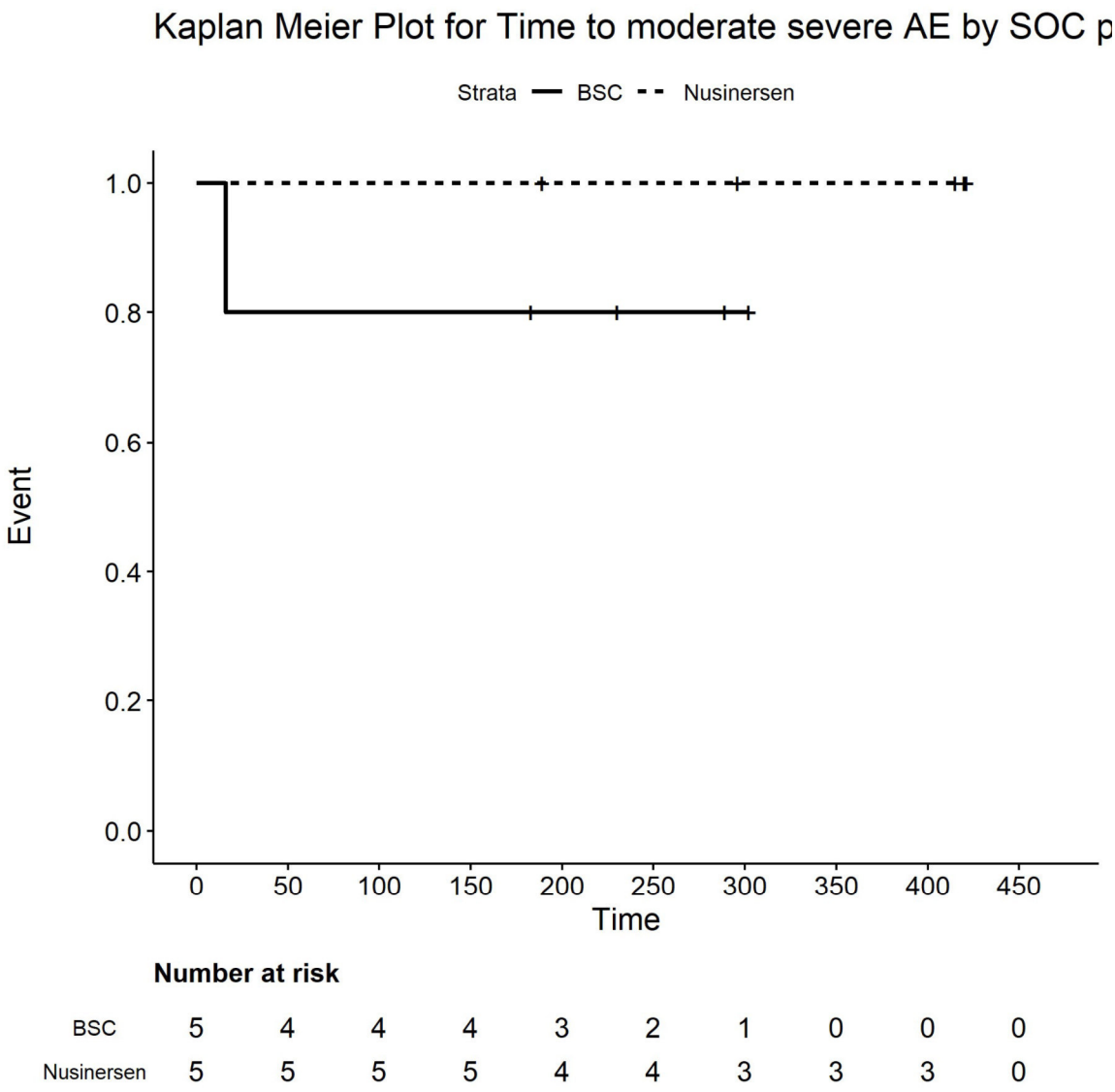
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



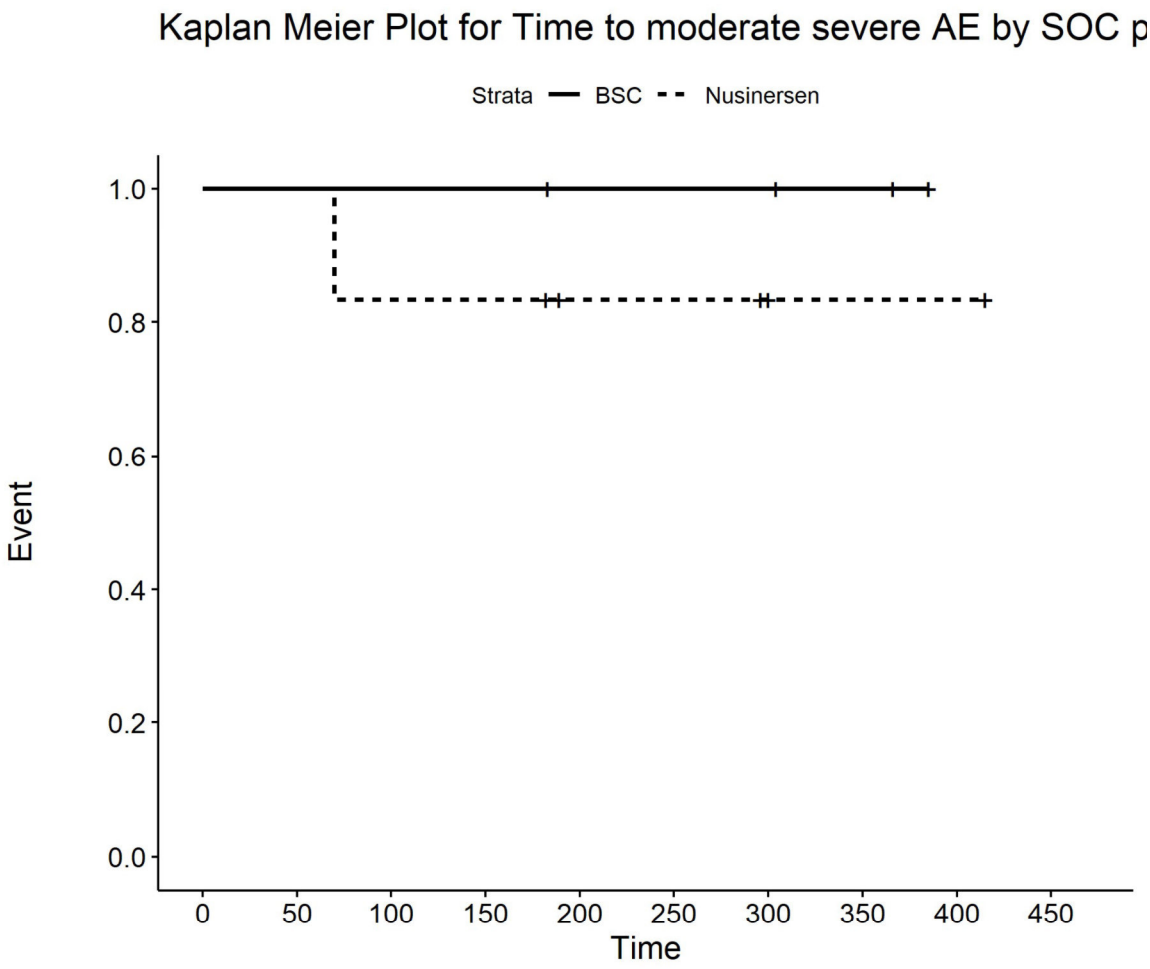
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



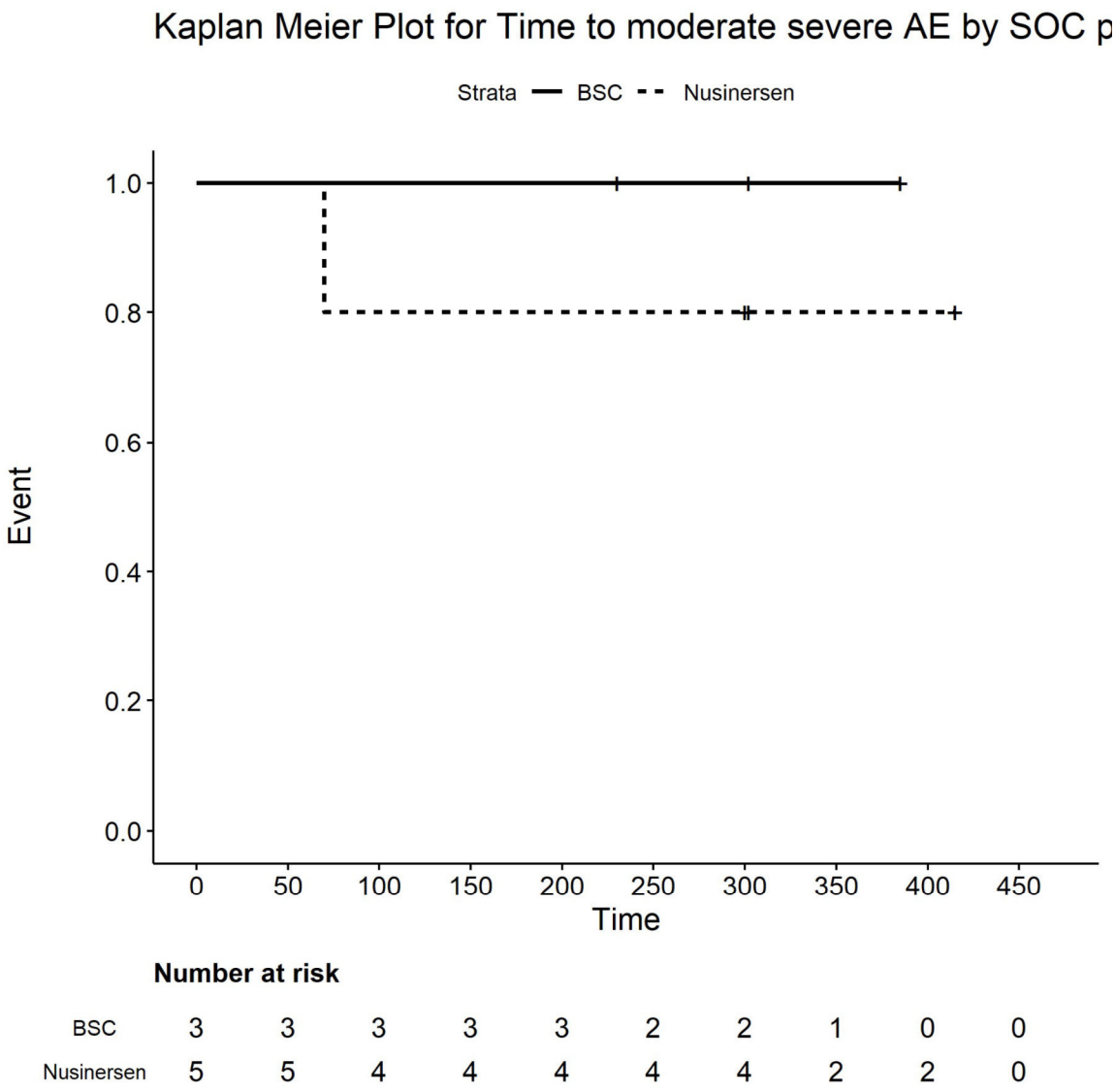
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



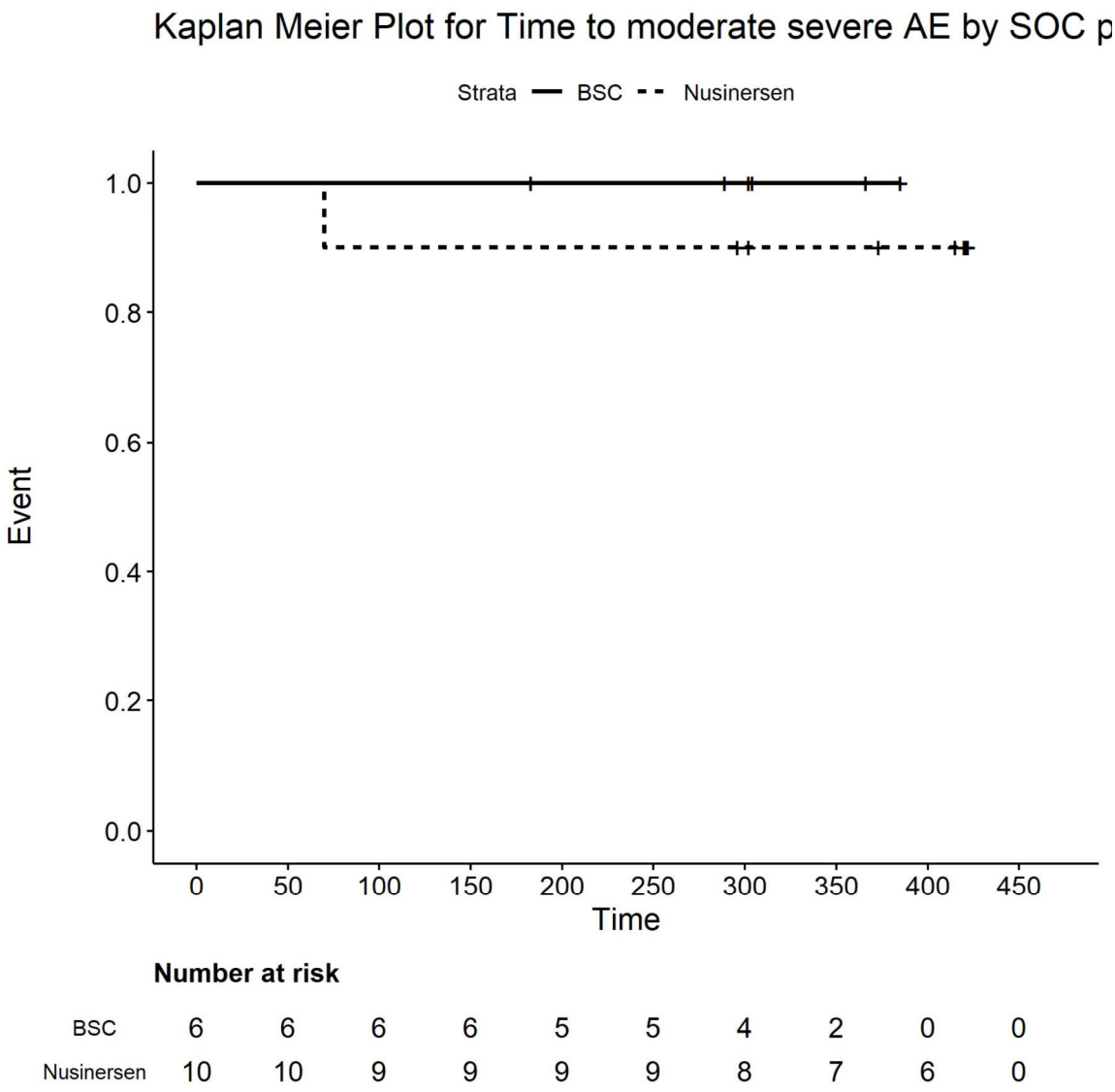
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



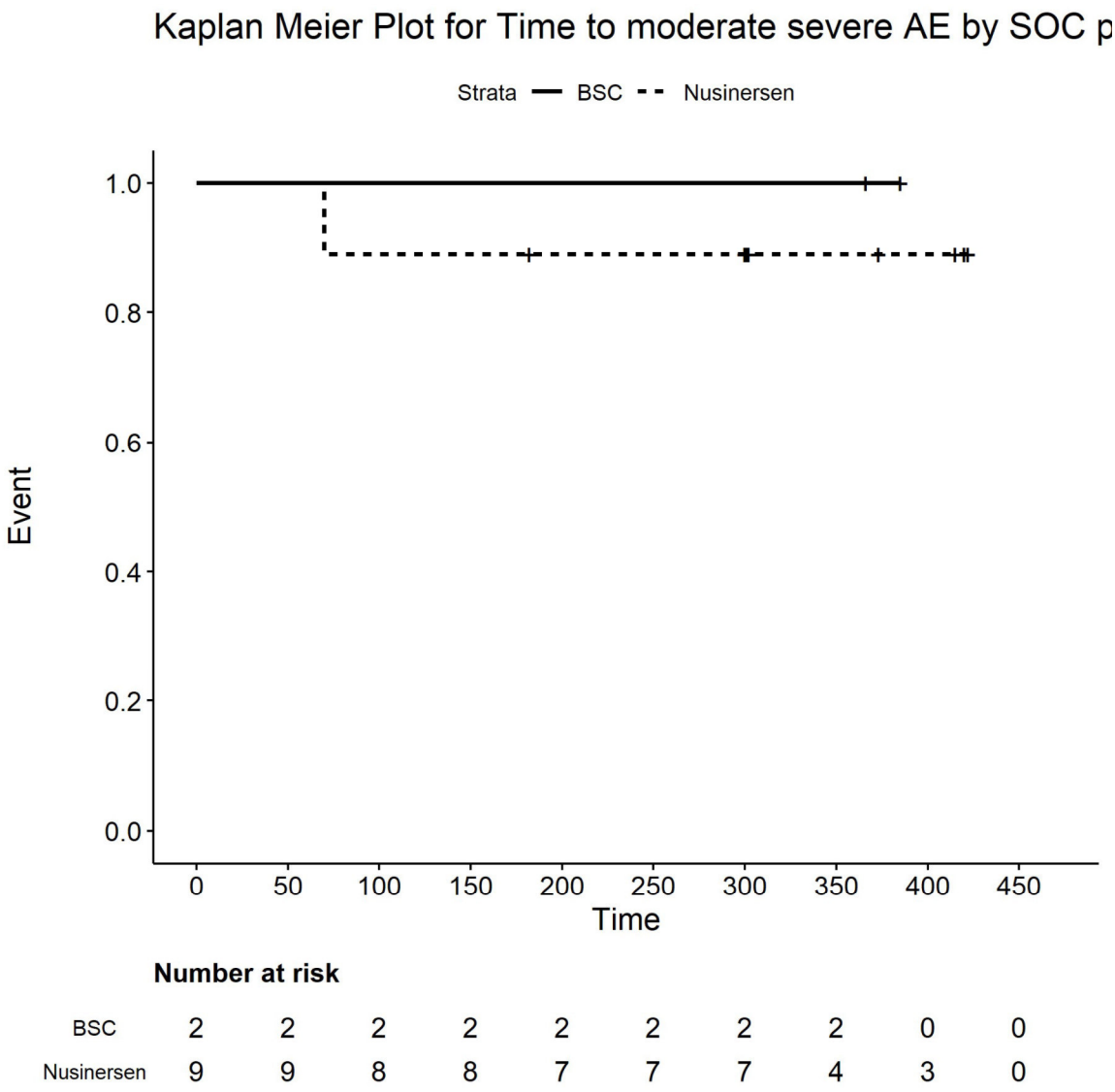
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



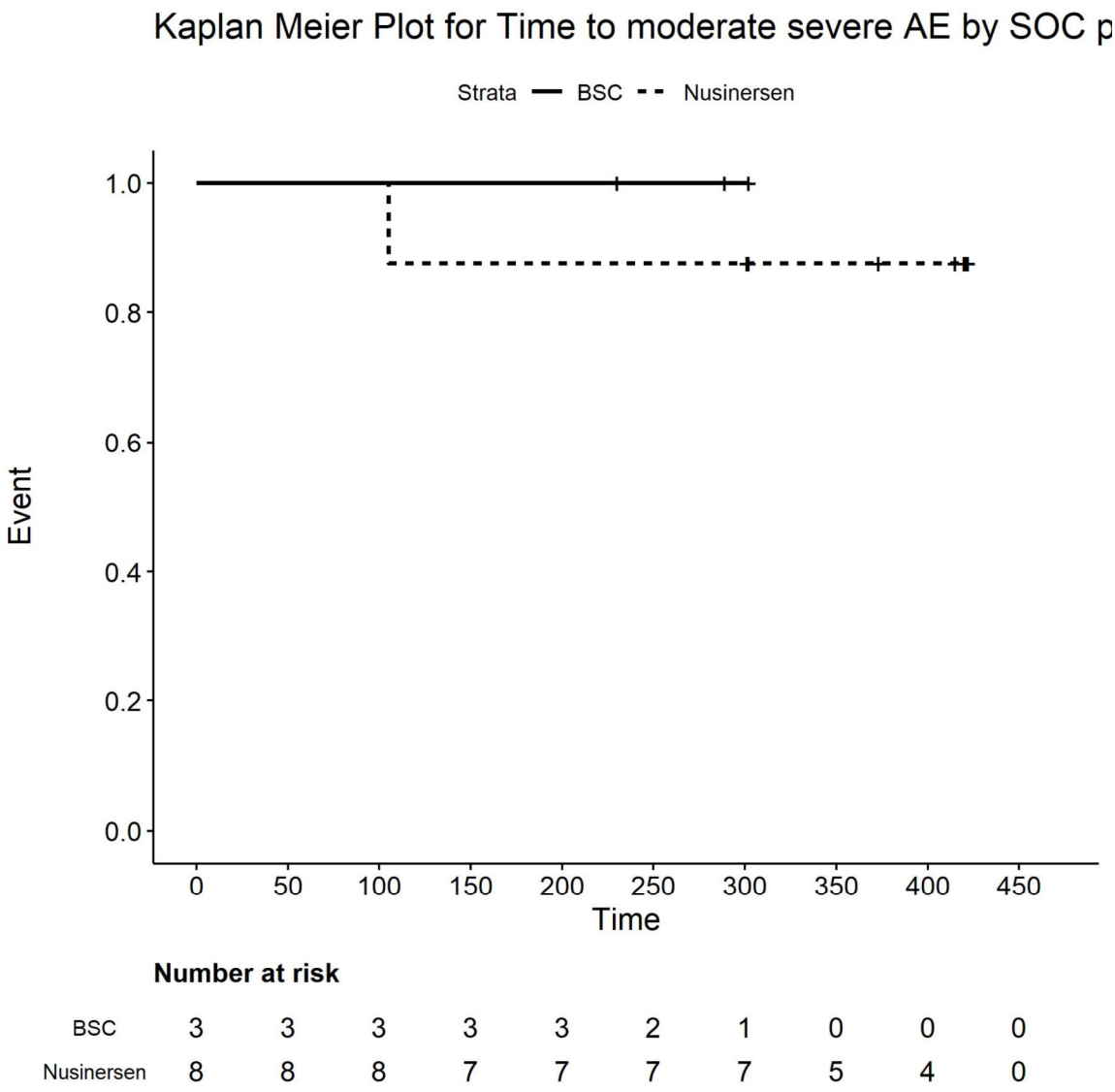
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



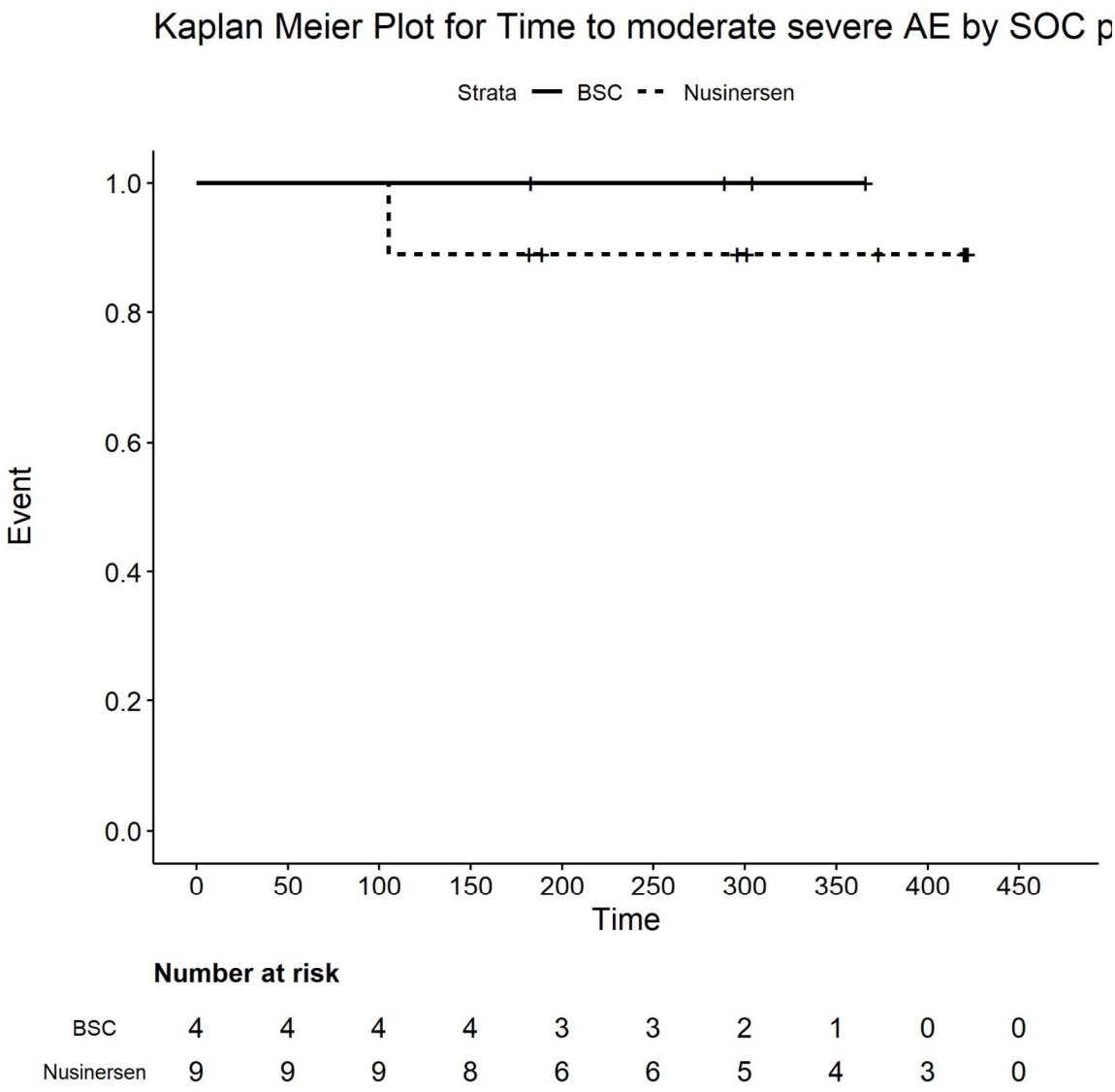
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



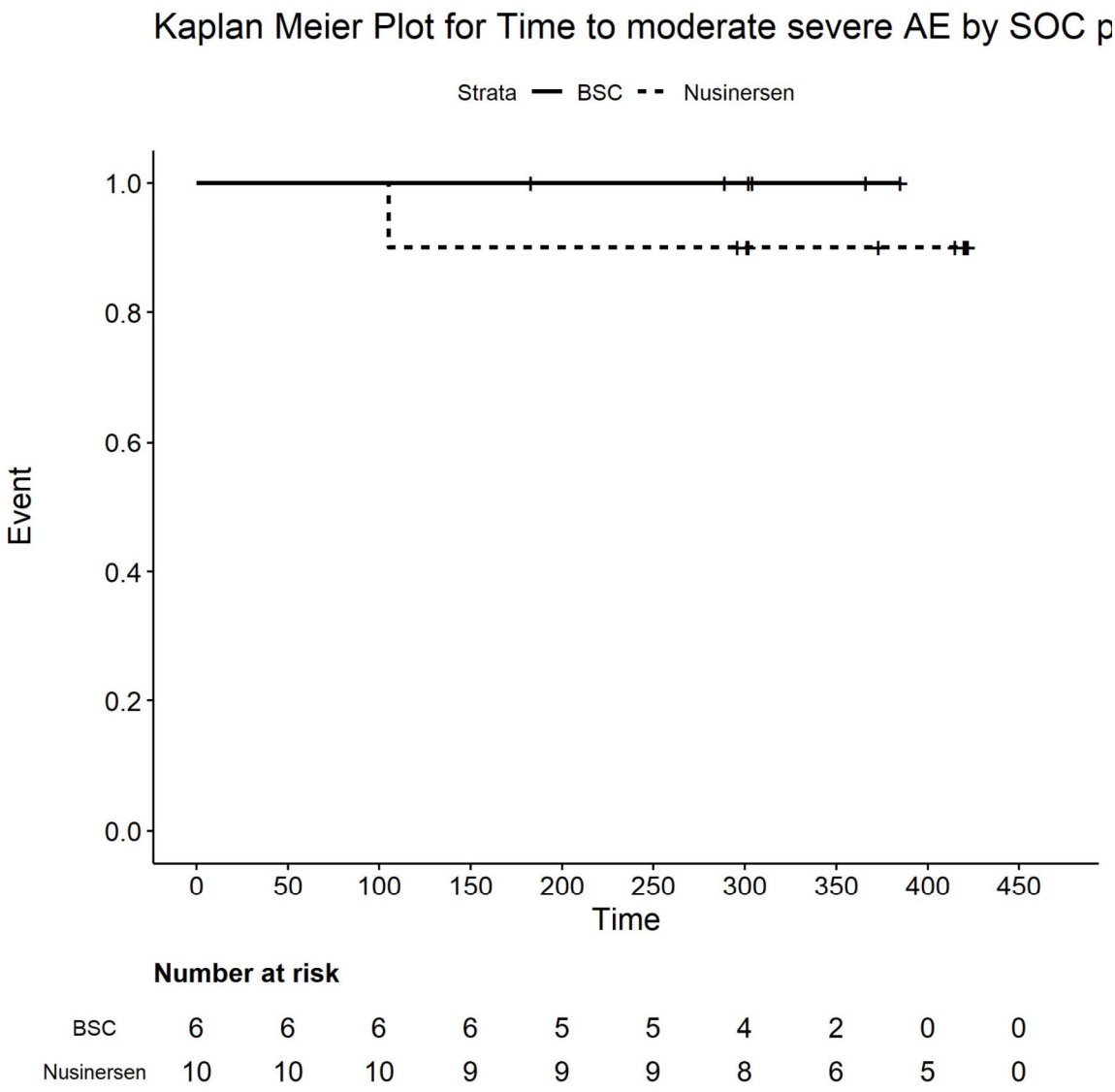
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



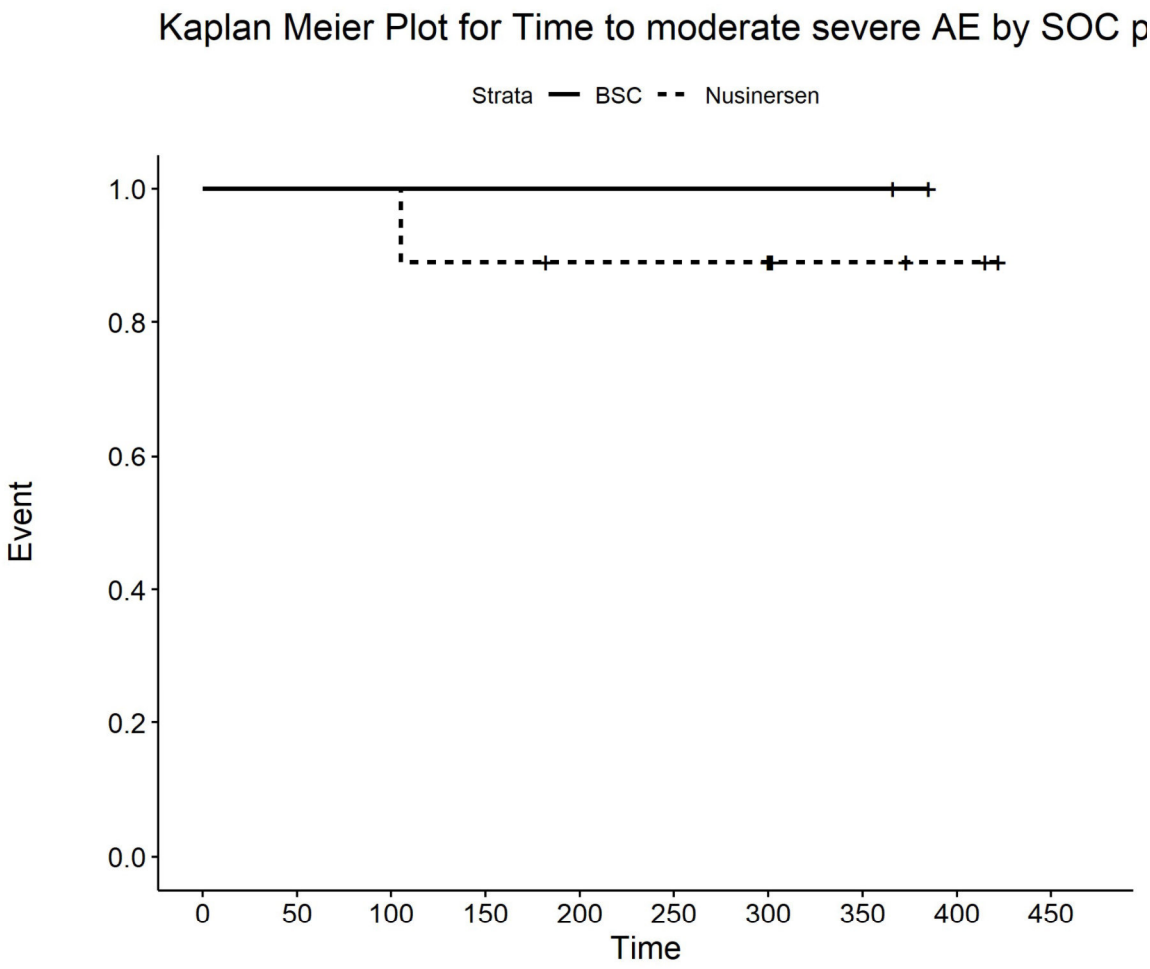
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



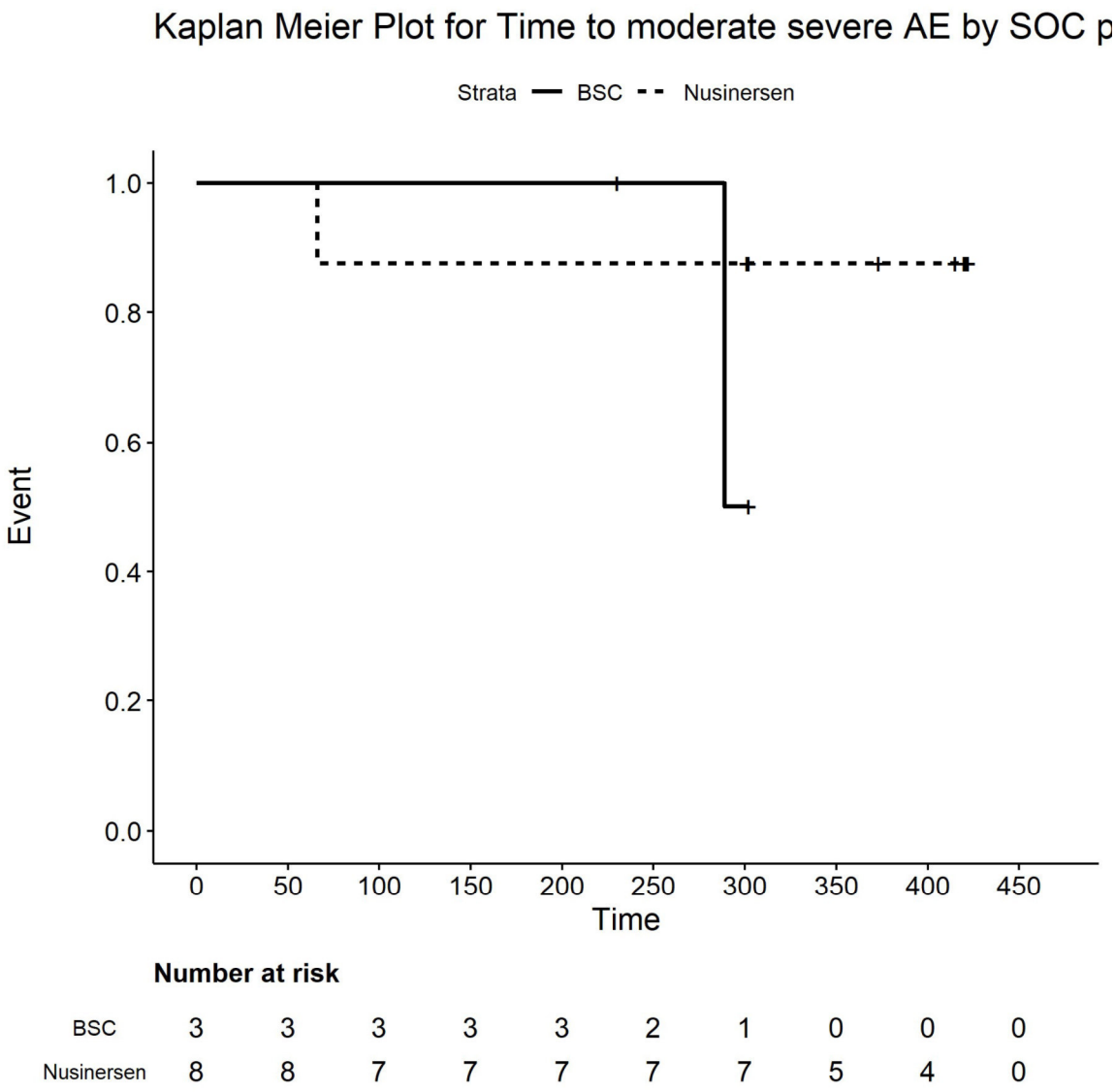
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



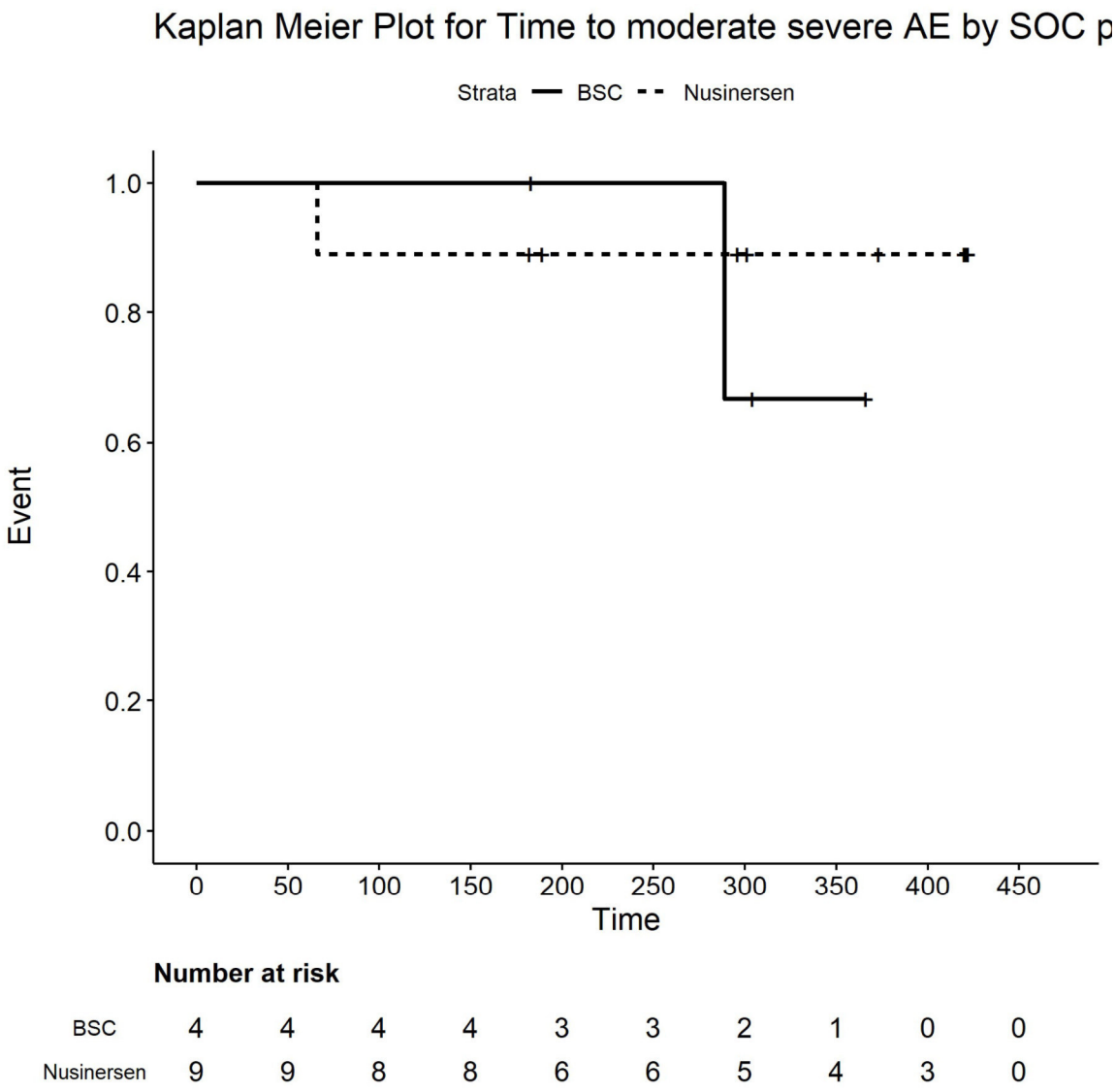
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



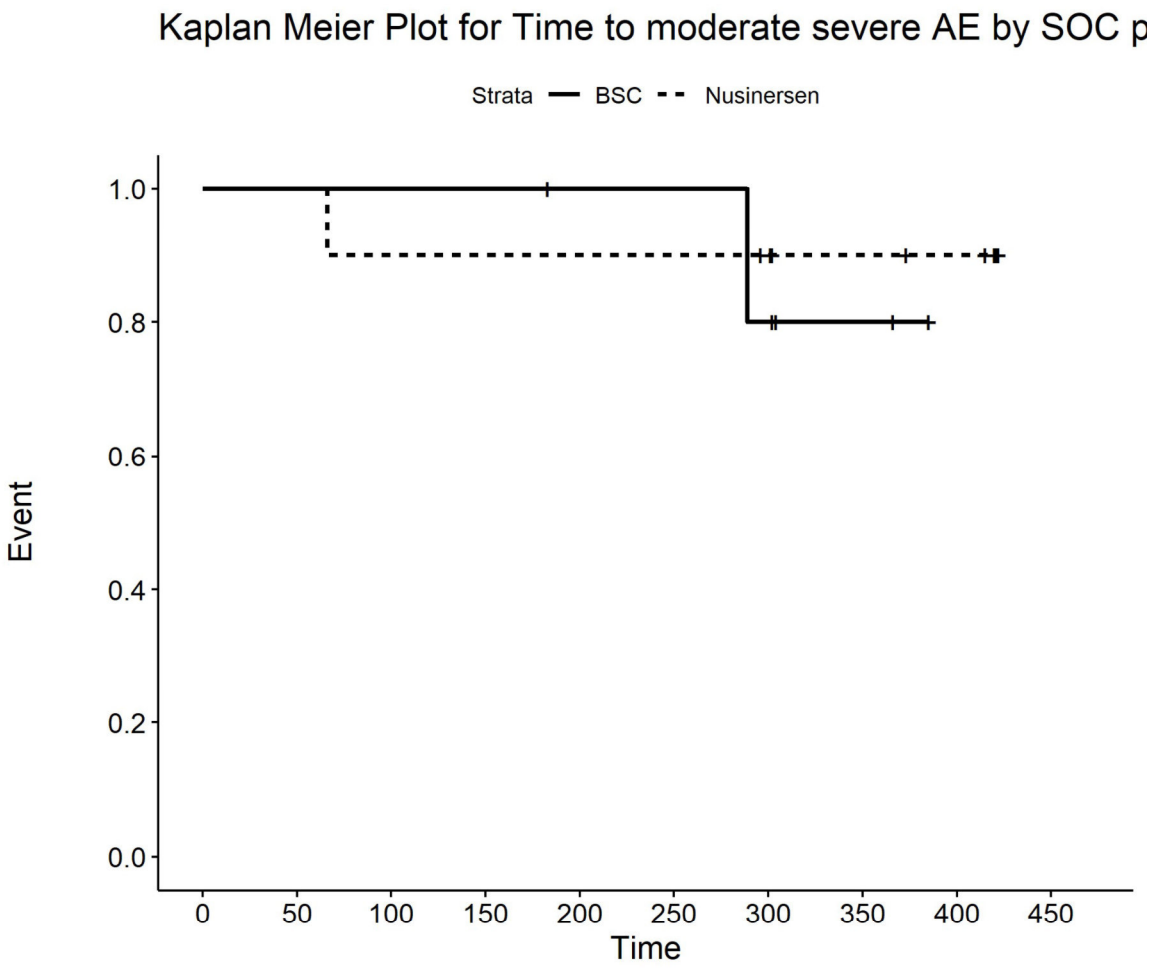
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	4	0



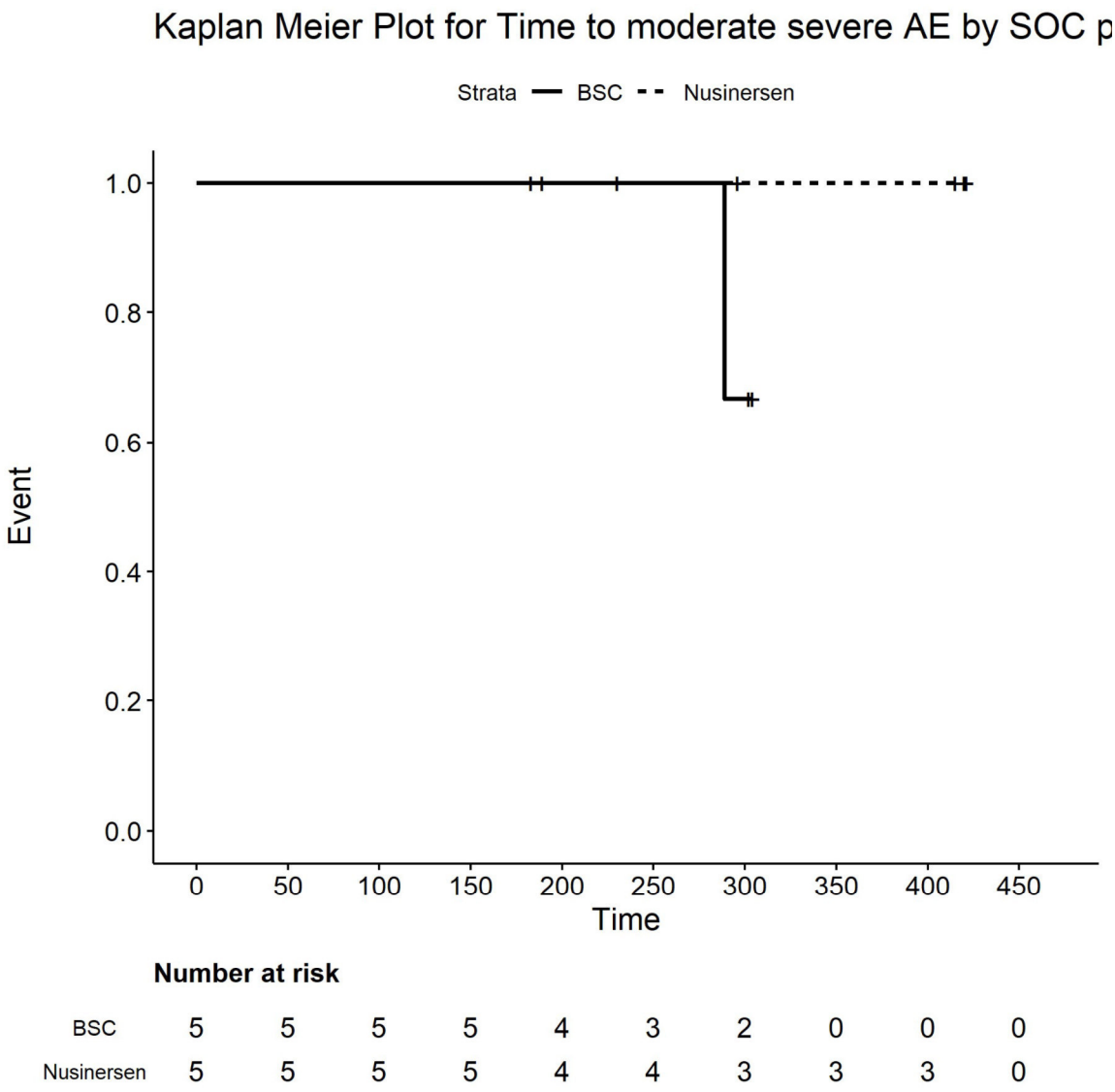
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



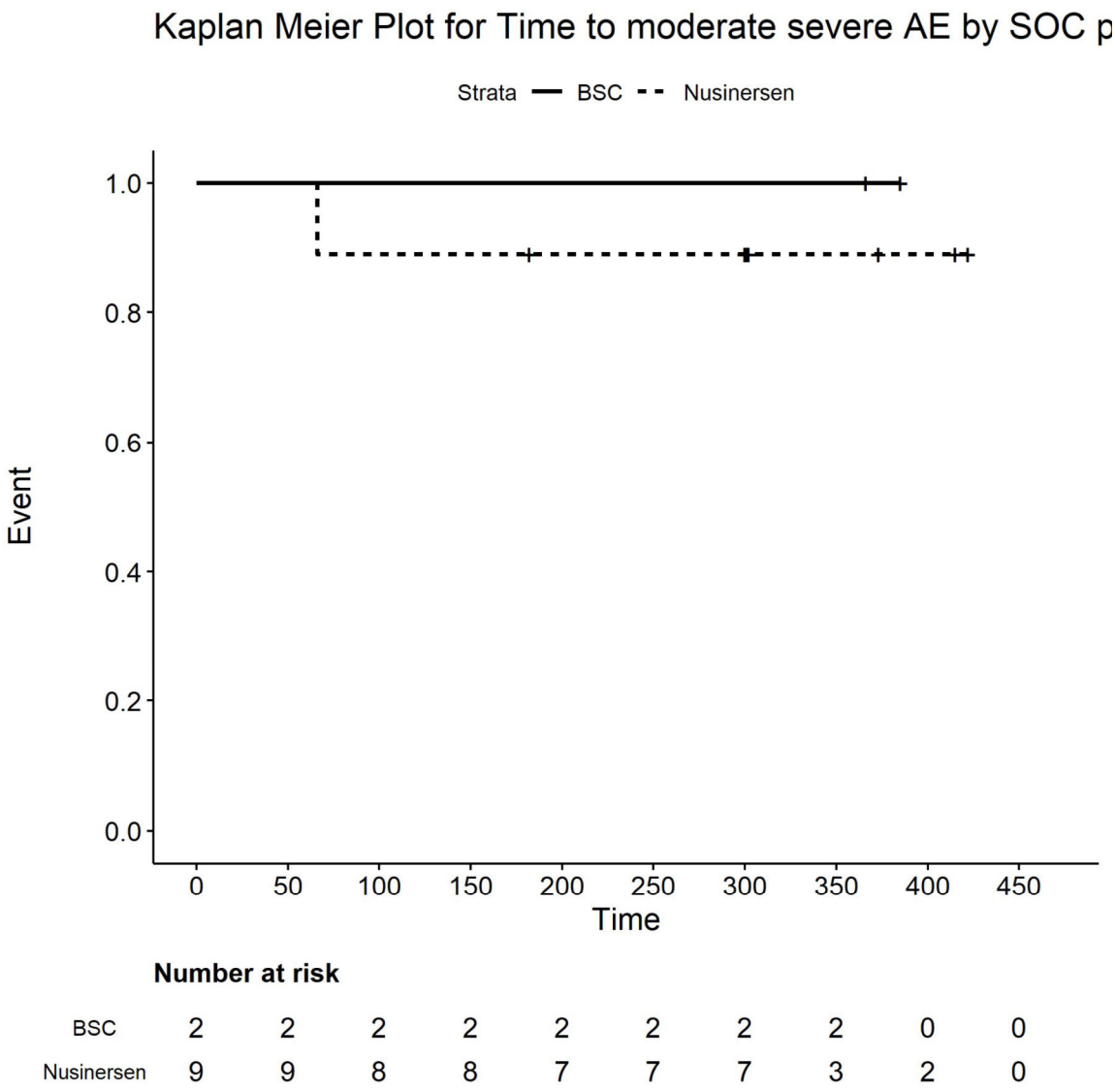
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



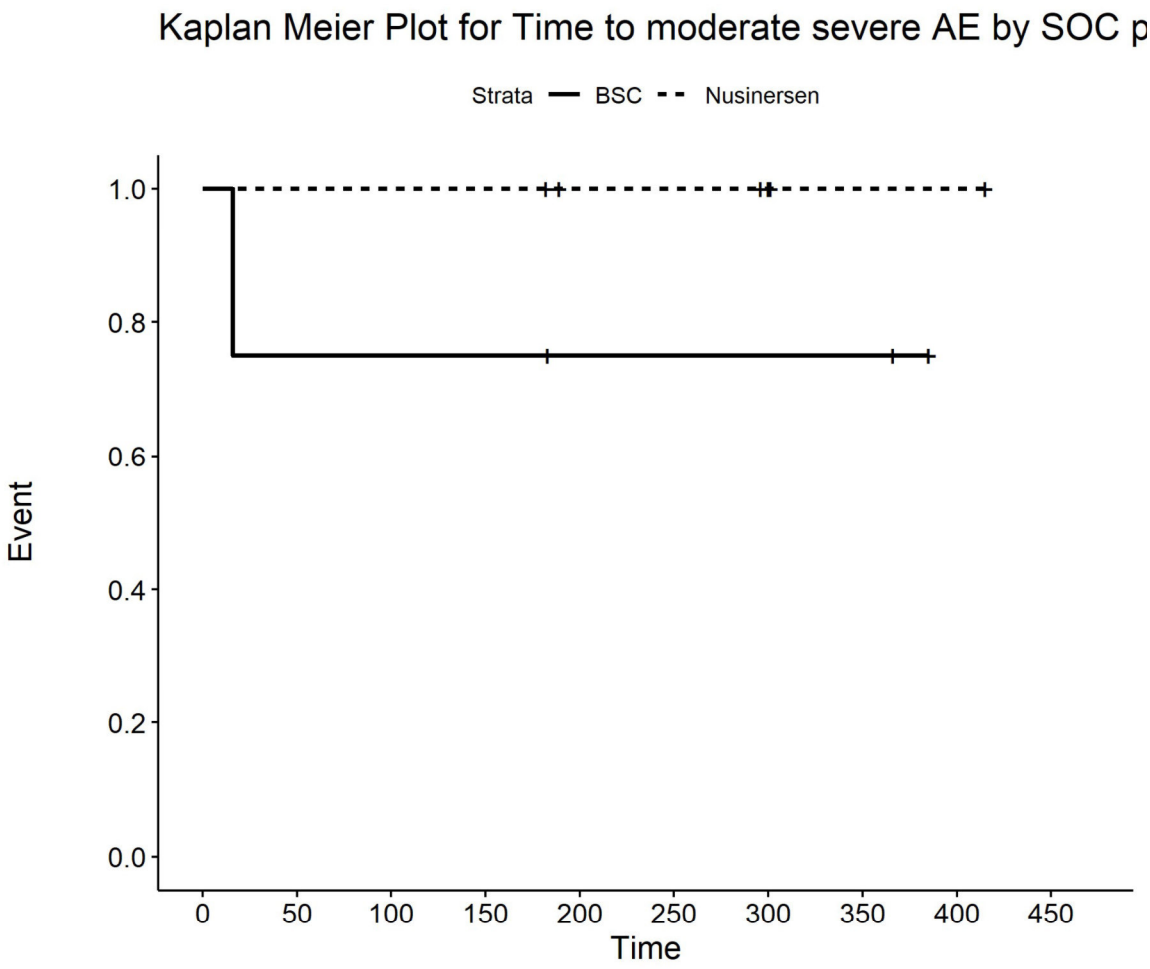
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



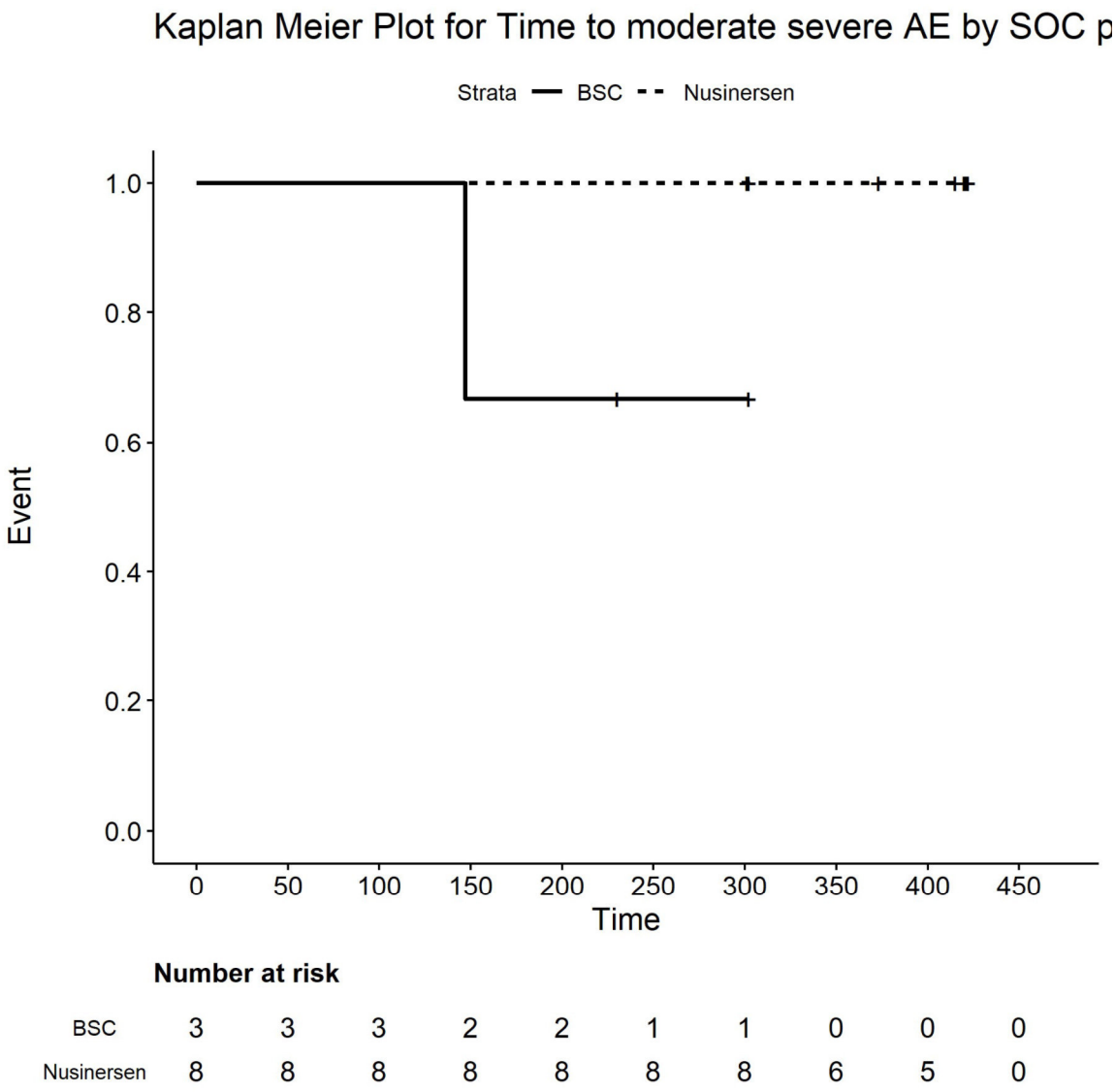
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	2	0



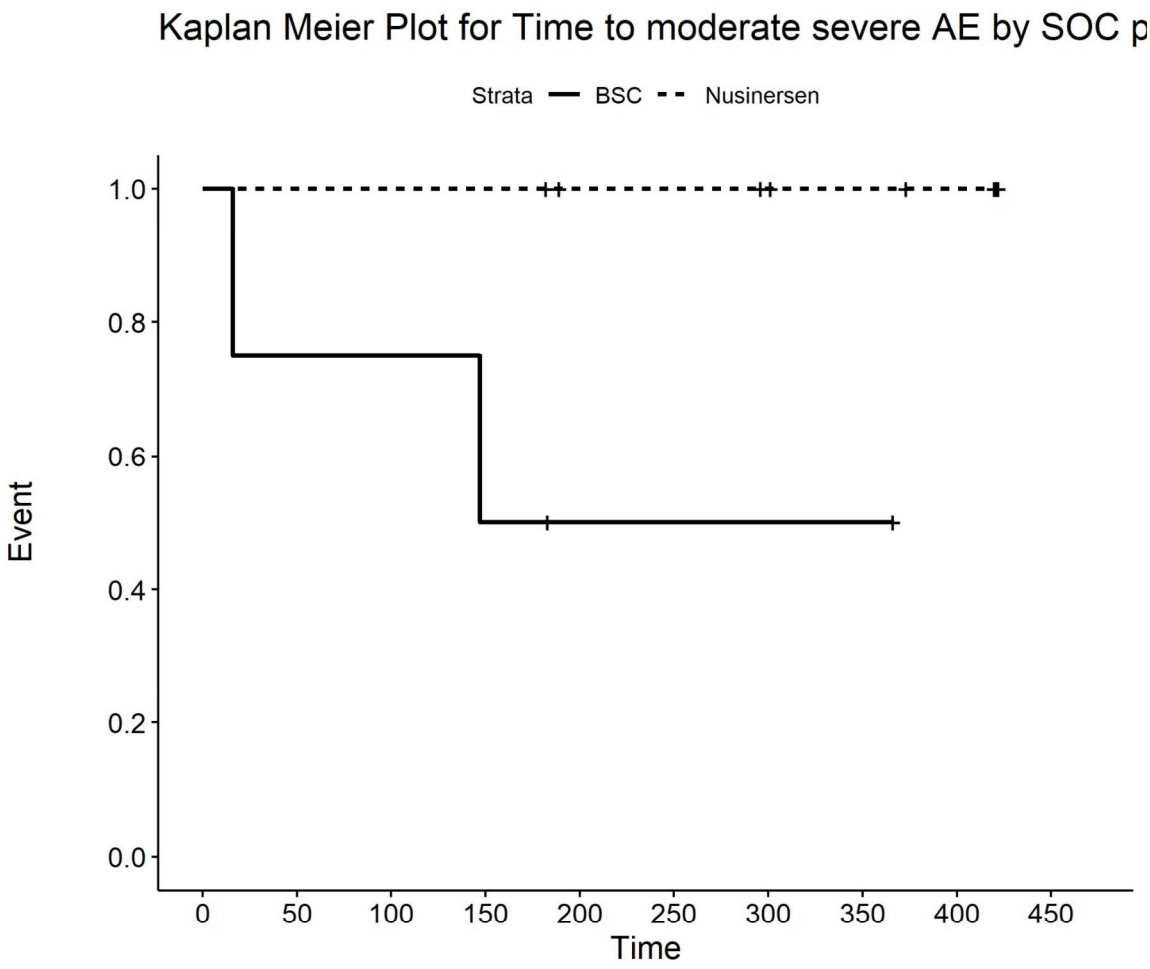
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



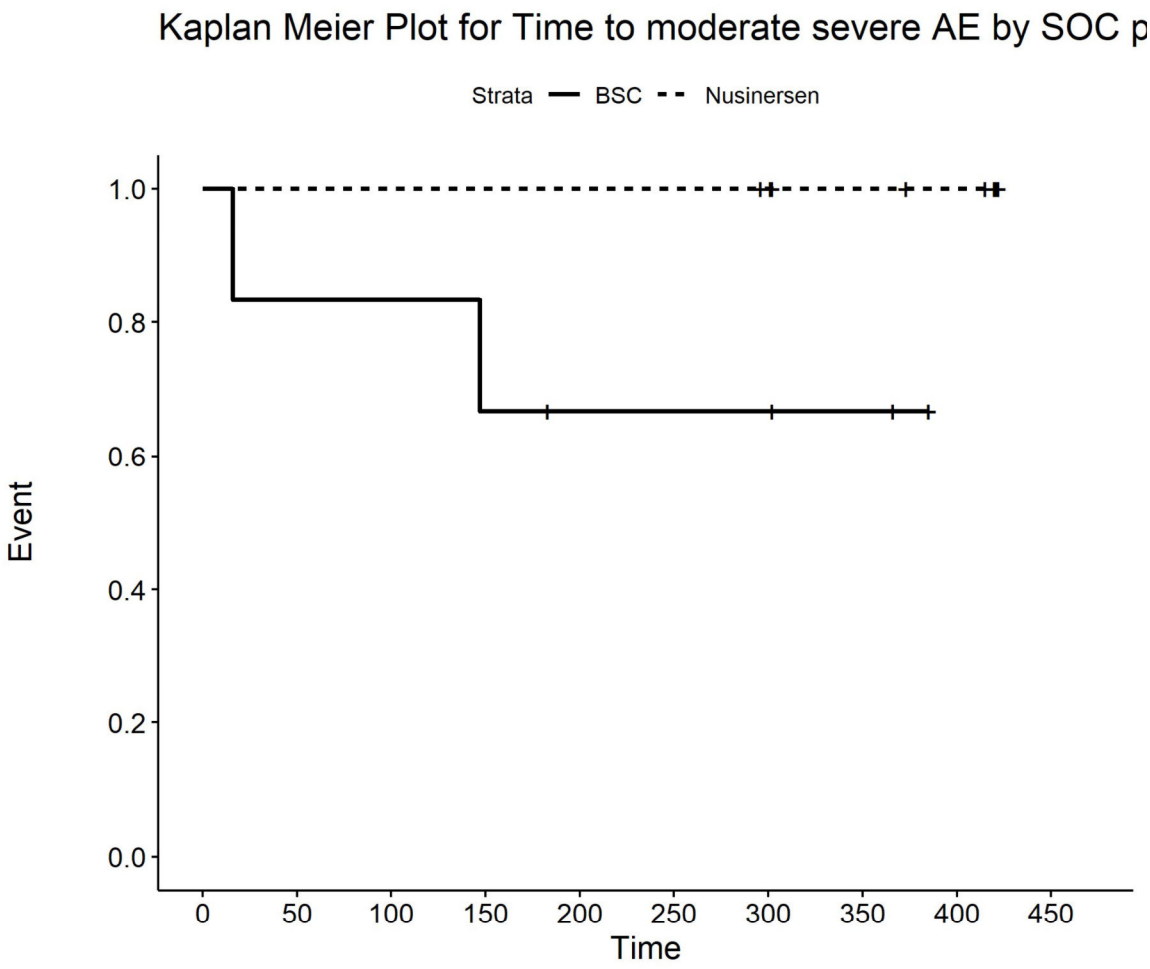
Number at risk

BSC	3	3	3	2	2	1	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



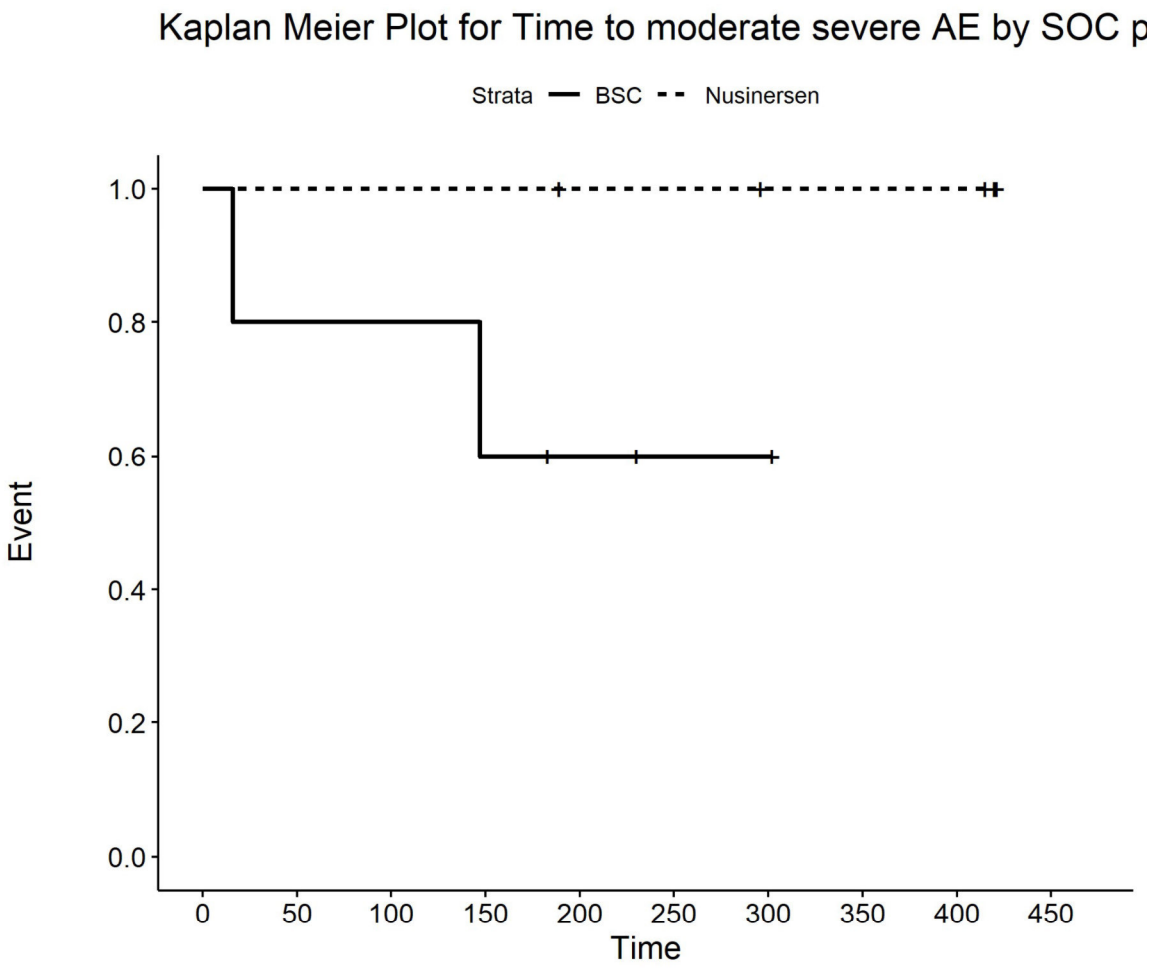
Number at risk

BSC	4	3	3	2	1	1	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



Number at risk

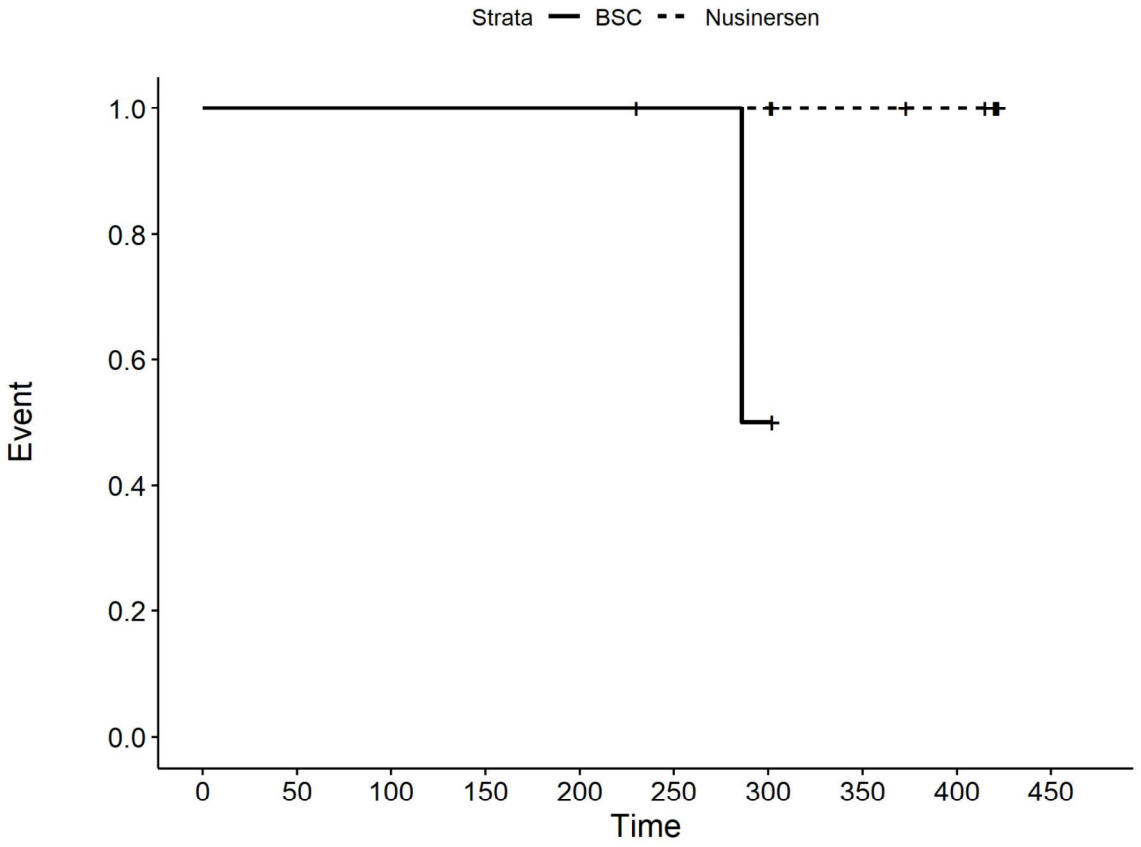
BSC	6	5	5	4	3	3	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



Number at risk

BSC	5	4	4	3	2	1	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0

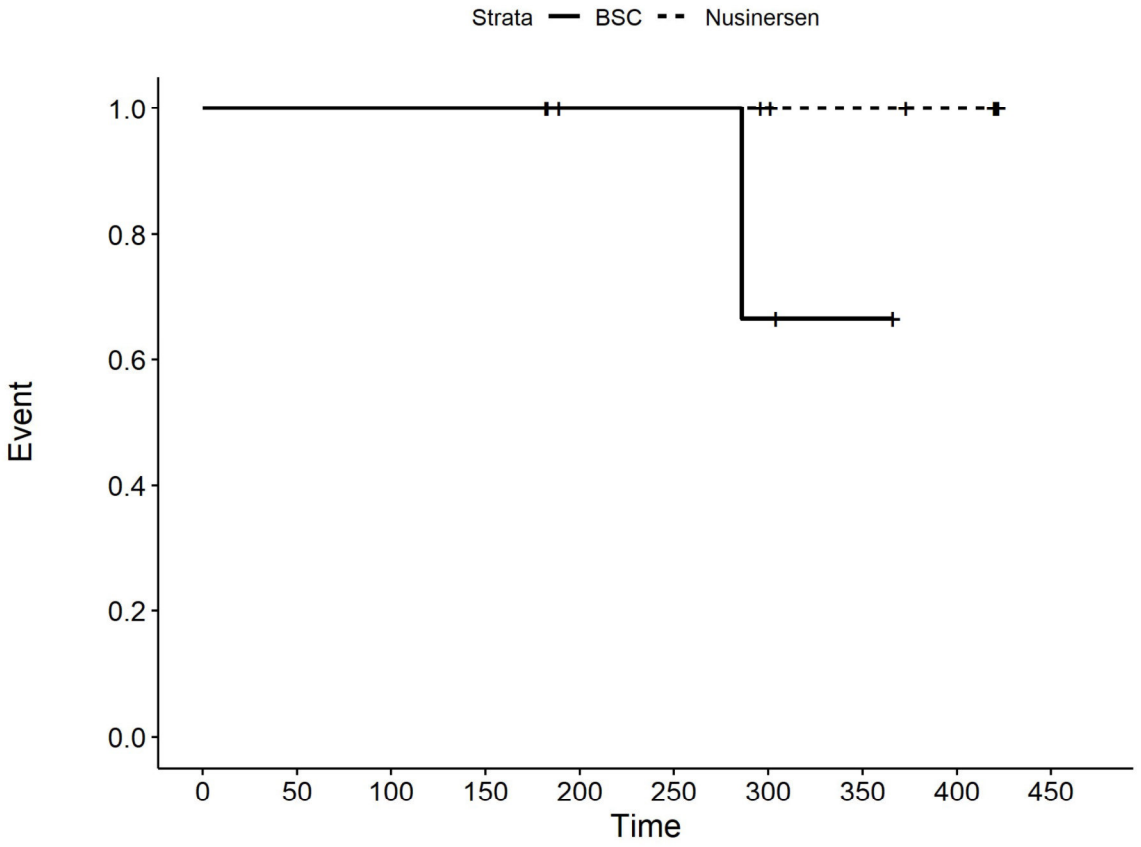
Kaplan Meier Plot for
Time to moderate severe AE by SOC pct SG Hypoxic : ischa



Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0

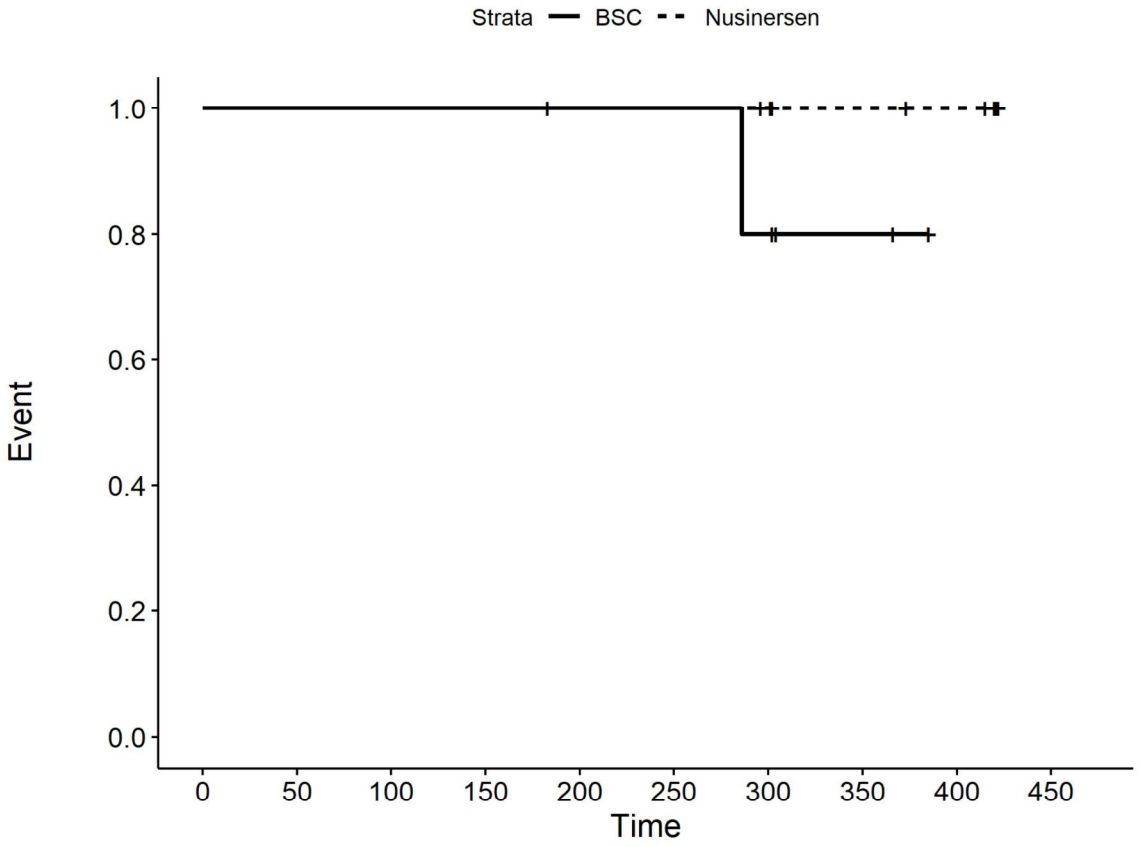
Kaplan Meier Plot for
Time to moderate severe AE by SOC pct SG Hypoxic : ischa



Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0

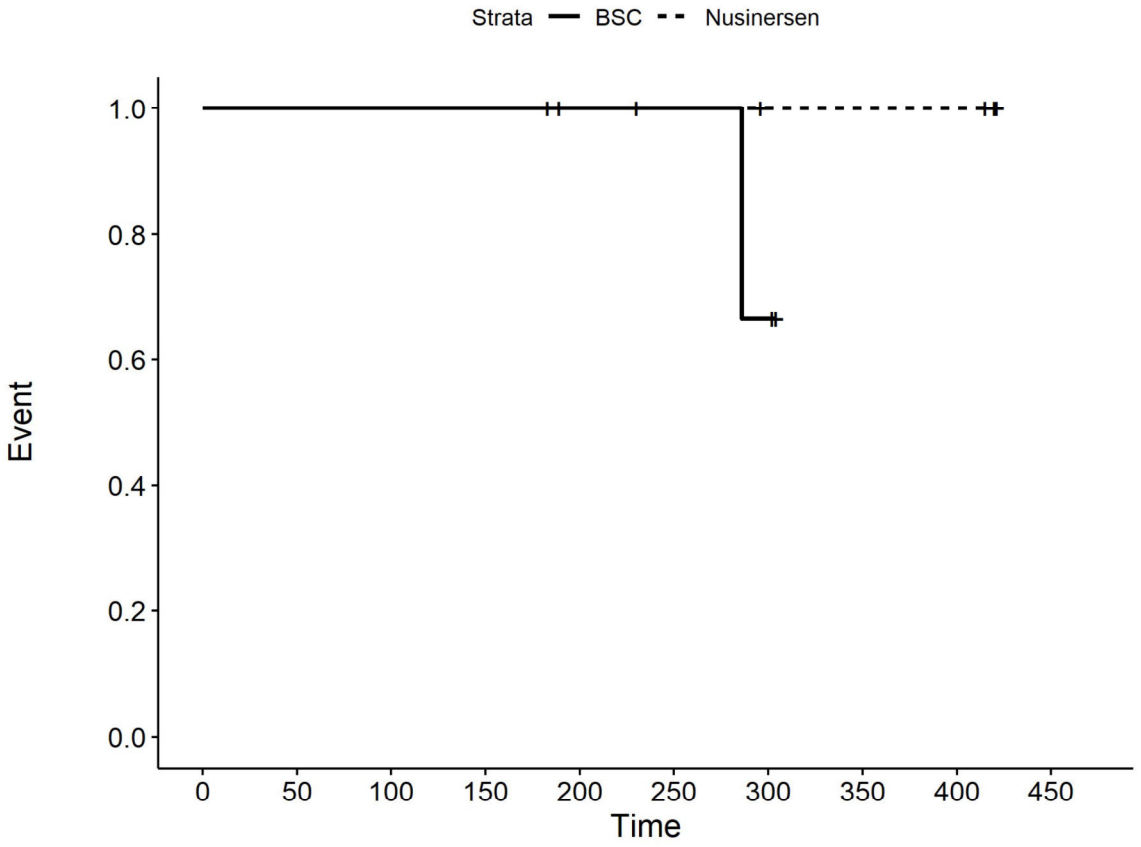
Kaplan Meier Plot for
Time to moderate severe AE by SOC pct SG Hypoxic : ischa



Number at risk

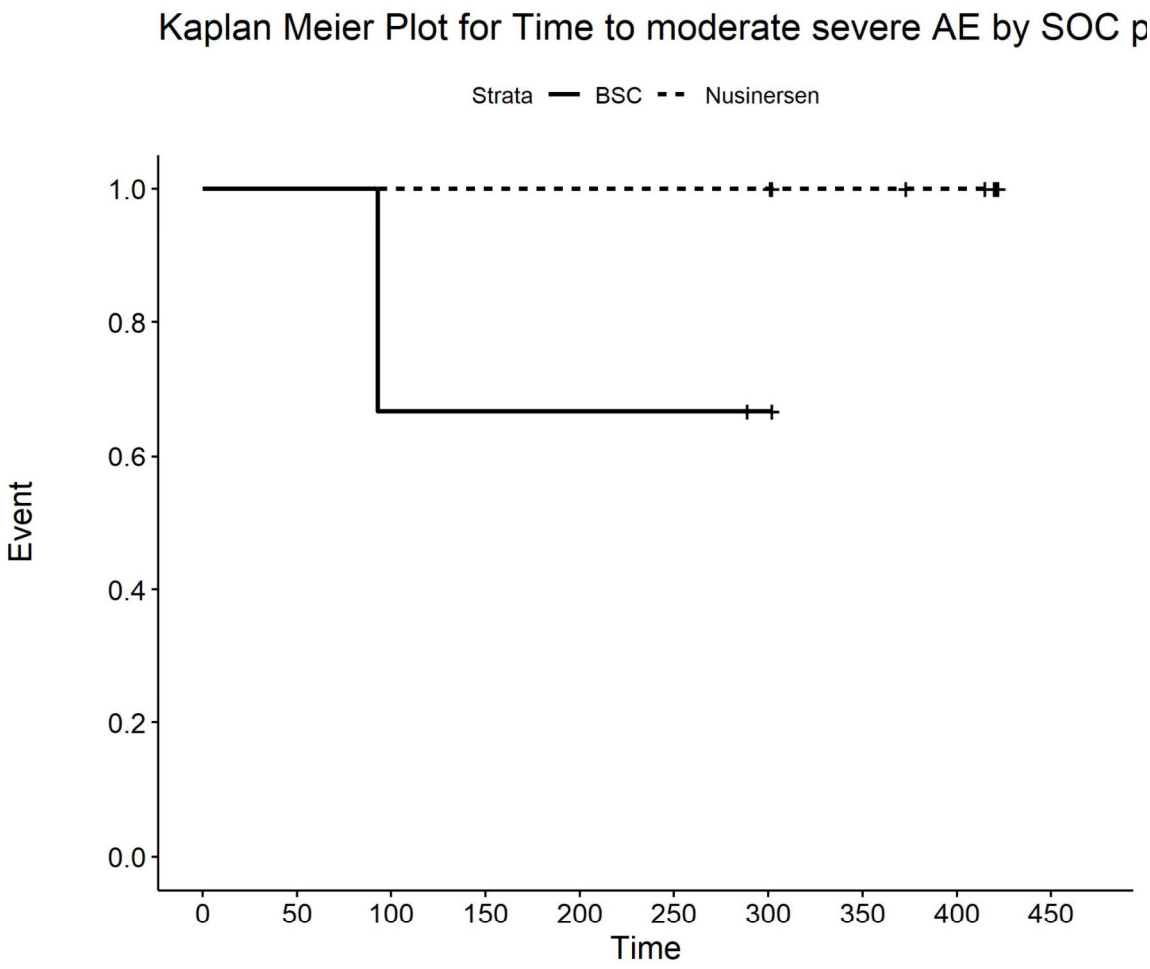
BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0

Kaplan Meier Plot for
Time to moderate severe AE by SOC pct SG Hypoxic : ischa



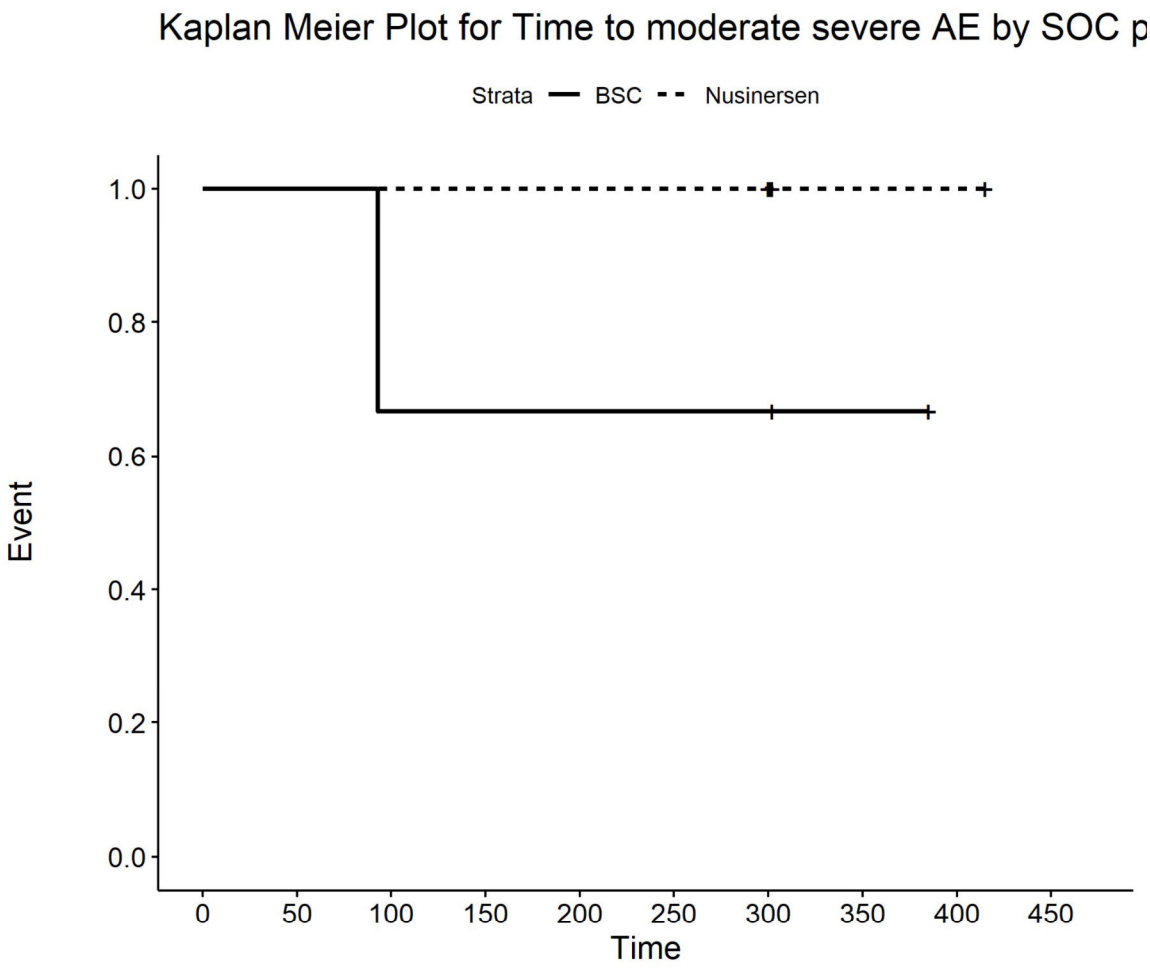
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



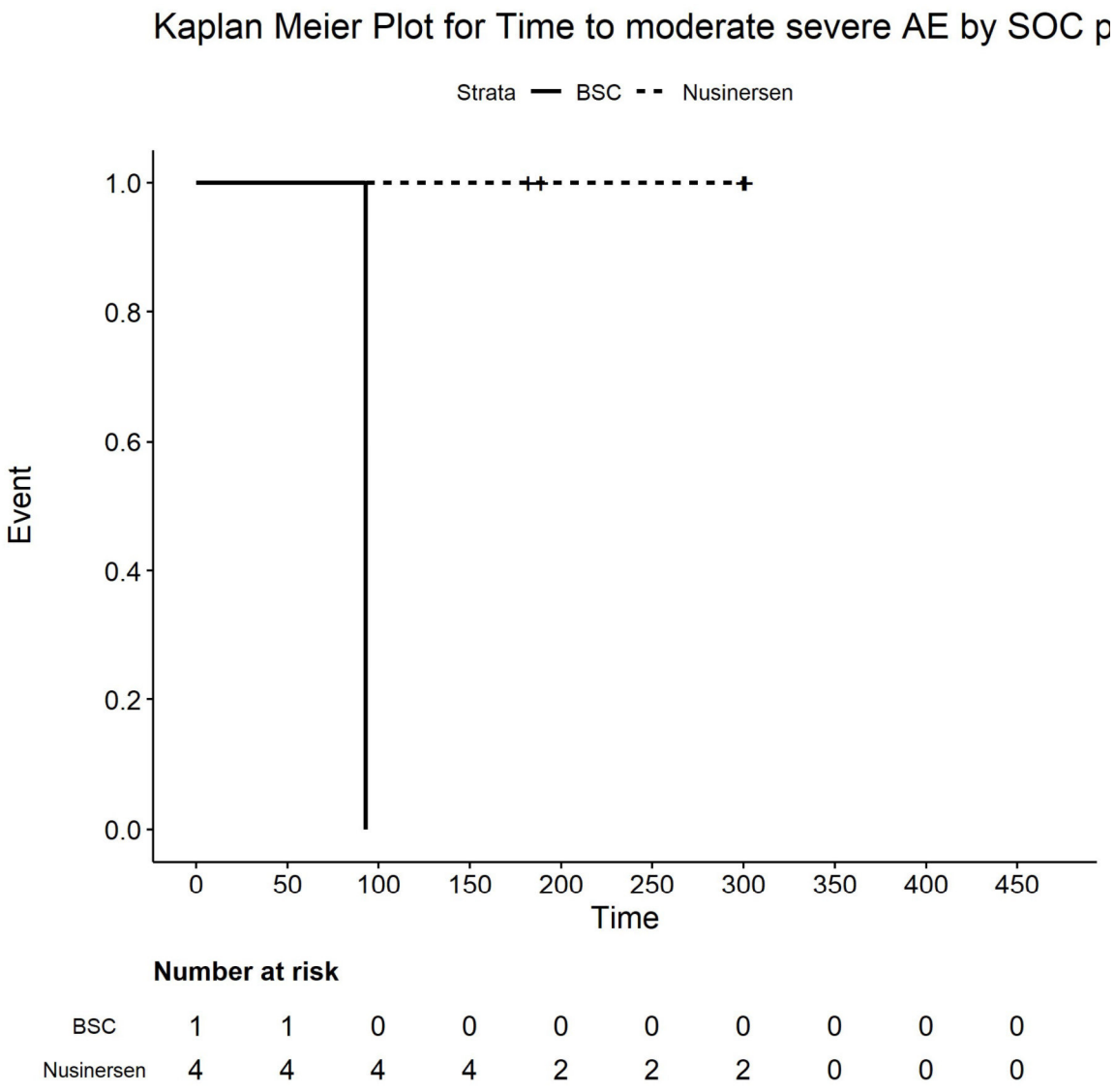
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



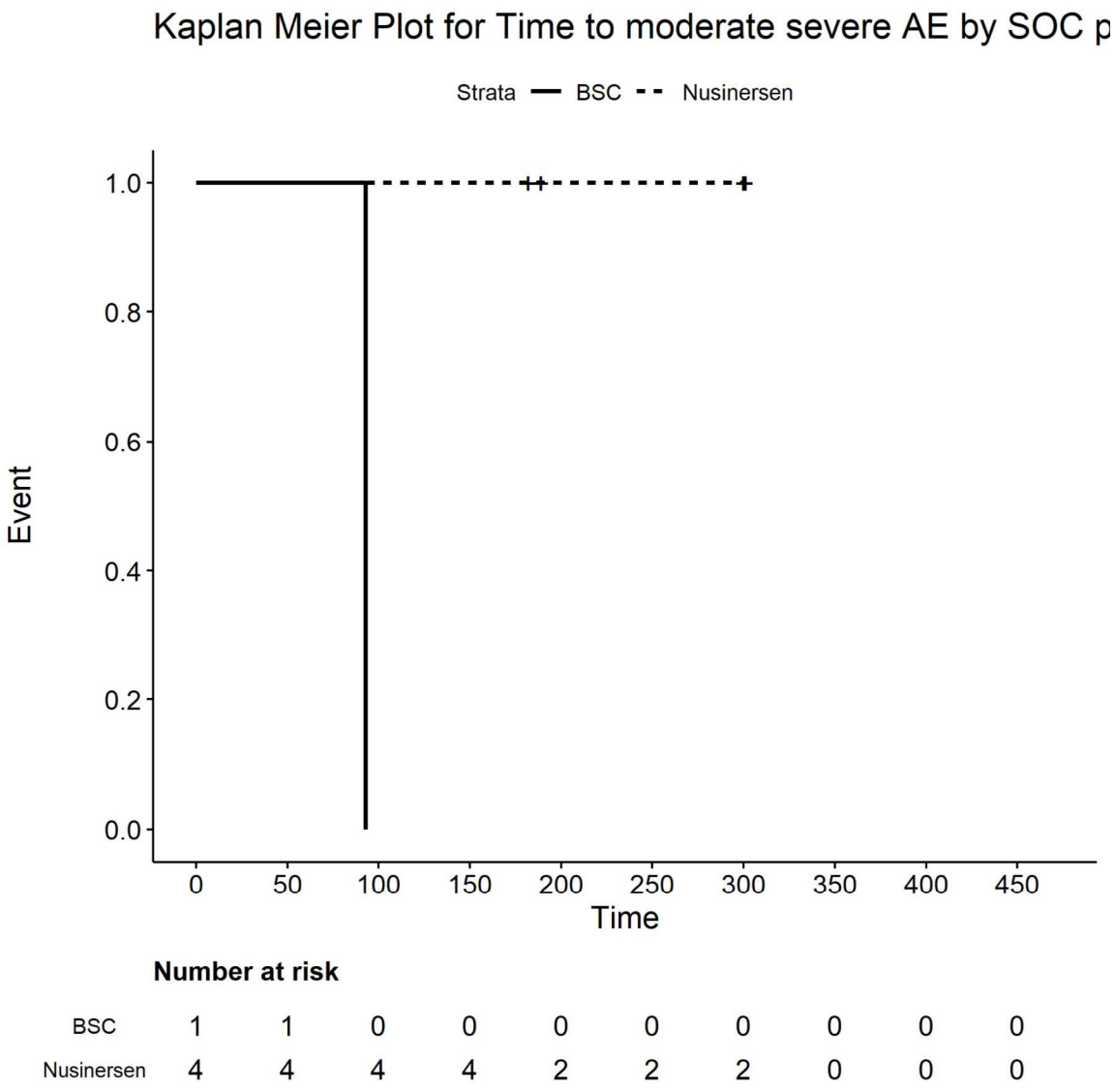
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



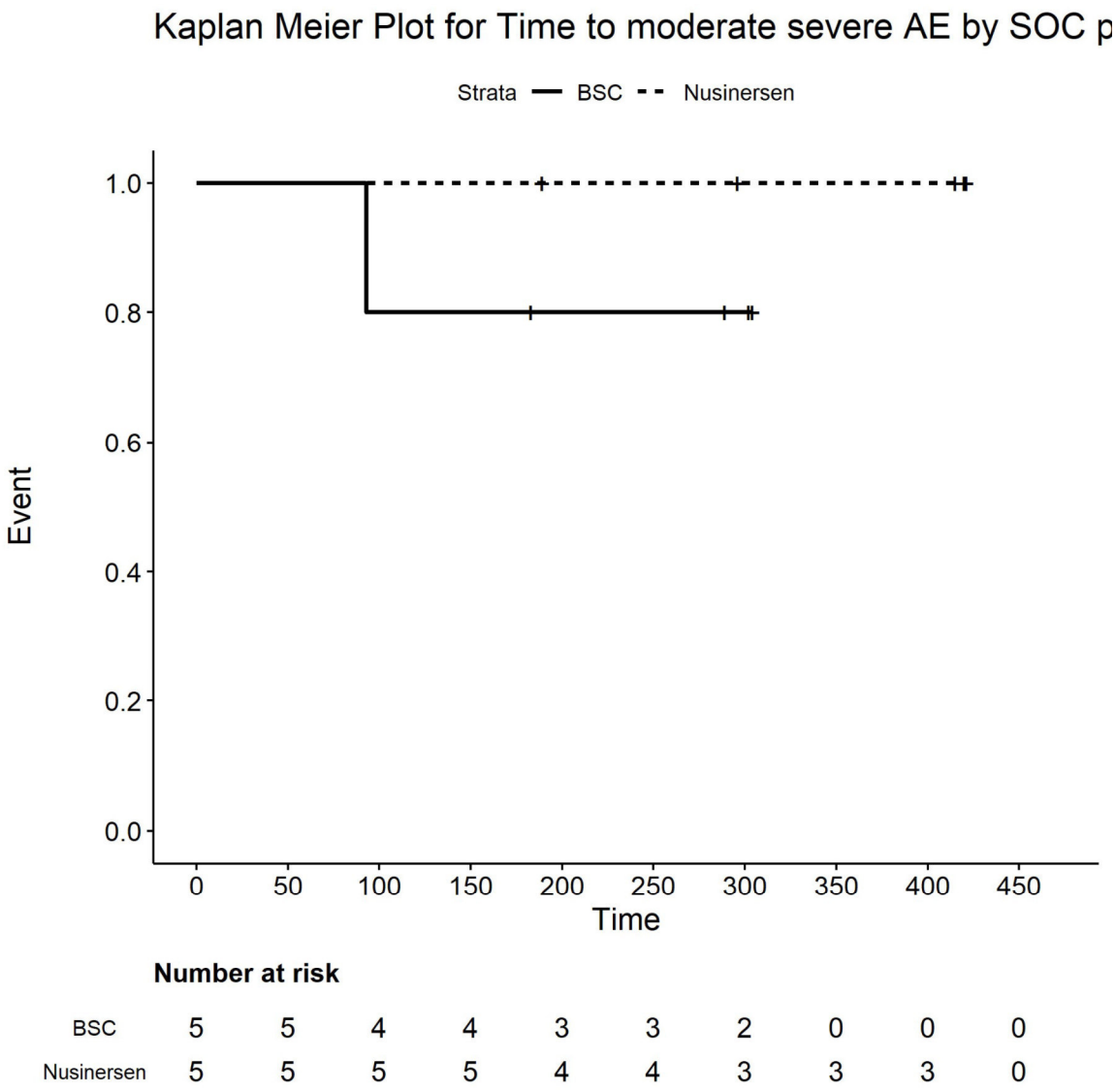
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



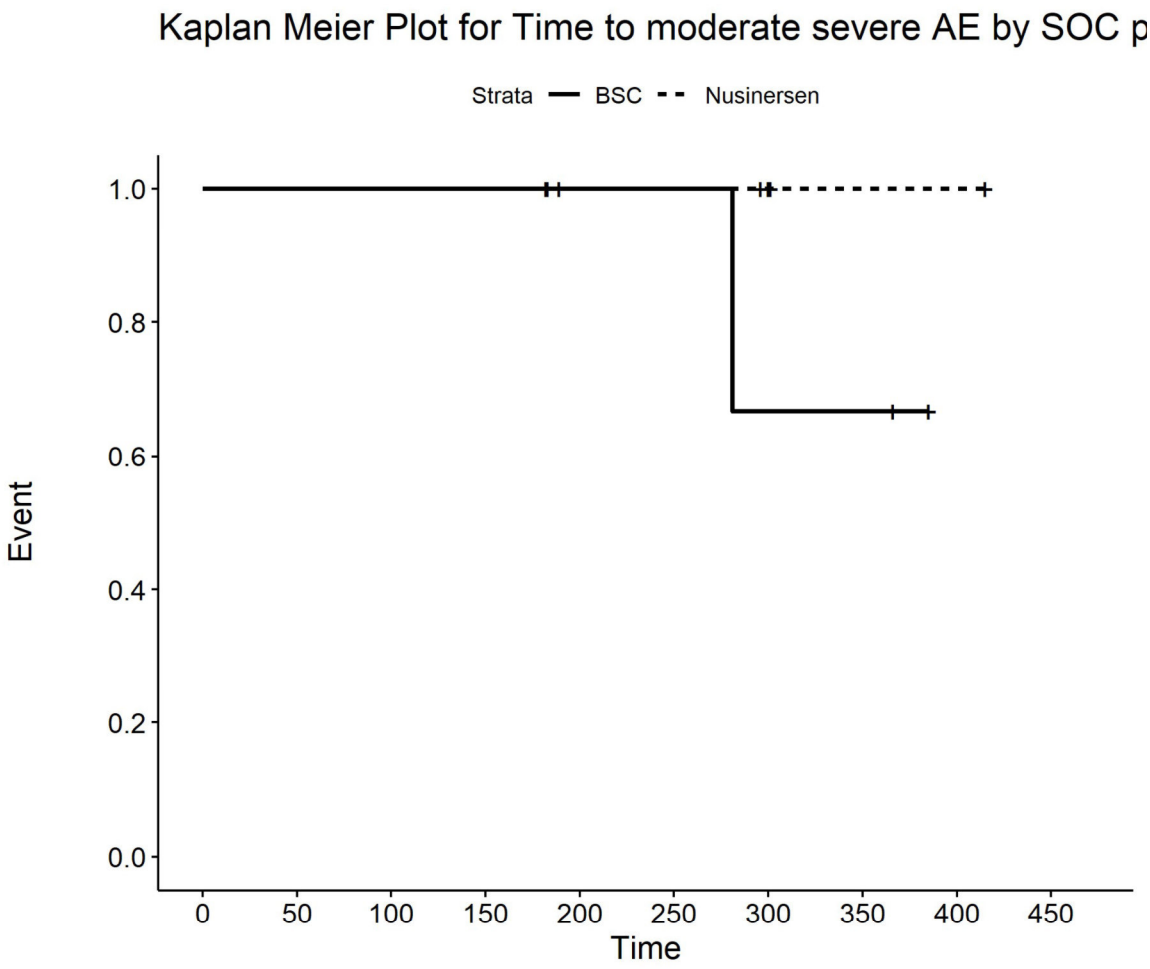
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



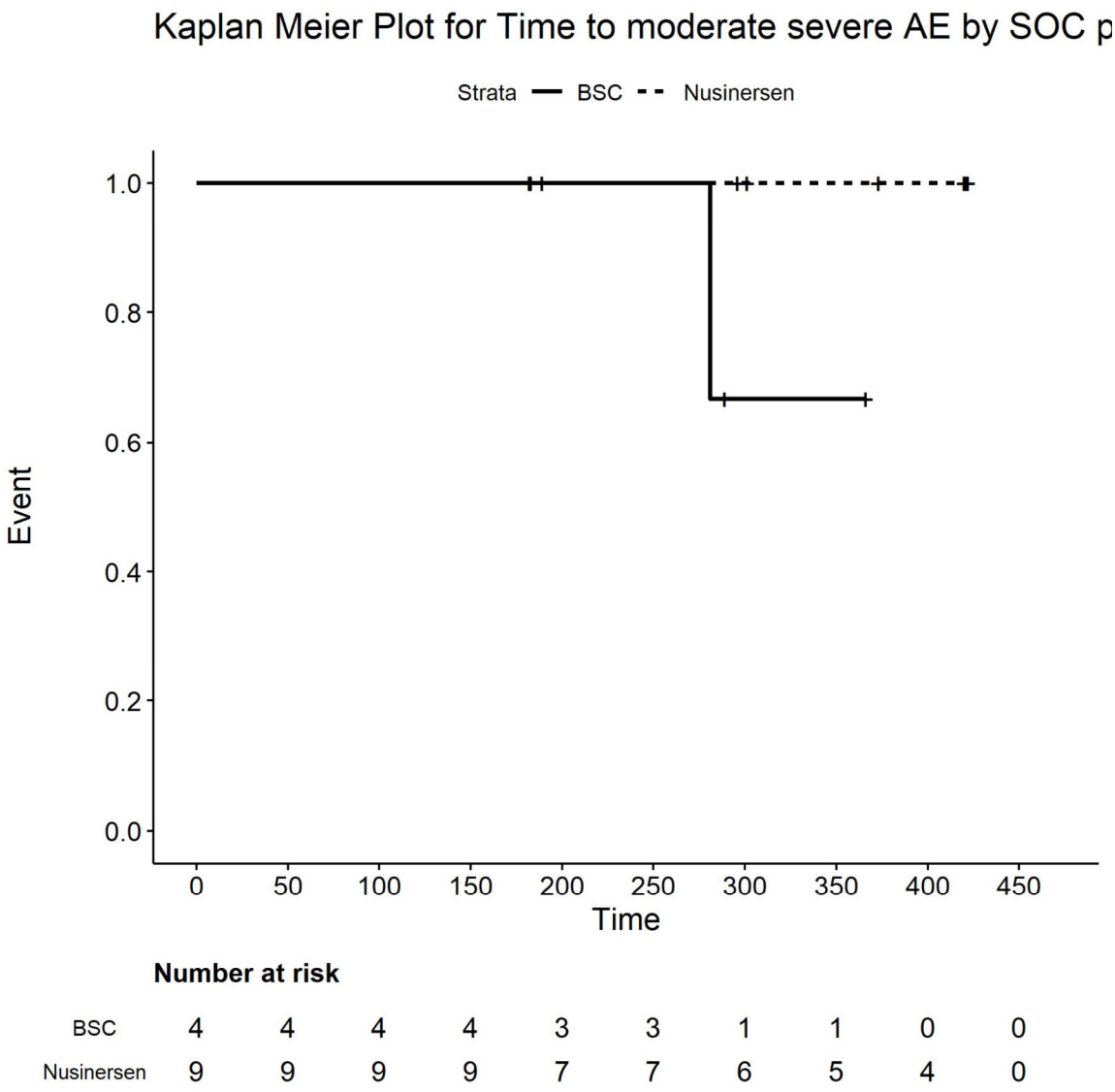
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



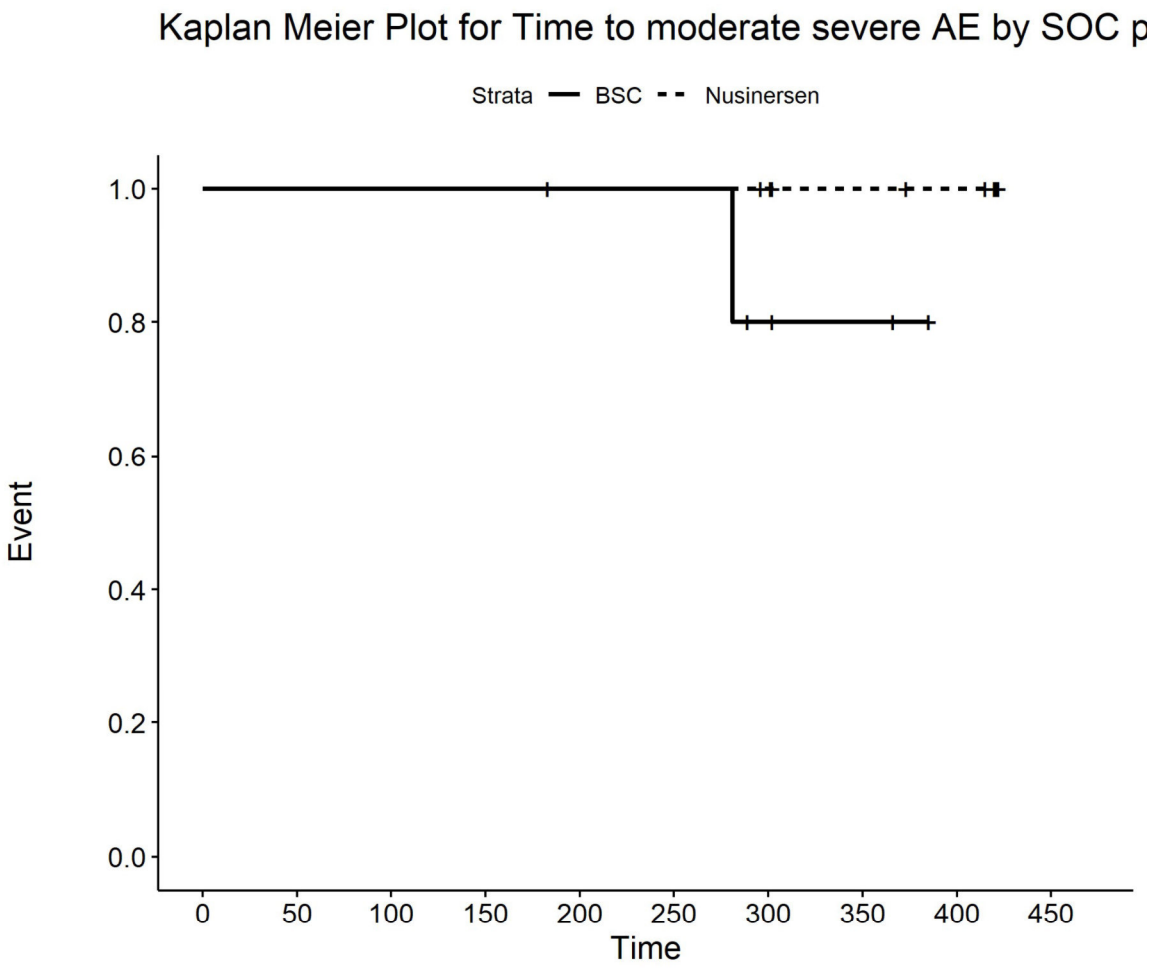
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



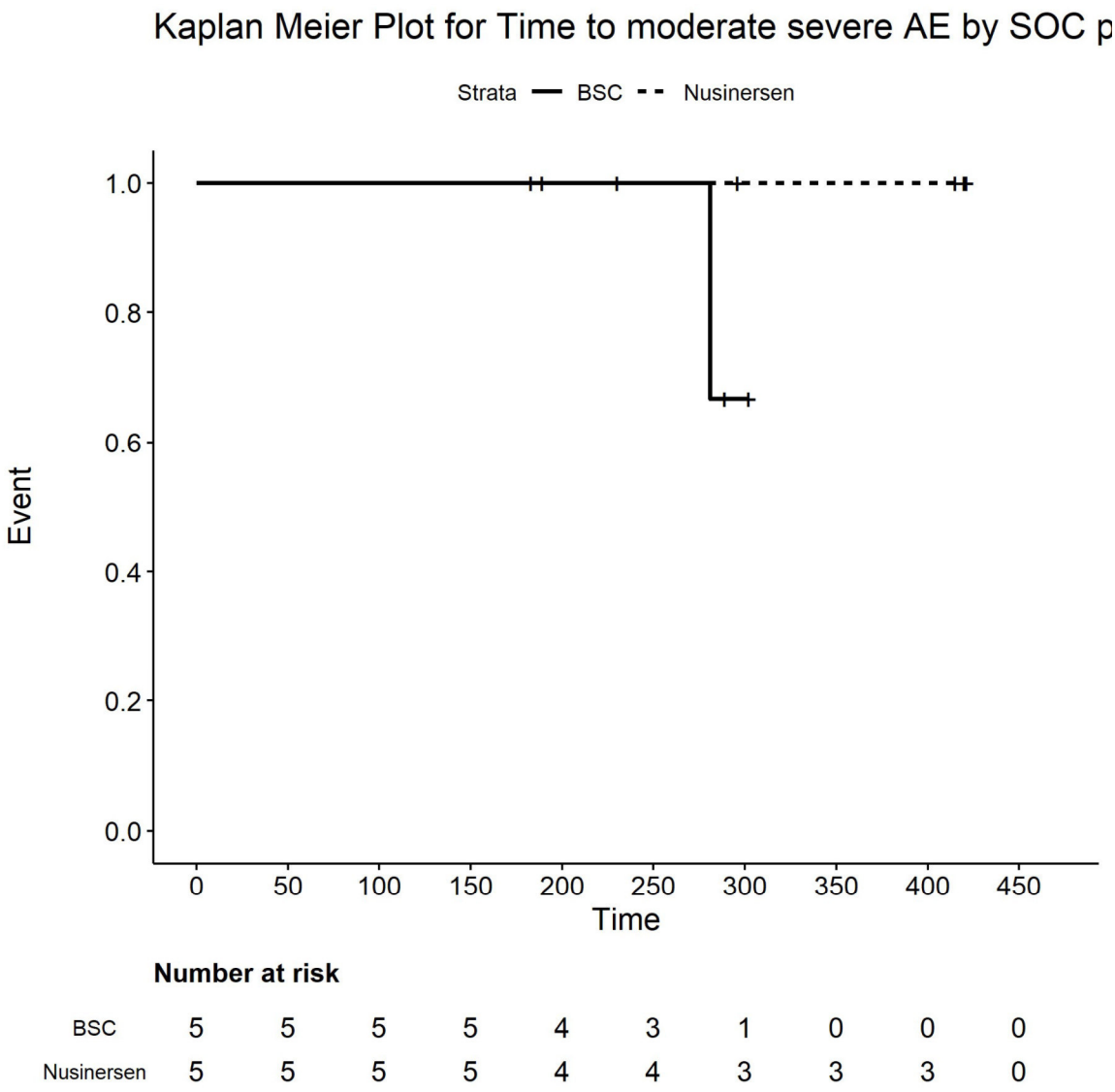
Number at risk

BSC	4	4	4	4	3	3	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



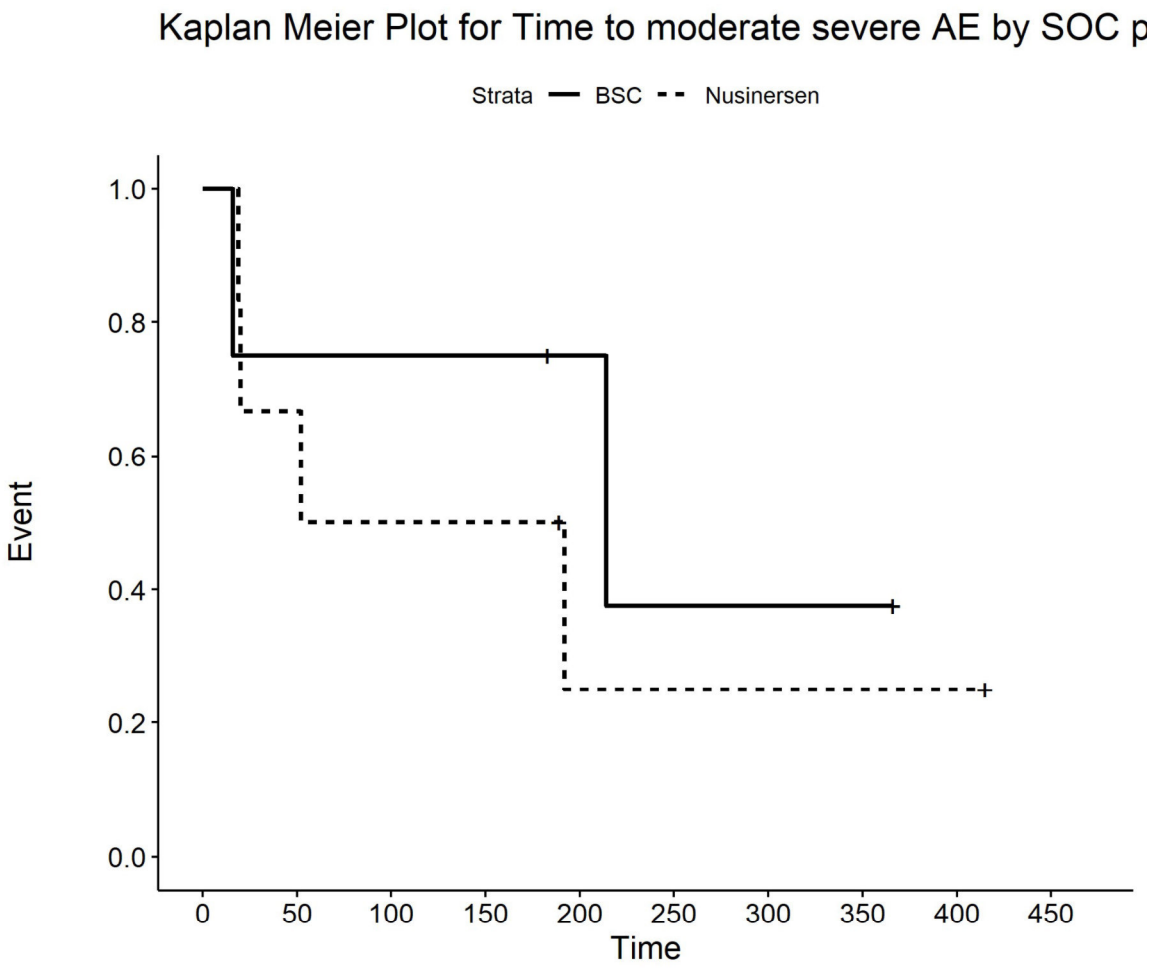
Number at risk

BSC	6	6	6	6	5	5	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



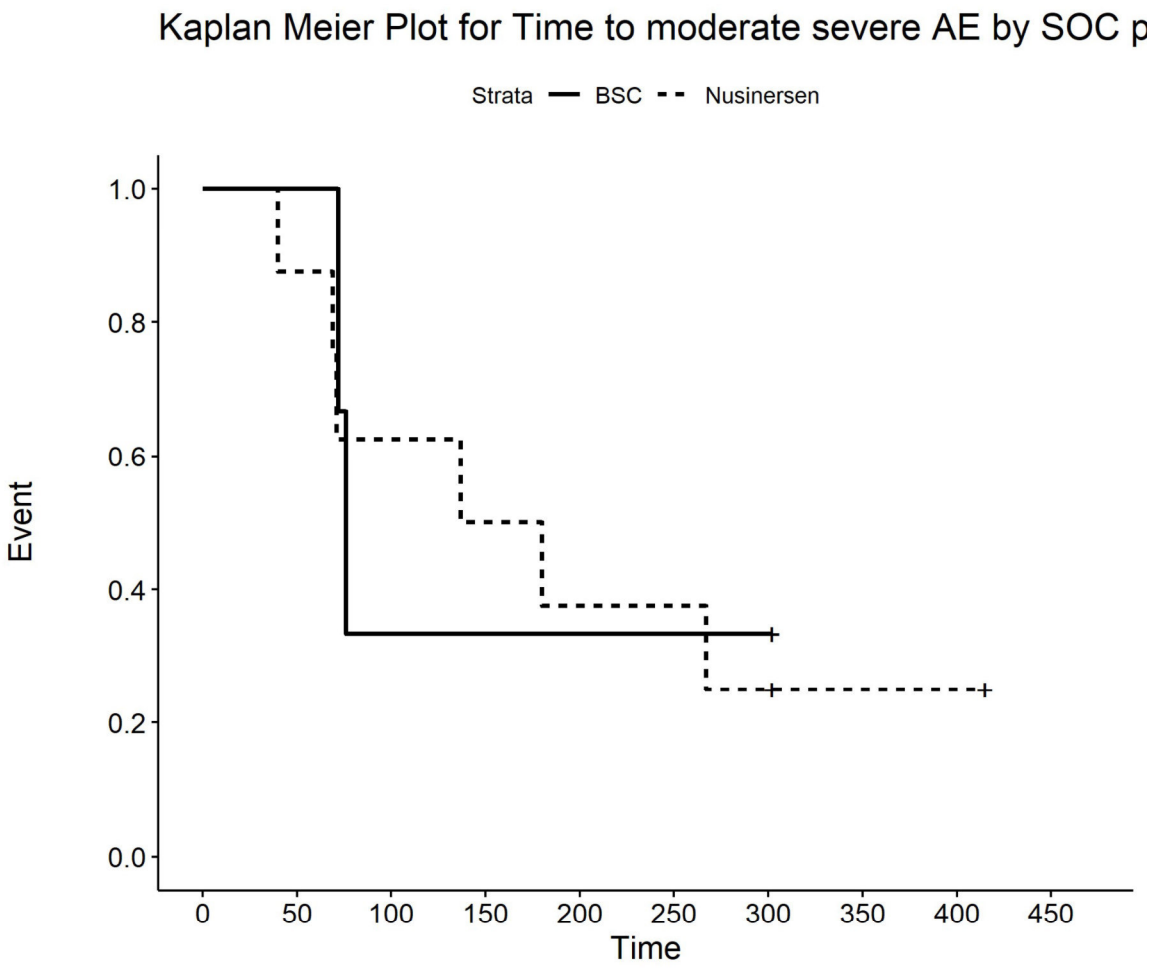
Number at risk

BSC	5	5	5	5	4	3	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



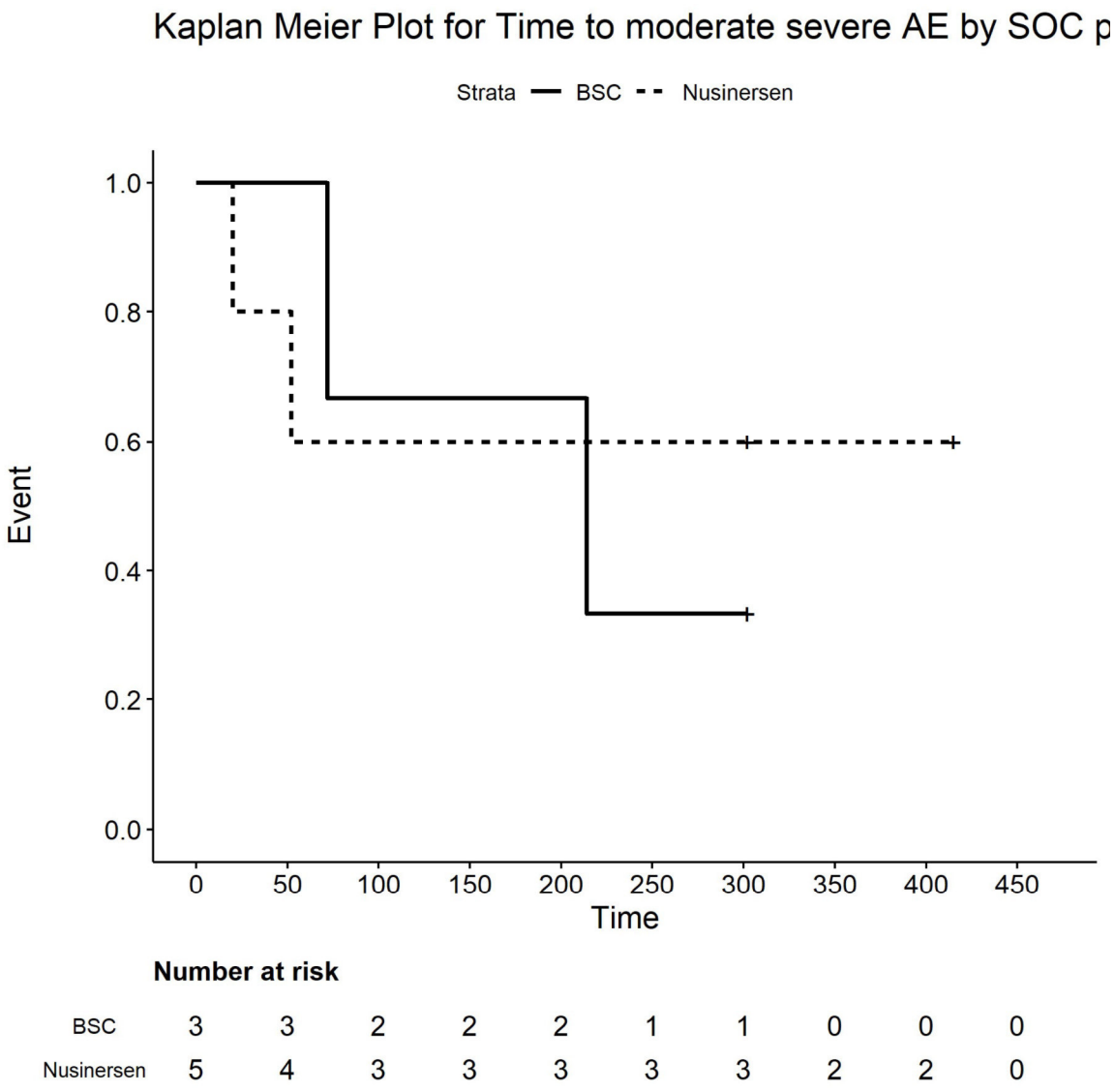
Number at risk

BSC	4	3	3	3	2	1	1	1	0	0
Nusinersen	6	4	3	3	1	1	1	1	1	0



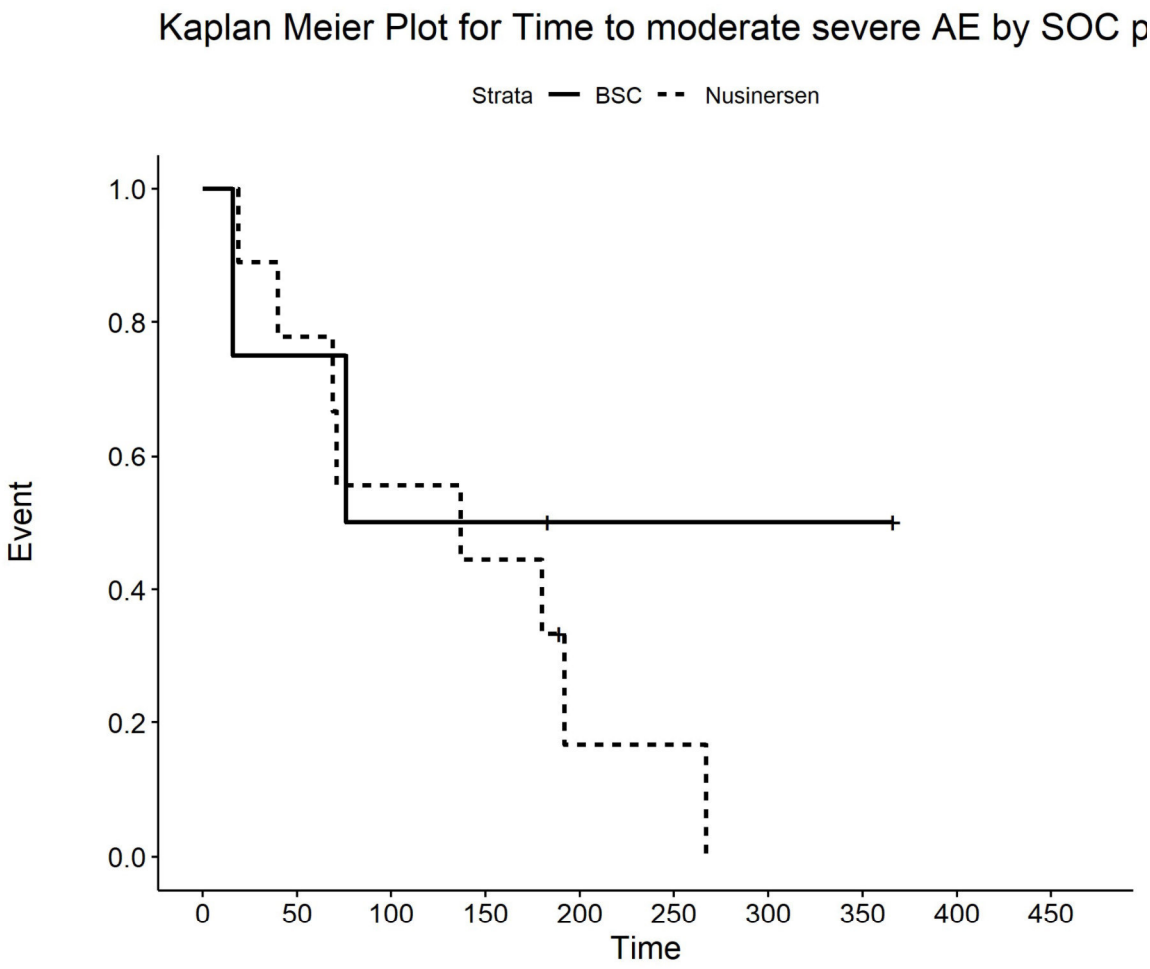
Number at risk

BSC	3	3	1	1	1	1	1	0	0	0
Nusinersen	8	7	5	4	3	3	2	1	1	0



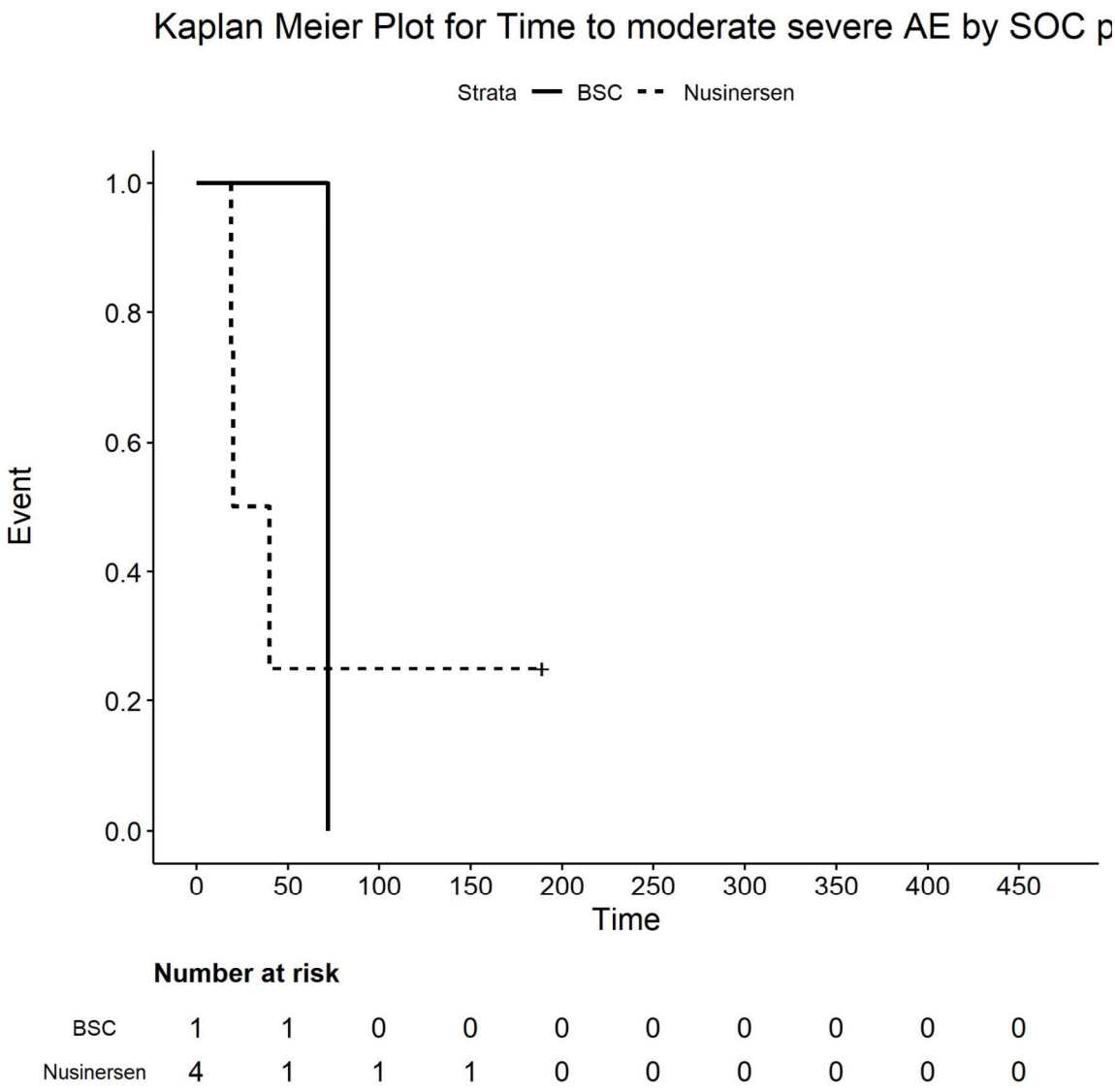
Number at risk

BSC	3	3	2	2	2	1	1	0	0	0
Nusinersen	5	4	3	3	3	3	3	2	2	0



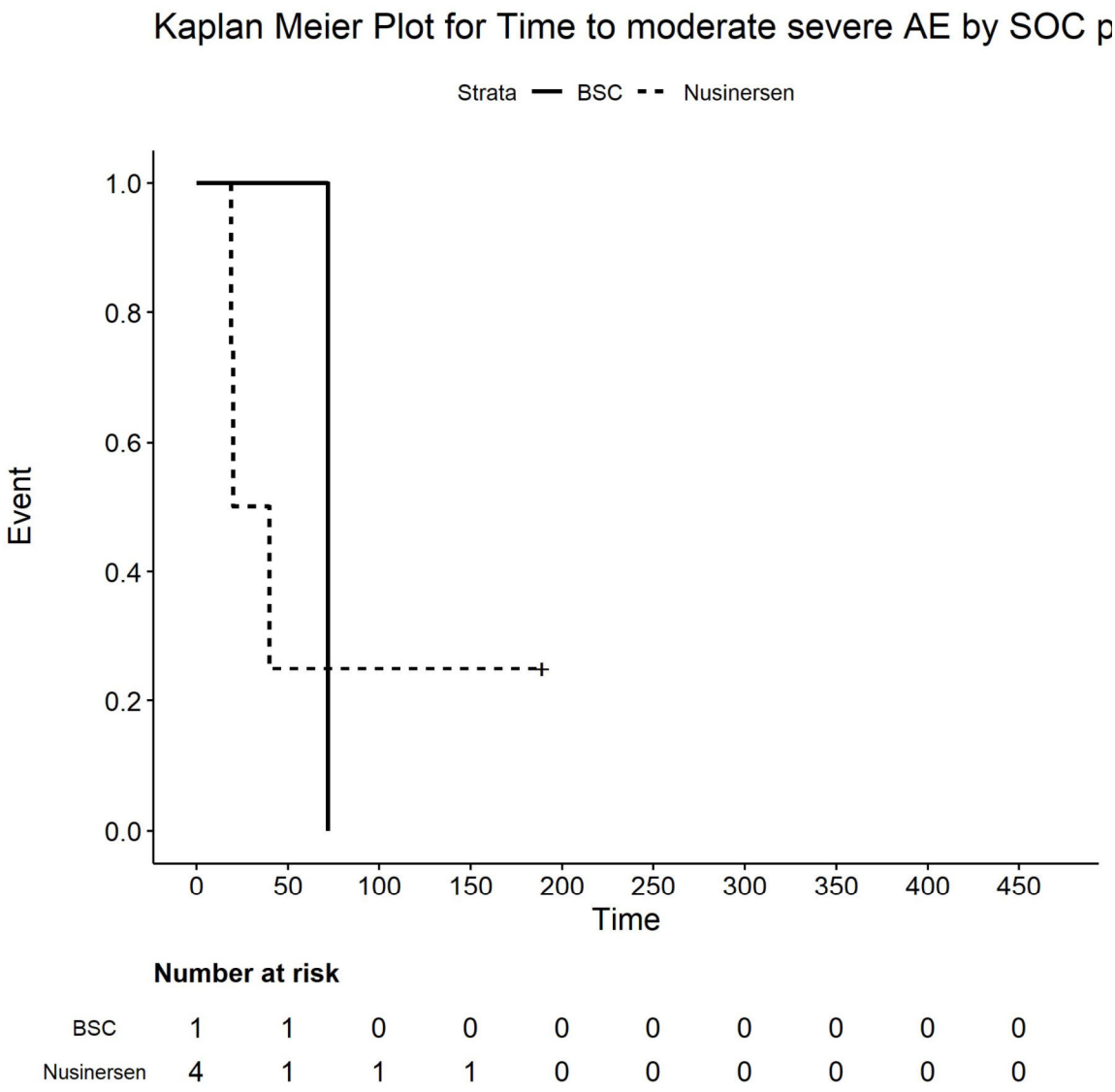
Number at risk

BSC	4	3	2	2	1	1	1	1	0	0
Nusinersen	9	7	5	4	1	1	0	0	0	0



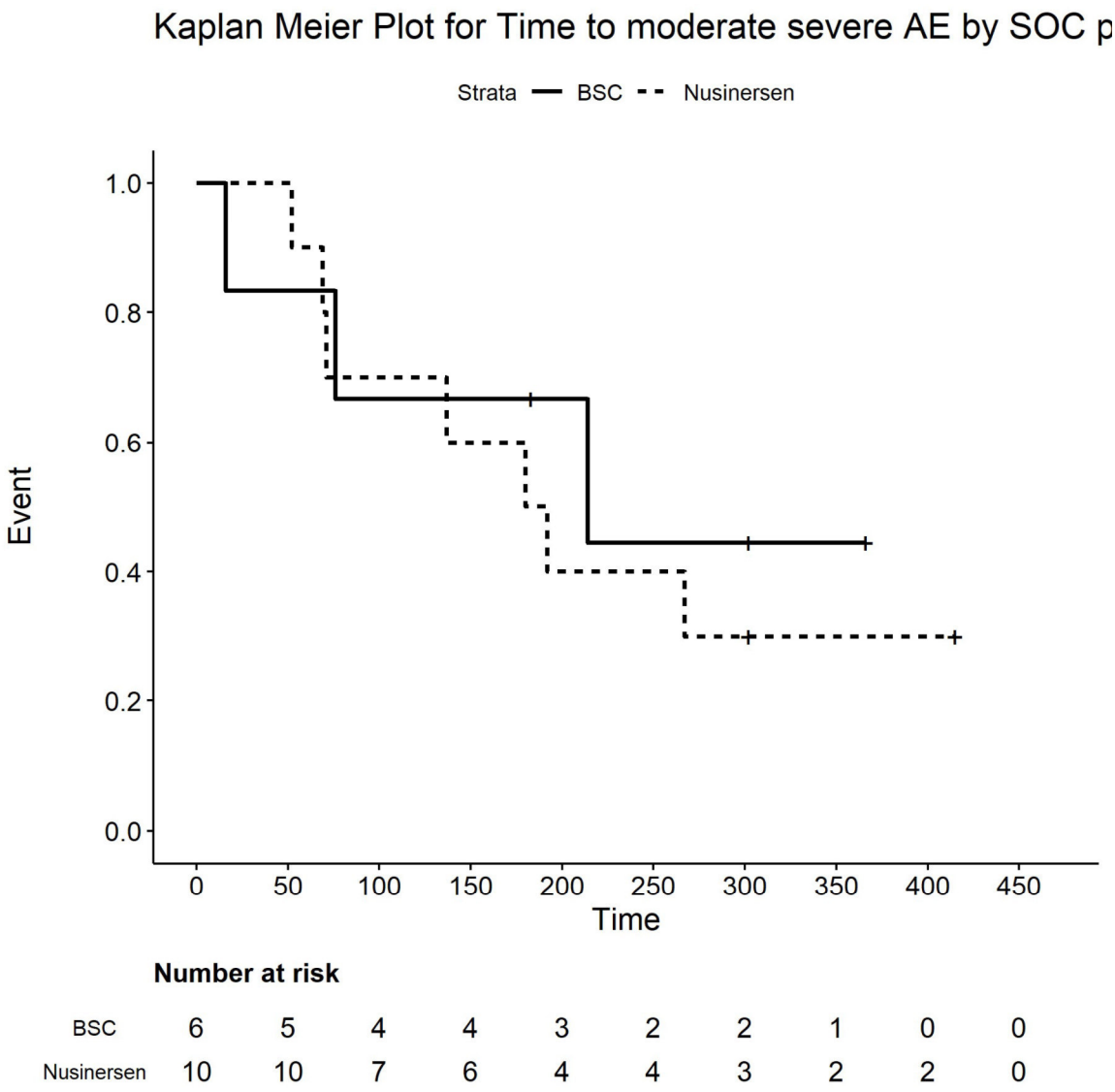
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	1	1	1	0	0	0	0	0	0



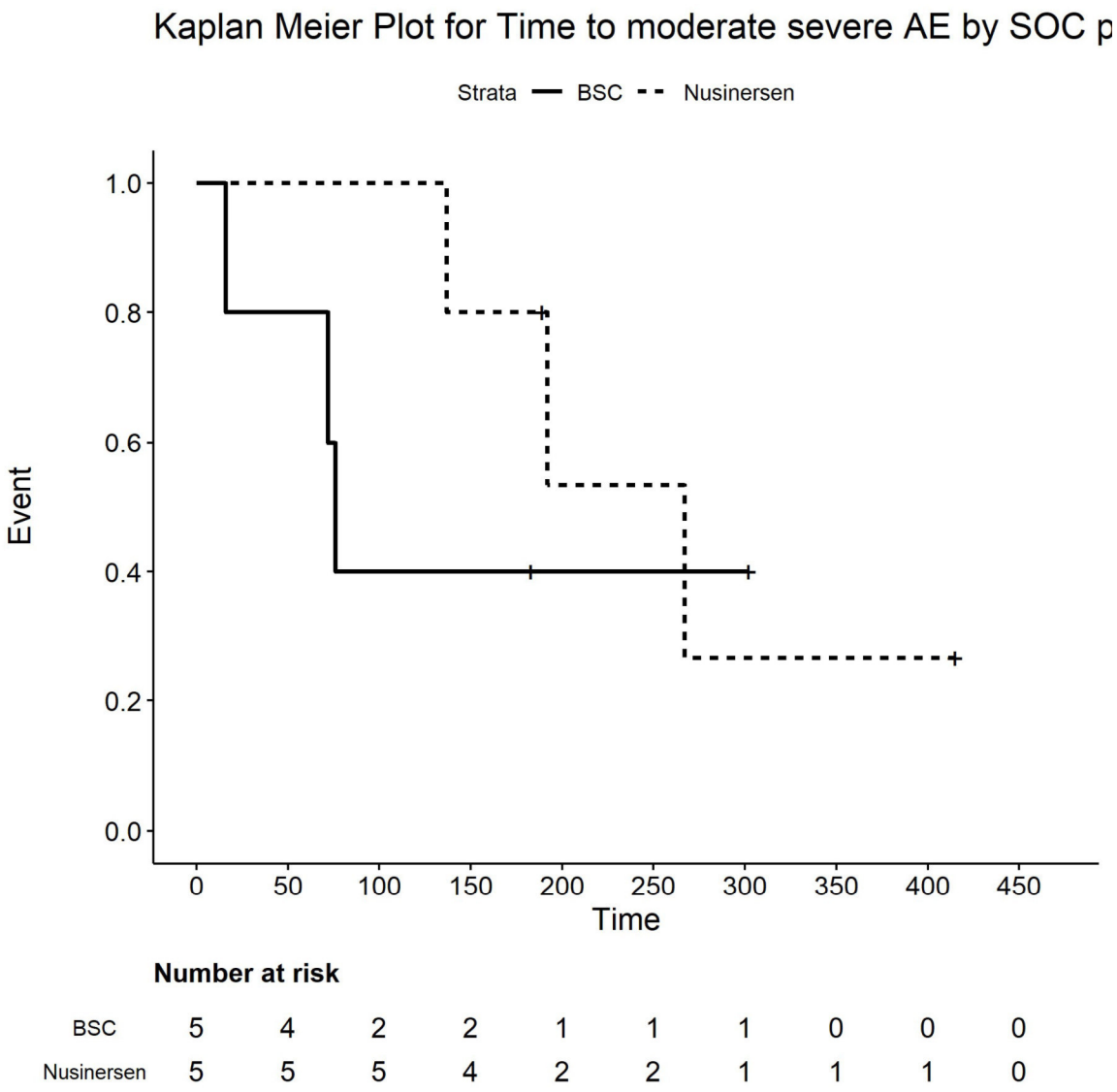
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	1	1	1	0	0	0	0	0	0



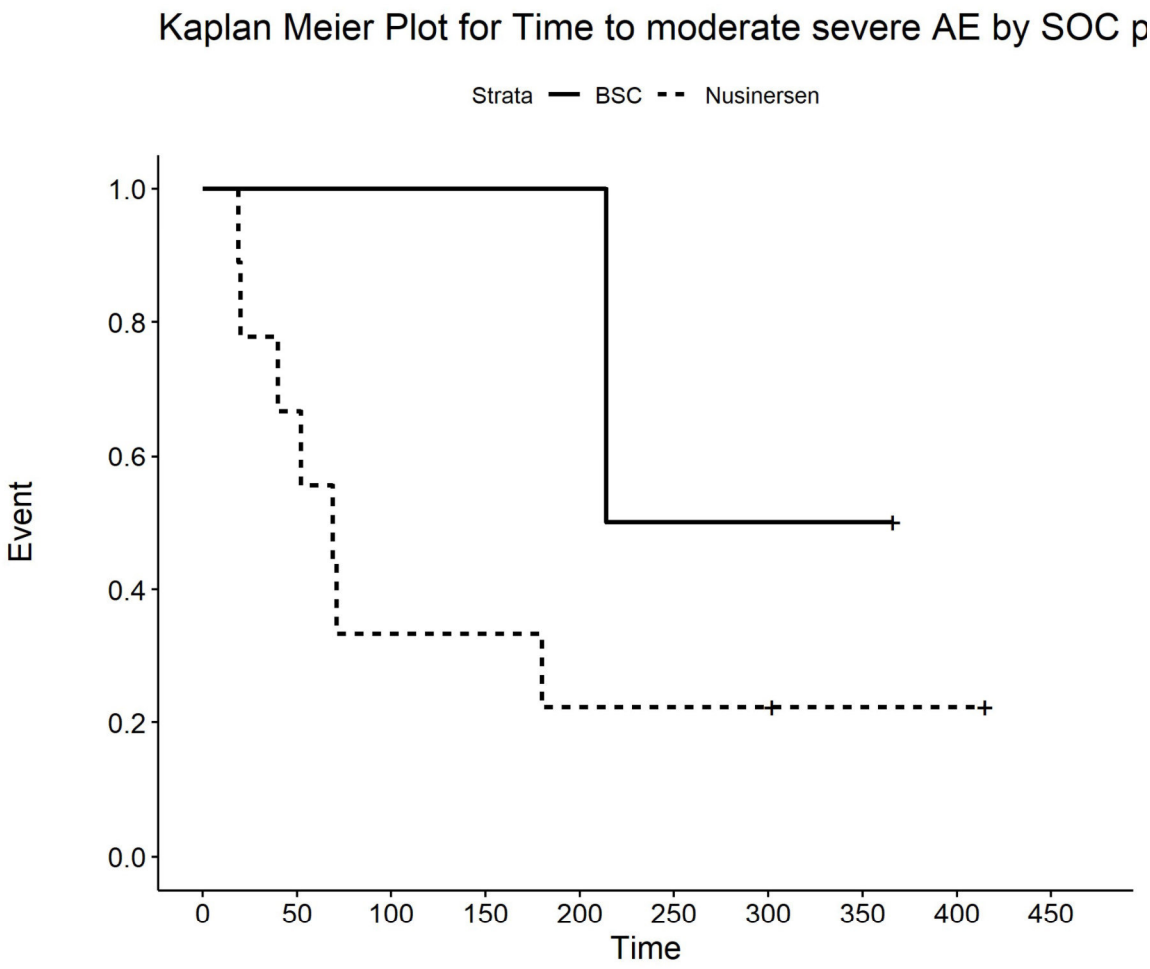
Number at risk

BSC	6	5	4	4	3	2	2	1	0	0
Nusinersen	10	10	7	6	4	4	3	2	2	0



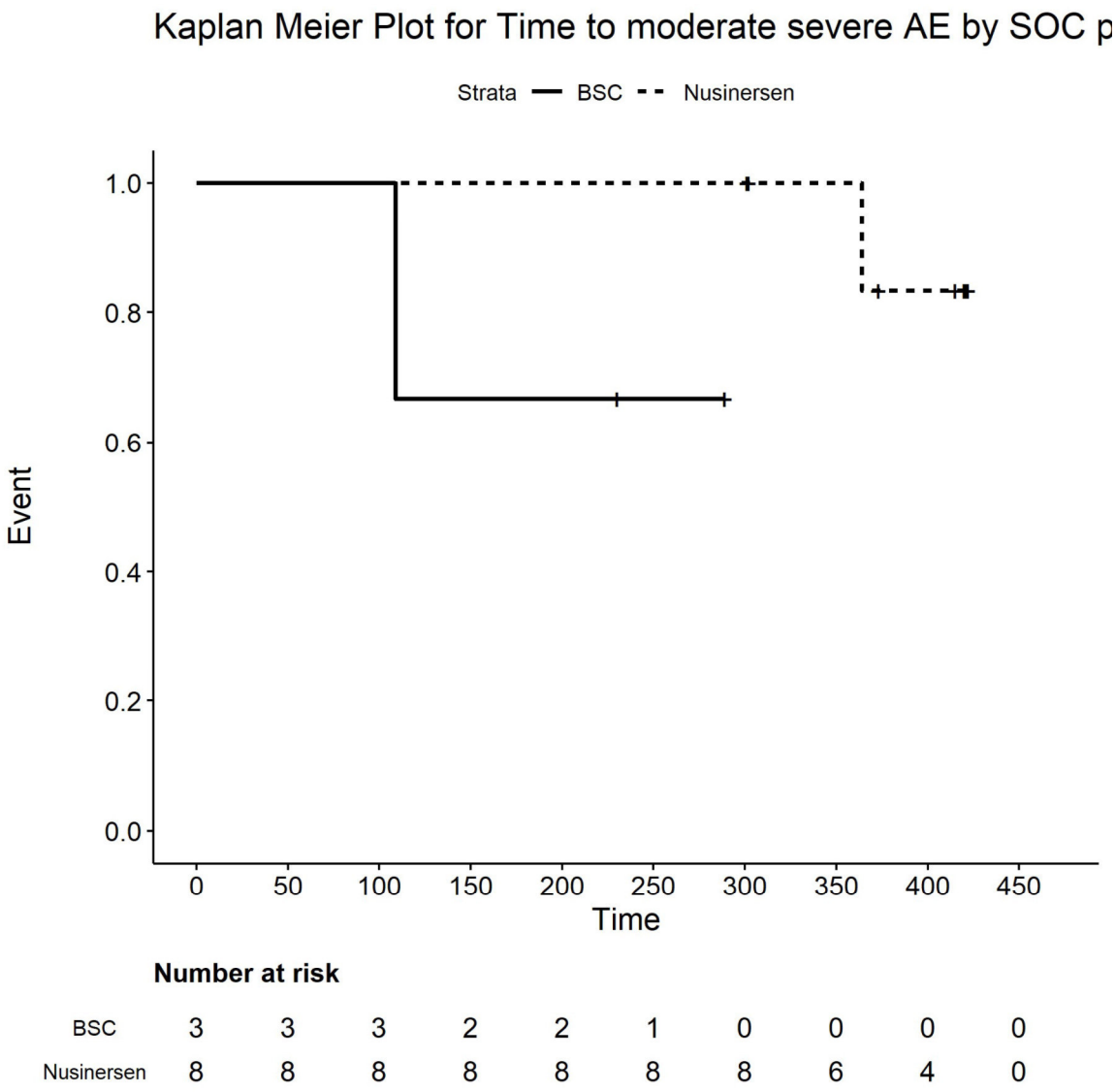
Number at risk

BSC	5	4	2	2	1	1	1	0	0	0
Nusinersen	5	5	5	4	2	2	1	1	1	0



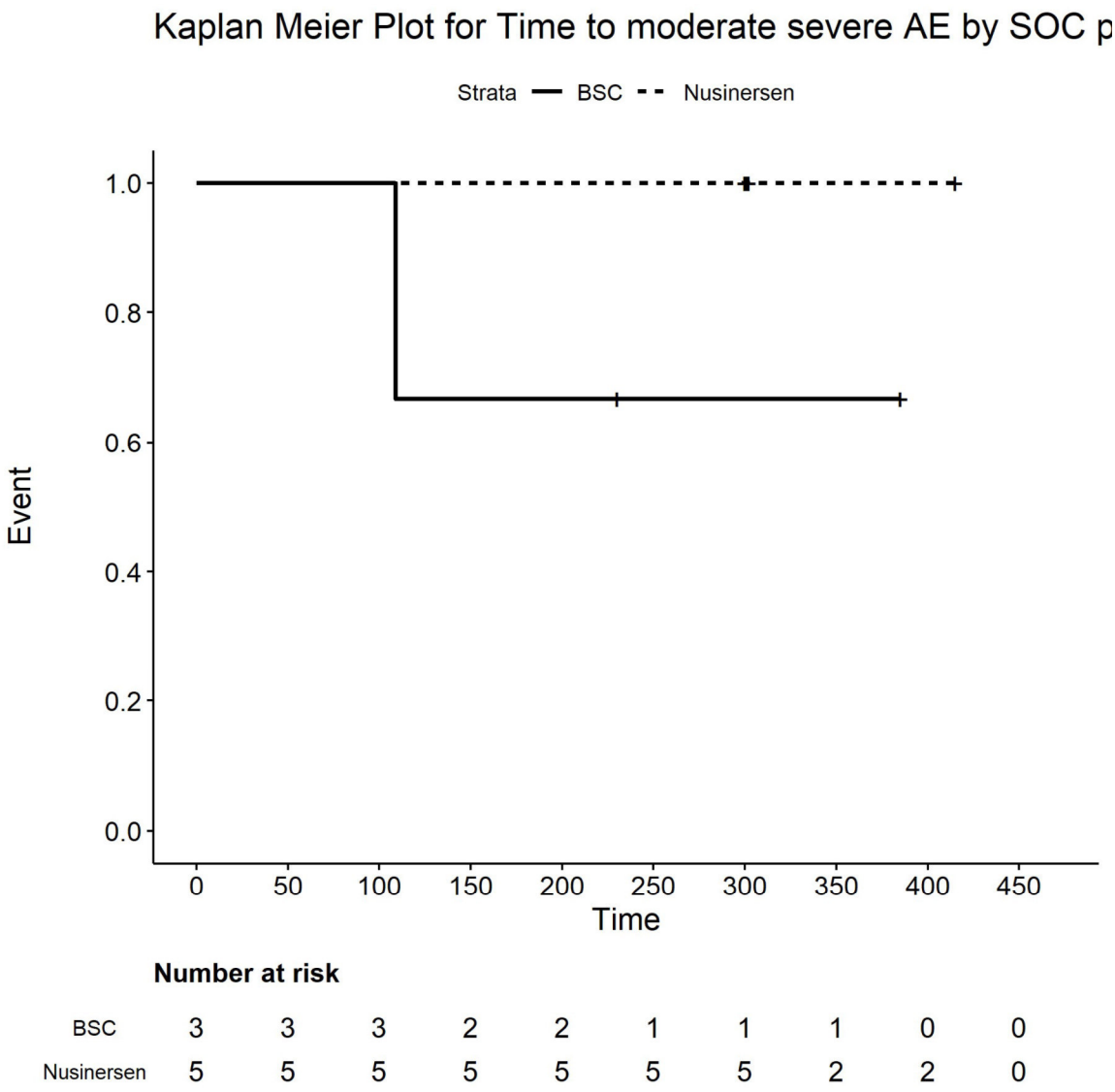
Number at risk

BSC	2	2	2	2	2	1	1	1	0	0
Nusinersen	9	6	3	3	2	2	2	1	1	0



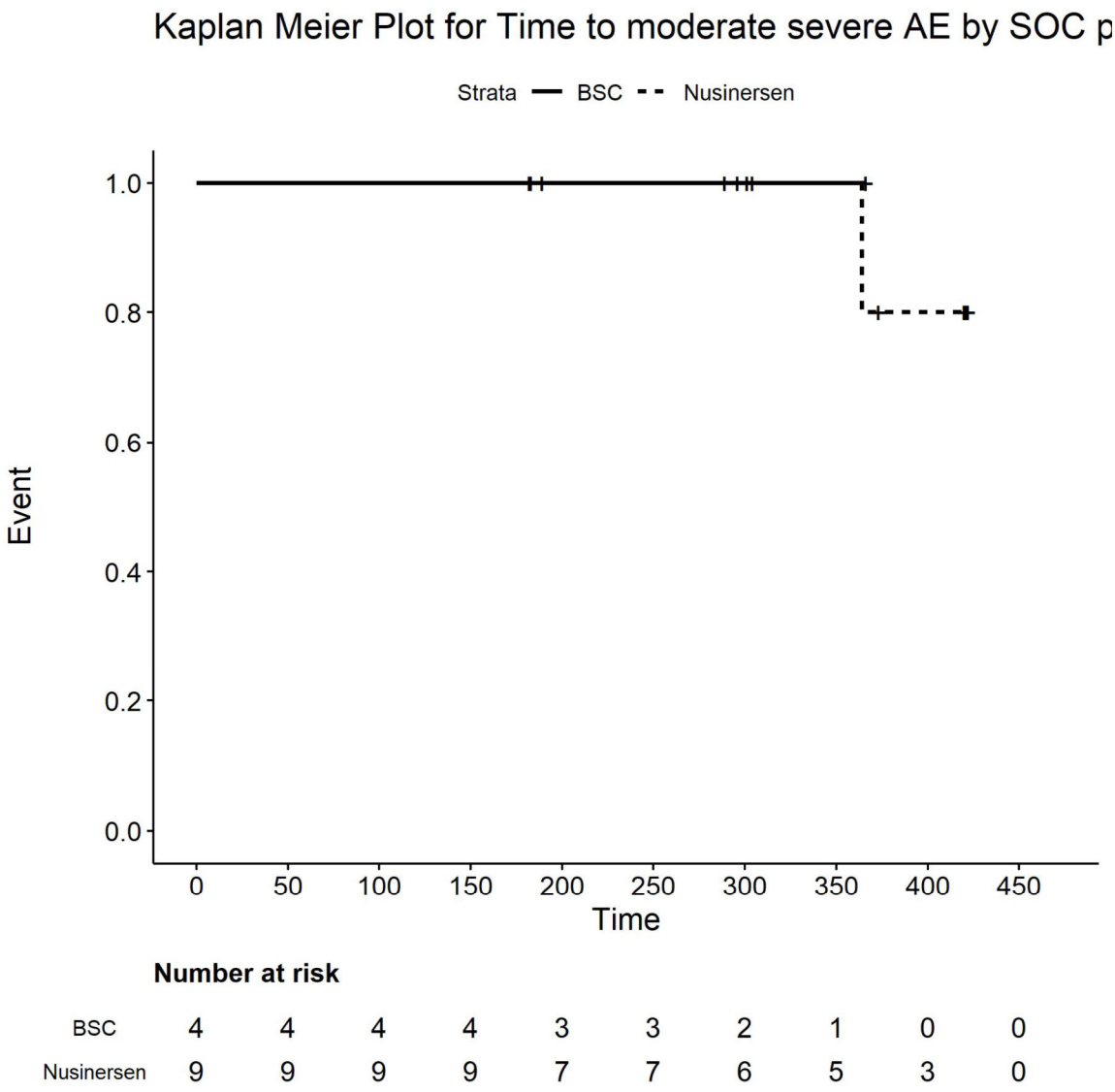
Number at risk

BSC	3	3	3	2	2	1	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	4	0



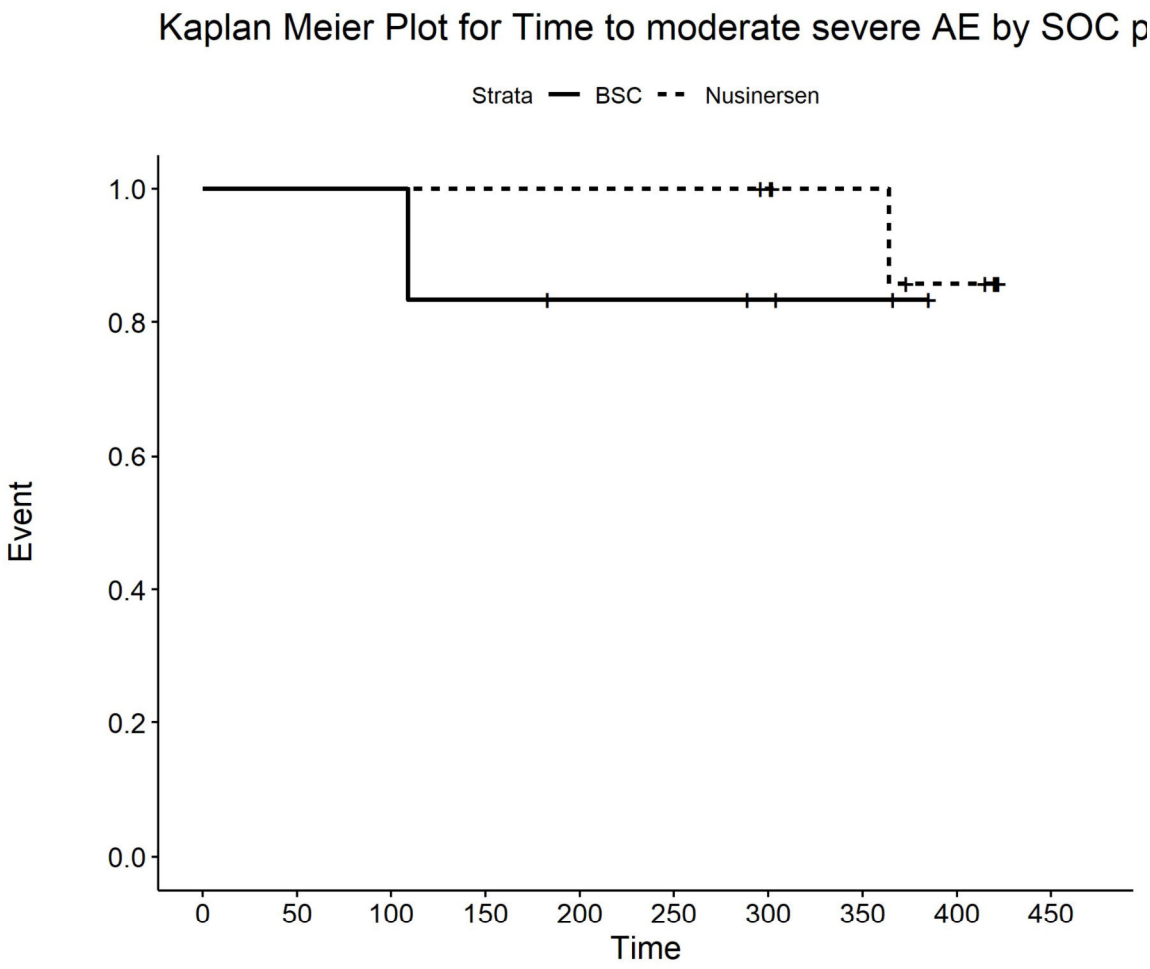
Number at risk

BSC	3	3	3	2	2	1	1	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



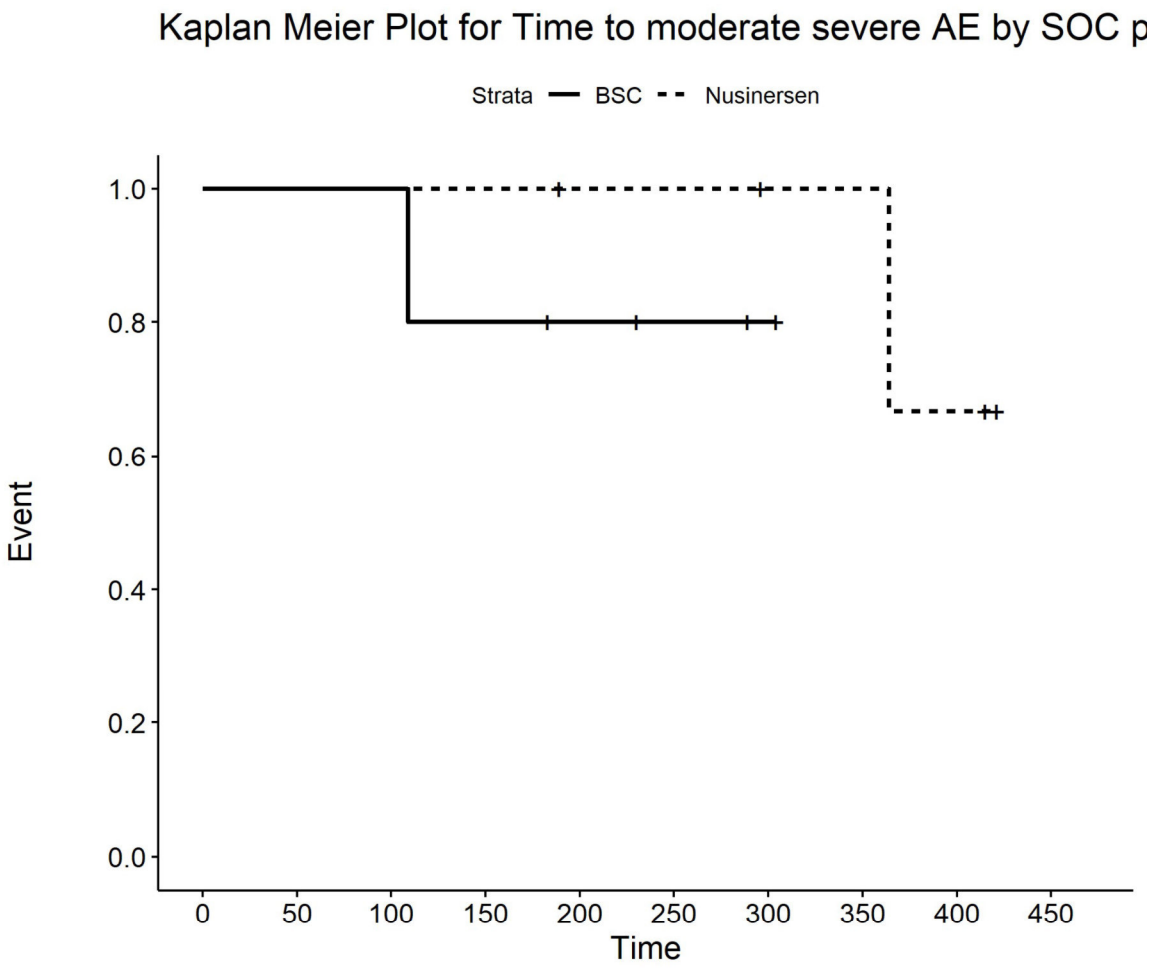
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	3	0



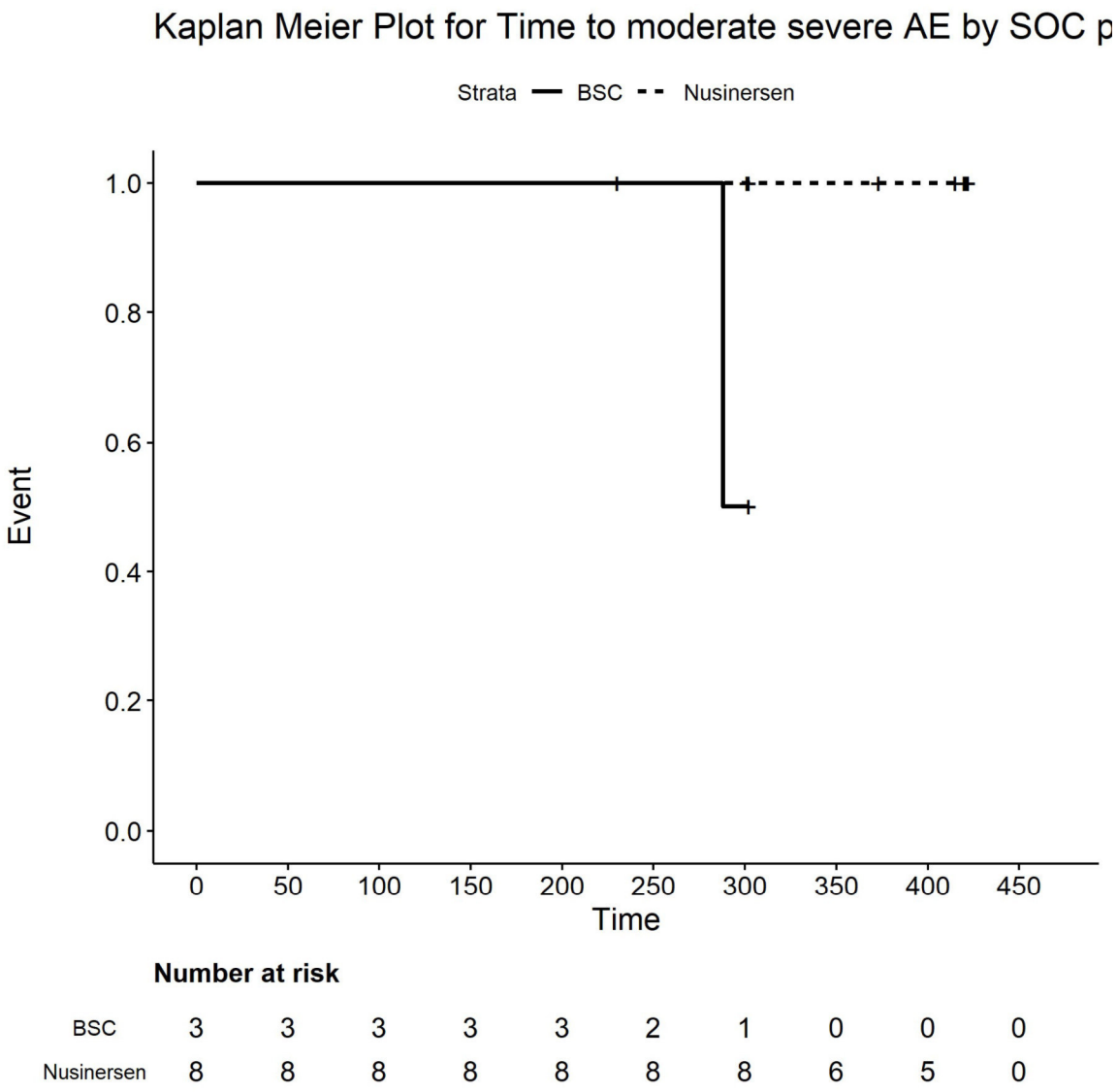
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	5	0



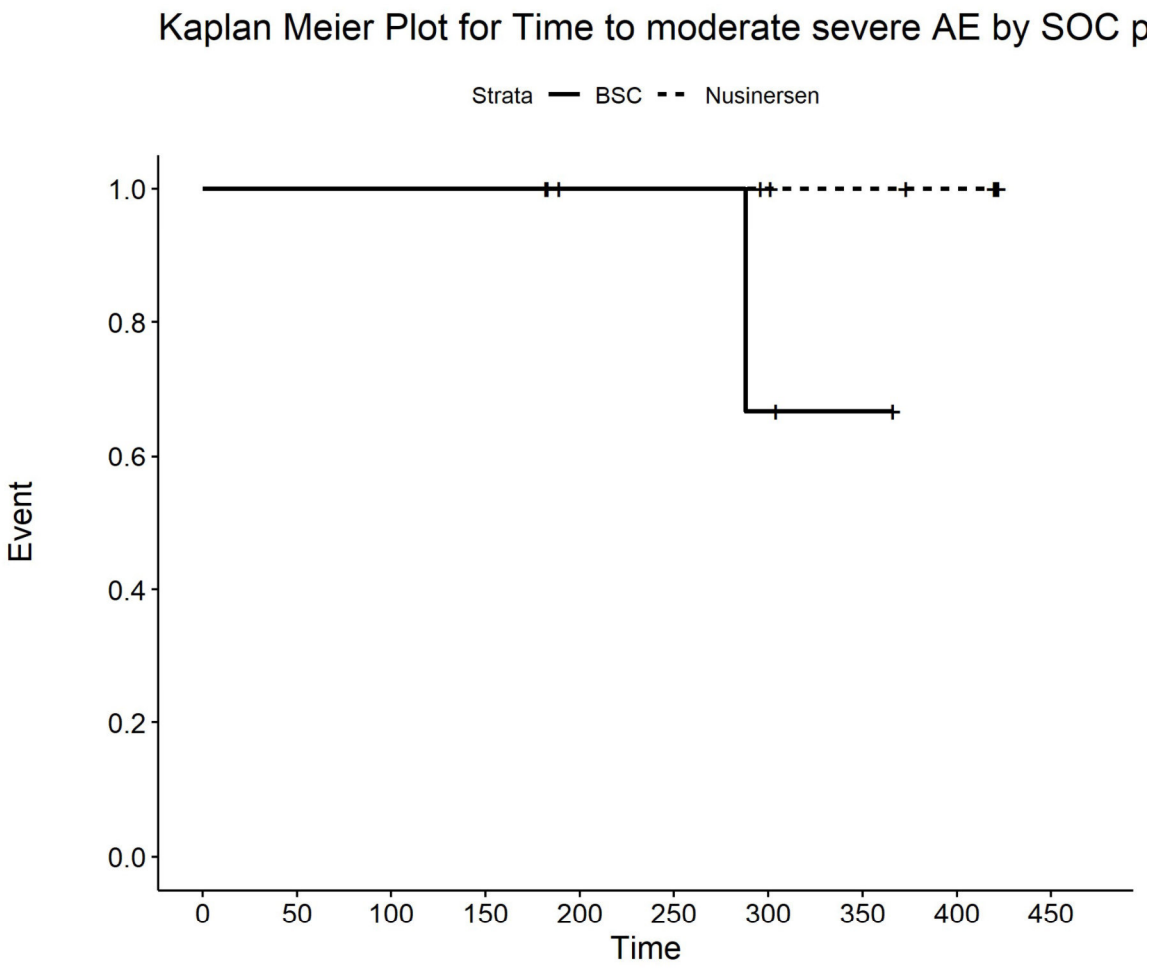
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	2	0



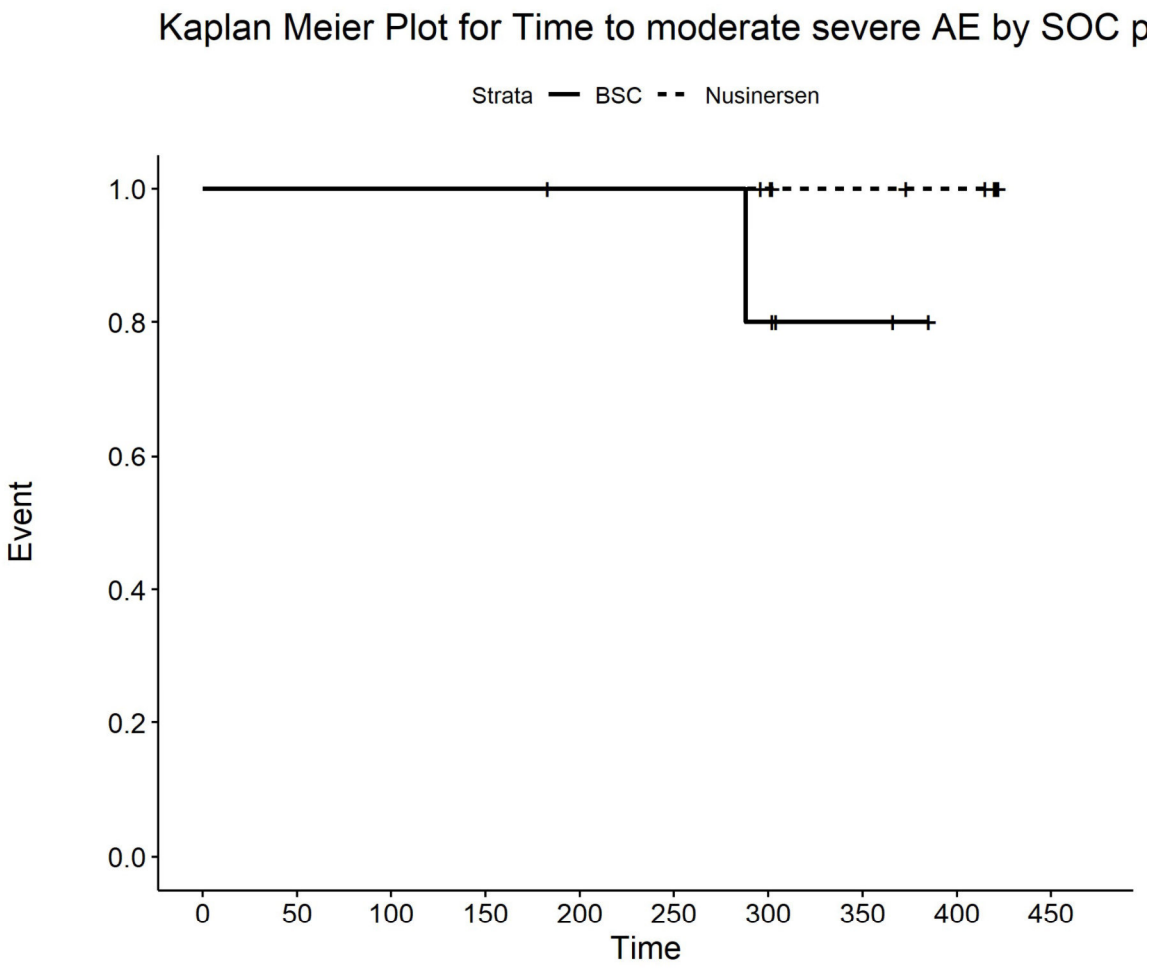
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



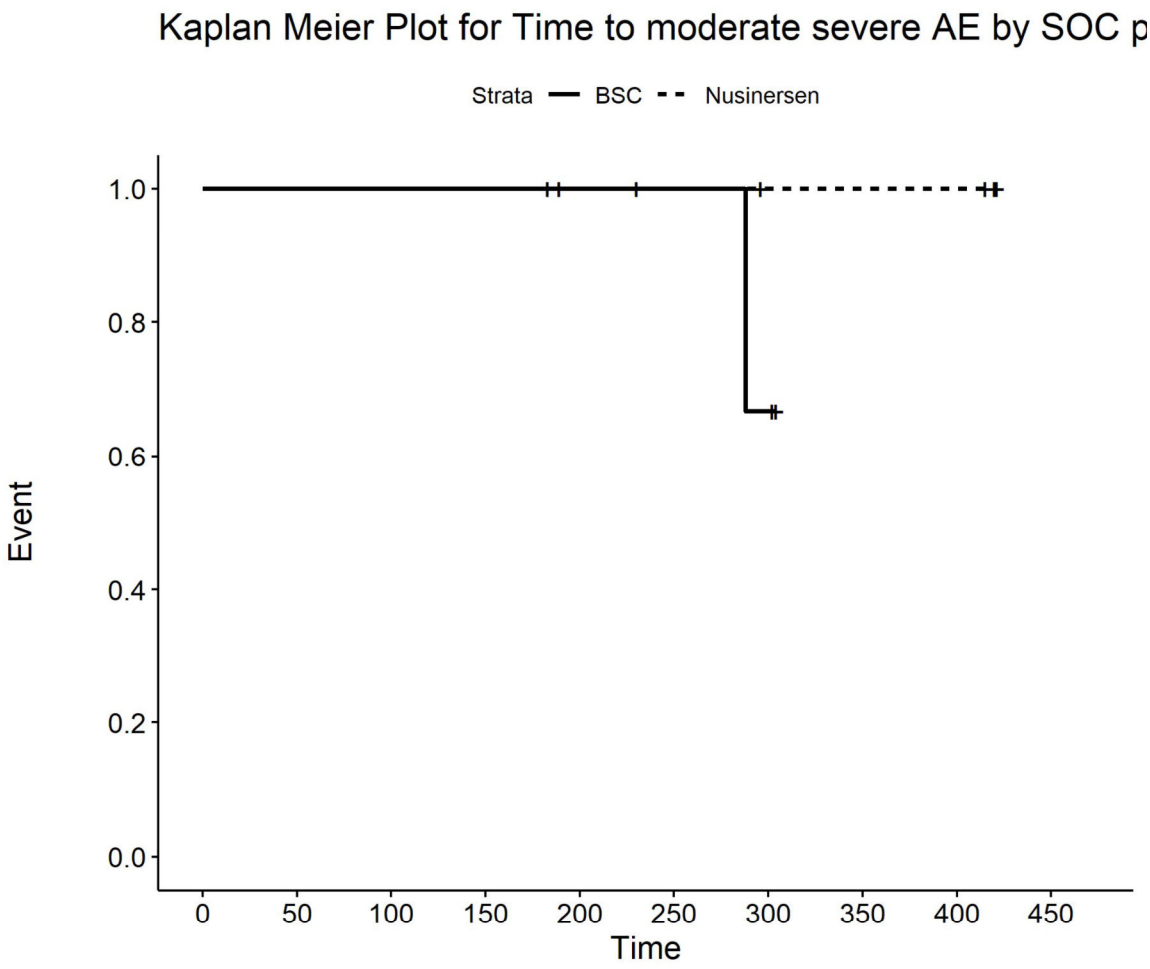
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



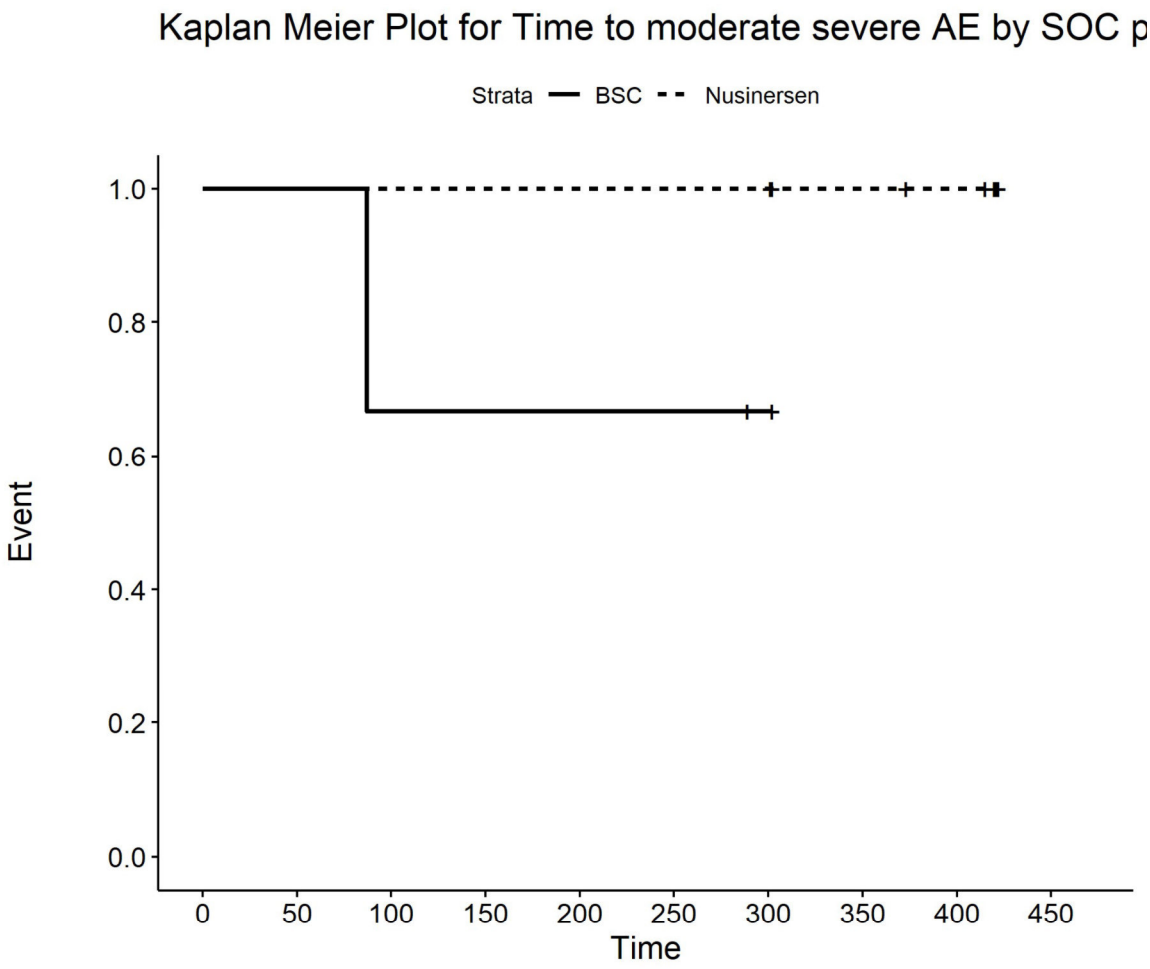
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



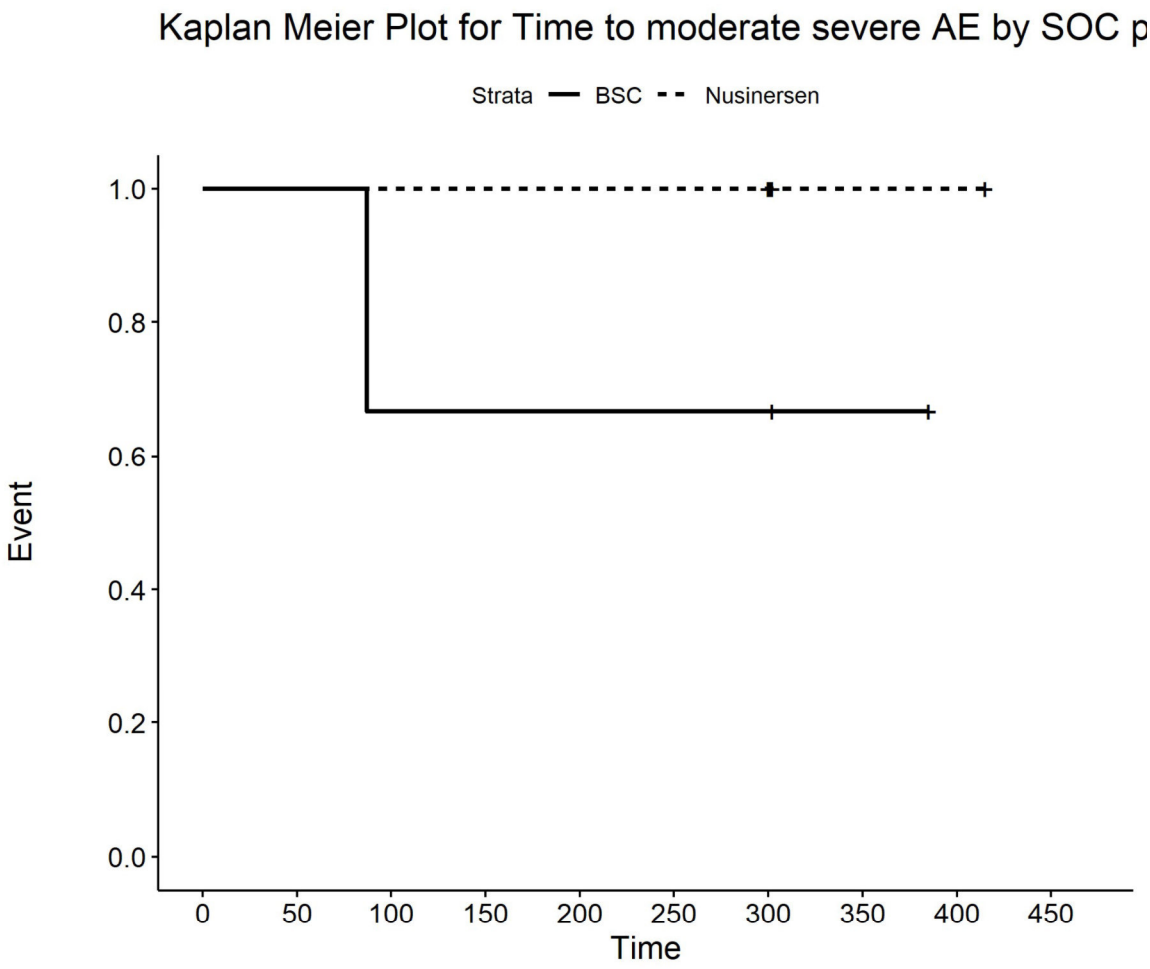
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



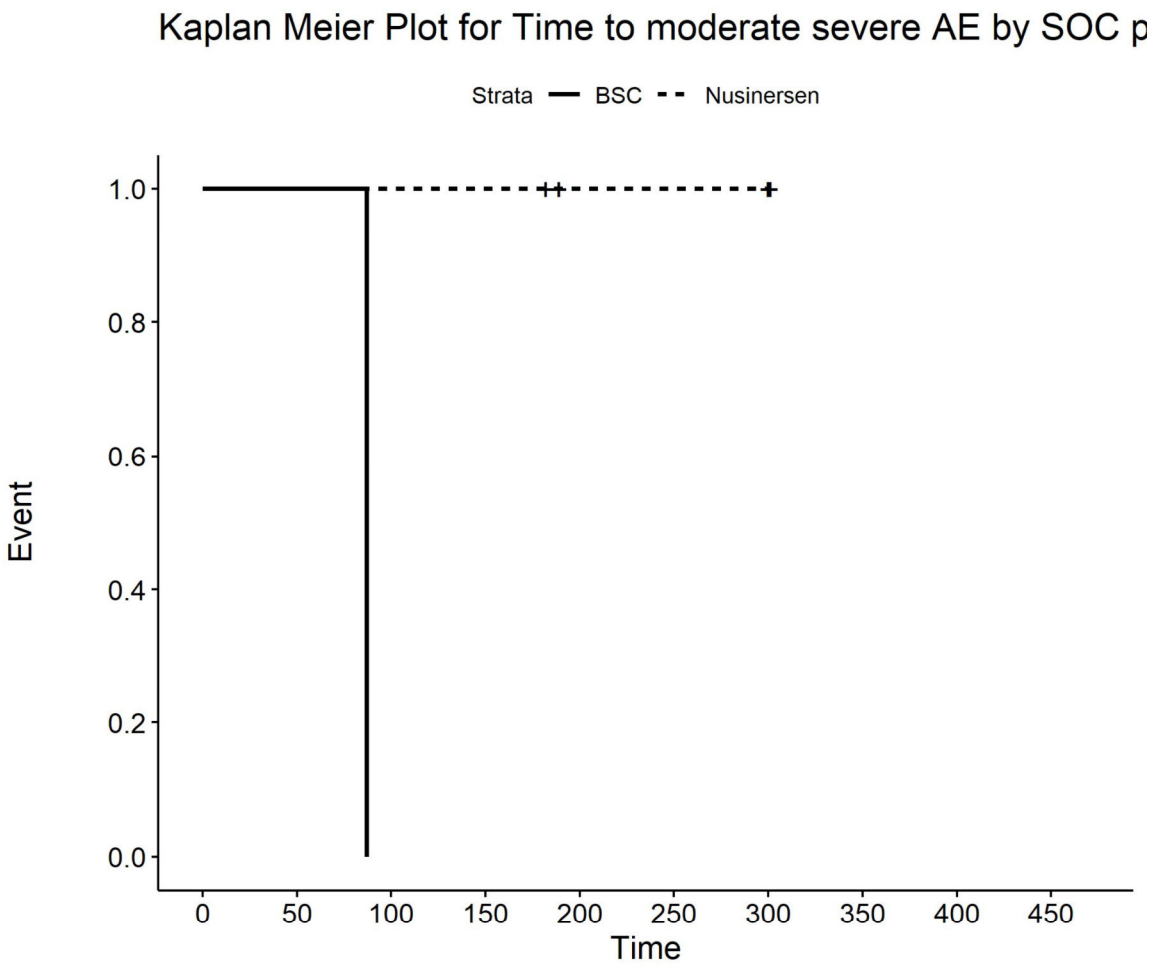
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



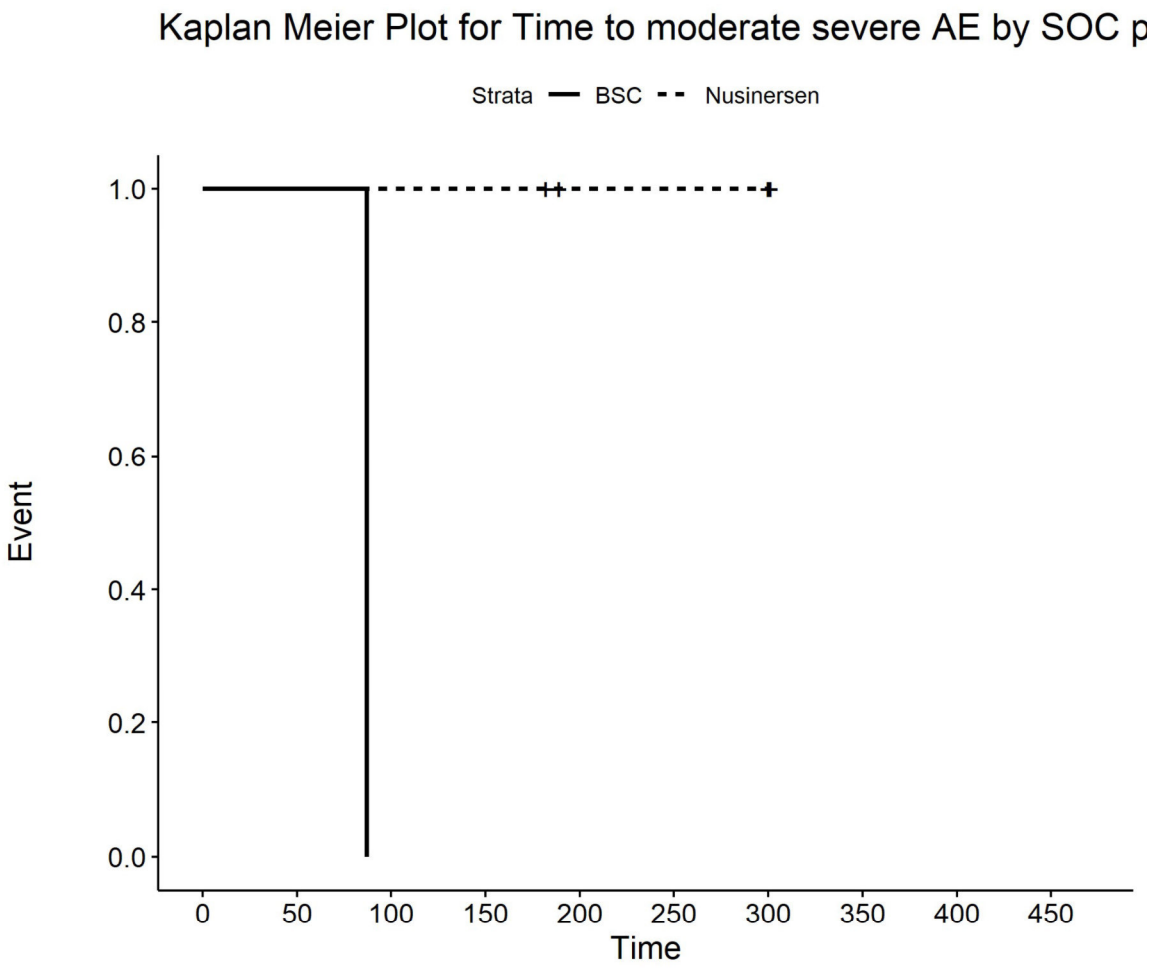
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



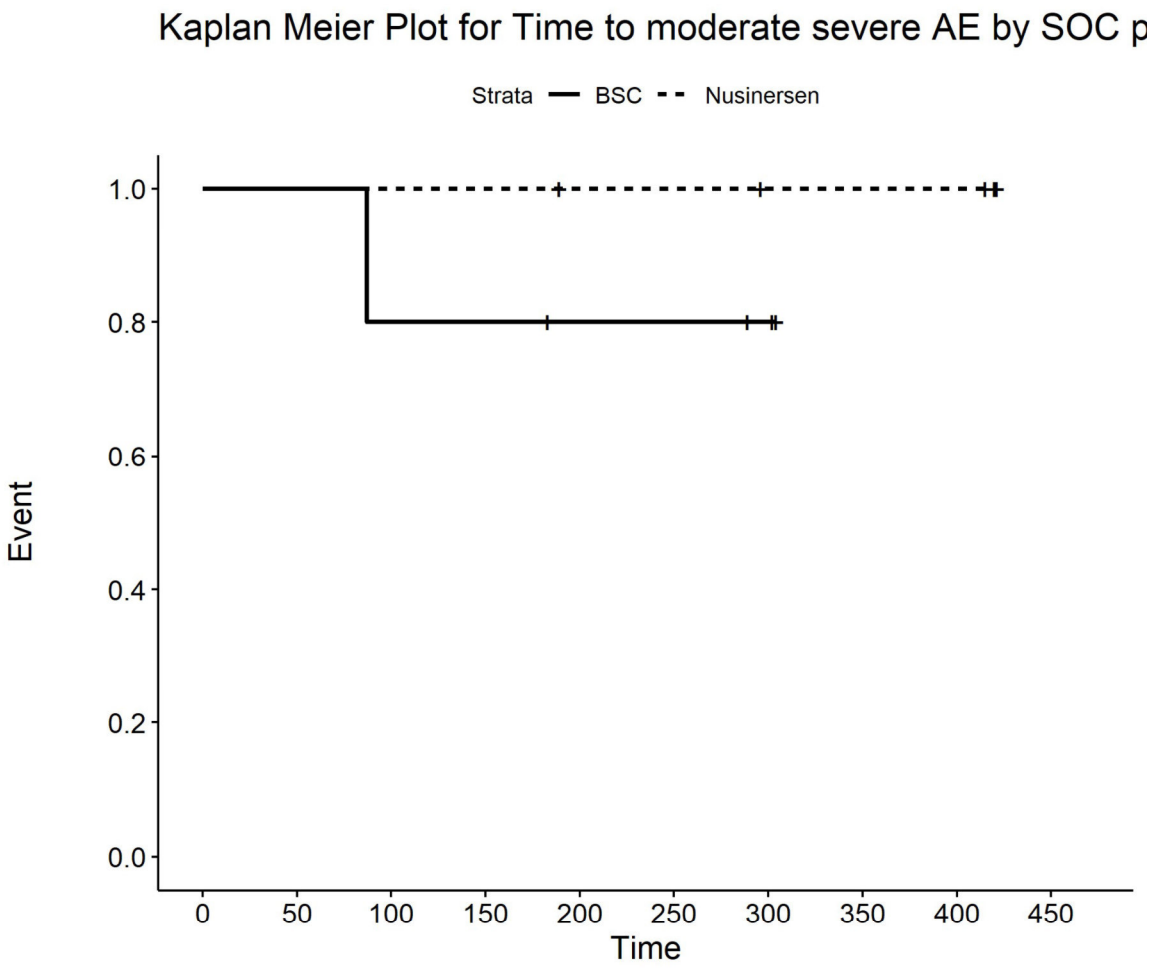
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



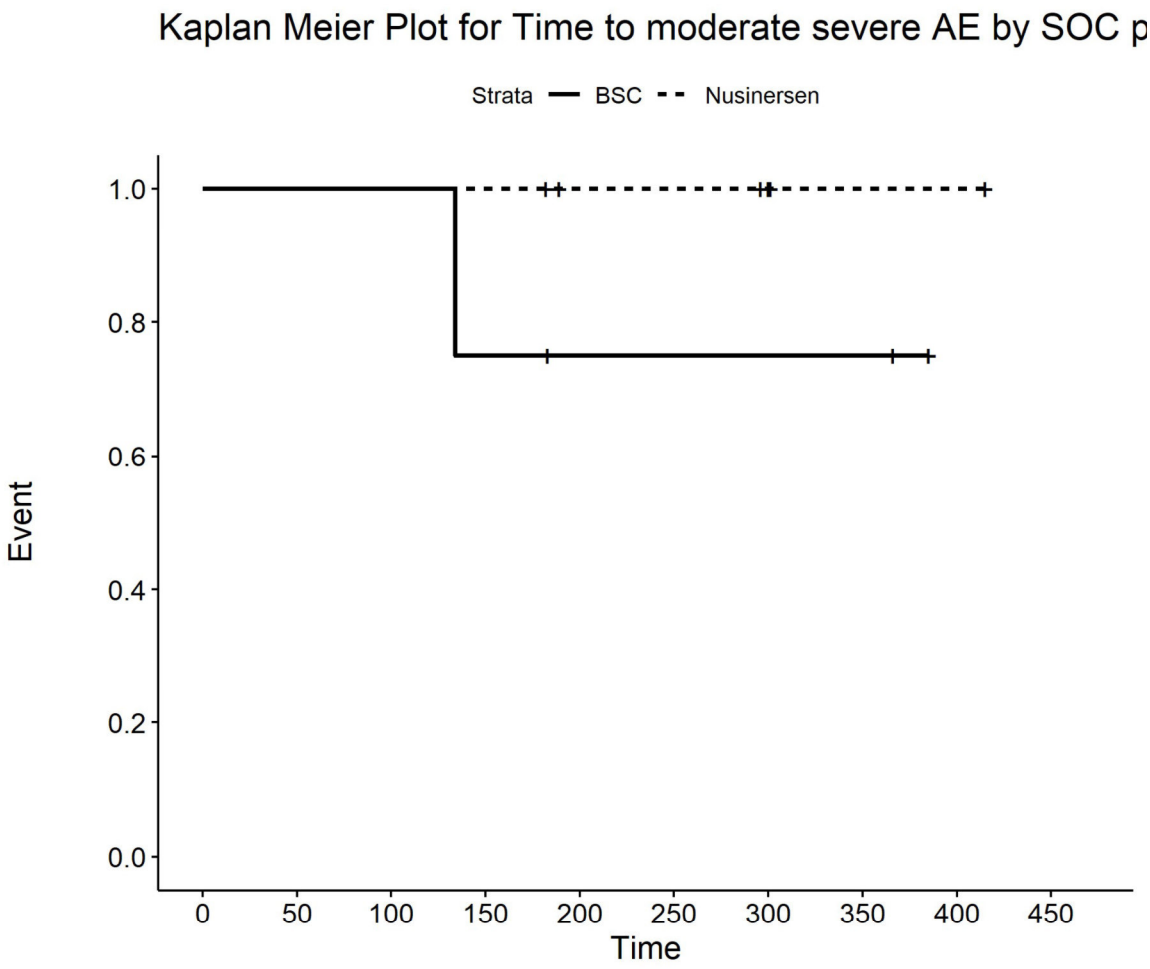
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



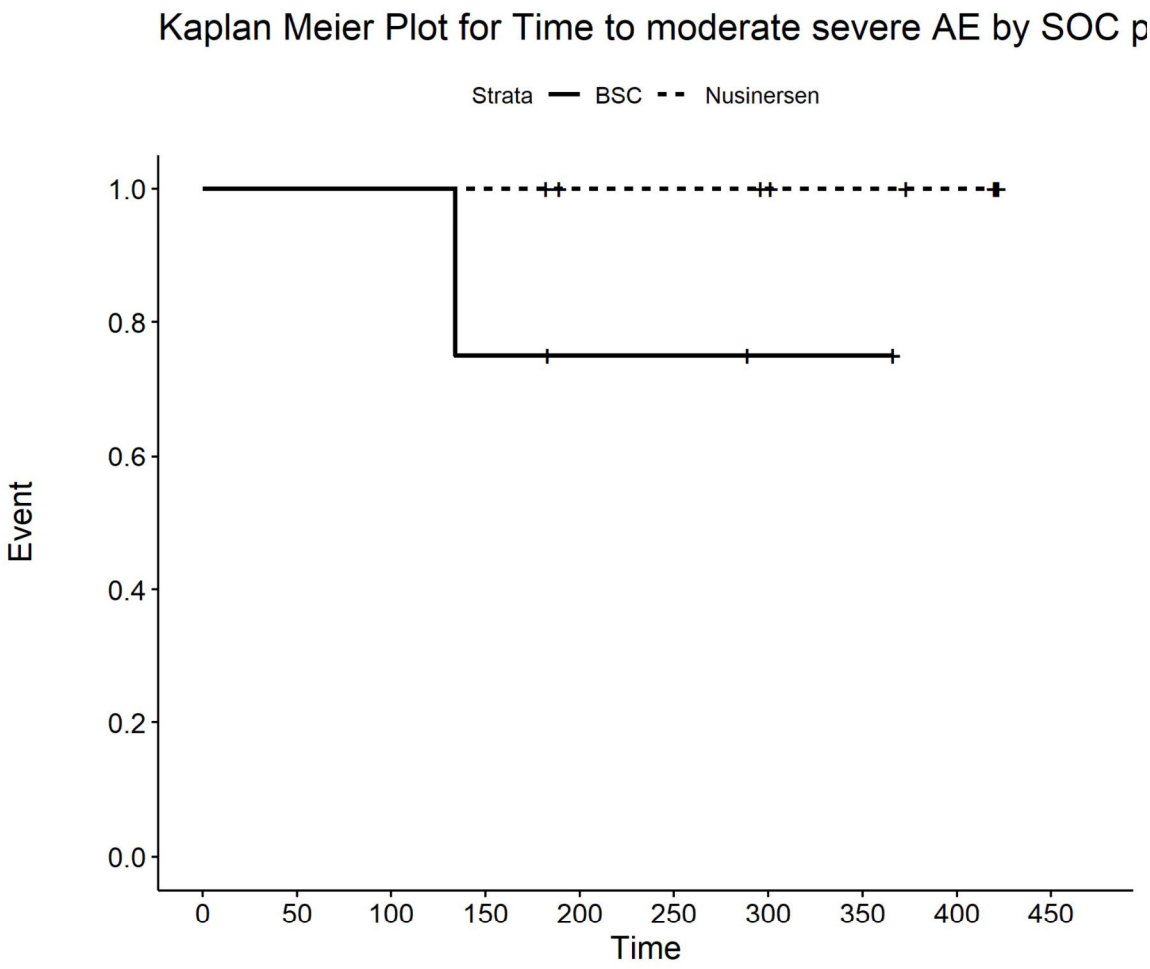
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



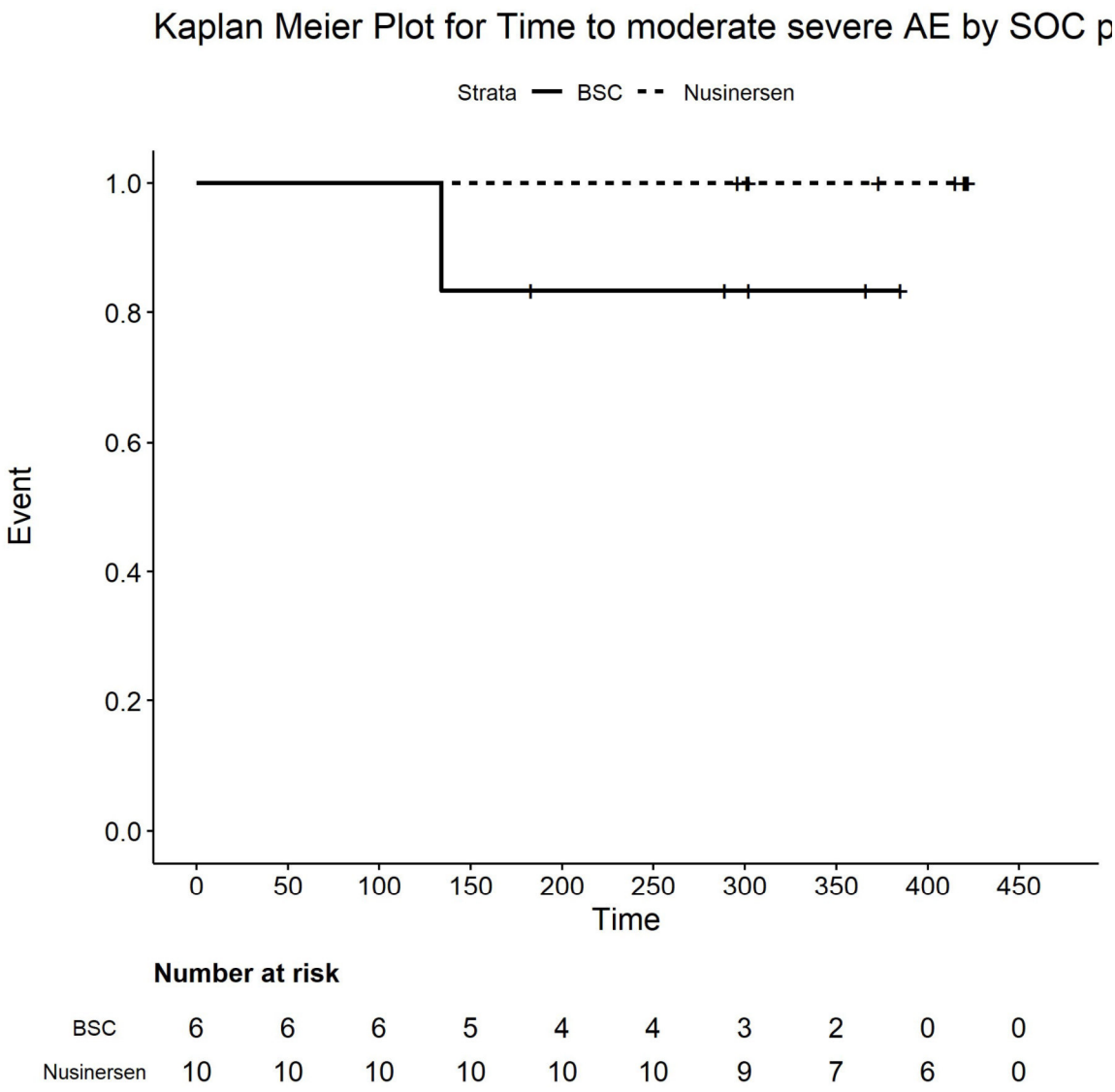
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



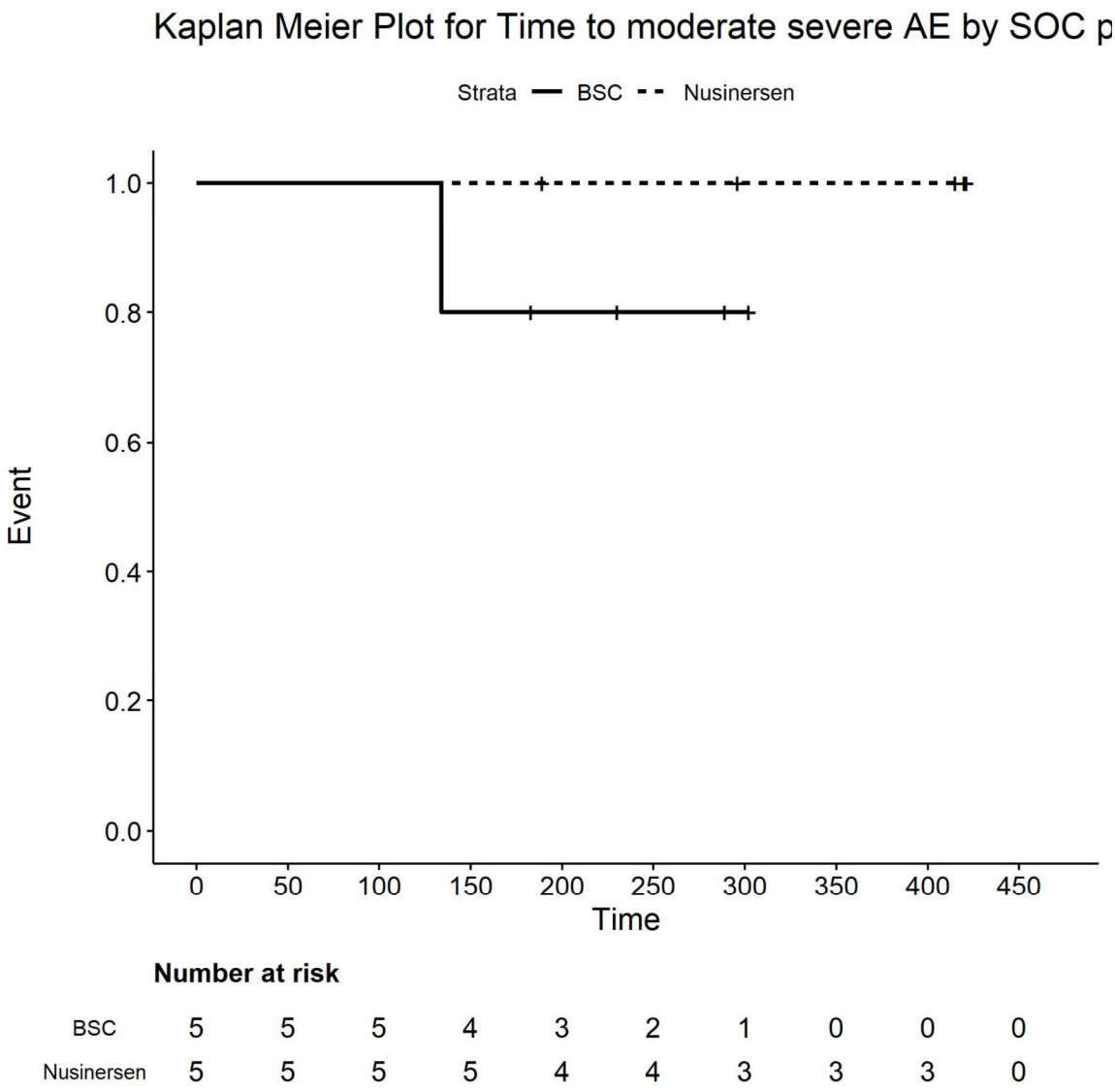
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



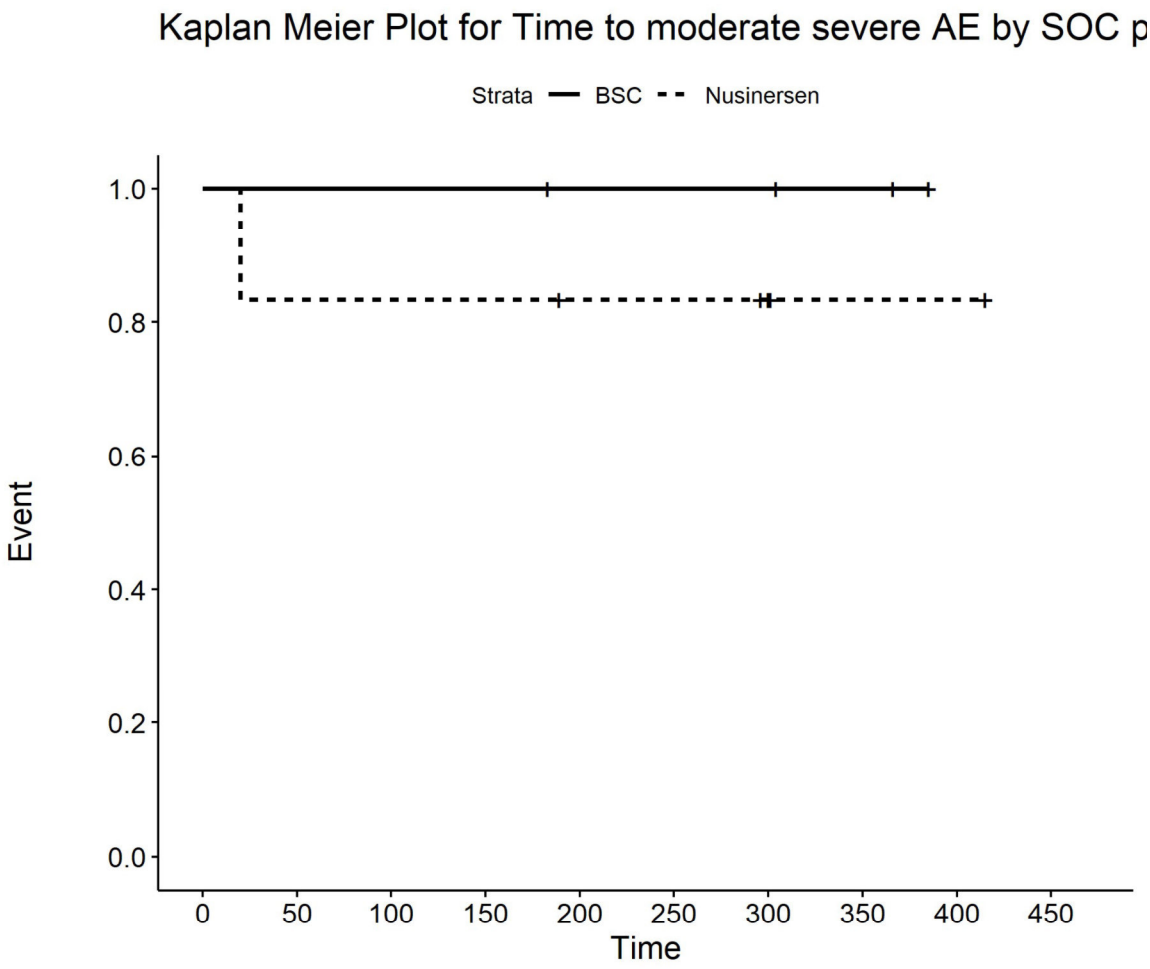
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



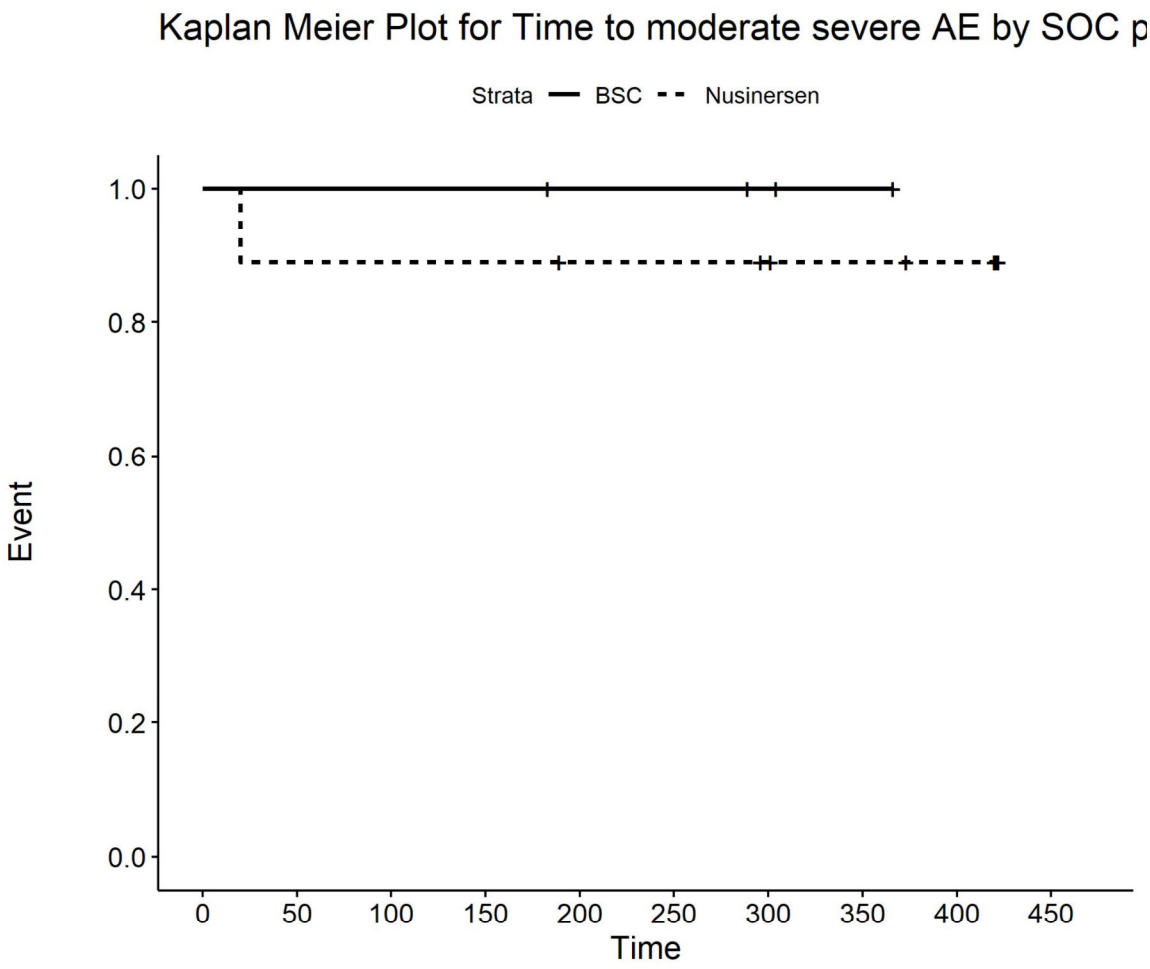
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



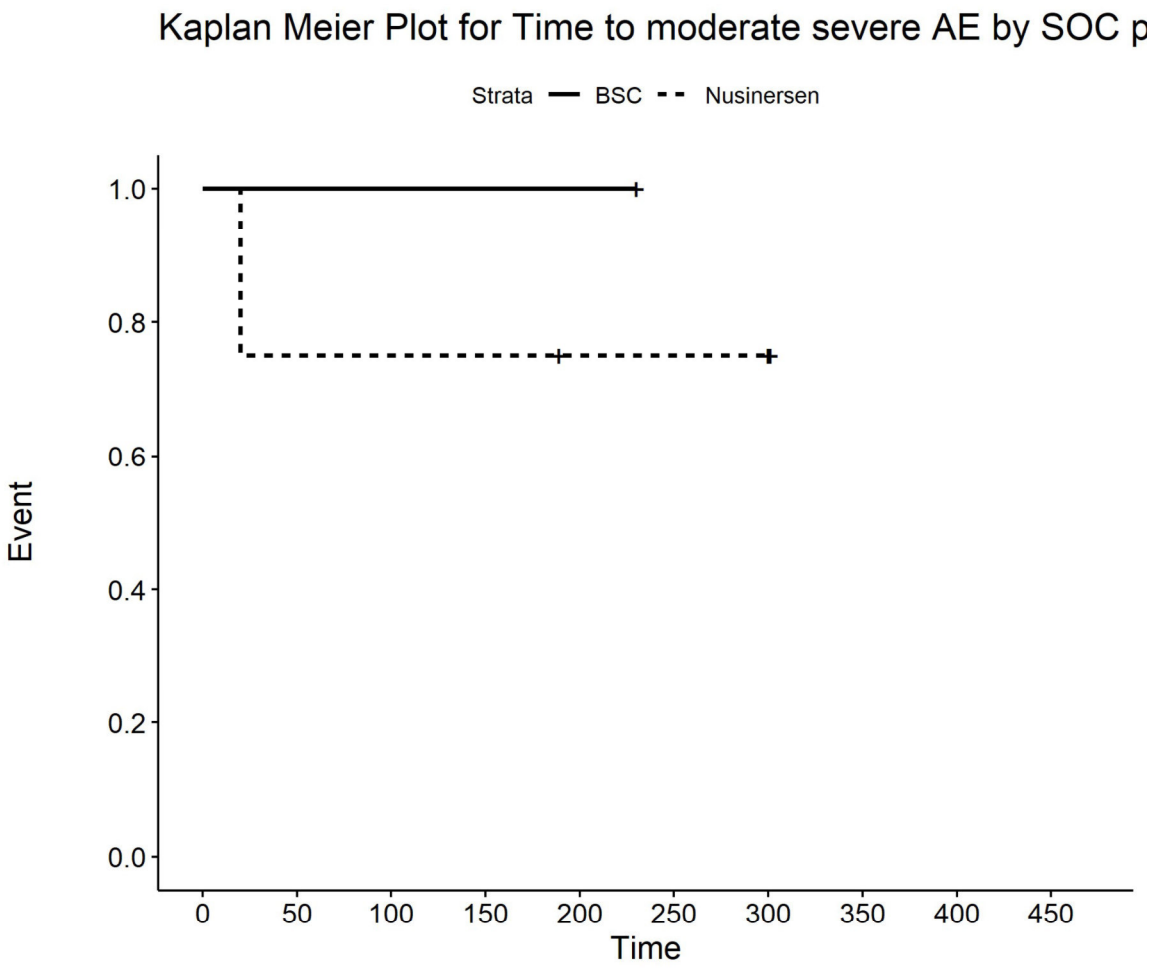
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	4	4	3	1	1	0



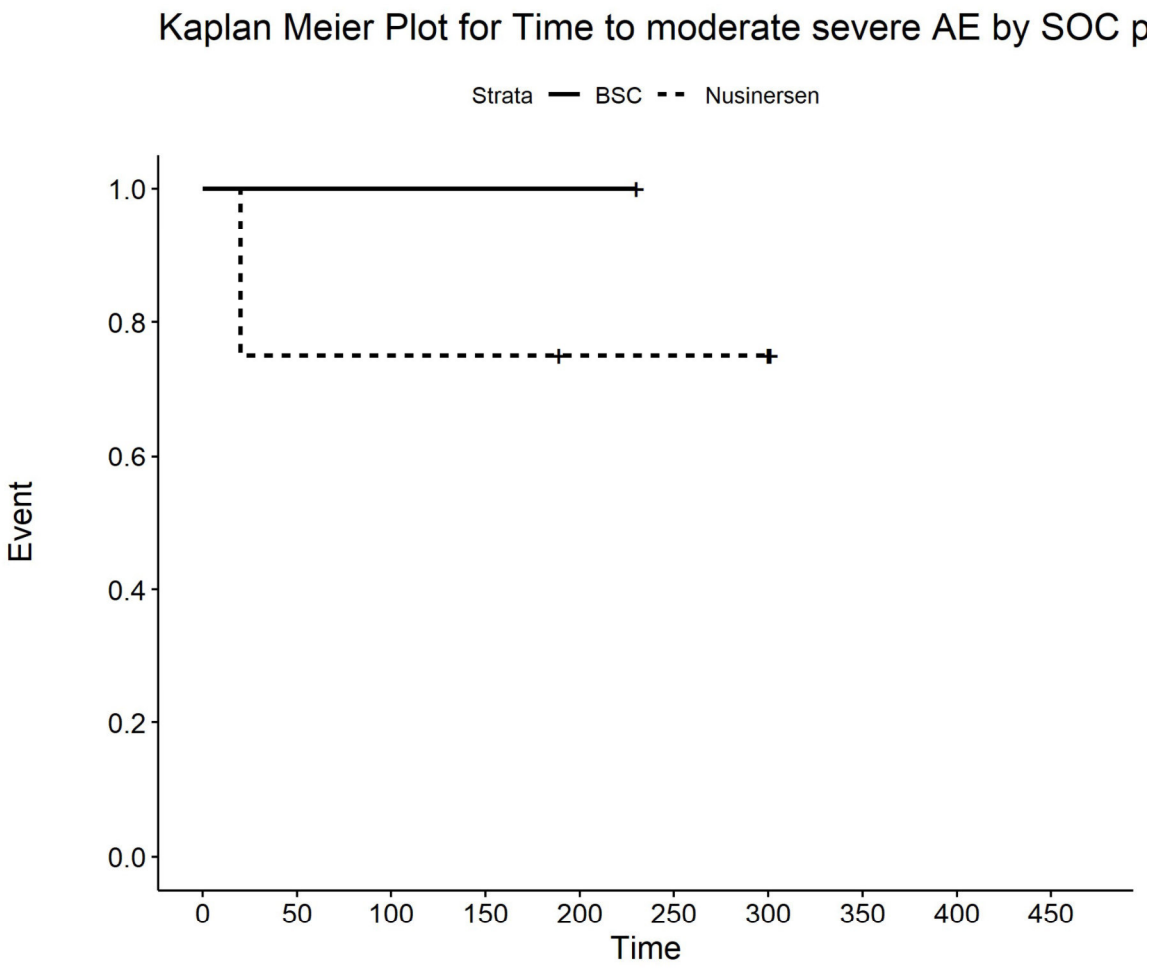
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	7	7	6	5	4	0



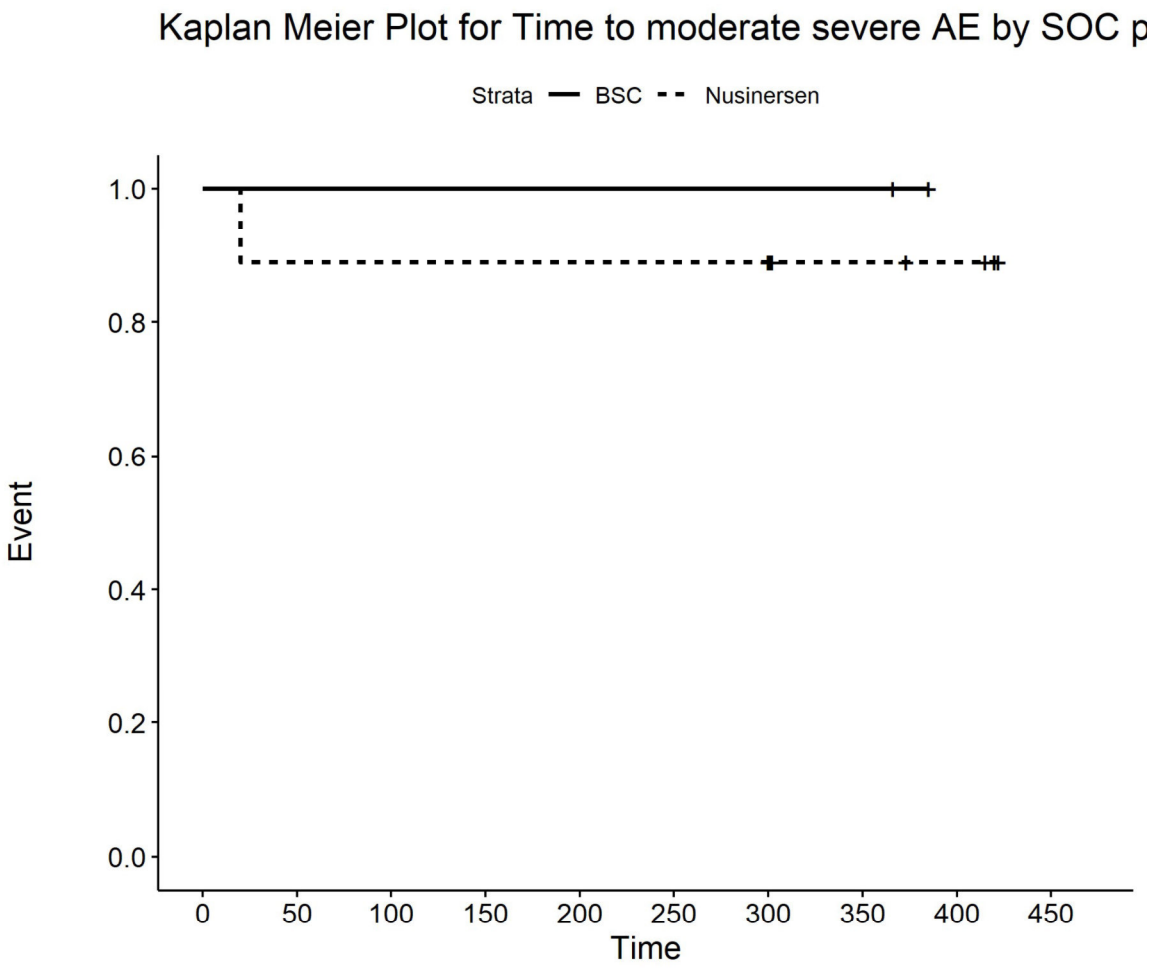
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



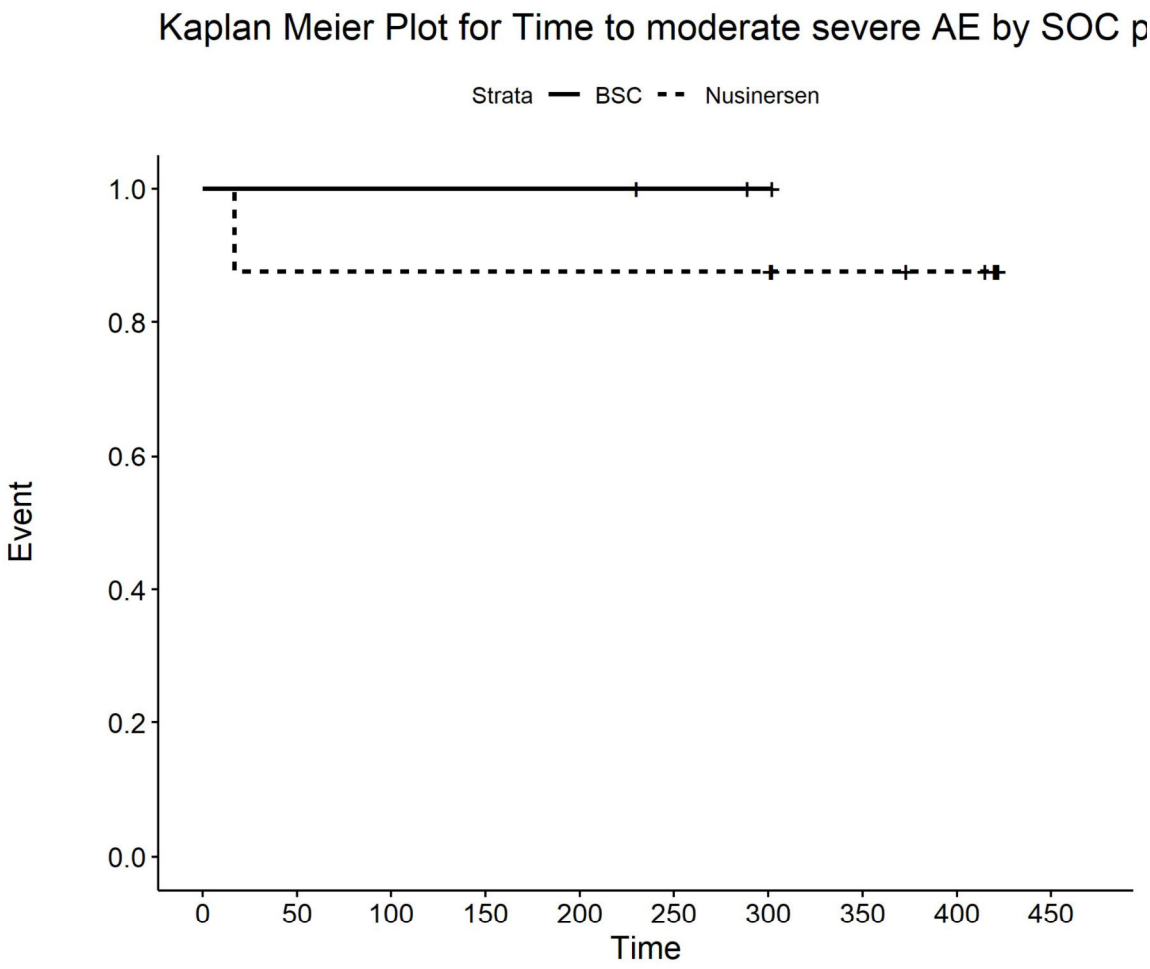
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



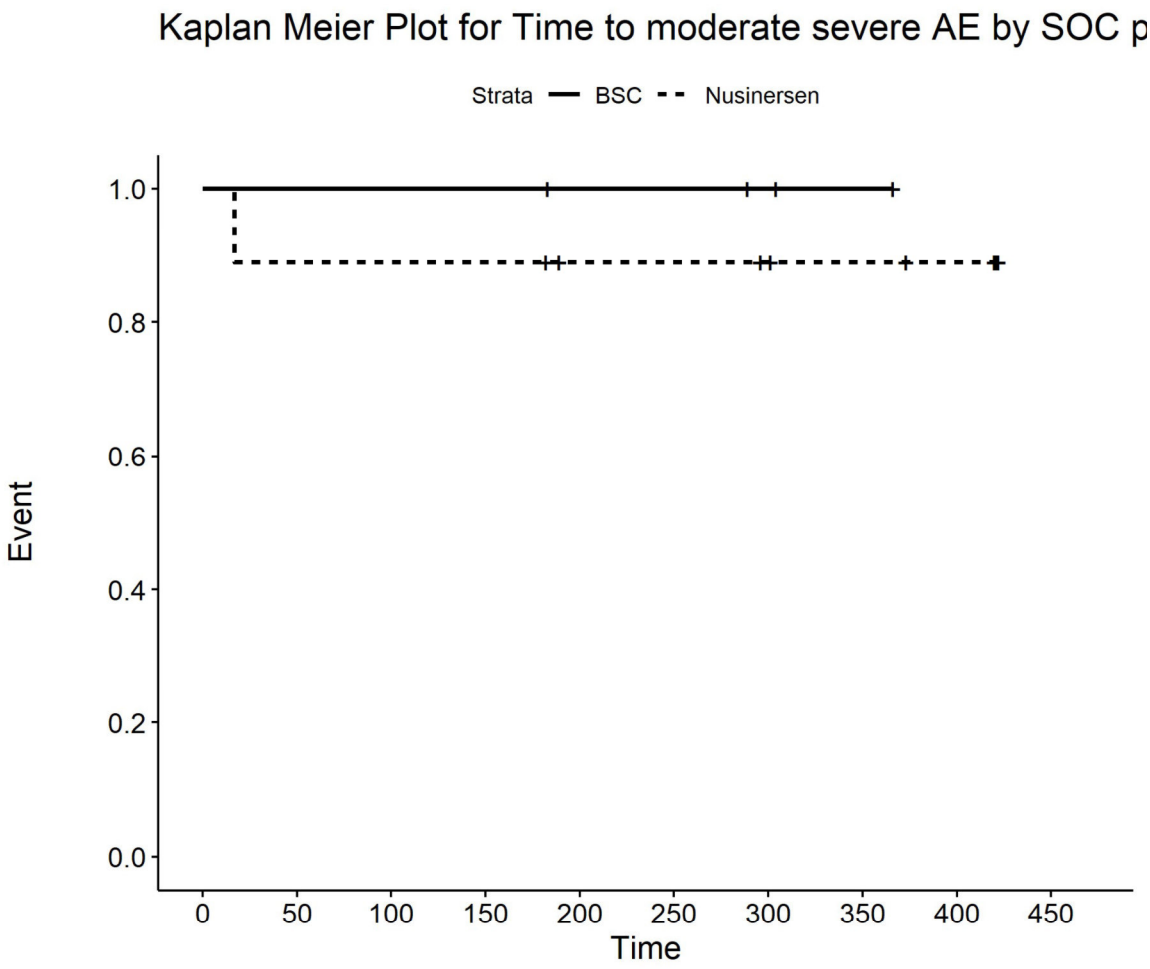
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	8	8	8	4	3	0



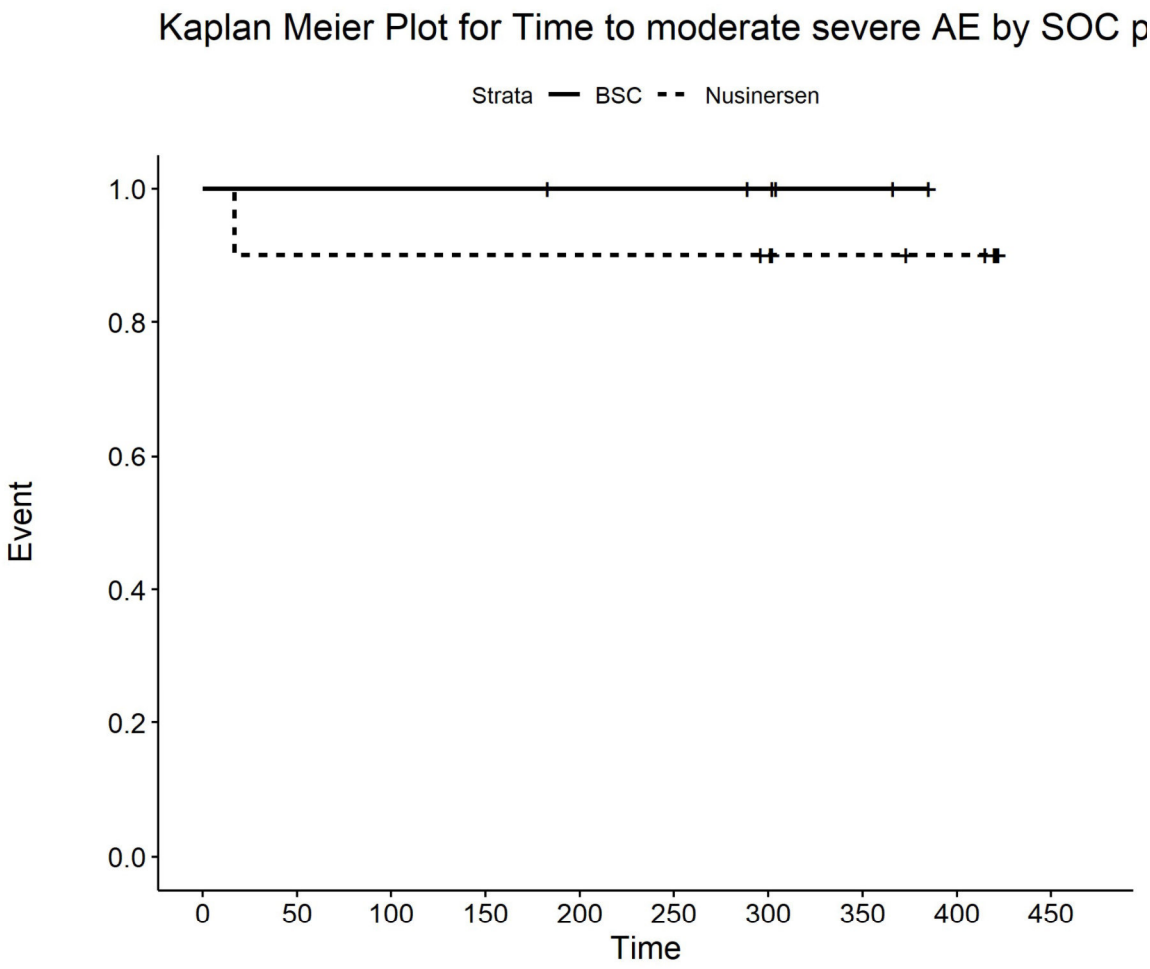
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	7	7	7	7	7	5	4	0



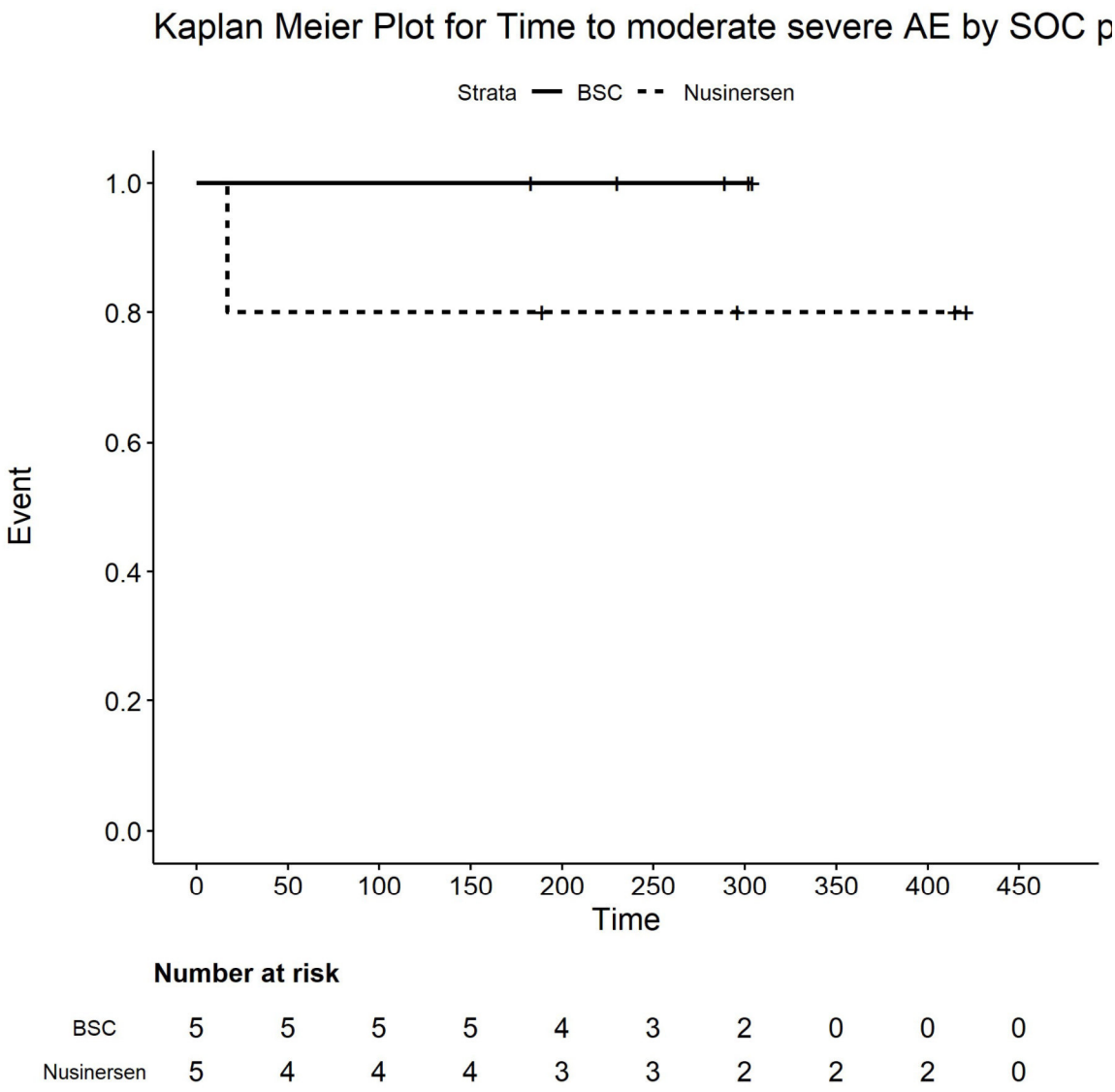
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	4	3	0



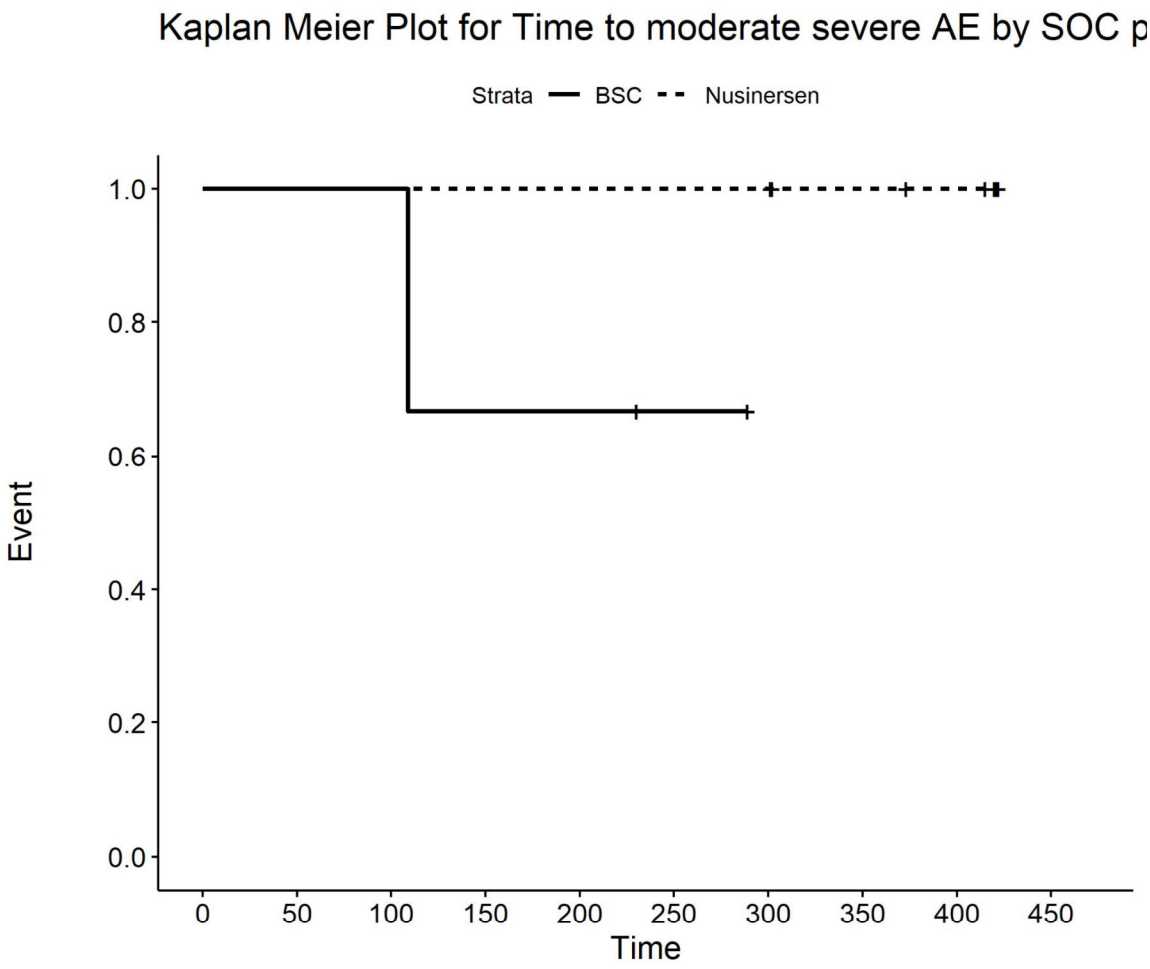
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	9	9	9	9	8	6	5	0



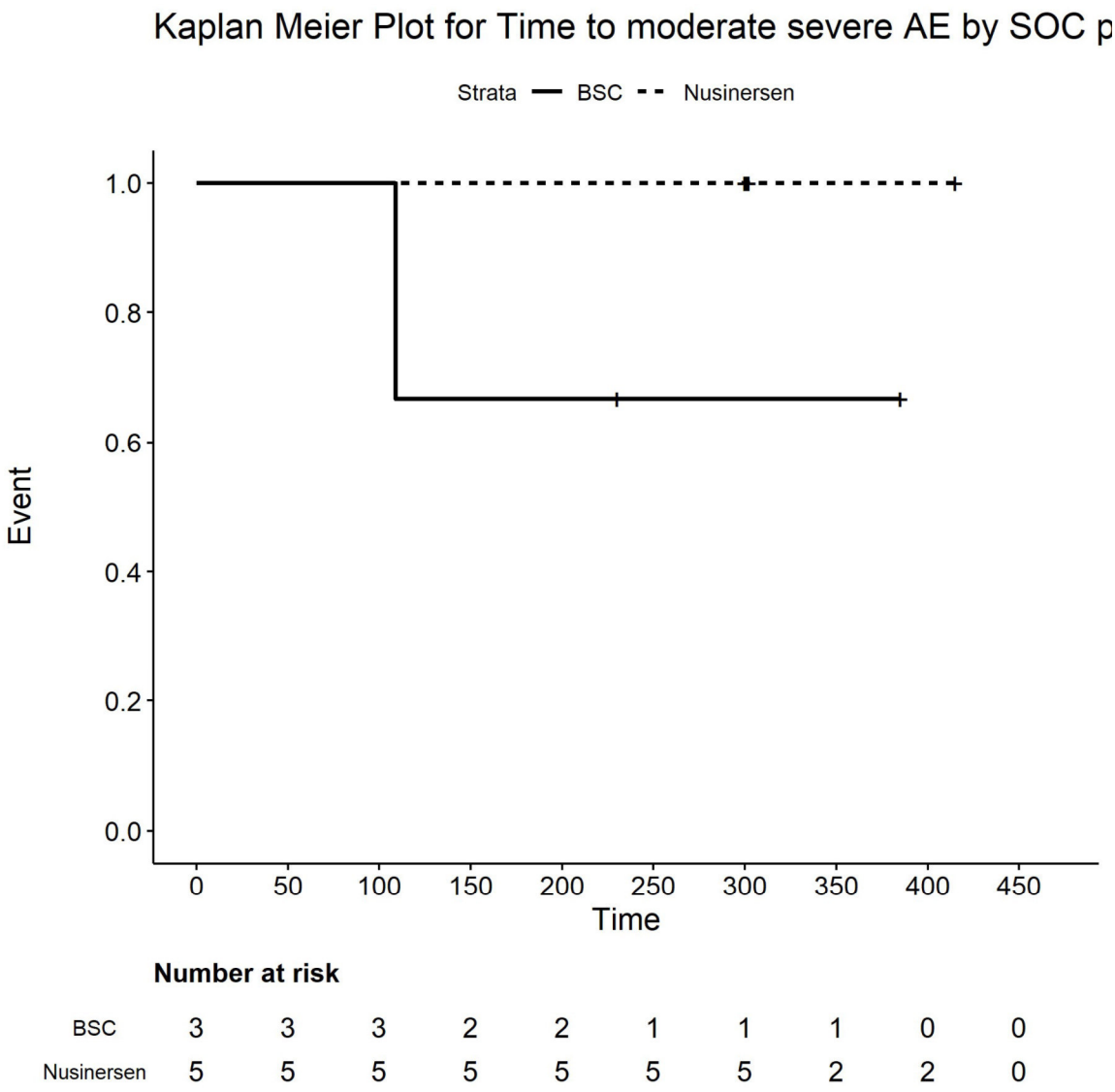
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	4	4	4	3	3	2	2	2	0



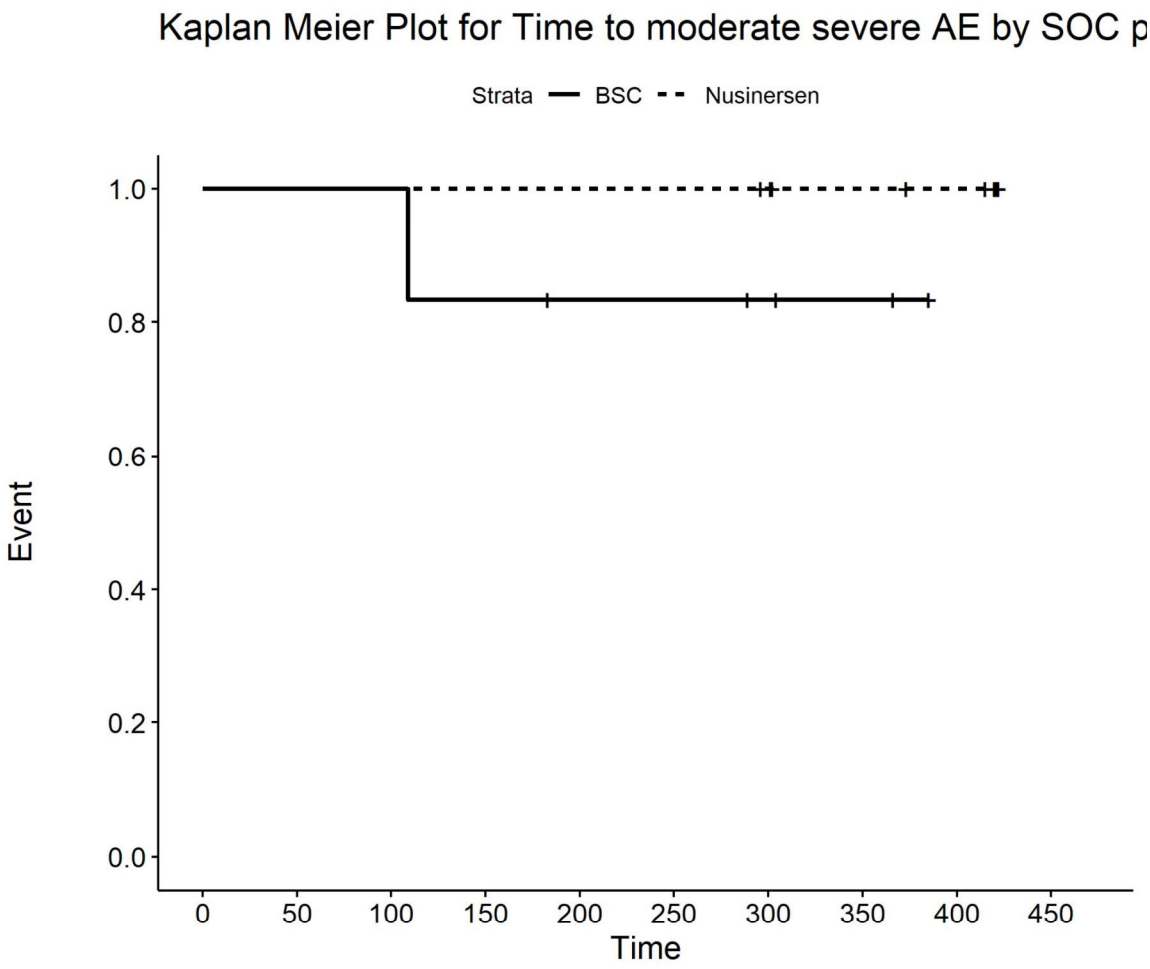
Number at risk

BSC	3	3	3	2	2	1	0	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



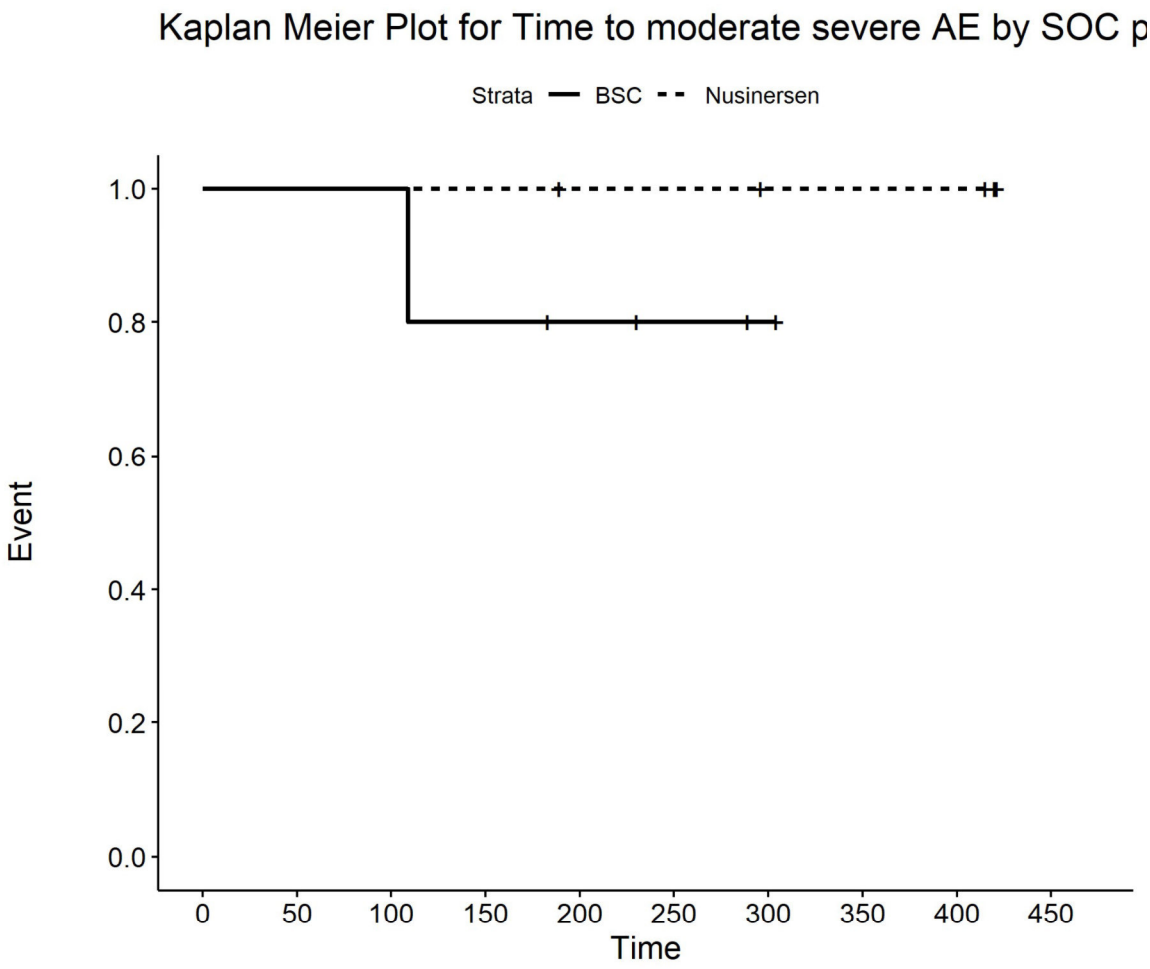
Number at risk

BSC	3	3	3	2	2	1	1	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



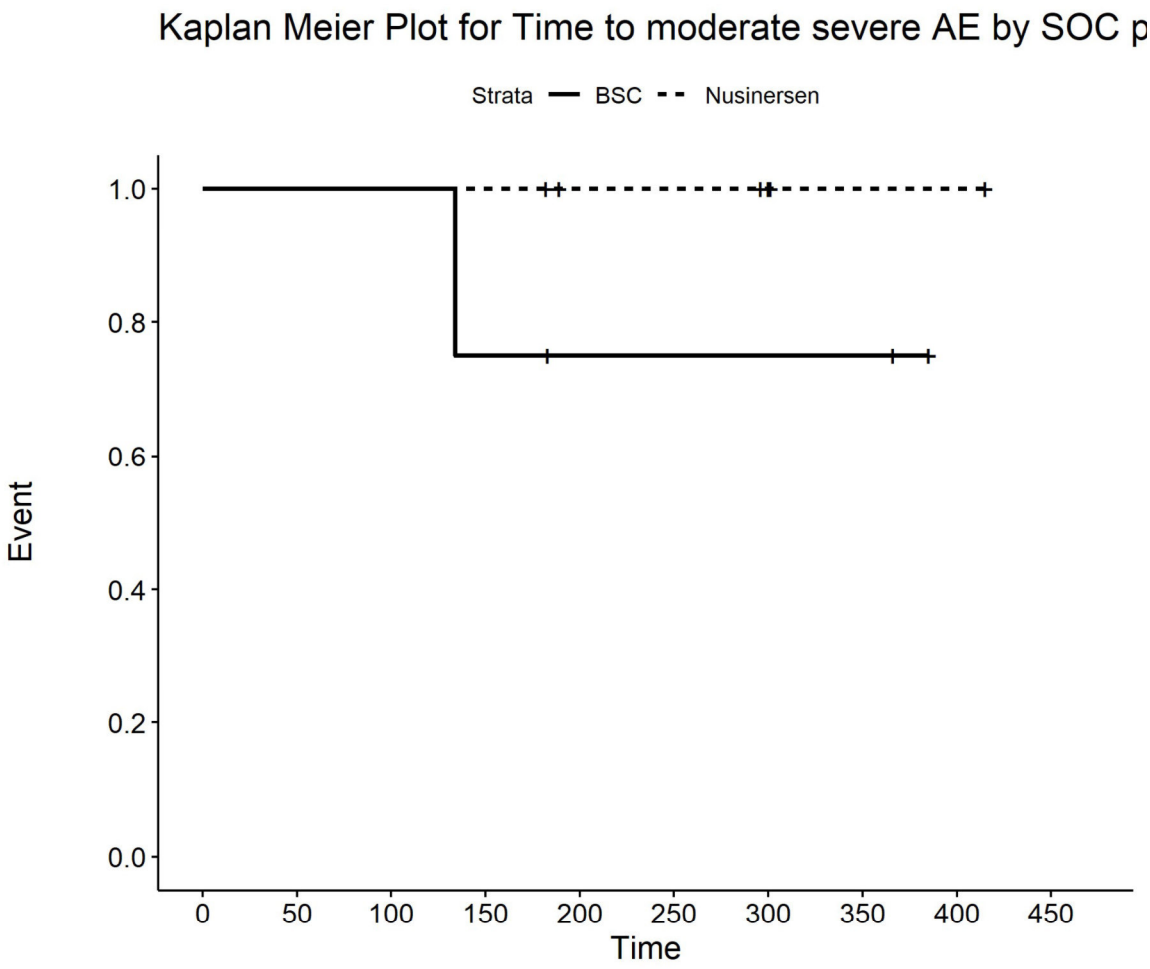
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



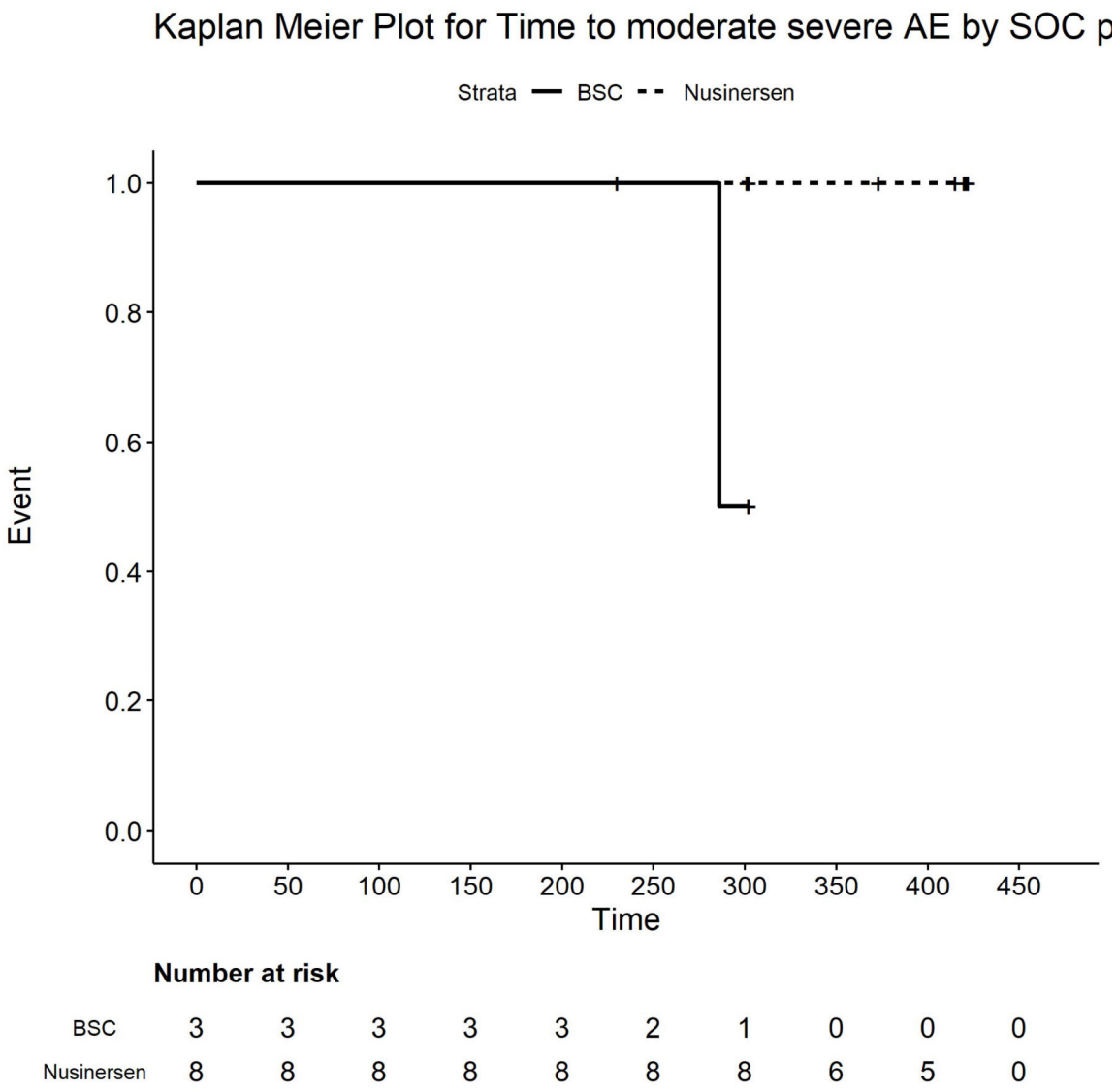
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



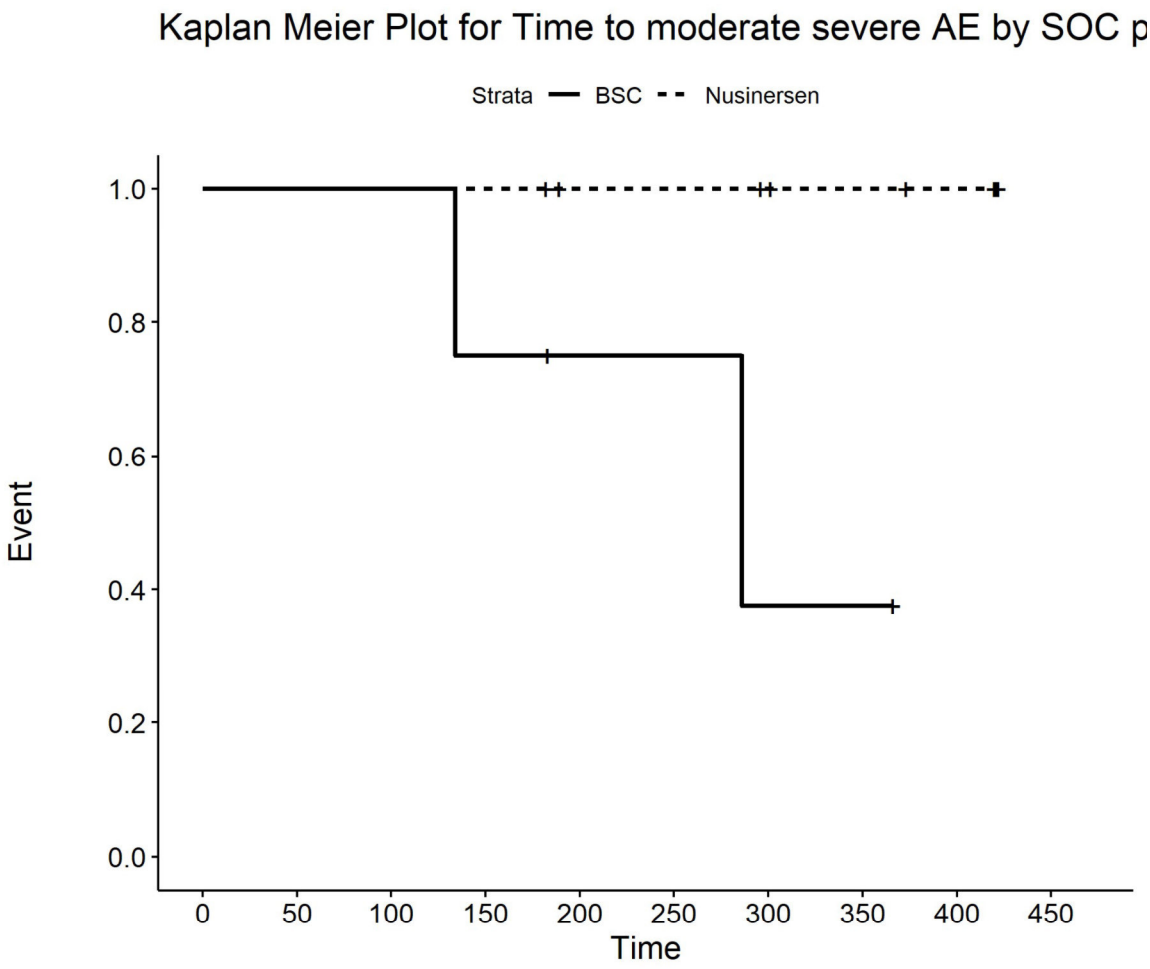
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



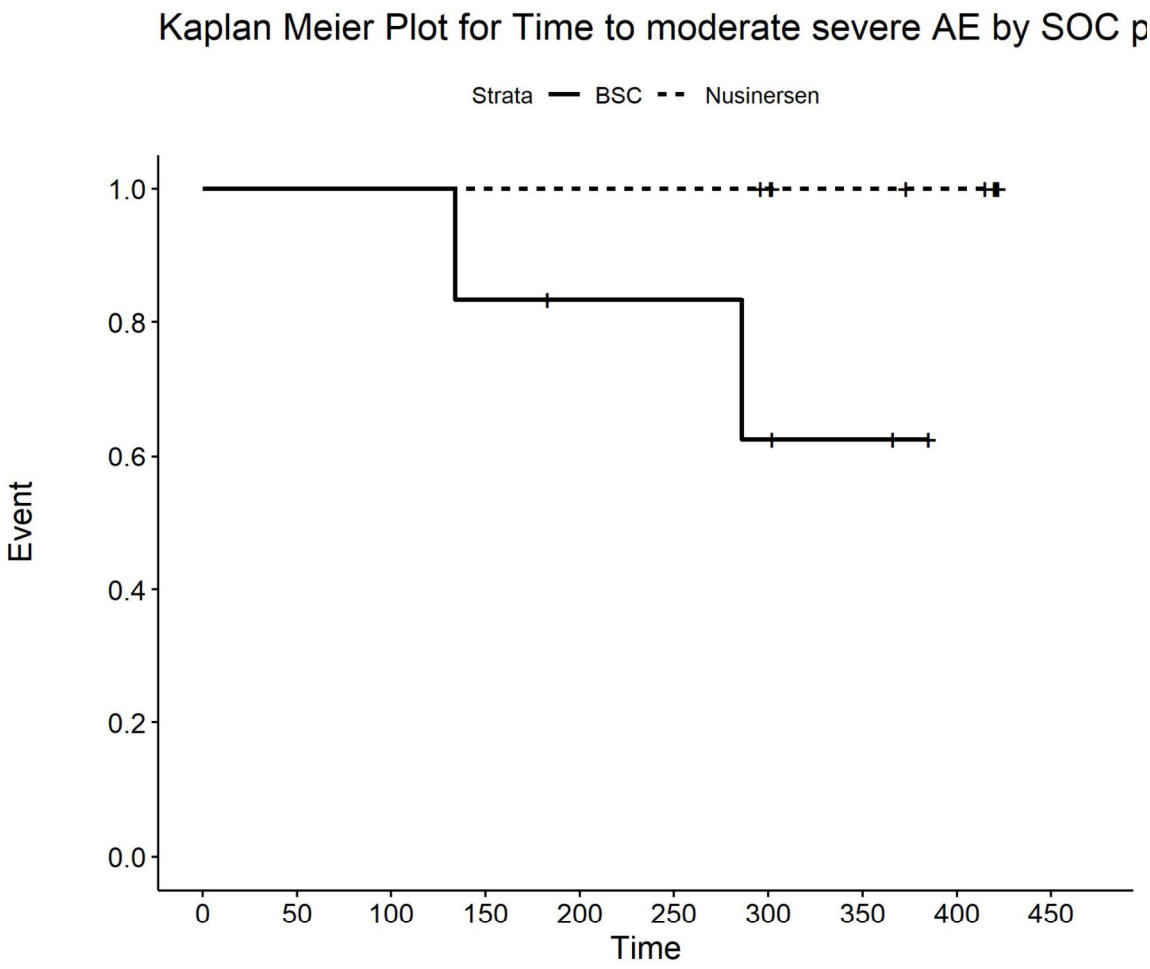
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



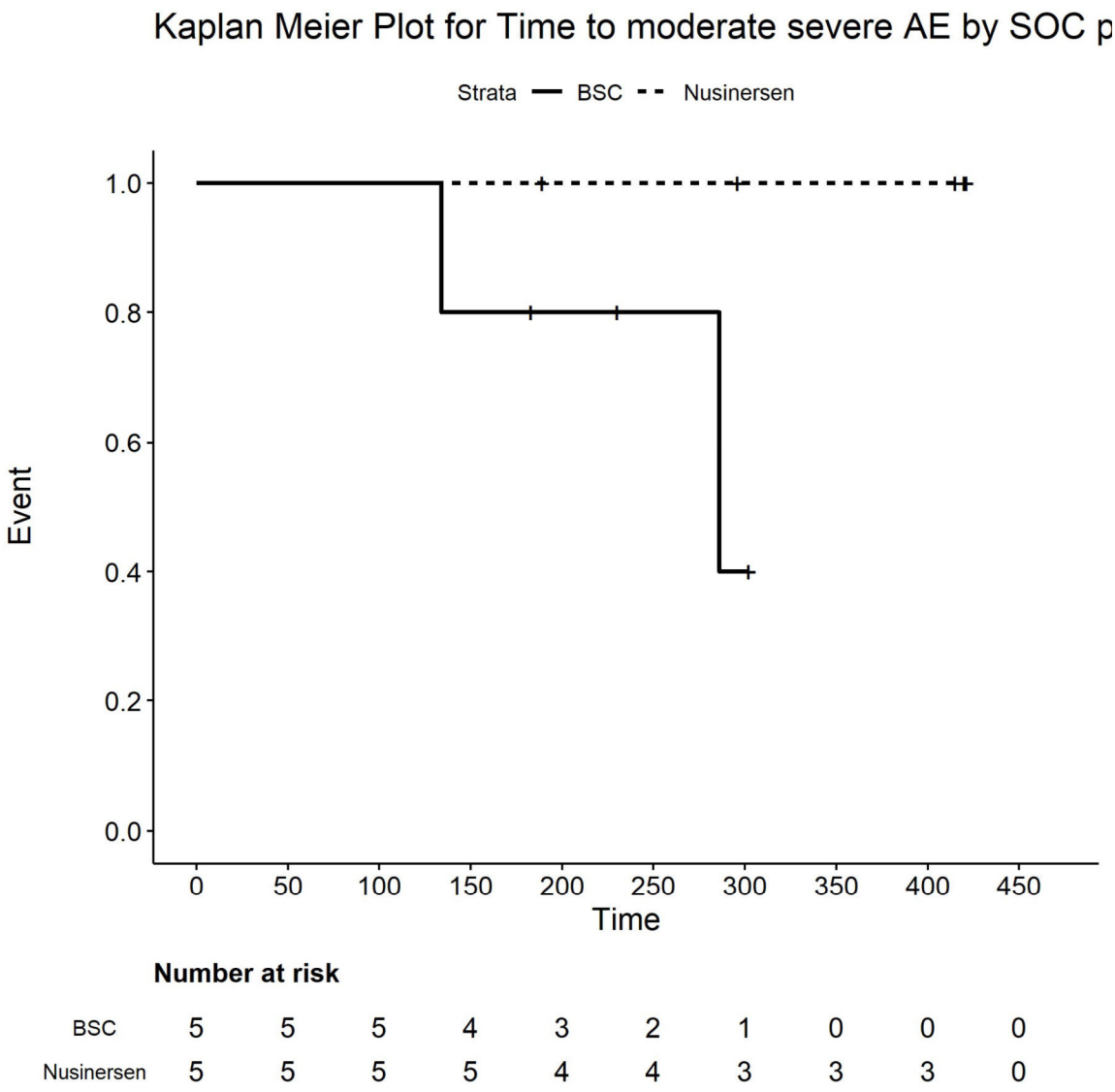
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



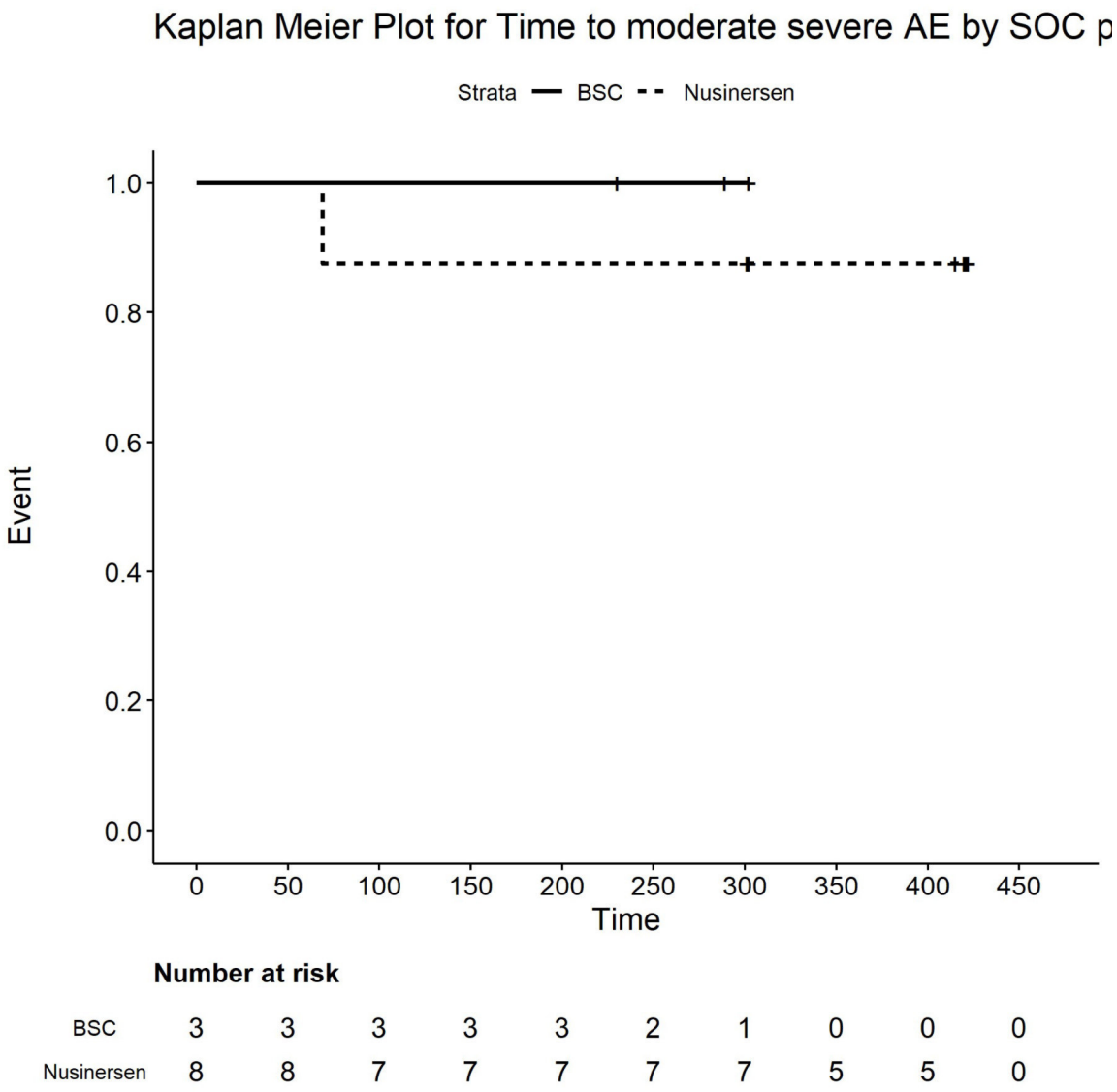
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



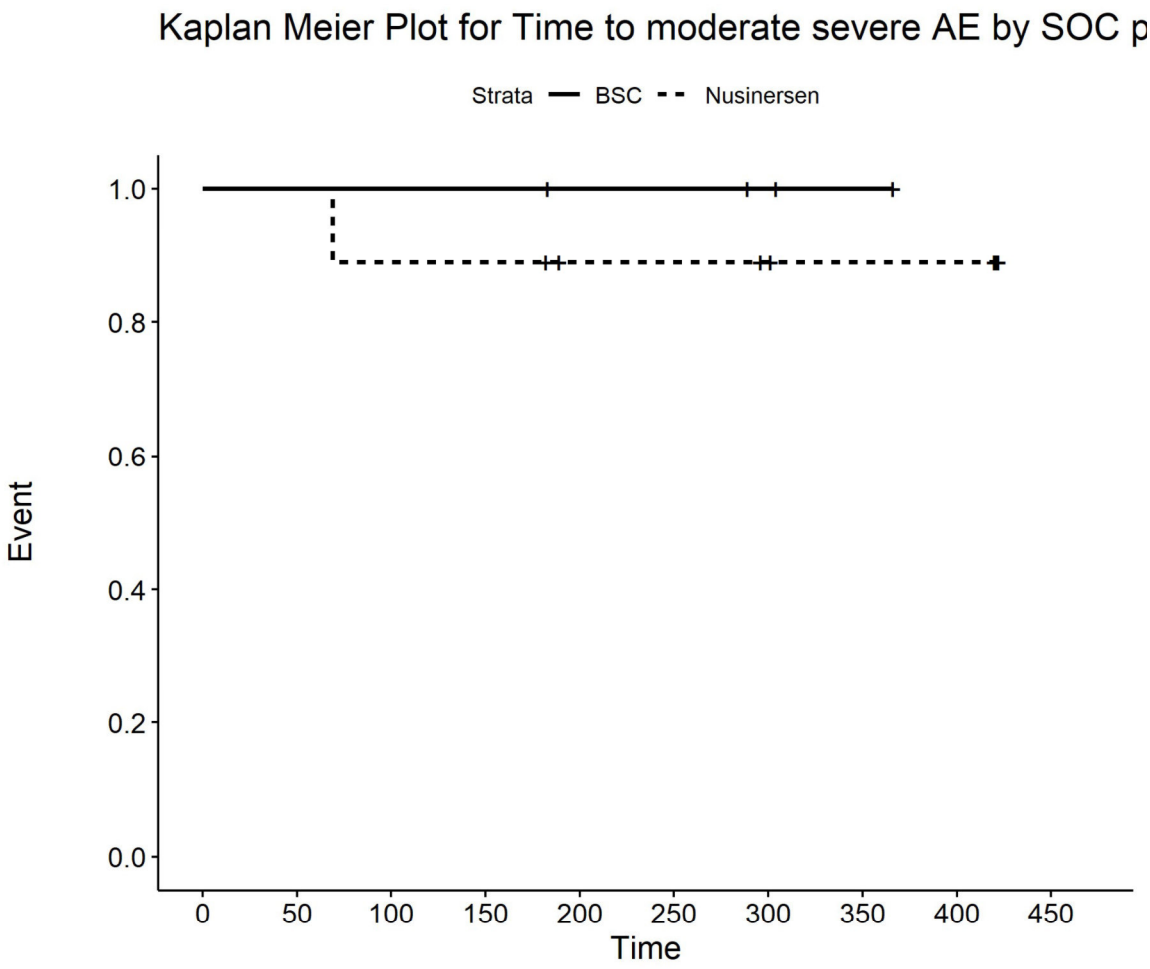
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



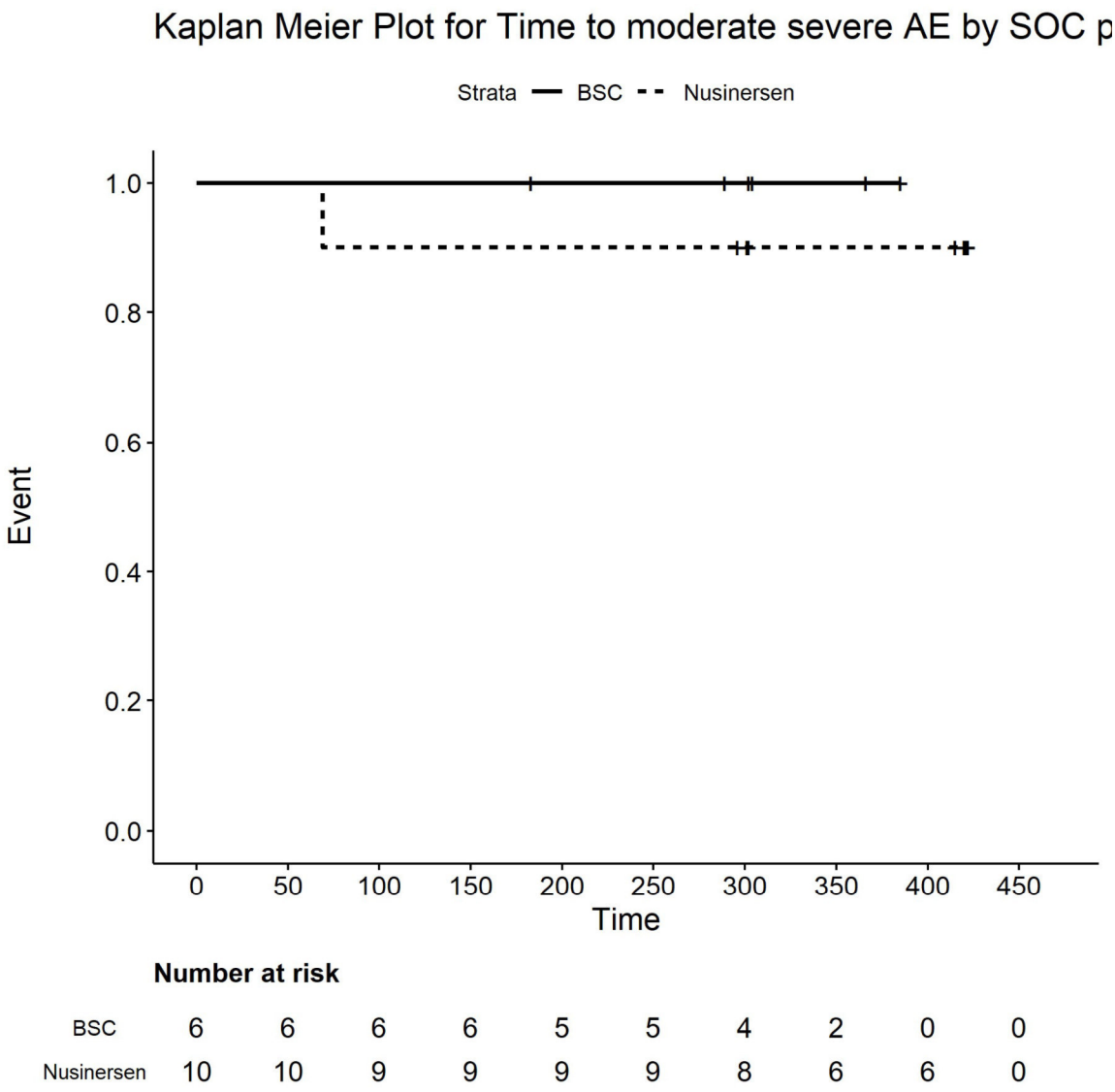
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	5	0



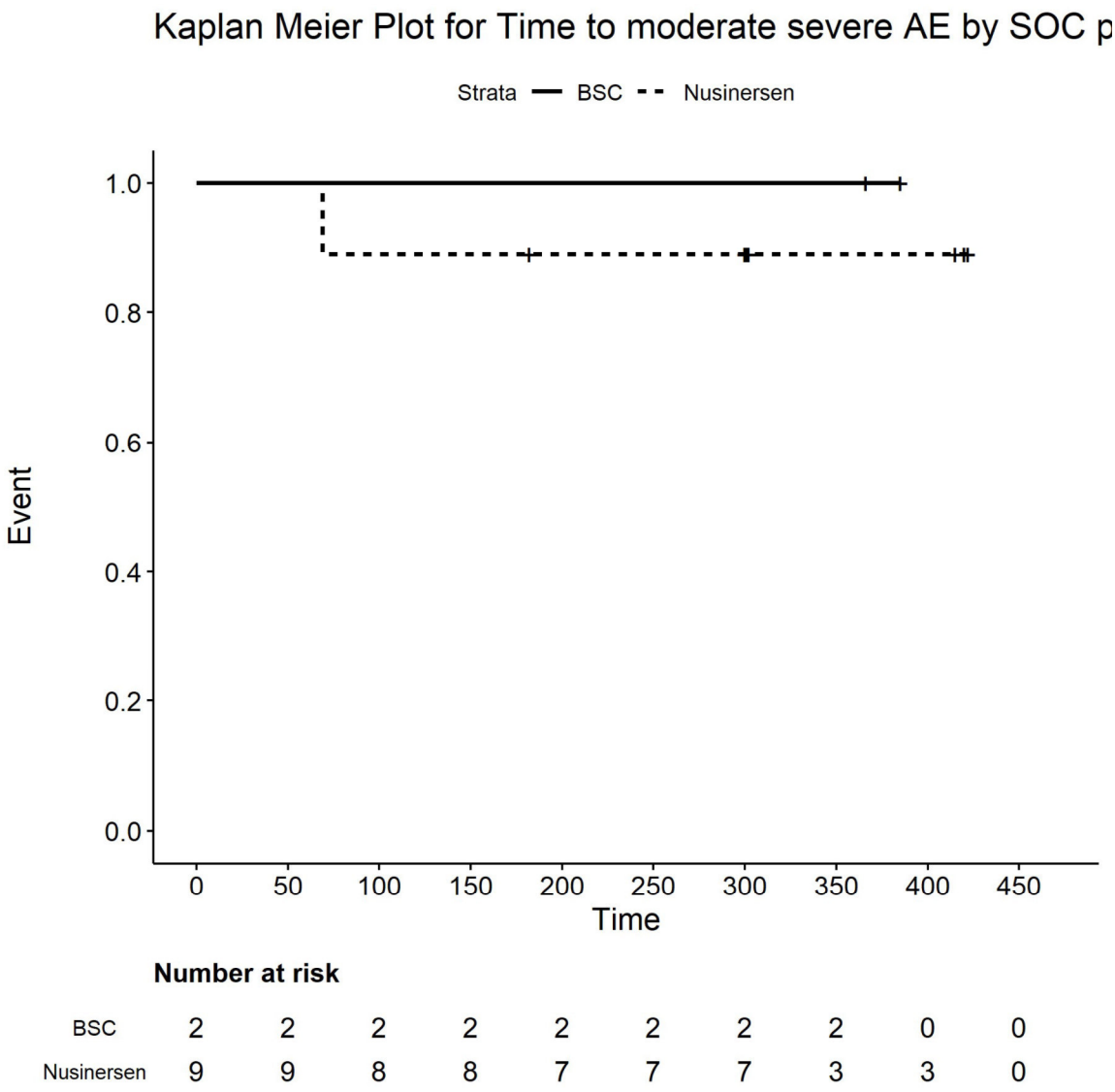
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	4	0



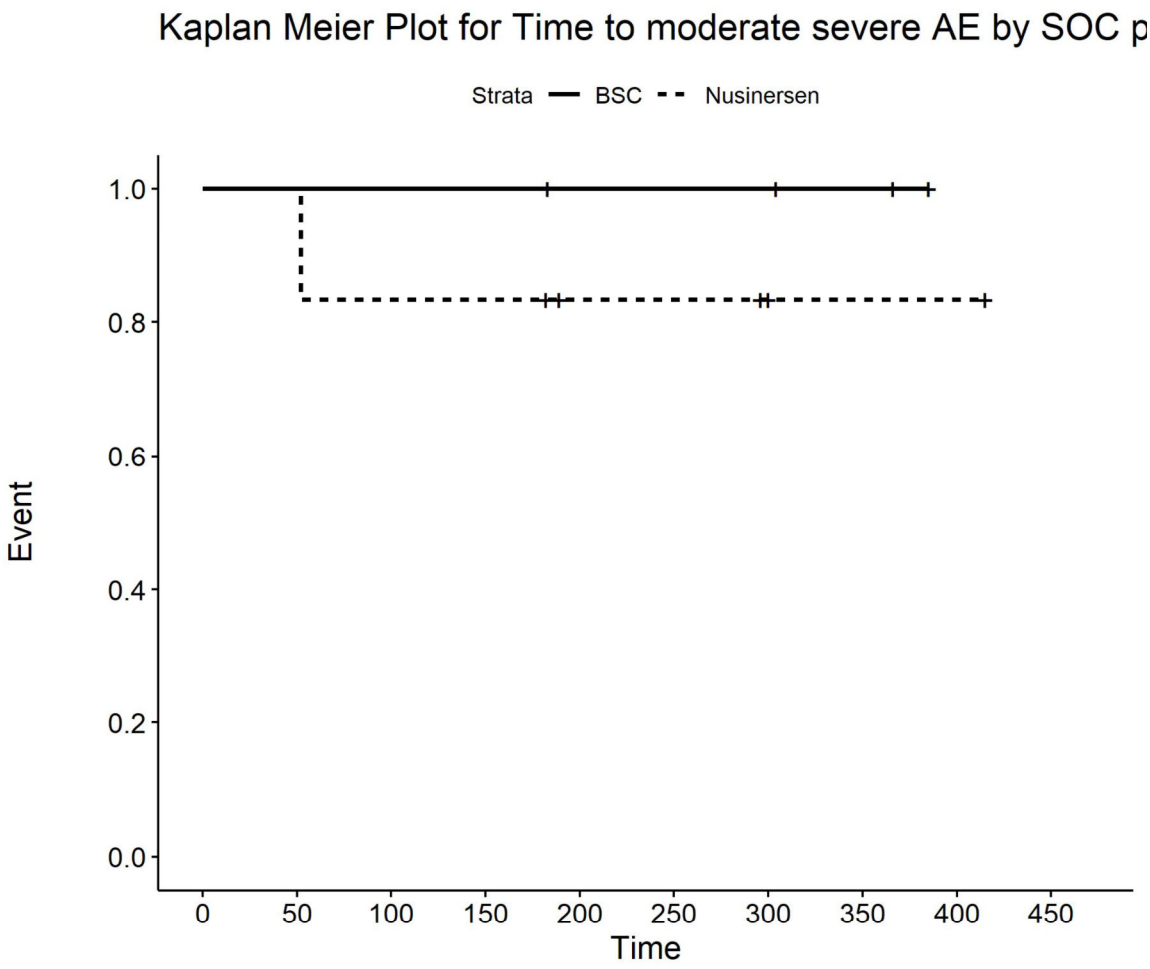
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	6	0



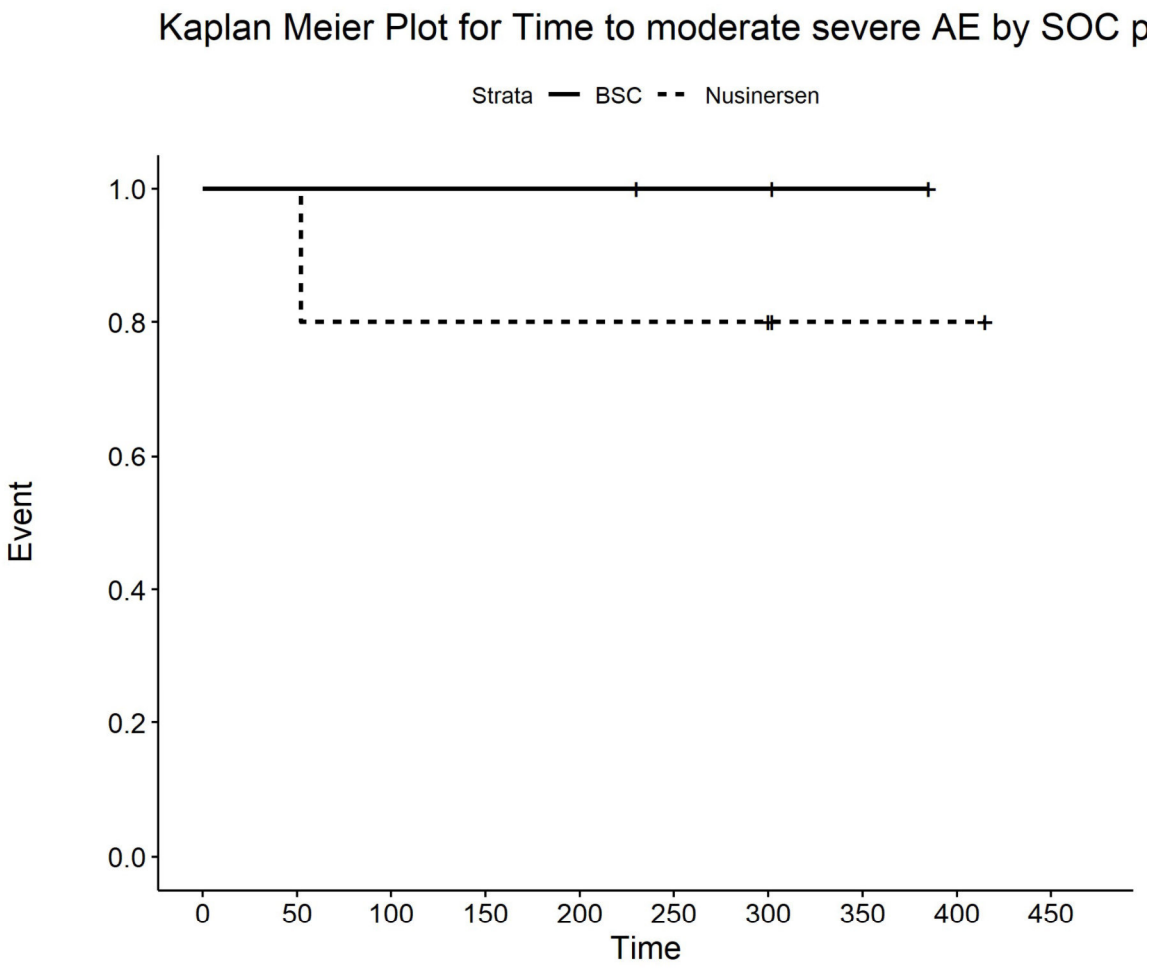
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	3	0



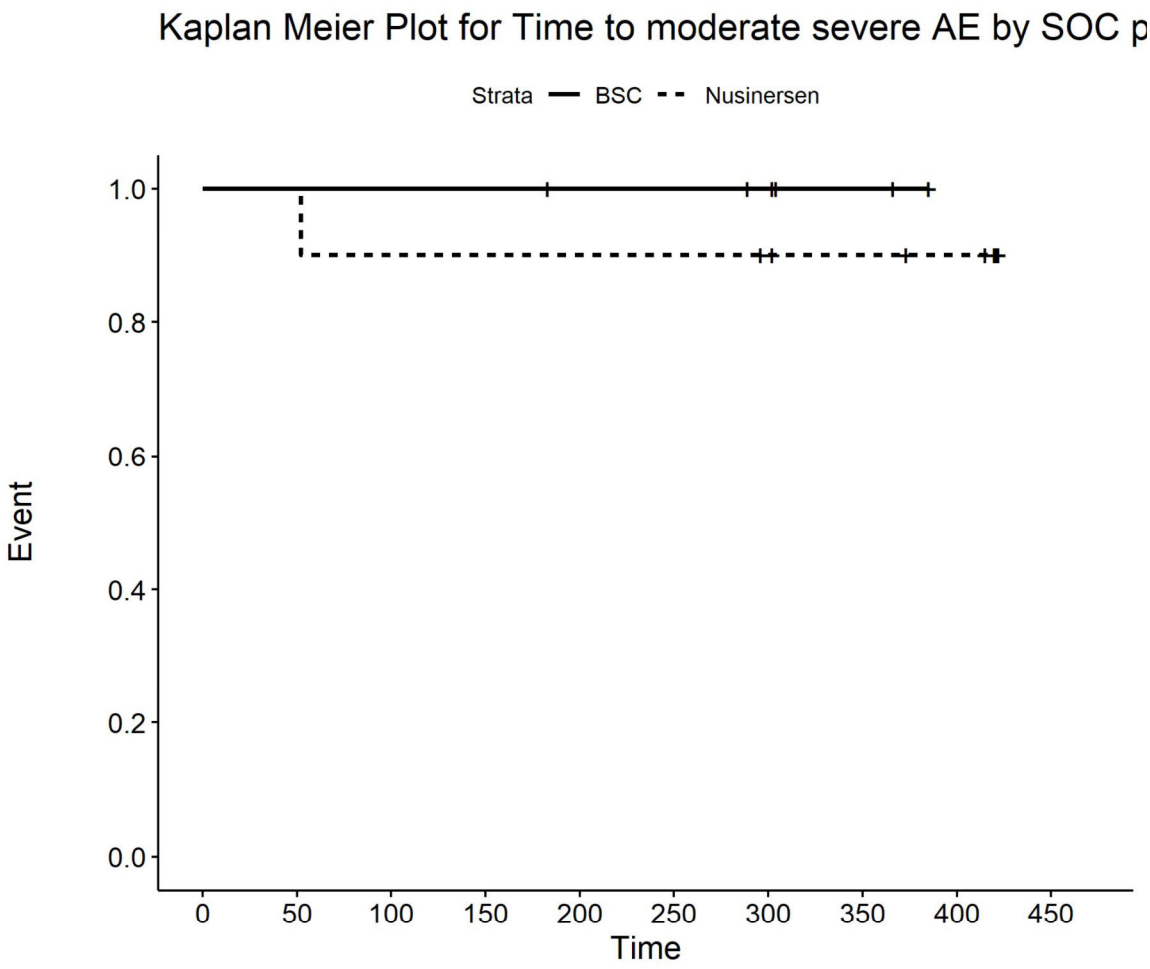
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	5	5	3	3	2	1	1	0



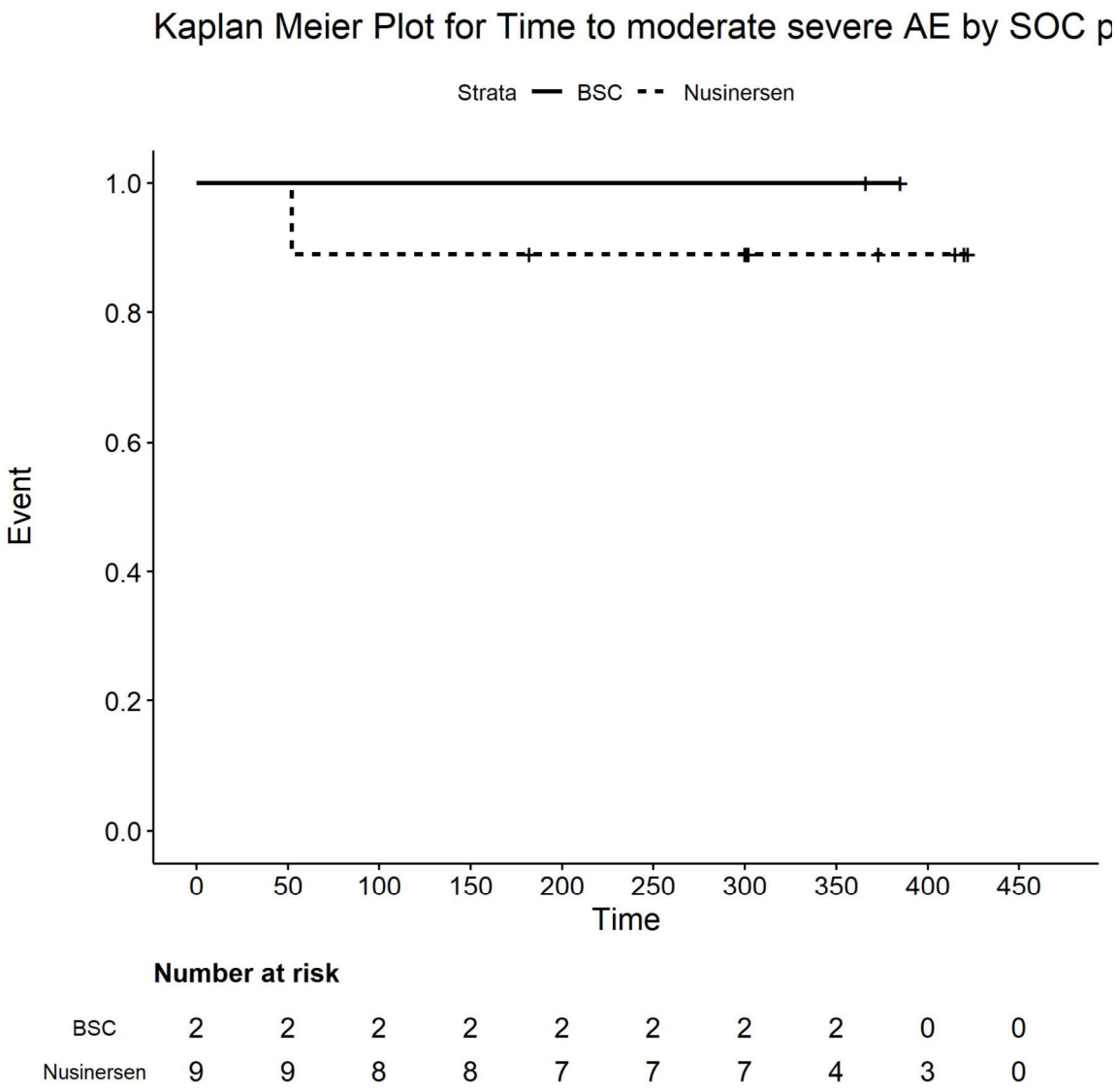
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	4	4	4	4	4	2	2	0



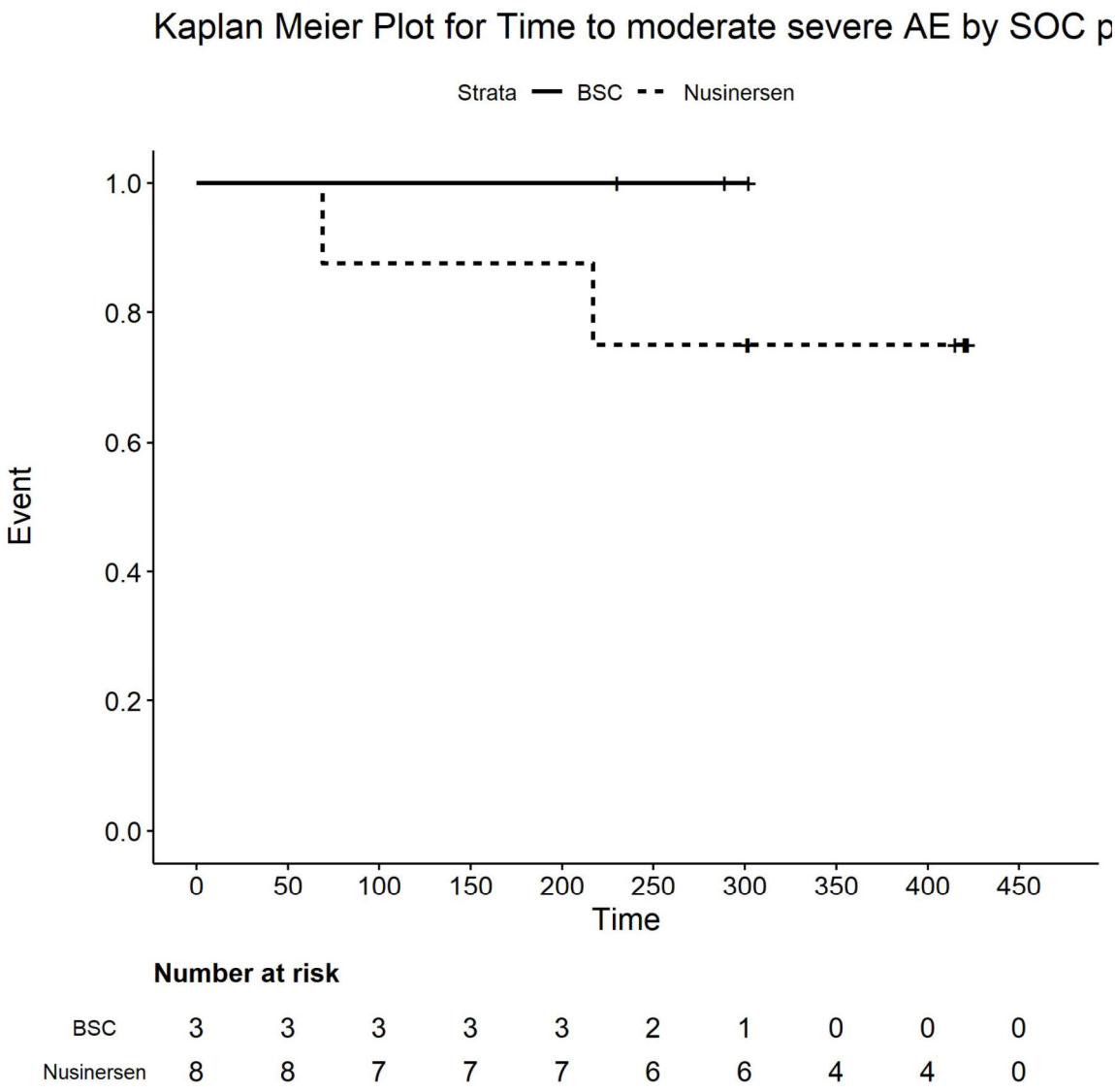
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	7	6	0



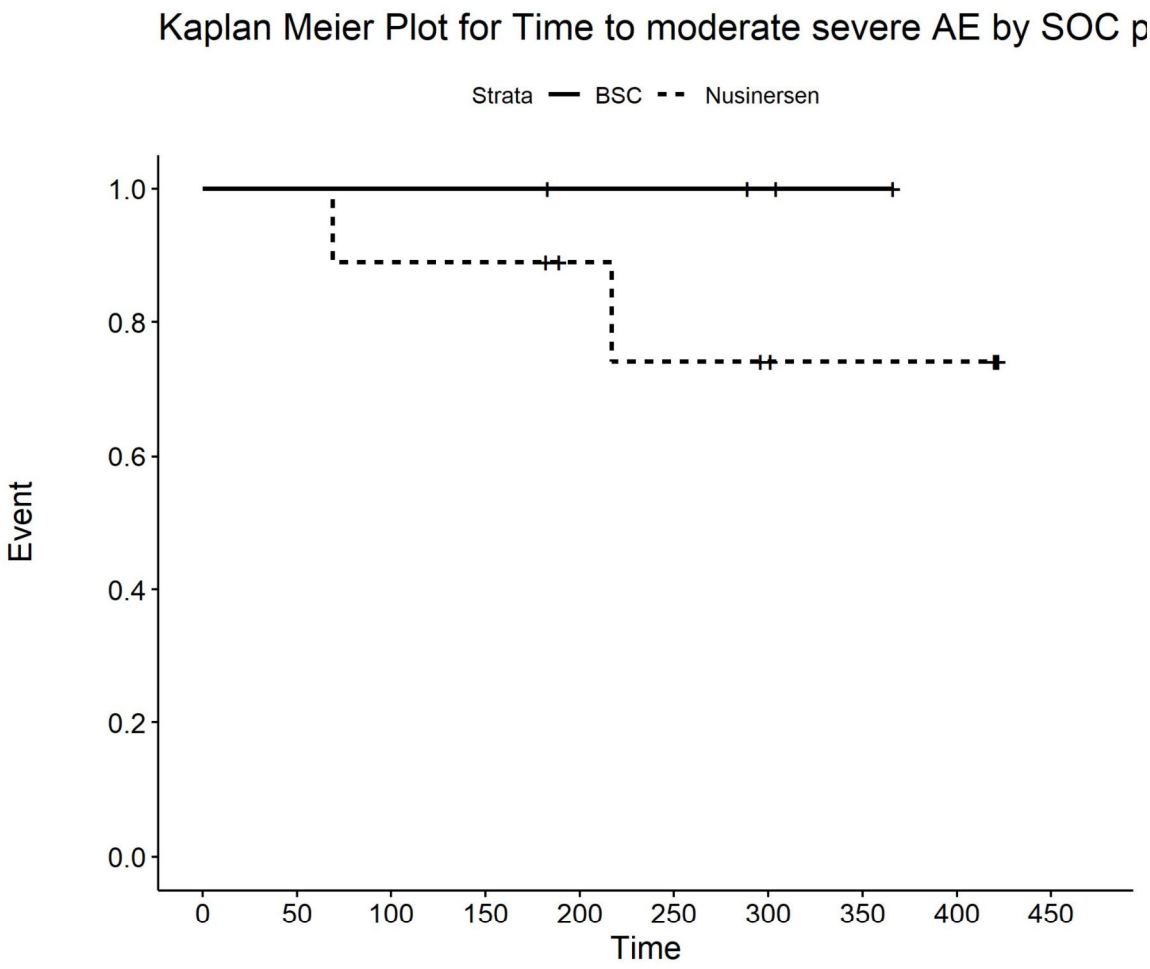
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	4	3	0



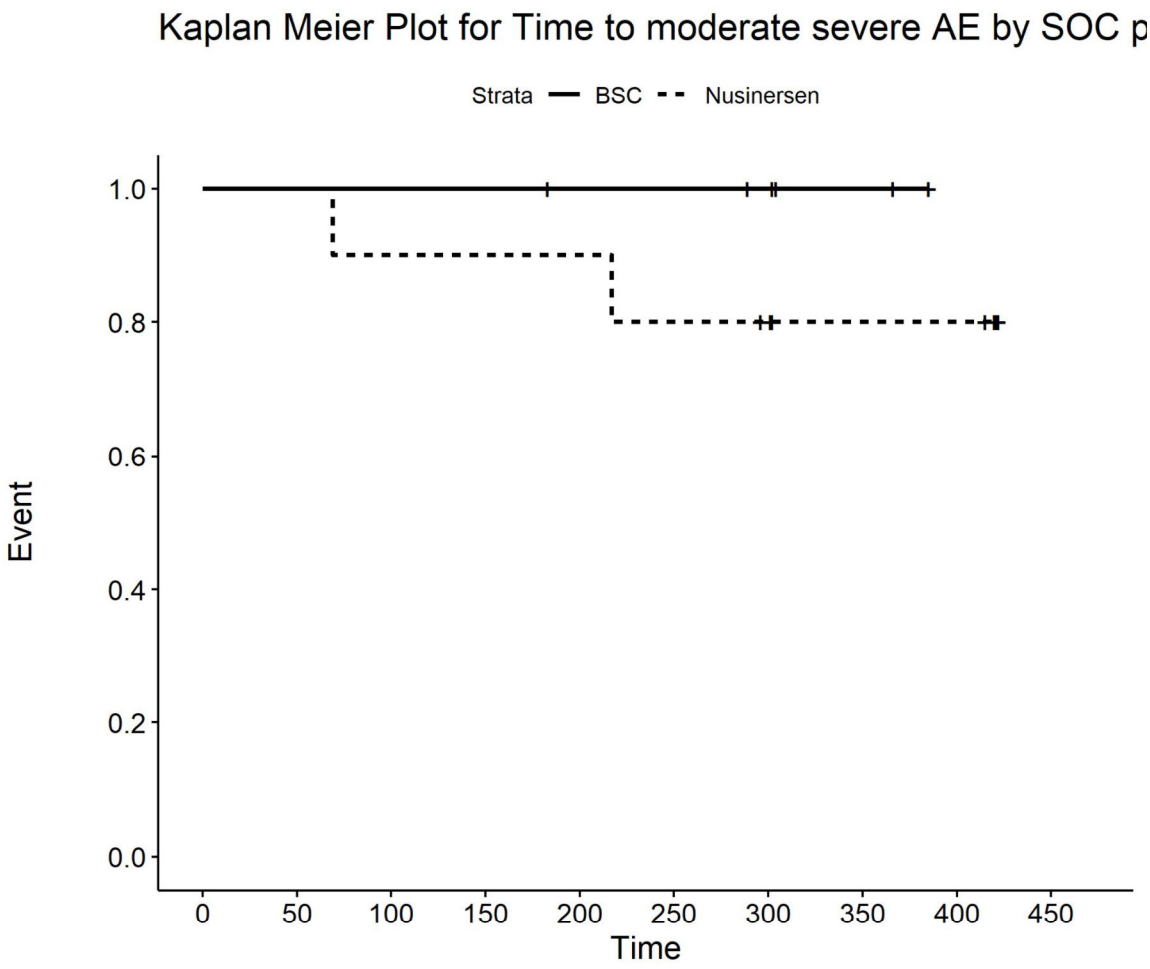
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	6	6	4	4	0



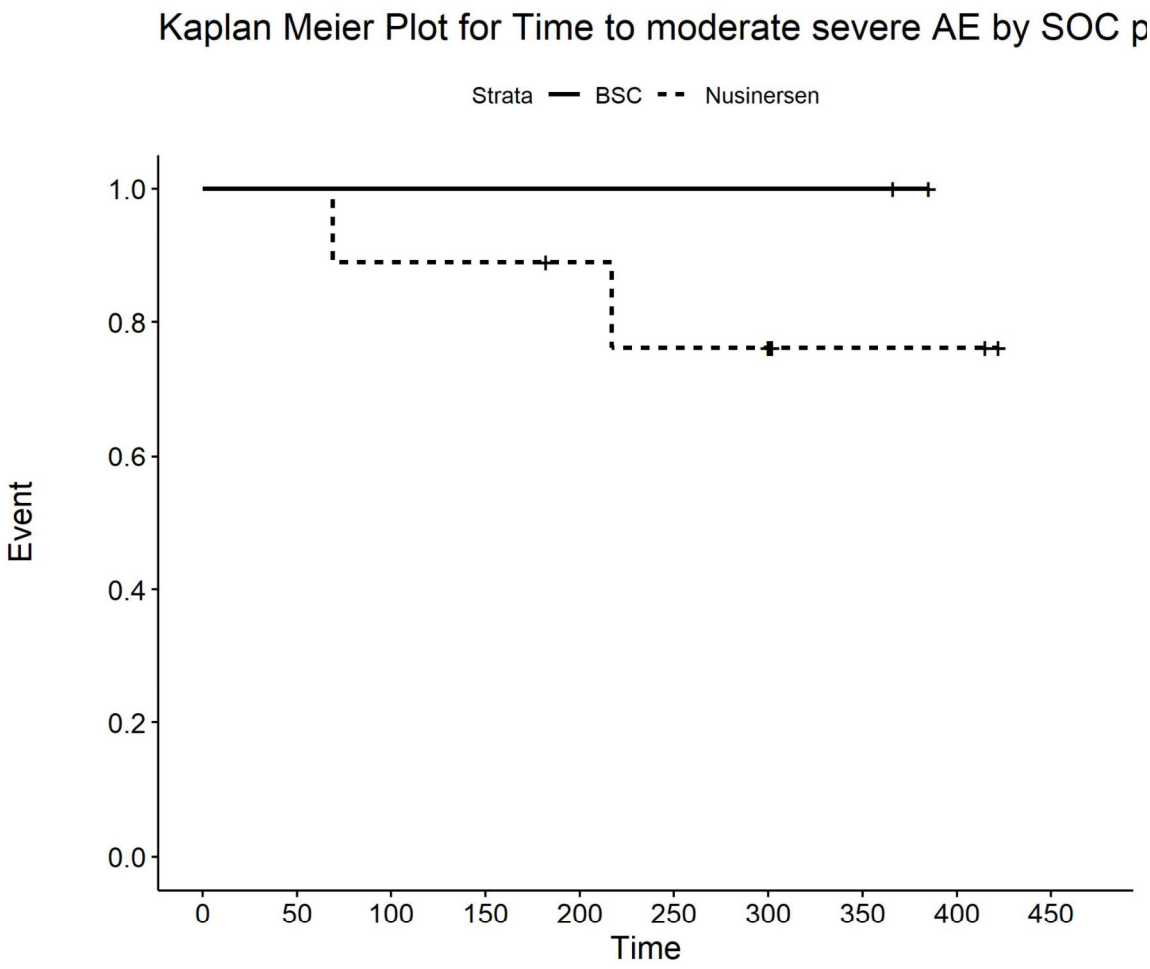
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	5	4	3	3	0



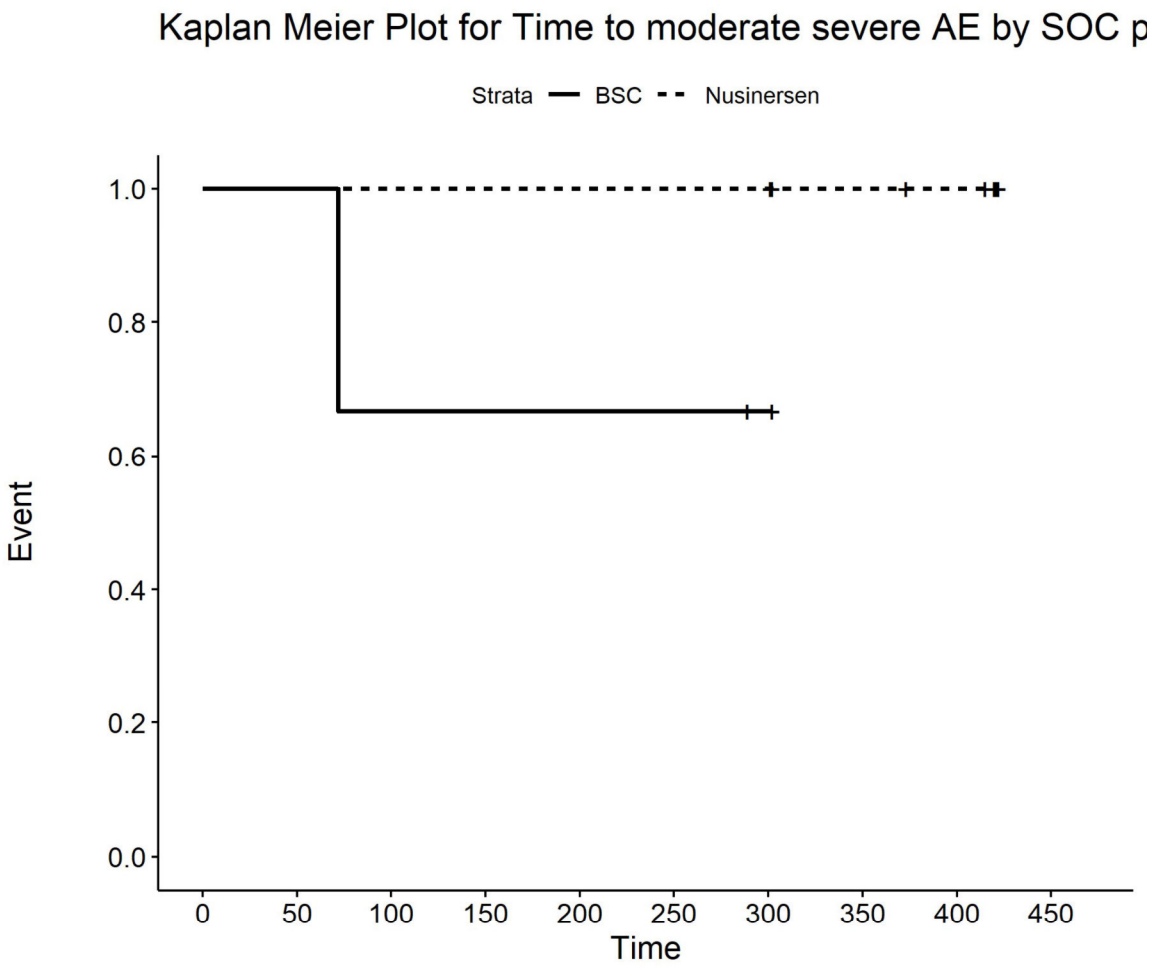
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	8	7	5	5	0



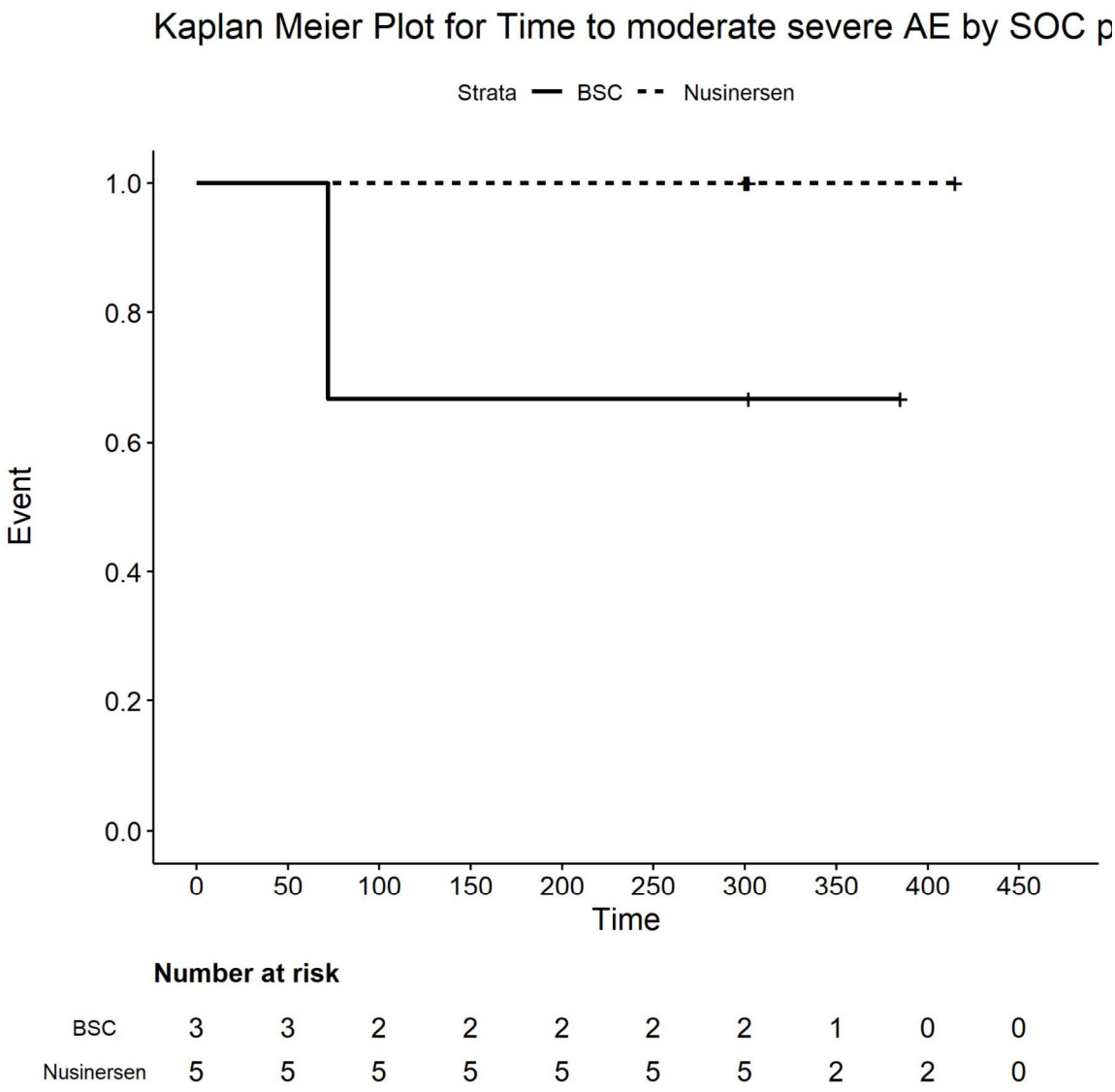
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	6	6	2	2	0



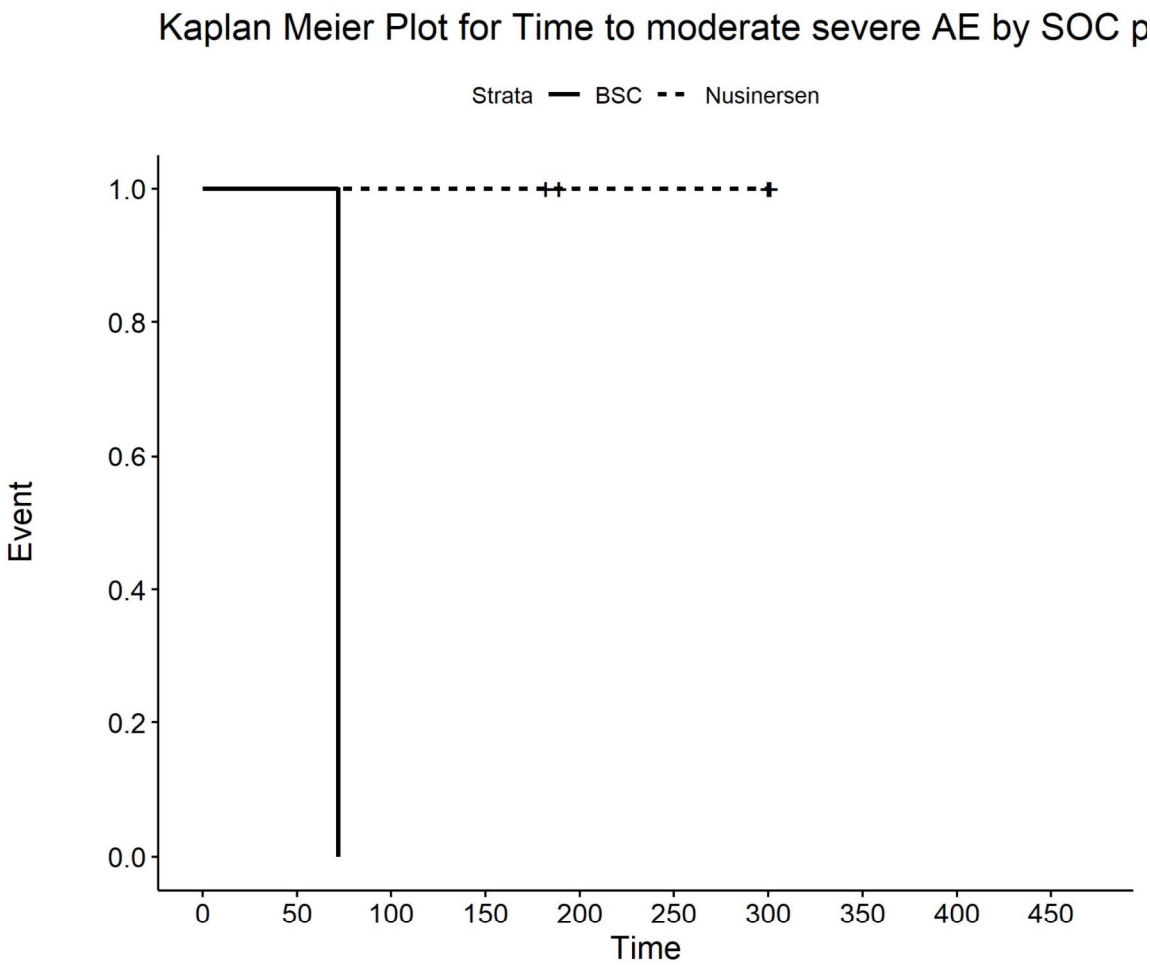
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



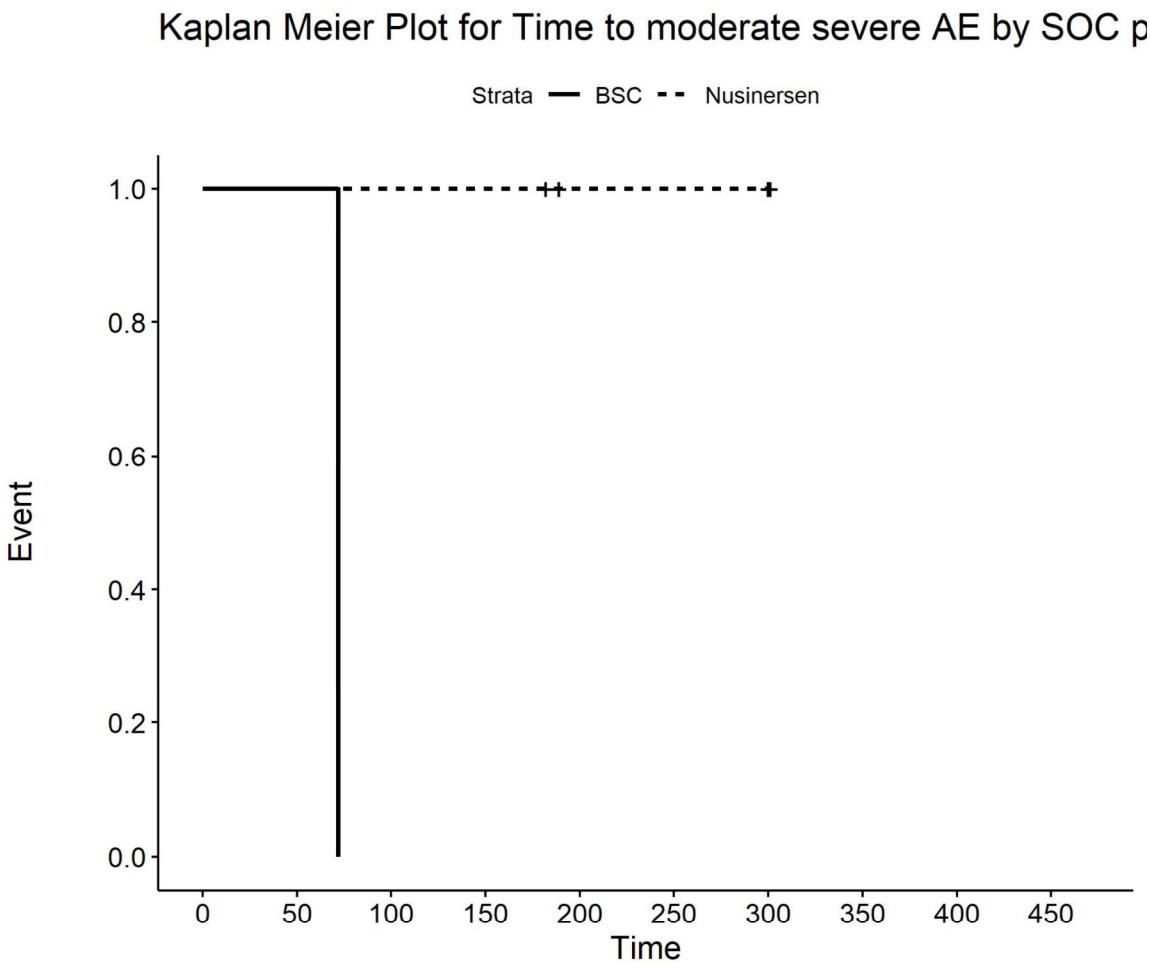
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



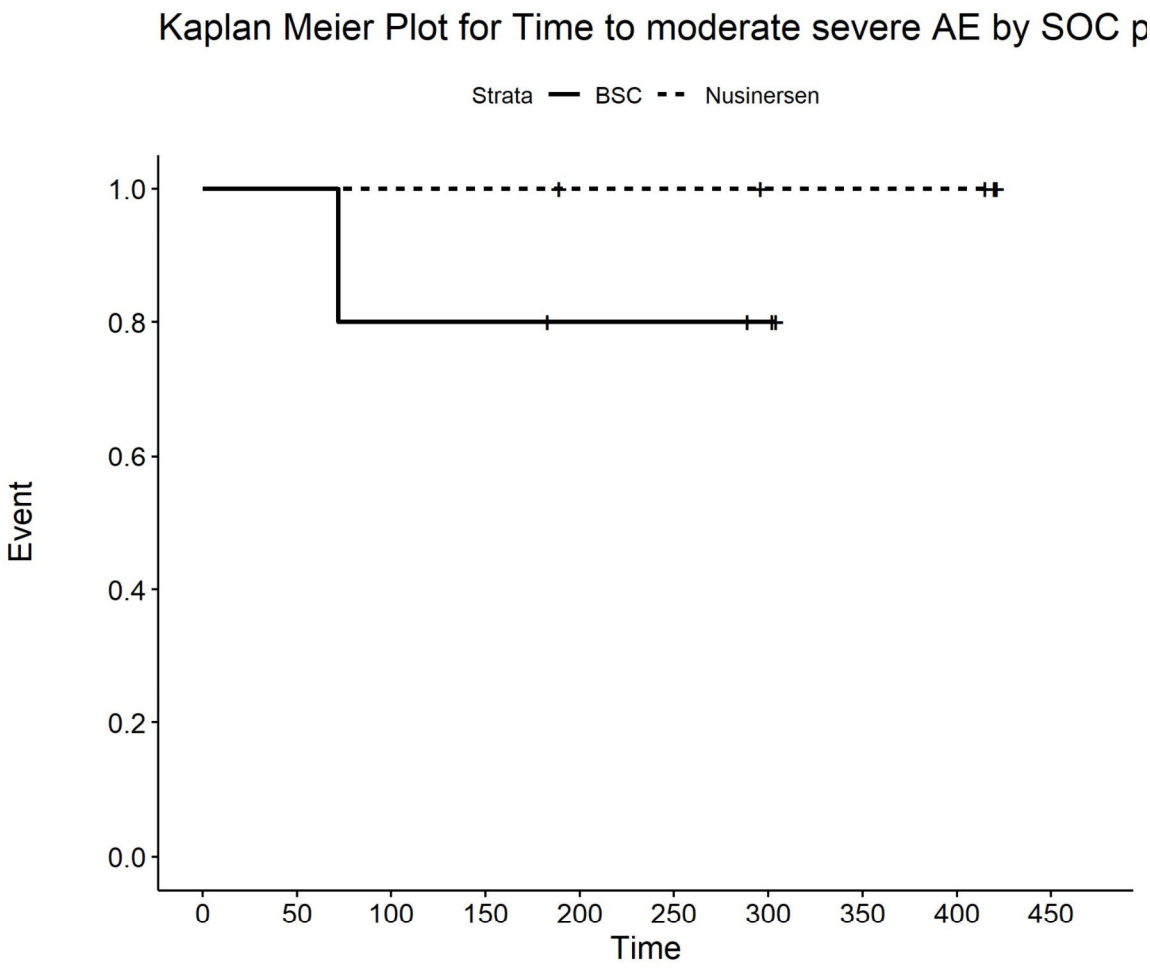
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



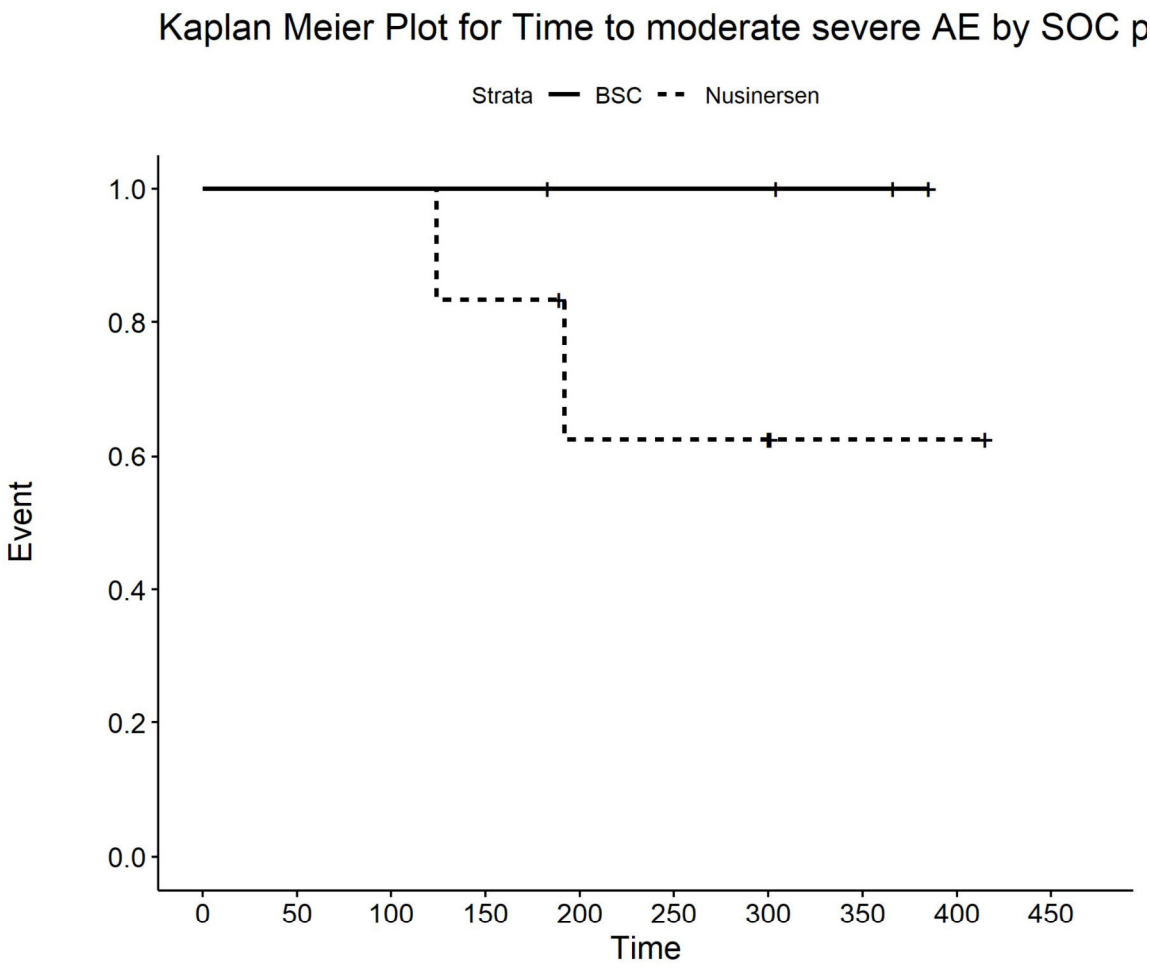
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



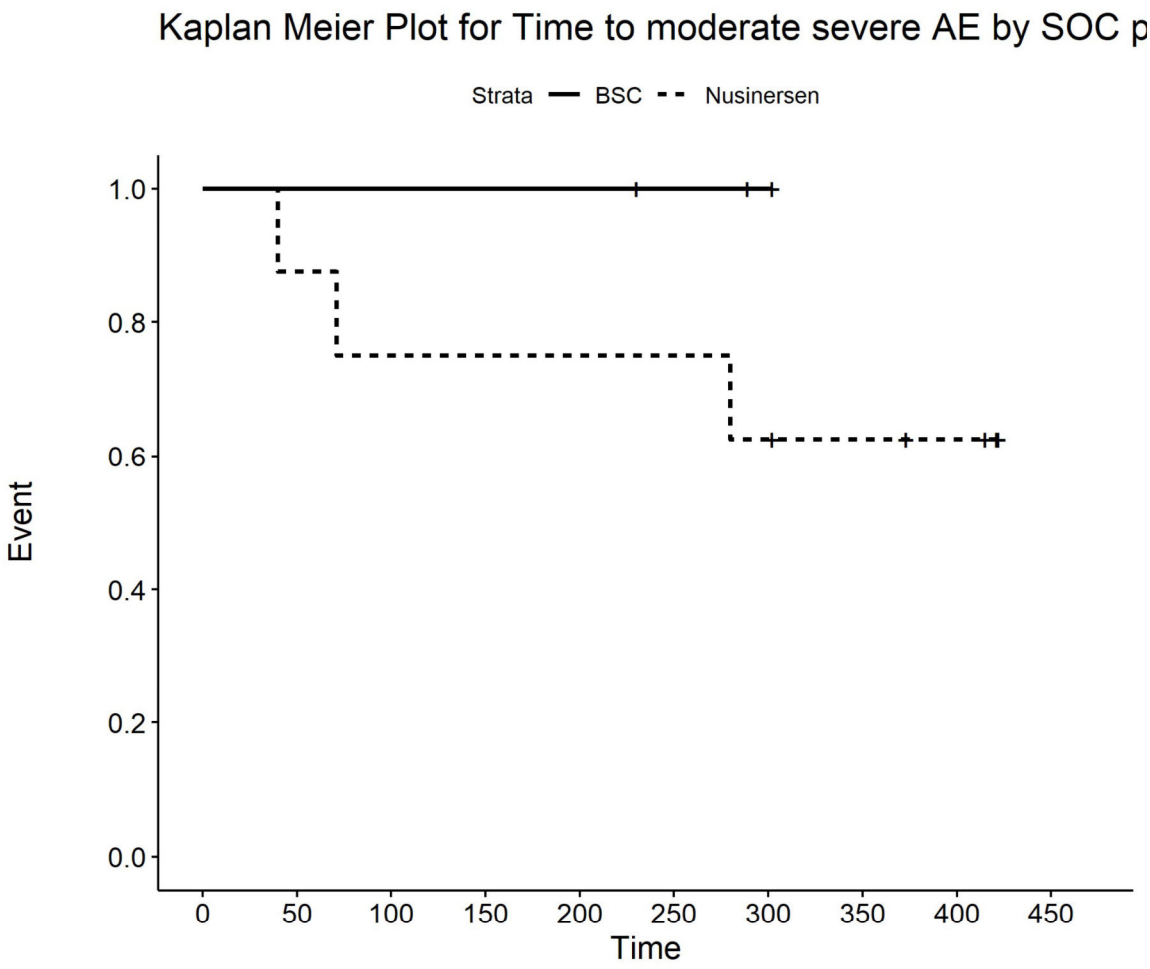
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



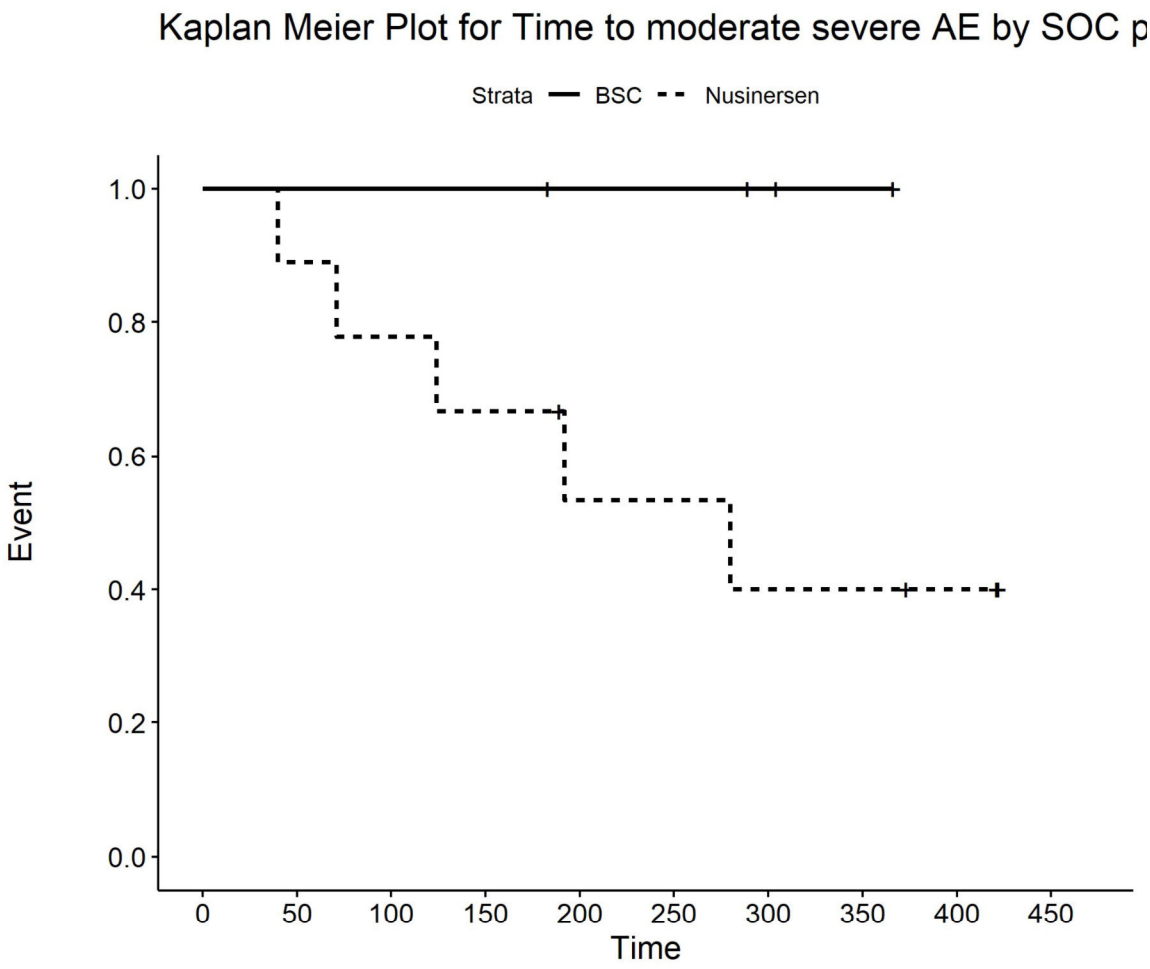
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	5	3	3	3	1	1	0



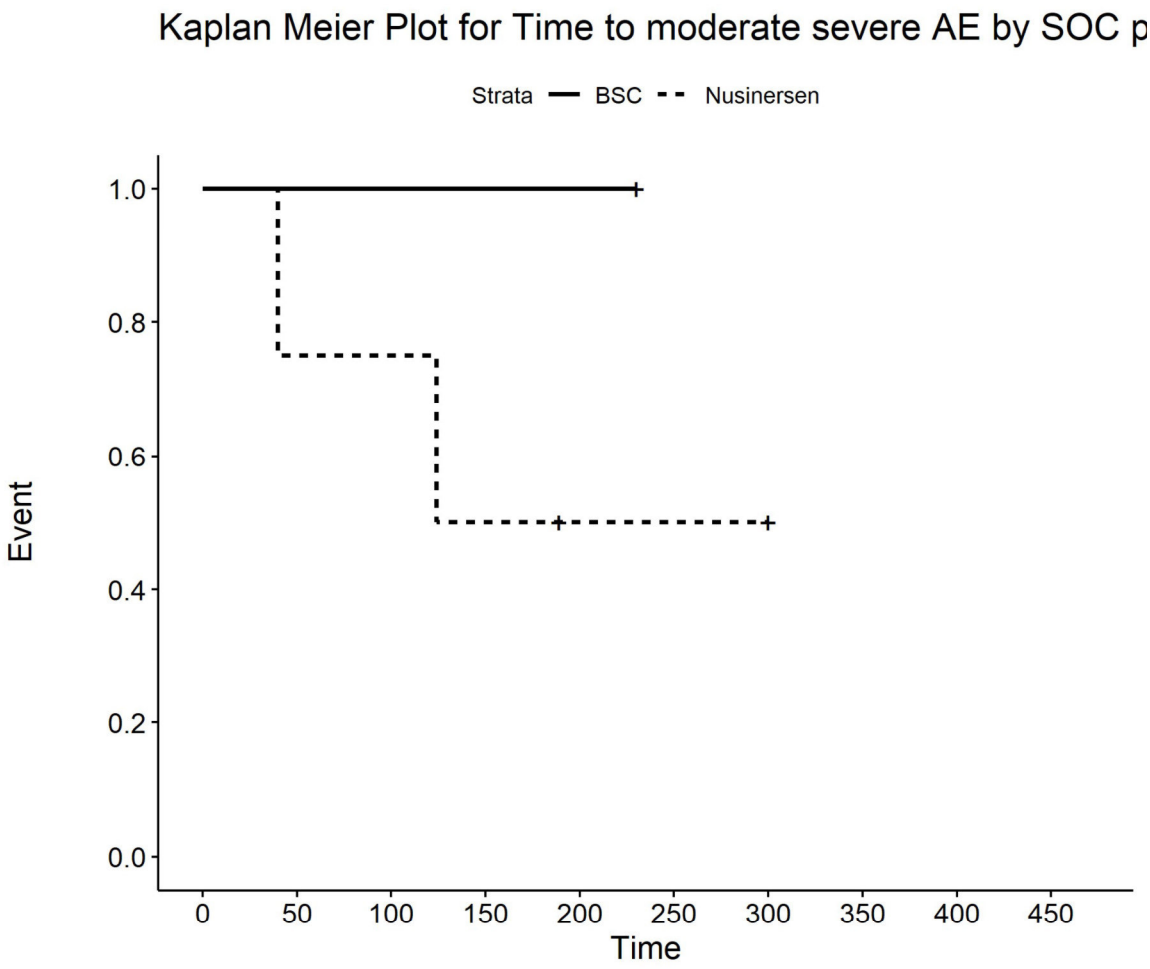
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	6	6	6	6	5	4	3	0



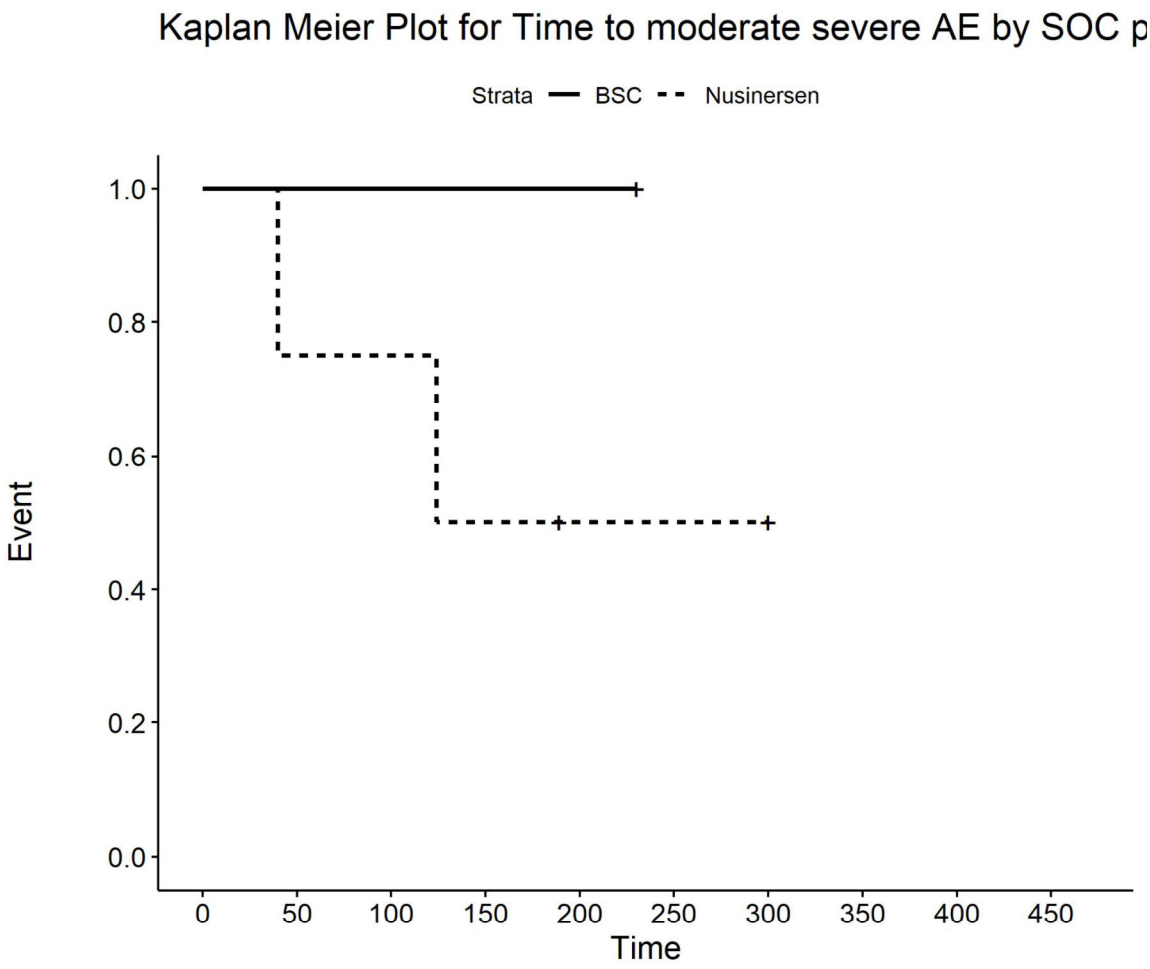
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	7	6	4	4	3	3	2	0



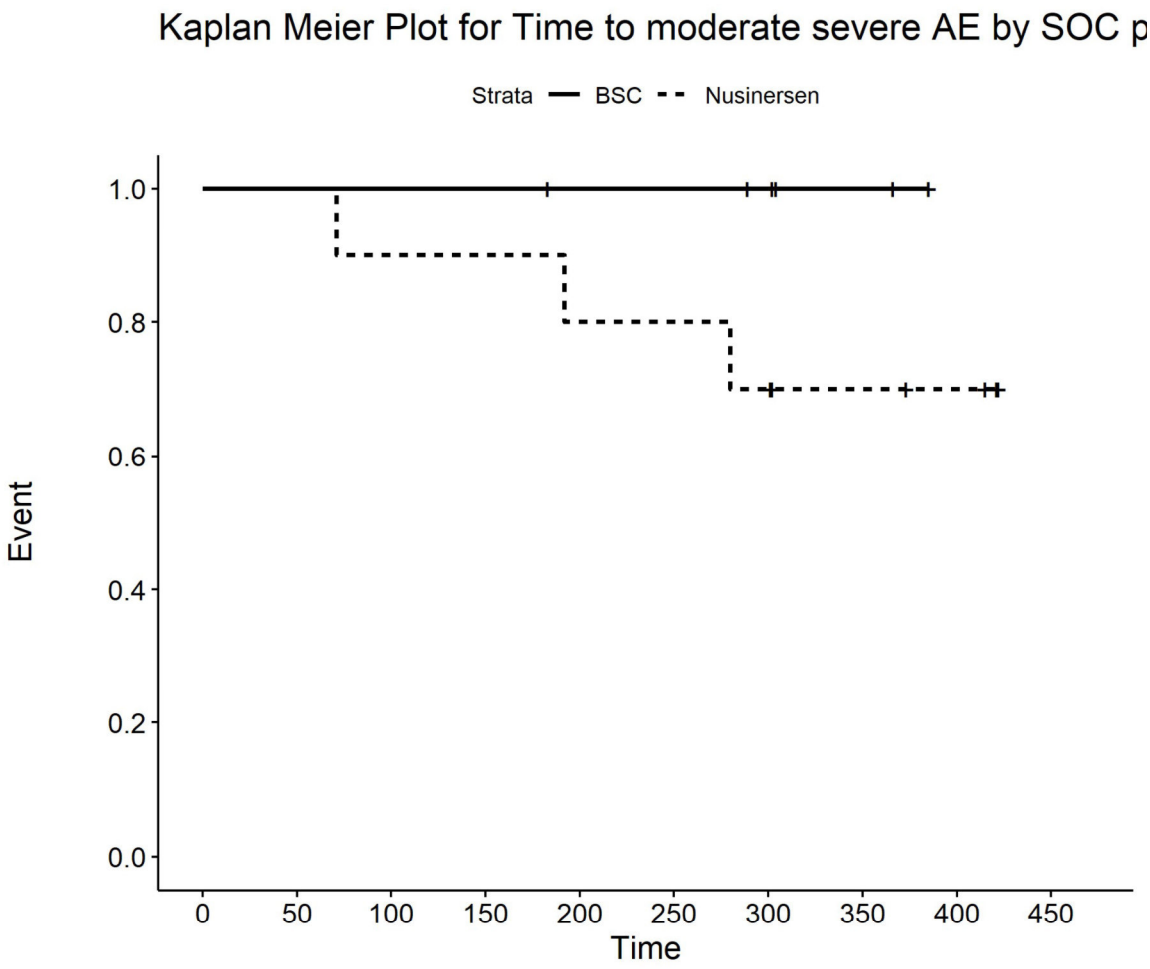
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



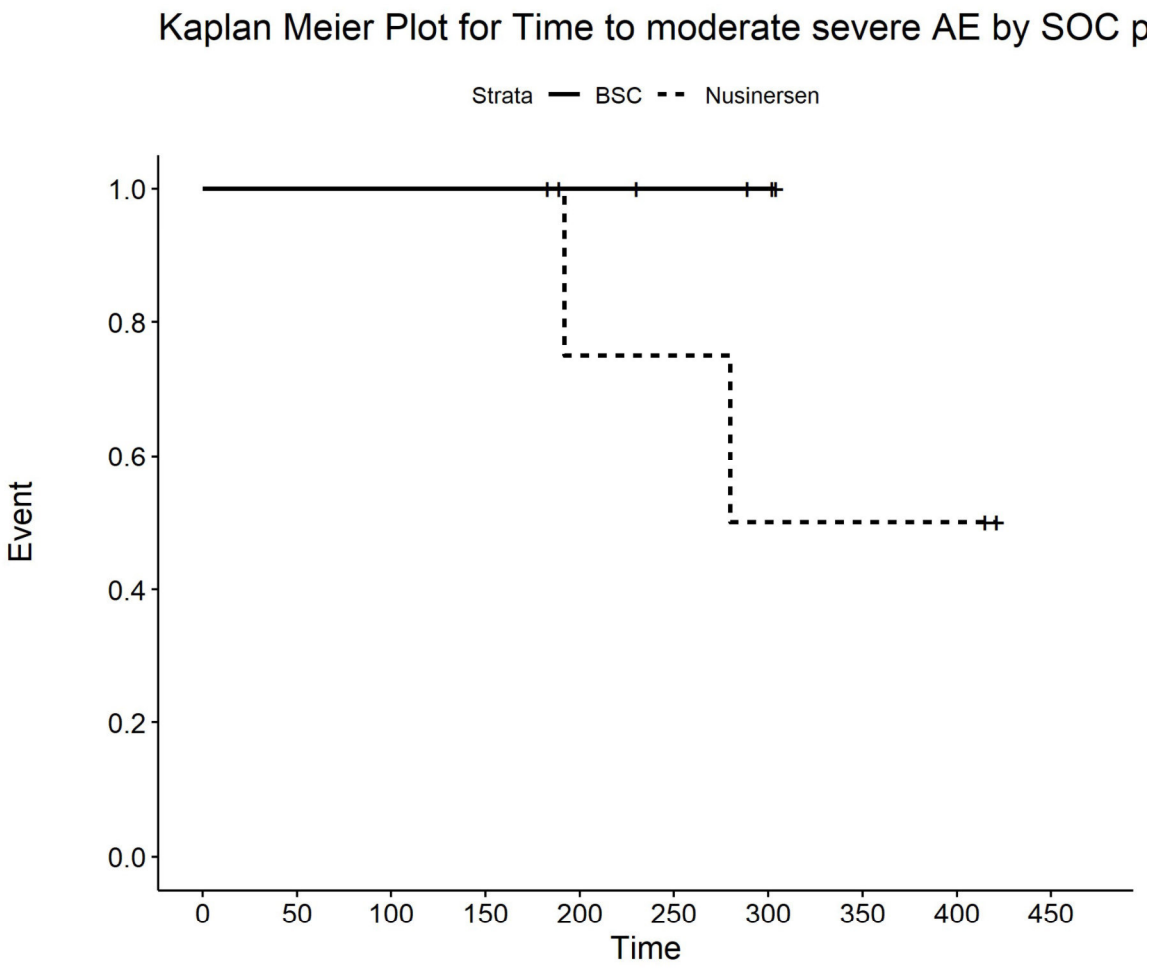
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



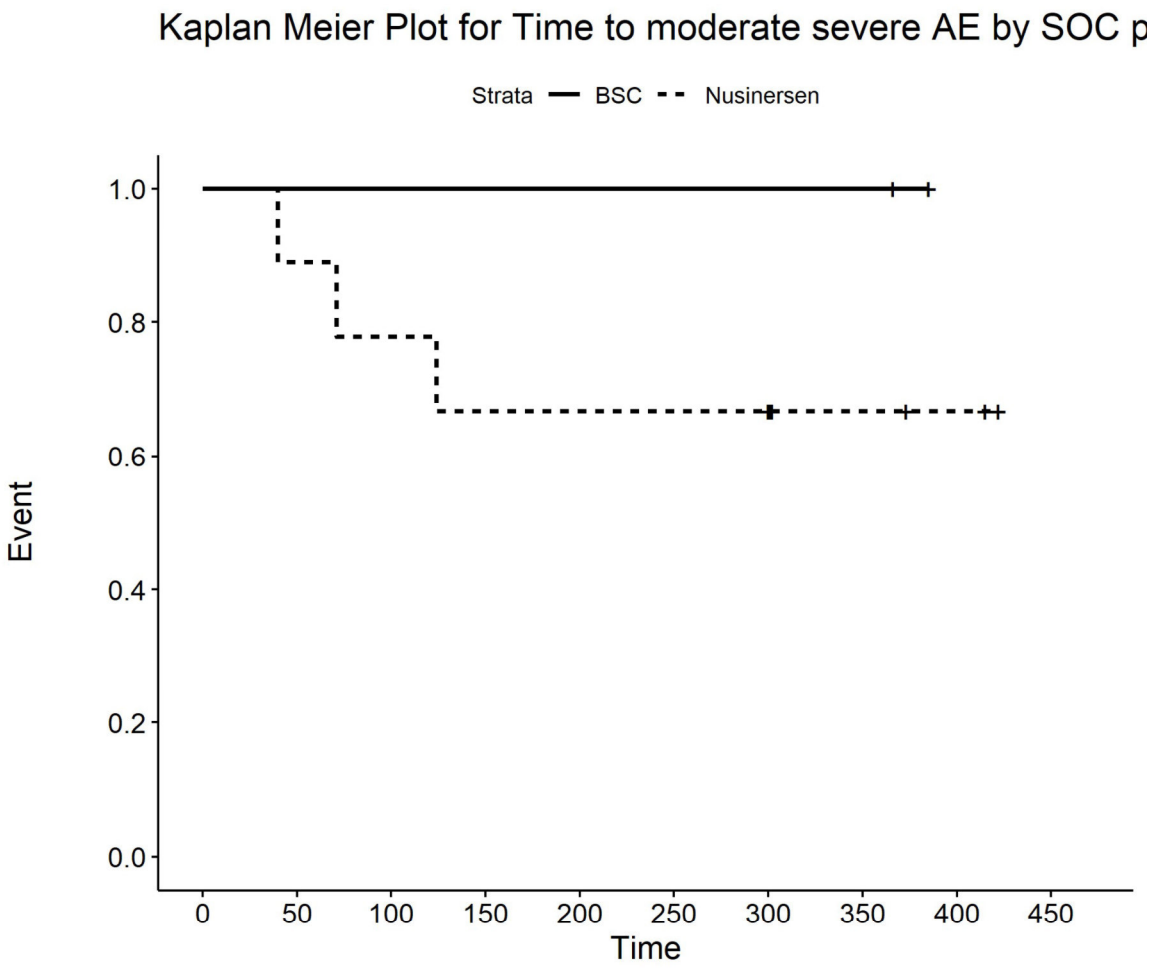
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	8	8	7	5	4	0



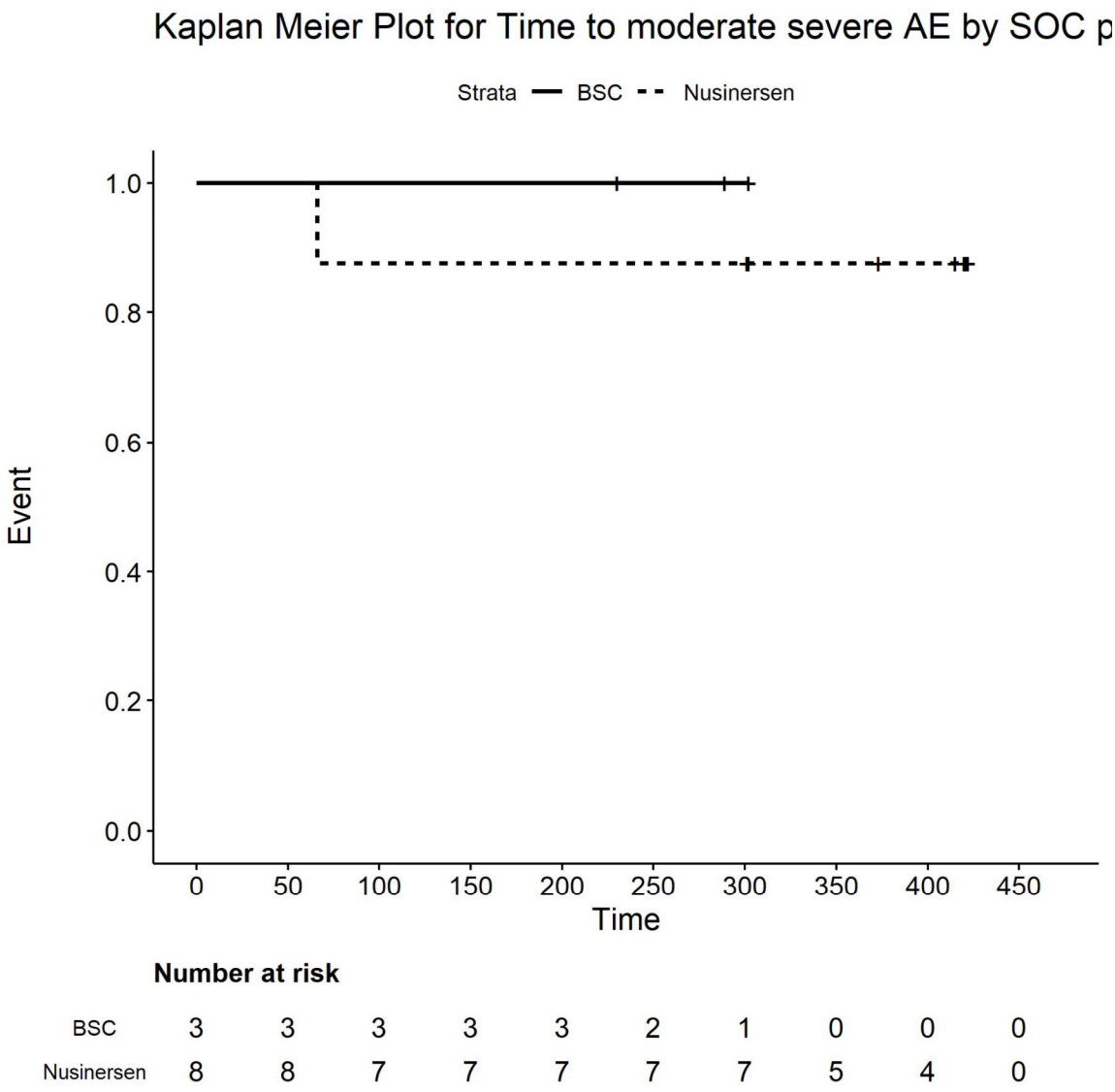
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	3	3	2	2	2	0



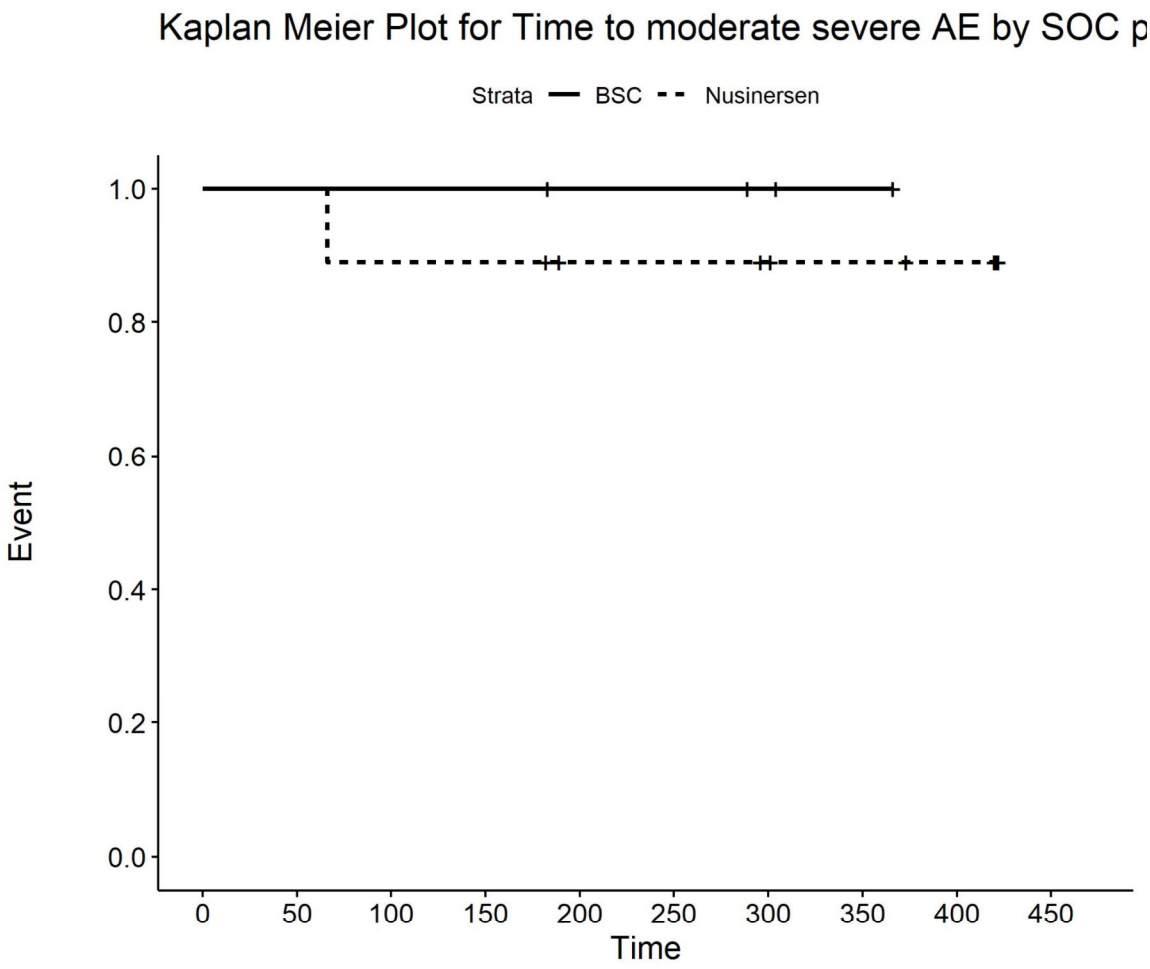
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	7	6	6	6	6	3	2	0



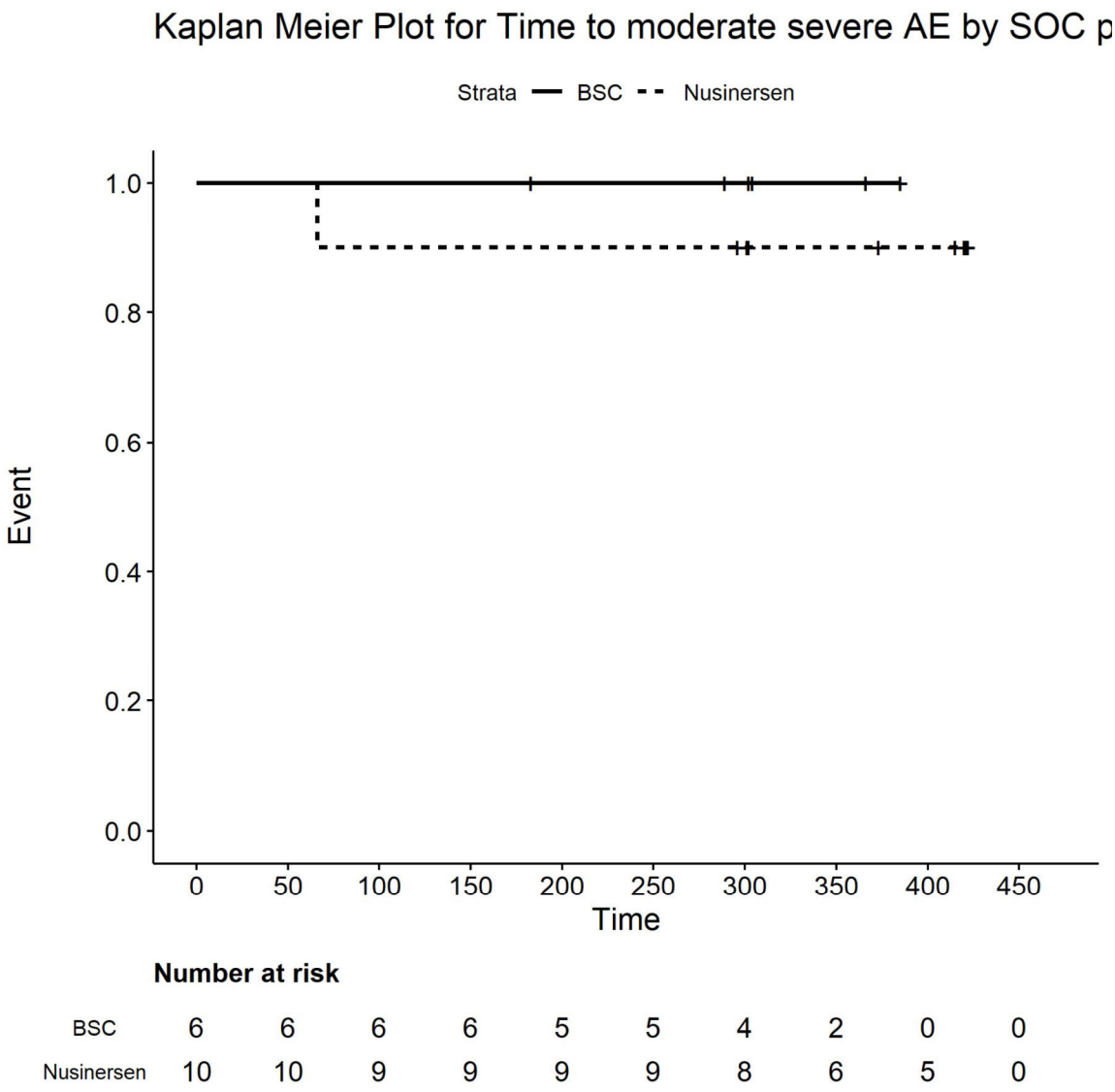
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	4	0



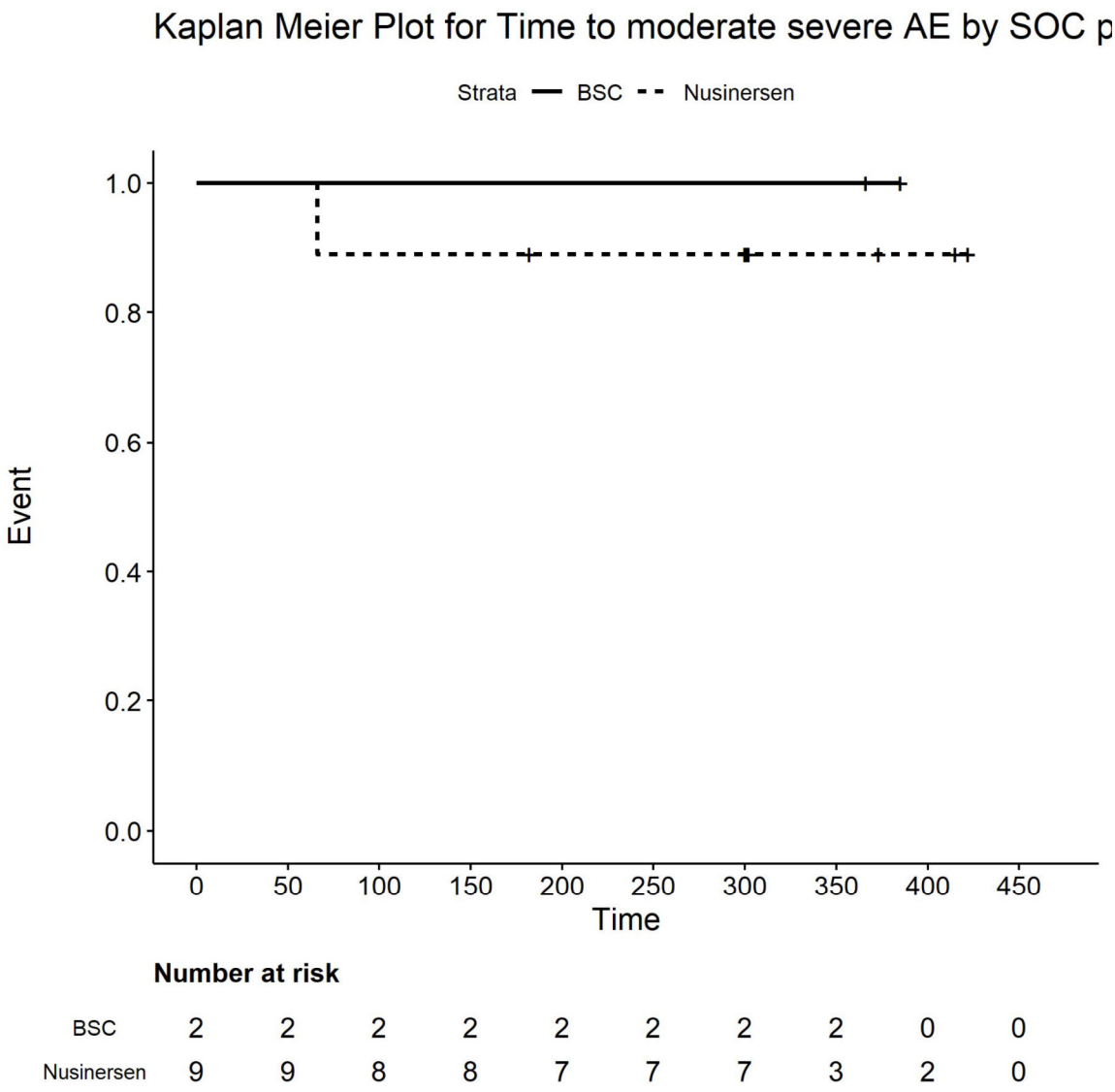
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



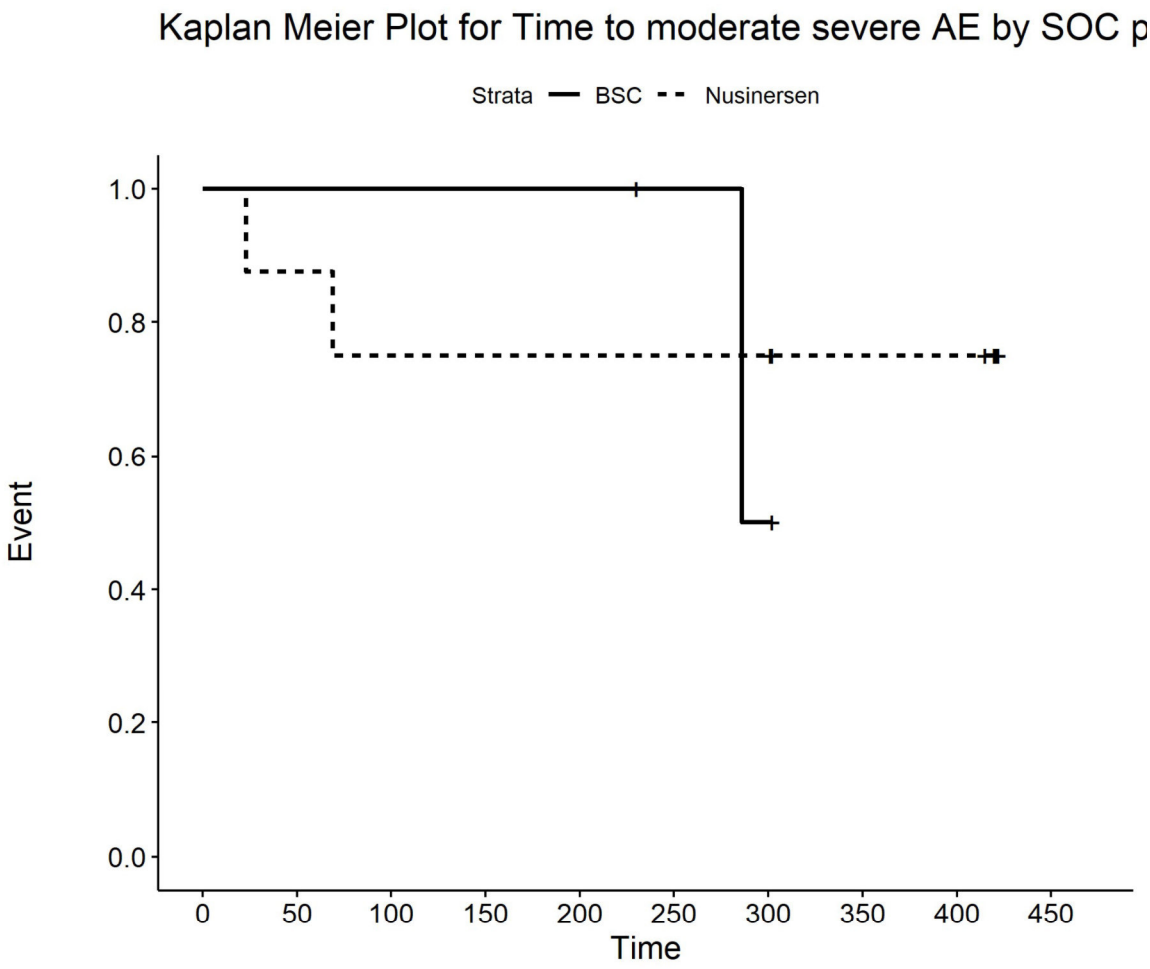
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



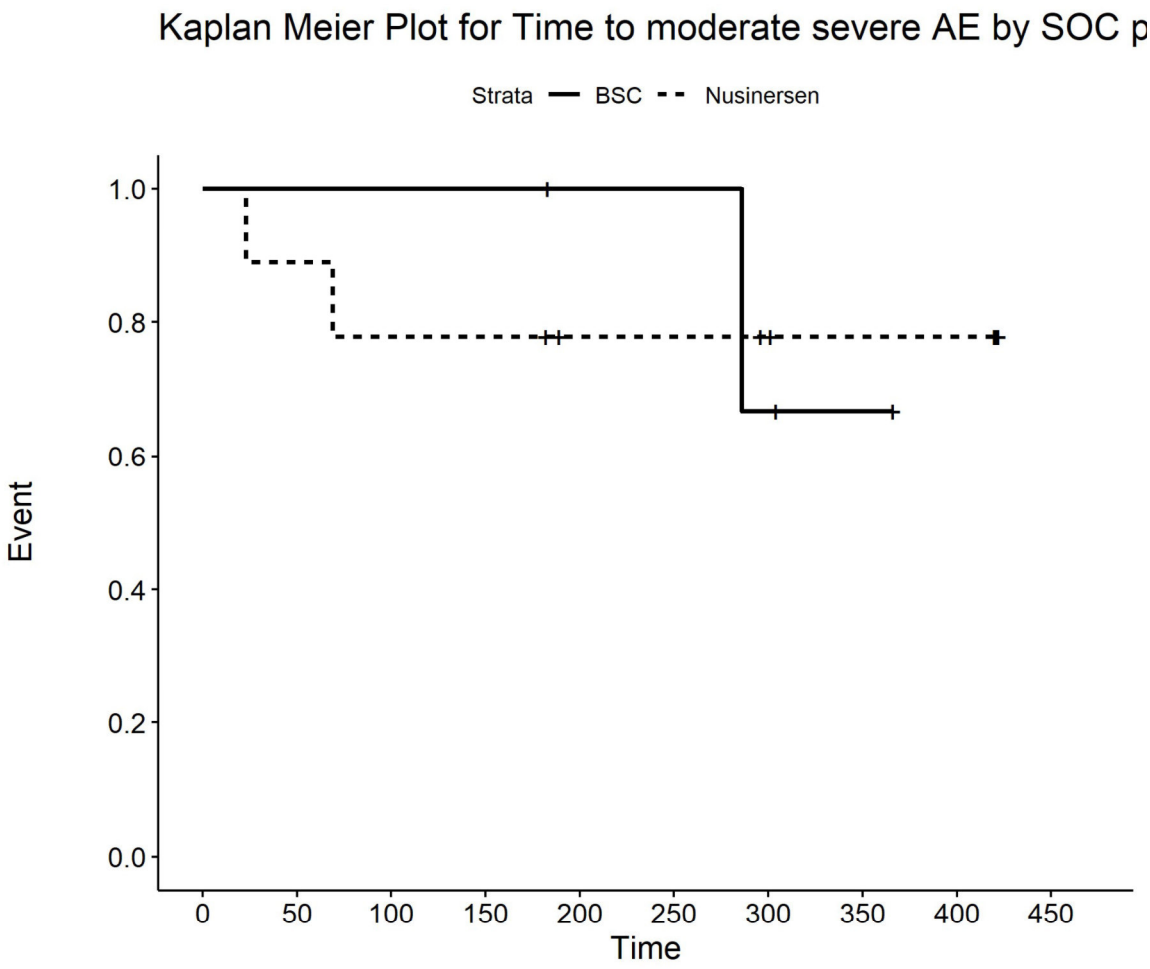
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	2	0



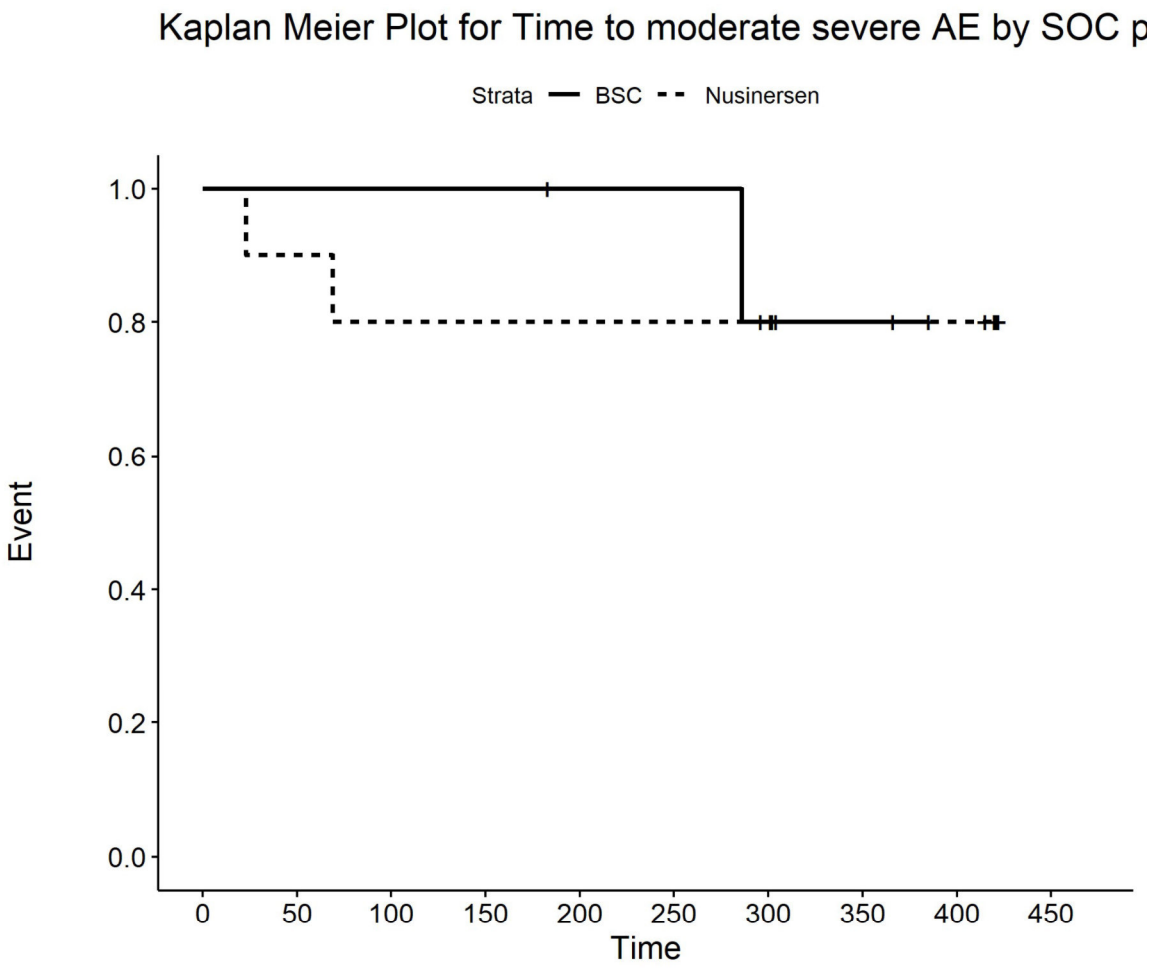
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	6	6	6	6	6	4	4	0



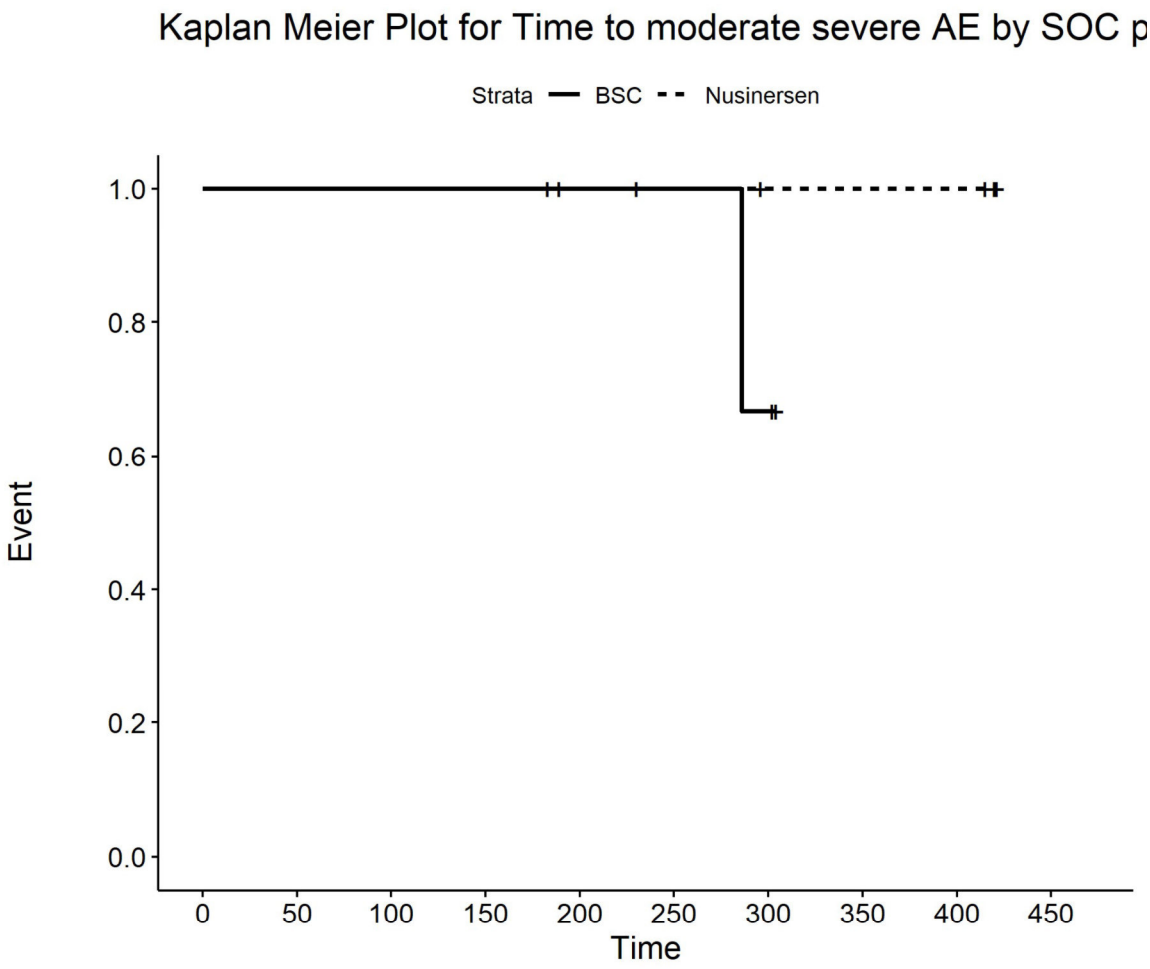
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	7	7	5	5	4	3	3	0



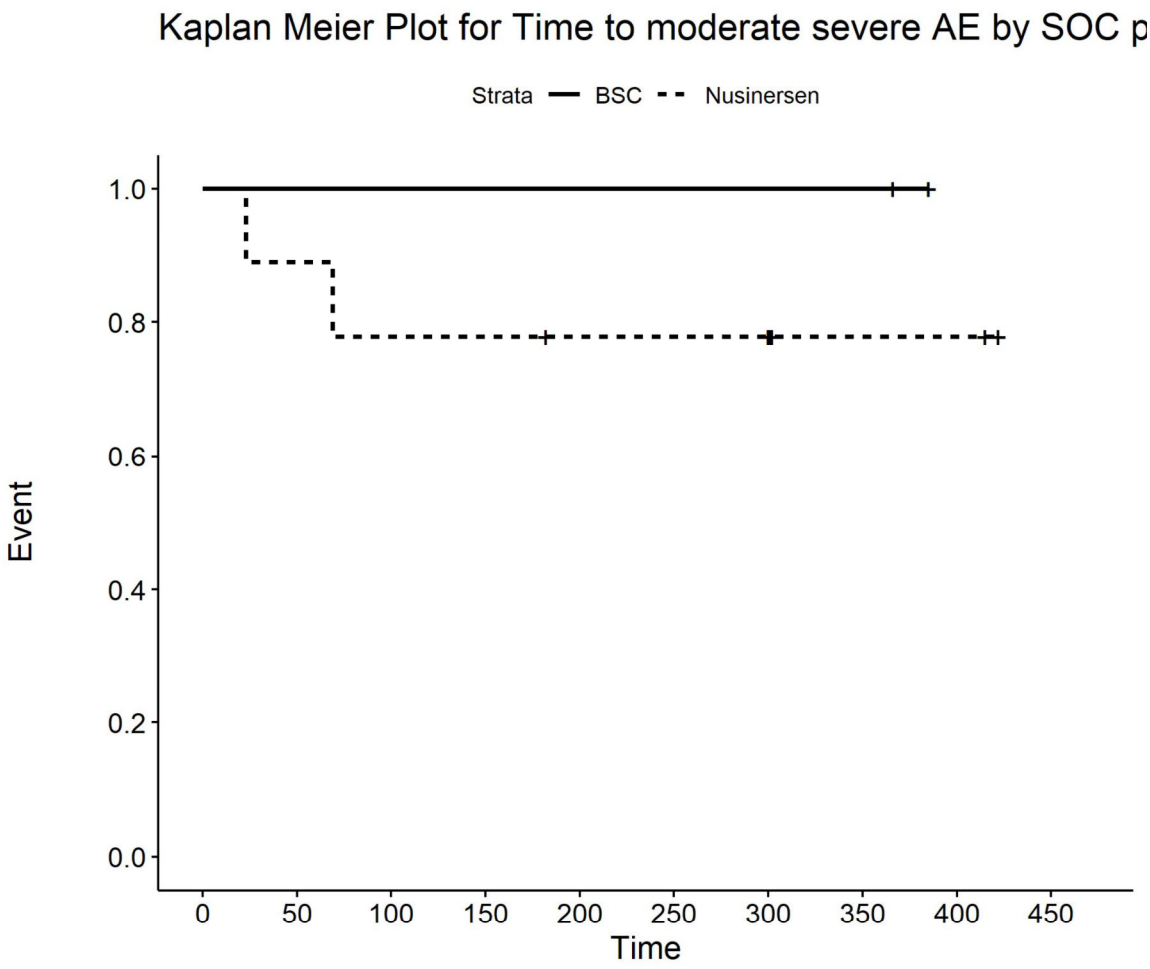
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	8	8	8	8	7	5	5	0



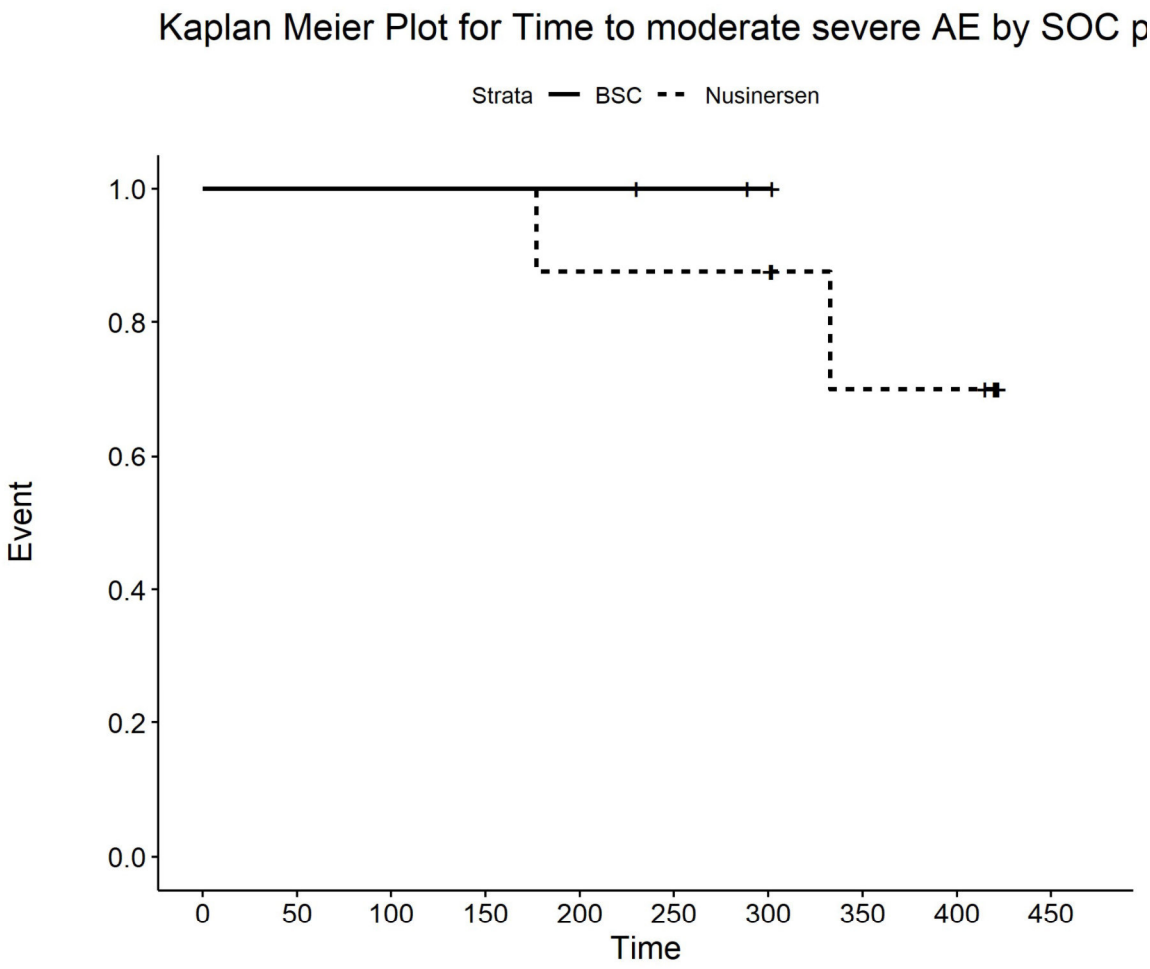
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



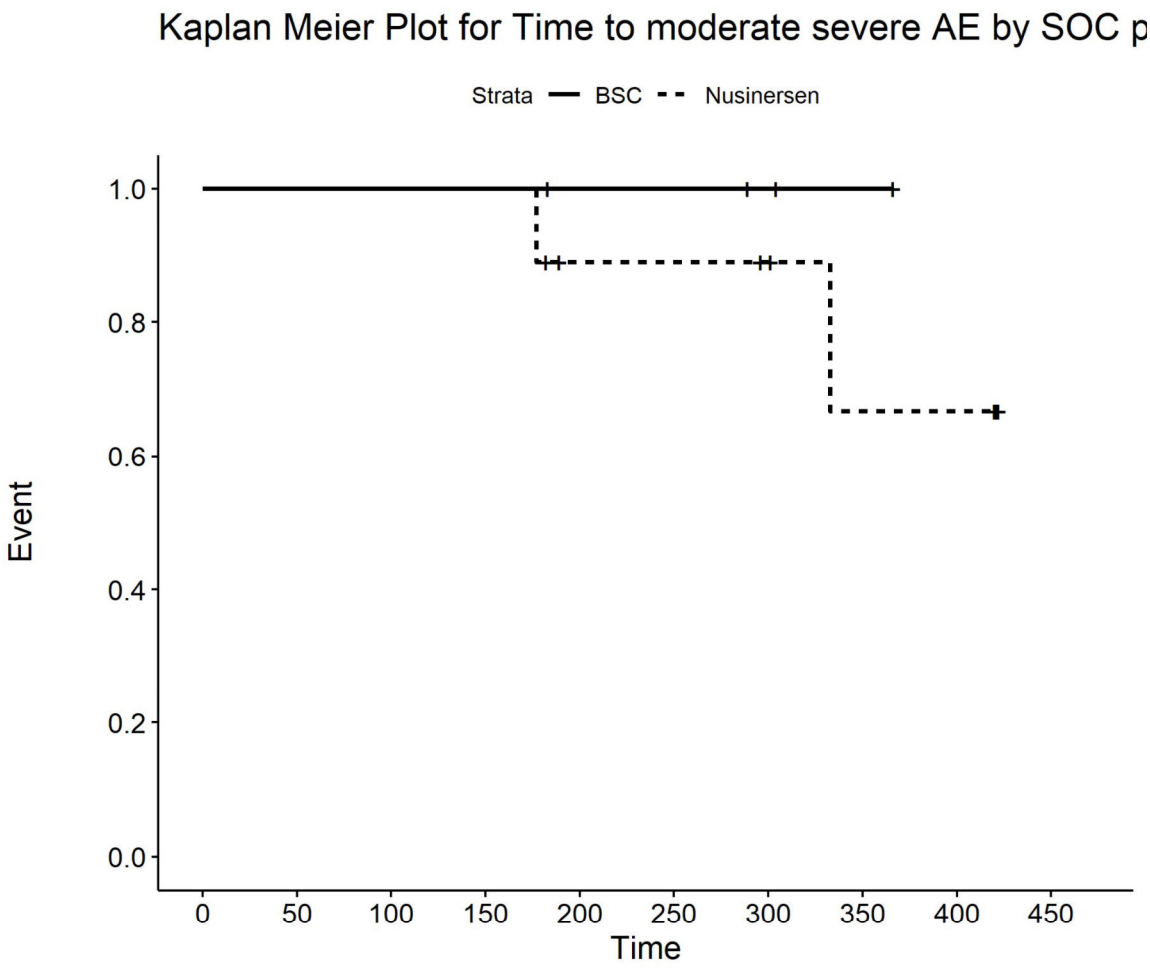
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	7	7	6	6	6	2	2	0



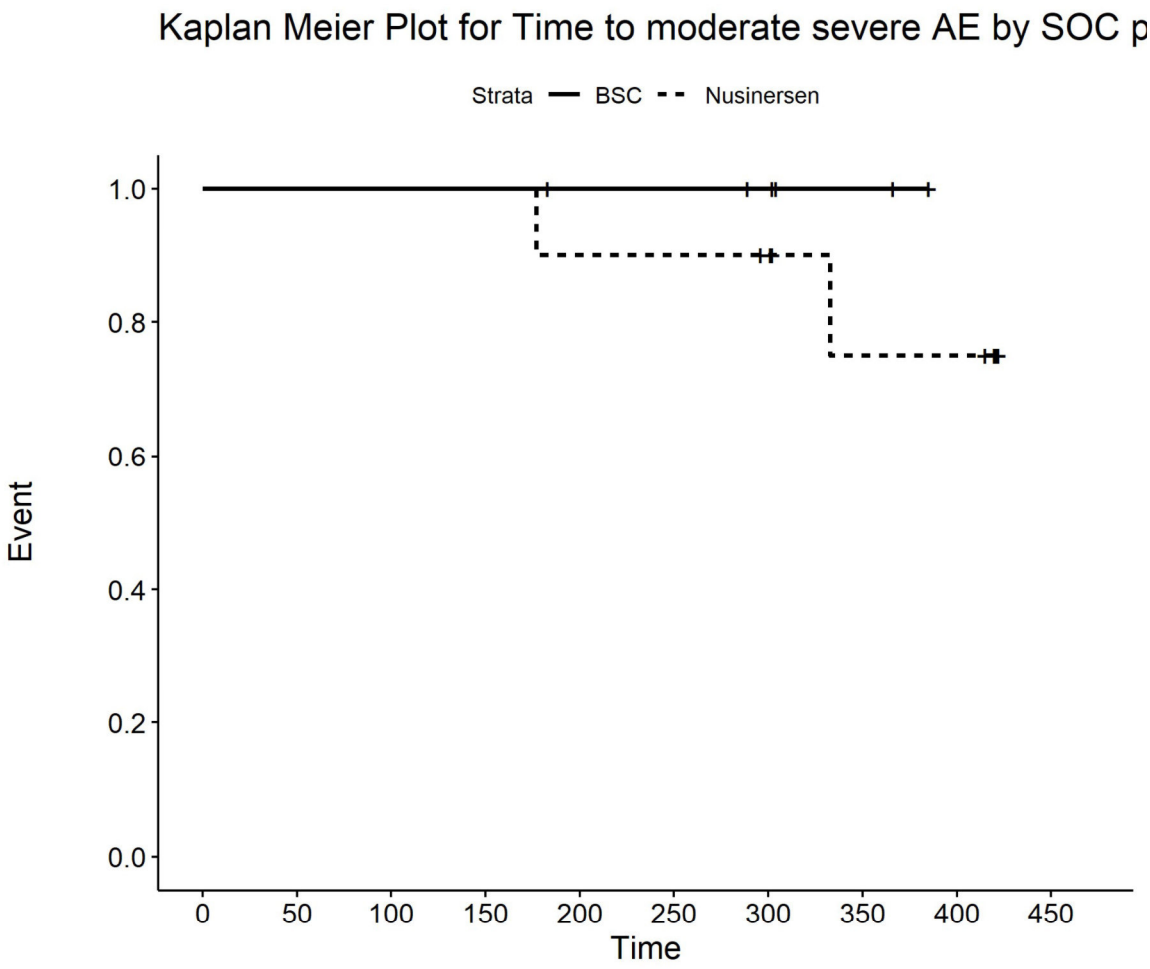
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	7	7	7	4	4	0



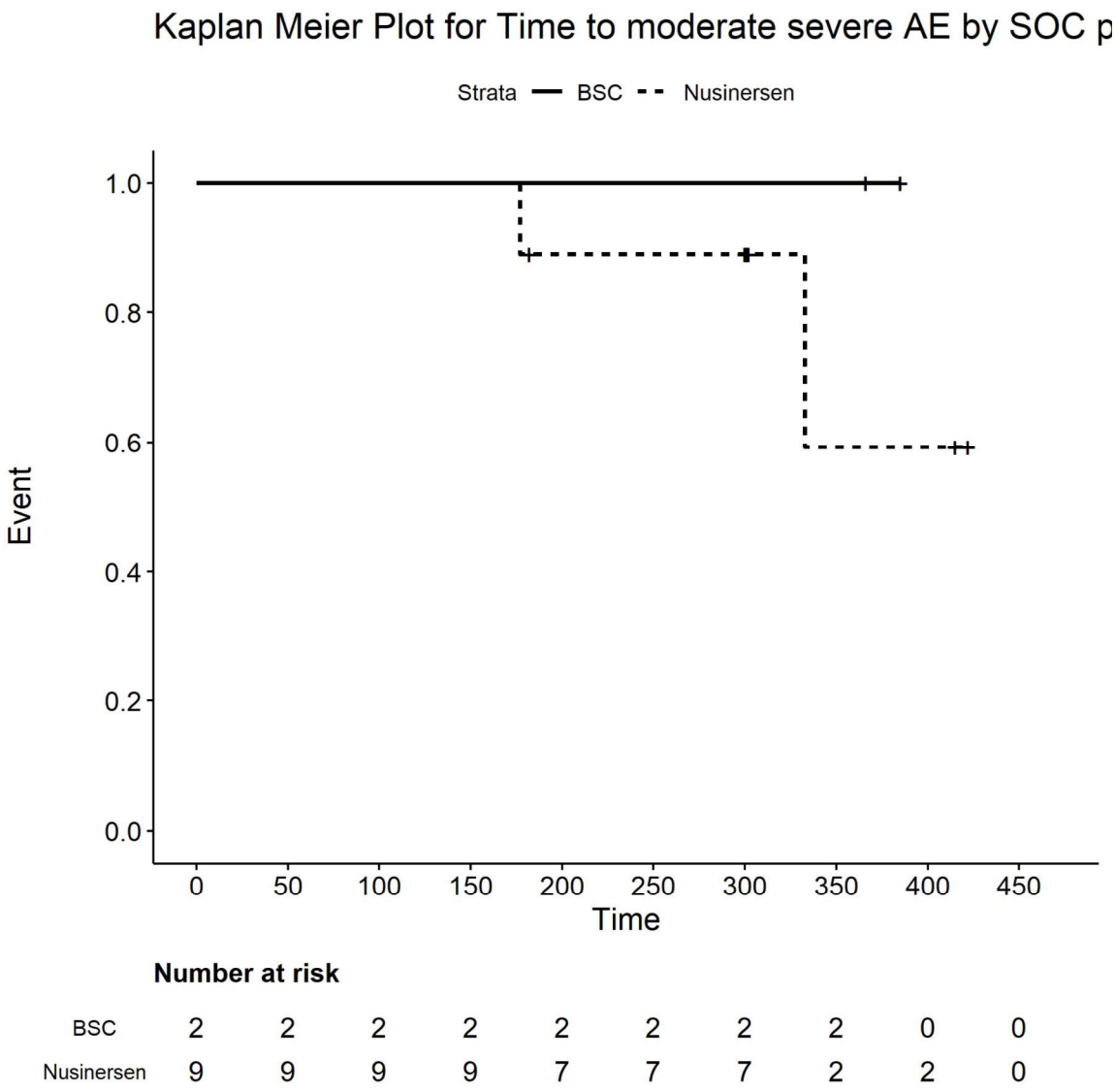
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	6	6	5	3	3	0



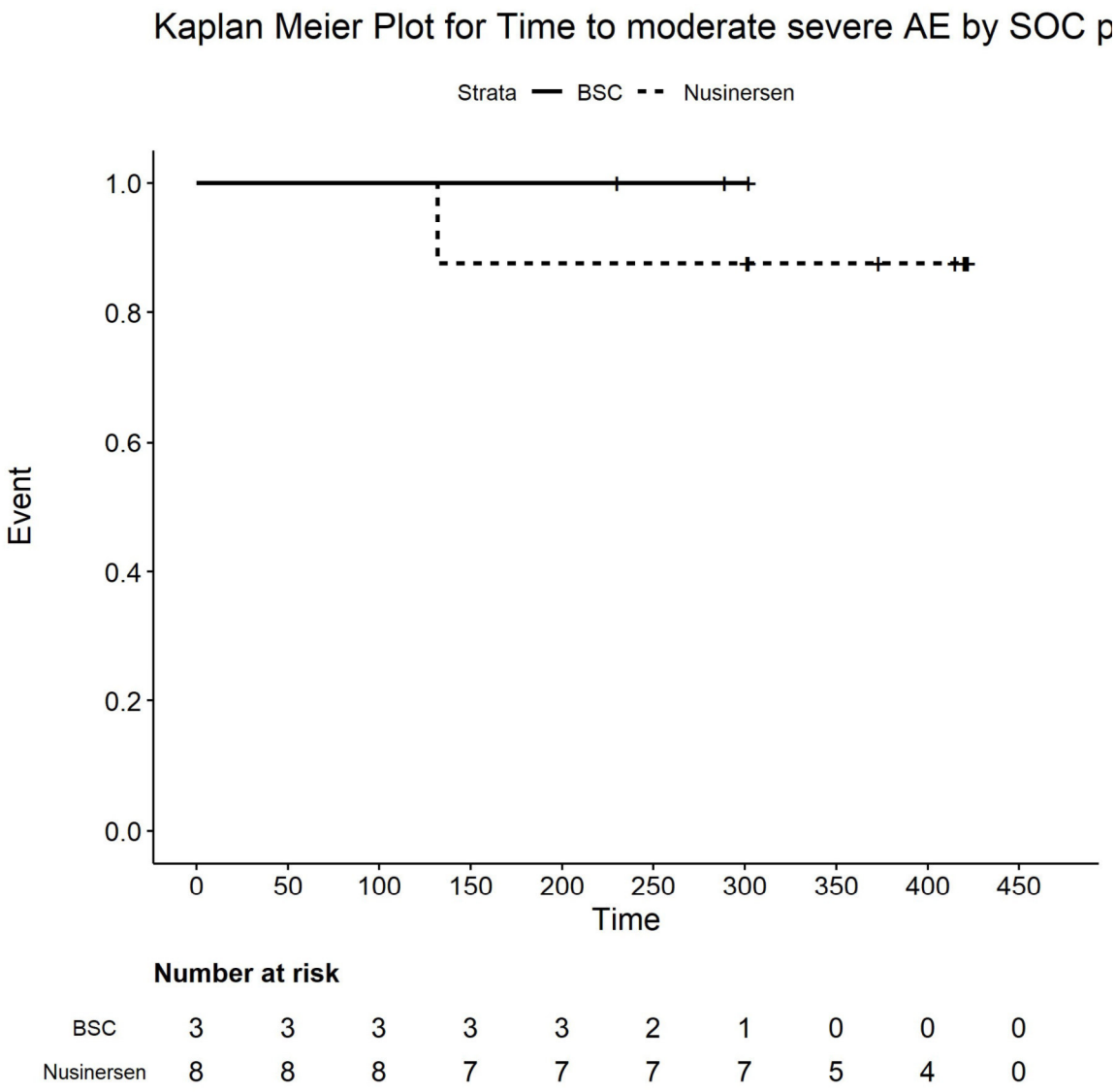
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	9	9	8	5	5	0



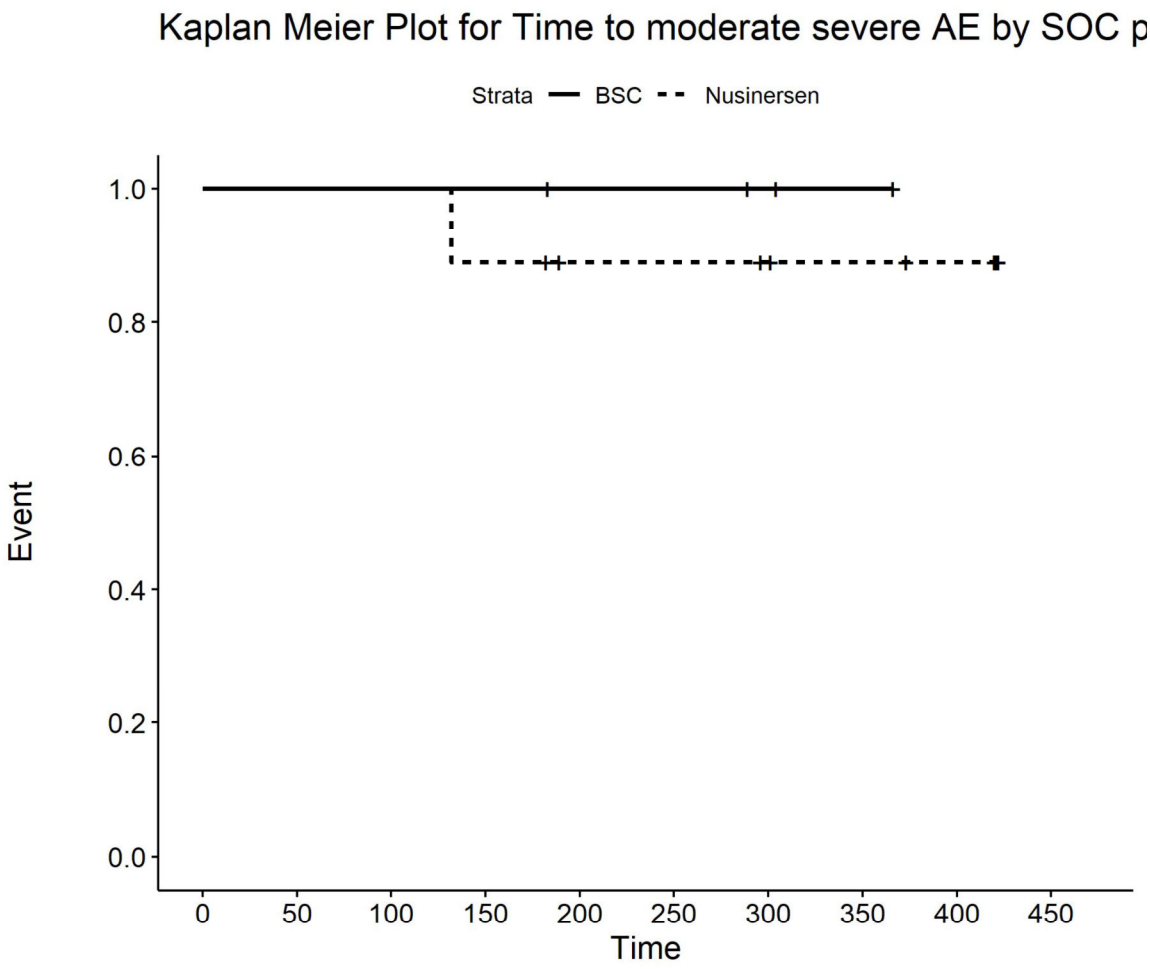
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	7	7	7	2	2	0



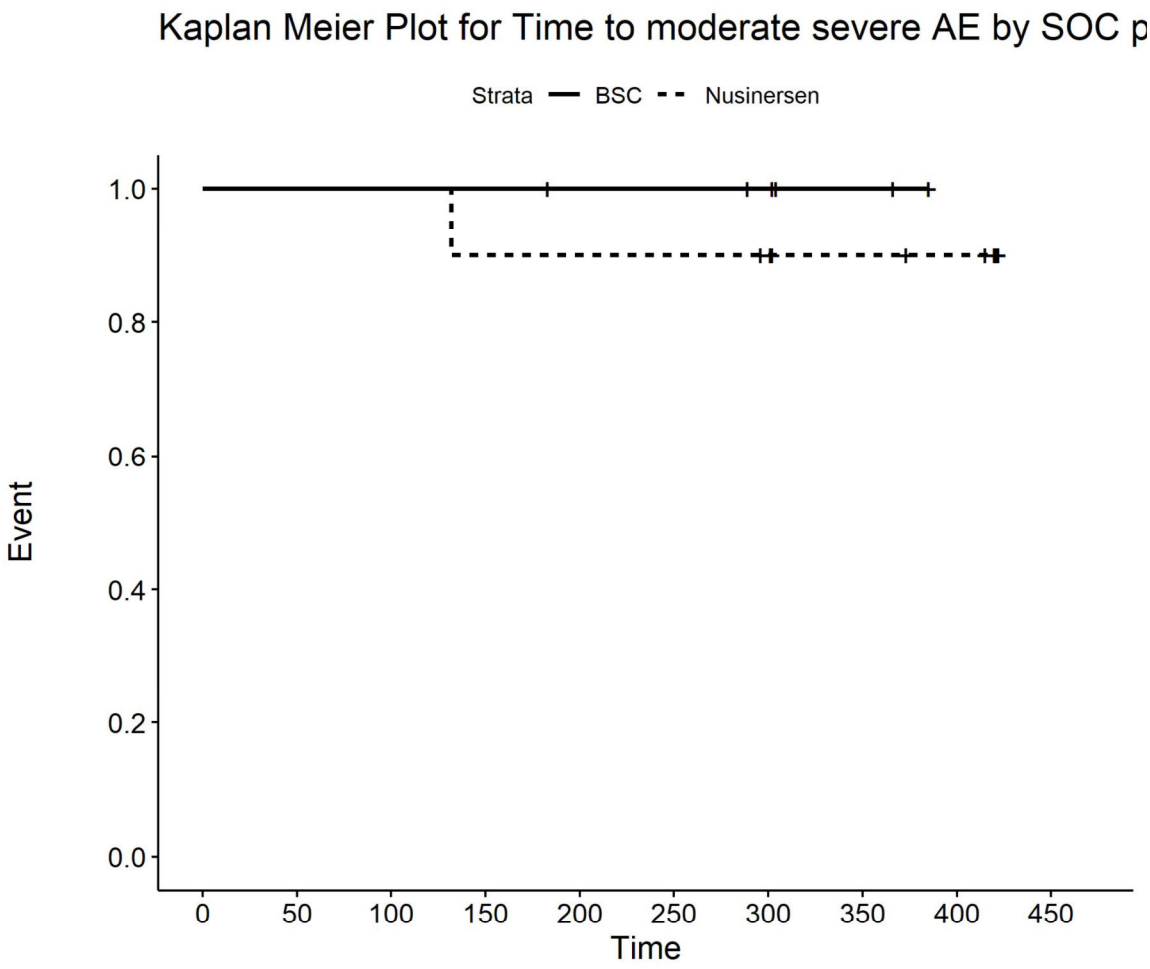
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



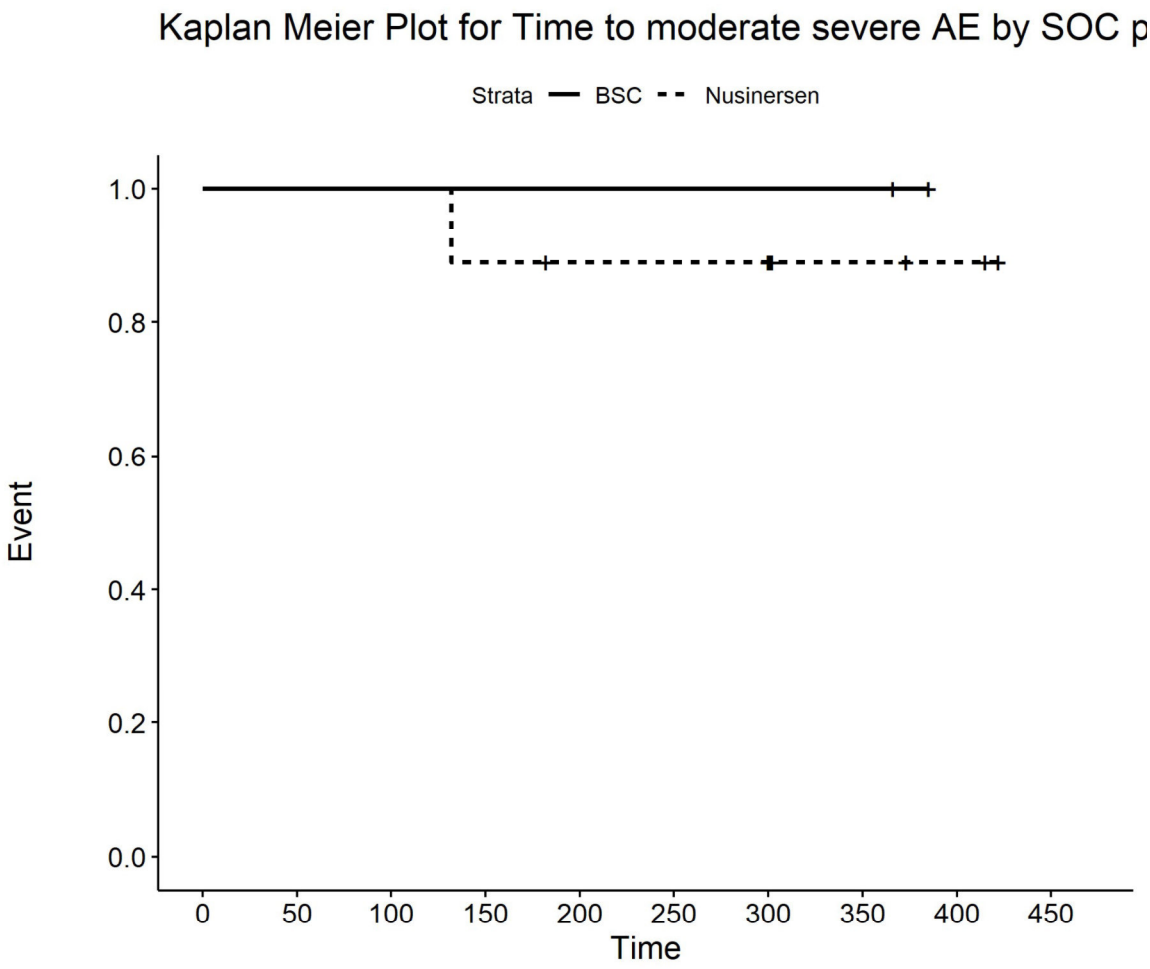
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



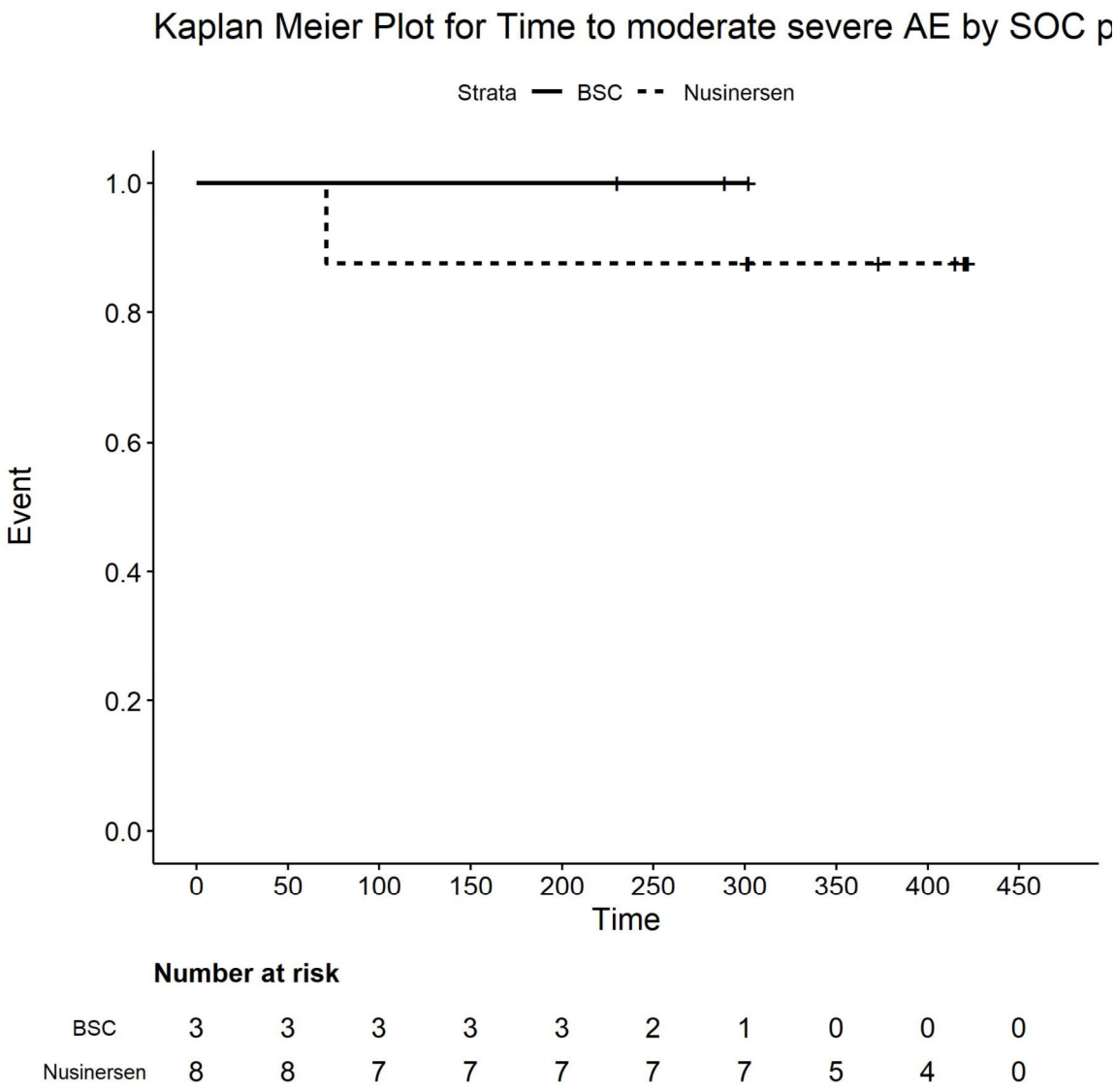
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



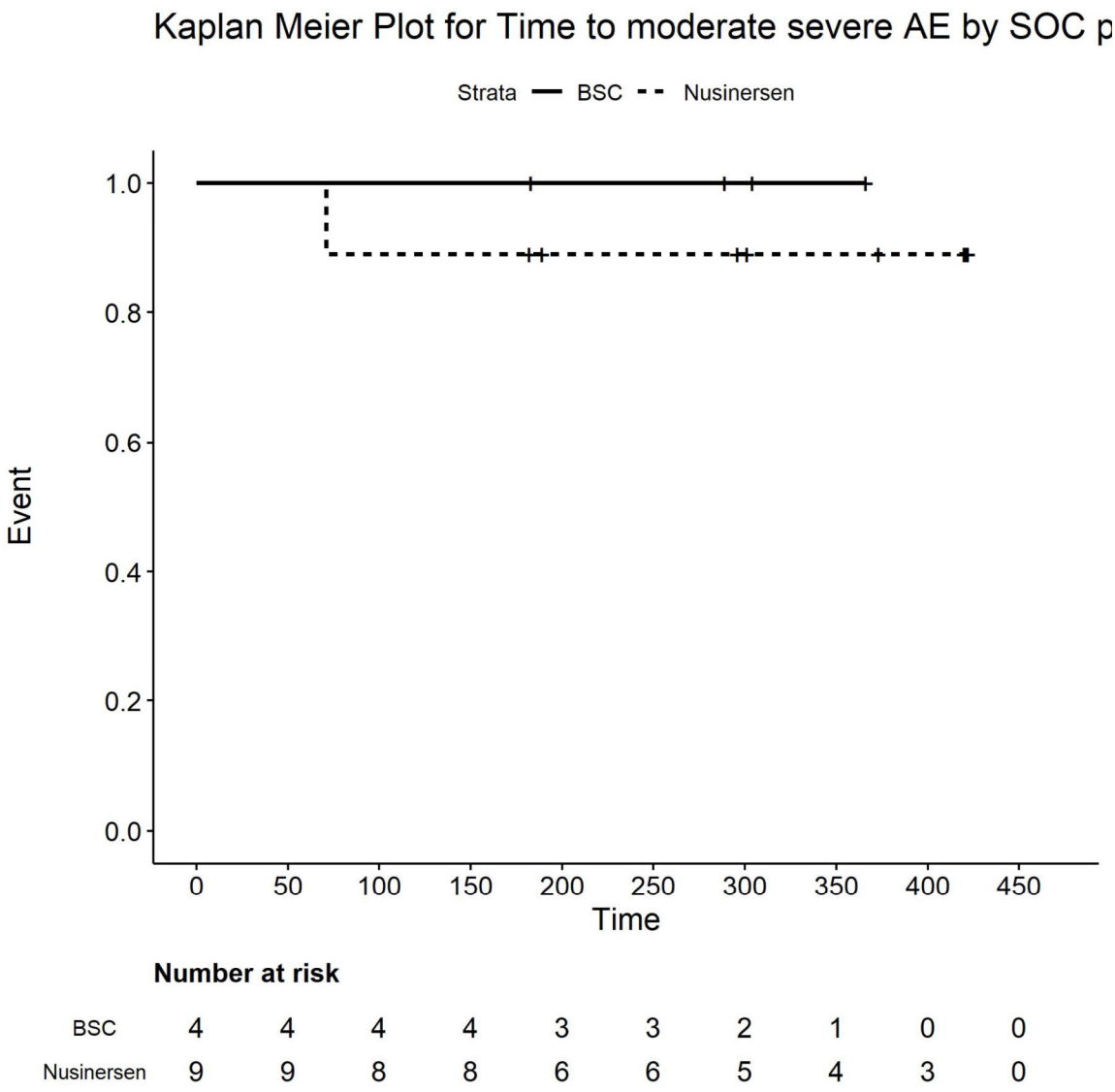
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



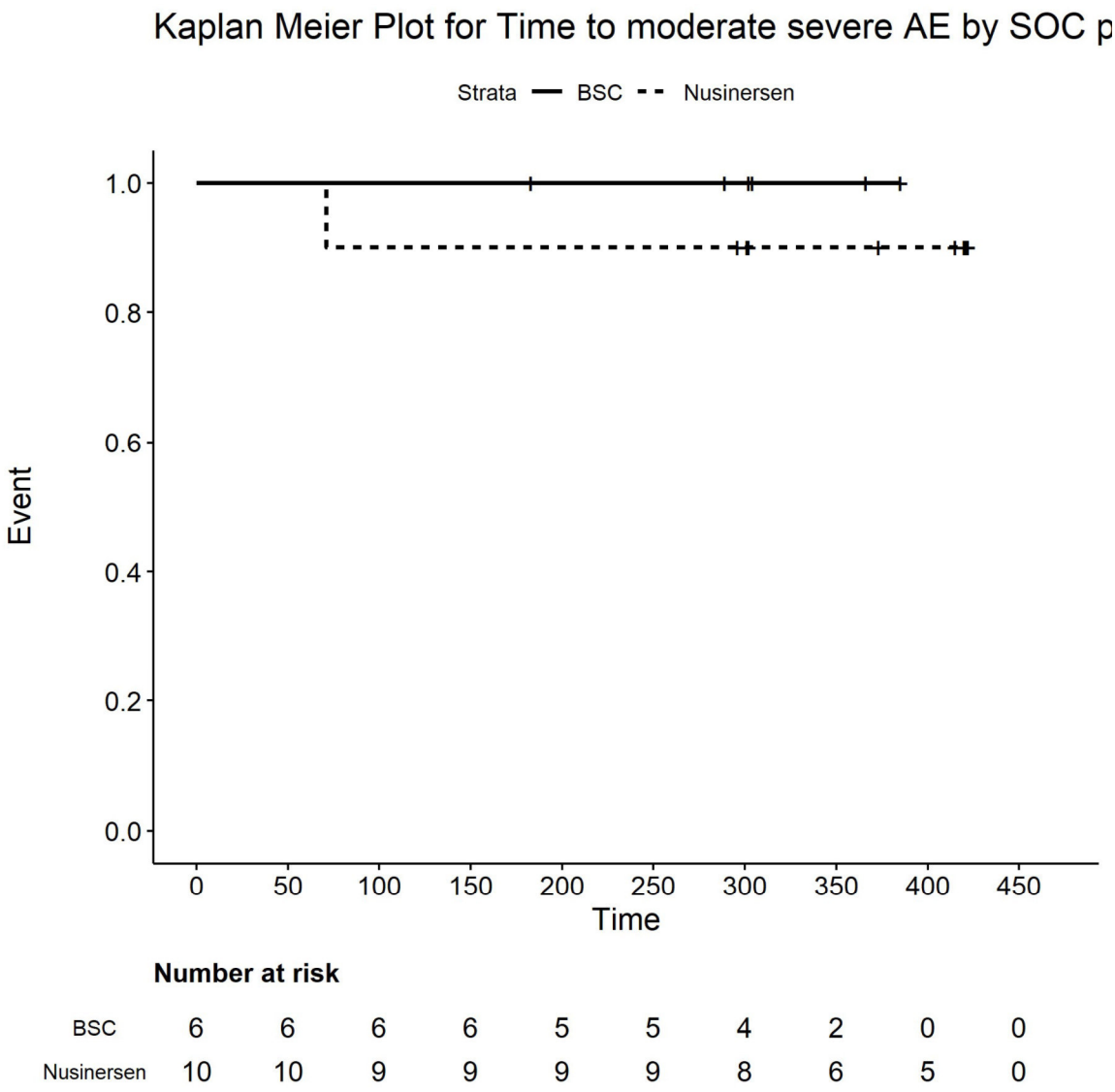
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	4	0



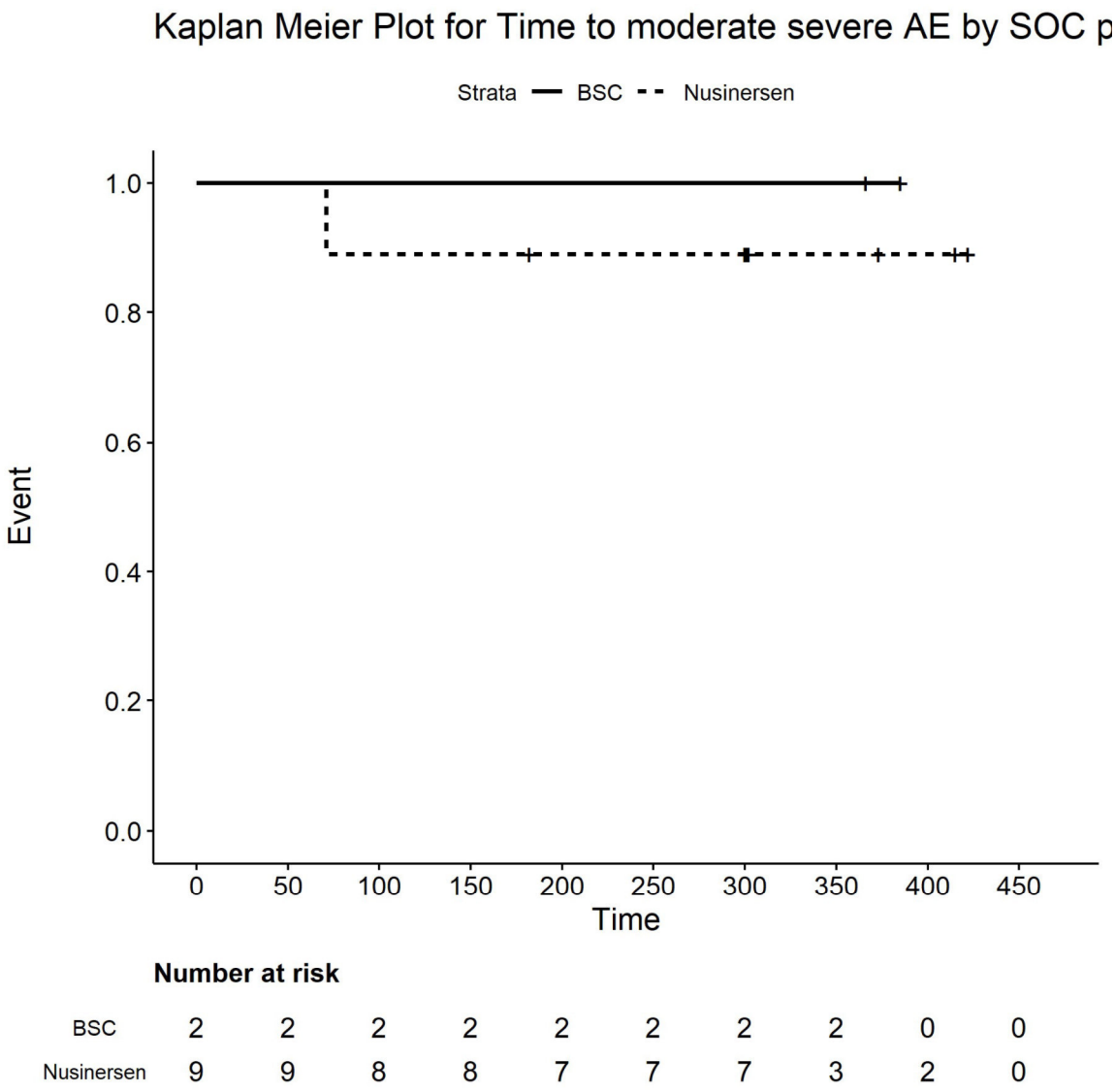
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



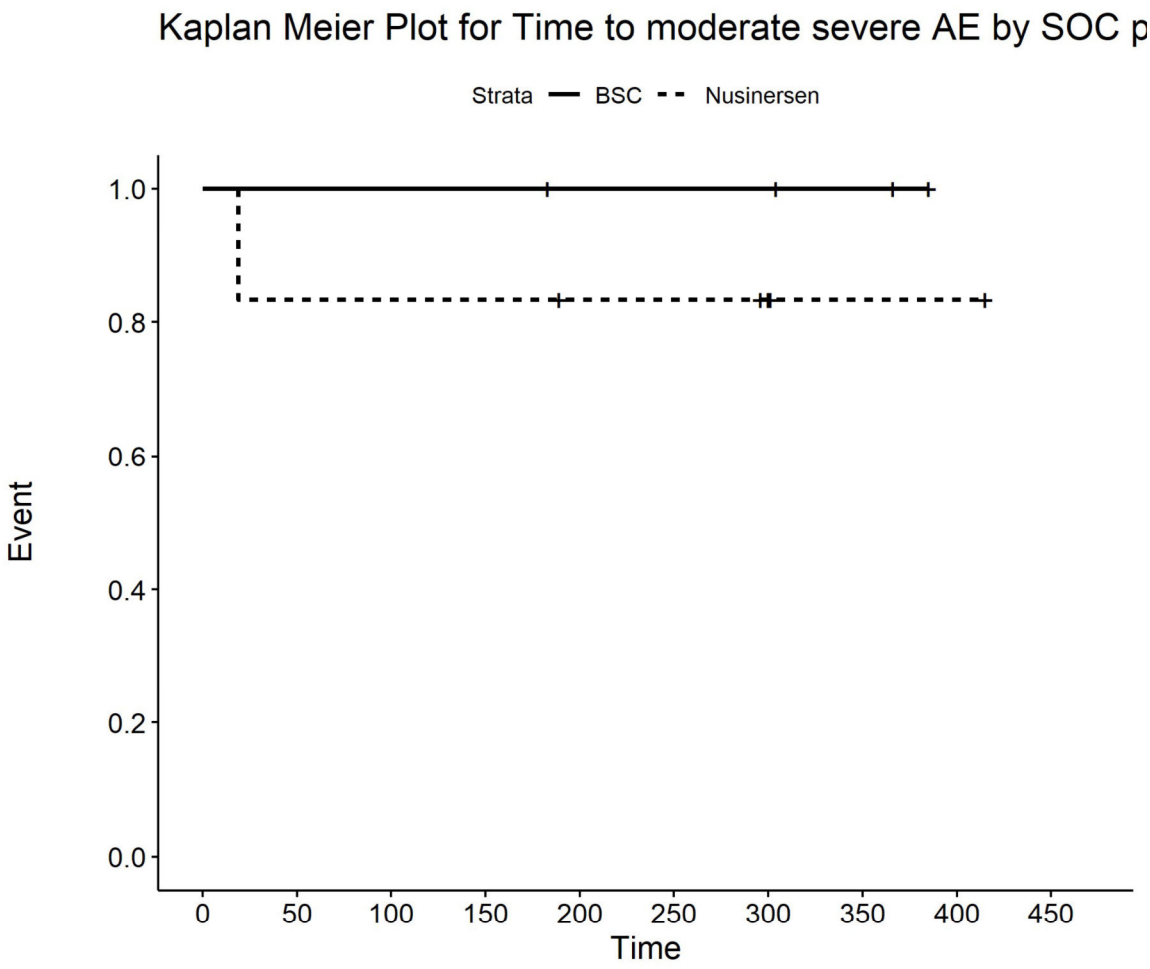
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



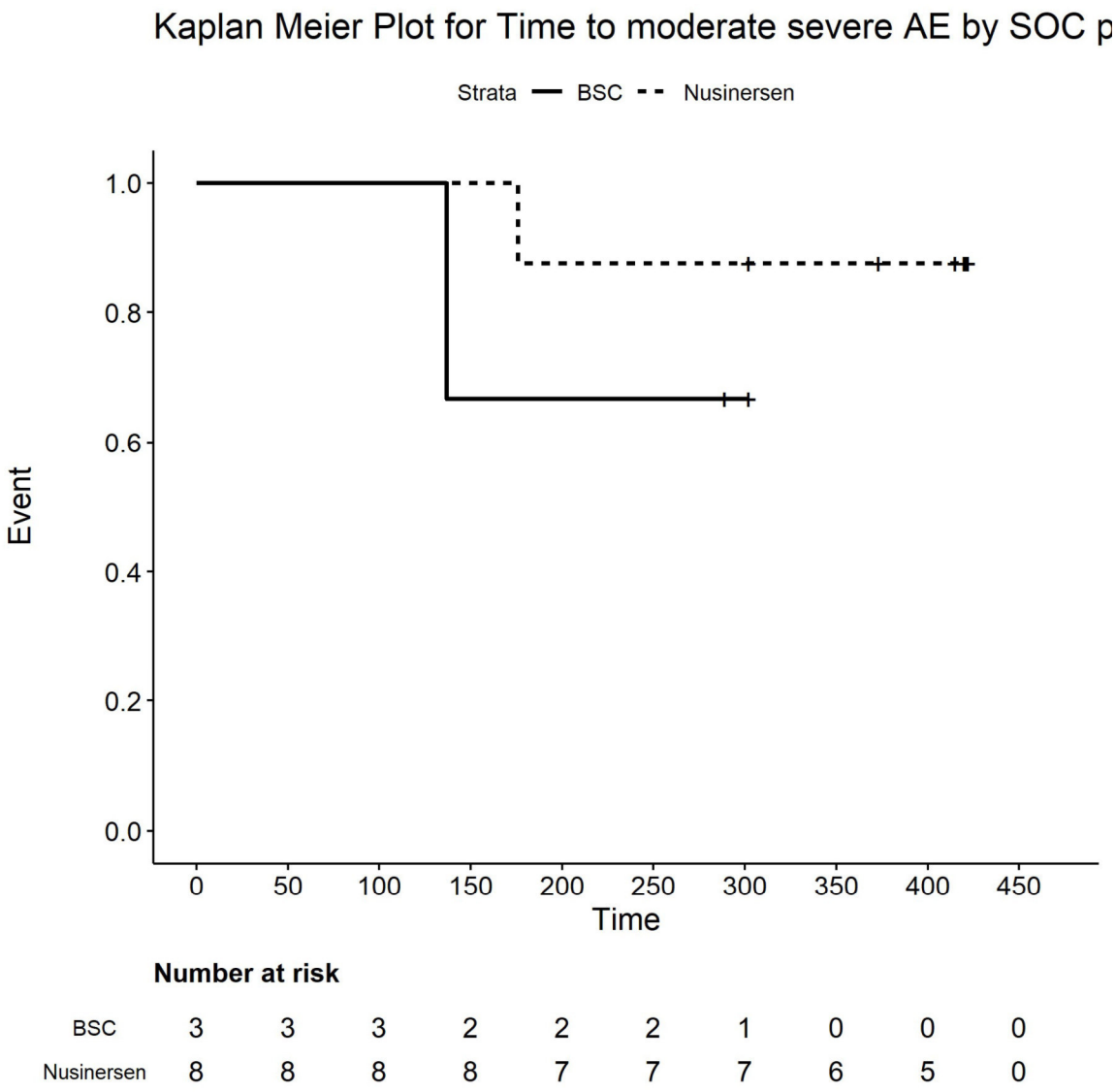
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	2	0



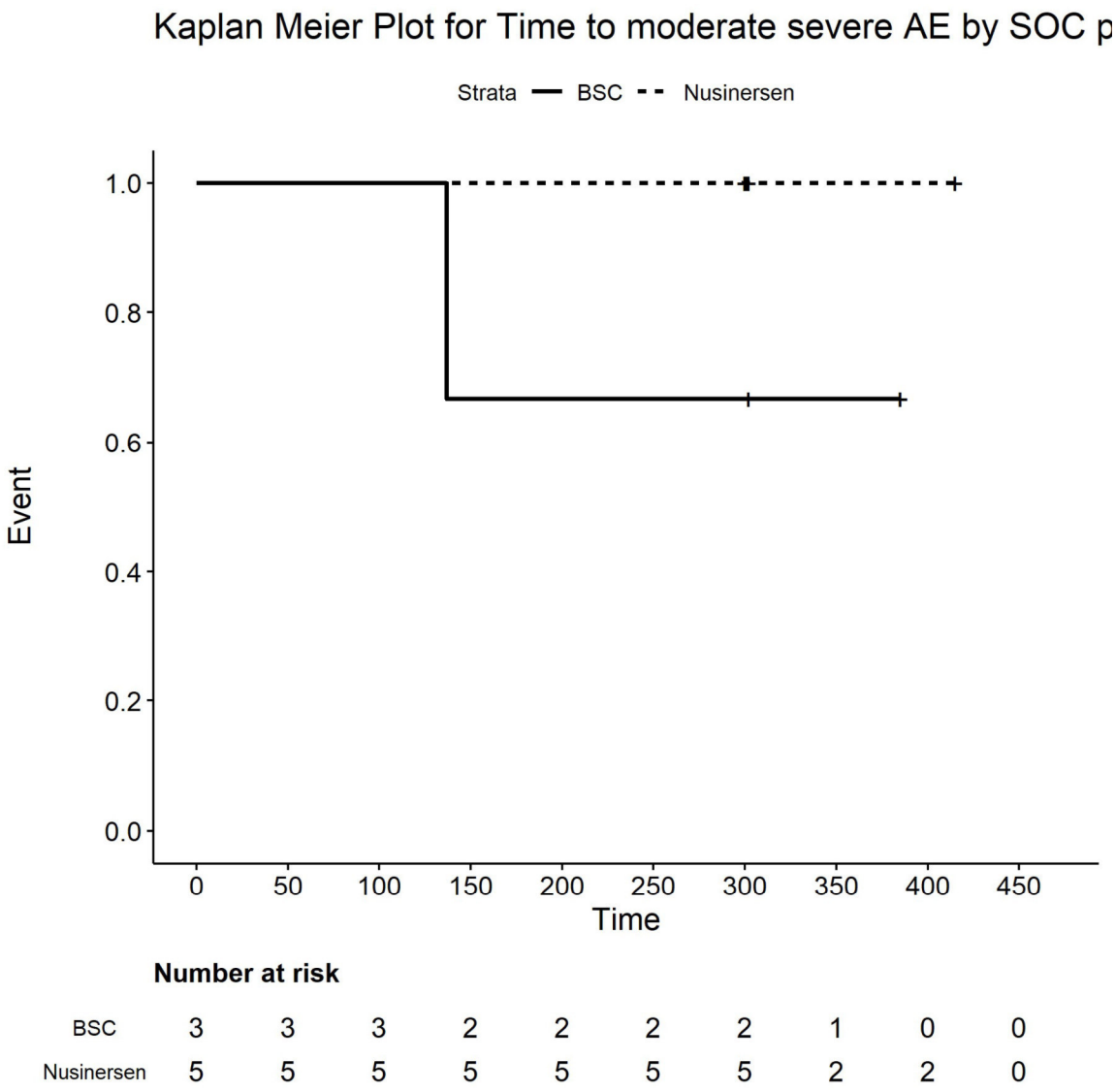
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	4	4	3	1	1	0



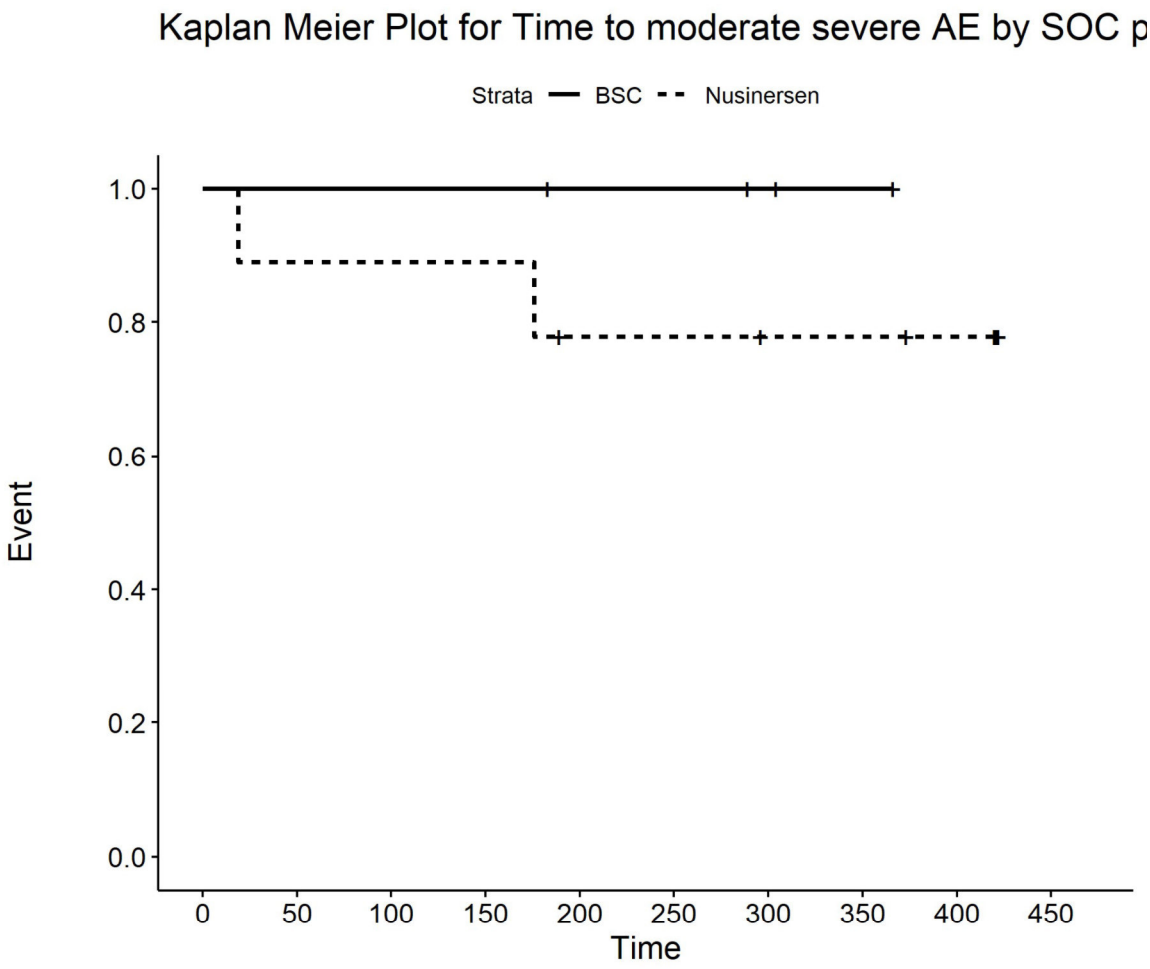
Number at risk

BSC	3	3	3	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	7	7	7	6	5	0



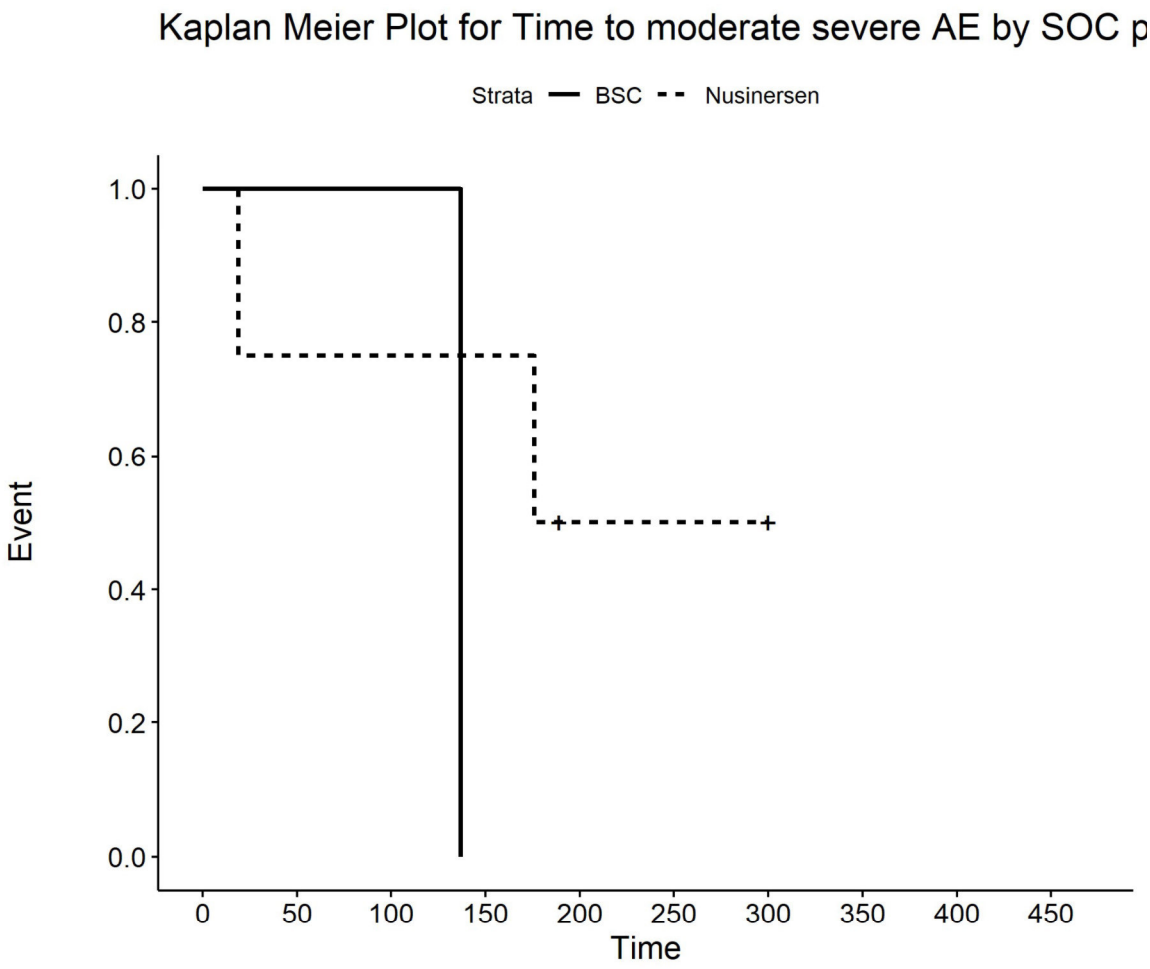
Number at risk

BSC	3	3	3	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



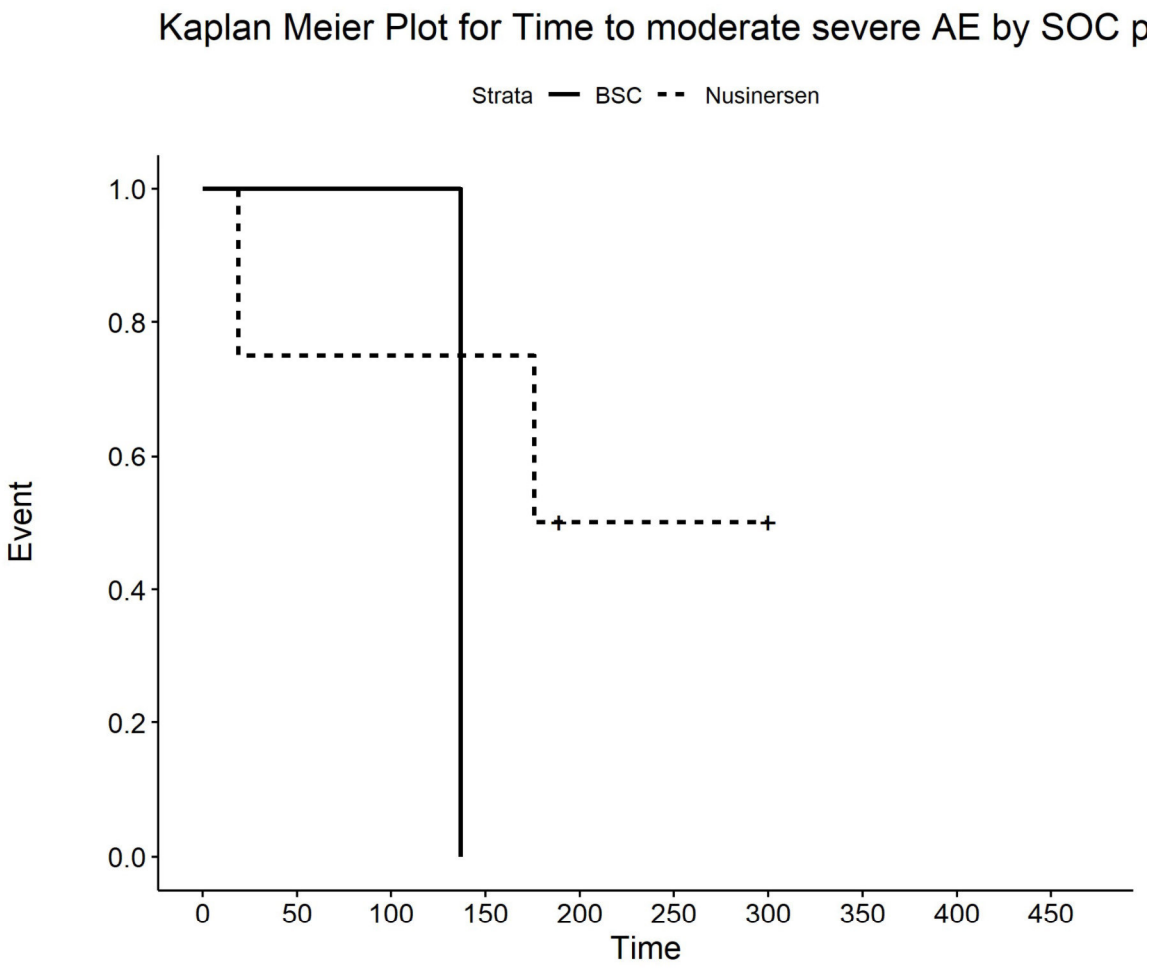
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	6	6	5	5	4	0



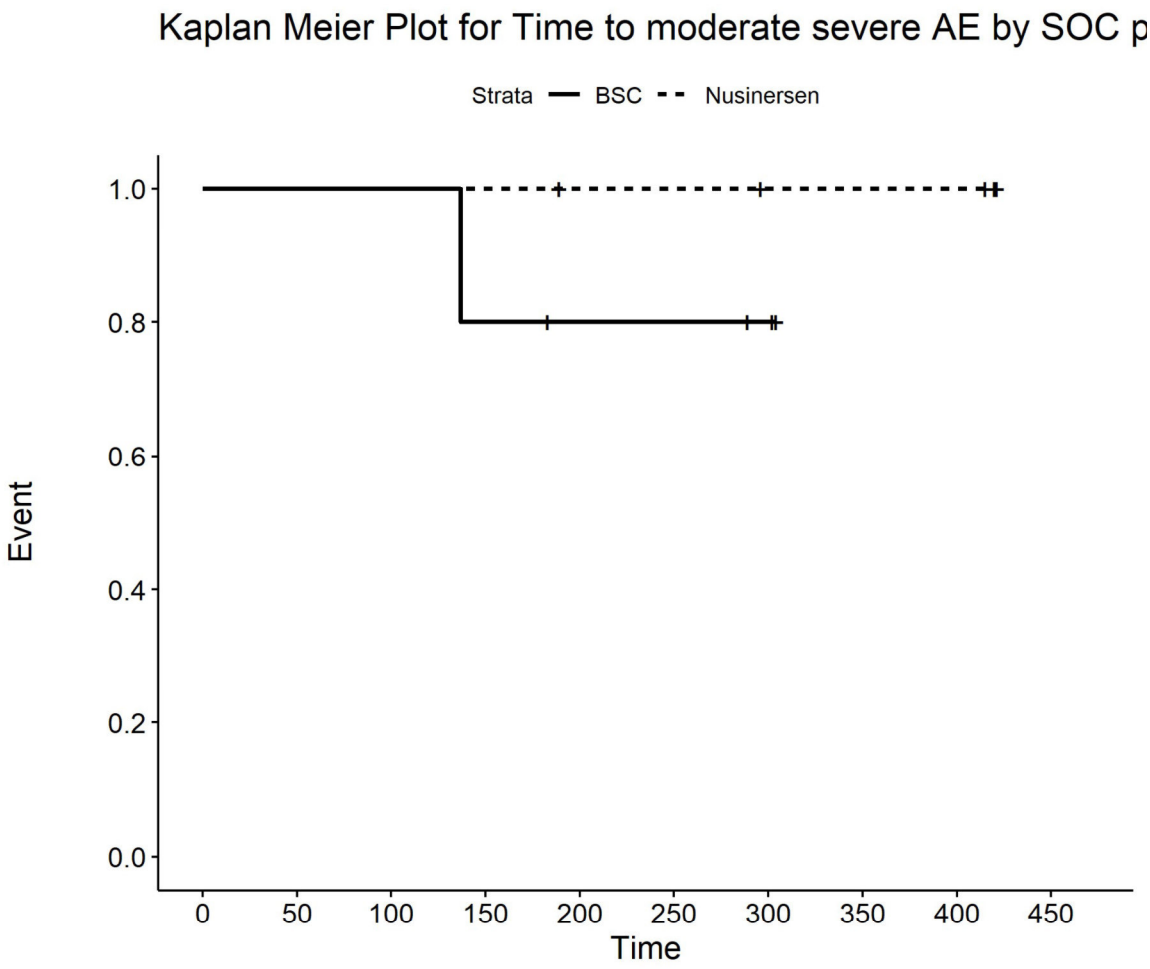
Number at risk

BSC	1	1	1	0	0	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



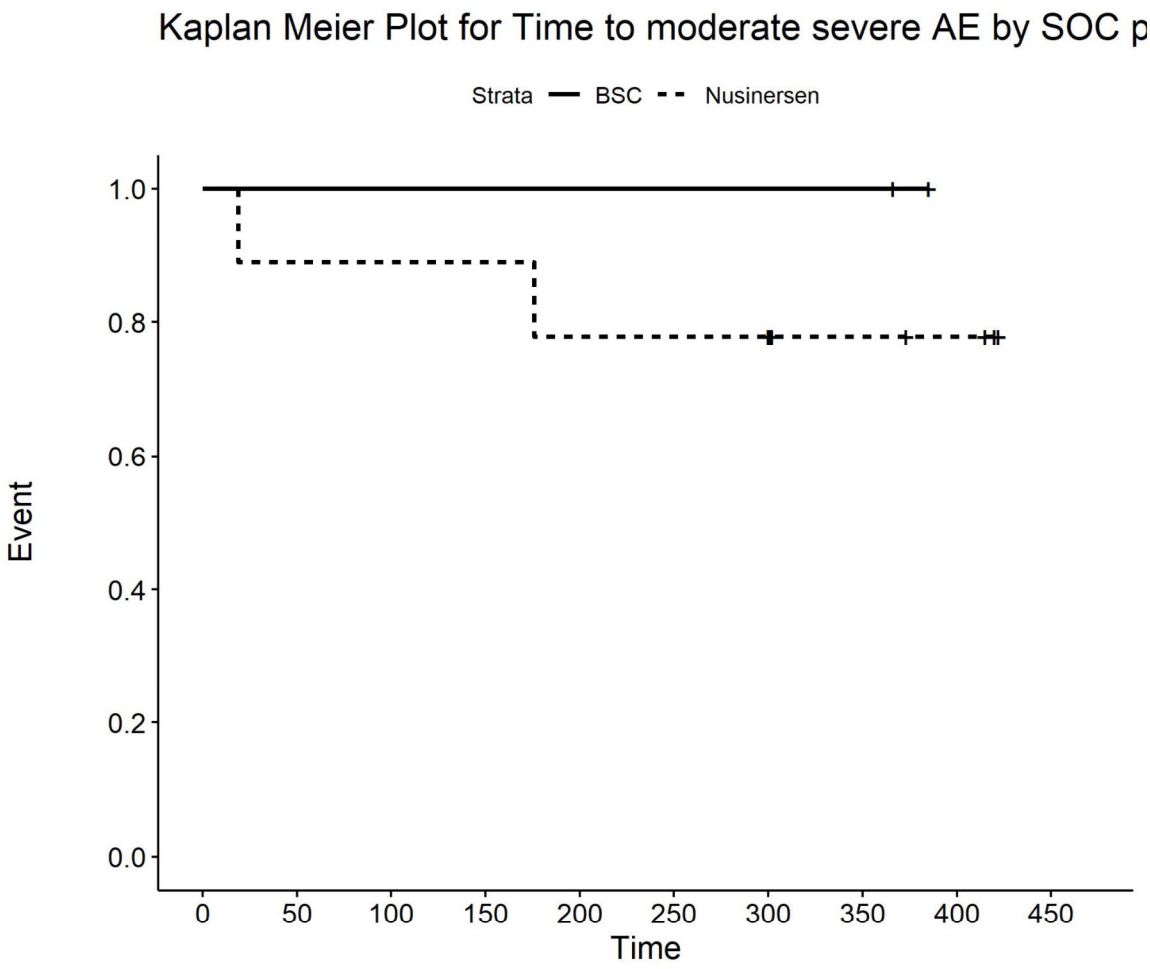
Number at risk

BSC	1	1	1	0	0	0	0	0	0	0
Nusinersen	4	3	3	3	1	1	1	0	0	0



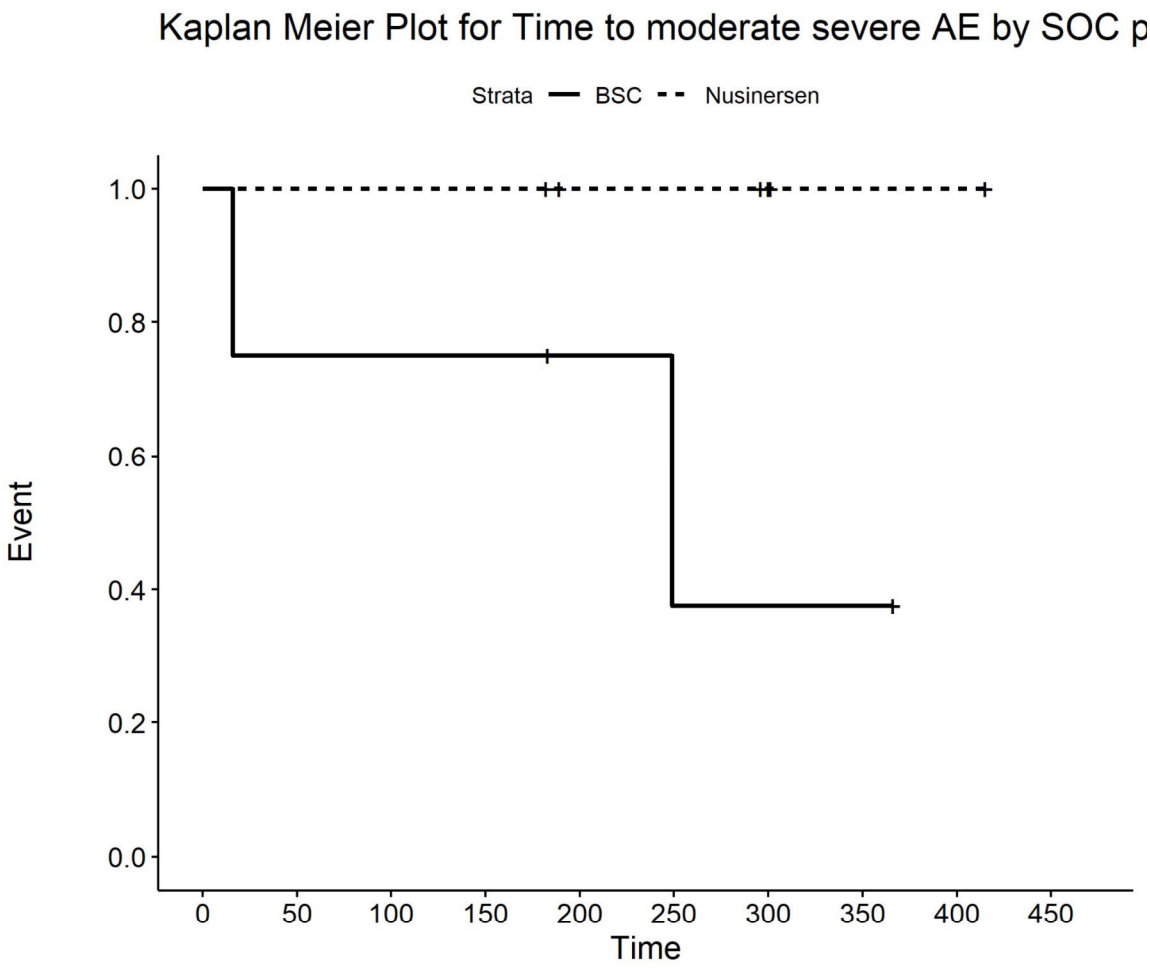
Number at risk

BSC	5	5	5	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



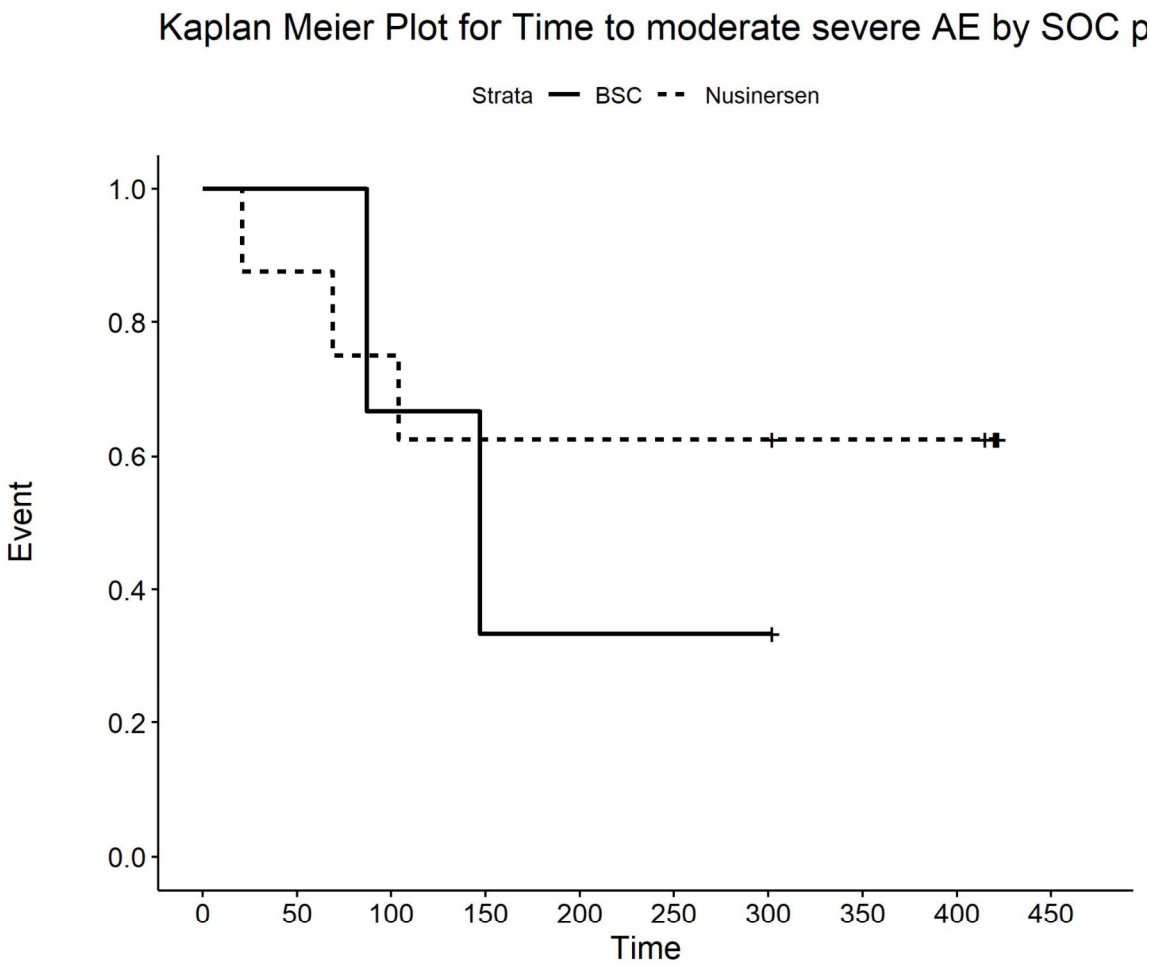
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	7	7	7	4	3	0



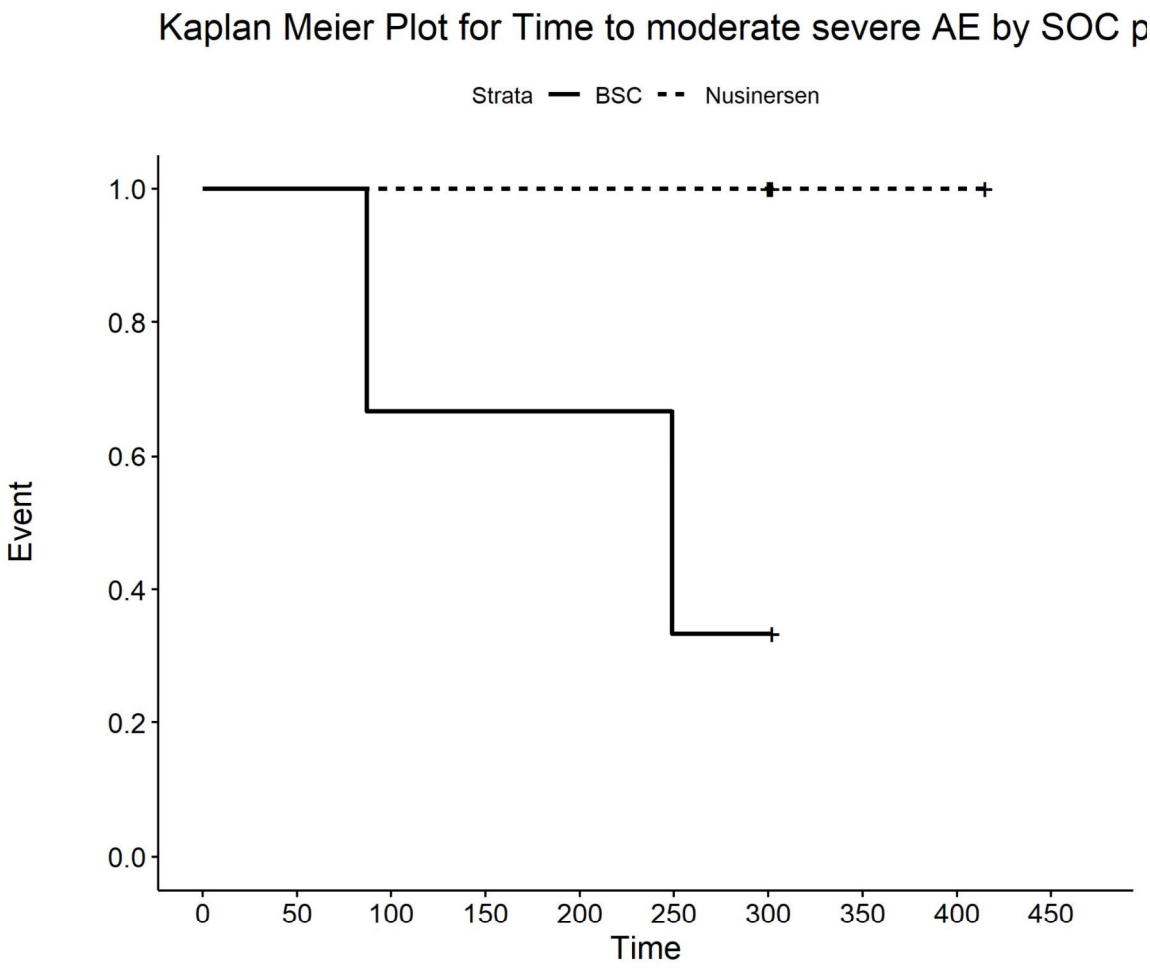
Number at risk

BSC	4	3	3	3	2	1	1	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



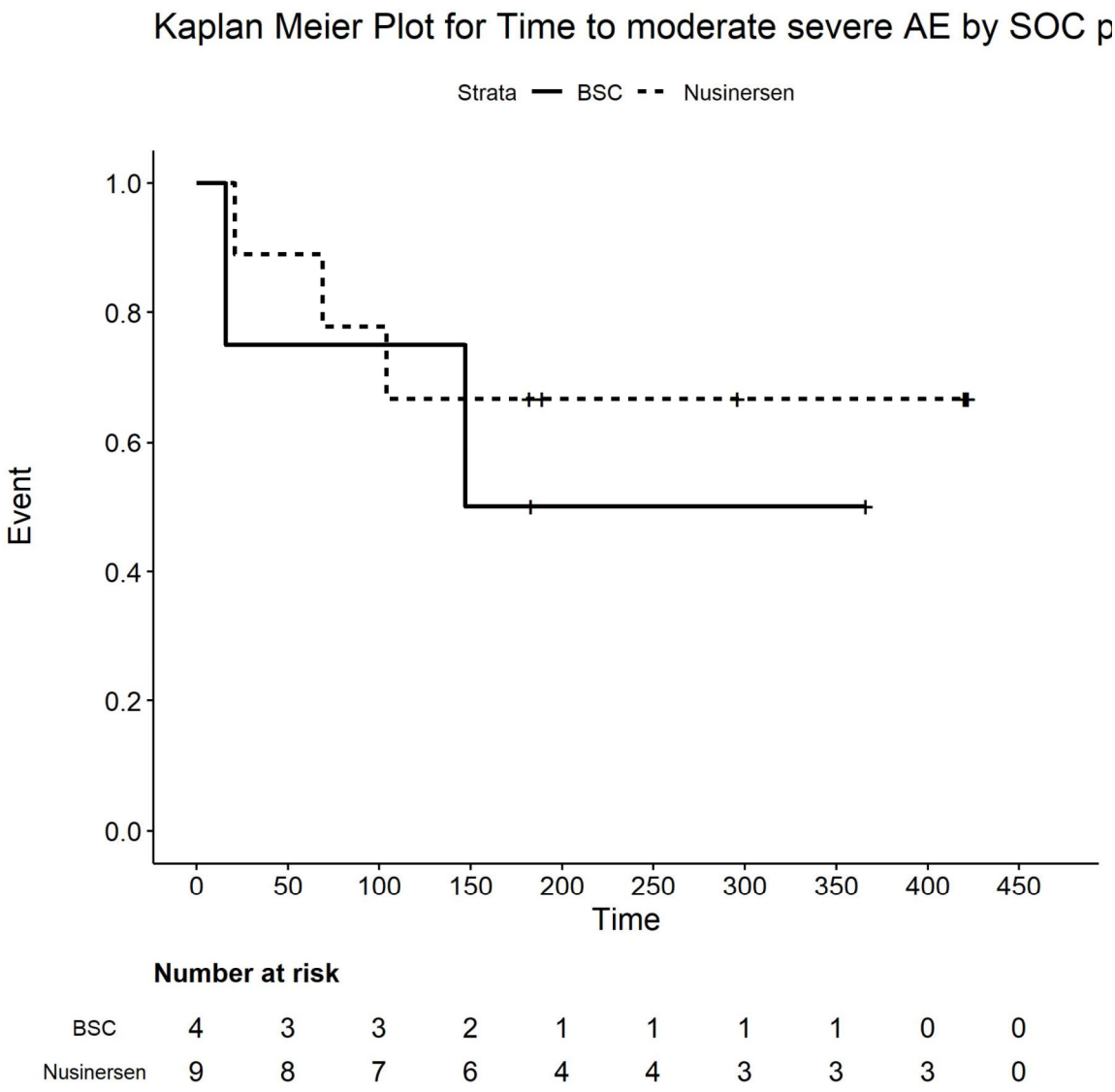
Number at risk

BSC	3	3	2	1	1	1	1	0	0	0
Nusinersen	8	7	6	5	5	5	5	4	4	0



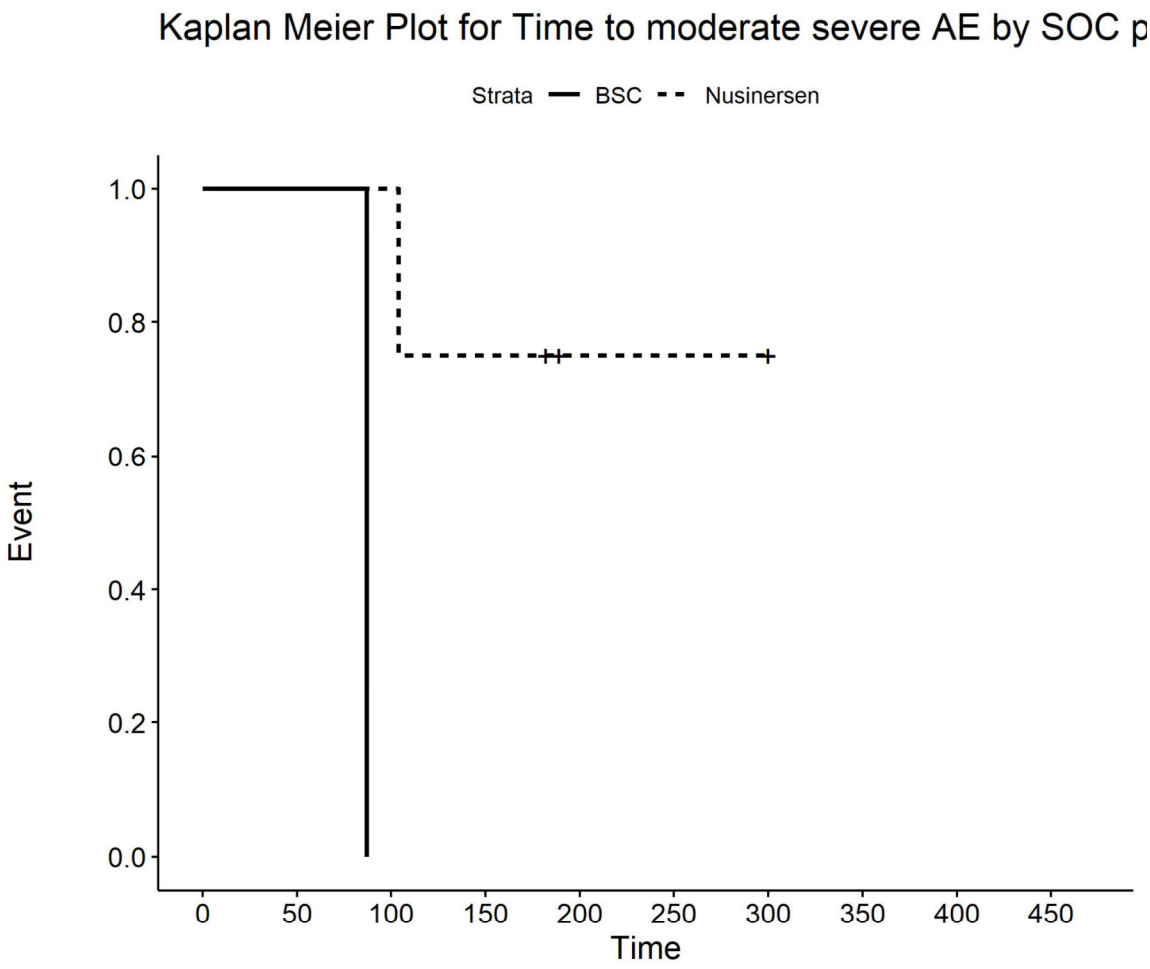
Number at risk

BSC	3	3	2	2	2	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



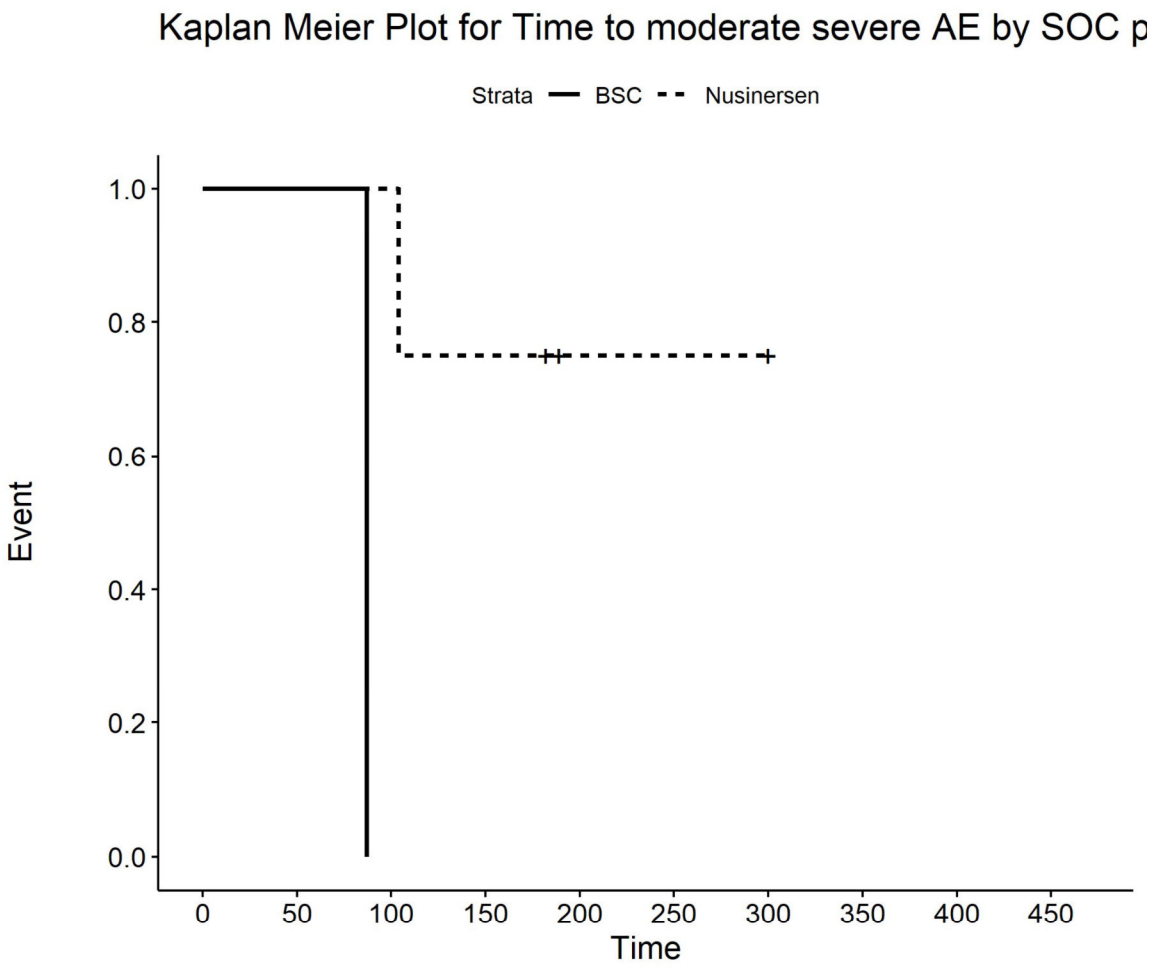
Number at risk

BSC	4	3	3	2	1	1	1	1	0	0
Nusinersen	9	8	7	6	4	4	3	3	3	0



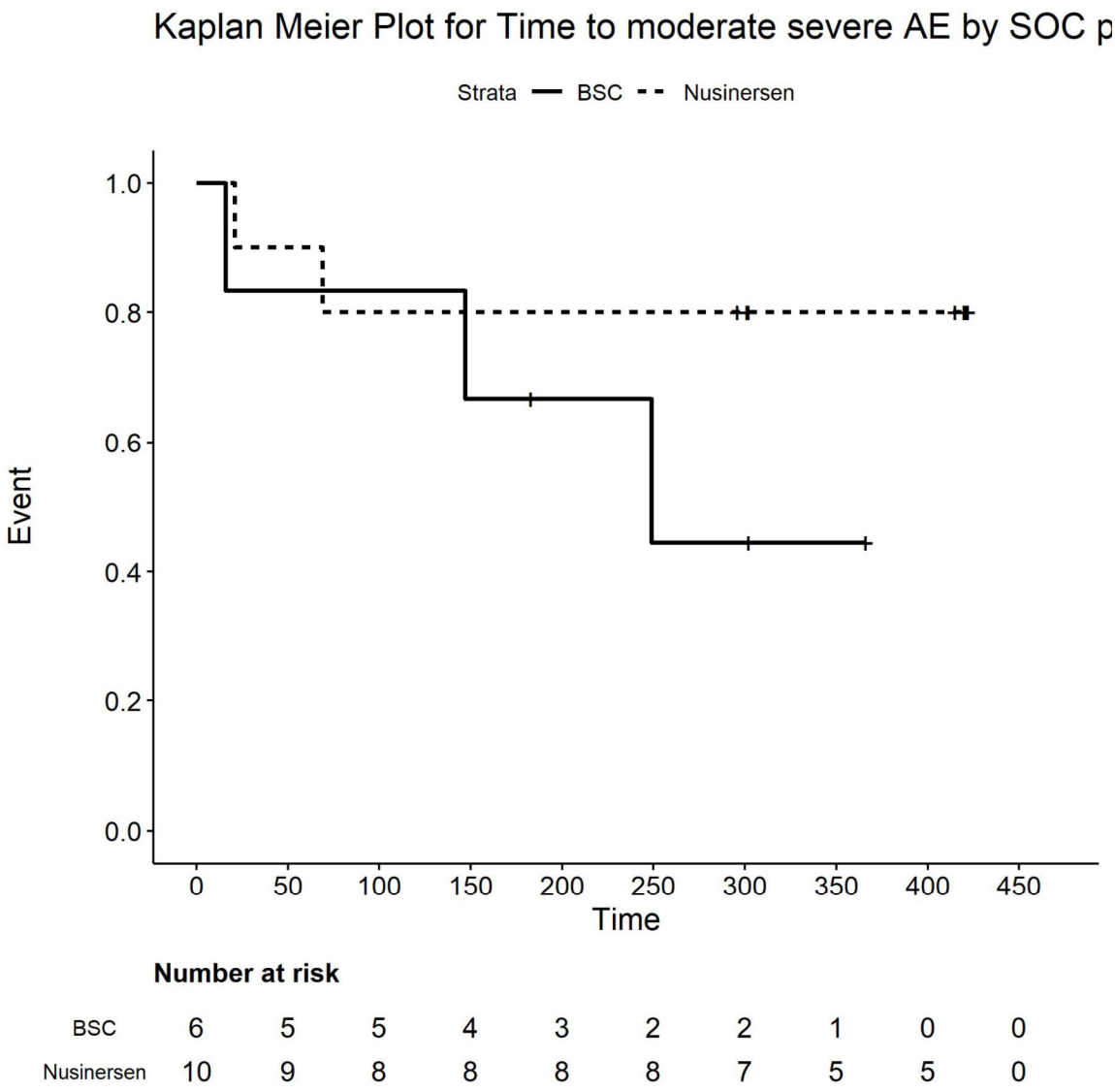
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



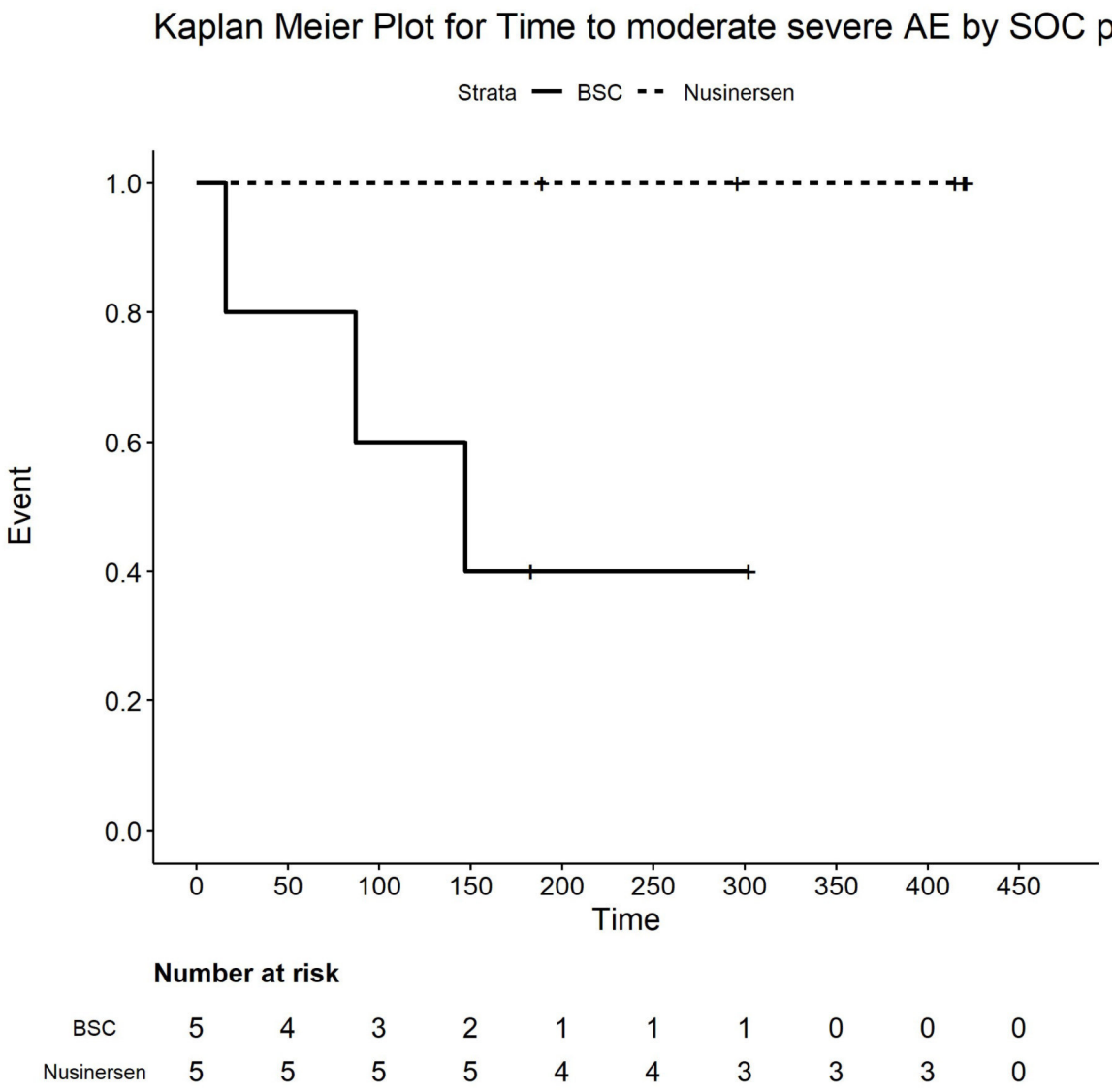
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



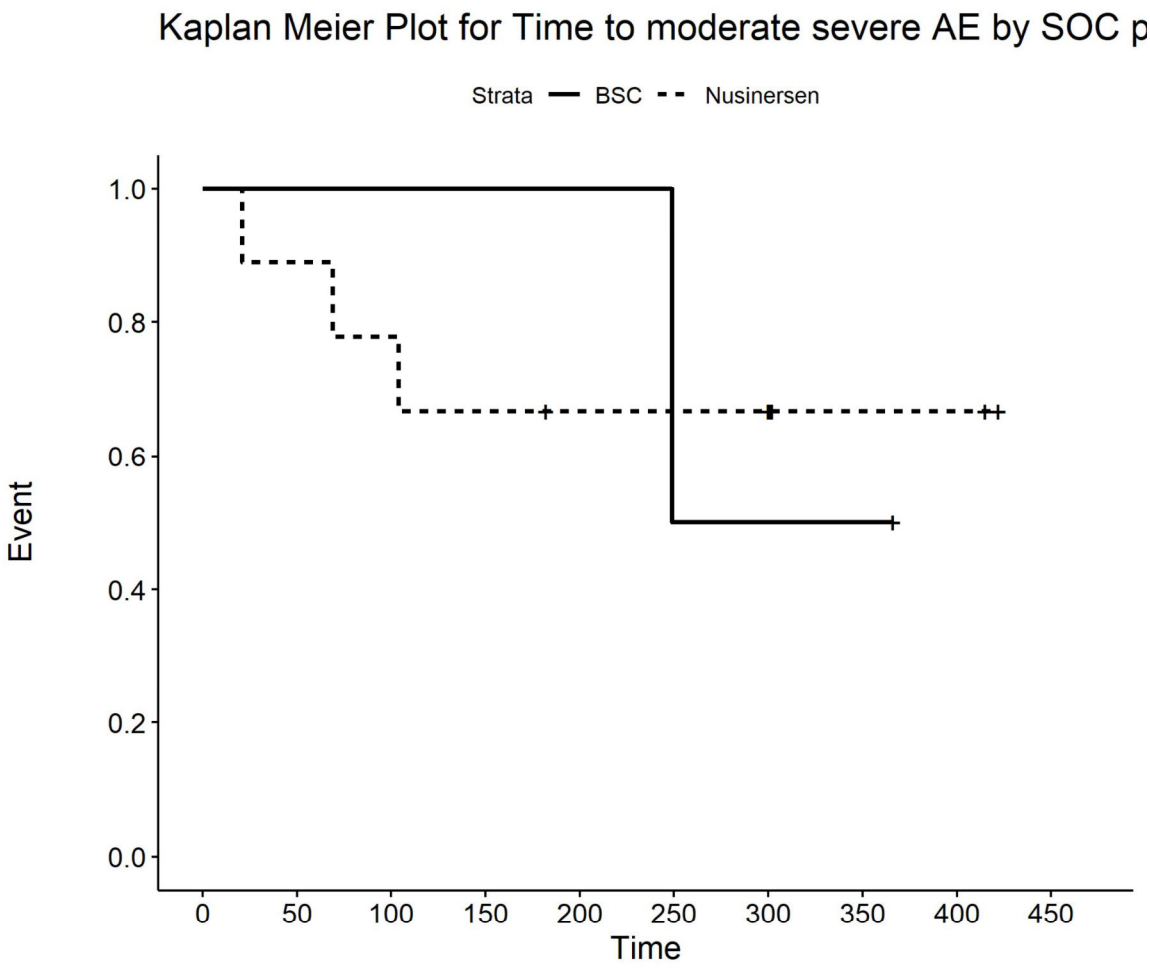
Number at risk

BSC	6	5	5	4	3	2	2	1	0	0
Nusinersen	10	9	8	8	8	8	7	5	5	0



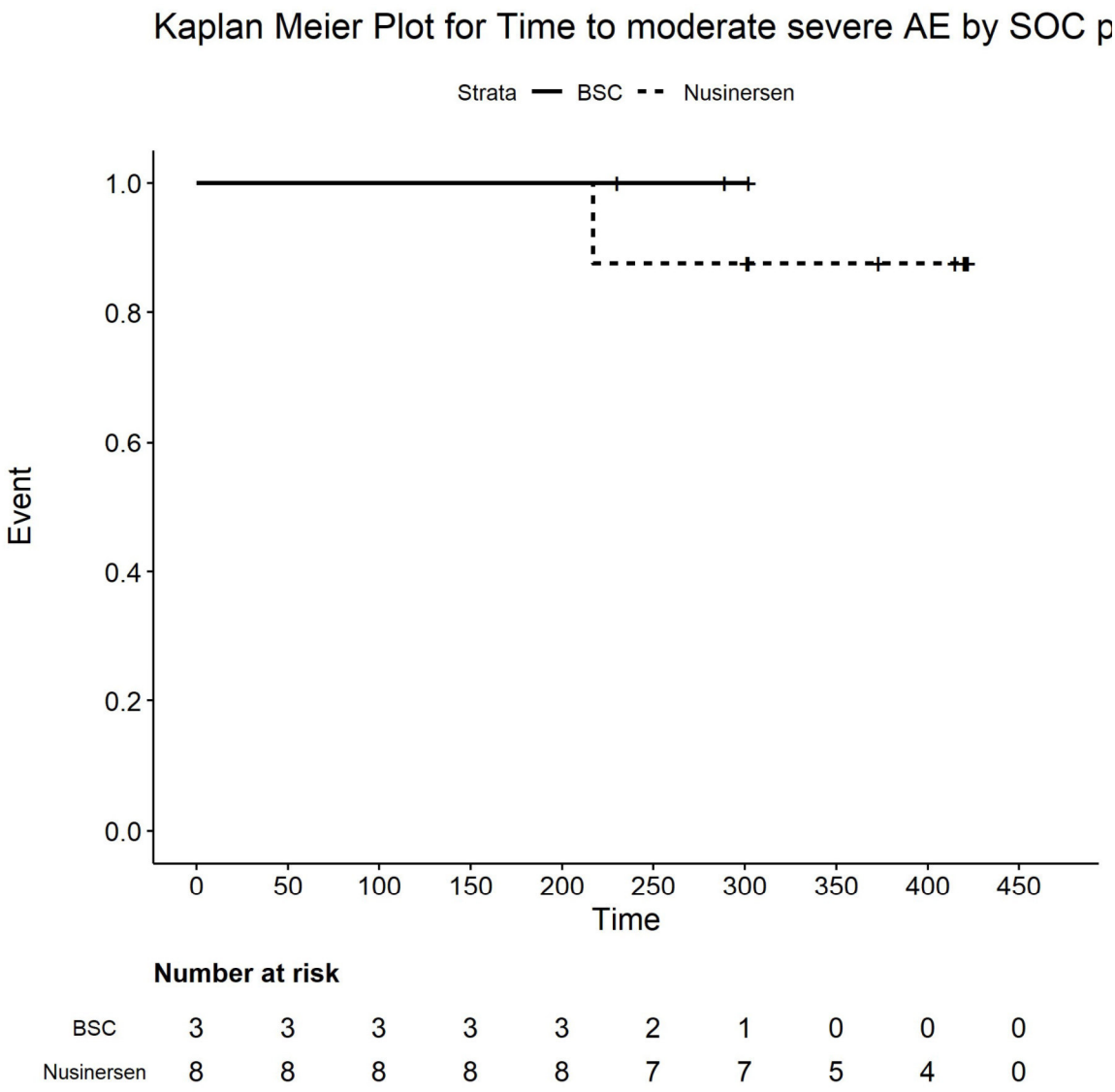
Number at risk

BSC	5	4	3	2	1	1	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



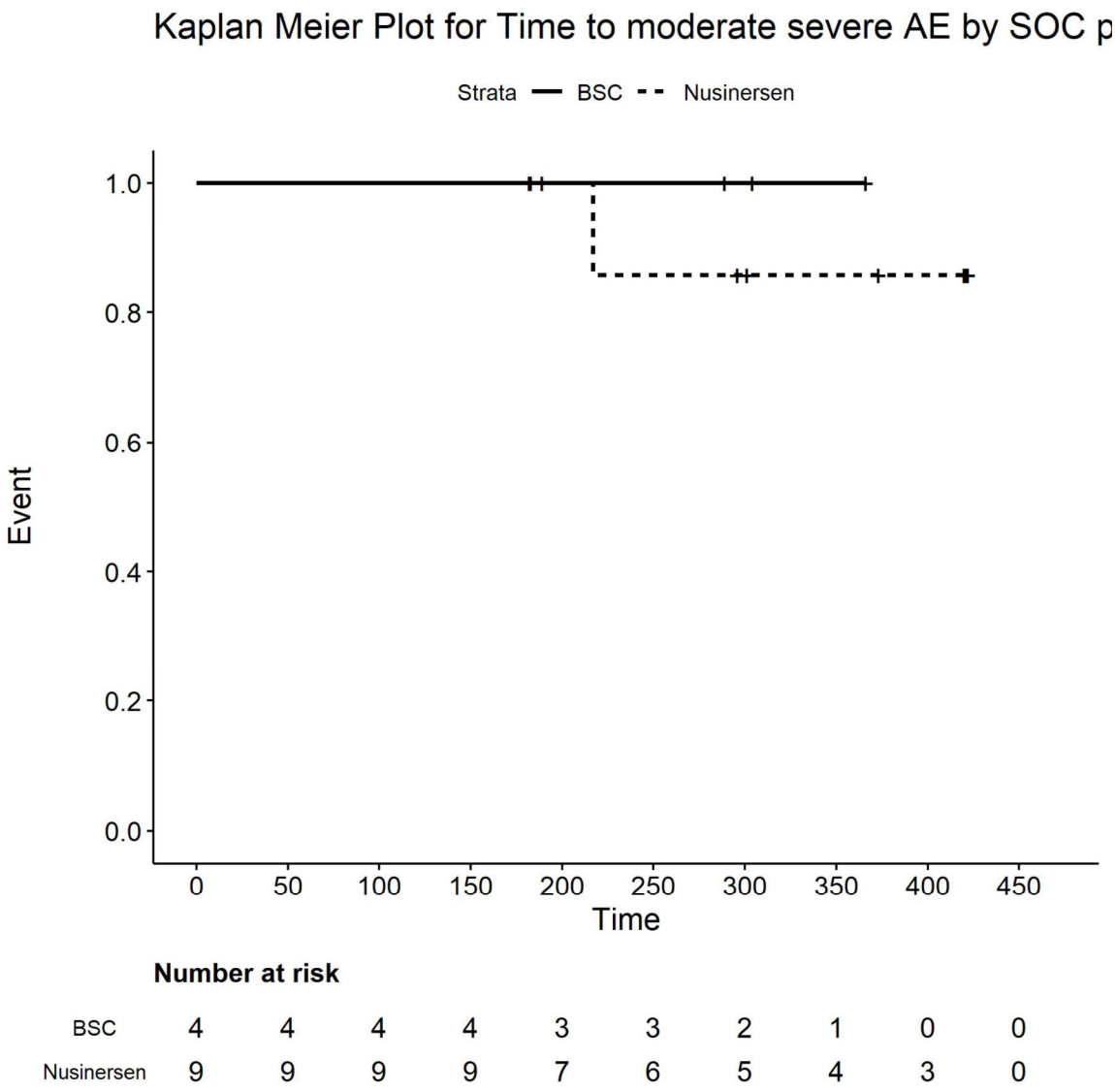
Number at risk

BSC	2	2	2	2	2	1	1	1	0	0
Nusinersen	9	8	7	6	5	5	5	2	2	0



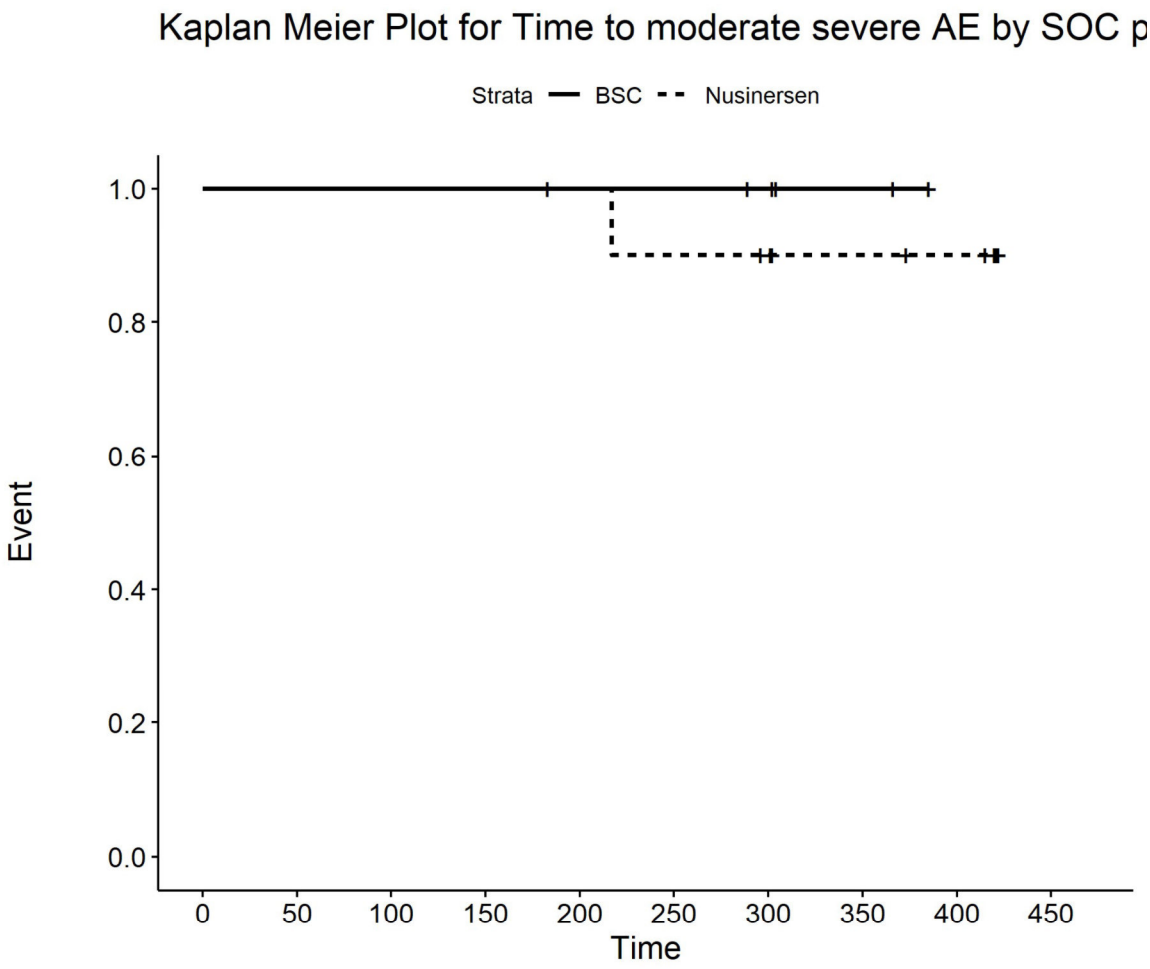
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



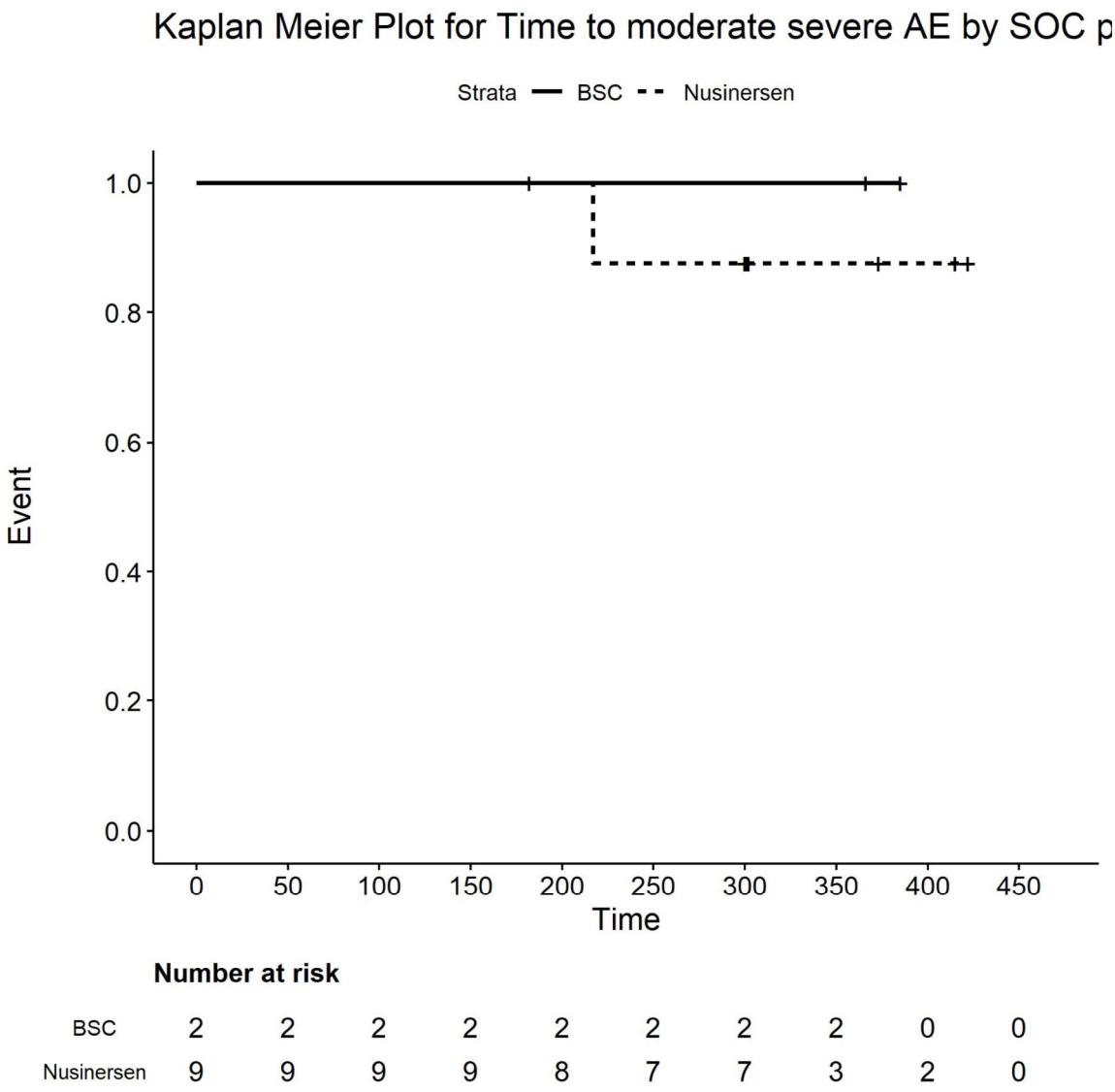
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



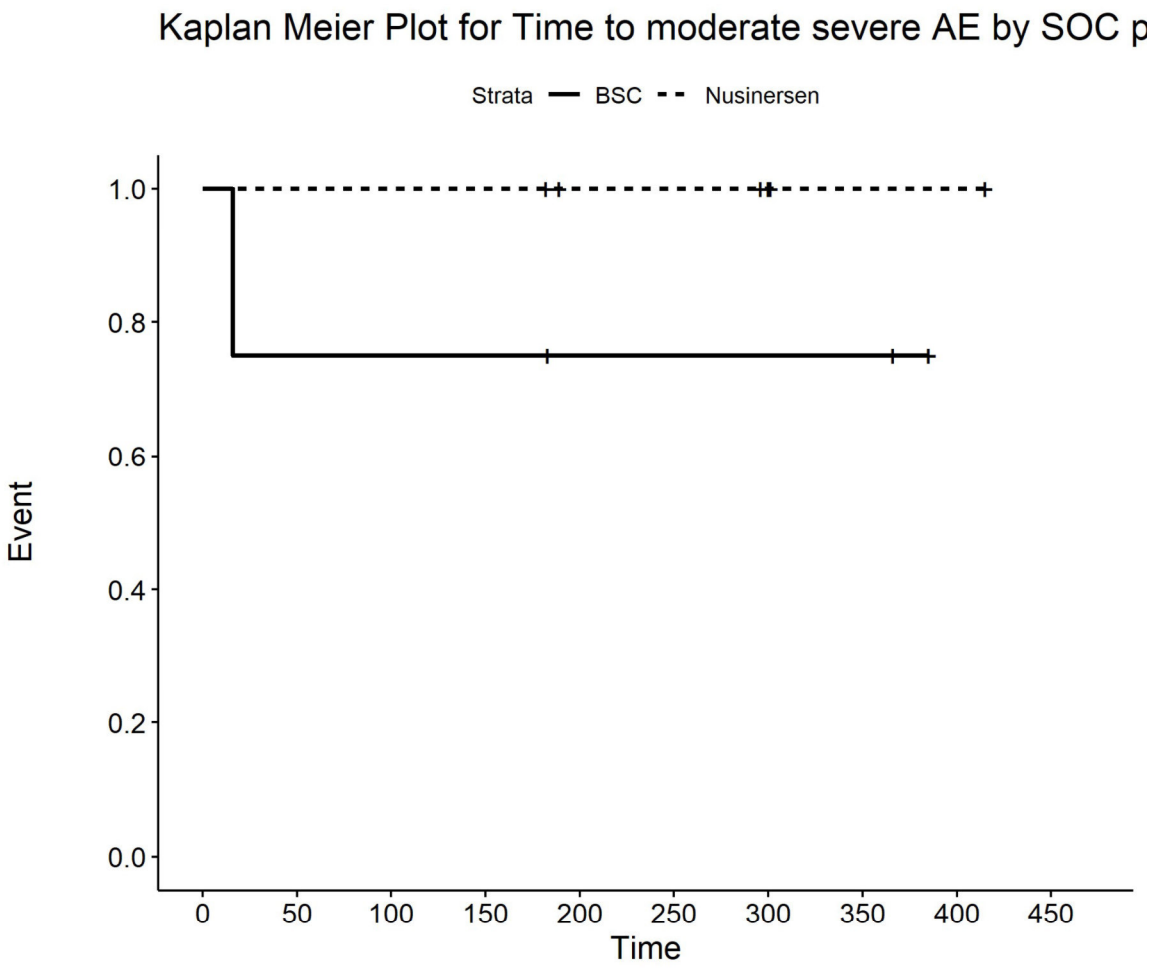
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



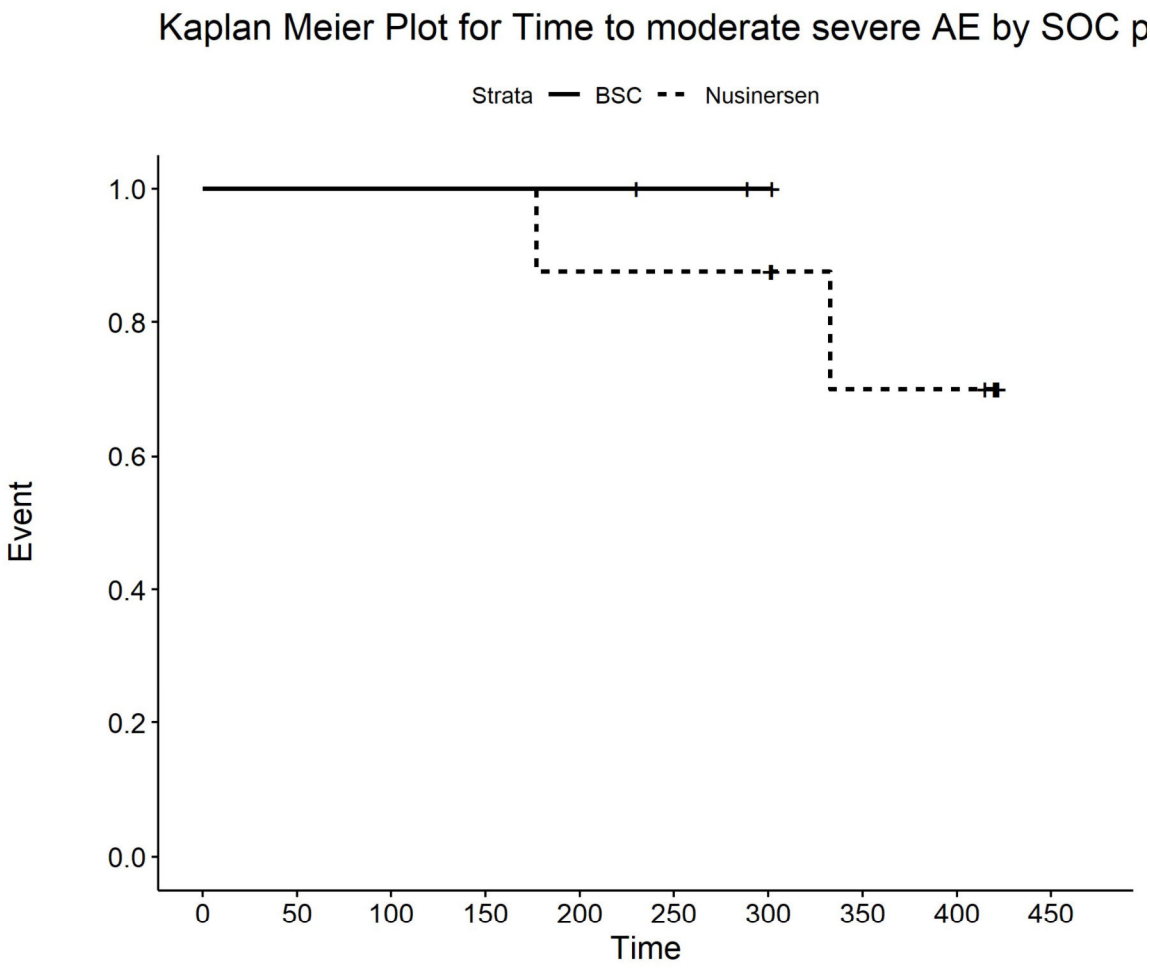
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	2	0



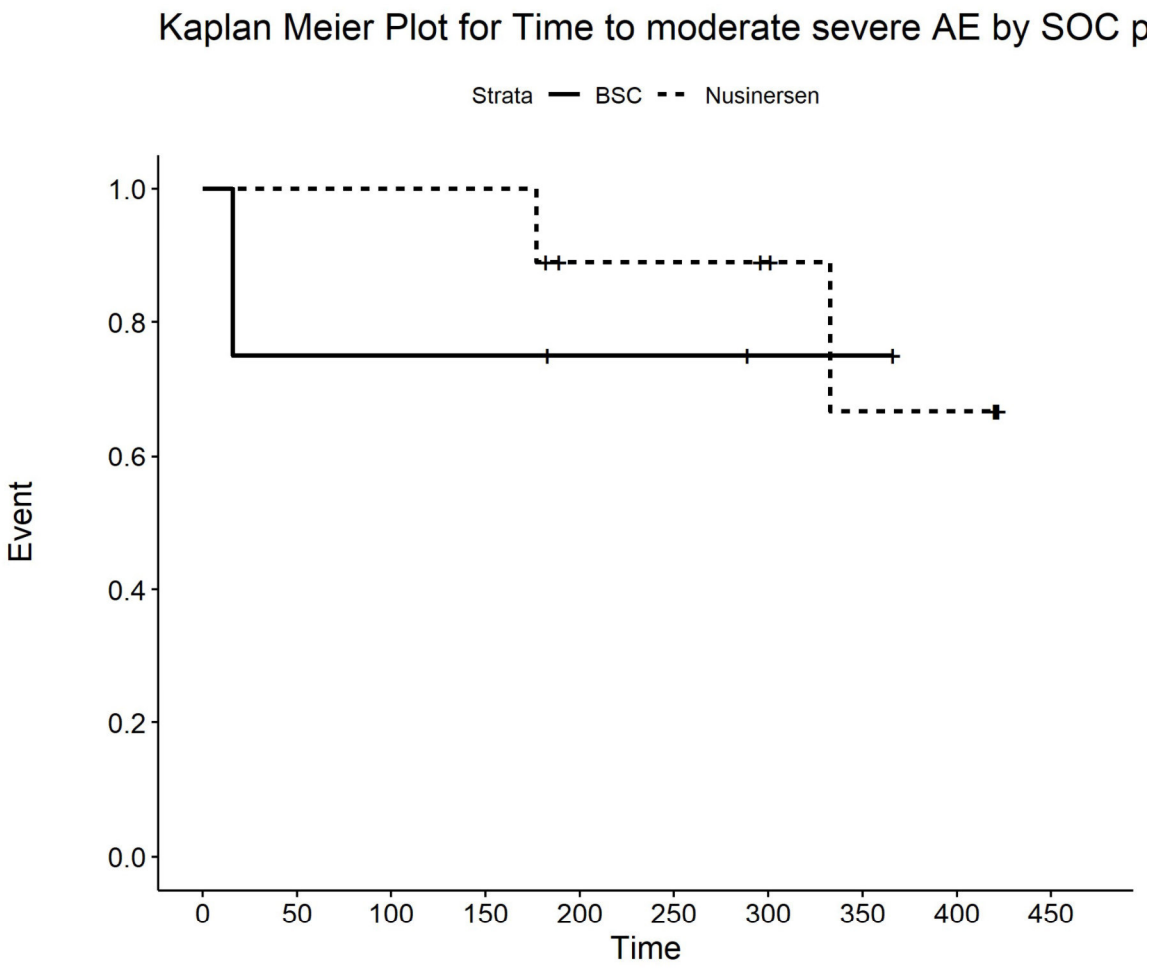
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



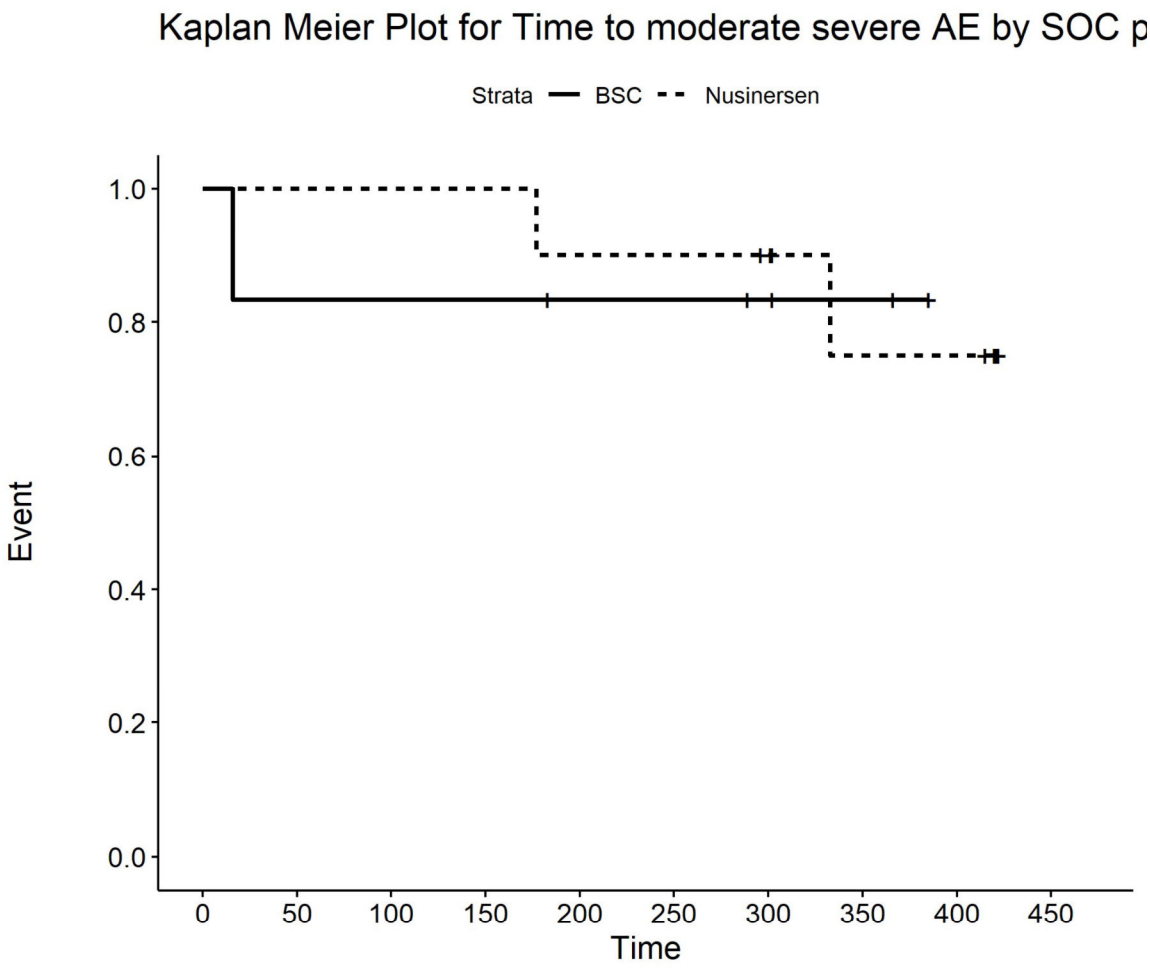
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	7	7	7	4	4	0



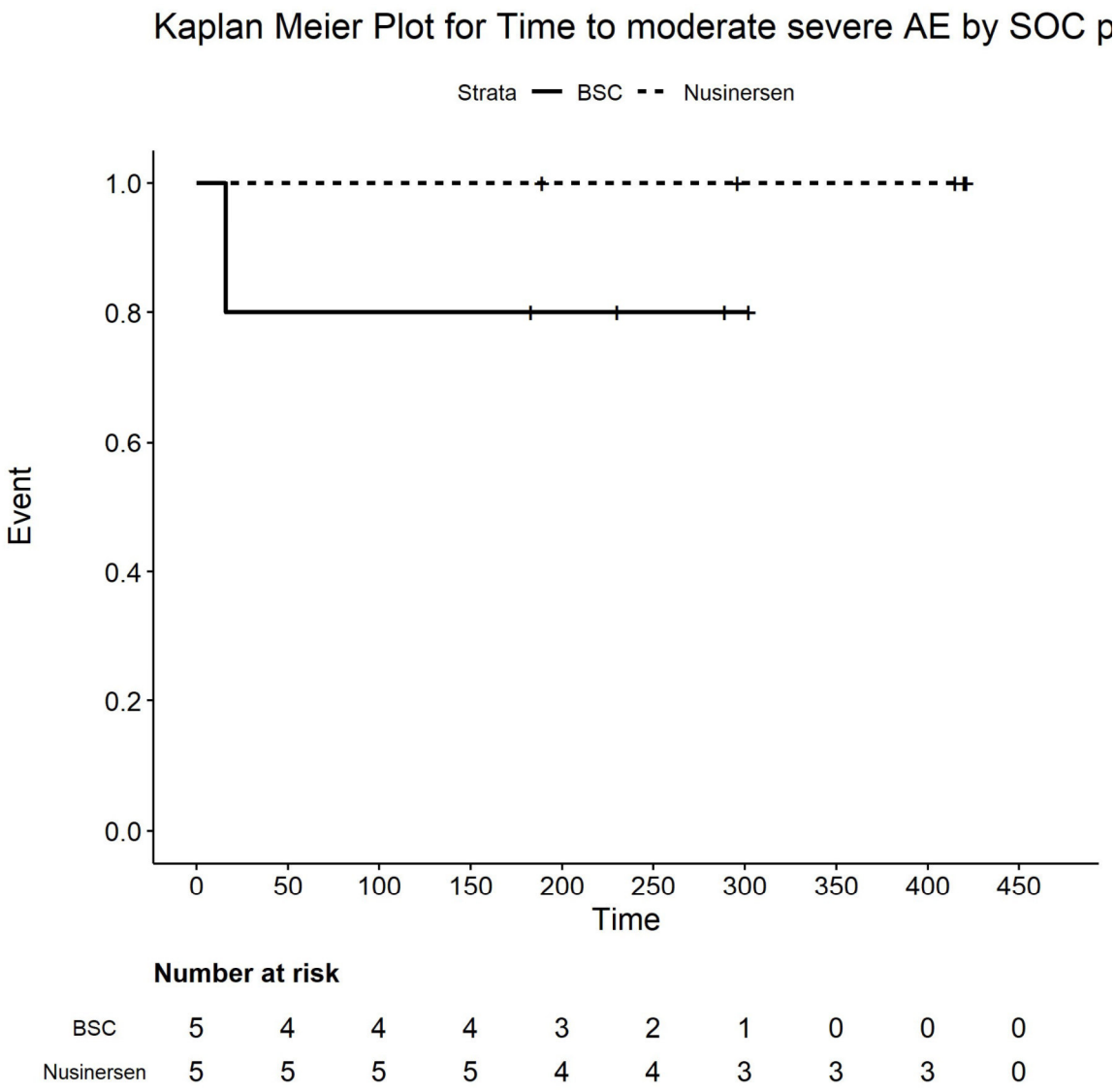
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	6	6	5	3	3	0



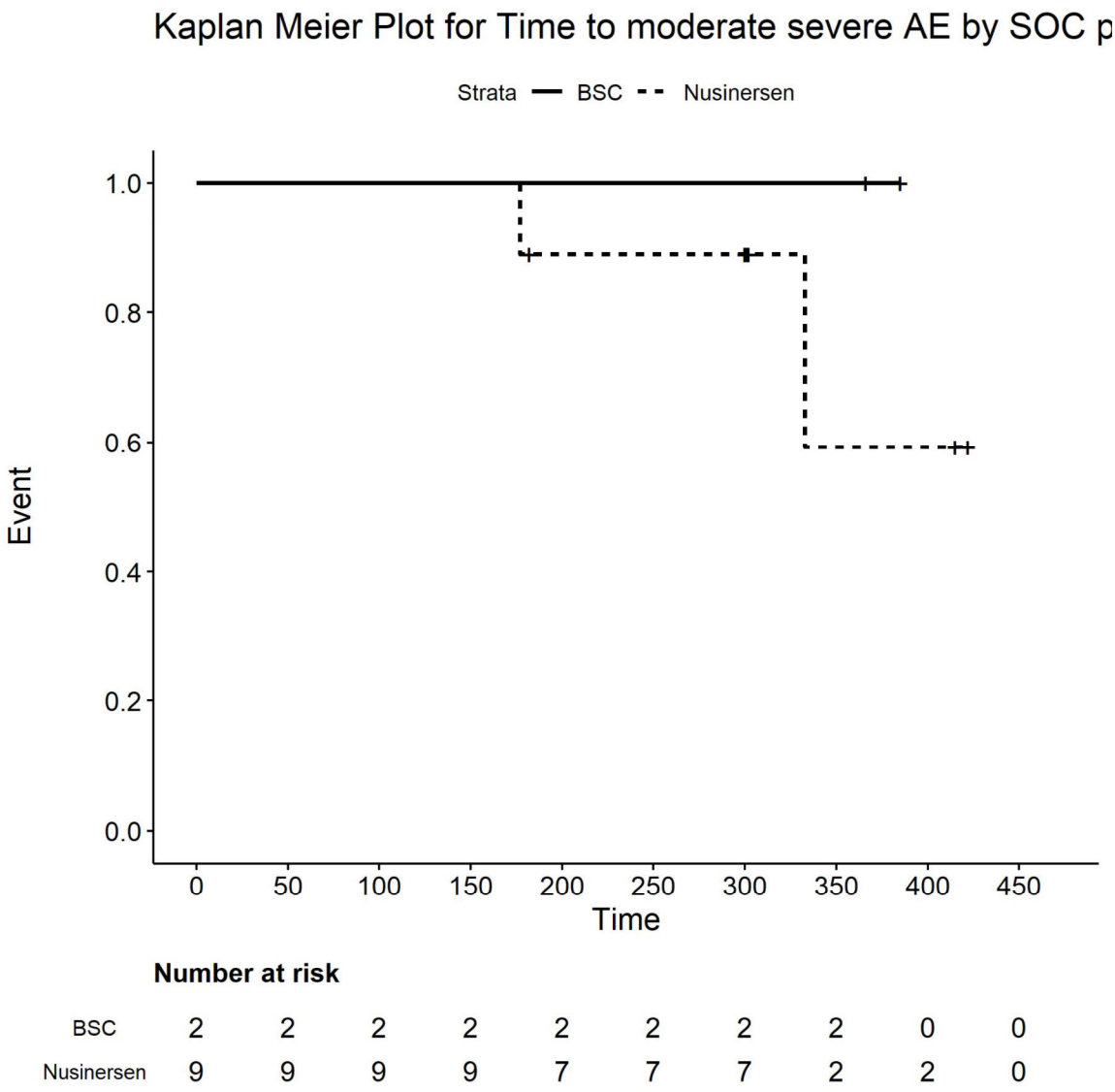
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	9	9	8	5	5	0



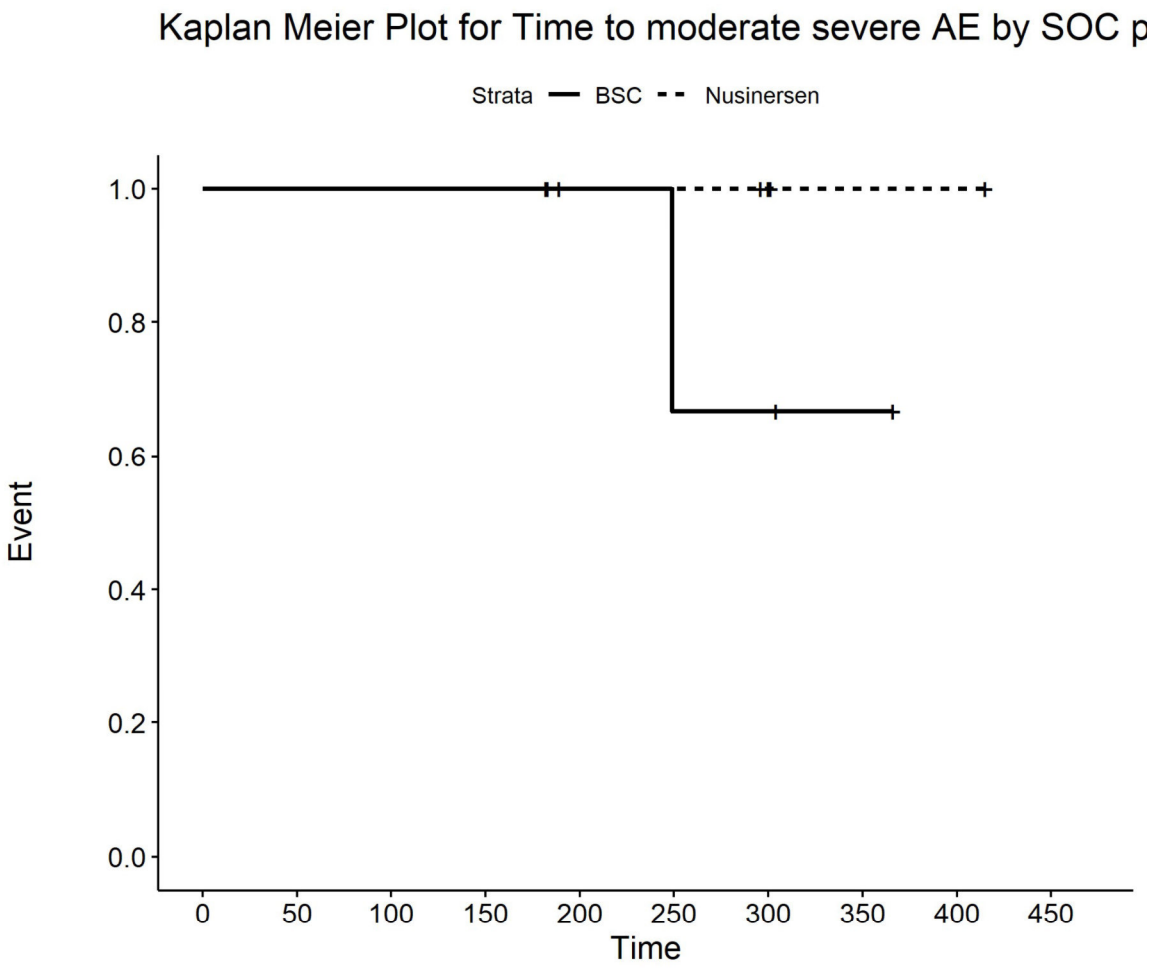
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



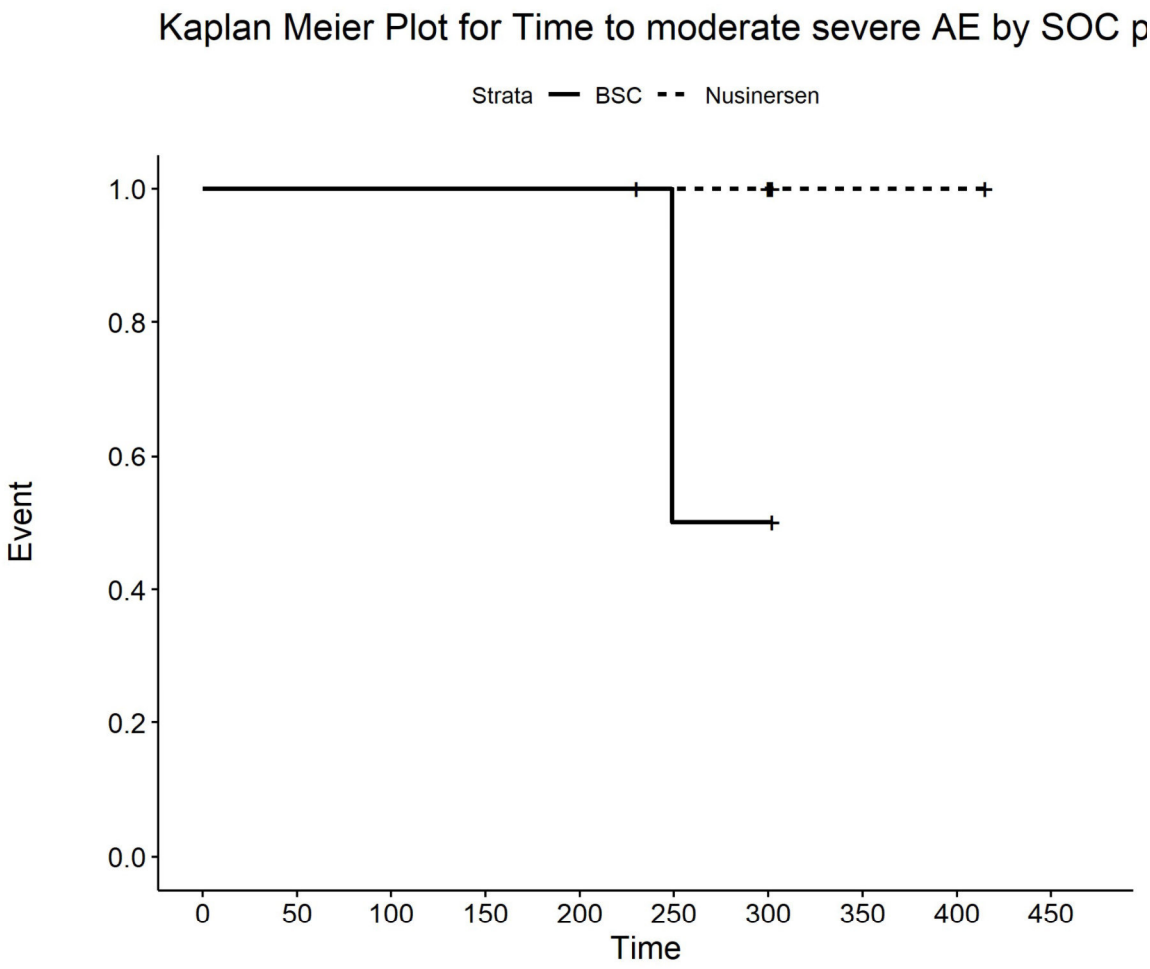
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	7	7	7	2	2	0



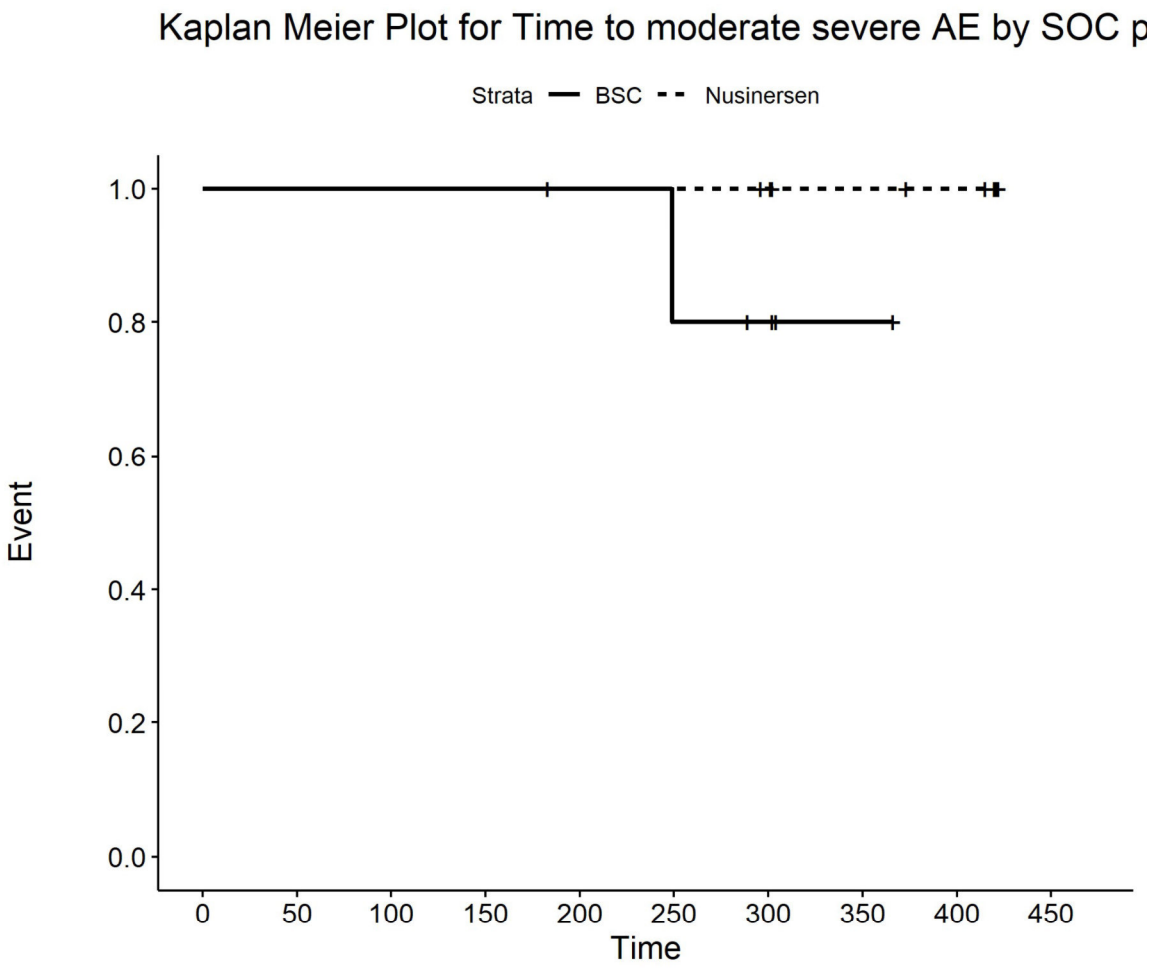
Number at risk

BSC	4	4	4	4	3	2	2	1	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



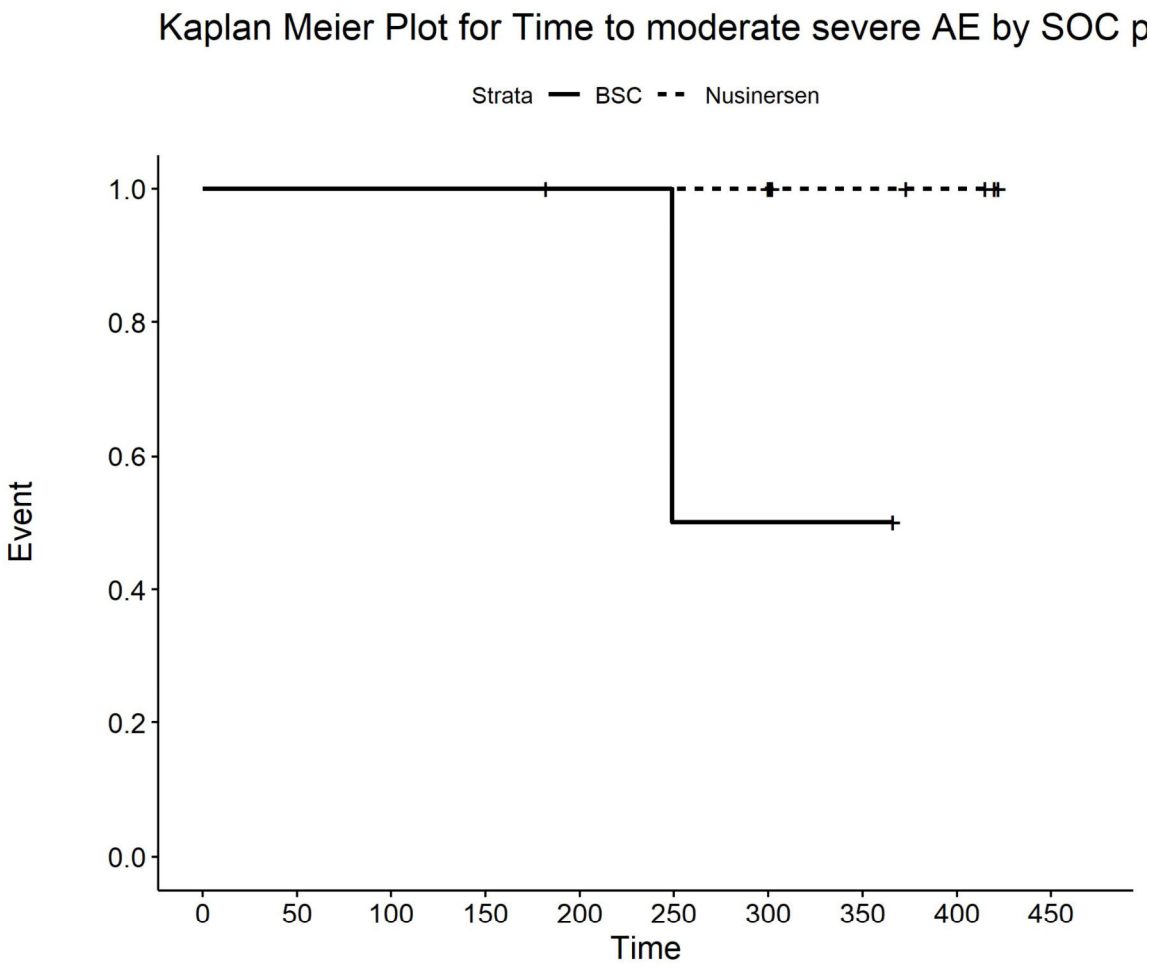
Number at risk

BSC	3	3	3	3	3	1	1	0	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



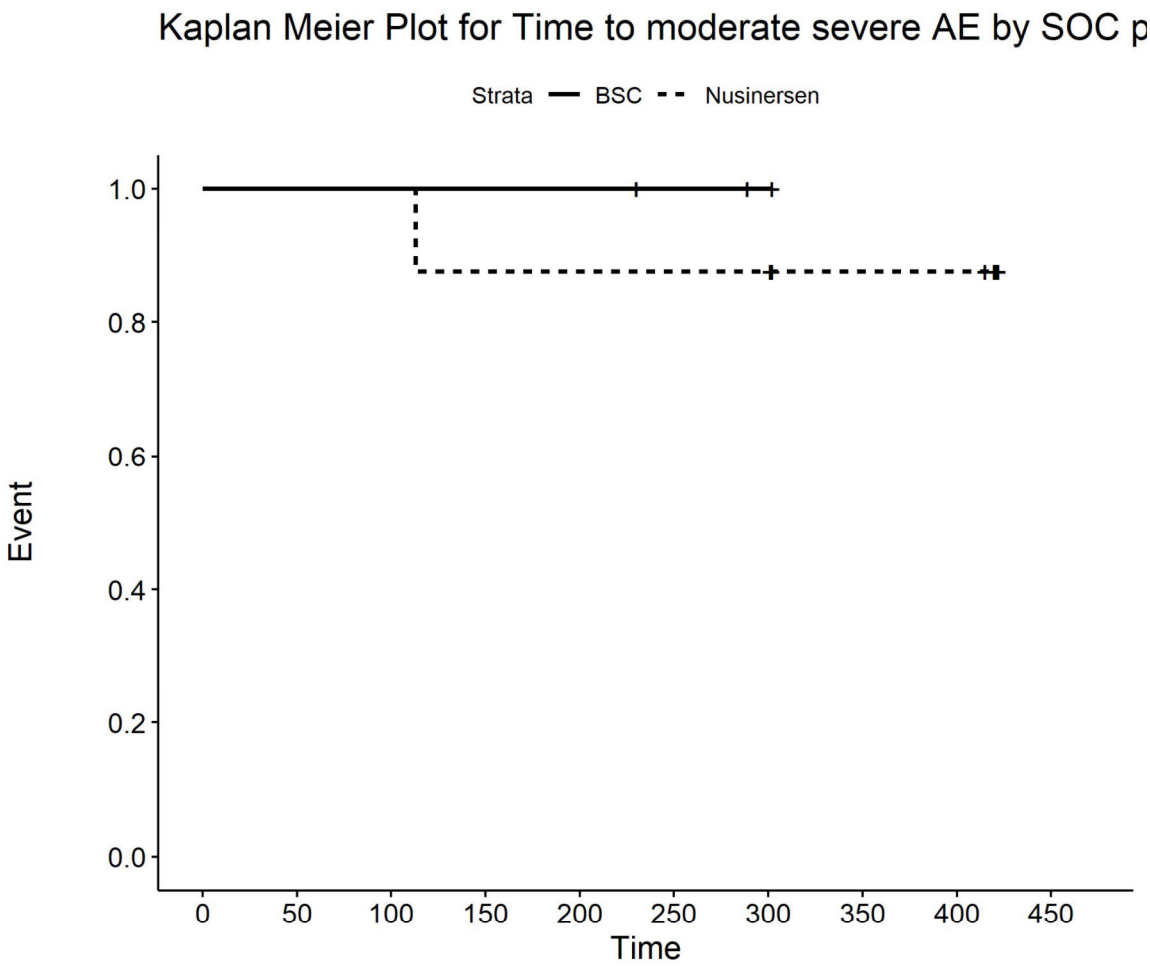
Number at risk

BSC	6	6	6	6	5	4	3	1	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



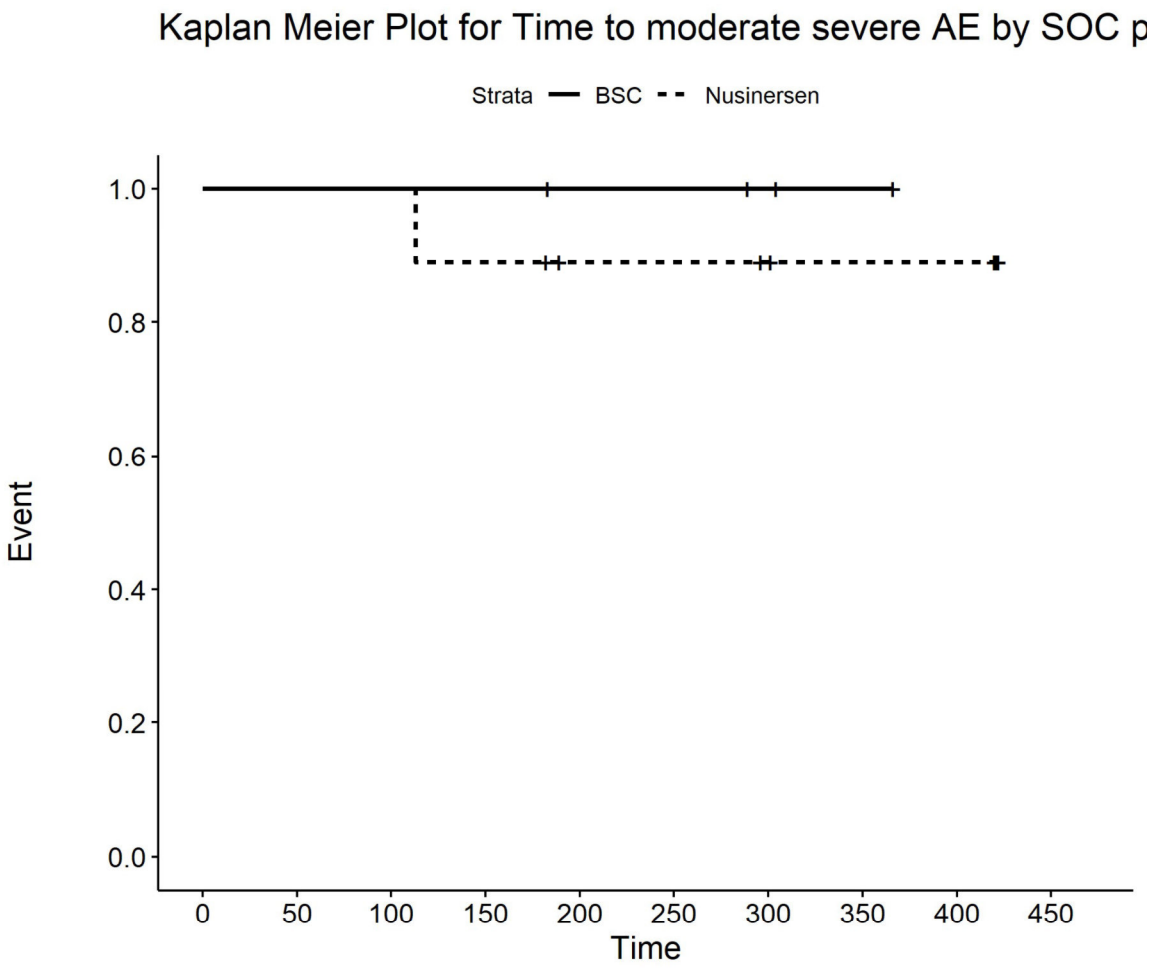
Number at risk

BSC	2	2	2	2	2	1	1	1	0	0
Nusinersen	9	9	9	9	8	8	8	4	3	0



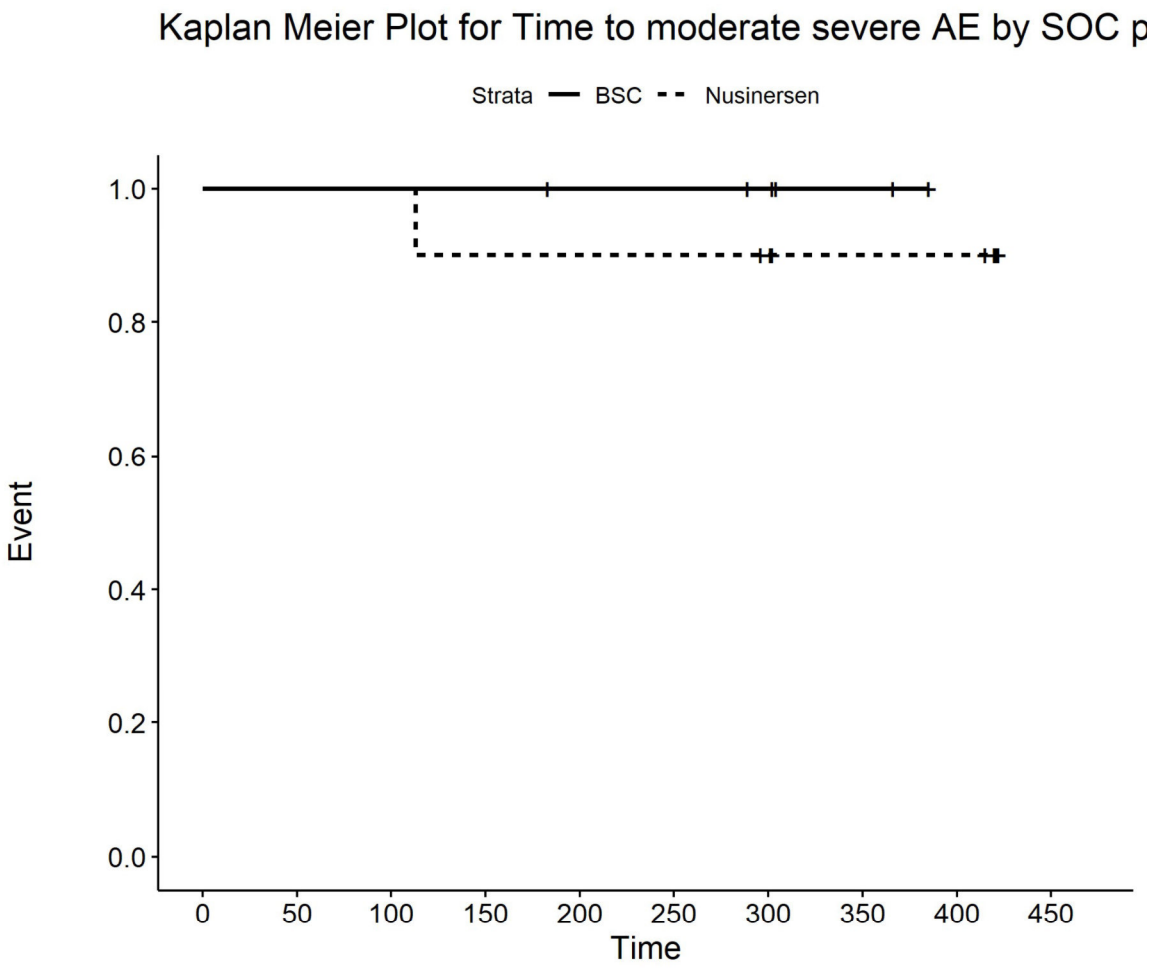
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	5	0



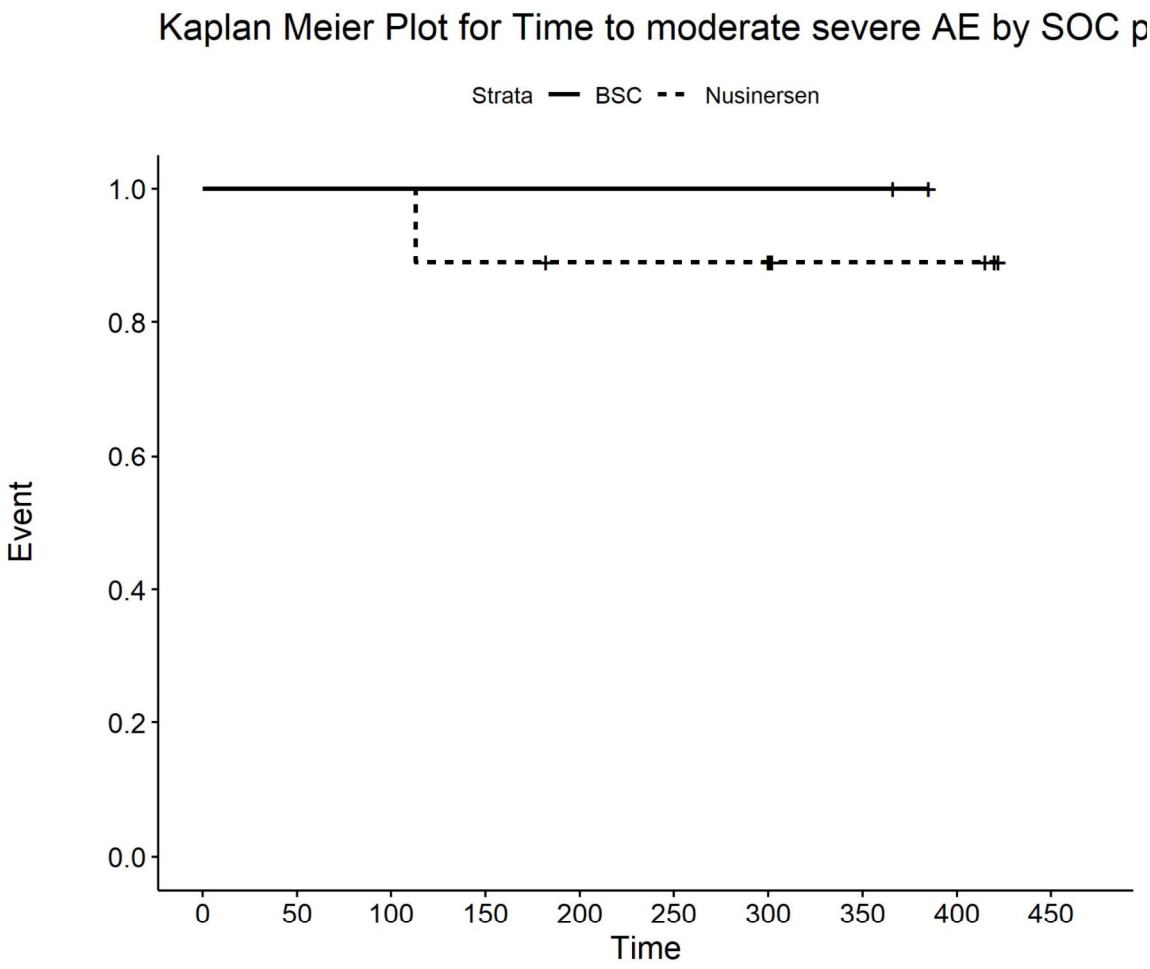
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	4	0



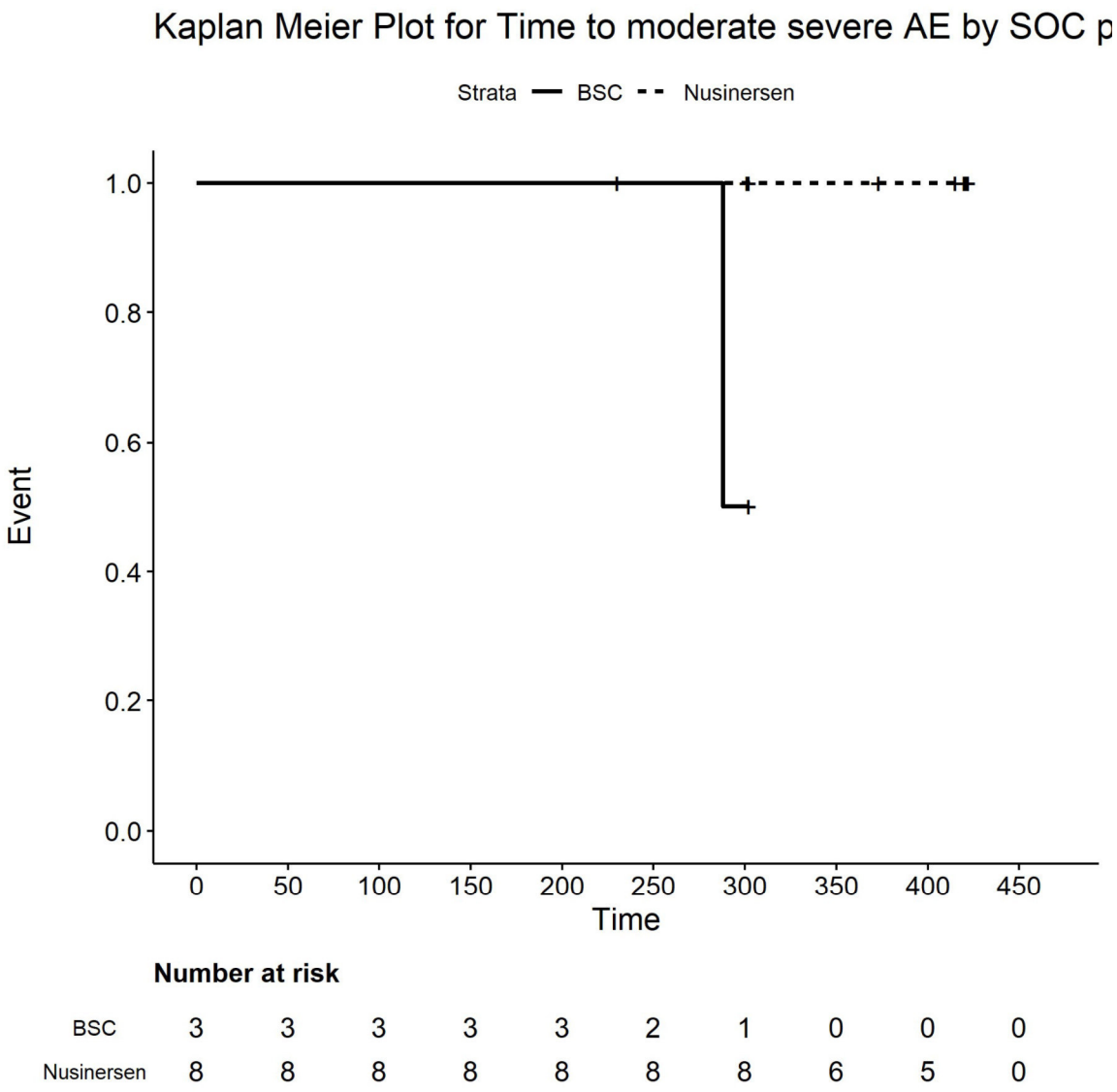
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	6	0



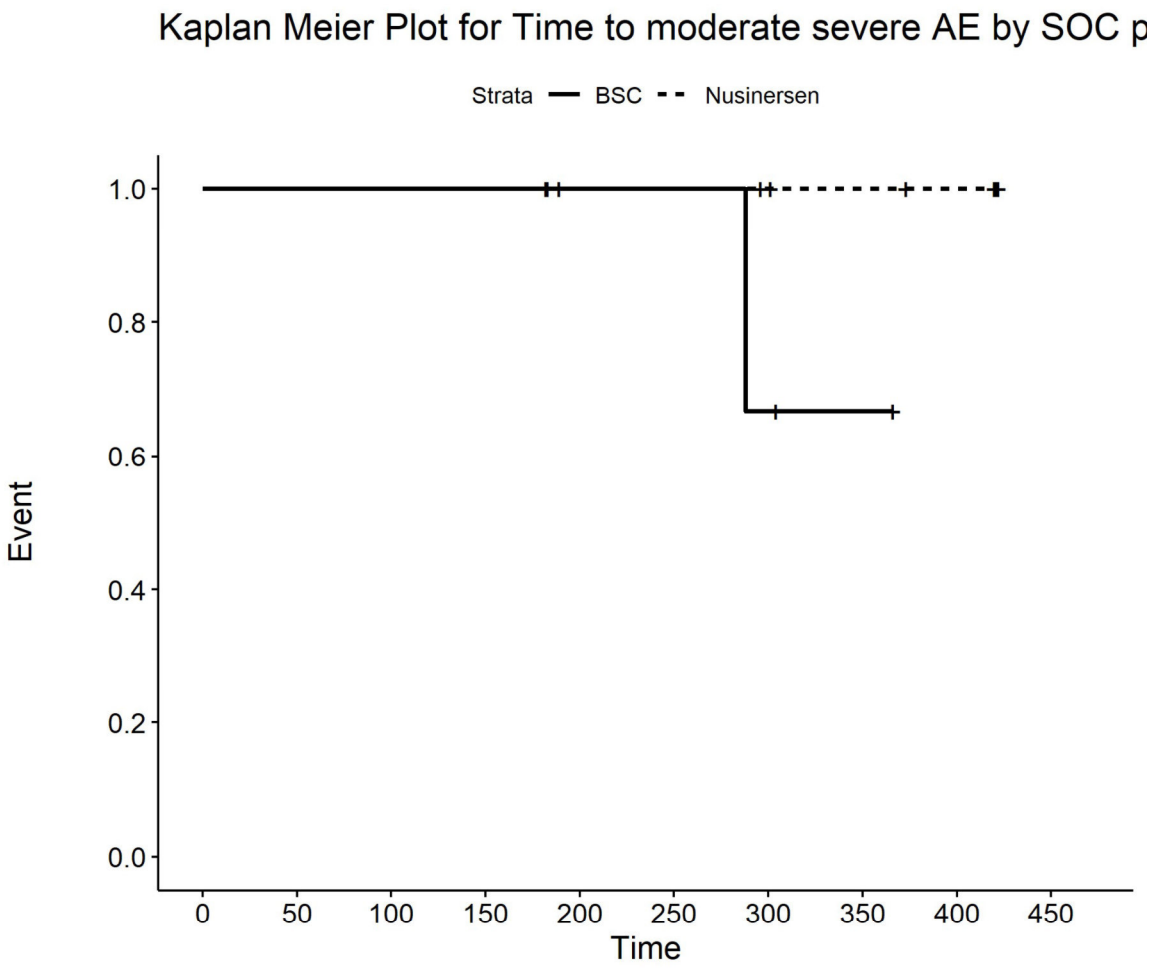
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	3	0



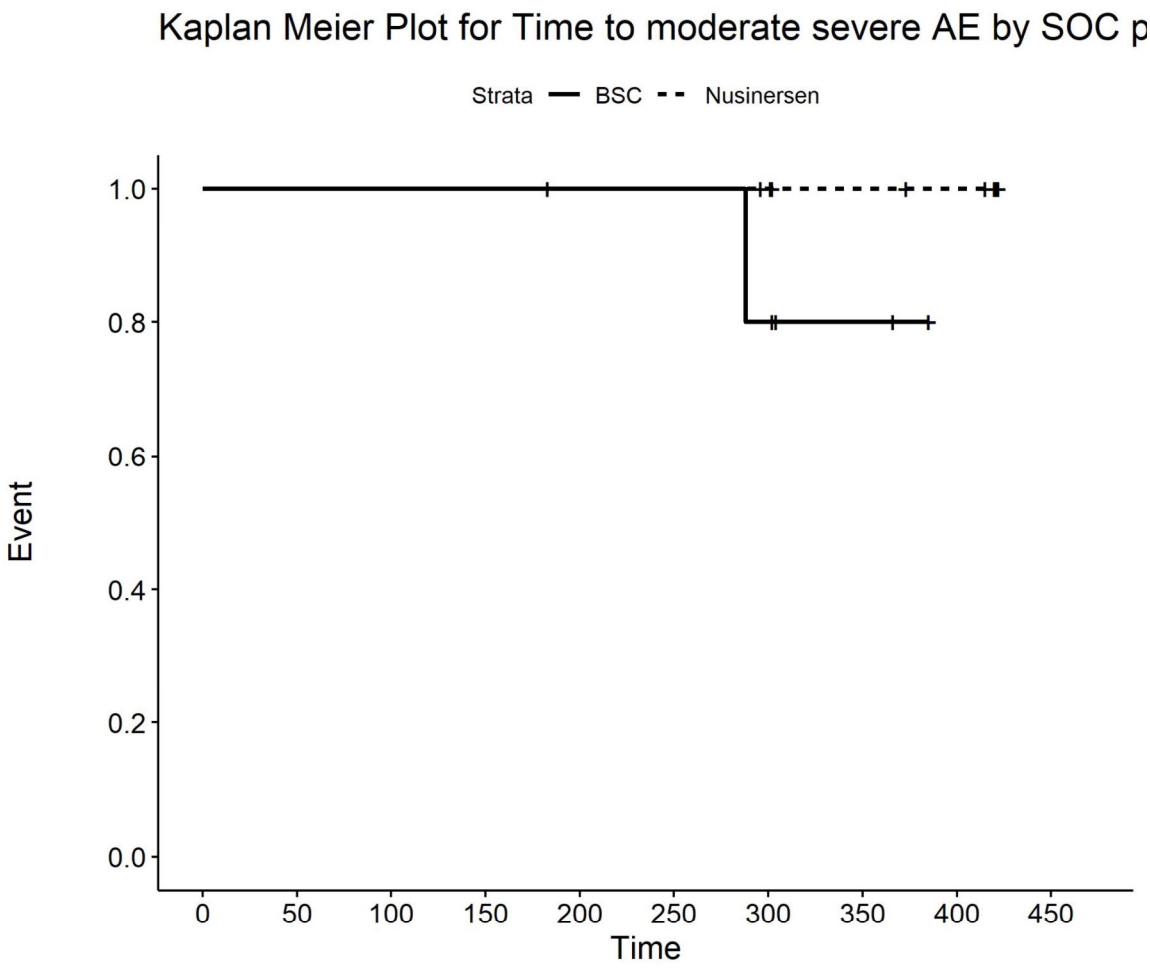
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



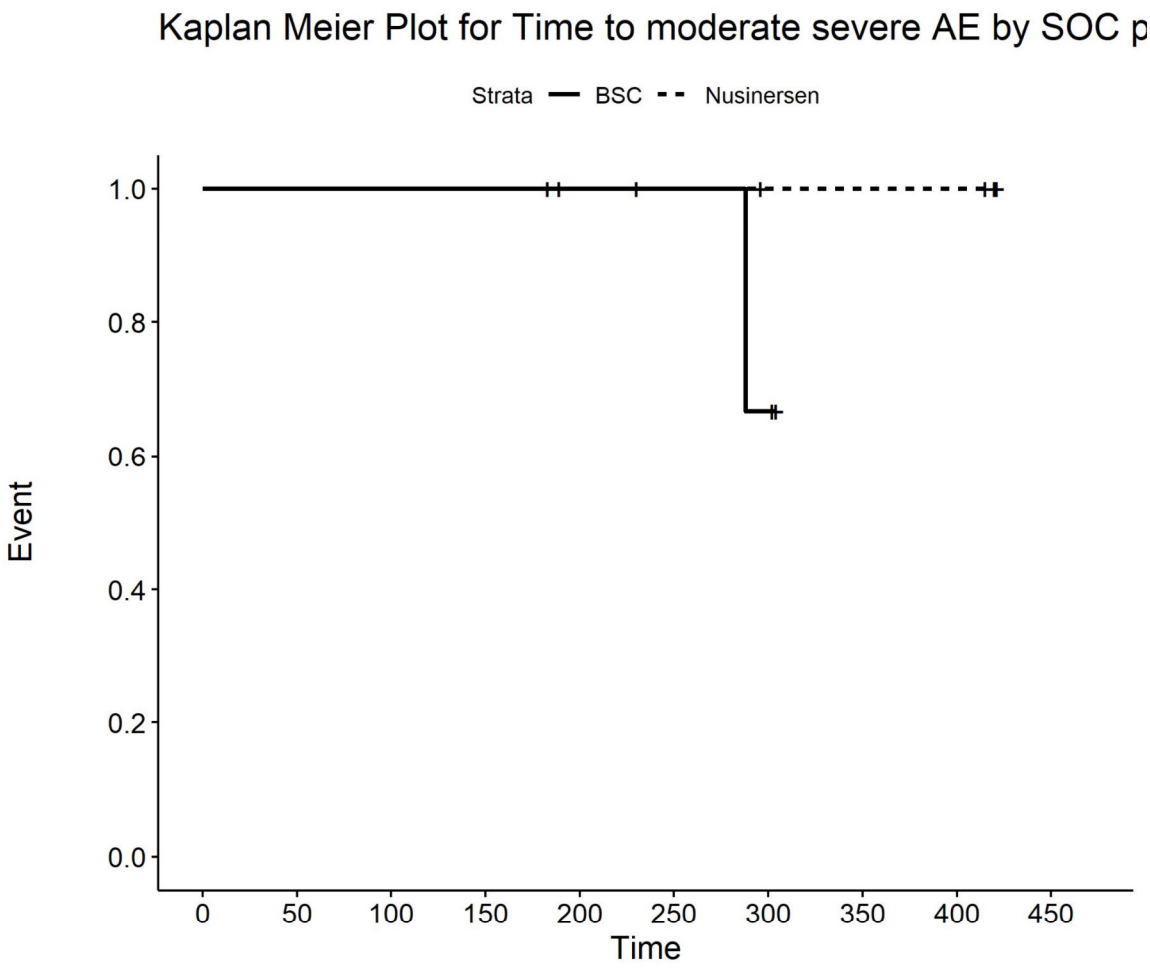
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



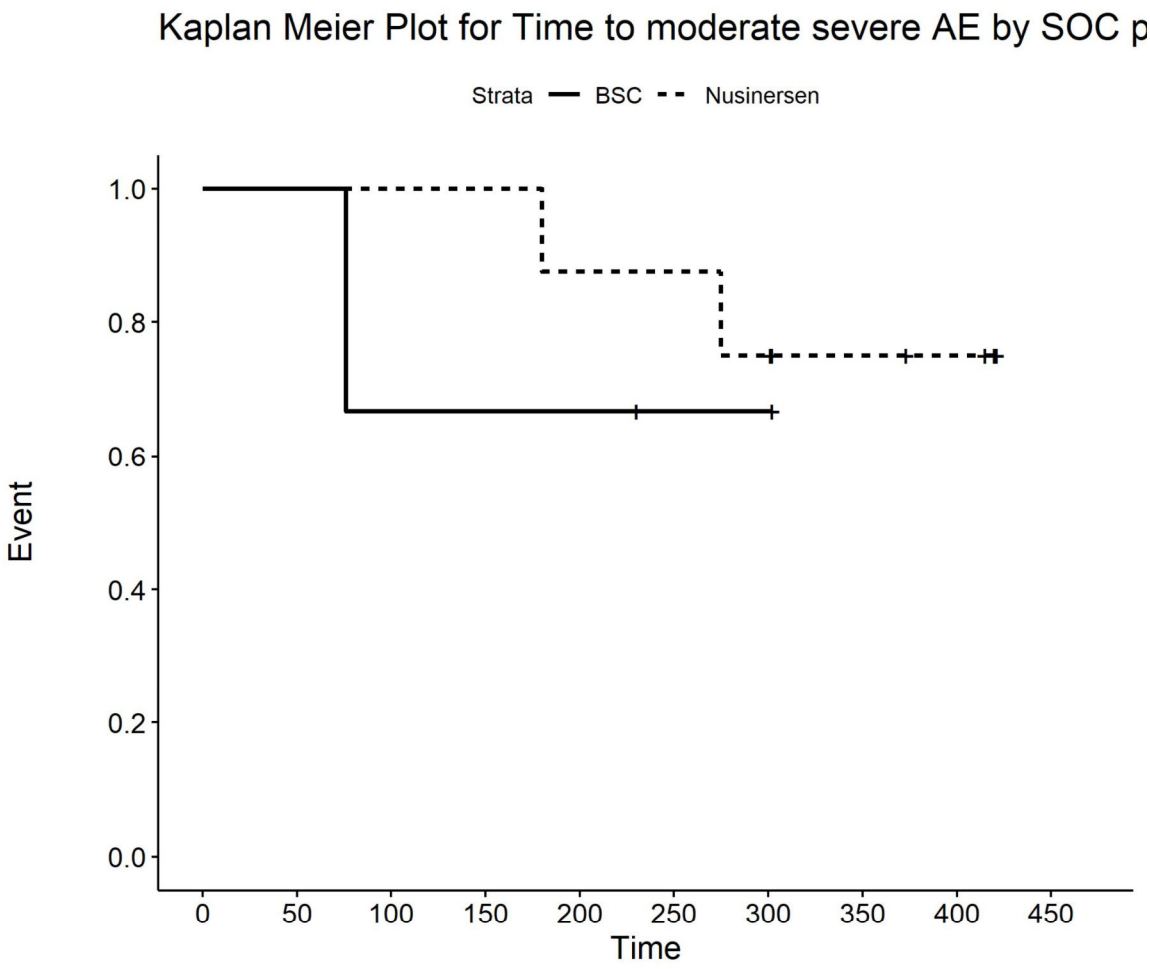
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



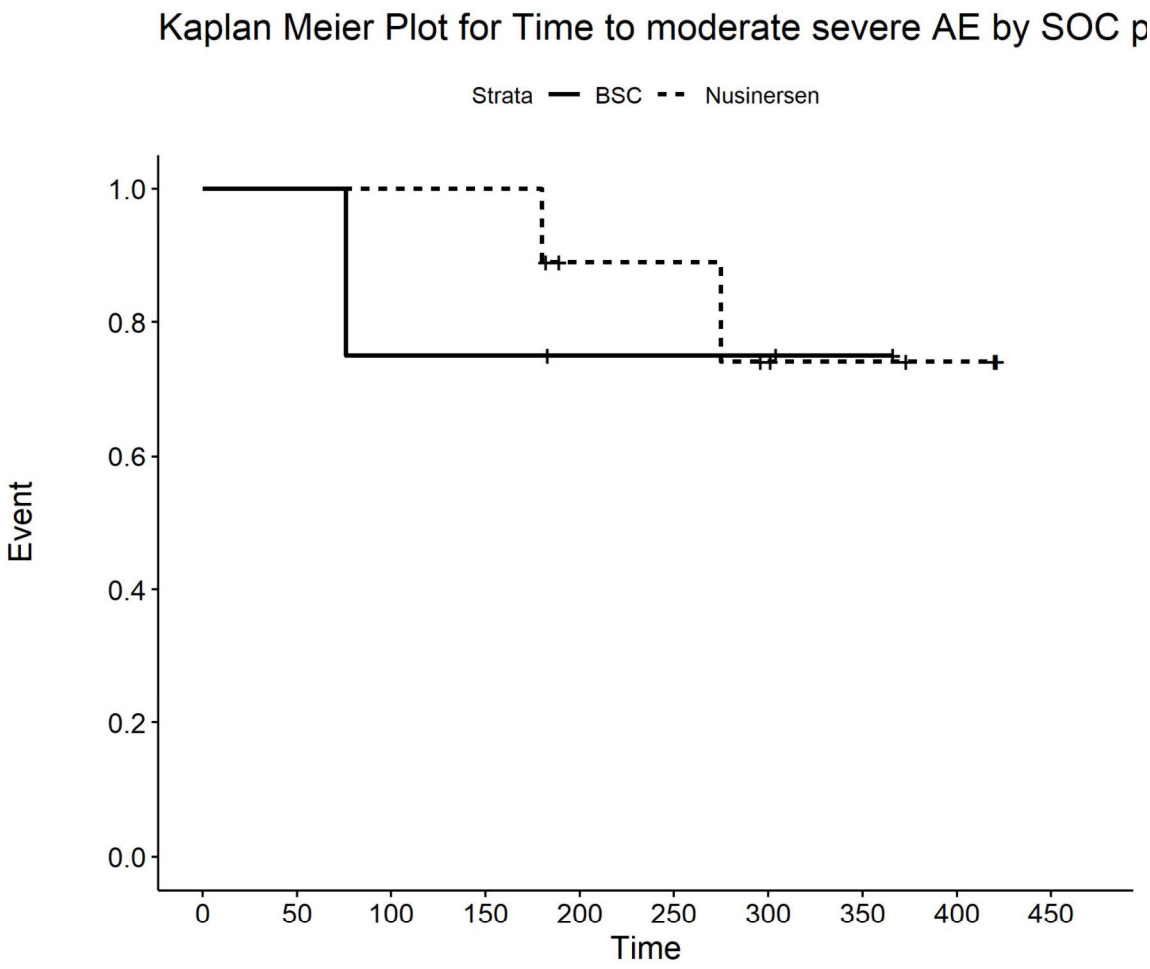
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



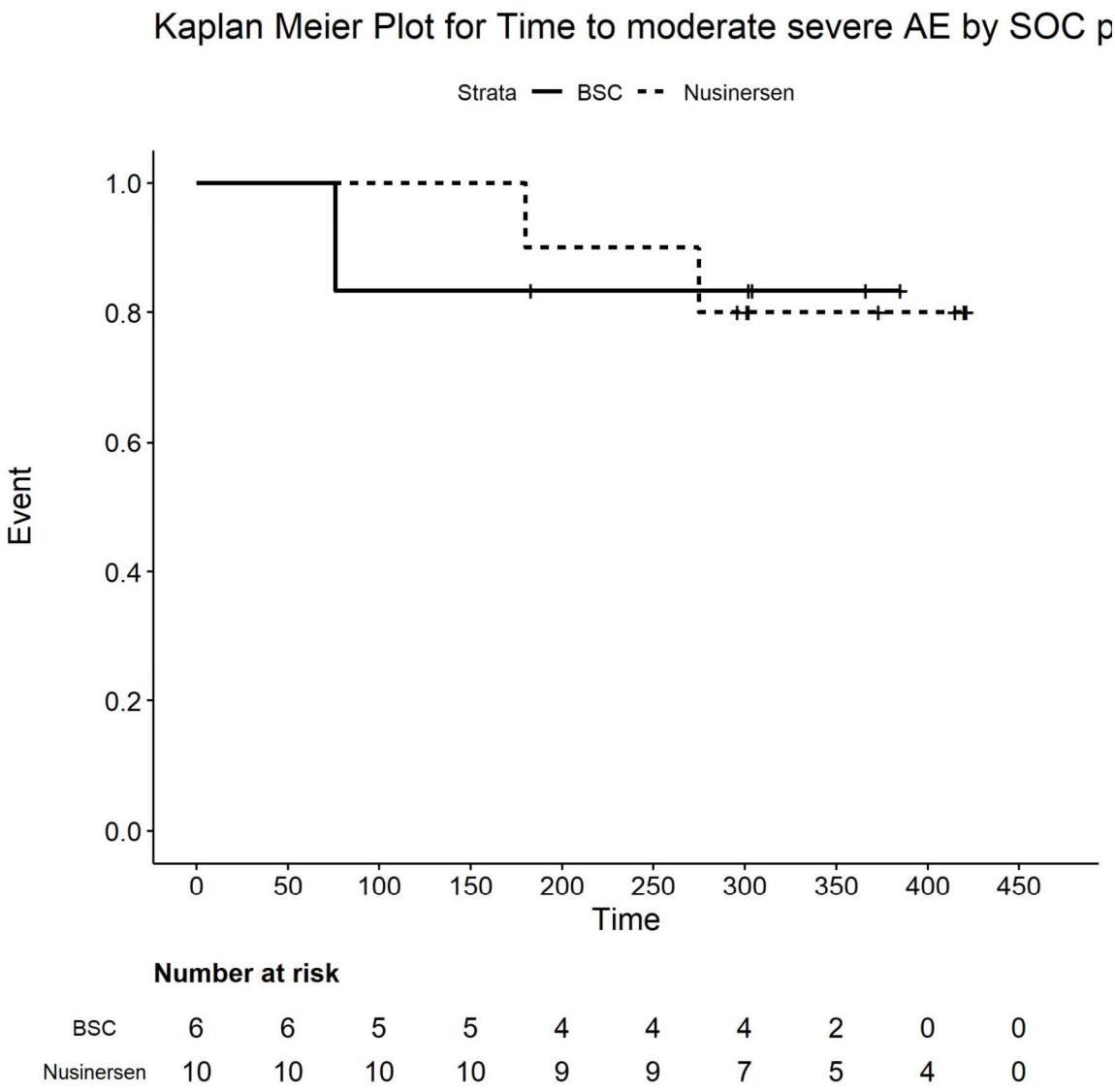
Number at risk

BSC	3	3	2	2	2	1	1	0	0	0
Nusinersen	8	8	8	8	7	7	6	4	3	0



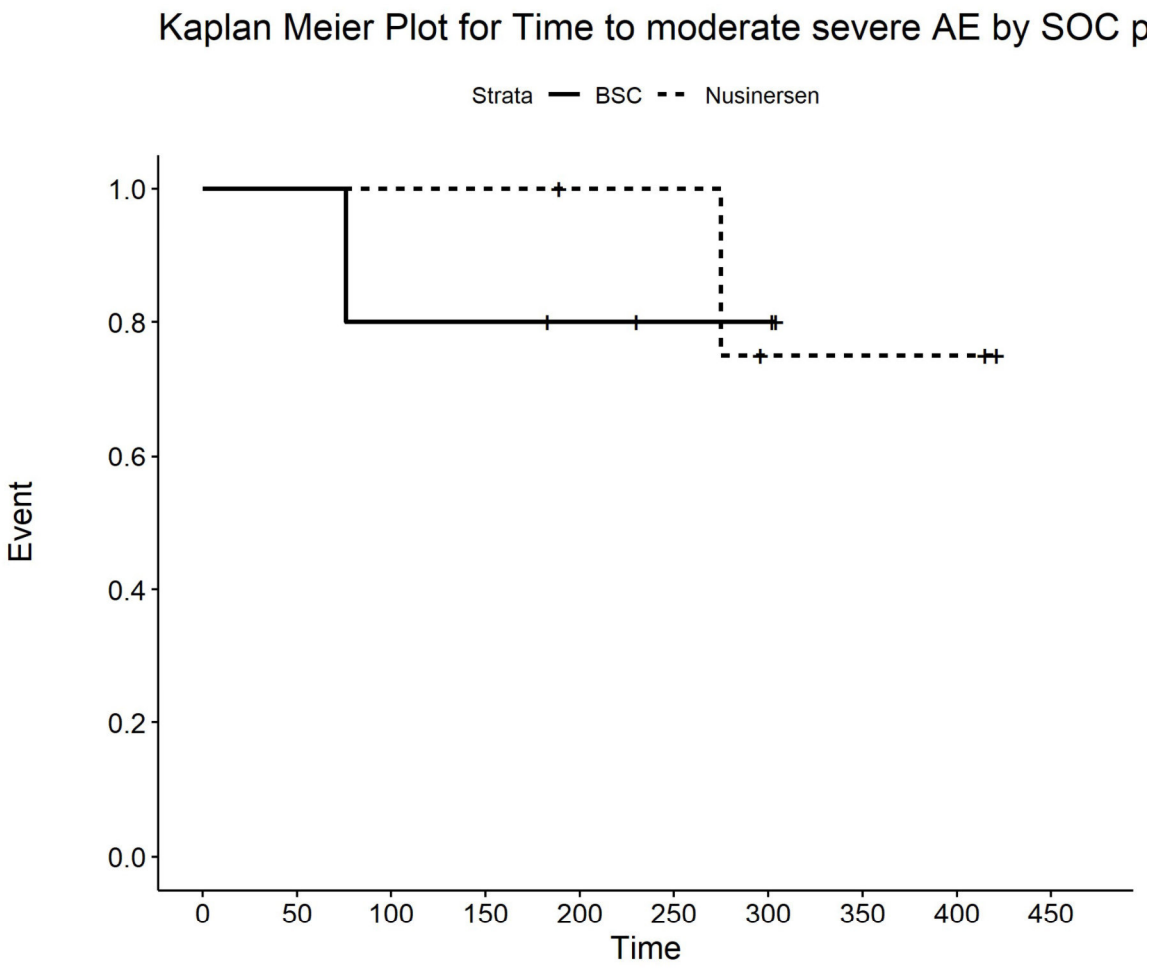
Number at risk

BSC	4	4	3	3	2	2	2	1	0	0
Nusinersen	9	9	9	9	6	6	4	3	2	0



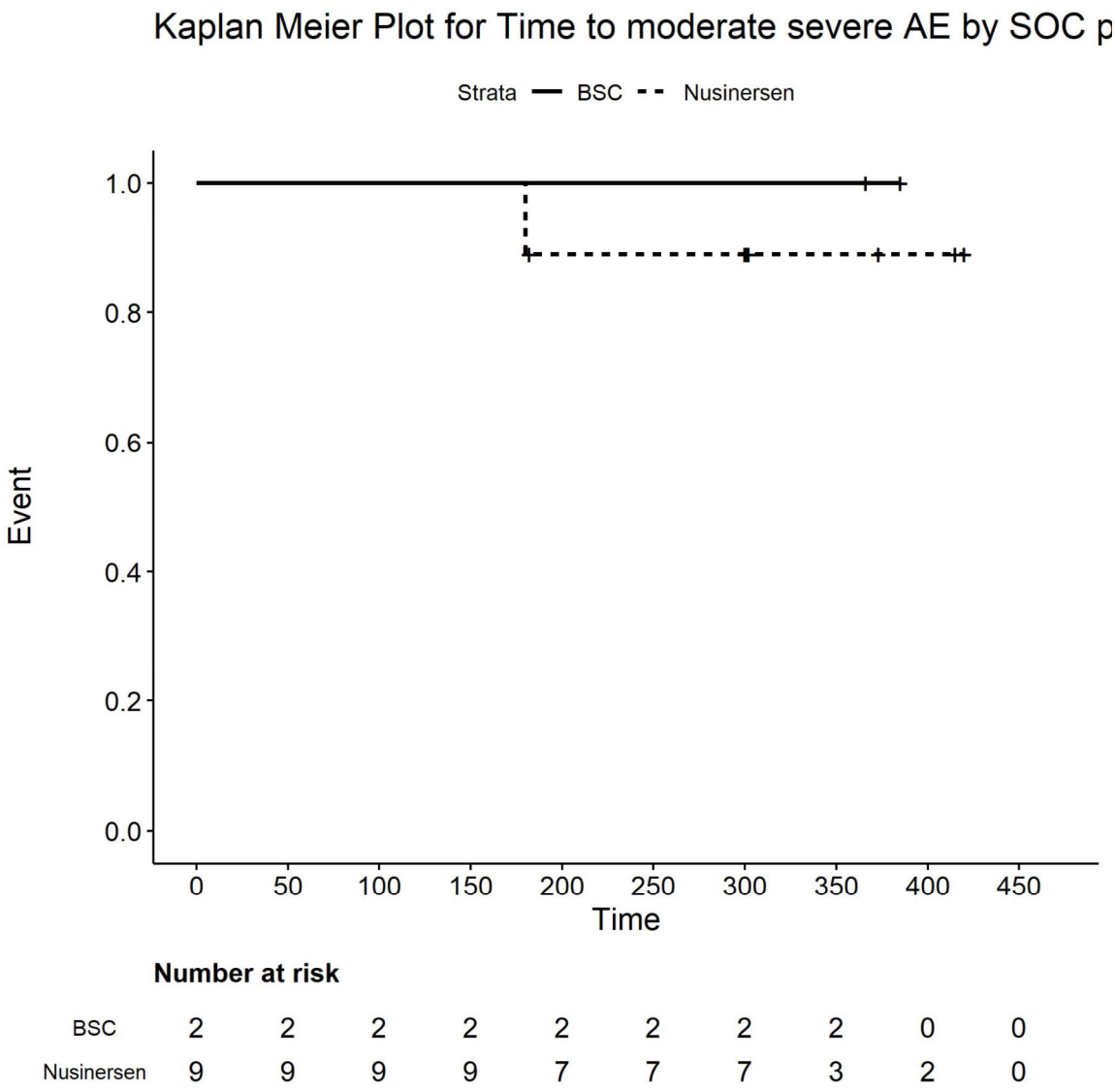
Number at risk

BSC	6	6	5	5	4	4	4	2	0	0
Nusinersen	10	10	10	10	9	9	7	5	4	0



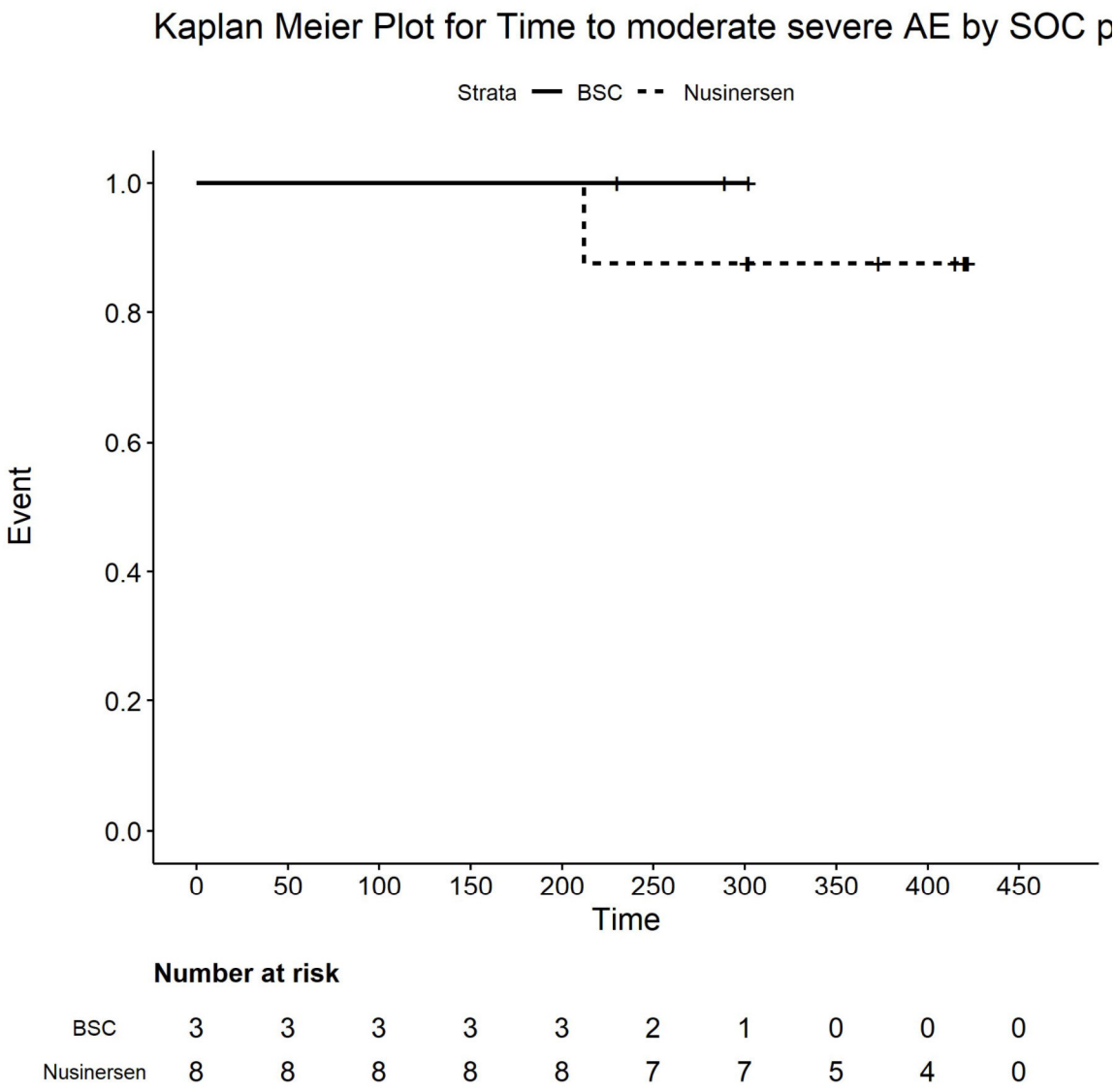
Number at risk

BSC	5	5	4	4	3	2	2	0	0	0
Nusinersen	5	5	5	5	4	4	2	2	2	0



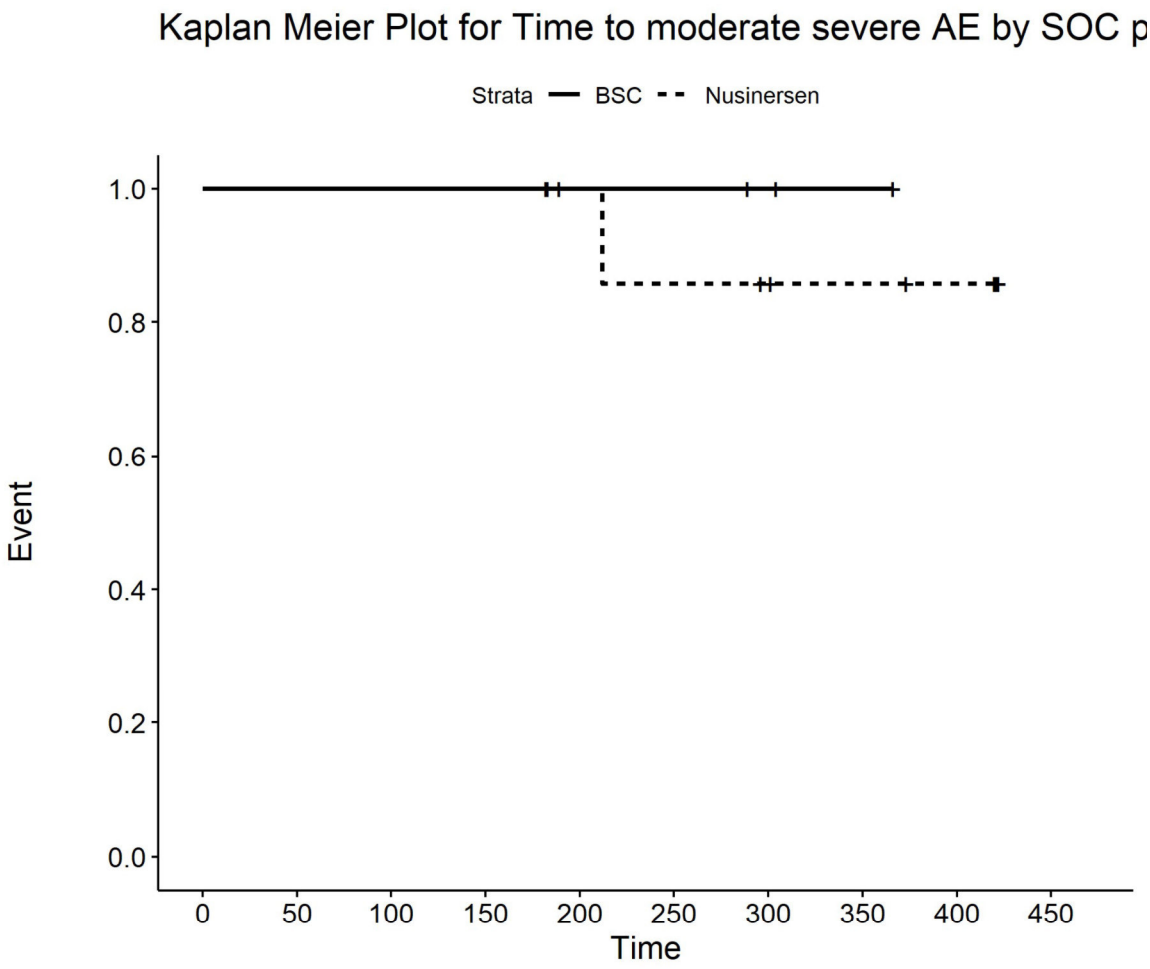
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	7	7	7	3	2	0



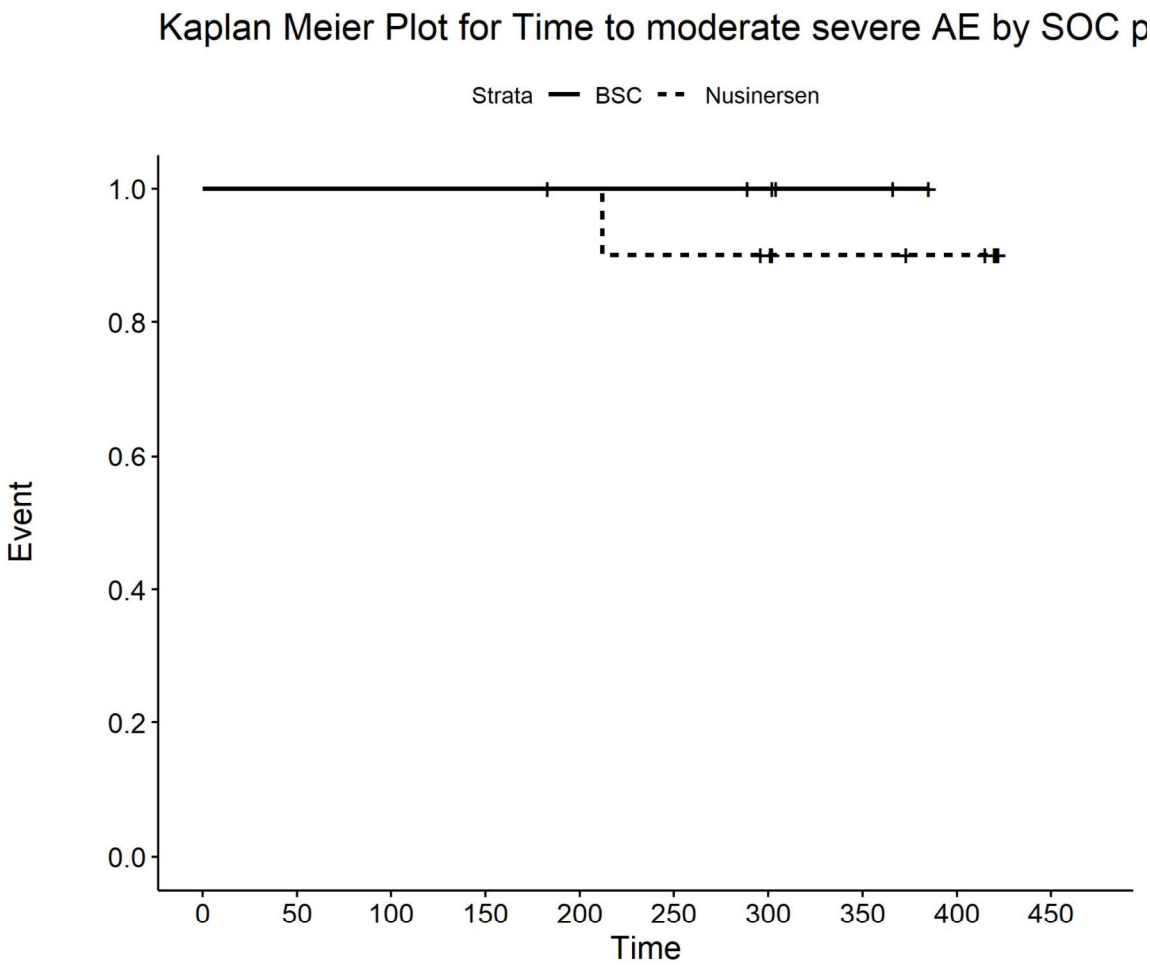
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



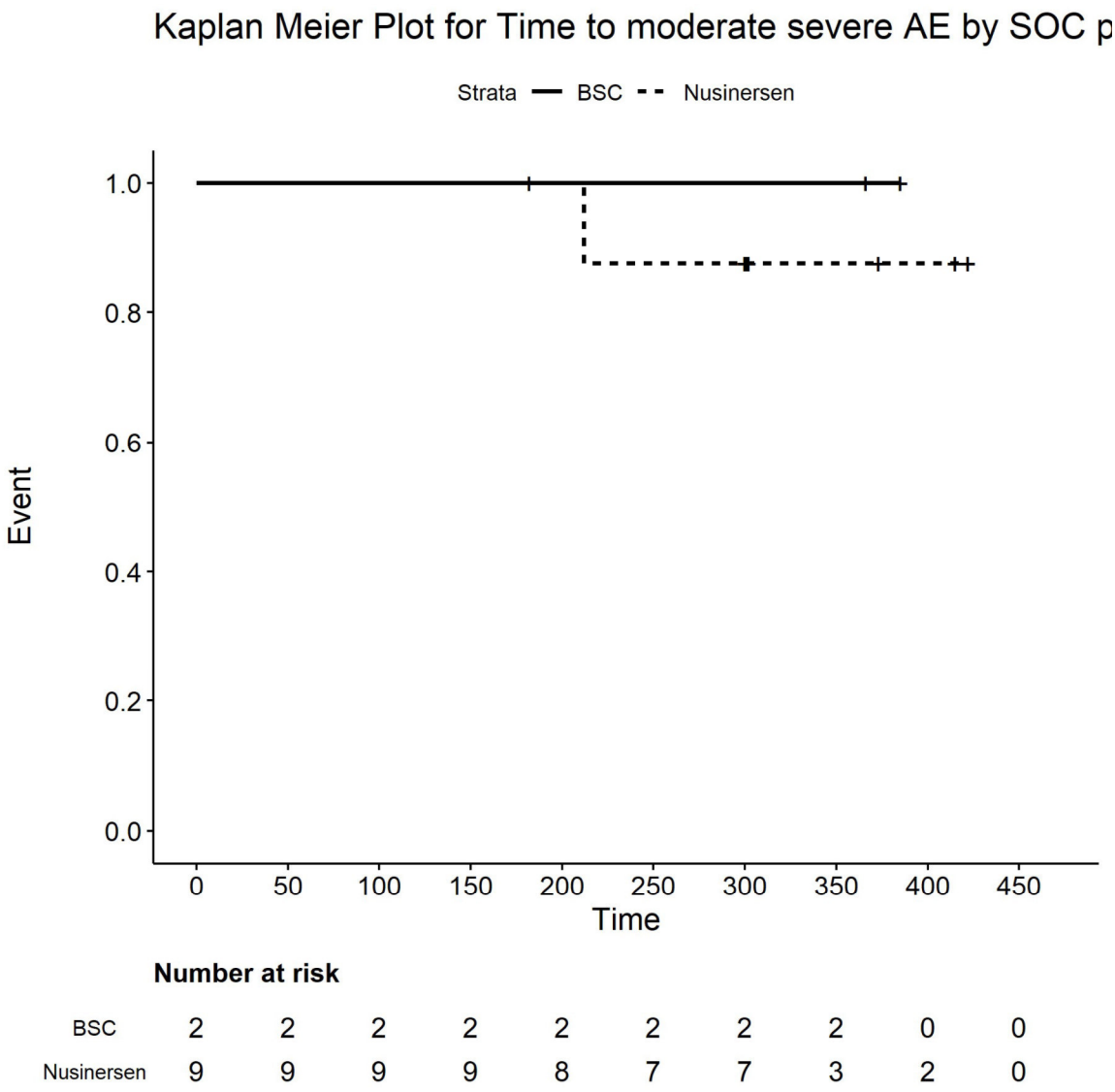
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



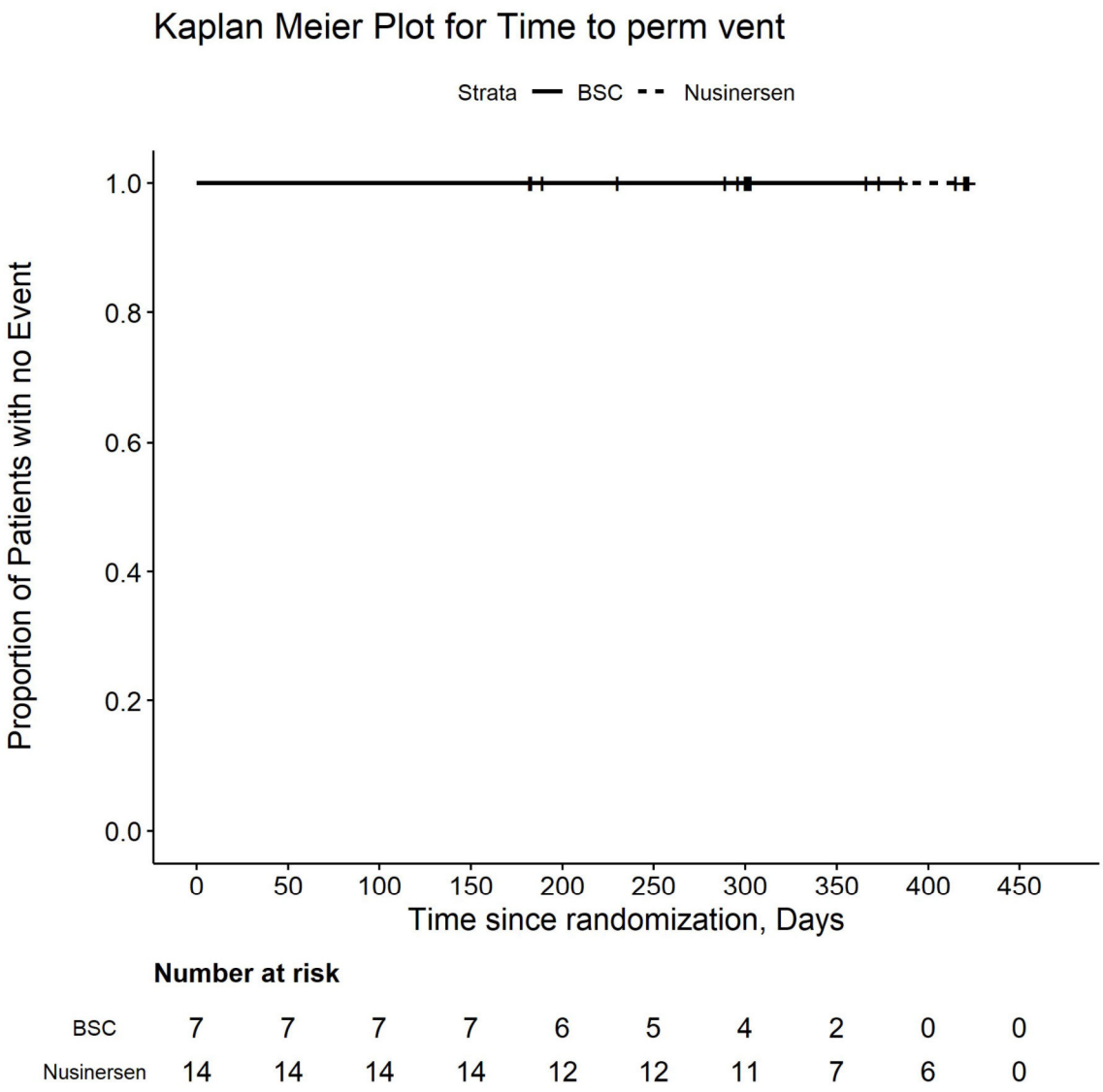
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



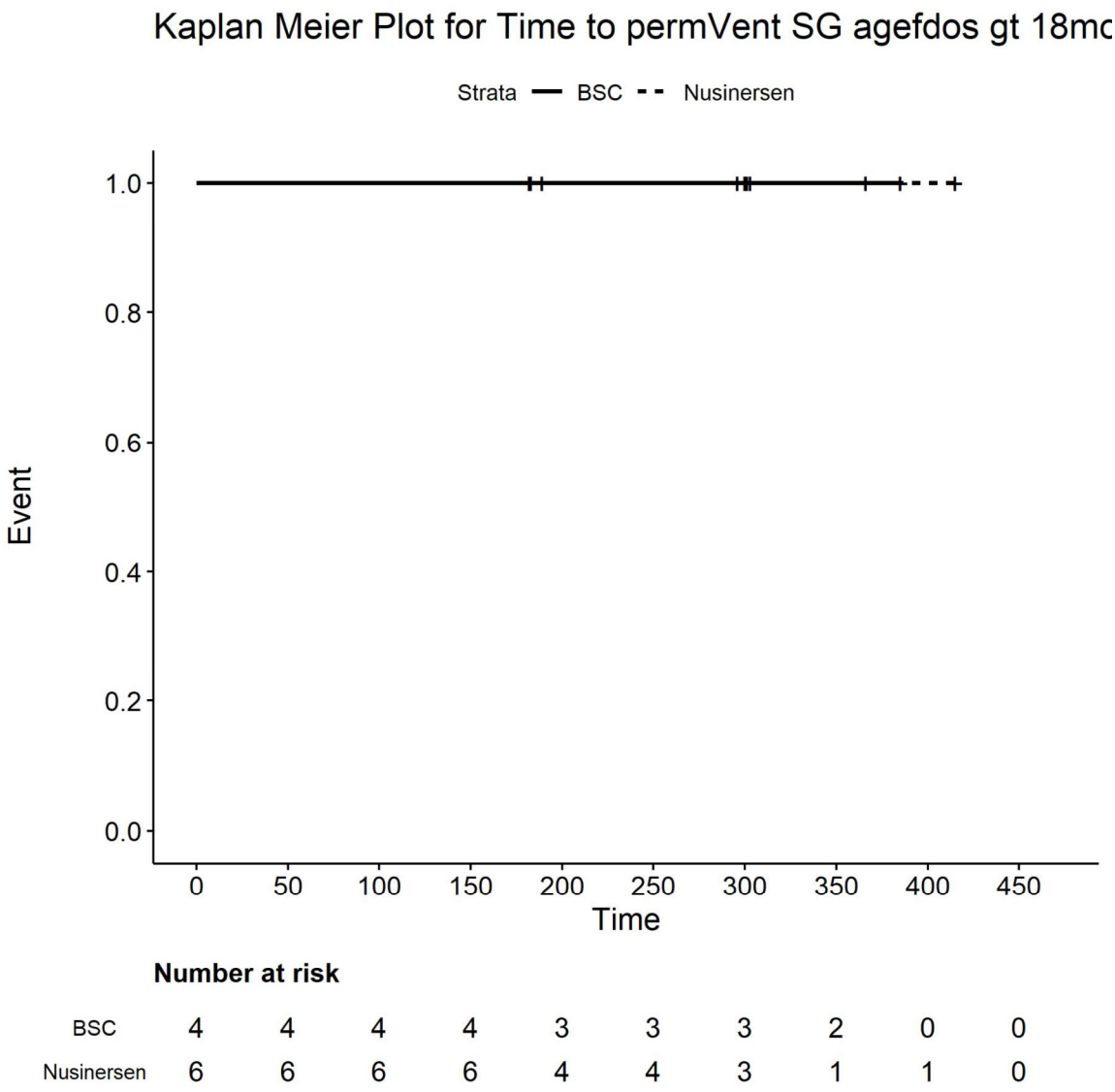
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	2	0



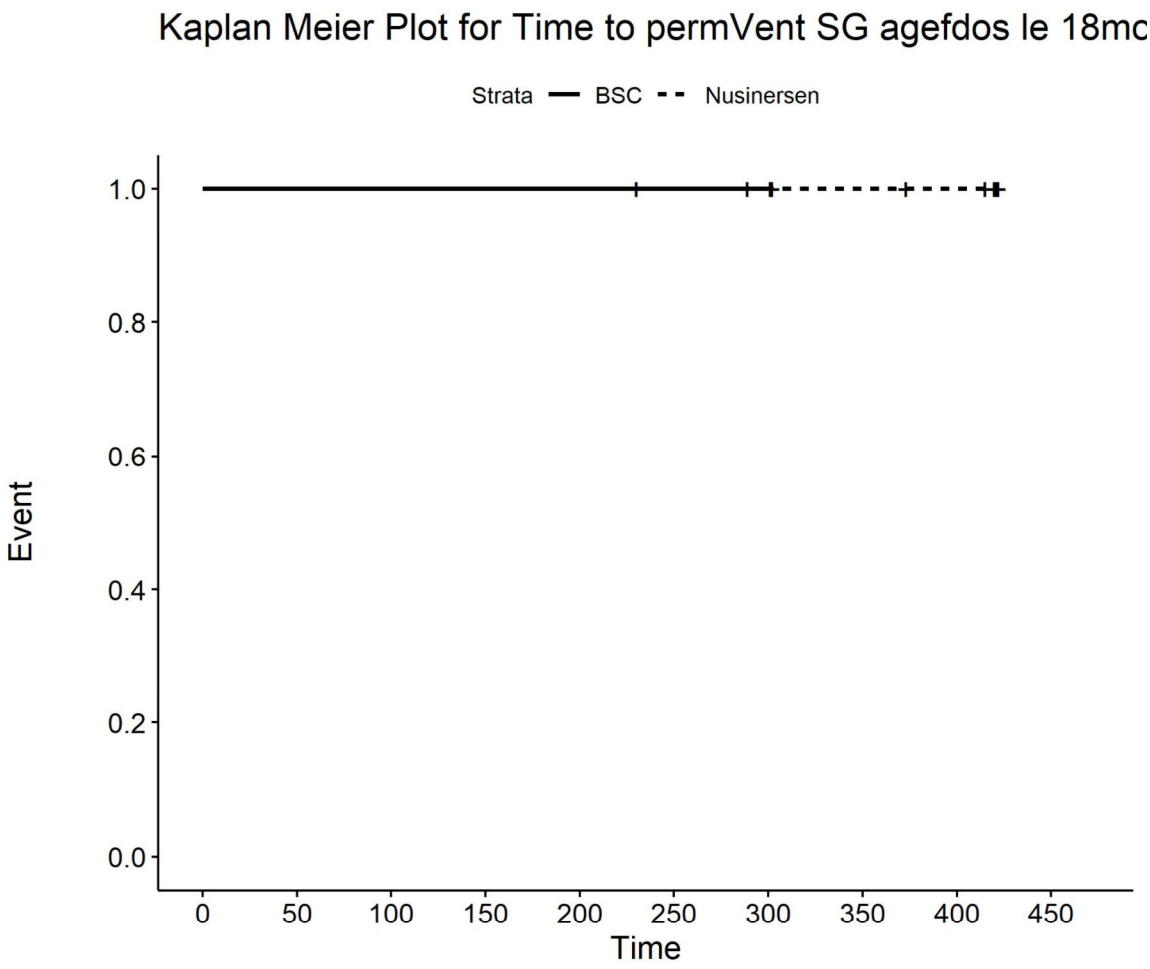
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



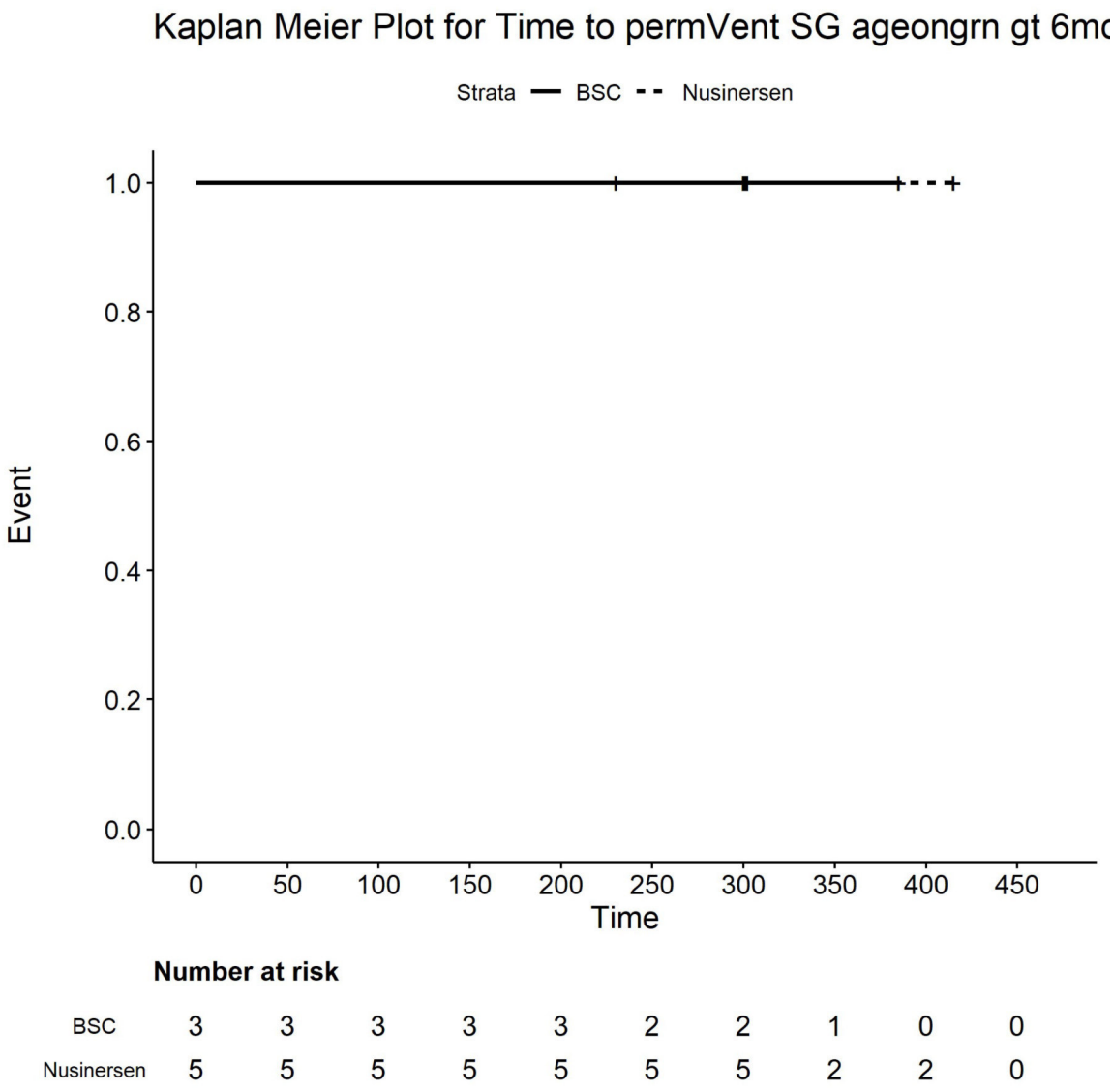
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



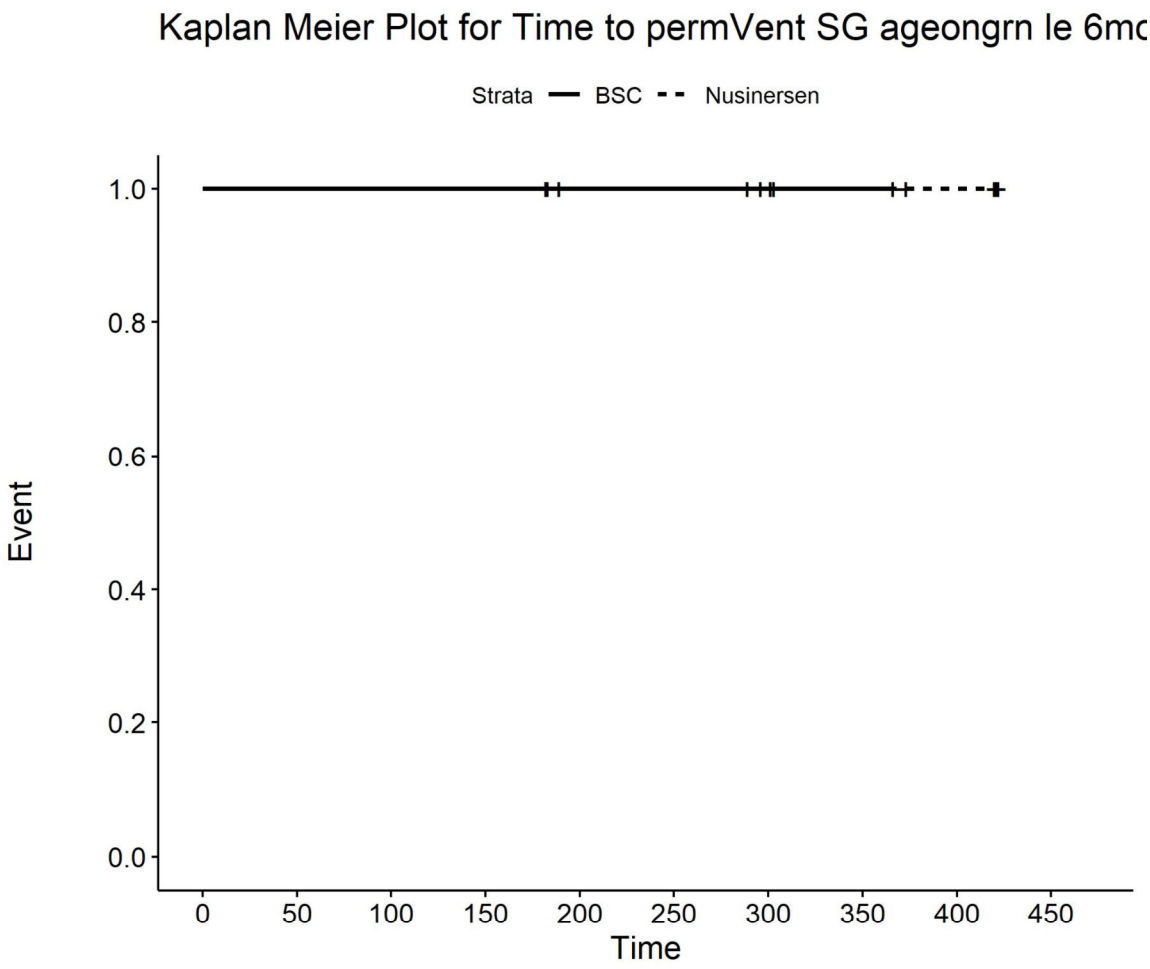
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



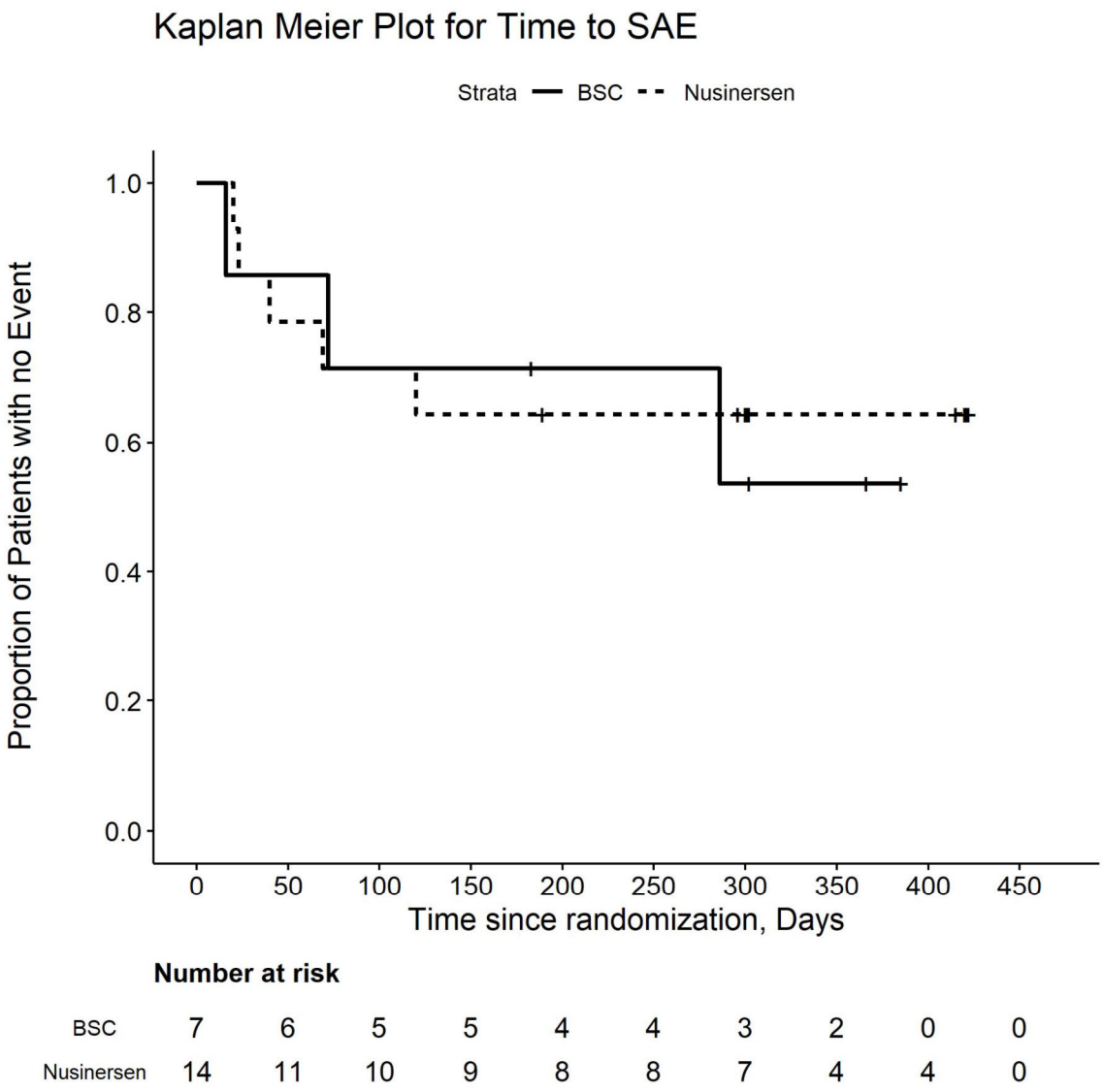
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



Number at risk

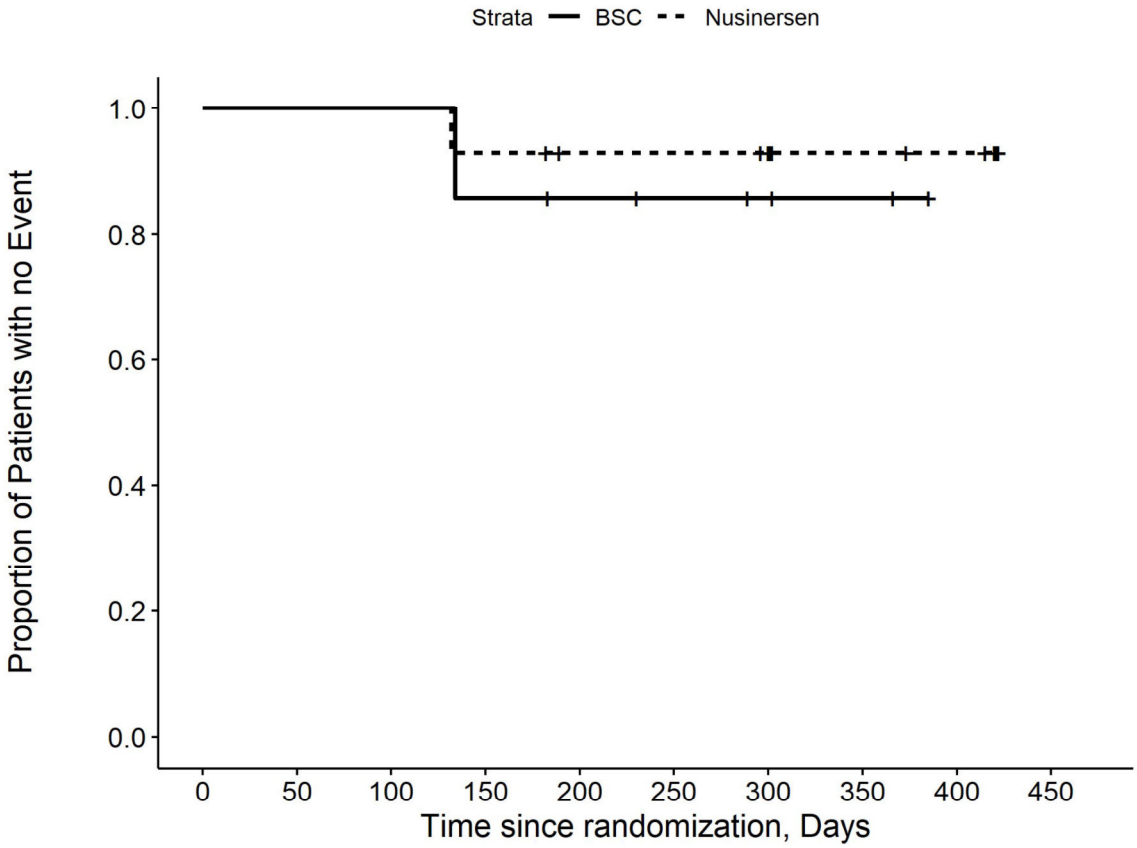
BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



Number at risk

BSC	7	6	5	5	4	4	3	2	0	0
Nusinersen	14	11	10	9	8	8	7	4	4	0

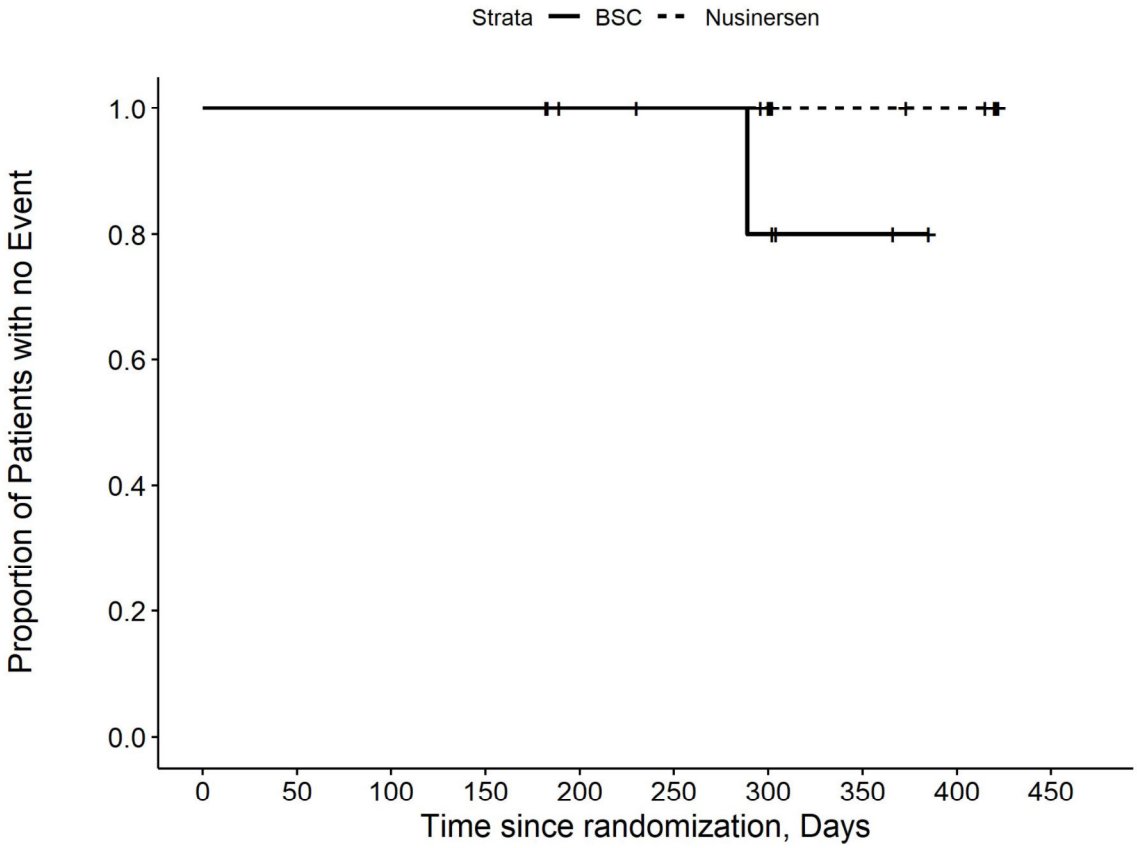
Kaplan Meier Plot for Time to SAE by PT pct
Acute respiratory failure



Number at risk

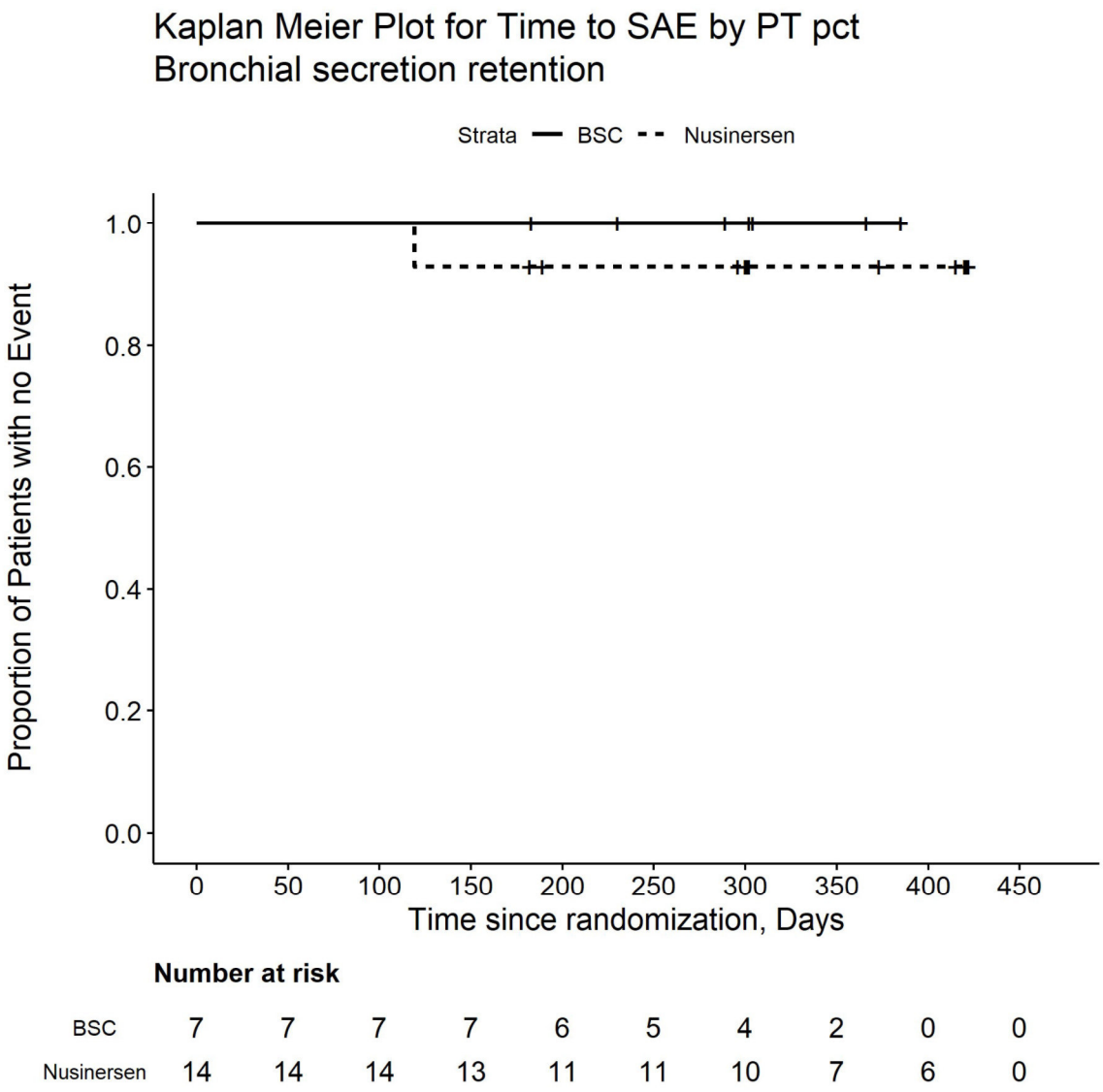
BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	13	11	11	10	6	5	0

Kaplan Meier Plot for Time to SAE by PT pct
Brain death



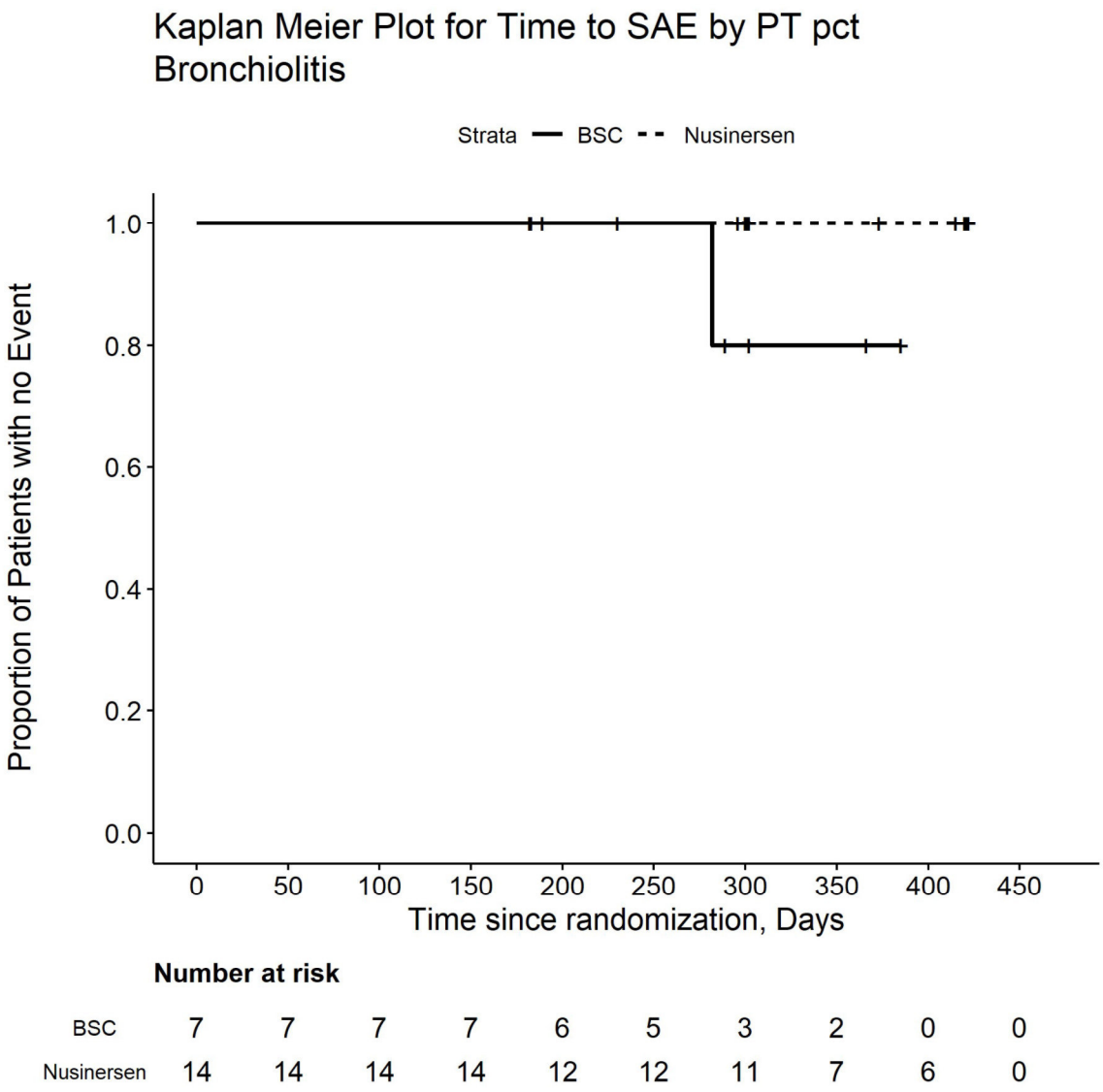
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

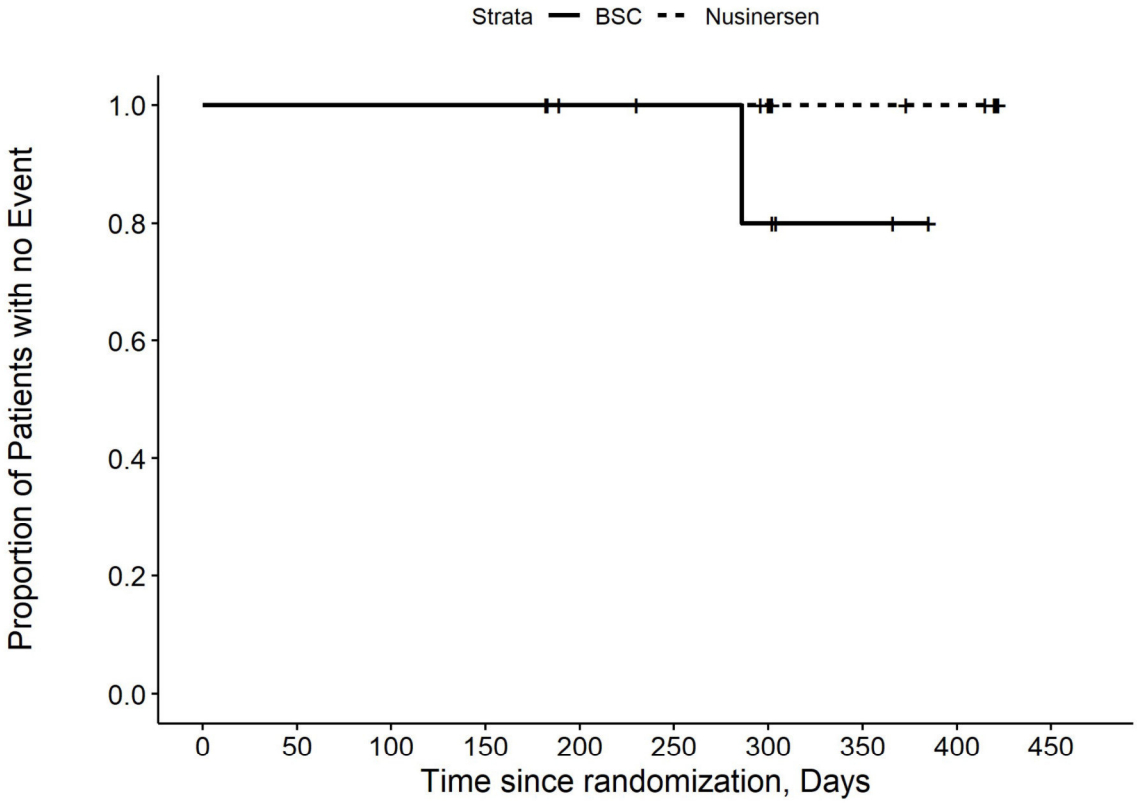
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	11	11	10	7	6	0



Number at risk

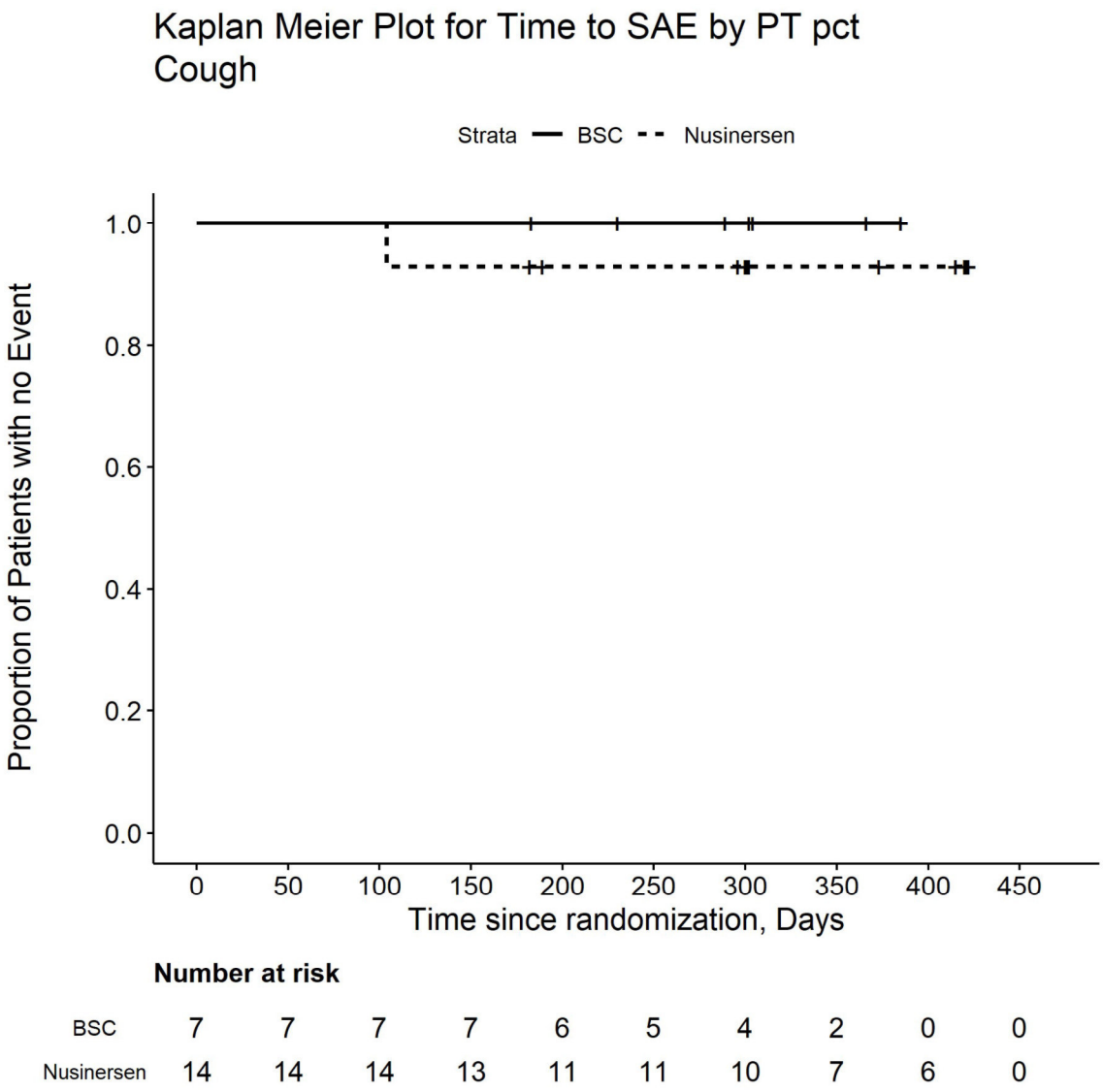
BSC	7	7	7	7	6	5	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for
Time to SAE by PT pct
Cardio : respiratory arrest



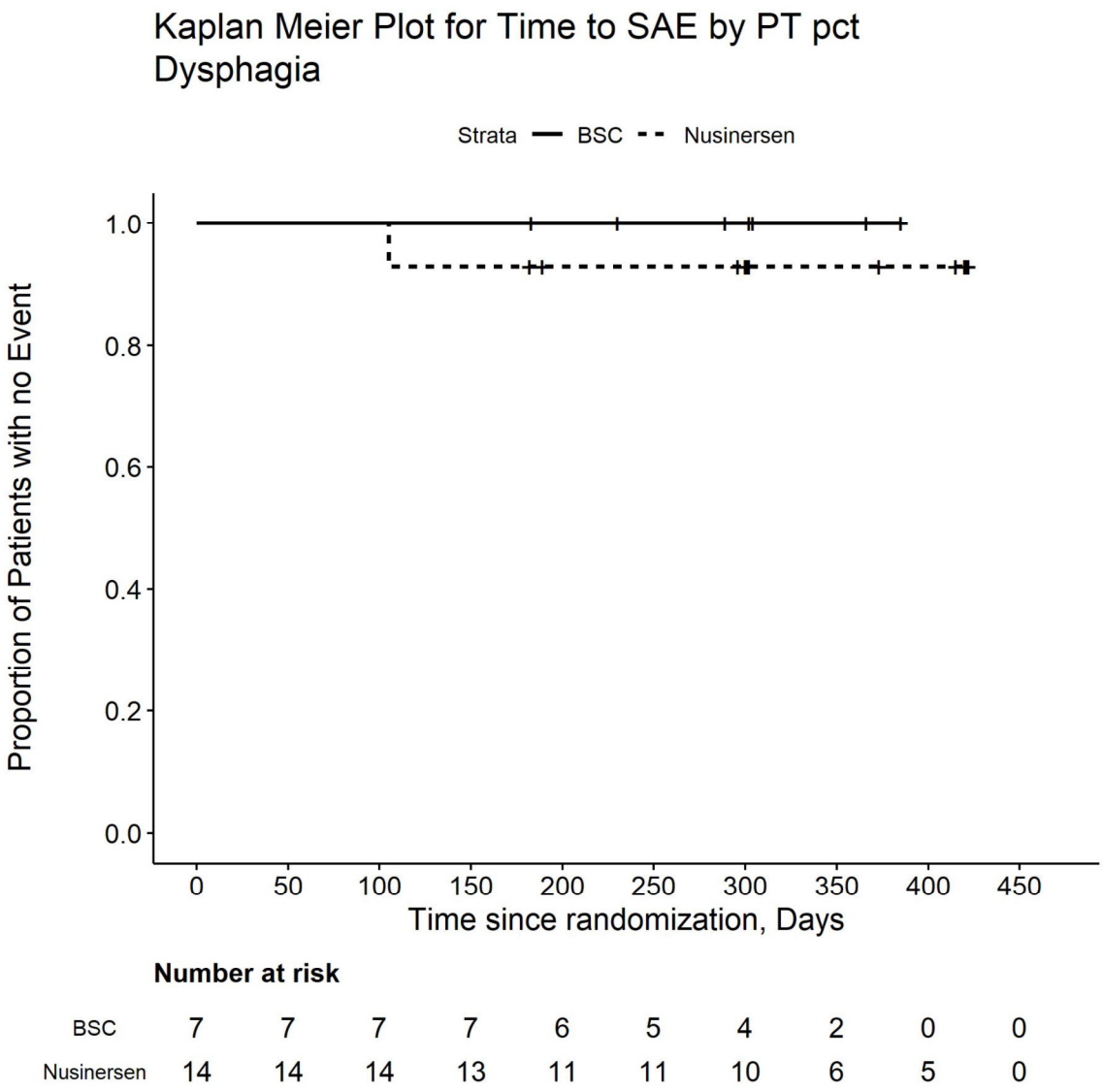
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



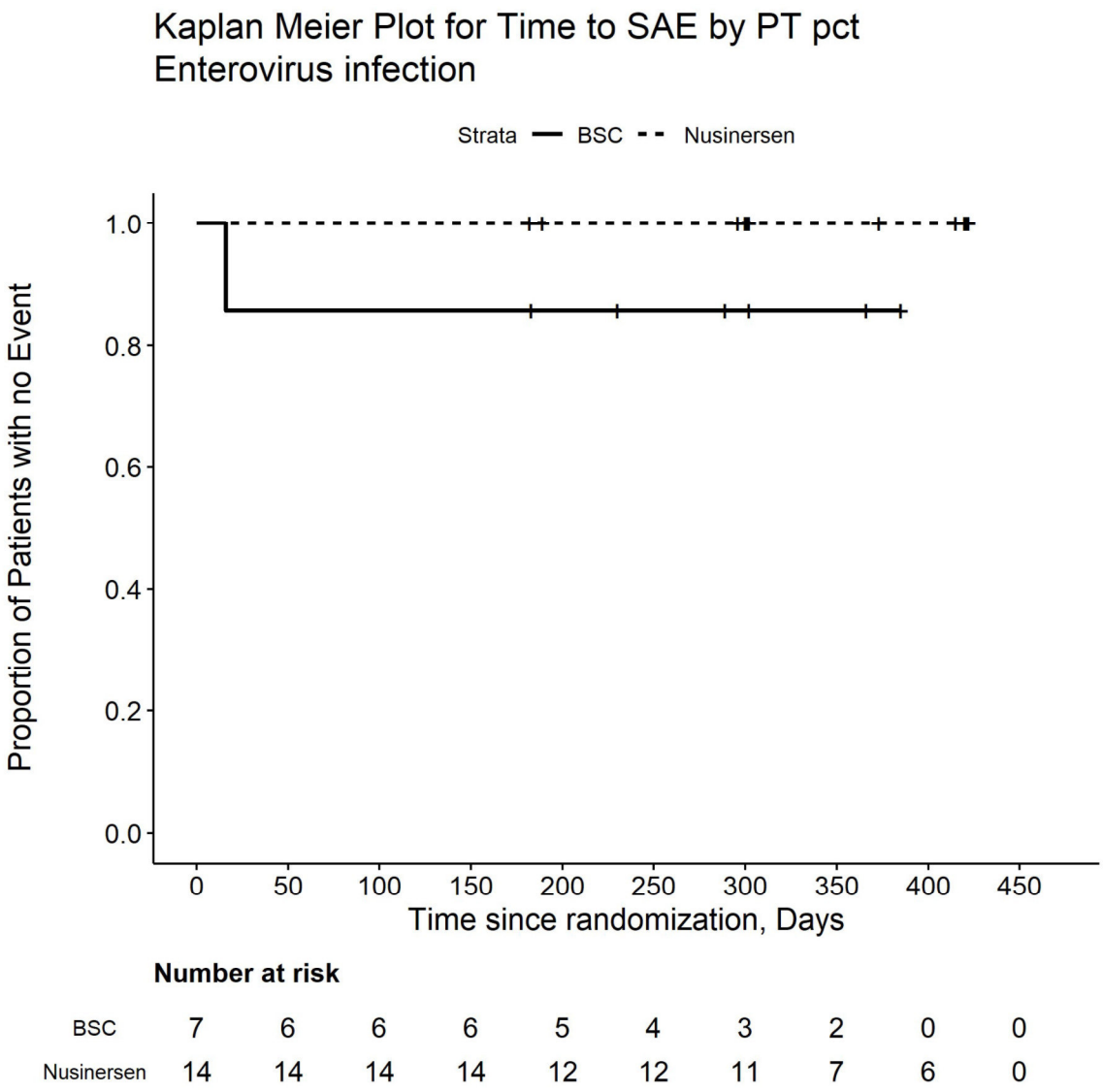
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	11	11	10	7	6	0



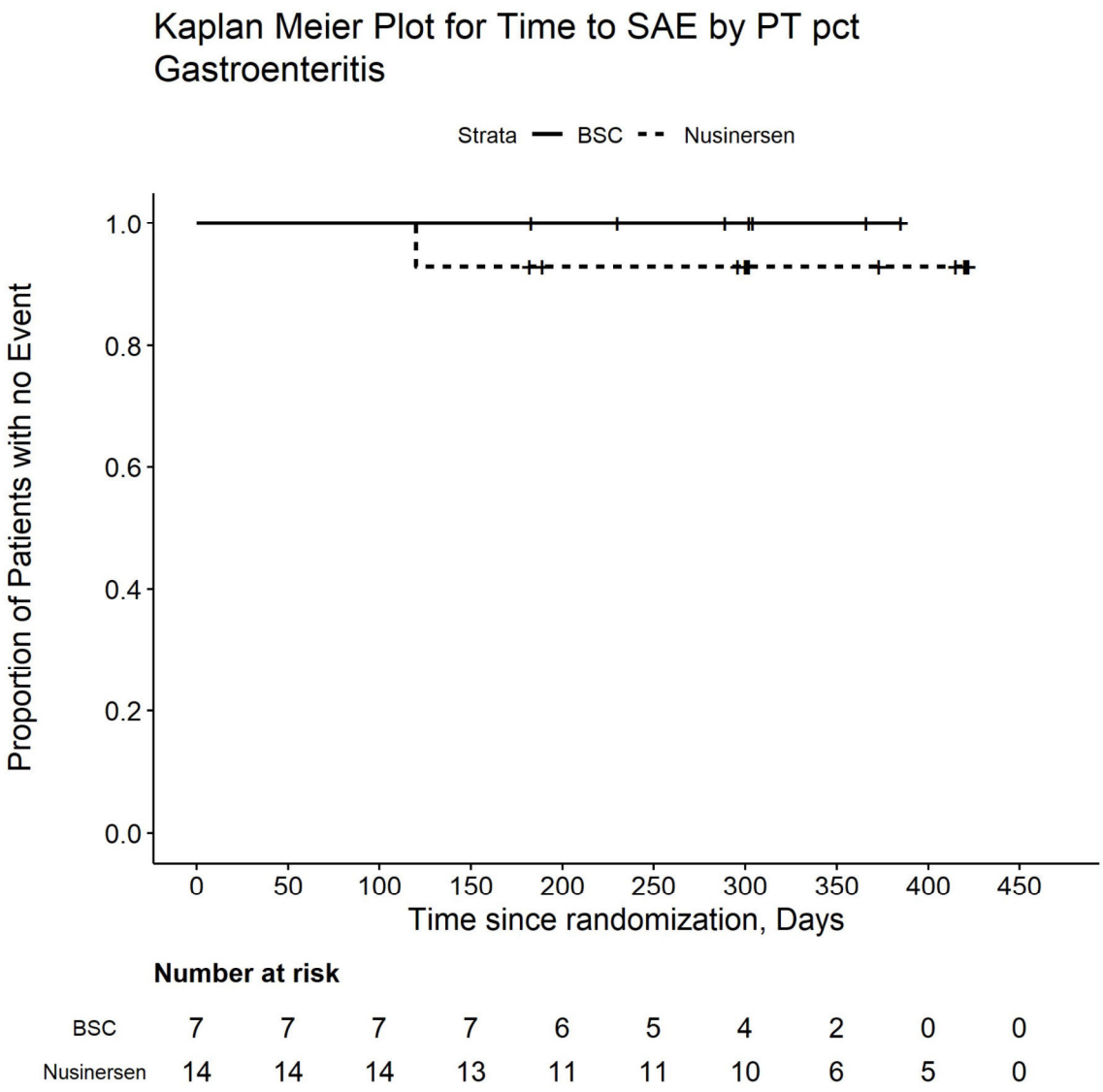
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	11	11	10	6	5	0



Number at risk

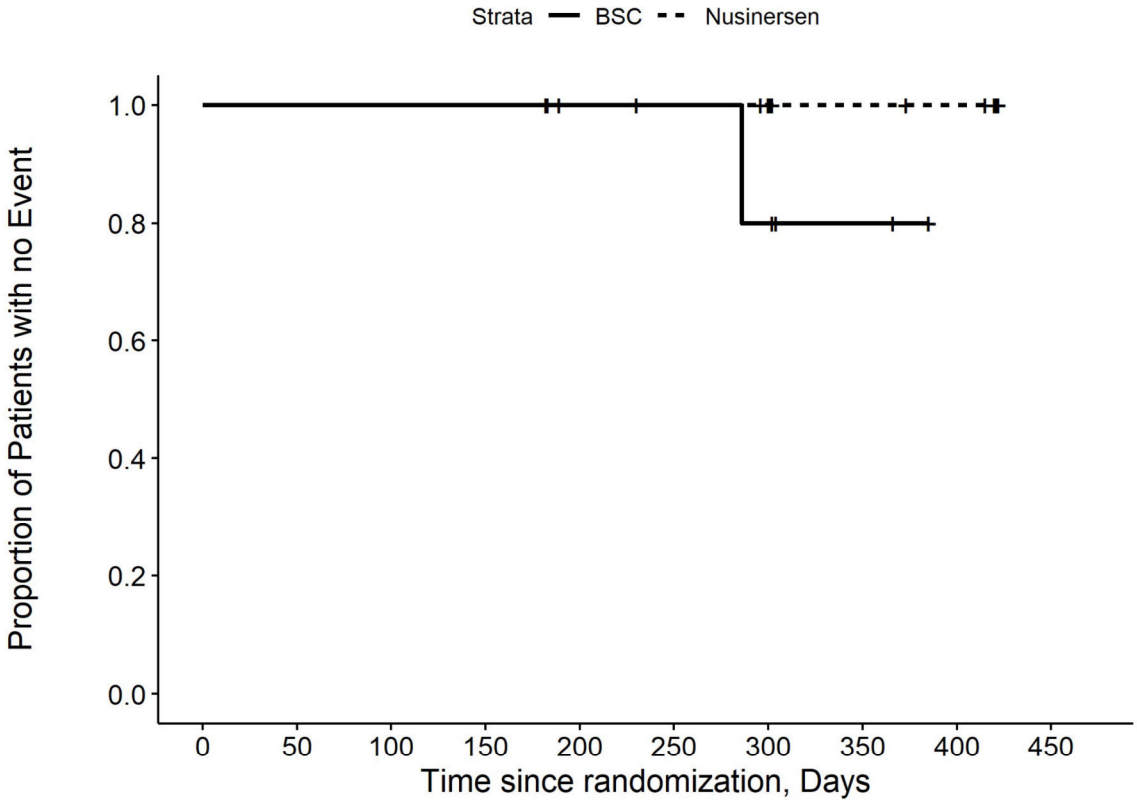
BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

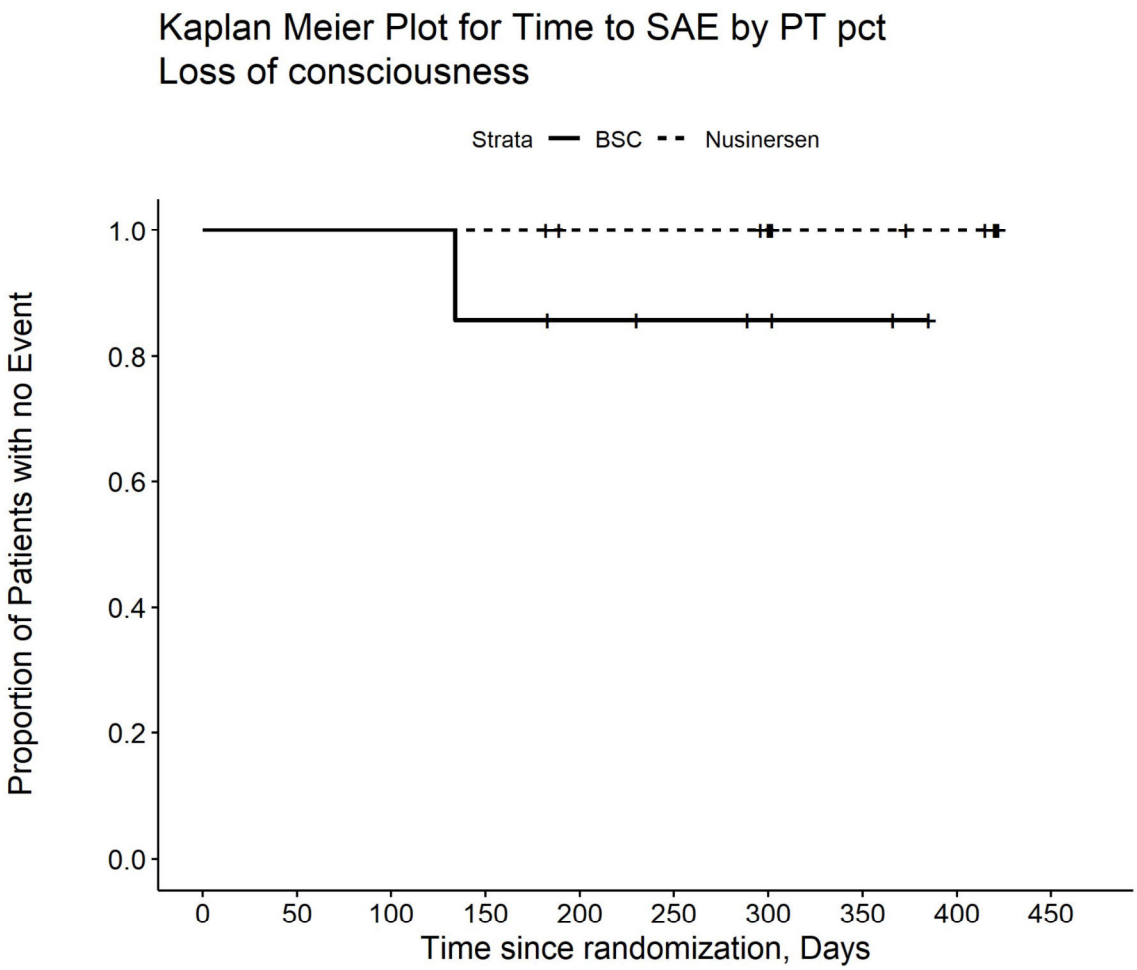
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	11	11	10	6	5	0

Kaplan Meier Plot for
Time to SAE by PT pct
Hypoxic : ischaemic encephalopathy



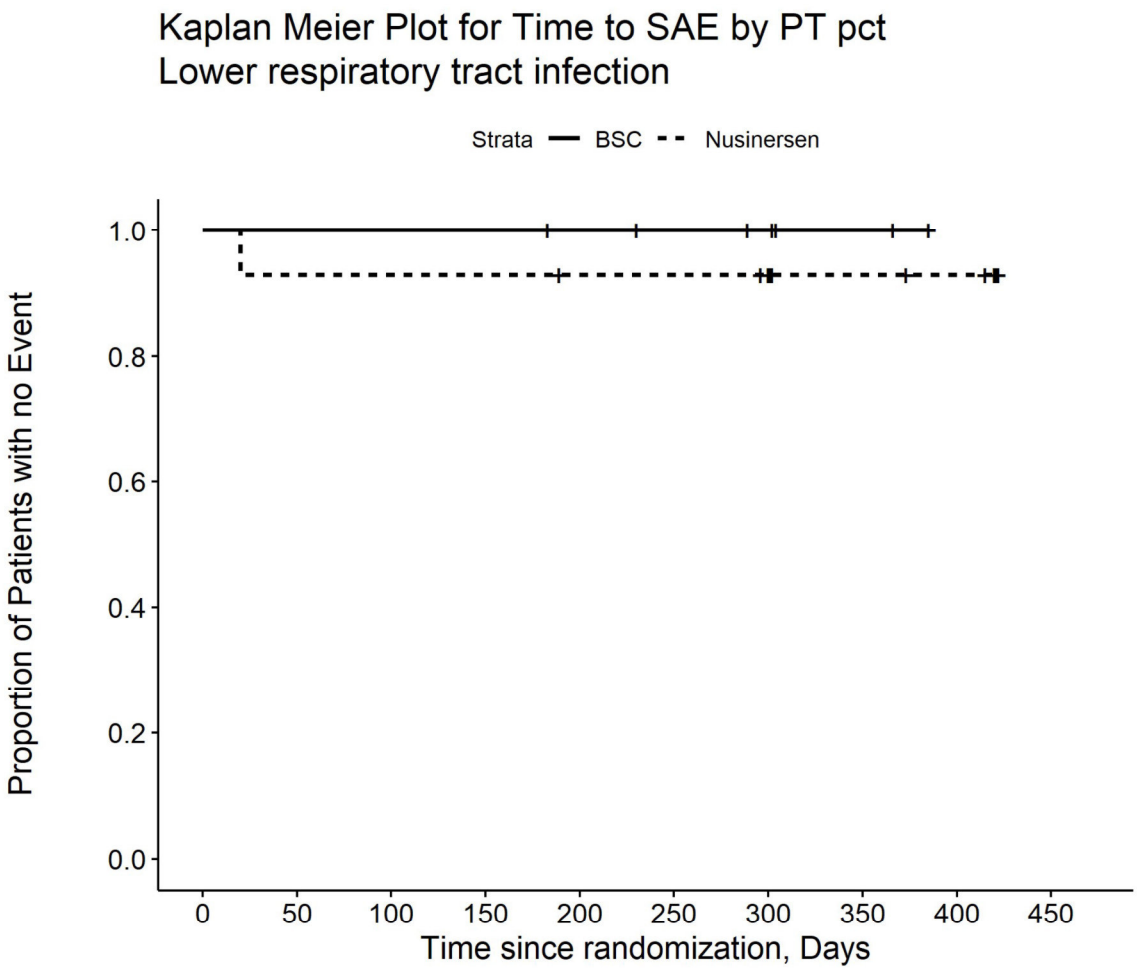
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



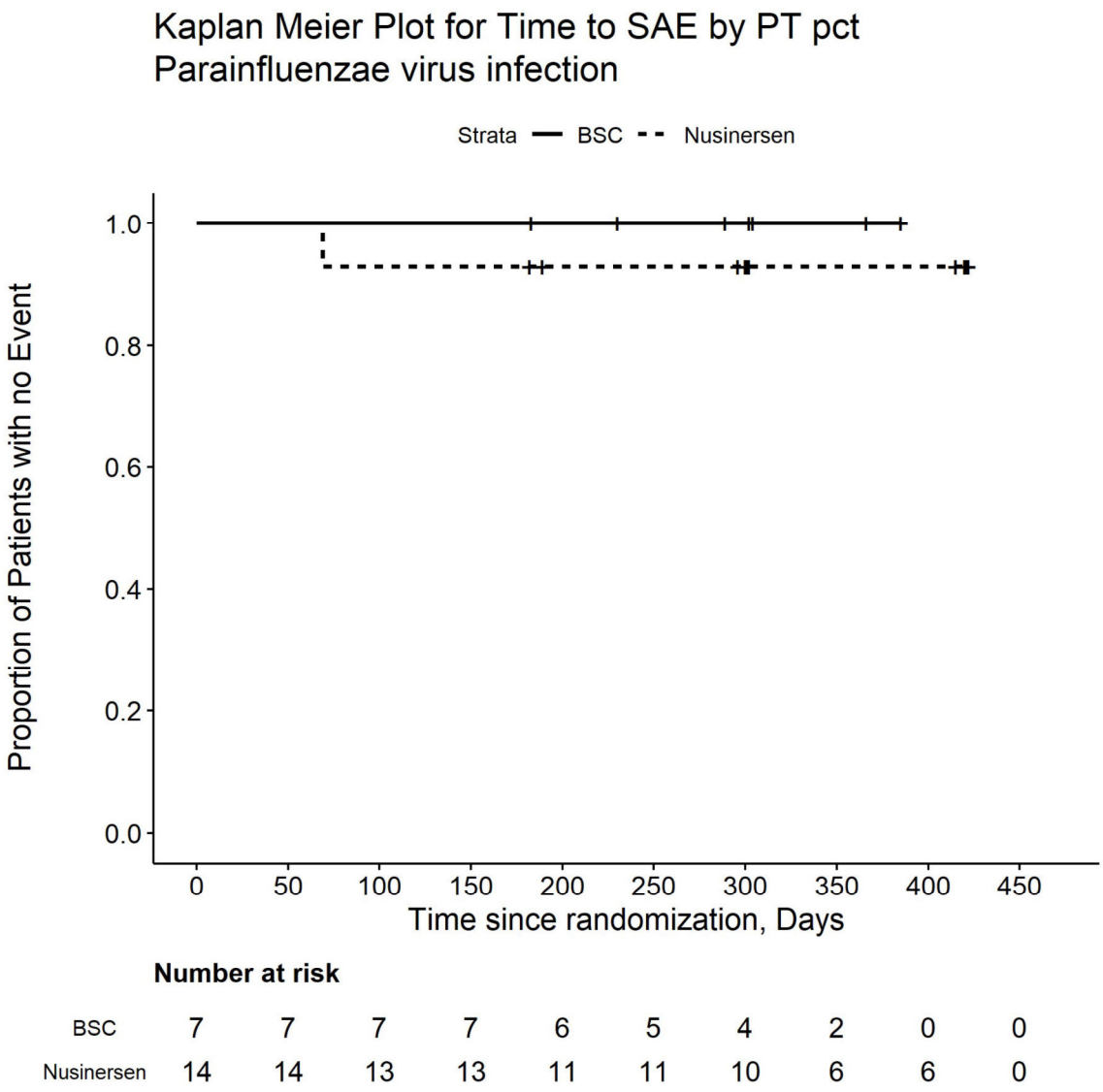
Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

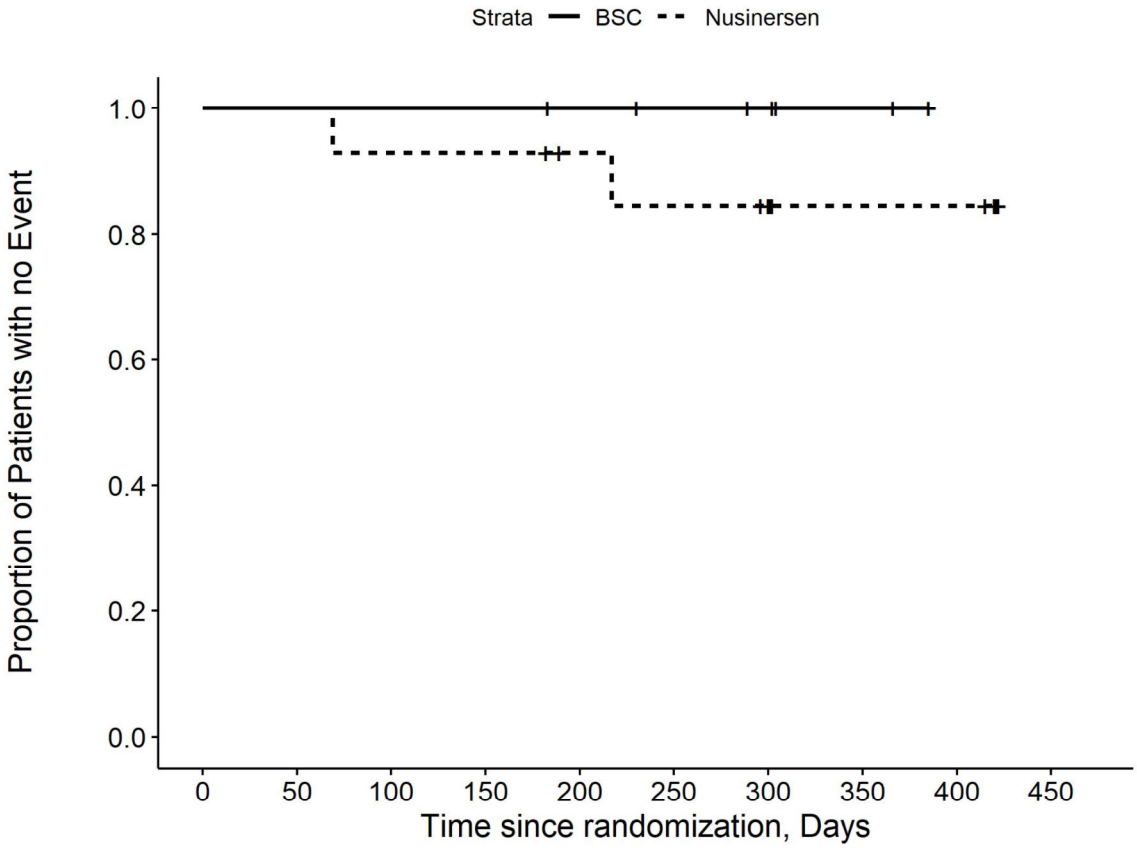
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	13	13	12	12	11	7	6	0



Number at risk

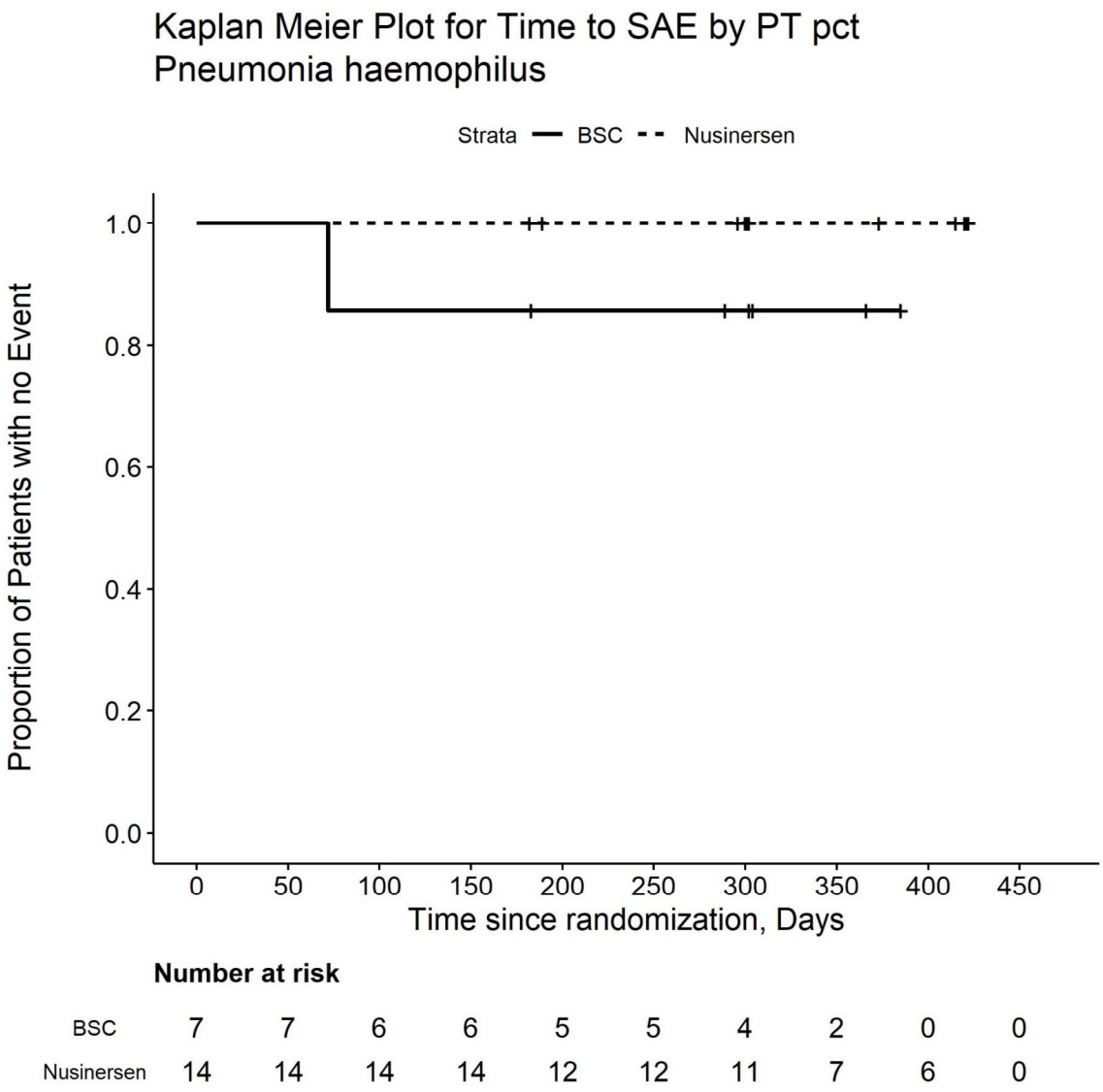
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	13	13	11	11	10	6	6	0

Kaplan Meier Plot for Time to SAE by PT pct
Pneumonia aspiration



Number at risk

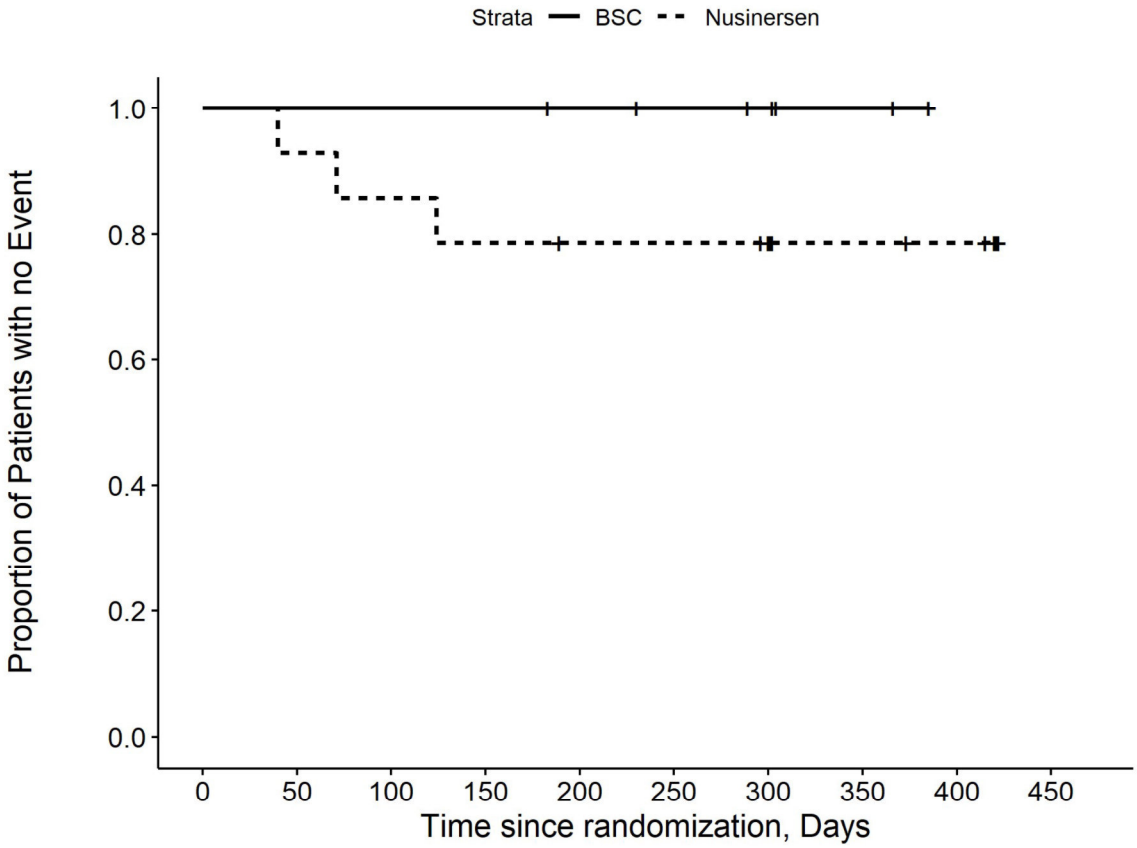
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	13	13	11	10	9	5	5	0



Number at risk

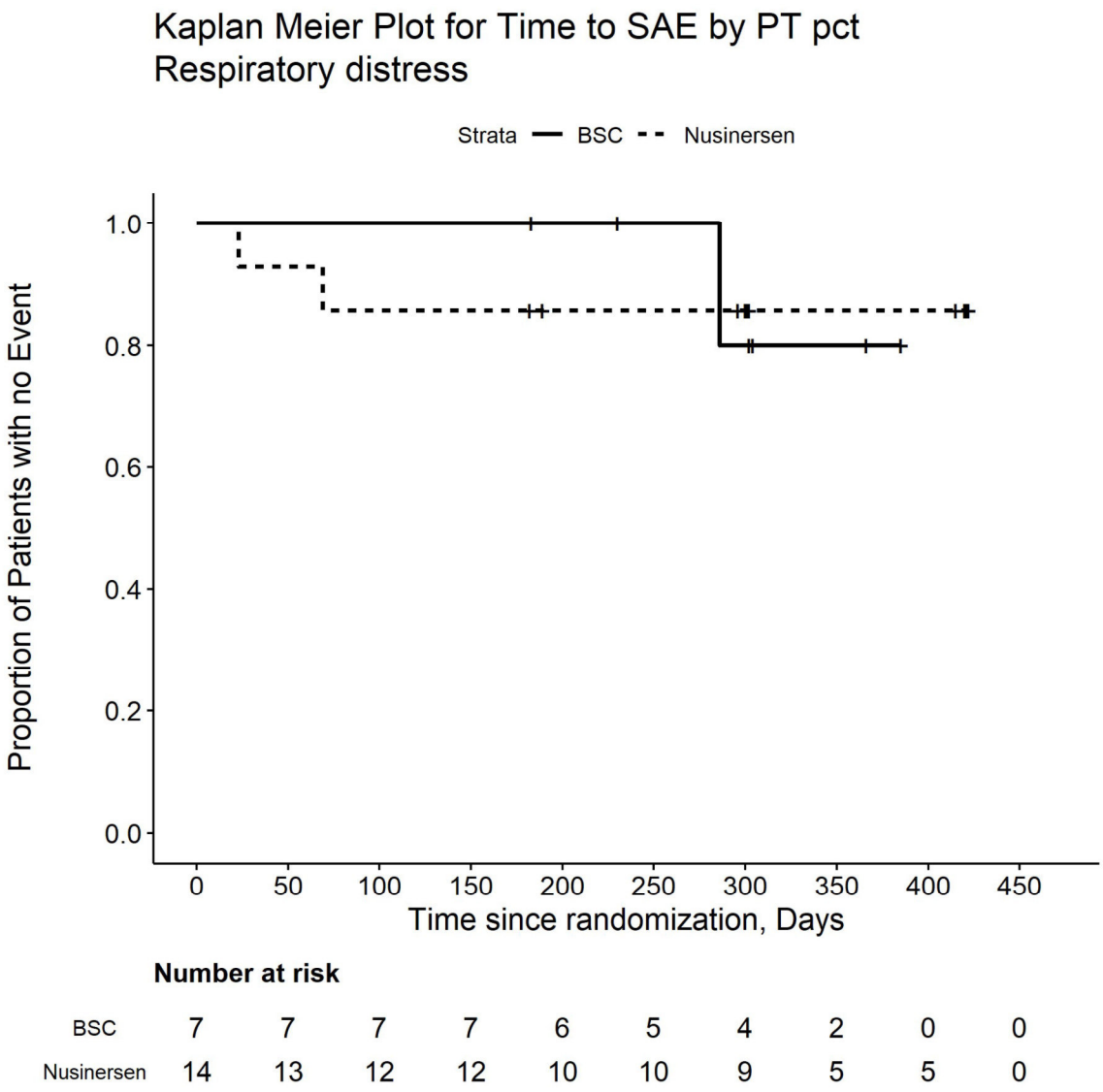
BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for Time to SAE by PT pct Pneumonia



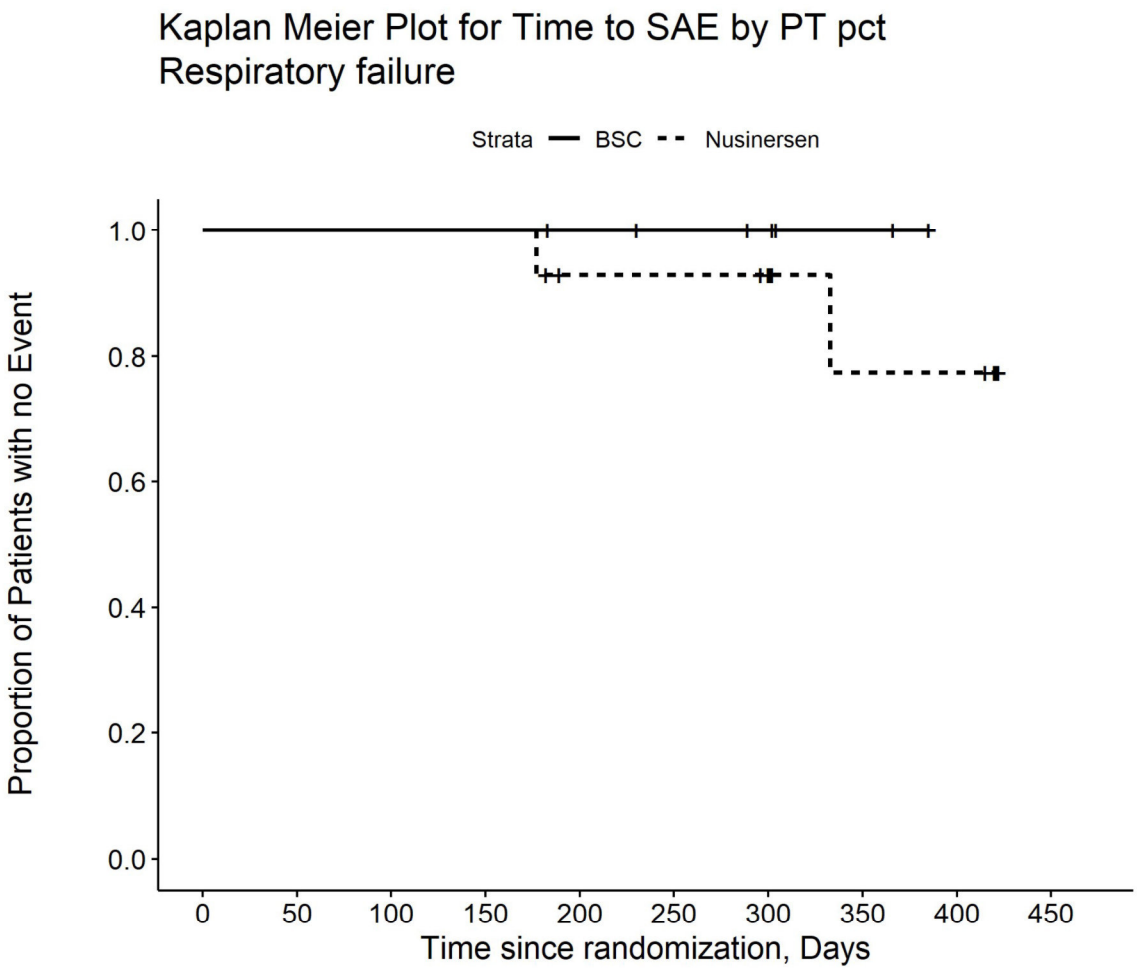
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	12	11	10	10	9	6	5	0



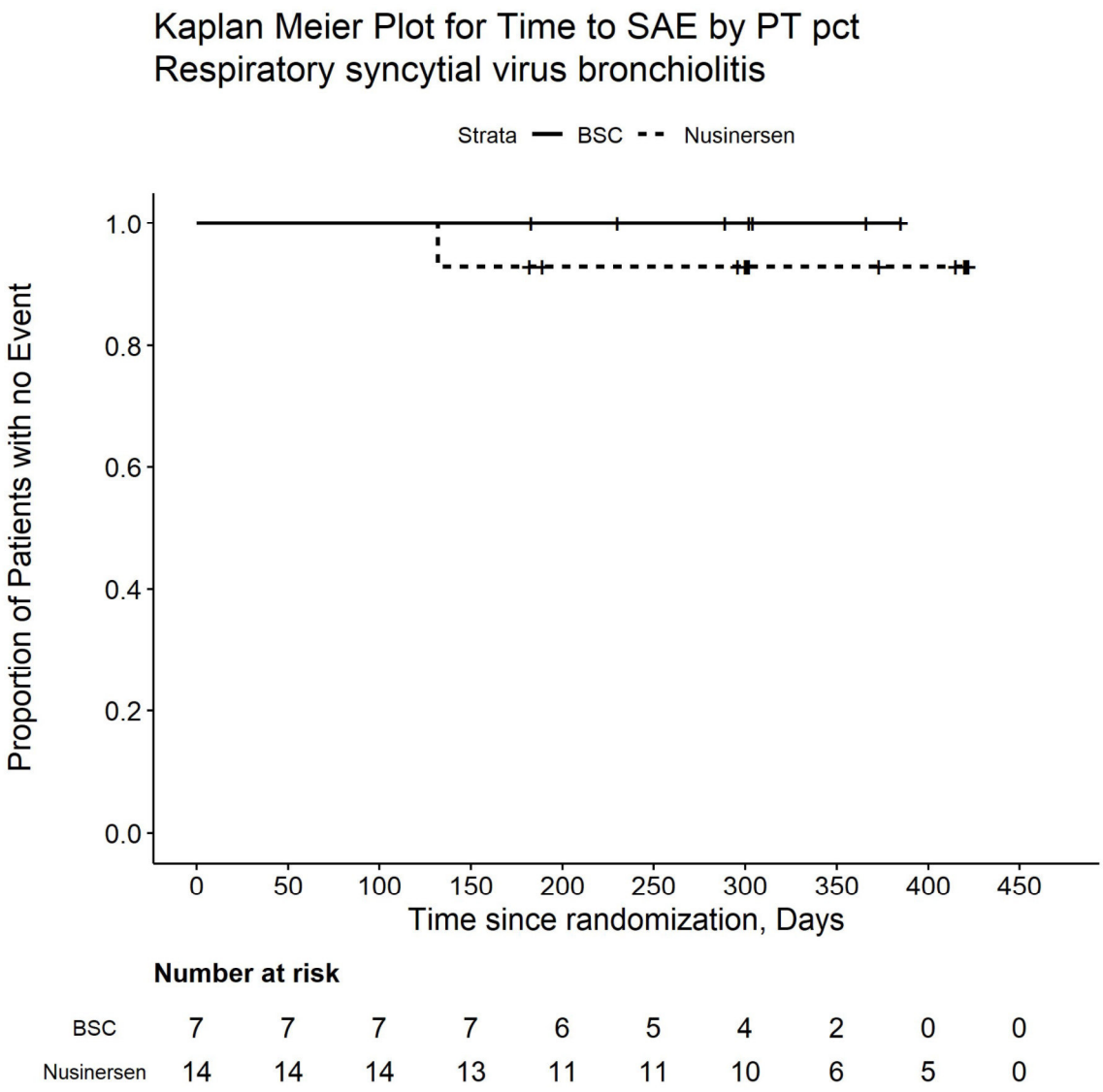
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	12	12	10	10	9	5	5	0



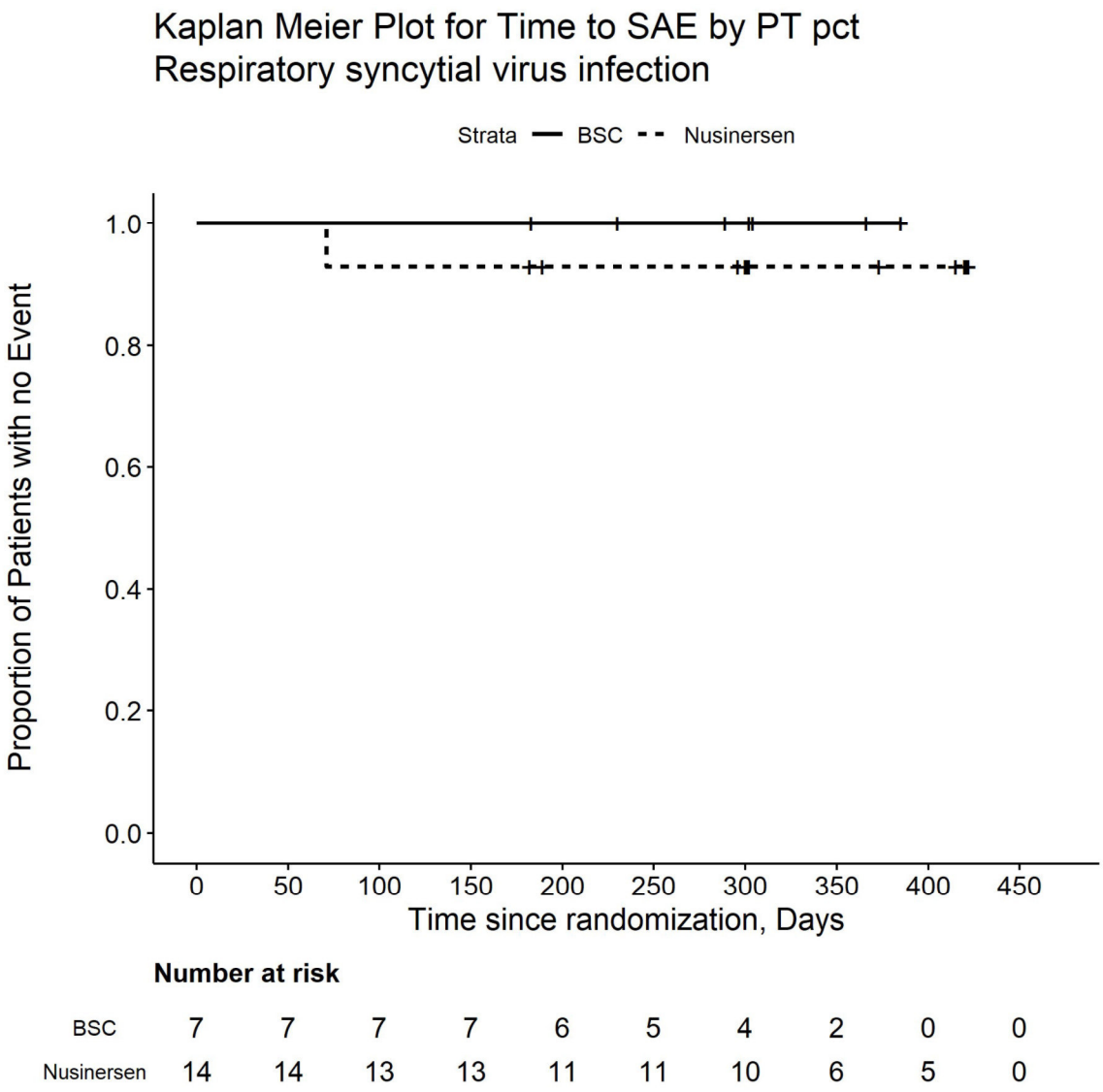
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	11	11	10	5	5	0



Number at risk

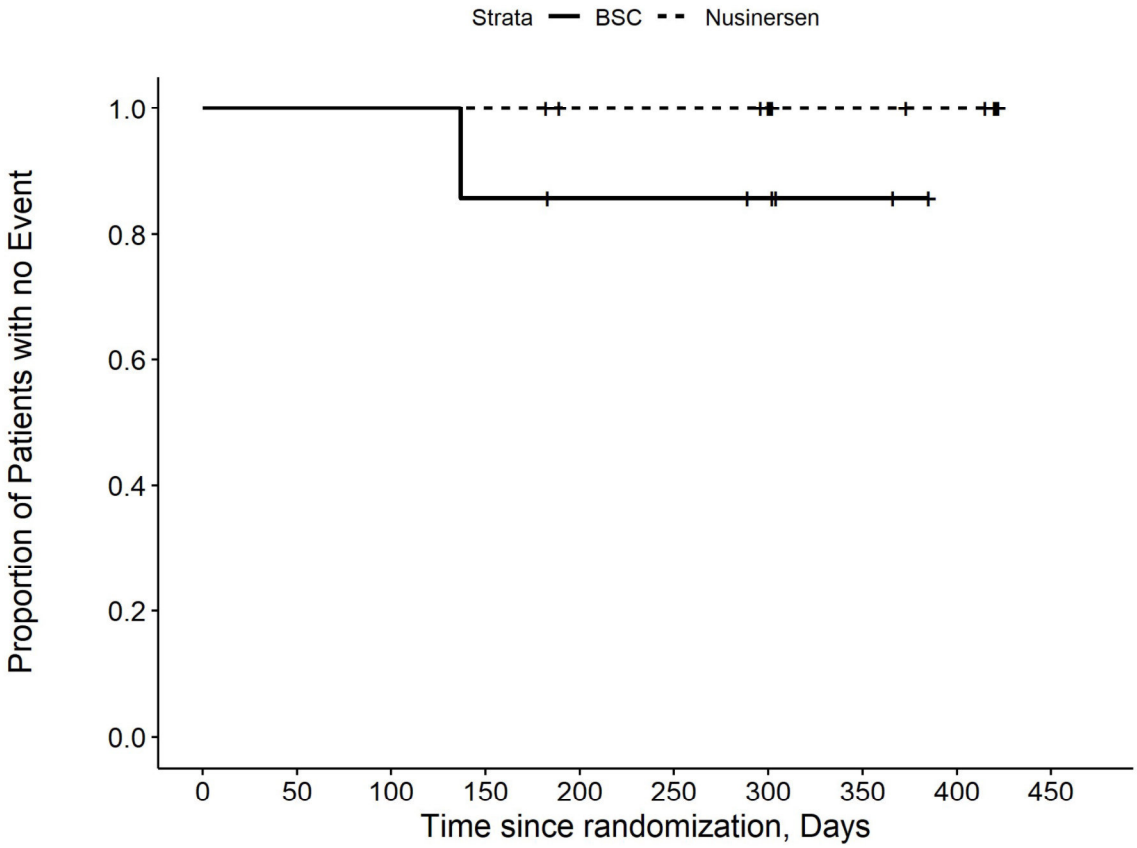
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	11	11	10	6	5	0



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	13	13	11	11	10	6	5	0

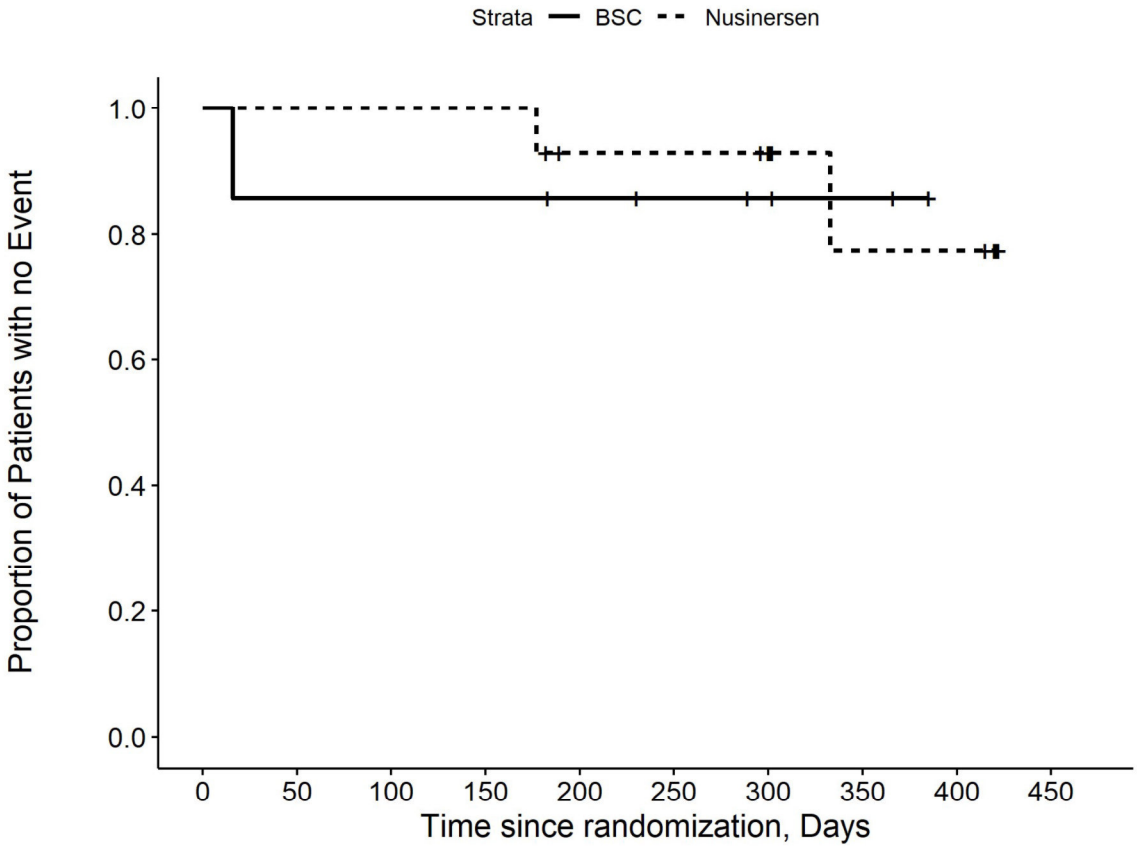
Kaplan Meier Plot for Time to SAE by PT pct
Respiratory tract infection



Number at risk

BSC	7	7	7	6	5	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

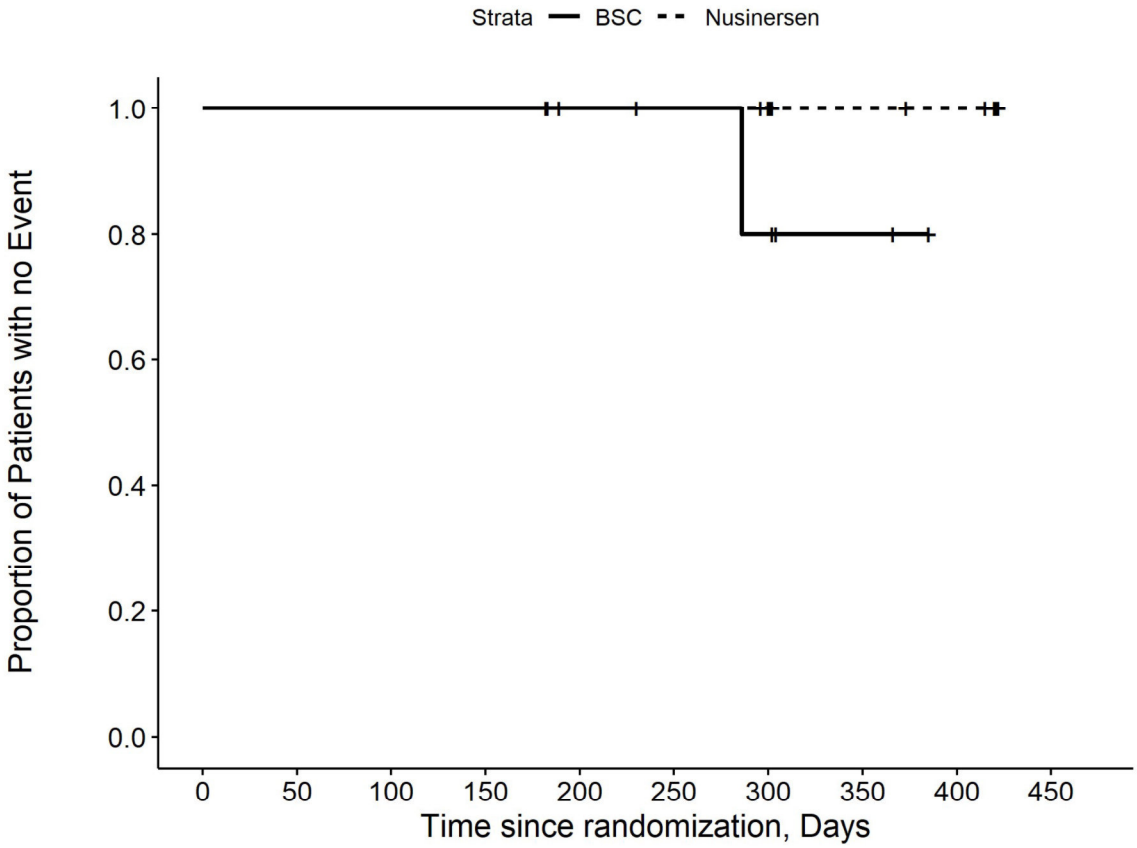
Kaplan Meier Plot for Time to SAE by PT pct Rhinovirus infection



Number at risk

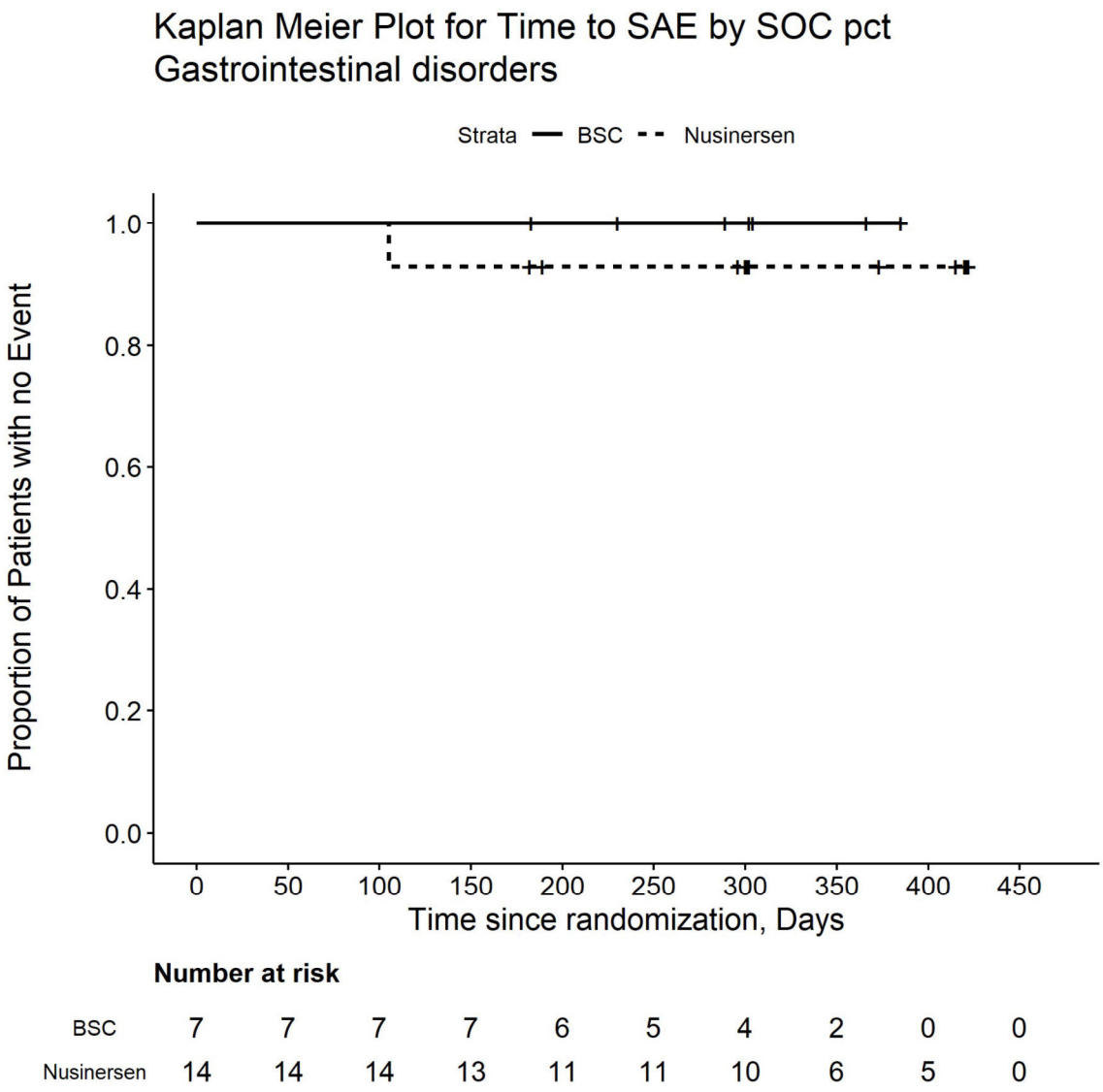
BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	11	11	10	5	5	0

Kaplan Meier Plot for Time to SAE by SOC pct
Cardiac disorders

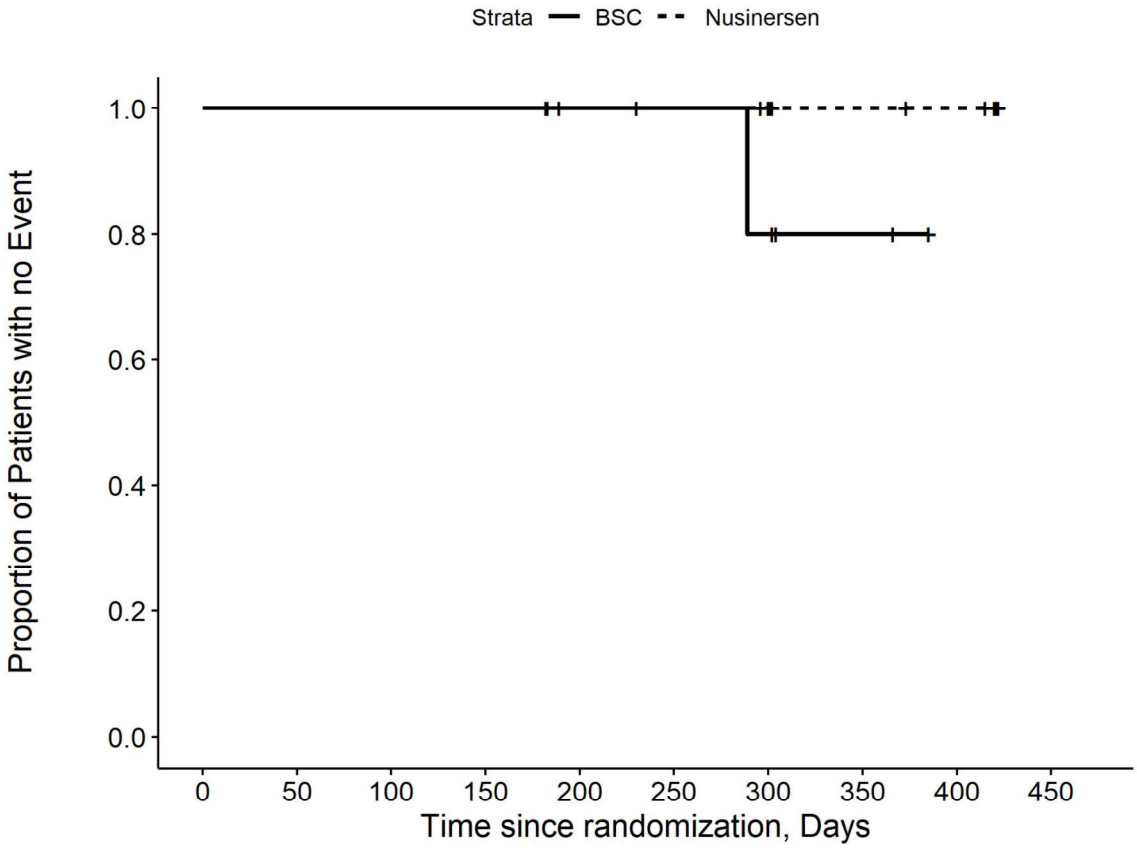


Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0


Kaplan Meier Plot for Time to SAE by SOC pct
Gastrointestinal disorders
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0 50 100 150 200 250 300 350 400 450
Time since randomization, Days
Number at risk
BSC 7 7 7 7 6 5 4 2 0 0
Nusinersen 14 14 14 13 11 11 10 6 5 0

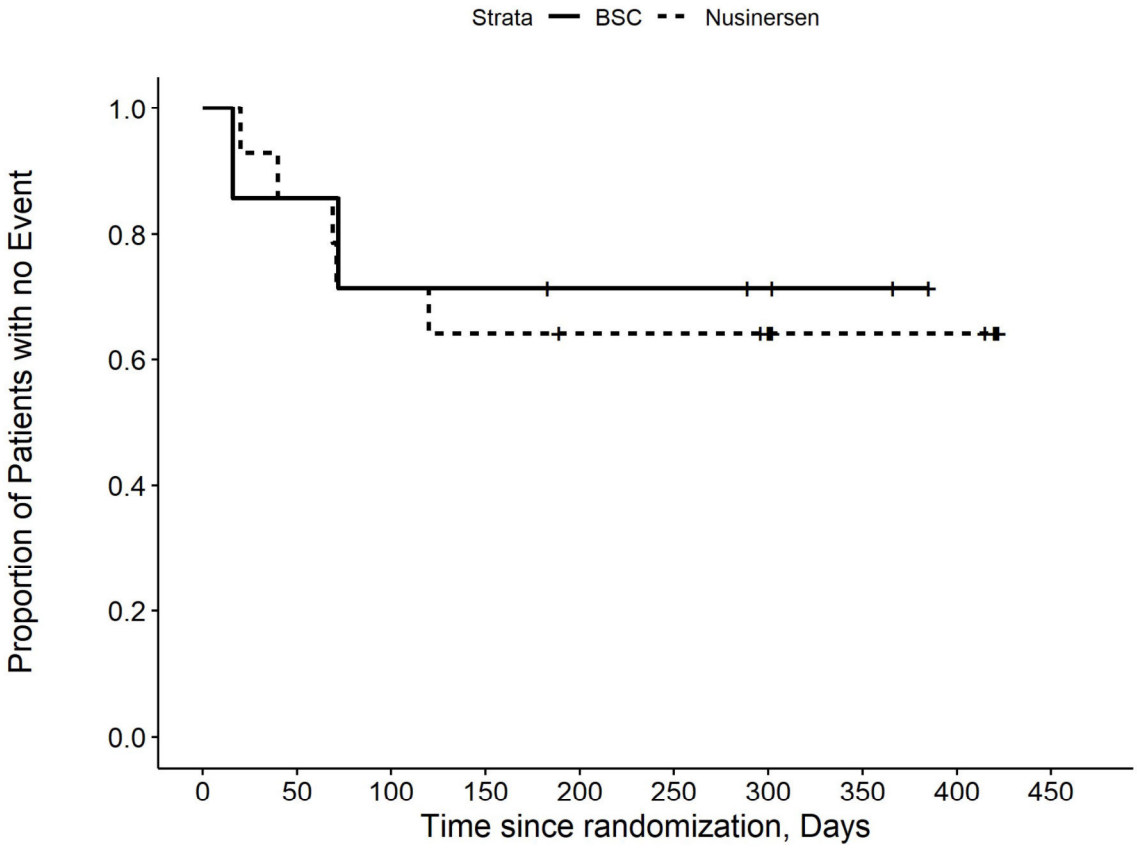
Kaplan Meier Plot for Time to SAE by SOC pct
General disorders and administration site conditions



Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

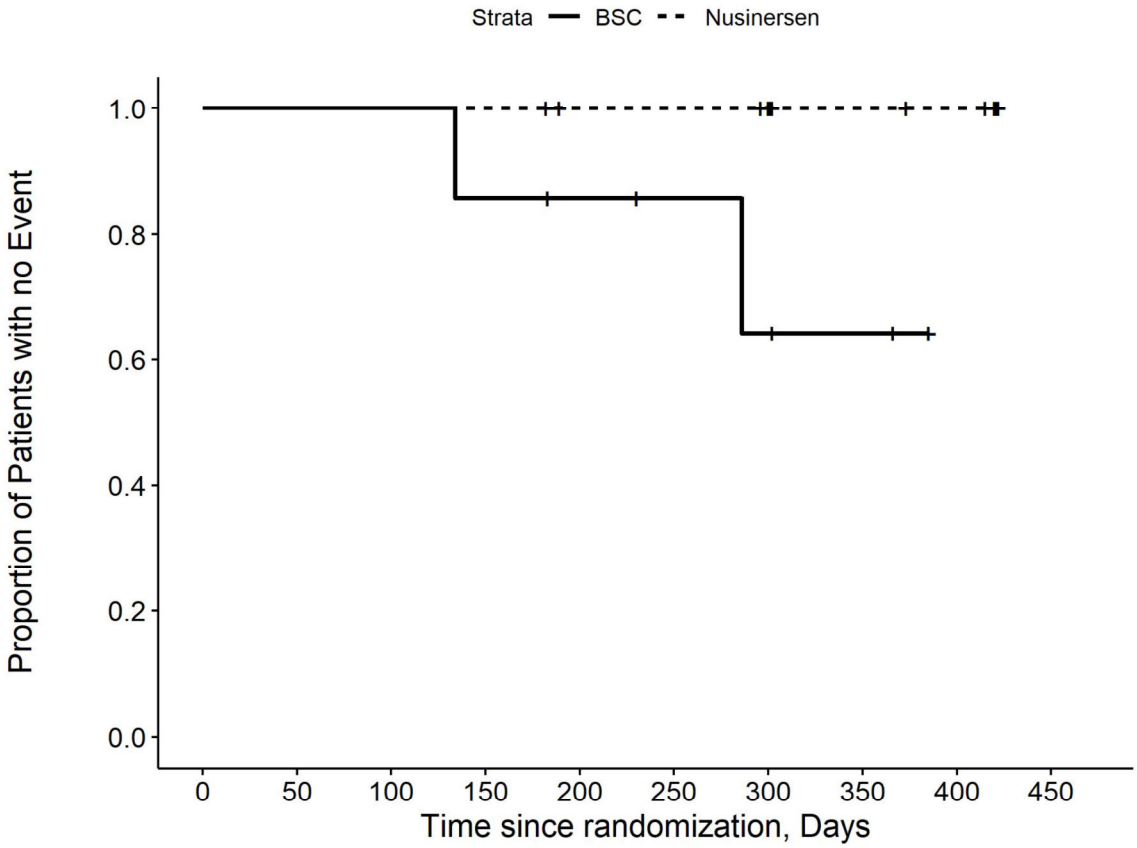
Kaplan Meier Plot for Time to SAE by SOC pct
Infections and infestations



Number at risk

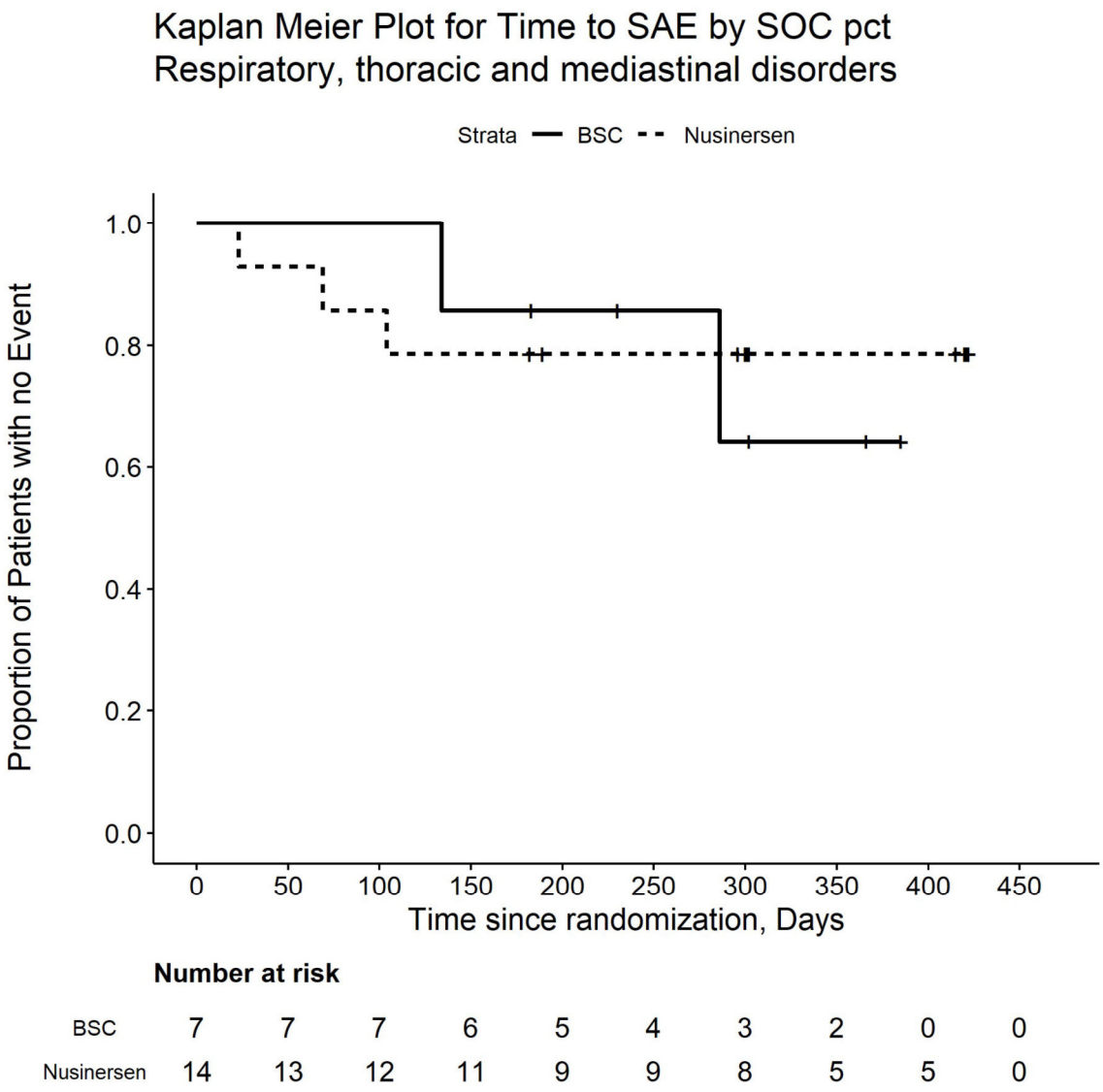
BSC	7	6	5	5	4	4	3	2	0	0
Nusinersen	14	12	10	9	8	8	7	4	4	0

Kaplan Meier Plot for Time to SAE by SOC pct
Nervous system disorders



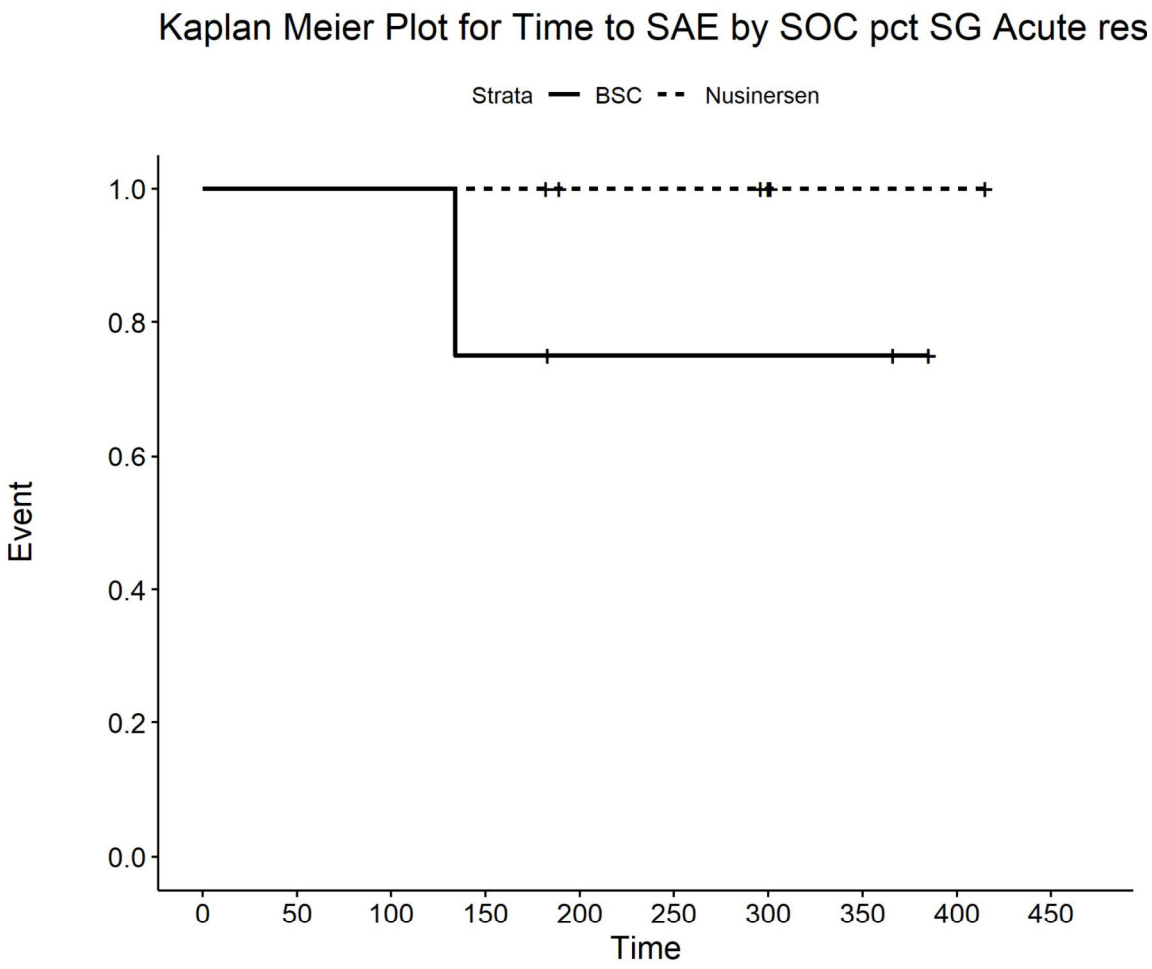
Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



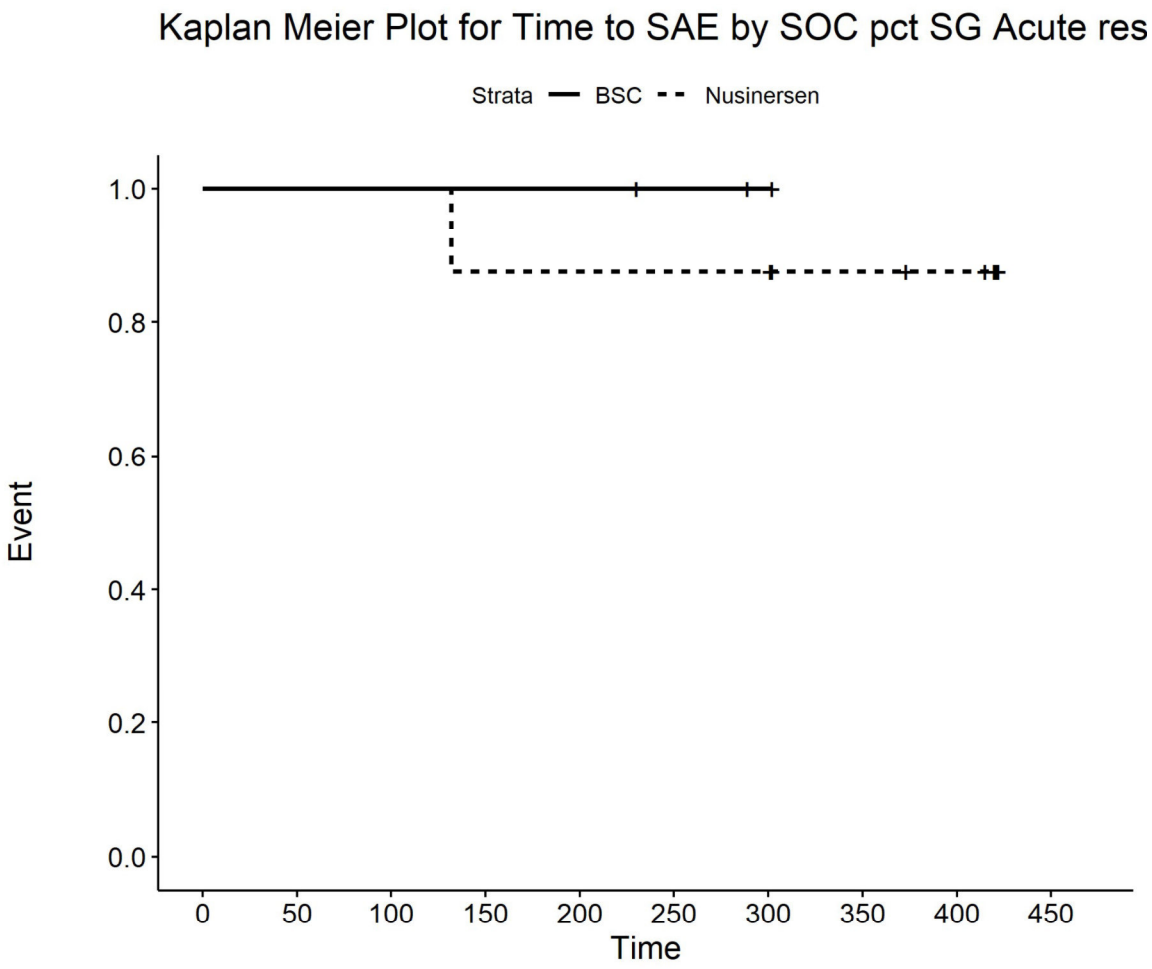
Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	13	12	11	9	9	8	5	5	0



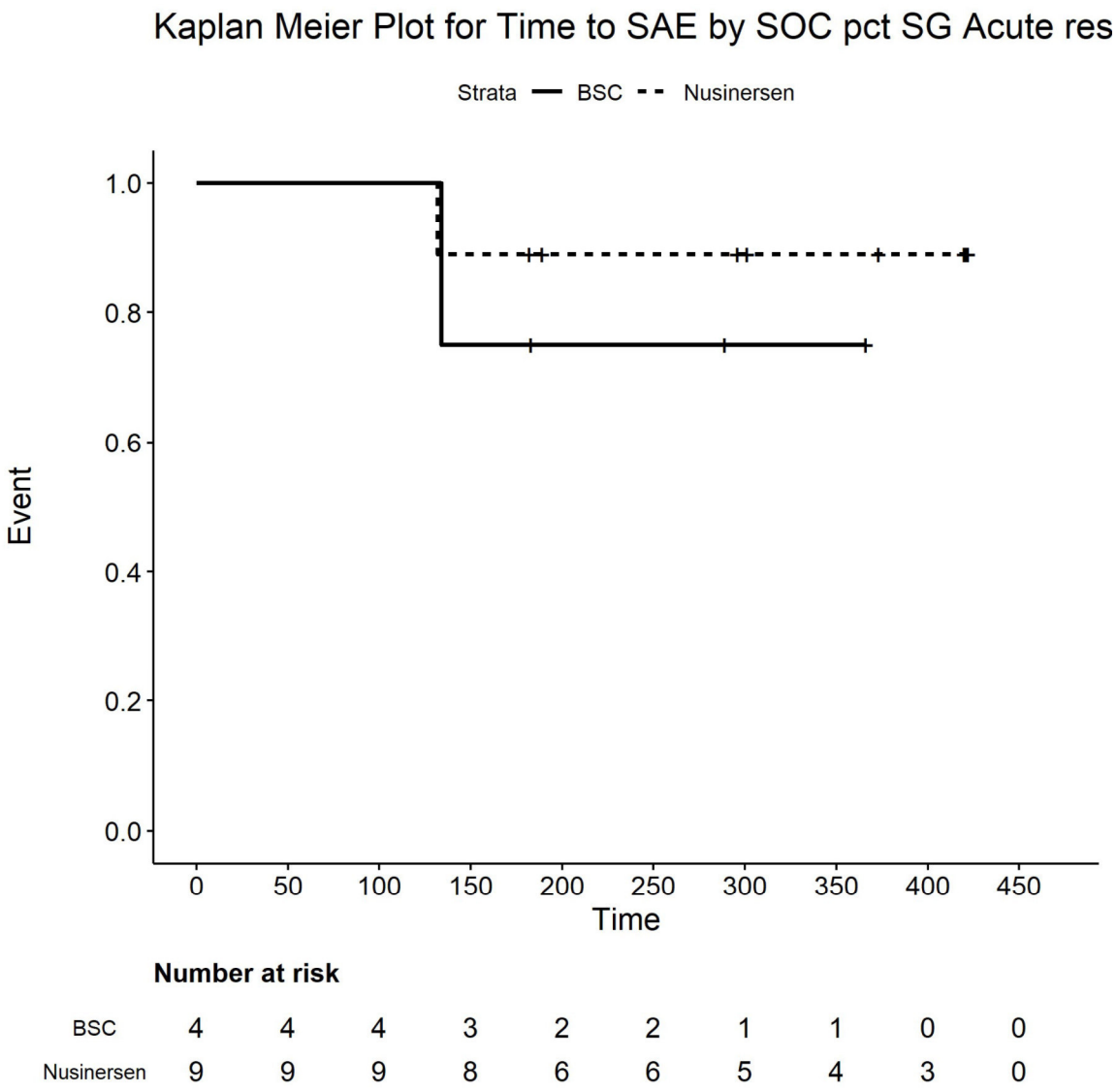
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



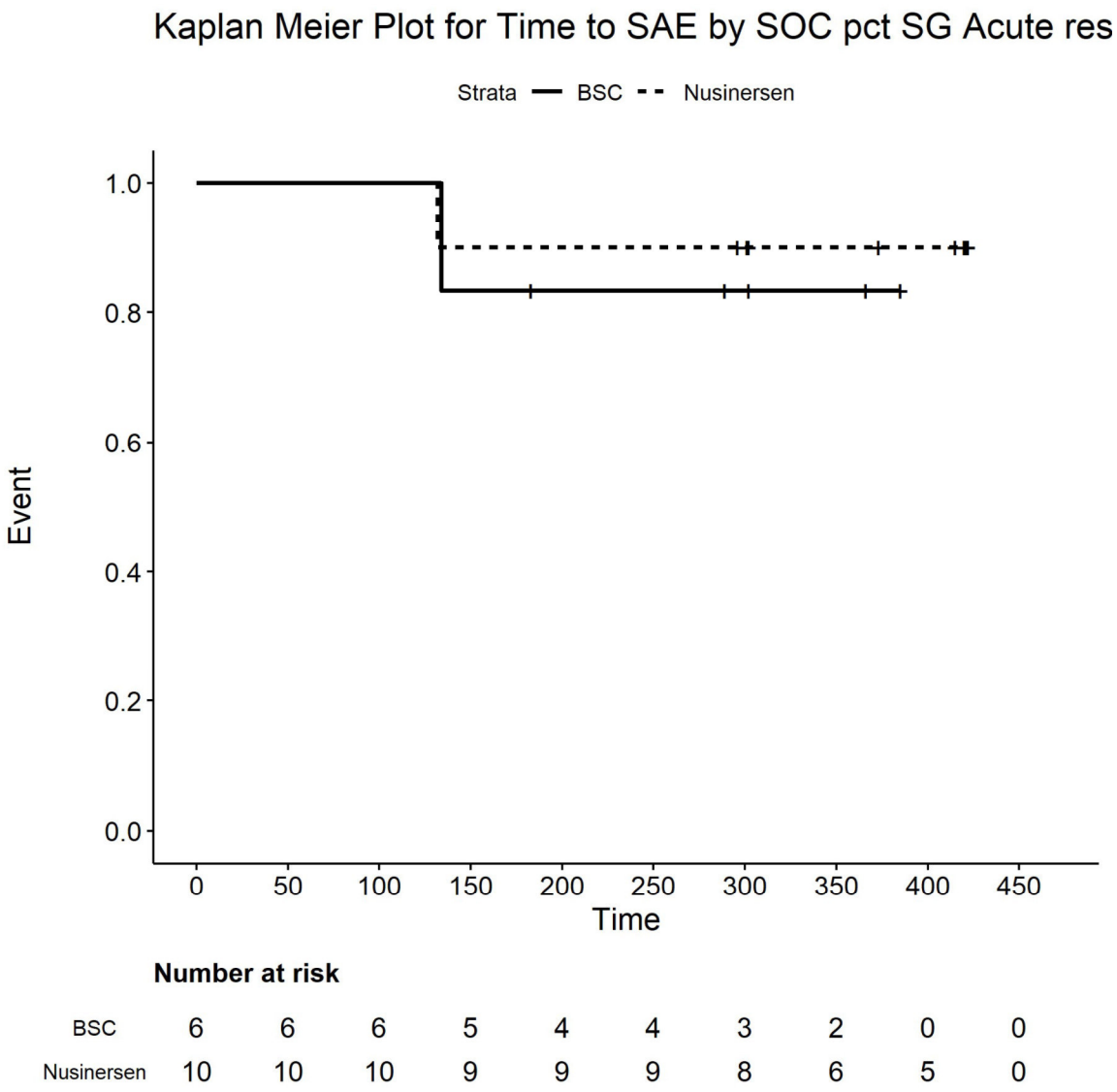
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



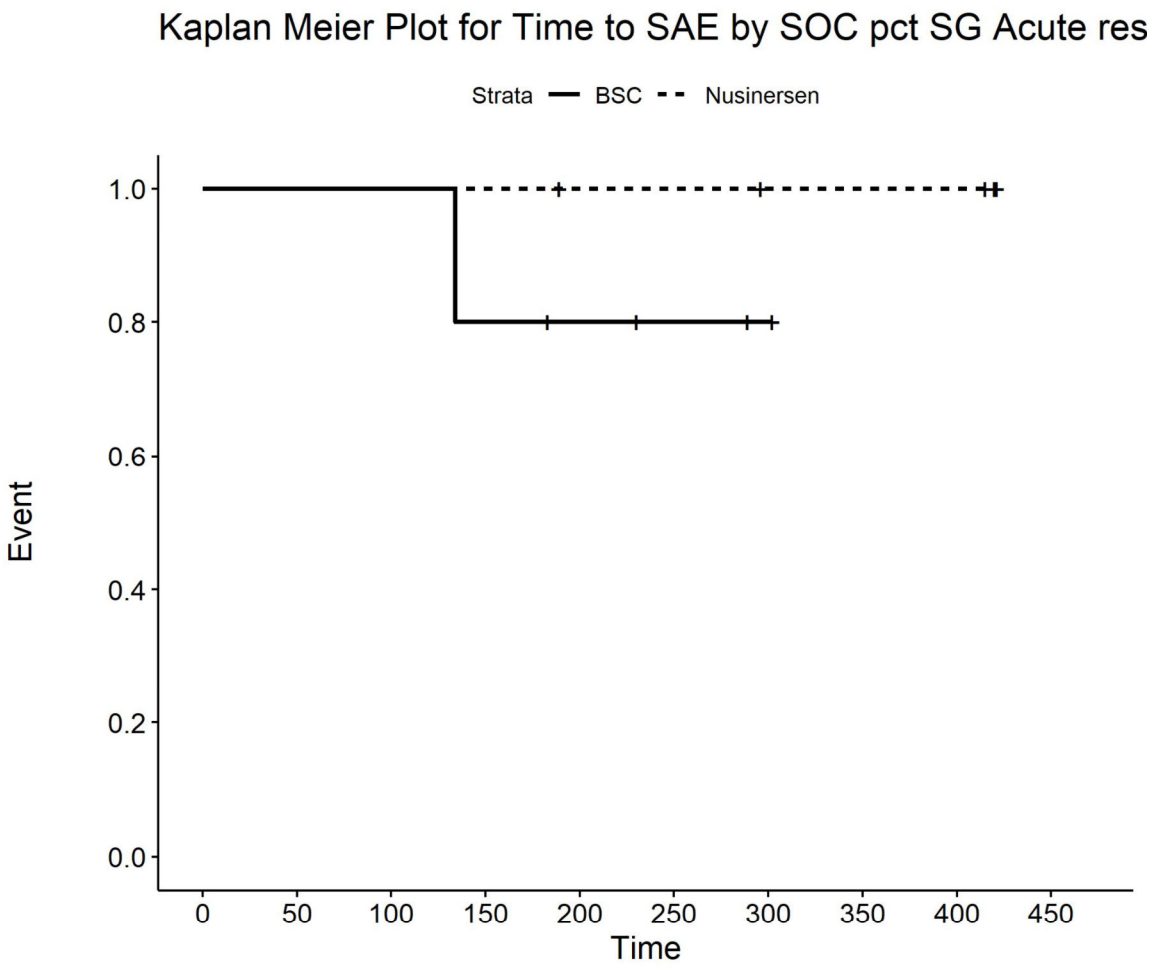
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



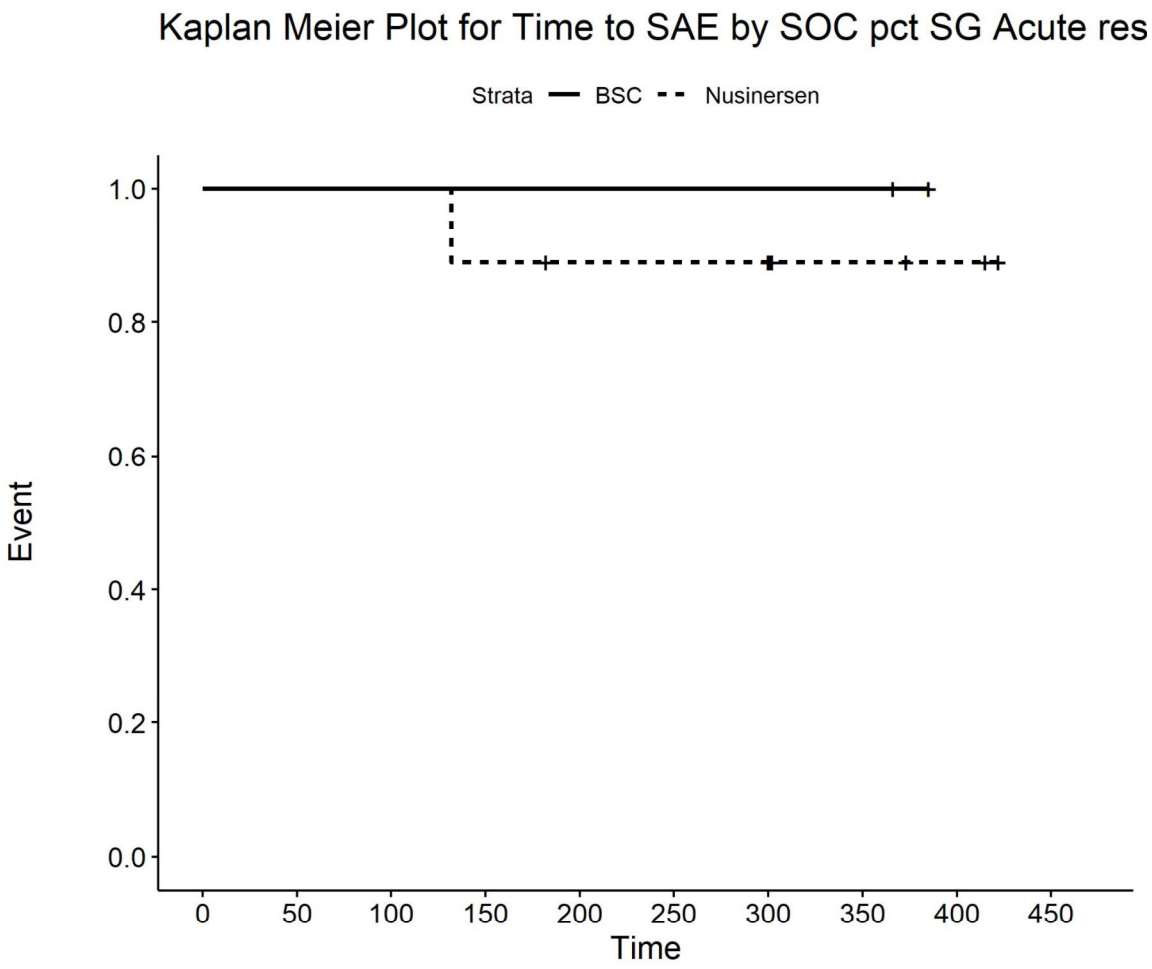
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



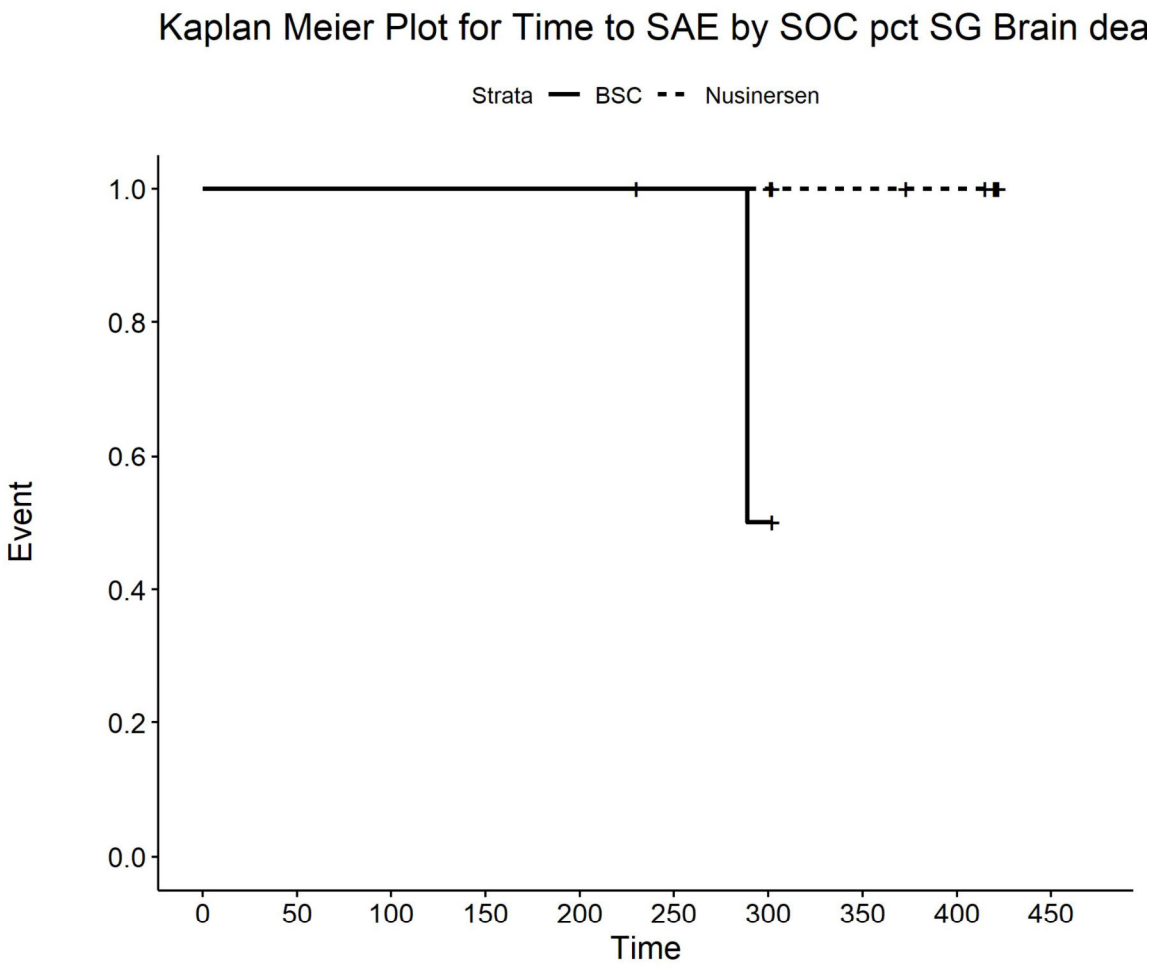
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



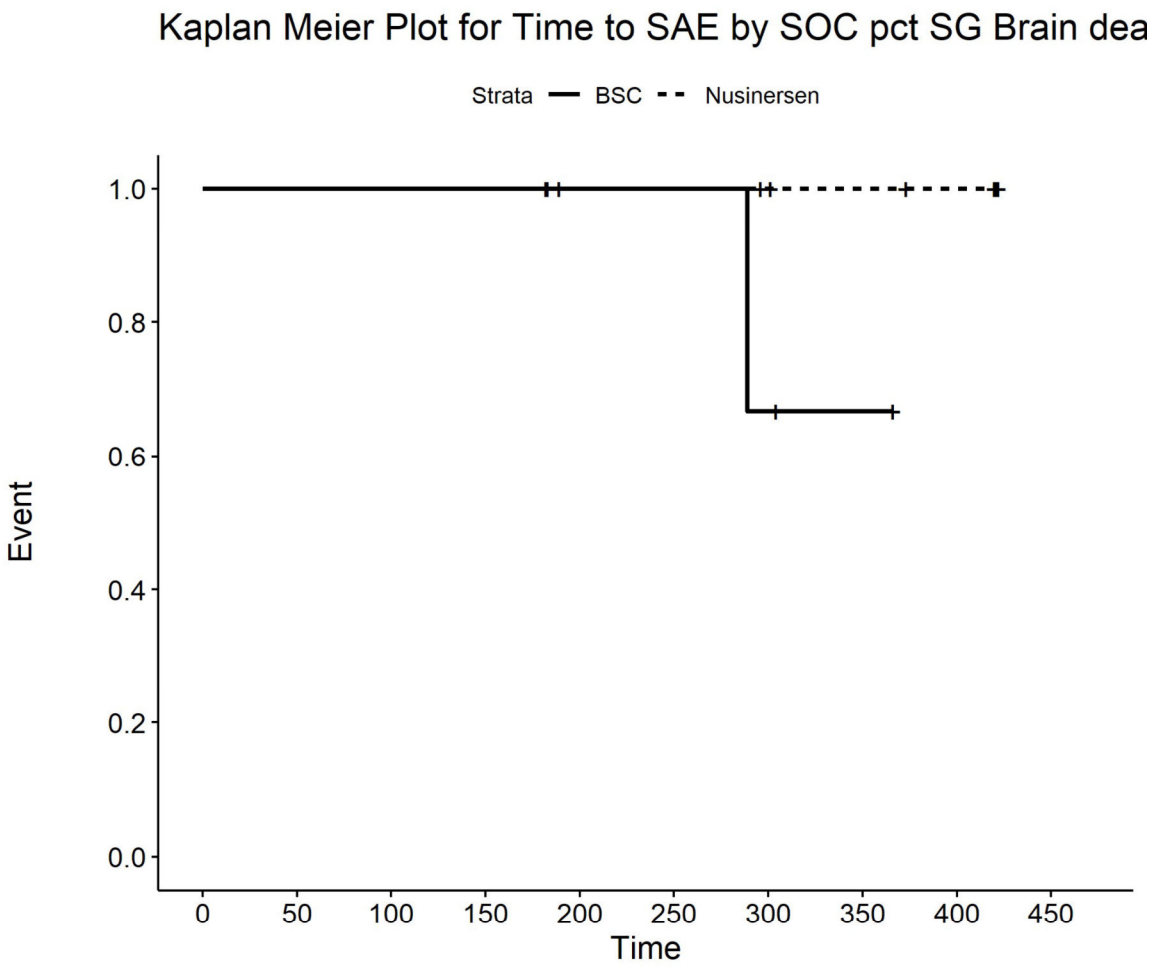
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



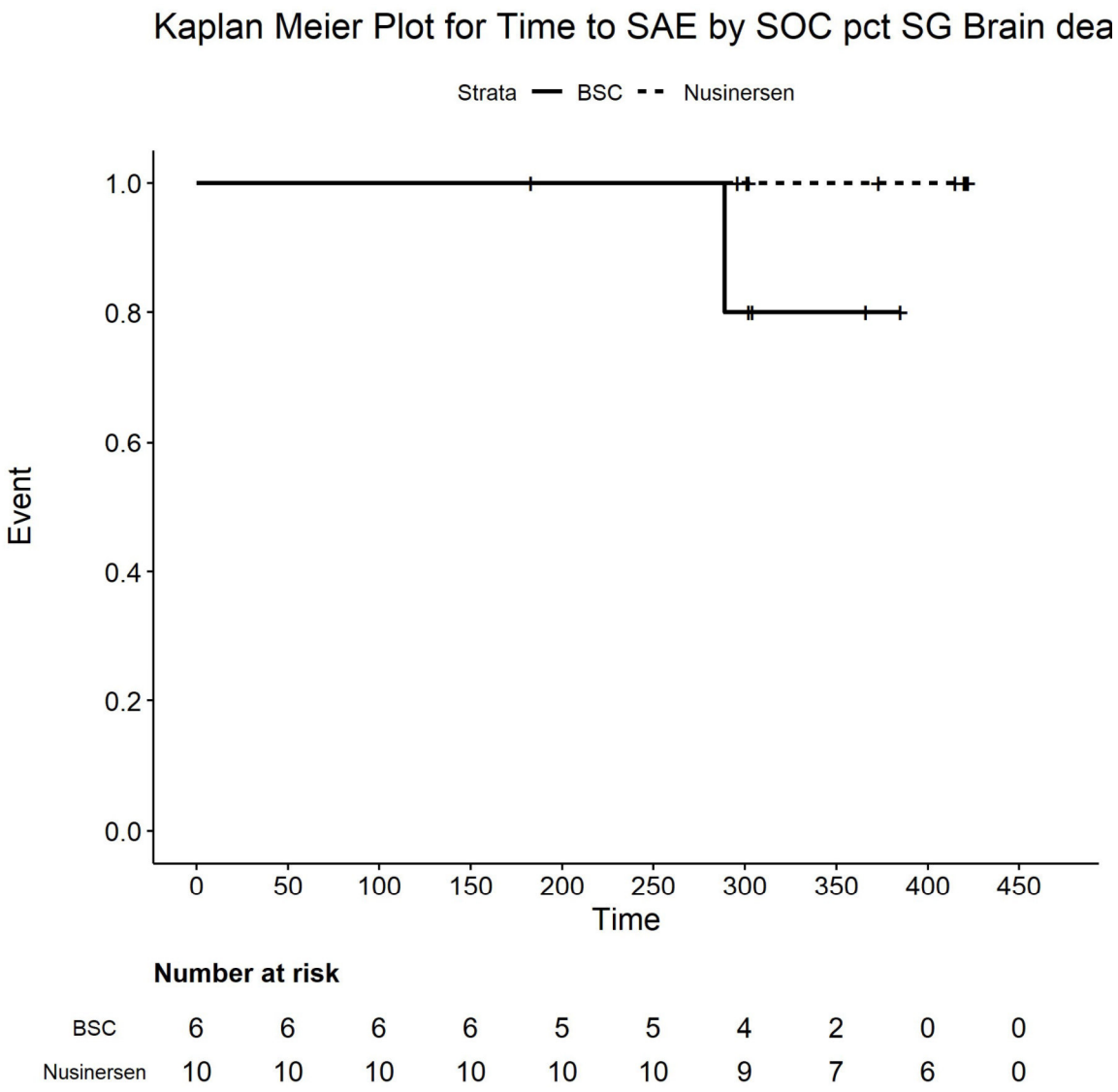
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



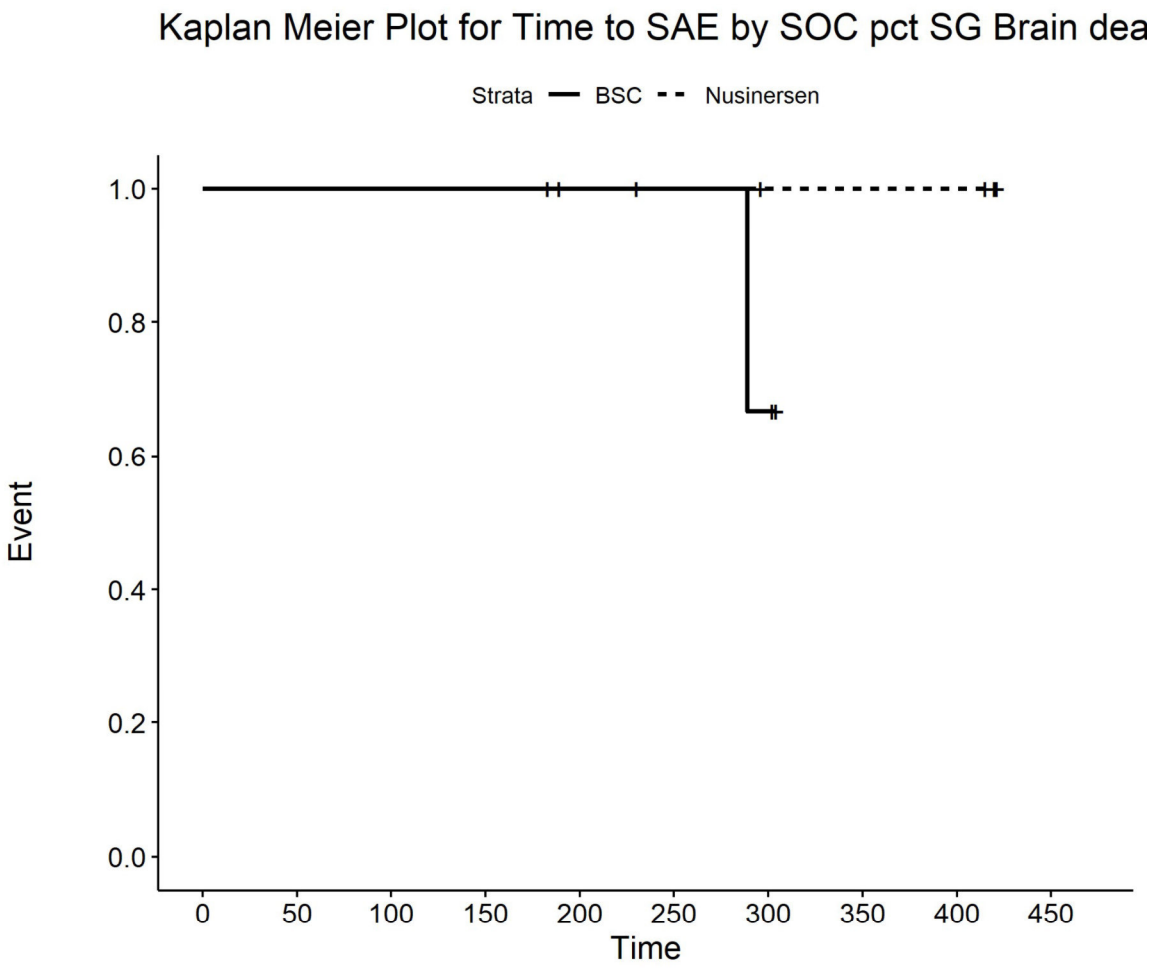
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



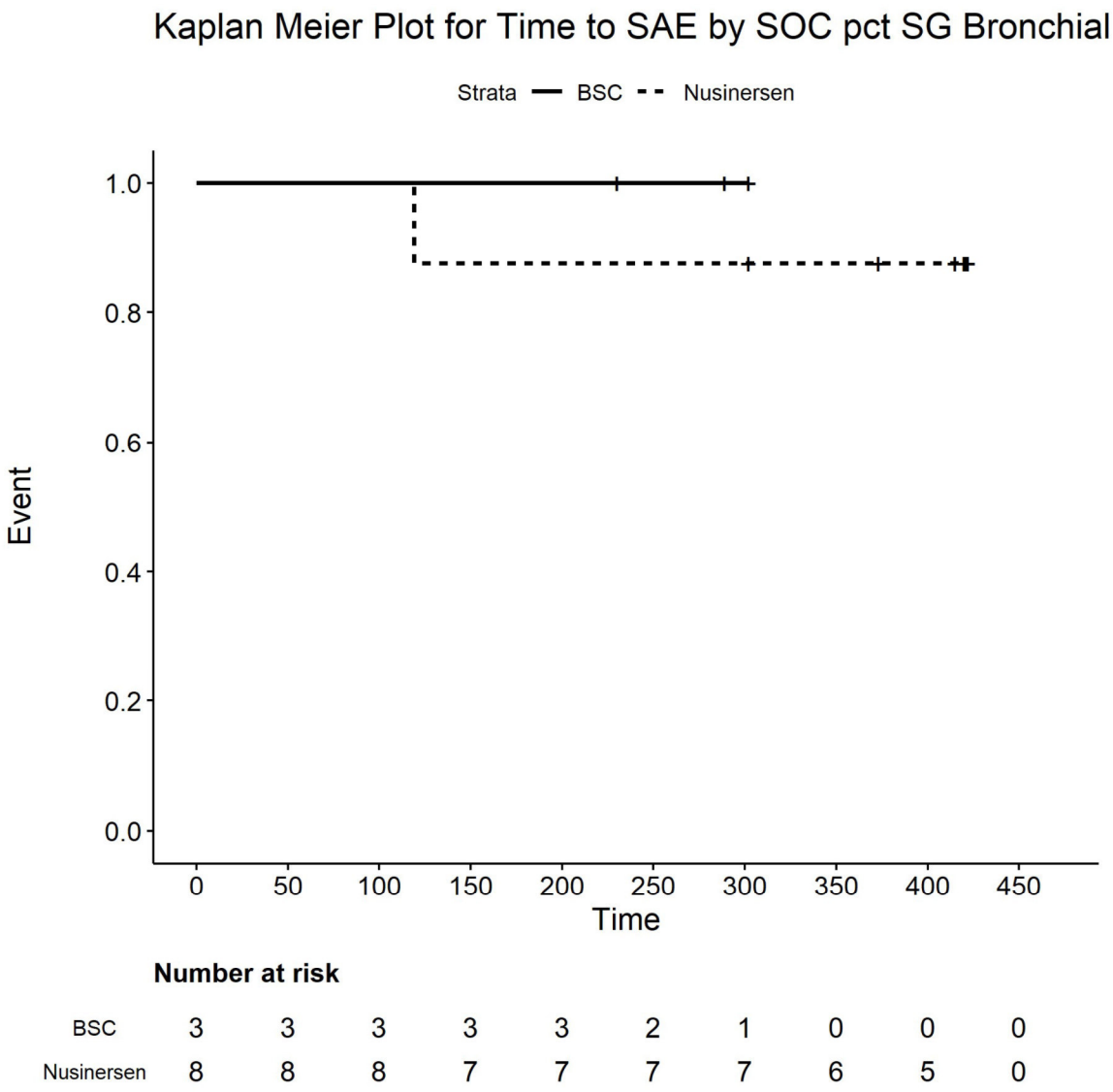
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



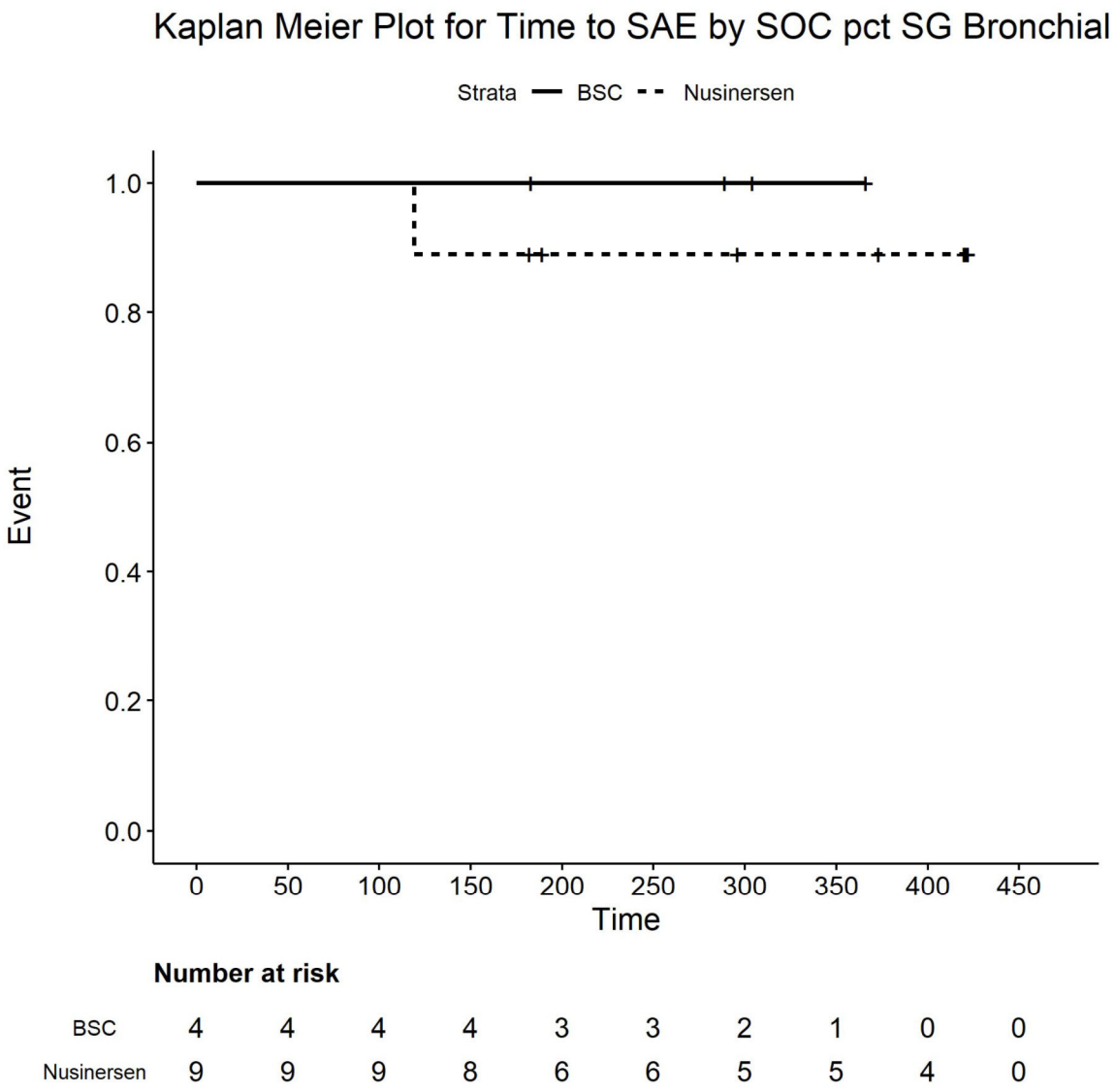
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



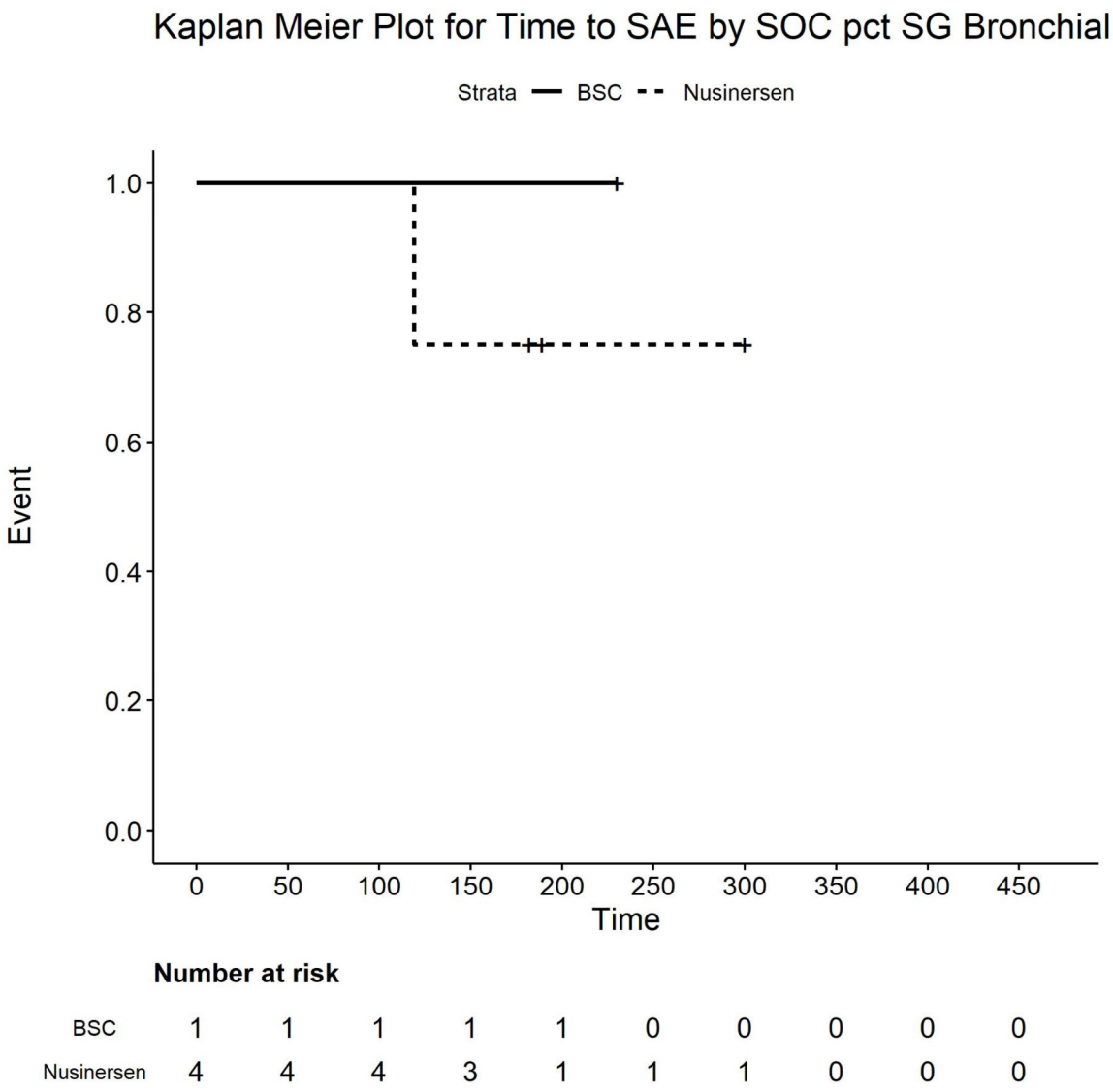
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	6	5	0



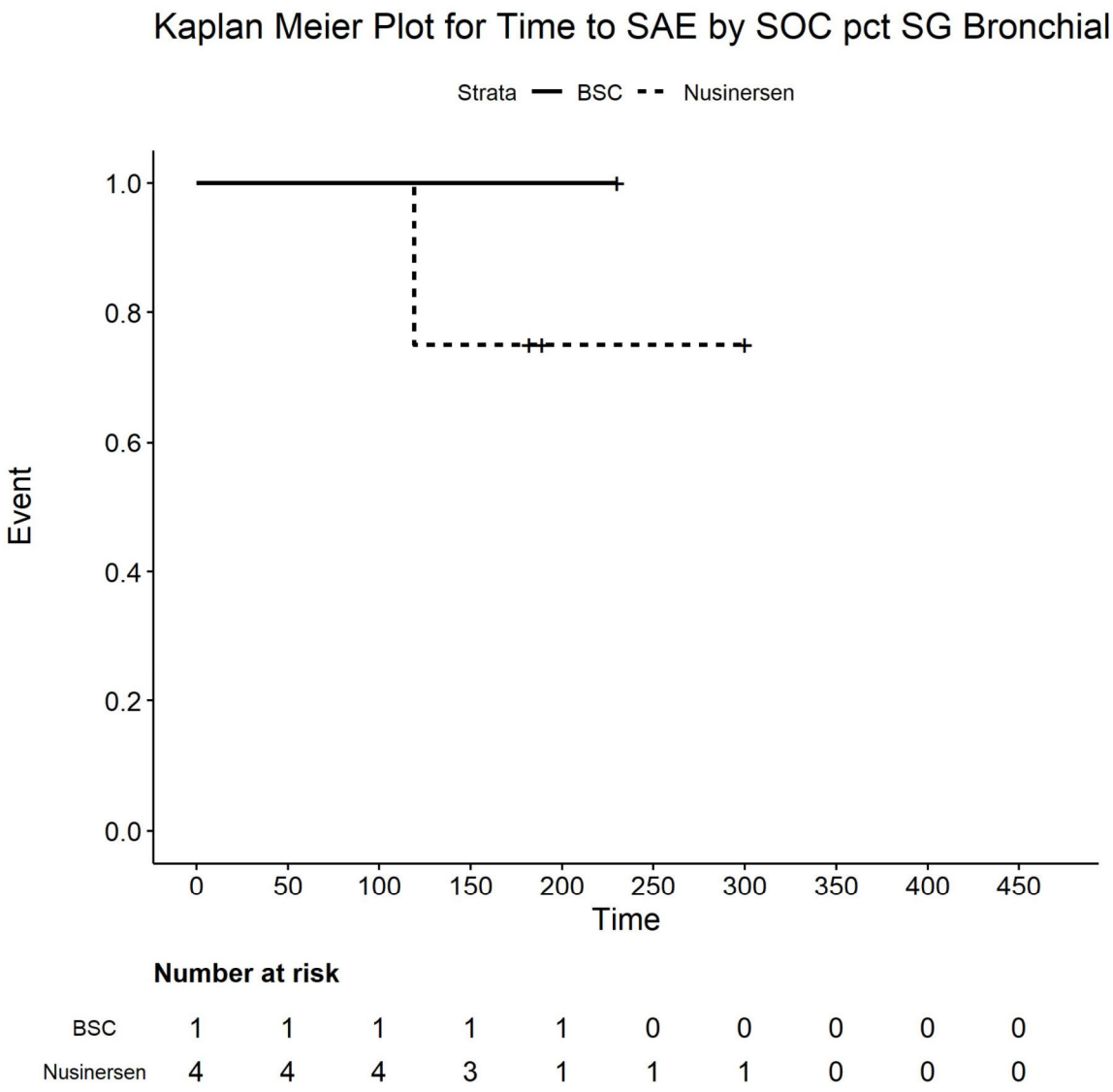
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	5	4	0



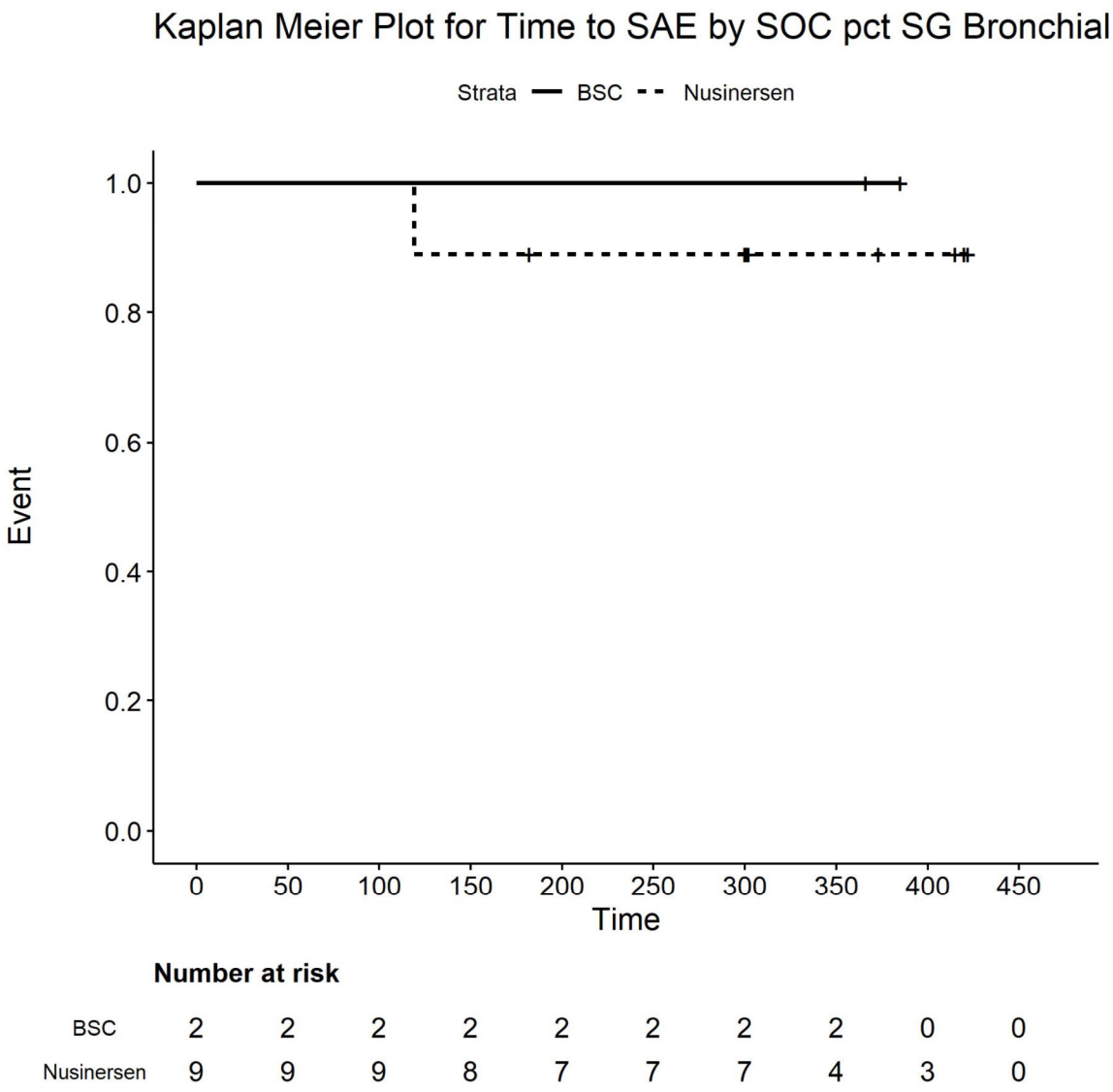
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



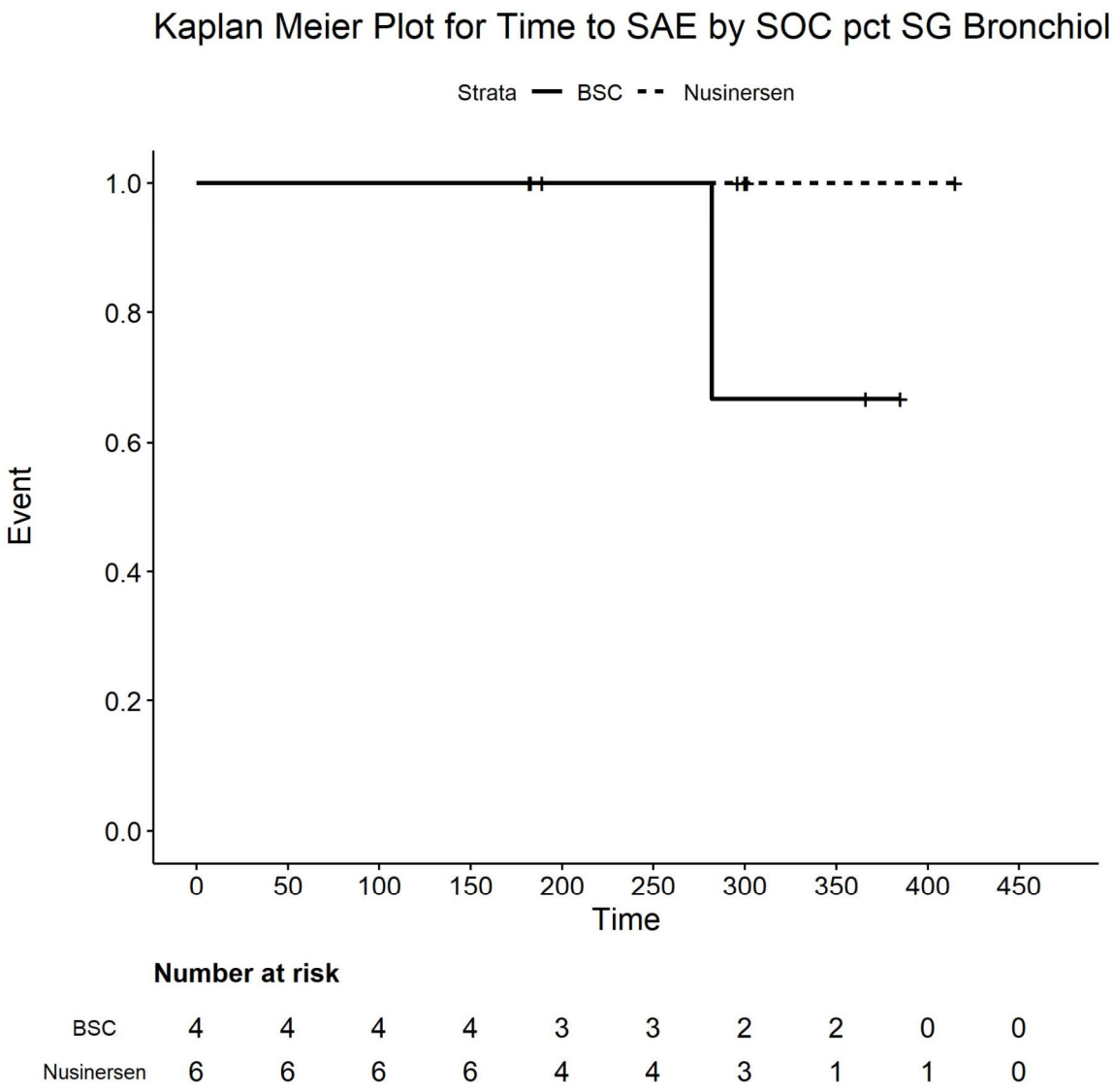
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



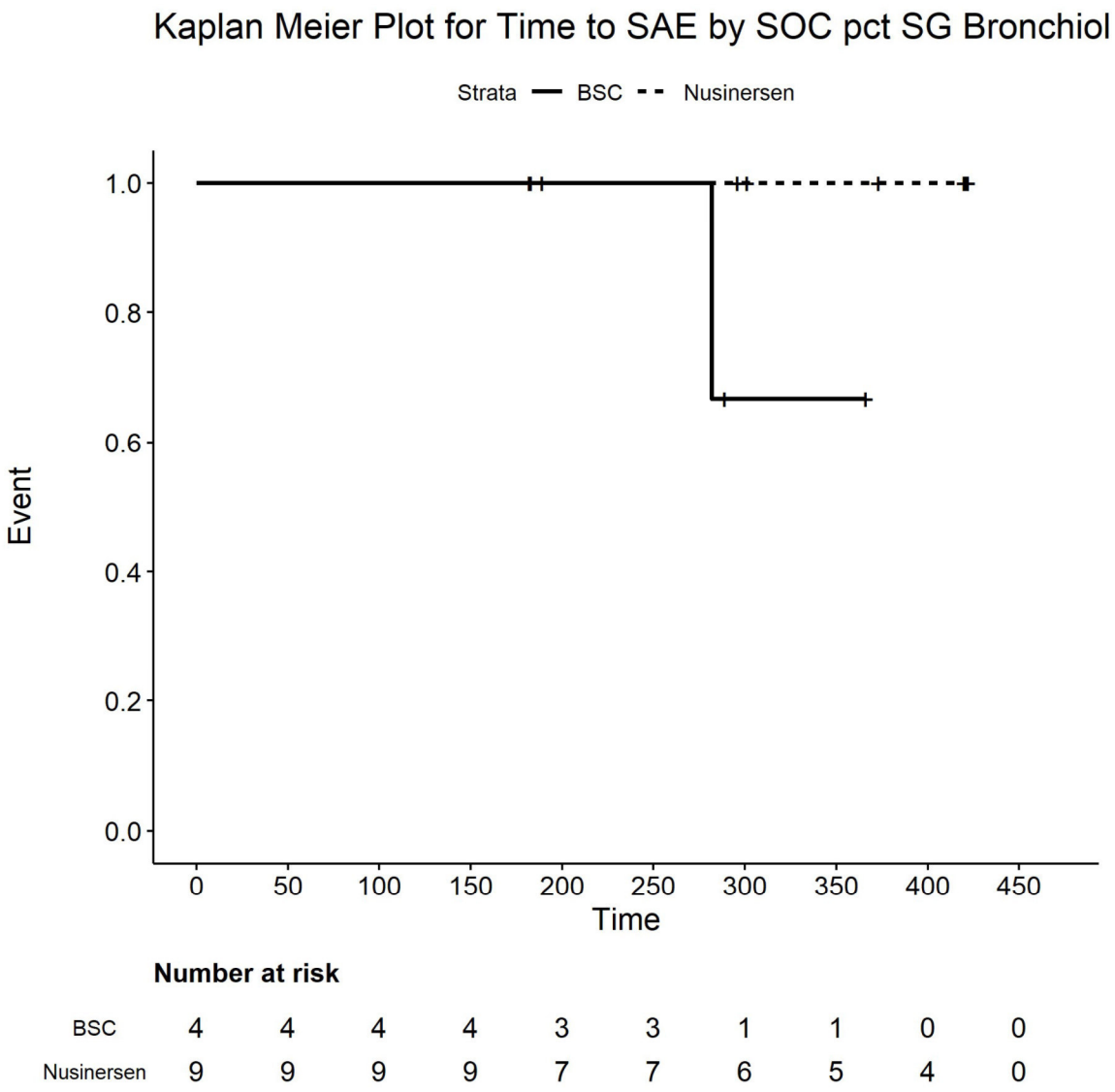
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	4	3	0



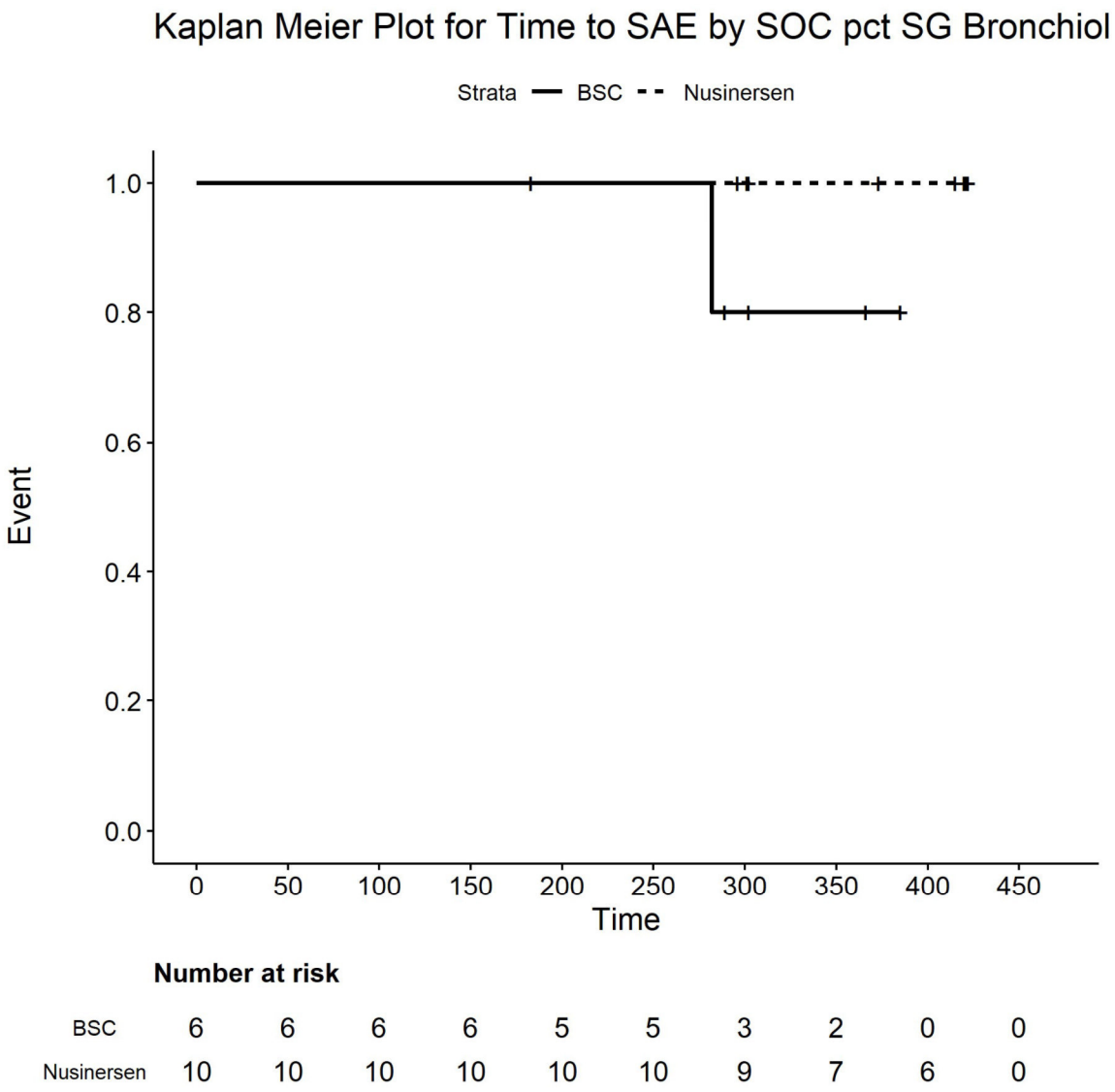
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



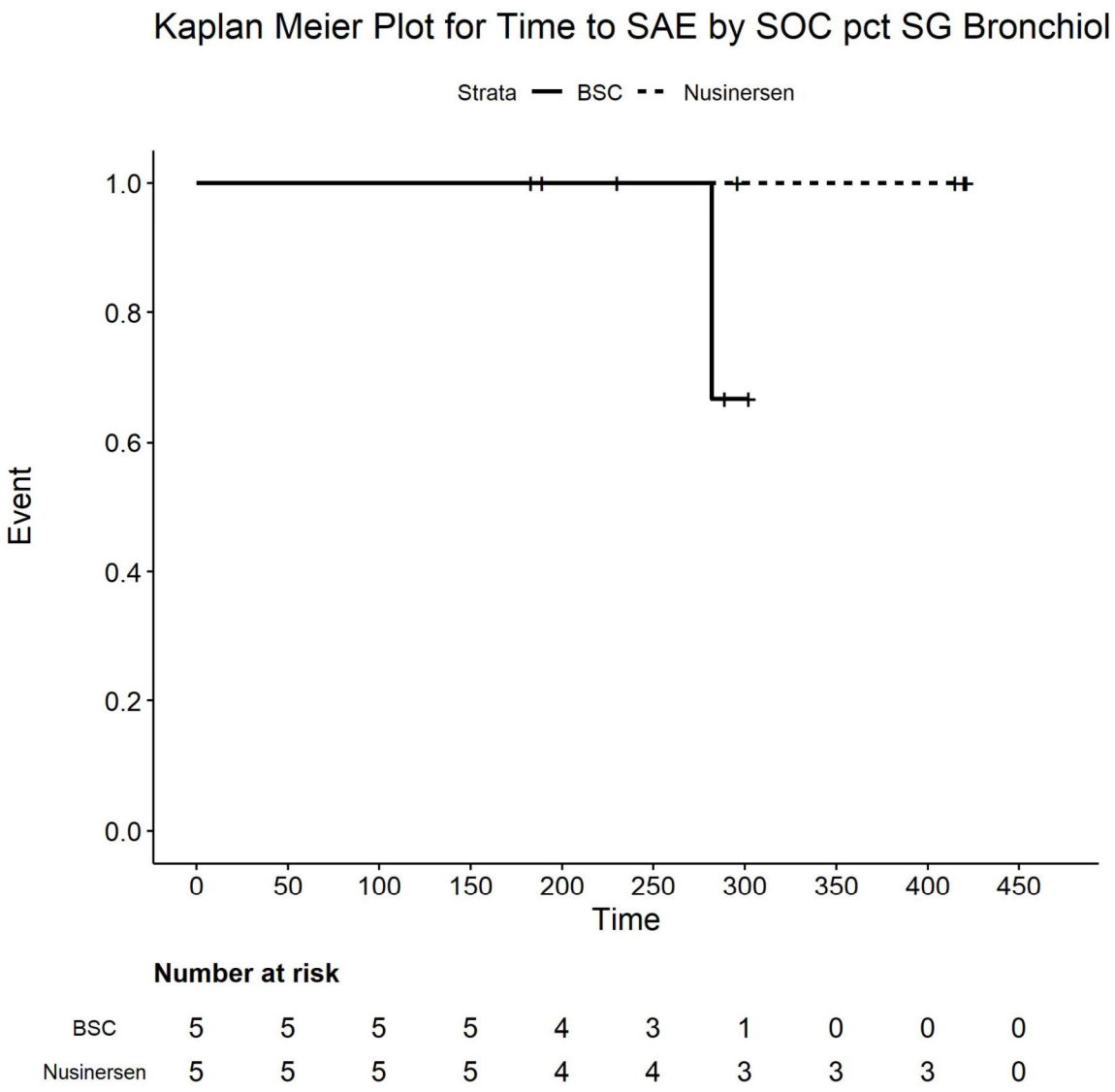
Number at risk

BSC	4	4	4	4	3	3	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



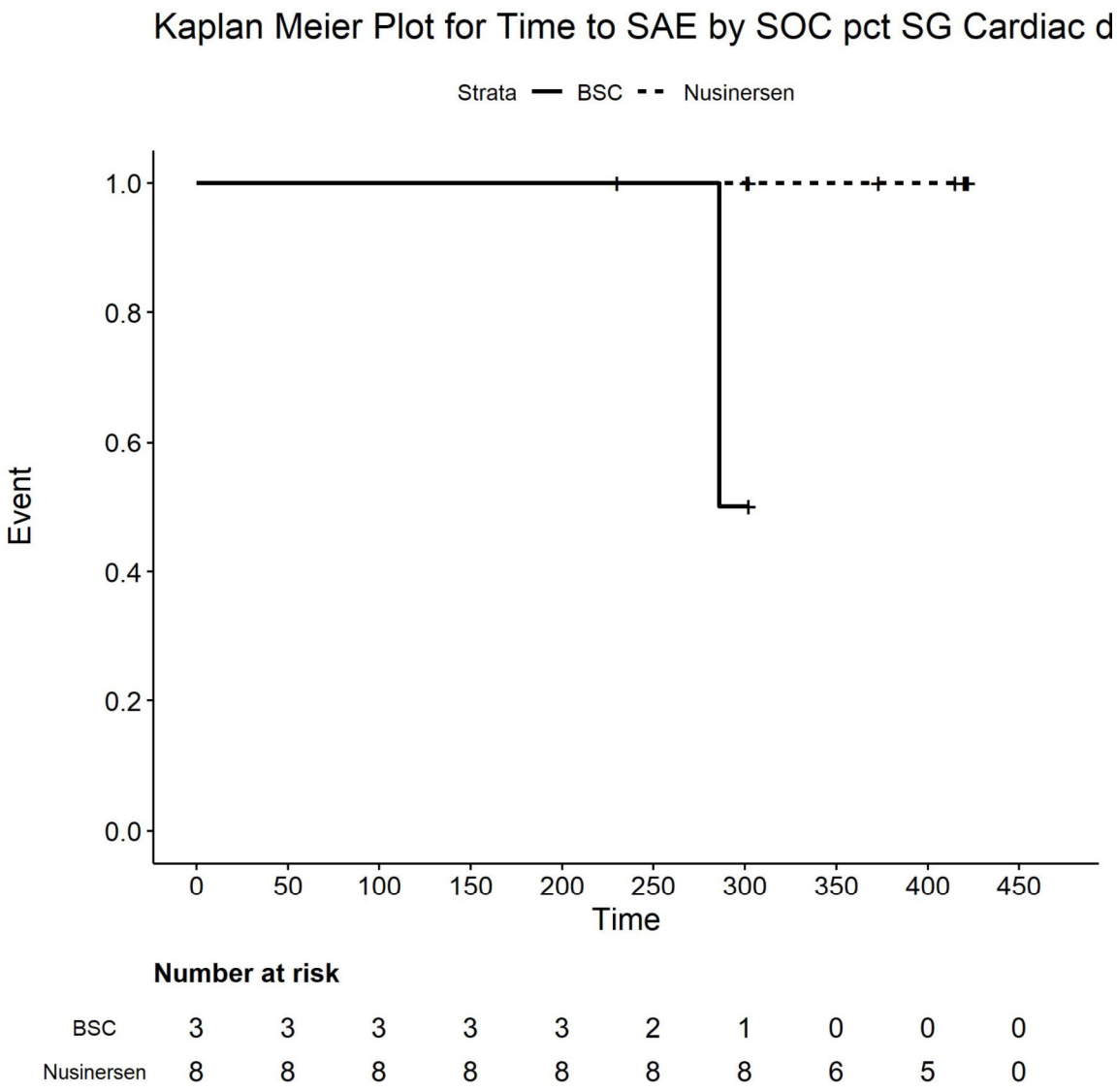
Number at risk

BSC	6	6	6	6	5	5	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



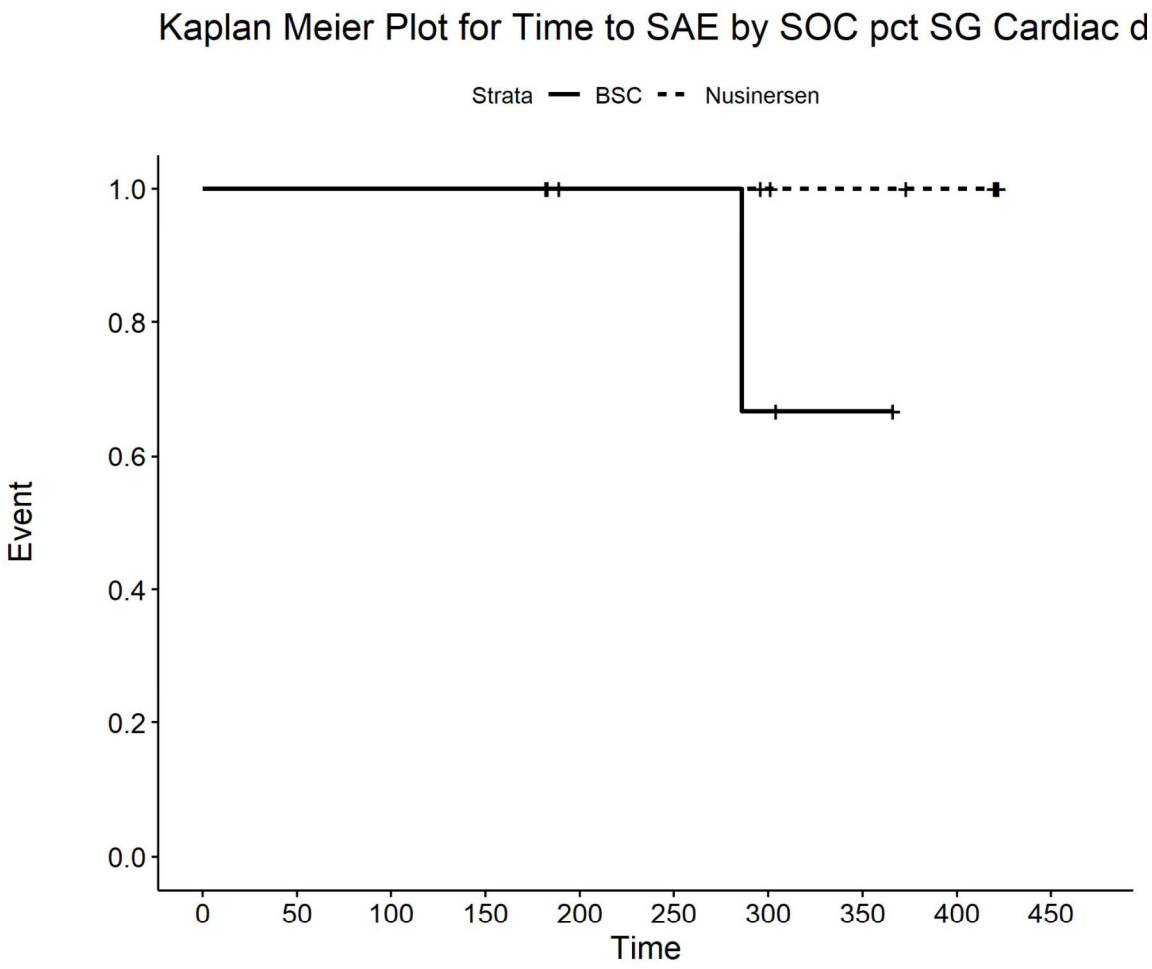
Number at risk

BSC	5	5	5	5	4	3	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



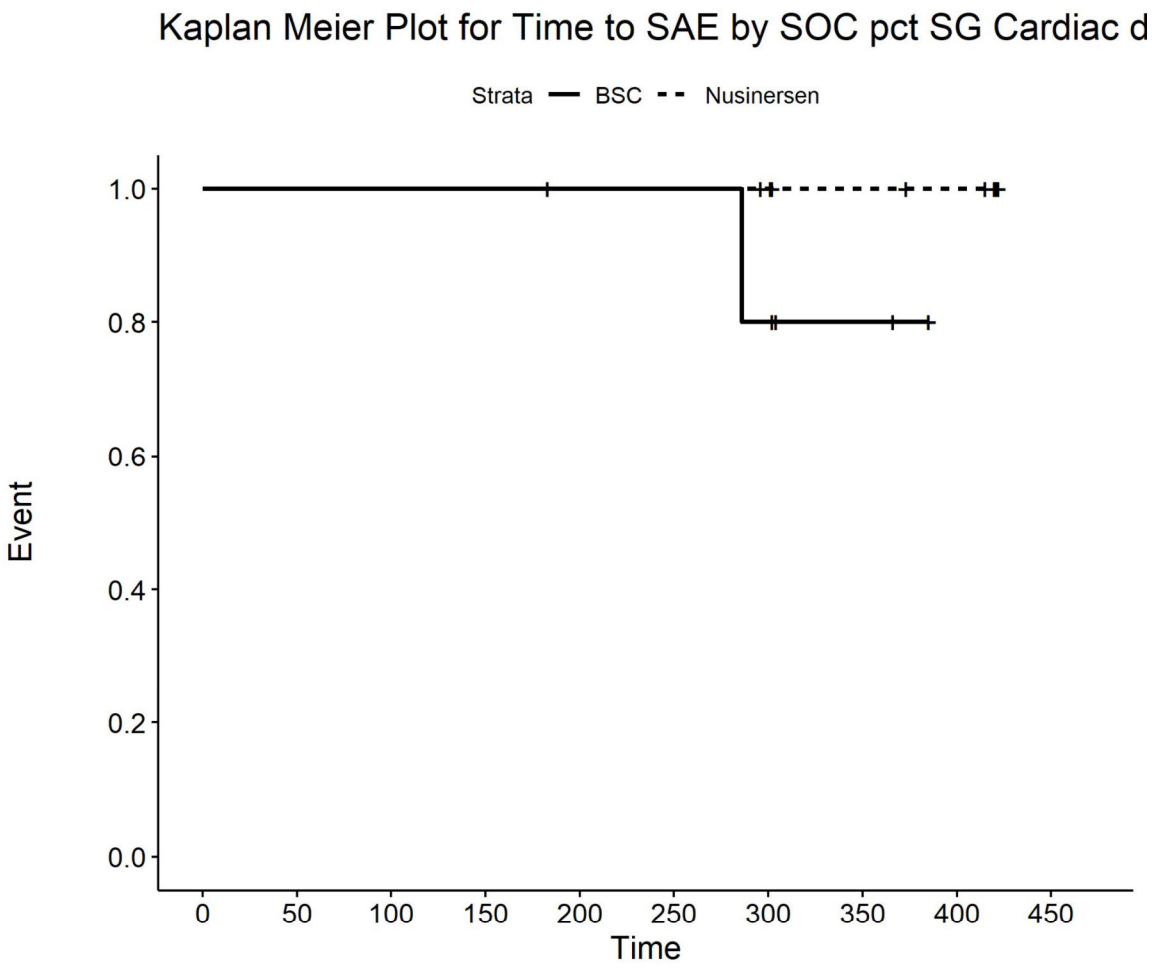
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



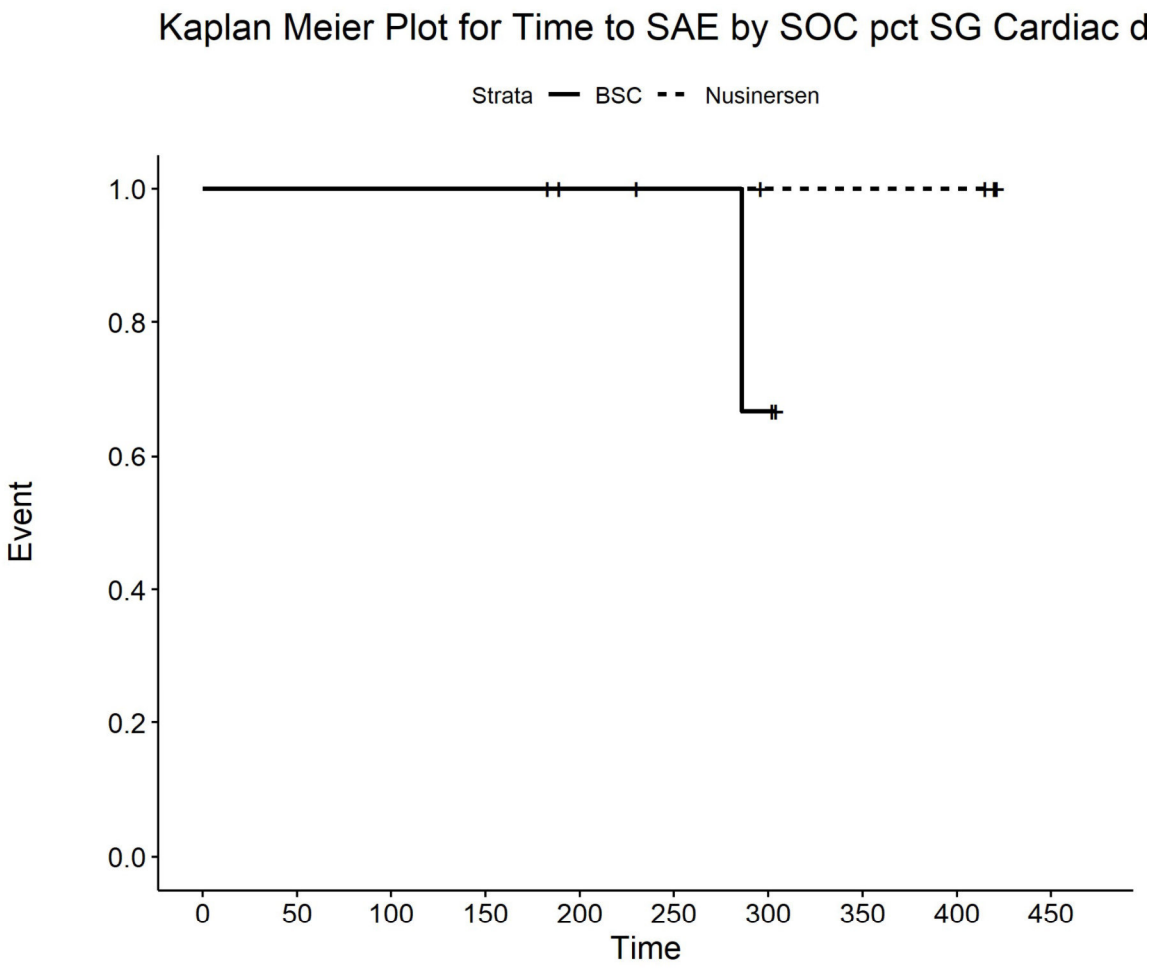
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



Number at risk

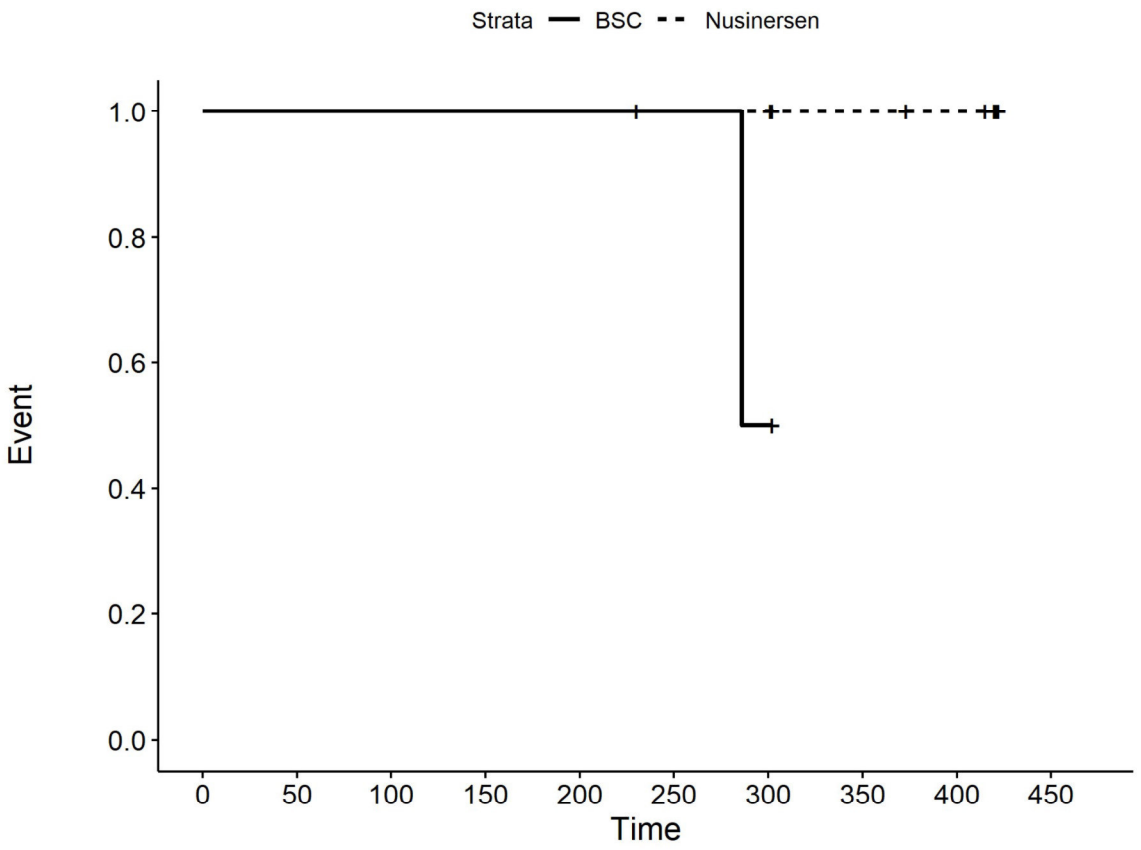
BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0

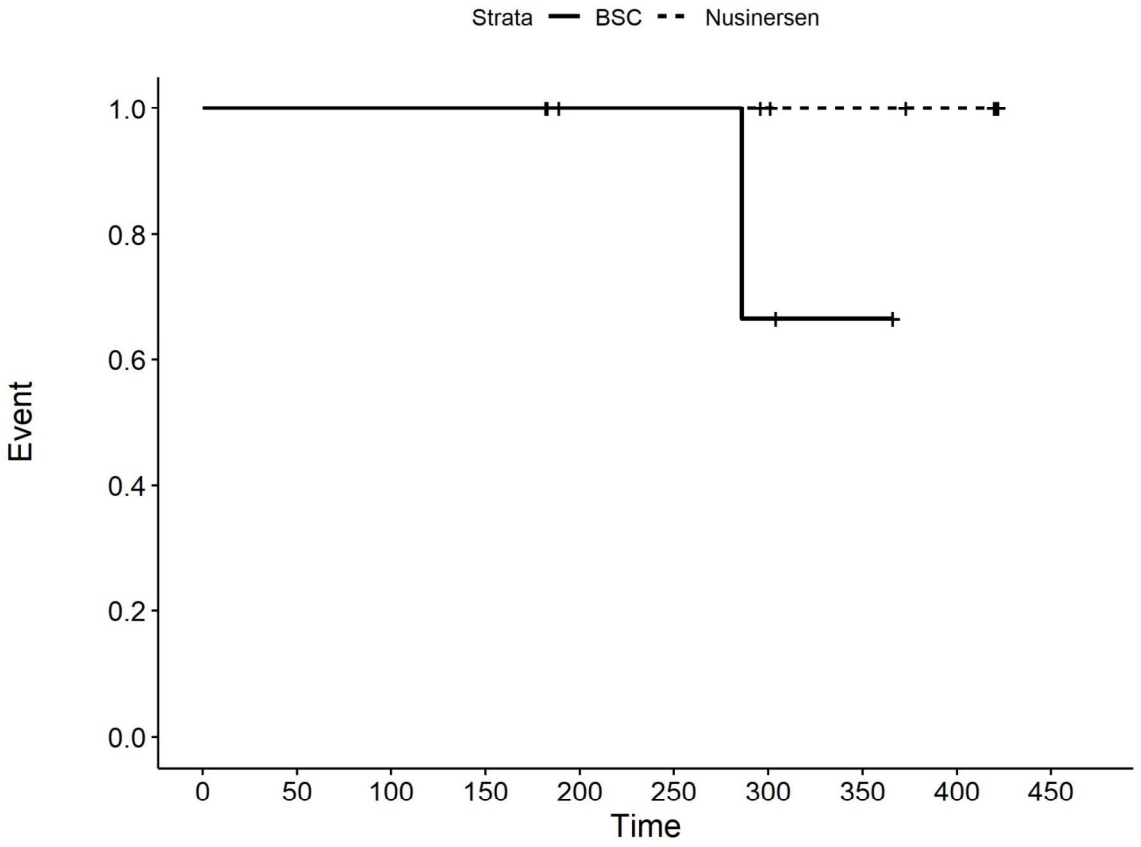
Kaplan Meier Plot for
Time to SAE by SOC pct SG Cardio : respiratory arrest agefc



Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0

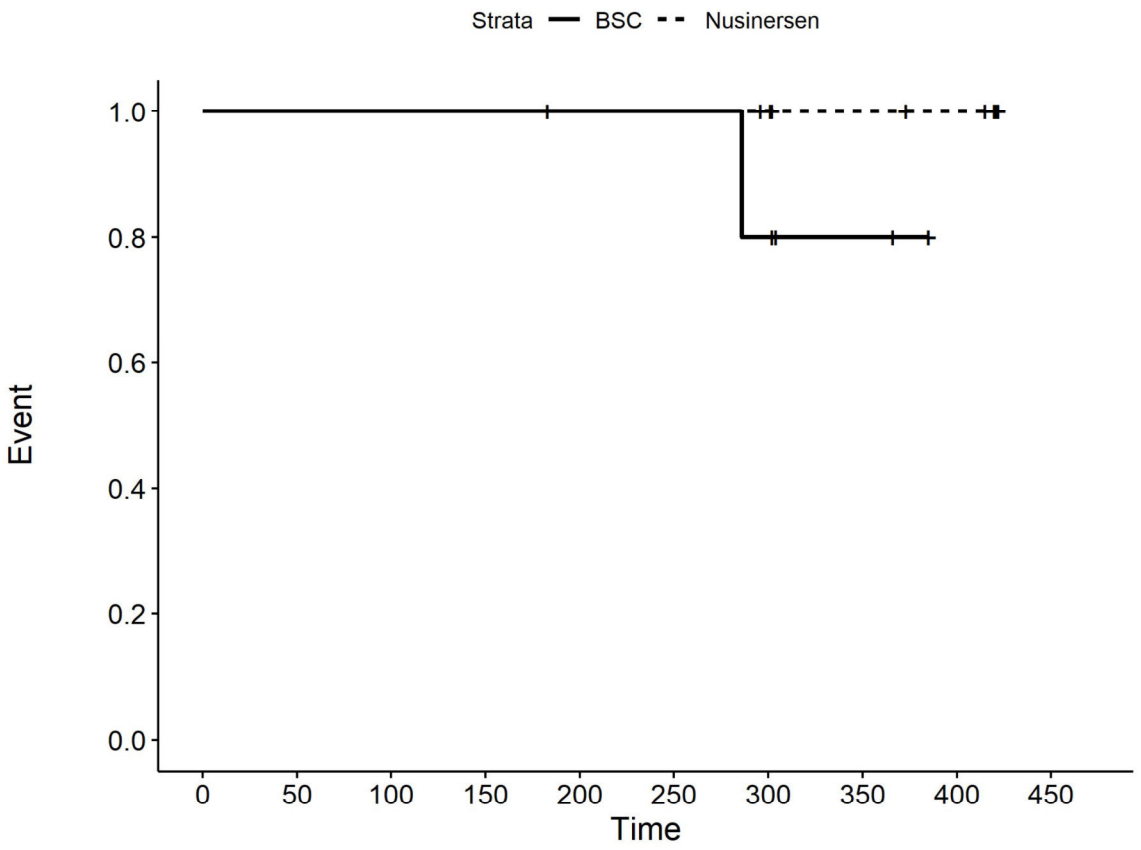
Kaplan Meier Plot for
Time to SAE by SOC pct SG Cardio : respiratory arrest ageo



Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0

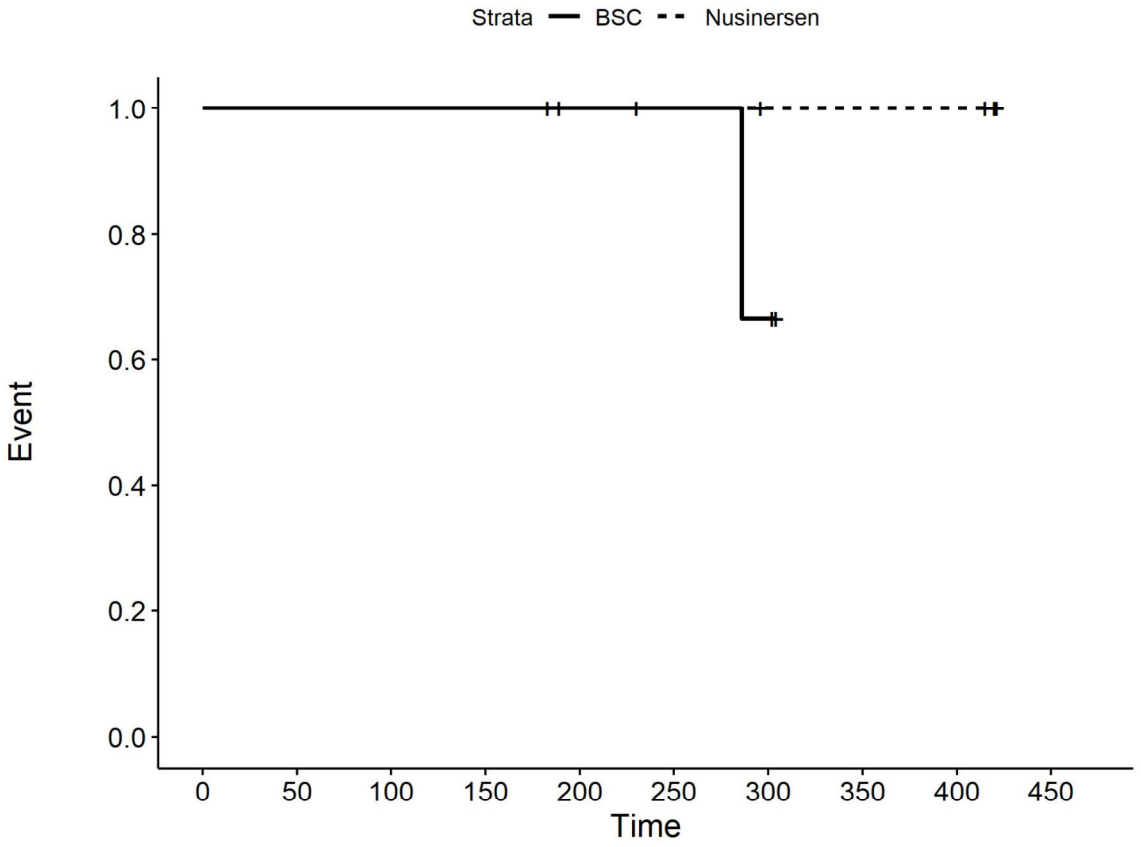
Kaplan Meier Plot for
Time to SAE by SOC pct SG Cardio : respiratory arrest coun



Number at risk

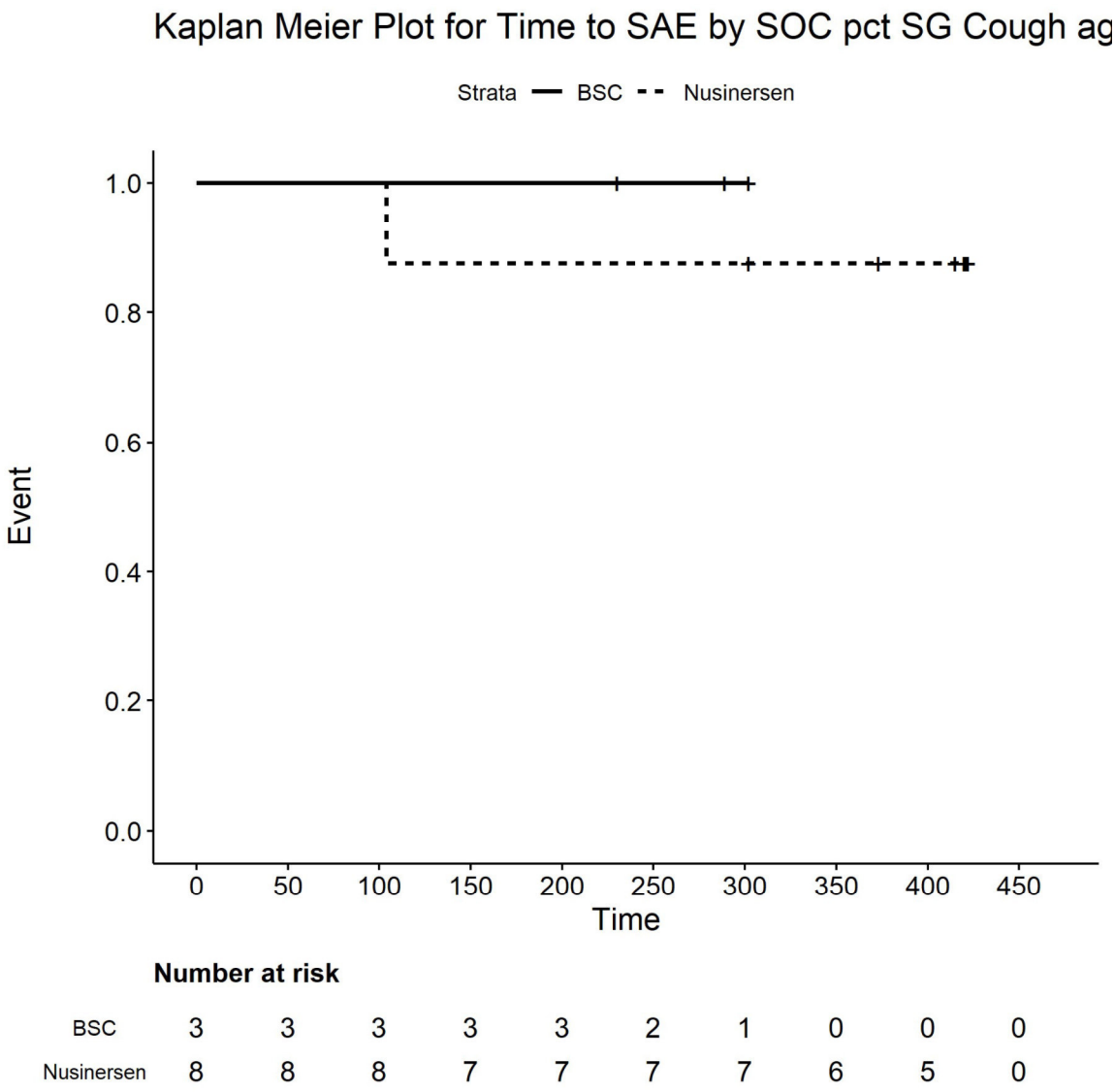
BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0

Kaplan Meier Plot for
Time to SAE by SOC pct SG Cardio : respiratory arrest sex f



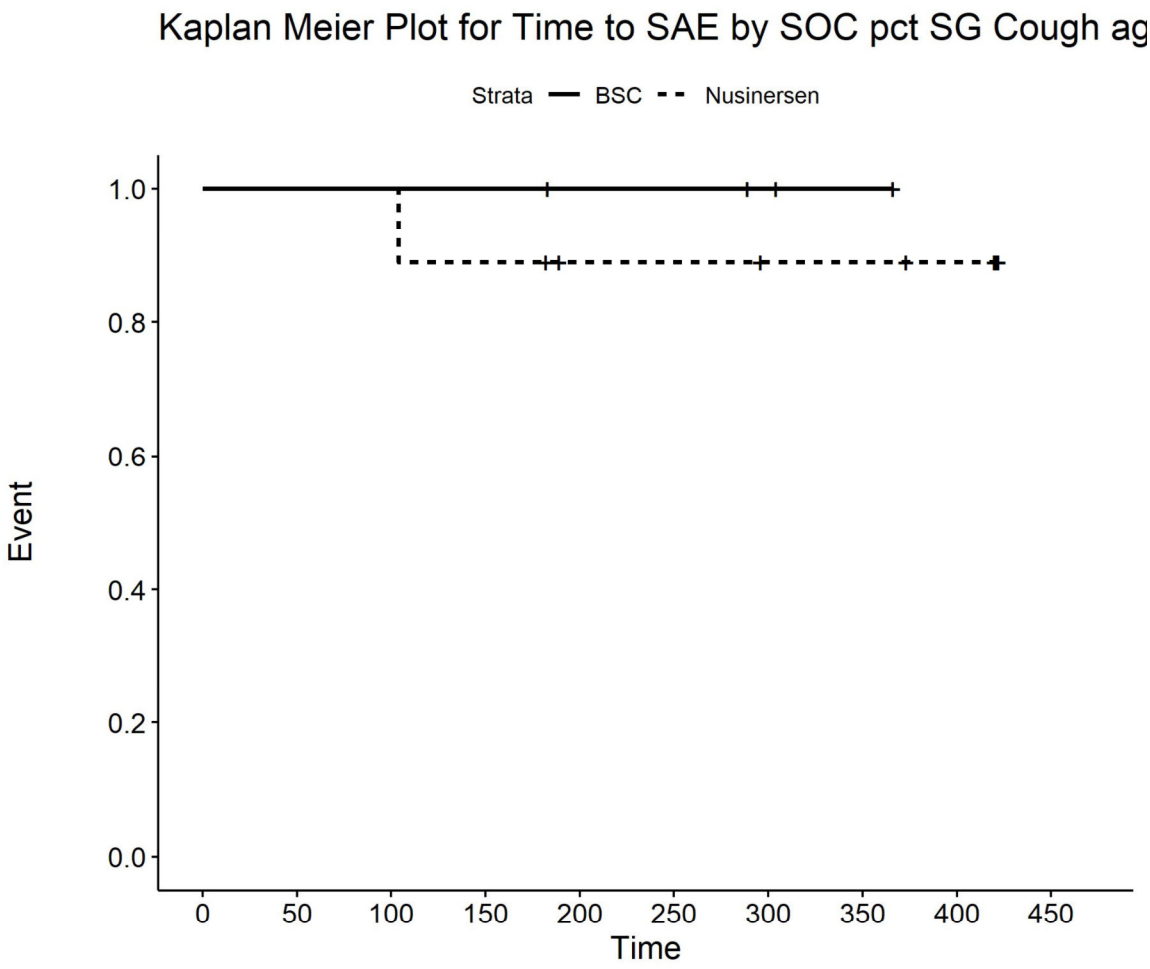
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



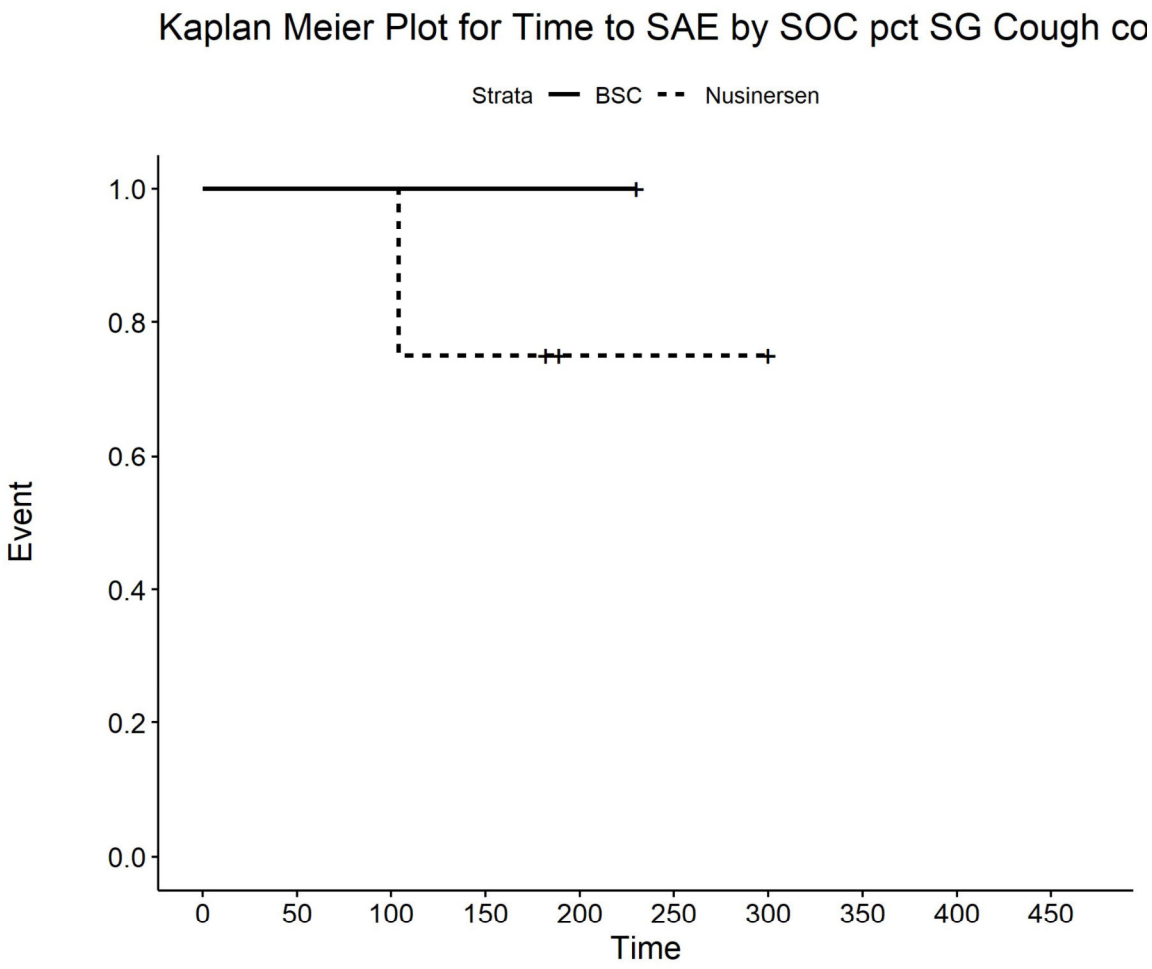
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	6	5	0



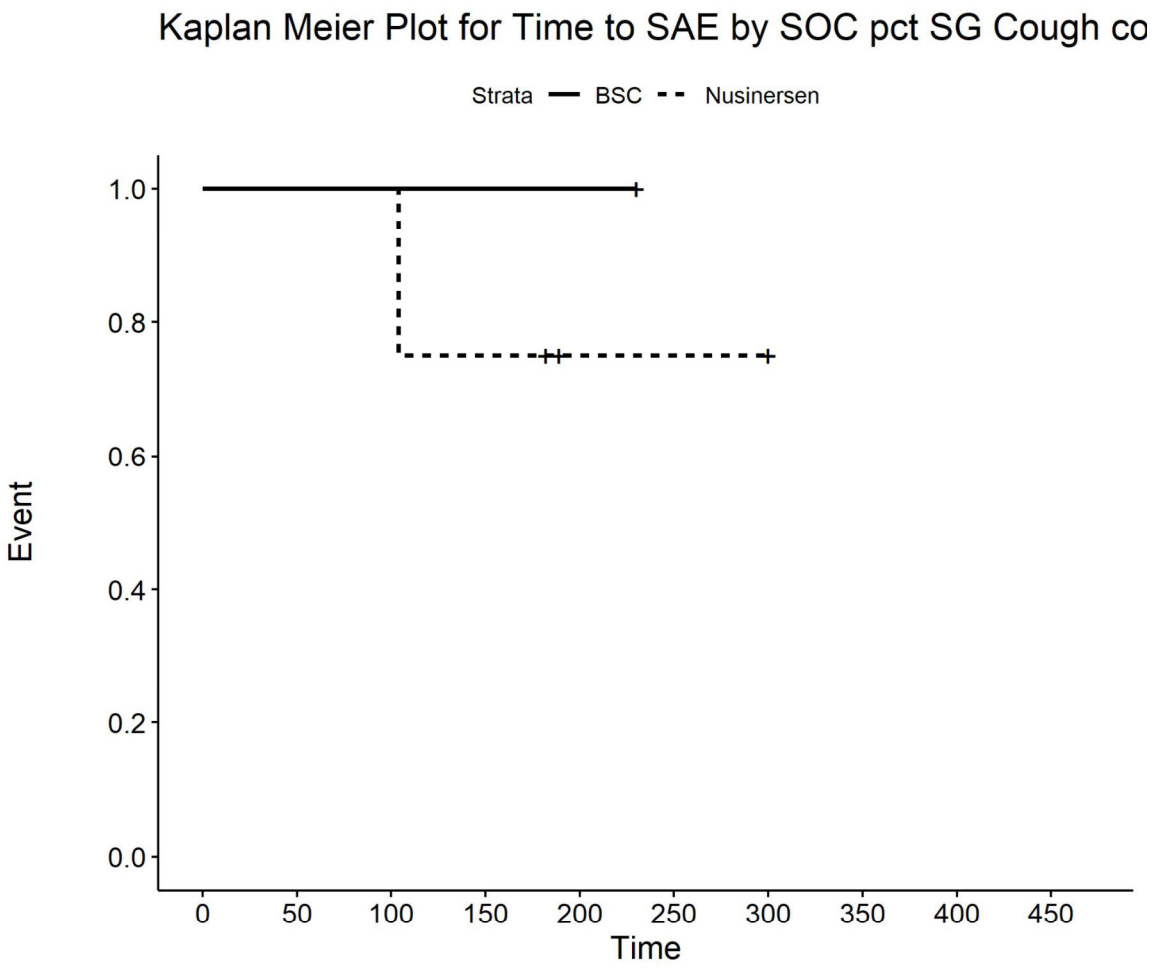
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	5	4	0



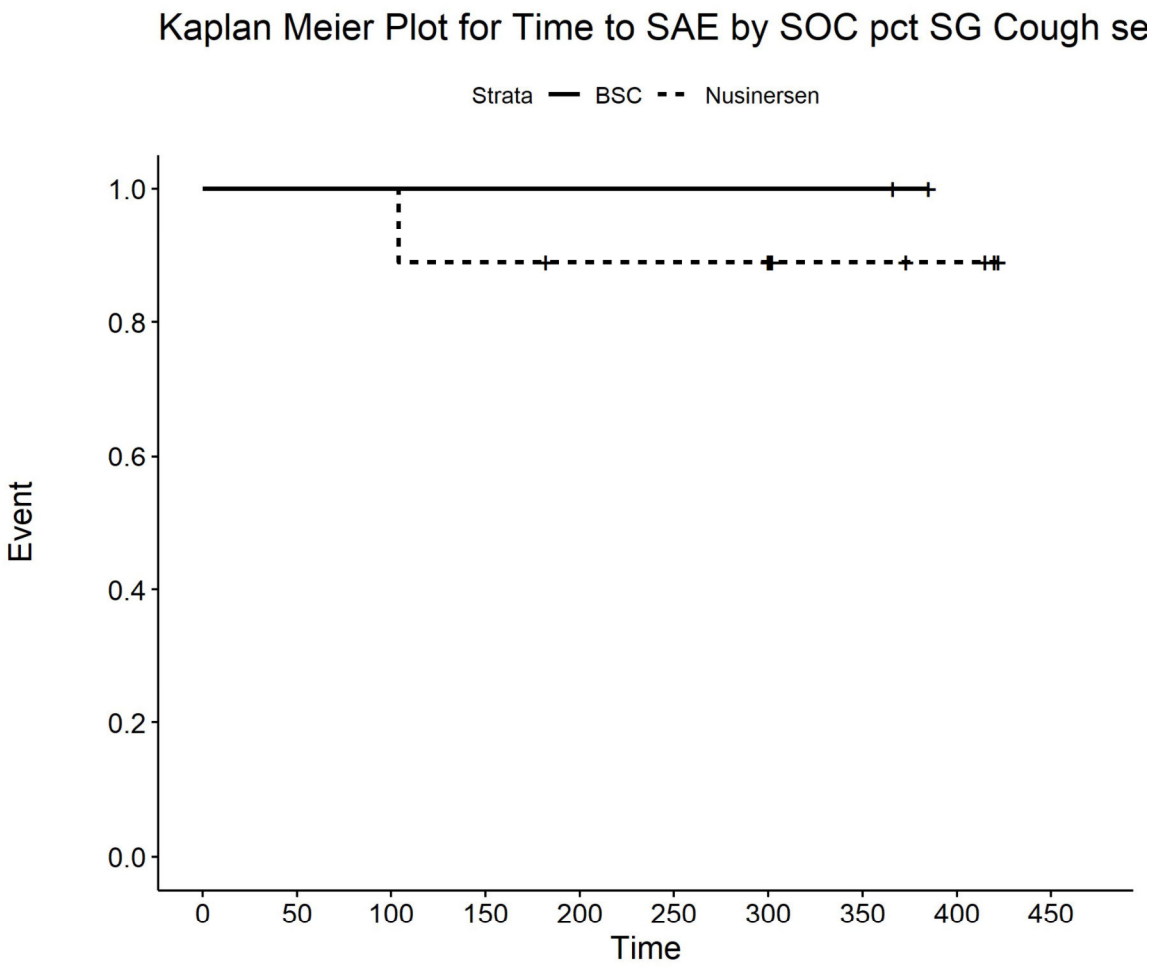
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



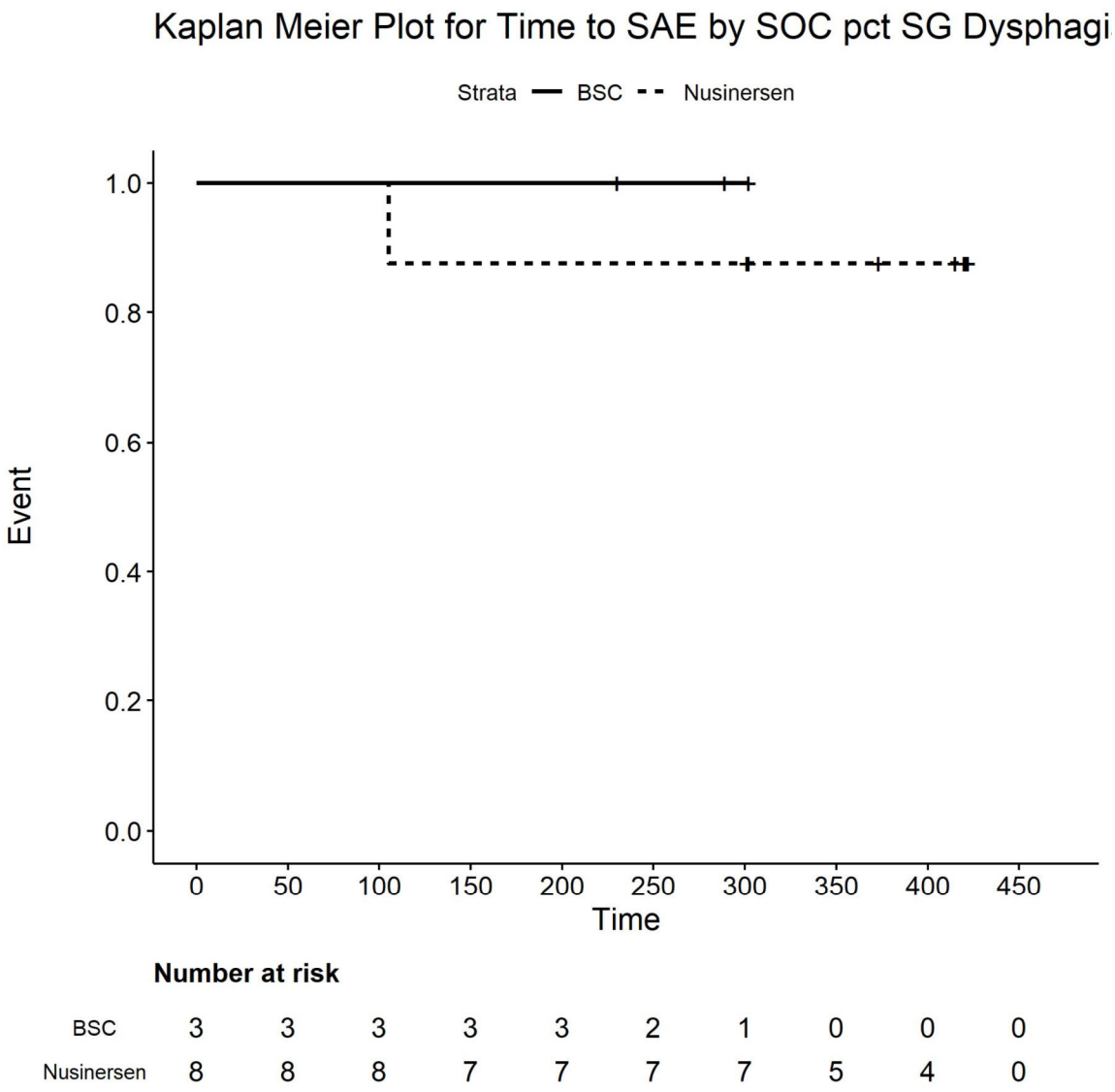
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



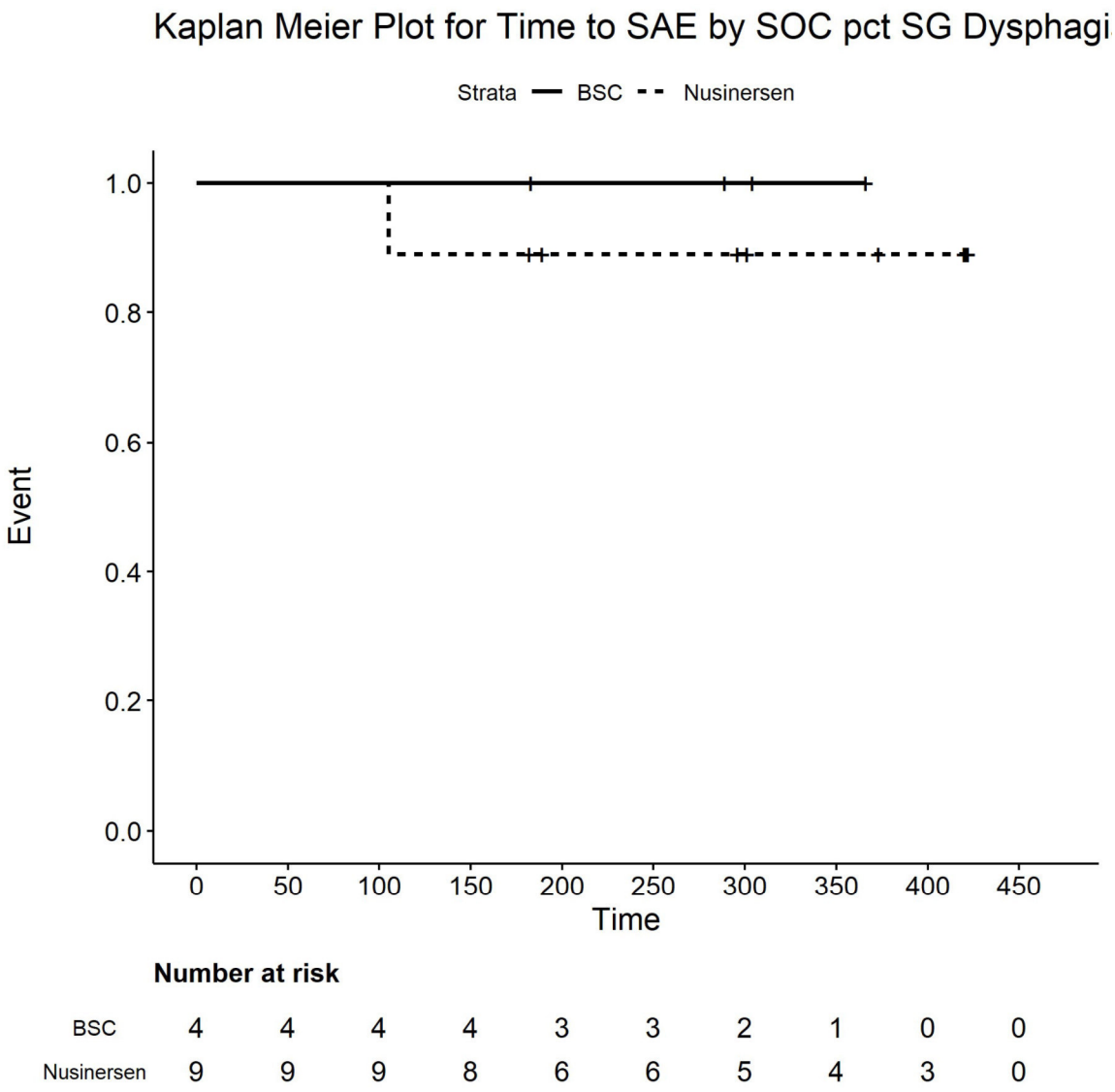
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	4	3	0



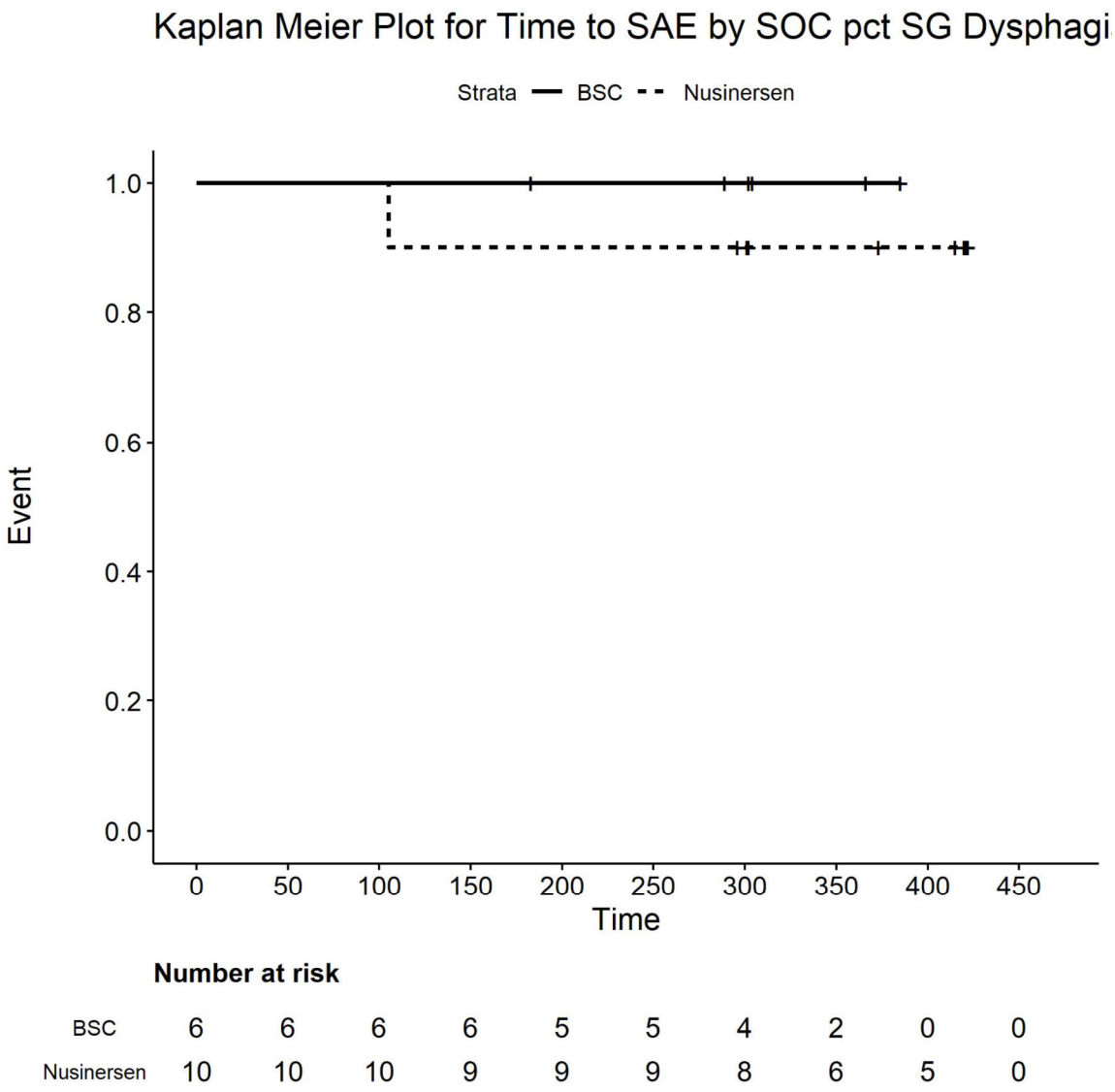
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



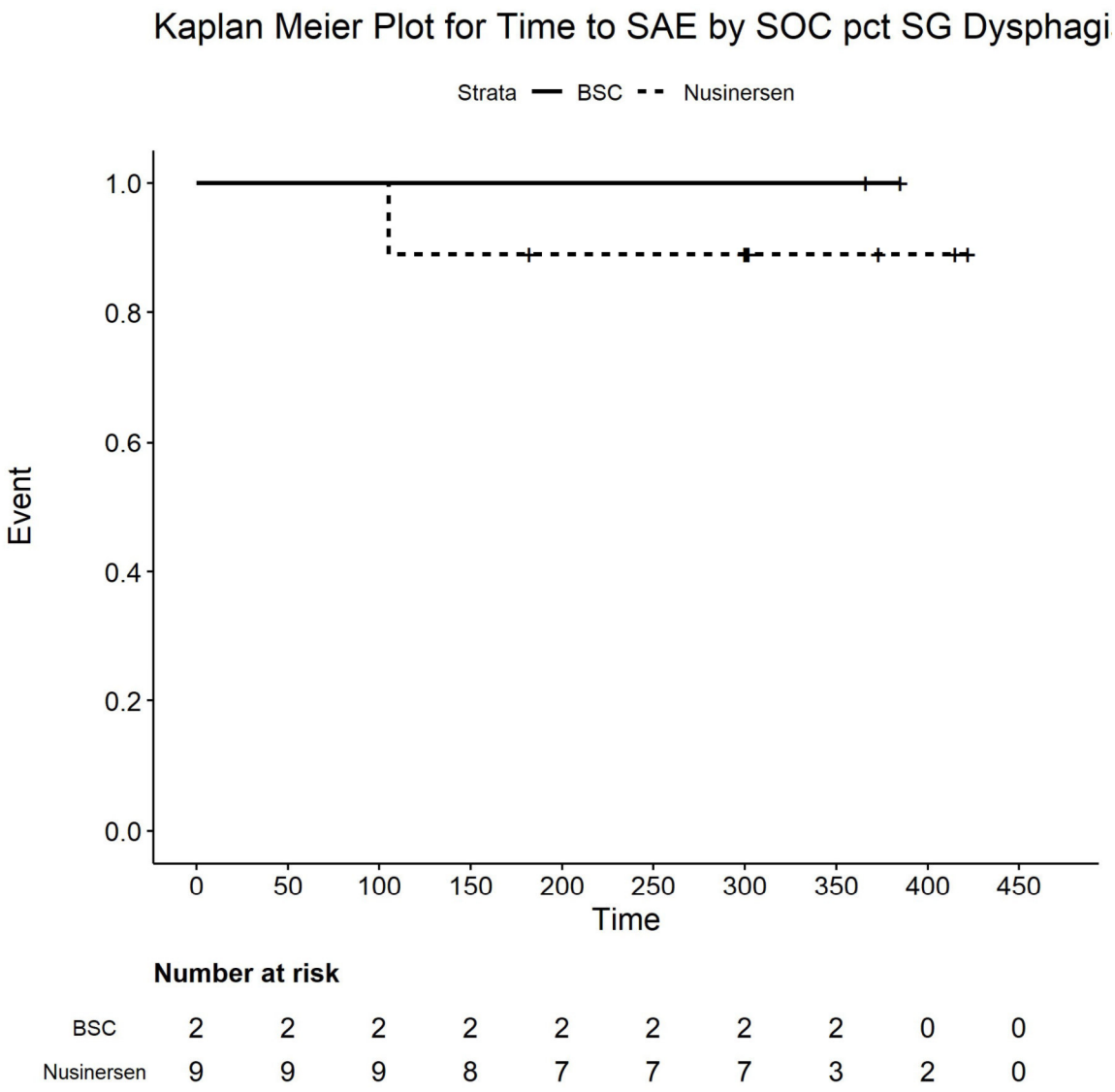
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



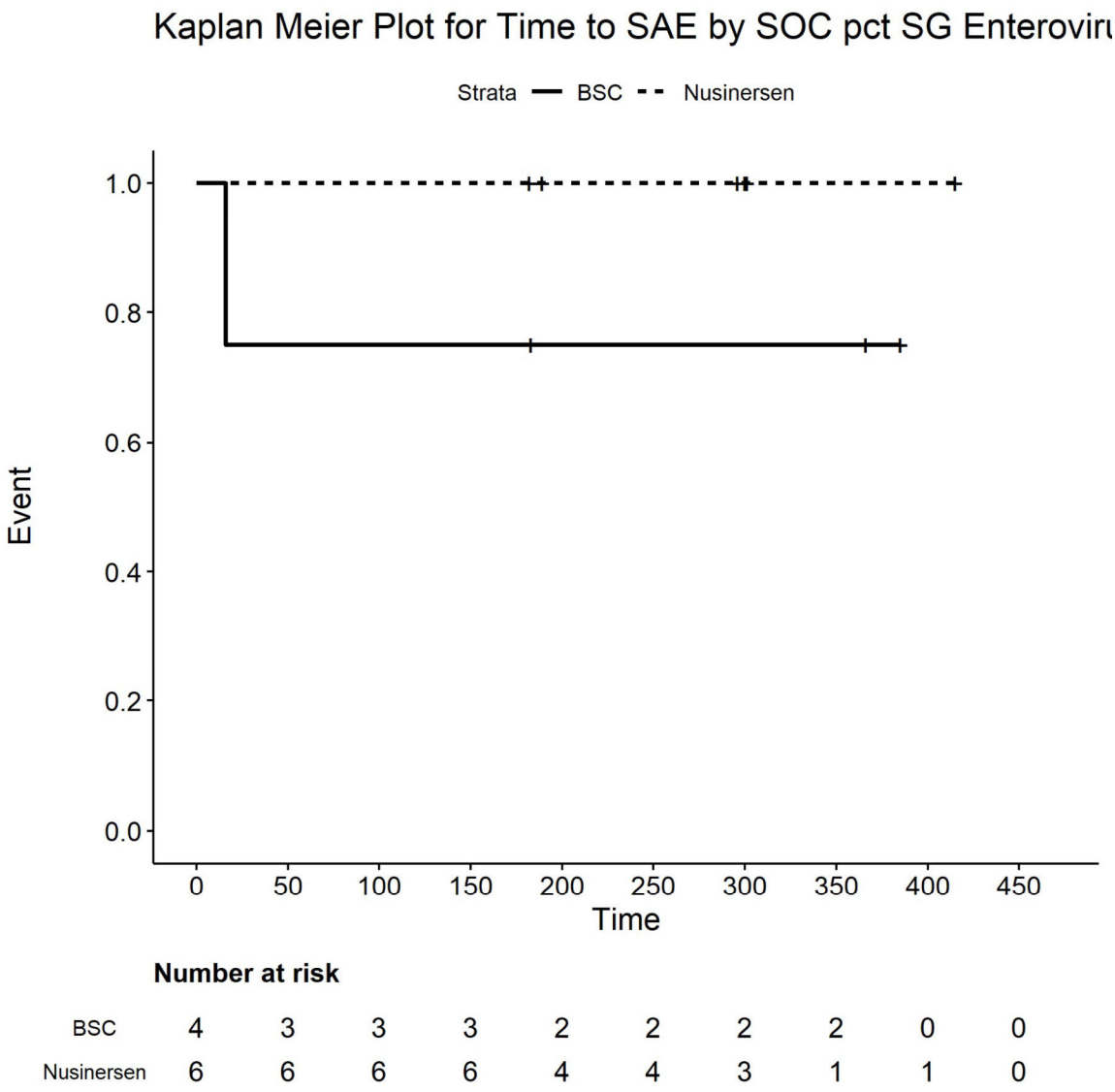
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



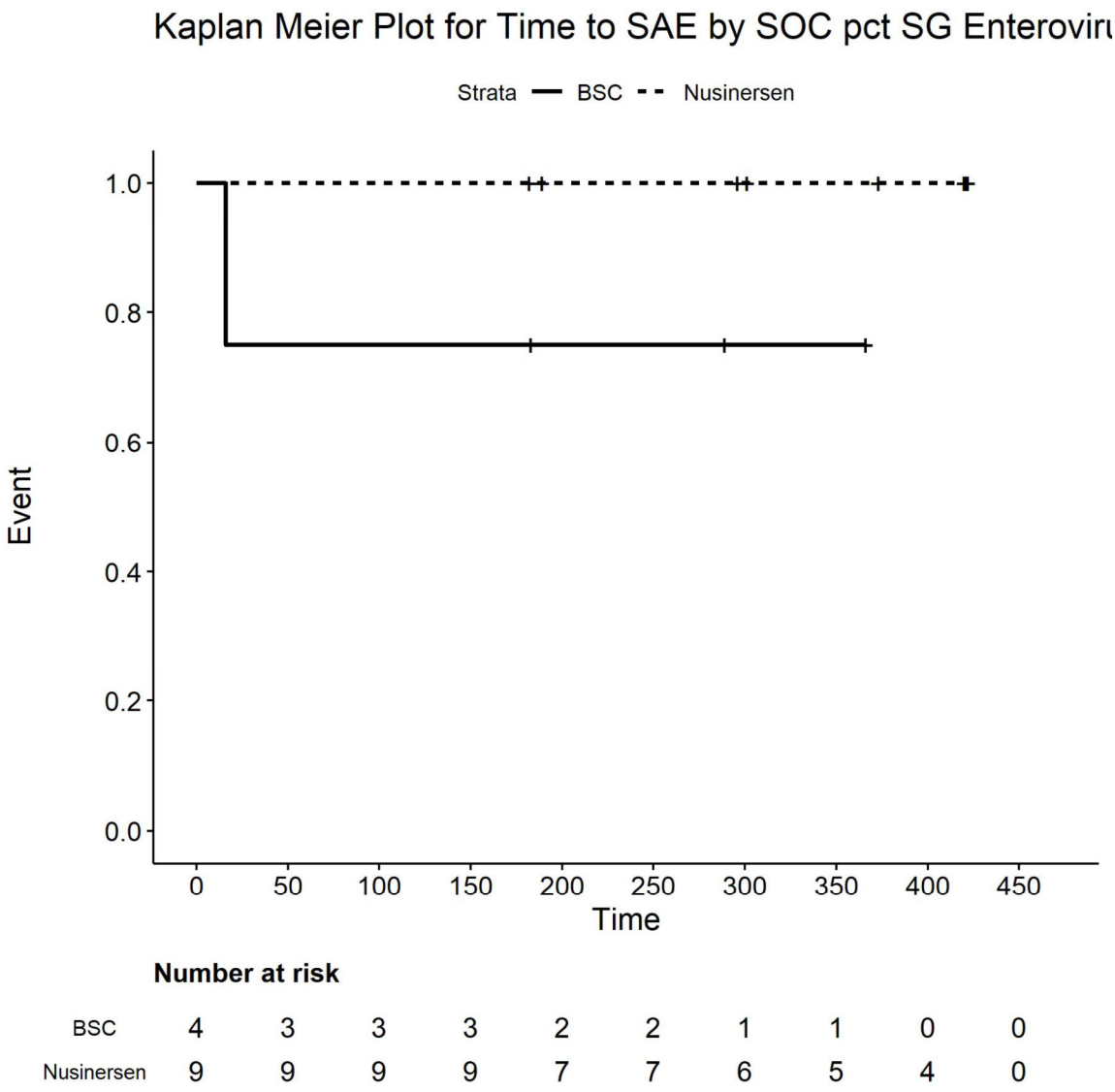
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



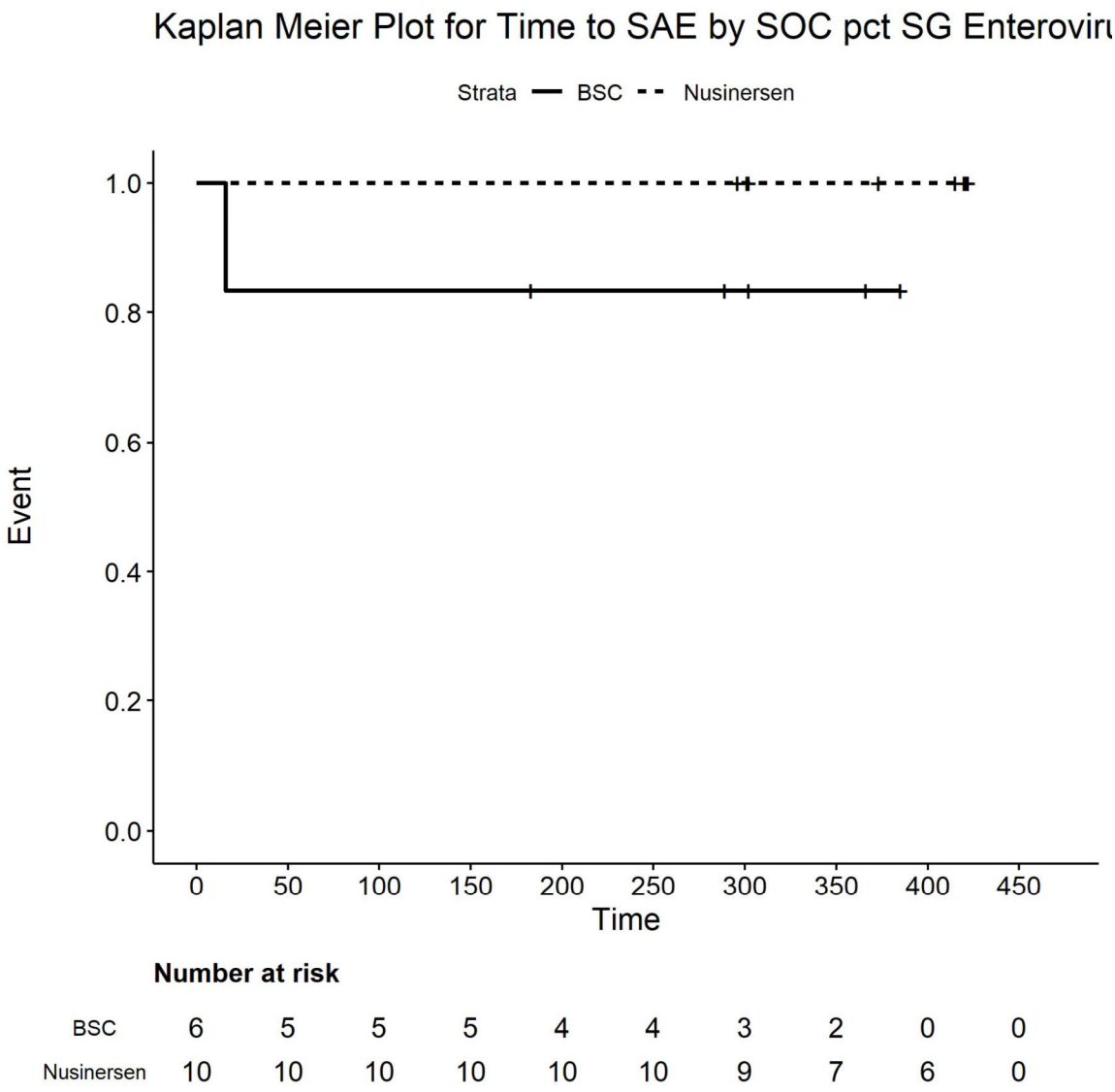
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



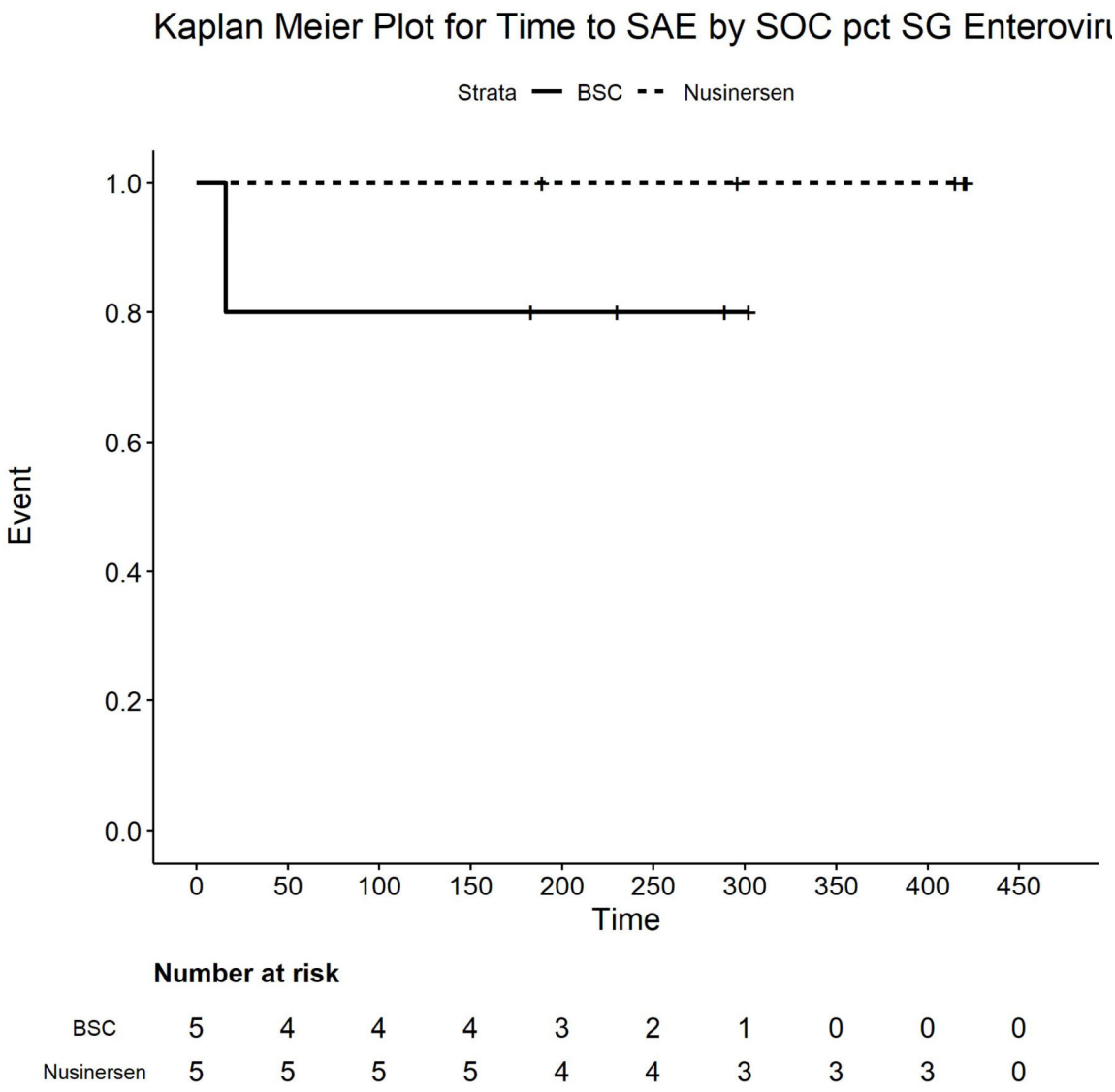
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



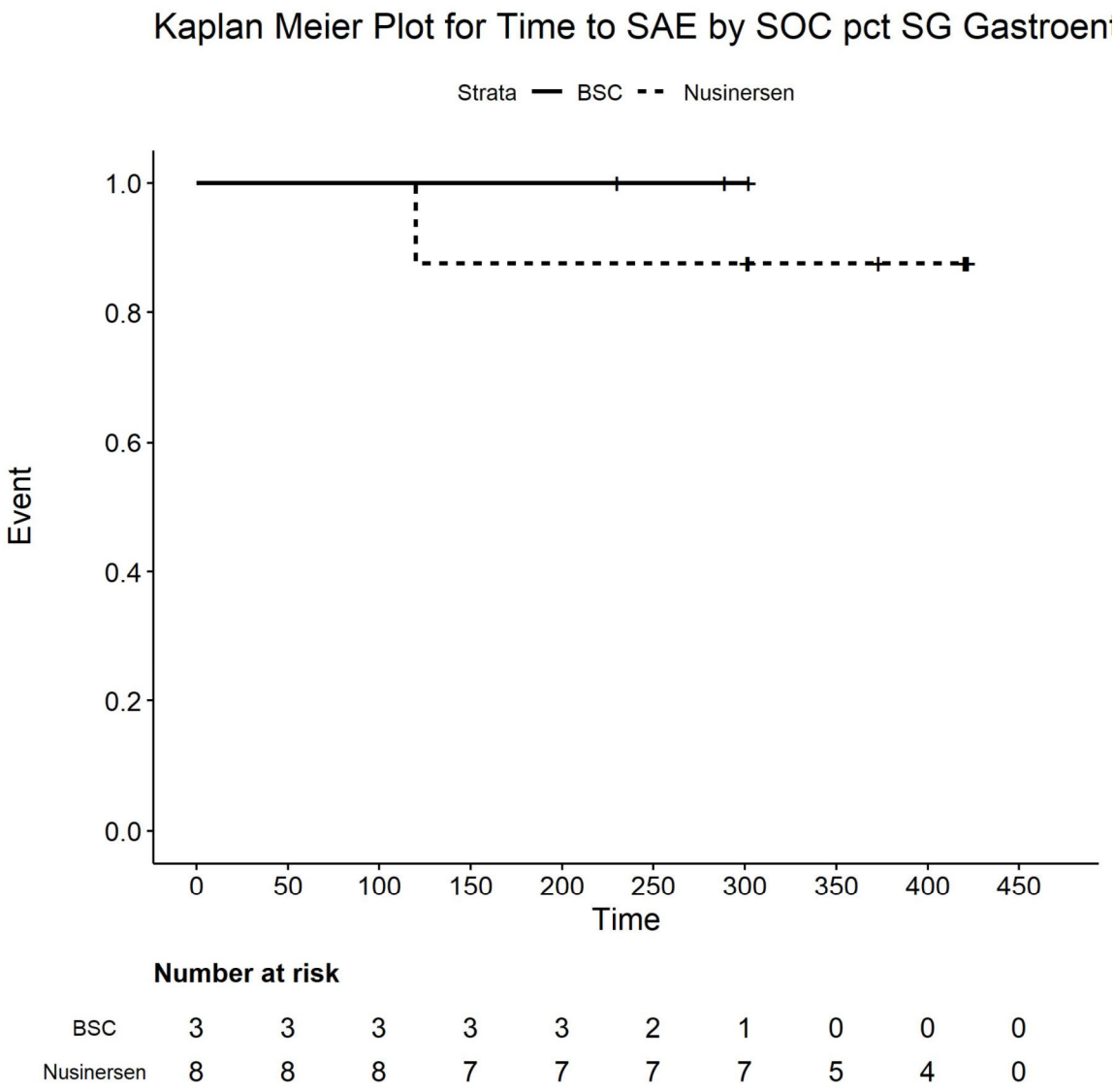
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



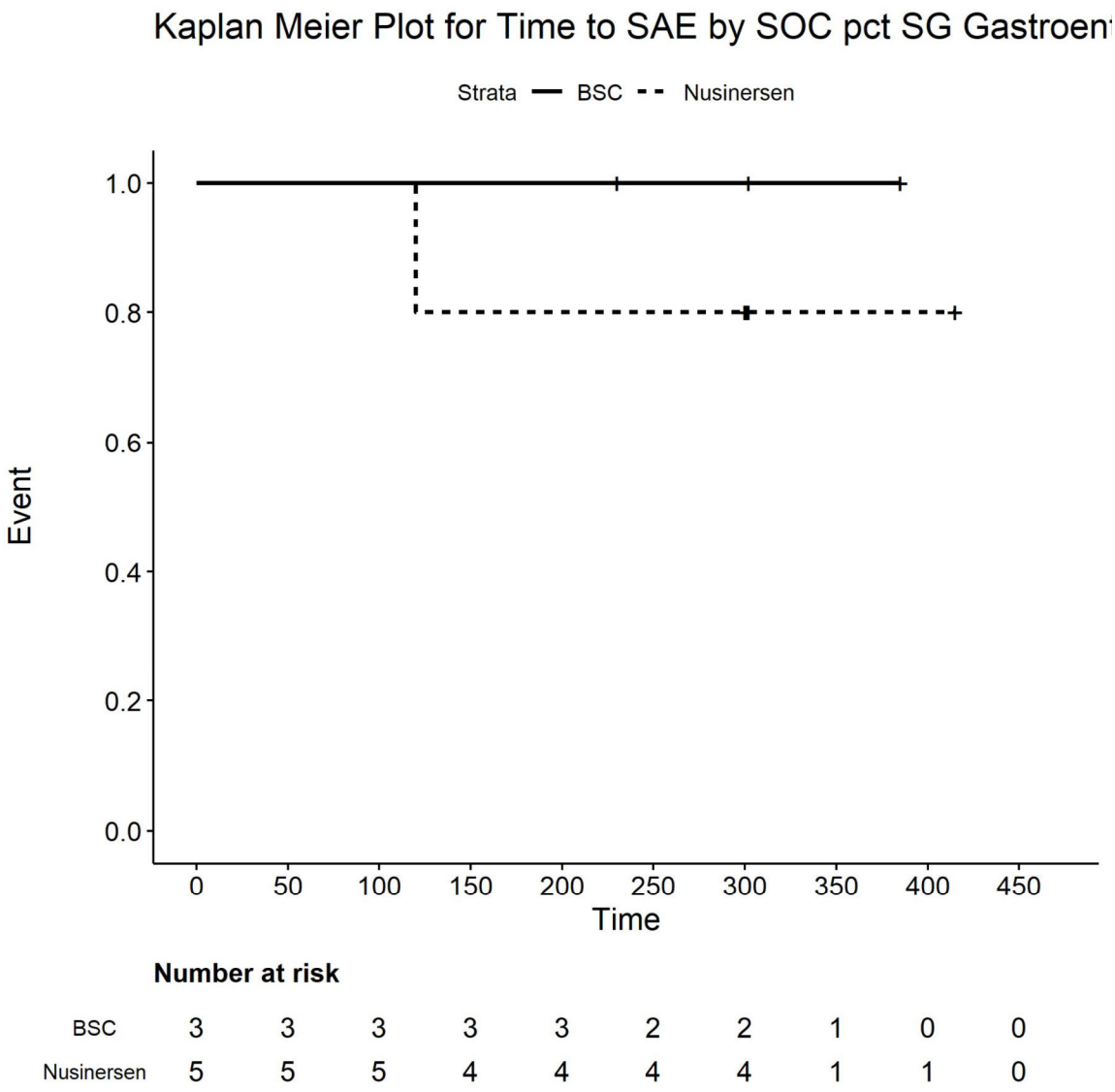
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



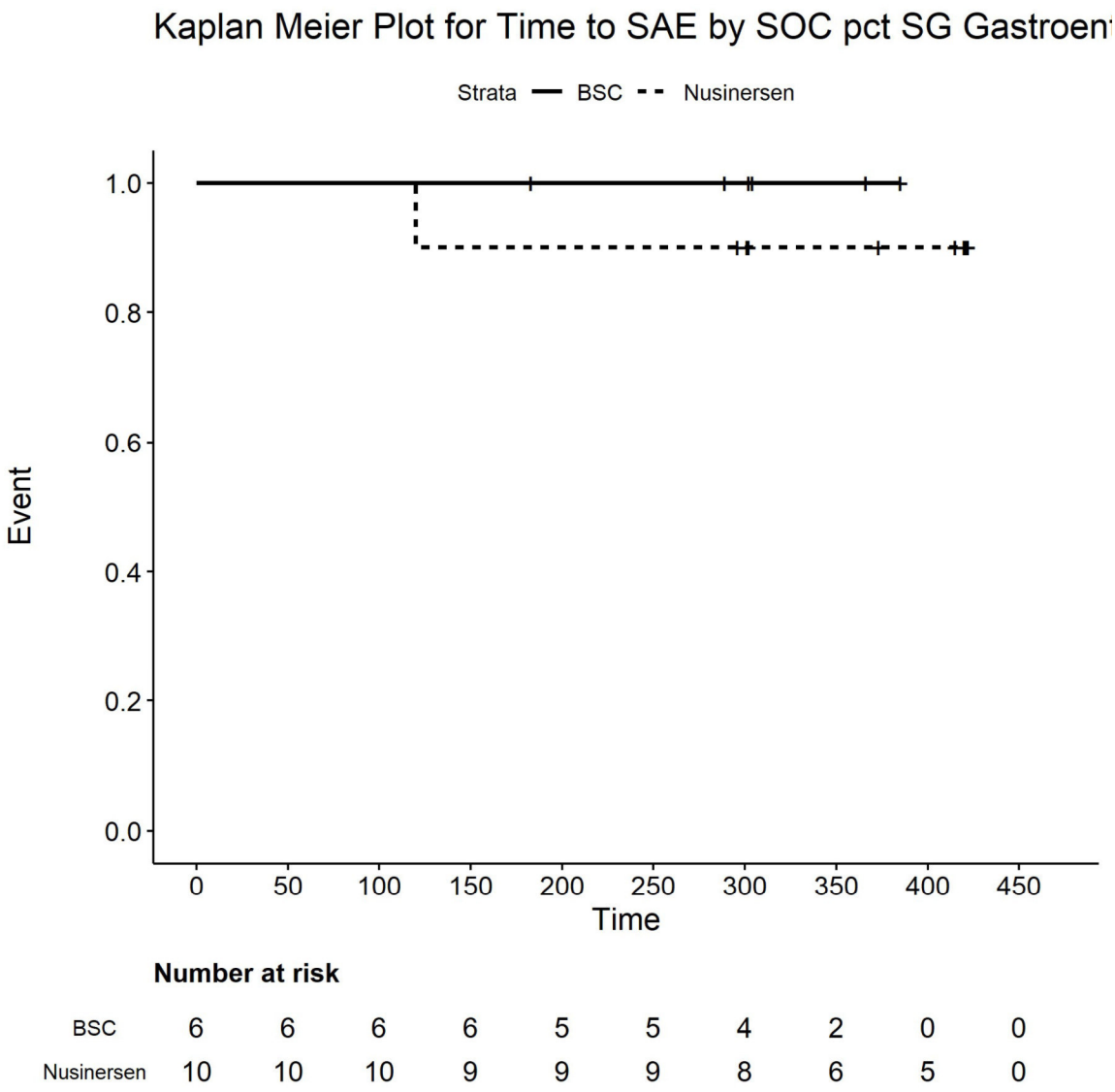
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



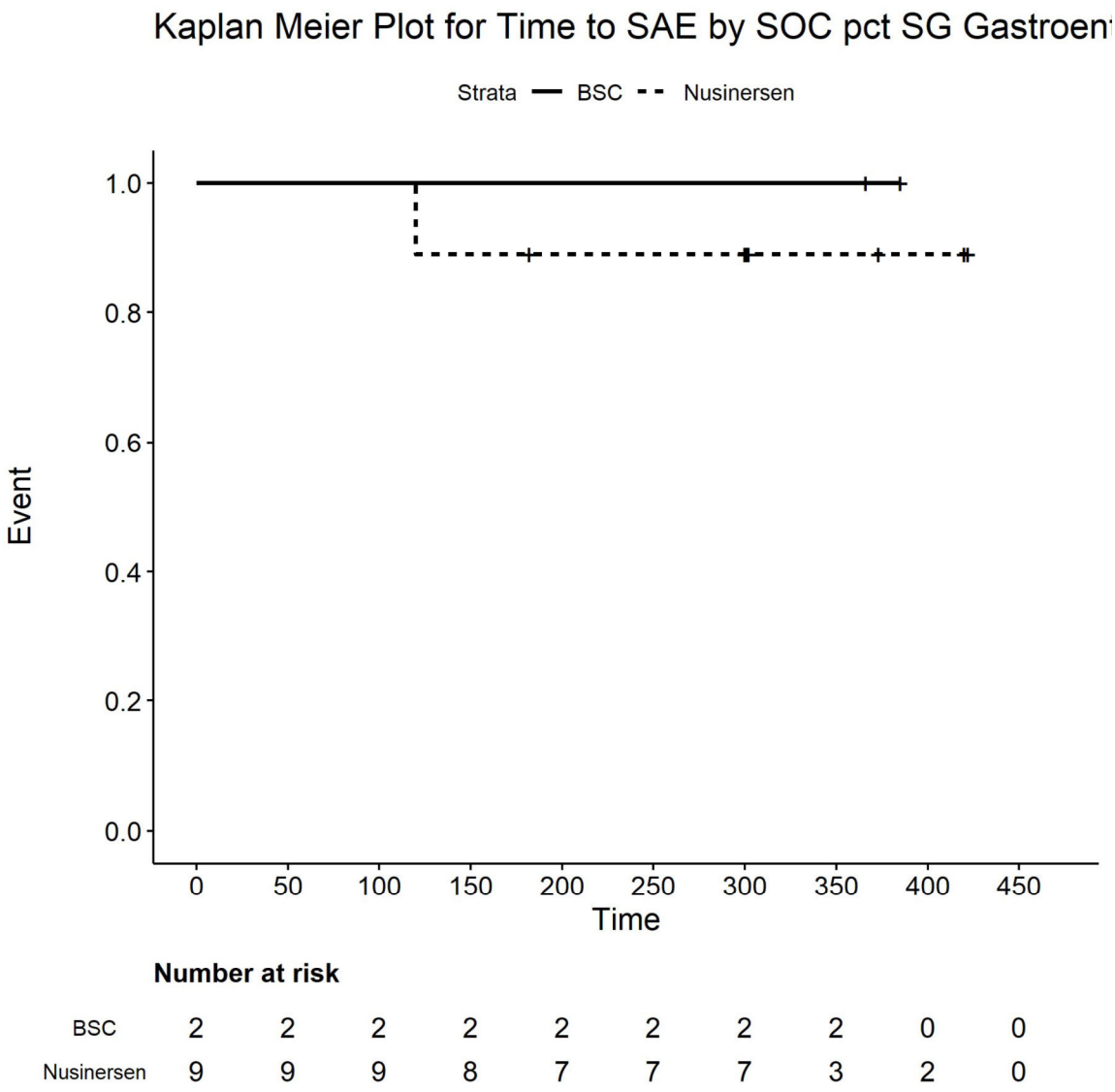
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	4	4	4	4	1	1	0



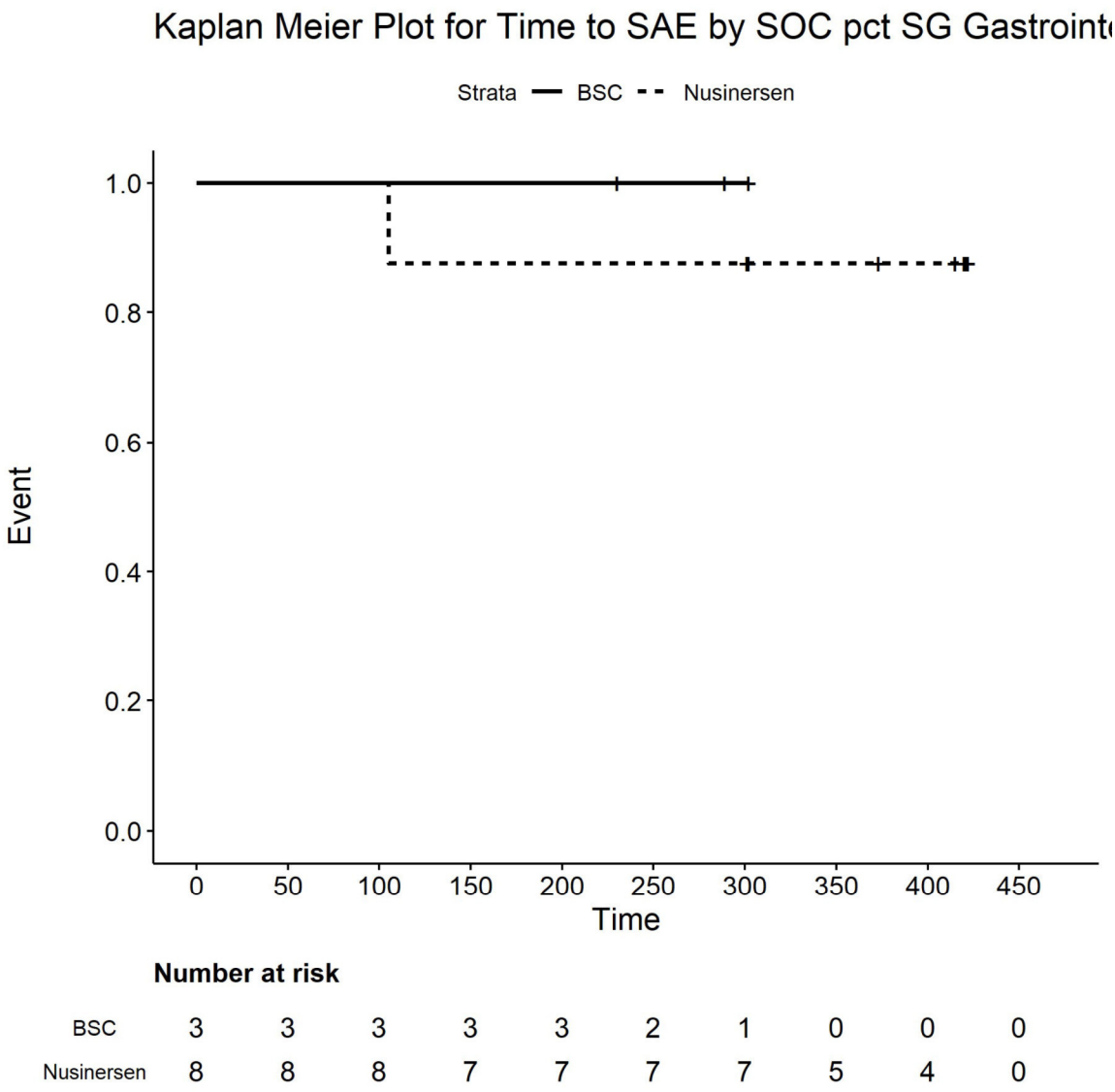
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



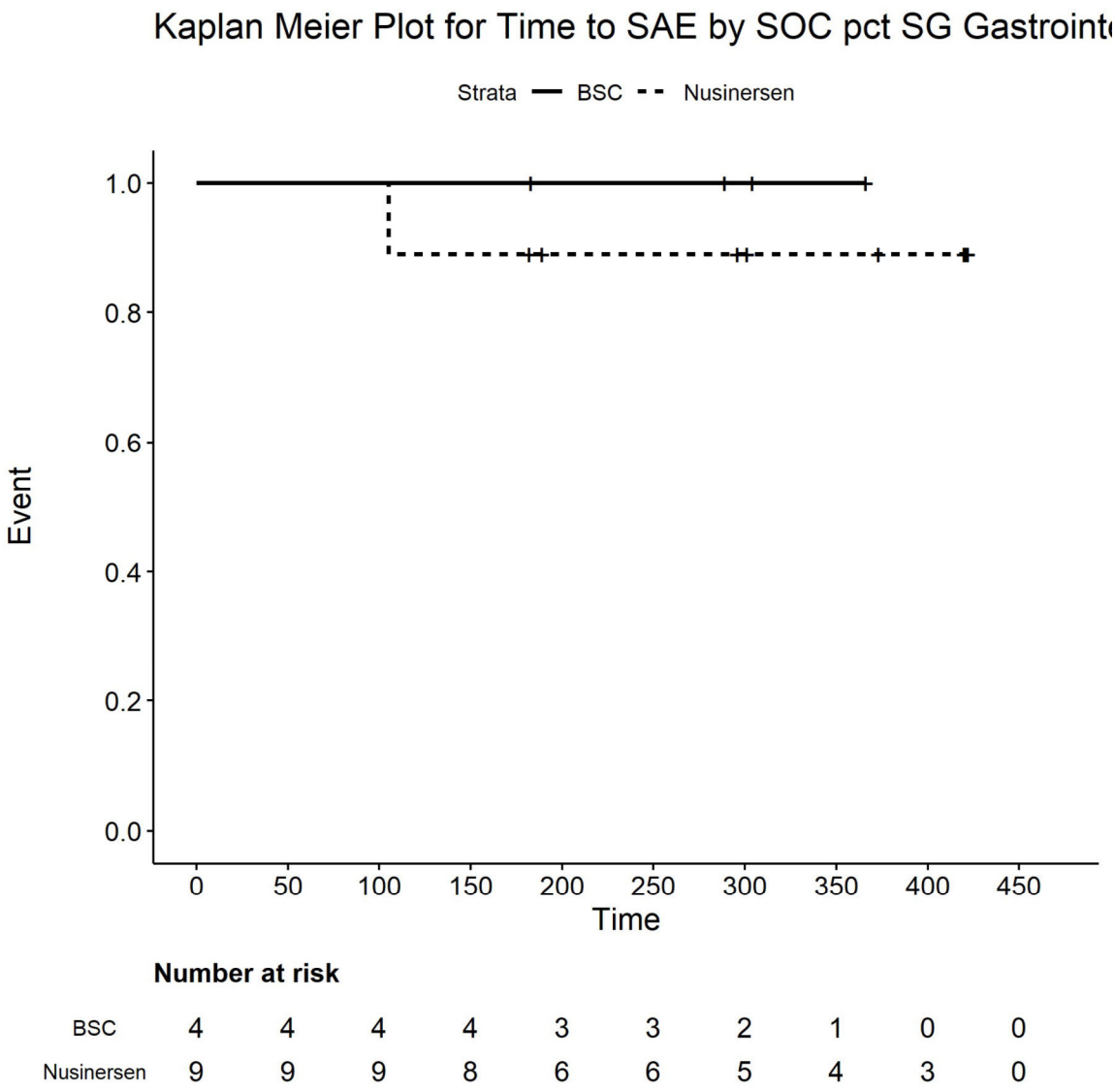
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



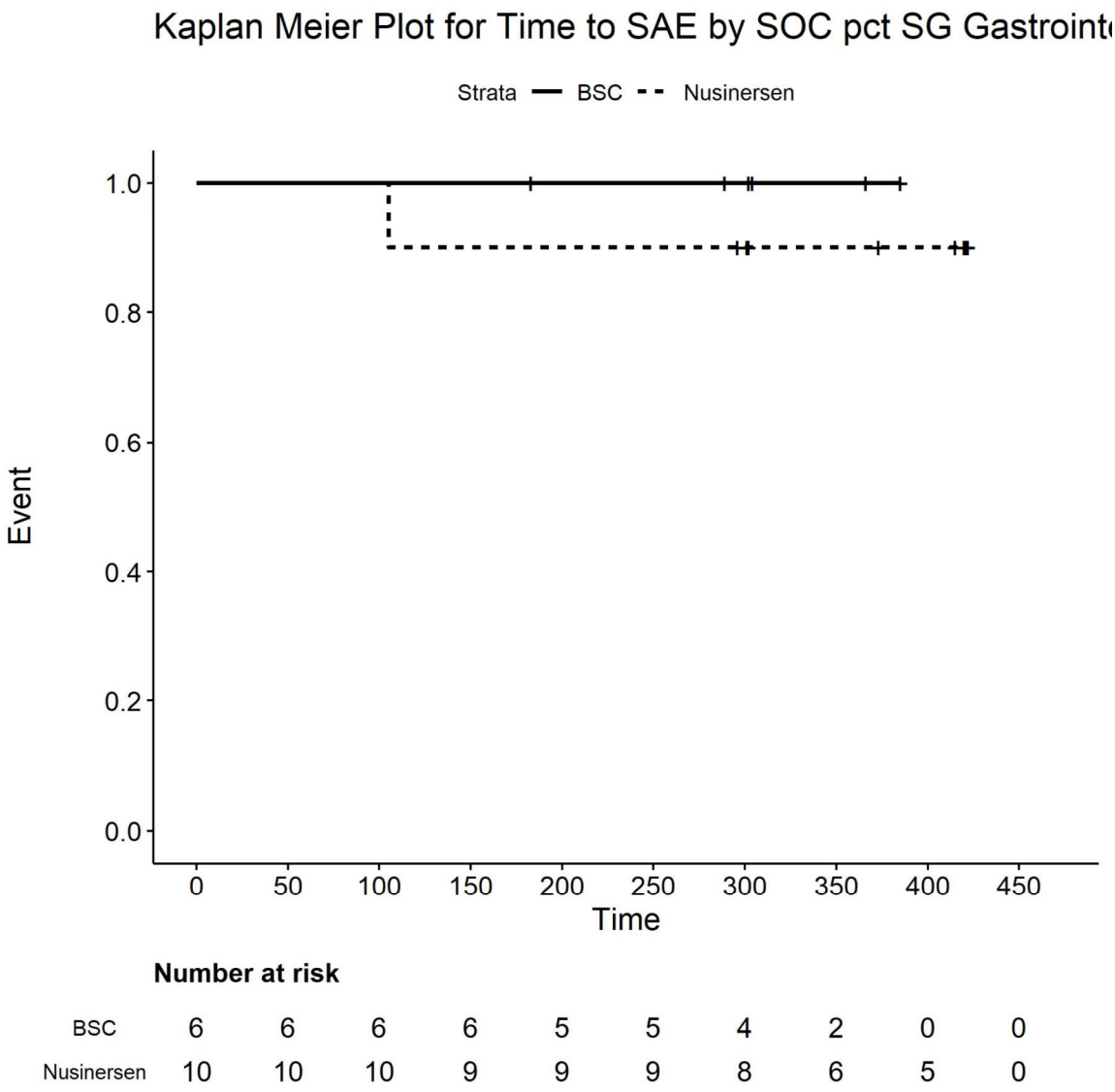
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



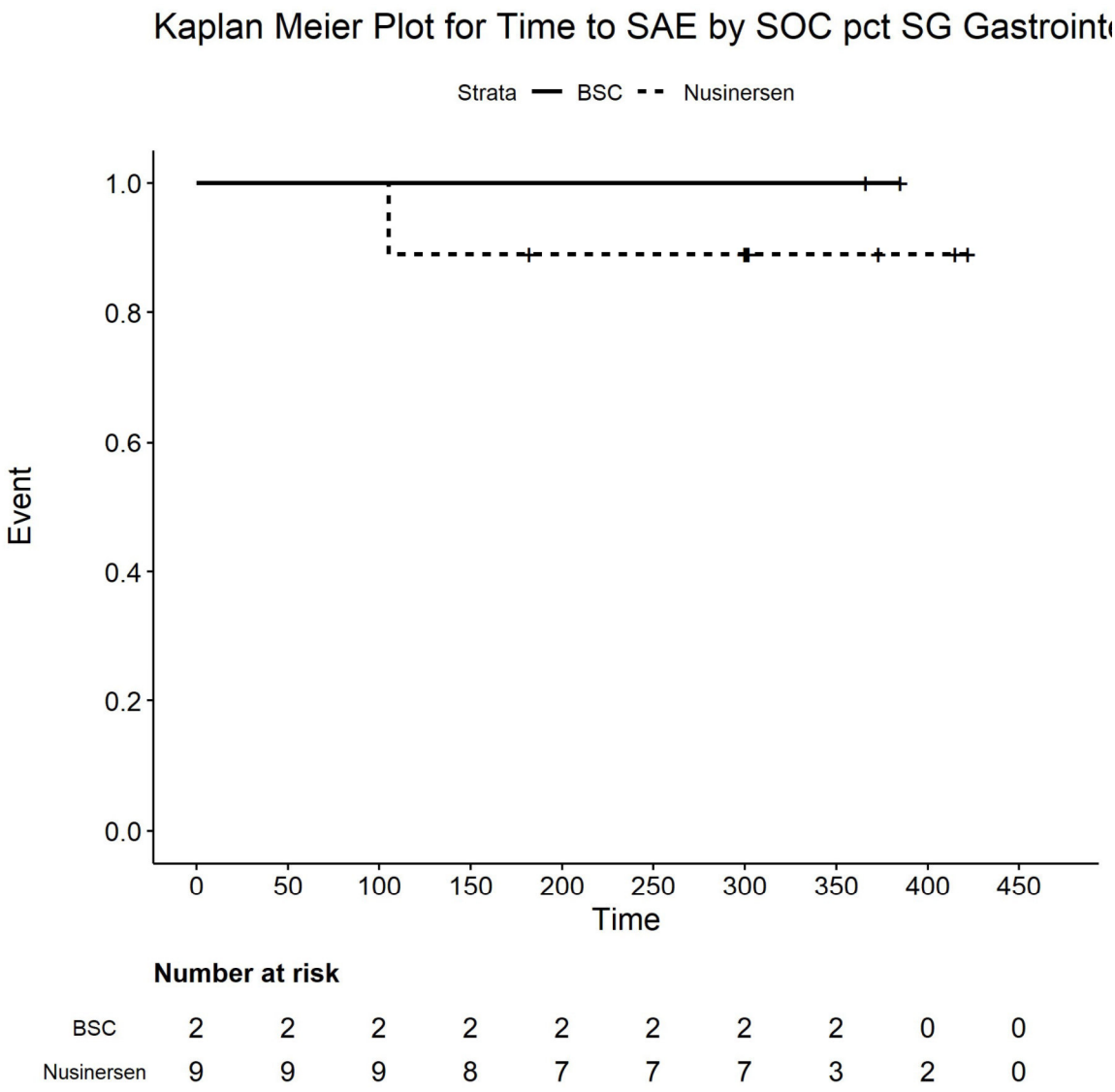
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



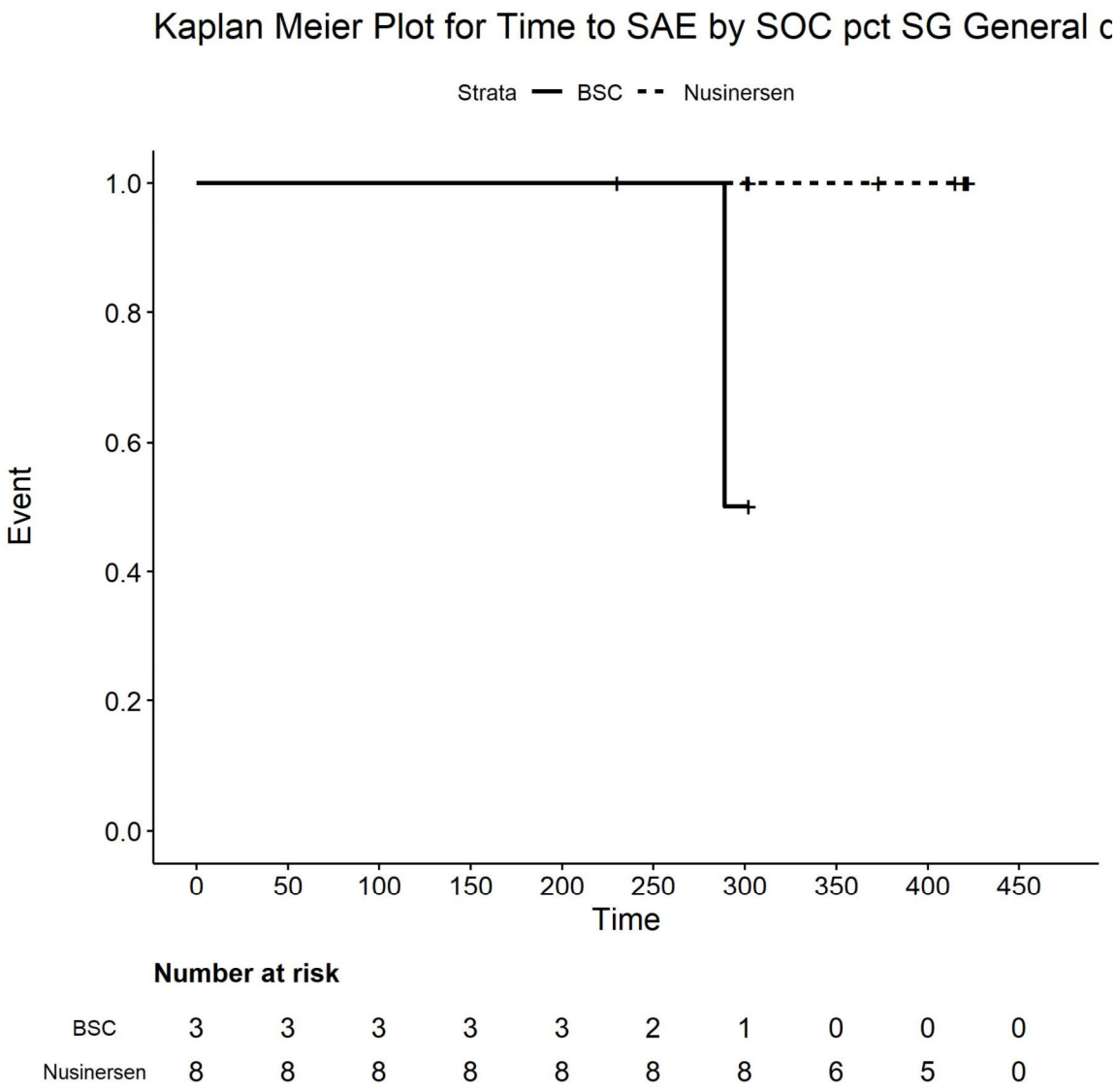
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



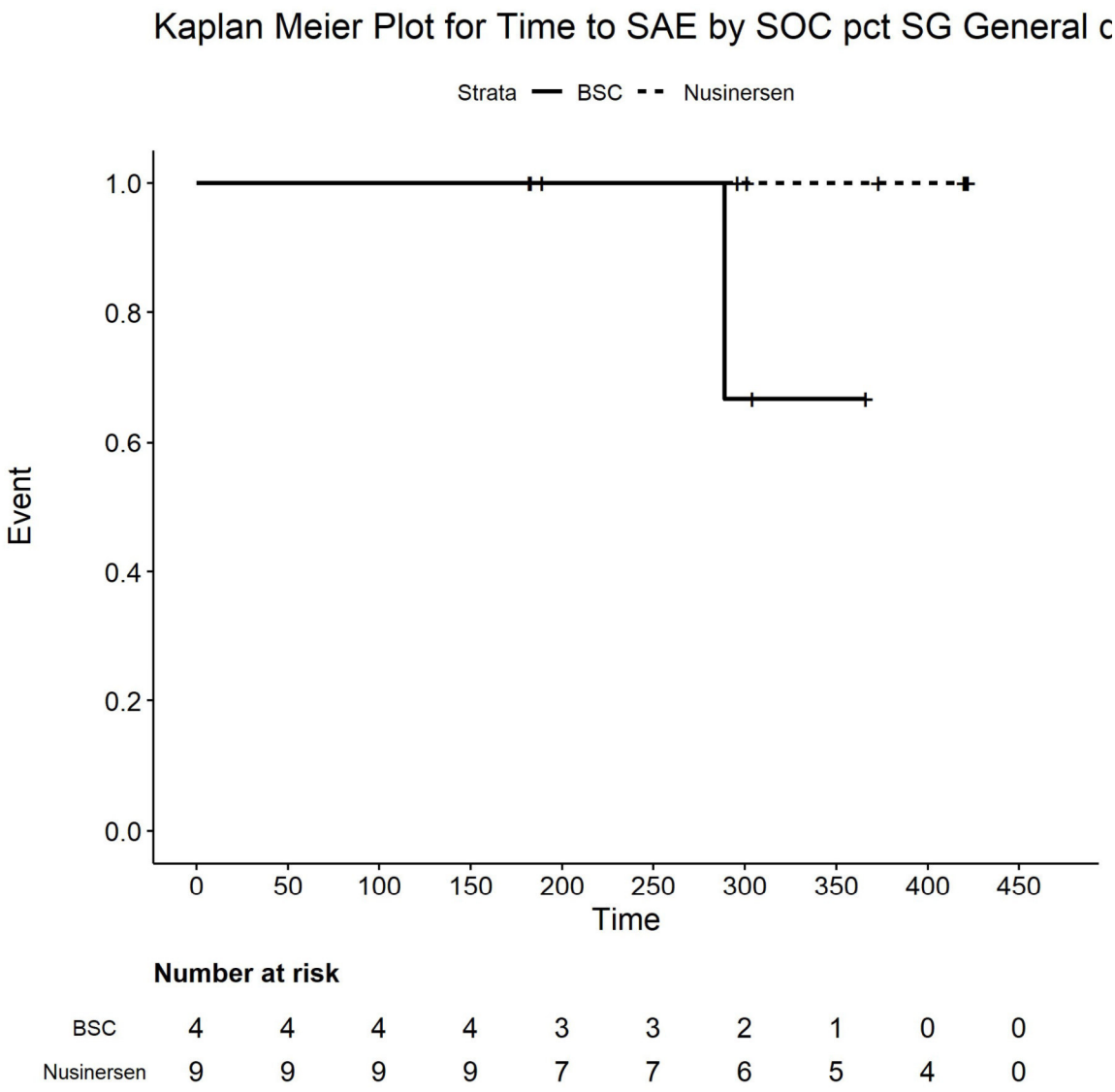
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



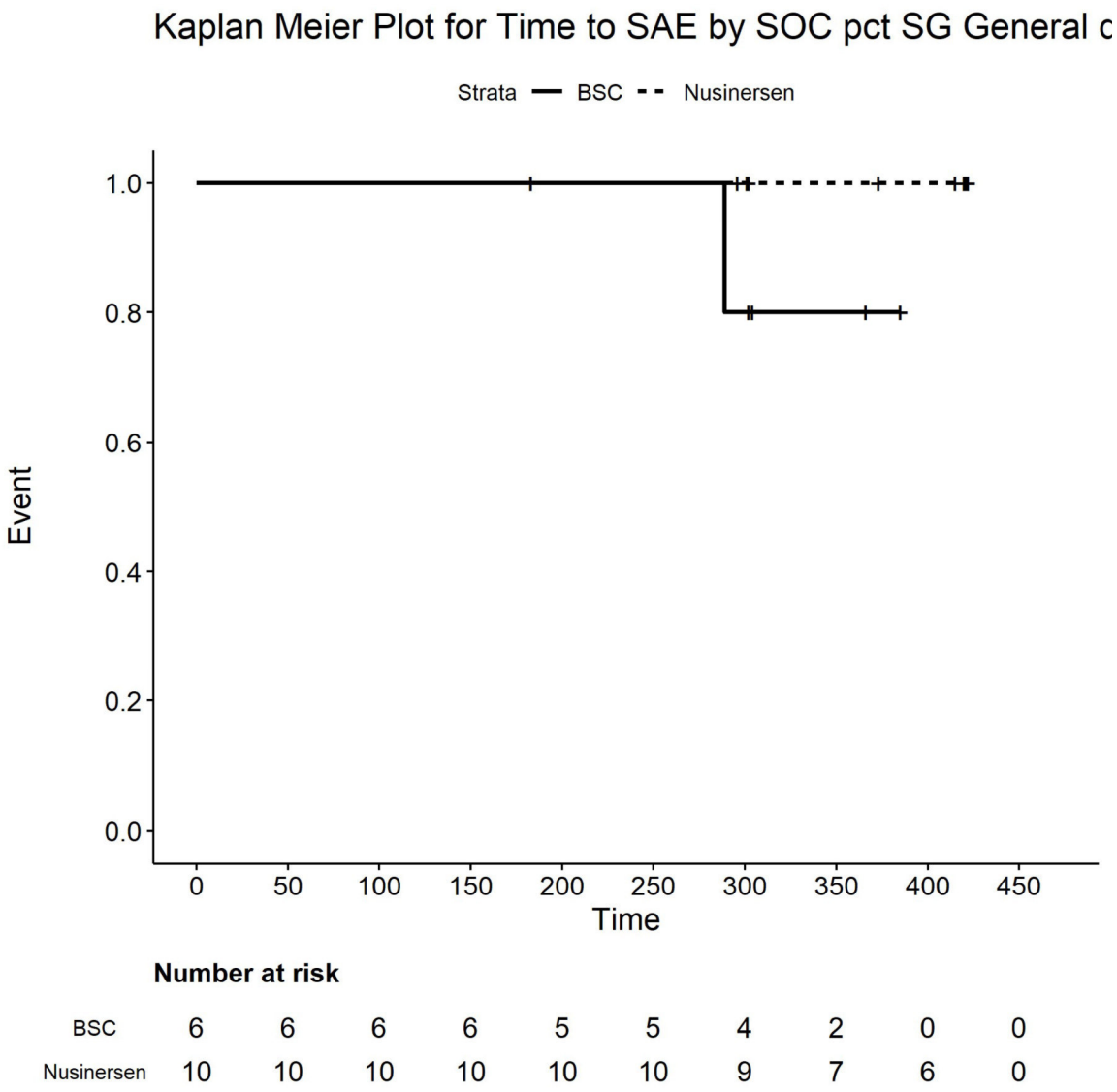
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



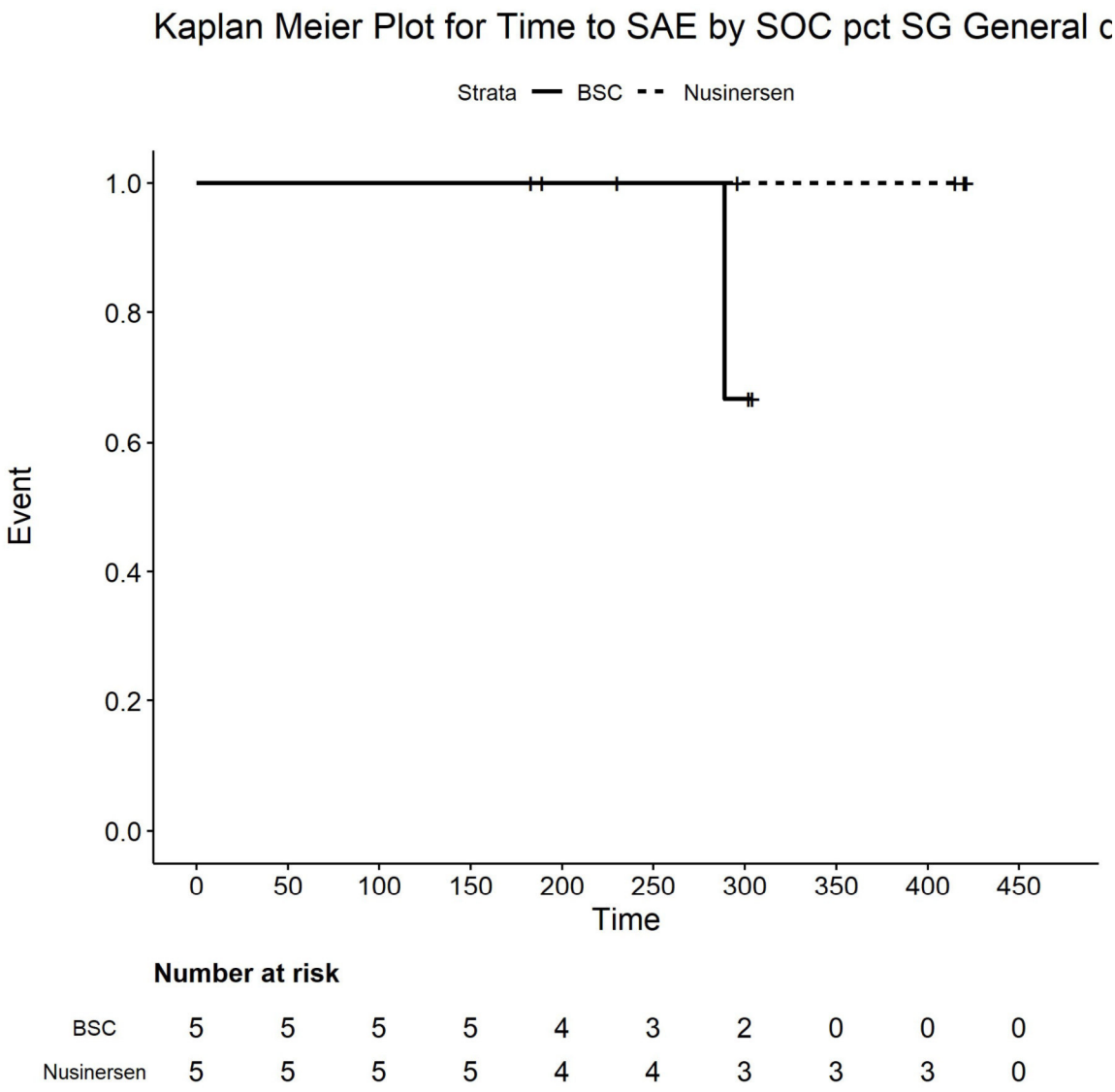
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



Number at risk

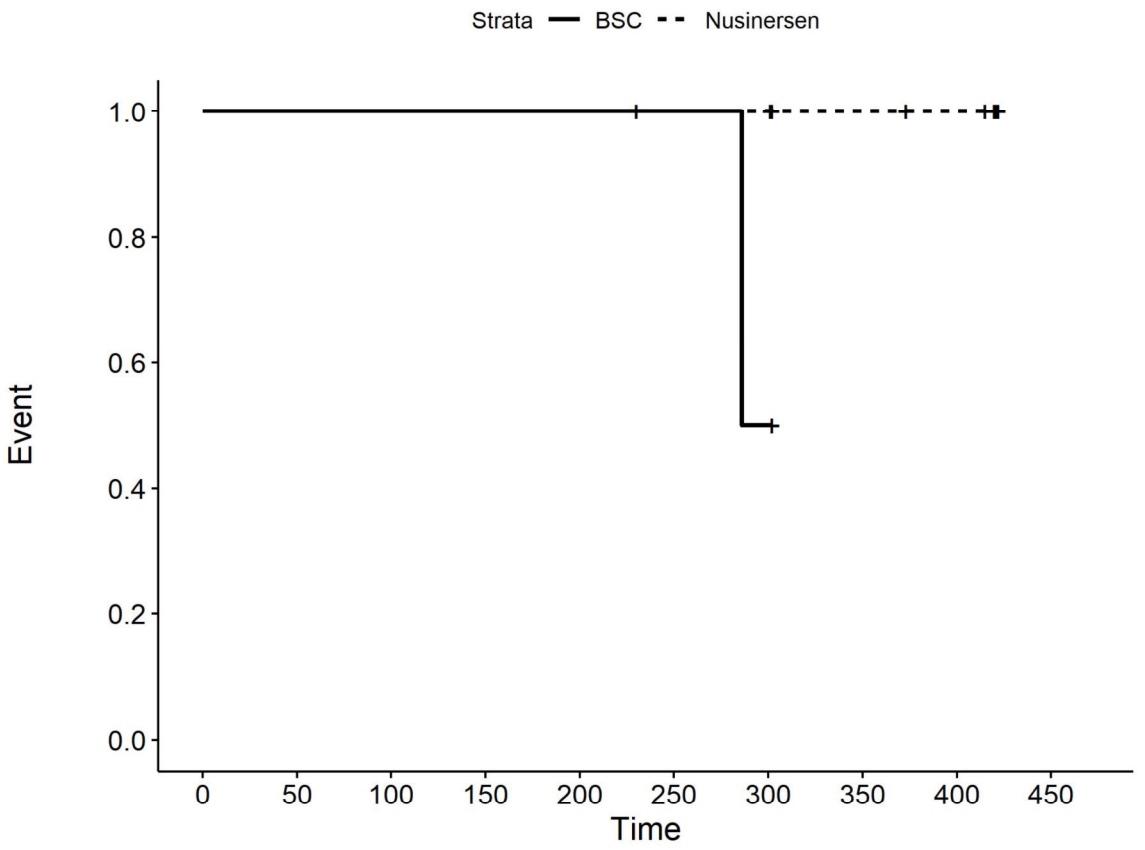
BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0

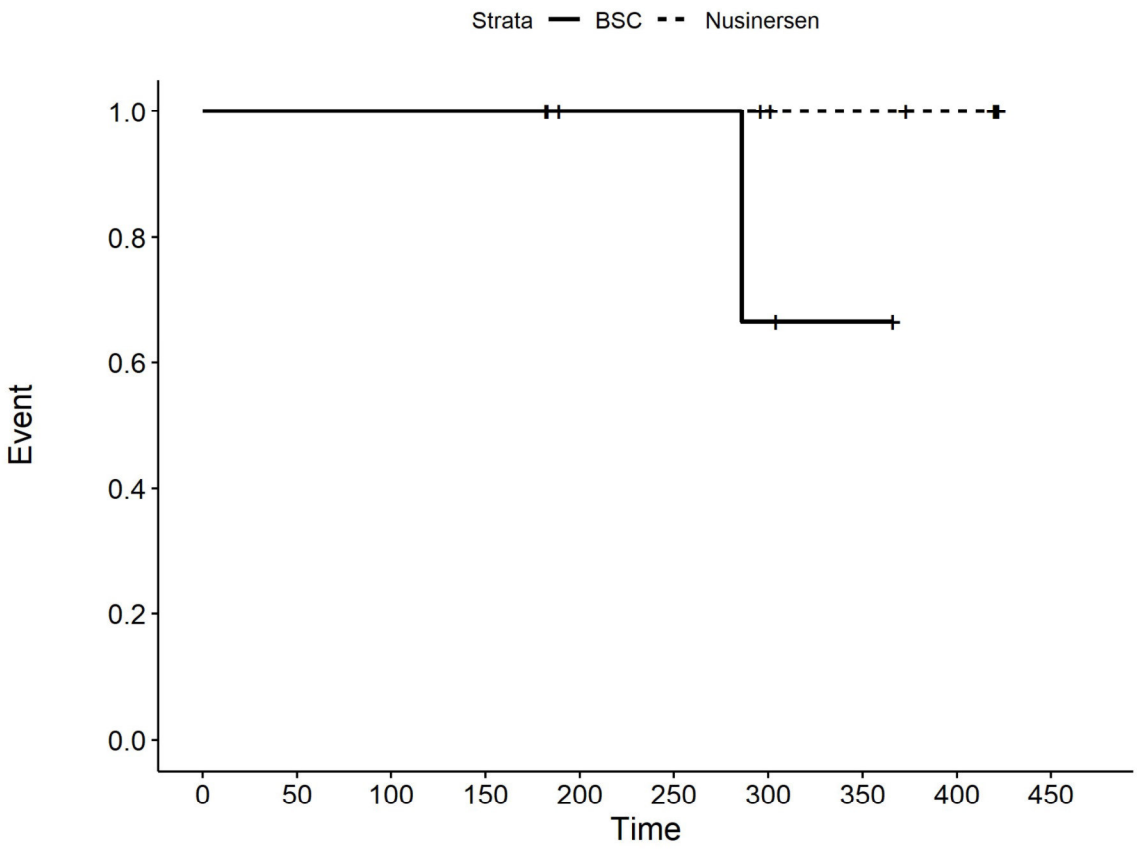
Kaplan Meier Plot for
Time to SAE by SOC pct SG Hypoxic : ischaemic encephalo



Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0

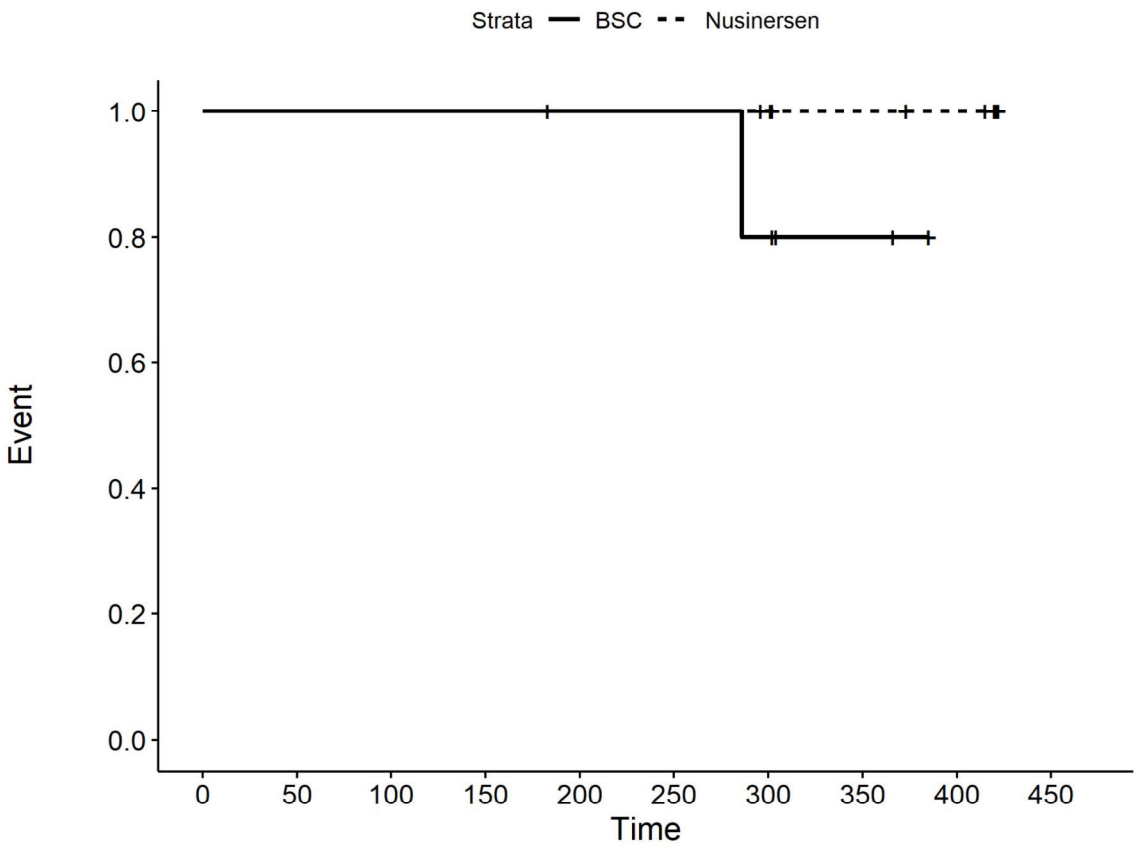
Kaplan Meier Plot for
Time to SAE by SOC pct SG Hypoxic : ischaemic encephalo



Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0

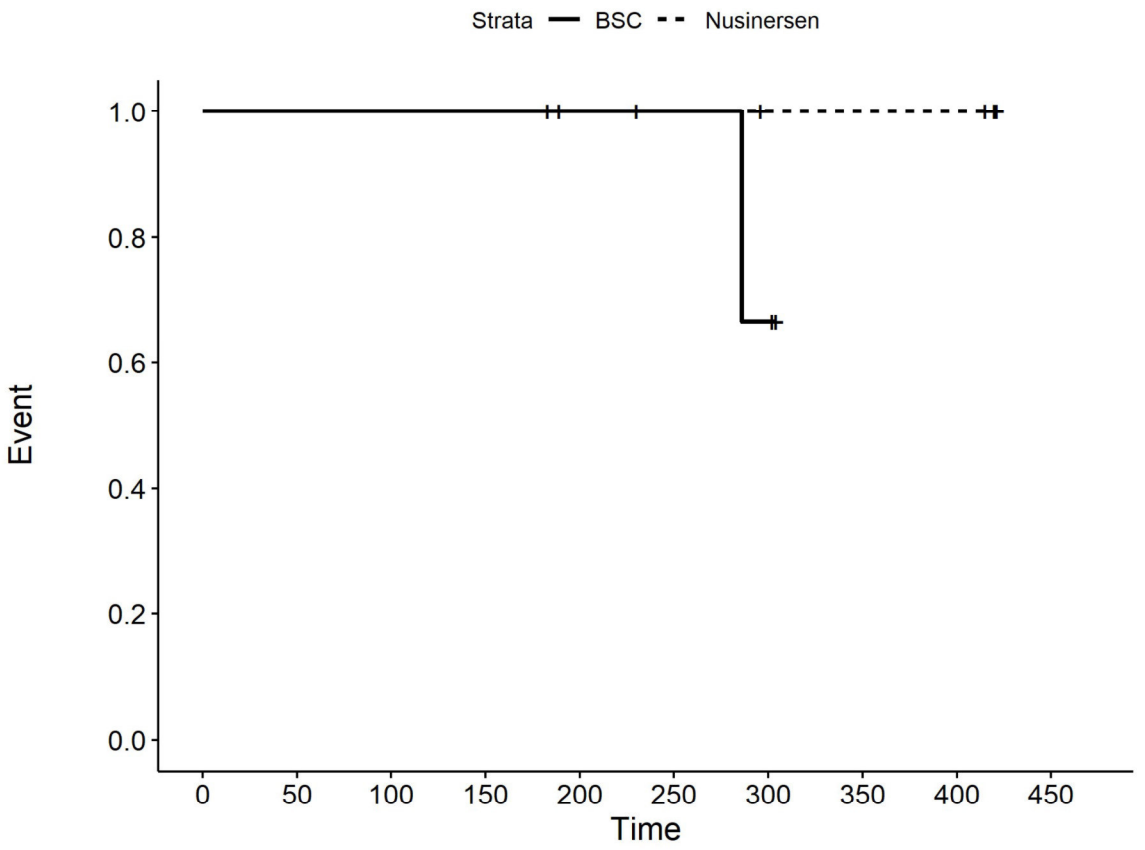
Kaplan Meier Plot for
Time to SAE by SOC pct SG Hypoxic : ischaemic encephalo



Number at risk

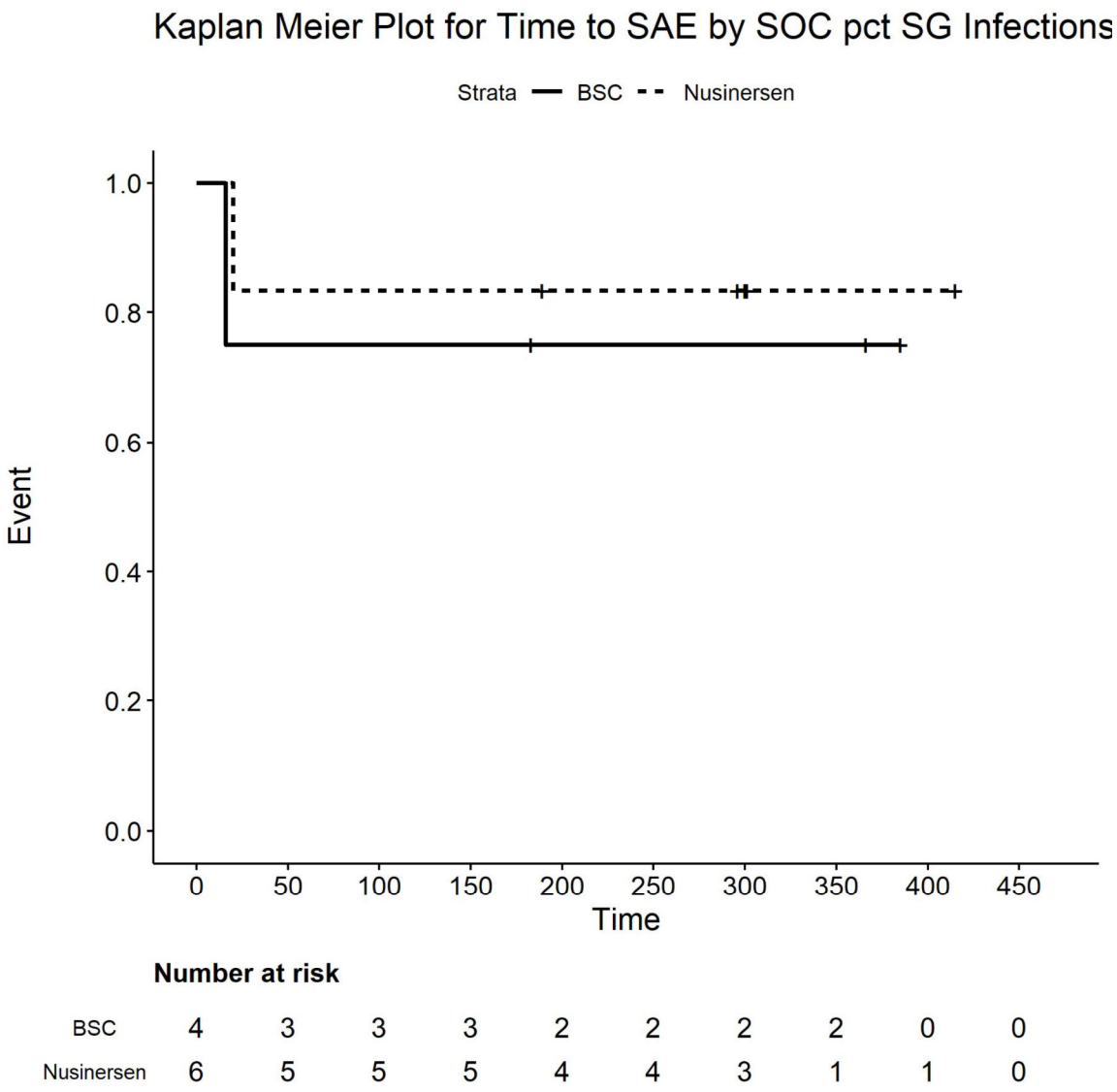
BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0

Kaplan Meier Plot for
Time to SAE by SOC pct SG Hypoxic : ischaemic encephalo



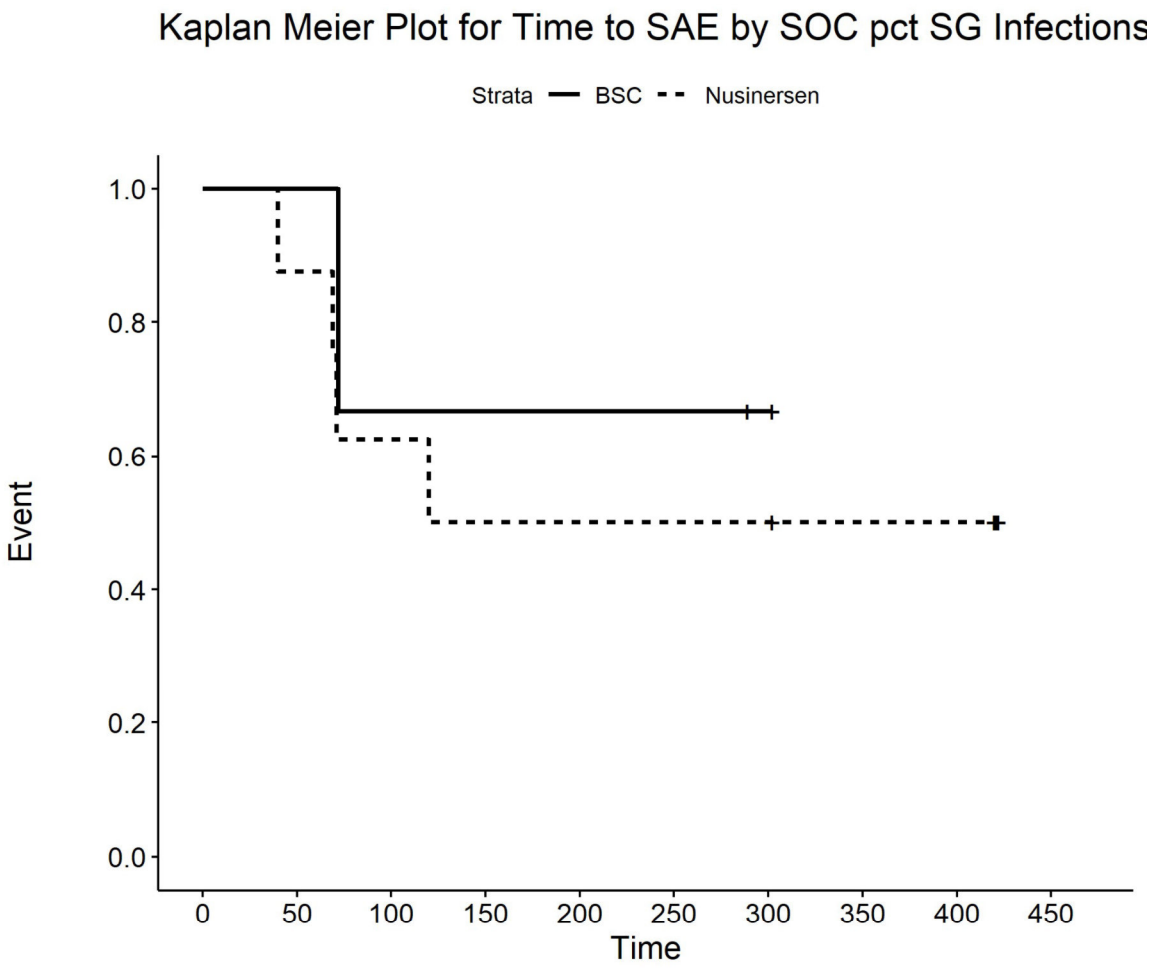
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



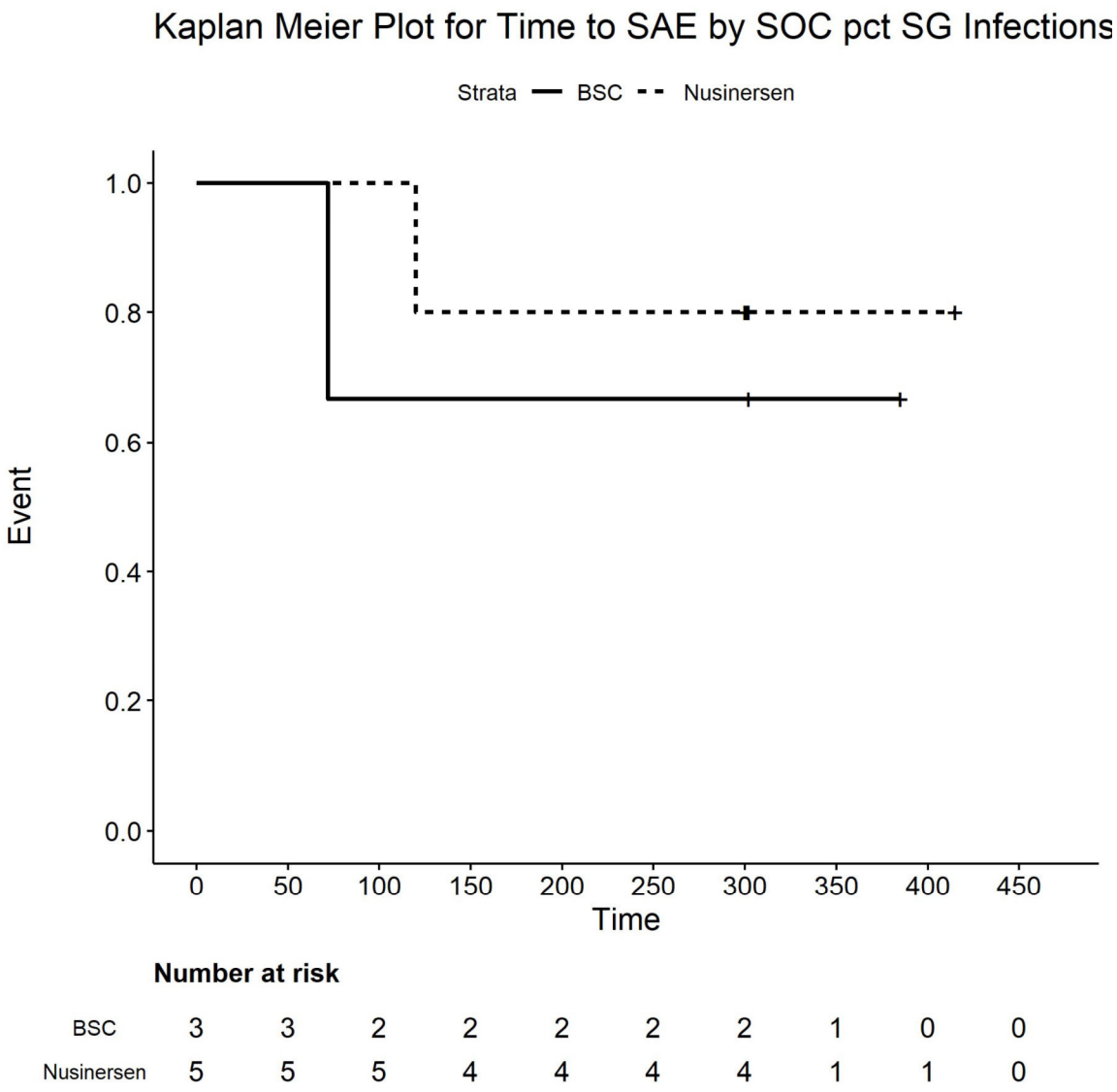
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	5	5	5	4	4	3	1	1	0



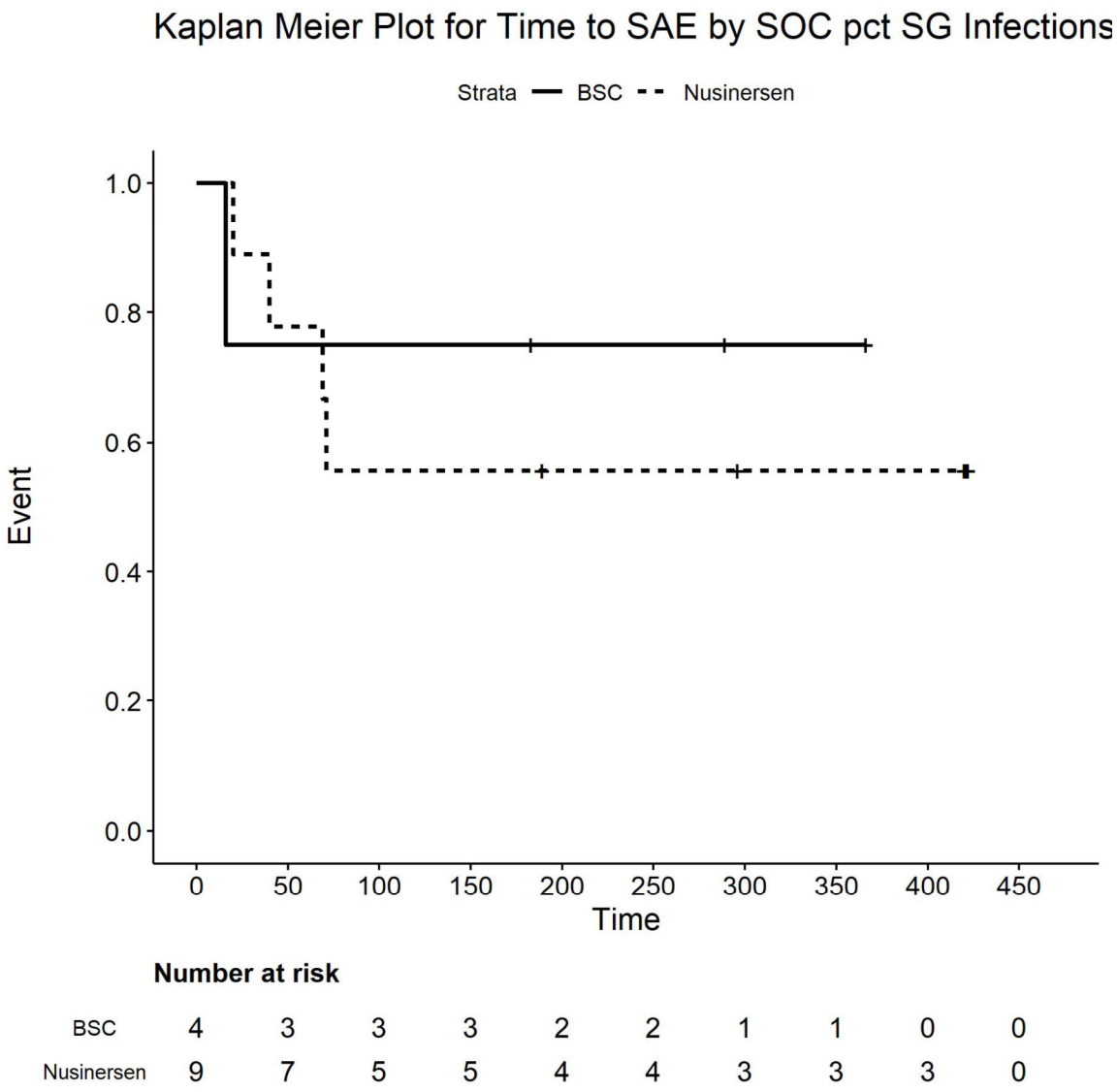
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	7	5	4	4	4	4	3	3	0



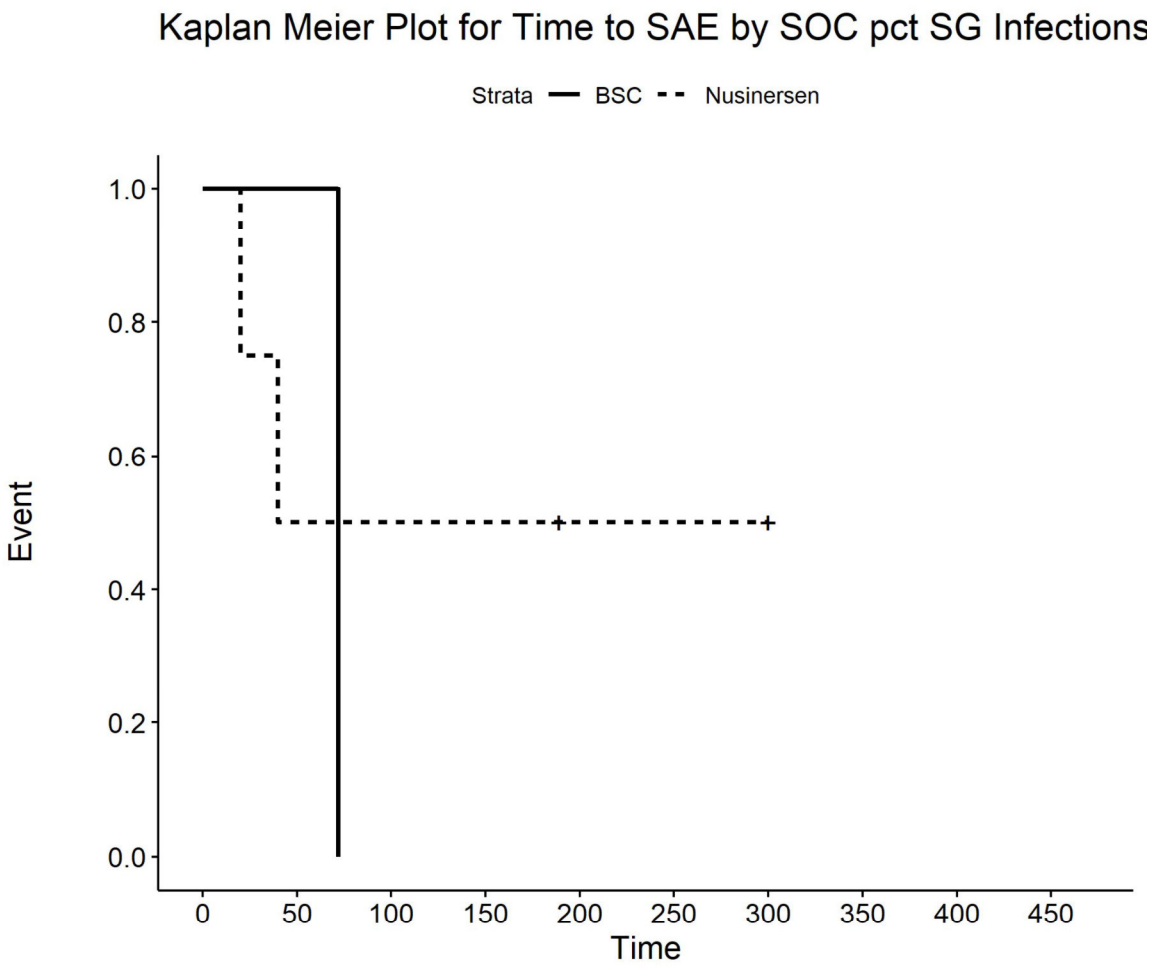
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	4	4	4	4	1	1	0



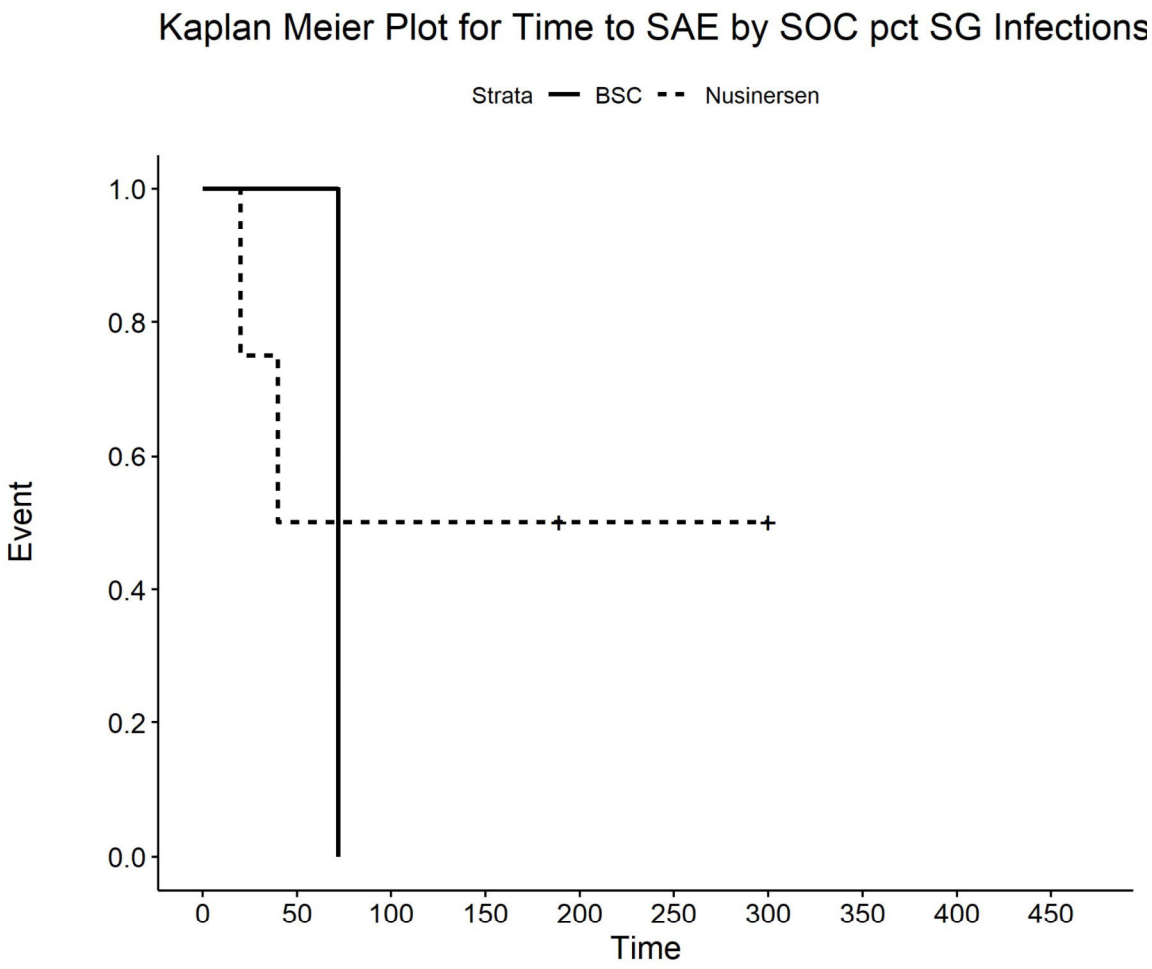
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	7	5	5	4	4	3	3	3	0



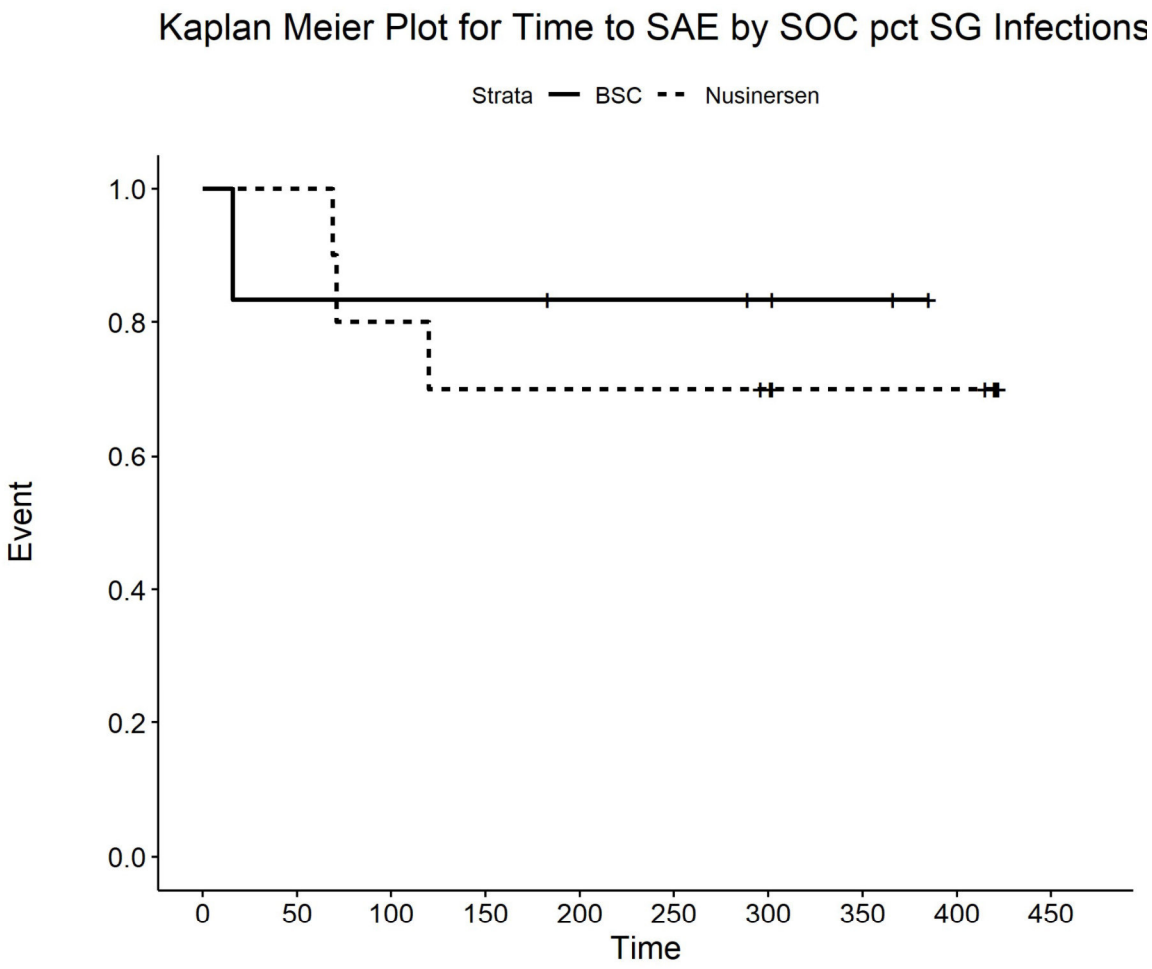
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	2	2	2	1	1	1	0	0	0



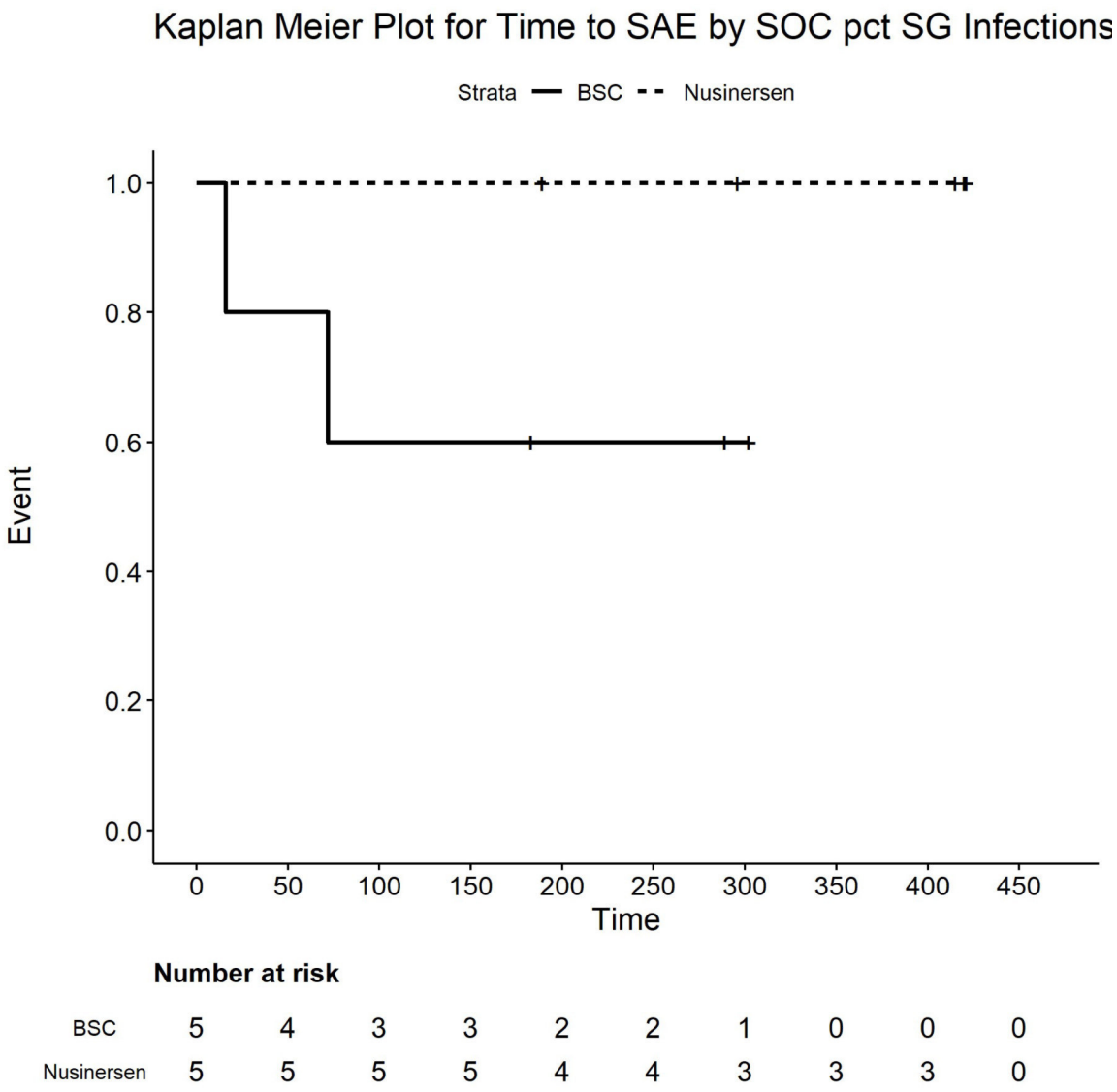
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	2	2	2	1	1	1	0	0	0



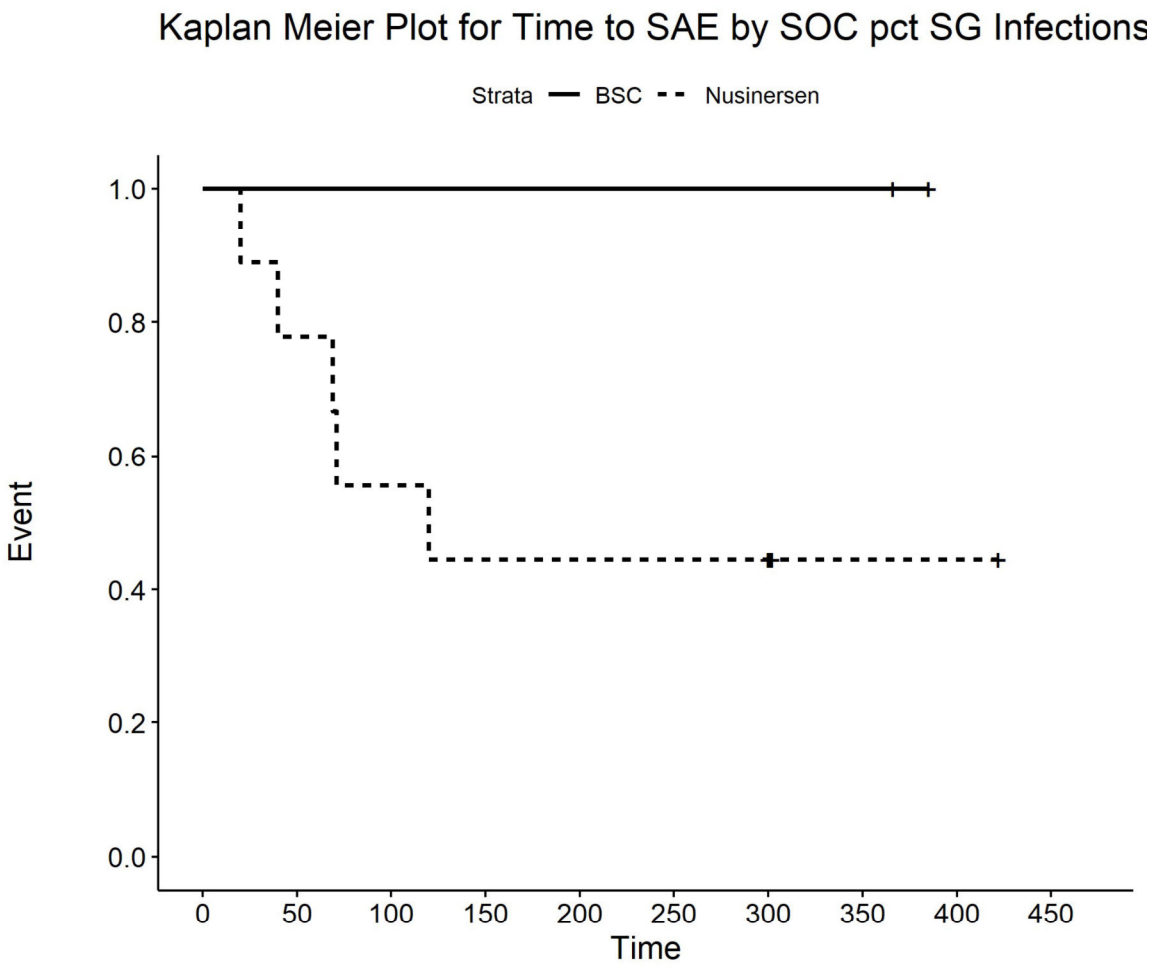
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	8	7	7	7	6	4	4	0



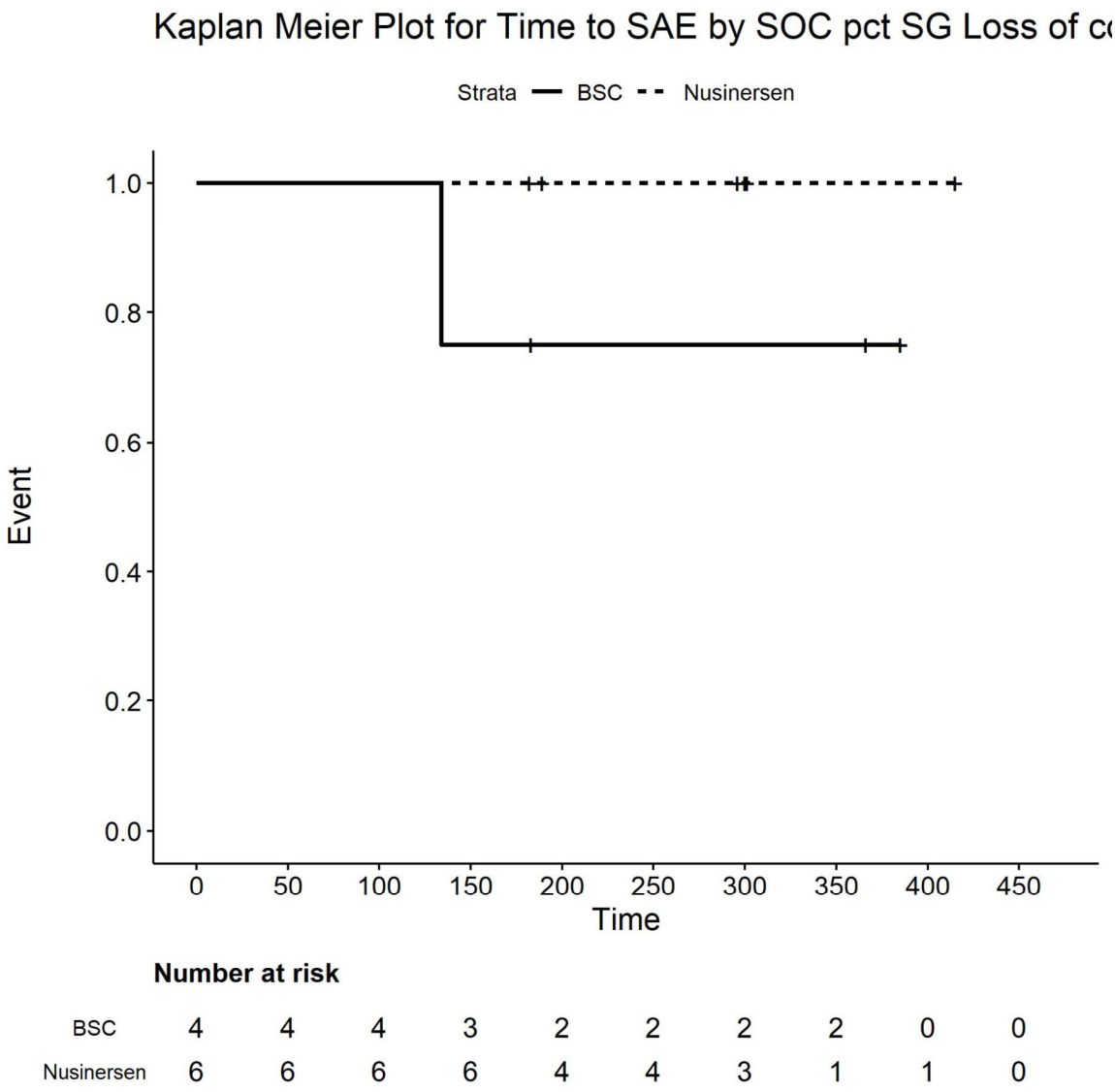
Number at risk

BSC	5	4	3	3	2	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



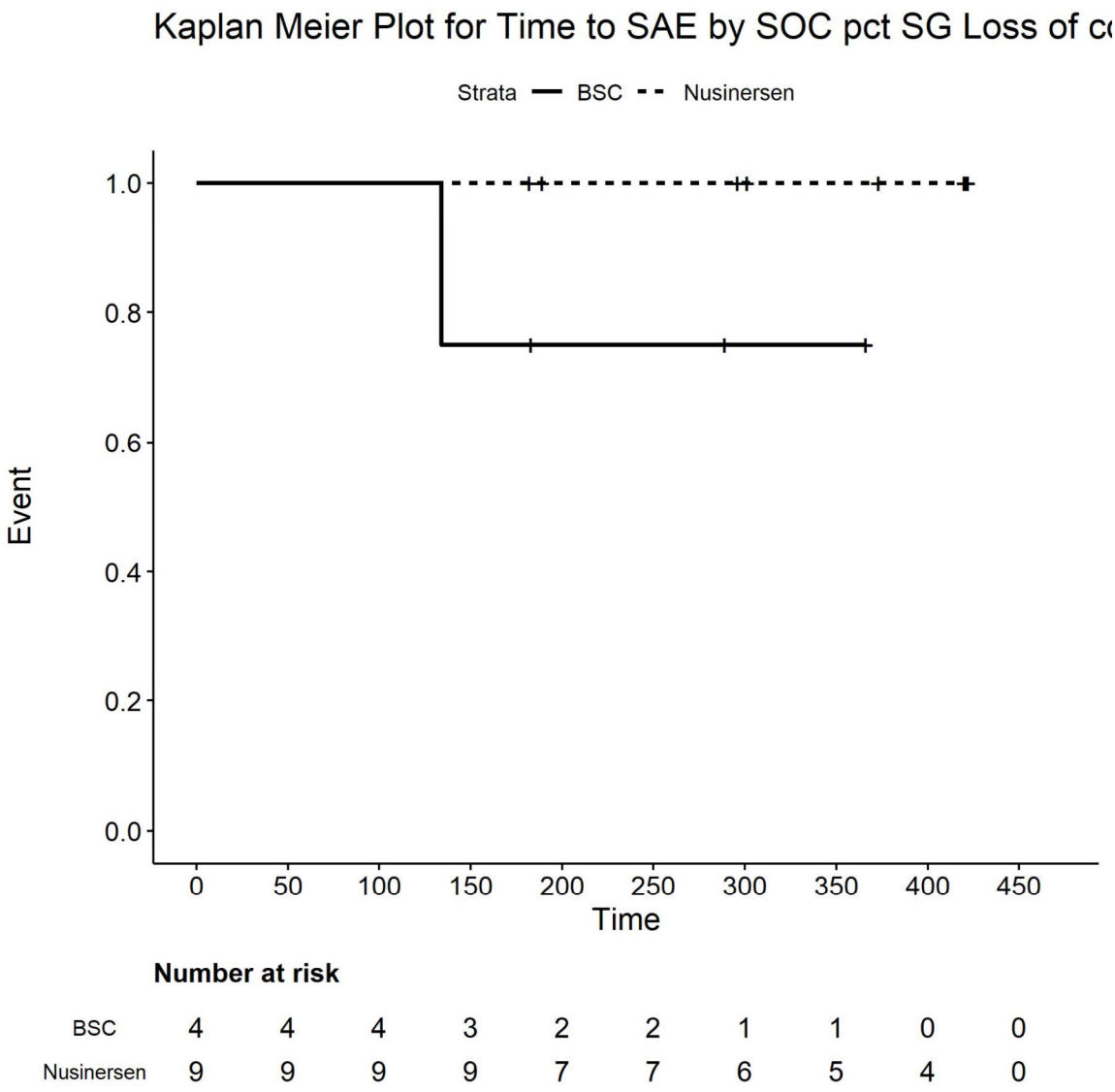
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	5	4	4	4	4	1	1	0



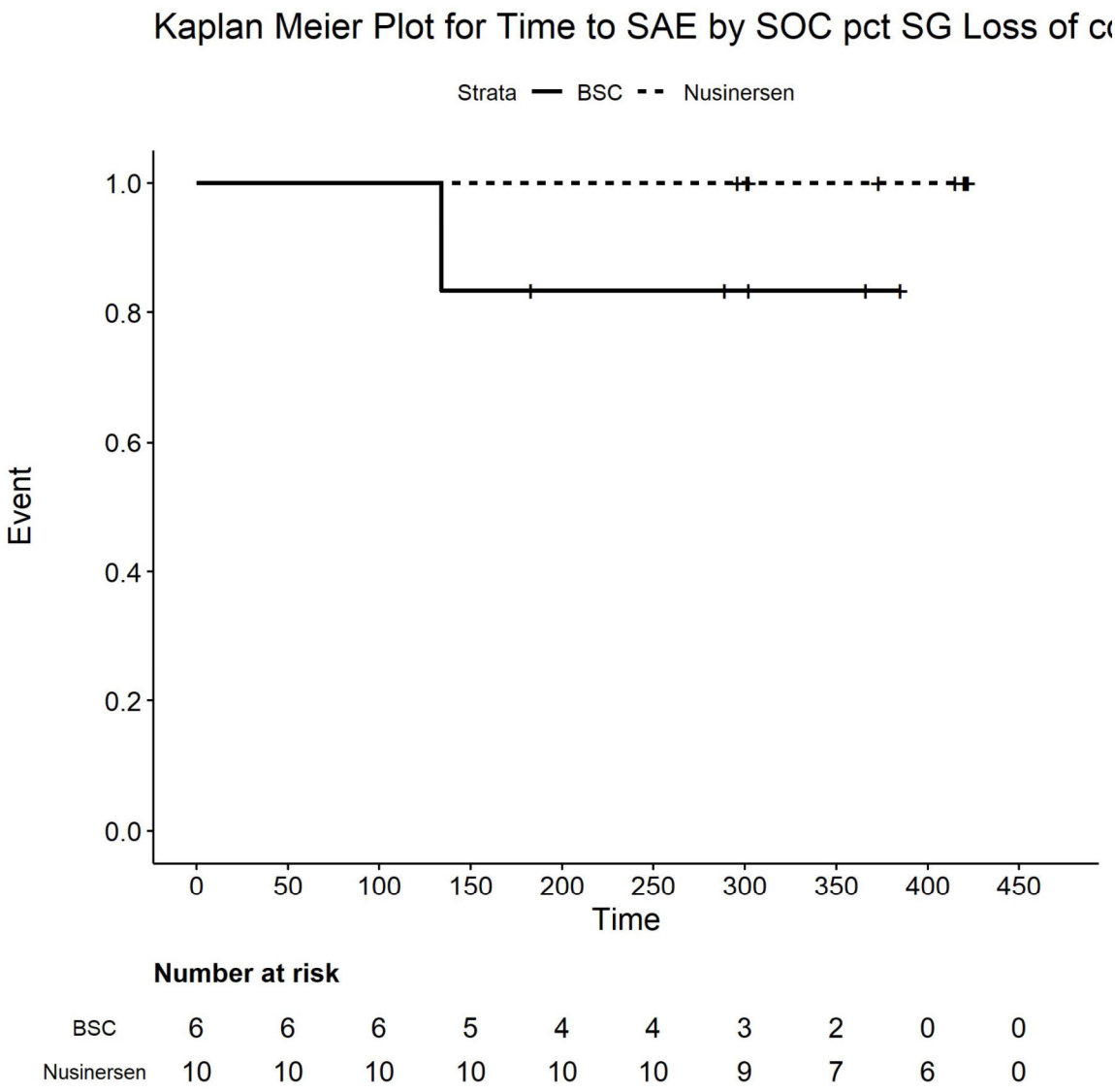
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



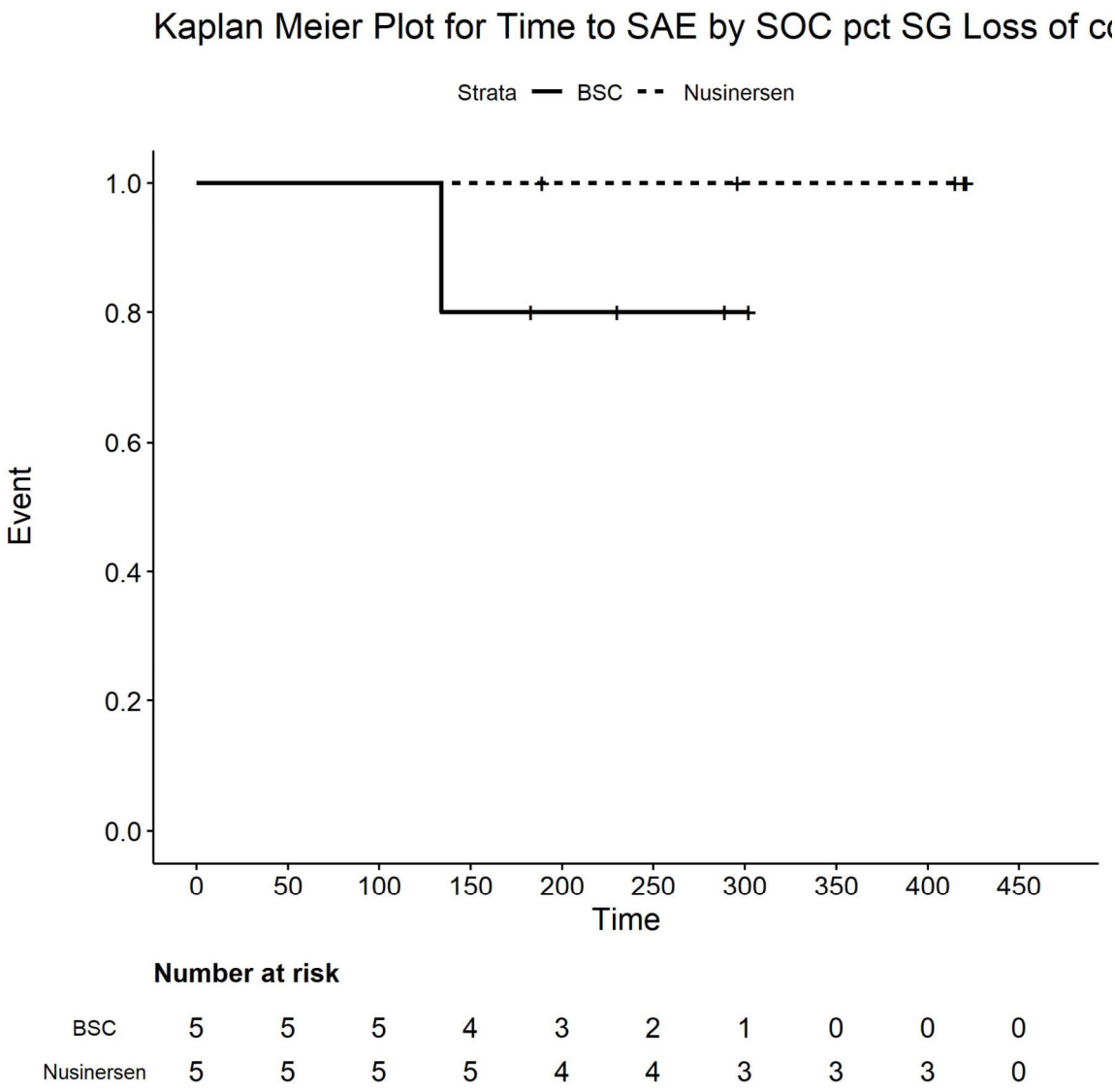
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



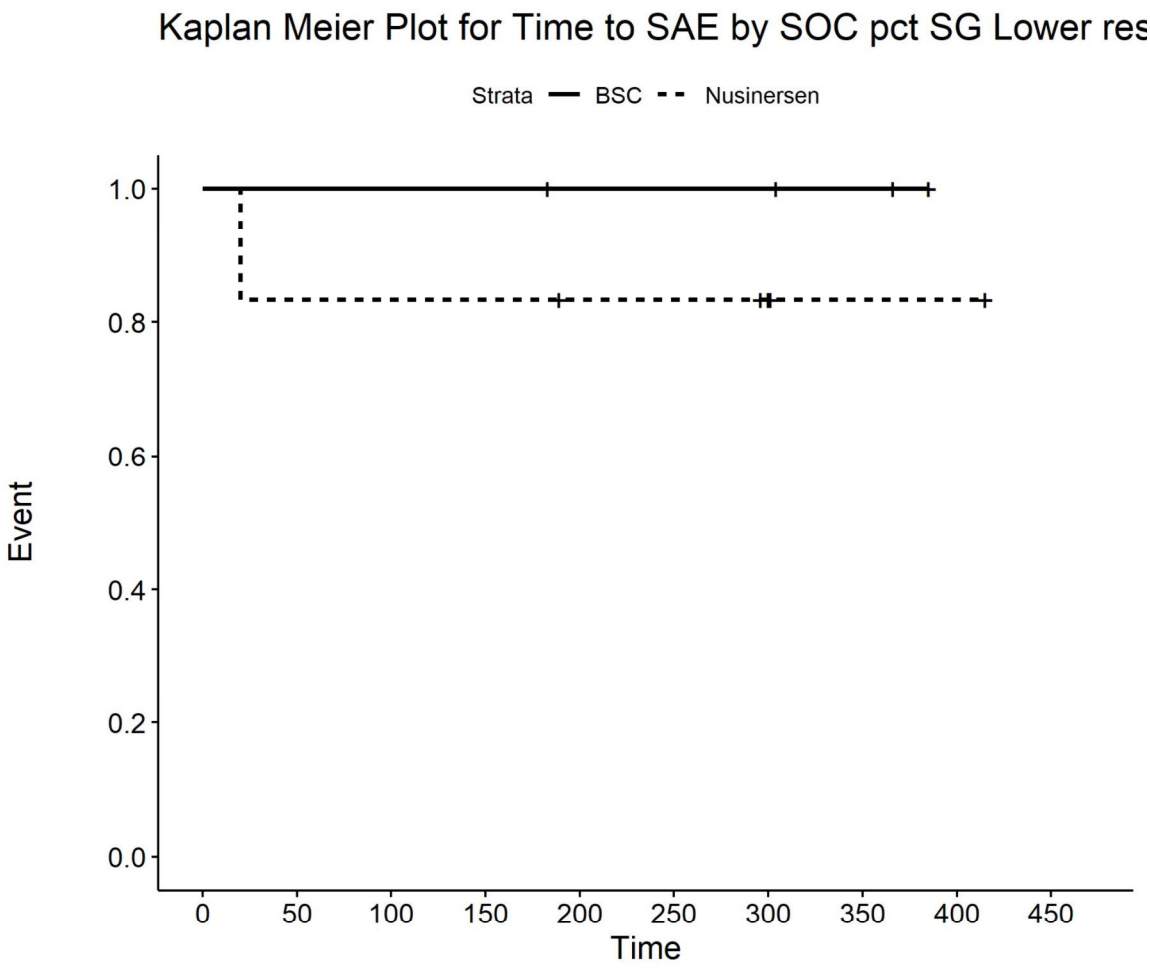
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



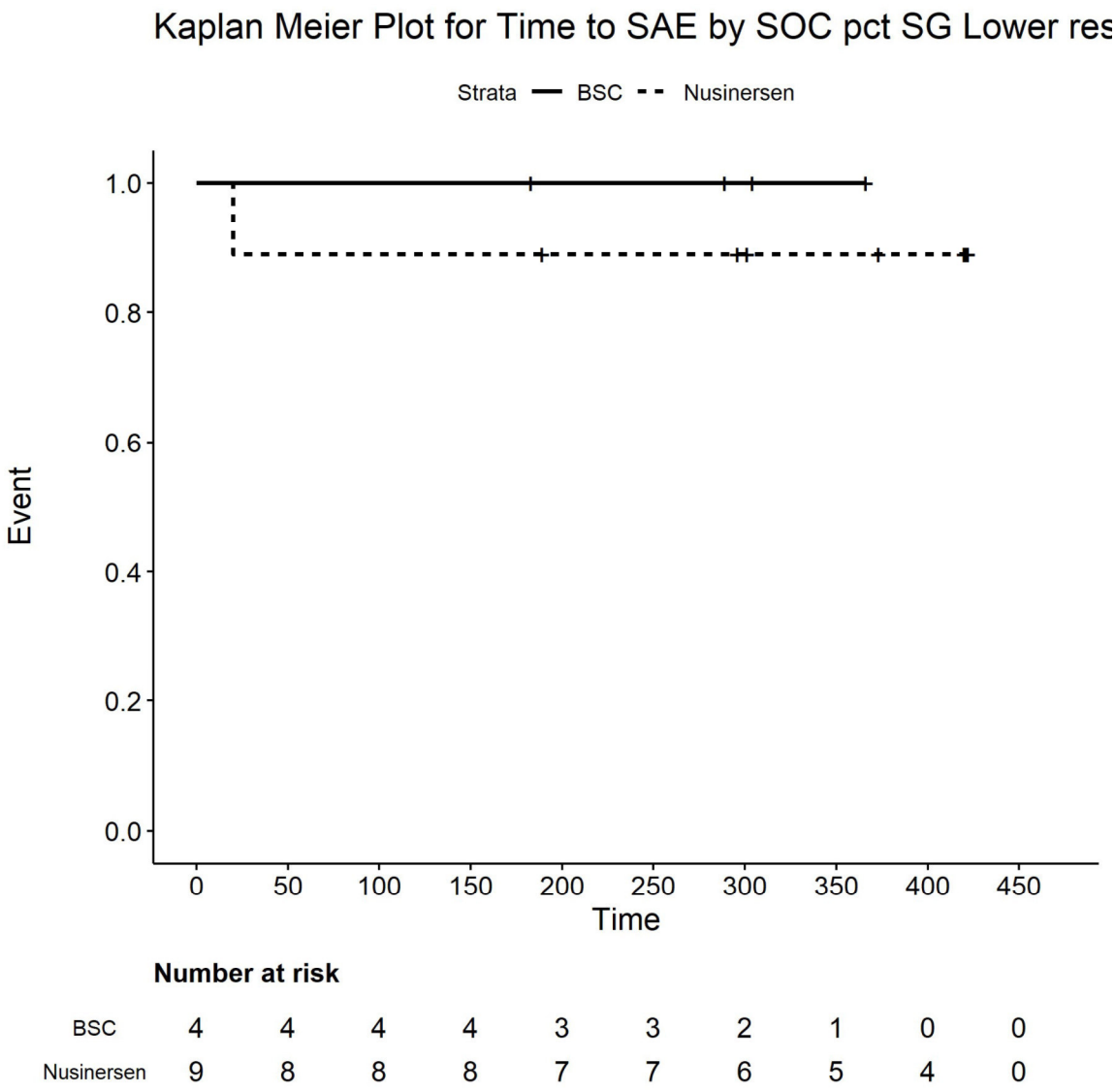
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



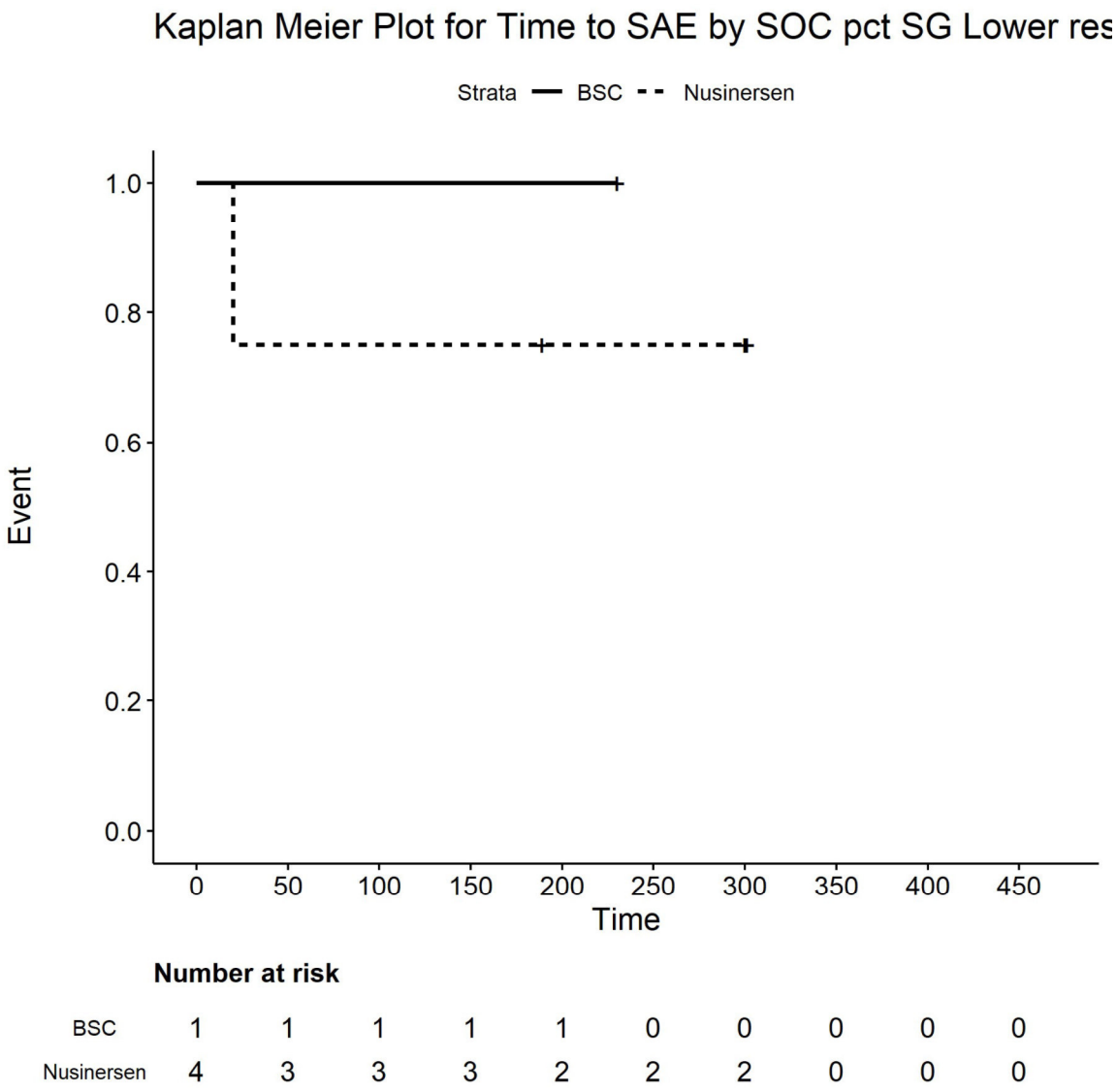
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	4	4	3	1	1	0



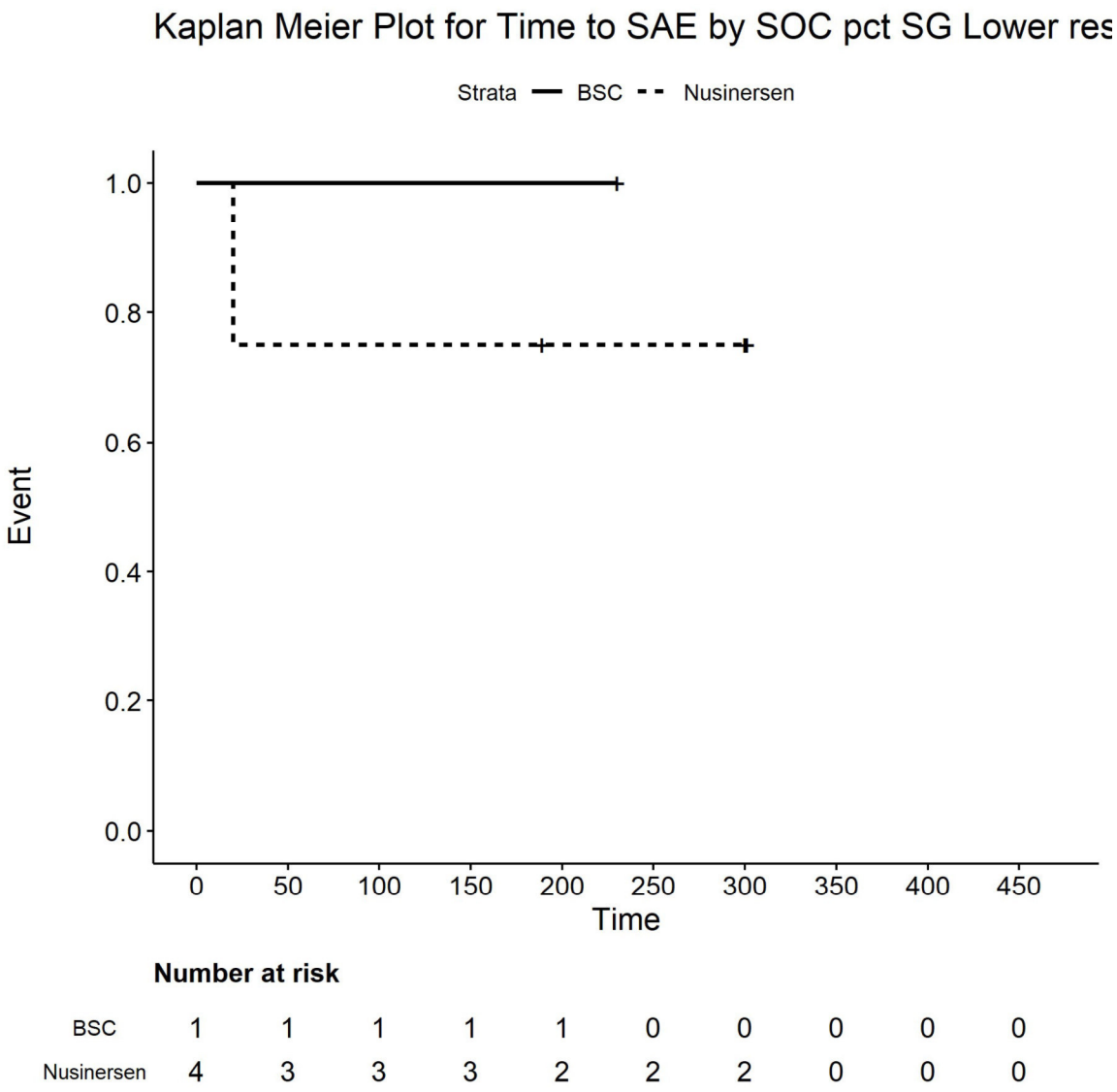
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	7	7	6	5	4	0



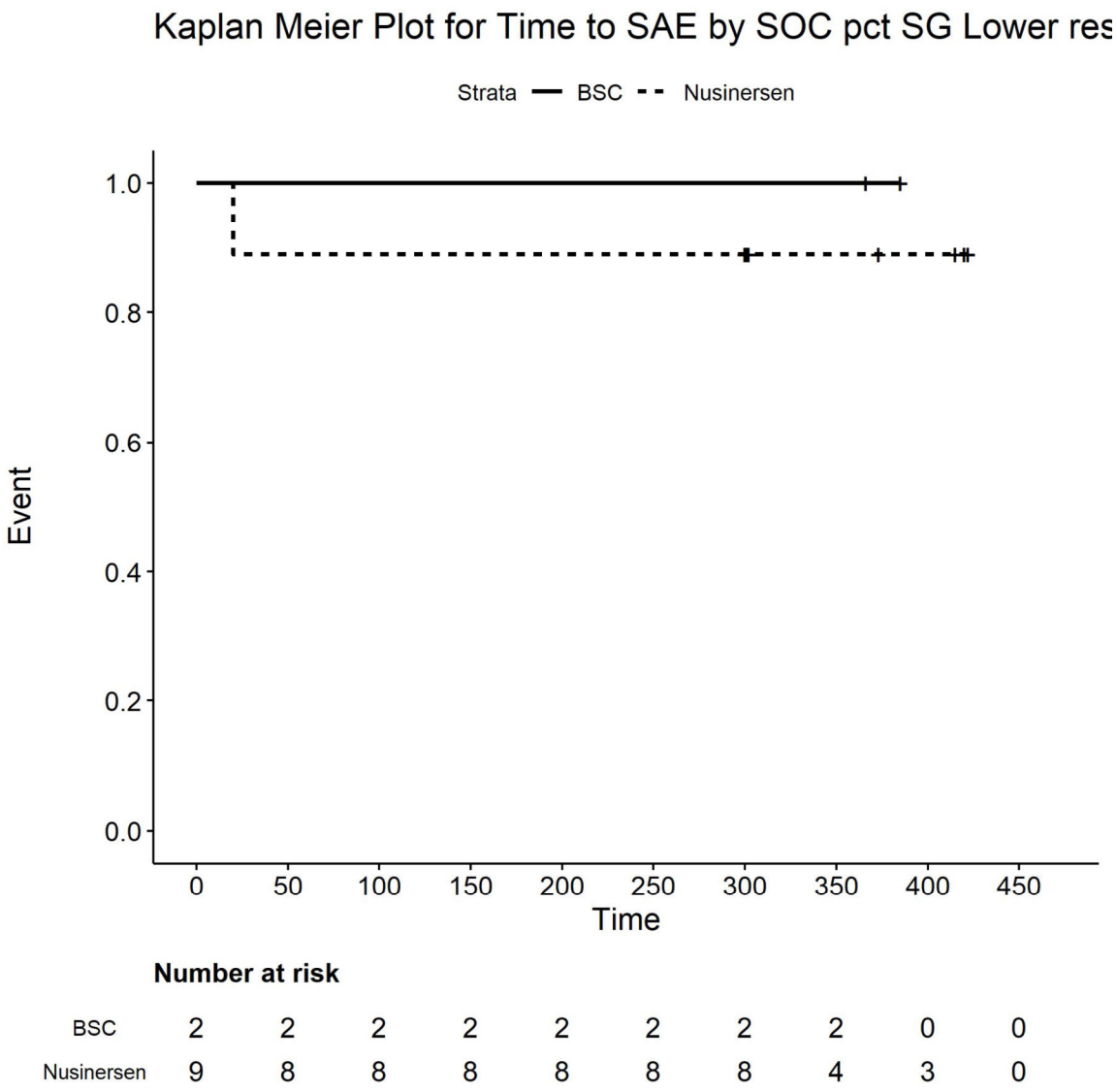
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



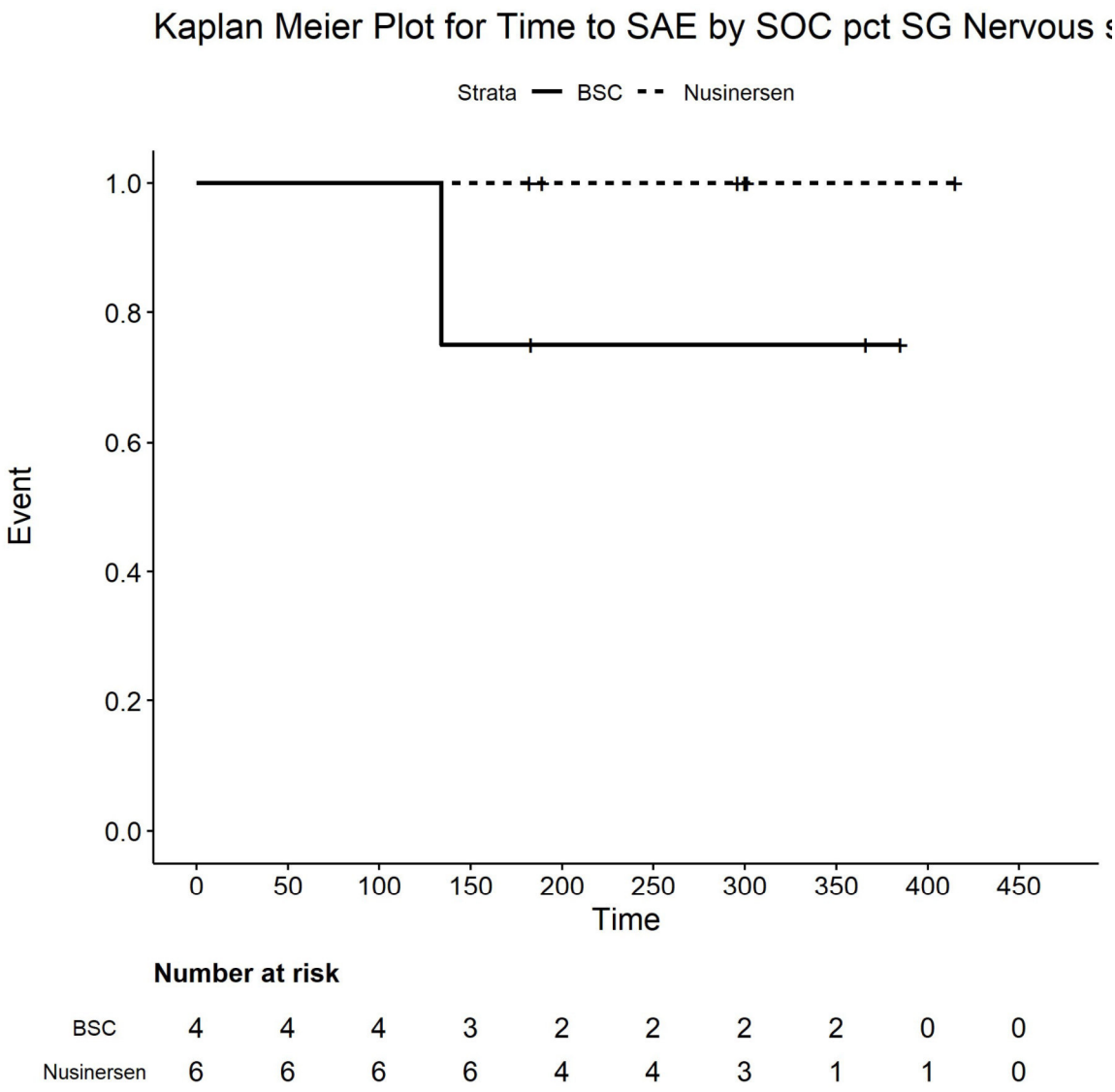
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



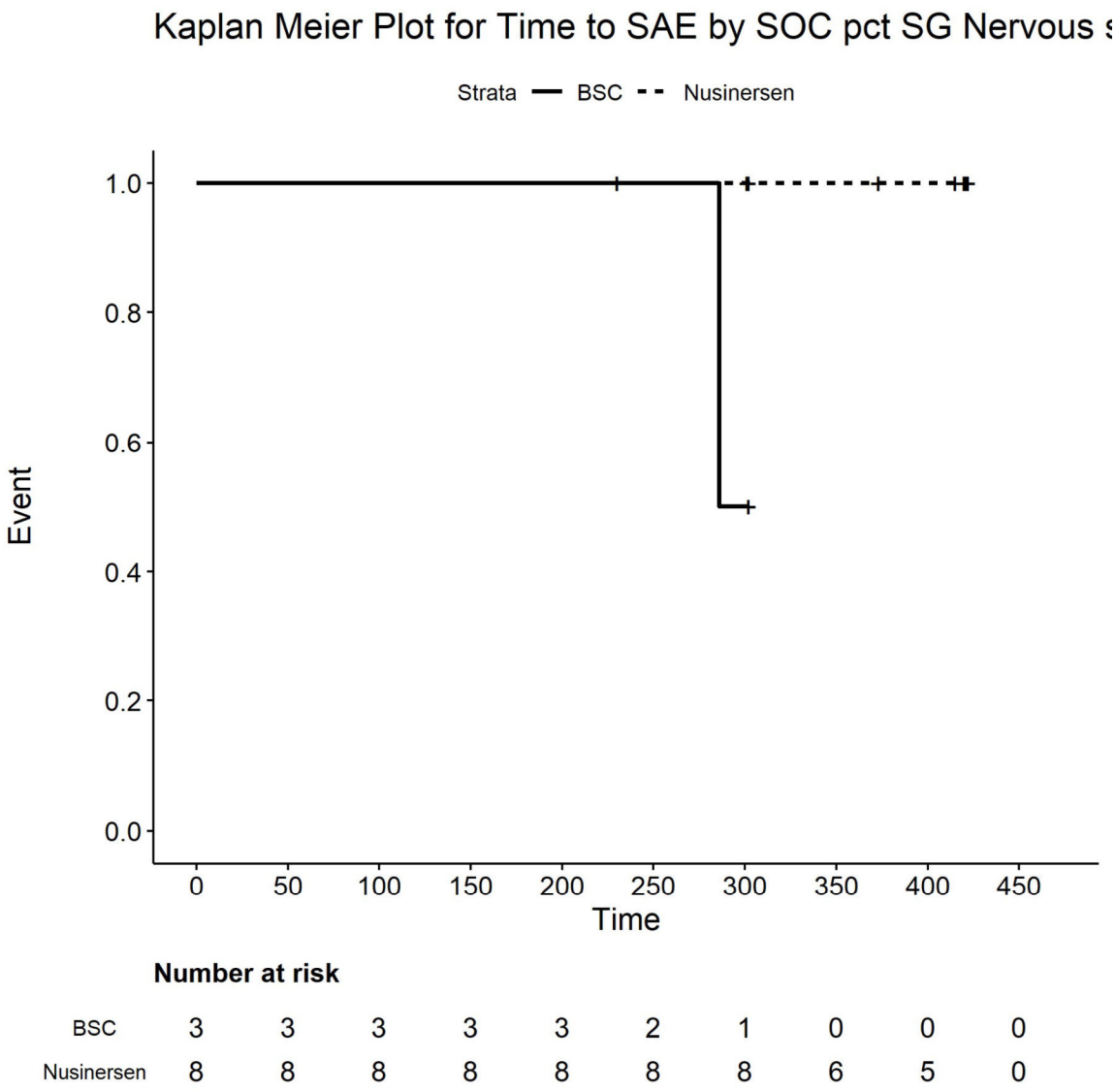
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	8	8	8	4	3	0



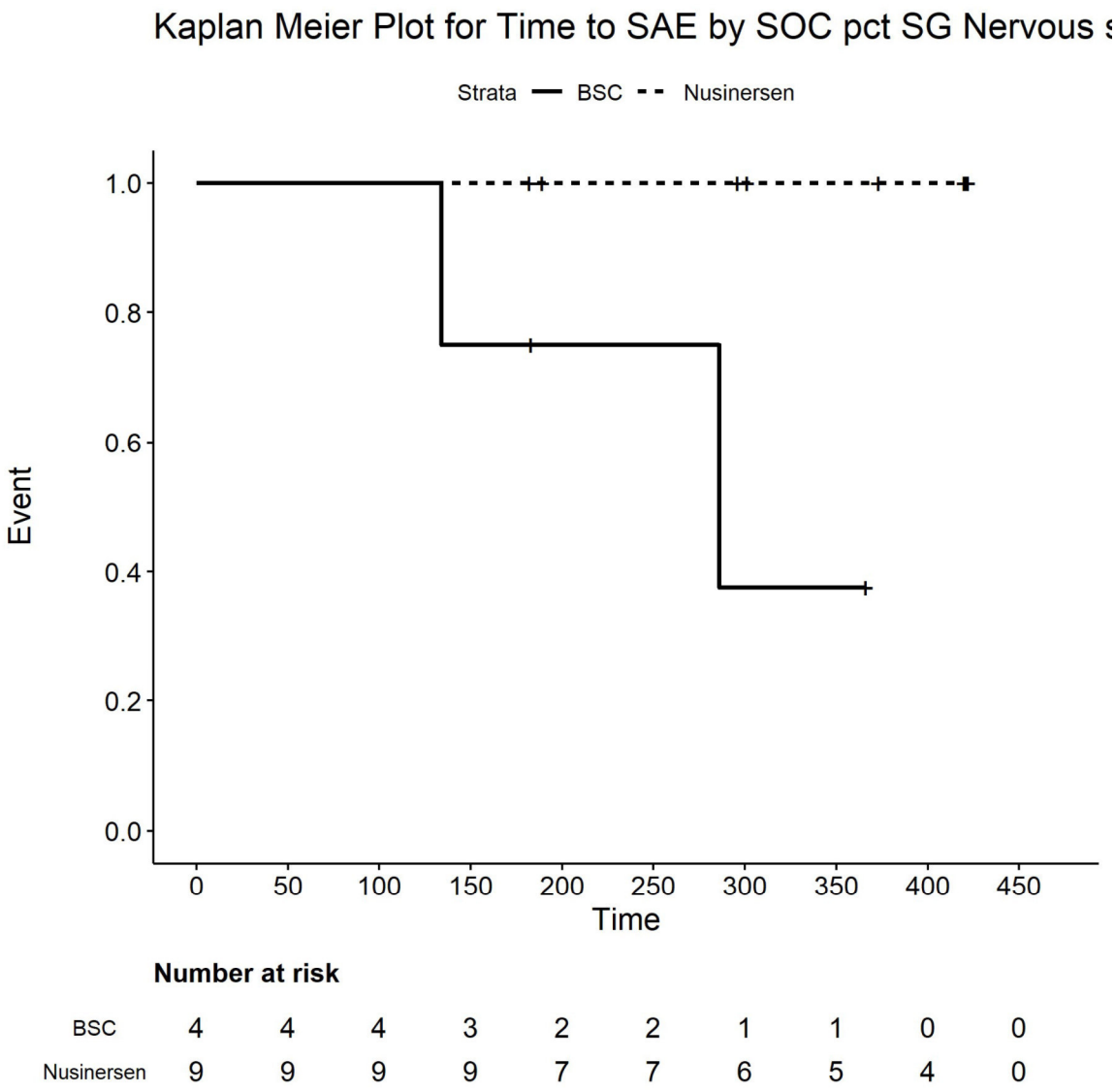
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



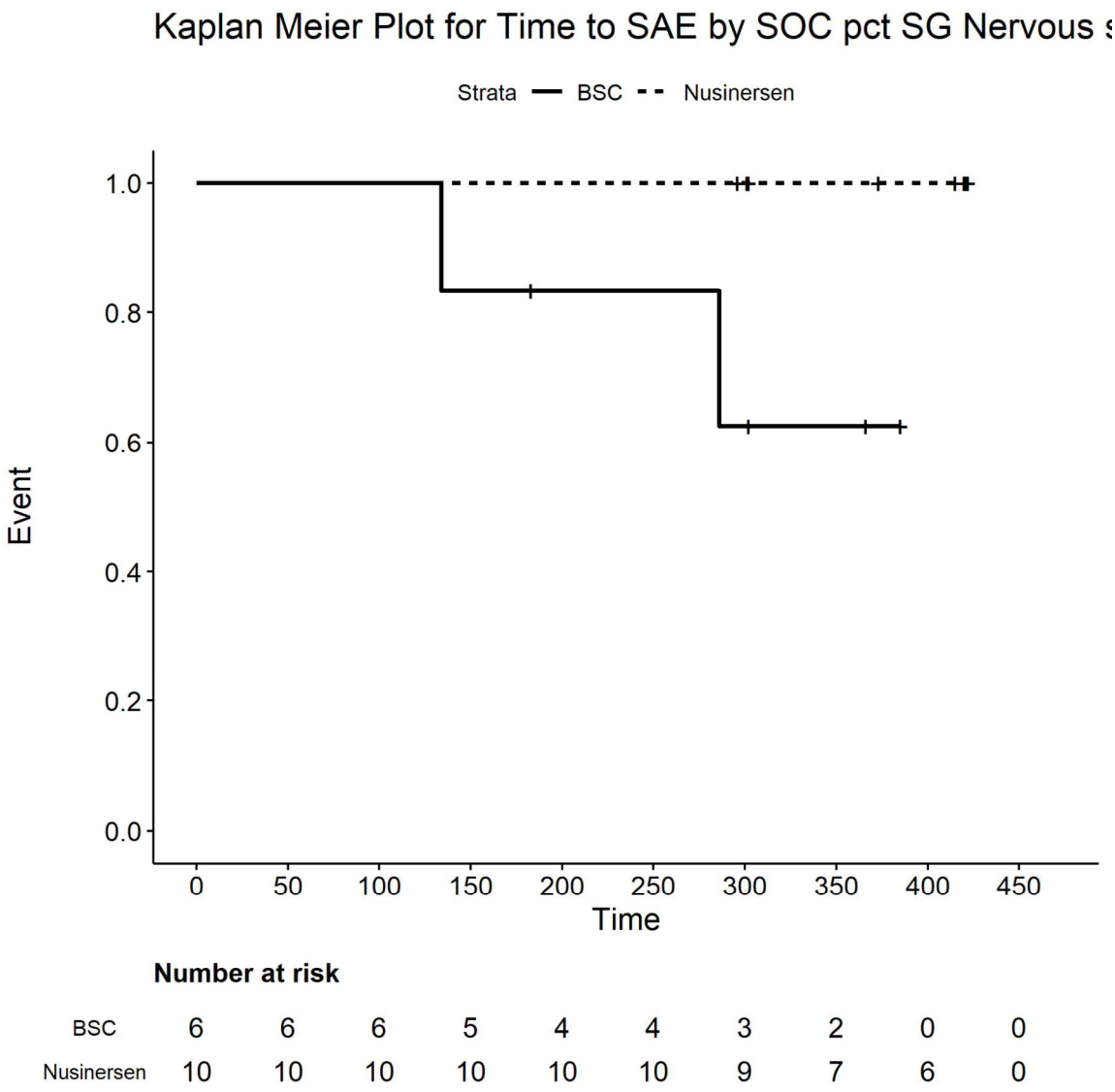
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



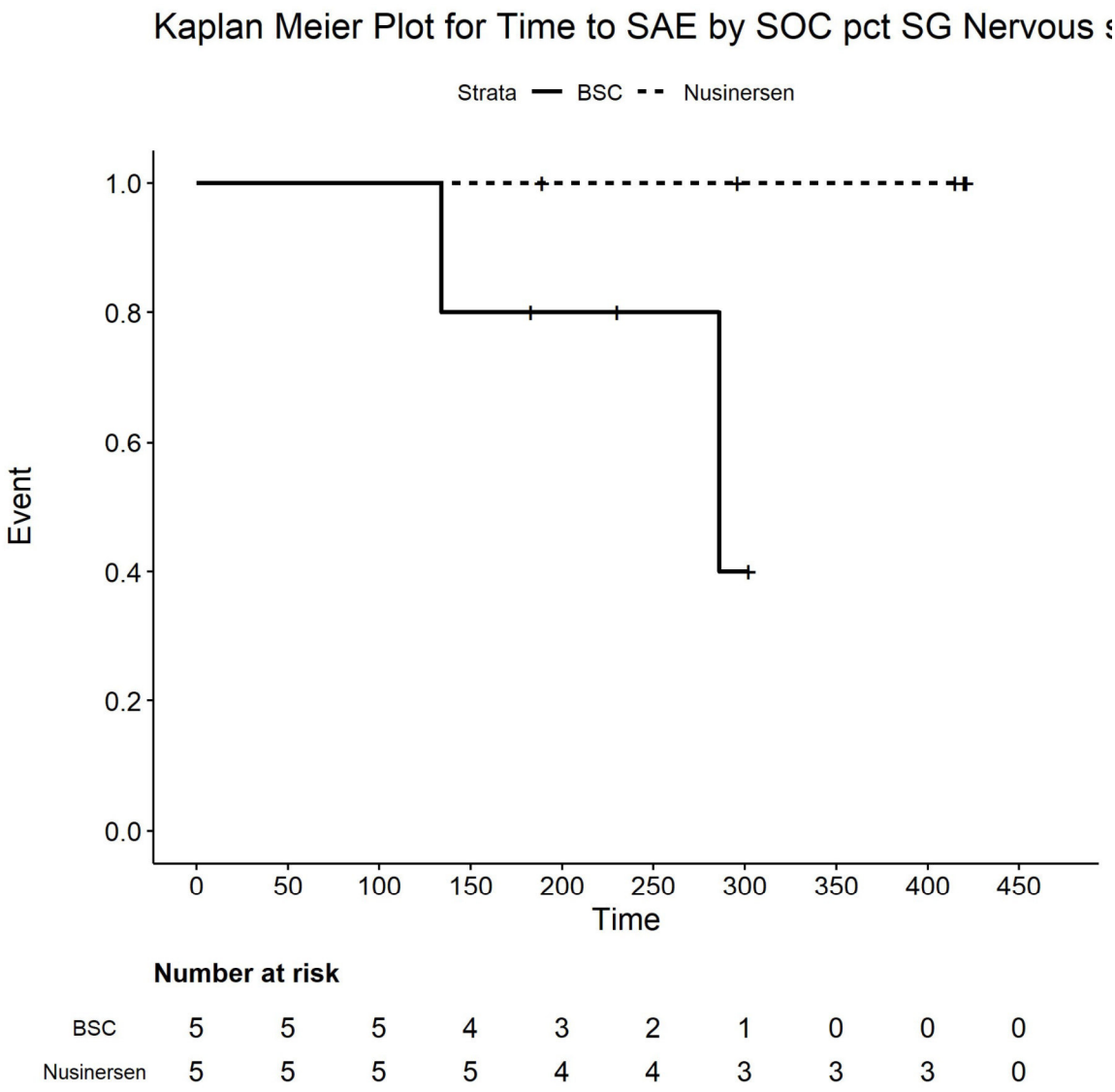
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



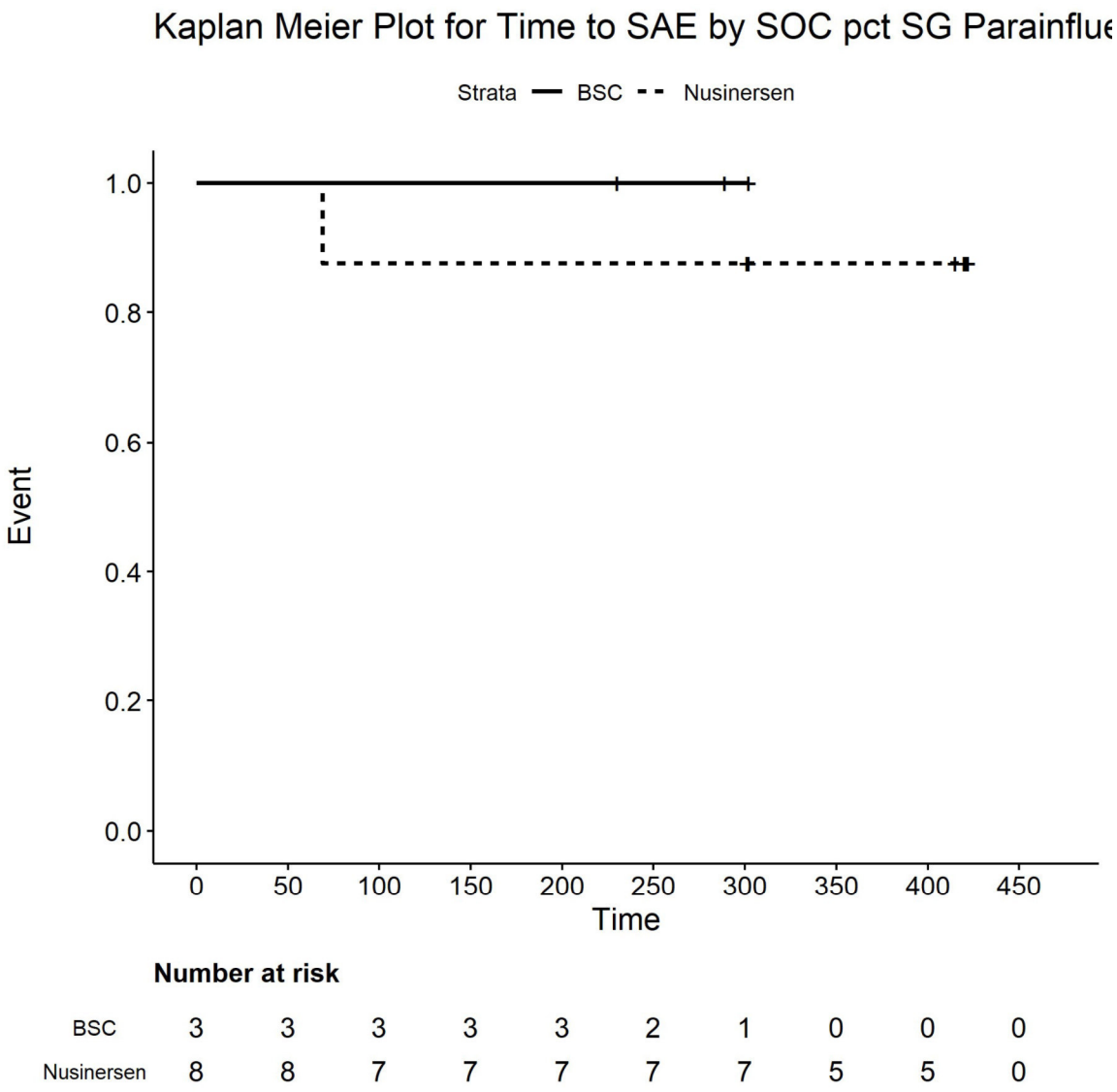
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



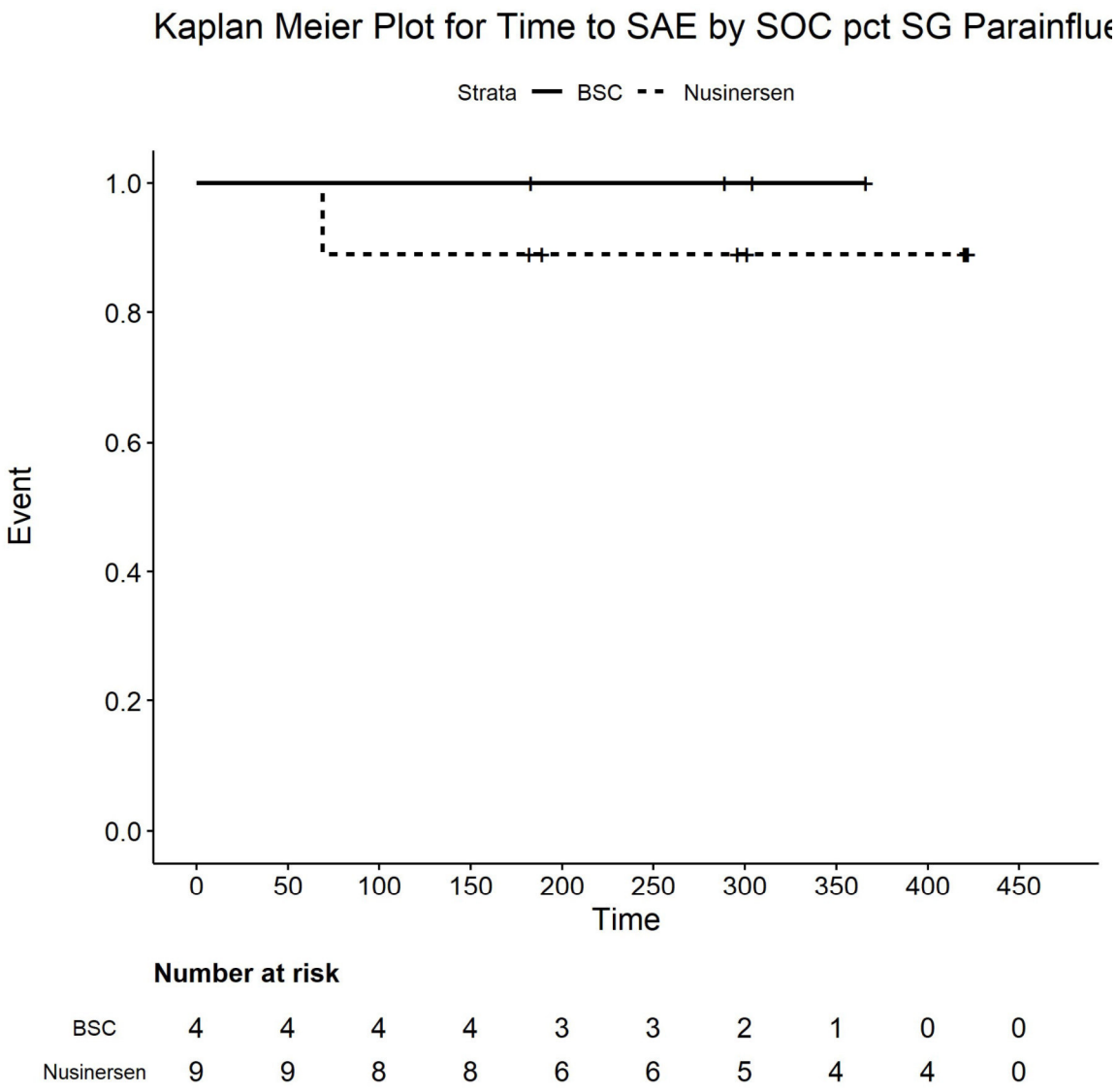
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



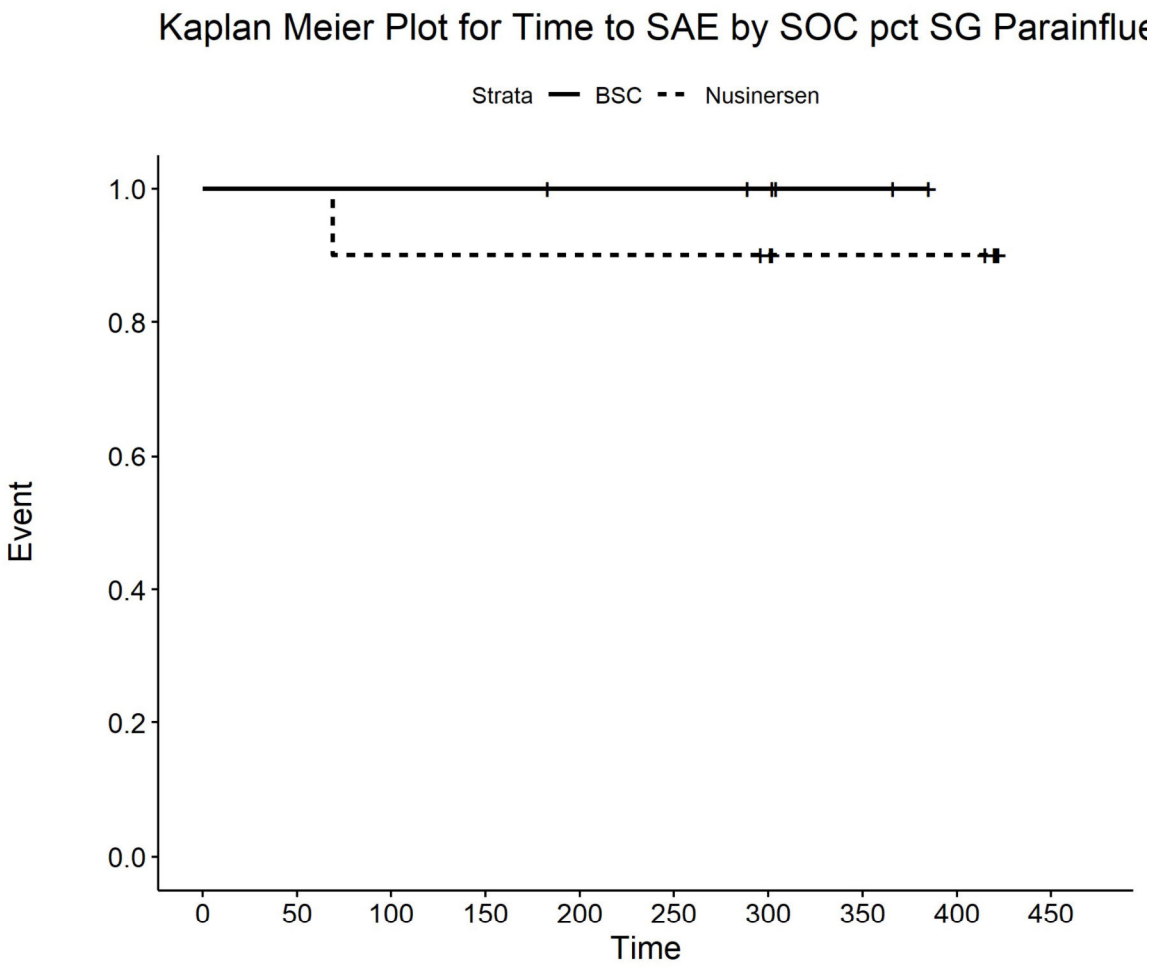
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	5	0



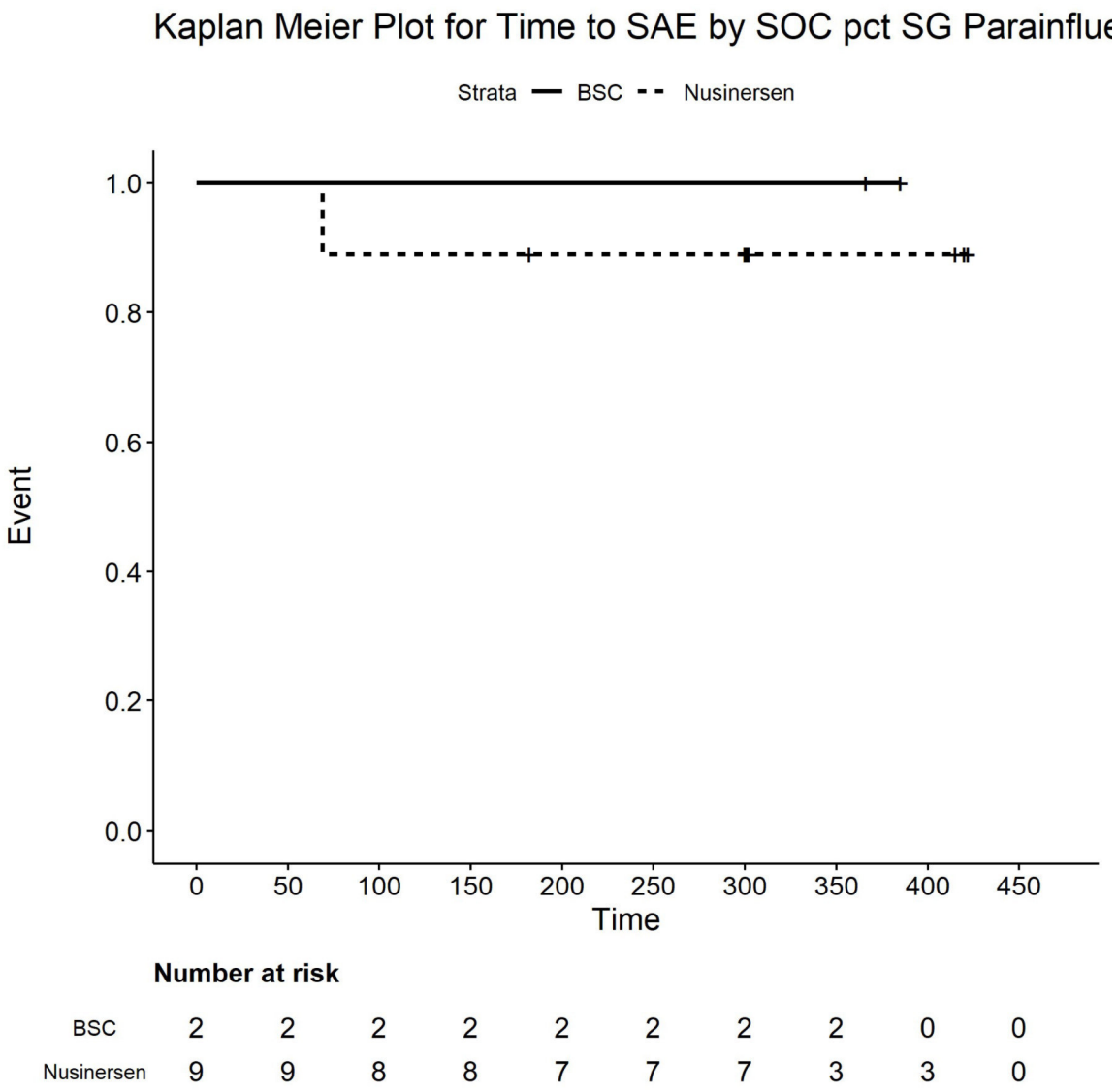
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	4	0



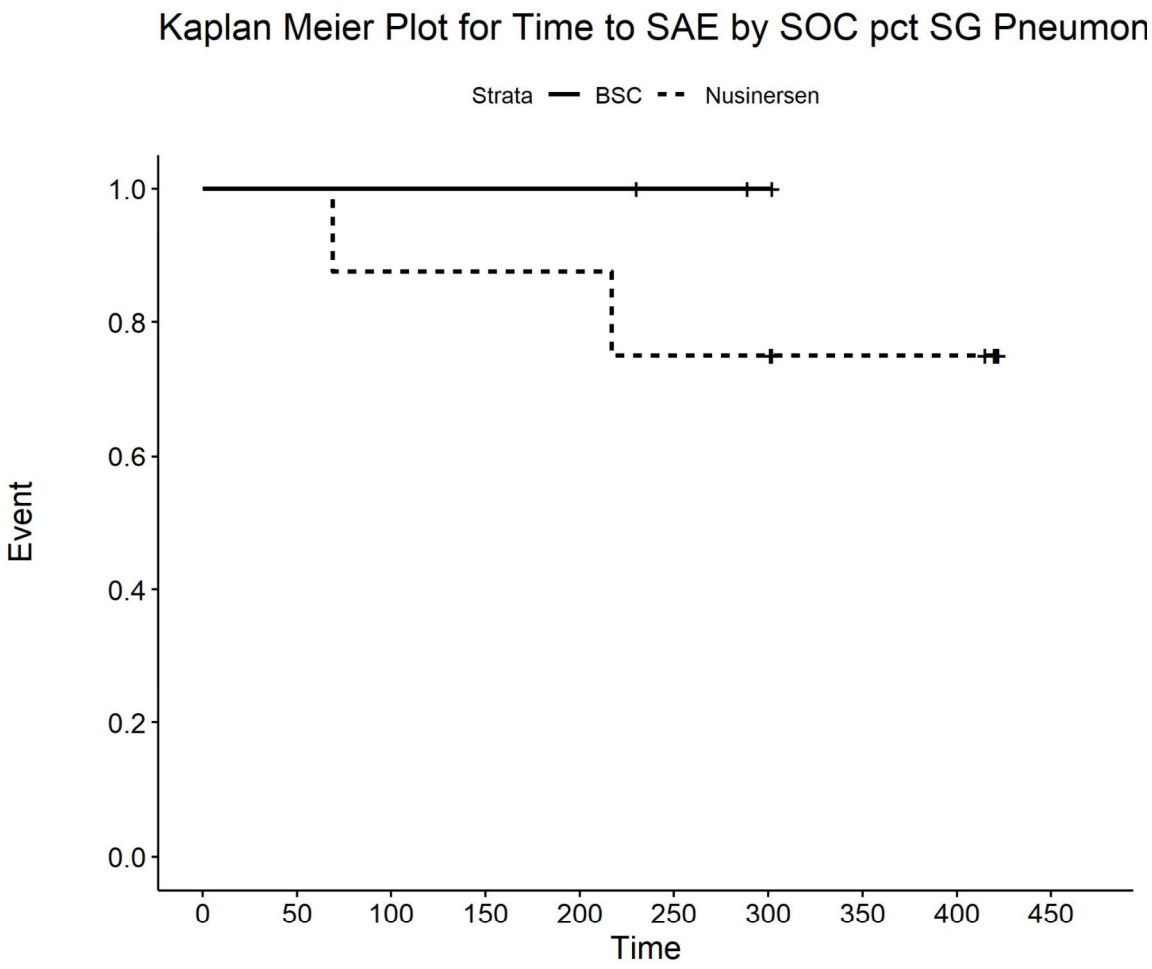
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	6	0



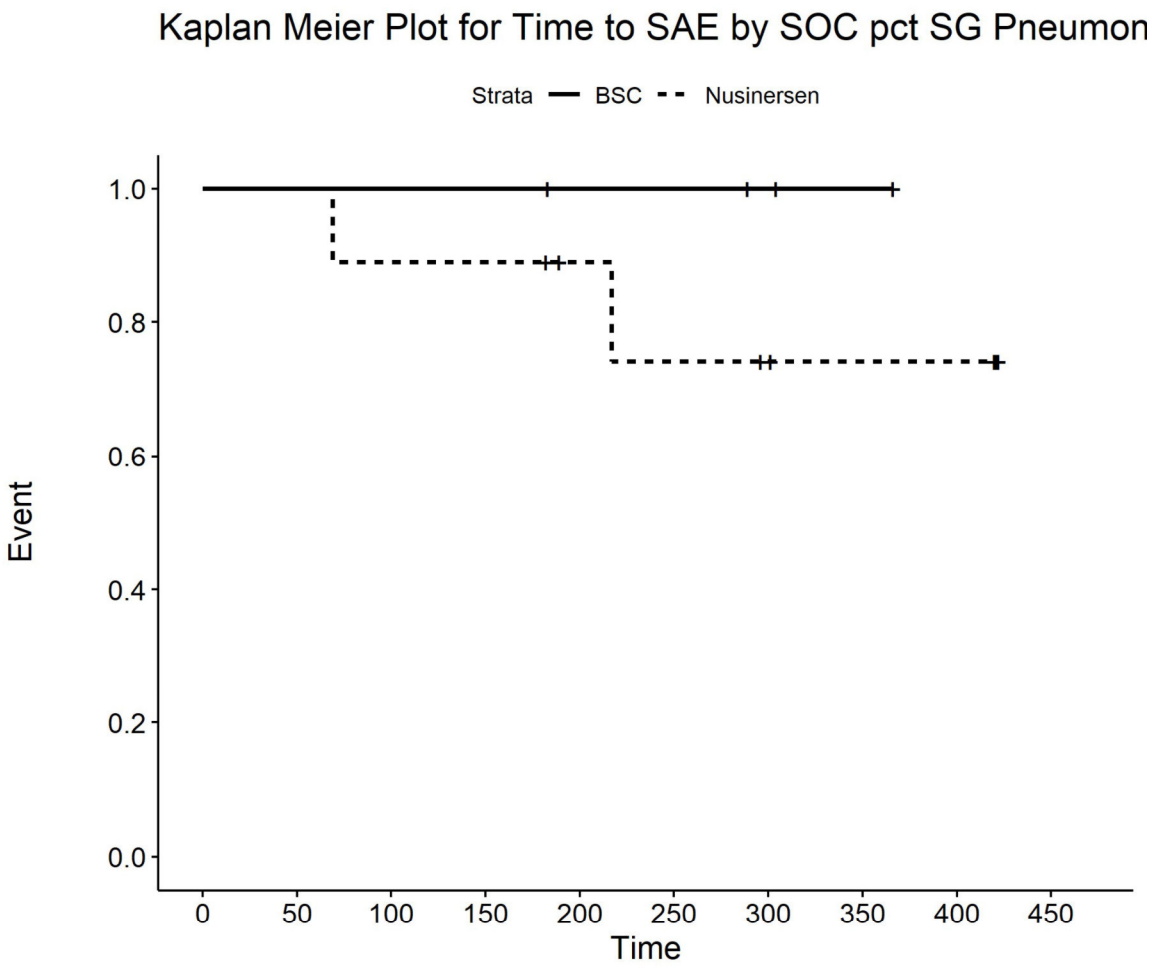
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	3	0



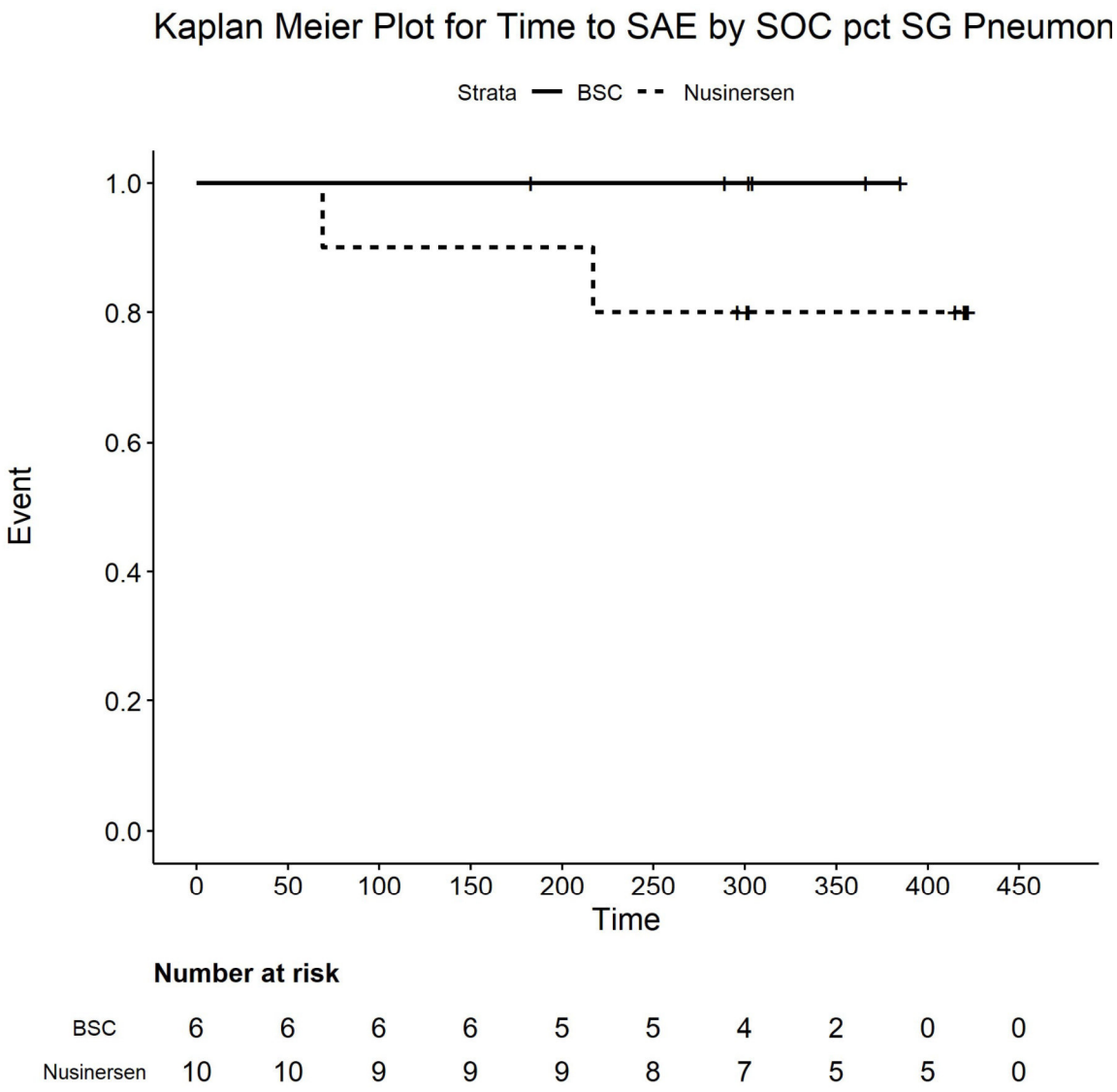
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	6	6	4	4	0



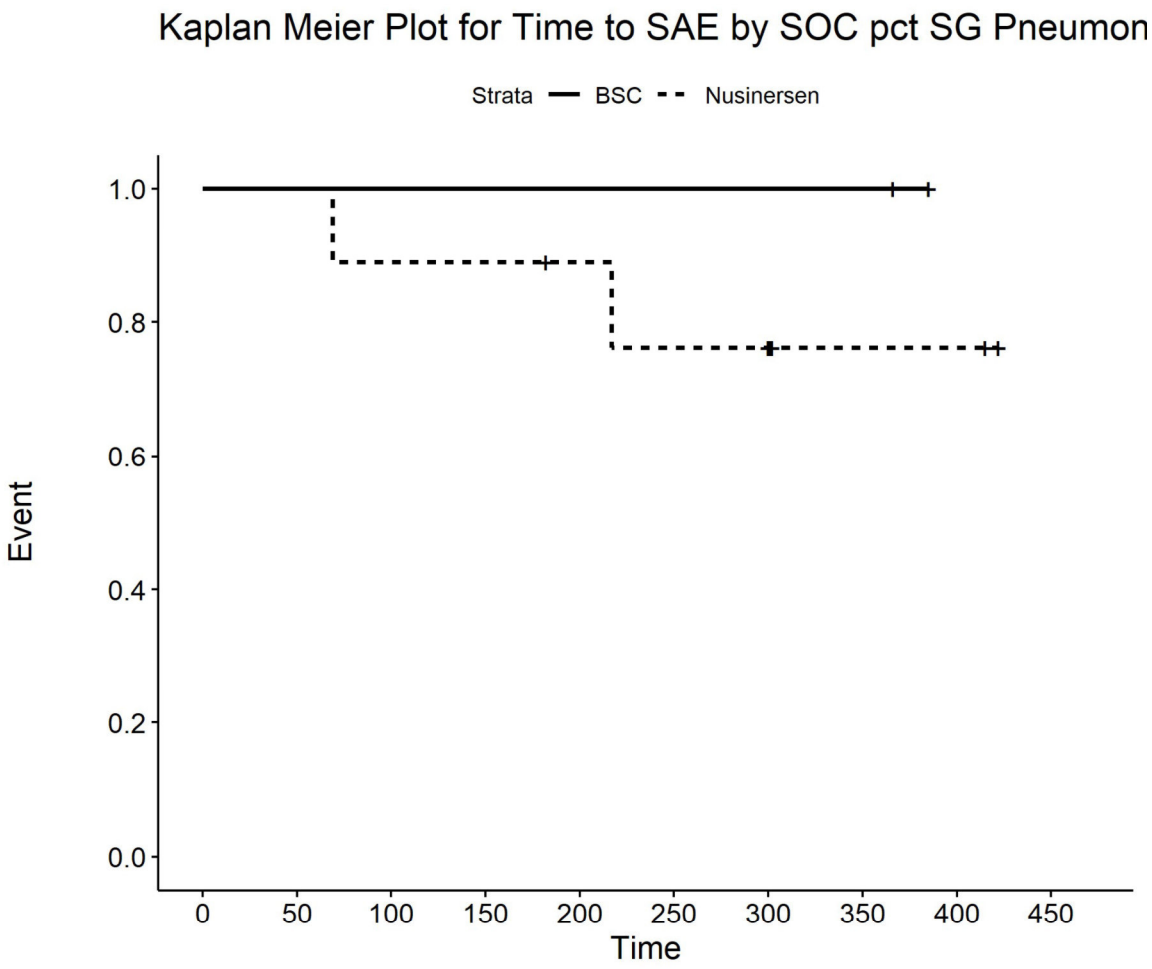
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	5	4	3	3	0



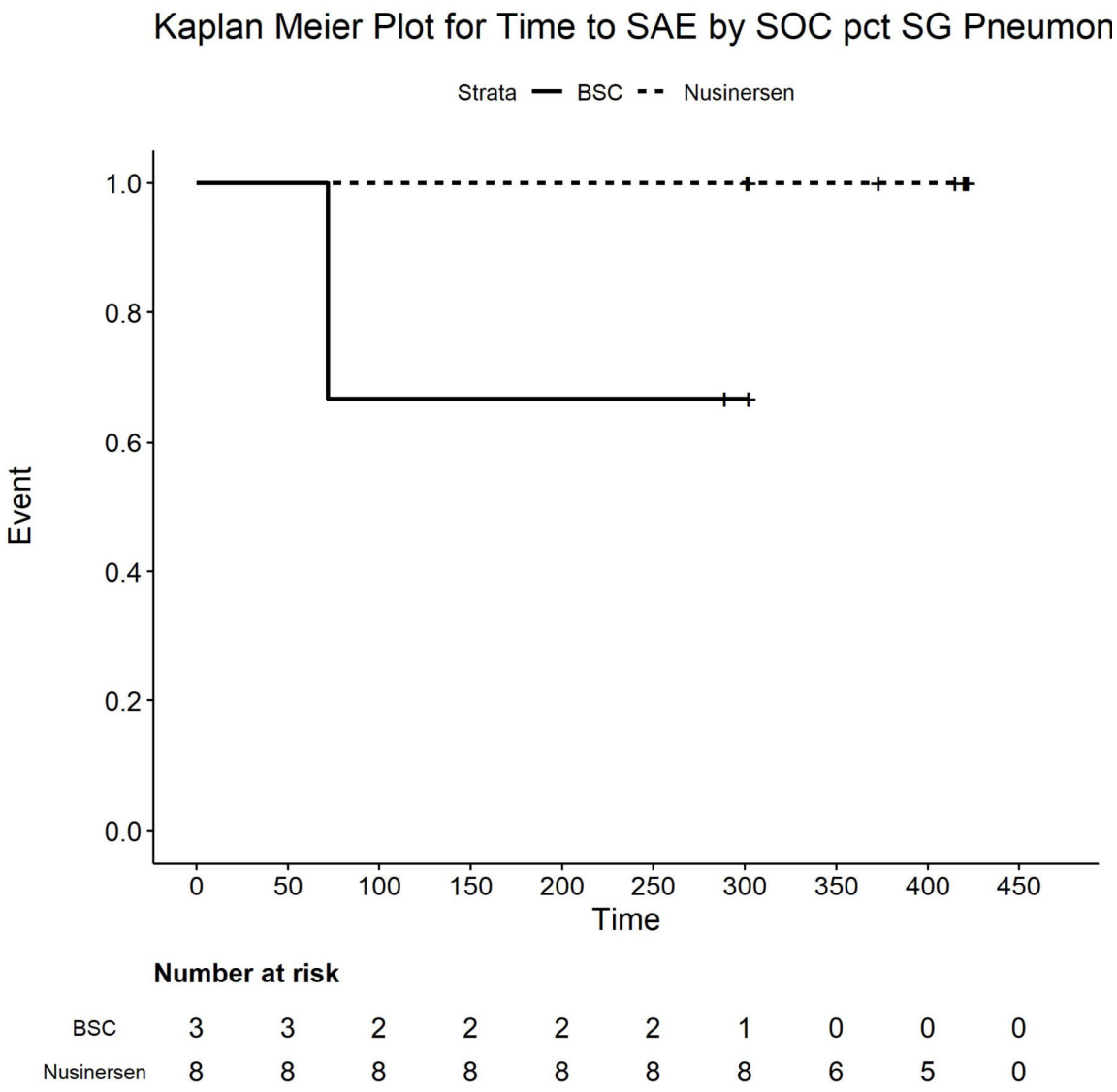
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	8	7	5	5	0



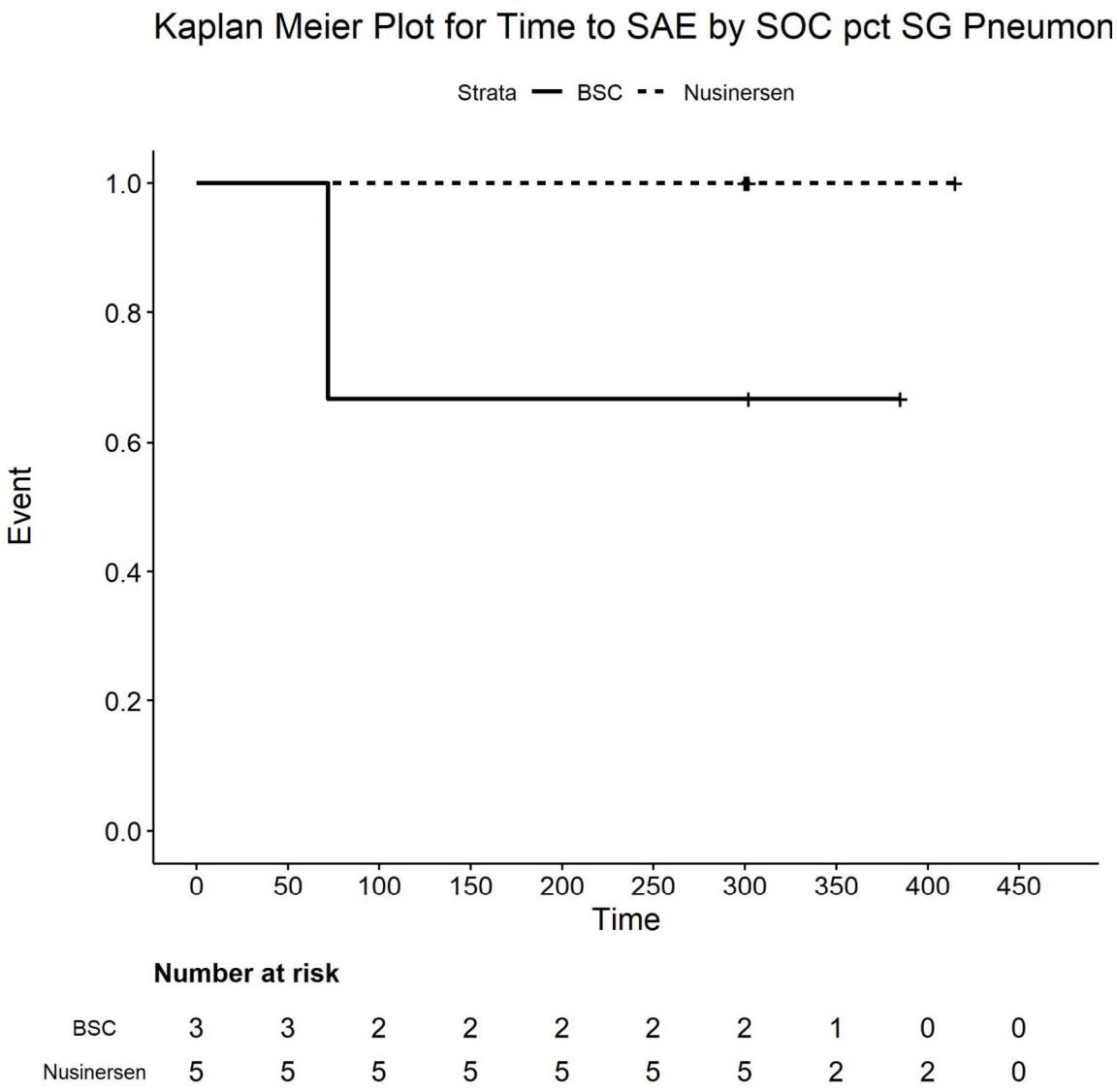
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	6	6	2	2	0



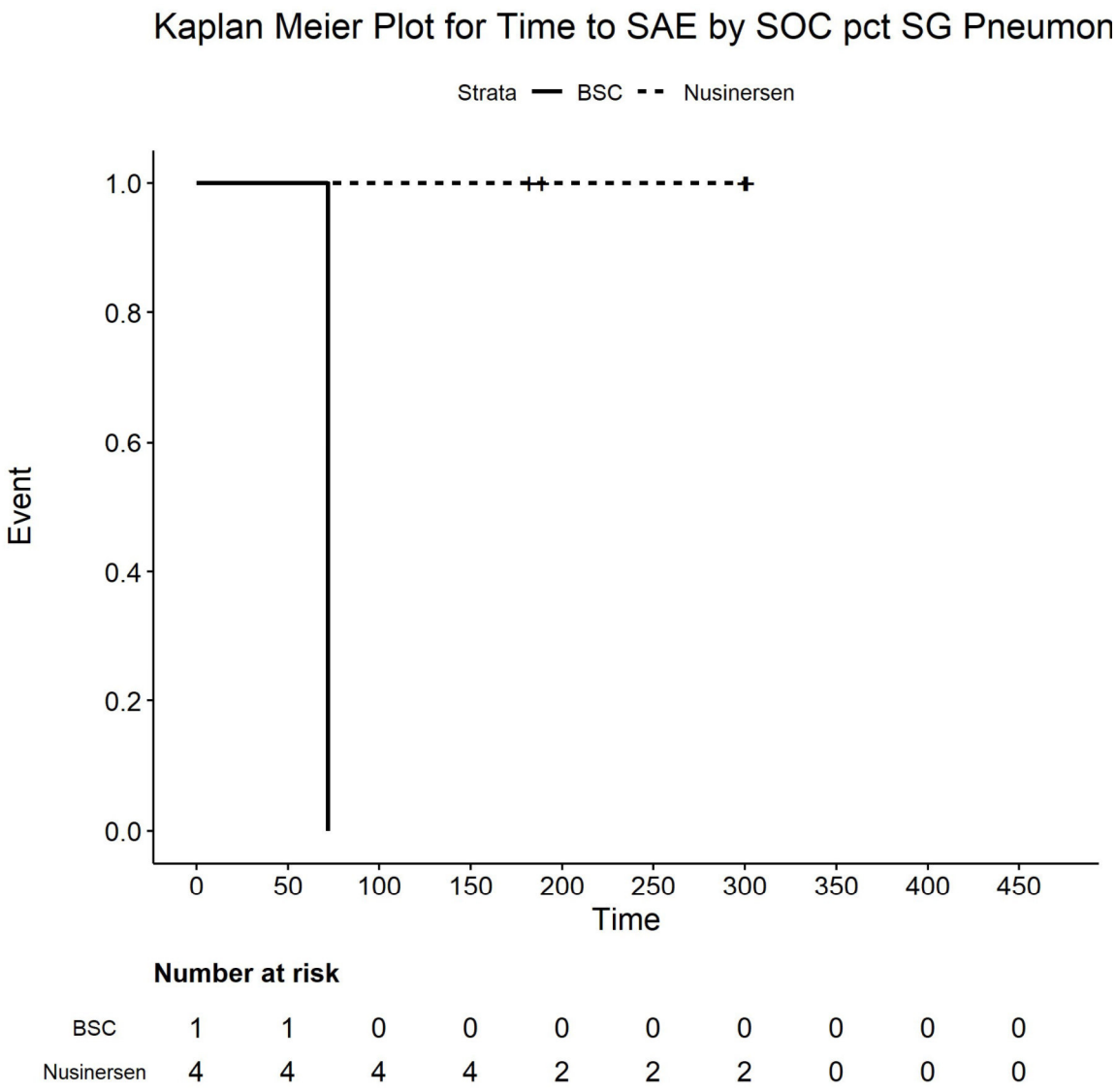
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



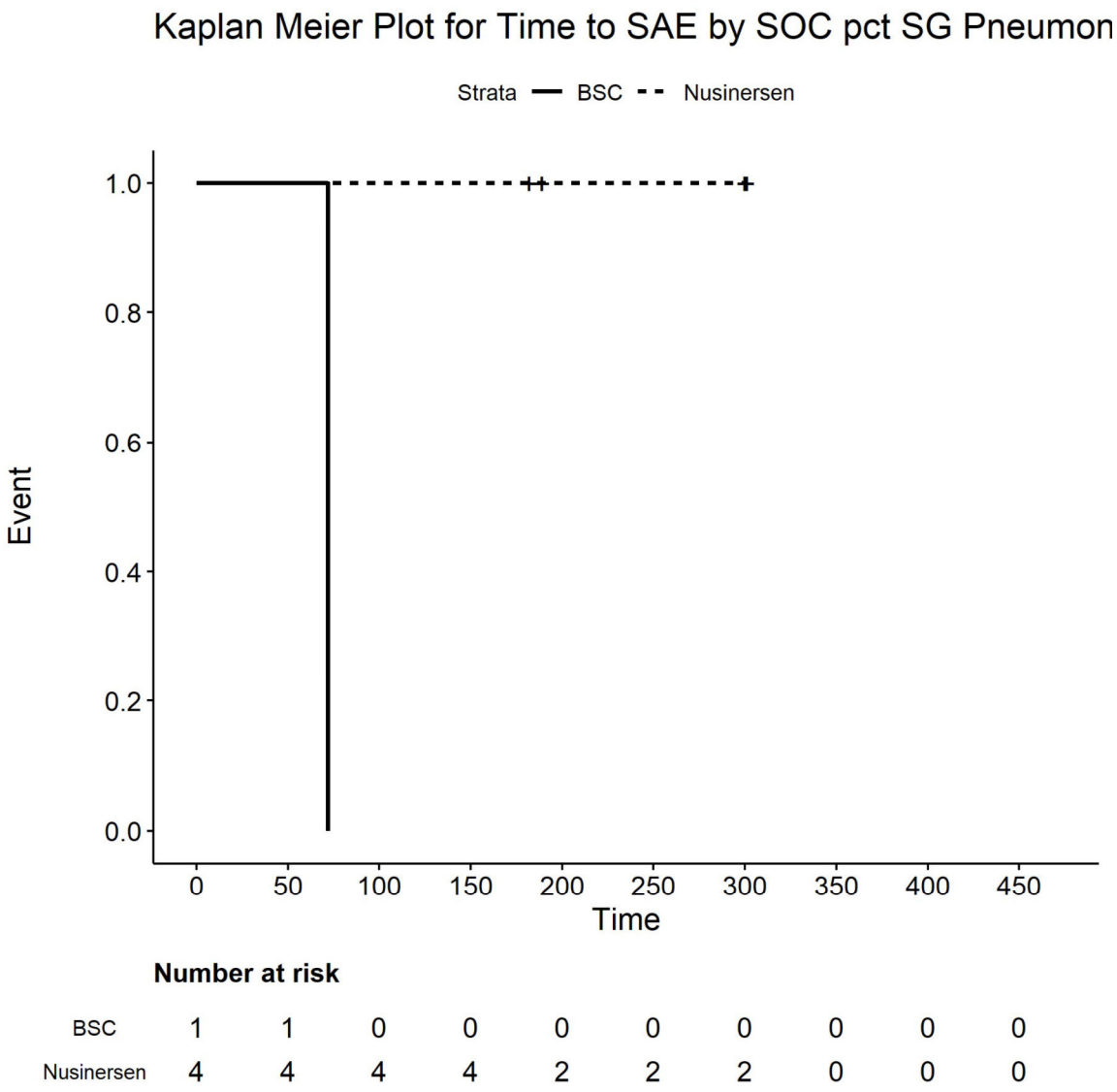
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



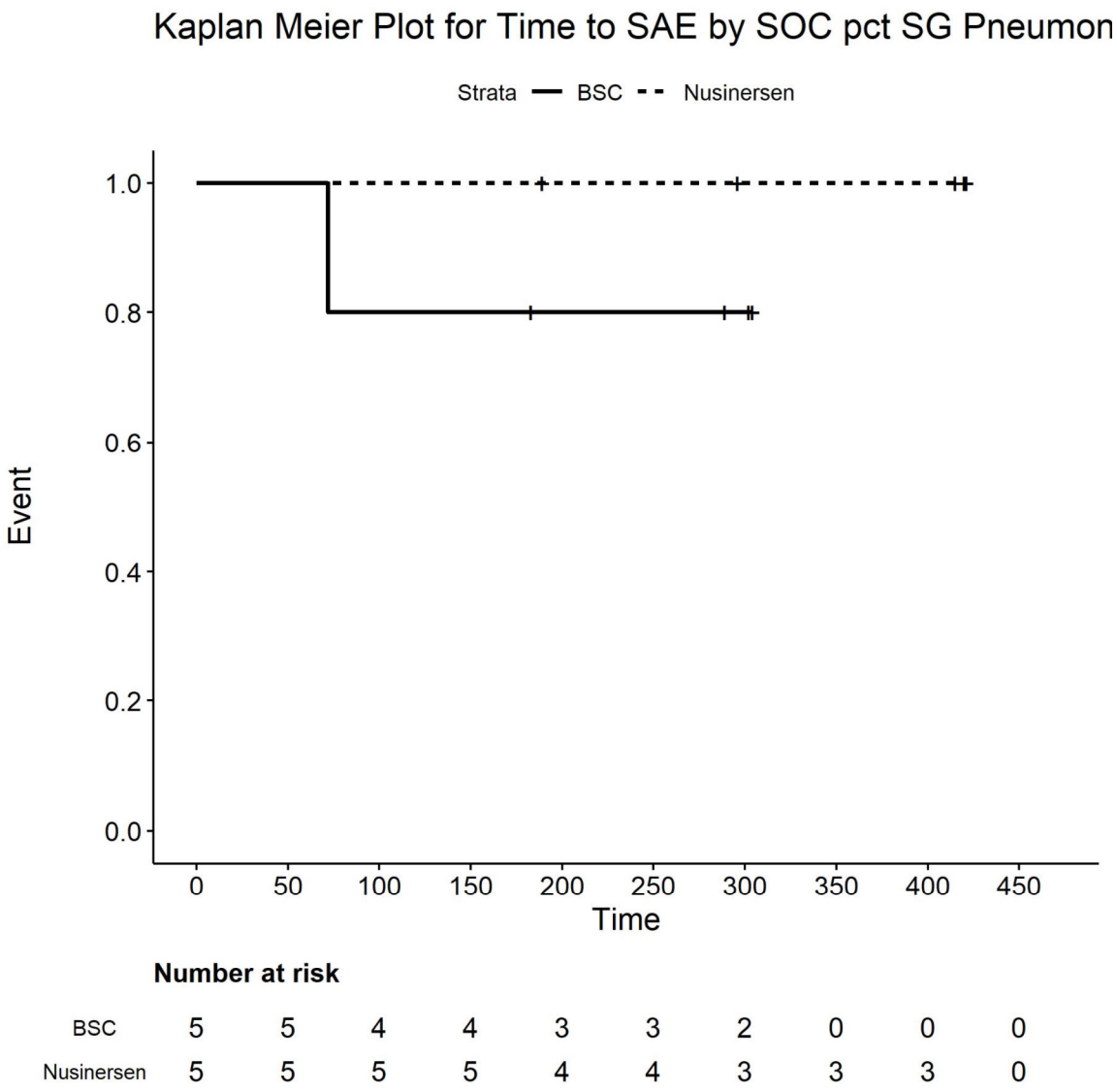
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



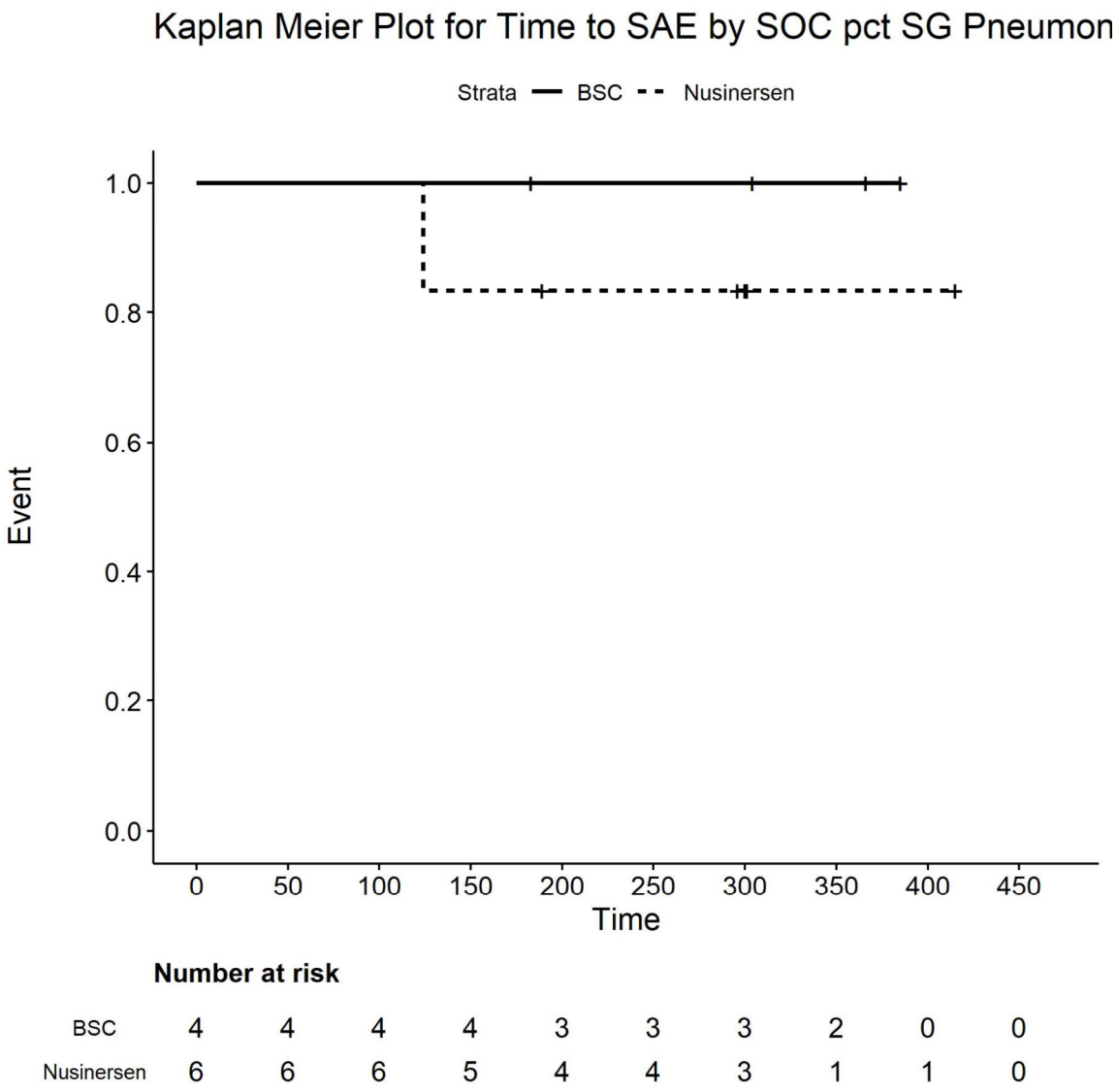
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



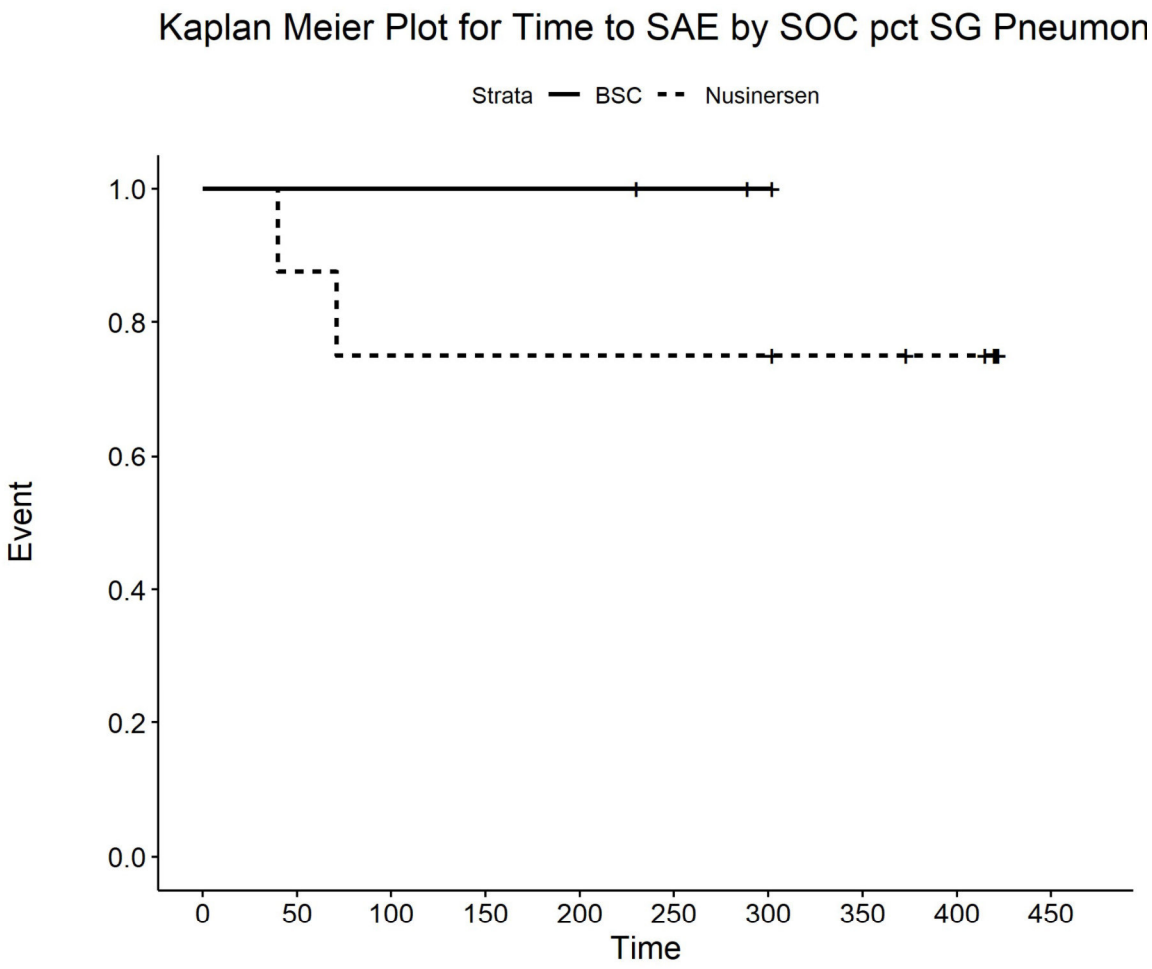
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



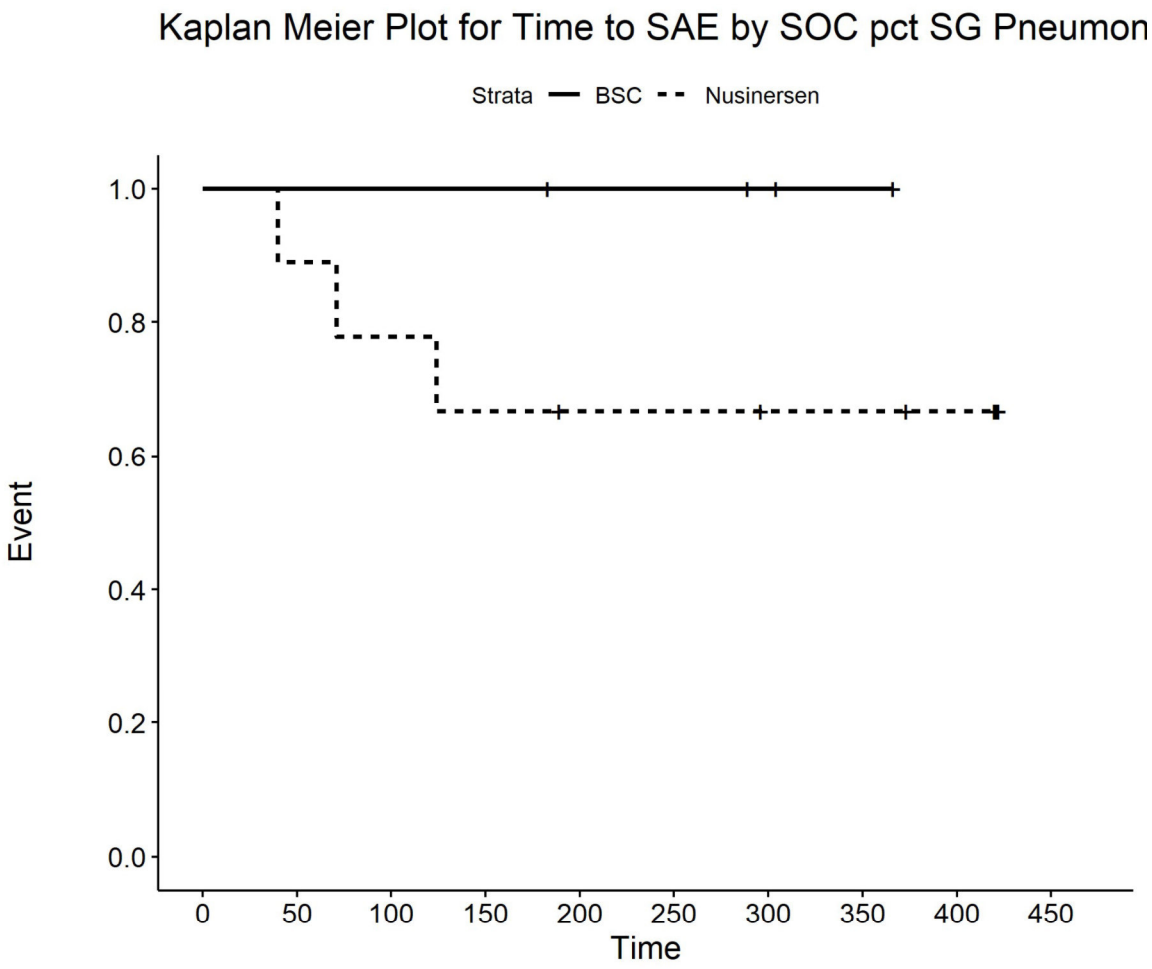
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	5	4	4	3	1	1	0



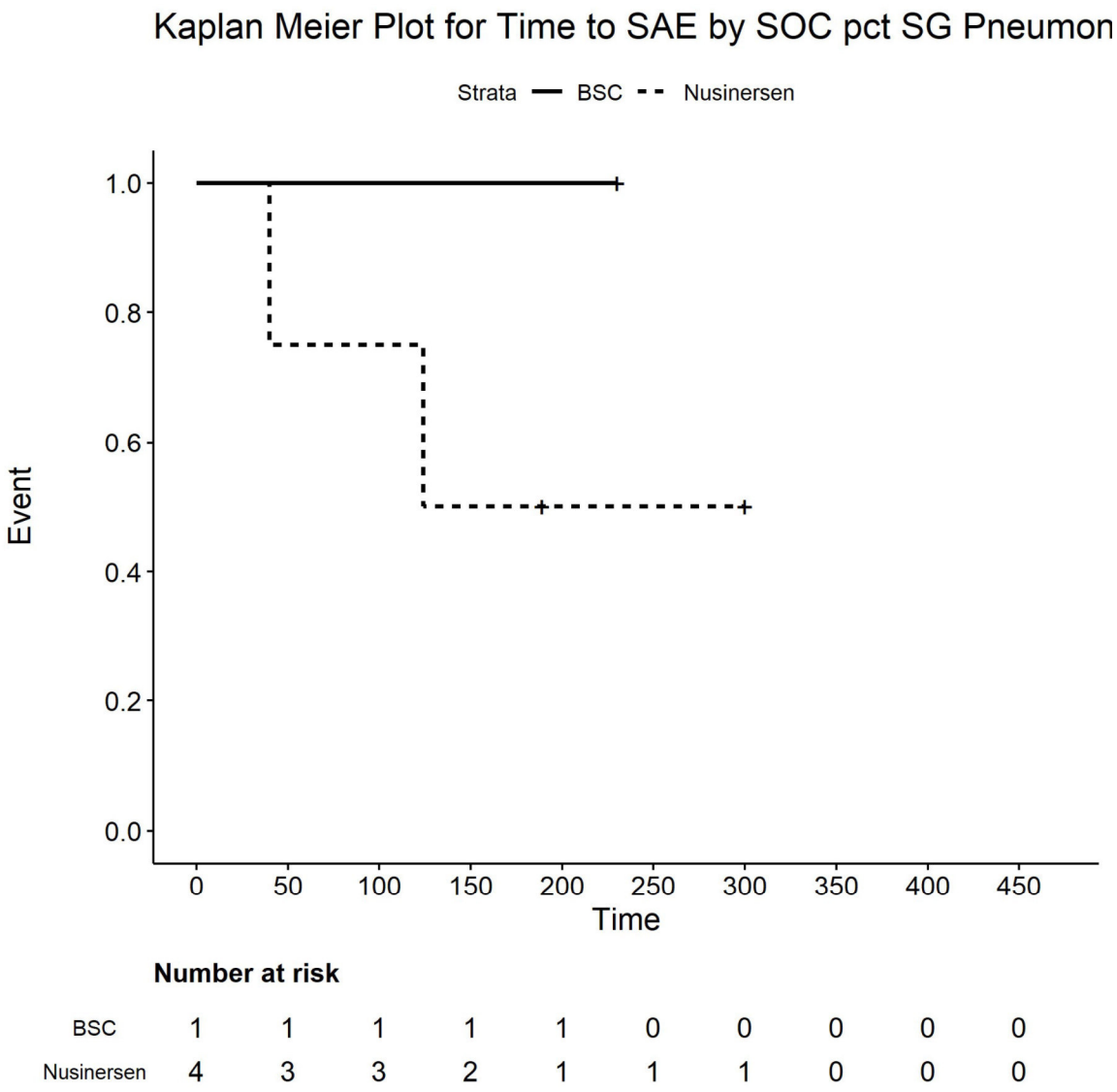
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	6	6	6	6	6	5	4	0



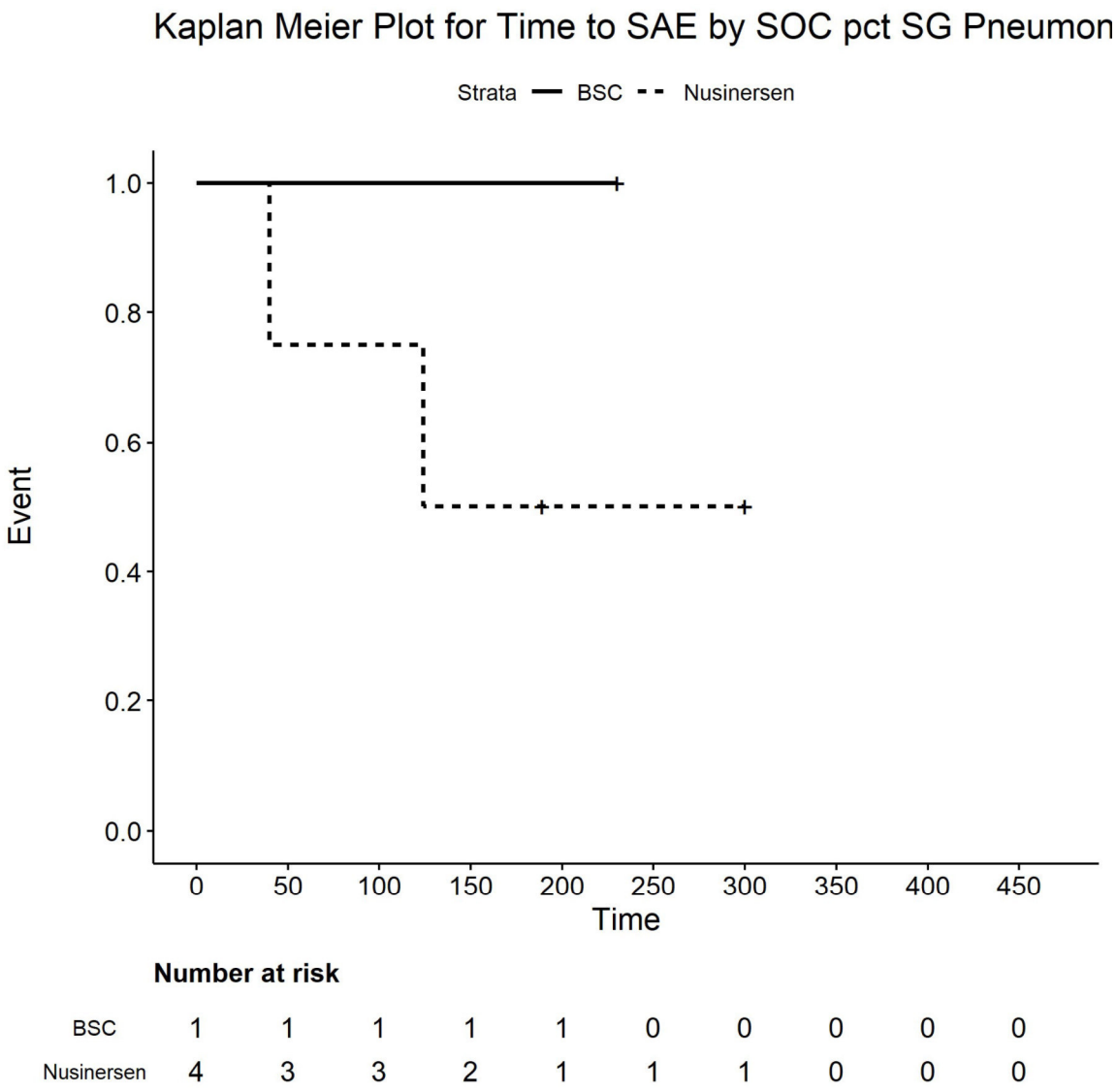
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	7	6	5	5	4	4	3	0



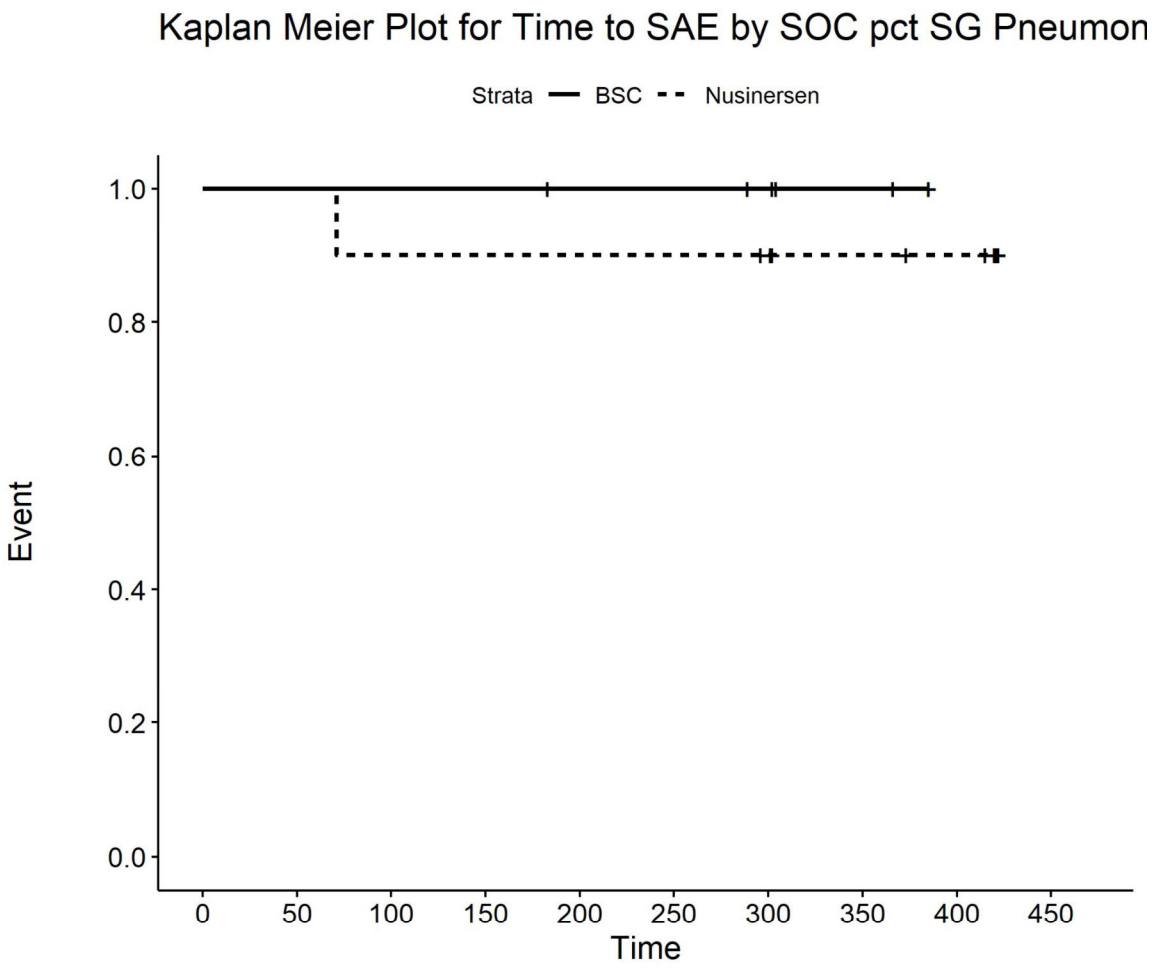
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



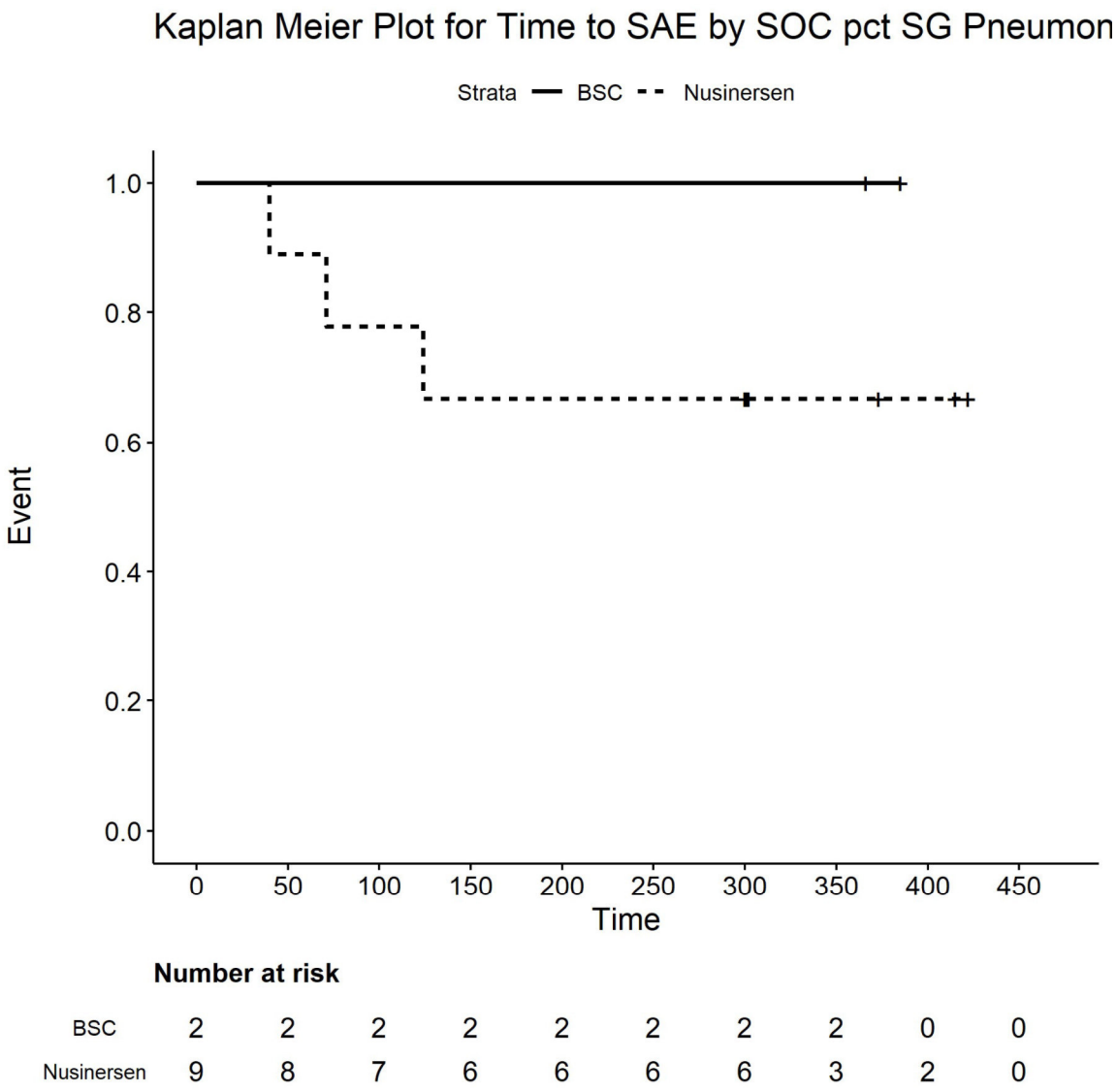
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



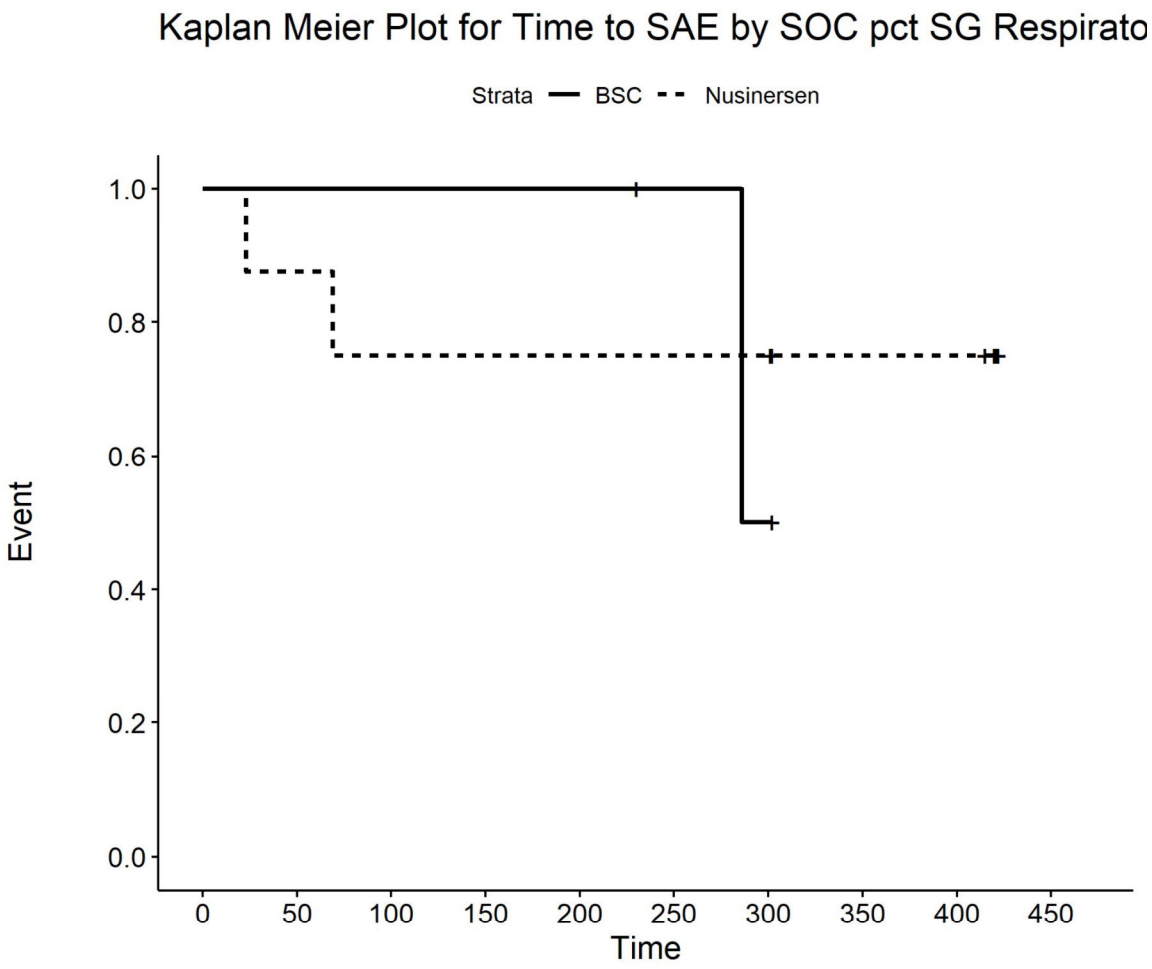
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



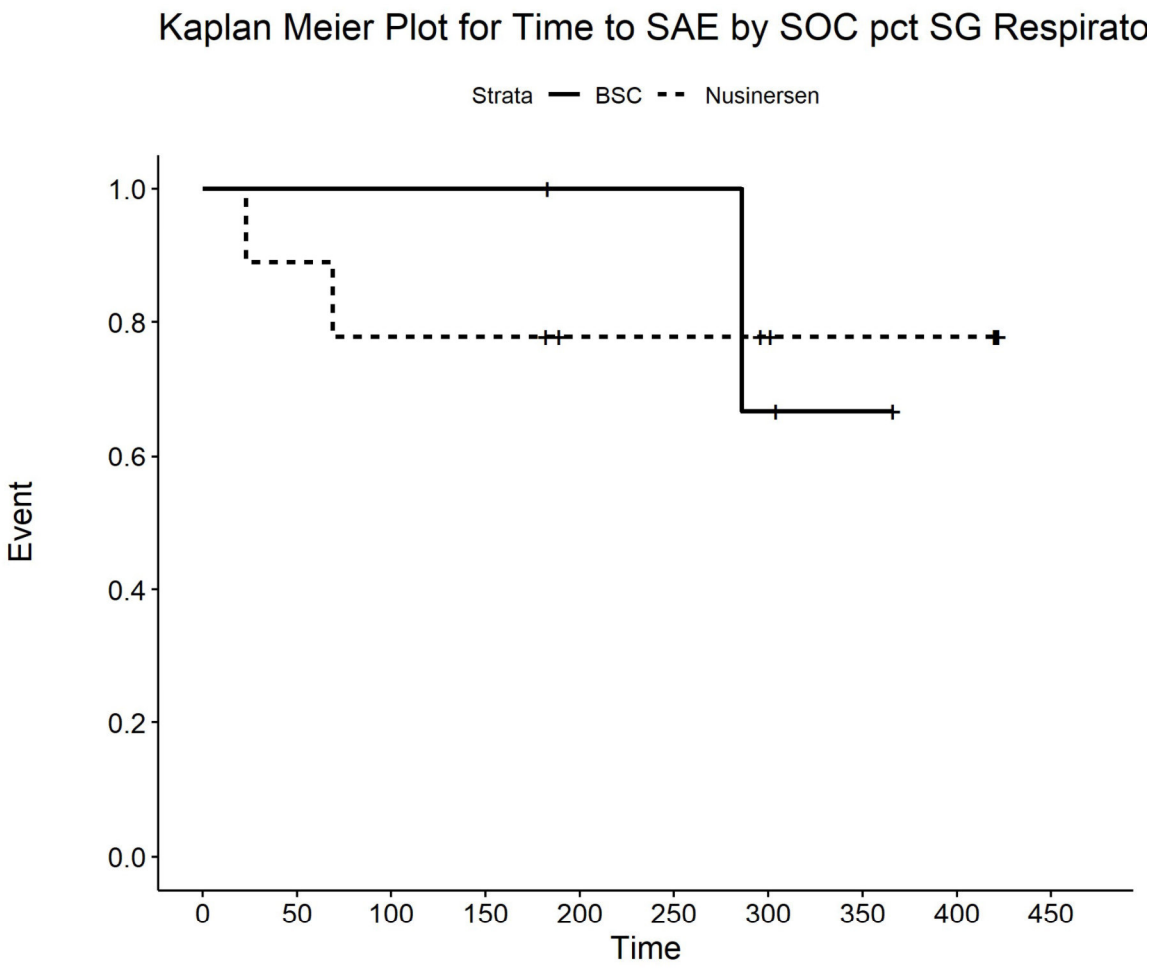
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	7	6	6	6	6	3	2	0



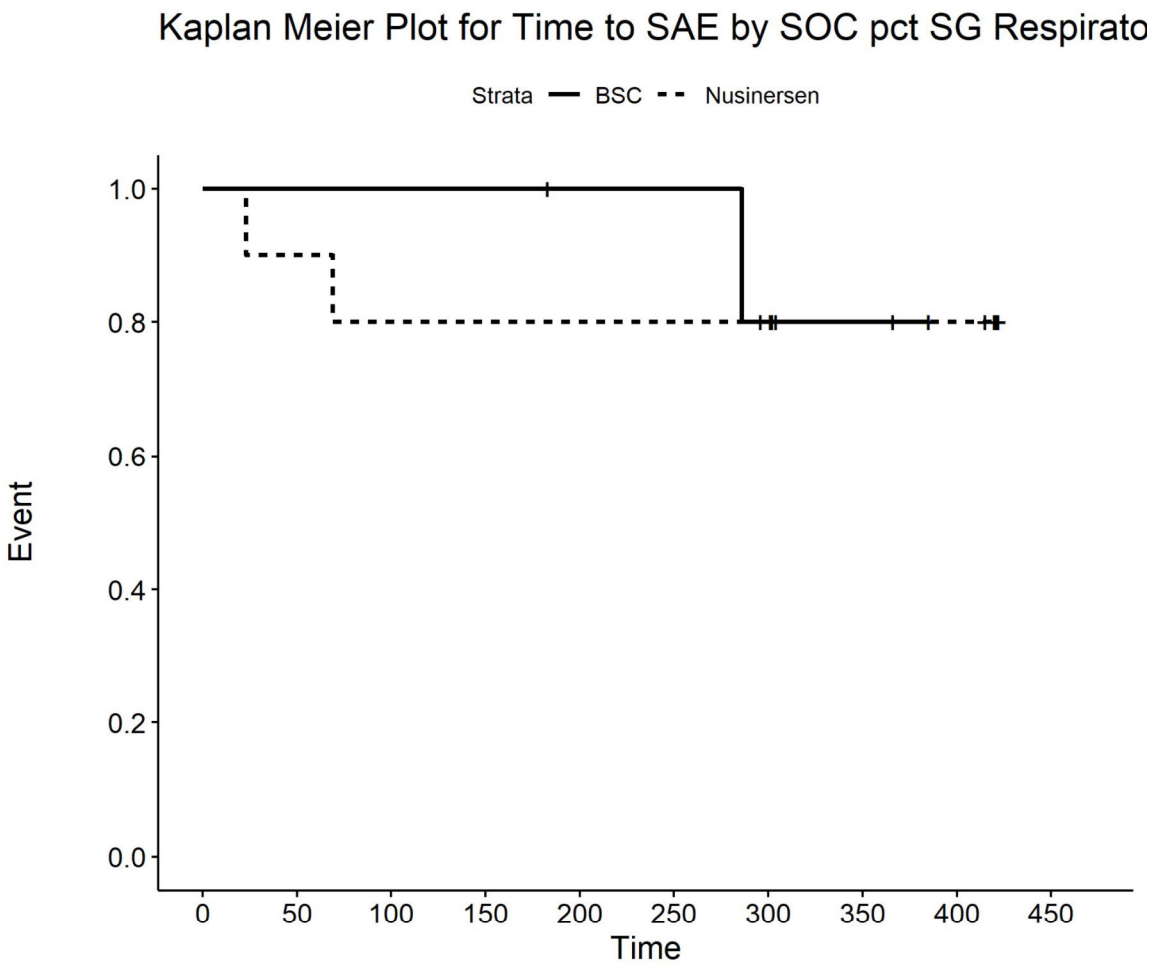
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	6	6	6	6	6	4	4	0



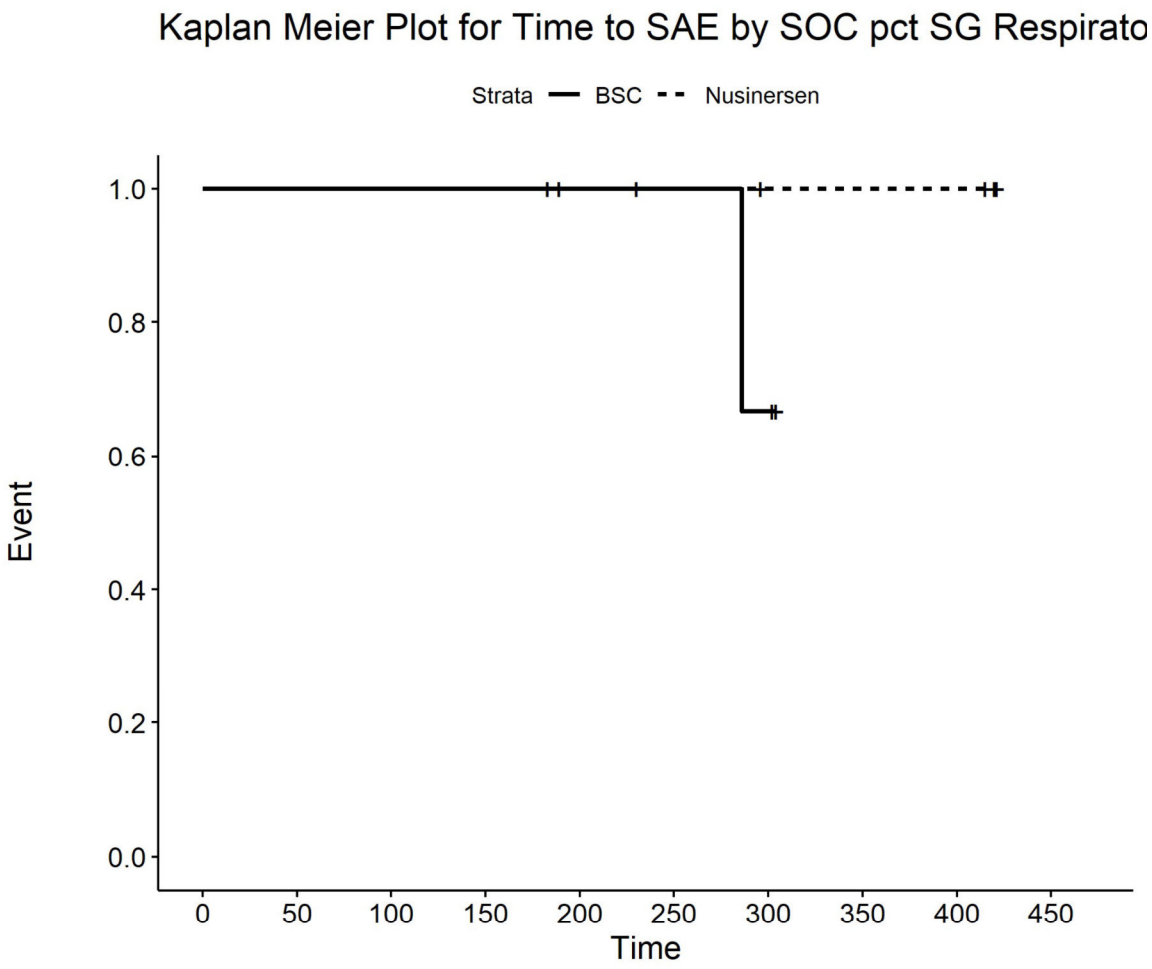
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	7	7	5	5	4	3	3	0



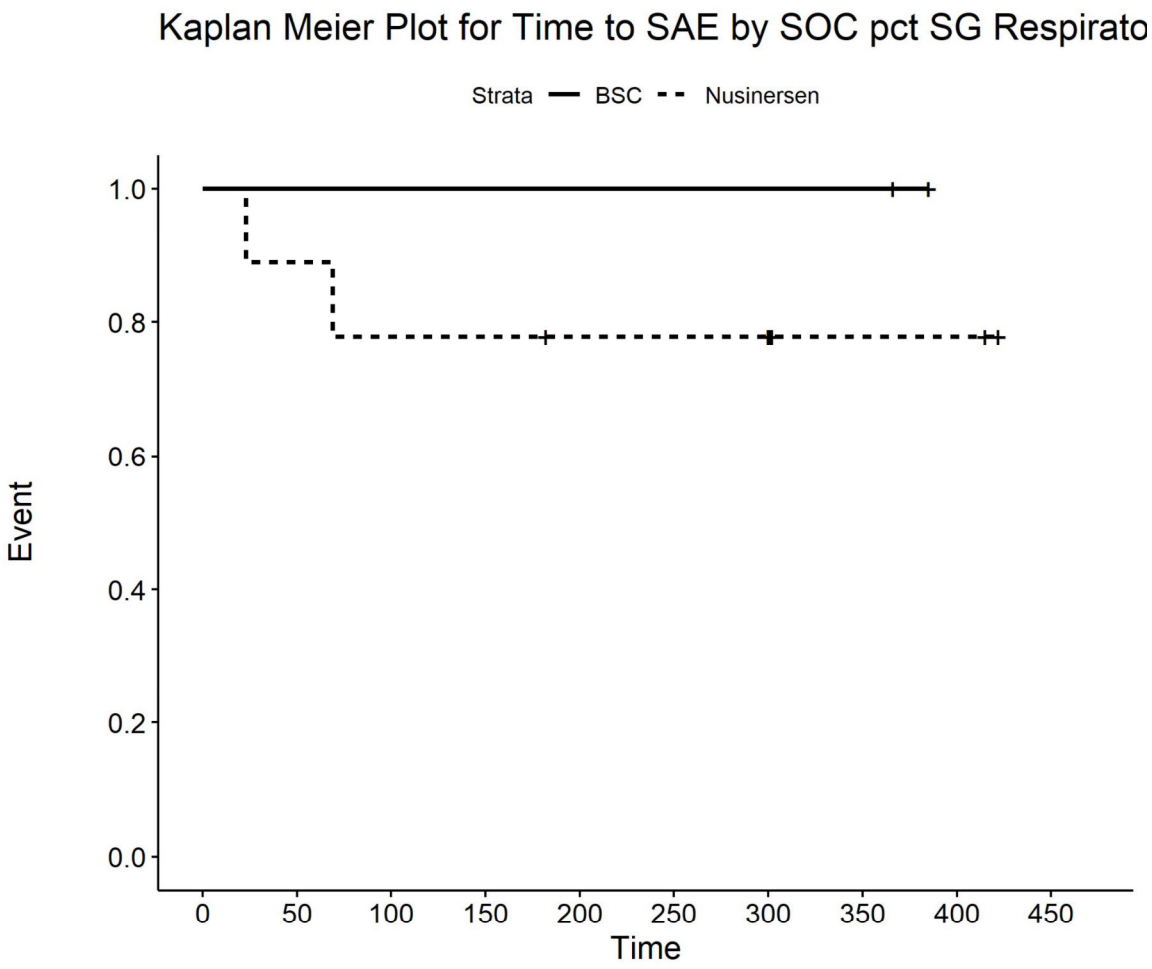
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	9	8	8	8	8	7	5	5	0



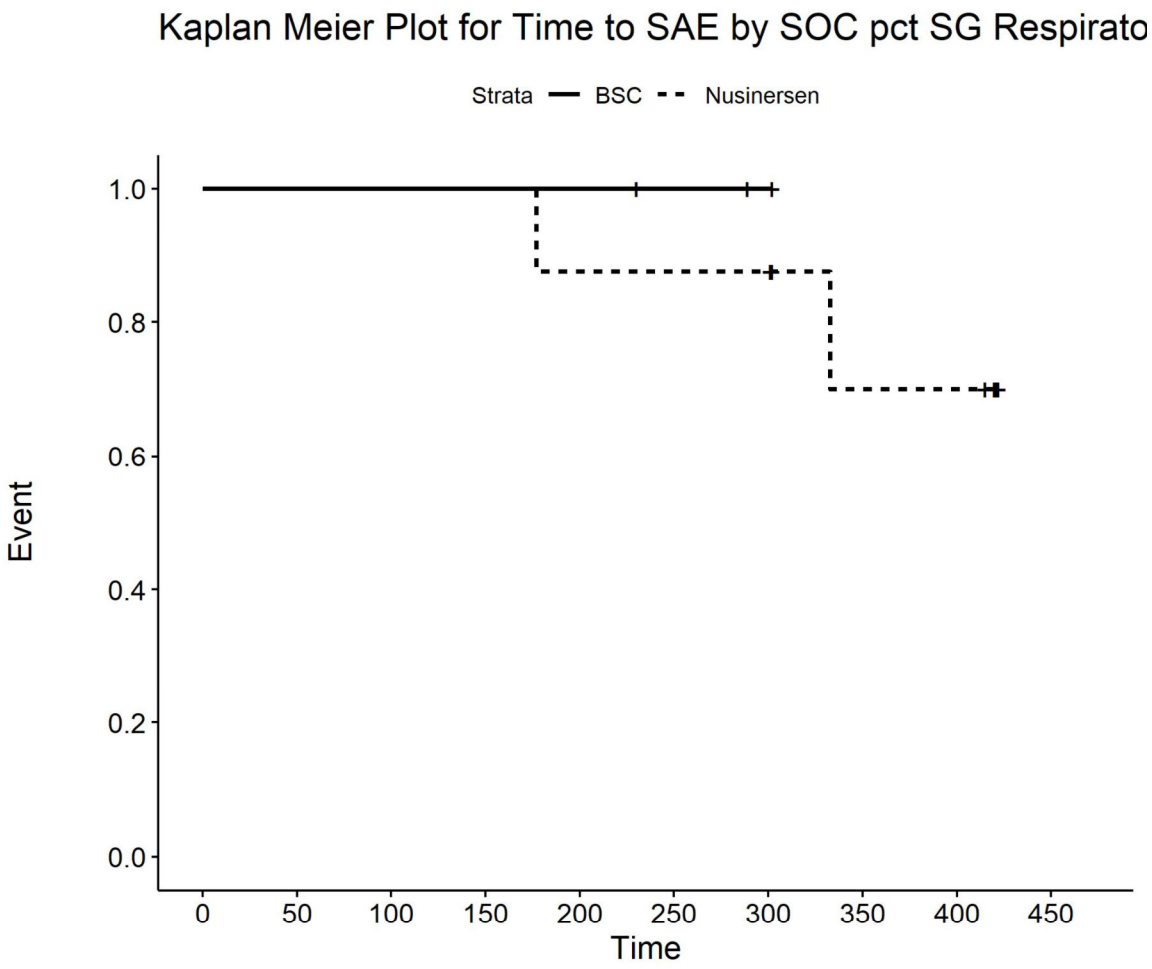
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



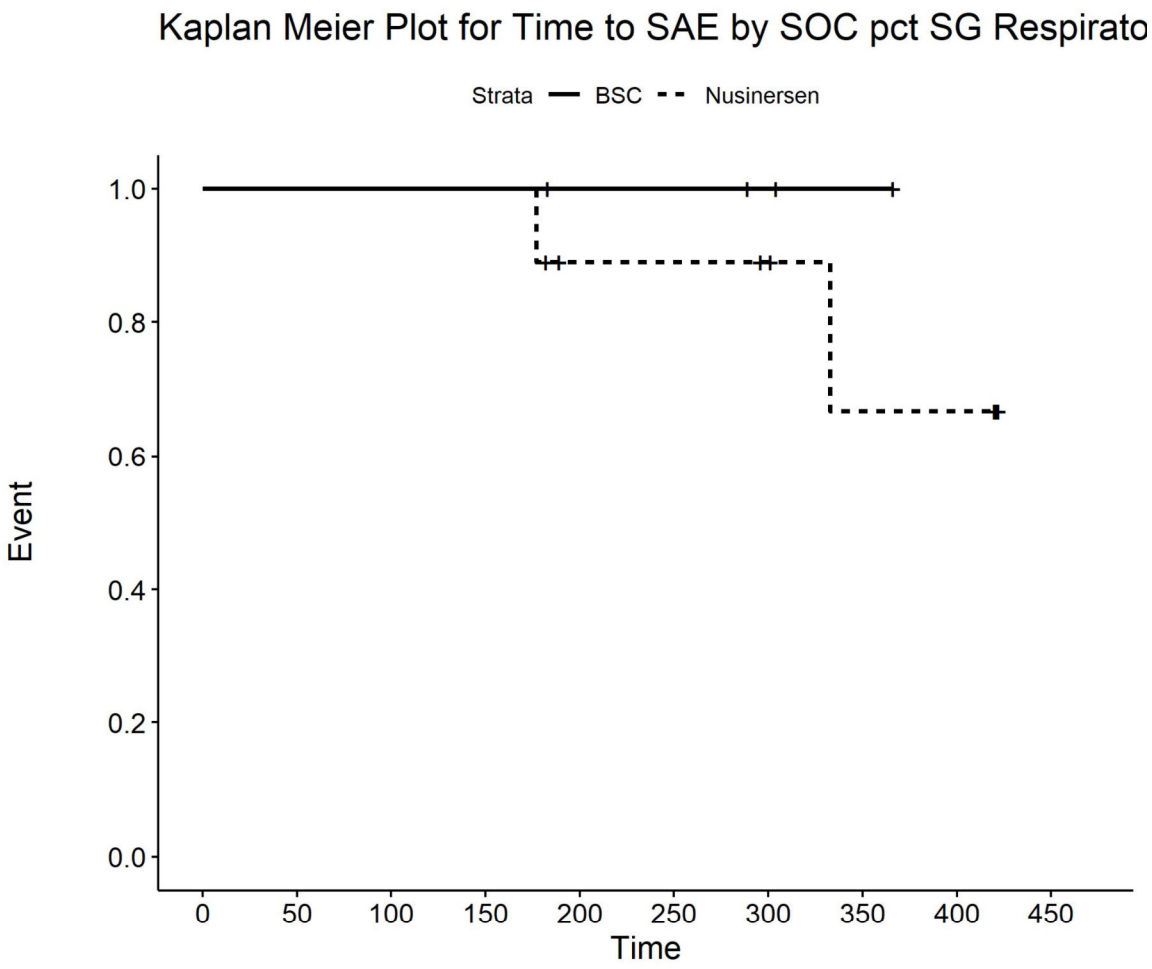
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	7	7	6	6	6	2	2	0



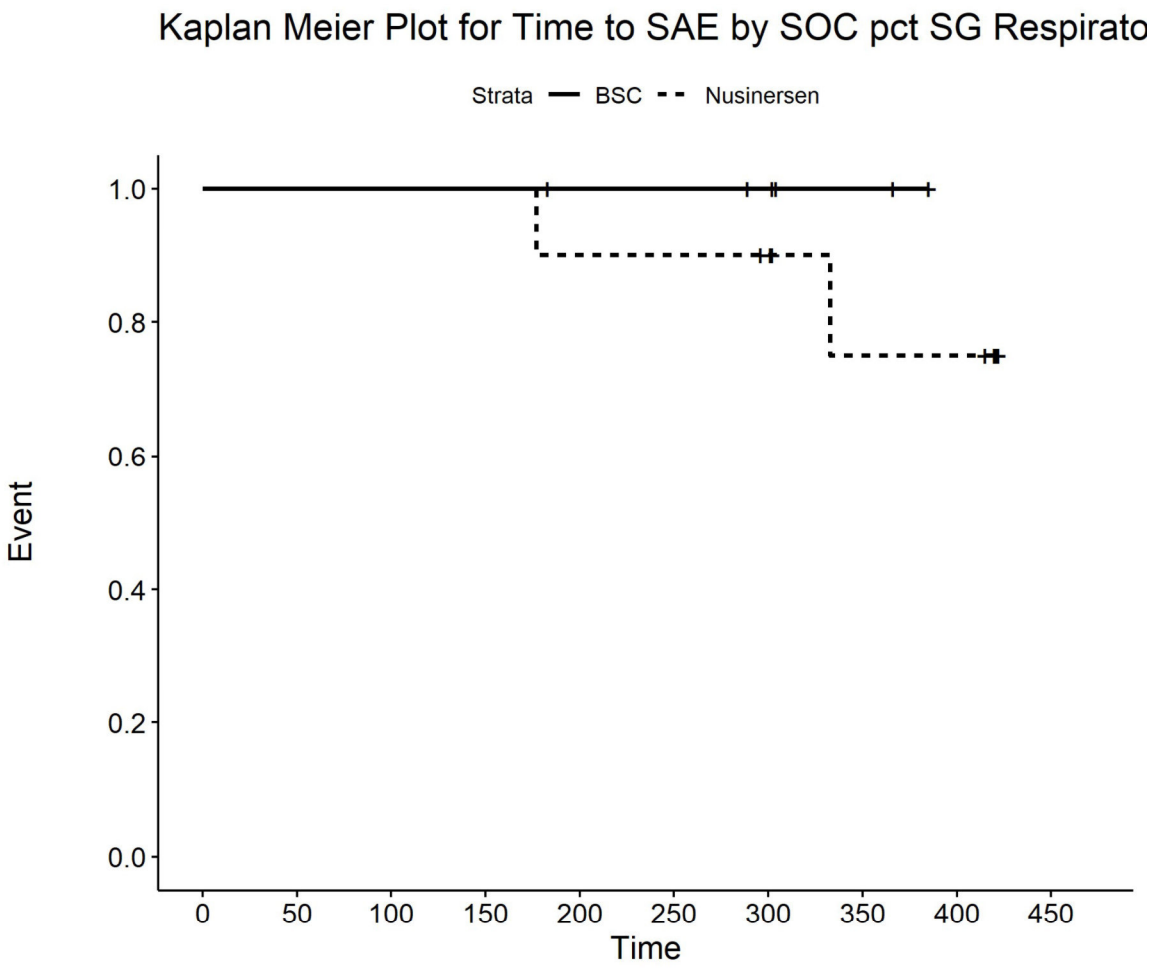
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	7	7	7	4	4	0



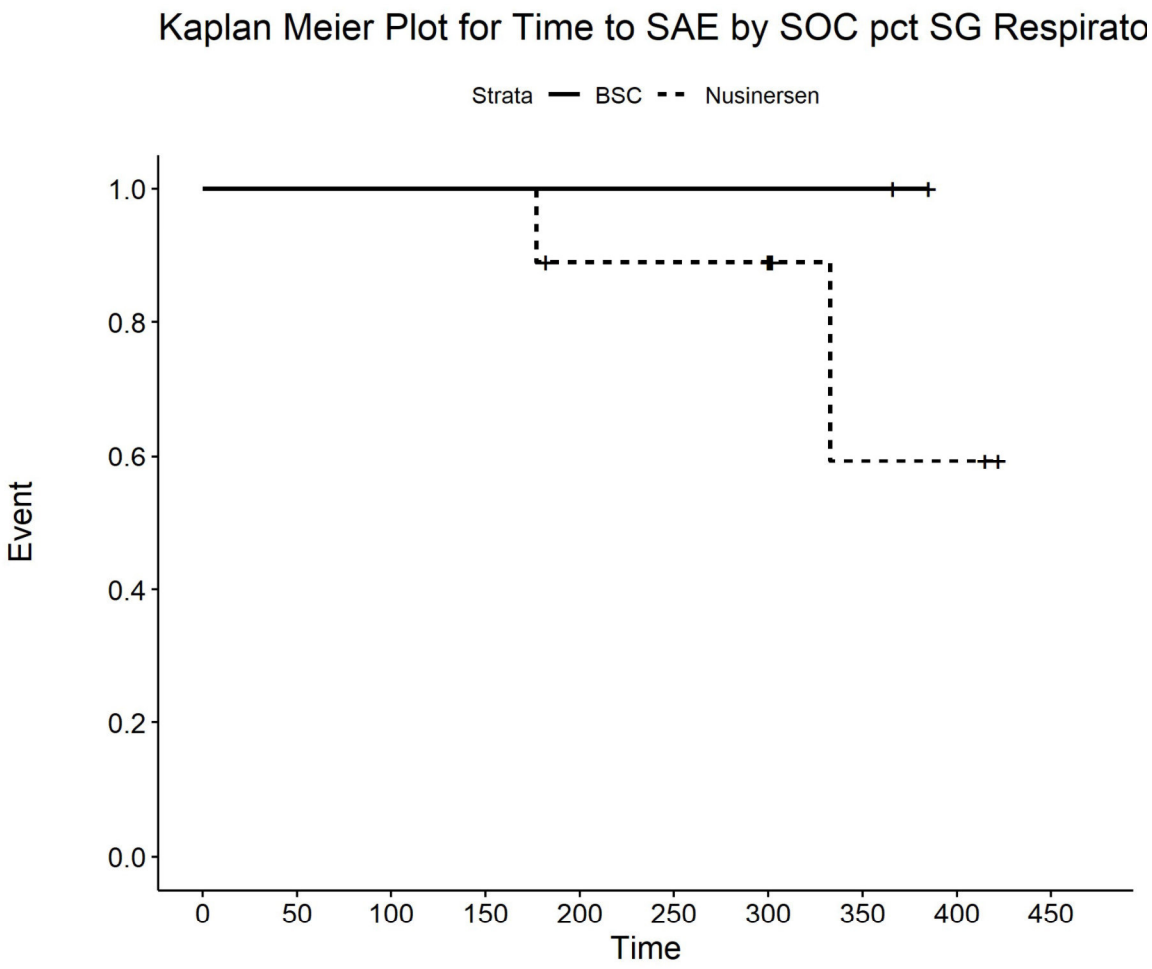
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	6	6	5	3	3	0



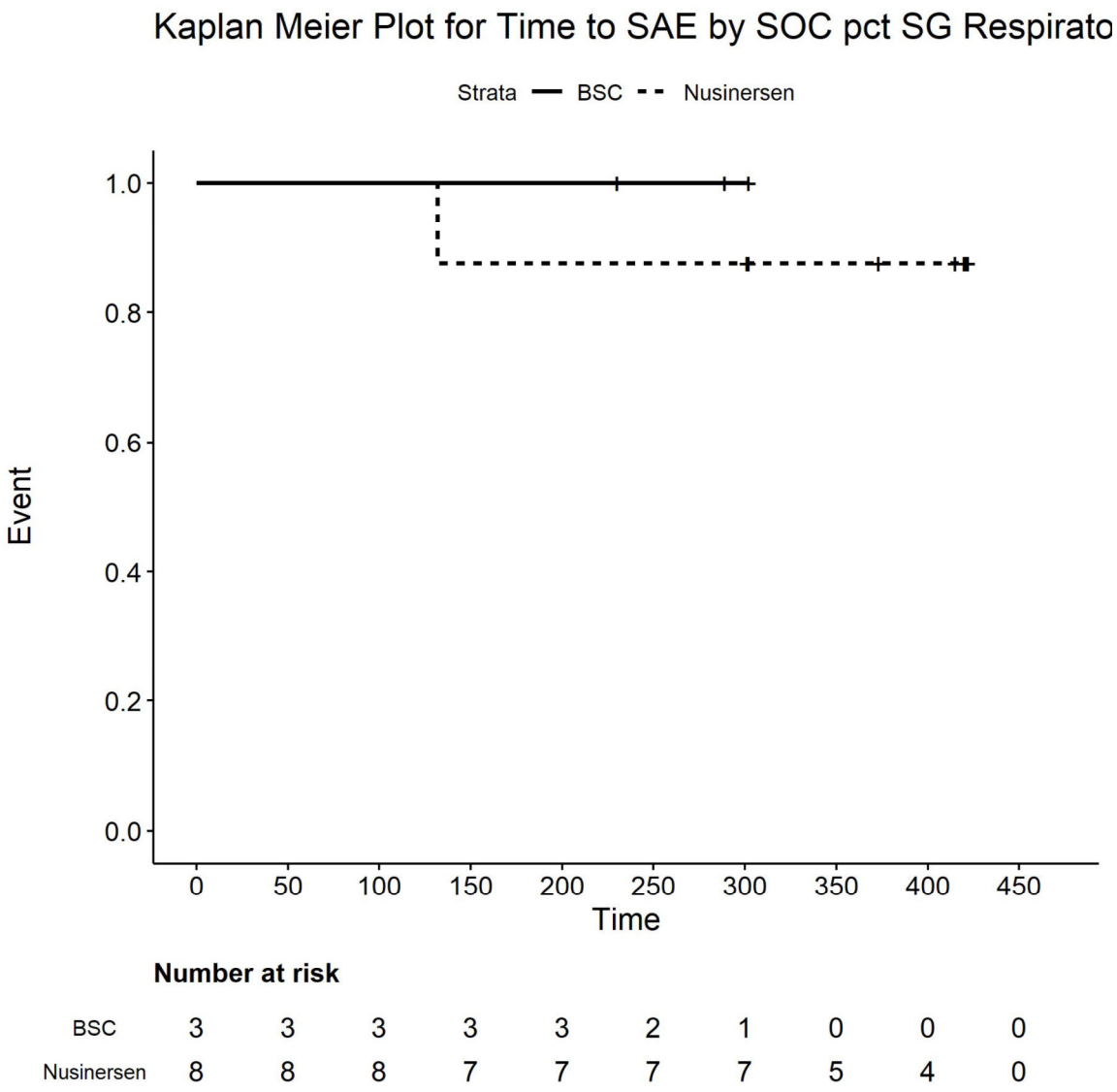
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	9	9	8	5	5	0



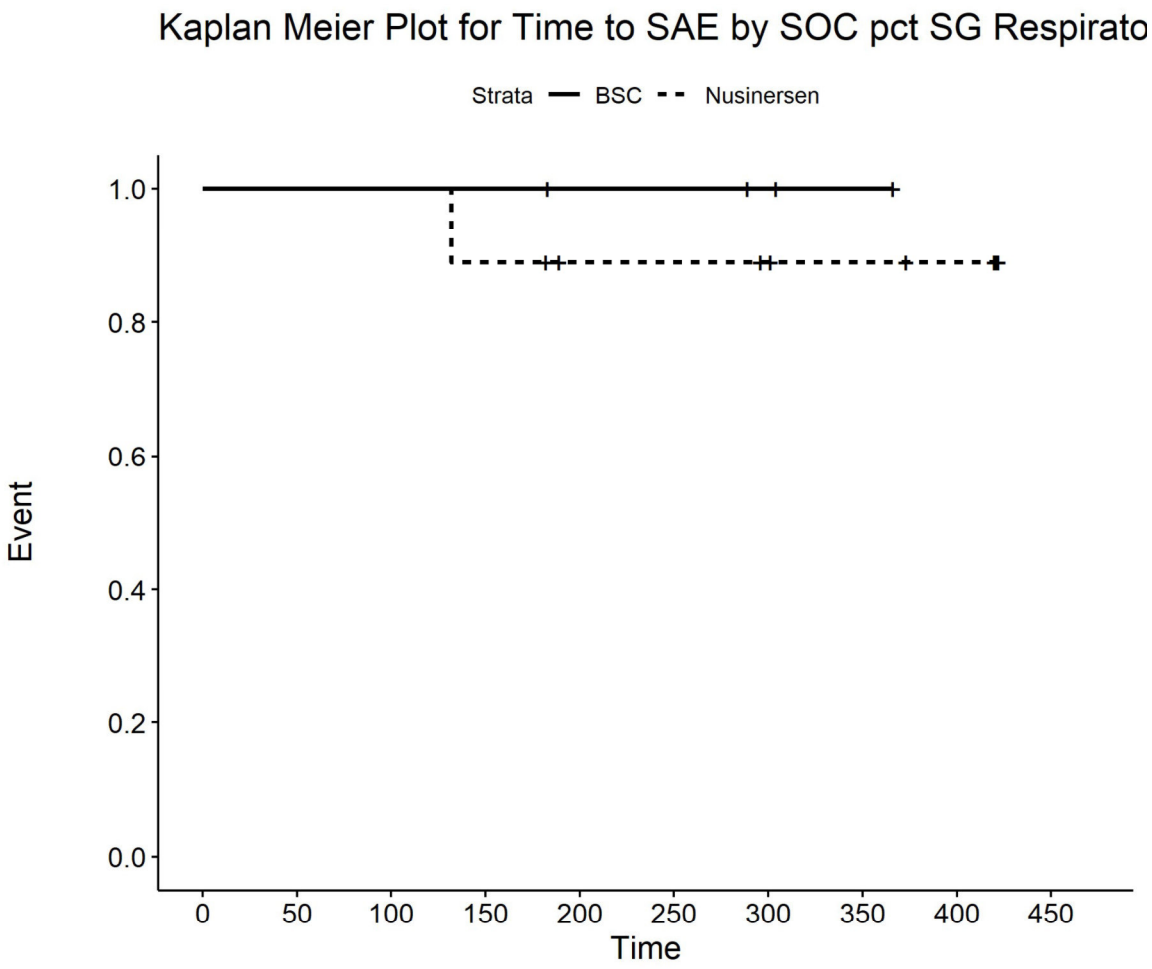
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	7	7	7	2	2	0



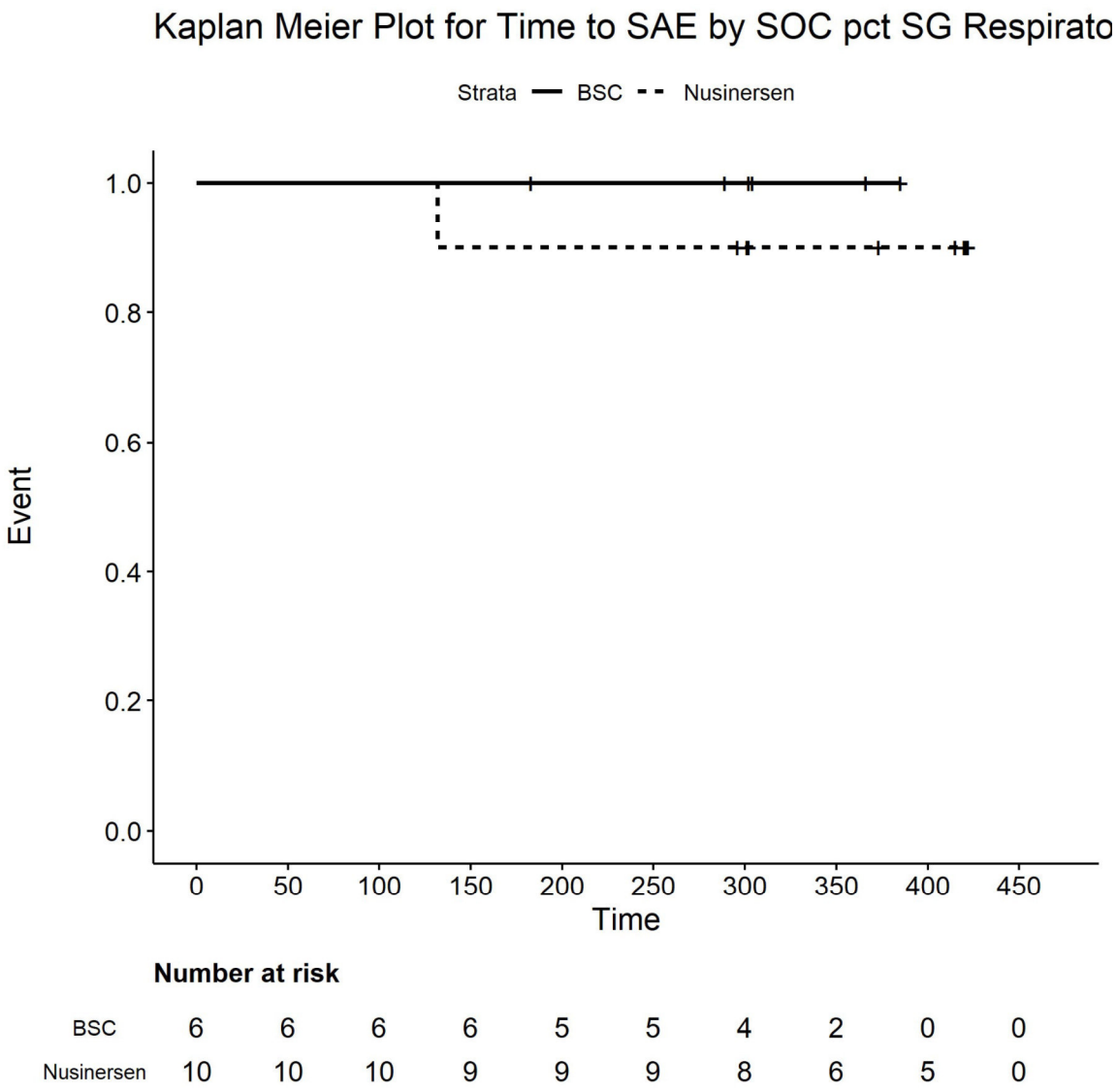
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



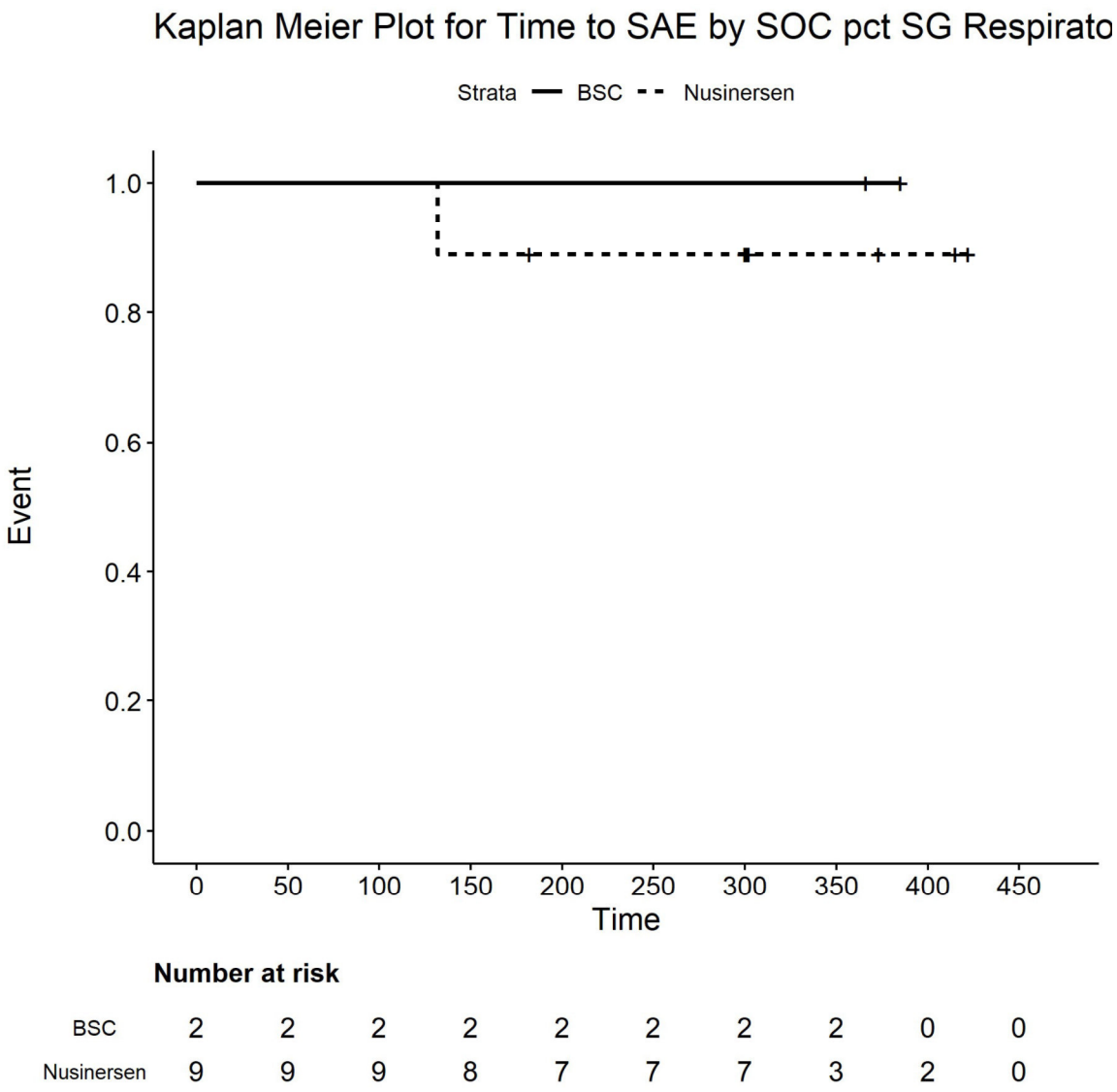
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



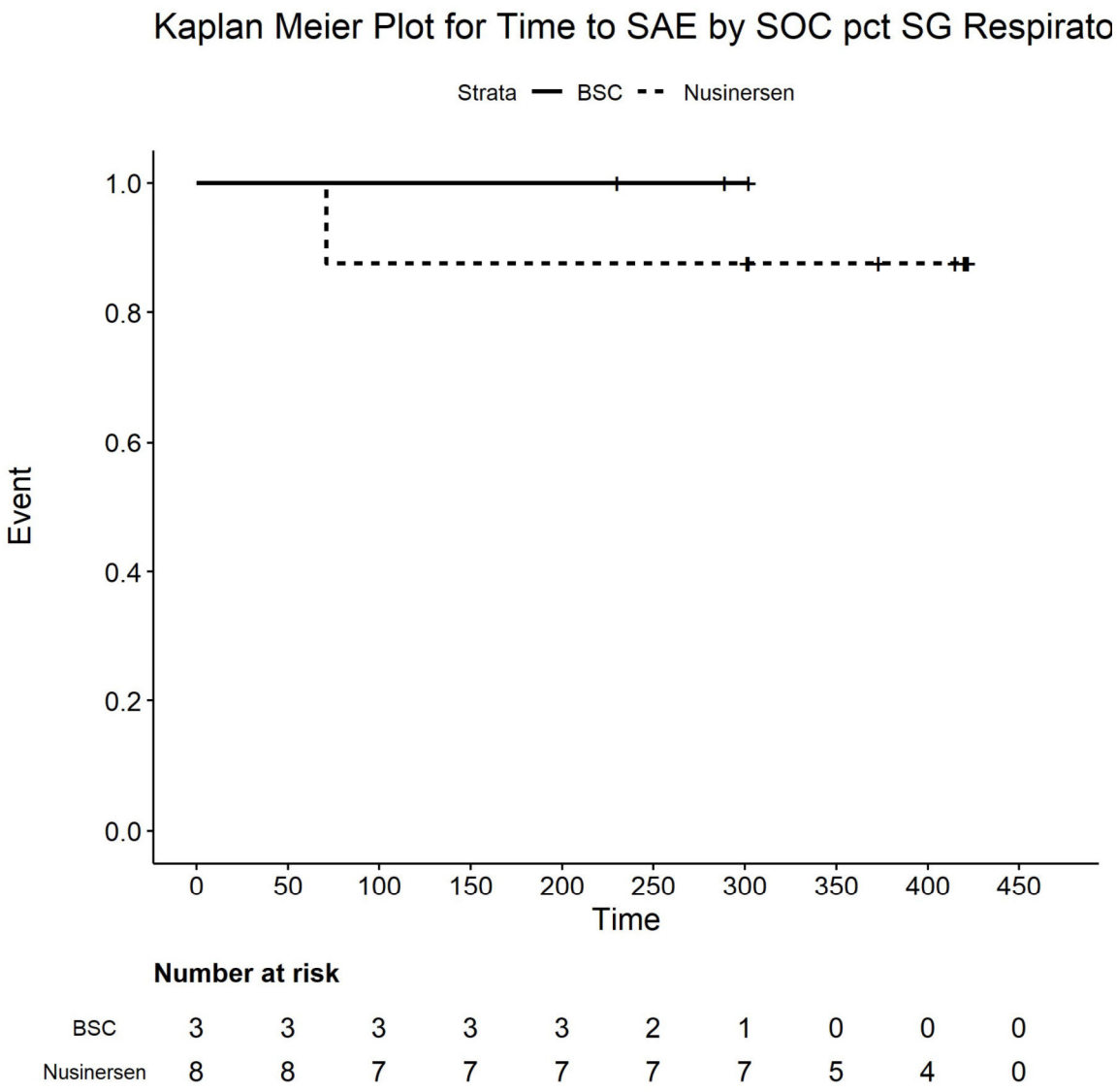
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



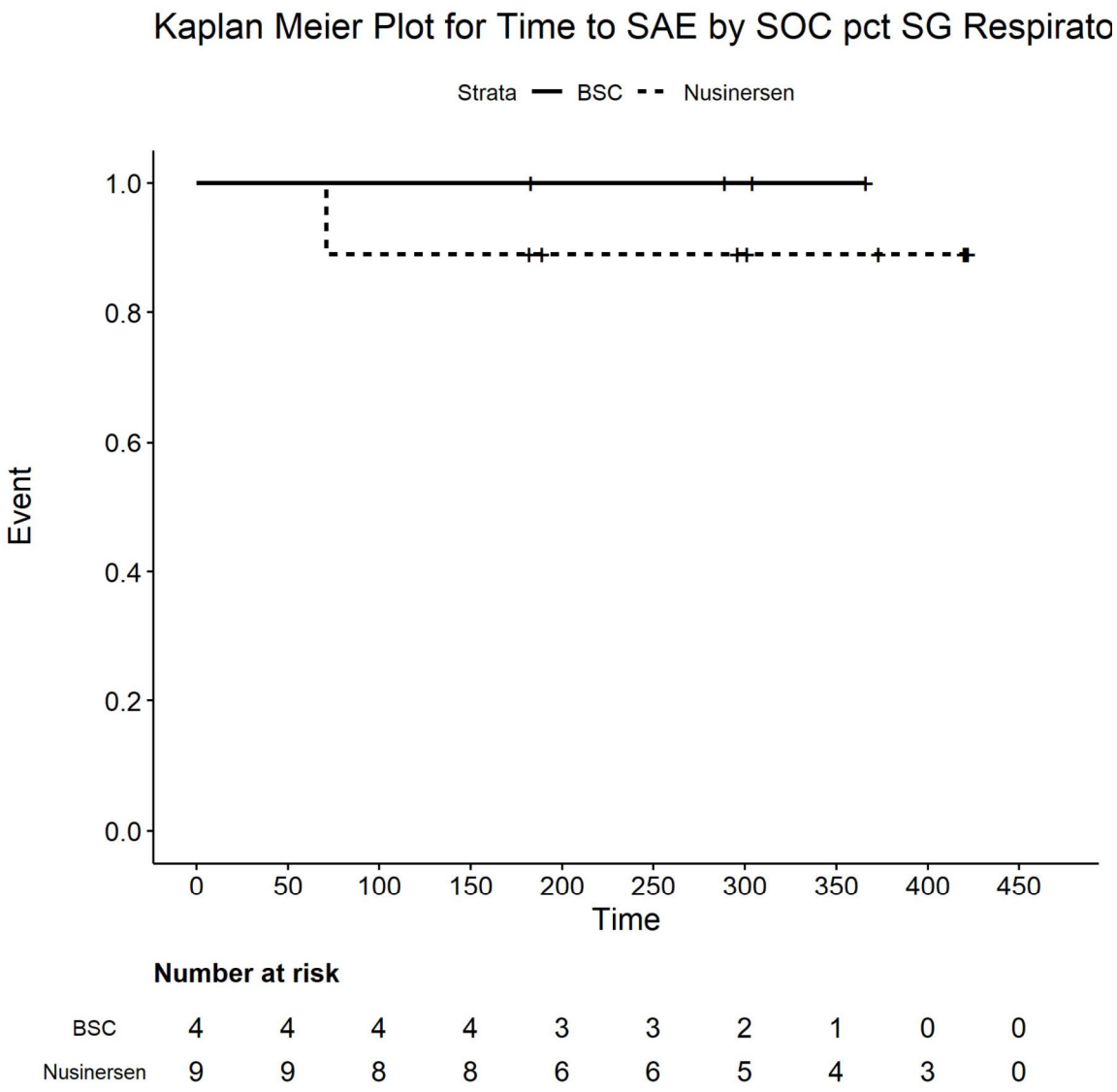
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



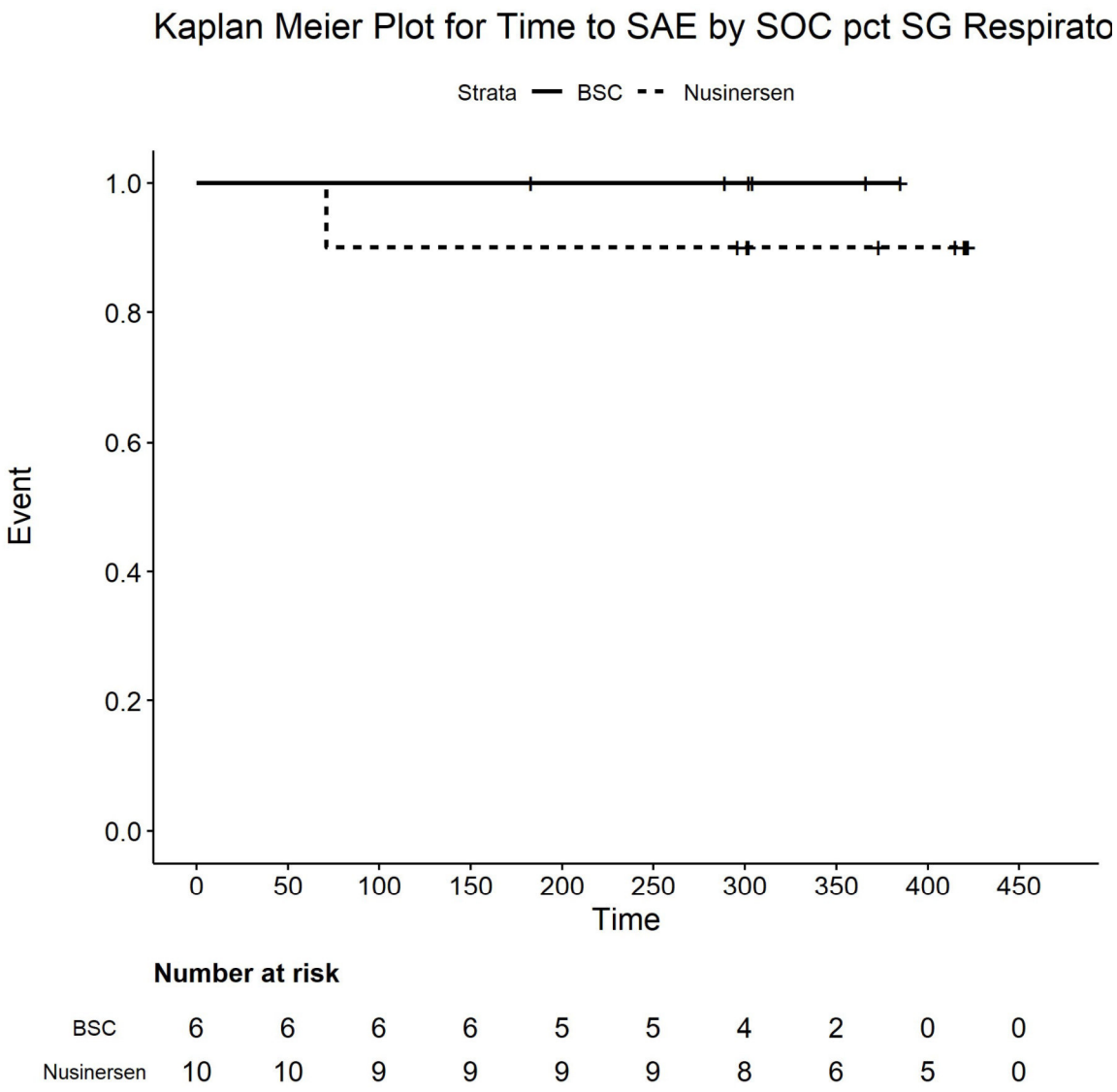
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	4	0



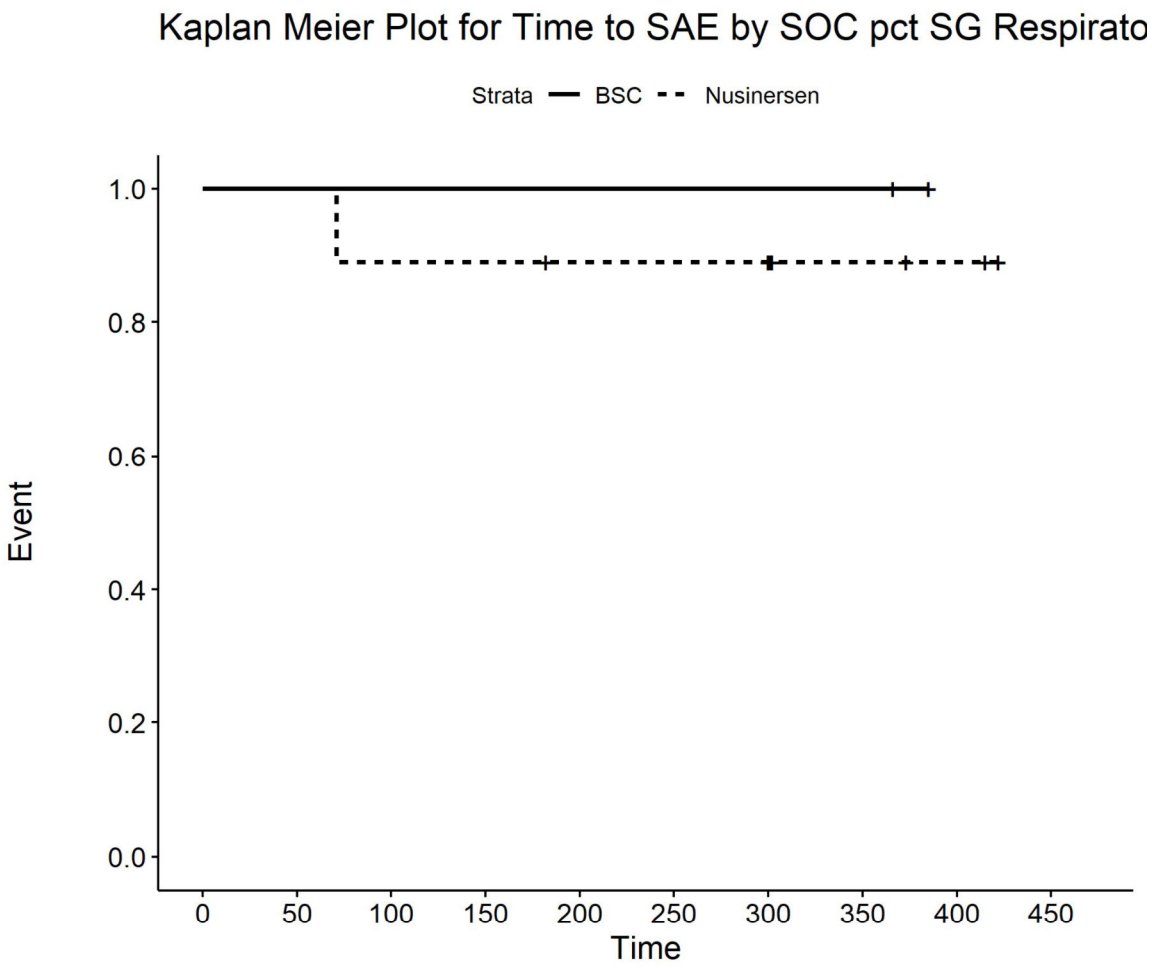
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



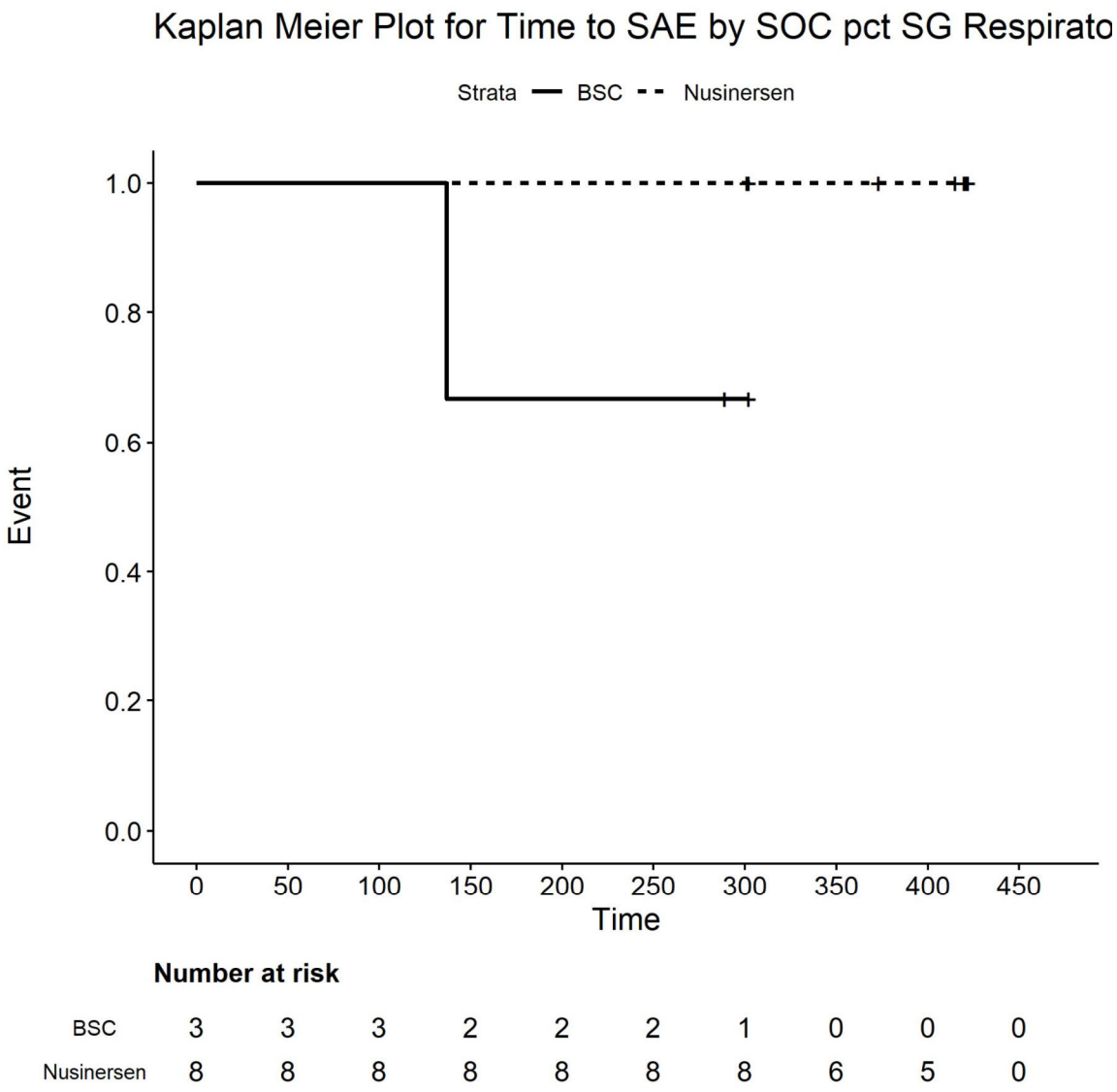
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



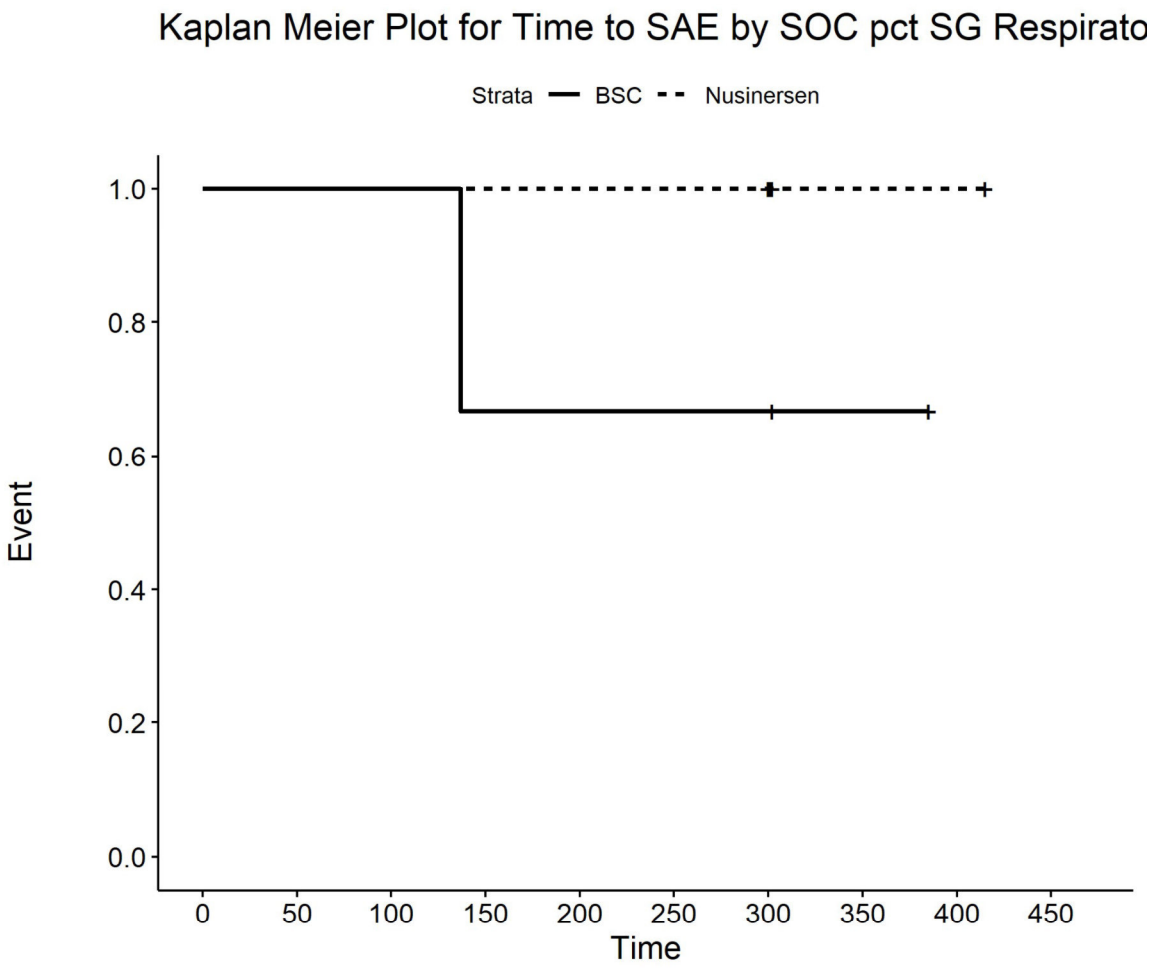
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	2	0



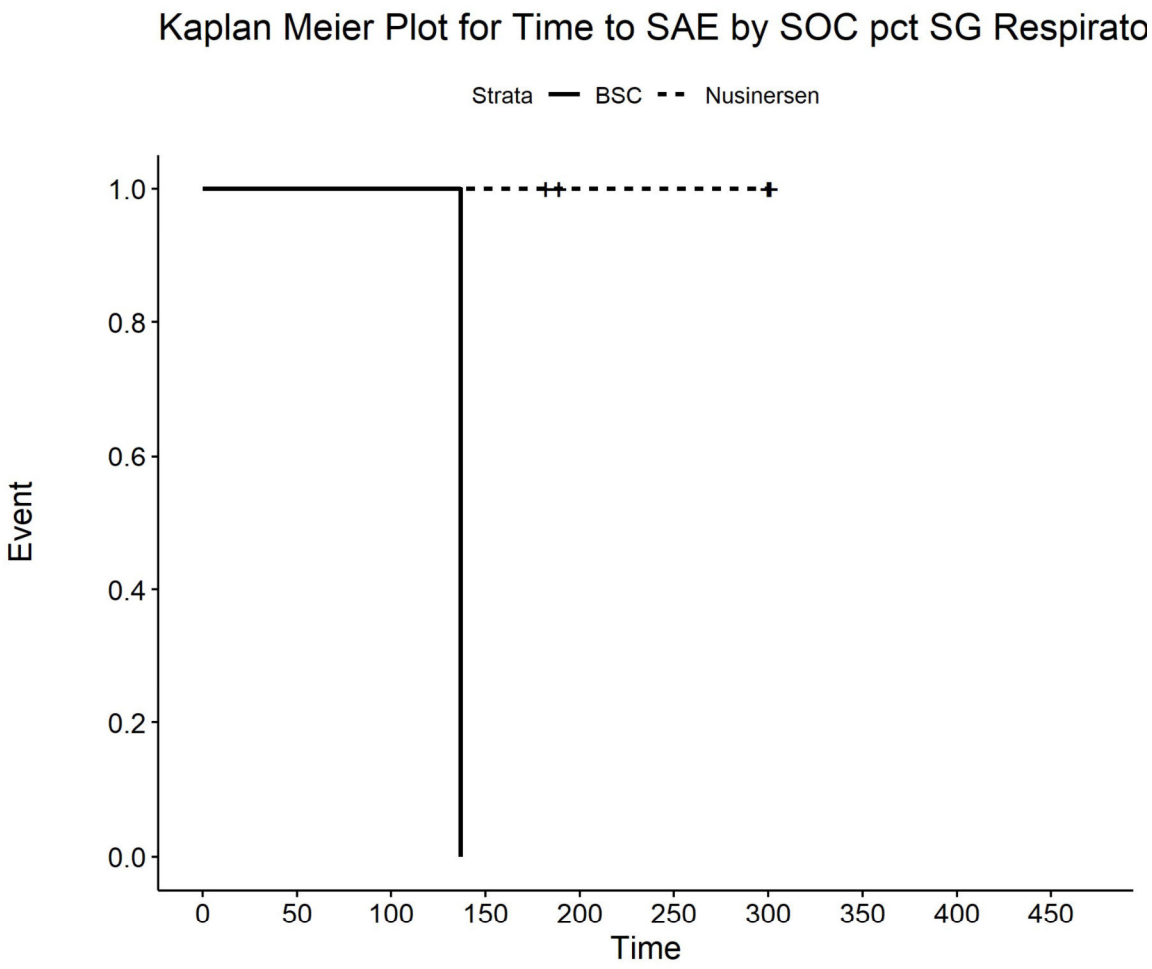
Number at risk

BSC	3	3	3	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



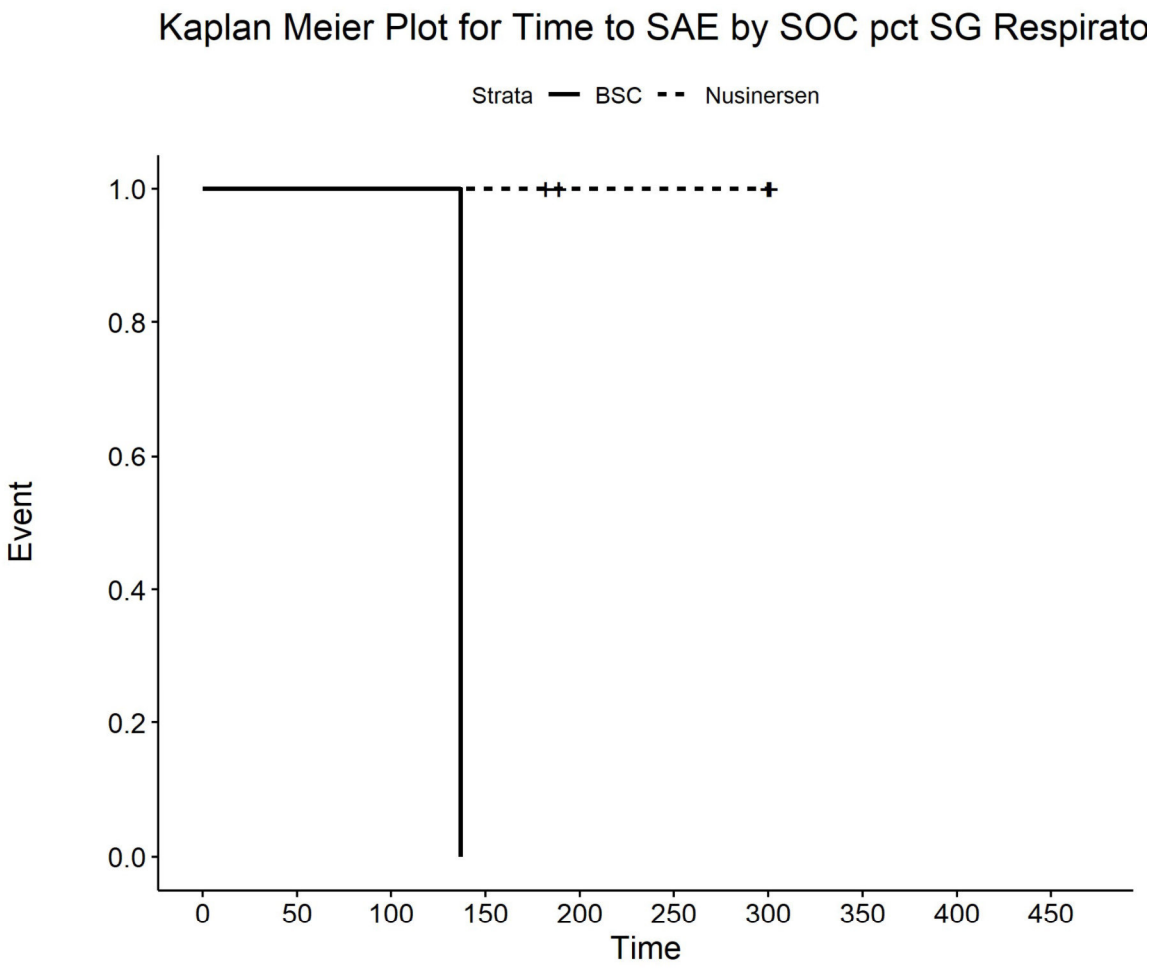
Number at risk

BSC	3	3	3	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



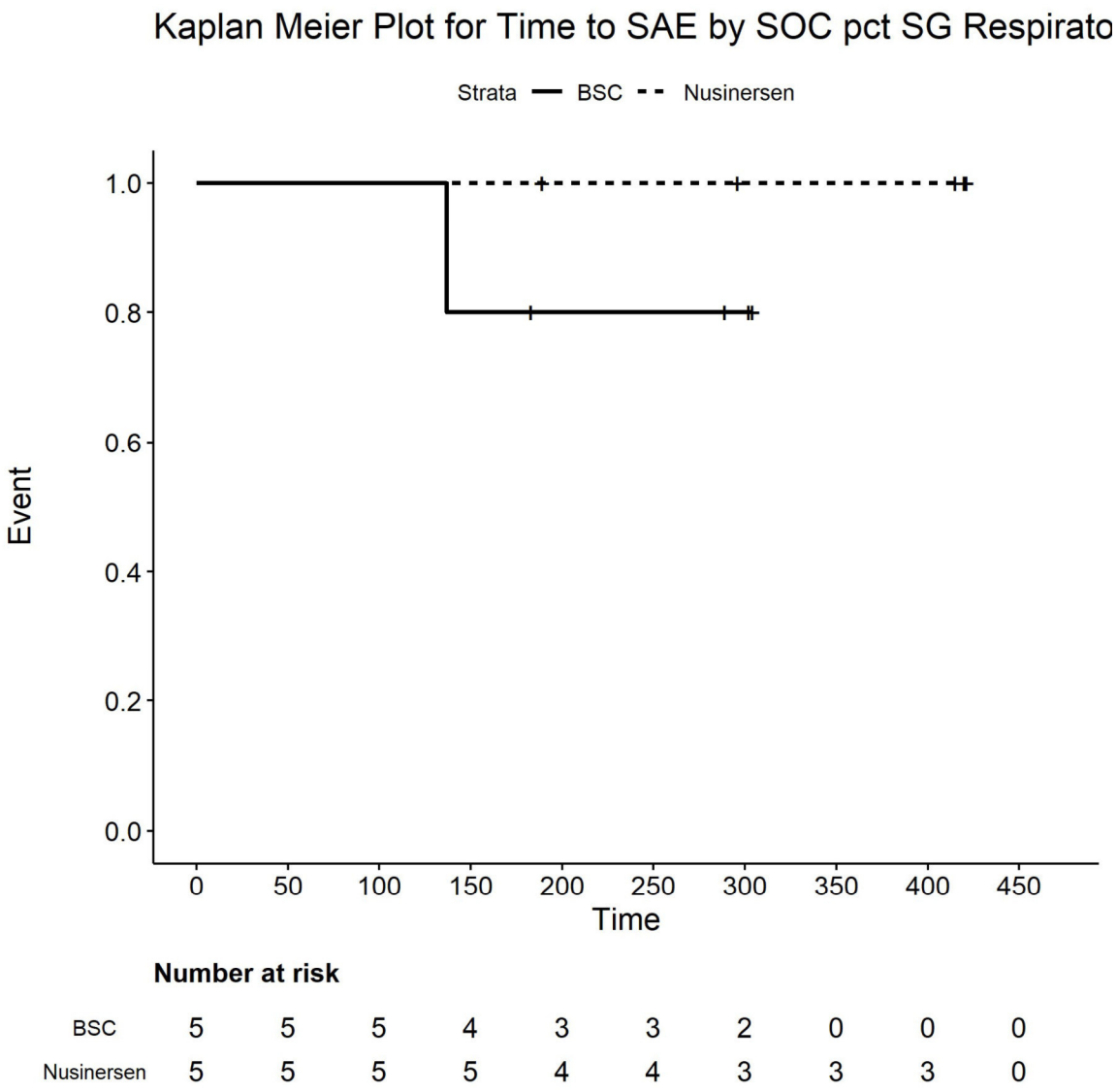
Number at risk

BSC	1	1	1	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



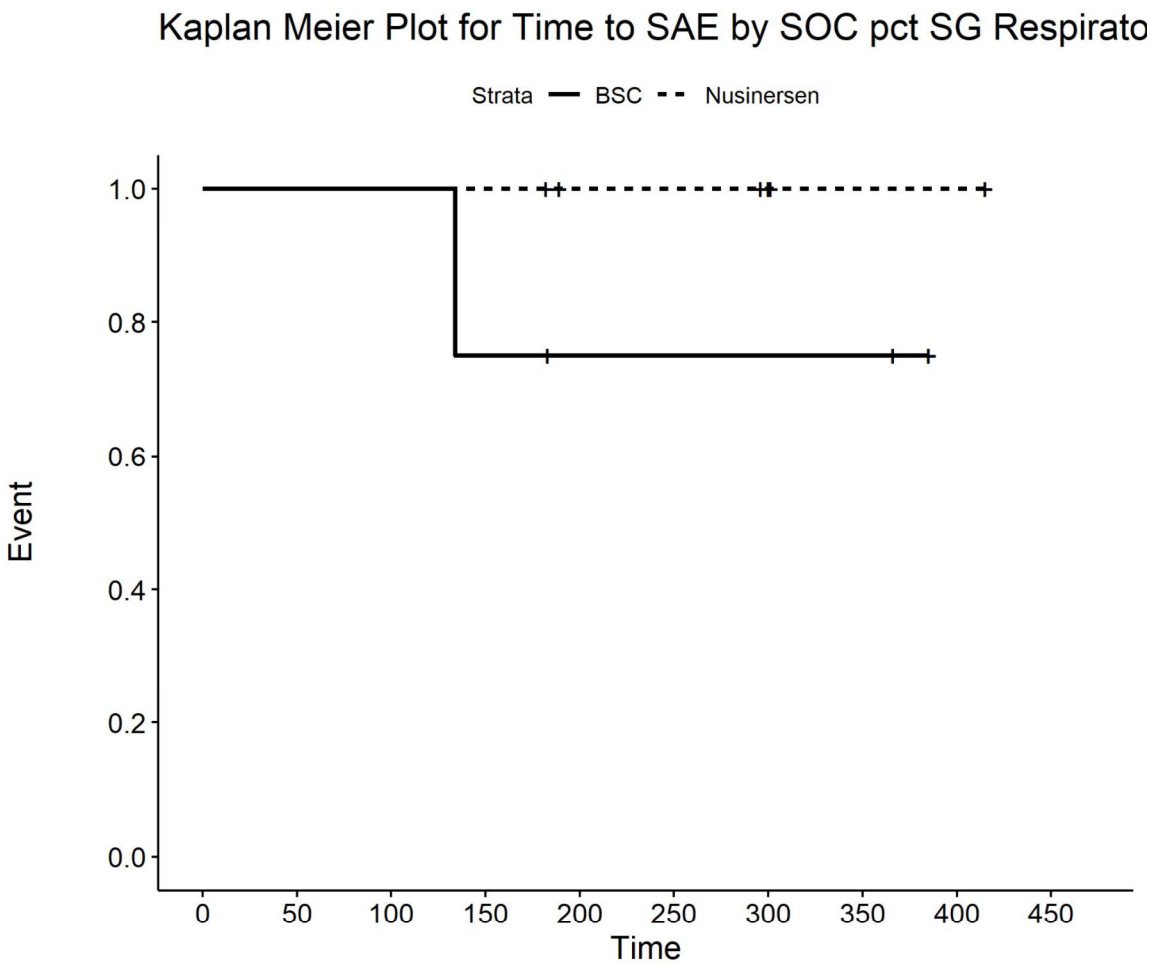
Number at risk

BSC	1	1	1	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



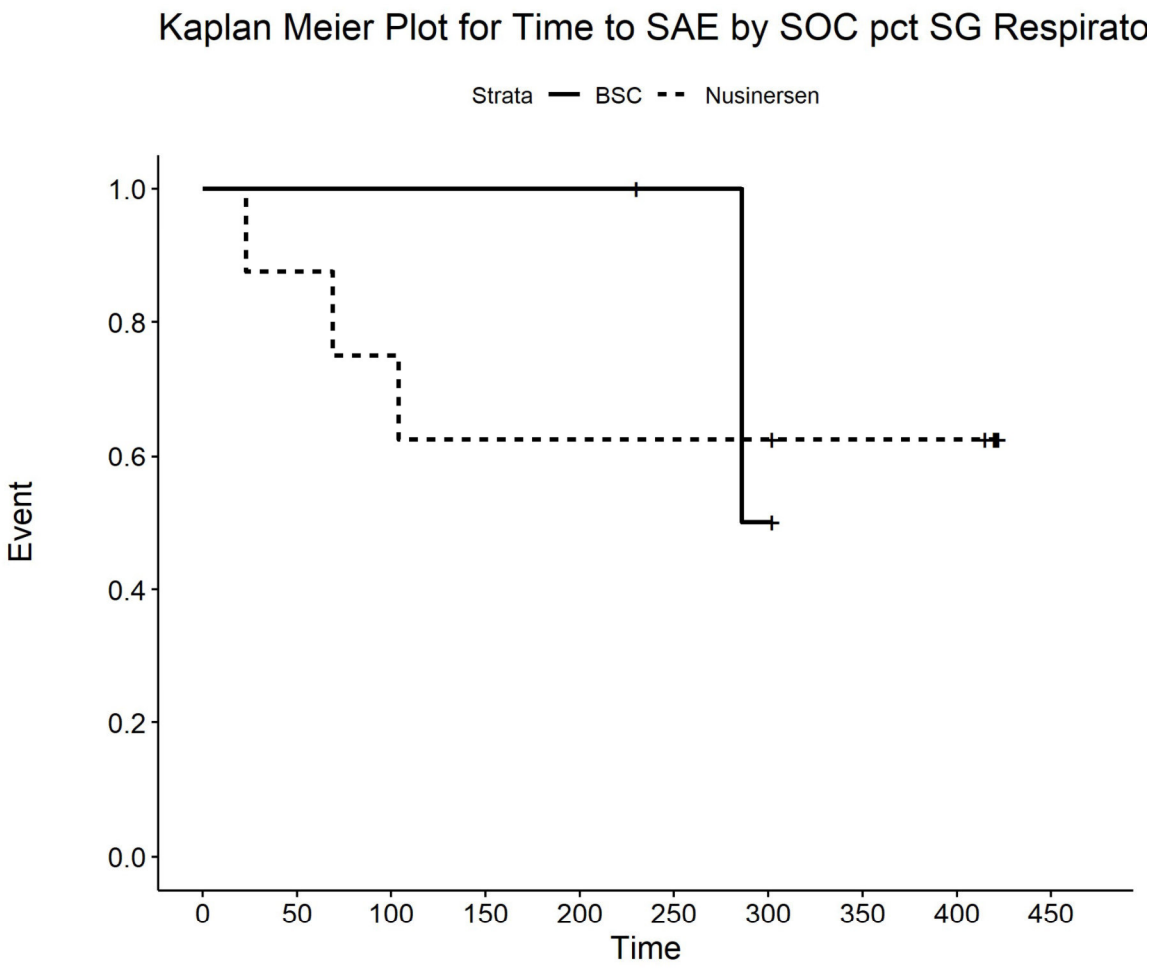
Number at risk

BSC	5	5	5	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



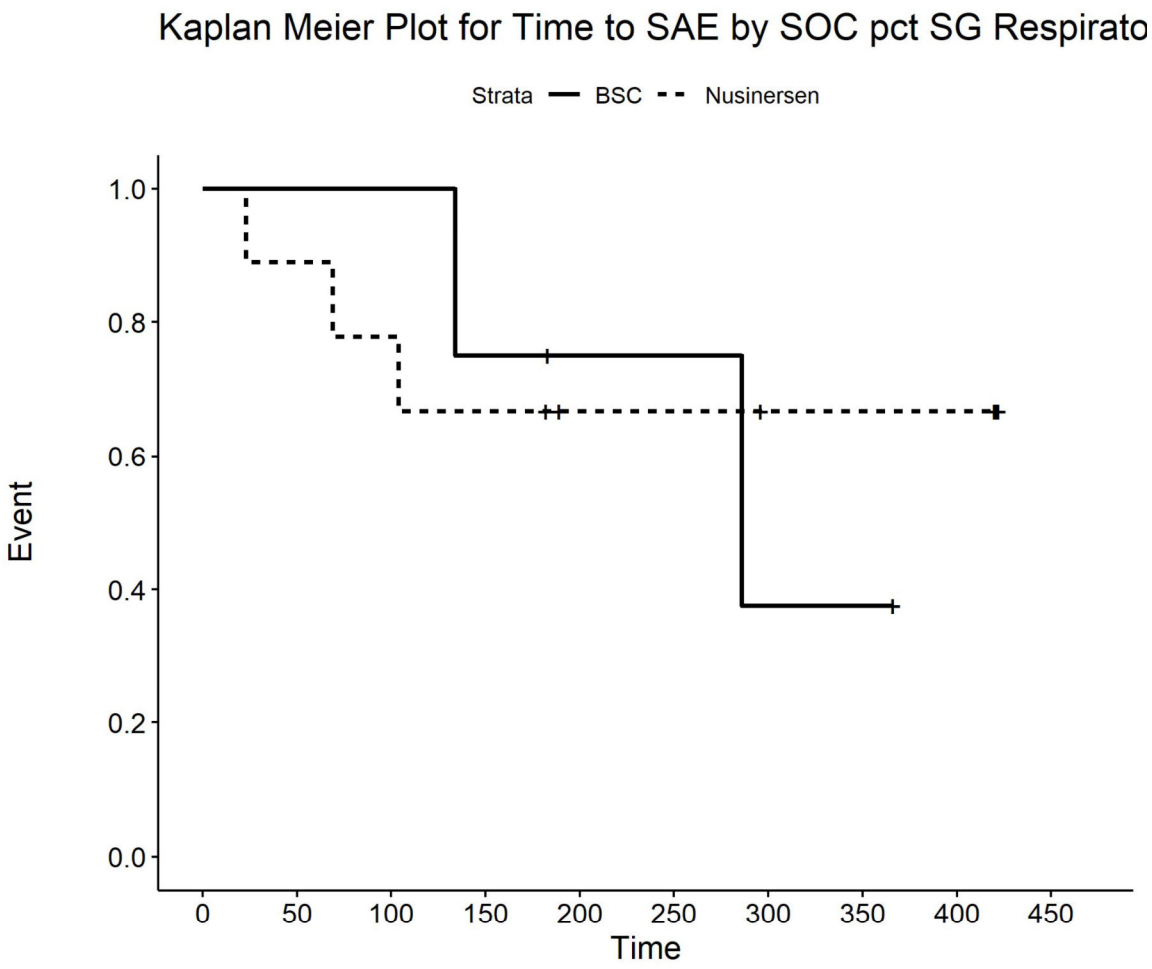
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



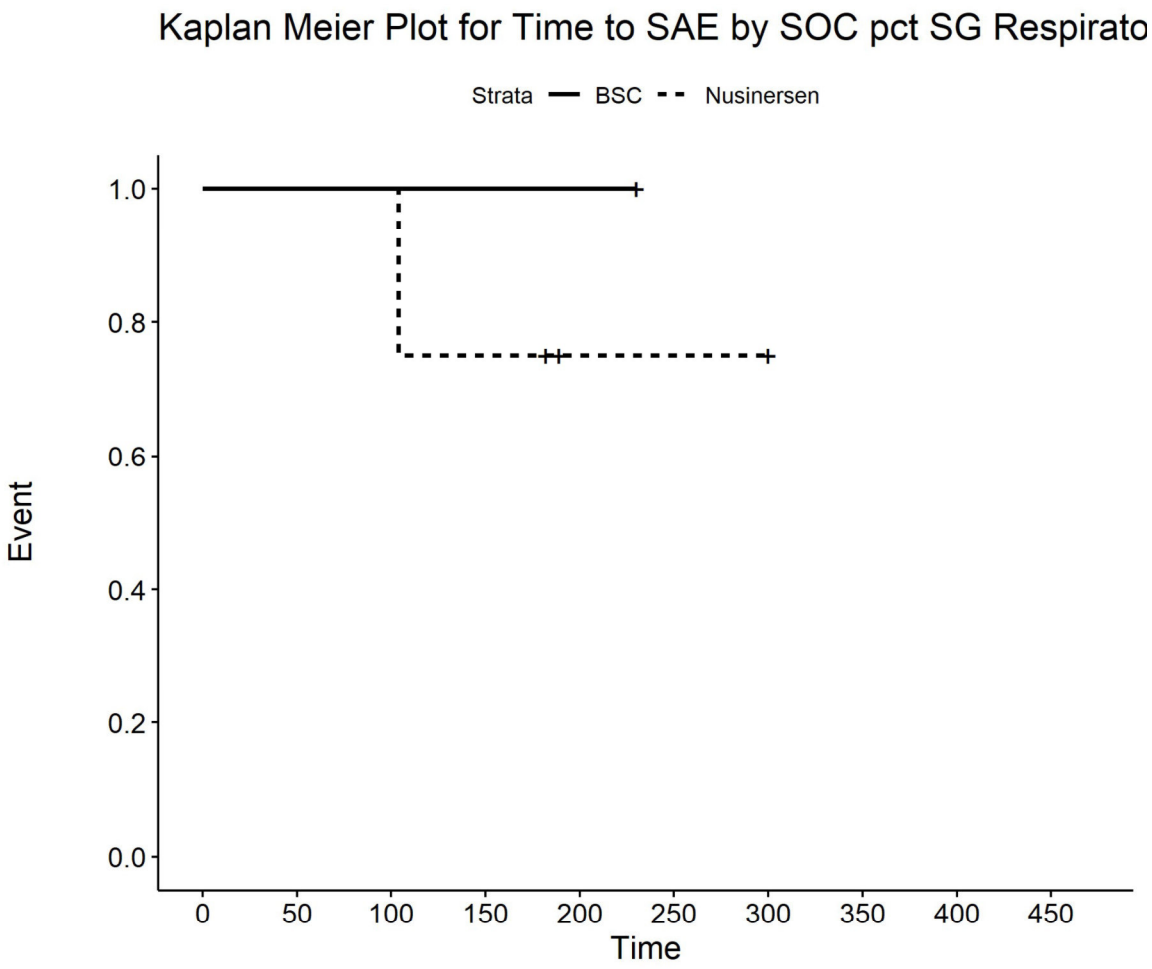
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	6	5	5	5	5	4	4	0



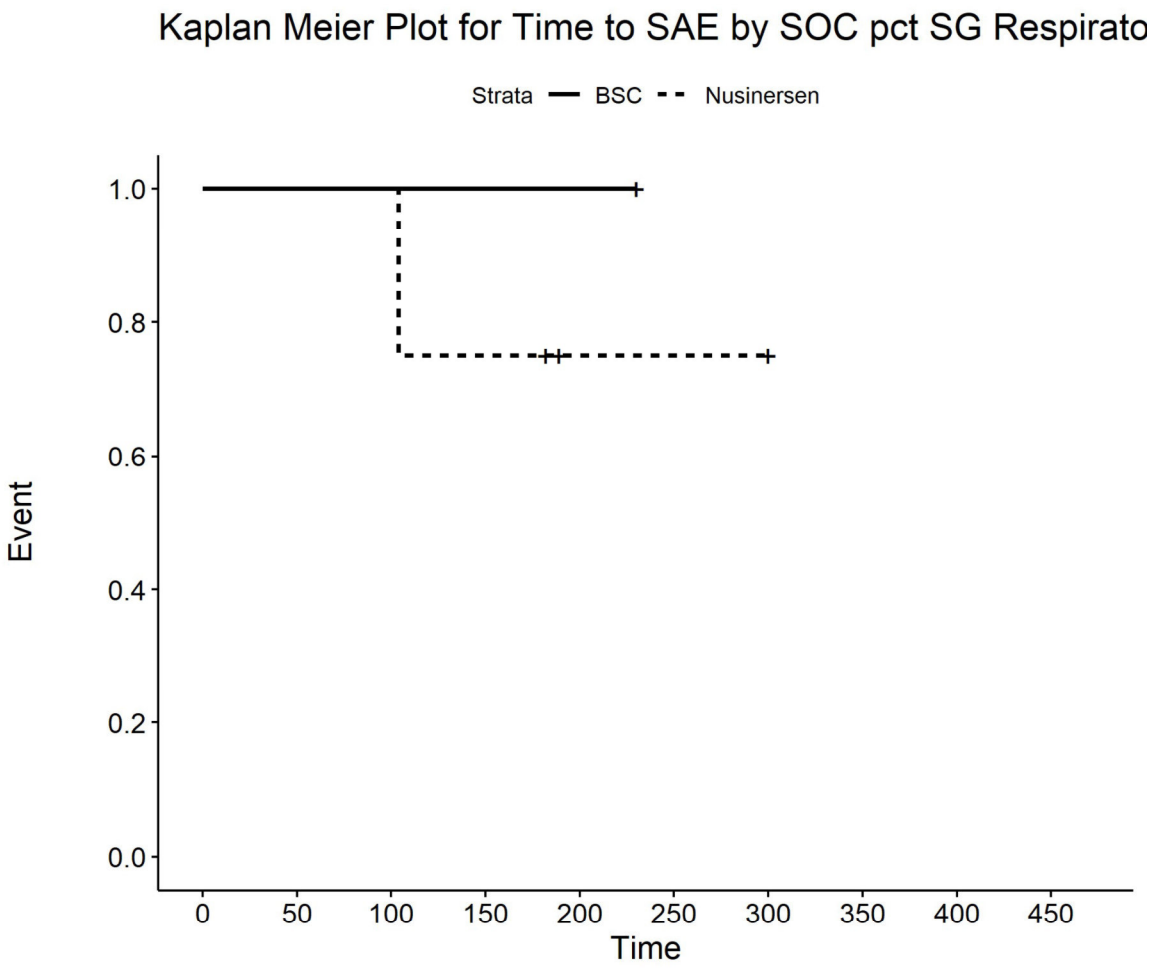
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	8	7	6	4	4	3	3	3	0



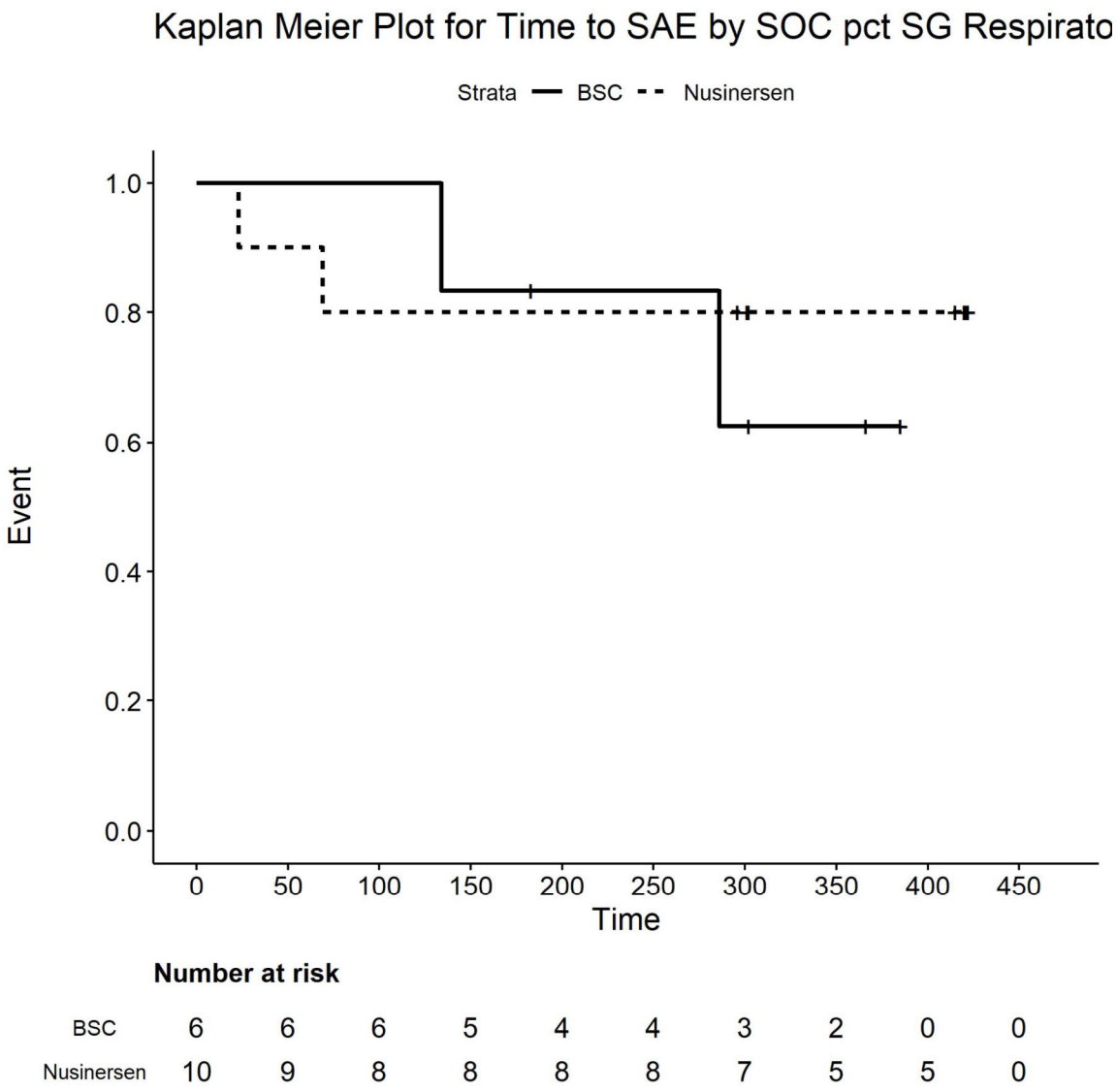
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



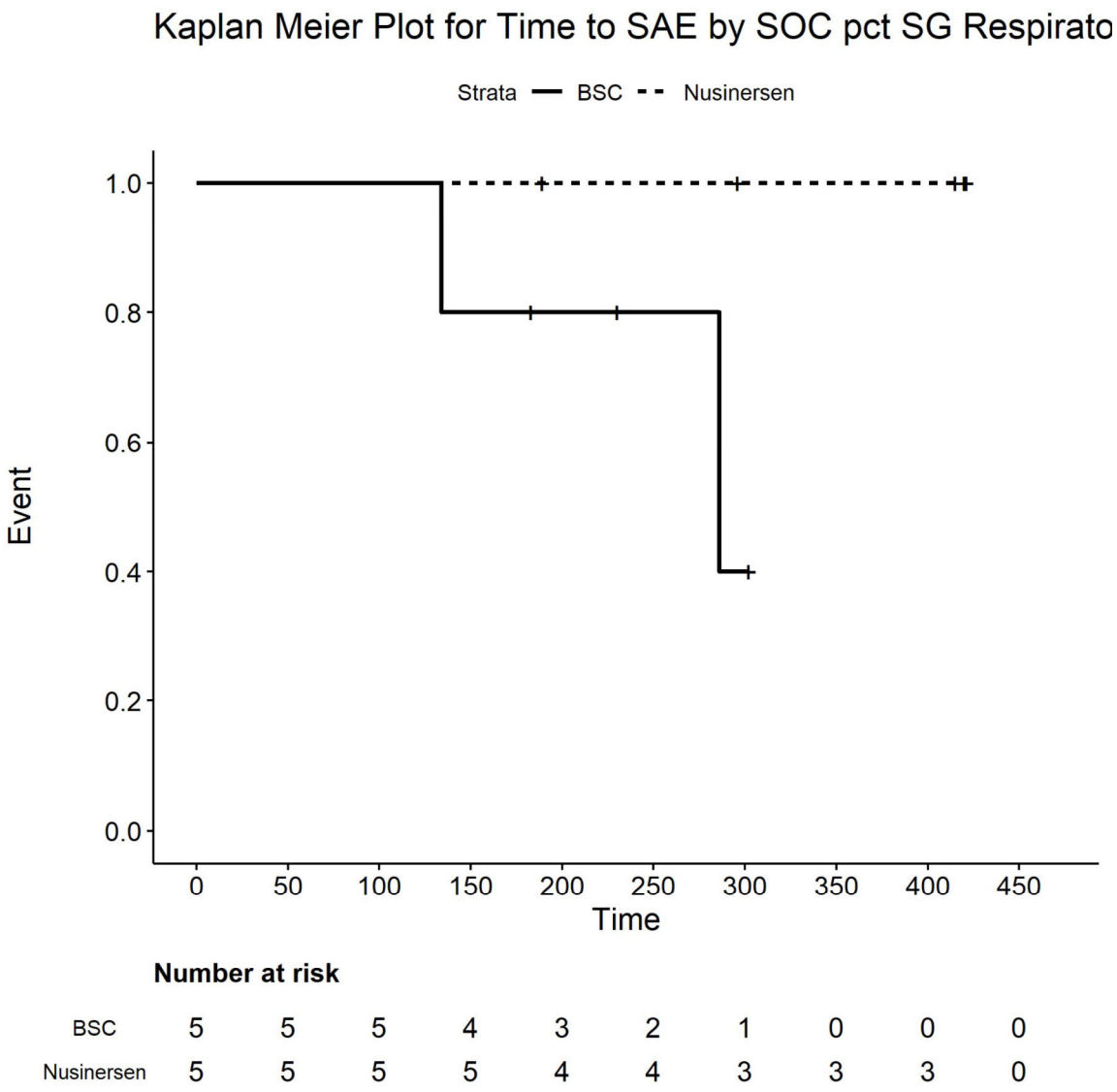
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



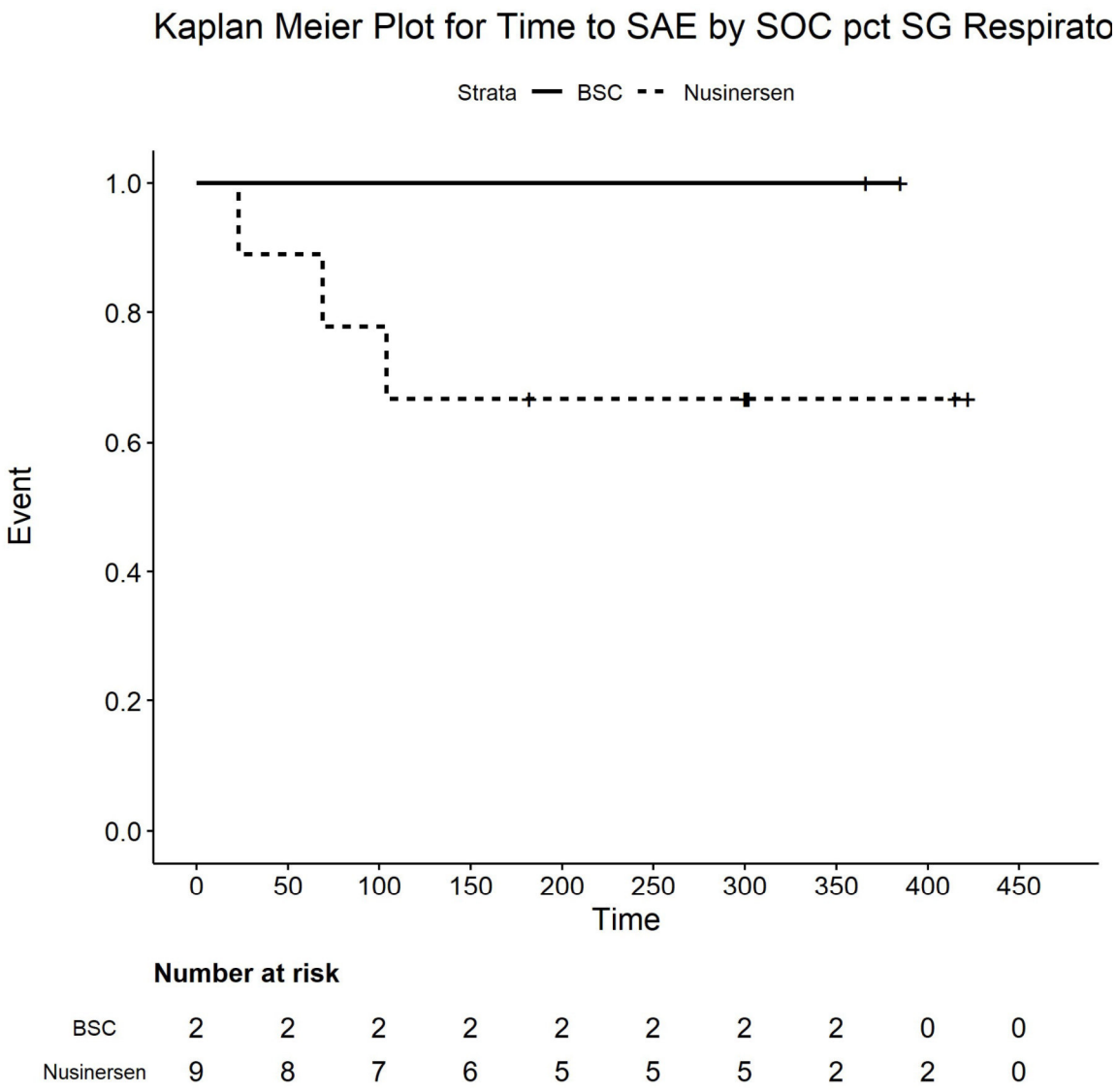
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	9	8	8	8	8	7	5	5	0



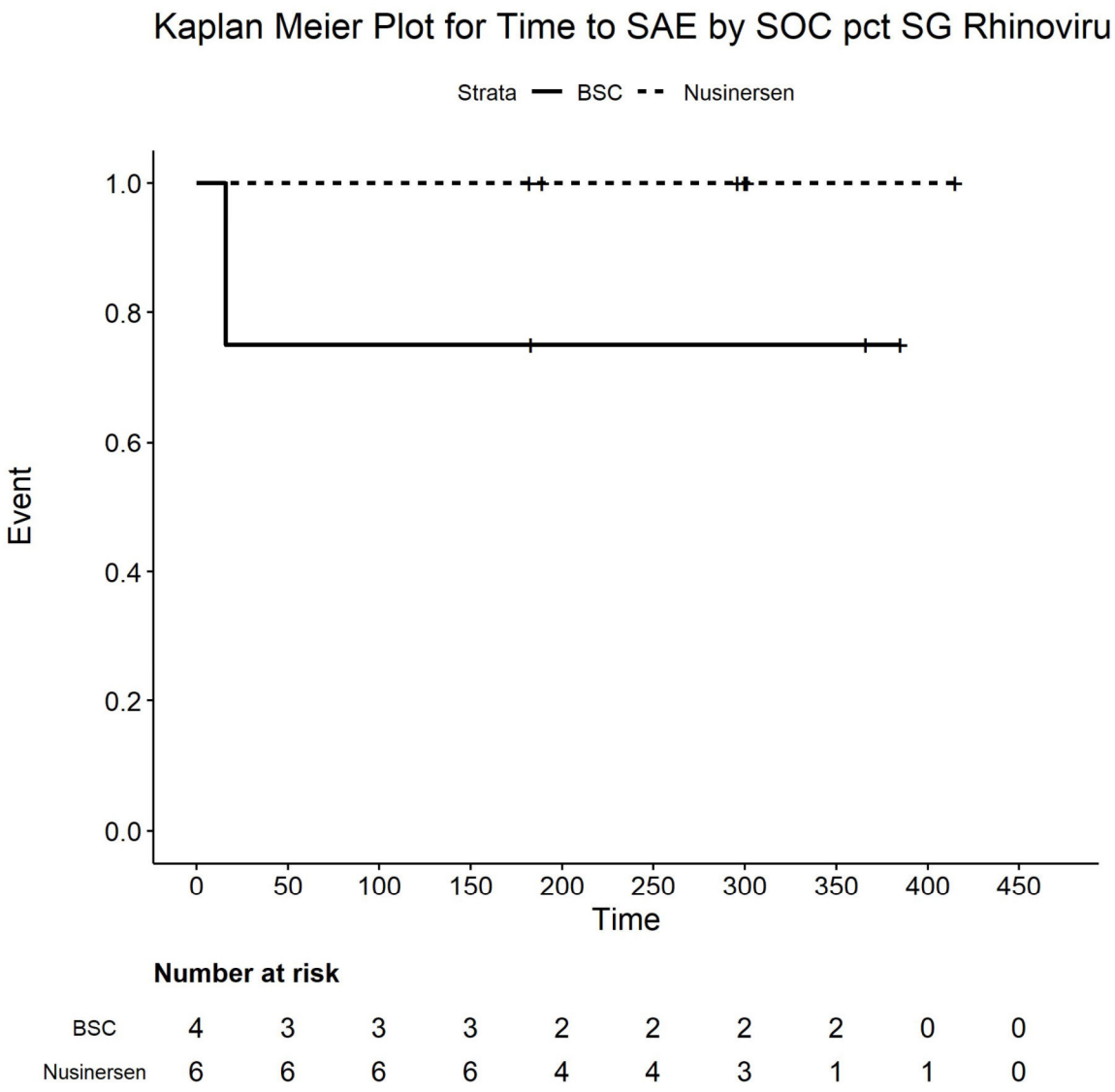
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



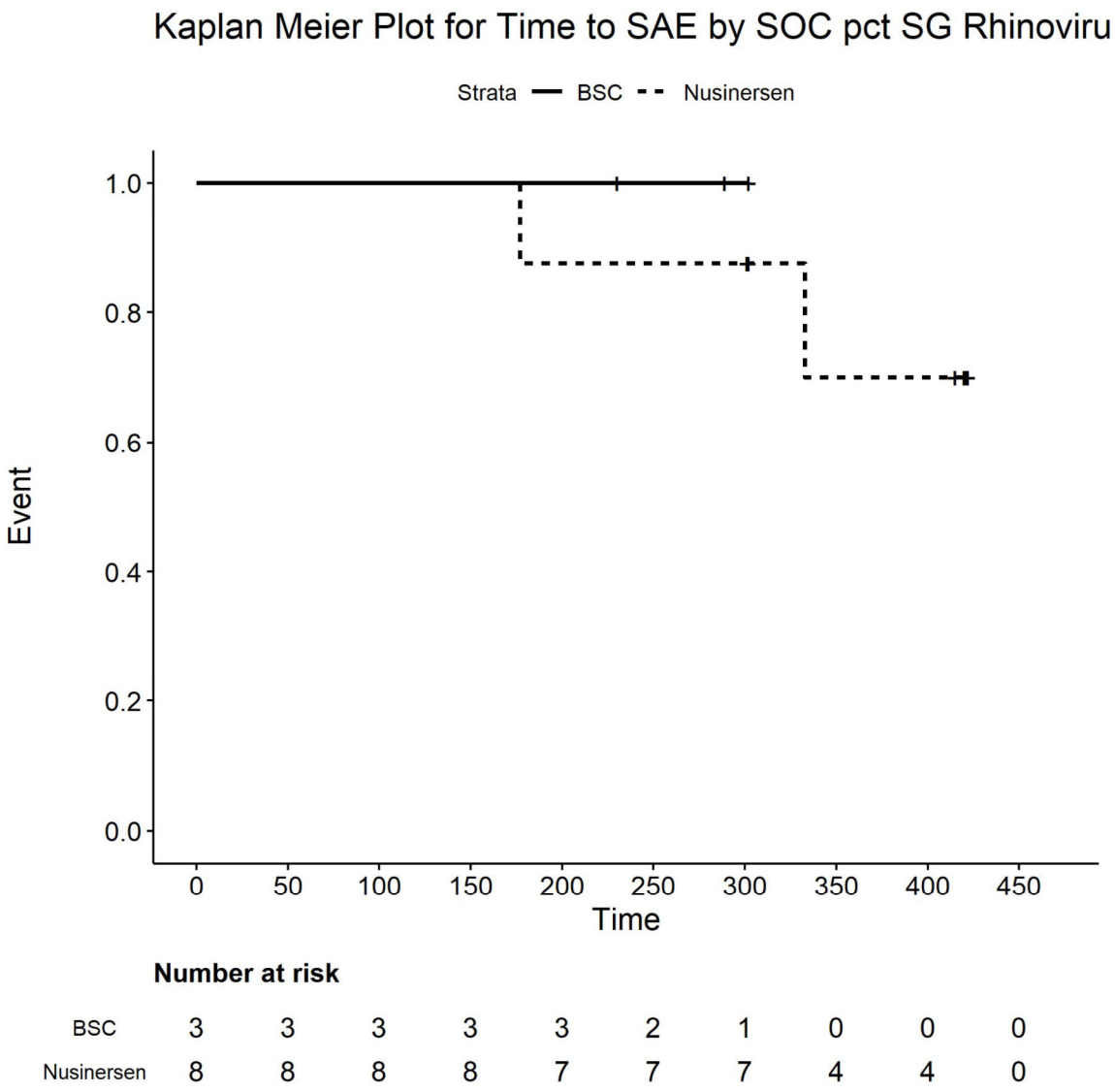
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	7	6	5	5	5	2	2	0



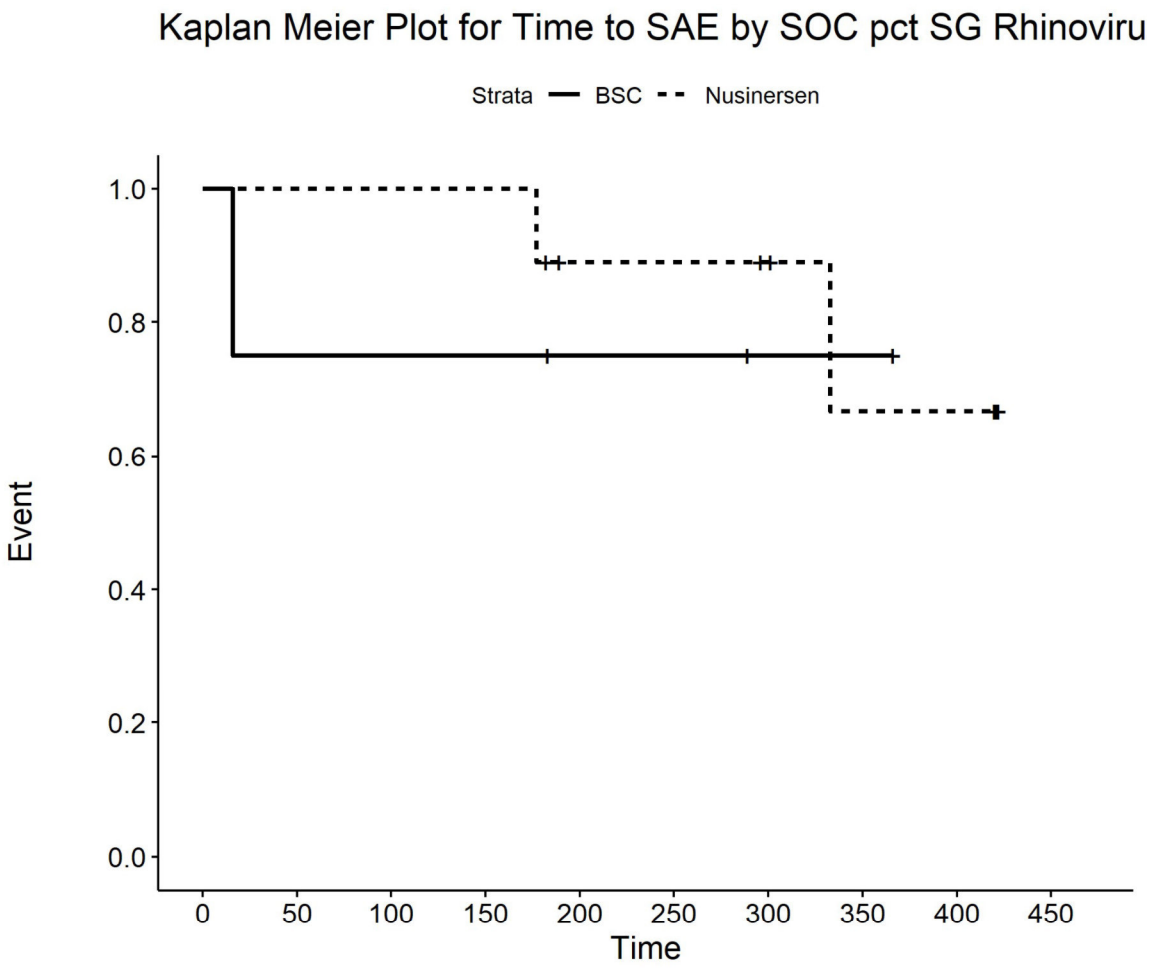
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



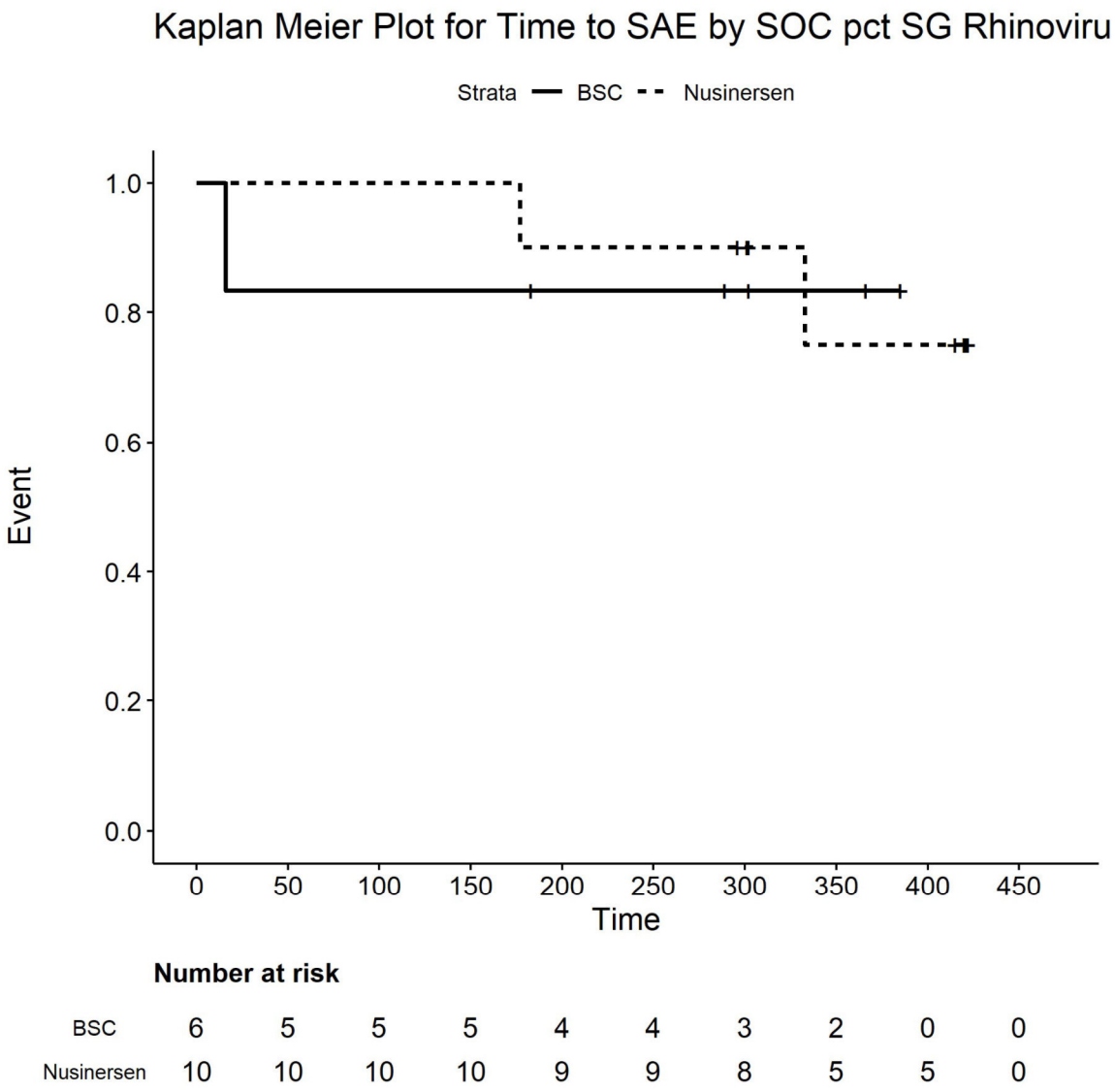
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	7	7	7	4	4	0



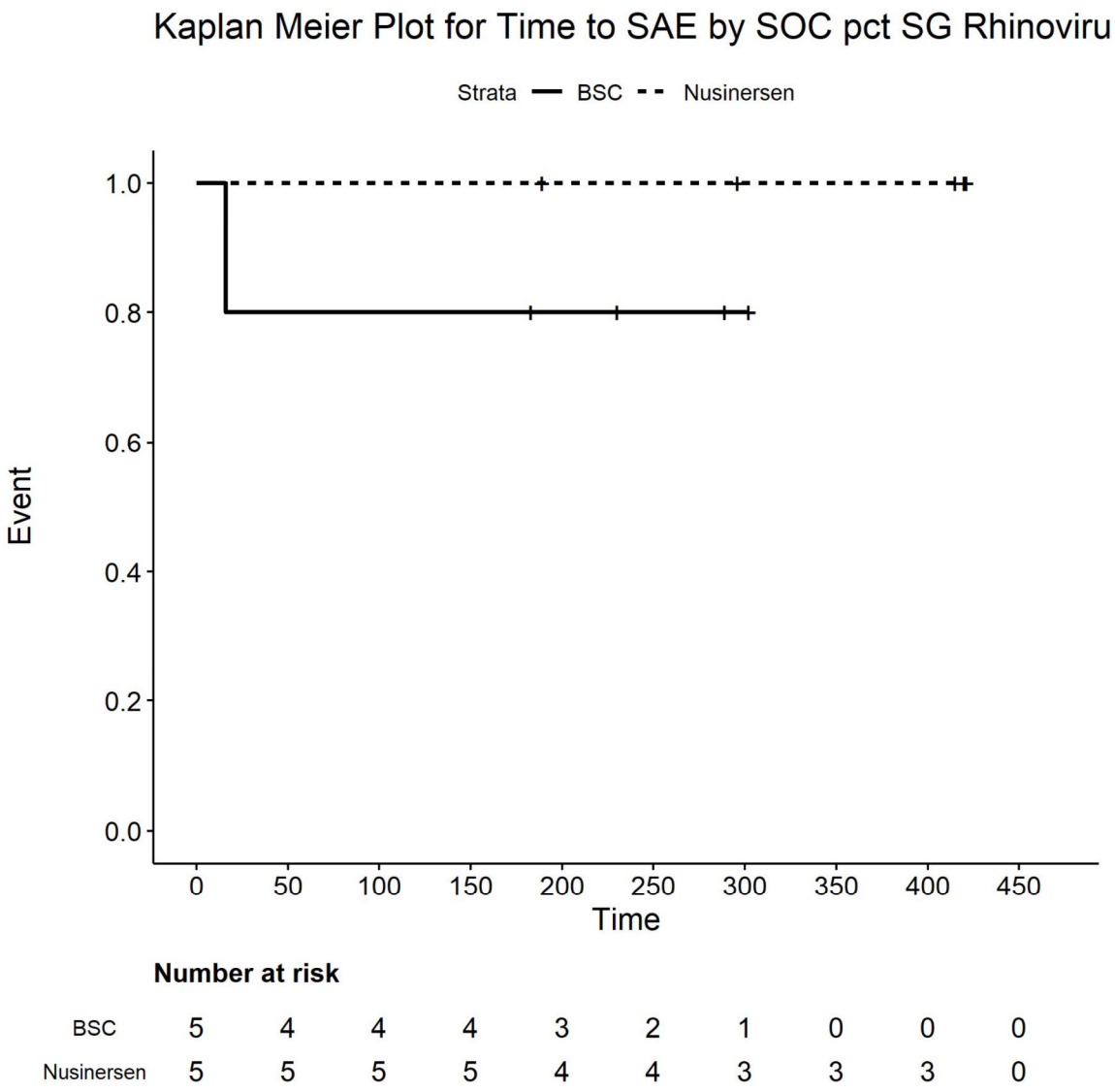
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	6	6	5	3	3	0



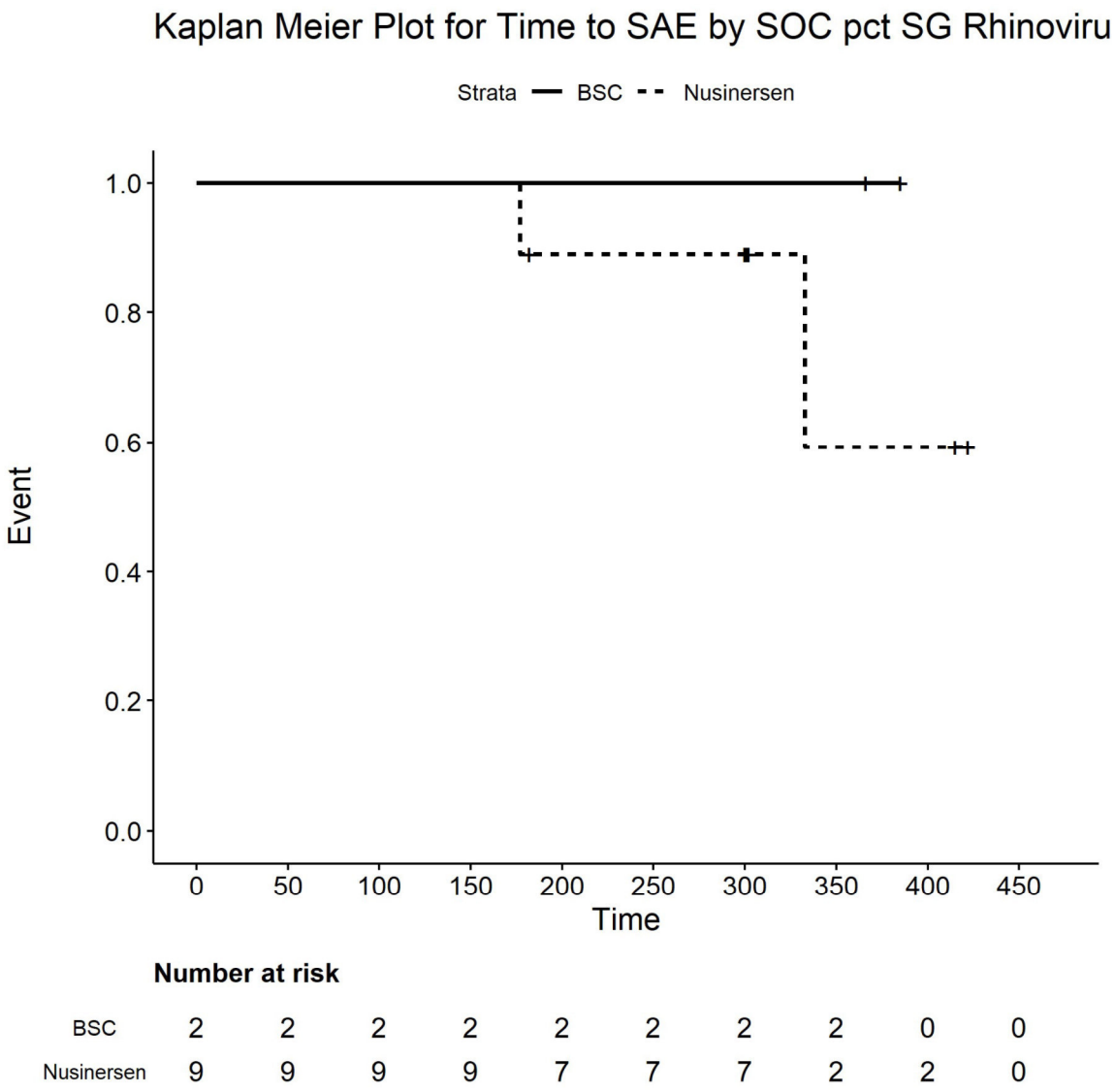
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	9	9	8	5	5	0



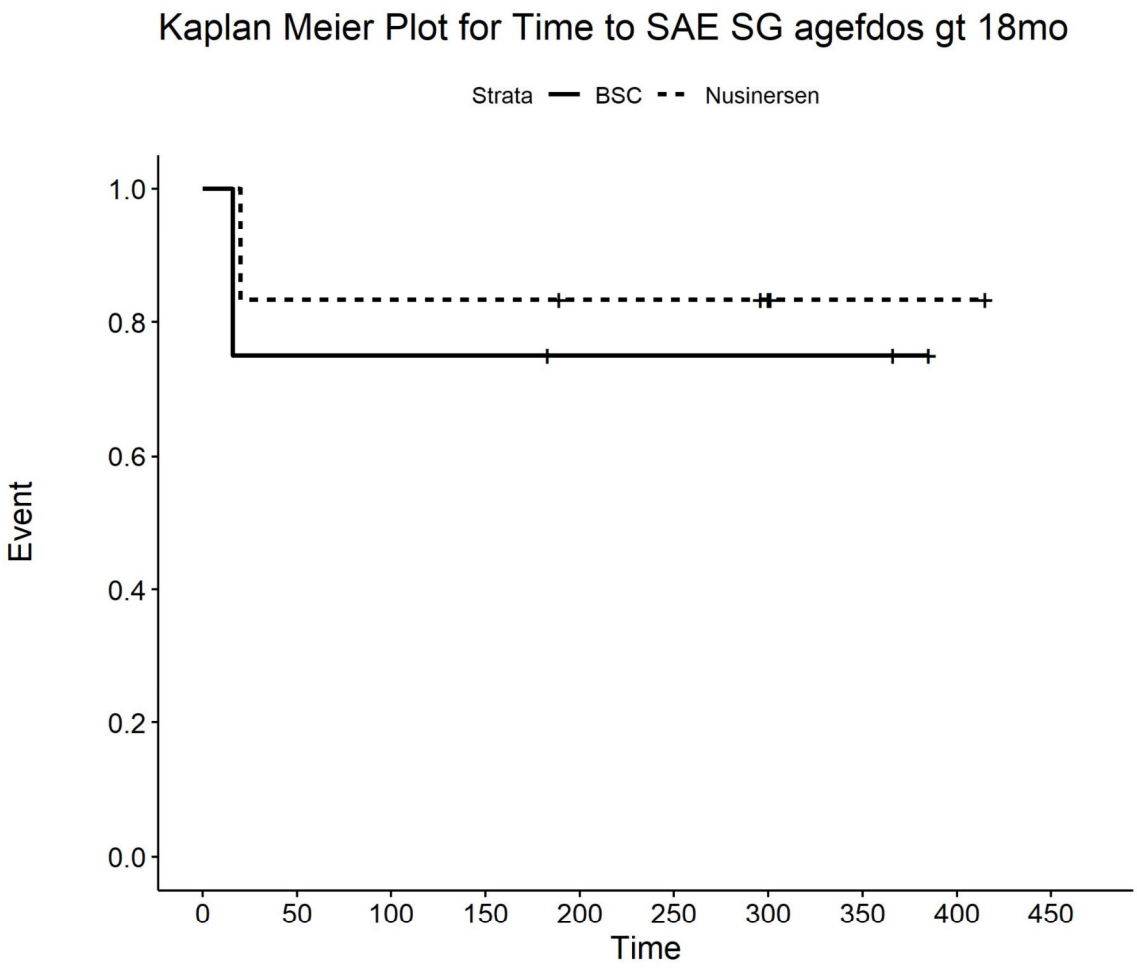
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



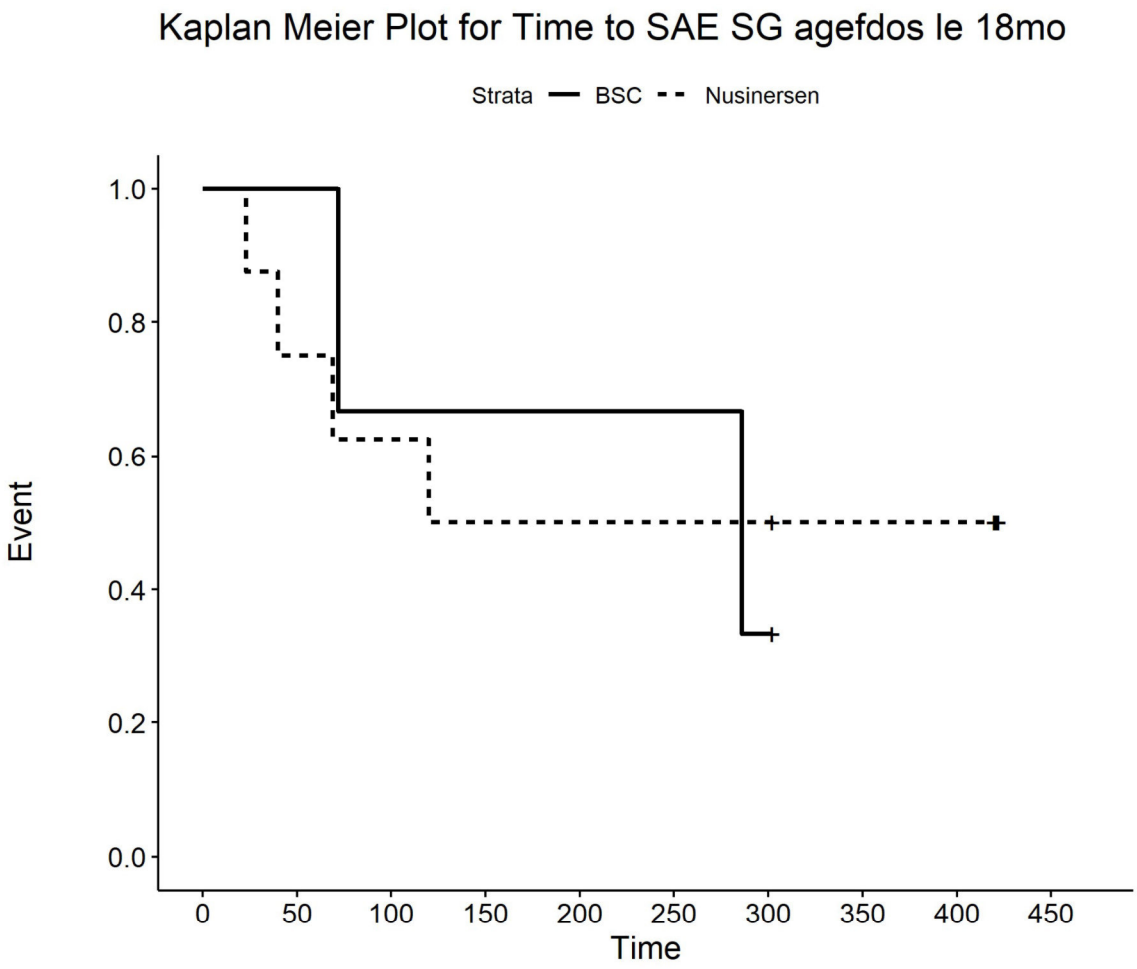
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	7	7	7	2	2	0



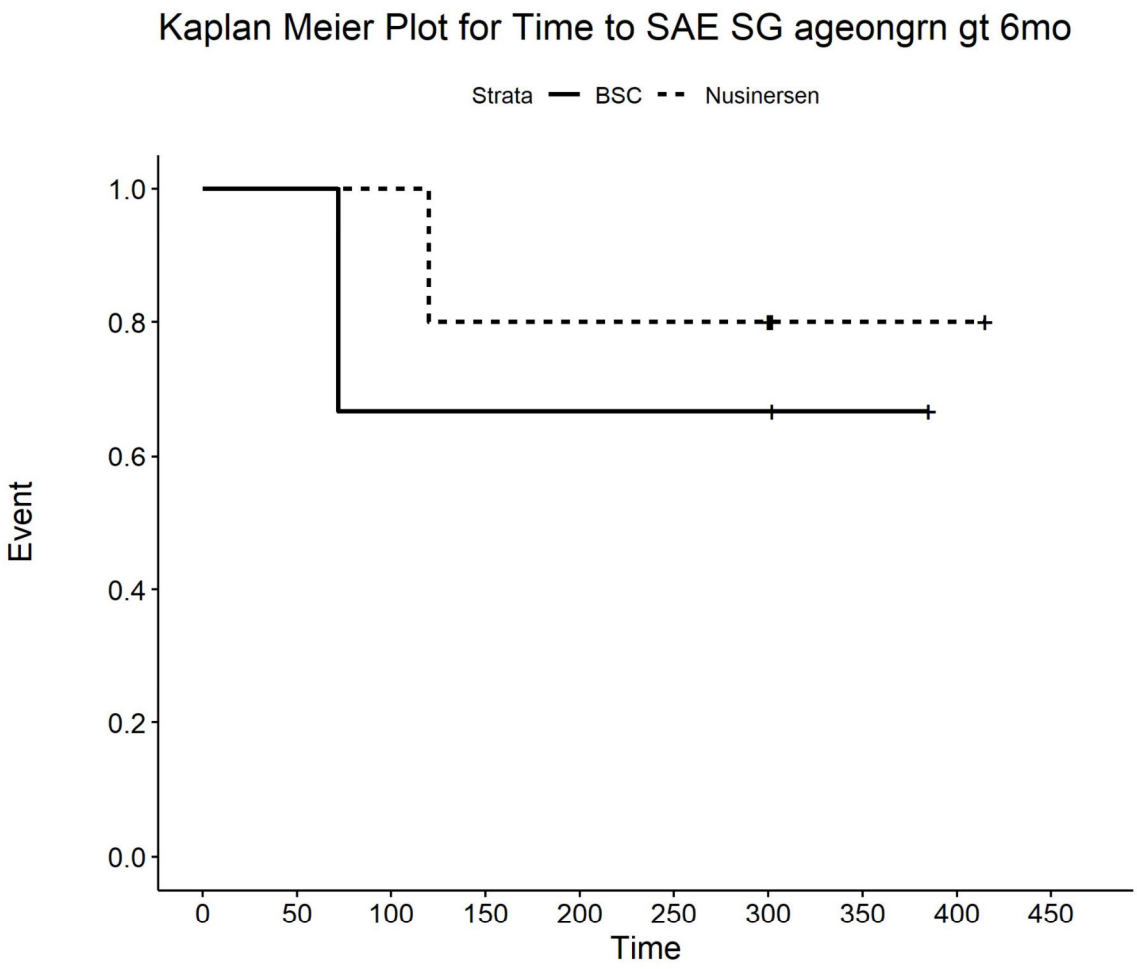
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	5	5	5	4	4	3	1	1	0



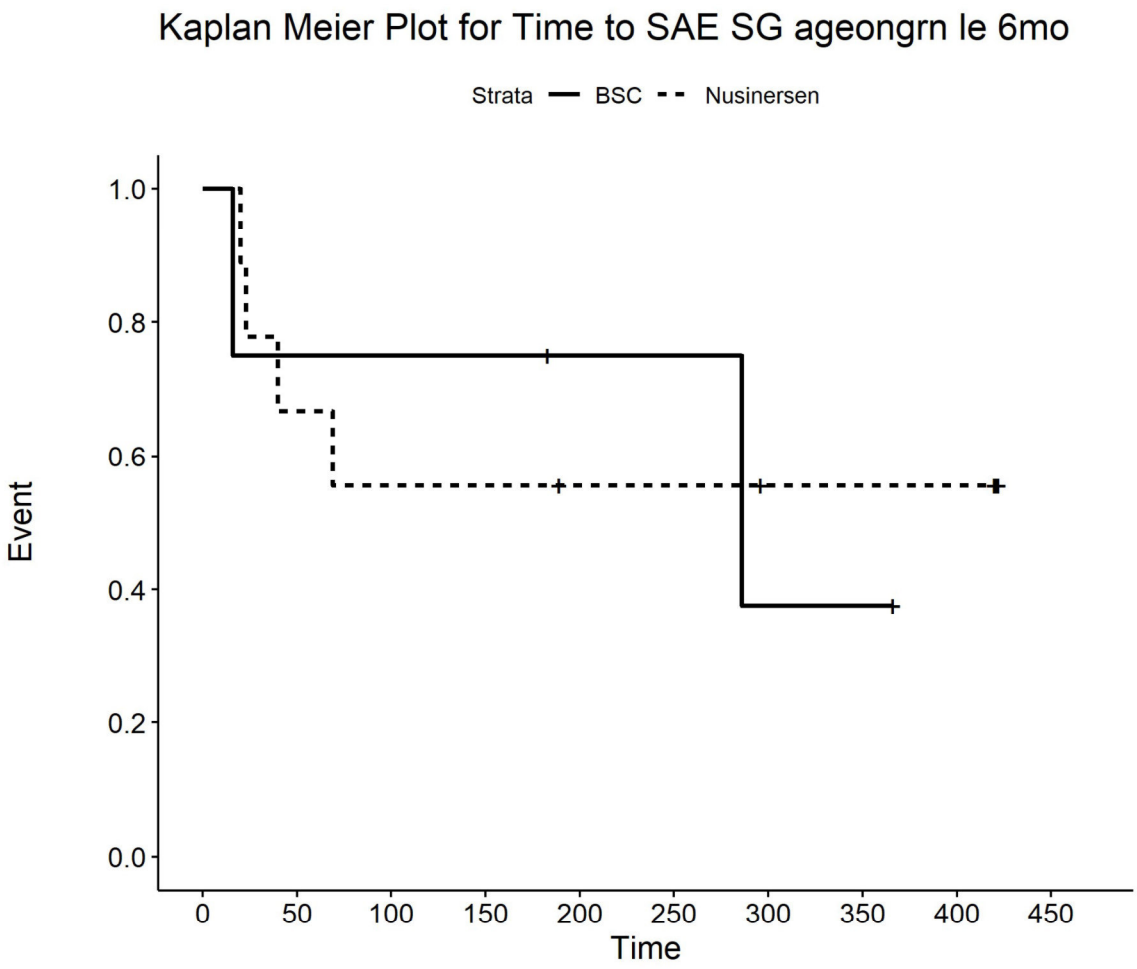
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	6	5	4	4	4	4	3	3	0



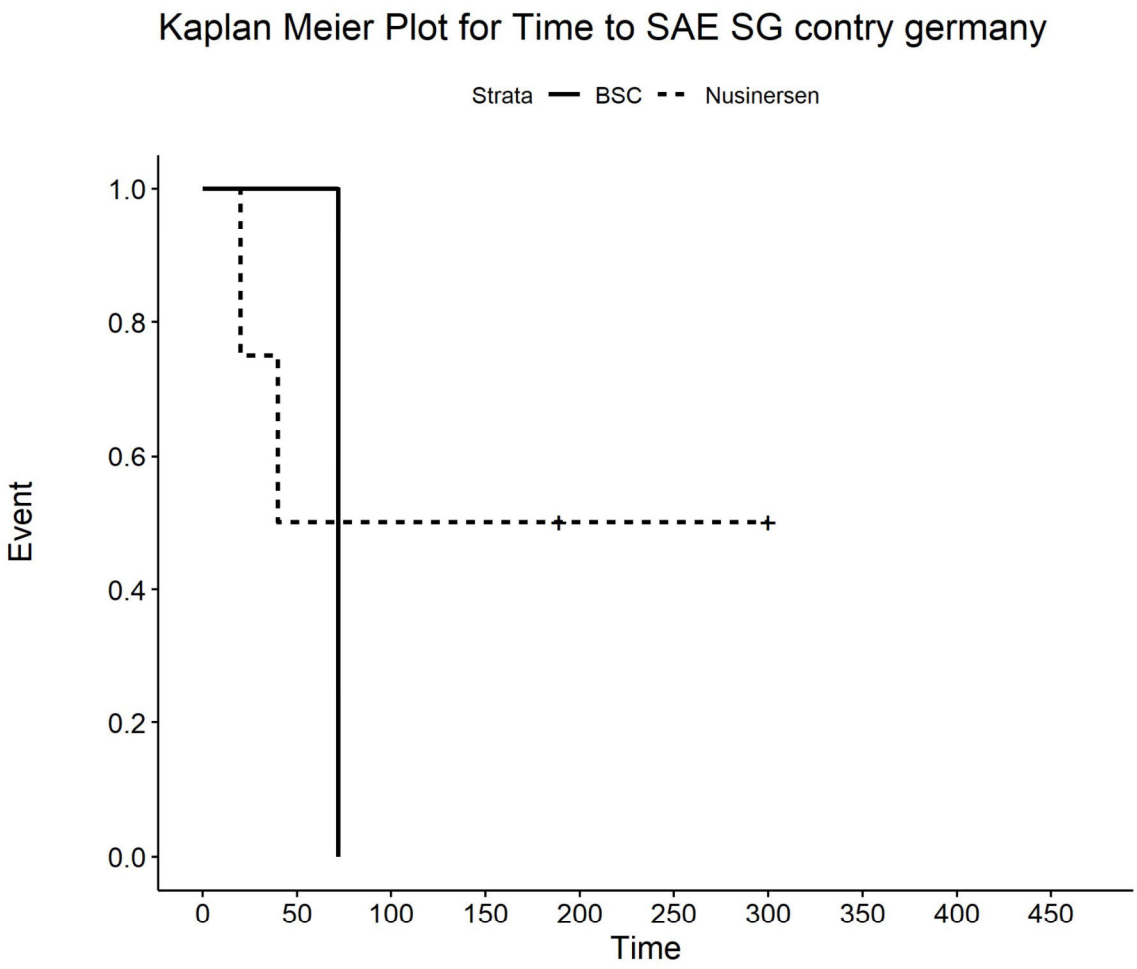
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	4	4	4	4	1	1	0



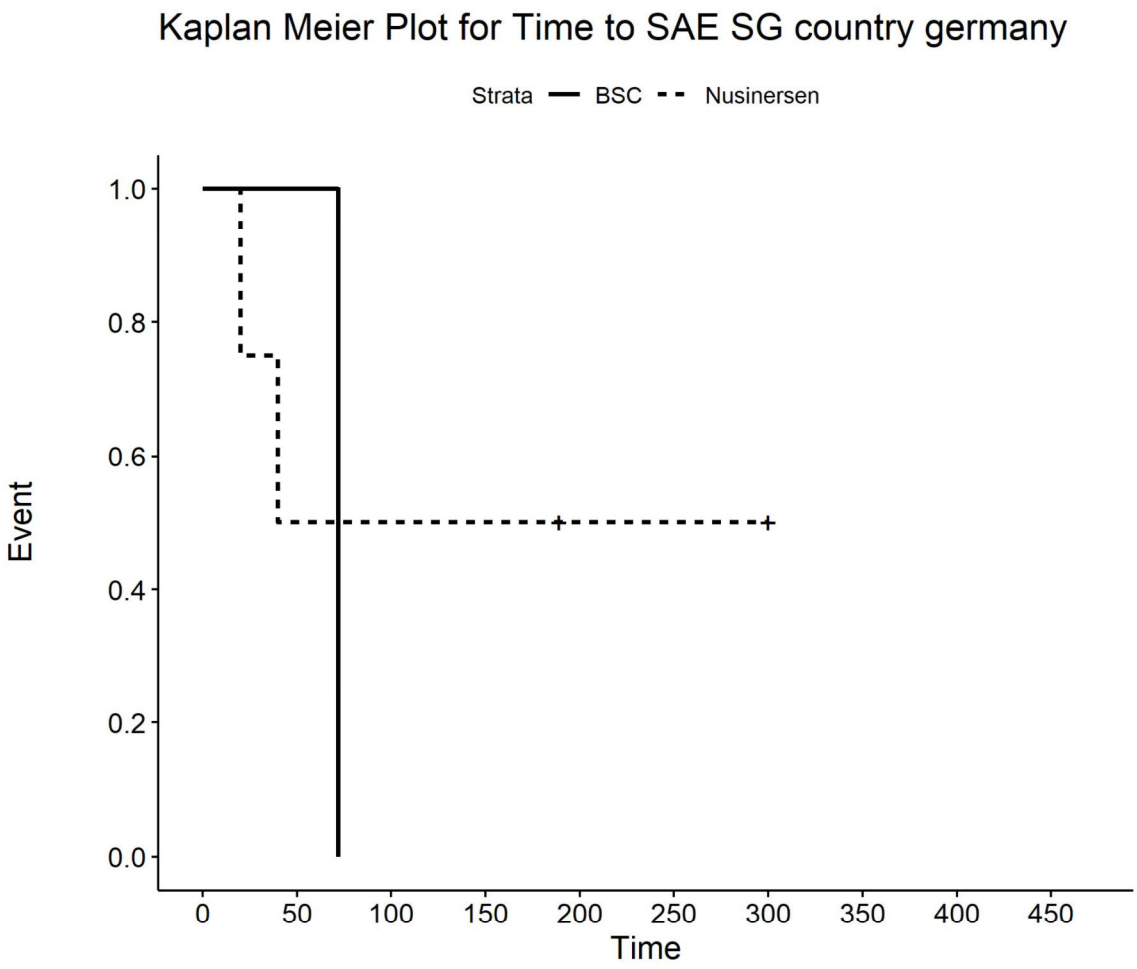
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	6	5	5	4	4	3	3	3	0



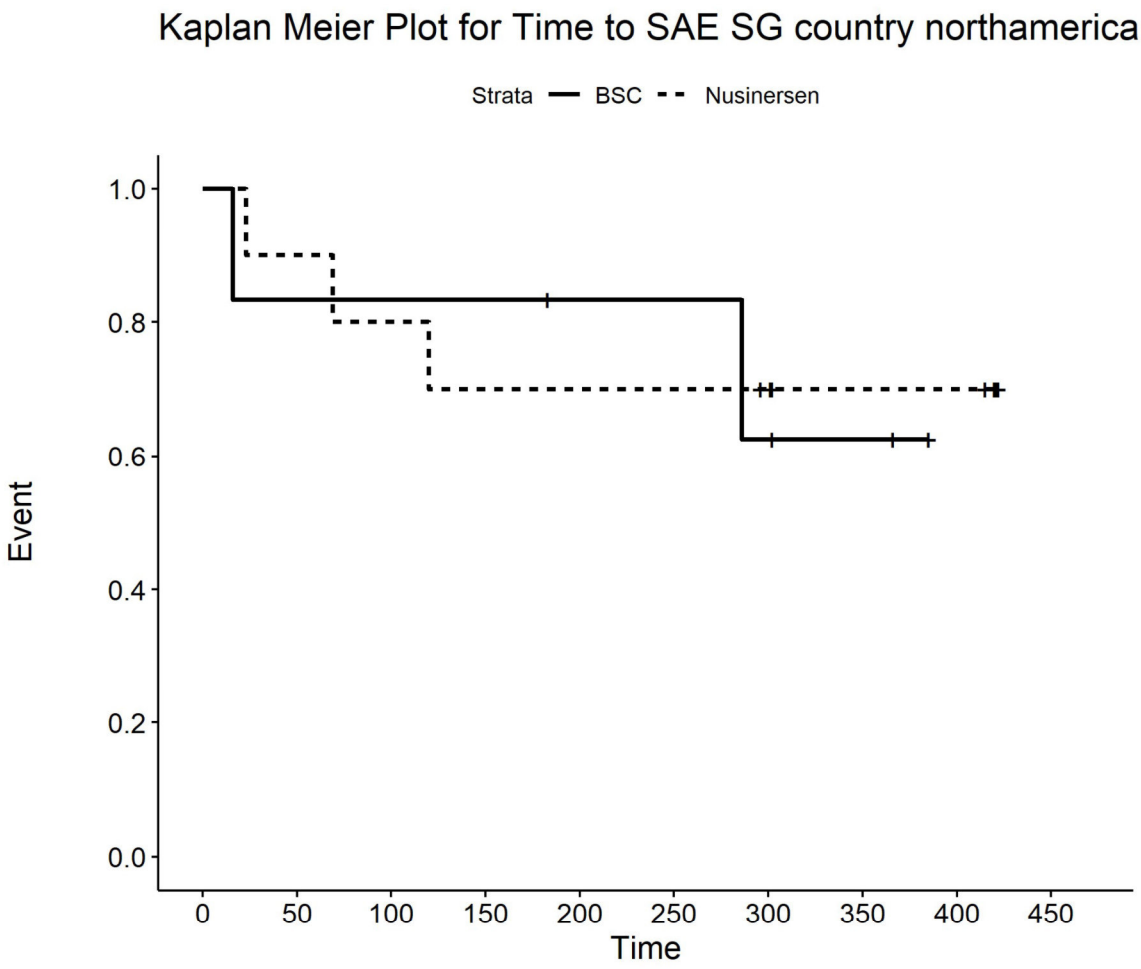
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	2	2	2	1	1	1	0	0	0



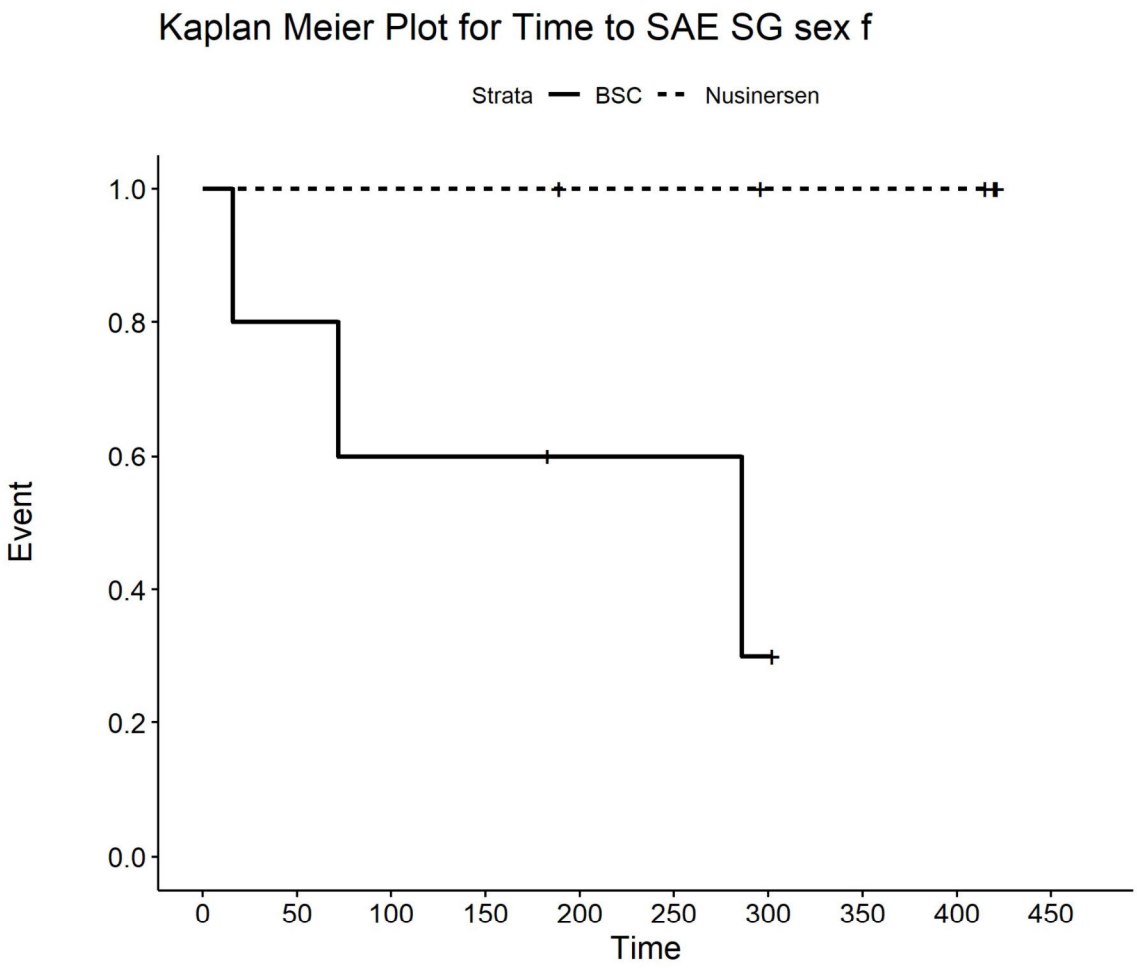
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	2	2	2	1	1	1	0	0	0



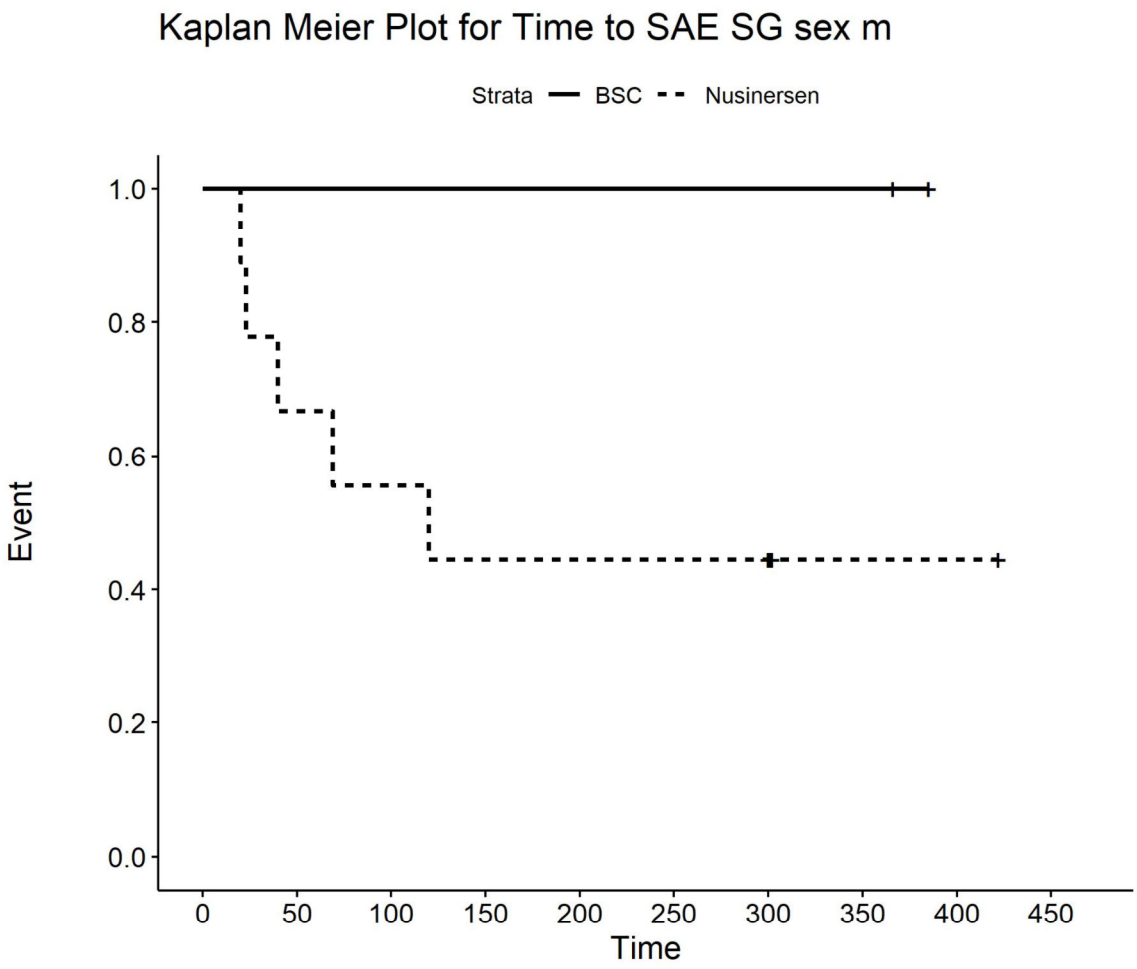
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	9	8	7	7	7	6	4	4	0



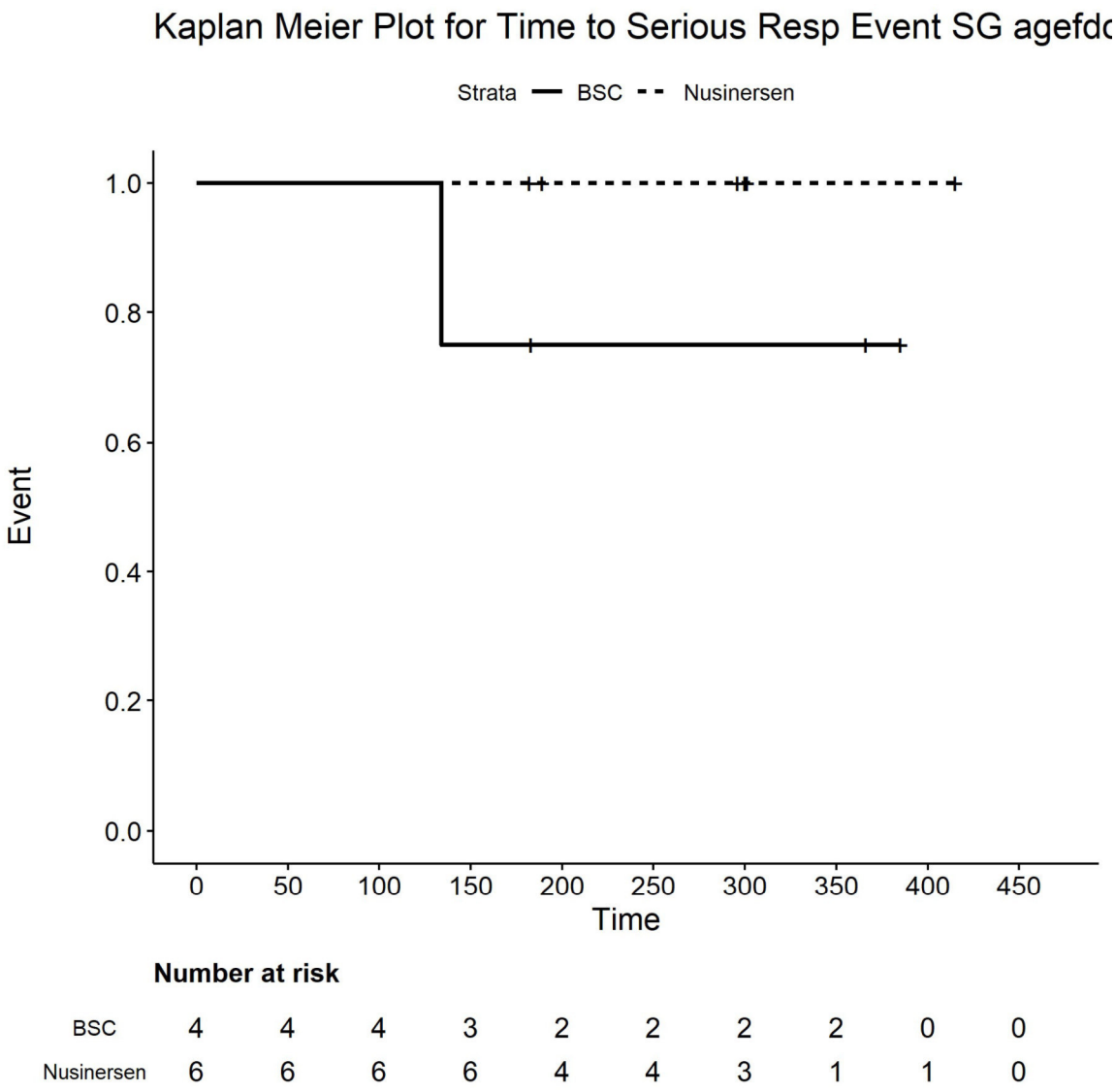
Number at risk

BSC	5	4	3	3	2	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



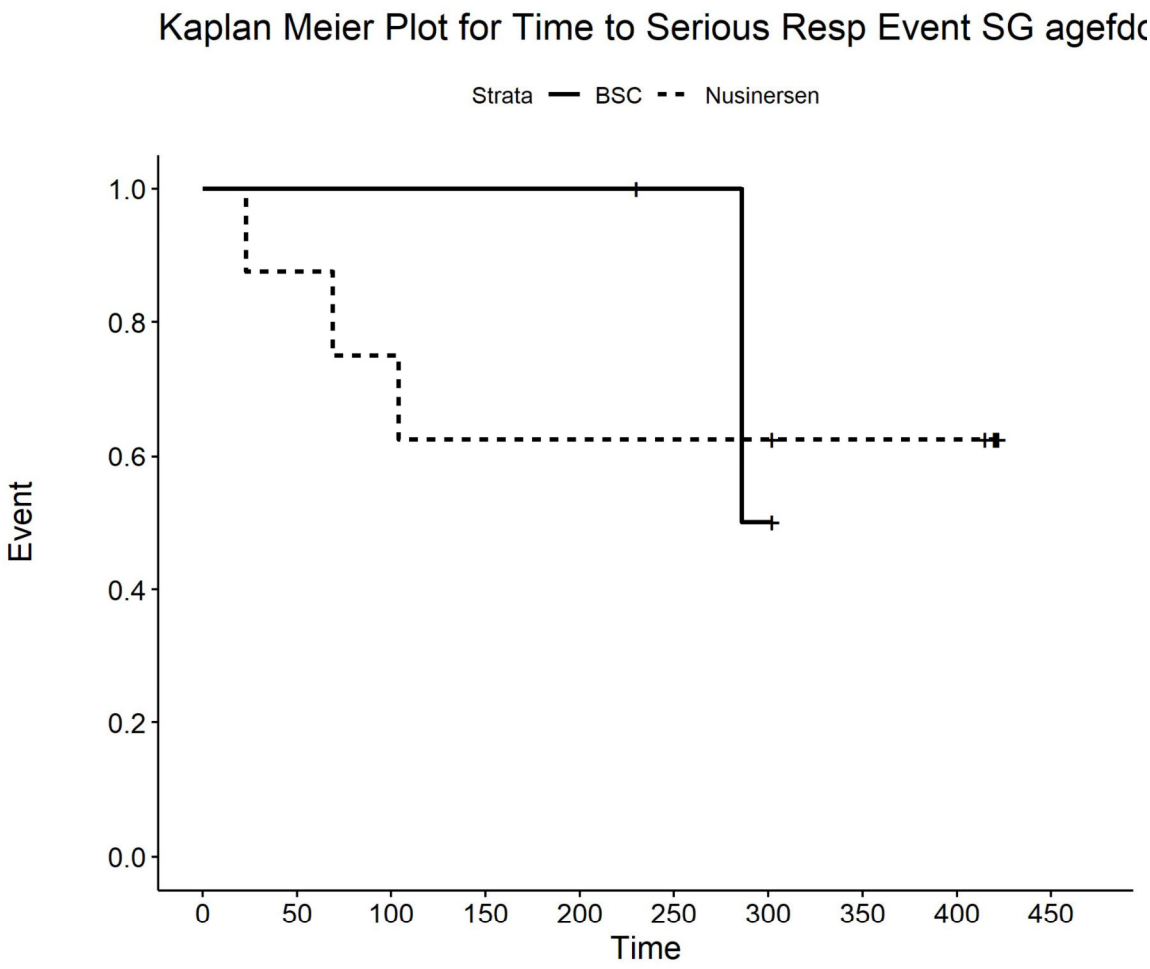
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	6	5	4	4	4	4	1	1	0



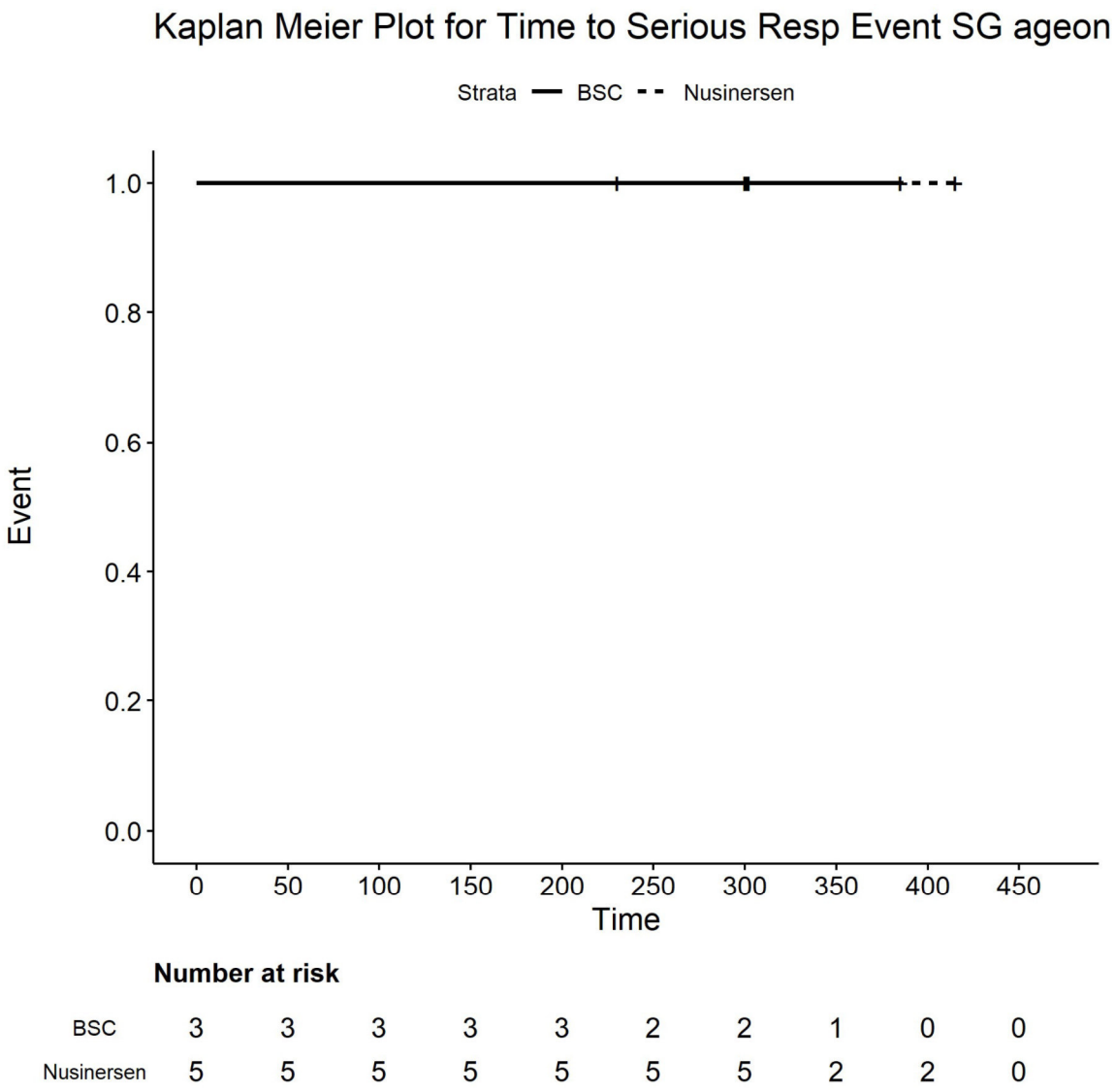
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



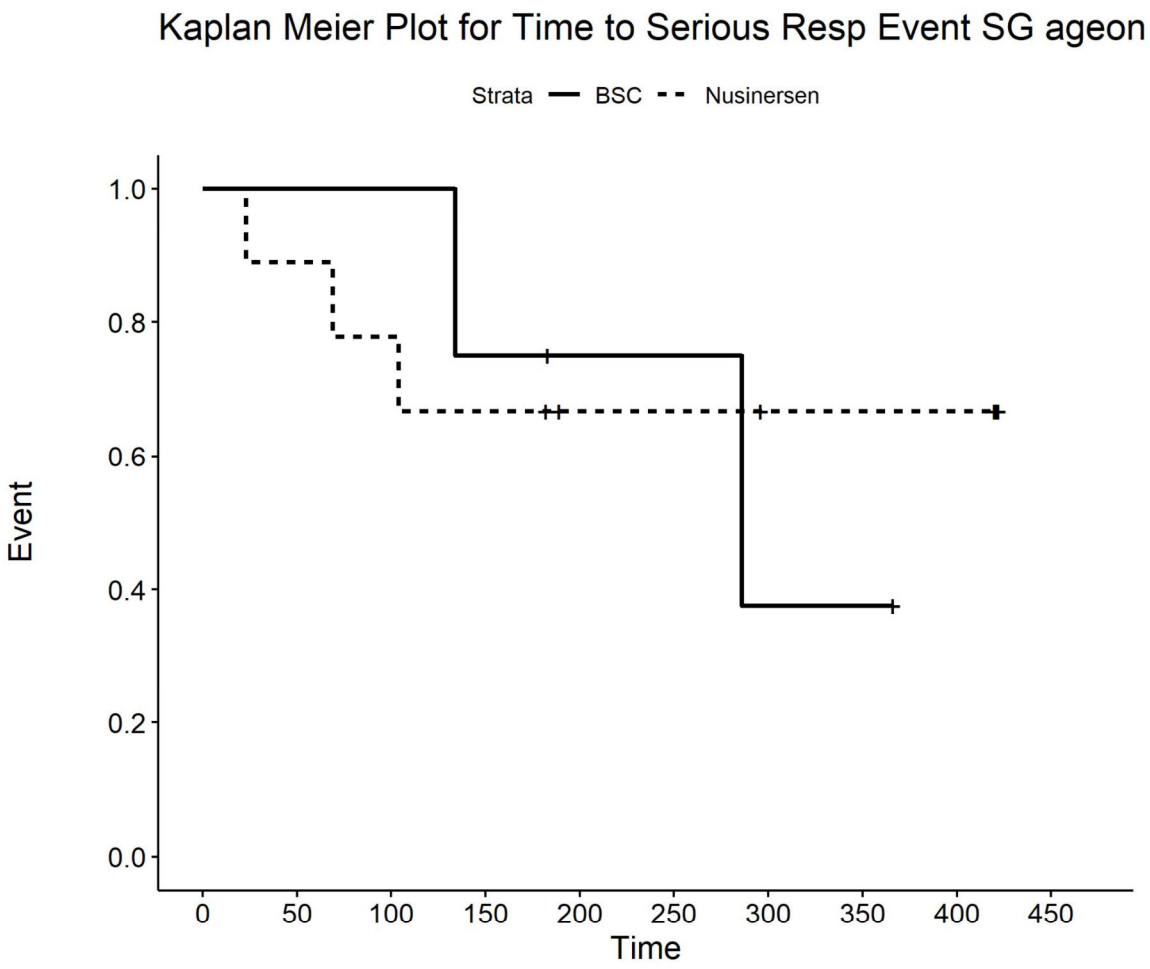
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	6	5	5	5	5	4	4	0



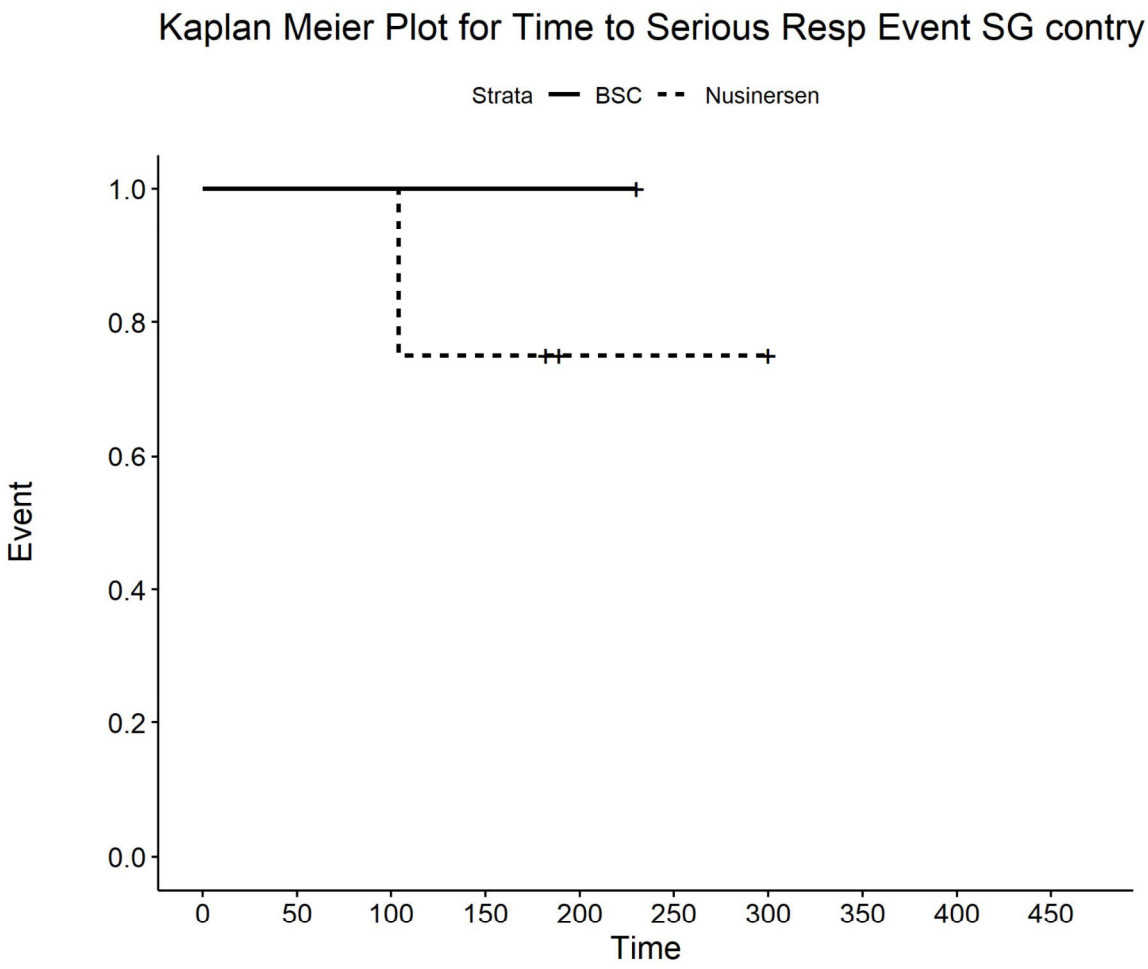
Number at risk

BSC	3	3	3	3	3	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



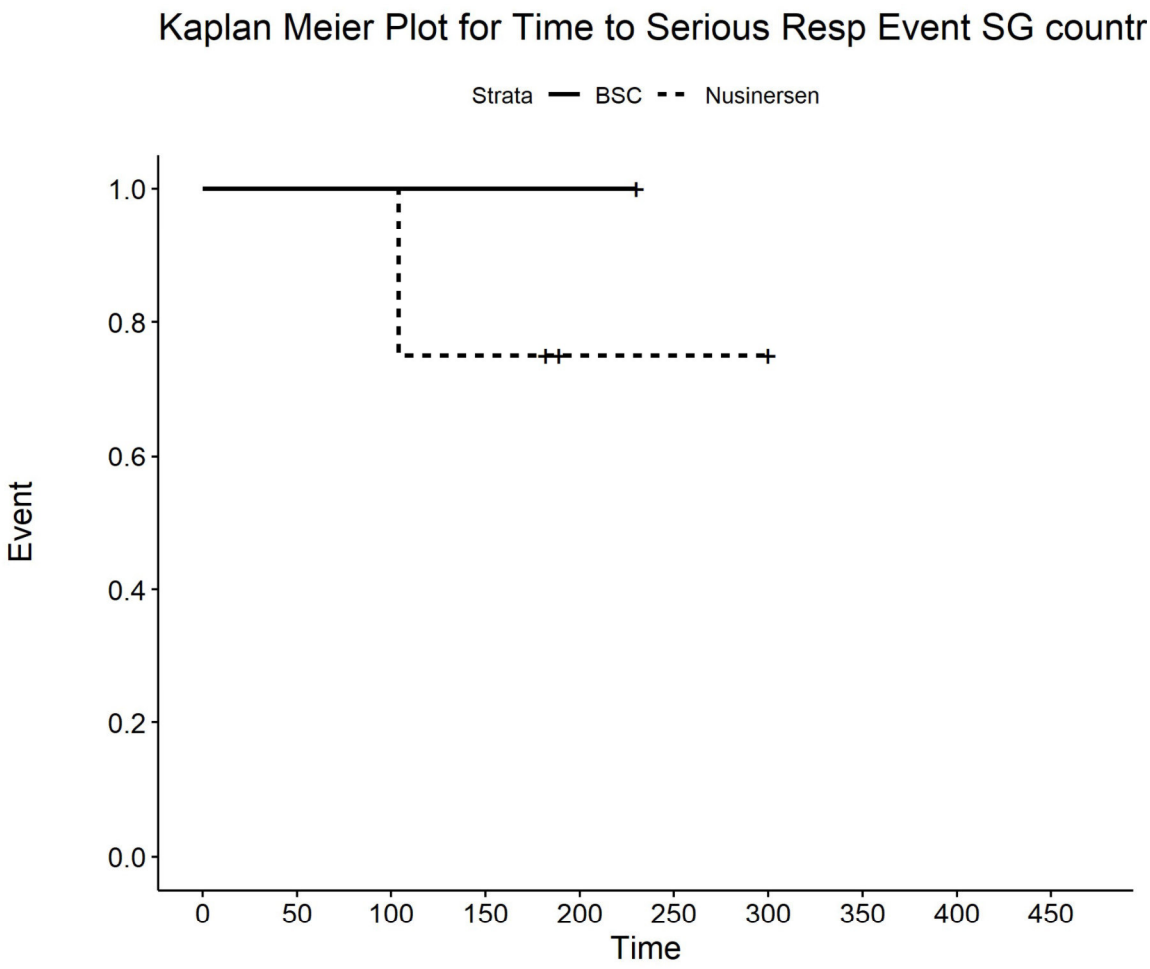
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	8	7	6	4	4	3	3	3	0



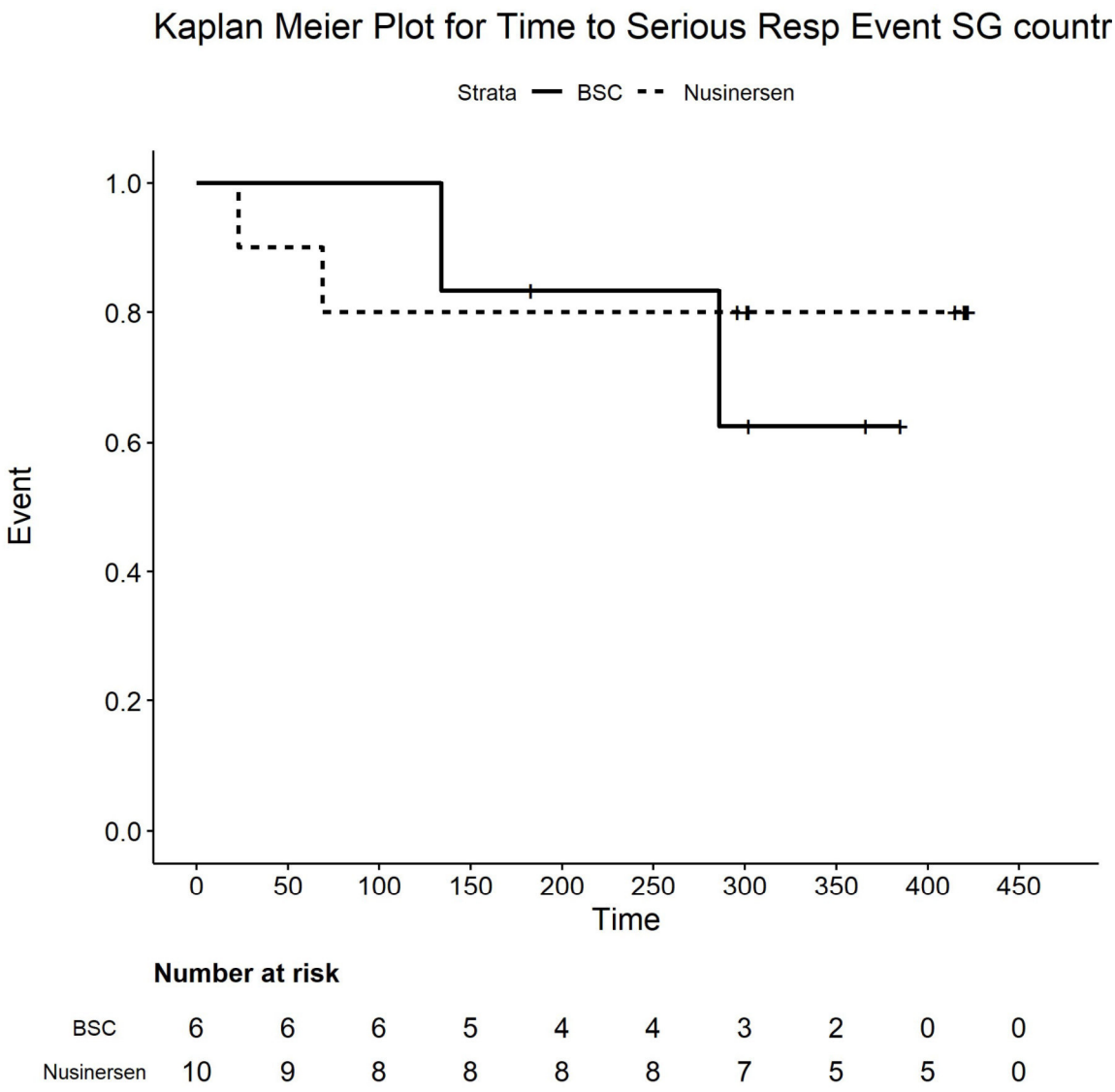
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



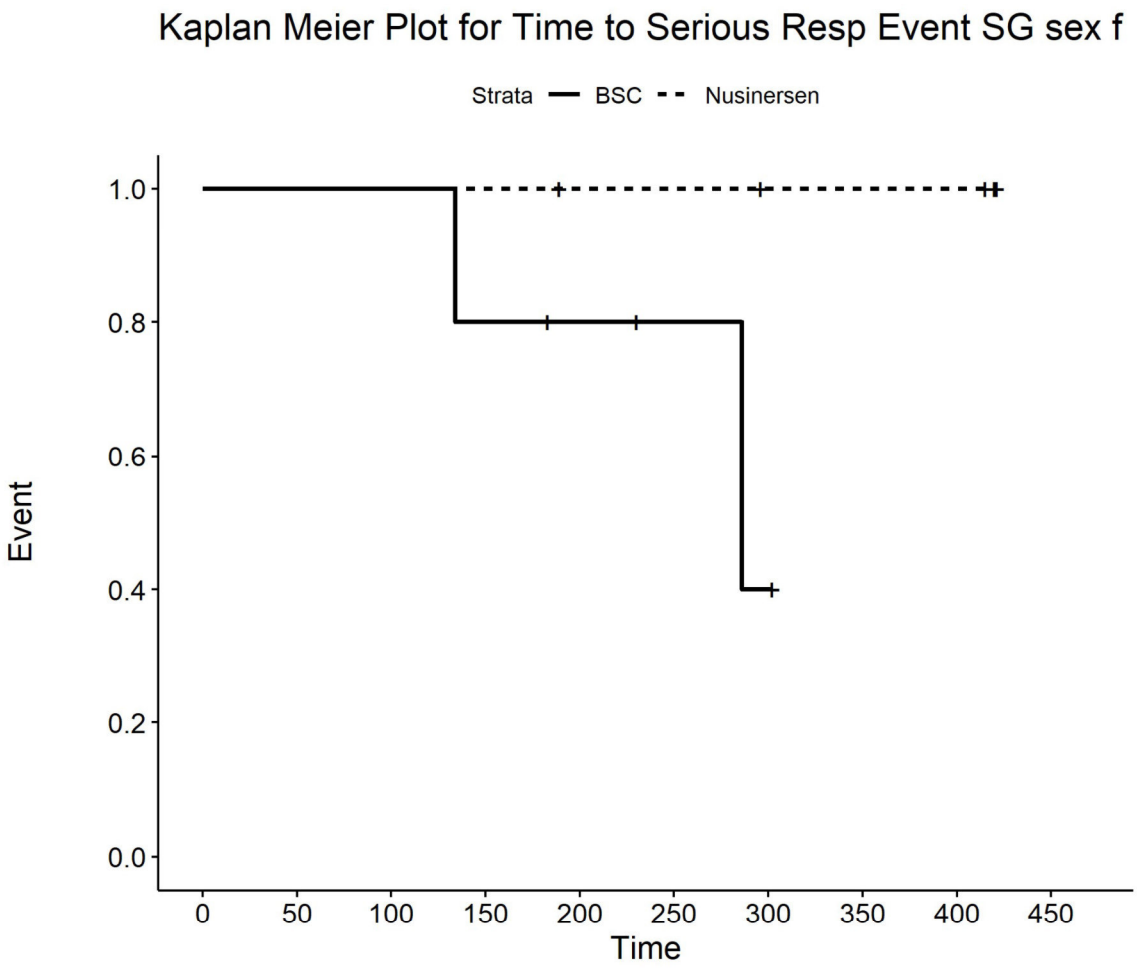
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



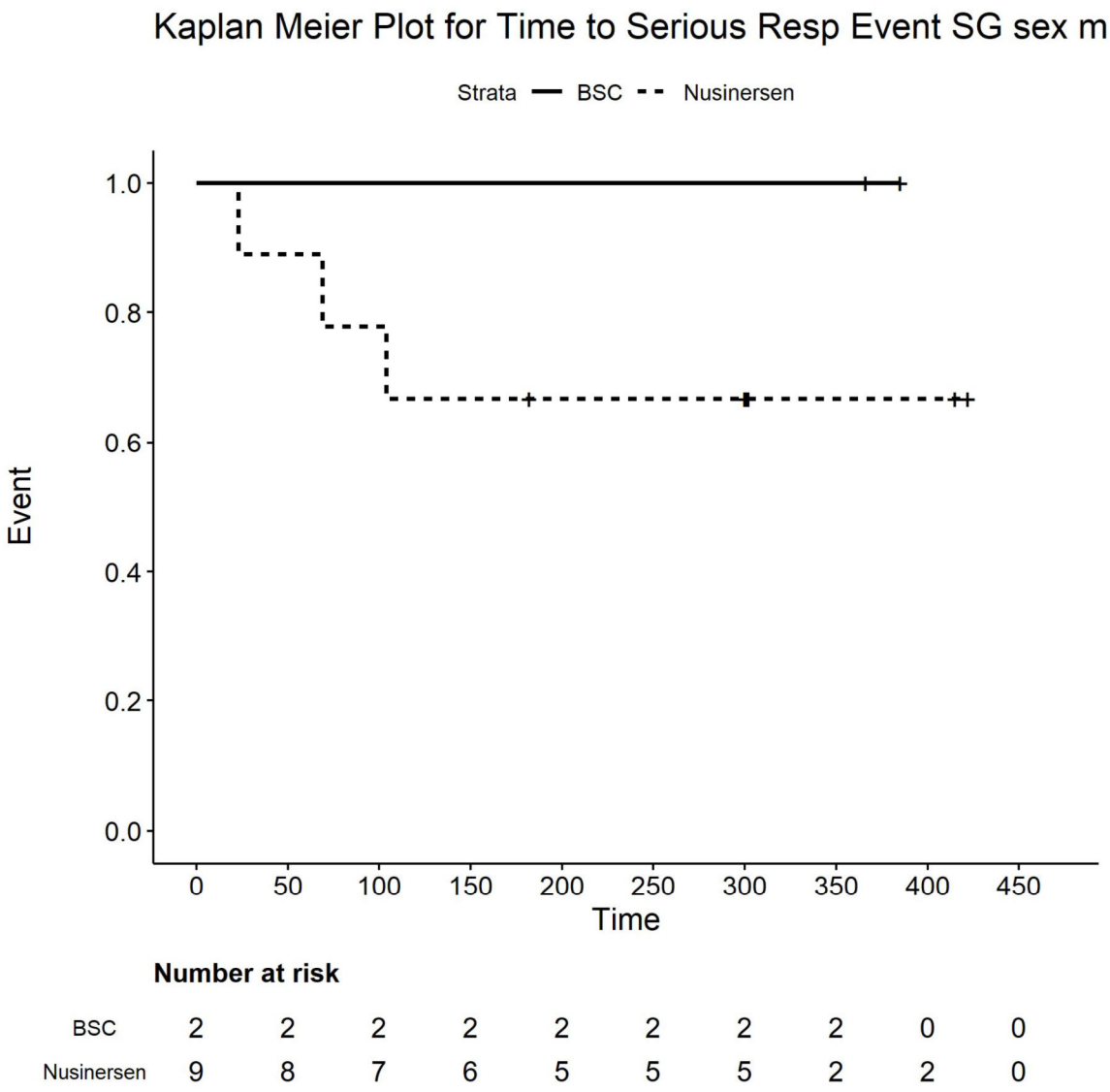
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	9	8	8	8	8	7	5	5	0



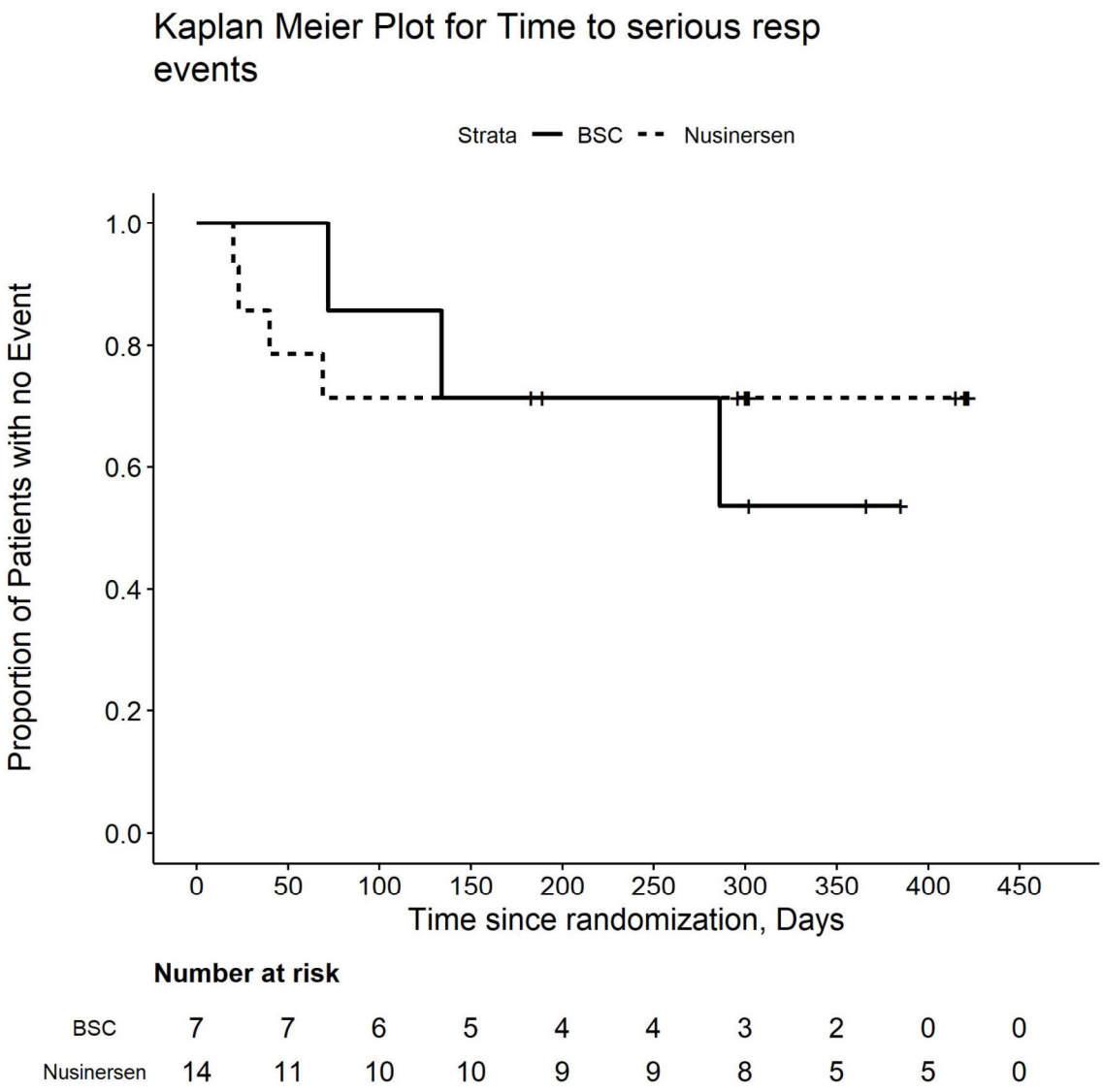
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



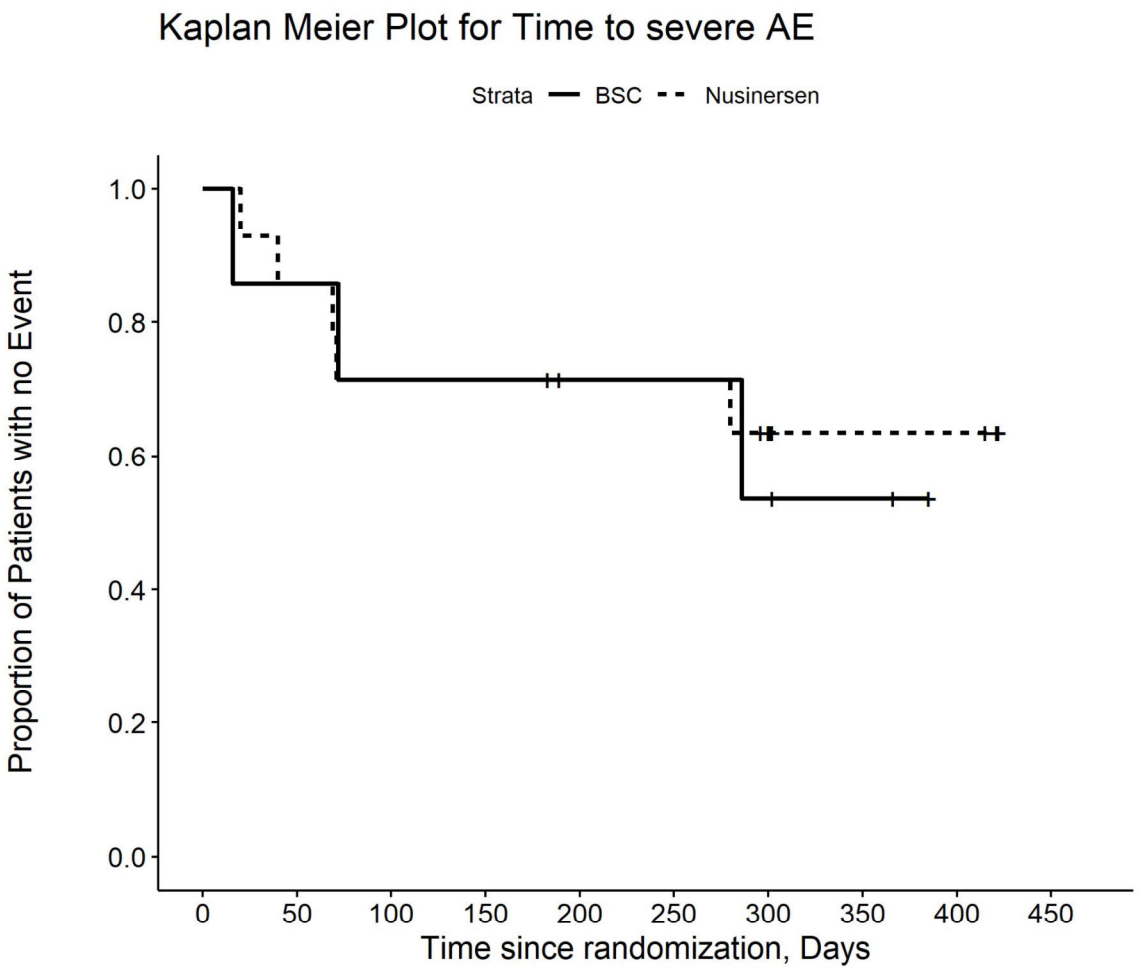
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	7	6	5	5	5	2	2	0



Number at risk

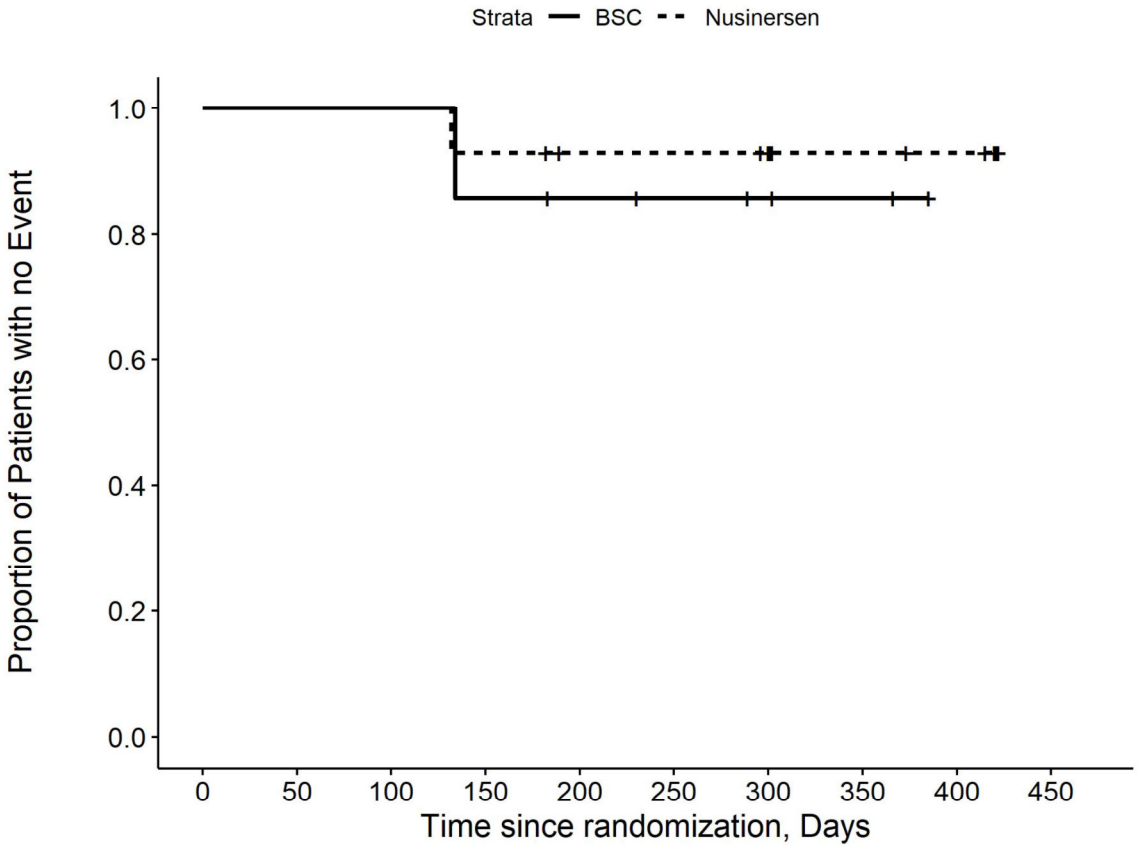
BSC	7	7	6	5	4	4	3	2	0	0
Nusinersen	14	11	10	10	9	9	8	5	5	0



Number at risk

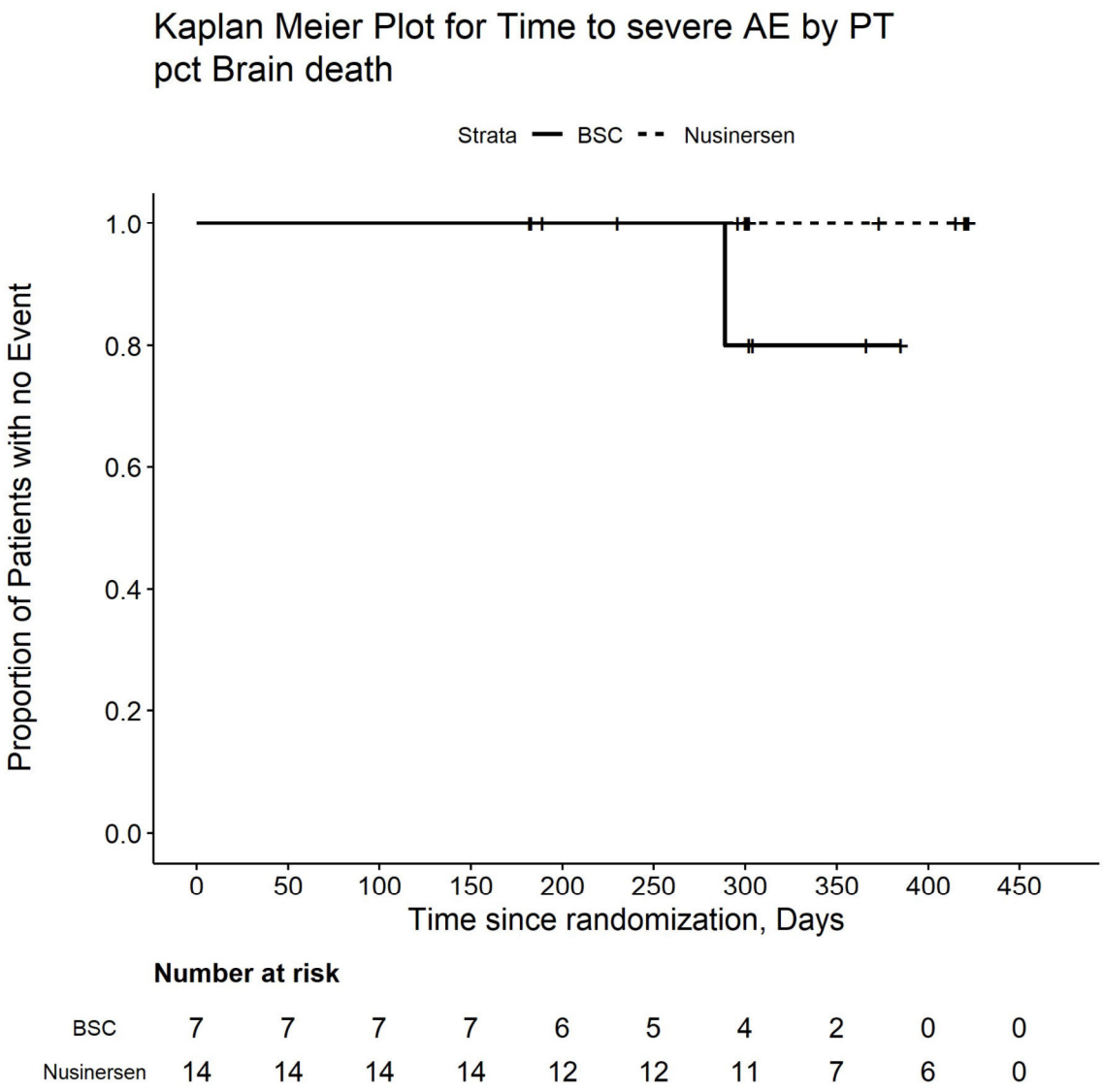
BSC	7	6	5	5	4	4	3	2	0	0
Nusinersen	14	12	10	10	9	9	7	4	4	0

Kaplan Meier Plot for Time to severe AE by PT
pct Acute respiratory failure



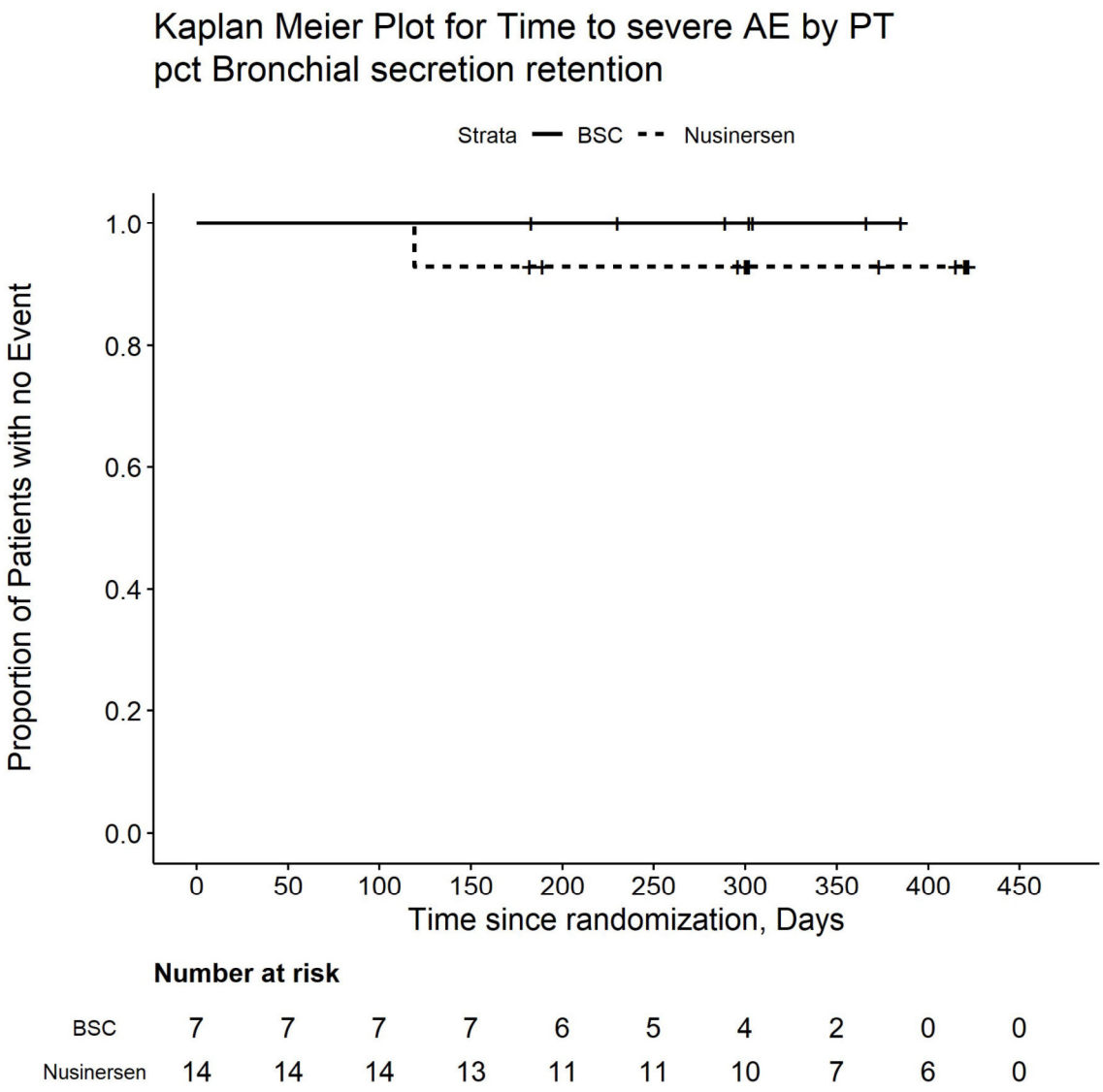
Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	13	11	11	10	6	5	0



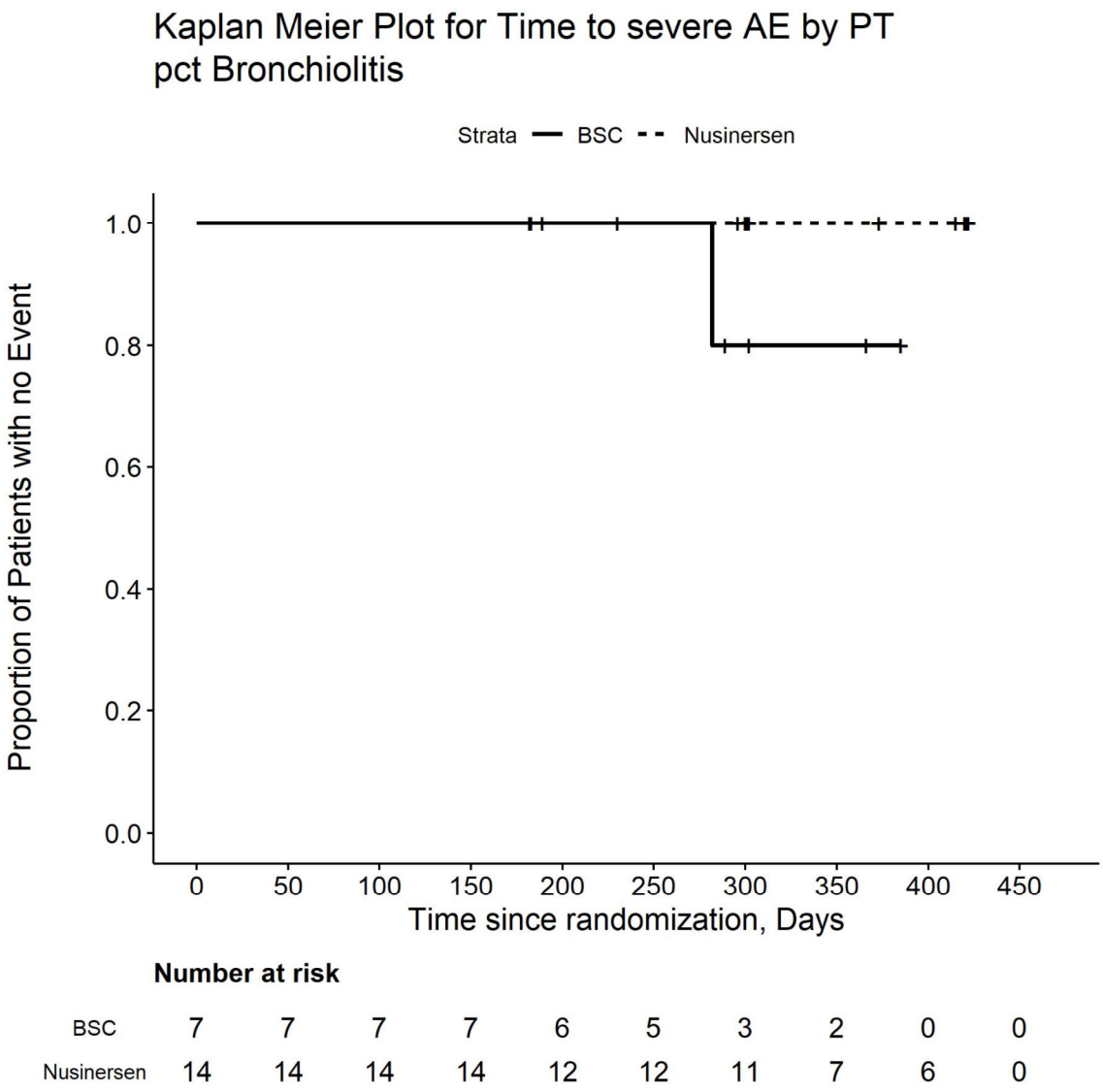
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

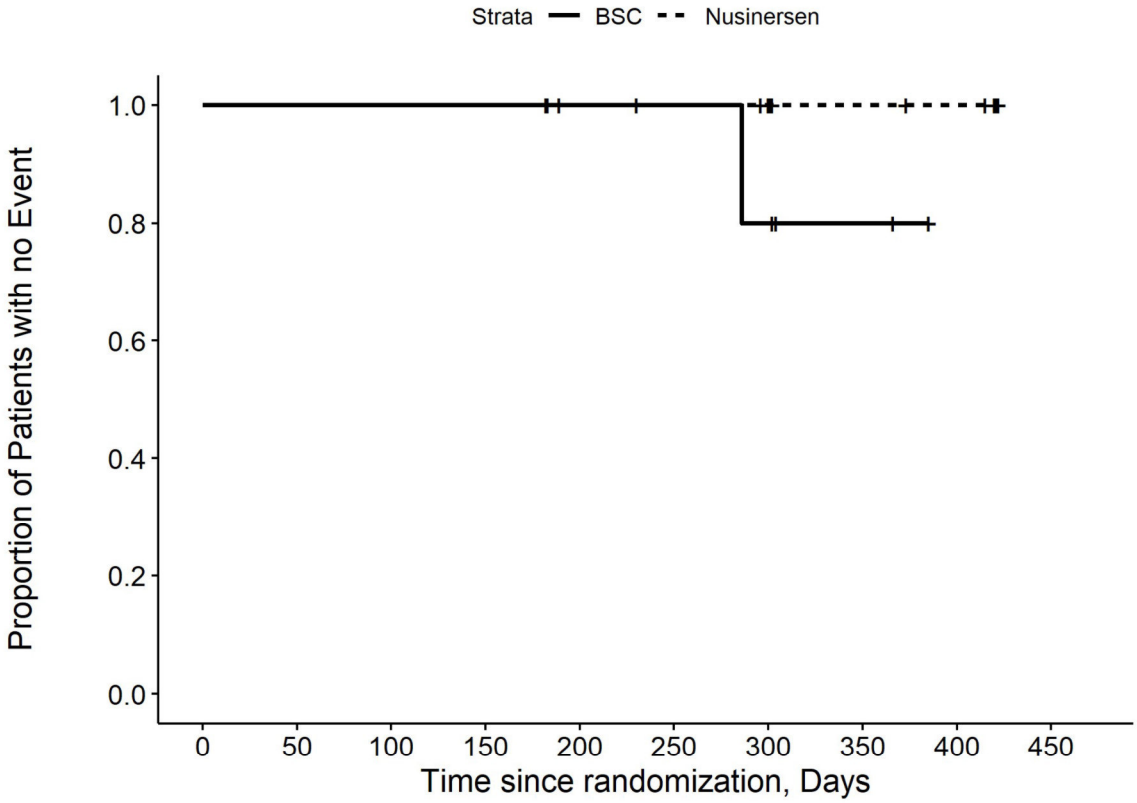
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	11	11	10	7	6	0



Number at risk

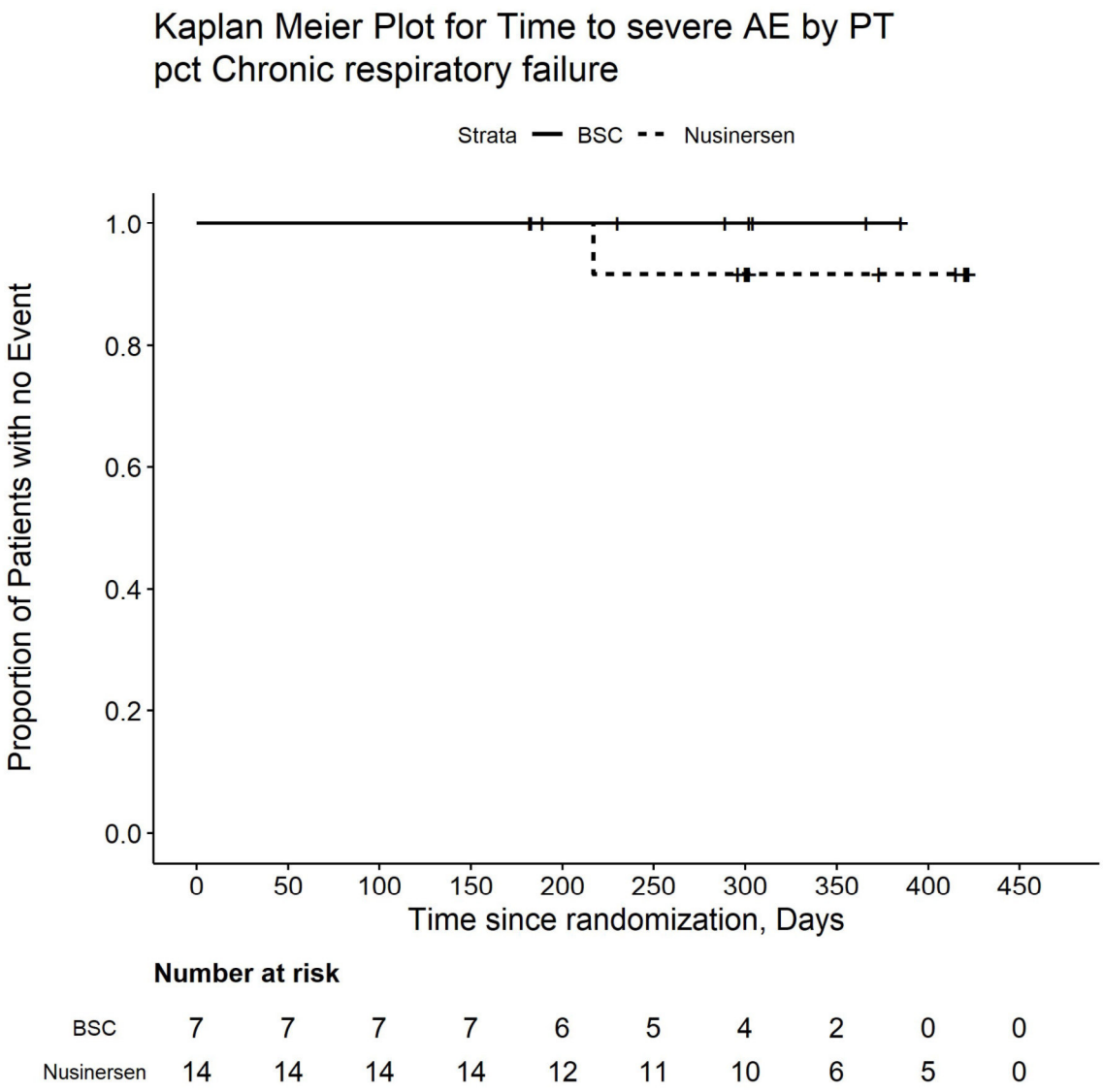
BSC	7	7	7	7	6	5	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for
Time to severe AE by PT
pct Cardio : respiratory arrest



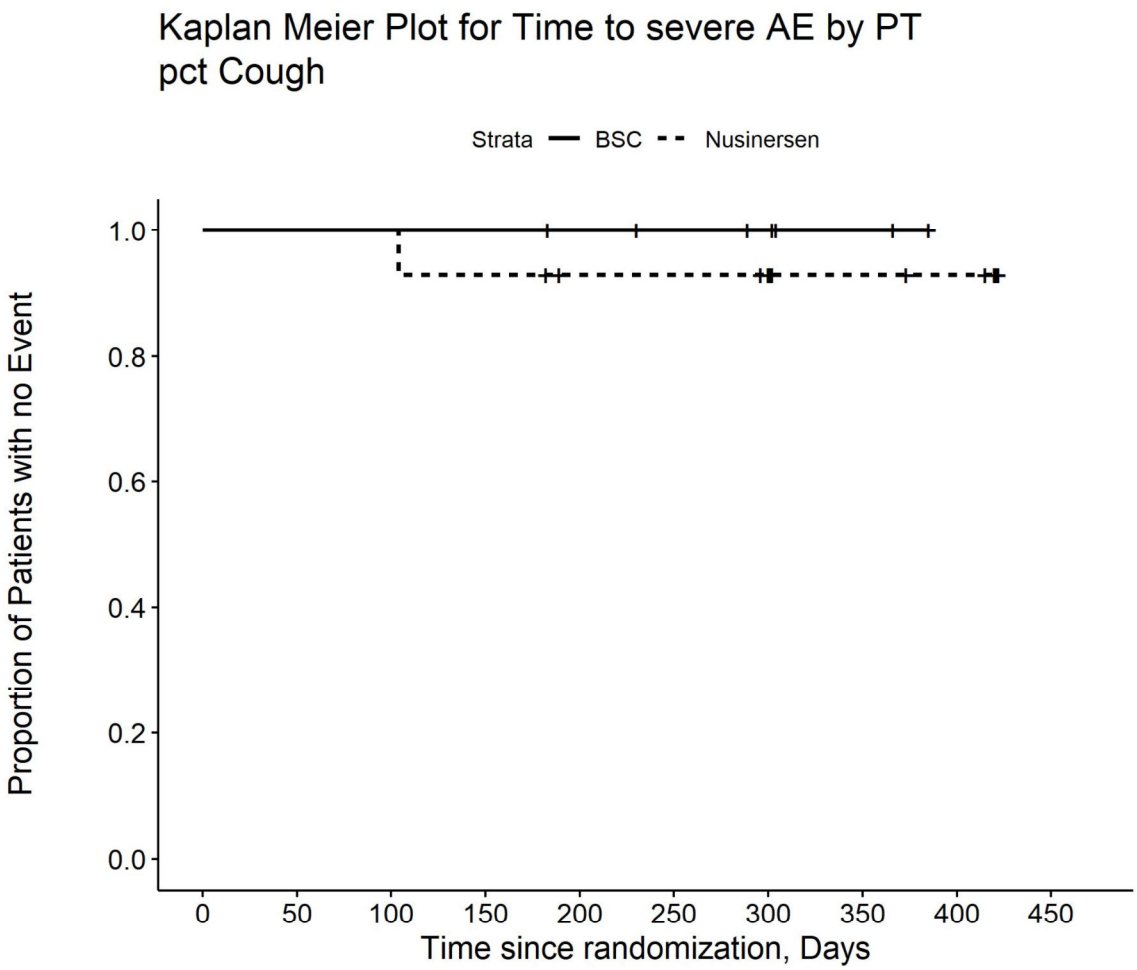
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



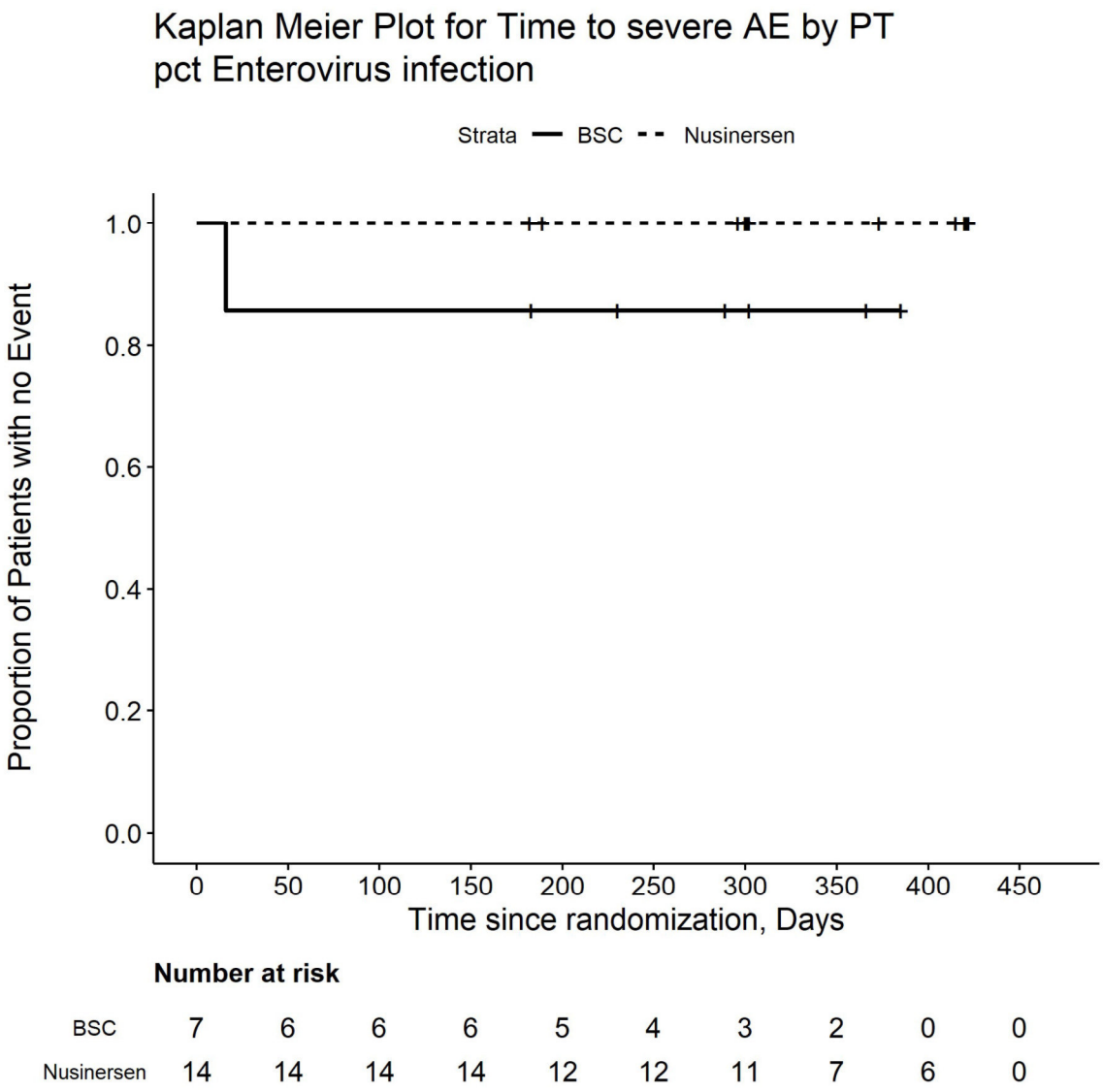
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	11	10	6	5	0



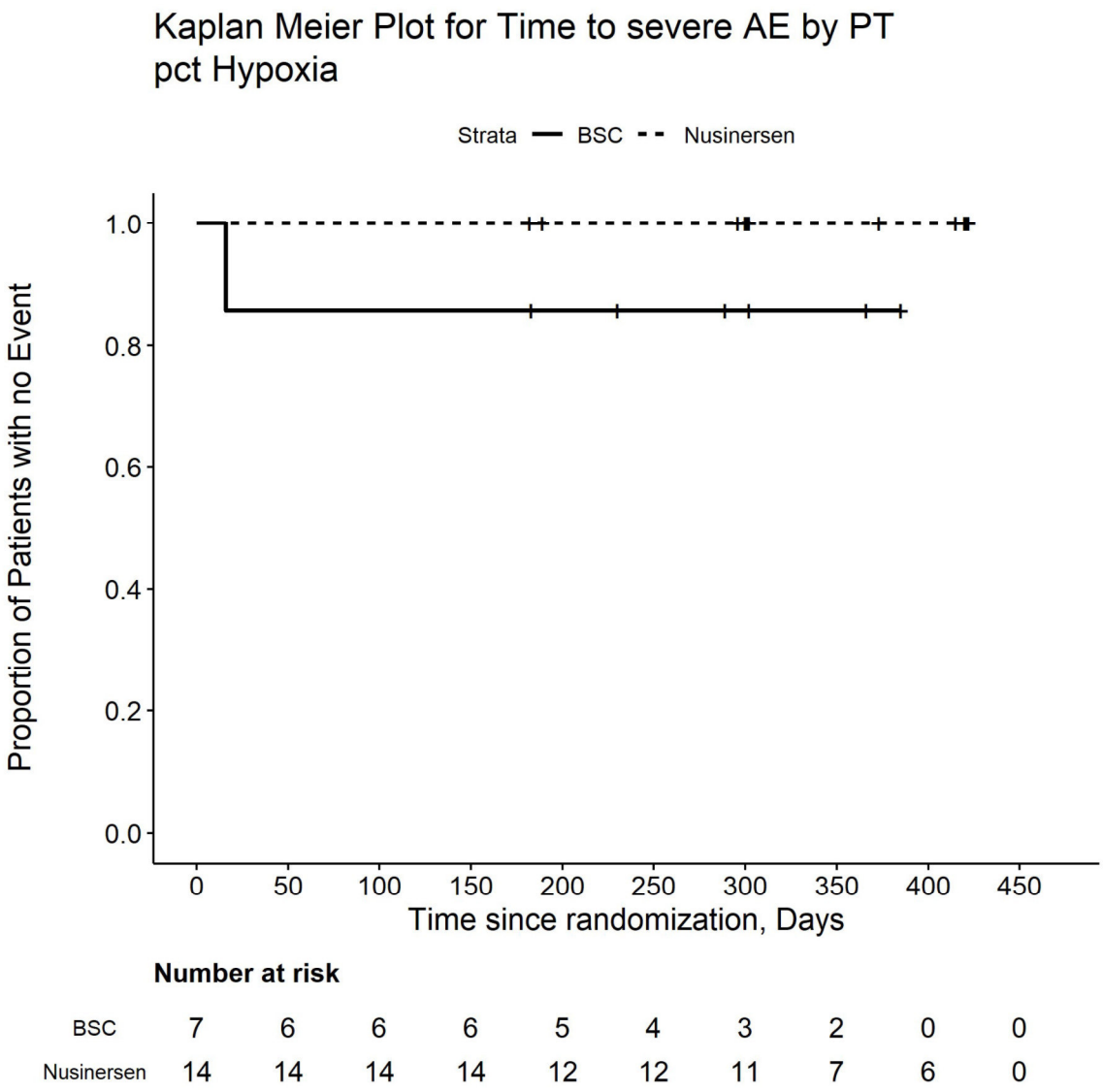
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	11	11	10	7	6	0



Number at risk

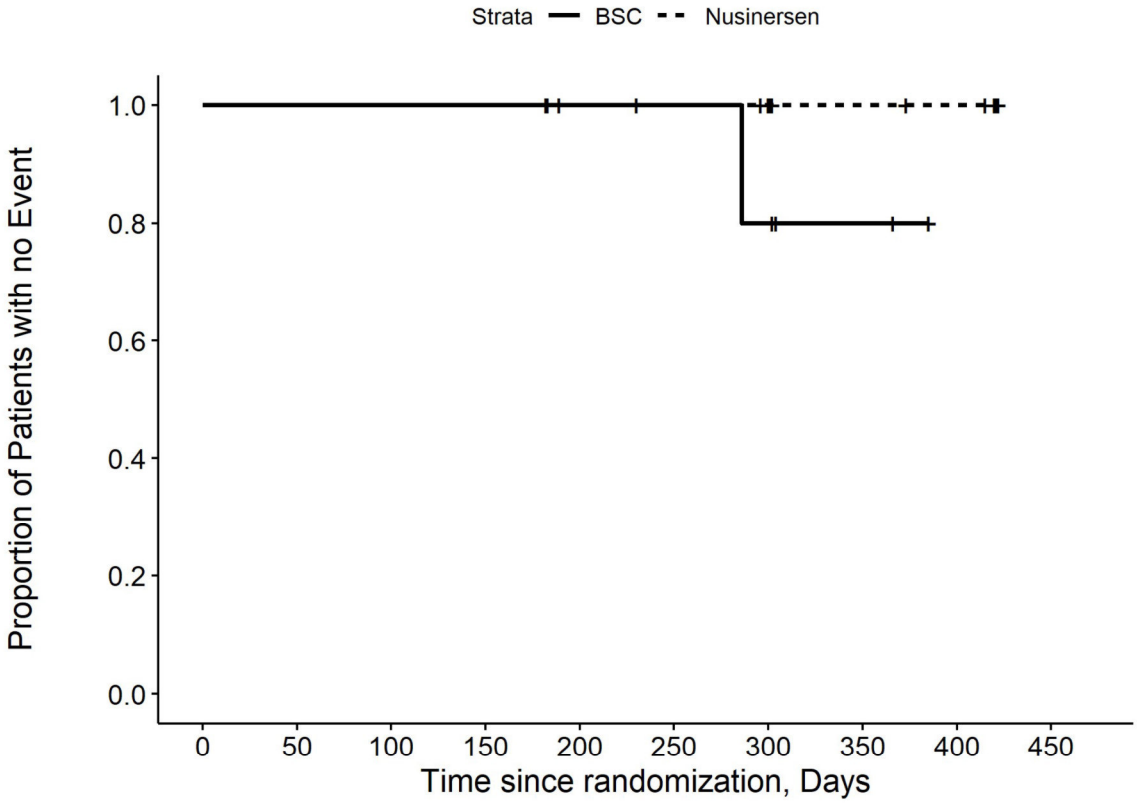
BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



Number at risk

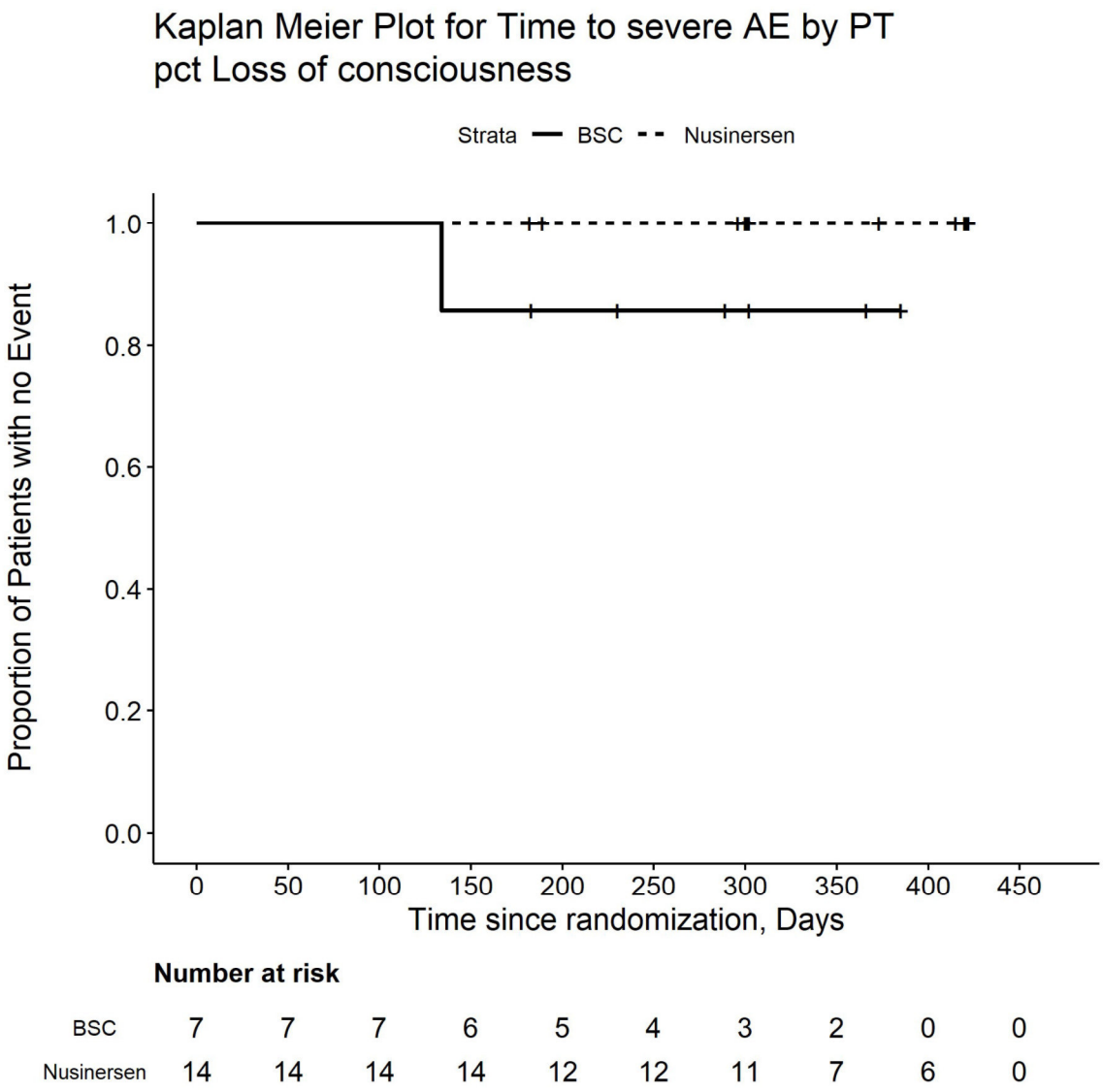
BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for
Time to severe AE by PT
pct Hypoxic : ischaemic encephalopathy



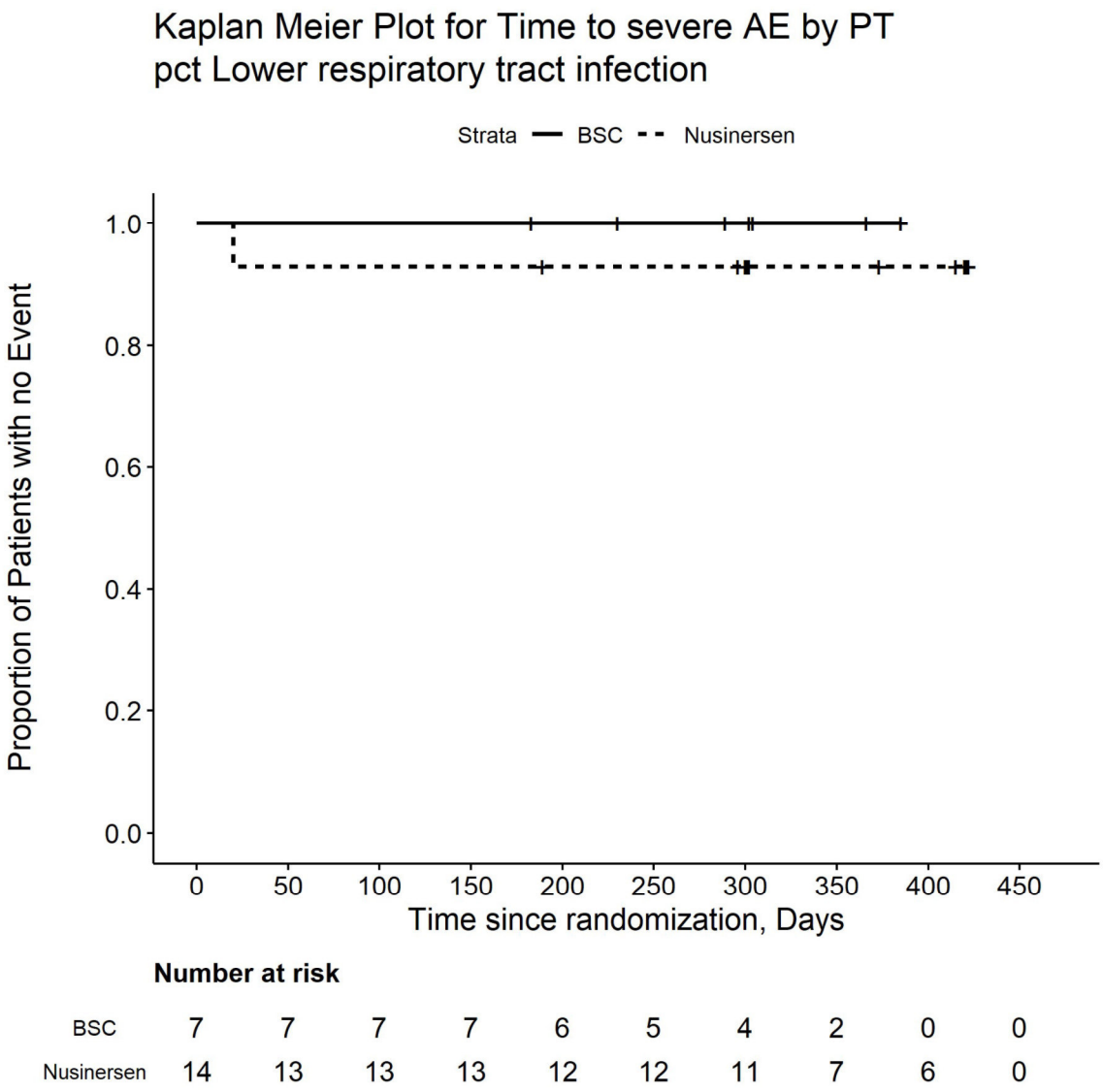
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



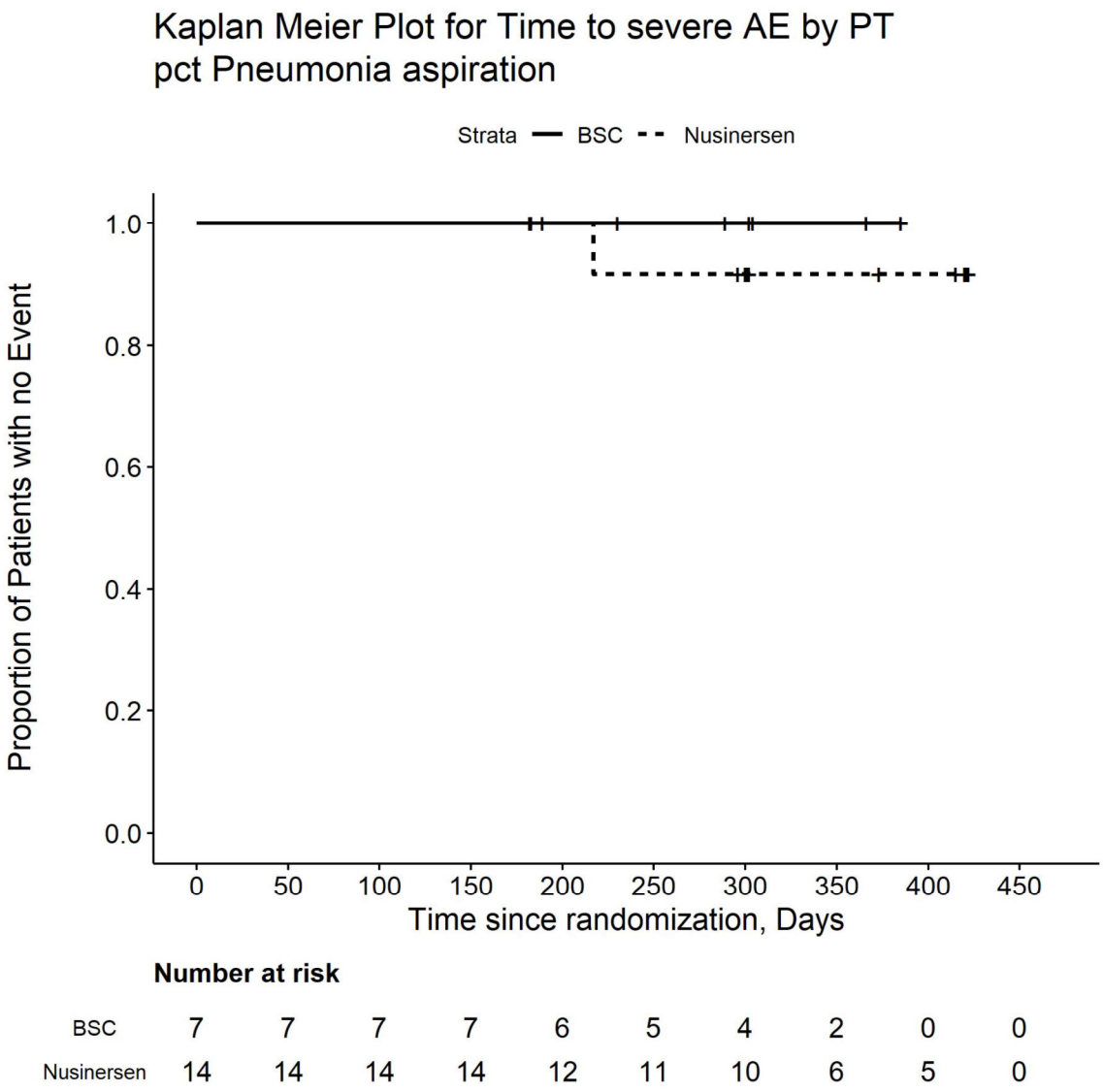
Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



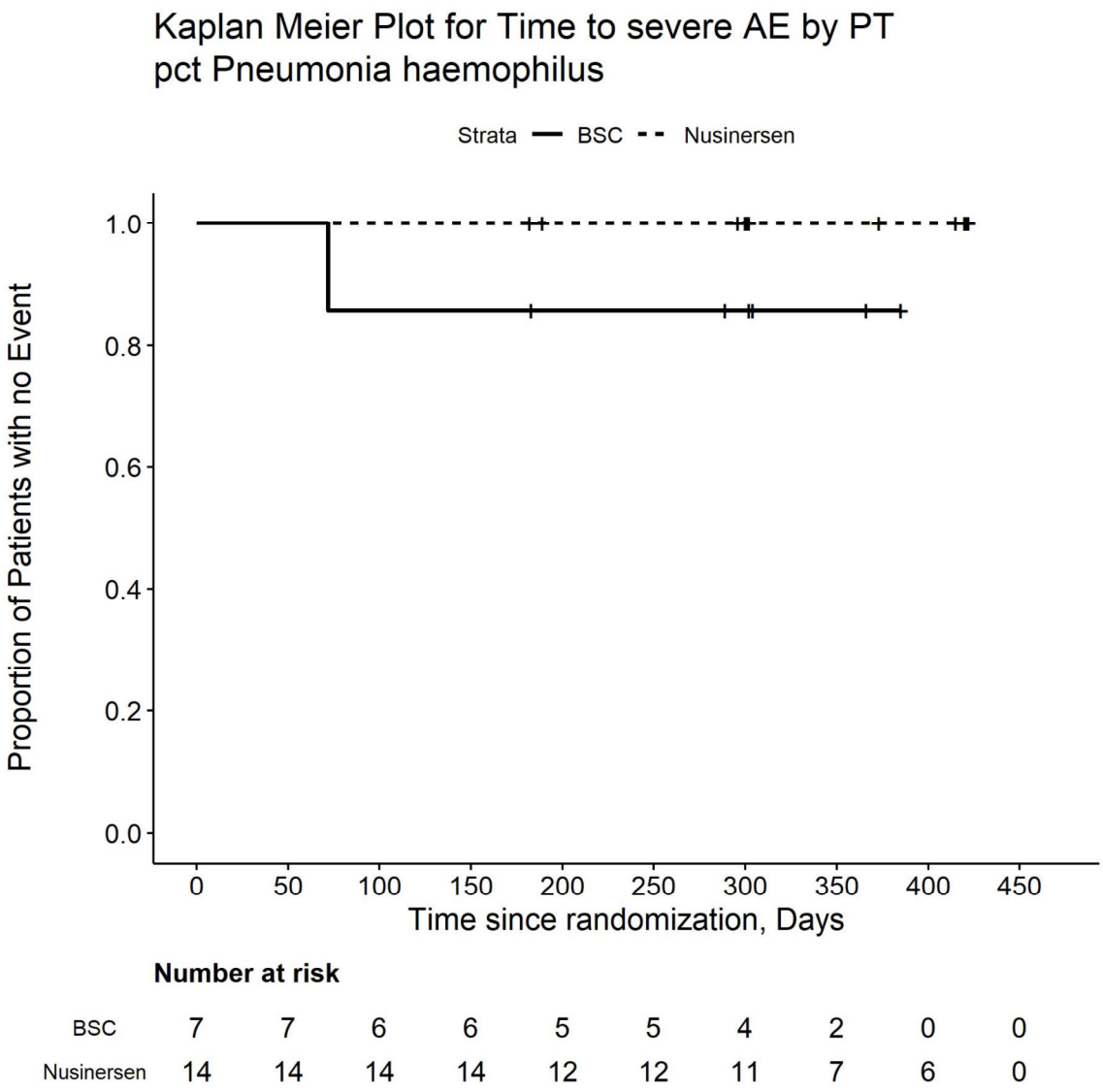
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	13	13	12	12	11	7	6	0



Number at risk

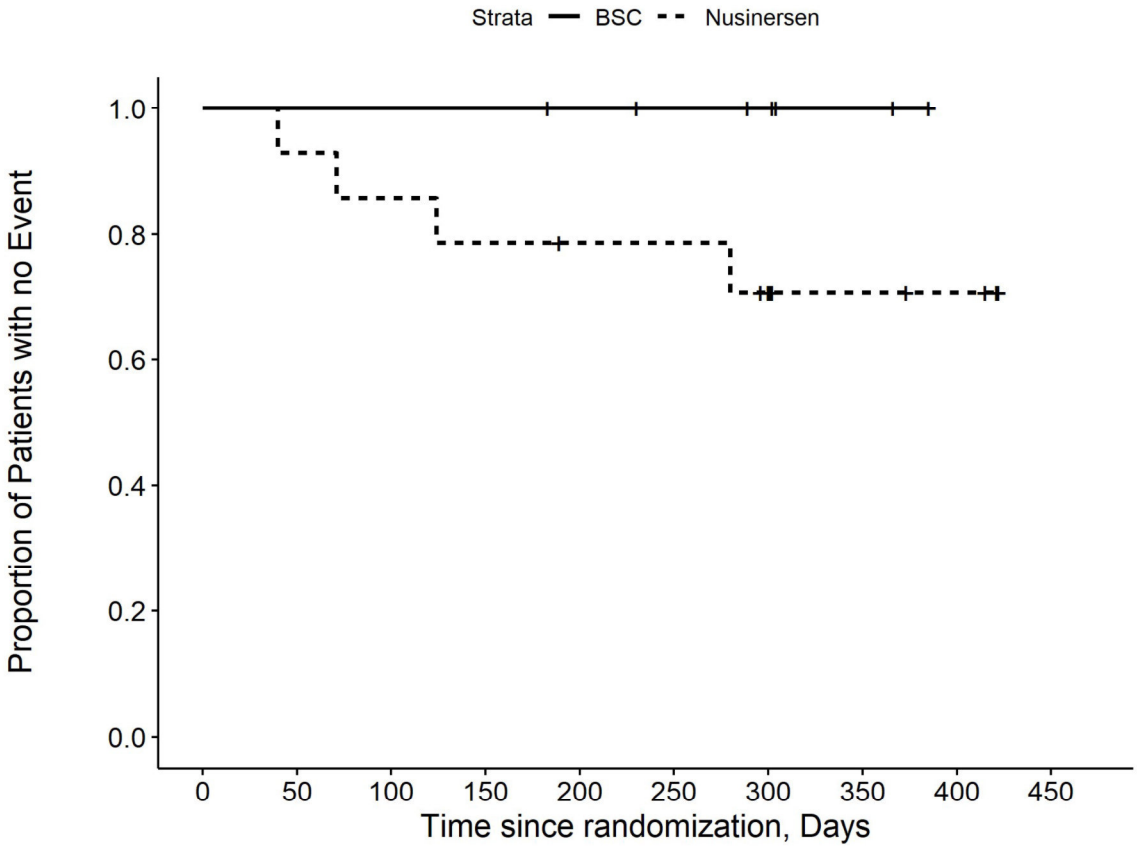
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	11	10	6	5	0



Number at risk

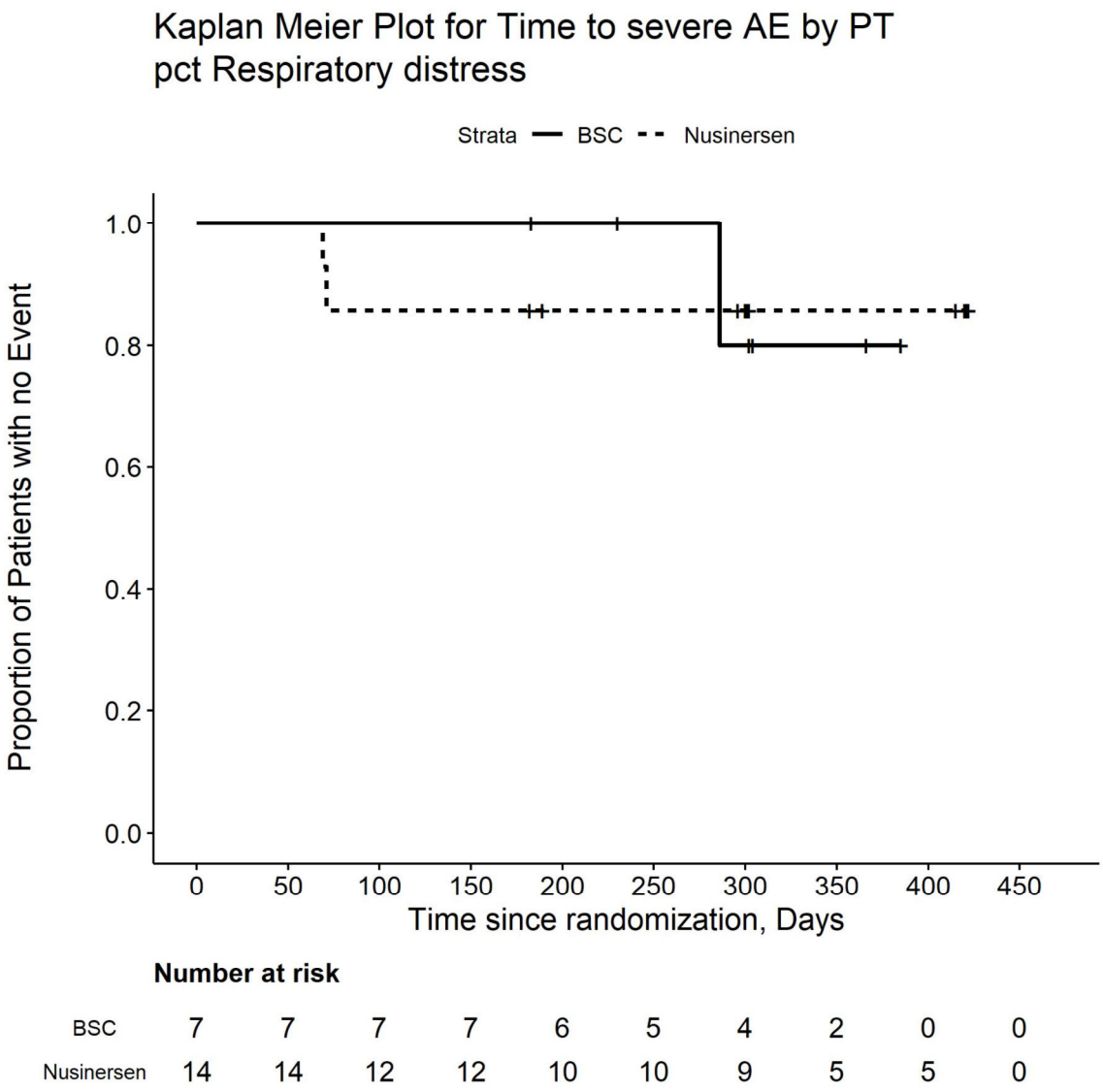
BSC	7	7	6	6	5	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for Time to severe AE by PT
pct Pneumonia



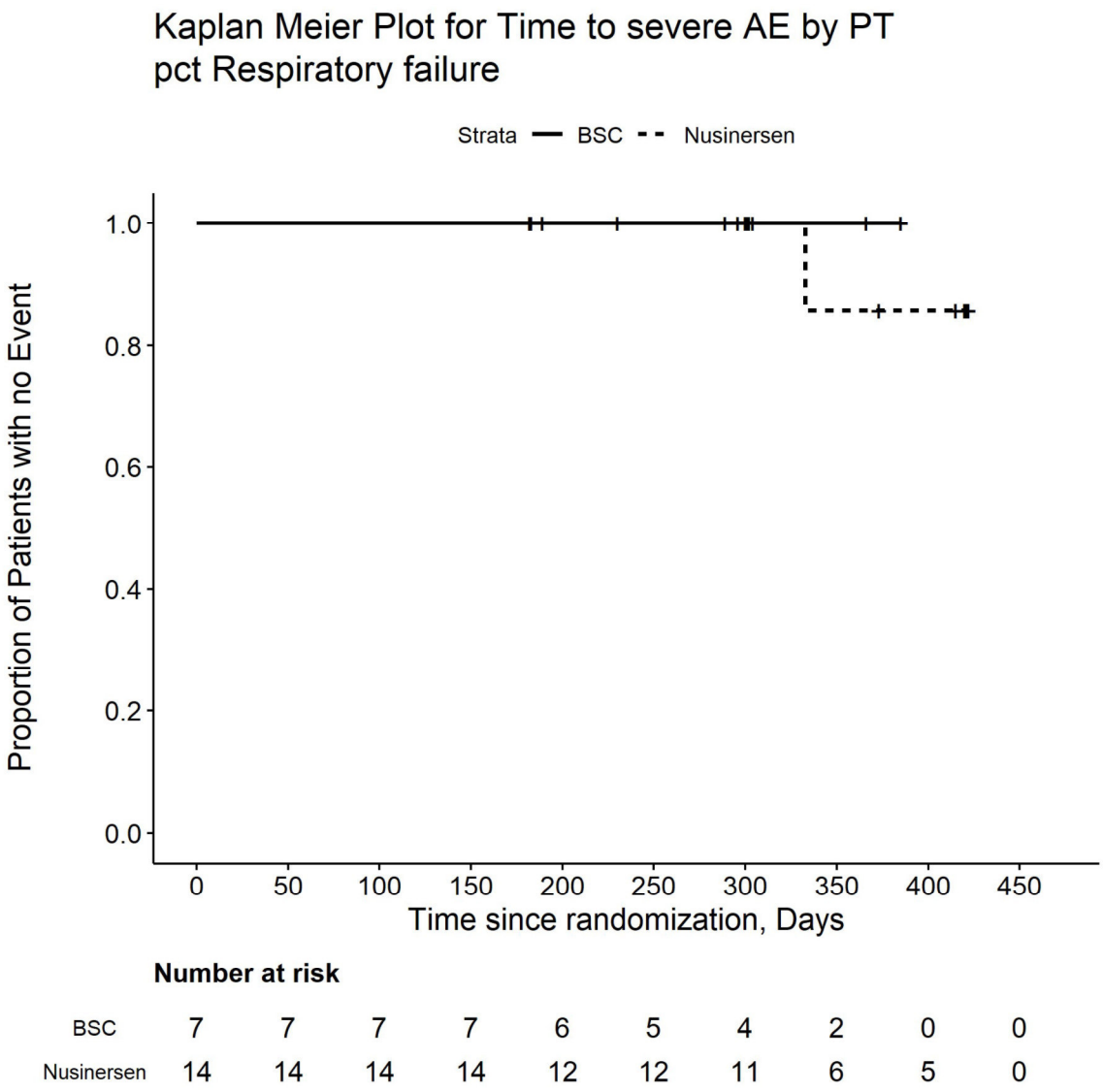
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	13	12	11	10	10	8	5	4	0



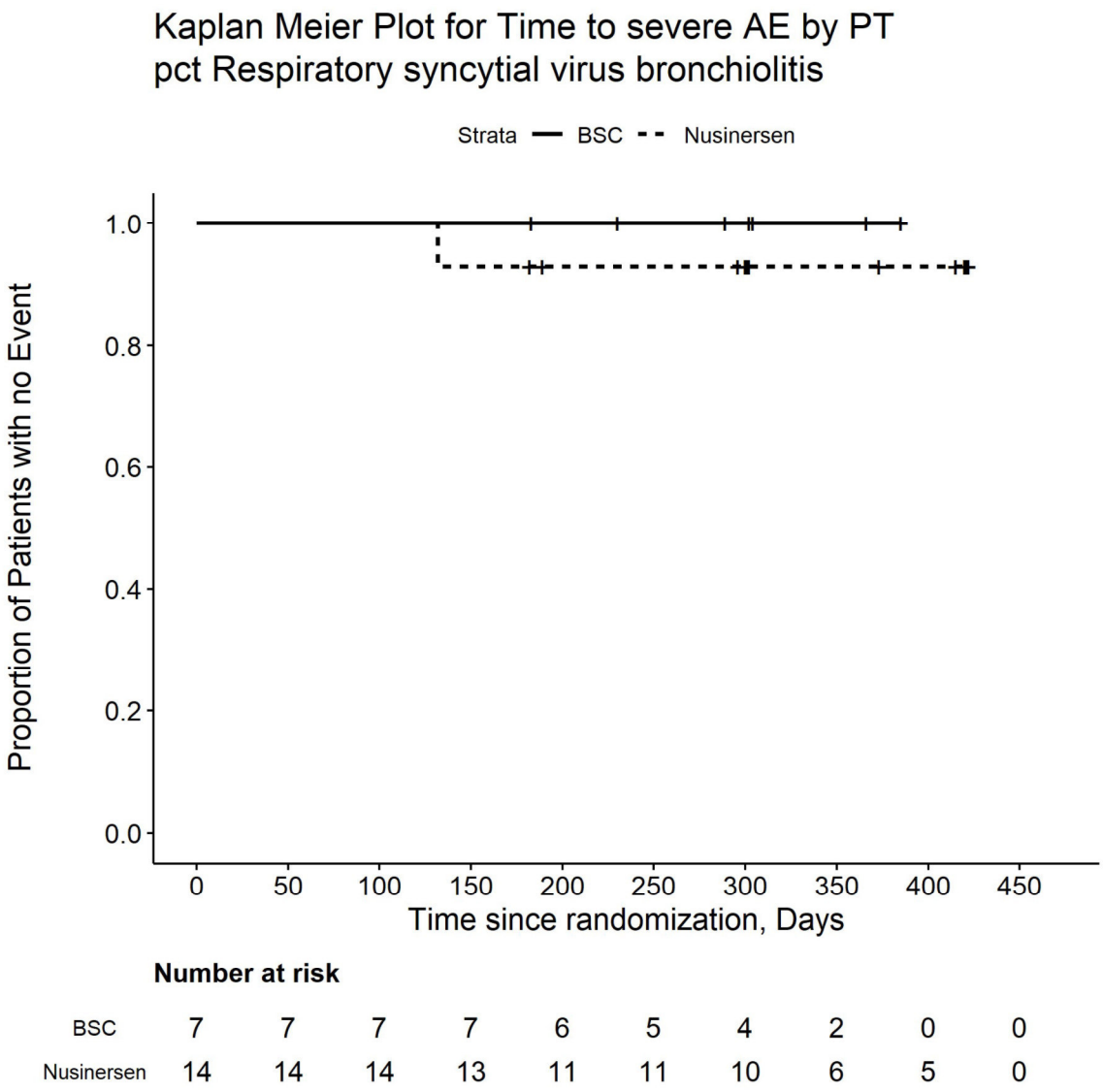
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	12	12	10	10	9	5	5	0



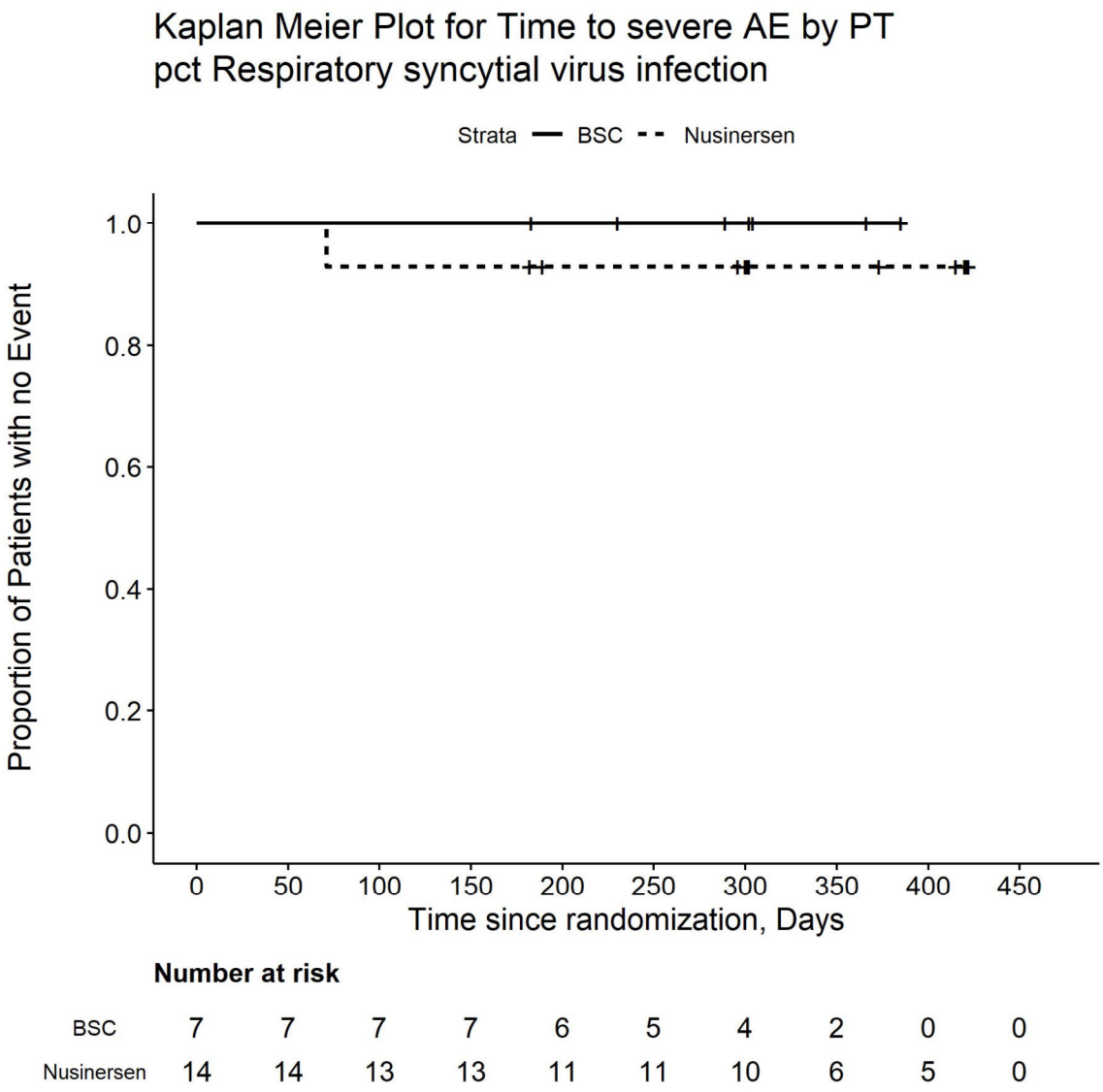
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	6	5	0



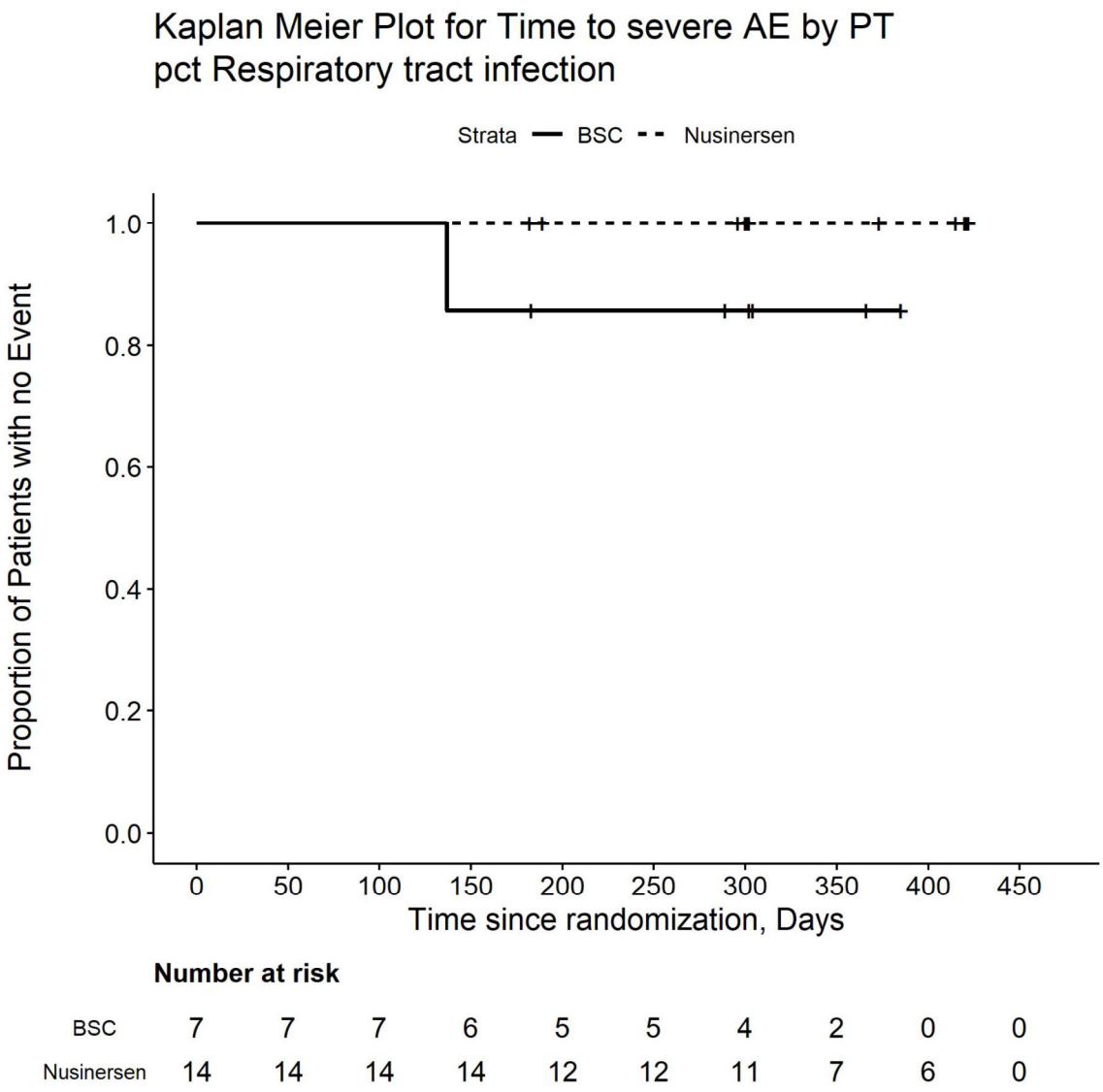
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	13	11	11	10	6	5	0



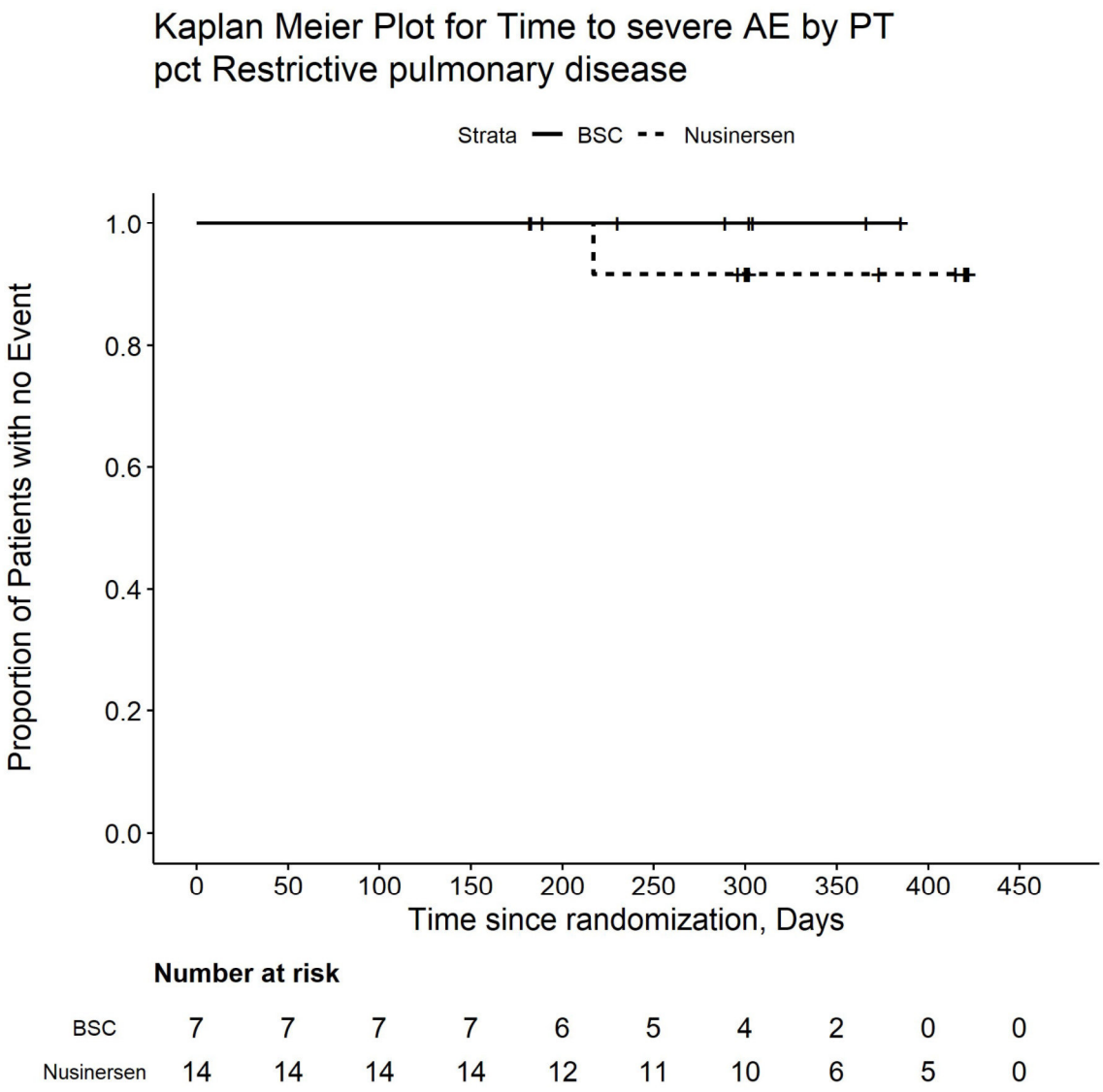
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	13	13	11	11	10	6	5	0



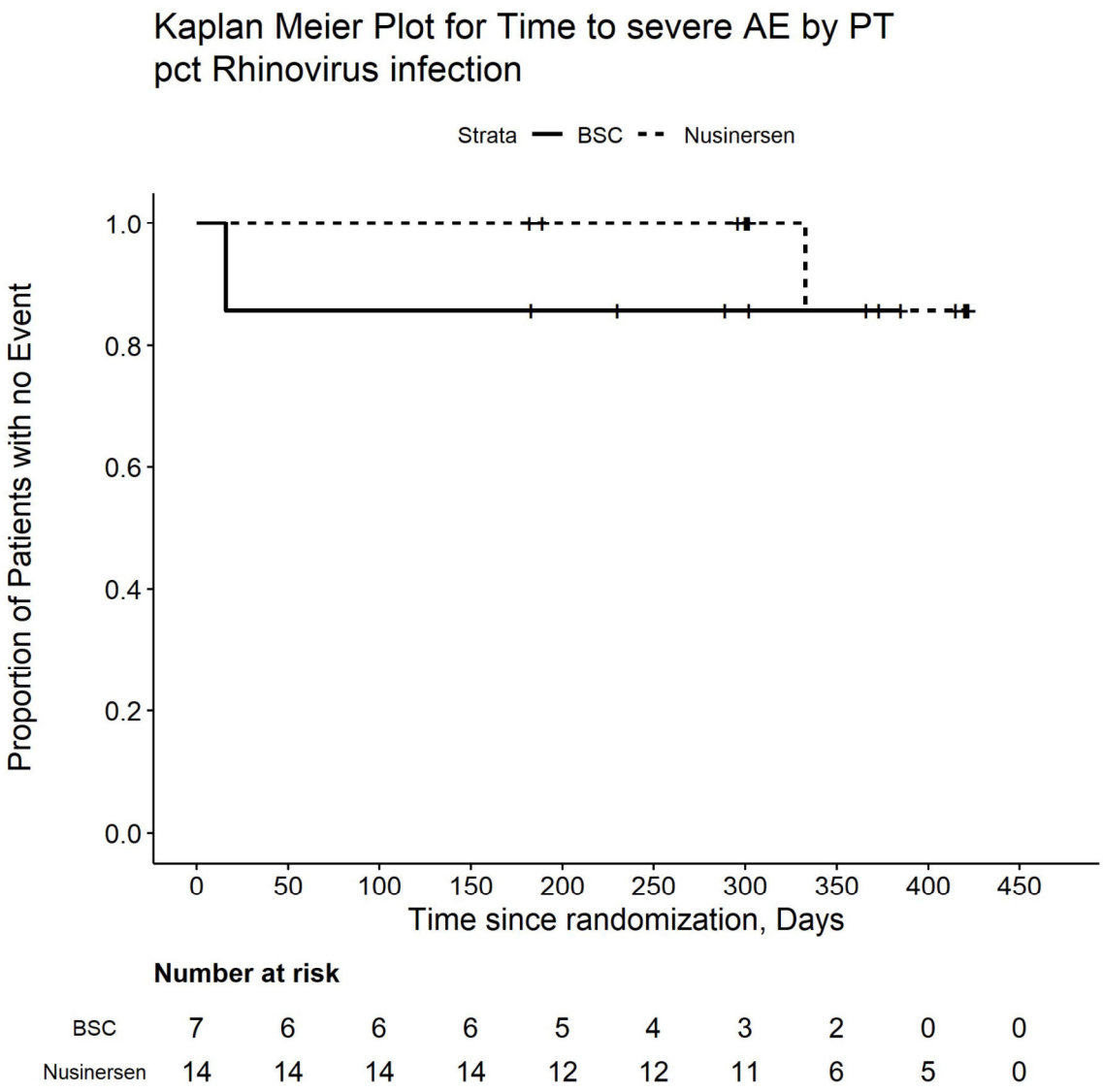
Number at risk

BSC	7	7	7	6	5	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



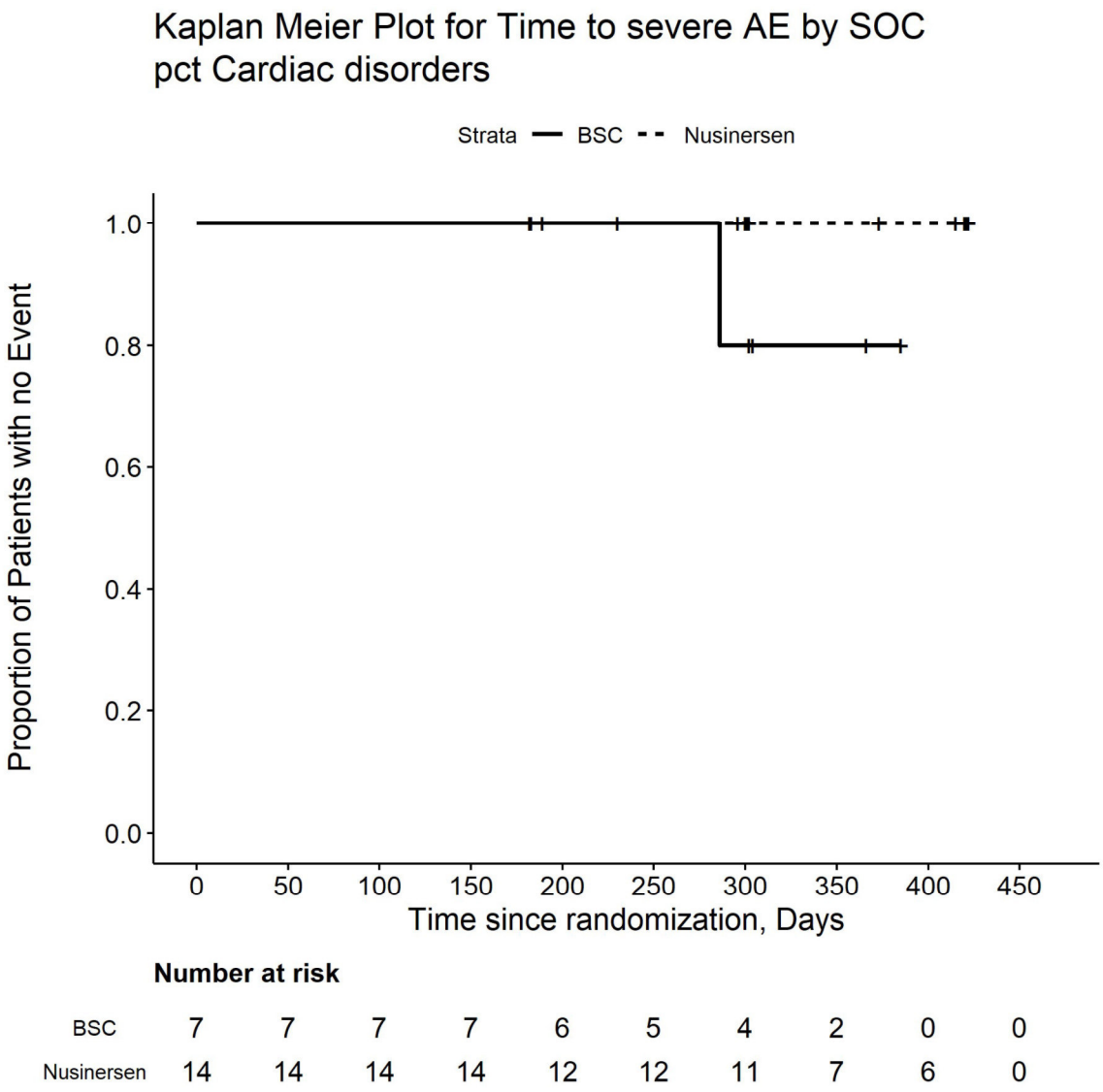
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	11	10	6	5	0



Number at risk

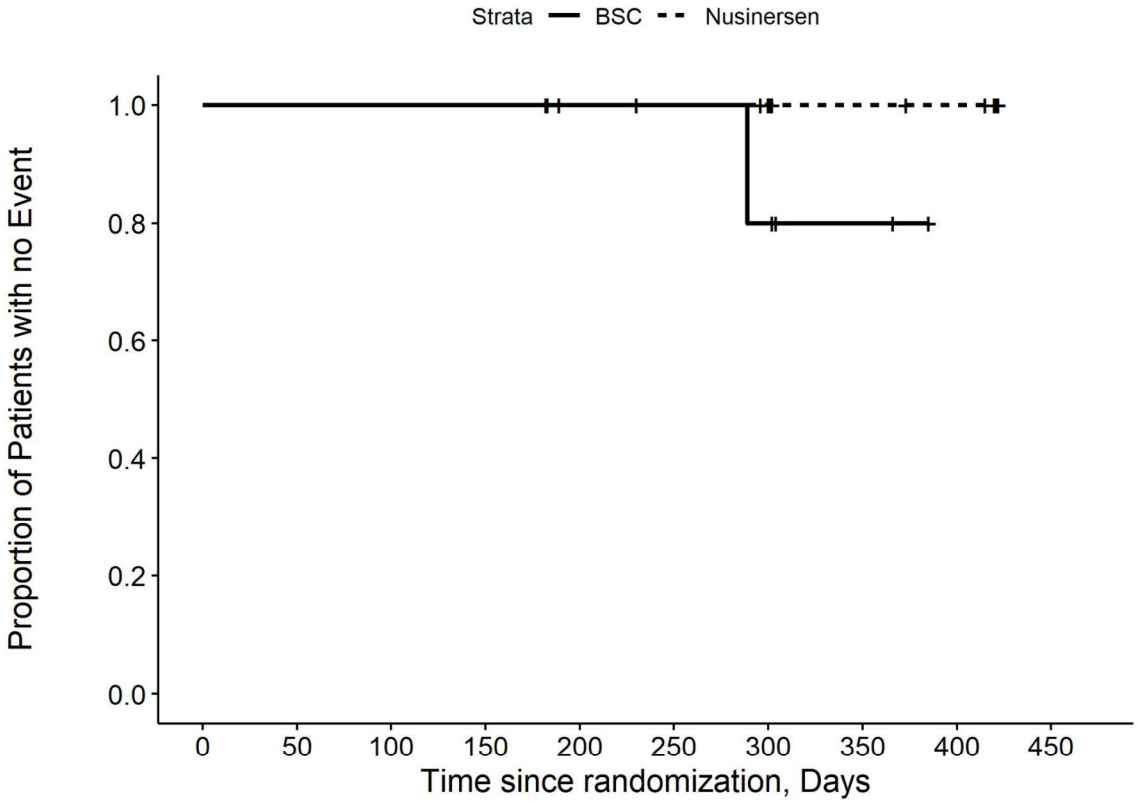
BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	6	5	0



Number at risk

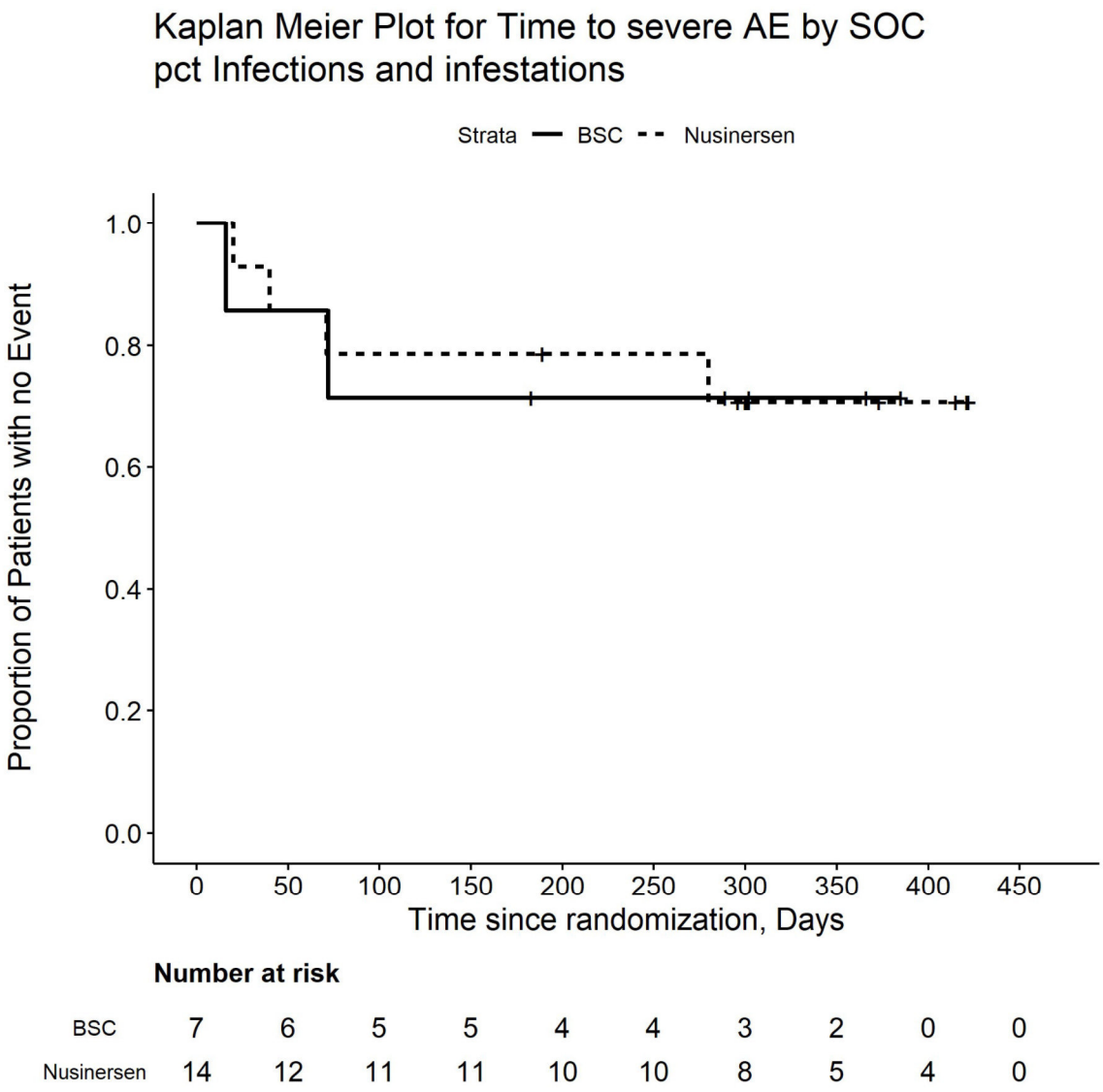
BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0

Kaplan Meier Plot for Time to severe AE by SOC pct General disorders and administration site conditions



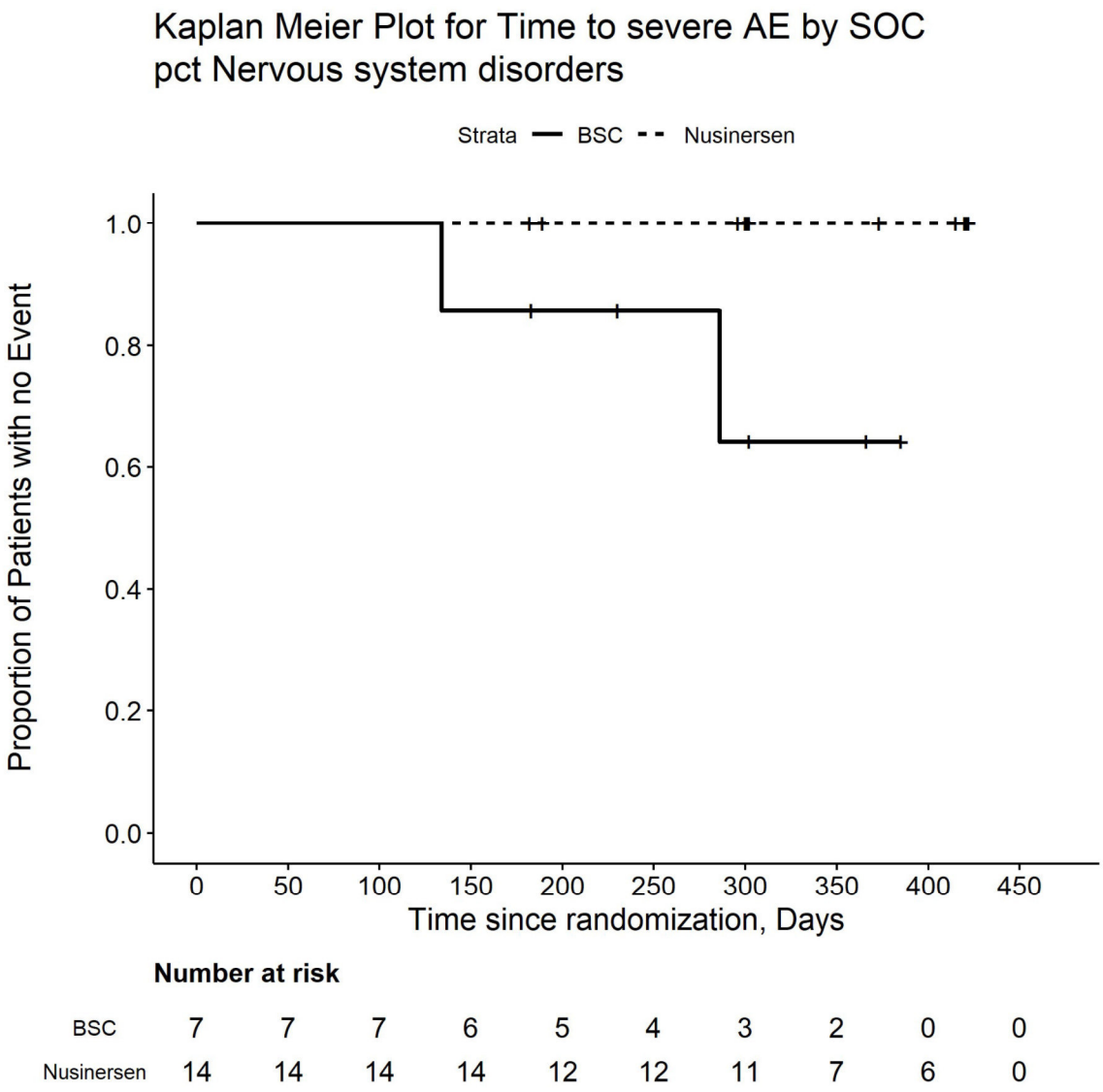
Number at risk

BSC	7	7	7	7	6	5	4	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



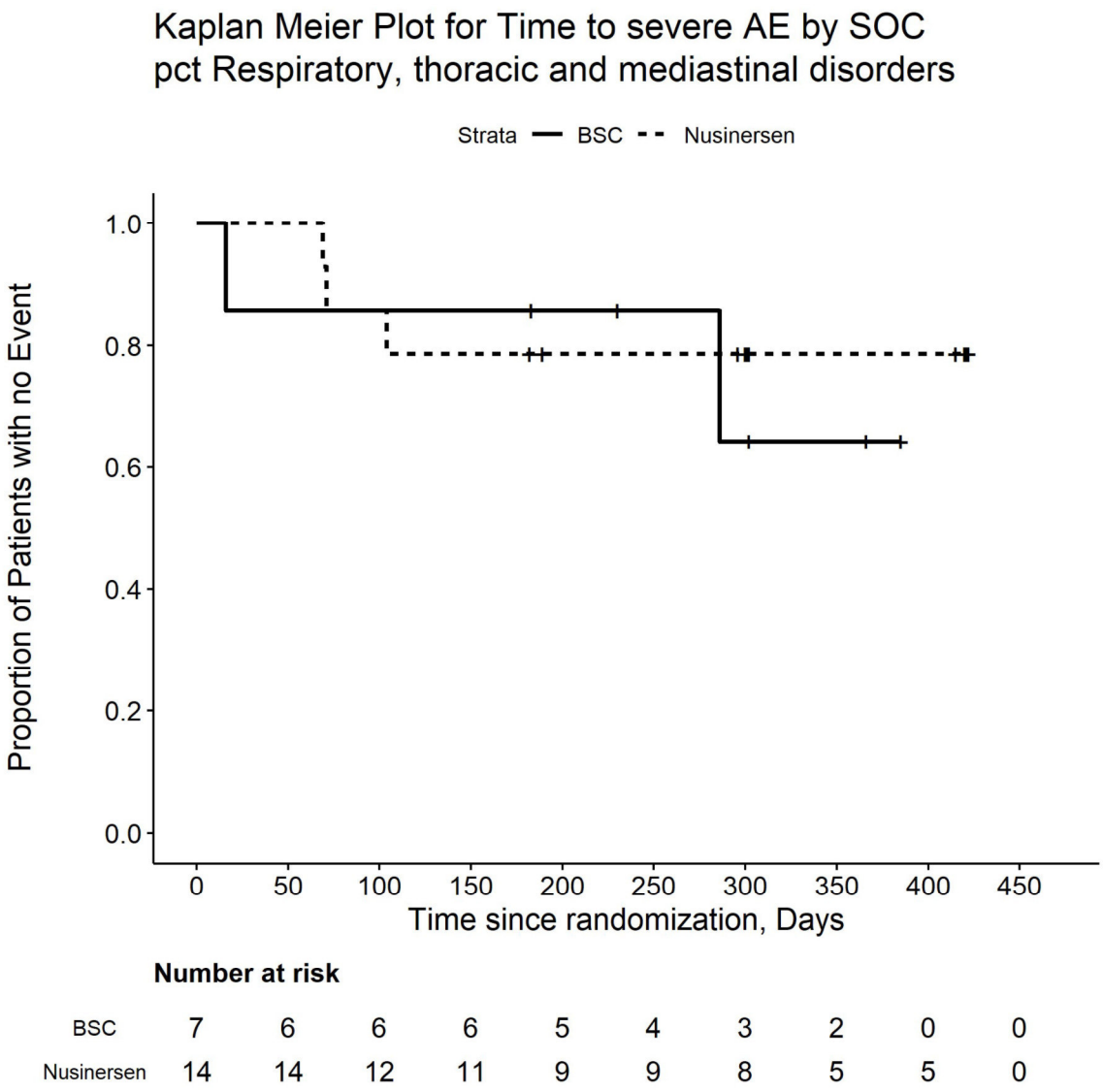
Number at risk

BSC	7	6	5	5	4	4	3	2	0	0
Nusinersen	14	12	11	11	10	10	8	5	4	0



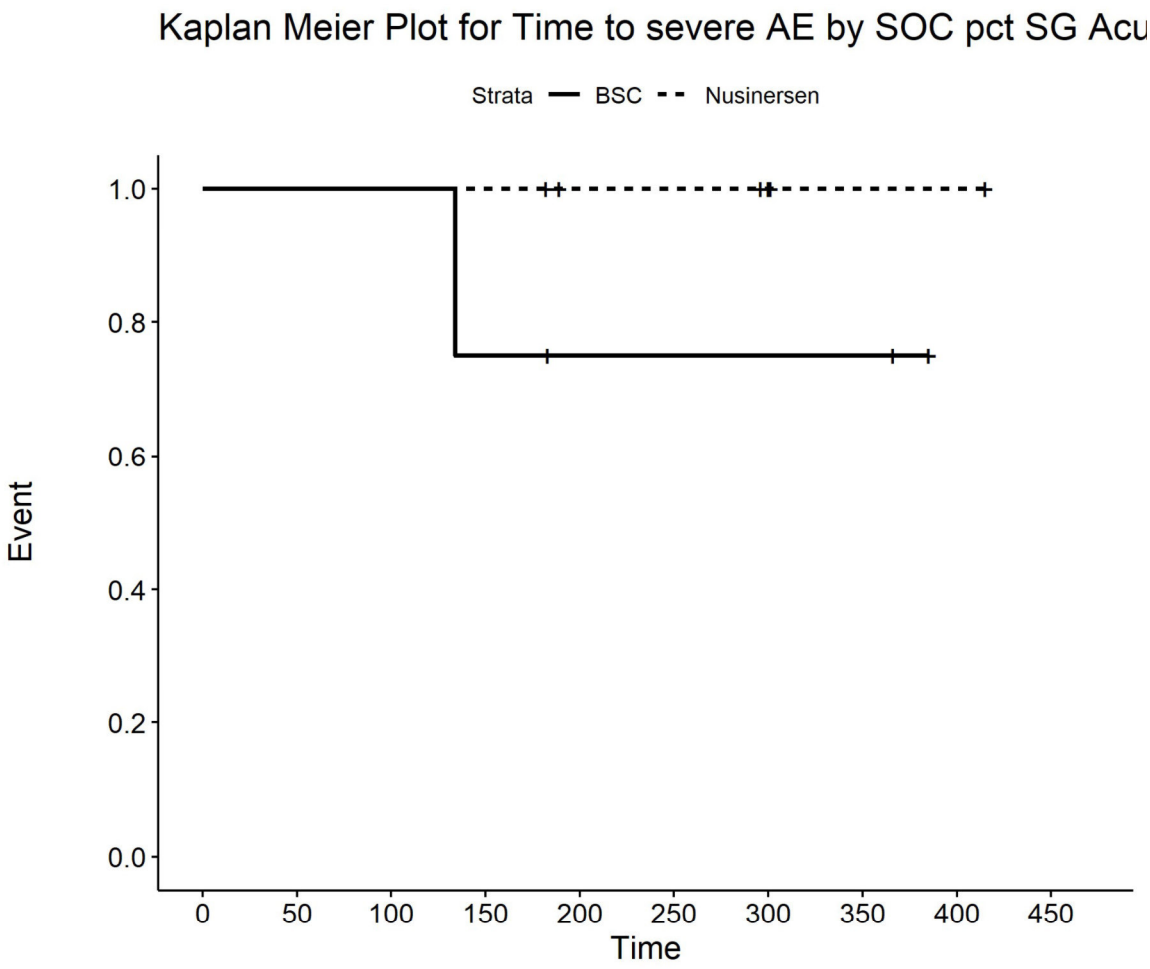
Number at risk

BSC	7	7	7	6	5	4	3	2	0	0
Nusinersen	14	14	14	14	12	12	11	7	6	0



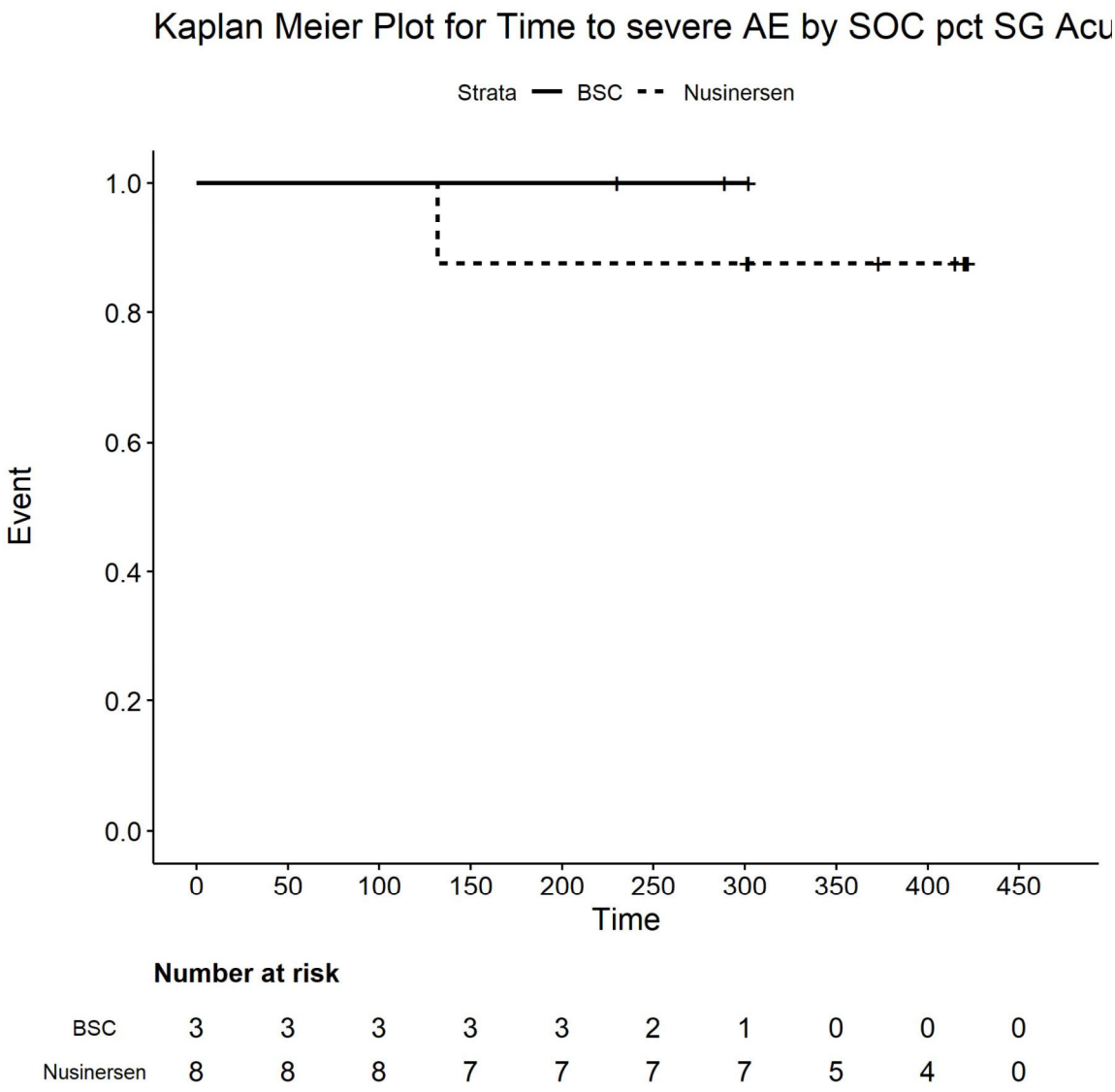
Number at risk

BSC	7	6	6	6	5	4	3	2	0	0
Nusinersen	14	14	12	11	9	9	8	5	5	0



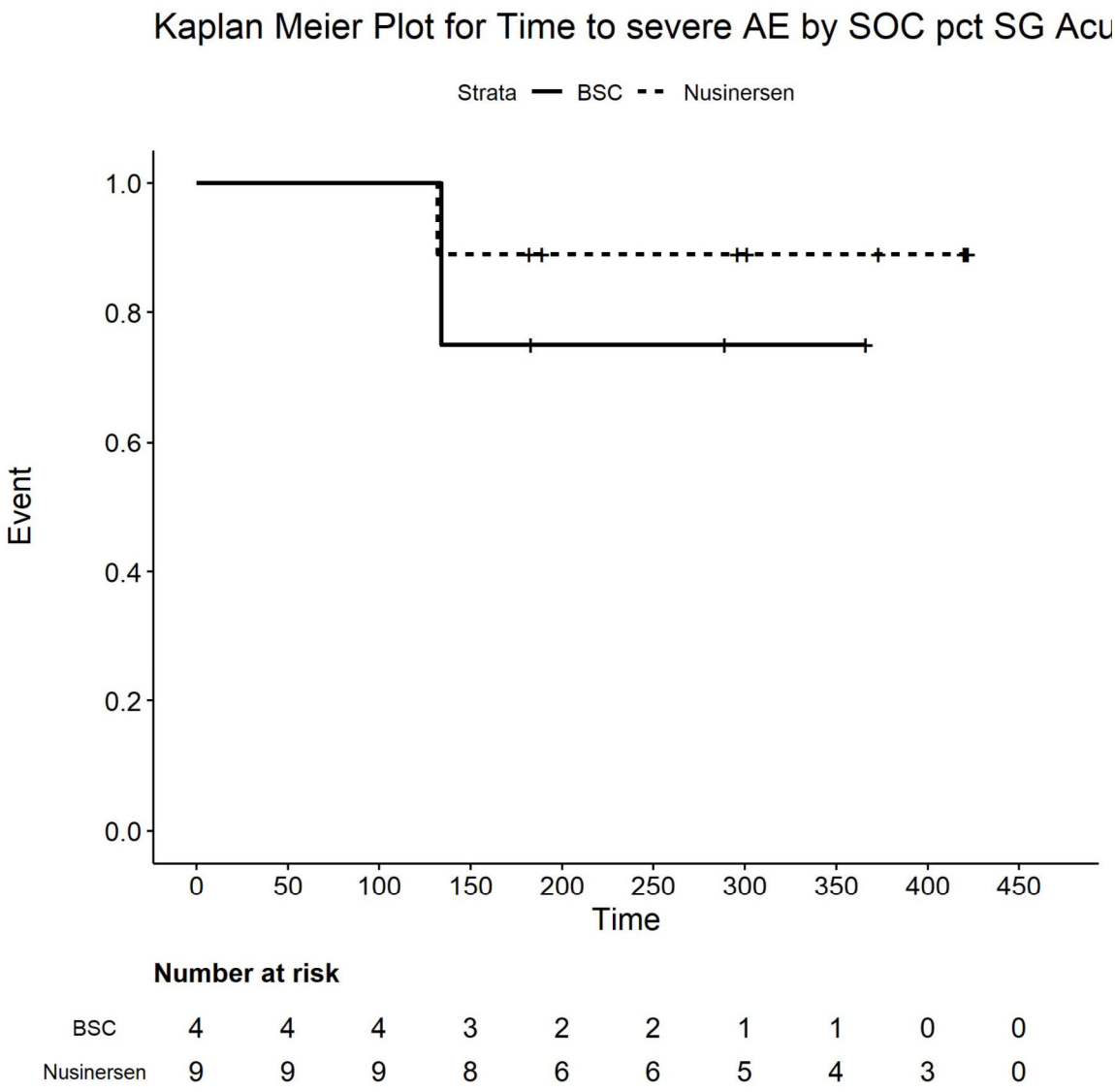
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



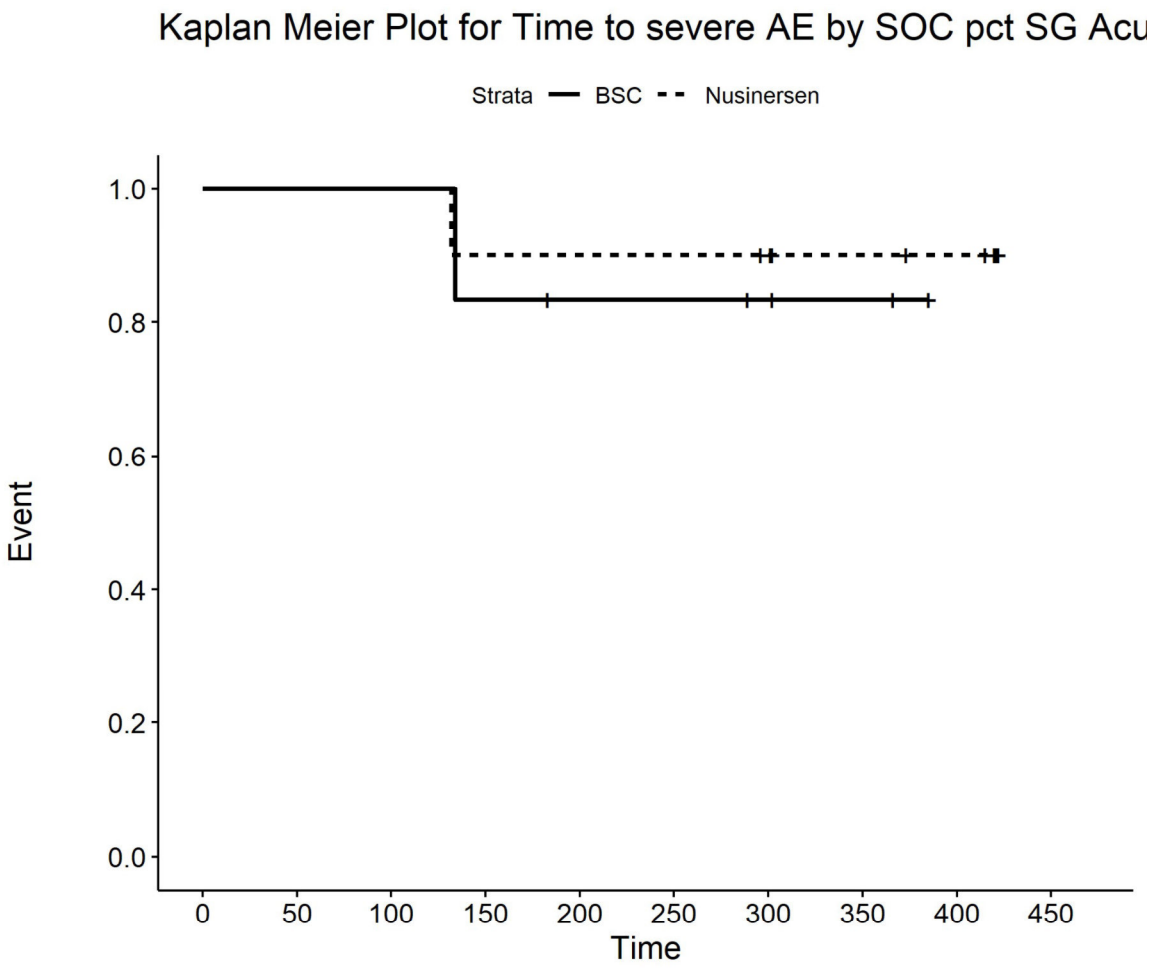
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



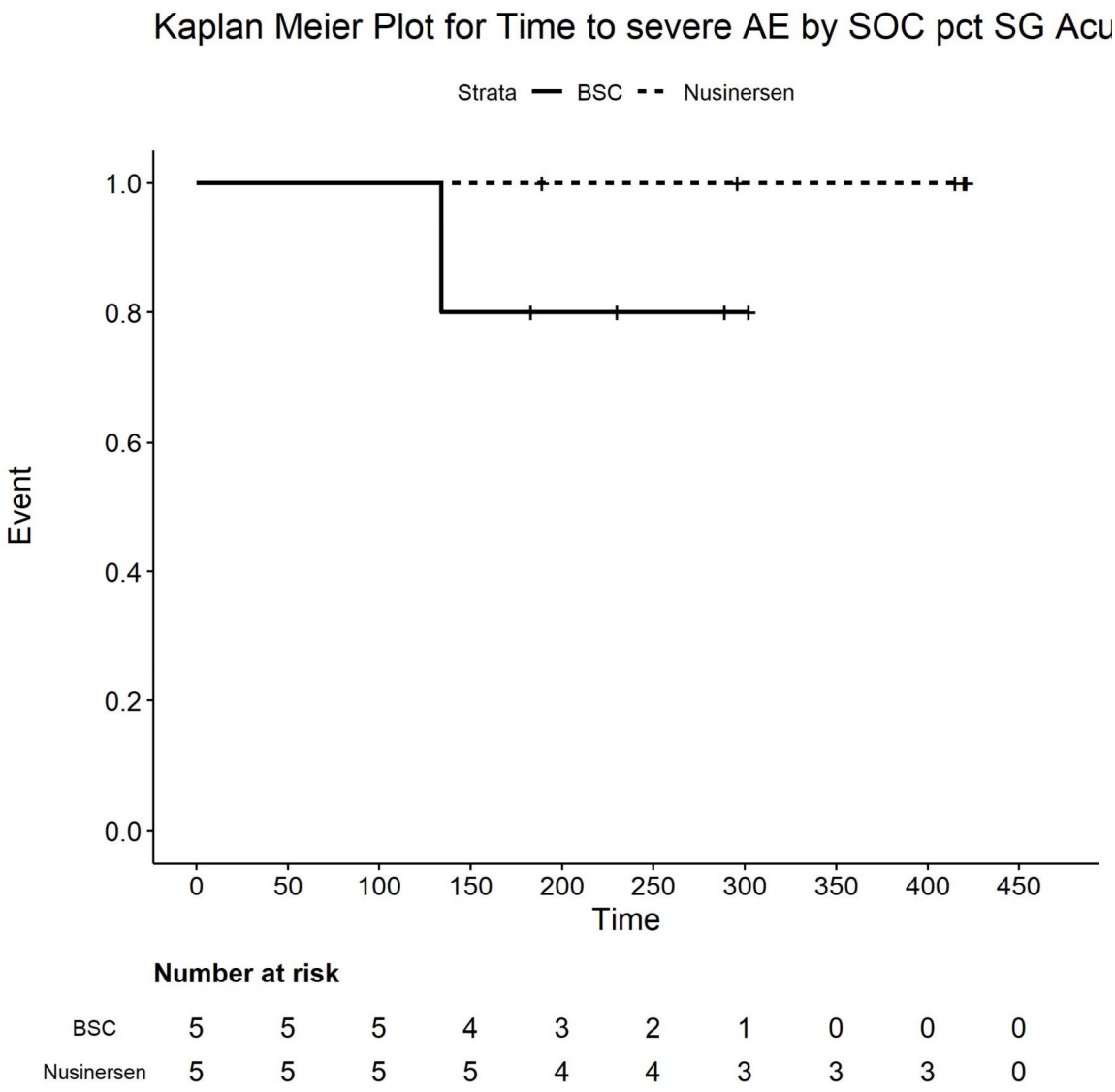
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



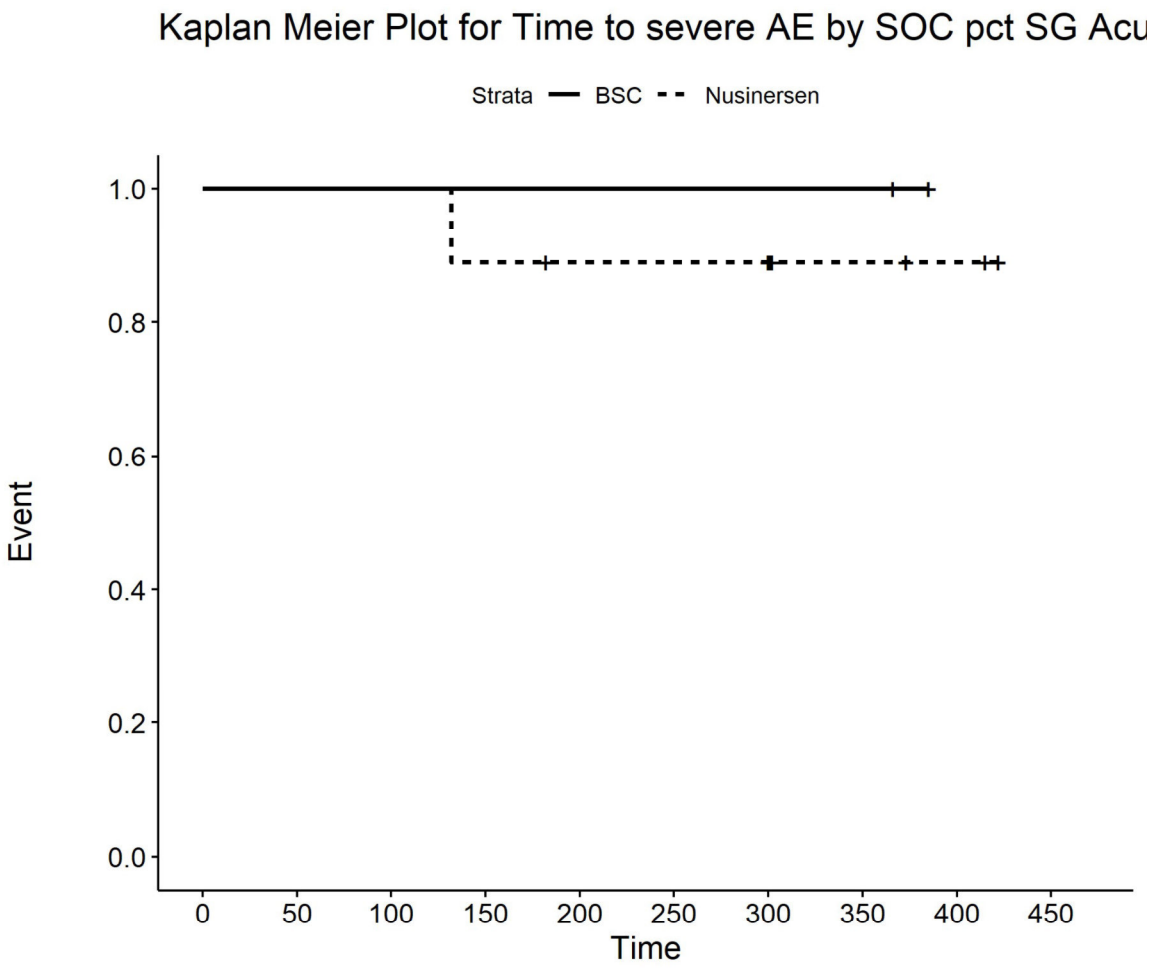
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



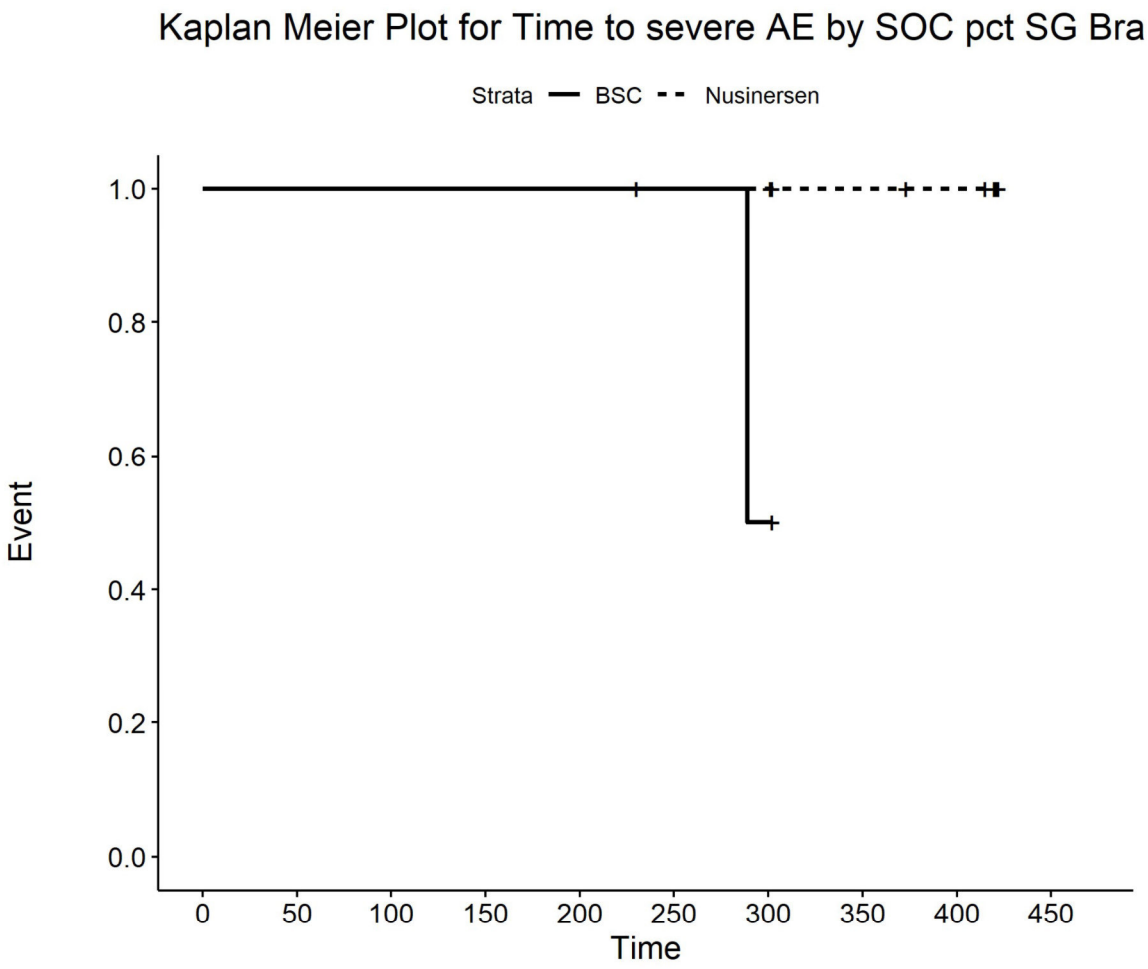
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



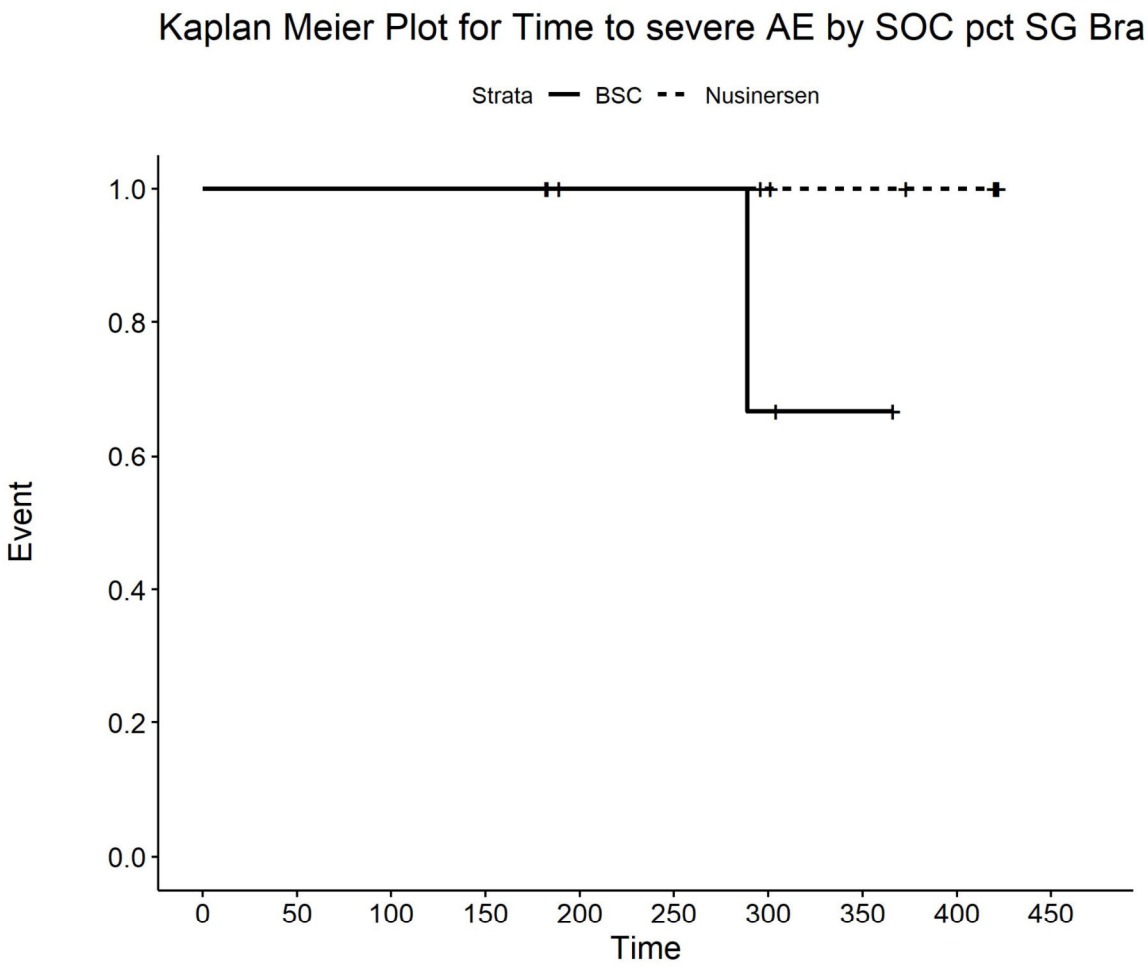
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



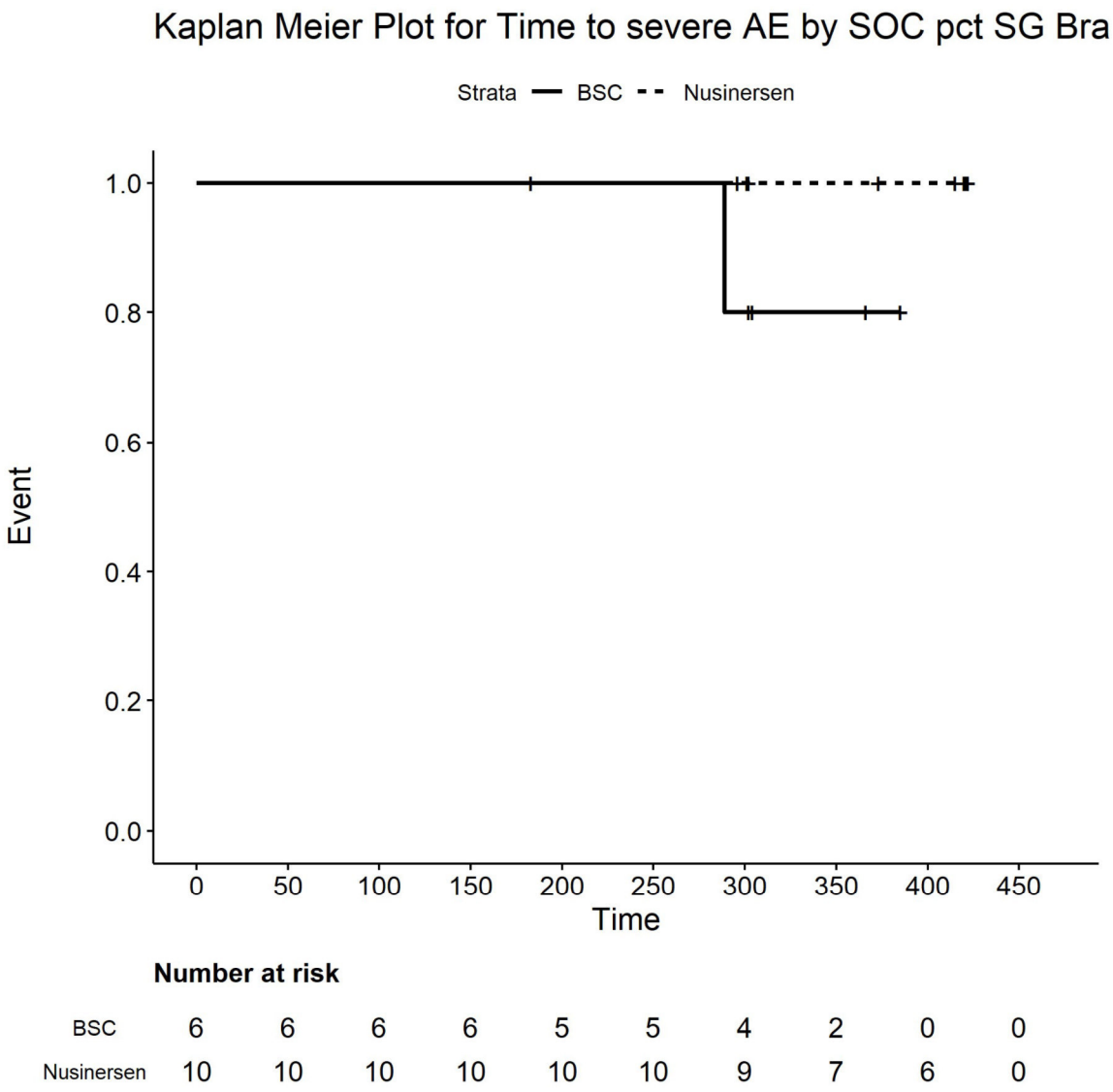
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



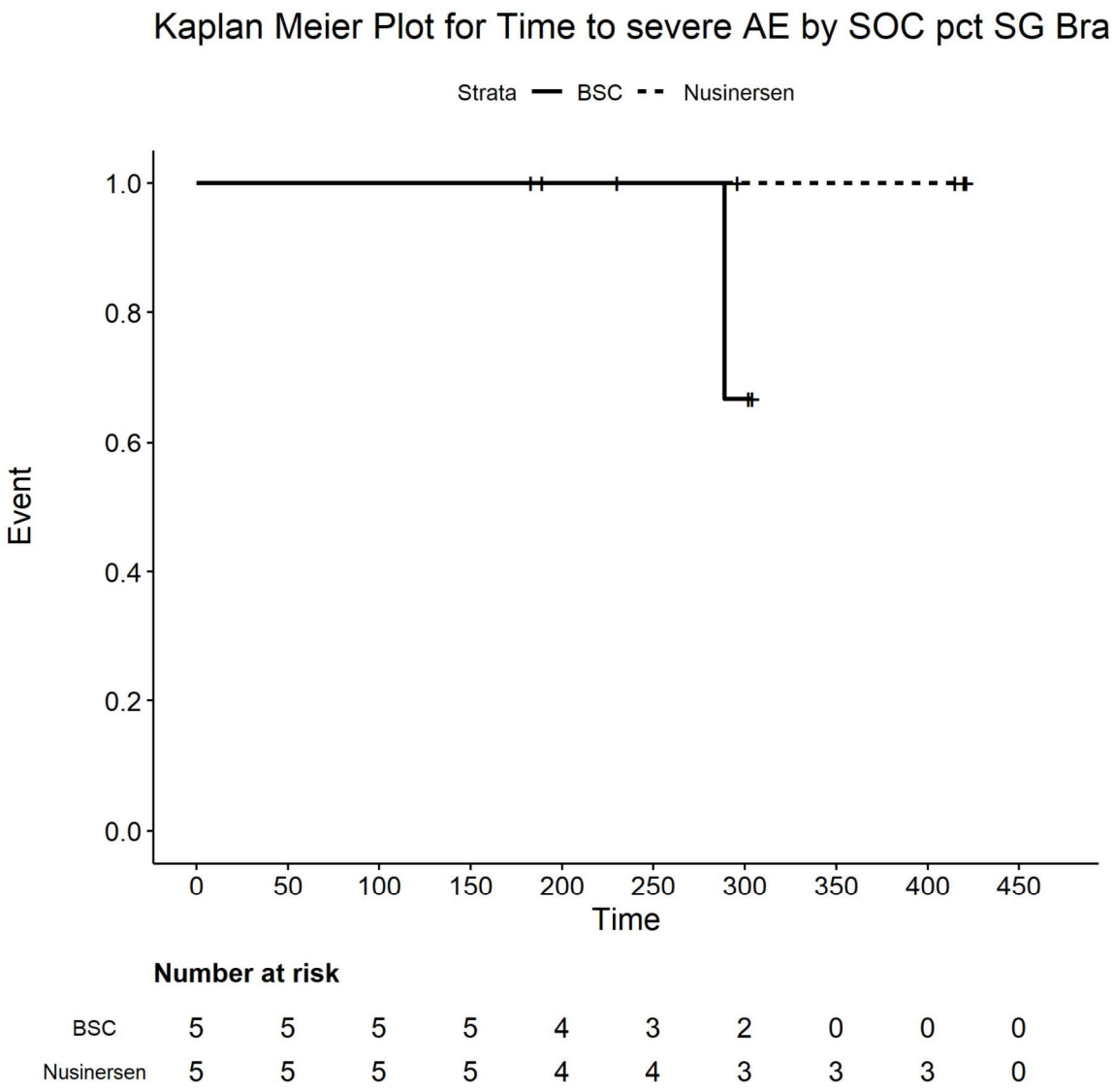
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



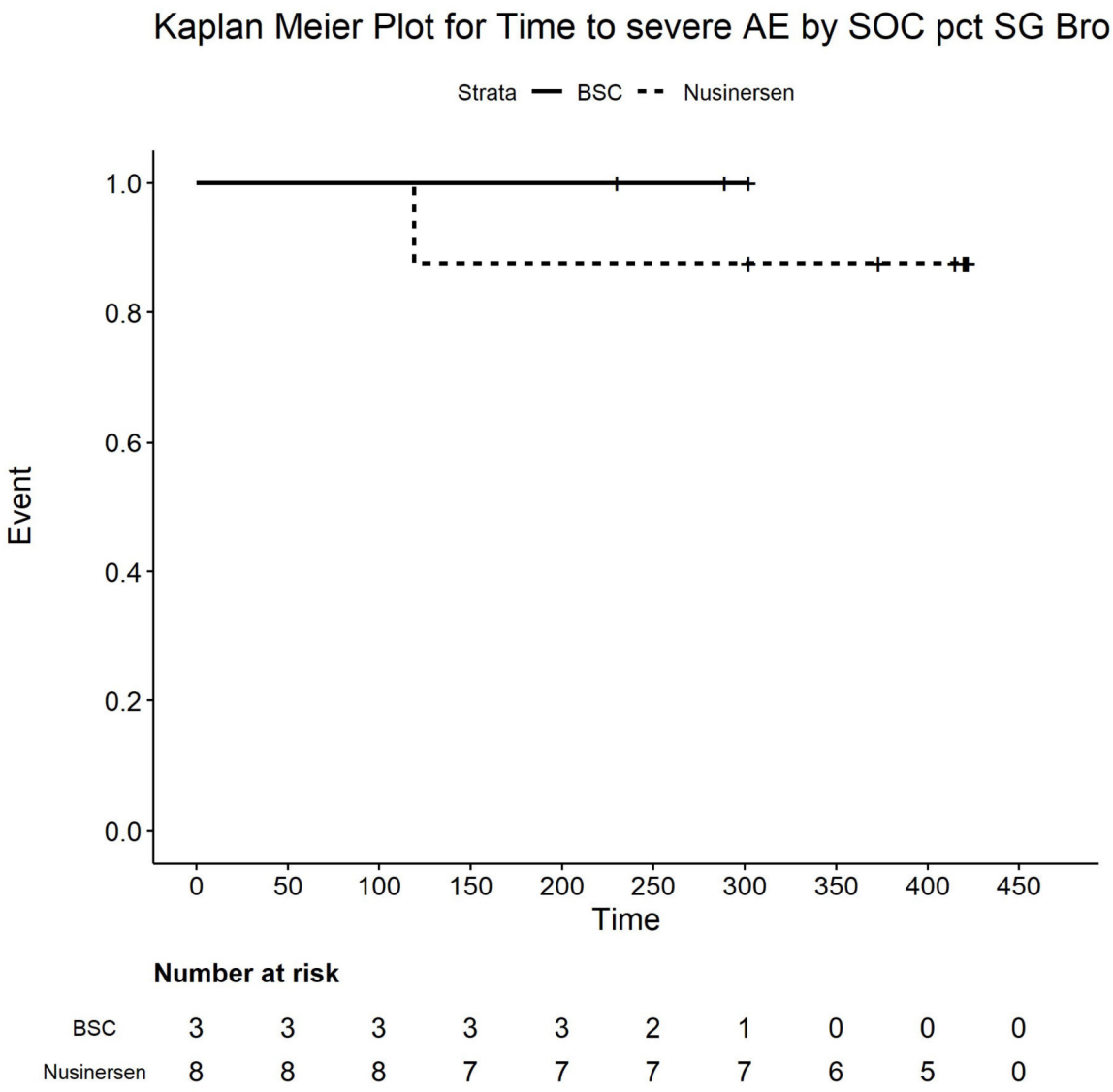
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



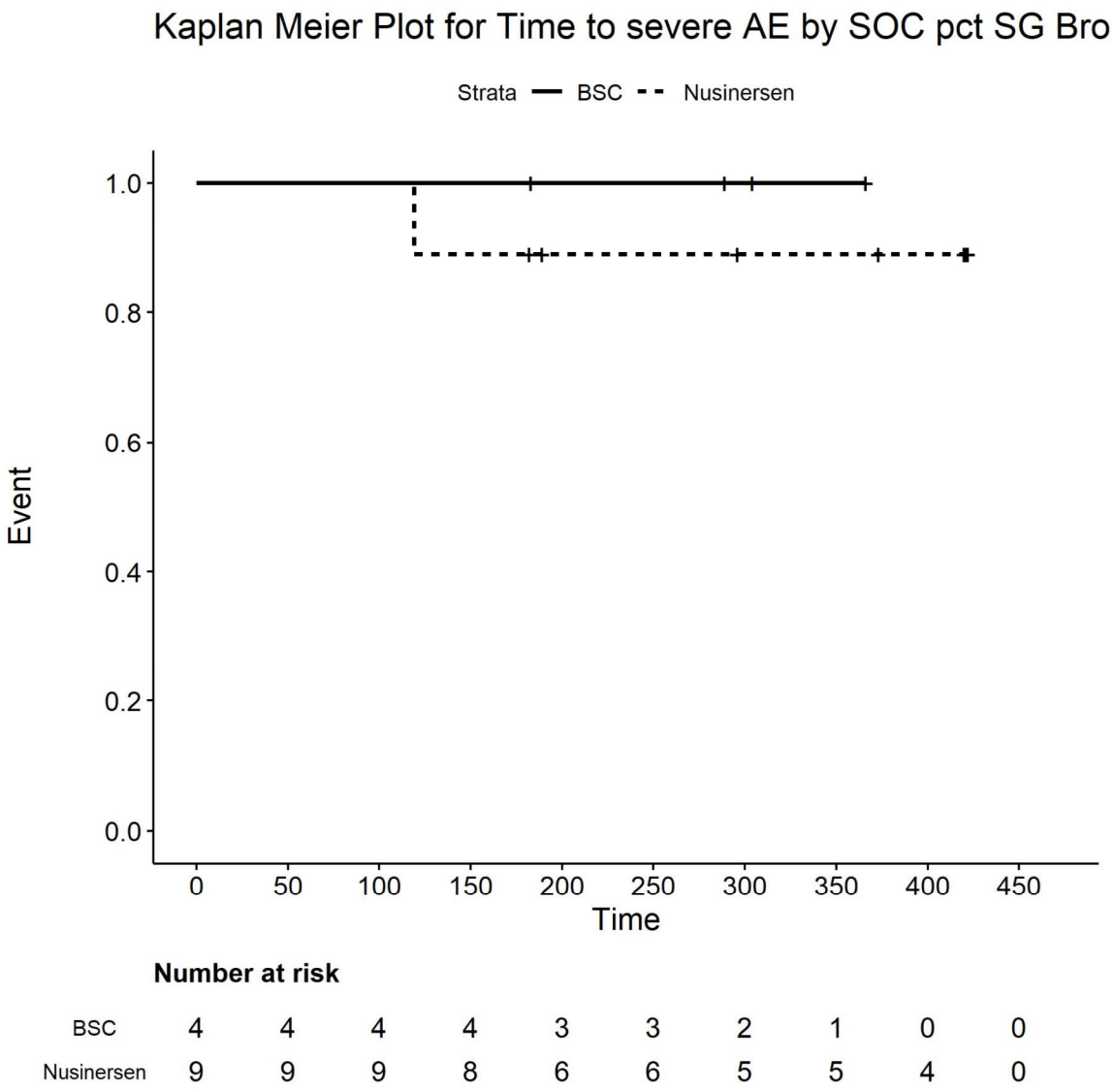
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



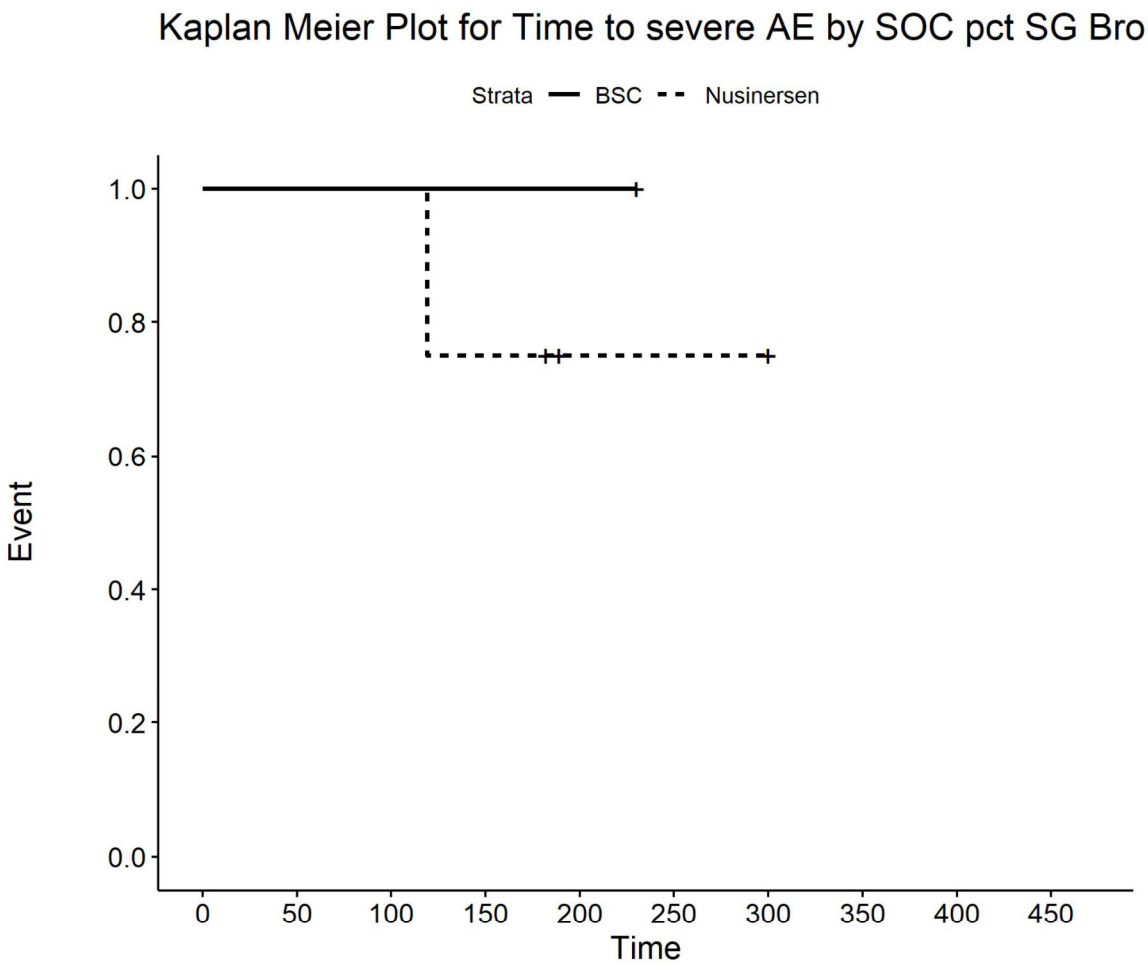
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	6	5	0



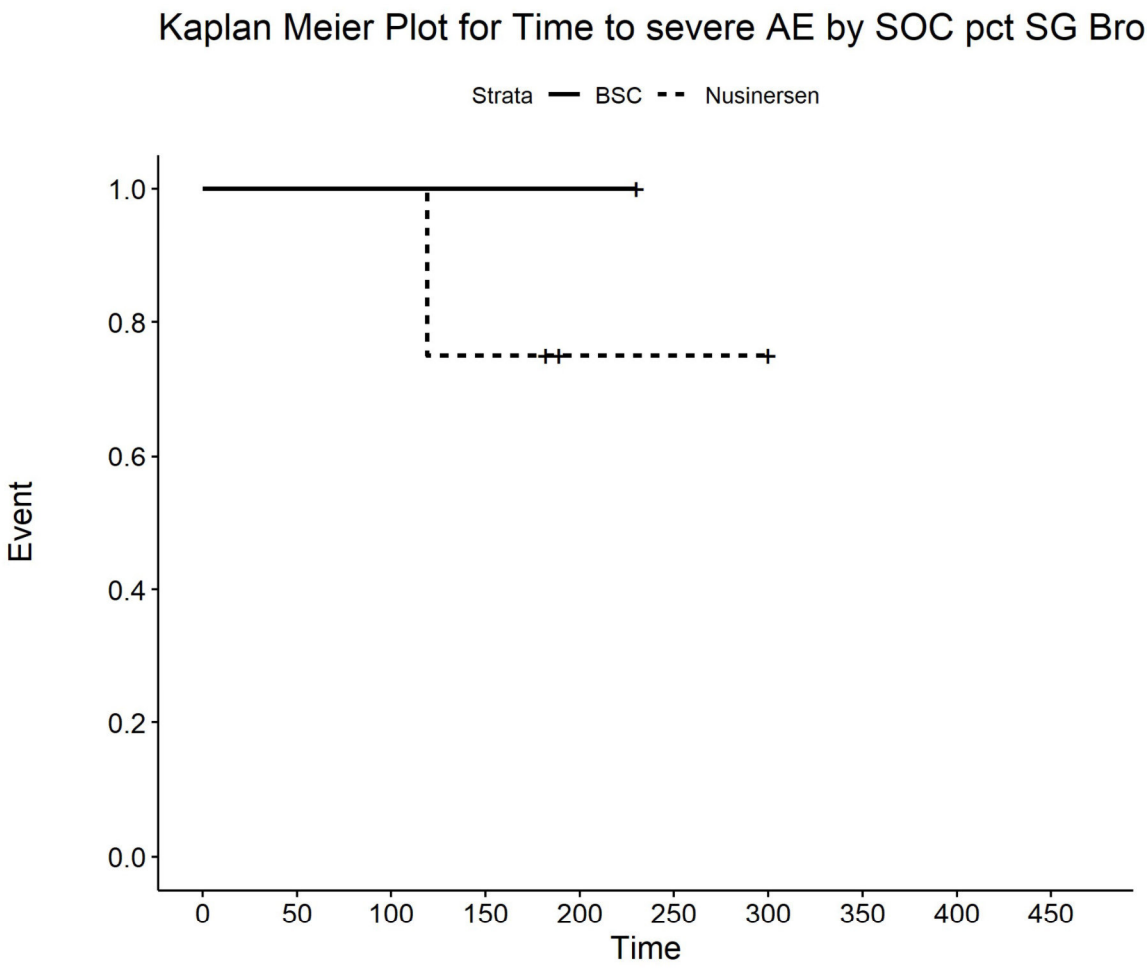
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	5	4	0



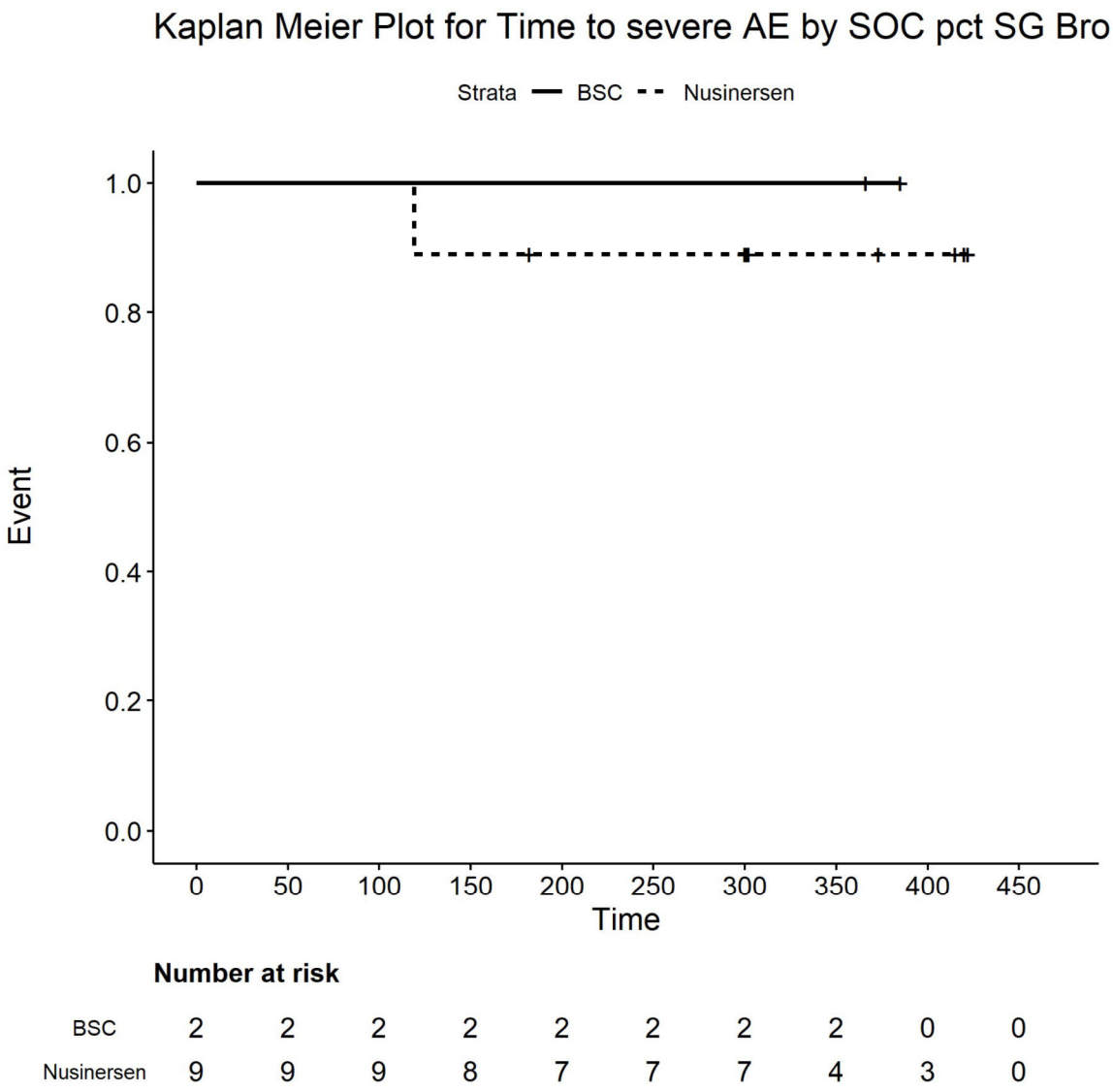
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



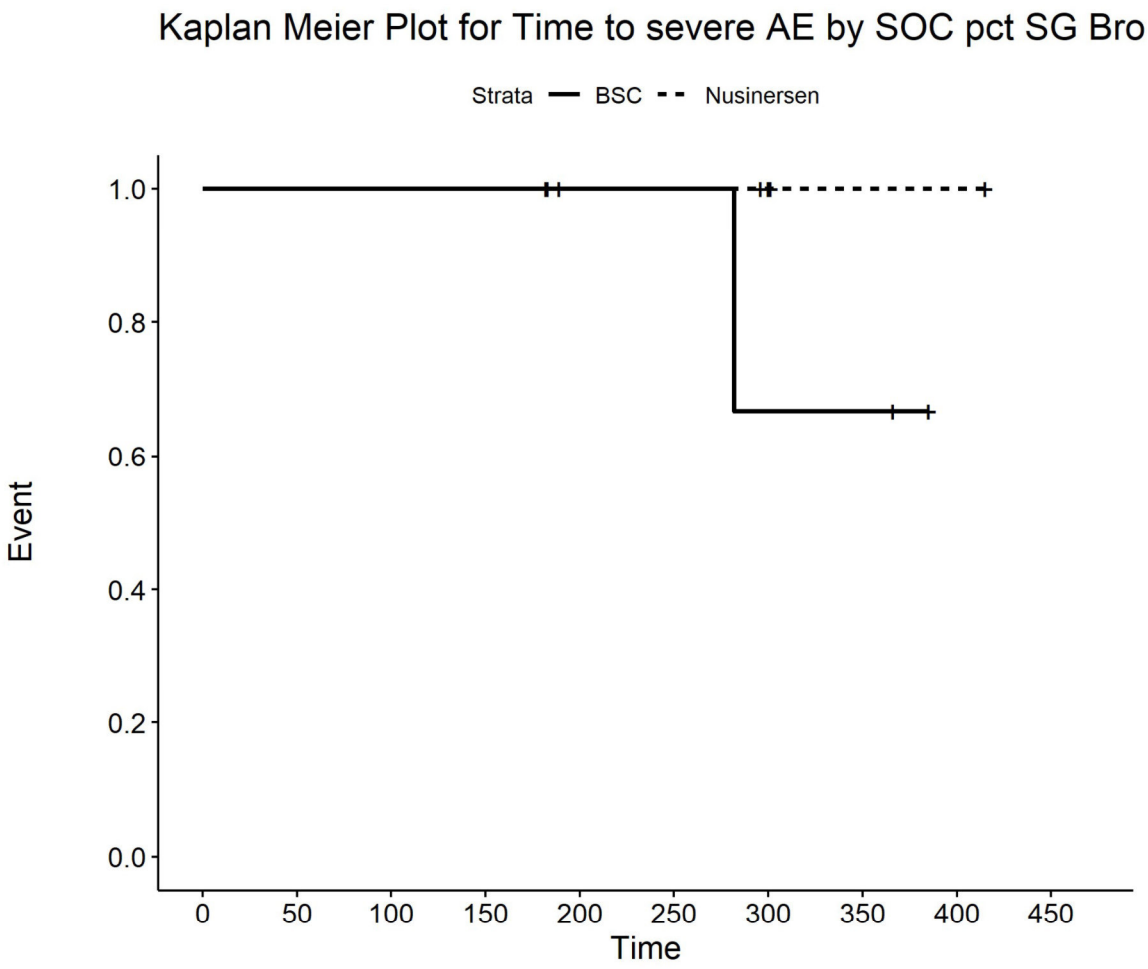
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



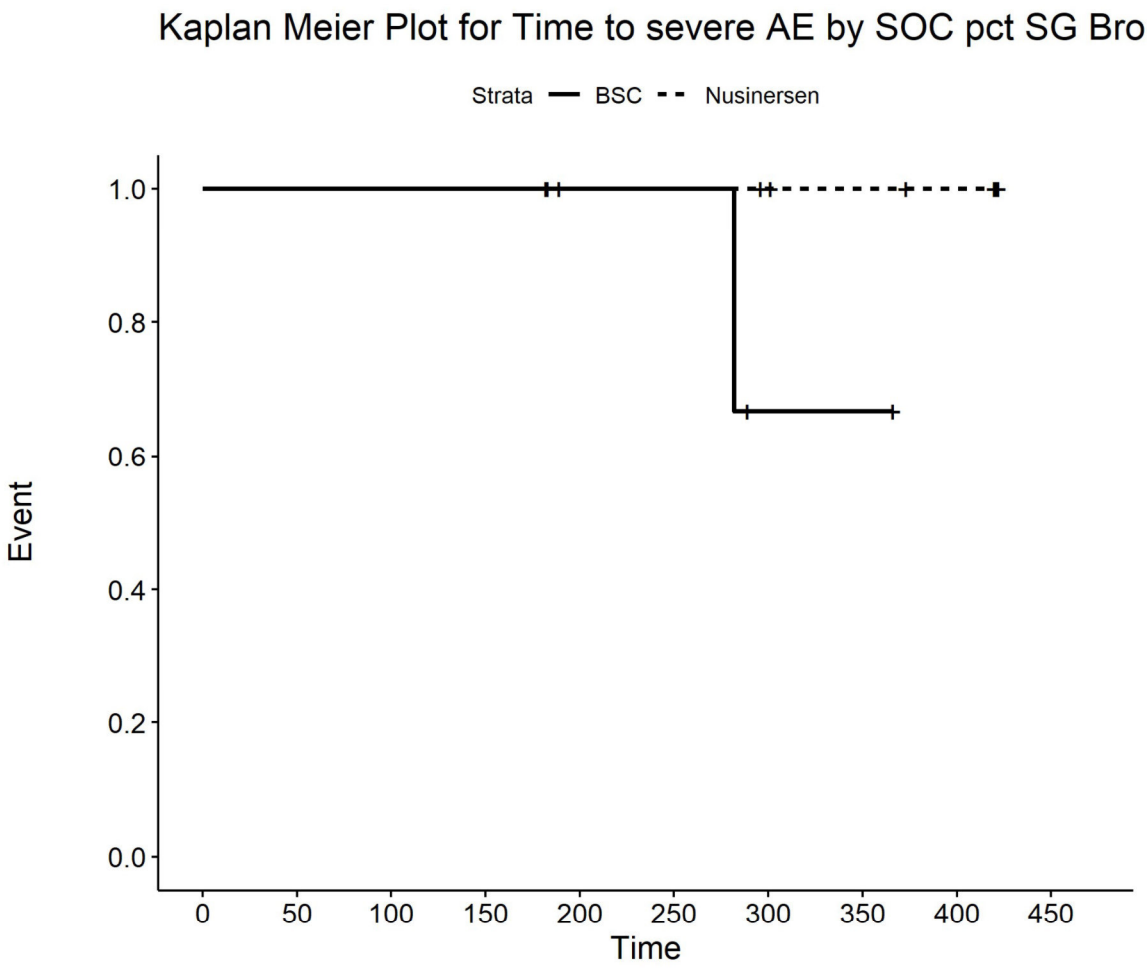
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	4	3	0



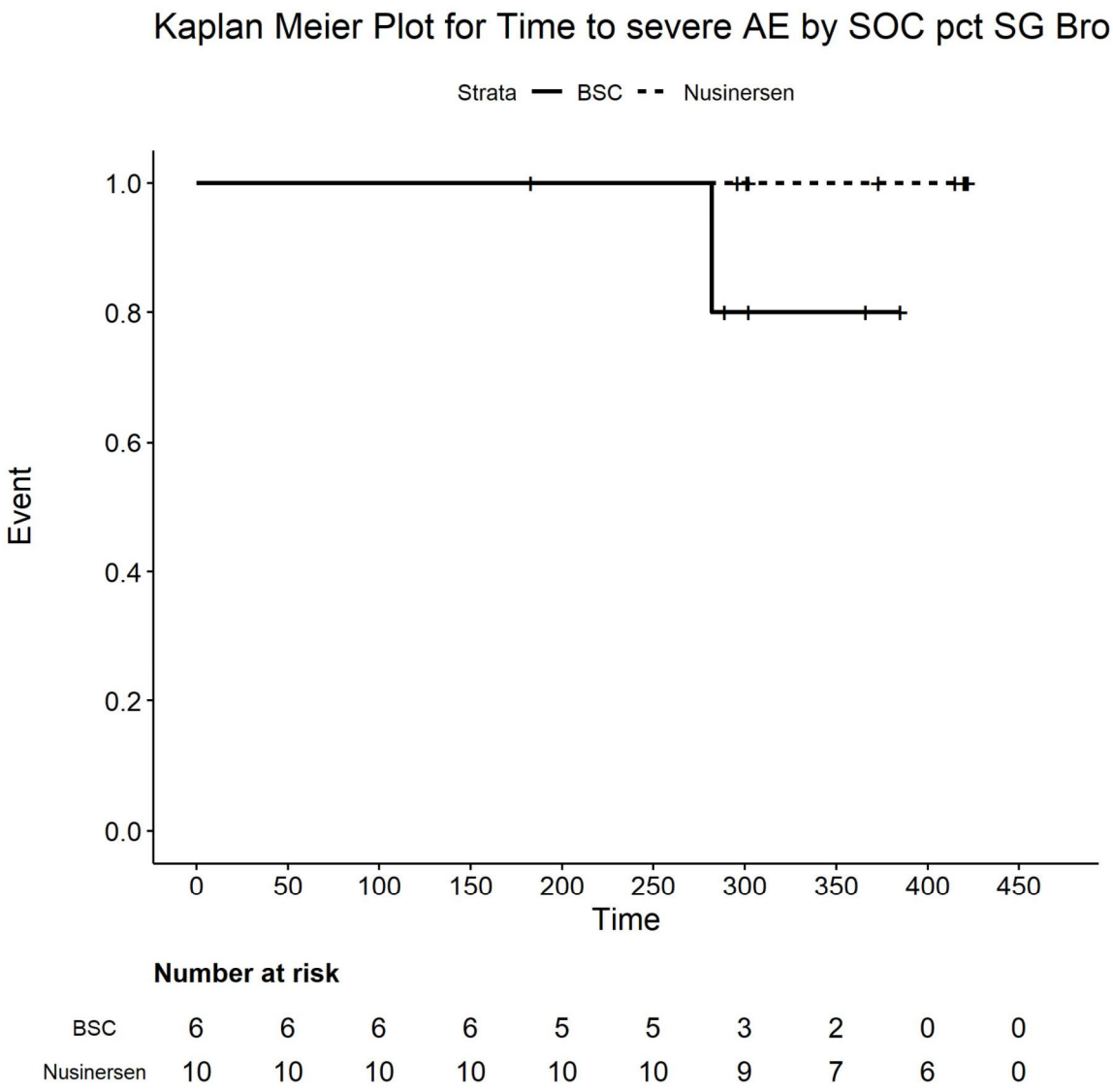
Number at risk

BSC	4	4	4	4	3	3	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



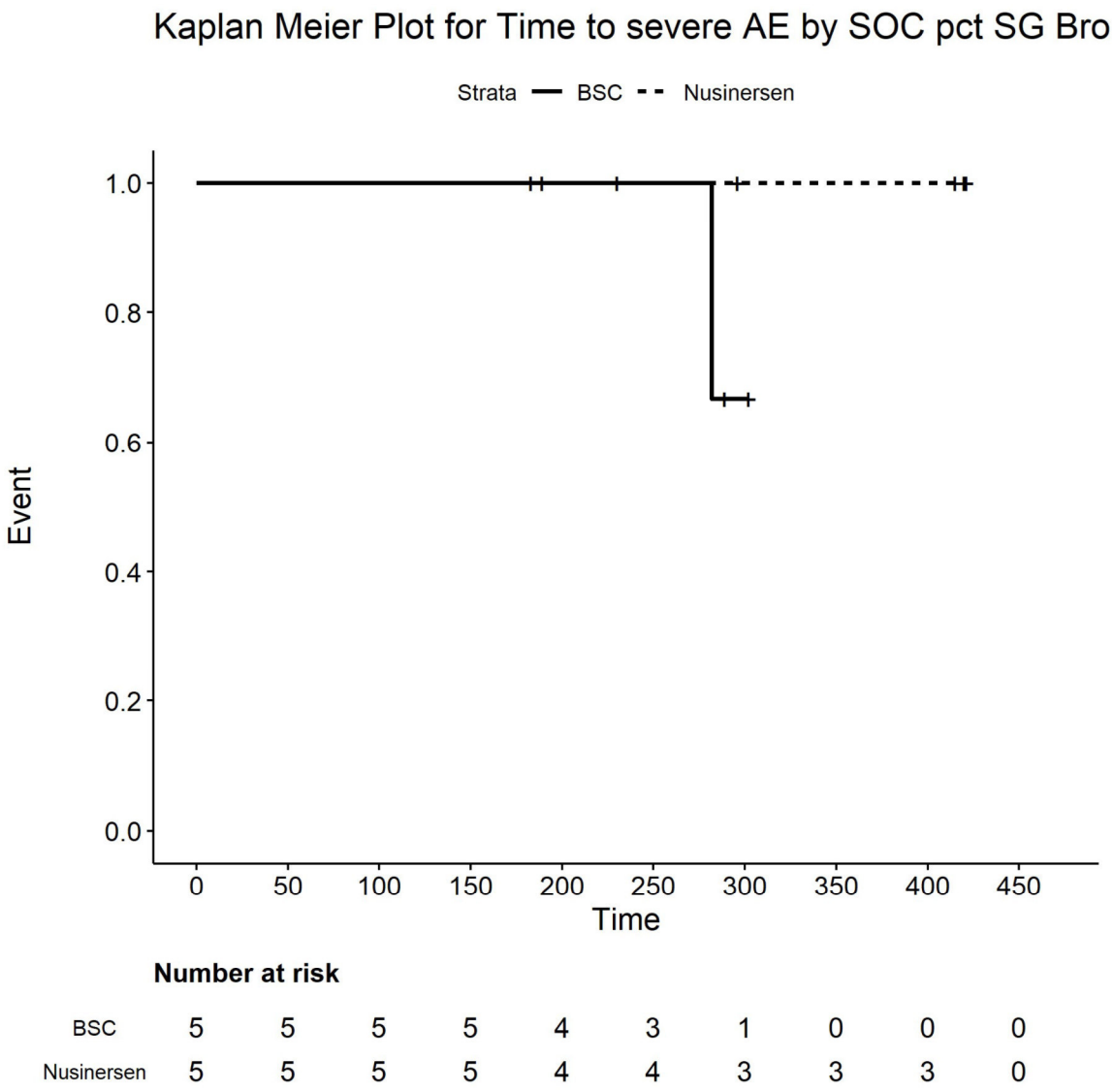
Number at risk

BSC	4	4	4	4	3	3	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



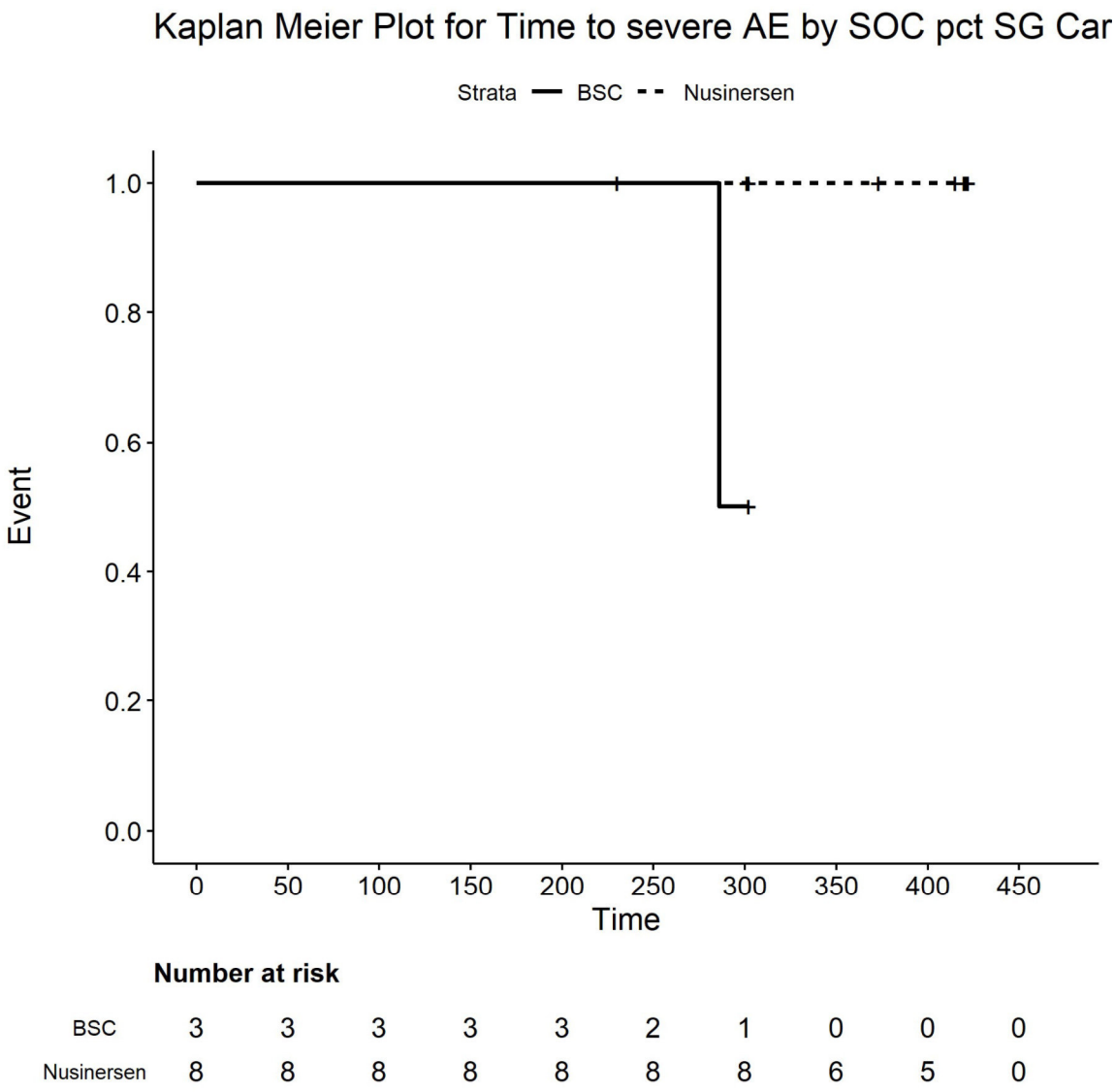
Number at risk

BSC	6	6	6	6	5	5	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



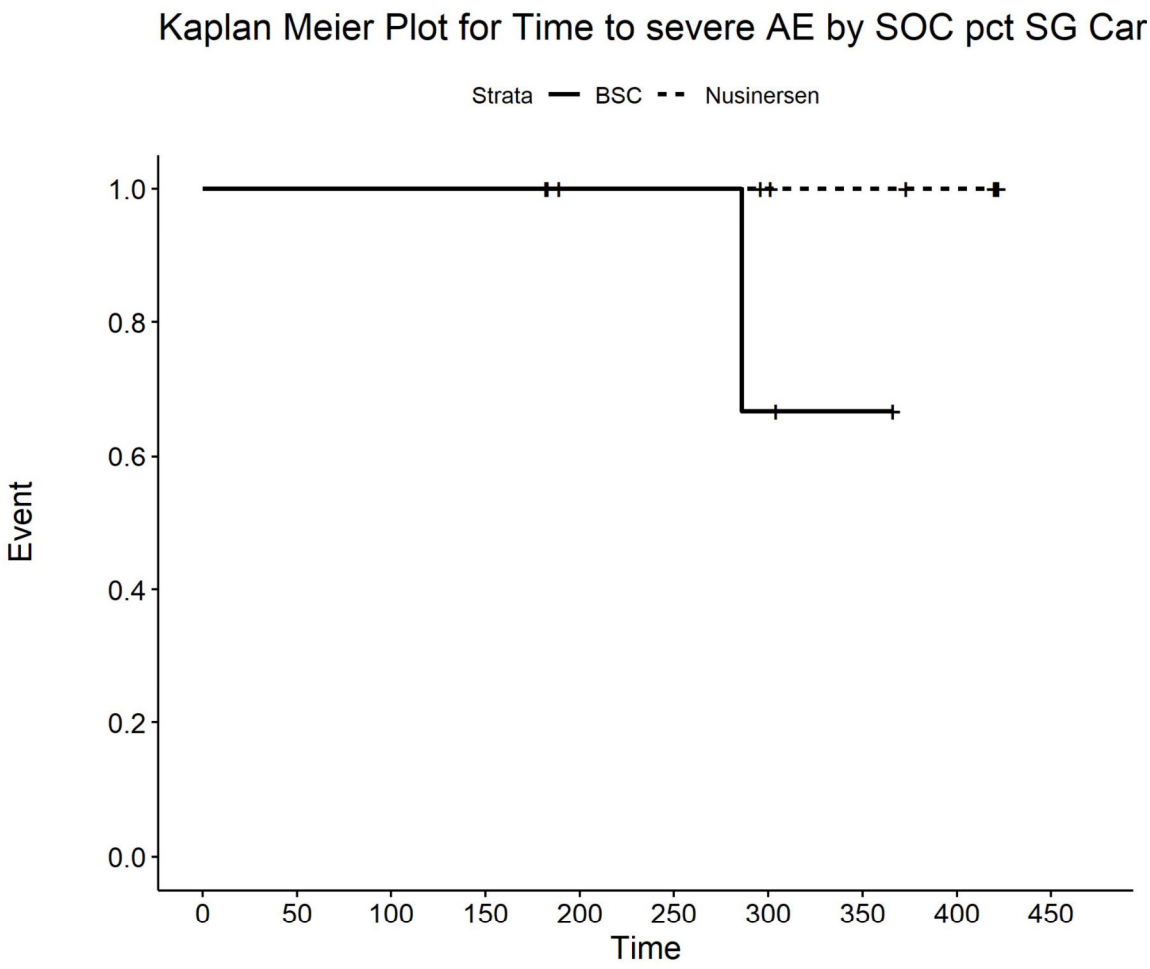
Number at risk

BSC	5	5	5	5	4	3	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



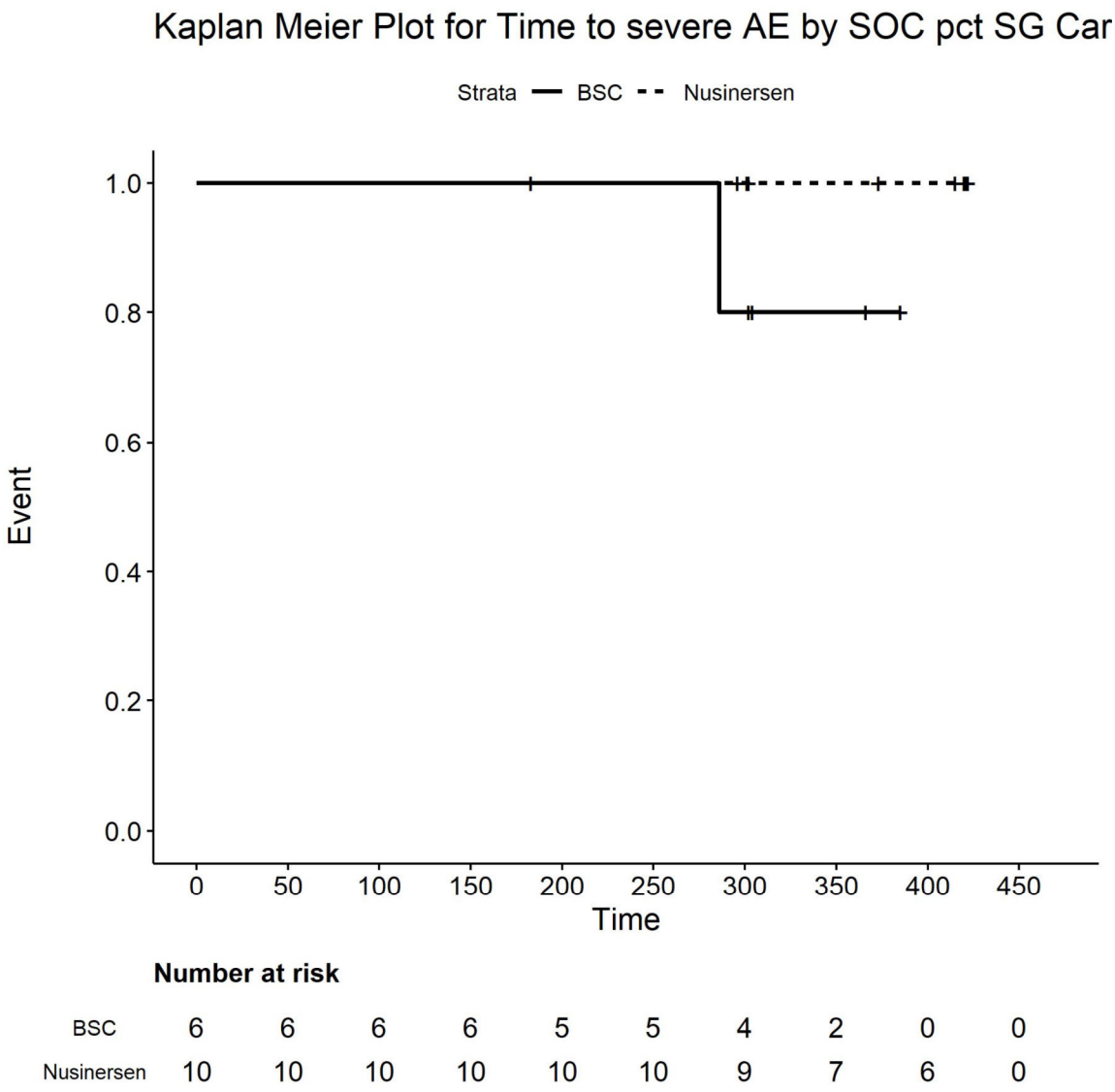
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



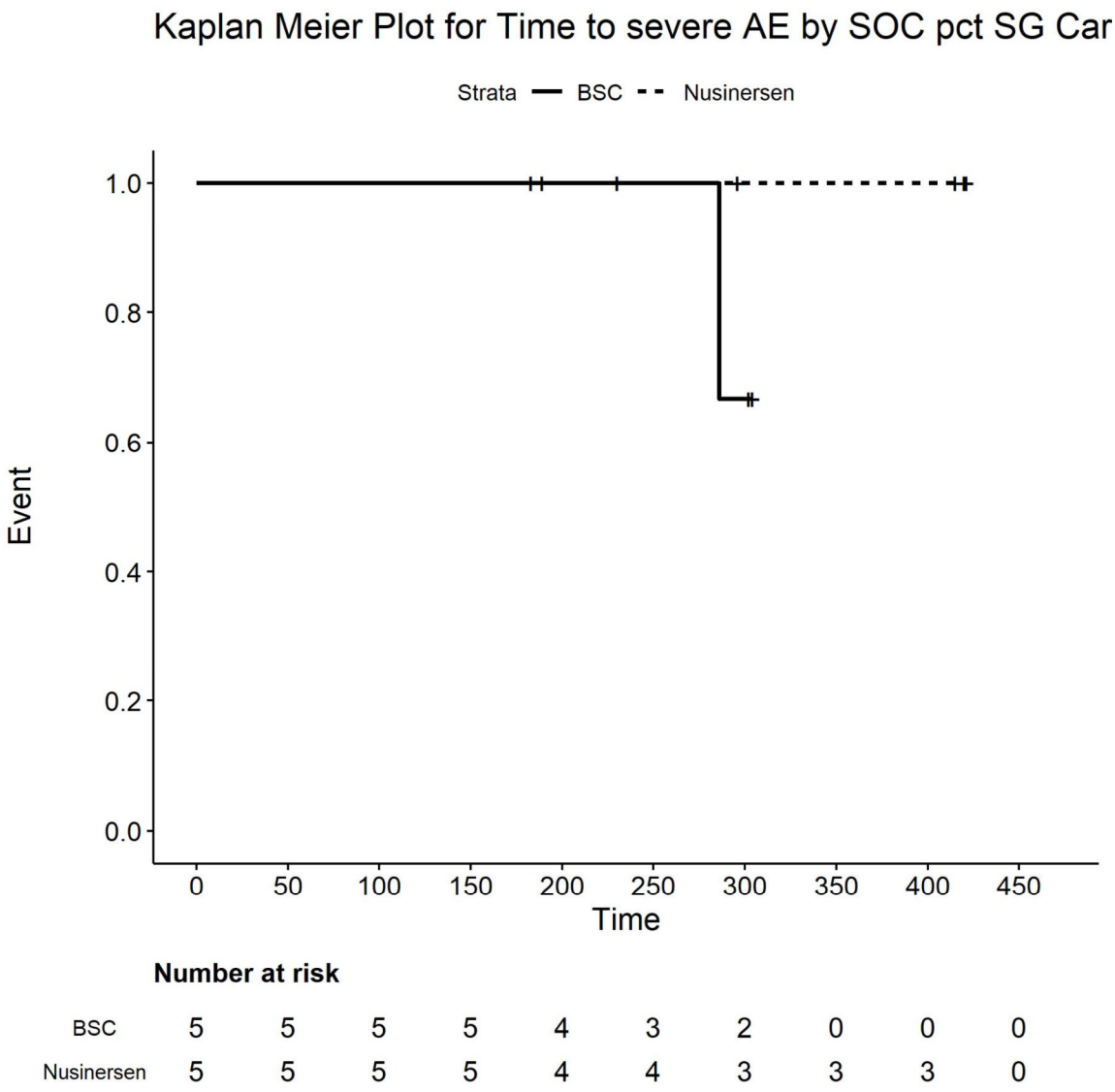
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



Number at risk

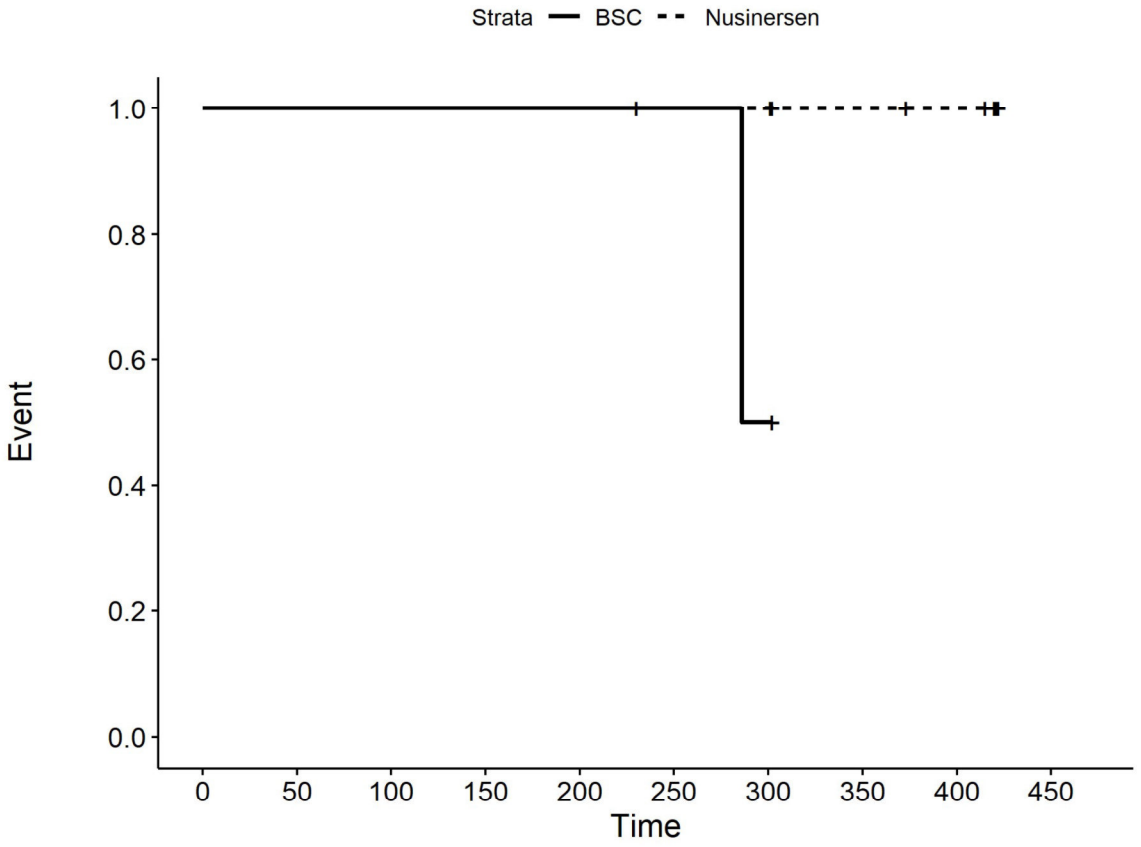
BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



Number at risk

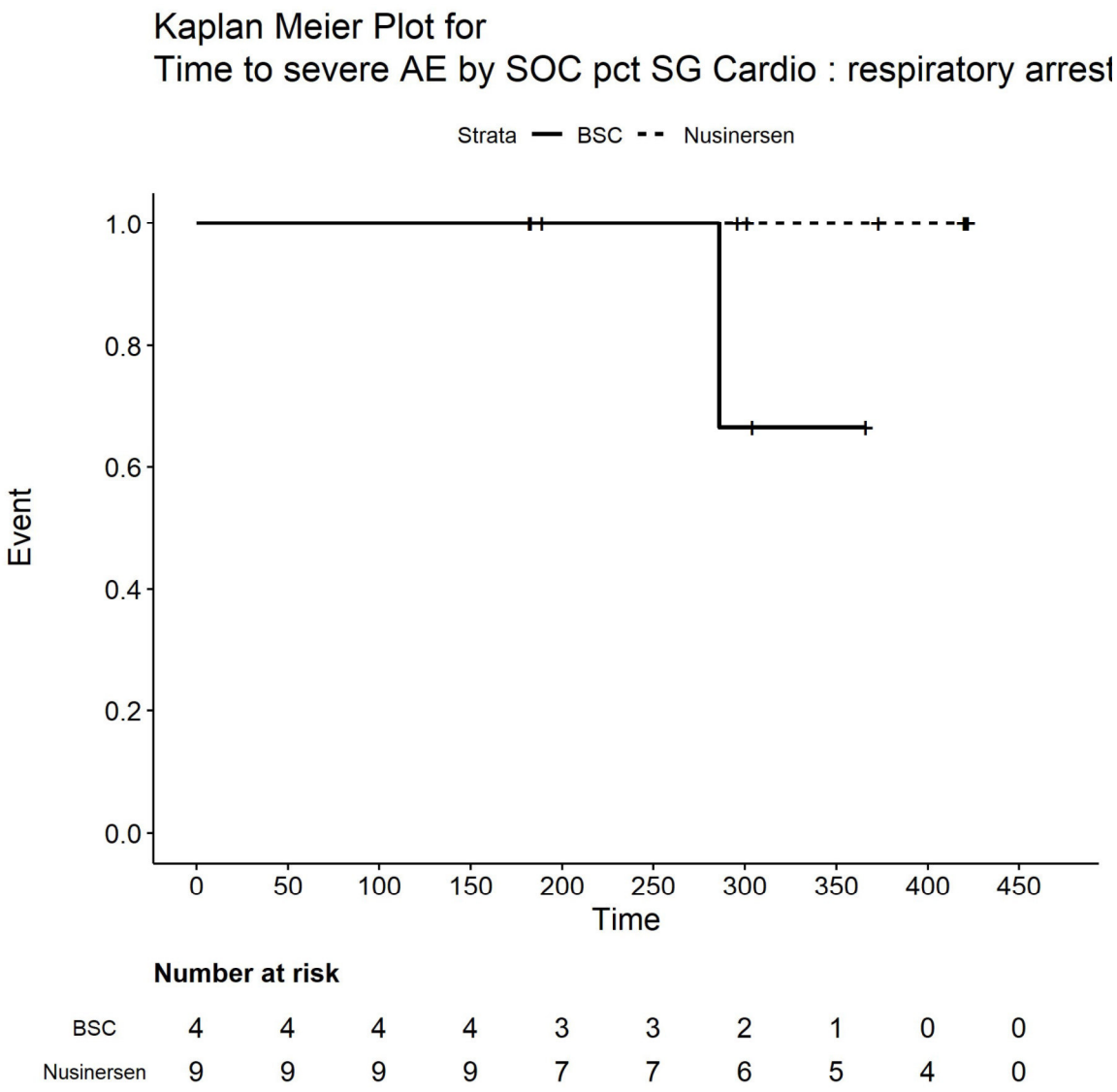
BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0

Kaplan Meier Plot for
Time to severe AE by SOC pct SG Cardio : respiratory arrest



Number at risk

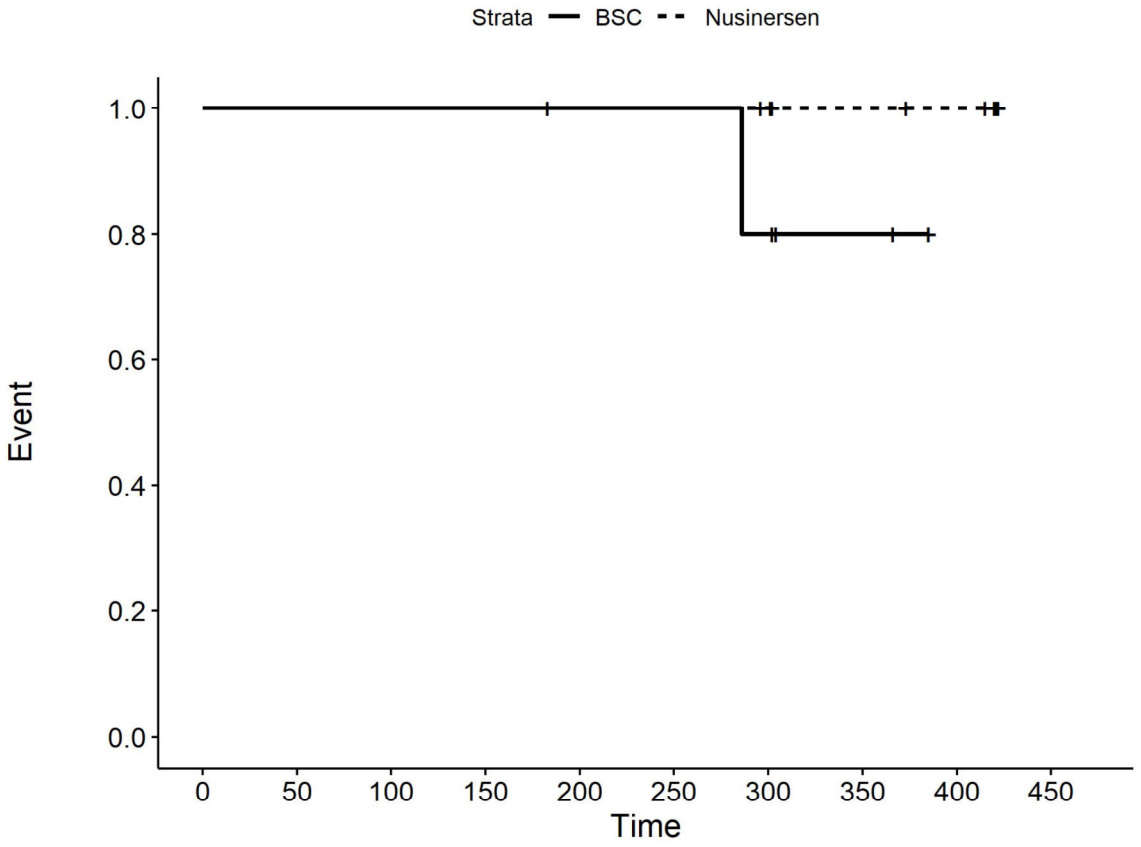
BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



Number at risk

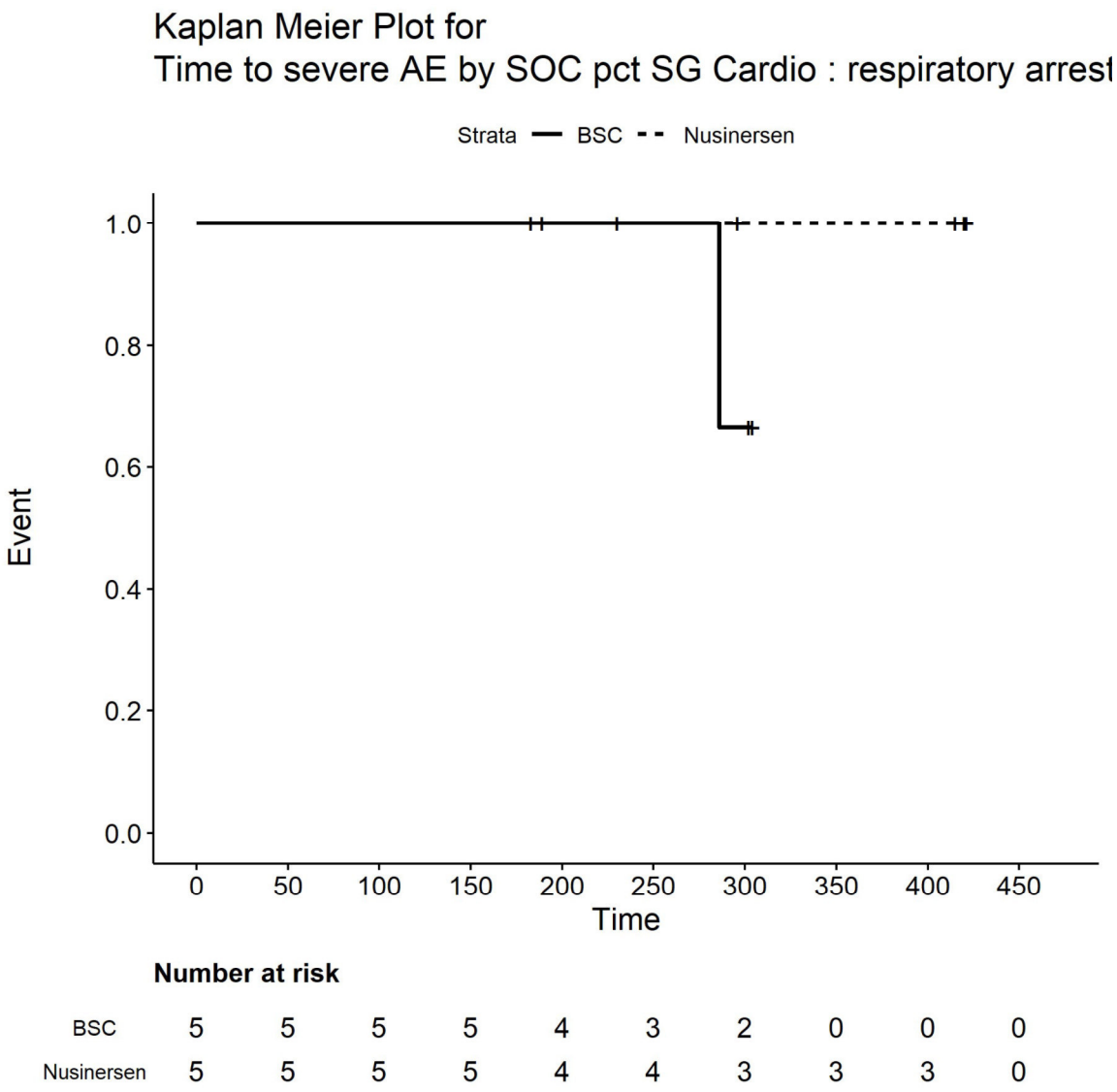
BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0

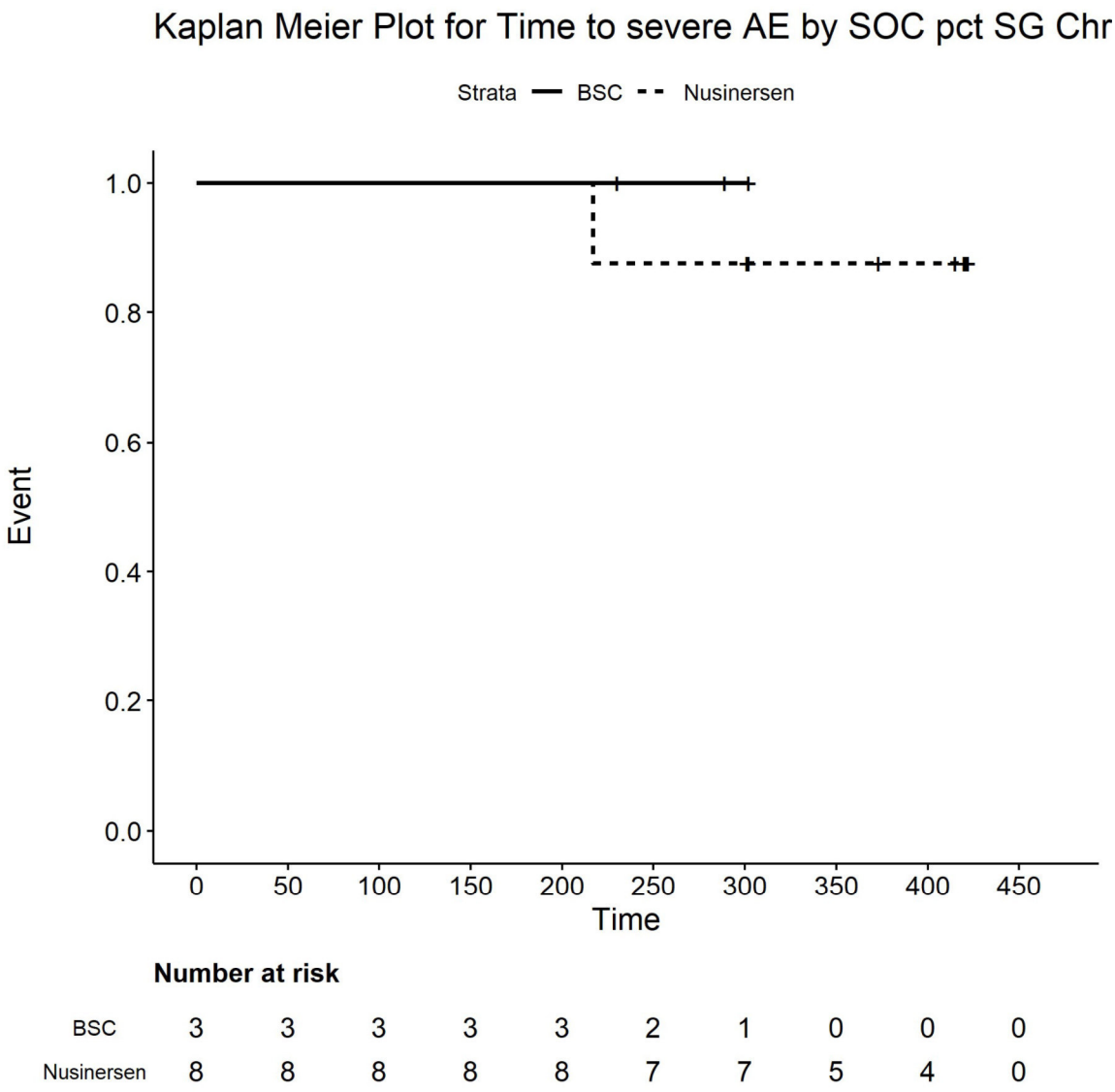
Kaplan Meier Plot for
Time to severe AE by SOC pct SG Cardio : respiratory arrest



Number at risk

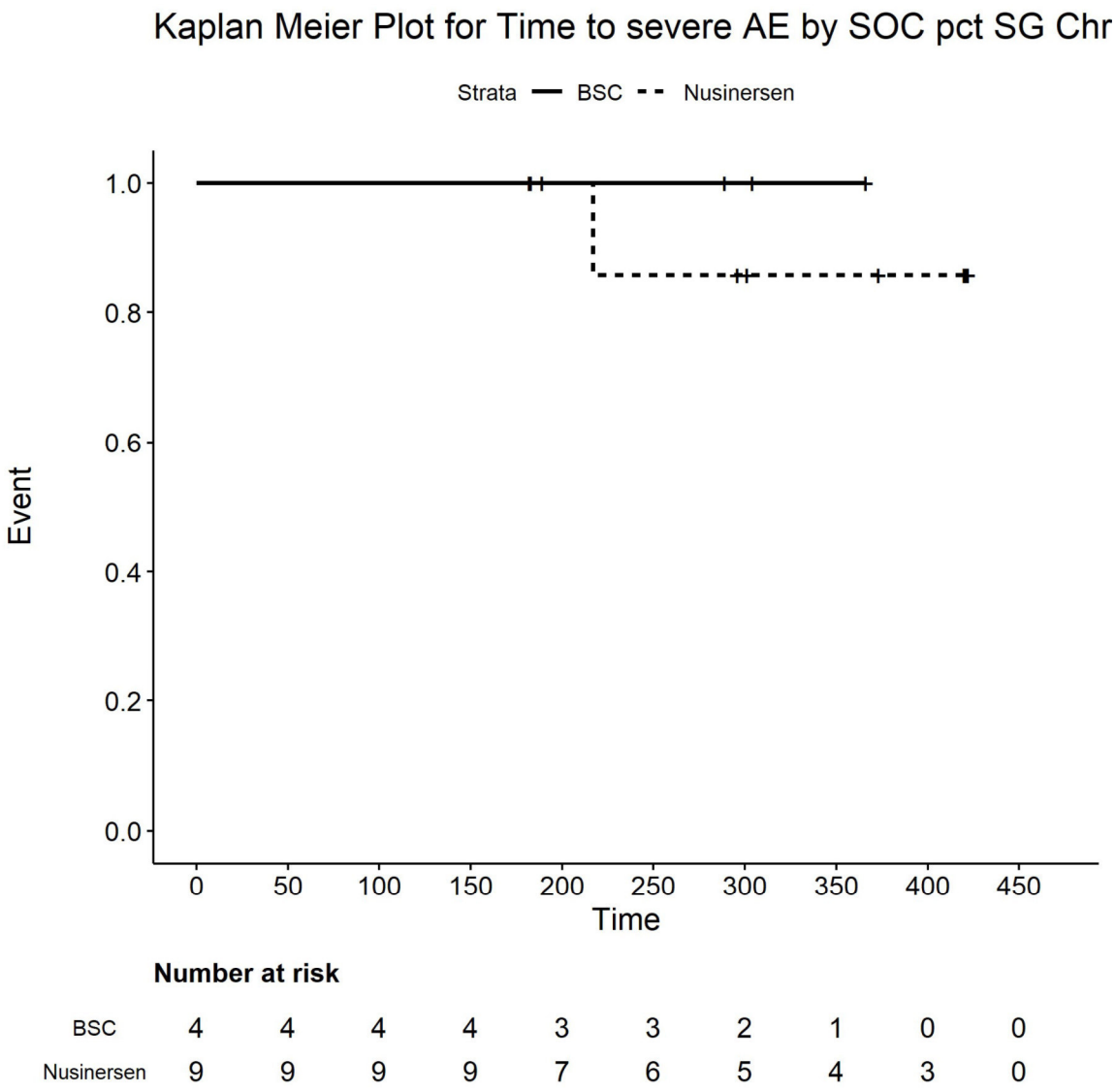
BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0


Kaplan Meier Plot for
Time to severe AE by SOC pct SG Cardio : respiratory arrest
Strata BSC Nusinersen
Event
1.0
0.8
0.6
0.4
0.2
0.0
0 50 100 150 200 250 300 350 400 450
Time
Number at risk
BSC 5 5 5 5 4 3 2 0 0 0
Nusinersen 5 5 5 5 4 4 3 3 3 0



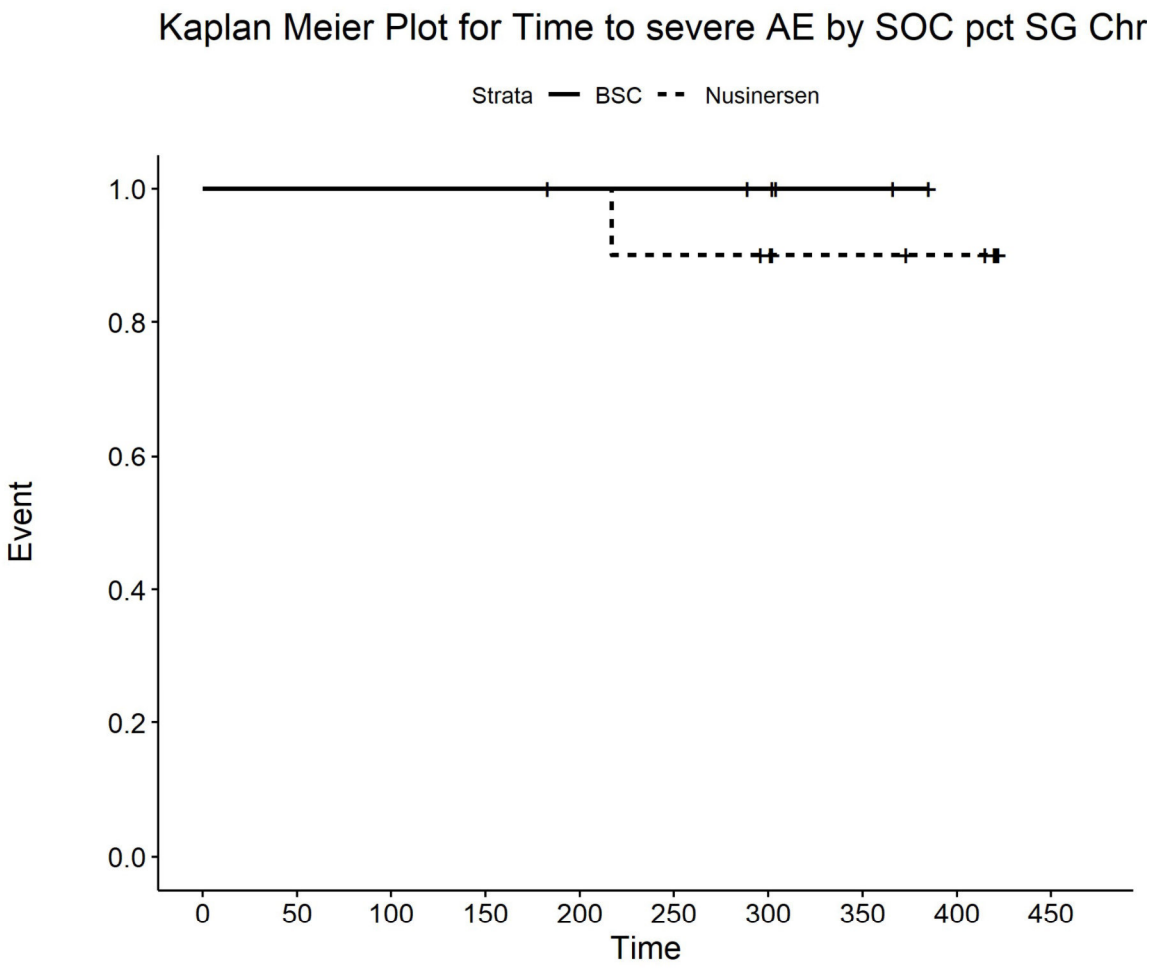
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



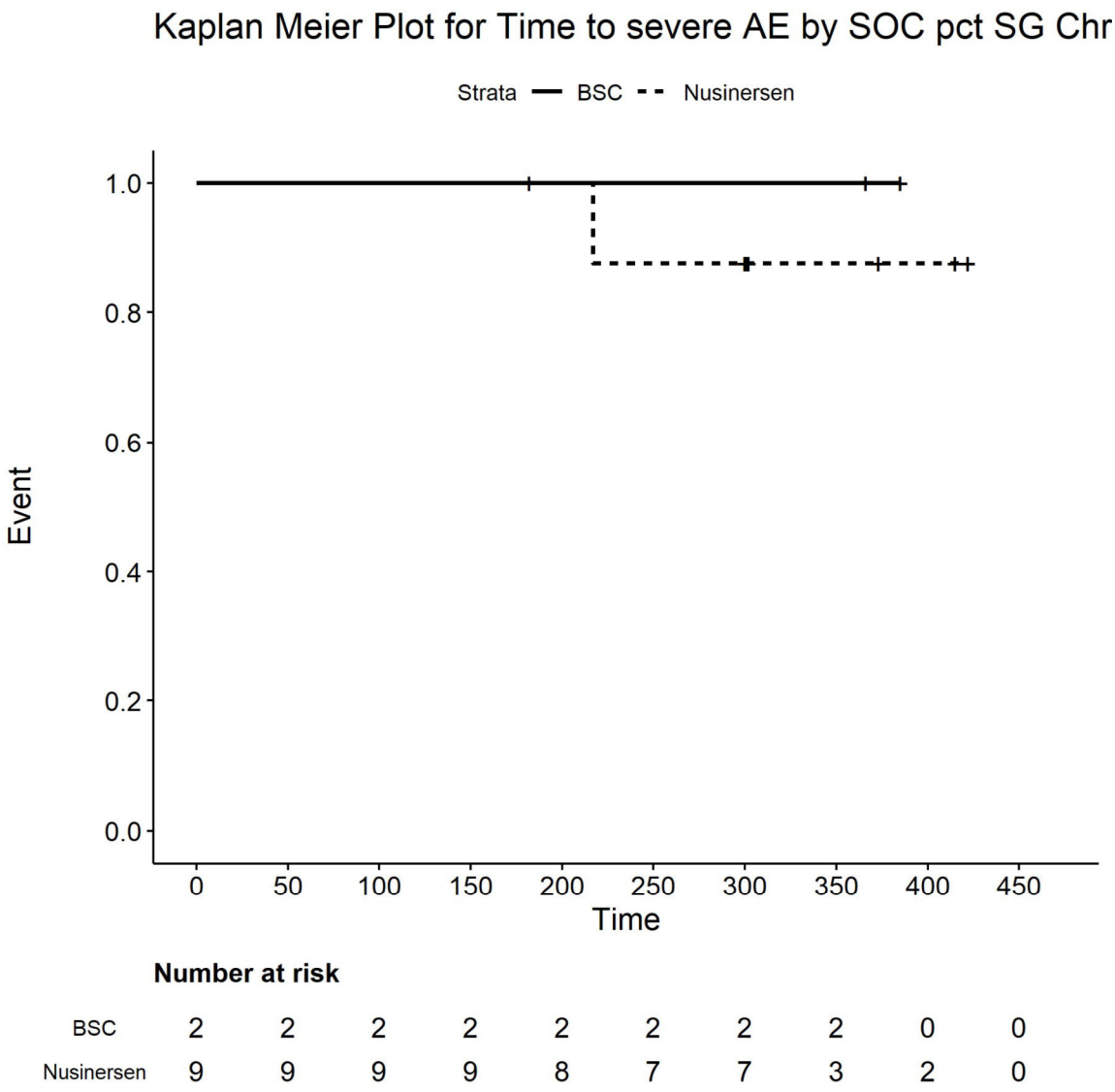
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



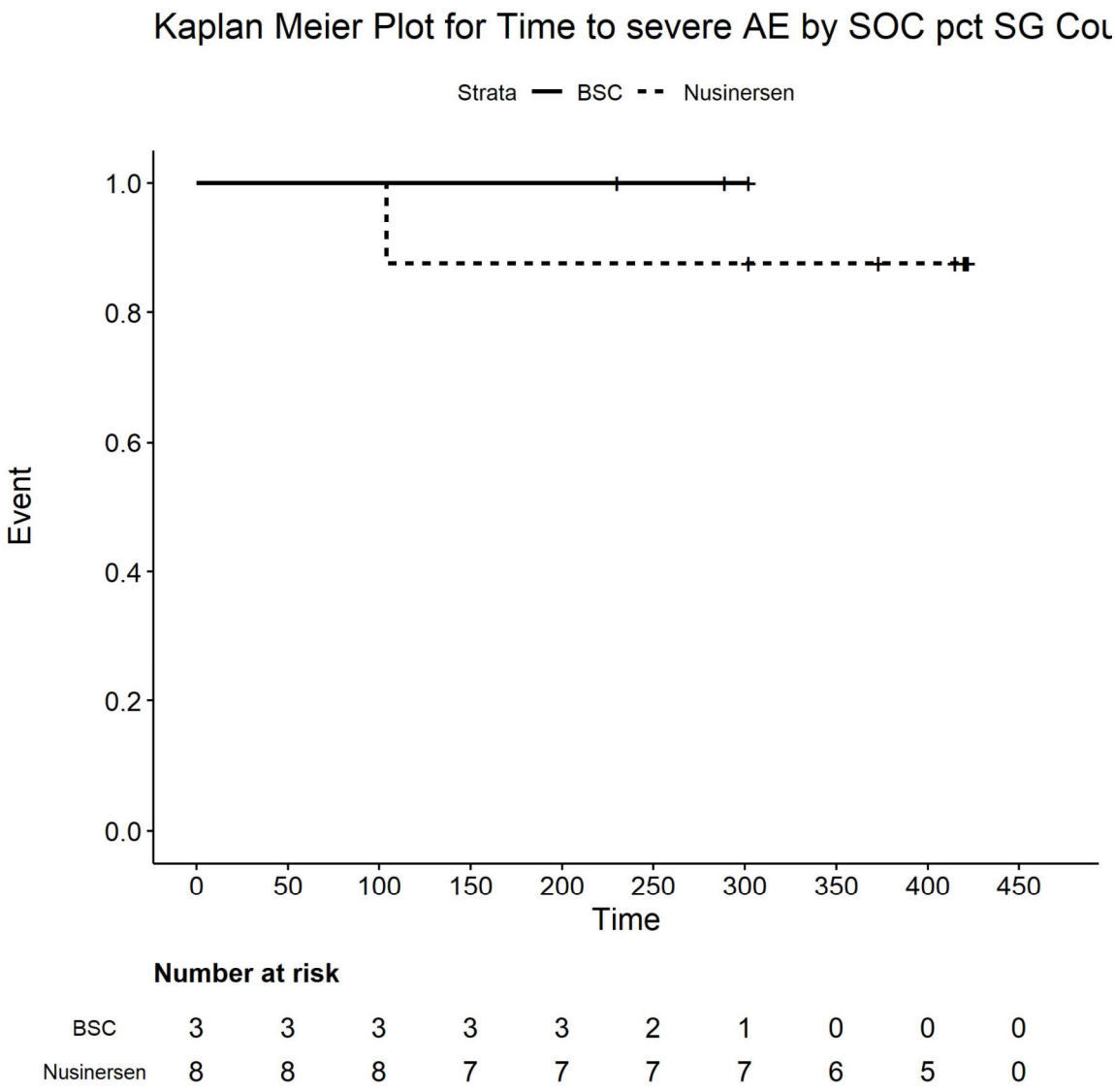
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



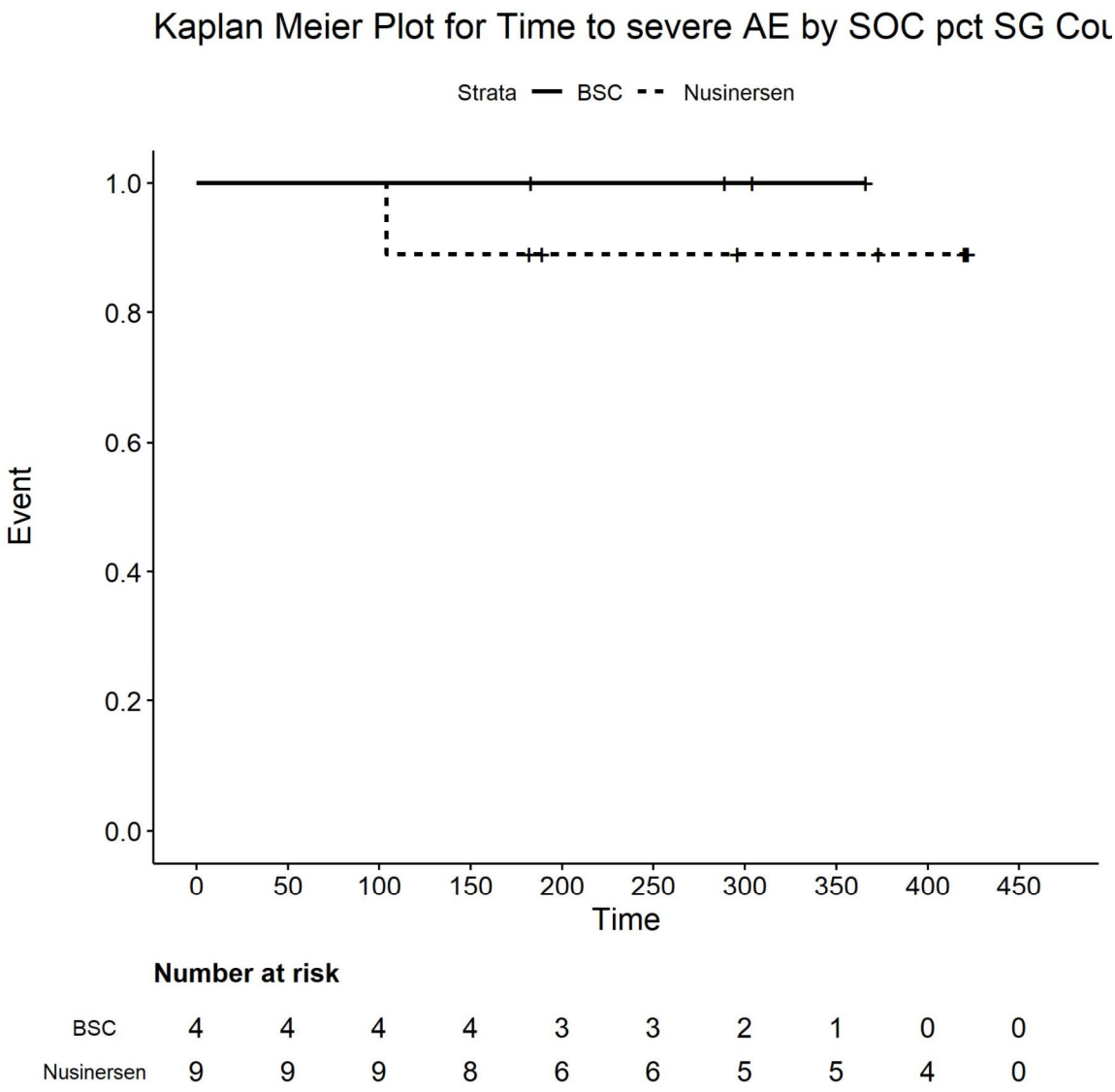
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	2	0



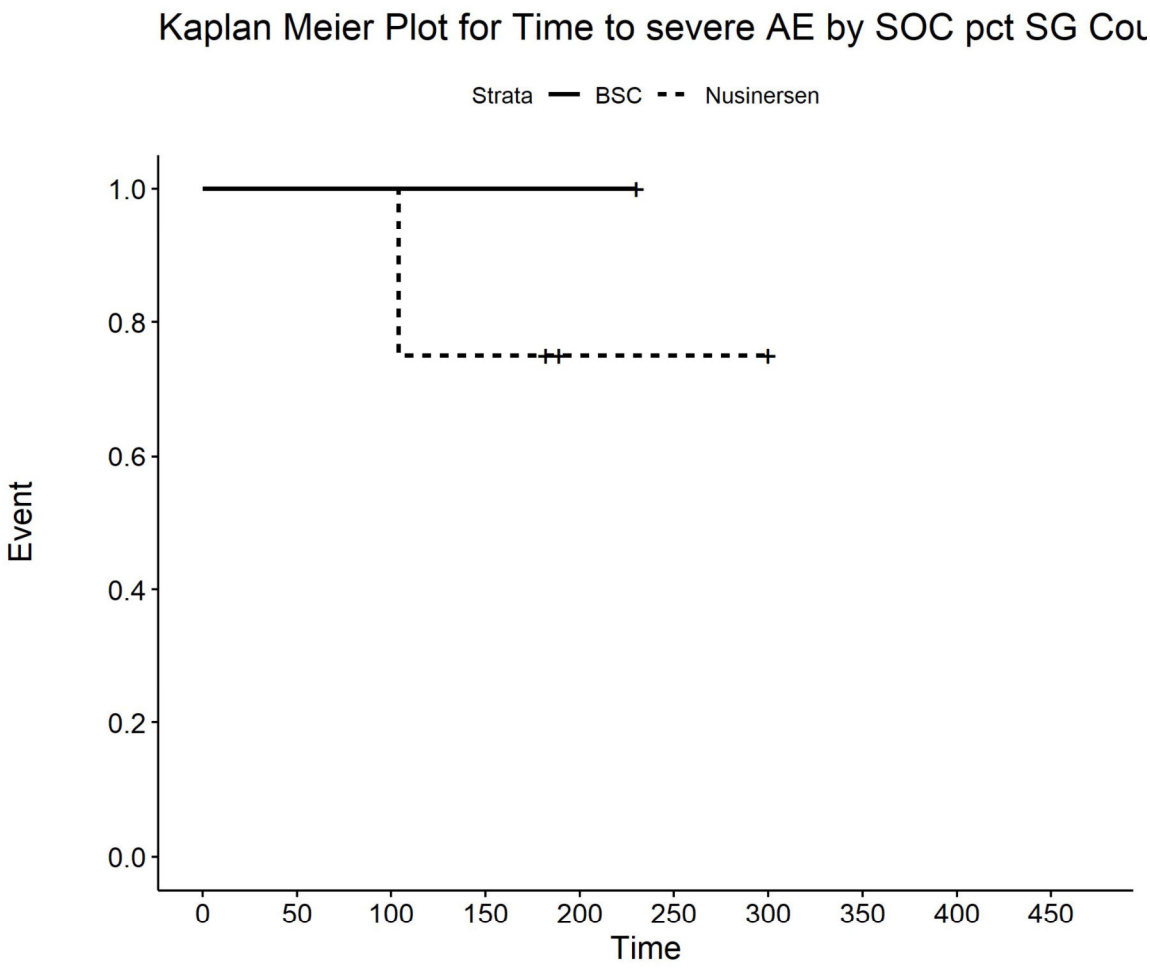
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	6	5	0



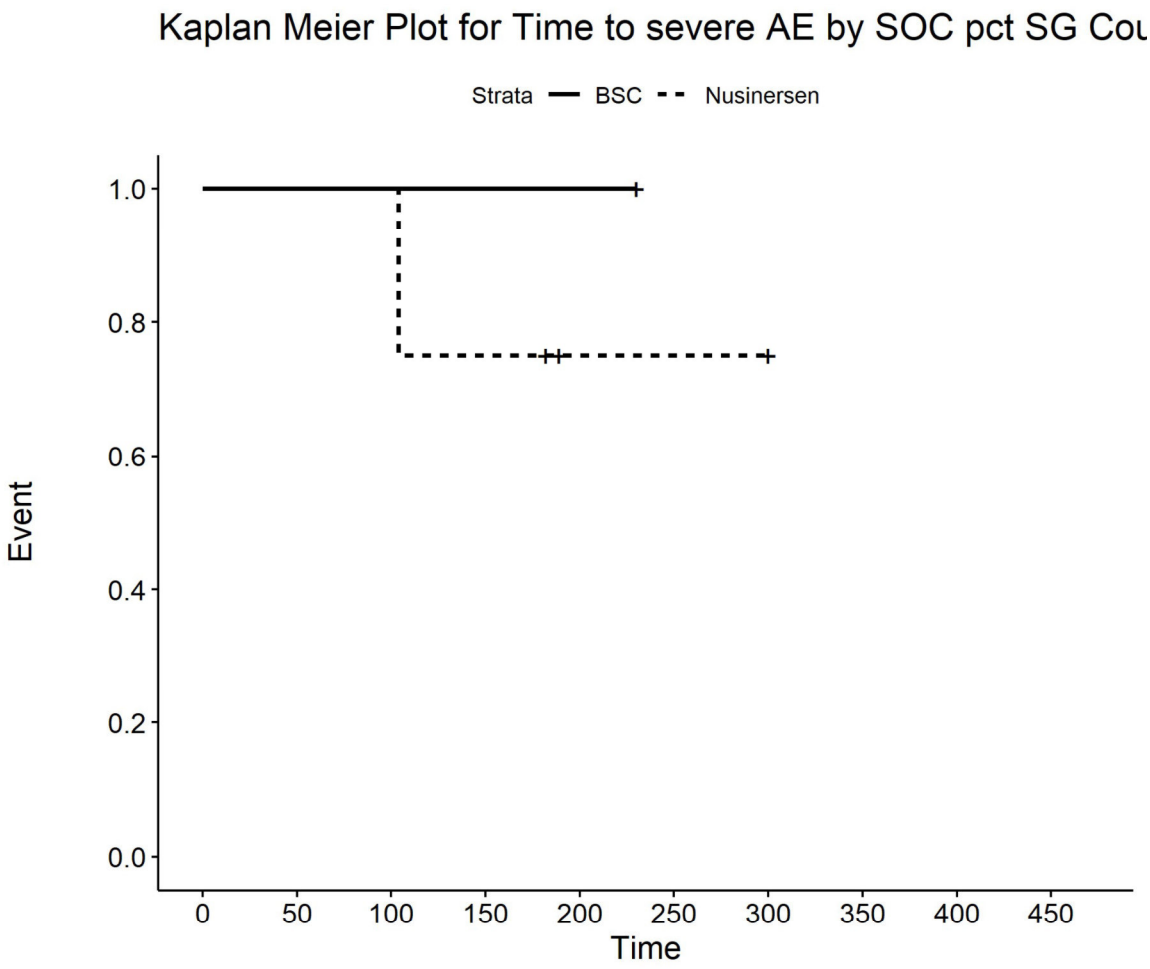
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	5	4	0



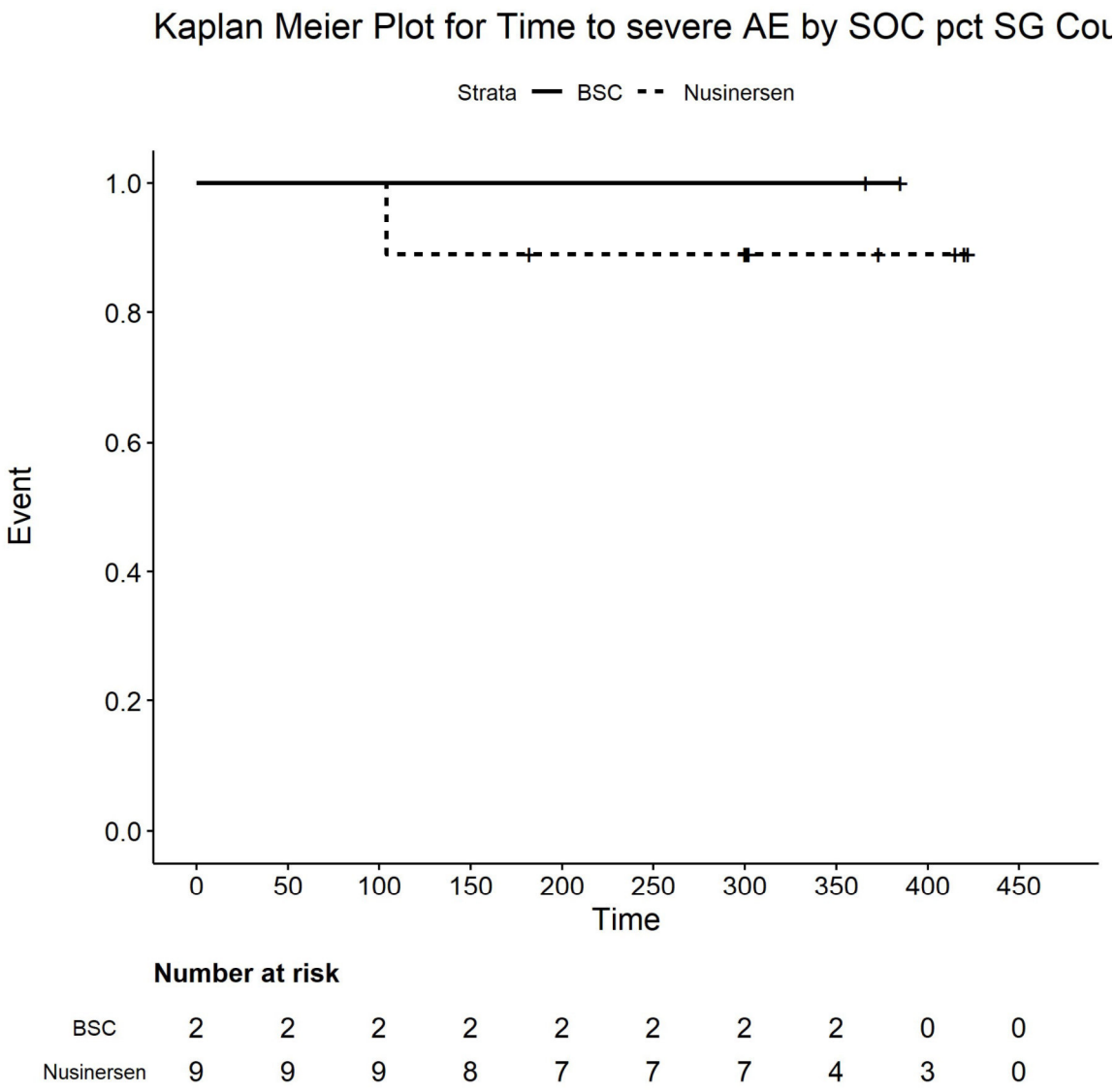
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



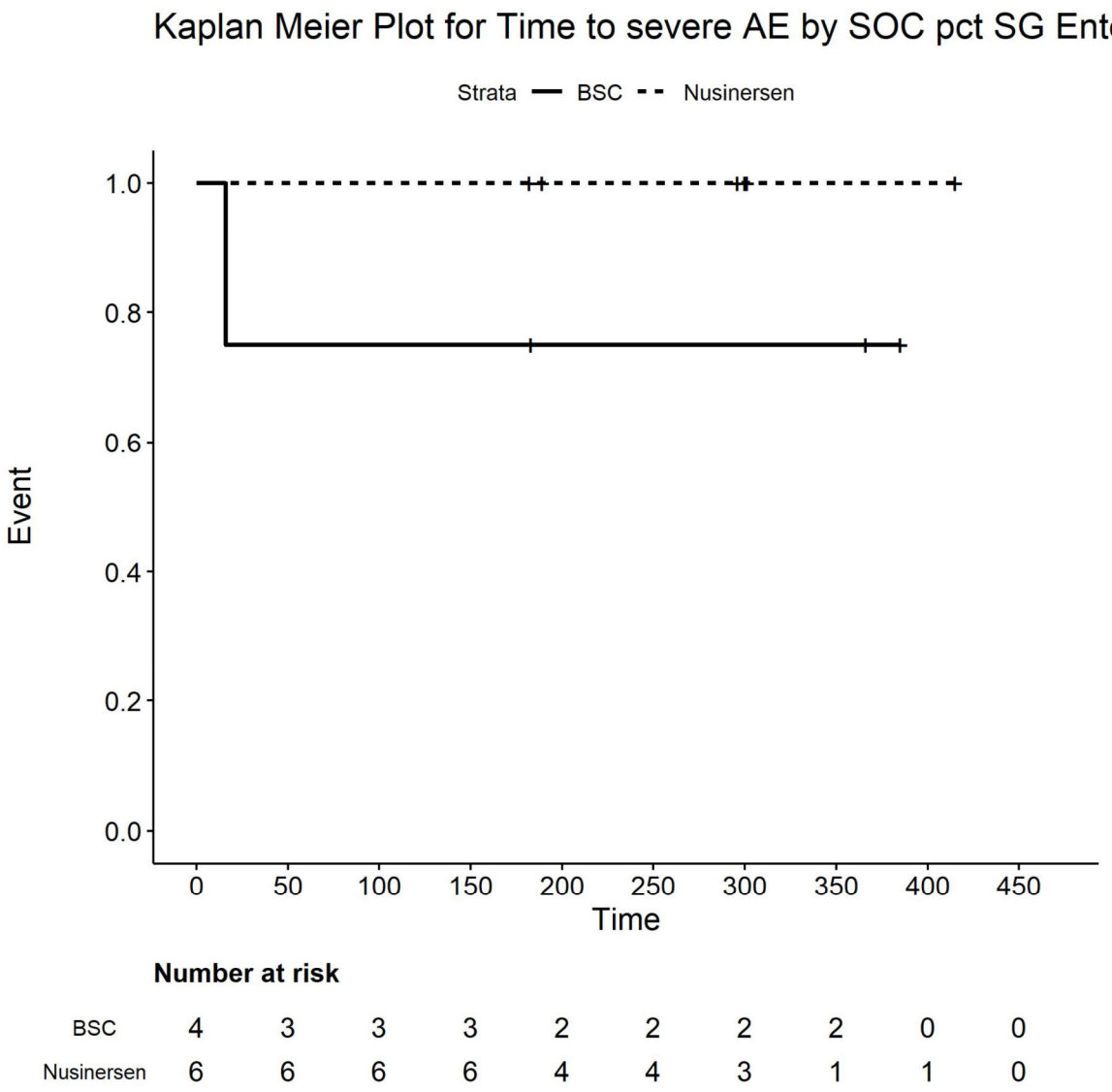
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



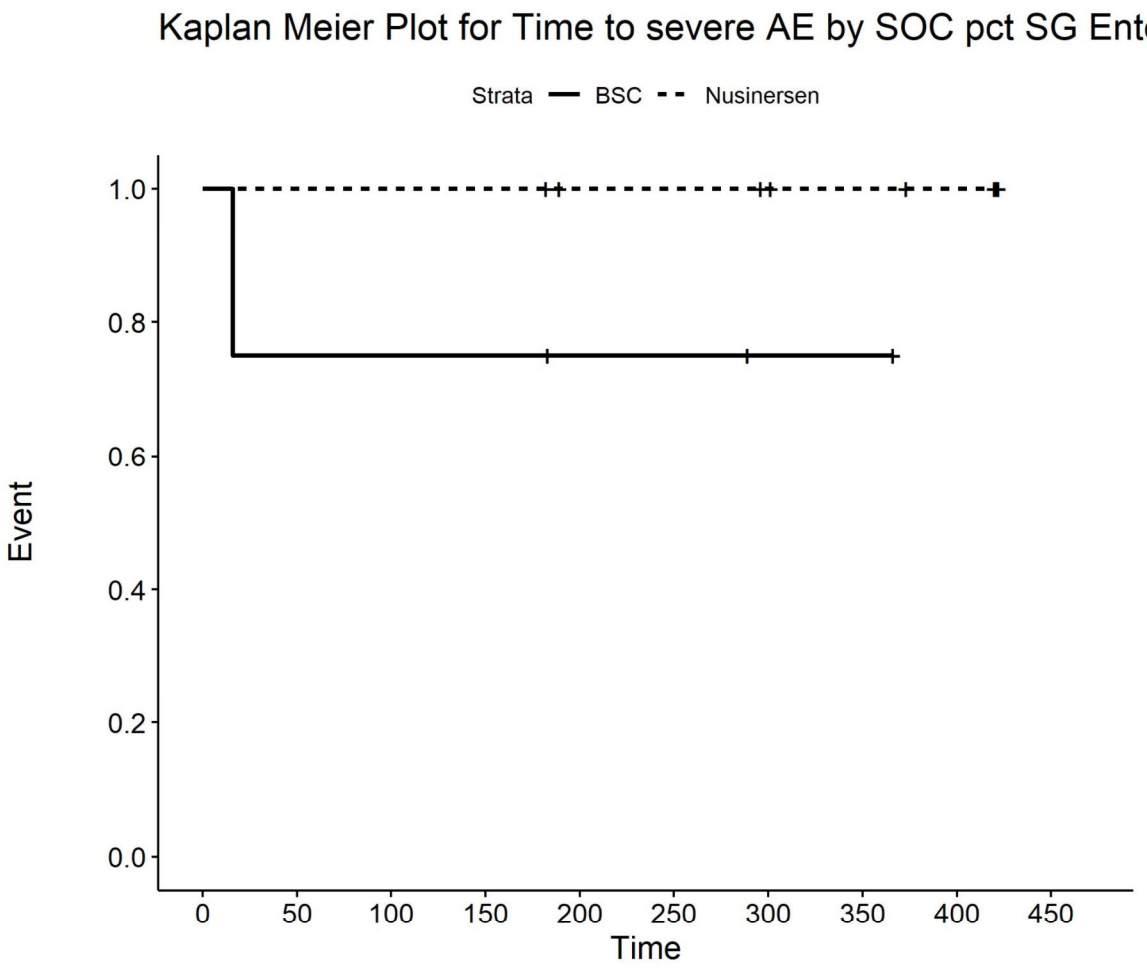
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	4	3	0



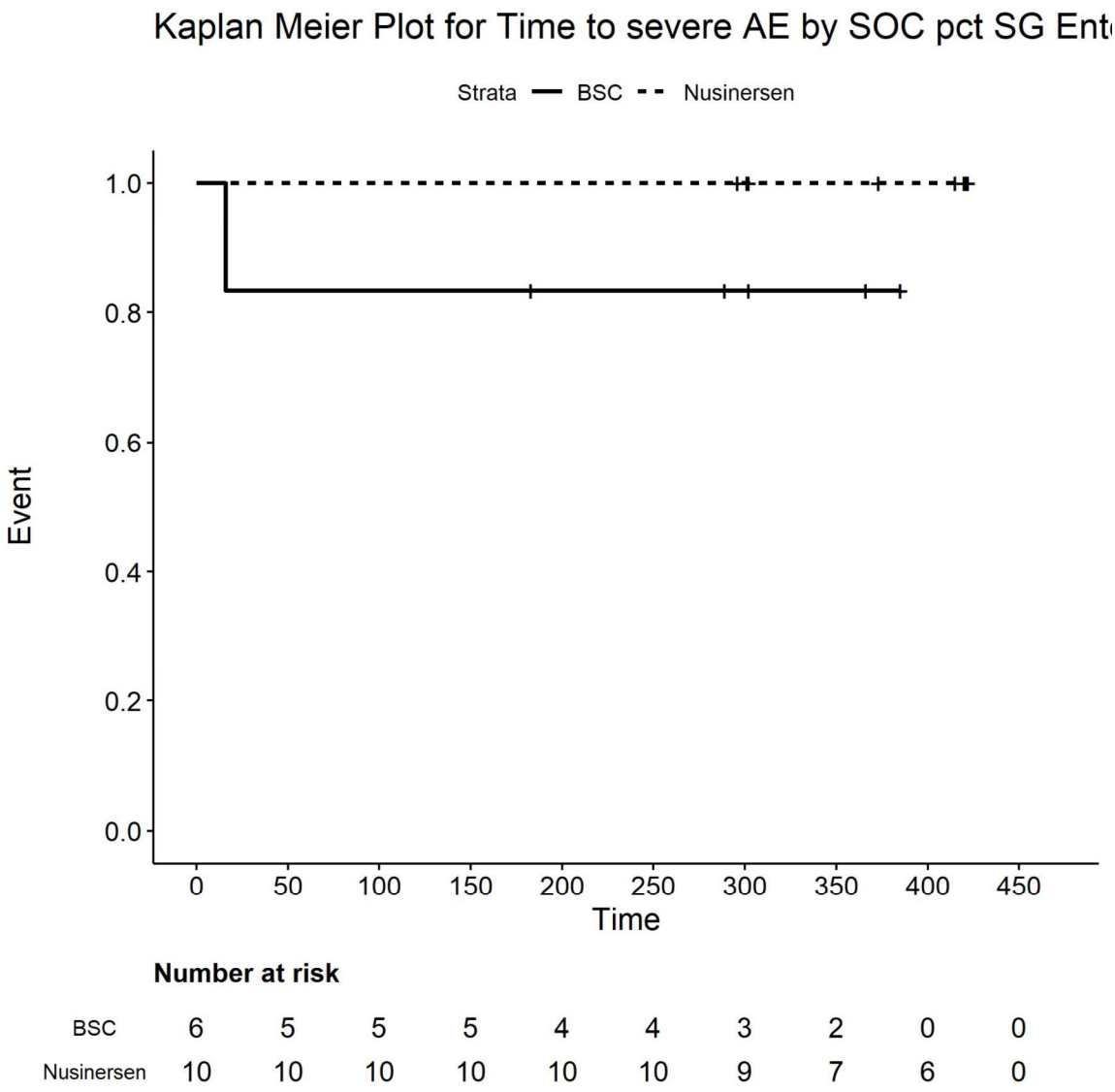
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



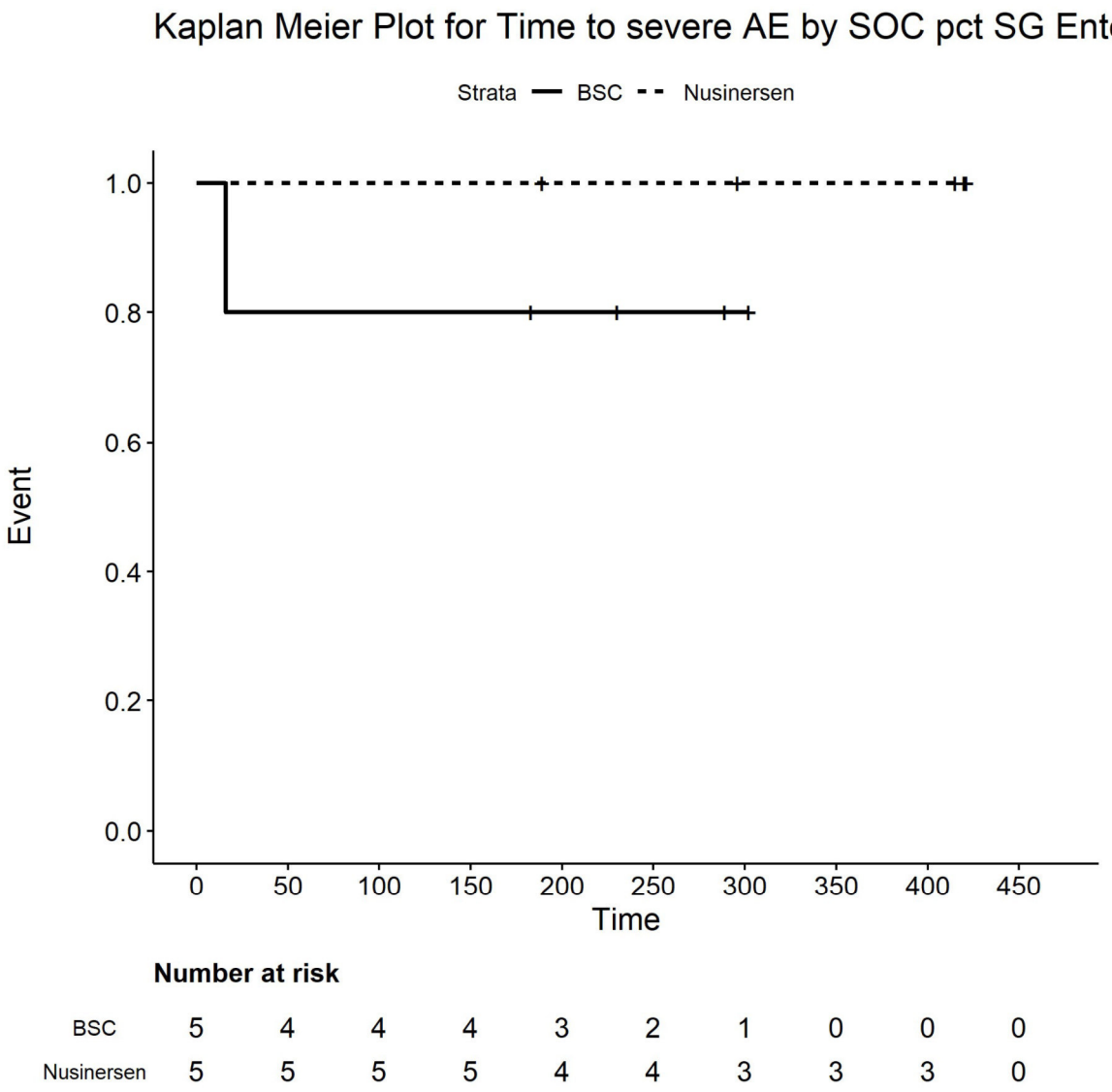
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



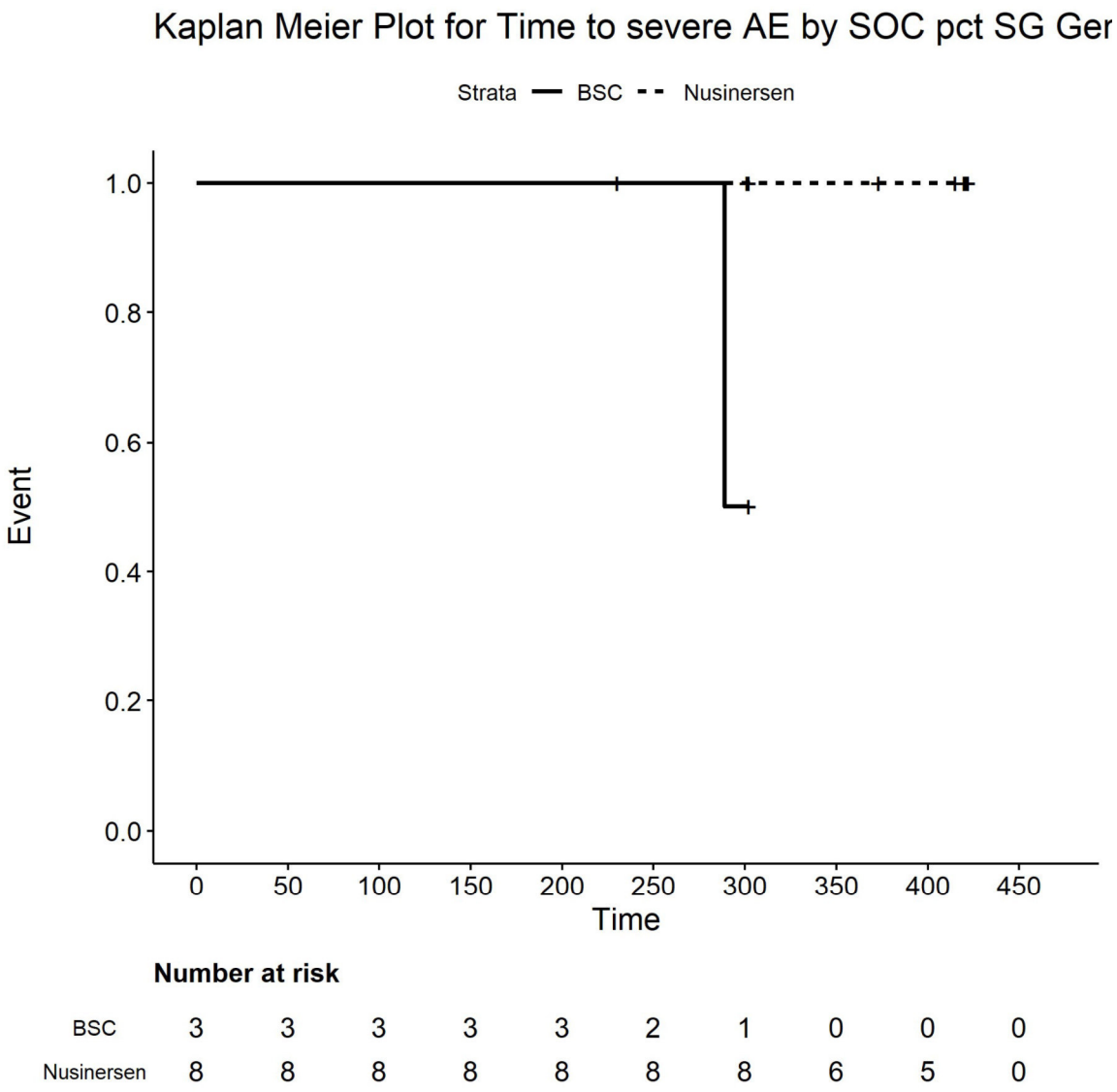
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



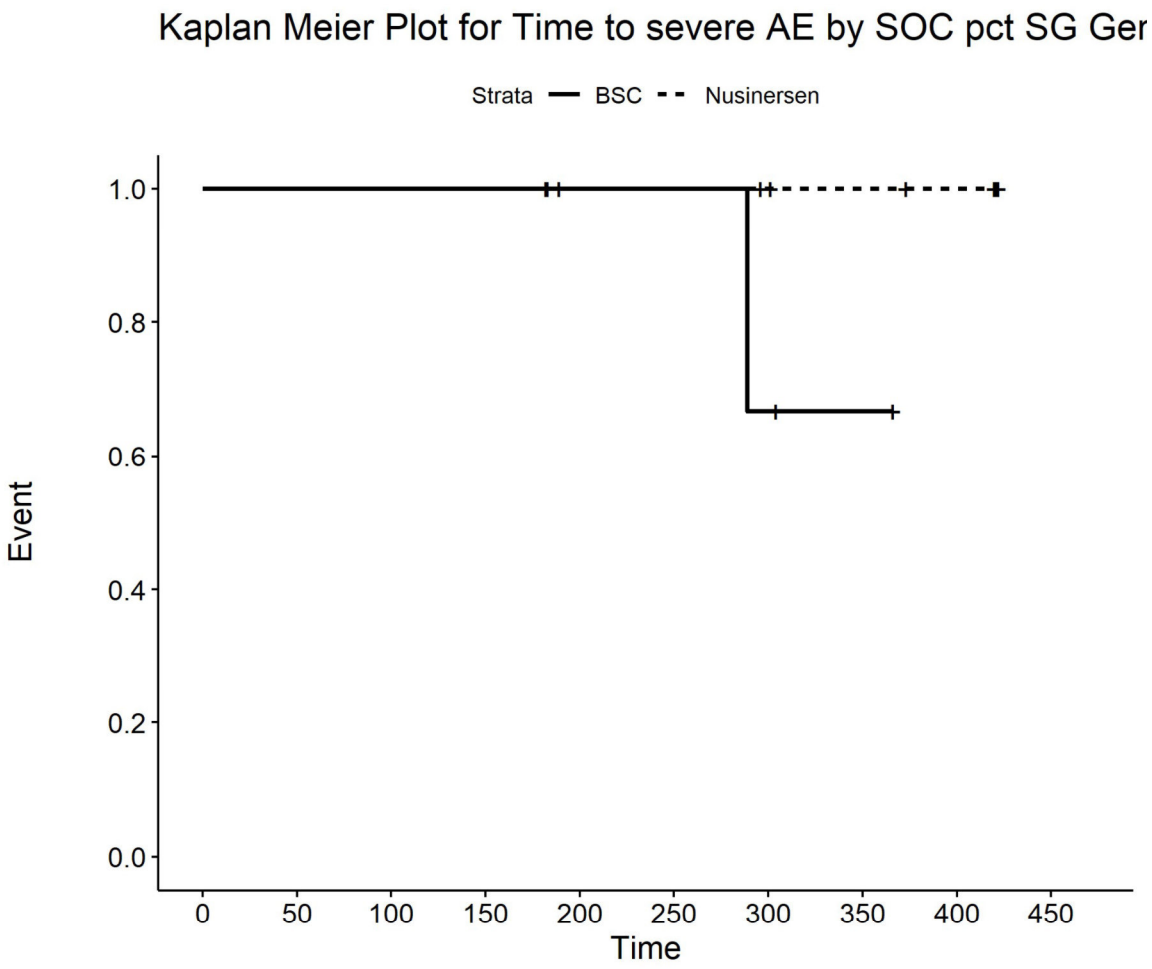
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



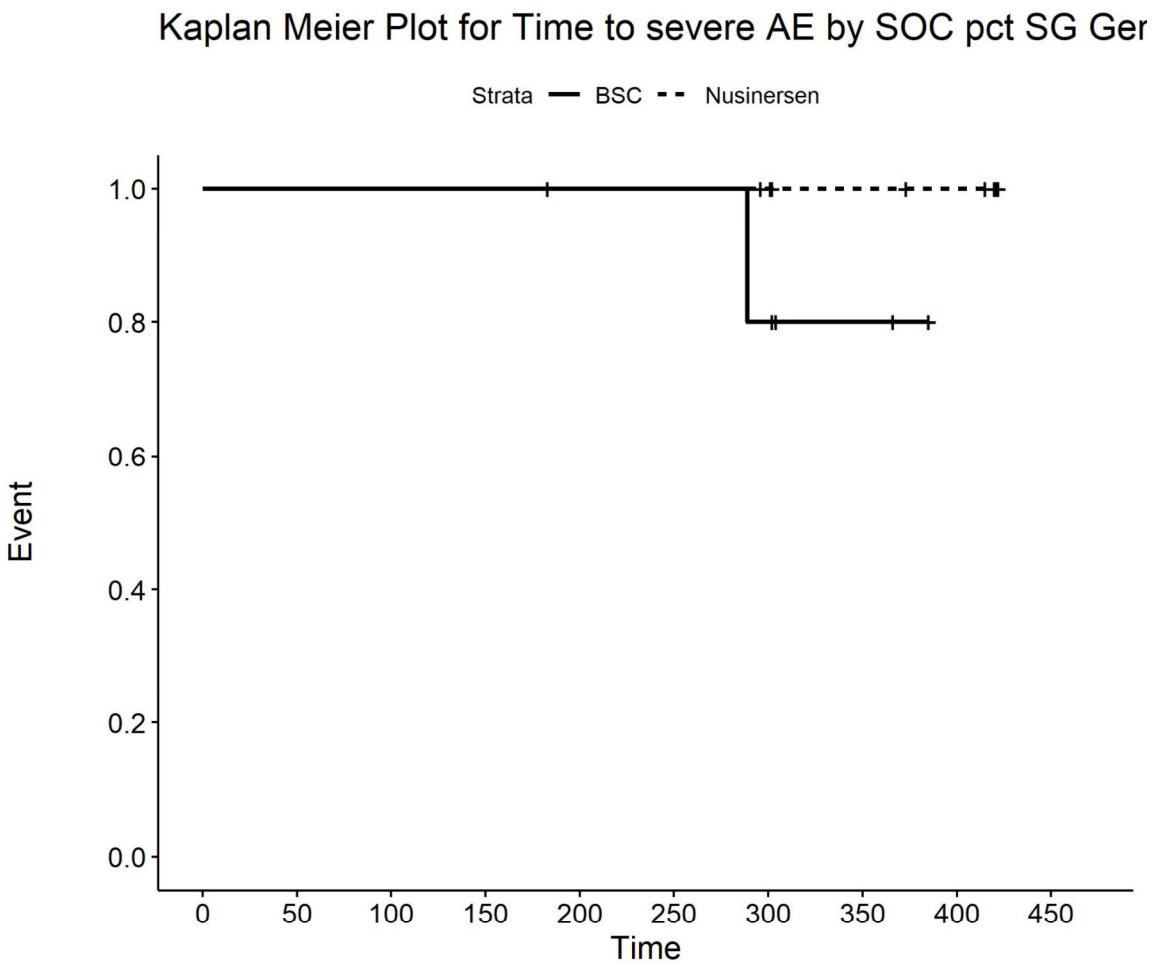
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



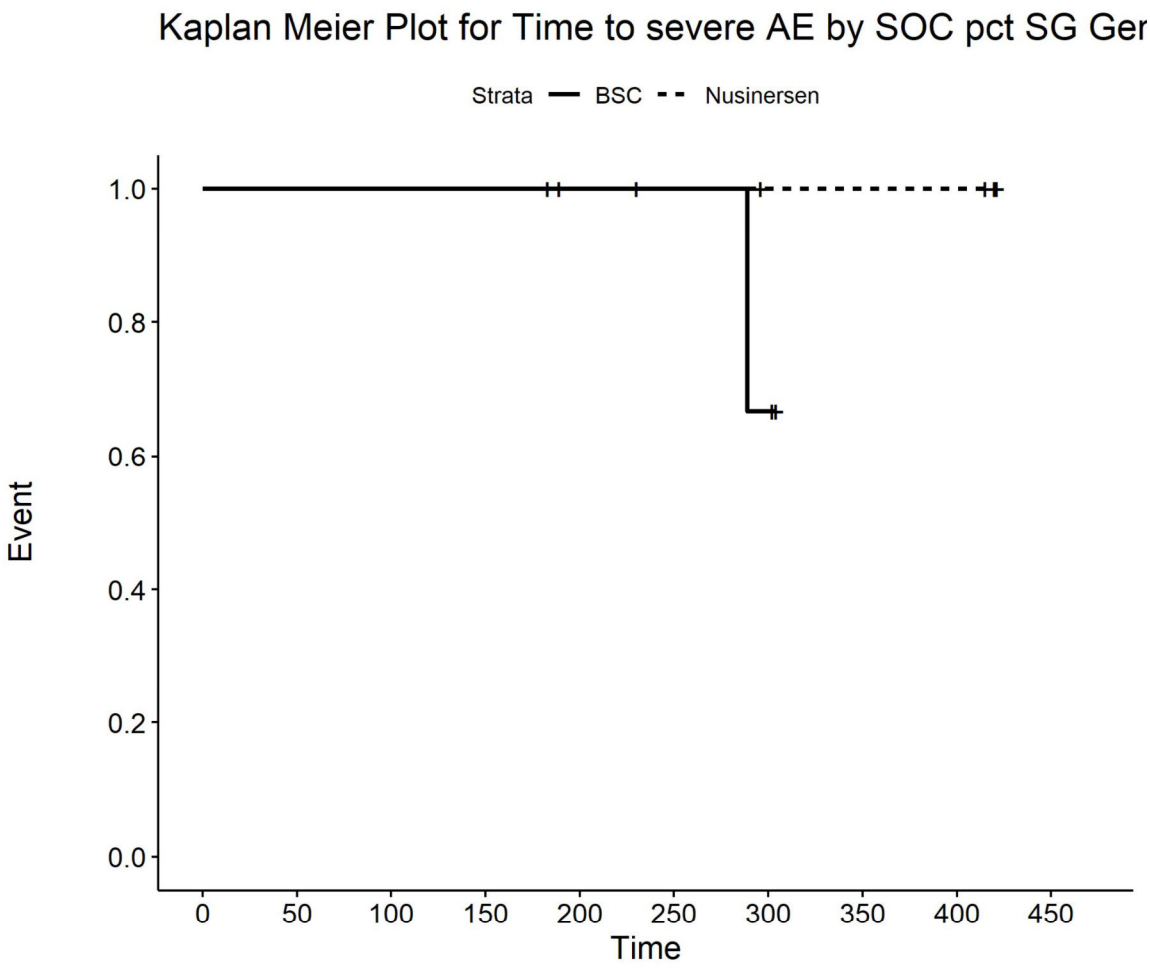
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



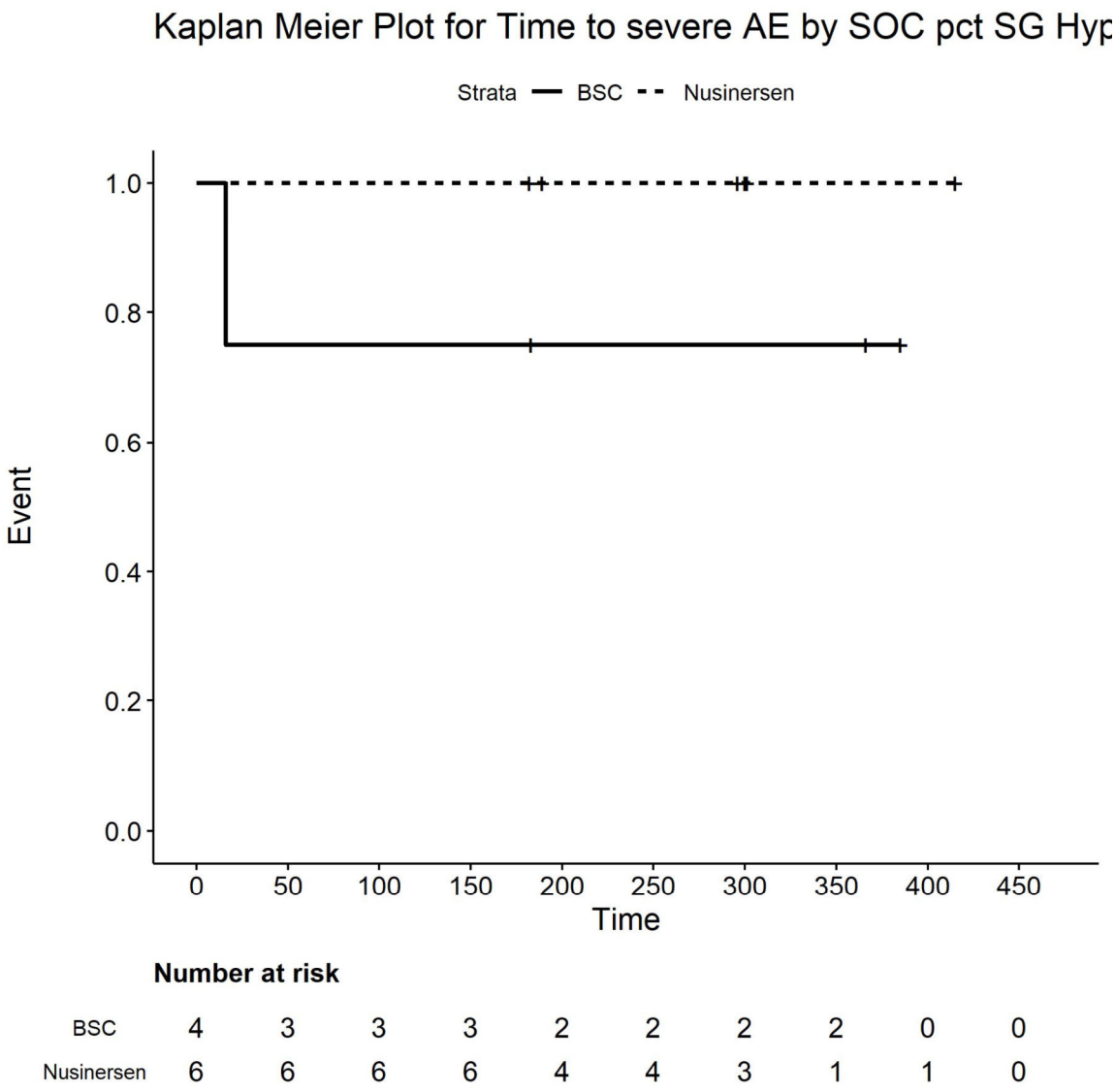
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



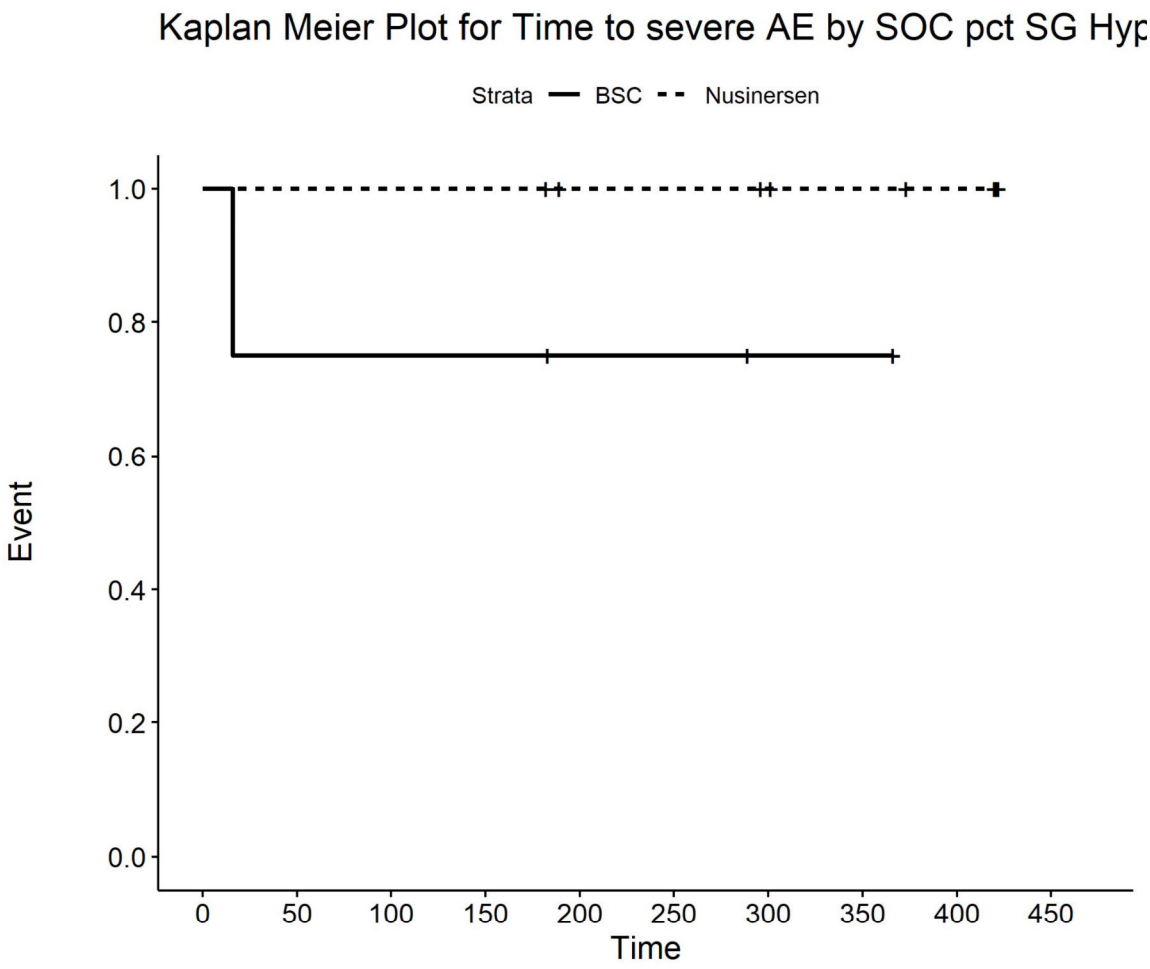
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



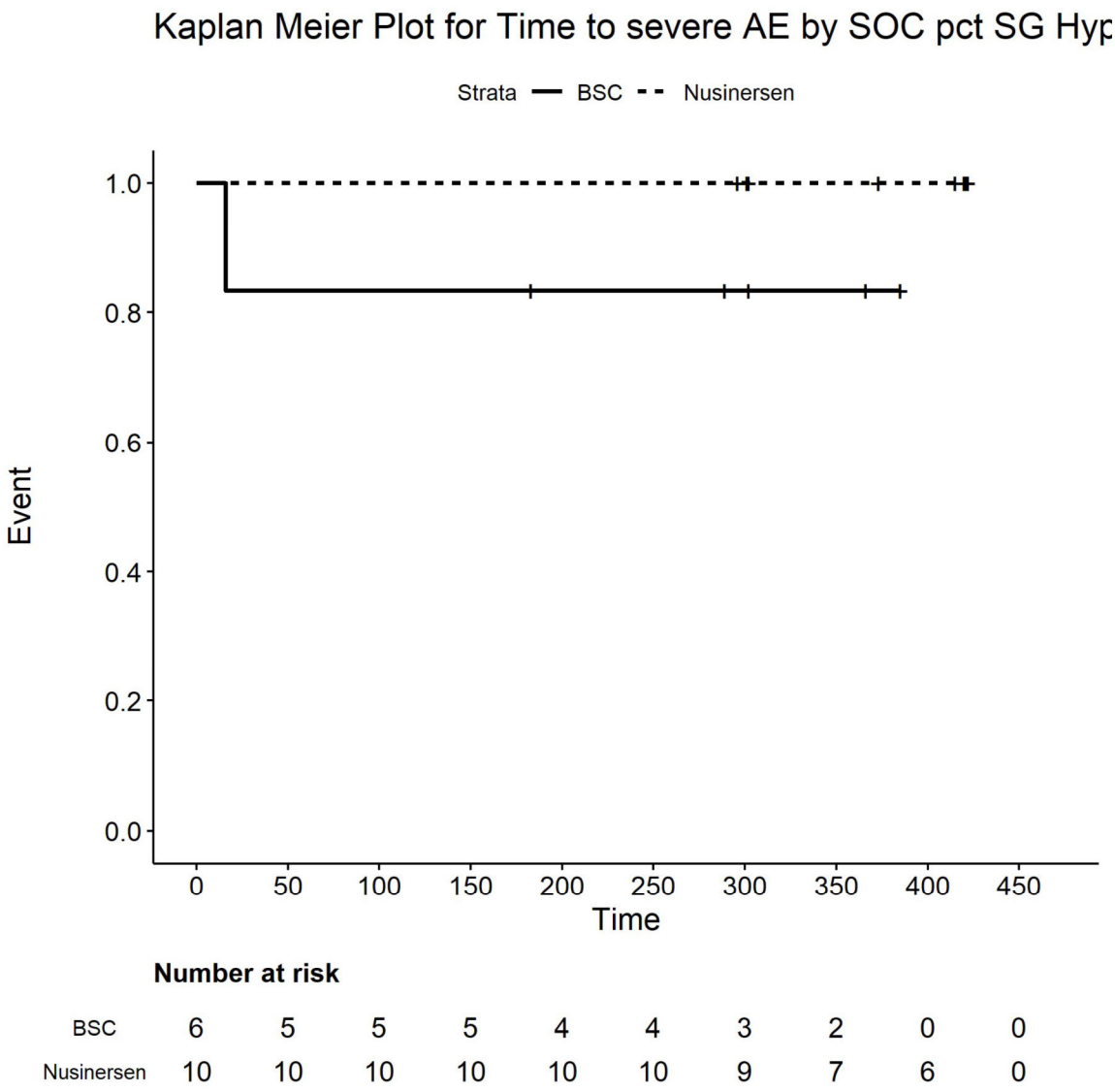
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



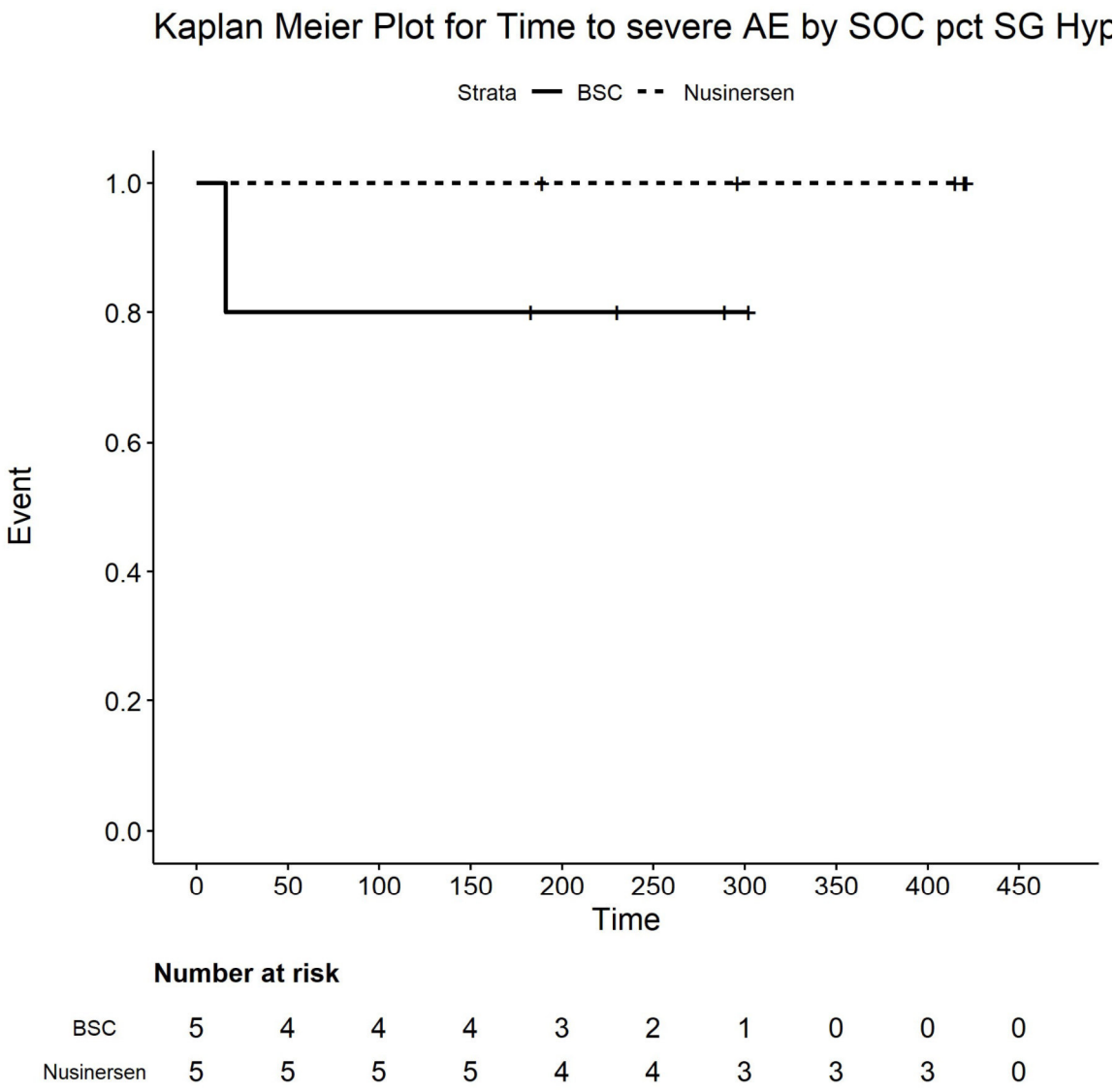
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



Number at risk

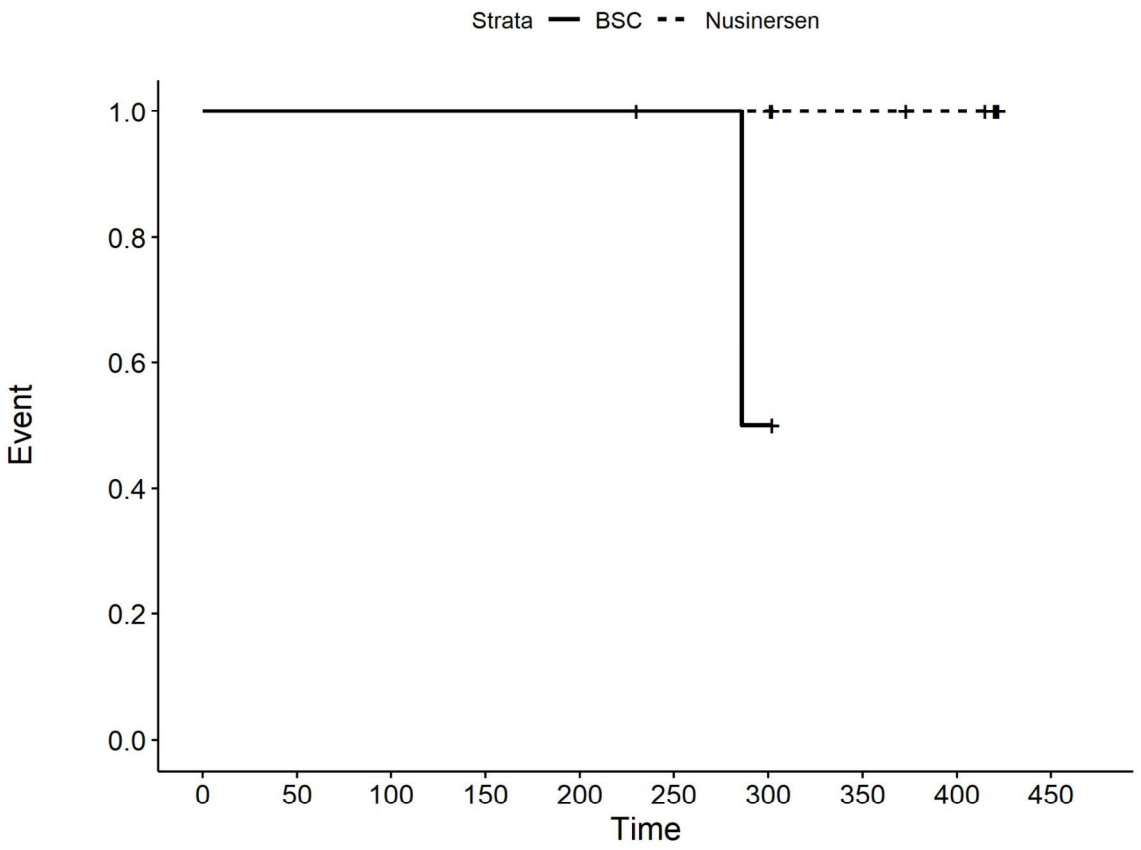
BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0

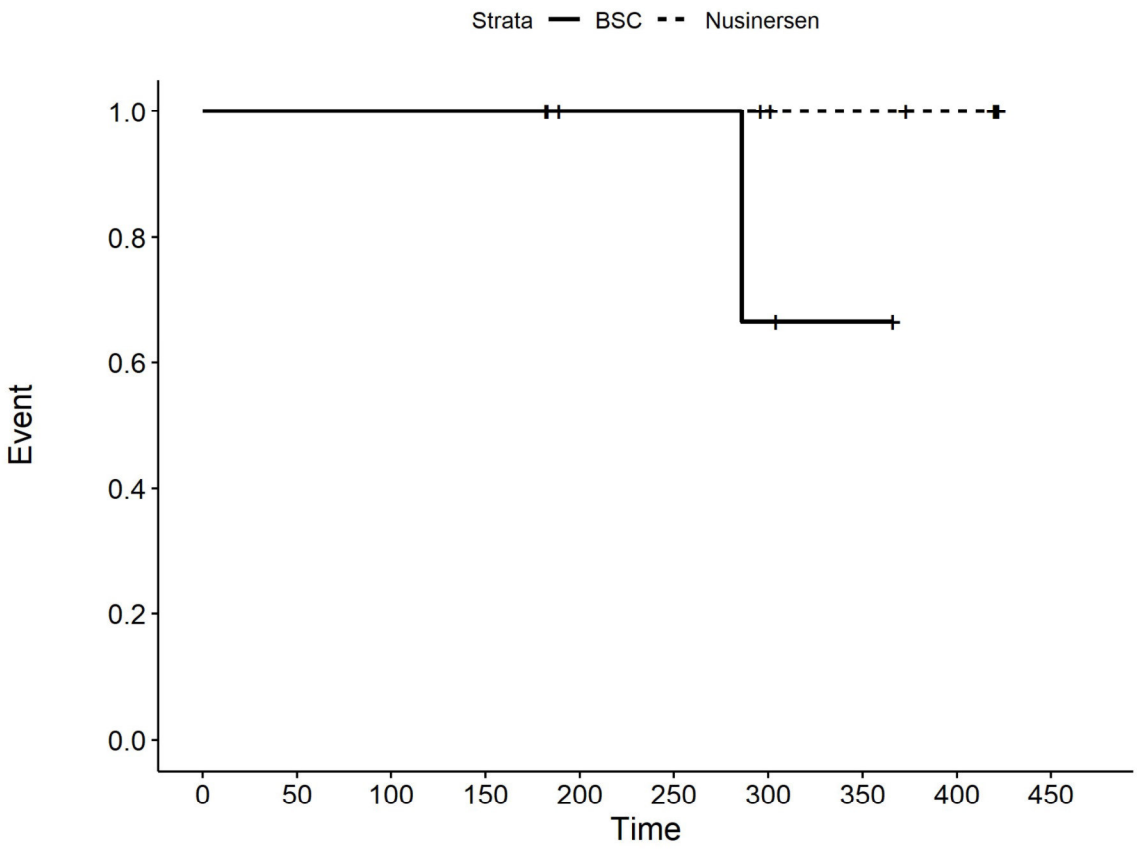
Kaplan Meier Plot for
Time to severe AE by SOC pct SG Hypoxic : ischaemic ence



Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0

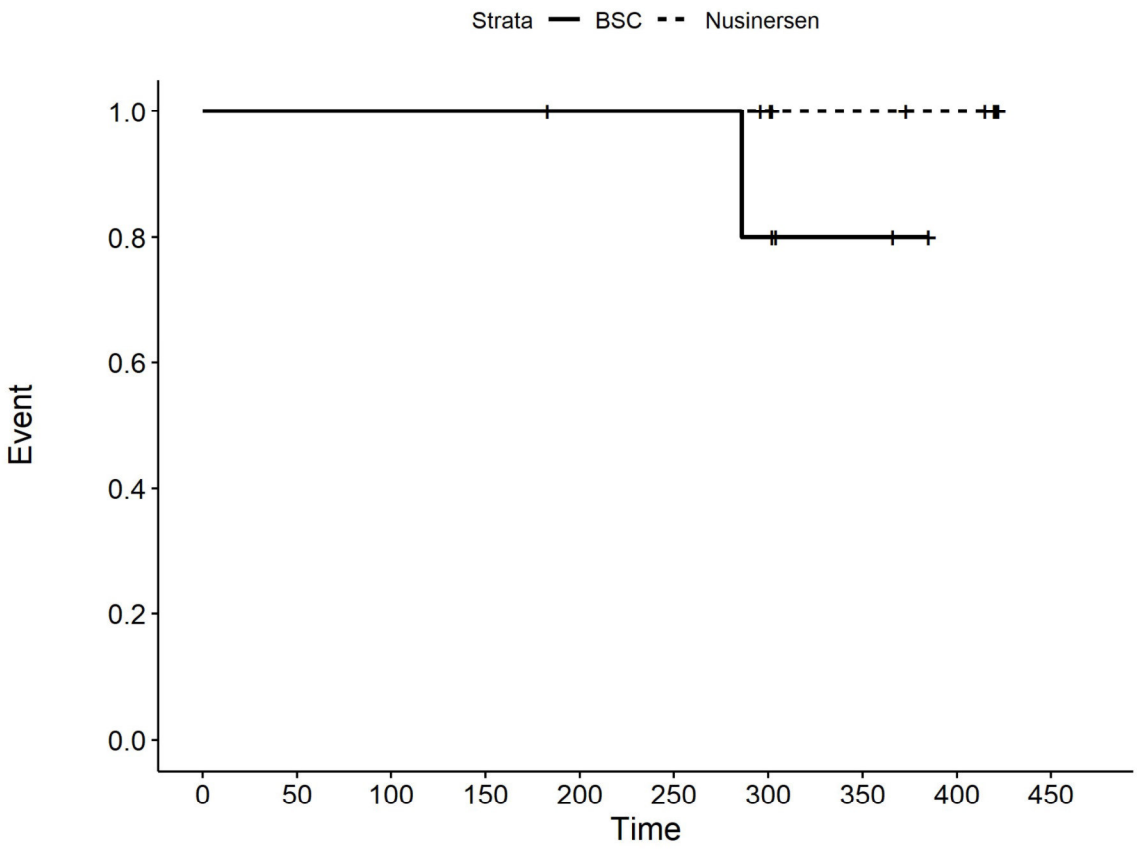
Kaplan Meier Plot for
Time to severe AE by SOC pct SG Hypoxic : ischaemic ence



Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0

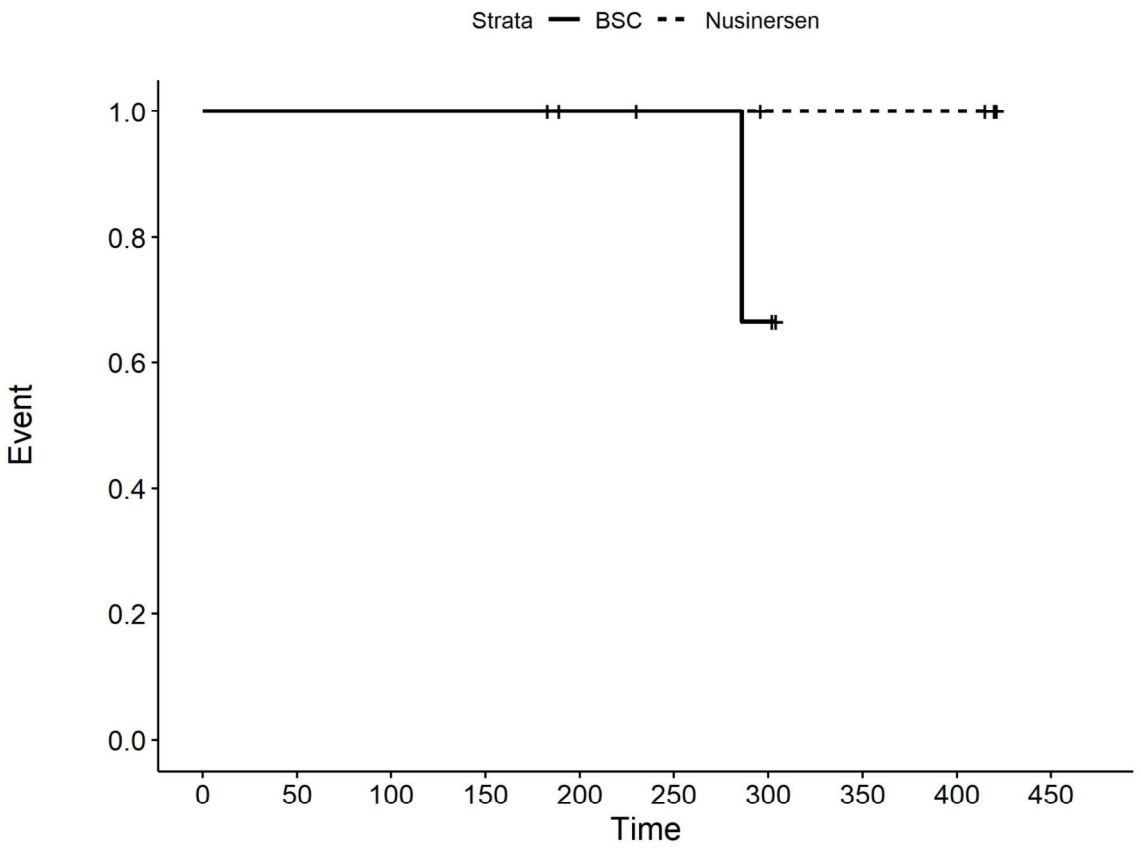
Kaplan Meier Plot for
Time to severe AE by SOC pct SG Hypoxic : ischaemic ence



Number at risk

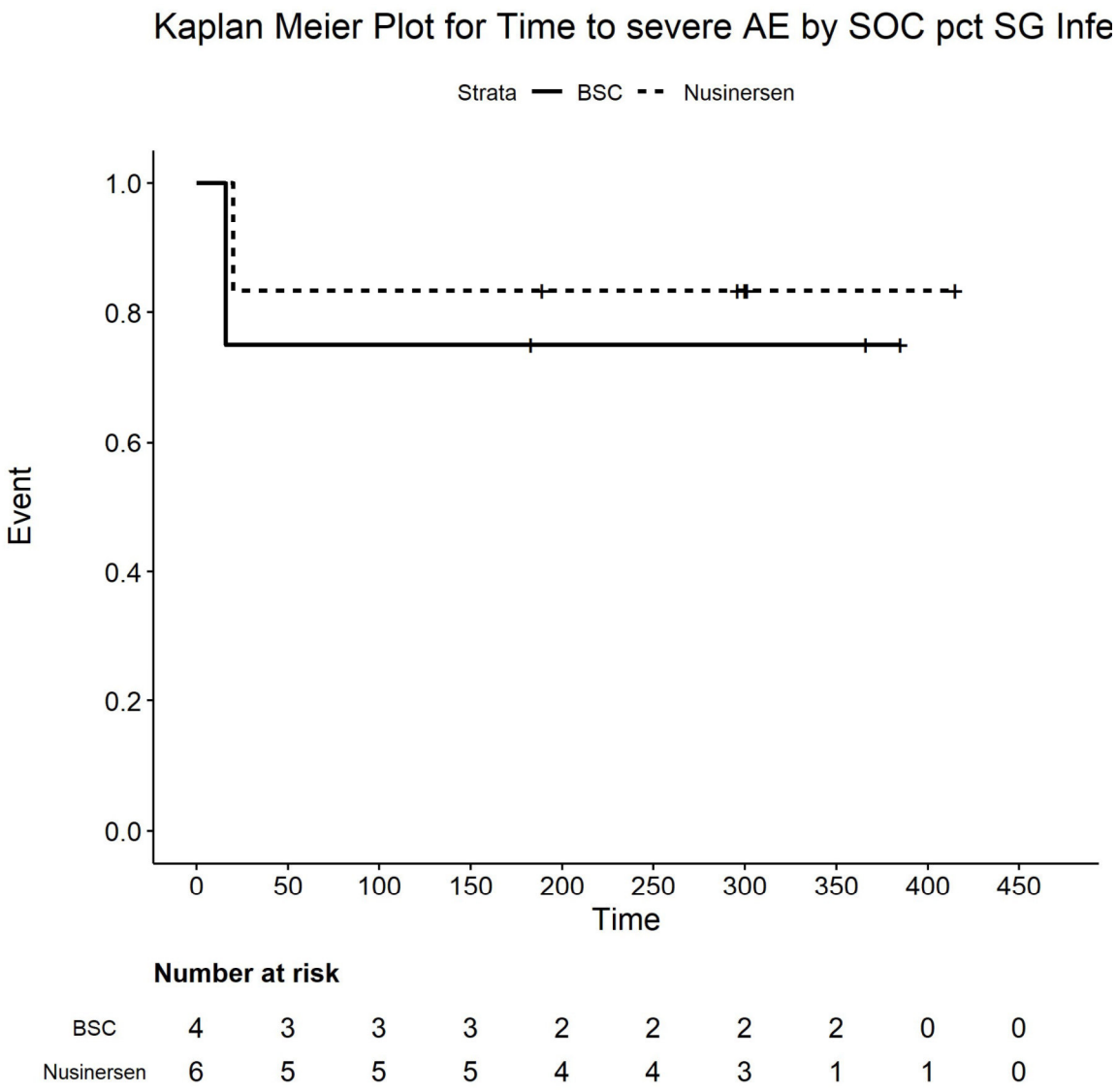
BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0

Kaplan Meier Plot for
Time to severe AE by SOC pct SG Hypoxic : ischaemic ence



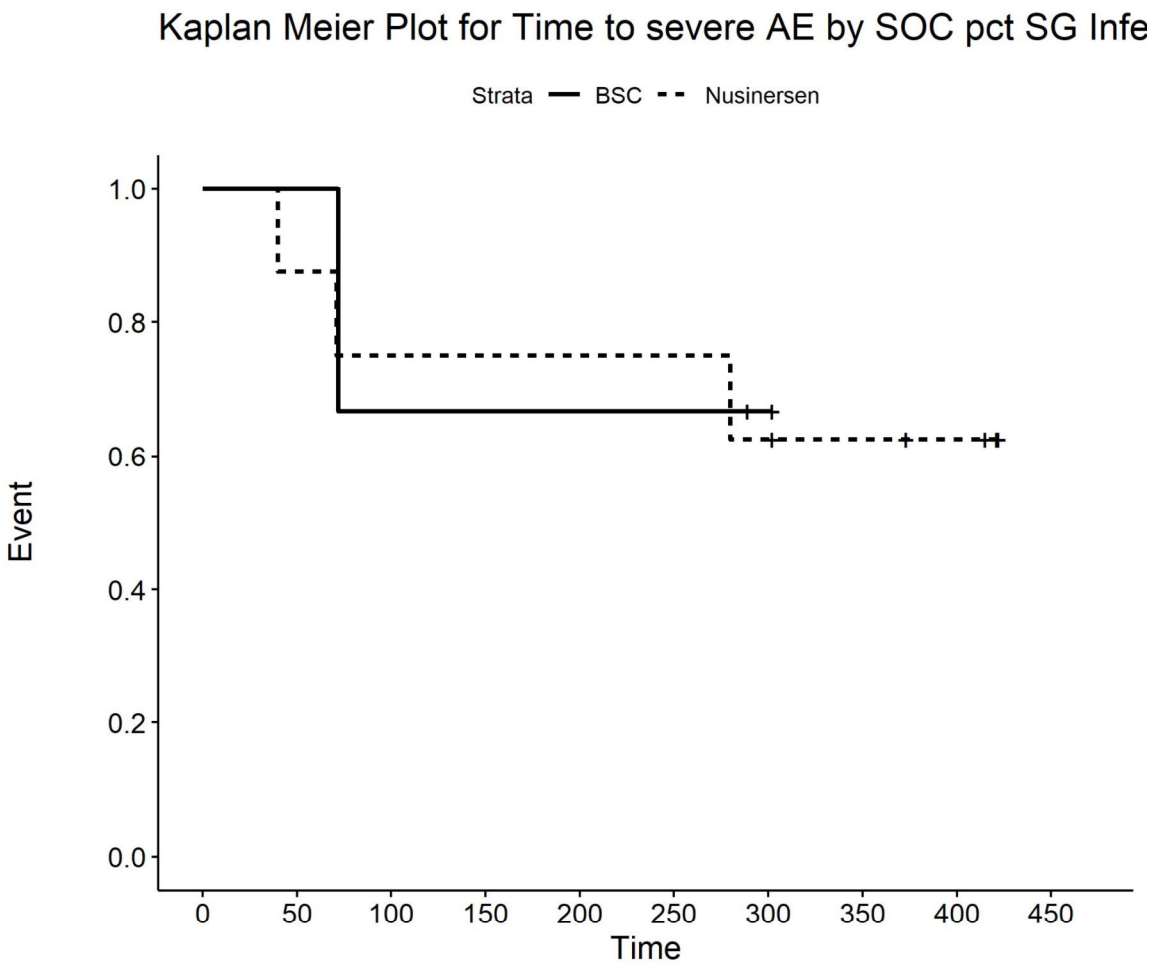
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



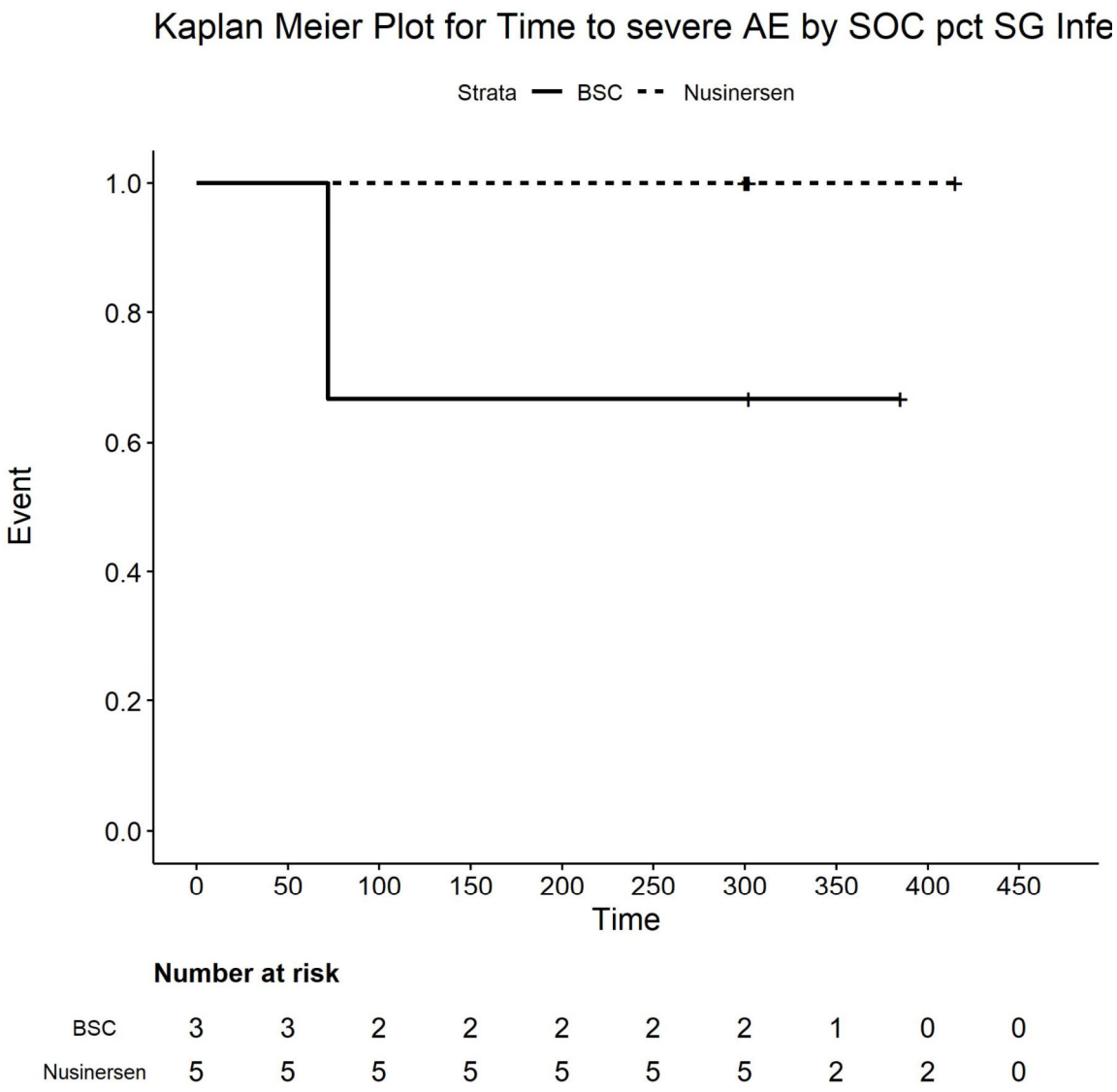
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	5	5	5	4	4	3	1	1	0



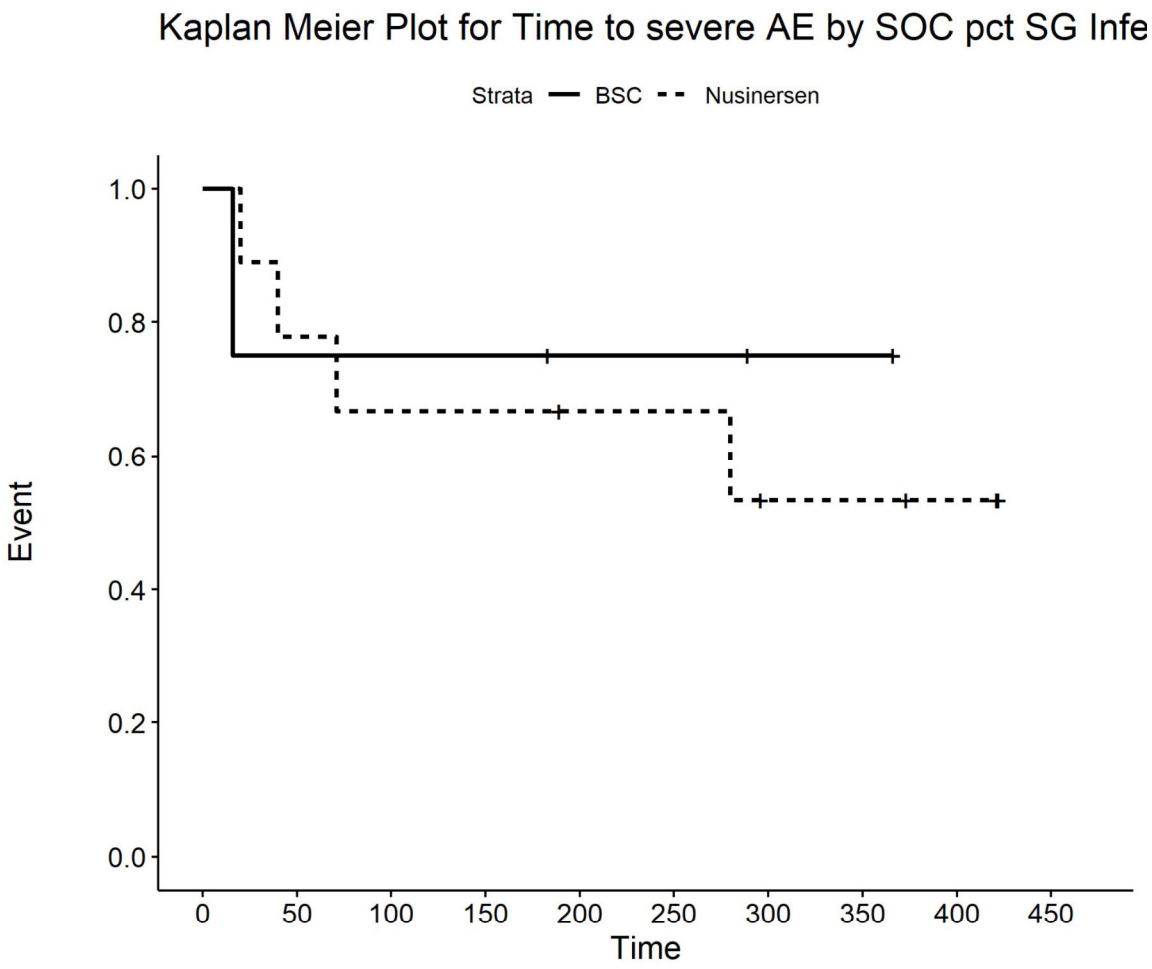
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	7	6	6	6	6	5	4	3	0



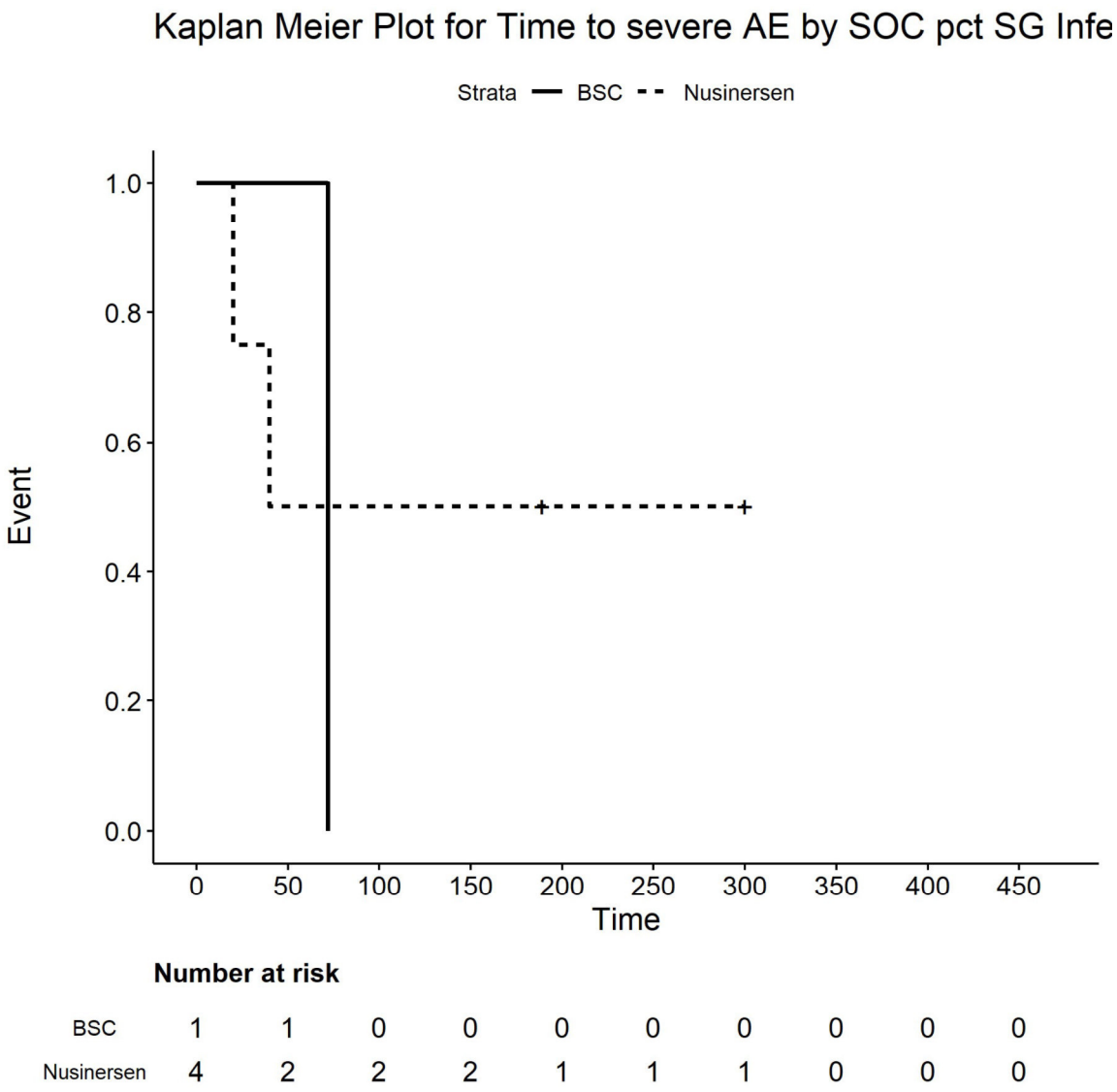
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



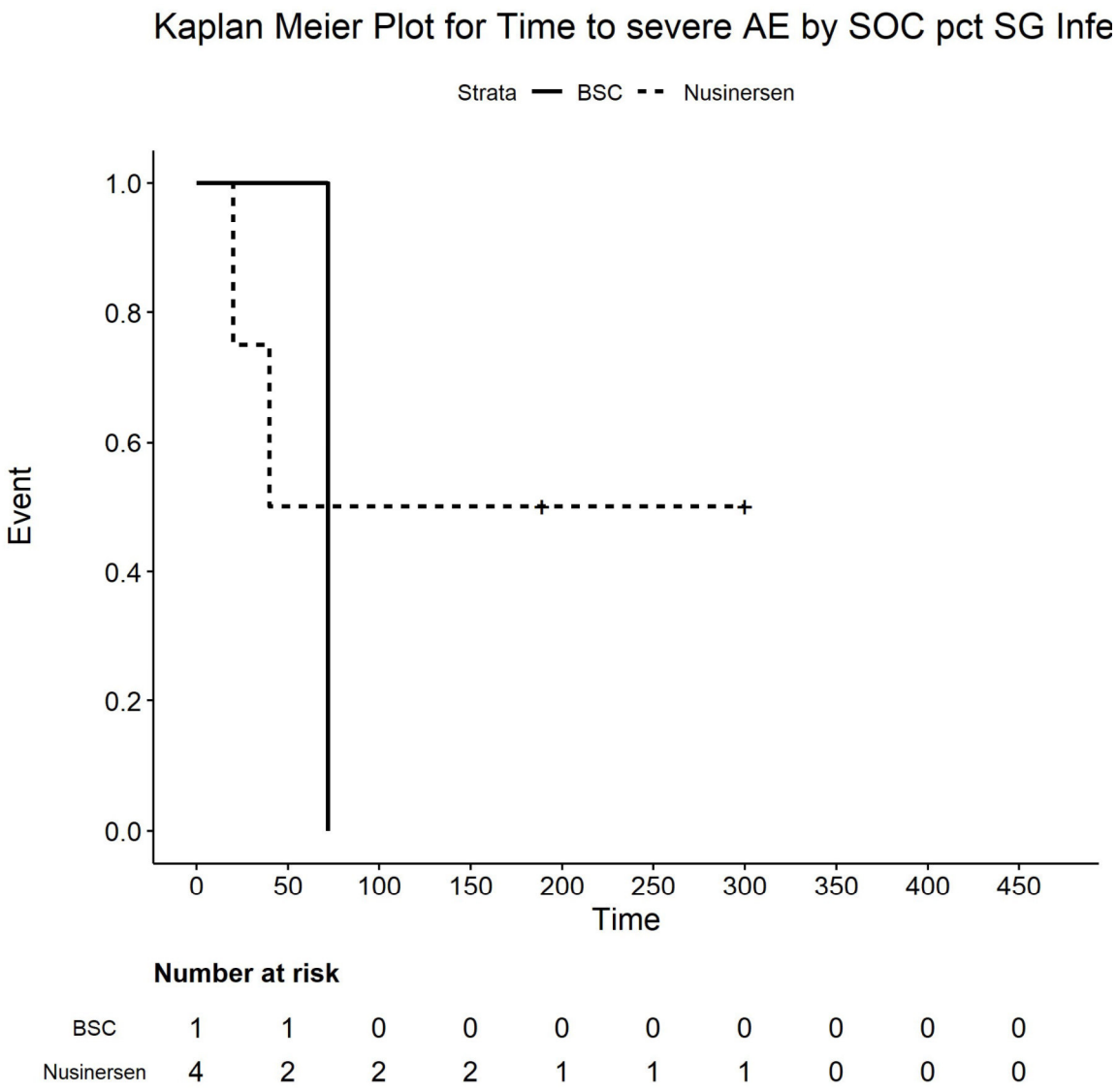
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	7	6	6	5	5	3	3	2	0



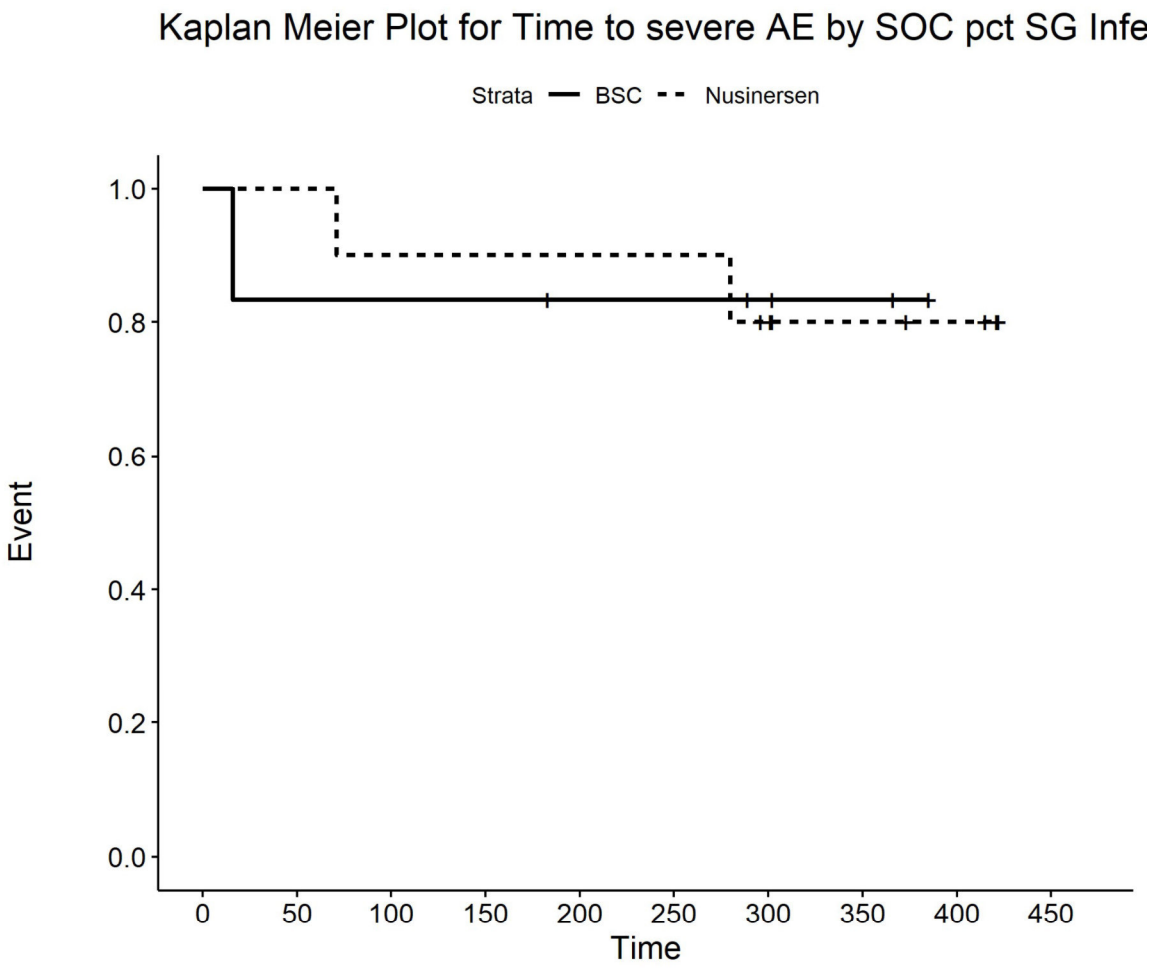
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	2	2	2	1	1	1	0	0	0



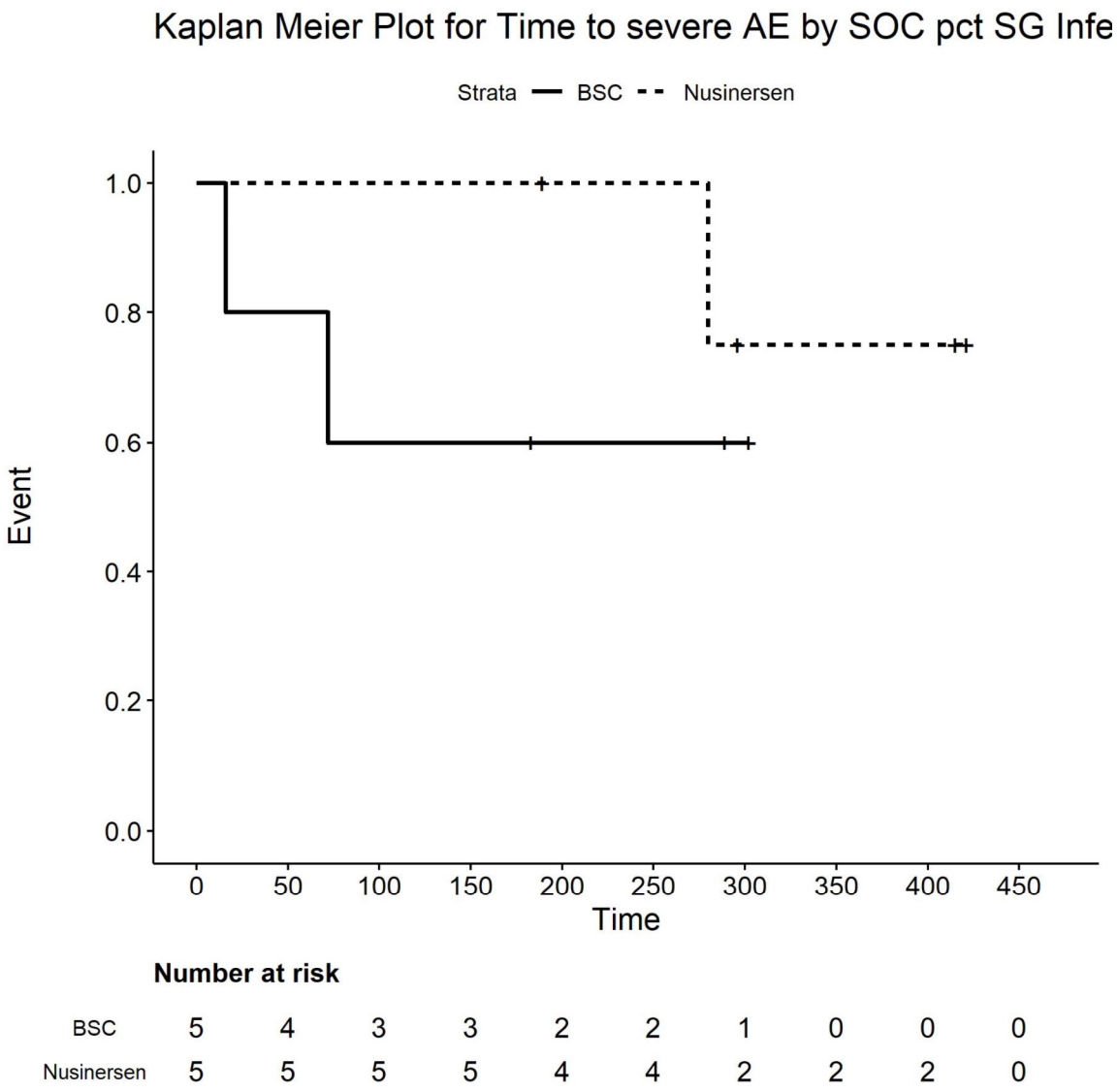
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	2	2	2	1	1	1	0	0	0



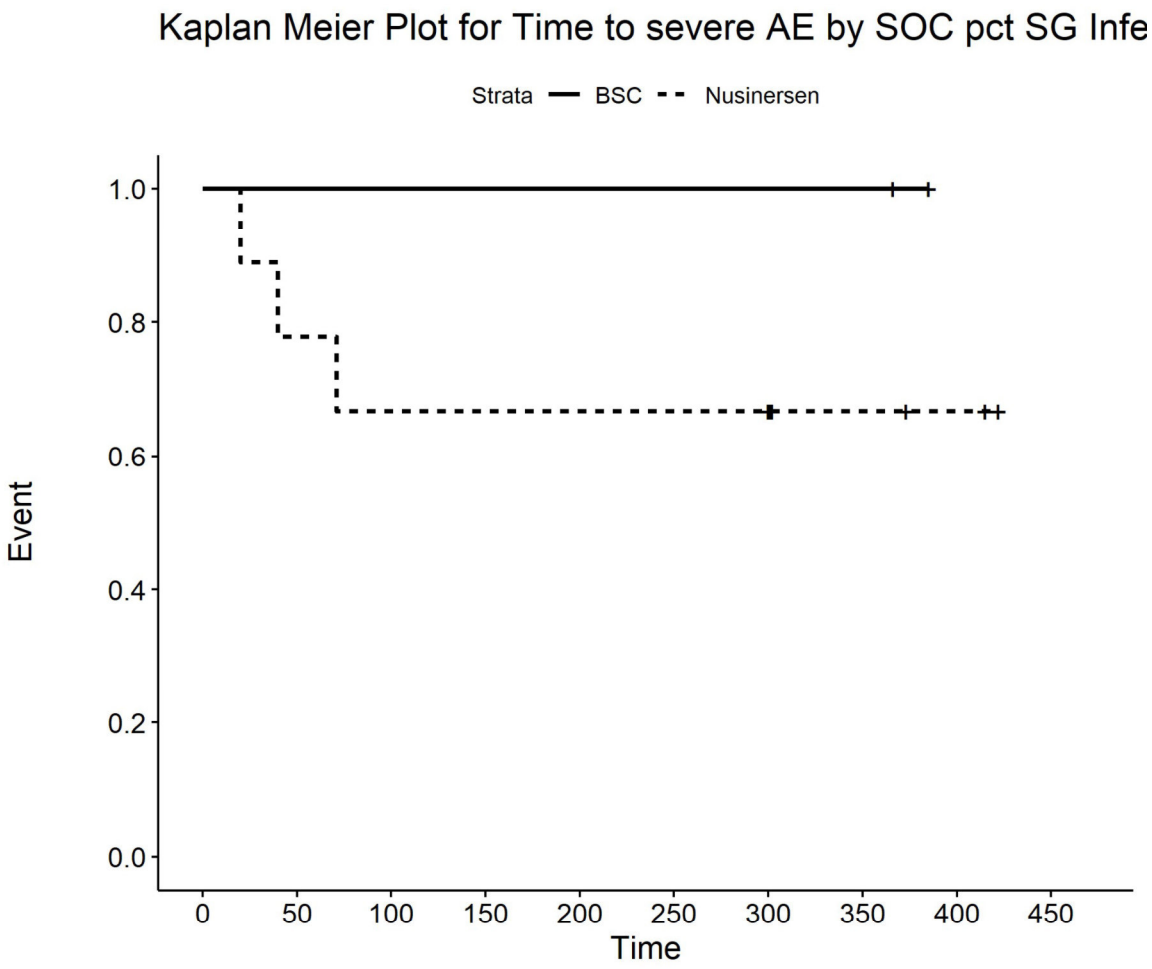
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	9	9	9	9	7	5	4	0



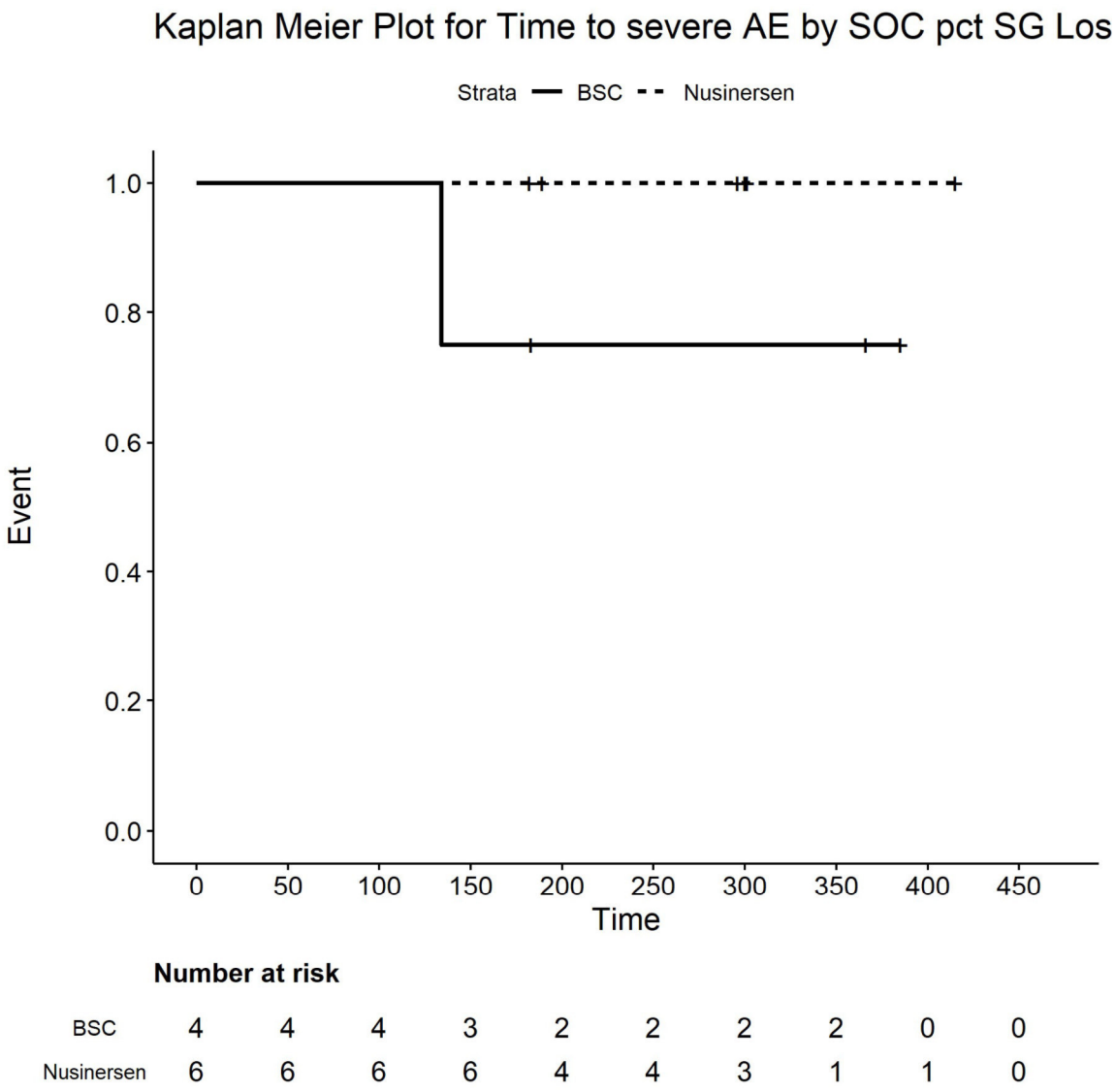
Number at risk

BSC	5	4	3	3	2	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	2	2	2	0



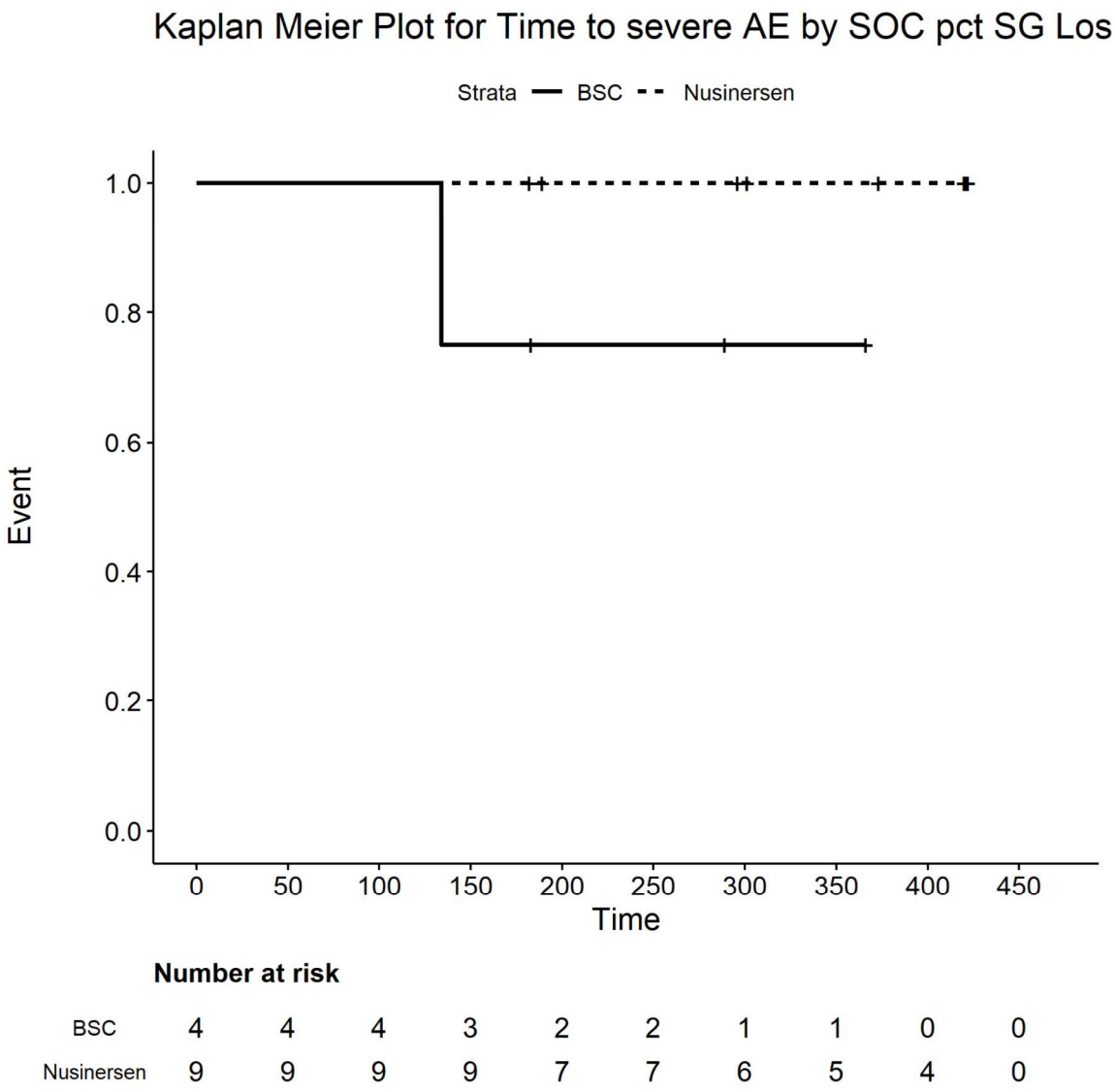
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	6	6	6	6	6	3	2	0



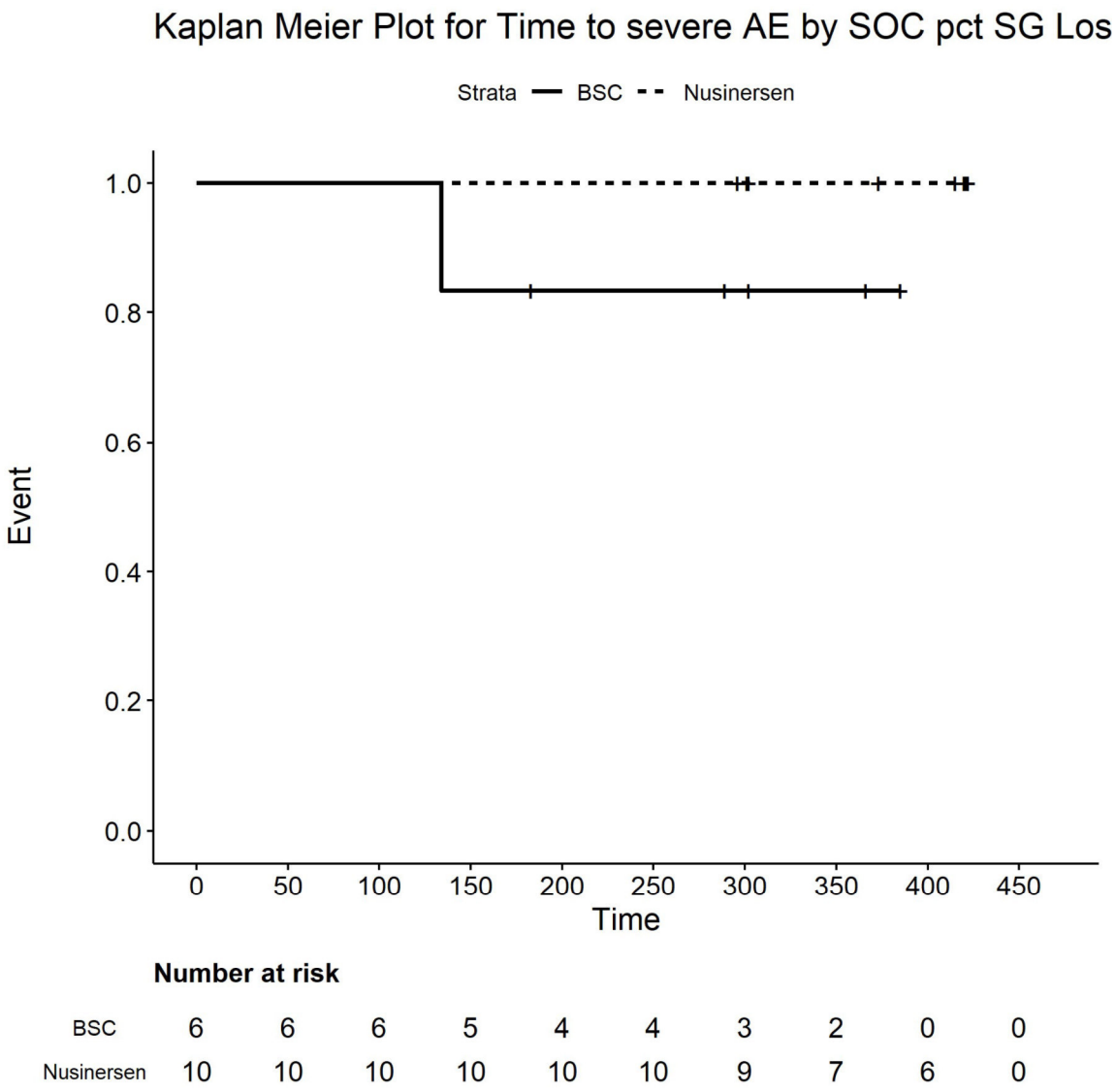
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



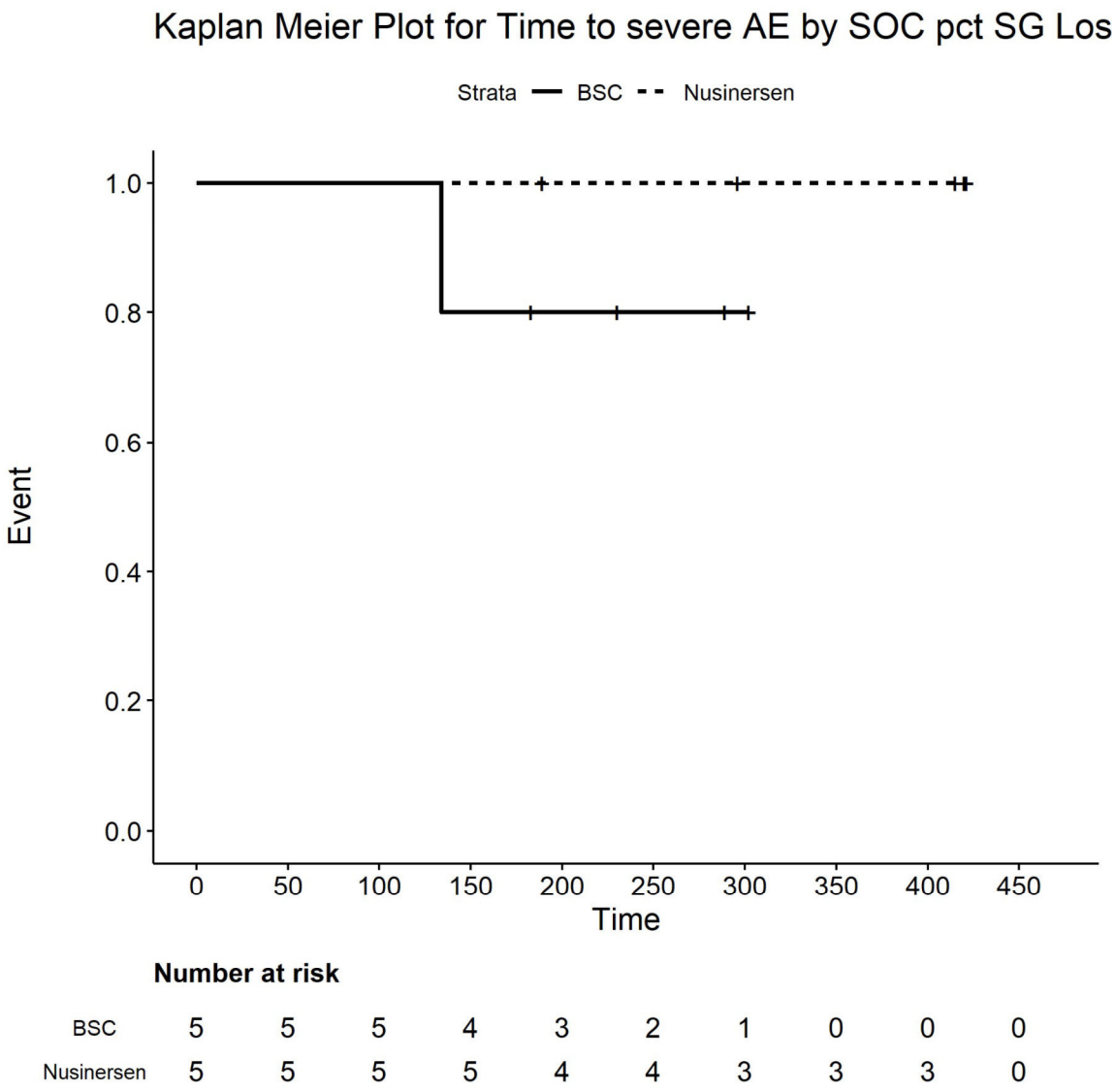
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



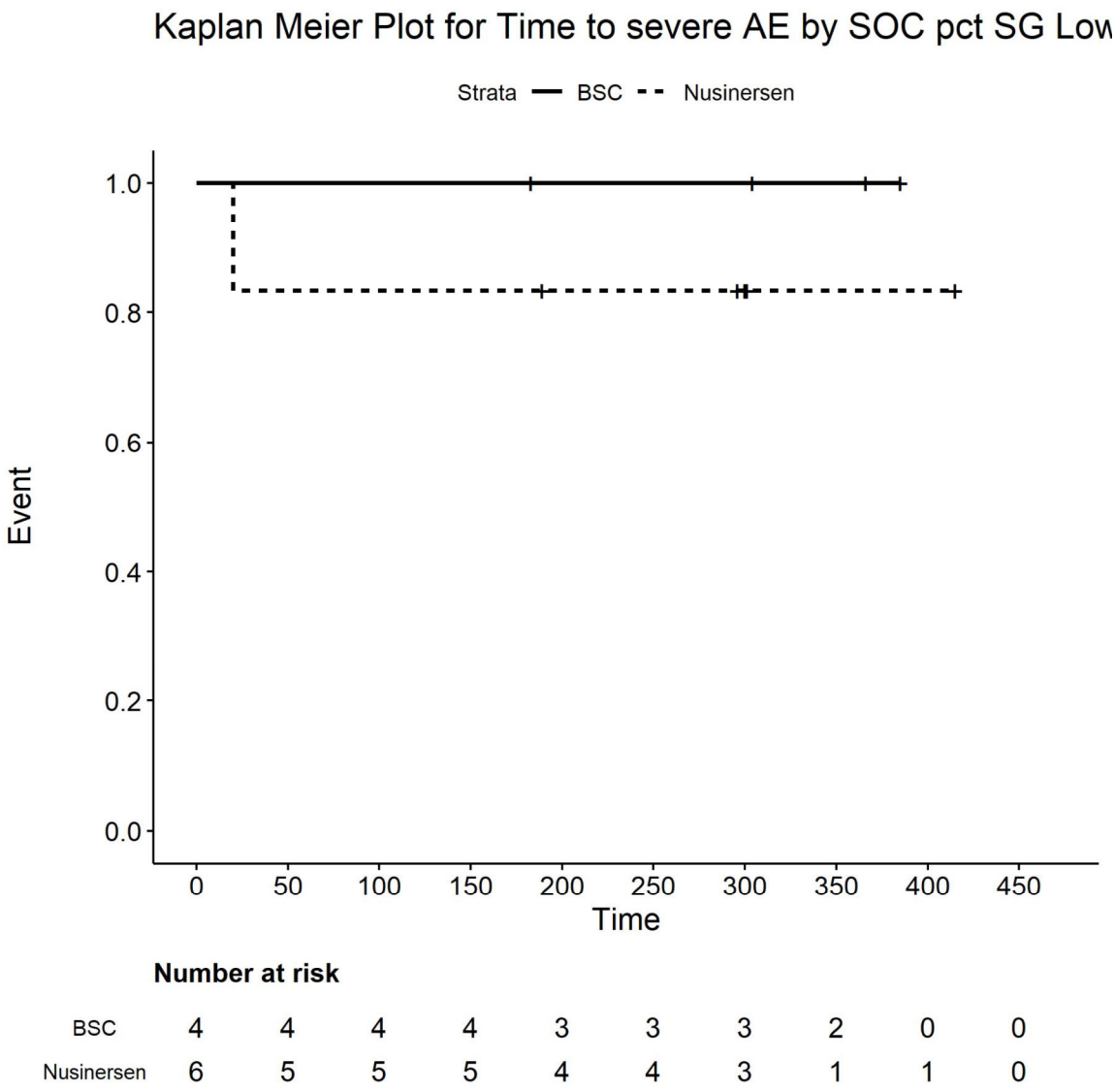
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



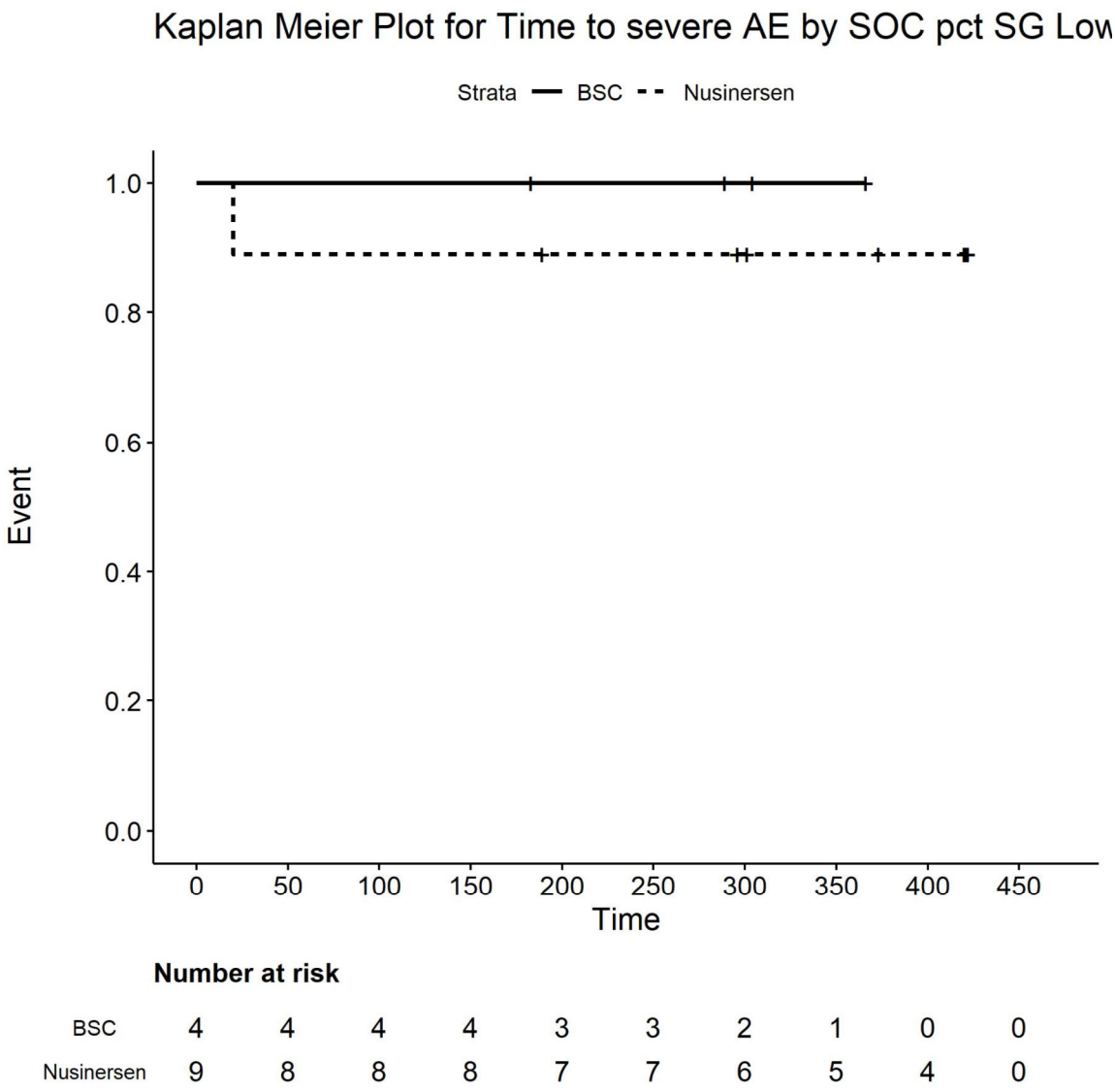
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



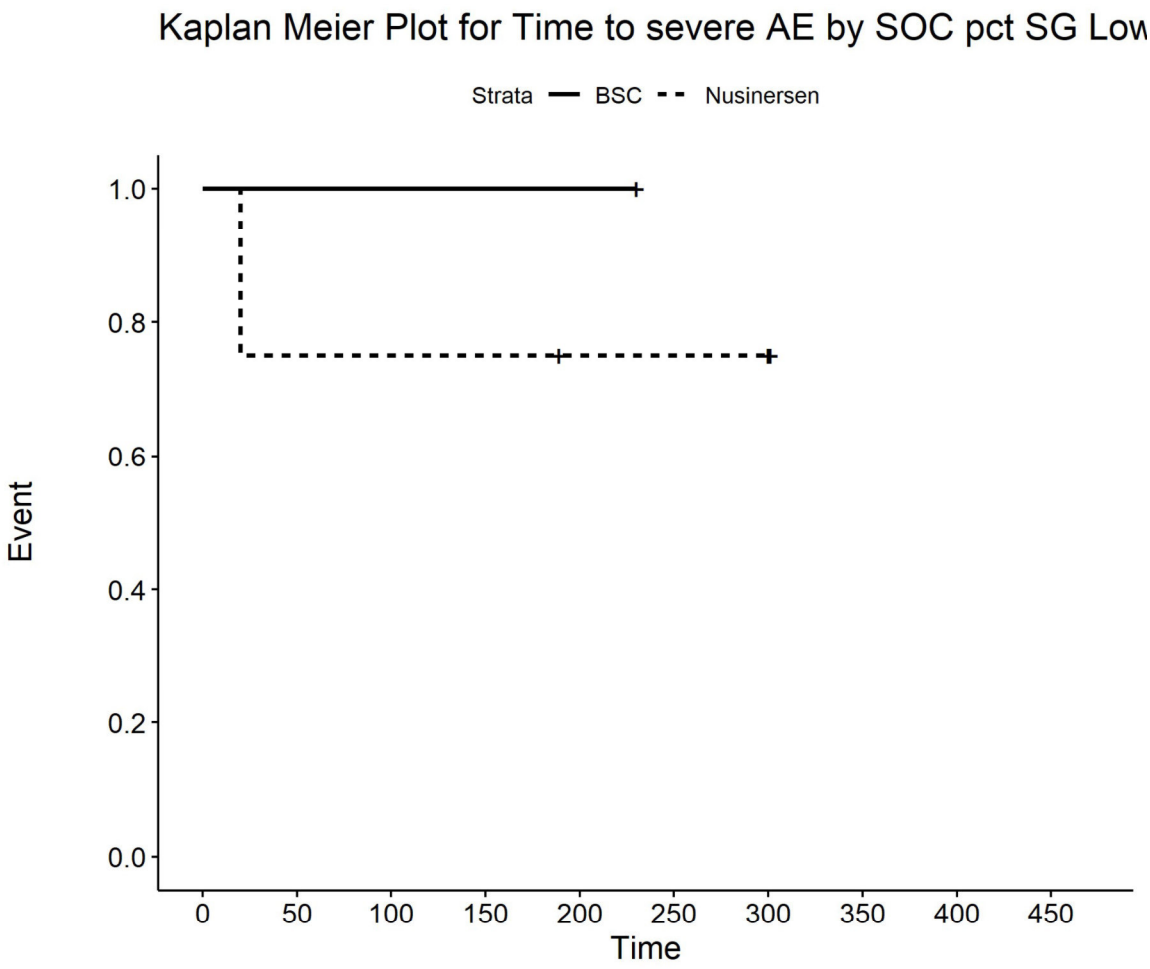
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	5	5	5	4	4	3	1	1	0



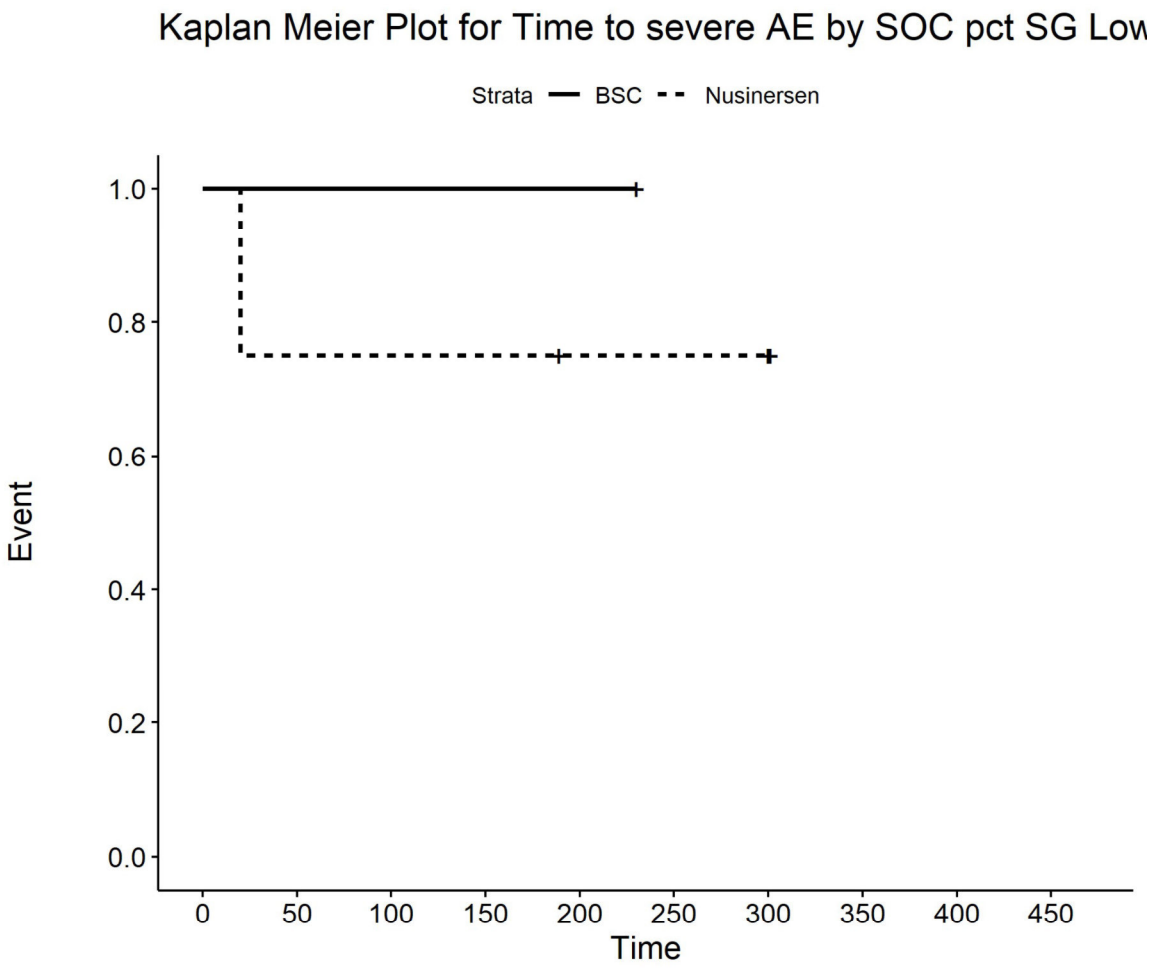
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	8	8	7	7	6	5	4	0



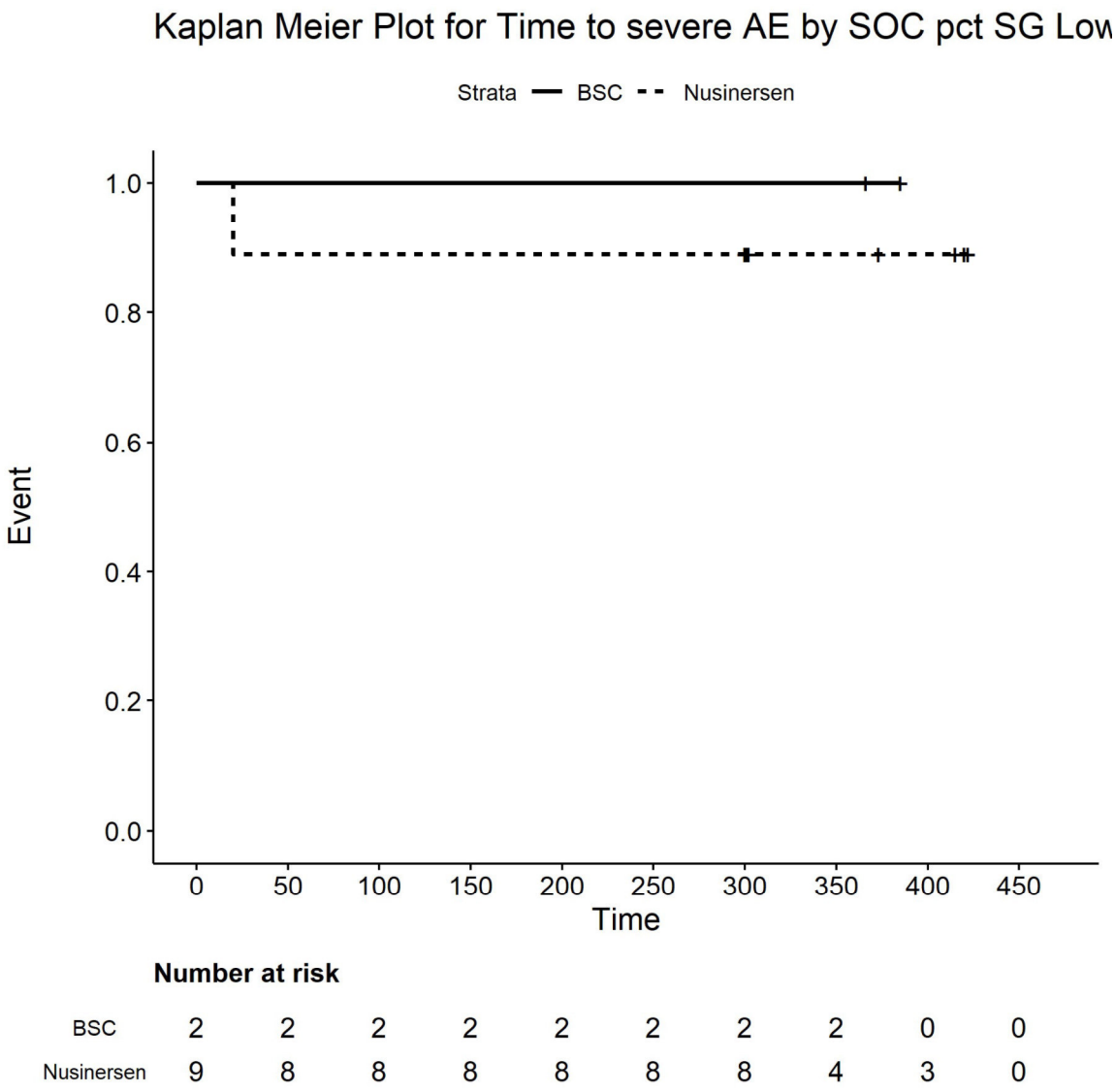
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



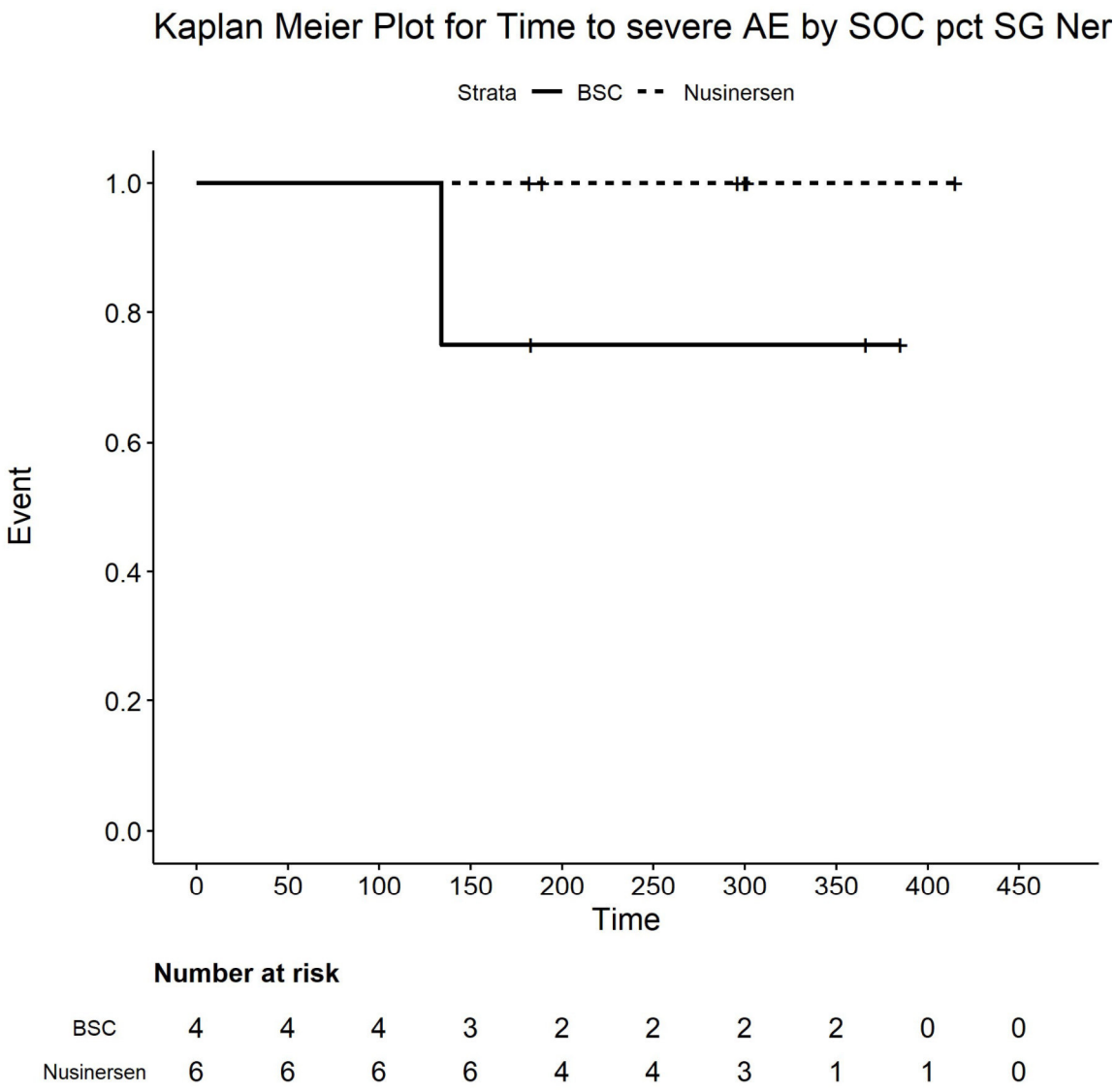
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	3	2	2	2	0	0	0



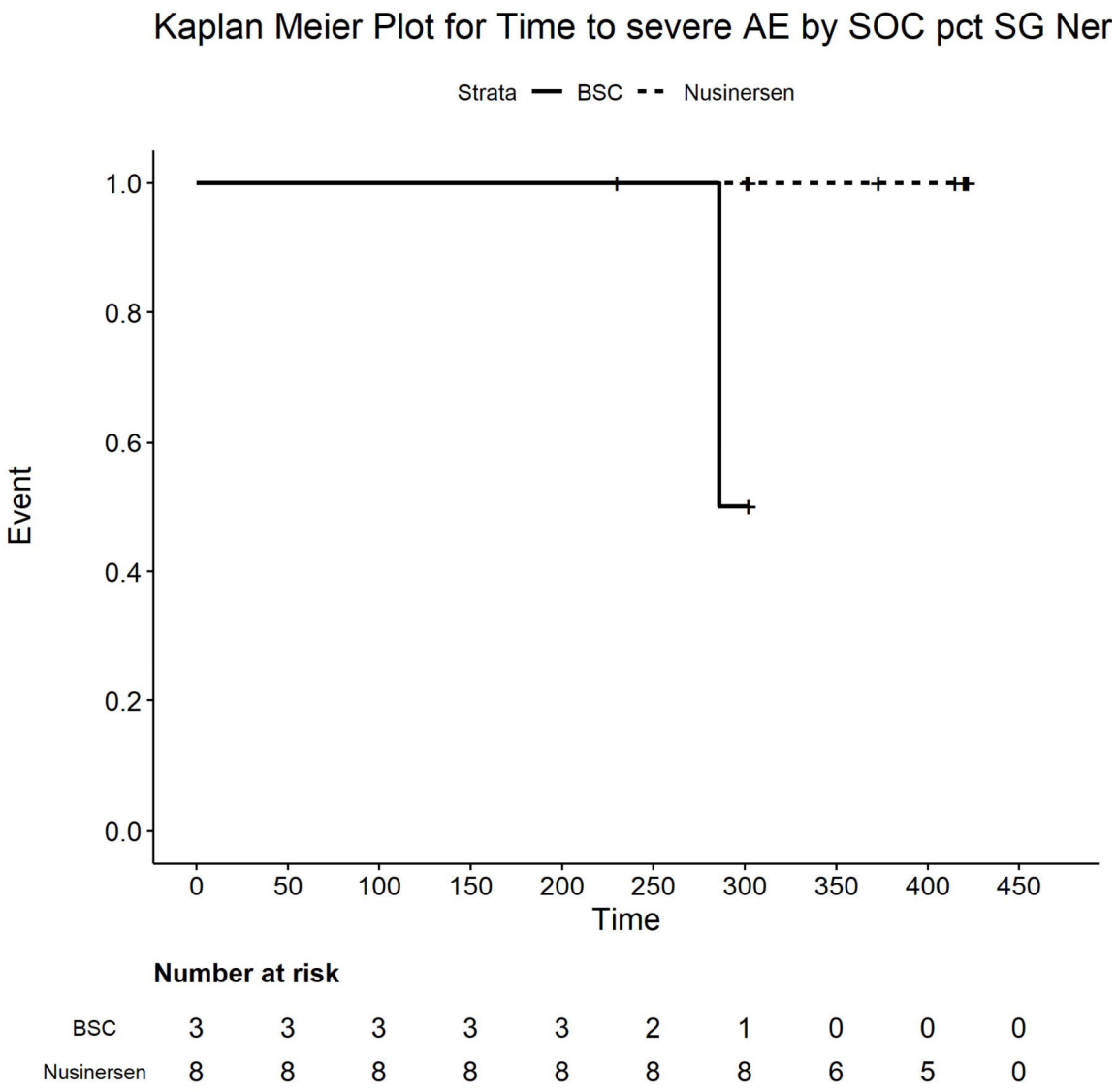
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	8	8	8	8	8	4	3	0



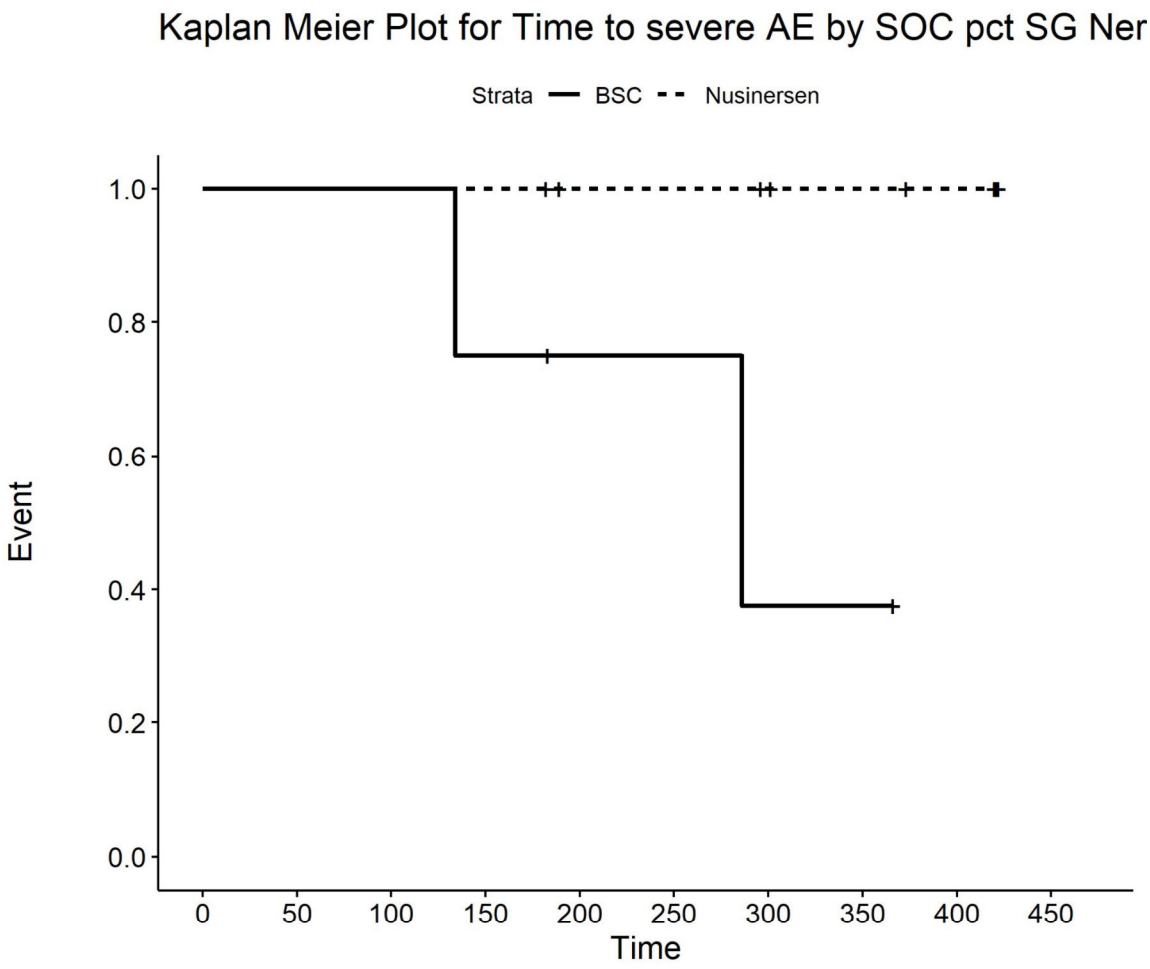
Number at risk

BSC	4	4	4	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



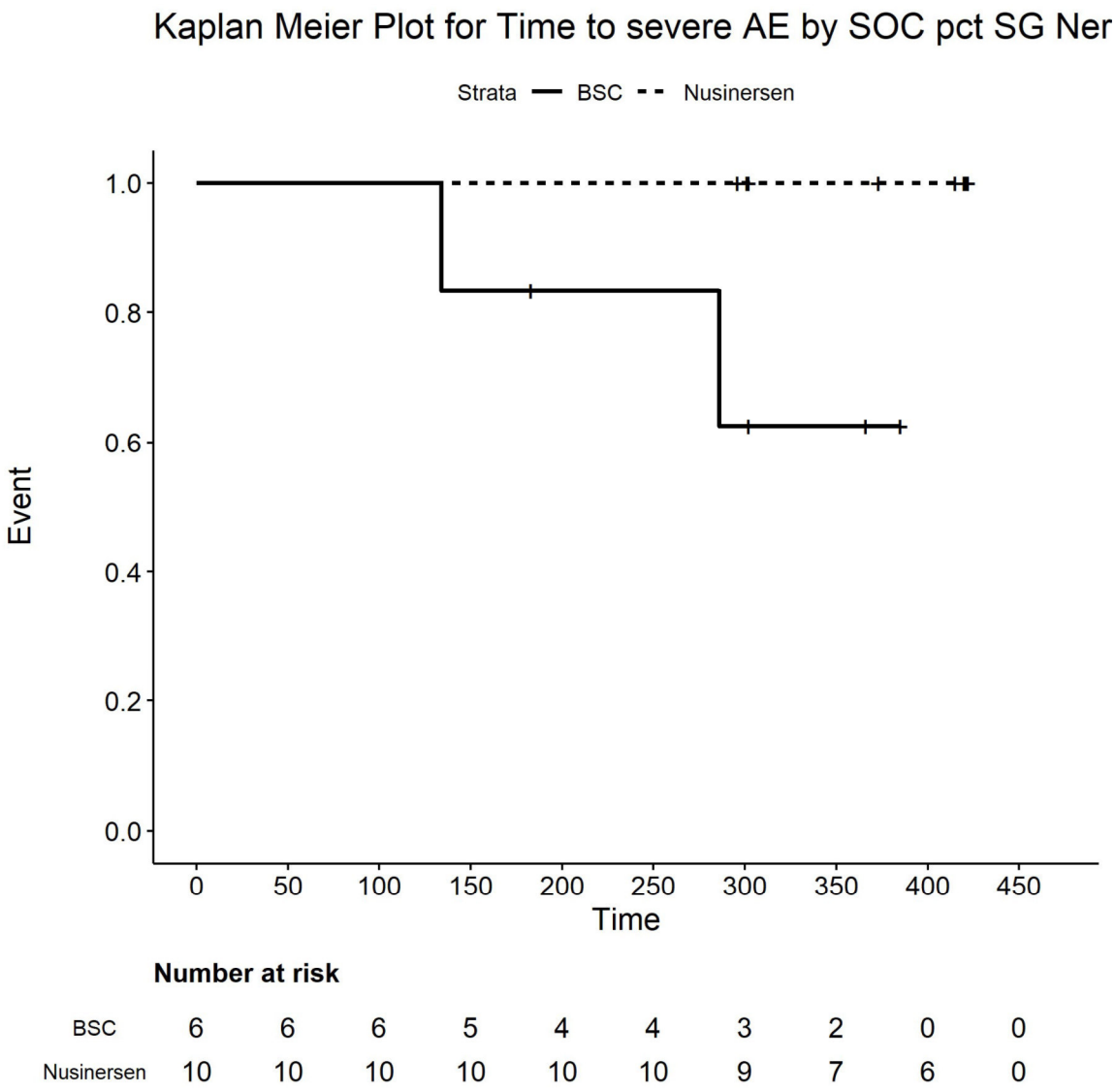
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



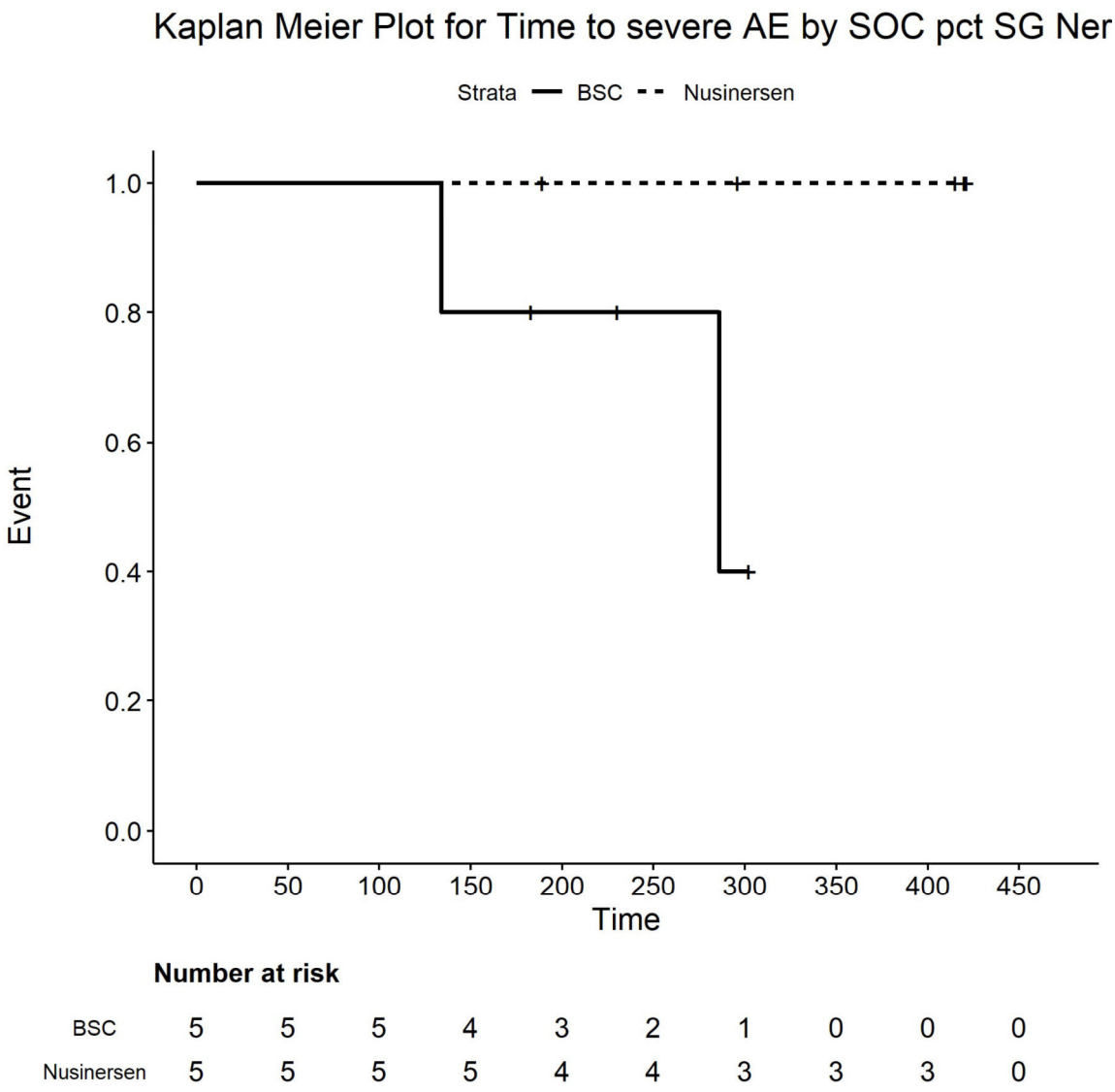
Number at risk

BSC	4	4	4	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	5	4	0



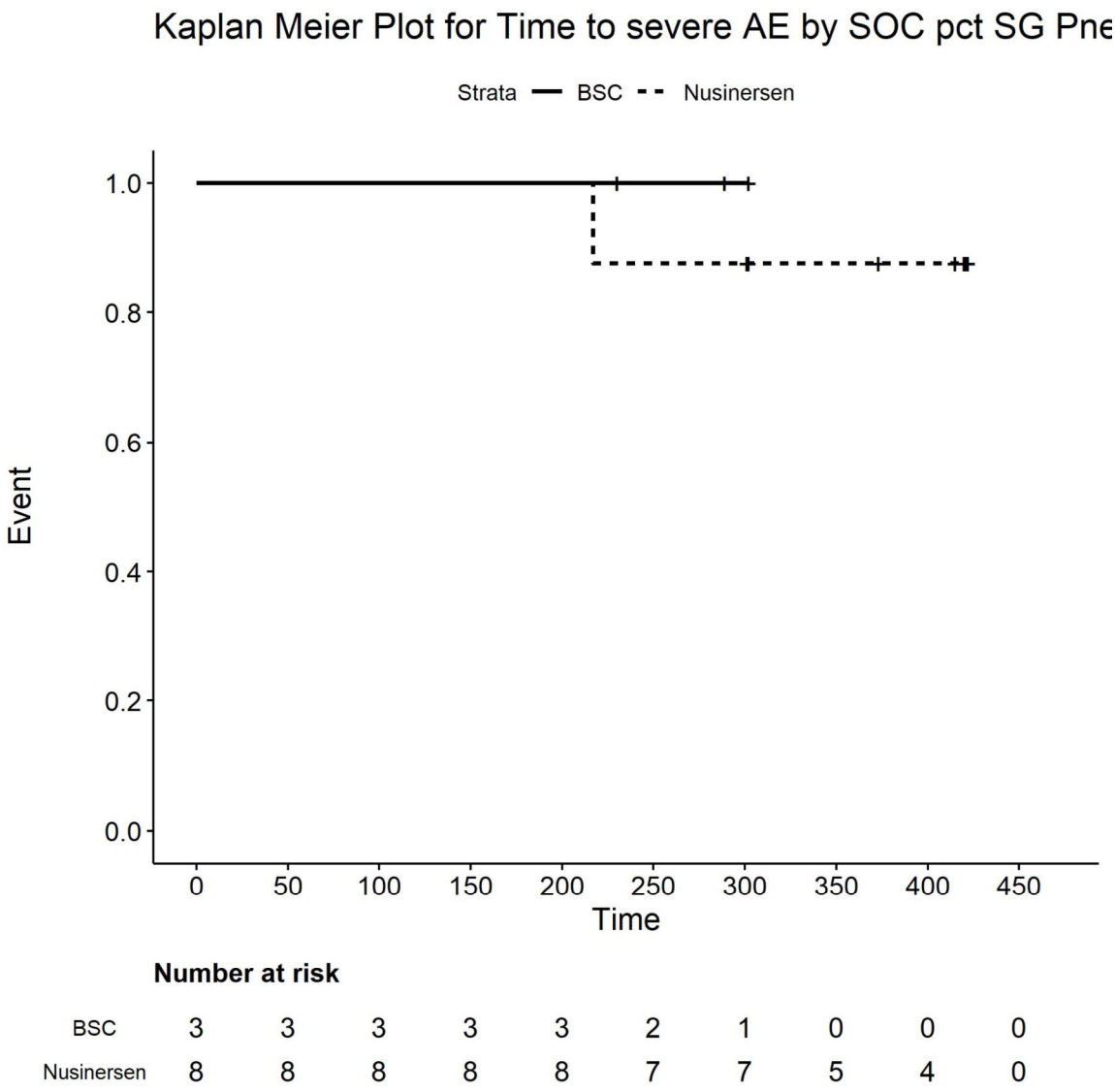
Number at risk

BSC	6	6	6	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	7	6	0



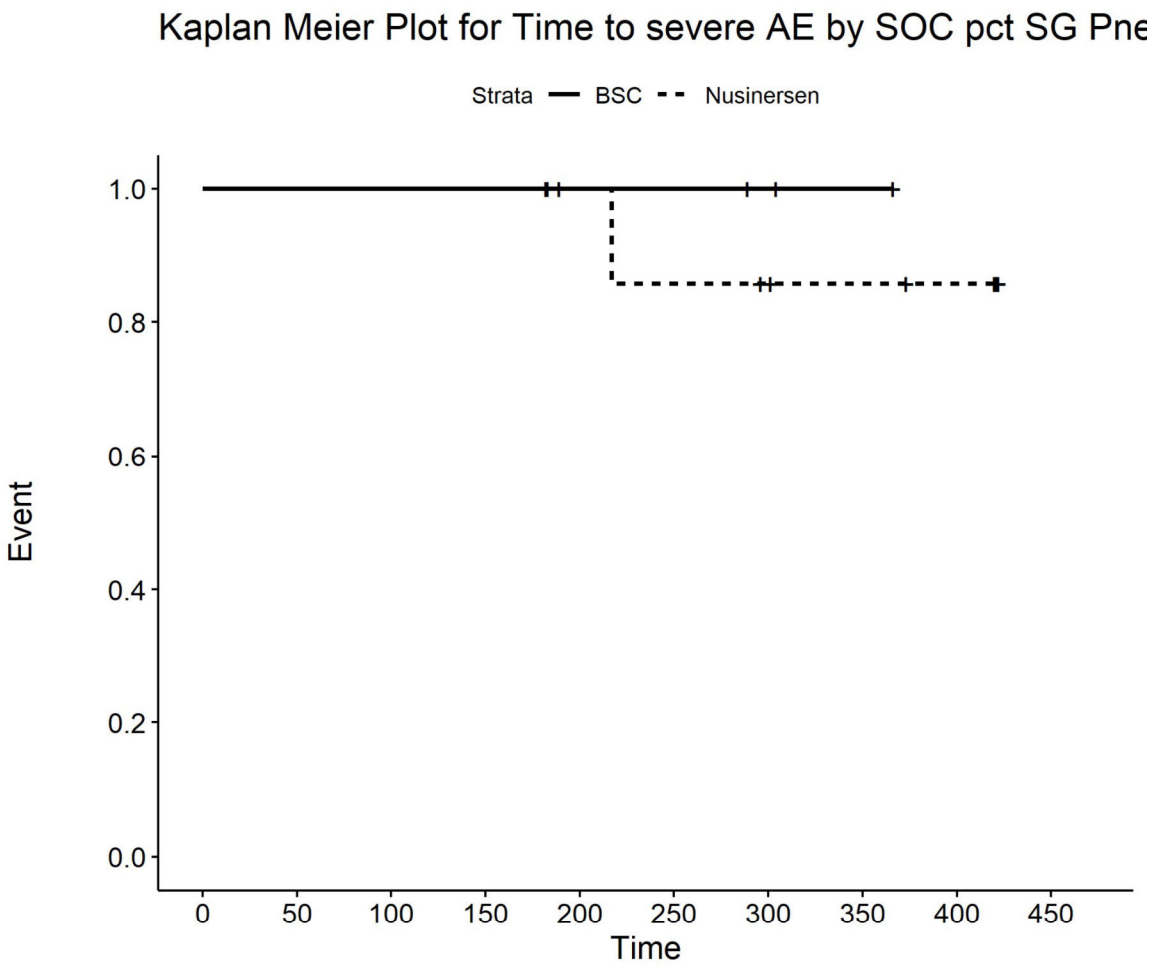
Number at risk

BSC	5	5	5	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



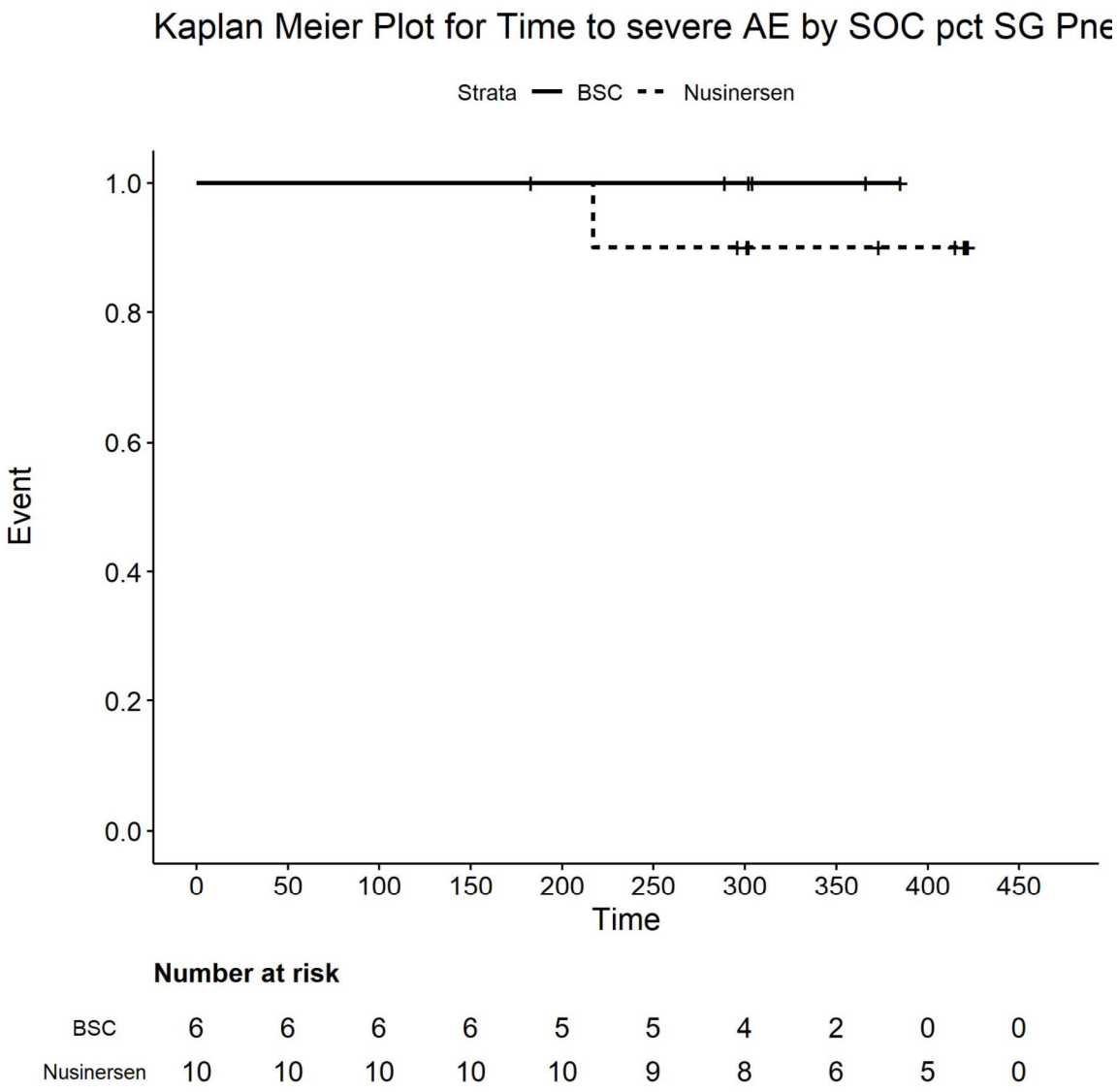
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



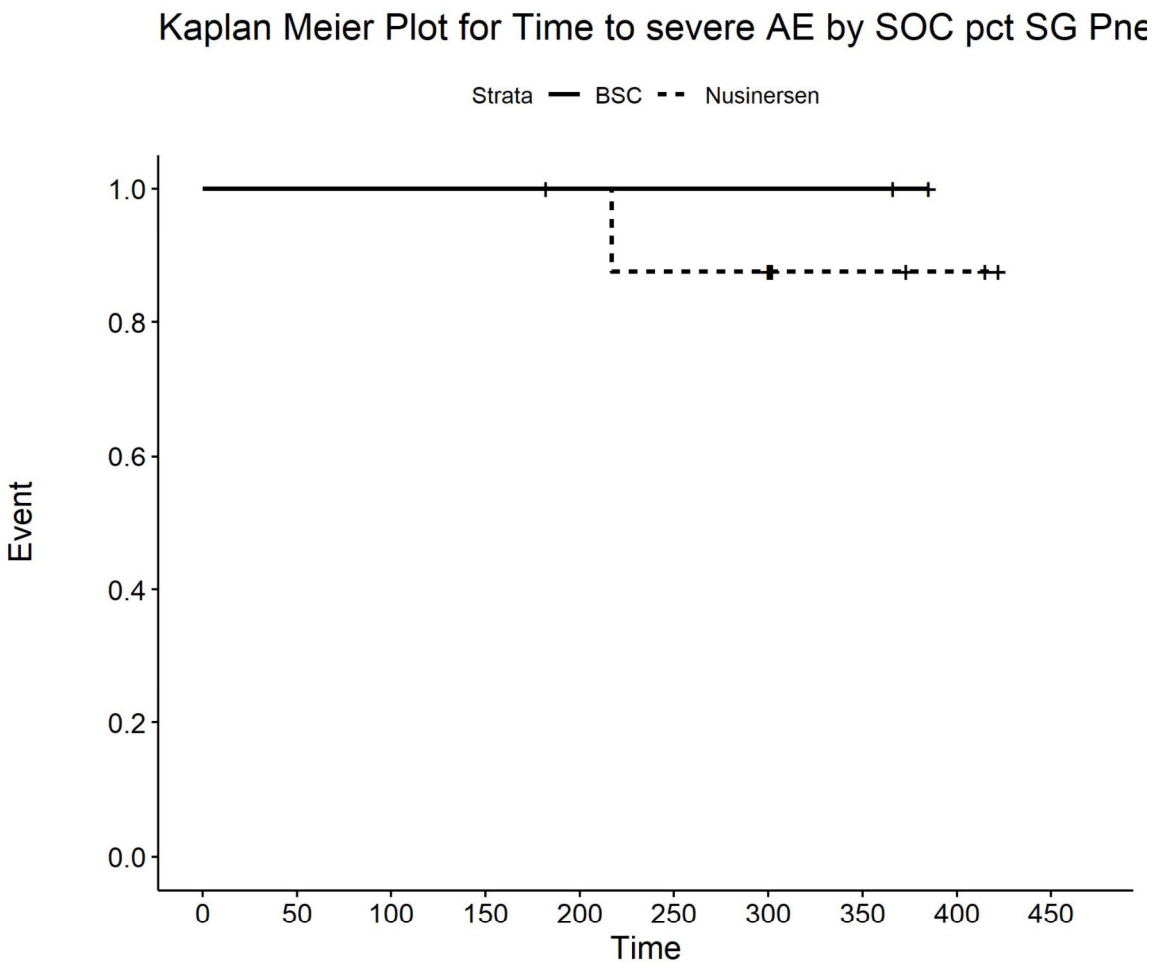
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



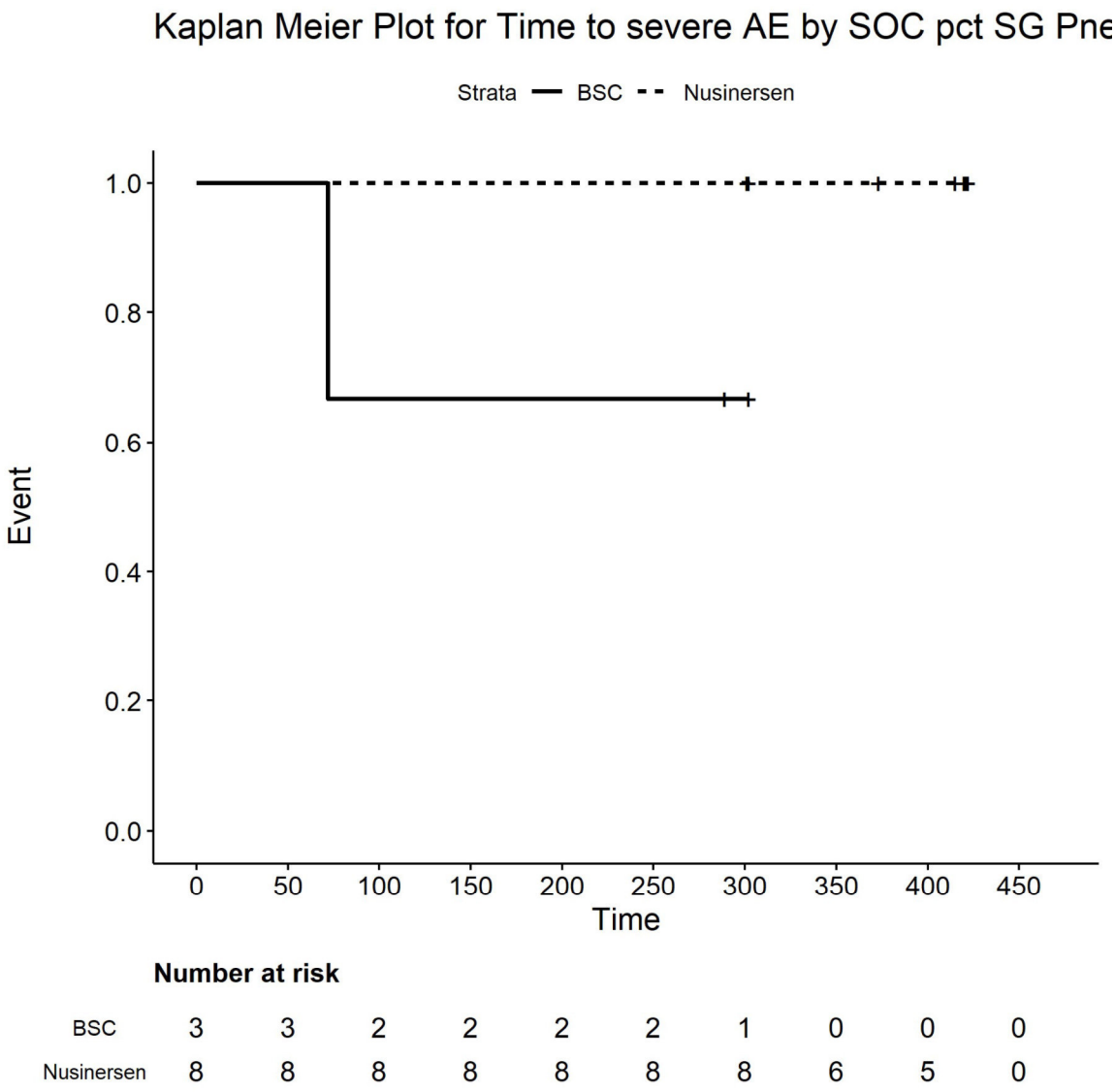
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



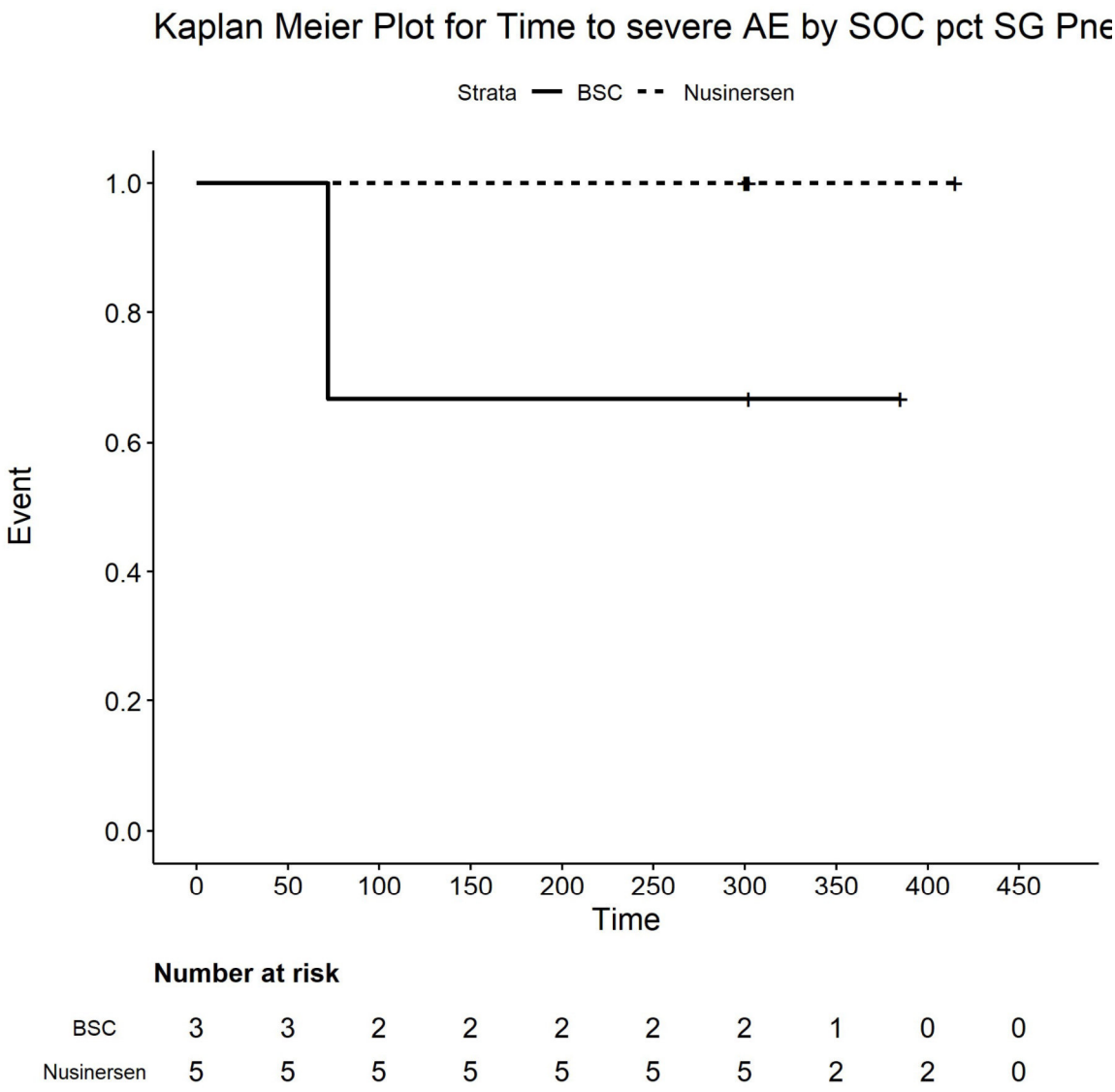
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	2	0



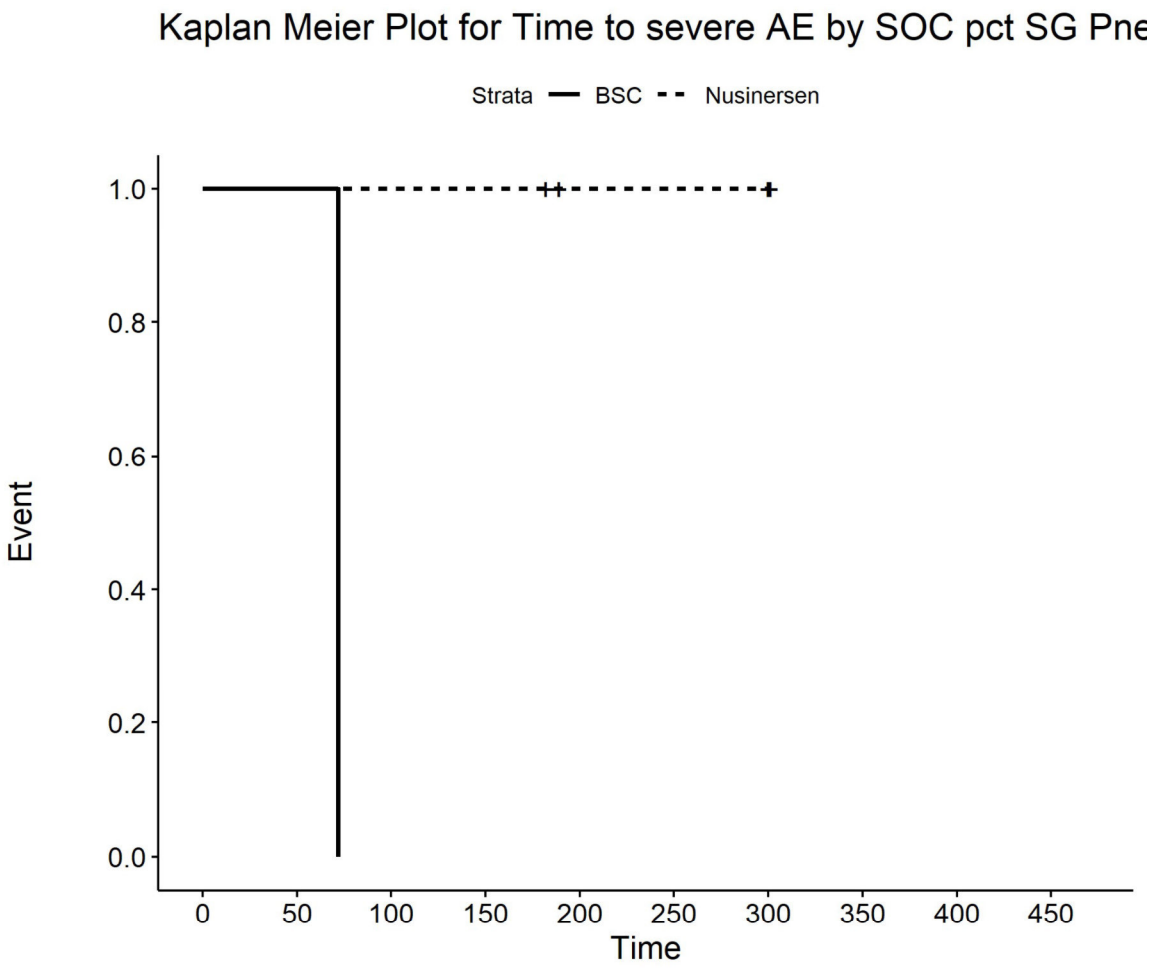
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



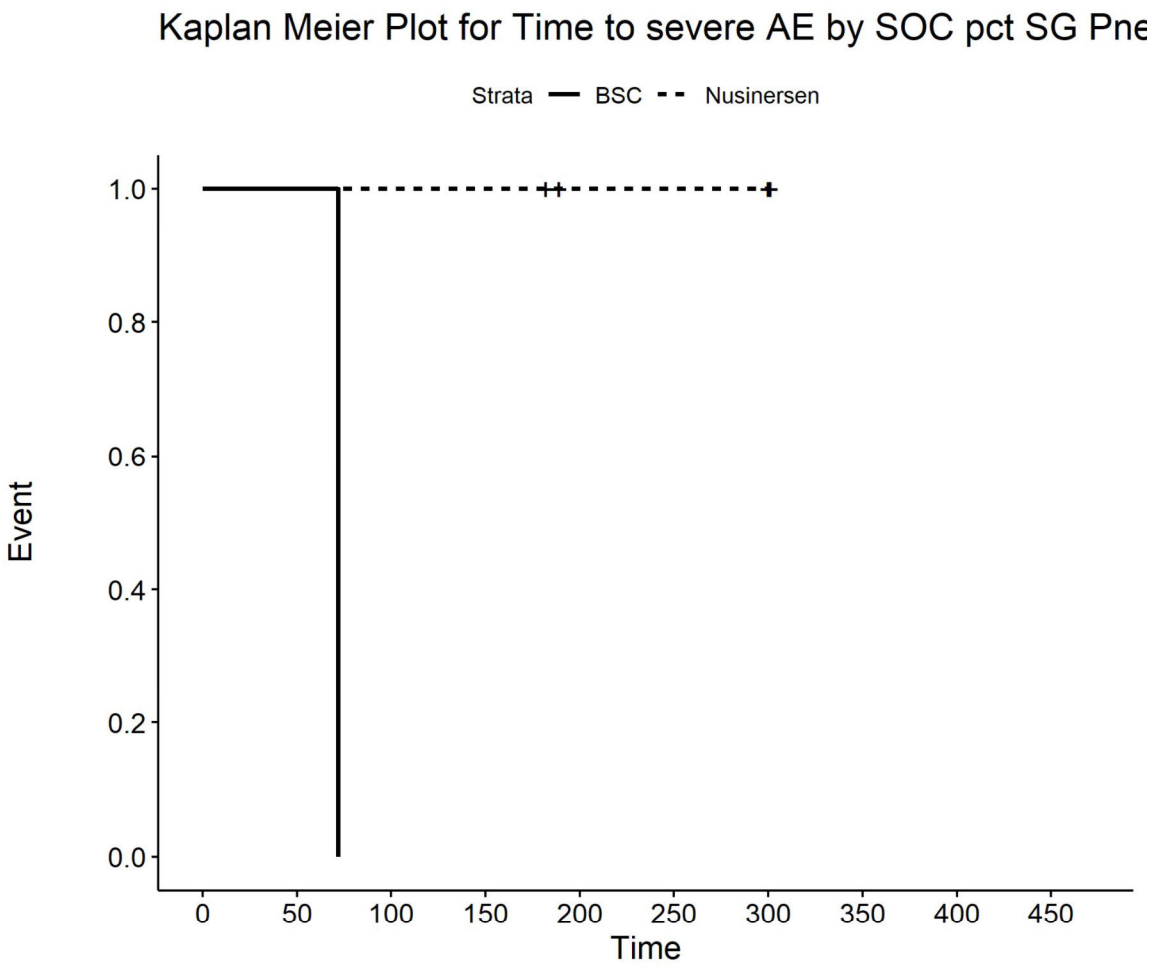
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



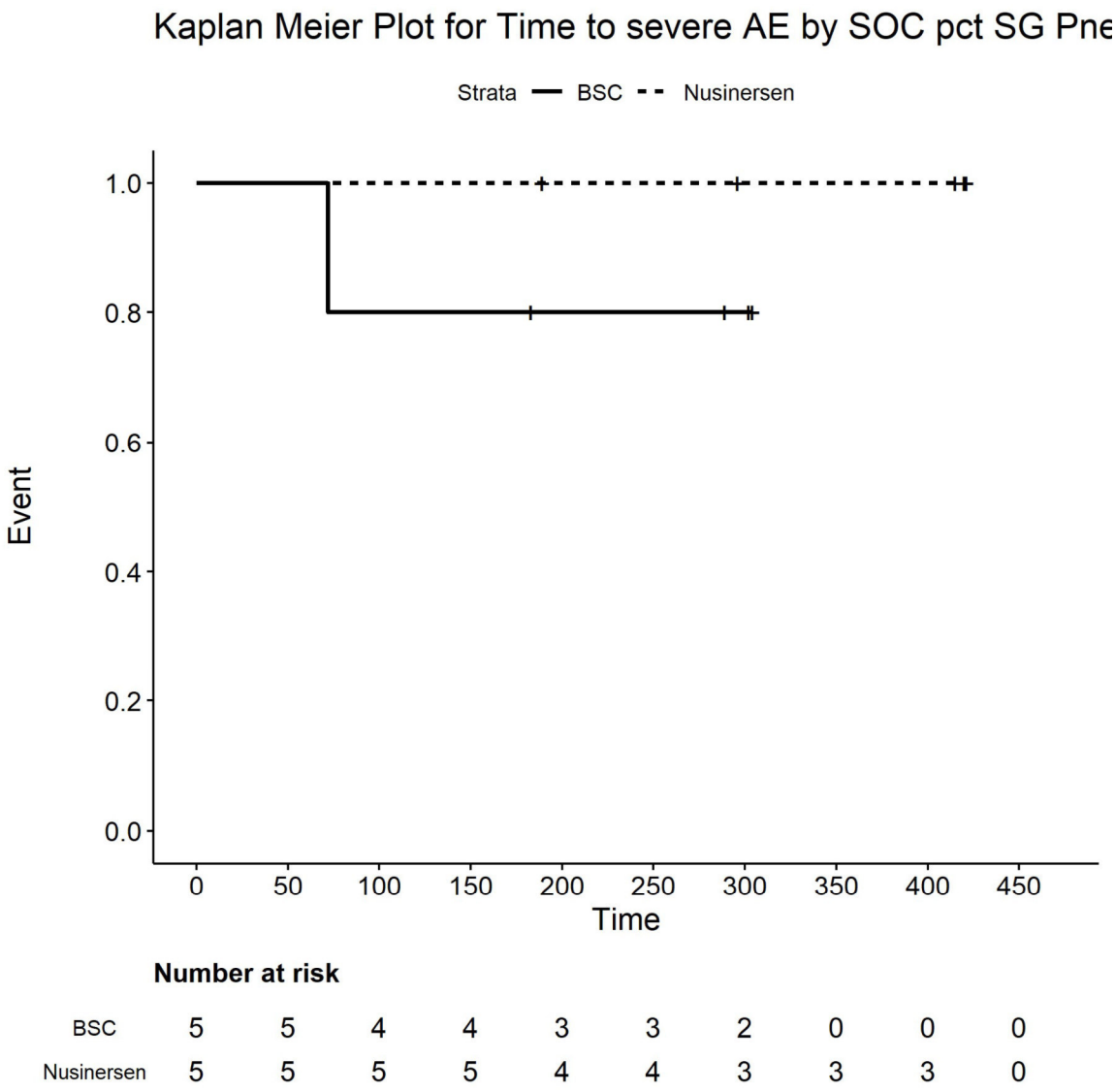
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



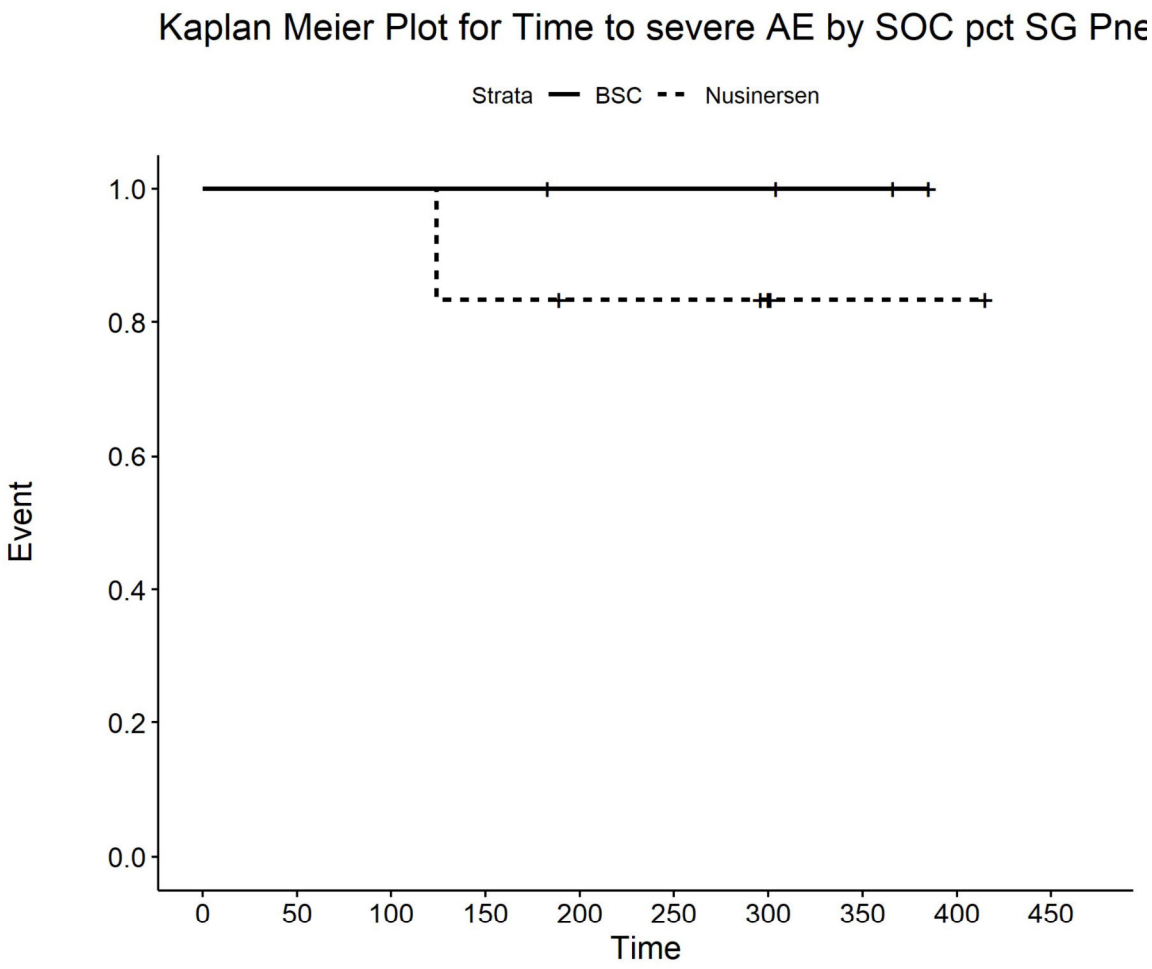
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



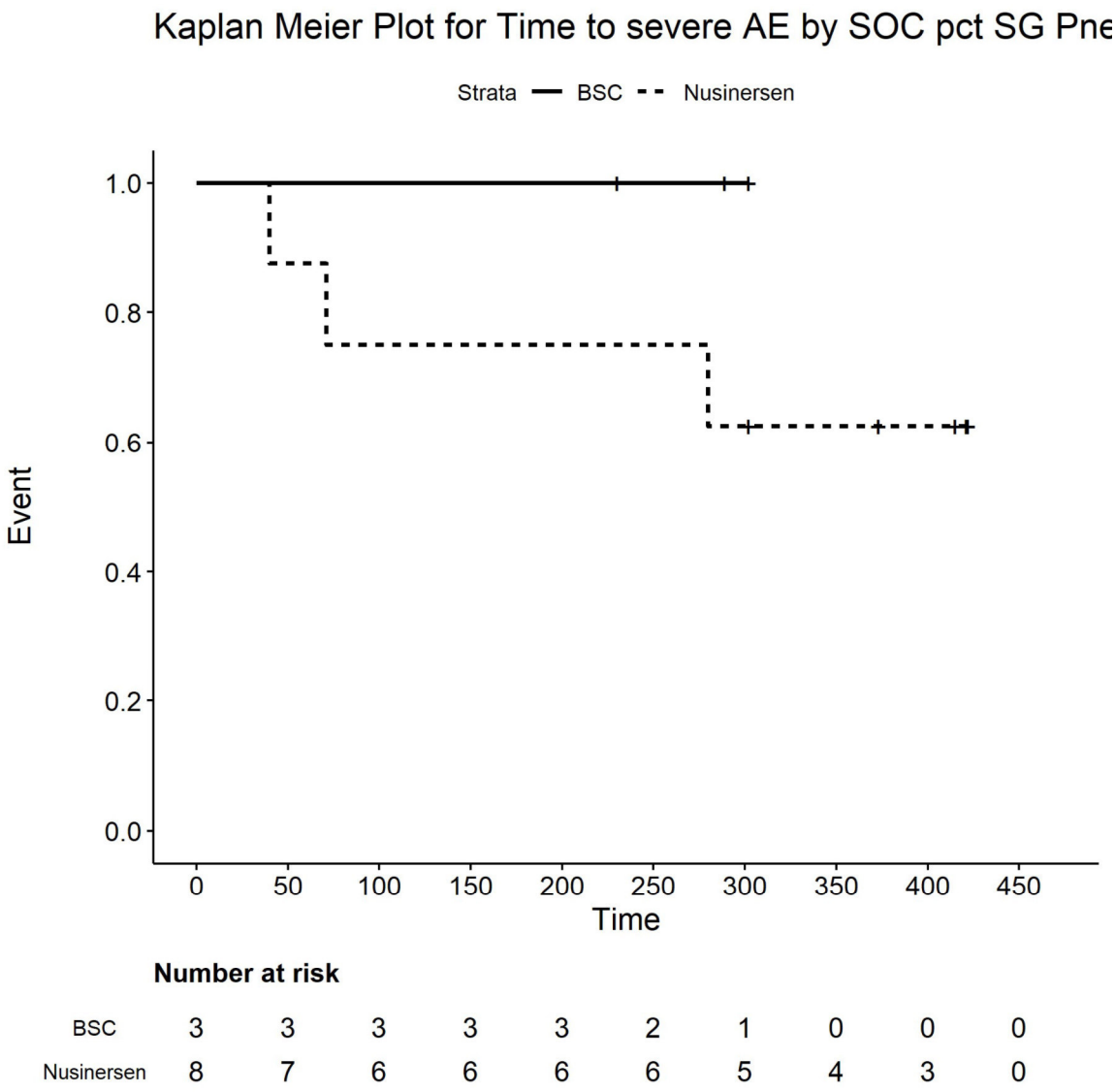
Number at risk

BSC	5	5	4	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



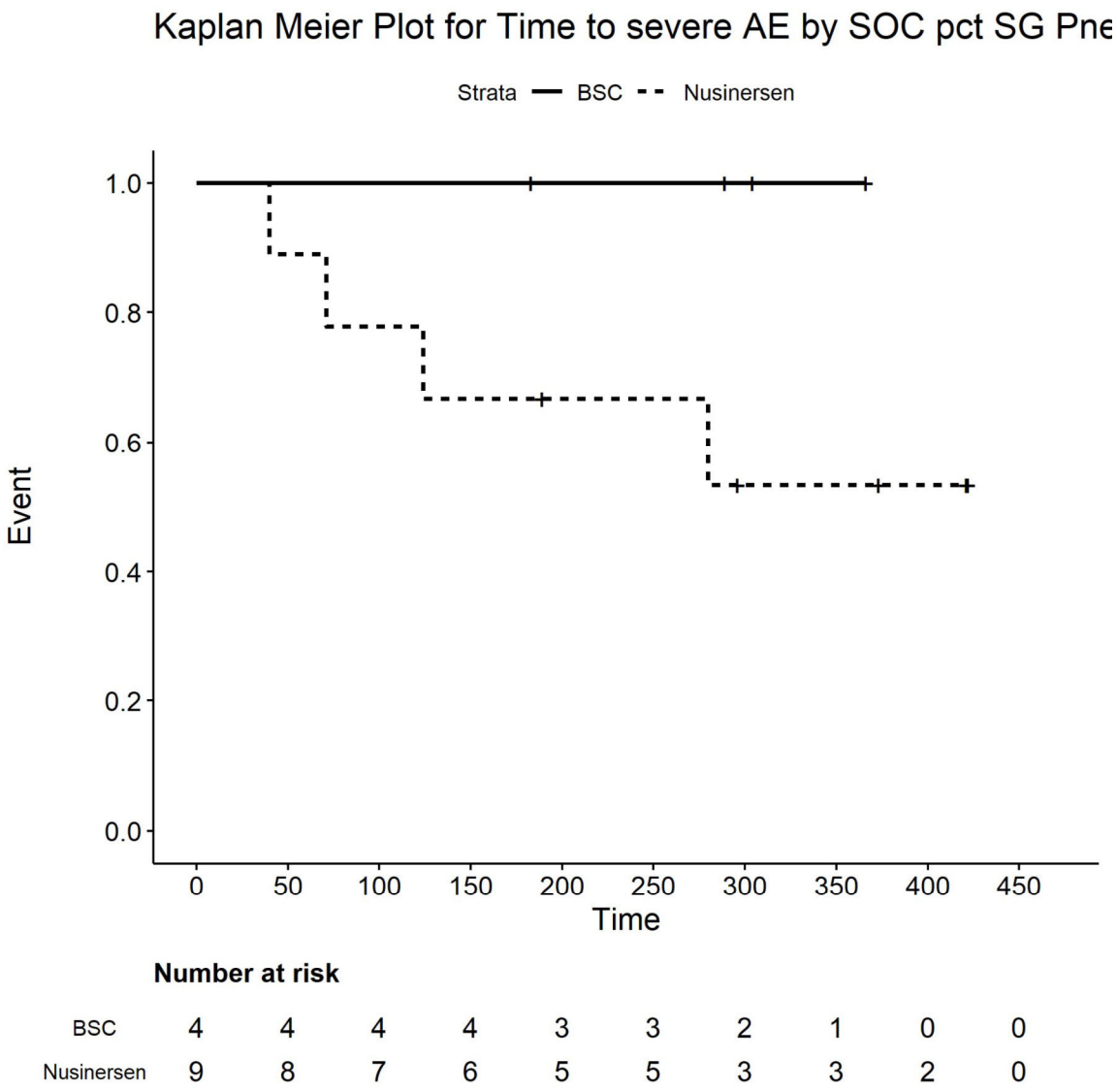
Number at risk

BSC	4	4	4	4	3	3	3	2	0	0
Nusinersen	6	6	6	5	4	4	3	1	1	0



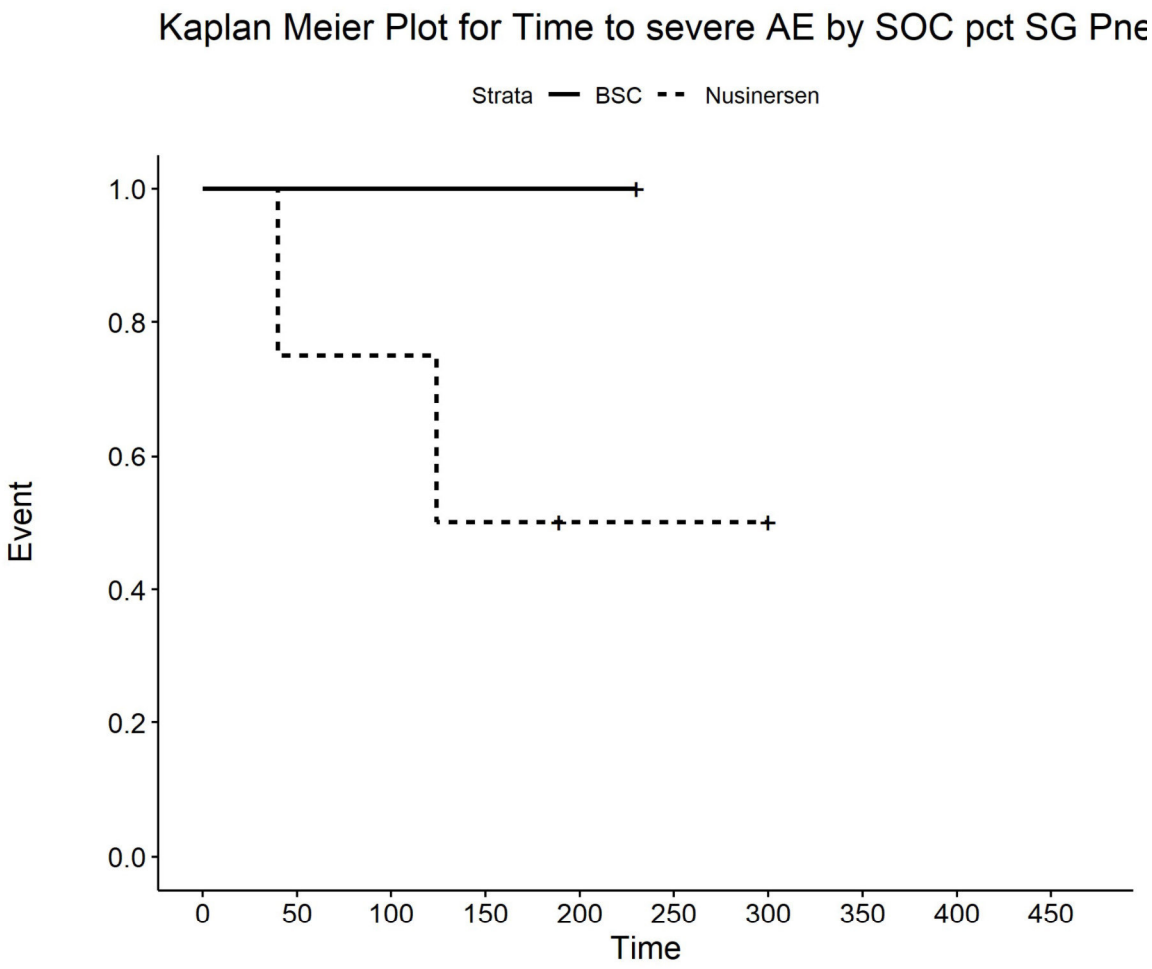
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	7	6	6	6	6	5	4	3	0



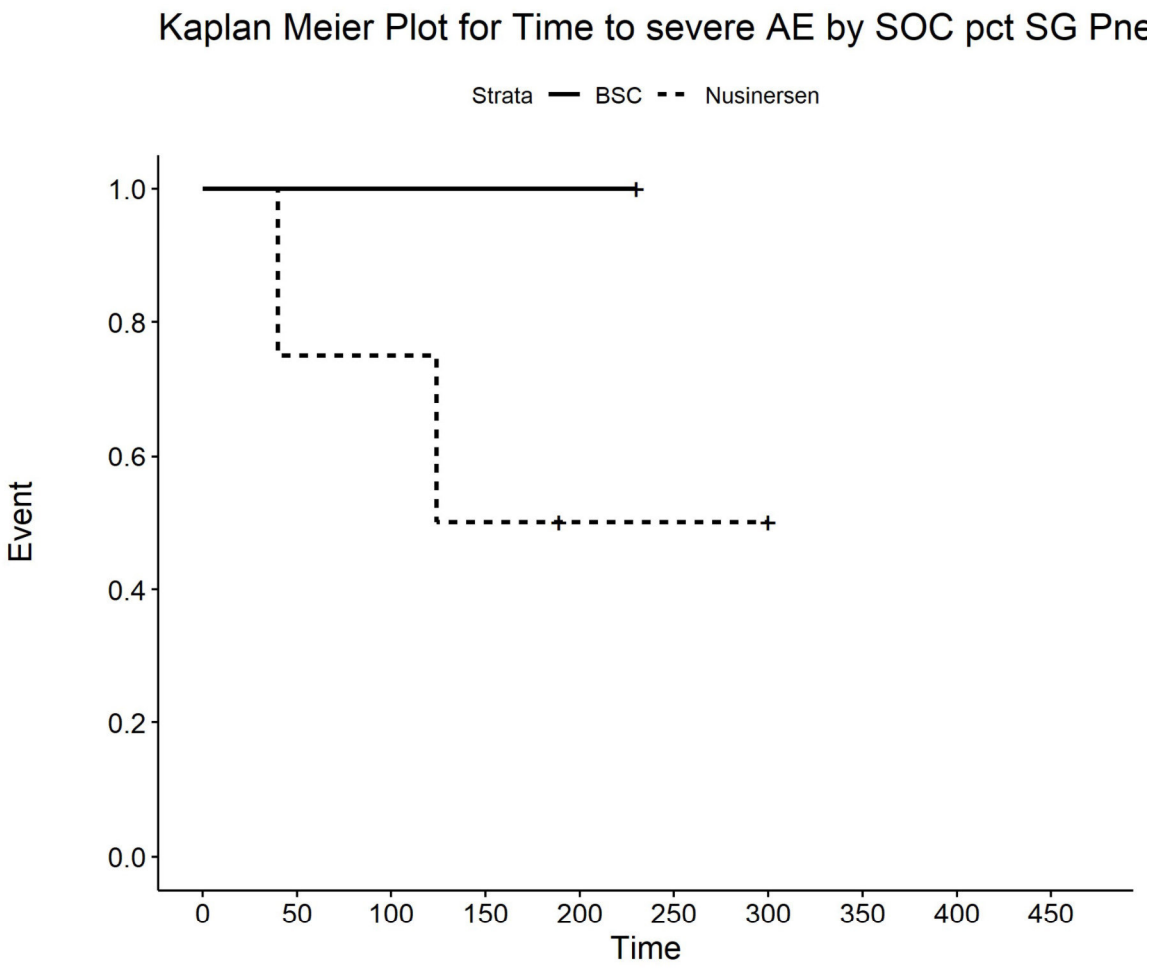
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	8	7	6	5	5	3	3	2	0



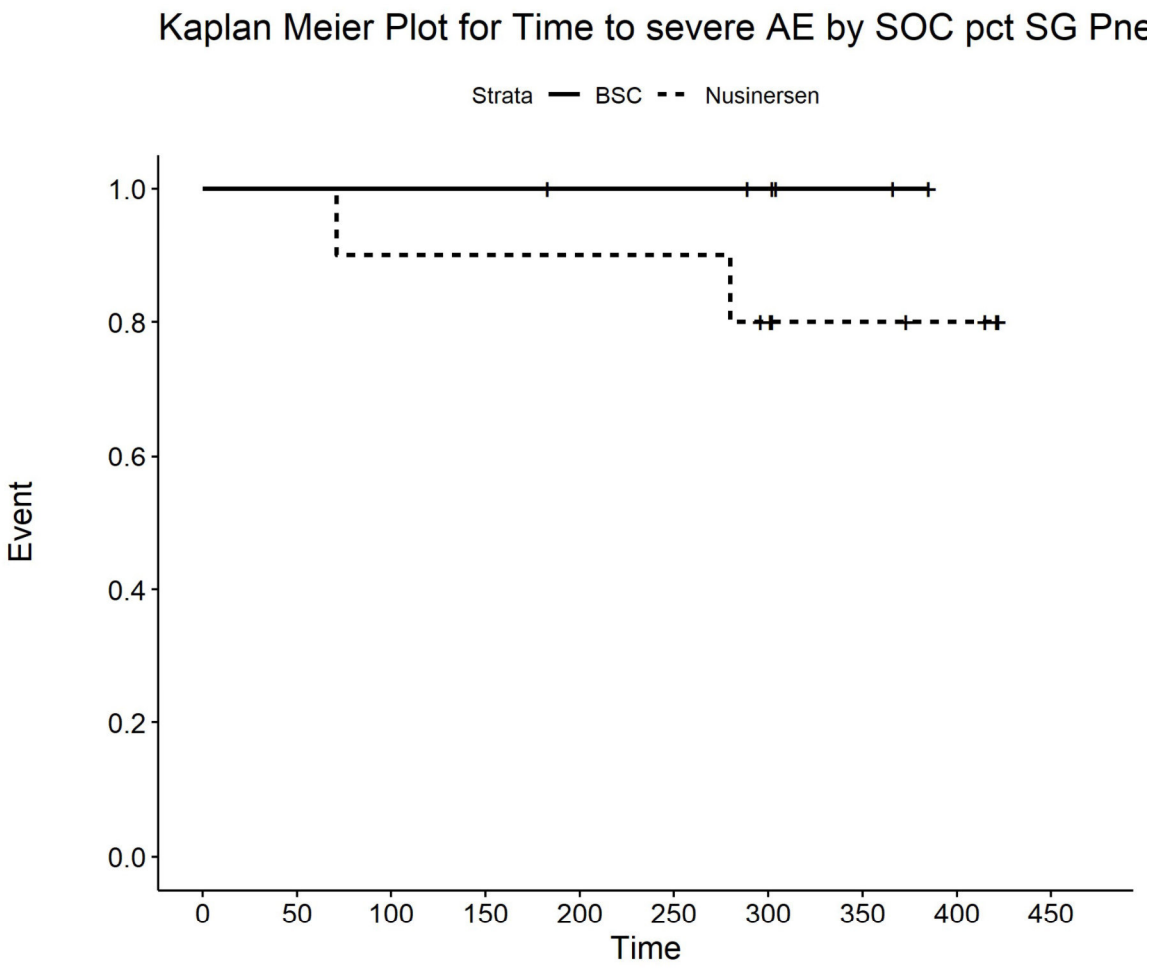
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



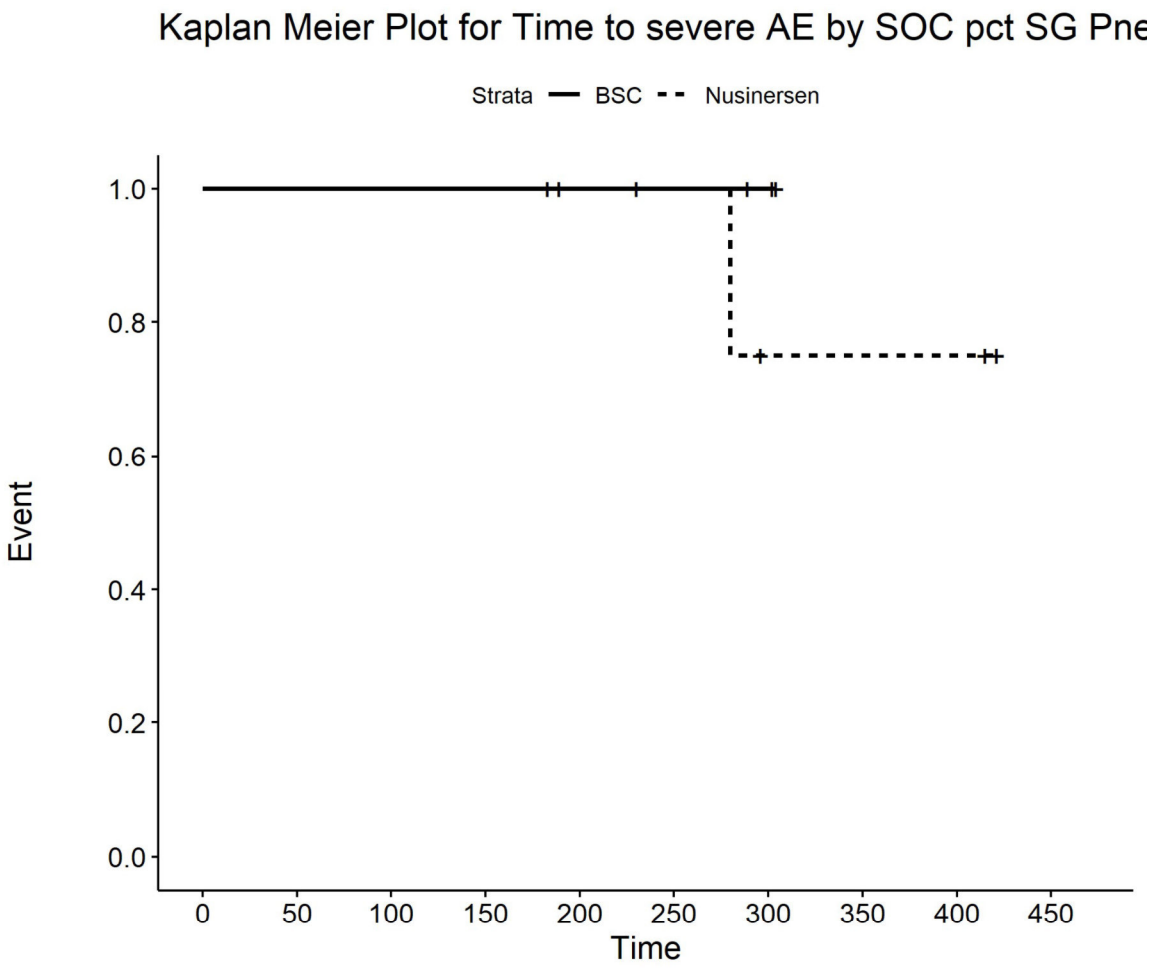
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



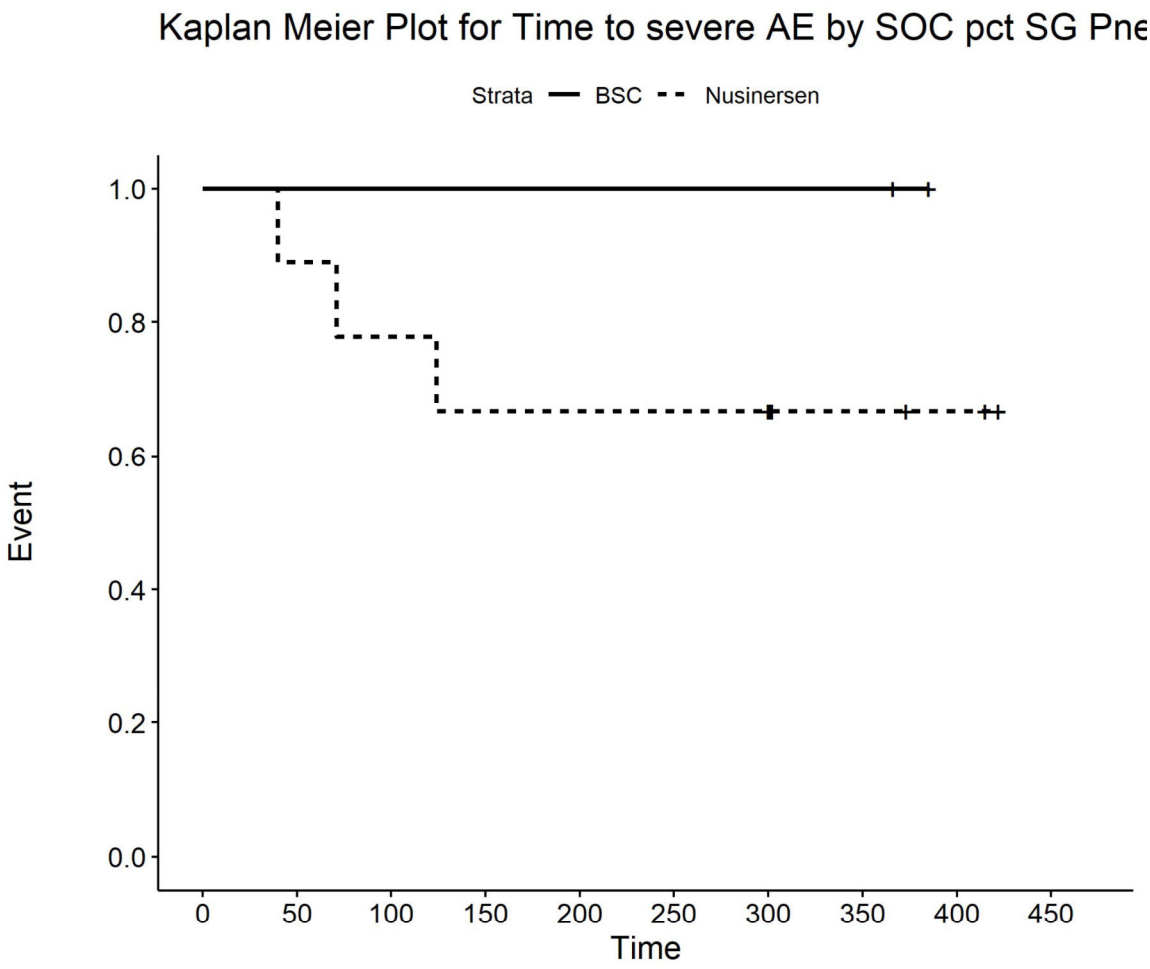
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	7	5	4	0



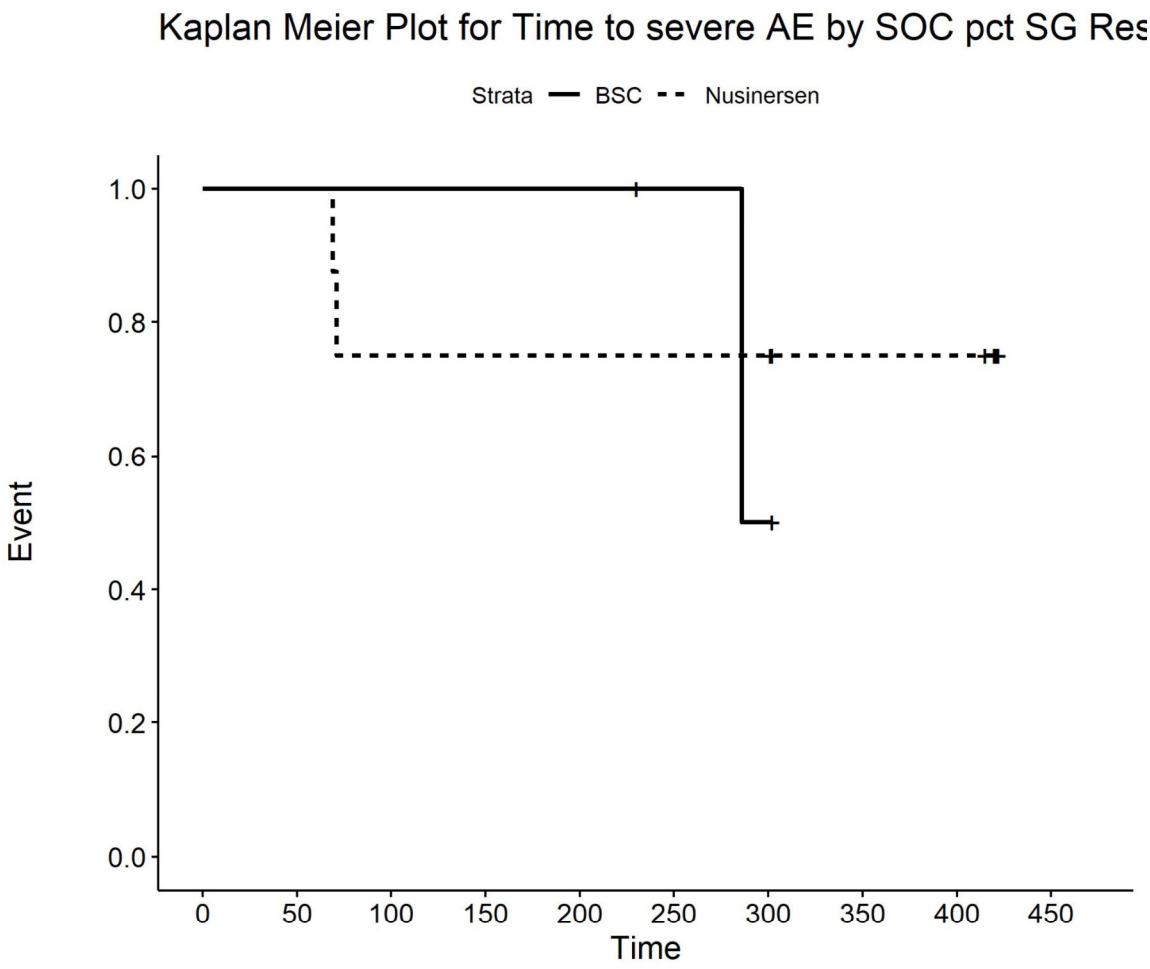
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	2	2	2	0



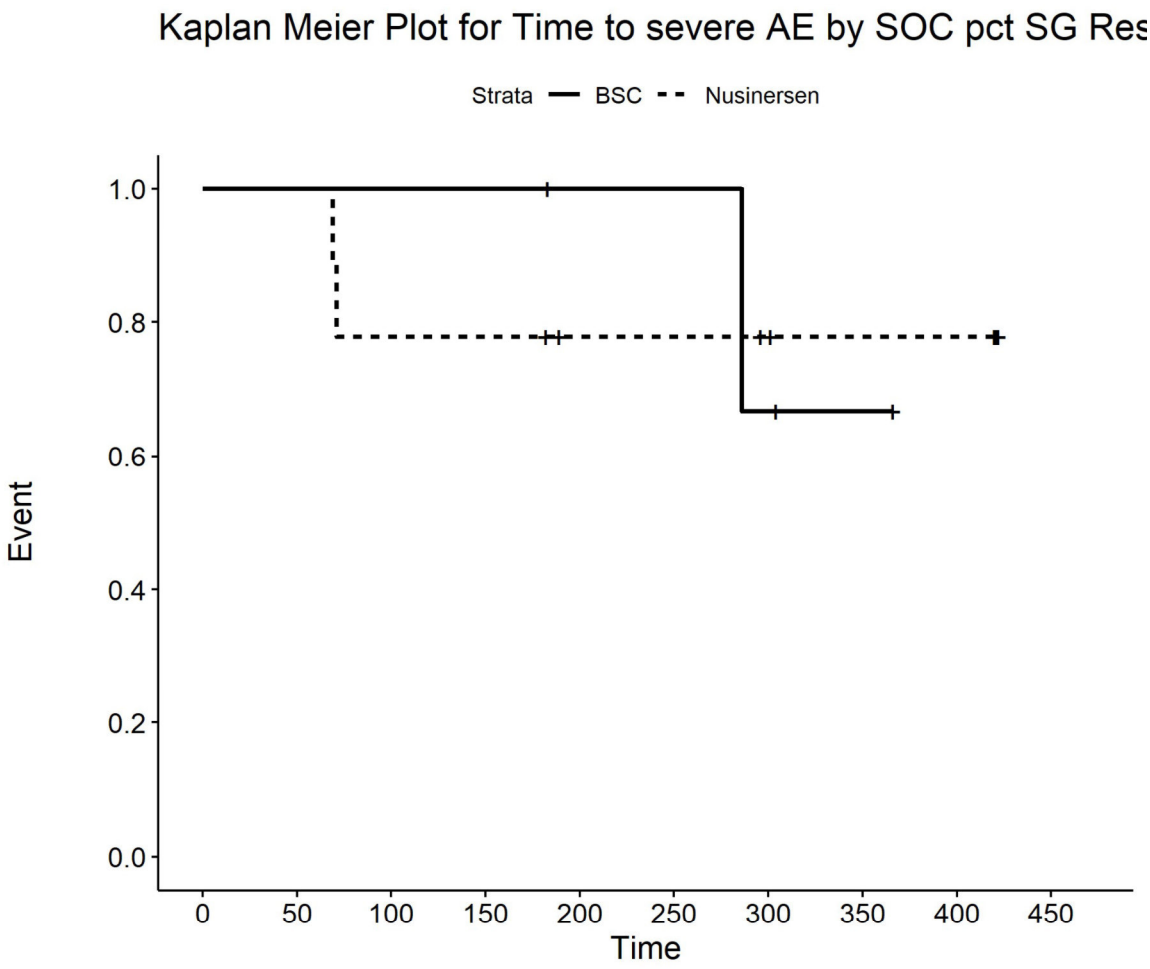
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	8	7	6	6	6	6	3	2	0



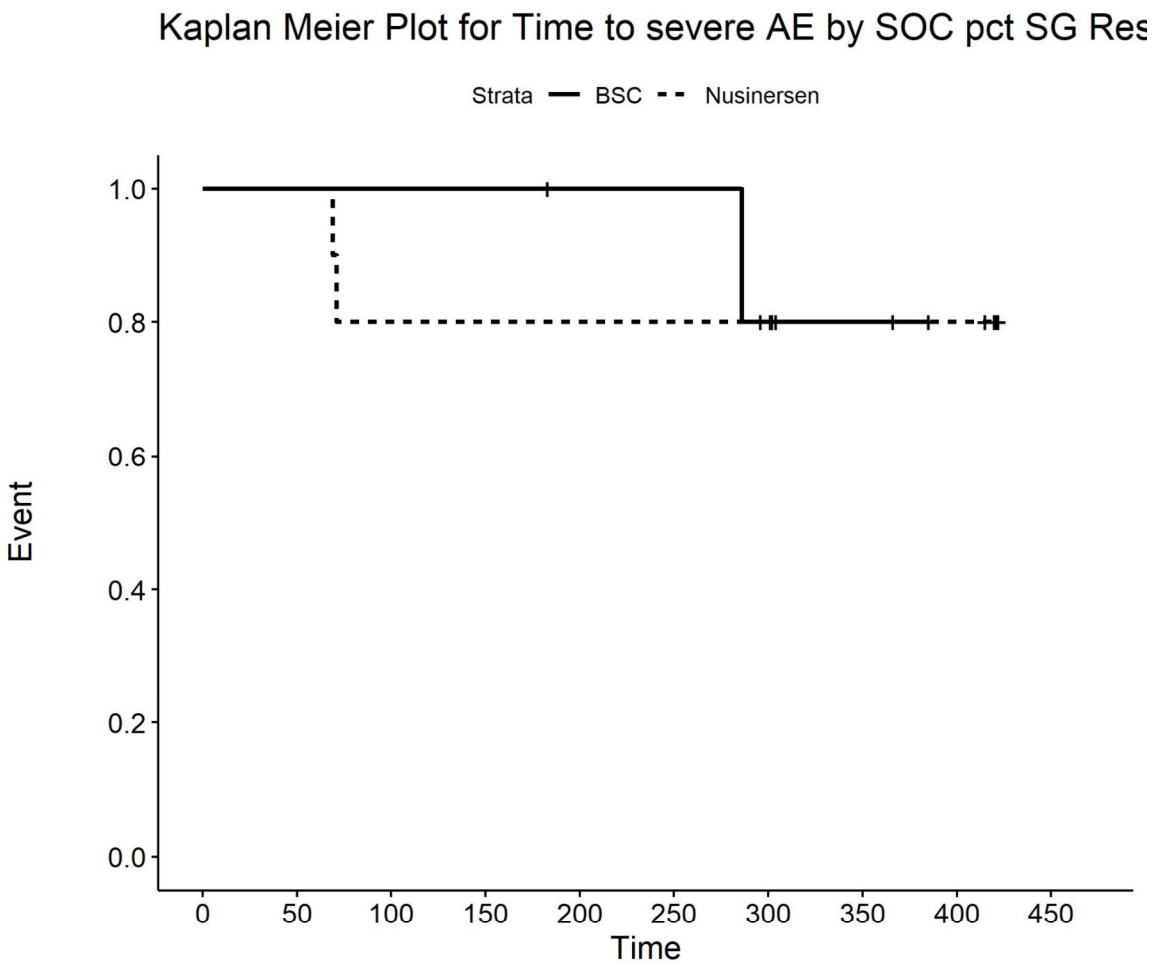
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	6	6	6	6	6	4	4	0



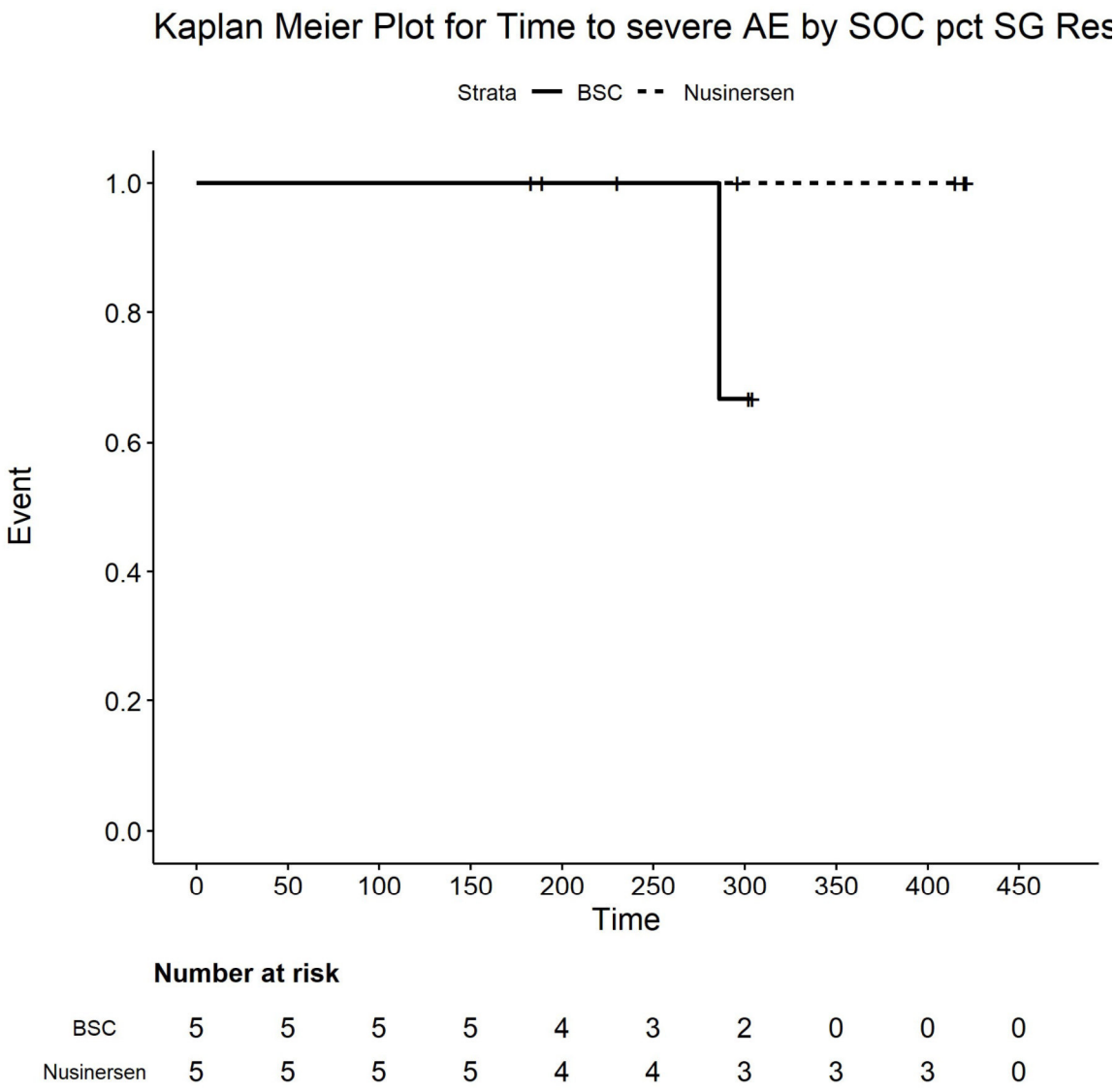
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	7	7	5	5	4	3	3	0



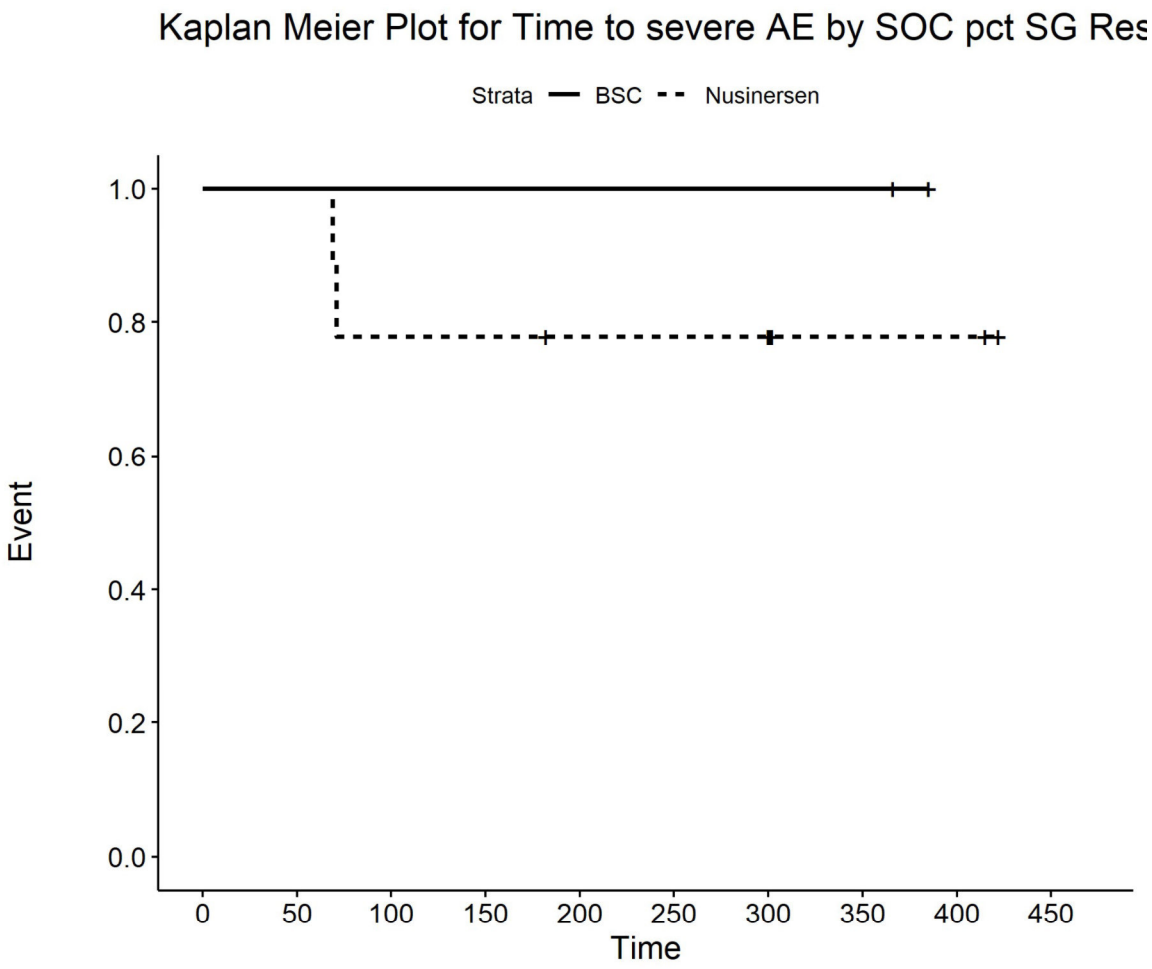
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	8	8	8	8	7	5	5	0



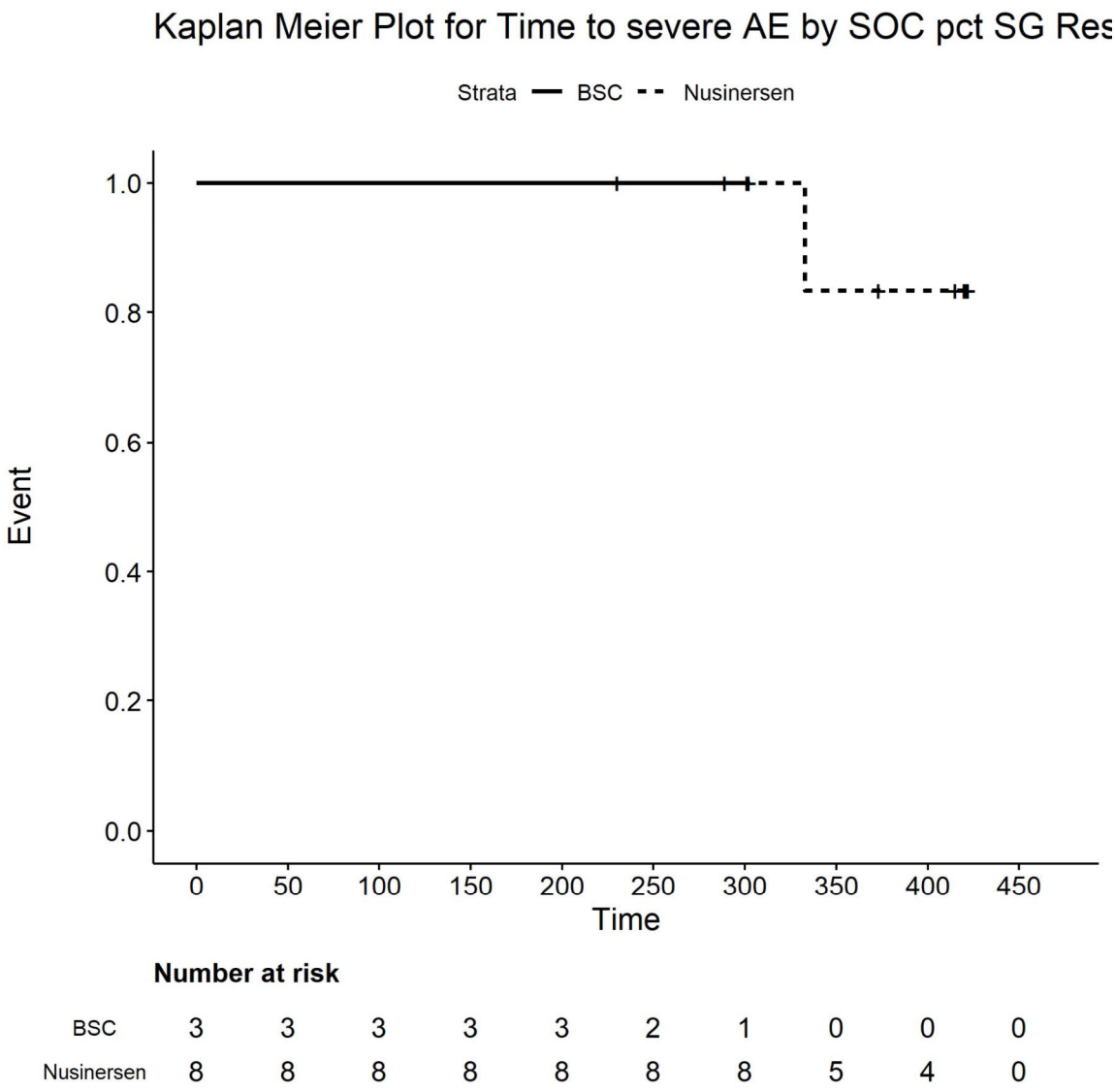
Number at risk

BSC	5	5	5	5	4	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



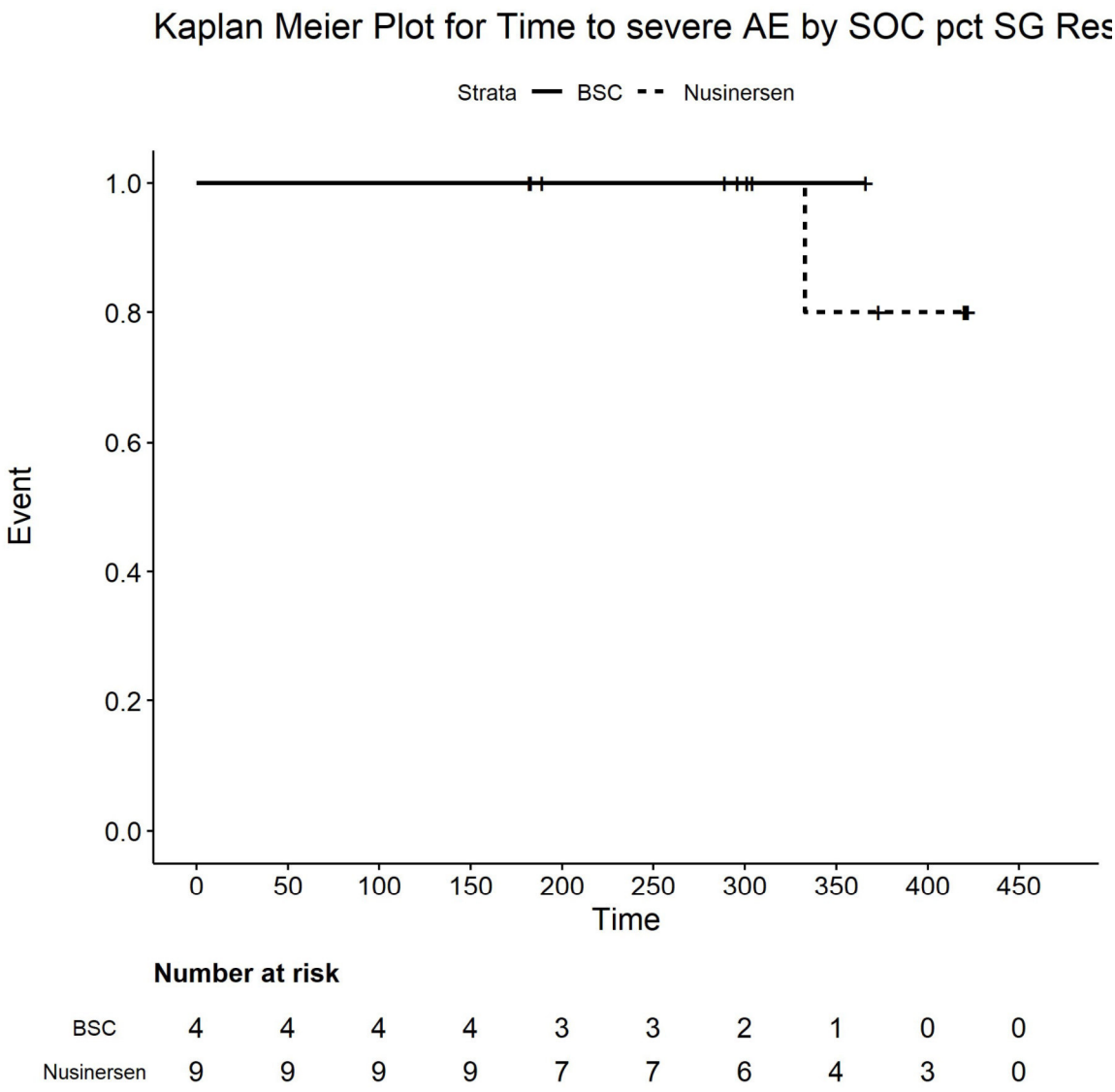
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	7	7	6	6	6	2	2	0



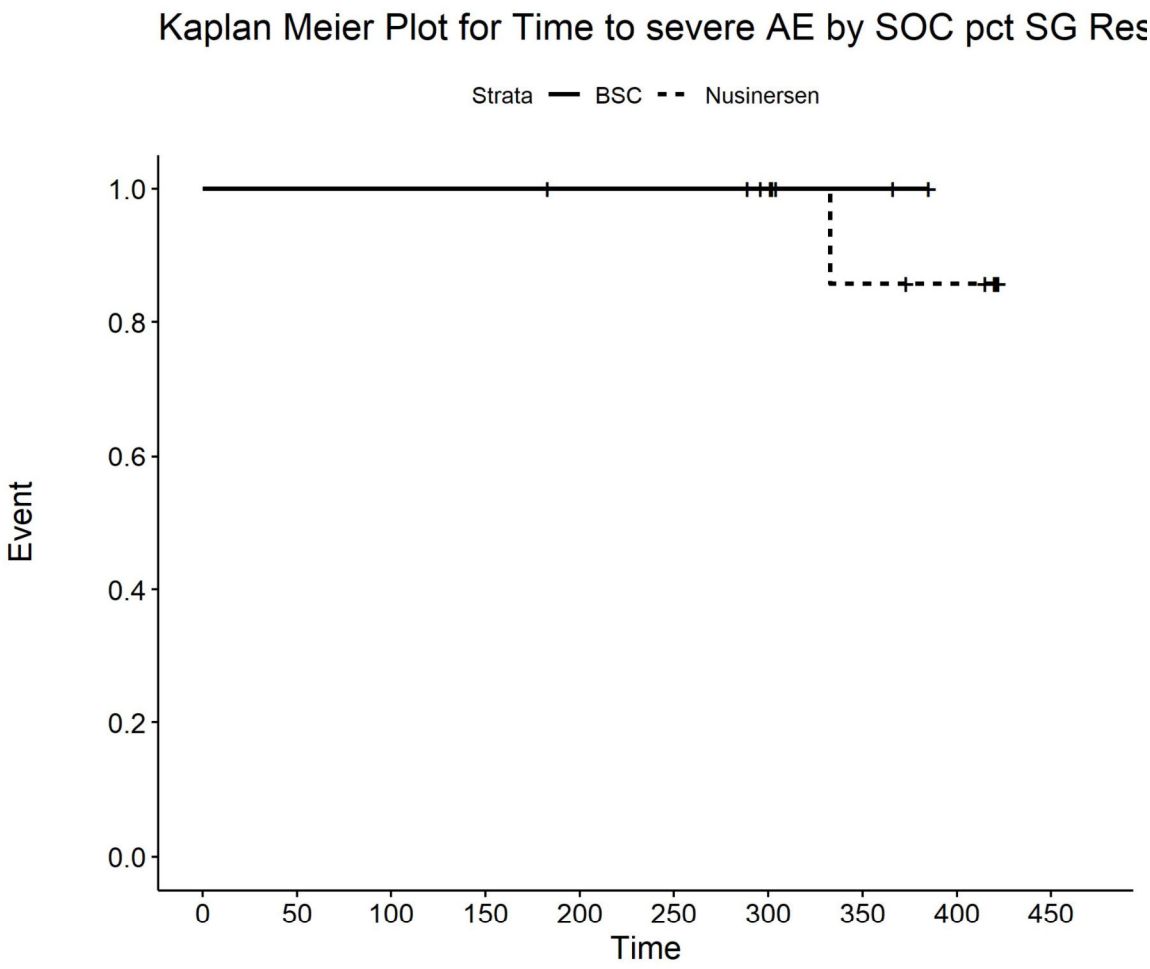
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	5	4	0



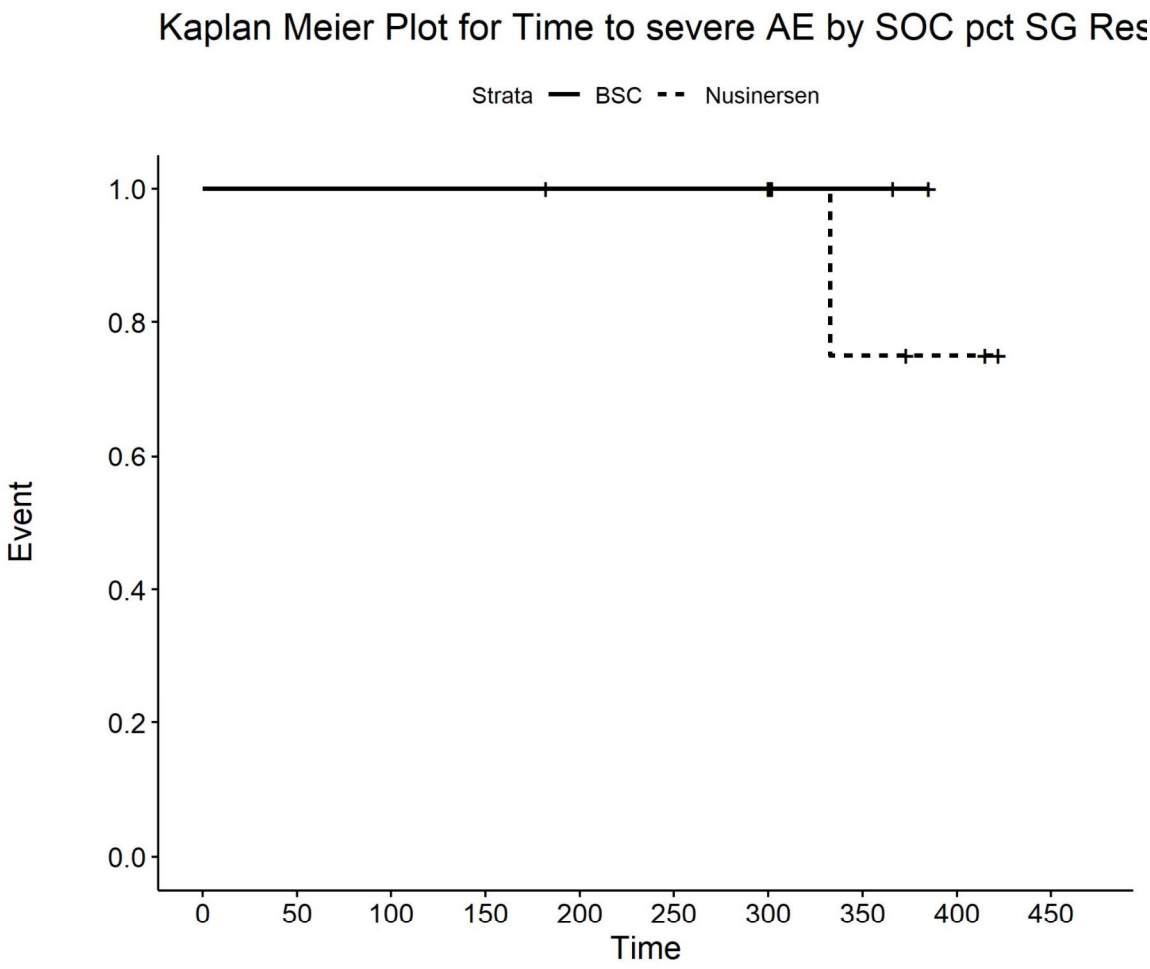
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	7	6	4	3	0



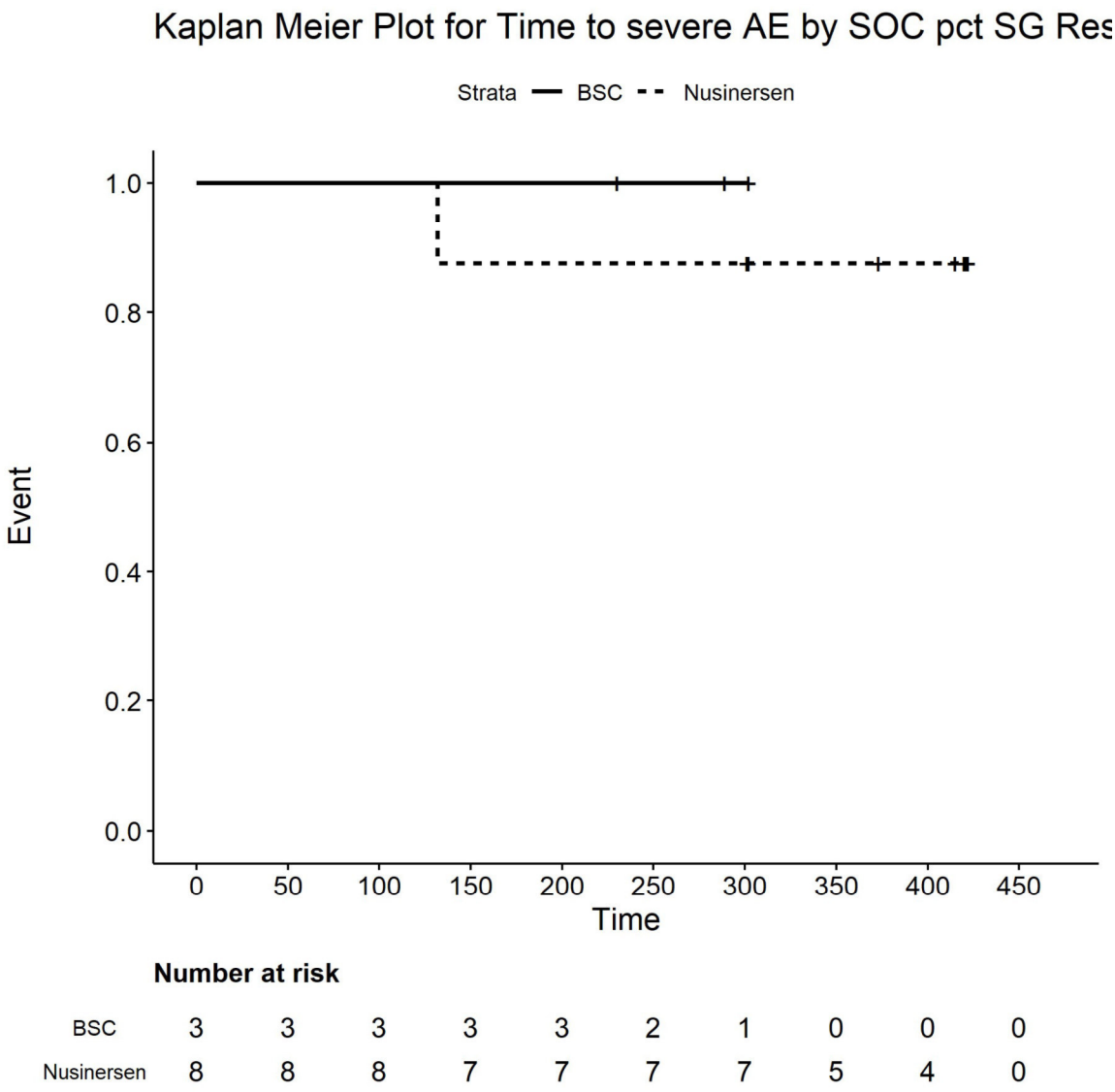
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	10	9	6	5	0



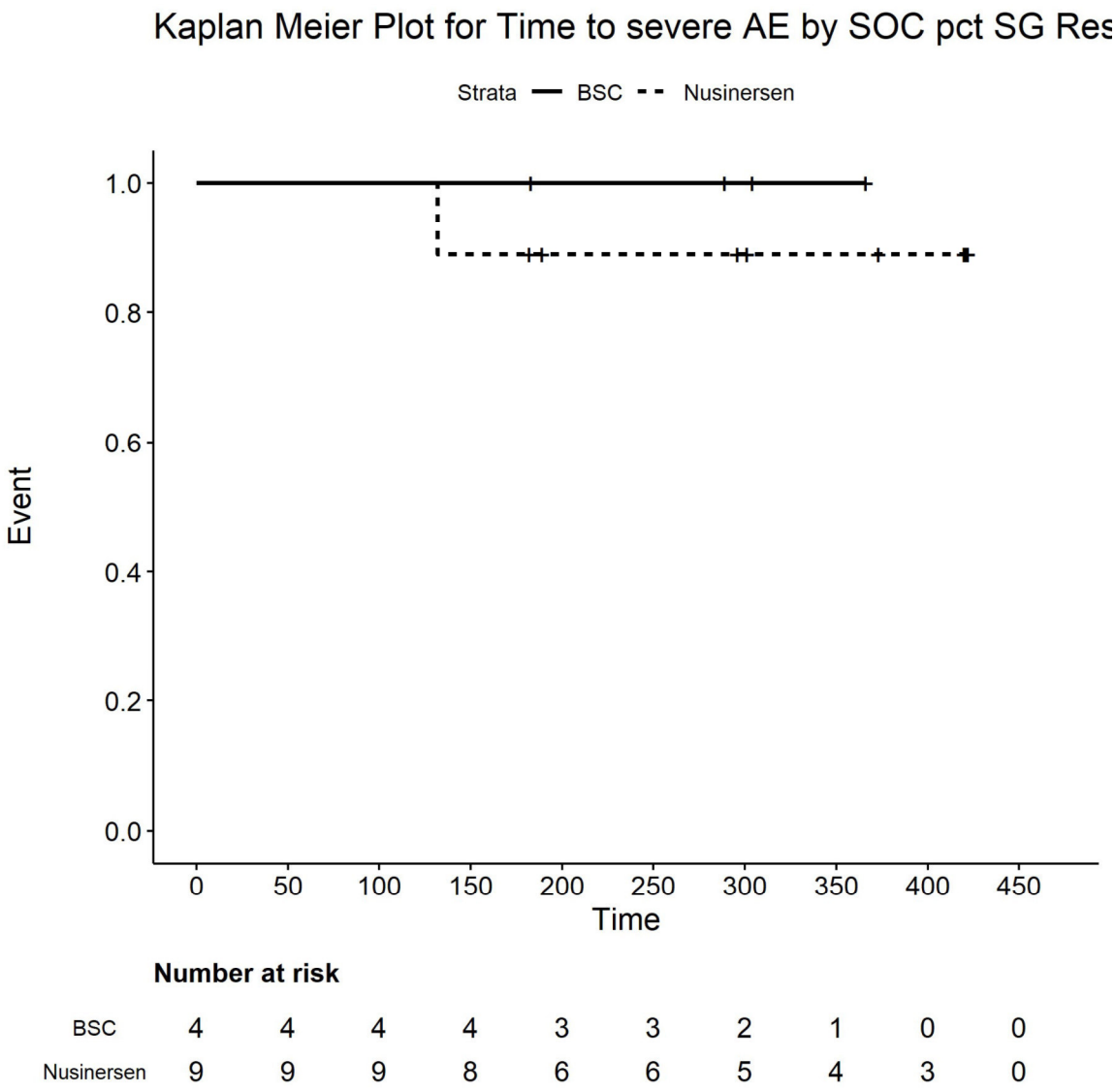
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	8	3	2	0



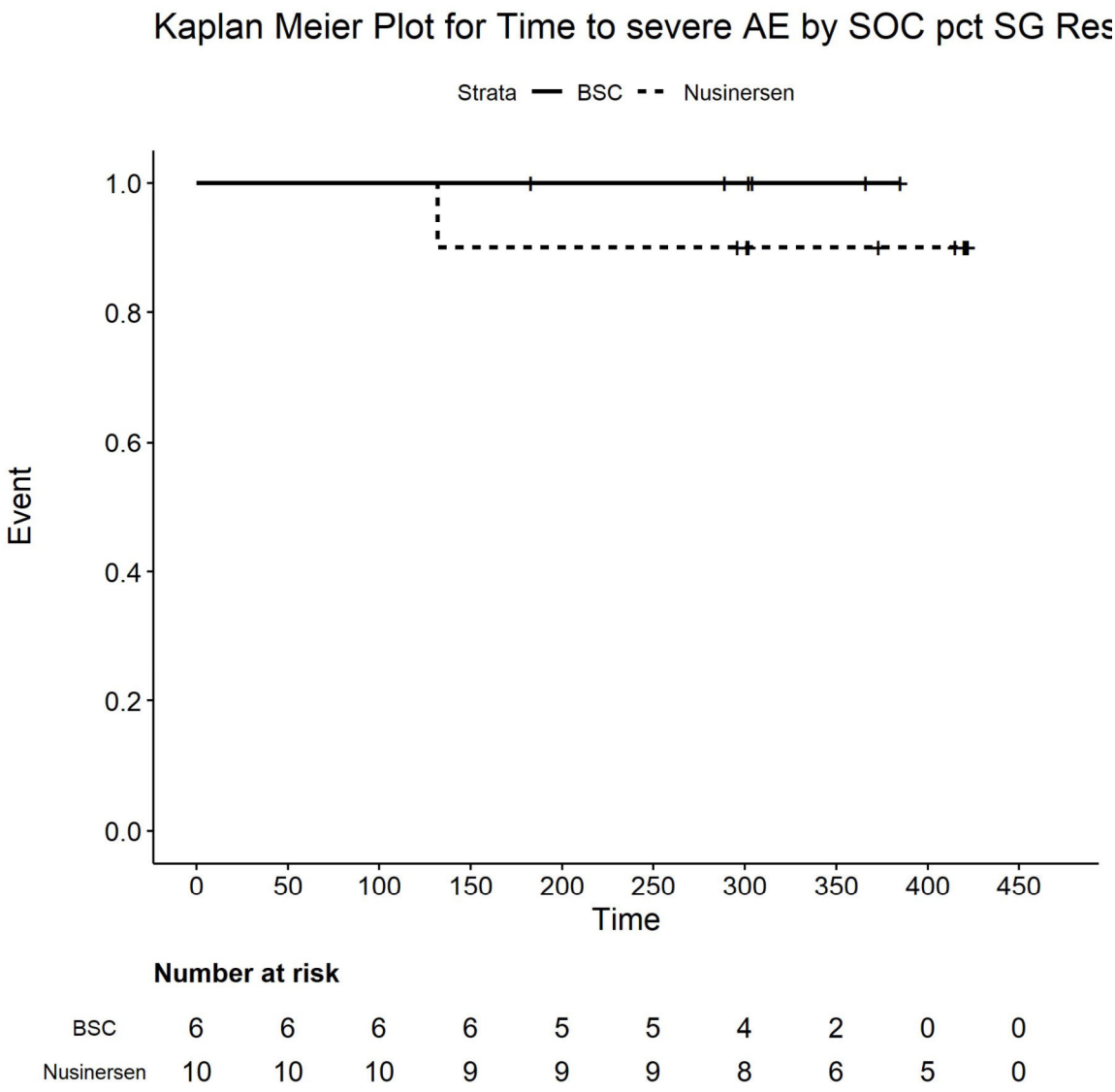
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	7	7	7	7	5	4	0



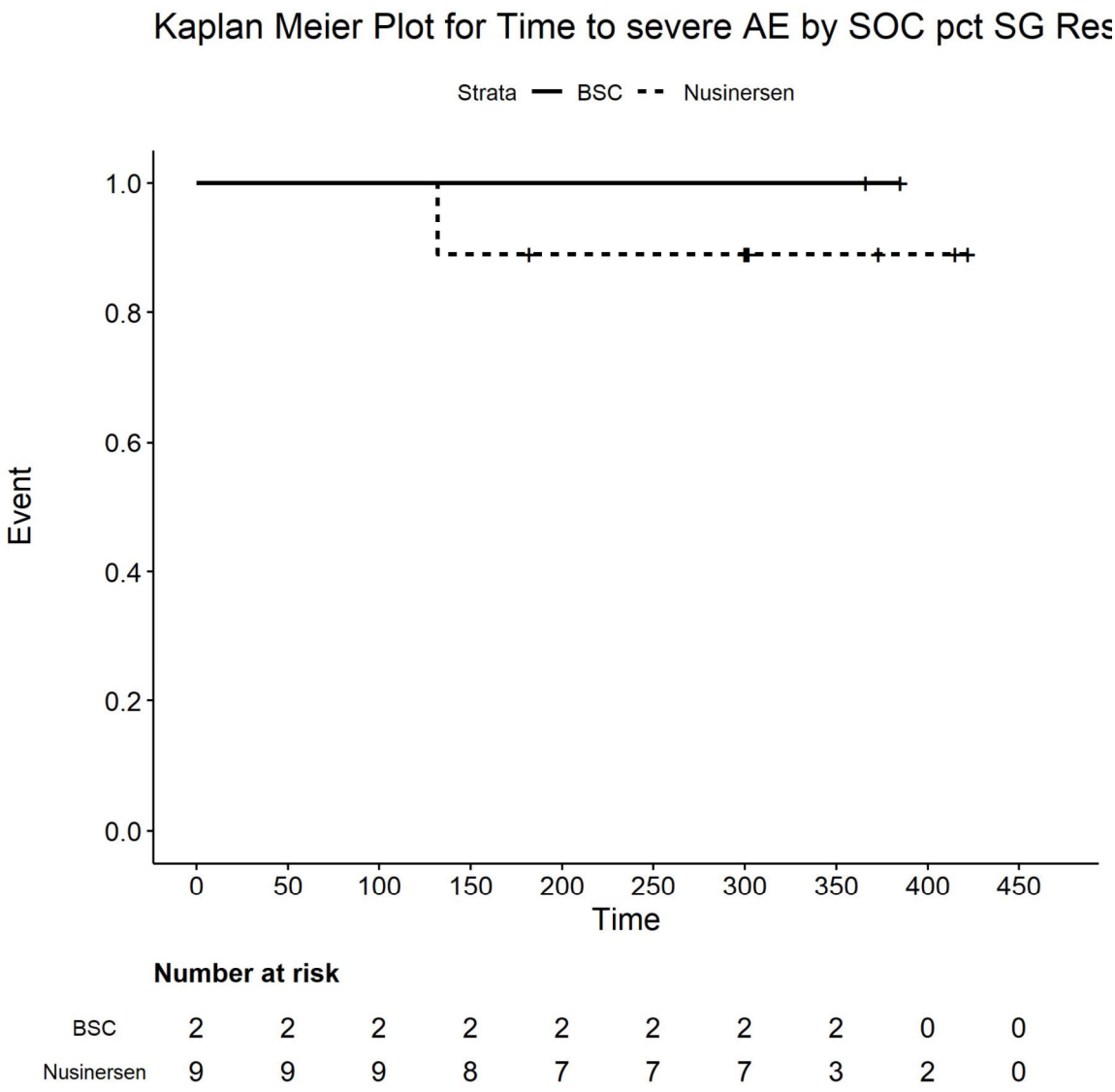
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	8	6	6	5	4	3	0



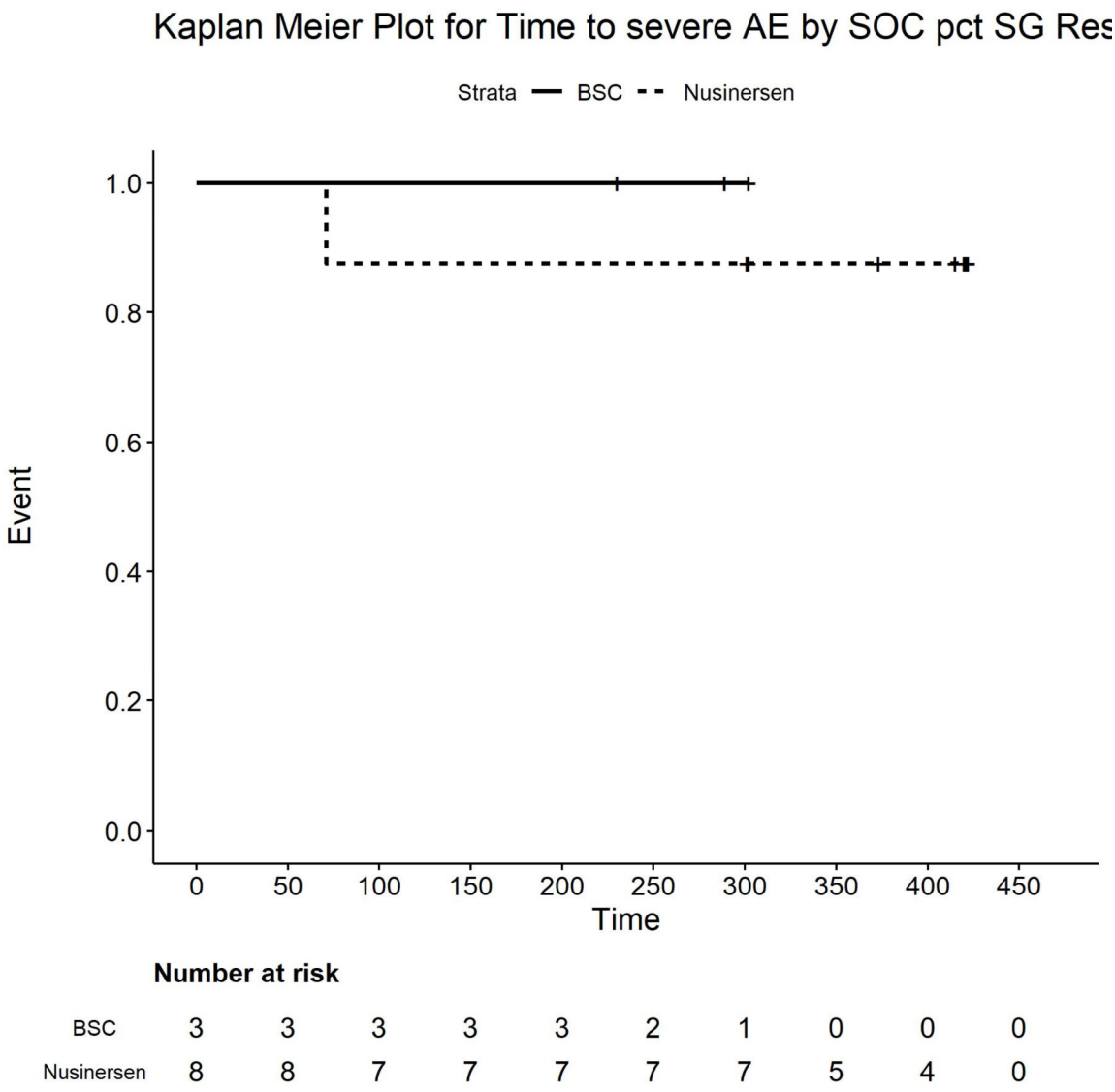
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	9	9	9	8	6	5	0



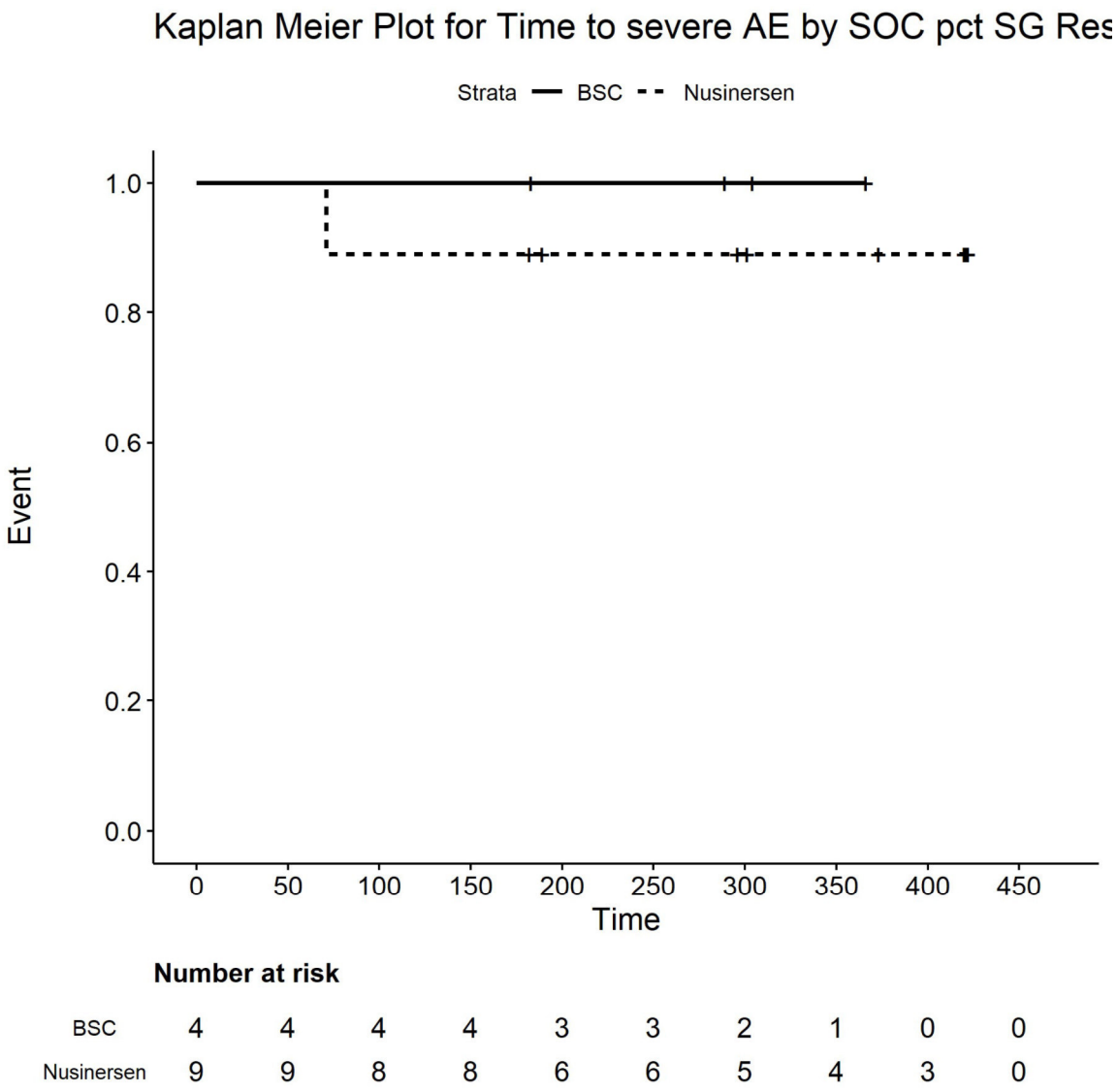
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	8	7	7	7	3	2	0



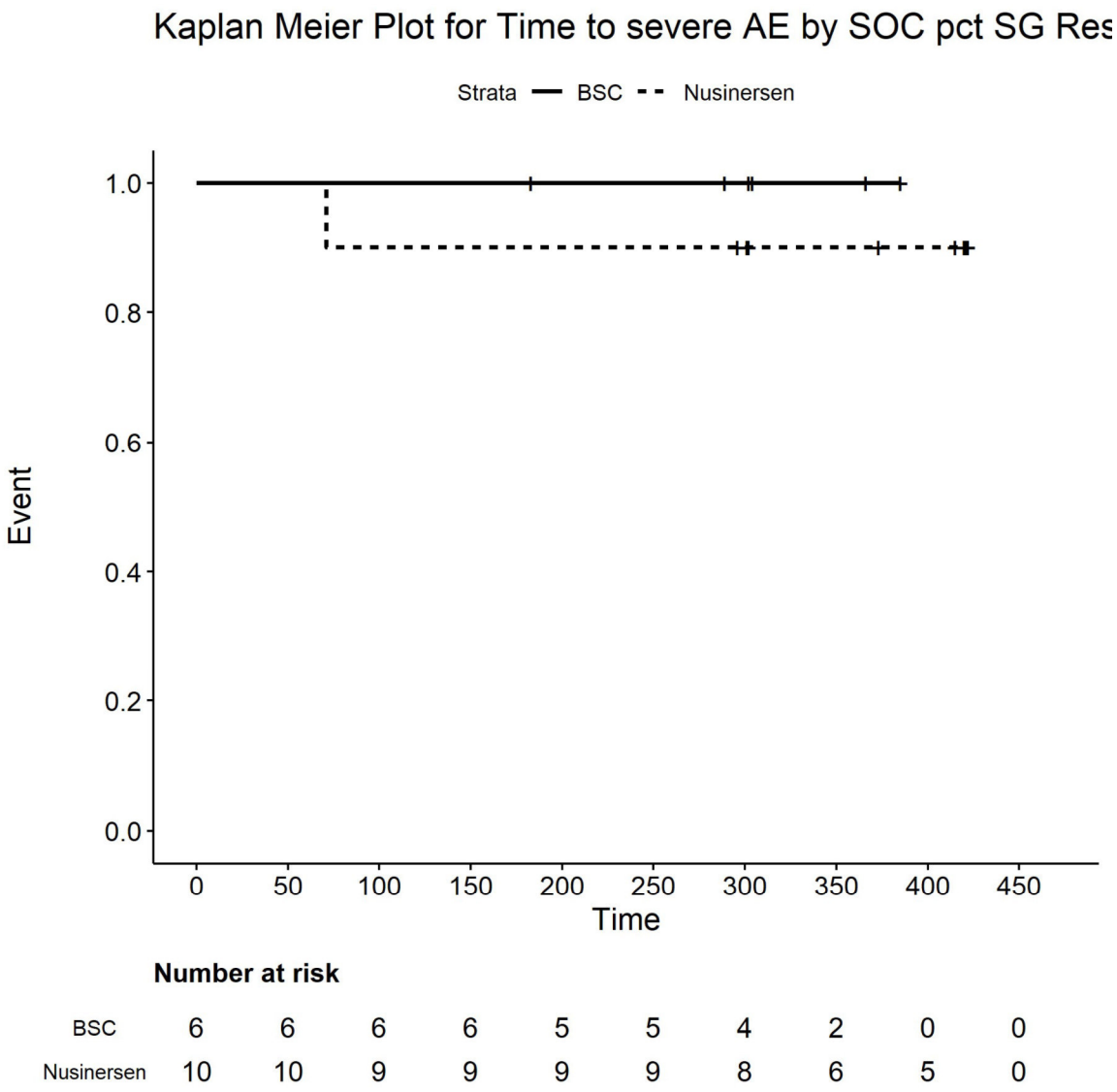
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	7	7	7	7	7	5	4	0



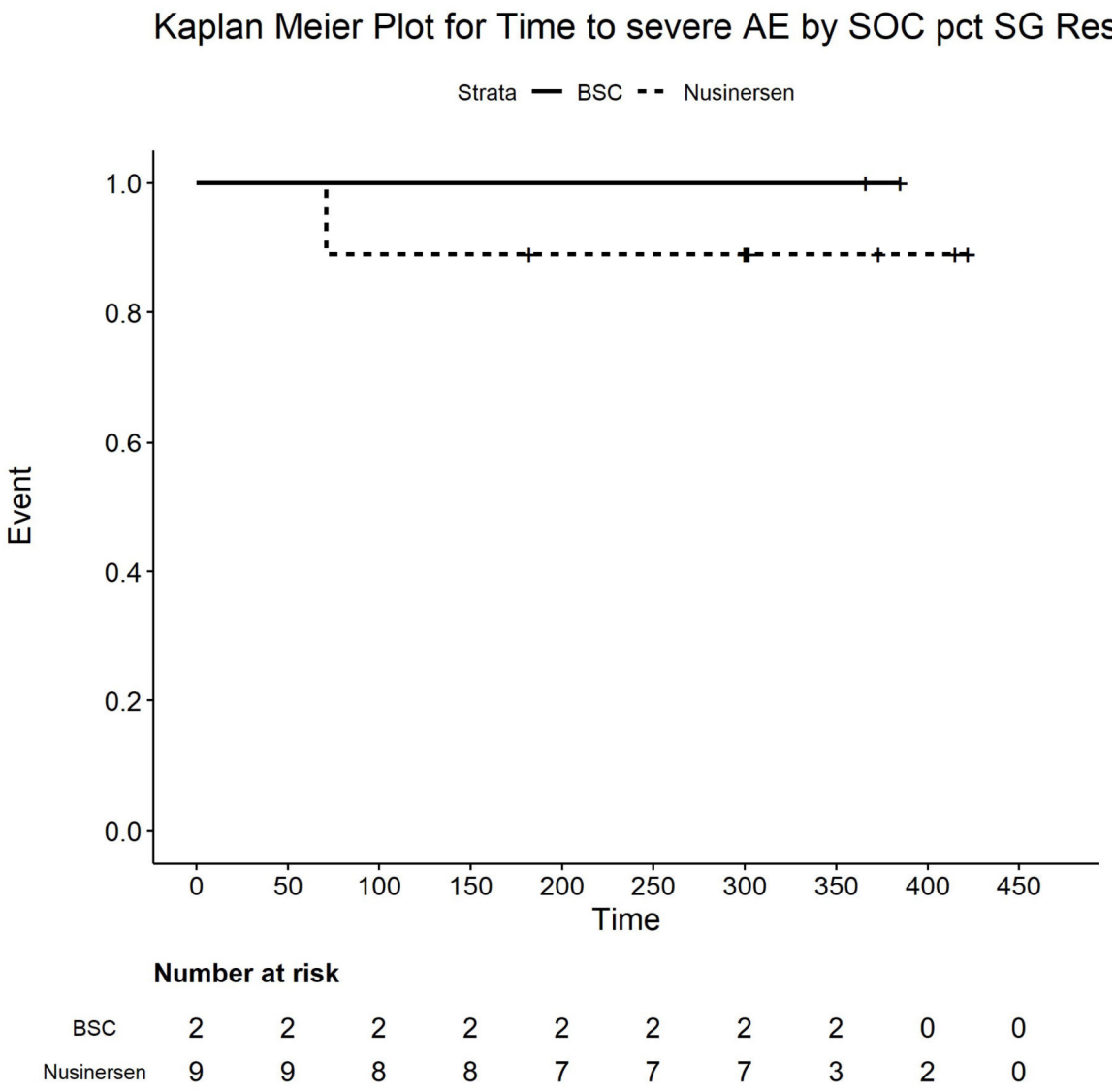
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	8	8	6	6	5	4	3	0



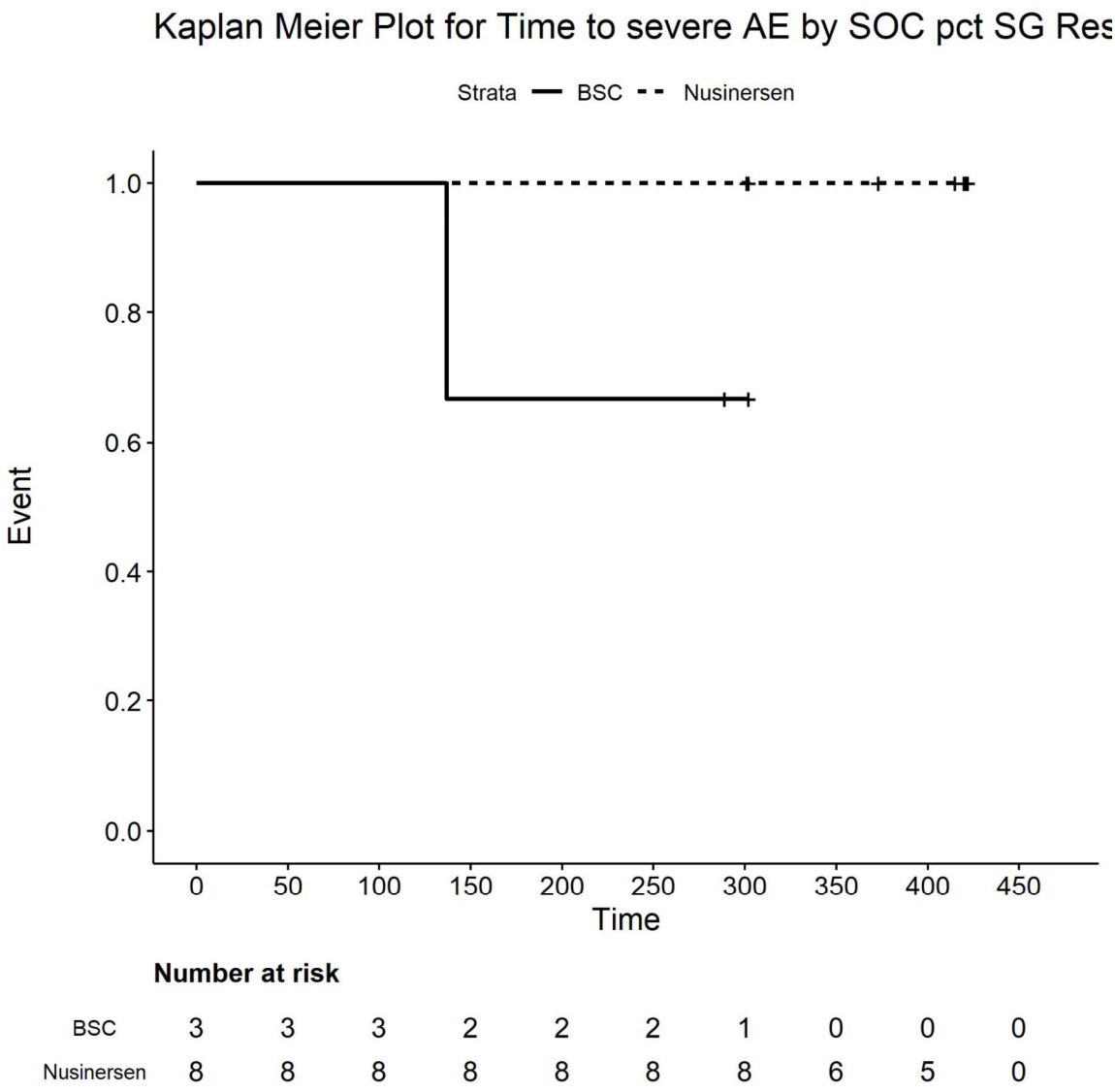
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	9	9	9	9	8	6	5	0



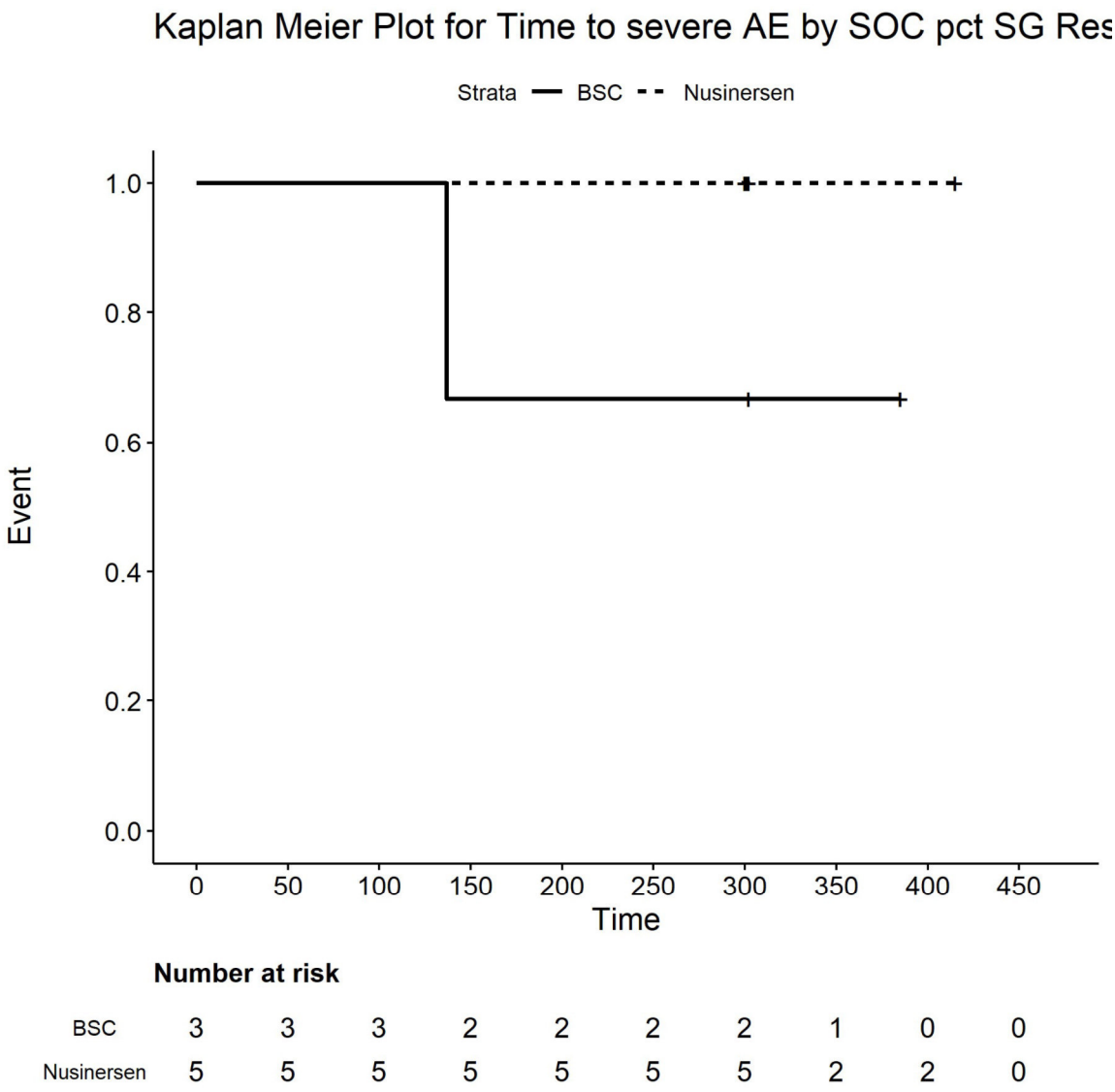
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	8	8	7	7	7	3	2	0



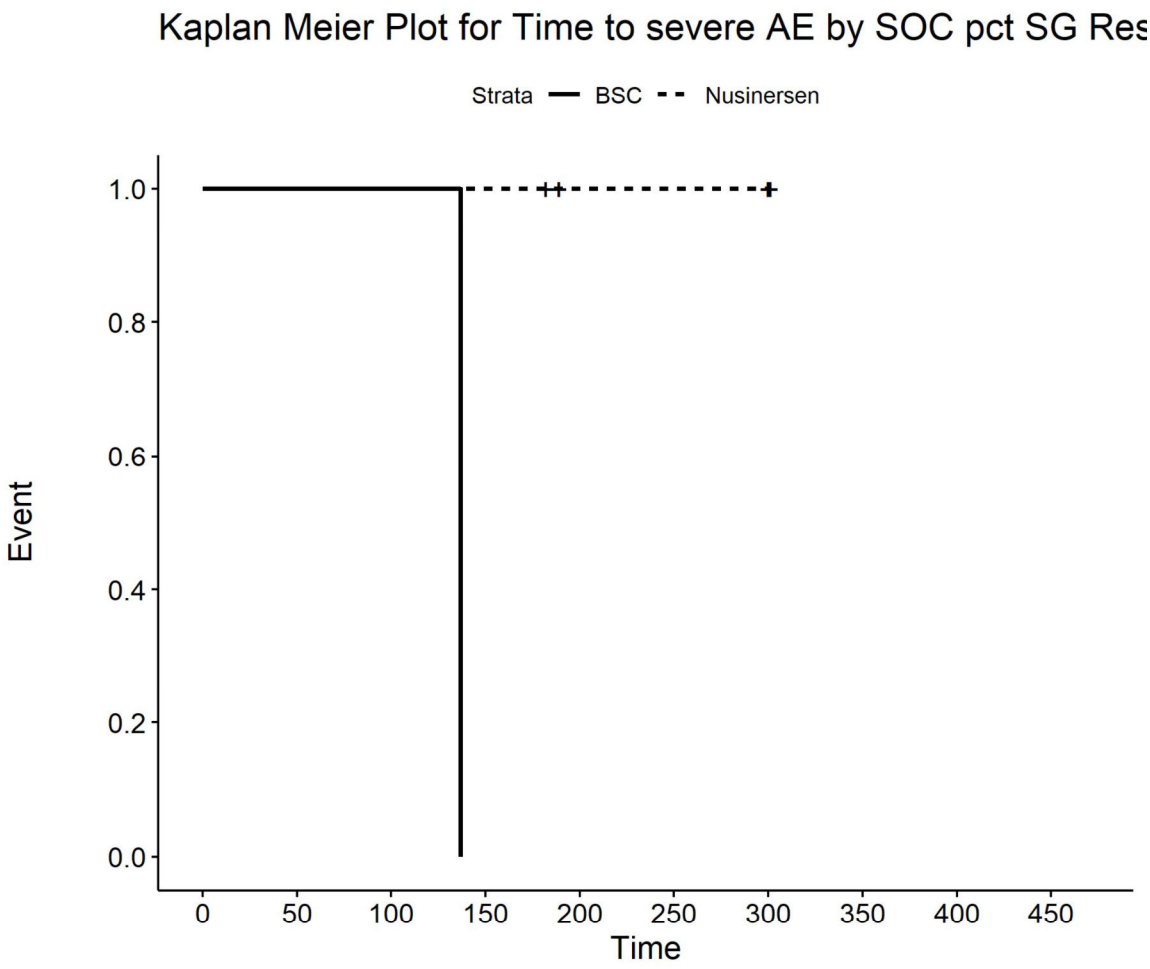
Number at risk

BSC	3	3	3	2	2	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	6	5	0



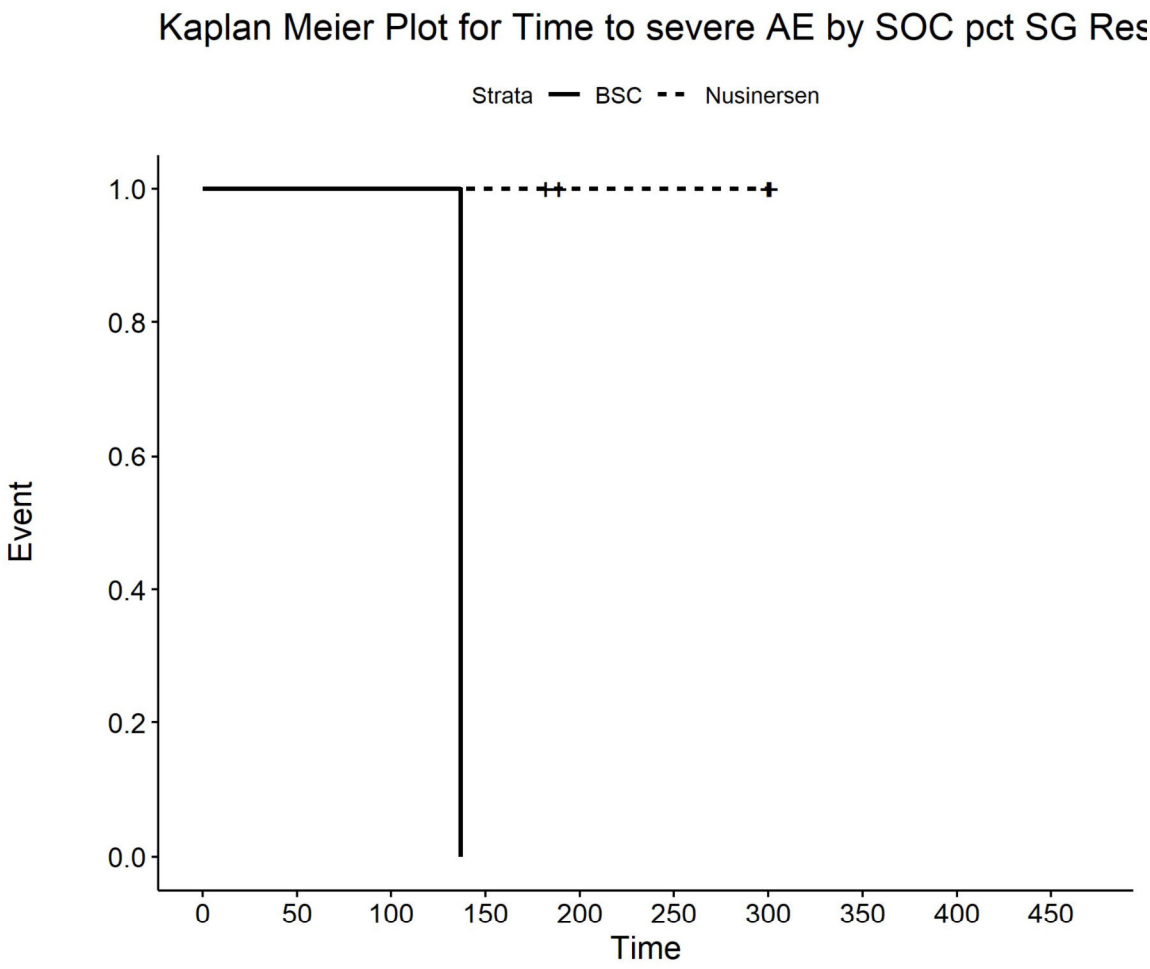
Number at risk

BSC	3	3	3	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



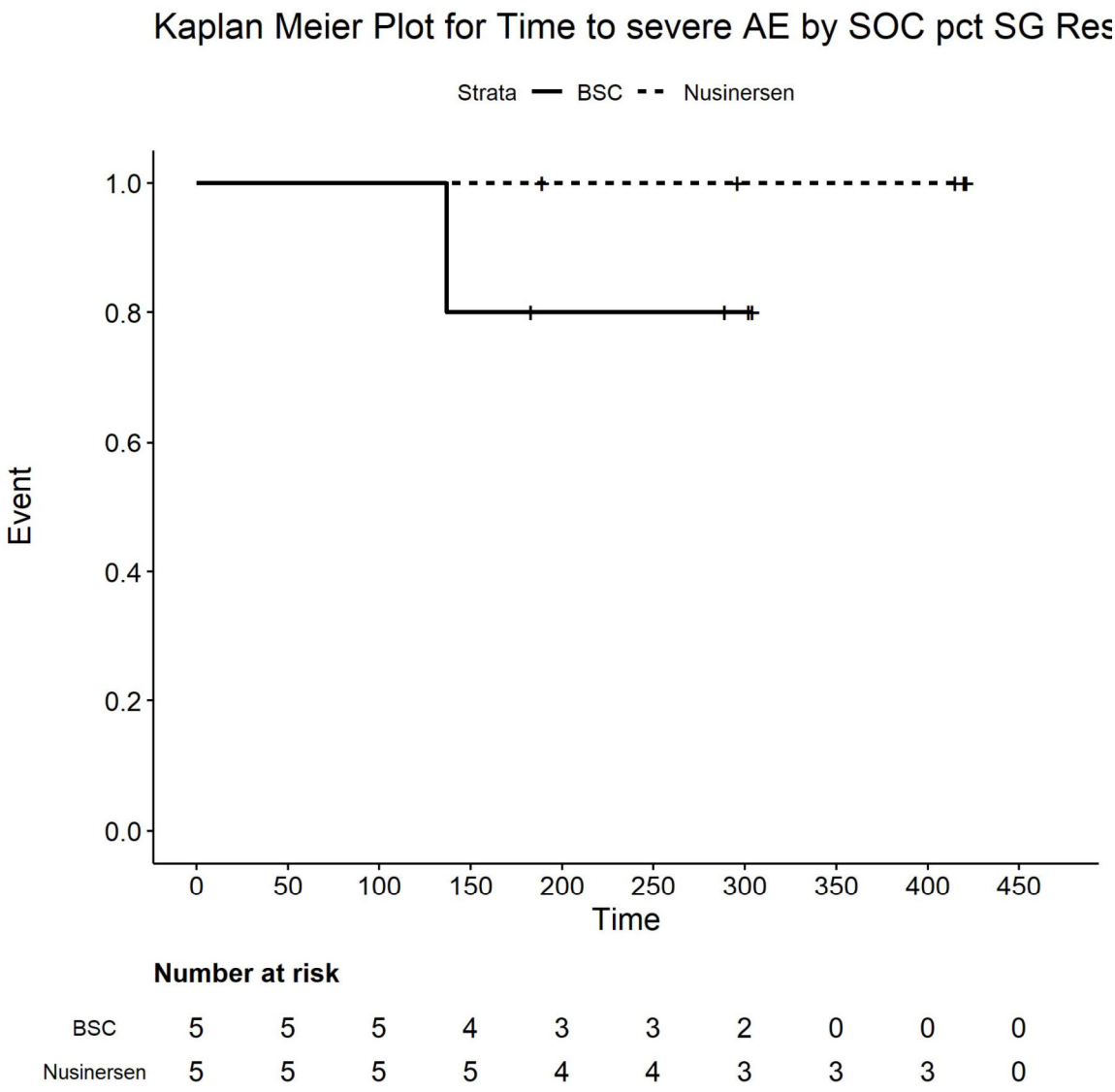
Number at risk

BSC	1	1	1	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



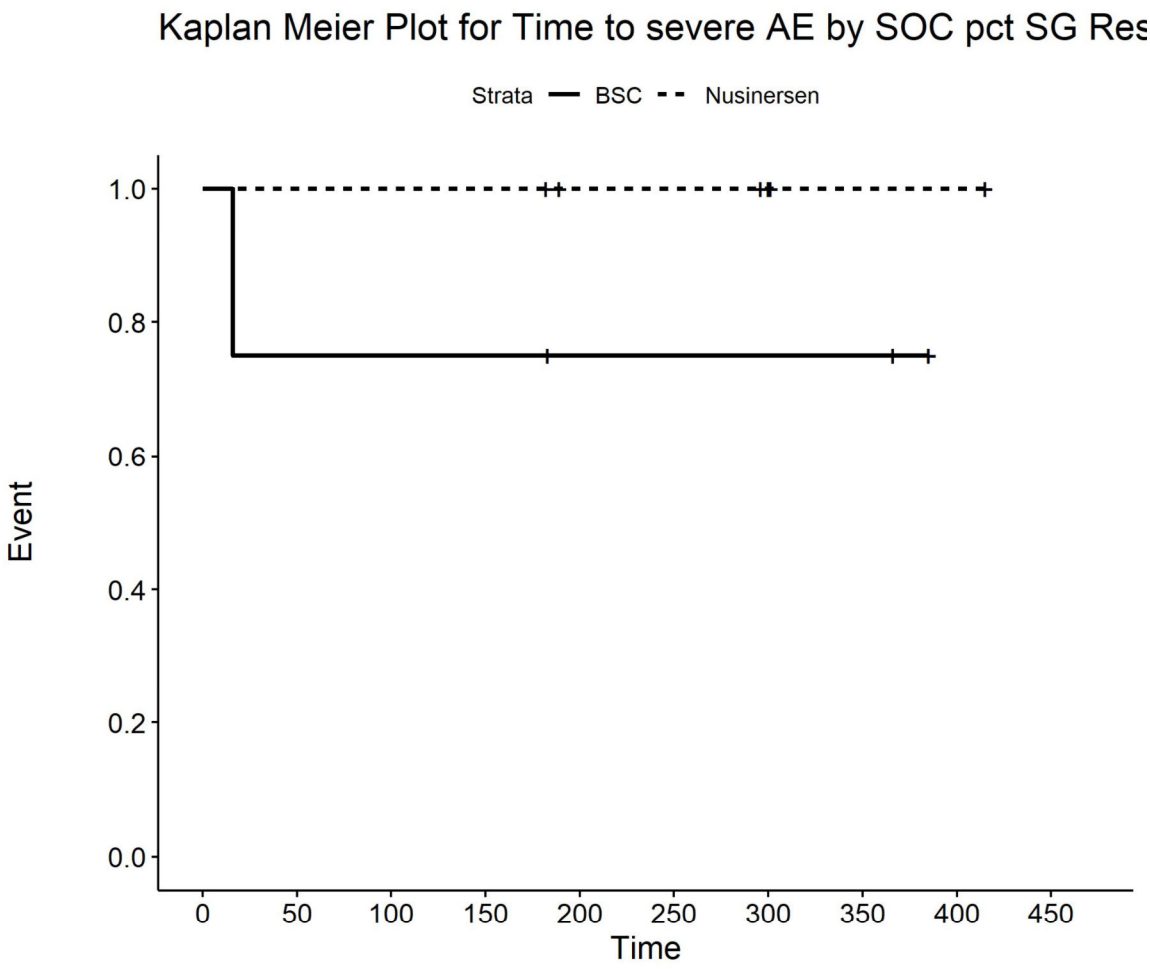
Number at risk

BSC	1	1	1	0	0	0	0	0	0	0
Nusinersen	4	4	4	4	2	2	2	0	0	0



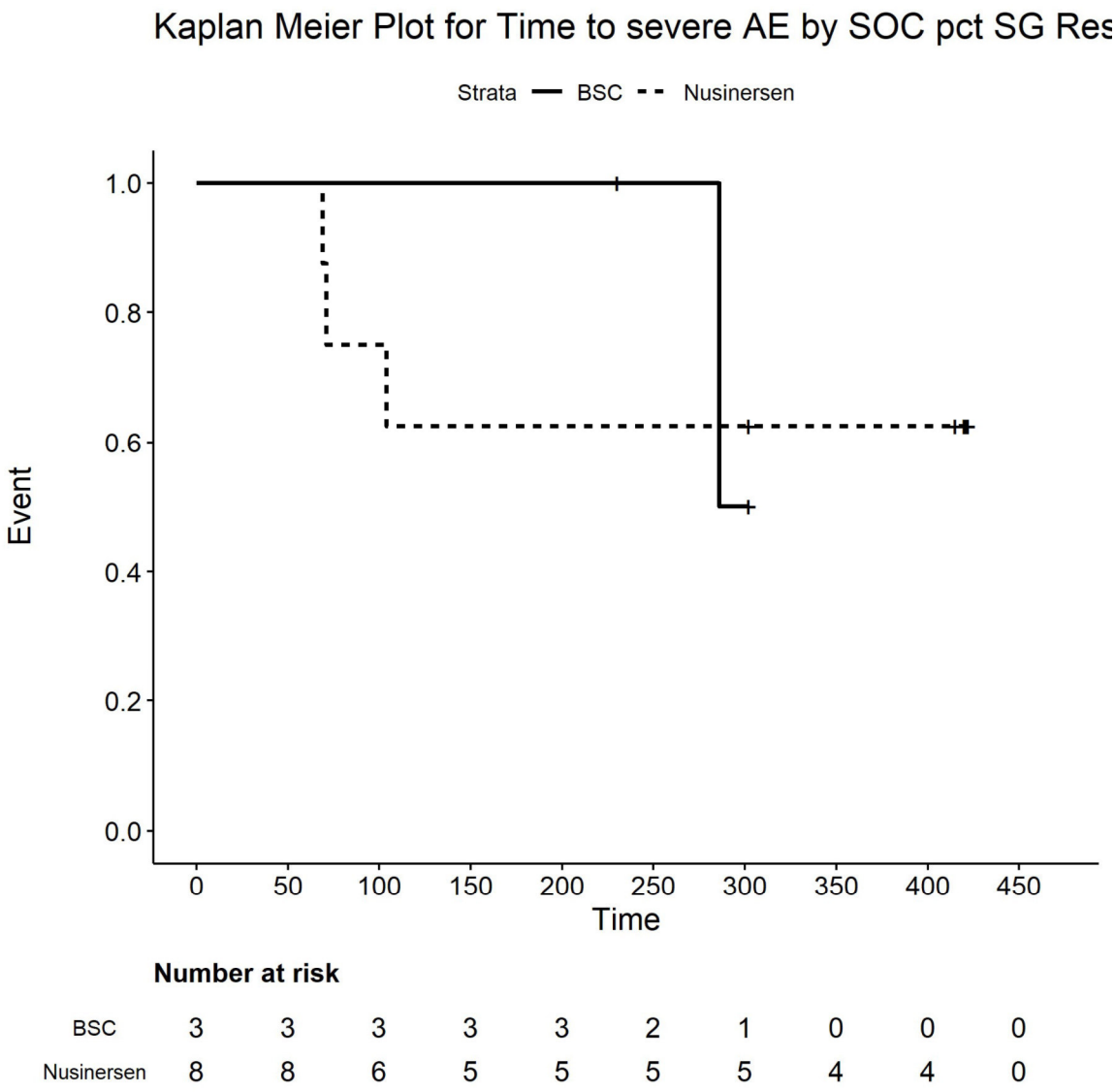
Number at risk

BSC	5	5	5	4	3	3	2	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



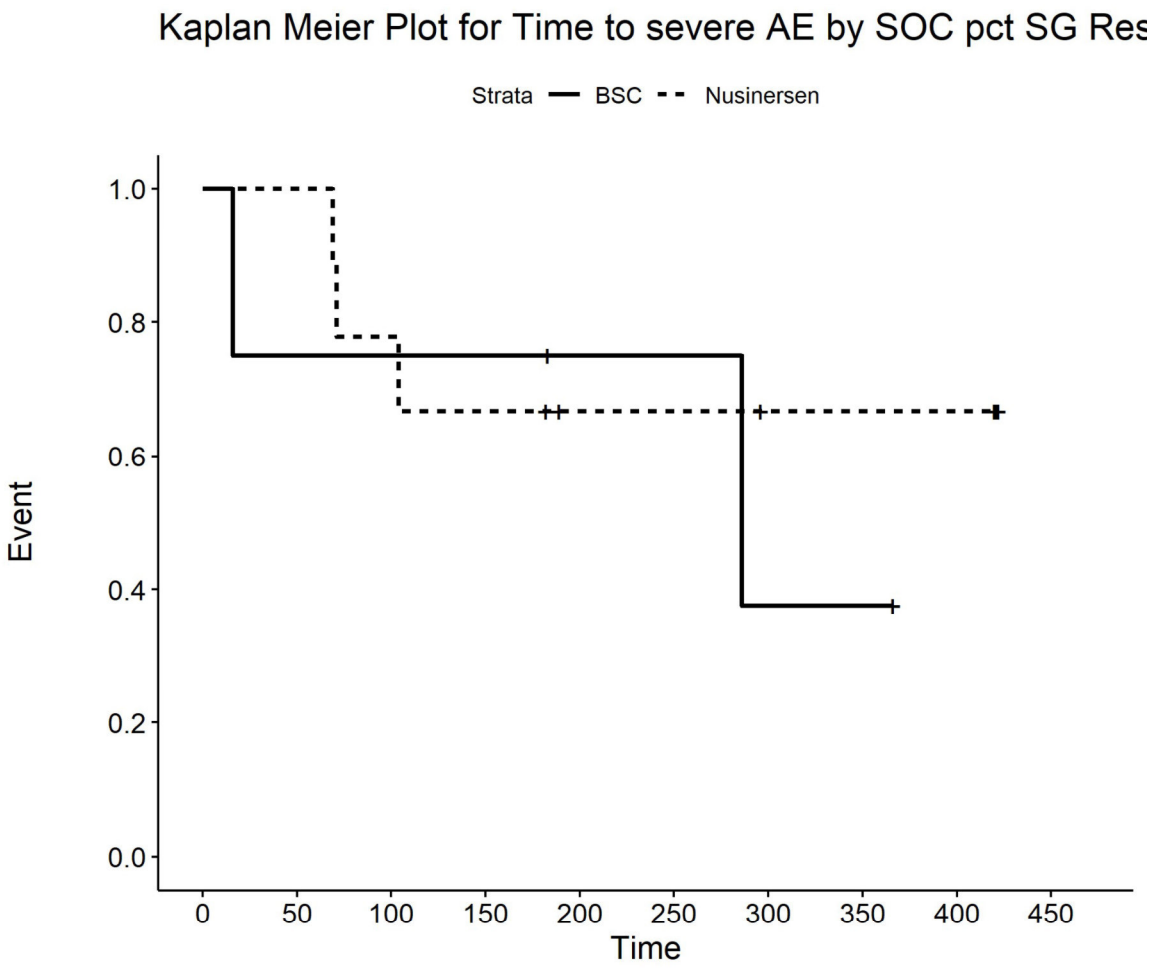
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



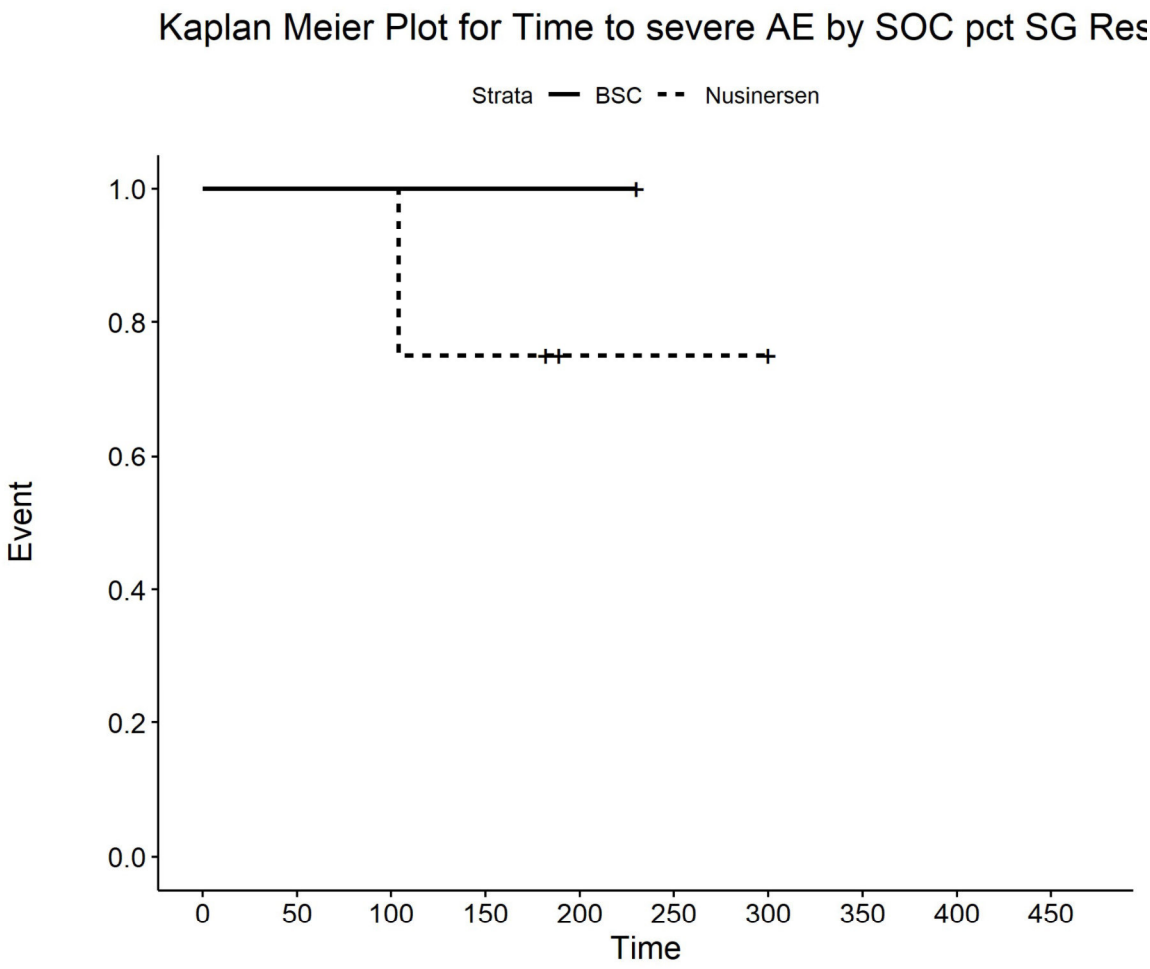
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	6	5	5	5	5	4	4	0



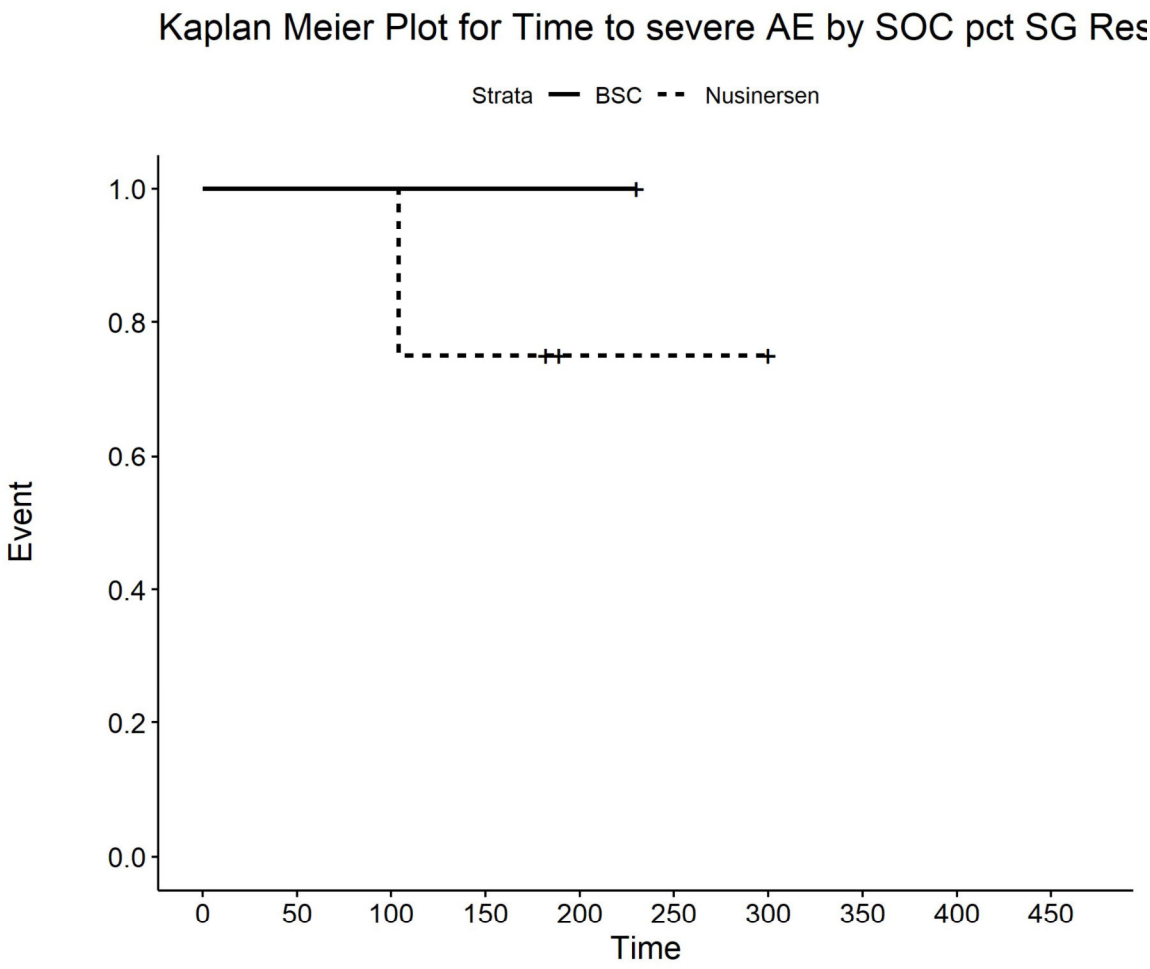
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	9	7	6	4	4	3	3	3	0



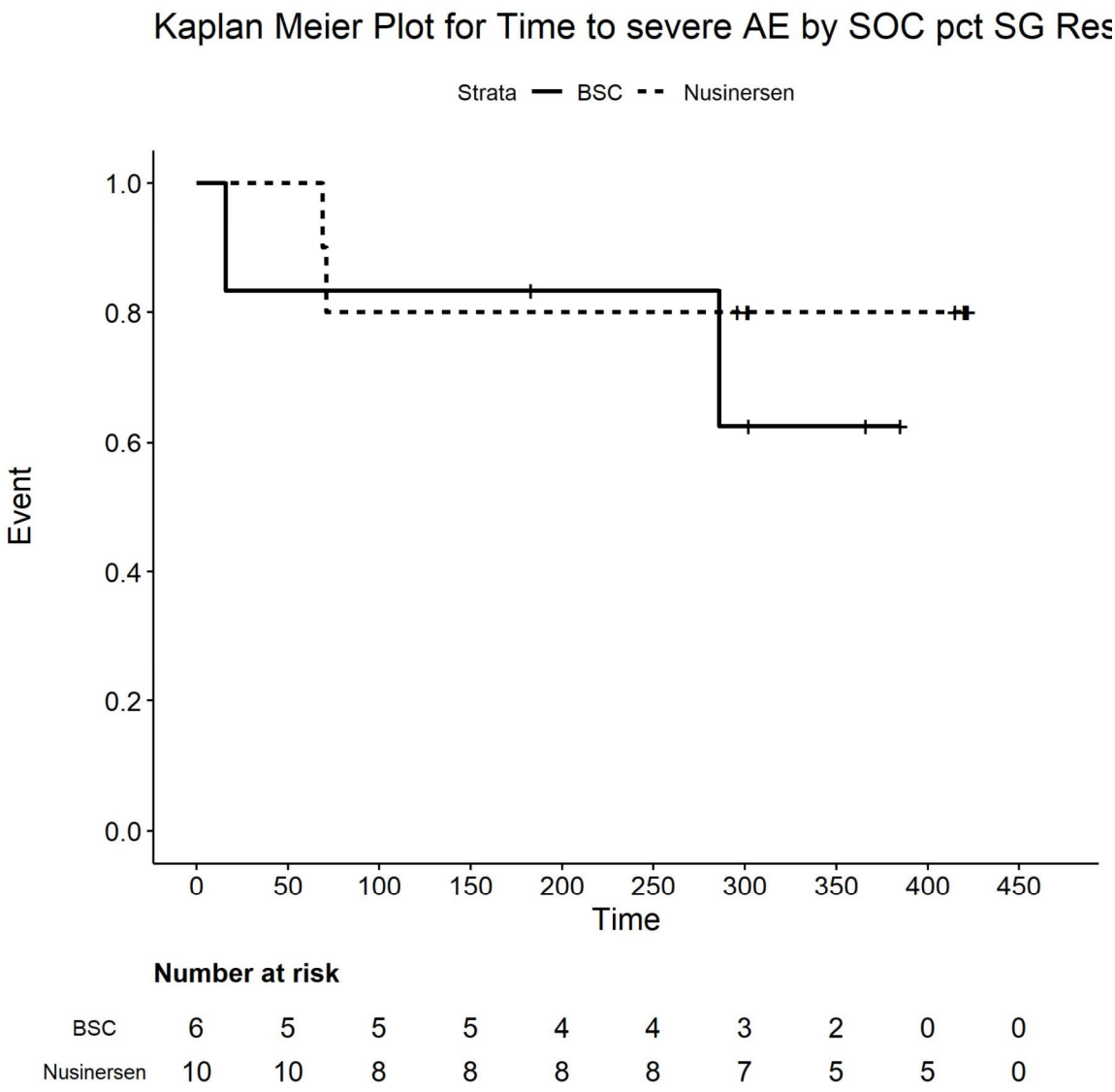
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



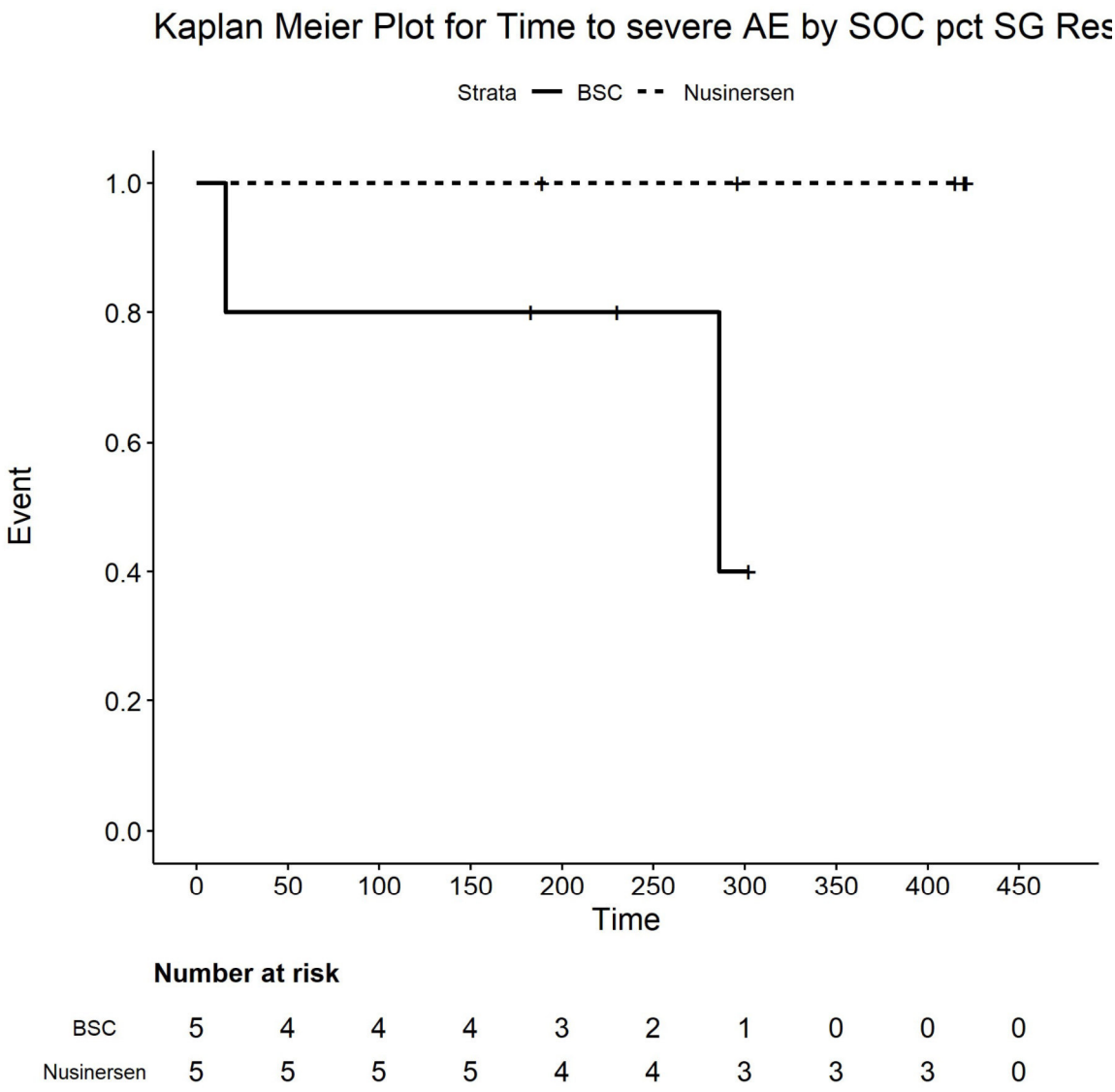
Number at risk

BSC	1	1	1	1	1	0	0	0	0	0
Nusinersen	4	4	4	3	1	1	1	0	0	0



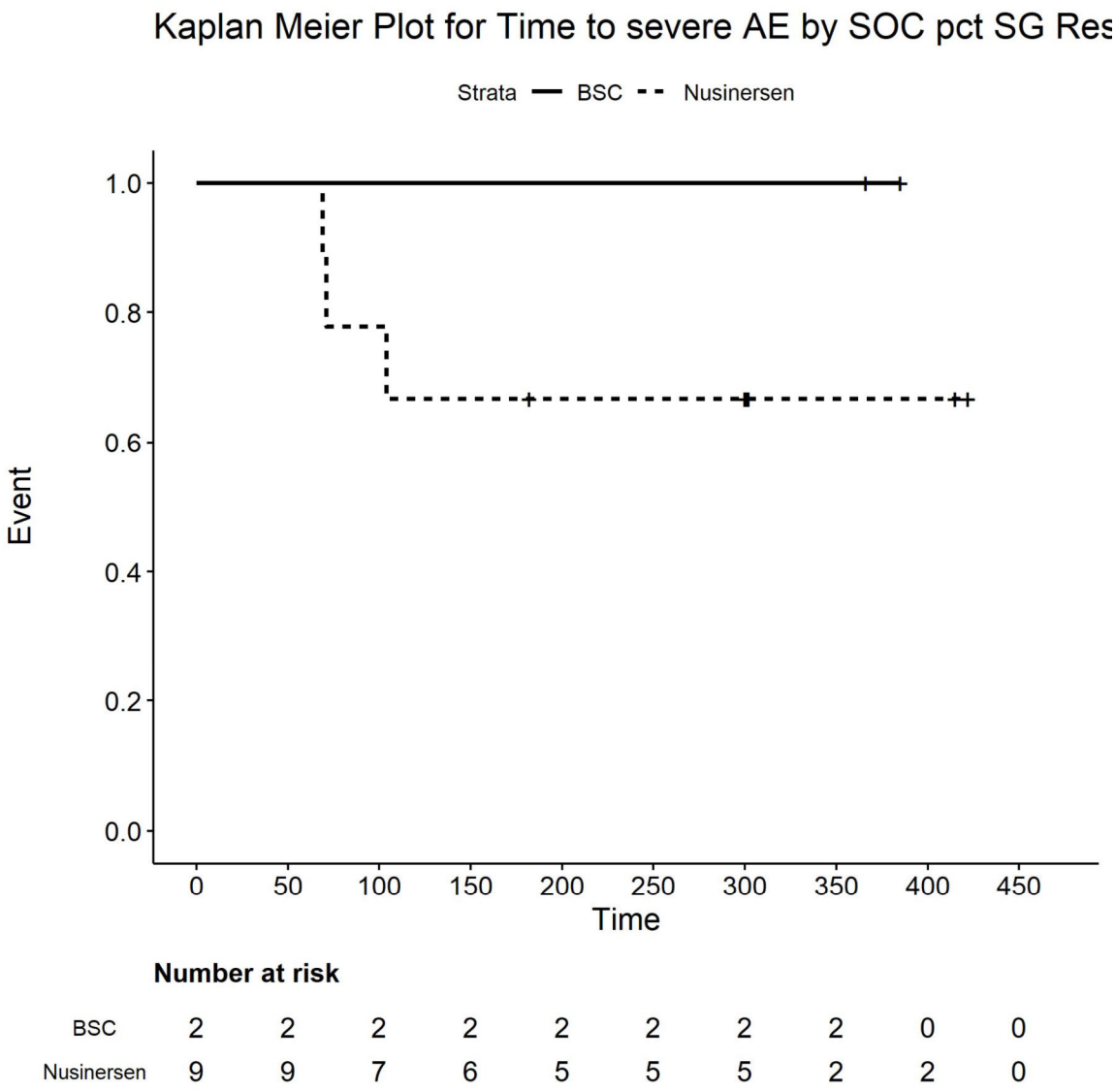
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	8	8	8	8	7	5	5	0



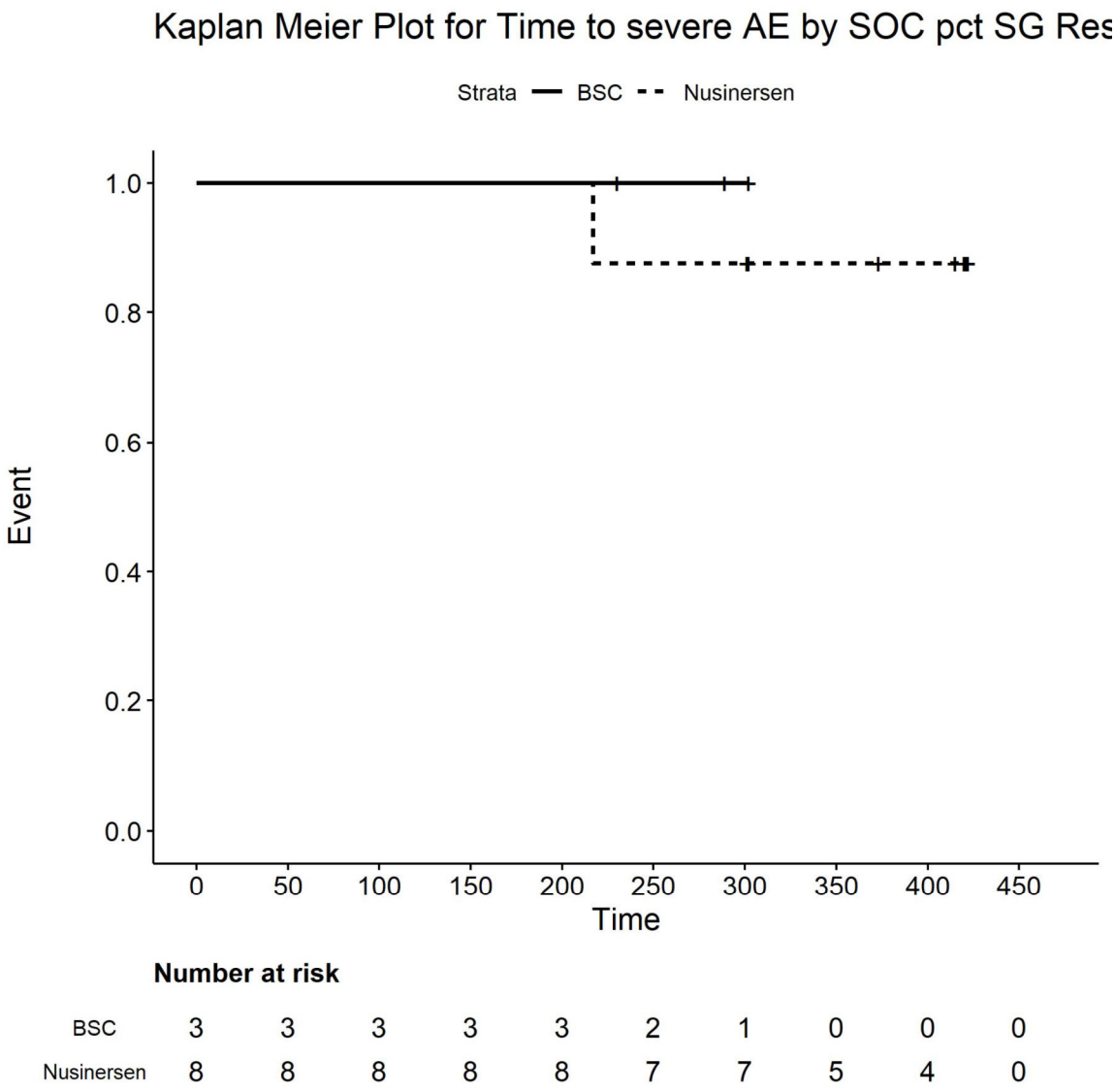
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



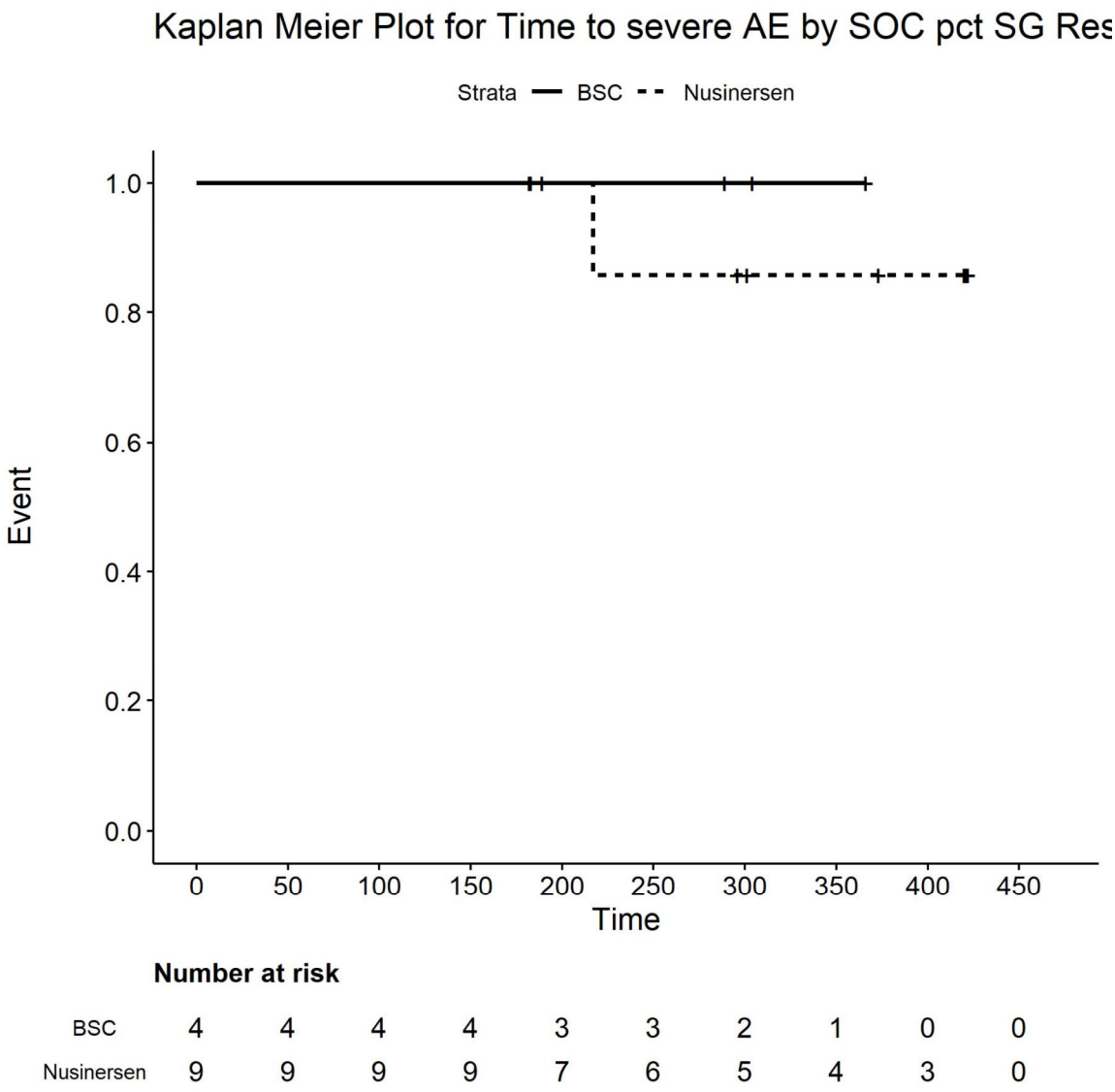
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	7	6	5	5	5	2	2	0



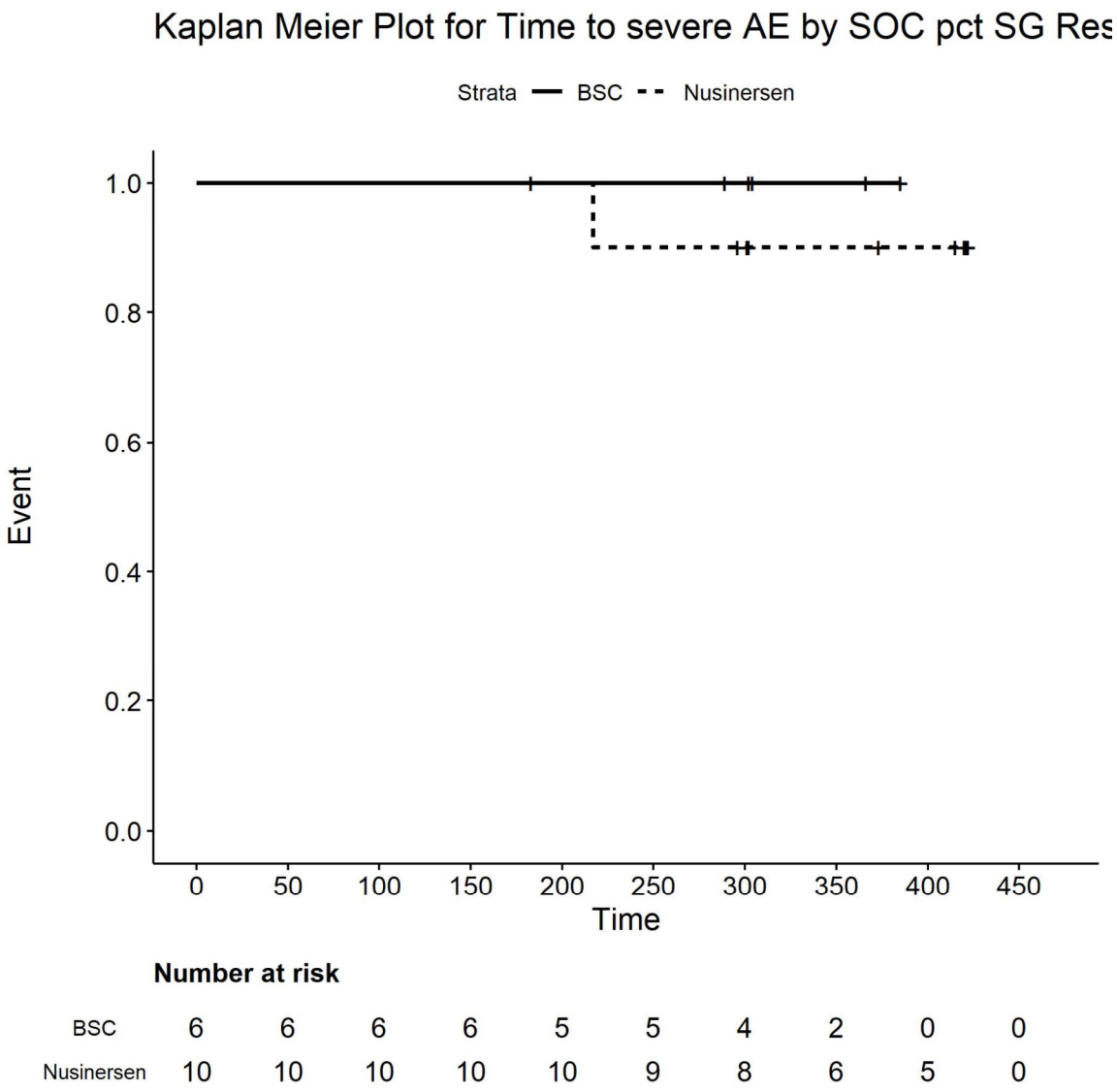
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	7	7	5	4	0



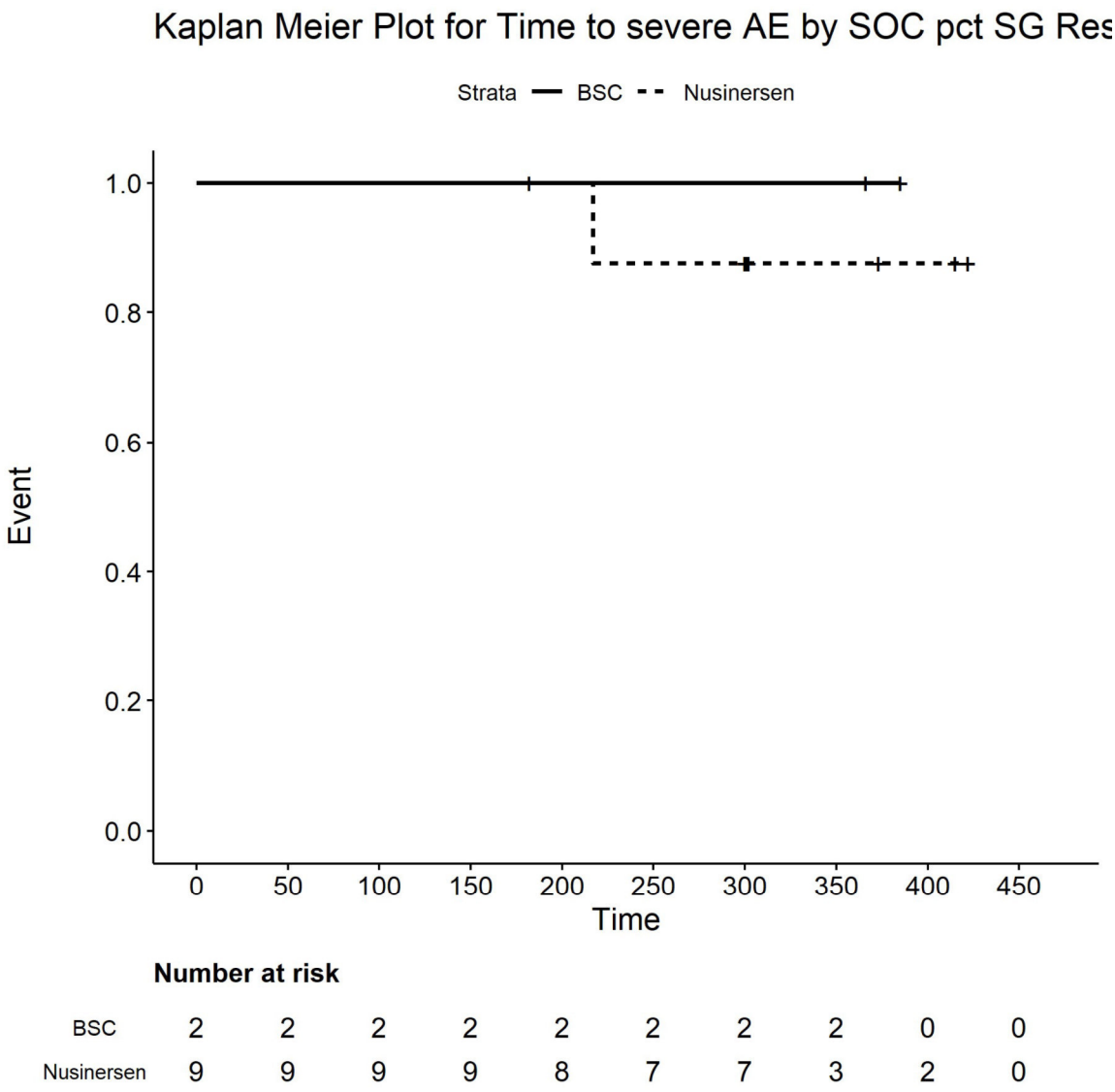
Number at risk

BSC	4	4	4	4	3	3	2	1	0	0
Nusinersen	9	9	9	9	7	6	5	4	3	0



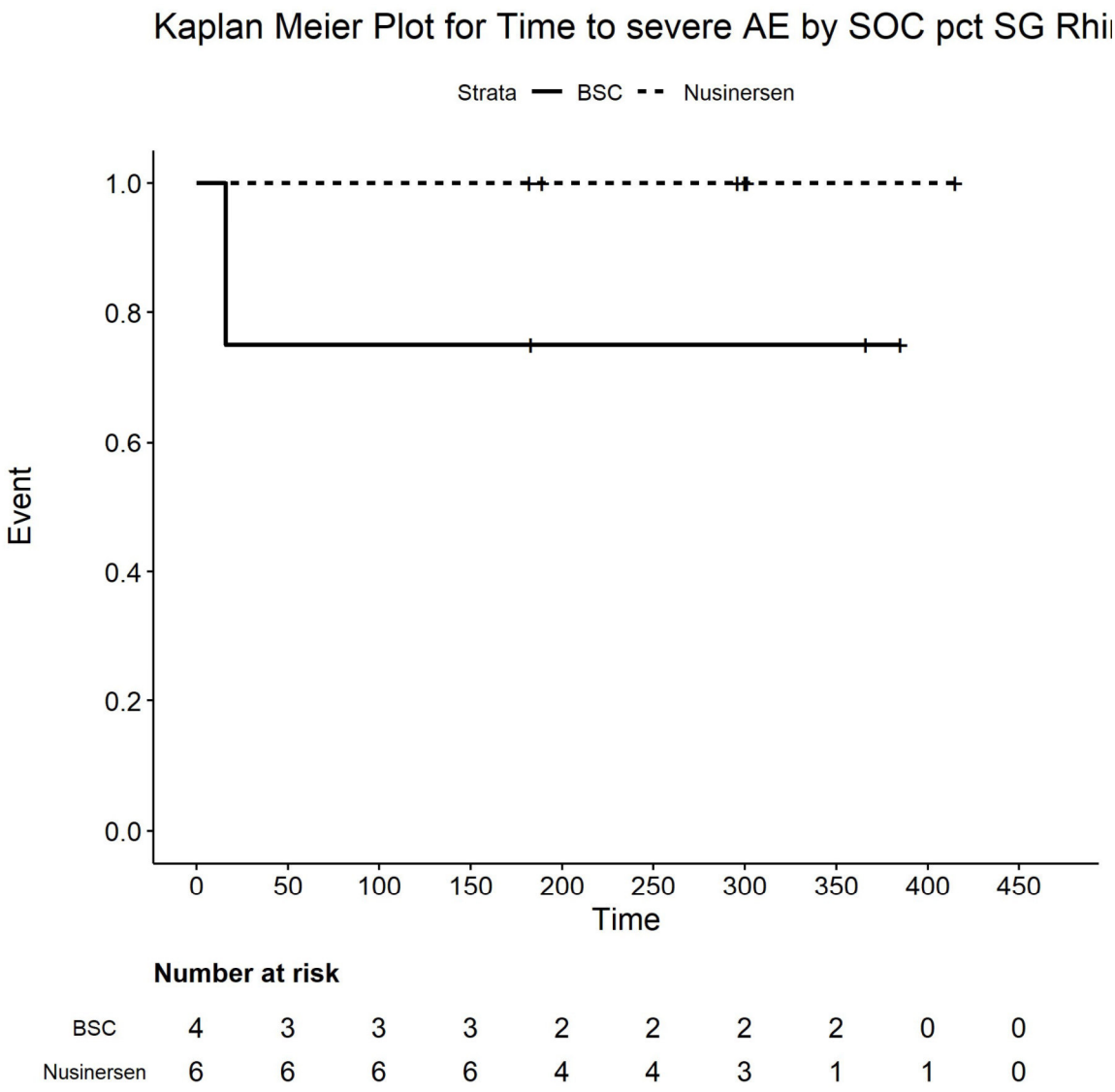
Number at risk

BSC	6	6	6	6	5	5	4	2	0	0
Nusinersen	10	10	10	10	10	9	8	6	5	0



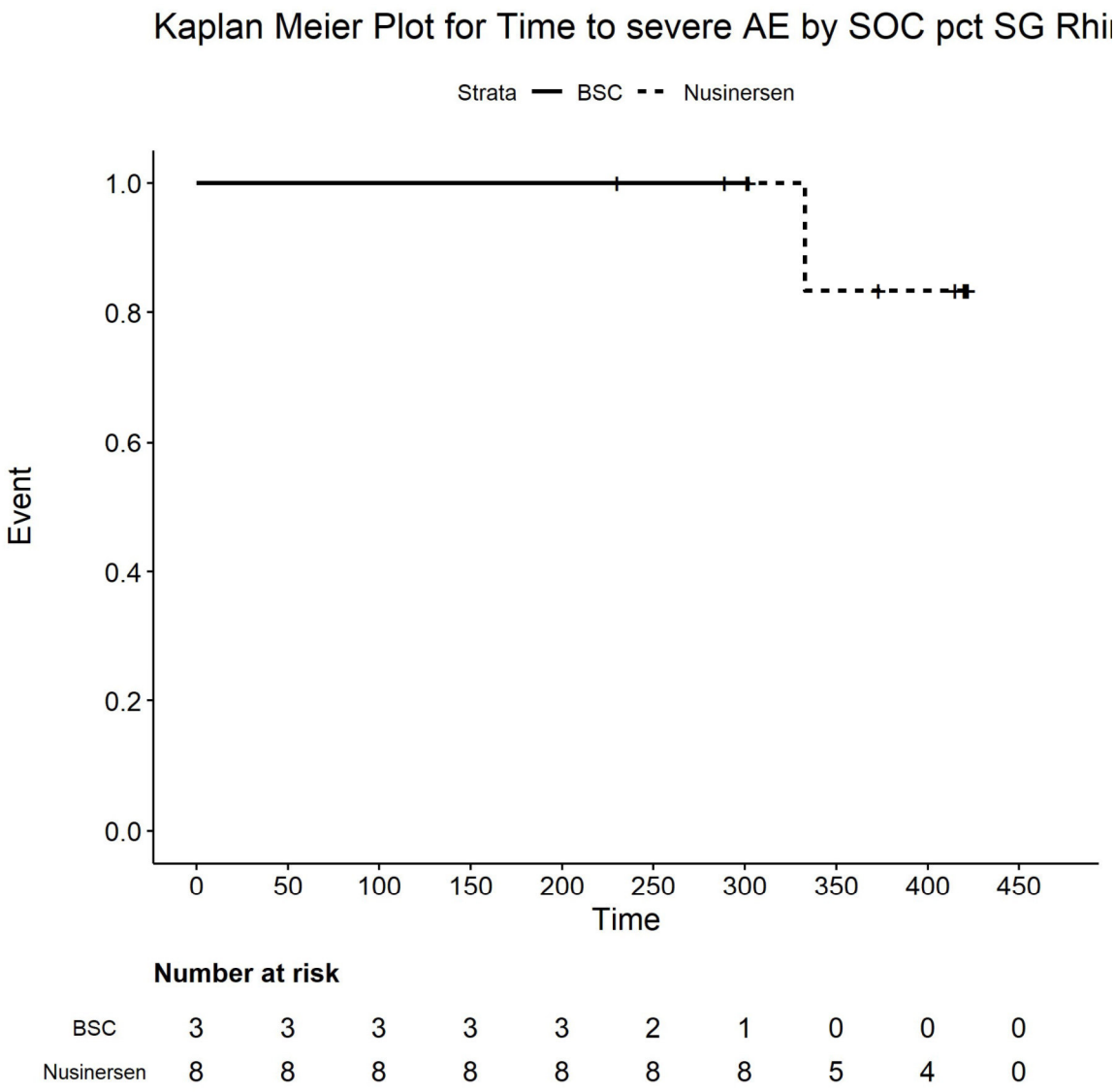
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	7	7	3	2	0



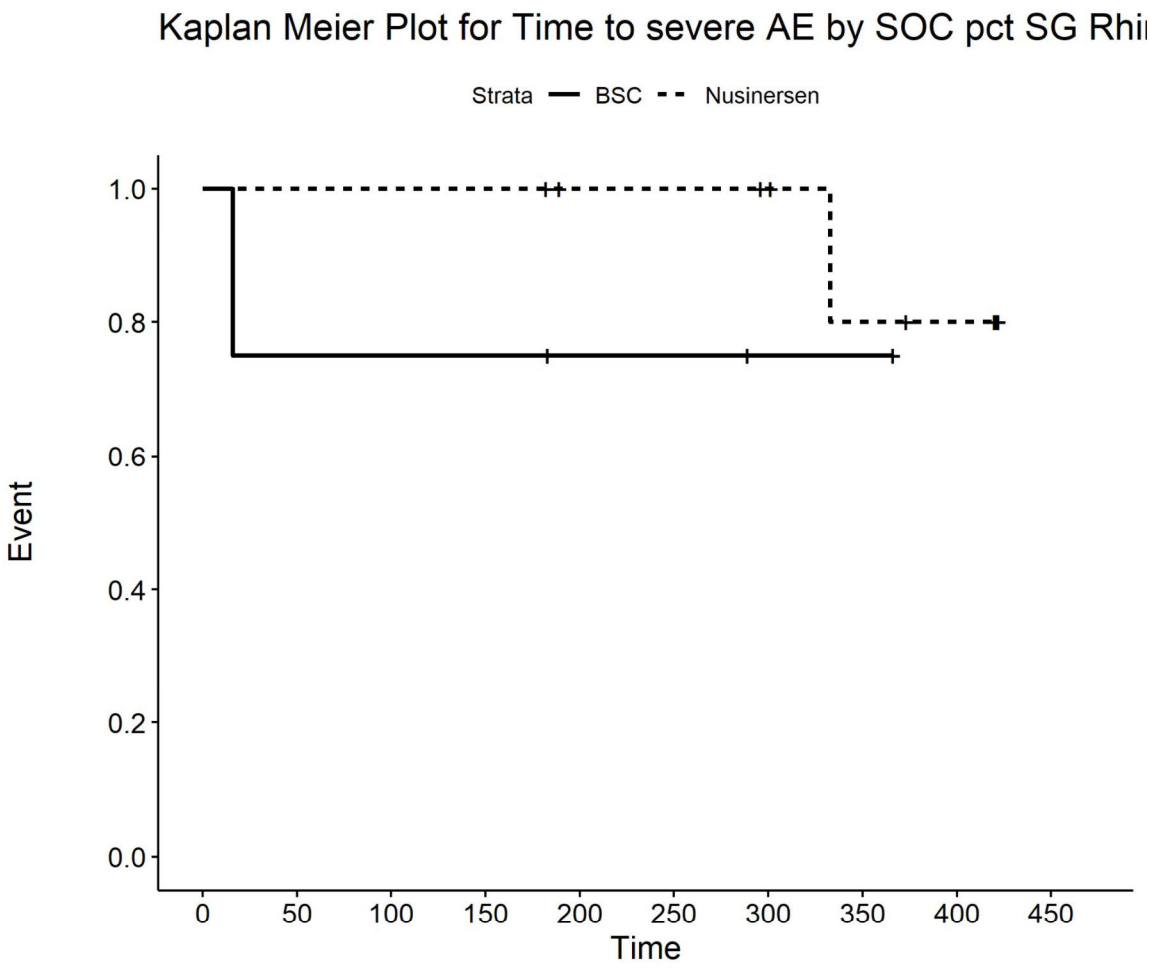
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	6	6	6	4	4	3	1	1	0



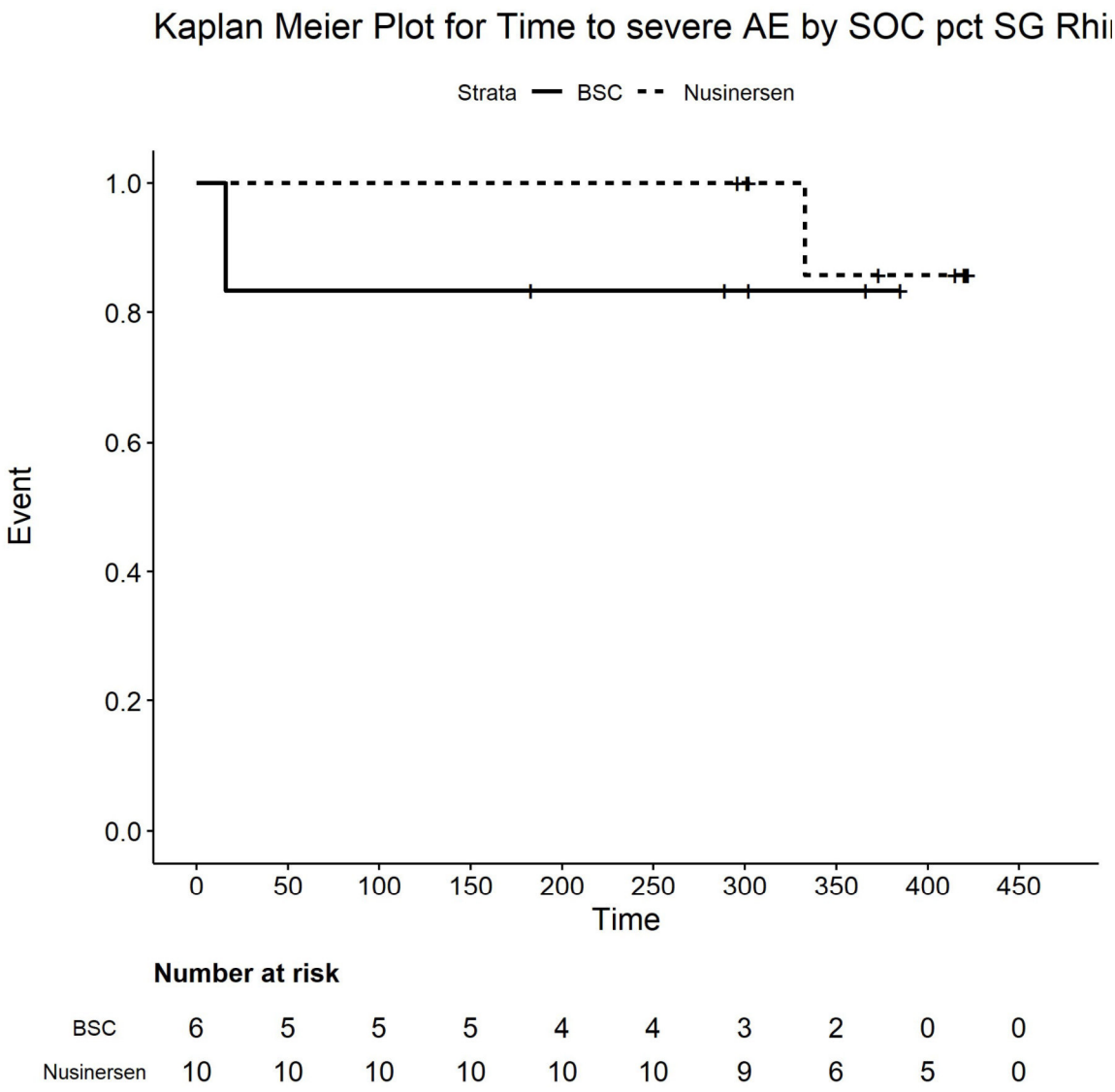
Number at risk

BSC	3	3	3	3	3	2	1	0	0	0
Nusinersen	8	8	8	8	8	8	8	5	4	0



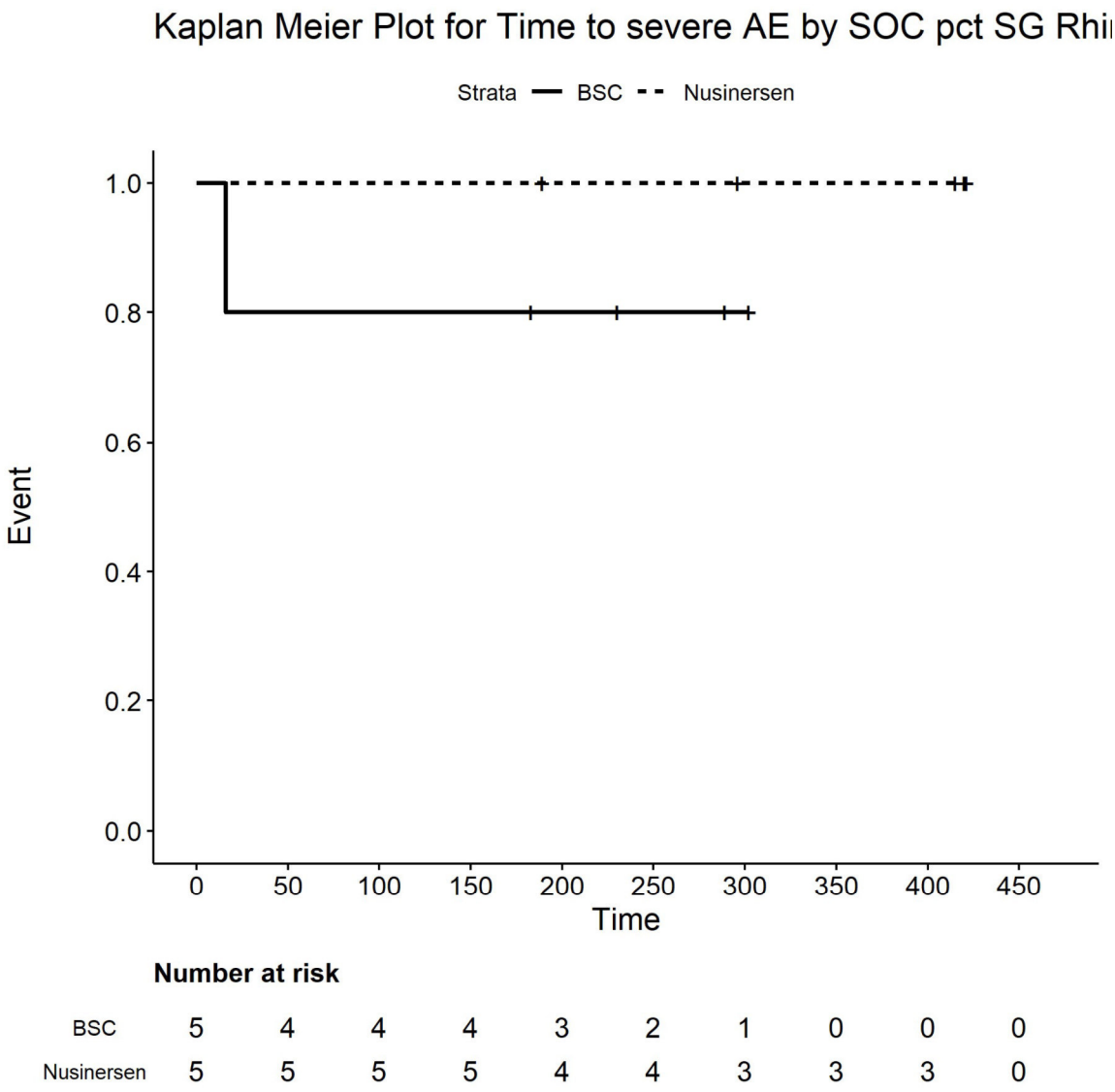
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	9	9	9	7	7	6	4	3	0



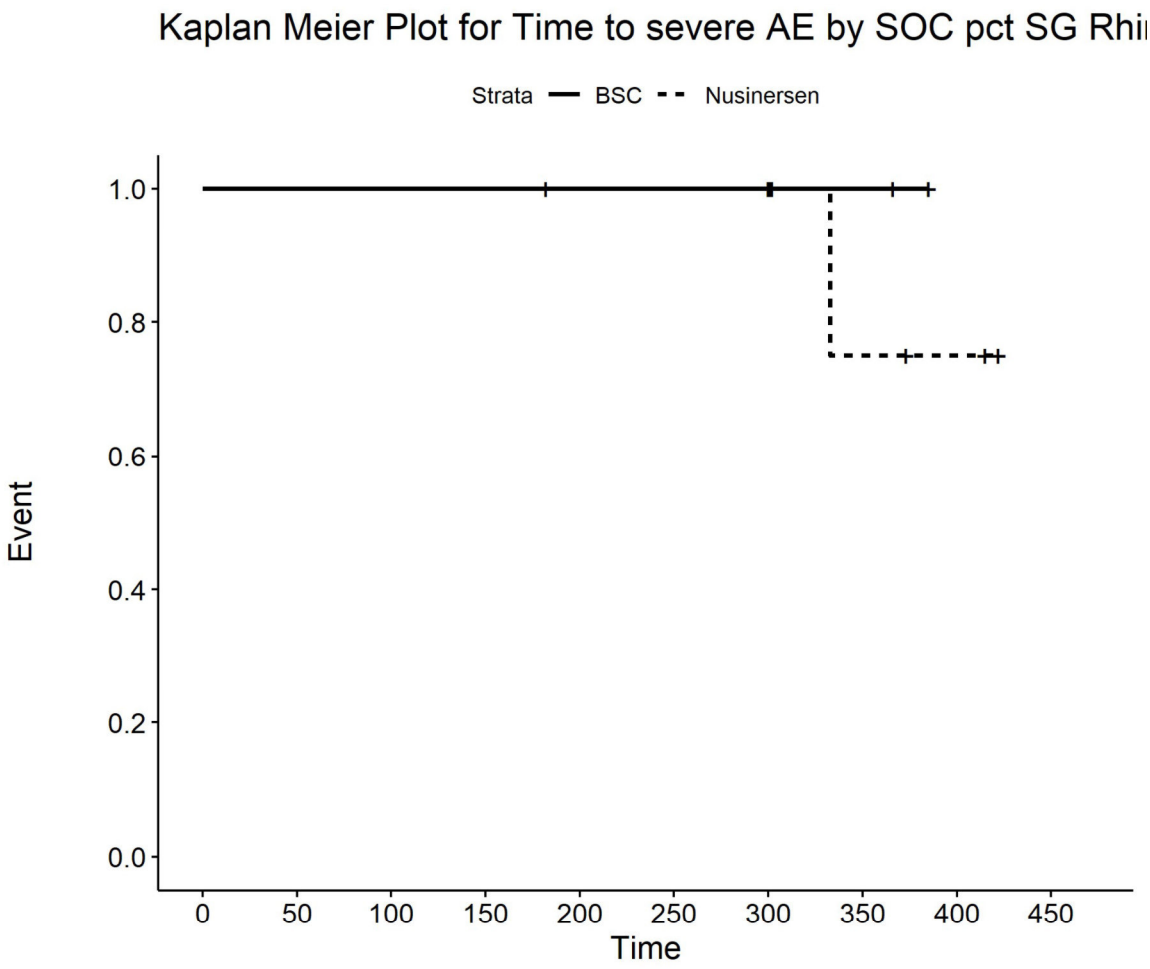
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	10	10	10	10	9	6	5	0



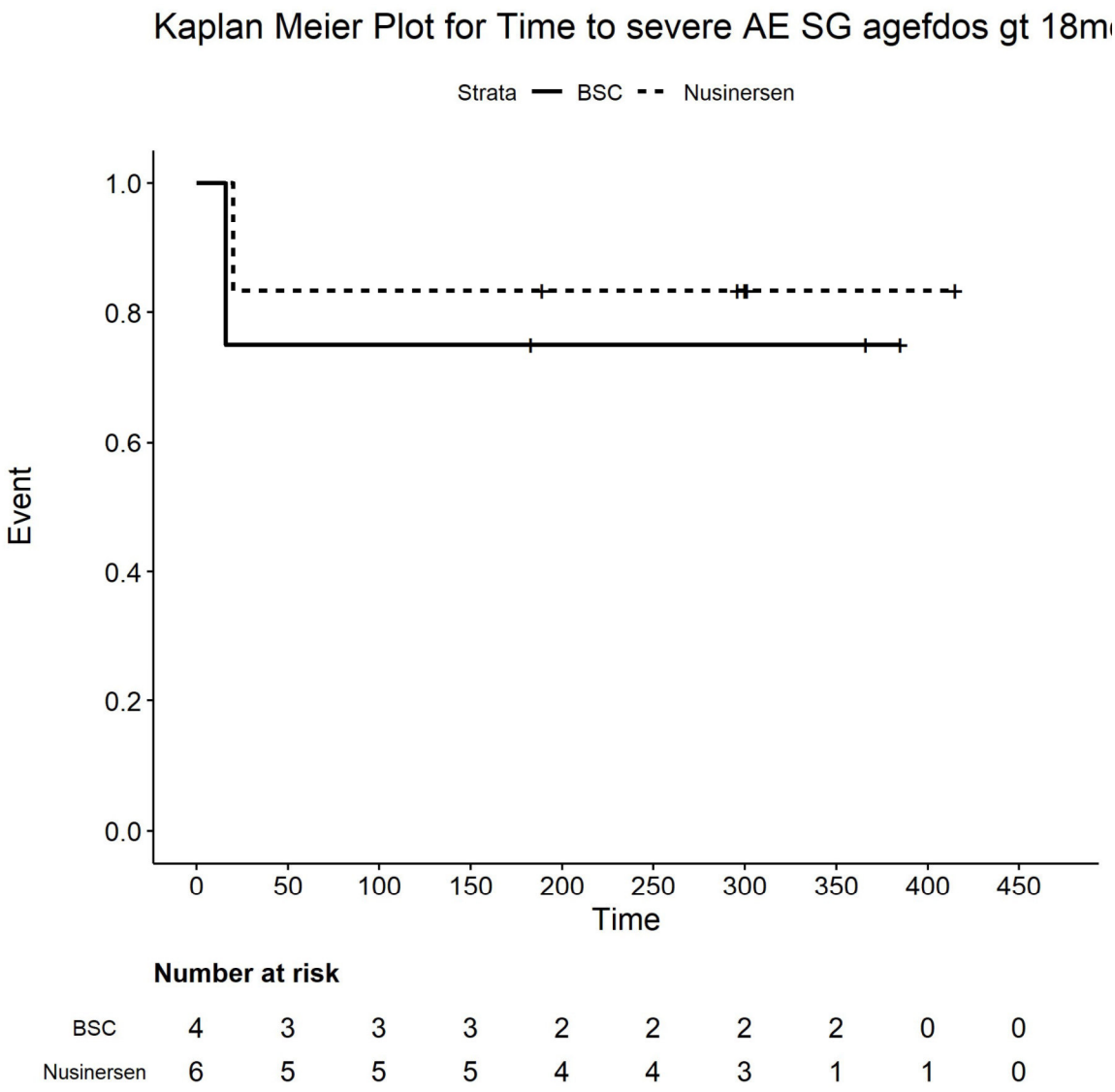
Number at risk

BSC	5	4	4	4	3	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	3	3	3	0



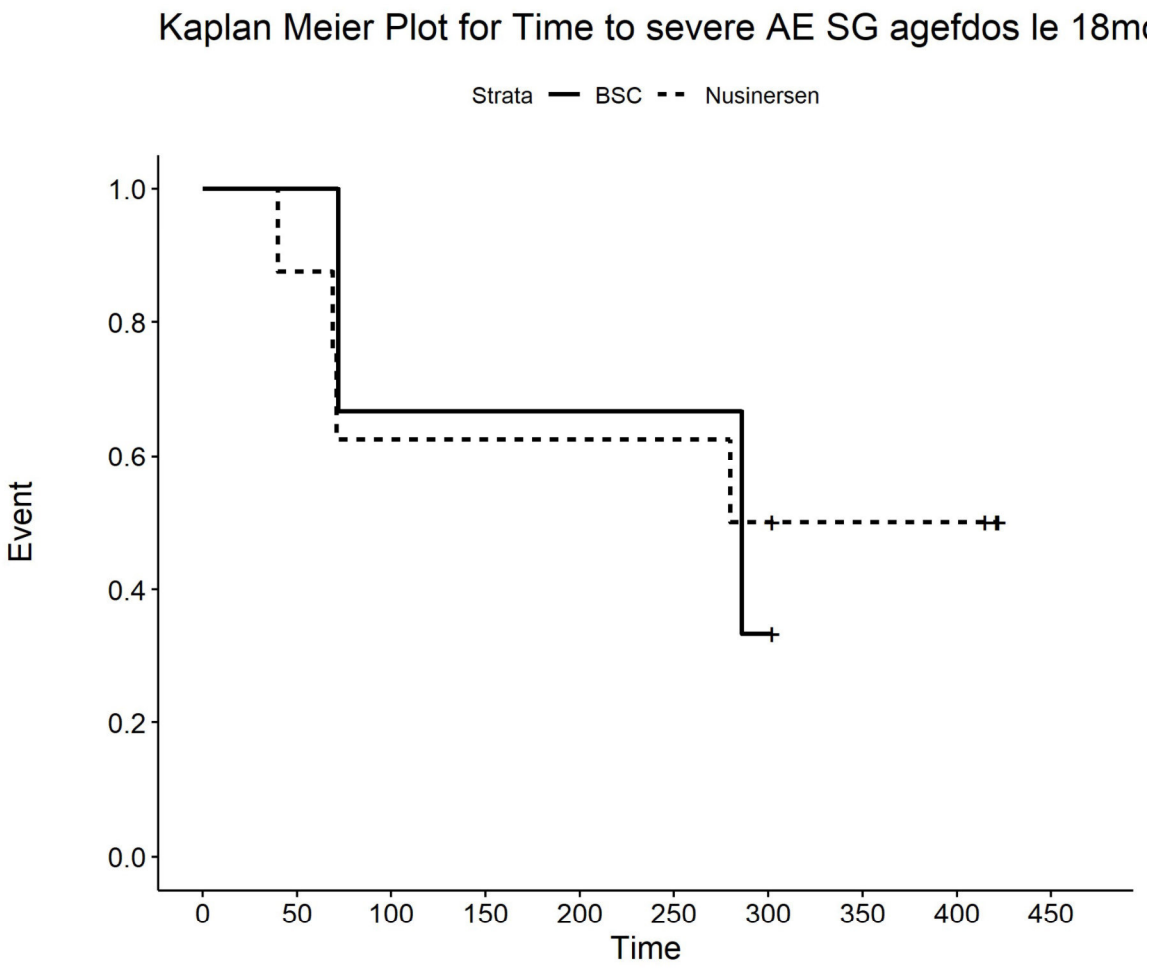
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	9	9	9	8	8	8	3	2	0



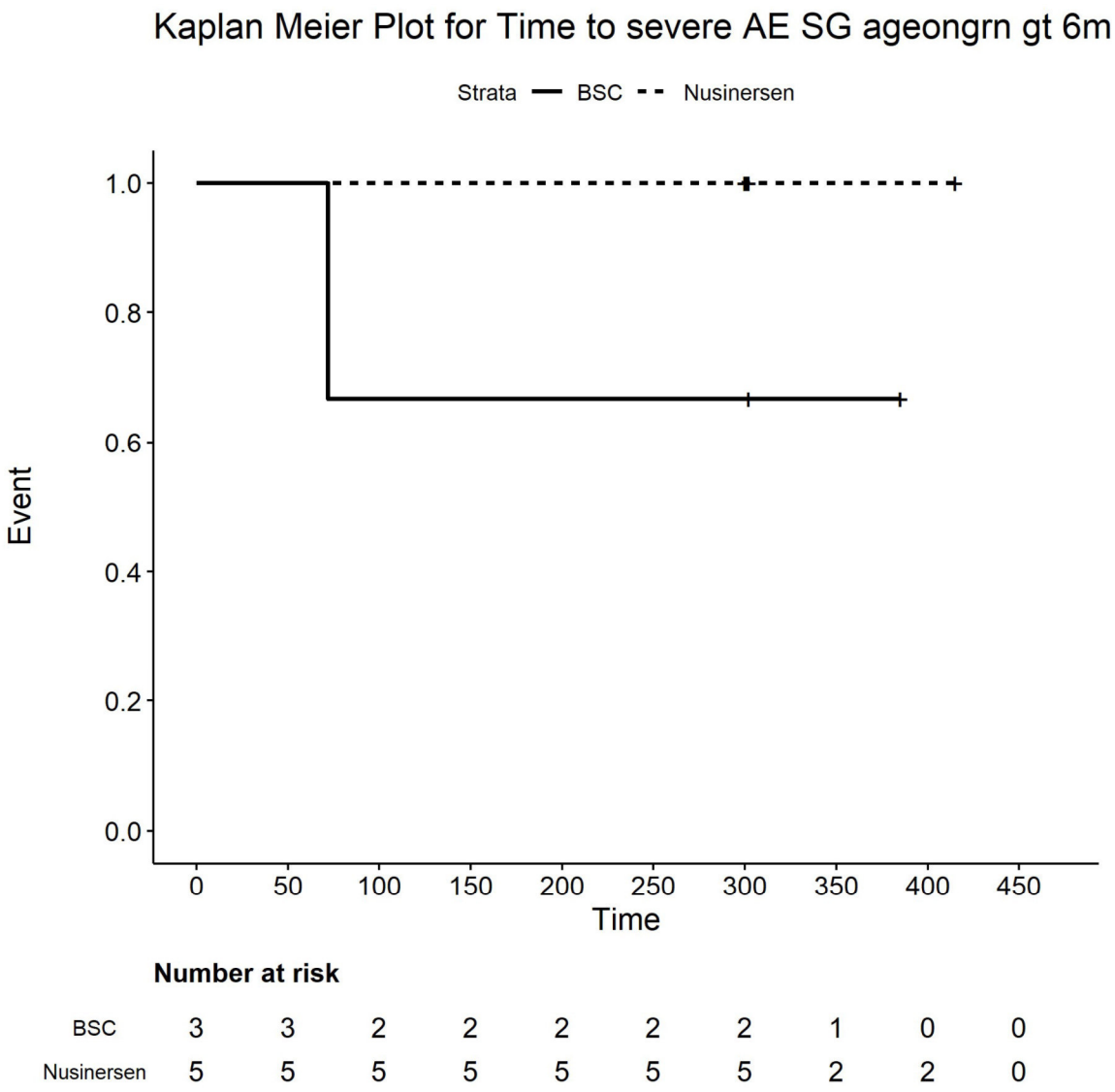
Number at risk

BSC	4	3	3	3	2	2	2	2	0	0
Nusinersen	6	5	5	5	4	4	3	1	1	0



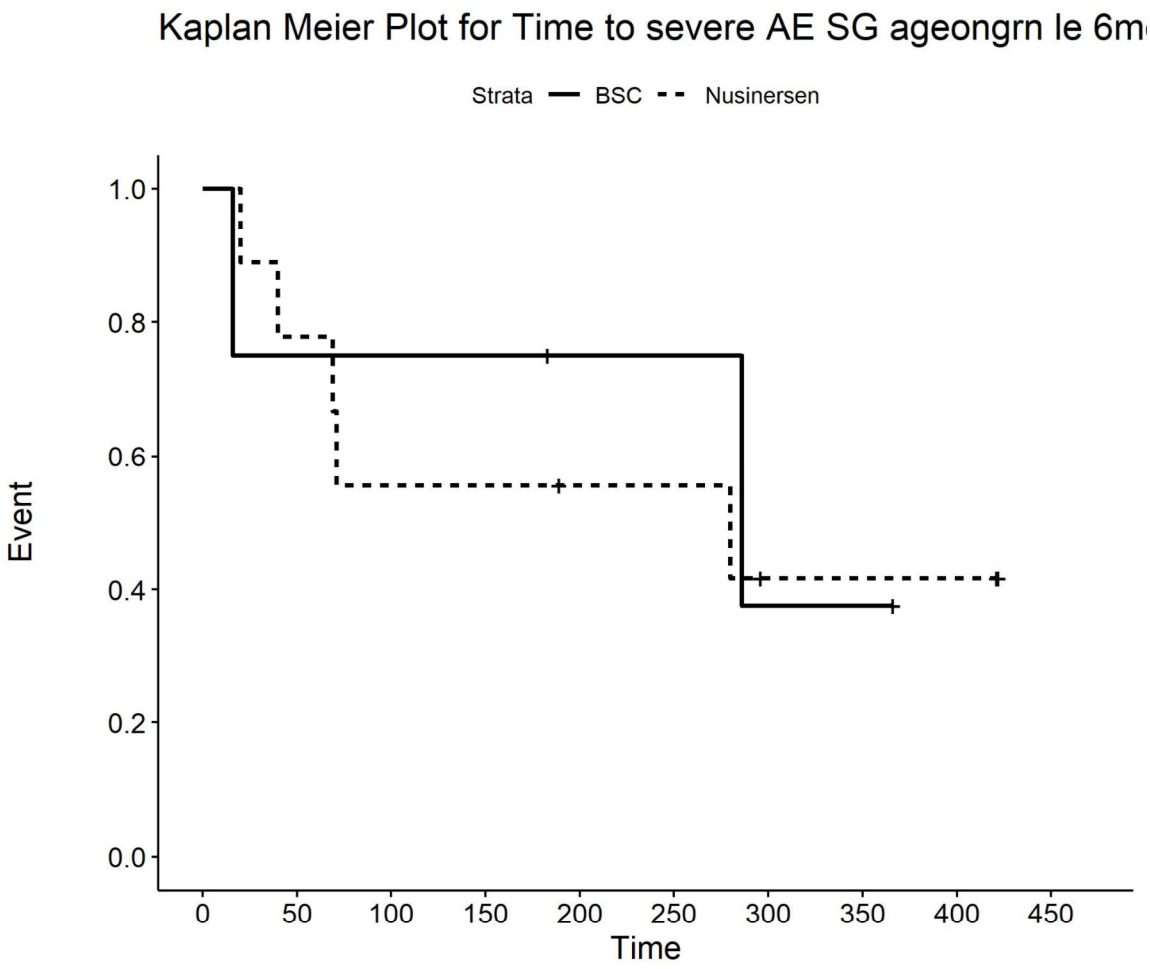
Number at risk

BSC	3	3	2	2	2	2	1	0	0	0
Nusinersen	8	7	5	5	5	5	4	3	3	0



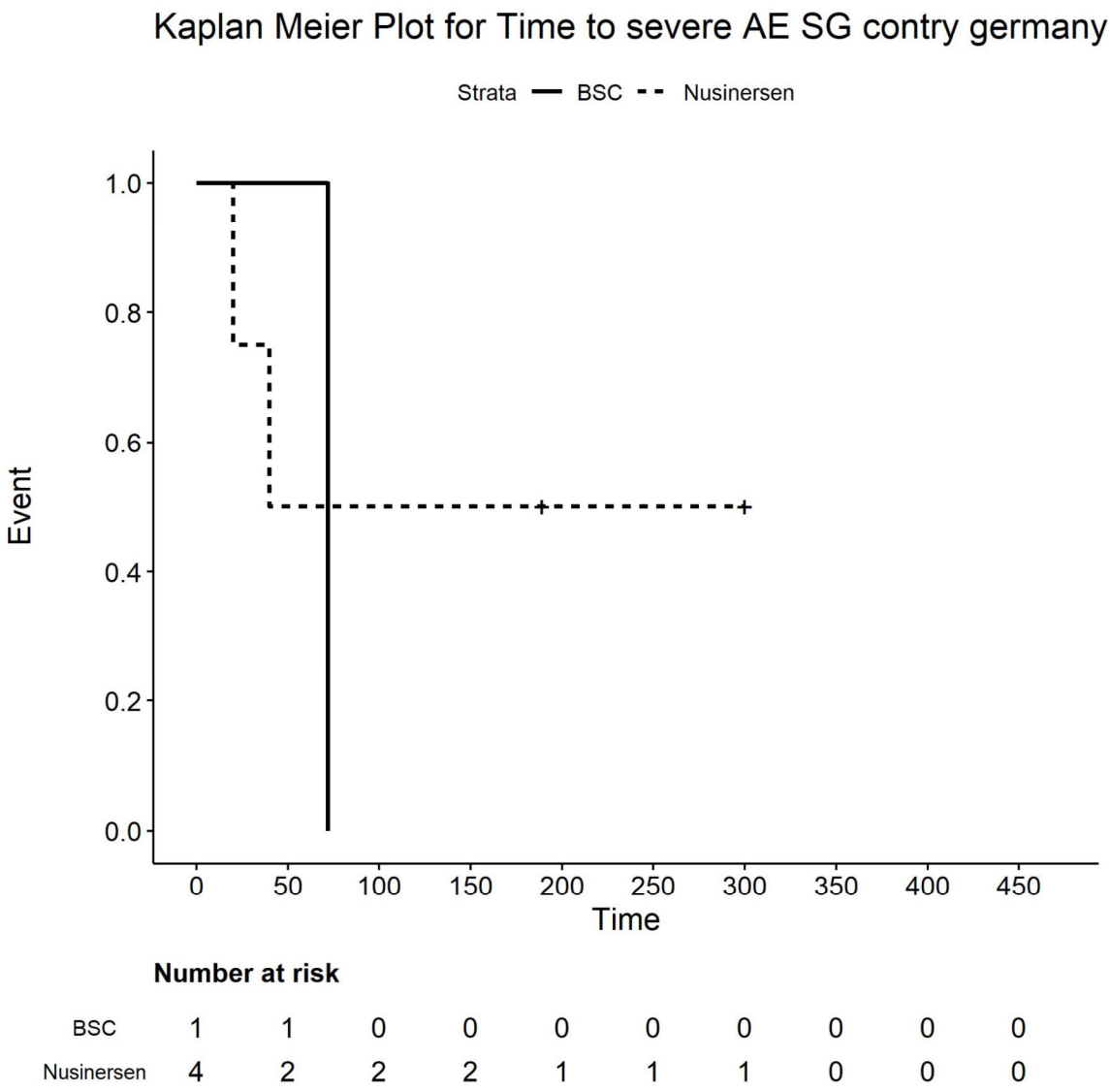
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



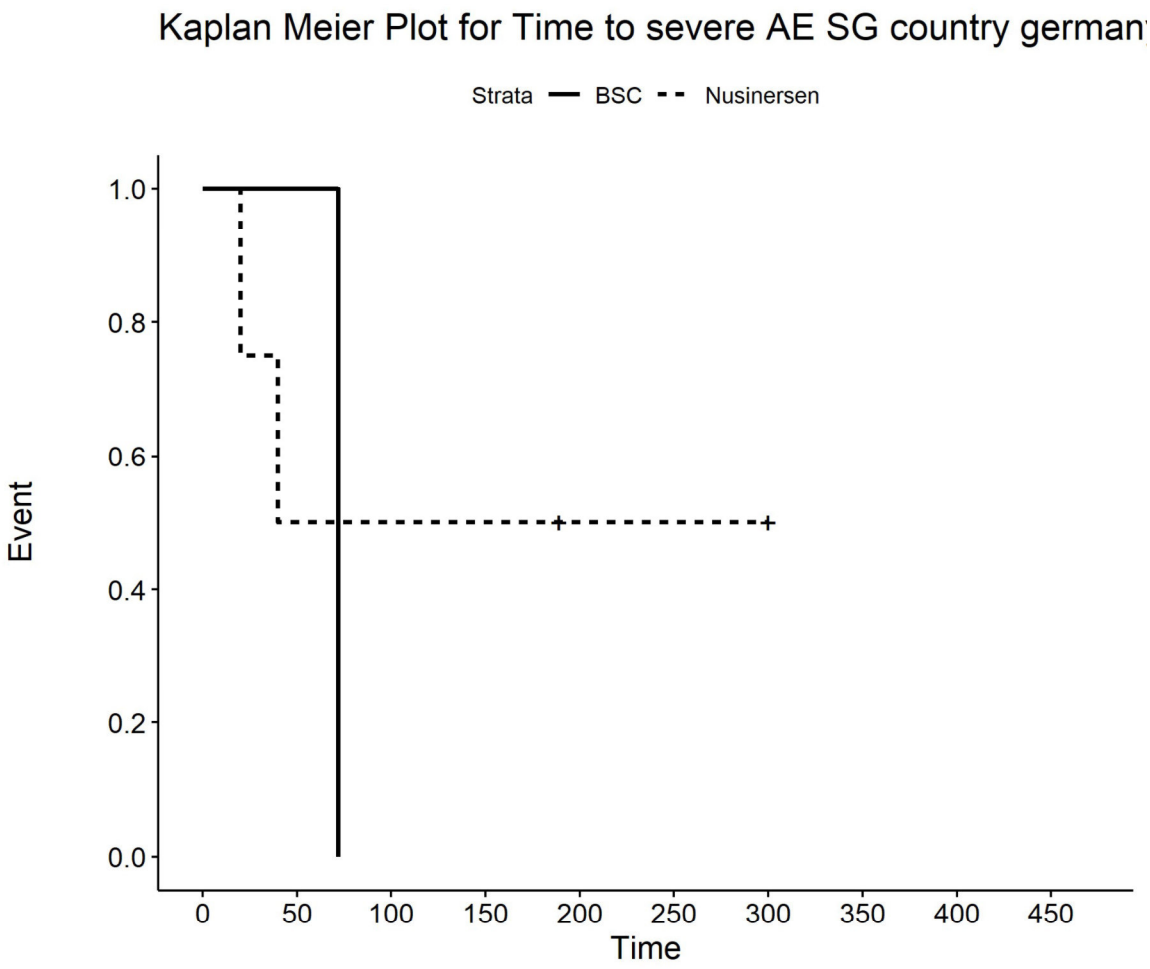
Number at risk

BSC	4	3	3	3	2	2	1	1	0	0
Nusinersen	9	7	5	5	4	4	2	2	2	0



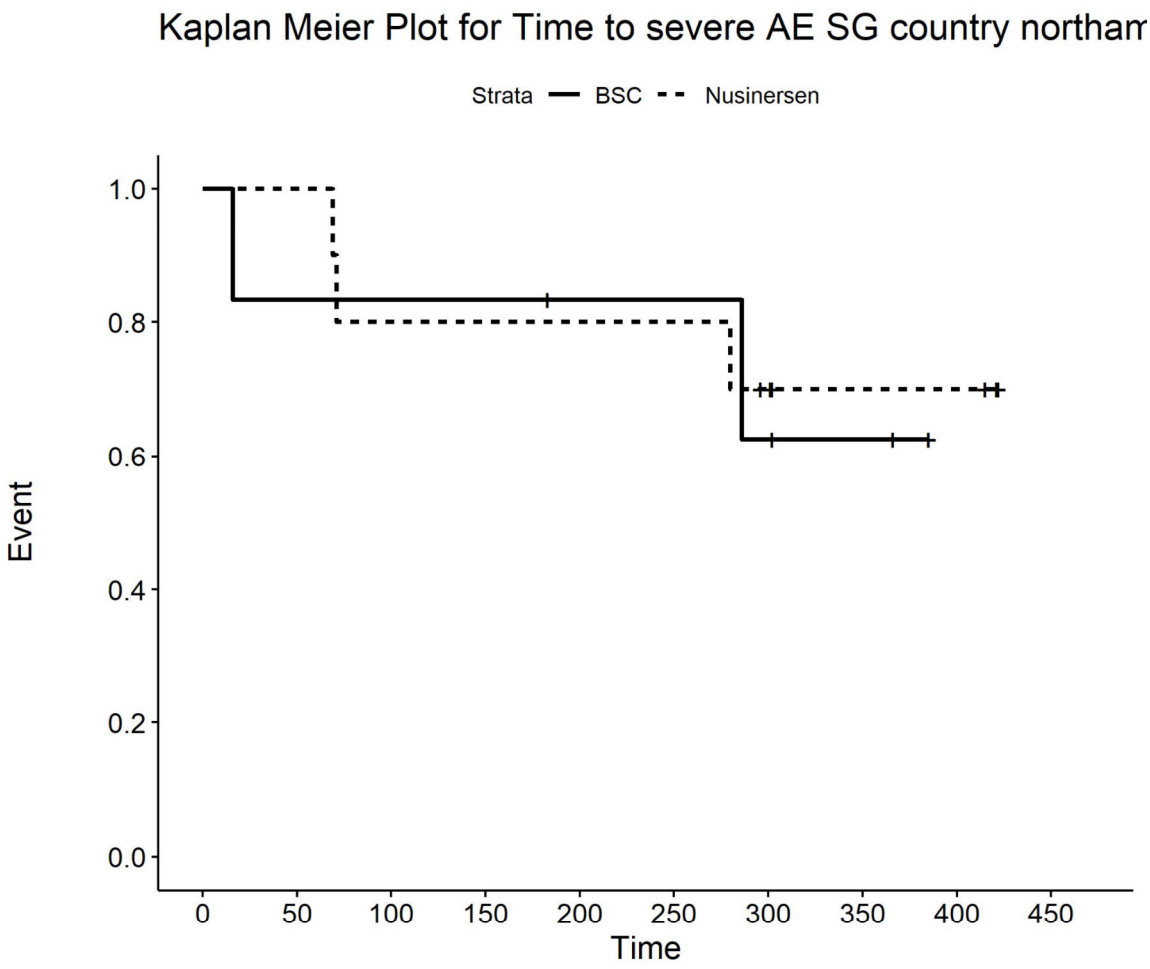
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	2	2	2	1	1	1	0	0	0



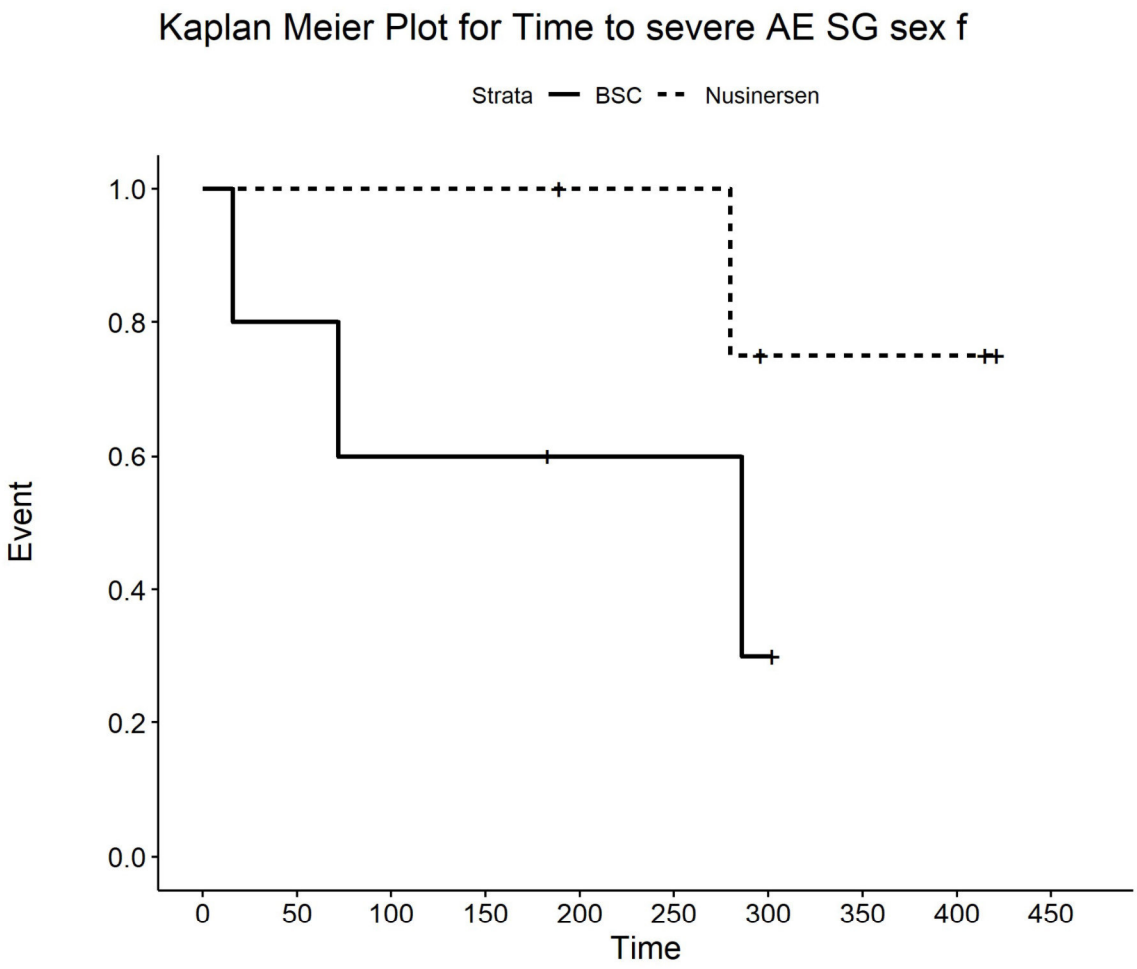
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	2	2	2	1	1	1	0	0	0



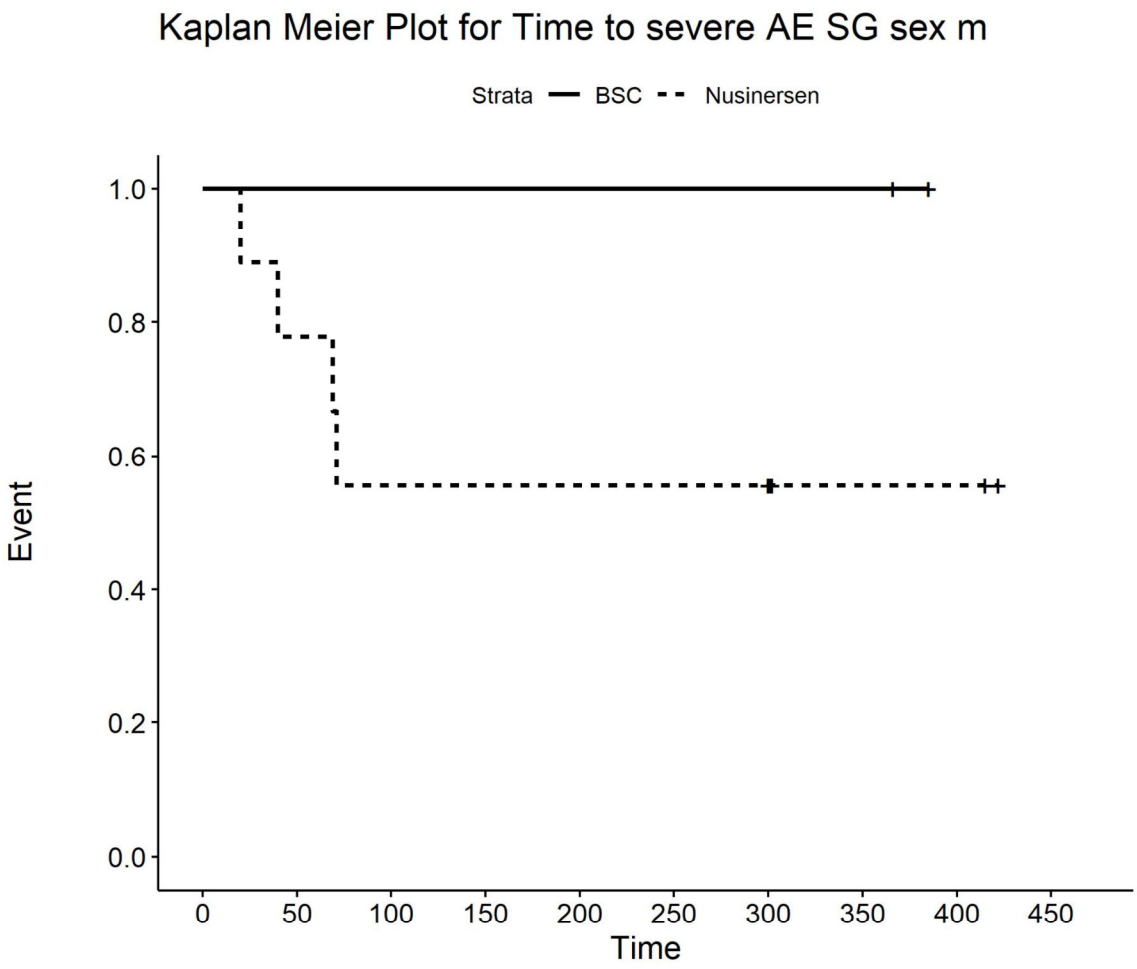
Number at risk

BSC	6	5	5	5	4	4	3	2	0	0
Nusinersen	10	10	8	8	8	8	6	4	4	0



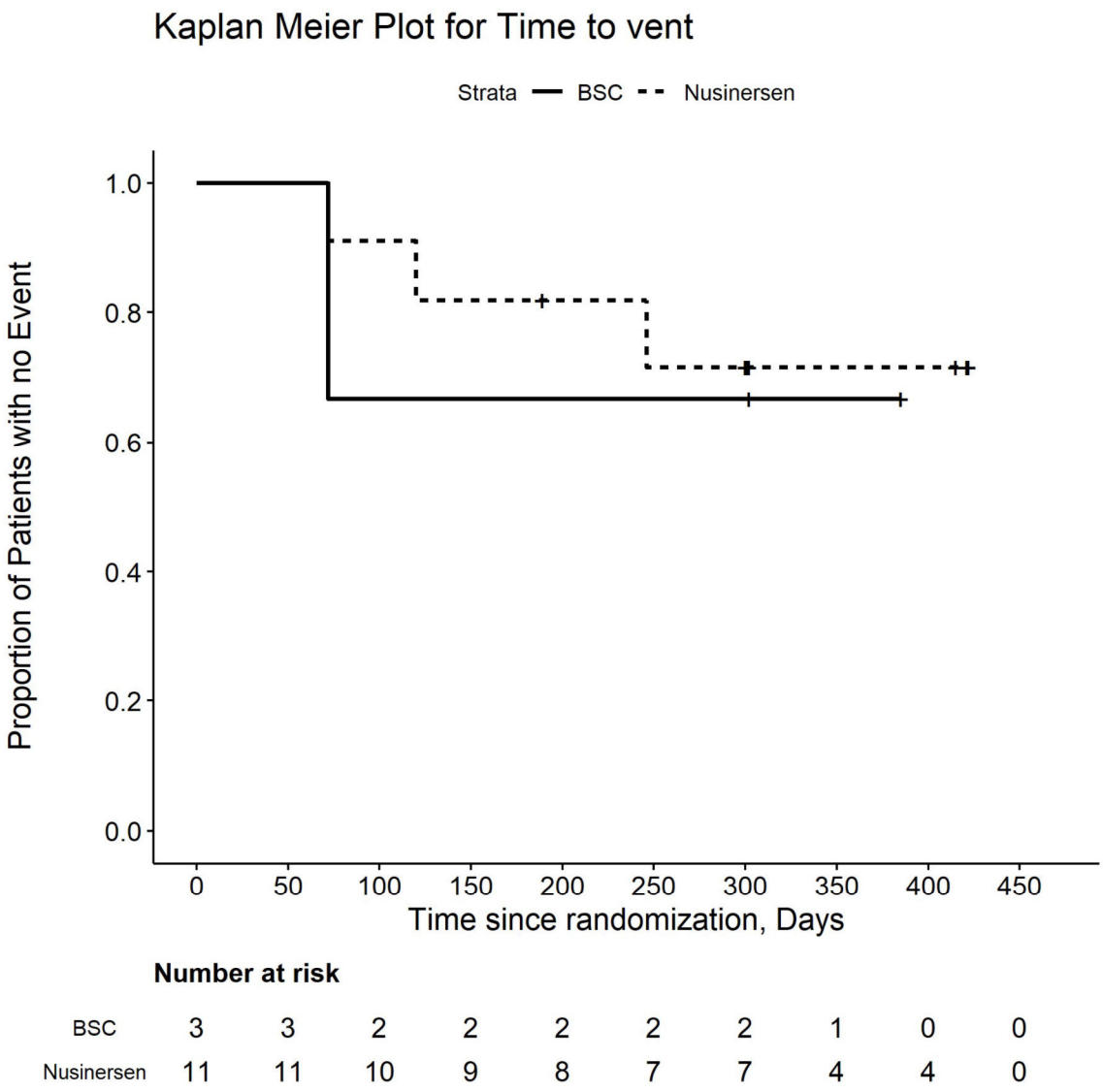
Number at risk

BSC	5	4	3	3	2	2	1	0	0	0
Nusinersen	5	5	5	5	4	4	2	2	2	0



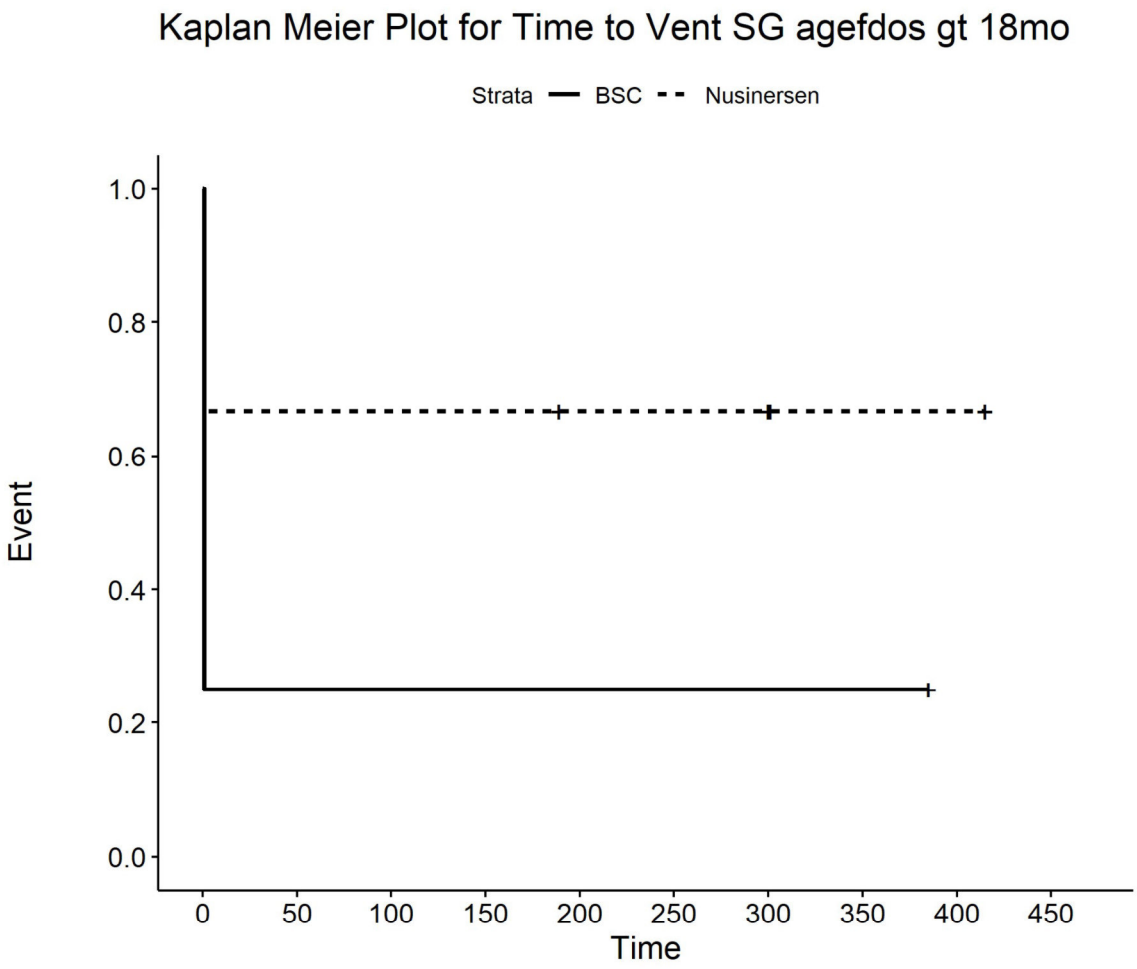
Number at risk

BSC	2	2	2	2	2	2	2	2	0	0
Nusinersen	9	7	5	5	5	5	5	2	2	0



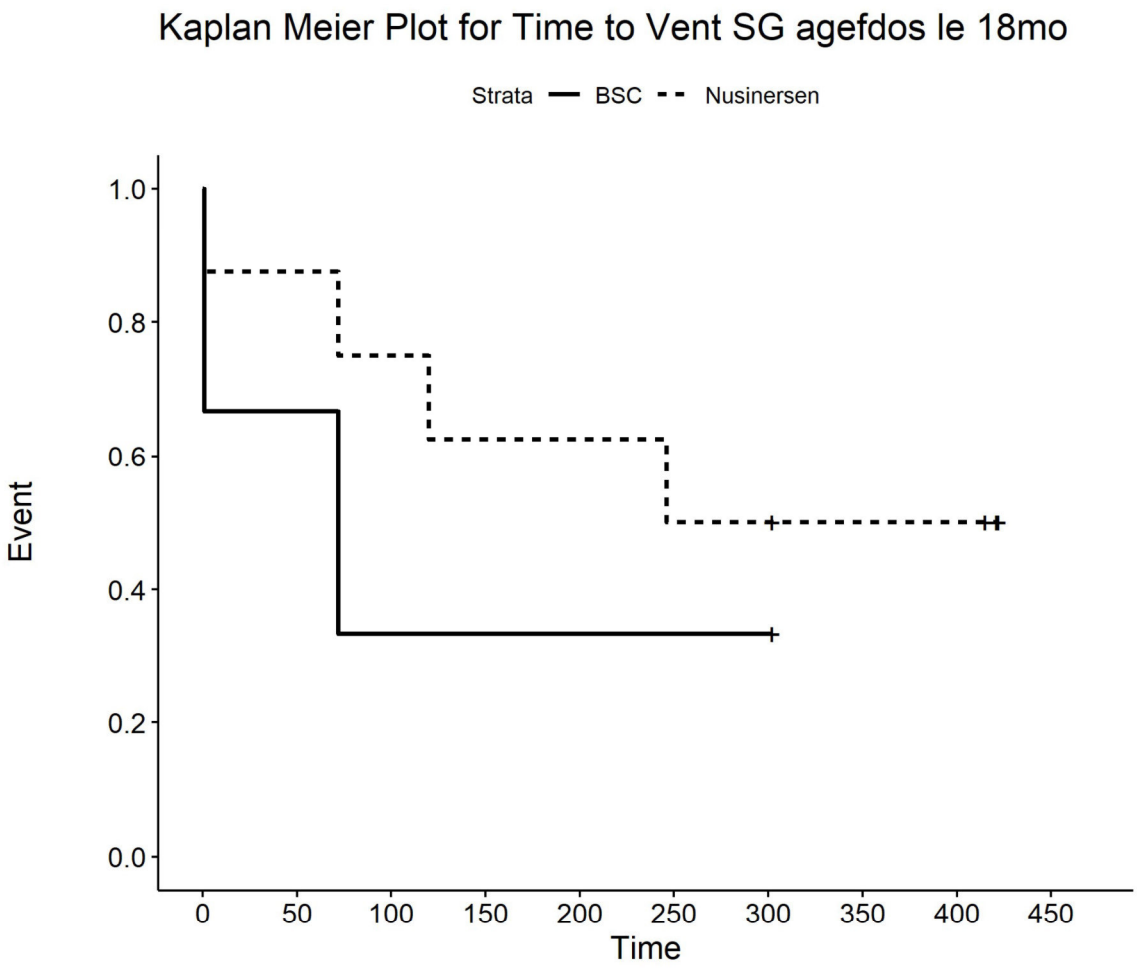
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	11	11	10	9	8	7	7	4	4	0



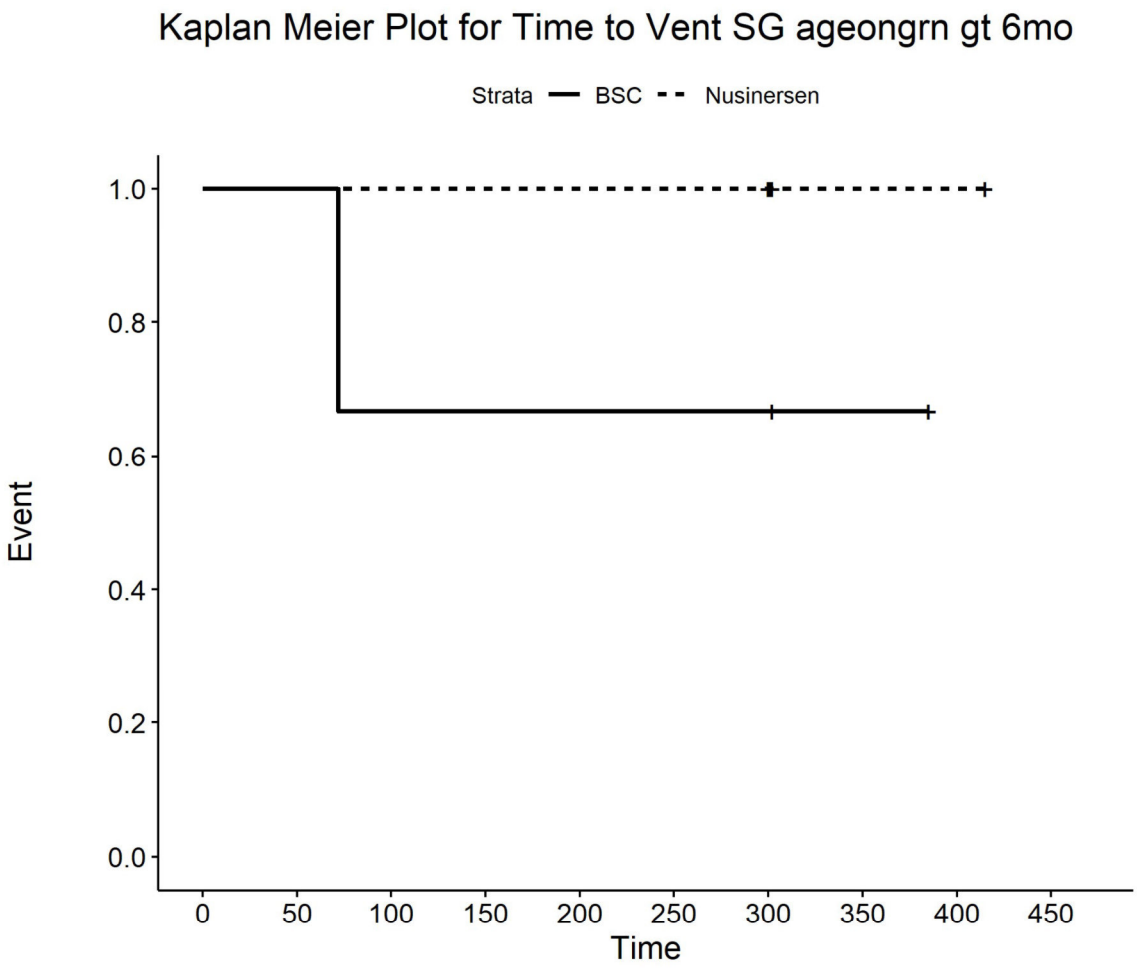
Number at risk

BSC	4	1	1	1	1	1	1	1	0	0
Nusinersen	6	4	4	4	3	3	3	1	1	0



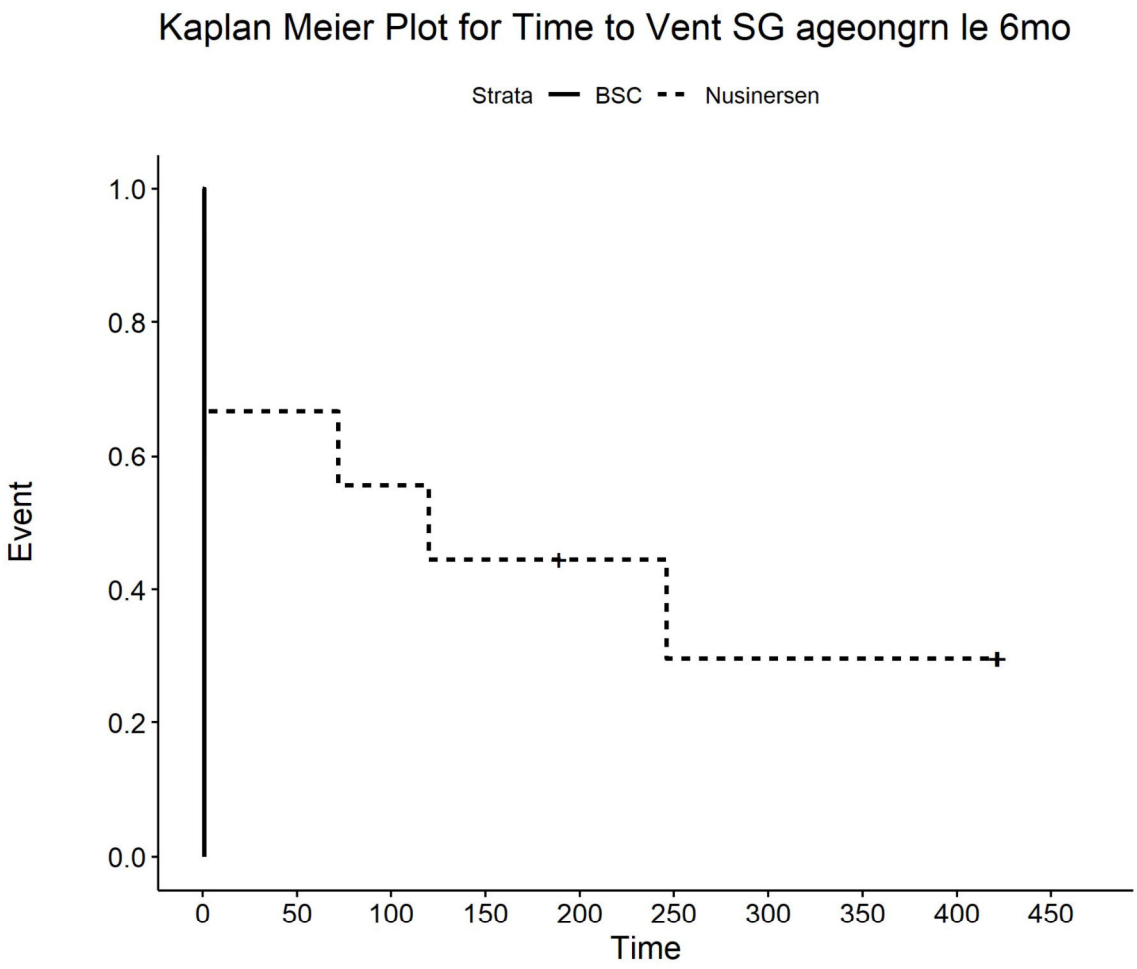
Number at risk

BSC	3	2	1	1	1	1	1	0	0	0
Nusinersen	8	7	6	5	5	4	4	3	3	0



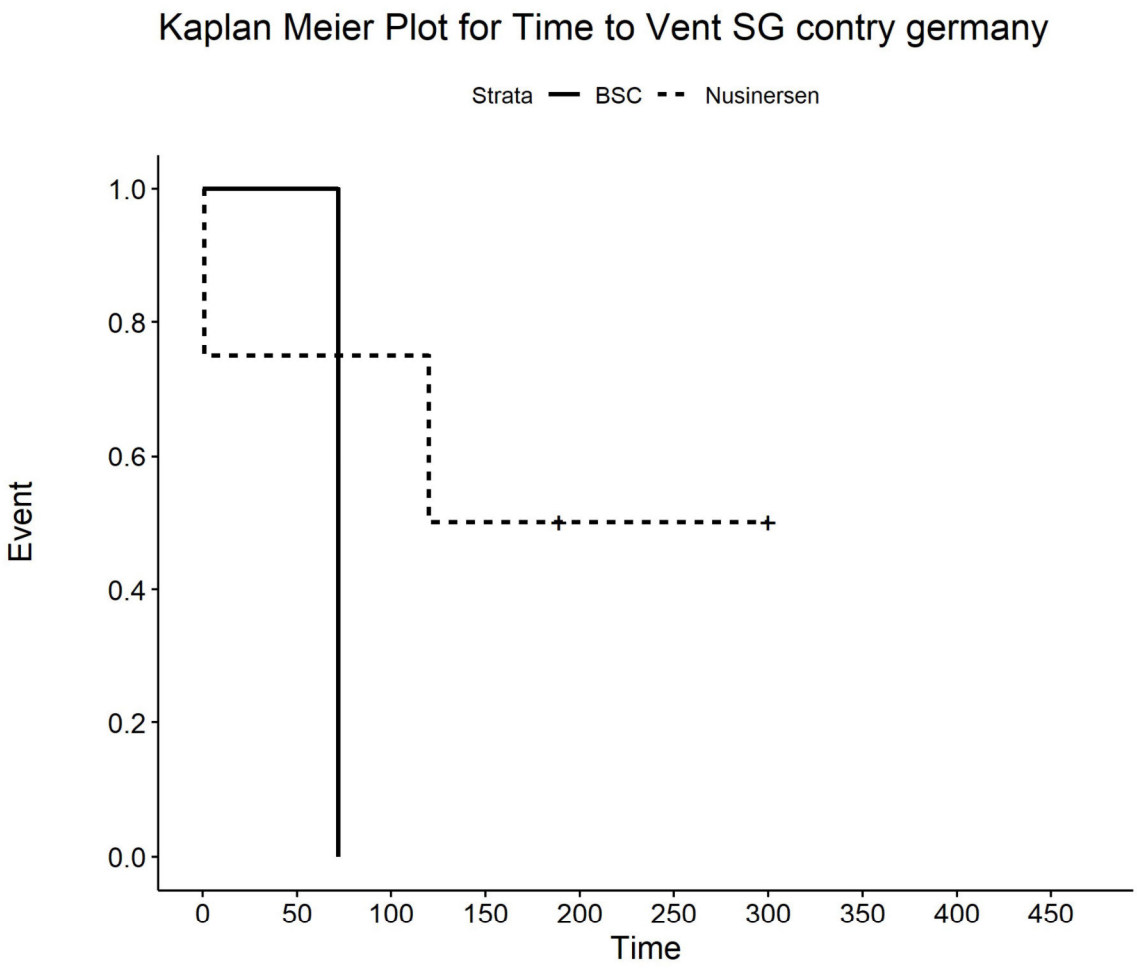
Number at risk

BSC	3	3	2	2	2	2	2	1	0	0
Nusinersen	5	5	5	5	5	5	5	2	2	0



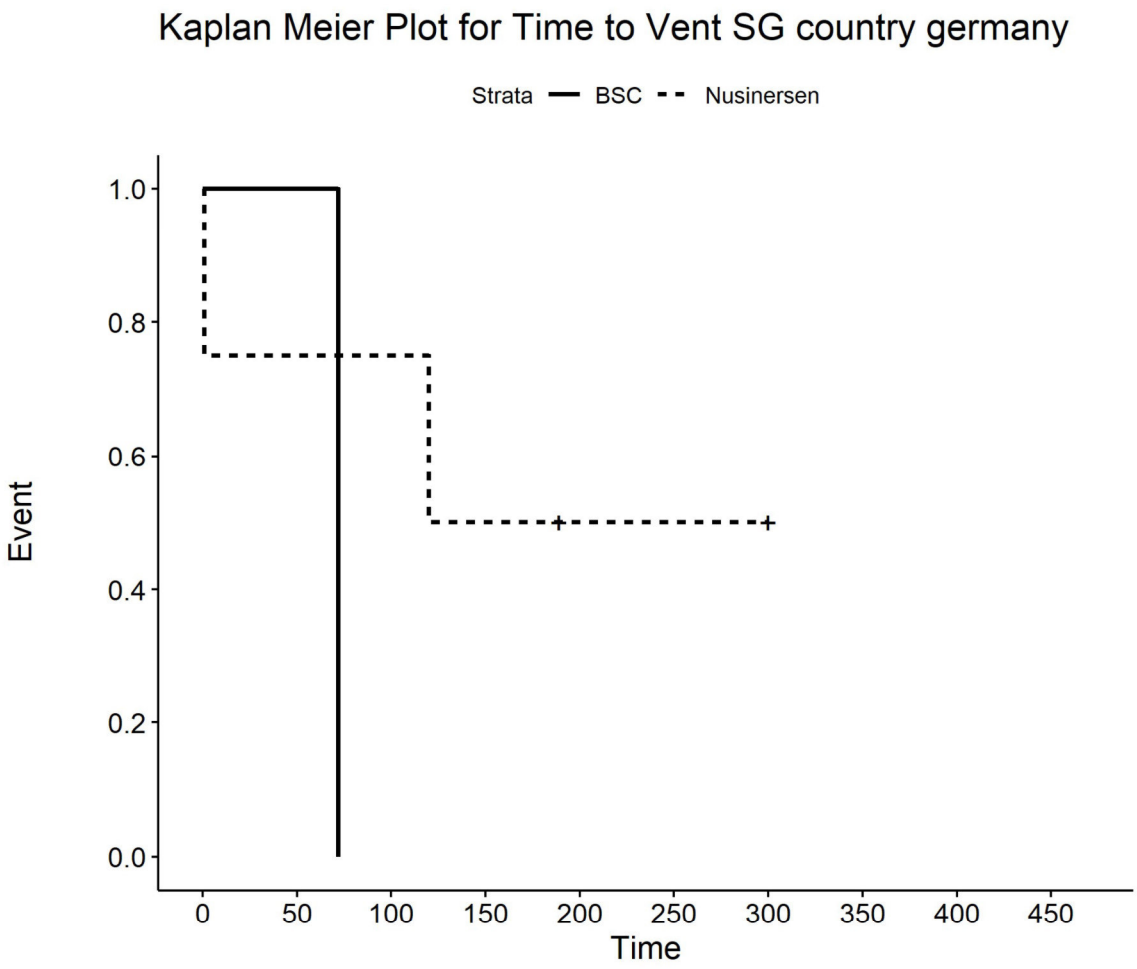
Number at risk

BSC	4	0	0	0	0	0	0	0	0	0
Nusinersen	9	6	5	4	3	2	2	2	2	0



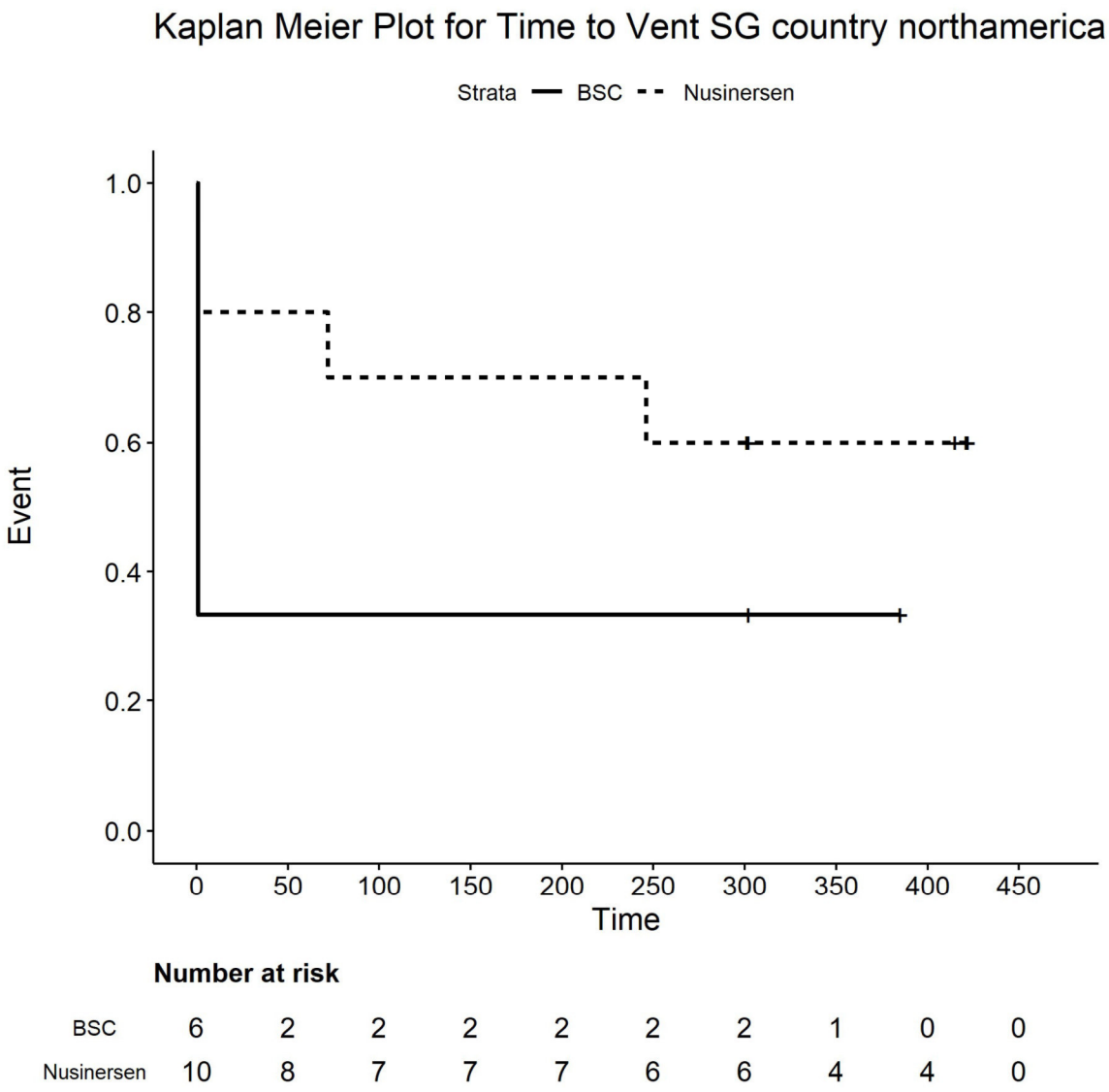
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



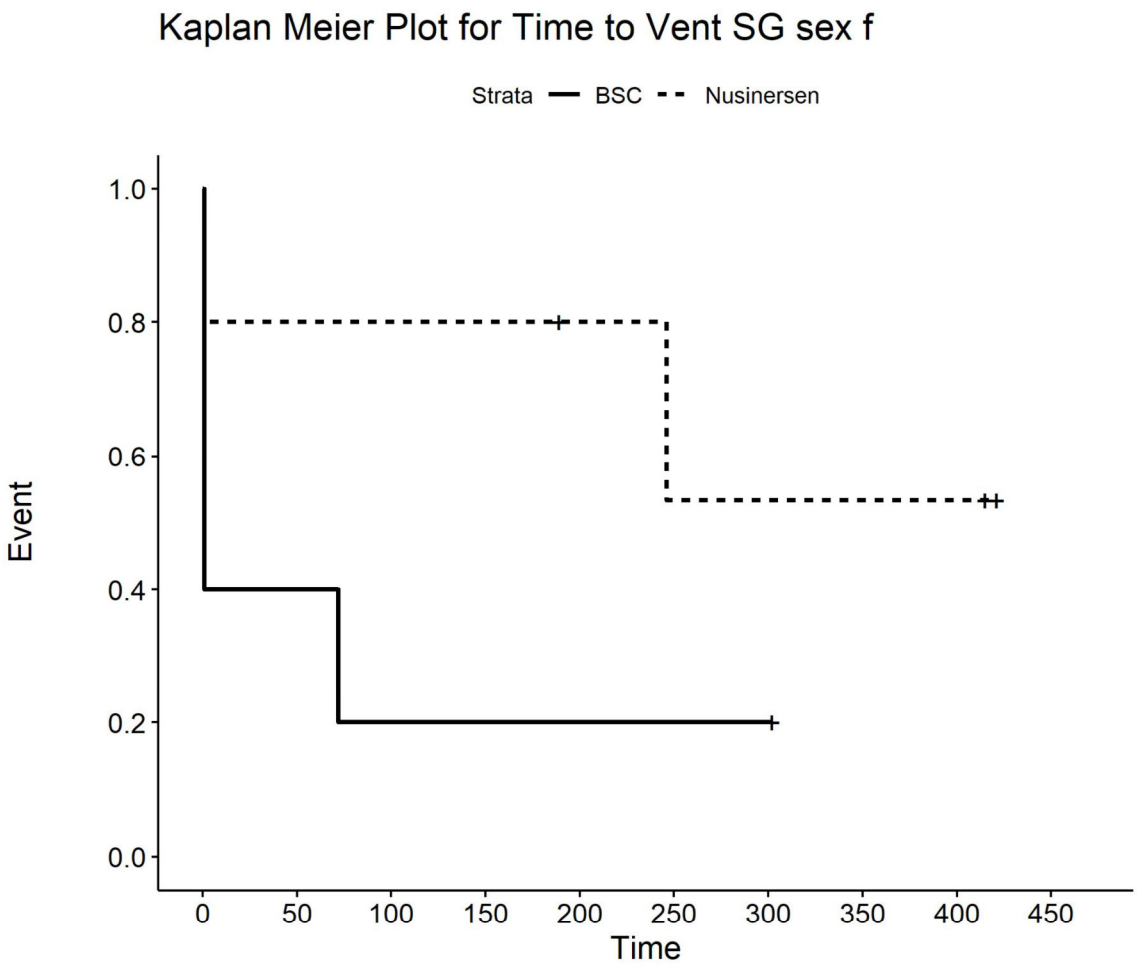
Number at risk

BSC	1	1	0	0	0	0	0	0	0	0
Nusinersen	4	3	3	2	1	1	1	0	0	0



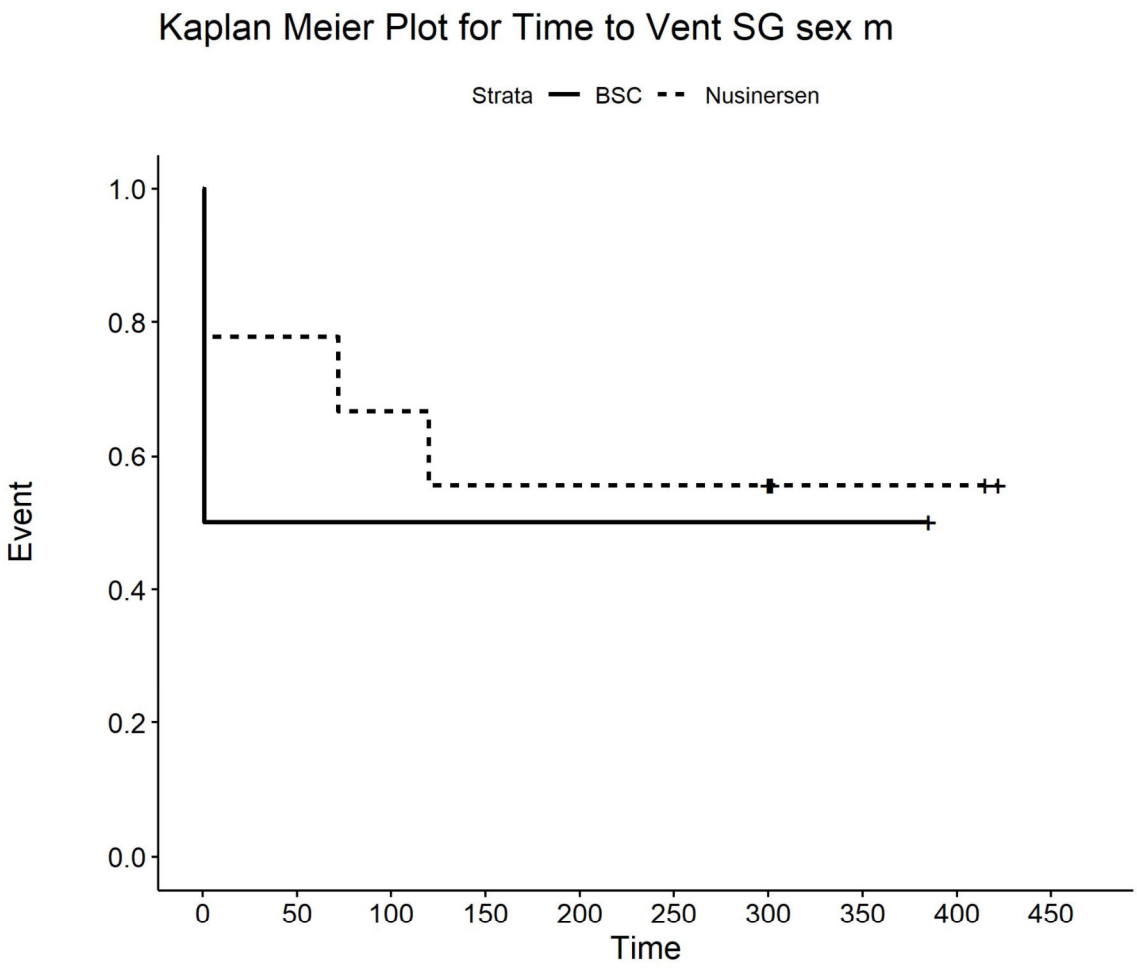
Number at risk

BSC	6	2	2	2	2	2	2	1	0	0
Nusinersen	10	8	7	7	7	6	6	4	4	0



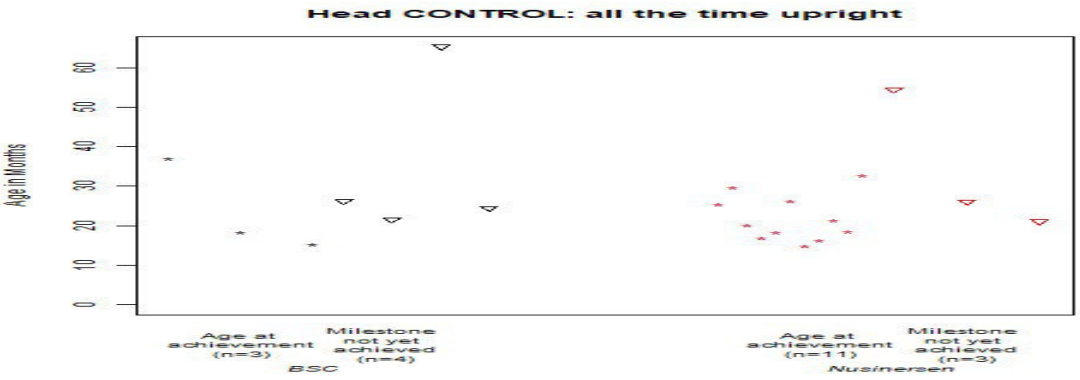
Number at risk

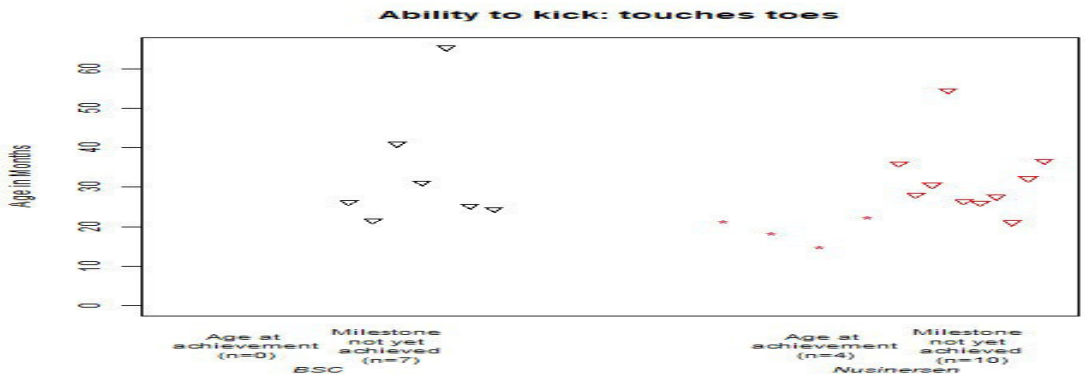
BSC	5	2	1	1	1	1	1	0	0	0
Nusinersen	5	4	4	4	3	2	2	2	2	0

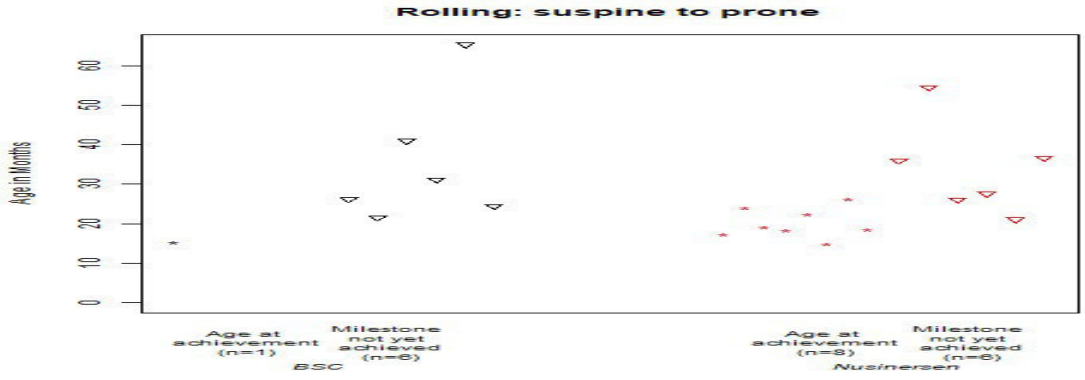


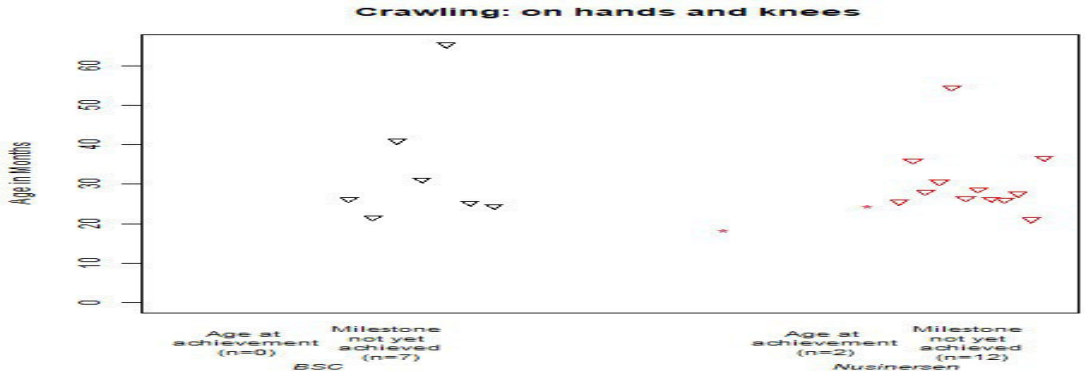
Number at risk

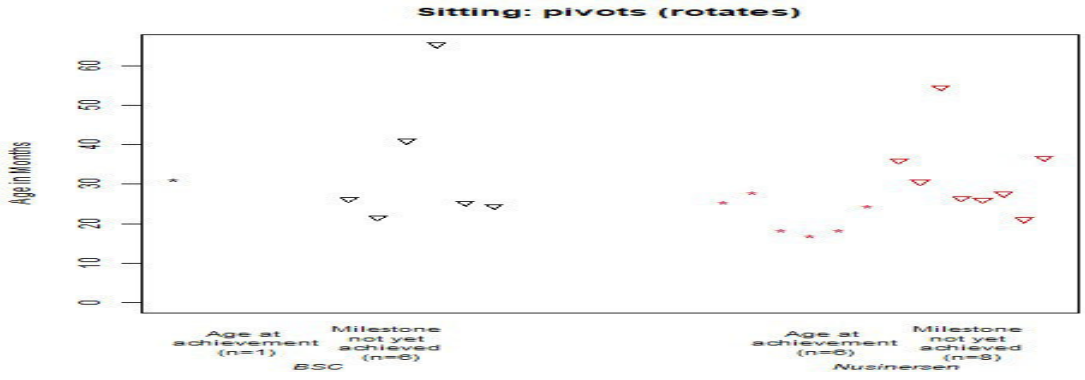
BSC	2	1	1	1	1	1	1	1	0	0
Nusinersen	9	7	6	5	5	5	5	2	2	0

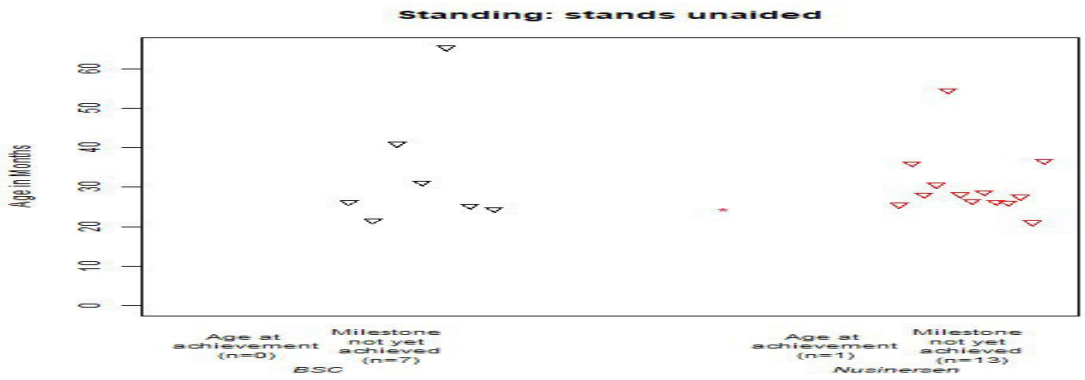


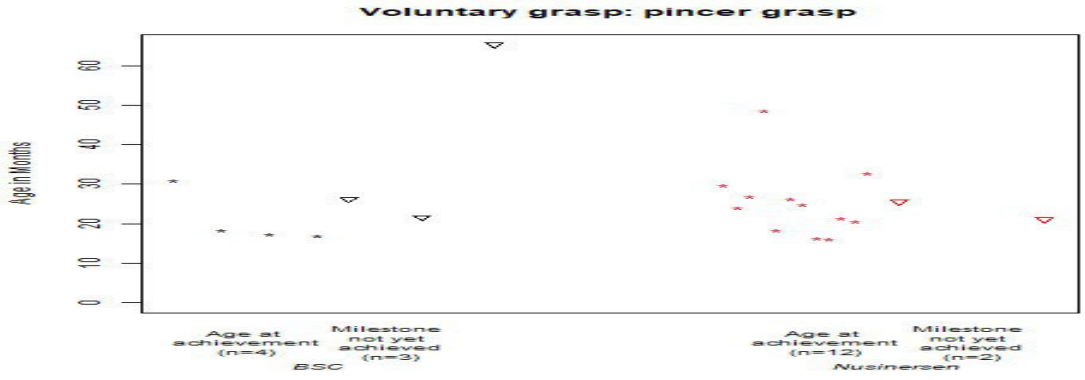

Ability to kick: touches toes
Age in Months
0
10
20
30
40
50
60
Age at achievement (n=0)
Milestone not yet achieved (n=7)
BSC
Age at achievement (n=4)
Milestone not yet achieved (n=10)
Nusinersen


Rolling: suspine to prone
Age in Months
0
10
20
30
40
50
60
Age at achievement (n=1)
Milestone not yet achieved (n=6)
BSC
Age at achievement (n=8)
Milestone not yet achieved (n=6)
Nusinersen

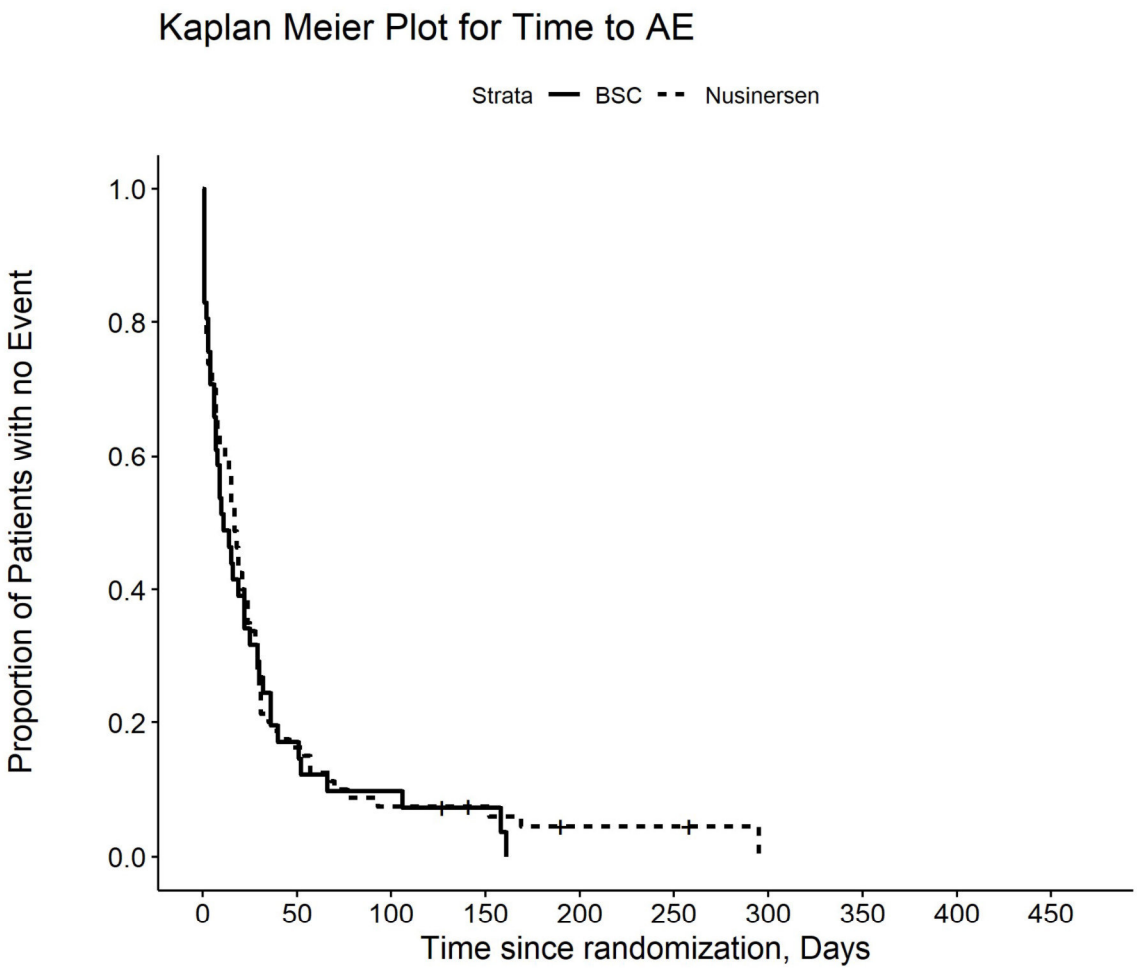

Crawling: on hands and knees
Age in Months
0
10
20
30
40
50
60
Age at achievement (n=0)
Milestone not yet achieved (n=7)
BSC
Age at achievement (n=2)
Milestone not yet achieved (n=12)
Nusinersen


Sitting: pivots (rotates)
Age in Months
0
10
20
30
40
50
60
Age at achievement (n=1)
Milestone not yet achieved (n=6)
BSC
Age at achievement (n=6)
Milestone not yet achieved (n=8)
Nusinersen


Standing: stands unaided
Age in Months
0
10
20
30
40
50
60
Age at achievement (n=0)
Milestone not yet achieved (n=7)
BSC
Age at achievement (n=1)
Milestone not yet achieved (n=13)
Nusinersen


Voluntary grasp: pincer grasp
Age in Months
0
10
20
30
40
50
60
Age at achievement (n=4)
Milestone not yet achieved (n=3)
BSC
Age at achievement (n=12)
Milestone not yet achieved (n=2)
Nusinersen

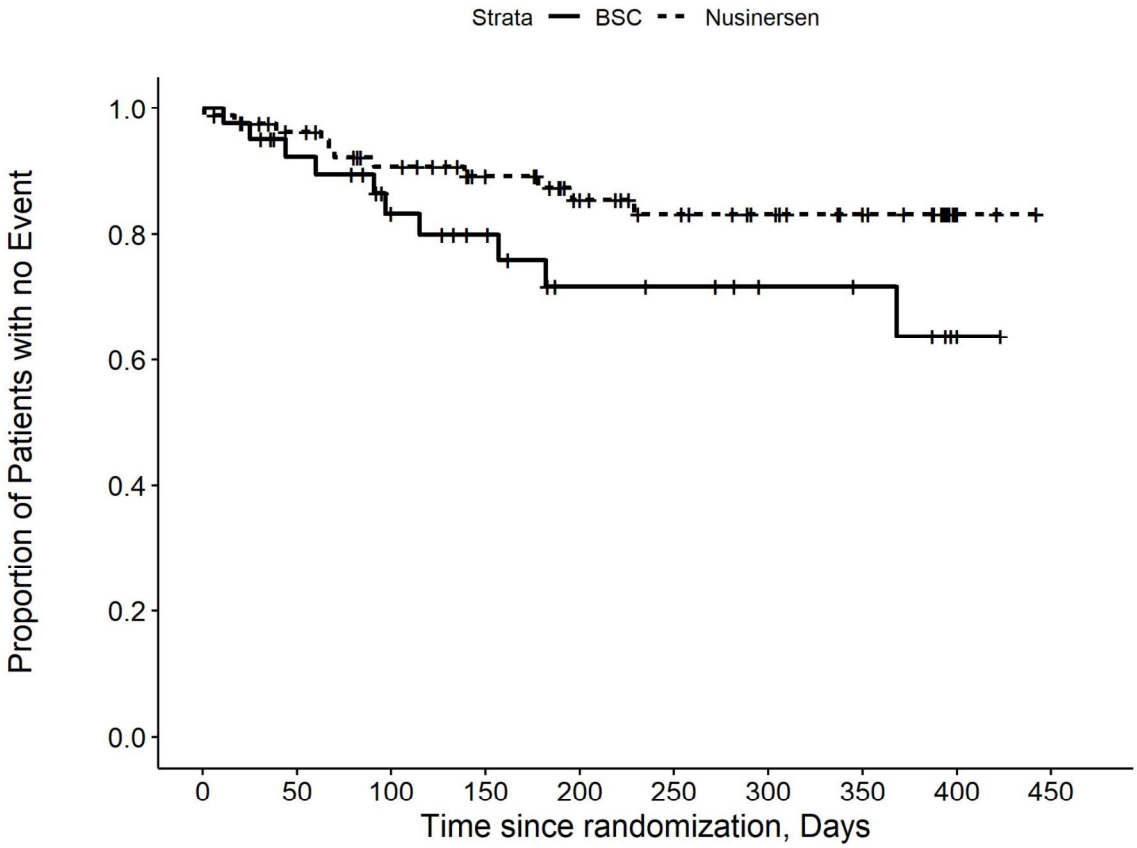

Walking: walking independently
Age in Months
0
10
20
30
40
50
60
Age at achievement (n=0)
Milestone not yet achieved (n=7)
BSC
Age at achievement (n=1)
Milestone not yet achieved (n=13)
Nusinersen



Number at risk

BSC	41	7	4	2	0	0	0	0	0	0
Nusinersen	80	13	6	5	2	2	0	0	0	0

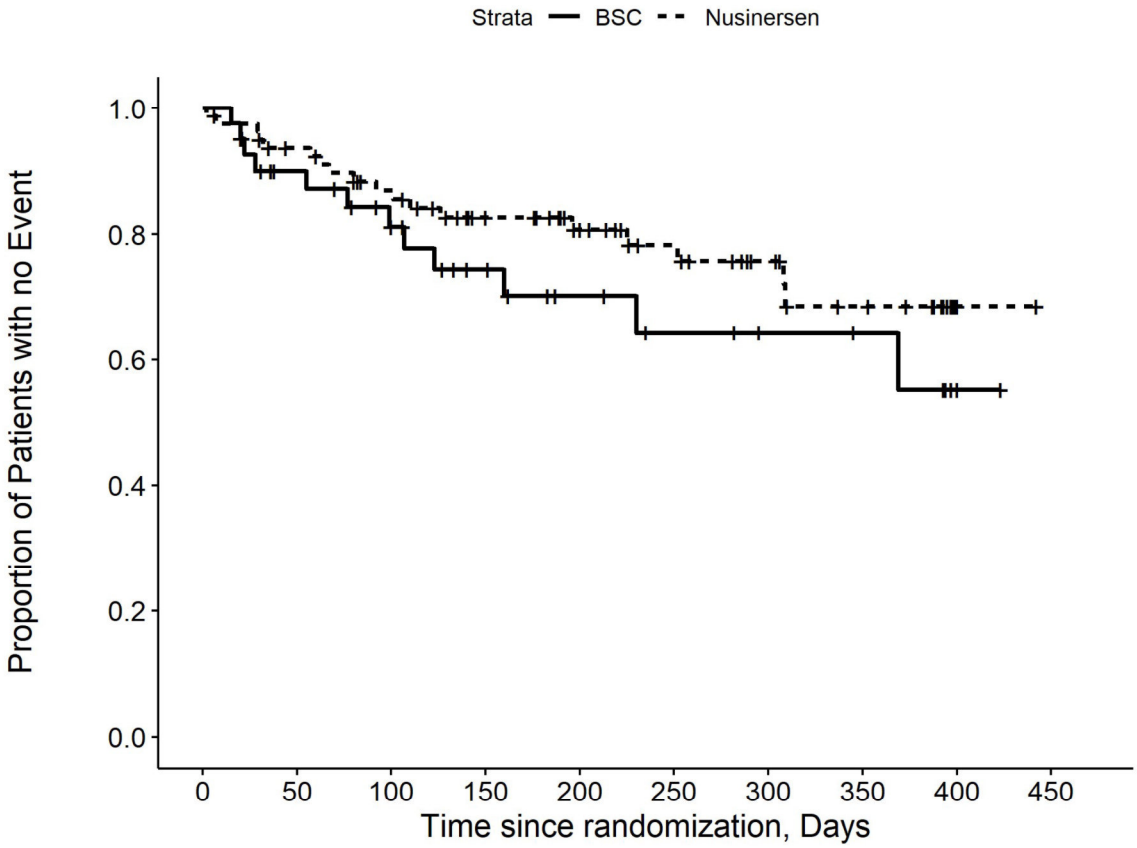
Kaplan Meier Plot for Time to AE by PT pct
Acute respiratory failure



Number at risk

BSC	41	33	26	21	14	13	10	9	3	0
Nusinersen	80	73	64	54	42	34	29	24	8	0

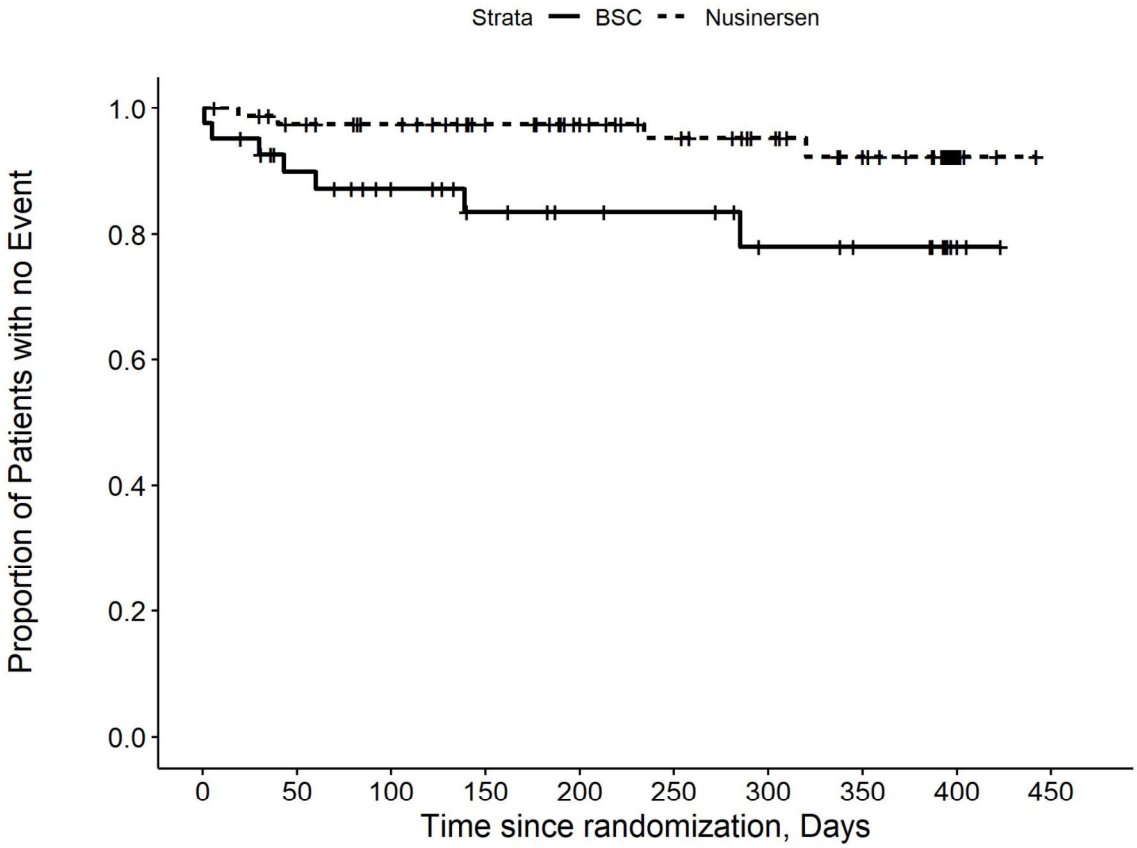
Kaplan Meier Plot for Time to AE by PT pct Atelectasis



Number at risk

BSC	41	32	26	19	13	10	8	7	2	0
Nusinersen	80	71	62	50	39	31	23	17	4	0

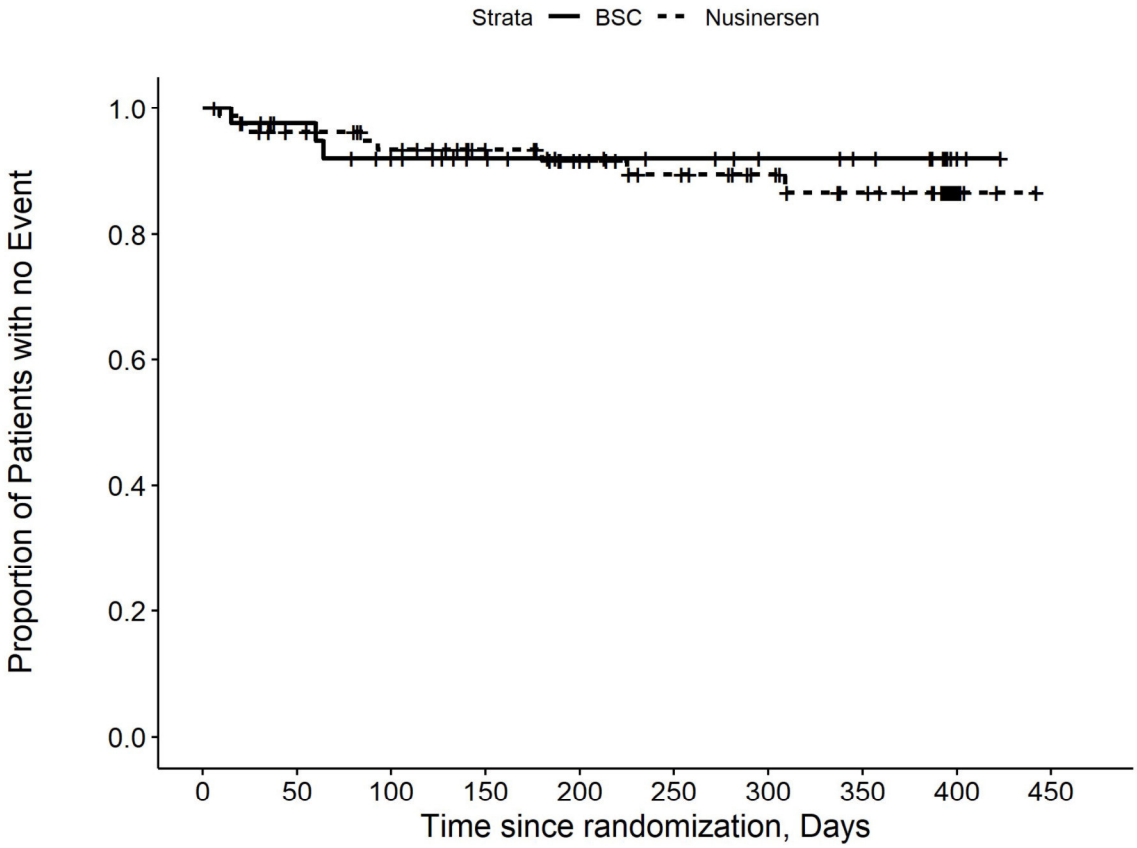
Kaplan Meier Plot for Time to AE by PT pct
Bronchial secretion retention



Number at risk

BSC	41	33	28	22	18	17	13	11	4	0
Nusinersen	80	74	69	60	50	42	35	29	10	0

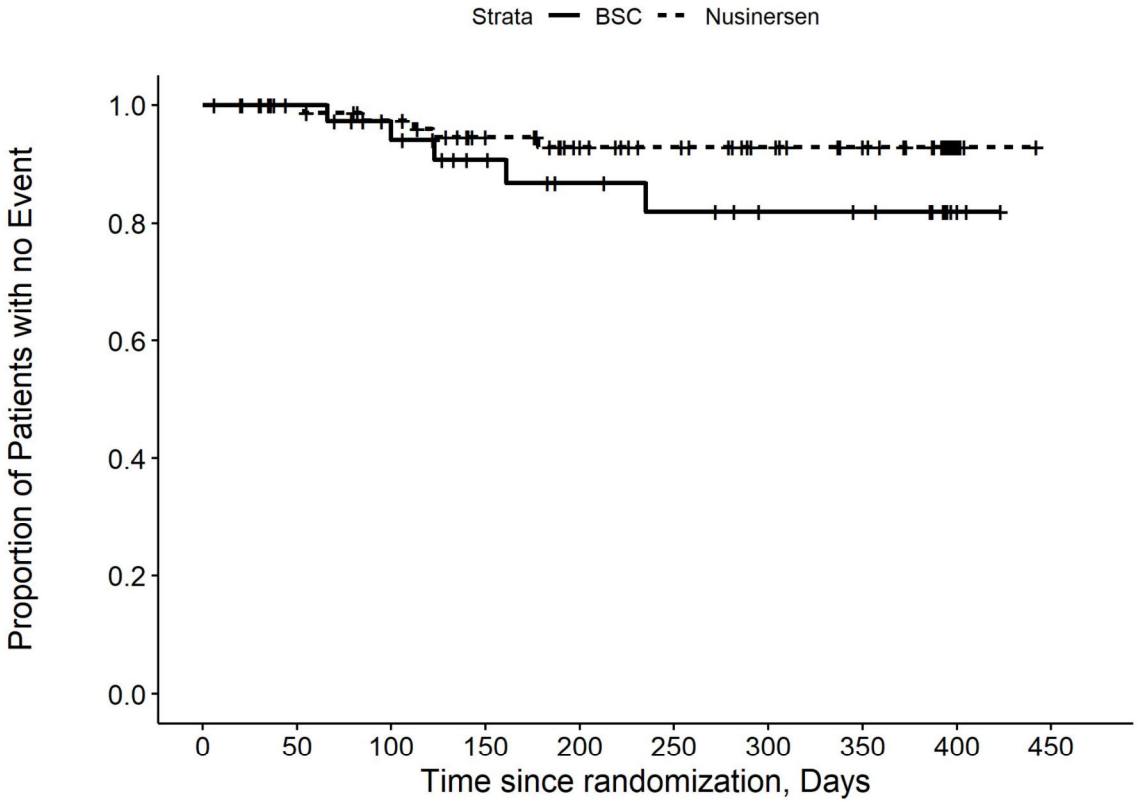
Kaplan Meier Plot for Time to AE by PT pct
Bronchiolitis



Number at risk

BSC	41	35	31	25	20	18	15	13	4	0
Nusinersen	80	73	66	57	47	40	33	27	10	0

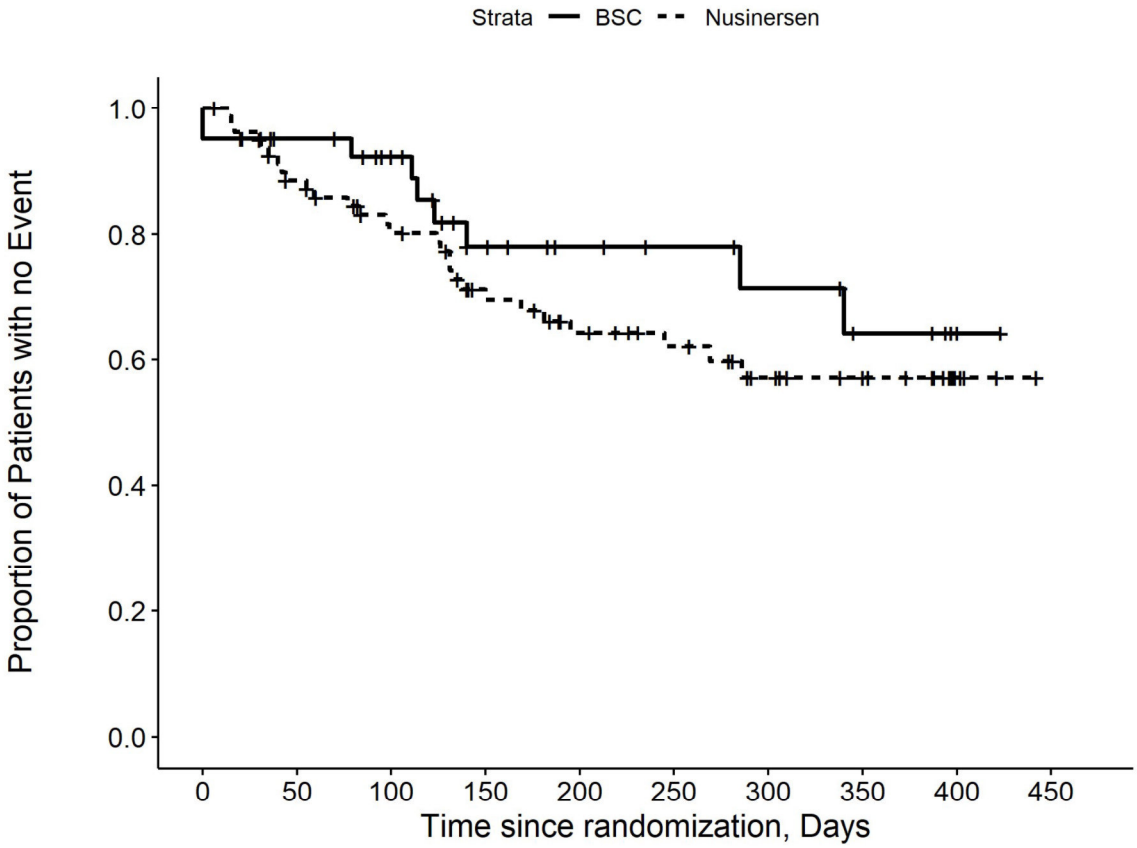
Kaplan Meier Plot for
Time to AE by PT pct
Cardio : respiratory arrest



Number at risk

BSC	41	36	31	24	19	17	14	13	4	0
Nusinersen	80	76	71	61	50	43	35	30	10	0

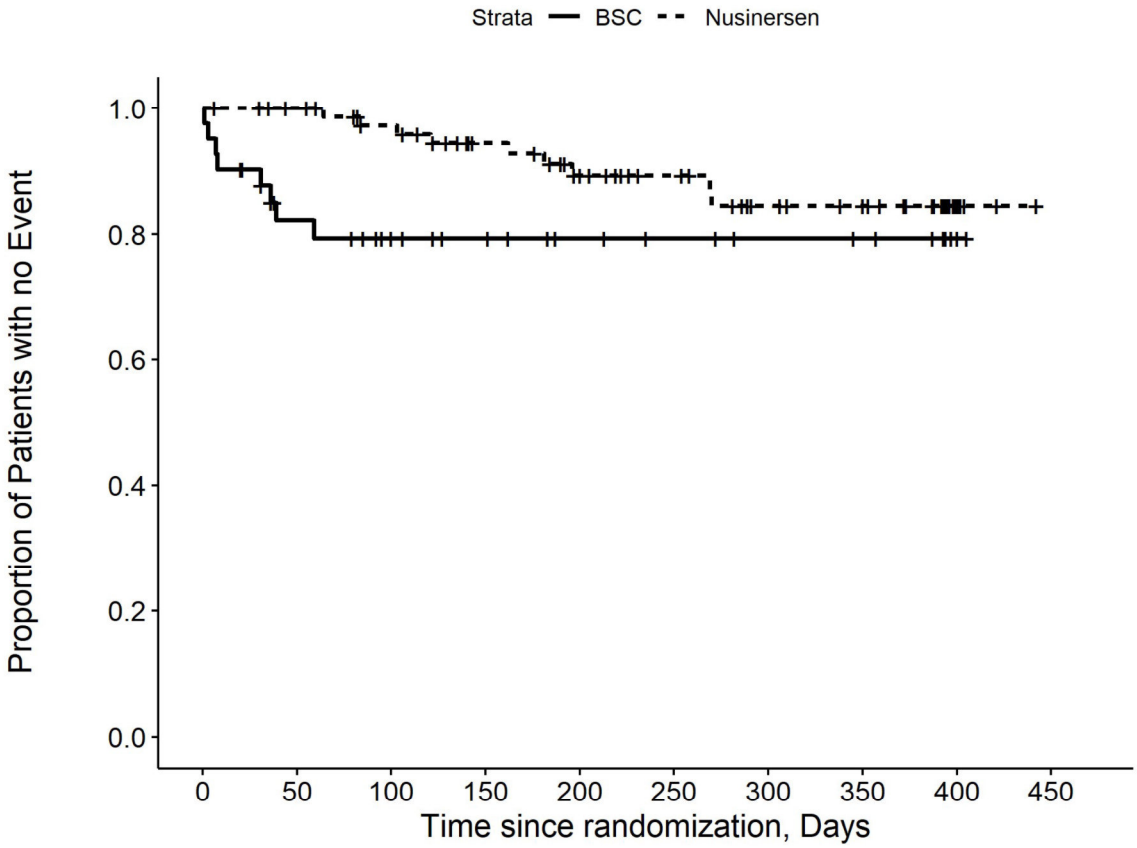
Kaplan Meier Plot for Time to AE by PT pct
Constipation



Number at risk

BSC	41	34	29	19	15	13	11	8	3	0
Nusinersen	80	67	56	43	34	28	20	16	4	0

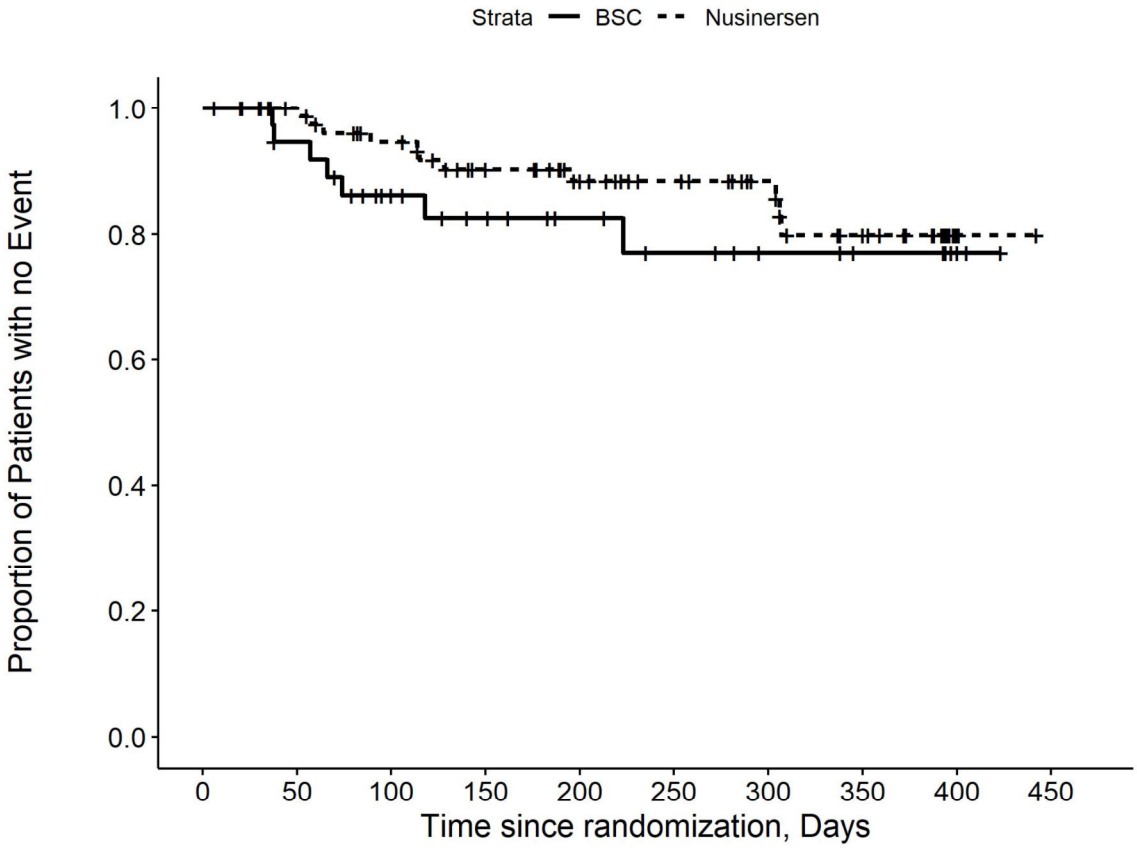
Kaplan Meier Plot for Time to AE by PT pct Cough



Number at risk

BSC	41	29	24	20	15	13	11	10	3	0
Nusinersen	80	76	69	58	48	40	31	28	11	0

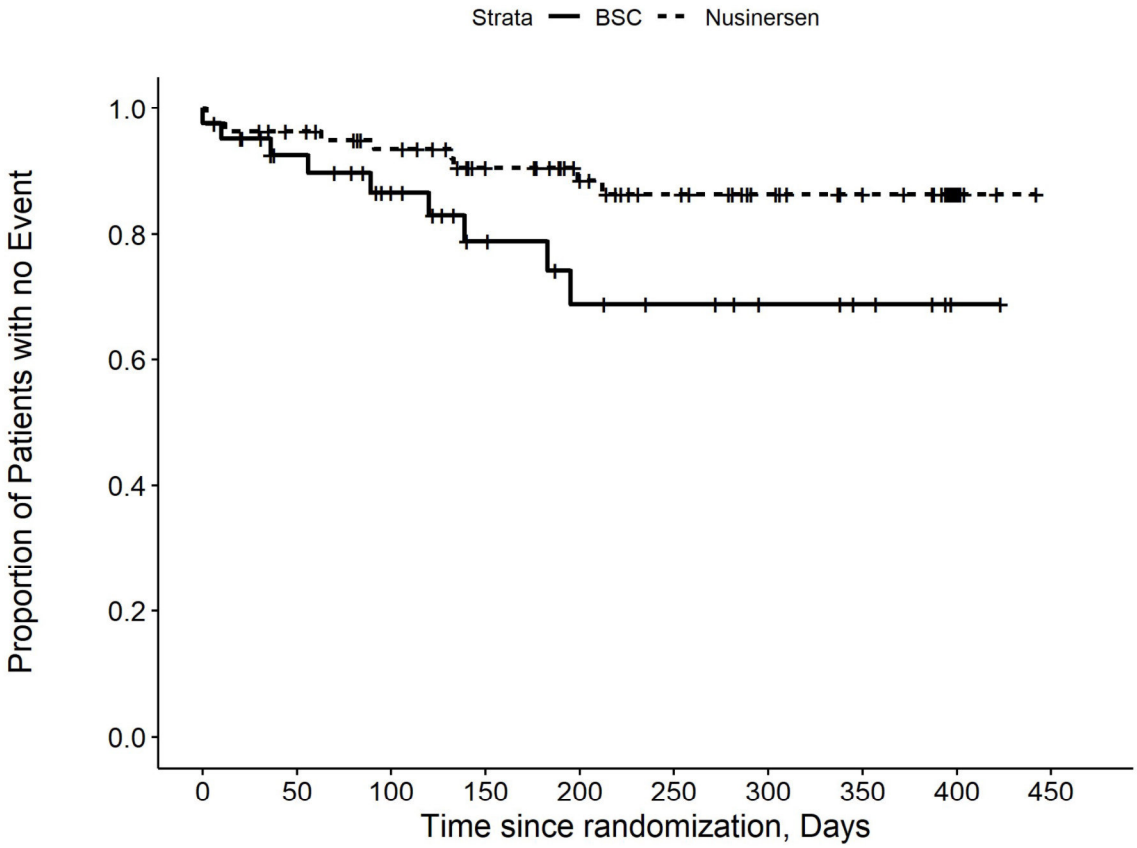
Kaplan Meier Plot for Time to AE by PT pct Diarrhoea



Number at risk

BSC	41	34	26	21	16	13	10	8	4	0
Nusinersen	80	76	67	57	47	39	32	24	6	0

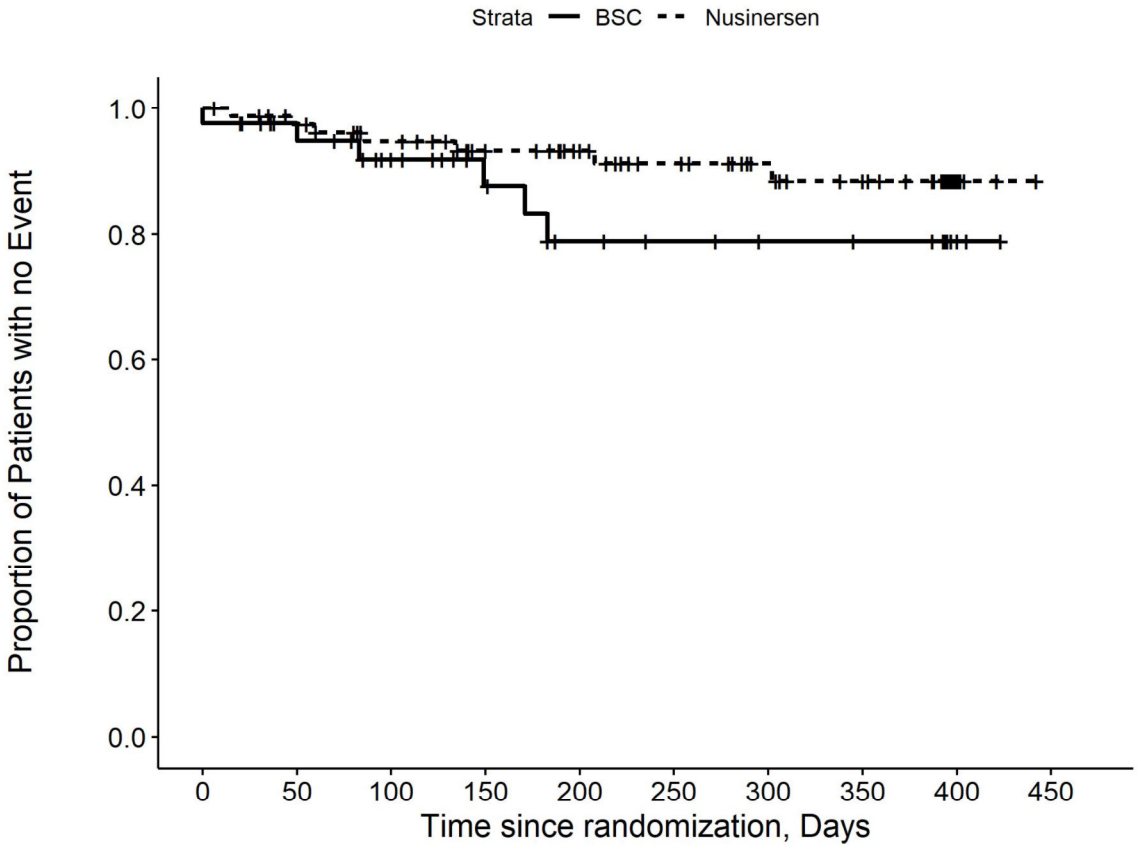
Kaplan Meier Plot for Time to AE by PT pct Dysphagia



Number at risk

BSC	41	33	26	18	13	11	8	6	1	0
Nusinersen	80	73	66	55	44	35	27	22	8	0

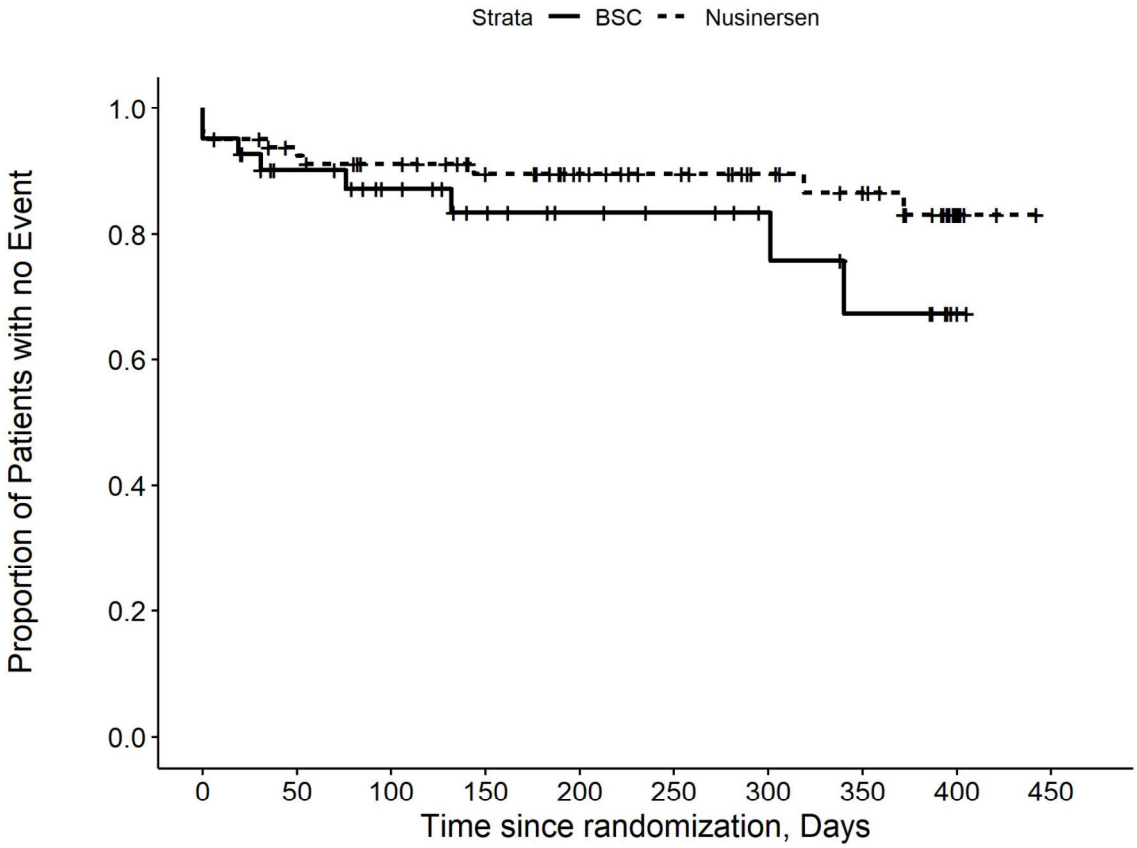
Kaplan Meier Plot for Time to AE by PT pct Dyspnoea



Number at risk

BSC	41	35	28	21	15	13	11	10	4	0
Nusinersen	80	74	67	57	49	41	33	28	11	0

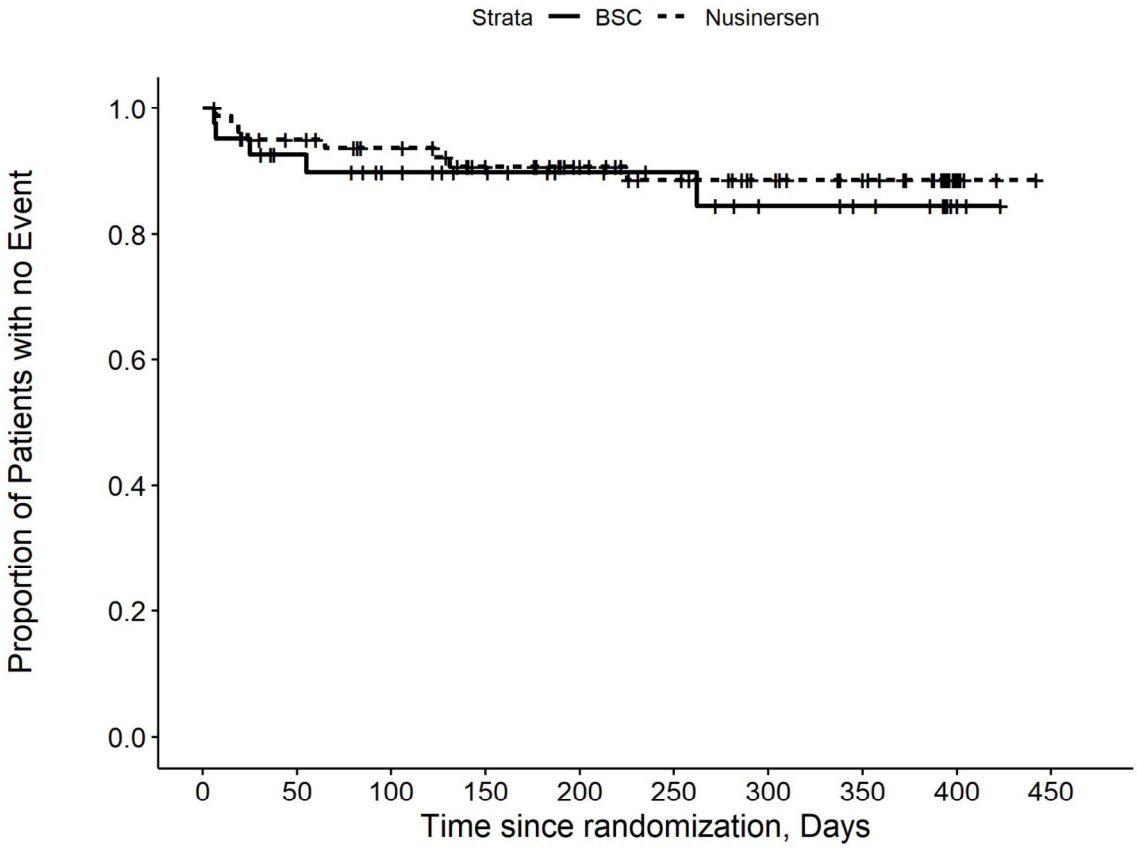
Kaplan Meier Plot for Time to AE by PT pct
Gastrooesophageal reflux disease



Number at risk

BSC	41	32	26	20	16	14	11	8	2	0
Nusinersen	80	71	65	57	47	40	32	28	11	0

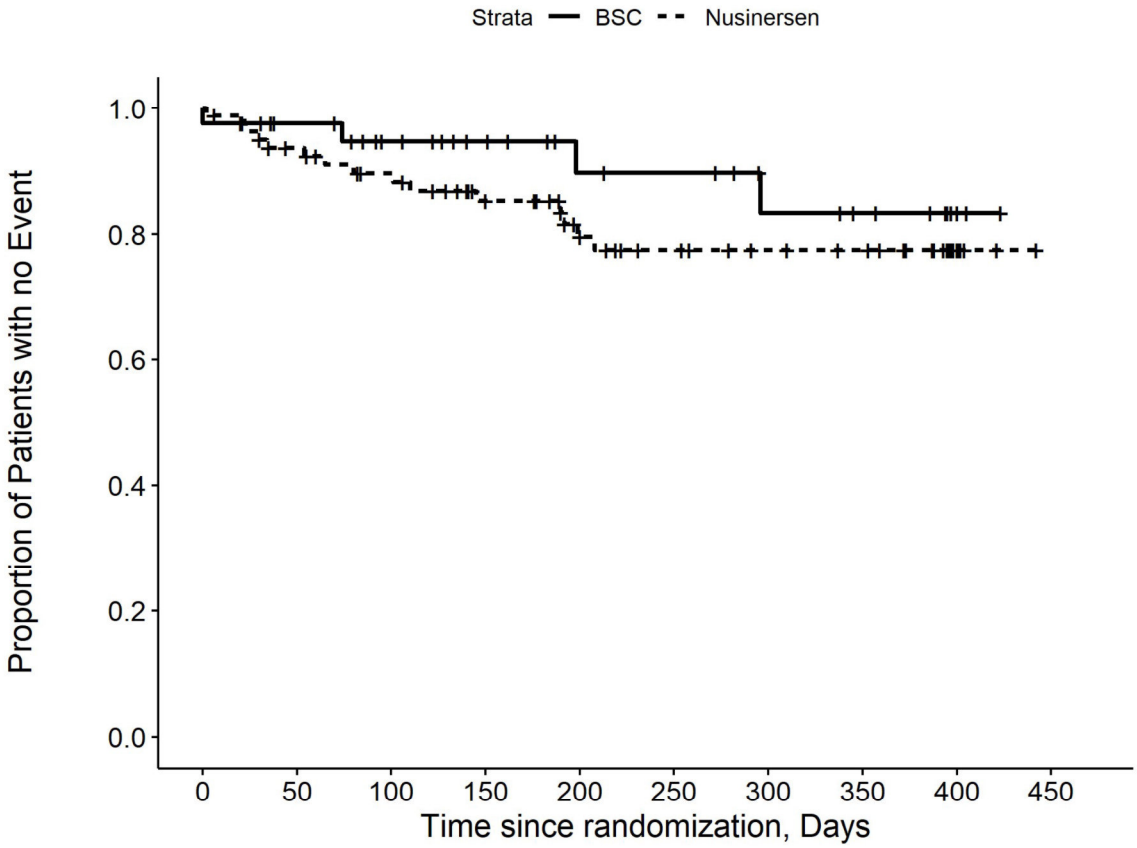
Kaplan Meier Plot for Time to AE by PT pct
Nasal congestion



Number at risk

BSC	41	33	28	24	19	17	13	11	3	0
Nusinersen	80	73	67	57	47	38	31	26	9	0

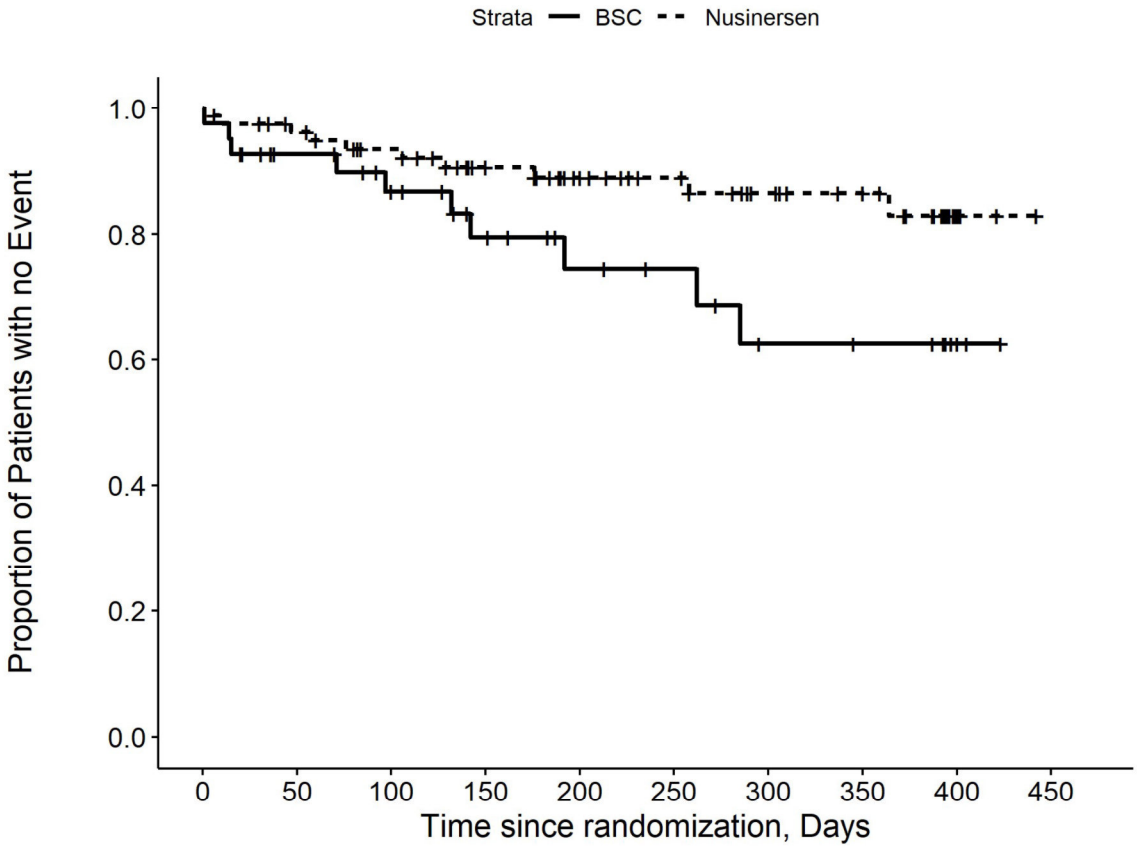
Kaplan Meier Plot for Time to AE by PT pct
Nasopharyngitis



Number at risk

BSC	41	35	29	24	18	17	13	11	4	0
Nusinersen	80	71	64	53	40	33	28	26	11	0

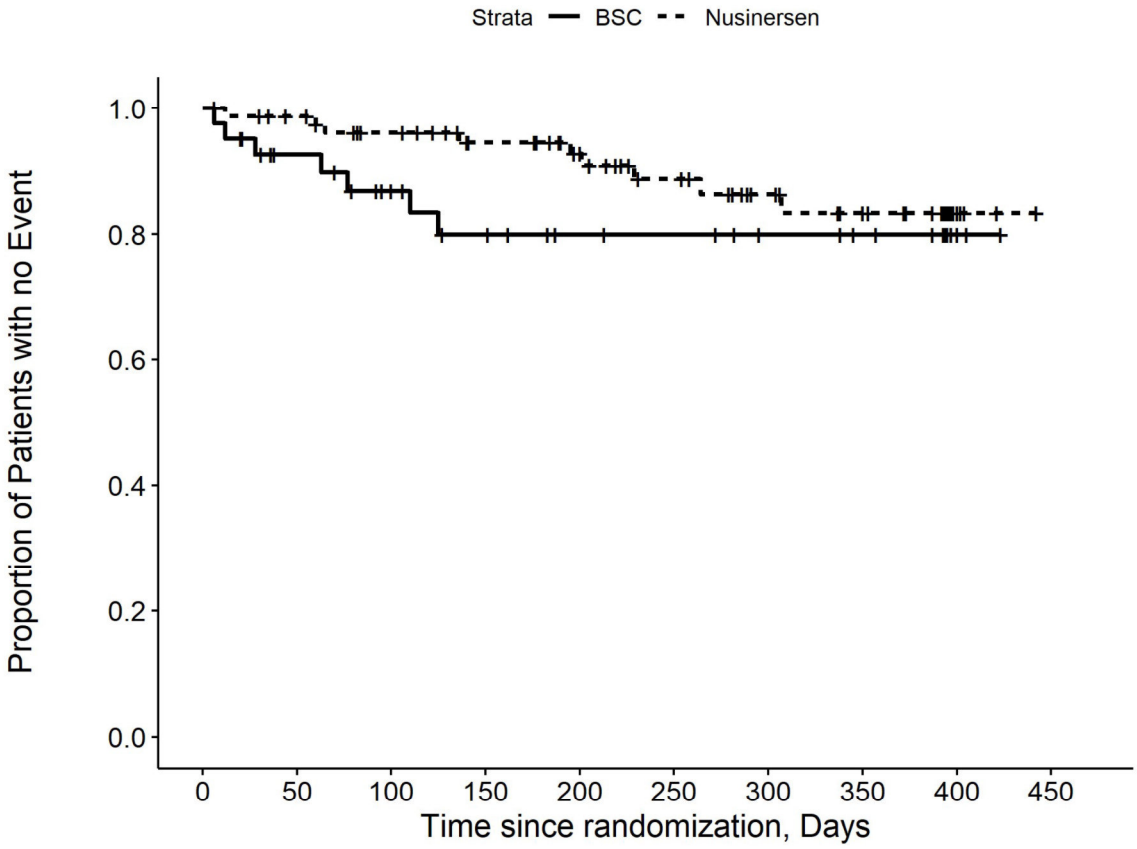
Kaplan Meier Plot for Time to AE by PT pct
Oxygen saturation decreased



Number at risk

BSC	41	33	28	21	15	13	9	8	4	0
Nusinersen	80	73	66	55	45	38	30	26	8	0

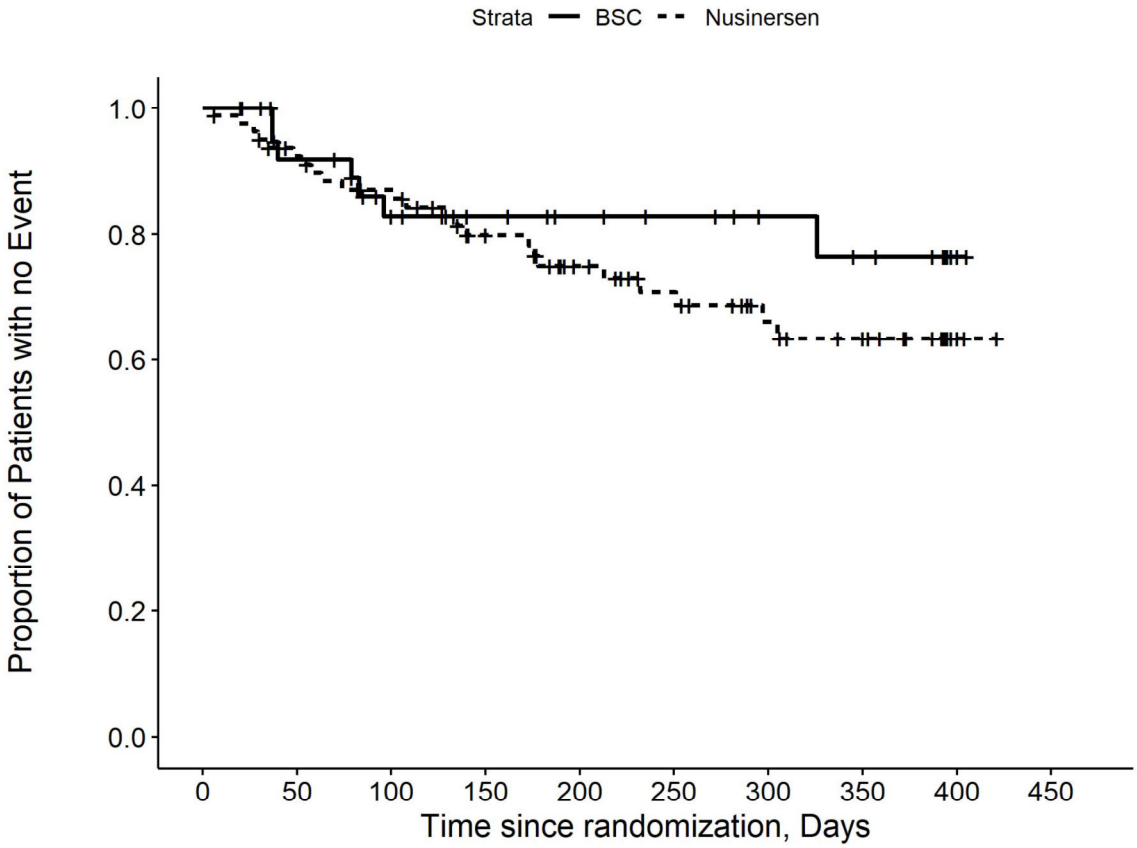
Kaplan Meier Plot for Time to AE by PT pct
Pneumonia aspiration



Number at risk

BSC	41	33	27	22	18	17	14	12	4	0
Nusinersen	80	75	68	59	50	40	31	26	10	0

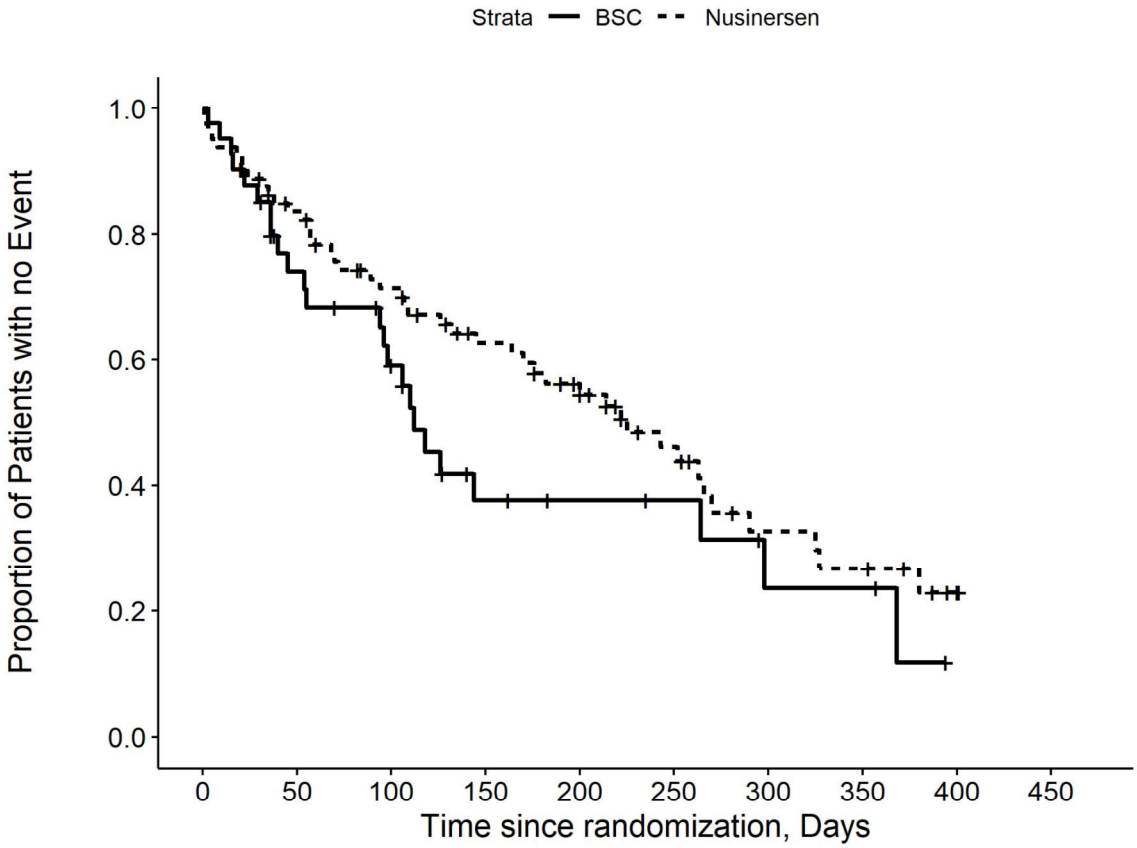
Kaplan Meier Plot for Time to AE by PT pct
Pneumonia



Number at risk

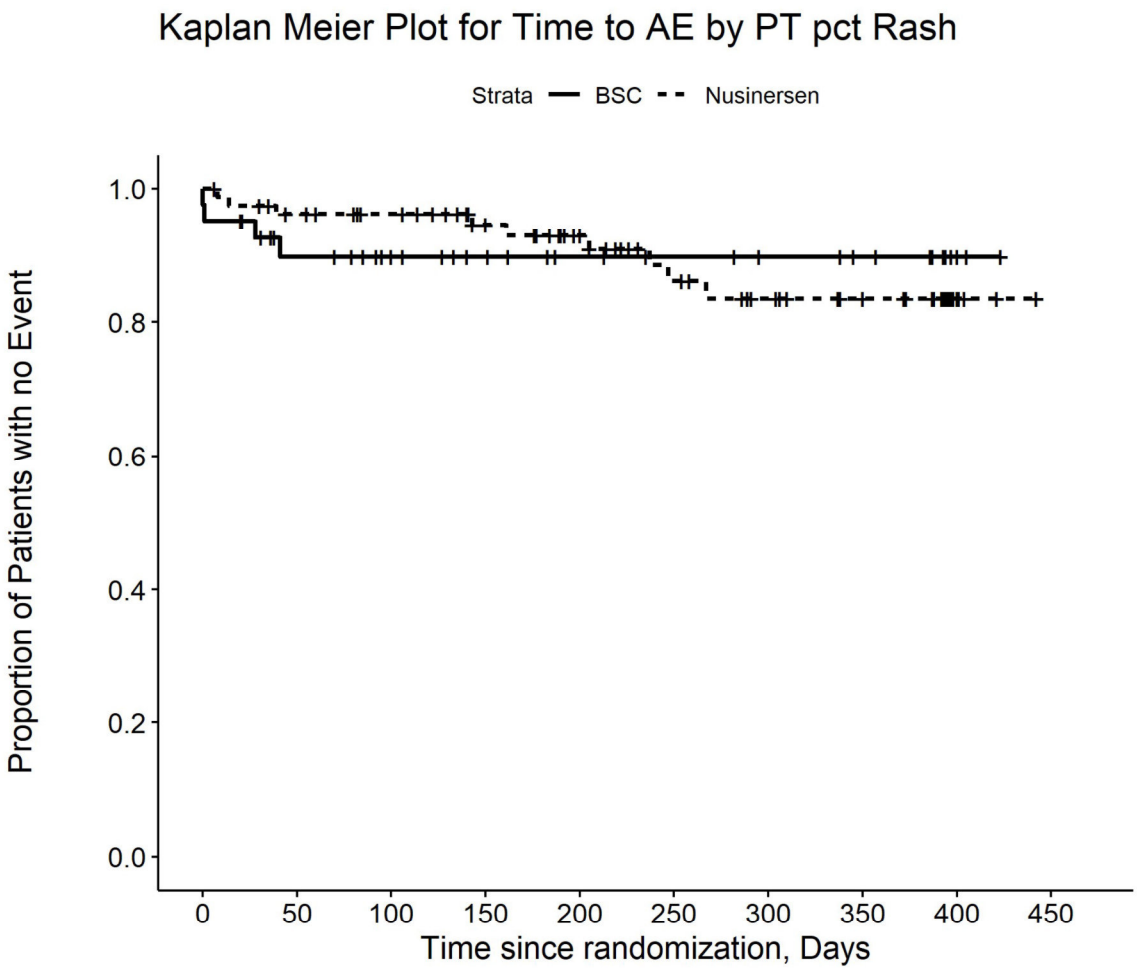
BSC	41	33	26	21	18	16	13	11	3	0
Nusinersen	80	70	63	51	40	33	25	21	7	0

Kaplan Meier Plot for Time to AE by PT pct Pyrexia



Number at risk

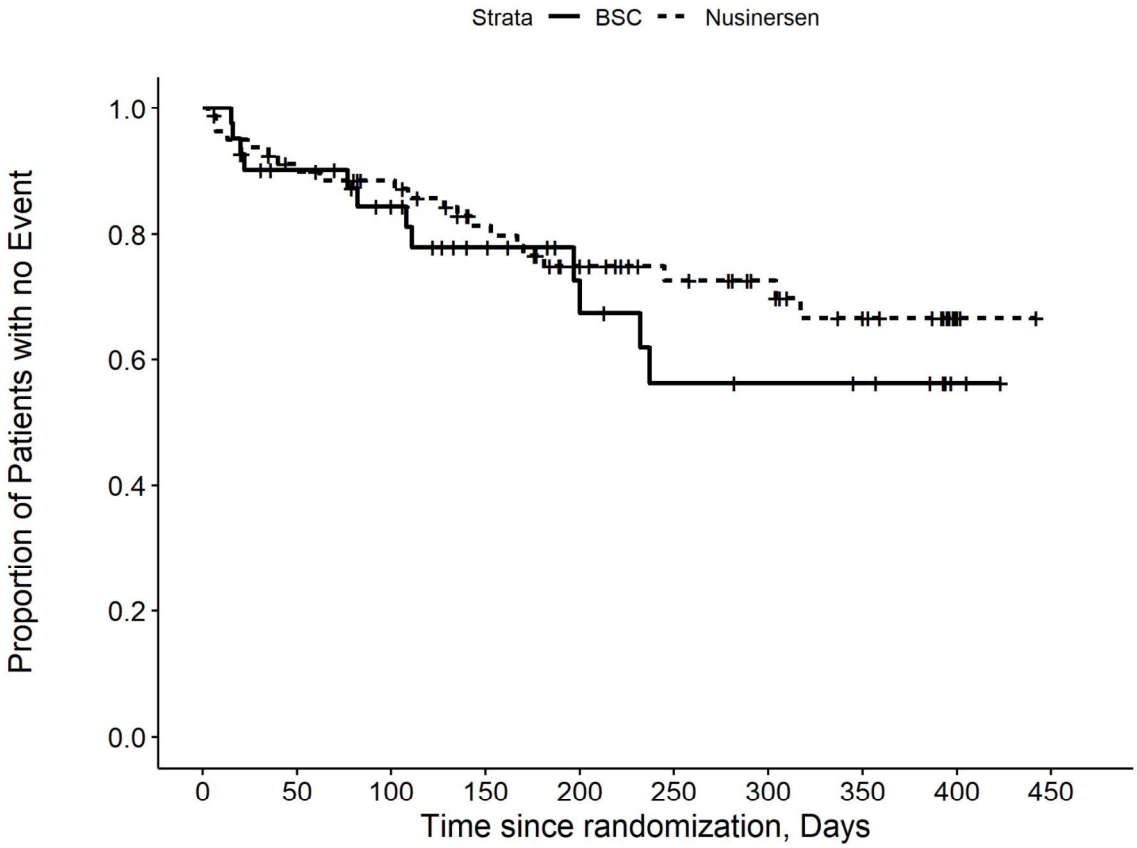
BSC	41	26	19	9	7	6	3	3	0	0
Nusinersen	80	64	51	39	32	20	11	9	3	0



Number at risk

BSC	41	32	27	22	17	15	13	11	3	0
Nusinersen	80	73	68	58	47	36	29	24	8	0

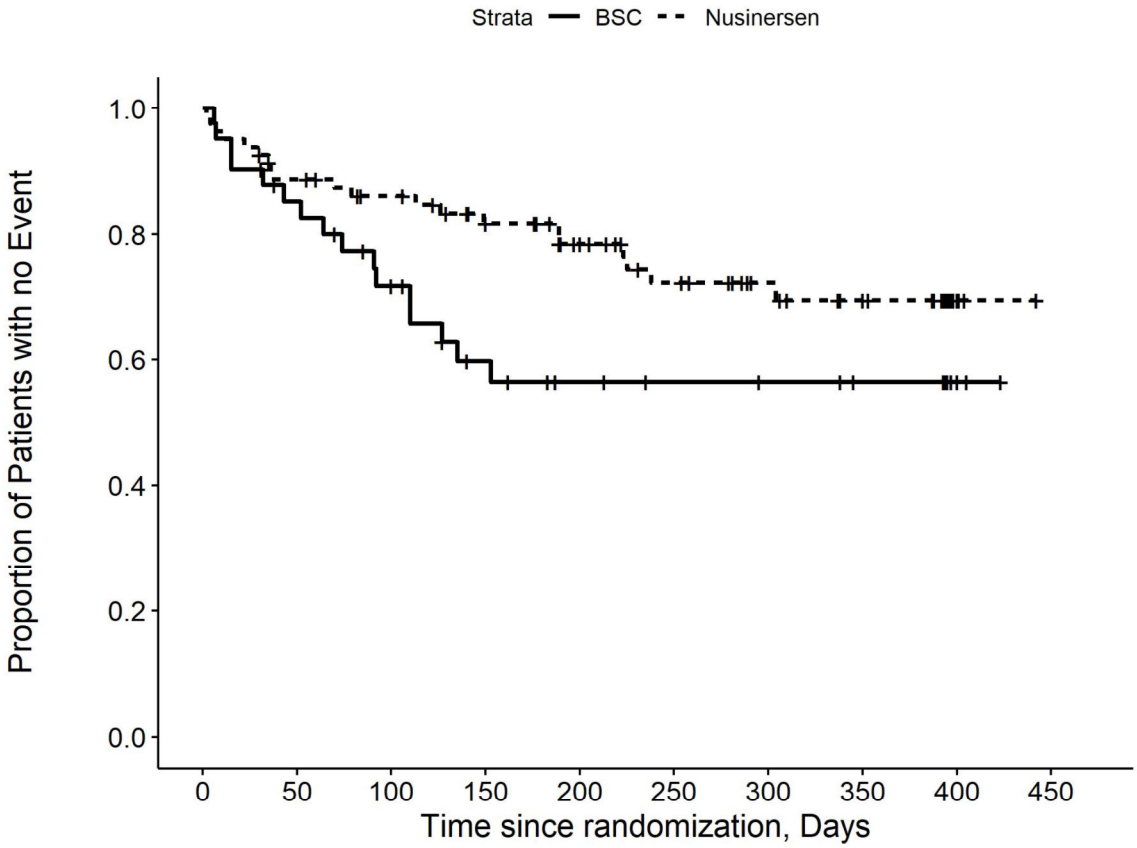
Kaplan Meier Plot for Time to AE by PT pct
Respiratory distress



Number at risk

BSC	41	33	28	20	14	10	9	8	2	0
Nusinersen	80	70	64	52	40	32	26	20	7	0

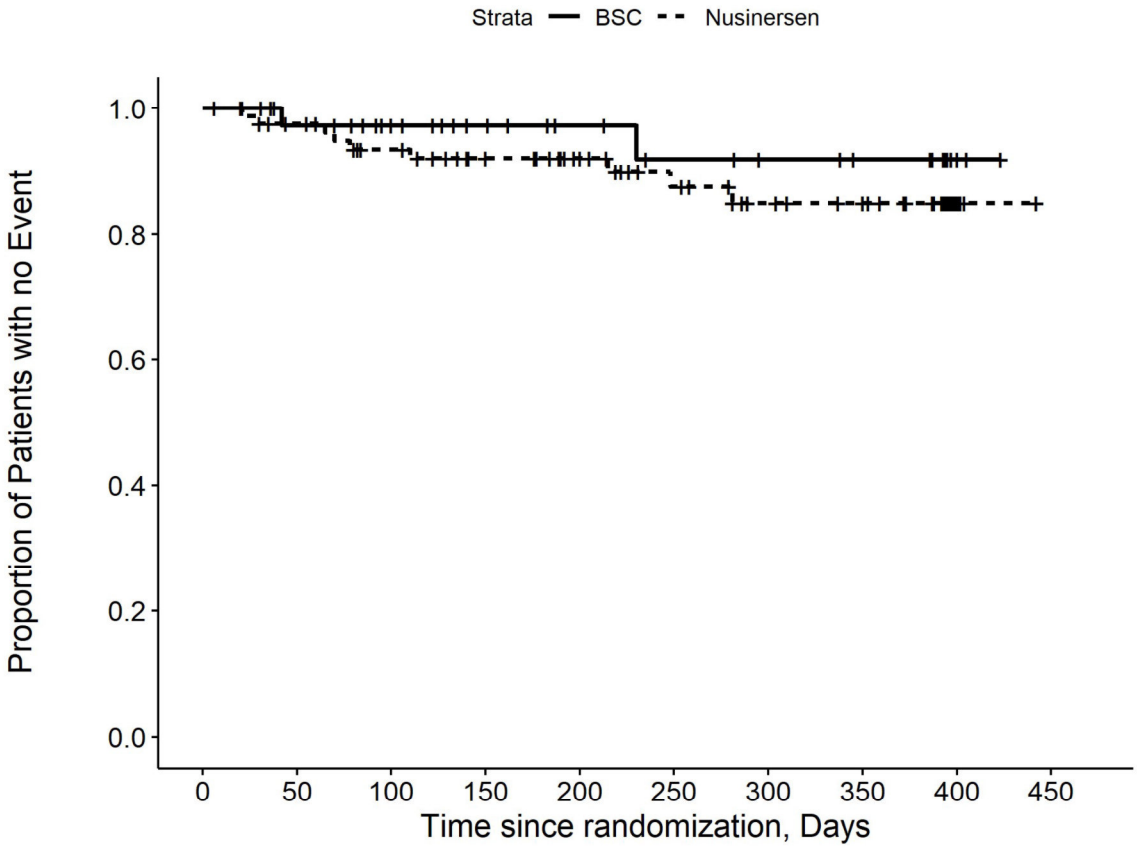
Kaplan Meier Plot for Time to AE by PT pct
Respiratory failure



Number at risk

BSC	41	33	26	18	14	12	11	9	4	0
Nusinersen	80	69	63	54	44	34	26	21	8	0

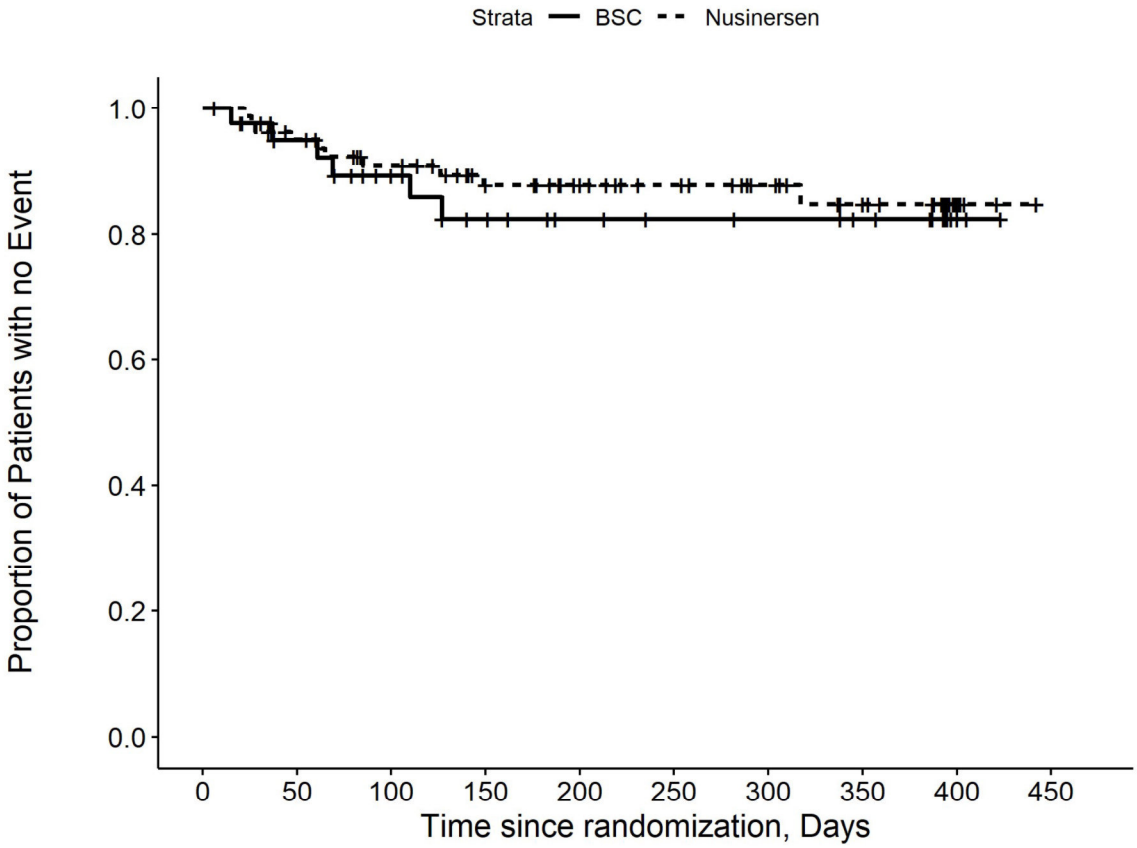
Kaplan Meier Plot for Time to AE by PT pct
Respiratory tract infection



Number at risk

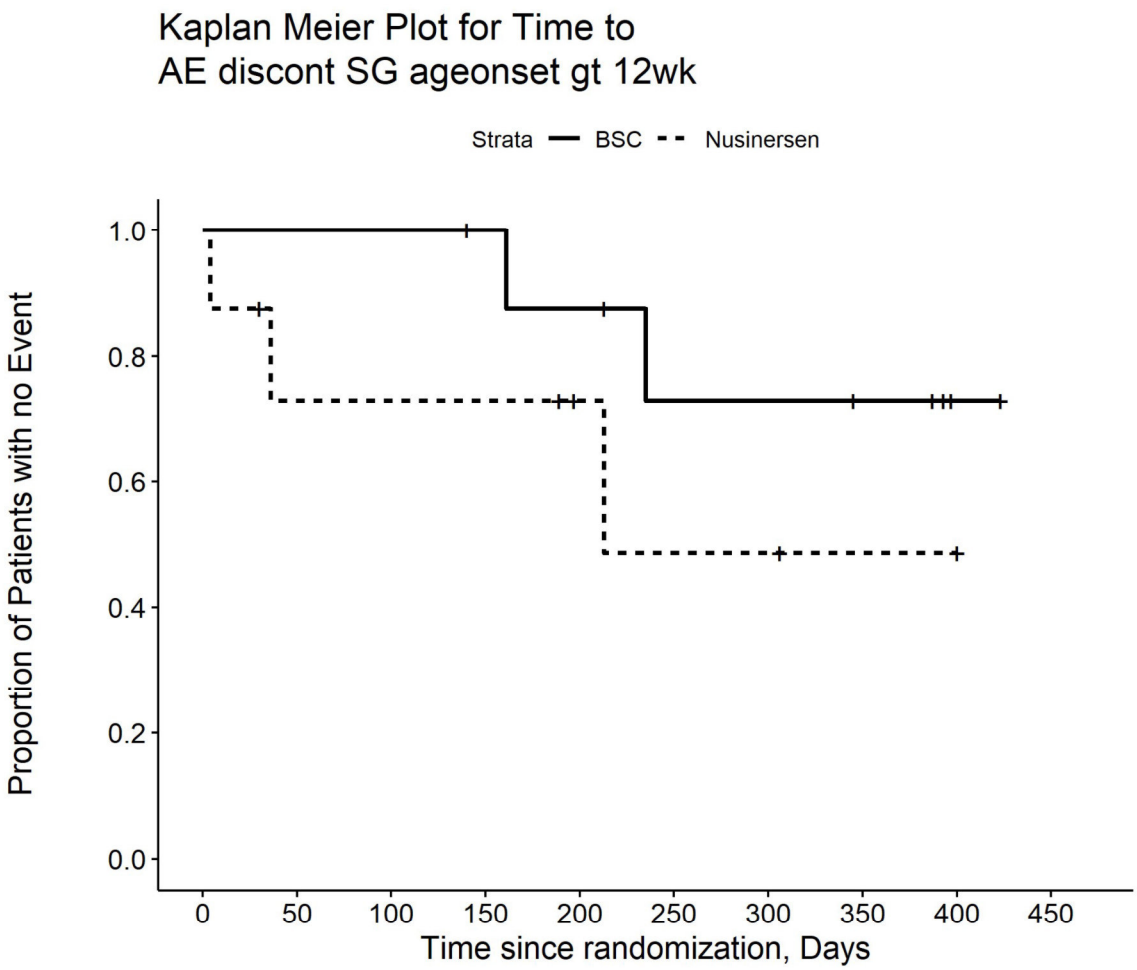
BSC	41	35	30	24	19	16	14	12	4	0
Nusinersen	80	74	66	57	47	37	29	26	9	0

Kaplan Meier Plot for Time to AE by PT pct
Rhinovirus infection



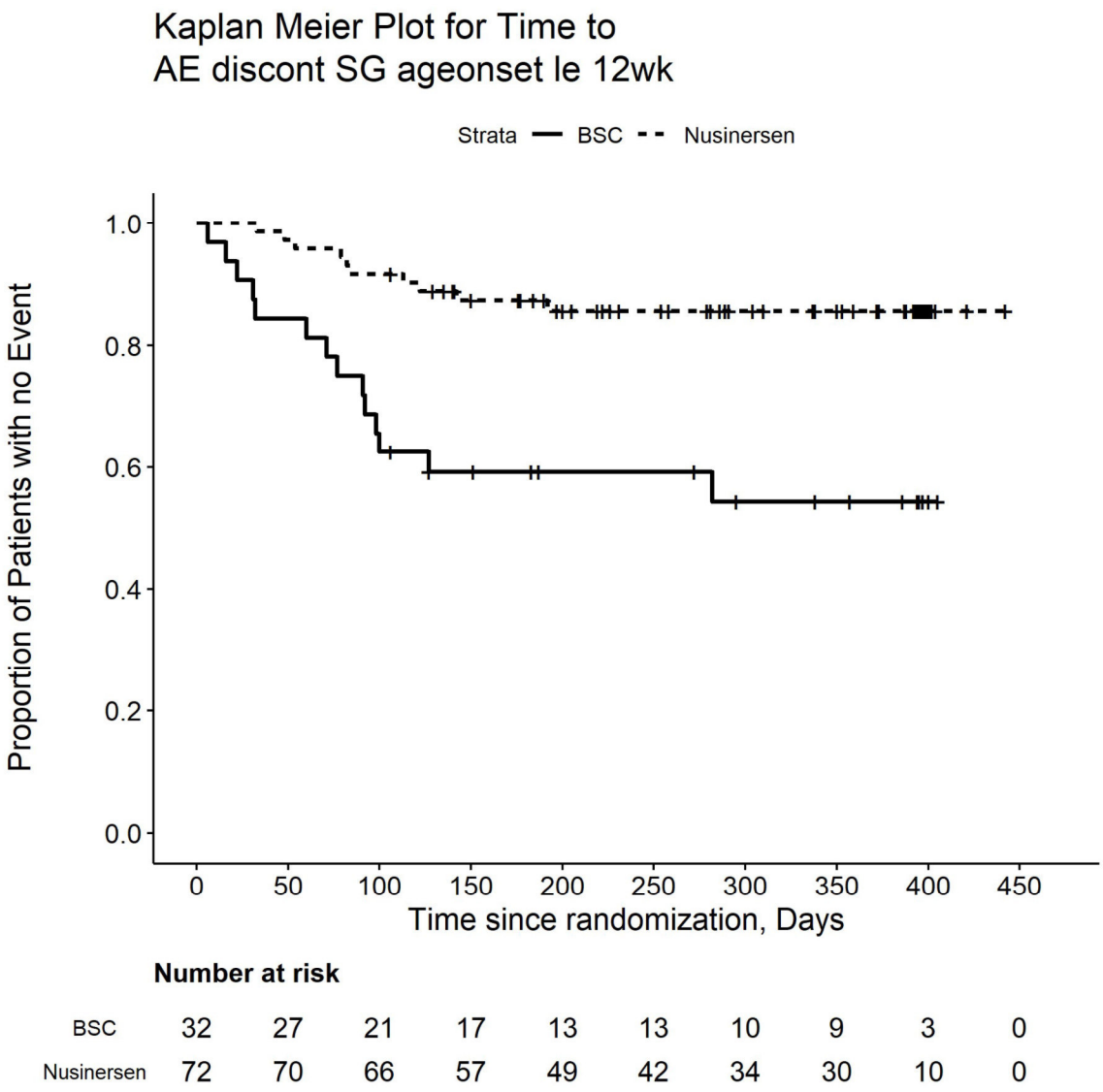
Number at risk

BSC	41	34	28	22	17	15	14	12	3	0
Nusinersen	80	73	65	54	46	39	32	26	11	0



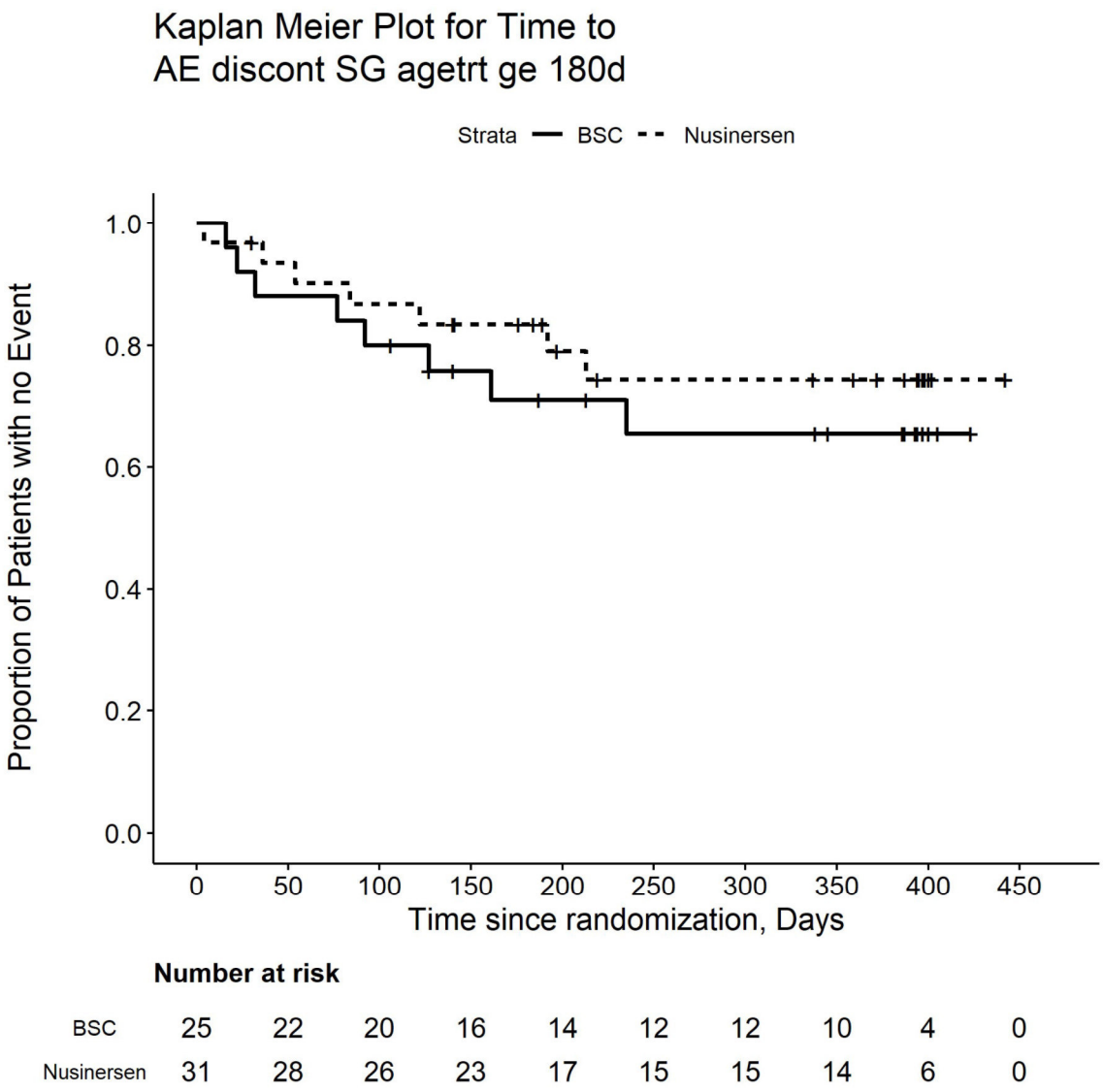
Number at risk

BSC	9	9	9	8	7	5	5	4	1	0
Nusinersen	8	5	5	5	3	2	2	1	1	0



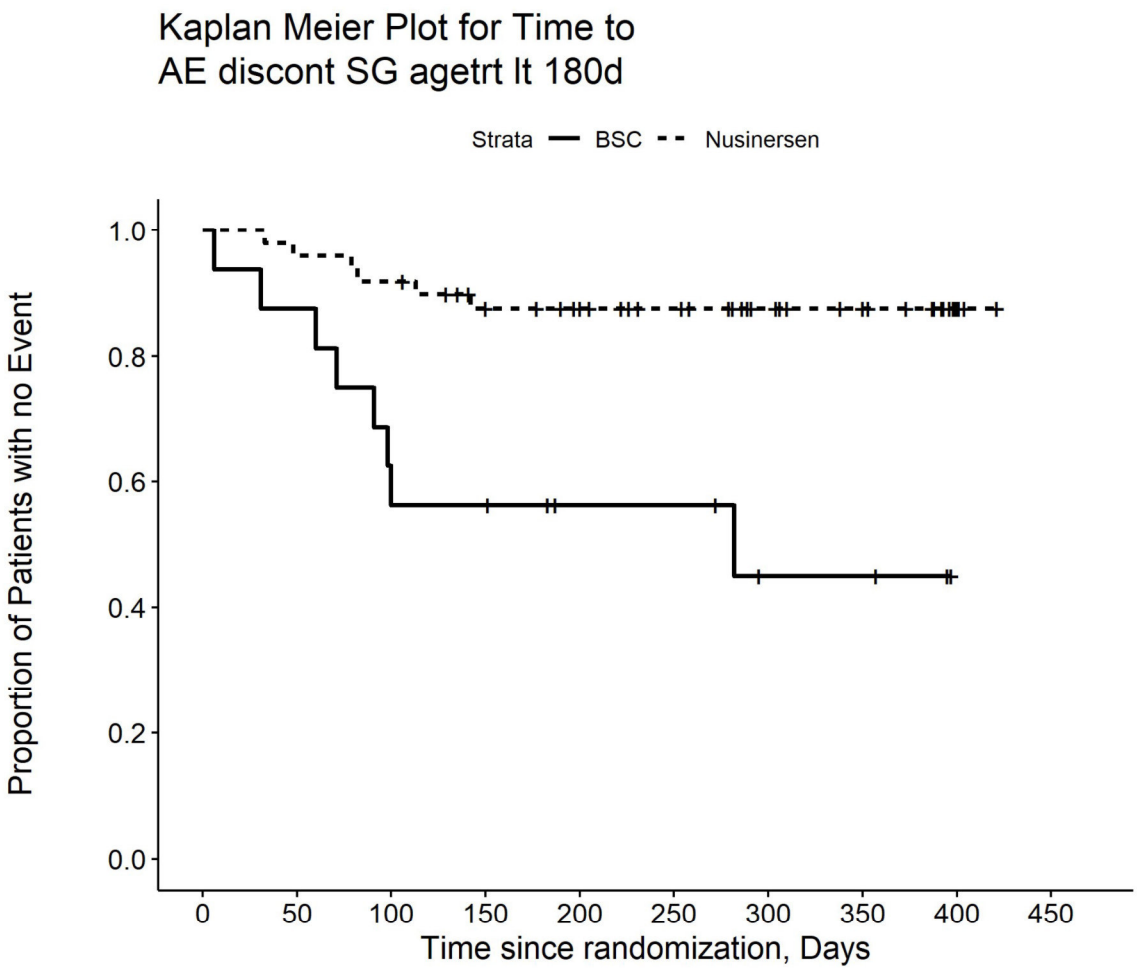
Number at risk

BSC	32	27	21	17	13	13	10	9	3	0
Nusinersen	72	70	66	57	49	42	34	30	10	0



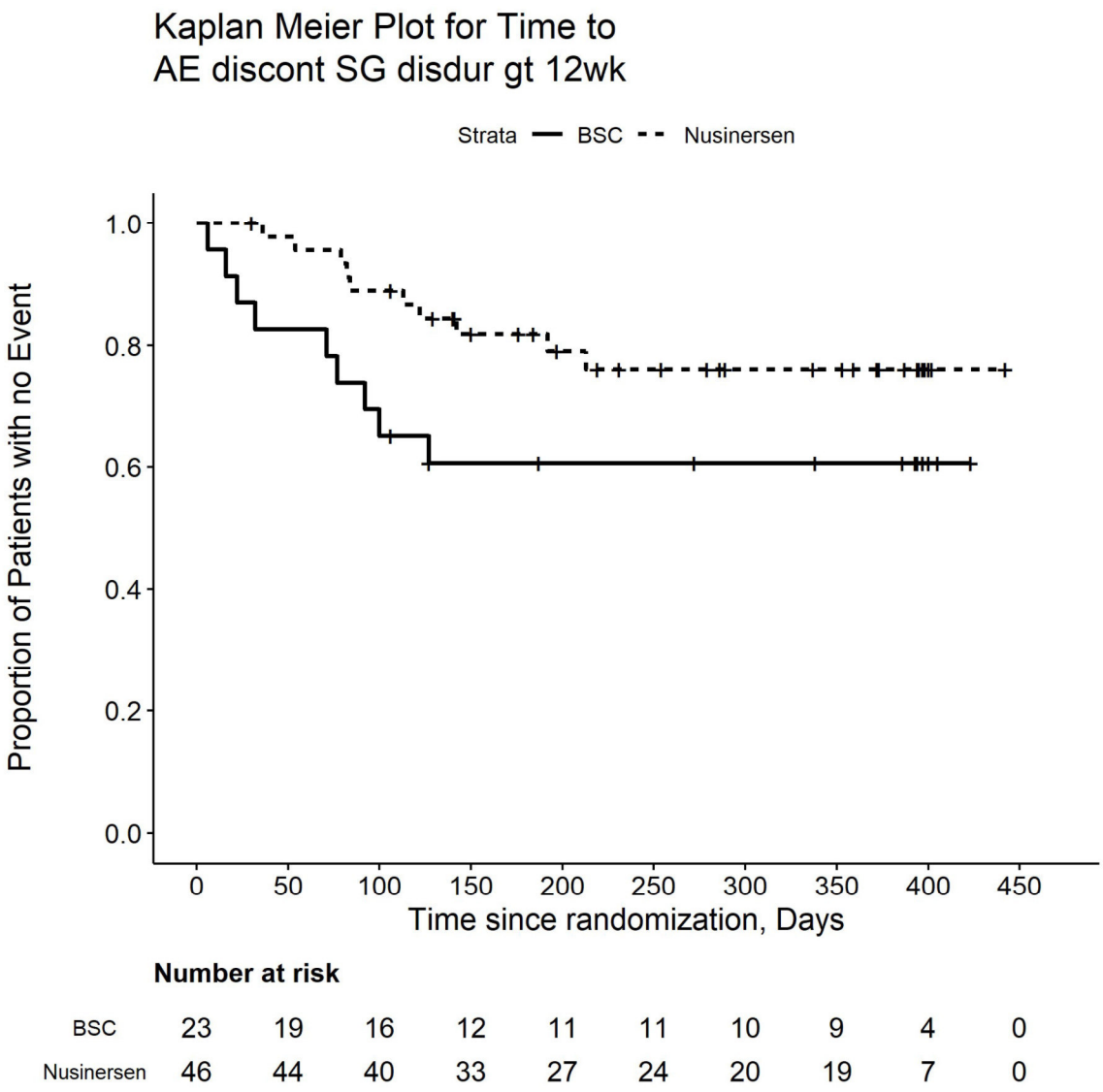
Number at risk

BSC	25	22	20	16	14	12	12	10	4	0
Nusinersen	31	28	26	23	17	15	15	14	6	0



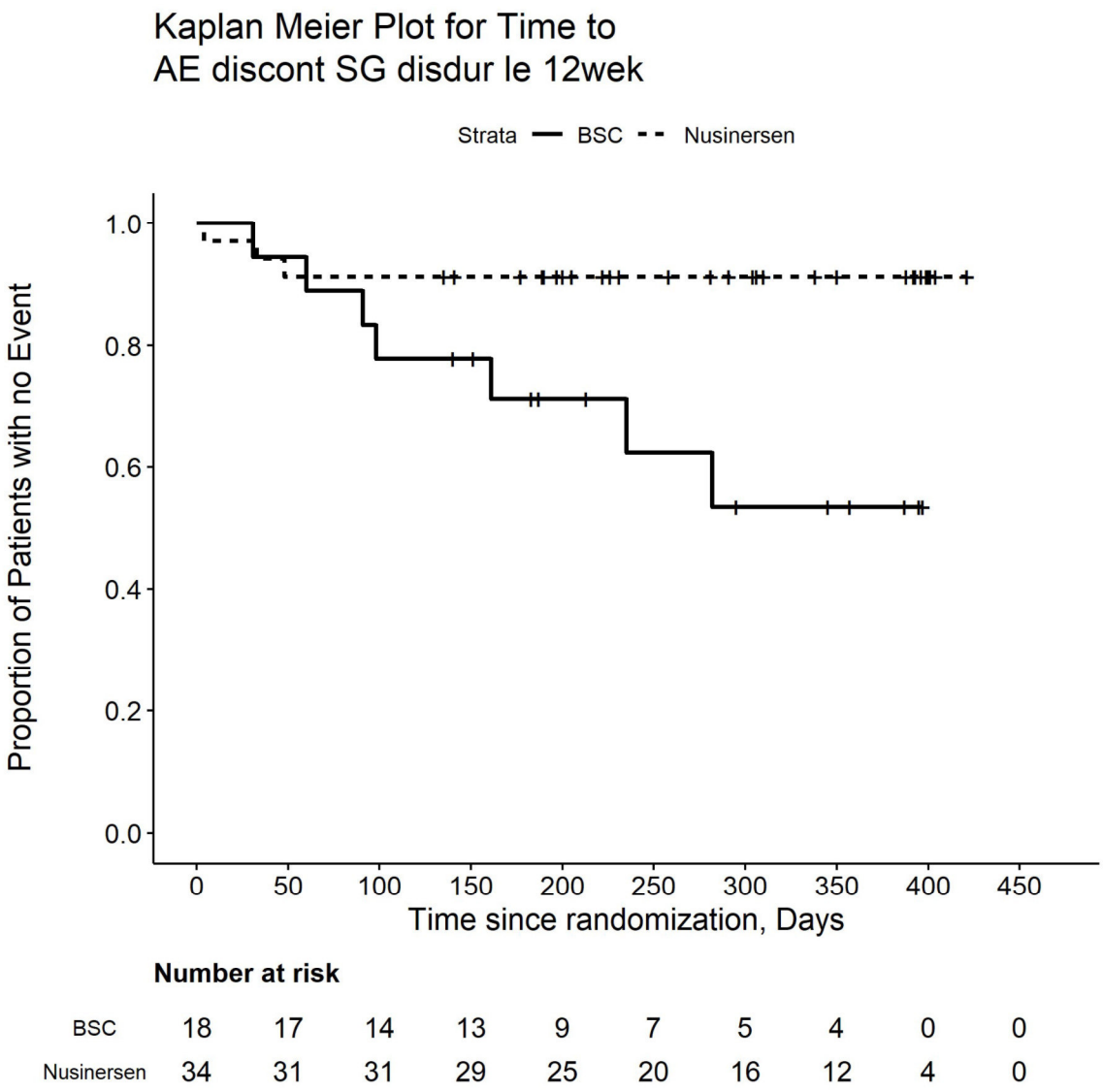
Number at risk

BSC	16	14	10	9	6	6	3	3	0	0
Nusinersen	49	47	45	39	35	29	21	17	5	0



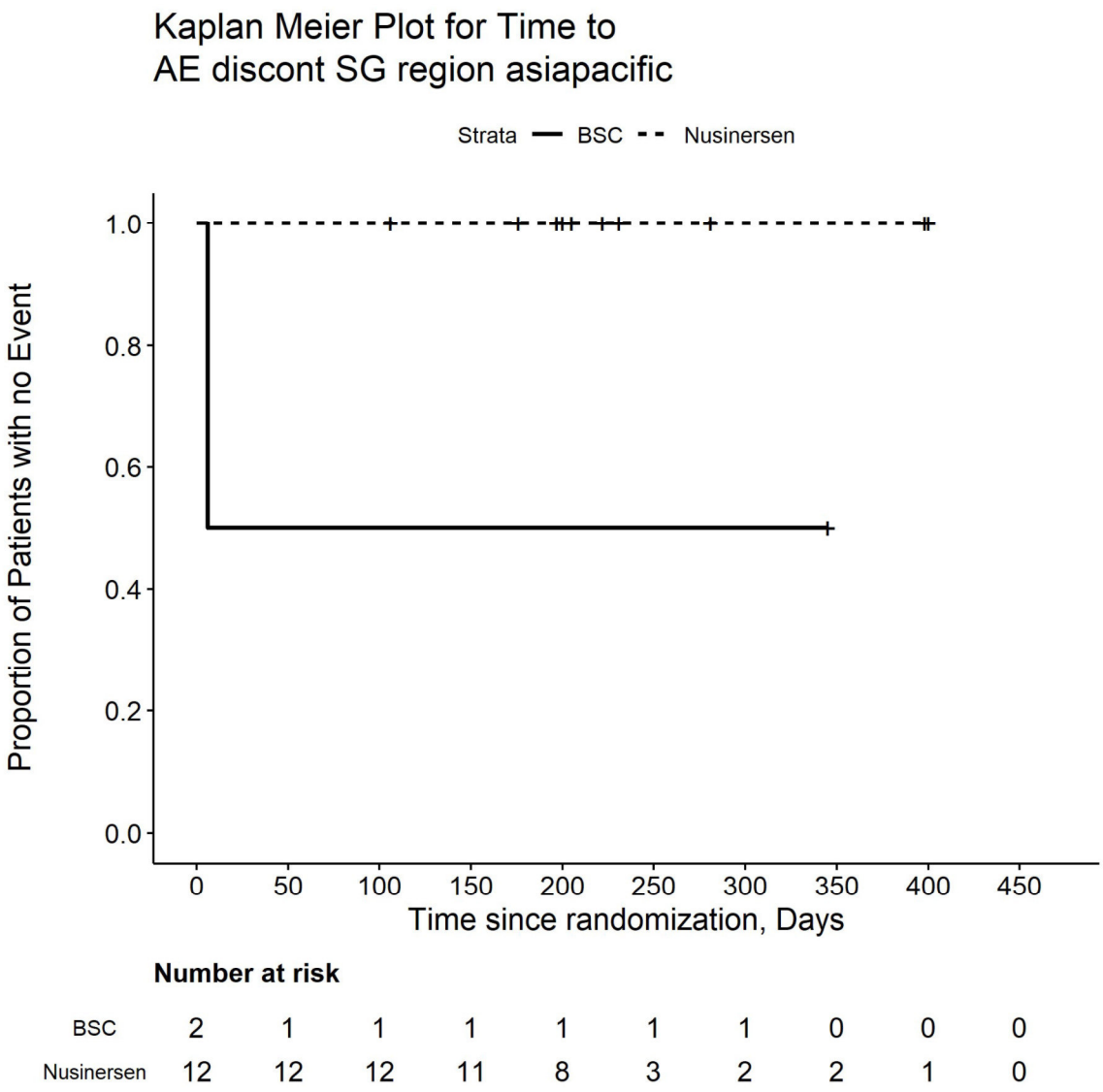
Number at risk

BSC	23	19	16	12	11	11	10	9	4	0
Nusinersen	46	44	40	33	27	24	20	19	7	0



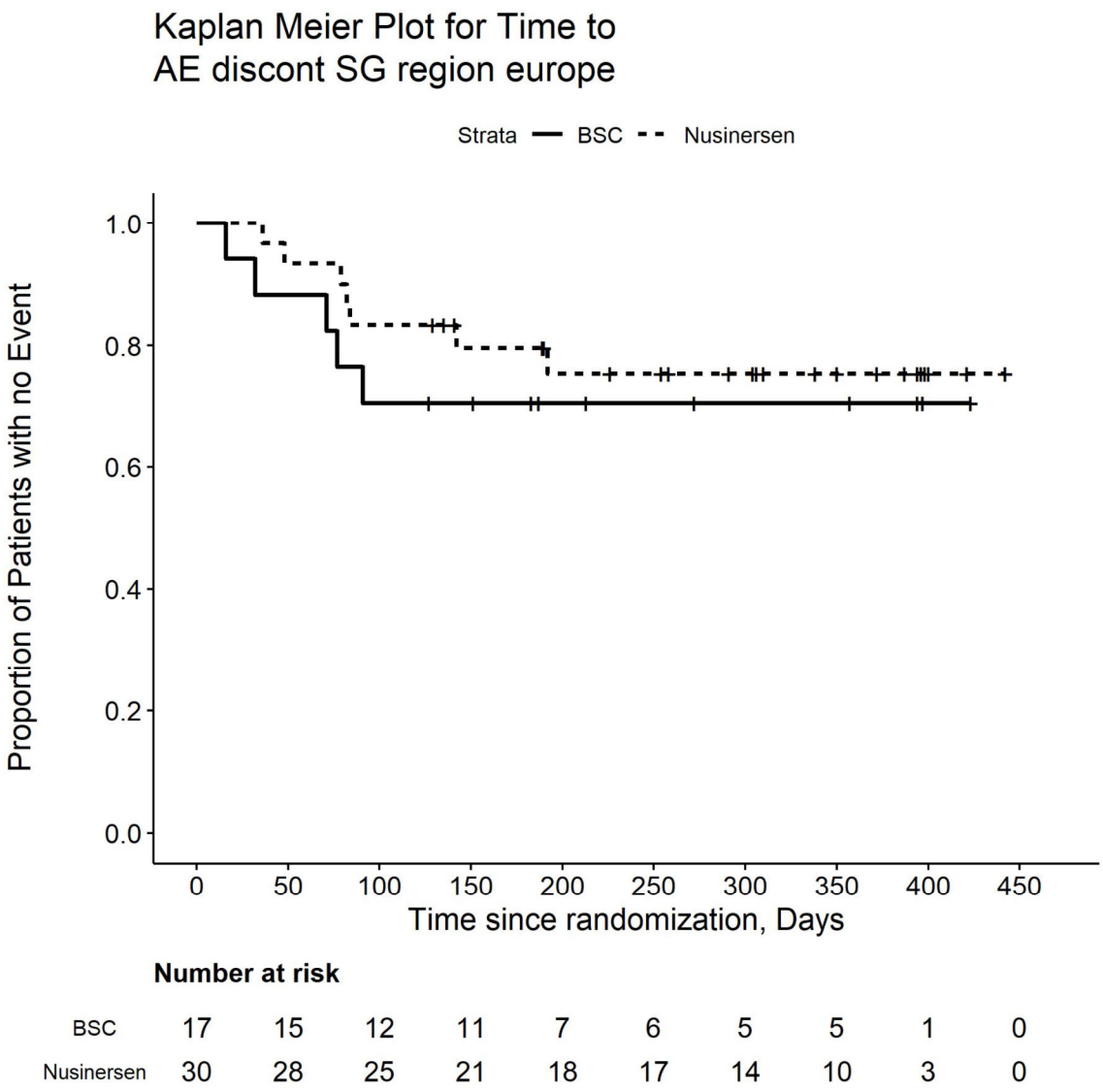
Number at risk

BSC	18	17	14	13	9	7	5	4	0	0
Nusinersen	34	31	31	29	25	20	16	12	4	0



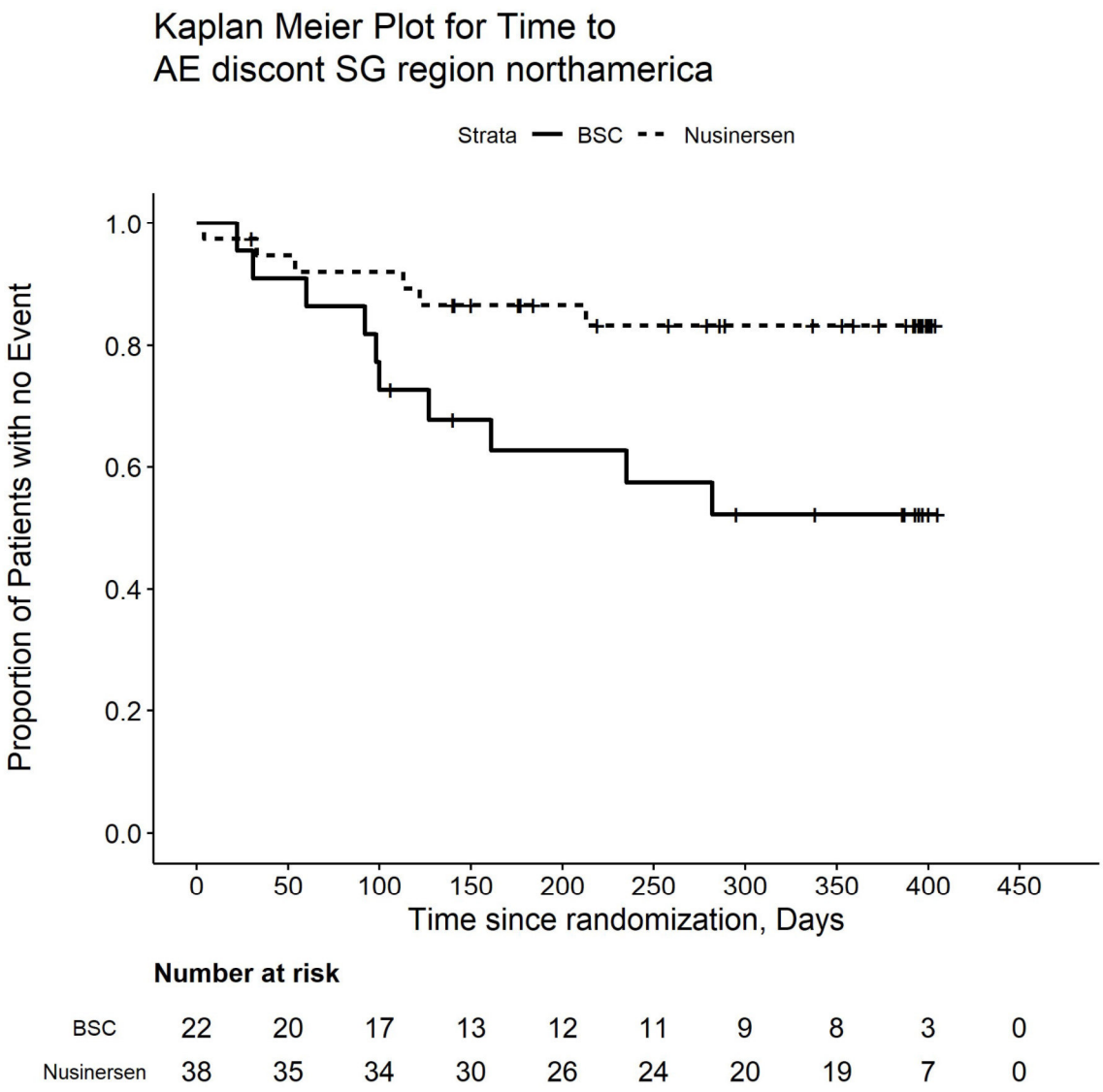
Number at risk

BSC	2	1	1	1	1	1	1	0	0	0
Nusinersen	12	12	12	11	8	3	2	2	1	0



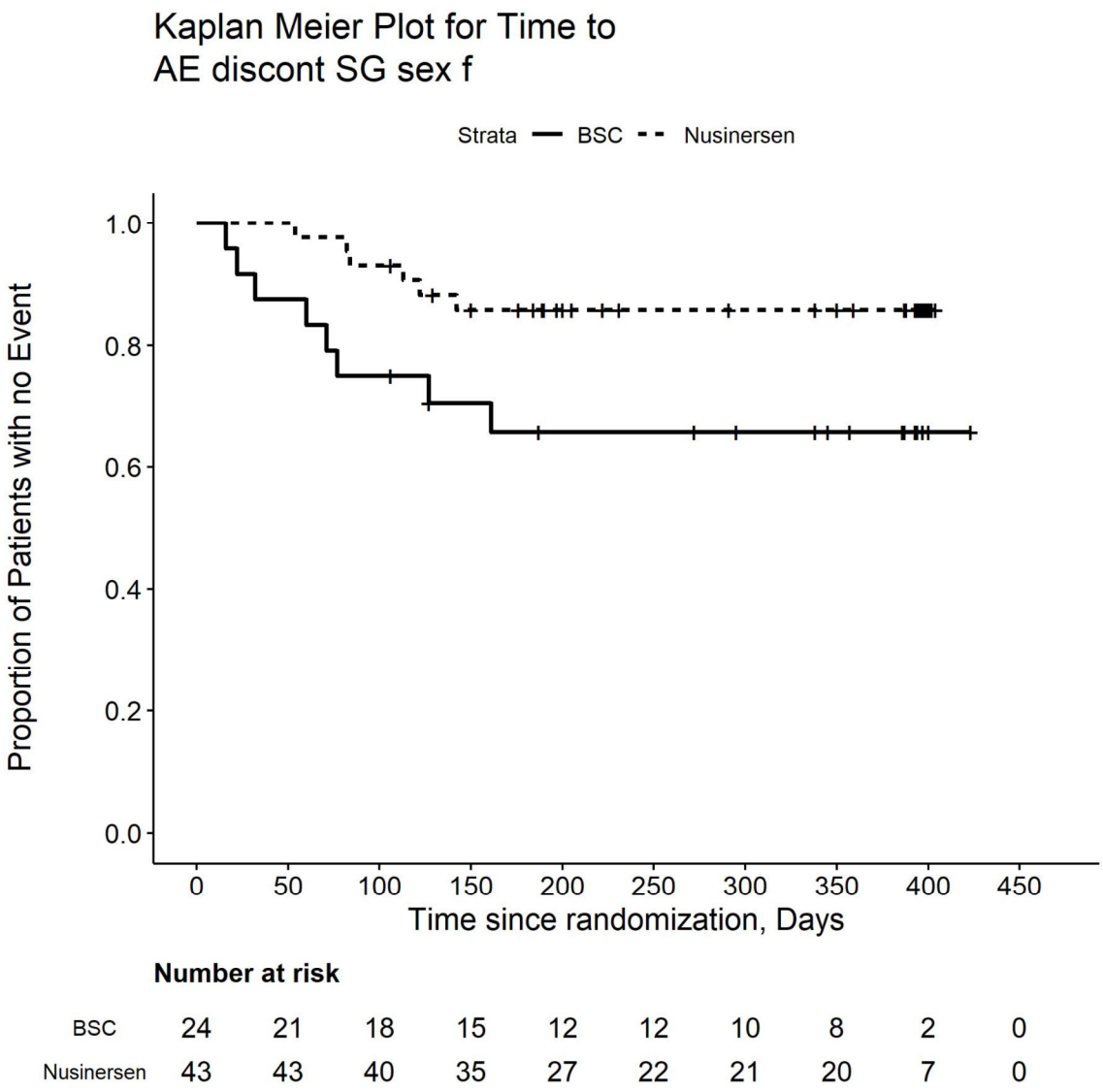
Number at risk

BSC	17	15	12	11	7	6	5	5	1	0
Nusinersen	30	28	25	21	18	17	14	10	3	0



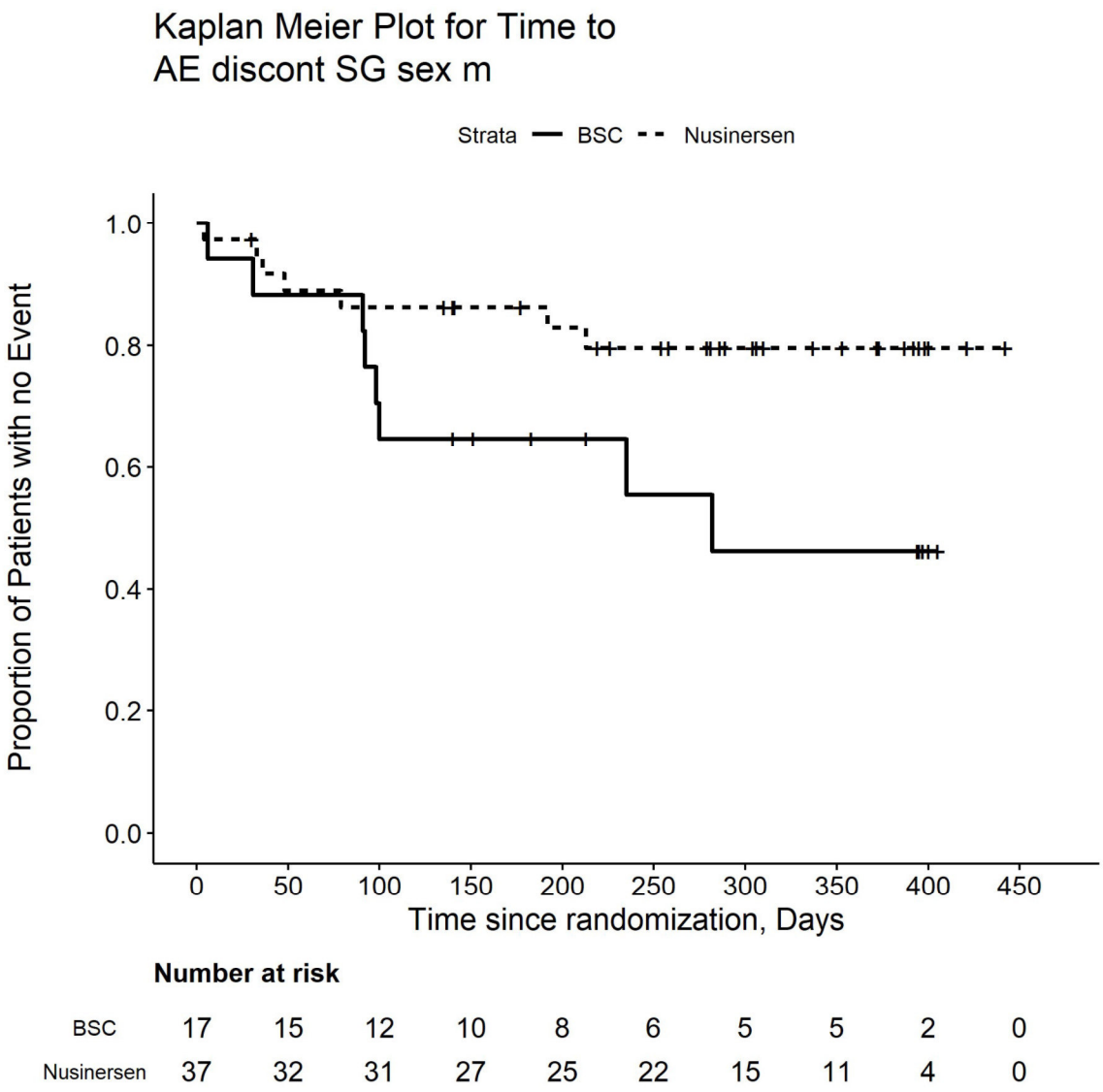
Number at risk

BSC	22	20	17	13	12	11	9	8	3	0
Nusinersen	38	35	34	30	26	24	20	19	7	0



Number at risk

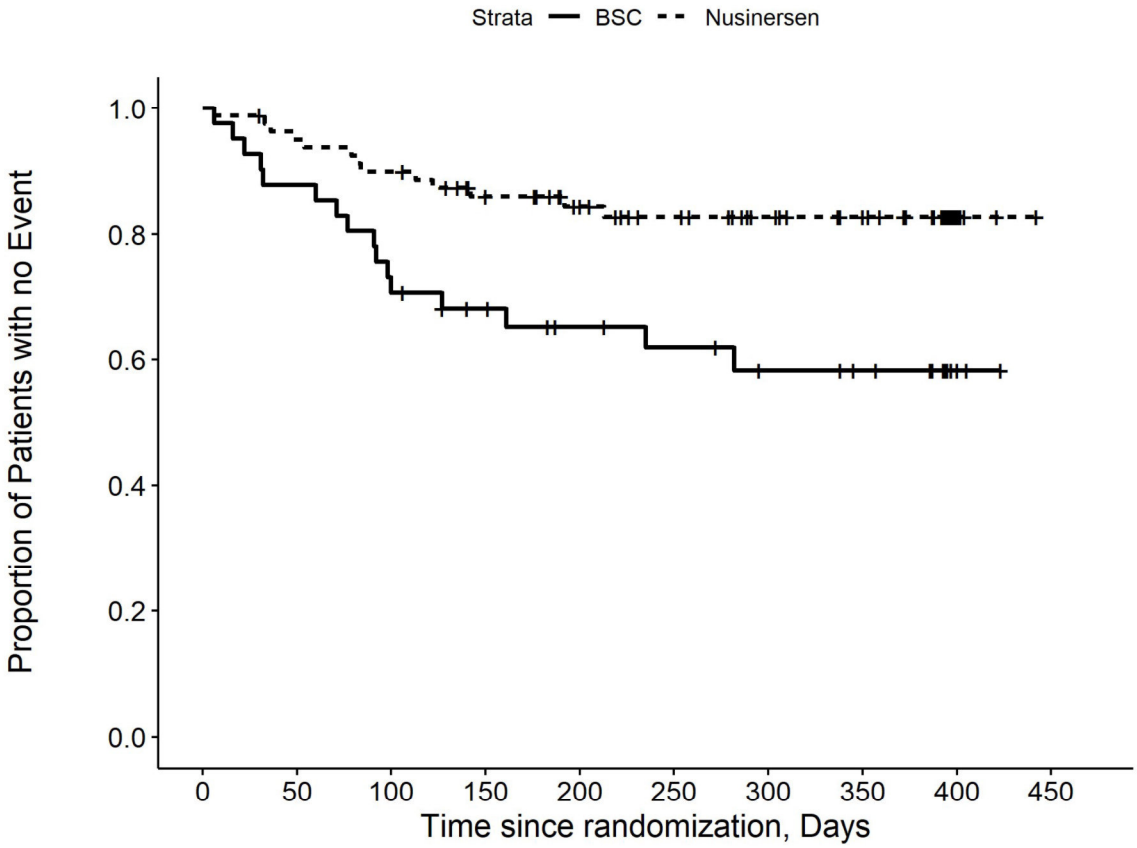
BSC	24	21	18	15	12	12	10	8	2	0
Nusinersen	43	43	40	35	27	22	21	20	7	0



Number at risk

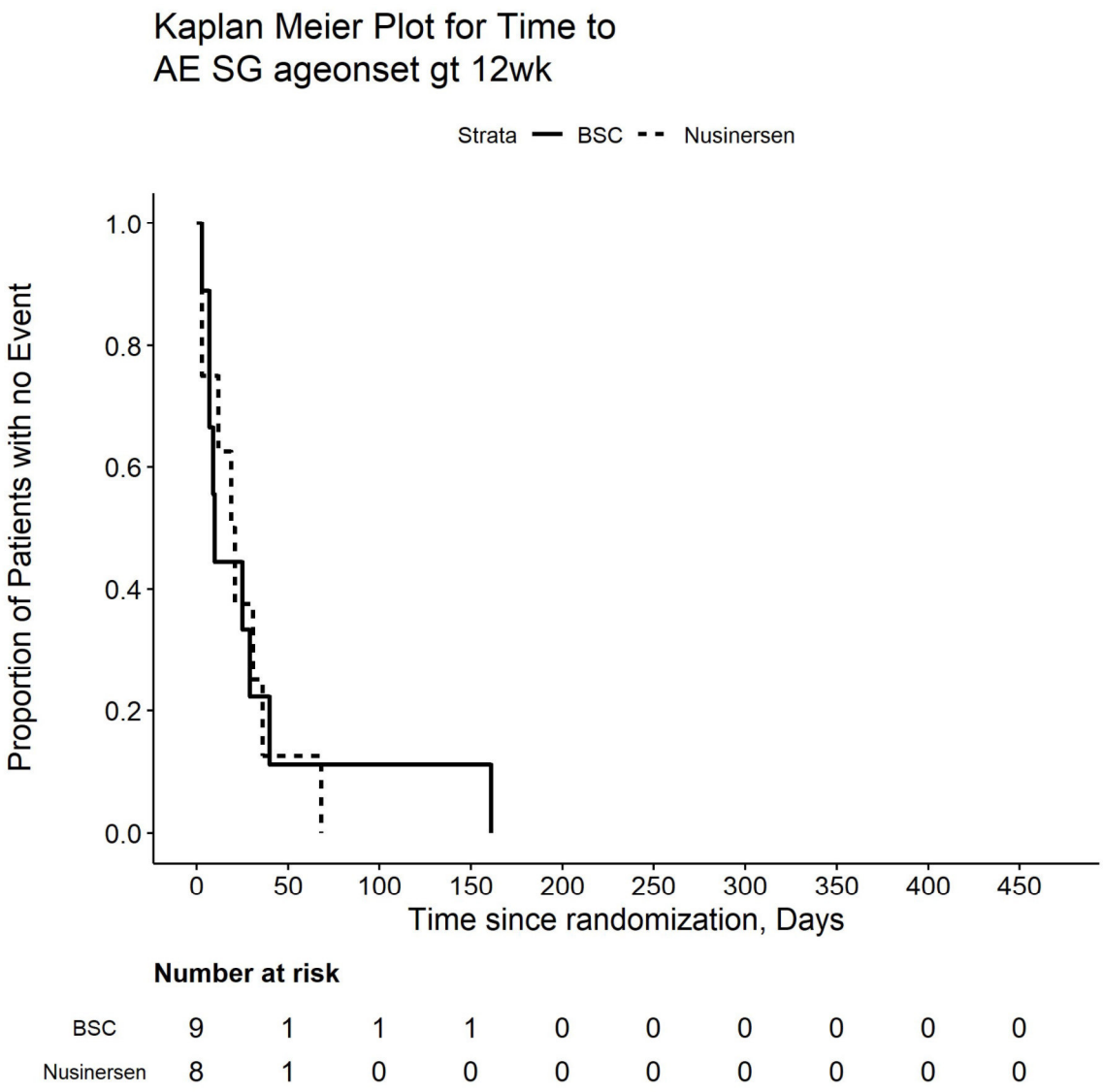
BSC	17	15	12	10	8	6	5	5	2	0
Nusinersen	37	32	31	27	25	22	15	11	4	0

Kaplan Meier Plot for Time to AE leading to discont



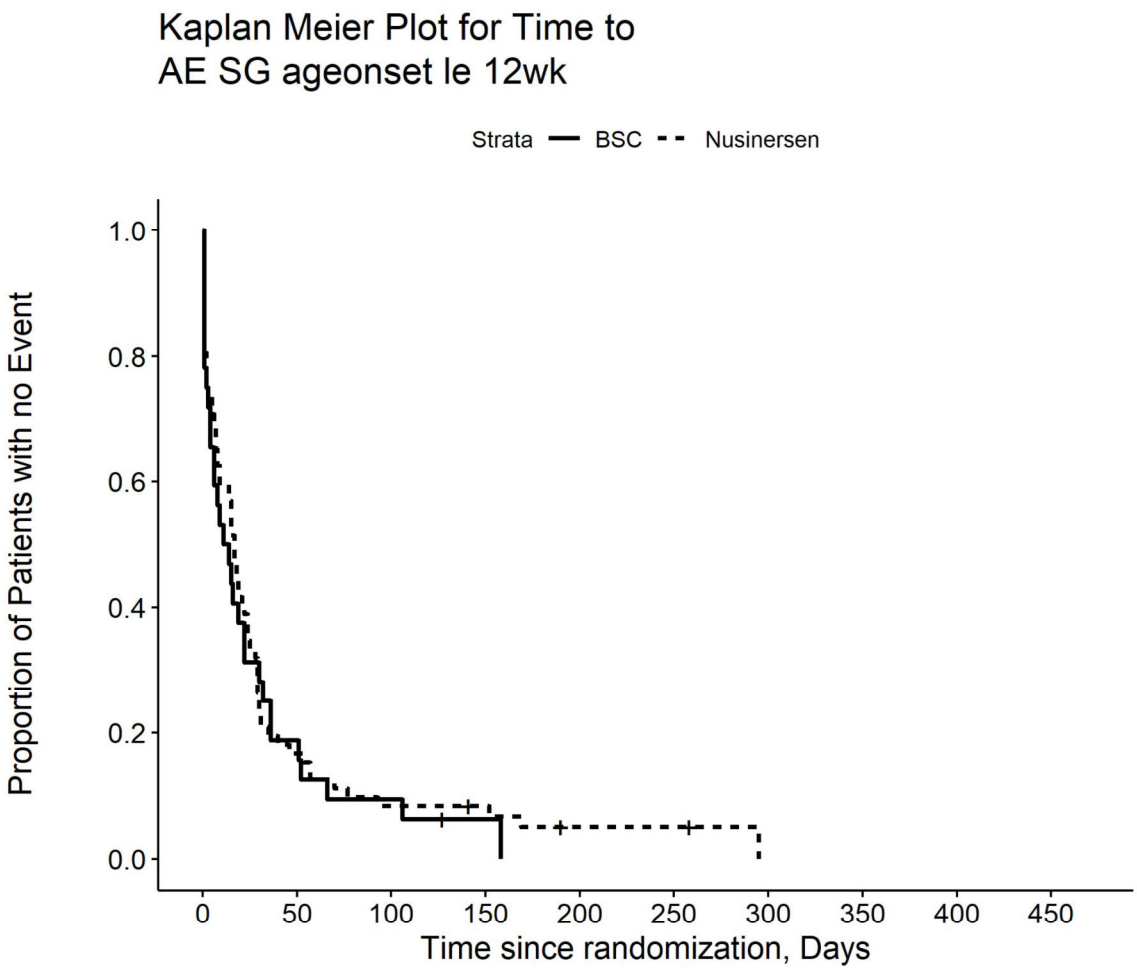
Number at risk

BSC	41	36	30	25	20	18	15	13	4	0
Nusinersen	80	75	71	62	52	44	36	31	11	0



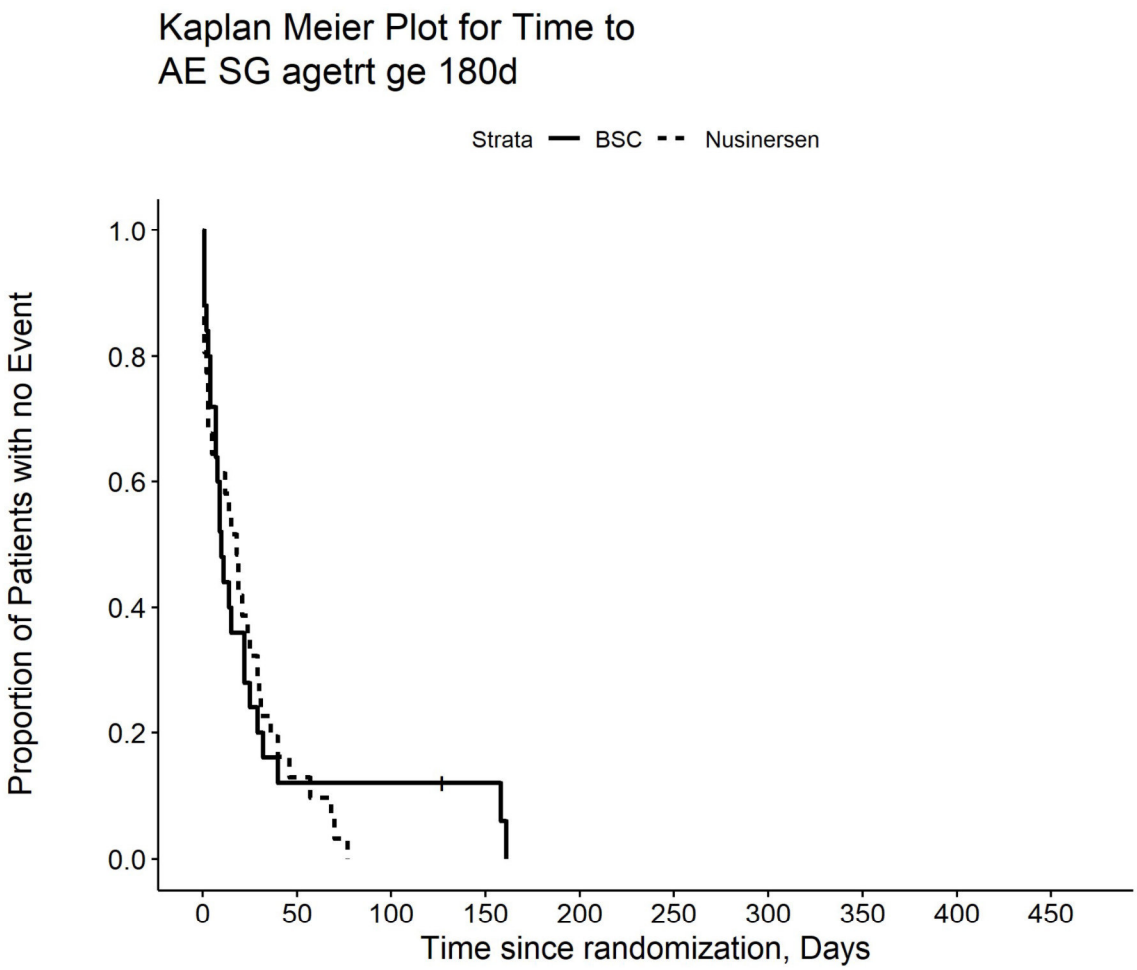
Number at risk

BSC	9	1	1	1	0	0	0	0	0	0
Nusinersen	8	1	0	0	0	0	0	0	0	0



Number at risk

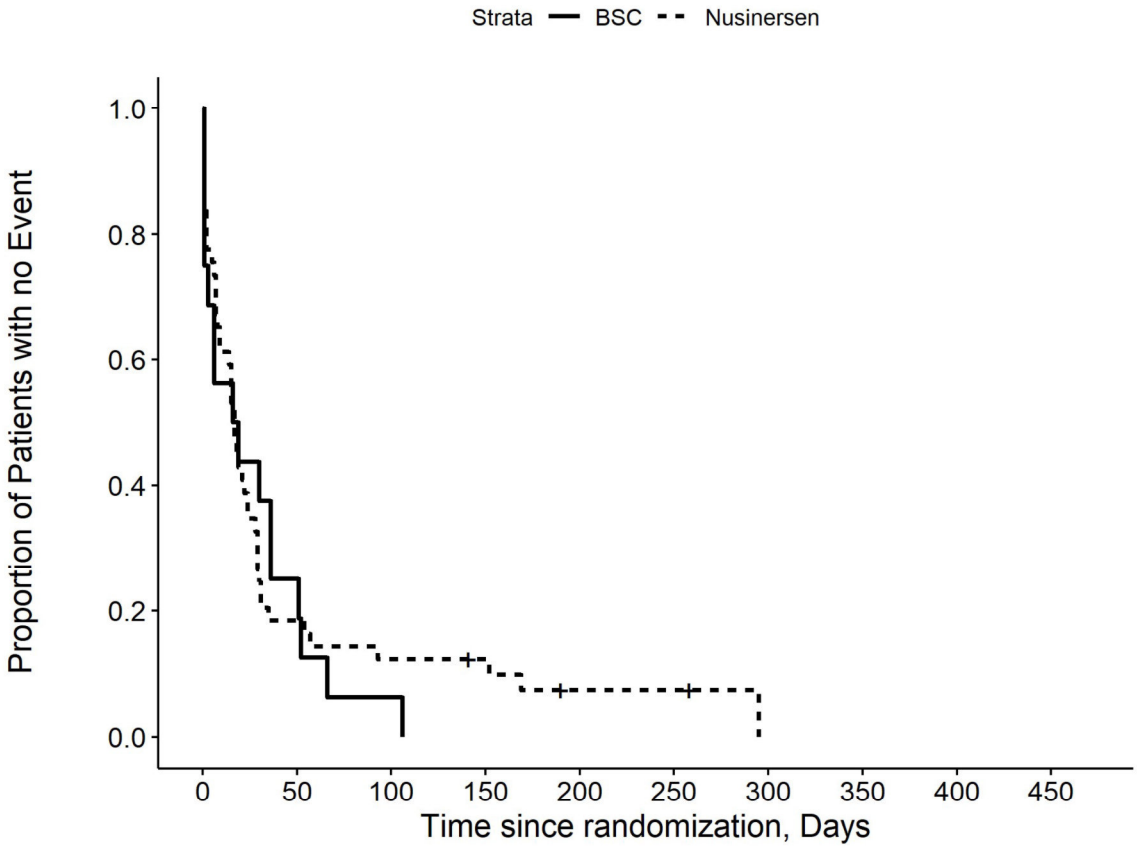
BSC	32	6	3	1	0	0	0	0	0	0
Nusinersen	72	12	6	5	2	2	0	0	0	0



Number at risk

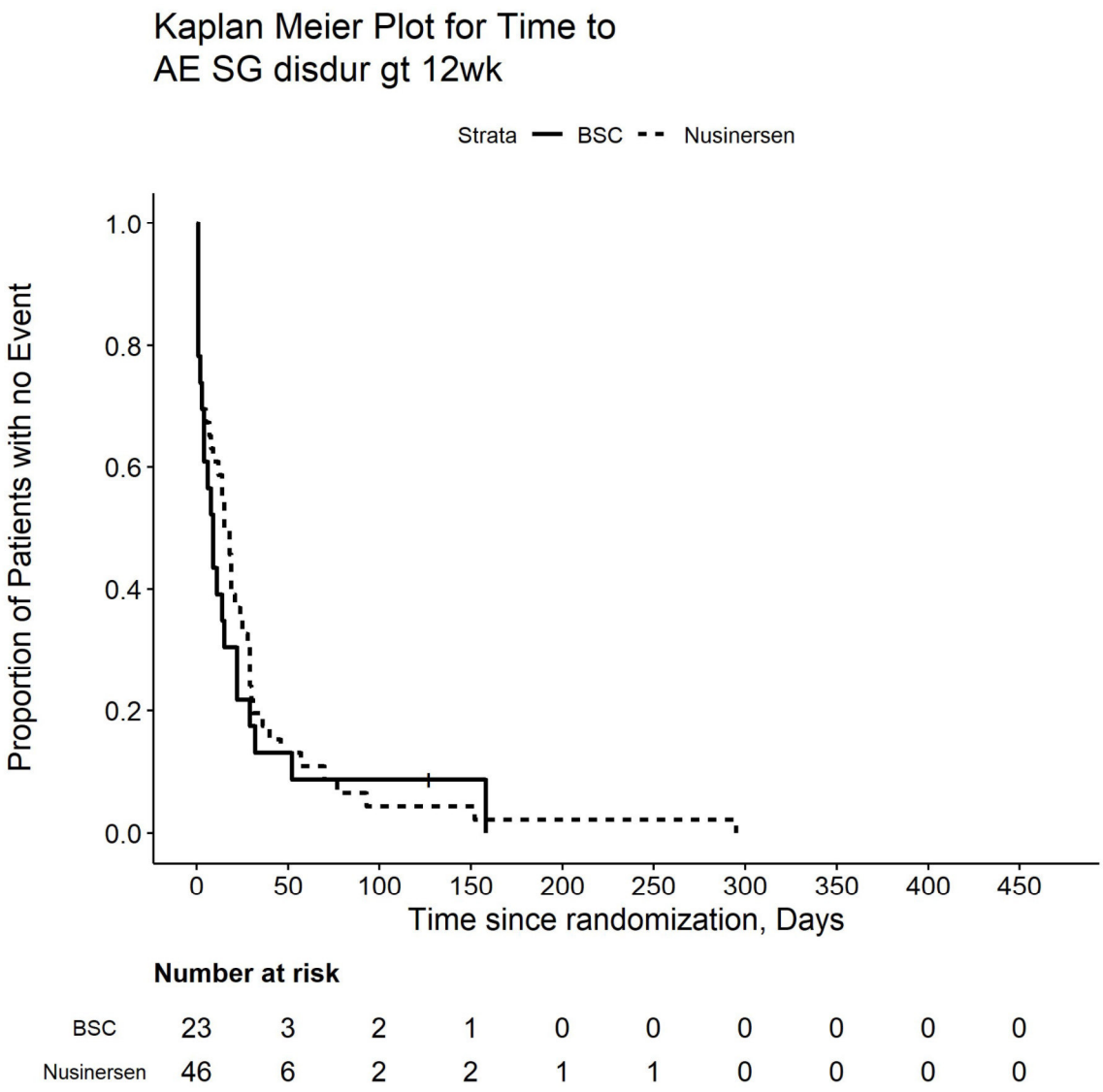
BSC	25	3	3	2	0	0	0	0	0	0
Nusinersen	31	4	0	0	0	0	0	0	0	0

Kaplan Meier Plot for Time to
AE SG agetrt lt 180d

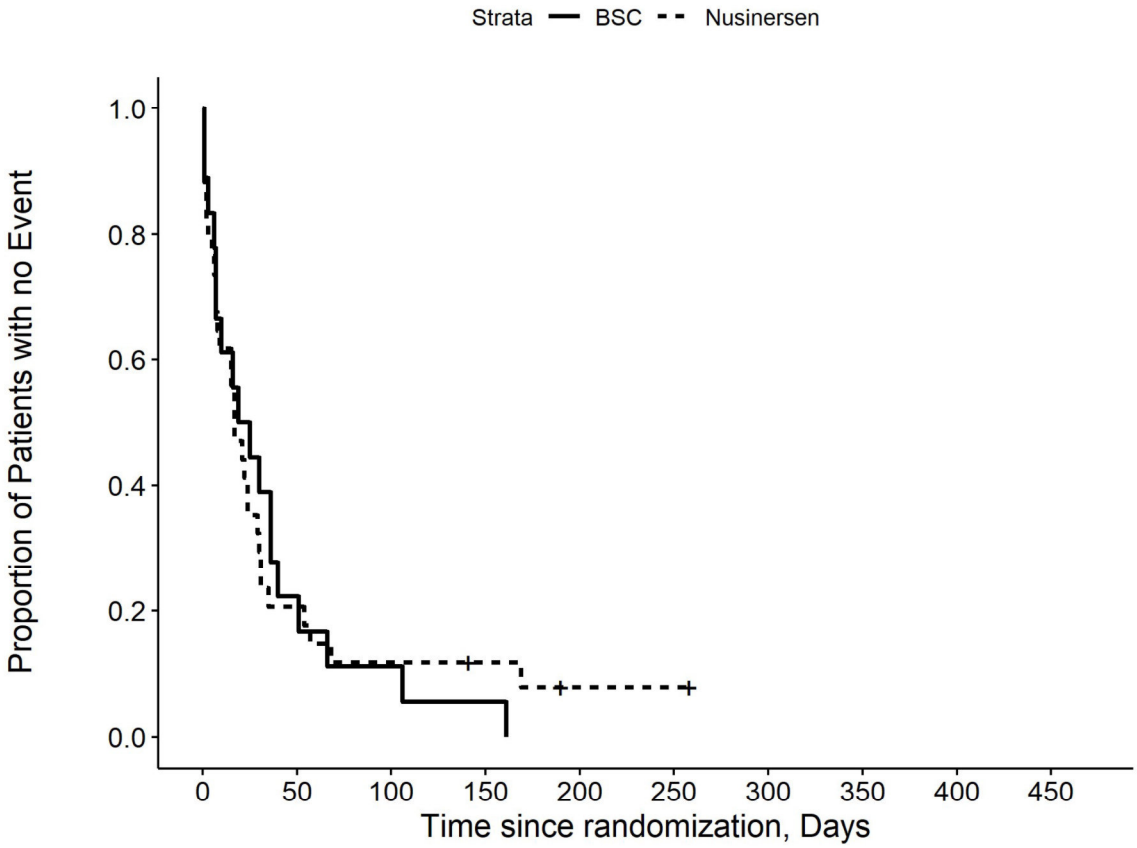


Number at risk

BSC	16	4	1	0	0	0	0	0	0	0
Nusinersen	49	9	6	5	2	2	0	0	0	0

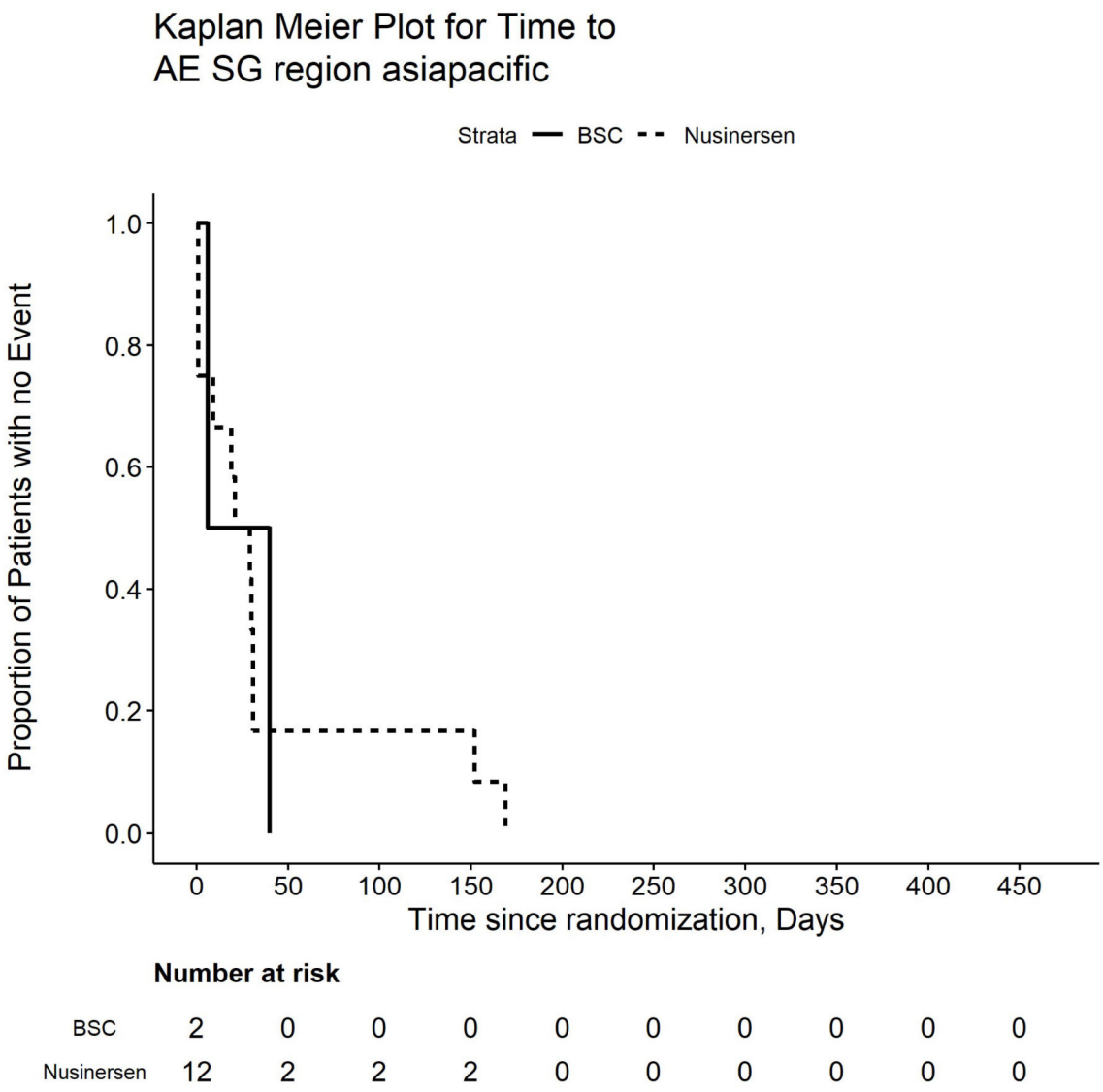

Kaplan Meier Plot for Time to
AE SG disdur gt 12wk
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0
50
100
150
200
250
300
350
400
450
Time since randomization, Days
Number at risk
BSC 23 3 2 1 0 0 0 0 0 0
Nusinersen 46 6 2 2 1 1 0 0 0 0

Kaplan Meier Plot for Time to
AE SG disdur le 12wek



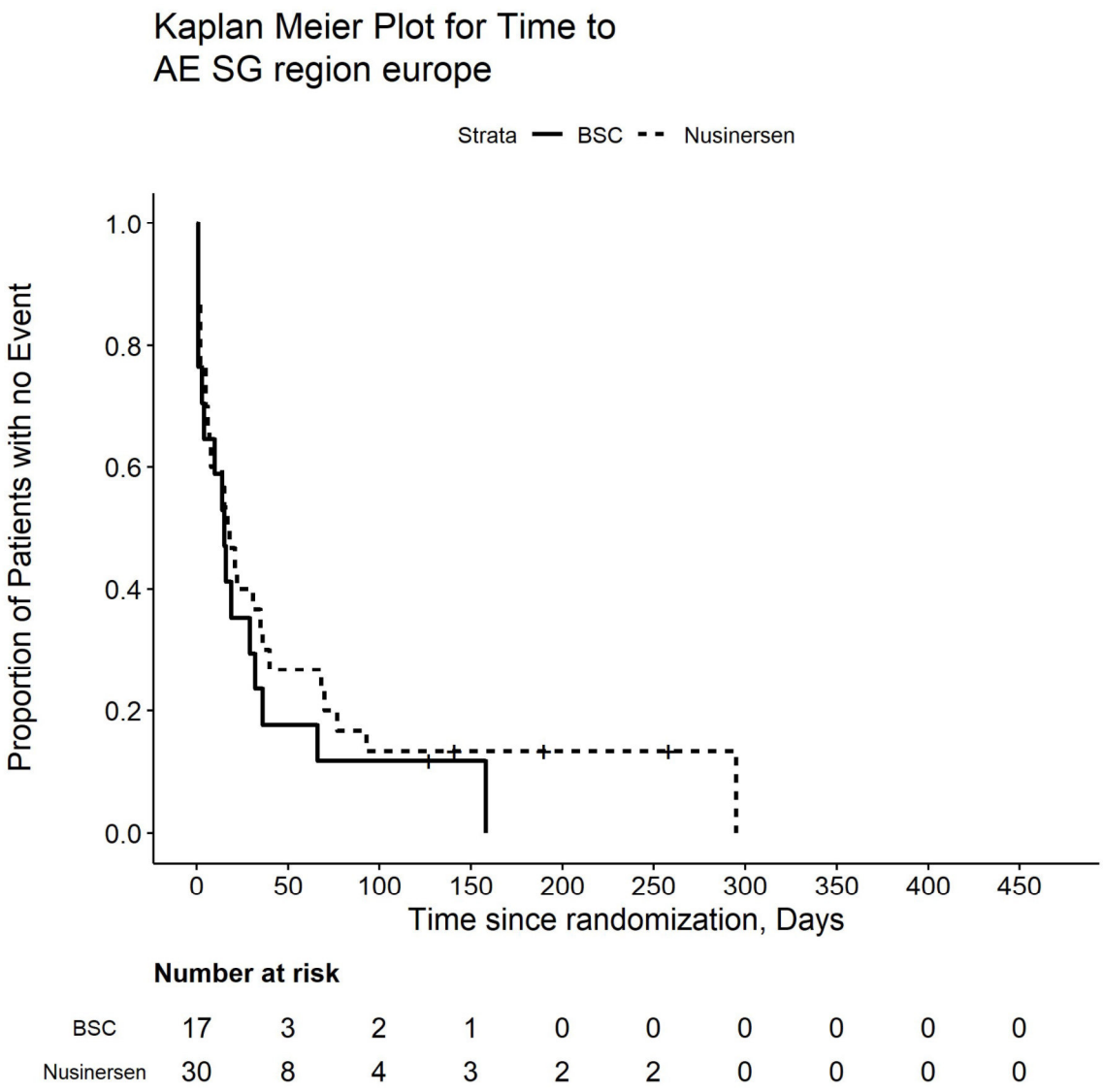
Number at risk

BSC	18	4	2	1	0	0	0	0	0	0
Nusinersen	34	7	4	3	1	1	0	0	0	0



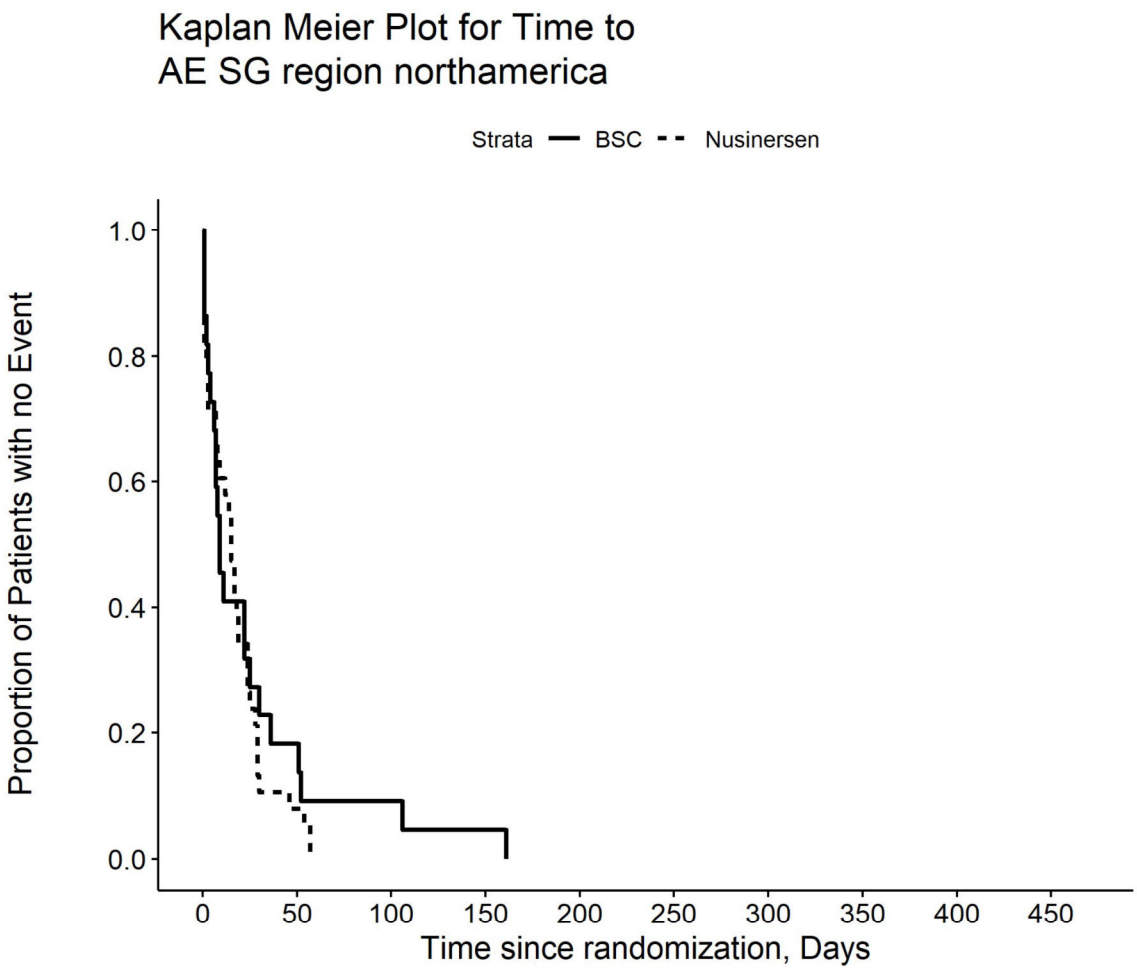
Number at risk

BSC	2	0	0	0	0	0	0	0	0	0
Nusinersen	12	2	2	2	0	0	0	0	0	0



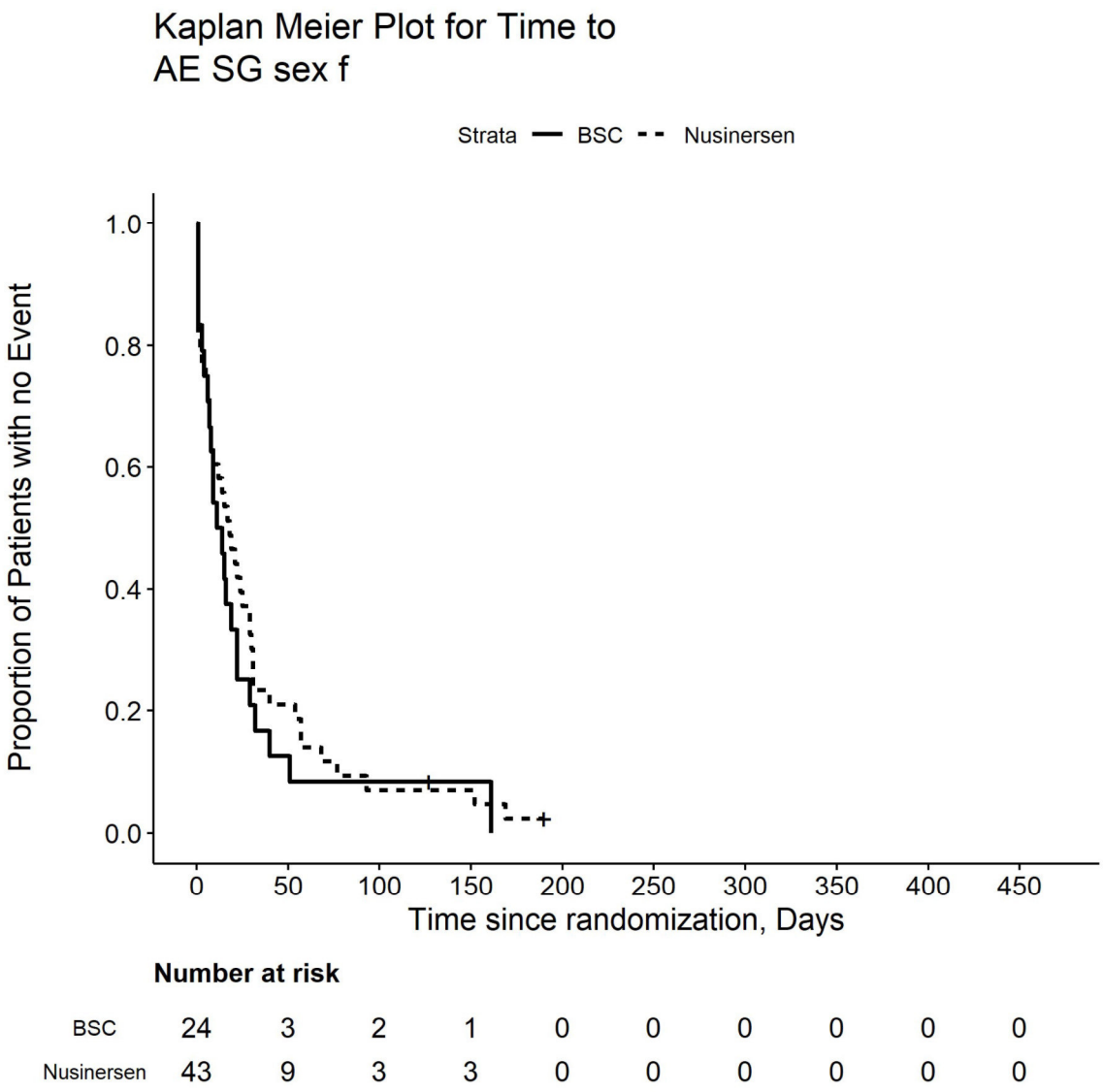
Number at risk

BSC	17	3	2	1	0	0	0	0	0	0
Nusinersen	30	8	4	3	2	2	0	0	0	0



Number at risk

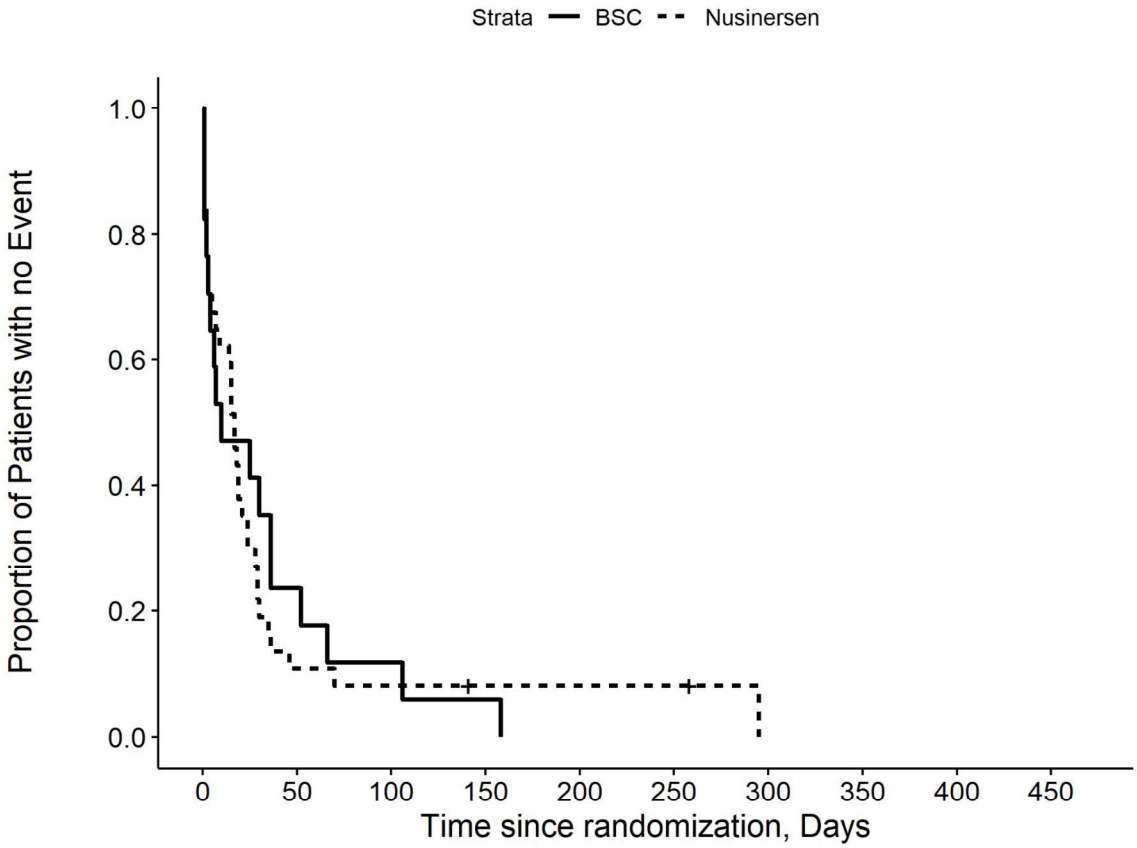
BSC	22	4	2	1	0	0	0	0	0	0
Nusinersen	38	3	0	0	0	0	0	0	0	0



Number at risk

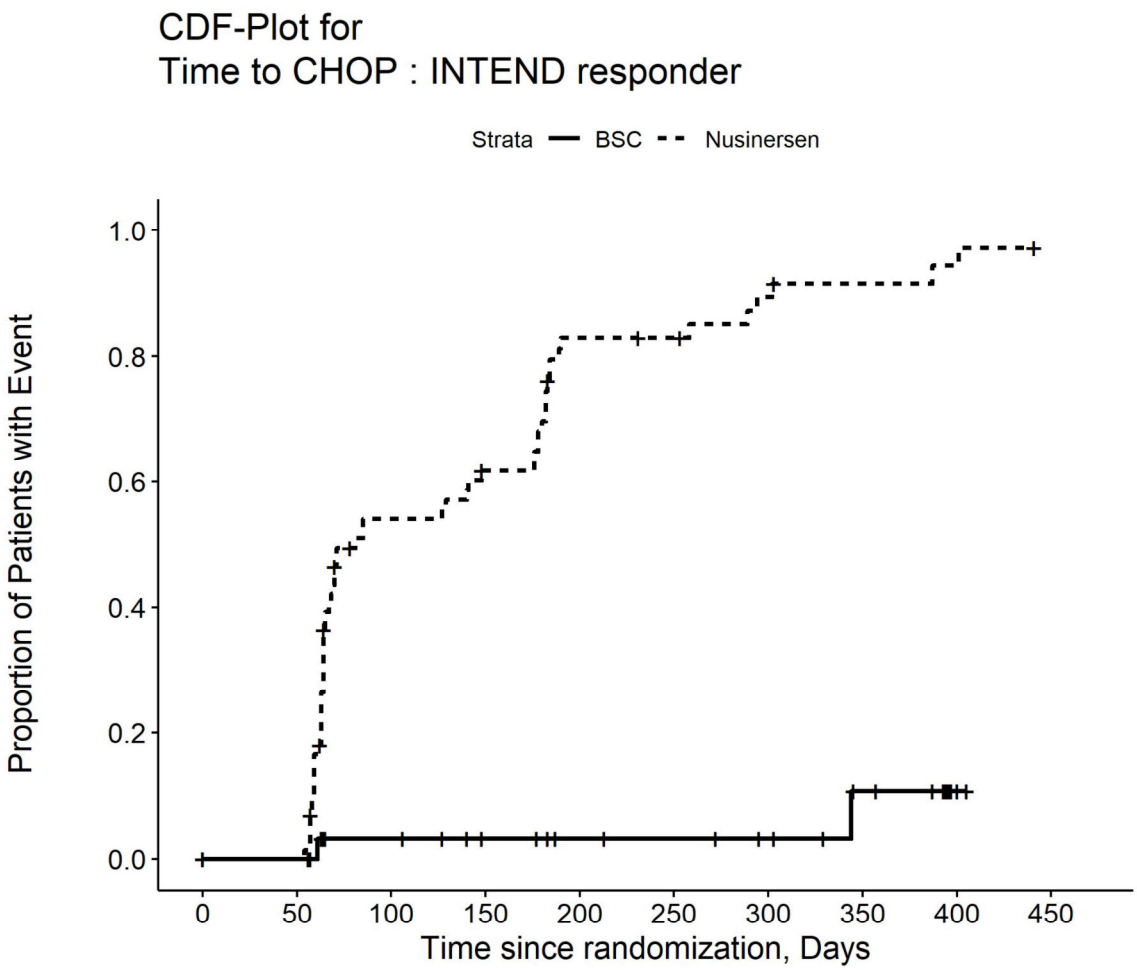
BSC	24	3	2	1	0	0	0	0	0	0
Nusinersen	43	9	3	3	0	0	0	0	0	0

Kaplan Meier Plot for Time to
AE SG sex m



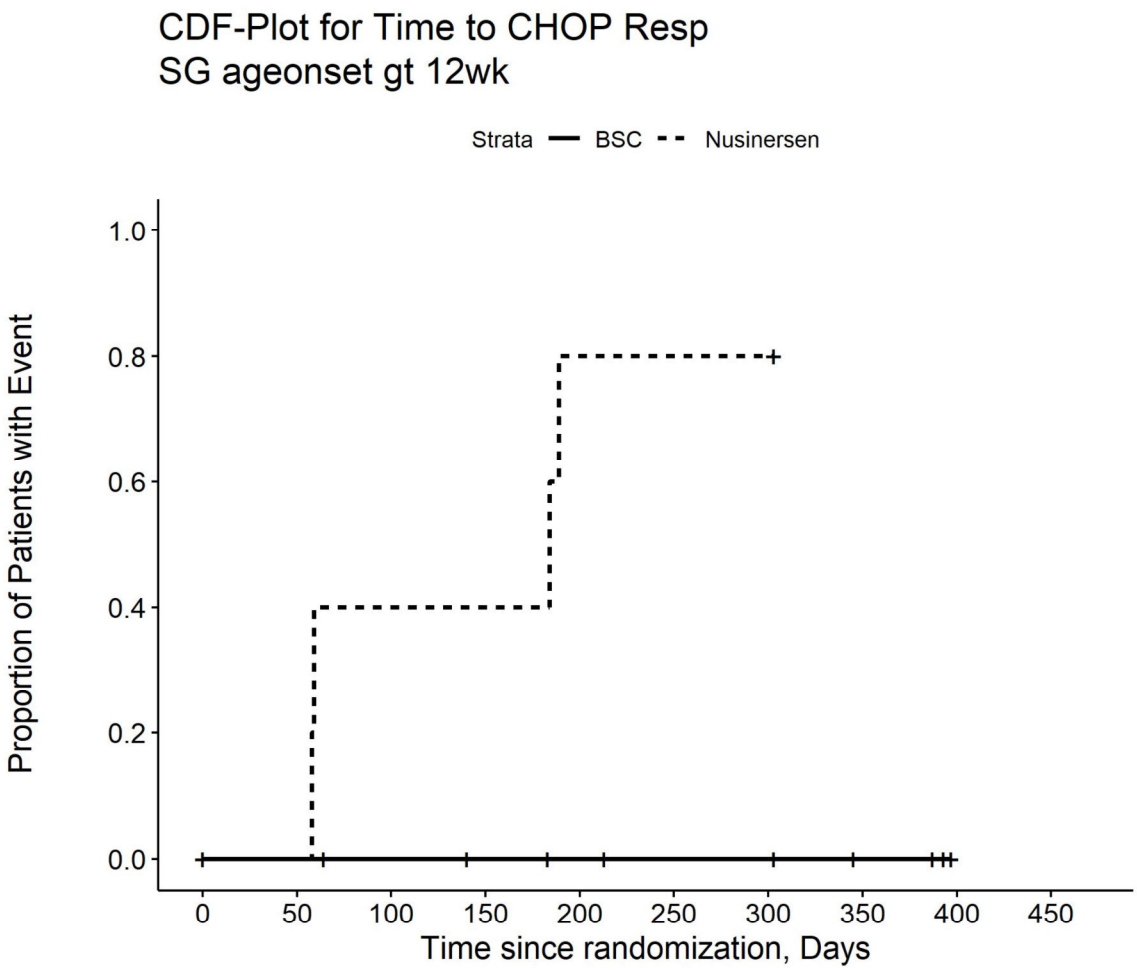
Number at risk

BSC	17	4	2	1	0	0	0	0	0	0
Nusinersen	37	4	3	2	2	2	0	0	0	0



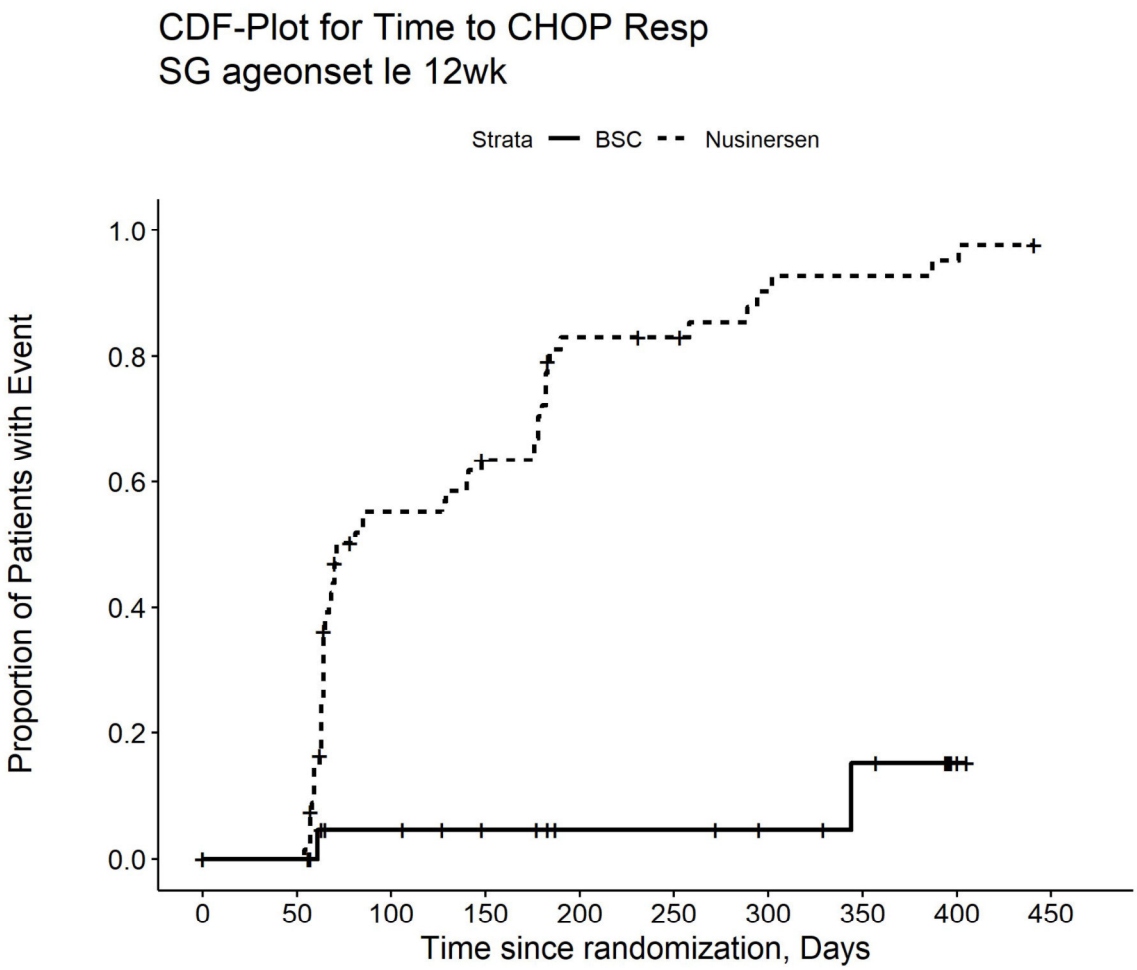
Number at risk

BSC	41	33	26	22	18	17	15	11	2	0
Nusinersen	80	73	30	24	10	9	5	3	2	0



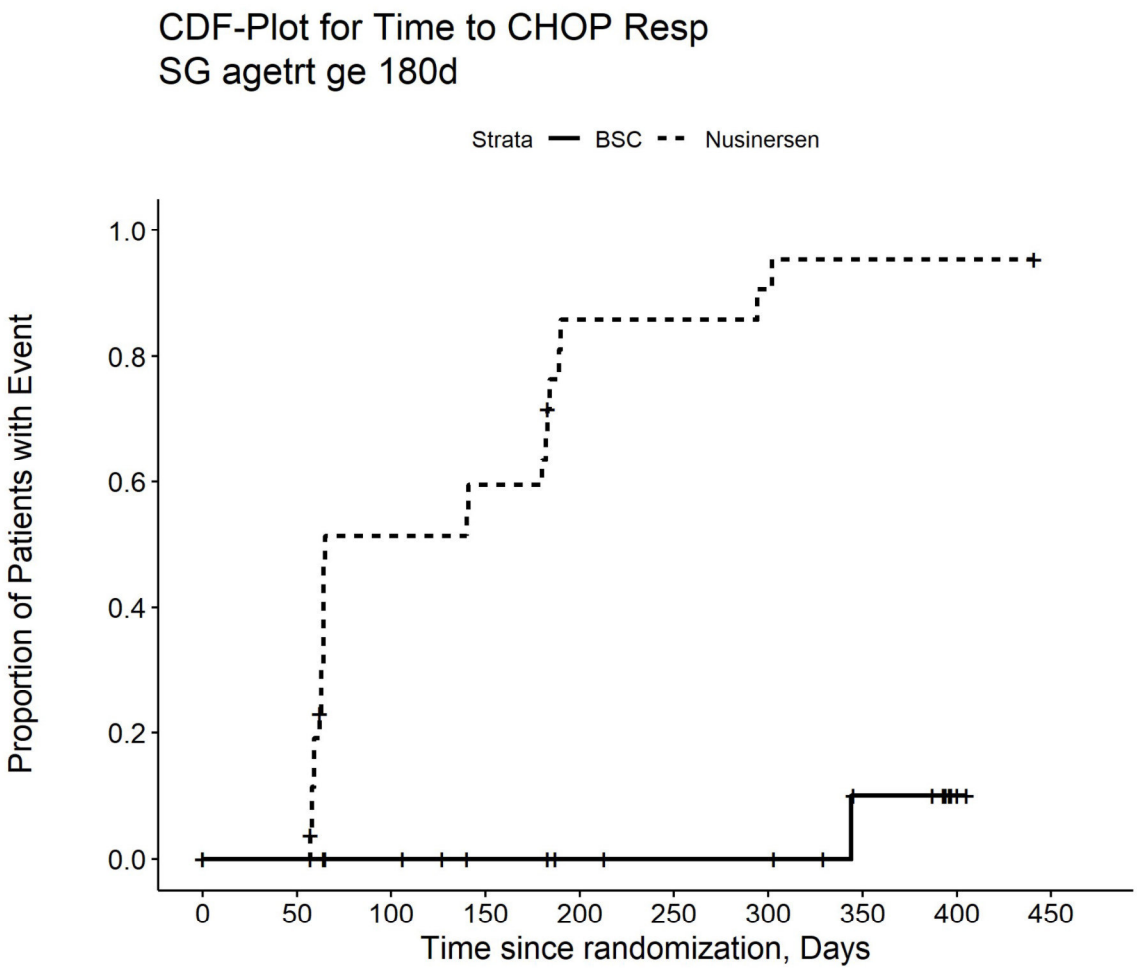
Number at risk

BSC	9	9	8	7	6	5	5	3	0	0
Nusinersen	8	5	3	3	1	1	1	0	0	0



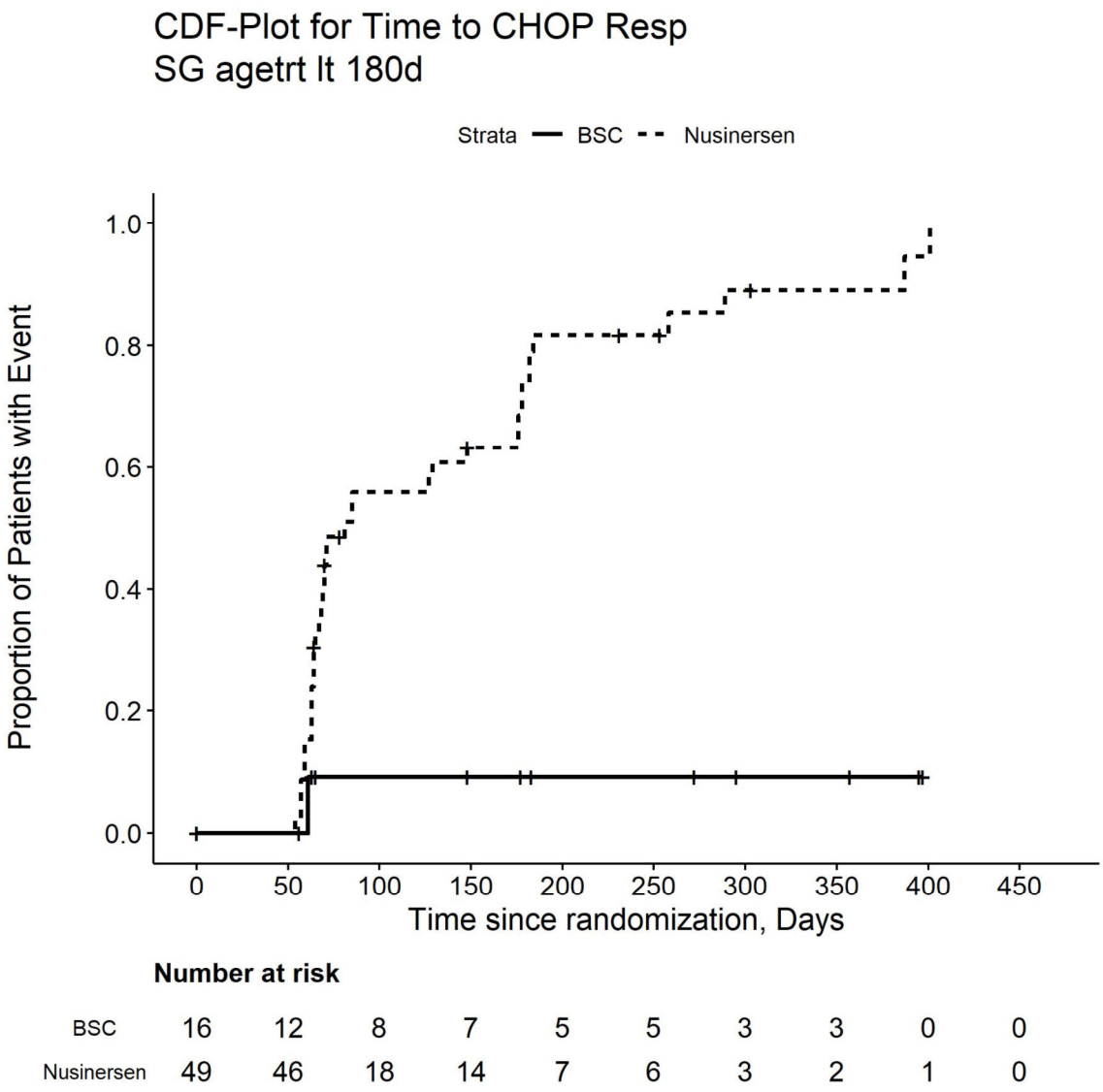
Number at risk

BSC	32	24	18	15	12	12	10	8	2	0
Nusinersen	72	68	27	21	9	8	4	3	2	0



Number at risk

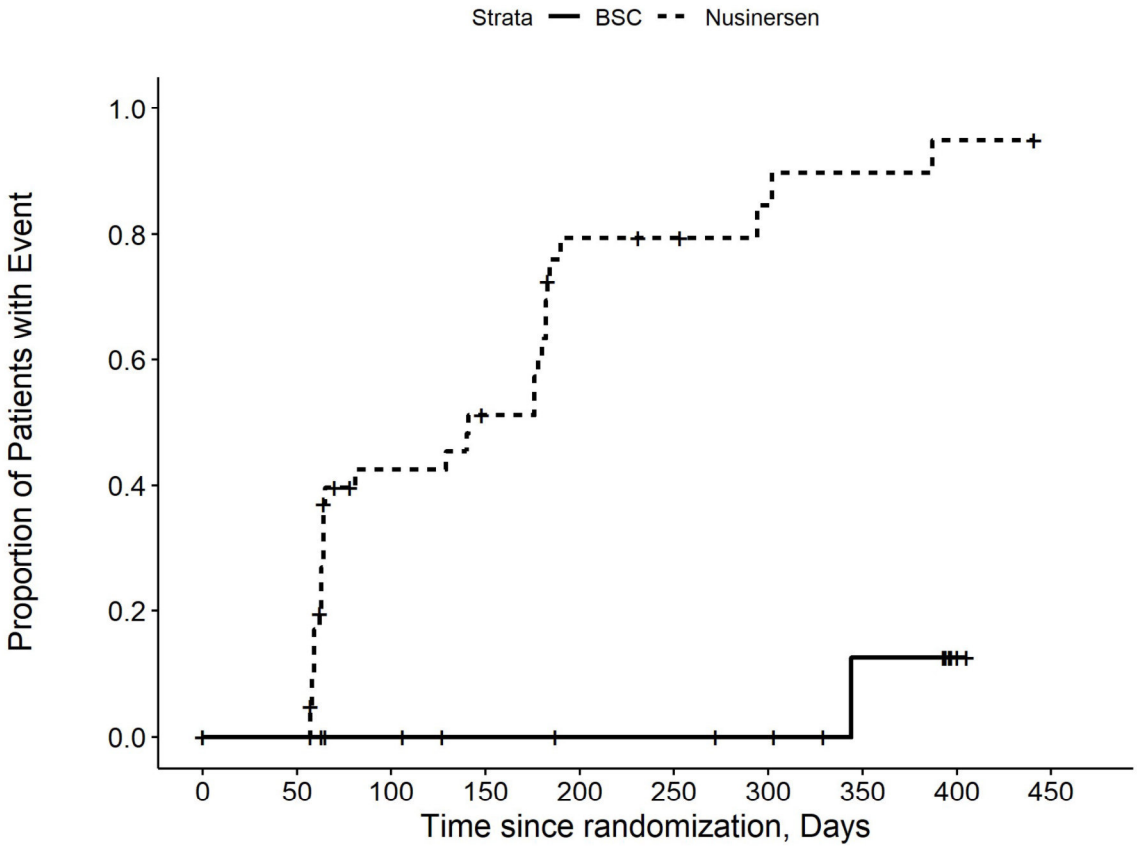
BSC	25	21	18	15	13	12	12	8	2	0
Nusinersen	31	27	12	10	3	3	2	1	1	0



Number at risk

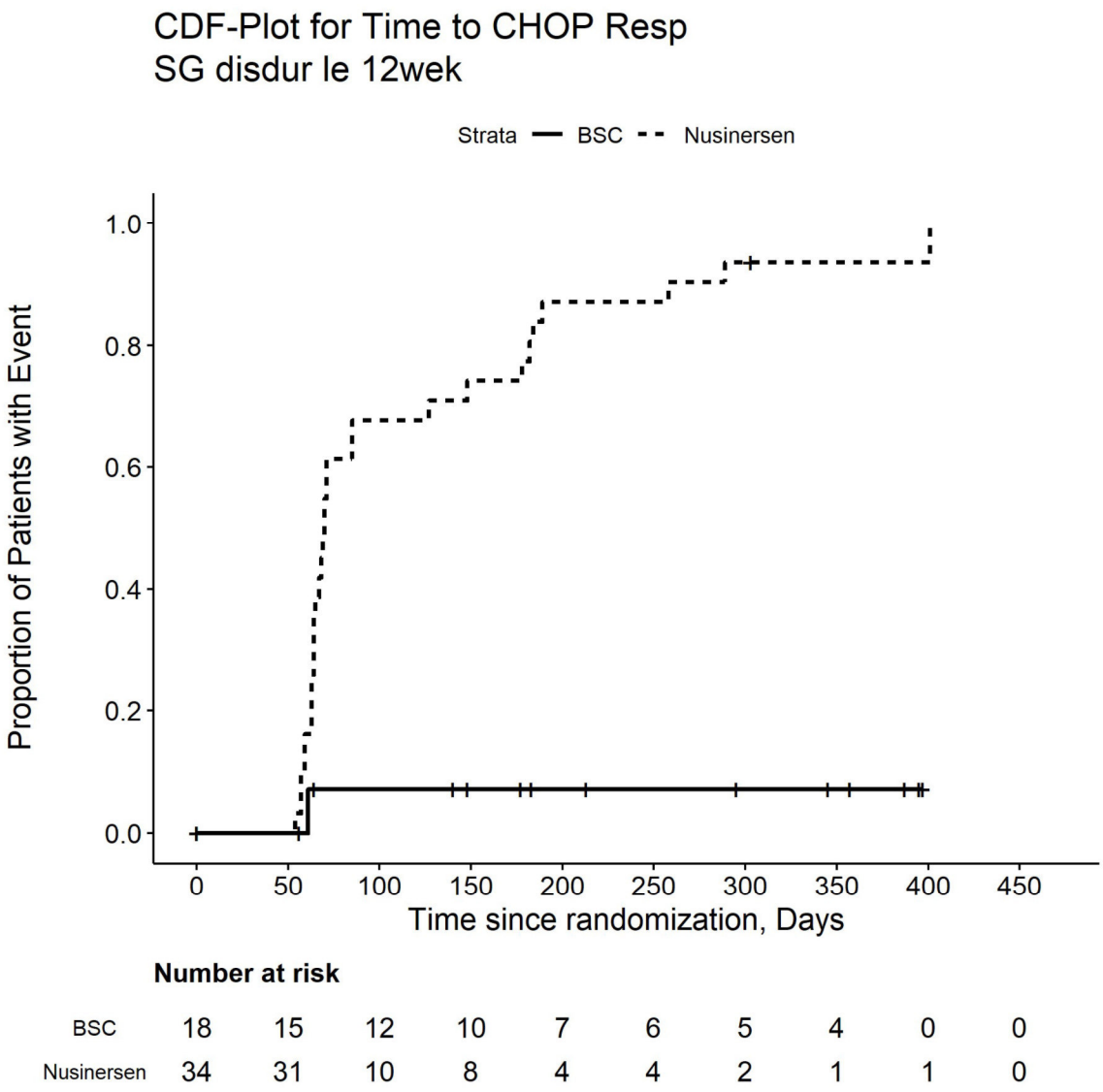
BSC	16	12	8	7	5	5	3	3	0	0
Nusinersen	49	46	18	14	7	6	3	2	1	0

CDF-Plot for Time to CHOP Resp
SG disdur gt 12wk



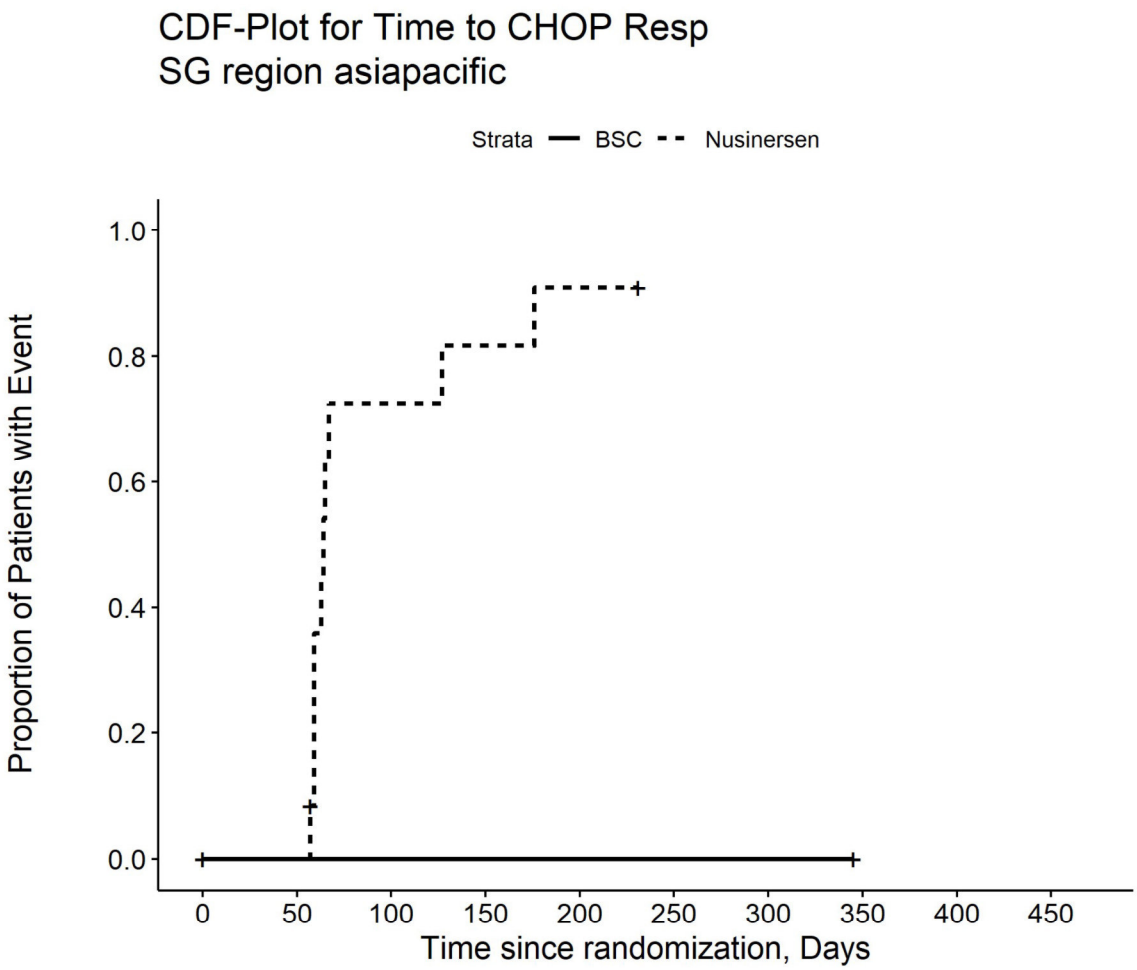
Number at risk

BSC	23	18	14	12	11	11	10	7	2	0
Nusinersen	46	42	20	16	6	5	3	2	1	0



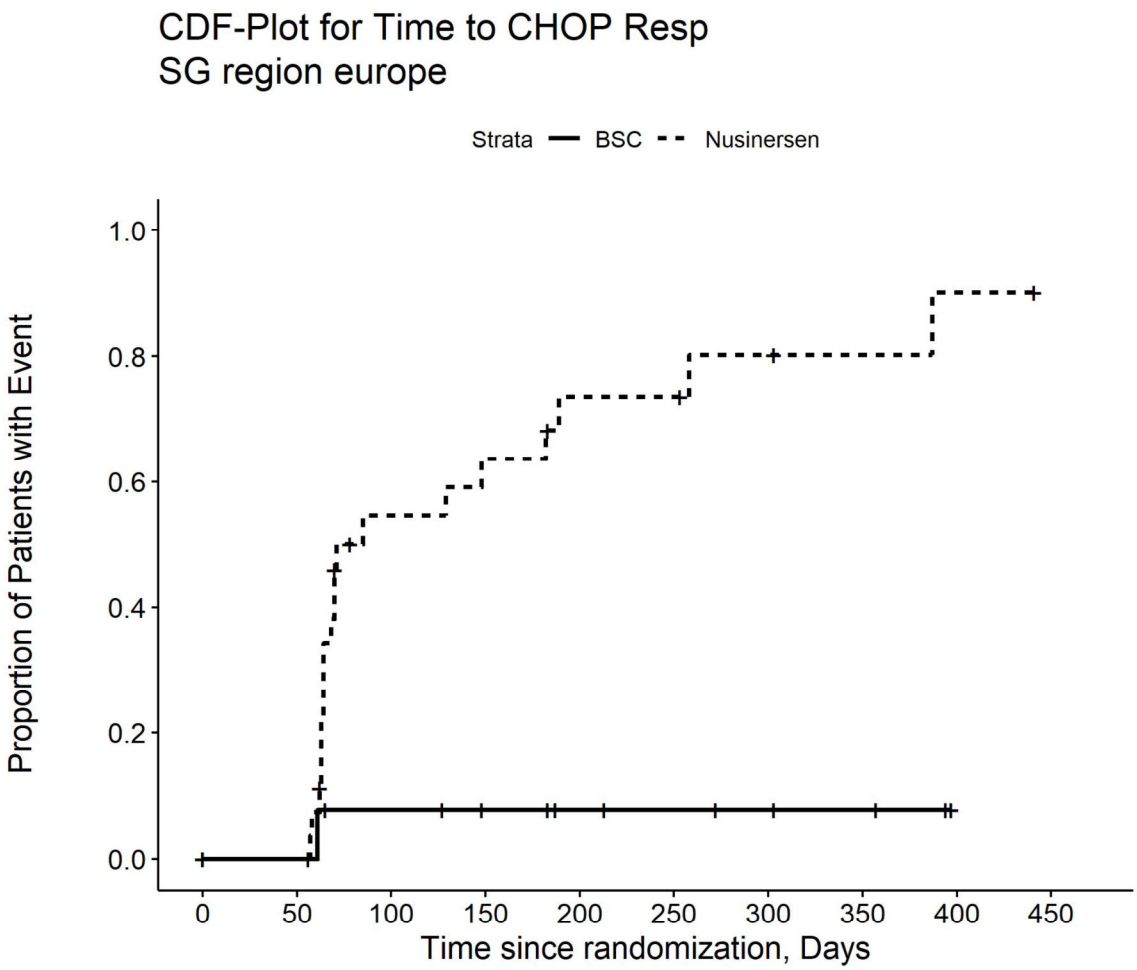
Number at risk

BSC	18	15	12	10	7	6	5	4	0	0
Nusinersen	34	31	10	8	4	4	2	1	1	0



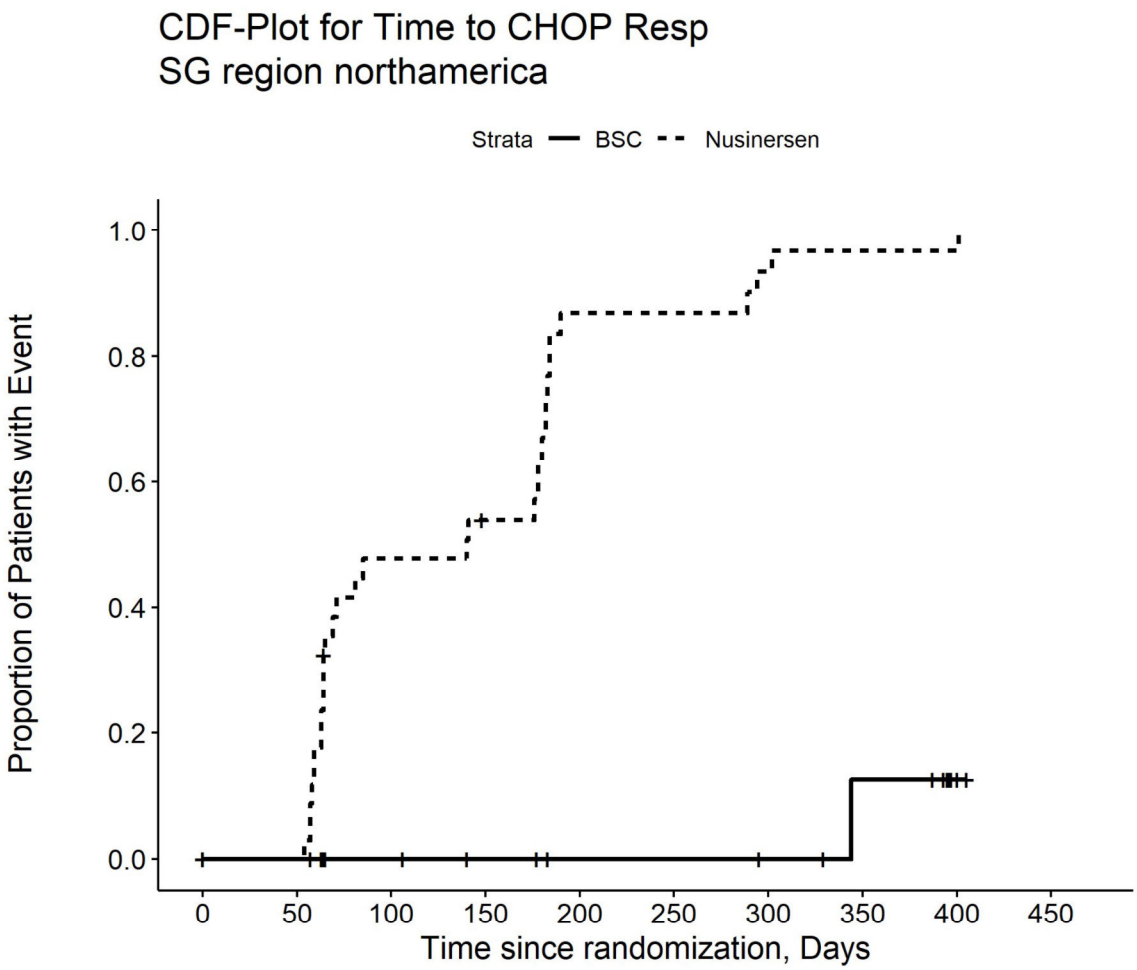
Number at risk

BSC	2	1	1	1	1	1	1	0	0	0
Nusinersen	12	12	3	2	1	0	0	0	0	0



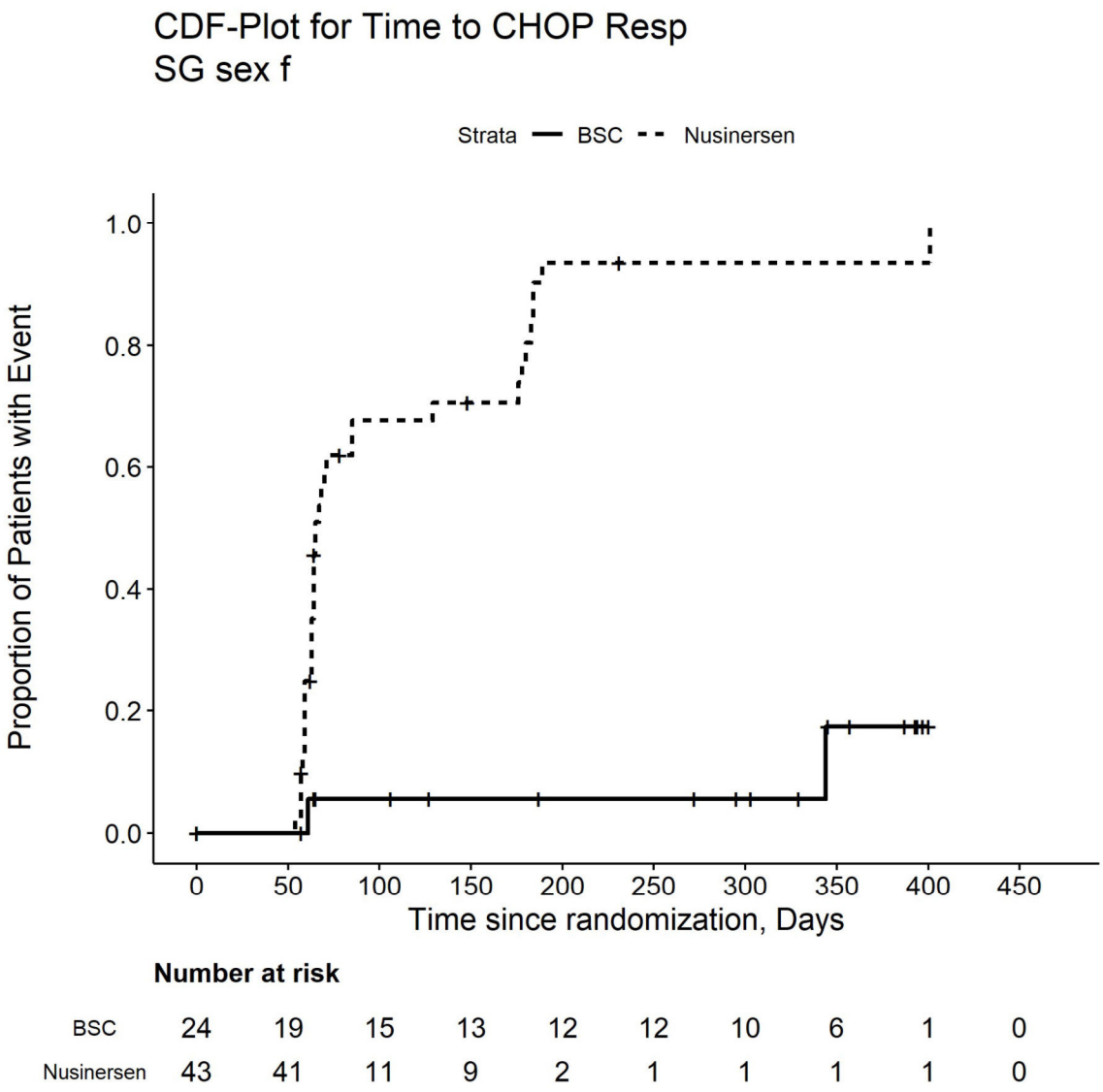
Number at risk

BSC	17	14	11	9	7	6	5	4	0	0
Nusinersen	30	27	10	8	5	5	3	2	1	0



Number at risk

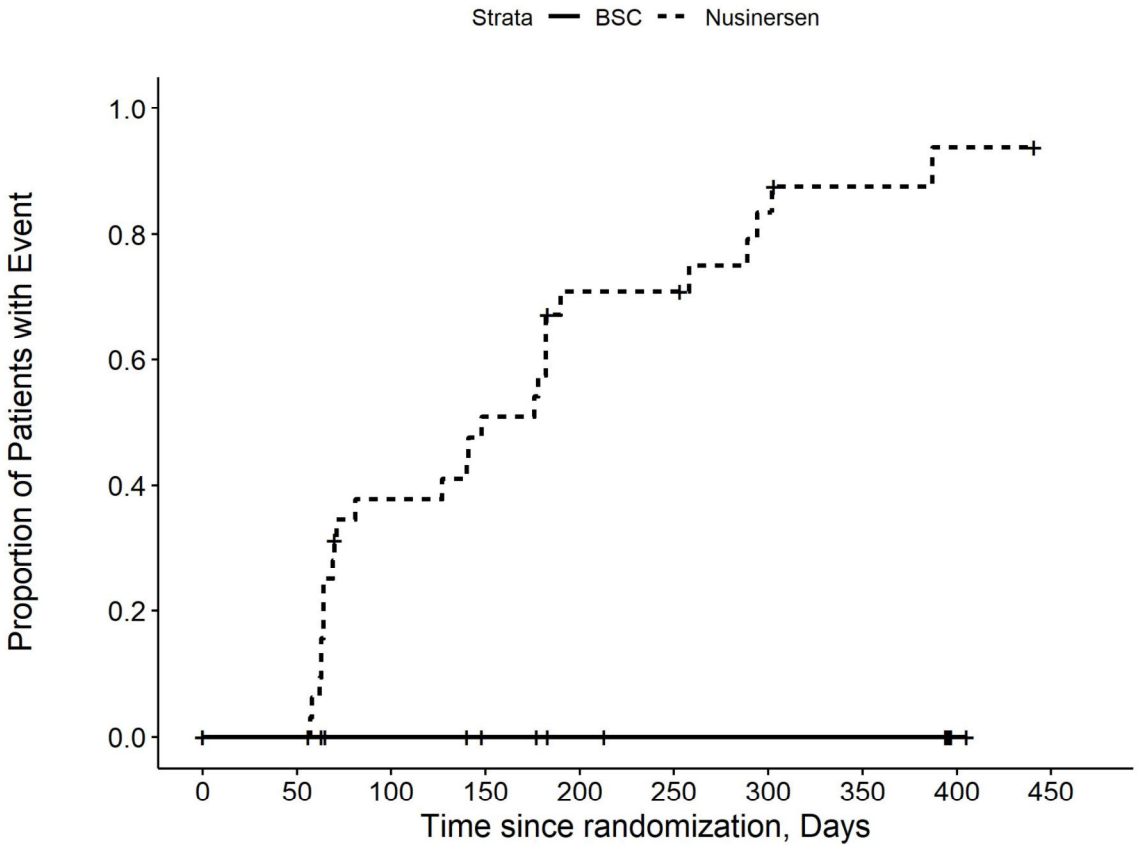
BSC	22	18	14	12	10	10	9	7	2	0
Nusinersen	38	34	17	14	4	4	2	1	1	0



Number at risk

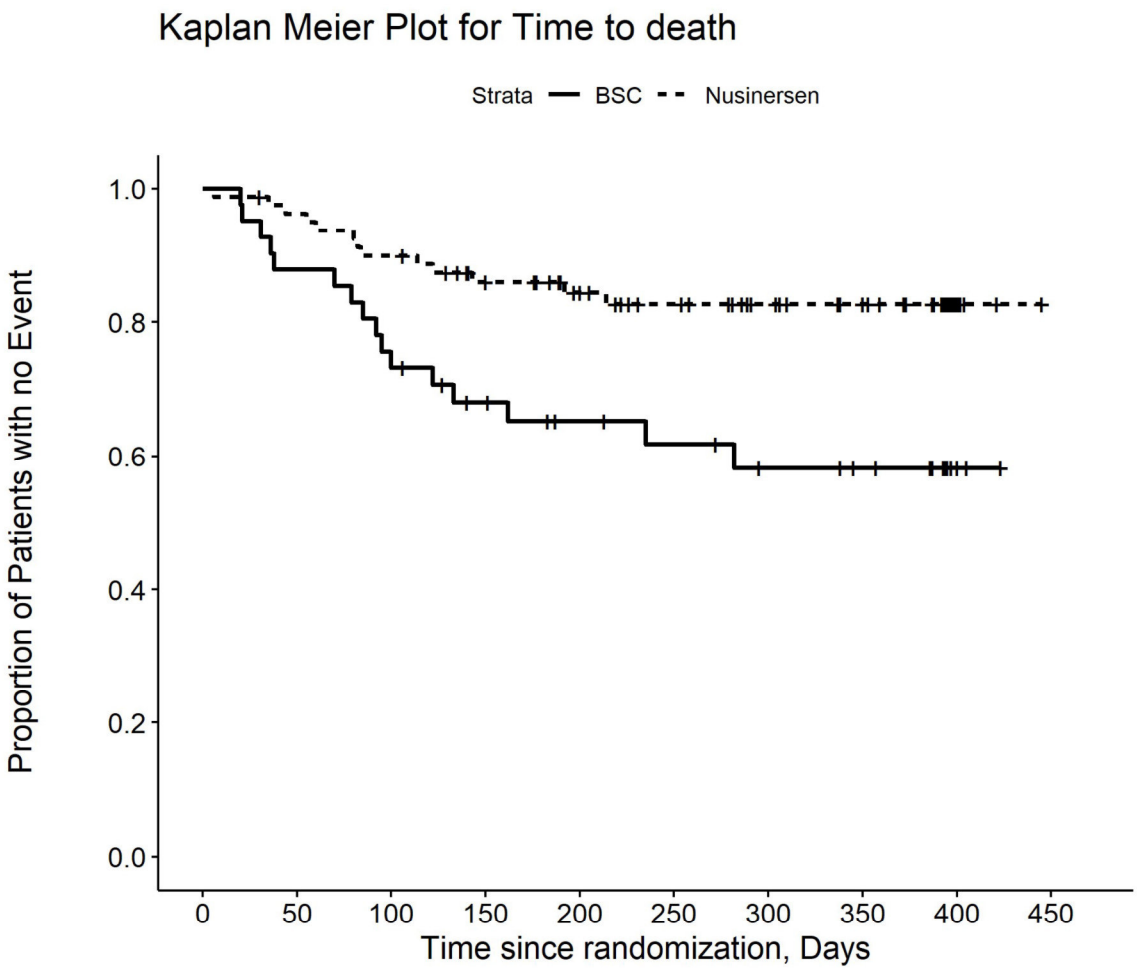
BSC	24	19	15	13	12	12	10	6	1	0
Nusinersen	43	41	11	9	2	1	1	1	1	0

CDF-Plot for Time to CHOP Resp
SG sex m



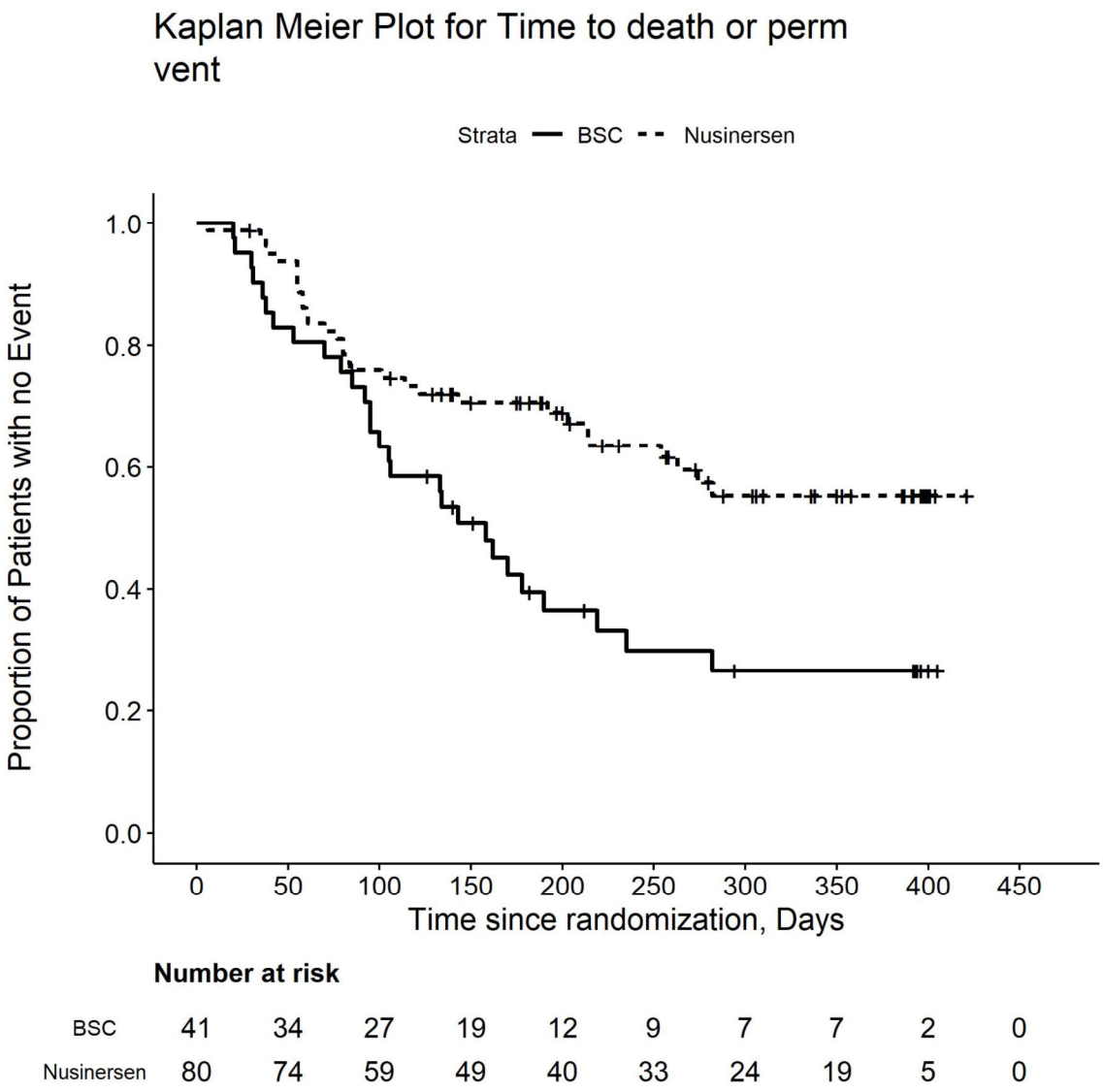
Number at risk

BSC	17	14	11	9	6	5	5	5	1	0
Nusinersen	37	32	19	15	8	8	4	2	1	0



Number at risk

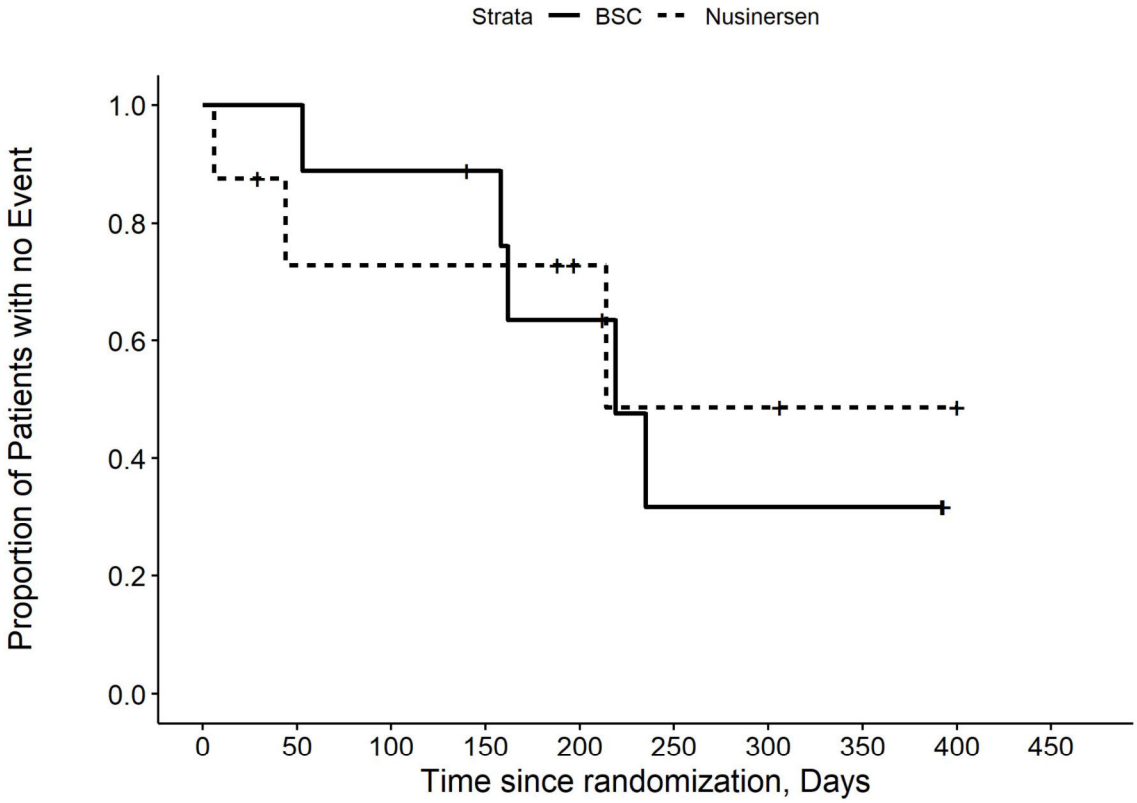
BSC	41	36	31	25	20	18	15	13	4	0
Nusinersen	80	76	71	62	52	44	36	31	11	0



Number at risk

BSC	41	34	27	19	12	9	7	7	2	0
Nusinersen	80	74	59	49	40	33	24	19	5	0

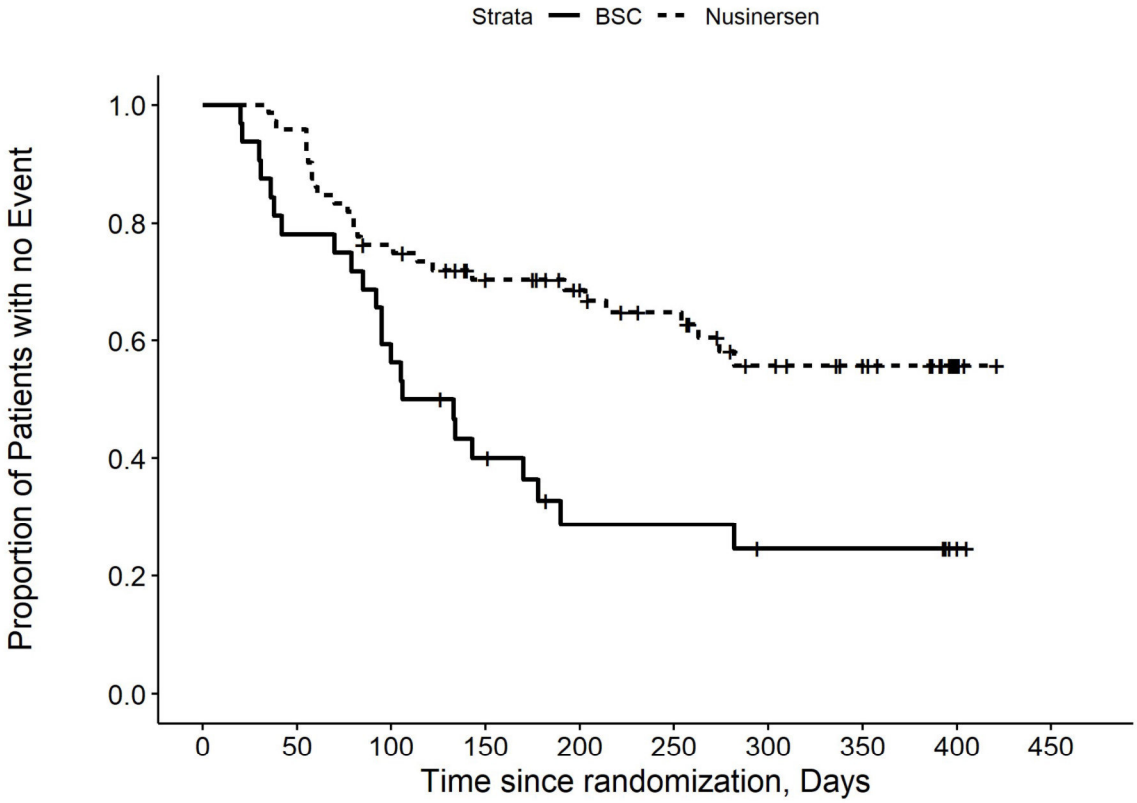
Kaplan Meier Plot for Time to death or permVent SG ageonset gt 12wk



Number at risk

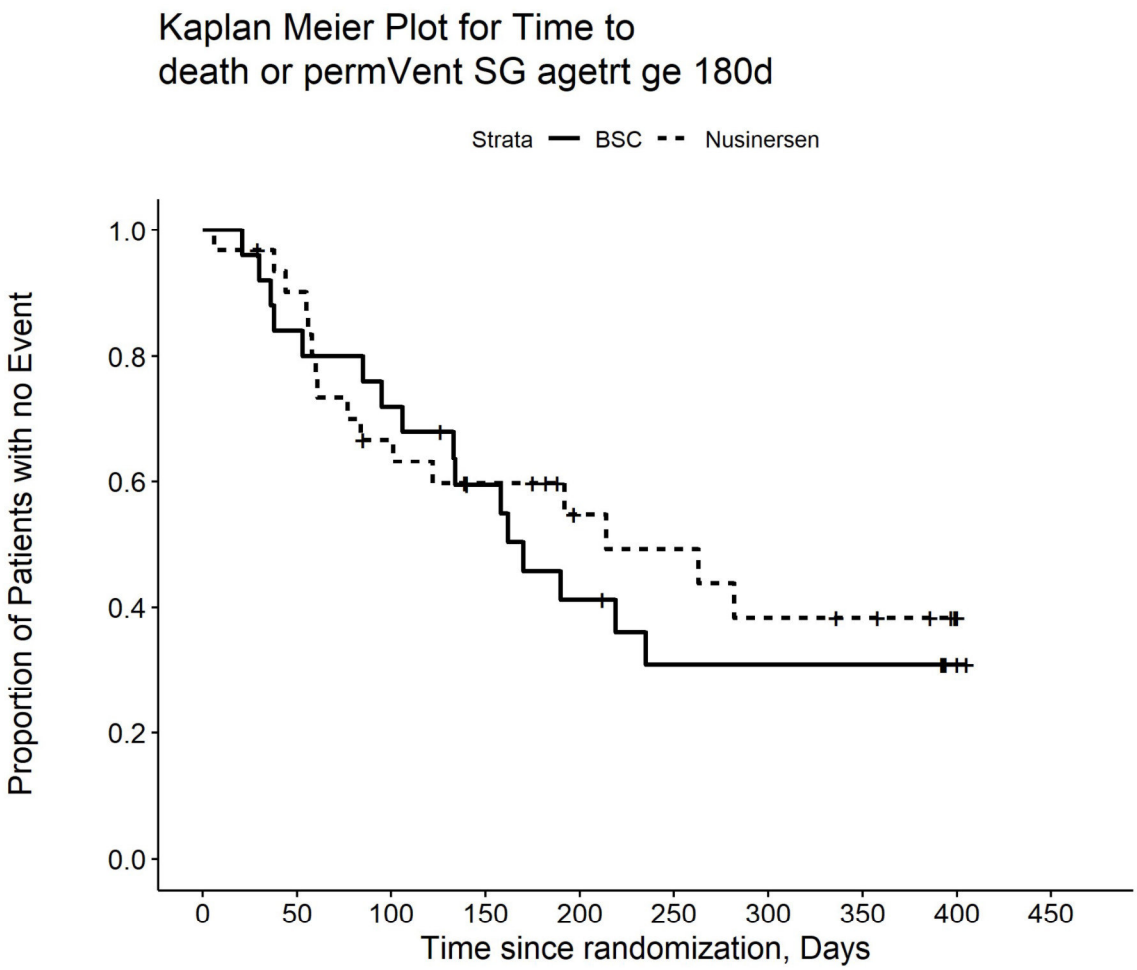
BSC	9	9	8	7	5	2	2	2	0	0
Nusinersen	8	5	5	5	3	2	2	1	1	0

Kaplan Meier Plot for Time to death or permVent SG ageonset le 12wk



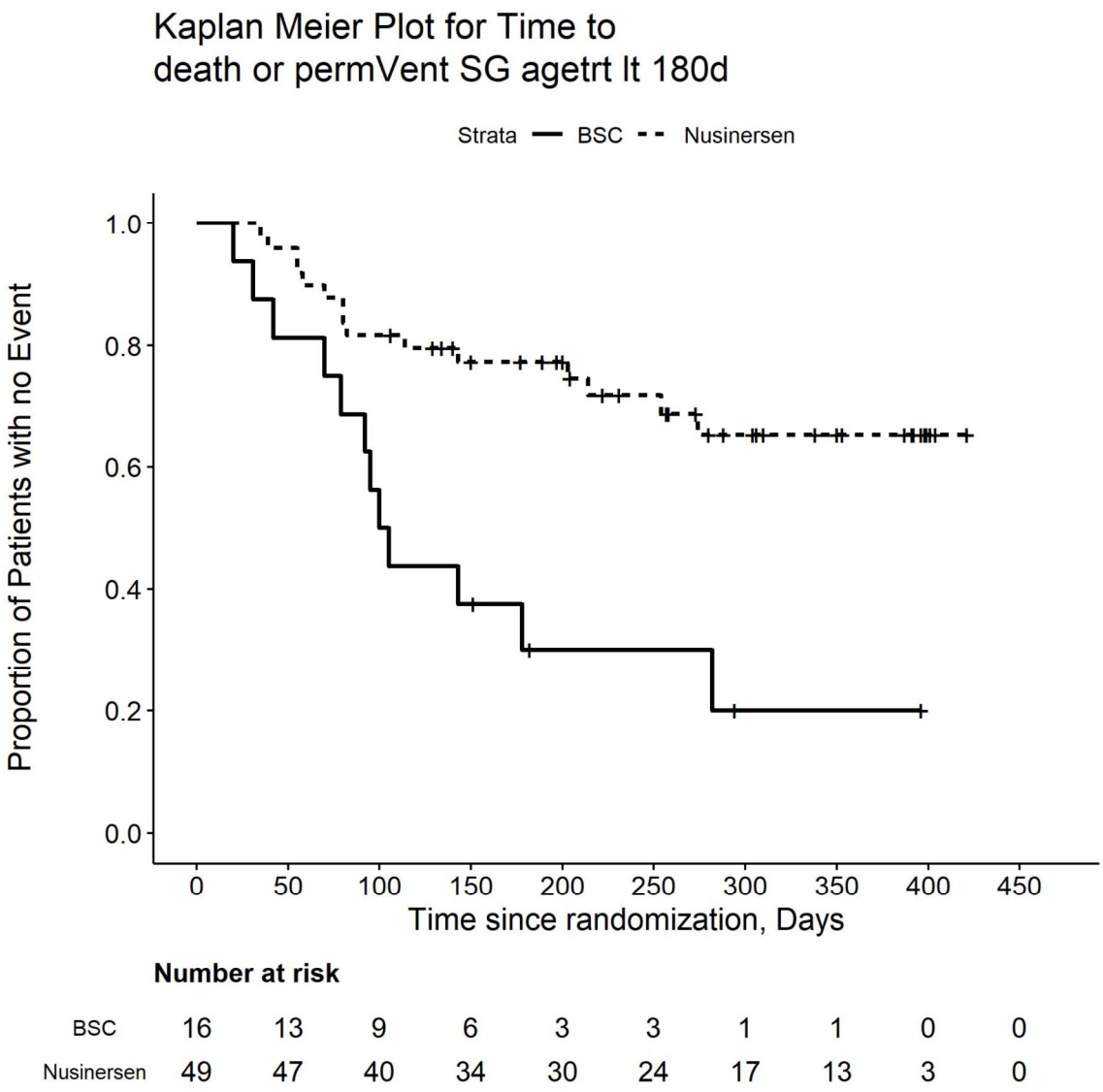
Number at risk

BSC	32	25	19	12	7	7	5	5	2	0
Nusinersen	72	69	54	44	37	31	22	18	4	0



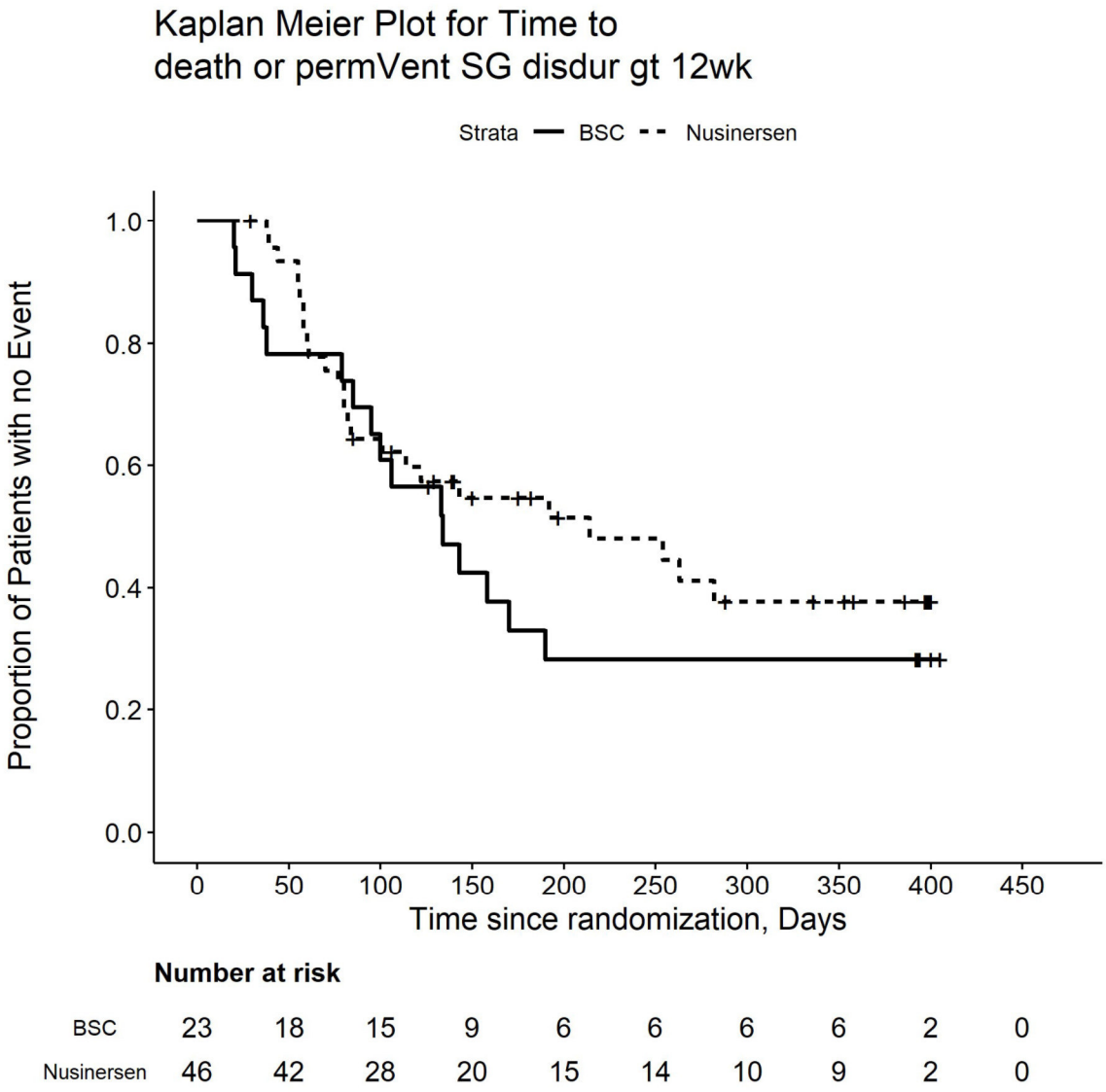
Number at risk

BSC	25	21	18	13	9	6	6	6	2	0
Nusinersen	31	27	19	15	10	9	7	6	2	0



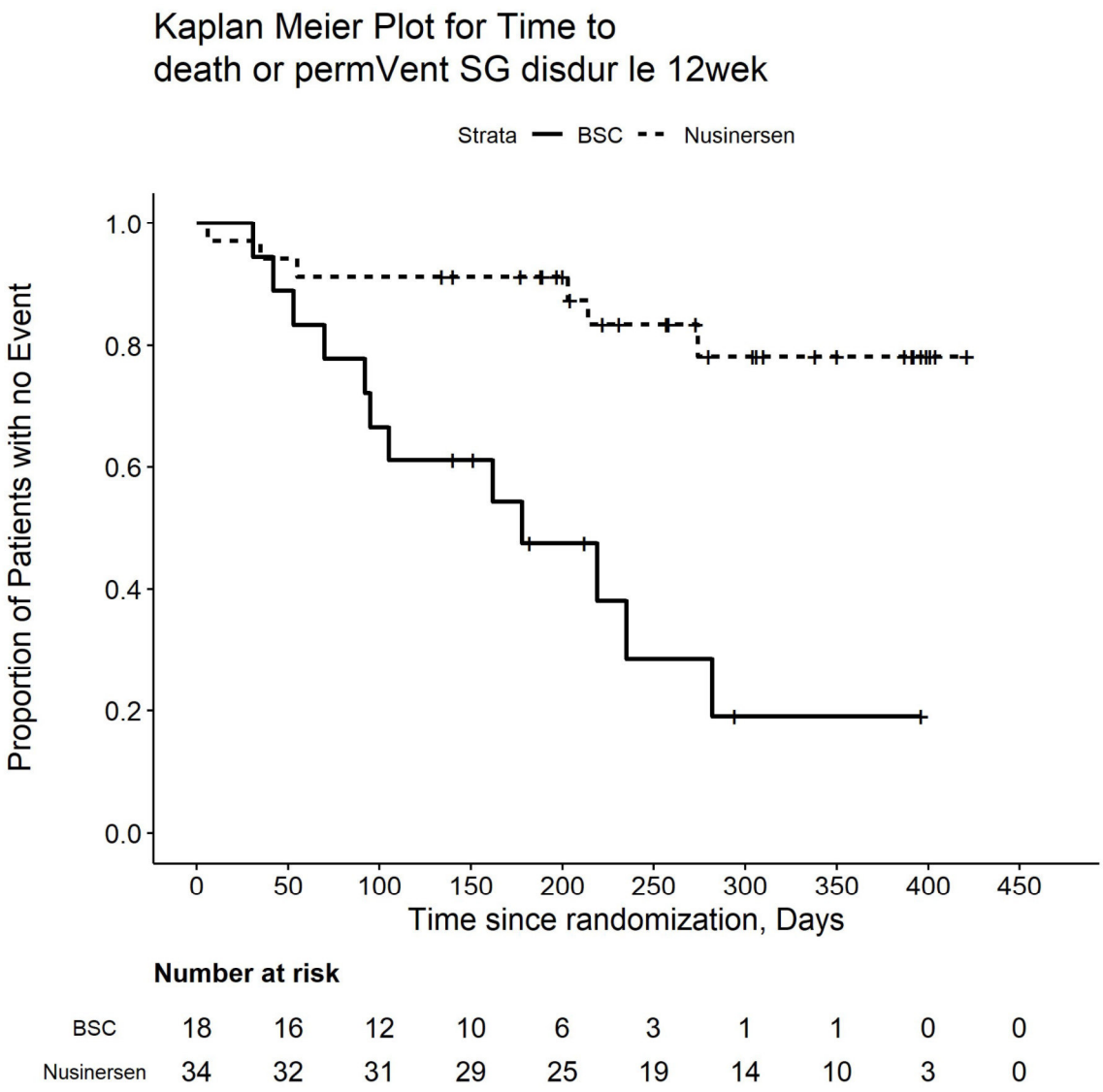
Number at risk

BSC	16	13	9	6	3	3	1	1	0	0
Nusinersen	49	47	40	34	30	24	17	13	3	0



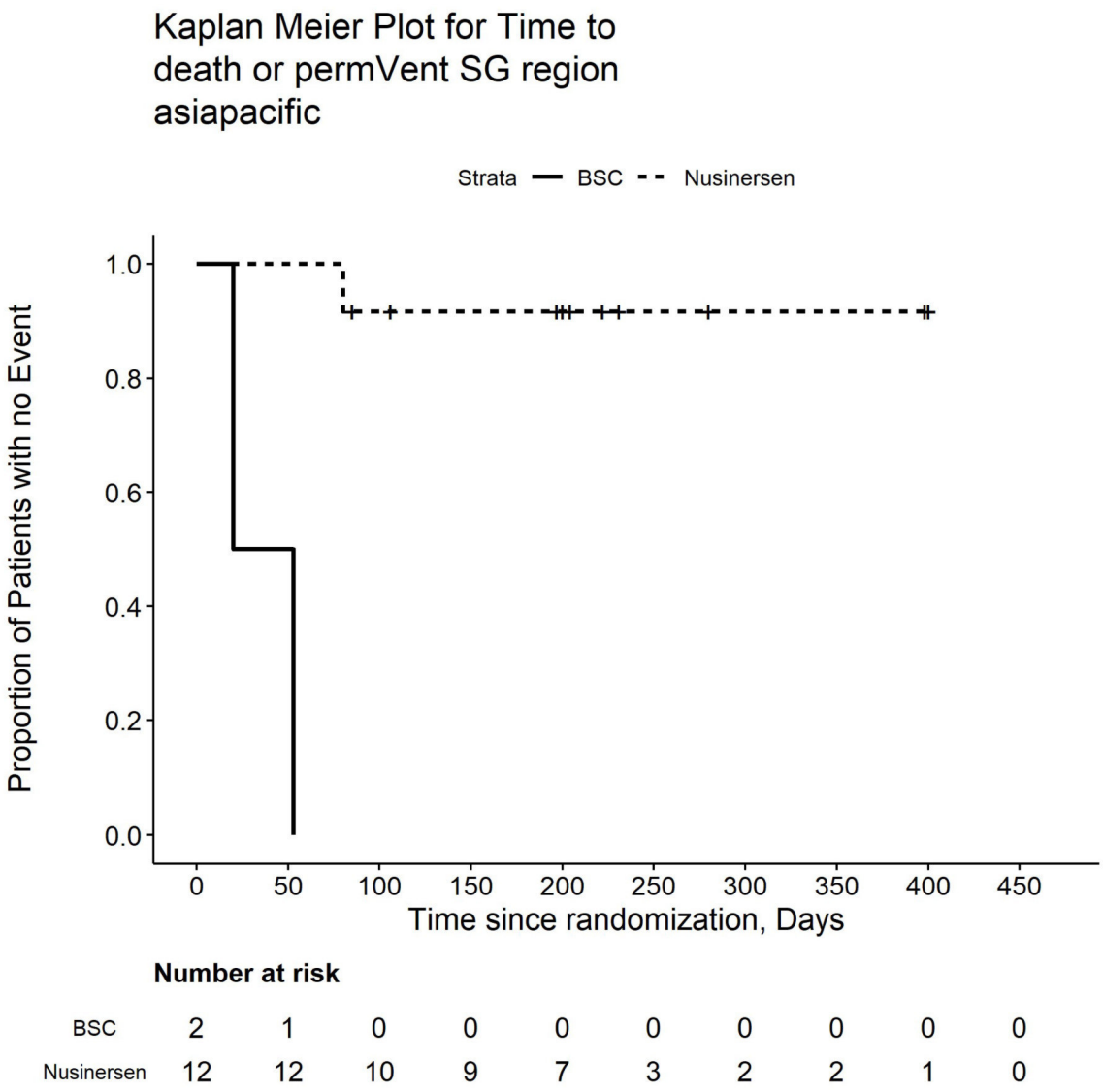
Number at risk

BSC	23	18	15	9	6	6	6	6	2	0
Nusinersen	46	42	28	20	15	14	10	9	2	0



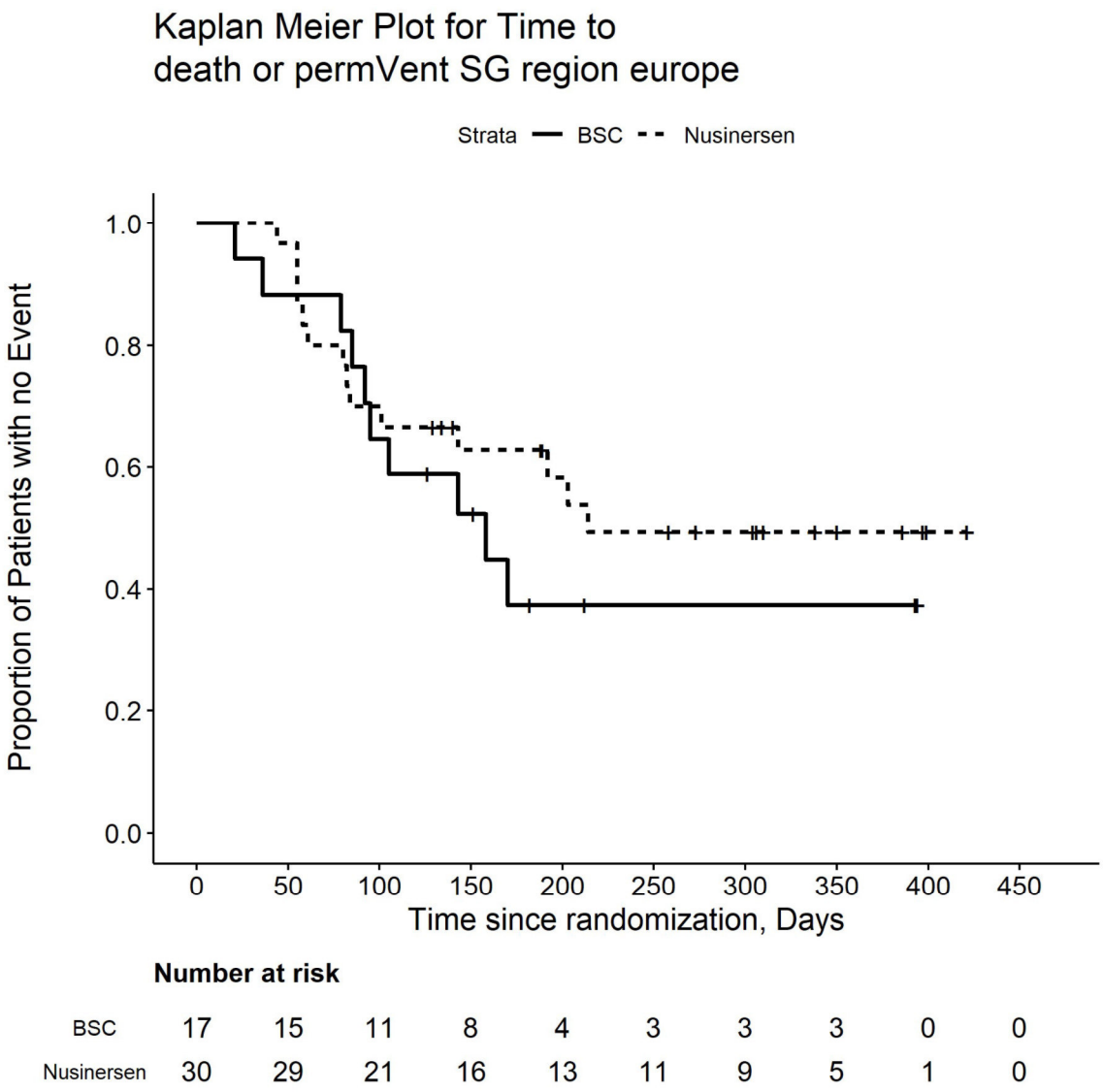
Number at risk

BSC	18	16	12	10	6	3	1	1	0	0
Nusinersen	34	32	31	29	25	19	14	10	3	0



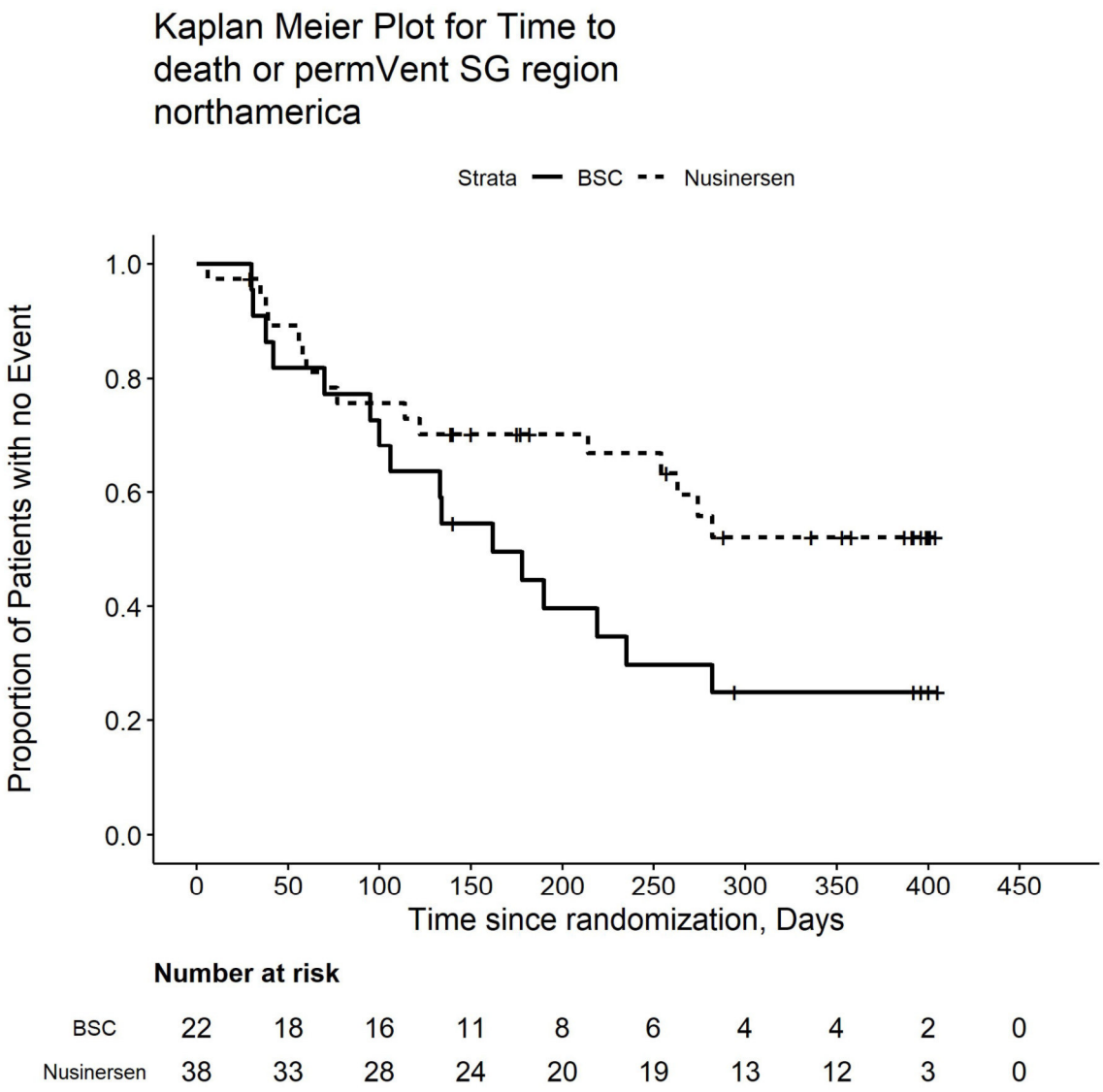
Number at risk

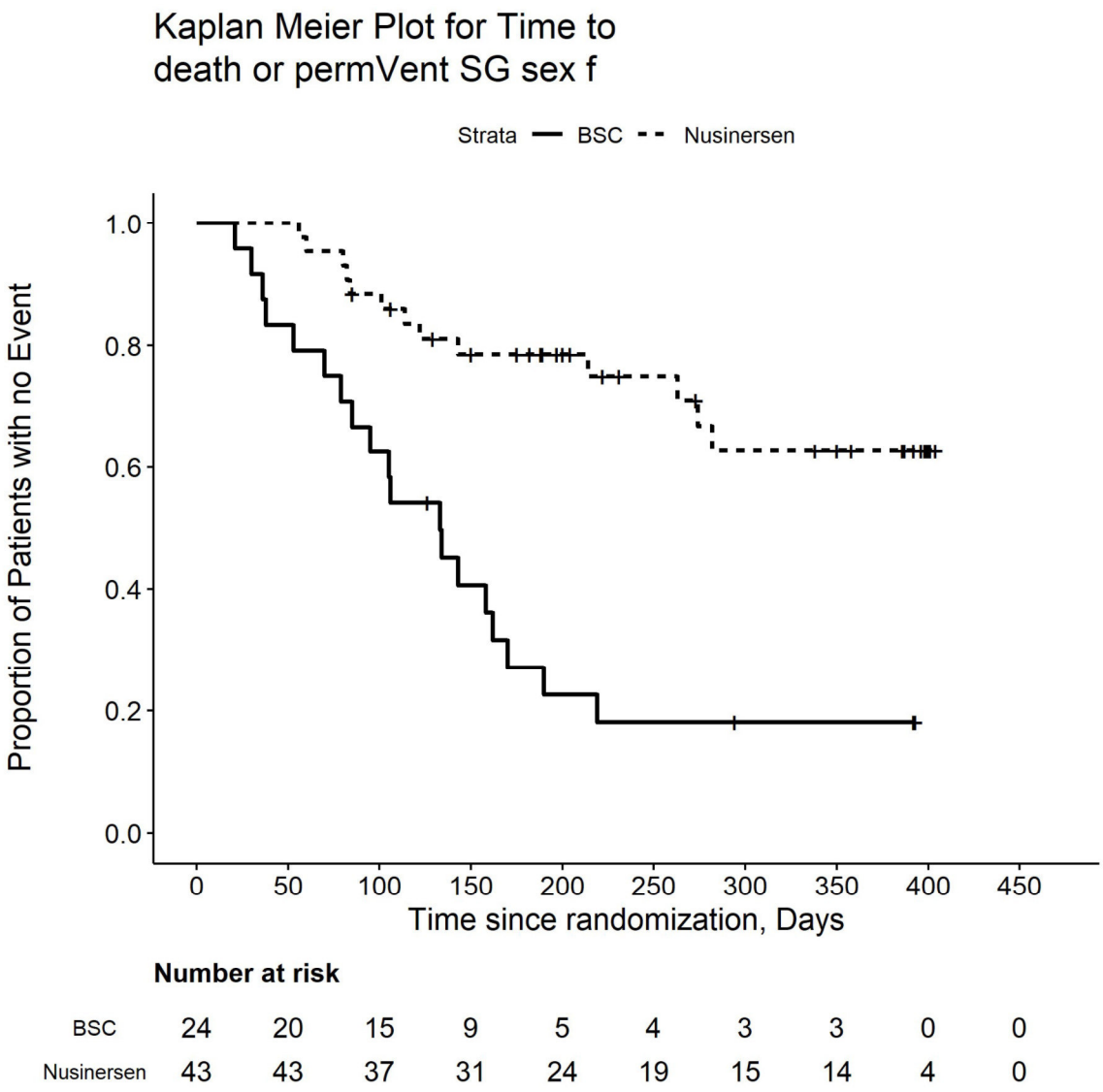
BSC	2	1	0	0	0	0	0	0	0	0
Nusinersen	12	12	10	9	7	3	2	2	1	0



Number at risk

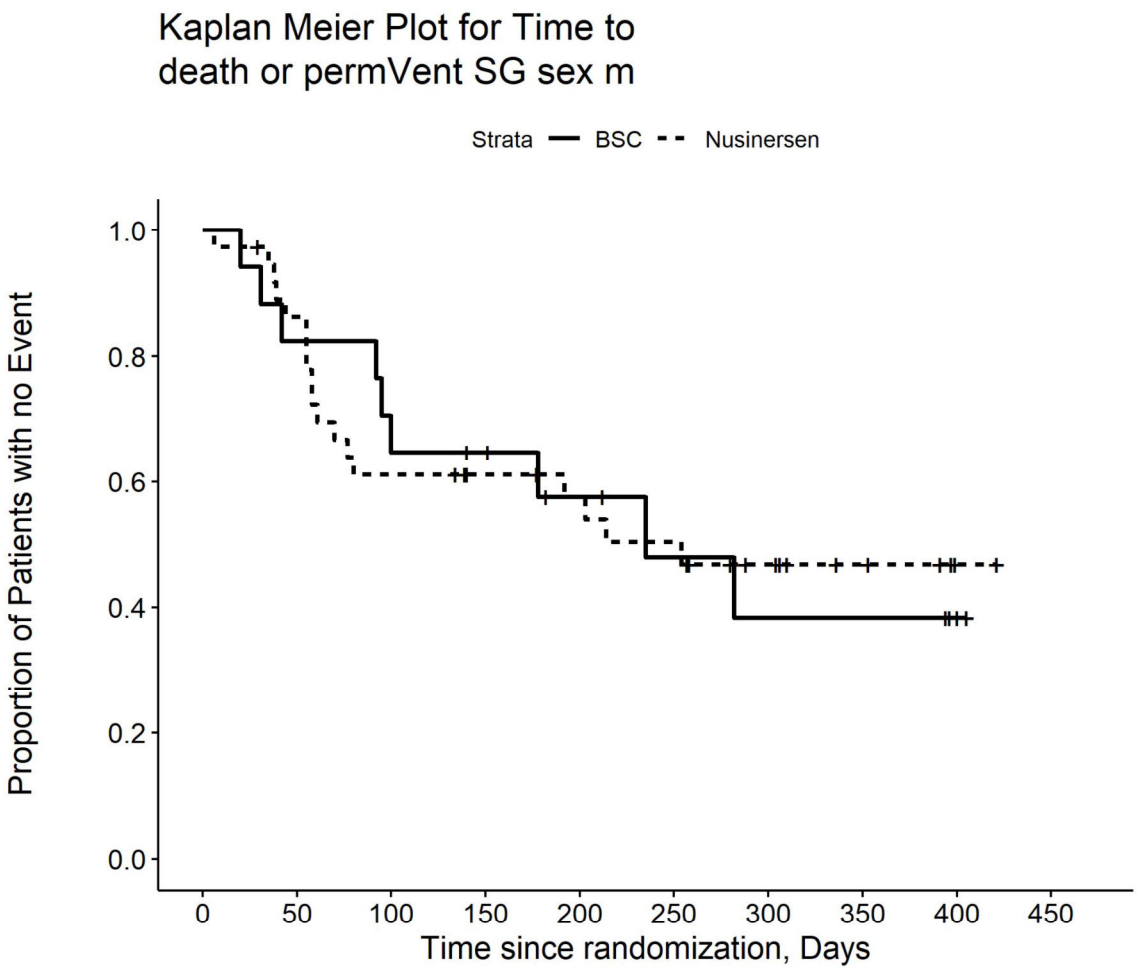
BSC	17	15	11	8	4	3	3	3	0	0
Nusinersen	30	29	21	16	13	11	9	5	1	0


Kaplan Meier Plot for Time to death or permVent SG region northamerica
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0 50 100 150 200 250 300 350 400 450
Time since randomization, Days
Number at risk
BSC 22 18 16 11 8 6 4 4 2 0
Nusinersen 38 33 28 24 20 19 13 12 3 0



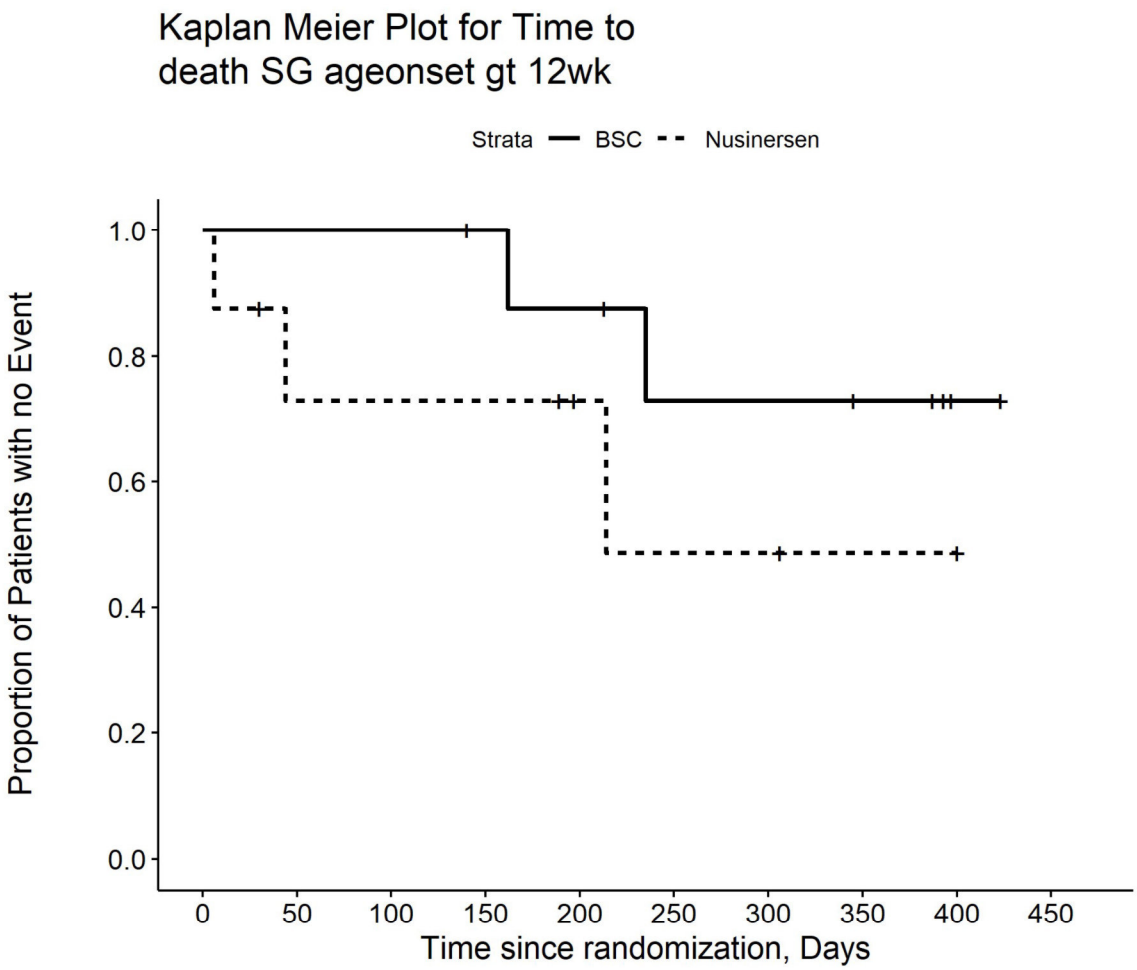
Number at risk

BSC	24	20	15	9	5	4	3	3	0	0
Nusinersen	43	43	37	31	24	19	15	14	4	0



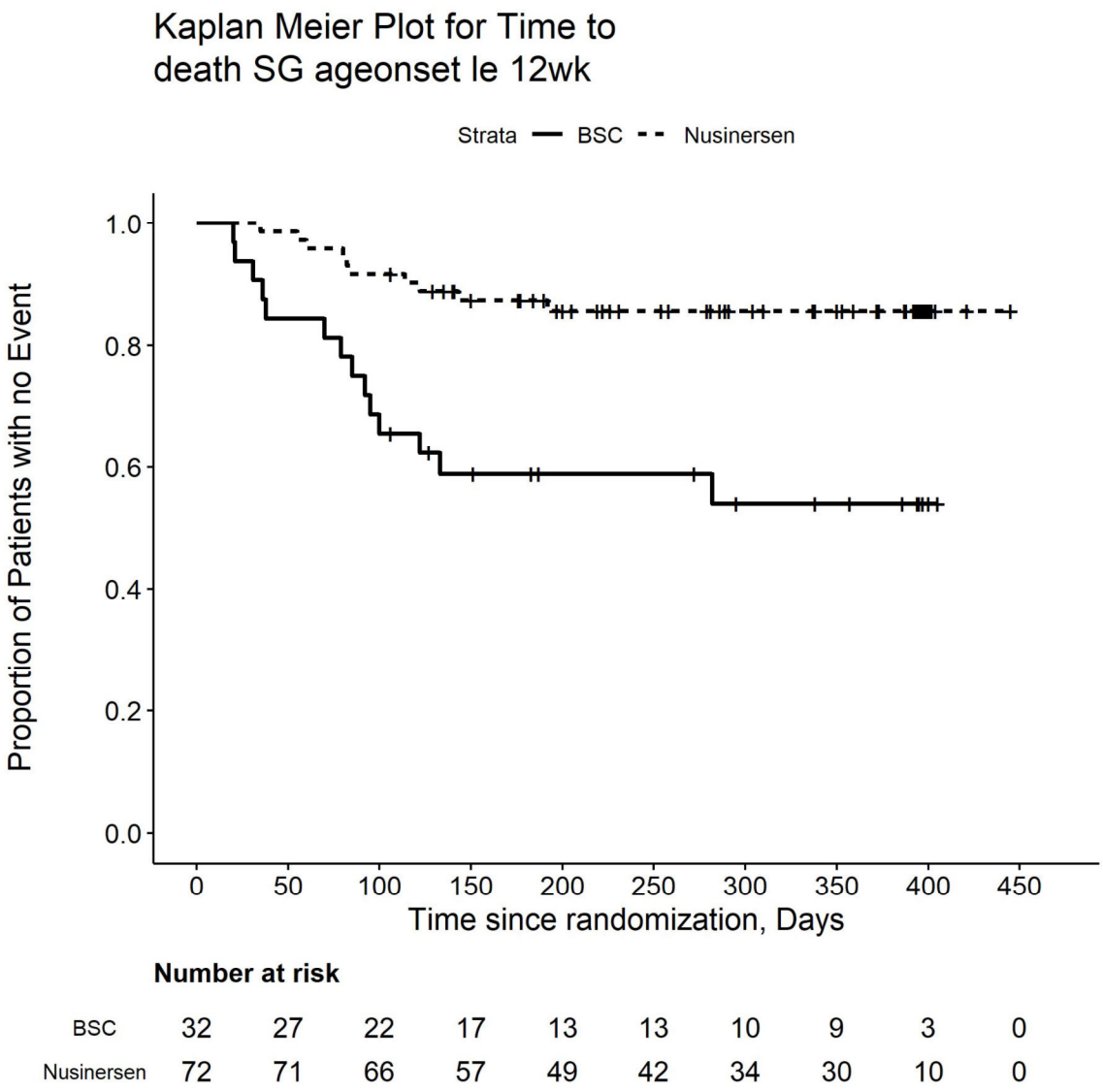
Number at risk

BSC	17	14	12	10	7	5	4	4	2	0
Nusinersen	37	31	22	18	16	14	9	5	1	0



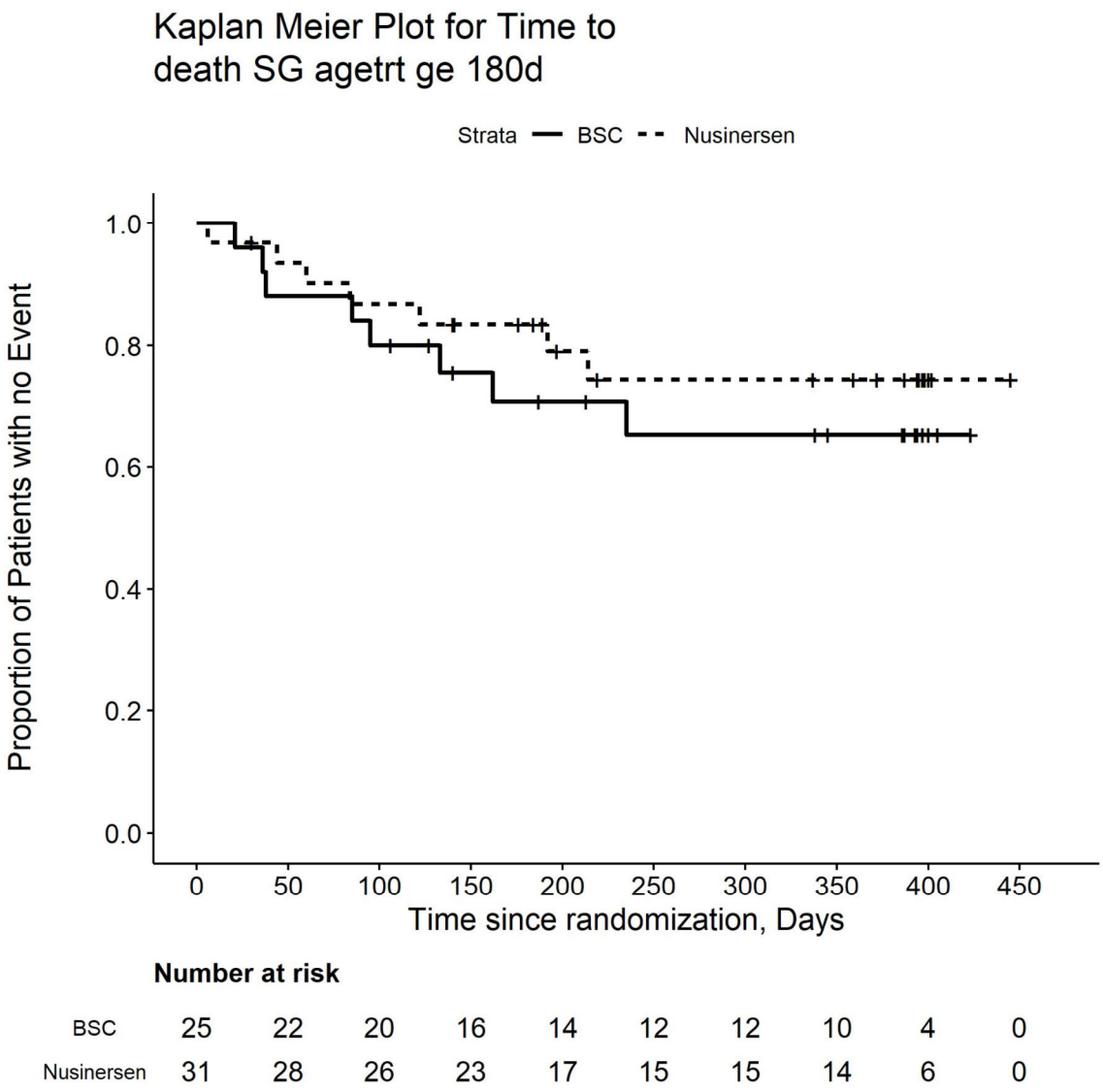
Number at risk

BSC	9	9	9	8	7	5	5	4	1	0
Nusinersen	8	5	5	5	3	2	2	1	1	0



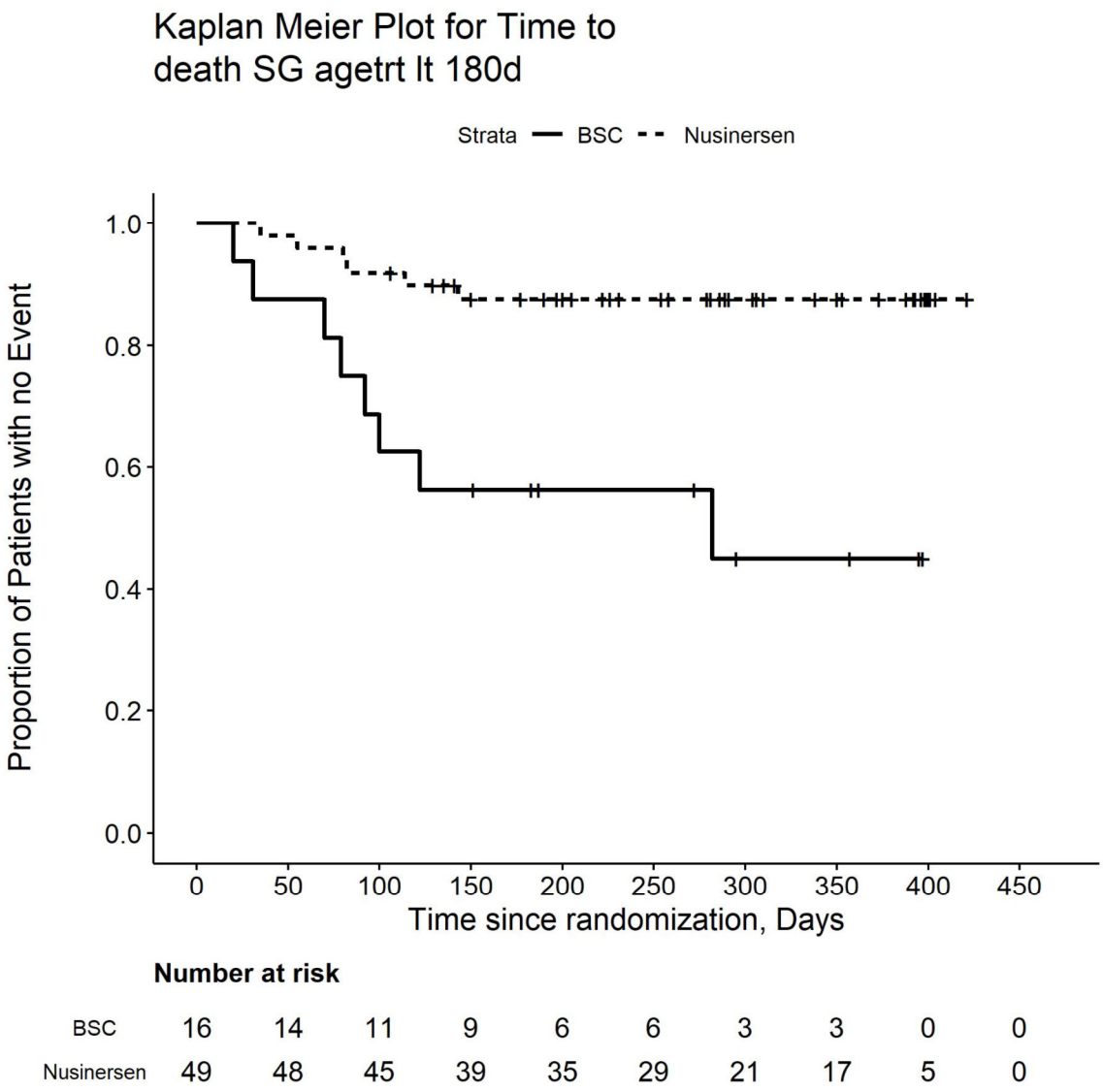
Number at risk

BSC	32	27	22	17	13	13	10	9	3	0
Nusinersen	72	71	66	57	49	42	34	30	10	0



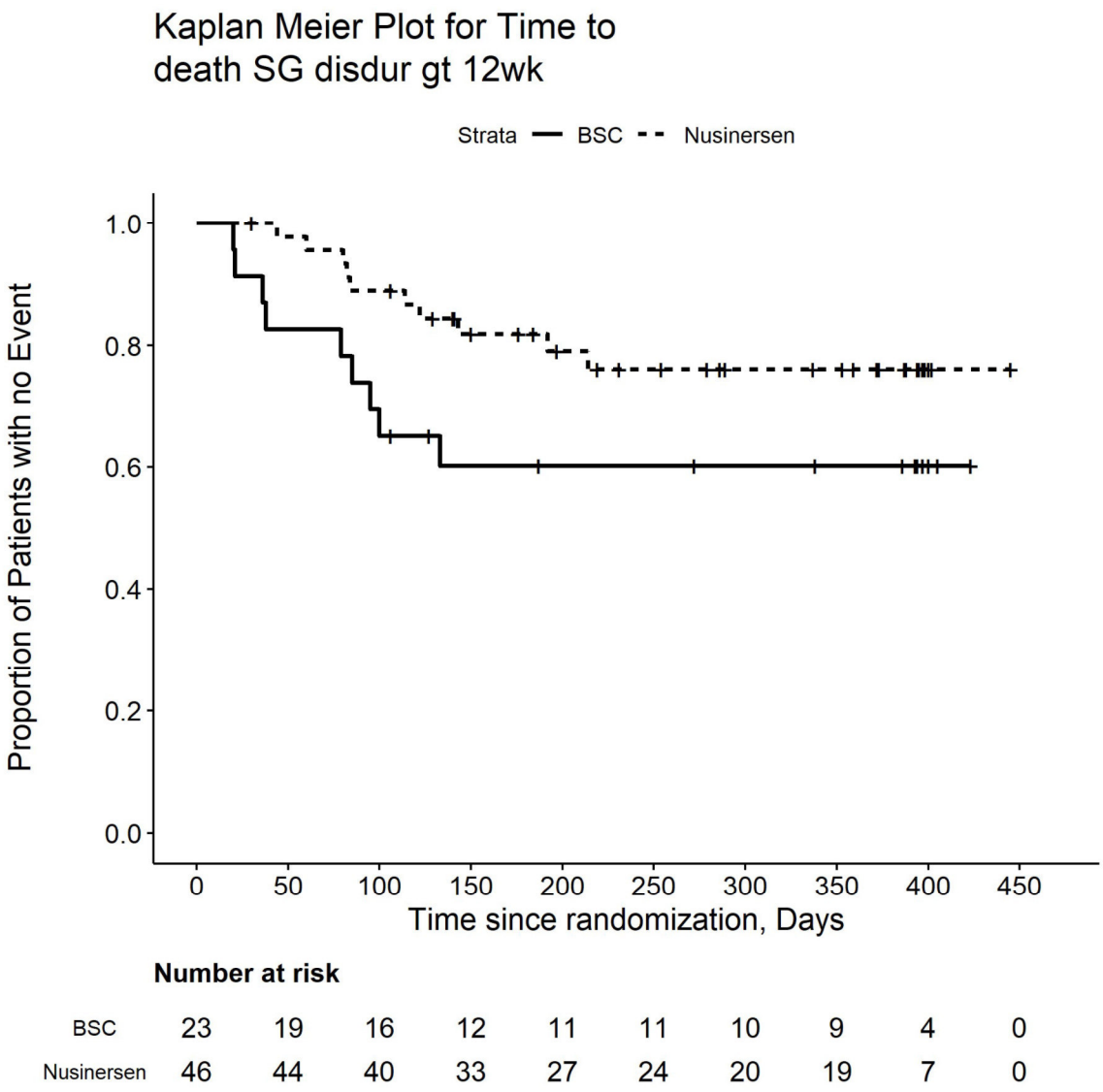
Number at risk

BSC	25	22	20	16	14	12	12	10	4	0
Nusinersen	31	28	26	23	17	15	15	14	6	0



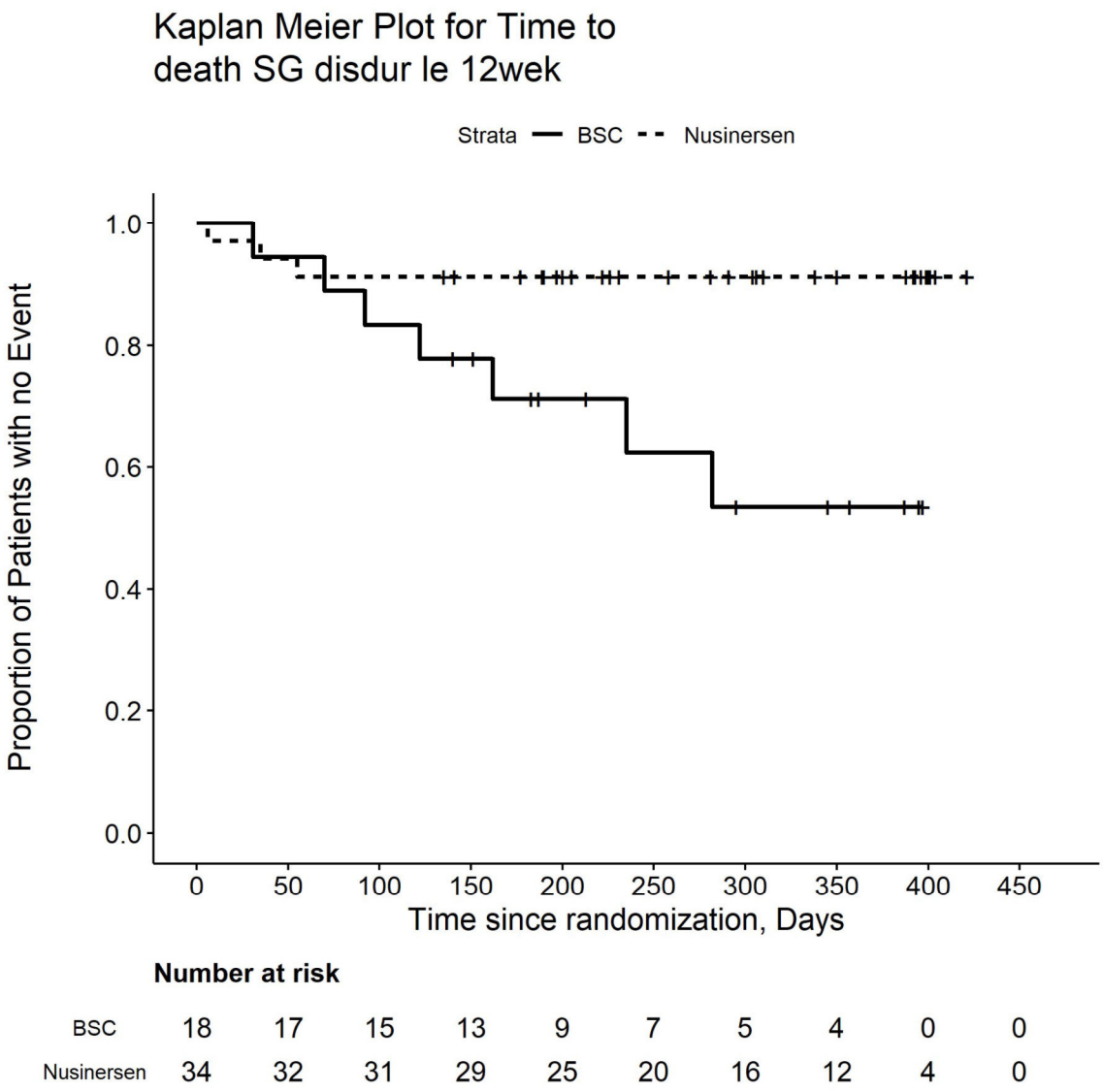
Number at risk

BSC	16	14	11	9	6	6	3	3	0	0
Nusinersen	49	48	45	39	35	29	21	17	5	0



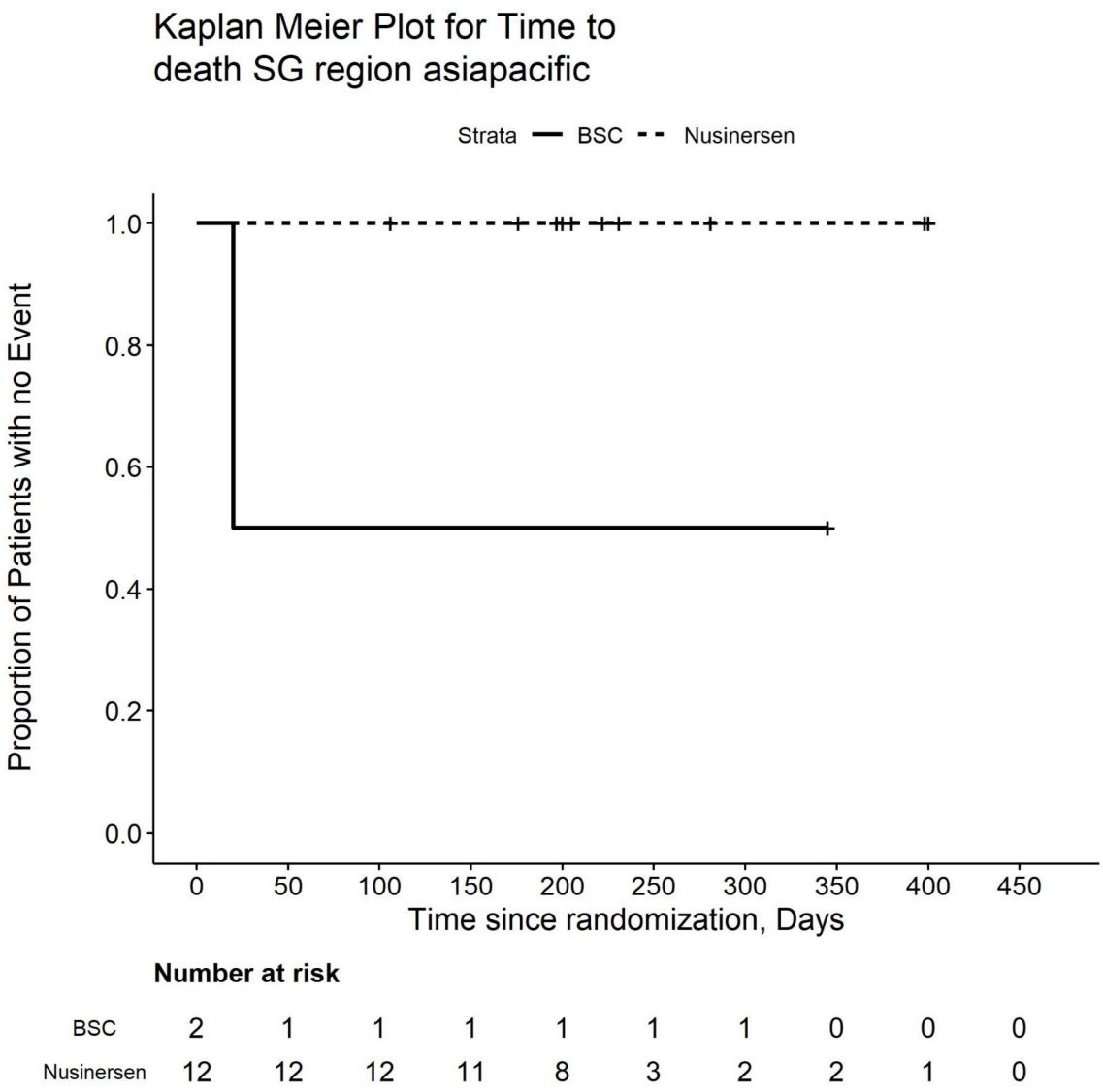
Number at risk

BSC	23	19	16	12	11	11	10	9	4	0
Nusinersen	46	44	40	33	27	24	20	19	7	0



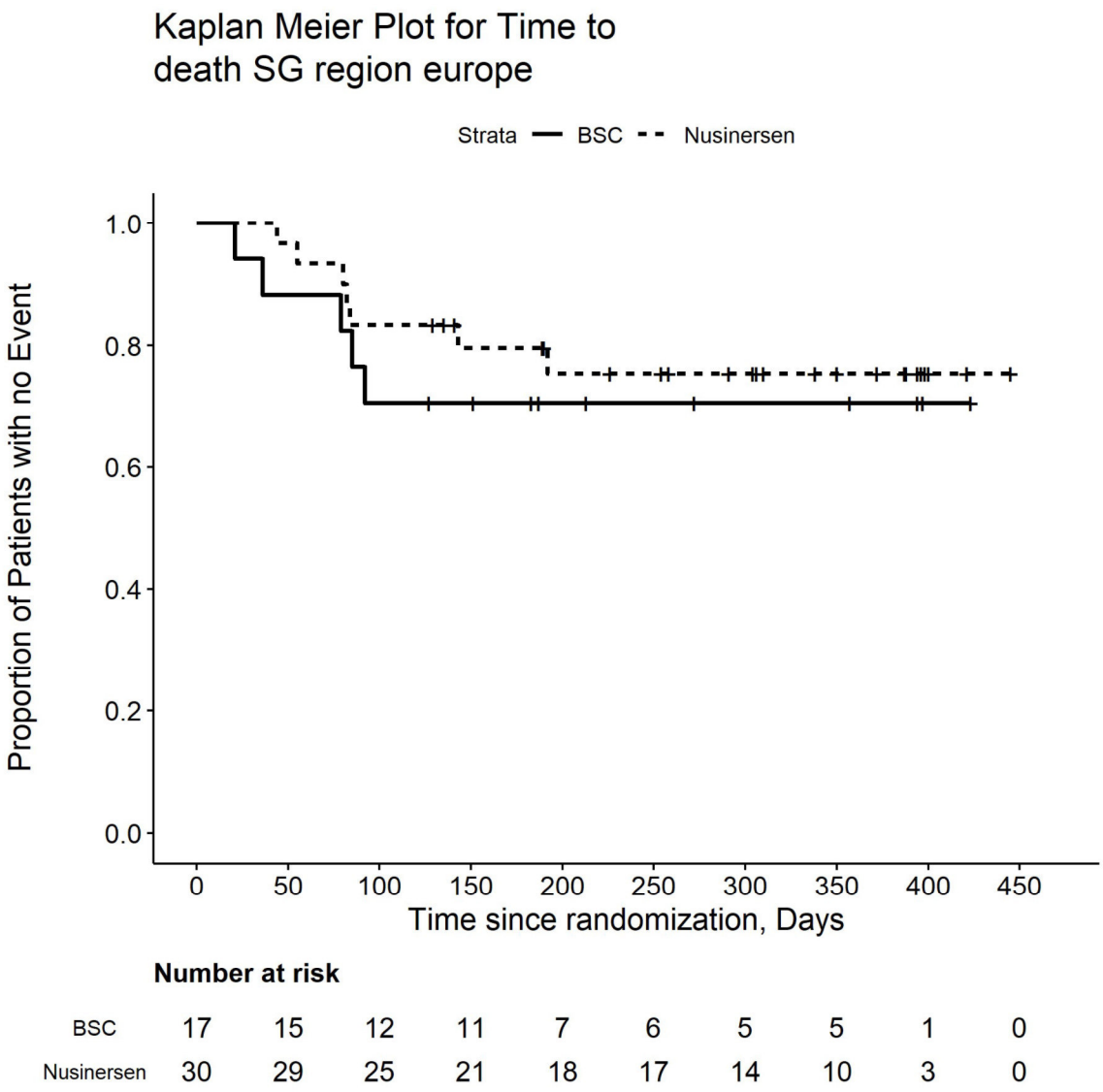
Number at risk

BSC	18	17	15	13	9	7	5	4	0	0
Nusinersen	34	32	31	29	25	20	16	12	4	0



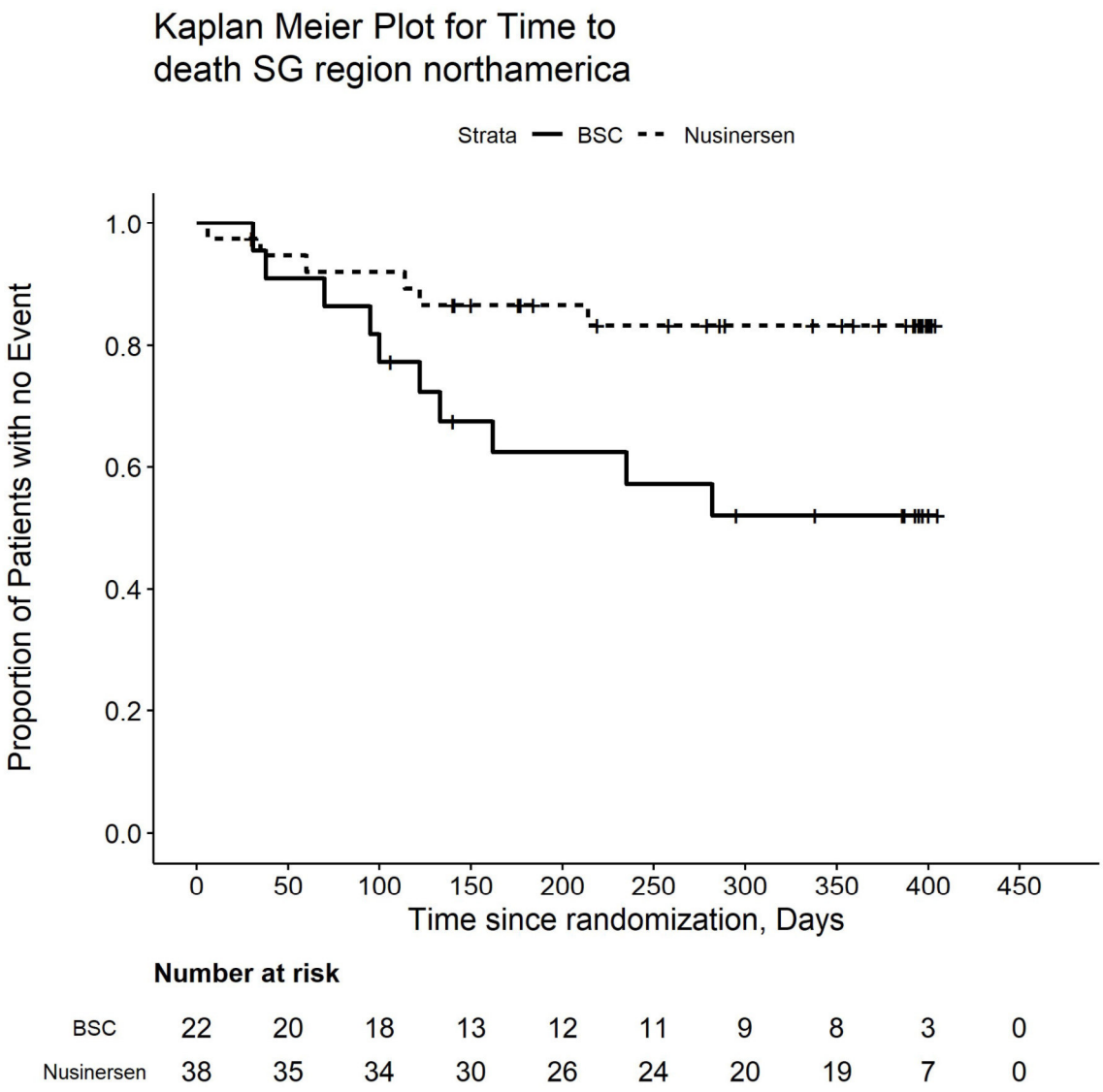
Number at risk

BSC	2	1	1	1	1	1	1	0	0	0
Nusinersen	12	12	12	11	8	3	2	2	1	0



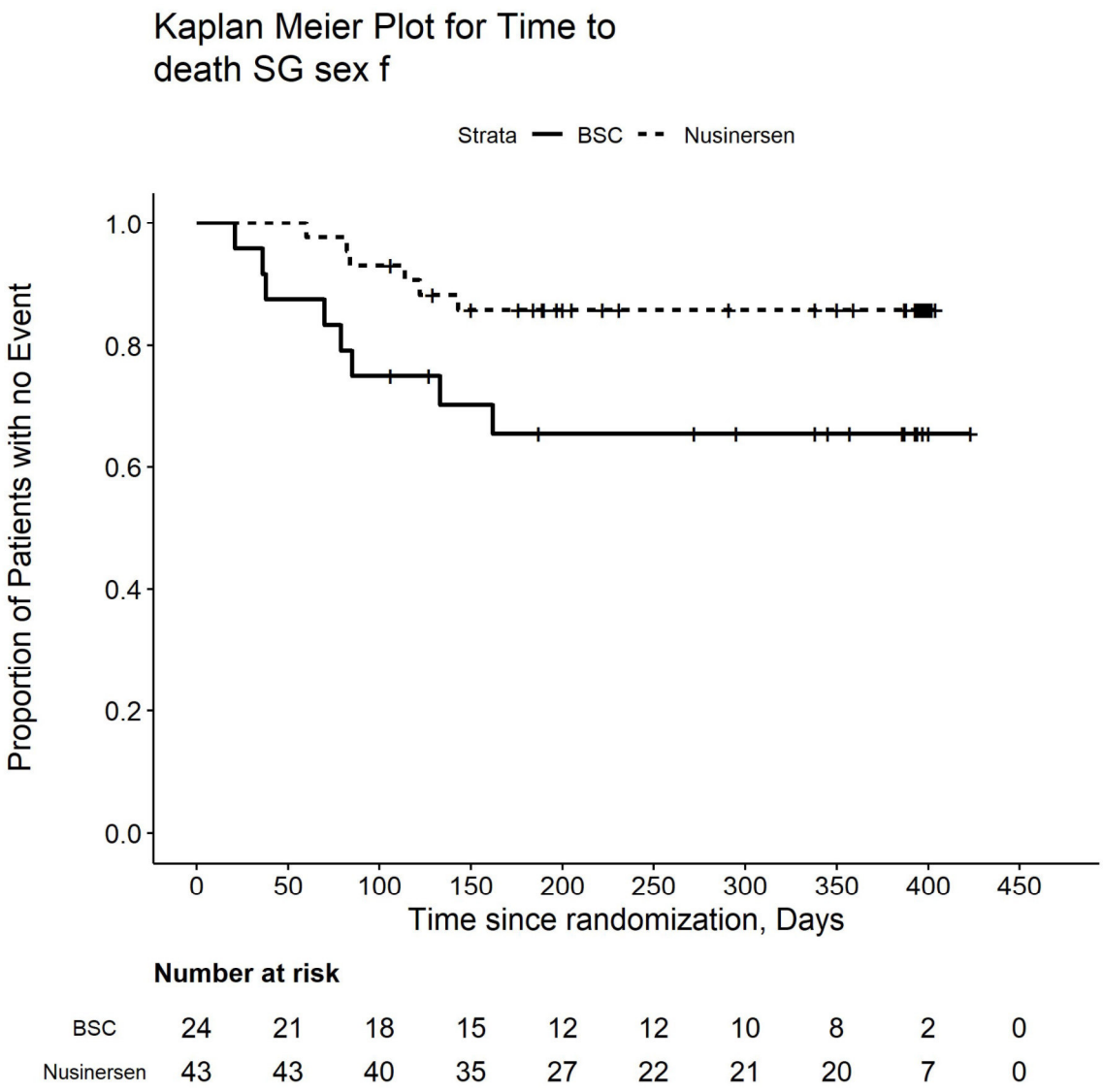
Number at risk

BSC	17	15	12	11	7	6	5	5	1	0
Nusinersen	30	29	25	21	18	17	14	10	3	0



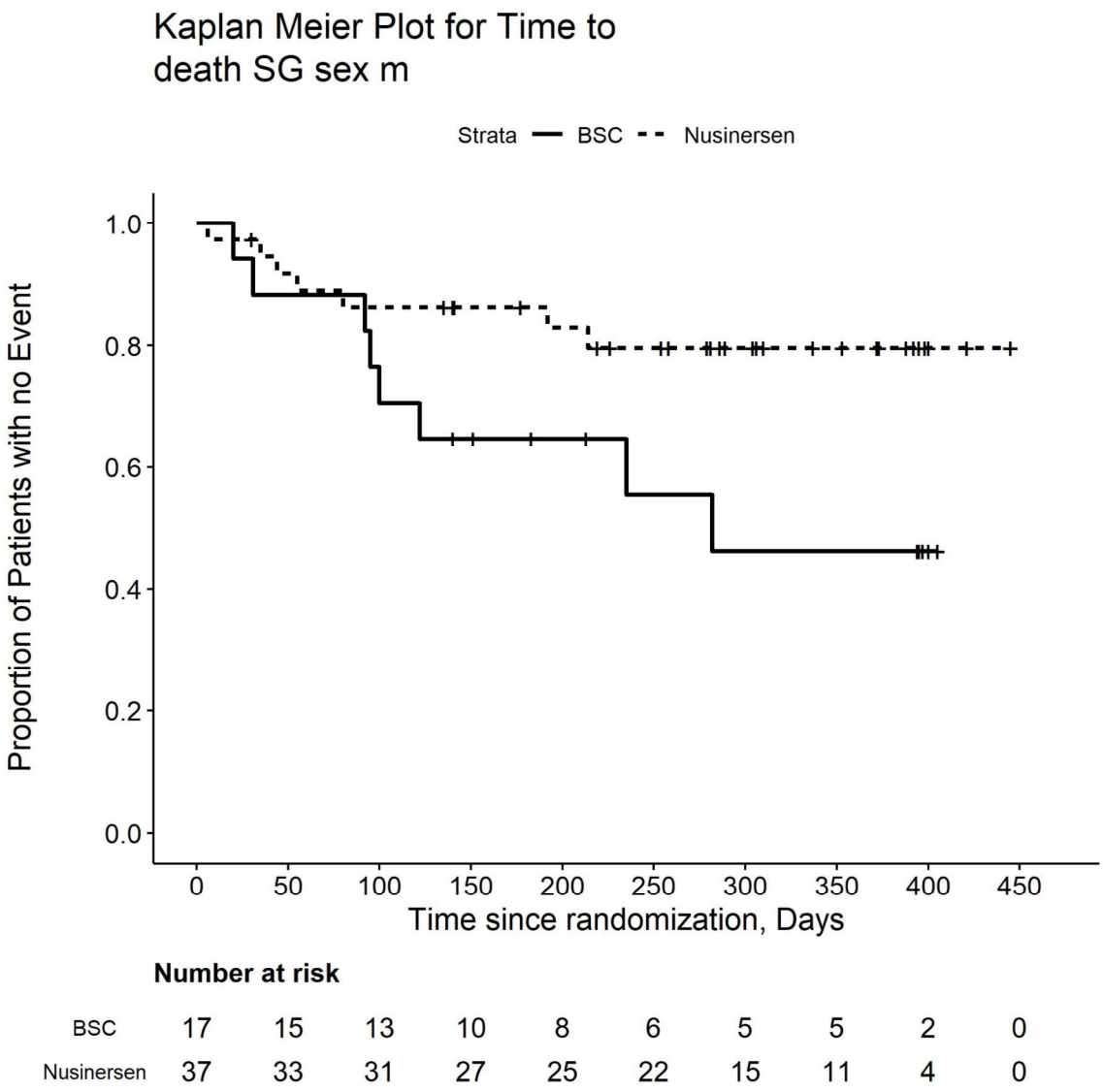
Number at risk

BSC	22	20	18	13	12	11	9	8	3	0
Nusinersen	38	35	34	30	26	24	20	19	7	0



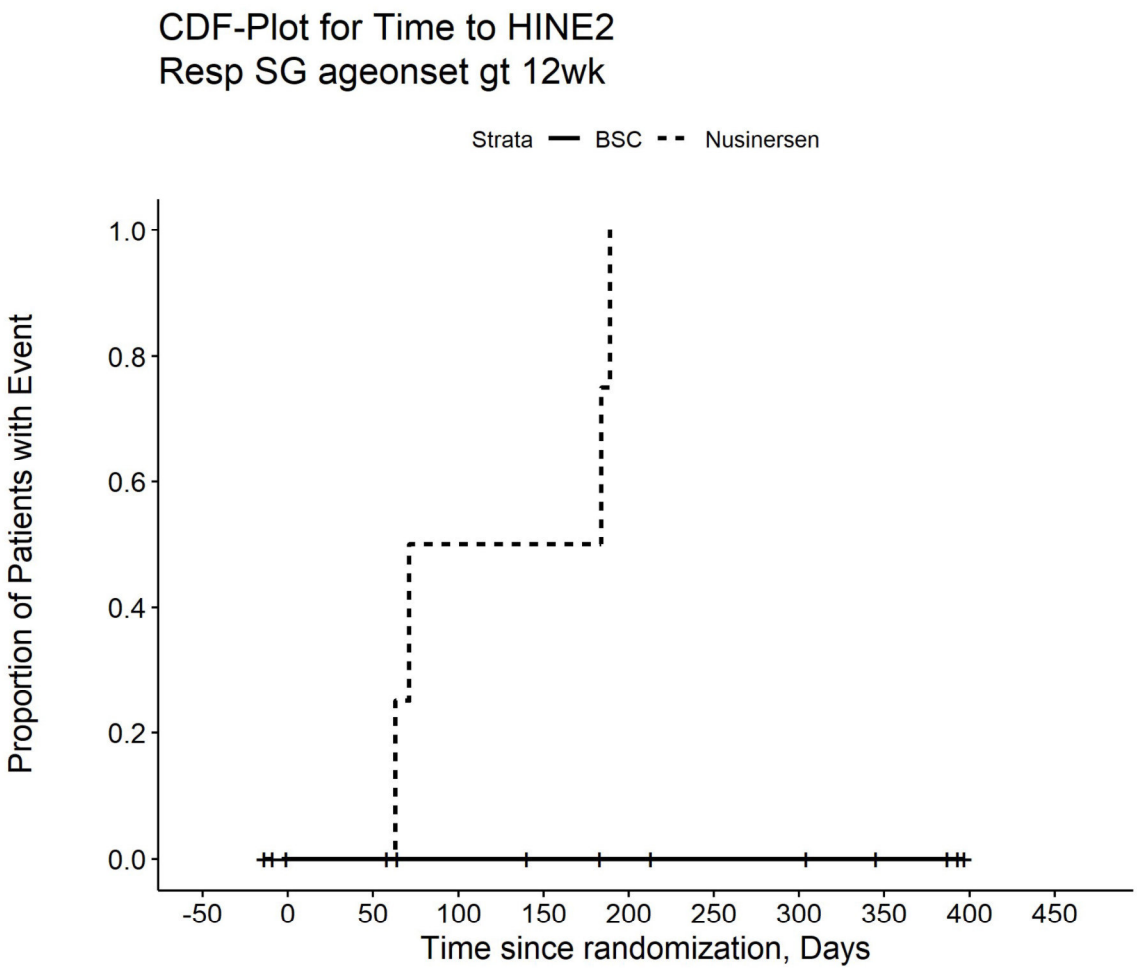
Number at risk

BSC	24	21	18	15	12	12	10	8	2	0
Nusinersen	43	43	40	35	27	22	21	20	7	0



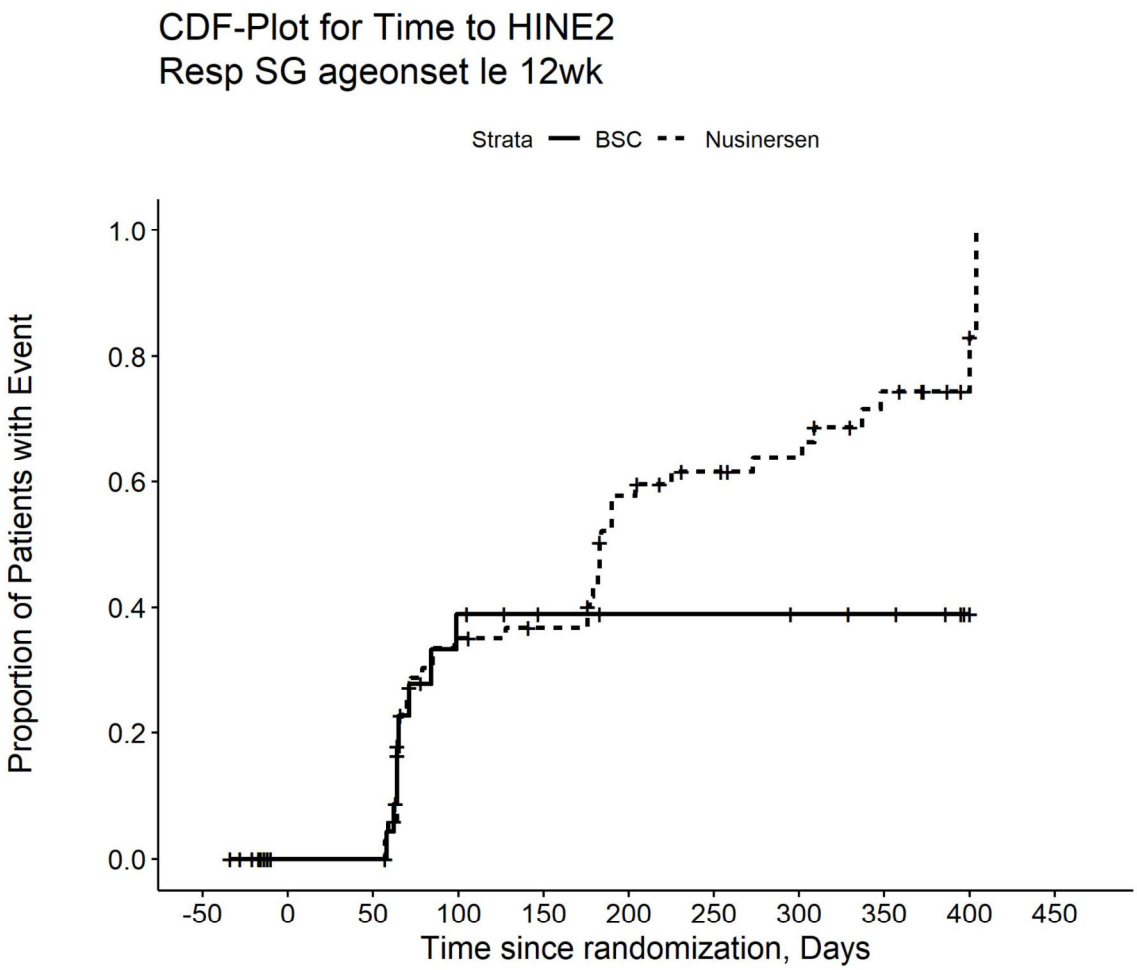
Number at risk

BSC	17	15	13	10	8	6	5	5	2	0
Nusinersen	37	33	31	27	25	22	15	11	4	0



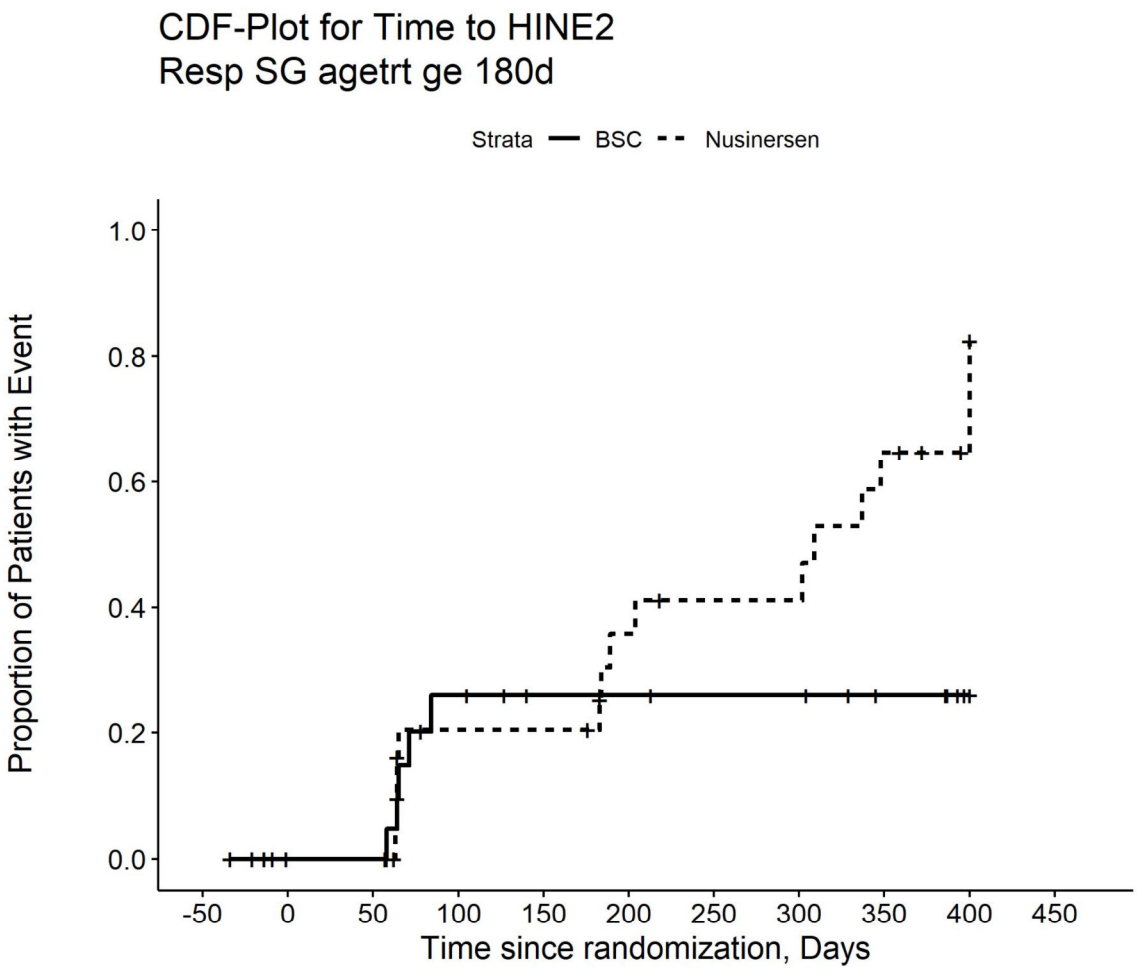
Number at risk

BSC	9	9	9	8	7	6	5	5	3	0	0
Nusinersen	8	5	5	2	2	0	0	0	0	0	0



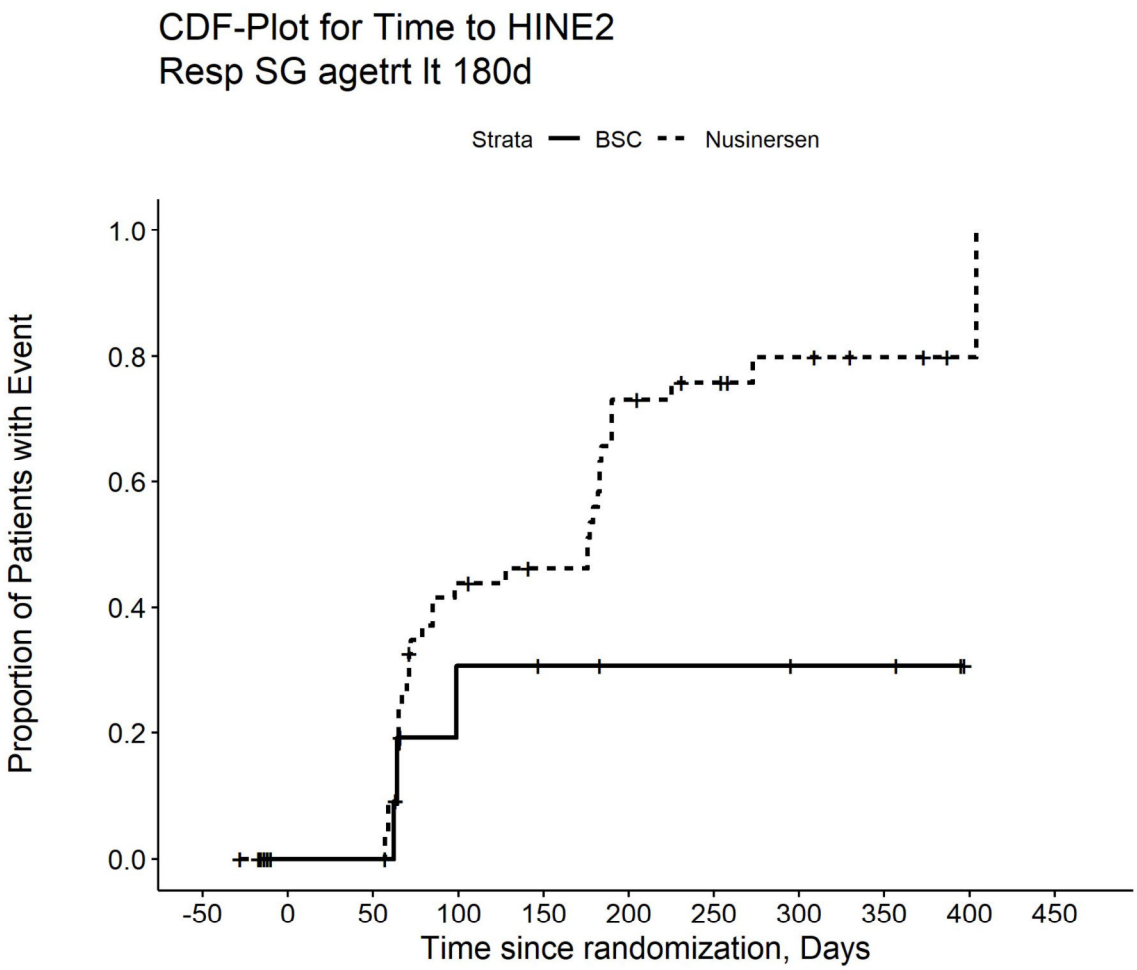
Number at risk

BSC	32	25	25	11	8	7	7	6	5	1	0
Nusinersen	72	68	68	41	38	23	18	15	9	3	0



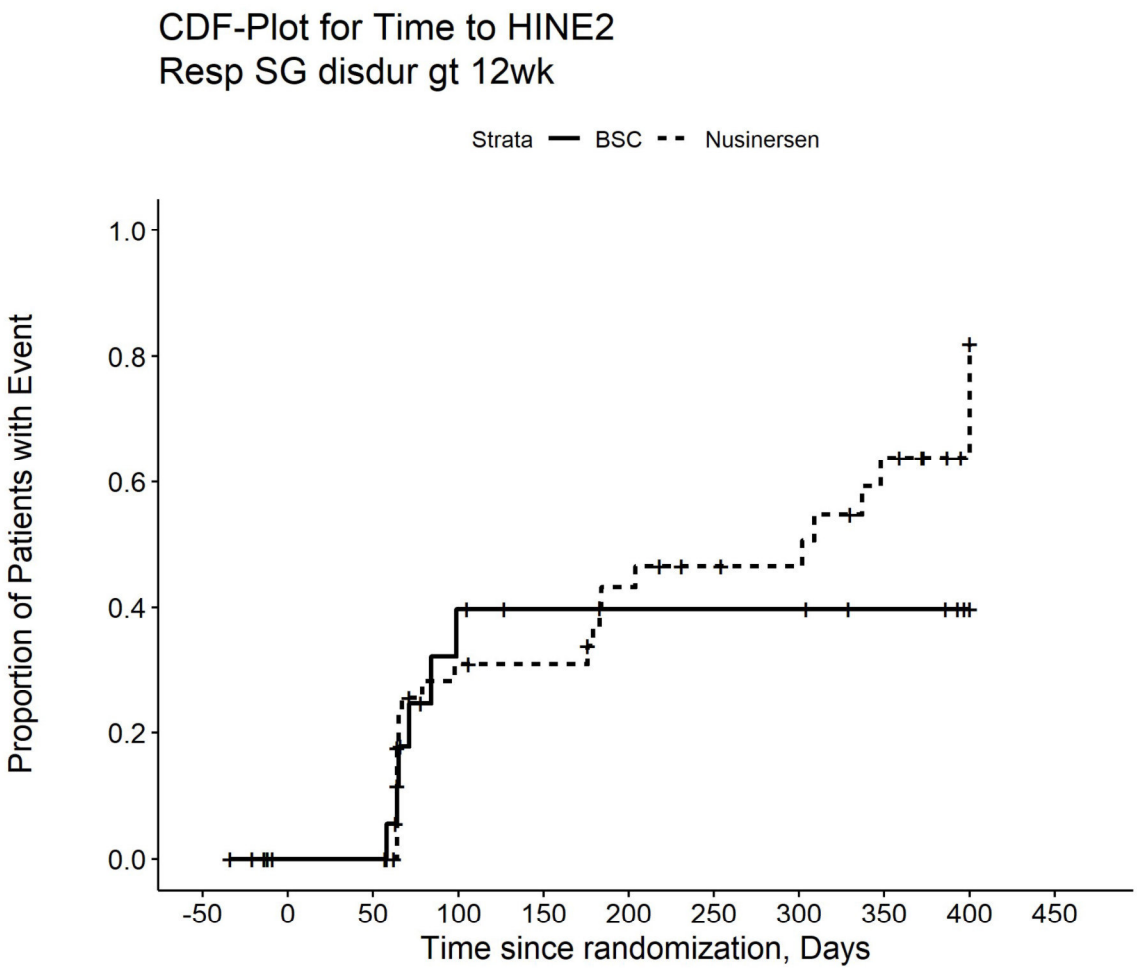
Number at risk

BSC	25	22	22	13	10	9	8	8	5	1	0
Nusinersen	31	27	27	18	18	12	10	10	6	2	0



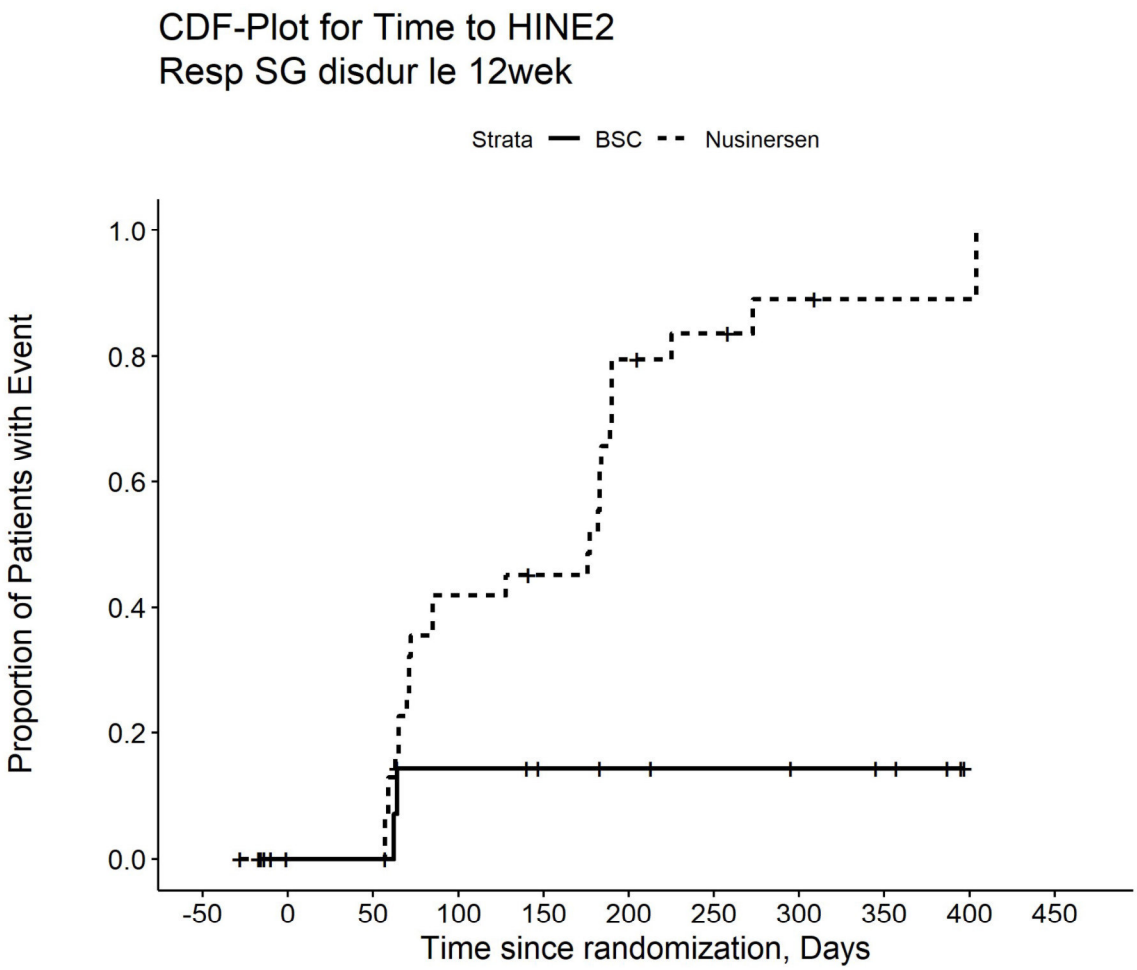
Number at risk

BSC	16	12	12	6	5	4	4	3	3	0	0
Nusinersen	49	46	46	25	22	11	8	5	3	1	0



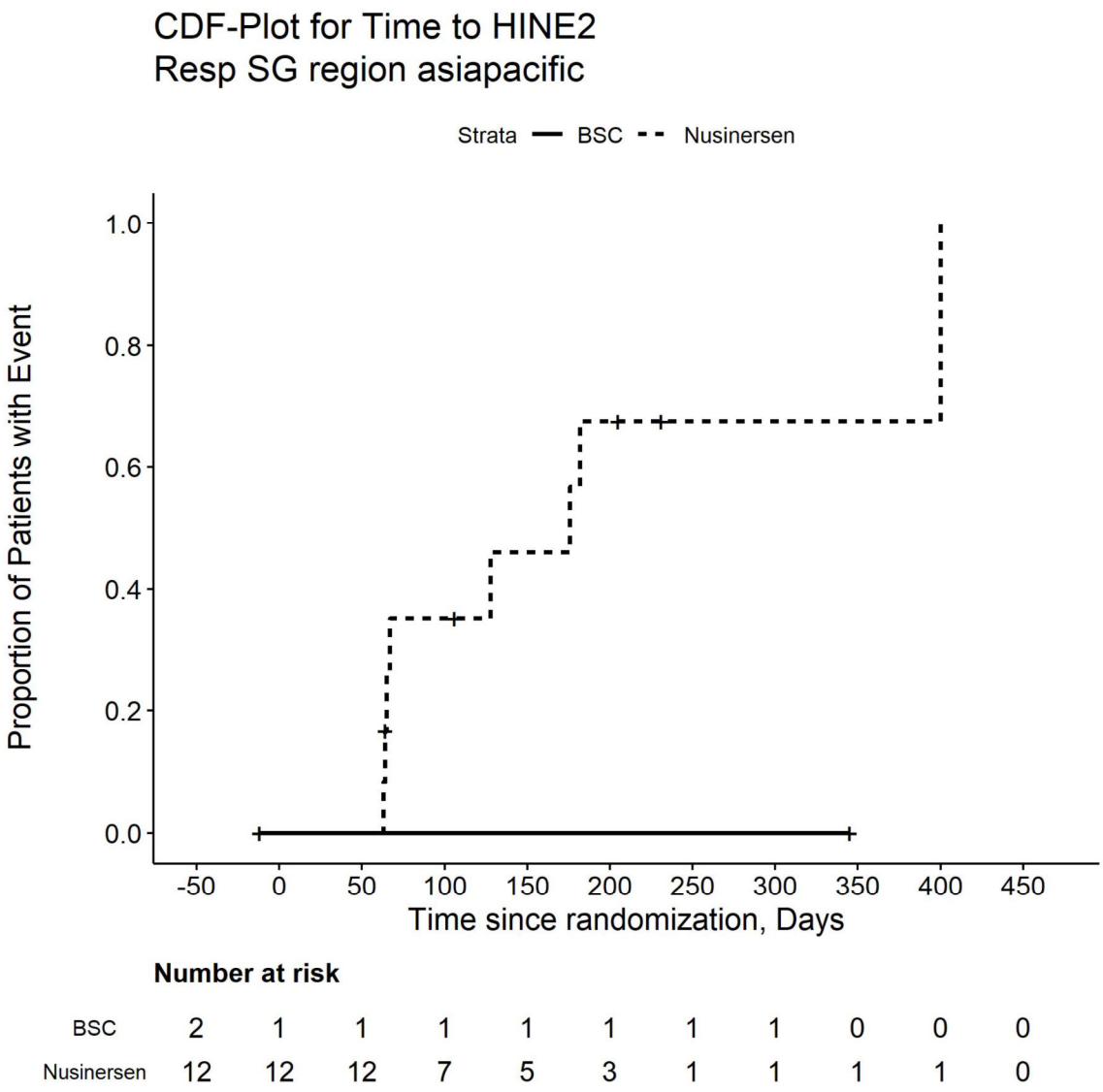
Number at risk

BSC	23	19	19	8	6	6	6	6	4	1	0
Nusinersen	46	42	42	25	24	17	14	13	8	2	0



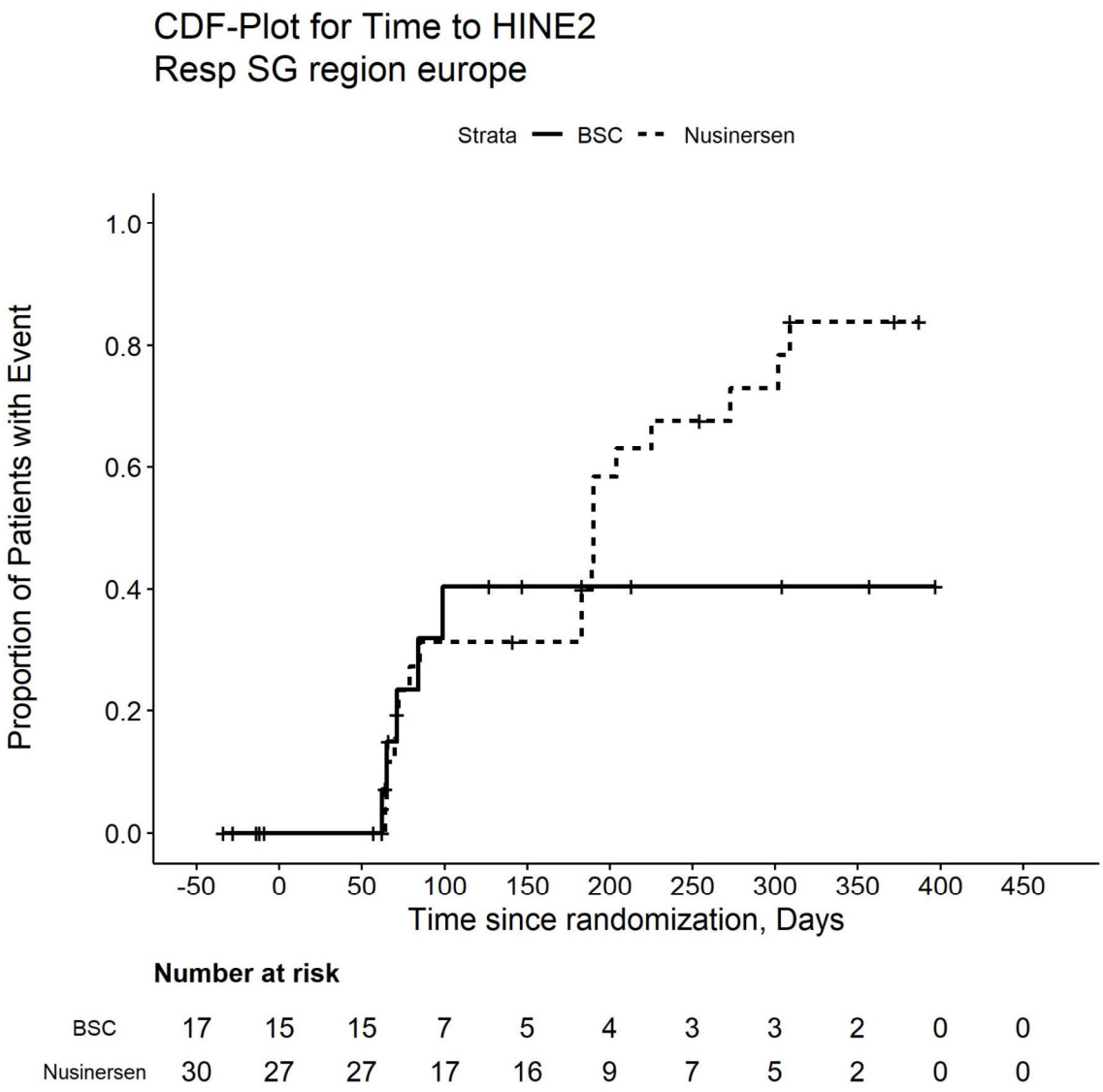
Number at risk

BSC	18	15	15	11	9	7	6	5	4	0	0
Nusinersen	34	31	31	18	16	6	4	2	1	1	0



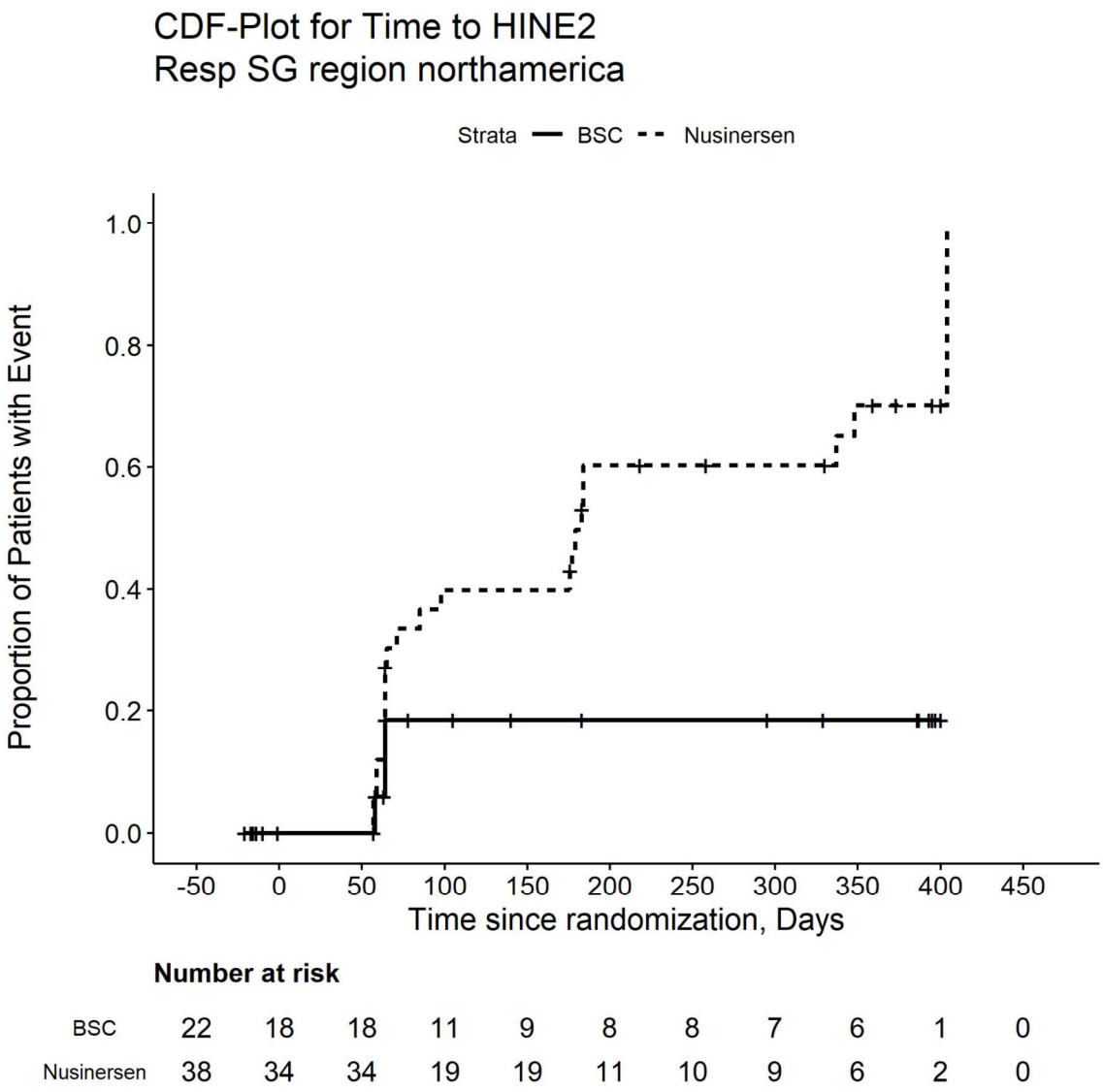
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0	0
Nusinersen	12	12	12	7	5	3	1	1	1	1	0



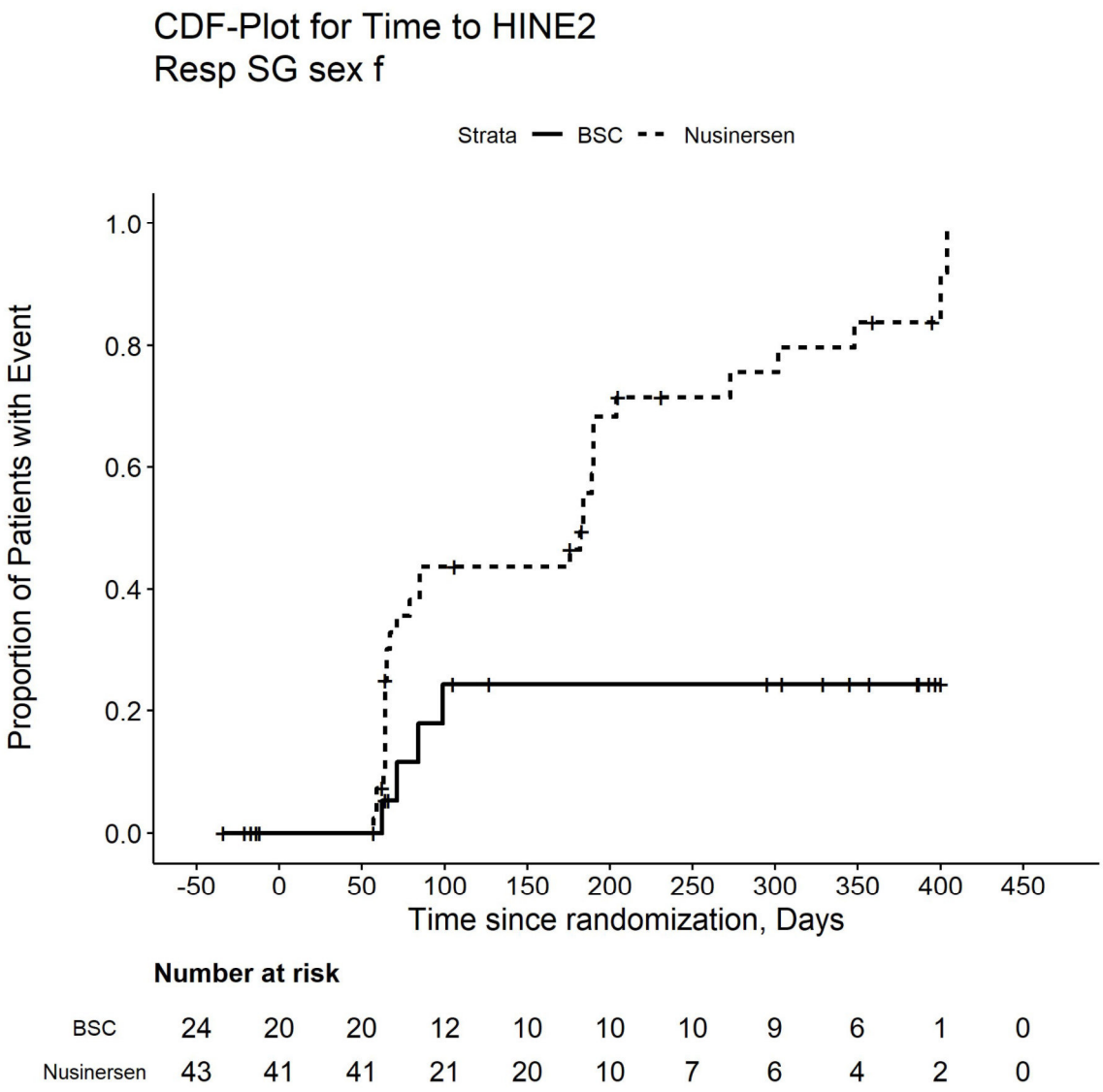
Number at risk

BSC	17	15	15	7	5	4	3	3	2	0	0
Nusinersen	30	27	27	17	16	9	7	5	2	0	0



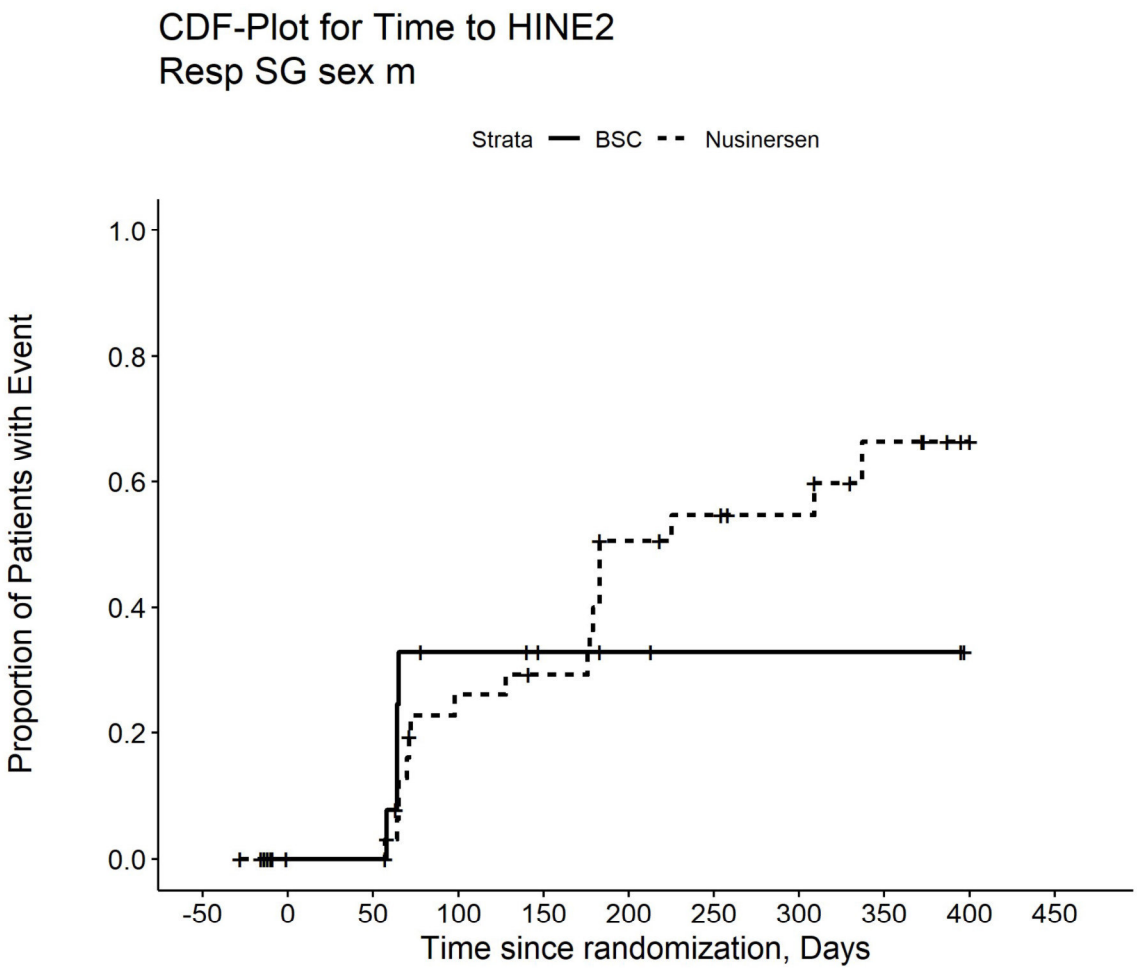
Number at risk

BSC	22	18	18	11	9	8	8	7	6	1	0
Nusinersen	38	34	34	19	19	11	10	9	6	2	0



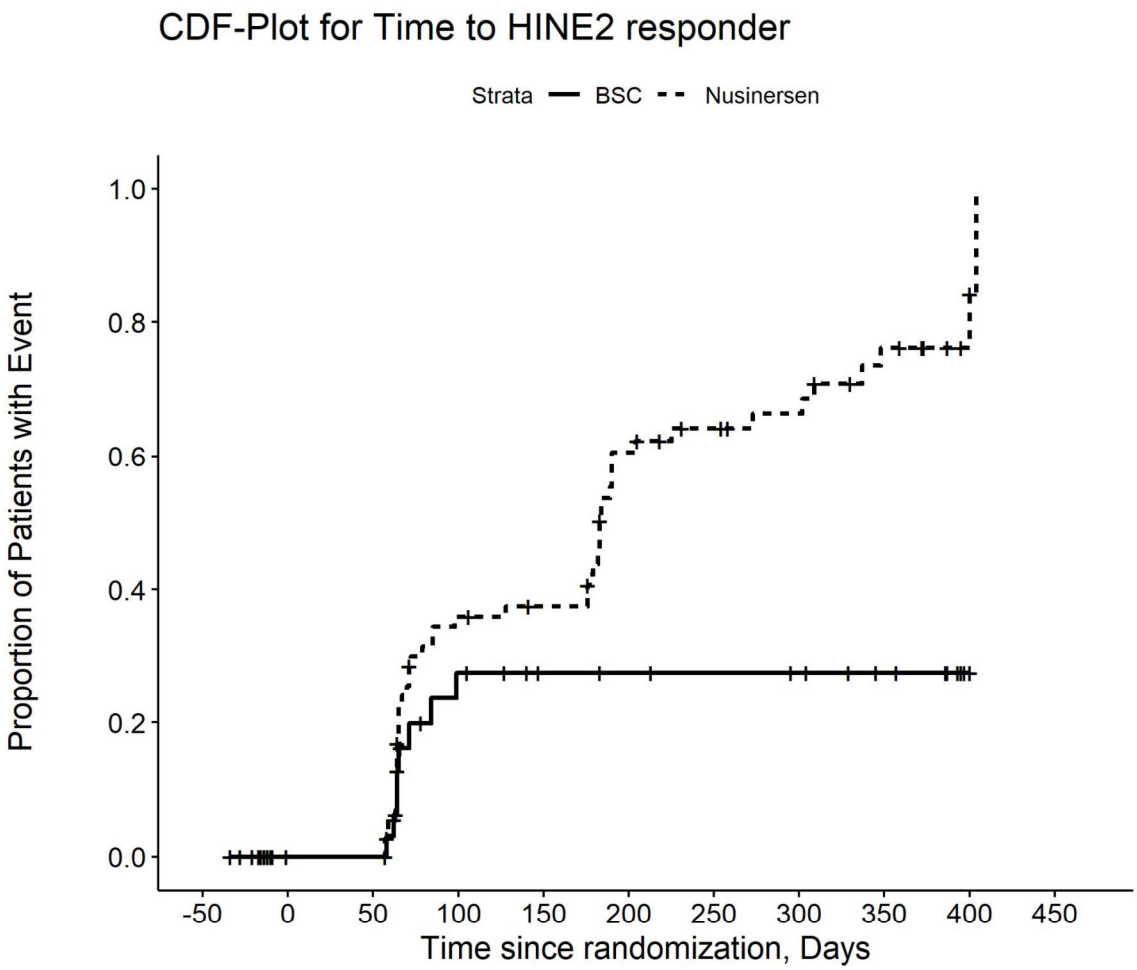
Number at risk

BSC	24	20	20	12	10	10	10	9	6	1	0
Nusinersen	43	41	41	21	20	10	7	6	4	2	0



Number at risk

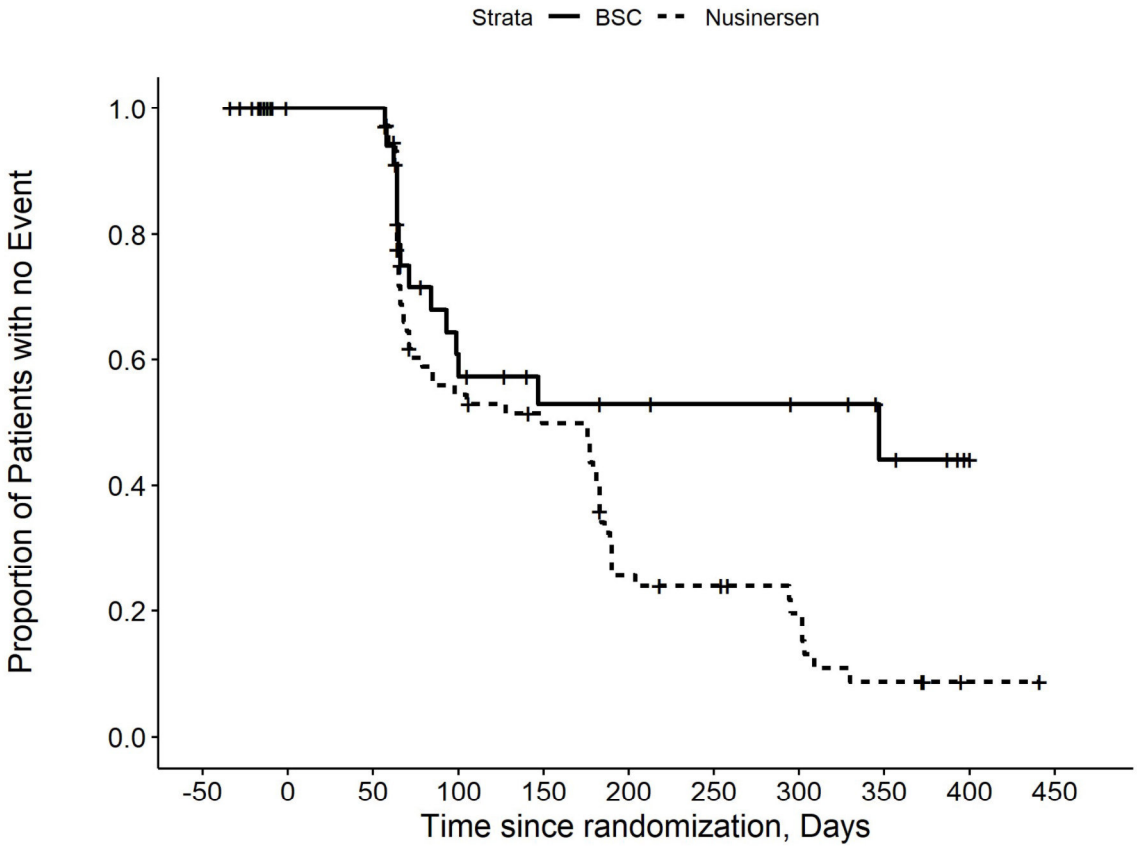
BSC	17	14	14	7	5	3	2	2	2	0	0
Nusinersen	37	32	32	22	20	13	11	9	5	1	0



Number at risk

BSC	41	34	34	19	15	13	12	11	8	1	0
Nusinersen	80	73	73	43	40	23	18	15	9	3	0

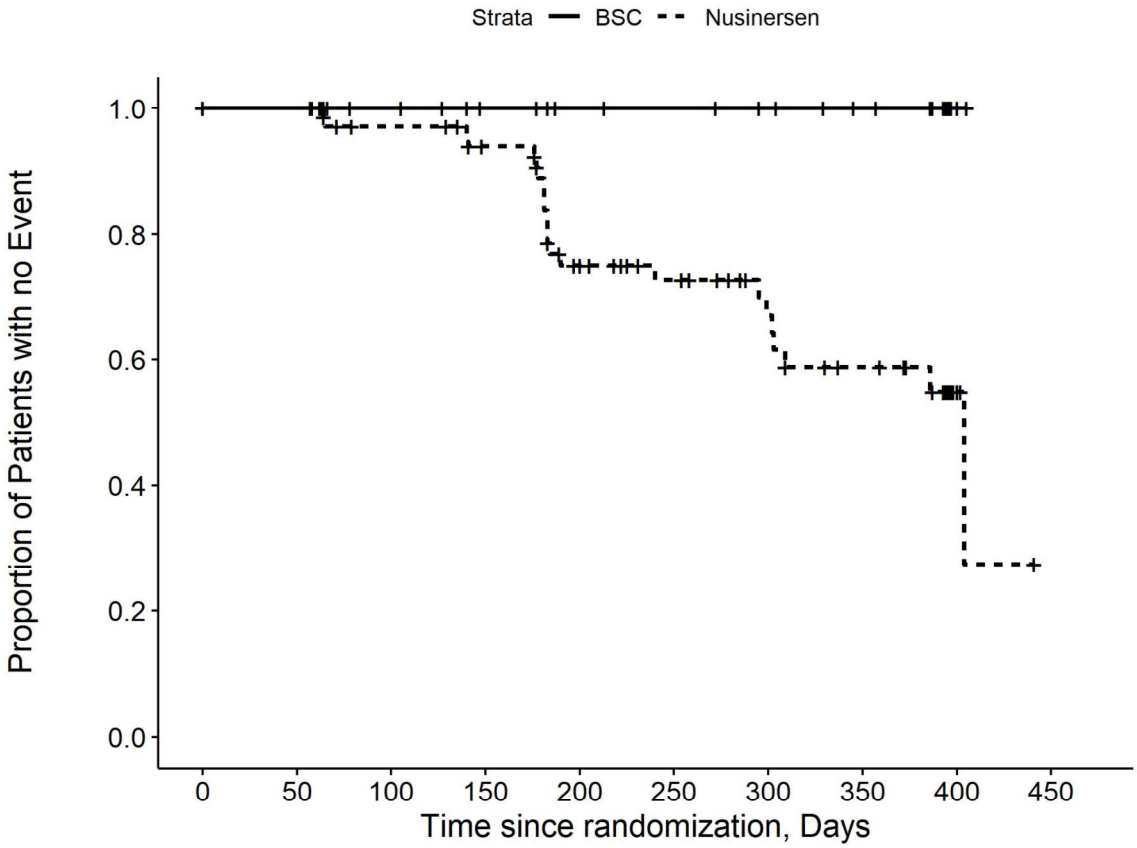
Kaplan Meier Plot for Time to HINE2 responder totscore



Number at risk

BSC	41	34	34	17	12	10	9	8	5	1	0
Nusinersen	80	73	73	37	32	15	13	9	4	1	0

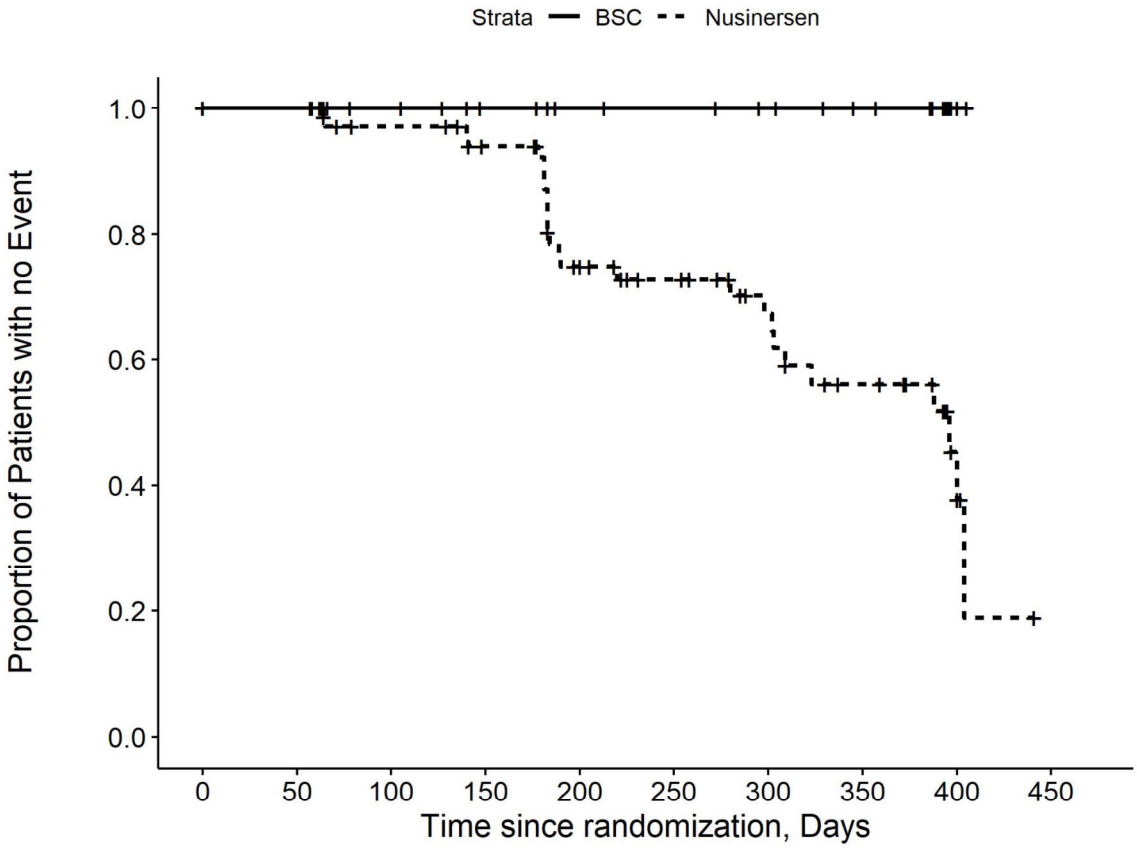
Kaplan Meier Plot for Time to HINE2 responder totscore posthoc



Number at risk

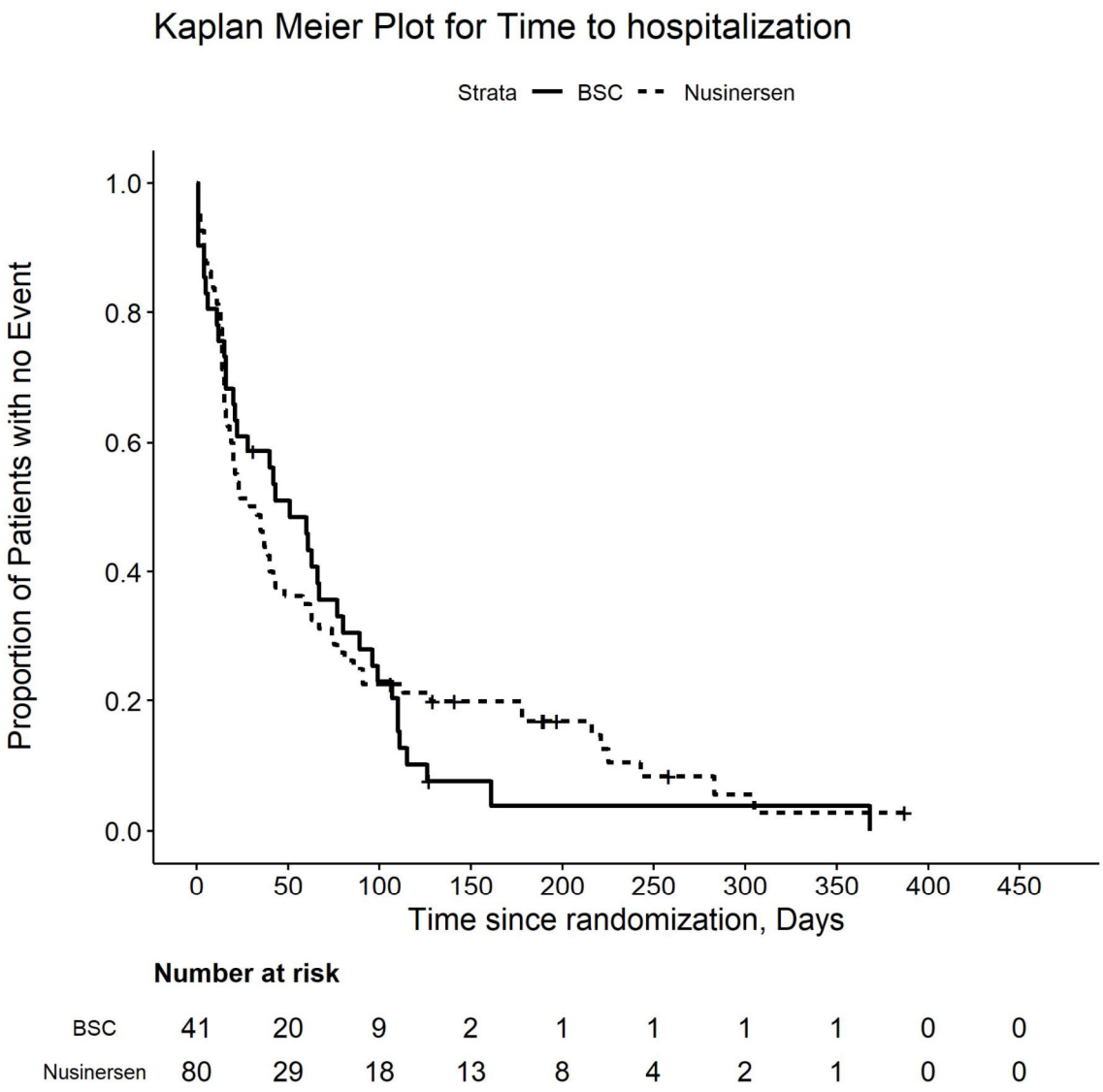
BSC	41	34	27	23	18	17	15	12	2	0
Nusinersen	80	72	63	57	40	33	24	18	6	0

Kaplan Meier Plot for Time to HINE2 responder totscrvg posthoc



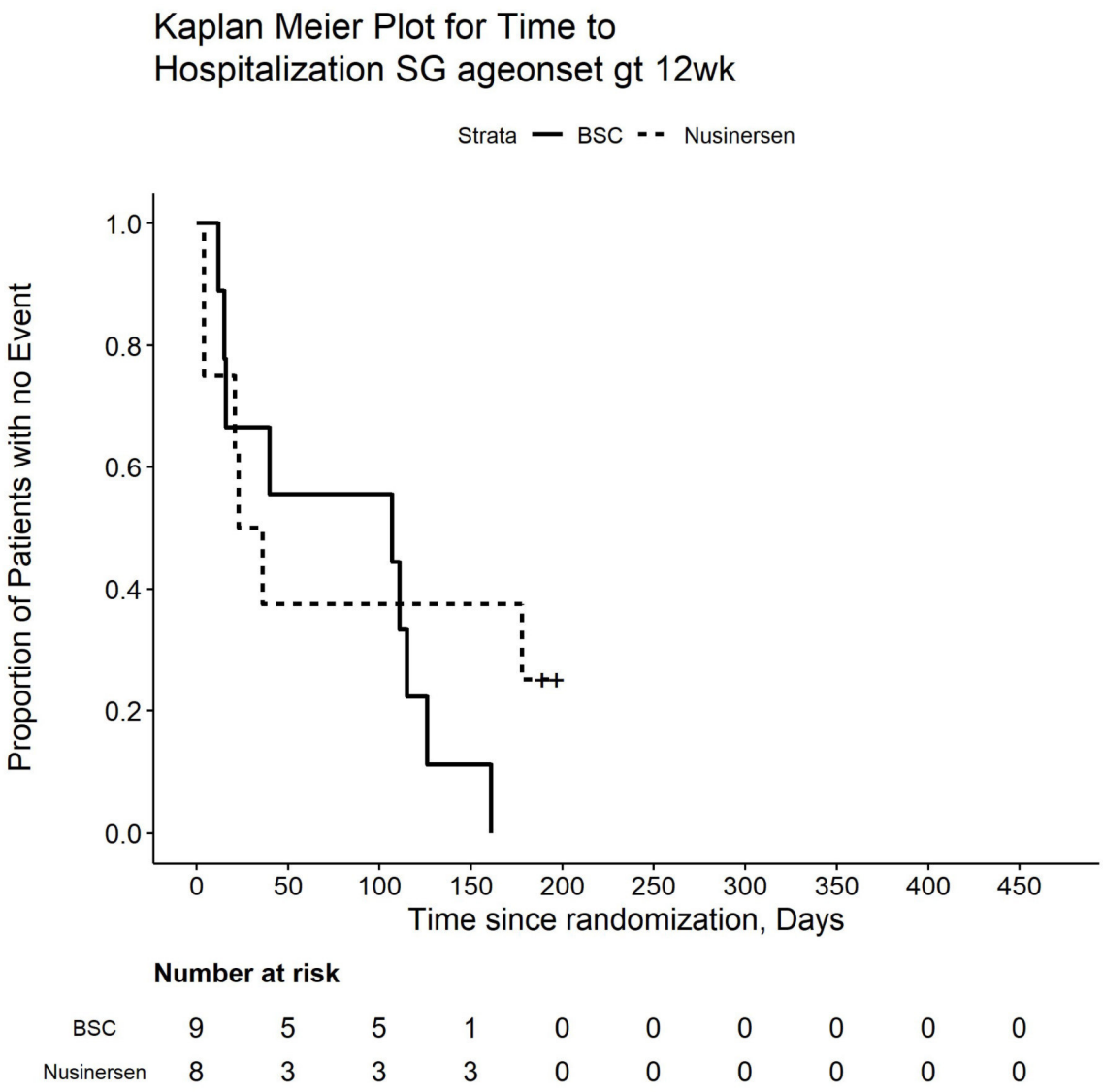
Number at risk

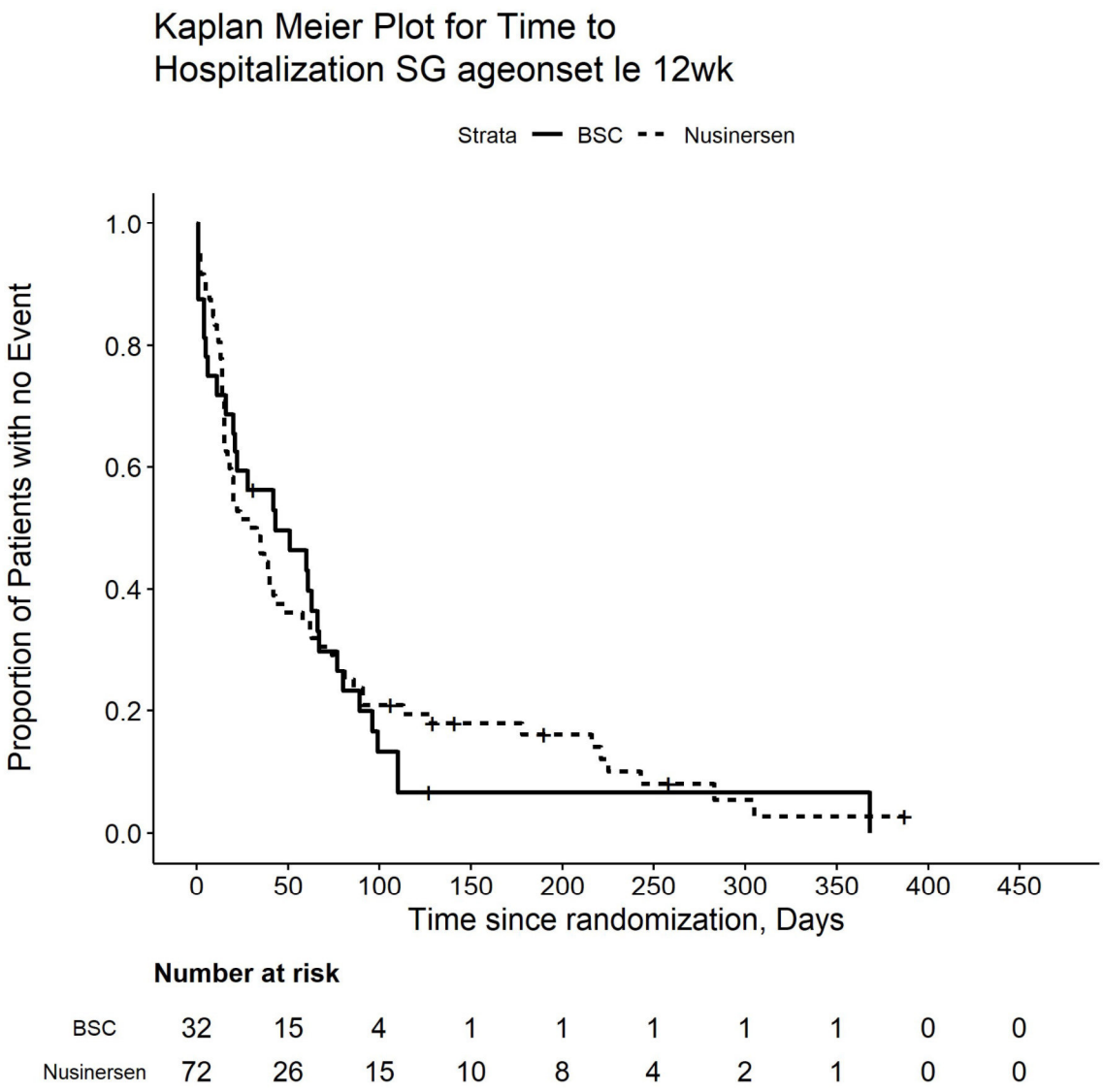
BSC	41	34	27	23	18	17	15	12	2	0
Nusinersen	80	72	63	57	40	33	24	17	6	0

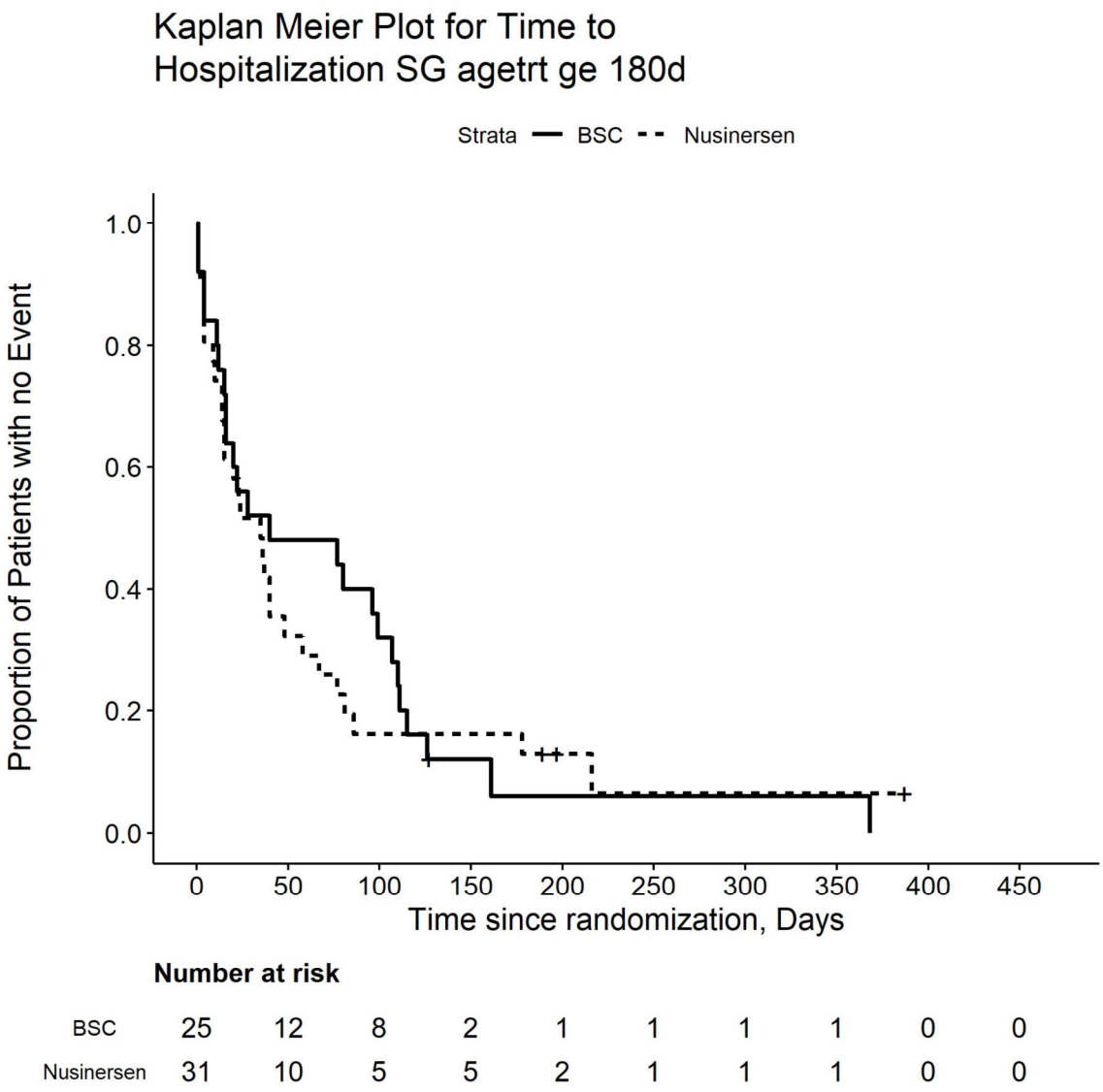


Number at risk

BSC	41	20	9	2	1	1	1	1	0	0
Nusinersen	80	29	18	13	8	4	2	1	0	0

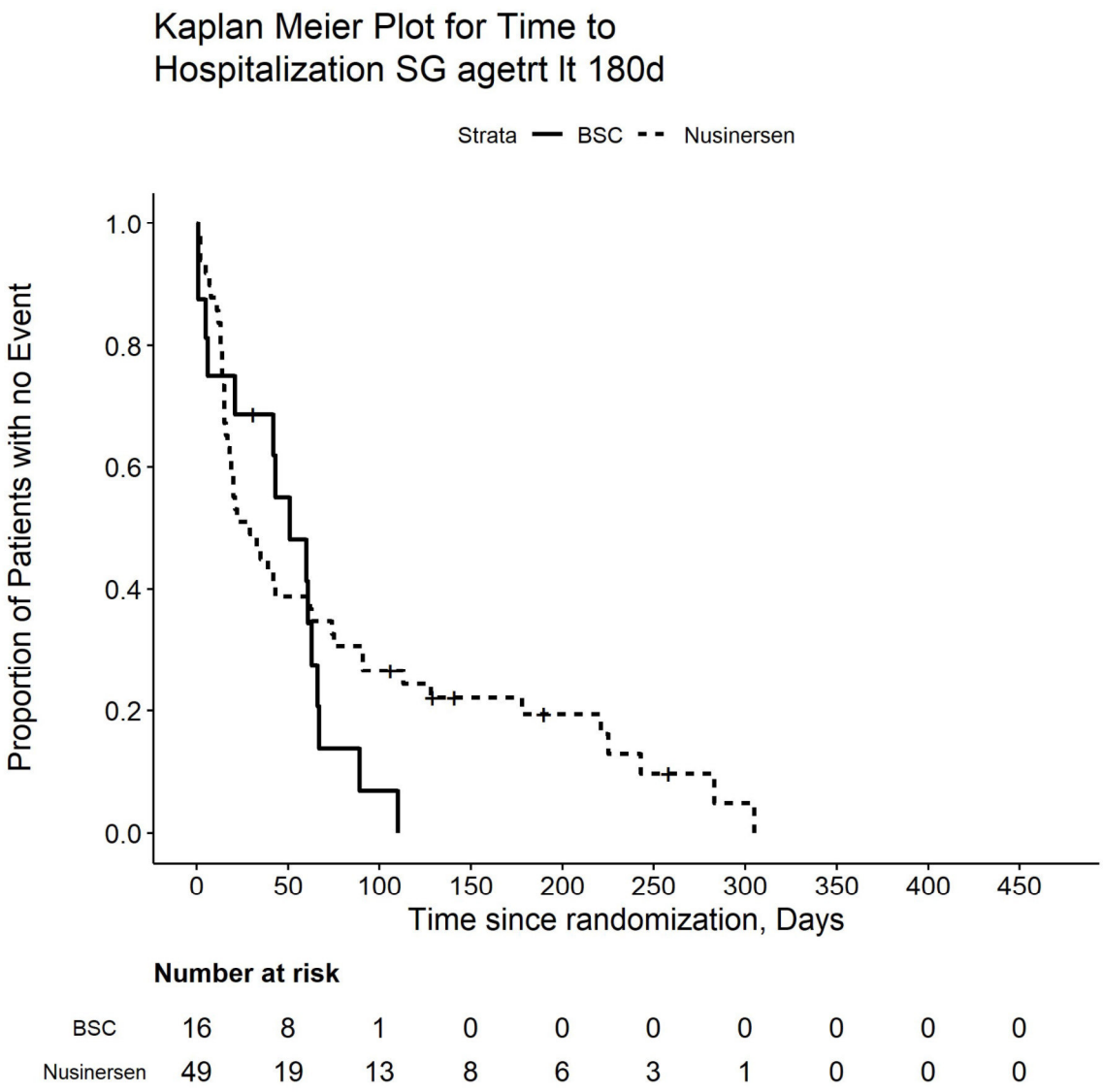

Kaplan Meier Plot for Time to
Hospitalization SG ageonset gt 12wk
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0 50 100 150 200 250 300 350 400 450
Time since randomization, Days
Number at risk
BSC 9 5 5 1 0 0 0 0 0 0
Nusinersen 8 3 3 3 0 0 0 0 0 0


Kaplan Meier Plot for Time to
Hospitalization SG ageonset le 12wk
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0
50
100
150
200
250
300
350
400
450
Time since randomization, Days
Number at risk
BSC 32 15 4 1 1 1 1 1 0 0
Nusinersen 72 26 15 10 8 4 2 1 0 0

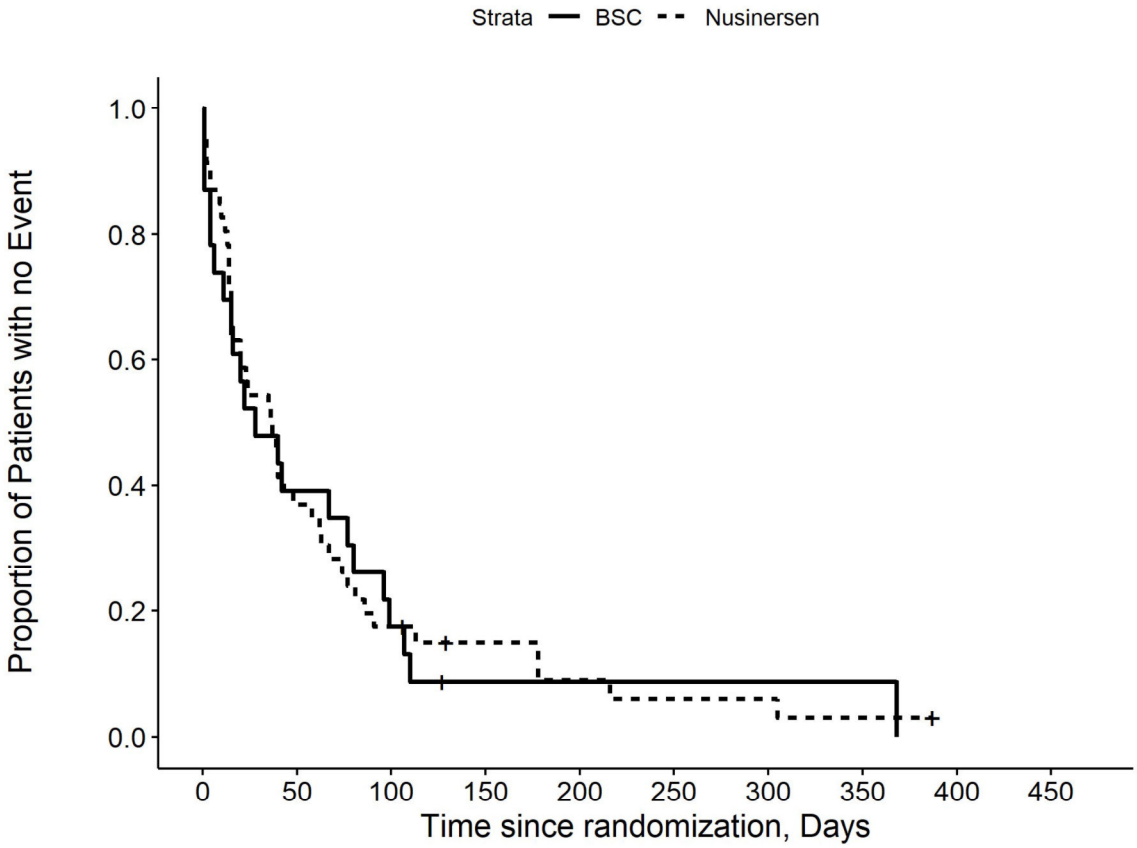


Number at risk

BSC	25	12	8	2	1	1	1	1	0	0
Nusinersen	31	10	5	5	2	1	1	1	0	0


Kaplan Meier Plot for Time to Hospitalization SG agetrt lt 180d
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0
50
100
150
200
250
300
350
400
450
Time since randomization, Days
Number at risk
BSC 16 8 1 0 0 0 0 0 0 0
Nusinersen 49 19 13 8 6 3 1 0 0 0

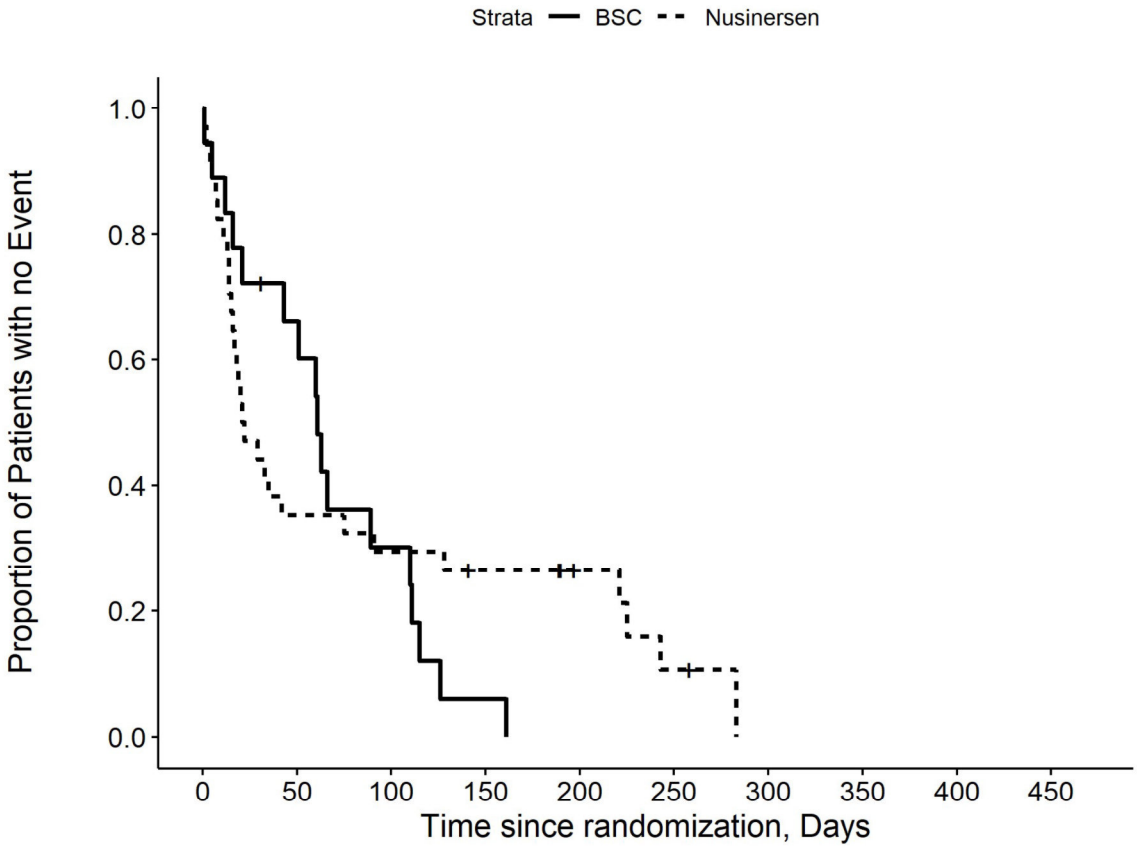
Kaplan Meier Plot for Time to Hospitalization SG disdur gt 12wk



Number at risk

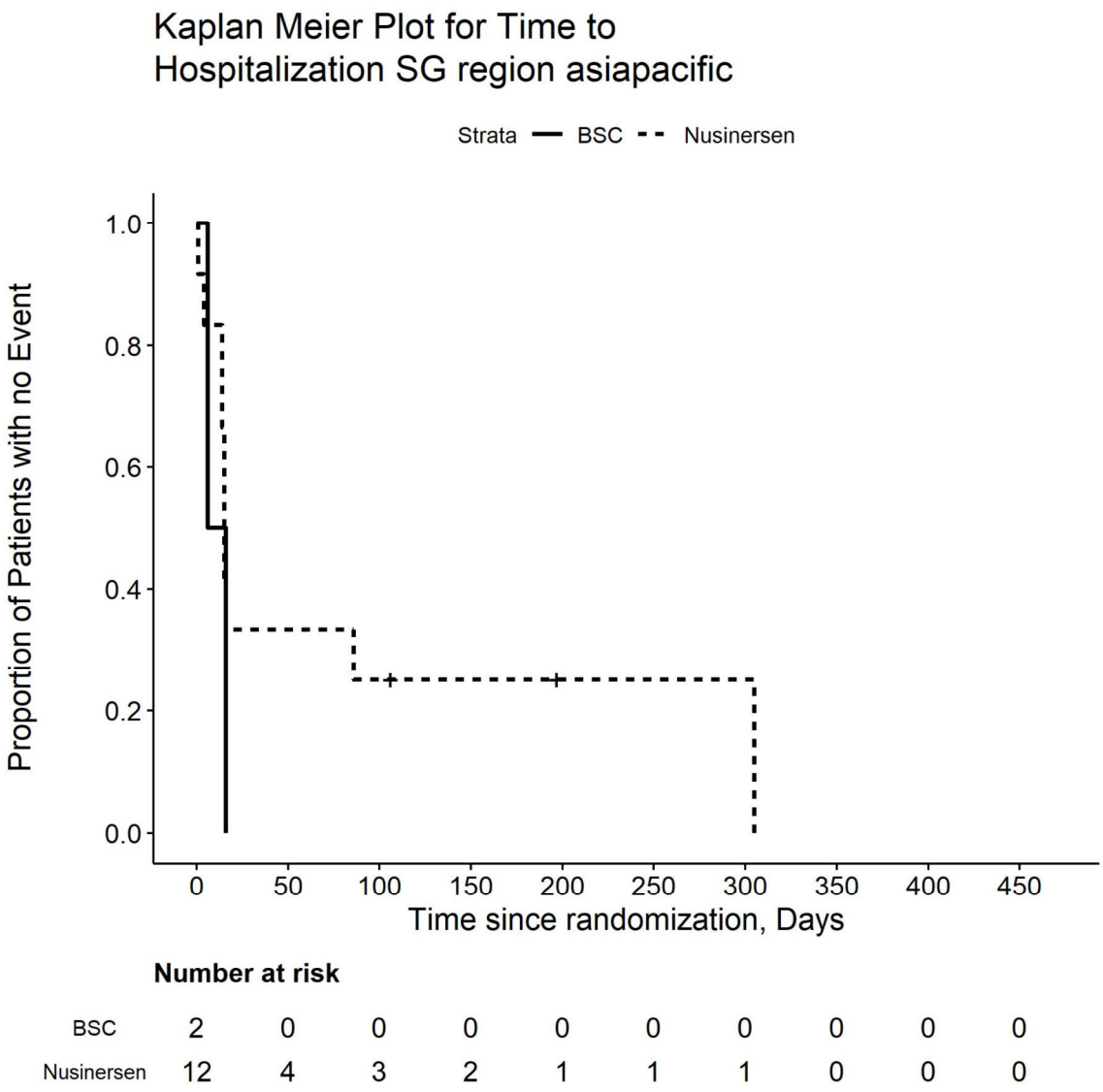
BSC	23	9	4	1	1	1	1	1	0	0
Nusinersen	46	17	8	5	3	2	2	1	0	0

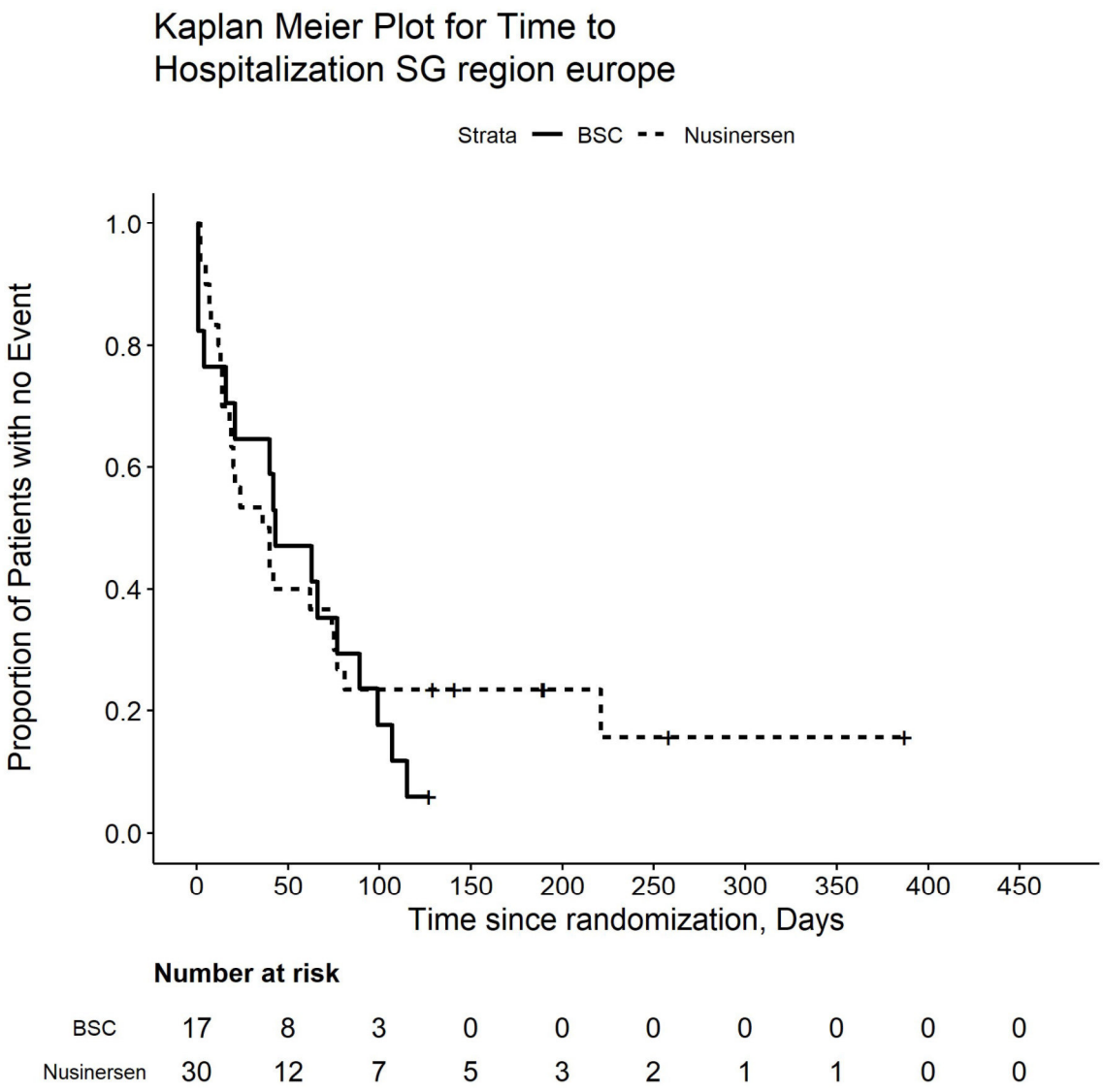
Kaplan Meier Plot for Time to Hospitalization SG disdur le 12wek



Number at risk

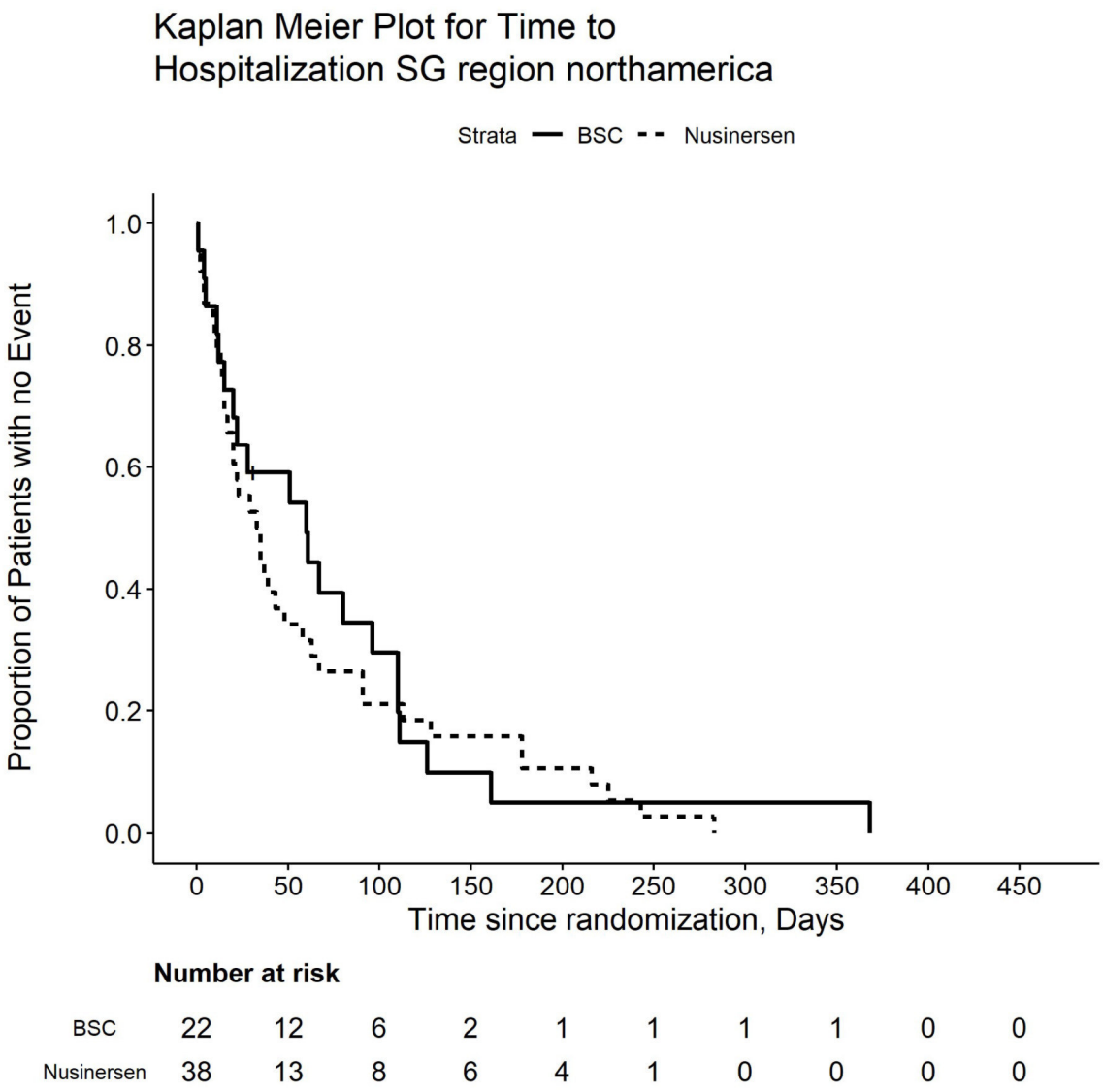
BSC	18	11	5	1	0	0	0	0	0	0
Nusinersen	34	12	10	8	5	2	0	0	0	0


Kaplan Meier Plot for Time to Hospitalization SG region asiapacific
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0
50
100
150
200
250
300
350
400
450
Time since randomization, Days
Number at risk
BSC 2 0 0 0 0 0 0 0 0 0
Nusinersen 12 4 3 2 1 1 1 0 0 0



Number at risk

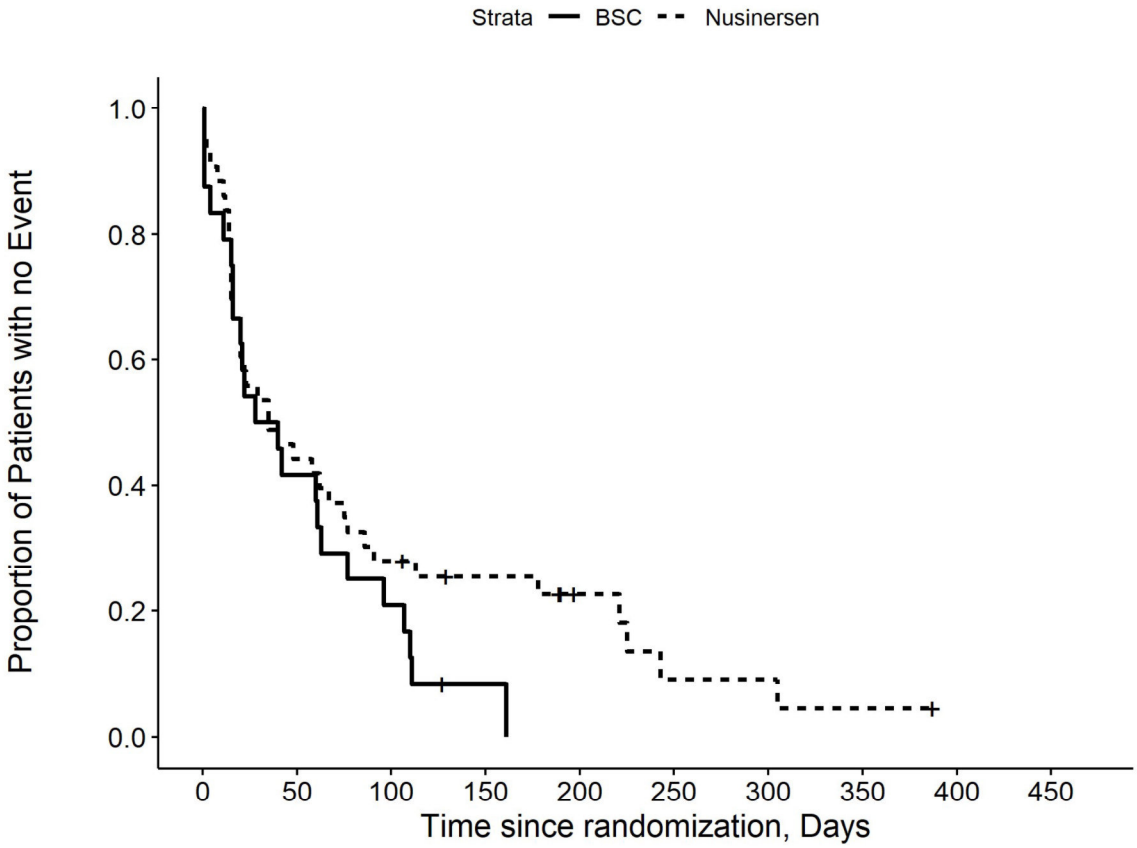
BSC	17	8	3	0	0	0	0	0	0	0
Nusinersen	30	12	7	5	3	2	1	1	0	0



Number at risk

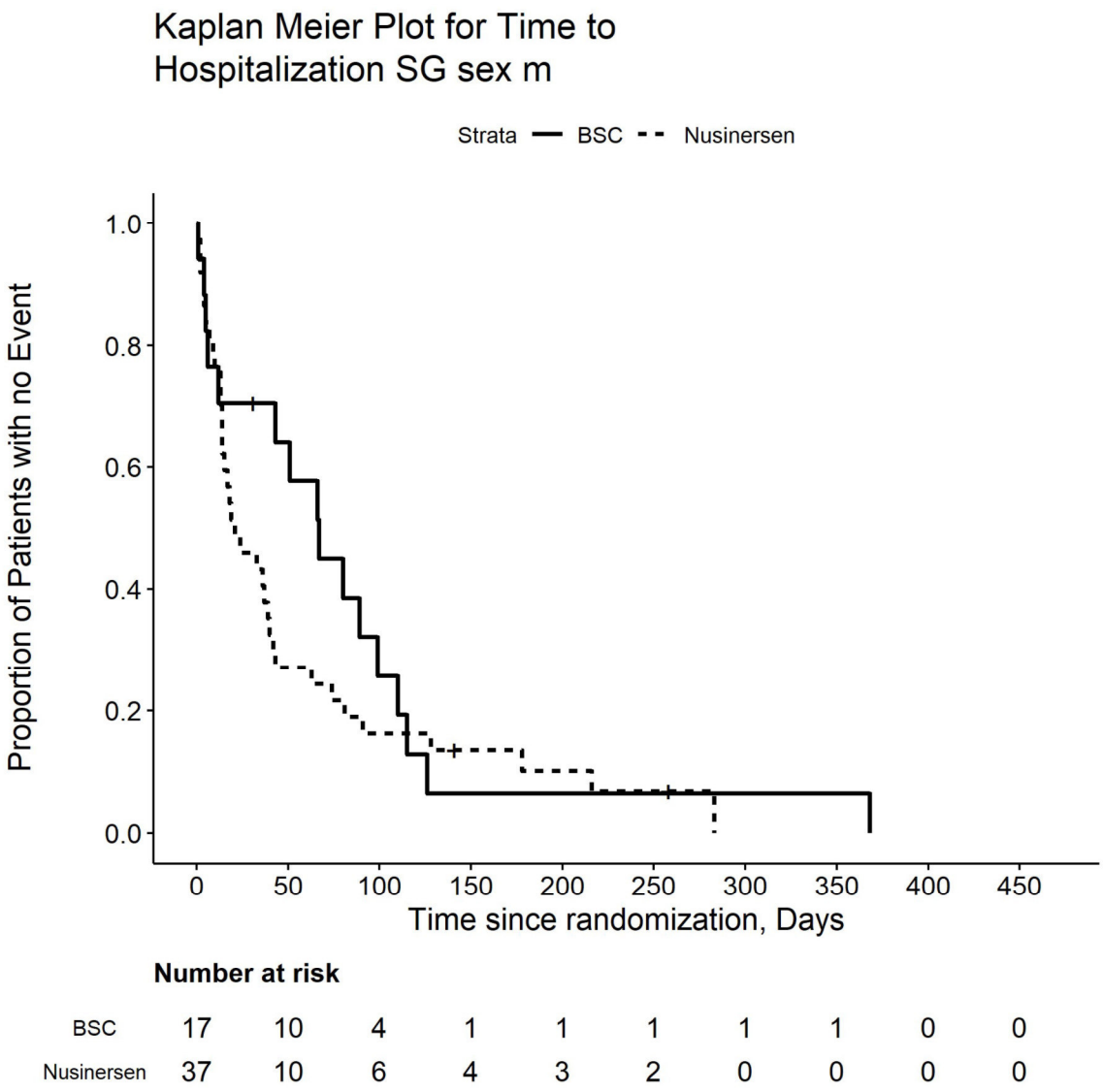
BSC	22	12	6	2	1	1	1	1	0	0
Nusinersen	38	13	8	6	4	1	0	0	0	0

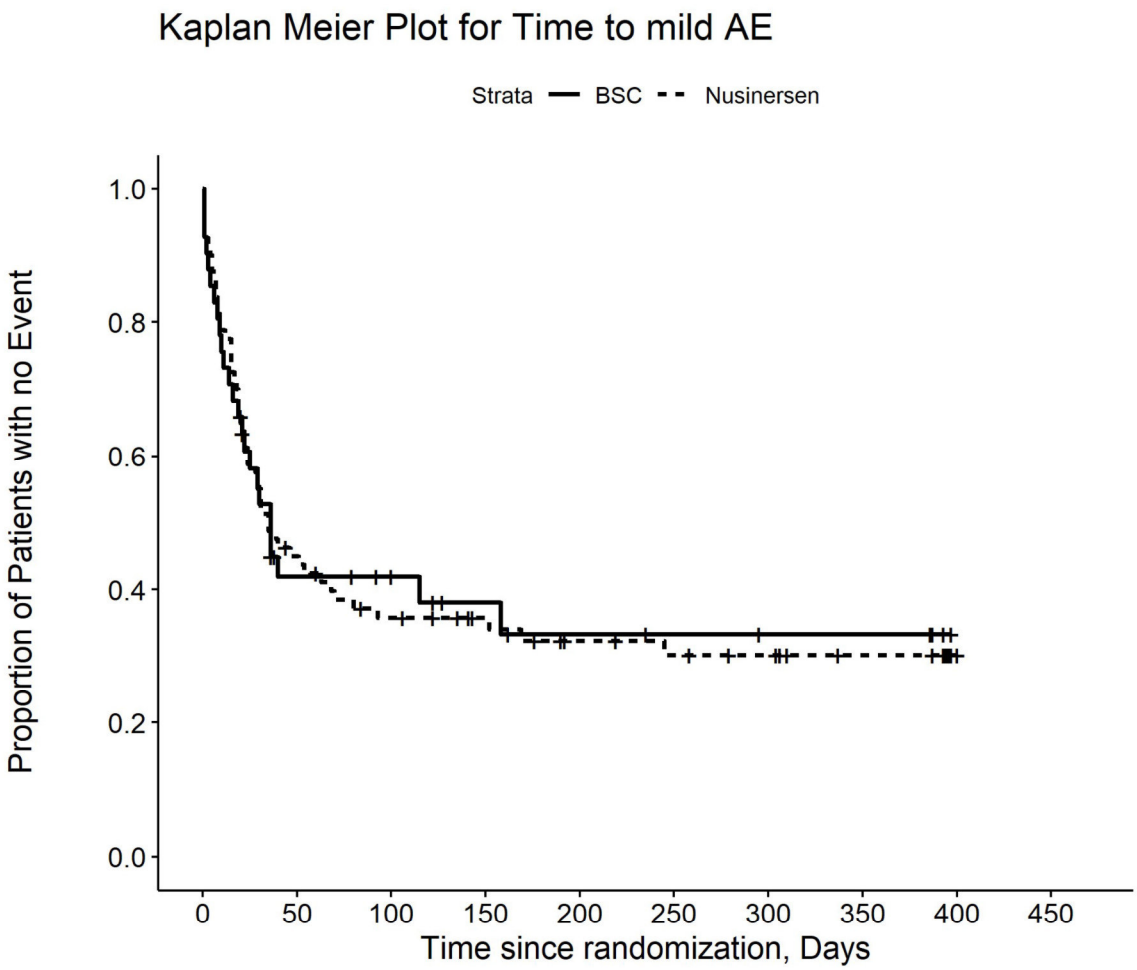
Kaplan Meier Plot for Time to Hospitalization SG sex f



Number at risk

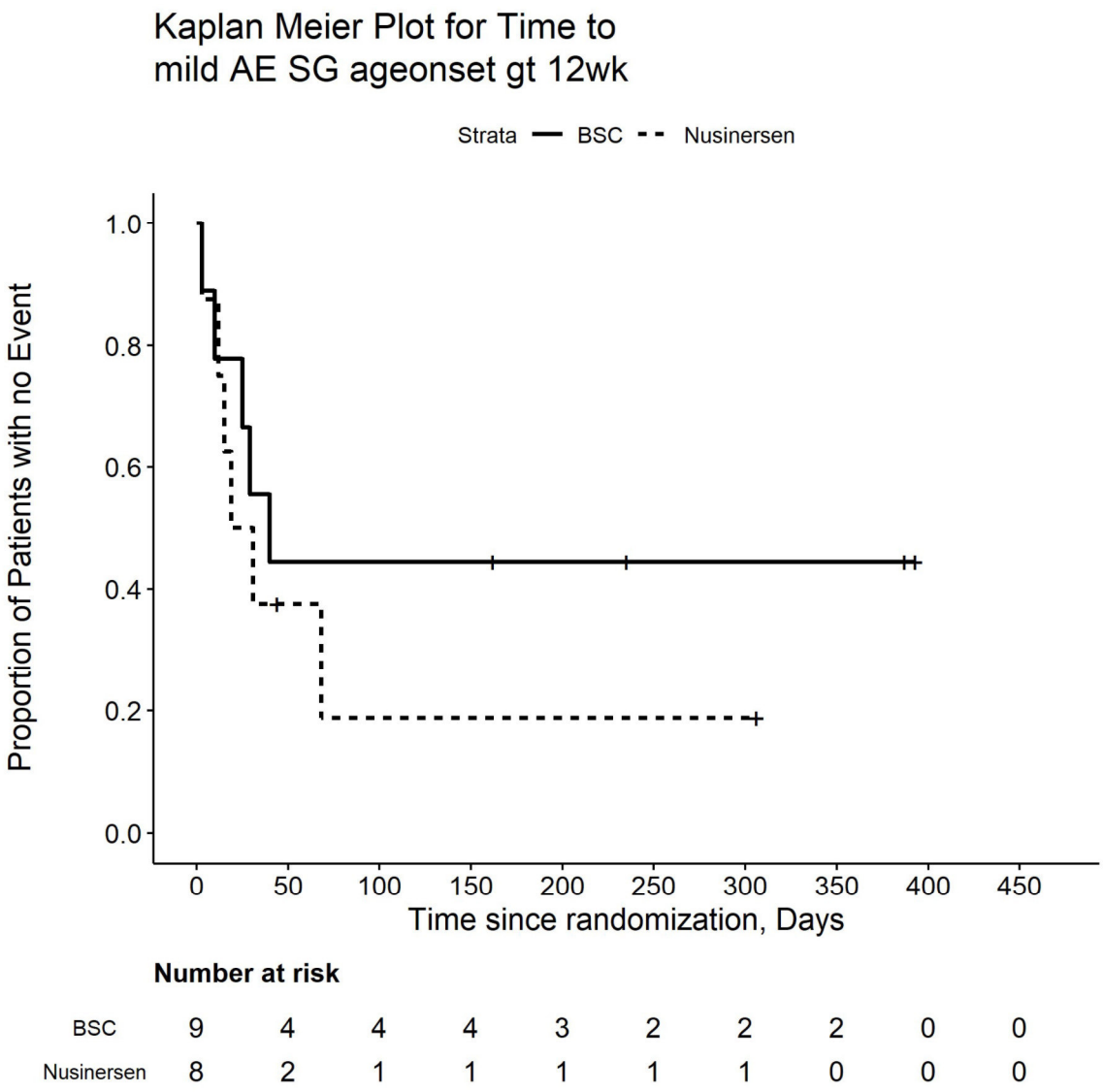
BSC	24	10	5	1	0	0	0	0	0	0
Nusinersen	43	19	12	9	5	2	2	1	0	0


Kaplan Meier Plot for Time to Hospitalization SG sex m
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0 50 100 150 200 250 300 350 400 450
Time since randomization, Days
Number at risk
BSC 17 10 4 1 1 1 1 1 0 0
Nusinersen 37 10 6 4 3 2 0 0 0 0



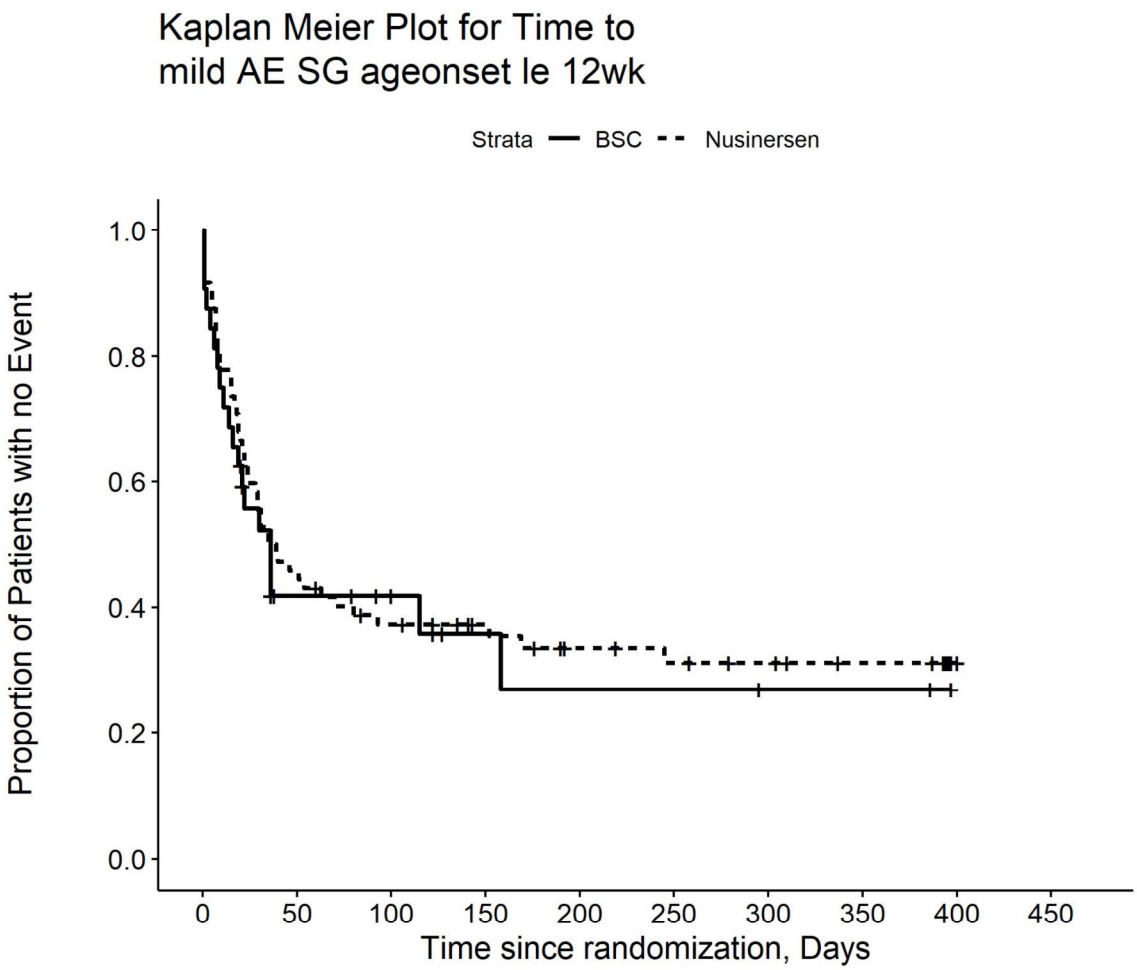
Number at risk

BSC	41	14	12	8	6	5	4	4	0	0
Nusinersen	80	35	26	21	16	14	11	7	1	0



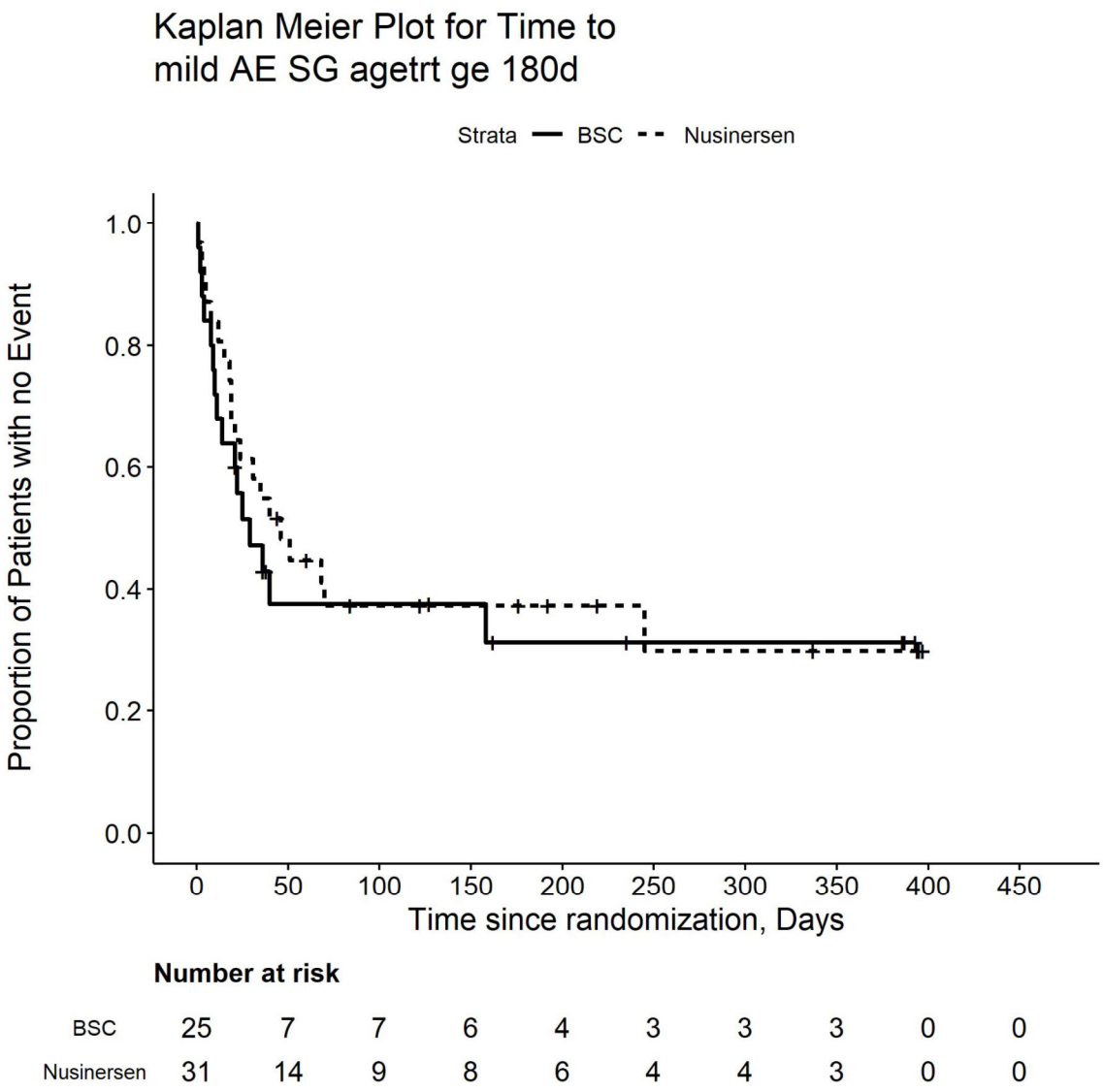
Number at risk

BSC	9	4	4	4	3	2	2	2	0	0
Nusinersen	8	2	1	1	1	1	1	0	0	0



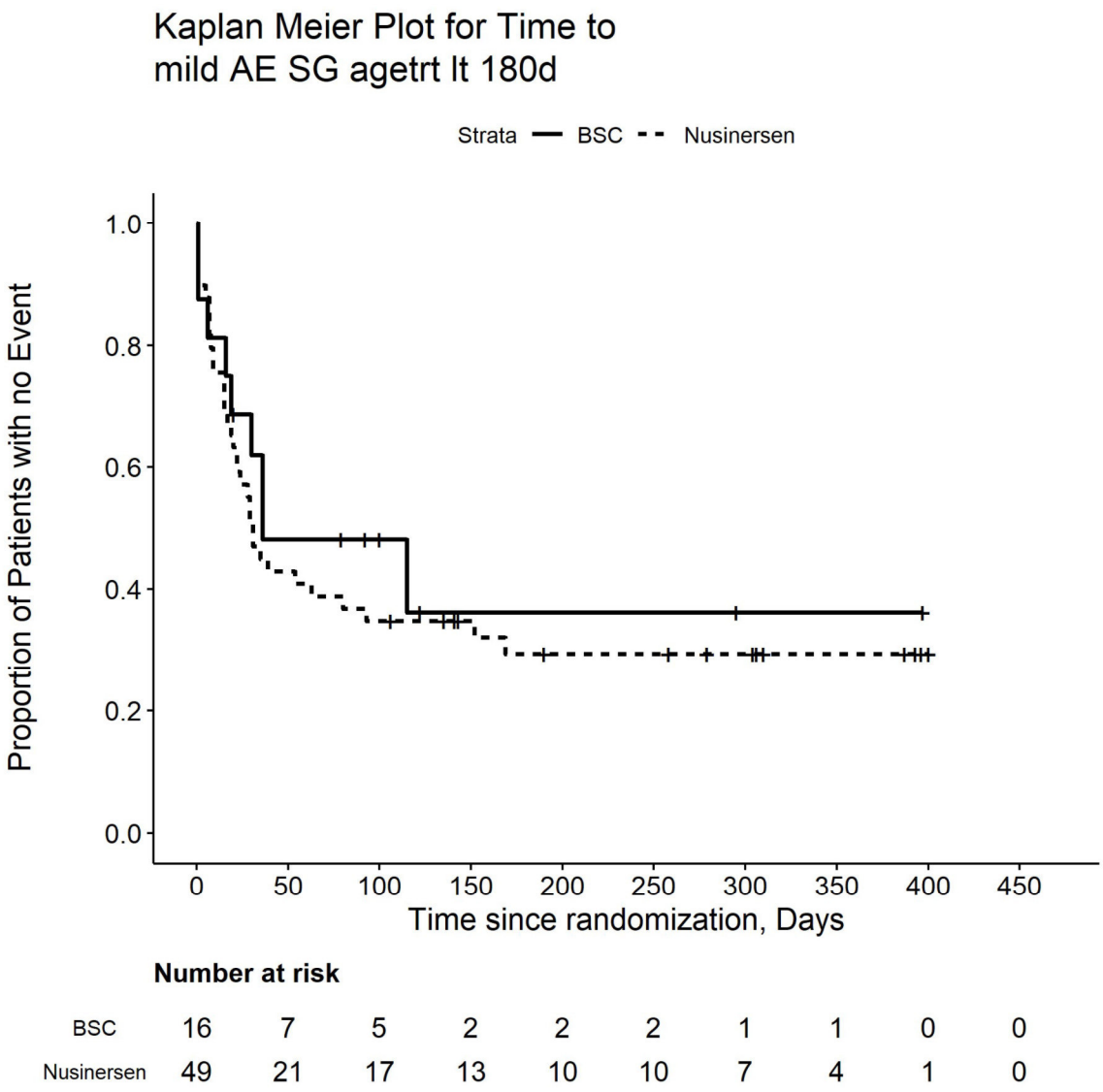
Number at risk

BSC	32	10	8	4	3	3	2	2	0	0
Nusinersen	72	33	25	20	15	13	10	7	1	0



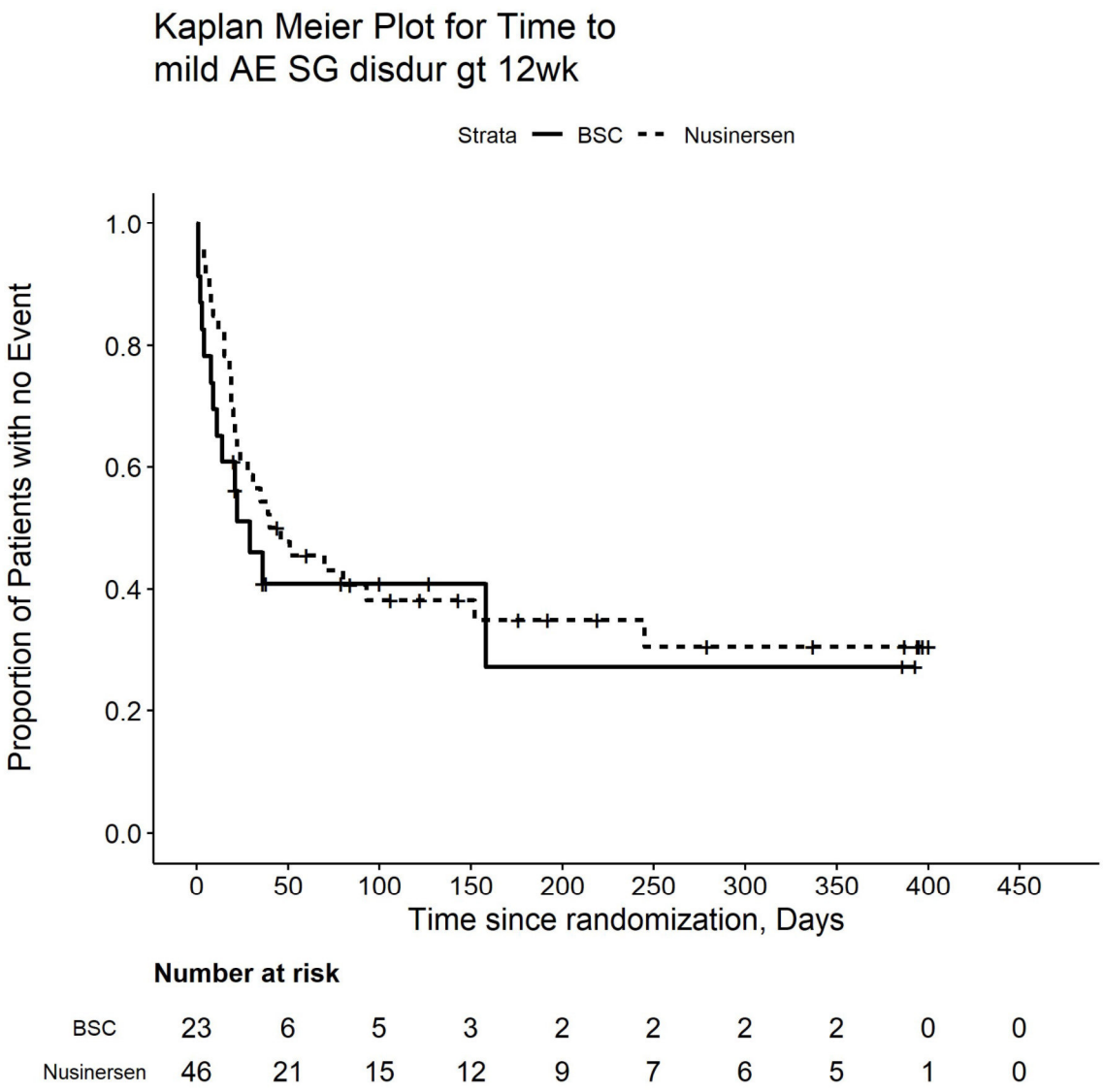
Number at risk

BSC	25	7	7	6	4	3	3	3	0	0
Nusinersen	31	14	9	8	6	4	4	3	0	0



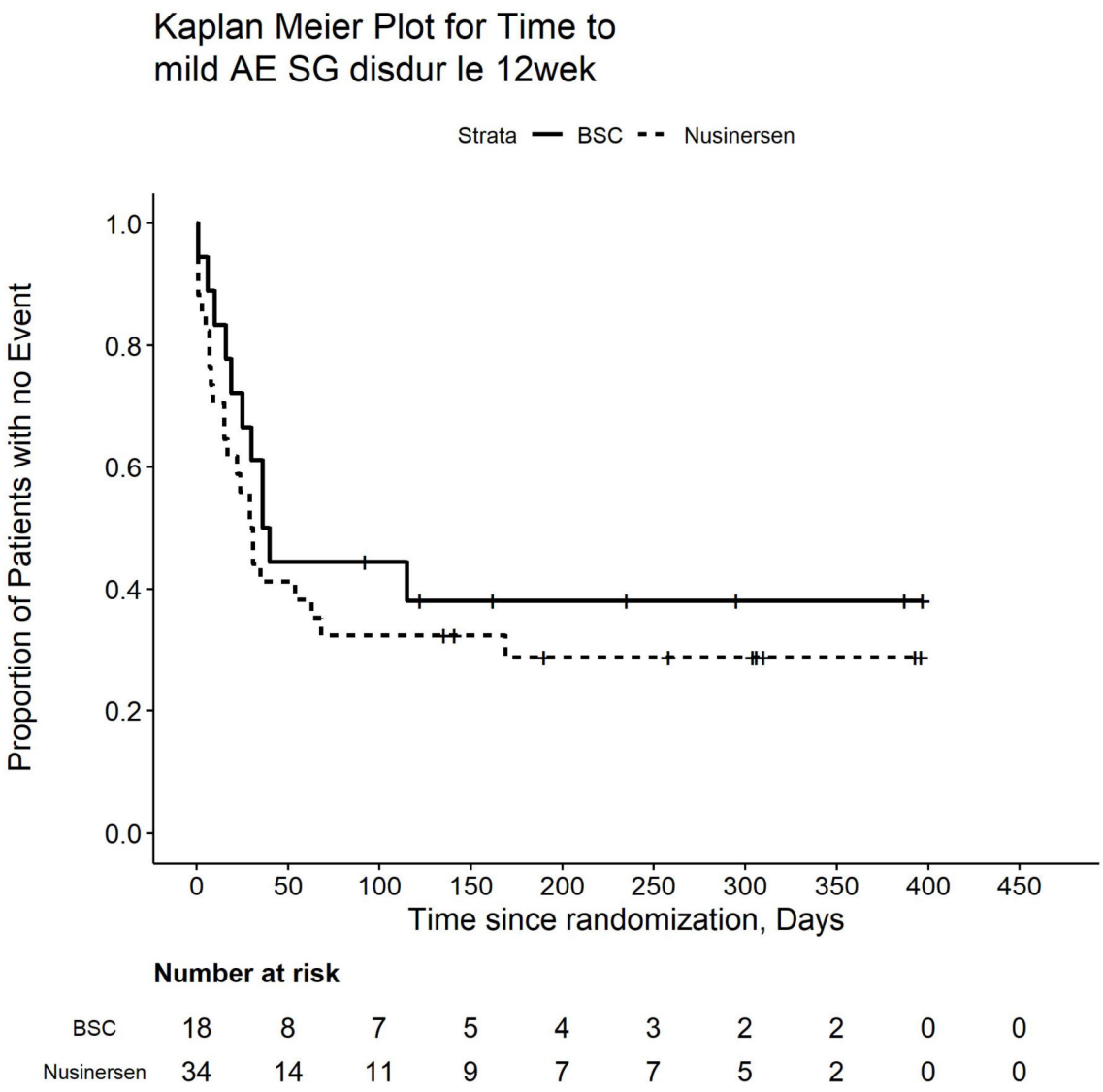
Number at risk

BSC	16	7	5	2	2	2	1	1	0	0
Nusinersen	49	21	17	13	10	10	7	4	1	0



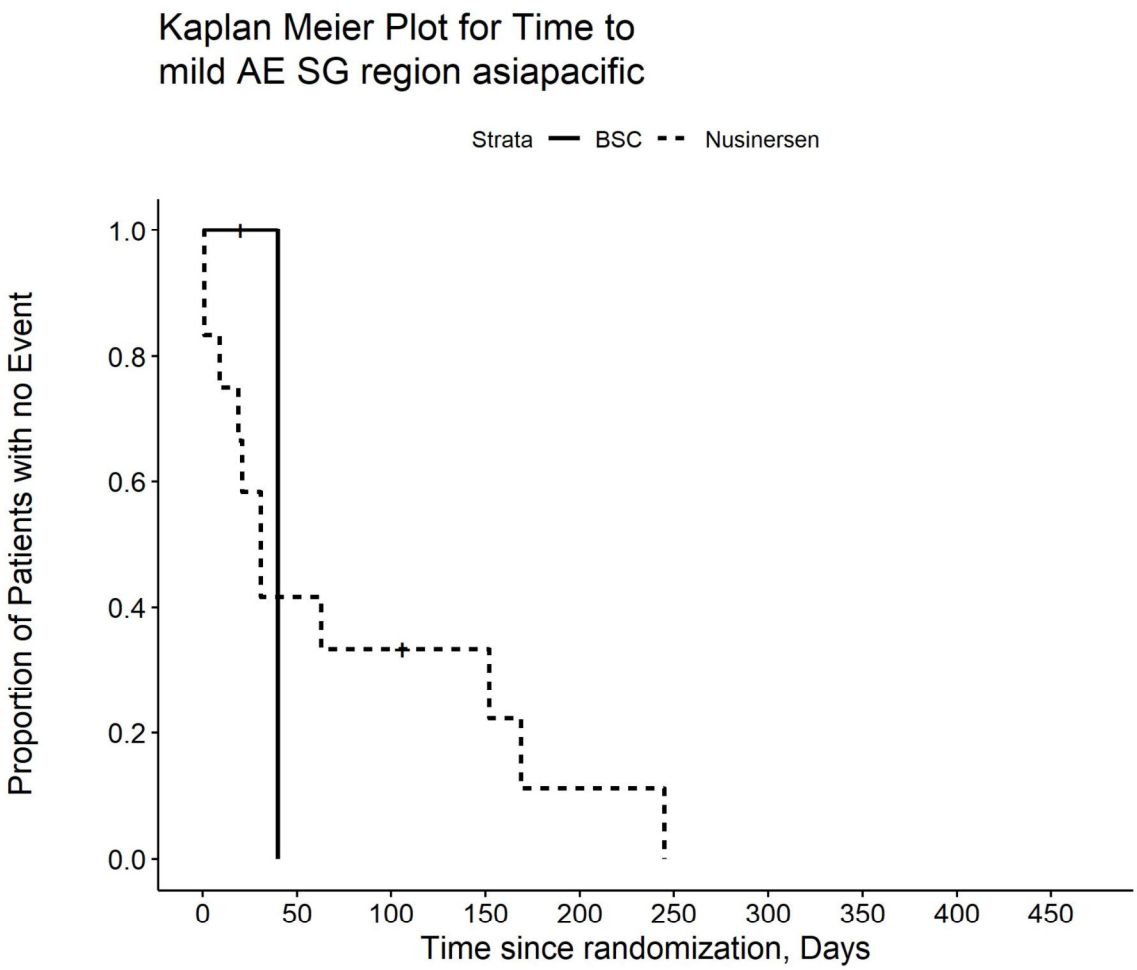
Number at risk

BSC	23	6	5	3	2	2	2	2	0	0
Nusinersen	46	21	15	12	9	7	6	5	1	0



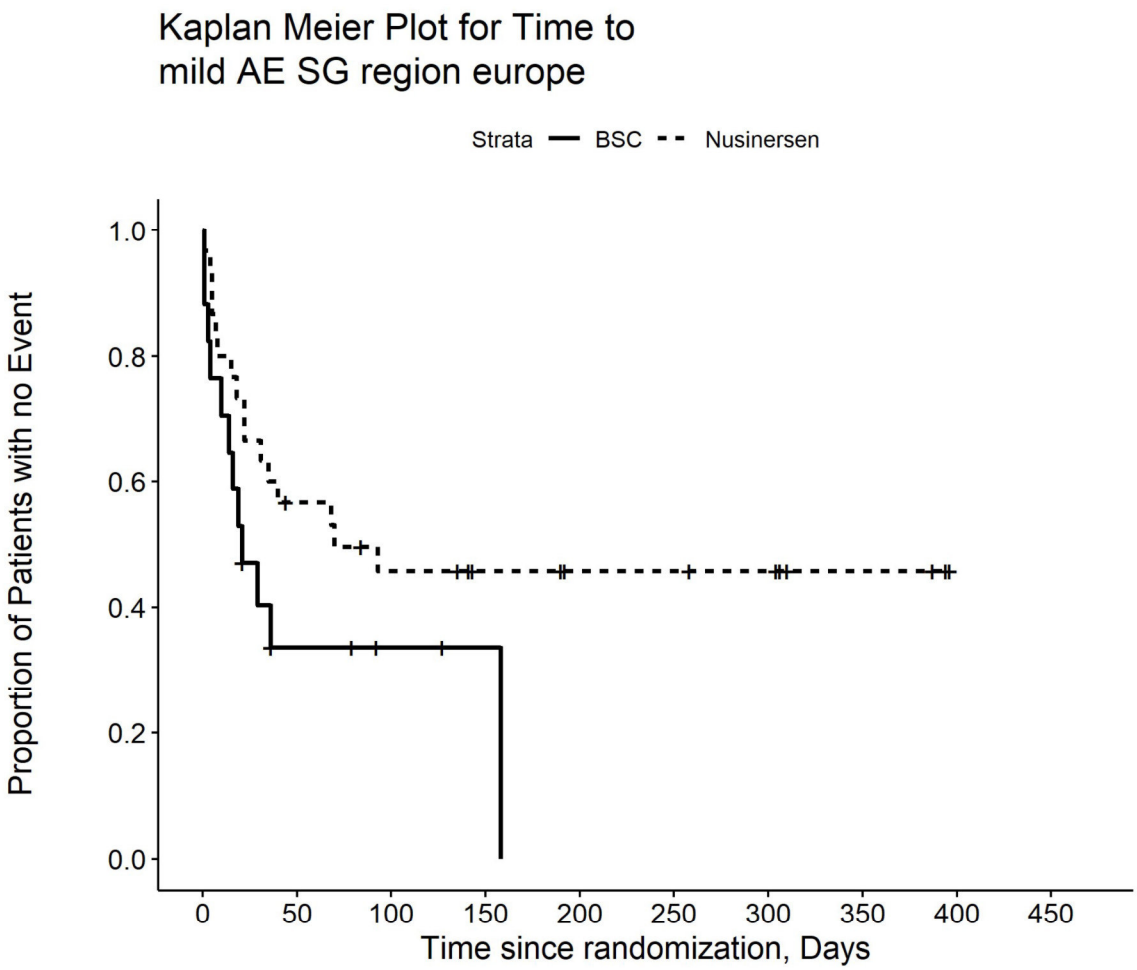
Number at risk

BSC	18	8	7	5	4	3	2	2	0	0
Nusinersen	34	14	11	9	7	7	5	2	0	0



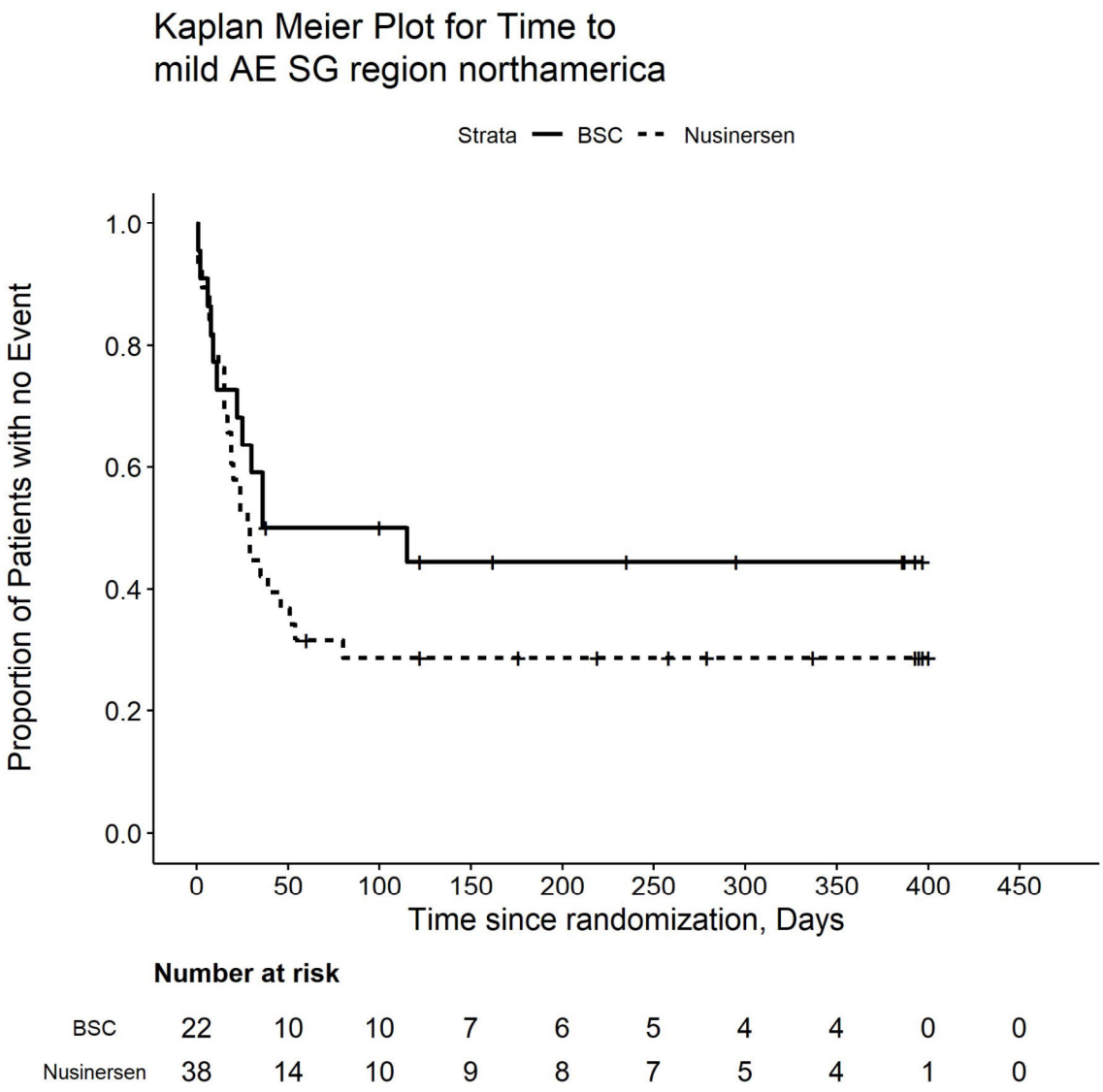
Number at risk

BSC	2	0	0	0	0	0	0	0	0	0
Nusinersen	12	5	4	3	1	0	0	0	0	0



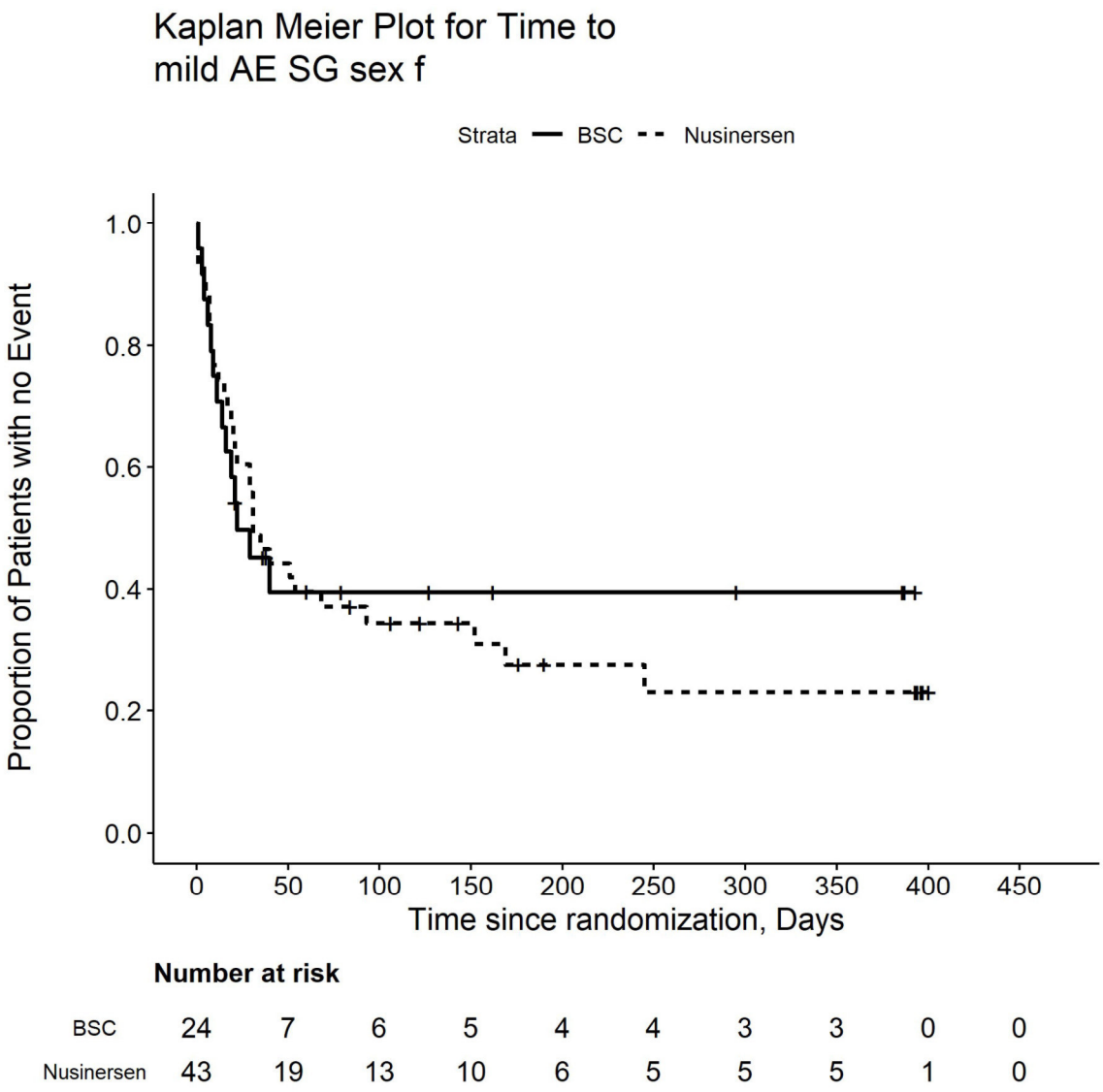
Number at risk

BSC	17	4	2	1	0	0	0	0	0	0
Nusinersen	30	16	12	9	7	7	6	3	0	0



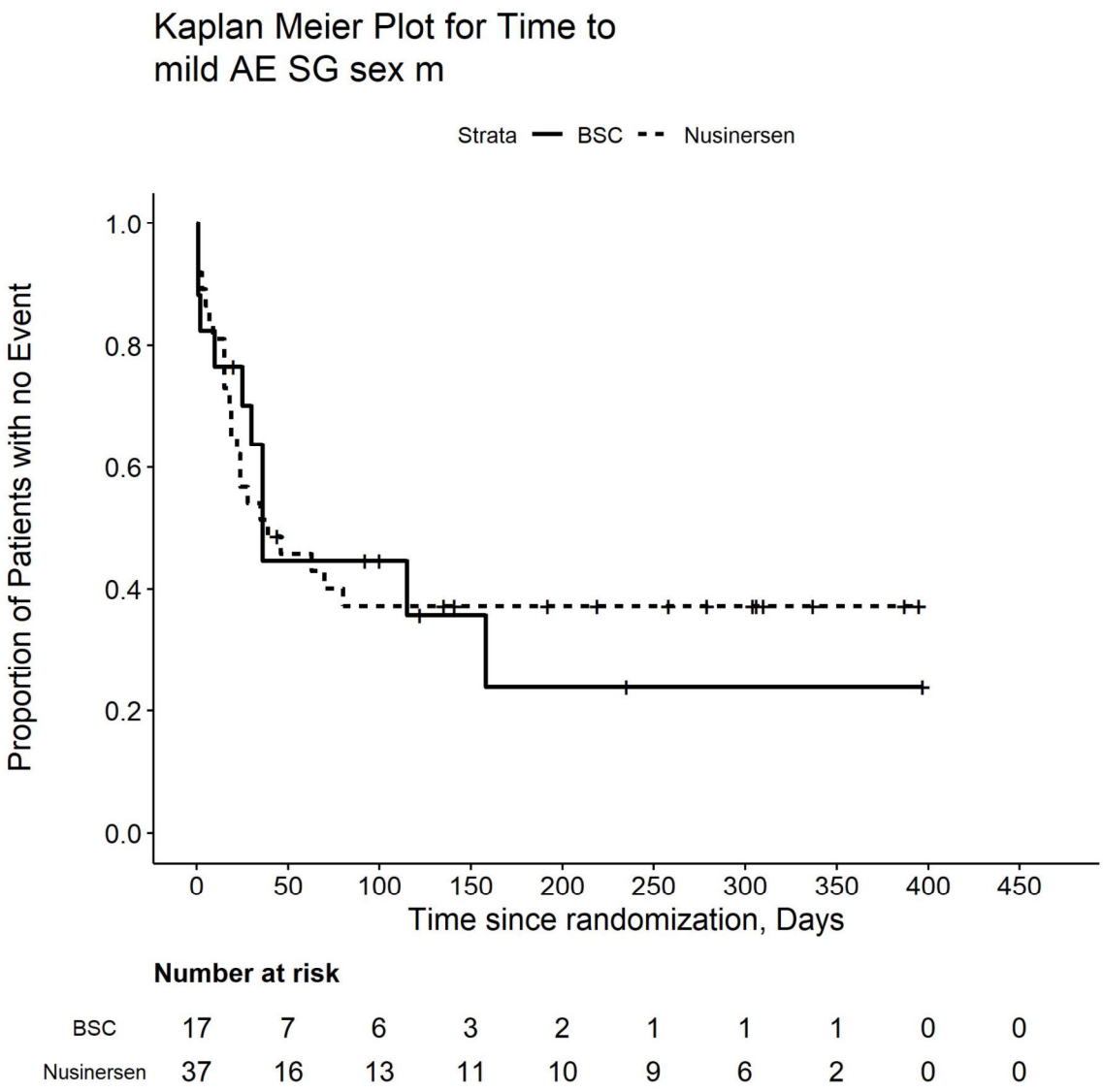
Number at risk

BSC	22	10	10	7	6	5	4	4	0	0
Nusinersen	38	14	10	9	8	7	5	4	1	0



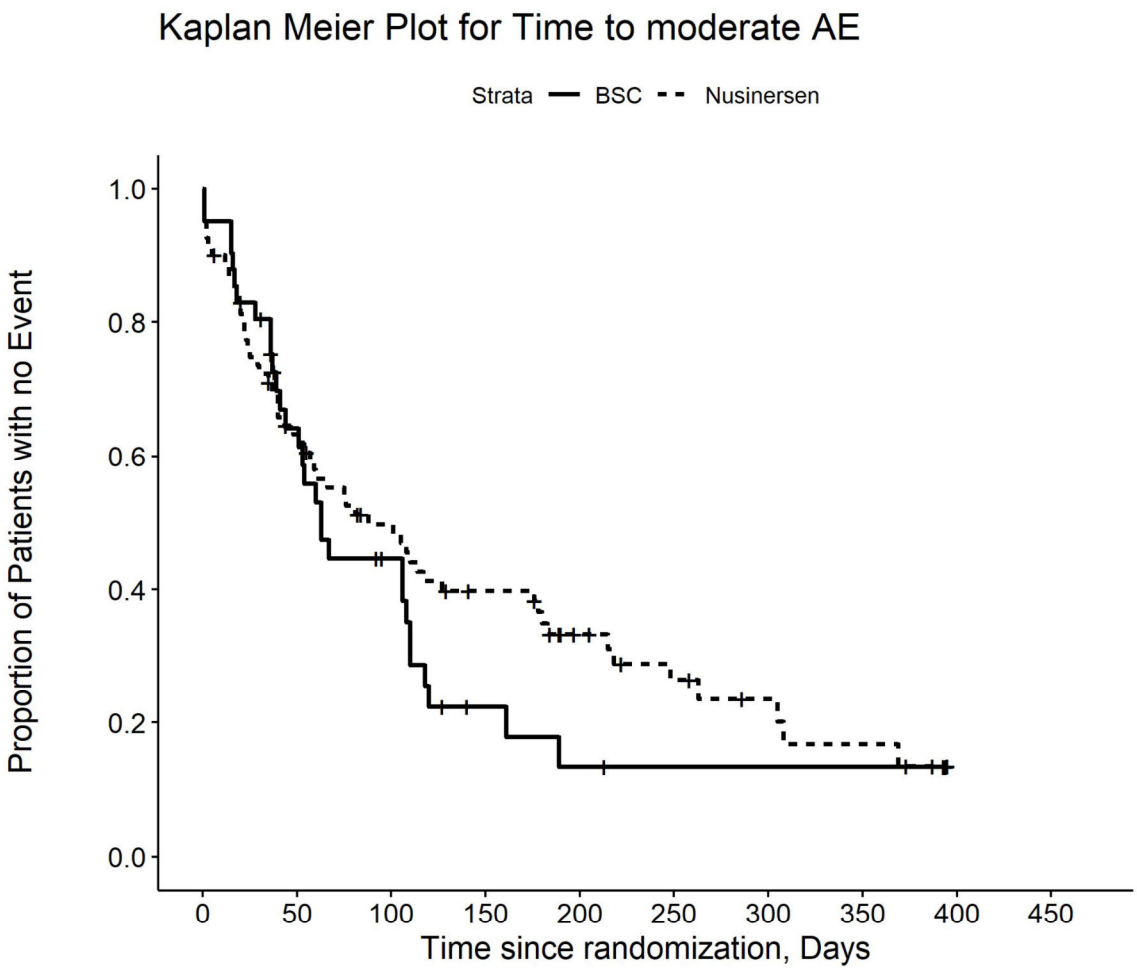
Number at risk

BSC	24	7	6	5	4	4	3	3	0	0
Nusinersen	43	19	13	10	6	5	5	5	1	0



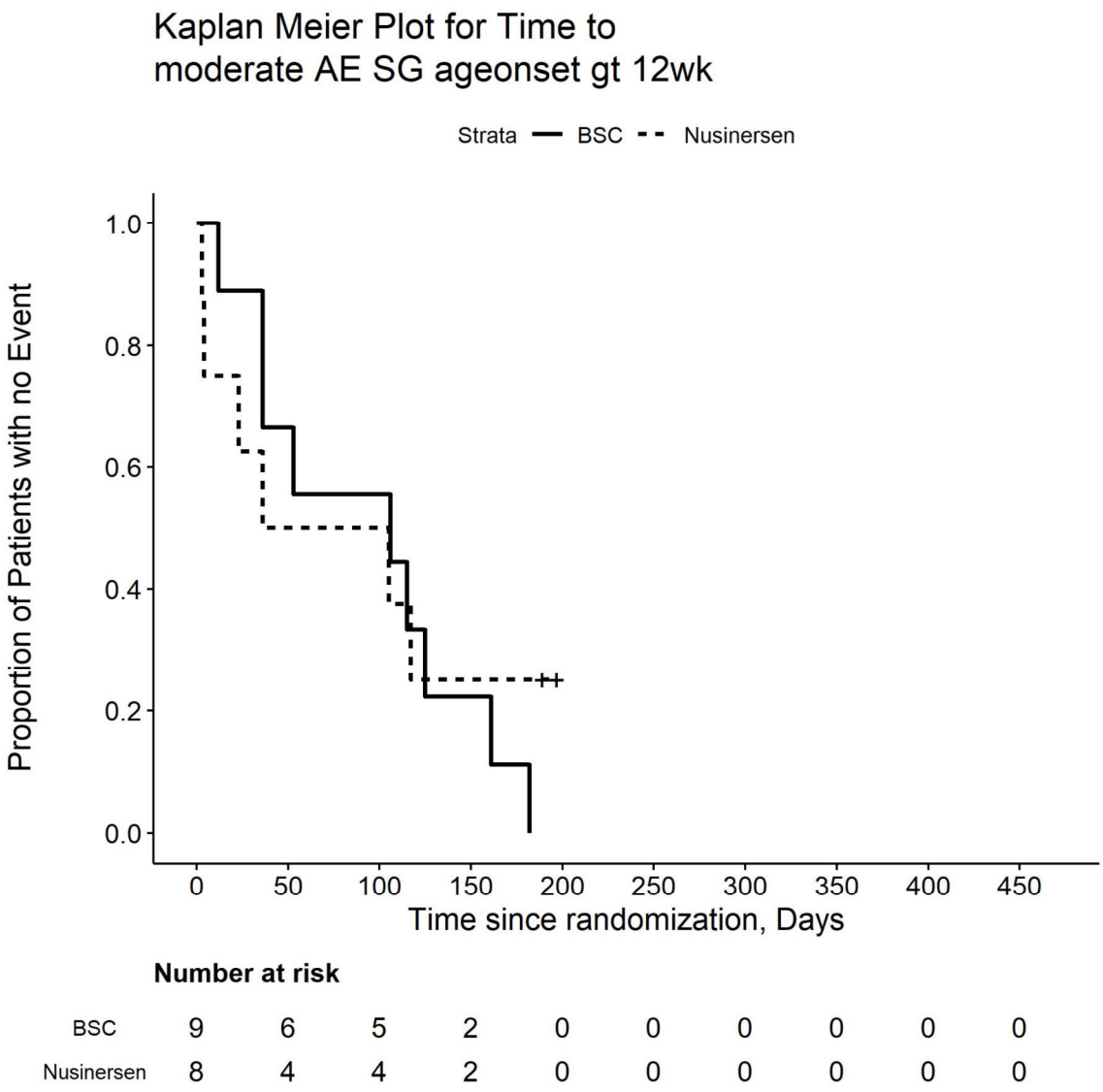
Number at risk

BSC	17	7	6	3	2	1	1	1	0	0
Nusinersen	37	16	13	11	10	9	6	2	0	0



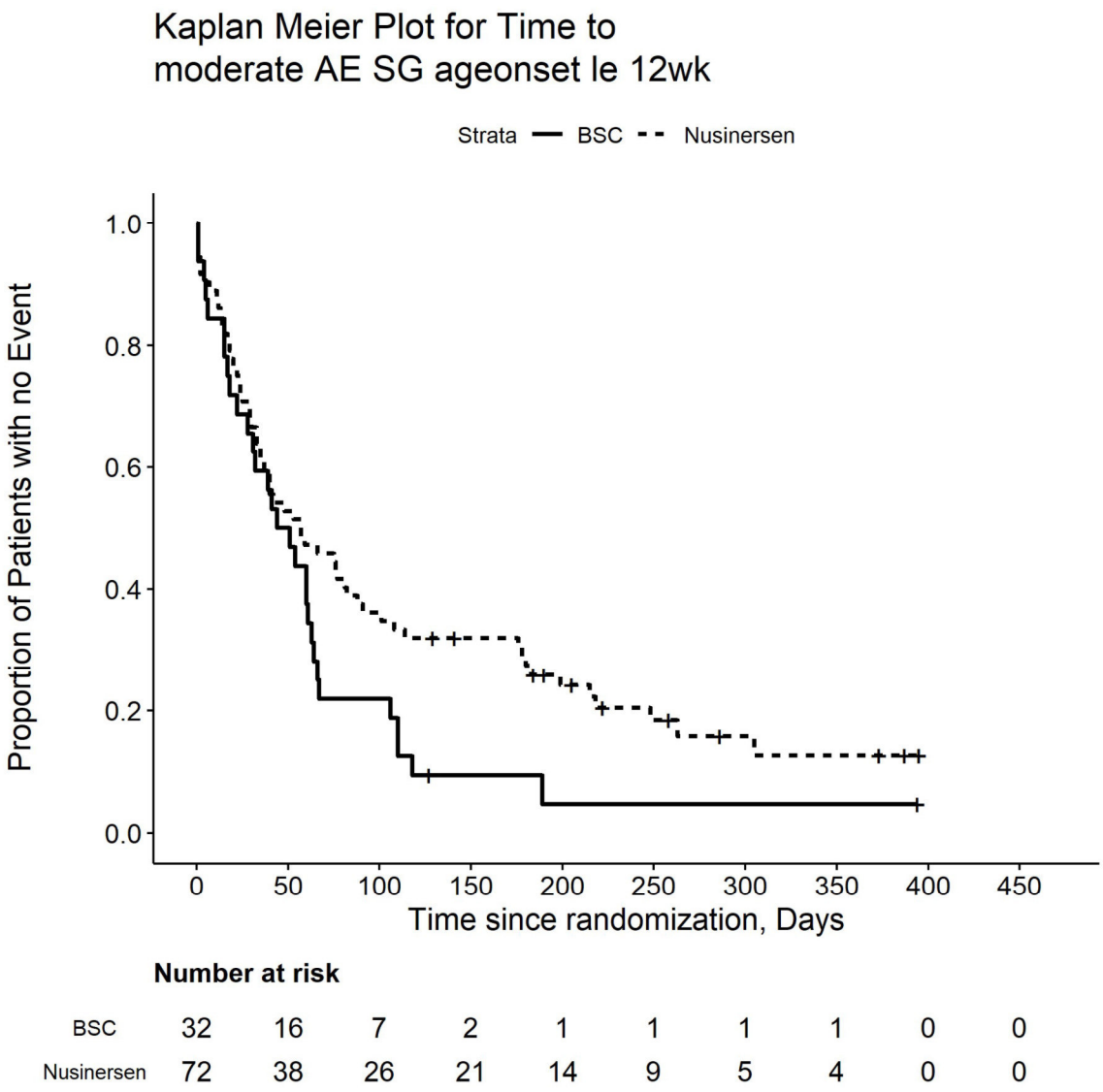
Number at risk

BSC	41	23	14	5	3	2	2	2	0	0
Nusinersen	80	48	35	26	16	11	7	5	0	0



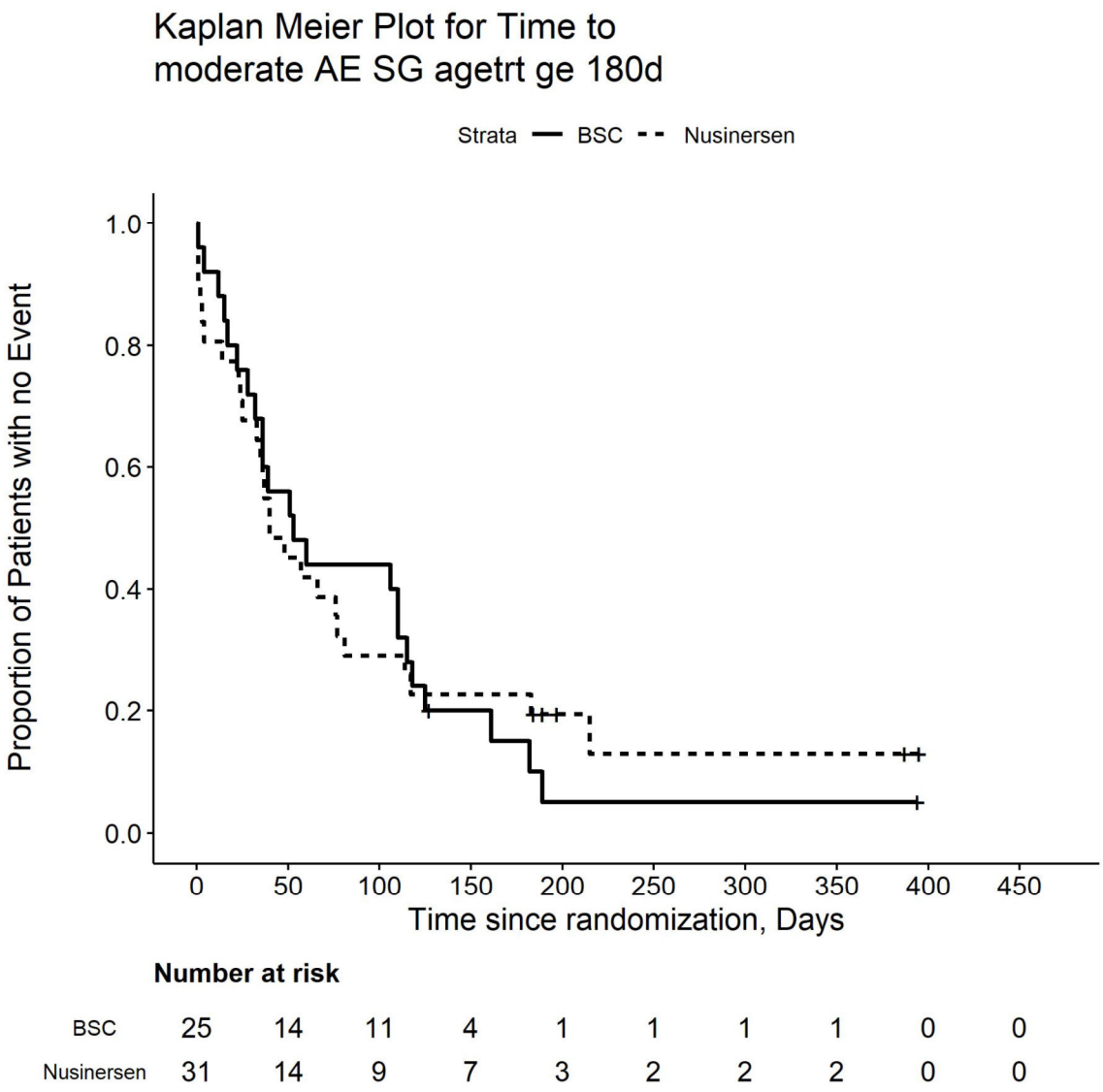
Number at risk

BSC	9	6	5	2	0	0	0	0	0	0
Nusinersen	8	4	4	2	0	0	0	0	0	0



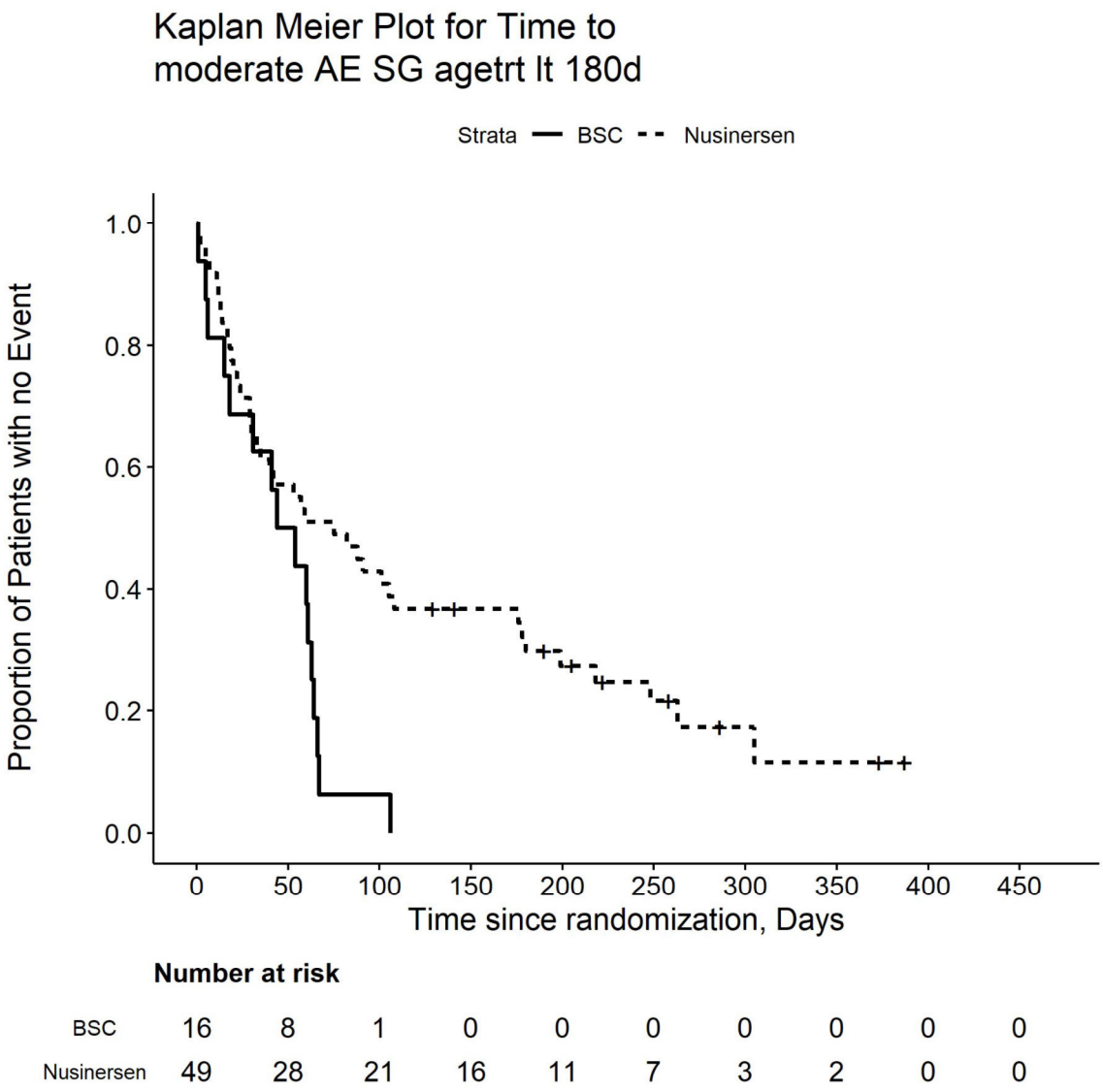
Number at risk

BSC	32	16	7	2	1	1	1	1	0	0
Nusinersen	72	38	26	21	14	9	5	4	0	0



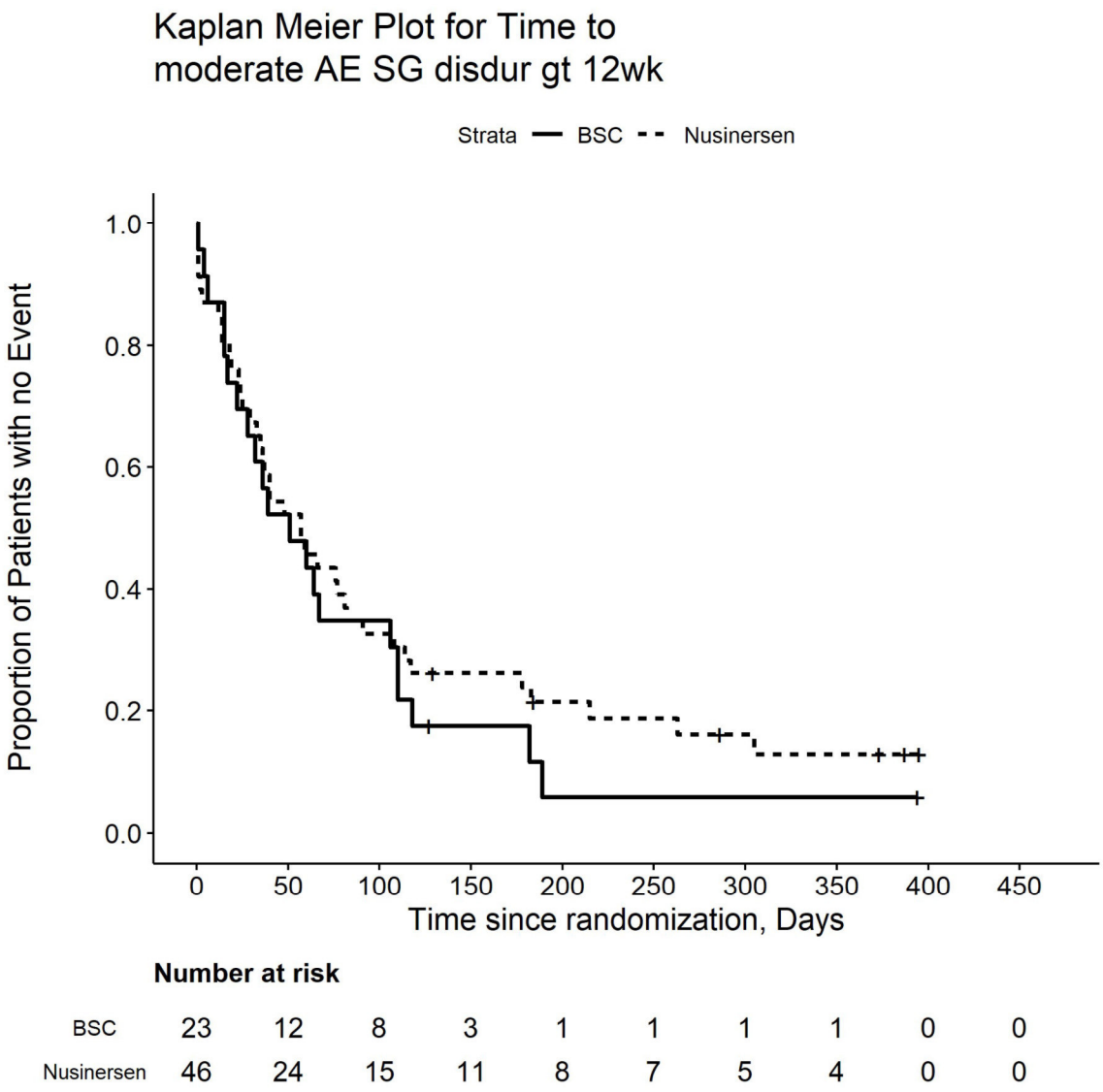
Number at risk

BSC	25	14	11	4	1	1	1	1	0	0
Nusinersen	31	14	9	7	3	2	2	2	0	0



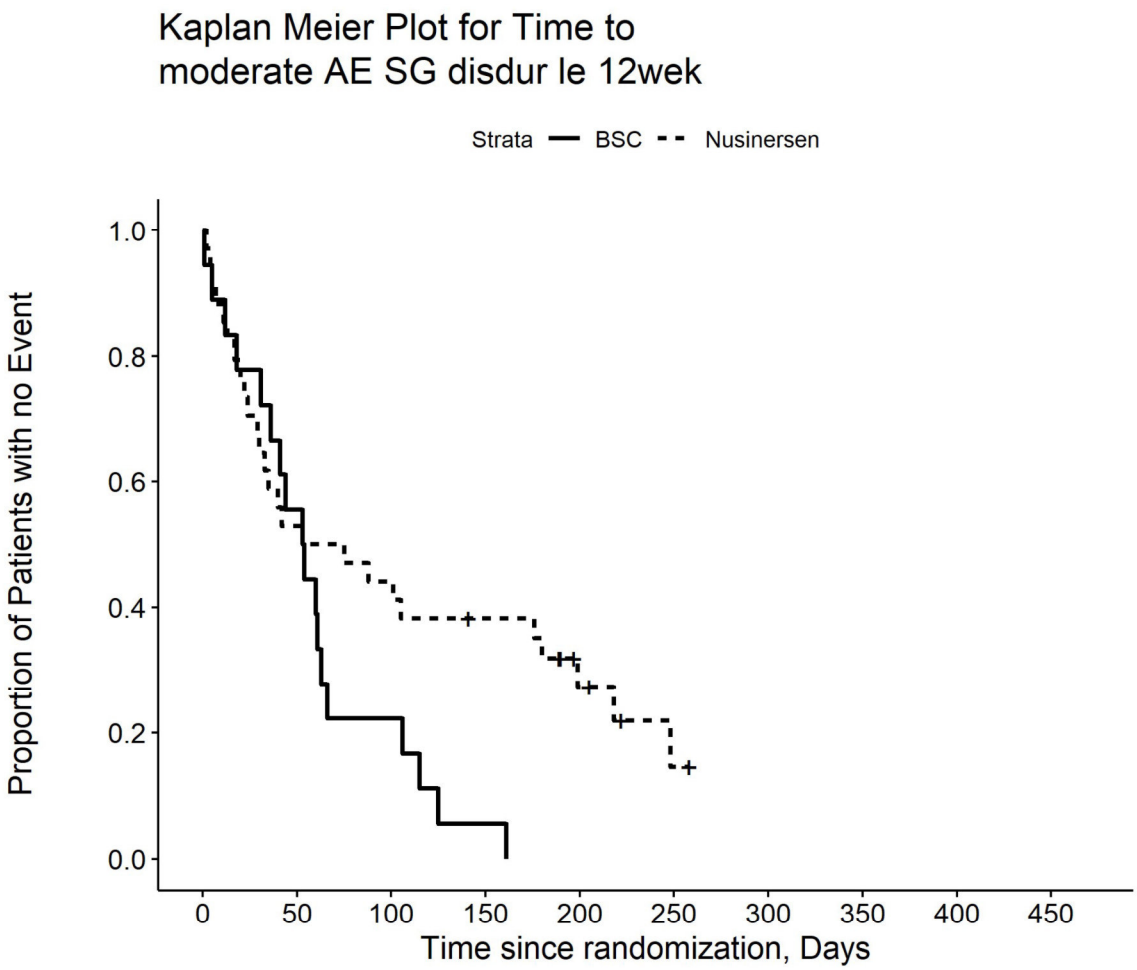
Number at risk

BSC	16	8	1	0	0	0	0	0	0	0
Nusinersen	49	28	21	16	11	7	3	2	0	0



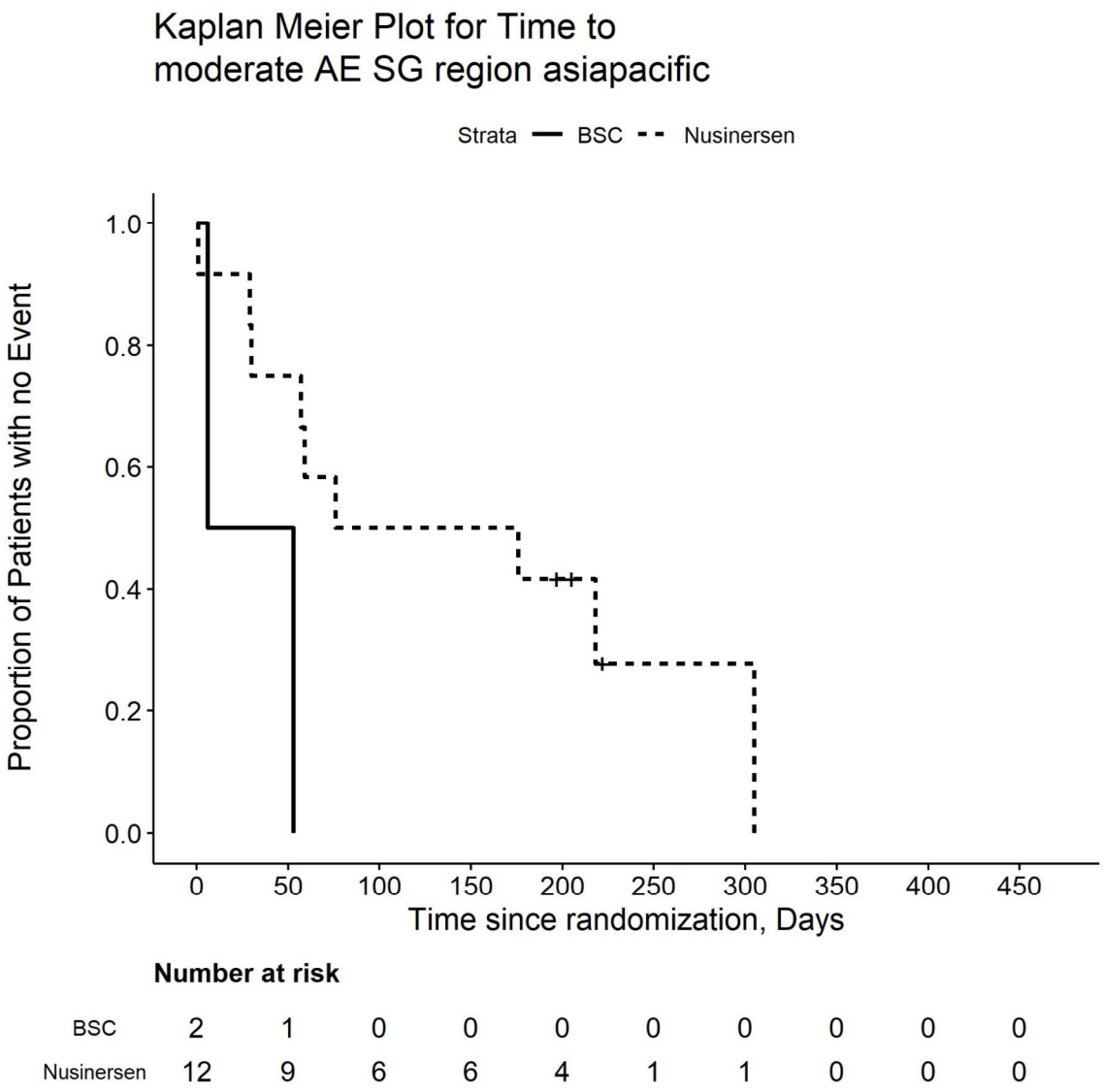
Number at risk

BSC	23	12	8	3	1	1	1	1	0	0
Nusinersen	46	24	15	11	8	7	5	4	0	0



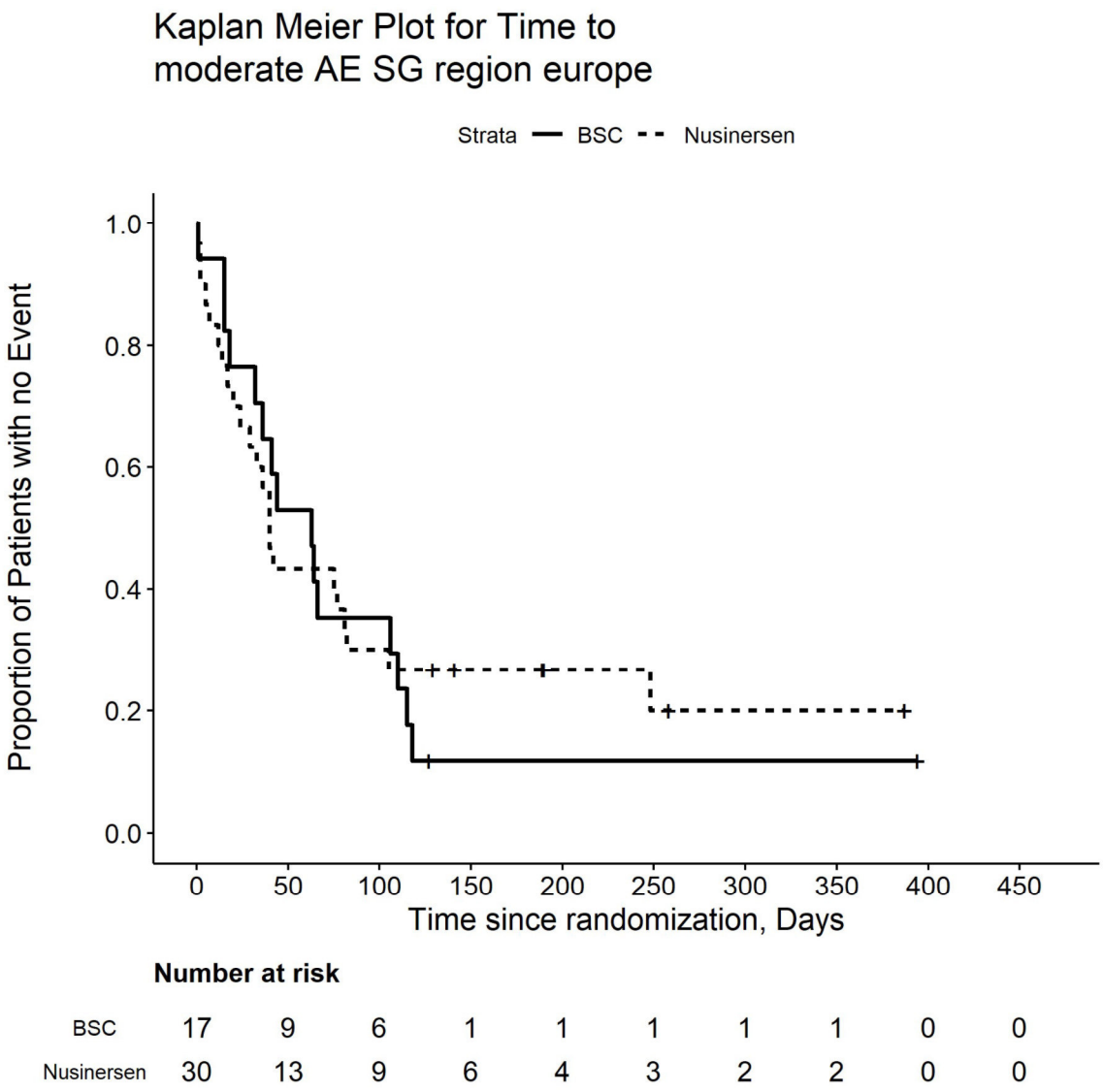
Number at risk

BSC	18	10	4	1	0	0	0	0	0	0
Nusinersen	34	18	15	12	6	2	0	0	0	0



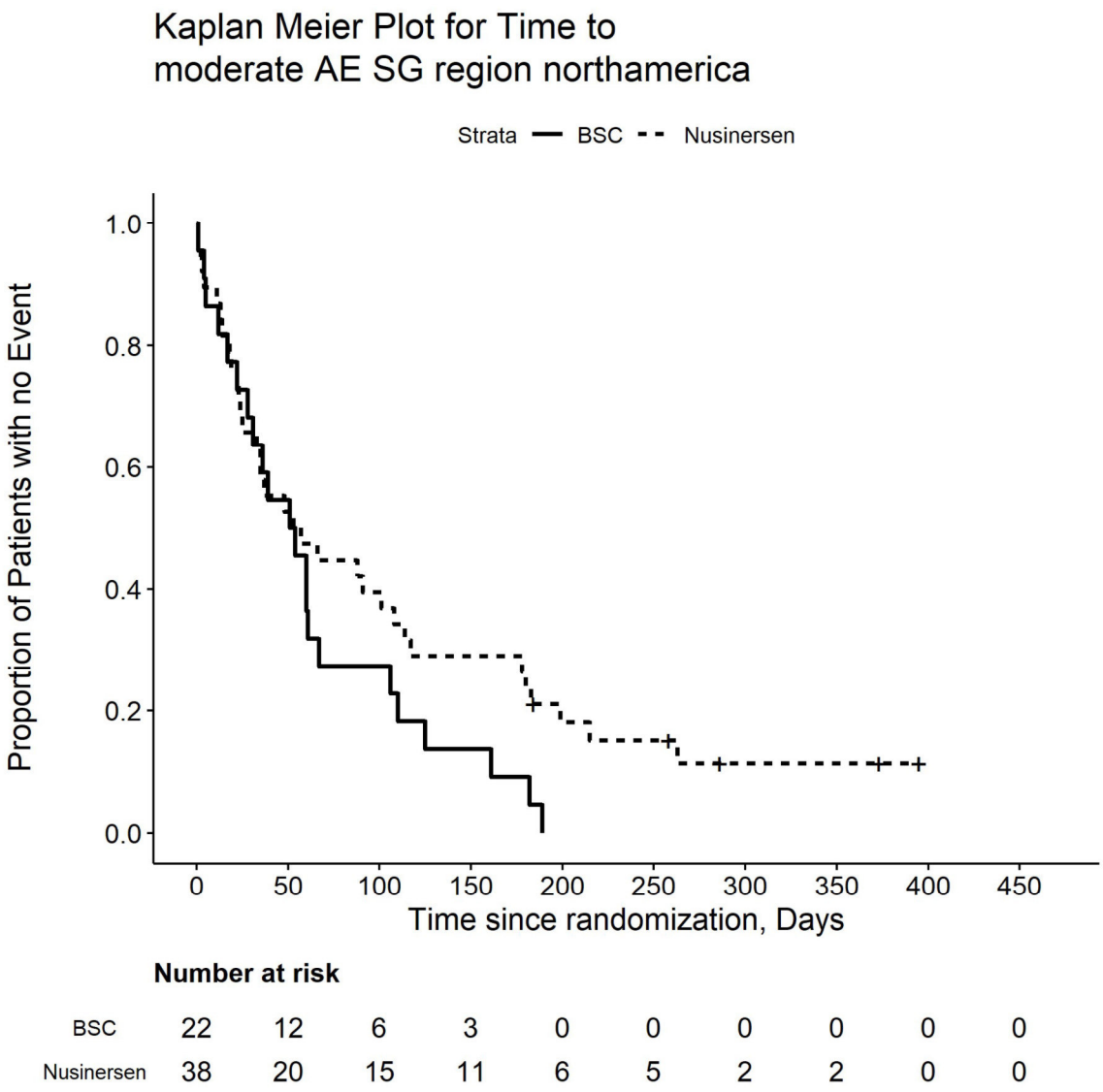
Number at risk

BSC	2	1	0	0	0	0	0	0	0	0
Nusinersen	12	9	6	6	4	1	1	0	0	0



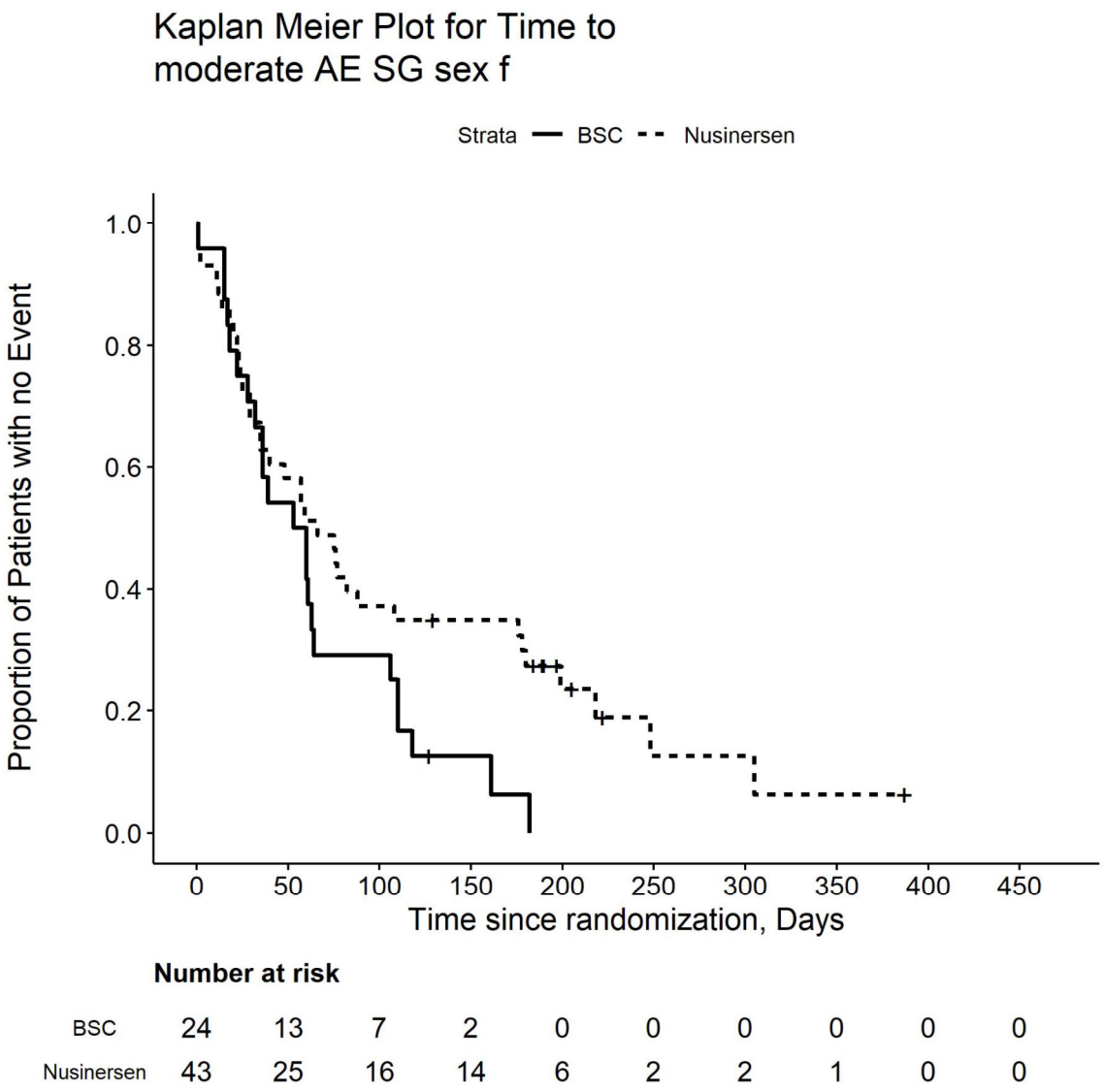
Number at risk

BSC	17	9	6	1	1	1	1	1	0	0
Nusinersen	30	13	9	6	4	3	2	2	0	0



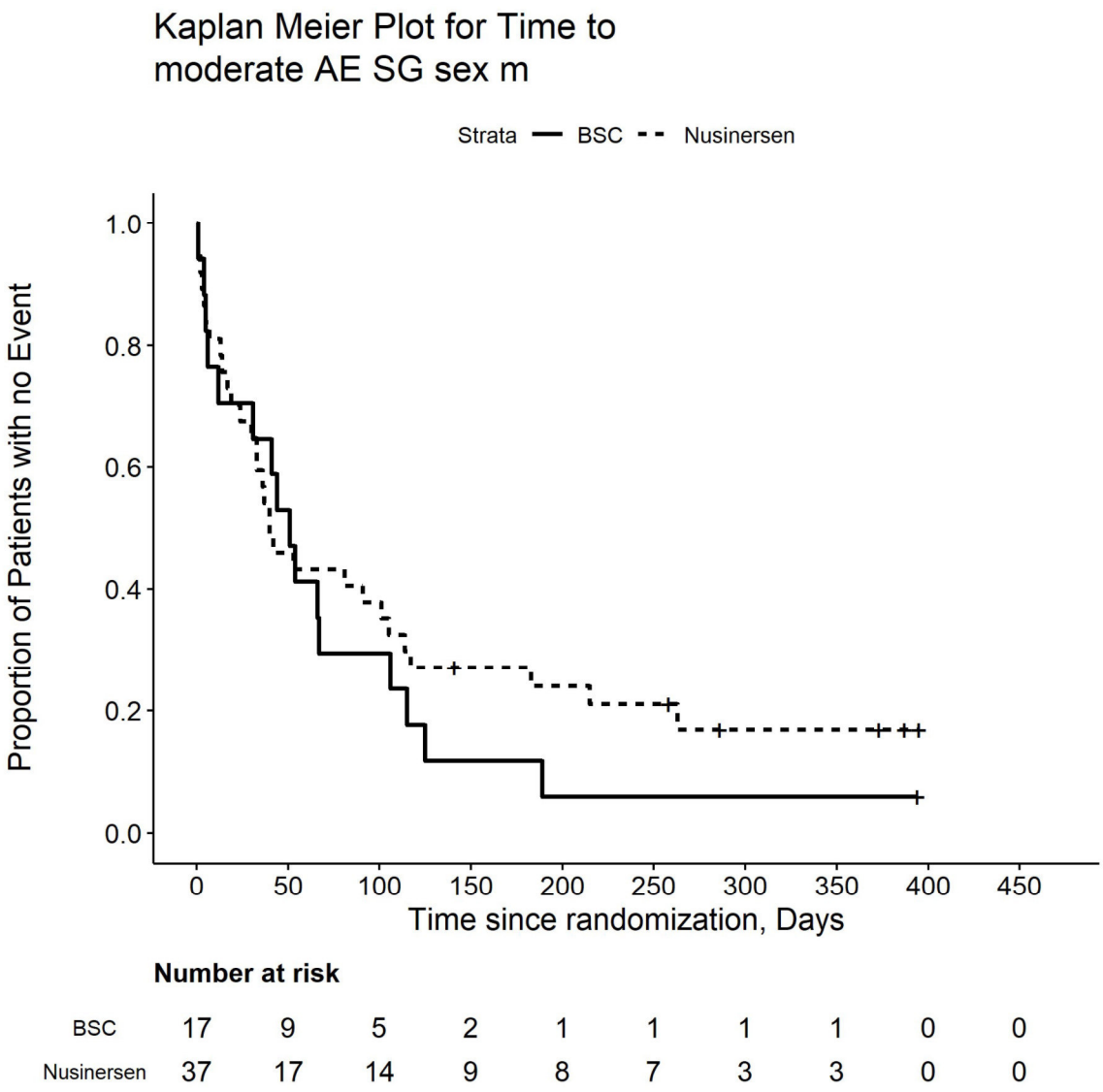
Number at risk

BSC	22	12	6	3	0	0	0	0	0	0
Nusinersen	38	20	15	11	6	5	2	2	0	0



Number at risk

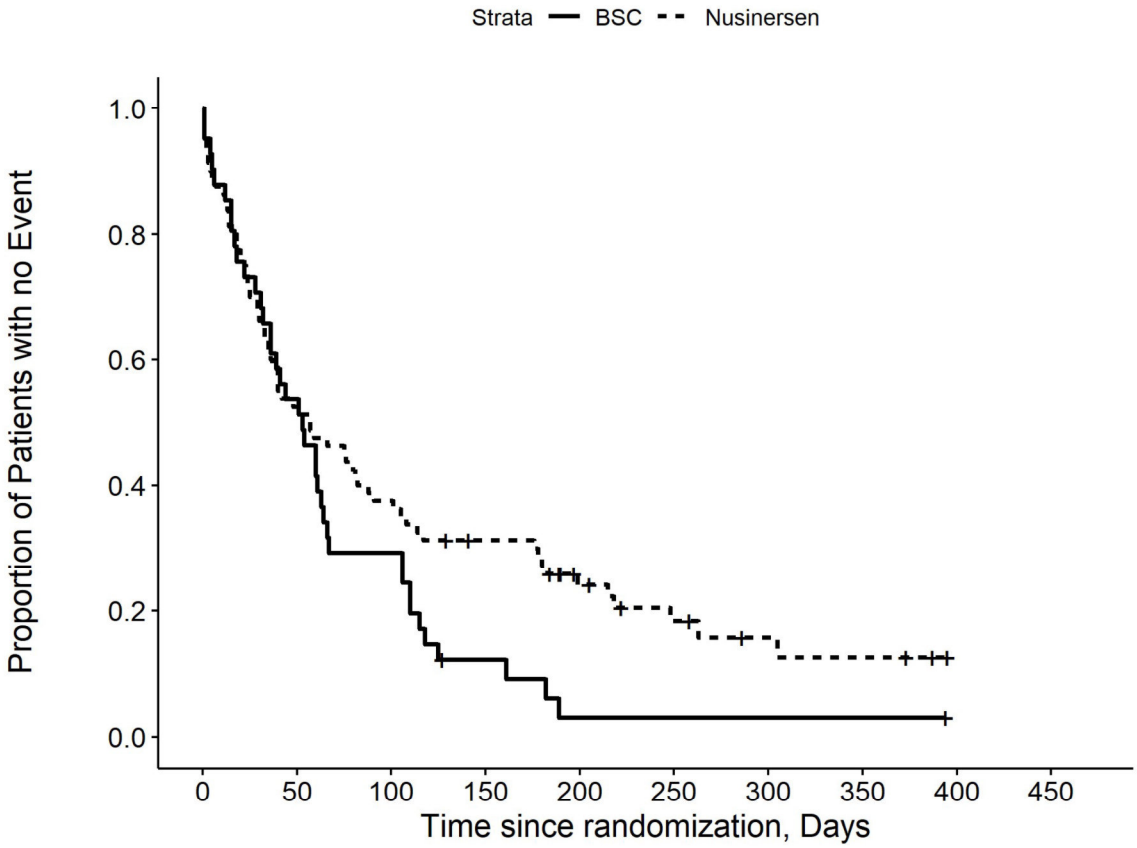
BSC	24	13	7	2	0	0	0	0	0	0
Nusinersen	43	25	16	14	6	2	2	1	0	0



Number at risk

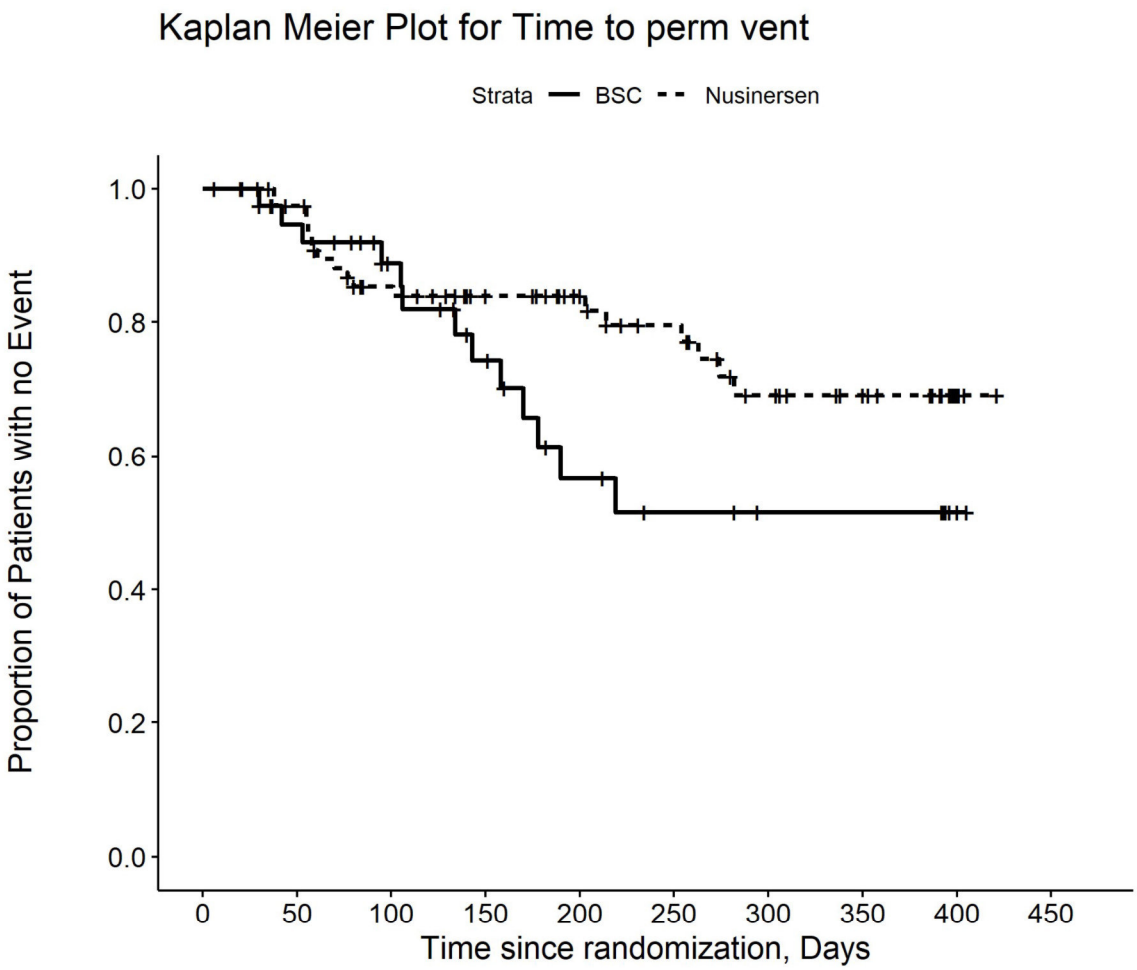
BSC	17	9	5	2	1	1	1	1	0	0
Nusinersen	37	17	14	9	8	7	3	3	0	0

Kaplan Meier Plot for Time to moderate or severe AE



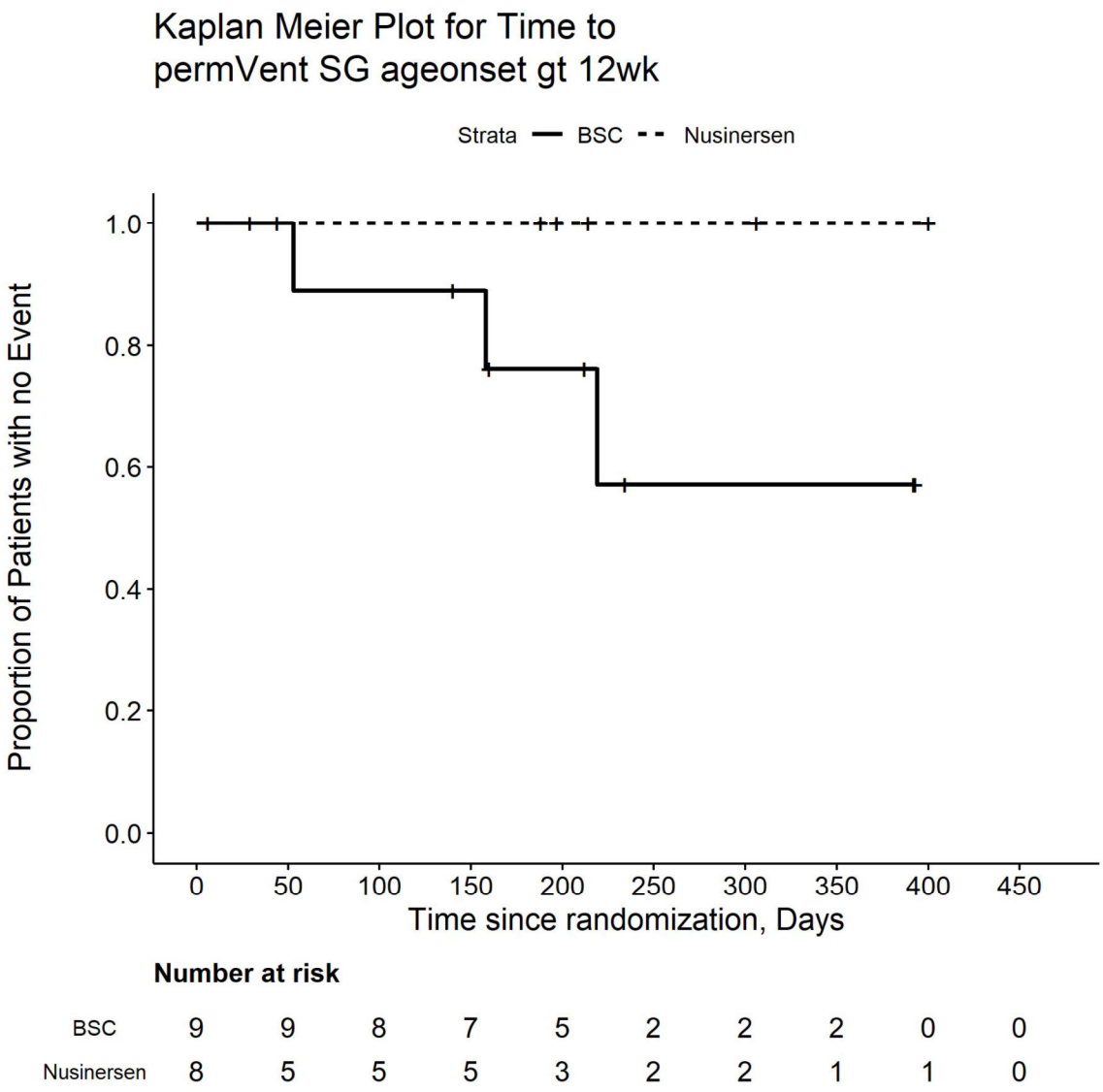
Number at risk

BSC	41	22	12	4	1	1	1	1	0	0
Nusinersen	80	42	30	23	14	9	5	4	0	0



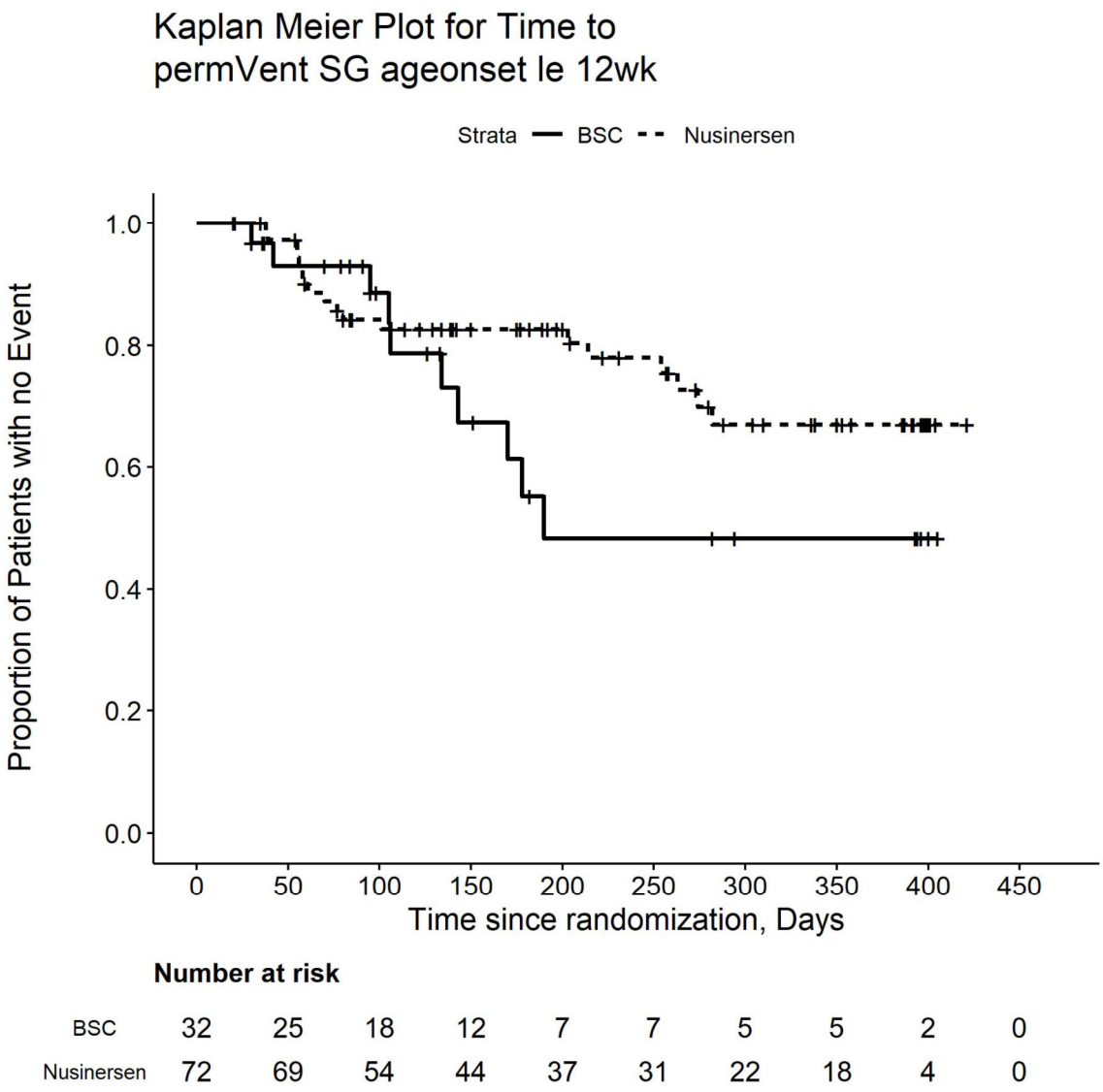
Number at risk

BSC	41	34	26	19	12	9	7	7	2	0
Nusinersen	80	74	59	49	40	33	24	19	5	0



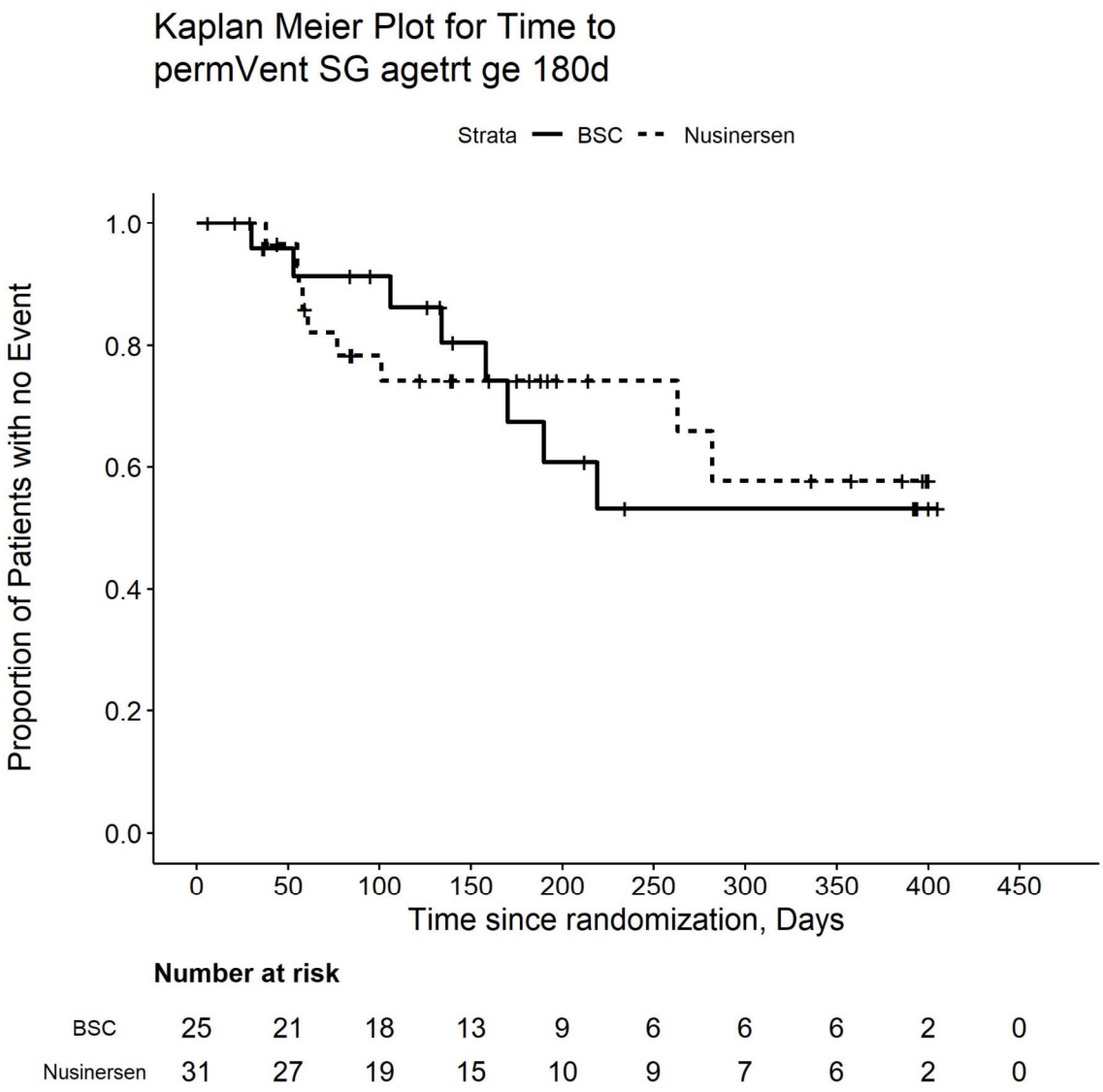
Number at risk

BSC	9	9	8	7	5	2	2	2	0	0
Nusinersen	8	5	5	5	3	2	2	1	1	0



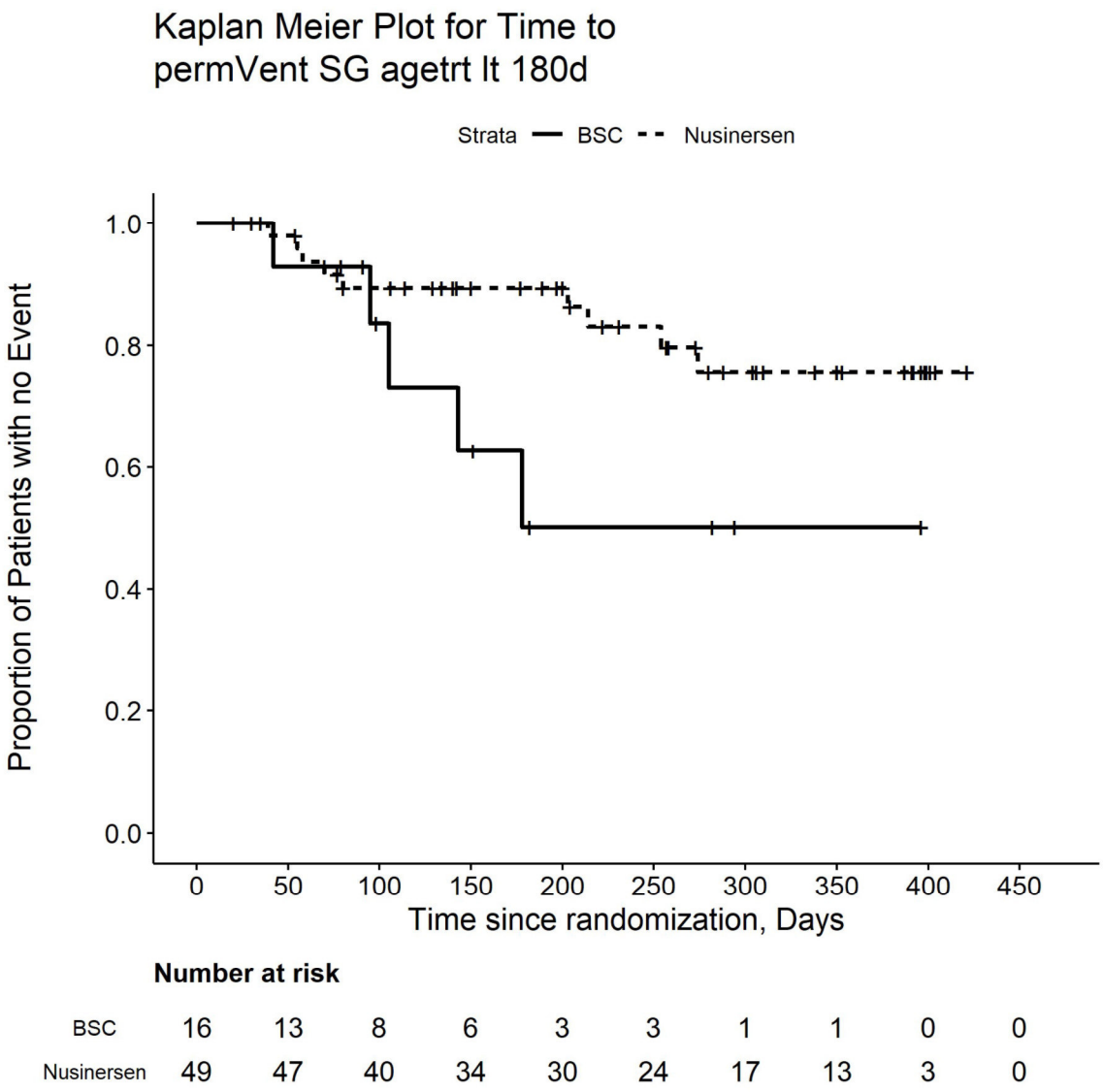
Number at risk

BSC	32	25	18	12	7	7	5	5	2	0
Nusinersen	72	69	54	44	37	31	22	18	4	0



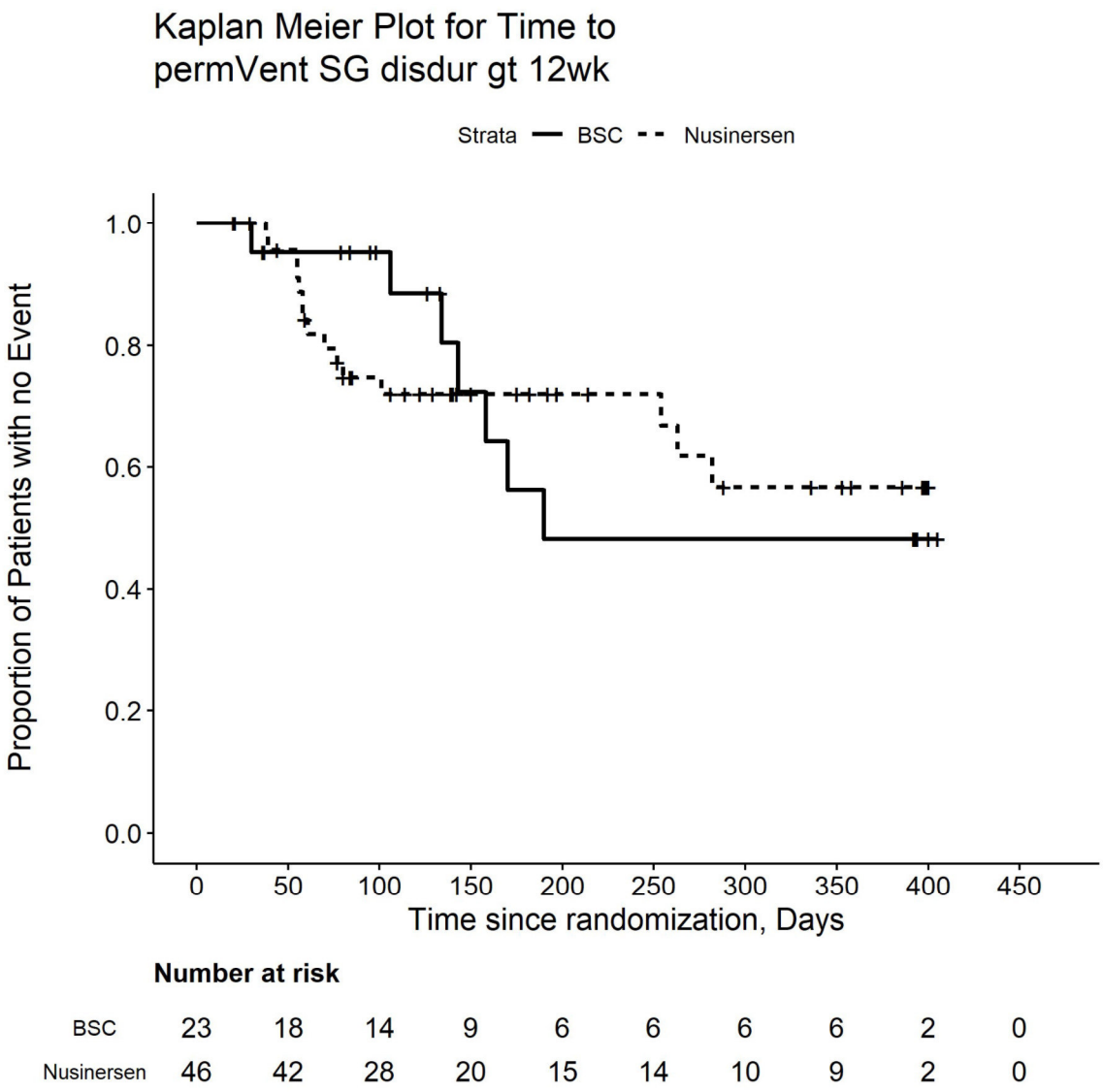
Number at risk

BSC	25	21	18	13	9	6	6	6	2	0
Nusinersen	31	27	19	15	10	9	7	6	2	0



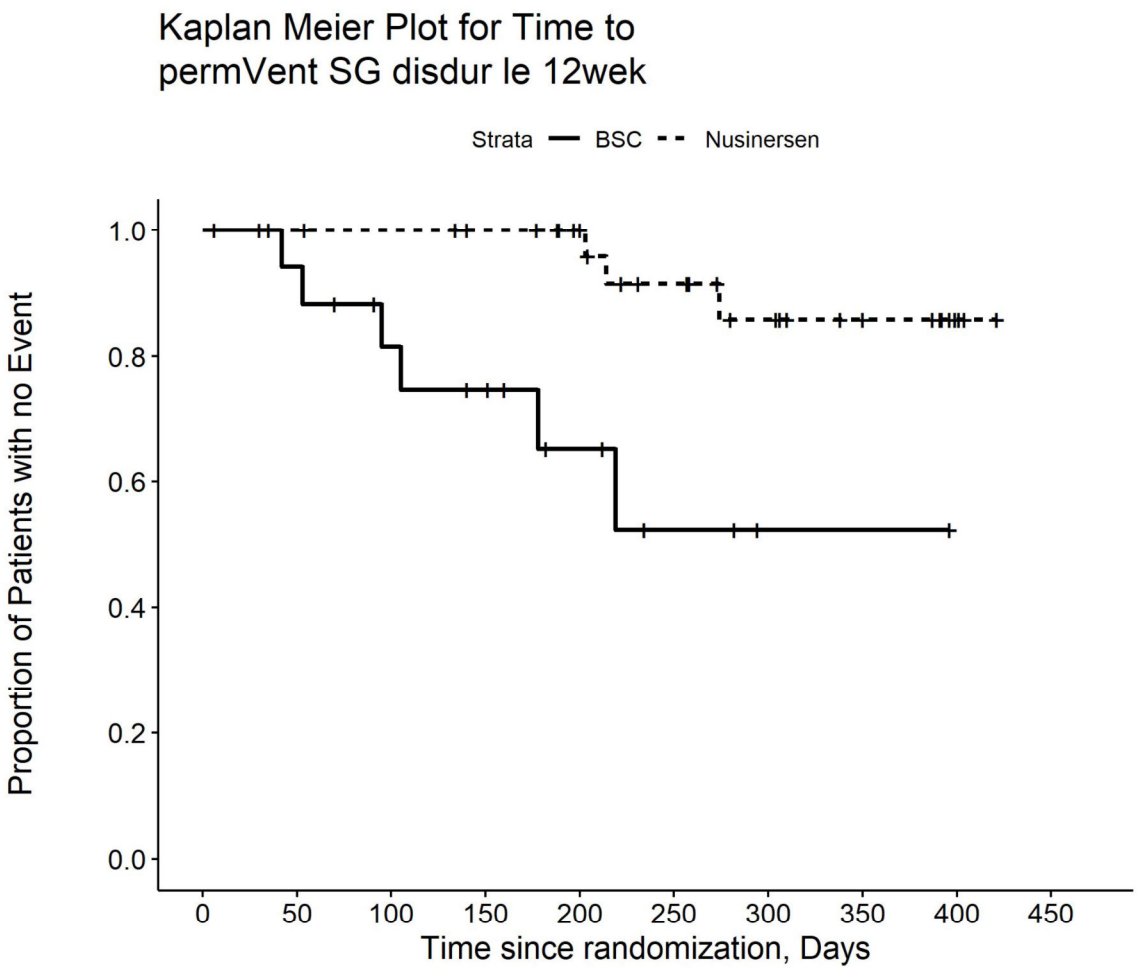
Number at risk

BSC	16	13	8	6	3	3	1	1	0	0
Nusinersen	49	47	40	34	30	24	17	13	3	0



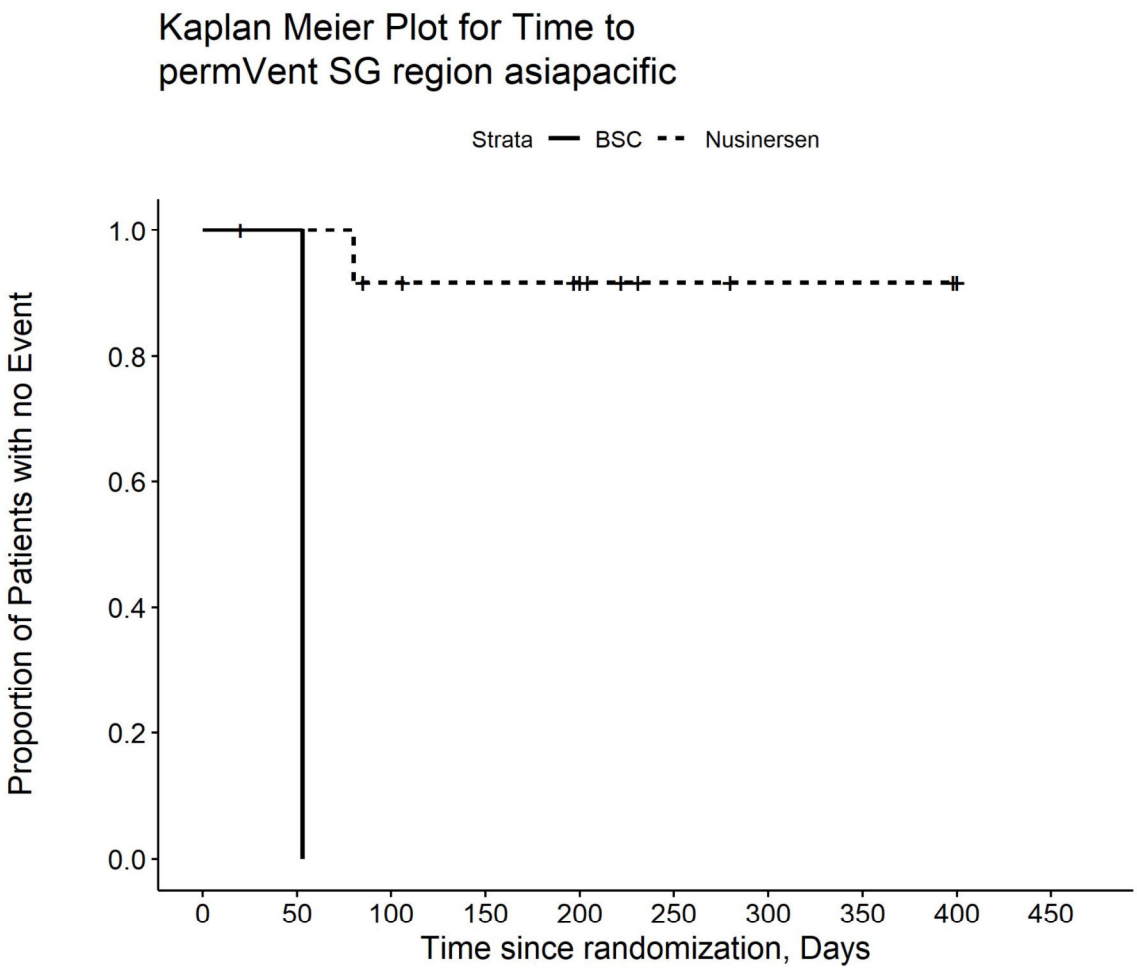
Number at risk

BSC	23	18	14	9	6	6	6	6	2	0
Nusinersen	46	42	28	20	15	14	10	9	2	0



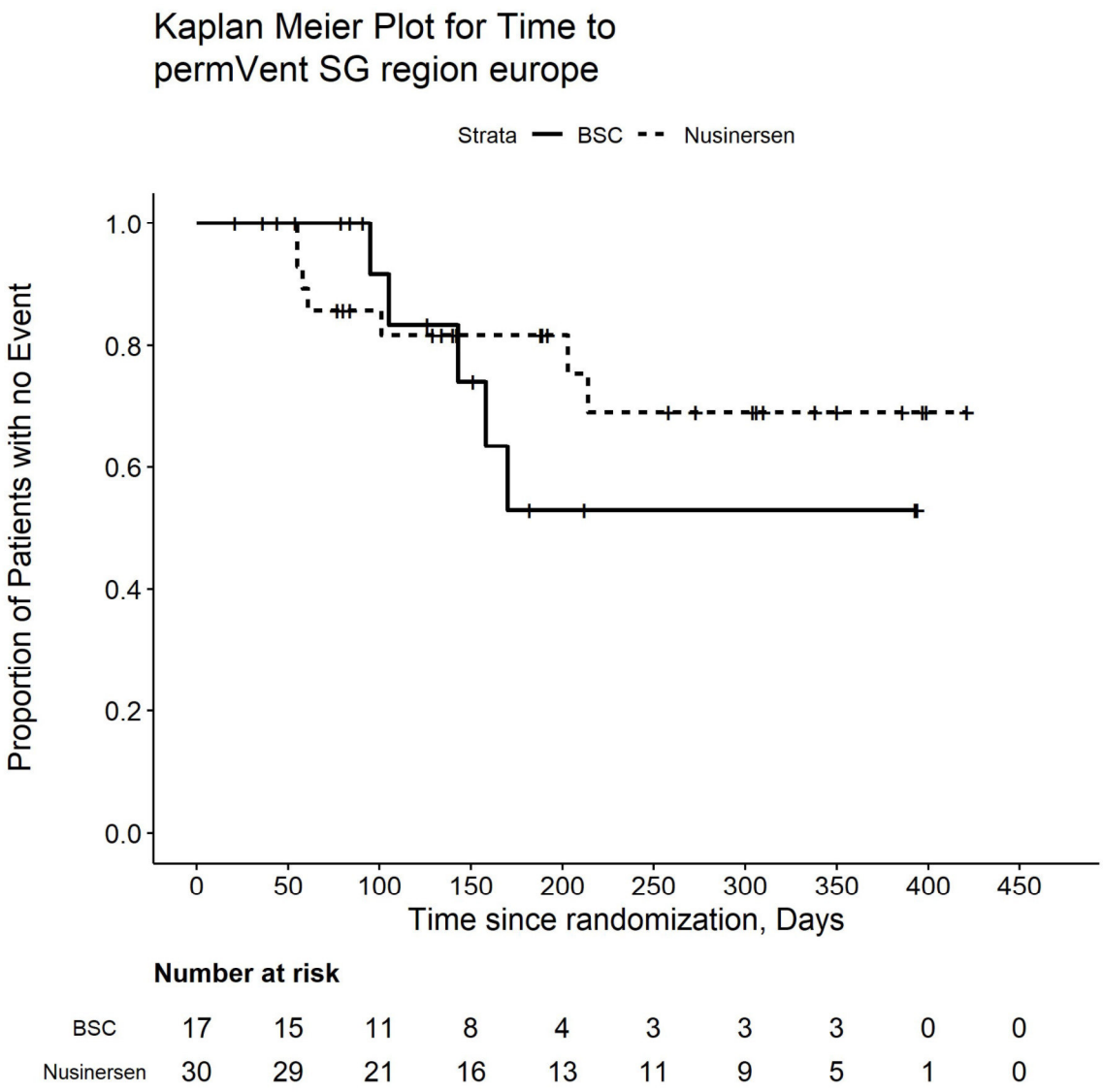
Number at risk

BSC	18	16	12	10	6	3	1	1	0	0
Nusinersen	34	32	31	29	25	19	14	10	3	0



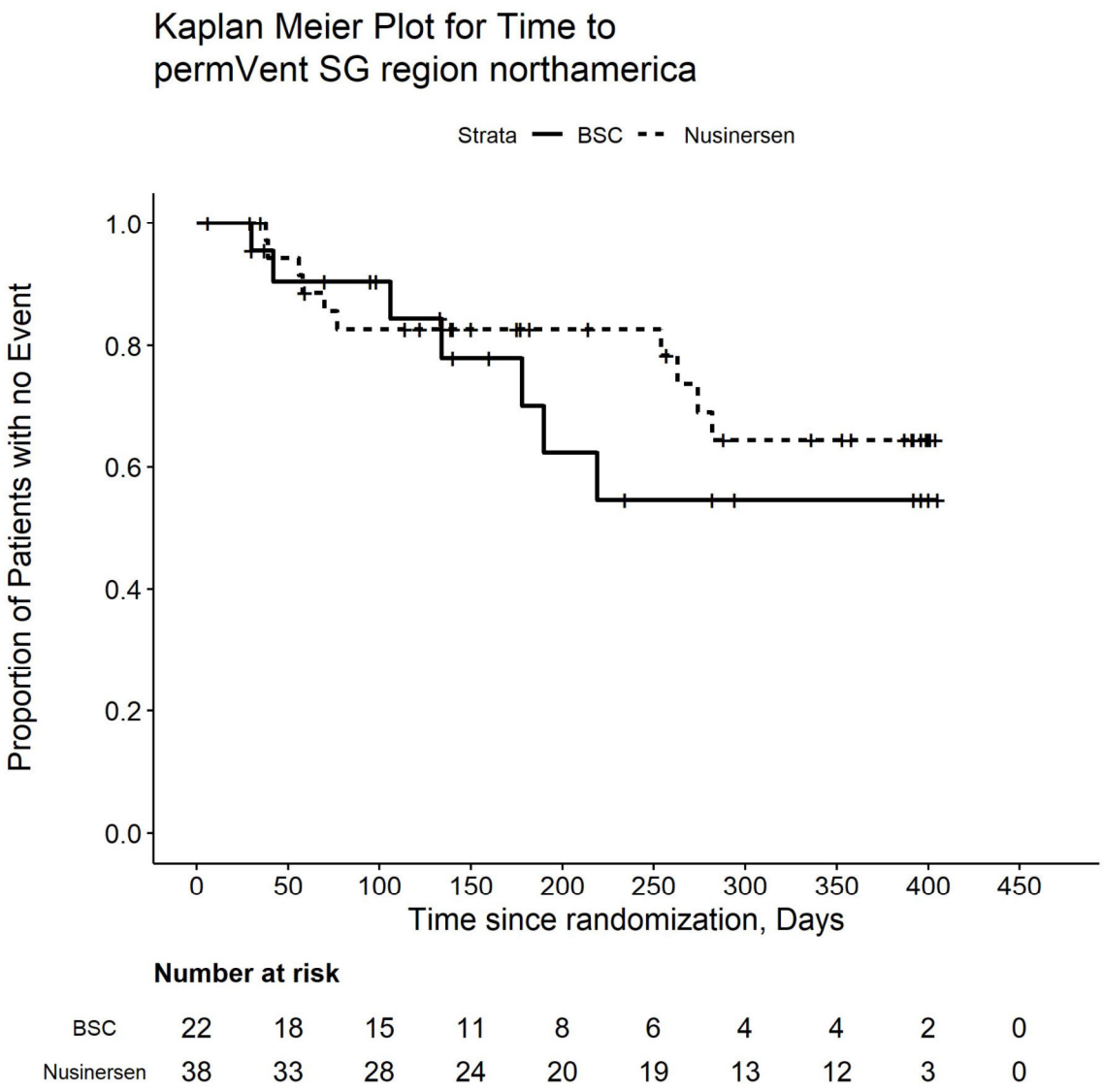
Number at risk

BSC	2	1	0	0	0	0	0	0	0	0
Nusinersen	12	12	10	9	7	3	2	2	1	0



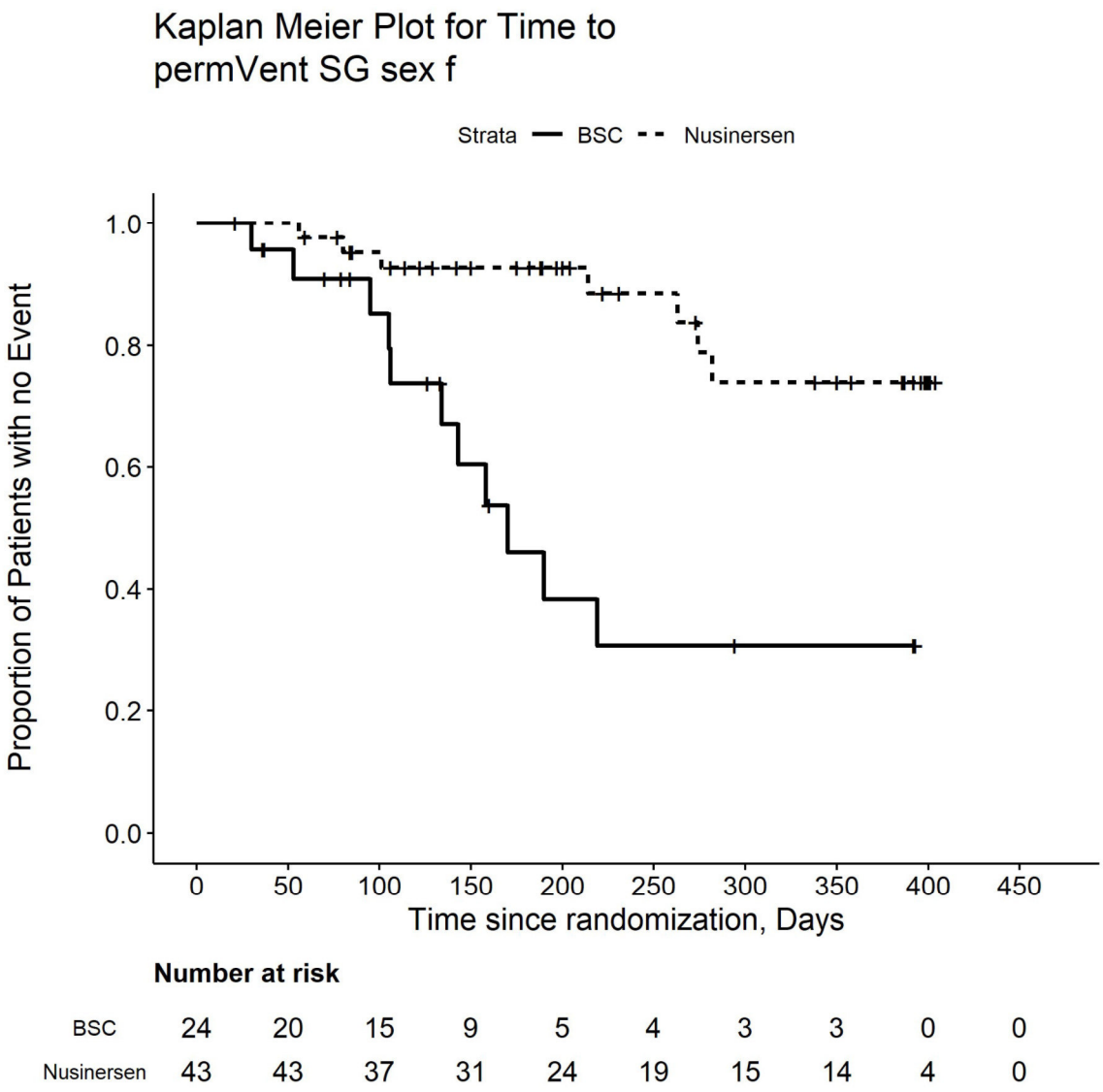
Number at risk

BSC	17	15	11	8	4	3	3	3	0	0
Nusinersen	30	29	21	16	13	11	9	5	1	0



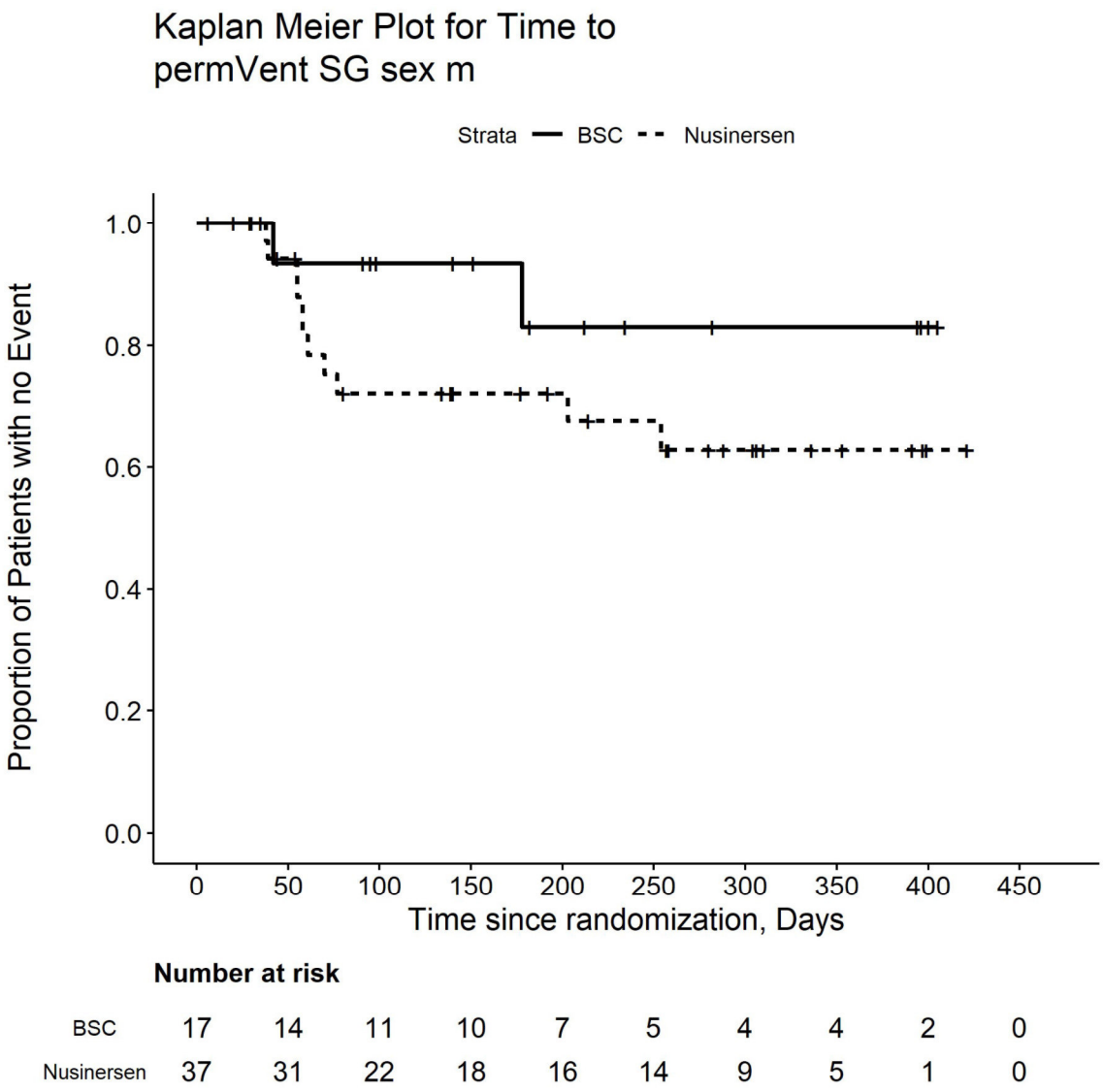
Number at risk

BSC	22	18	15	11	8	6	4	4	2	0
Nusinersen	38	33	28	24	20	19	13	12	3	0



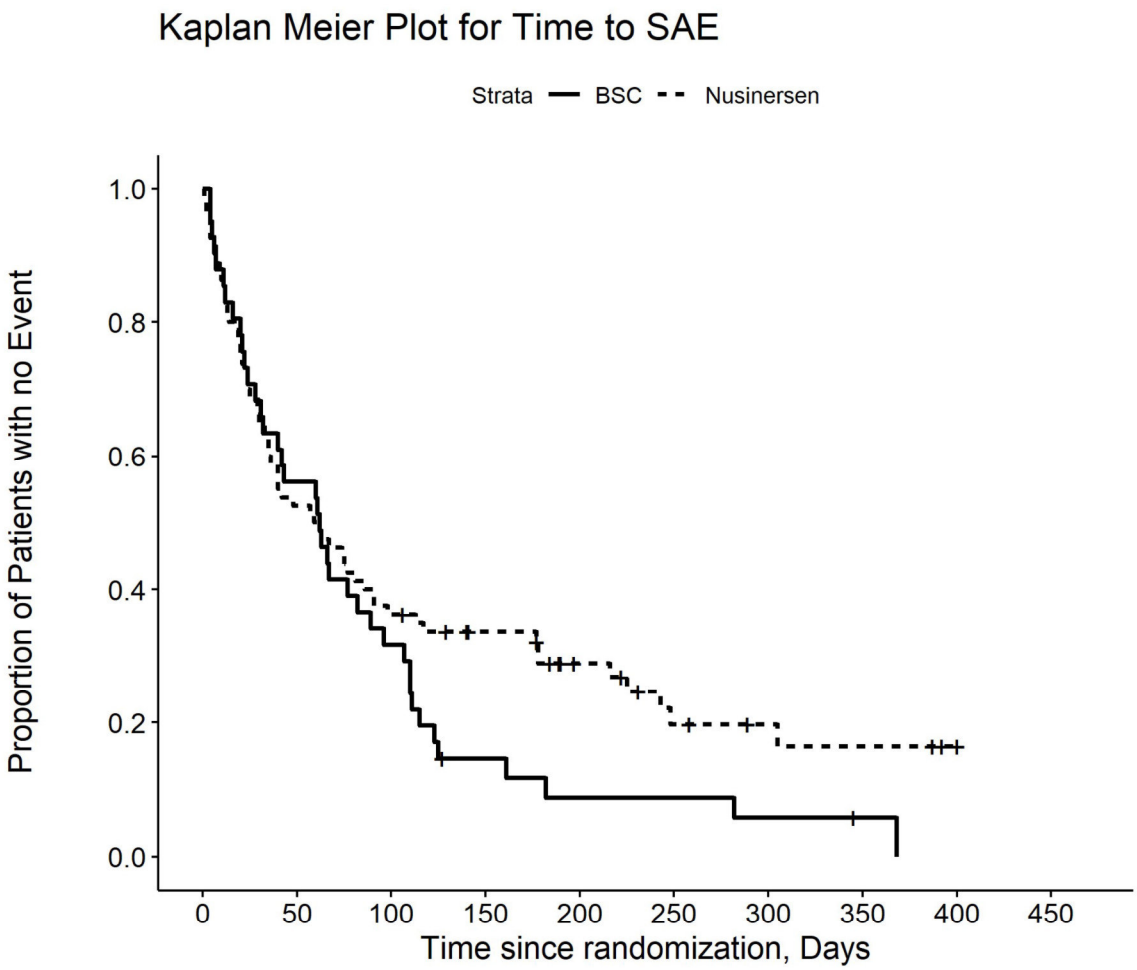
Number at risk

BSC	24	20	15	9	5	4	3	3	0	0
Nusinersen	43	43	37	31	24	19	15	14	4	0



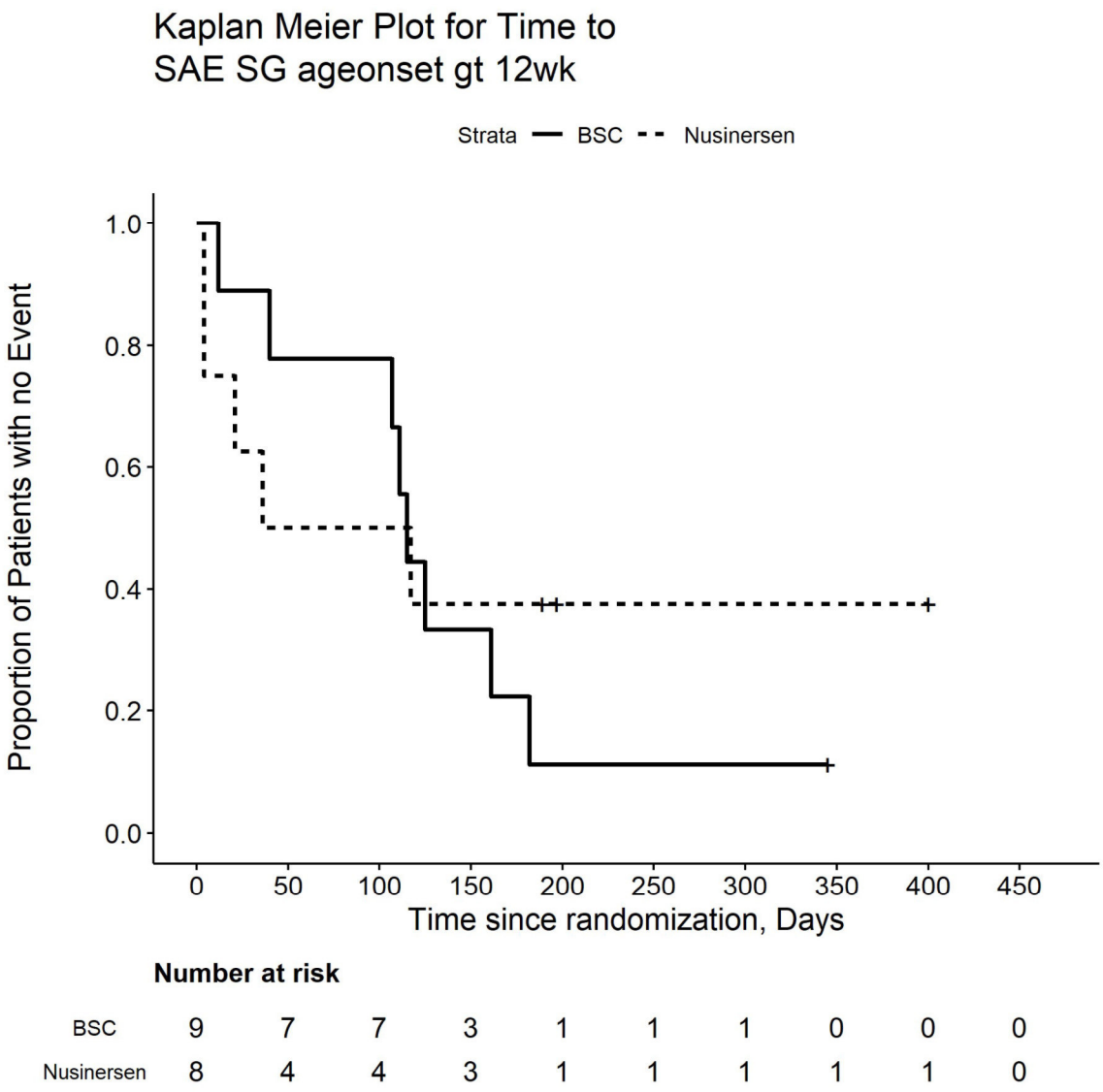
Number at risk

BSC	17	14	11	10	7	5	4	4	2	0
Nusinersen	37	31	22	18	16	14	9	5	1	0



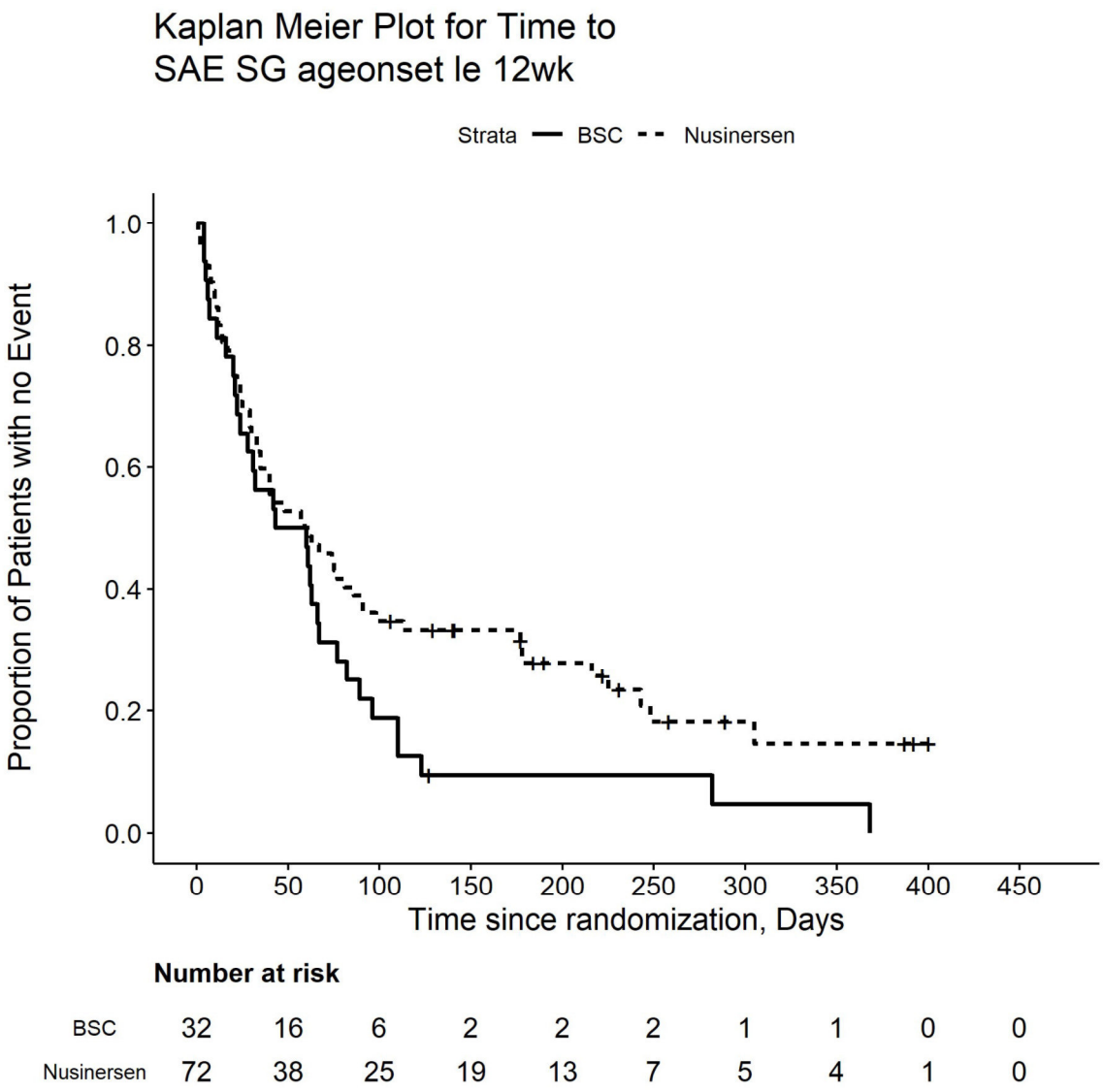
Number at risk

BSC	41	23	13	5	3	3	2	1	0	0
Nusinersen	80	42	29	22	14	8	6	5	2	0



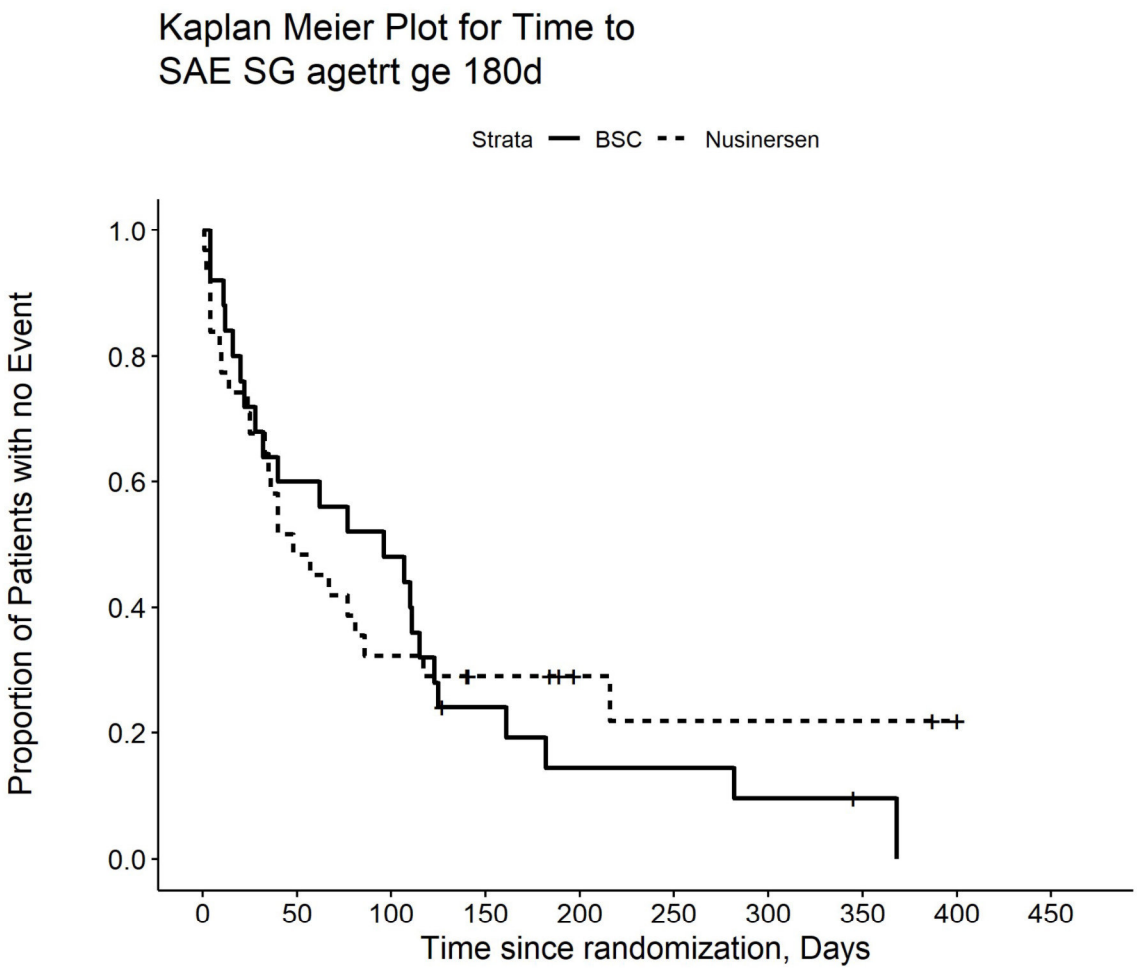
Number at risk

BSC	9	7	7	3	1	1	1	0	0	0
Nusinersen	8	4	4	3	1	1	1	1	1	0



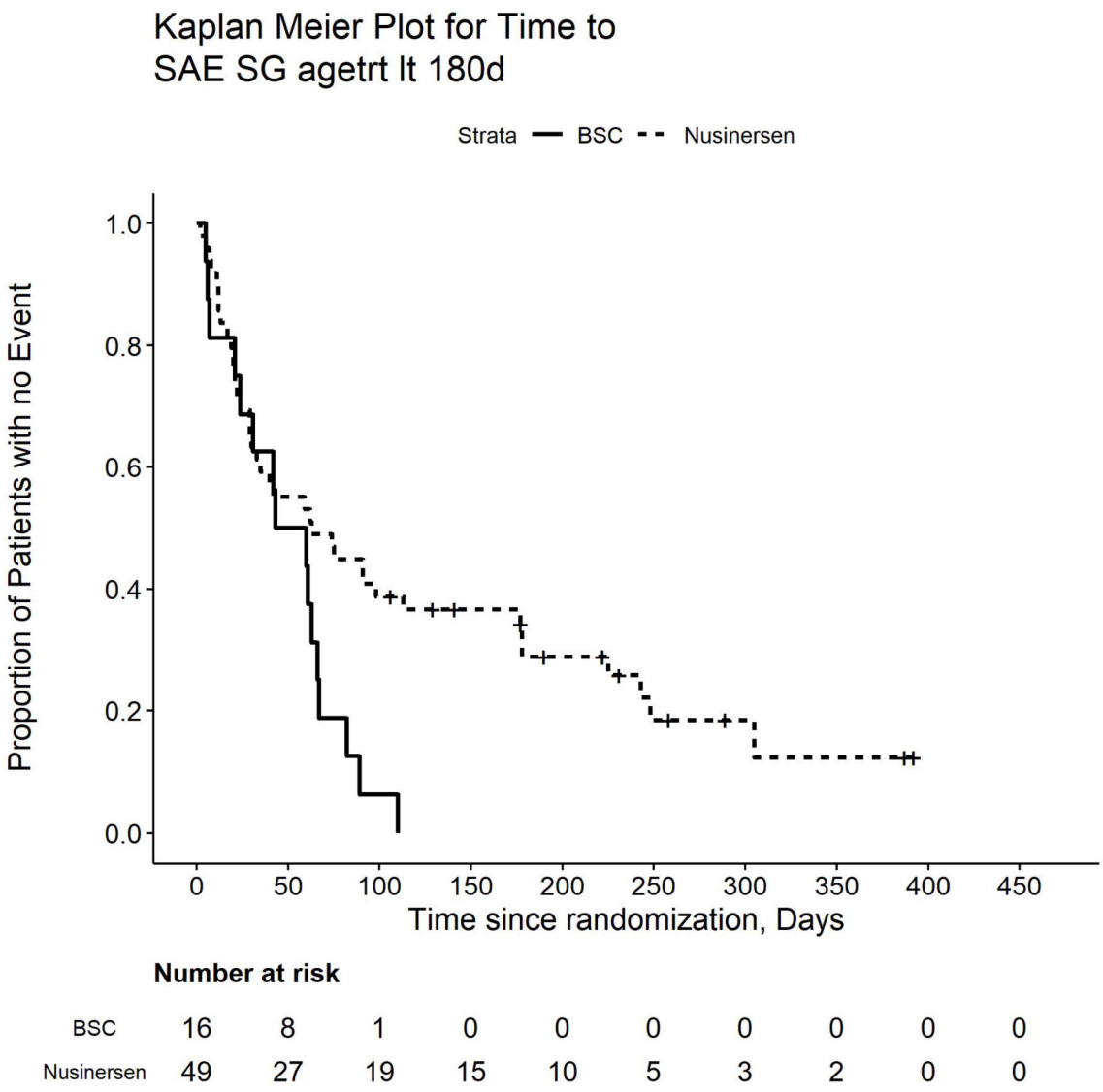
Number at risk

BSC	32	16	6	2	2	2	1	1	0	0
Nusinersen	72	38	25	19	13	7	5	4	1	0



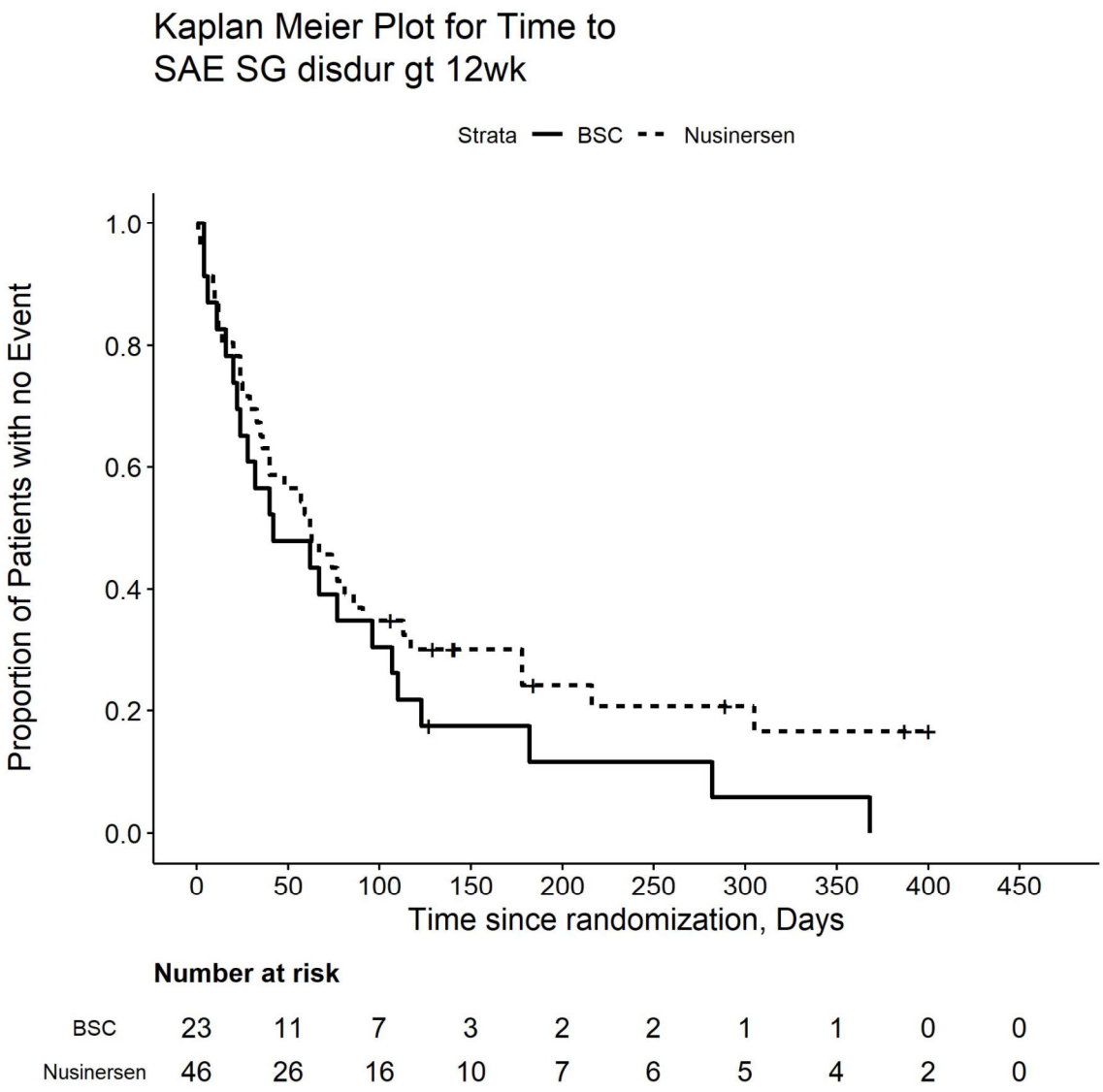
Number at risk

BSC	25	15	12	5	3	3	2	1	0	0
Nusinersen	31	15	10	7	4	3	3	3	2	0



Number at risk

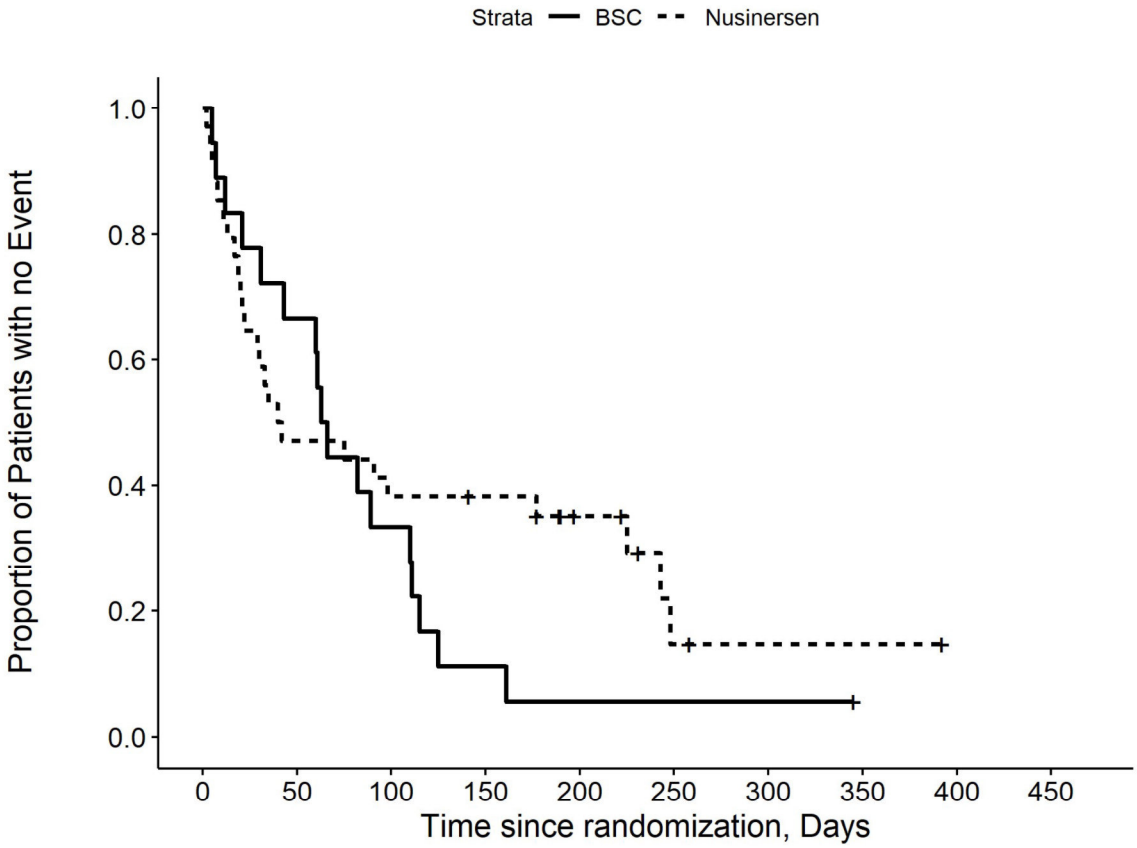
BSC	16	8	1	0	0	0	0	0	0	0
Nusinersen	49	27	19	15	10	5	3	2	0	0



Number at risk

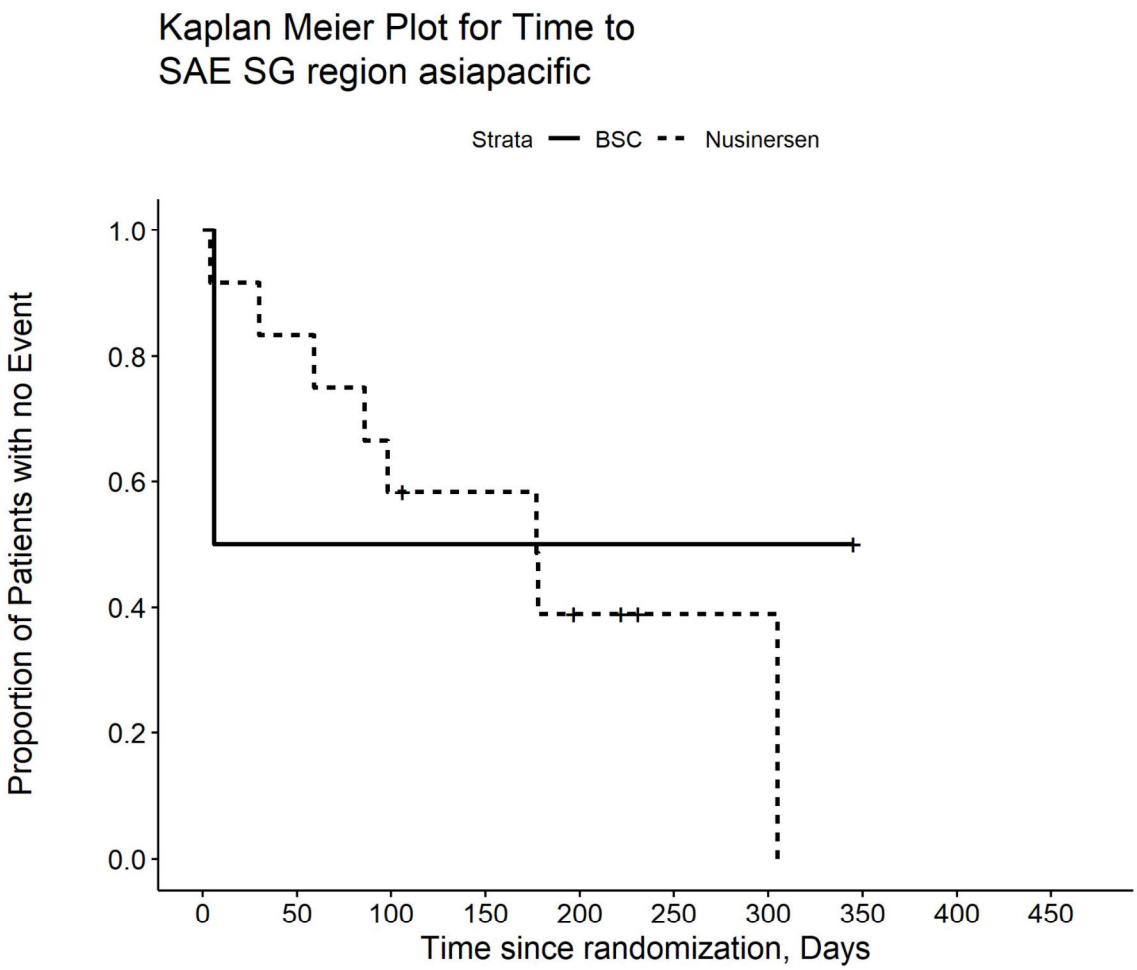
BSC	23	11	7	3	2	2	1	1	0	0
Nusinersen	46	26	16	10	7	6	5	4	2	0

Kaplan Meier Plot for Time to
SAE SG disdur le 12wek



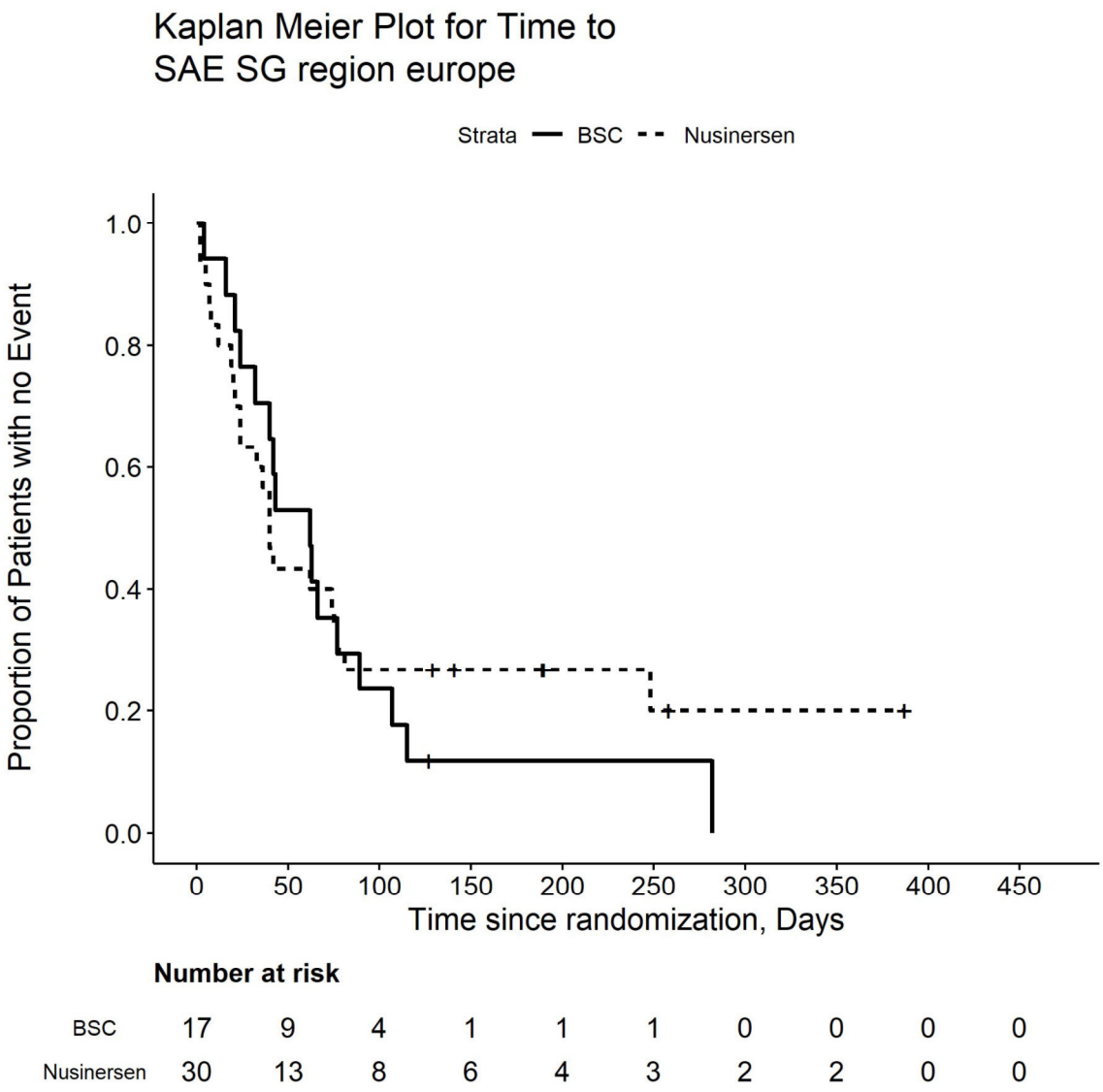
Number at risk

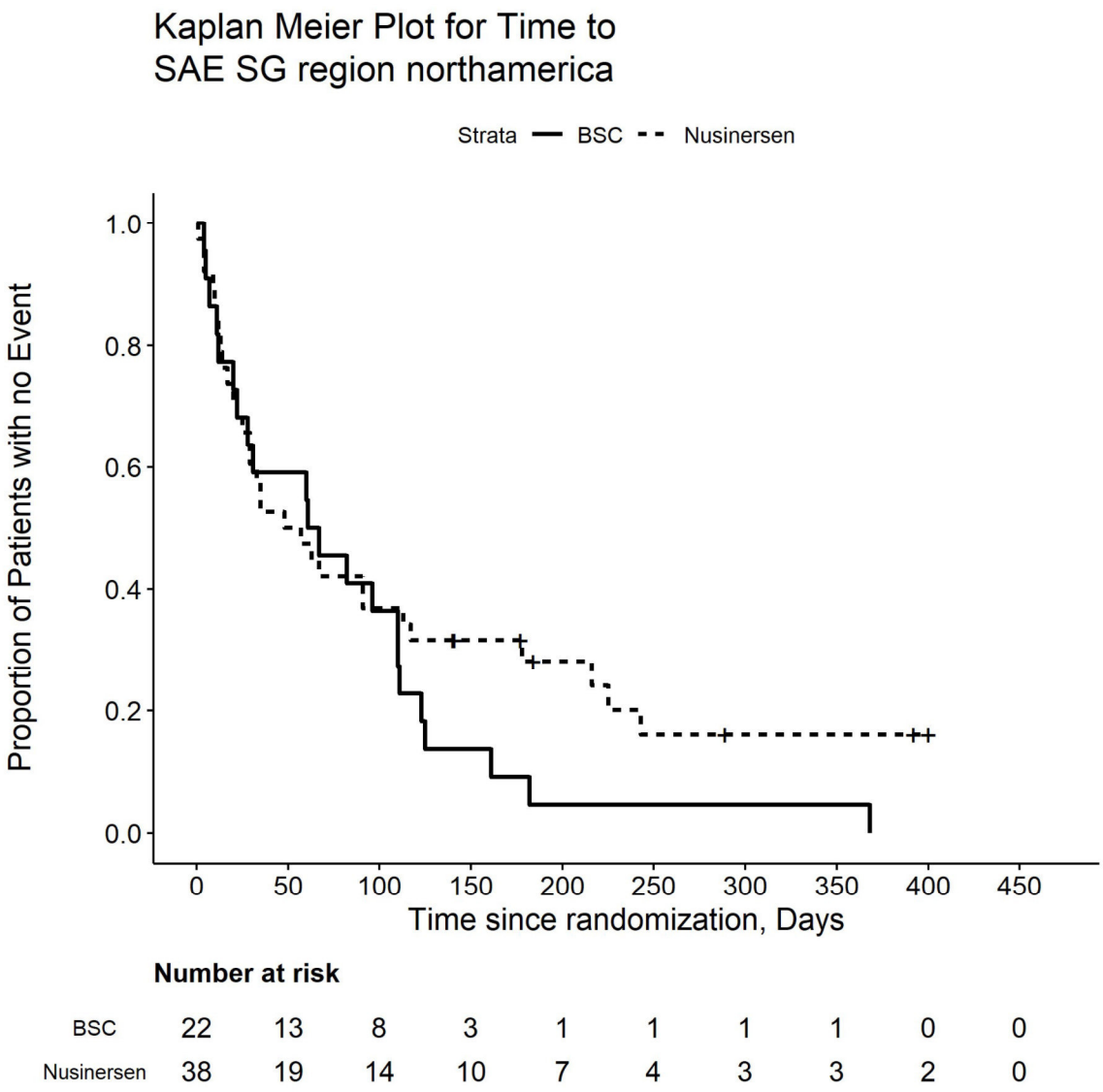
BSC	18	12	6	2	1	1	1	0	0	0
Nusinersen	34	16	13	12	7	2	1	1	0	0



Number at risk

BSC	2	1	1	1	1	1	1	0	0	0
Nusinersen	12	10	7	6	3	1	1	0	0	0

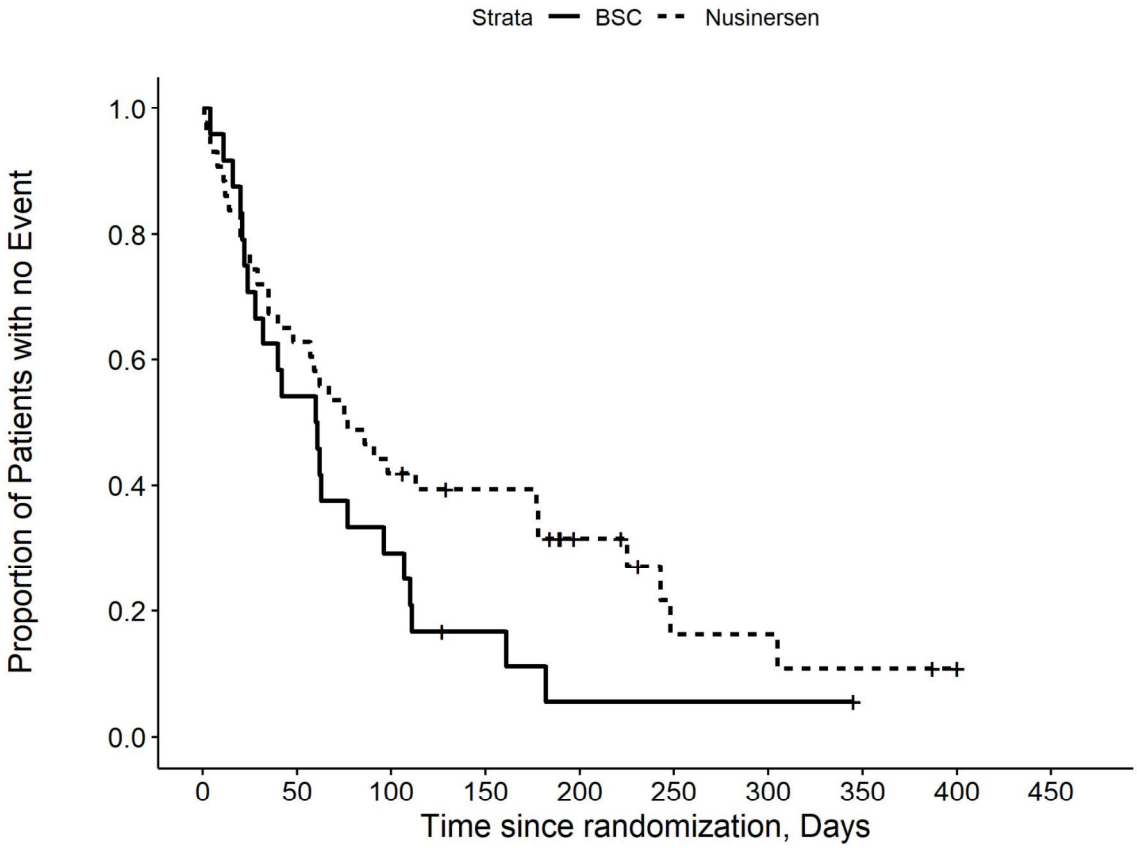

Kaplan Meier Plot for Time to
SAE SG region europe
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0
50
100
150
200
250
300
350
400
450
Time since randomization, Days
Number at risk
BSC 17 9 4 1 1 1 0 0 0 0
Nusinersen 30 13 8 6 4 3 2 2 0 0



Number at risk

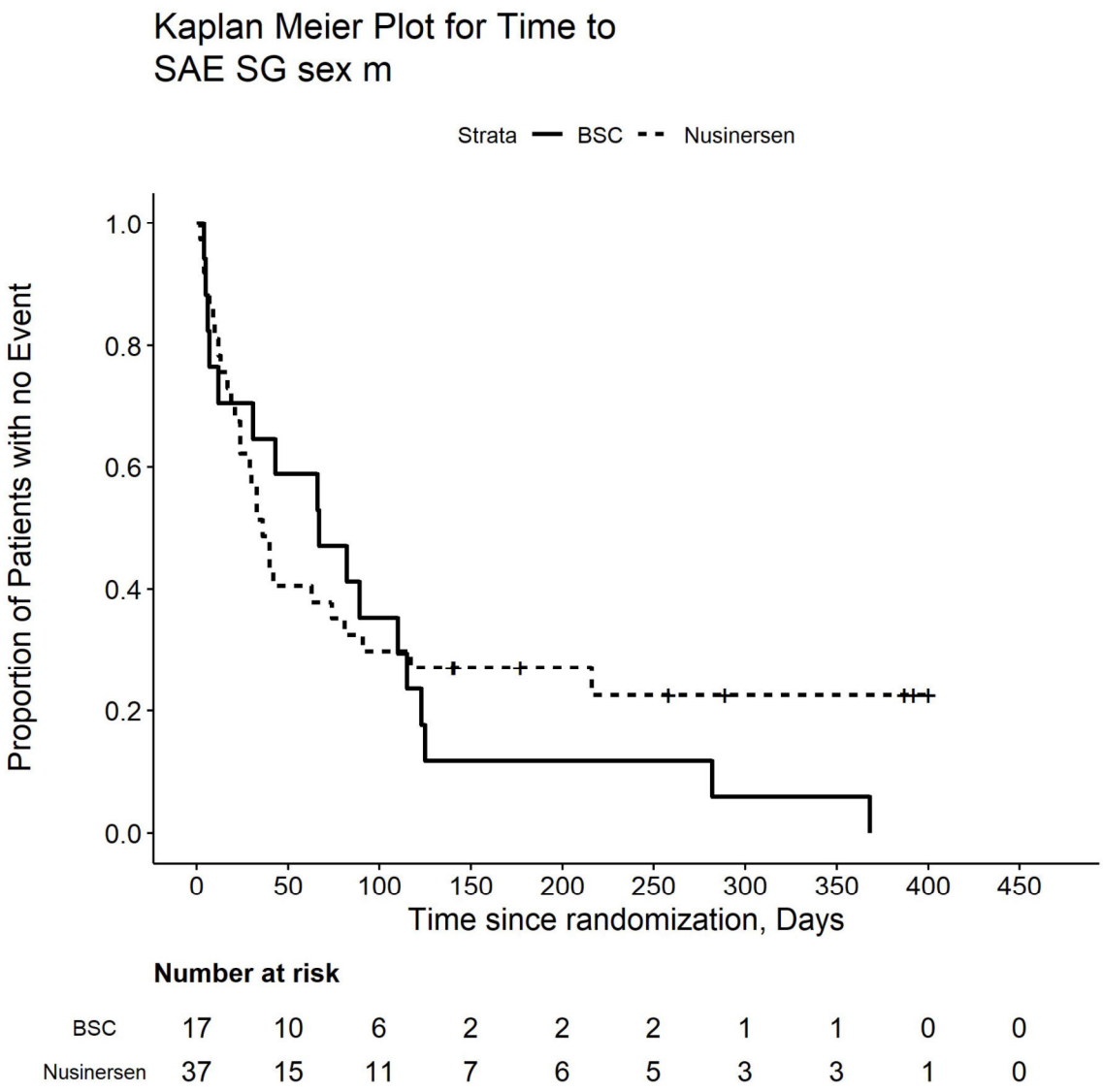
BSC	22	13	8	3	1	1	1	1	0	0
Nusinersen	38	19	14	10	7	4	3	3	2	0

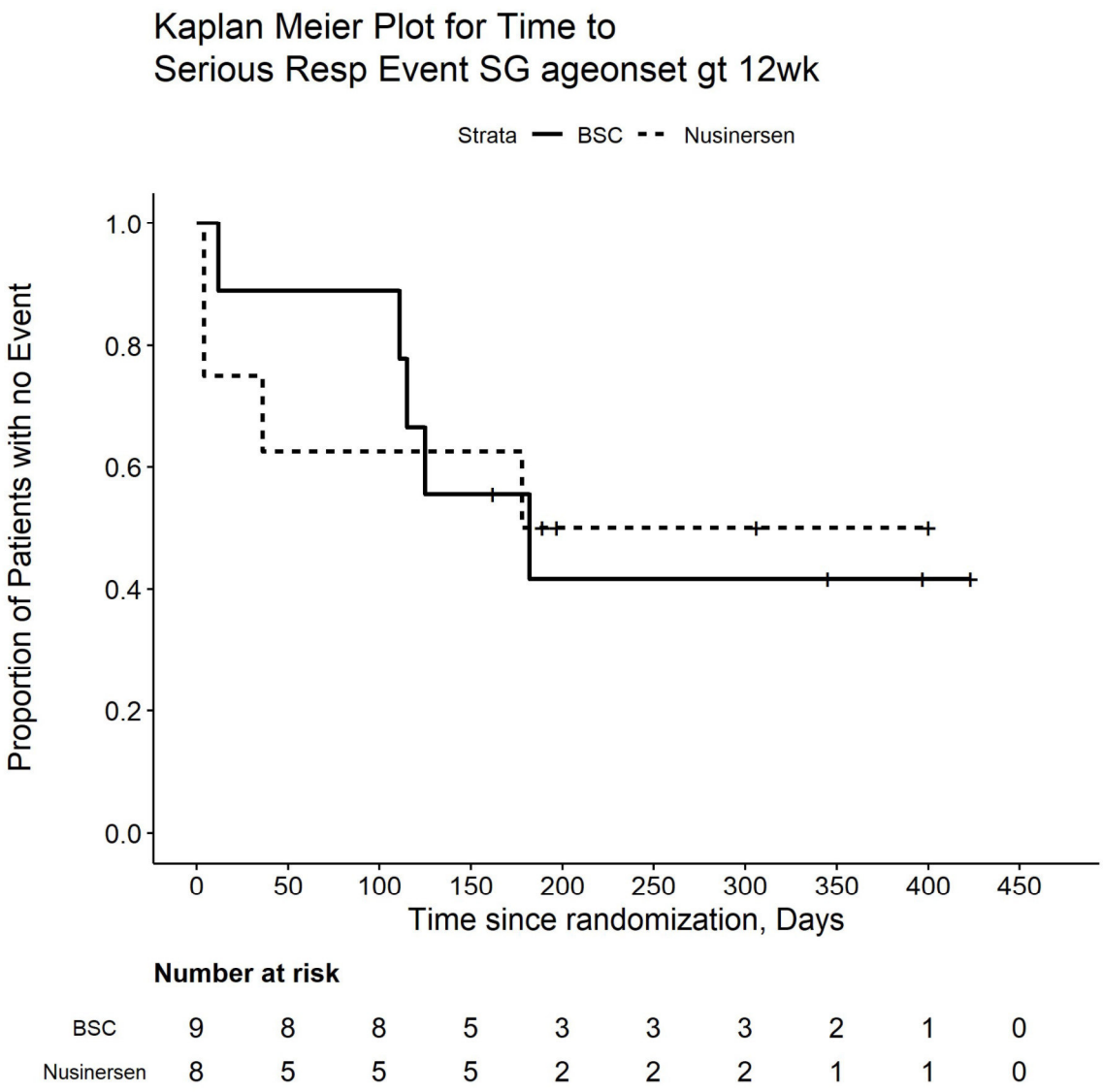
Kaplan Meier Plot for Time to
SAE SG sex f



Number at risk

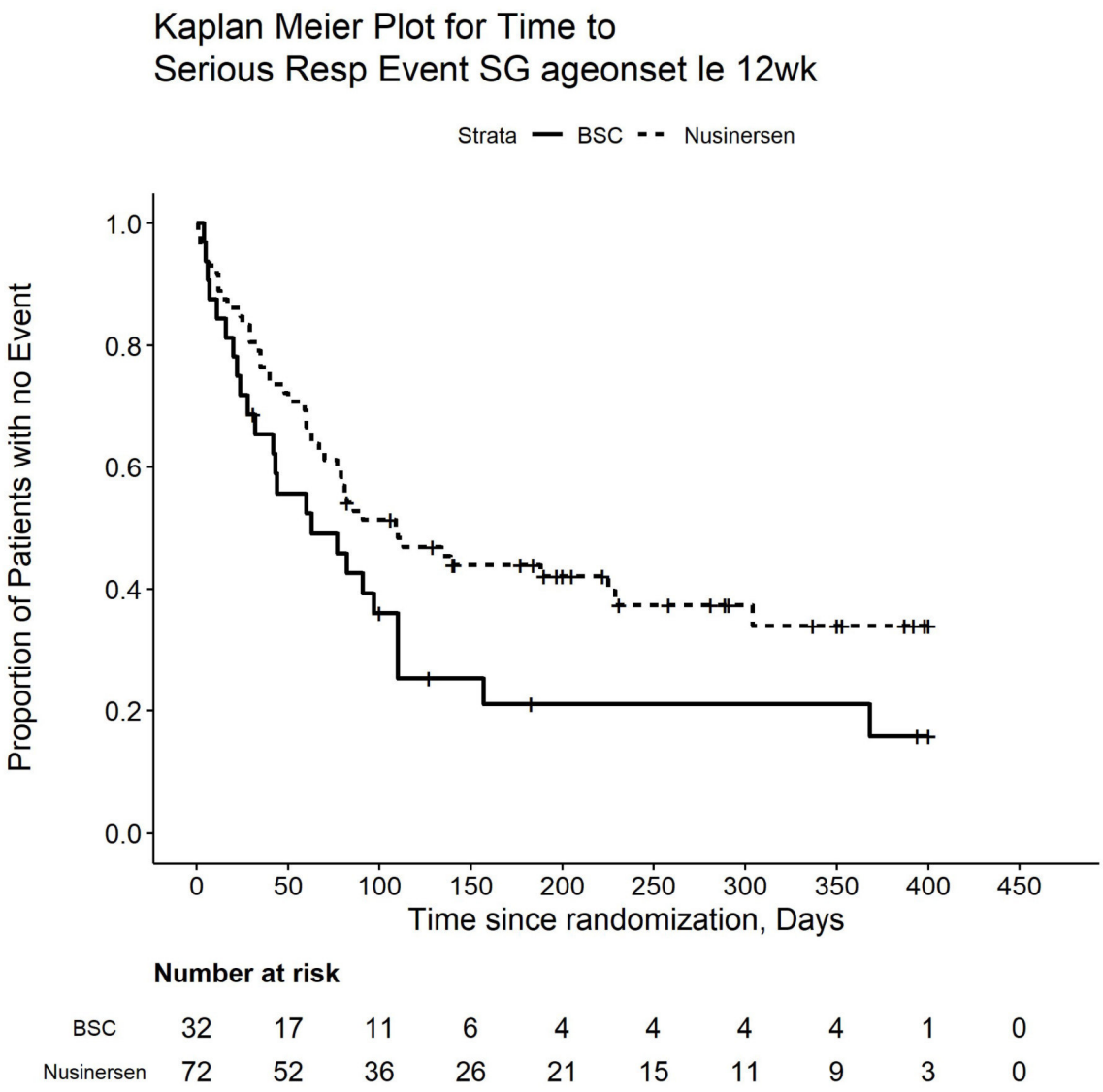
BSC	24	13	7	3	1	1	1	0	0	0
Nusinersen	43	27	18	15	8	3	3	2	1	0


Kaplan Meier Plot for Time to
SAE SG sex m
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0
50
100
150
200
250
300
350
400
450
Time since randomization, Days
Number at risk
BSC 17 10 6 2 2 2 1 1 0 0
Nusinersen 37 15 11 7 6 5 3 3 1 0



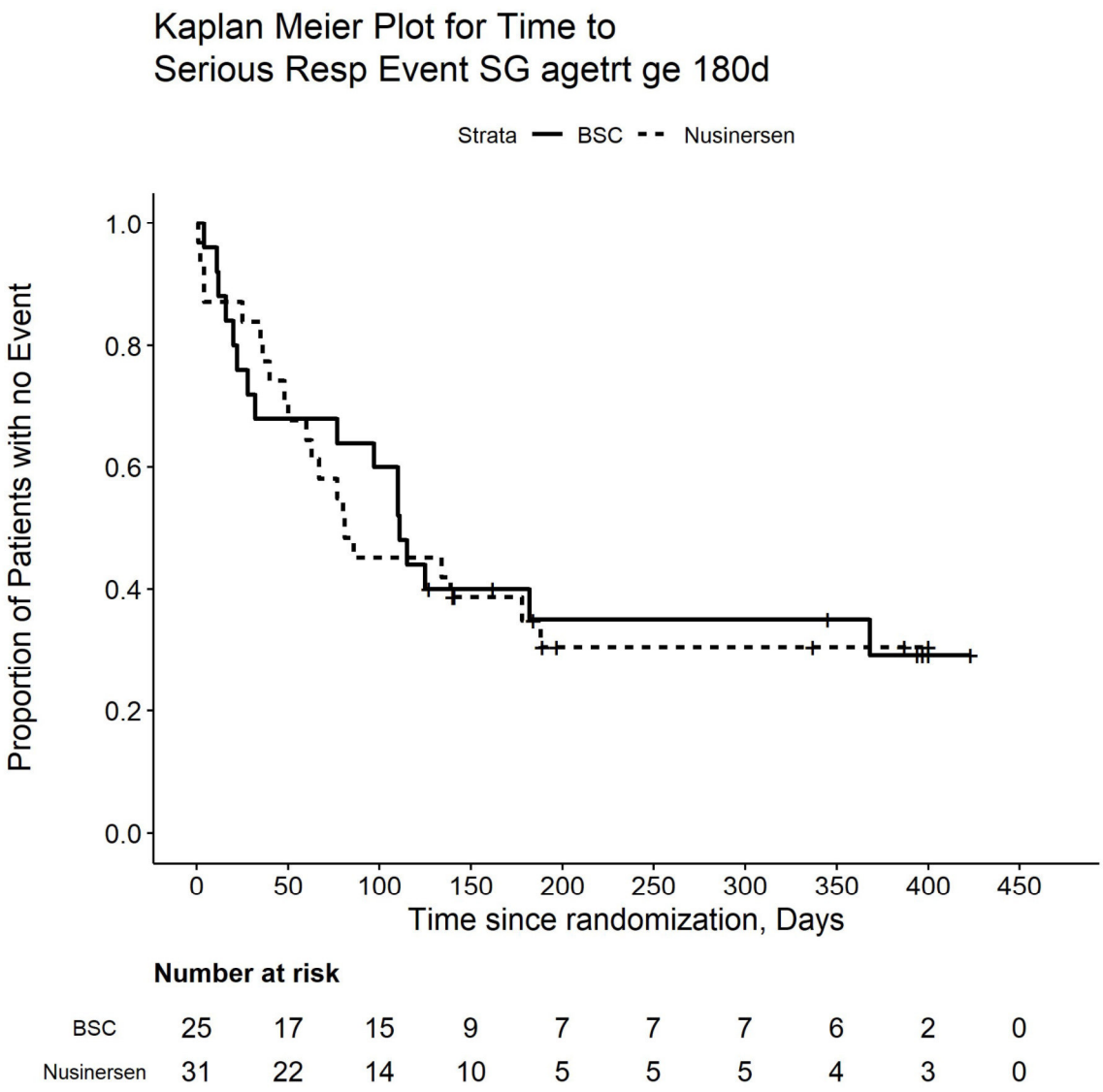
Number at risk

BSC	9	8	8	5	3	3	3	2	1	0
Nusinersen	8	5	5	5	2	2	2	1	1	0



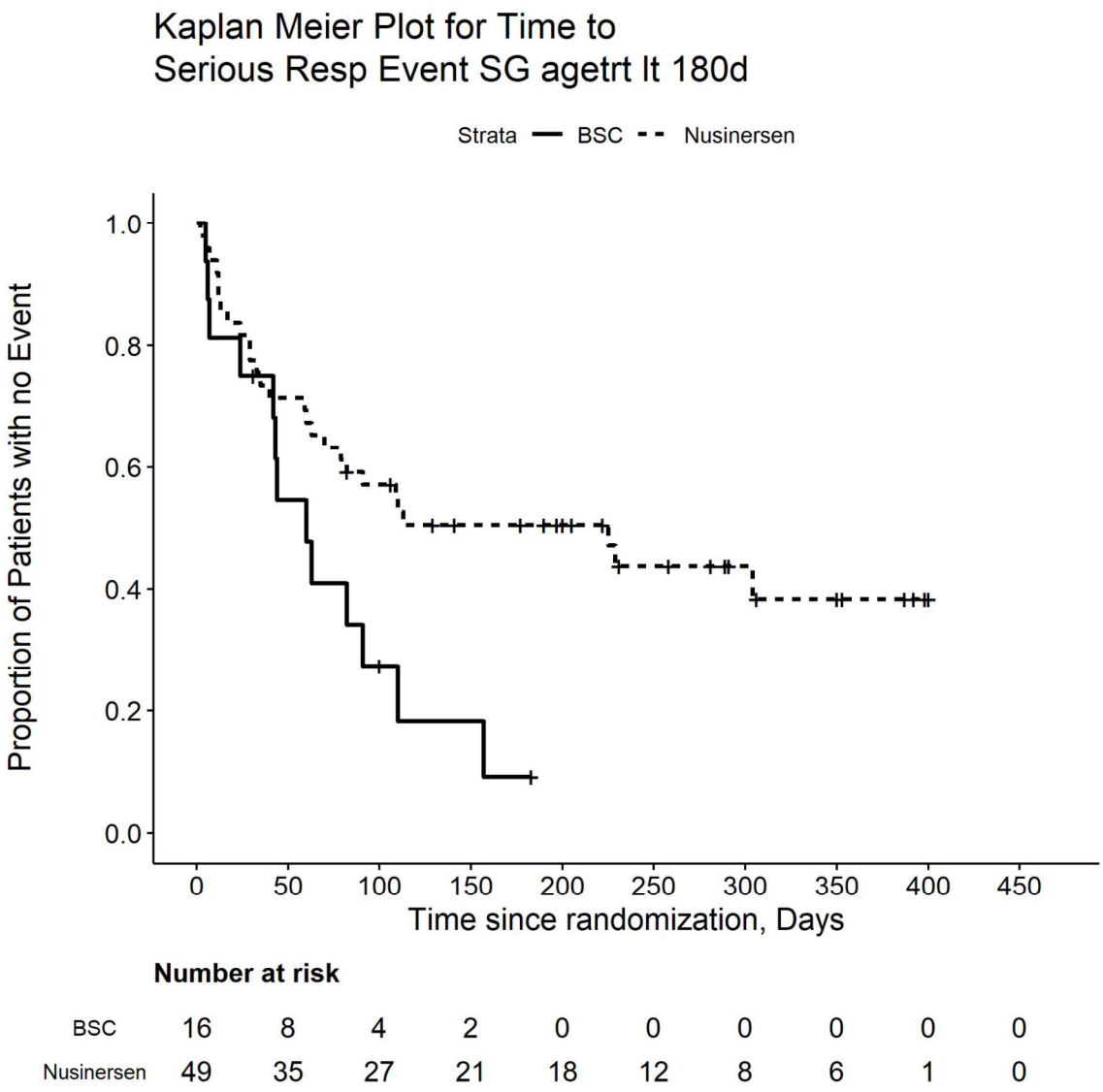
Number at risk

BSC	32	17	11	6	4	4	4	4	1	0
Nusinersen	72	52	36	26	21	15	11	9	3	0



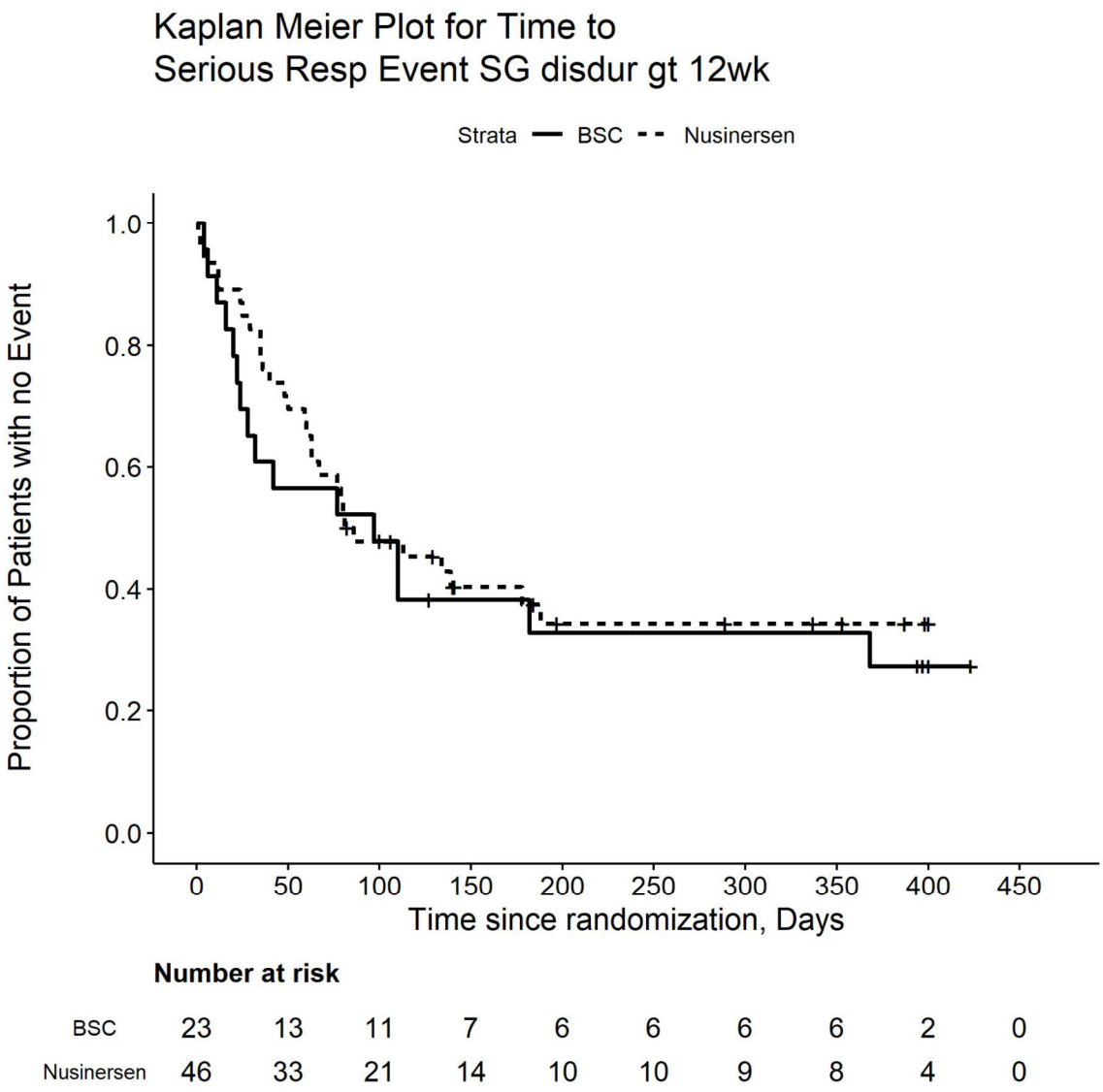
Number at risk

BSC	25	17	15	9	7	7	7	6	2	0
Nusinersen	31	22	14	10	5	5	5	4	3	0



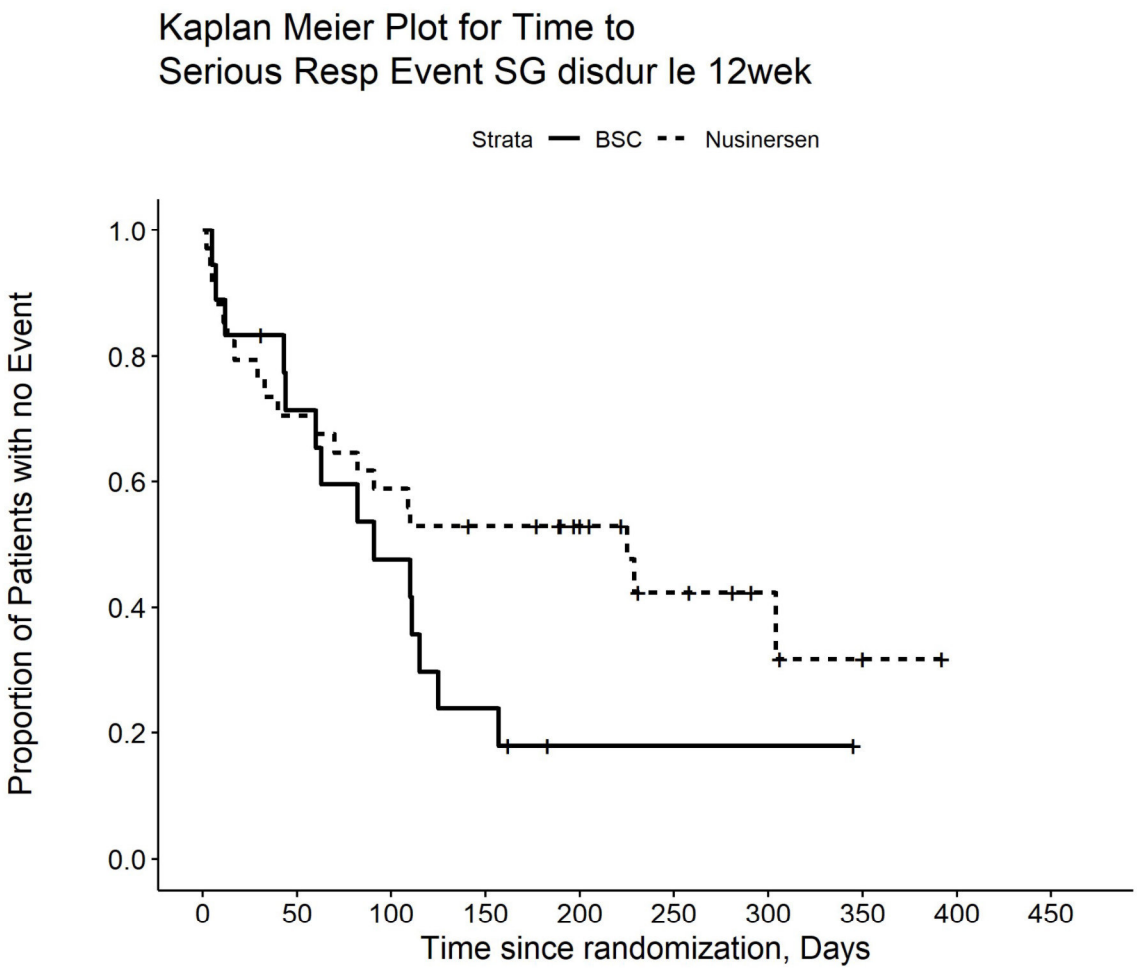
Number at risk

BSC	16	8	4	2	0	0	0	0	0	0
Nusinersen	49	35	27	21	18	12	8	6	1	0



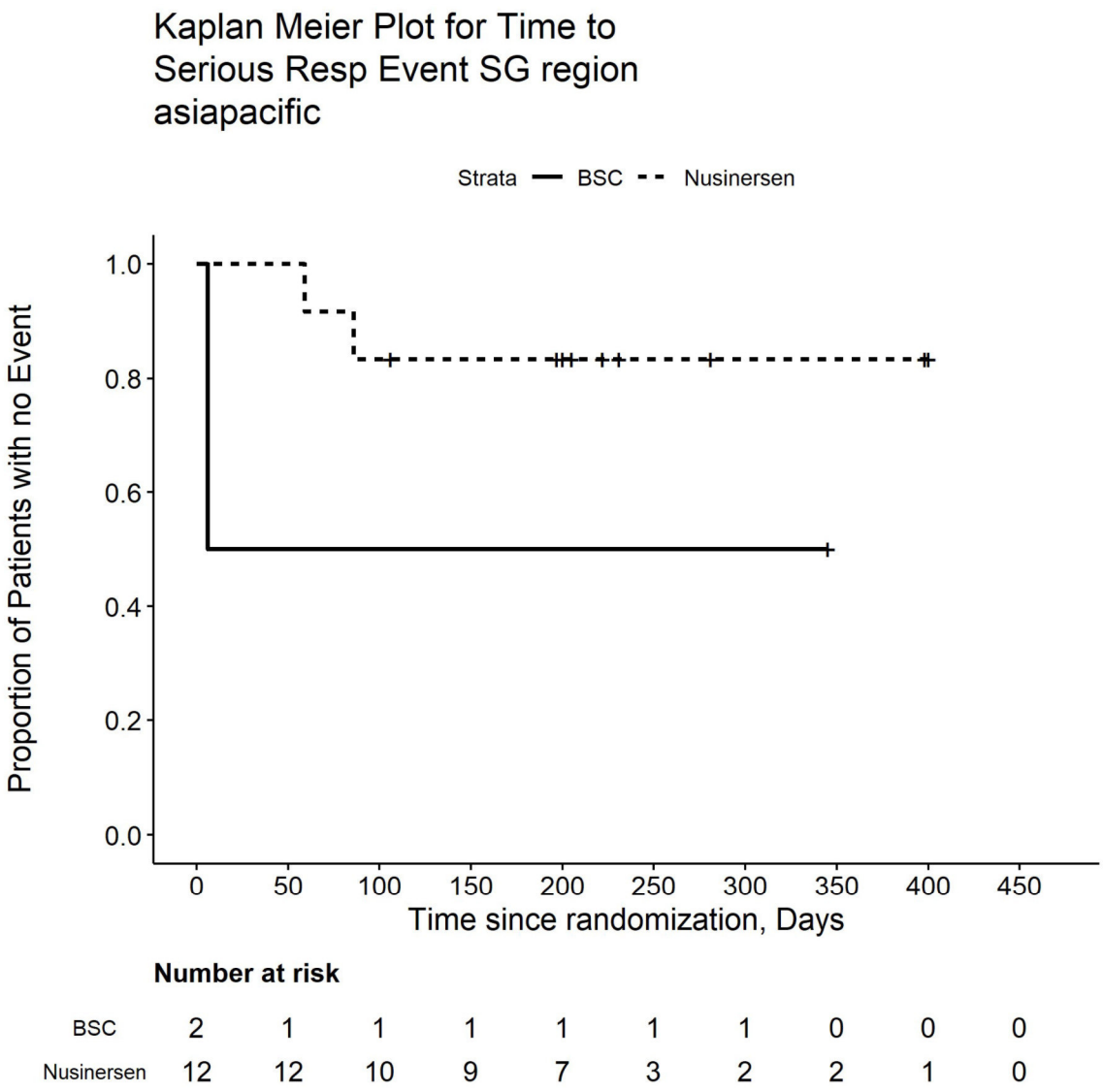
Number at risk

BSC	23	13	11	7	6	6	6	6	2	0
Nusinersen	46	33	21	14	10	10	9	8	4	0



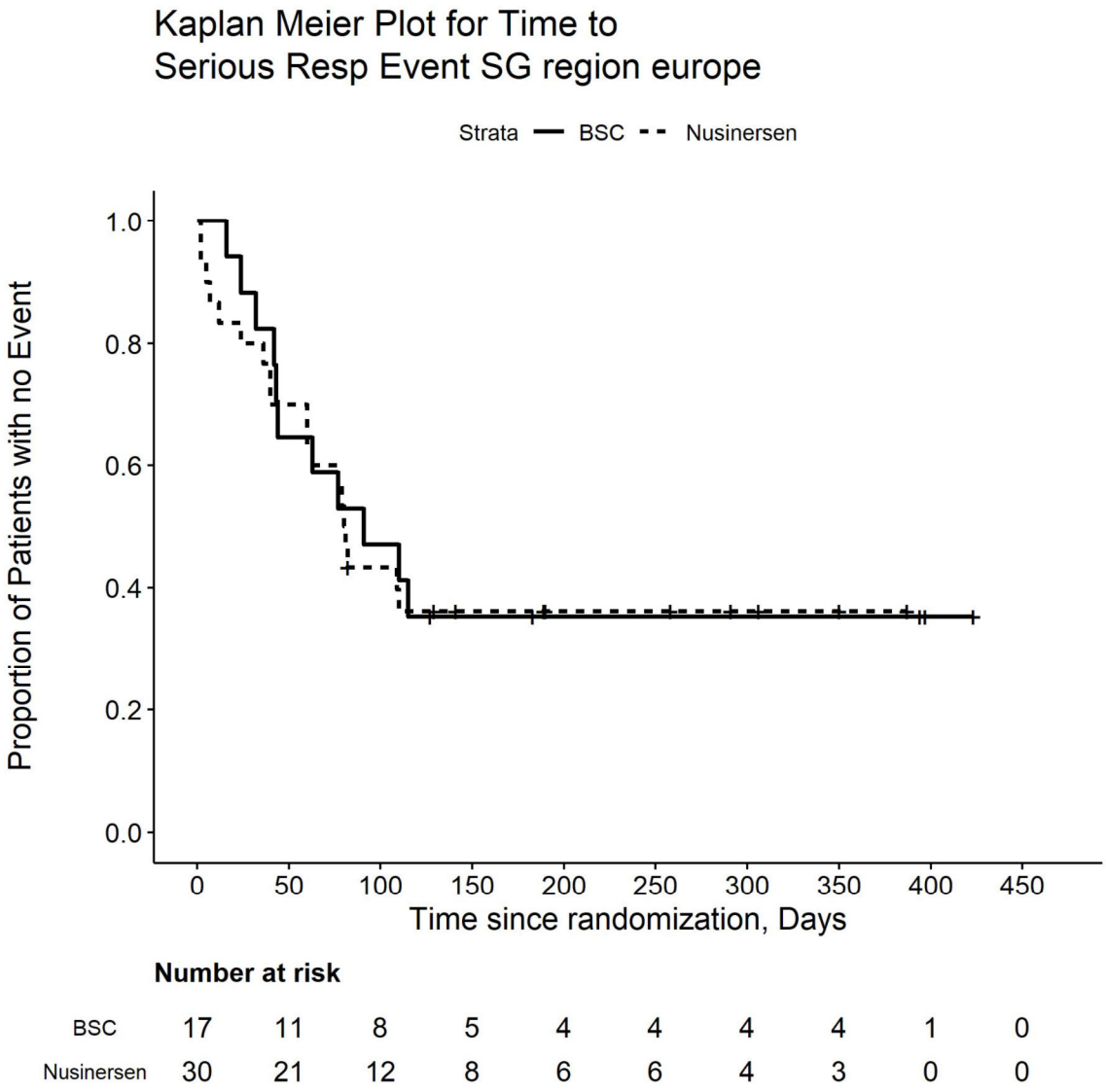
Number at risk

BSC	18	12	8	4	1	1	1	0	0	0
Nusinersen	34	24	20	17	13	7	4	2	0	0



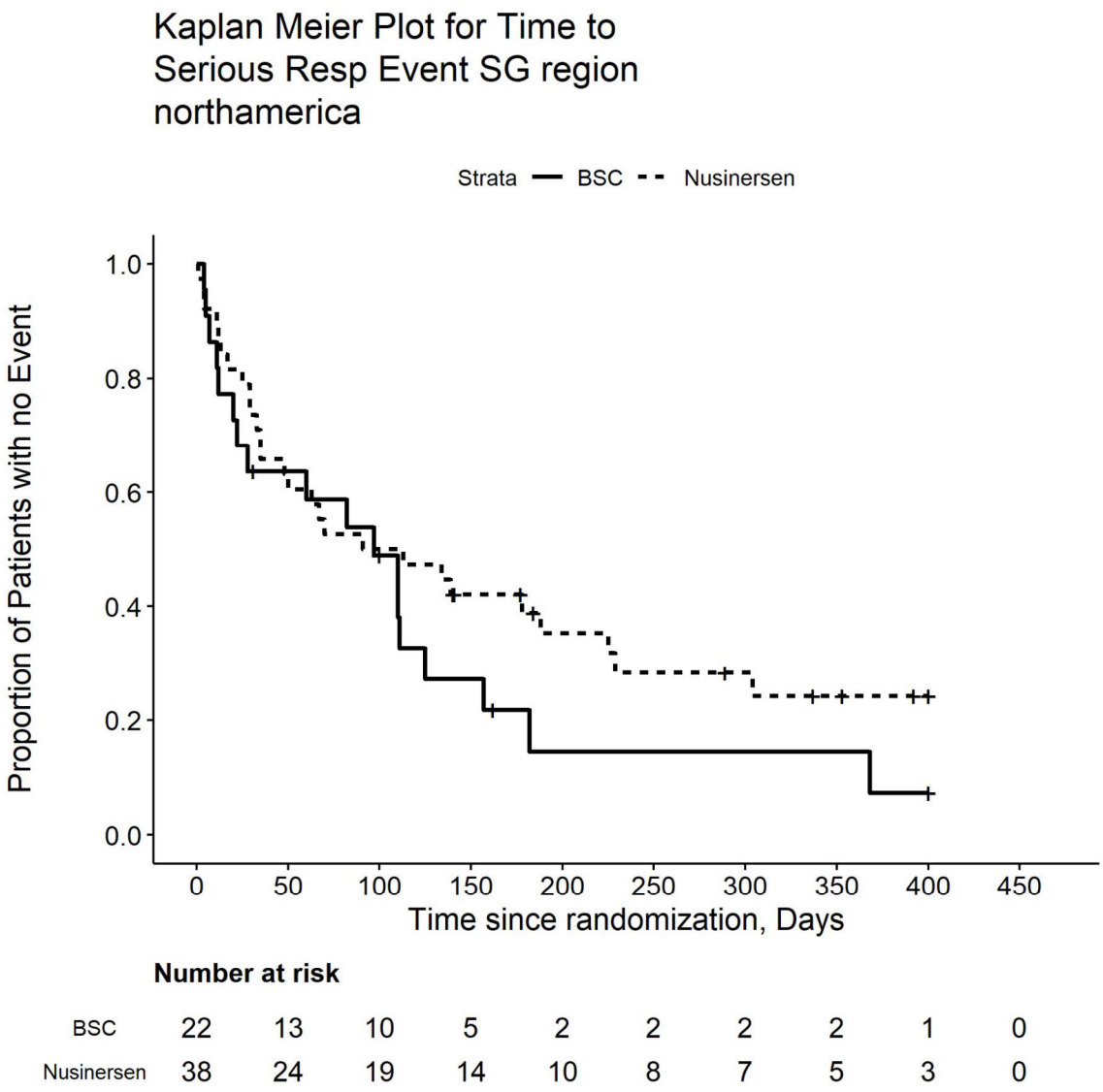
Number at risk

BSC	2	1	1	1	1	1	1	0	0	0
Nusinersen	12	12	10	9	7	3	2	2	1	0



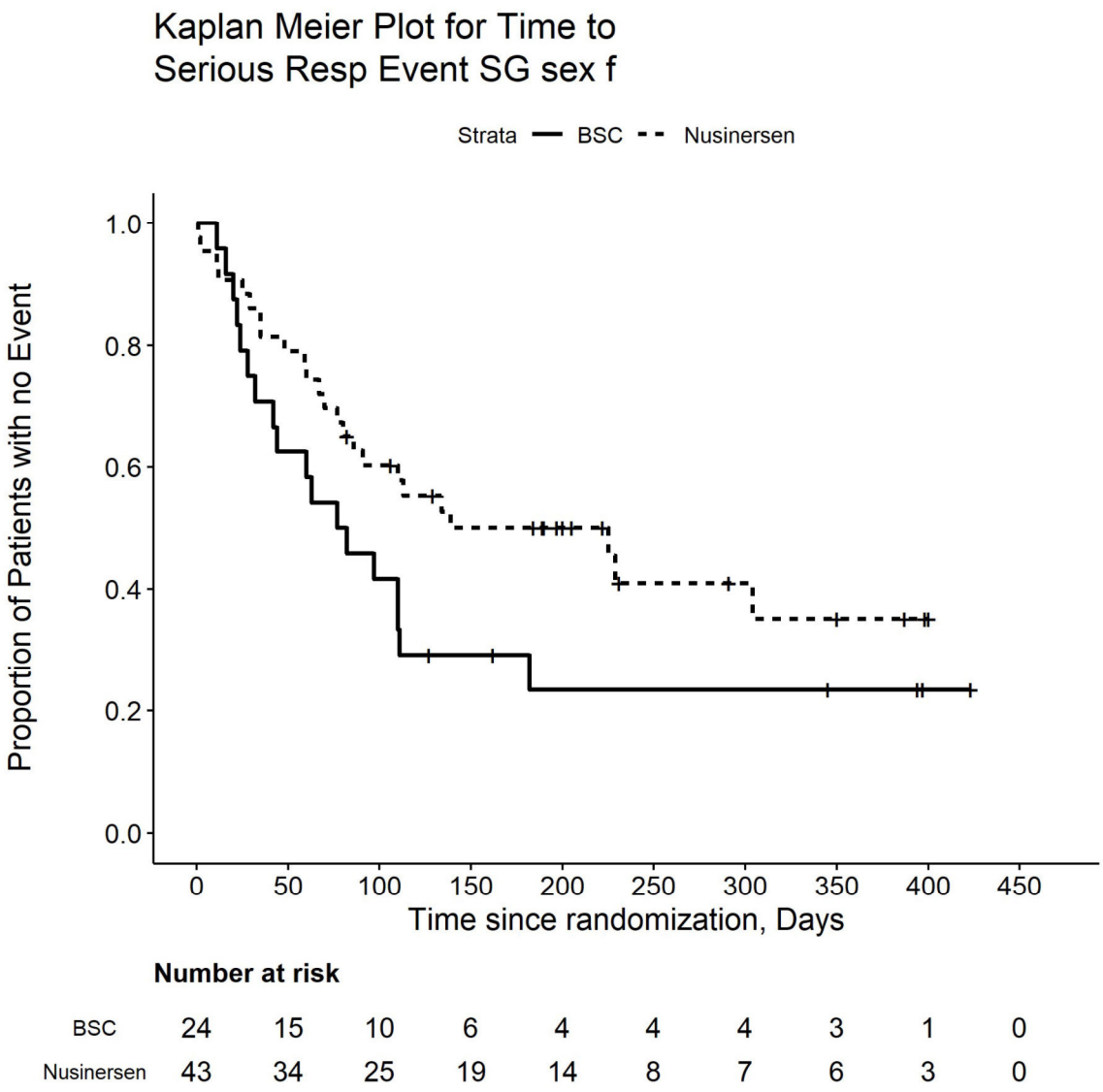
Number at risk

BSC	17	11	8	5	4	4	4	4	1	0
Nusinersen	30	21	12	8	6	6	4	3	0	0



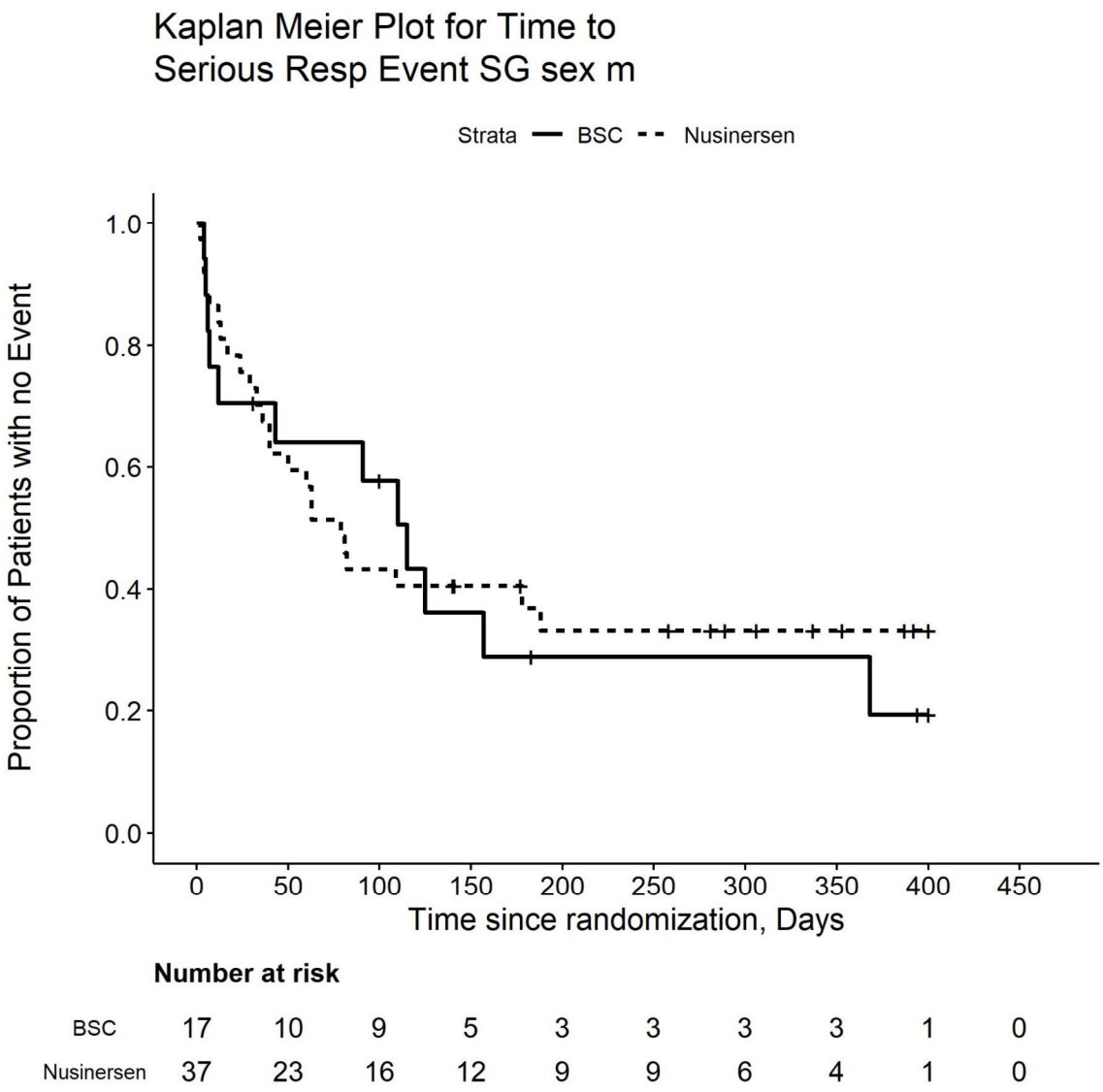
Number at risk

BSC	22	13	10	5	2	2	2	2	1	0
Nusinersen	38	24	19	14	10	8	7	5	3	0



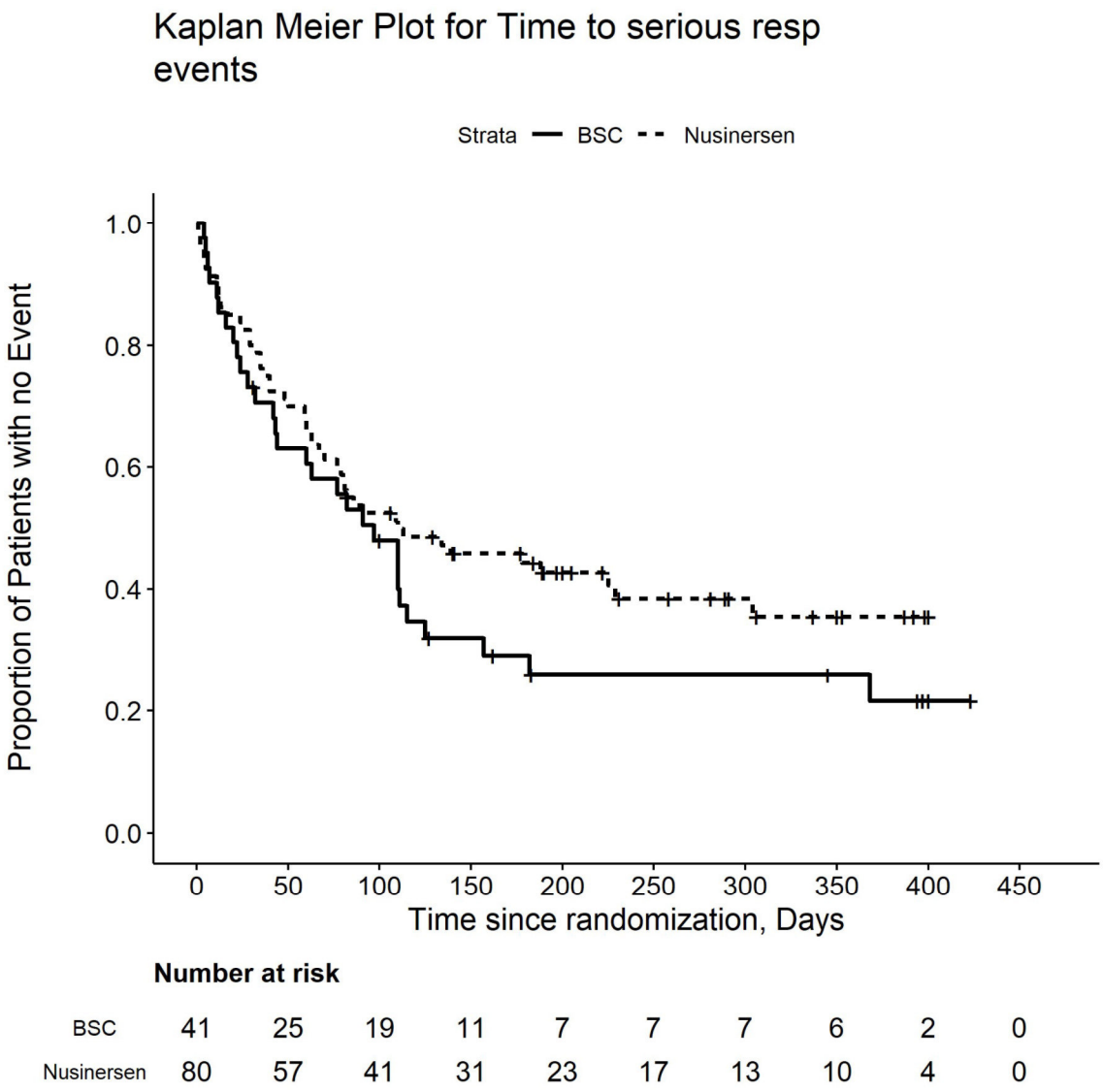
Number at risk

BSC	24	15	10	6	4	4	4	3	1	0
Nusinersen	43	34	25	19	14	8	7	6	3	0



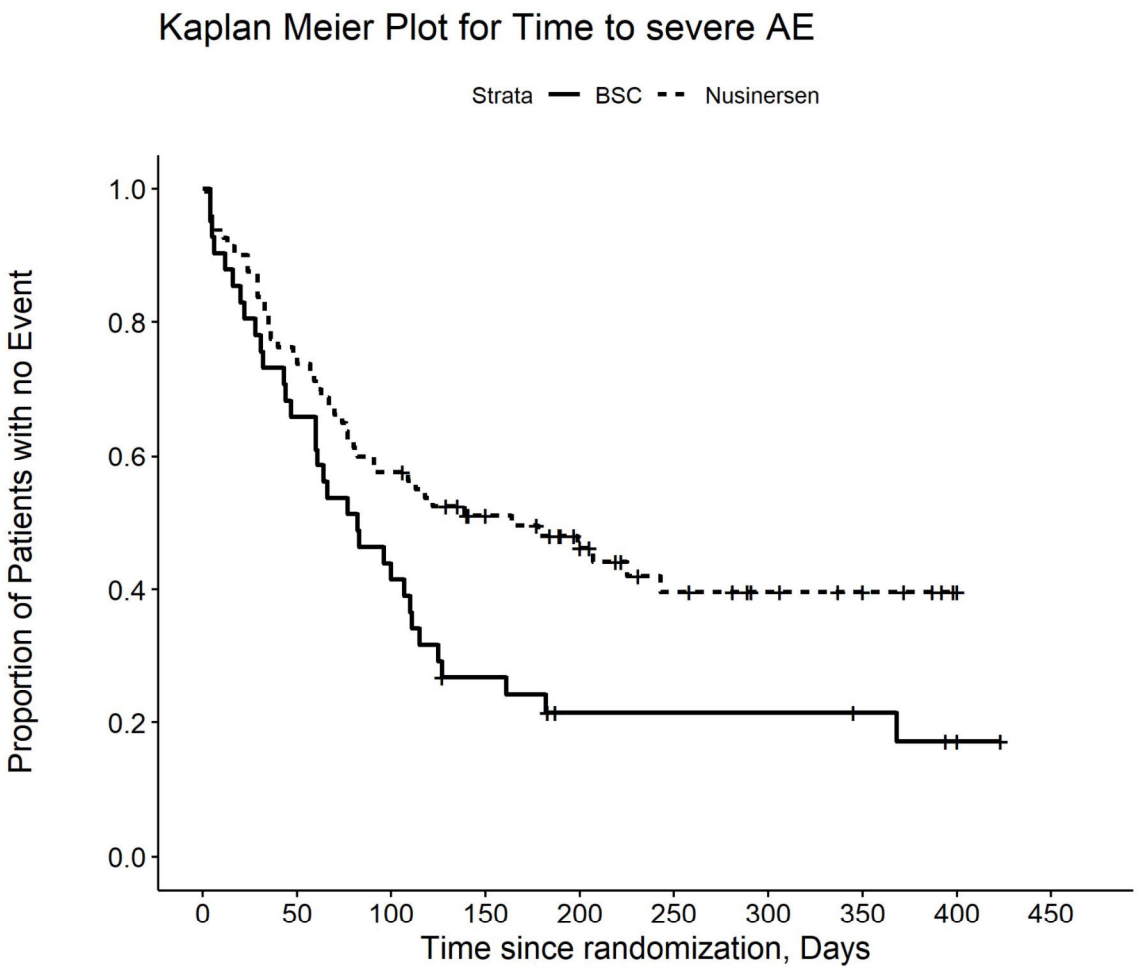
Number at risk

BSC	17	10	9	5	3	3	3	3	1	0
Nusinersen	37	23	16	12	9	9	6	4	1	0



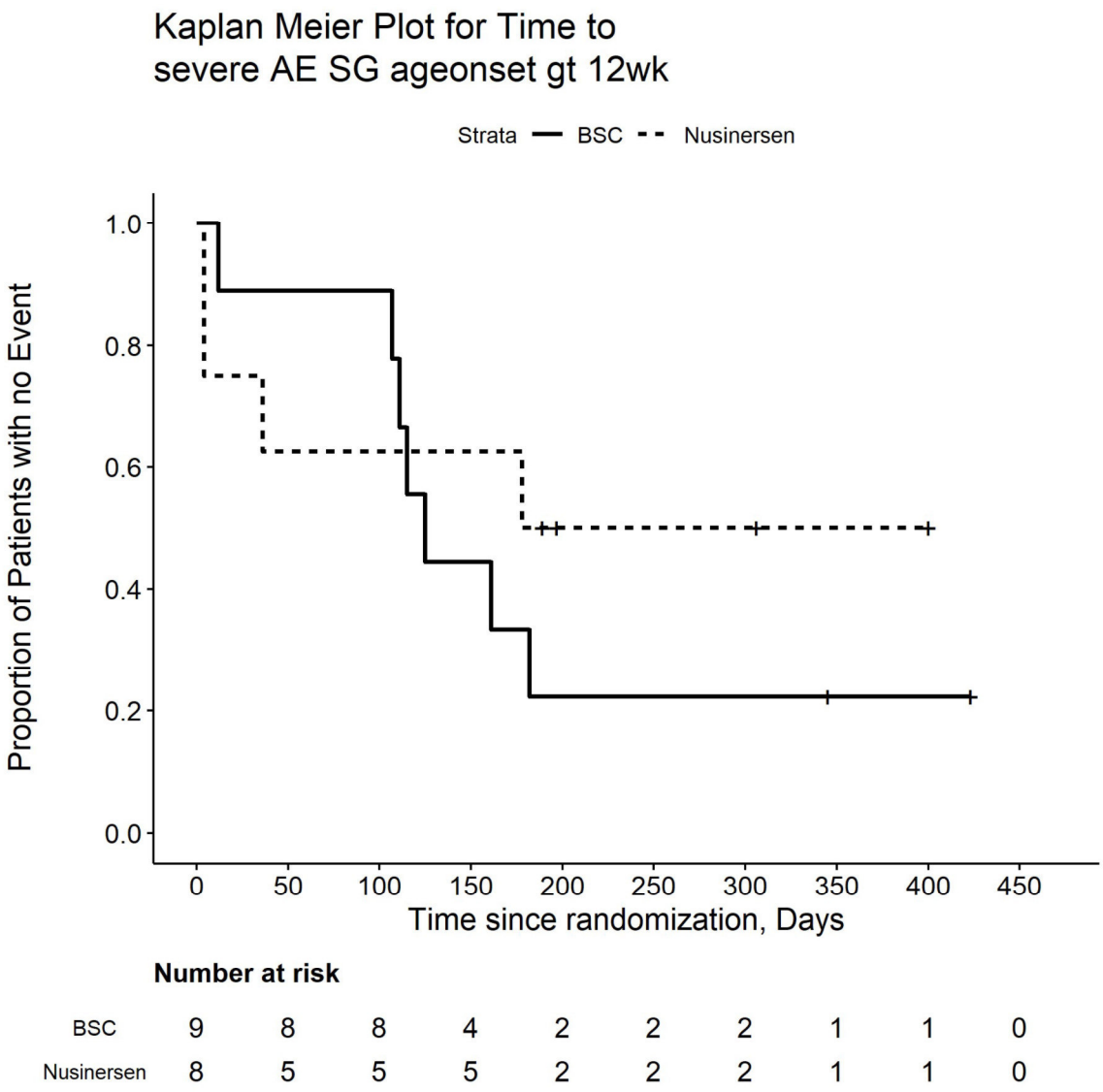
Number at risk

BSC	41	25	19	11	7	7	7	6	2	0
Nusinersen	80	57	41	31	23	17	13	10	4	0



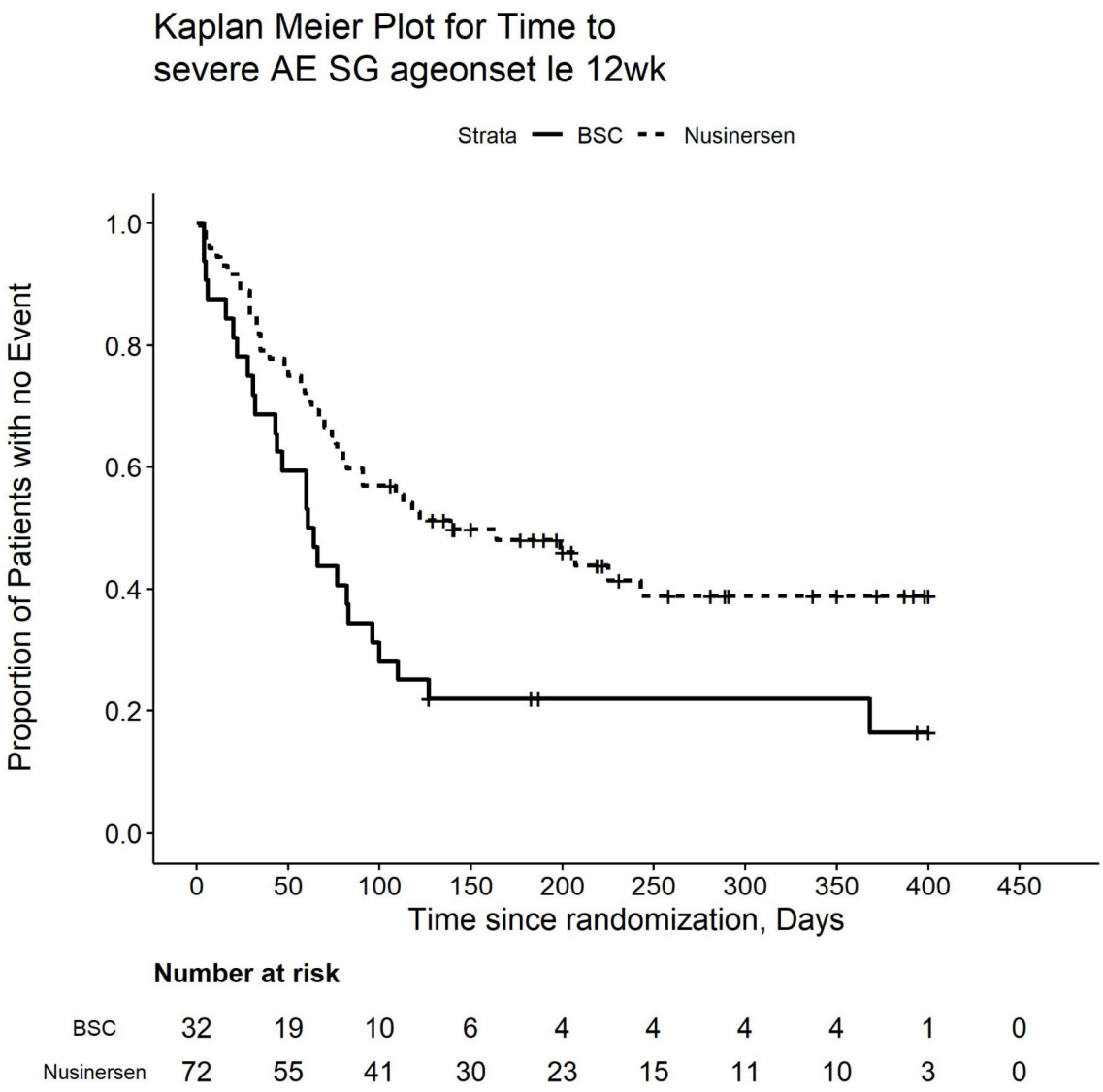
Number at risk

BSC	41	27	18	10	6	6	6	5	2	0
Nusinersen	80	60	46	35	25	17	13	11	4	0



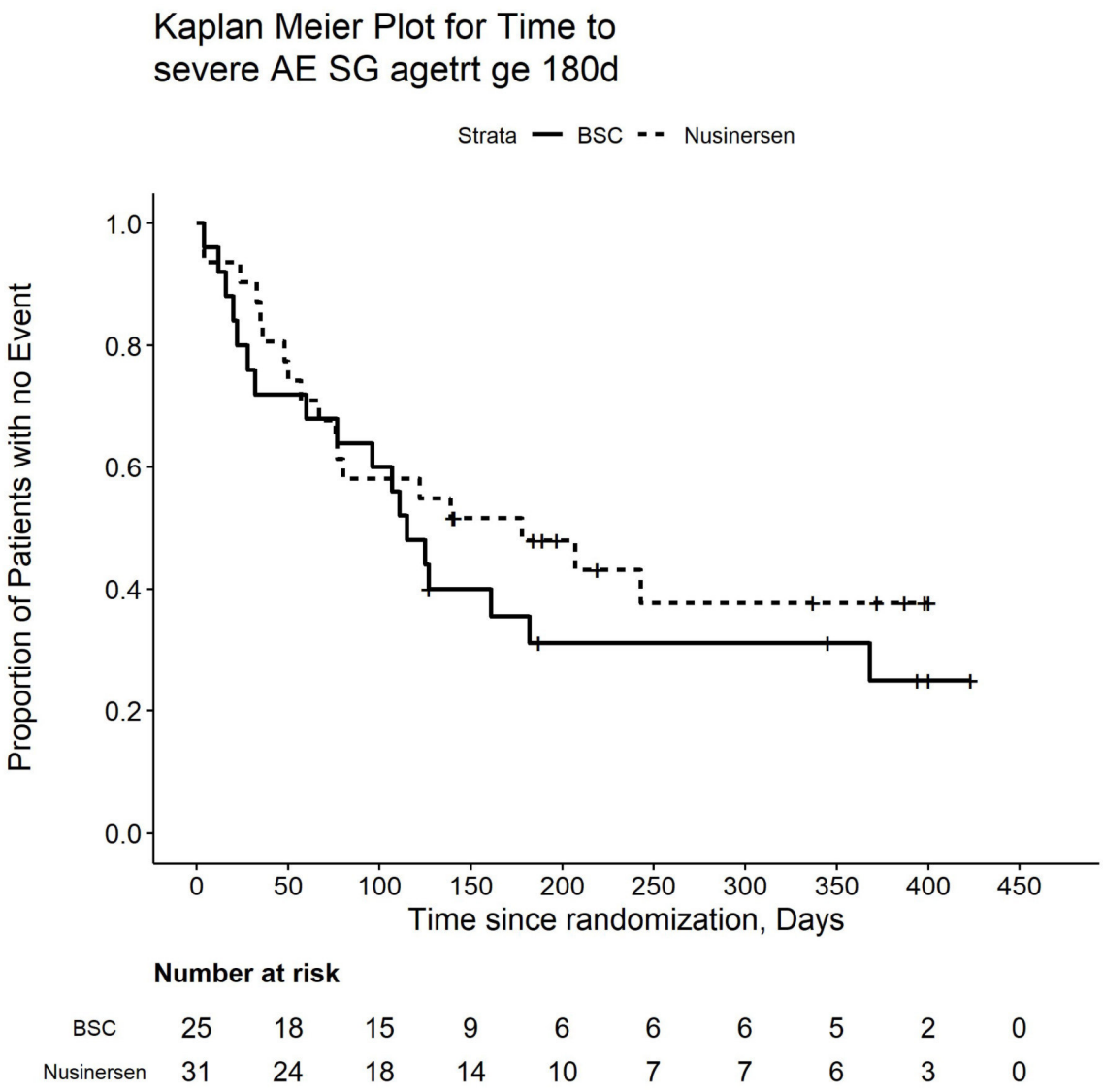
Number at risk

BSC	9	8	8	4	2	2	2	1	1	0
Nusinersen	8	5	5	5	2	2	2	1	1	0



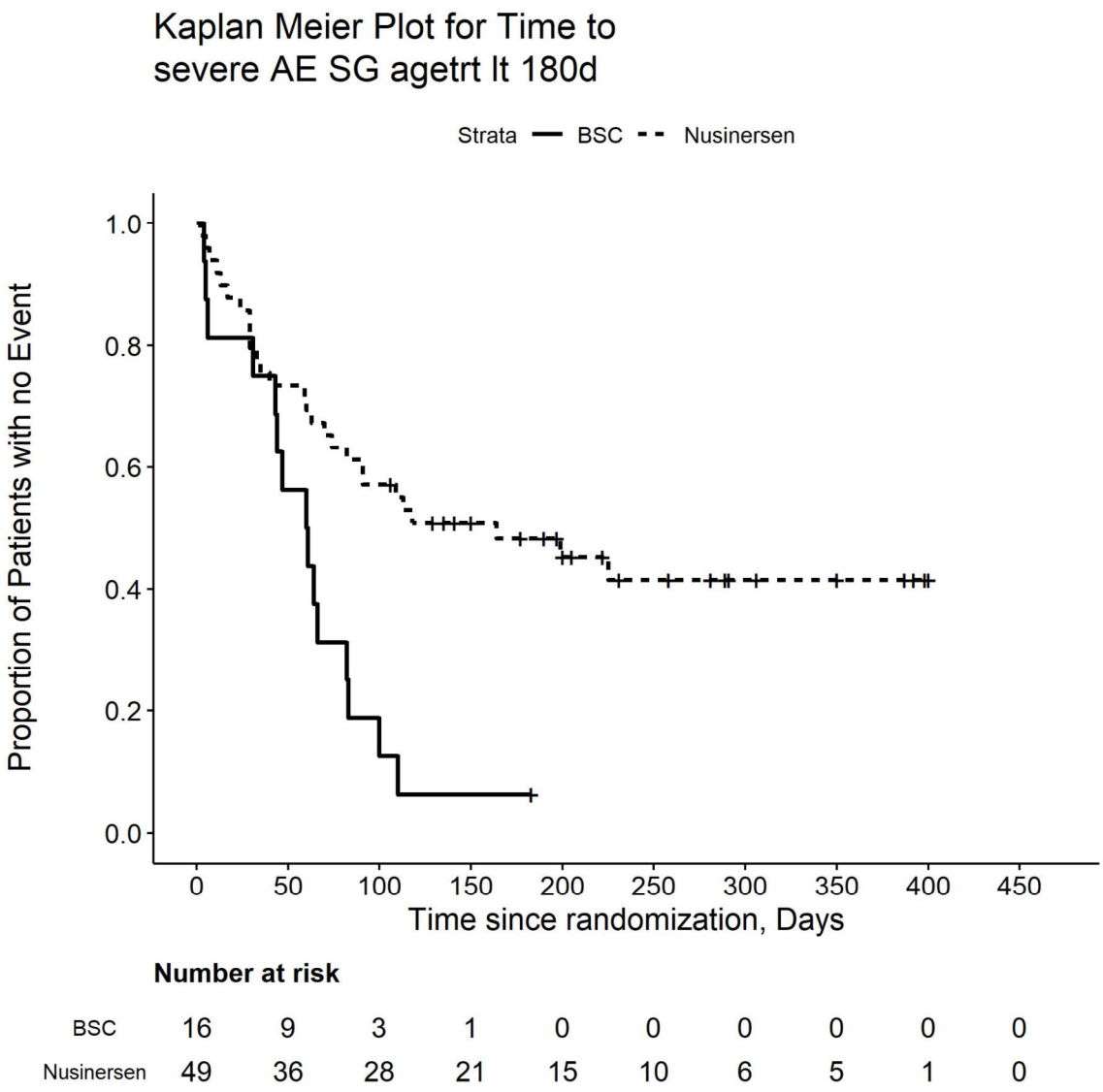
Number at risk

BSC	32	19	10	6	4	4	4	4	1	0
Nusinersen	72	55	41	30	23	15	11	10	3	0



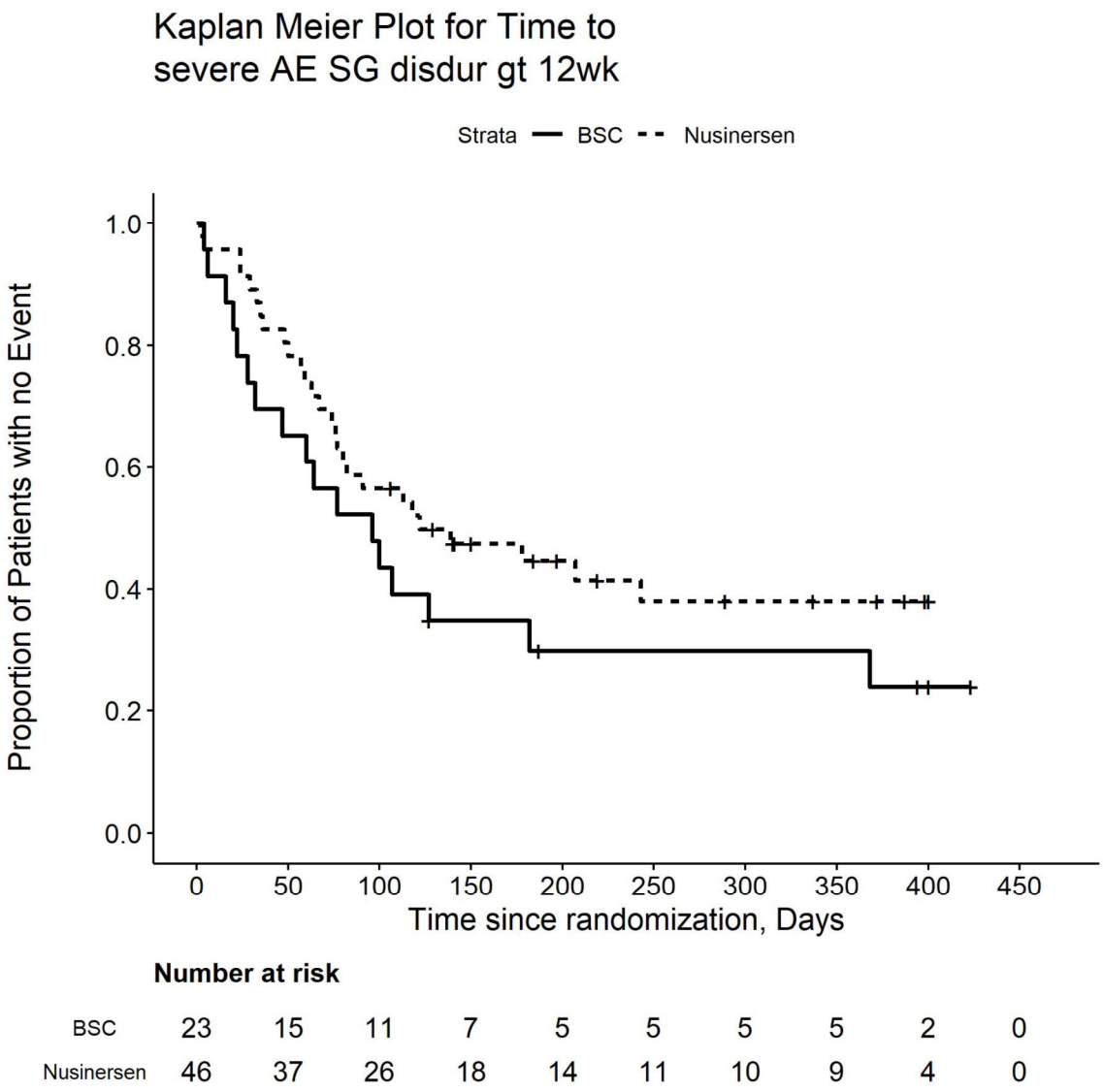
Number at risk

BSC	25	18	15	9	6	6	6	5	2	0
Nusinersen	31	24	18	14	10	7	7	6	3	0



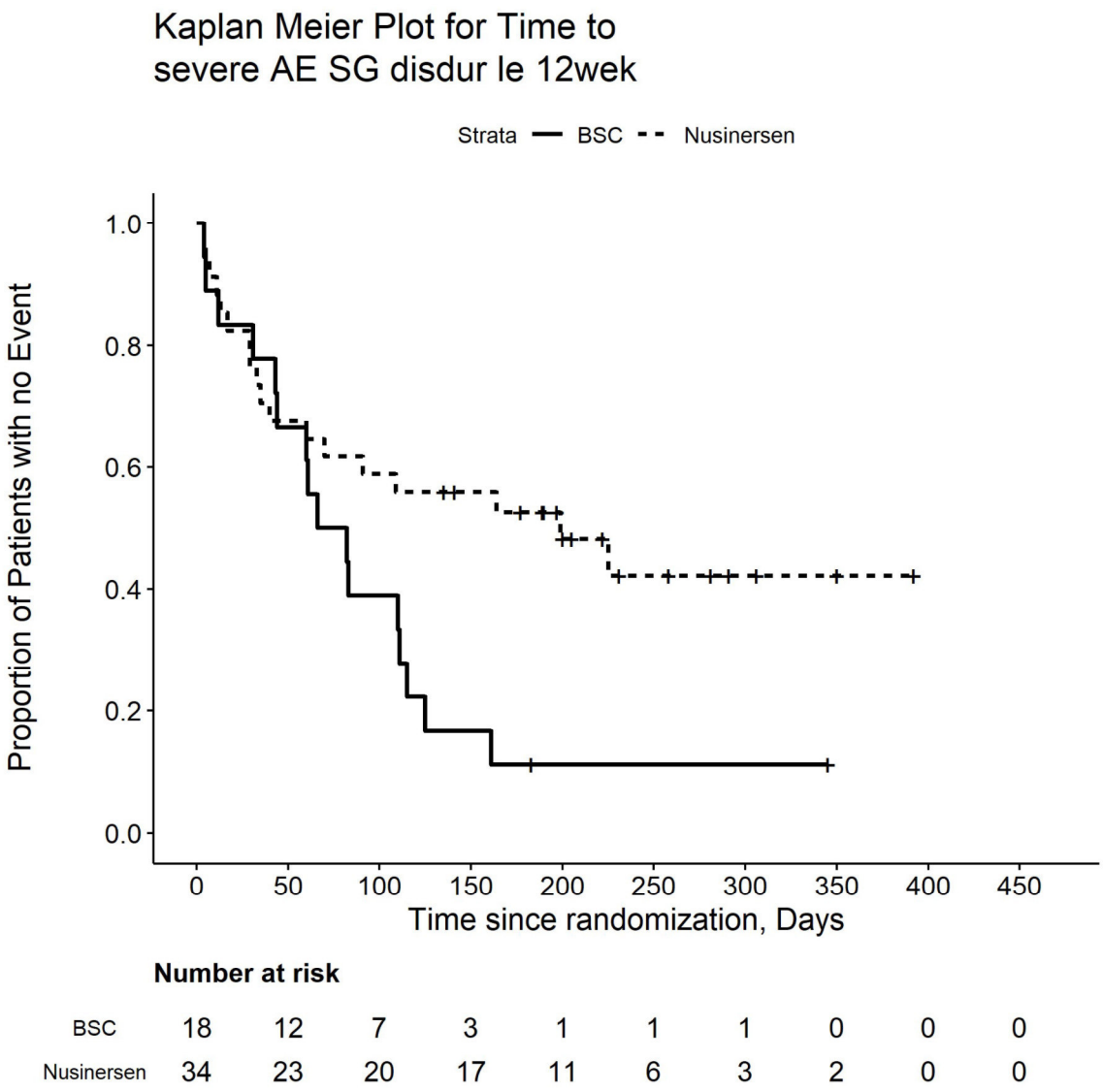
Number at risk

BSC	16	9	3	1	0	0	0	0	0	0
Nusinersen	49	36	28	21	15	10	6	5	1	0



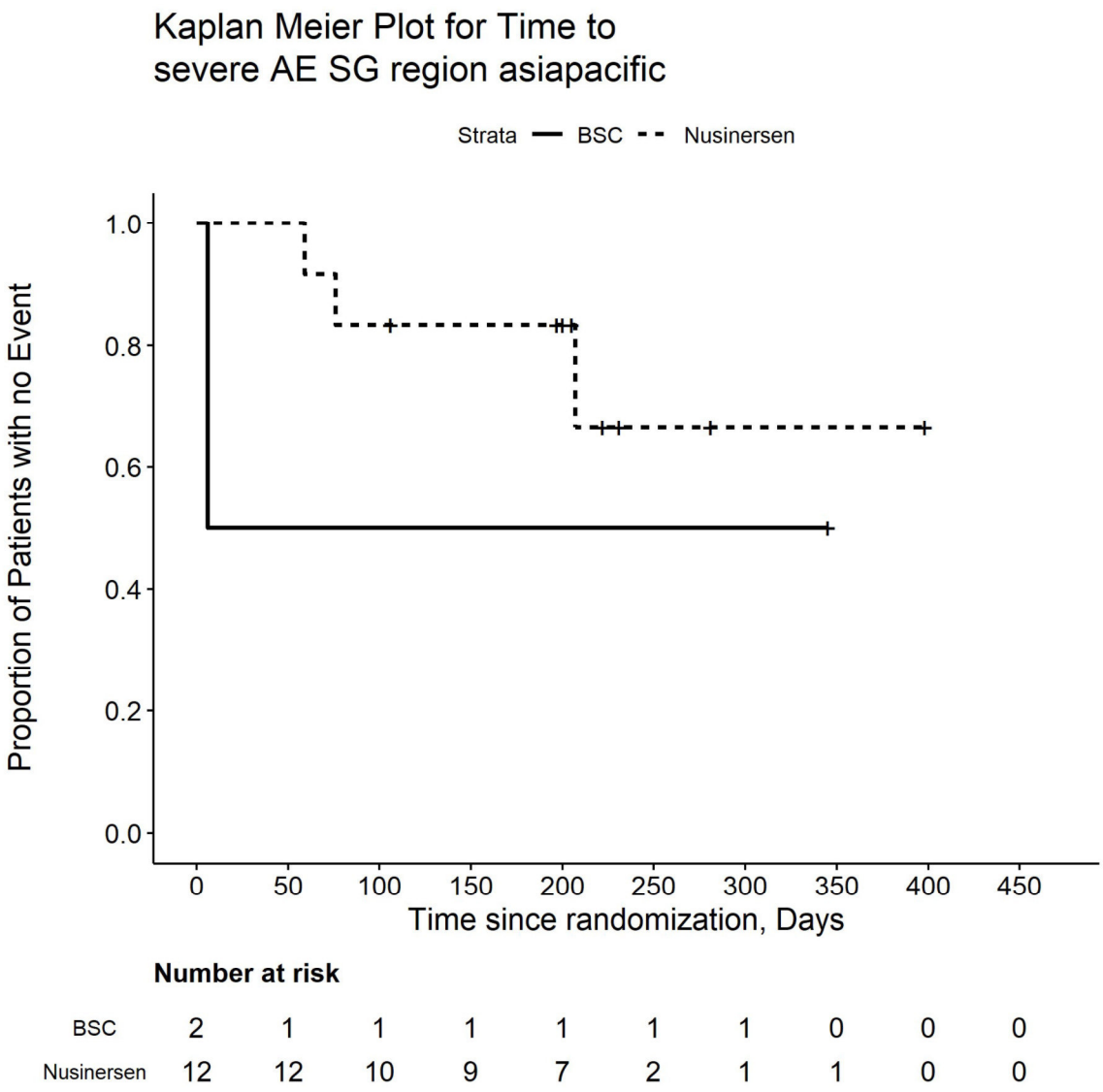
Number at risk

BSC	23	15	11	7	5	5	5	5	2	0
Nusinersen	46	37	26	18	14	11	10	9	4	0



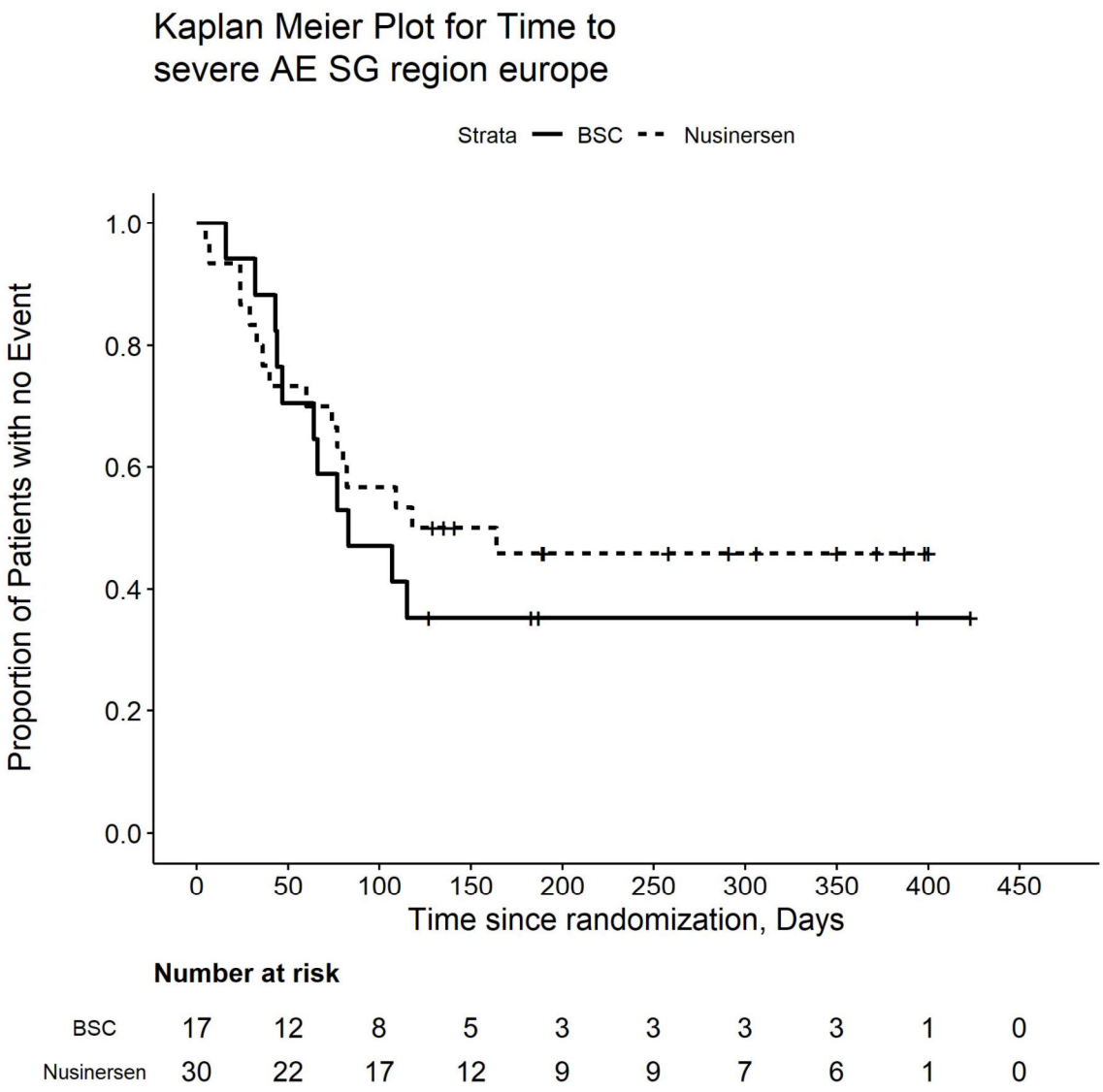
Number at risk

BSC	18	12	7	3	1	1	1	0	0	0
Nusinersen	34	23	20	17	11	6	3	2	0	0



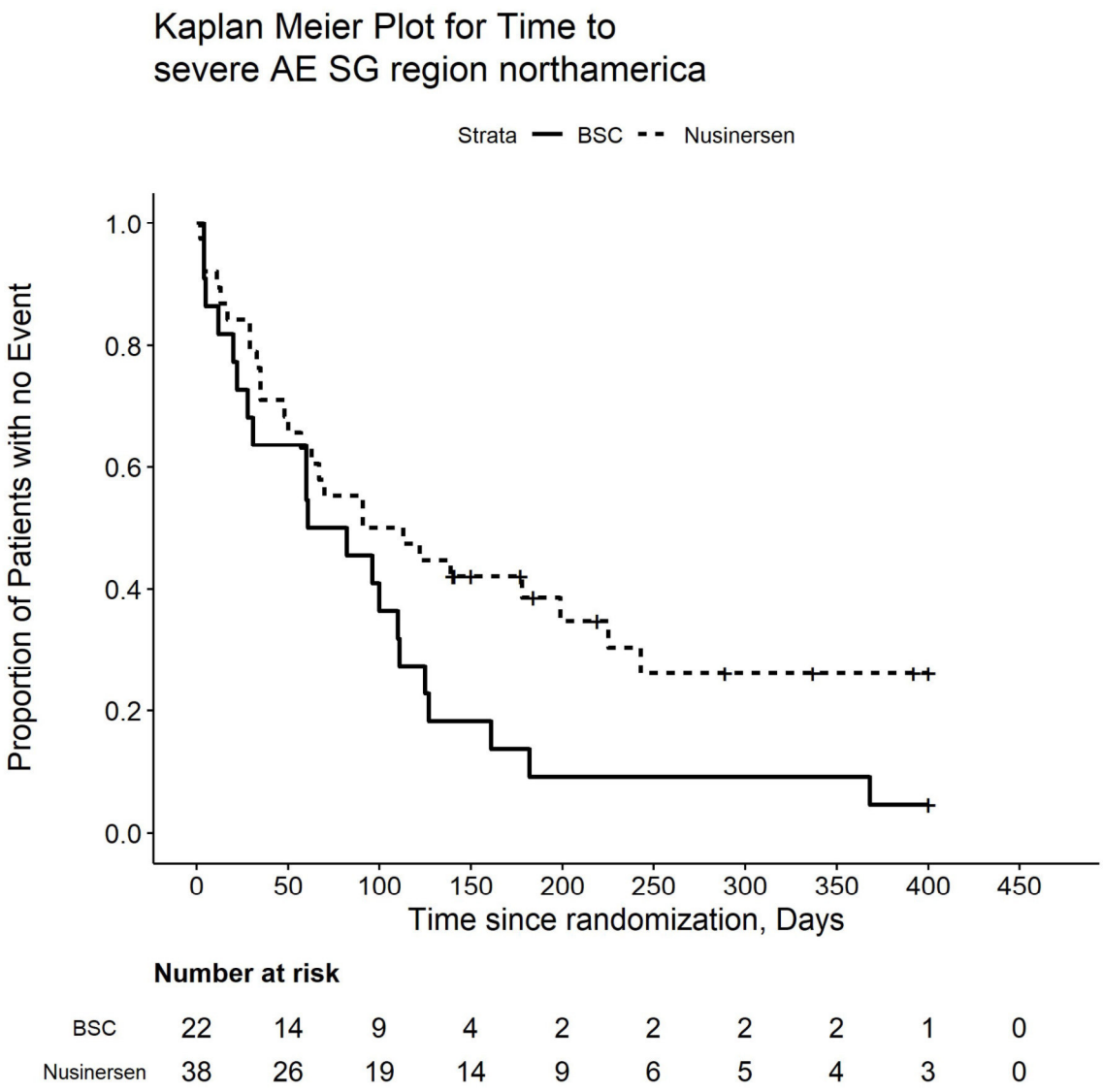
Number at risk

BSC	2	1	1	1	1	1	1	0	0	0
Nusinersen	12	12	10	9	7	2	1	1	0	0



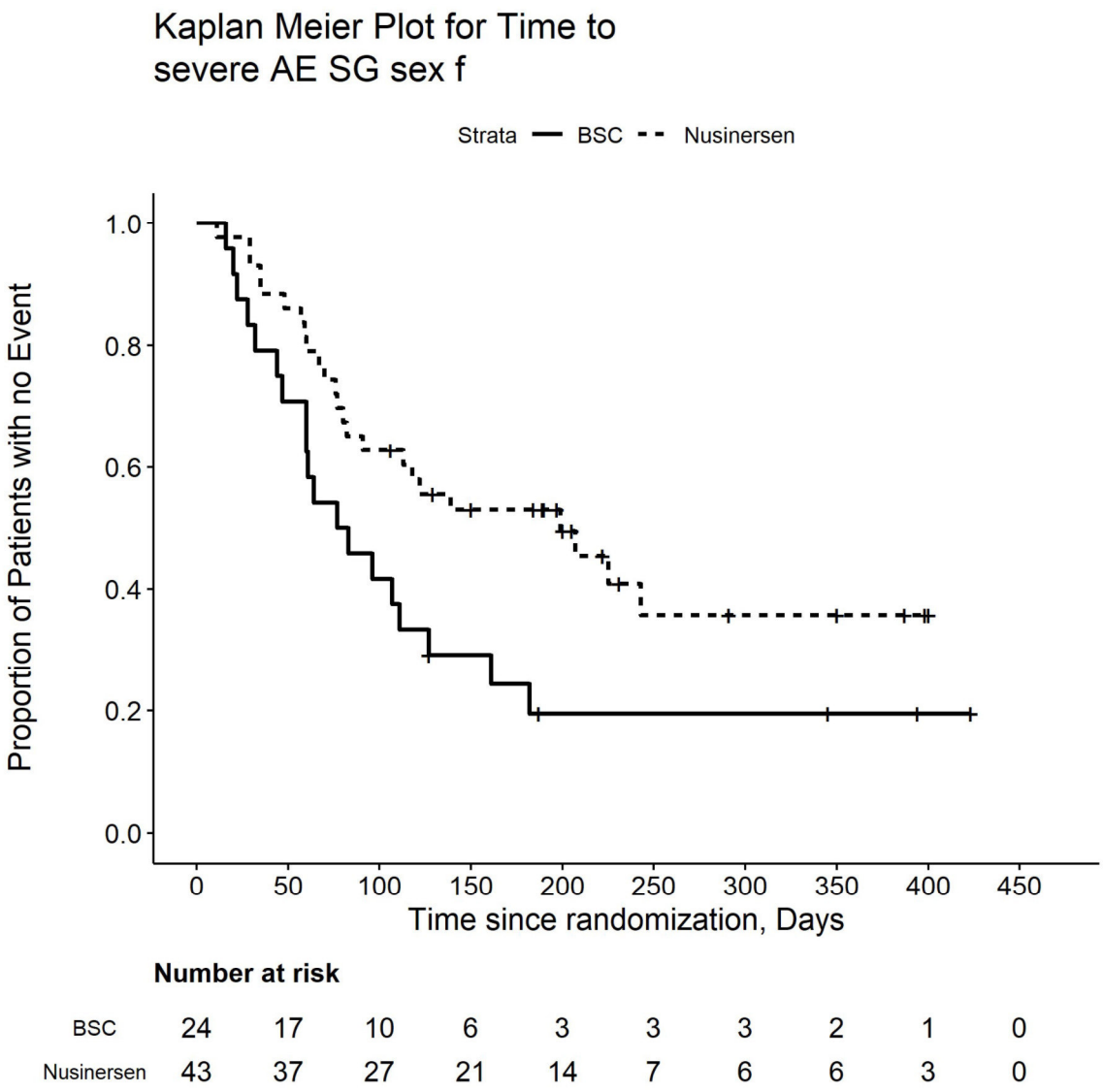
Number at risk

BSC	17	12	8	5	3	3	3	3	1	0
Nusinersen	30	22	17	12	9	9	7	6	1	0



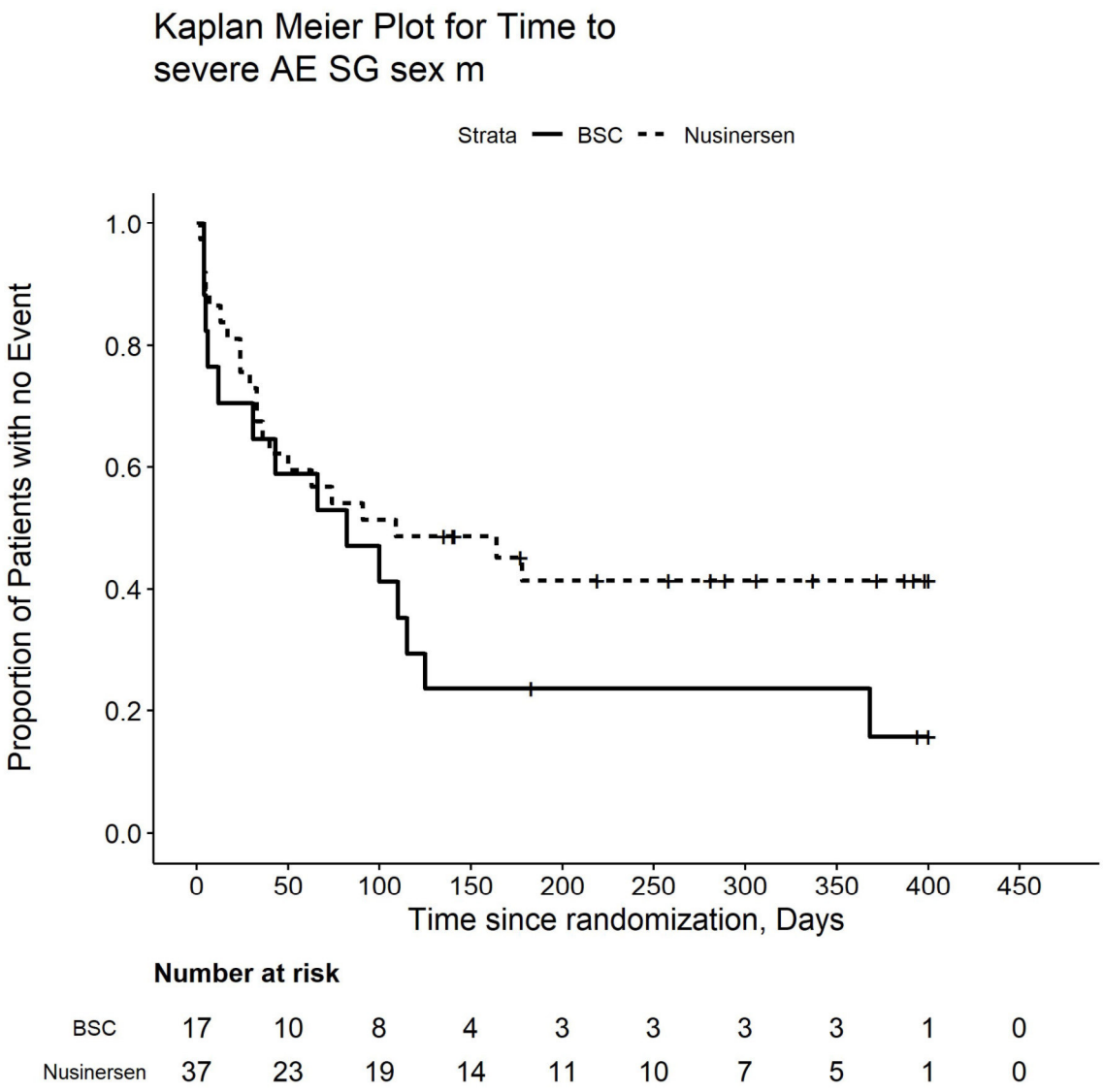
Number at risk

BSC	22	14	9	4	2	2	2	2	1	0
Nusinersen	38	26	19	14	9	6	5	4	3	0



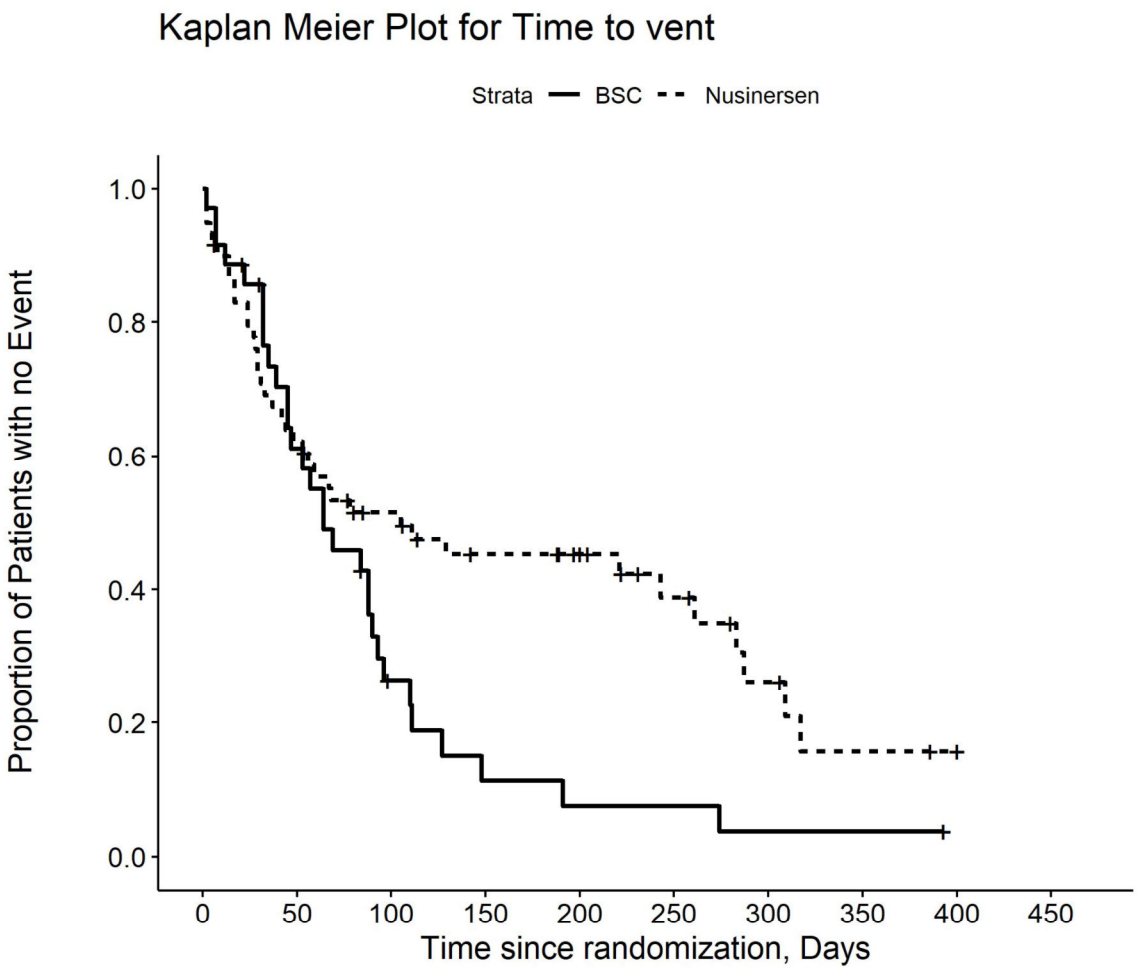
Number at risk

BSC	24	17	10	6	3	3	3	2	1	0
Nusinersen	43	37	27	21	14	7	6	6	3	0



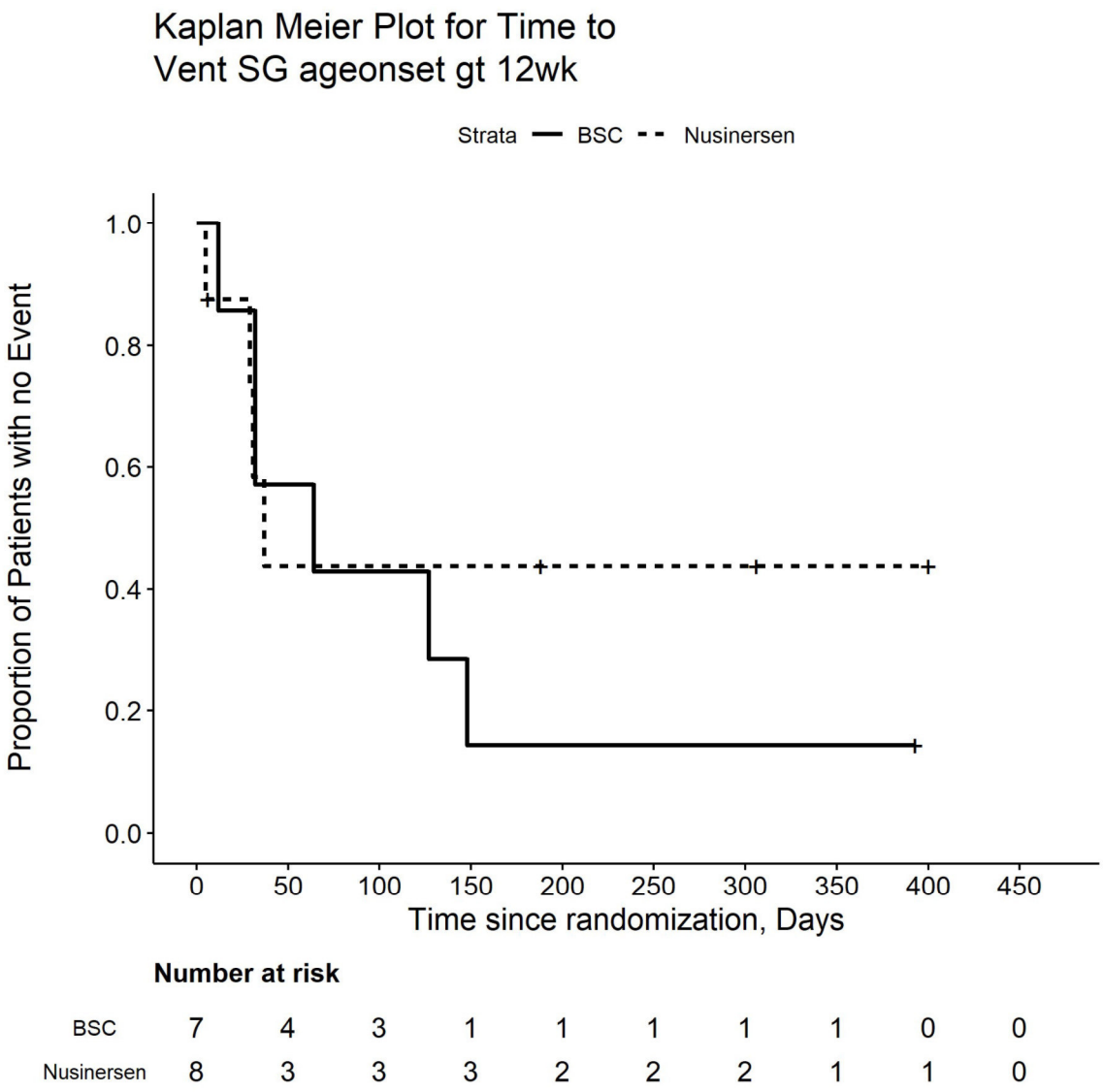
Number at risk

BSC	17	10	8	4	3	3	3	3	1	0
Nusinersen	37	23	19	14	11	10	7	5	1	0



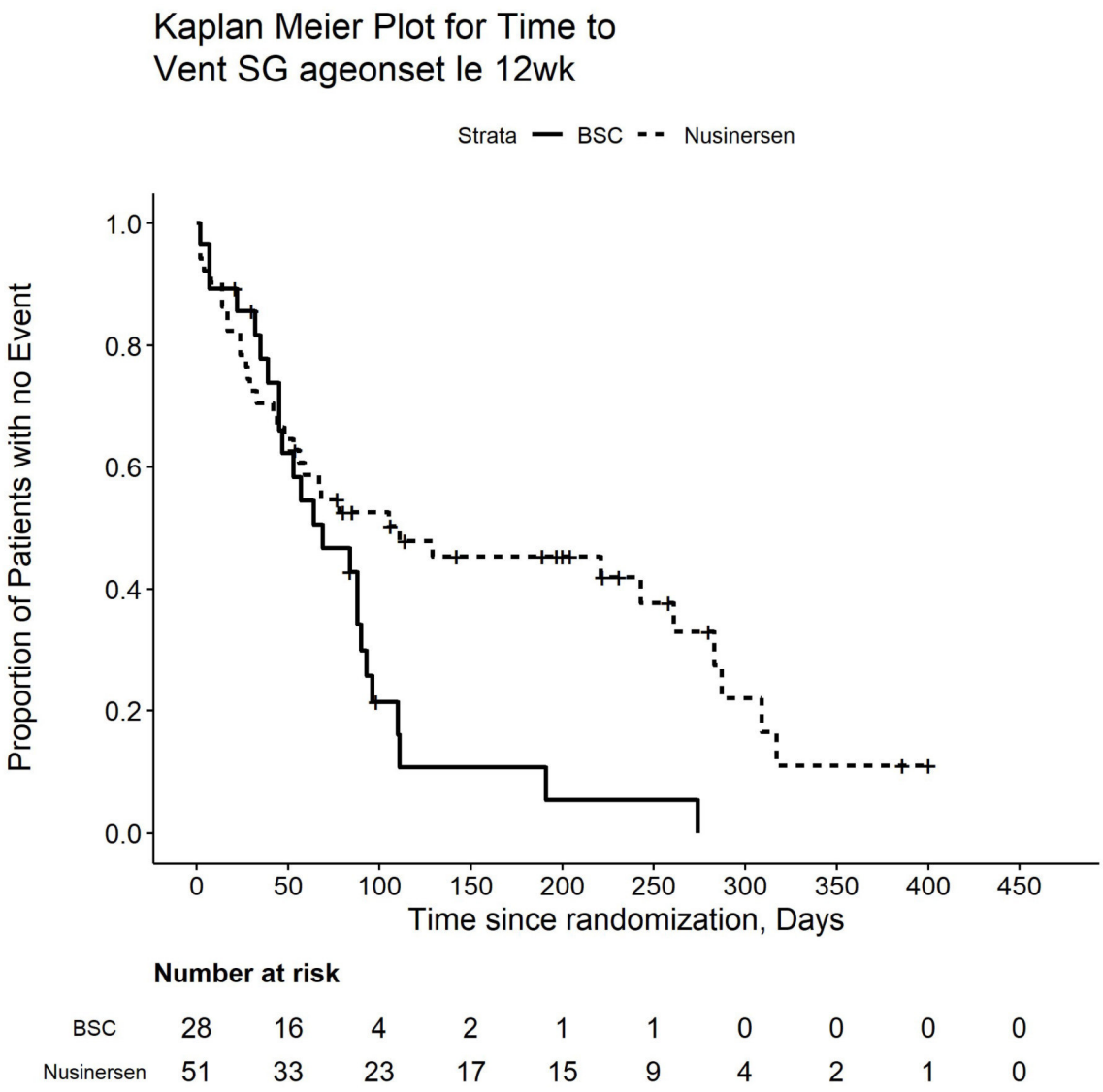
Number at risk

BSC	35	20	7	3	2	2	1	1	0	0
Nusinersen	59	36	26	20	17	11	6	3	2	0



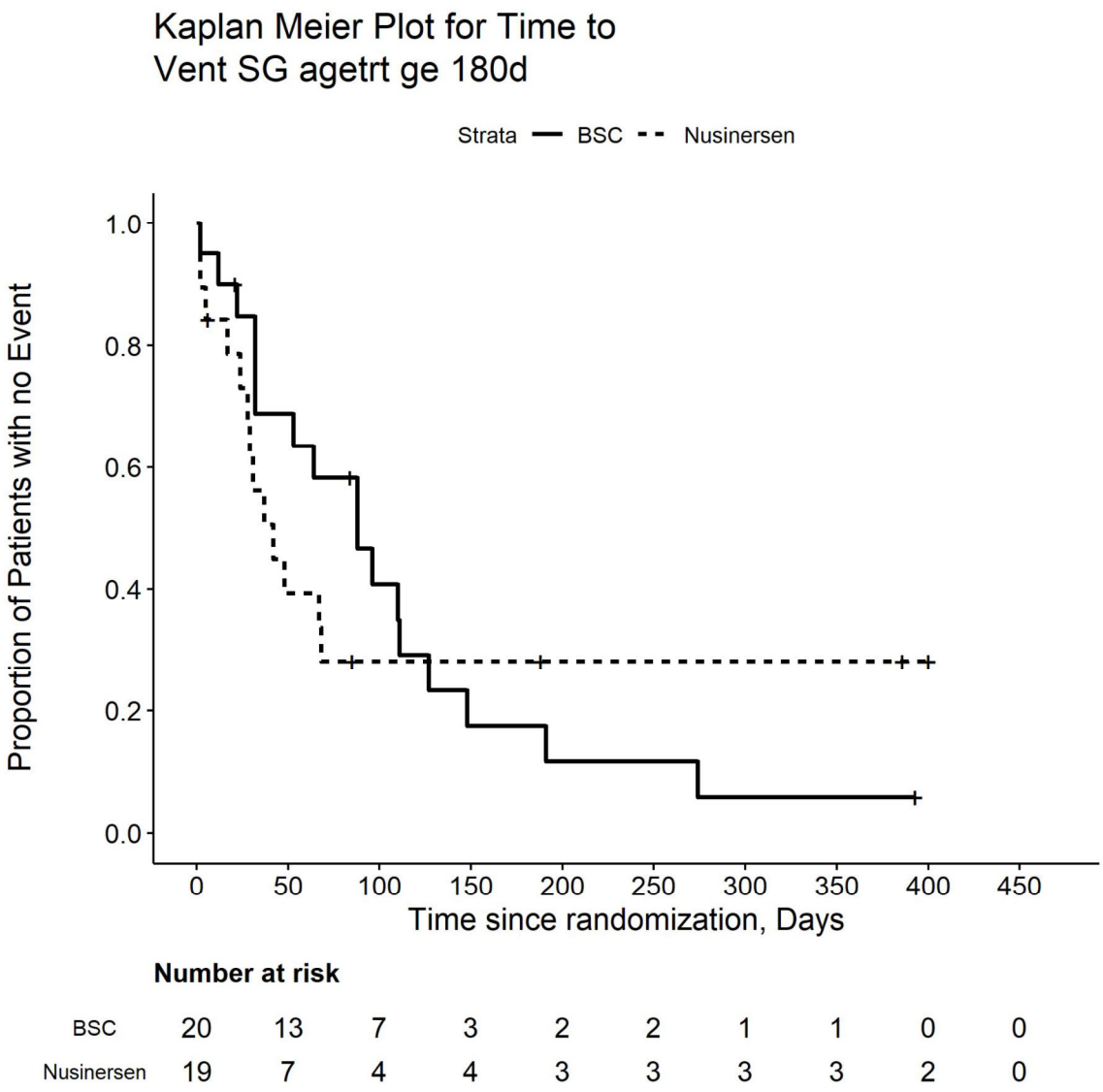
Number at risk

BSC	7	4	3	1	1	1	1	1	0	0
Nusinersen	8	3	3	3	2	2	2	1	1	0



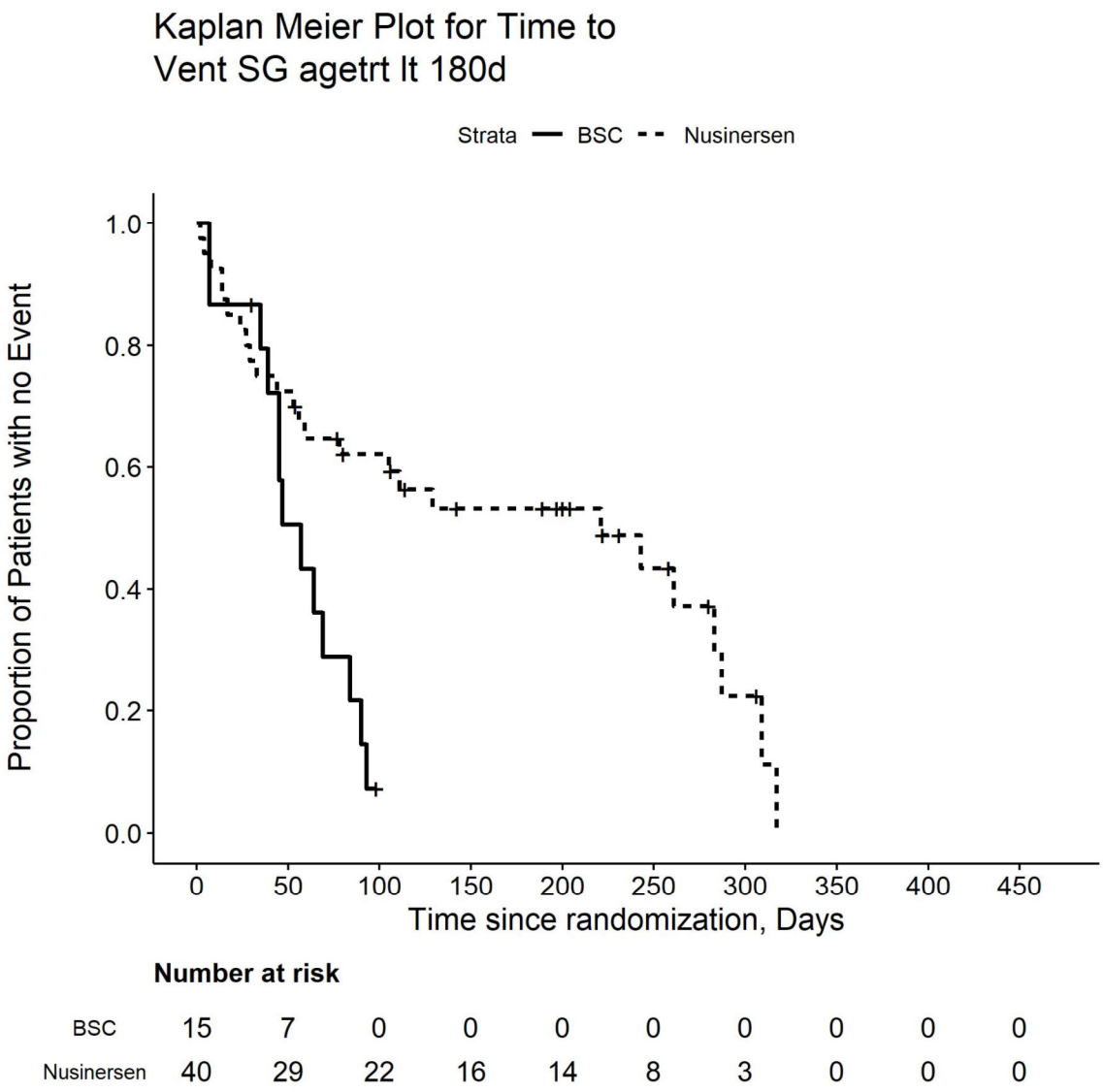
Number at risk

BSC	28	16	4	2	1	1	0	0	0	0
Nusinersen	51	33	23	17	15	9	4	2	1	0



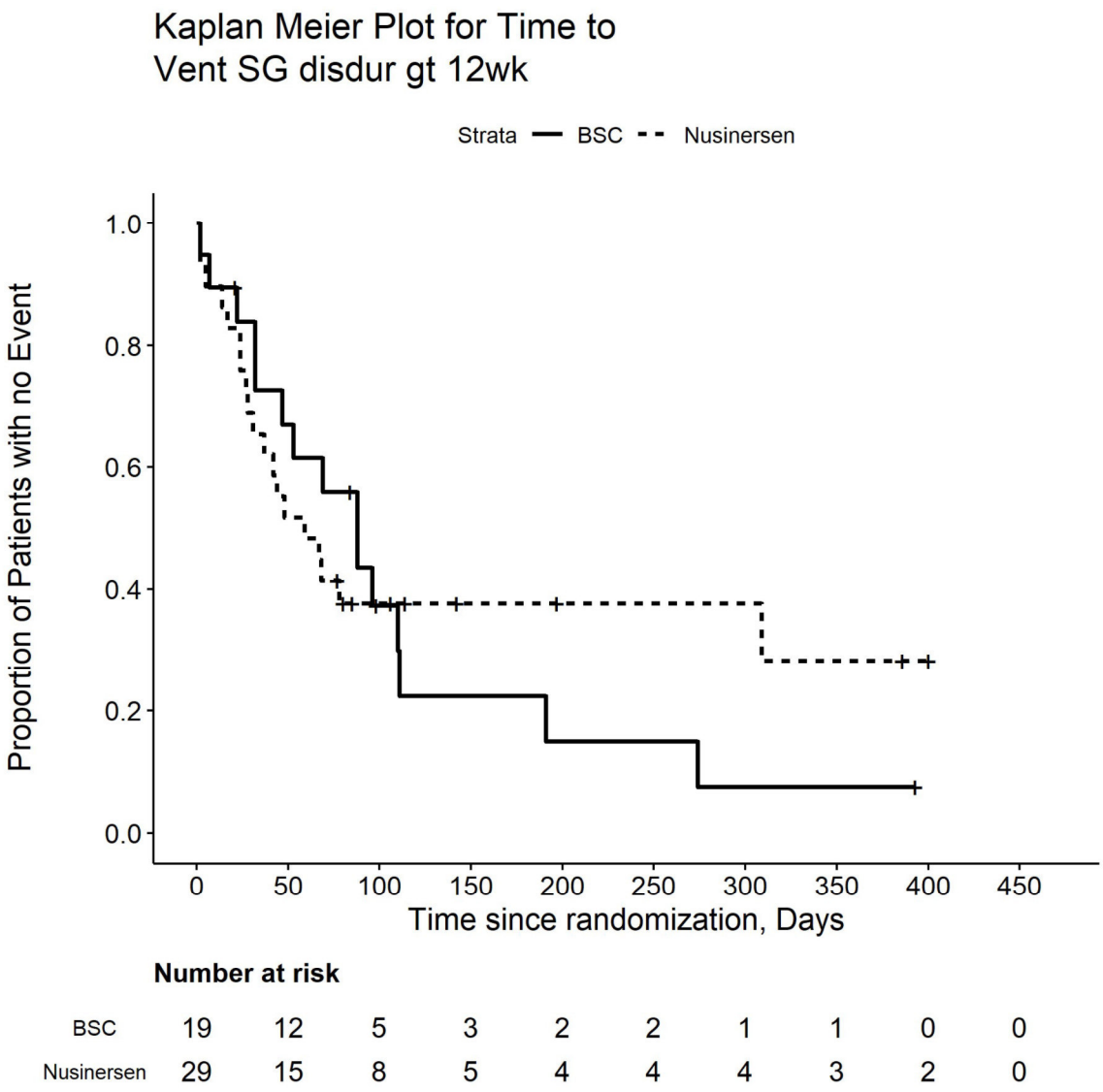
Number at risk

BSC	20	13	7	3	2	2	1	1	0	0
Nusinersen	19	7	4	4	3	3	3	3	2	0



Number at risk

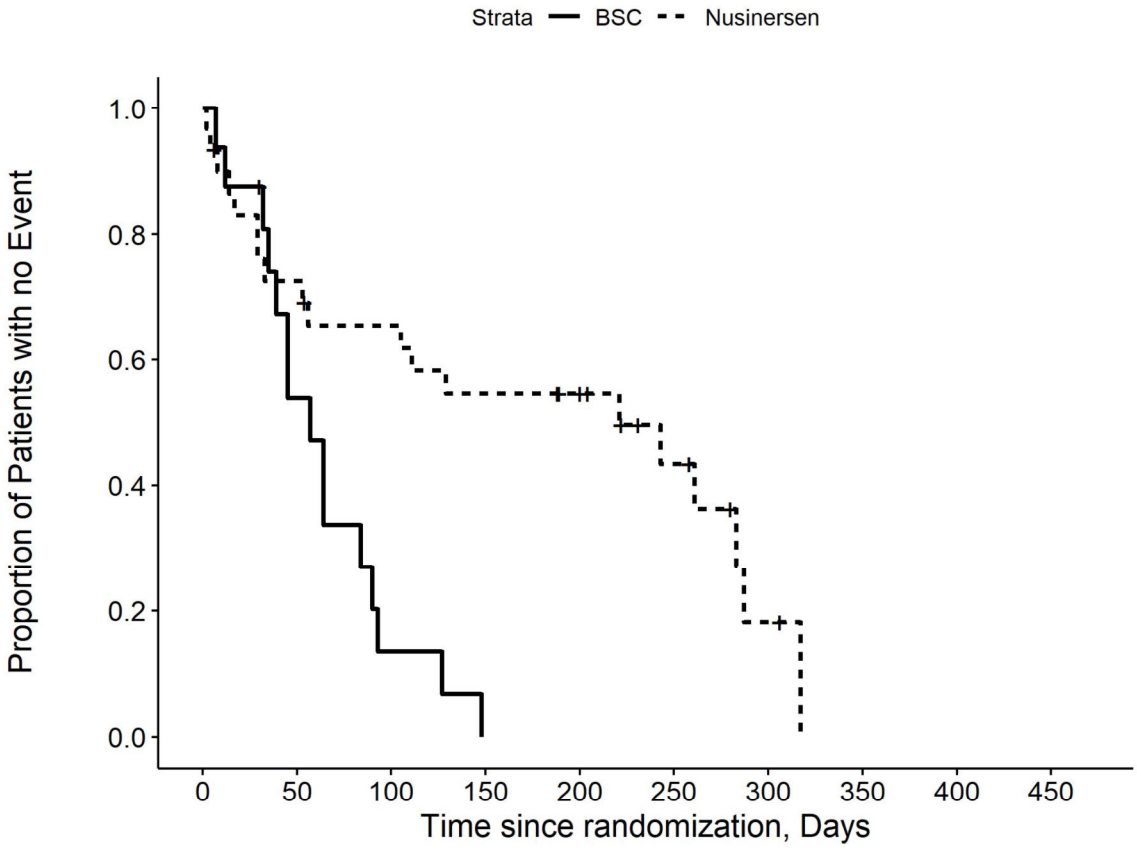
BSC	15	7	0	0	0	0	0	0	0	0
Nusinersen	40	29	22	16	14	8	3	0	0	0



Number at risk

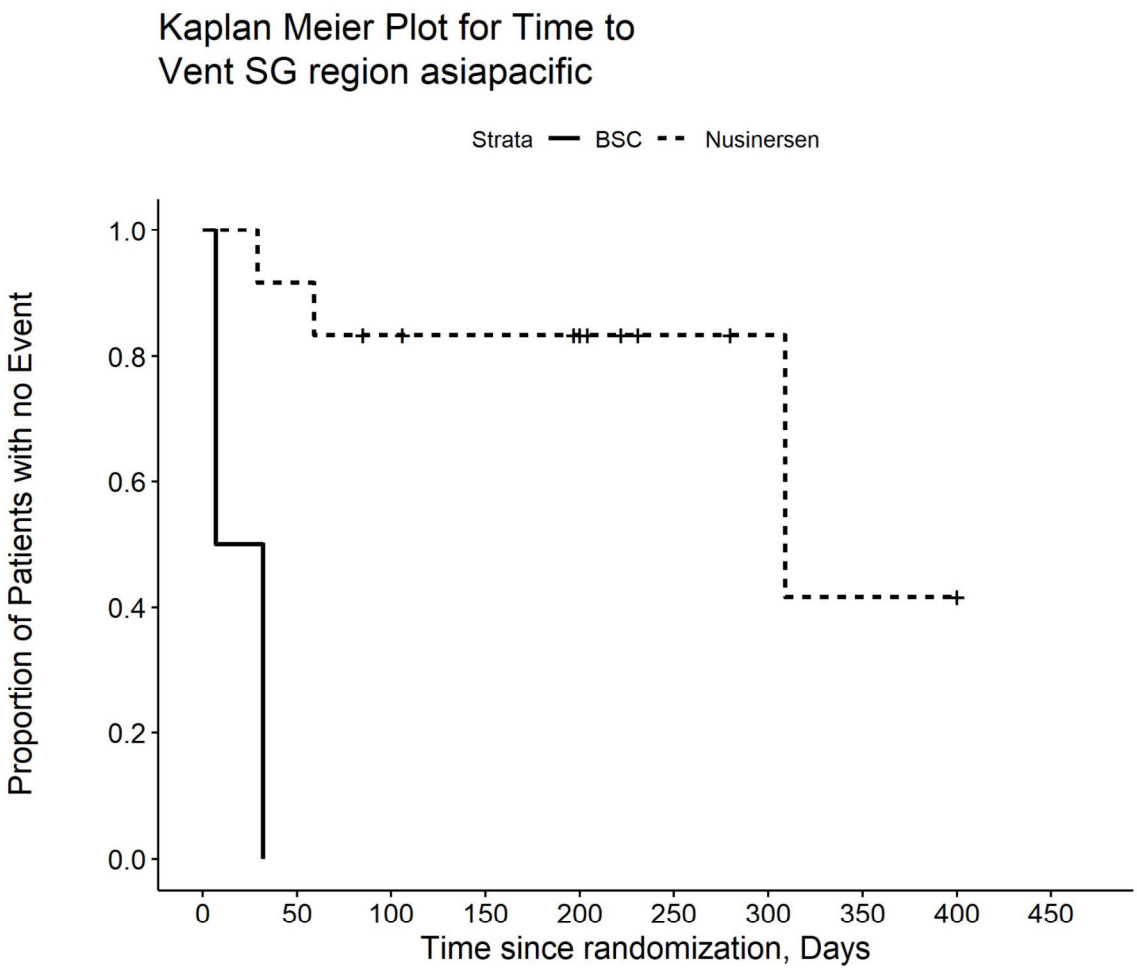
BSC	19	12	5	3	2	2	1	1	0	0
Nusinersen	29	15	8	5	4	4	4	3	2	0

Kaplan Meier Plot for Time to
Vent SG disdur le 12wek



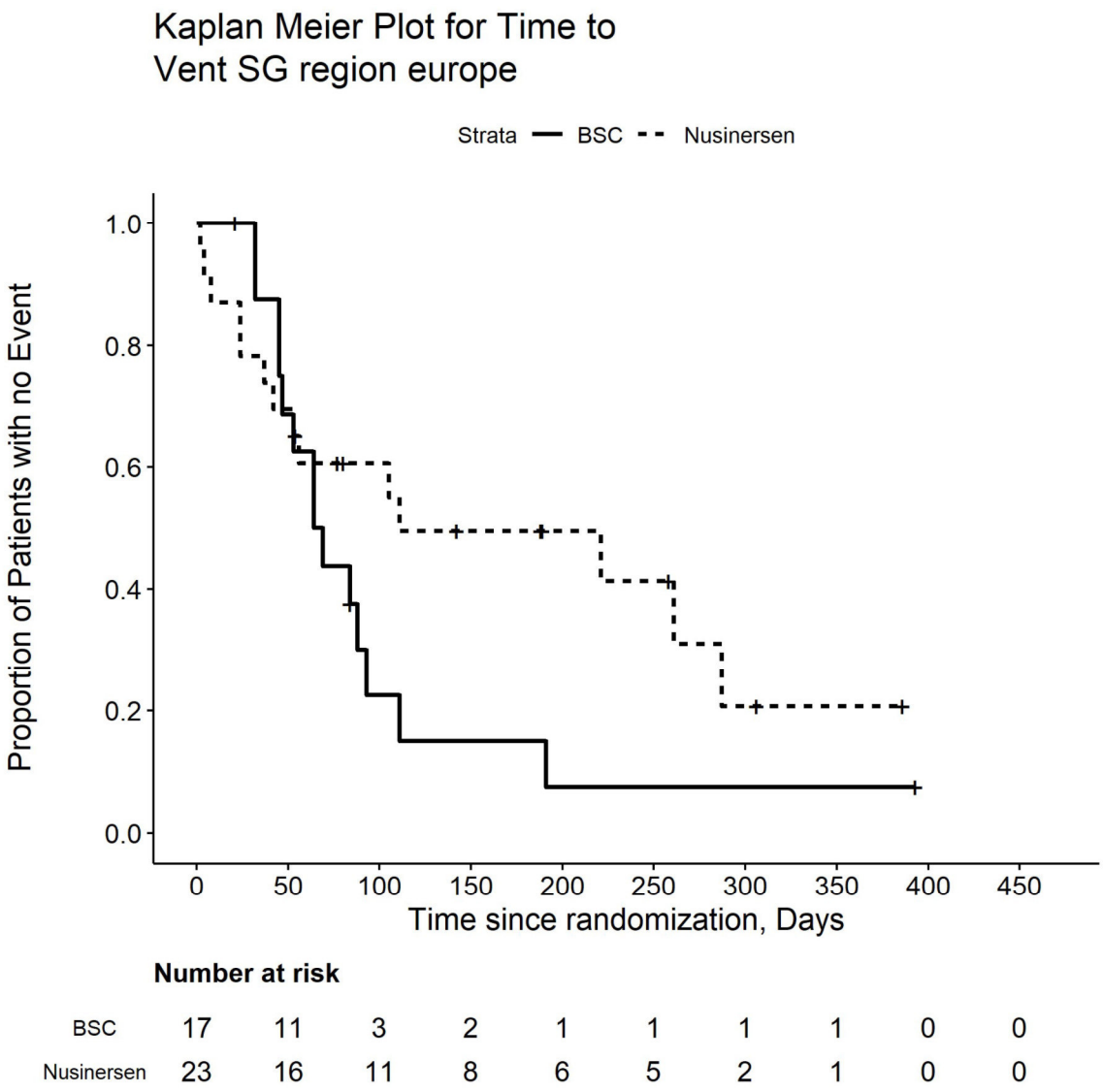
Number at risk

BSC	16	8	2	0	0	0	0	0	0	0
Nusinersen	30	21	18	15	13	7	2	0	0	0



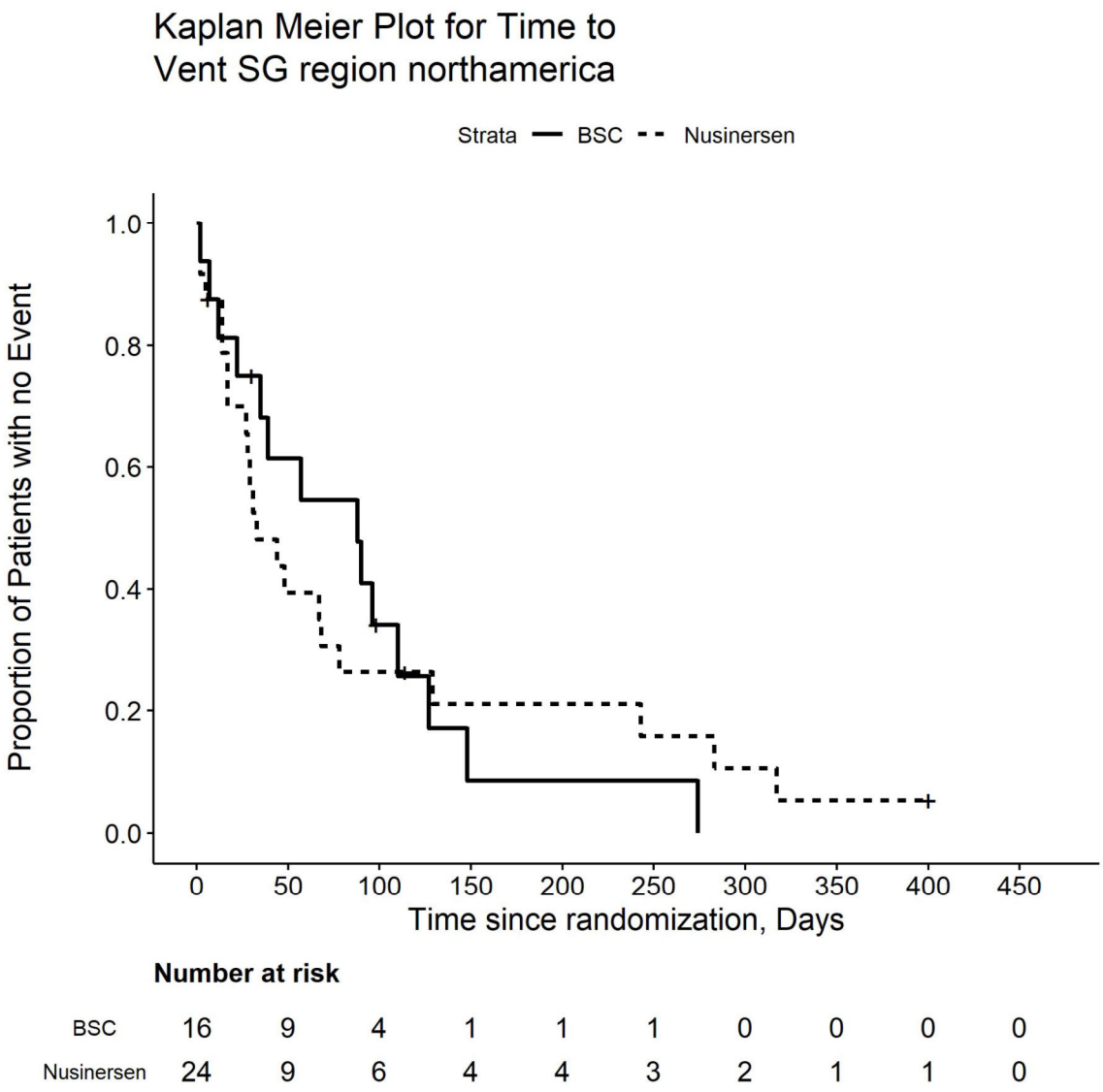
Number at risk

BSC	2	0	0	0	0	0	0	0	0	0
Nusinersen	12	11	9	8	7	3	2	1	1	0



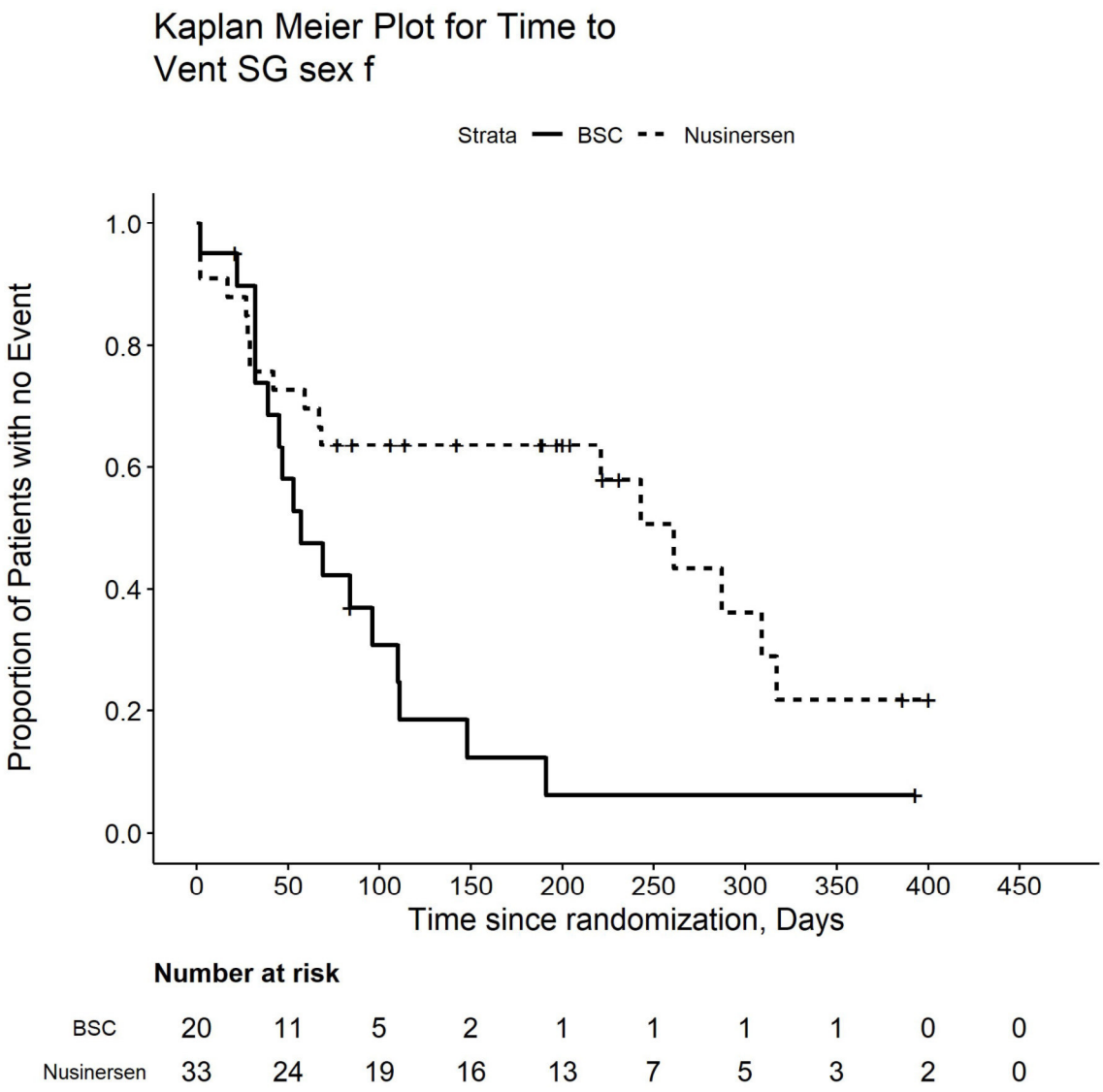
Number at risk

BSC	17	11	3	2	1	1	1	1	0	0
Nusinersen	23	16	11	8	6	5	2	1	0	0



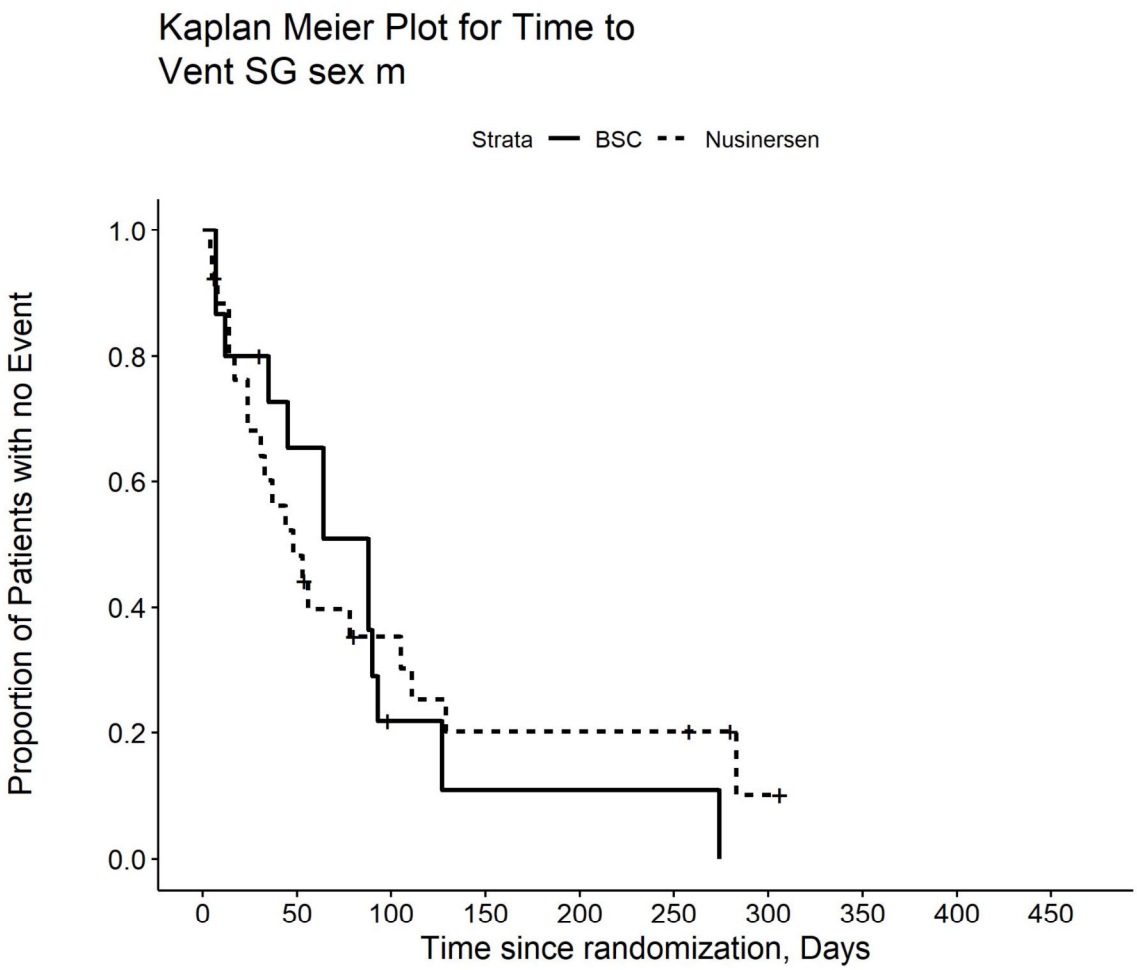
Number at risk

BSC	16	9	4	1	1	1	0	0	0	0
Nusinersen	24	9	6	4	4	3	2	1	1	0



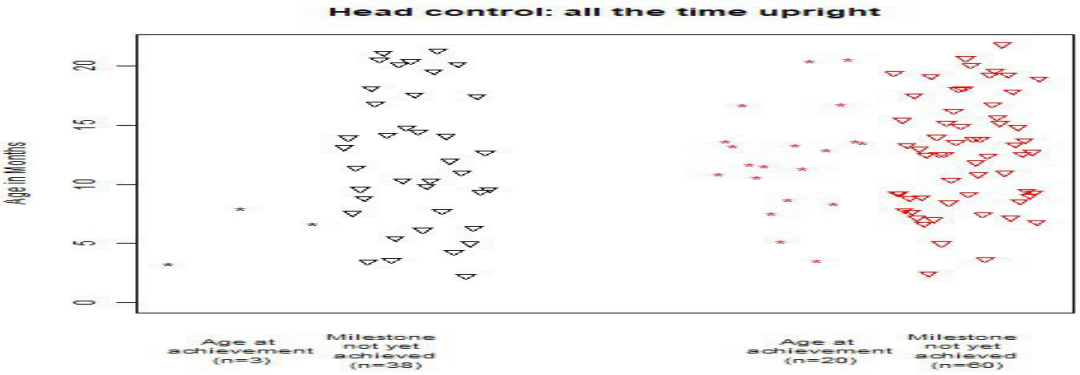
Number at risk

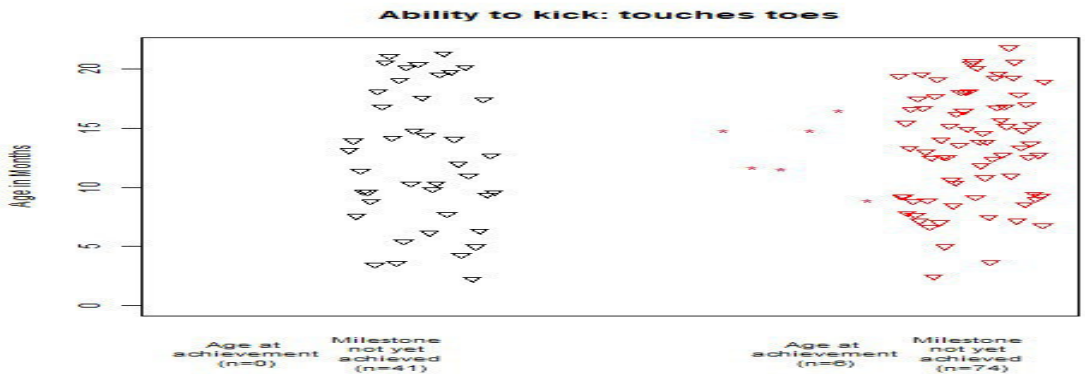
BSC	20	11	5	2	1	1	1	1	0	0
Nusinersen	33	24	19	16	13	7	5	3	2	0

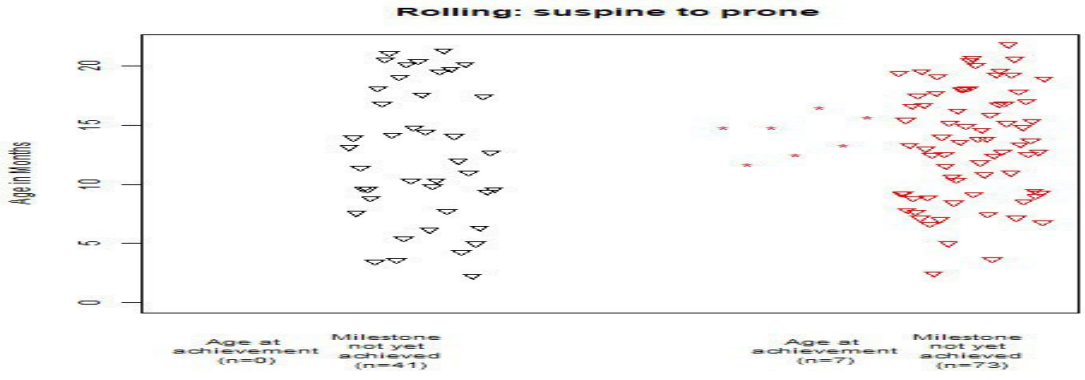


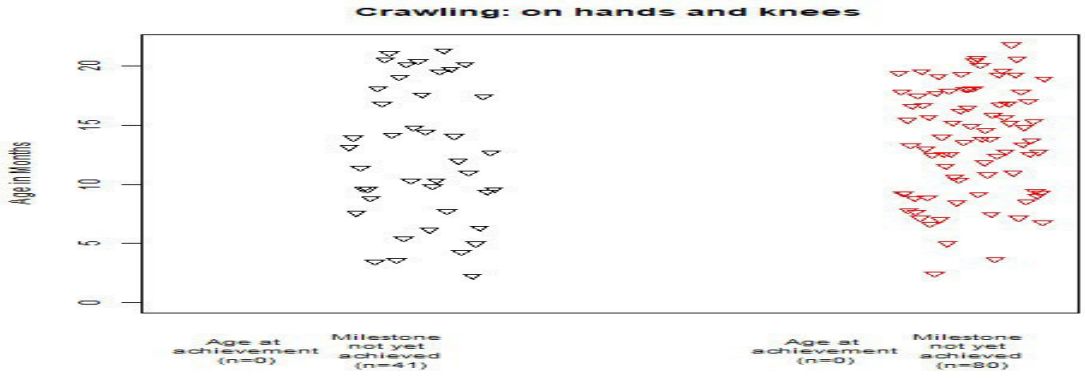
Number at risk

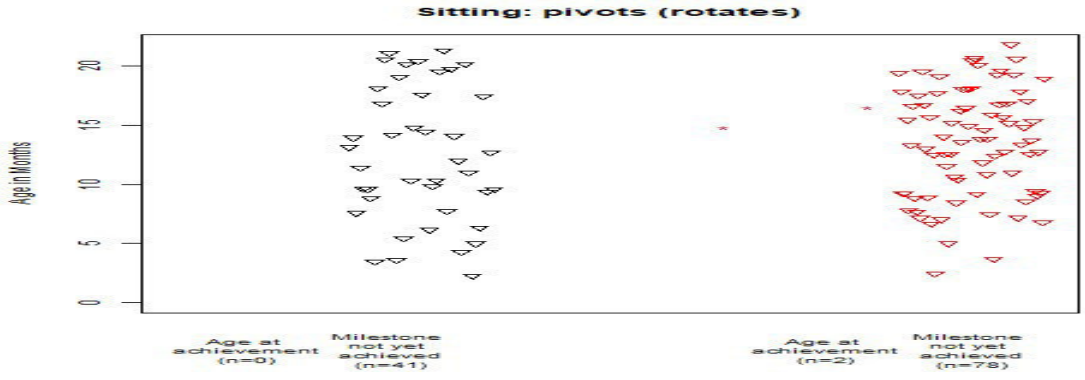
BSC	15	9	2	1	1	1	0	0	0	0
Nusinersen	26	12	7	4	4	4	1	0	0	0

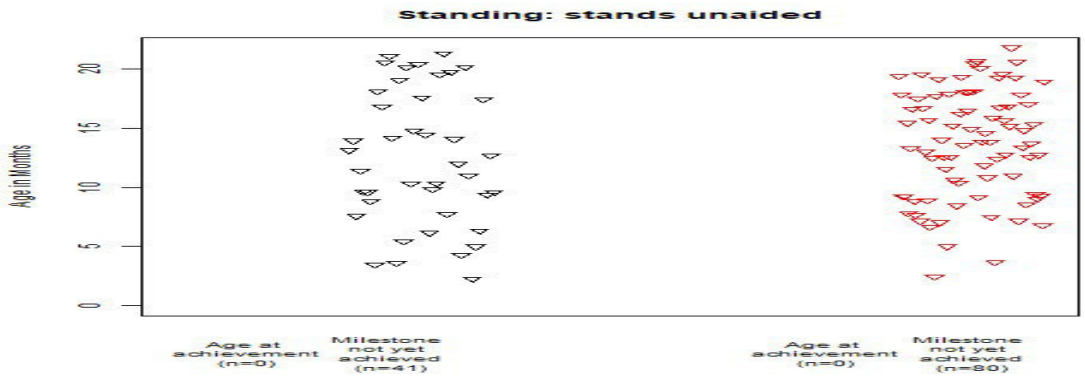


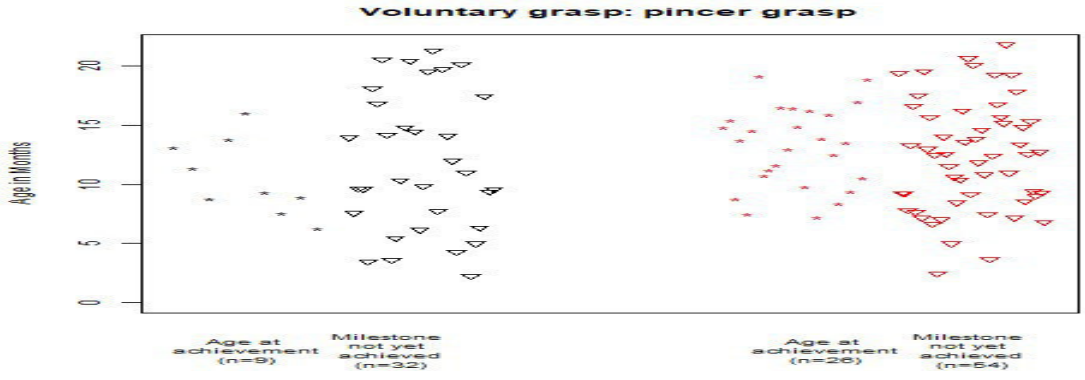

Ability to kick: touches toes
Age in Months
0
5
10
15
20
Age at achievement (n=0)
Milestone not yet achieved (n=41)
Age at achievement (n=6)
Milestone not yet achieved (n=74)

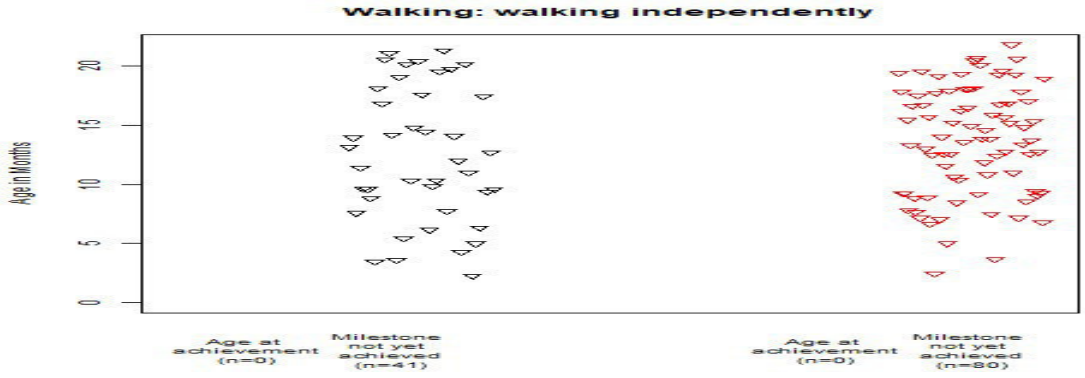

Rolling: suspine to prone
Age in Months
0
5
10
15
20
Age at achievement (n=0)
Milestone not yet achieved (n=41)
Age at achievement (n=7)
Milestone not yet achieved (n=73)

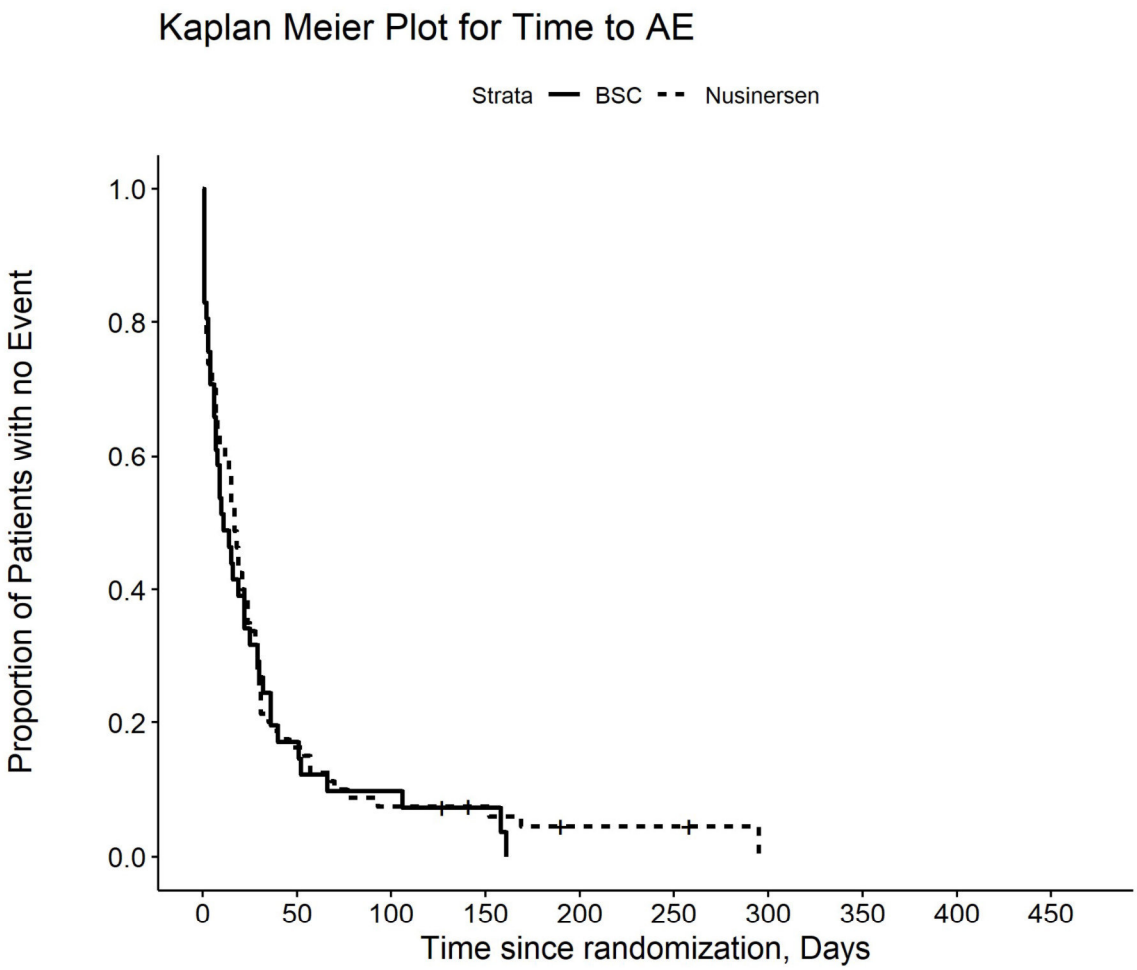

Crawling: on hands and knees
Age in Months
0
5
10
15
20
Age at achievement (n=0)
Milestone not yet achieved (n=41)
Age at achievement (n=0)
Milestone not yet achieved (n=80)


Sitting: pivots (rotates)
Age in Months
0
5
10
15
20
Age at achievement (n=0)
Milestone not yet achieved (n=41)
Age at achievement (n=2)
Milestone not yet achieved (n=78)


Standing: stands unaided
Age in Months
0
5
10
15
20
Age at achievement (n=0)
Milestone not yet achieved (n=41)
Age at achievement (n=0)
Milestone not yet achieved (n=80)


Voluntary grasp: pincer grasp
Age in Months
0
5
10
15
20
Age at achievement (n=9)
Milestone not yet achieved (n=32)
Age at achievement (n=26)
Milestone not yet achieved (n=64)

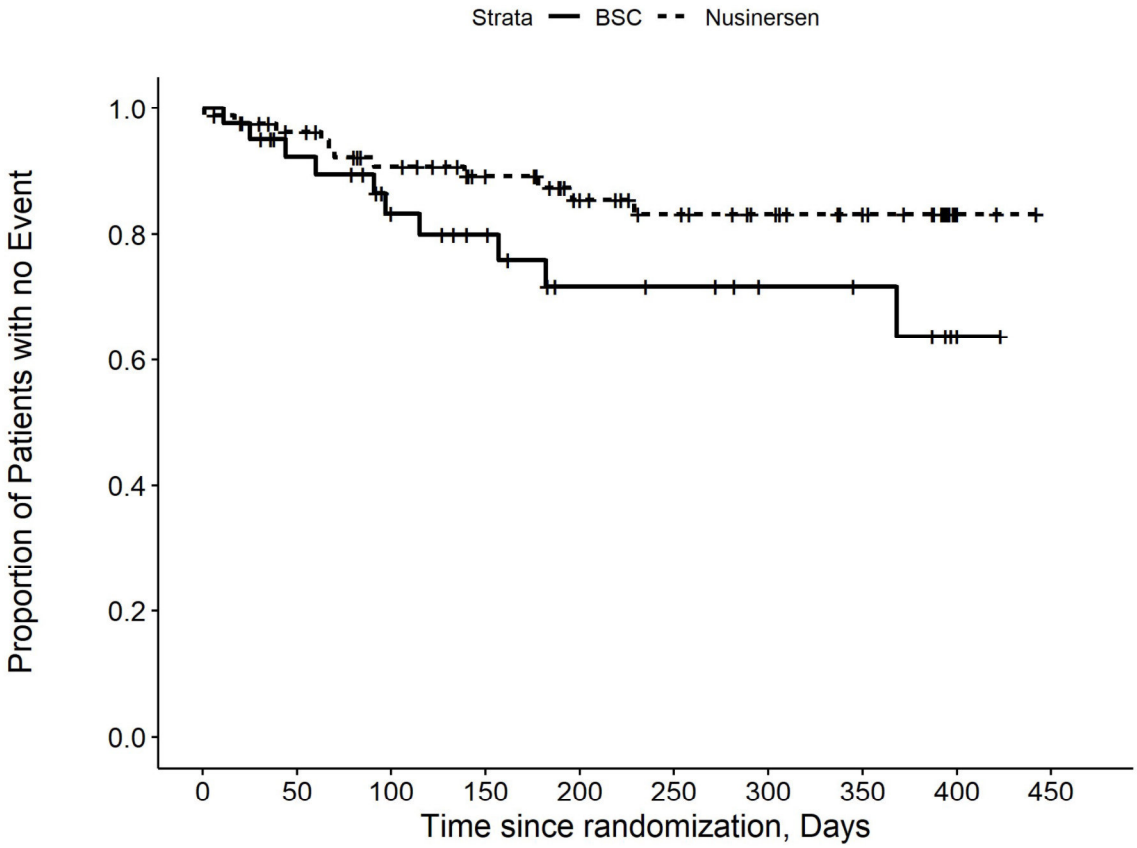

Walking: walking independently
Age in Months
0
5
10
15
20
Age at achievement (n=0)
Milestone not yet achieved (n=41)
Age at achievement (n=0)
Milestone not yet achieved (n=80)



Number at risk

BSC	41	7	4	2	0	0	0	0	0	0
Nusinersen	80	13	6	5	2	2	0	0	0	0

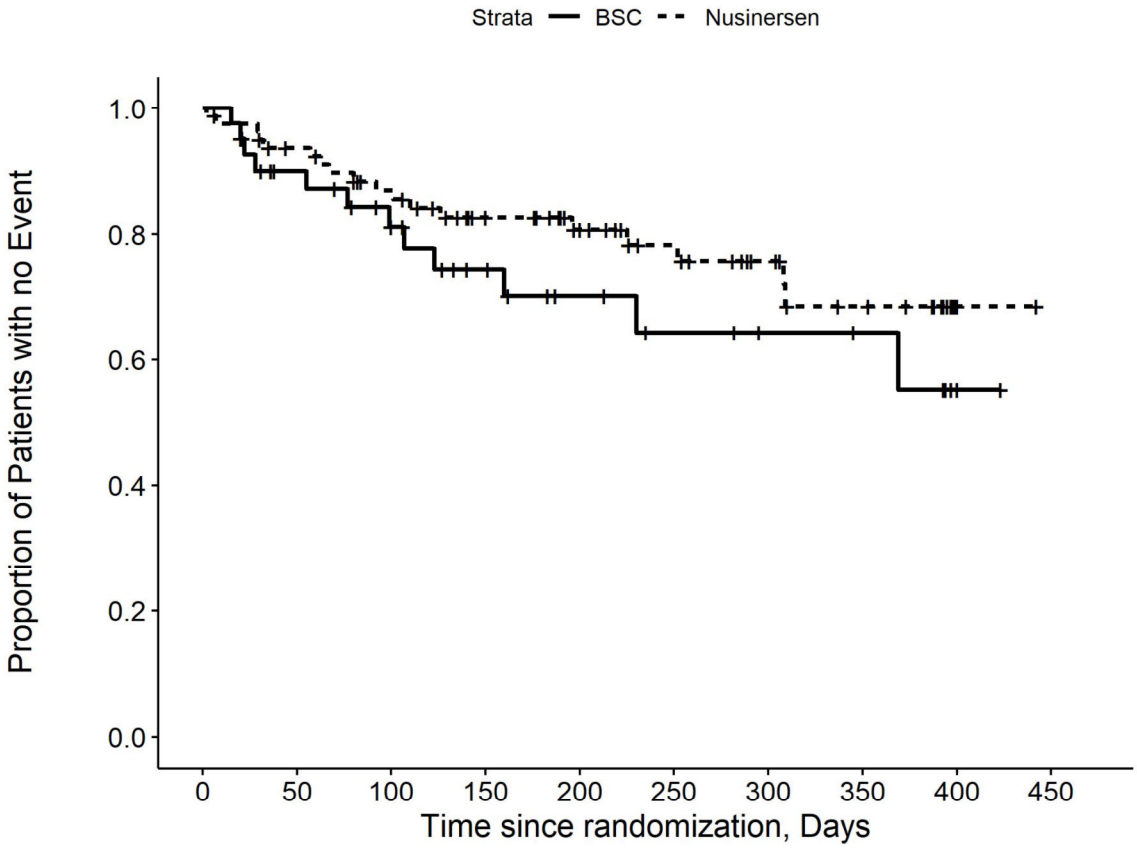
Kaplan Meier Plot for Time to AE by PT pct
Acute respiratory failure



Number at risk

BSC	41	33	26	21	14	13	10	9	3	0
Nusinersen	80	73	64	54	42	34	29	24	8	0

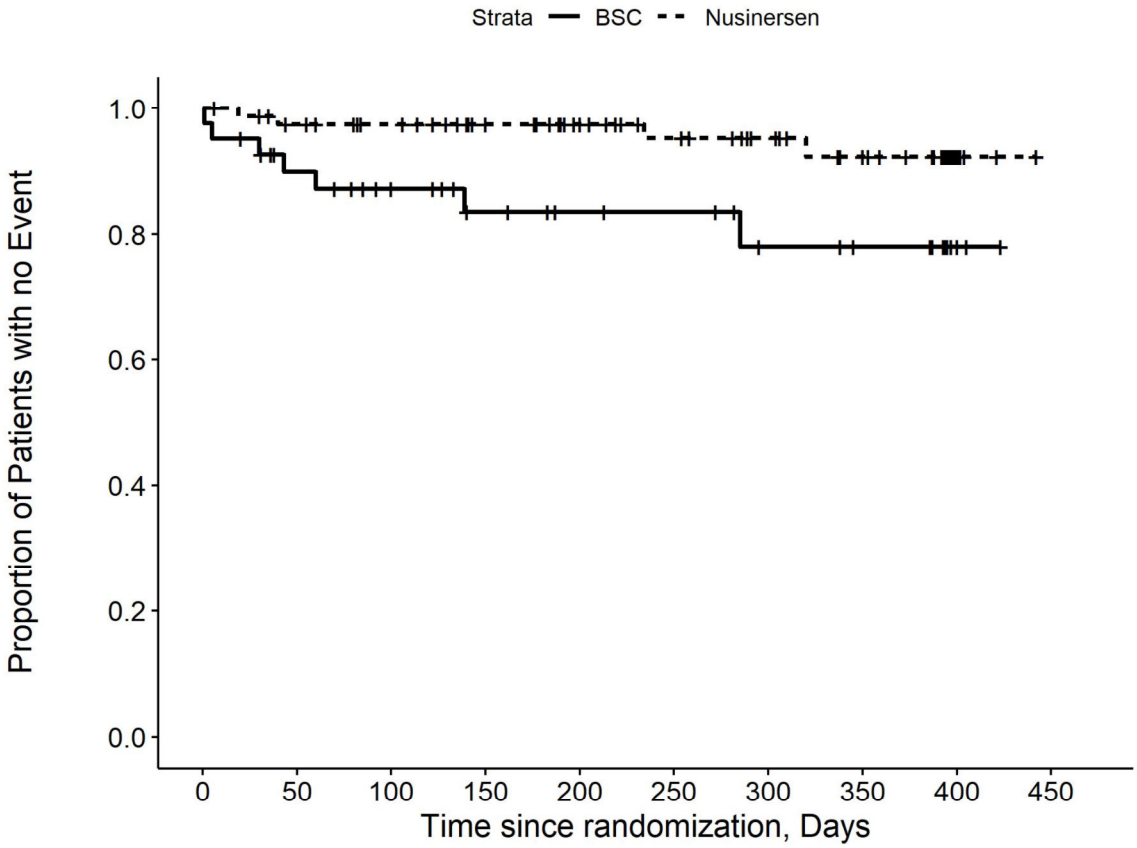
Kaplan Meier Plot for Time to AE by PT pct Atelectasis



Number at risk

BSC	41	32	26	19	13	10	8	7	2	0
Nusinersen	80	71	62	50	39	31	23	17	4	0

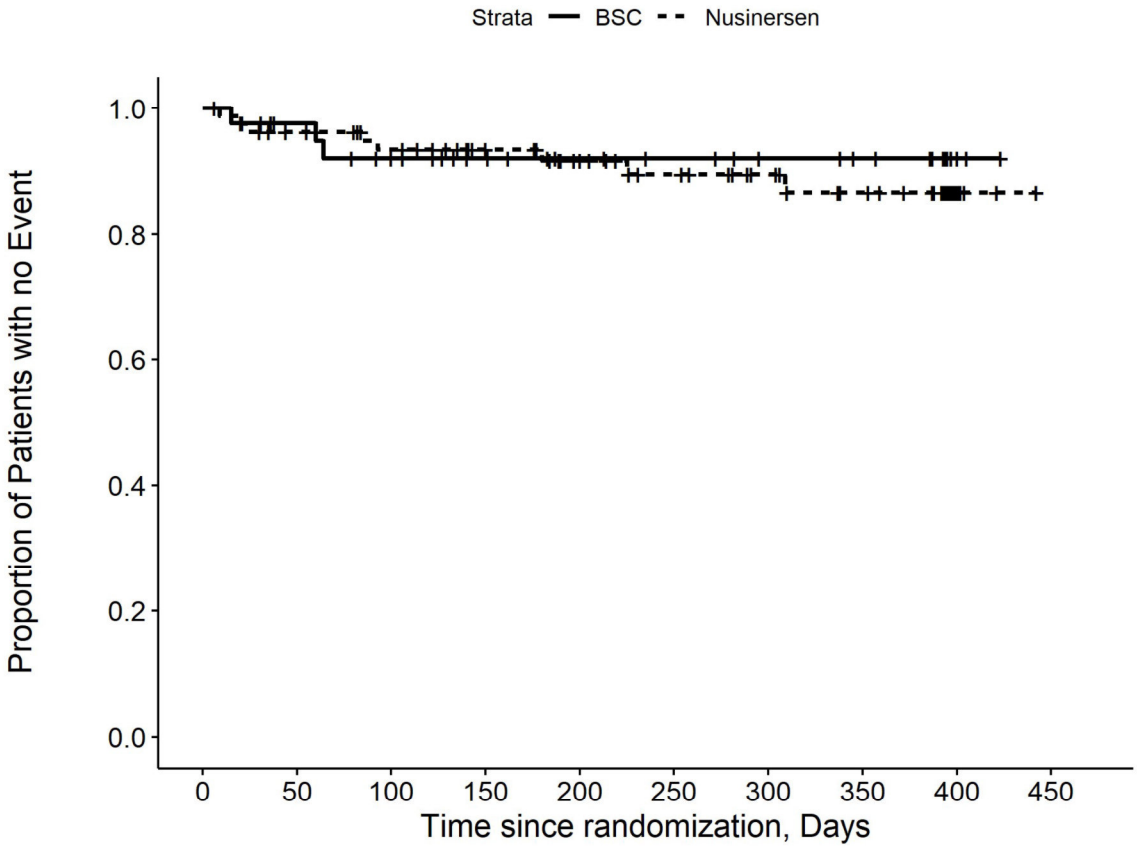
Kaplan Meier Plot for Time to AE by PT pct
Bronchial secretion retention



Number at risk

BSC	41	33	28	22	18	17	13	11	4	0
Nusinersen	80	74	69	60	50	42	35	29	10	0

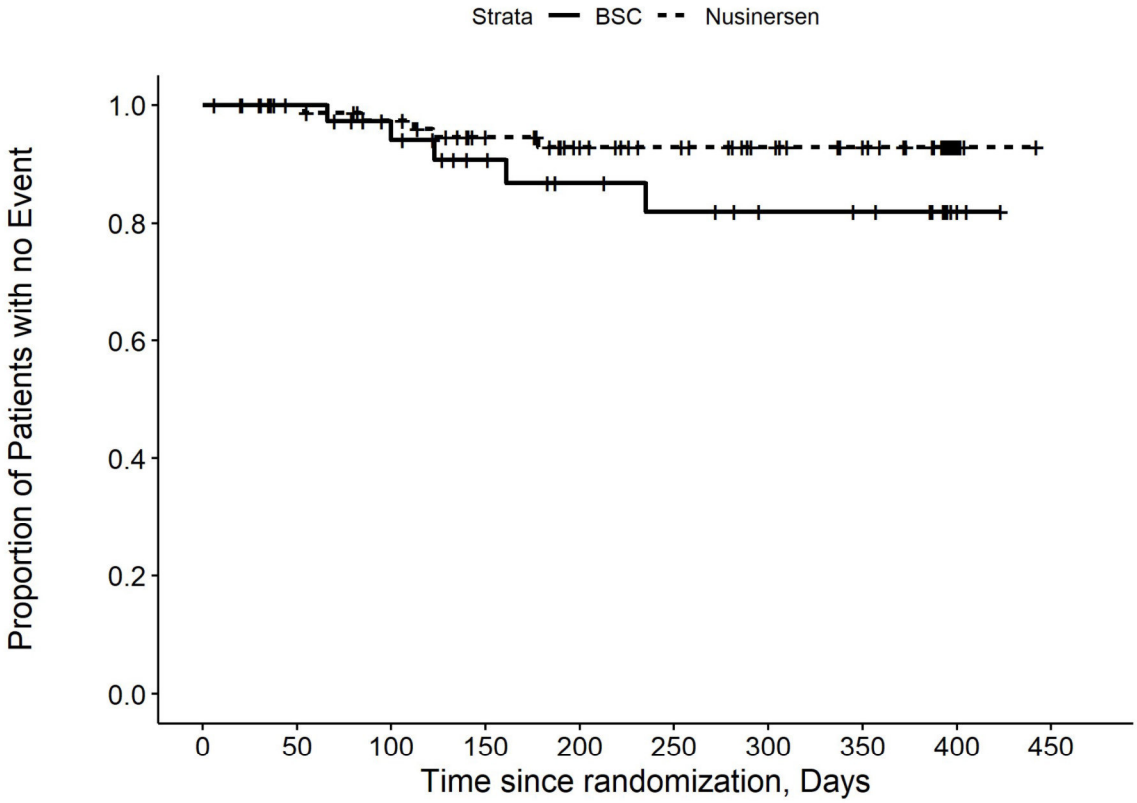
Kaplan Meier Plot for Time to AE by PT pct
Bronchiolitis



Number at risk

BSC	41	35	31	25	20	18	15	13	4	0
Nusinersen	80	73	66	57	47	40	33	27	10	0

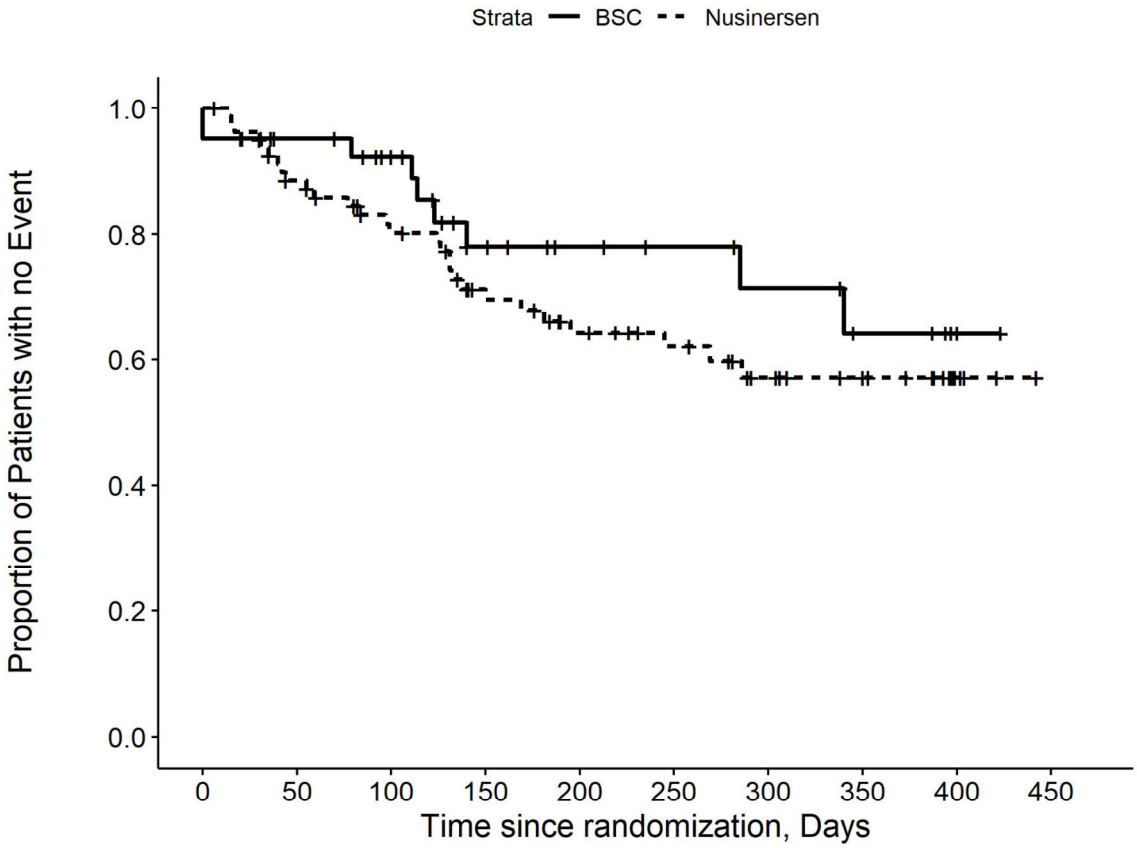
Kaplan Meier Plot for
Time to AE by PT pct
Cardio : respiratory arrest



Number at risk

BSC	41	36	31	24	19	17	14	13	4	0
Nusinersen	80	76	71	61	50	43	35	30	10	0

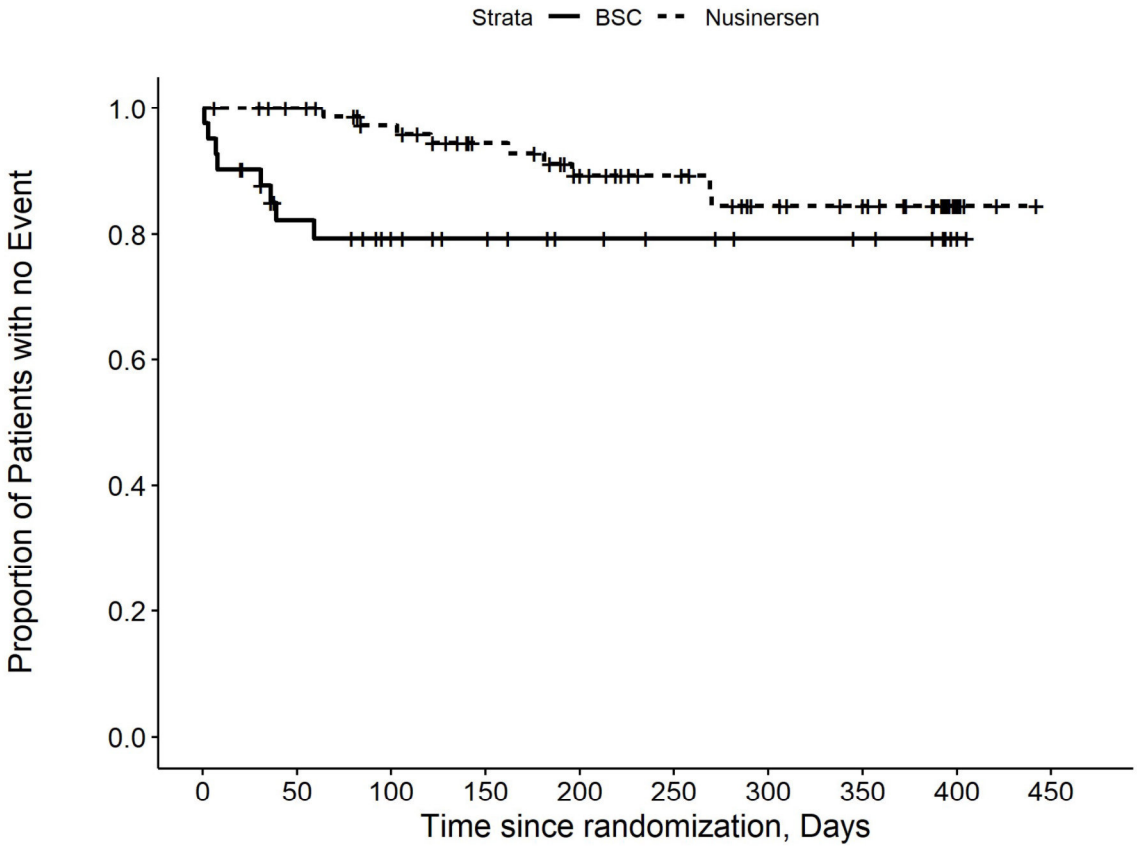
Kaplan Meier Plot for Time to AE by PT pct
Constipation



Number at risk

BSC	41	34	29	19	15	13	11	8	3	0
Nusinersen	80	67	56	43	34	28	20	16	4	0

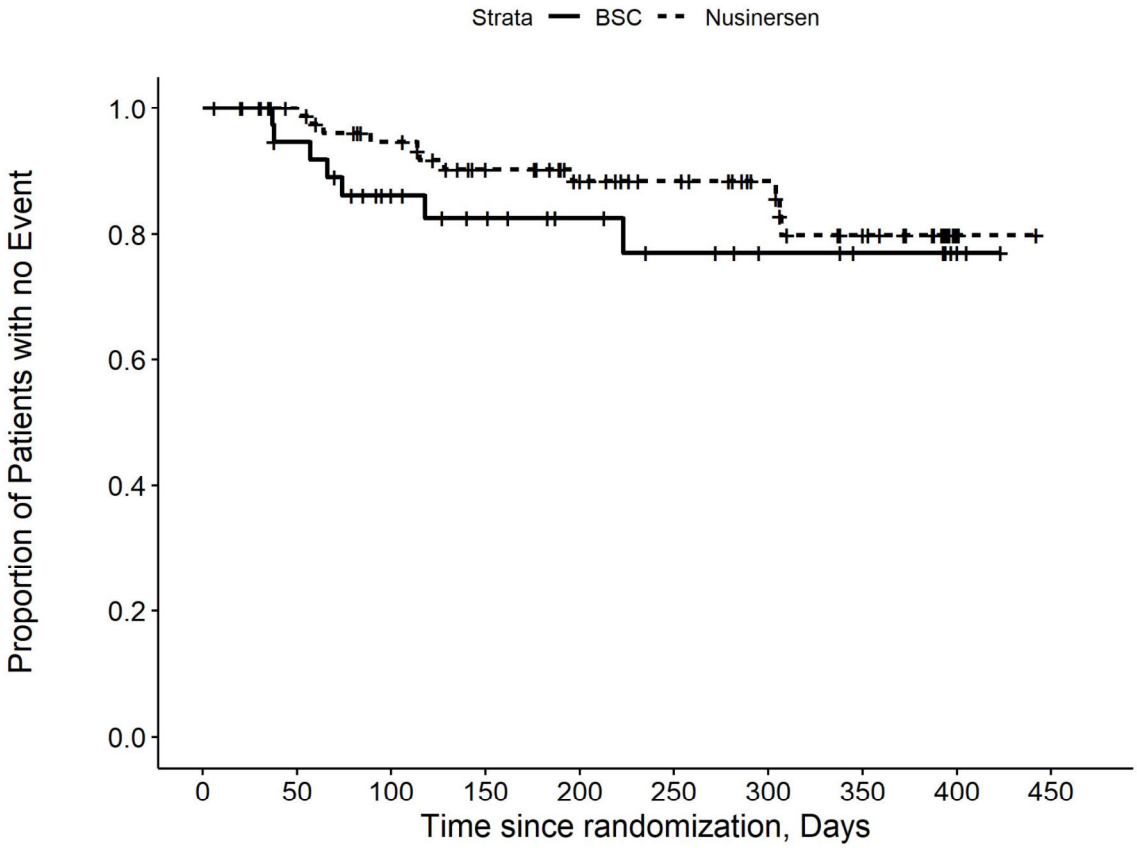
Kaplan Meier Plot for Time to AE by PT pct Cough



Number at risk

BSC	41	29	24	20	15	13	11	10	3	0
Nusinersen	80	76	69	58	48	40	31	28	11	0

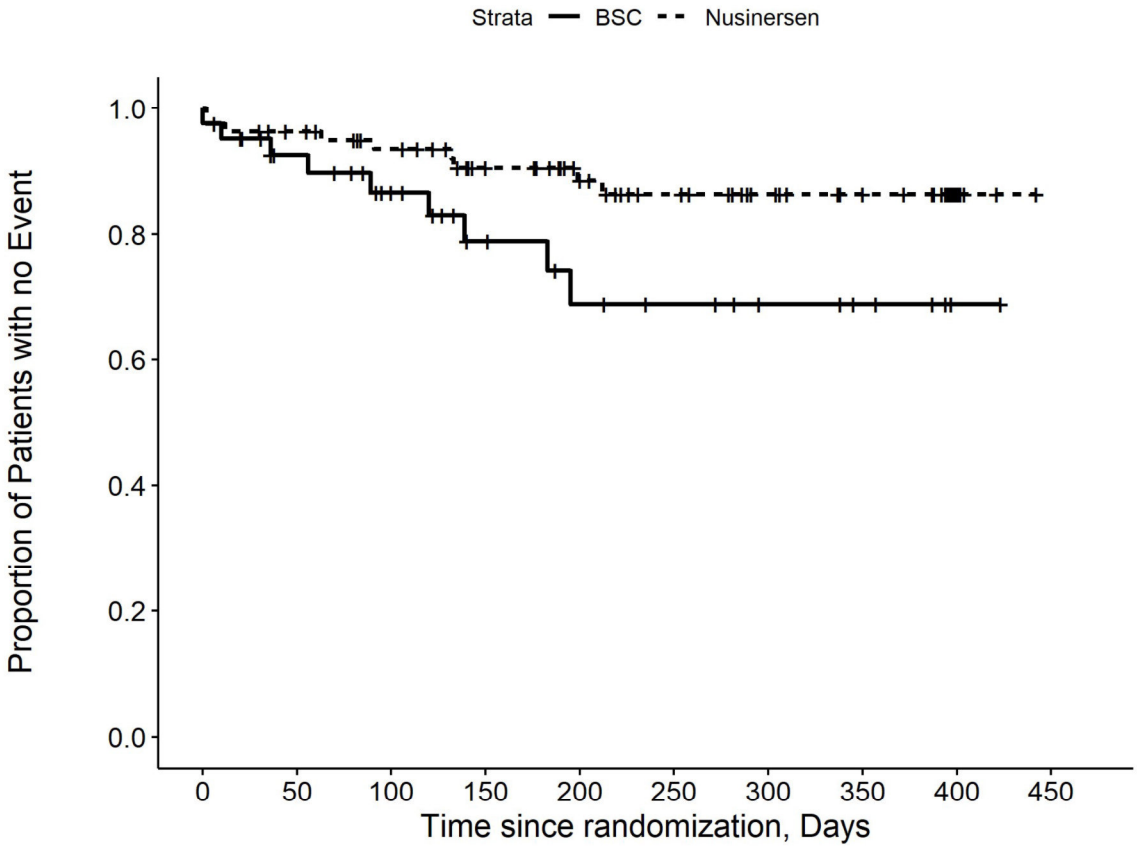
Kaplan Meier Plot for Time to AE by PT pct Diarrhoea



Number at risk

BSC	41	34	26	21	16	13	10	8	4	0
Nusinersen	80	76	67	57	47	39	32	24	6	0

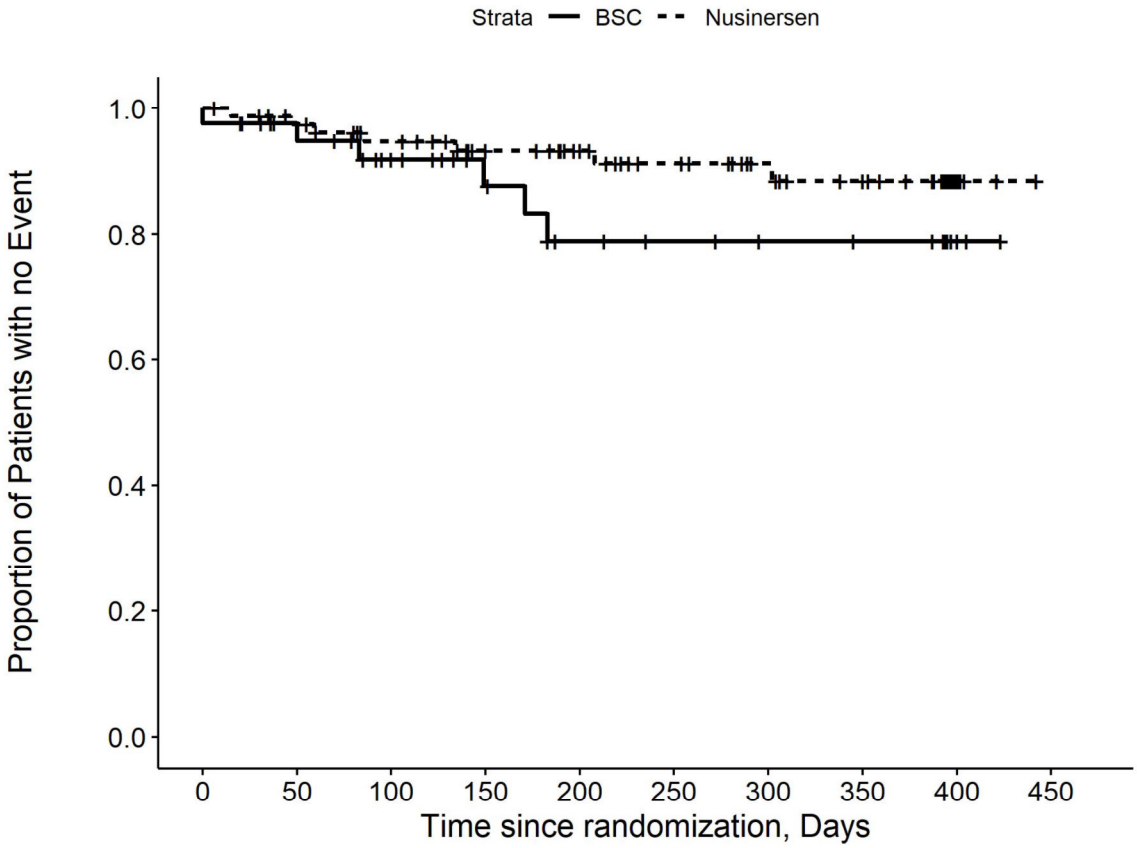
Kaplan Meier Plot for Time to AE by PT pct Dysphagia



Number at risk

BSC	41	33	26	18	13	11	8	6	1	0
Nusinersen	80	73	66	55	44	35	27	22	8	0

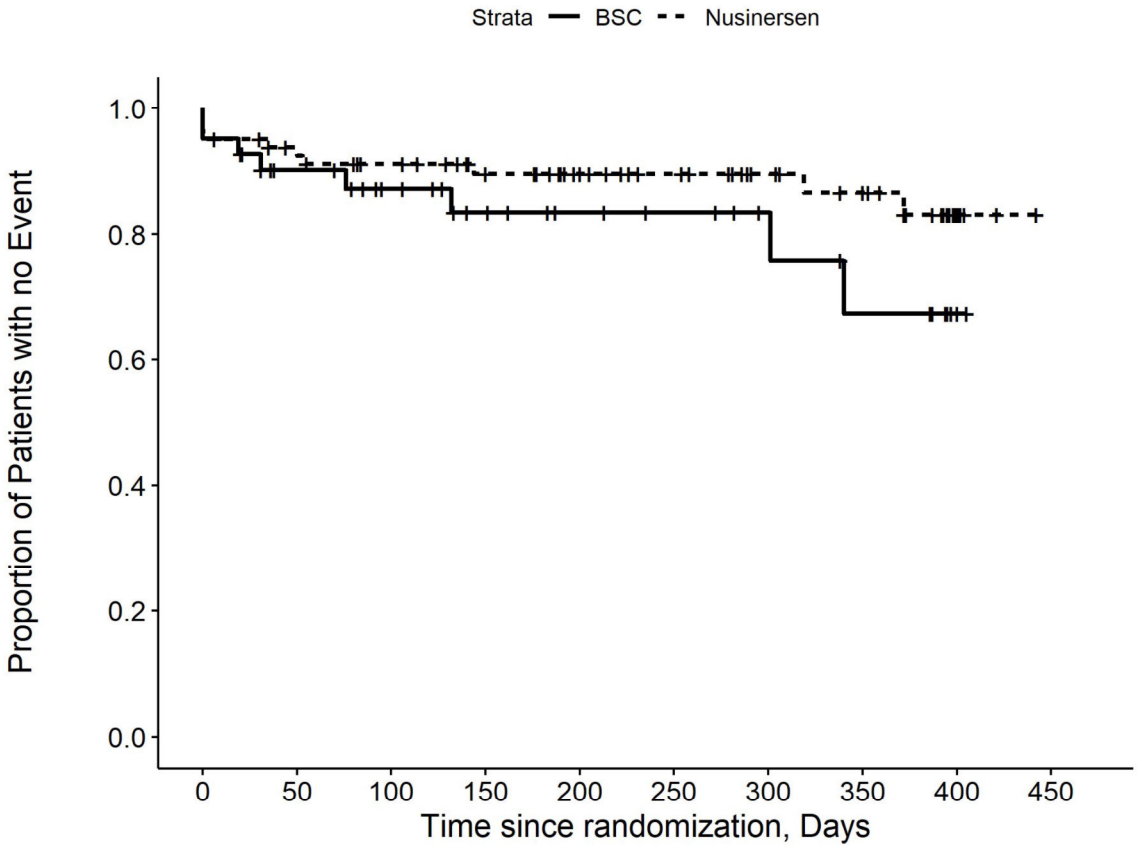
Kaplan Meier Plot for Time to AE by PT pct Dyspnoea



Number at risk

BSC	41	35	28	21	15	13	11	10	4	0
Nusinersen	80	74	67	57	49	41	33	28	11	0

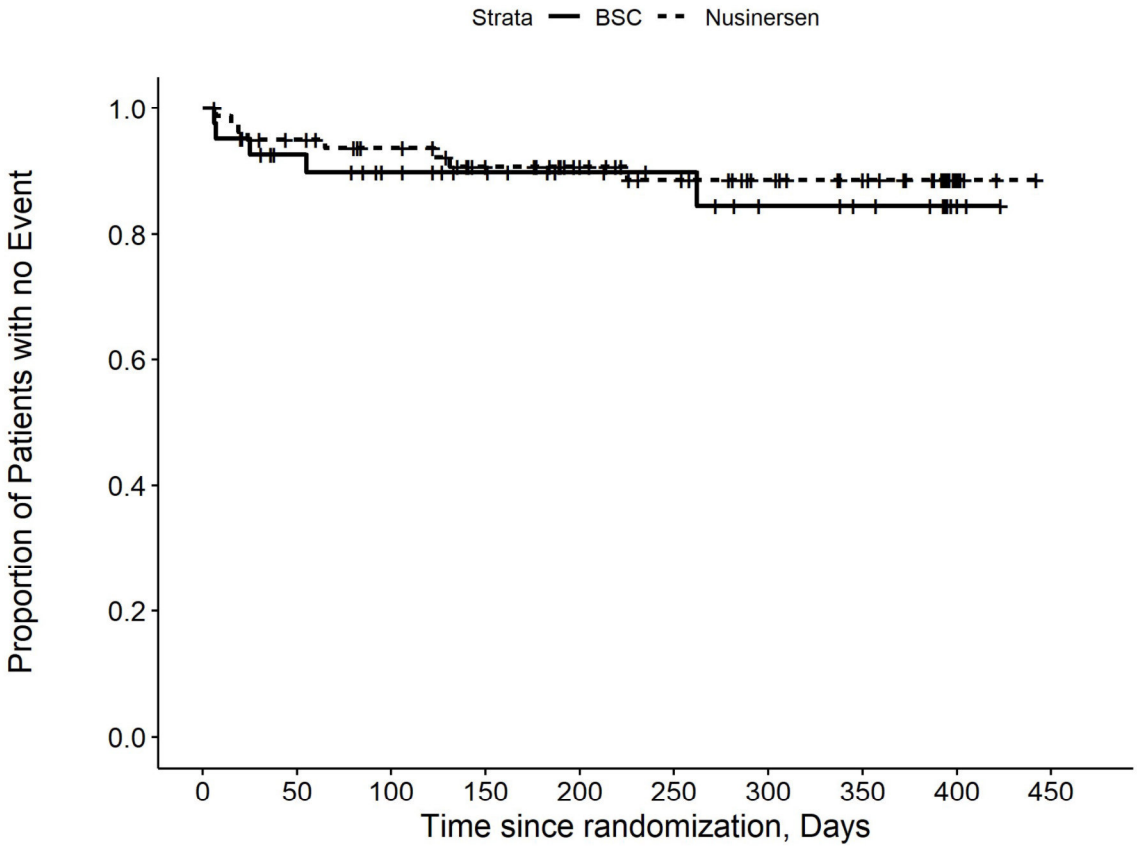
Kaplan Meier Plot for Time to AE by PT pct
Gastrooesophageal reflux disease



Number at risk

BSC	41	32	26	20	16	14	11	8	2	0
Nusinersen	80	71	65	57	47	40	32	28	11	0

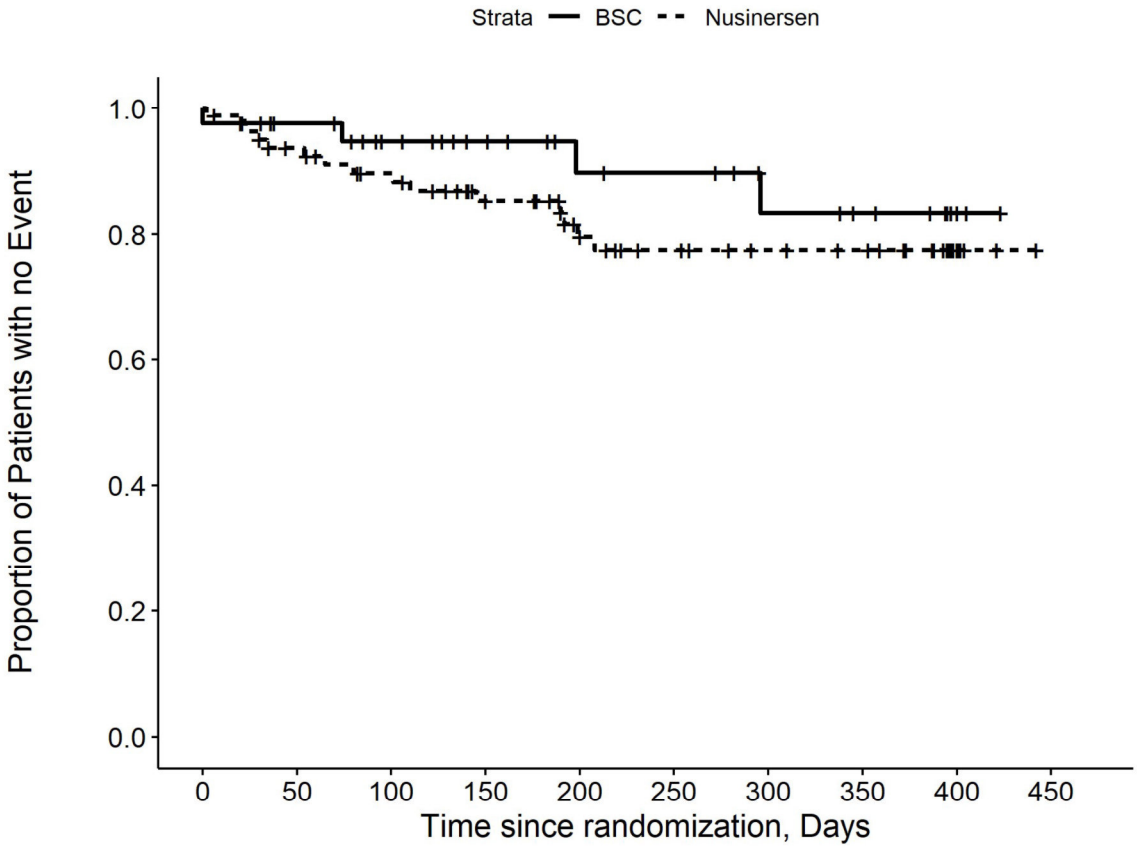
Kaplan Meier Plot for Time to AE by PT pct
Nasal congestion



Number at risk

BSC	41	33	28	24	19	17	13	11	3	0
Nusinersen	80	73	67	57	47	38	31	26	9	0

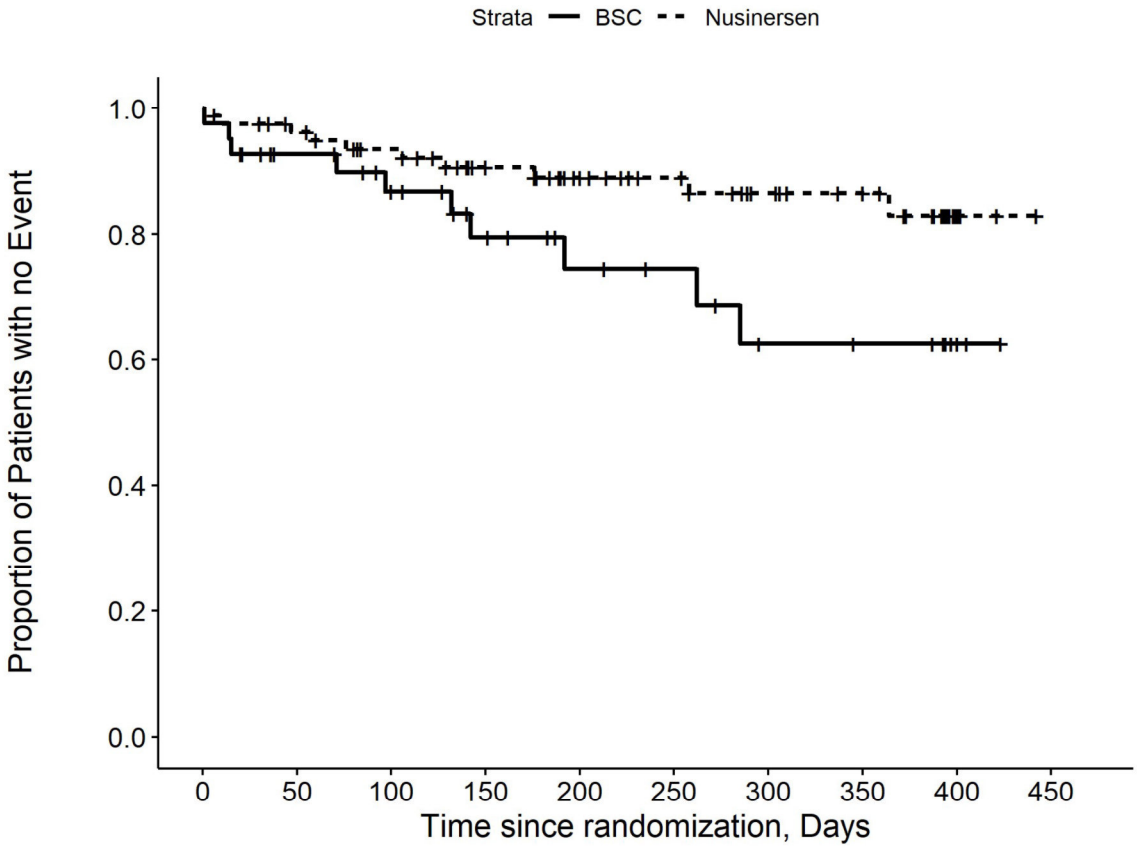
Kaplan Meier Plot for Time to AE by PT pct
Nasopharyngitis



Number at risk

BSC	41	35	29	24	18	17	13	11	4	0
Nusinersen	80	71	64	53	40	33	28	26	11	0

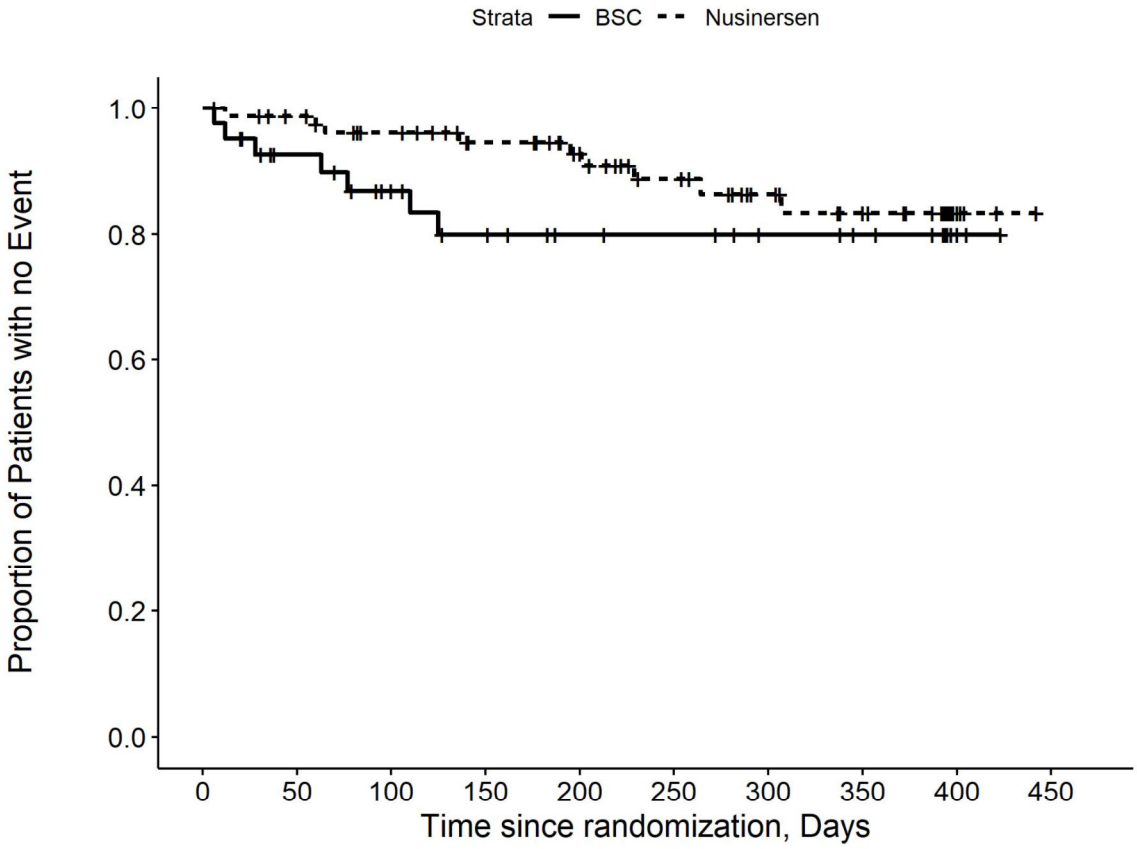
Kaplan Meier Plot for Time to AE by PT pct
Oxygen saturation decreased



Number at risk

BSC	41	33	28	21	15	13	9	8	4	0
Nusinersen	80	73	66	55	45	38	30	26	8	0

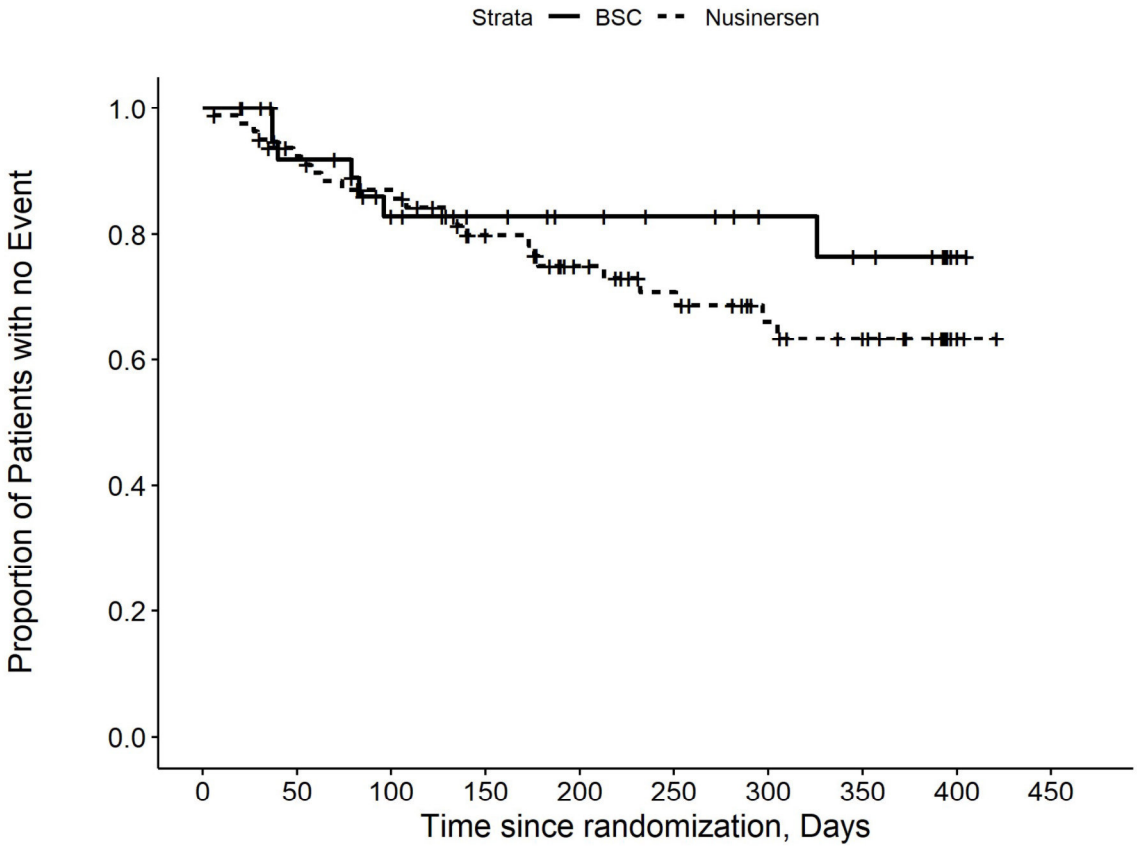
Kaplan Meier Plot for Time to AE by PT pct
Pneumonia aspiration



Number at risk

BSC	41	33	27	22	18	17	14	12	4	0
Nusinersen	80	75	68	59	50	40	31	26	10	0

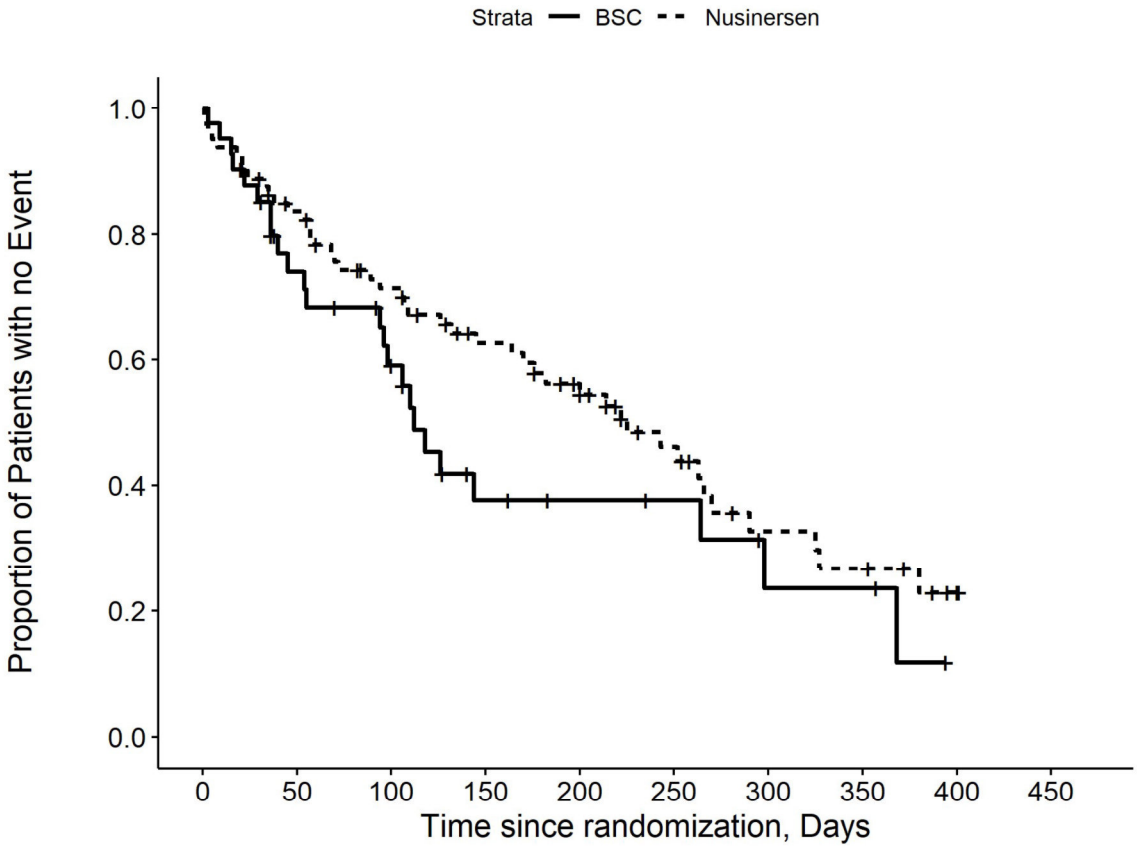
Kaplan Meier Plot for Time to AE by PT pct
Pneumonia



Number at risk

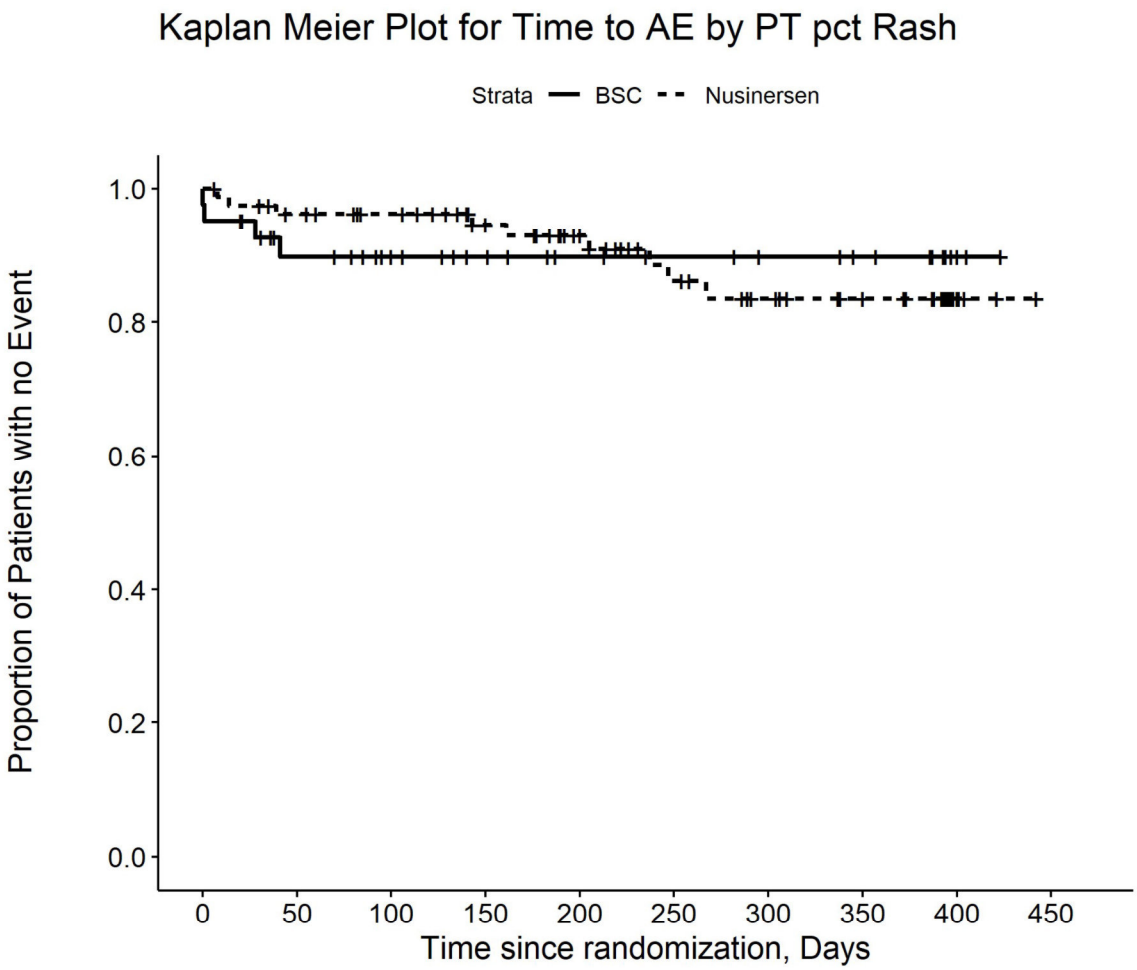
BSC	41	33	26	21	18	16	13	11	3	0
Nusinersen	80	70	63	51	40	33	25	21	7	0

Kaplan Meier Plot for Time to AE by PT pct Pyrexia



Number at risk

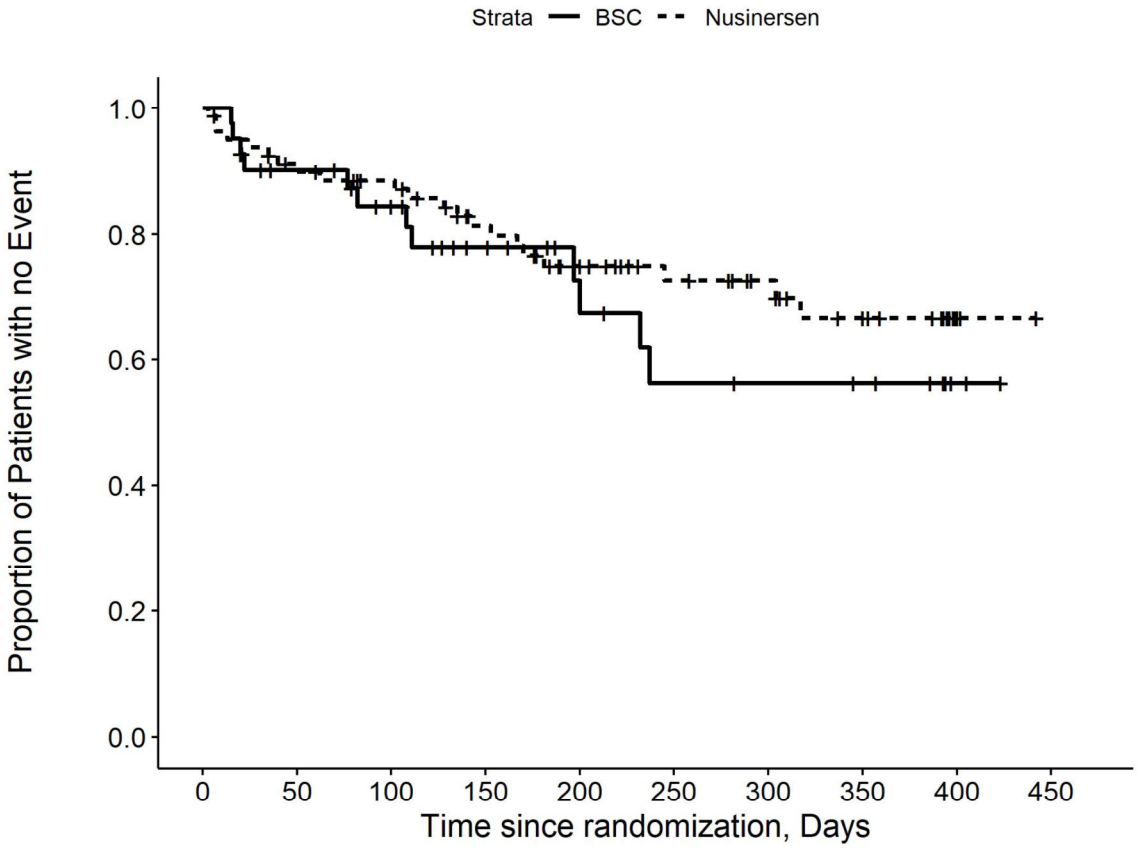
BSC	41	26	19	9	7	6	3	3	0	0
Nusinersen	80	64	51	39	32	20	11	9	3	0



Number at risk

BSC	41	32	27	22	17	15	13	11	3	0
Nusinersen	80	73	68	58	47	36	29	24	8	0

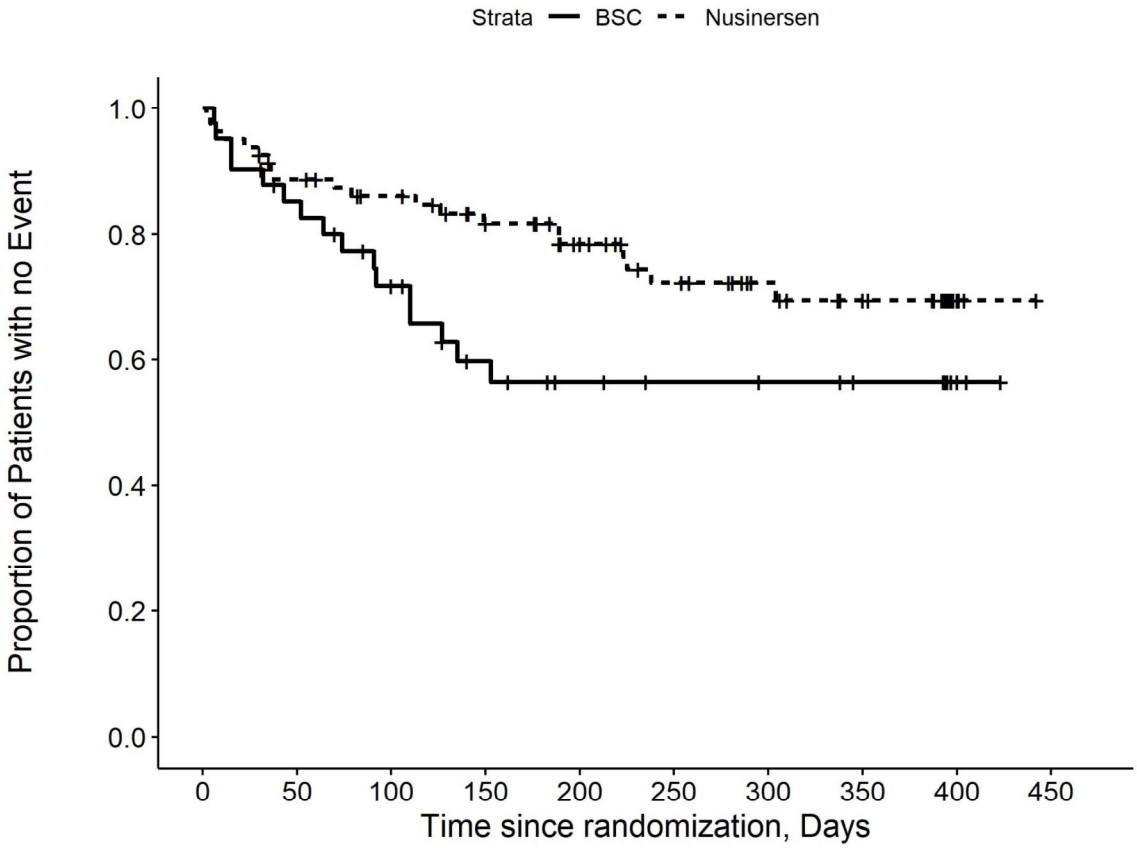
Kaplan Meier Plot for Time to AE by PT pct
Respiratory distress



Number at risk

BSC	41	33	28	20	14	10	9	8	2	0
Nusinersen	80	70	64	52	40	32	26	20	7	0

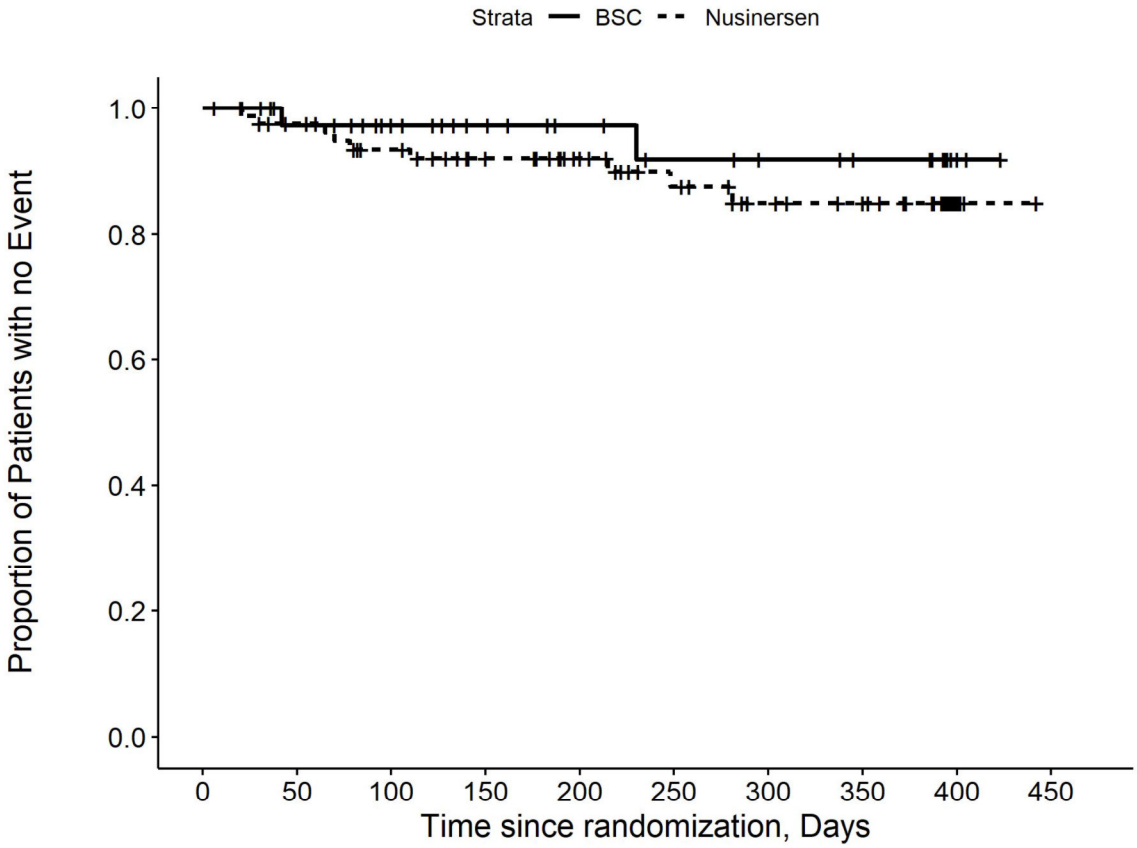
Kaplan Meier Plot for Time to AE by PT pct
Respiratory failure



Number at risk

BSC	41	33	26	18	14	12	11	9	4	0
Nusinersen	80	69	63	54	44	34	26	21	8	0

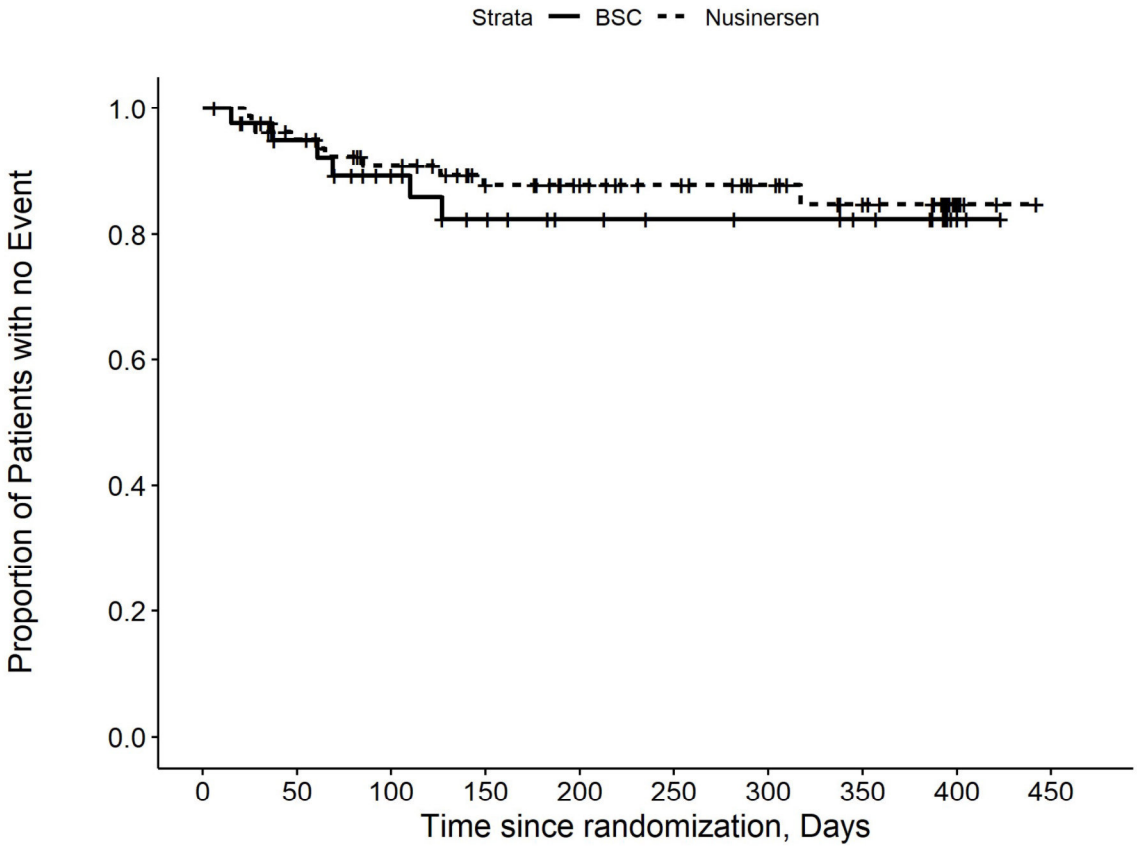
Kaplan Meier Plot for Time to AE by PT pct
Respiratory tract infection



Number at risk

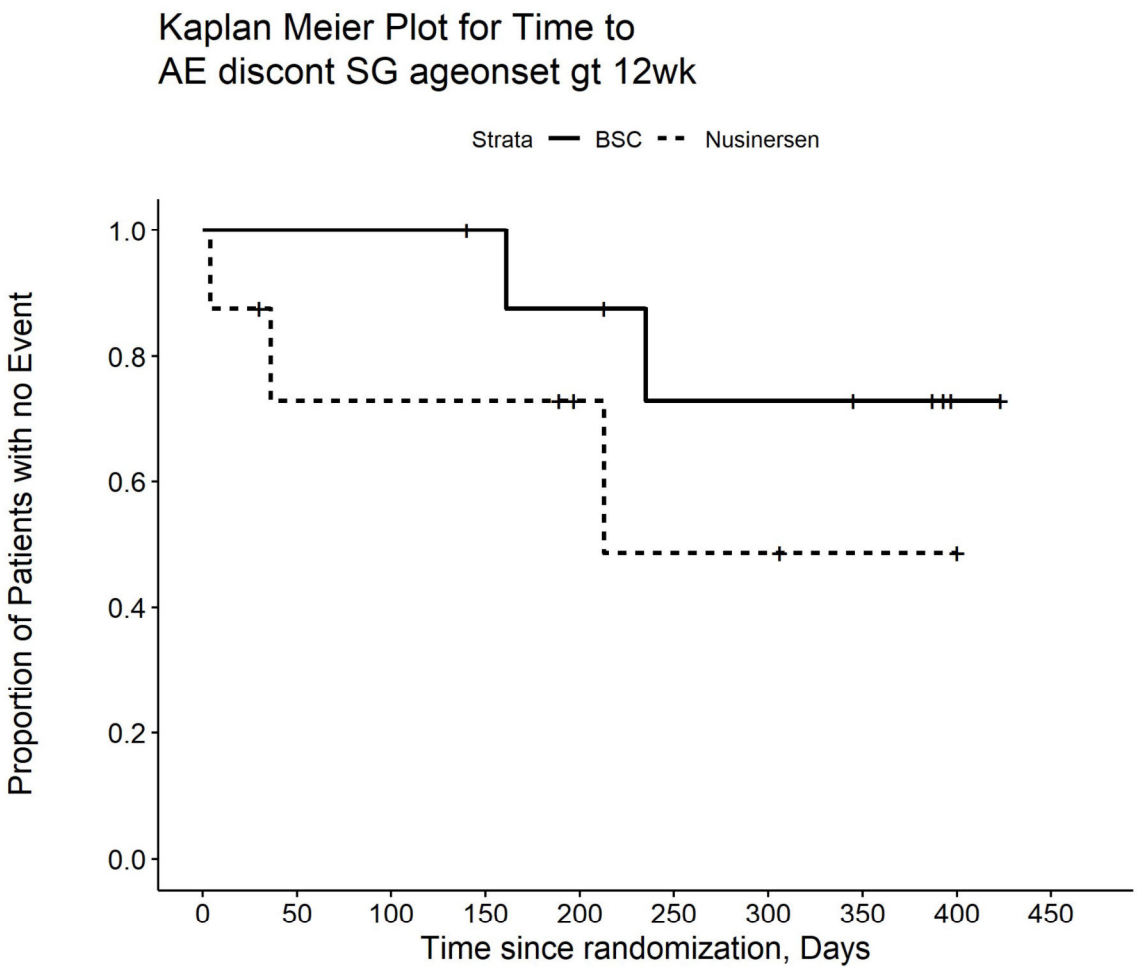
BSC	41	35	30	24	19	16	14	12	4	0
Nusinersen	80	74	66	57	47	37	29	26	9	0

Kaplan Meier Plot for Time to AE by PT pct
Rhinovirus infection



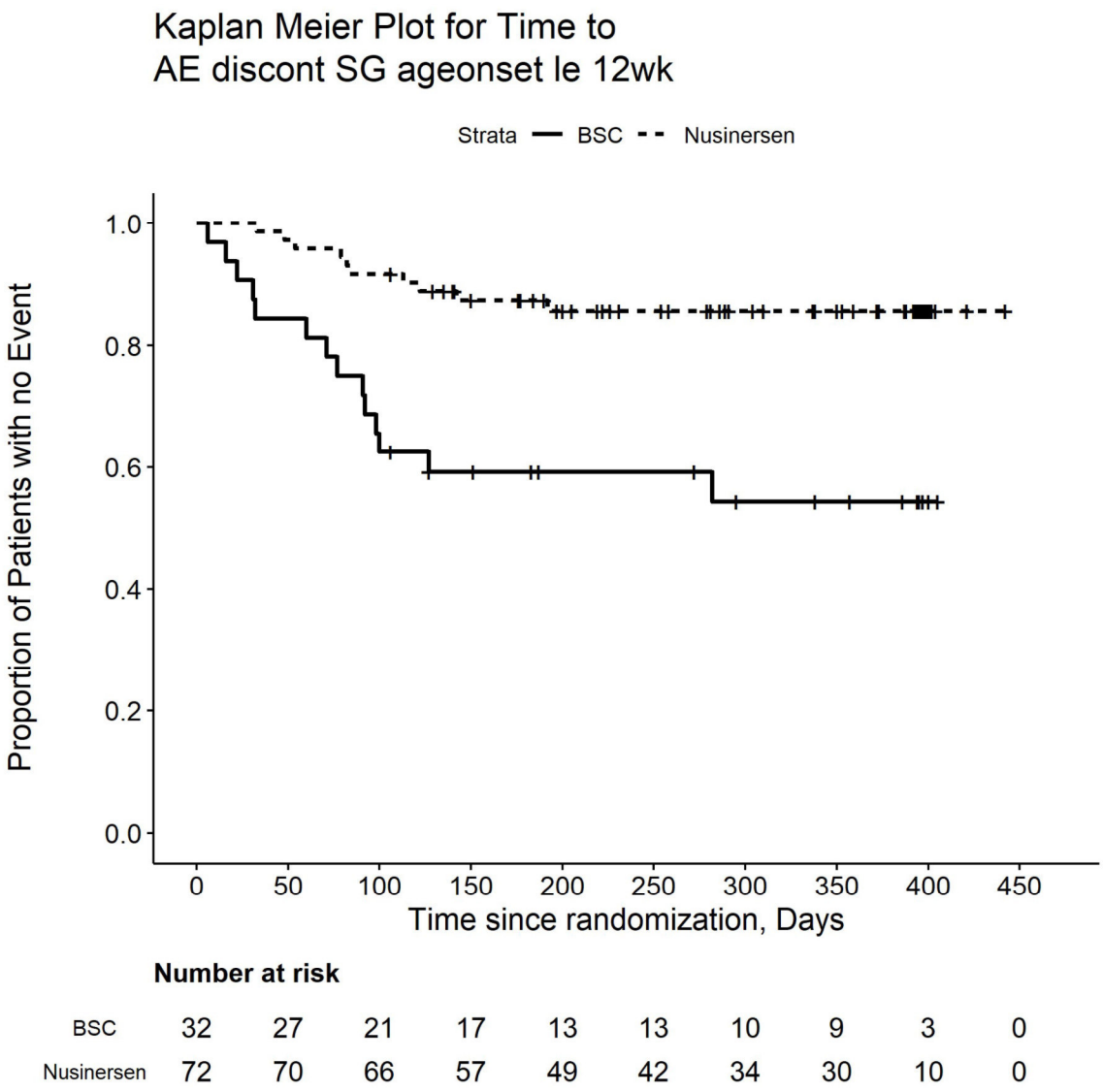
Number at risk

BSC	41	34	28	22	17	15	14	12	3	0
Nusinersen	80	73	65	54	46	39	32	26	11	0



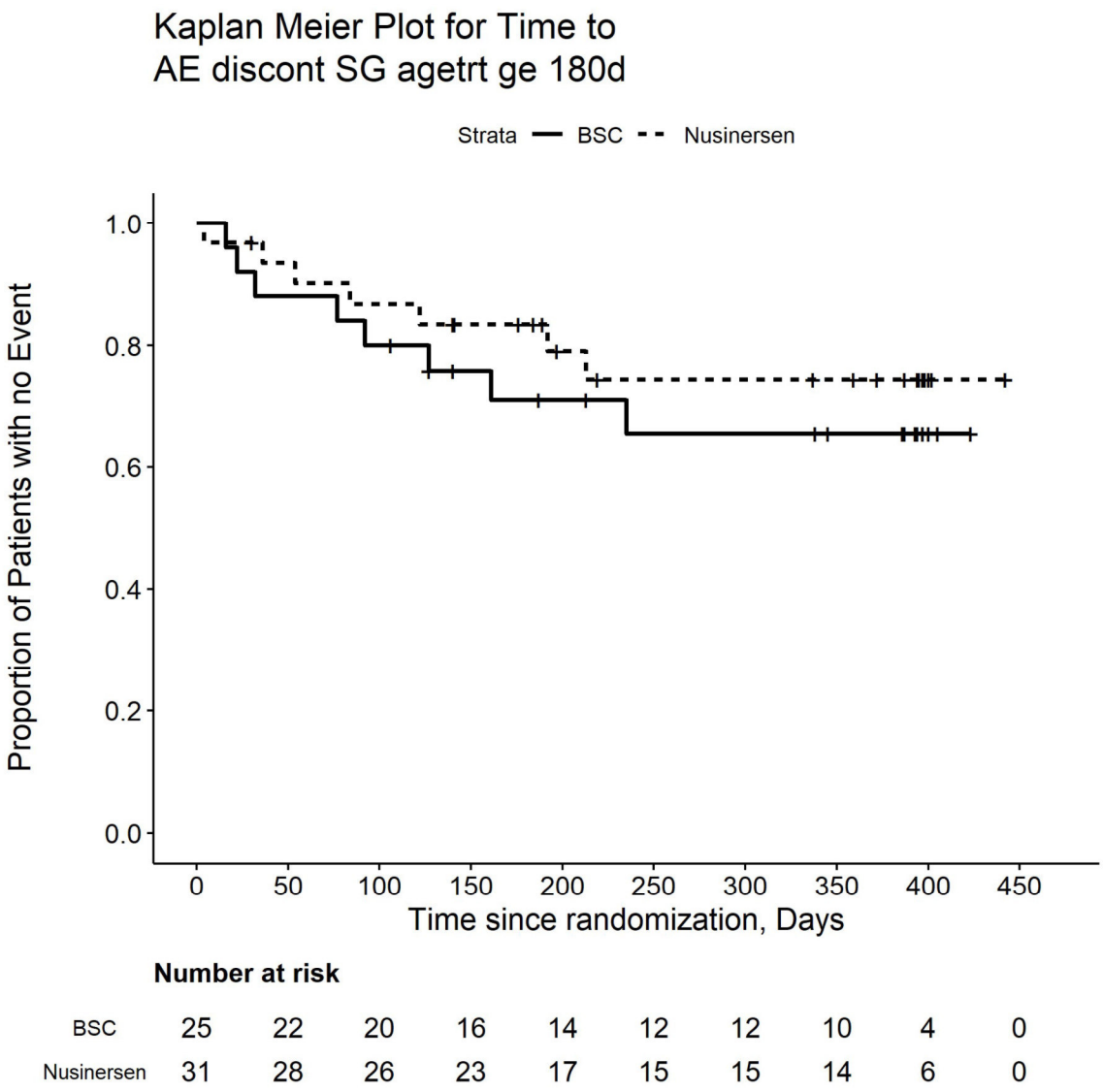
Number at risk

BSC	9	9	9	8	7	5	5	4	1	0
Nusinersen	8	5	5	5	3	2	2	1	1	0



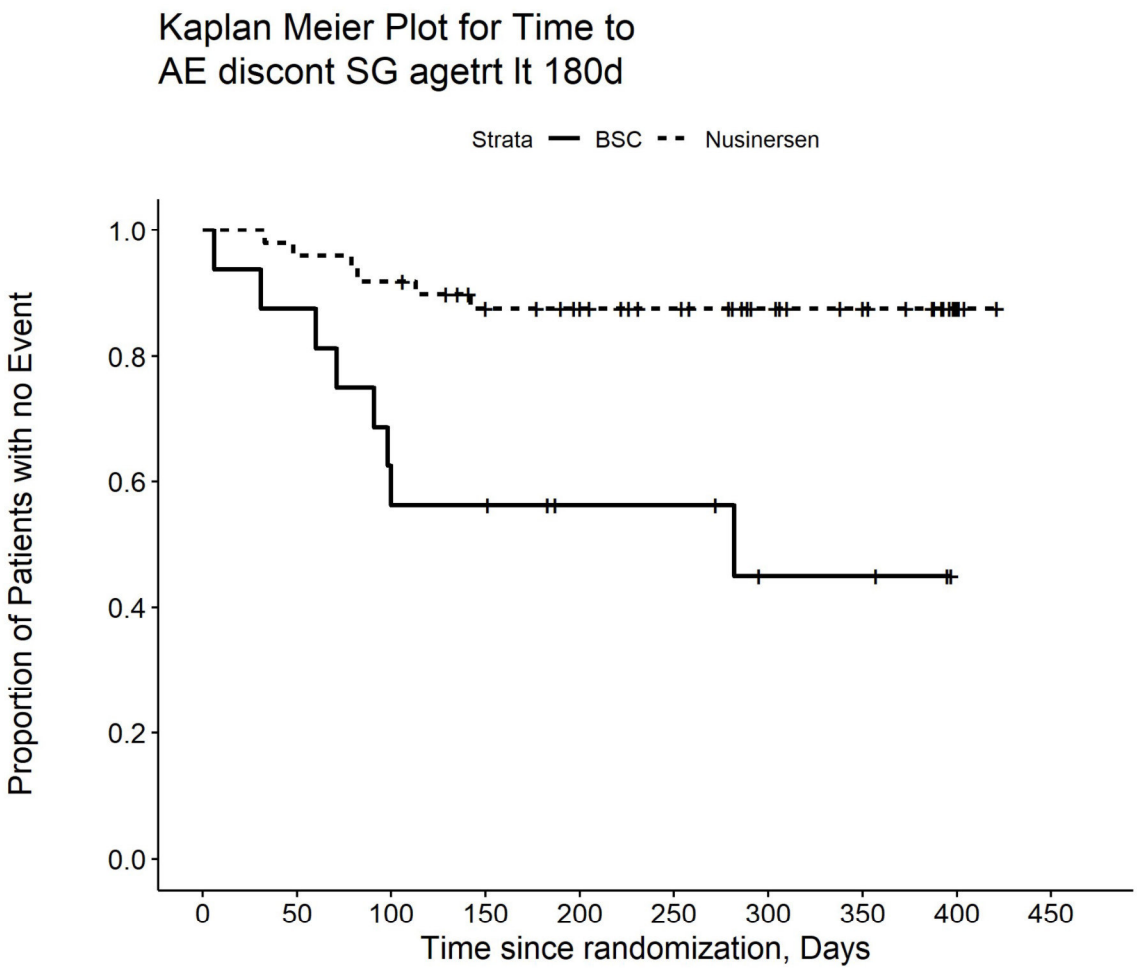
Number at risk

BSC	32	27	21	17	13	13	10	9	3	0
Nusinersen	72	70	66	57	49	42	34	30	10	0



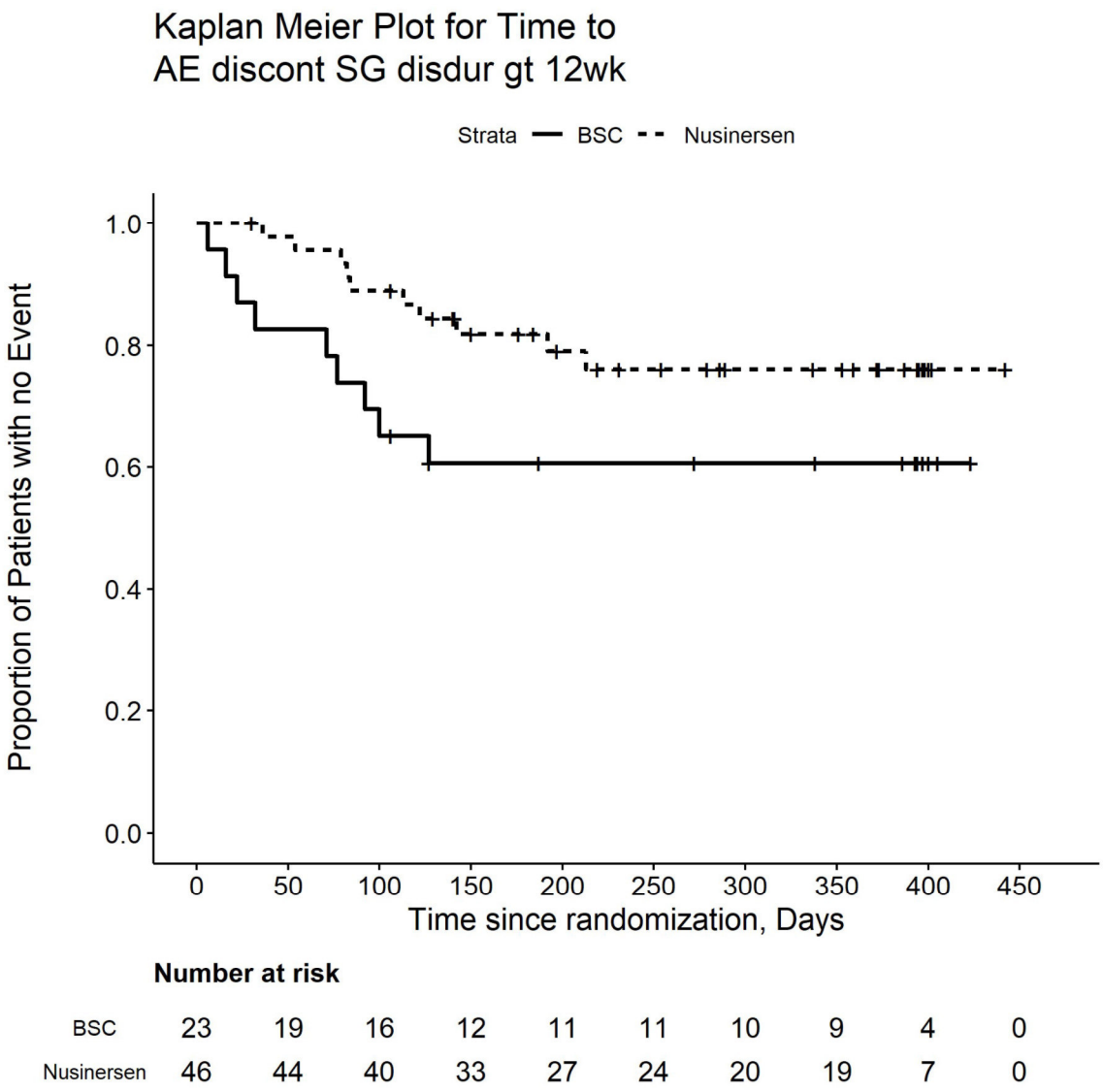
Number at risk

BSC	25	22	20	16	14	12	12	10	4	0
Nusinersen	31	28	26	23	17	15	15	14	6	0



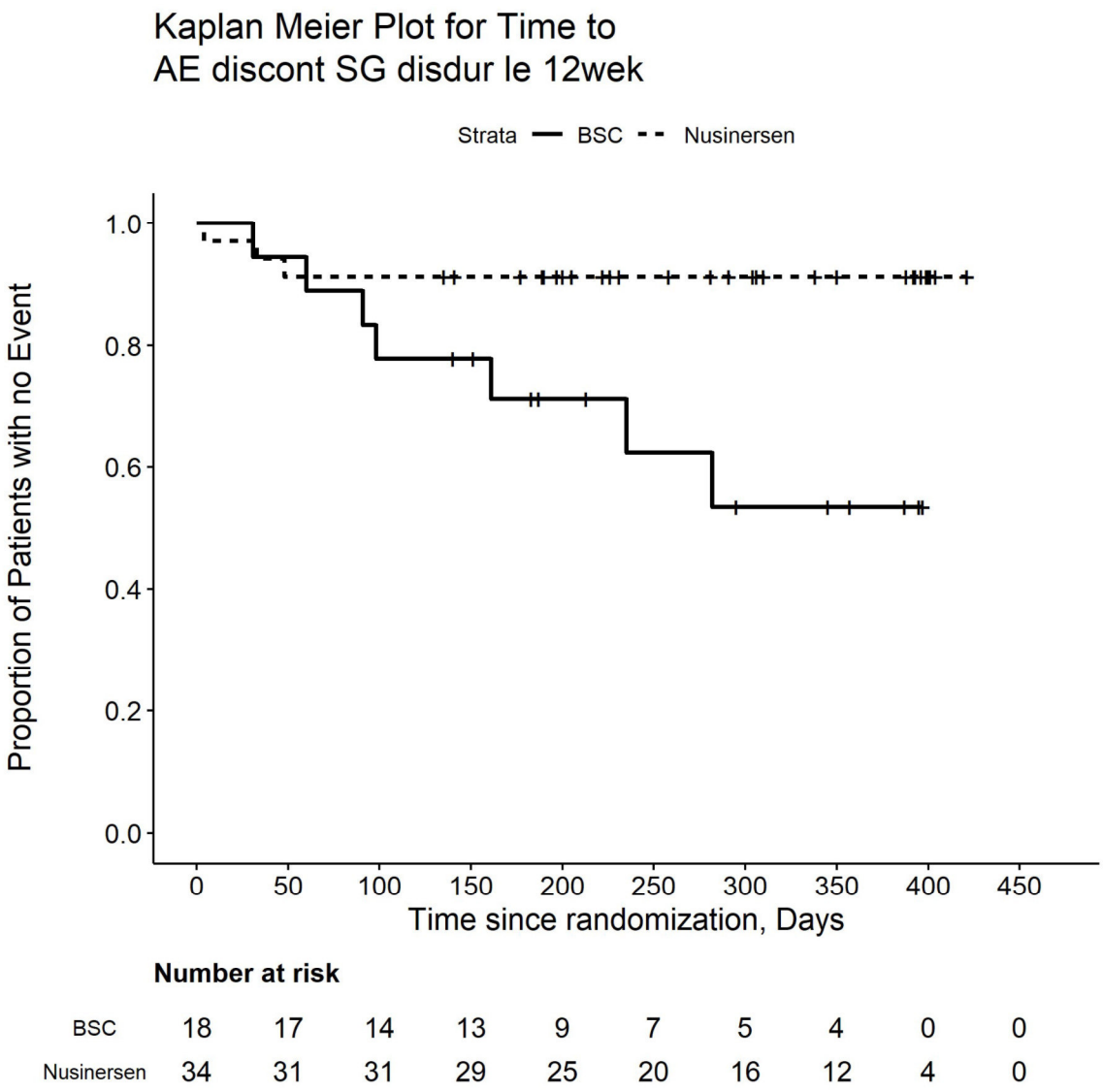
Number at risk

BSC	16	14	10	9	6	6	3	3	0	0
Nusinersen	49	47	45	39	35	29	21	17	5	0



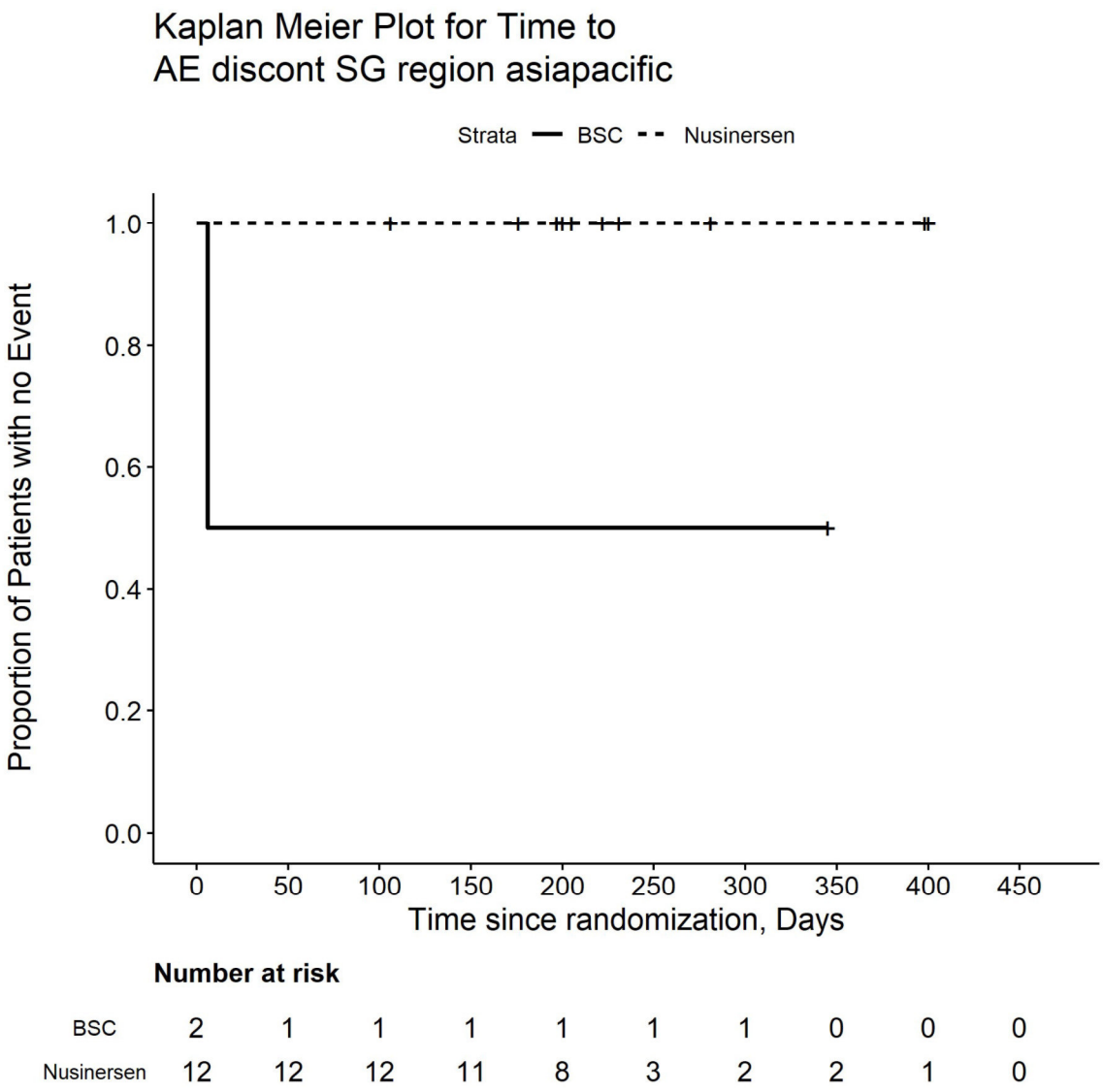
Number at risk

BSC	23	19	16	12	11	11	10	9	4	0
Nusinersen	46	44	40	33	27	24	20	19	7	0



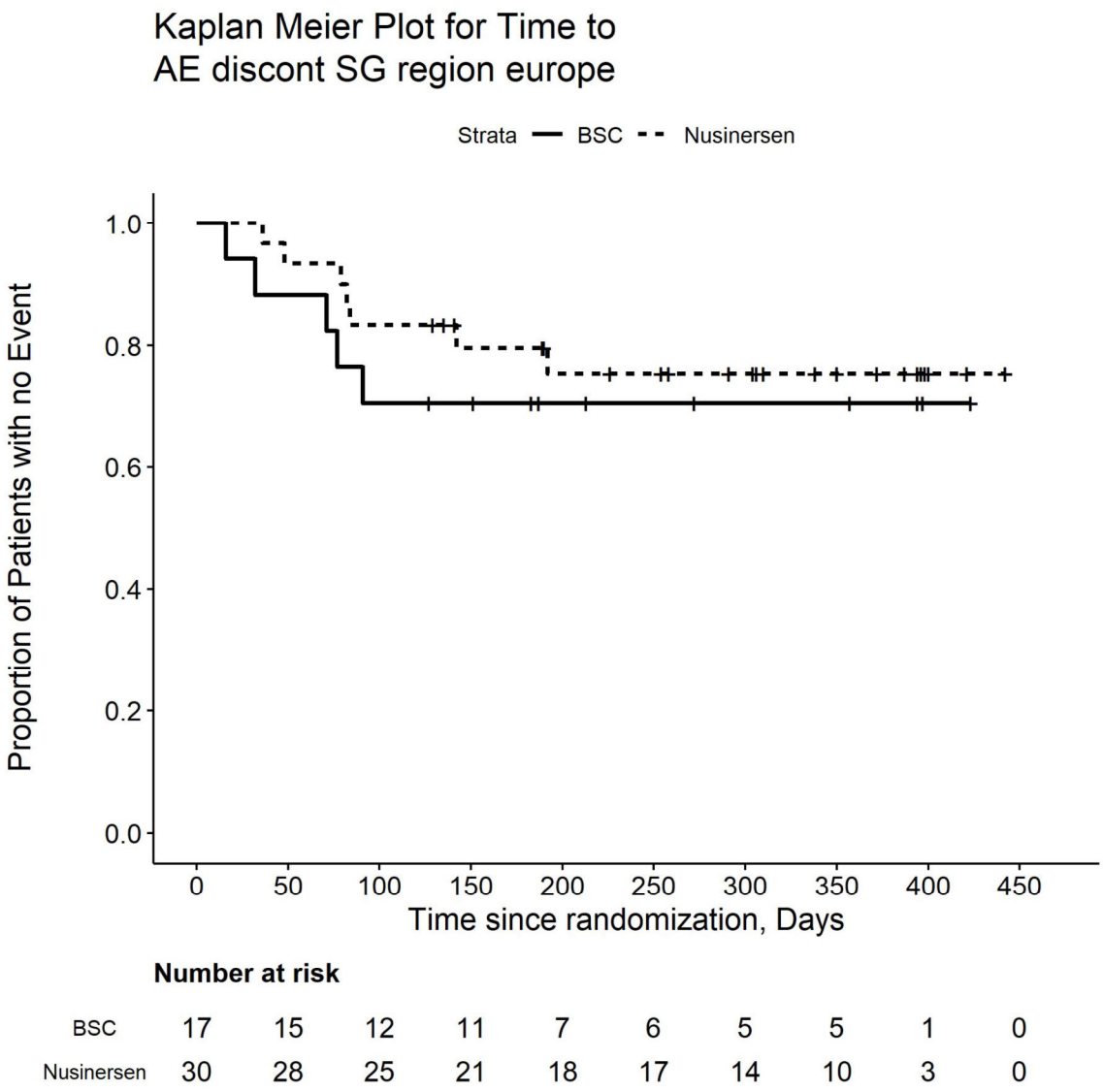
Number at risk

BSC	18	17	14	13	9	7	5	4	0	0
Nusinersen	34	31	31	29	25	20	16	12	4	0



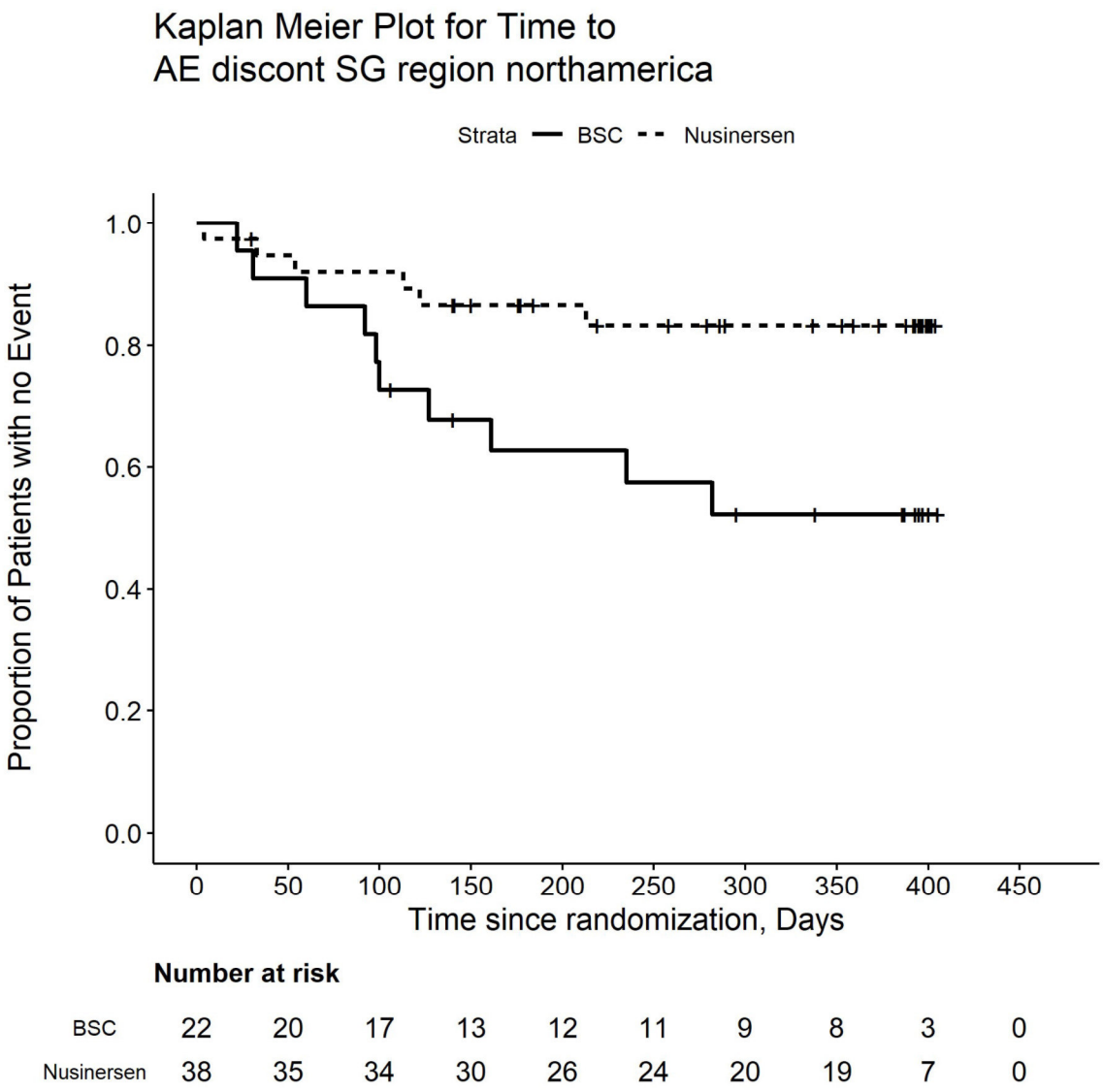
Number at risk

BSC	2	1	1	1	1	1	1	0	0	0
Nusinersen	12	12	12	11	8	3	2	2	1	0



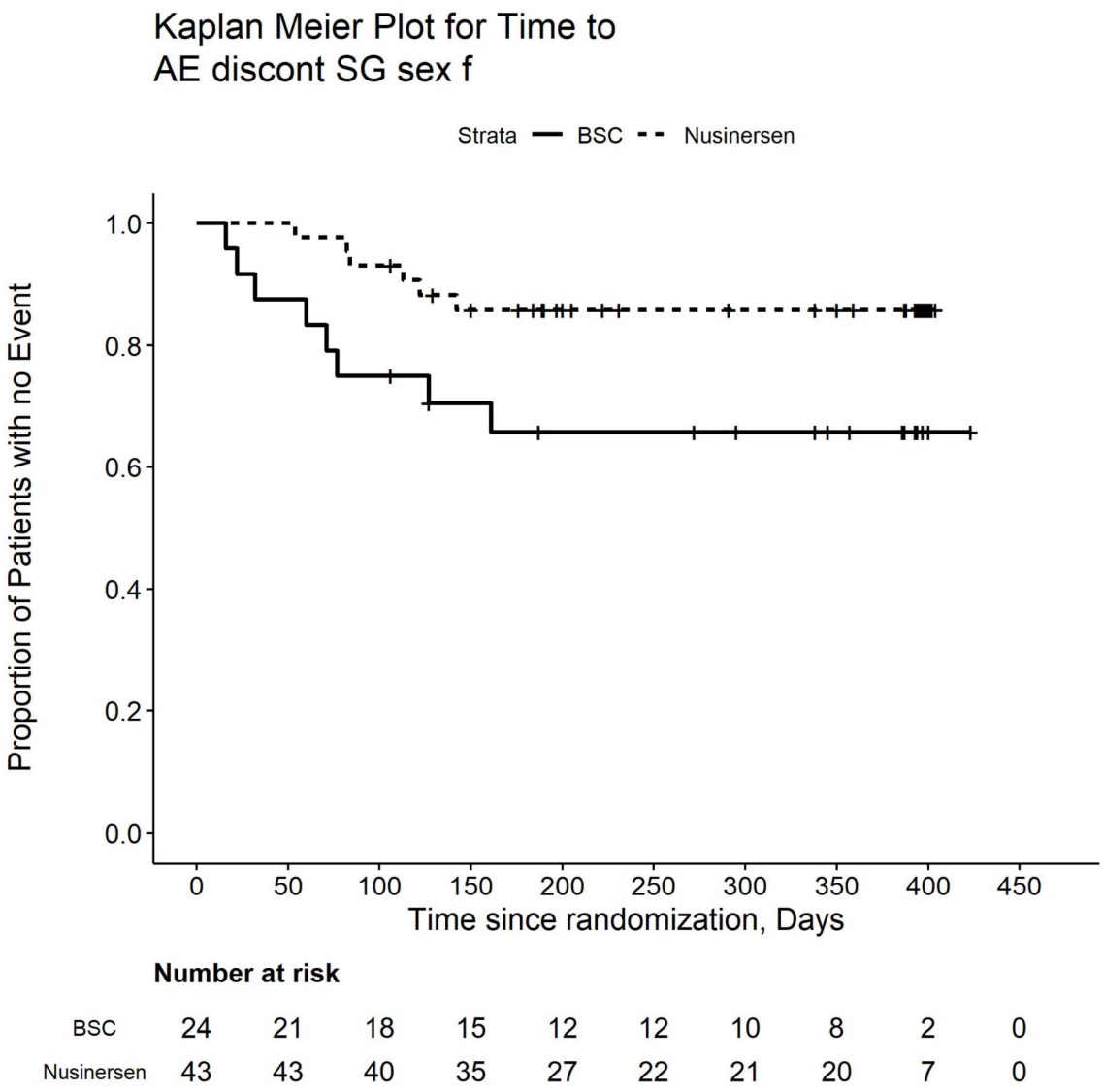
Number at risk

BSC	17	15	12	11	7	6	5	5	1	0
Nusinersen	30	28	25	21	18	17	14	10	3	0



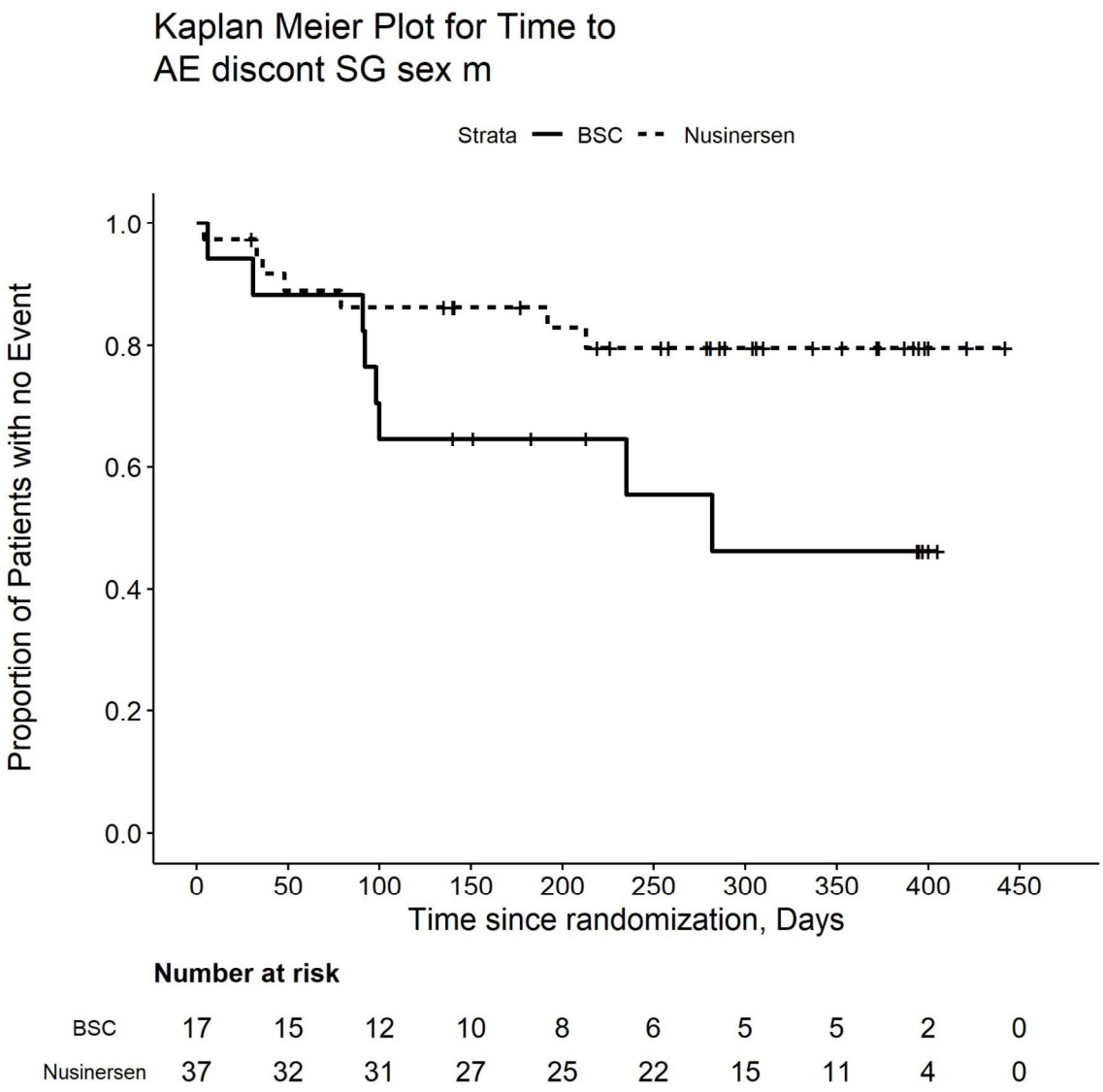
Number at risk

BSC	22	20	17	13	12	11	9	8	3	0
Nusinersen	38	35	34	30	26	24	20	19	7	0



Number at risk

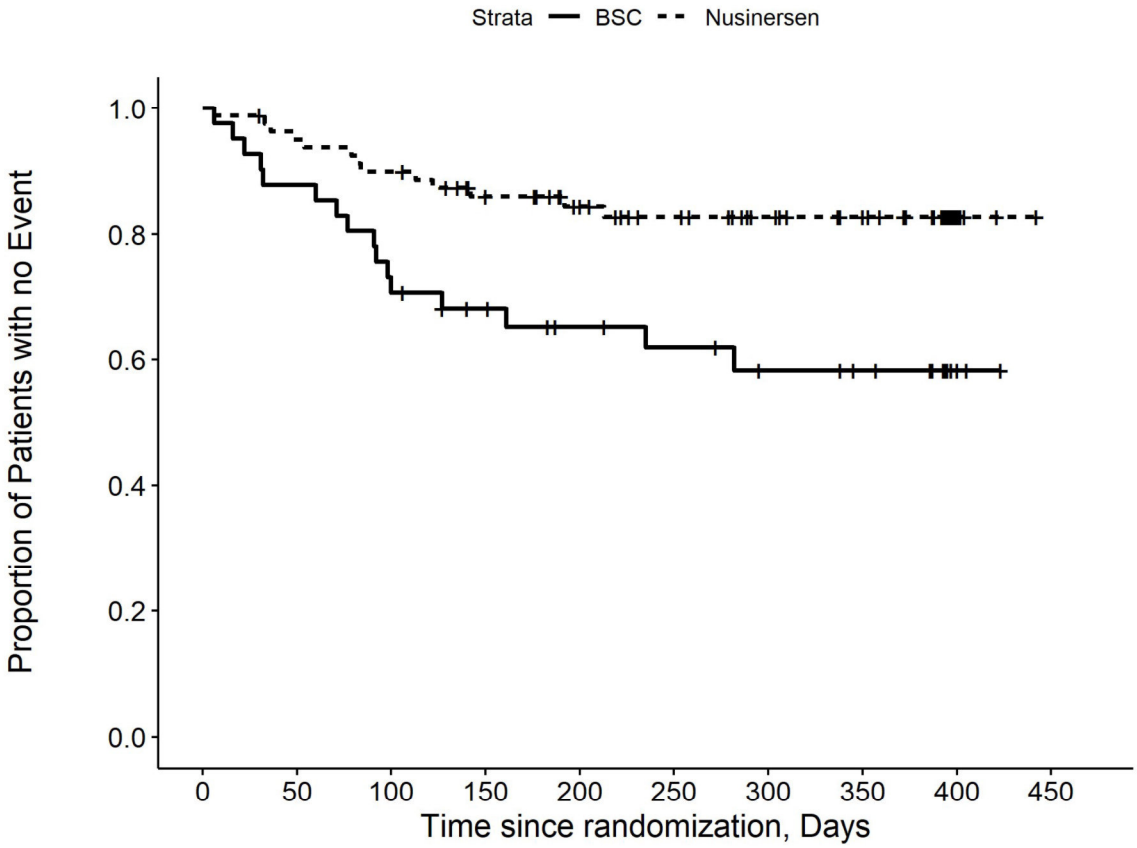
BSC	24	21	18	15	12	12	10	8	2	0
Nusinersen	43	43	40	35	27	22	21	20	7	0



Number at risk

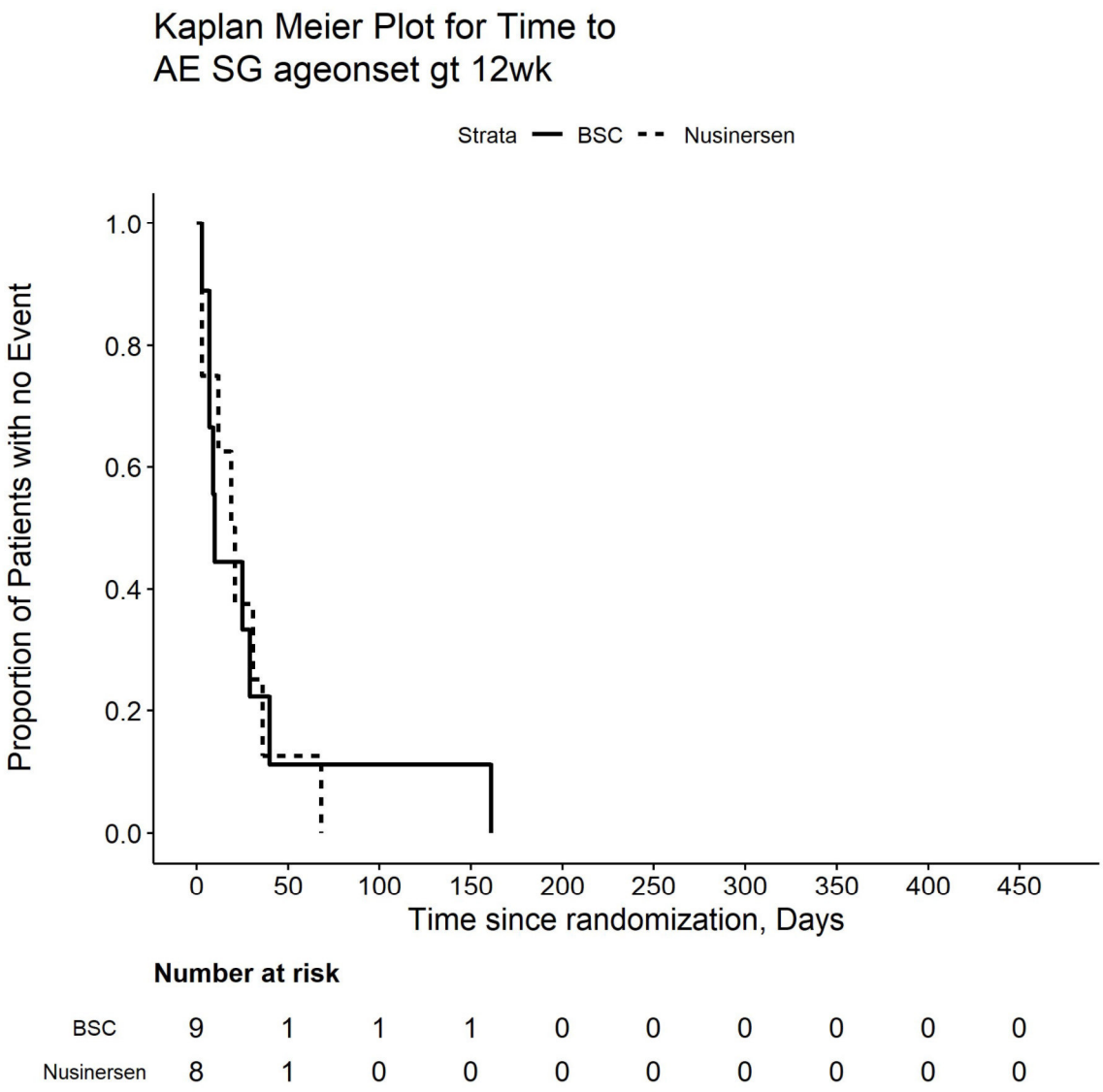
BSC	17	15	12	10	8	6	5	5	2	0
Nusinersen	37	32	31	27	25	22	15	11	4	0

Kaplan Meier Plot for Time to AE leading to discont



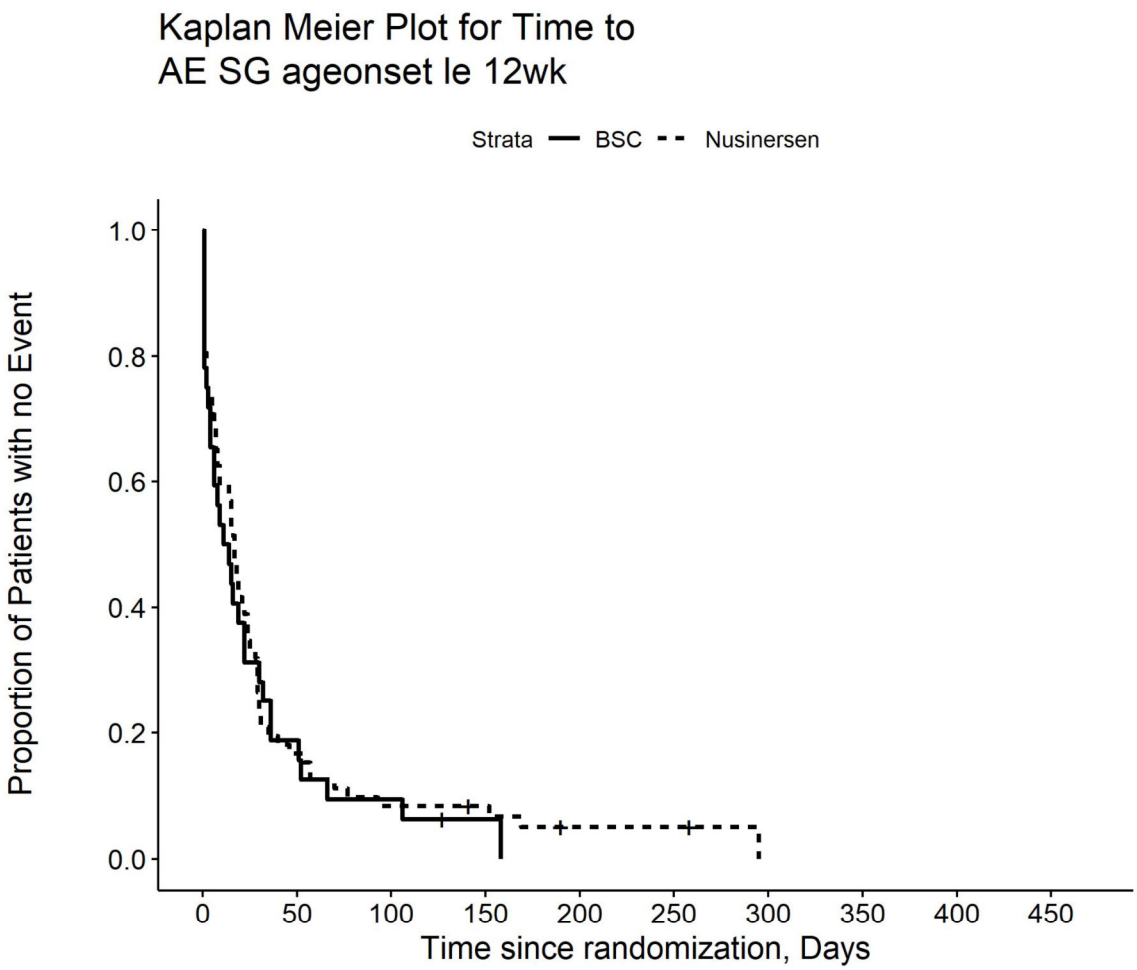
Number at risk

BSC	41	36	30	25	20	18	15	13	4	0
Nusinersen	80	75	71	62	52	44	36	31	11	0



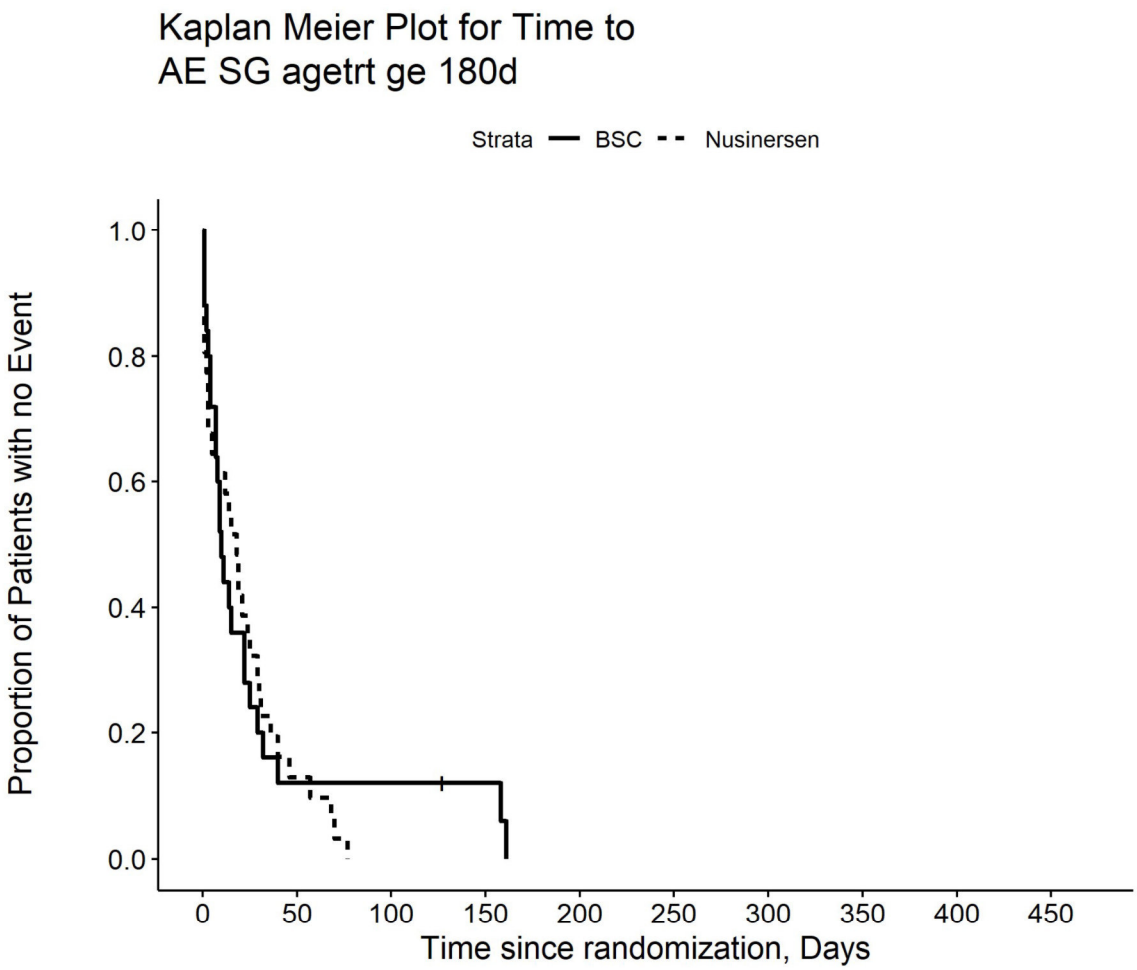
Number at risk

BSC	9	1	1	1	0	0	0	0	0	0
Nusinersen	8	1	0	0	0	0	0	0	0	0



Number at risk

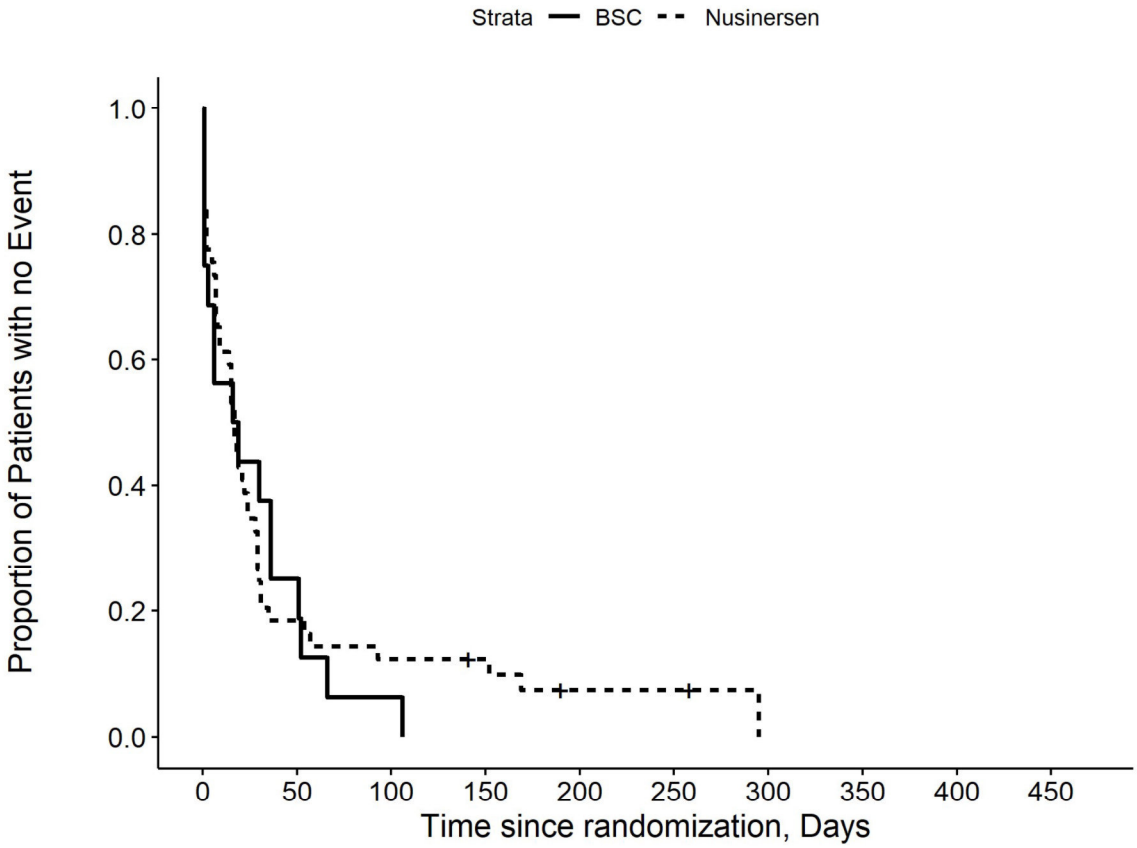
BSC	32	6	3	1	0	0	0	0	0	0
Nusinersen	72	12	6	5	2	2	0	0	0	0



Number at risk

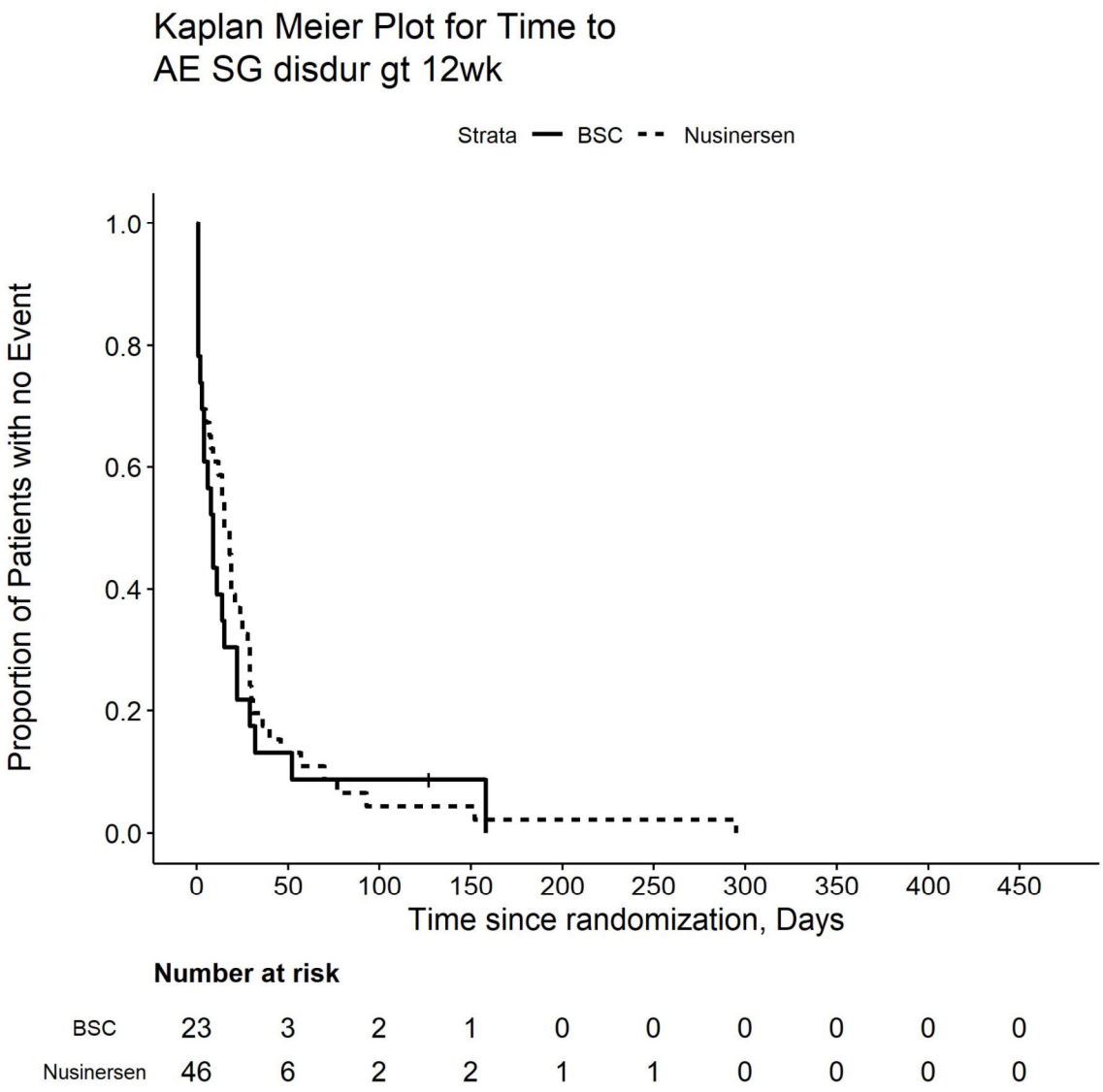
BSC	25	3	3	2	0	0	0	0	0	0
Nusinersen	31	4	0	0	0	0	0	0	0	0

Kaplan Meier Plot for Time to
AE SG agetrt lt 180d

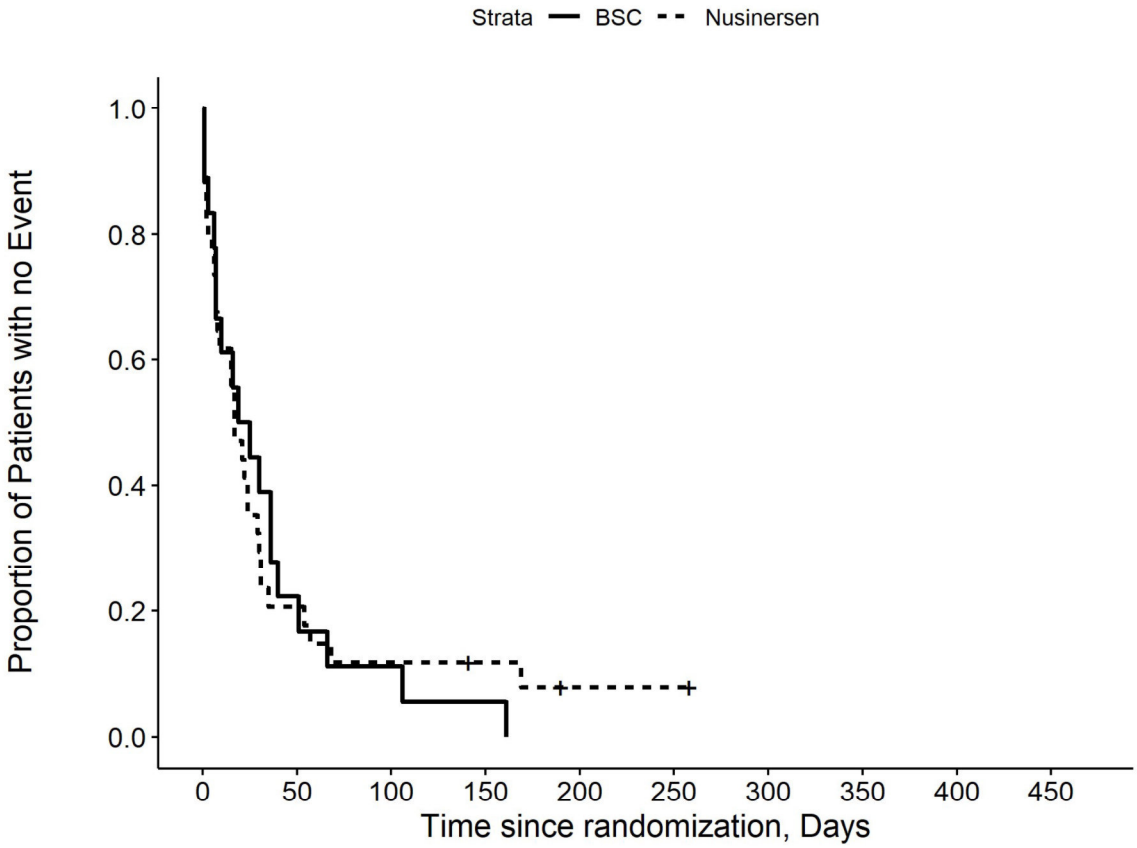


Number at risk

BSC	16	4	1	0	0	0	0	0	0	0
Nusinersen	49	9	6	5	2	2	0	0	0	0

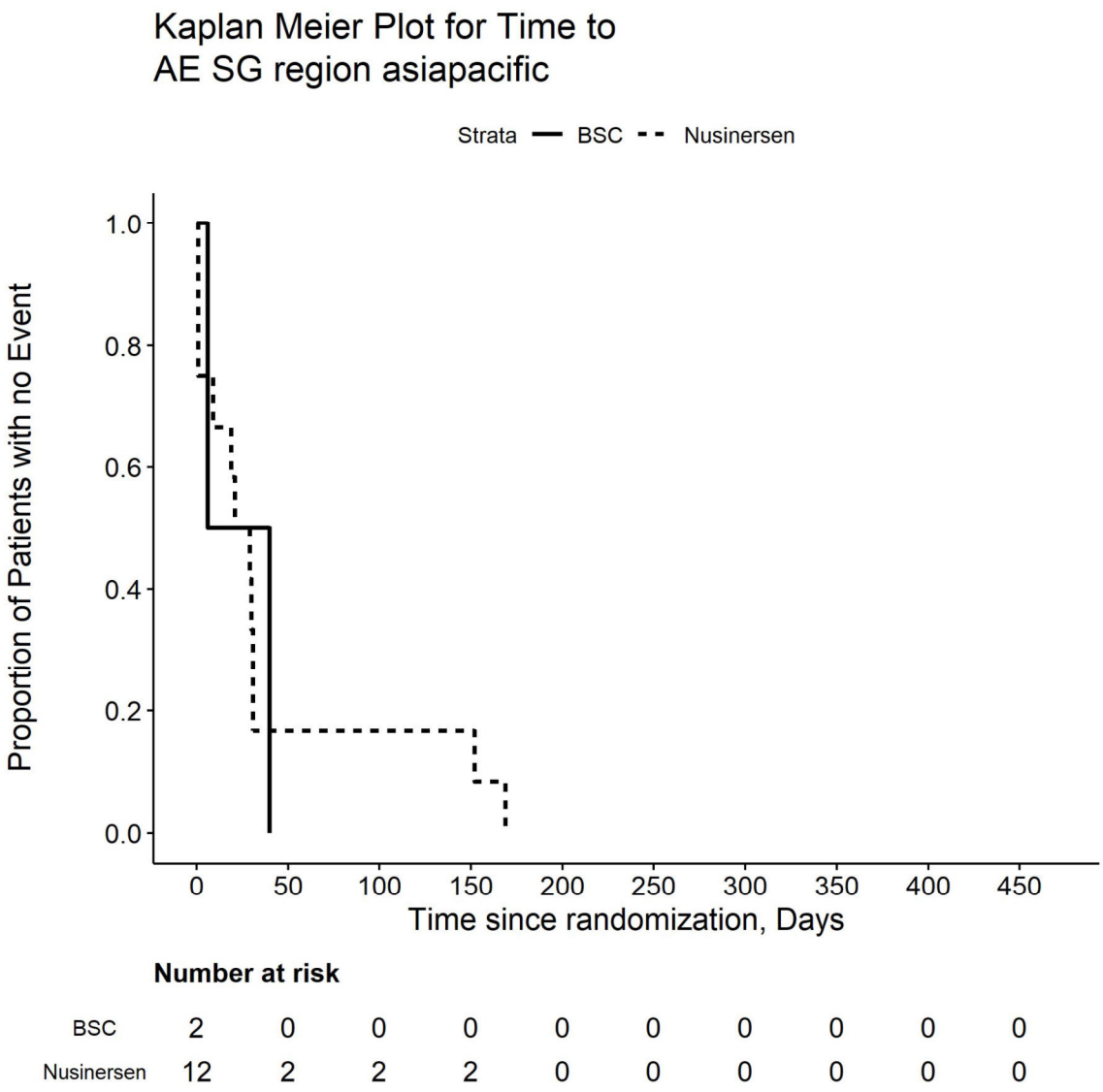

Kaplan Meier Plot for Time to
AE SG disdur gt 12wk
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0
50
100
150
200
250
300
350
400
450
Time since randomization, Days
Number at risk
BSC 23 3 2 1 0 0 0 0 0 0
Nusinersen 46 6 2 2 1 1 0 0 0 0

Kaplan Meier Plot for Time to
AE SG disdur le 12wek



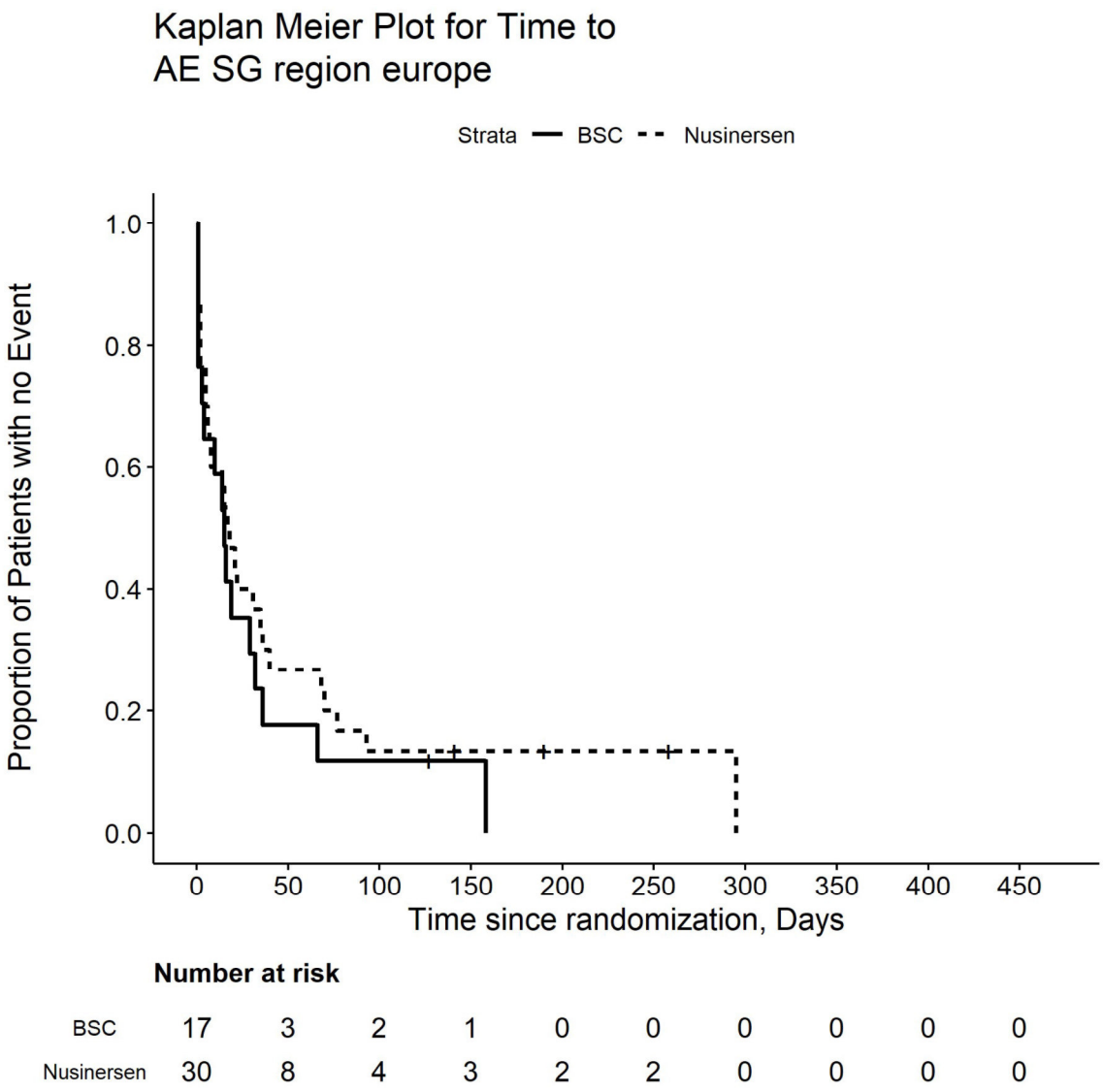
Number at risk

BSC	18	4	2	1	0	0	0	0	0	0
Nusinersen	34	7	4	3	1	1	0	0	0	0



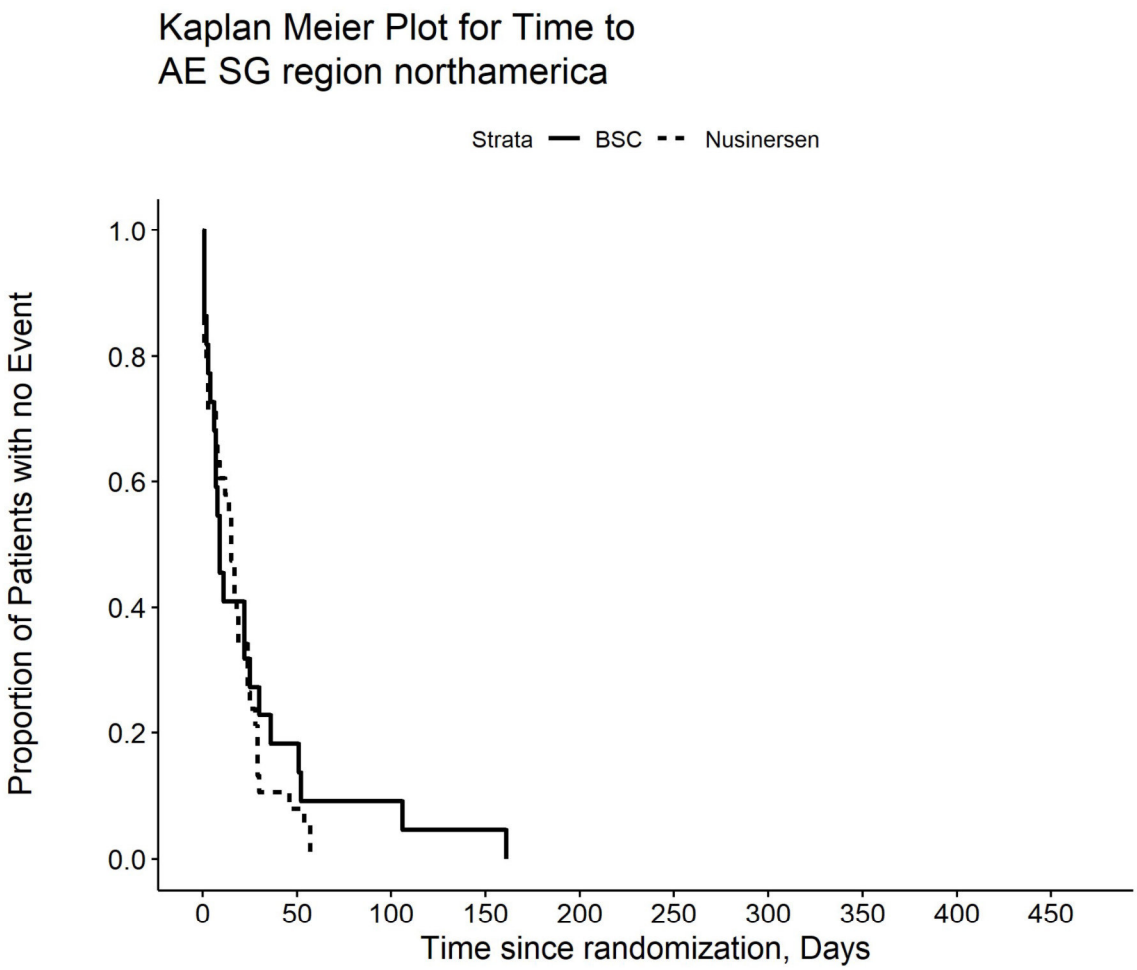
Number at risk

BSC	2	0	0	0	0	0	0	0	0	0
Nusinersen	12	2	2	2	0	0	0	0	0	0



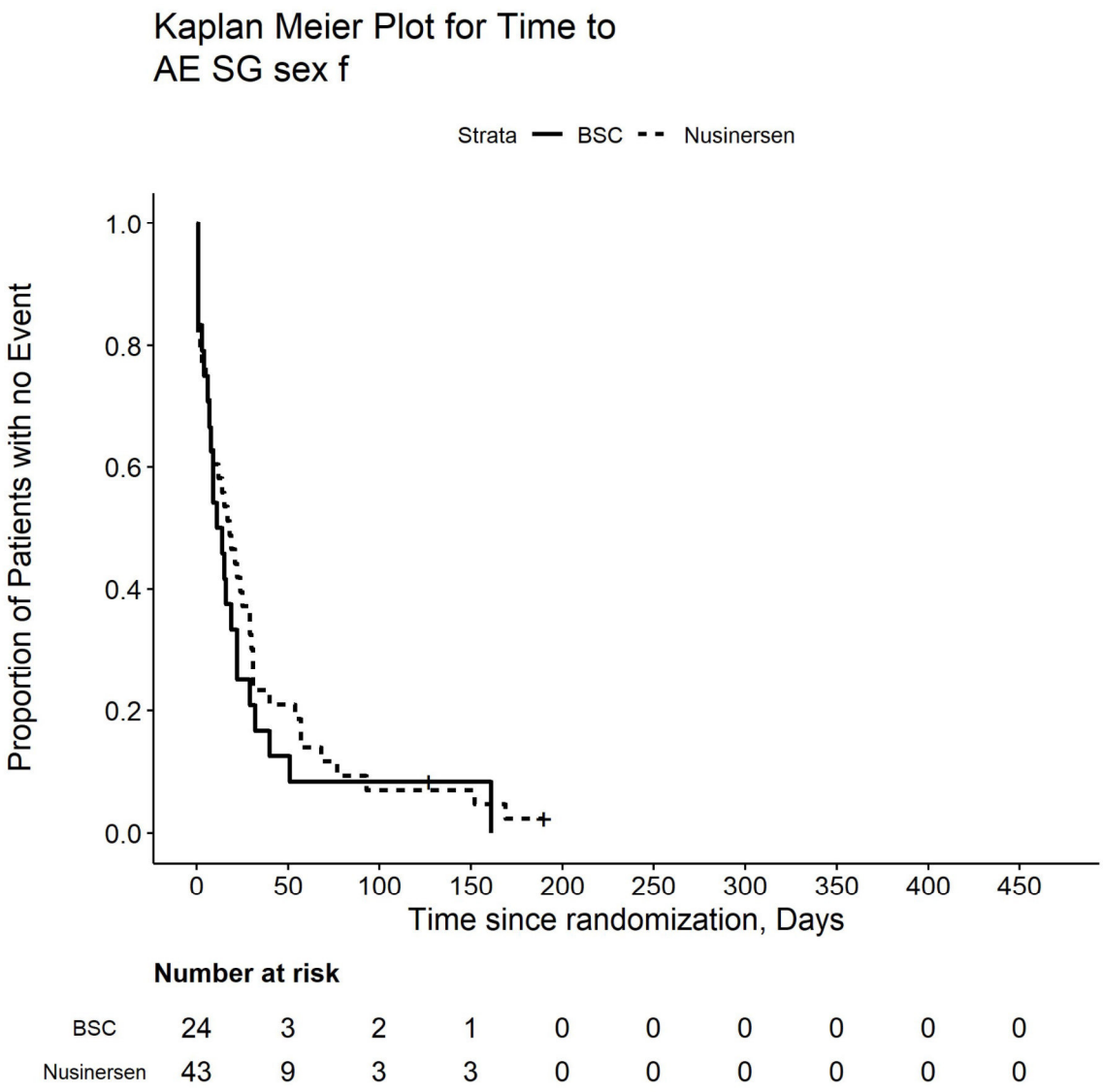
Number at risk

BSC	17	3	2	1	0	0	0	0	0	0
Nusinersen	30	8	4	3	2	2	0	0	0	0



Number at risk

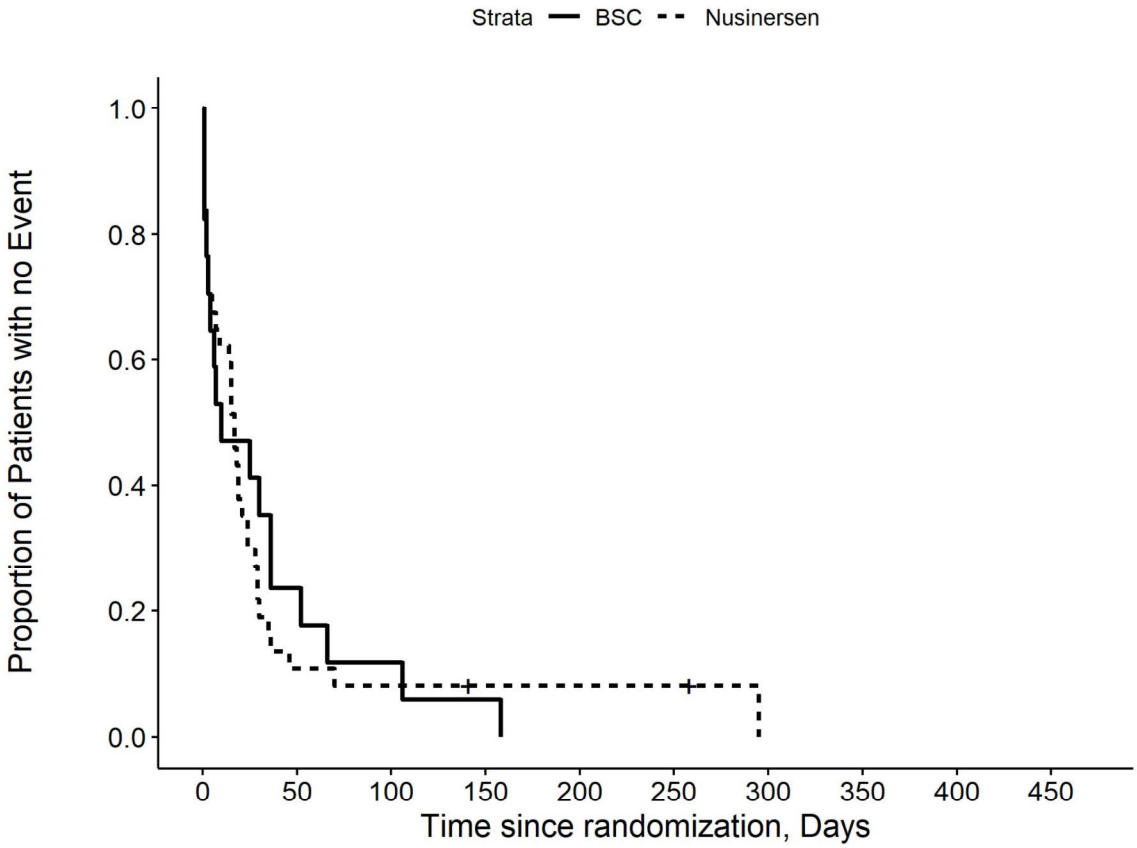
BSC	22	4	2	1	0	0	0	0	0	0
Nusinersen	38	3	0	0	0	0	0	0	0	0



Number at risk

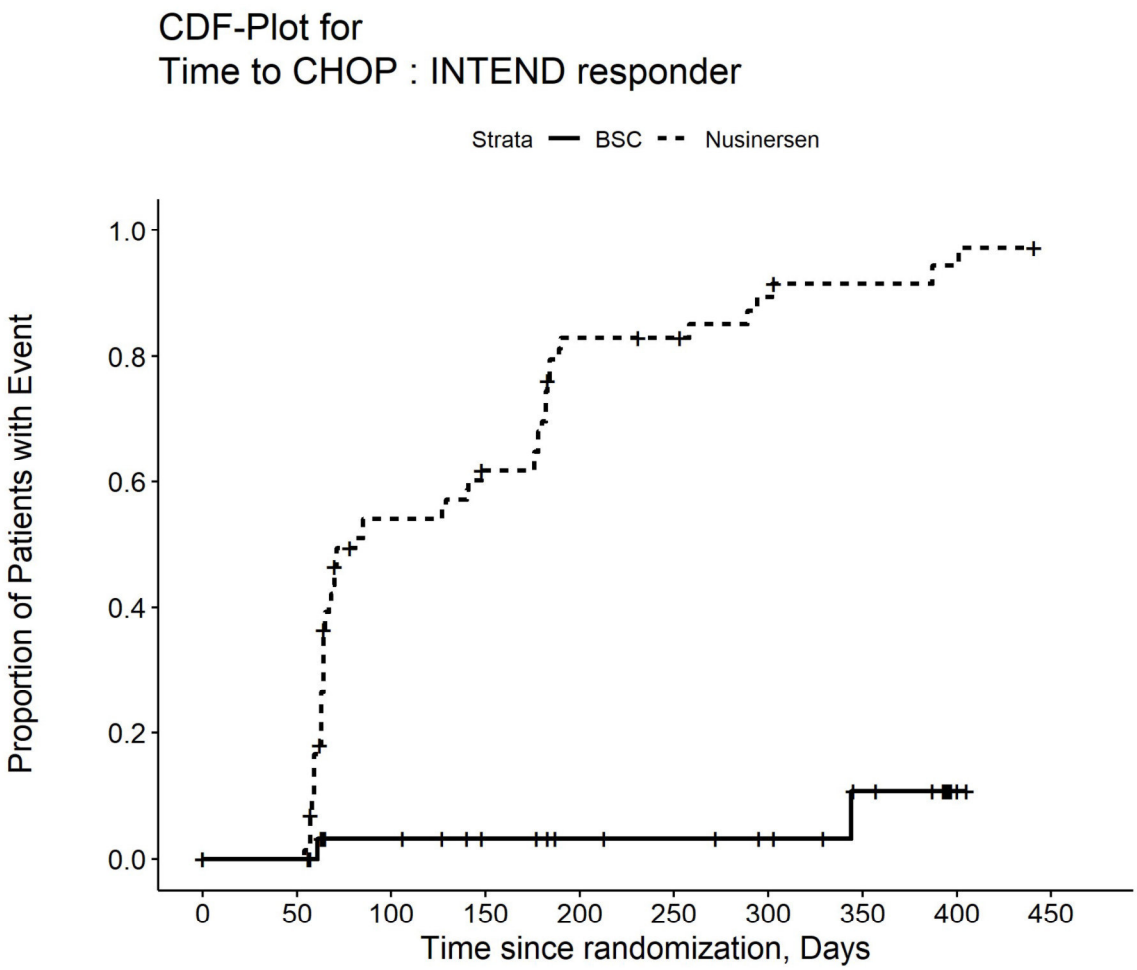
BSC	24	3	2	1	0	0	0	0	0	0
Nusinersen	43	9	3	3	0	0	0	0	0	0

Kaplan Meier Plot for Time to
AE SG sex m



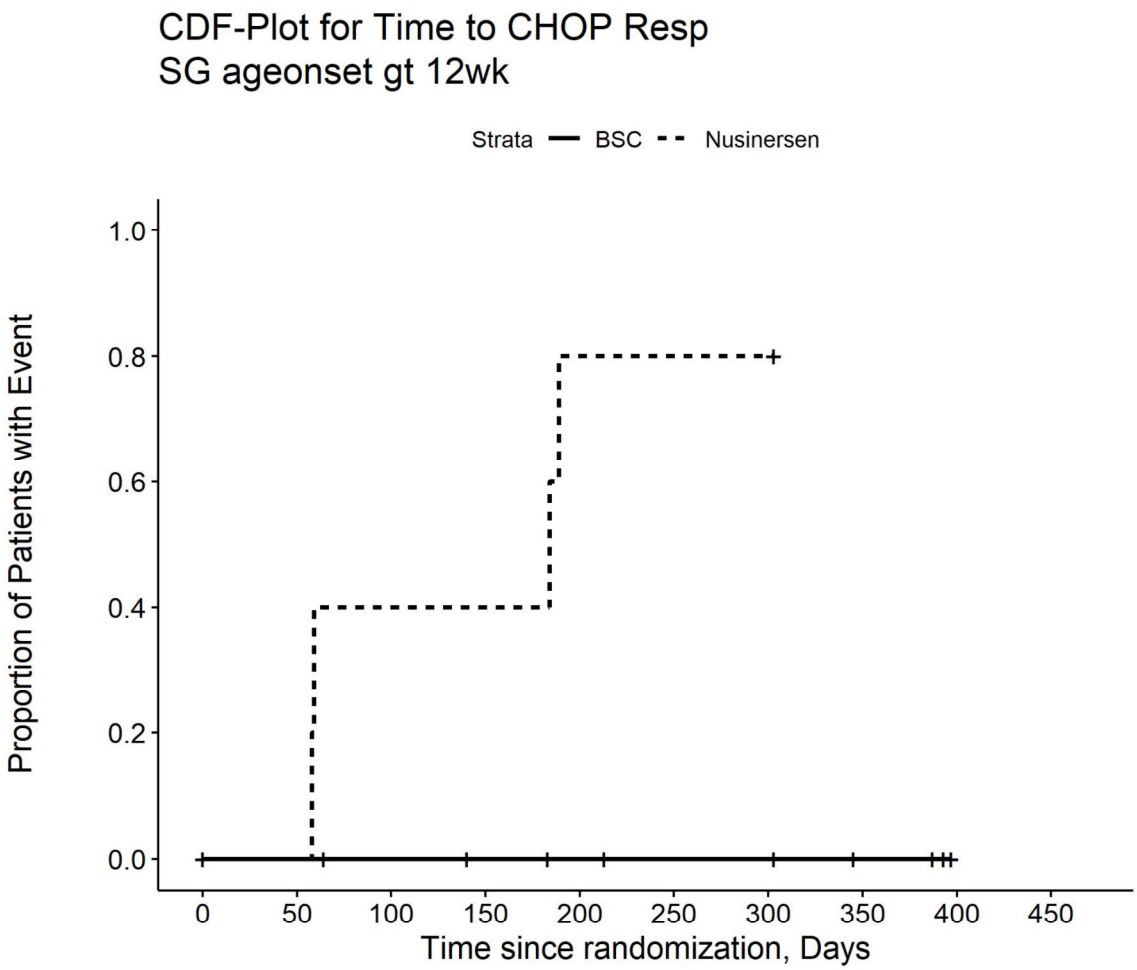
Number at risk

BSC	17	4	2	1	0	0	0	0	0	0
Nusinersen	37	4	3	2	2	2	0	0	0	0



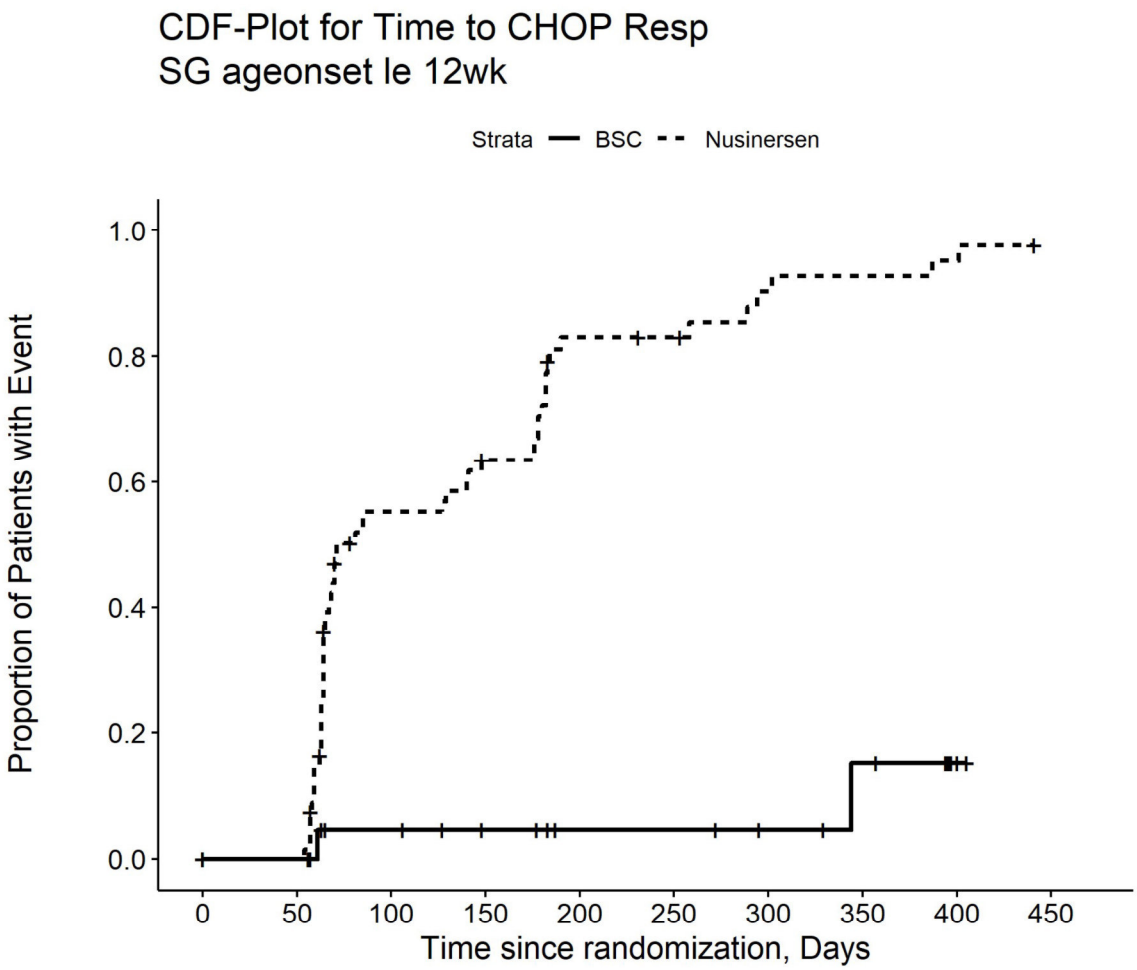
Number at risk

BSC	41	33	26	22	18	17	15	11	2	0
Nusinersen	80	73	30	24	10	9	5	3	2	0



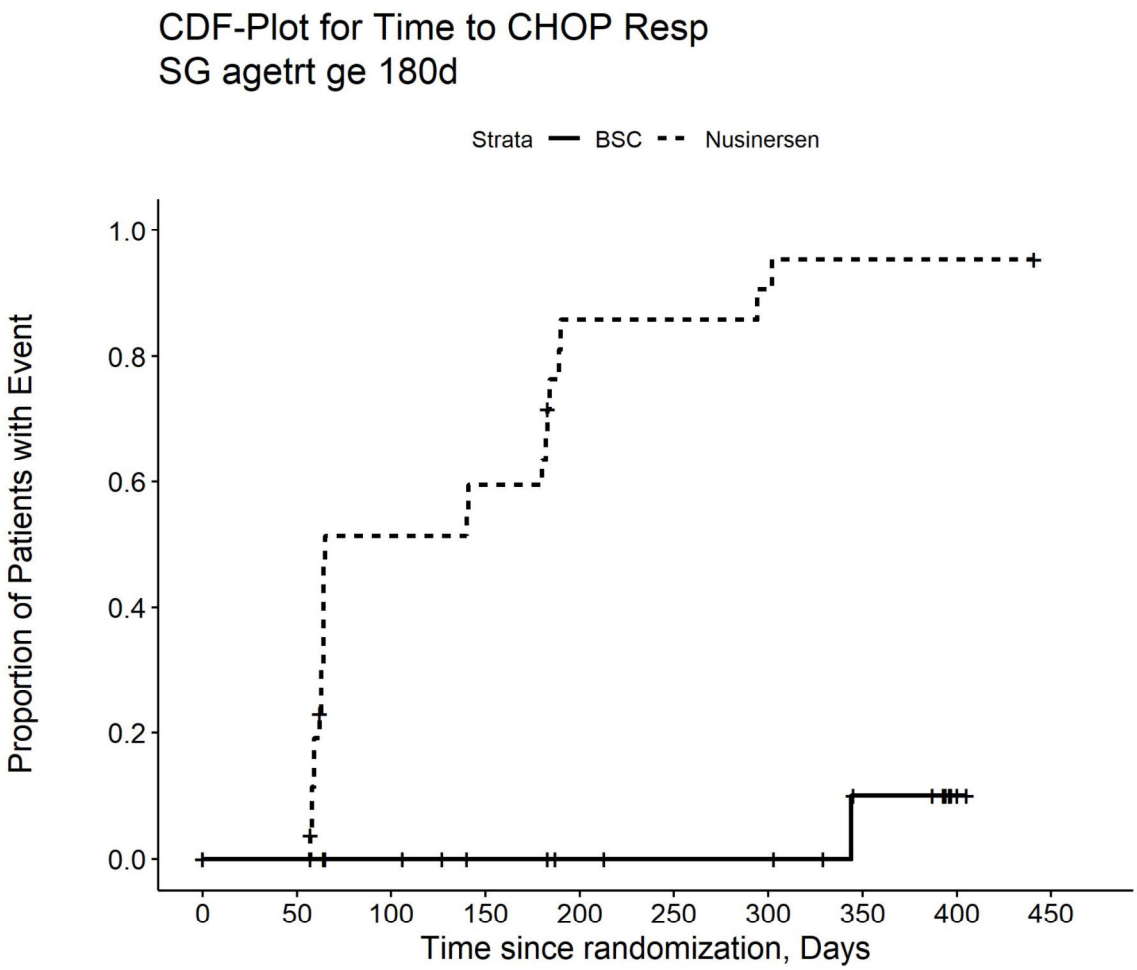
Number at risk

BSC	9	9	8	7	6	5	5	3	0	0
Nusinersen	8	5	3	3	1	1	1	0	0	0



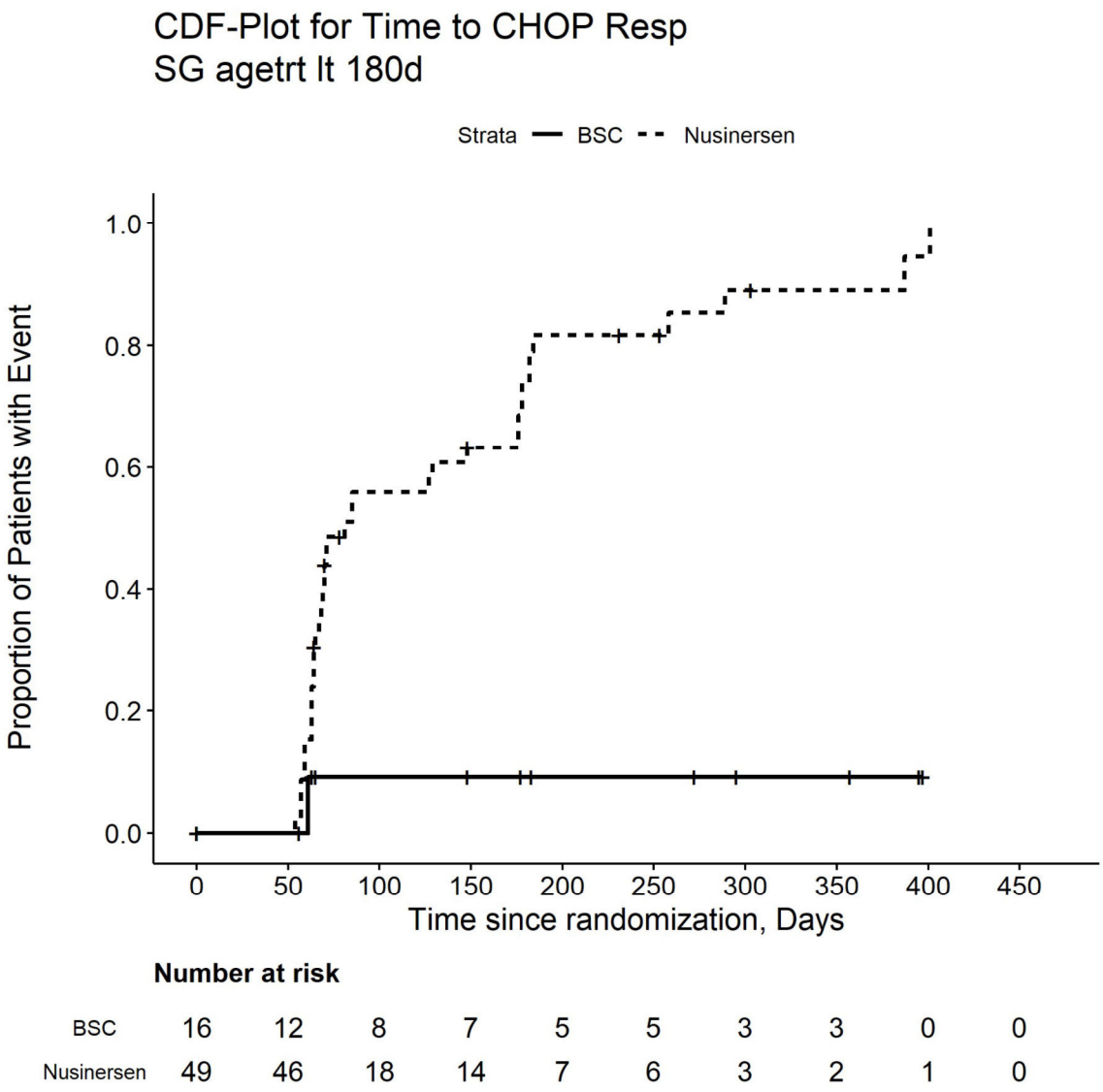
Number at risk

BSC	32	24	18	15	12	12	10	8	2	0
Nusinersen	72	68	27	21	9	8	4	3	2	0



Number at risk

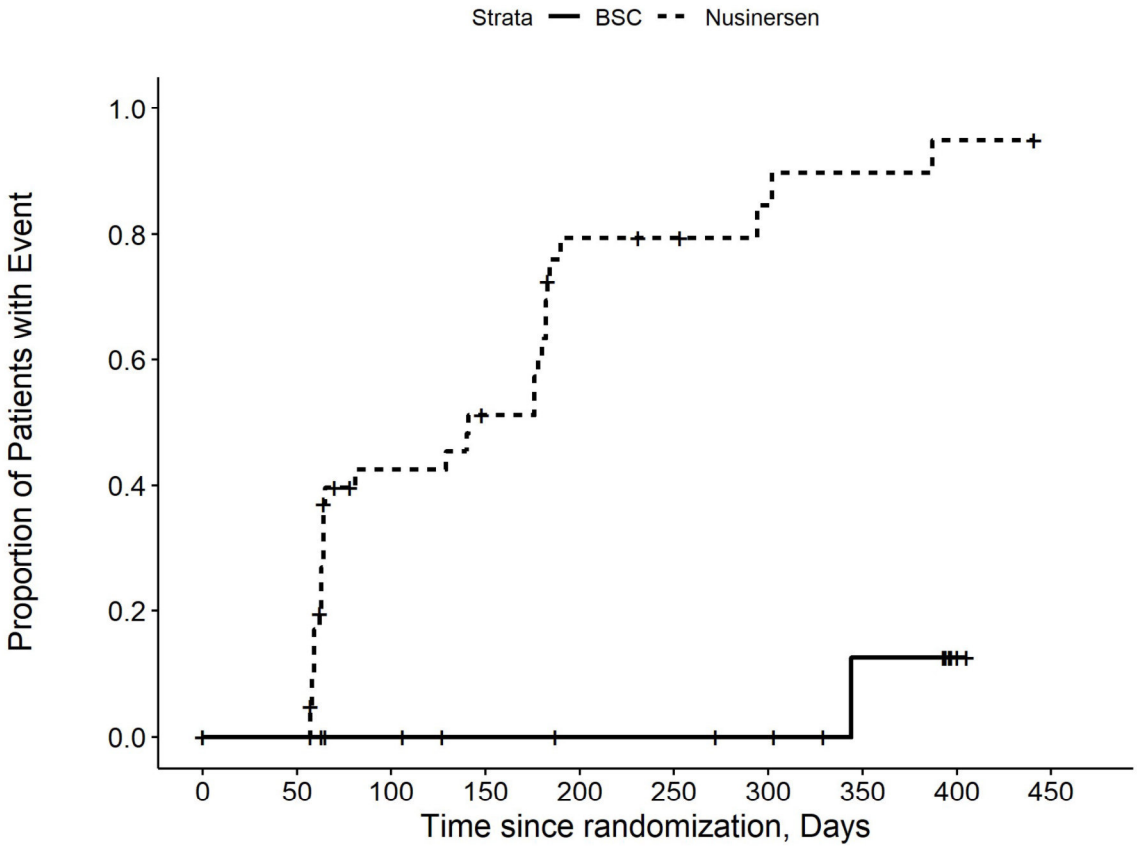
BSC	25	21	18	15	13	12	12	8	2	0
Nusinersen	31	27	12	10	3	3	2	1	1	0



Number at risk

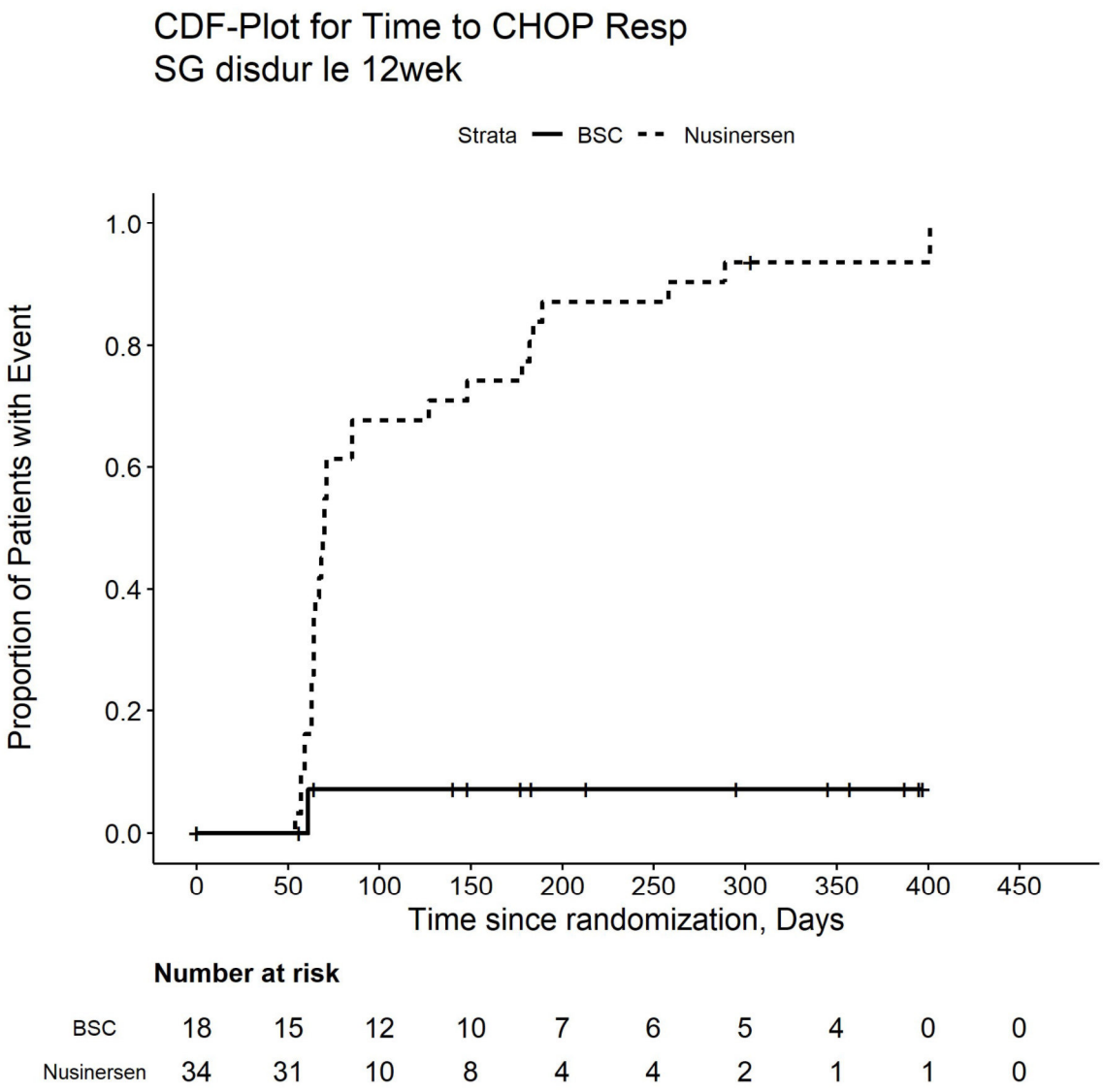
BSC	16	12	8	7	5	5	3	3	0	0
Nusinersen	49	46	18	14	7	6	3	2	1	0

CDF-Plot for Time to CHOP Resp
SG disdur gt 12wk



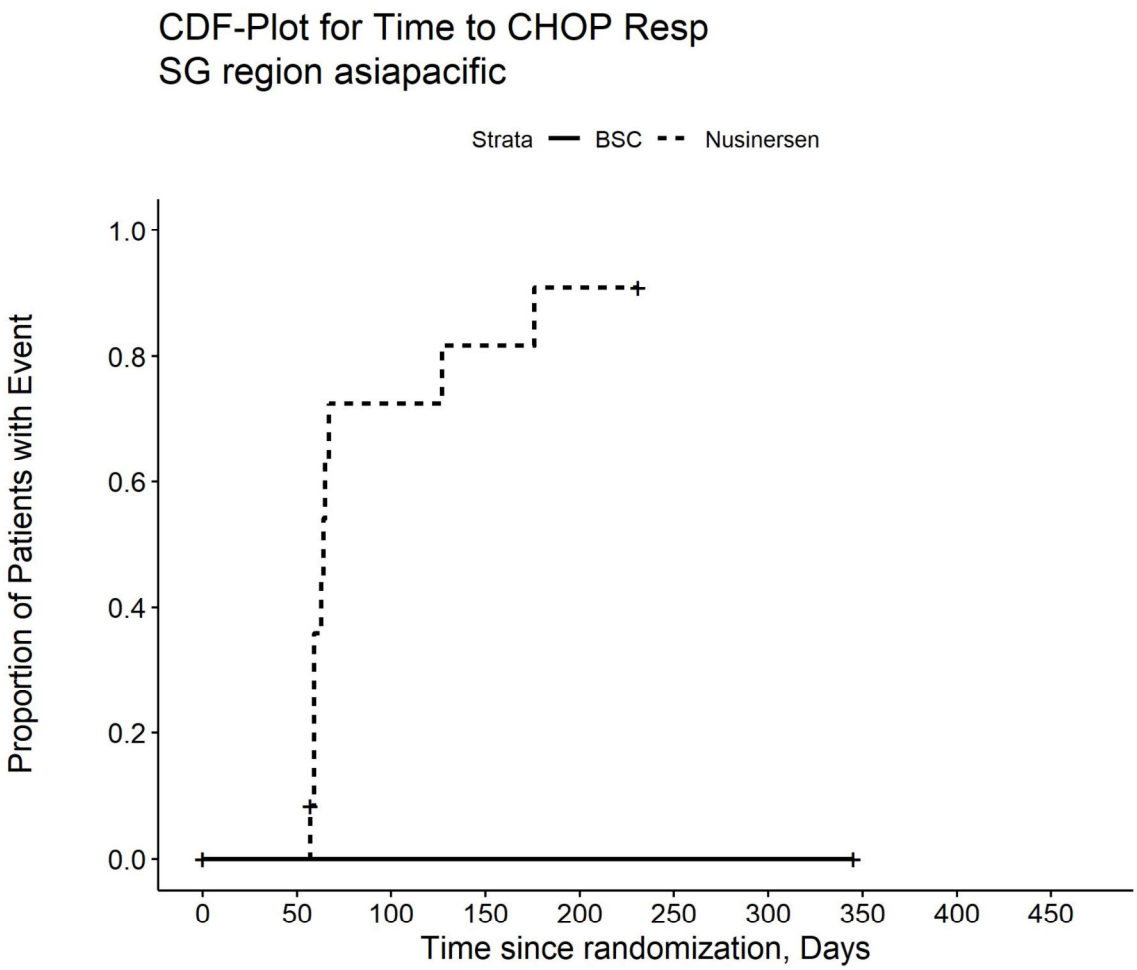
Number at risk

BSC	23	18	14	12	11	11	10	7	2	0
Nusinersen	46	42	20	16	6	5	3	2	1	0



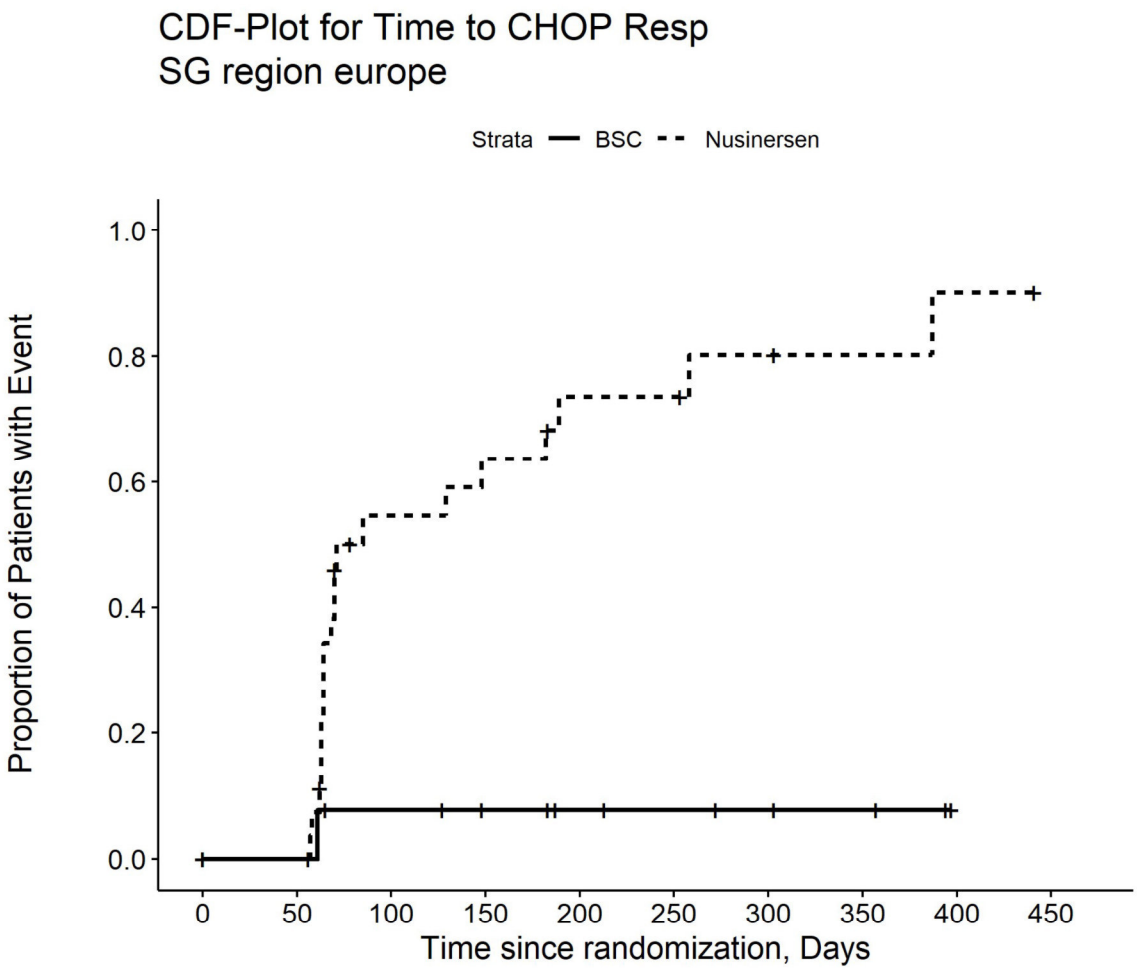
Number at risk

BSC	18	15	12	10	7	6	5	4	0	0
Nusinersen	34	31	10	8	4	4	2	1	1	0



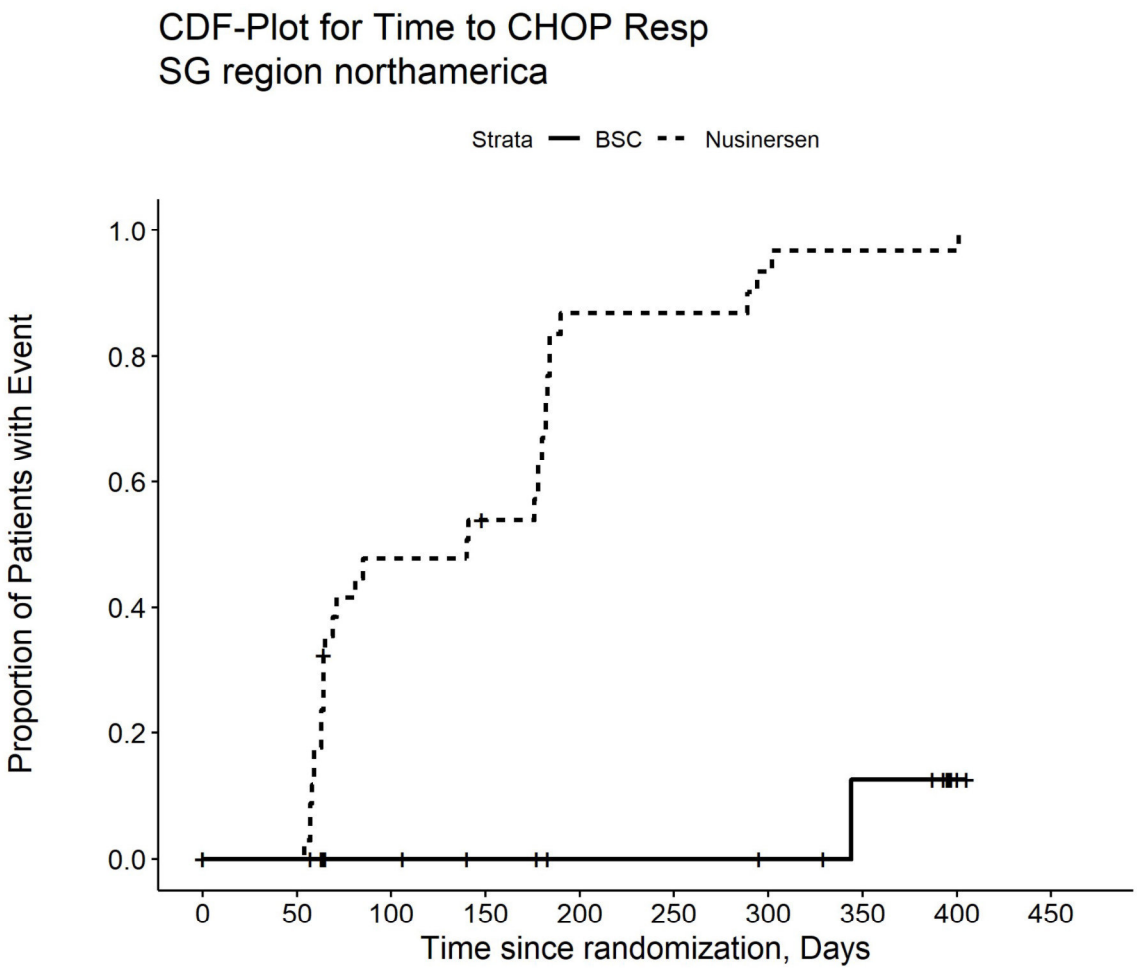
Number at risk

BSC	2	1	1	1	1	1	1	0	0	0
Nusinersen	12	12	3	2	1	0	0	0	0	0



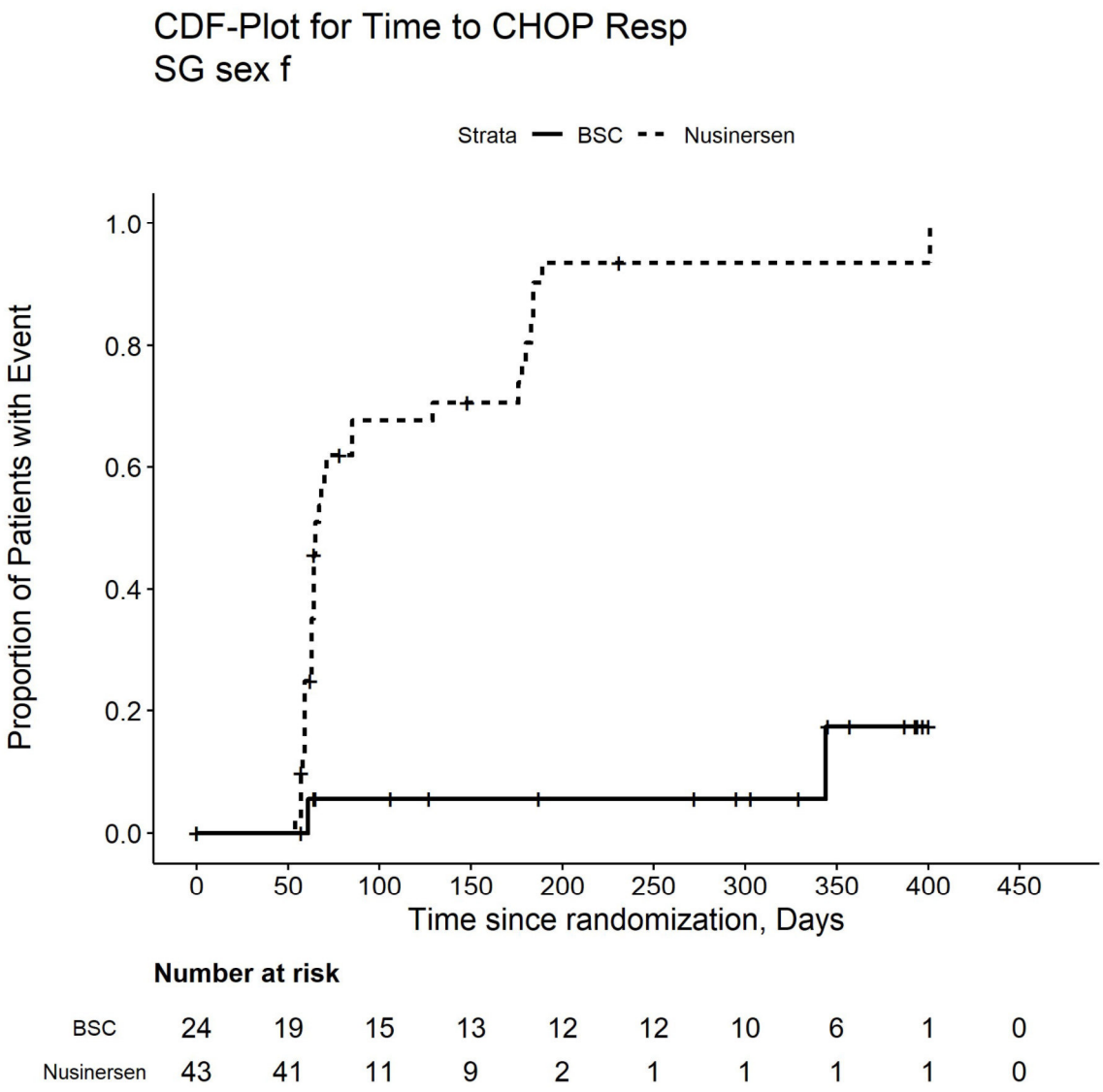
Number at risk

BSC	17	14	11	9	7	6	5	4	0	0
Nusinersen	30	27	10	8	5	5	3	2	1	0



Number at risk

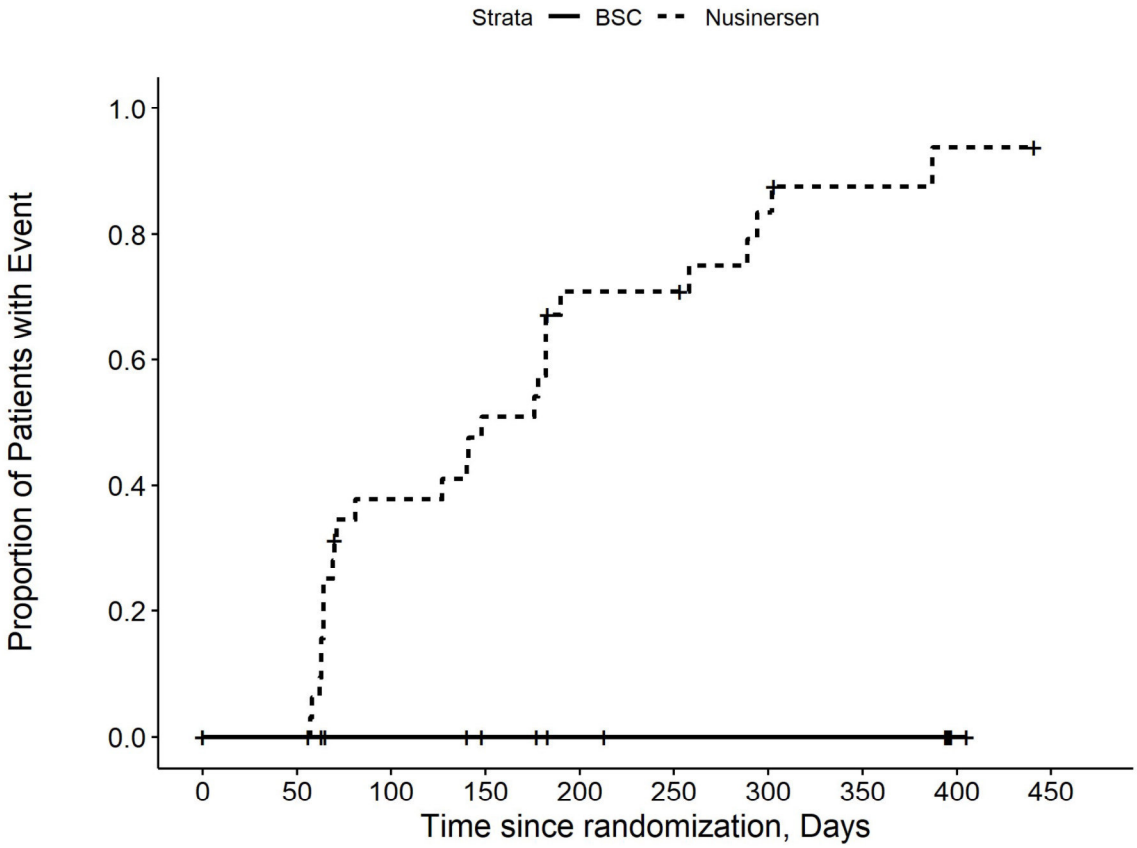
BSC	22	18	14	12	10	10	9	7	2	0
Nusinersen	38	34	17	14	4	4	2	1	1	0



Number at risk

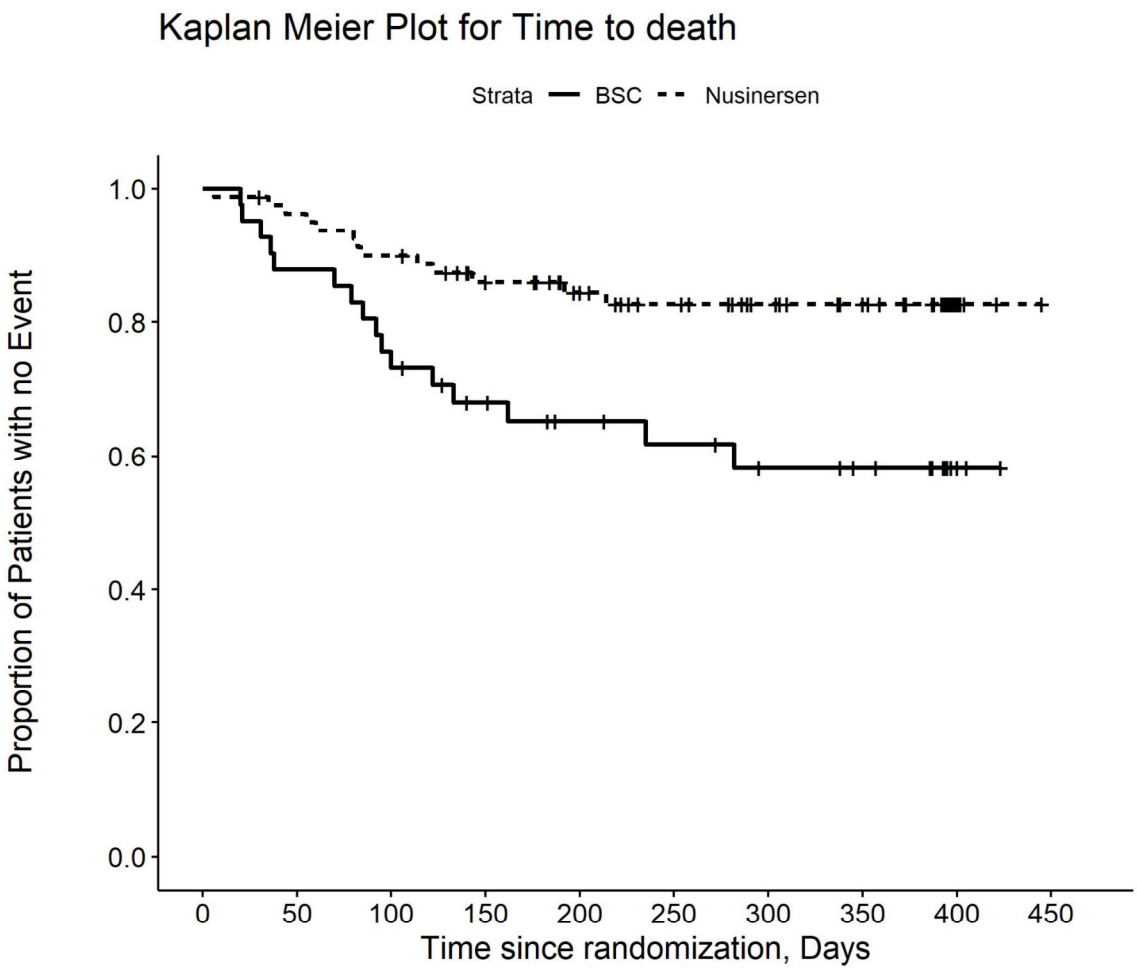
BSC	24	19	15	13	12	12	10	6	1	0
Nusinersen	43	41	11	9	2	1	1	1	1	0

CDF-Plot for Time to CHOP Resp
SG sex m



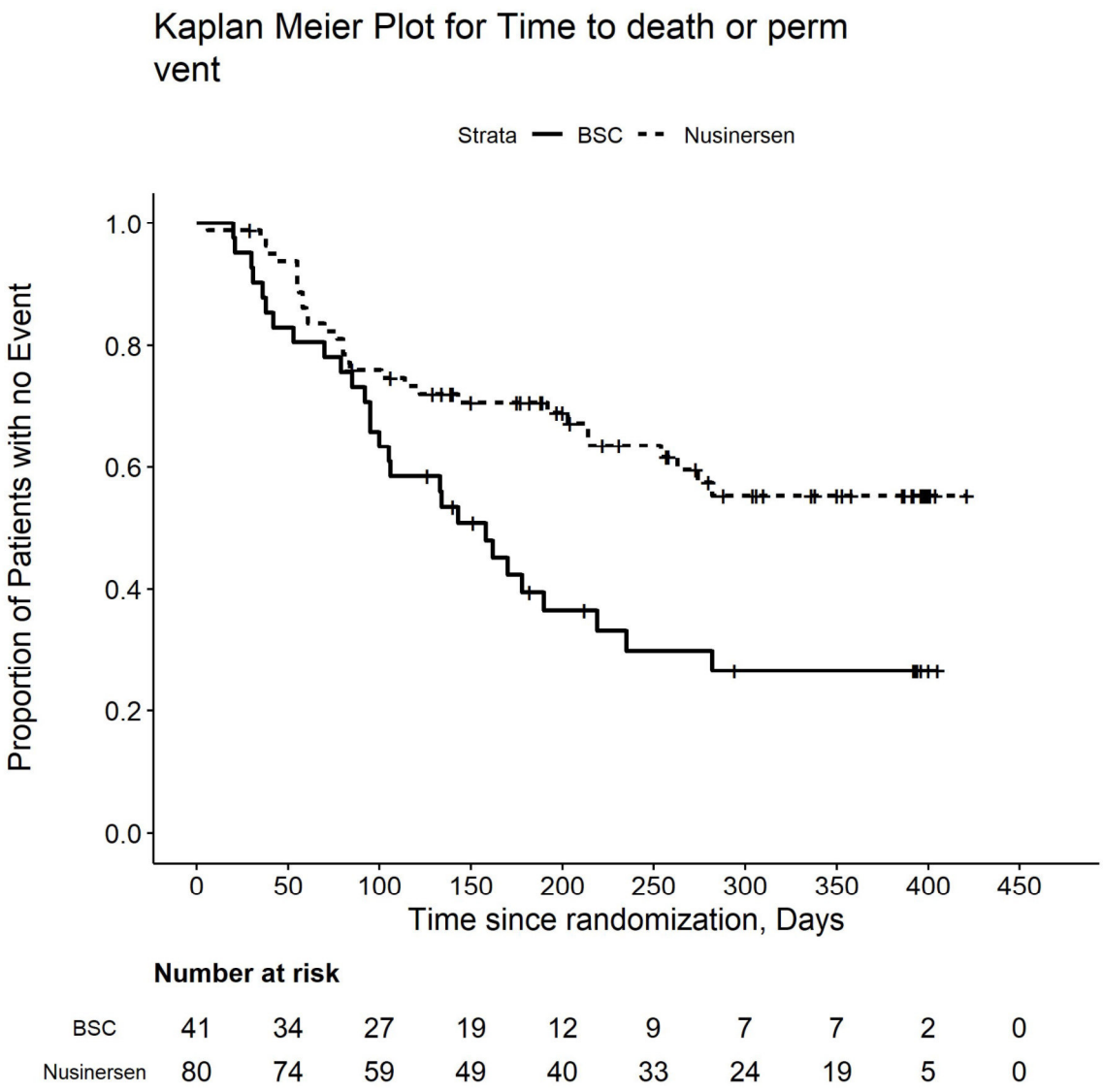
Number at risk

BSC	17	14	11	9	6	5	5	5	1	0
Nusinersen	37	32	19	15	8	8	4	2	1	0



Number at risk

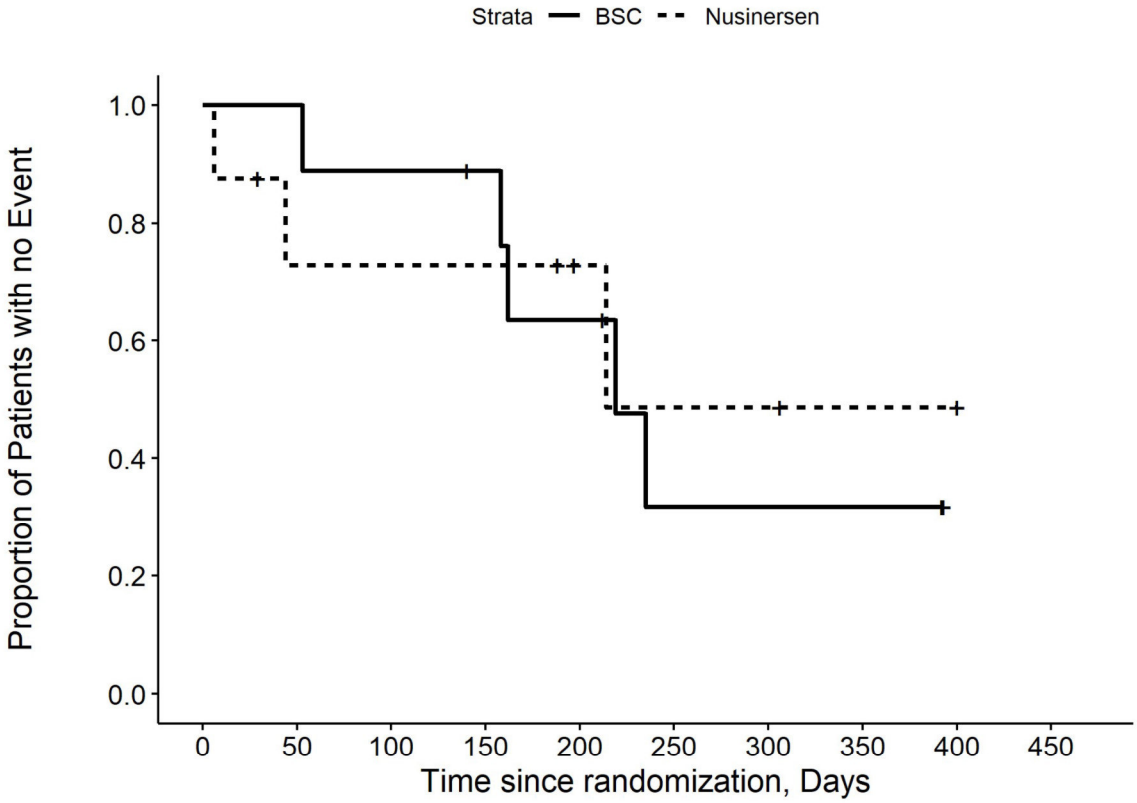
BSC	41	36	31	25	20	18	15	13	4	0
Nusinersen	80	76	71	62	52	44	36	31	11	0



Number at risk

BSC	41	34	27	19	12	9	7	7	2	0
Nusinersen	80	74	59	49	40	33	24	19	5	0

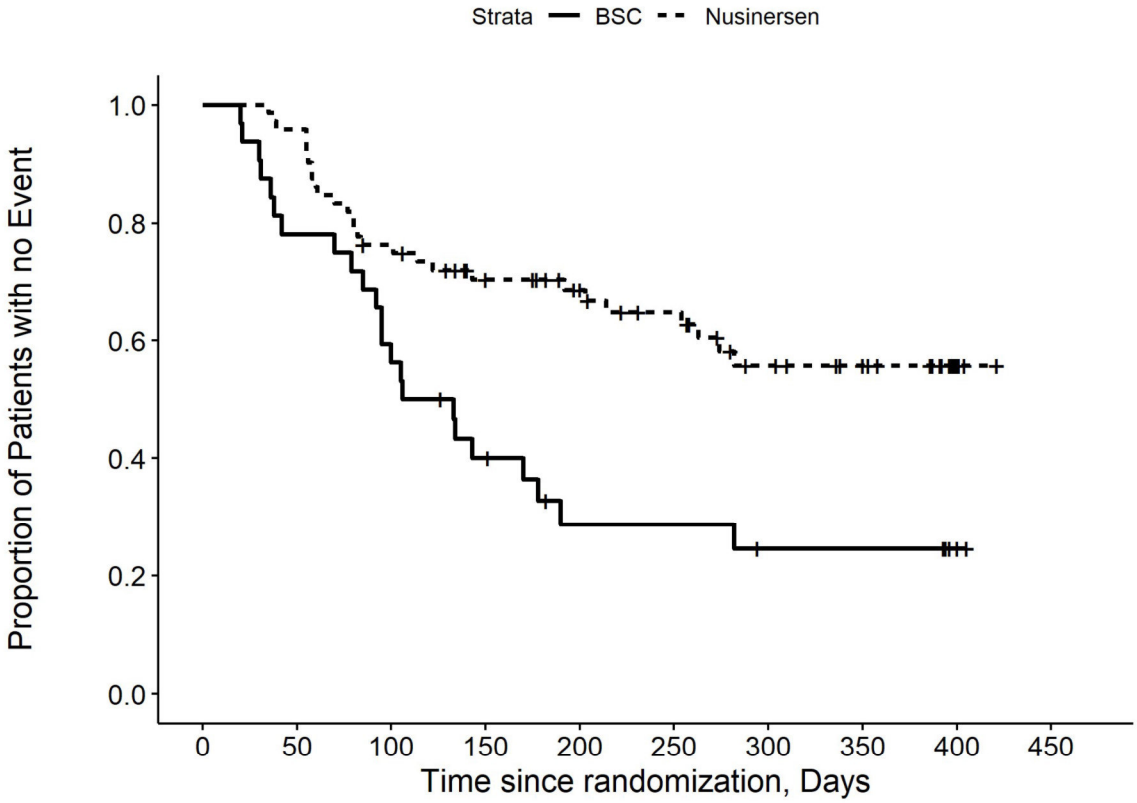
Kaplan Meier Plot for Time to death or permVent SG ageonset gt 12wk



Number at risk

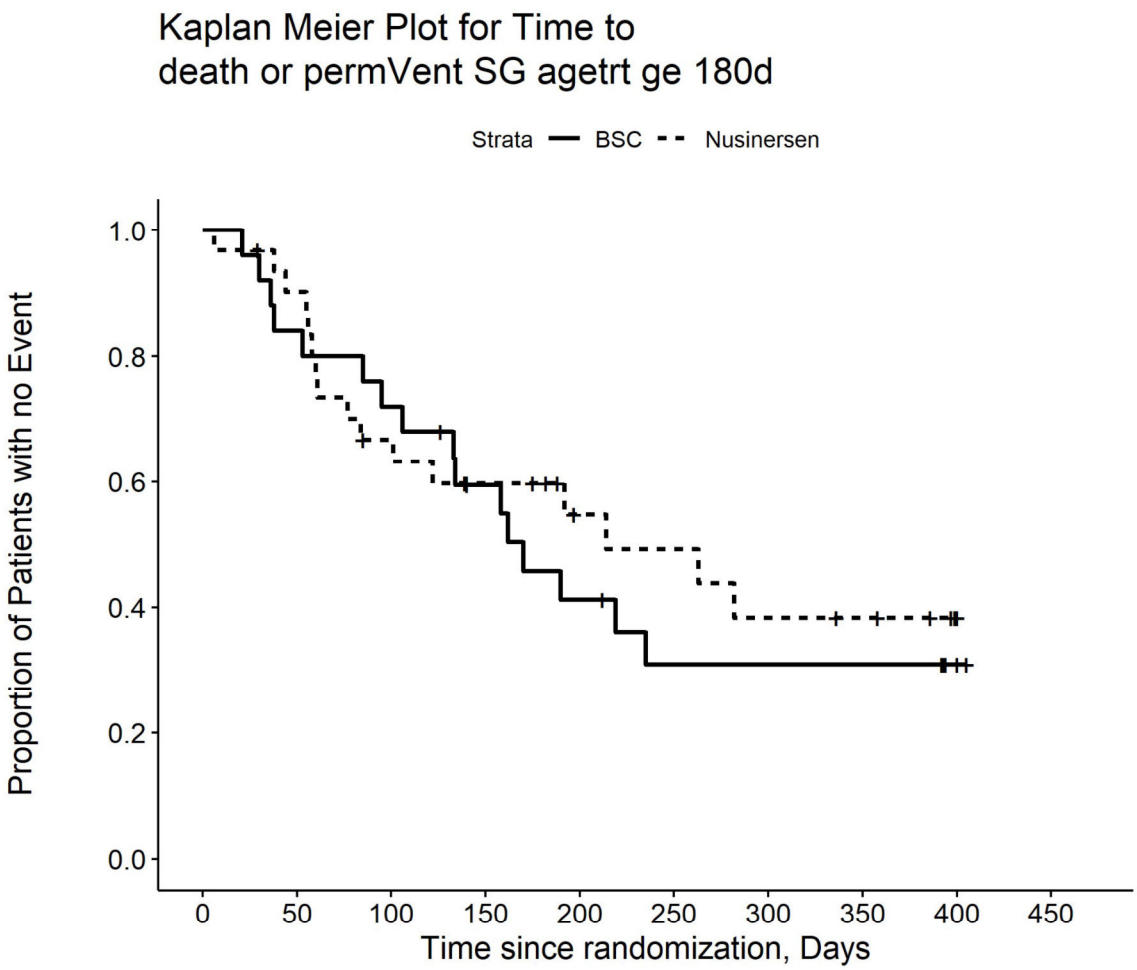
BSC	9	9	8	7	5	2	2	2	0	0
Nusinersen	8	5	5	5	3	2	2	1	1	0

Kaplan Meier Plot for Time to death or permVent SG ageonset le 12wk



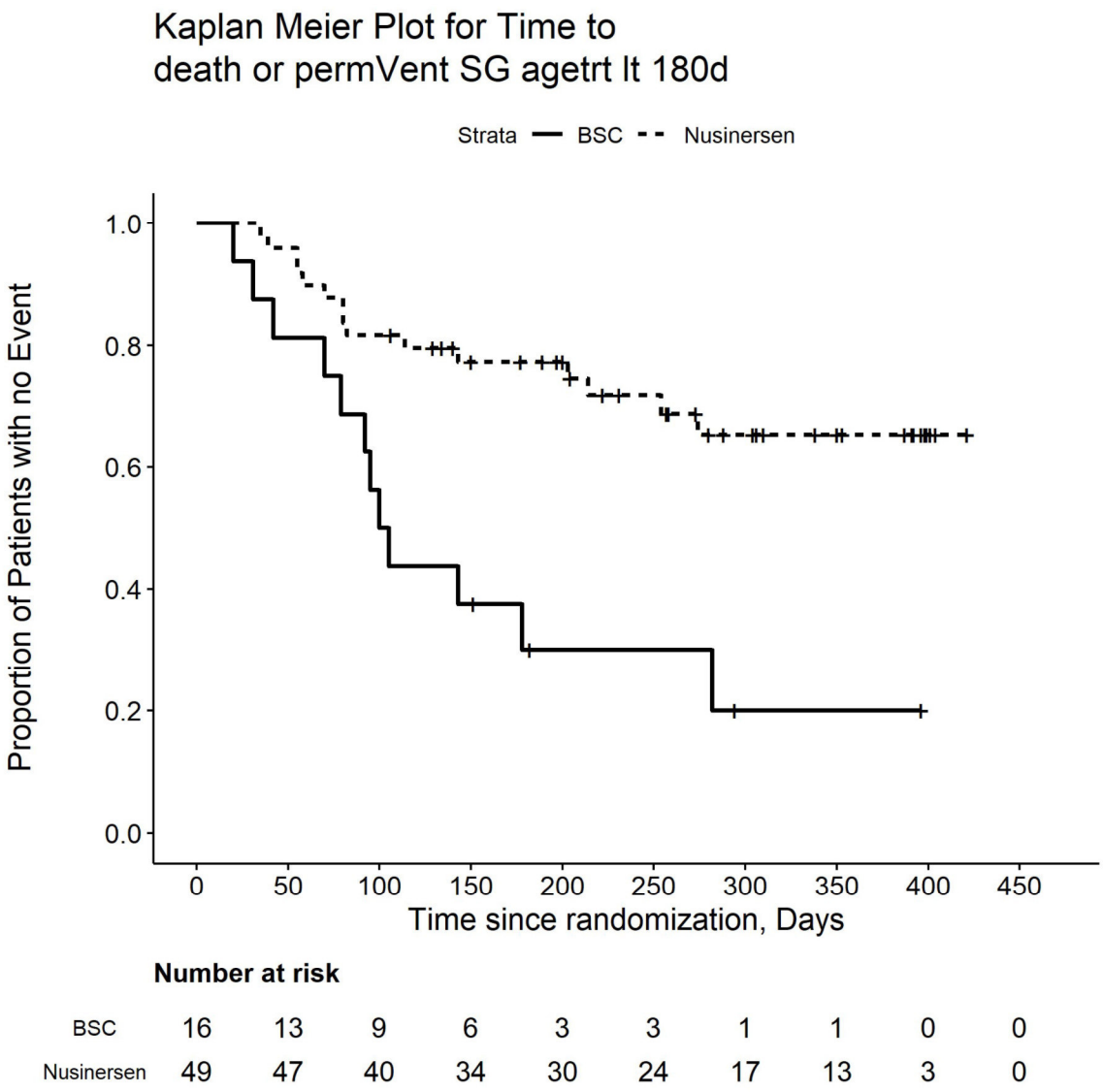
Number at risk

BSC	32	25	19	12	7	7	5	5	2	0
Nusinersen	72	69	54	44	37	31	22	18	4	0



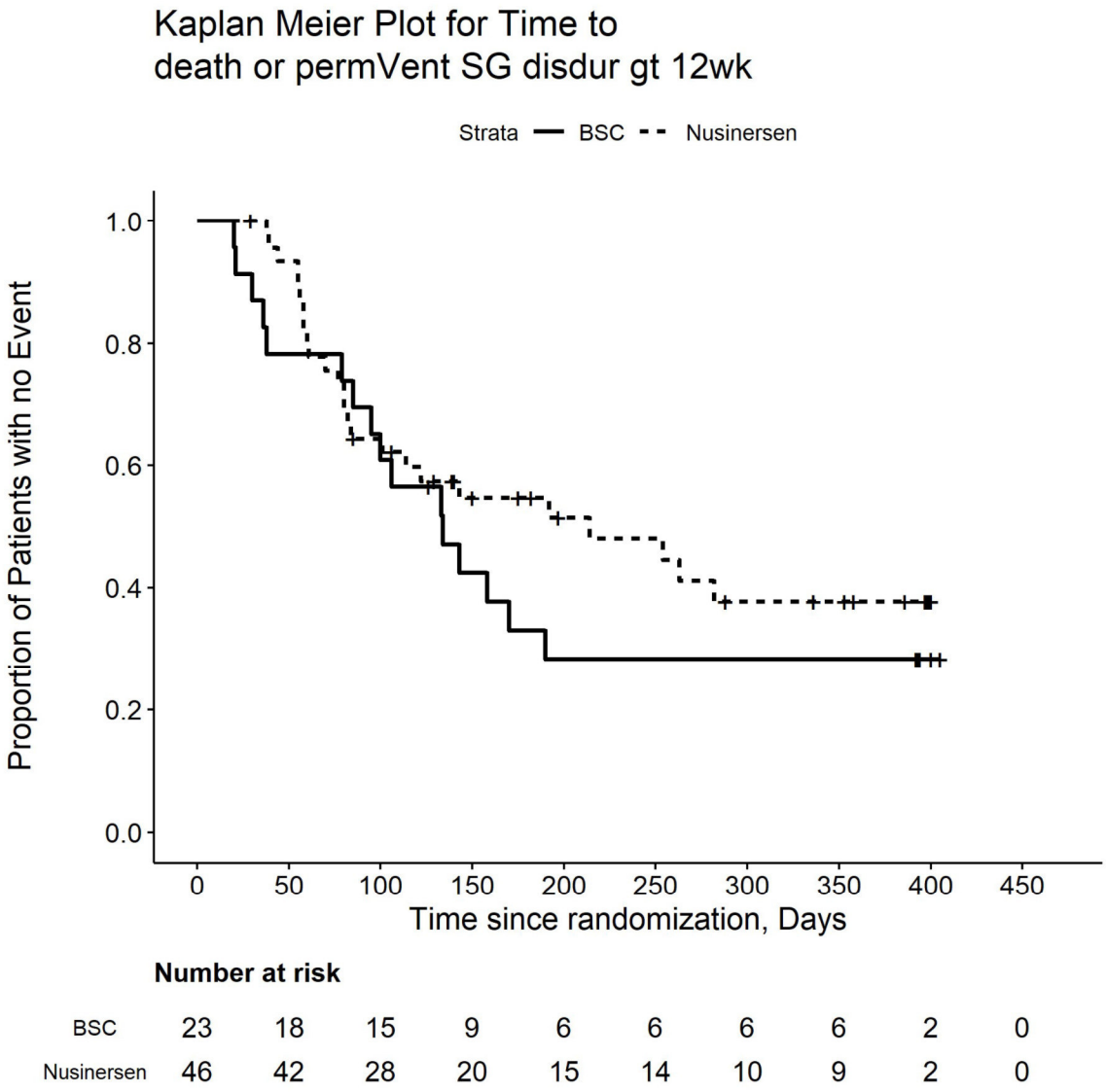
Number at risk

BSC	25	21	18	13	9	6	6	6	2	0
Nusinersen	31	27	19	15	10	9	7	6	2	0



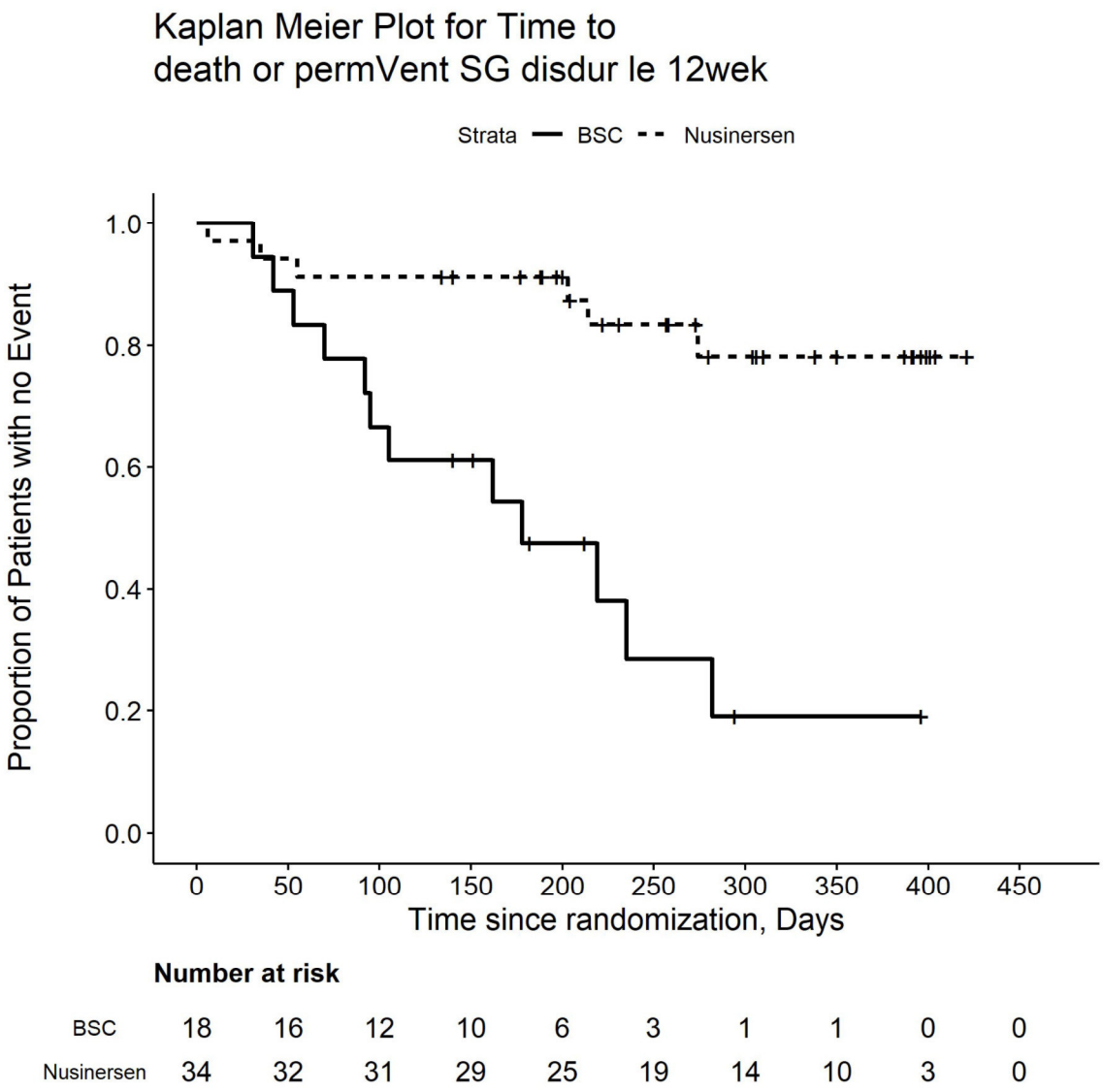
Number at risk

BSC	16	13	9	6	3	3	1	1	0	0
Nusinersen	49	47	40	34	30	24	17	13	3	0



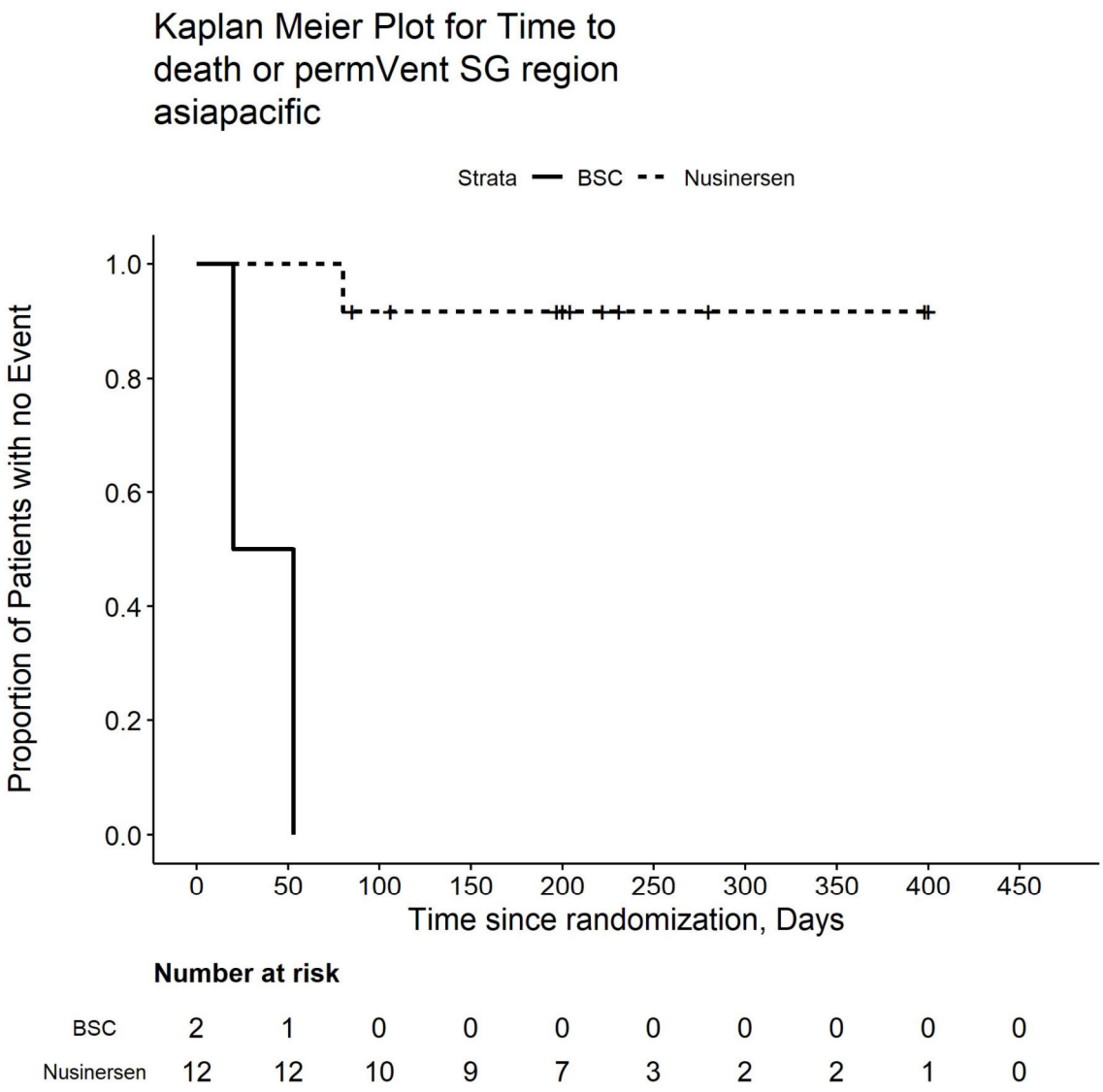
Number at risk

BSC	23	18	15	9	6	6	6	6	2	0
Nusinersen	46	42	28	20	15	14	10	9	2	0



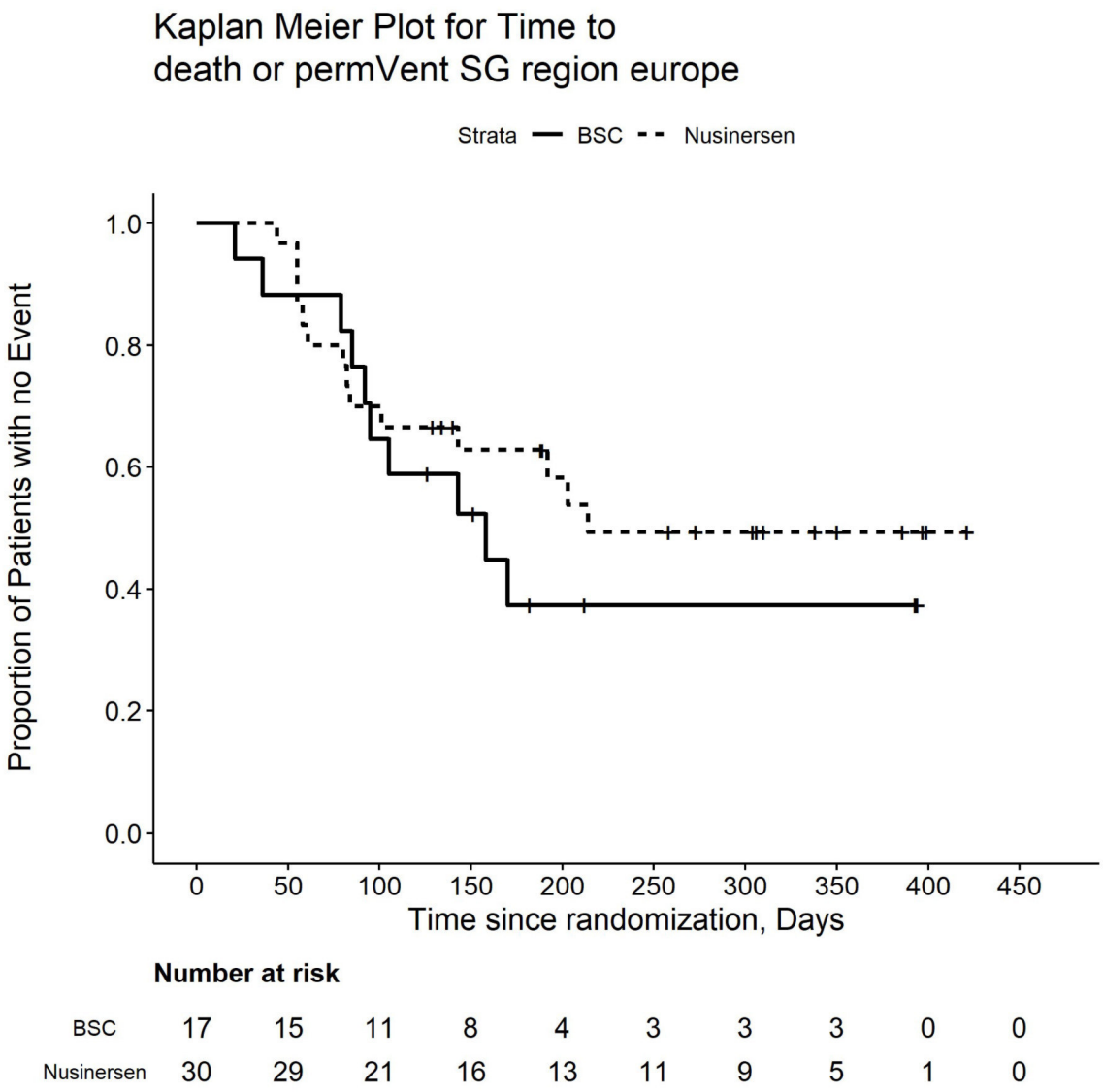
Number at risk

BSC	18	16	12	10	6	3	1	1	0	0
Nusinersen	34	32	31	29	25	19	14	10	3	0



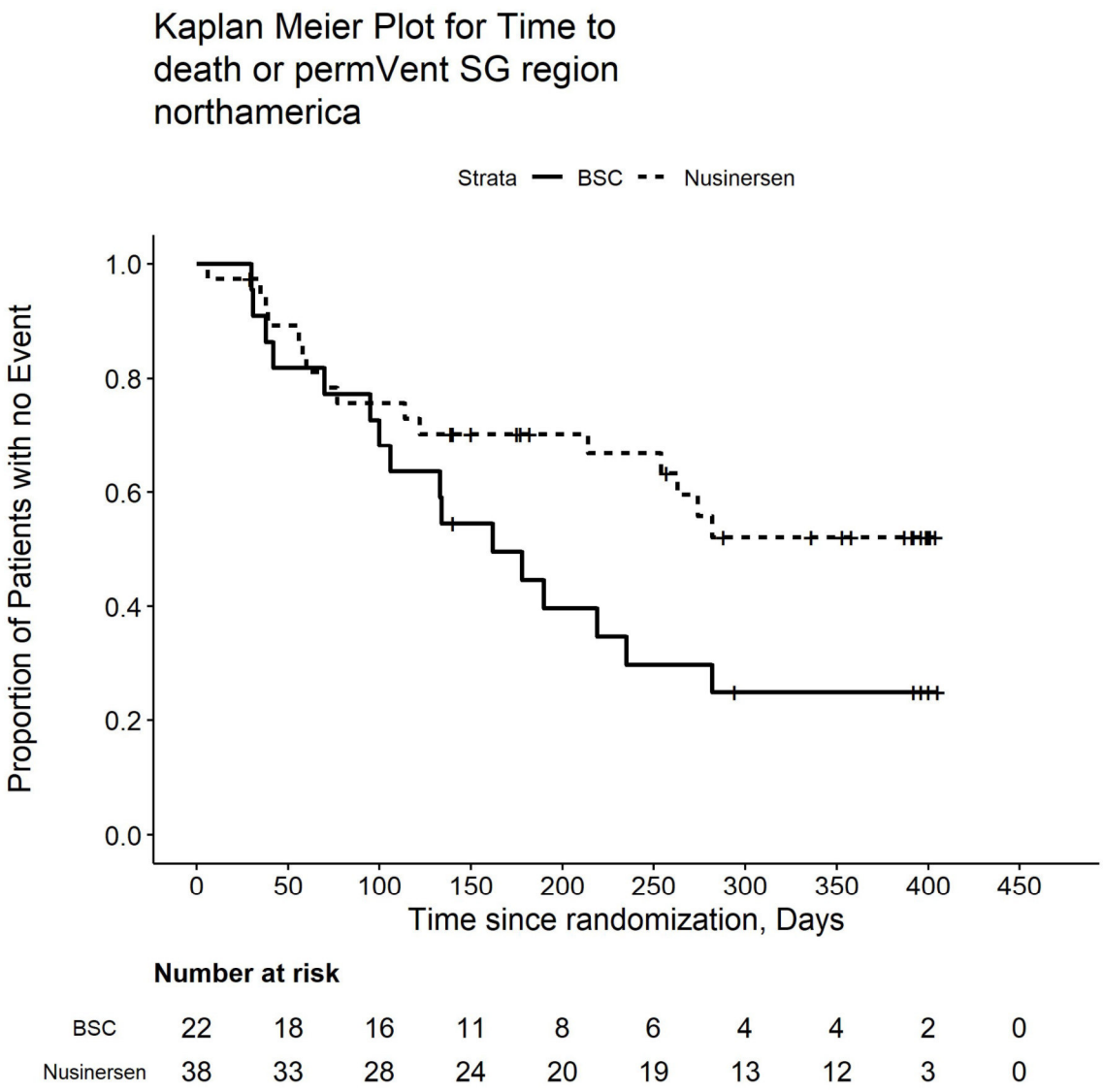
Number at risk

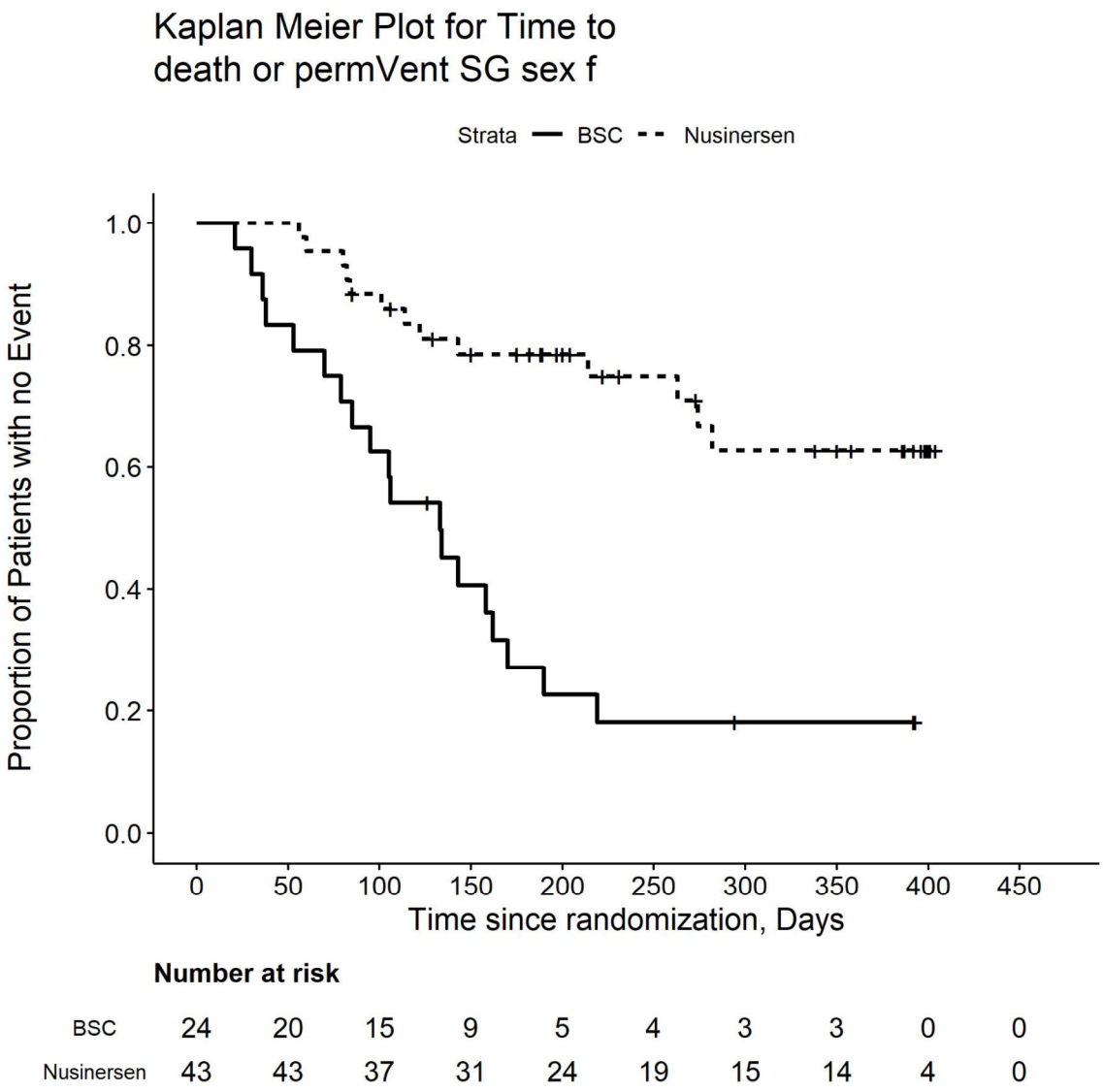
BSC	2	1	0	0	0	0	0	0	0	0
Nusinersen	12	12	10	9	7	3	2	2	1	0



Number at risk

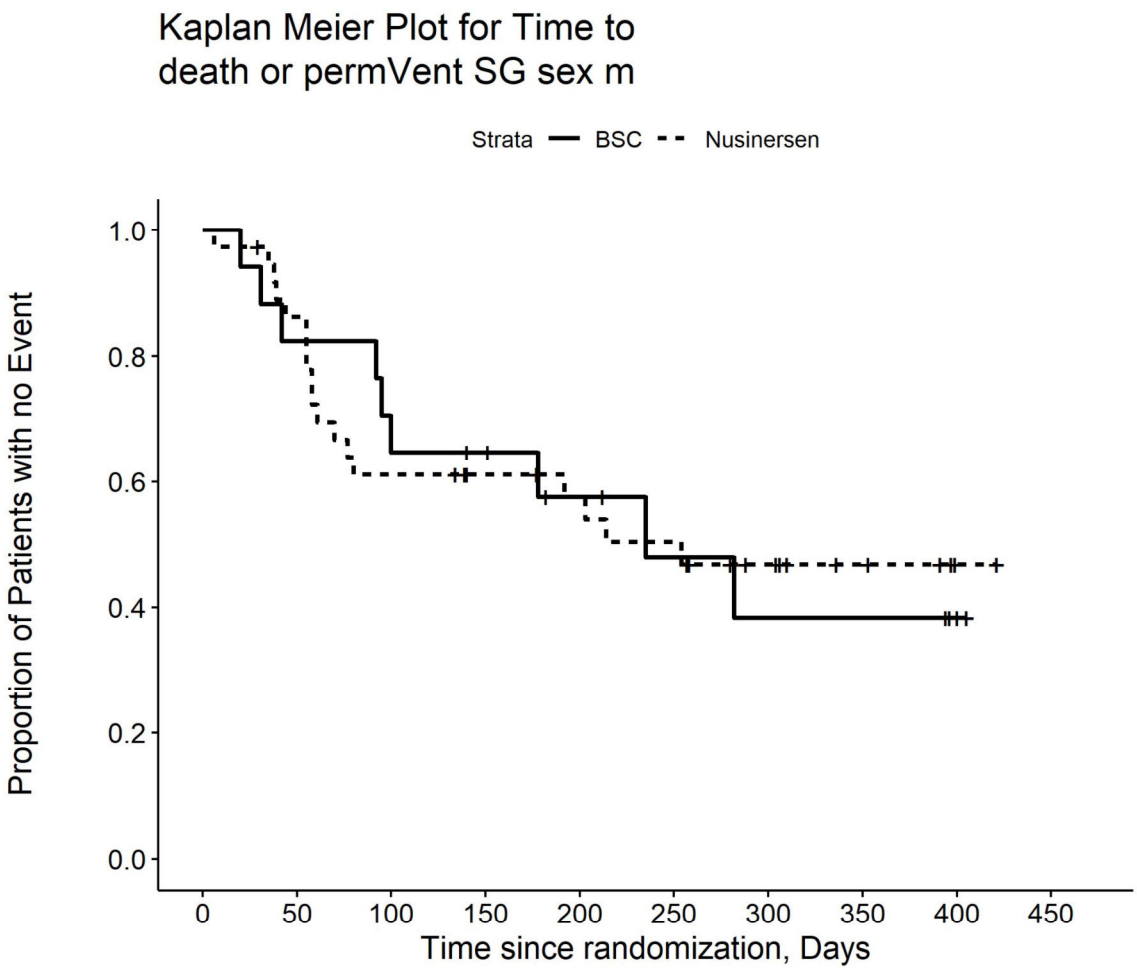
BSC	17	15	11	8	4	3	3	3	0	0
Nusinersen	30	29	21	16	13	11	9	5	1	0


Kaplan Meier Plot for Time to death or permVent SG region northamerica
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0 50 100 150 200 250 300 350 400 450
Time since randomization, Days
Number at risk
BSC 22 18 16 11 8 6 4 4 2 0
Nusinersen 38 33 28 24 20 19 13 12 3 0



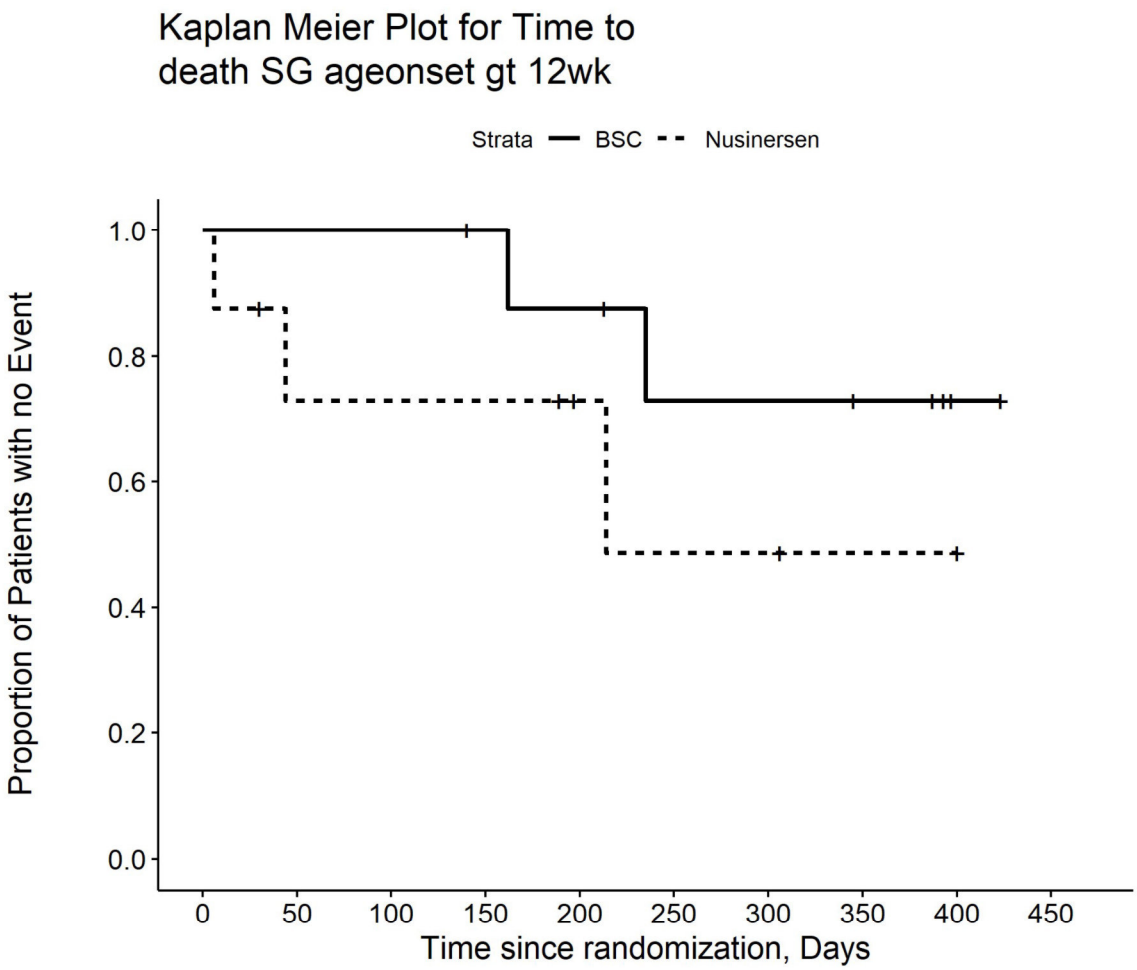
Number at risk

BSC	24	20	15	9	5	4	3	3	0	0
Nusinersen	43	43	37	31	24	19	15	14	4	0



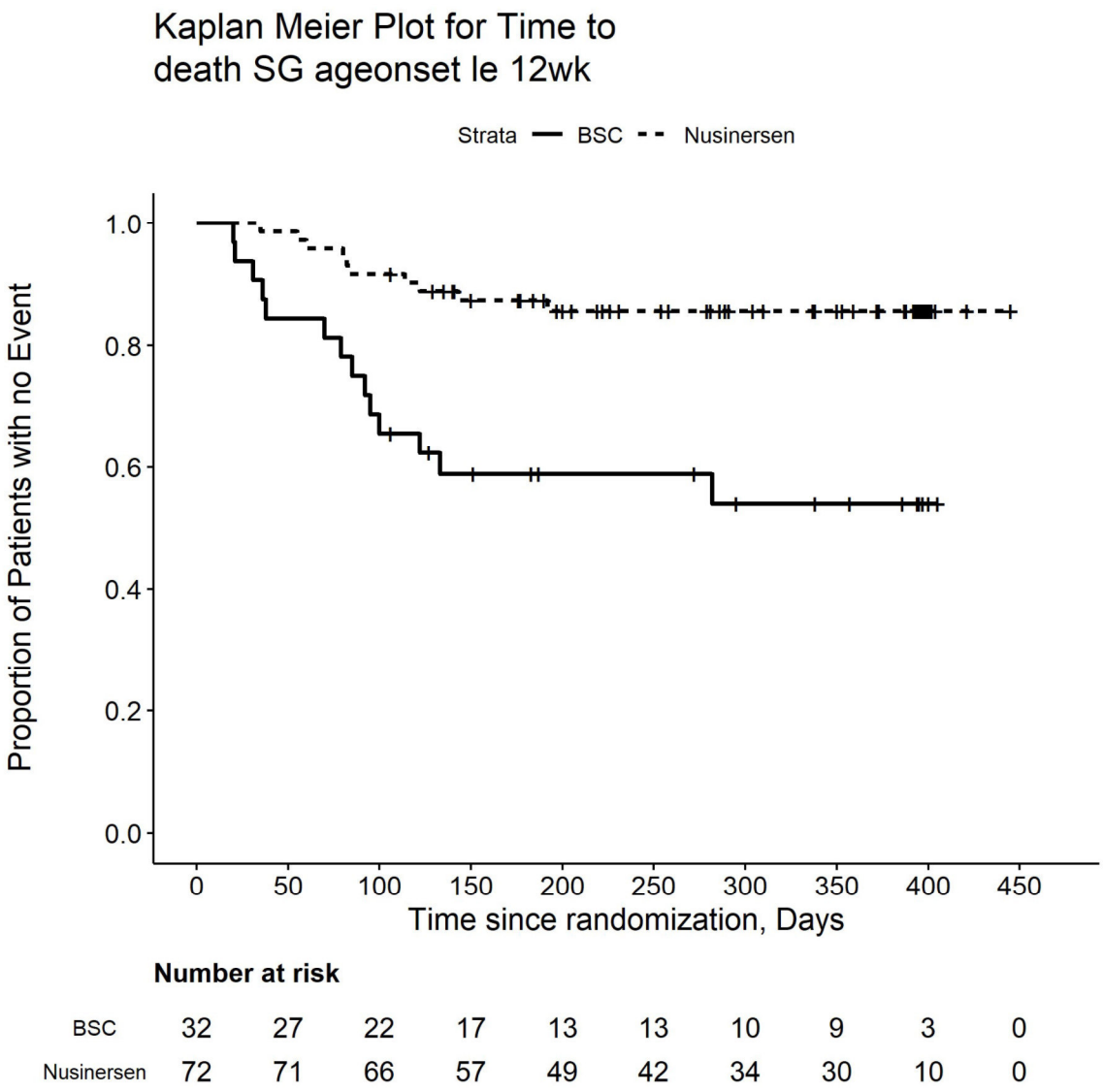
Number at risk

BSC	17	14	12	10	7	5	4	4	2	0
Nusinersen	37	31	22	18	16	14	9	5	1	0



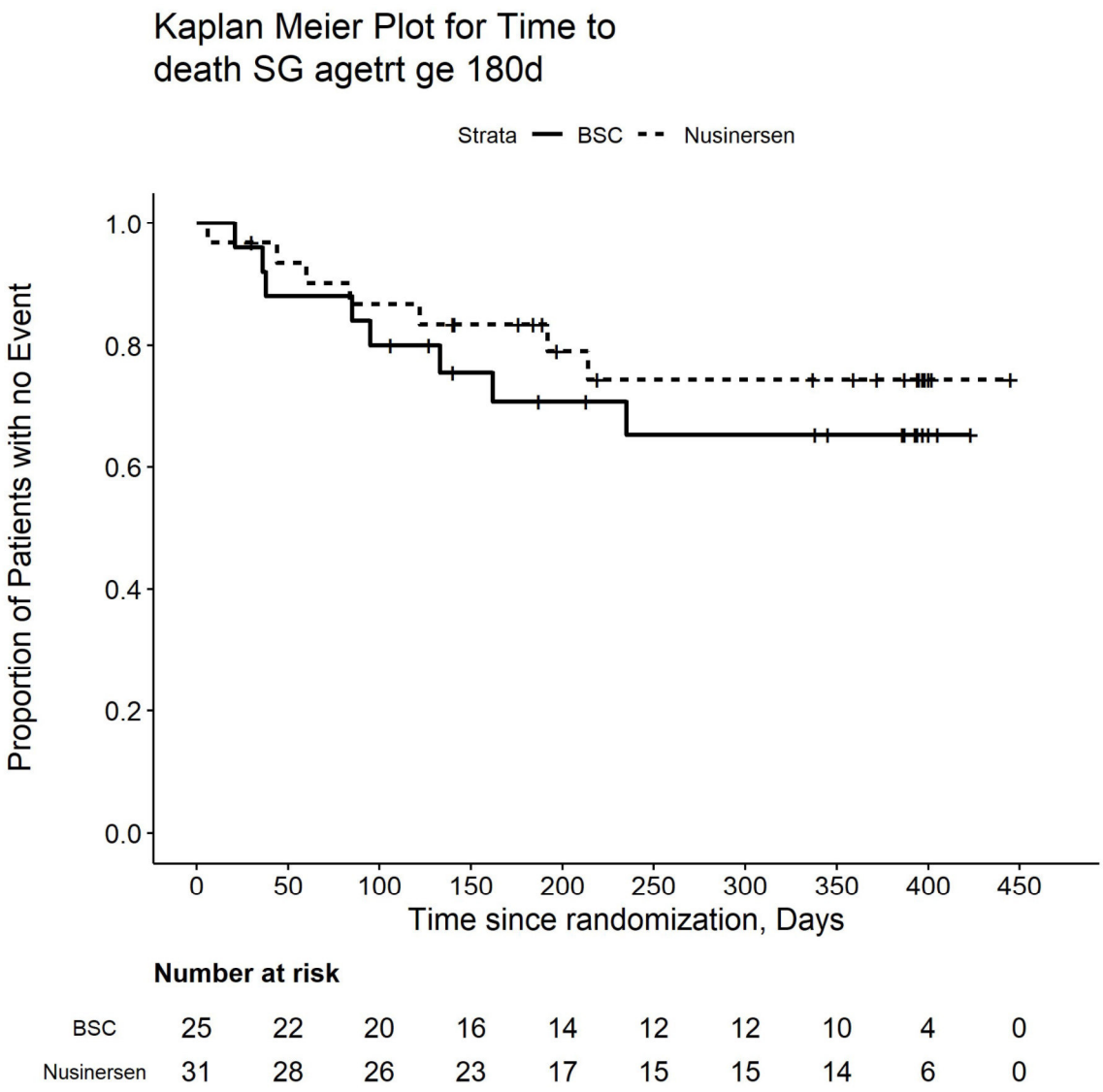
Number at risk

BSC	9	9	9	8	7	5	5	4	1	0
Nusinersen	8	5	5	5	3	2	2	1	1	0



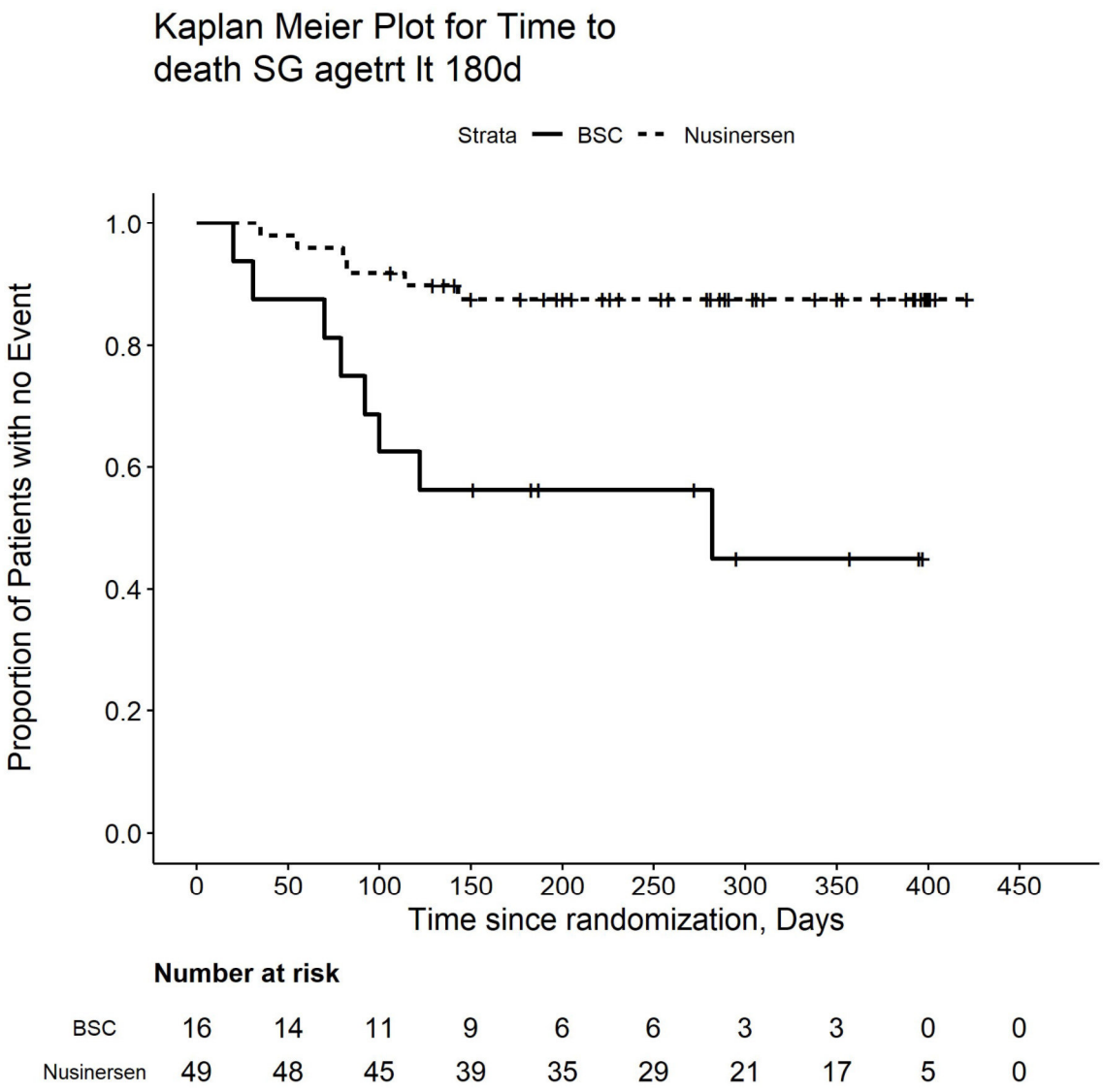
Number at risk

BSC	32	27	22	17	13	13	10	9	3	0
Nusinersen	72	71	66	57	49	42	34	30	10	0



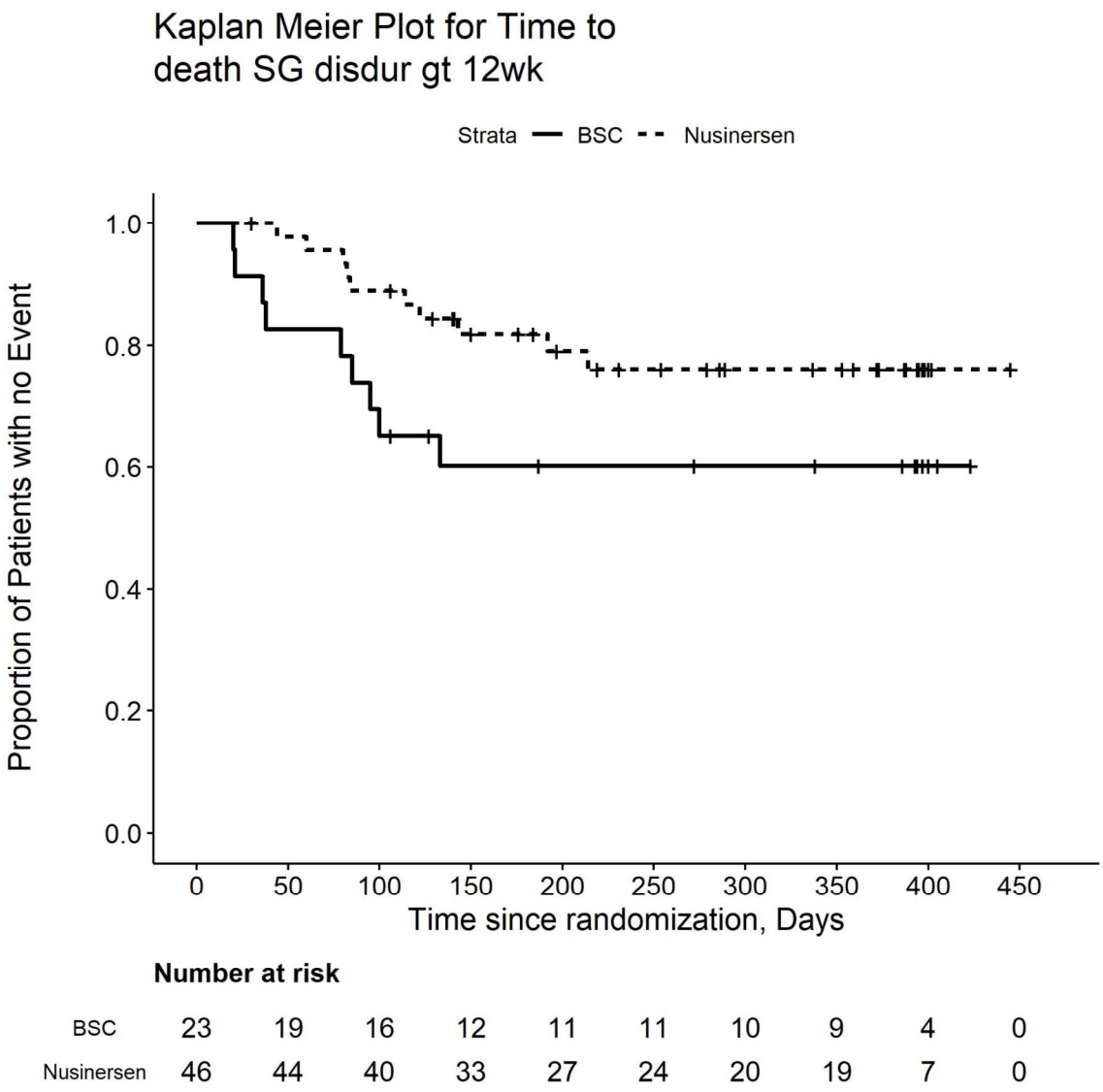
Number at risk

BSC	25	22	20	16	14	12	12	10	4	0
Nusinersen	31	28	26	23	17	15	15	14	6	0



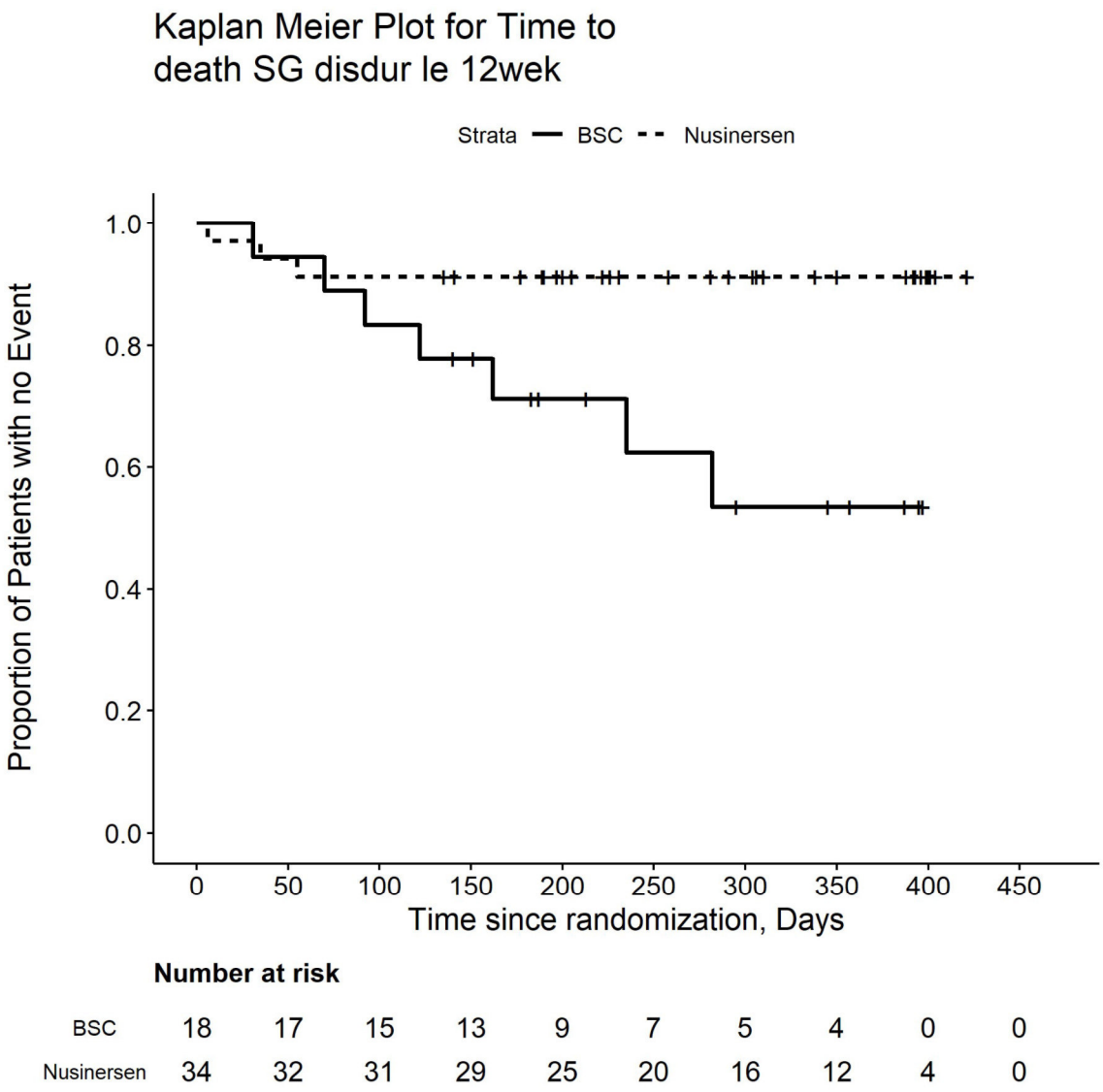
Number at risk

BSC	16	14	11	9	6	6	3	3	0	0
Nusinersen	49	48	45	39	35	29	21	17	5	0



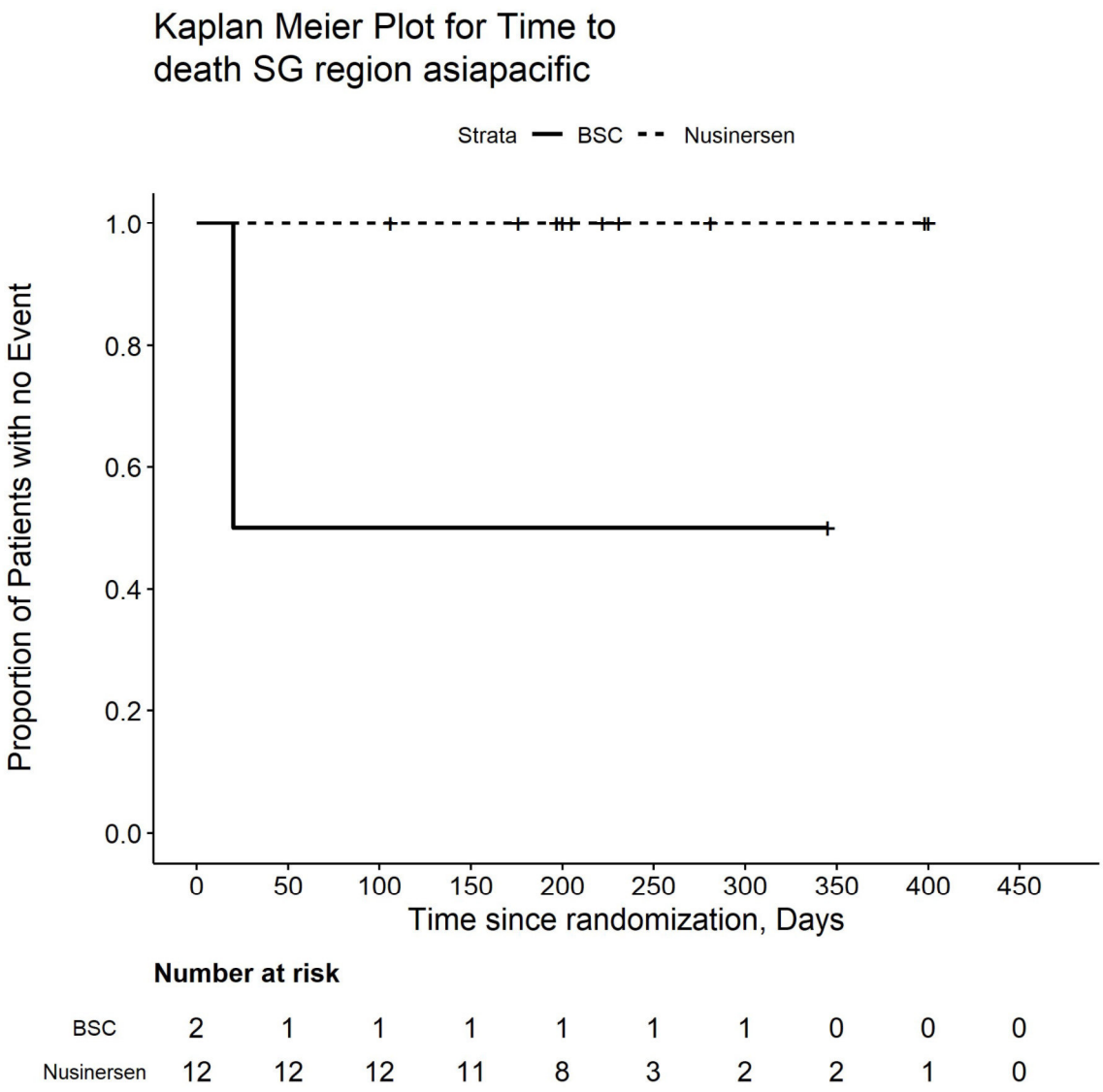
Number at risk

BSC	23	19	16	12	11	11	10	9	4	0
Nusinersen	46	44	40	33	27	24	20	19	7	0



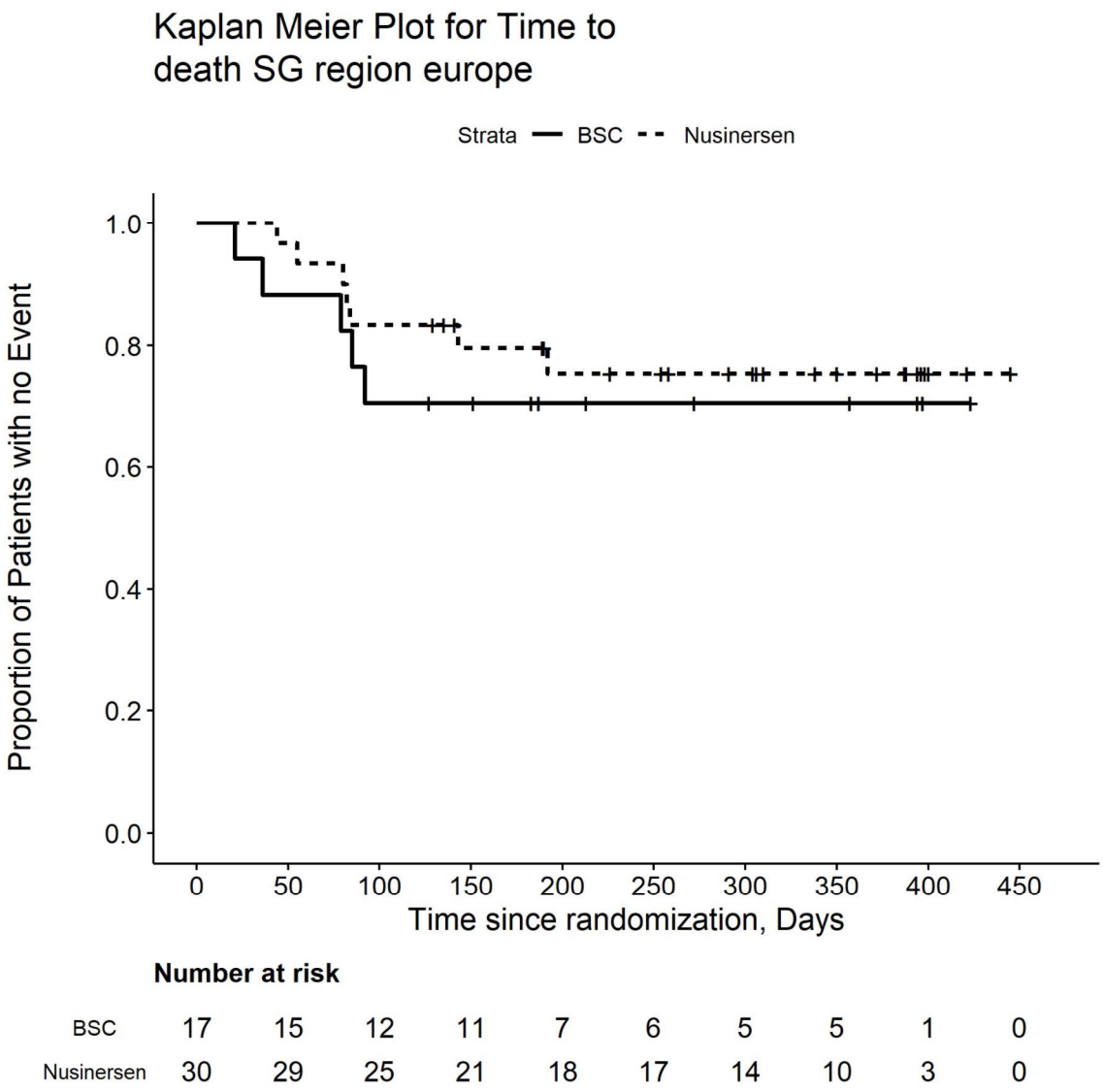
Number at risk

BSC	18	17	15	13	9	7	5	4	0	0
Nusinersen	34	32	31	29	25	20	16	12	4	0



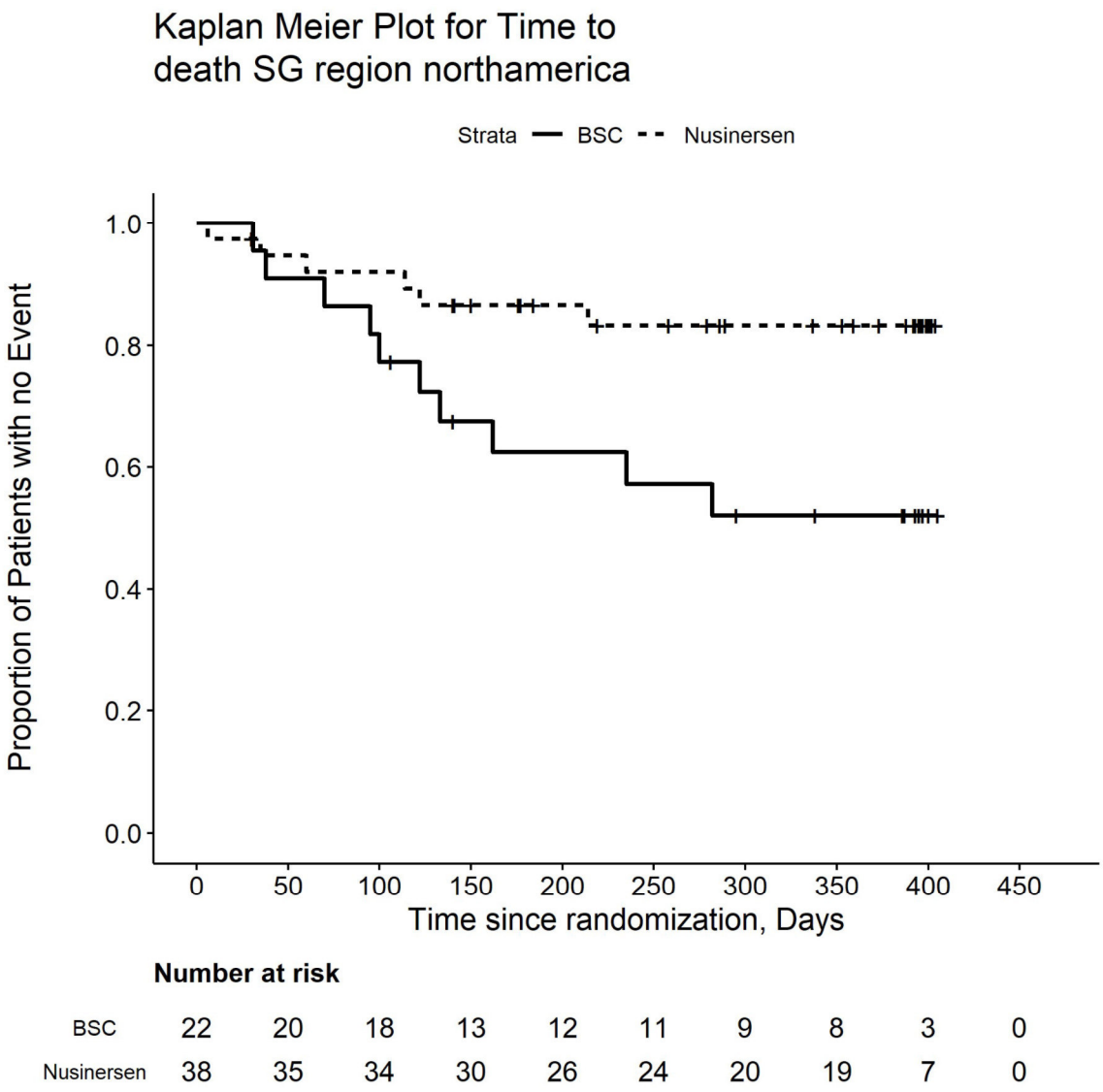
Number at risk

BSC	2	1	1	1	1	1	1	0	0	0
Nusinersen	12	12	12	11	8	3	2	2	1	0



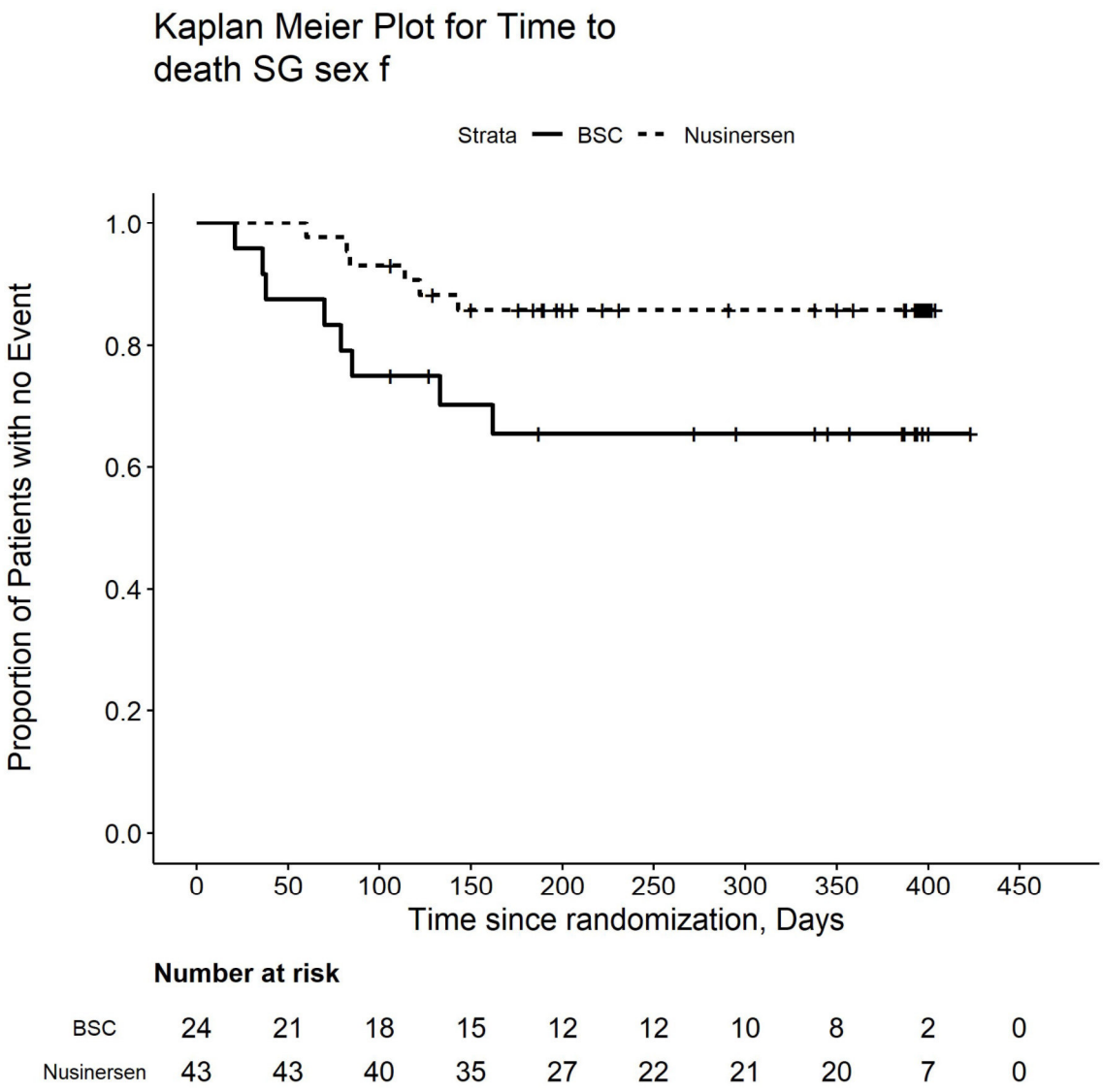
Number at risk

BSC	17	15	12	11	7	6	5	5	1	0
Nusinersen	30	29	25	21	18	17	14	10	3	0



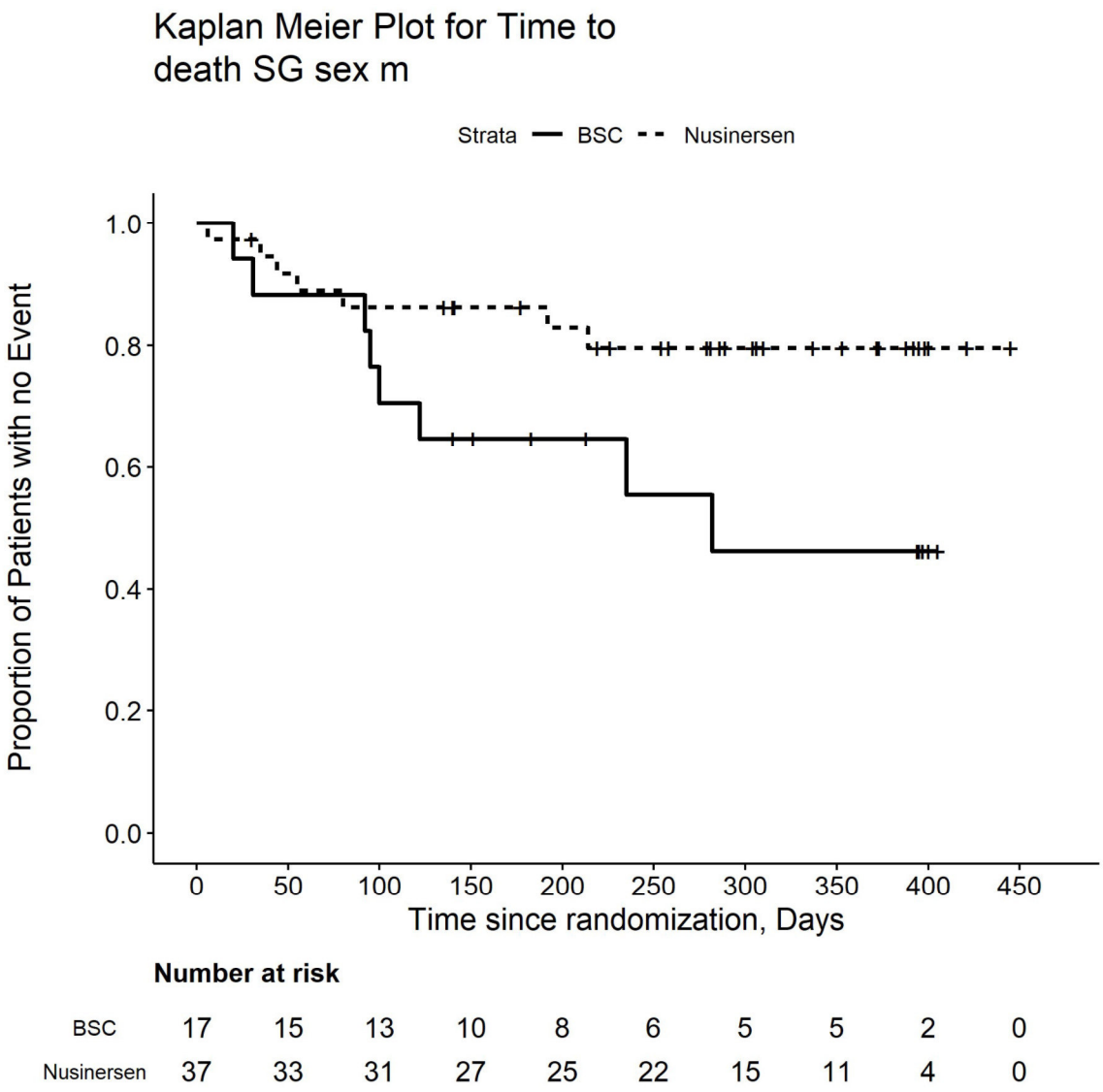
Number at risk

BSC	22	20	18	13	12	11	9	8	3	0
Nusinersen	38	35	34	30	26	24	20	19	7	0



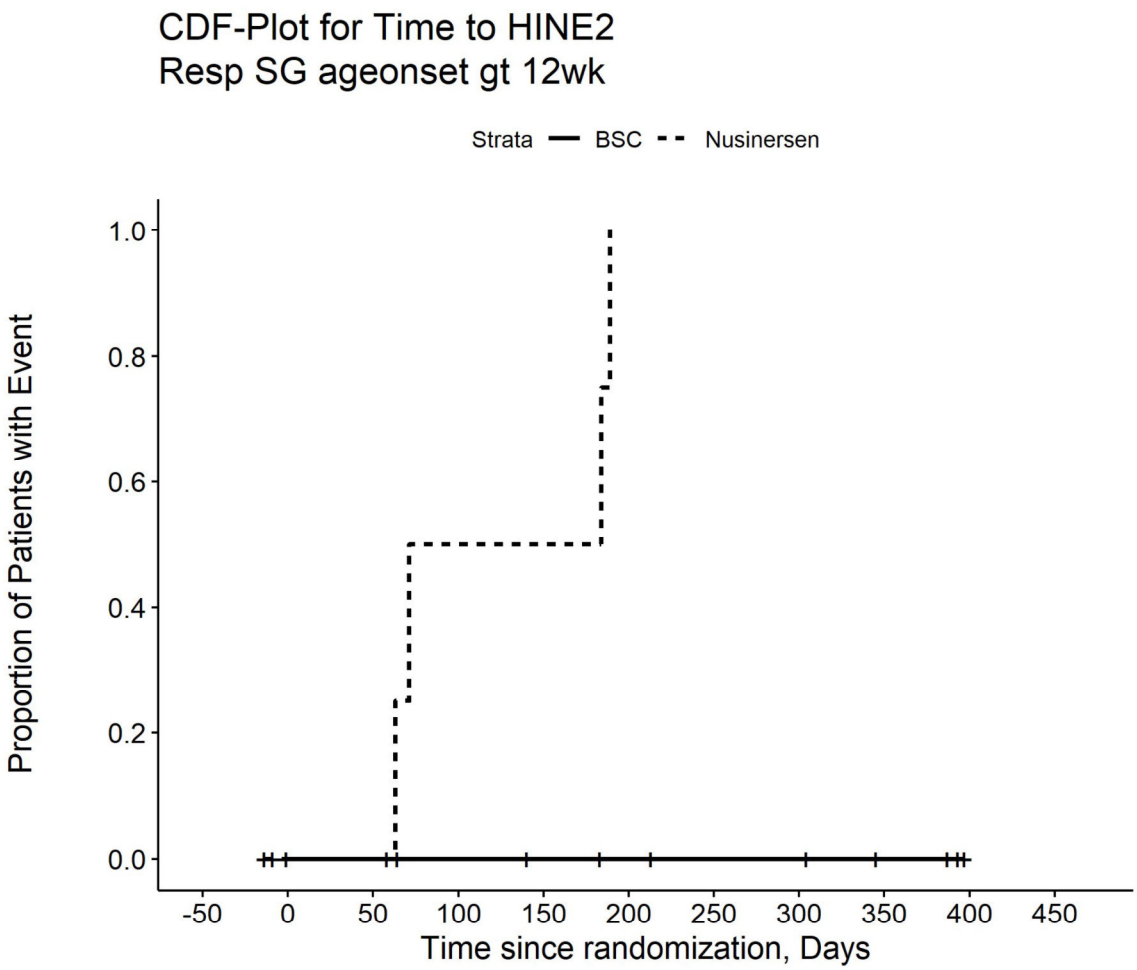
Number at risk

BSC	24	21	18	15	12	12	10	8	2	0
Nusinersen	43	43	40	35	27	22	21	20	7	0



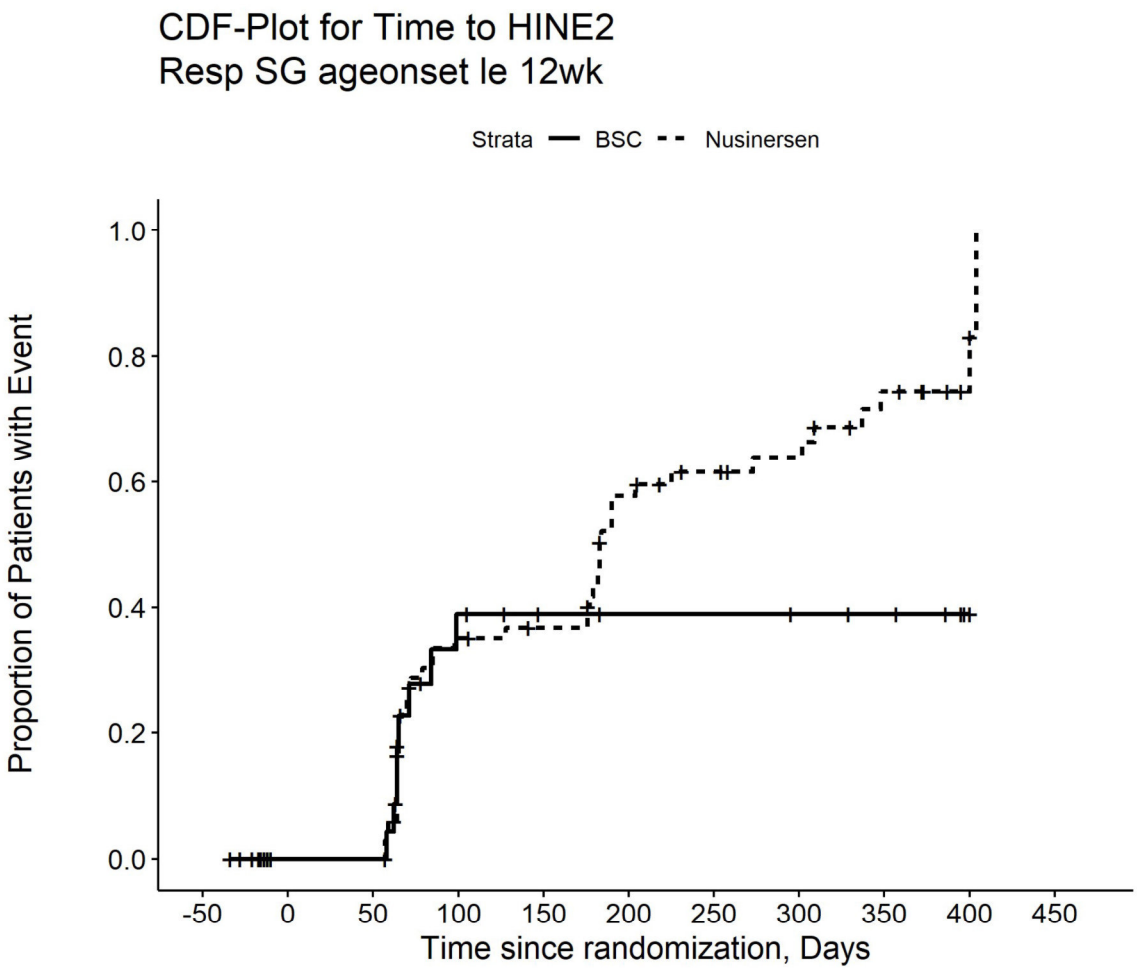
Number at risk

BSC	17	15	13	10	8	6	5	5	2	0
Nusinersen	37	33	31	27	25	22	15	11	4	0



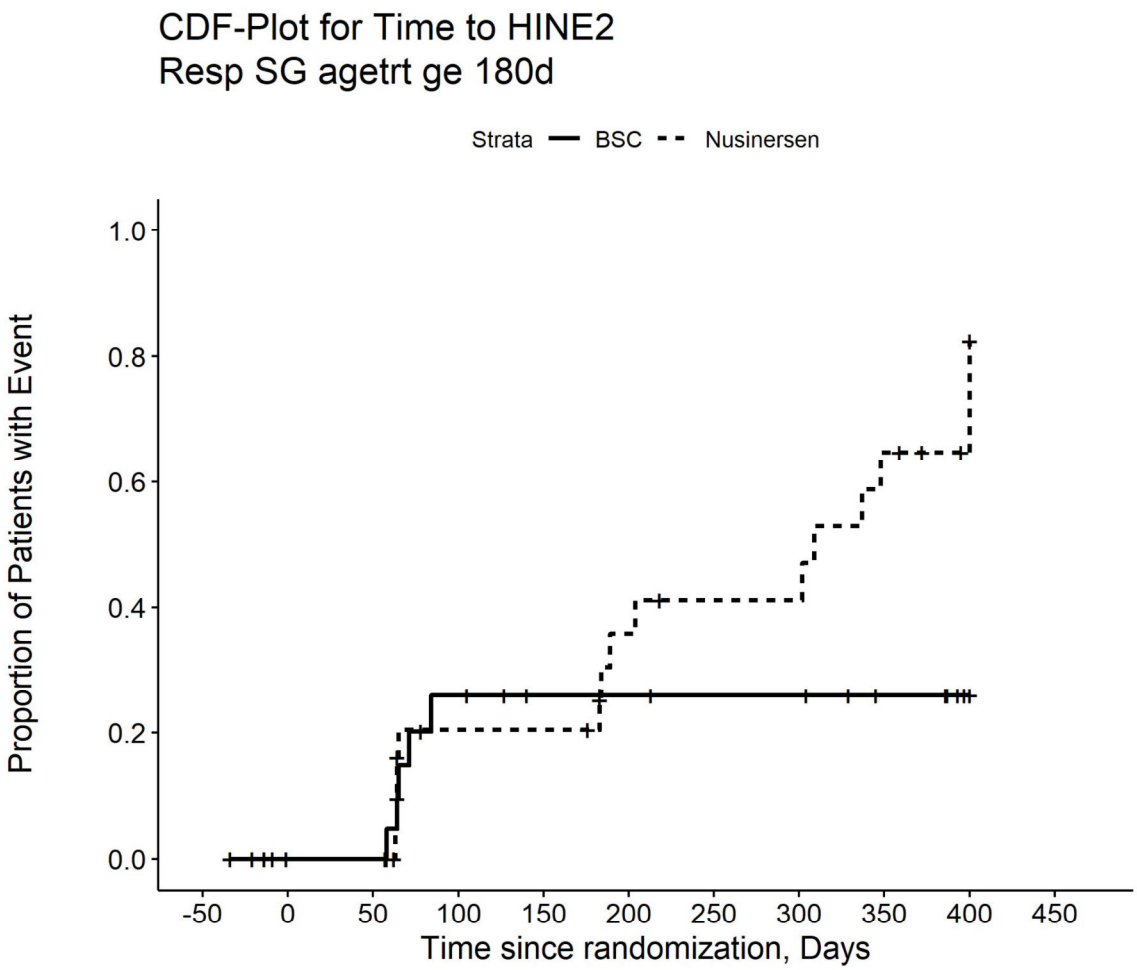
Number at risk

BSC	9	9	9	8	7	6	5	5	3	0	0
Nusinersen	8	5	5	2	2	0	0	0	0	0	0



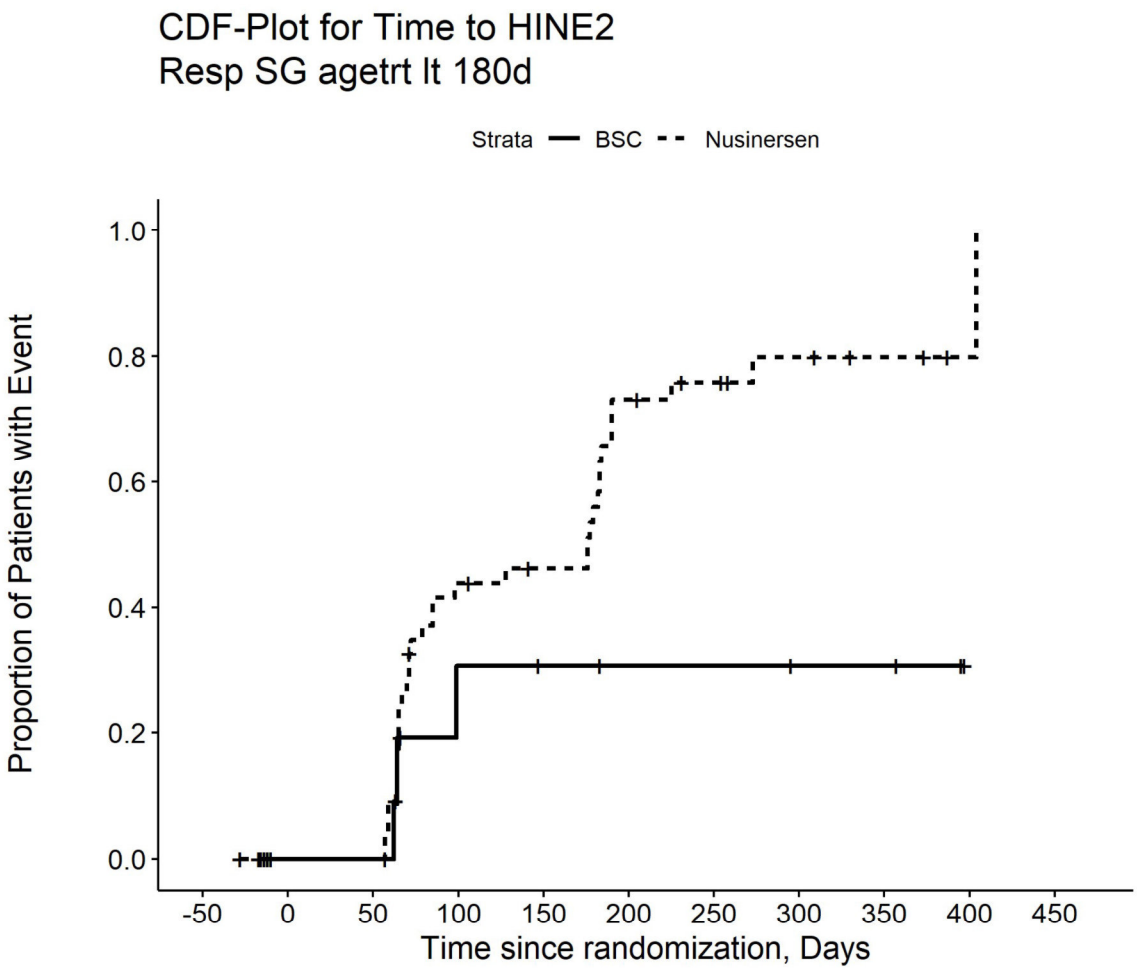
Number at risk

BSC	32	25	25	11	8	7	7	6	5	1	0
Nusinersen	72	68	68	41	38	23	18	15	9	3	0



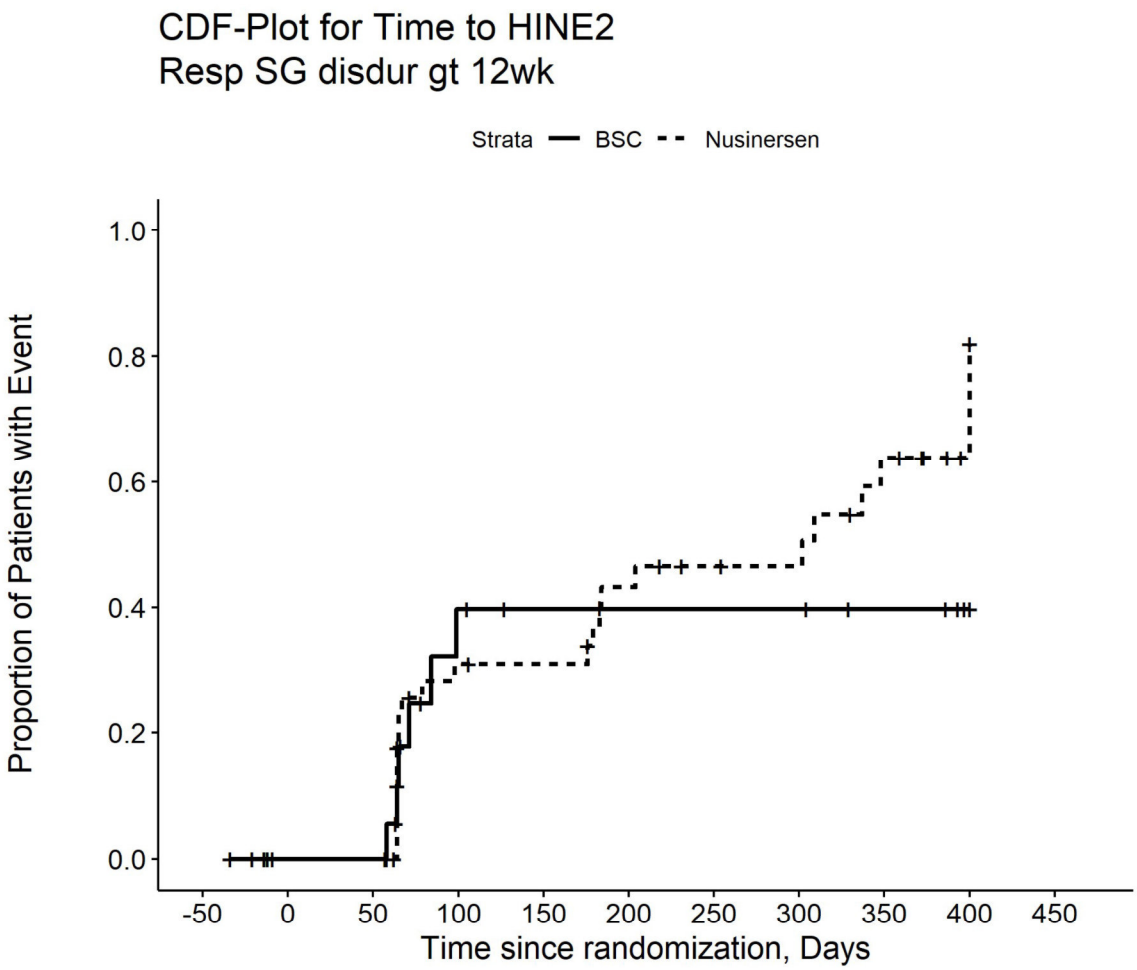
Number at risk

BSC	25	22	22	13	10	9	8	8	5	1	0
Nusinersen	31	27	27	18	18	12	10	10	6	2	0



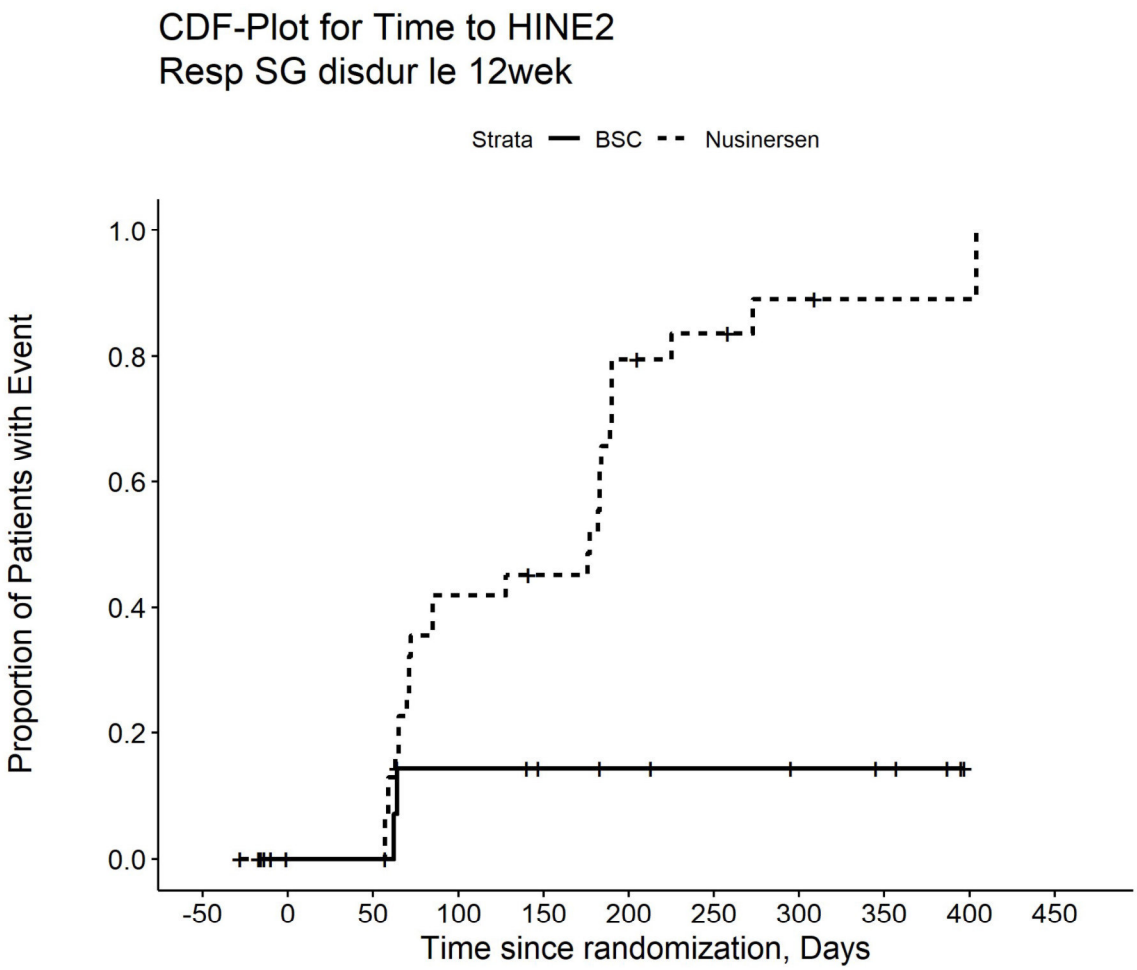
Number at risk

BSC	16	12	12	6	5	4	4	3	3	0	0
Nusinersen	49	46	46	25	22	11	8	5	3	1	0



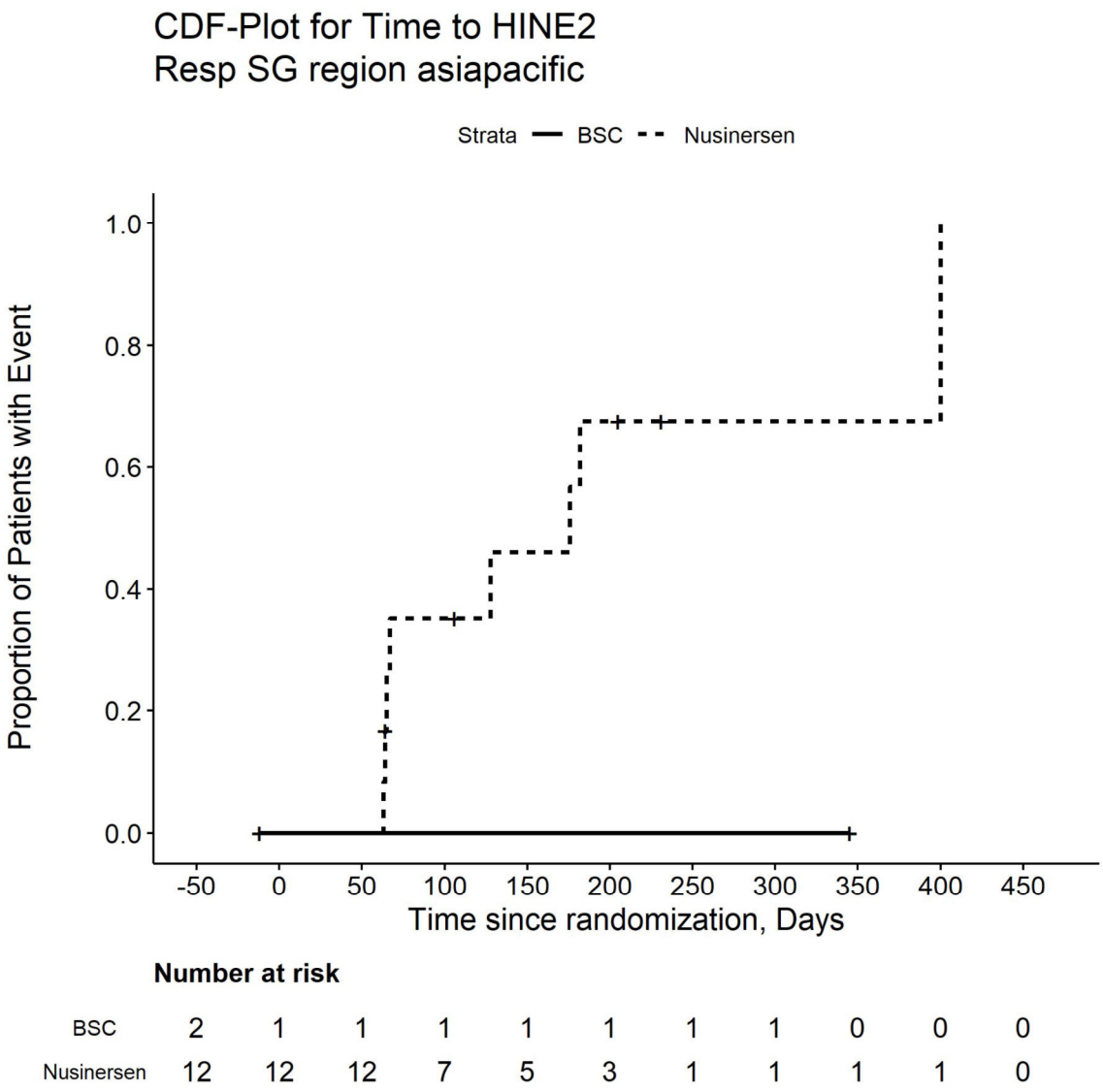
Number at risk

BSC	23	19	19	8	6	6	6	6	4	1	0
Nusinersen	46	42	42	25	24	17	14	13	8	2	0



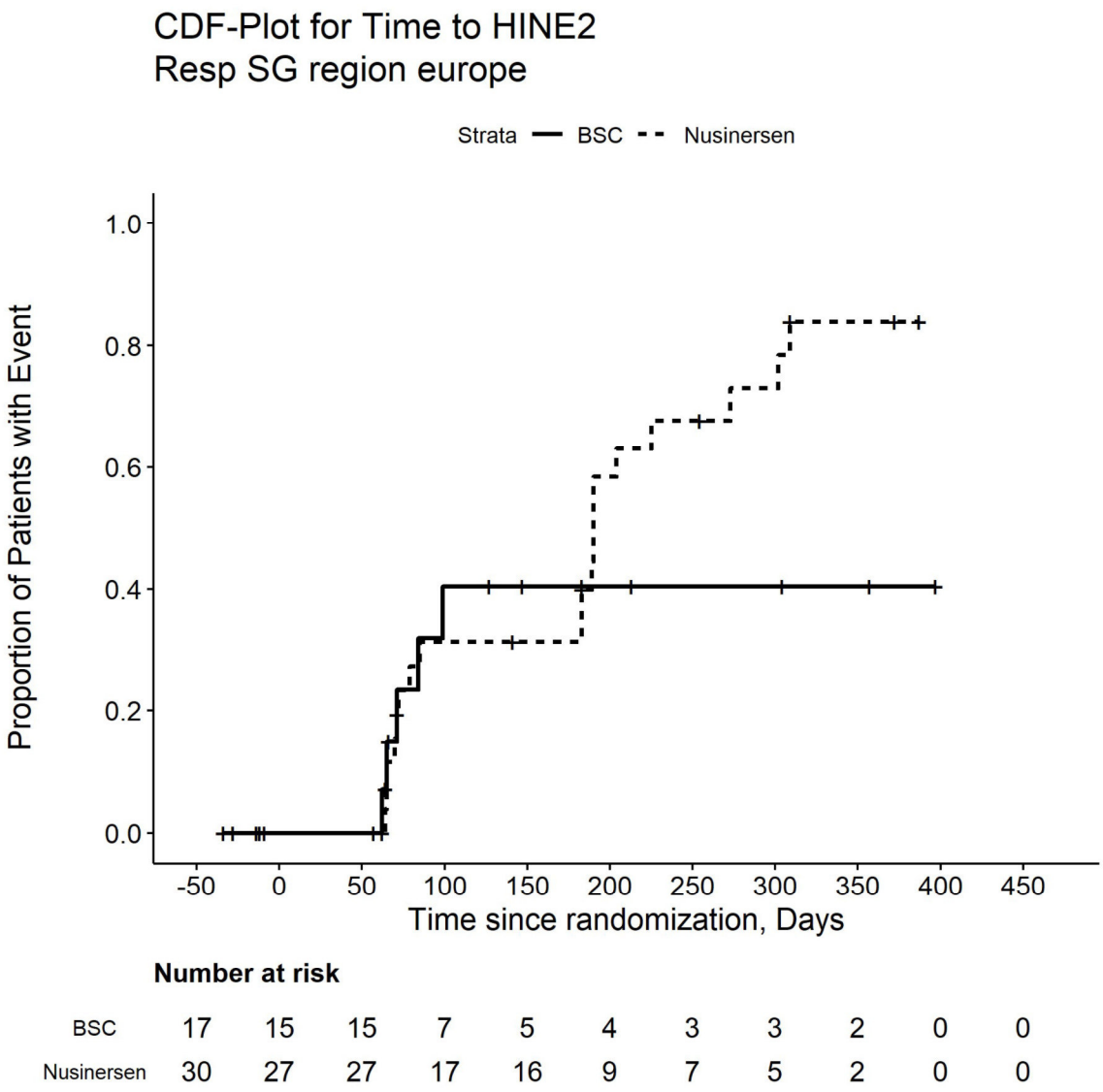
Number at risk

BSC	18	15	15	11	9	7	6	5	4	0	0
Nusinersen	34	31	31	18	16	6	4	2	1	1	0



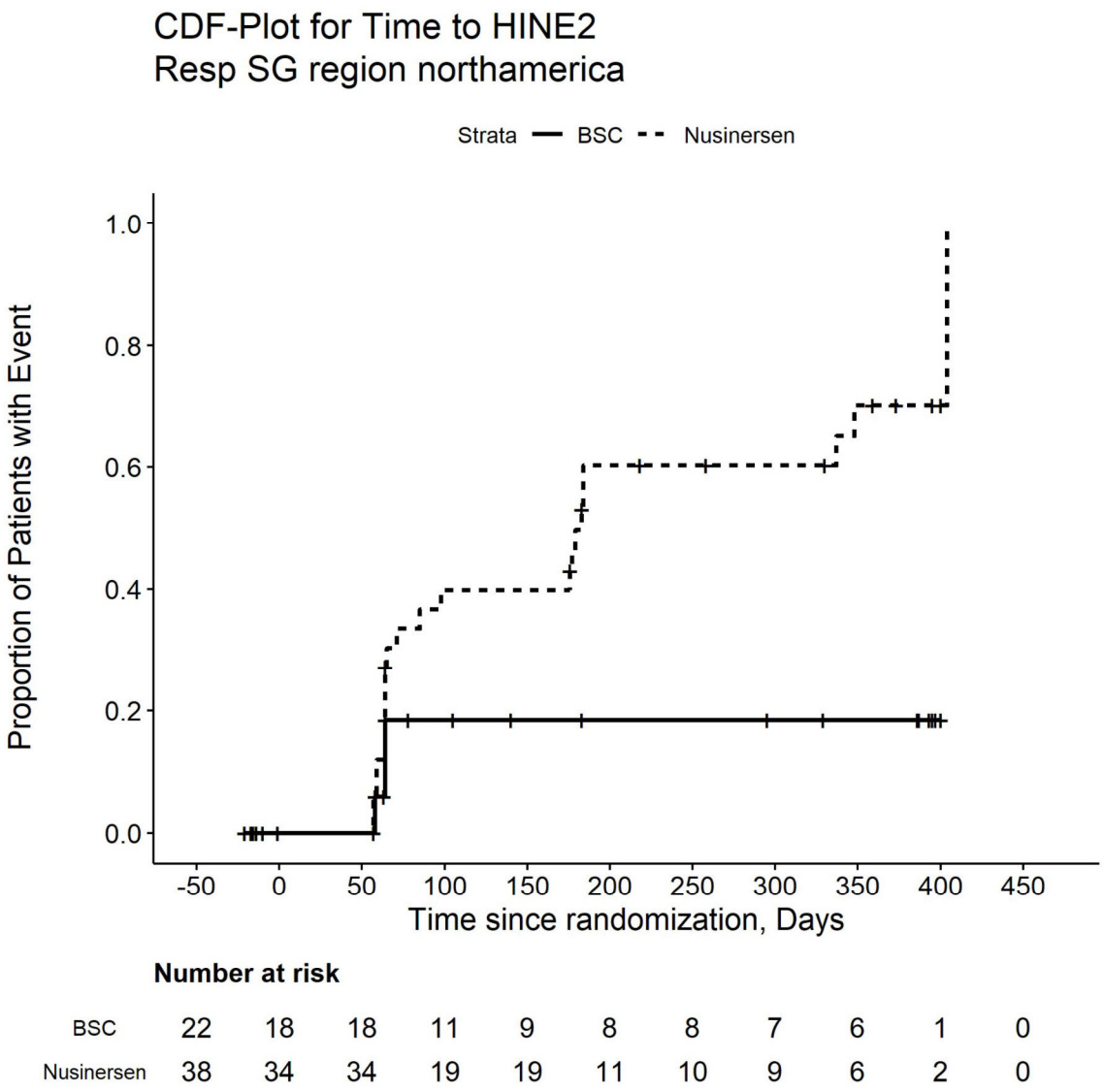
Number at risk

BSC	2	1	1	1	1	1	1	1	0	0	0
Nusinersen	12	12	12	7	5	3	1	1	1	1	0



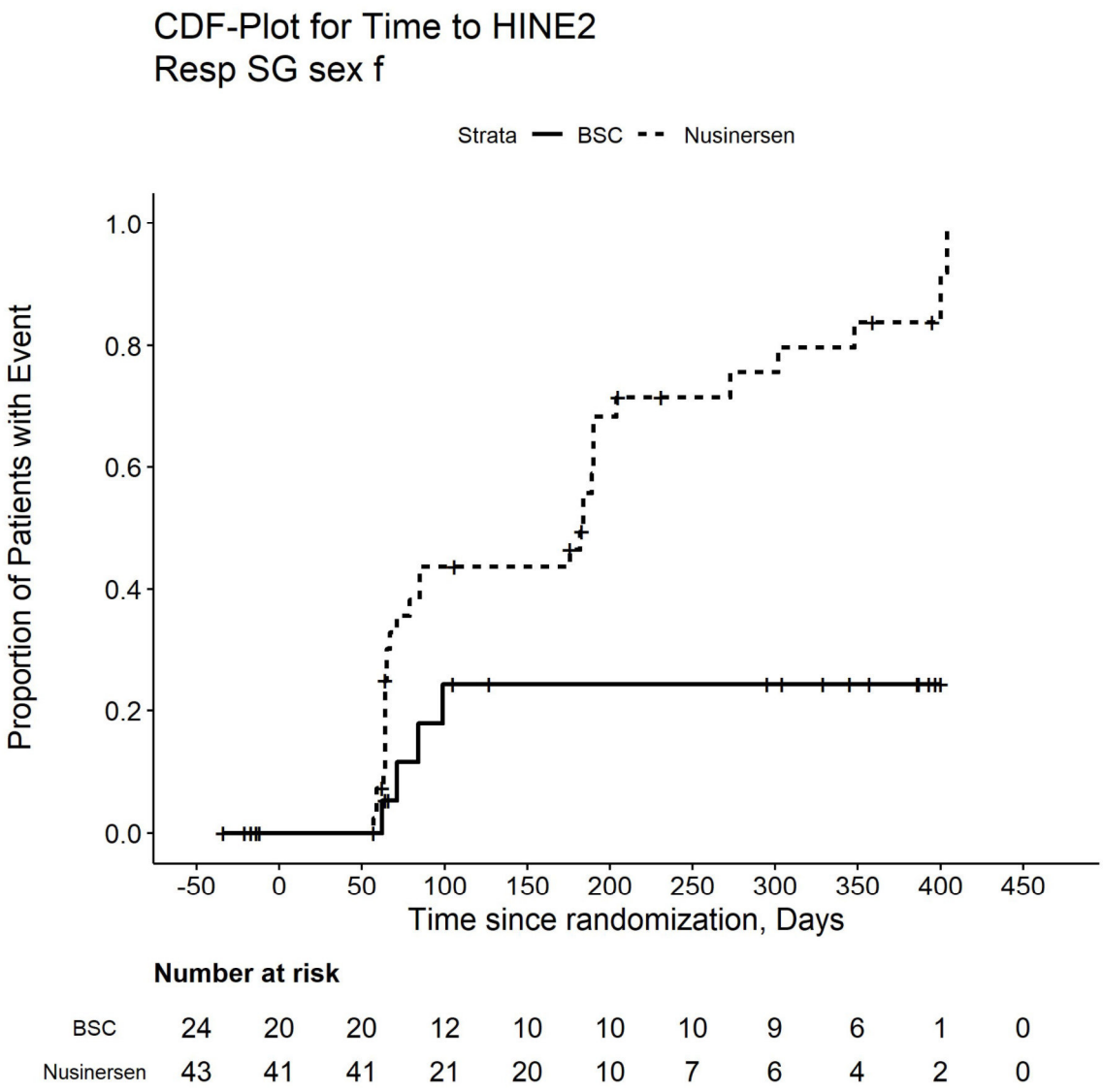
Number at risk

BSC	17	15	15	7	5	4	3	3	2	0	0
Nusinersen	30	27	27	17	16	9	7	5	2	0	0



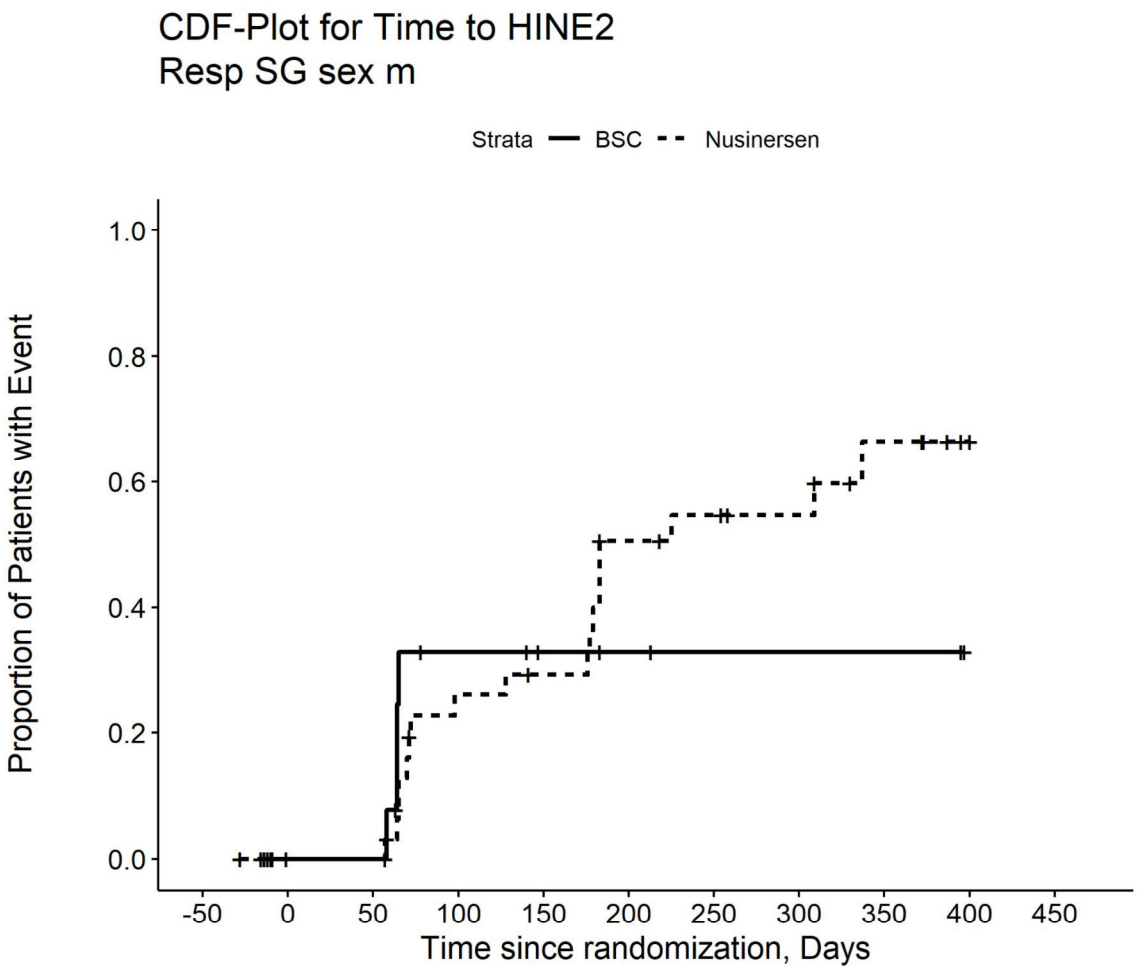
Number at risk

BSC	22	18	18	11	9	8	8	7	6	1	0
Nusinersen	38	34	34	19	19	11	10	9	6	2	0



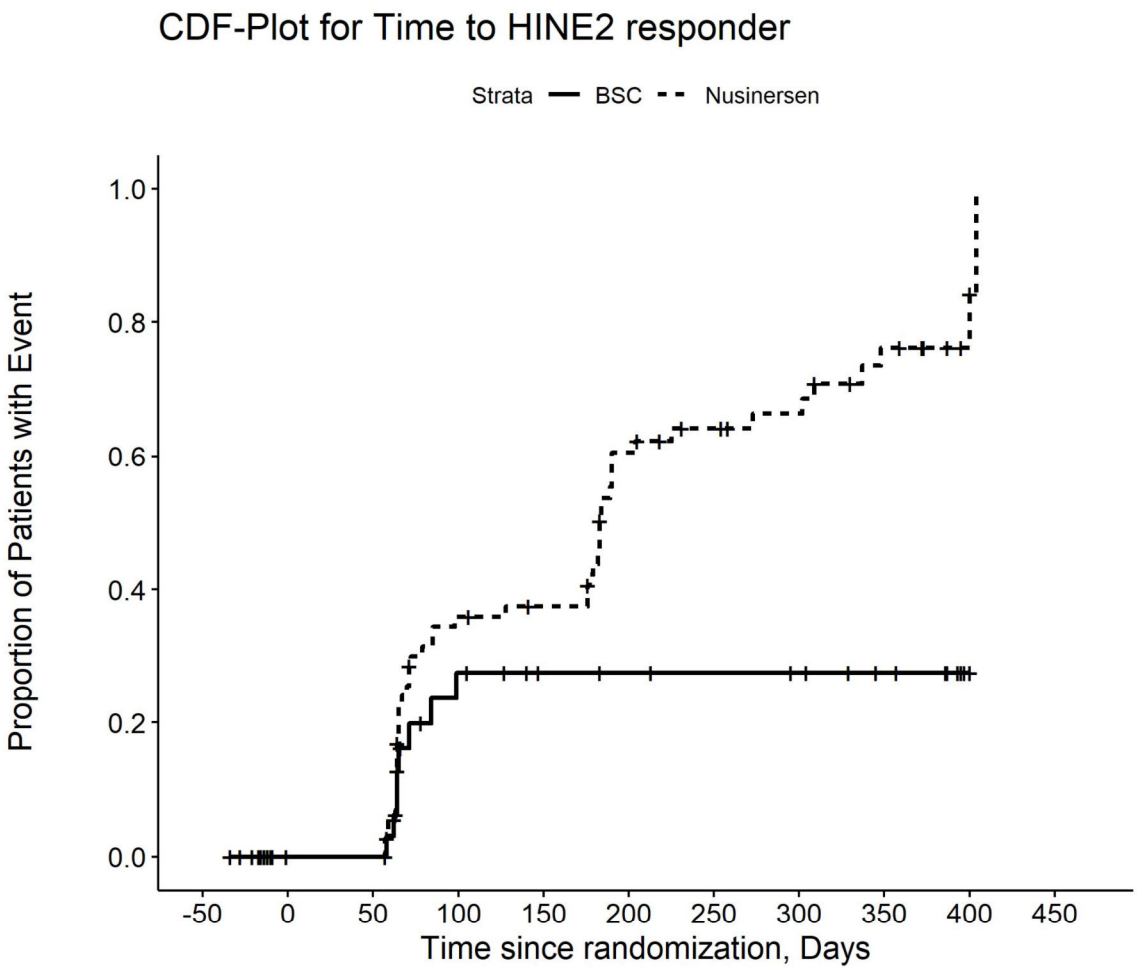
Number at risk

BSC	24	20	20	12	10	10	10	9	6	1	0
Nusinersen	43	41	41	21	20	10	7	6	4	2	0



Number at risk

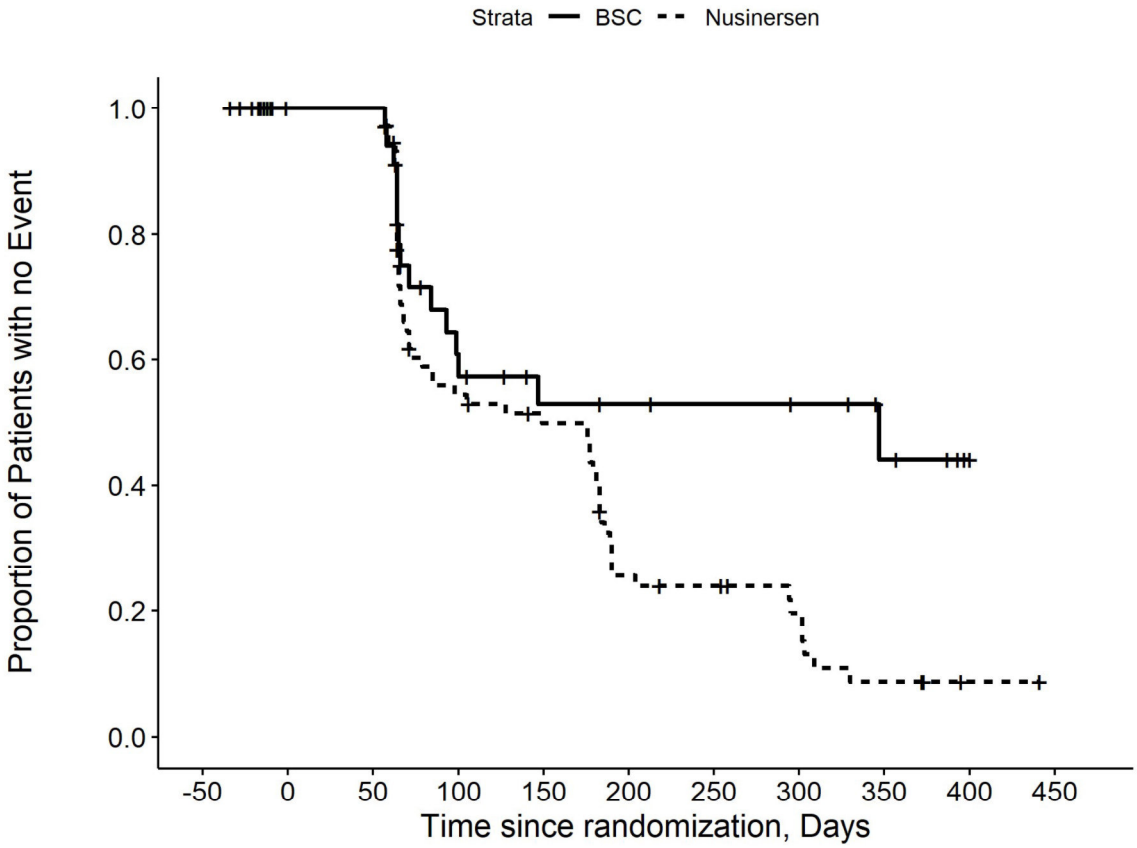
BSC	17	14	14	7	5	3	2	2	2	0	0
Nusinersen	37	32	32	22	20	13	11	9	5	1	0



Number at risk

BSC	41	34	34	19	15	13	12	11	8	1	0
Nusinersen	80	73	73	43	40	23	18	15	9	3	0

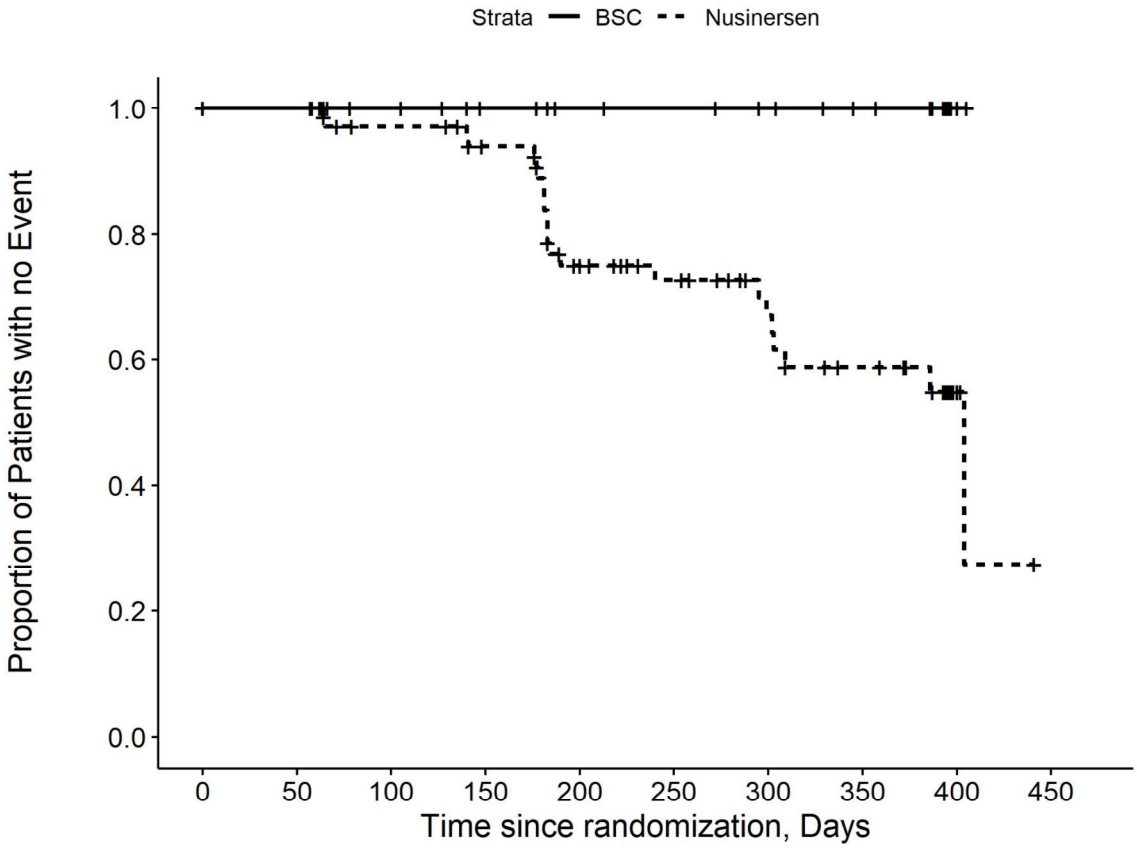
Kaplan Meier Plot for Time to HINE2 responder totscore



Number at risk

BSC	41	34	34	17	12	10	9	8	5	1	0
Nusinersen	80	73	73	37	32	15	13	9	4	1	0

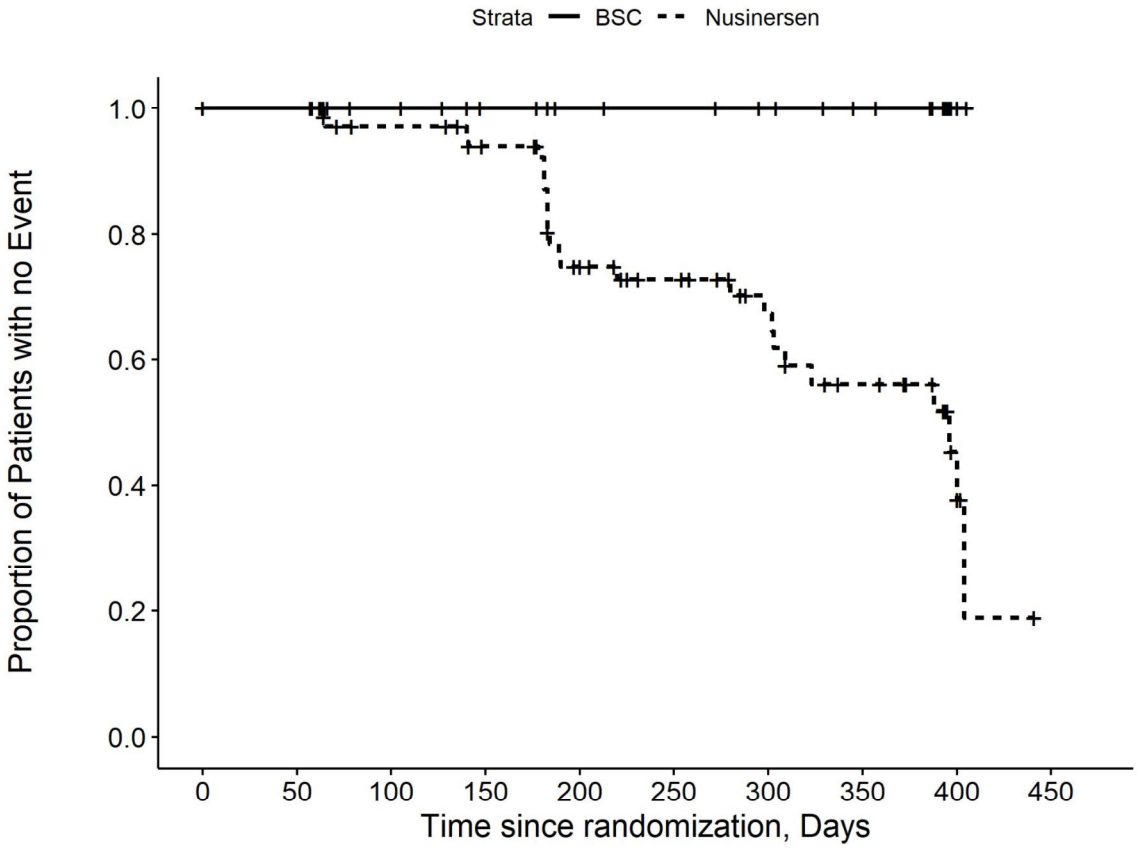
Kaplan Meier Plot for Time to HINE2 responder totscore posthoc



Number at risk

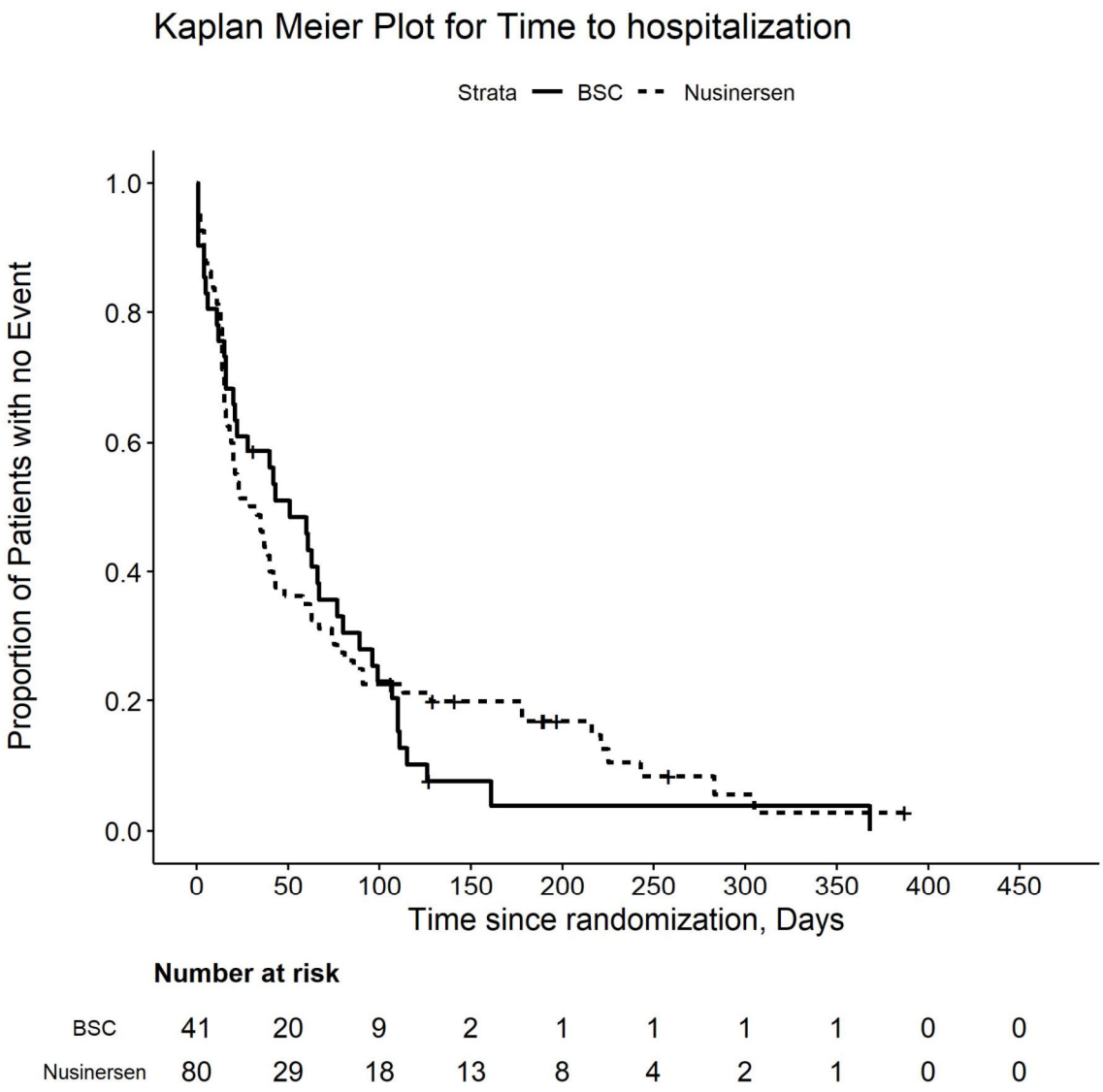
BSC	41	34	27	23	18	17	15	12	2	0
Nusinersen	80	72	63	57	40	33	24	18	6	0

Kaplan Meier Plot for Time to HINE2 responder totscrvg posthoc



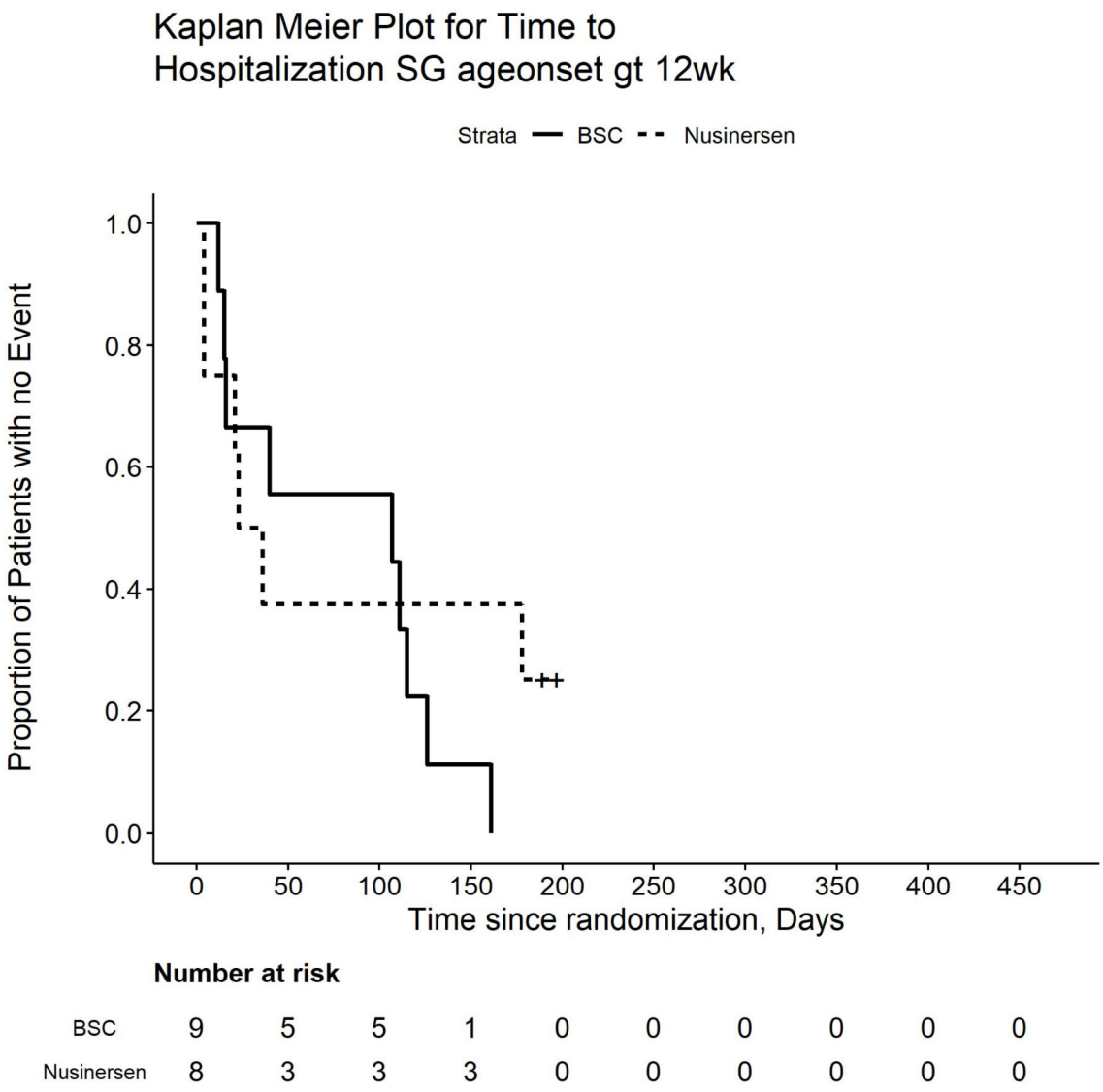
Number at risk

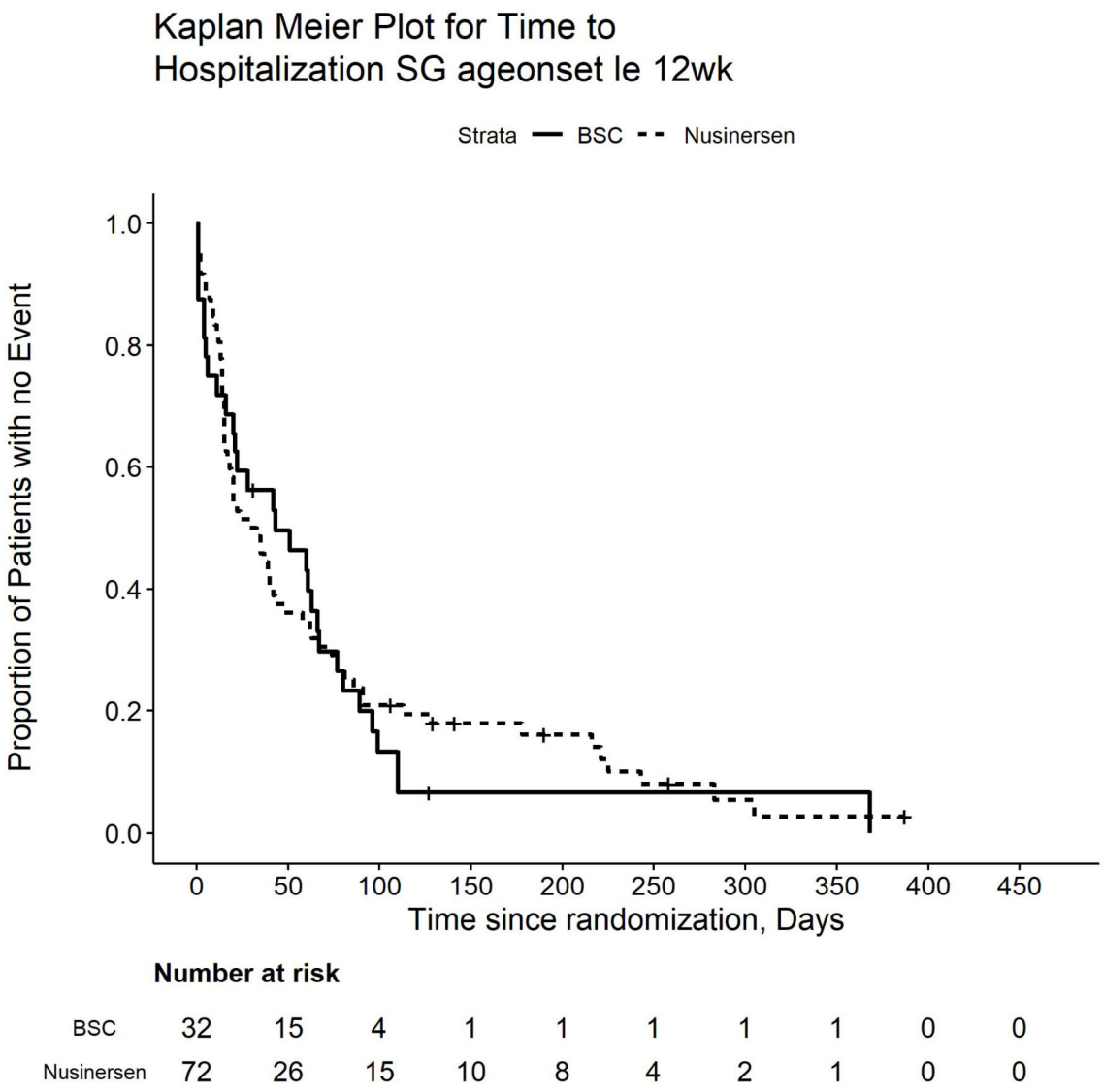
BSC	41	34	27	23	18	17	15	12	2	0
Nusinersen	80	72	63	57	40	33	24	17	6	0

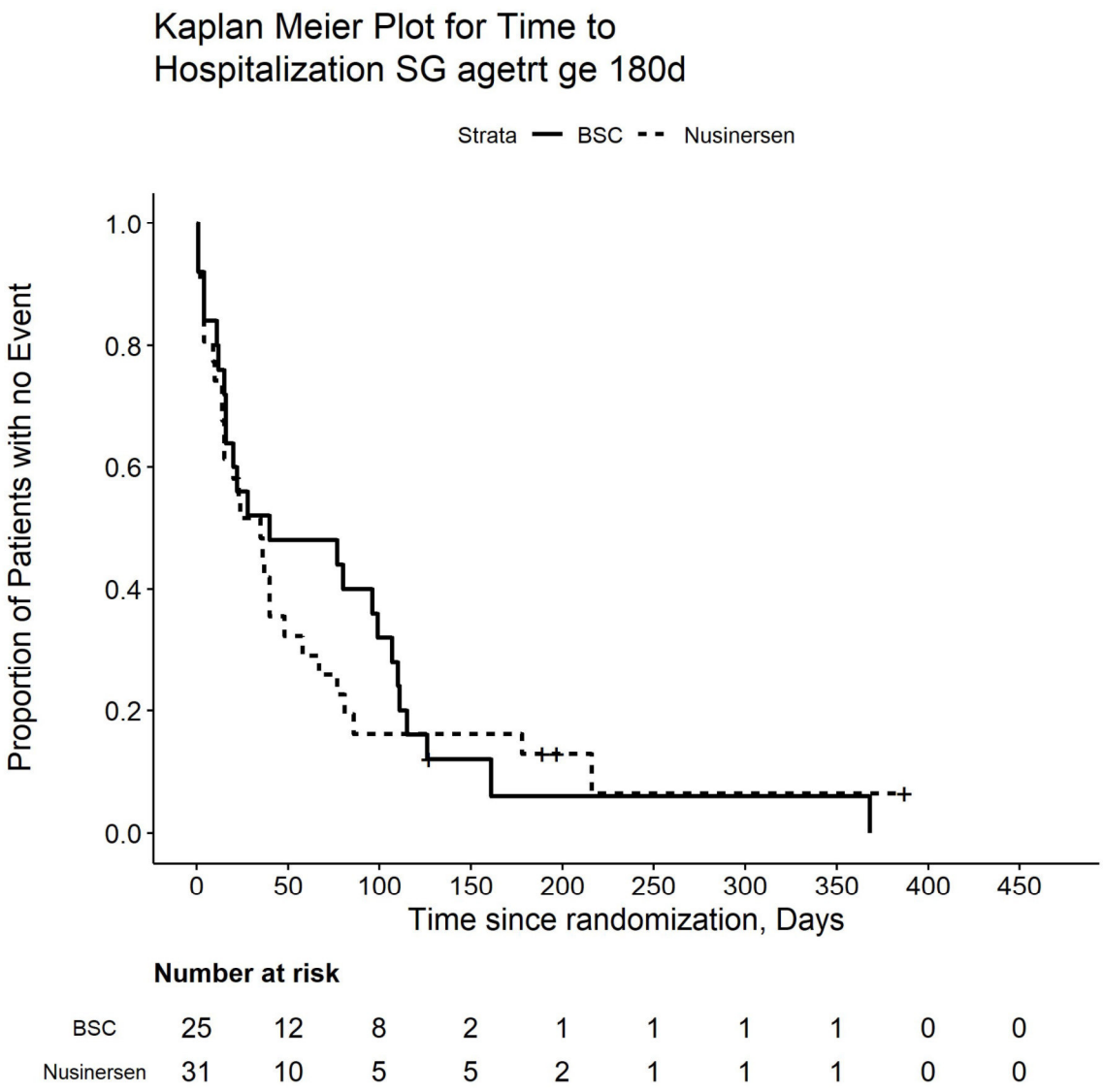


Number at risk

BSC	41	20	9	2	1	1	1	1	0	0
Nusinersen	80	29	18	13	8	4	2	1	0	0

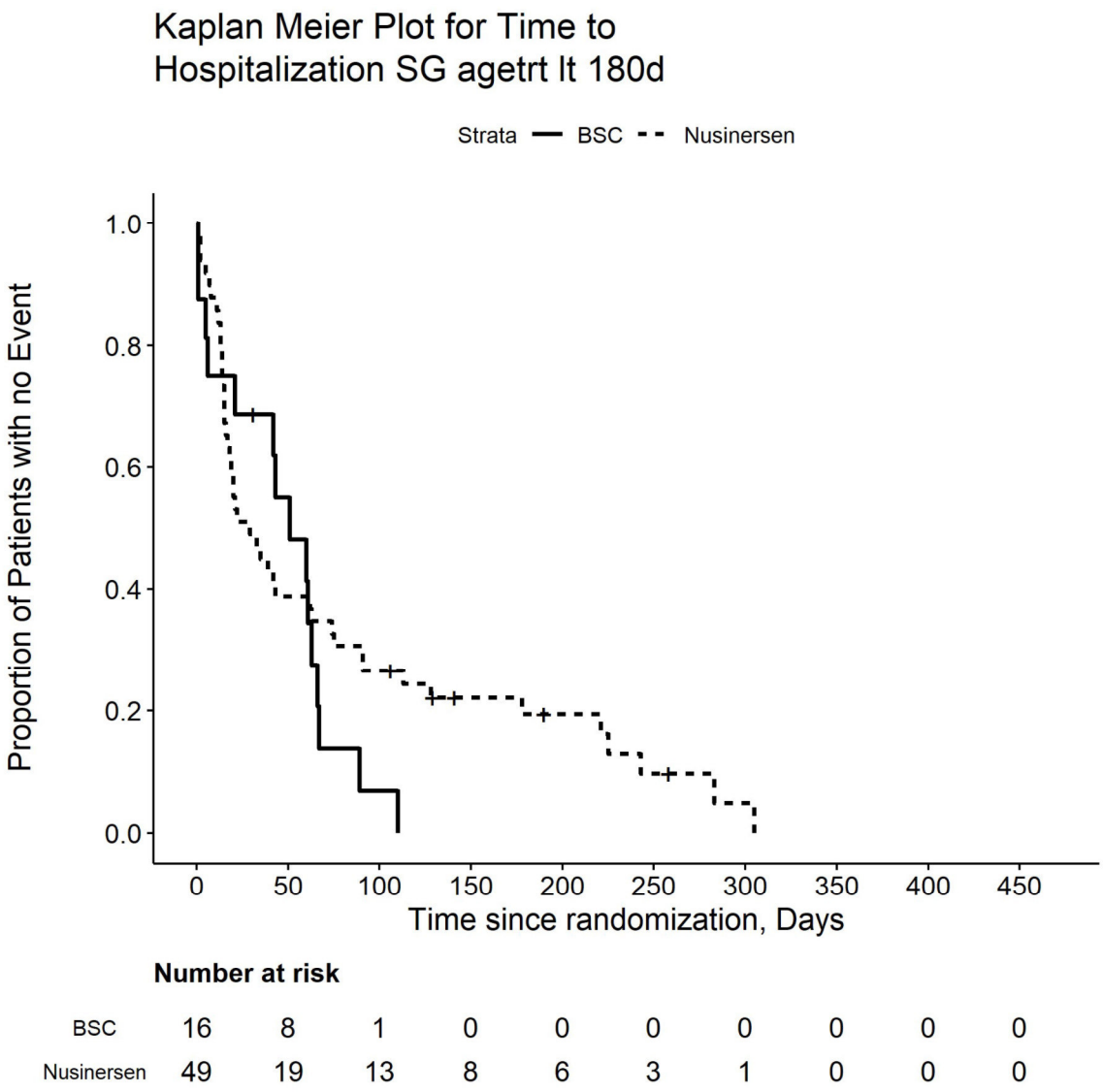

Kaplan Meier Plot for Time to
Hospitalization SG ageonset gt 12wk
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0 50 100 150 200 250 300 350 400 450
Time since randomization, Days
Number at risk
BSC 9 5 5 1 0 0 0 0 0 0
Nusinersen 8 3 3 3 0 0 0 0 0 0


Kaplan Meier Plot for Time to
Hospitalization SG ageonset le 12wk
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0
50
100
150
200
250
300
350
400
450
Time since randomization, Days
Number at risk
BSC 32 15 4 1 1 1 1 1 0 0
Nusinersen 72 26 15 10 8 4 2 1 0 0

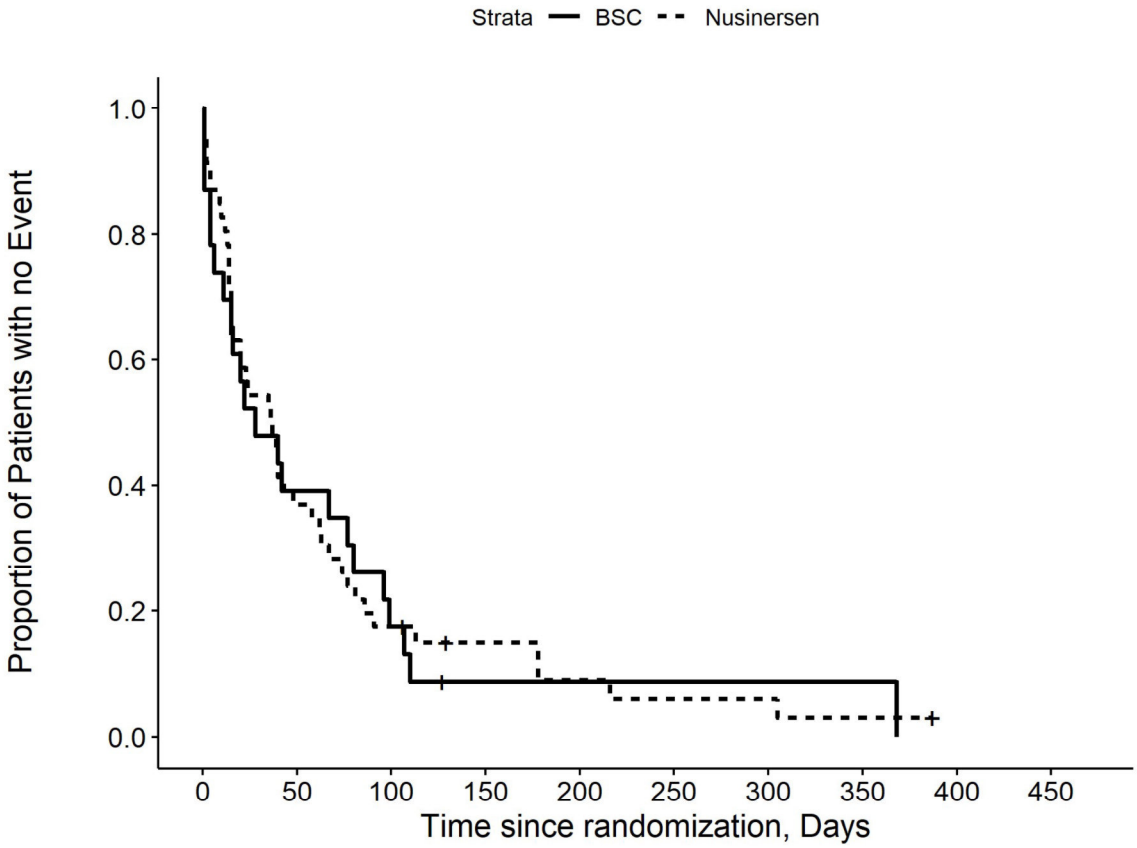


Number at risk

BSC	25	12	8	2	1	1	1	1	0	0
Nusinersen	31	10	5	5	2	1	1	1	0	0


Kaplan Meier Plot for Time to Hospitalization SG agetrt lt 180d
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0
50
100
150
200
250
300
350
400
450
Time since randomization, Days
Number at risk
BSC 16 8 1 0 0 0 0 0 0 0
Nusinersen 49 19 13 8 6 3 1 0 0 0

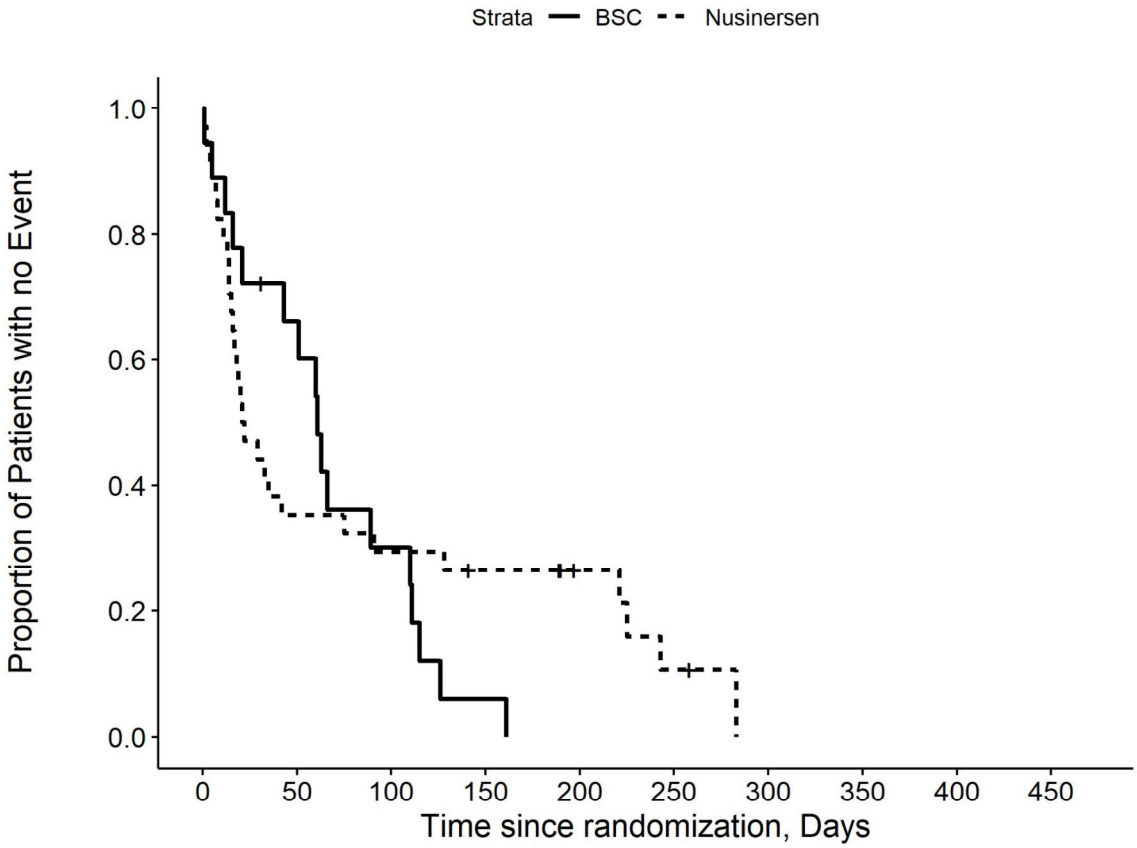
Kaplan Meier Plot for Time to Hospitalization SG disdur gt 12wk



Number at risk

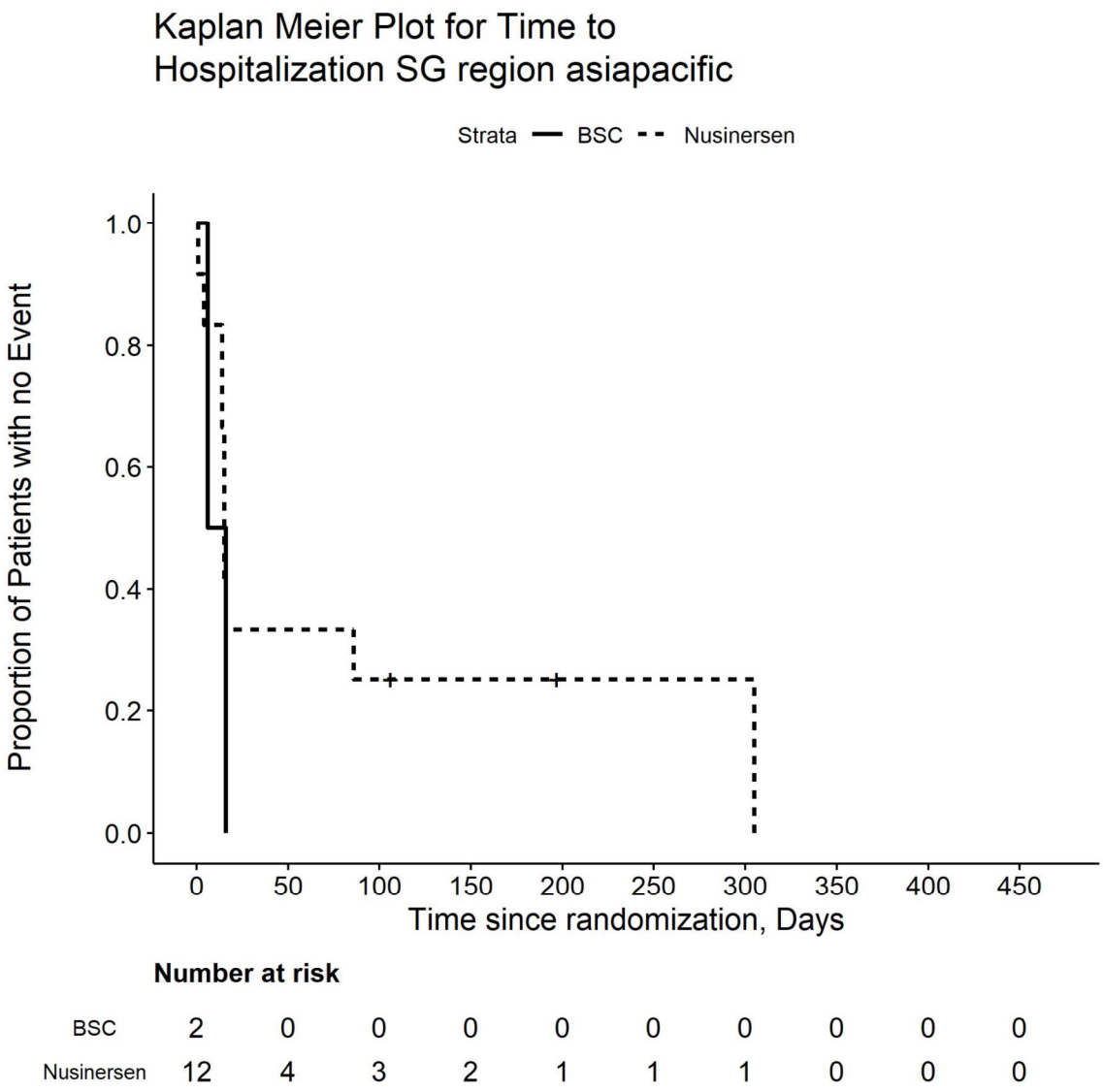
BSC	23	9	4	1	1	1	1	1	0	0
Nusinersen	46	17	8	5	3	2	2	1	0	0

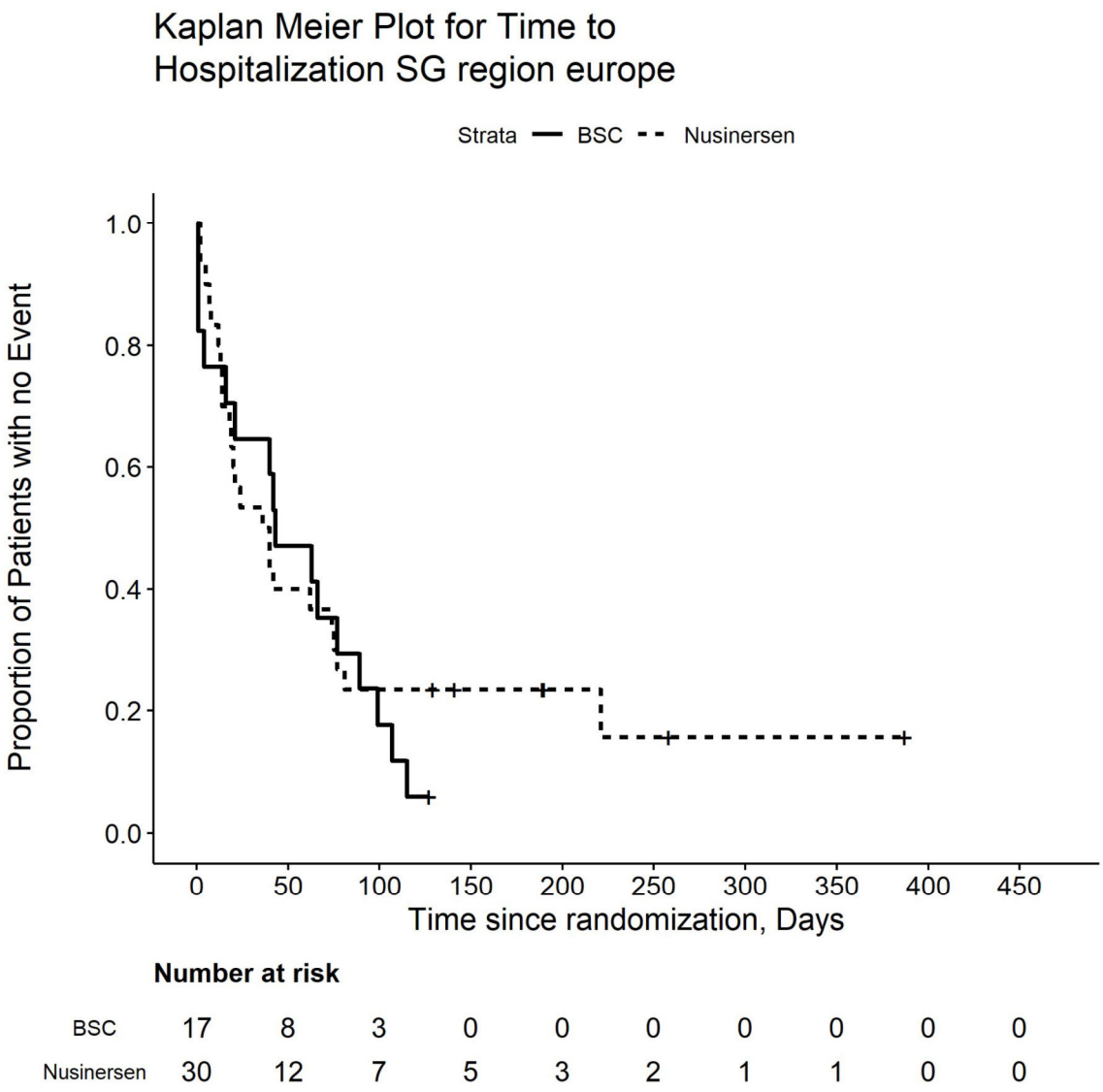
Kaplan Meier Plot for Time to Hospitalization SG disdur le 12wek



Number at risk

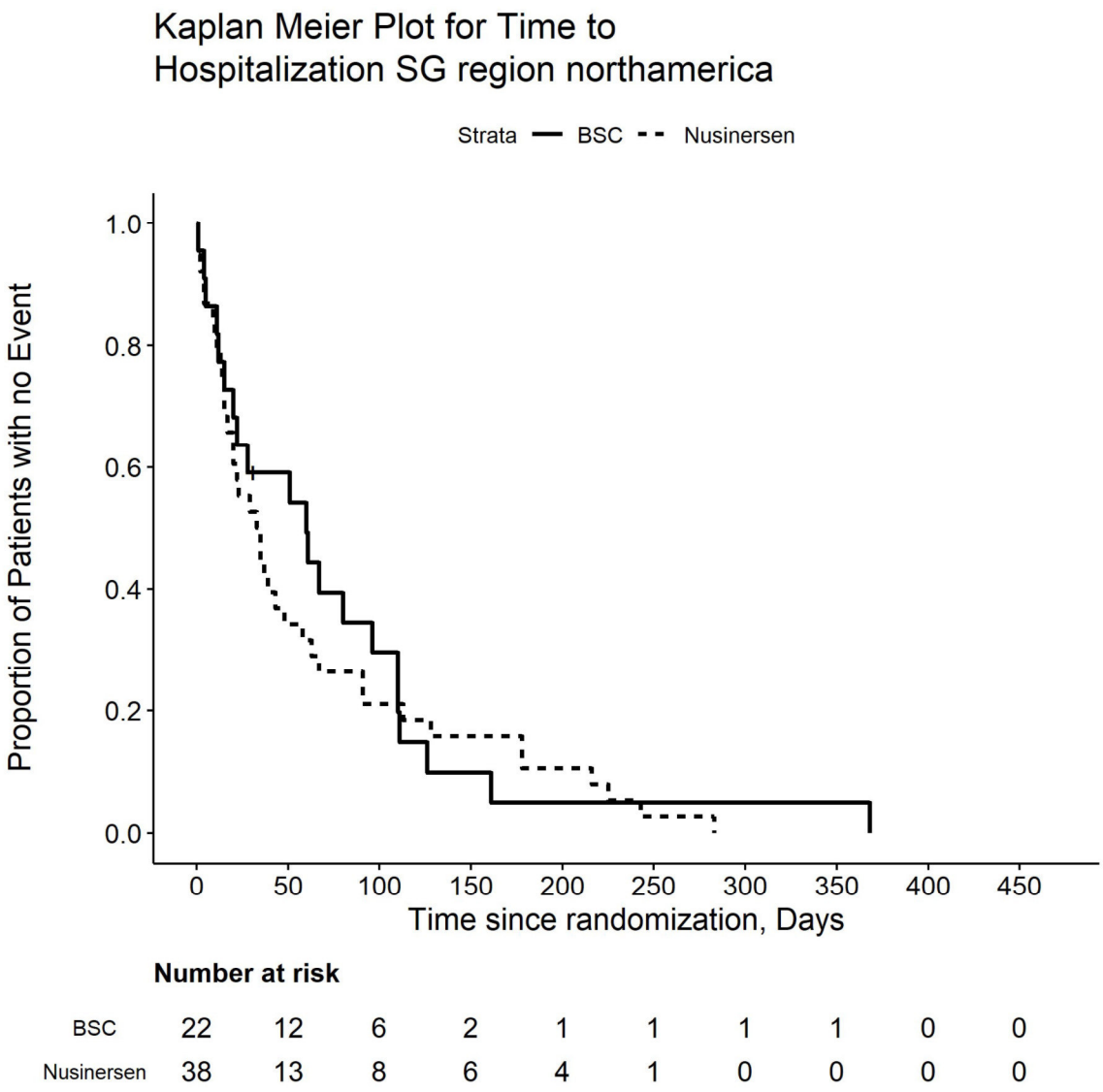
BSC	18	11	5	1	0	0	0	0	0	0
Nusinersen	34	12	10	8	5	2	0	0	0	0


Kaplan Meier Plot for Time to Hospitalization SG region asiapacific
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0
50
100
150
200
250
300
350
400
450
Time since randomization, Days
Number at risk
BSC 2 0 0 0 0 0 0 0 0 0
Nusinersen 12 4 3 2 1 1 1 0 0 0



Number at risk

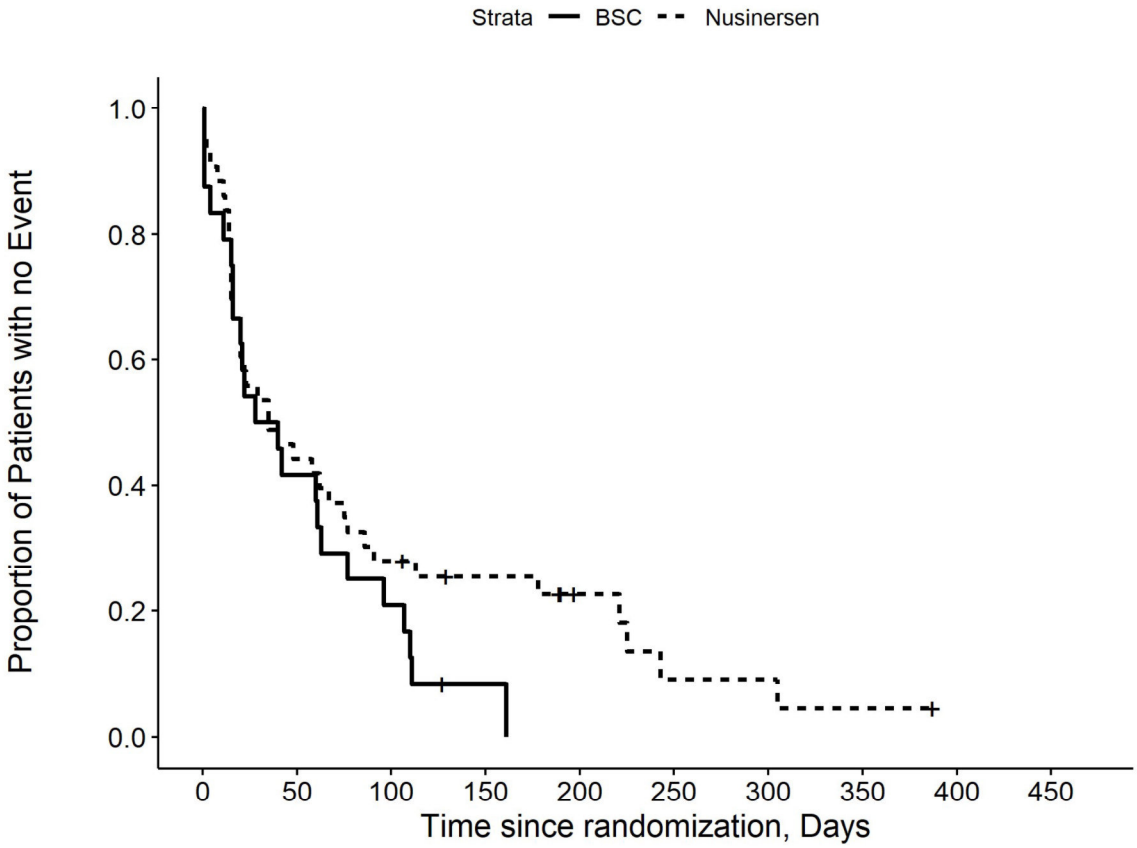
BSC	17	8	3	0	0	0	0	0	0	0
Nusinersen	30	12	7	5	3	2	1	1	0	0



Number at risk

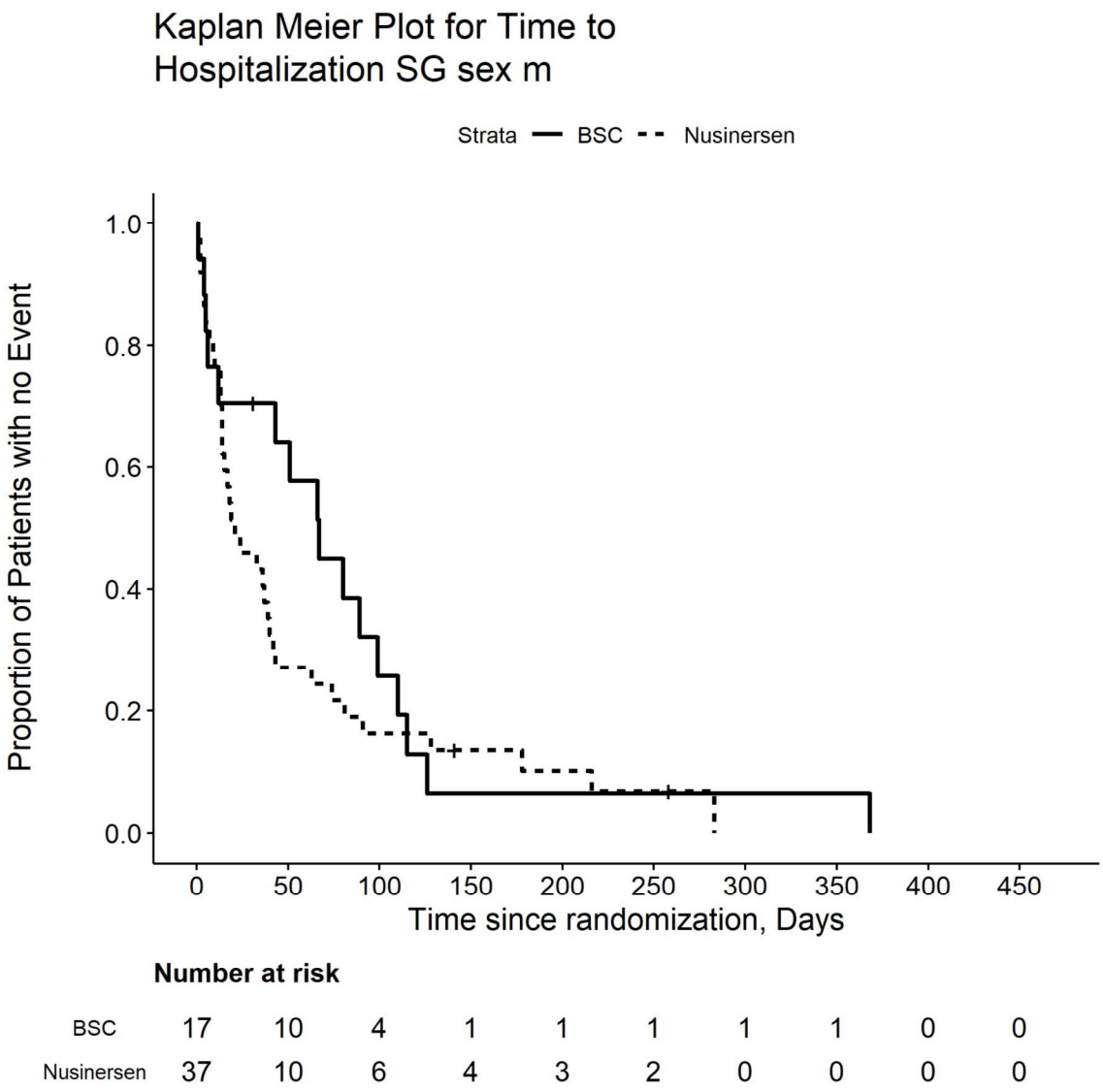
BSC	22	12	6	2	1	1	1	1	0	0
Nusinersen	38	13	8	6	4	1	0	0	0	0

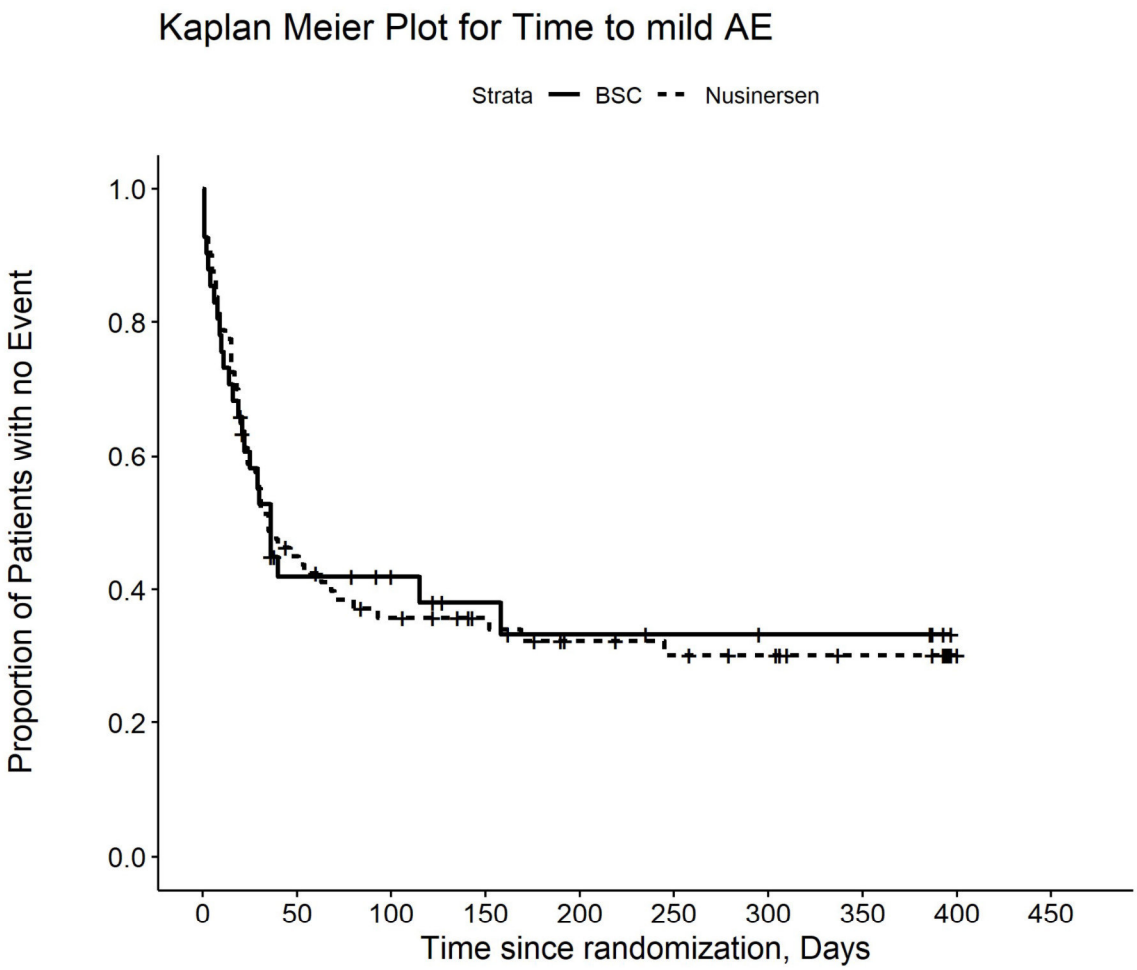
Kaplan Meier Plot for Time to Hospitalization SG sex f



Number at risk

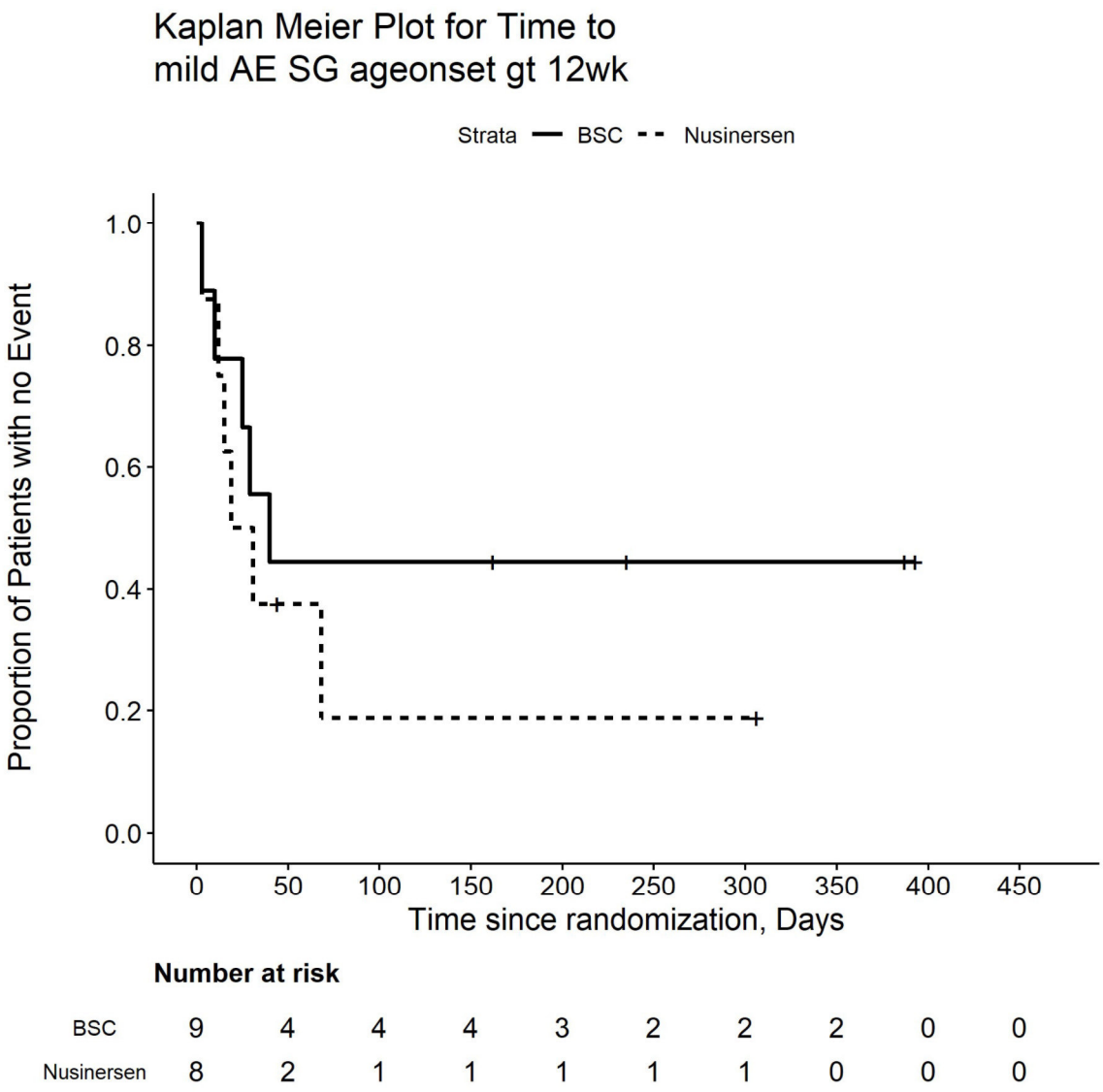
BSC	24	10	5	1	0	0	0	0	0	0
Nusinersen	43	19	12	9	5	2	2	1	0	0


Kaplan Meier Plot for Time to Hospitalization SG sex m
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0 50 100 150 200 250 300 350 400 450
Time since randomization, Days
Number at risk
BSC 17 10 4 1 1 1 1 1 0 0
Nusinersen 37 10 6 4 3 2 0 0 0 0



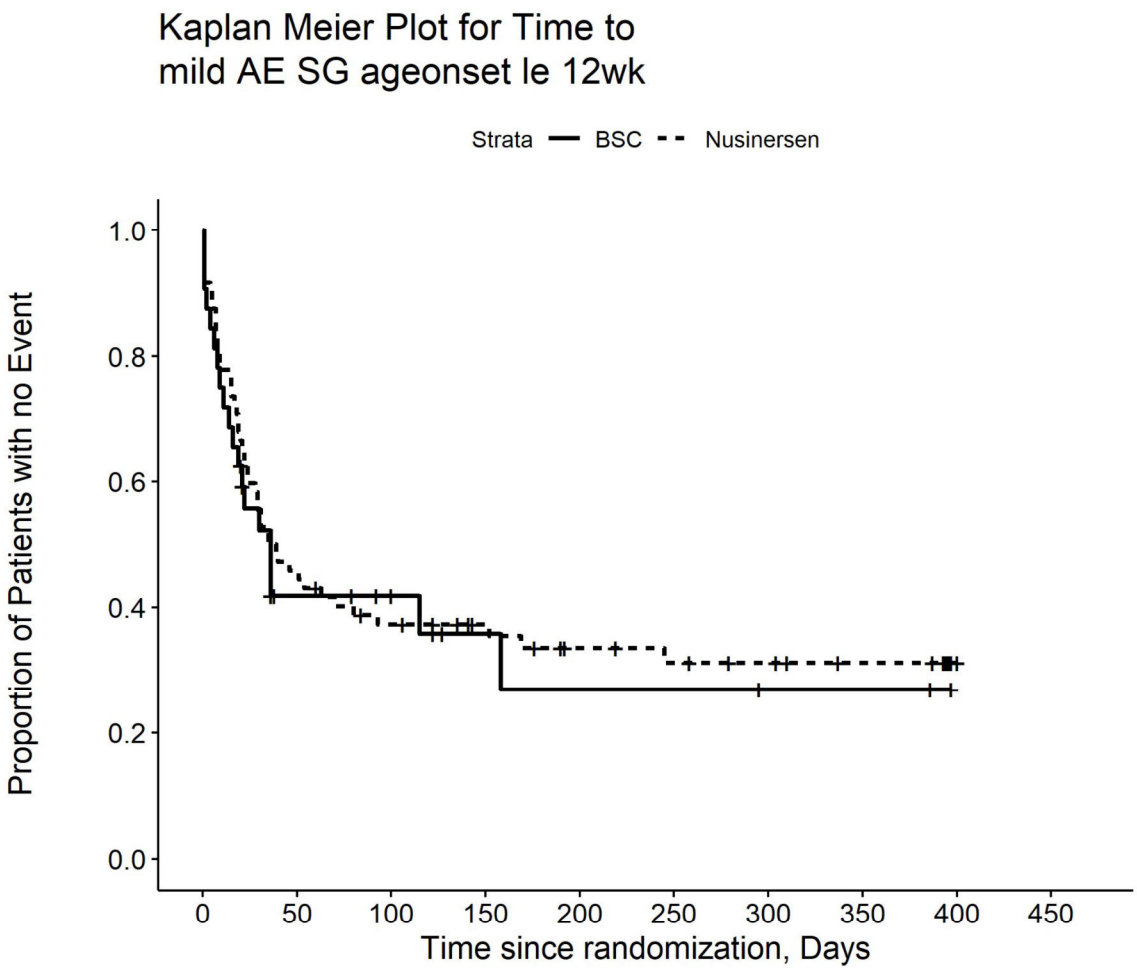
Number at risk

BSC	41	14	12	8	6	5	4	4	0	0
Nusinersen	80	35	26	21	16	14	11	7	1	0



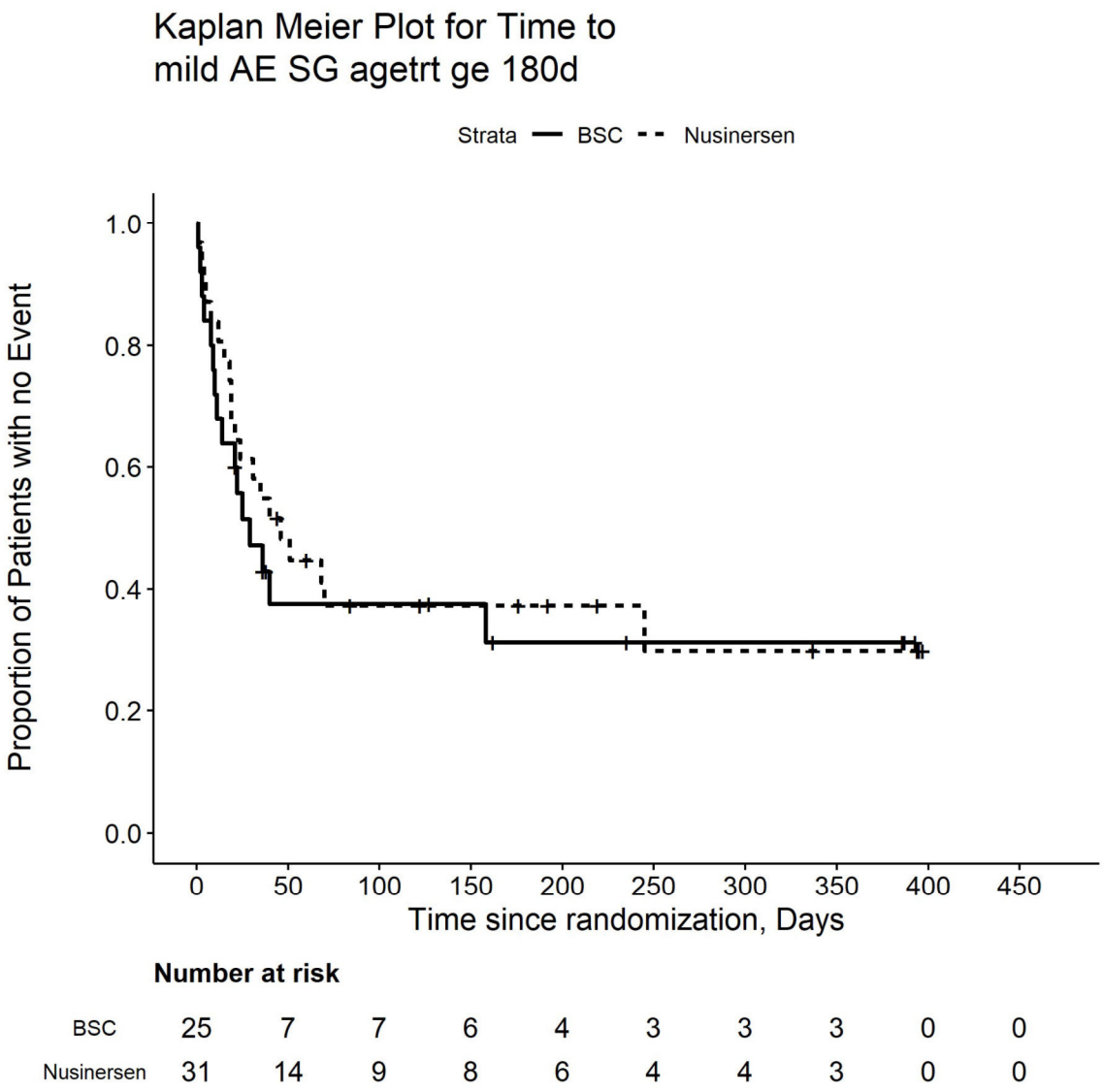
Number at risk

BSC	9	4	4	4	3	2	2	2	0	0
Nusinersen	8	2	1	1	1	1	1	0	0	0



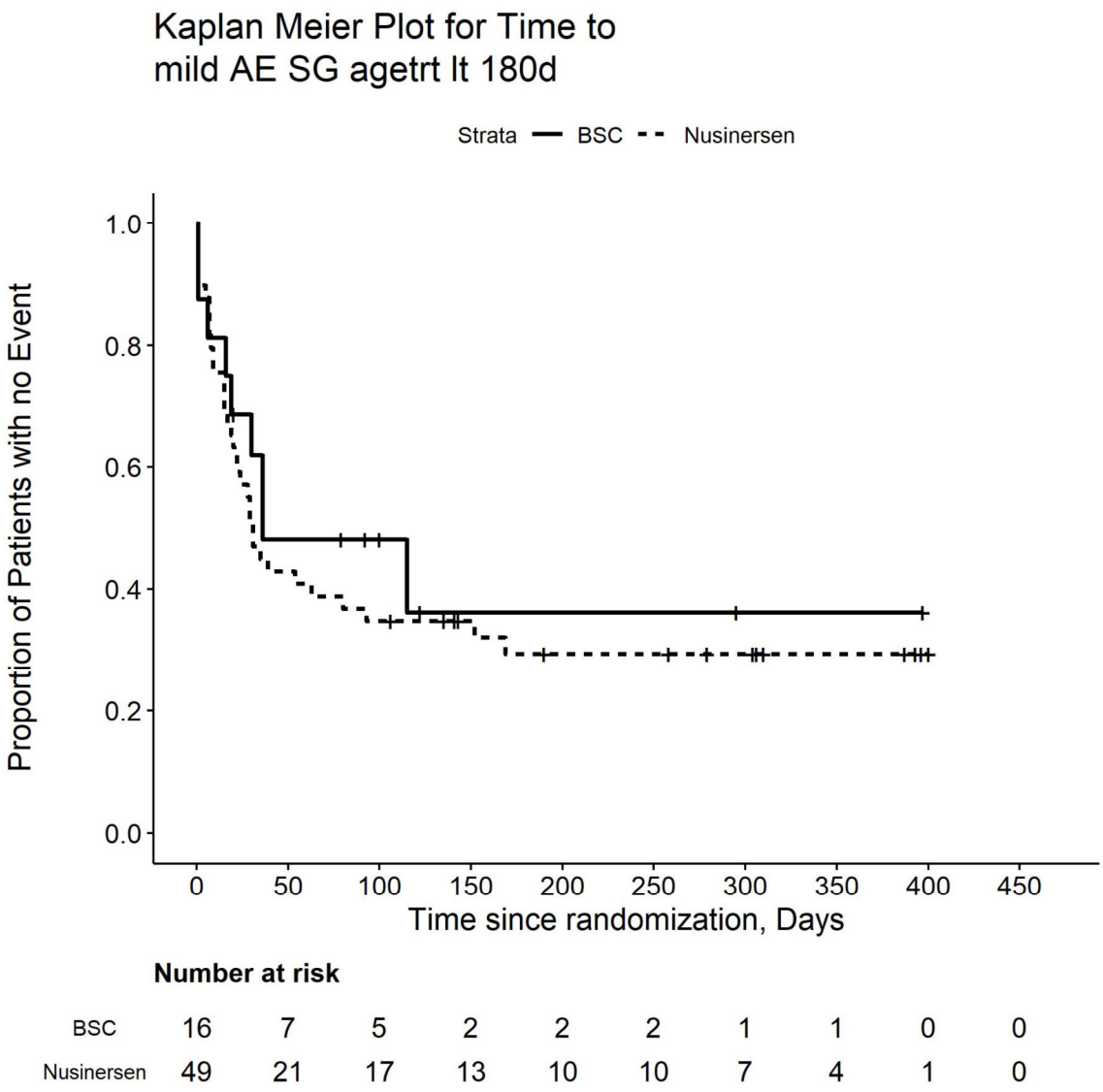
Number at risk

BSC	32	10	8	4	3	3	2	2	0	0
Nusinersen	72	33	25	20	15	13	10	7	1	0



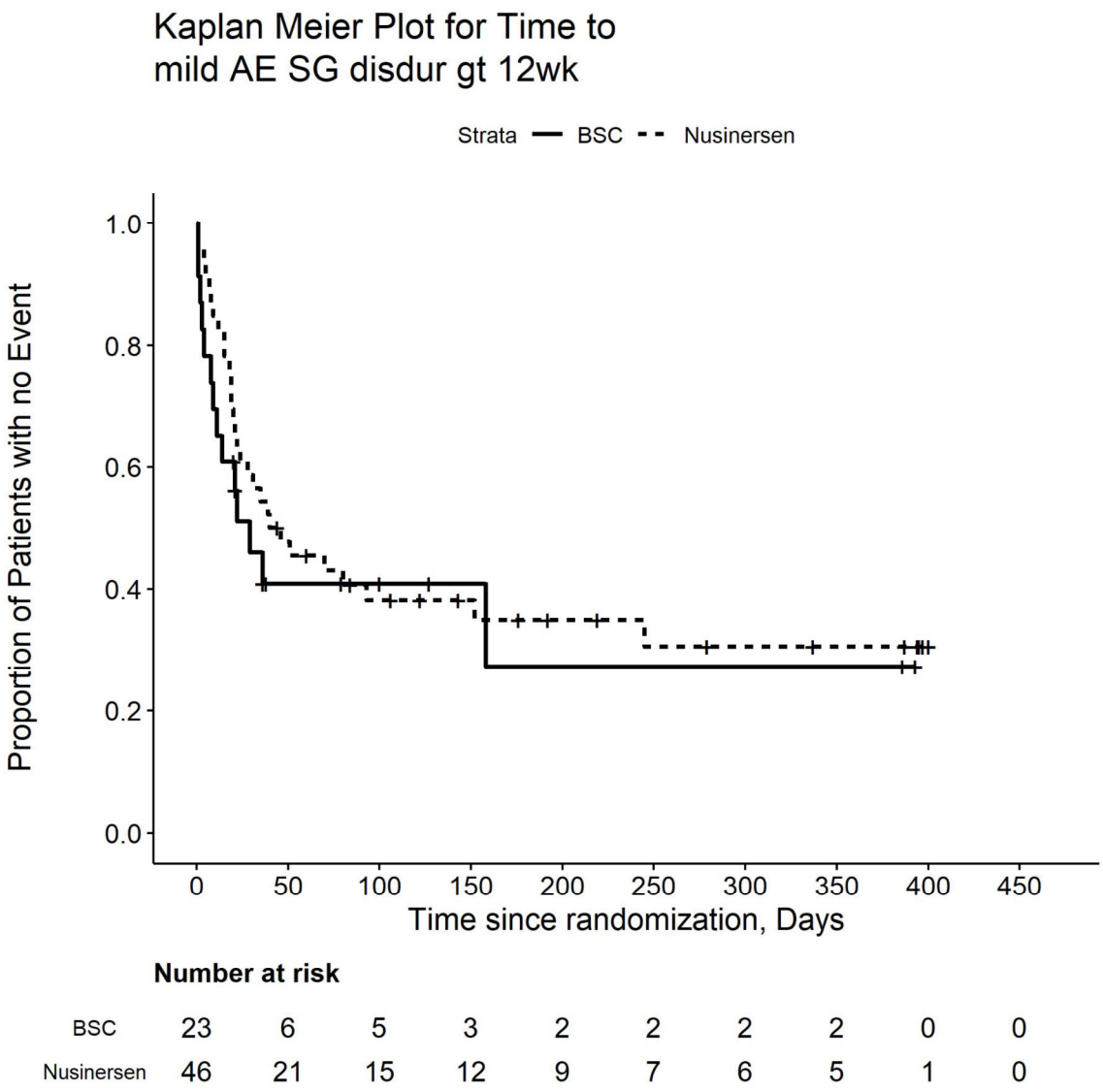
Number at risk

BSC	25	7	7	6	4	3	3	3	0	0
Nusinersen	31	14	9	8	6	4	4	3	0	0



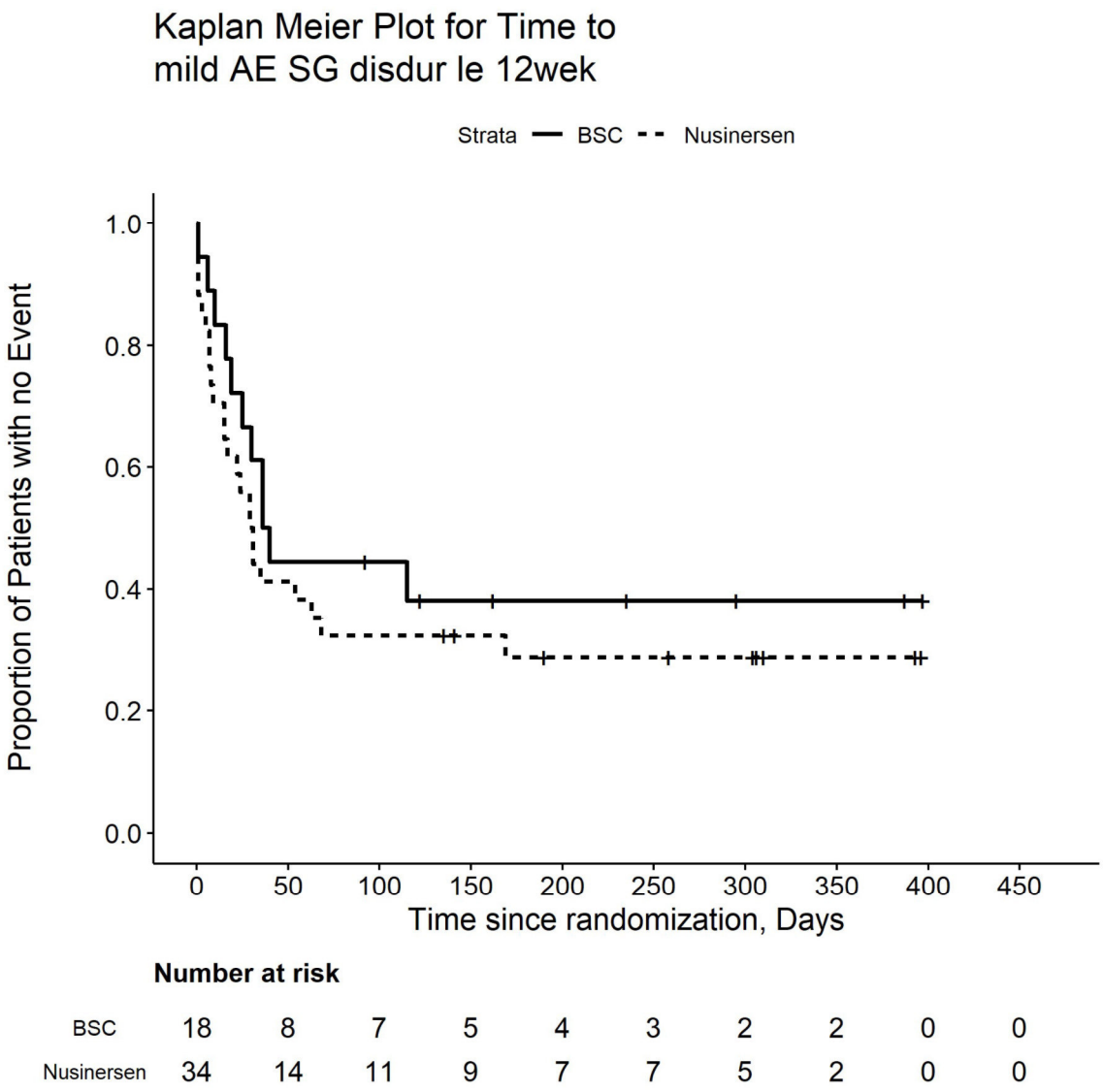
Number at risk

BSC	16	7	5	2	2	2	1	1	0	0
Nusinersen	49	21	17	13	10	10	7	4	1	0



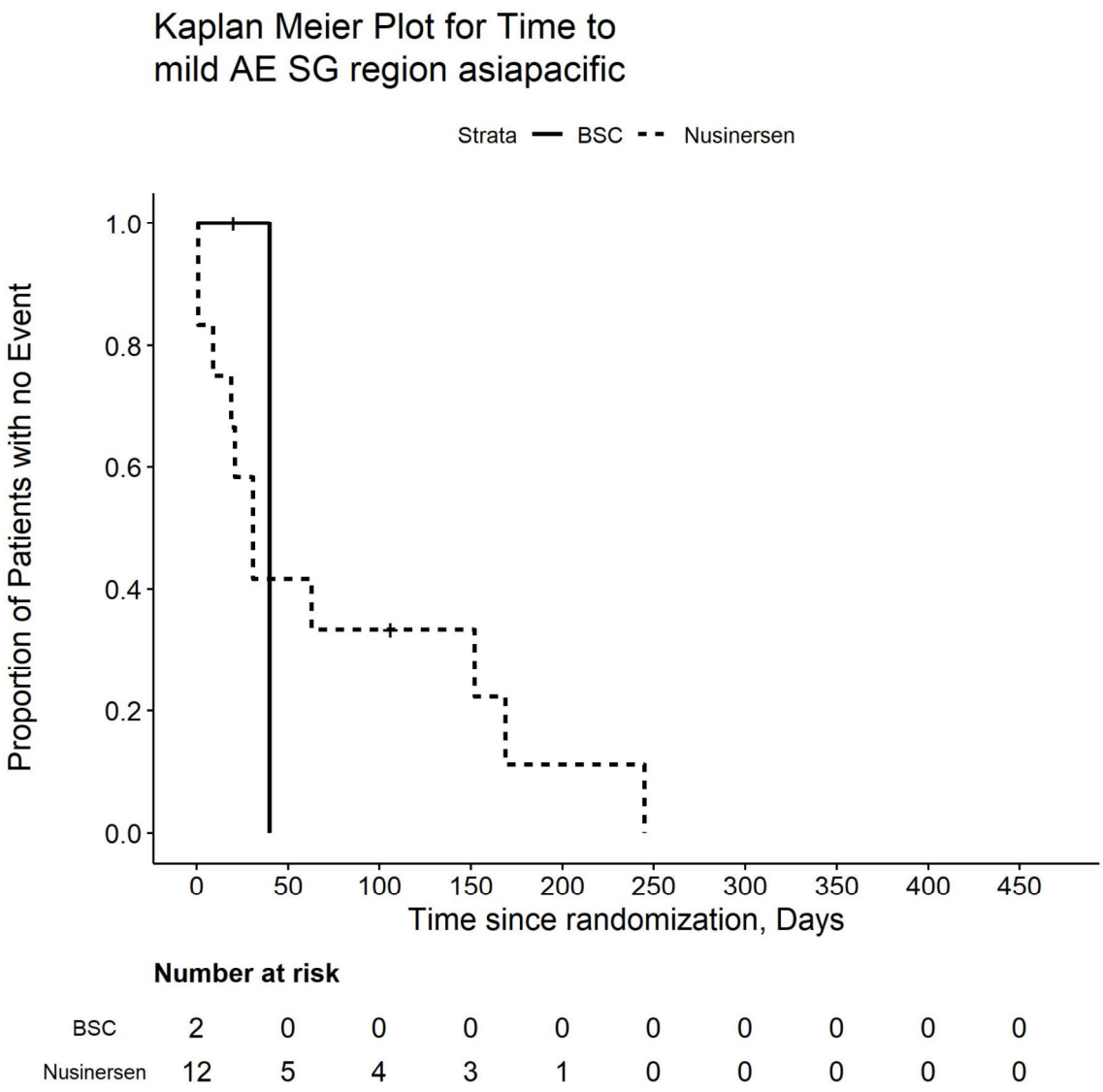
Number at risk

BSC	23	6	5	3	2	2	2	2	0	0
Nusinersen	46	21	15	12	9	7	6	5	1	0



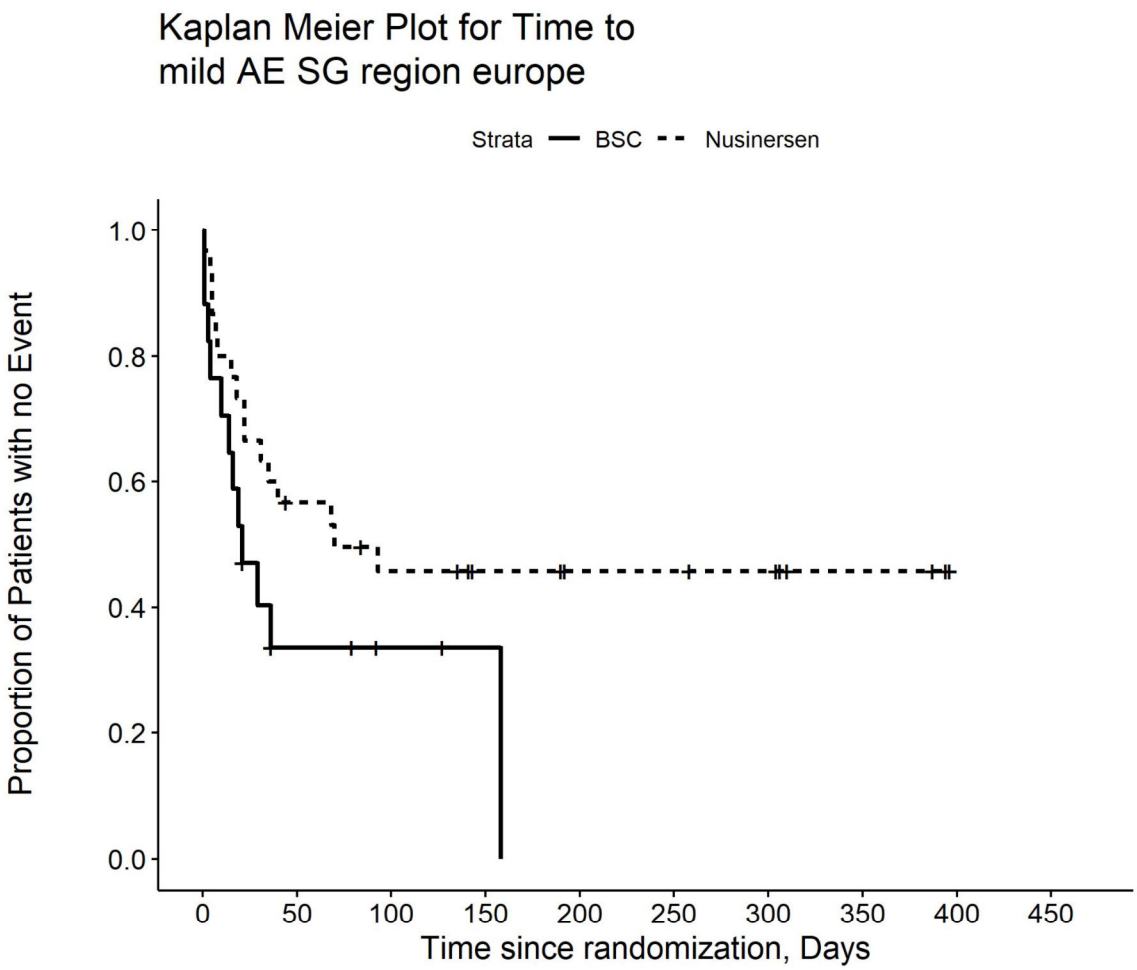
Number at risk

BSC	18	8	7	5	4	3	2	2	0	0
Nusinersen	34	14	11	9	7	7	5	2	0	0



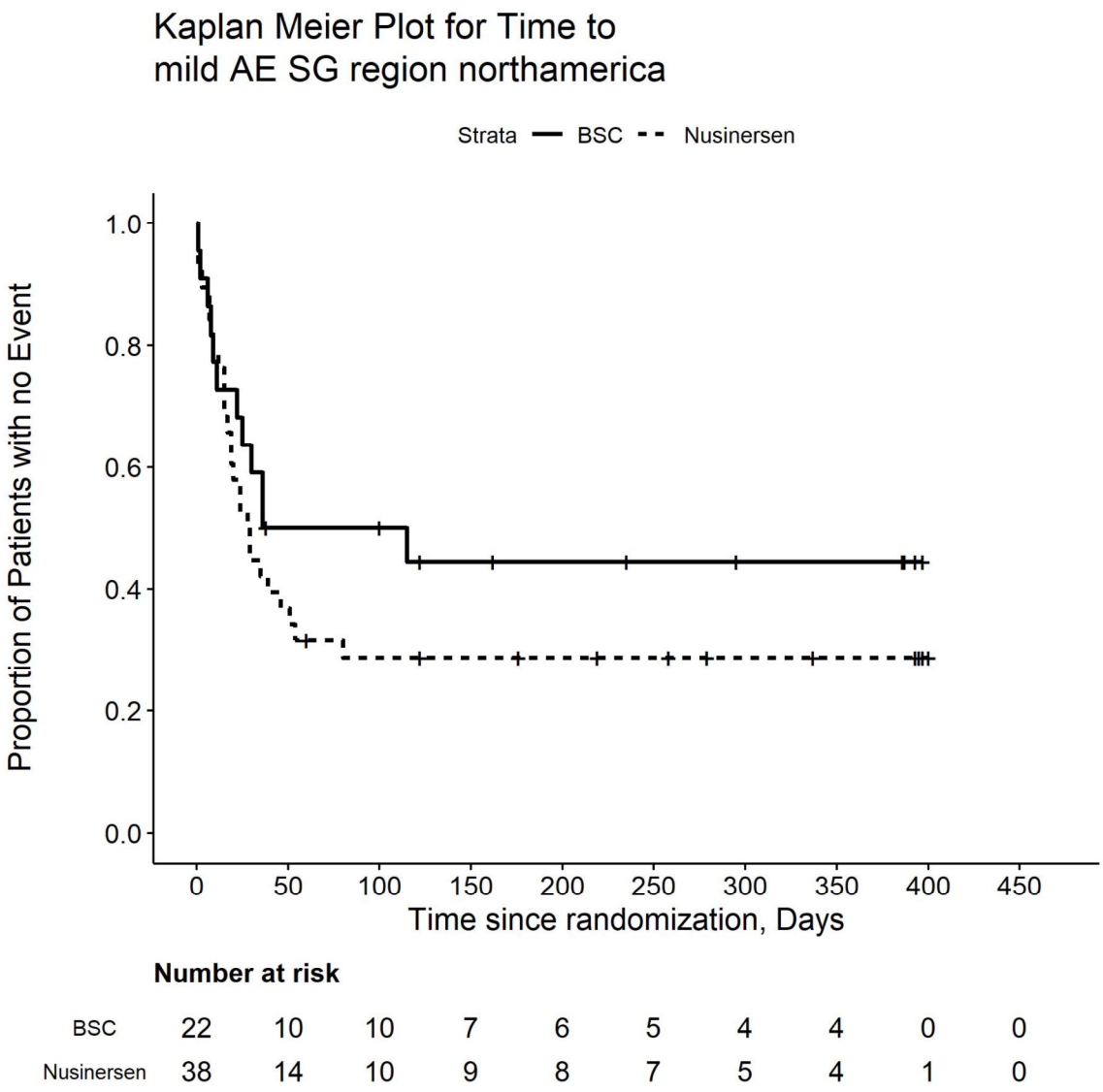
Number at risk

BSC	2	0	0	0	0	0	0	0	0	0
Nusinersen	12	5	4	3	1	0	0	0	0	0



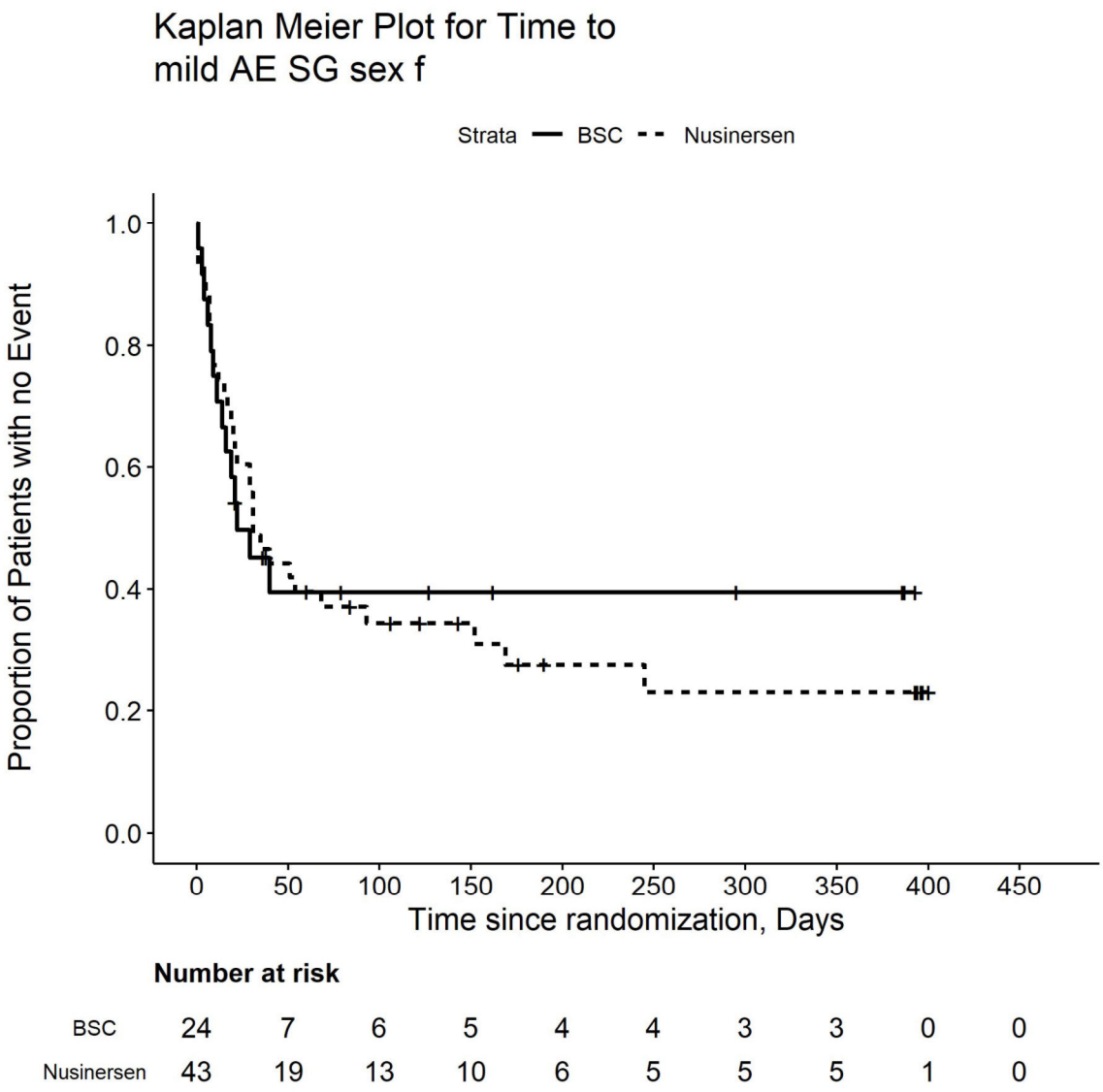
Number at risk

BSC	17	4	2	1	0	0	0	0	0	0
Nusinersen	30	16	12	9	7	7	6	3	0	0



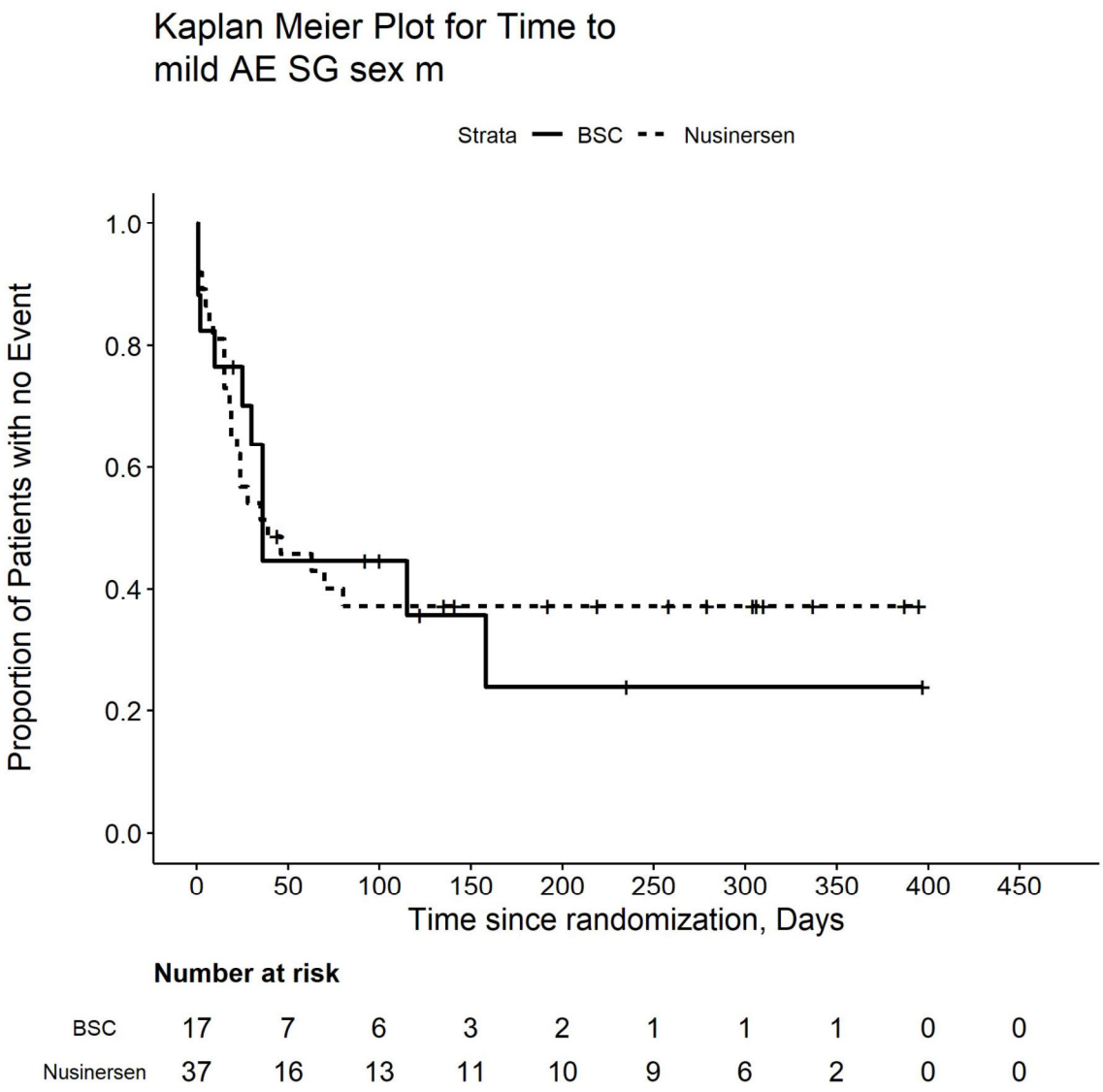
Number at risk

BSC	22	10	10	7	6	5	4	4	0	0
Nusinersen	38	14	10	9	8	7	5	4	1	0



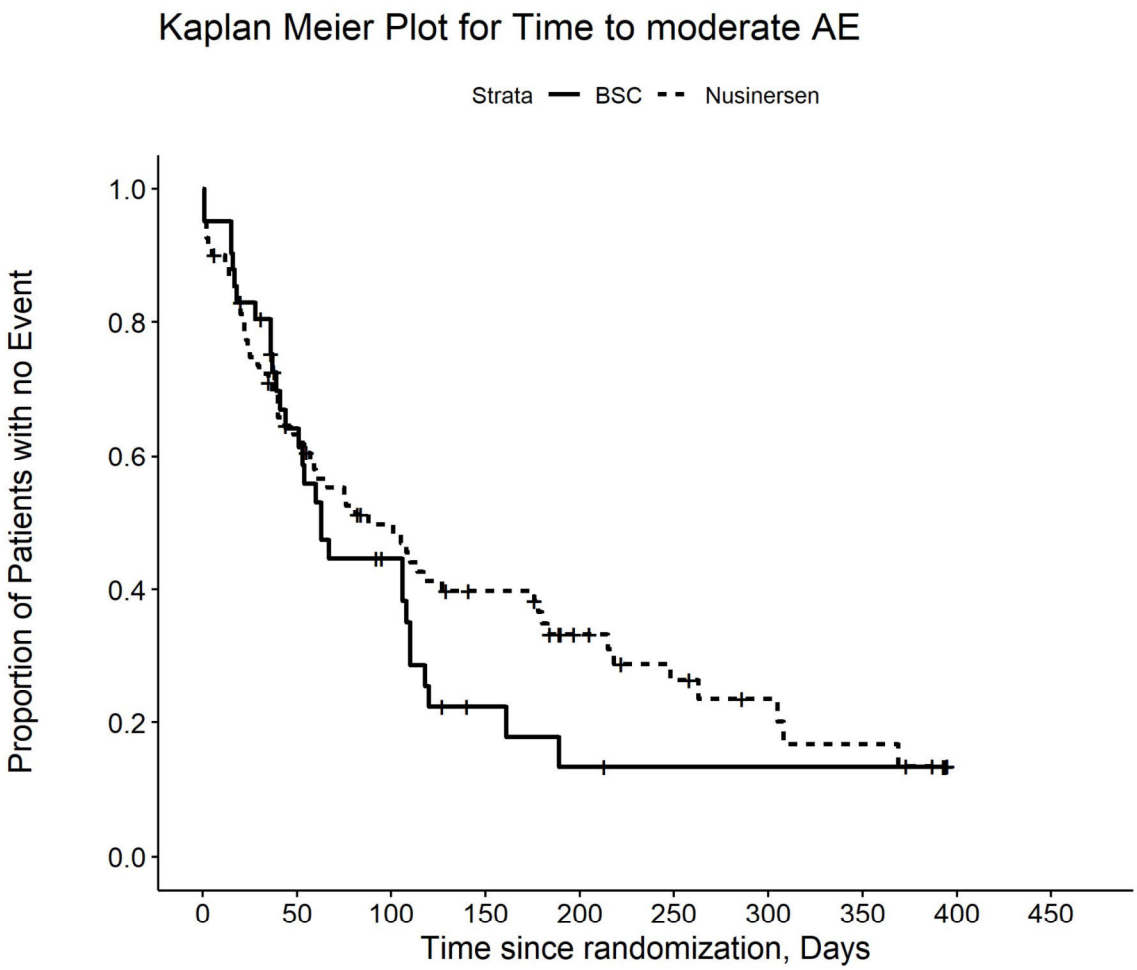
Number at risk

BSC	24	7	6	5	4	4	3	3	0	0
Nusinersen	43	19	13	10	6	5	5	5	1	0



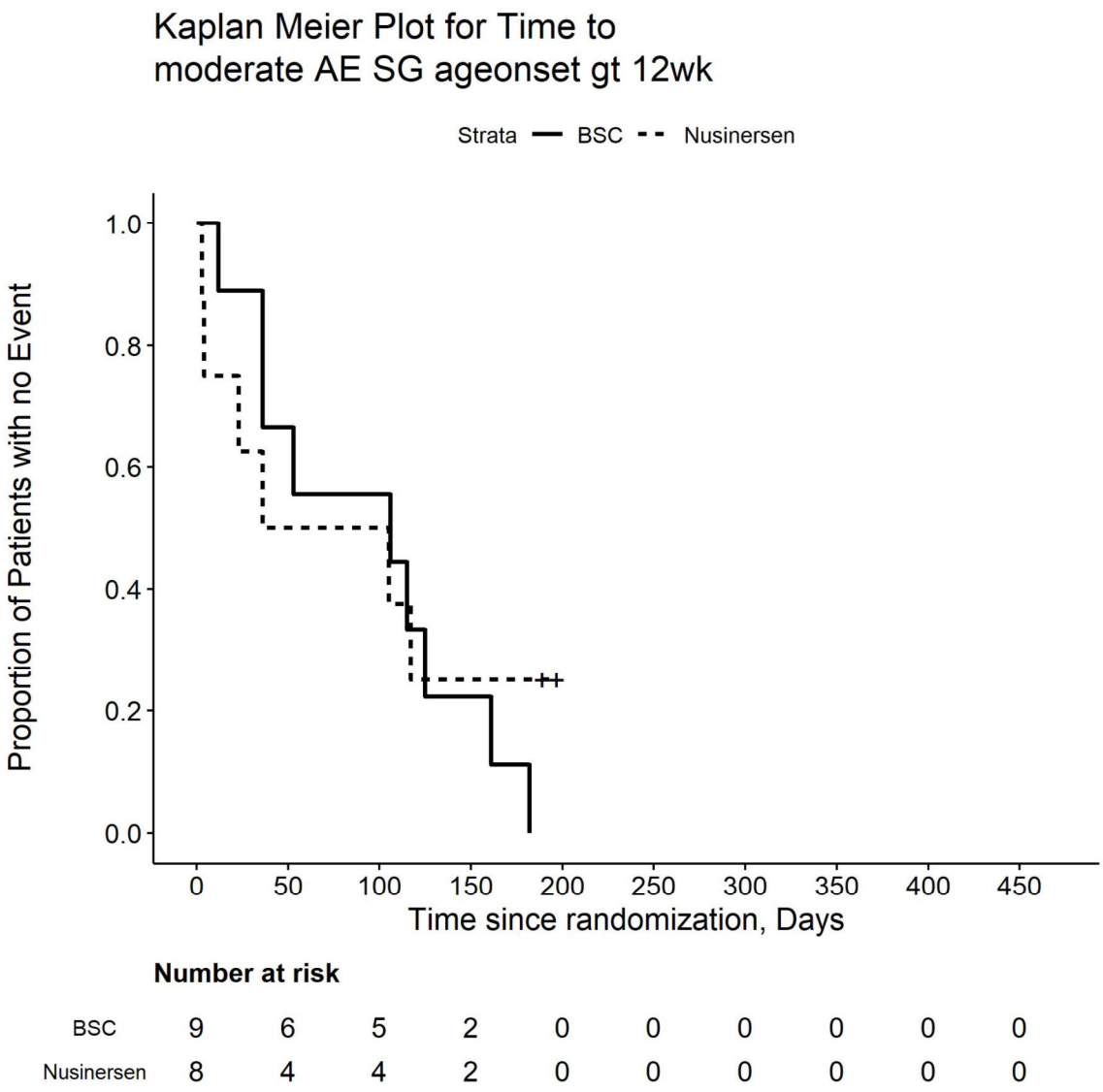
Number at risk

BSC	17	7	6	3	2	1	1	1	0	0
Nusinersen	37	16	13	11	10	9	6	2	0	0



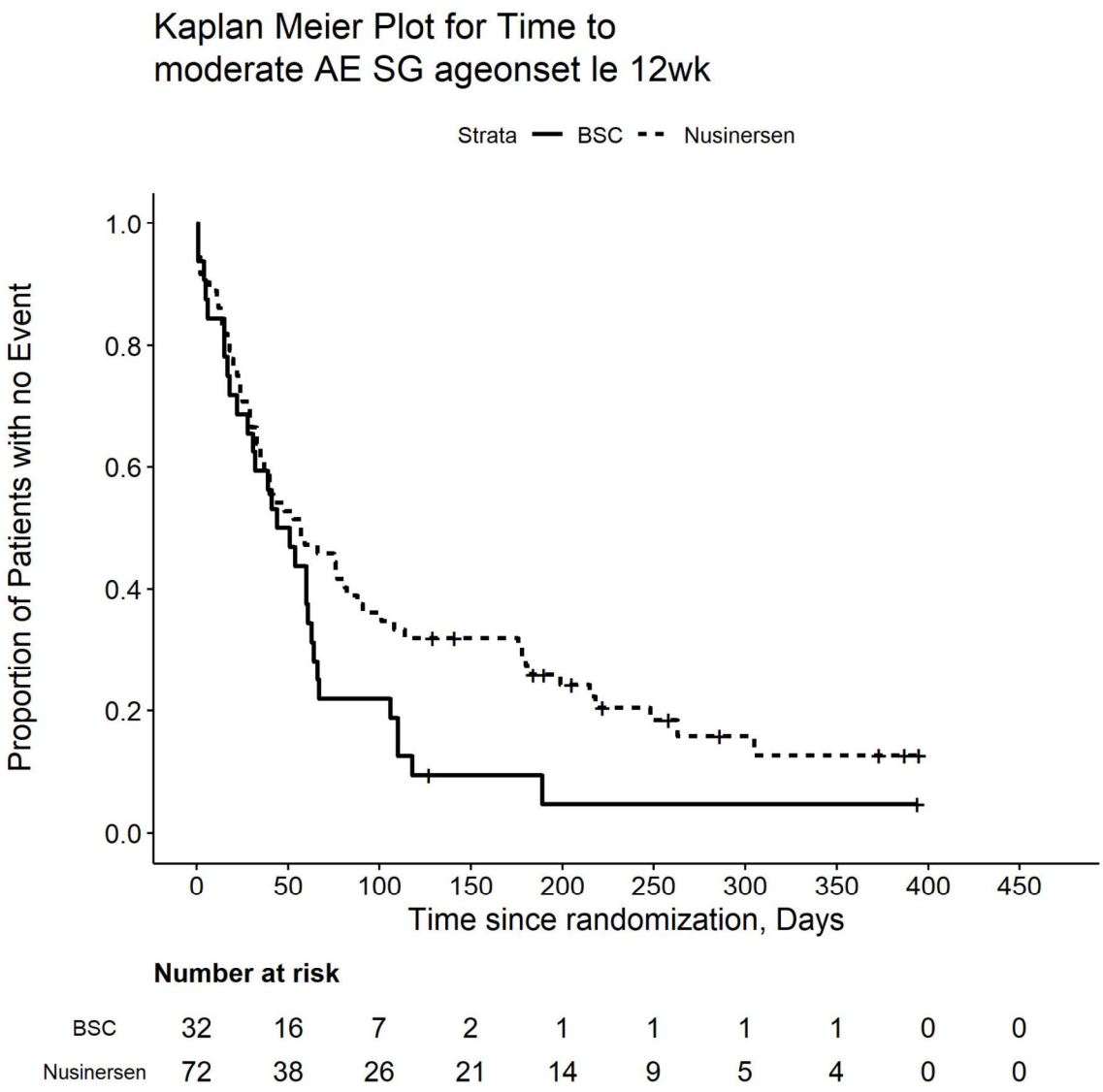
Number at risk

BSC	41	23	14	5	3	2	2	2	0	0
Nusinersen	80	48	35	26	16	11	7	5	0	0



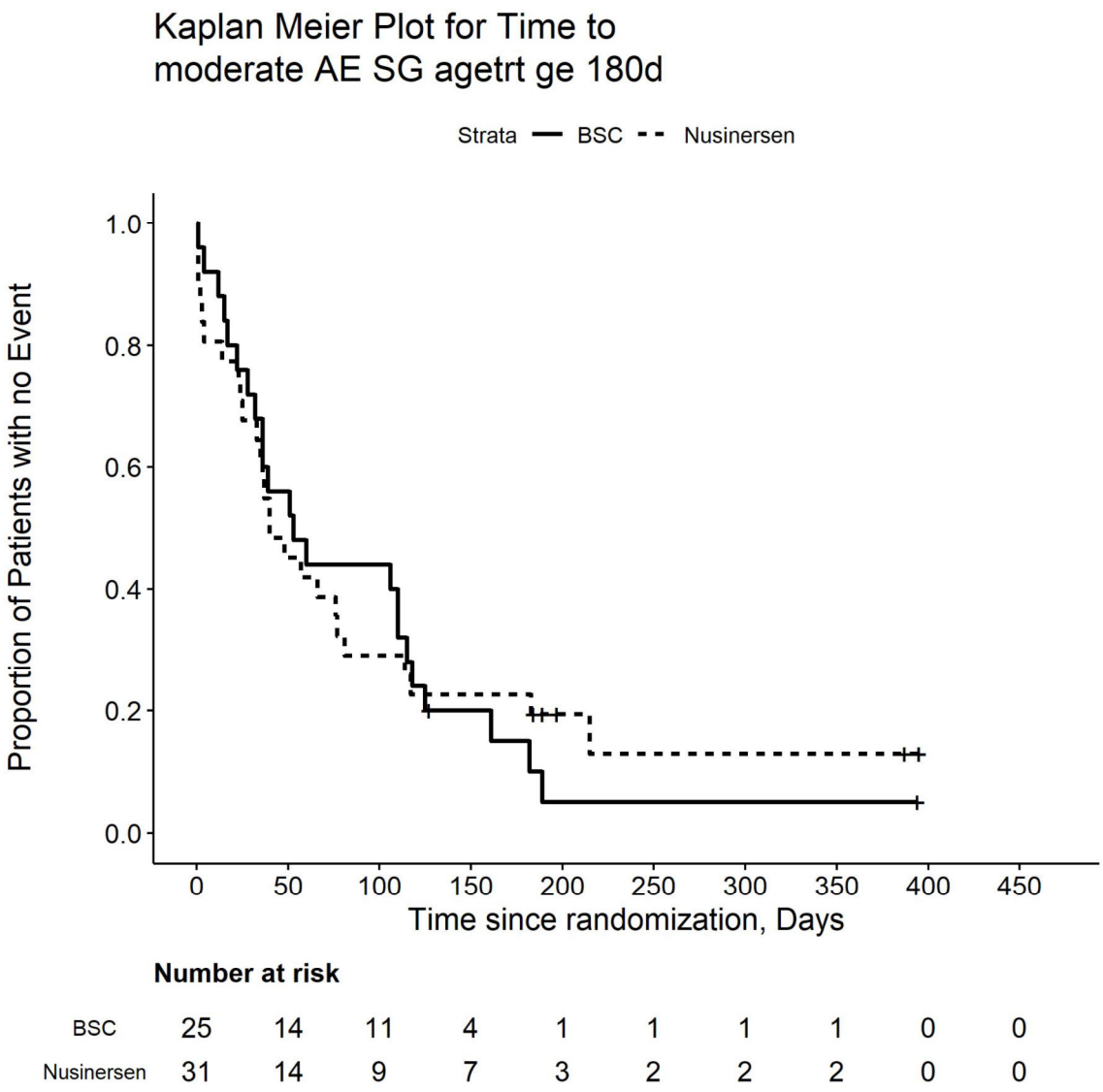
Number at risk

BSC	9	6	5	2	0	0	0	0	0	0
Nusinersen	8	4	4	2	0	0	0	0	0	0



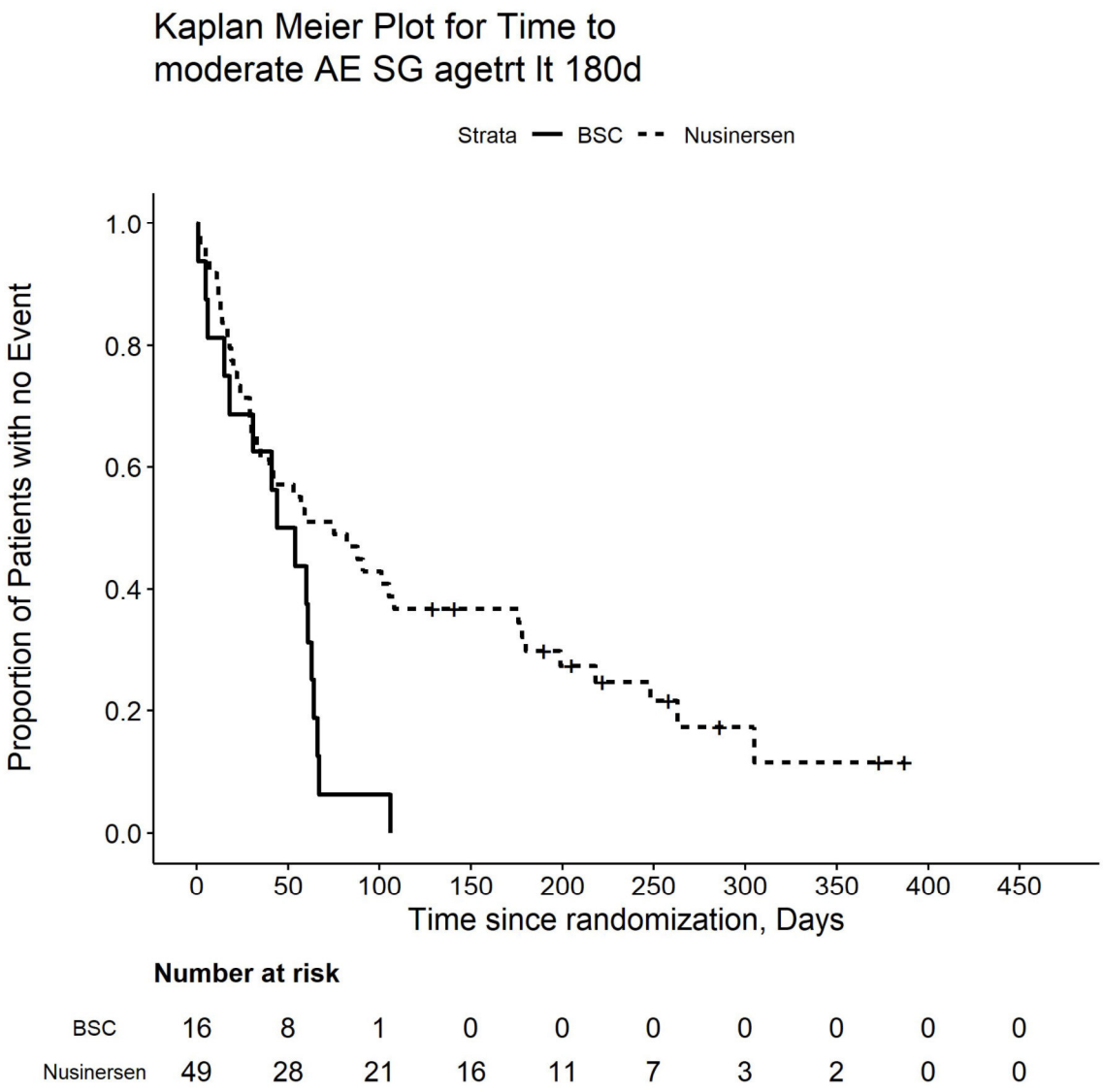
Number at risk

BSC	32	16	7	2	1	1	1	1	0	0
Nusinersen	72	38	26	21	14	9	5	4	0	0



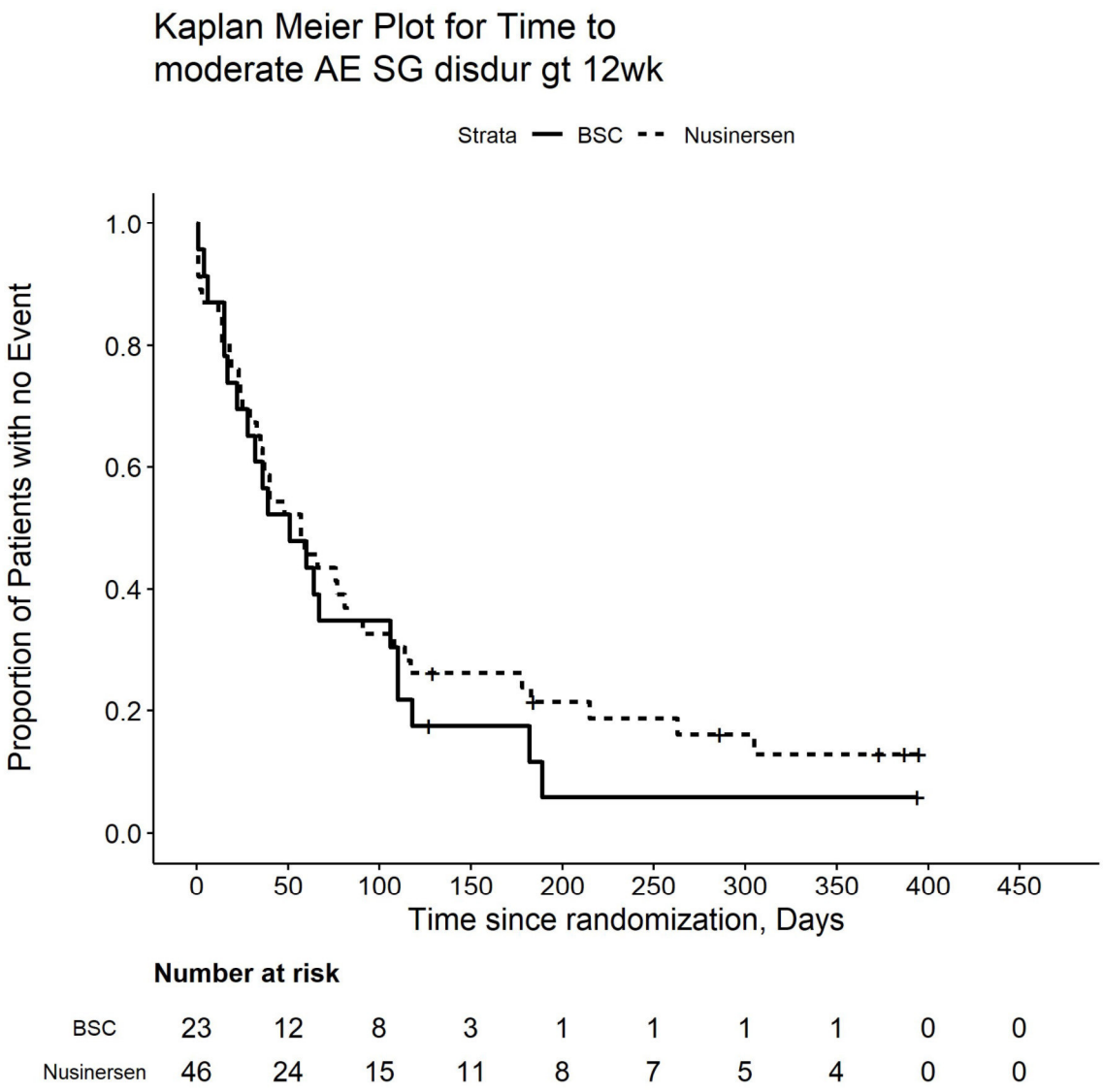
Number at risk

BSC	25	14	11	4	1	1	1	1	0	0
Nusinersen	31	14	9	7	3	2	2	2	0	0



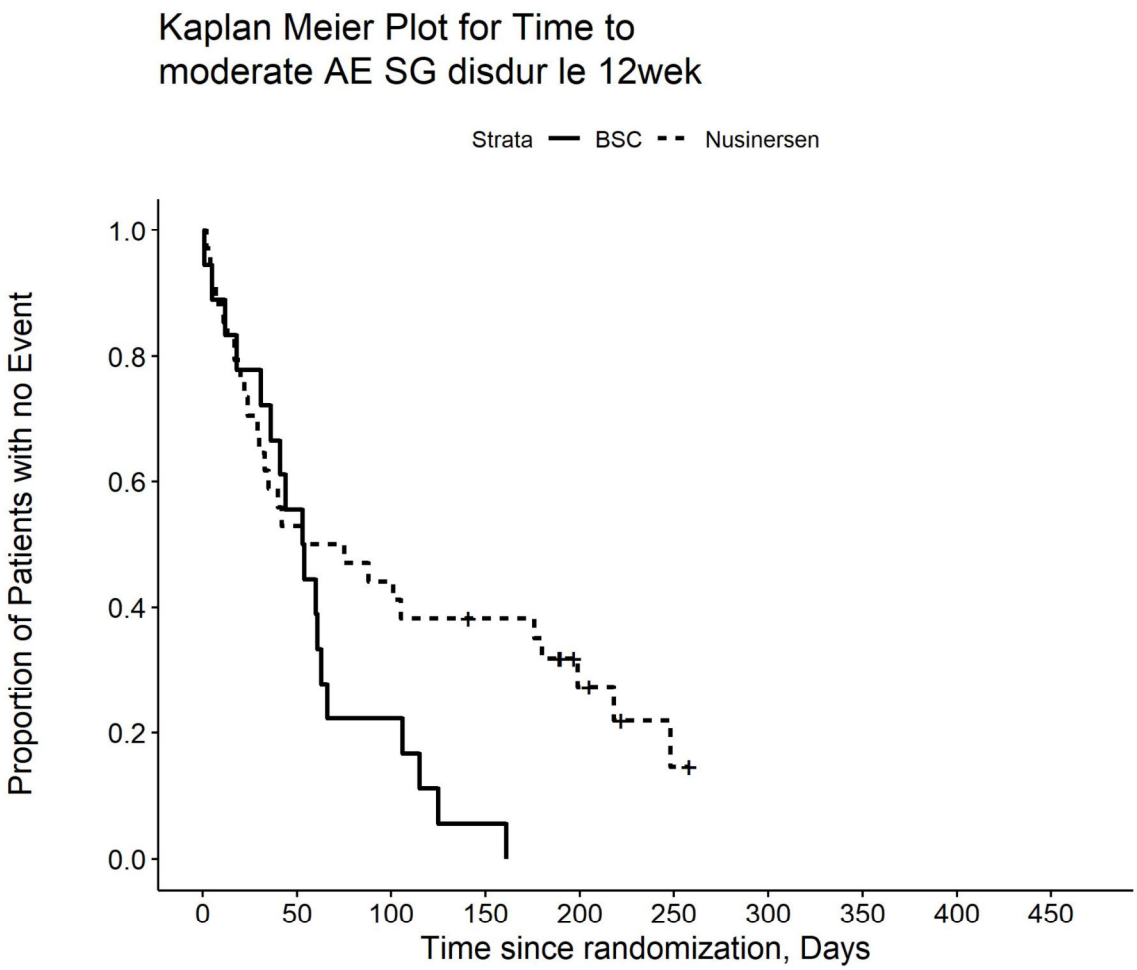
Number at risk

BSC	16	8	1	0	0	0	0	0	0	0
Nusinersen	49	28	21	16	11	7	3	2	0	0



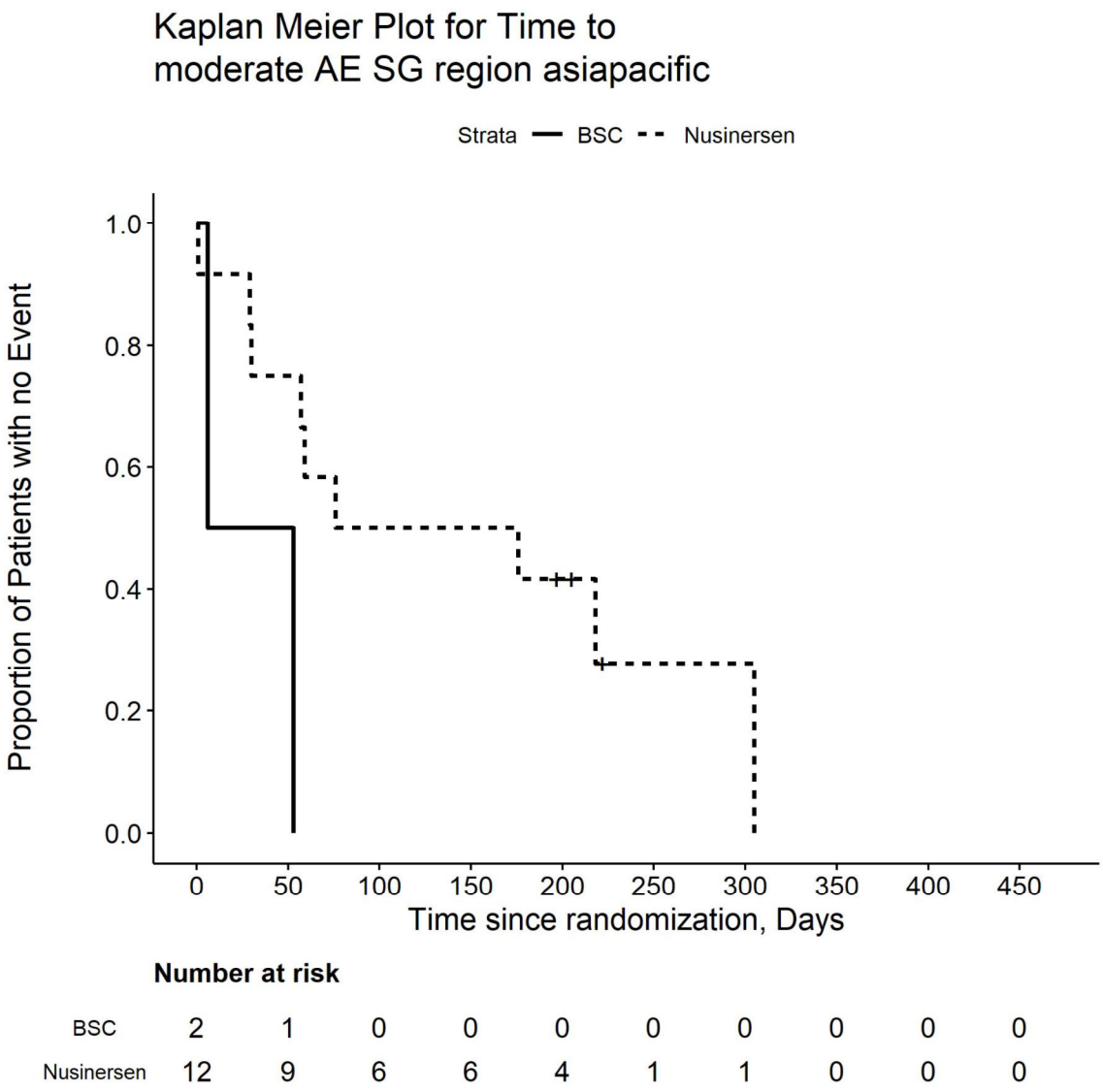
Number at risk

BSC	23	12	8	3	1	1	1	1	0	0
Nusinersen	46	24	15	11	8	7	5	4	0	0



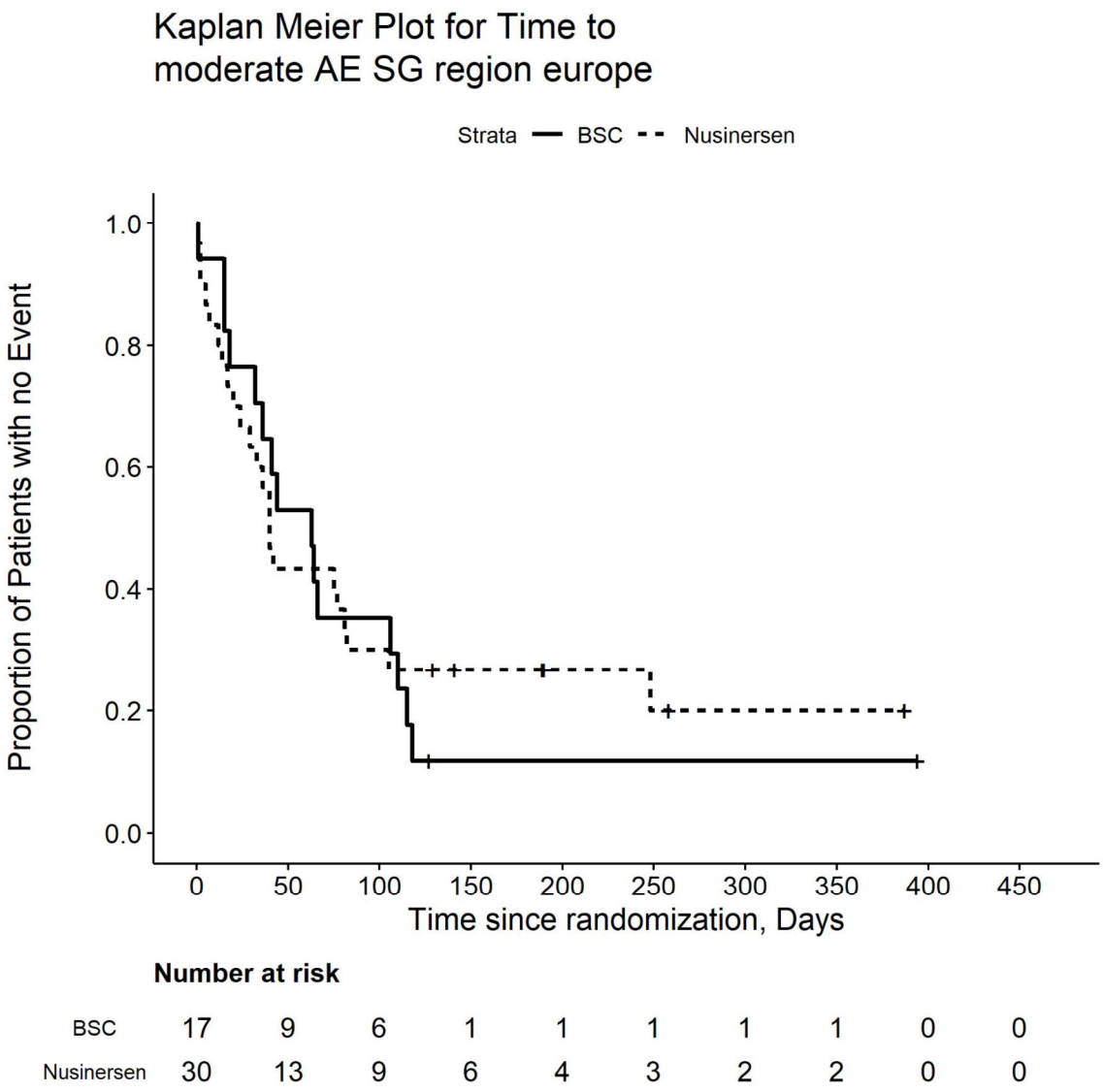
Number at risk

BSC	18	10	4	1	0	0	0	0	0	0
Nusinersen	34	18	15	12	6	2	0	0	0	0



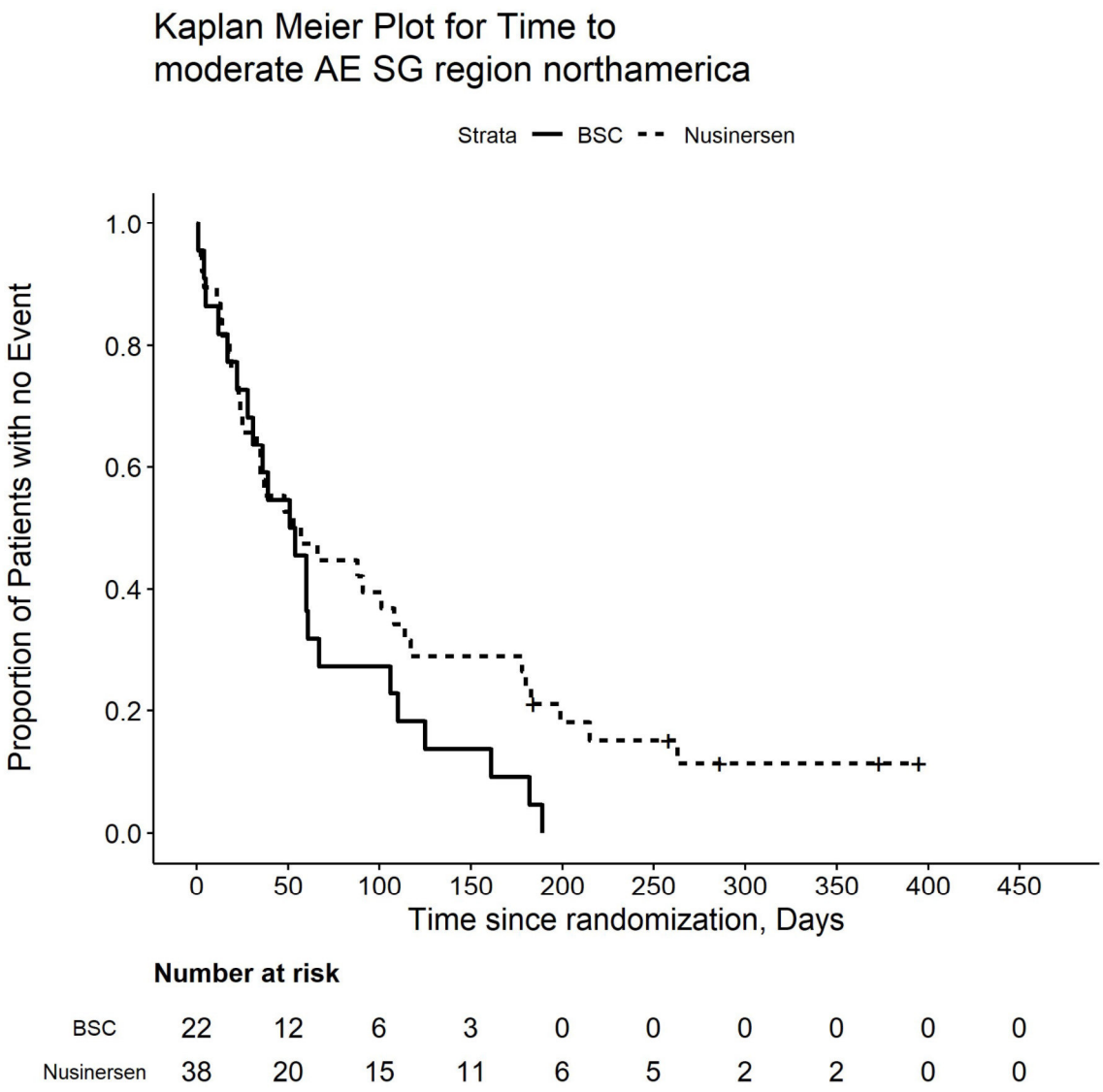
Number at risk

BSC	2	1	0	0	0	0	0	0	0	0
Nusinersen	12	9	6	6	4	1	1	0	0	0



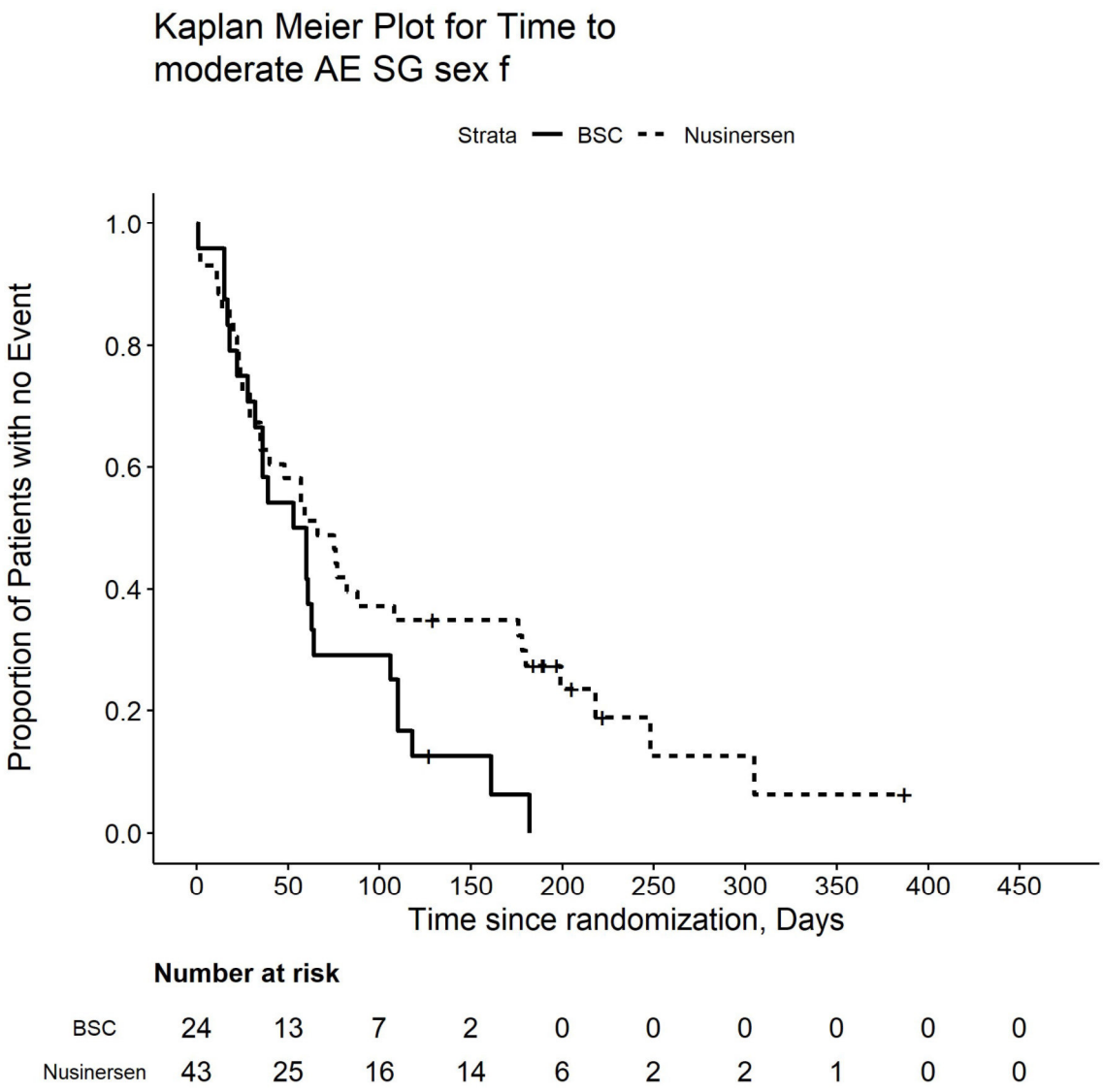
Number at risk

BSC	17	9	6	1	1	1	1	1	0	0
Nusinersen	30	13	9	6	4	3	2	2	0	0



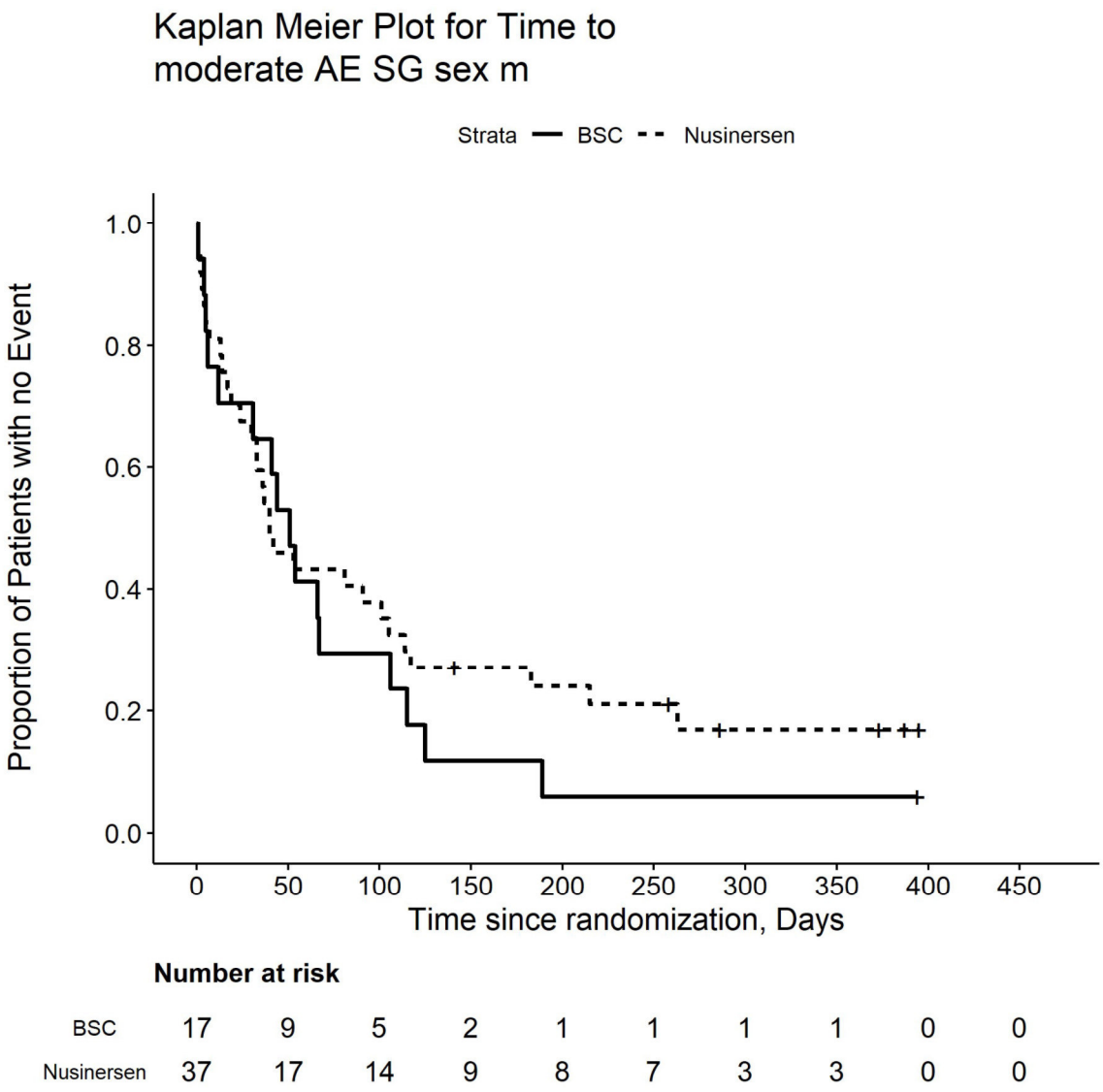
Number at risk

BSC	22	12	6	3	0	0	0	0	0	0
Nusinersen	38	20	15	11	6	5	2	2	0	0



Number at risk

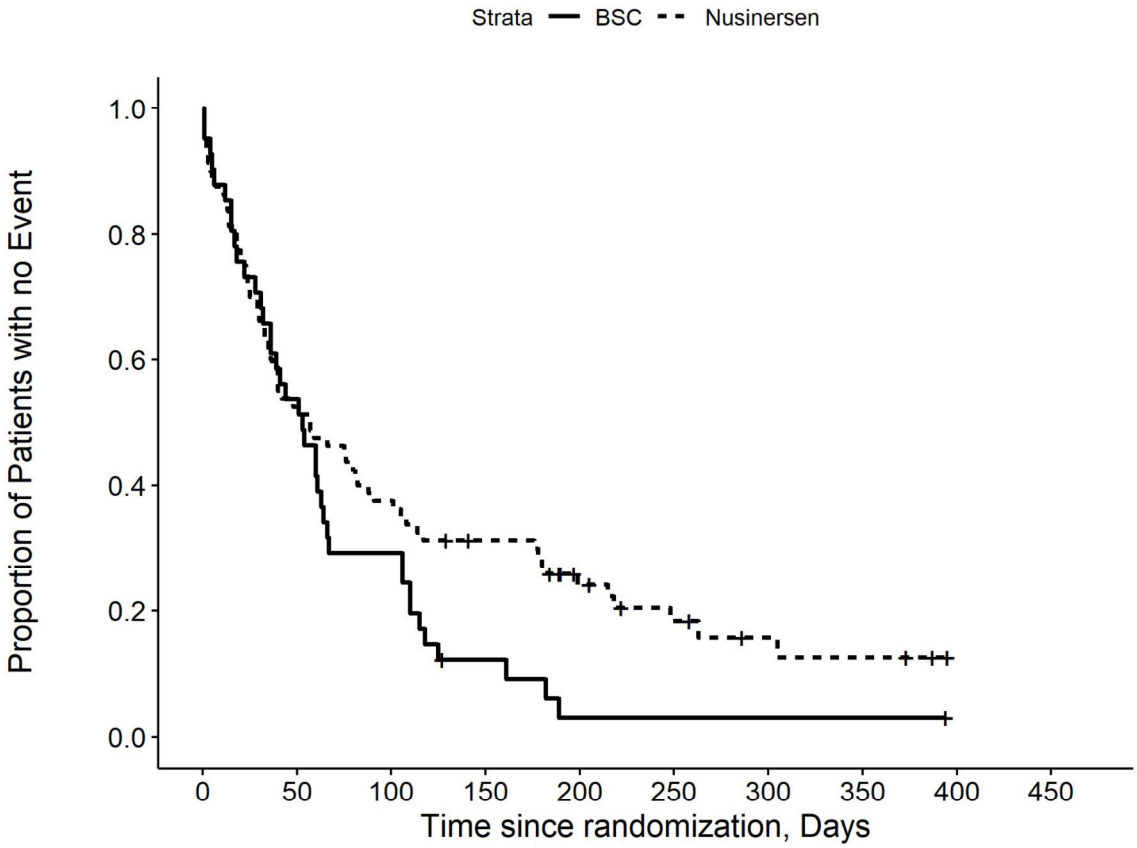
BSC	24	13	7	2	0	0	0	0	0	0
Nusinersen	43	25	16	14	6	2	2	1	0	0



Number at risk

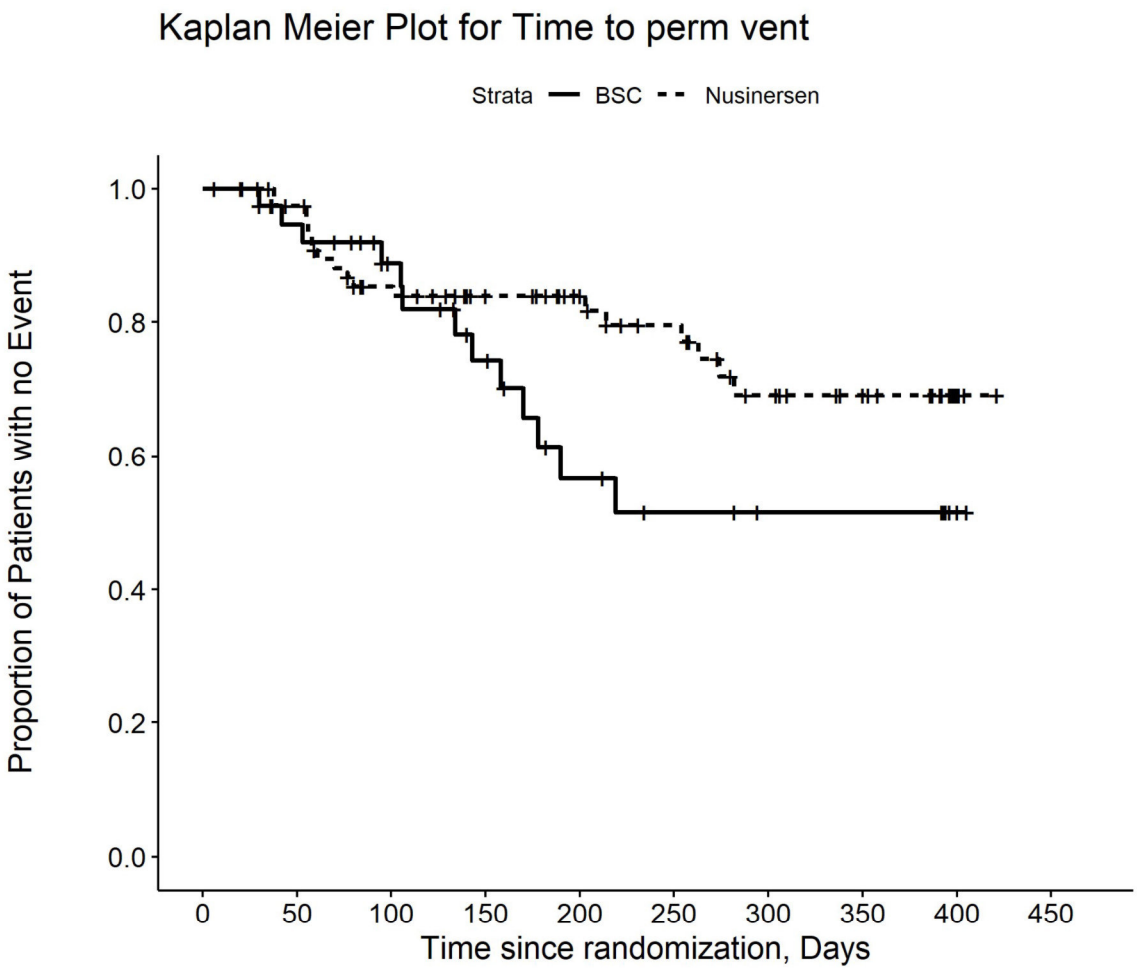
BSC	17	9	5	2	1	1	1	1	0	0
Nusinersen	37	17	14	9	8	7	3	3	0	0

Kaplan Meier Plot for Time to moderate or severe AE



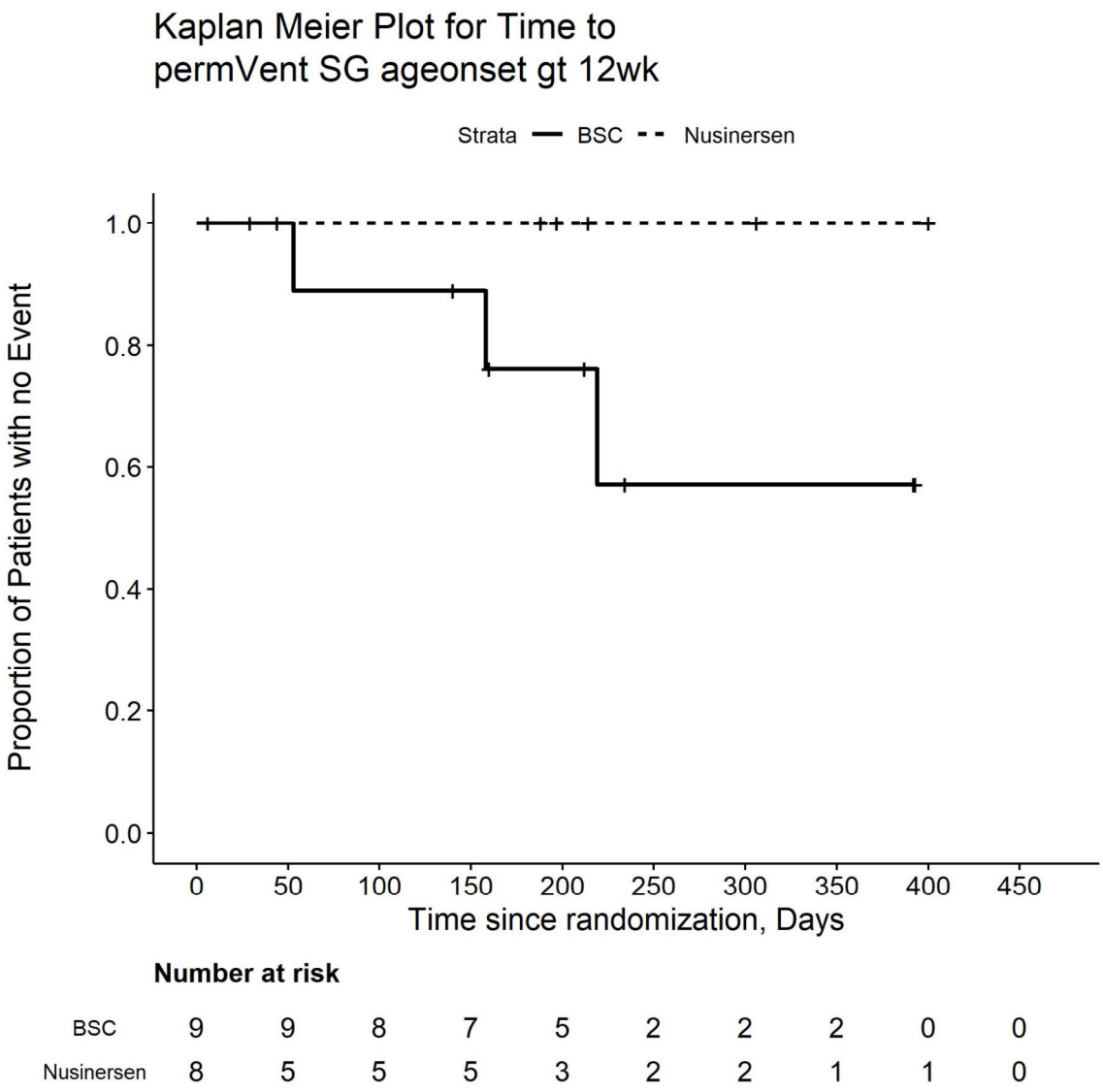
Number at risk

BSC	41	22	12	4	1	1	1	1	0	0
Nusinersen	80	42	30	23	14	9	5	4	0	0



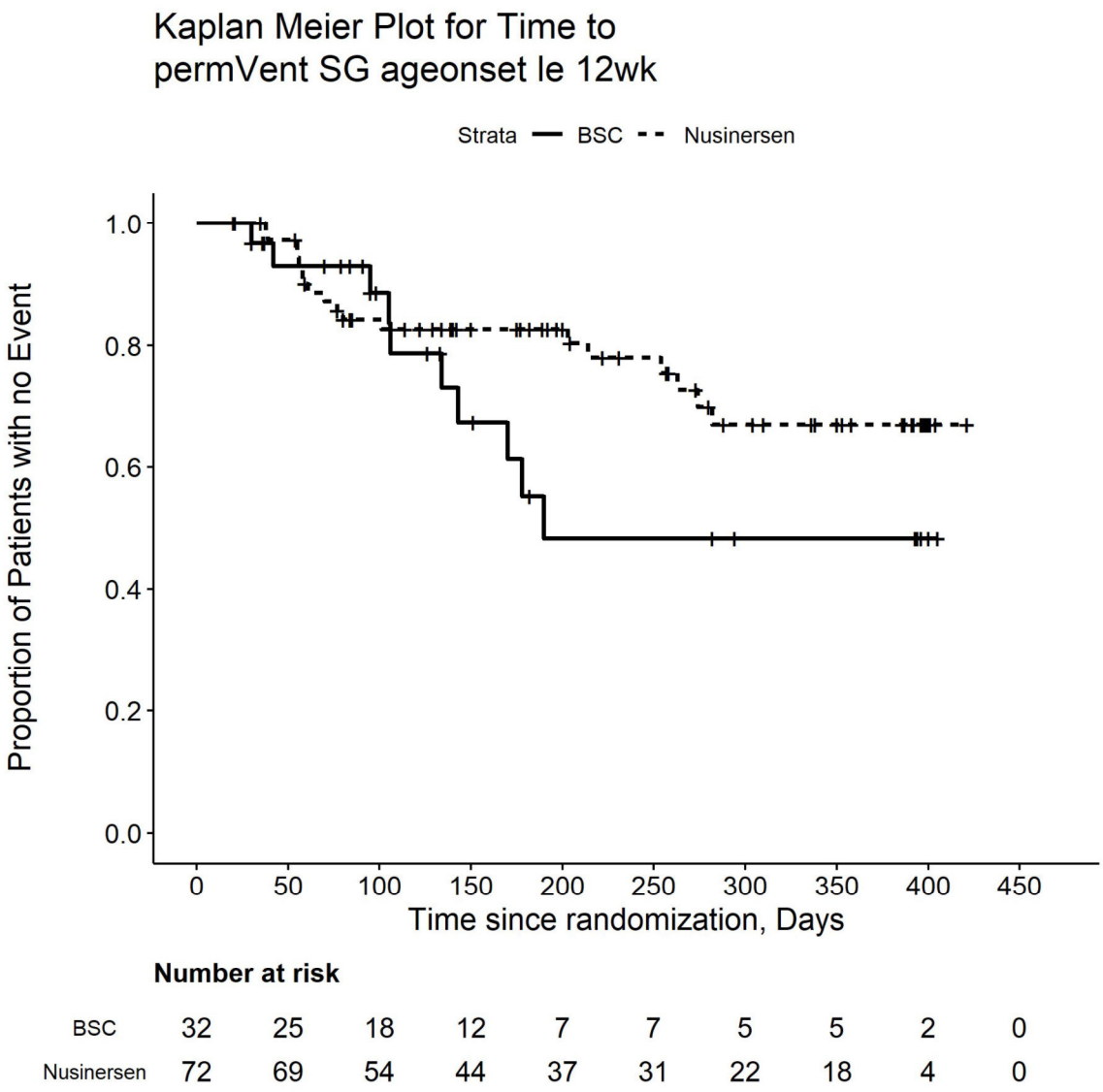
Number at risk

BSC	41	34	26	19	12	9	7	7	2	0
Nusinersen	80	74	59	49	40	33	24	19	5	0



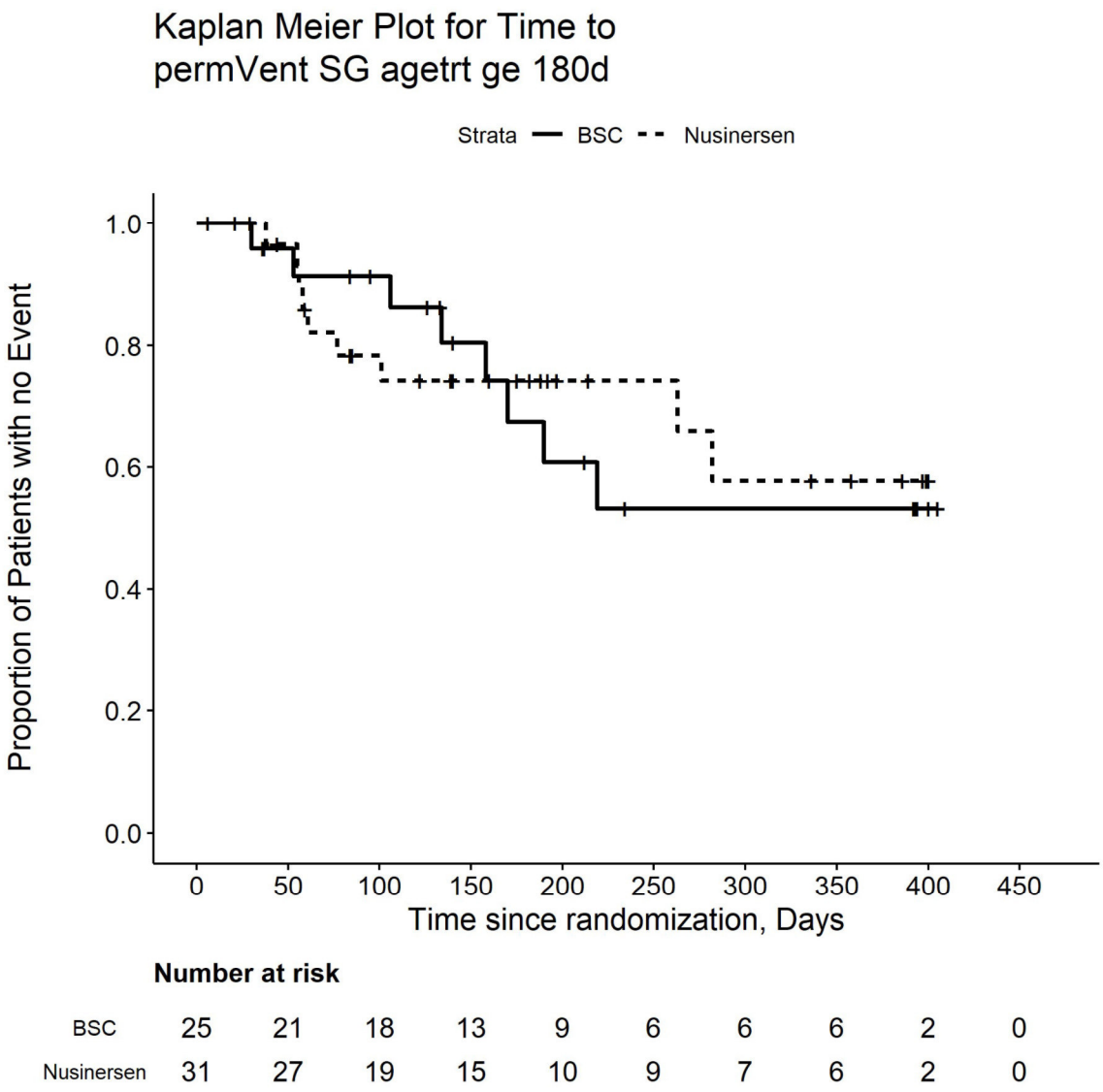
Number at risk

BSC	9	9	8	7	5	2	2	2	0	0
Nusinersen	8	5	5	5	3	2	2	1	1	0



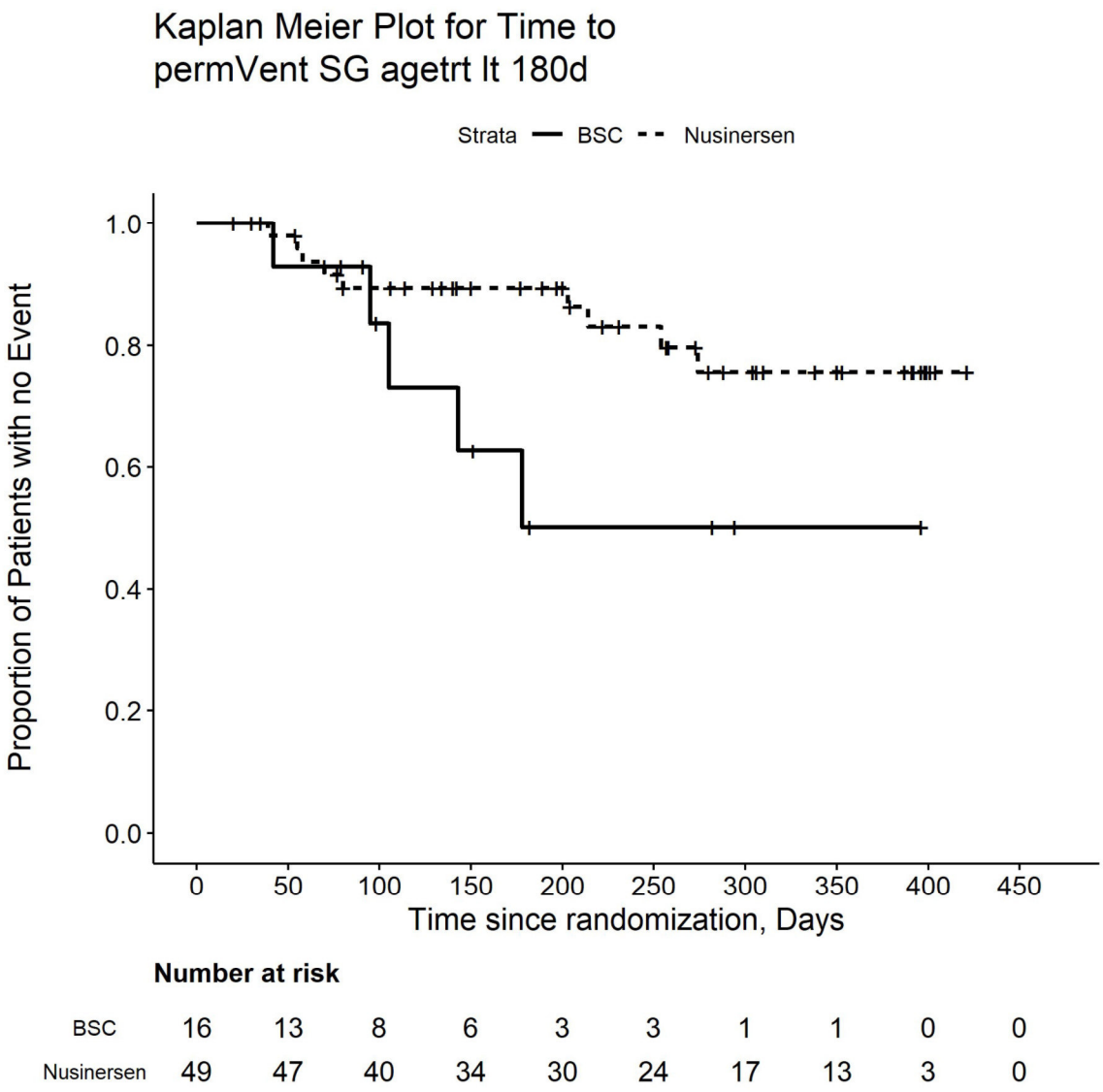
Number at risk

BSC	32	25	18	12	7	7	5	5	2	0
Nusinersen	72	69	54	44	37	31	22	18	4	0



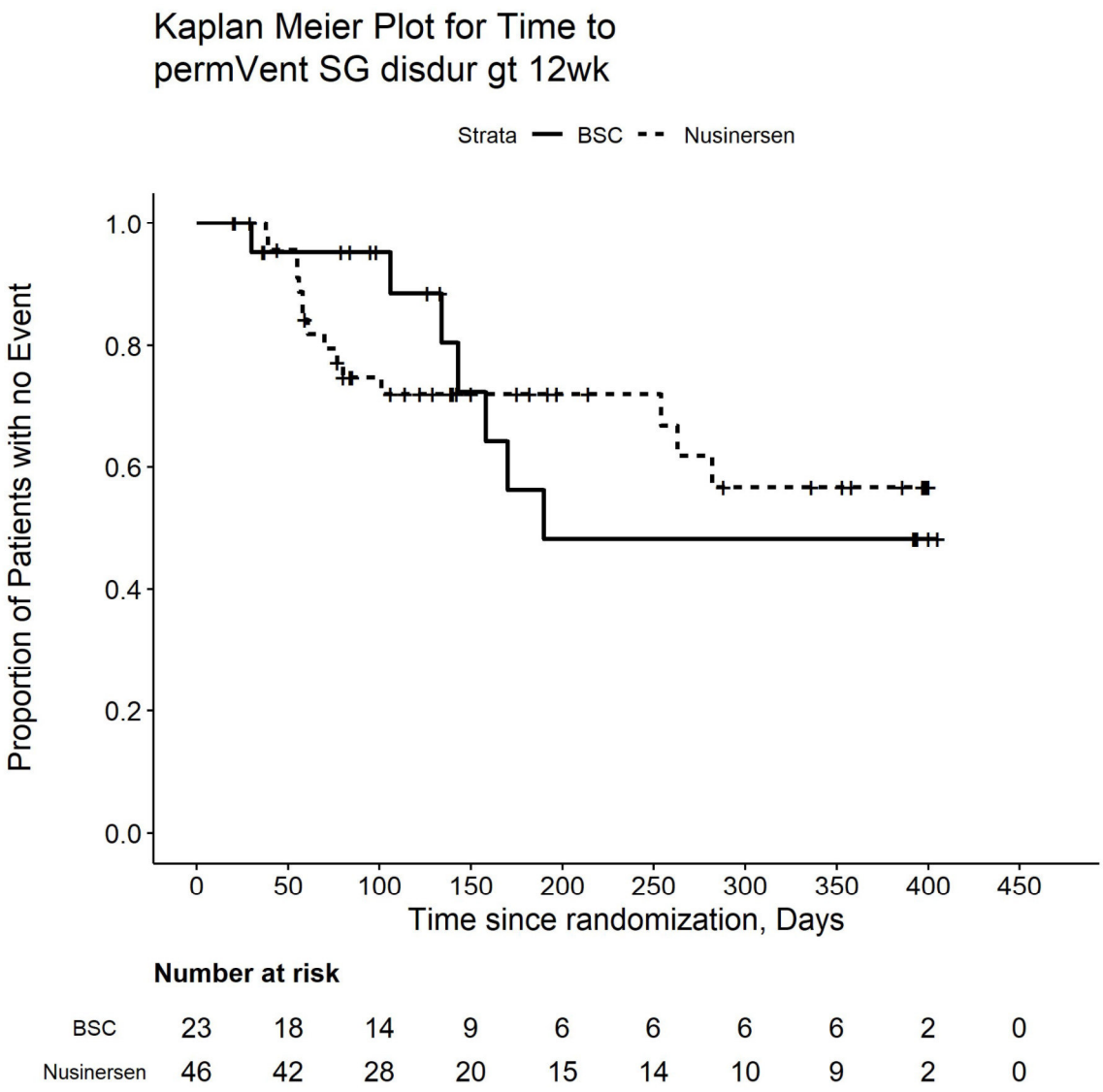
Number at risk

BSC	25	21	18	13	9	6	6	6	2	0
Nusinersen	31	27	19	15	10	9	7	6	2	0



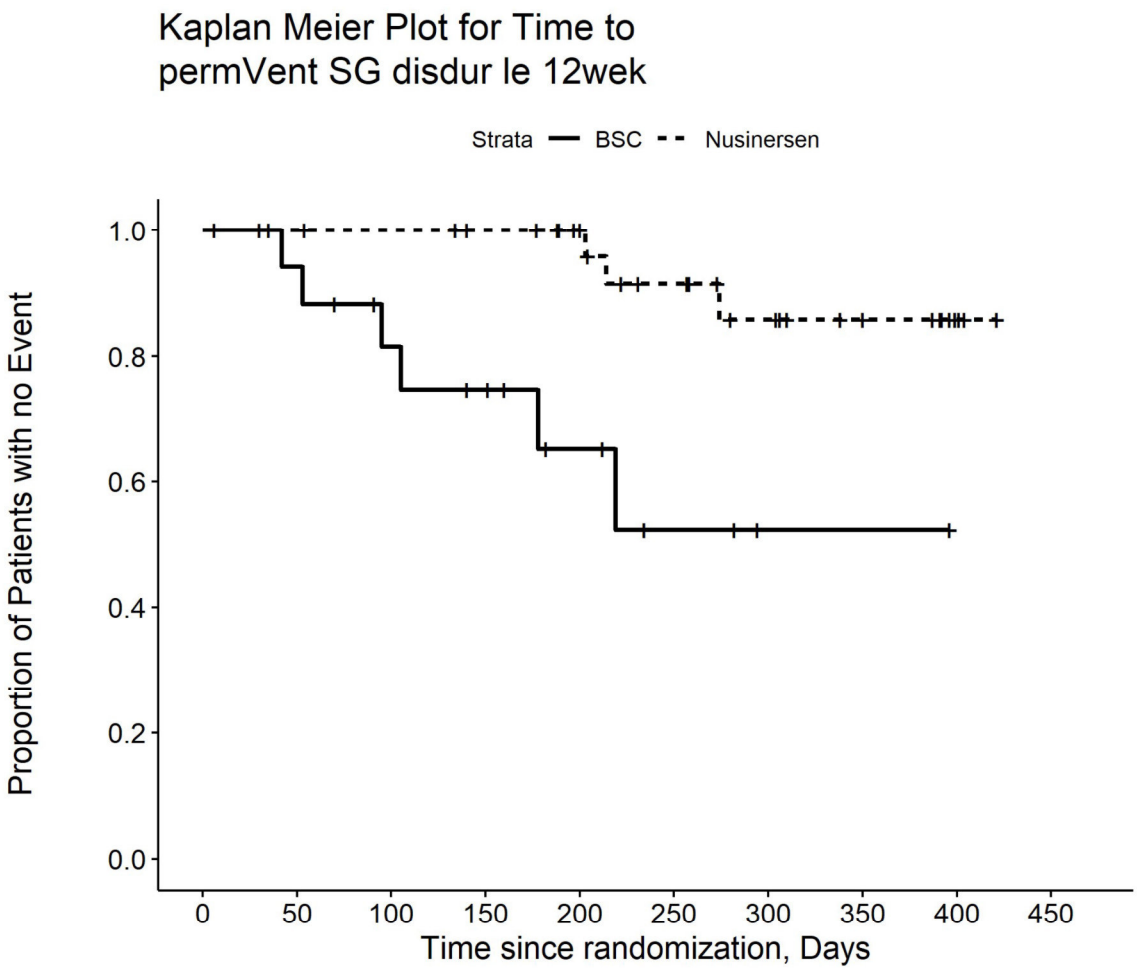
Number at risk

BSC	16	13	8	6	3	3	1	1	0	0
Nusinersen	49	47	40	34	30	24	17	13	3	0



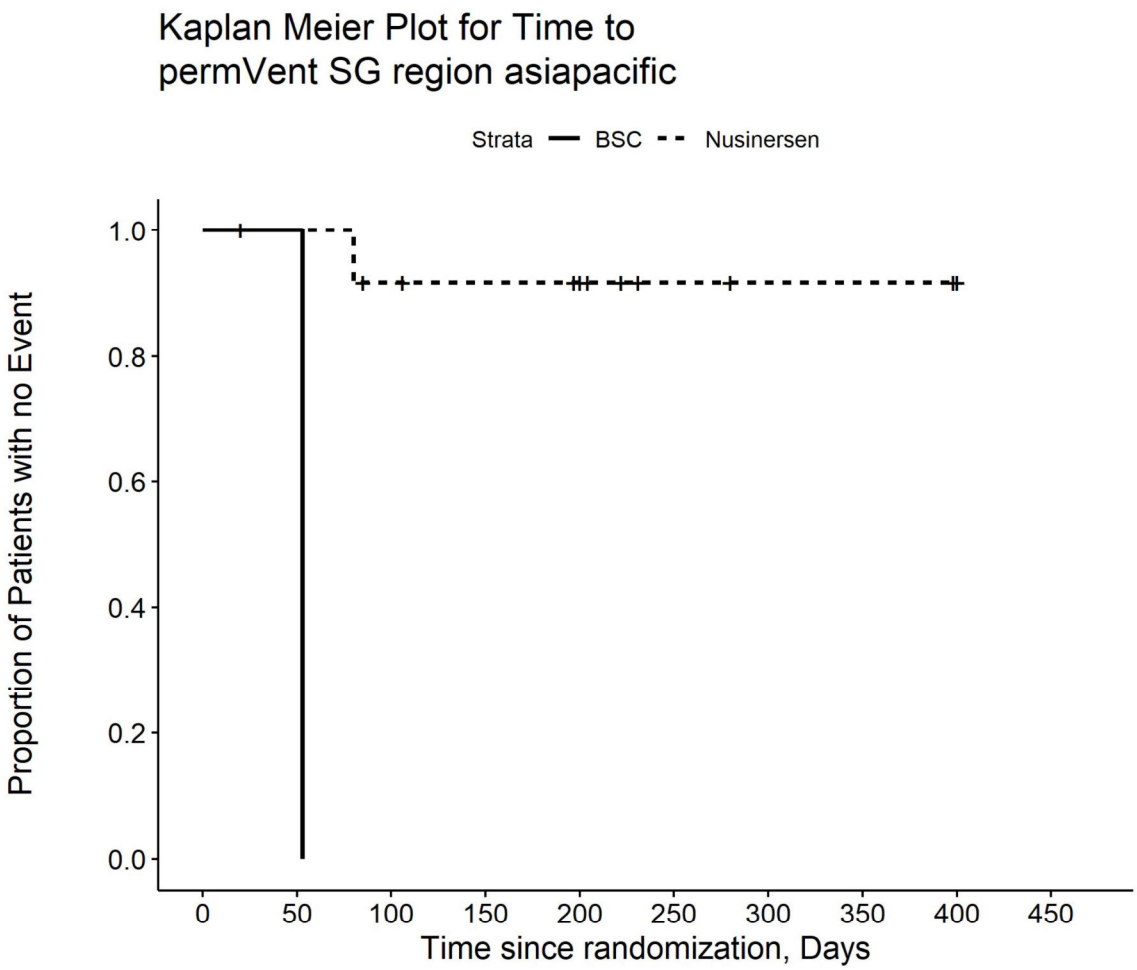
Number at risk

BSC	23	18	14	9	6	6	6	6	2	0
Nusinersen	46	42	28	20	15	14	10	9	2	0



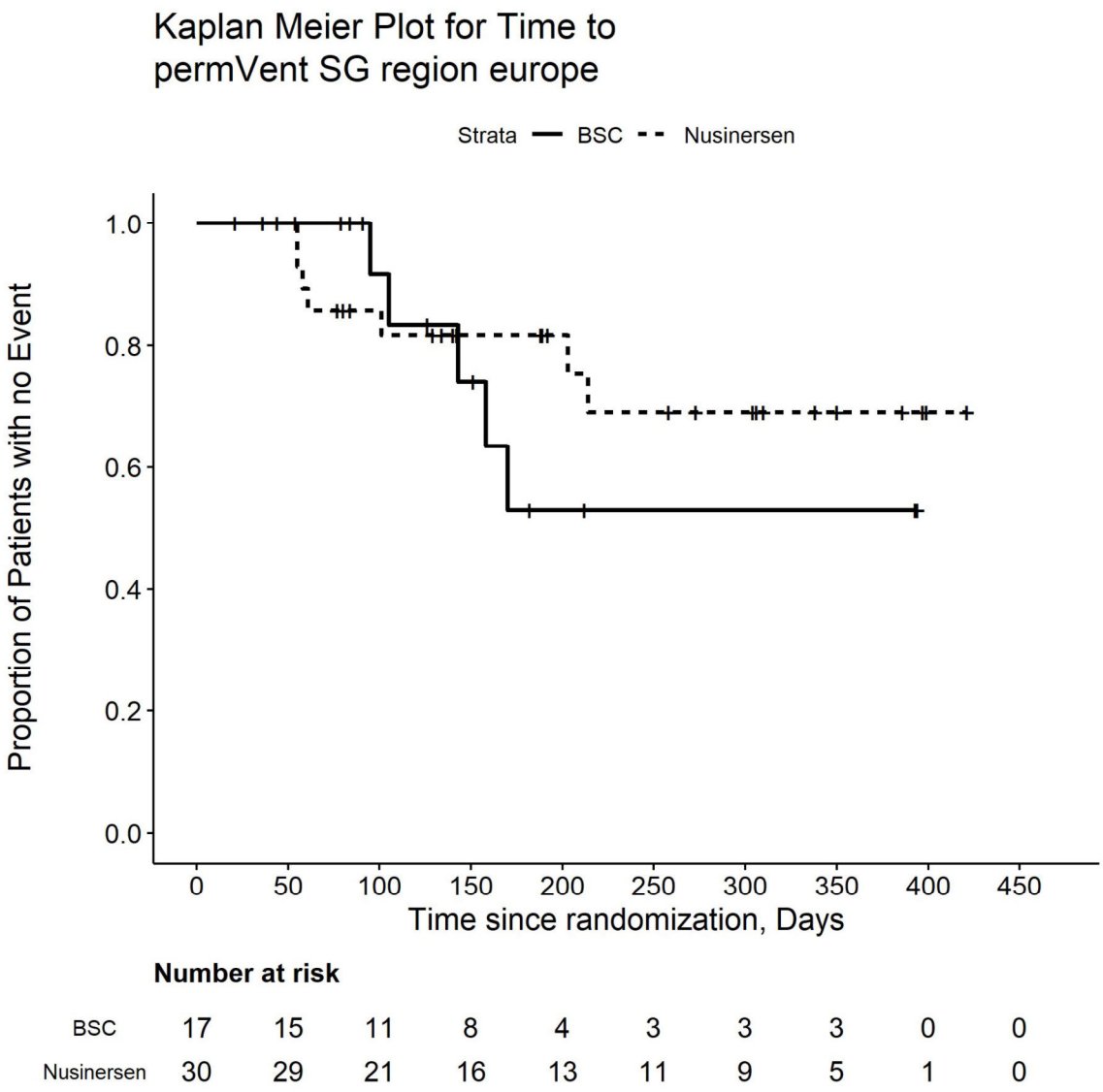
Number at risk

BSC	18	16	12	10	6	3	1	1	0	0
Nusinersen	34	32	31	29	25	19	14	10	3	0



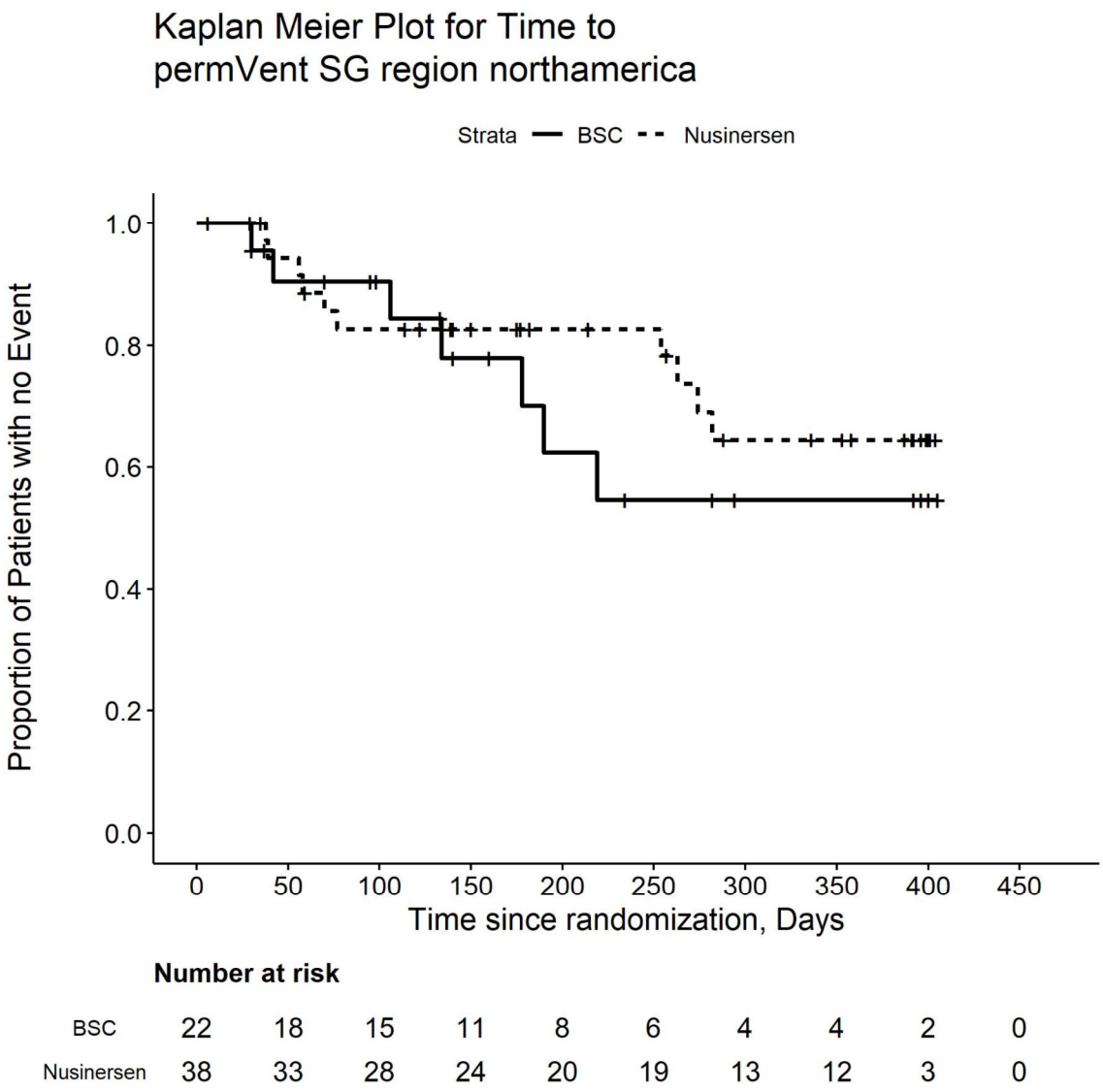
Number at risk

BSC	2	1	0	0	0	0	0	0	0	0
Nusinersen	12	12	10	9	7	3	2	2	1	0



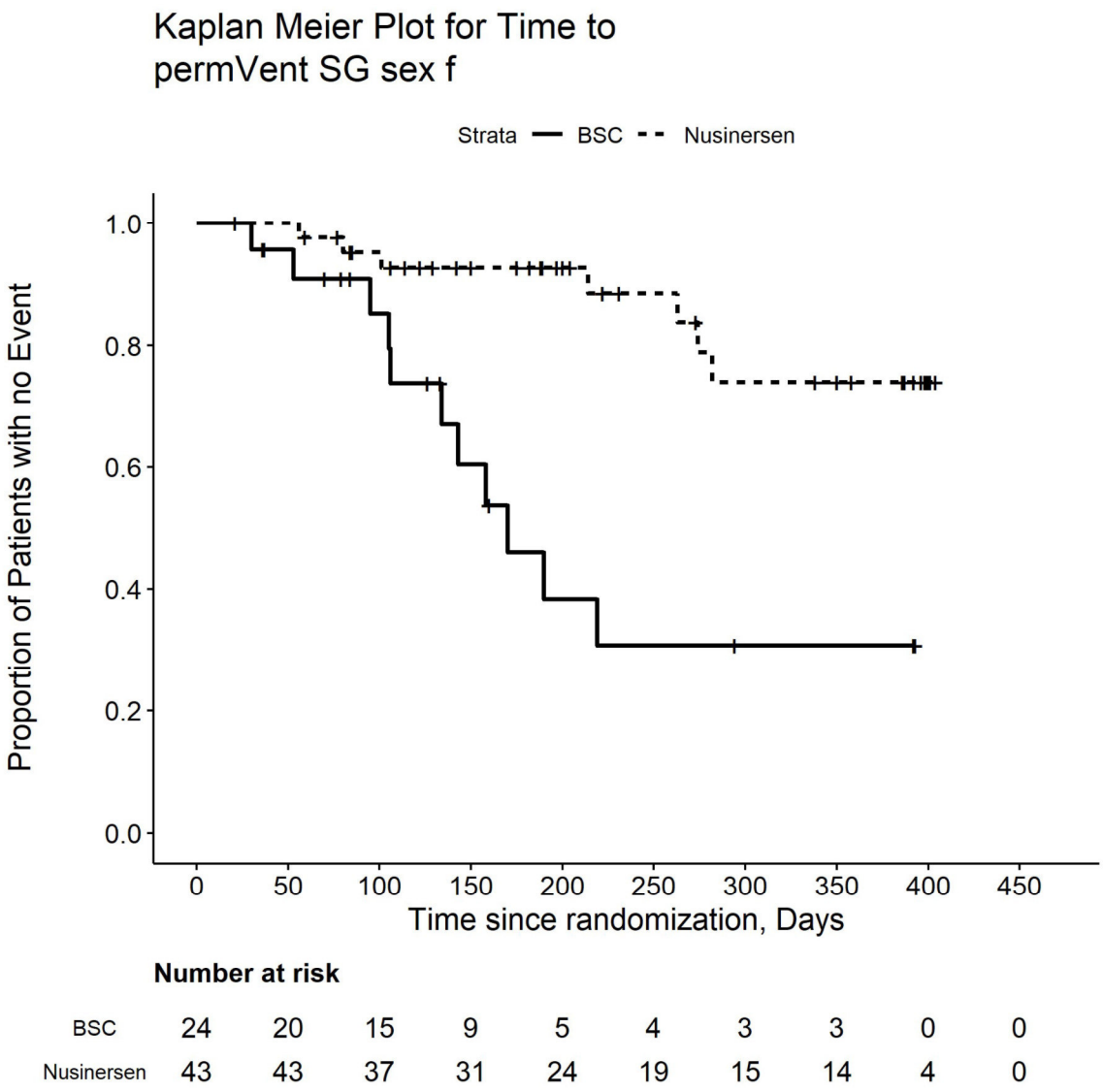
Number at risk

BSC	17	15	11	8	4	3	3	3	0	0
Nusinersen	30	29	21	16	13	11	9	5	1	0



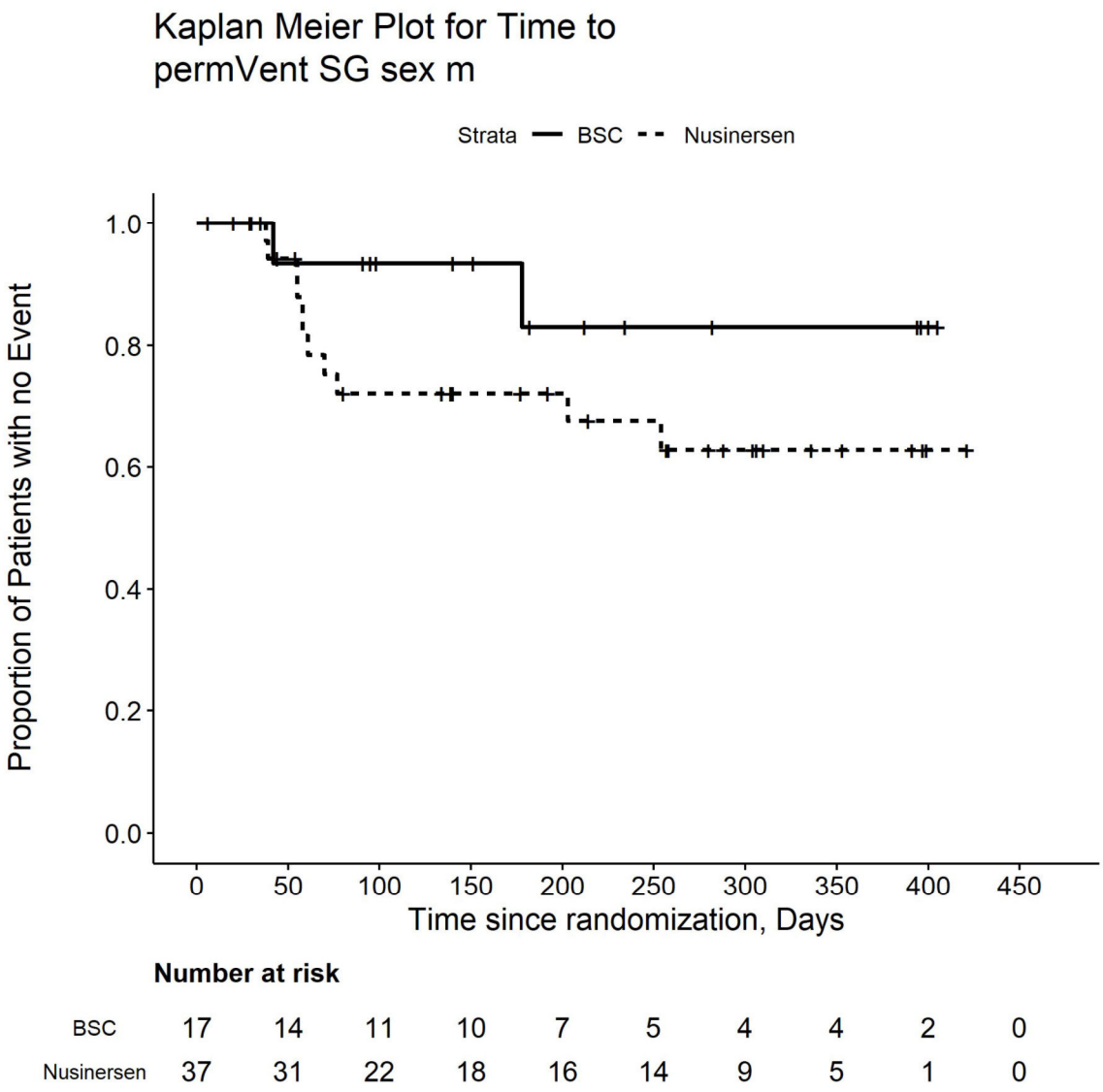
Number at risk

BSC	22	18	15	11	8	6	4	4	2	0
Nusinersen	38	33	28	24	20	19	13	12	3	0



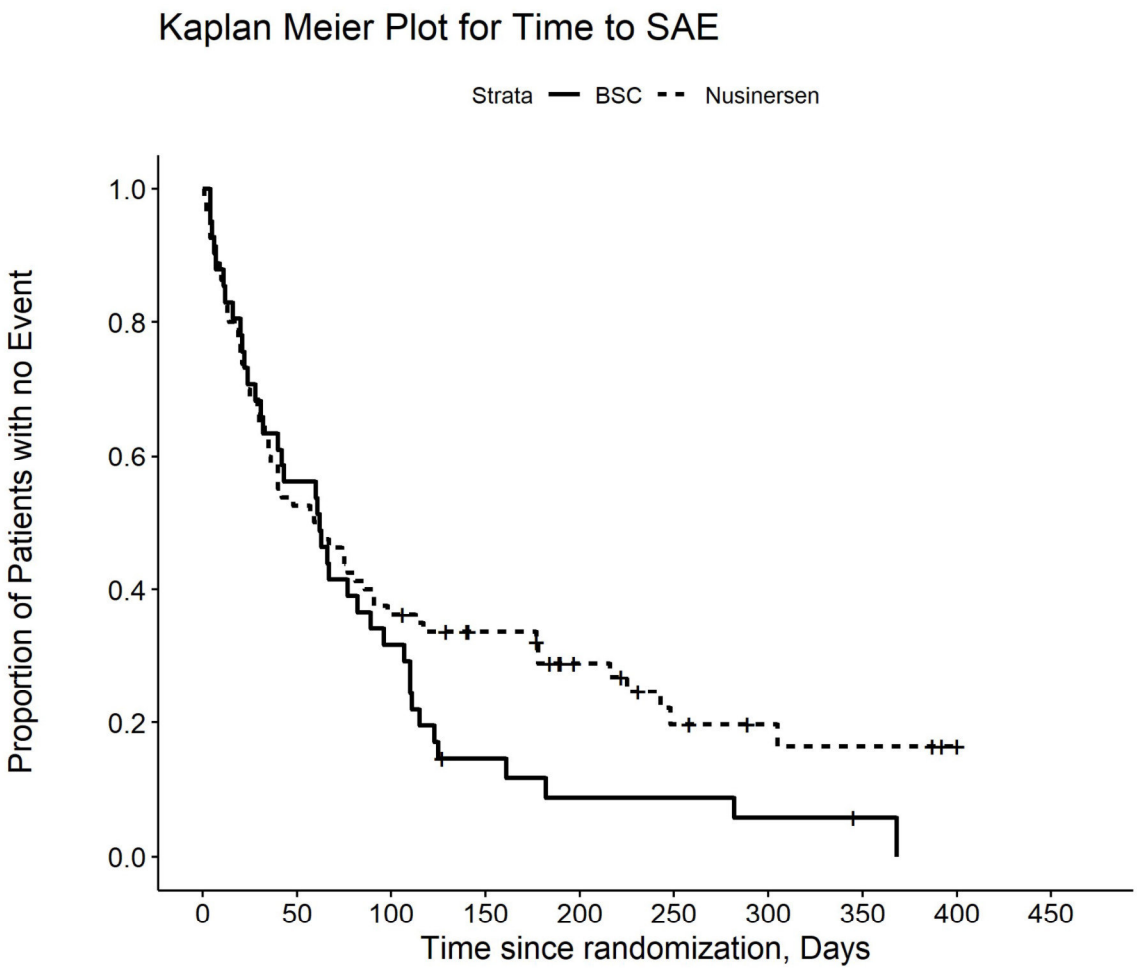
Number at risk

BSC	24	20	15	9	5	4	3	3	0	0
Nusinersen	43	43	37	31	24	19	15	14	4	0



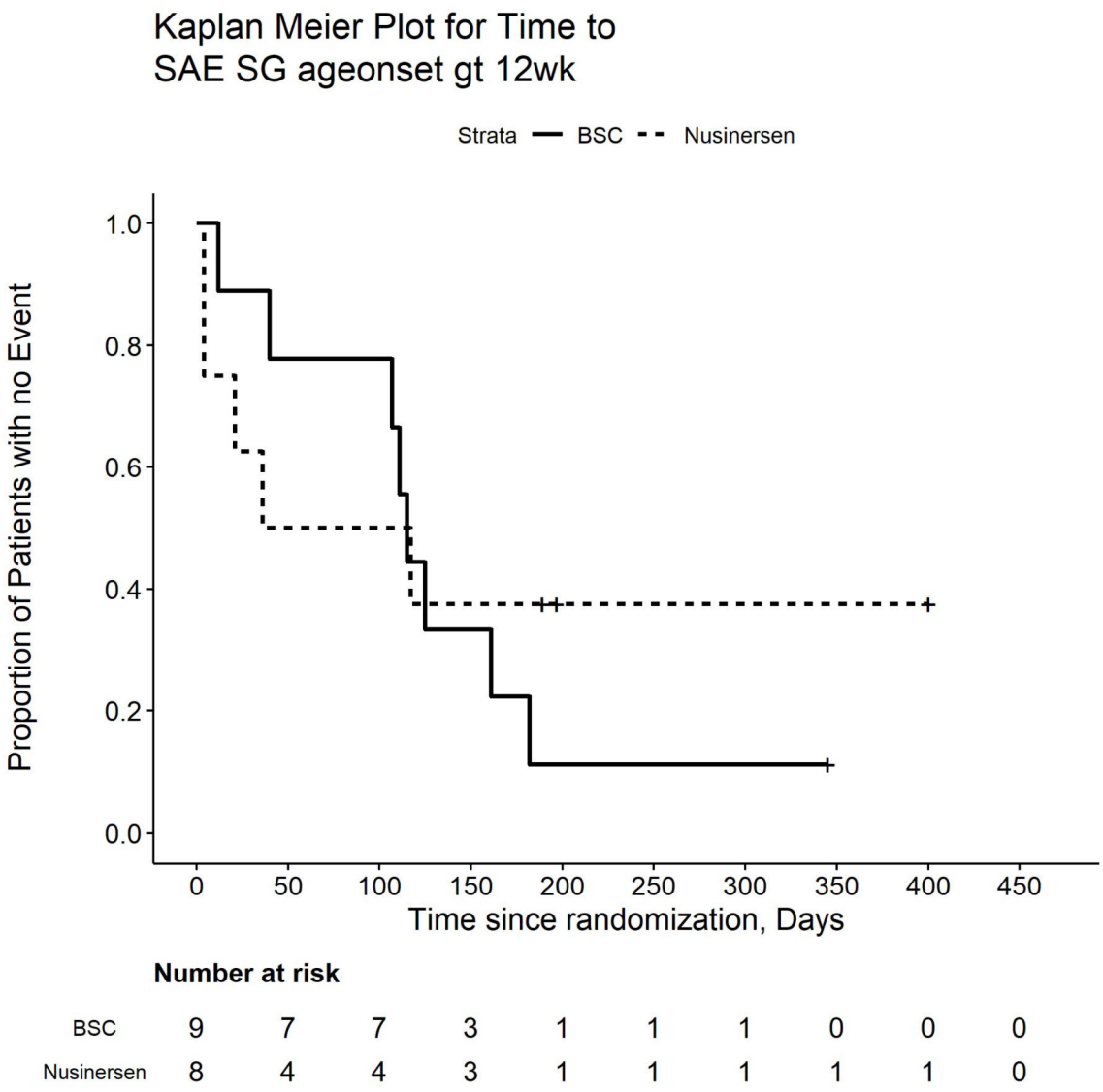
Number at risk

BSC	17	14	11	10	7	5	4	4	2	0
Nusinersen	37	31	22	18	16	14	9	5	1	0



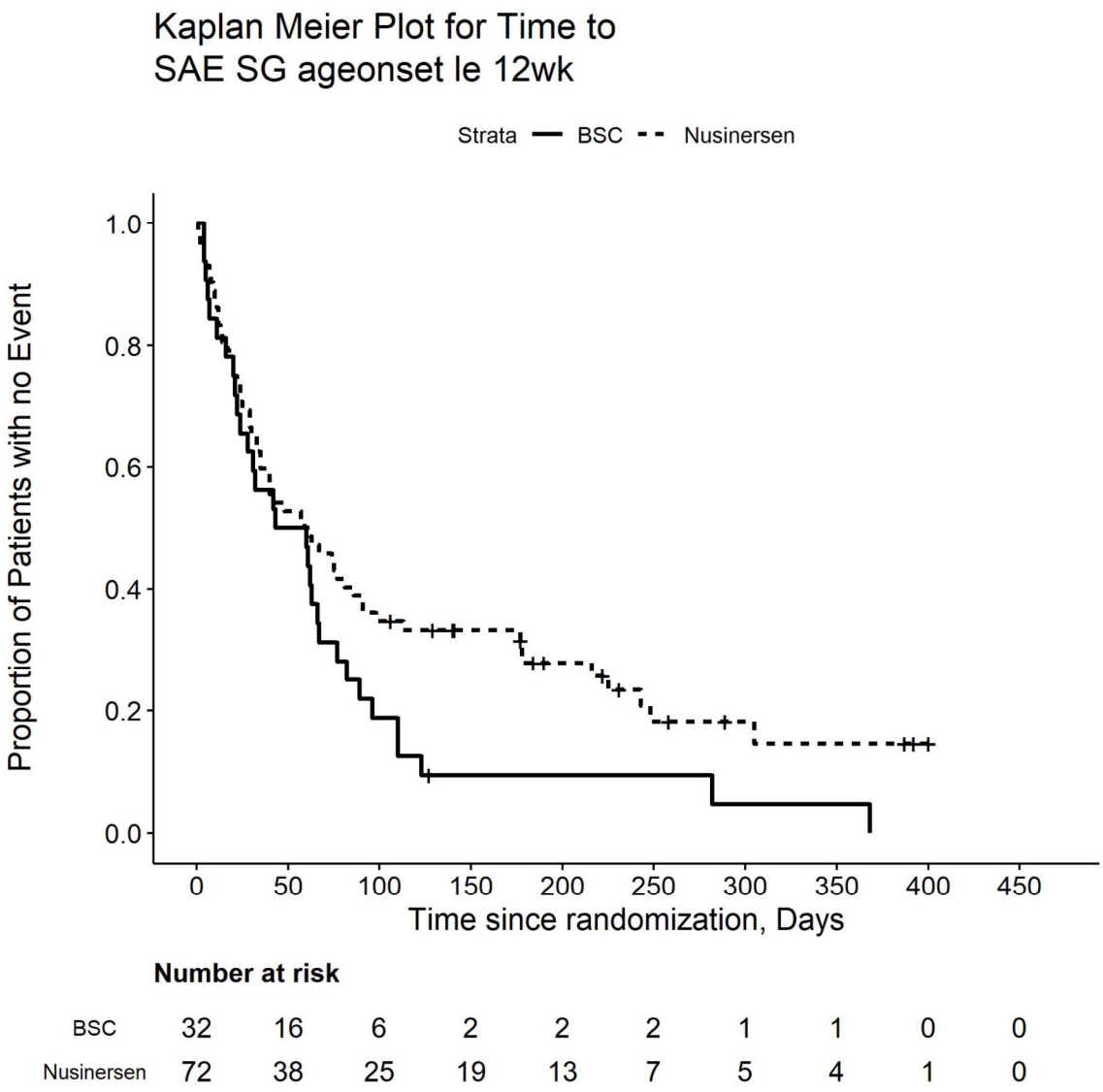
Number at risk

BSC	41	23	13	5	3	3	2	1	0	0
Nusinersen	80	42	29	22	14	8	6	5	2	0



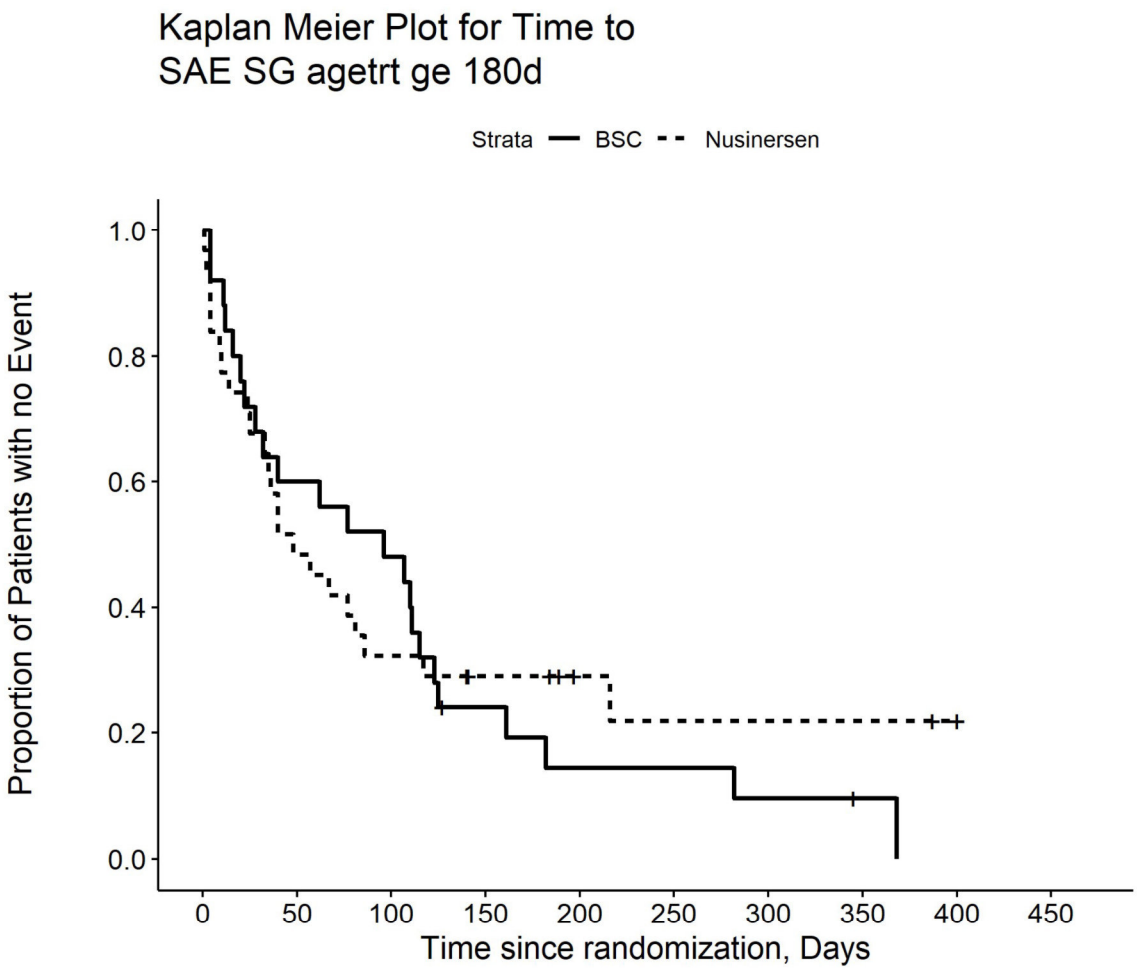
Number at risk

BSC	9	7	7	3	1	1	1	0	0	0
Nusinersen	8	4	4	3	1	1	1	1	1	0



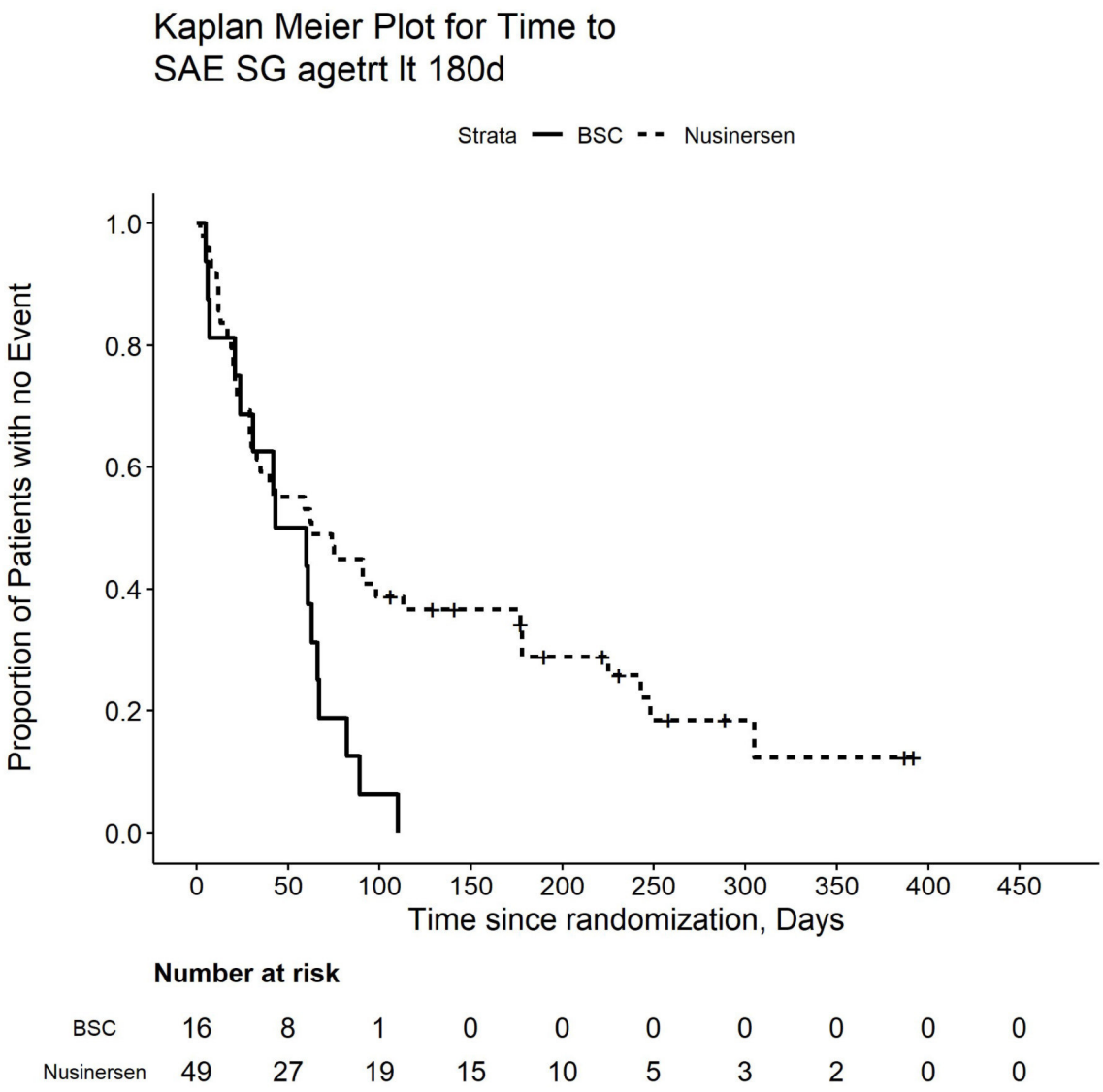
Number at risk

BSC	32	16	6	2	2	2	1	1	0	0
Nusinersen	72	38	25	19	13	7	5	4	1	0



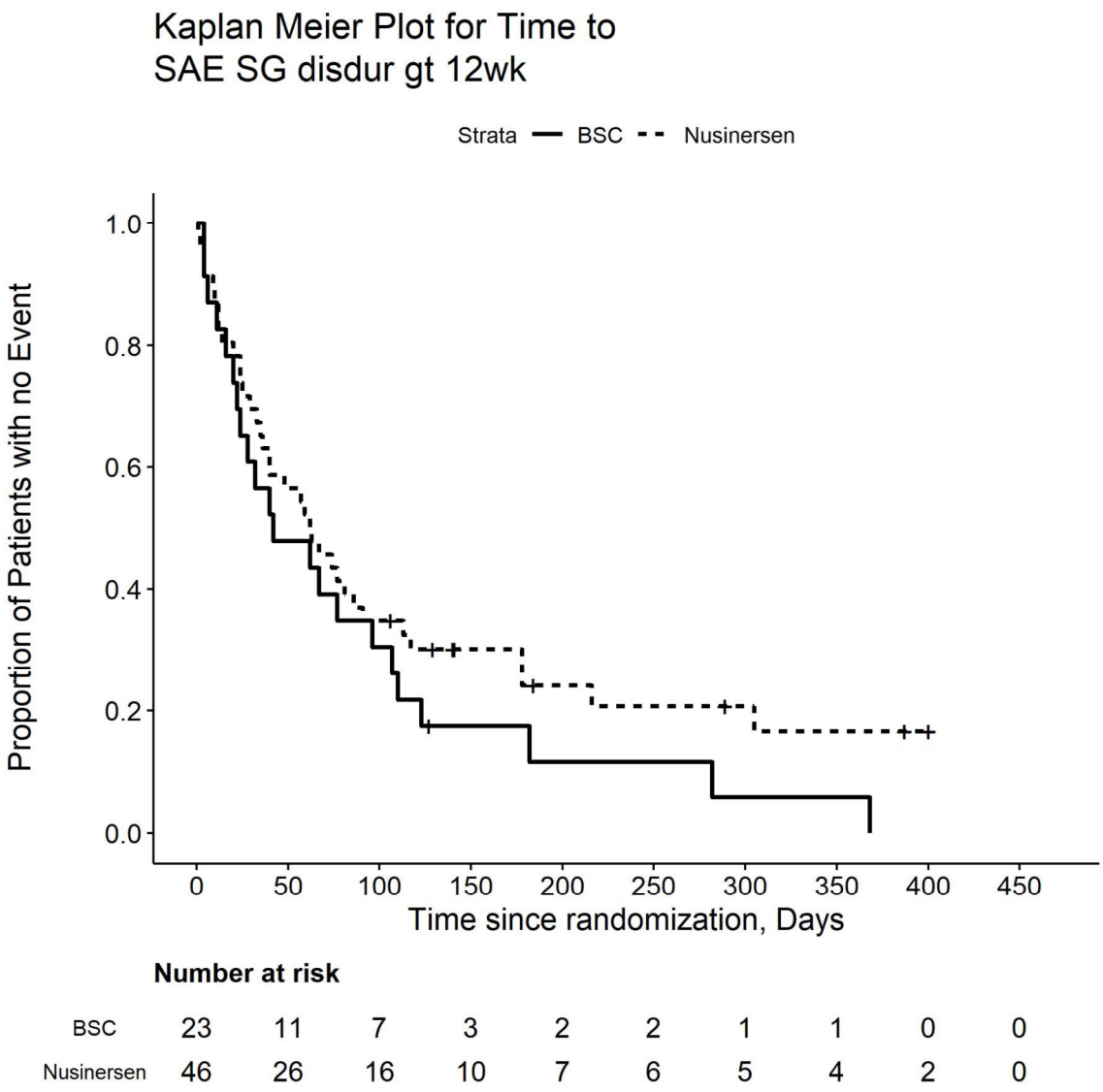
Number at risk

BSC	25	15	12	5	3	3	2	1	0	0
Nusinersen	31	15	10	7	4	3	3	3	2	0



Number at risk

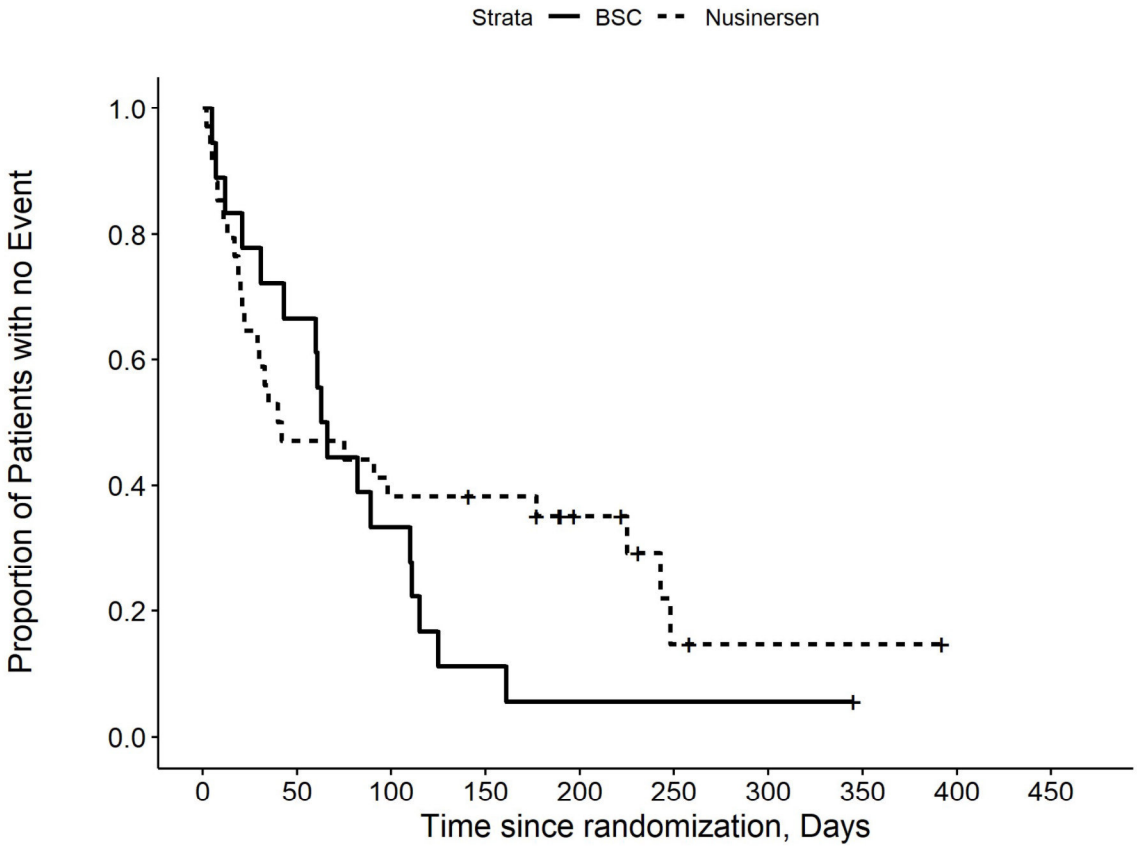
BSC	16	8	1	0	0	0	0	0	0	0
Nusinersen	49	27	19	15	10	5	3	2	0	0



Number at risk

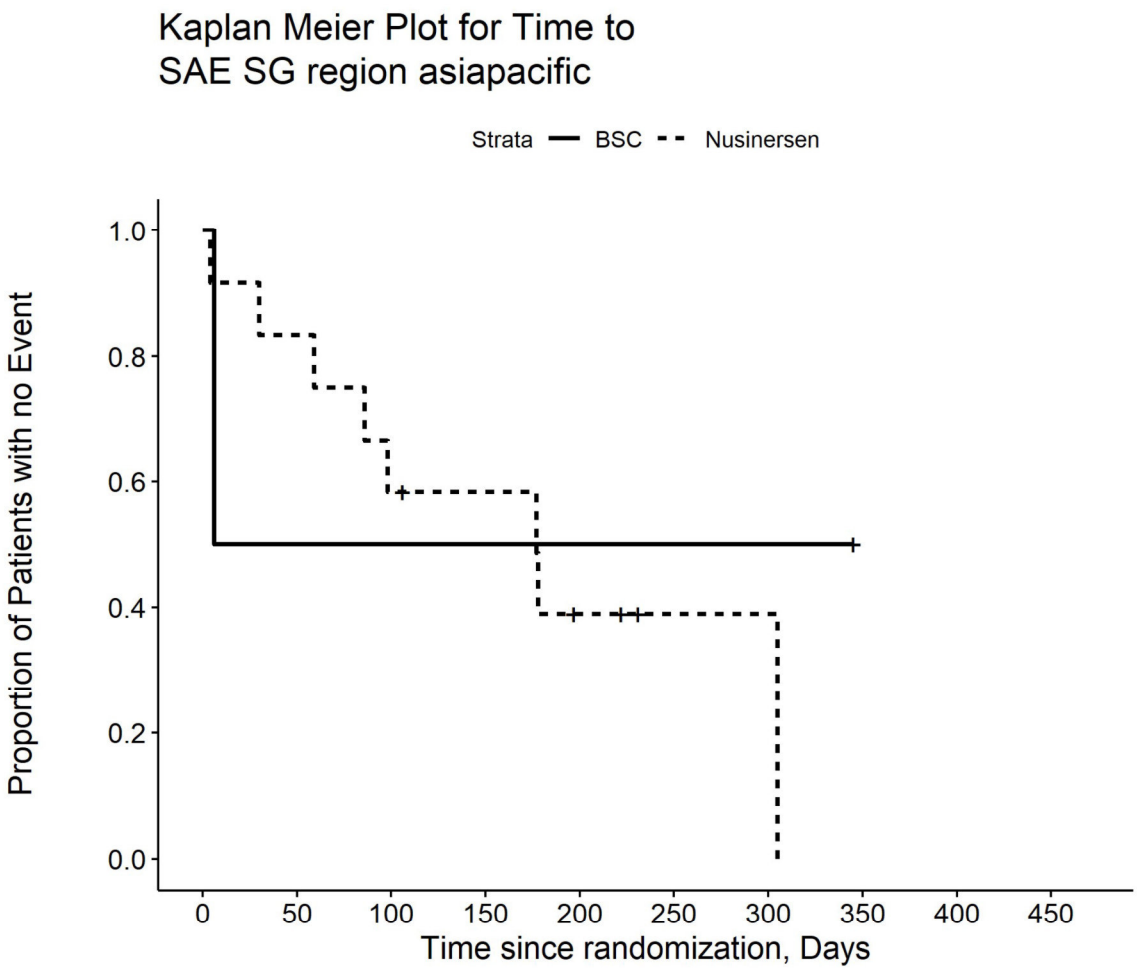
BSC	23	11	7	3	2	2	1	1	0	0
Nusinersen	46	26	16	10	7	6	5	4	2	0

Kaplan Meier Plot for Time to
SAE SG disdur le 12wek



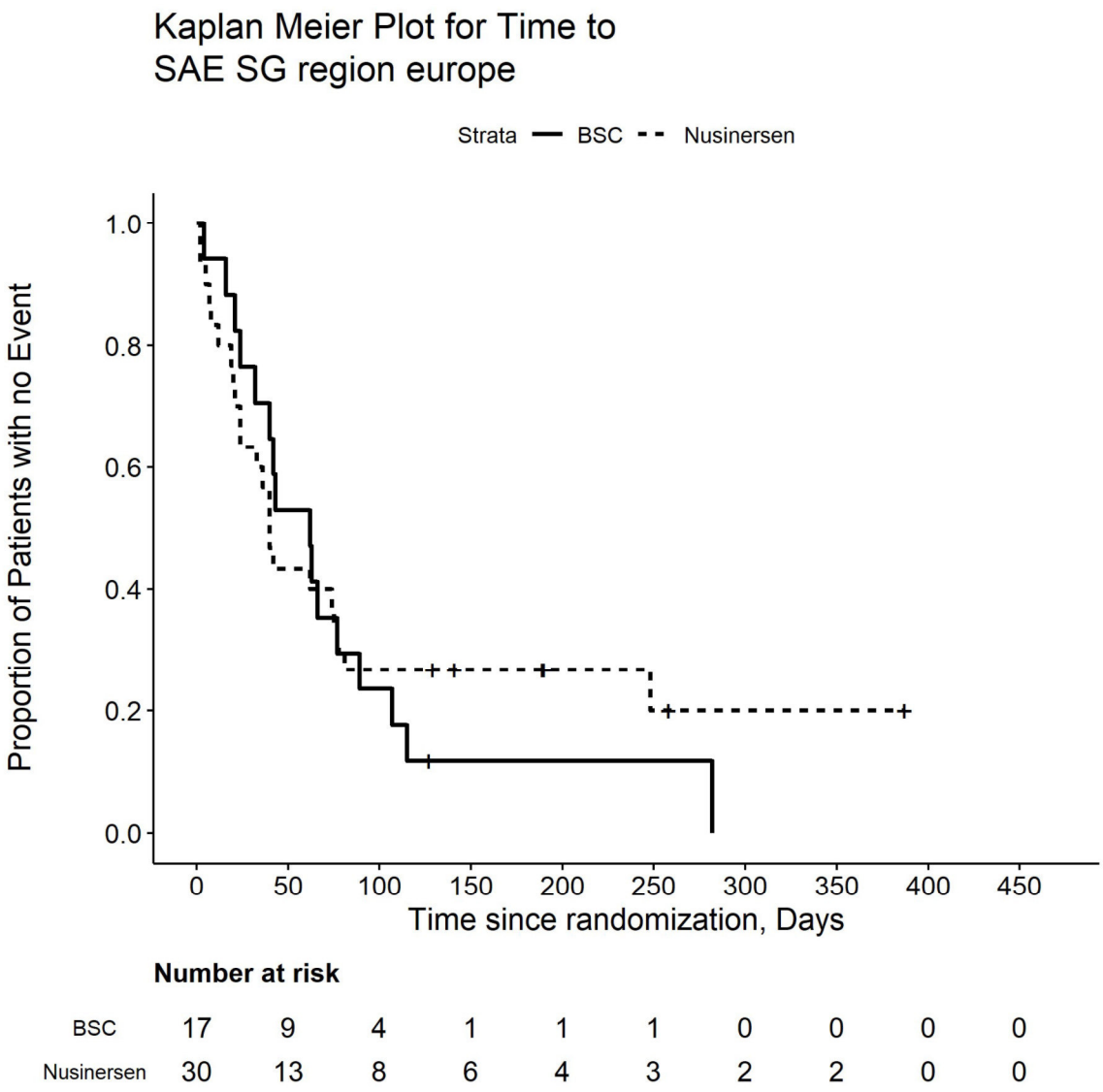
Number at risk

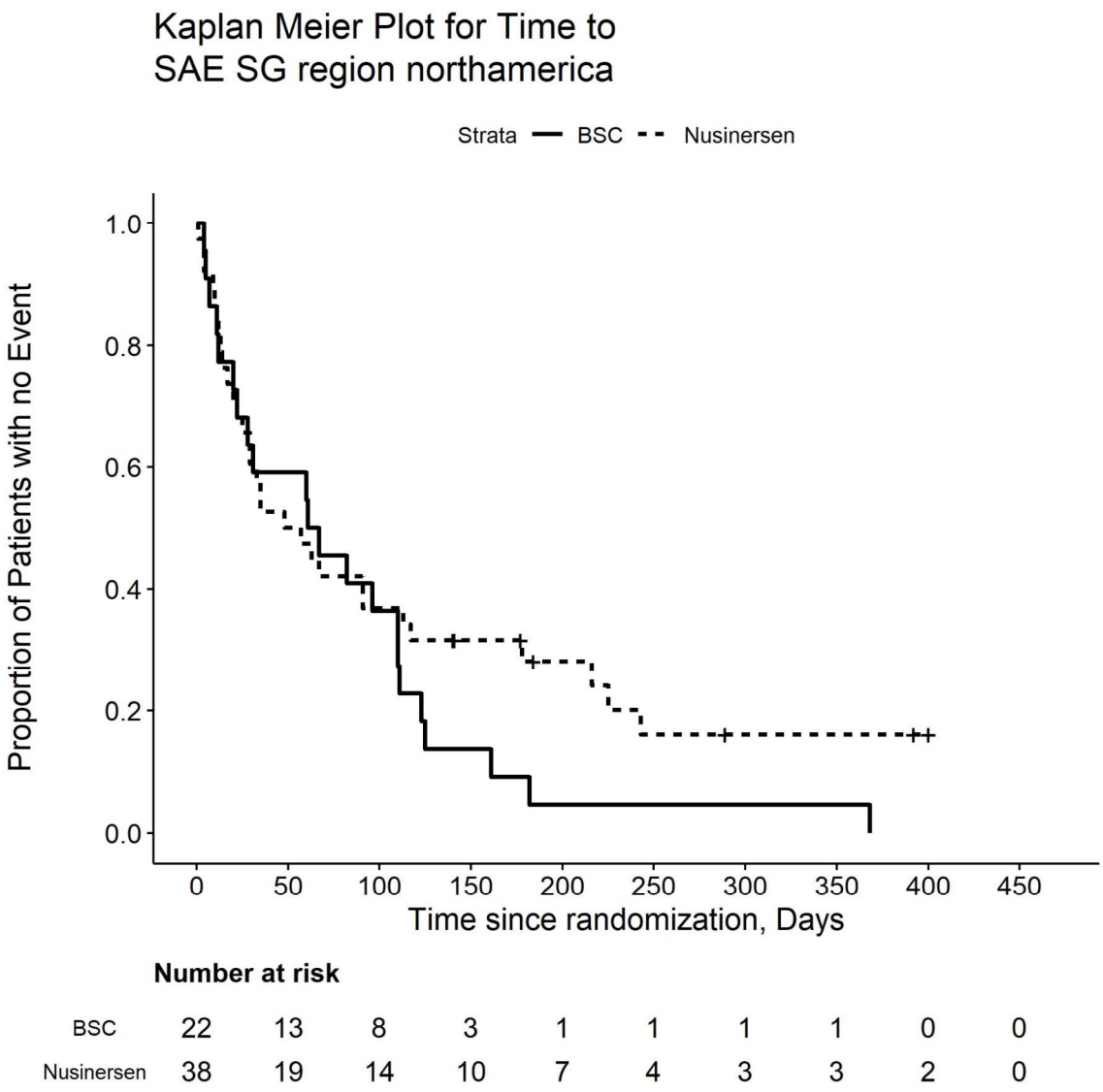
BSC	18	12	6	2	1	1	1	0	0	0
Nusinersen	34	16	13	12	7	2	1	1	0	0



Number at risk

BSC	2	1	1	1	1	1	1	0	0	0
Nusinersen	12	10	7	6	3	1	1	0	0	0

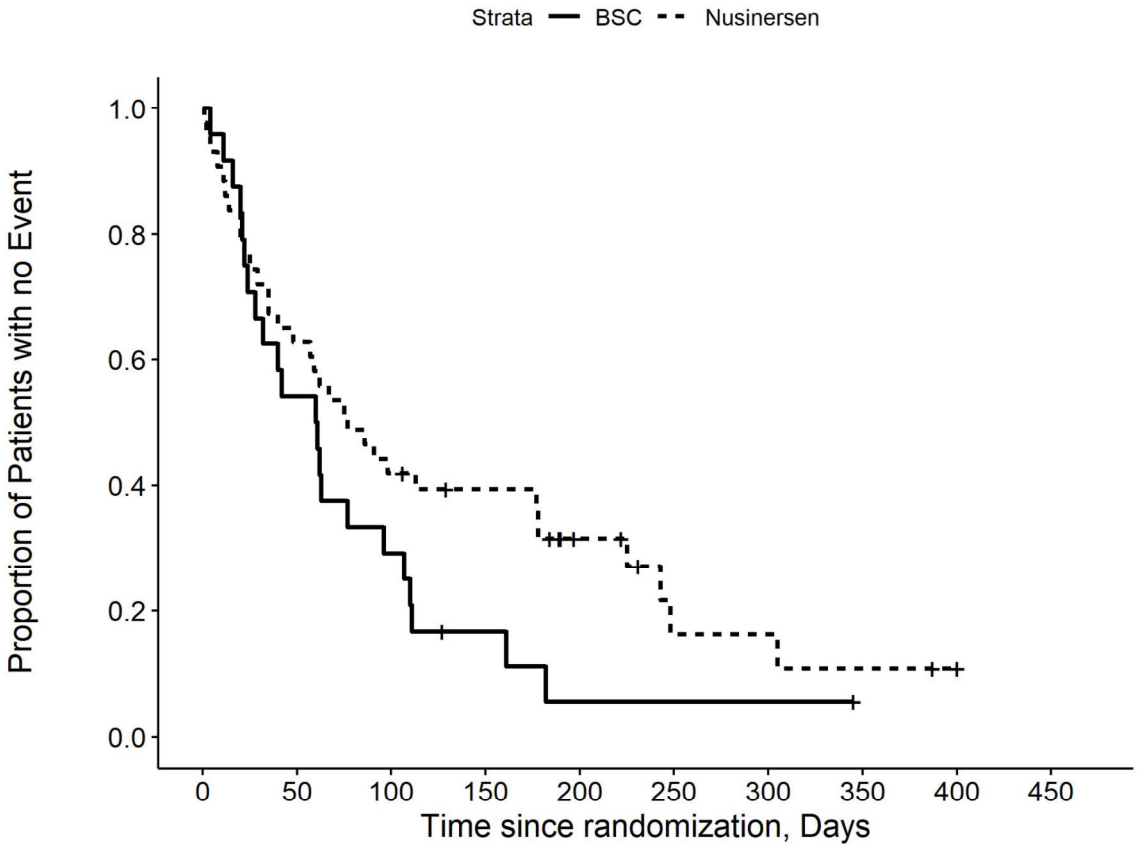

Kaplan Meier Plot for Time to
SAE SG region europe
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0 50 100 150 200 250 300 350 400 450
Time since randomization, Days
Number at risk
BSC 17 9 4 1 1 1 0 0 0 0
Nusinersen 30 13 8 6 4 3 2 2 0 0



Number at risk

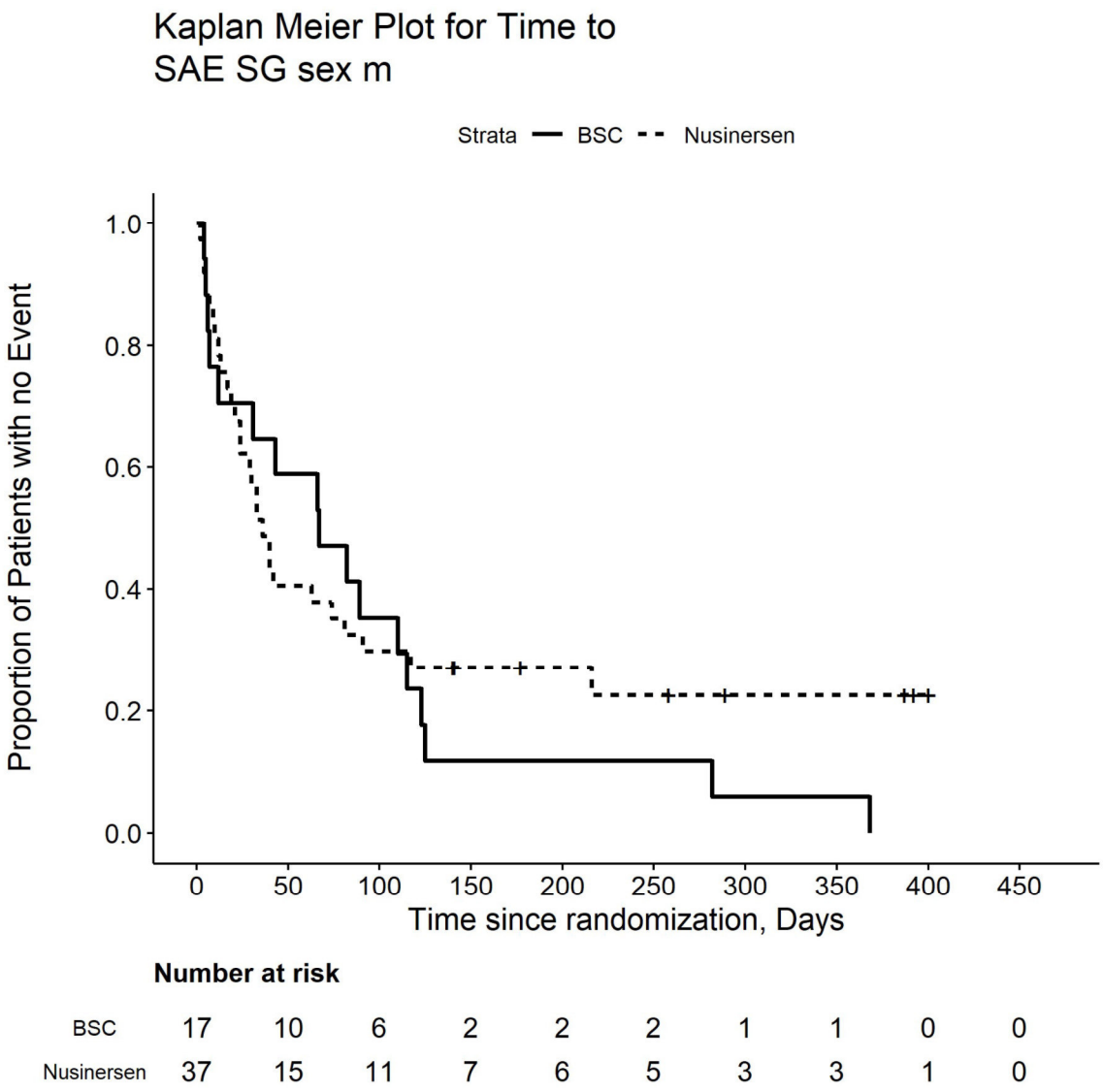
BSC	22	13	8	3	1	1	1	1	0	0
Nusinersen	38	19	14	10	7	4	3	3	2	0

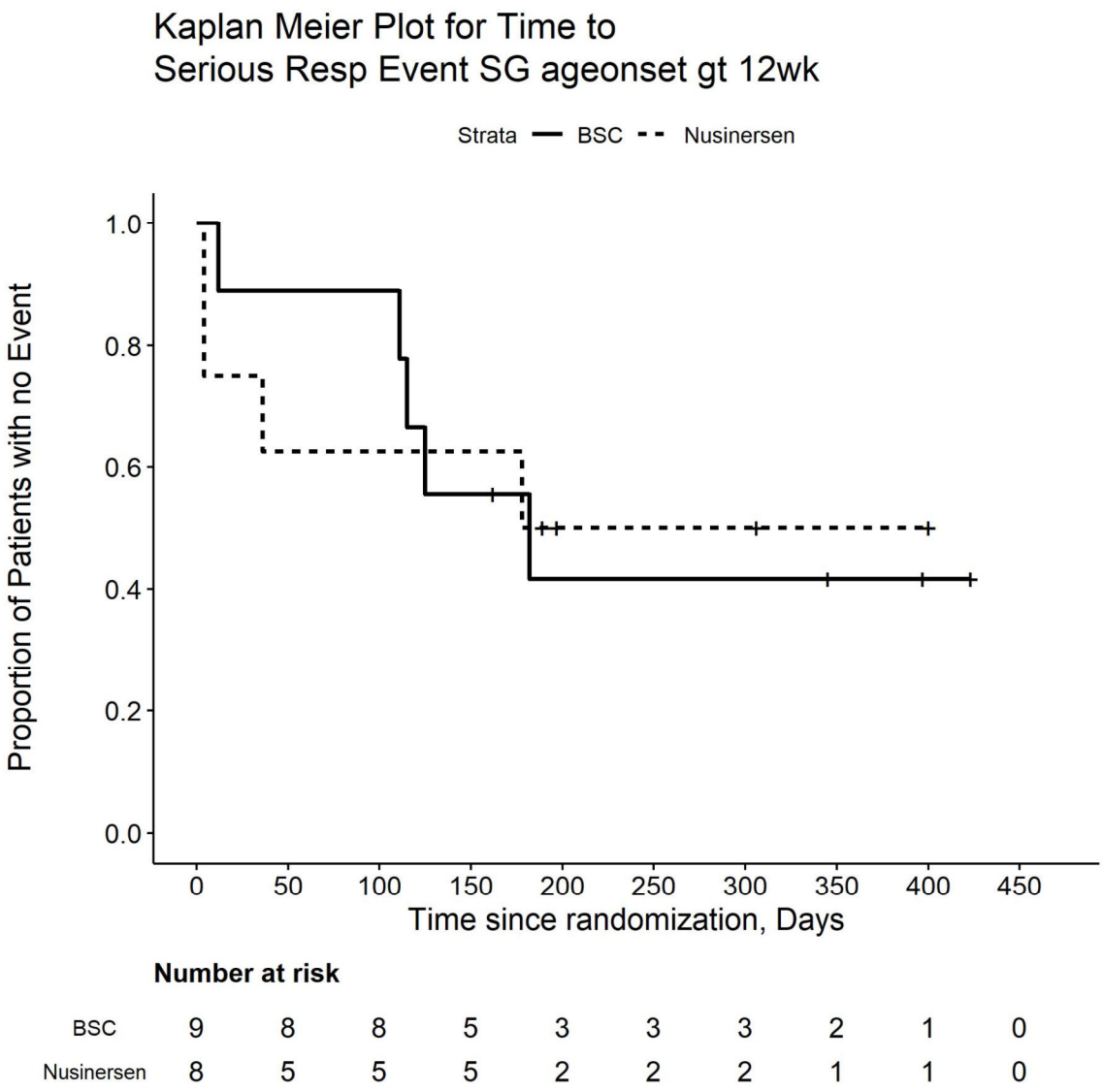
Kaplan Meier Plot for Time to
SAE SG sex f



Number at risk

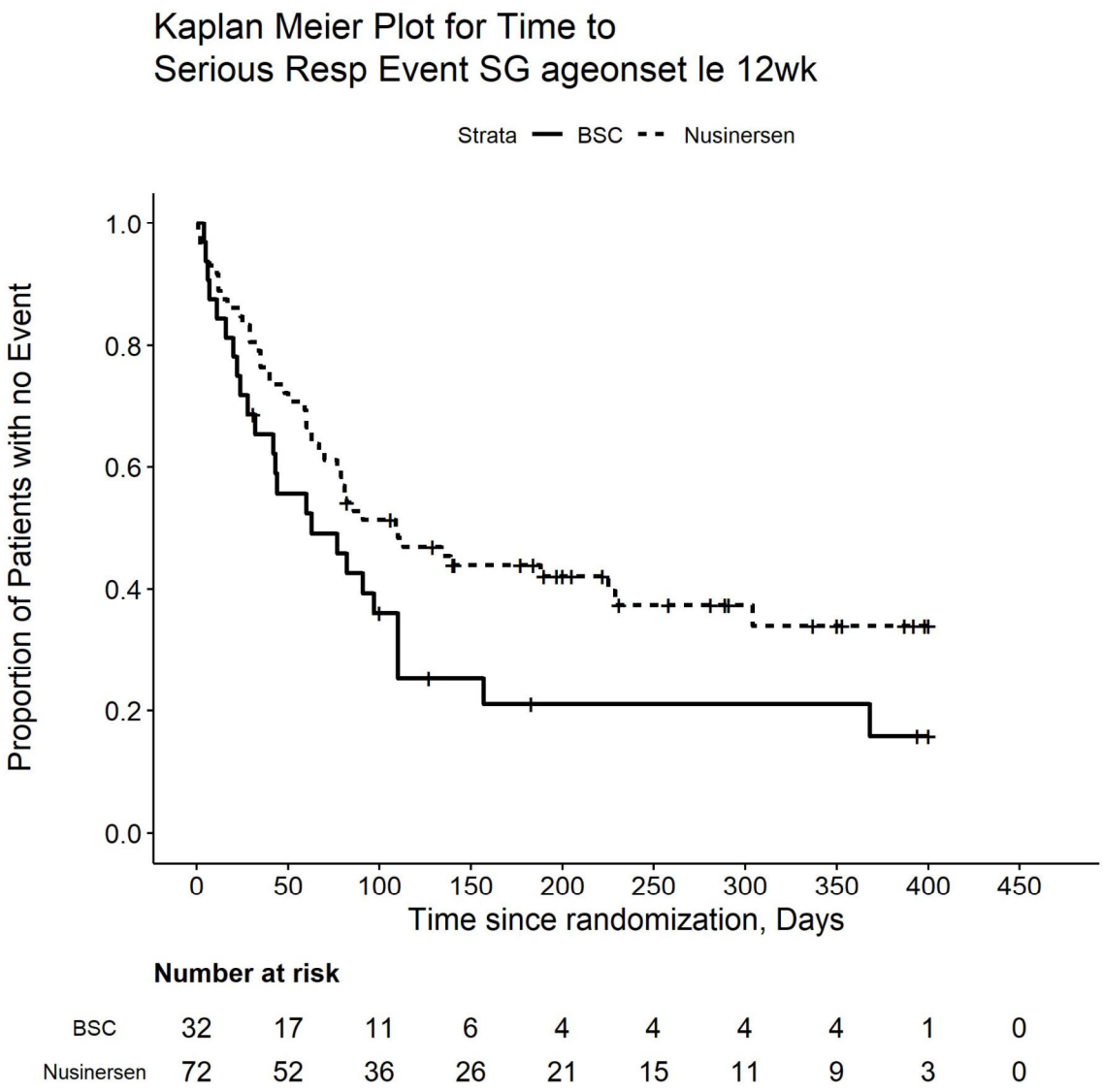
BSC	24	13	7	3	1	1	1	0	0	0
Nusinersen	43	27	18	15	8	3	3	2	1	0


Kaplan Meier Plot for Time to
SAE SG sex m
Strata BSC Nusinersen
Proportion of Patients with no Event
1.0
0.8
0.6
0.4
0.2
0.0
0
50
100
150
200
250
300
350
400
450
Time since randomization, Days
Number at risk
BSC 17 10 6 2 2 2 1 1 0 0
Nusinersen 37 15 11 7 6 5 3 3 1 0



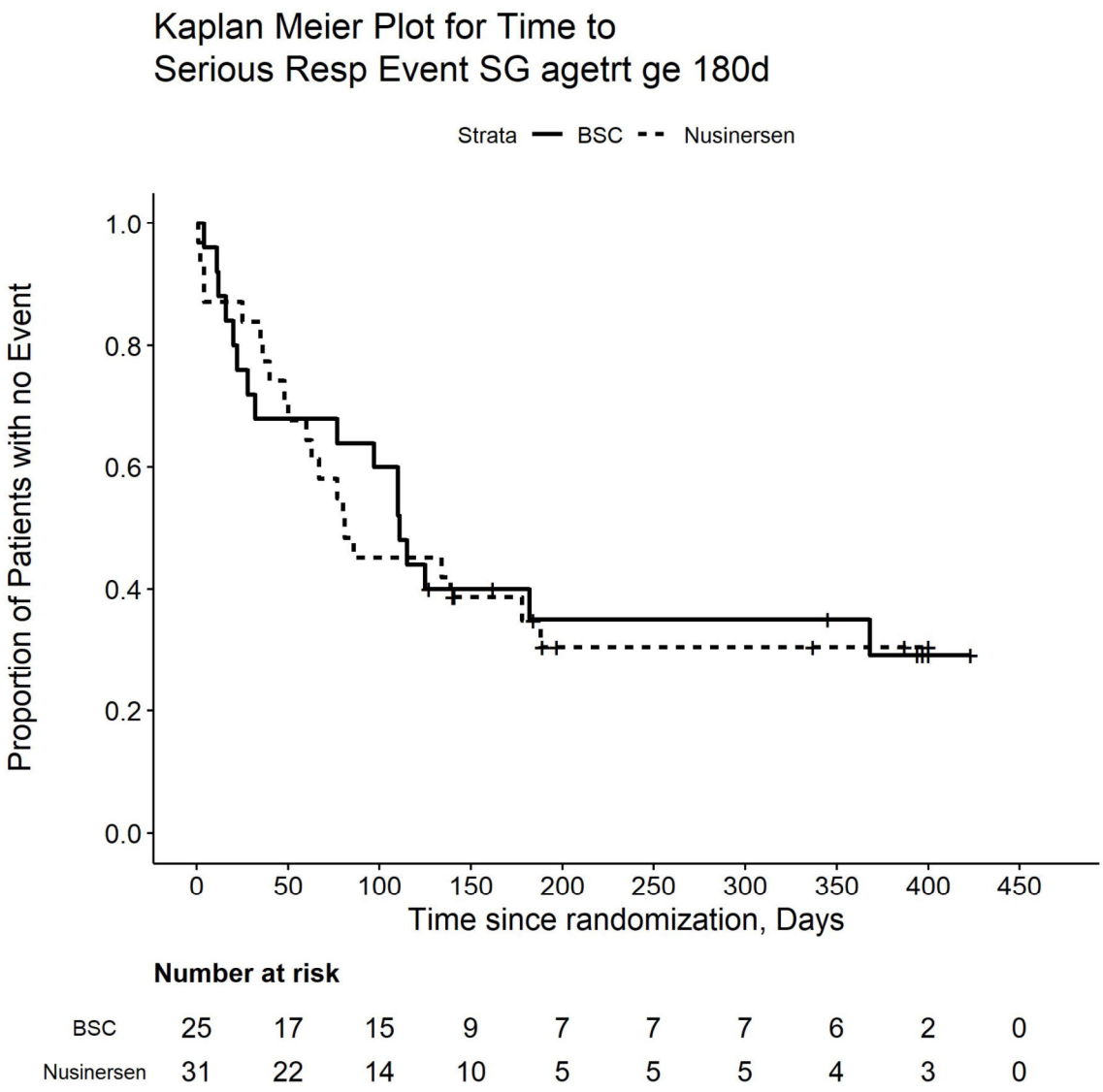
Number at risk

BSC	9	8	8	5	3	3	3	2	1	0
Nusinersen	8	5	5	5	2	2	2	1	1	0



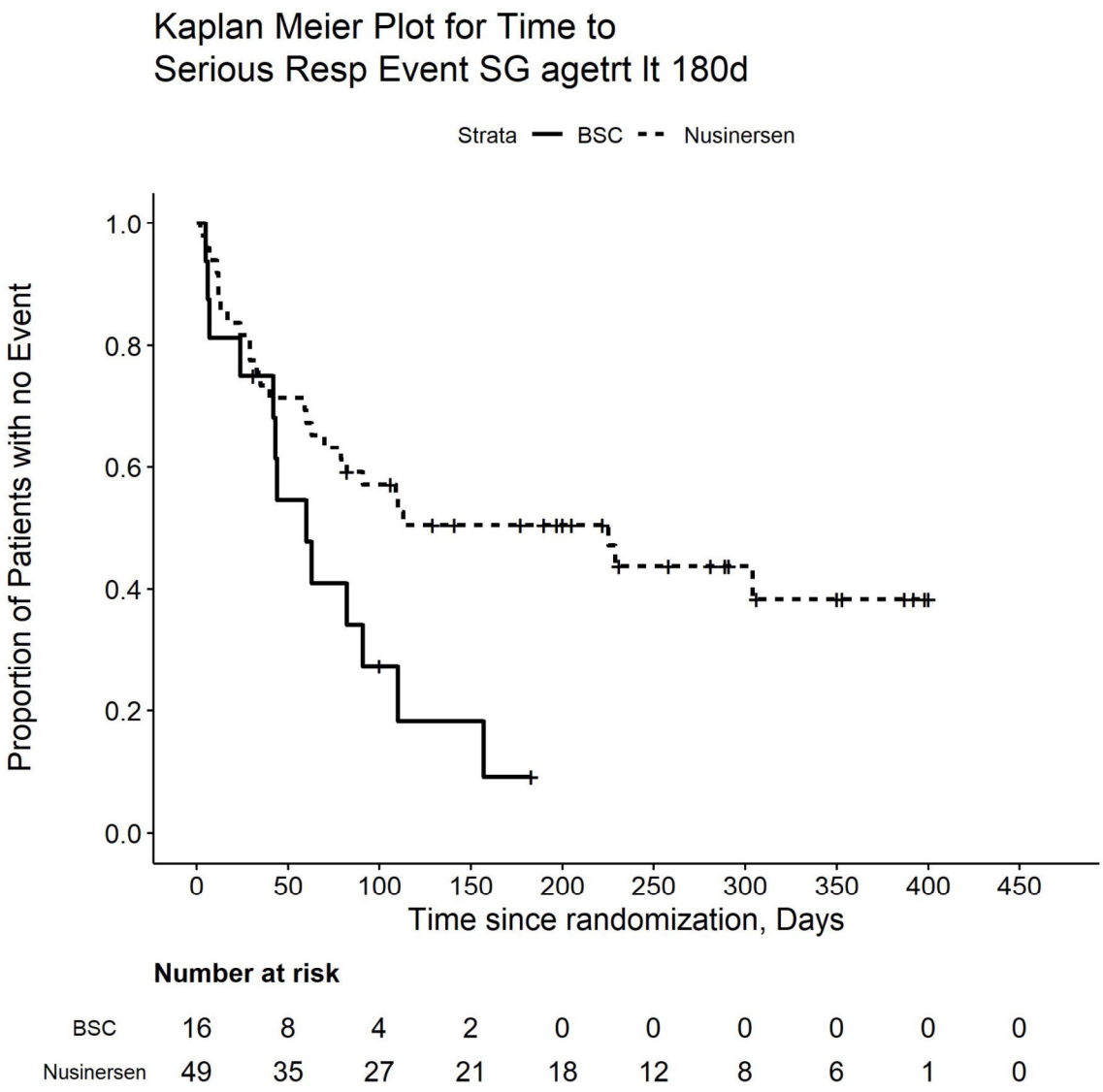
Number at risk

BSC	32	17	11	6	4	4	4	4	1	0
Nusinersen	72	52	36	26	21	15	11	9	3	0



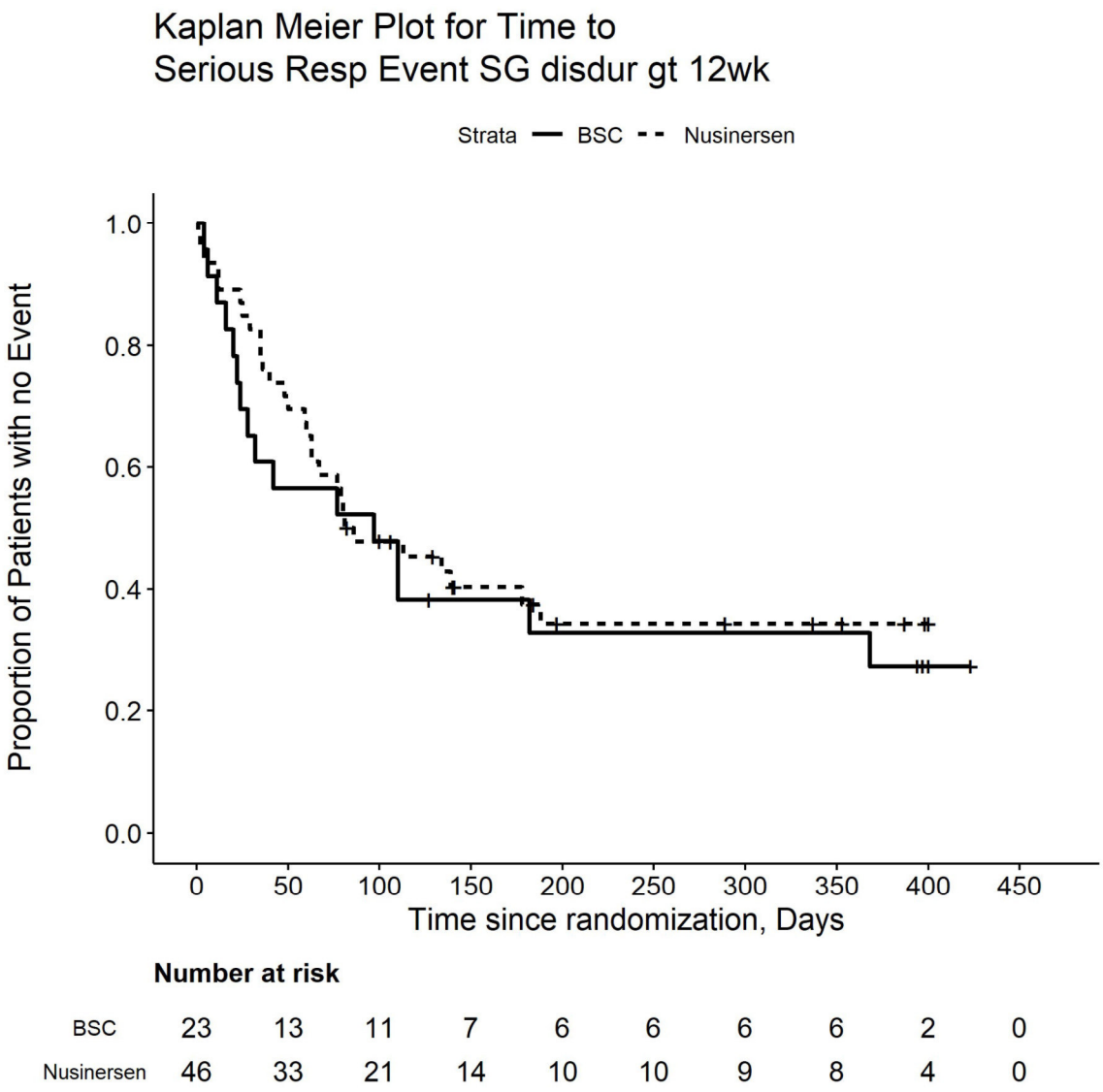
Number at risk

BSC	25	17	15	9	7	7	7	6	2	0
Nusinersen	31	22	14	10	5	5	5	4	3	0



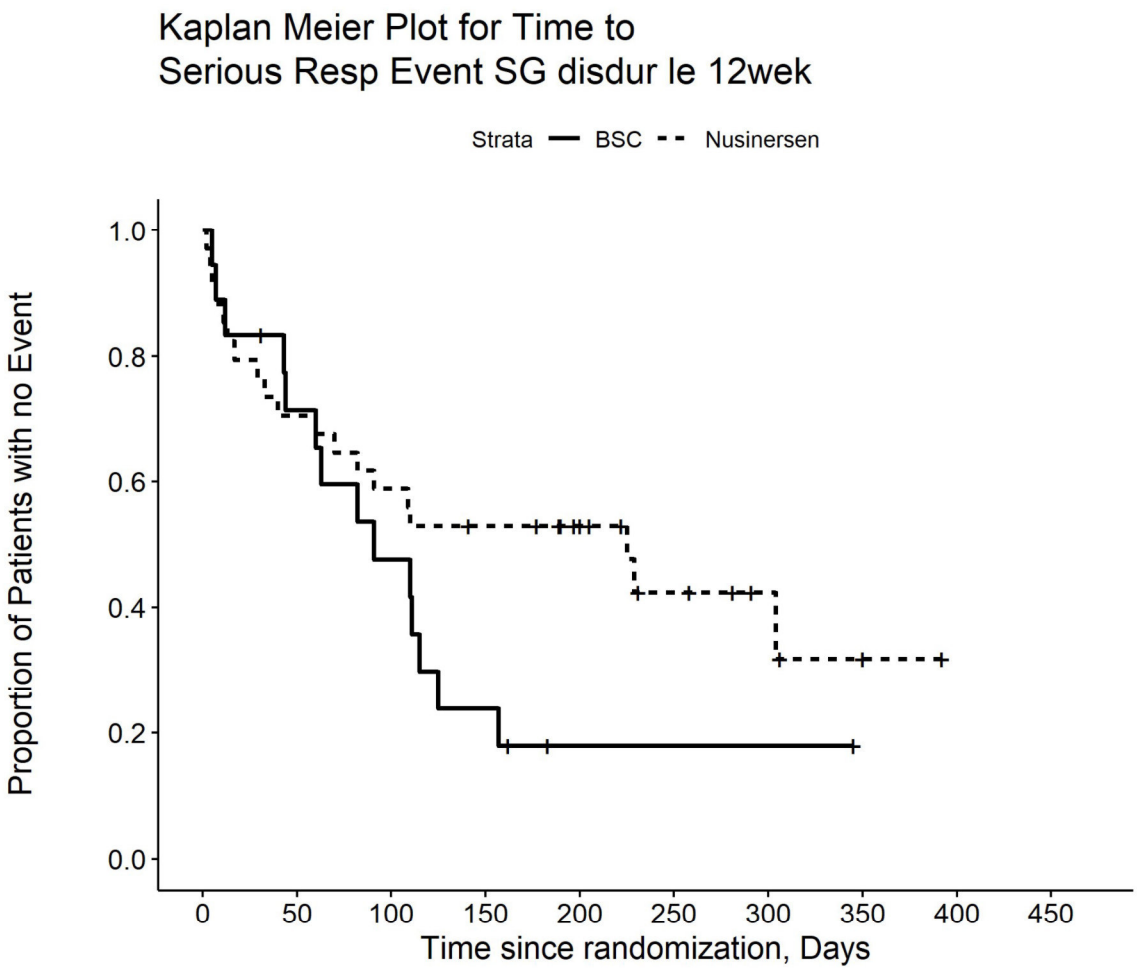
Number at risk

BSC	16	8	4	2	0	0	0	0	0	0
Nusinersen	49	35	27	21	18	12	8	6	1	0



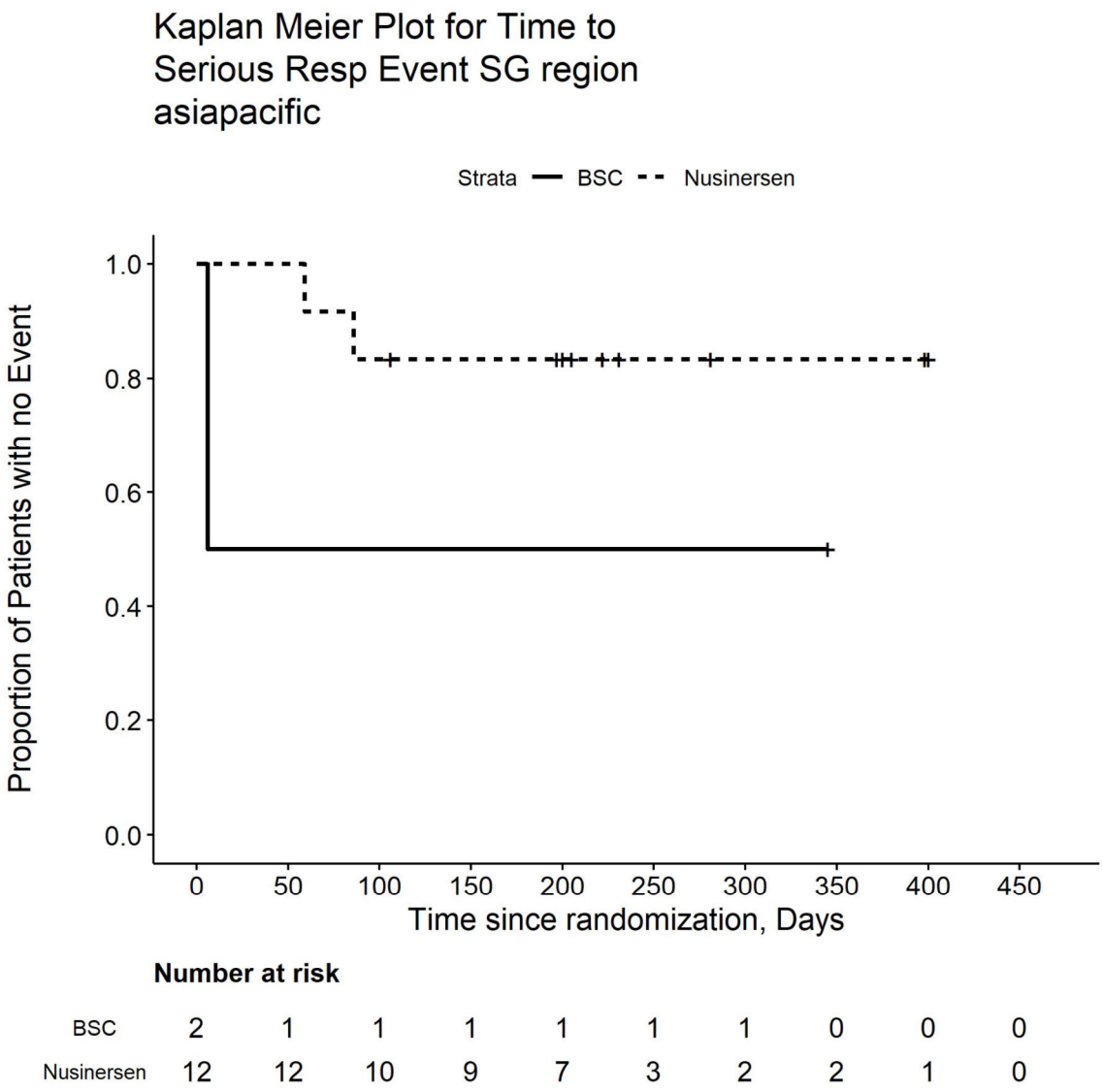
Number at risk

BSC	23	13	11	7	6	6	6	6	2	0
Nusinersen	46	33	21	14	10	10	9	8	4	0



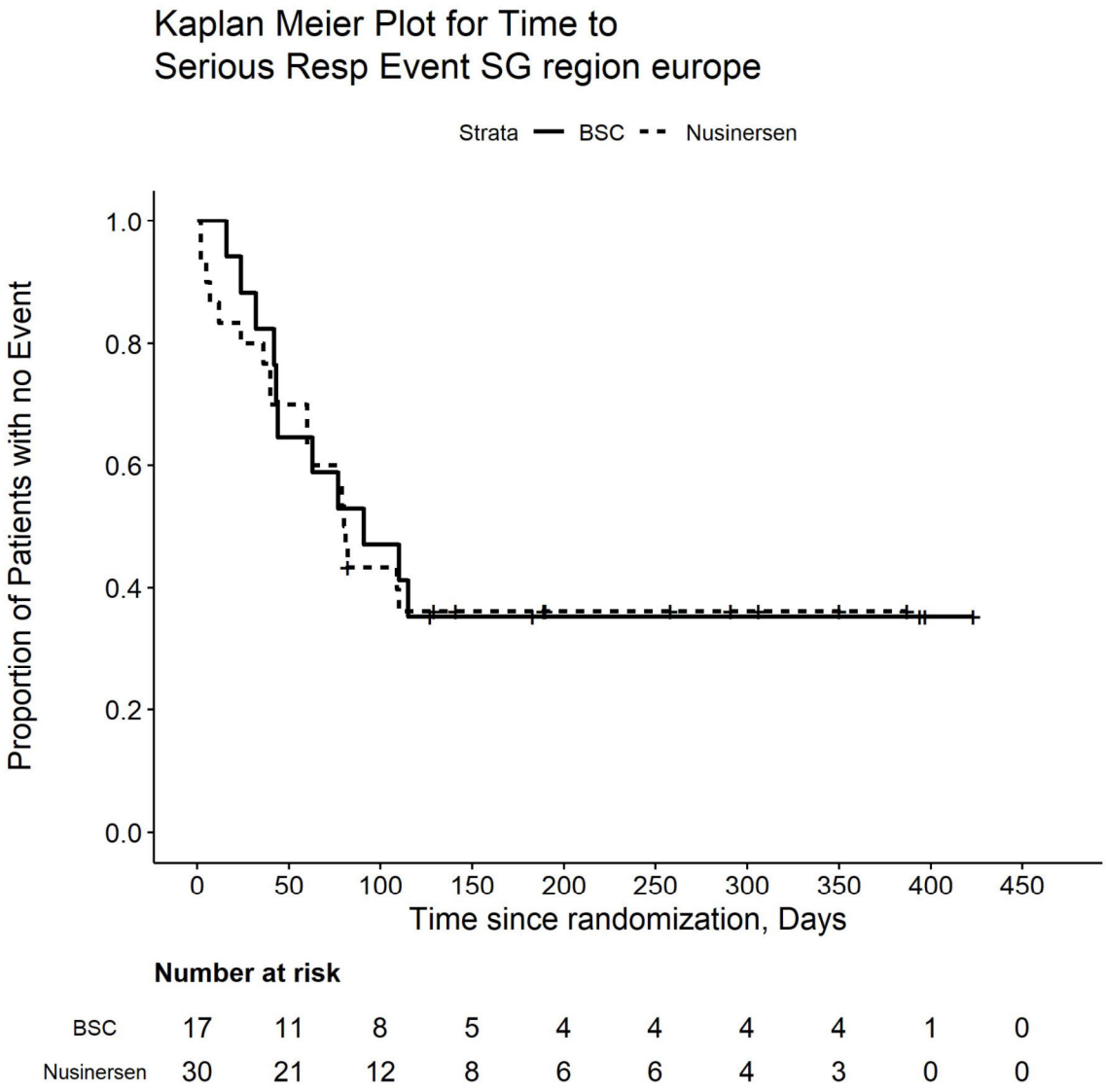
Number at risk

BSC	18	12	8	4	1	1	1	0	0	0
Nusinersen	34	24	20	17	13	7	4	2	0	0



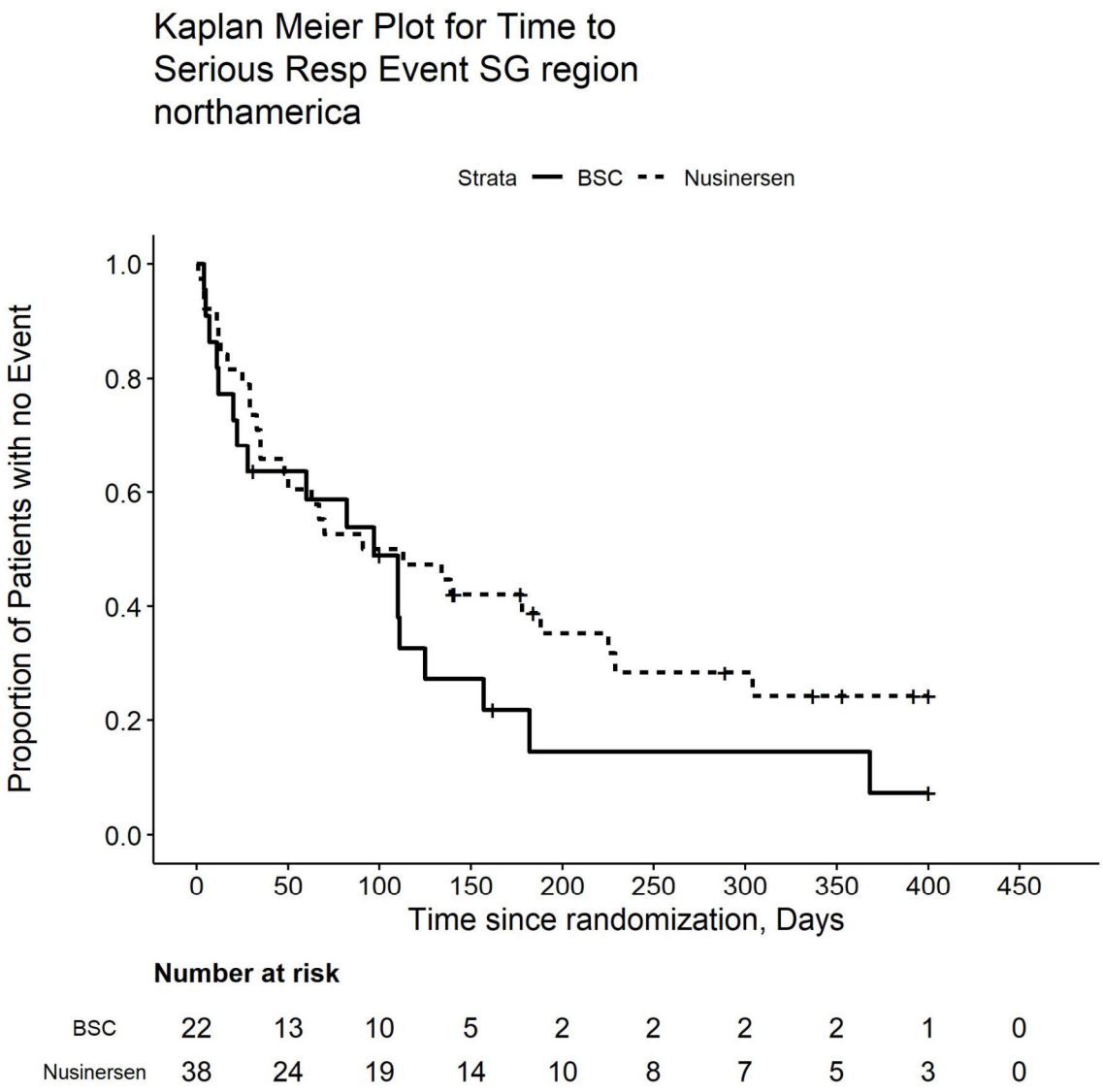
Number at risk

BSC	2	1	1	1	1	1	1	0	0	0
Nusinersen	12	12	10	9	7	3	2	2	1	0



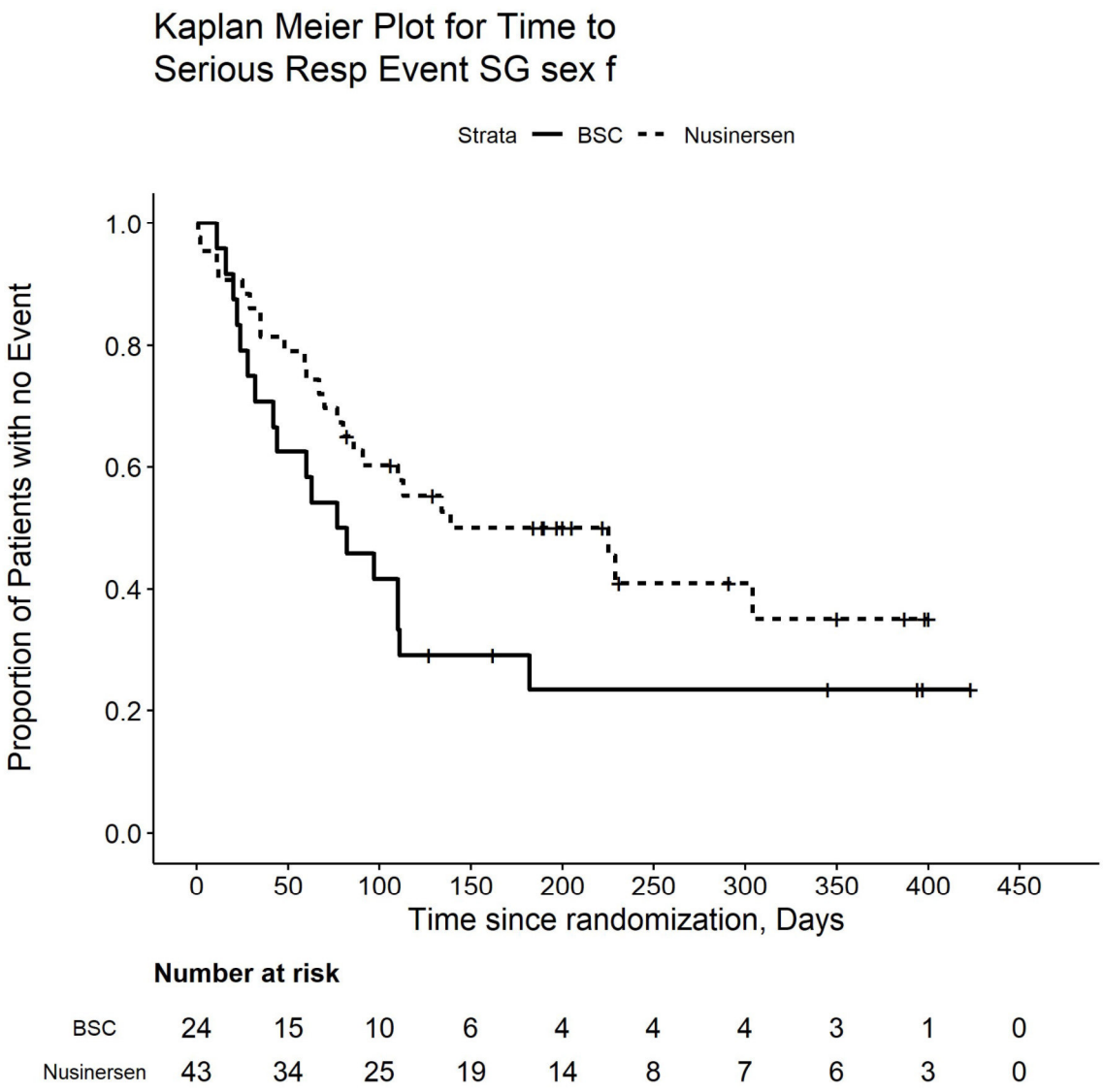
Number at risk

BSC	17	11	8	5	4	4	4	4	1	0
Nusinersen	30	21	12	8	6	6	4	3	0	0



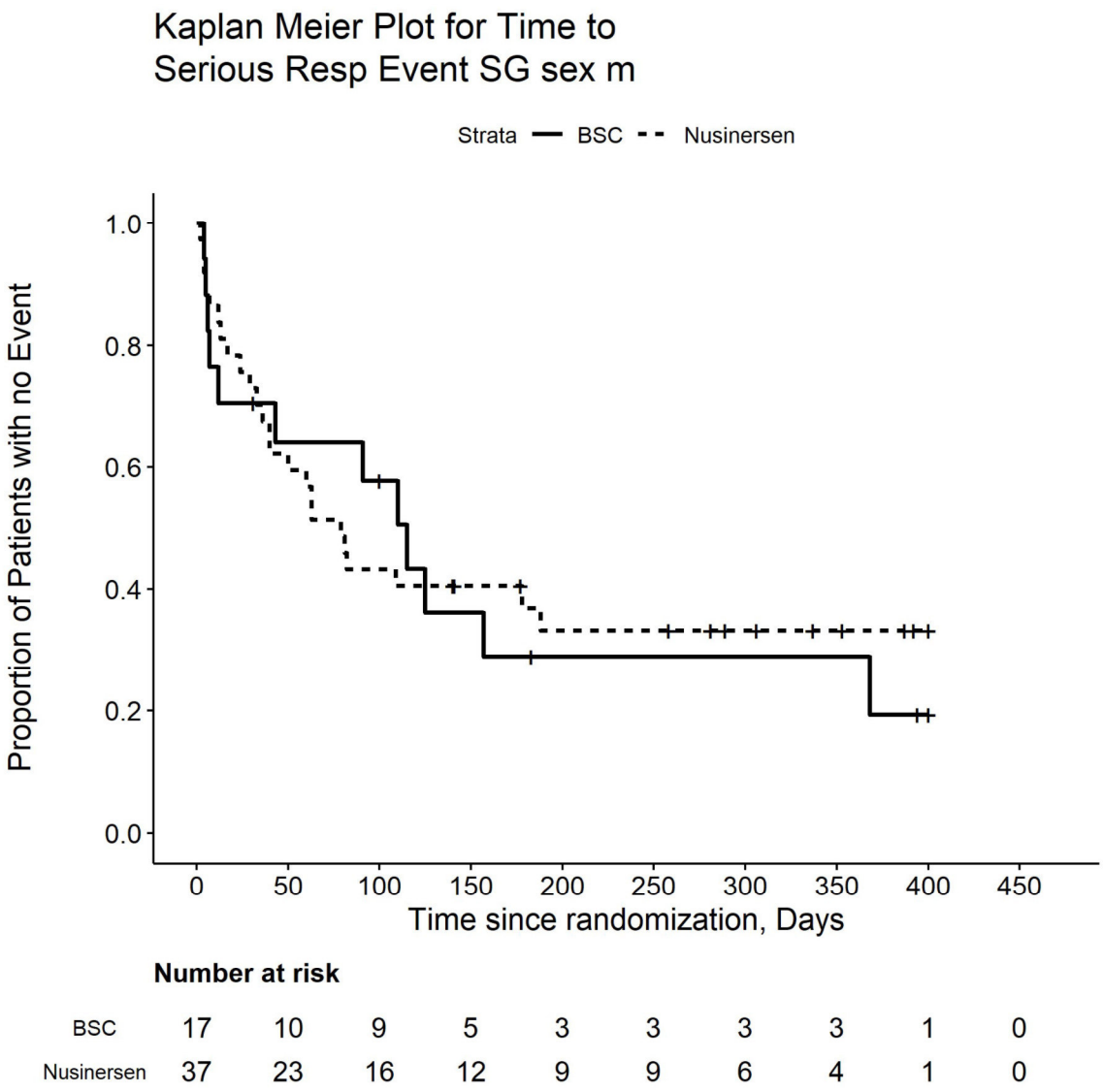
Number at risk

BSC	22	13	10	5	2	2	2	2	1	0
Nusinersen	38	24	19	14	10	8	7	5	3	0



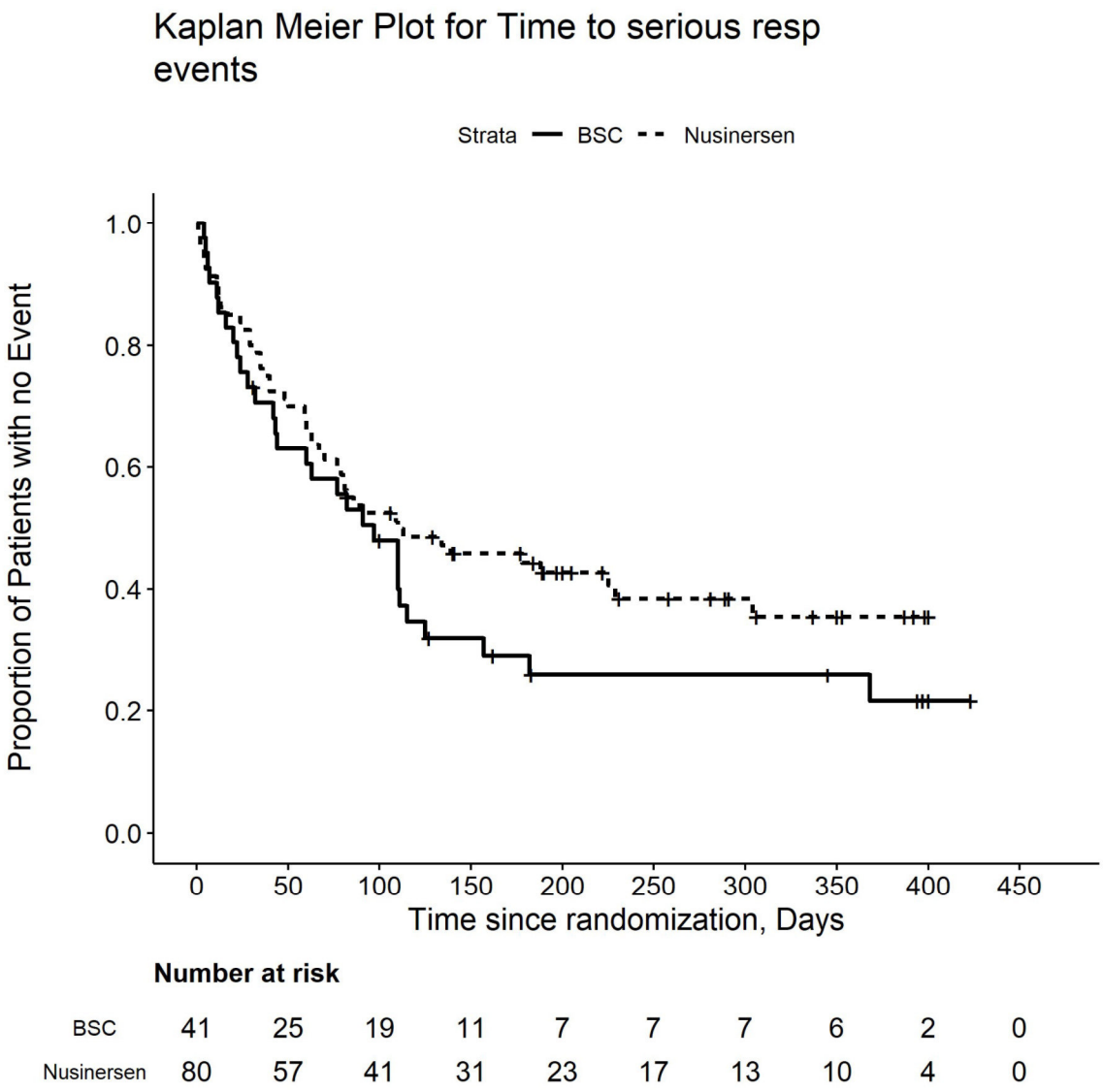
Number at risk

BSC	24	15	10	6	4	4	4	3	1	0
Nusinersen	43	34	25	19	14	8	7	6	3	0



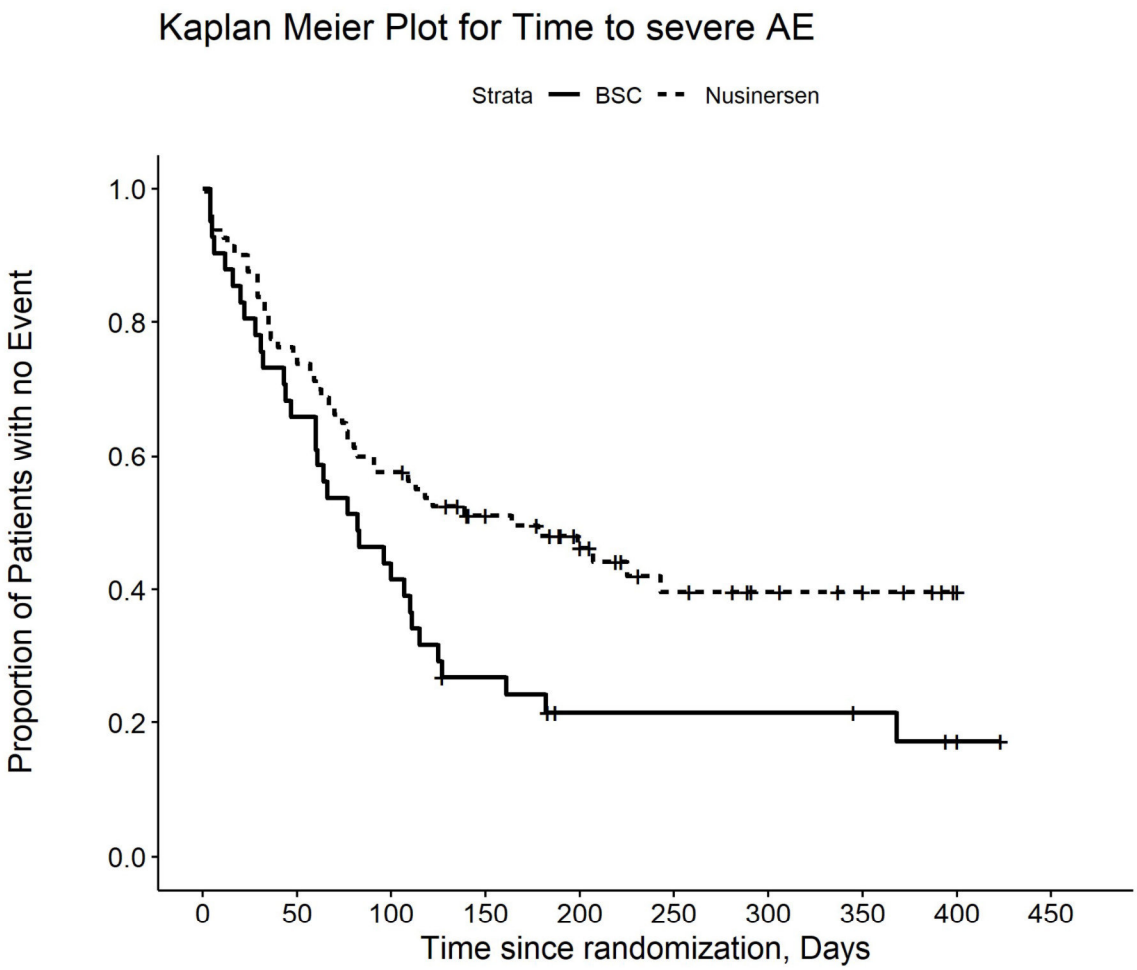
Number at risk

BSC	17	10	9	5	3	3	3	3	1	0
Nusinersen	37	23	16	12	9	9	6	4	1	0



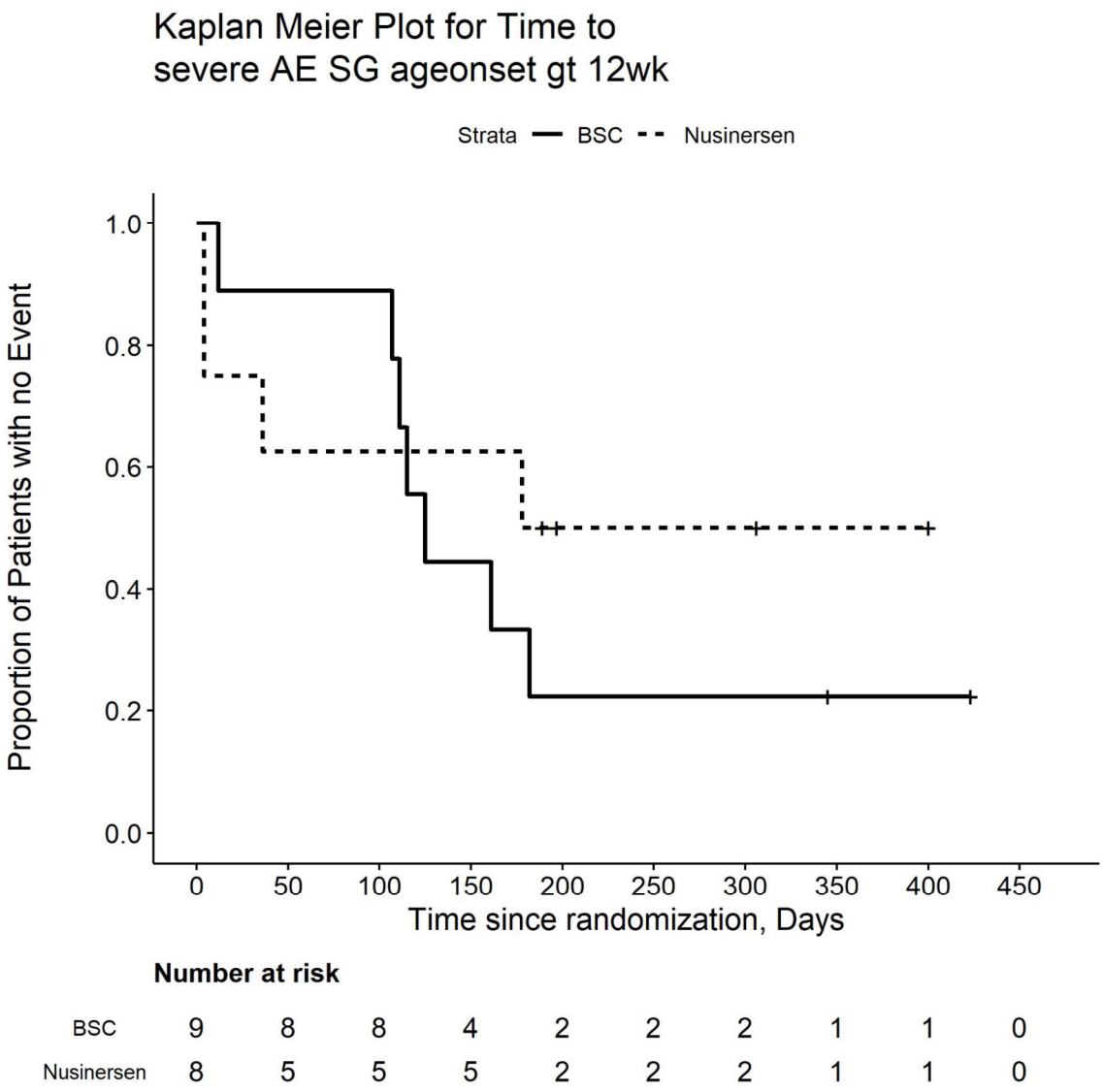
Number at risk

BSC	41	25	19	11	7	7	7	6	2	0
Nusinersen	80	57	41	31	23	17	13	10	4	0



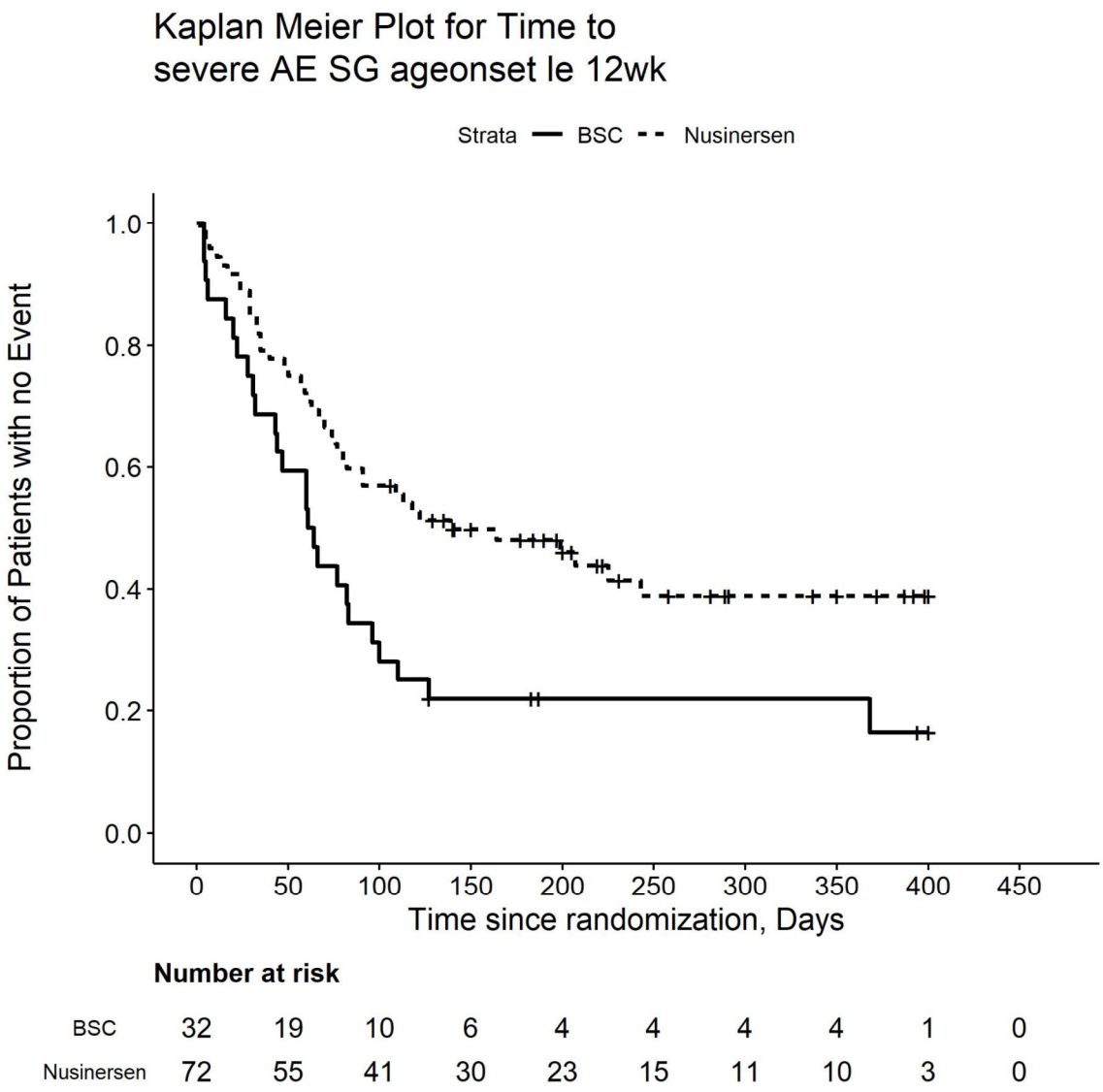
Number at risk

BSC	41	27	18	10	6	6	6	5	2	0
Nusinersen	80	60	46	35	25	17	13	11	4	0



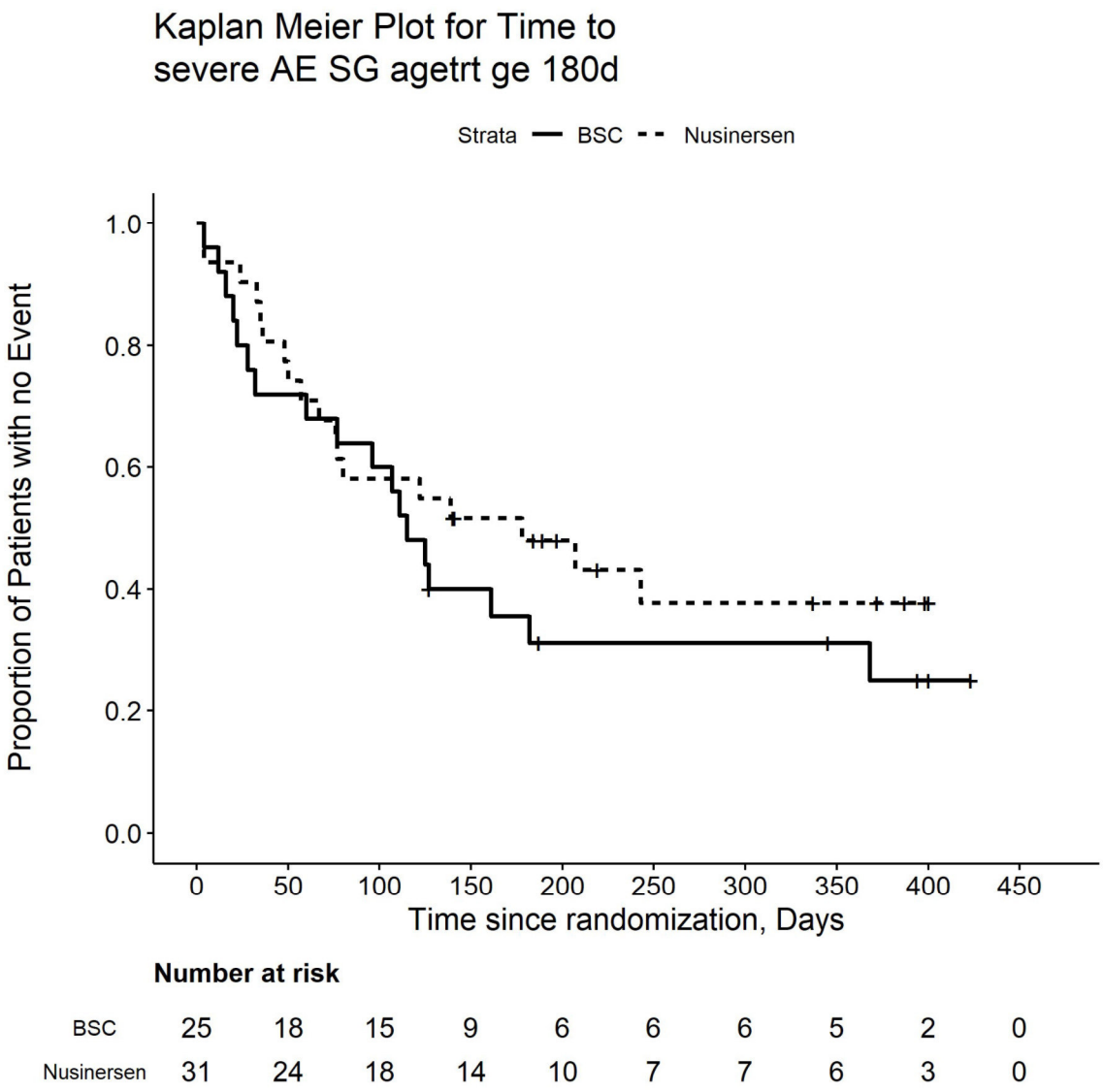
Number at risk

BSC	9	8	8	4	2	2	2	1	1	0
Nusinersen	8	5	5	5	2	2	2	1	1	0



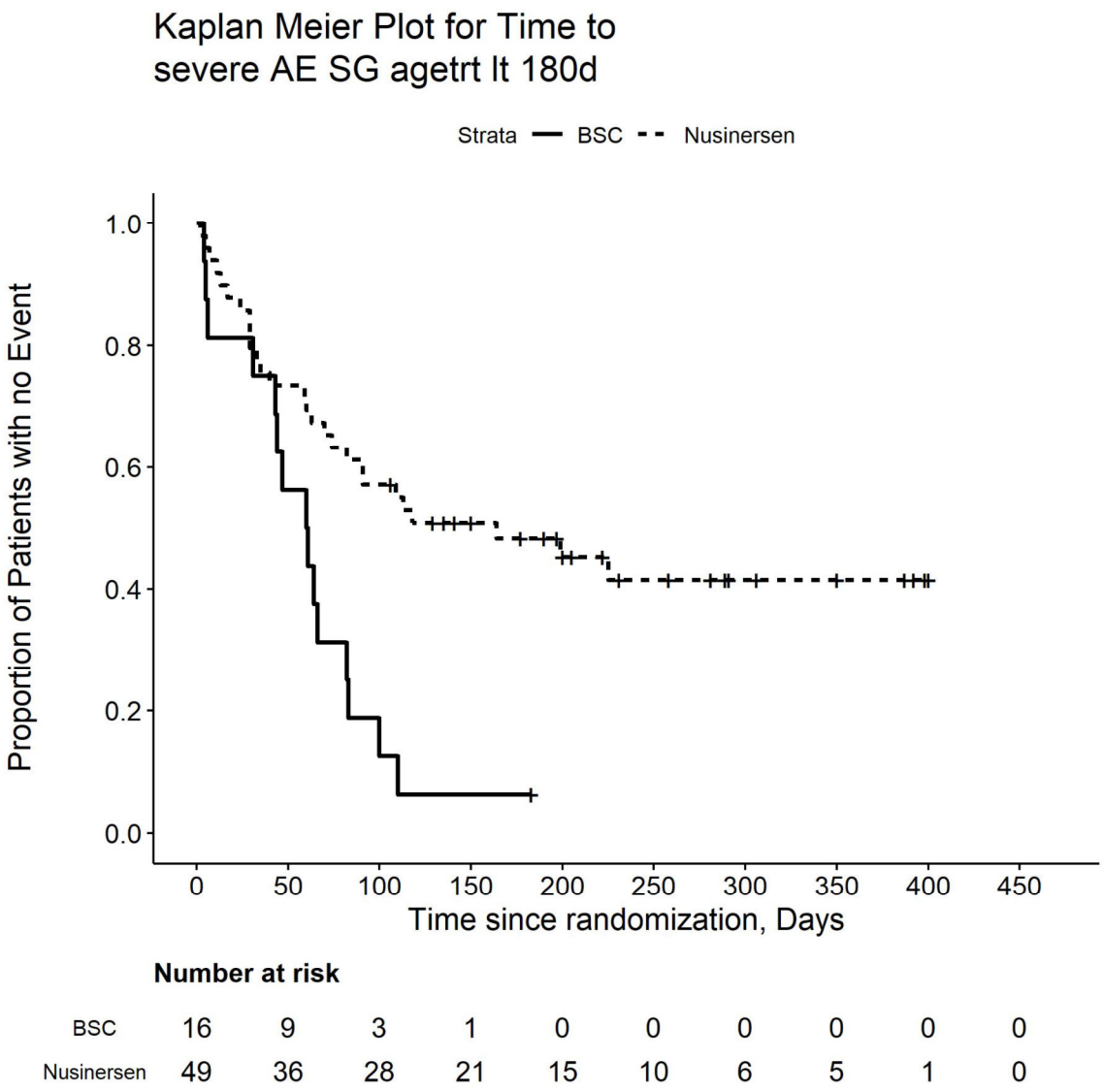
Number at risk

BSC	32	19	10	6	4	4	4	4	1	0
Nusinersen	72	55	41	30	23	15	11	10	3	0



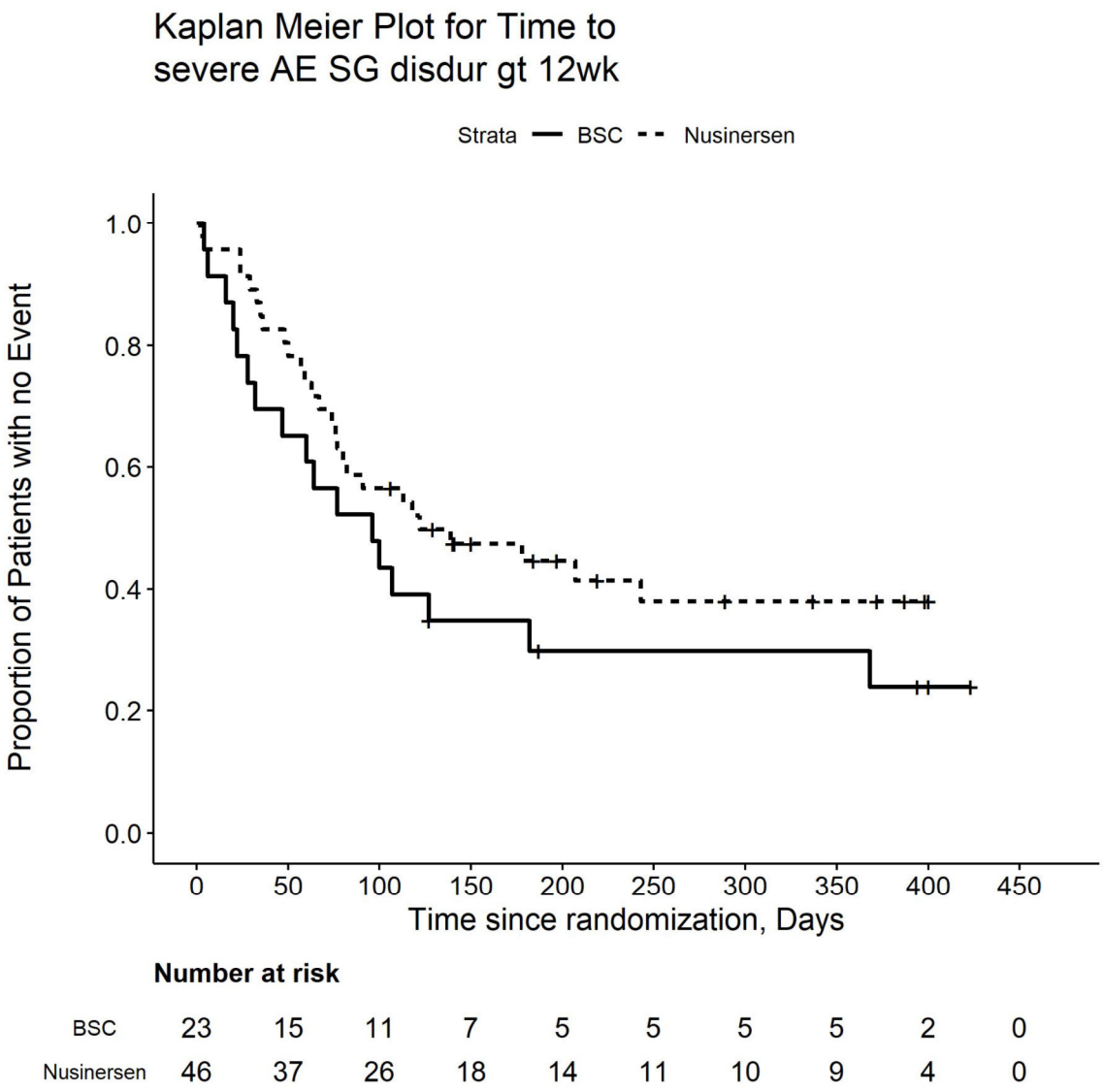
Number at risk

BSC	25	18	15	9	6	6	6	5	2	0
Nusinersen	31	24	18	14	10	7	7	6	3	0



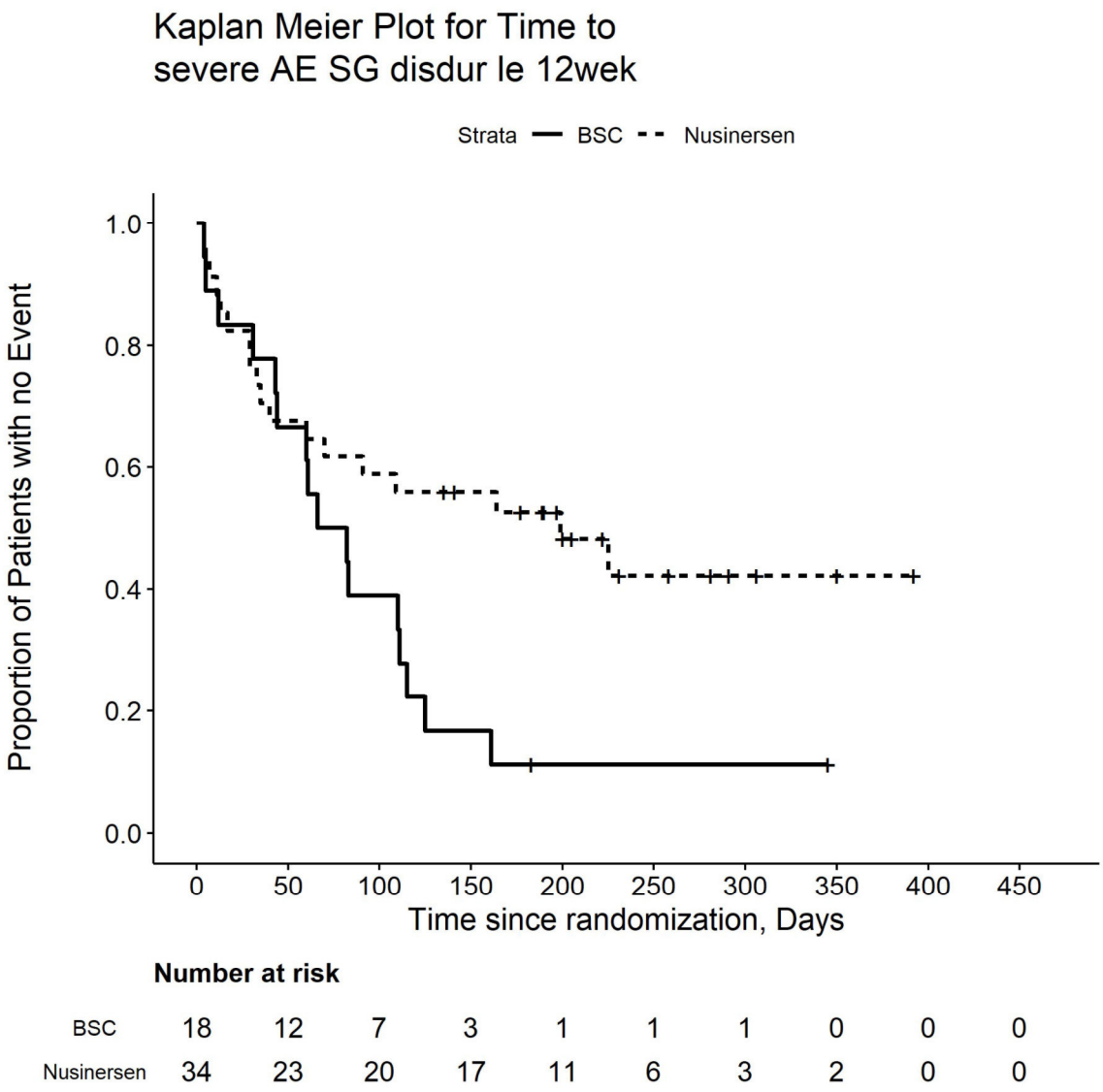
Number at risk

BSC	16	9	3	1	0	0	0	0	0	0
Nusinersen	49	36	28	21	15	10	6	5	1	0



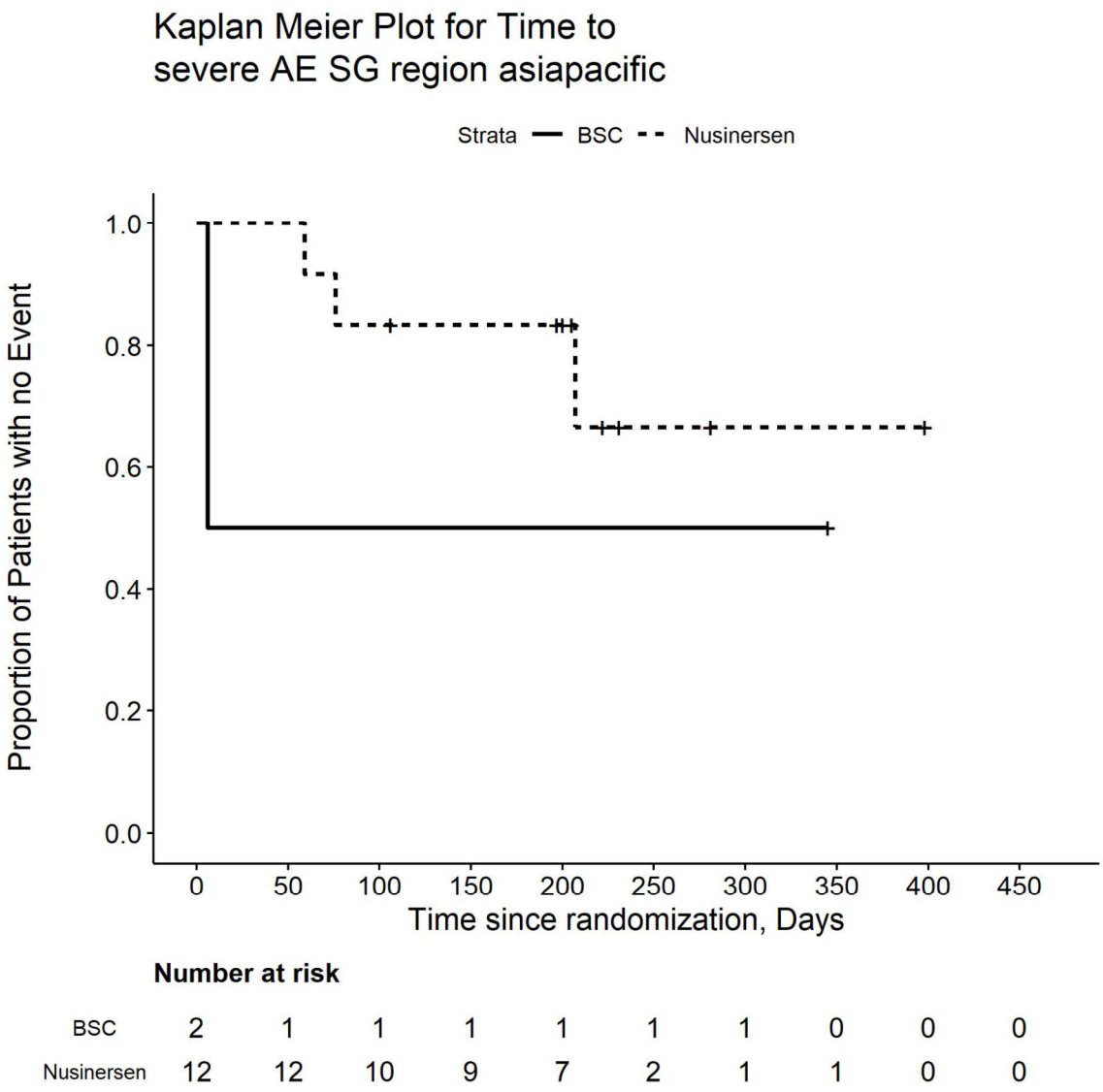
Number at risk

BSC	23	15	11	7	5	5	5	5	2	0
Nusinersen	46	37	26	18	14	11	10	9	4	0



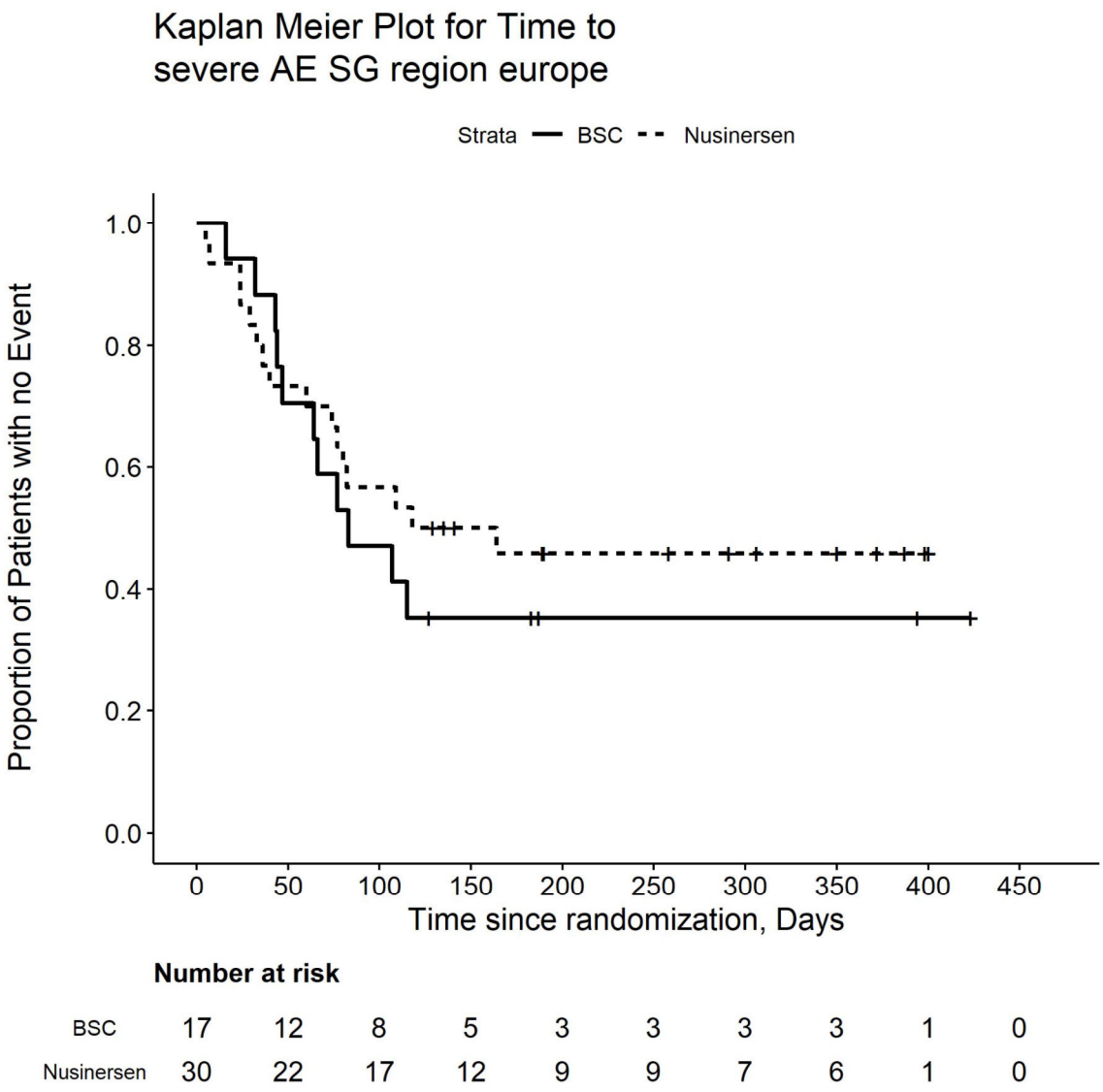
Number at risk

BSC	18	12	7	3	1	1	1	0	0	0
Nusinersen	34	23	20	17	11	6	3	2	0	0



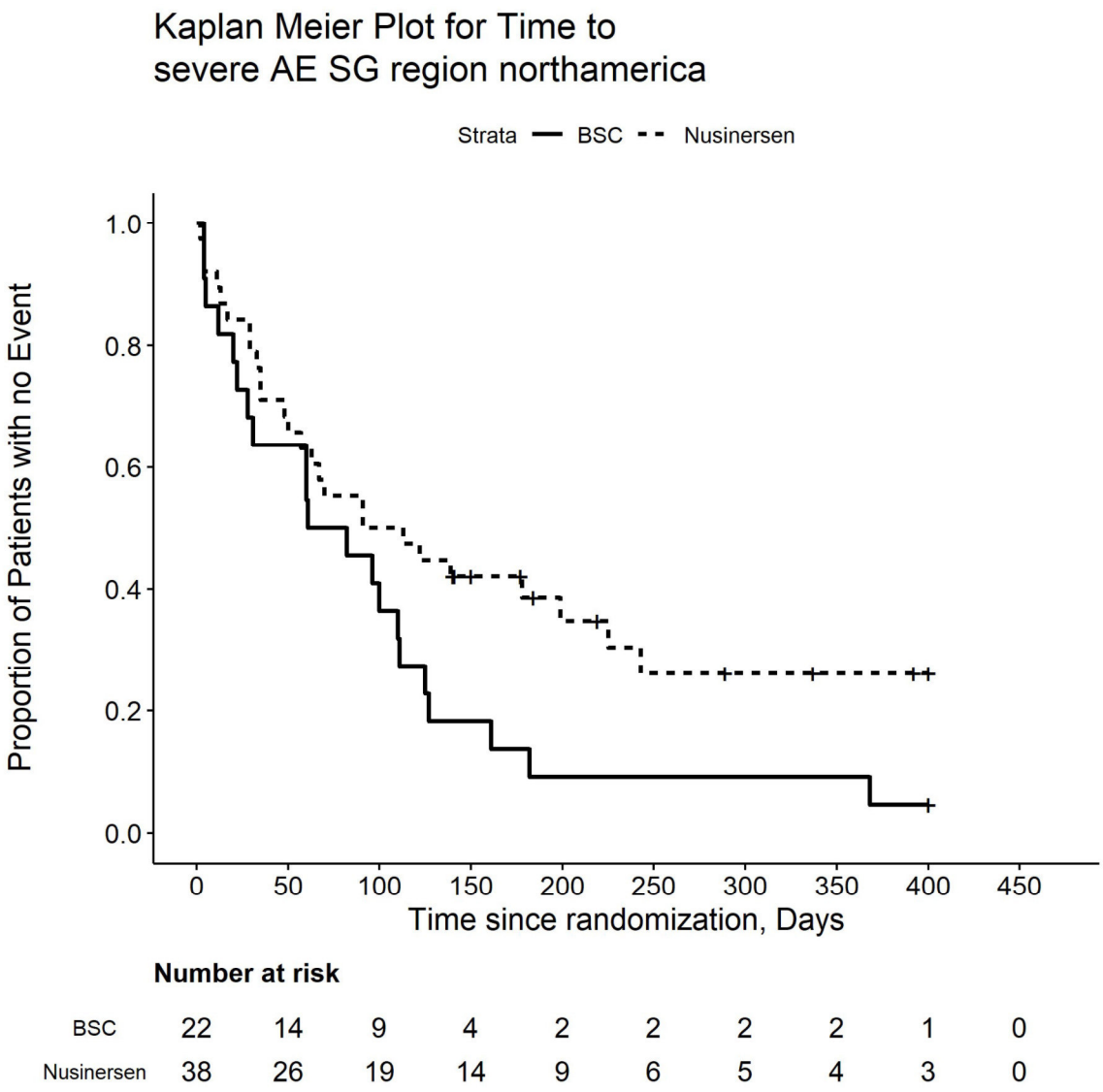
Number at risk

BSC	2	1	1	1	1	1	1	0	0	0
Nusinersen	12	12	10	9	7	2	1	1	0	0



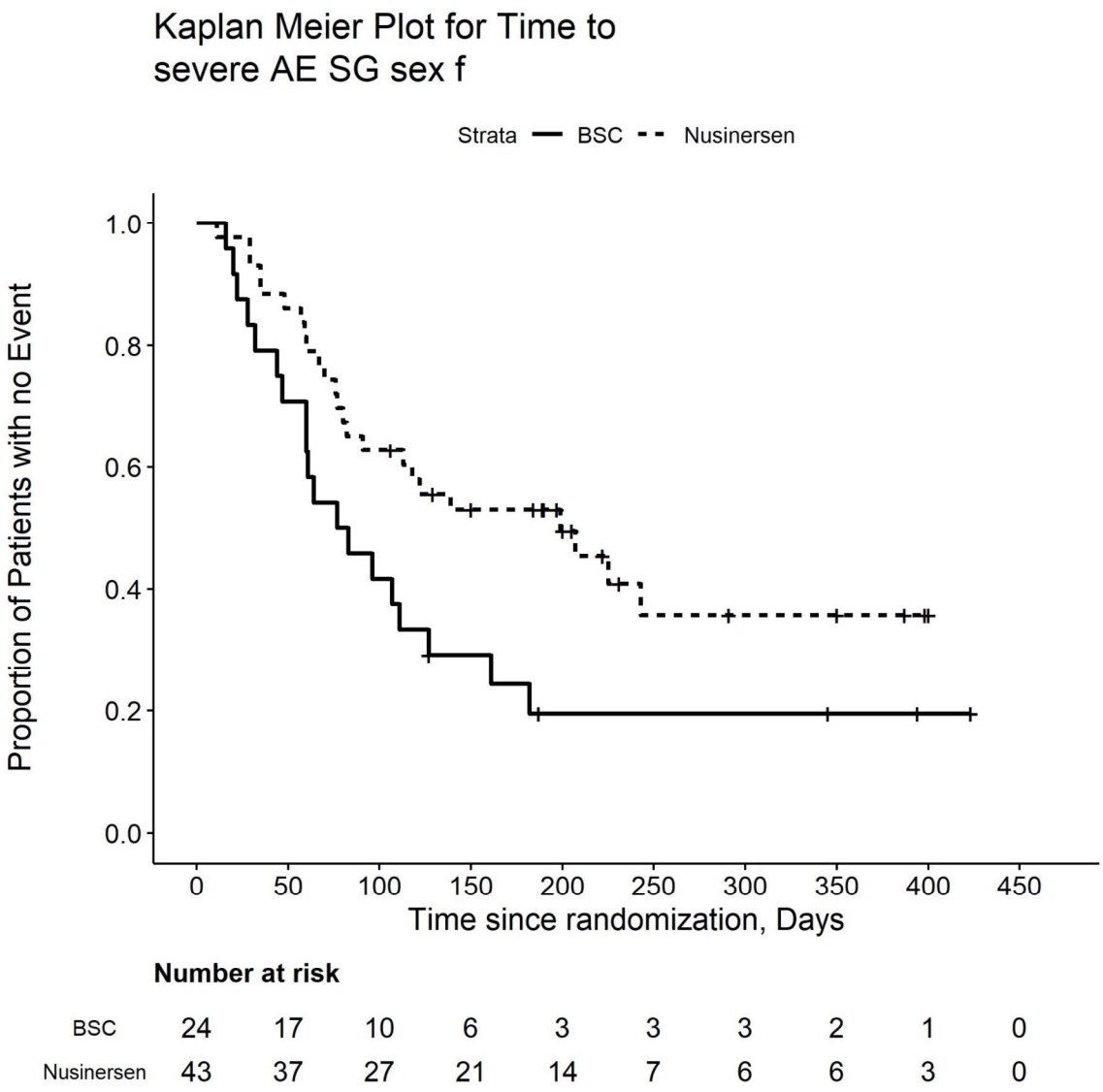
Number at risk

BSC	17	12	8	5	3	3	3	3	1	0
Nusinersen	30	22	17	12	9	9	7	6	1	0



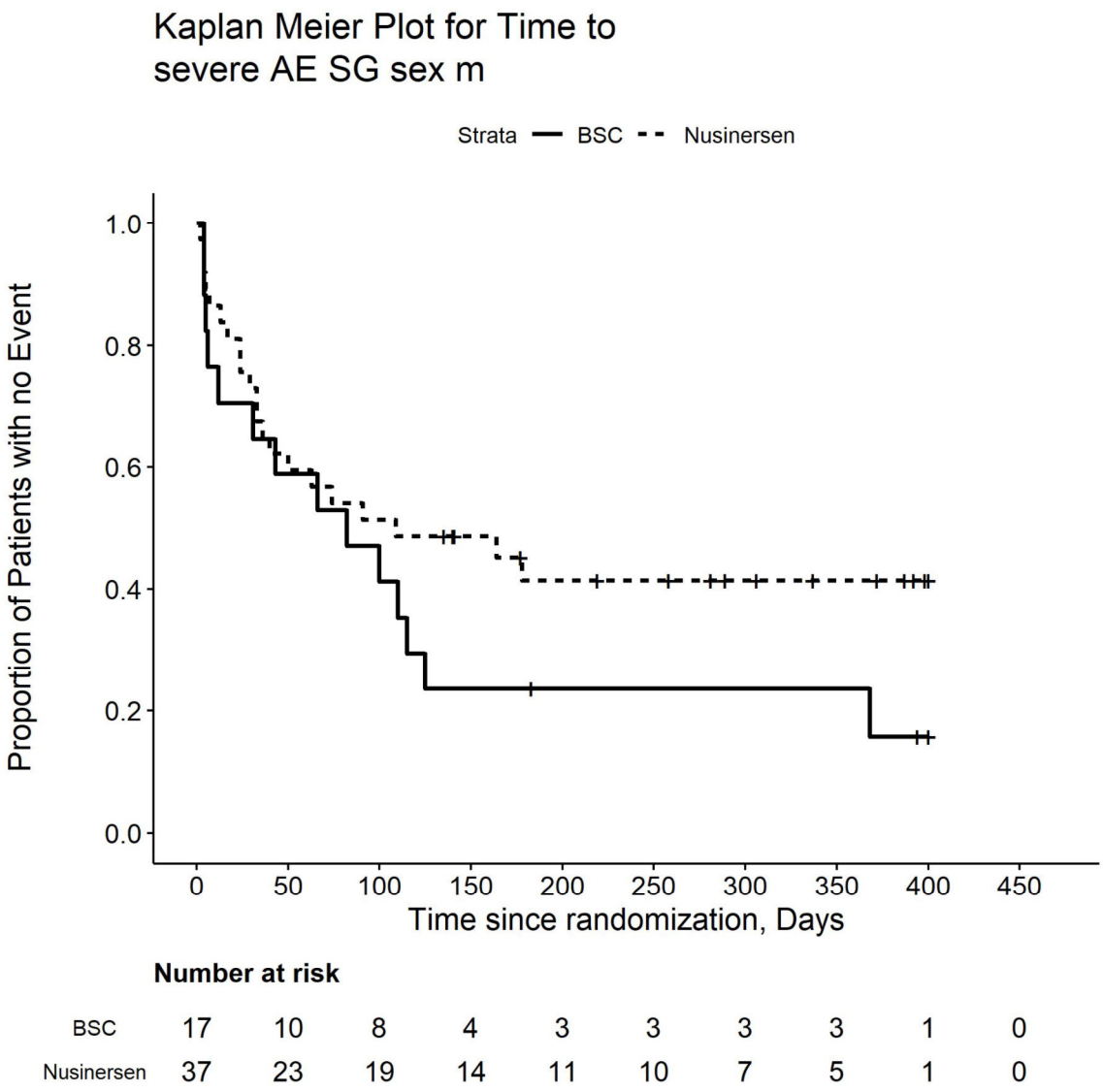
Number at risk

BSC	22	14	9	4	2	2	2	2	1	0
Nusinersen	38	26	19	14	9	6	5	4	3	0



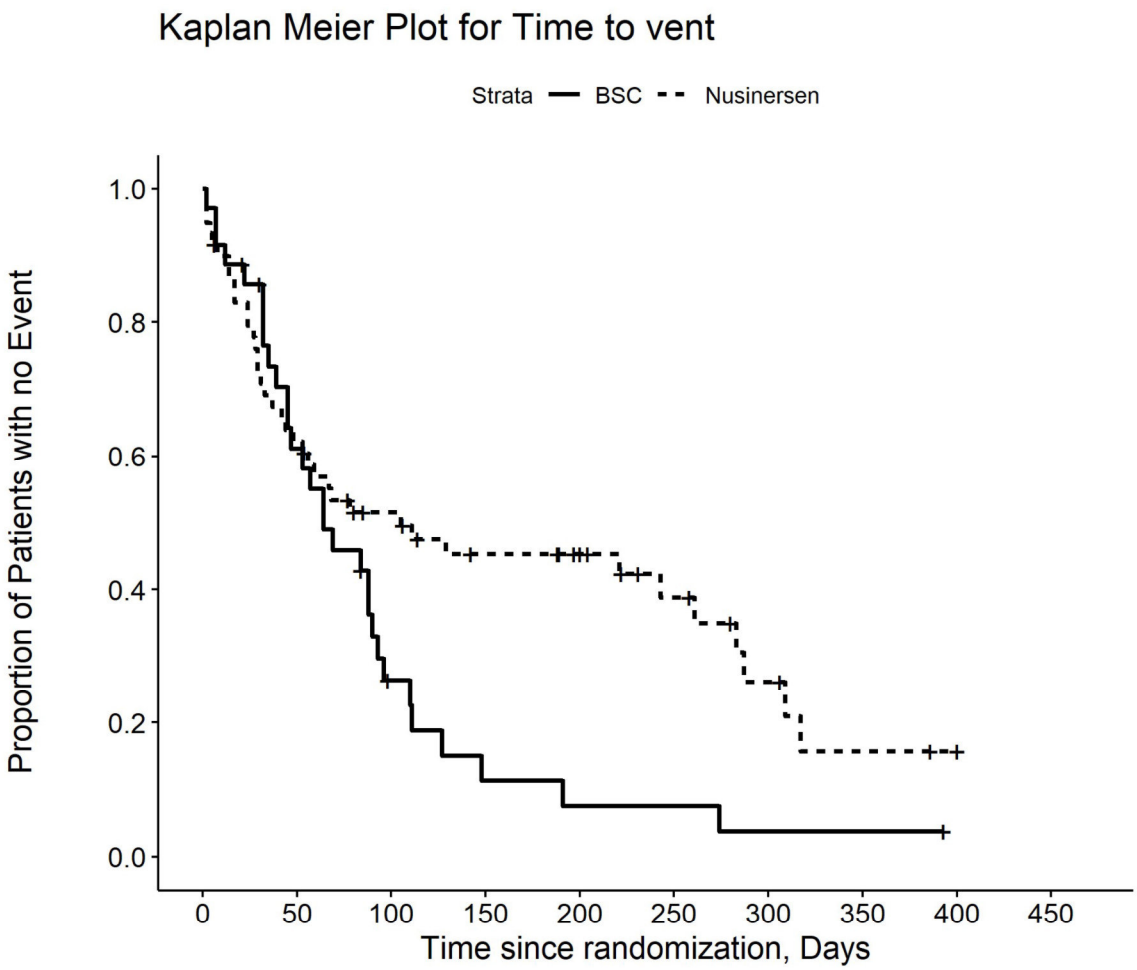
Number at risk

BSC	24	17	10	6	3	3	3	2	1	0
Nusinersen	43	37	27	21	14	7	6	6	3	0



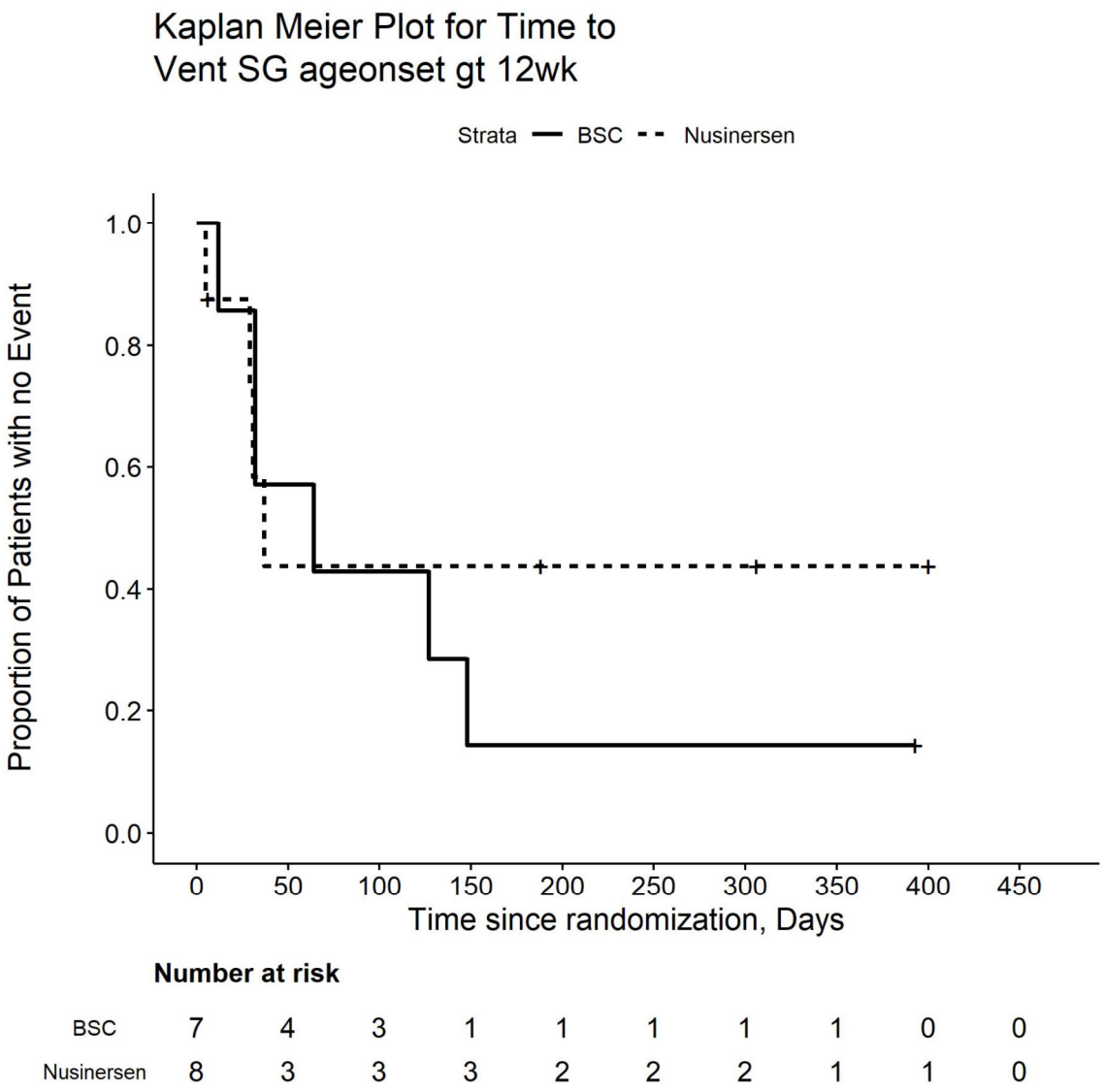
Number at risk

BSC	17	10	8	4	3	3	3	3	1	0
Nusinersen	37	23	19	14	11	10	7	5	1	0



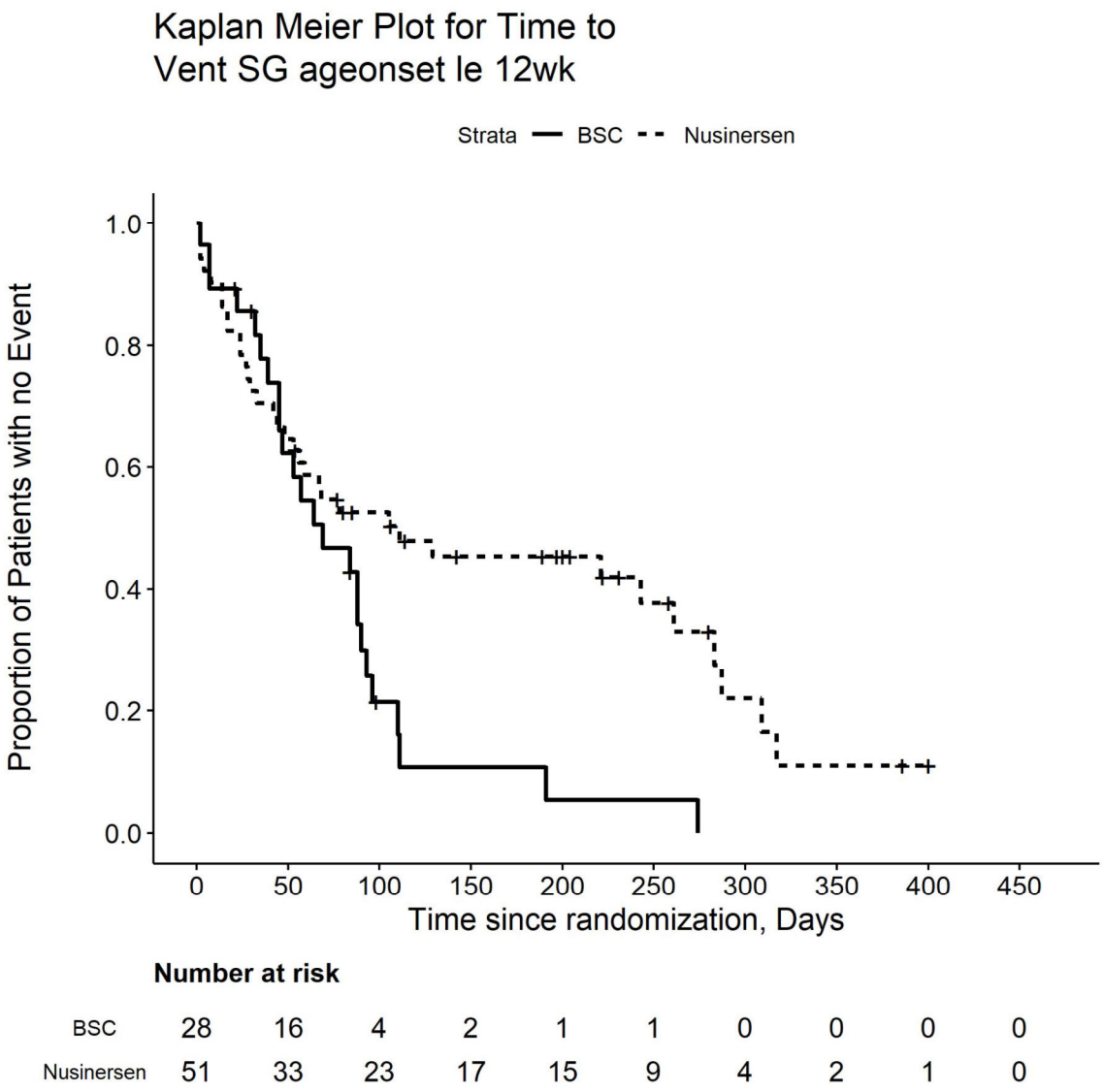
Number at risk

BSC	35	20	7	3	2	2	1	1	0	0
Nusinersen	59	36	26	20	17	11	6	3	2	0



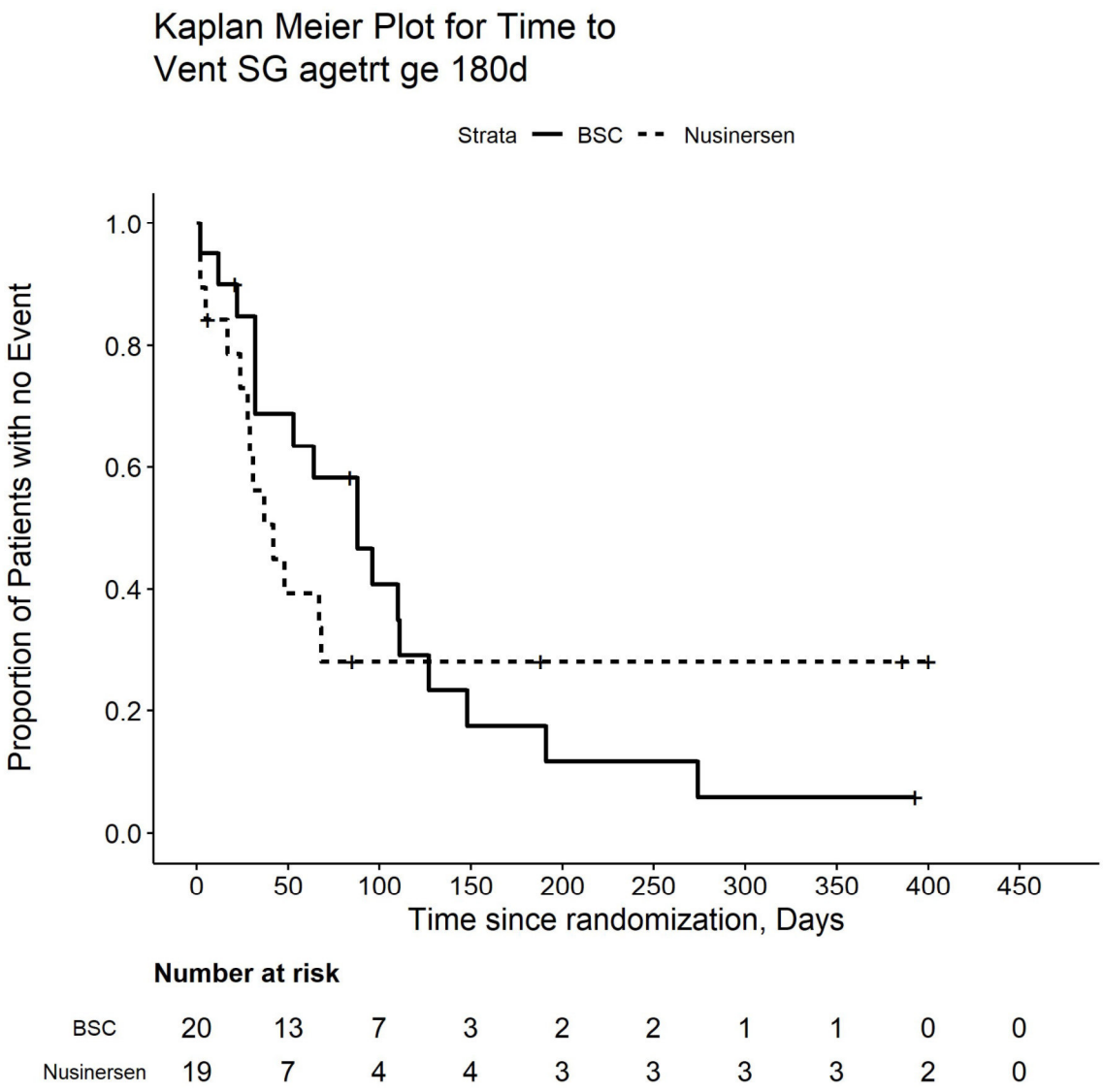
Number at risk

BSC	7	4	3	1	1	1	1	1	0	0
Nusinersen	8	3	3	3	2	2	2	1	1	0



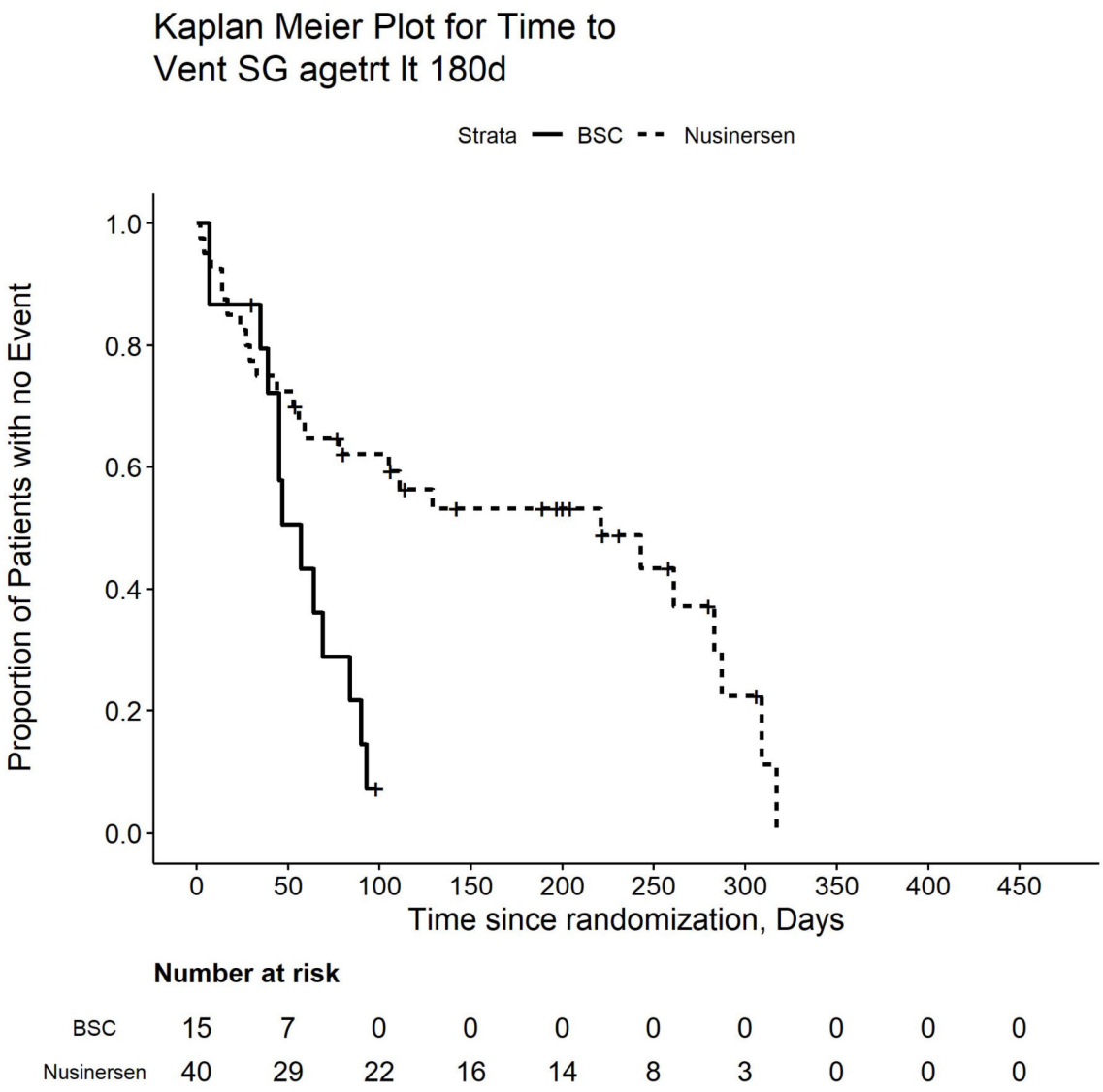
Number at risk

BSC	28	16	4	2	1	1	0	0	0	0
Nusinersen	51	33	23	17	15	9	4	2	1	0



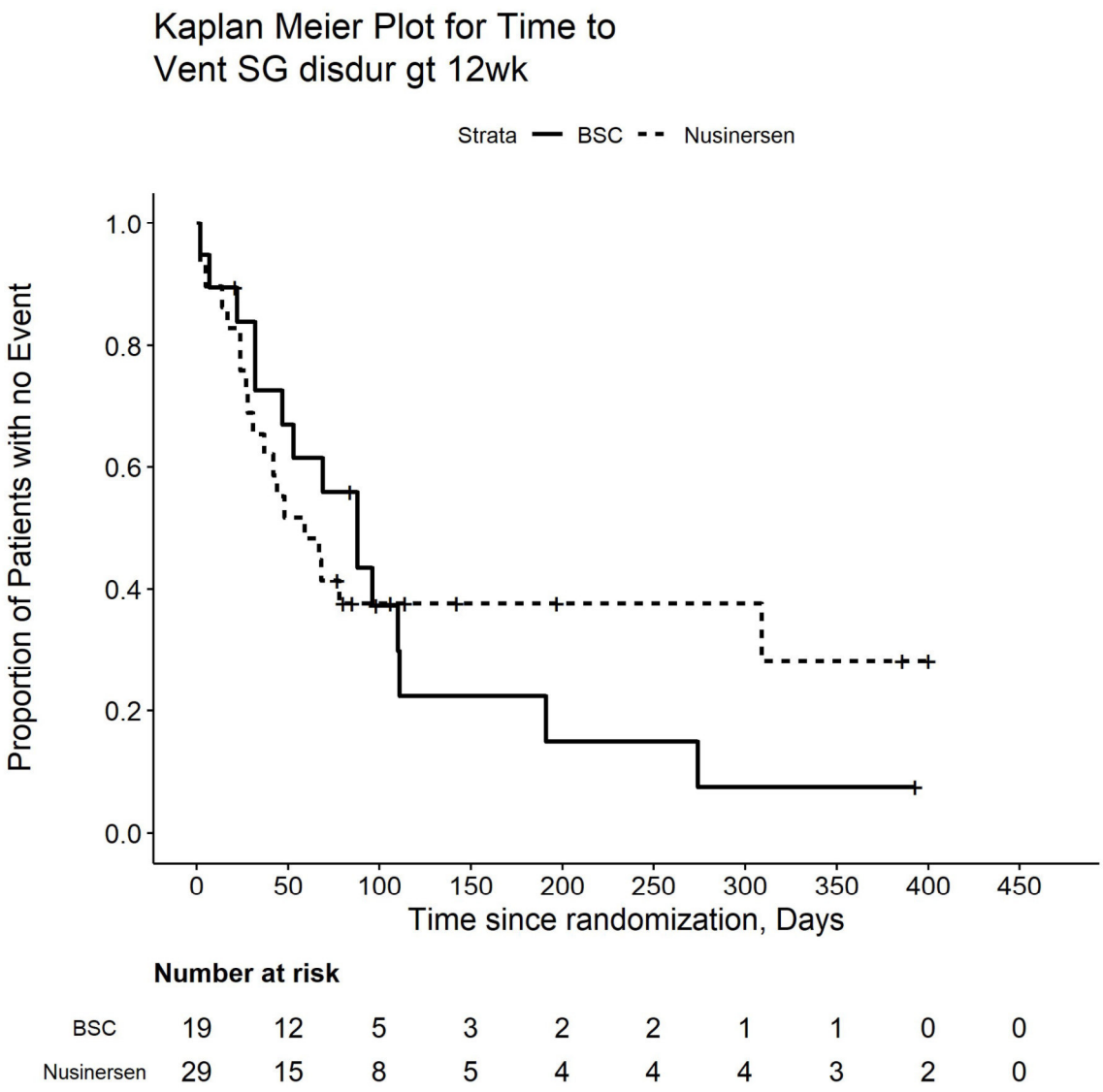
Number at risk

BSC	20	13	7	3	2	2	1	1	0	0
Nusinersen	19	7	4	4	3	3	3	3	2	0



Number at risk

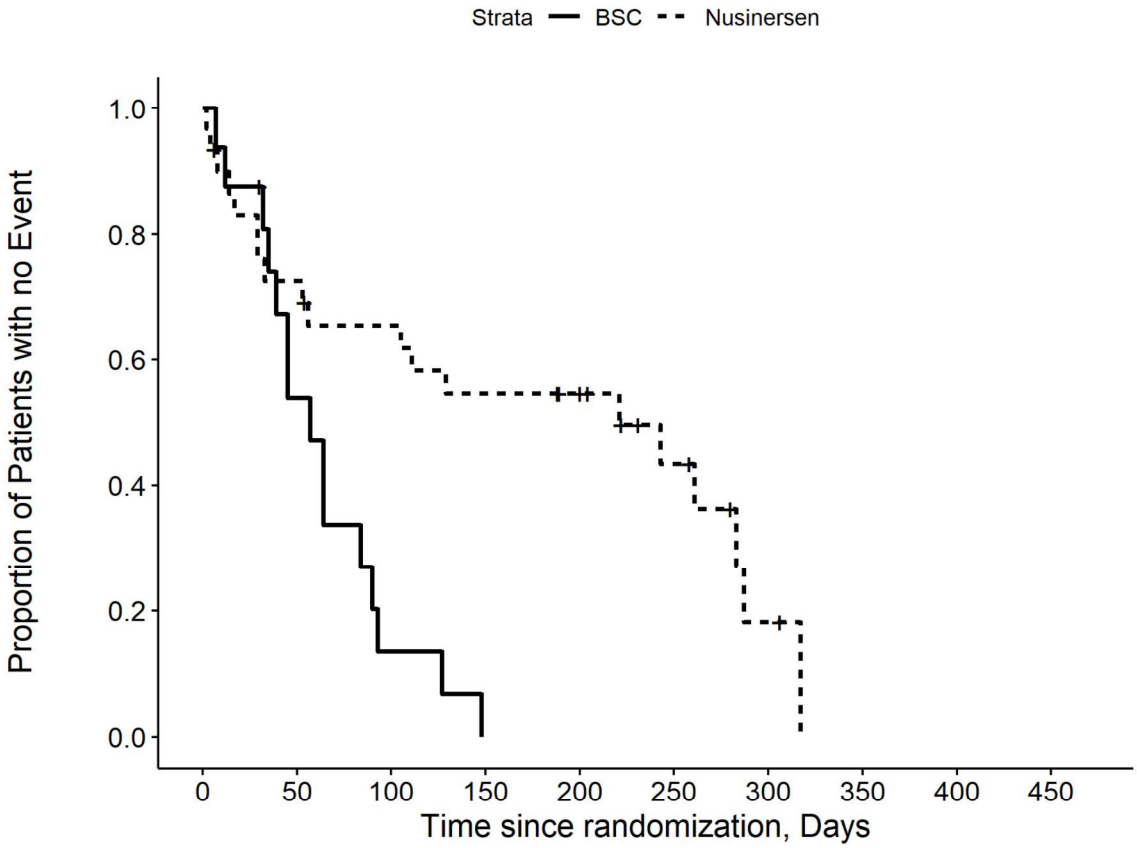
BSC	15	7	0	0	0	0	0	0	0	0
Nusinersen	40	29	22	16	14	8	3	0	0	0



Number at risk

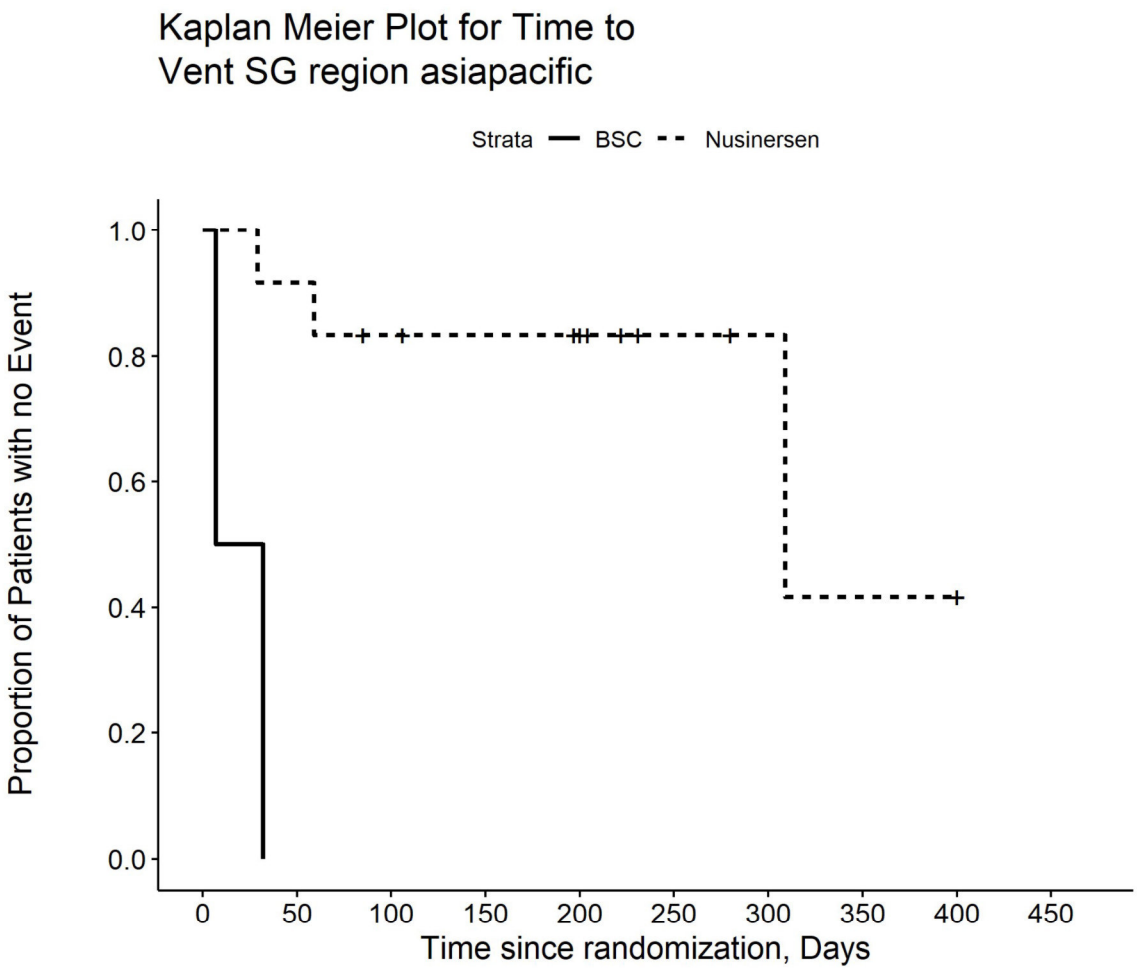
BSC	19	12	5	3	2	2	1	1	0	0
Nusinersen	29	15	8	5	4	4	4	3	2	0

Kaplan Meier Plot for Time to
Vent SG disdur le 12wek



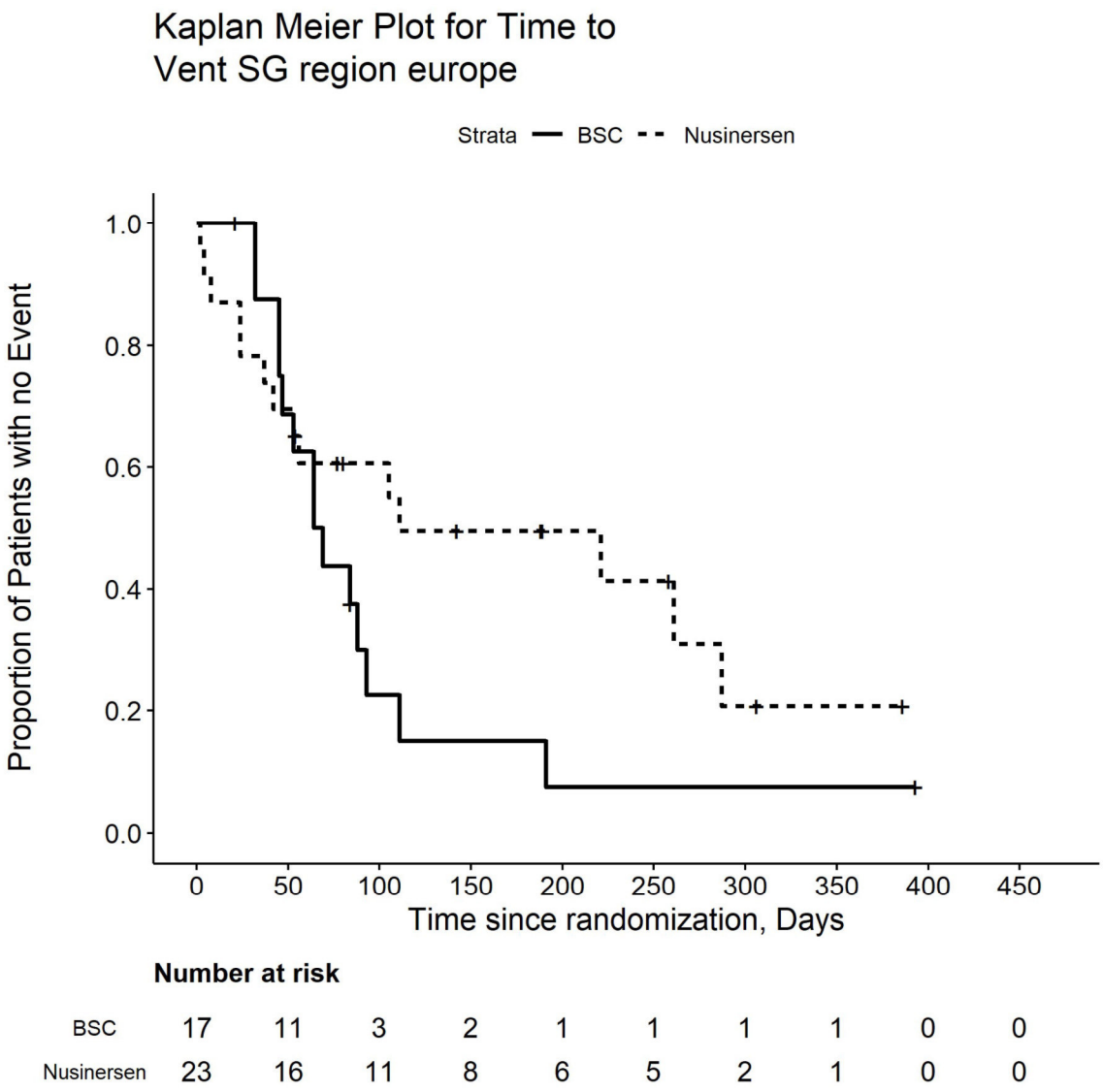
Number at risk

BSC	16	8	2	0	0	0	0	0	0	0
Nusinersen	30	21	18	15	13	7	2	0	0	0



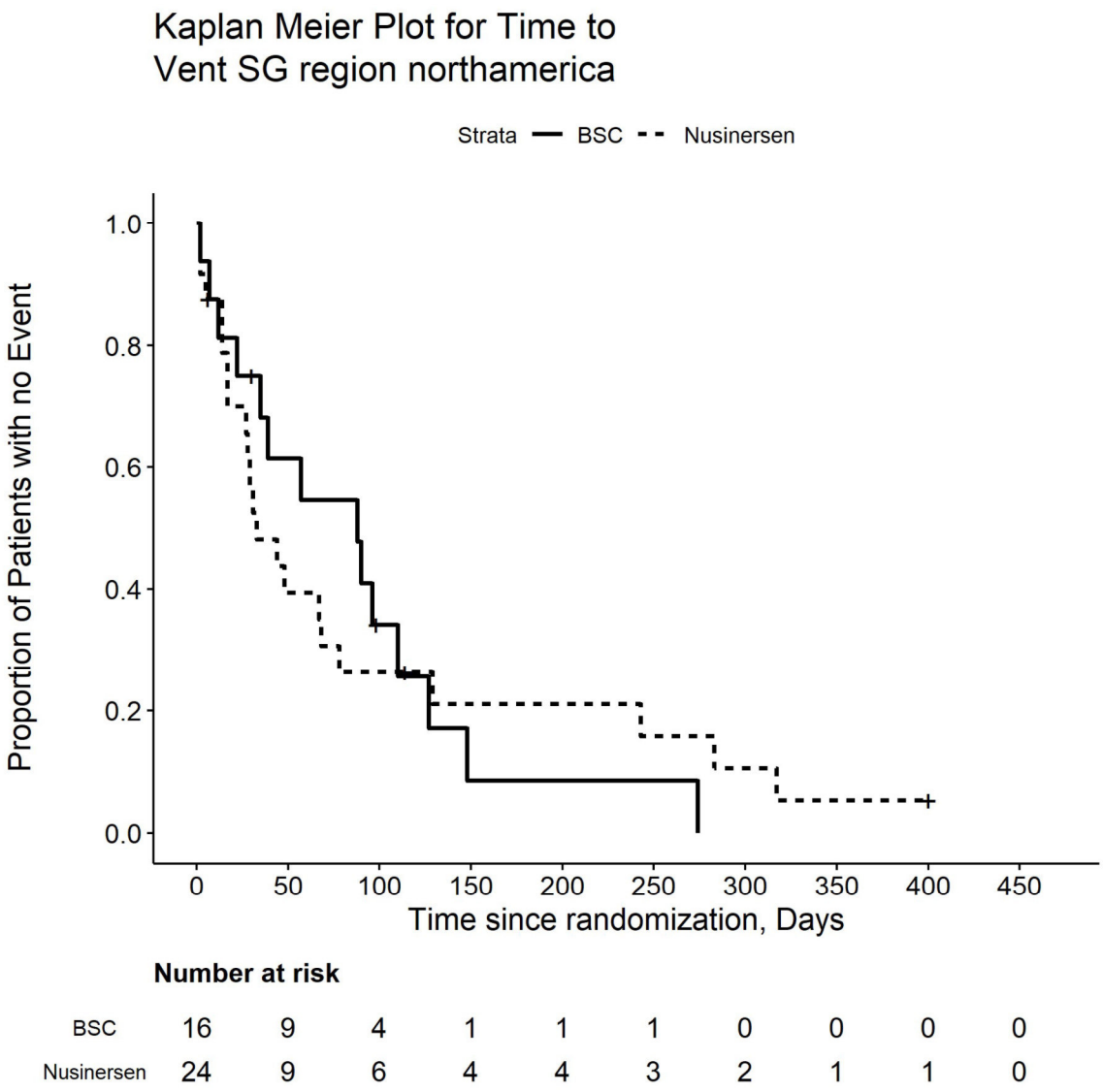
Number at risk

BSC	2	0	0	0	0	0	0	0	0	0
Nusinersen	12	11	9	8	7	3	2	1	1	0



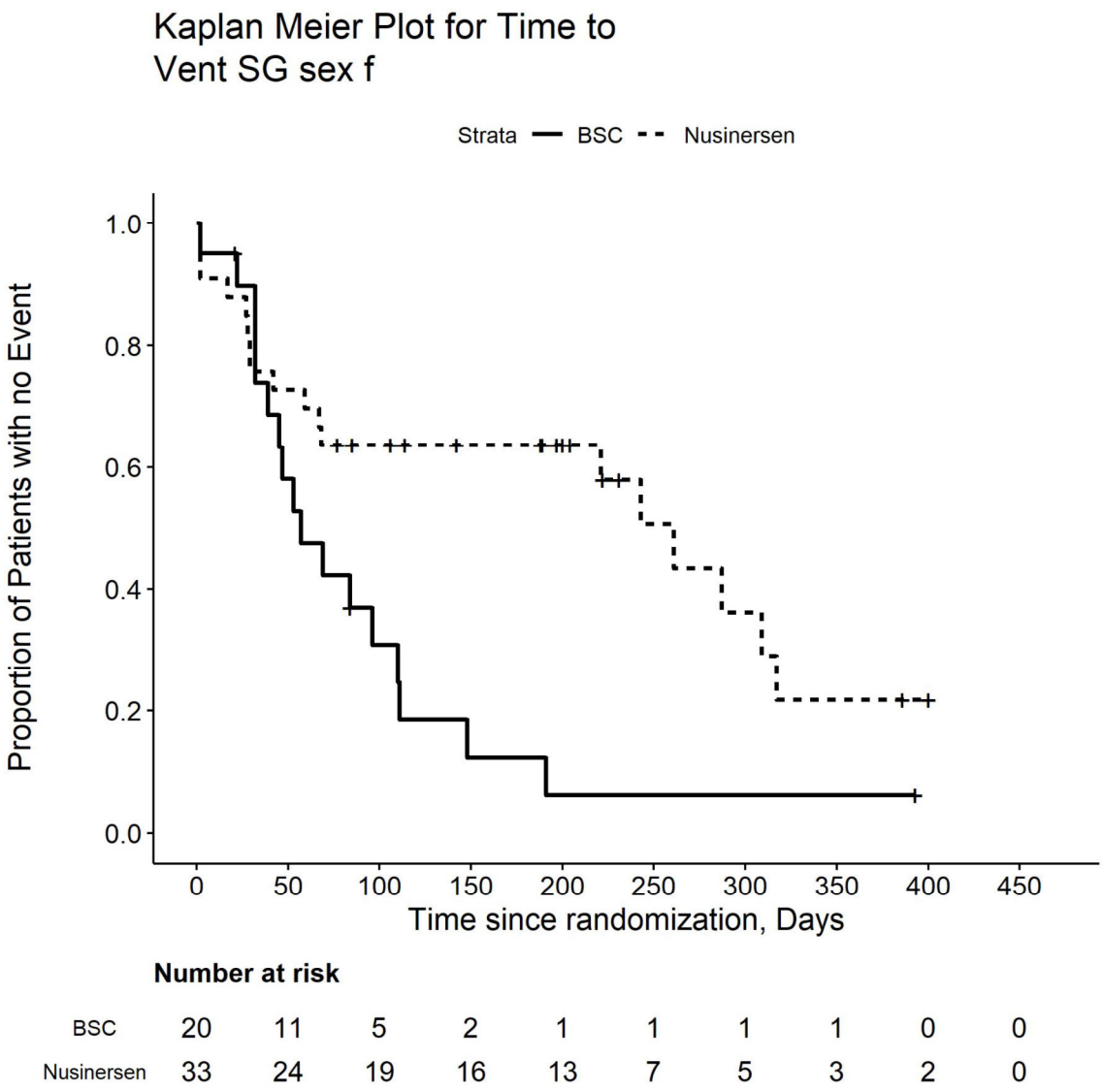
Number at risk

BSC	17	11	3	2	1	1	1	1	0	0
Nusinersen	23	16	11	8	6	5	2	1	0	0



Number at risk

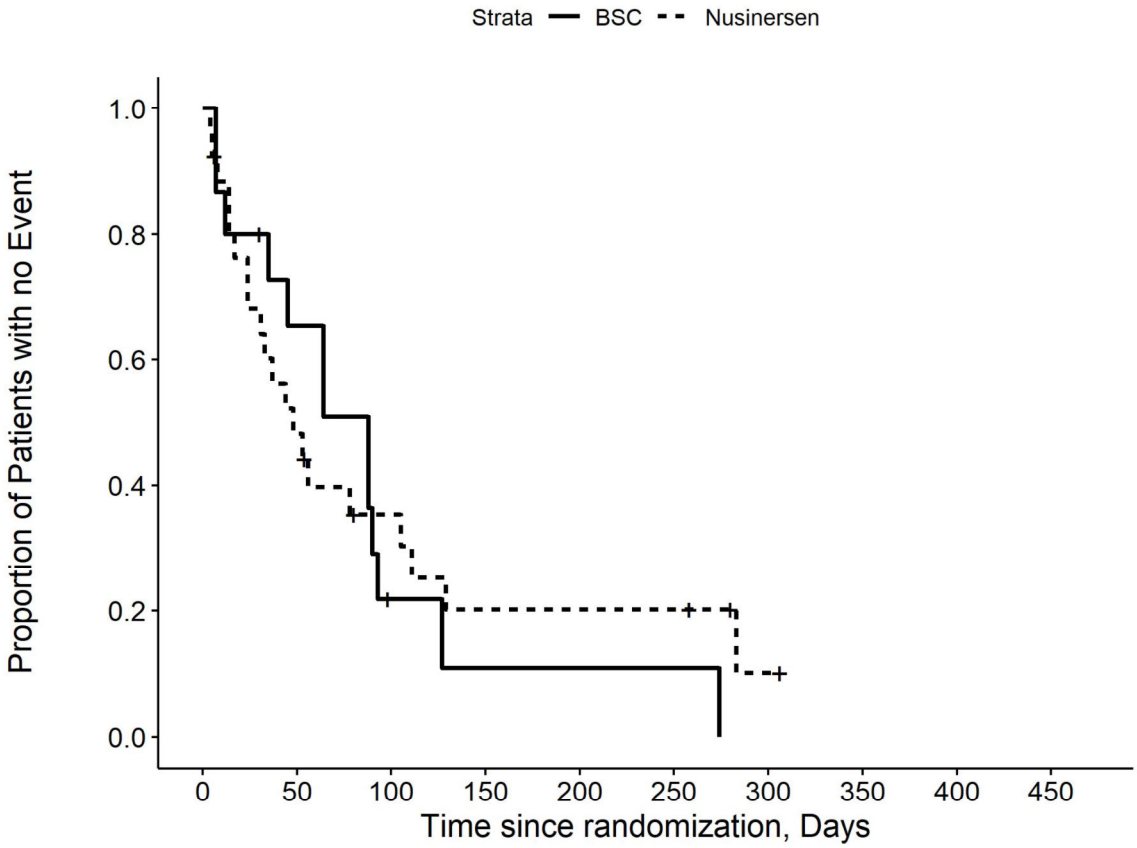
BSC	16	9	4	1	1	1	0	0	0	0
Nusinersen	24	9	6	4	4	3	2	1	1	0



Number at risk

BSC	20	11	5	2	1	1	1	1	0	0
Nusinersen	33	24	19	16	13	7	5	3	2	0

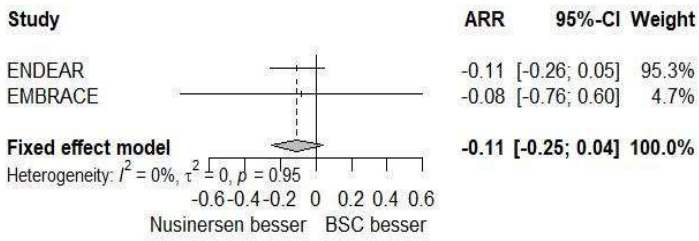
Kaplan Meier Plot for Time to Vent SG sex m



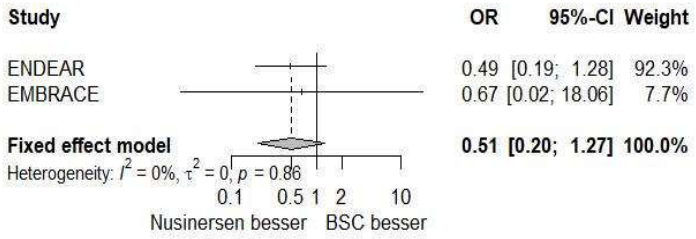
Number at risk

BSC	15	9	2	1	1	1	0	0	0	0
Nusinersen	26	12	7	4	4	4	1	0	0	0

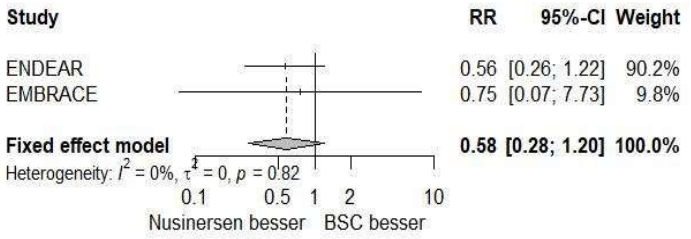
Forest Plot for Any AEs 10 pct PT Acute respiratory failure (ARR)



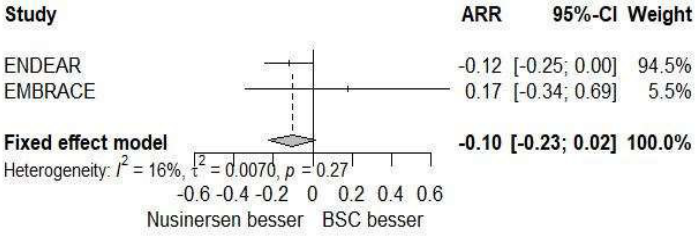
Forest Plot for Any AEs 10 pct PT Acute respiratory failure
(OR)



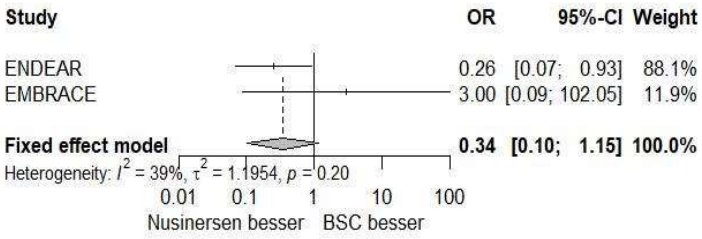
Forest Plot for Any AEs 10 pct PT Acute respiratory failure
(RR)



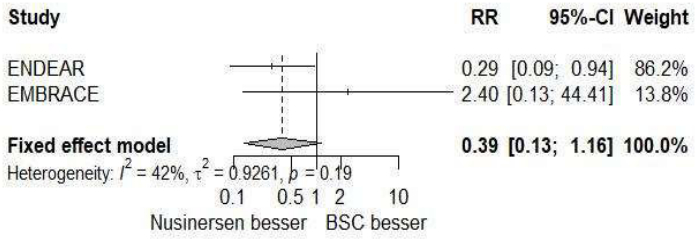
Forest Plot for Any AEs 10 pct PT Bronchial secretion
retention (ARR)



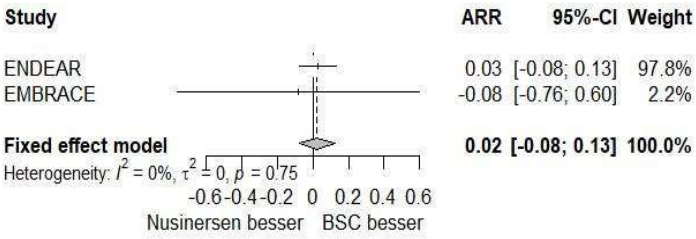
Forest Plot for Any AEs 10 pct PT Bronchial secretion
retention (OR)



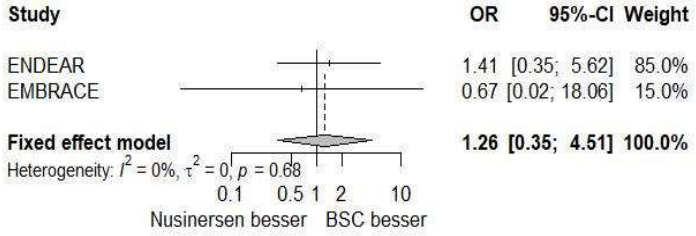
Forest Plot for Any AEs 10 pct PT Bronchial secretion retention (RR)



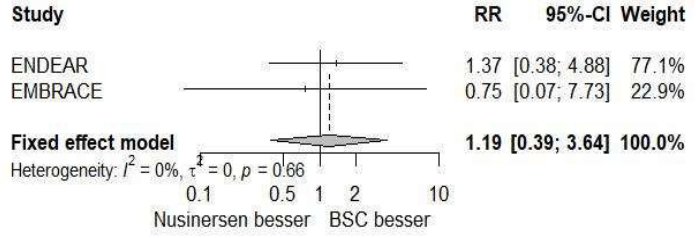
Forest Plot for Any AEs 10 pct PT Bronchiolitis (ARR)



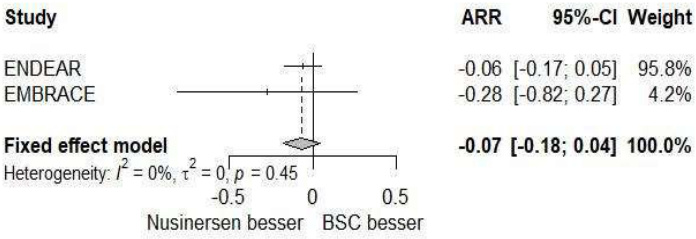
Forest Plot for Any AEs 10 pct PT Bronchiolitis (OR)



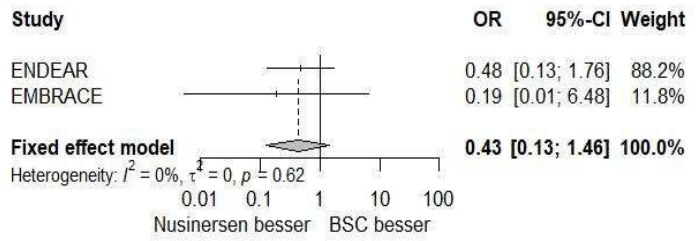
Forest Plot for Any AEs 10 pct PT Bronchiolitis (RR)



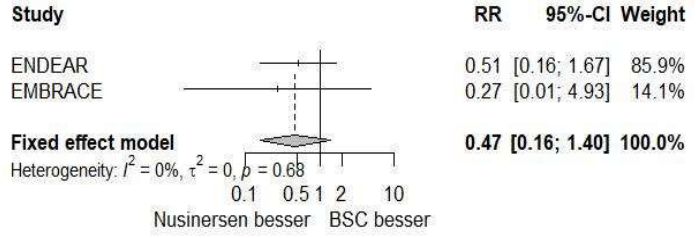
Forest Plot for Any AEs 10 pct PT Cardio-respiratory arrest
(ARR)



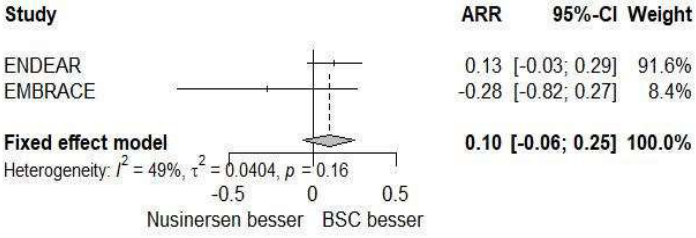
Forest Plot for Any AEs 10 pct PT Cardio-respiratory arrest
(OR)



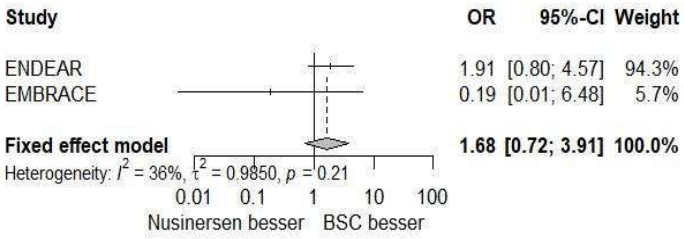
Forest Plot for Any AEs 10 pct PT Cardio-respiratory arrest
(RR)



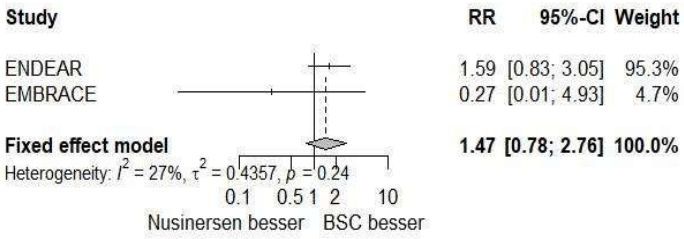
Forest Plot for Any AEs 10 pct PT Constipation (ARR)



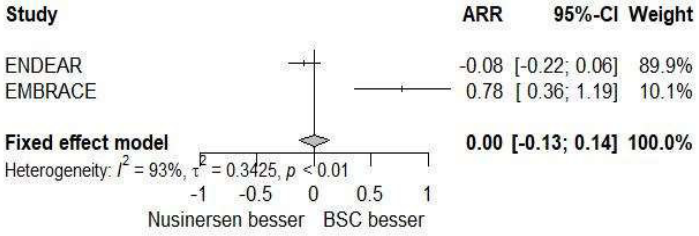
Forest Plot for Any AEs 10 pct PT Constipation (OR)



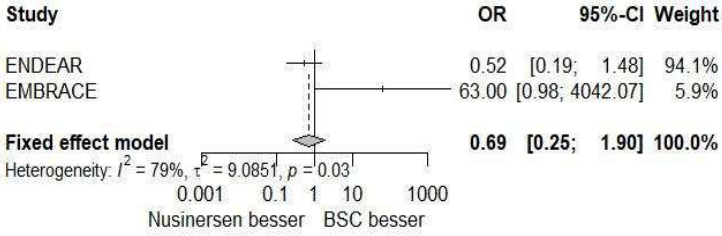
Forest Plot for Any AEs 10 pct PT Constipation (RR)



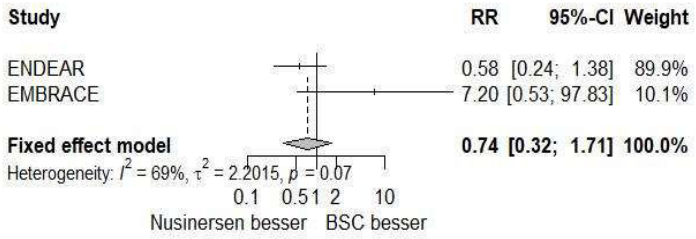
Forest Plot for Any AEs 10 pct PT Cough (ARR)



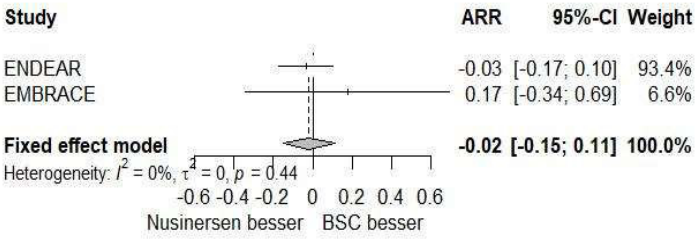
Forest Plot for Any AEs 10 pct PT Cough (OR)



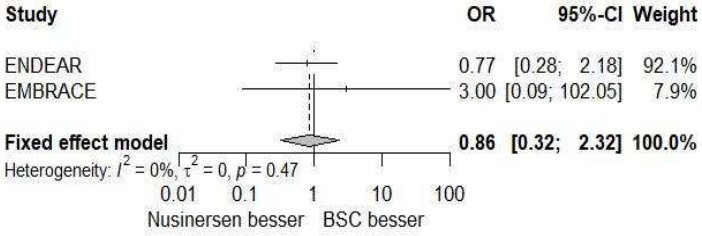
Forest Plot for Any AEs 10 pct PT Cough (RR)



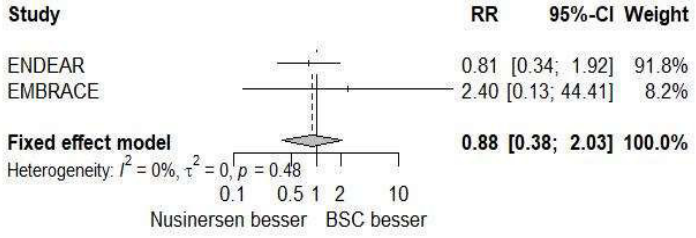
Forest Plot for Any AEs 10 pct PT Diarrhoea (ARR)



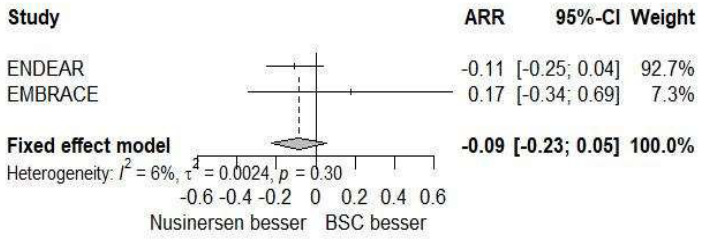
Forest Plot for Any AEs 10 pct PT Diarrhoea (OR)



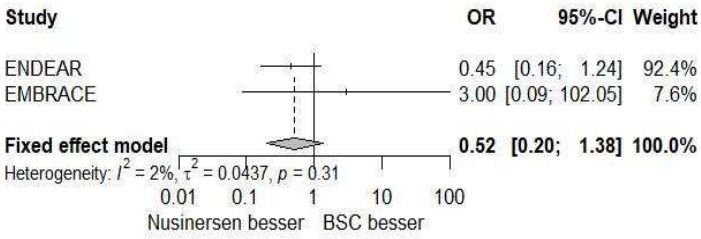
Forest Plot for Any AEs 10 pct PT Diarrhoea (RR)



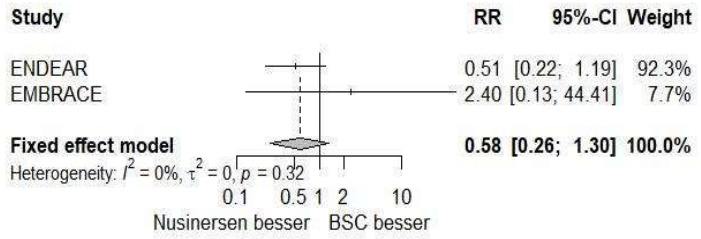
Forest Plot for Any AEs 10 pct PT Dysphagia (ARR)



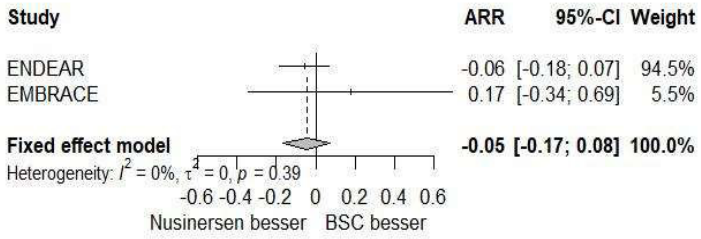
Forest Plot for Any AEs 10 pct PT Dysphagia (OR)



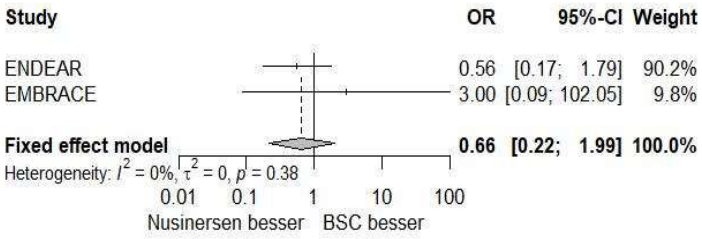
Forest Plot for Any AEs 10 pct PT Dysphagia (RR)



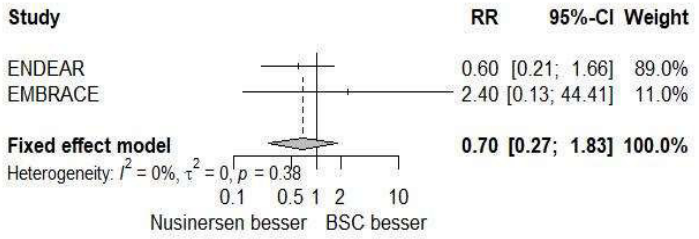
Forest Plot for Any AEs 10 pct PT Dyspnoea (ARR)



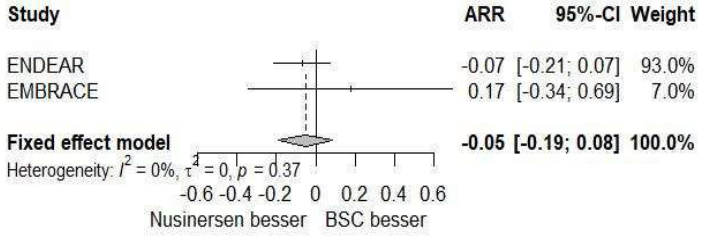
Forest Plot for Any AEs 10 pct PT Dyspnoea (OR)



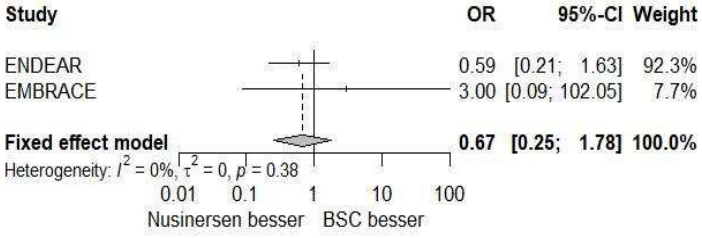
Forest Plot for Any AEs 10 pct PT Dyspnoea (RR)



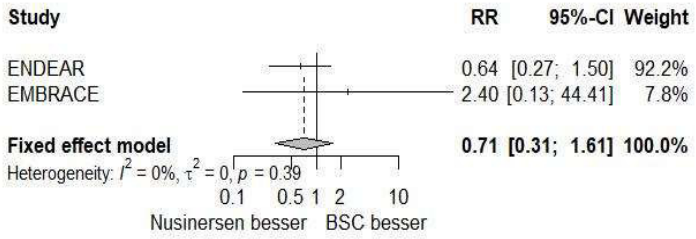
Forest Plot for Any AEs 10 pct PT Gastrooesophageal reflux disease (ARR)



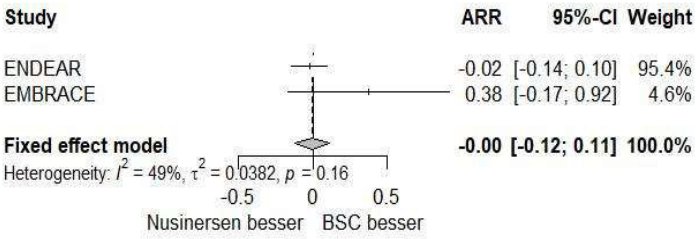
Forest Plot for Any AEs 10 pct PT Gastrooesophageal reflux disease (OR)



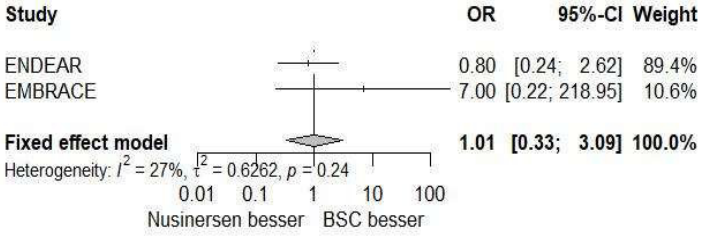
Forest Plot for Any AEs 10 pct PT Gastrooesophageal reflux disease (RR)



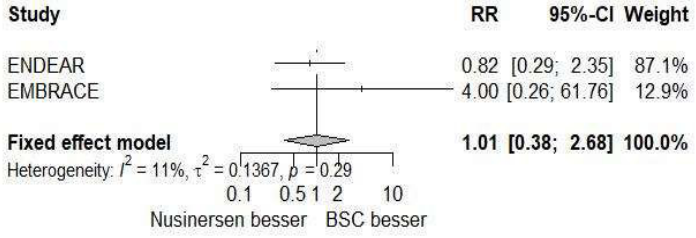
Forest Plot for Any AEs 10 pct PT Nasal congestion (ARR)



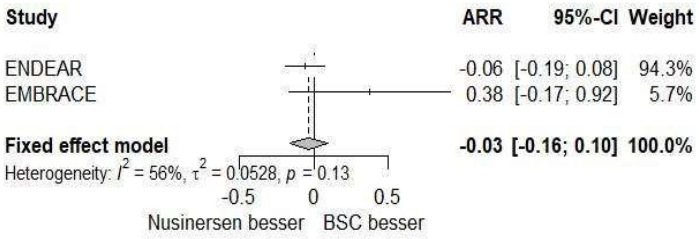
Forest Plot for Any AEs 10 pct PT Nasal congestion (OR)



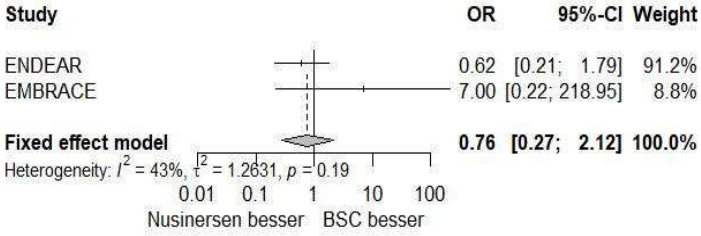
Forest Plot for Any AEs 10 pct PT Nasal congestion (RR)



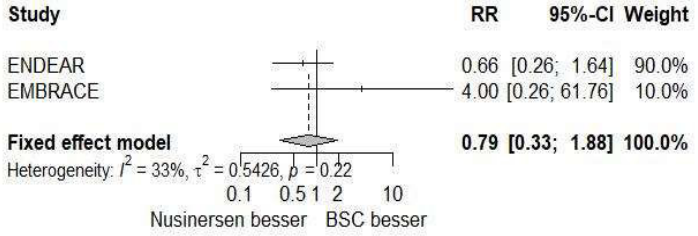
Forest Plot for Any AEs 10 pct PT Pneumonia aspiration (ARR)



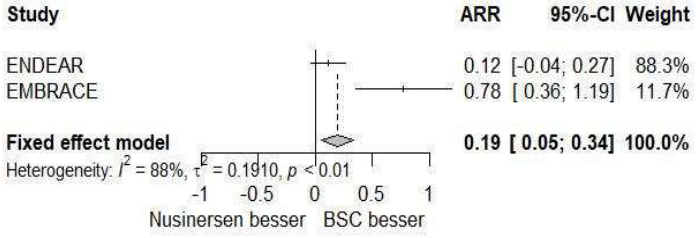
Forest Plot for Any AEs 10 pct PT Pneumonia aspiration (OR)



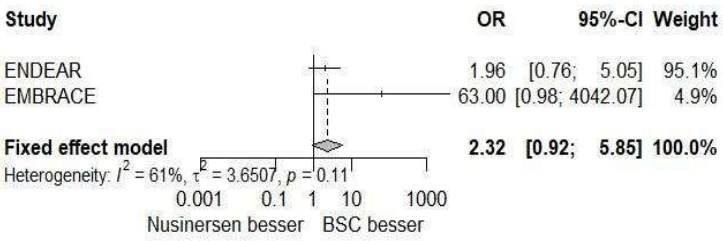
Forest Plot for Any AEs 10 pct PT Pneumonia aspiration (RR)



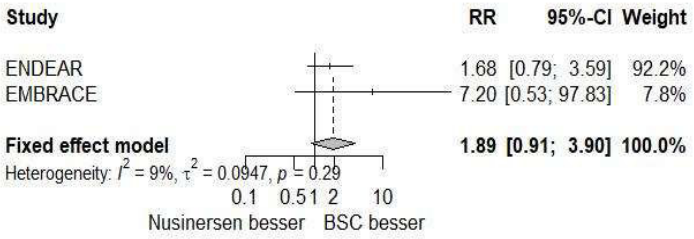
Forest Plot for Any AEs 10 pct PT Pneumonia (ARR)



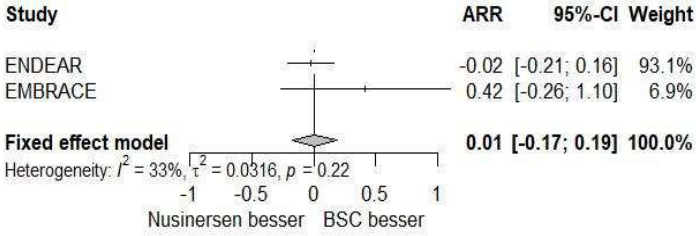
Forest Plot for Any AEs 10 pct PT Pneumonia (OR)



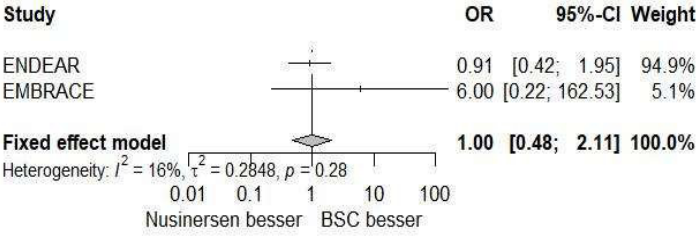
Forest Plot for Any AEs 10 pct PT Pneumonia (RR)



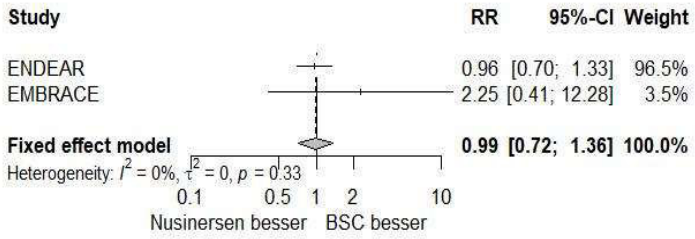
Forest Plot for Any AEs 10 pct PT Pyrexia (ARR)



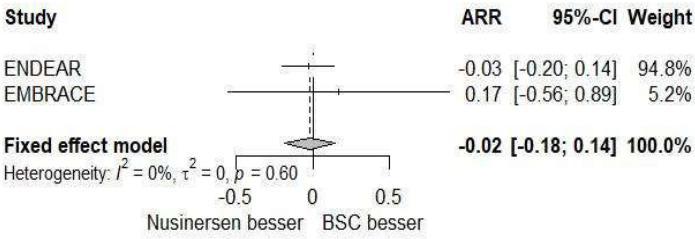
Forest Plot for Any AEs 10 pct PT Pyrexia (OR)



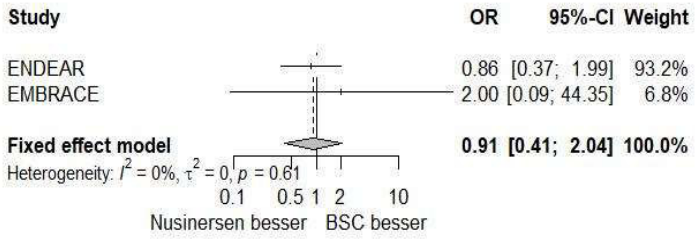
Forest Plot for Any AEs 10 pct PT Pyrexia (RR)



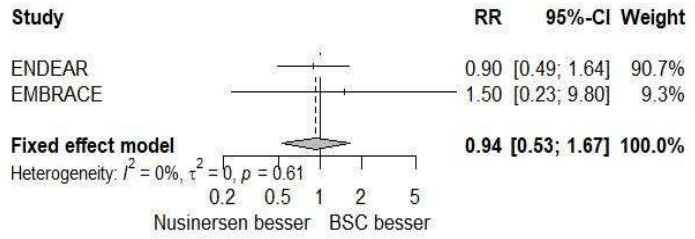
Forest Plot for Any AEs 10 pct PT Respiratory distress (ARR)



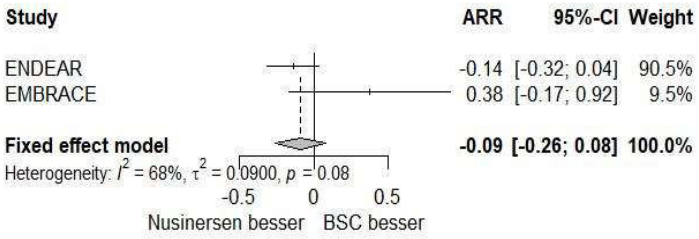
Forest Plot for Any AEs 10 pct PT Respiratory distress (OR)



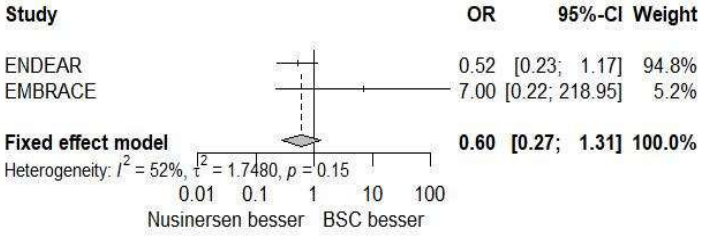
Forest Plot for Any AEs 10 pct PT Respiratory distress (RR)



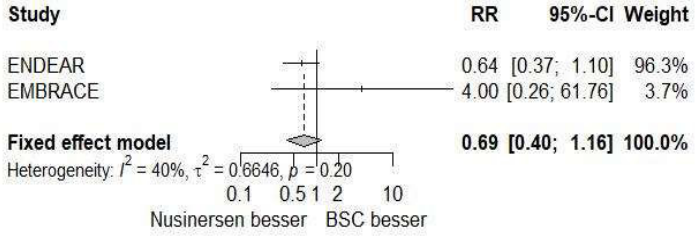
Forest Plot for Any AEs 10 pct PT Respiratory failure (ARR)



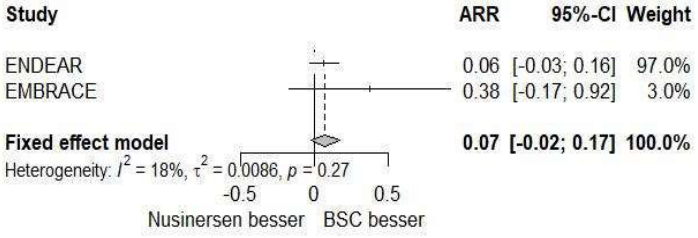
Forest Plot for Any AEs 10 pct PT Respiratory failure (OR)



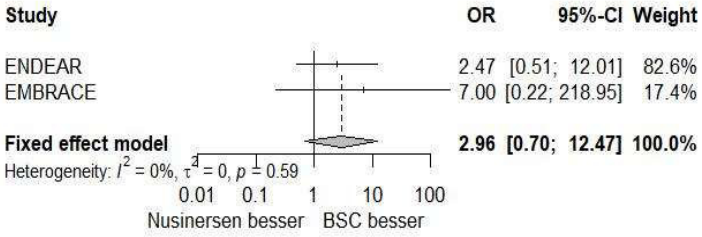
Forest Plot for Any AEs 10 pct PT Respiratory failure (RR)



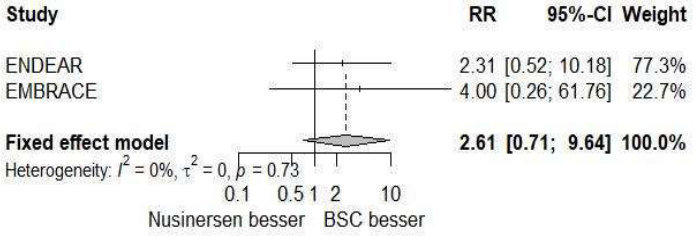
Forest Plot for Any AEs 10 pct PT Respiratory tract infection (ARR)



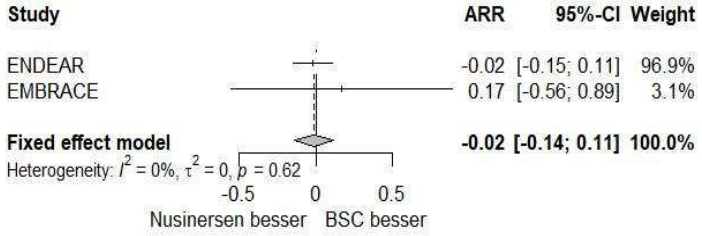
Forest Plot for Any AEs 10 pct PT Respiratory tract infection (OR)



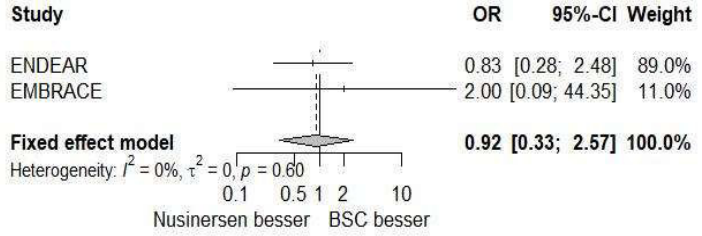
Forest Plot for Any AEs 10 pct PT Respiratory tract infection (RR)



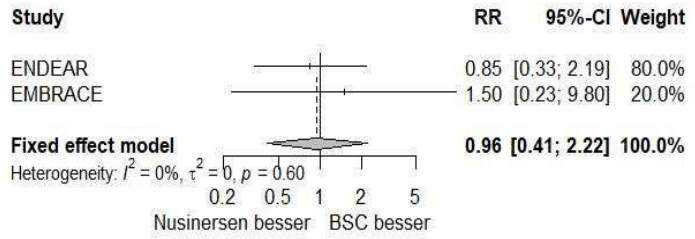
Forest Plot for Any AEs 10 pct PT Rhinovirus infection (ARR)



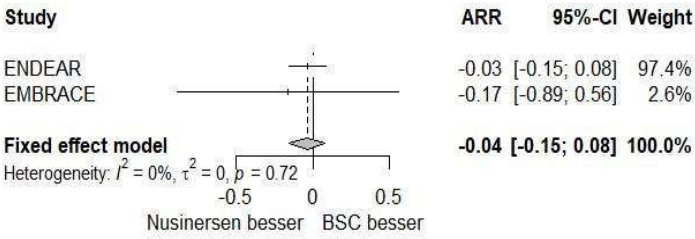
Forest Plot for Any AEs 10 pct PT Rhinovirus infection (OR)



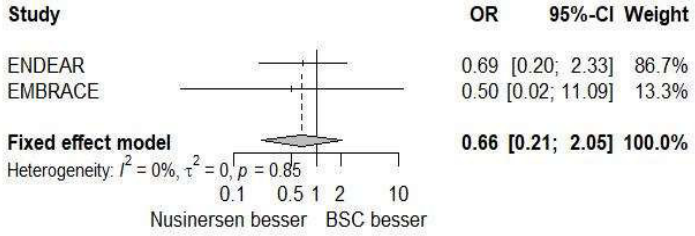
Forest Plot for Any AEs 10 pct PT Rhinovirus infection (RR)



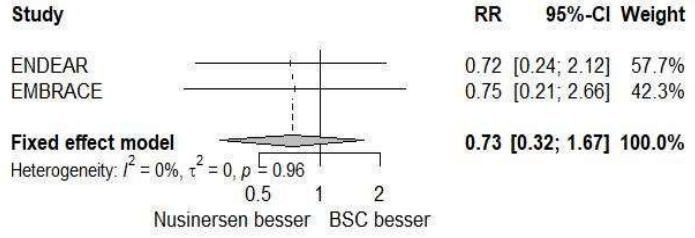
Forest Plot for Any AEs 10 pct PT Tachycardia (ARR)



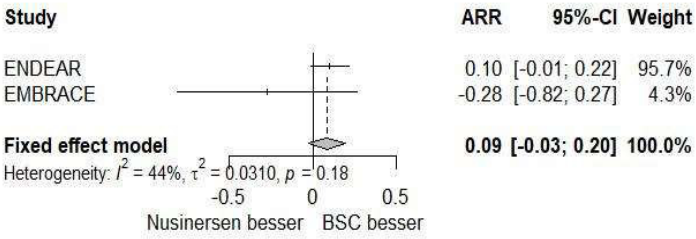
Forest Plot for Any AEs 10 pct PT Tachycardia (OR)



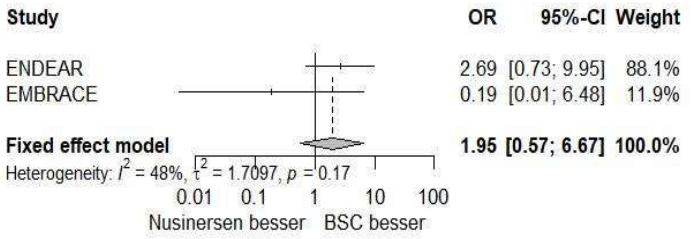
Forest Plot for Any AEs 10 pct PT Tachycardia (RR)



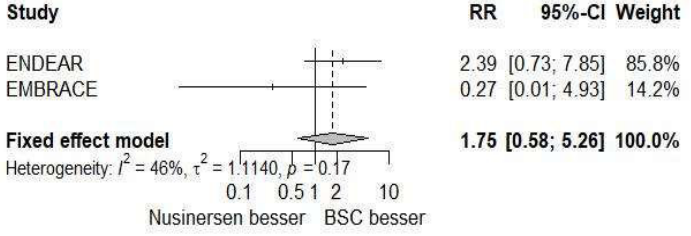
Forest Plot for Any AEs 10 pct PT Teething (ARR)



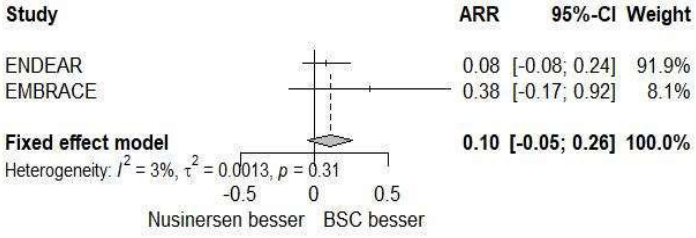
Forest Plot for Any AEs 10 pct PT Teething (OR)



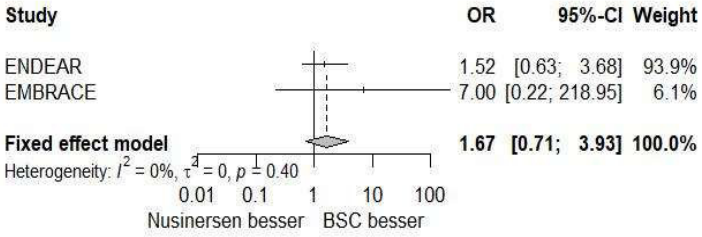
Forest Plot for Any AEs 10 pct PT Teething (RR)



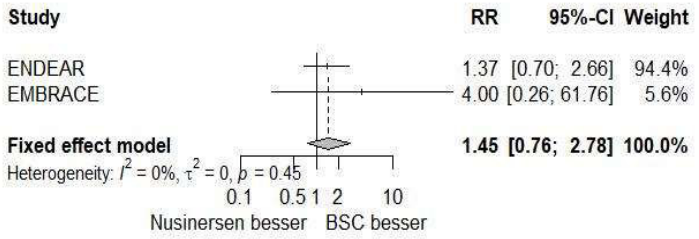
Forest Plot for Any AEs 10 pct PT Upper respiratory tract infection (ARR)



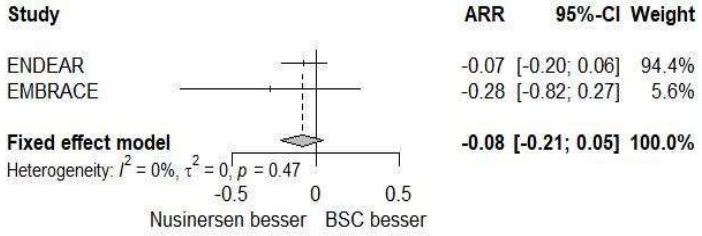
Forest Plot for Any AEs 10 pct PT Upper respiratory tract infection (OR)



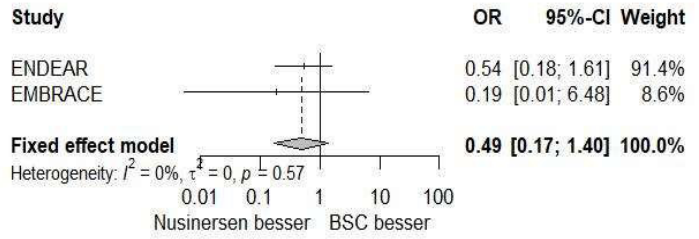
Forest Plot for Any AEs 10 pct PT Upper respiratory tract infection (RR)



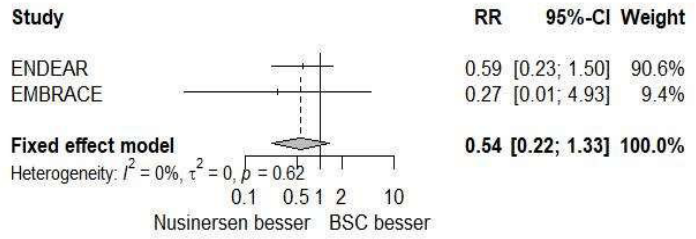
Forest Plot for Any AEs 10 pct PT Viral upper respiratory tract infection (ARR)



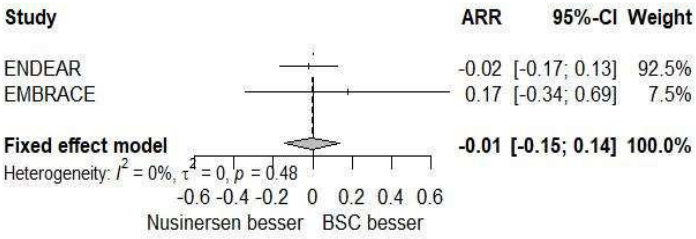
Forest Plot for Any AEs 10 pct PT Viral upper respiratory tract infection (OR)



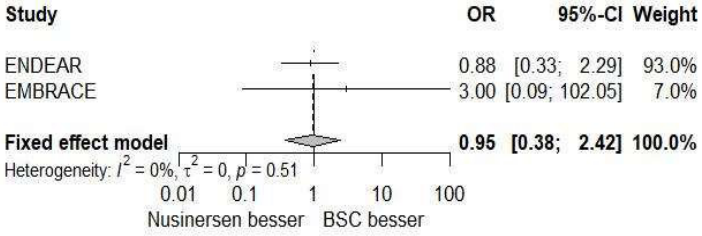
Forest Plot for Any AEs 10 pct PT Viral upper respiratory tract infection (RR)



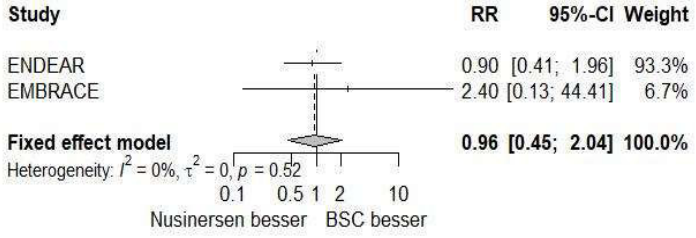
Forest Plot for Any AEs 10 pct PT Vomiting (ARR)



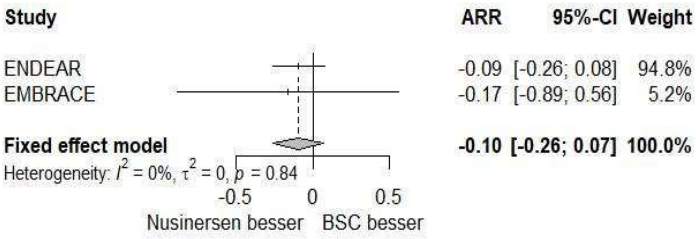
Forest Plot for Any AEs 10 pct PT Vomiting (OR)



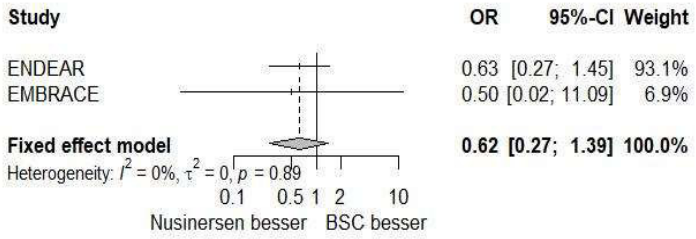
Forest Plot for Any AEs 10 pct PT Vomiting (RR)



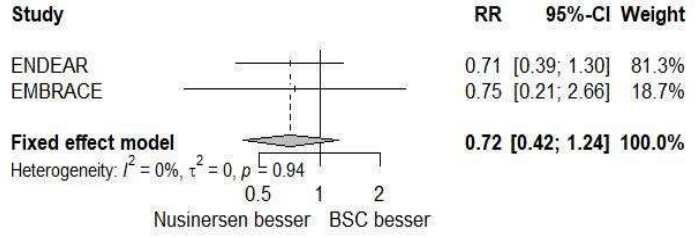
Forest Plot for Any AEs 10 pct SOC Cardiac disorders (ARR)



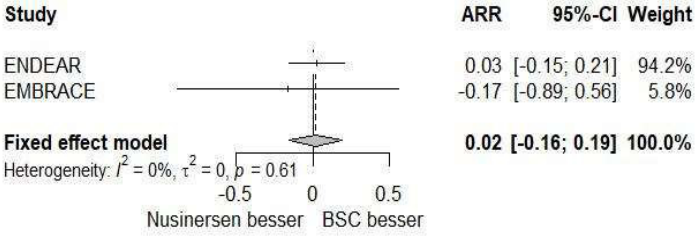
Forest Plot for Any AEs 10 pct SOC Cardiac disorders (OR)



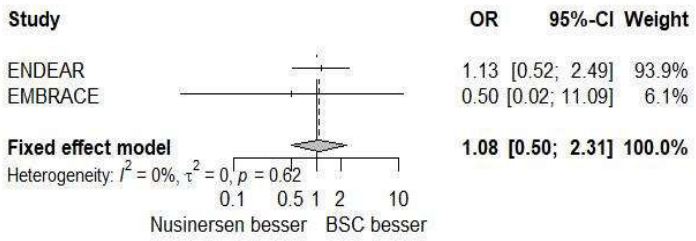
Forest Plot for Any AEs 10 pct SOC Cardiac disorders (RR)



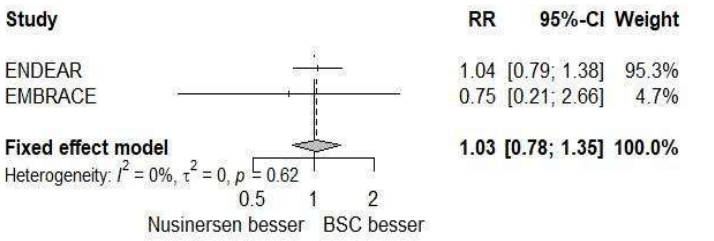
Forest Plot for Any AEs 10 pct SOC Gastrointestinal disorders (ARR)



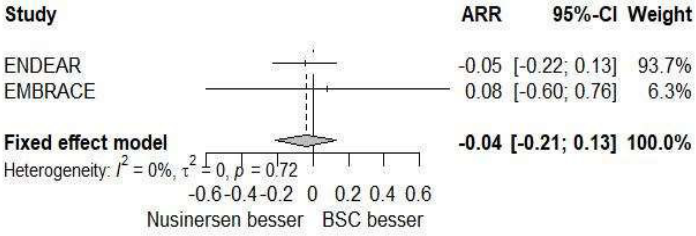
Forest Plot for Any AEs 10 pct SOC Gastrointestinal disorders (OR)



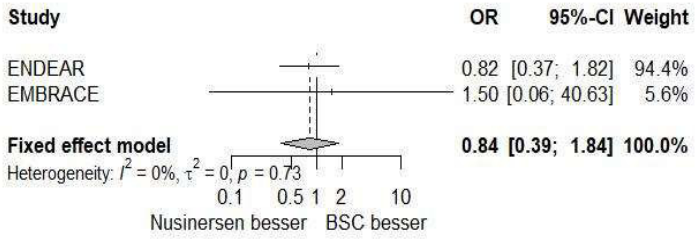
Forest Plot for Any AEs 10 pct SOC Gastrointestinal disorders (RR)



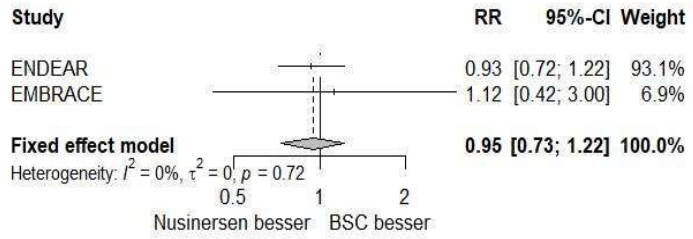
Forest Plot for Any AEs 10 pct SOC General disorders and administration site conditions (ARR)



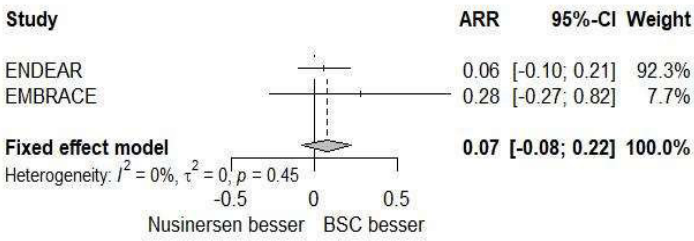
Forest Plot for Any AEs 10 pct SOC General disorders and administration site conditions (OR)



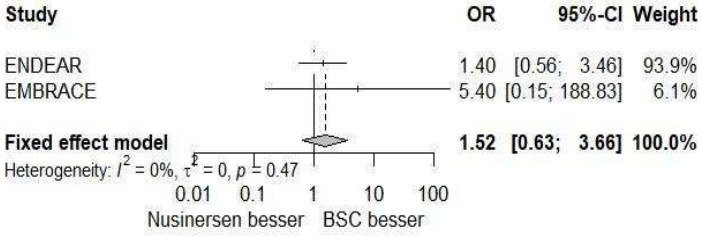
Forest Plot for Any AEs 10 pct SOC General disorders and administration site conditions (RR)



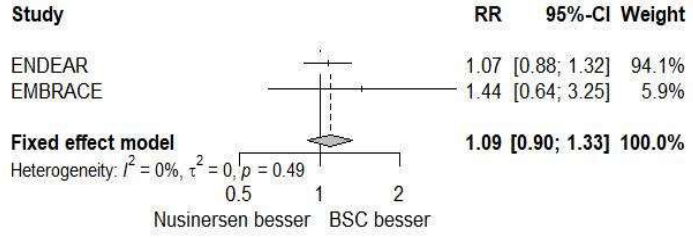
Forest Plot for Any AEs 10 pct SOC Infections and infestations (ARR)



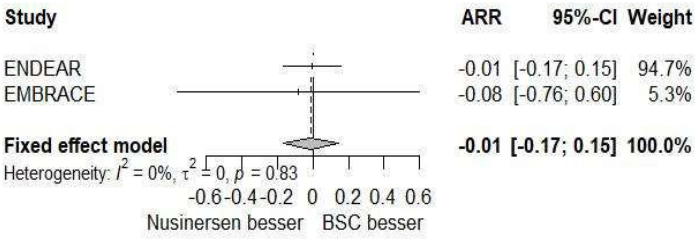
Forest Plot for Any AEs 10 pct SOC Infections and infestations (OR)



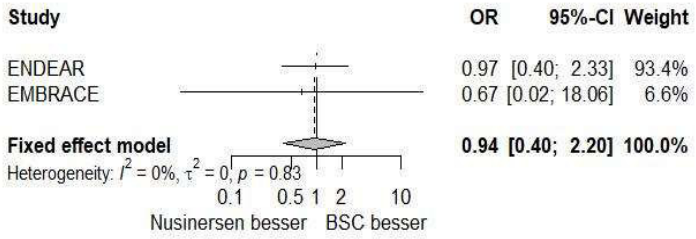
Forest Plot for Any AEs 10 pct SOC Infections and infestations (RR)



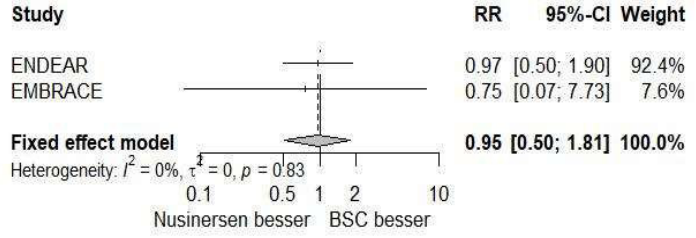
Forest Plot for Any AEs 10 pct SOC Injury, poisoning and procedural complications (ARR)



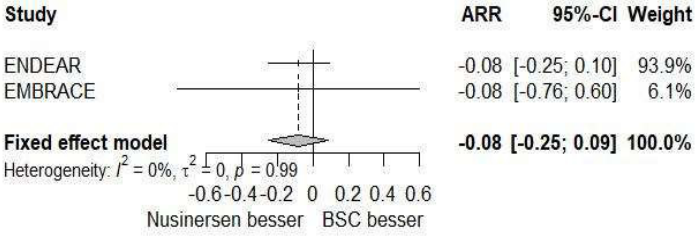
Forest Plot for Any AEs 10 pct SOC Injury, poisoning and procedural complications (OR)



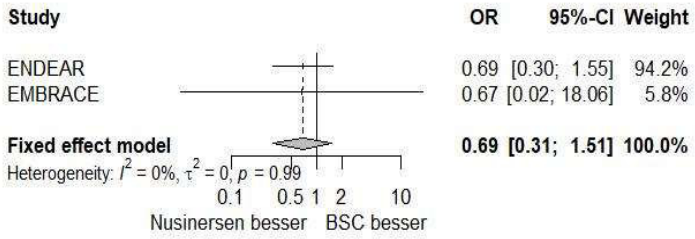
Forest Plot for Any AEs 10 pct SOC Injury, poisoning and procedural complications (RR)



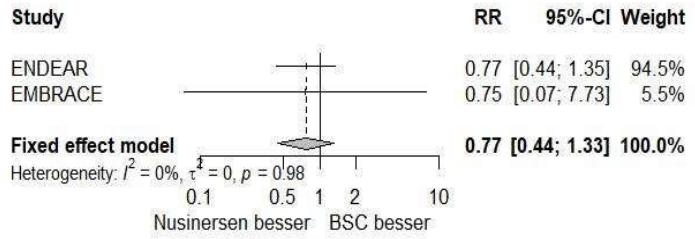
Forest Plot for Any AEs 10 pct SOC Investigations (ARR)



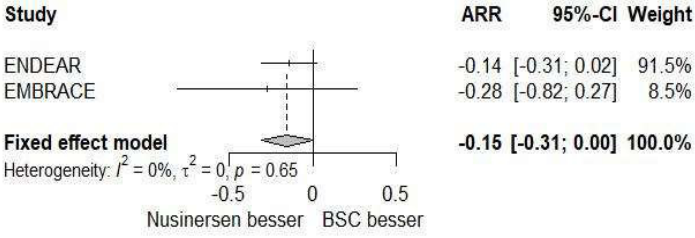
Forest Plot for Any AEs 10 pct SOC Investigations (OR)



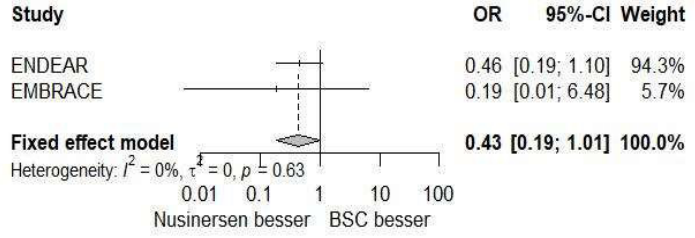
Forest Plot for Any AEs 10 pct SOC Investigations (RR)



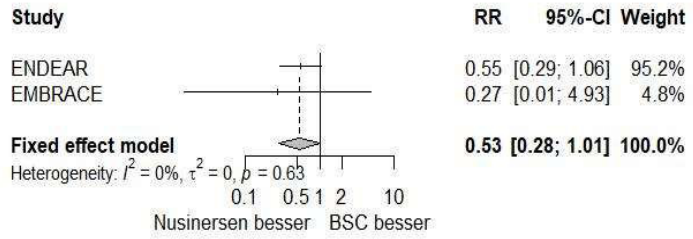
Forest Plot for Any AEs 10 pct SOC Metabolism and nutrition disorders (ARR)



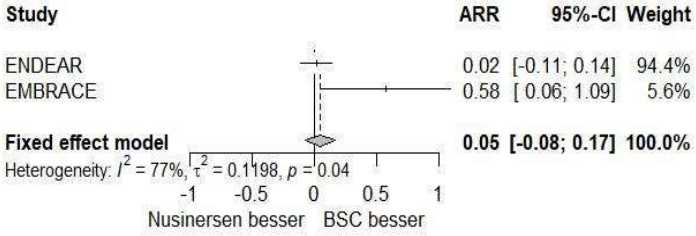
Forest Plot for Any AEs 10 pct SOC Metabolism and nutrition disorders (OR)



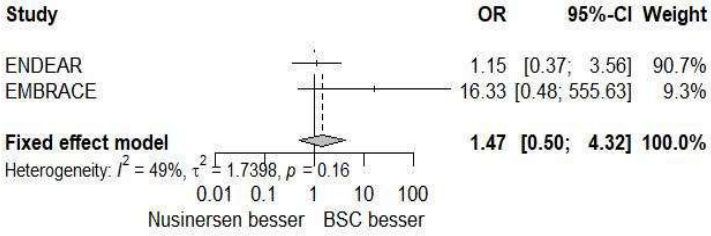
Forest Plot for Any AEs 10 pct SOC Metabolism and nutrition disorders (RR)



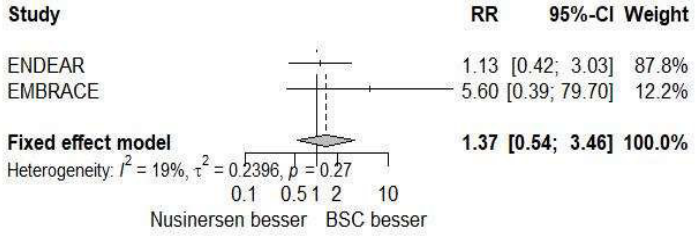
Forest Plot for Any AEs 10 pct SOC Musculoskeletal and connective tissue disorders (ARR)



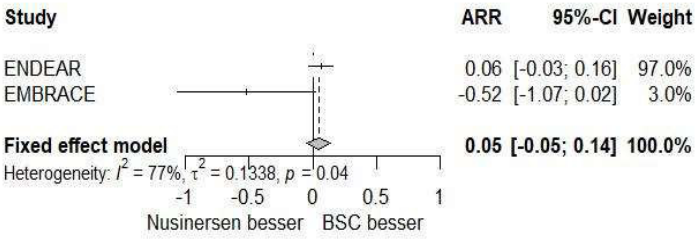
Forest Plot for Any AEs 10 pct SOC Musculoskeletal and connective tissue disorders (OR)



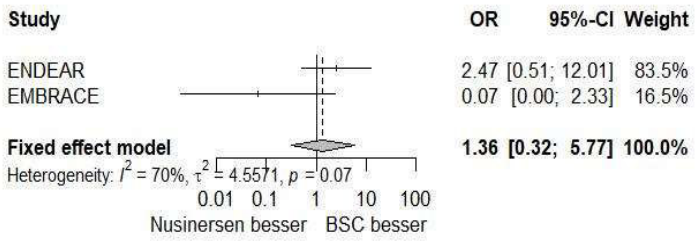
Forest Plot for Any AEs 10 pct SOC Musculoskeletal and connective tissue disorders (RR)



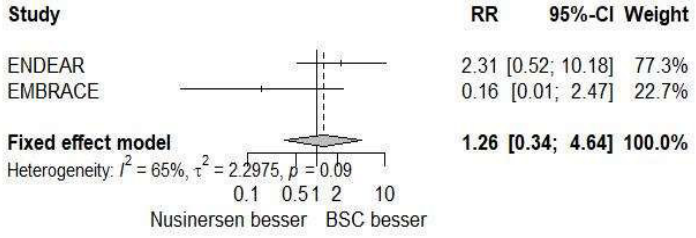
Forest Plot for Any AEs 10 pct SOC Nervous system disorders (ARR)



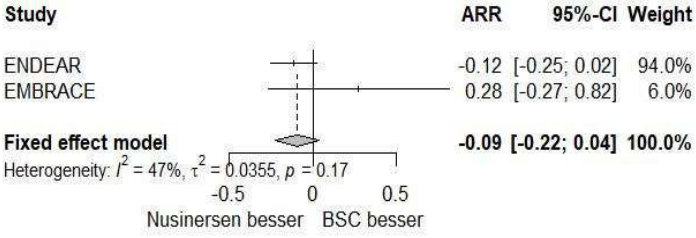
Forest Plot for Any AEs 10 pct SOC Nervous system disorders (OR)



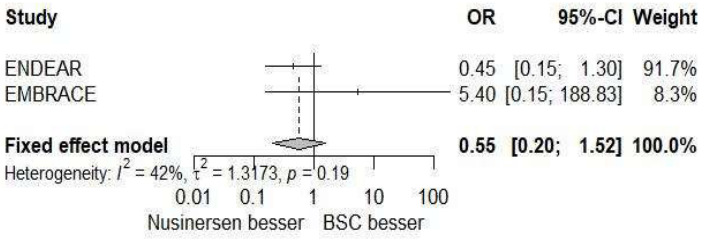
Forest Plot for Any AEs 10 pct SOC Nervous system disorders (RR)



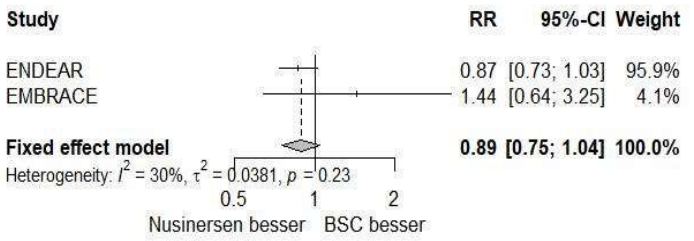
Forest Plot for Any AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders (ARR)



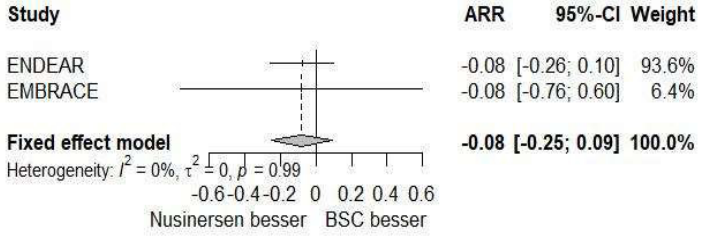
Forest Plot for Any AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders (OR)



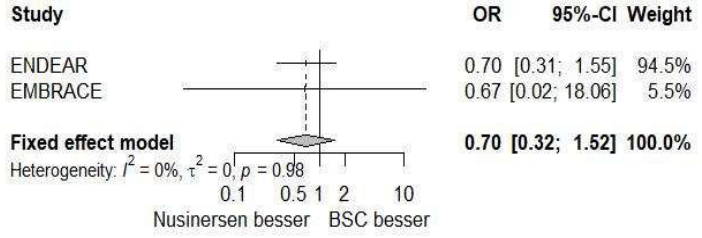
Forest Plot for Any AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders (RR)



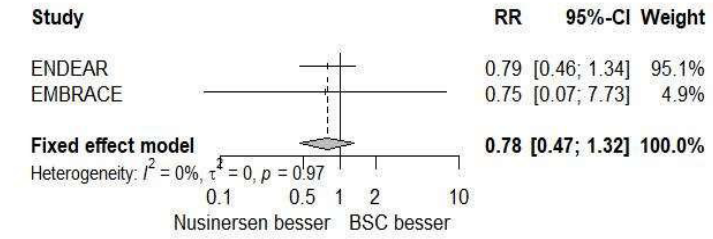
Forest Plot for Any AEs 10 pct SOC Skin and subcutaneous tissue disorders (ARR)



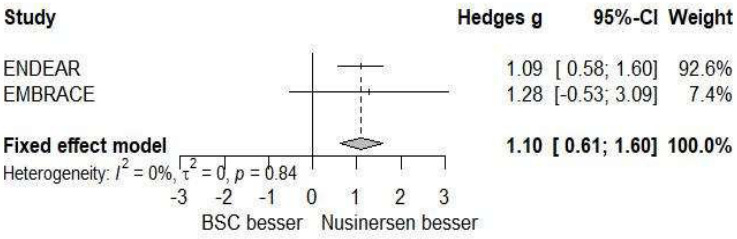
Forest Plot for Any AEs 10 pct SOC Skin and subcutaneous tissue disorders (OR)



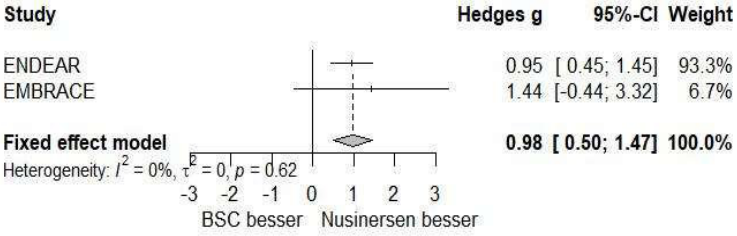
Forest Plot for Any AEs 10 pct SOC Skin and subcutaneous tissue disorders (RR)



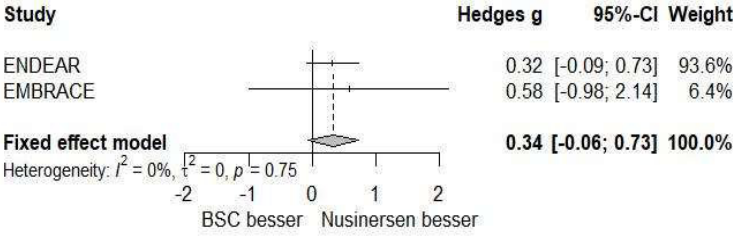
Forest Plot for Change from baseline in HINE-section 2 Day 183 TOTSCORE (Hedges g)



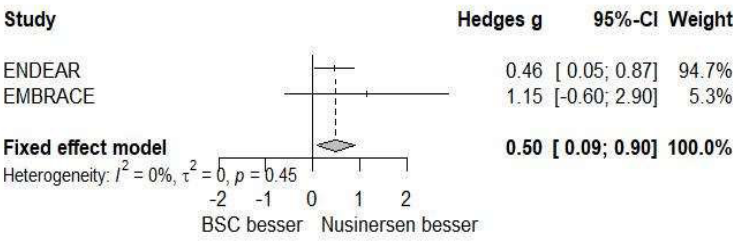
Forest Plot for Change from baseline in HINE-section 2 Day 183 (Hedges g)



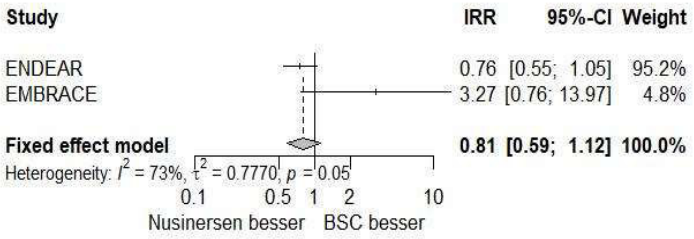
Forest Plot for Change from baseline in HINE-section 2 Day 64 TOTSCORE (Hedges g)



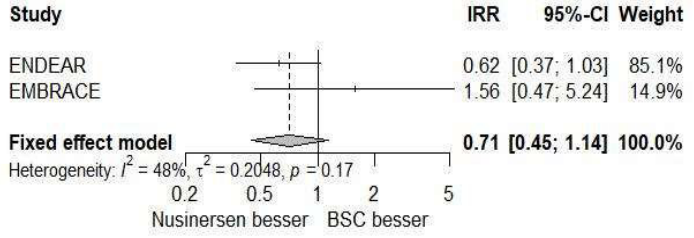
Forest Plot for Change from baseline in HINE-section 2 Day 64 (Hedges g)



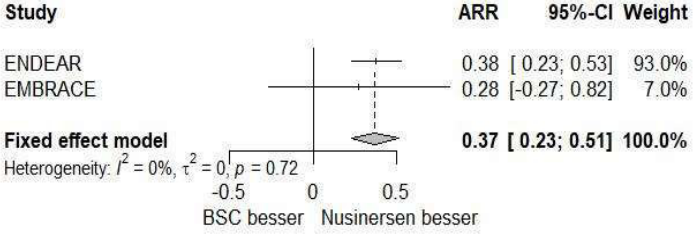
Forest Plot for Frequency of hospitalization (IRR)



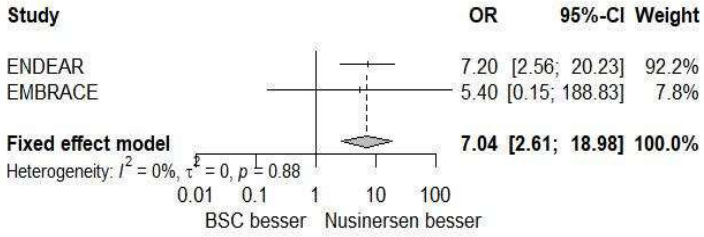
Forest Plot for Frequency of serious respiratory events (IRR)



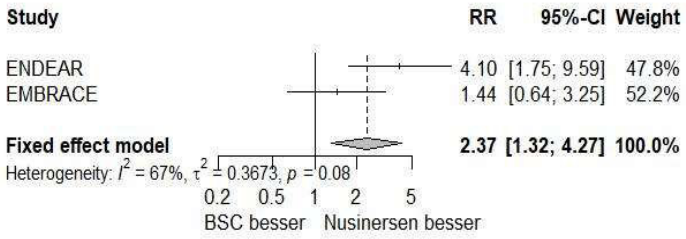
Forest Plot for HINE-Responder-section 2 Day 183 TOTSCORE (ARR)



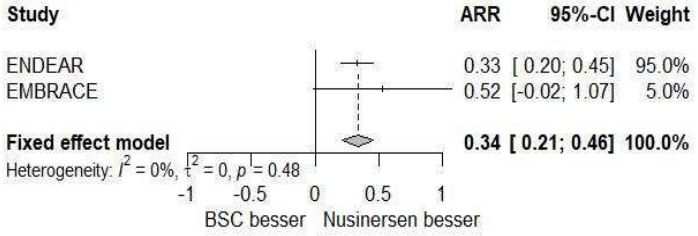
Forest Plot for HINE-Responder-section 2 Day 183 TOTSCORE
(OR)



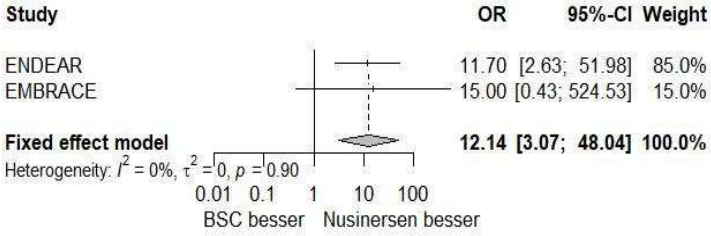
Forest Plot for HINE-Responder-section 2 Day 183 TOTSCORE
(RR)



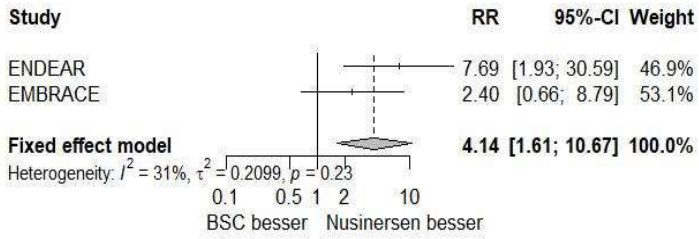
Forest Plot for HINE-Responder-section 2 Day 183 (ARR)



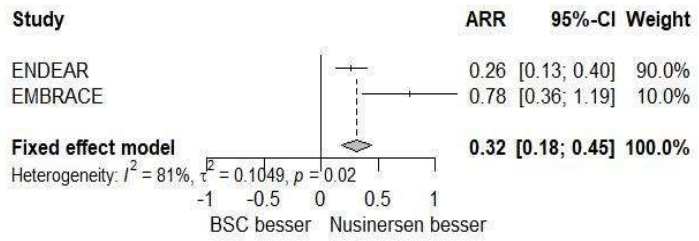
Forest Plot for HINE-Responder-section 2 Day 183 (OR)



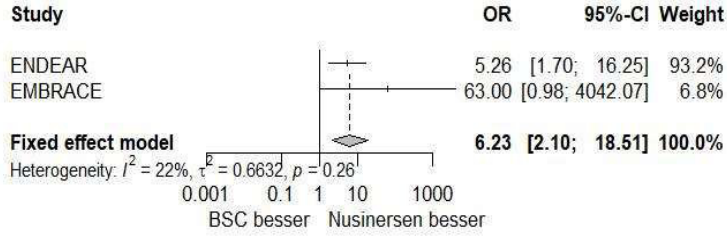
Forest Plot for HINE-Responder-section 2 Day 183 (RR)



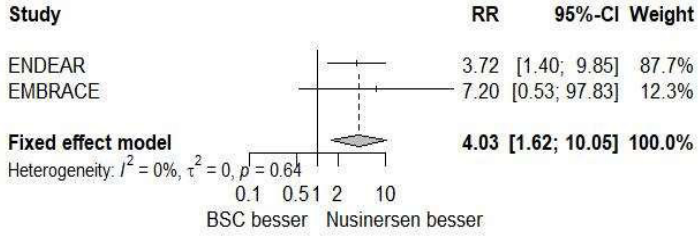
Forest Plot for HINE-Responder-section 2 Day 302 TOTSCORE (ARR)



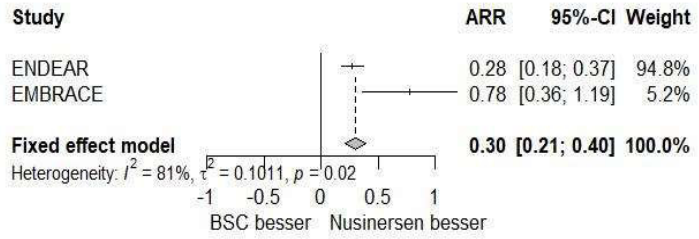
Forest Plot for HINE-Responder-section 2 Day 302 TOTSCORE (OR)



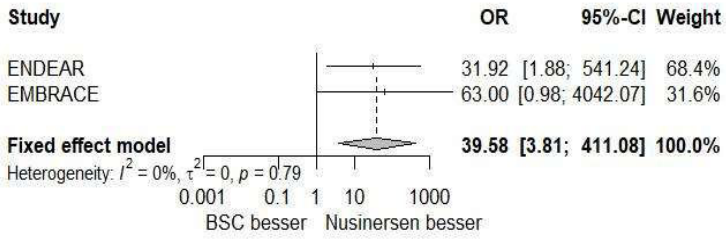
Forest Plot for HINE-Responder-section 2 Day 302 TOTSCORE (RR)



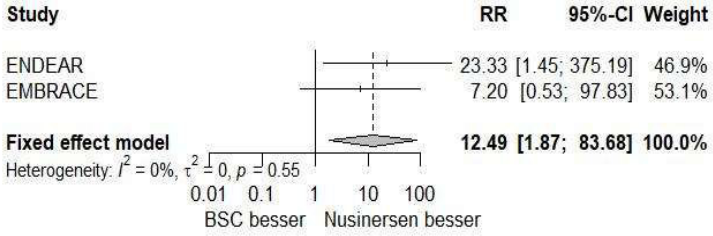
Forest Plot for HINE-Responder-section 2 Day 302 (ARR)



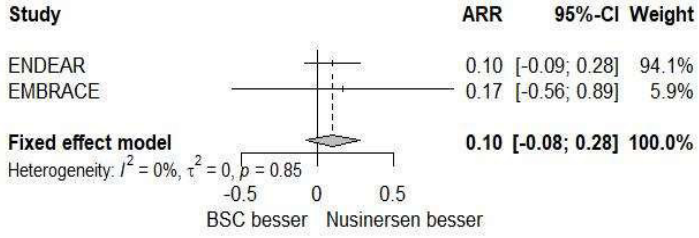
Forest Plot for HINE-Responder-section 2 Day 302 (OR)



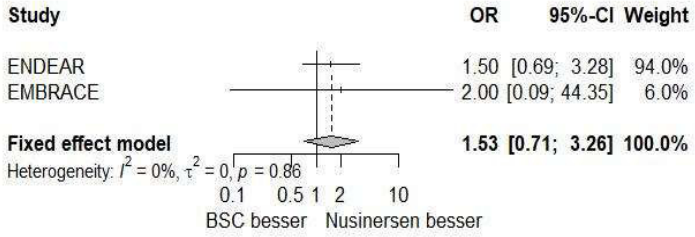
Forest Plot for HINE-Responder-section 2 Day 302 (RR)



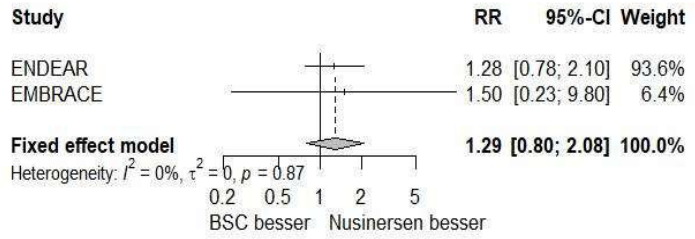
Forest Plot for HINE-Responder-section 2 Day 64 TOTSCORE (ARR)



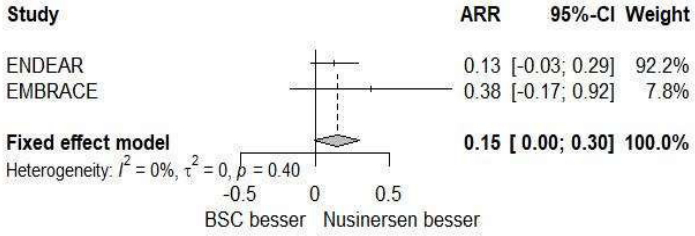
Forest Plot for HINE-Responder-section 2 Day 64 TOTSCORE
(OR)



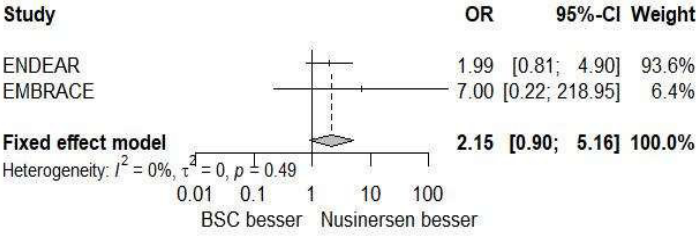
Forest Plot for HINE-Responder-section 2 Day 64 TOTSCORE
(RR)



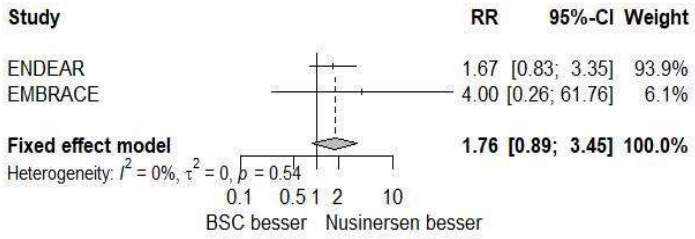
Forest Plot for HINE-Responder-section 2 Day 64 (ARR)



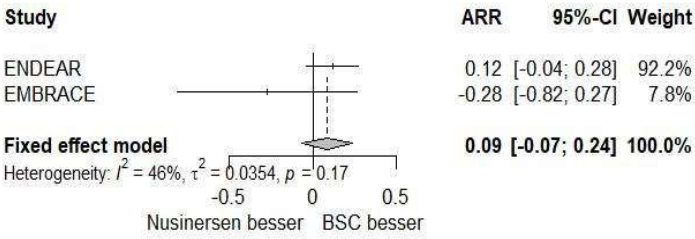
Forest Plot for HINE-Responder-section 2 Day 64 (OR)



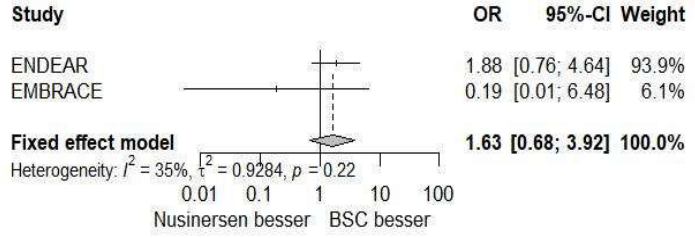
Forest Plot for HINE-Responder-section 2 Day 64 (RR)



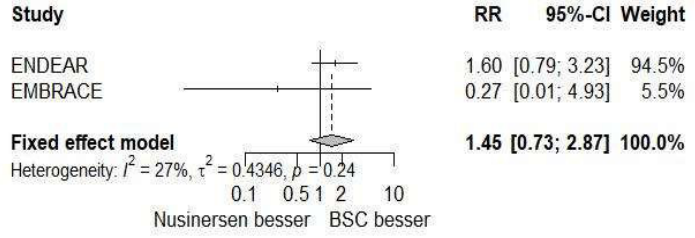
Forest Plot for Mild AEs 10 pct PT Constipation (ARR)



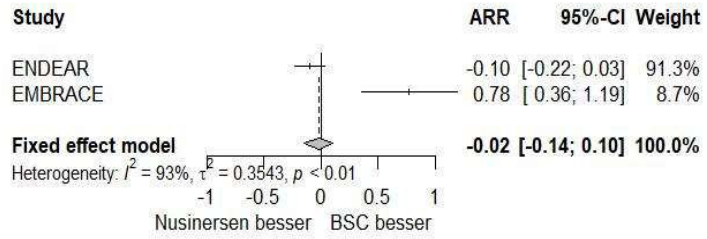
Forest Plot for Mild AEs 10 pct PT Constipation (OR)



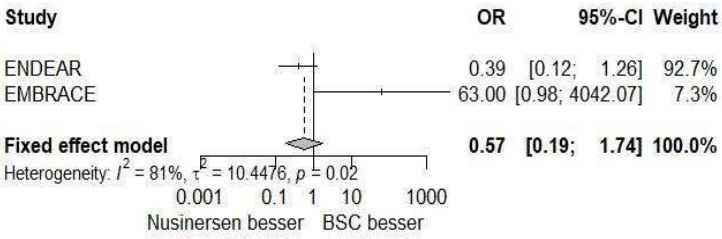
Forest Plot for Mild AEs 10 pct PT Constipation (RR)



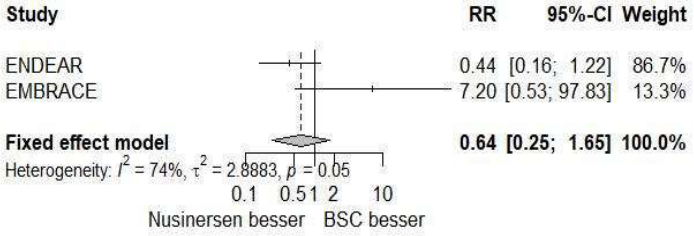
Forest Plot for Mild AEs 10 pct PT Cough (ARR)



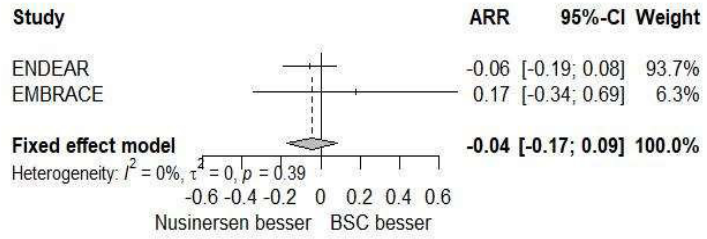
Forest Plot for Mild AEs 10 pct PT Cough (OR)



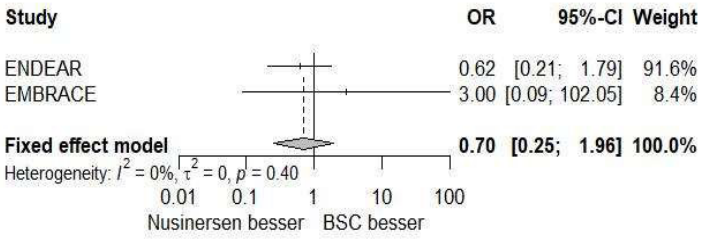
Forest Plot for Mild AEs 10 pct PT Cough (RR)



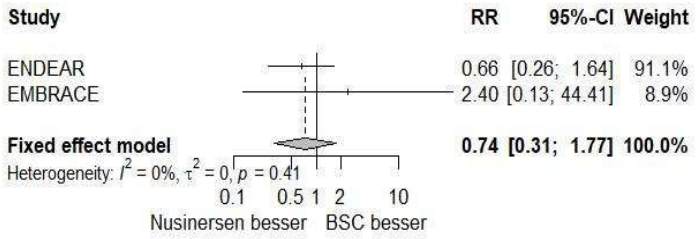
Forest Plot for Mild AEs 10 pct PT Diarrhoea (ARR)



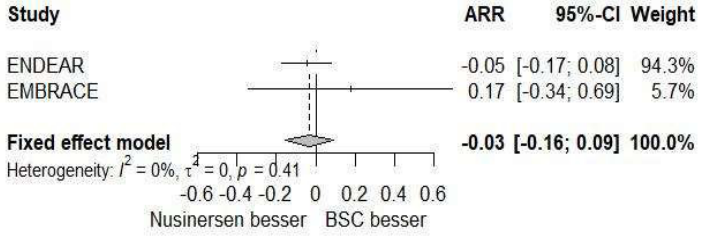
Forest Plot for Mild AEs 10 pct PT Diarrhoea (OR)



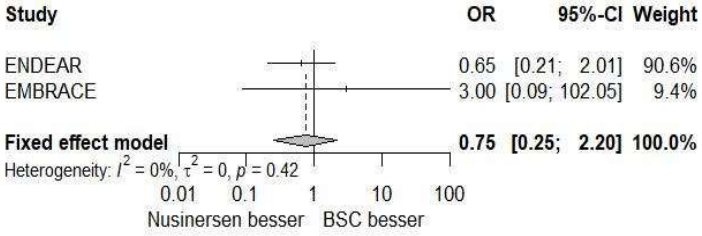
Forest Plot for Mild AEs 10 pct PT Diarrhoea (RR)



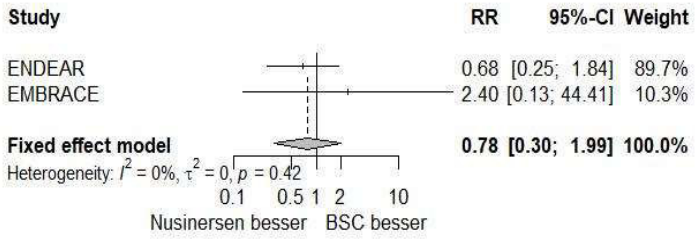
Forest Plot for Mild AEs 10 pct PT Gastrooesophageal reflux disease (ARR)



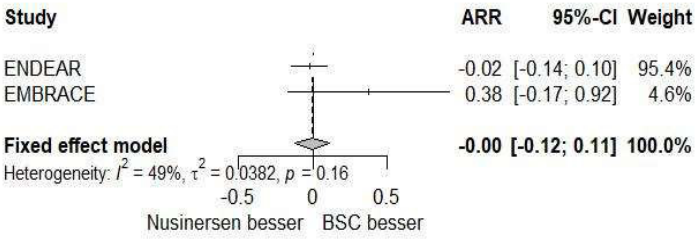
Forest Plot for Mild AEs 10 pct PT Gastrooesophageal reflux disease (OR)



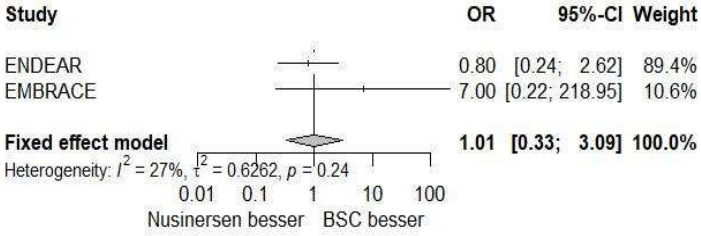
Forest Plot for Mild AEs 10 pct PT Gastrooesophageal reflux disease (RR)



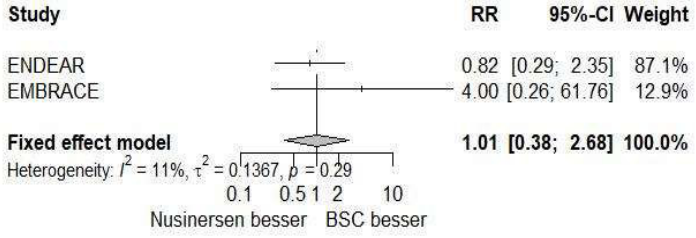
Forest Plot for Mild AEs 10 pct PT Nasal congestion (ARR)



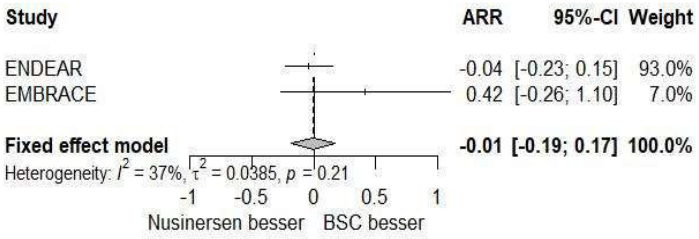
Forest Plot for Mild AEs 10 pct PT Nasal congestion (OR)



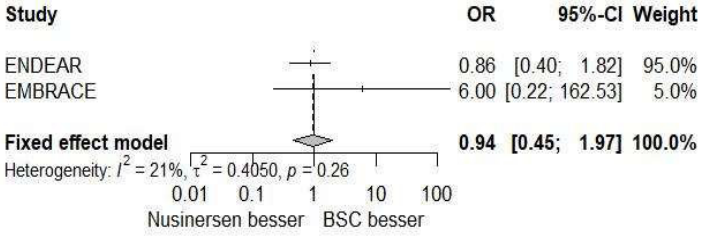
Forest Plot for Mild AEs 10 pct PT Nasal congestion (RR)



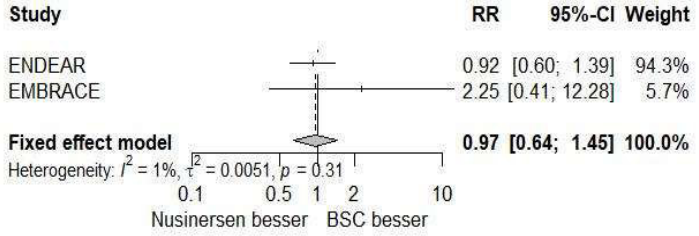
Forest Plot for Mild AEs 10 pct PT Pyrexia (ARR)



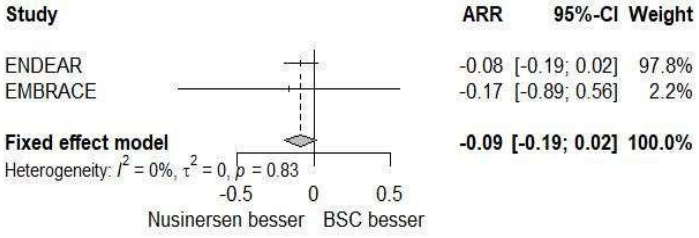
Forest Plot for Mild AEs 10 pct PT Pyrexia (OR)



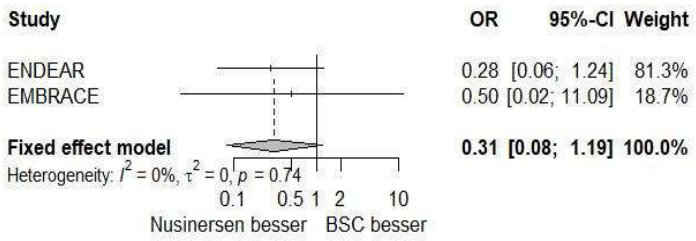
Forest Plot for Mild AEs 10 pct PT Pyrexia (RR)



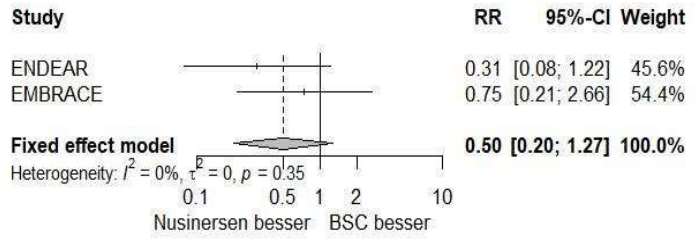
Forest Plot for Mild AEs 10 pct PT Tachycardia (ARR)



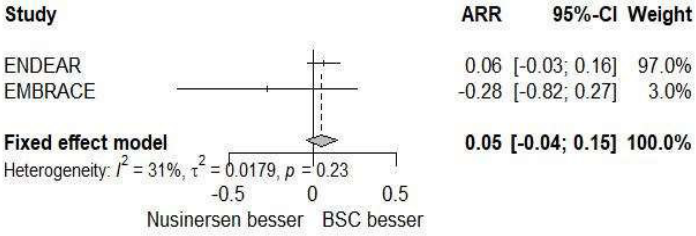
Forest Plot for Mild AEs 10 pct PT Tachycardia (OR)



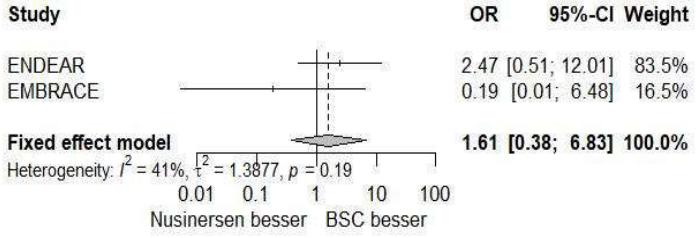
Forest Plot for Mild AEs 10 pct PT Tachycardia (RR)



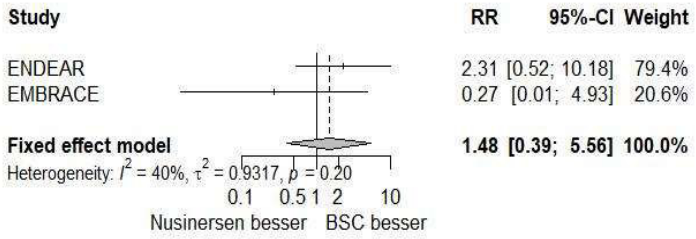
Forest Plot for Mild AEs 10 pct PT Teething (ARR)



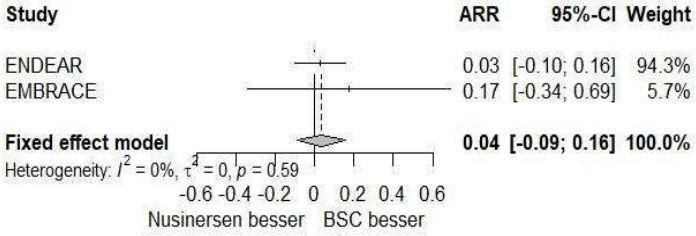
Forest Plot for Mild AEs 10 pct PT Teething (OR)



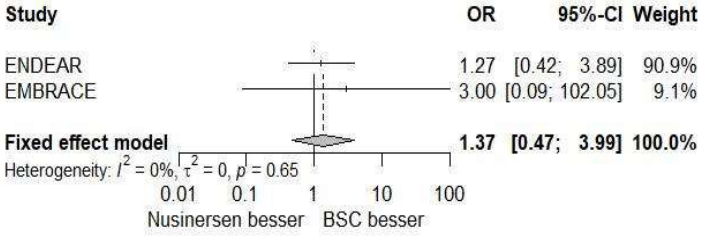
Forest Plot for Mild AEs 10 pct PT Teething (RR)



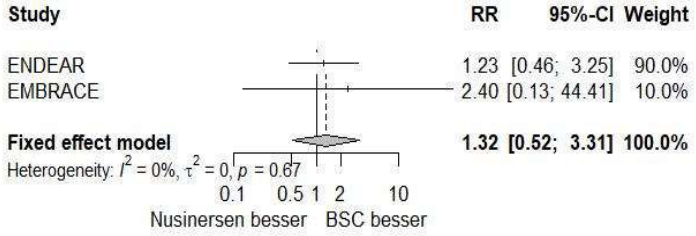
Forest Plot for Mild AEs 10 pct PT Upper respiratory tract infection (ARR)



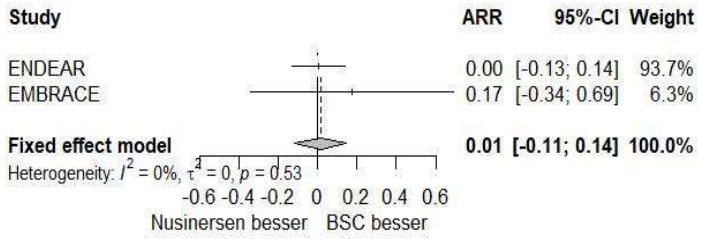
Forest Plot for Mild AEs 10 pct PT Upper respiratory tract infection (OR)



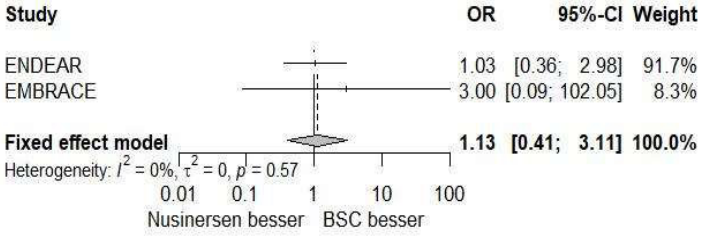
Forest Plot for Mild AEs 10 pct PT Upper respiratory tract infection (RR)



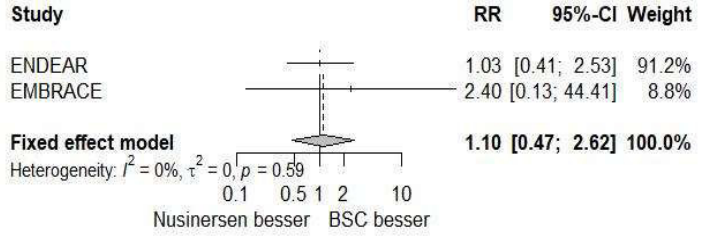
Forest Plot for Mild AEs 10 pct PT Vomiting (ARR)



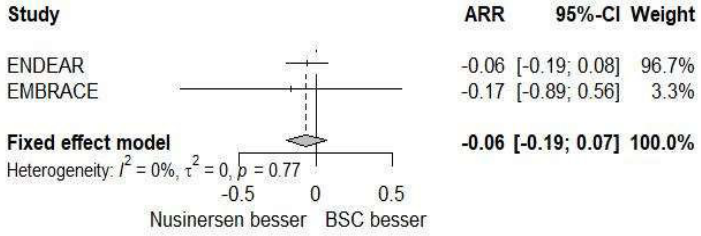
Forest Plot for Mild AEs 10 pct PT Vomiting (OR)



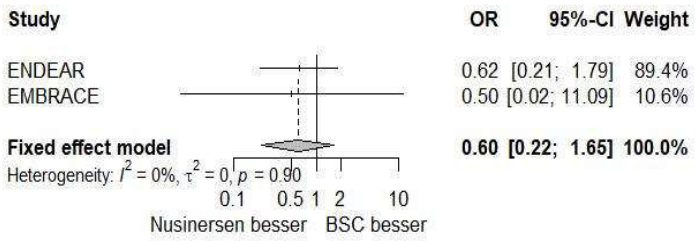
Forest Plot for Mild AEs 10 pct PT Vomiting (RR)



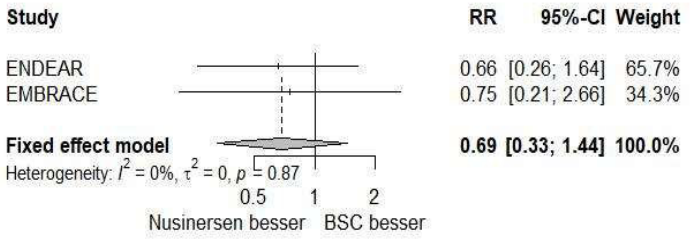
Forest Plot for Mild AEs 10 pct SOC Cardiac disorders (ARR)



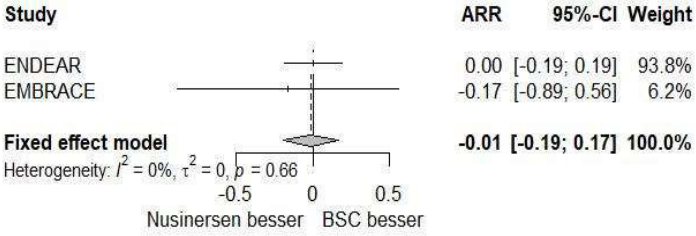
Forest Plot for Mild AEs 10 pct SOC Cardiac disorders (OR)



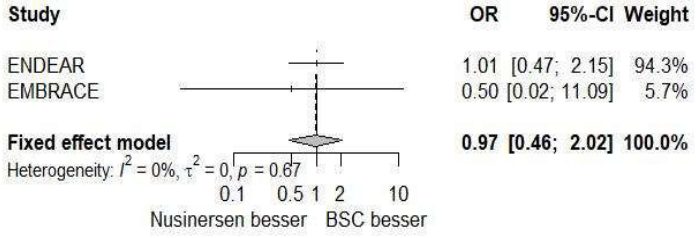
Forest Plot for Mild AEs 10 pct SOC Cardiac disorders (RR)



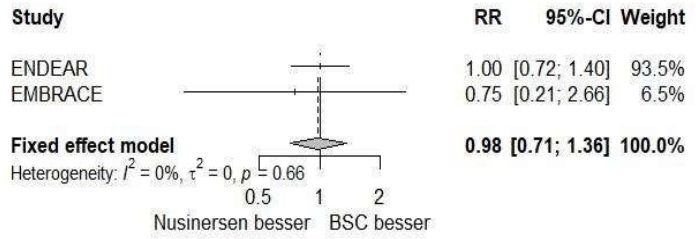
Forest Plot for Mild AEs 10 pct SOC Gastrointestinal disorders (ARR)



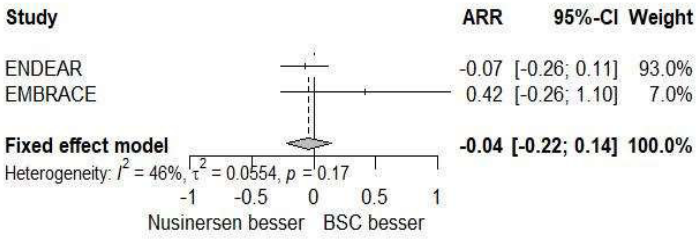
Forest Plot for Mild AEs 10 pct SOC Gastrointestinal disorders (OR)



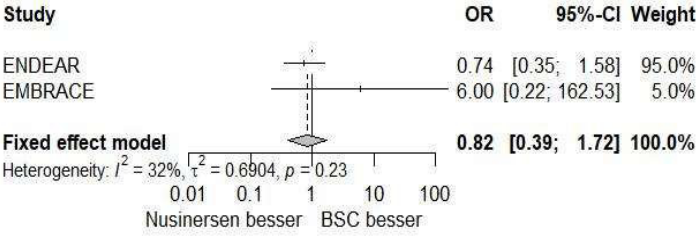
Forest Plot for Mild AEs 10 pct SOC Gastrointestinal disorders (RR)



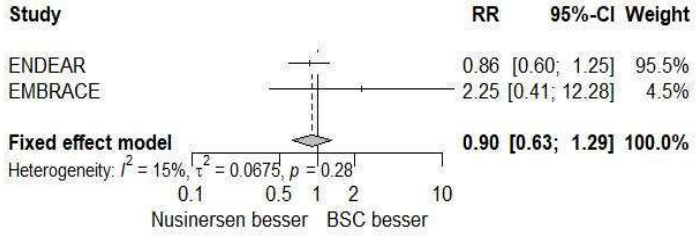
Forest Plot for Mild AEs 10 pct SOC General disorders and administration site conditions (ARR)



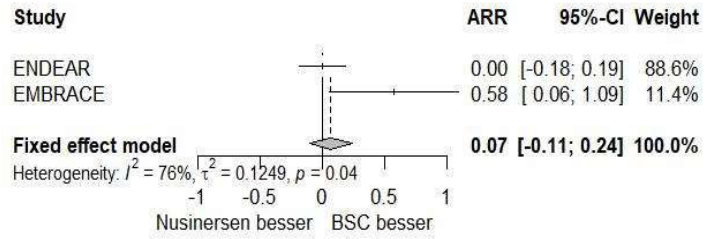
Forest Plot for Mild AEs 10 pct SOC General disorders and administration site conditions (OR)



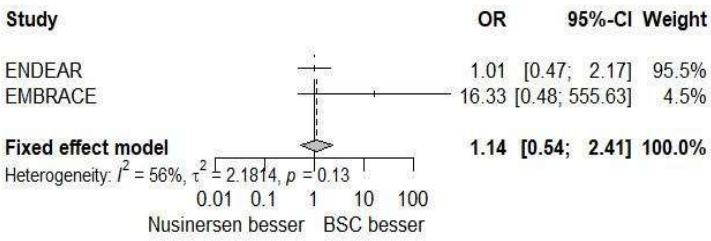
Forest Plot for Mild AEs 10 pct SOC General disorders and administration site conditions (RR)



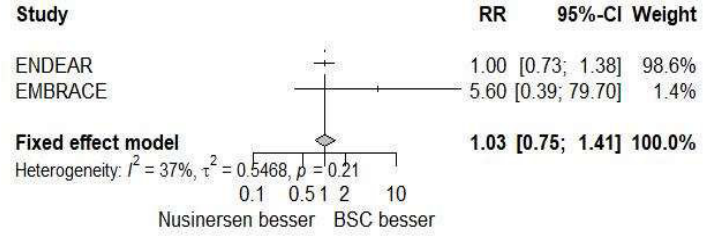
Forest Plot for Mild AEs 10 pct SOC Infections and infestations (ARR)



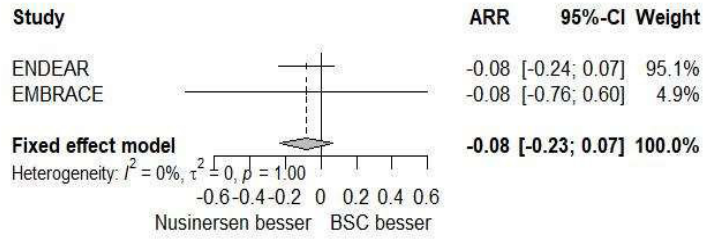
Forest Plot for Mild AEs 10 pct SOC Infections and infestations (OR)



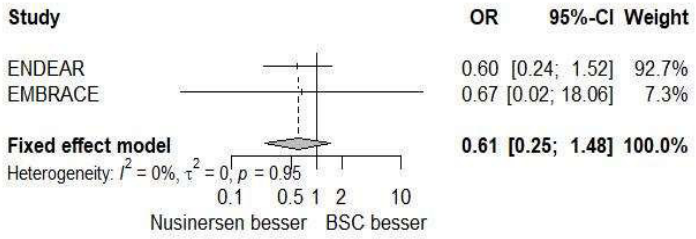
Forest Plot for Mild AEs 10 pct SOC Infections and infestations (RR)



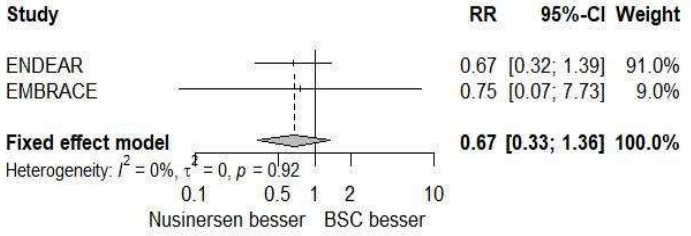
Forest Plot for Mild AEs 10 pct SOC Injury, poisoning and procedural complications (ARR)



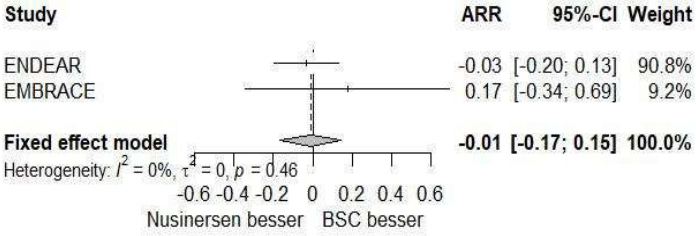
Forest Plot for Mild AEs 10 pct SOC Injury, poisoning and procedural complications (OR)



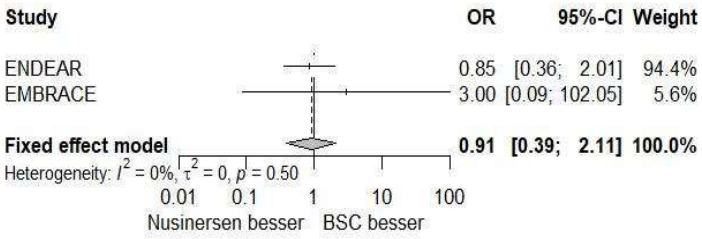
Forest Plot for Mild AEs 10 pct SOC Injury, poisoning and procedural complications (RR)



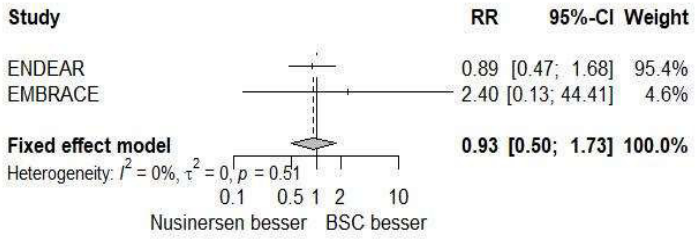
Forest Plot for Mild AEs 10 pct SOC Investigations (ARR)



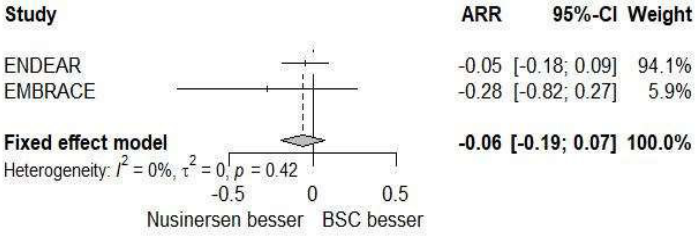
Forest Plot for Mild AEs 10 pct SOC Investigations (OR)



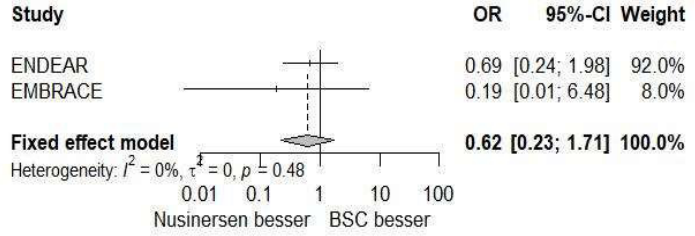
Forest Plot for Mild AEs 10 pct SOC Investigations (RR)



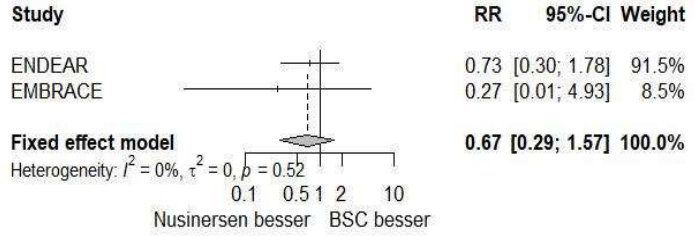
Forest Plot for Mild AEs 10 pct SOC Metabolism and nutrition disorders (ARR)



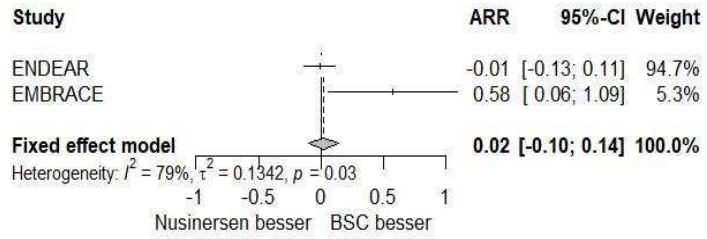
Forest Plot for Mild AEs 10 pct SOC Metabolism and nutrition disorders (OR)



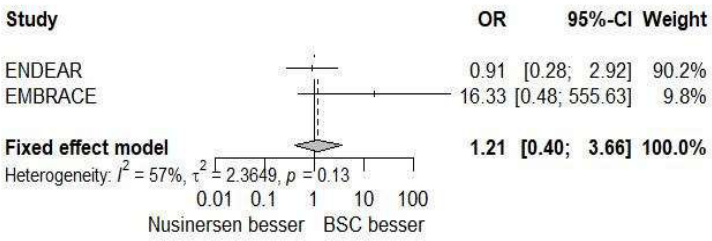
Forest Plot for Mild AEs 10 pct SOC Metabolism and nutrition disorders (RR)



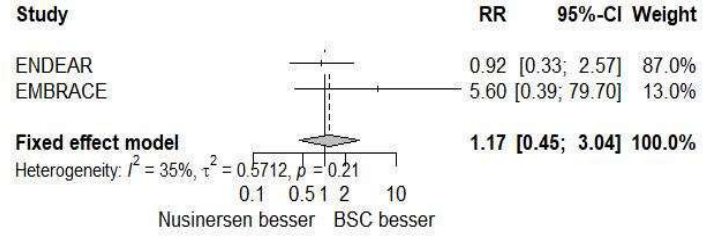
Forest Plot for Mild AEs 10 pct SOC Musculoskeletal and connective tissue disorders (ARR)



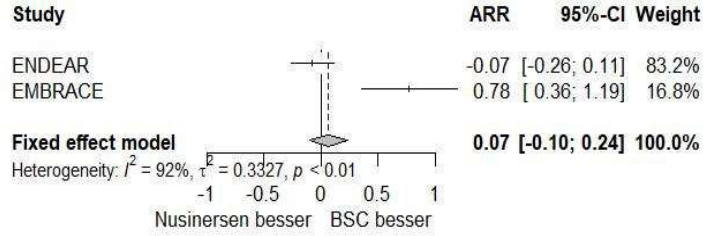
Forest Plot for Mild AEs 10 pct SOC Musculoskeletal and connective tissue disorders (OR)



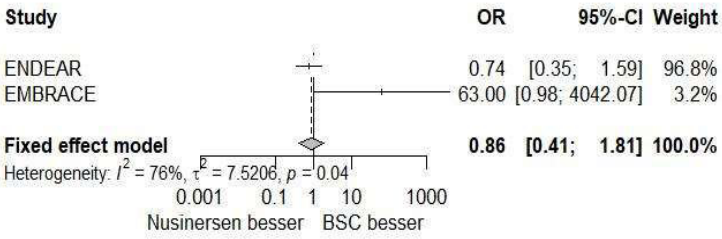
Forest Plot for Mild AEs 10 pct SOC Musculoskeletal and connective tissue disorders (RR)



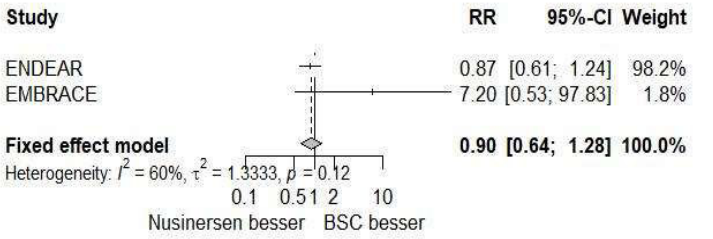
Forest Plot for Mild AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders (ARR)



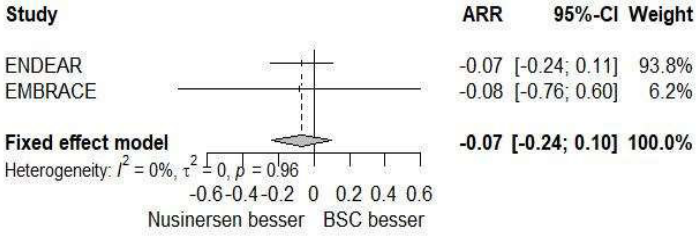
Forest Plot for Mild AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders (OR)



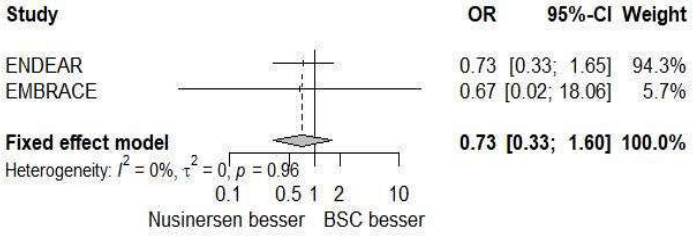
Forest Plot for Mild AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders (RR)



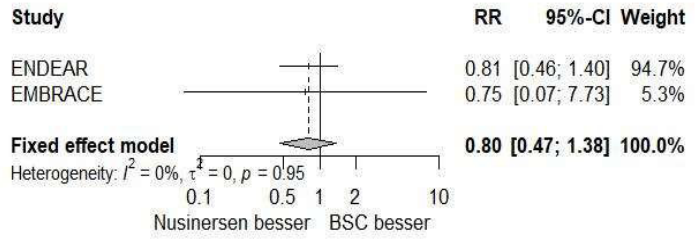
Forest Plot for Mild AEs 10 pct SOC Skin and subcutaneous tissue disorders (ARR)



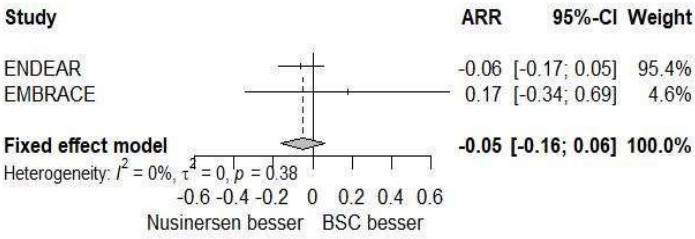
Forest Plot for Mild AEs 10 pct SOC Skin and subcutaneous tissue disorders (OR)



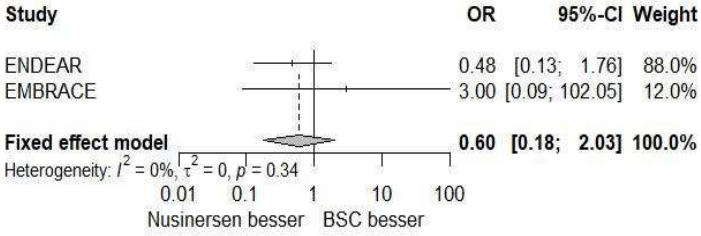
Forest Plot for Mild AEs 10 pct SOC Skin and subcutaneous tissue disorders (RR)



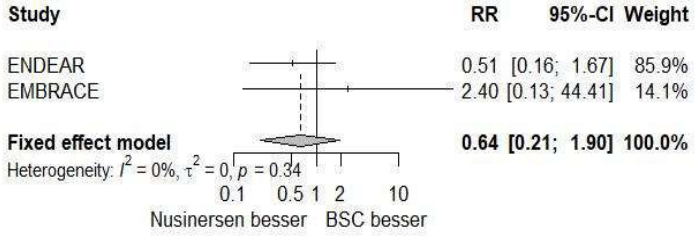
Forest Plot for Moderate AEs 10 pct PT Pneumonia aspiration (ARR)



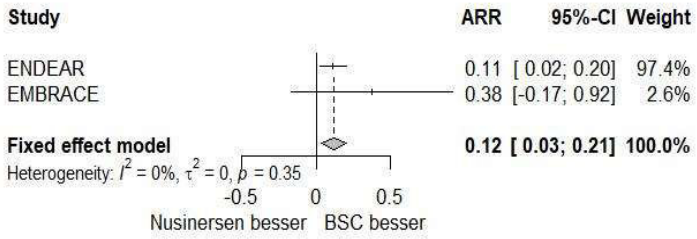
Forest Plot for Moderate AEs 10 pct PT Pneumonia aspiration (OR)



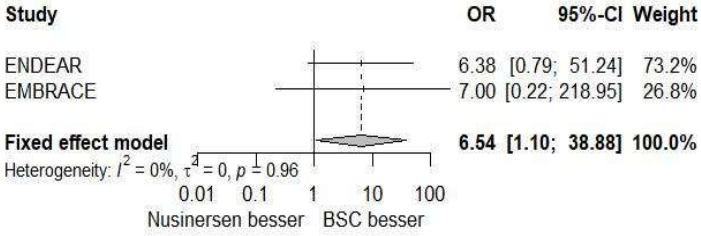
Forest Plot for Moderate AEs 10 pct PT Pneumonia aspiration (RR)



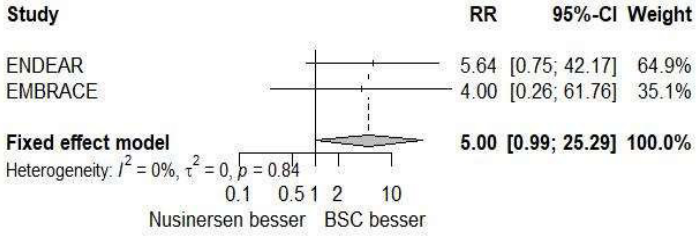
Forest Plot for Moderate AEs 10 pct PT Pneumonia (ARR)



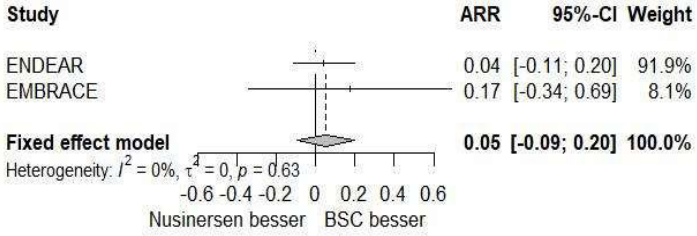
Forest Plot for Moderate AEs 10 pct PT Pneumonia (OR)



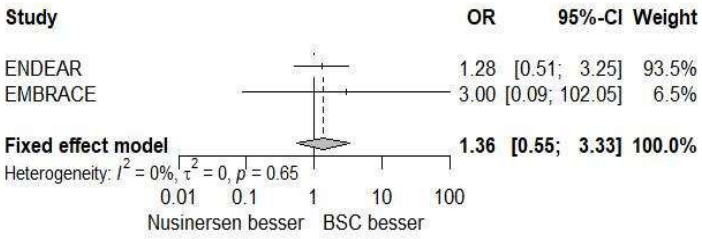
Forest Plot for Moderate AEs 10 pct PT Pneumonia (RR)



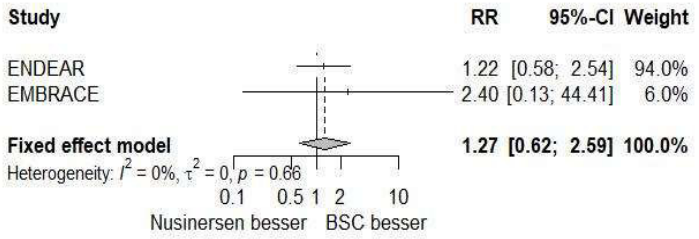
Forest Plot for Moderate AEs 10 pct PT Pyrexia (ARR)



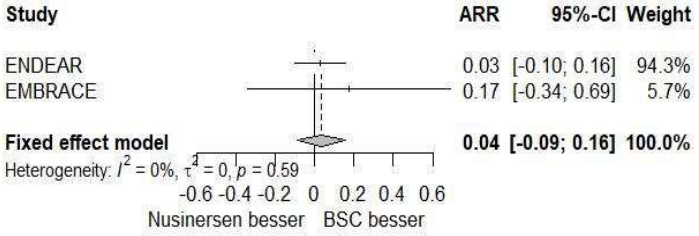
Forest Plot for Moderate AEs 10 pct PT Pyrexia (OR)



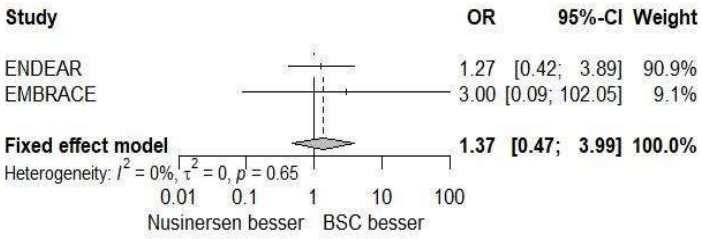
Forest Plot for Moderate AEs 10 pct PT Pyrexia (RR)



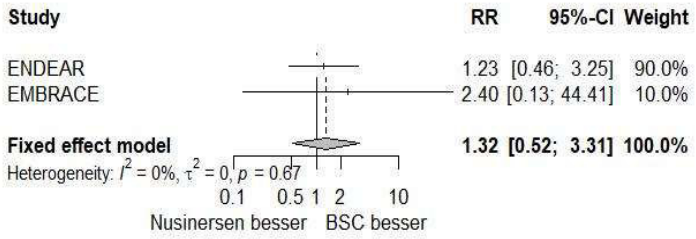
Forest Plot for Moderate AEs 10 pct PT Respiratory distress (ARR)



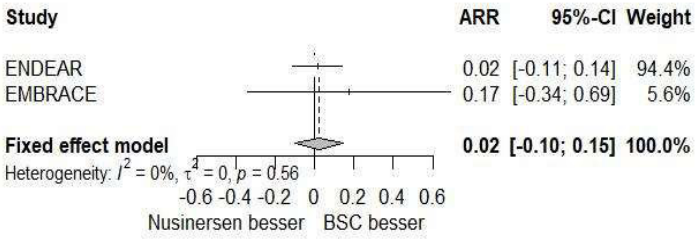
Forest Plot for Moderate AEs 10 pct PT Respiratory distress (OR)



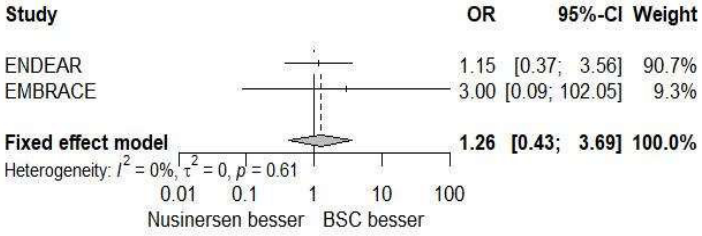
Forest Plot for Moderate AEs 10 pct PT Respiratory distress (RR)



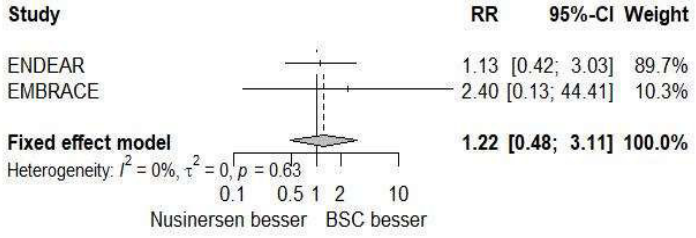
Forest Plot for Moderate AEs 10 pct PT Upper respiratory tract infection (ARR)



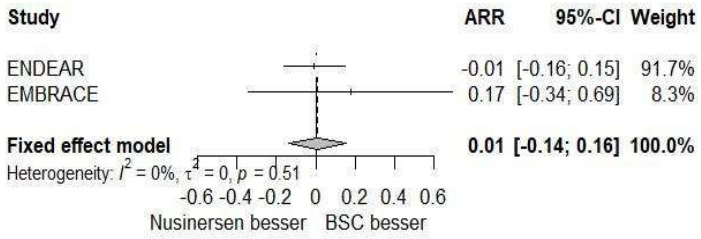
Forest Plot for Moderate AEs 10 pct PT Upper respiratory tract infection (OR)



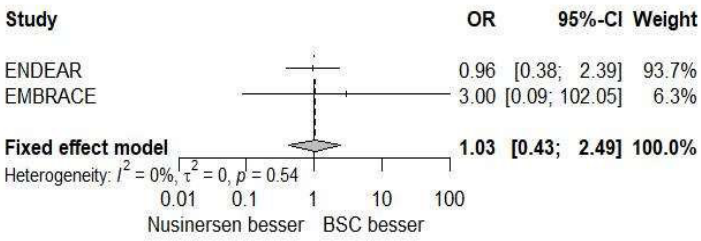
Forest Plot for Moderate AEs 10 pct PT Upper respiratory tract infection (RR)



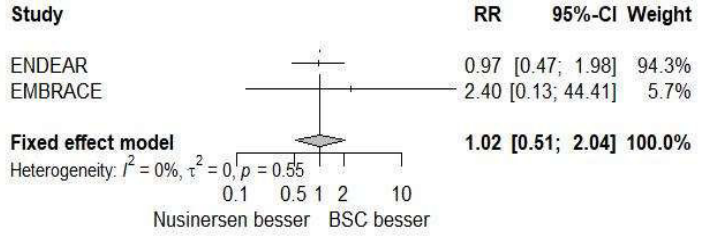
Forest Plot for Moderate AEs 10 pct SOC Gastrointestinal disorders (ARR)



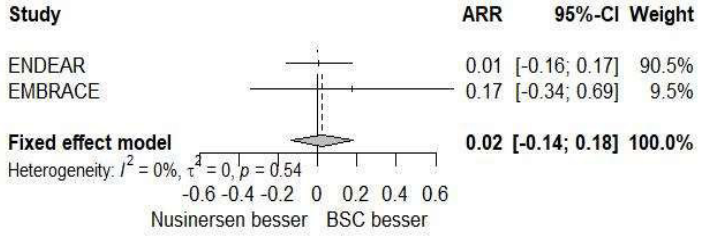
Forest Plot for Moderate AEs 10 pct SOC Gastrointestinal disorders (OR)



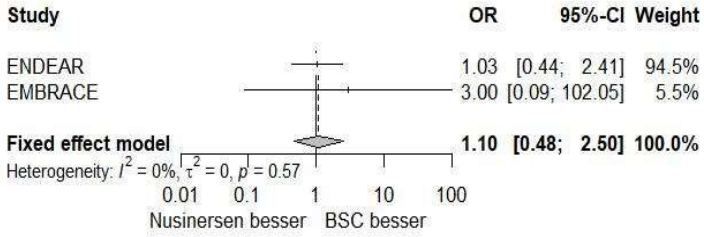
Forest Plot for Moderate AEs 10 pct SOC Gastrointestinal disorders (RR)



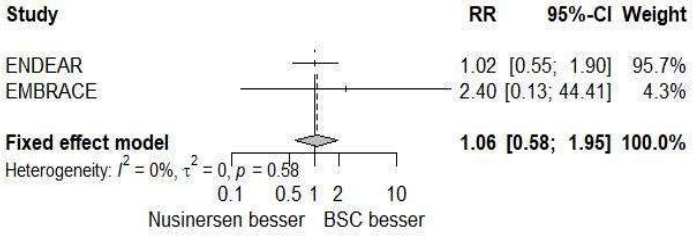
Forest Plot for Moderate AEs 10 pct SOC General disorders and administration site conditions (ARR)



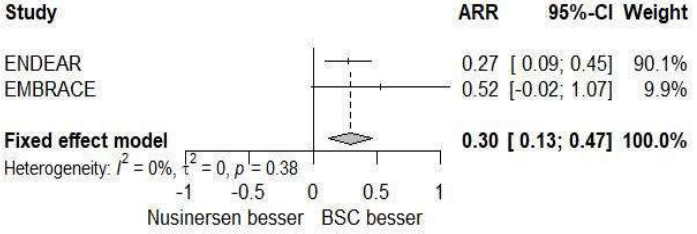
Forest Plot for Moderate AEs 10 pct SOC General disorders and administration site conditions (OR)



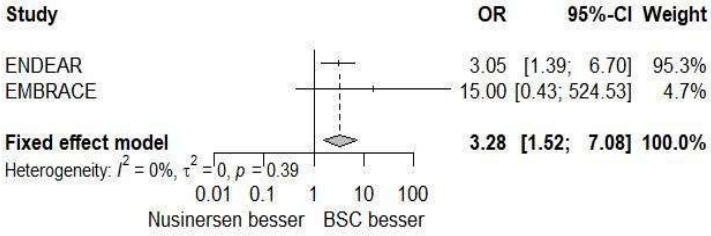
Forest Plot for Moderate AEs 10 pct SOC General disorders and administration site conditions (RR)



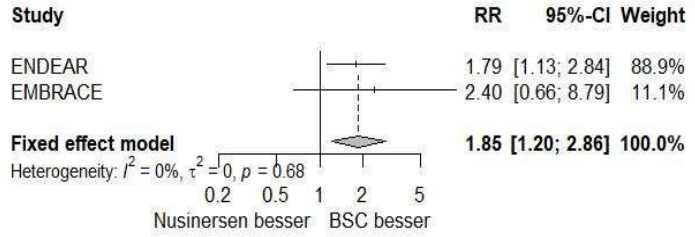
Forest Plot for Moderate AEs 10 pct SOC Infections and infestations (ARR)



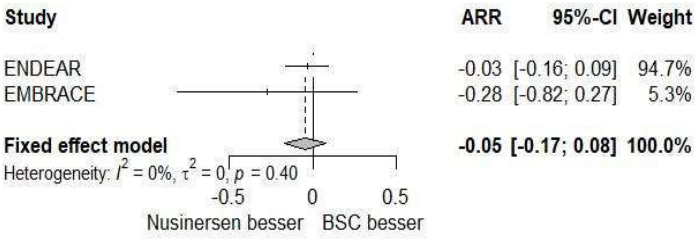
Forest Plot for Moderate AEs 10 pct SOC Infections and infestations (OR)



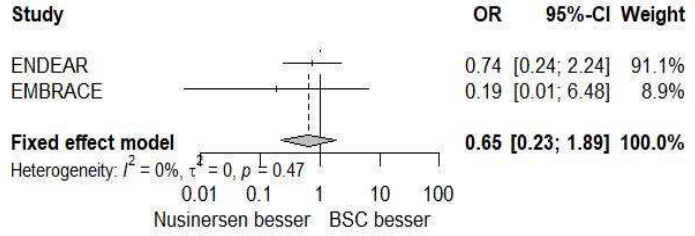
Forest Plot for Moderate AEs 10 pct SOC Infections and infestations (RR)



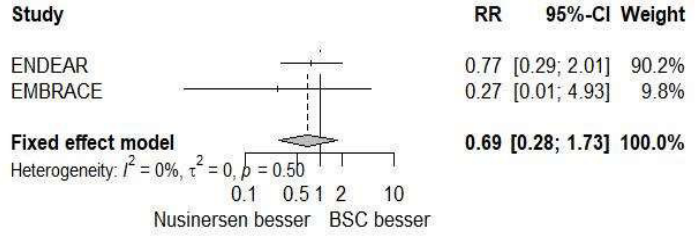
Forest Plot for Moderate AEs 10 pct SOC Investigations (ARR)



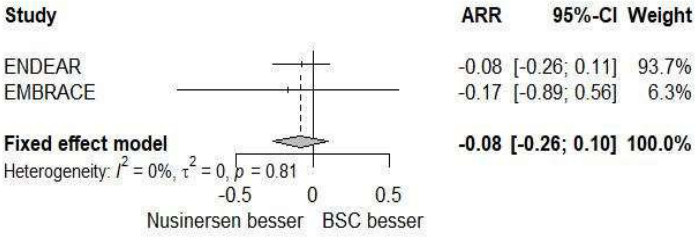
Forest Plot for Moderate AEs 10 pct SOC Investigations (OR)



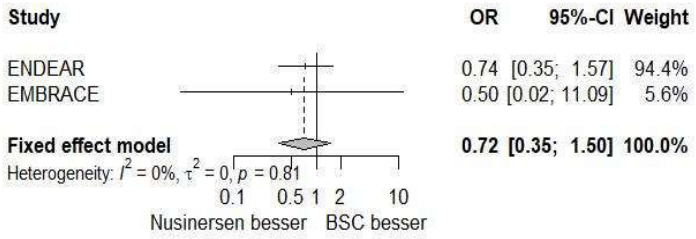
Forest Plot for Moderate AEs 10 pct SOC Investigations (RR)



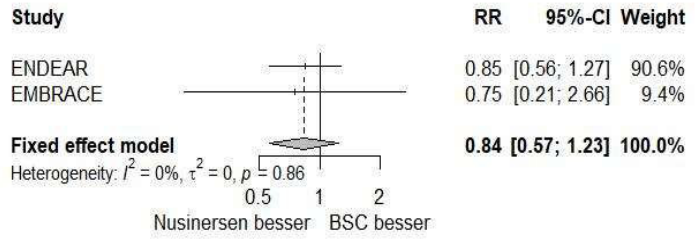
Forest Plot for Moderate AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders (ARR)



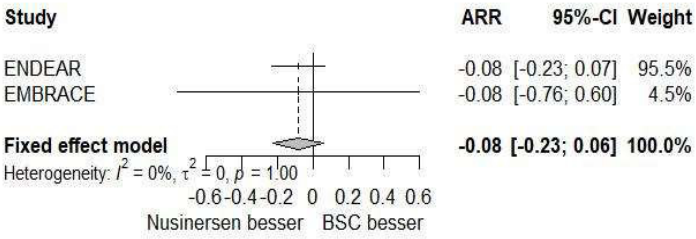
Forest Plot for Moderate AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders (OR)



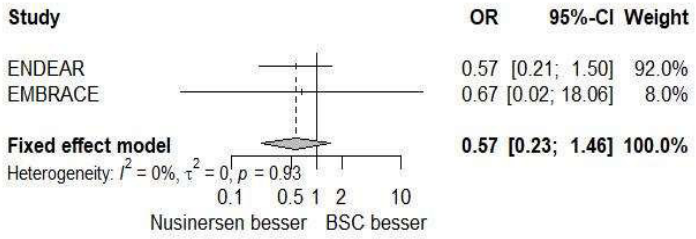
Forest Plot for Moderate AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders (RR)



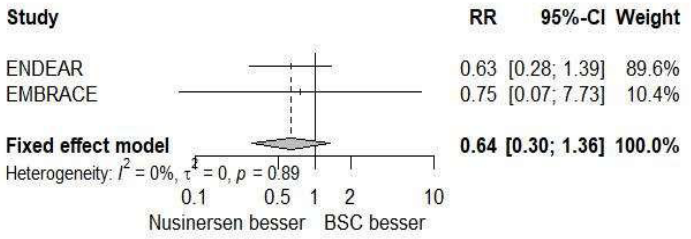
Forest Plot for Moderate or severe AEs 10 pct PT Acute respiratory failure (ARR)



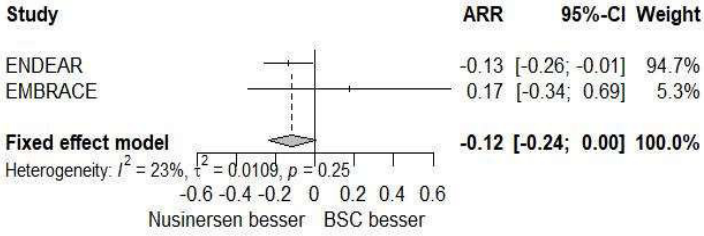
Forest Plot for Moderate or severe AEs 10 pct PT Acute respiratory failure (OR)



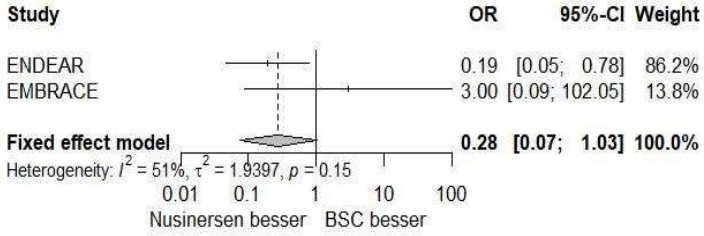
Forest Plot for Moderate or severe AEs 10 pct PT Acute respiratory failure (RR)



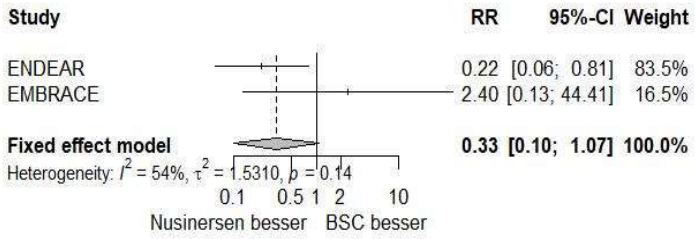
Forest Plot for Moderate or severe AEs 10 pct PT Bronchial secretion retention (ARR)



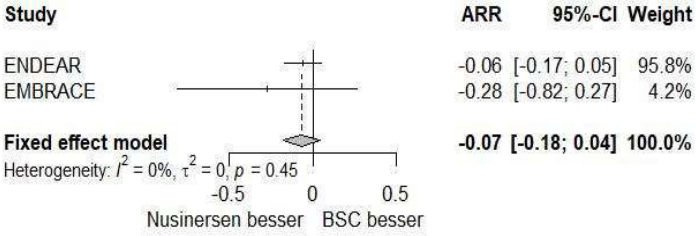
Forest Plot for Moderate or severe AEs 10 pct PT Bronchial secretion retention (OR)



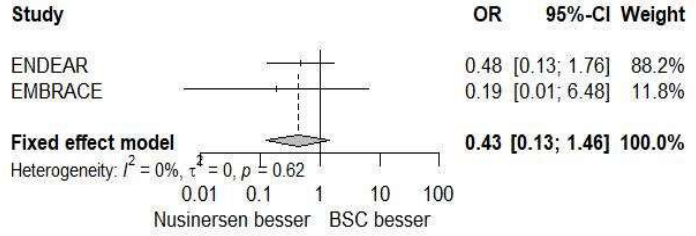
Forest Plot for Moderate or severe AEs 10 pct PT Bronchial secretion retention (RR)



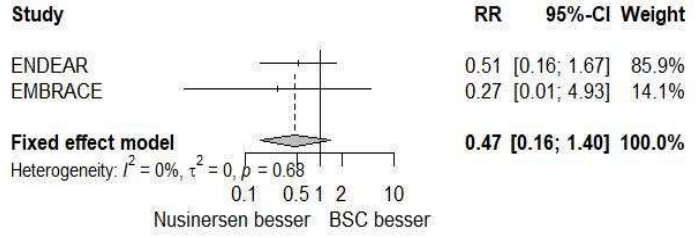
Forest Plot for Moderate or severe AEs 10 pct PT Cardio-respiratory arrest (ARR)



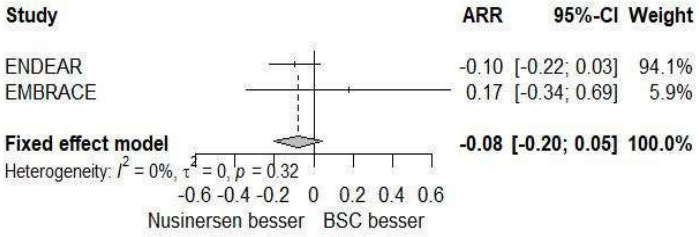
Forest Plot for Moderate or severe AEs 10 pct PT Cardio-respiratory arrest (OR)



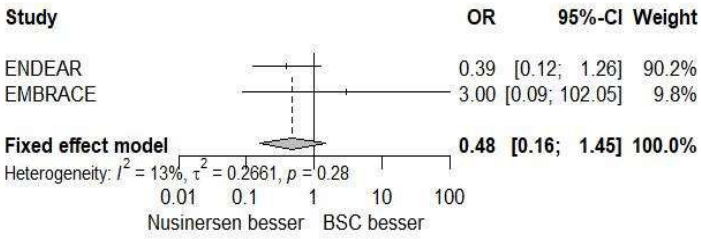
Forest Plot for Moderate or severe AEs 10 pct PT Cardio-respiratory arrest (RR)



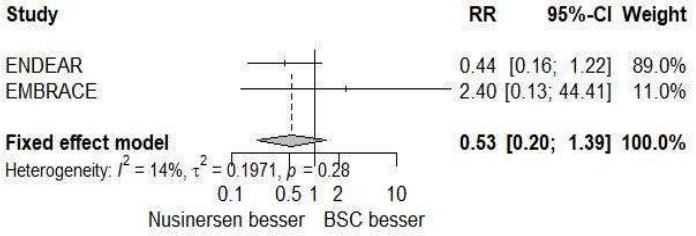
Forest Plot for Moderate or severe AEs 10 pct PT Dysphagia
(ARR)



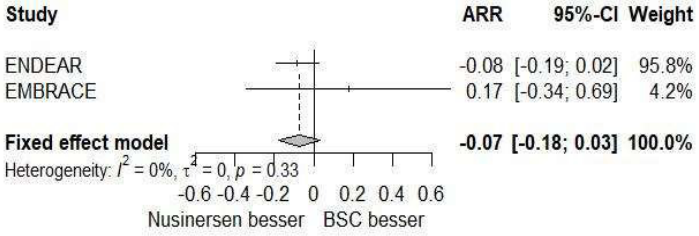
Forest Plot for Moderate or severe AEs 10 pct PT Dysphagia
(OR)



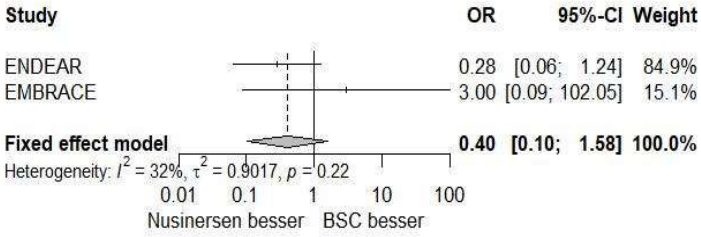
Forest Plot for Moderate or severe AEs 10 pct PT Dysphagia
(RR)



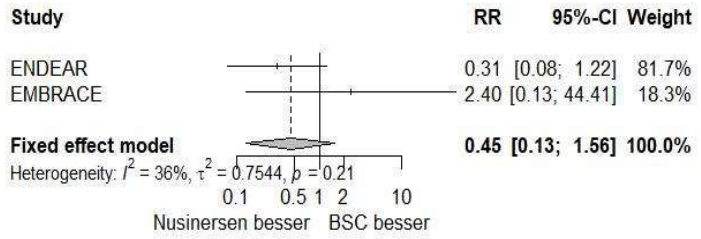
Forest Plot for Moderate or severe AEs 10 pct PT Dyspnoea
(ARR)



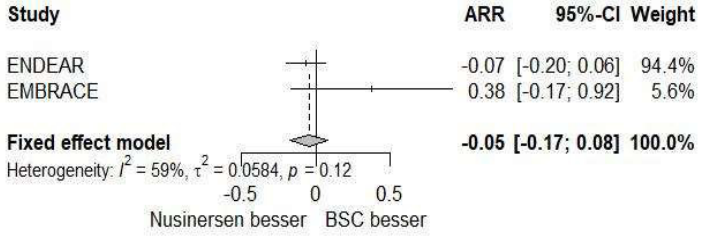
Forest Plot for Moderate or severe AEs 10 pct PT Dyspnoea (OR)



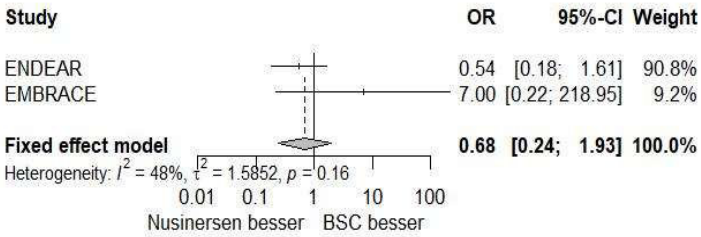
Forest Plot for Moderate or severe AEs 10 pct PT Dyspnoea (RR)



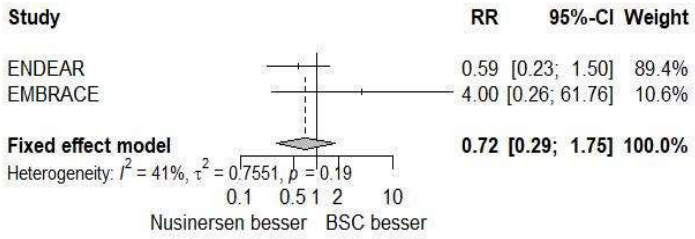
Forest Plot for Moderate or severe AEs 10 pct PT Pneumonia aspiration (ARR)



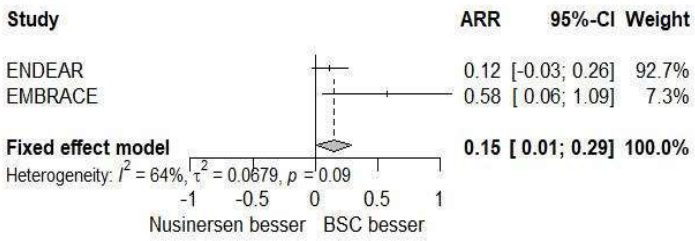
Forest Plot for Moderate or severe AEs 10 pct PT Pneumonia aspiration (OR)



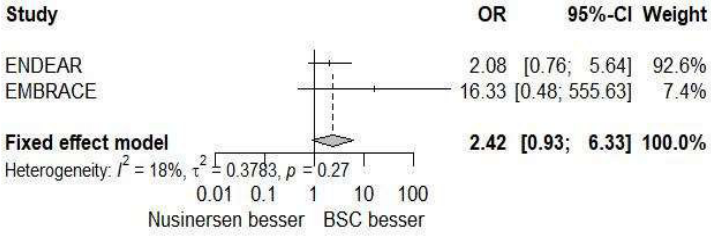
Forest Plot for Moderate or severe AEs 10 pct PT Pneumonia aspiration (RR)



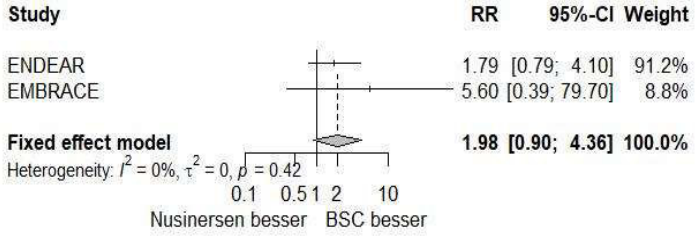
Forest Plot for Moderate or severe AEs 10 pct PT Pneumonia (ARR)



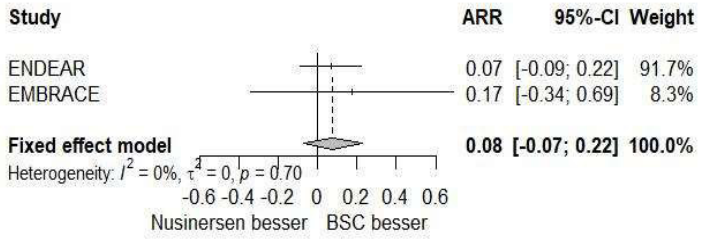
Forest Plot for Moderate or severe AEs 10 pct PT Pneumonia (OR)



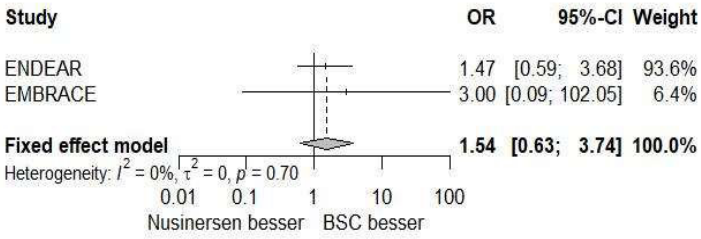
Forest Plot for Moderate or severe AEs 10 pct PT Pneumonia (RR)



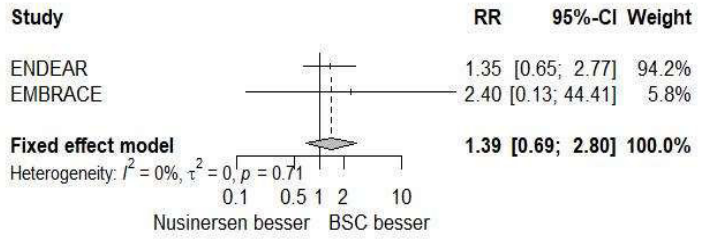
Forest Plot for Moderate or severe AEs 10 pct PT Pyrexia (ARR)



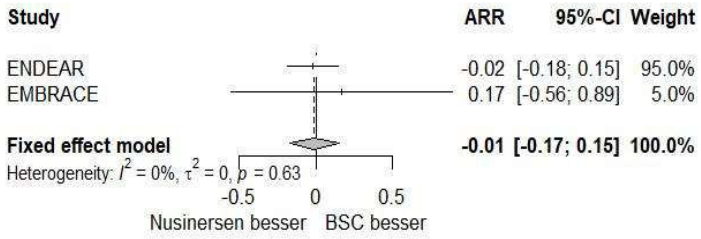
Forest Plot for Moderate or severe AEs 10 pct PT Pyrexia (OR)



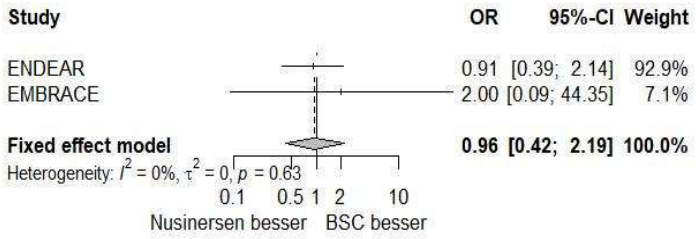
Forest Plot for Moderate or severe AEs 10 pct PT Pyrexia (RR)



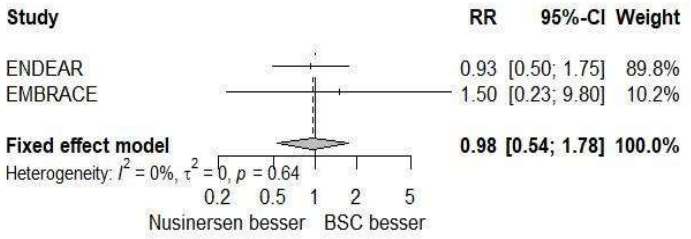
Forest Plot for Moderate or severe AEs 10 pct PT Respiratory distress (ARR)



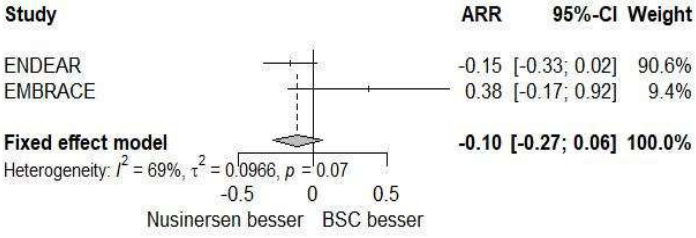
Forest Plot for Moderate or severe AEs 10 pct PT Respiratory distress (OR)



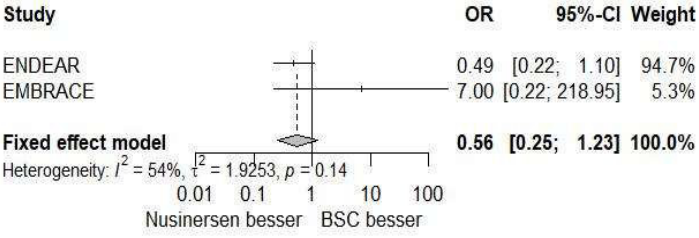
Forest Plot for Moderate or severe AEs 10 pct PT Respiratory distress (RR)



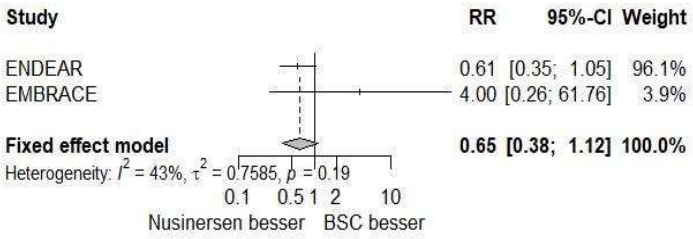
Forest Plot for Moderate or severe AEs 10 pct PT Respiratory failure (ARR)



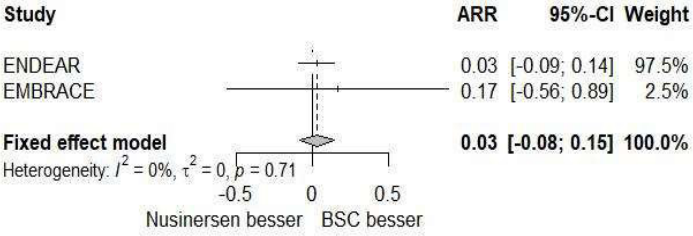
Forest Plot for Moderate or severe AEs 10 pct PT Respiratory failure (OR)



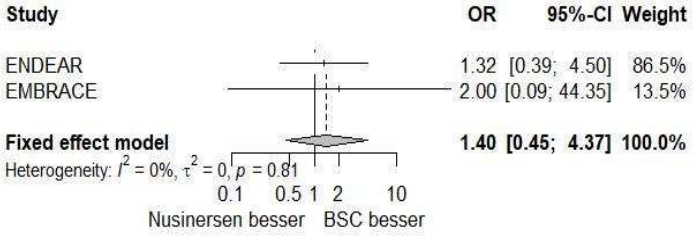
Forest Plot for Moderate or severe AEs 10 pct PT Respiratory failure (RR)



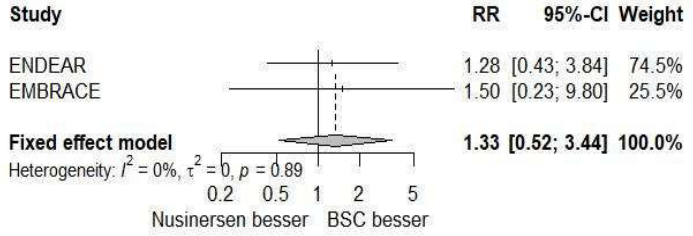
Forest Plot for Moderate or severe AEs 10 pct PT Rhinovirus infection (ARR)



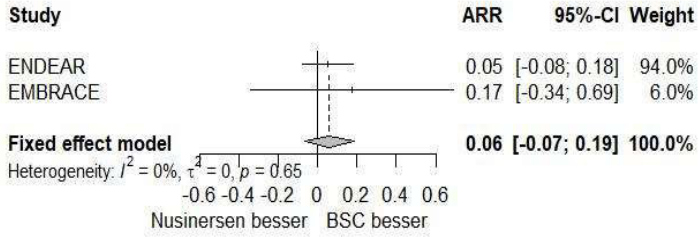
Forest Plot for Moderate or severe AEs 10 pct PT Rhinovirus infection (OR)



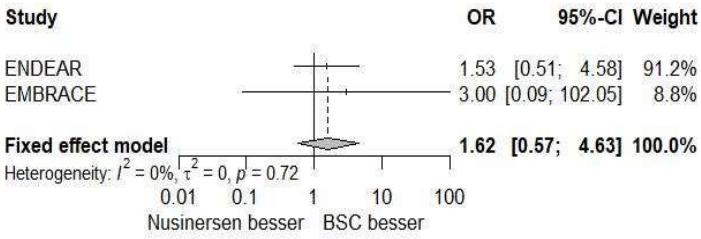
Forest Plot for Moderate or severe AEs 10 pct PT Rhinovirus infection (RR)



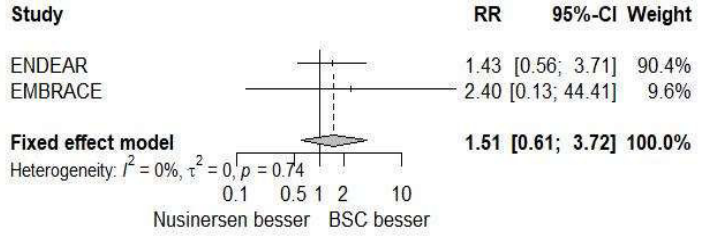
Forest Plot for Moderate or severe AEs 10 pct PT Upper respiratory tract infection (ARR)



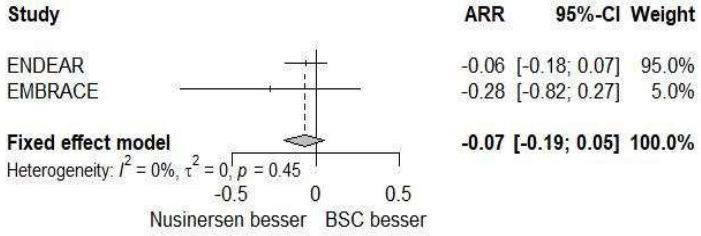
Forest Plot for Moderate or severe AEs 10 pct PT Upper respiratory tract infection (OR)



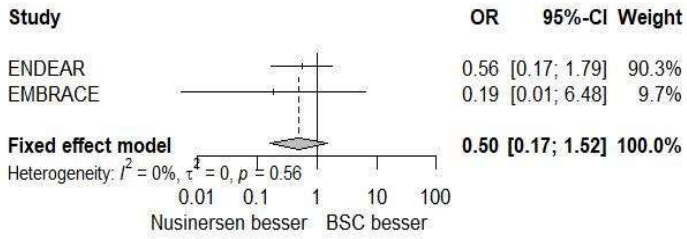
Forest Plot for Moderate or severe AEs 10 pct PT Upper respiratory tract infection (RR)



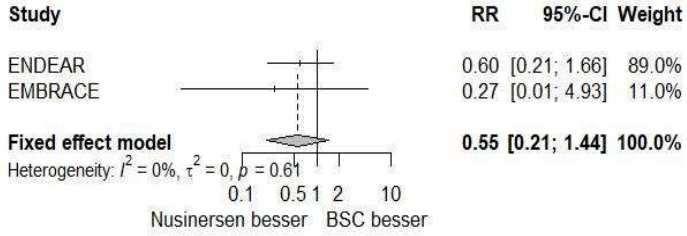
Forest Plot for Moderate or severe AEs 10 pct PT Viral upper respiratory tract infection (ARR)



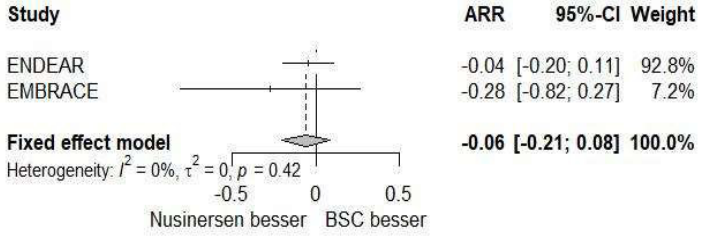
Forest Plot for Moderate or severe AEs 10 pct PT Viral upper respiratory tract infection (OR)



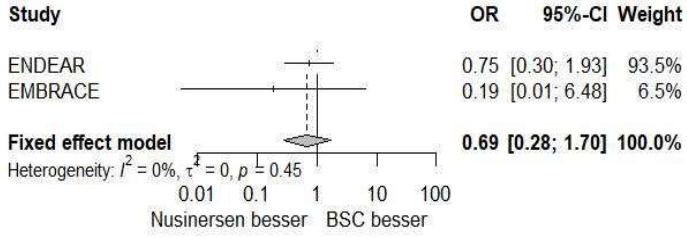
Forest Plot for Moderate or severe AEs 10 pct PT Viral upper respiratory tract infection (RR)



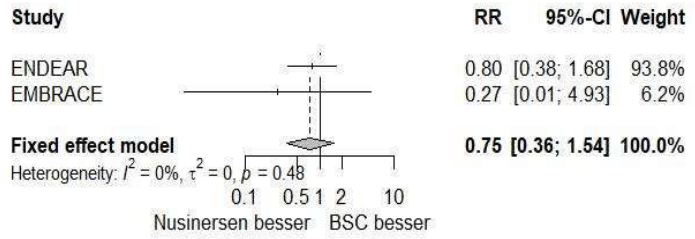
Forest Plot for Moderate or severe AEs 10 pct SOC Cardiac disorders (ARR)



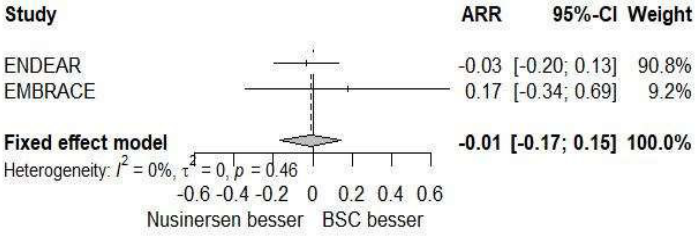
Forest Plot for Moderate or severe AEs 10 pct SOC Cardiac disorders (OR)



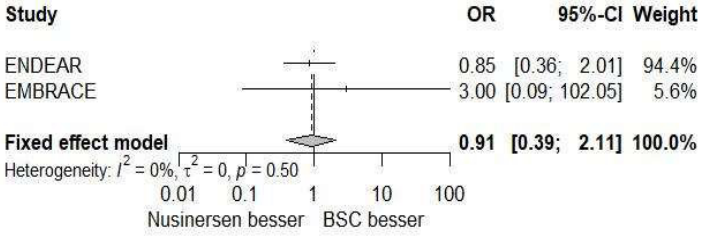
Forest Plot for Moderate or severe AEs 10 pct SOC Cardiac disorders (RR)



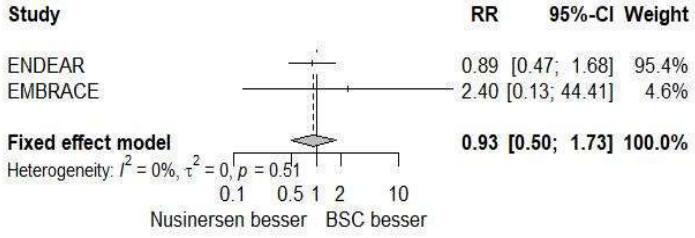
Forest Plot for Moderate or severe AEs 10 pct SOC Gastrointestinal disorders (ARR)



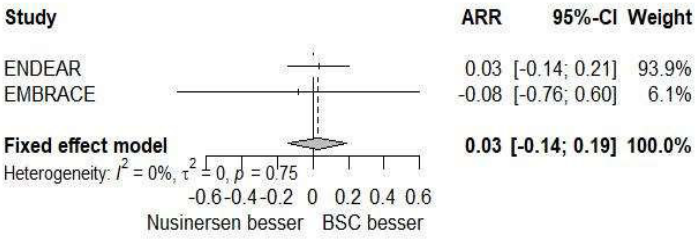
Forest Plot for Moderate or severe AEs 10 pct SOC Gastrointestinal disorders (OR)



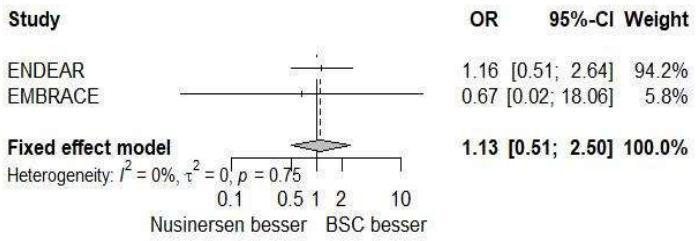
Forest Plot for Moderate or severe AEs 10 pct SOC Gastrointestinal disorders (RR)



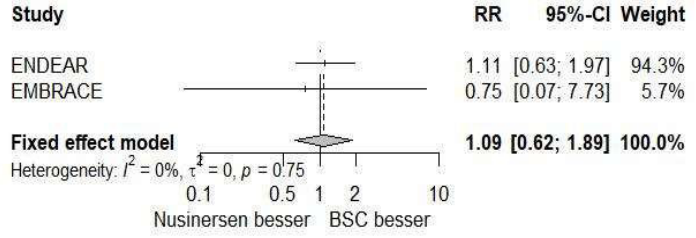
Forest Plot for Moderate or severe AEs 10 pct SOC General disorders and administration site conditions (ARR)



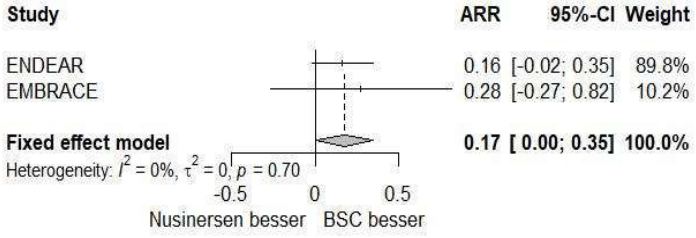
Forest Plot for Moderate or severe AEs 10 pct SOC General disorders and administration site conditions (OR)



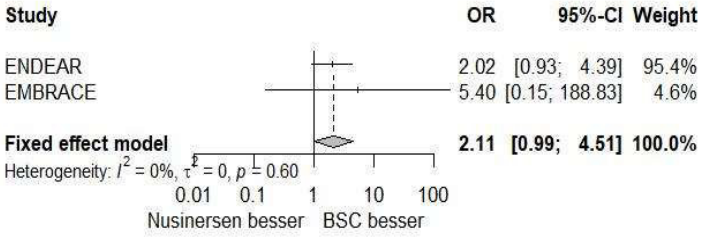
Forest Plot for Moderate or severe AEs 10 pct SOC General disorders and administration site conditions (RR)



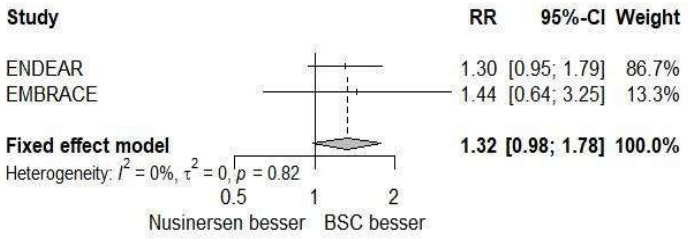
Forest Plot for Moderate or severe AEs 10 pct SOC Infections and infestations (ARR)



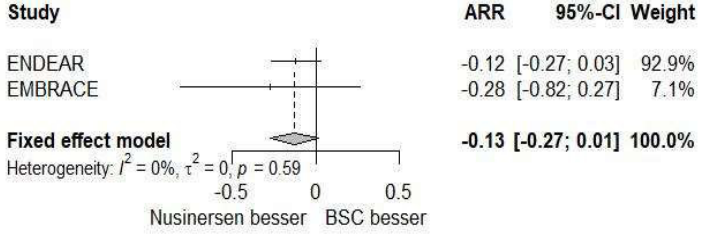
Forest Plot for Moderate or severe AEs 10 pct SOC Infections and infestations (OR)



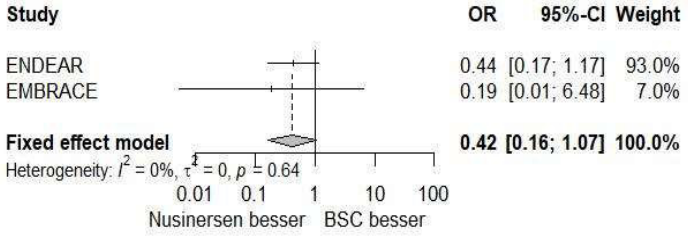
Forest Plot for Moderate or severe AEs 10 pct SOC Infections and infestations (RR)



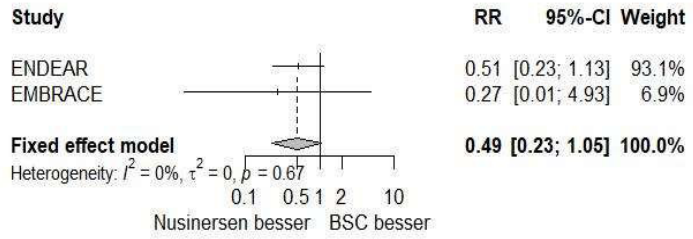
Forest Plot for Moderate or severe AEs 10 pct SOC Investigations (ARR)



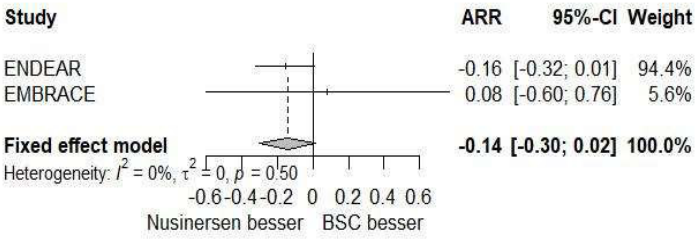
Forest Plot for Moderate or severe AEs 10 pct SOC Investigations (OR)



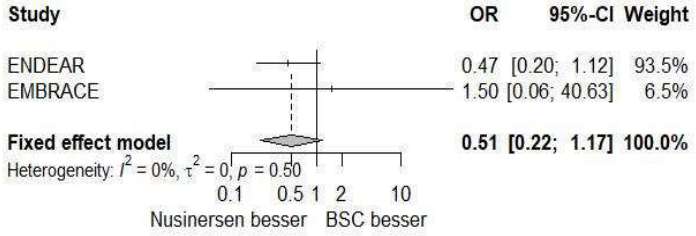
Forest Plot for Moderate or severe AEs 10 pct SOC
Investigations (RR)



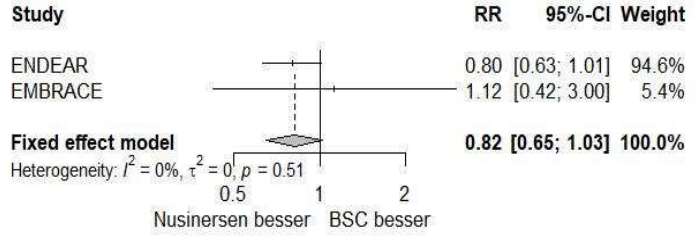
Forest Plot for Moderate or severe AEs 10 pct SOC
Respiratory, thoracic and mediastinal disorders (ARR)



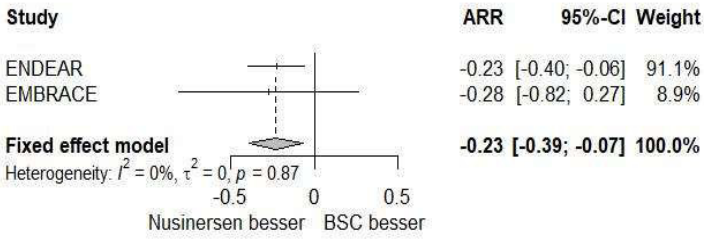
Forest Plot for Moderate or severe AEs 10 pct SOC
Respiratory, thoracic and mediastinal disorders (OR)



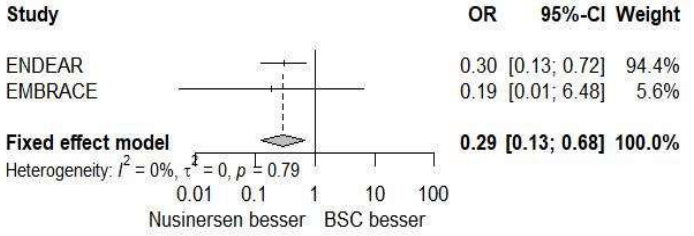
Forest Plot for Moderate or severe AEs 10 pct SOC
Respiratory, thoracic and mediastinal disorders (RR)



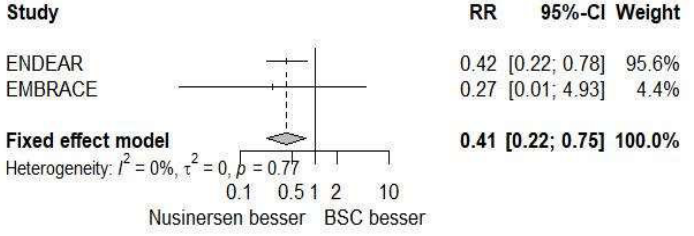
Forest Plot for Number of patients with adverse events leading to discontinuation of therapy (ARR)



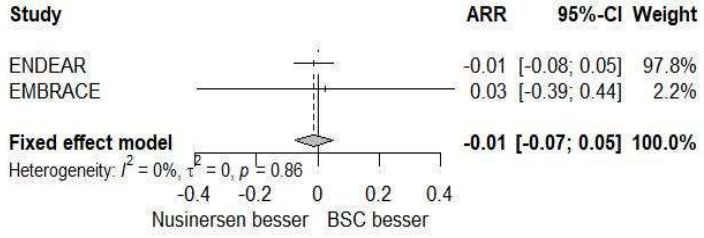
Forest Plot for Number of patients with adverse events leading to discontinuation of therapy (OR)



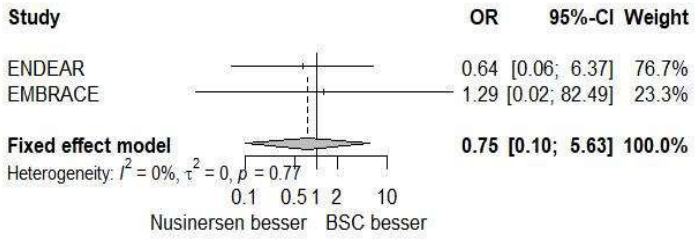
Forest Plot for Number of patients with adverse events leading to discontinuation of therapy (RR)



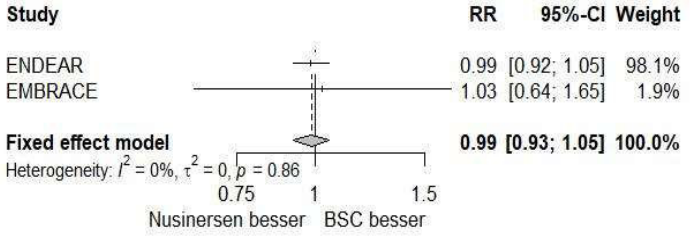
Forest Plot for Number of patients with adverse events (ARR)



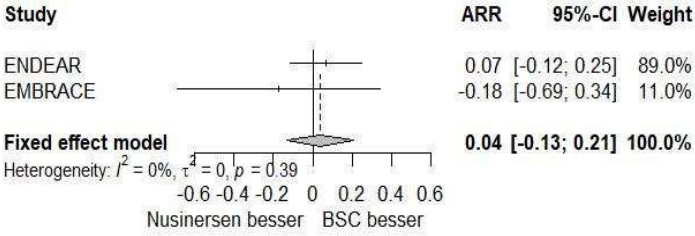
Forest Plot for Number of patients with adverse events (OR)



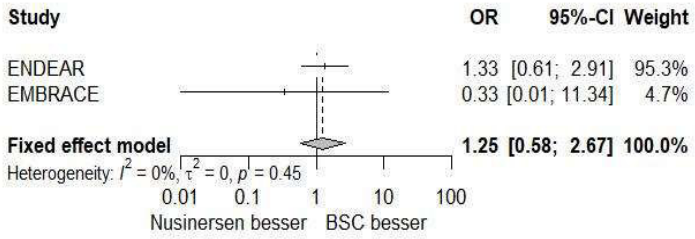
Forest Plot for Number of patients with adverse events (RR)



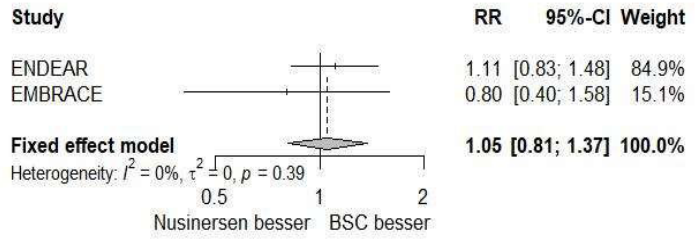
Forest Plot for Number of patients with mild adverse events (ARR)



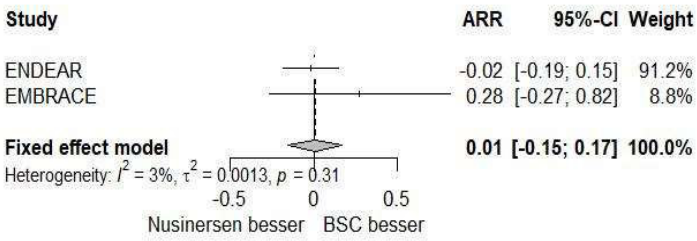
Forest Plot for Number of patients with mild adverse events (OR)



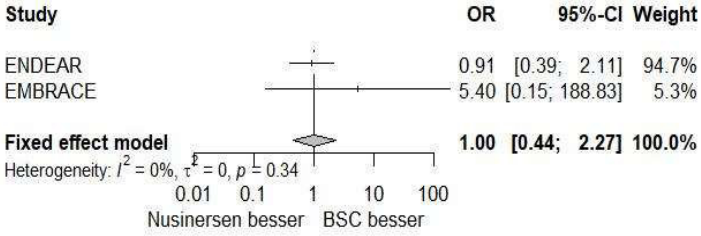
Forest Plot for Number of patients with mild adverse events (RR)



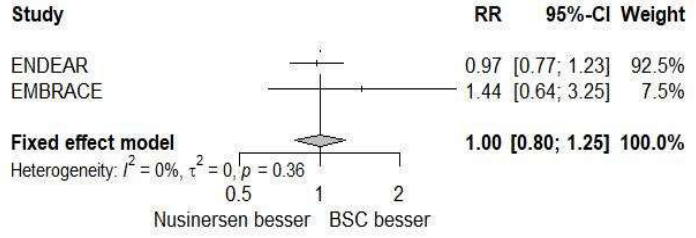
Forest Plot for Number of patients with moderate adverse events (ARR)



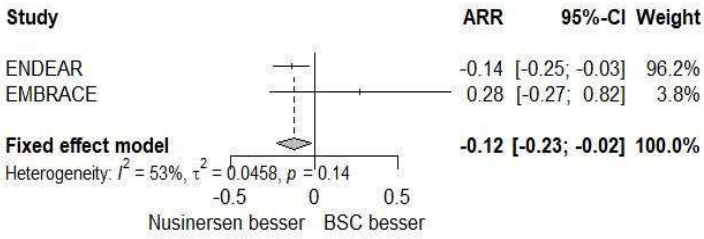
Forest Plot for Number of patients with moderate adverse events (OR)



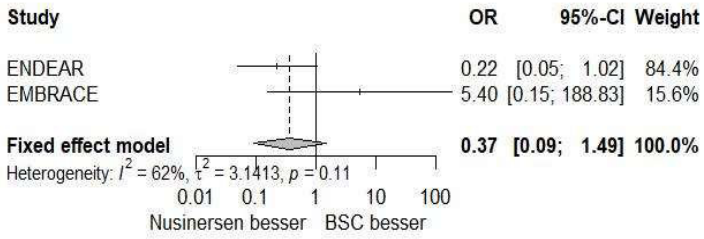
Forest Plot for Number of patients with moderate adverse events (RR)



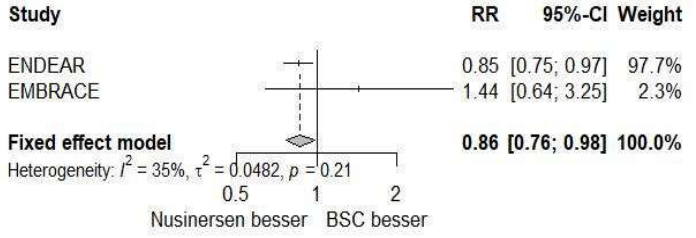
Forest Plot for Number of patients with moderate and severe adverse events (ARR)



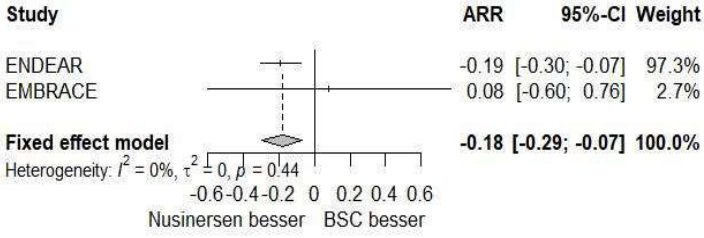
Forest Plot for Number of patients with moderate and severe adverse events (OR)



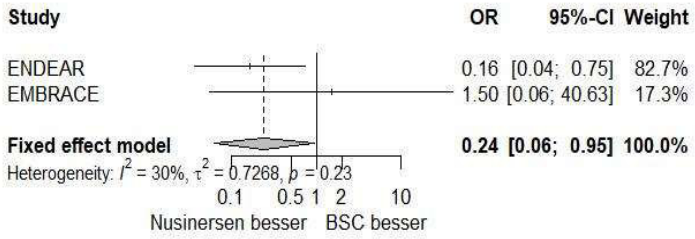
Forest Plot for Number of patients with moderate and severe adverse events (RR)



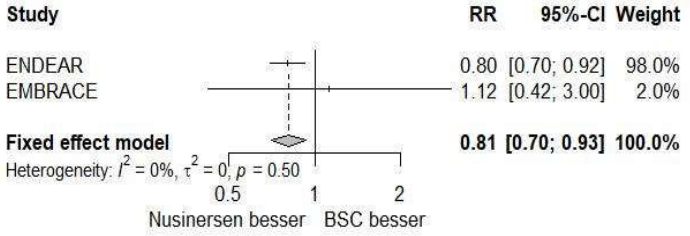
Forest Plot for Number of patients with serious adverse events (ARR)



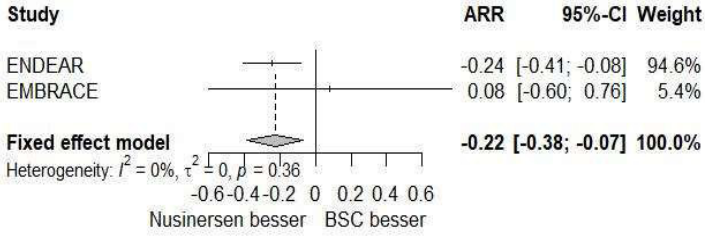
Forest Plot for Number of patients with serious adverse events (OR)



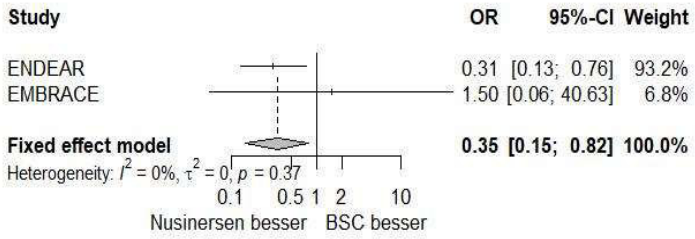
Forest Plot for Number of patients with serious adverse events (RR)



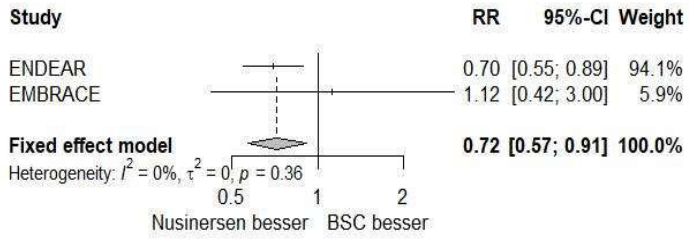
Forest Plot for Number of patients with severe adverse events (ARR)



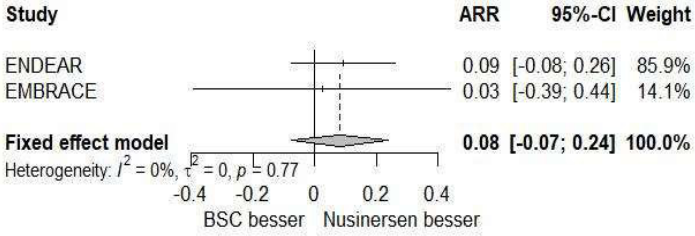
Forest Plot for Number of patients with severe adverse events (OR)



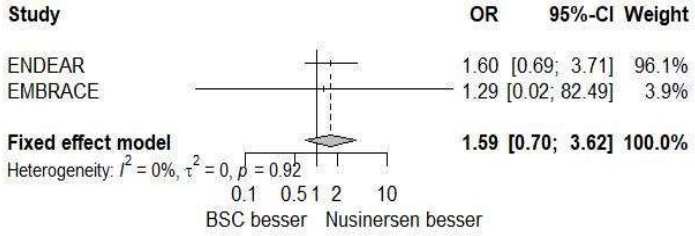
Forest Plot for Number of patients with severe adverse events (RR)



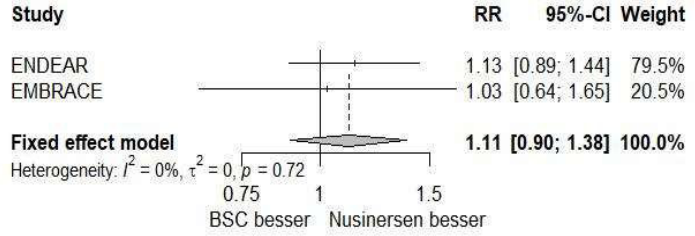
Forest Plot for Percent of subjects not requiring permanent ventilation (ARR)



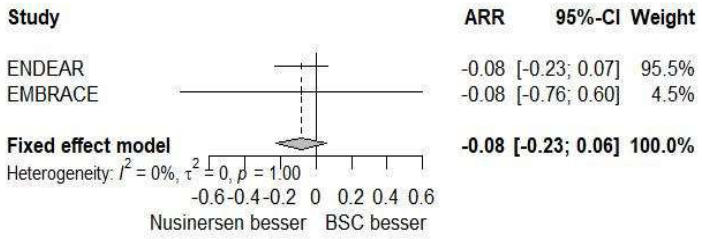
Forest Plot for Percent of subjects not requiring permanent ventilation (OR)



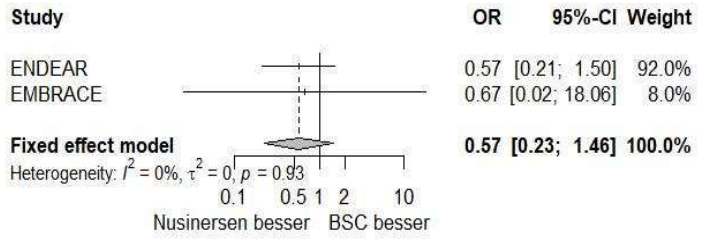
Forest Plot for Percent of subjects not requiring permanent ventilation (RR)



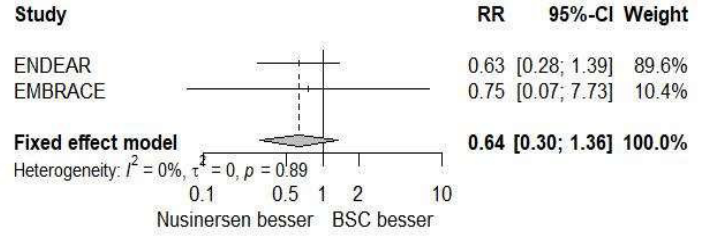
Forest Plot for SAEs 5 pct PT Acute respiratory failure
(ARR)



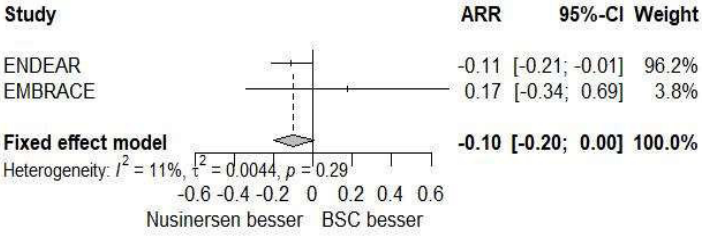
Forest Plot for SAEs 5 pct PT Acute respiratory failure (OR)



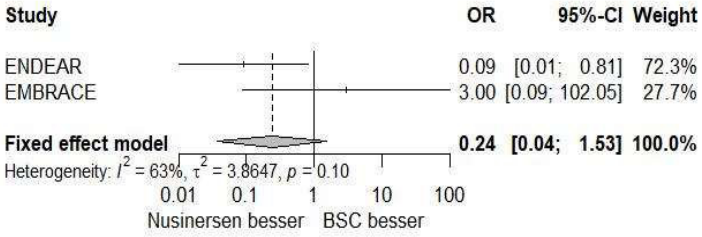
Forest Plot for SAEs 5 pct PT Acute respiratory failure (RR)



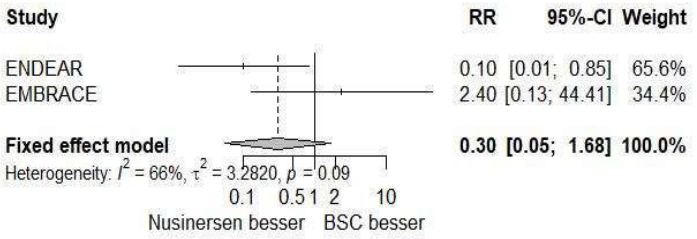
Forest Plot for SAEs 5 pct PT Bronchial secretion retention
(ARR)



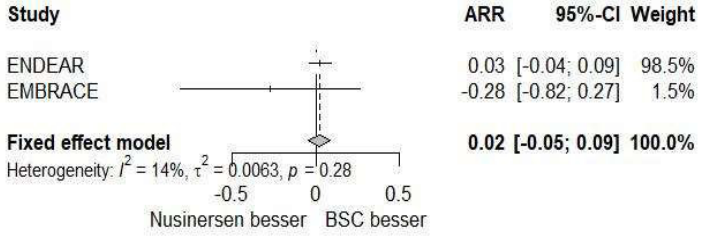
Forest Plot for SAEs 5 pct PT Bronchial secretion retention
(OR)



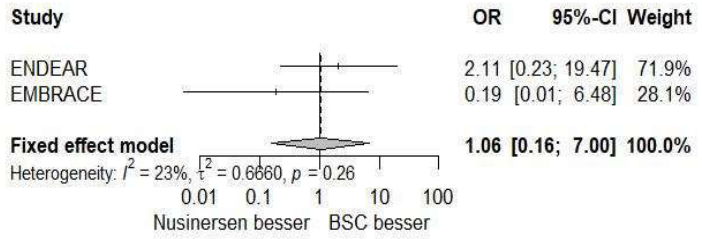
Forest Plot for SAEs 5 pct PT Bronchial secretion retention
(RR)



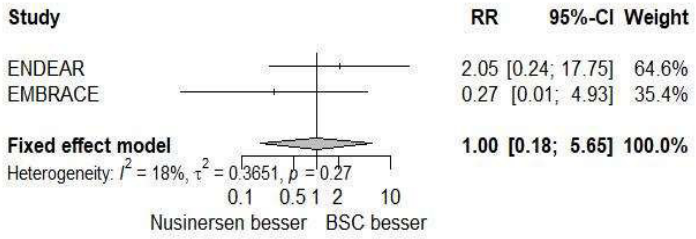
Forest Plot for SAEs 5 pct PT Bronchiolitis (ARR)



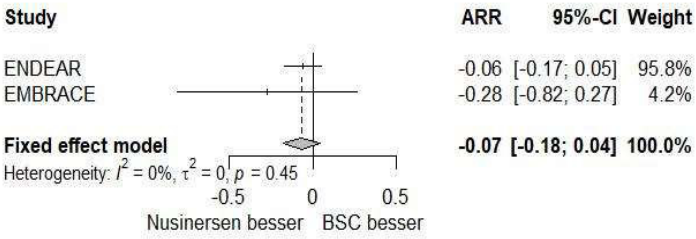
Forest Plot for SAEs 5 pct PT Bronchiolitis (OR)



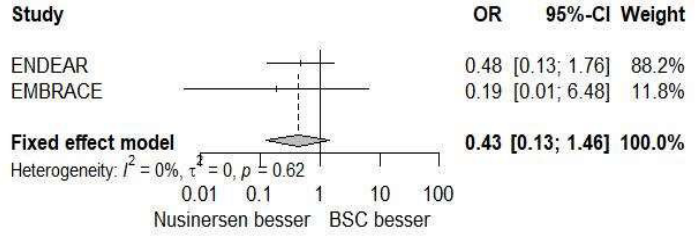
Forest Plot for SAEs 5 pct PT Bronchiolitis (RR)



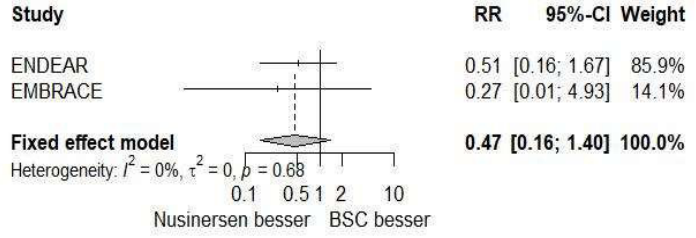
Forest Plot for SAEs 5 pct PT Cardio-respiratory arrest (ARR)



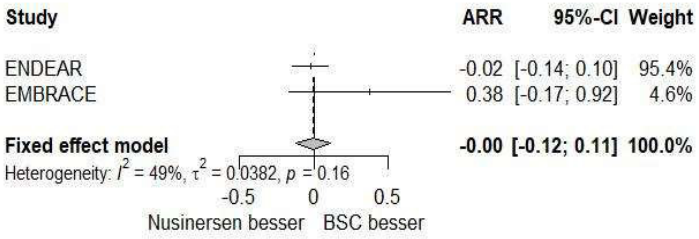
Forest Plot for SAEs 5 pct PT Cardio-respiratory arrest (OR)



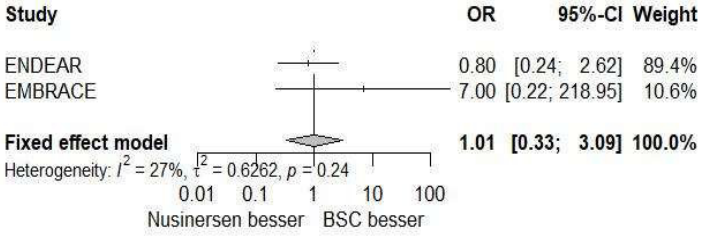
Forest Plot for SAEs 5 pct PT Cardio-respiratory arrest (RR)



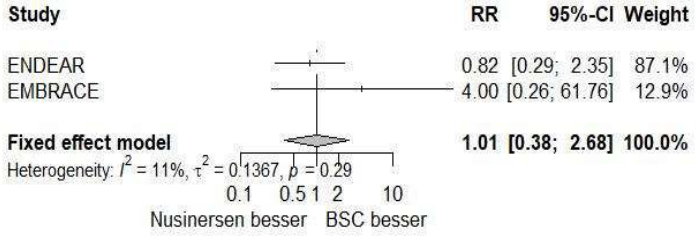
Forest Plot for SAEs 5 pct PT Pneumonia aspiration (ARR)



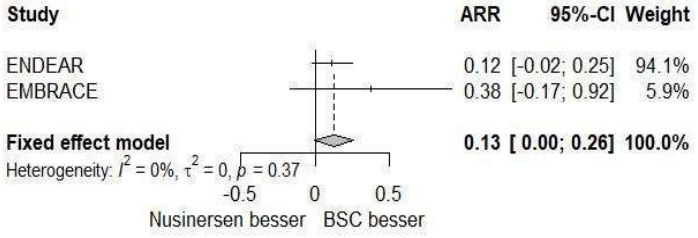
Forest Plot for SAEs 5 pct PT Pneumonia aspiration (OR)



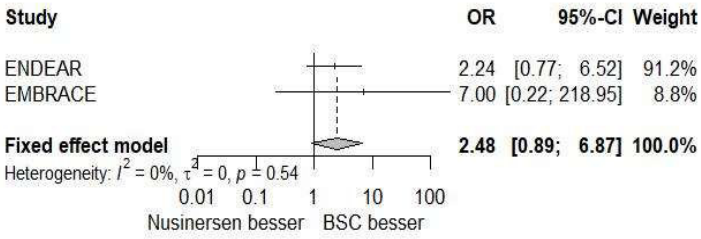
Forest Plot for SAEs 5 pct PT Pneumonia aspiration (RR)



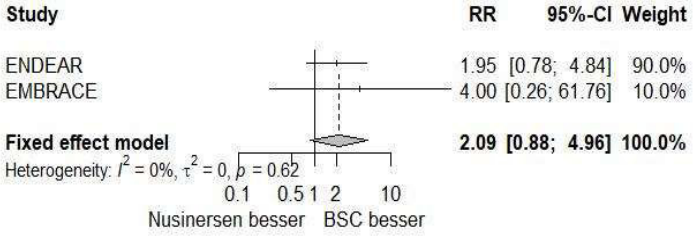
Forest Plot for SAEs 5 pct PT Pneumonia (ARR)



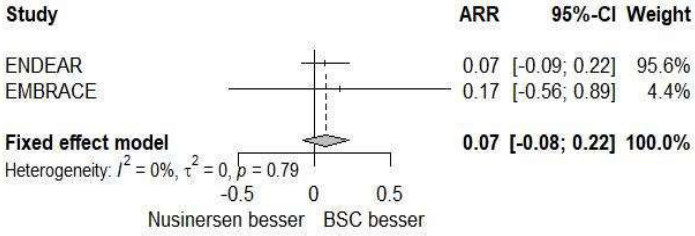
Forest Plot for SAEs 5 pct PT Pneumonia (OR)



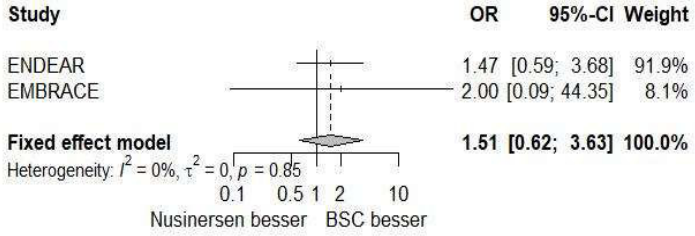
Forest Plot for SAEs 5 pct PT Pneumonia (RR)



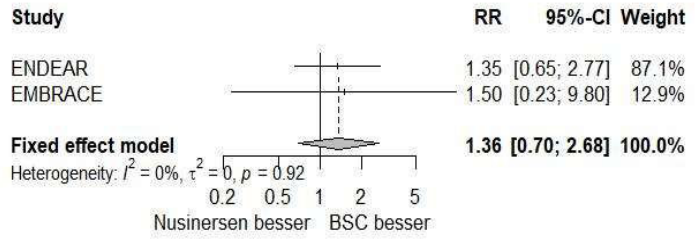
Forest Plot for SAEs 5 pct PT Respiratory distress (ARR)



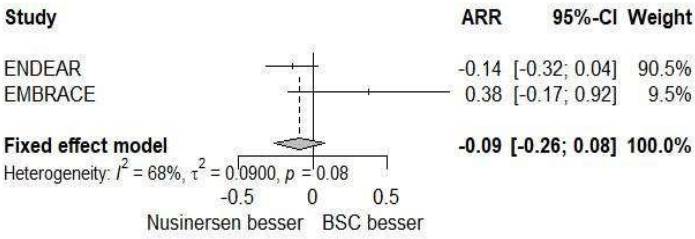
Forest Plot for SAEs 5 pct PT Respiratory distress (OR)



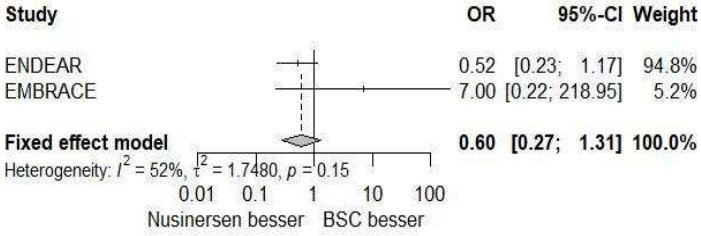
Forest Plot for SAEs 5 pct PT Respiratory distress (RR)



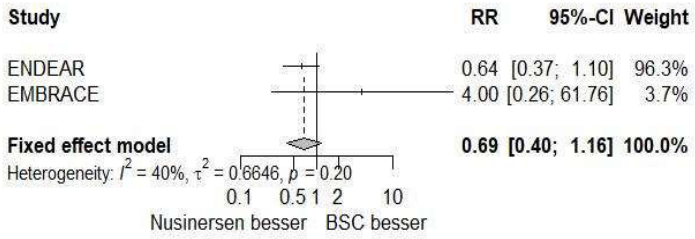
Forest Plot for SAEs 5 pct PT Respiratory failure (ARR)



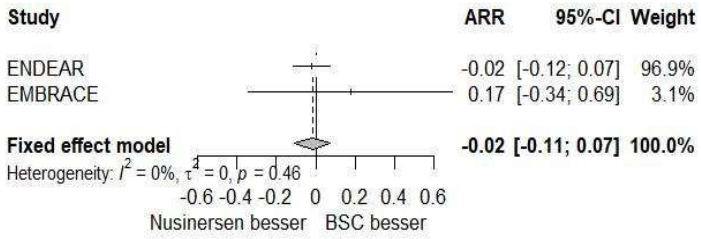
Forest Plot for SAEs 5 pct PT Respiratory failure (OR)



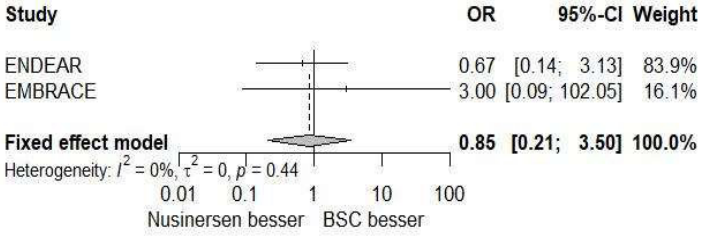
Forest Plot for SAEs 5 pct PT Respiratory failure (RR)



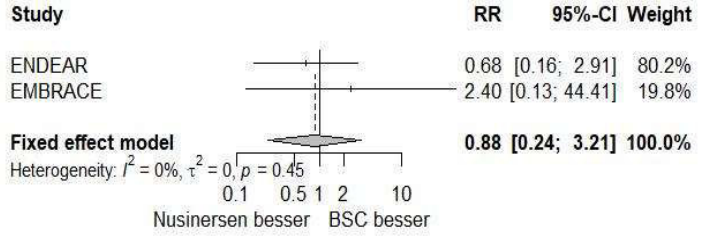
Forest Plot for SAEs 5 pct PT Respiratory syncytial virus bronchiolitis (ARR)



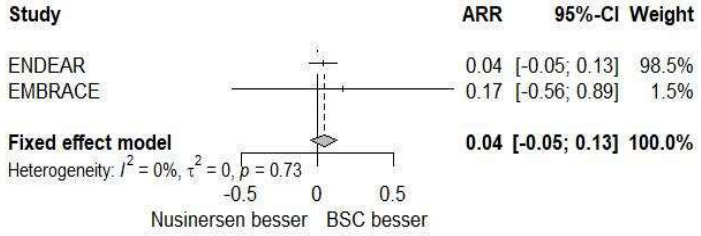
Forest Plot for SAEs 5 pct PT Respiratory syncytial virus bronchiolitis (OR)



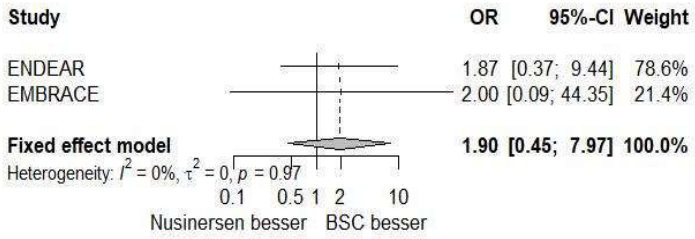
Forest Plot for SAEs 5 pct PT Respiratory syncytial virus bronchiolitis (RR)



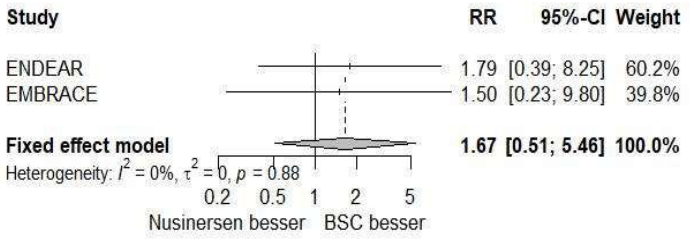
Forest Plot for SAEs 5 pct PT Rhinovirus infection (ARR)



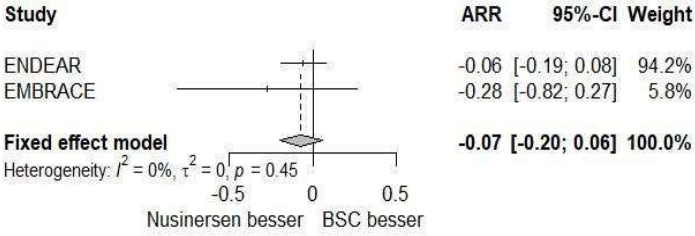
Forest Plot for SAEs 5 pct PT Rhinovirus infection (OR)



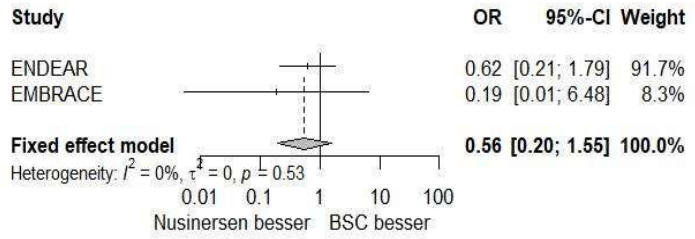
Forest Plot for SAEs 5 pct PT Rhinovirus infection (RR)



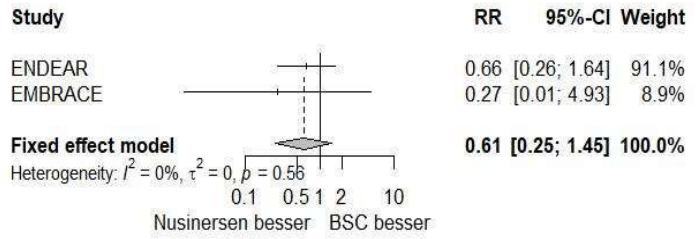
Forest Plot for SAEs 5 pct SOC Cardiac disorders (ARR)



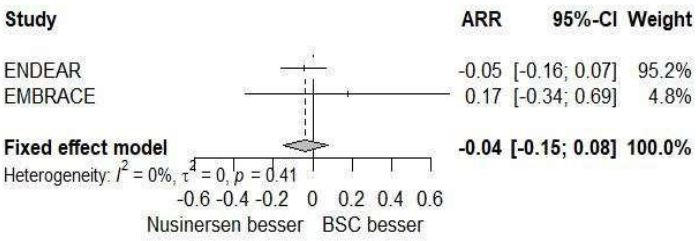
Forest Plot for SAEs 5 pct SOC Cardiac disorders (OR)



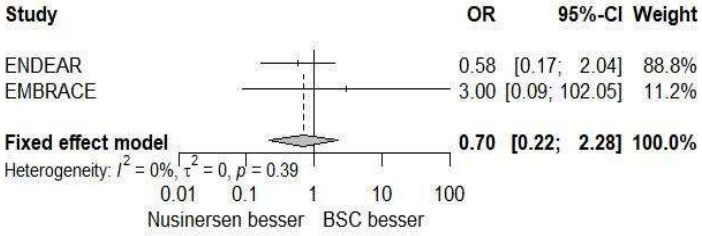
Forest Plot for SAEs 5 pct SOC Cardiac disorders (RR)



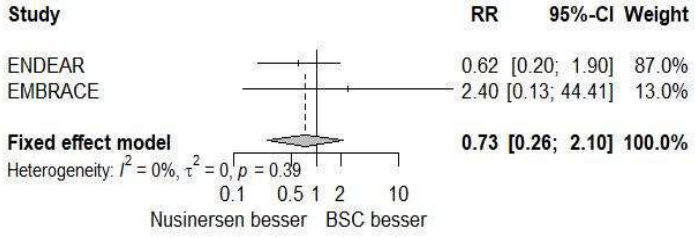
Forest Plot for SAEs 5 pct SOC Gastrointestinal disorders (ARR)



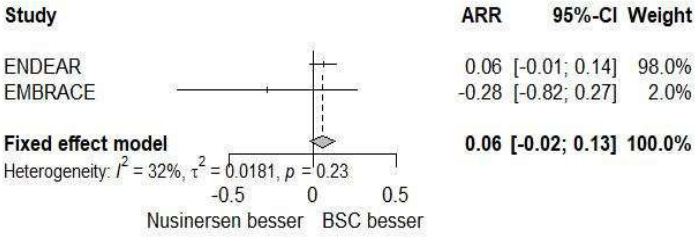
Forest Plot for SAEs 5 pct SOC Gastrointestinal disorders (OR)



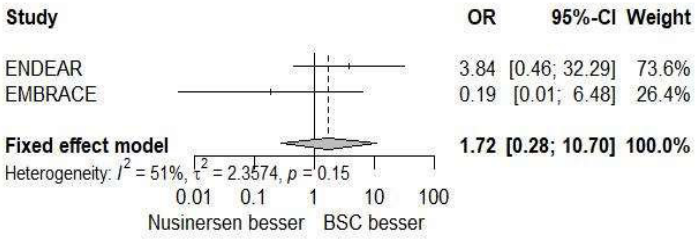
Forest Plot for SAEs 5 pct SOC Gastrointestinal disorders (RR)



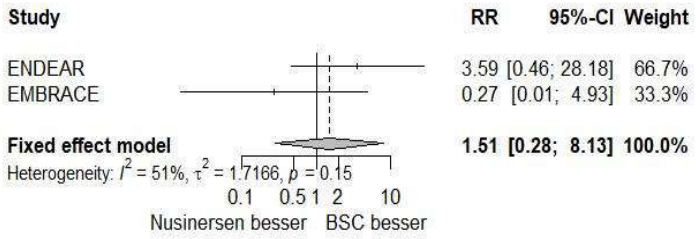
Forest Plot for SAEs 5 pct SOC General disorders and administration site conditions (ARR)



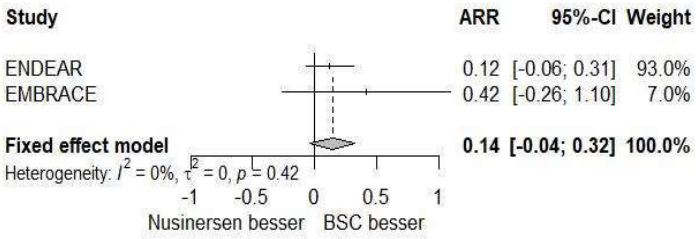
Forest Plot for SAEs 5 pct SOC General disorders and administration site conditions (OR)



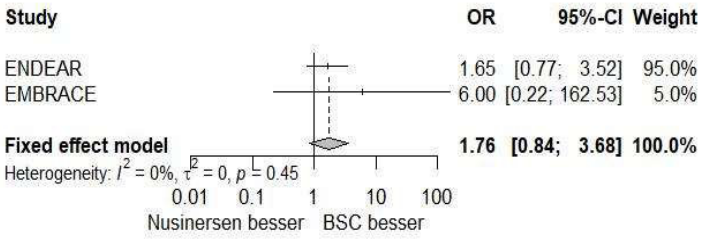
Forest Plot for SAEs 5 pct SOC General disorders and administration site conditions (RR)



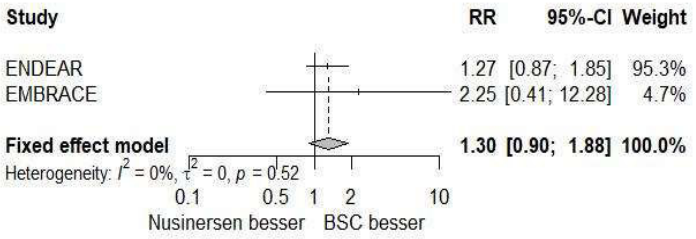
Forest Plot for SAEs 5 pct SOC Infections and infestations (ARR)



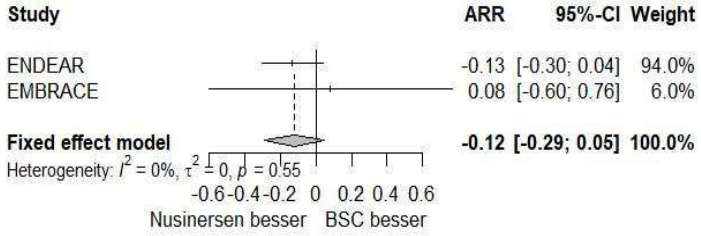
Forest Plot for SAEs 5 pct SOC Infections and infestations (OR)



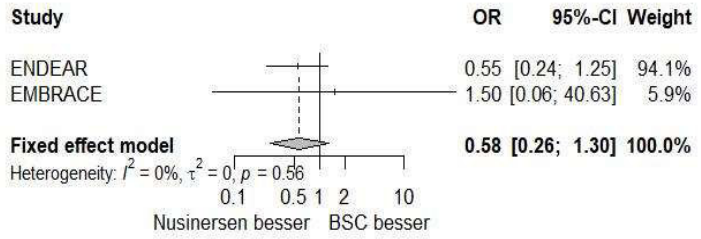
Forest Plot for SAEs 5 pct SOC Infections and infestations (RR)



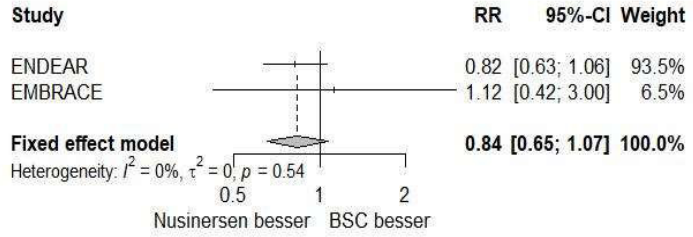
Forest Plot for SAEs 5 pct SOC Respiratory, thoracic and mediastinal disorders (ARR)



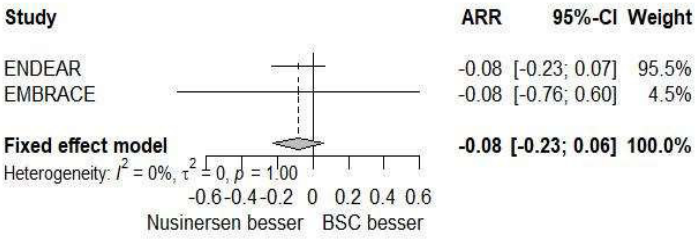
Forest Plot for SAEs 5 pct SOC Respiratory, thoracic and mediastinal disorders (OR)



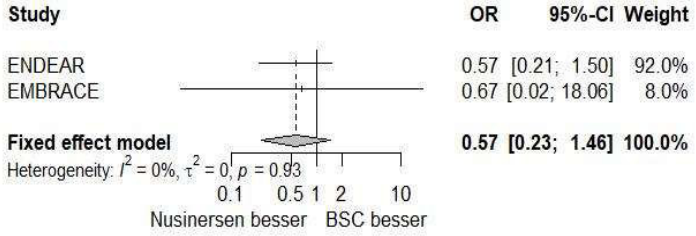
Forest Plot for SAEs 5 pct SOC Respiratory, thoracic and mediastinal disorders (RR)



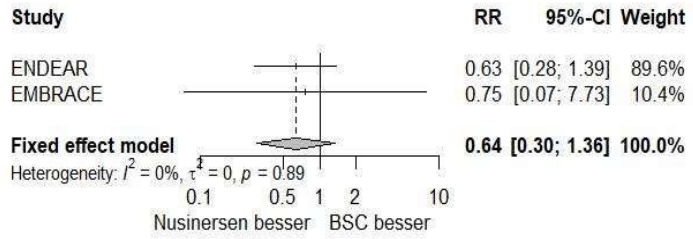
Forest Plot for Severe AEs 5 pct PT Acute respiratory failure (ARR)



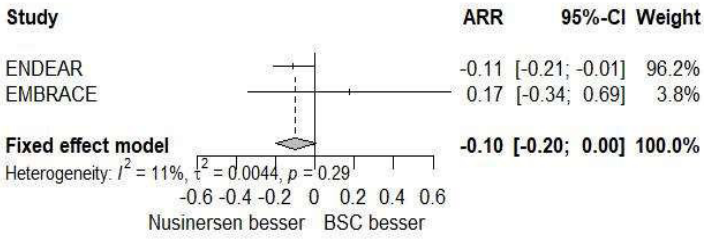
Forest Plot for Severe AEs 5 pct PT Acute respiratory failure (OR)



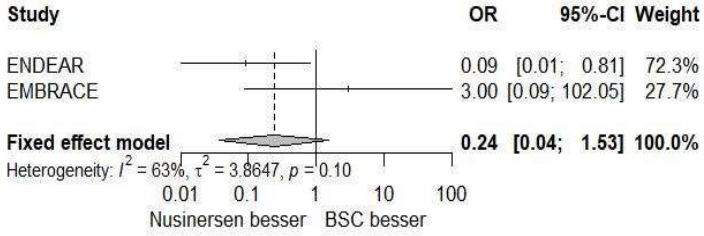
Forest Plot for Severe AEs 5 pct PT Acute respiratory failure (RR)



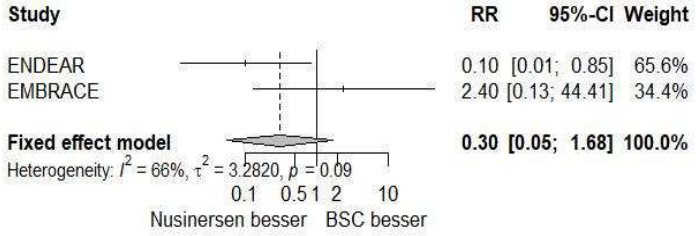
Forest Plot for Severe AEs 5 pct PT Bronchial secretion retention (ARR)



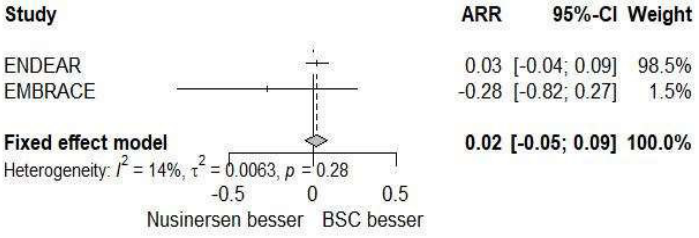
Forest Plot for Severe AEs 5 pct PT Bronchial secretion retention (OR)



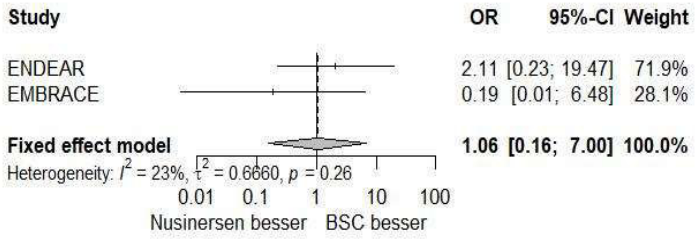
Forest Plot for Severe AEs 5 pct PT Bronchial secretion retention (RR)



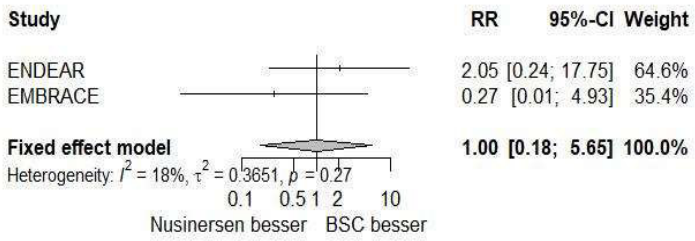
Forest Plot for Severe AEs 5 pct PT Bronchiolitis (ARR)



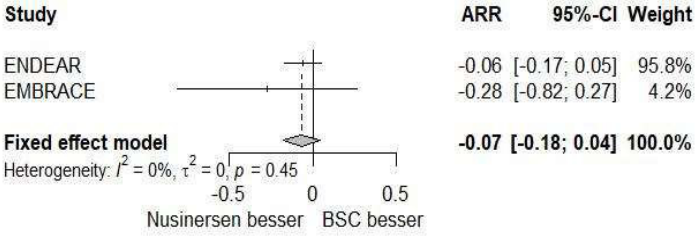
Forest Plot for Severe AEs 5 pct PT Bronchiolitis (OR)



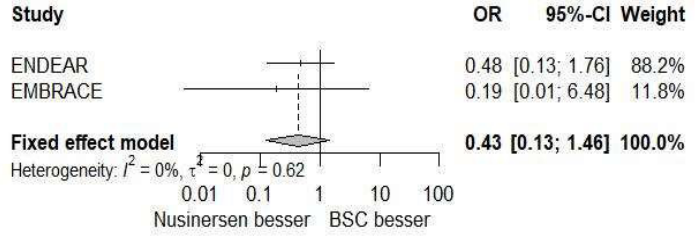
Forest Plot for Severe AEs 5 pct PT Bronchiolitis (RR)



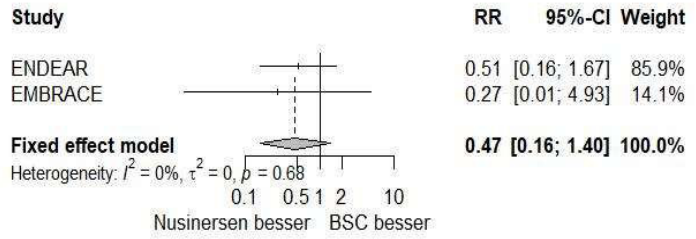
Forest Plot for Severe AEs 5 pct PT Cardio-respiratory arrest (ARR)



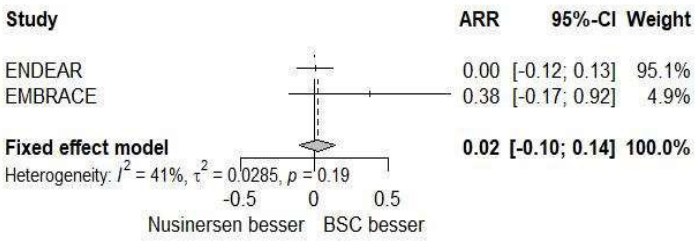
Forest Plot for Severe AEs 5 pct PT Cardio-respiratory arrest (OR)



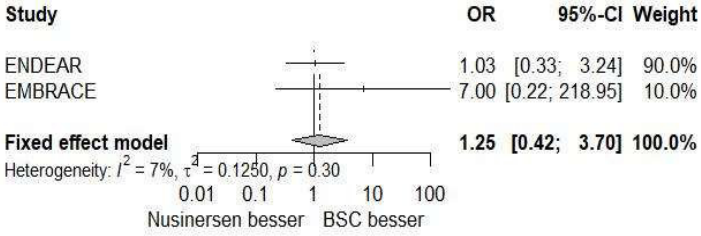
Forest Plot for Severe AEs 5 pct PT Cardio-respiratory arrest (RR)



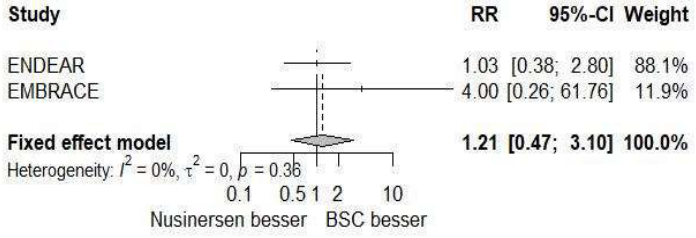
Forest Plot for Severe AEs 5 pct PT Pneumonia (ARR)



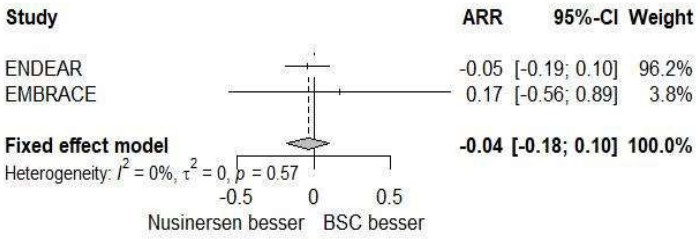
Forest Plot for Severe AEs 5 pct PT Pneumonia (OR)



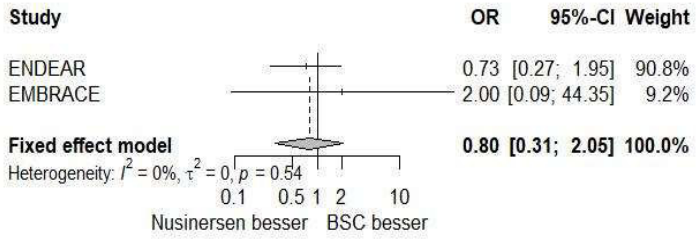
Forest Plot for Severe AEs 5 pct PT Pneumonia (RR)



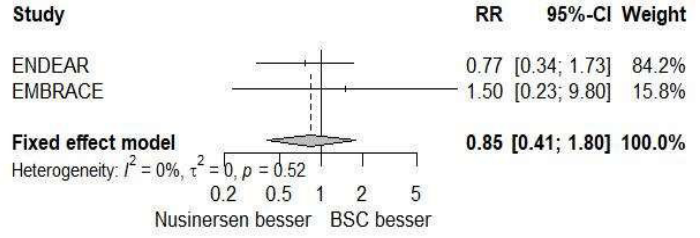
Forest Plot for Severe AEs 5 pct PT Respiratory distress
(ARR)



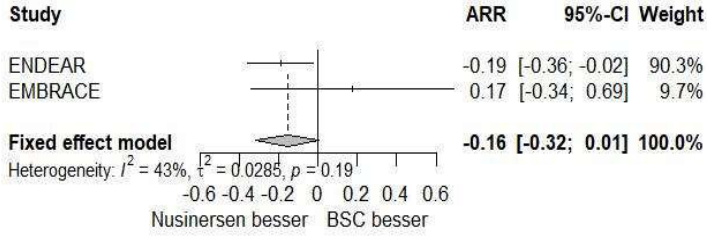
Forest Plot for Severe AEs 5 pct PT Respiratory distress
(OR)



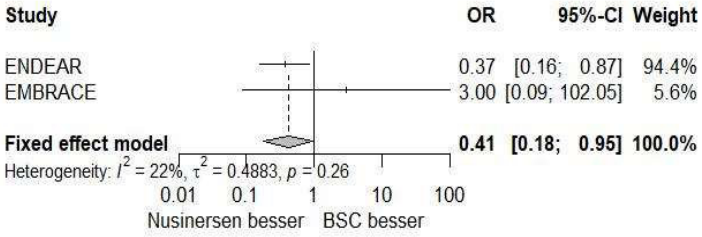
Forest Plot for Severe AEs 5 pct PT Respiratory distress
(RR)



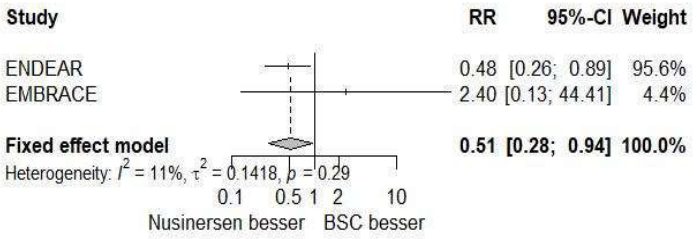
Forest Plot for Severe AEs 5 pct PT Respiratory failure
(ARR)



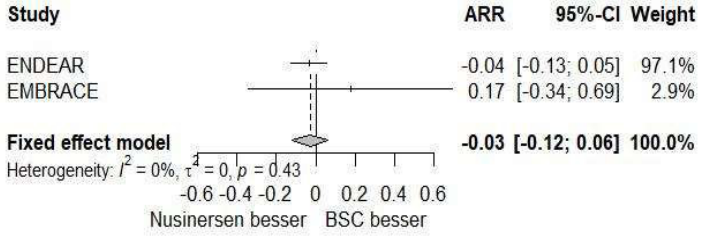
Forest Plot for Severe AEs 5 pct PT Respiratory failure (OR)



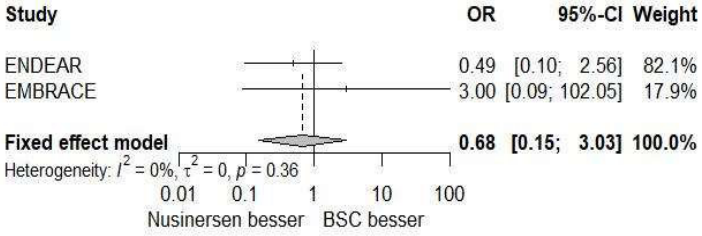
Forest Plot for Severe AEs 5 pct PT Respiratory failure (RR)



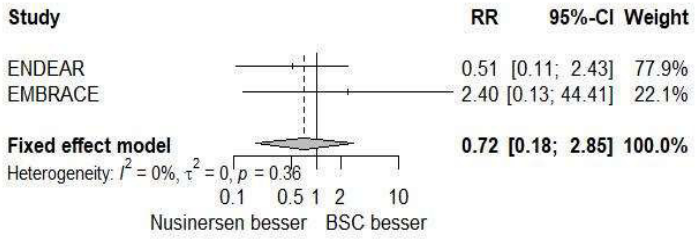
Forest Plot for Severe AEs 5 pct PT Respiratory syncytial virus bronchiolitis (ARR)



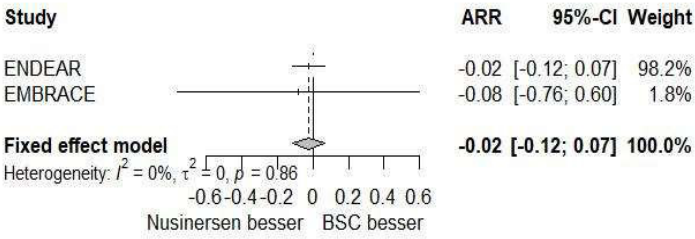
Forest Plot for Severe AEs 5 pct PT Respiratory syncytial virus bronchiolitis (OR)



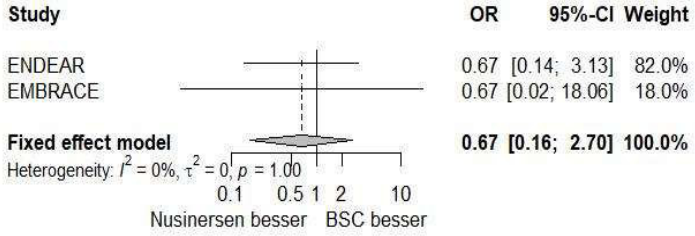
Forest Plot for Severe AEs 5 pct PT Respiratory syncytial virus bronchiolitis (RR)



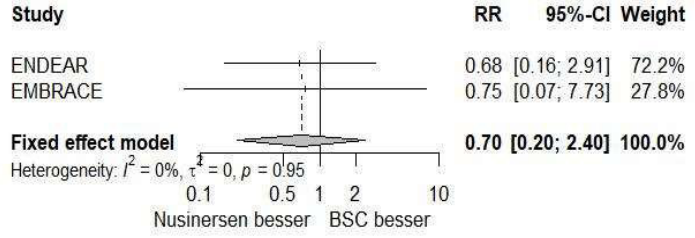
Forest Plot for Severe AEs 5 pct PT Rhinovirus infection (ARR)



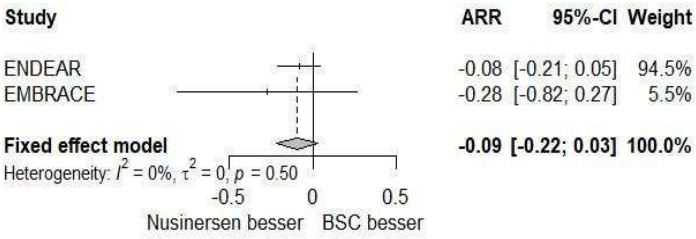
Forest Plot for Severe AEs 5 pct PT Rhinovirus infection (OR)



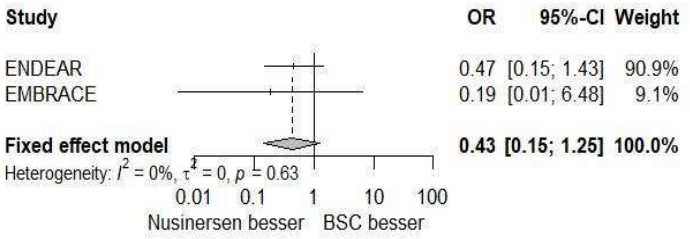
Forest Plot for Severe AEs 5 pct PT Rhinovirus infection (RR)



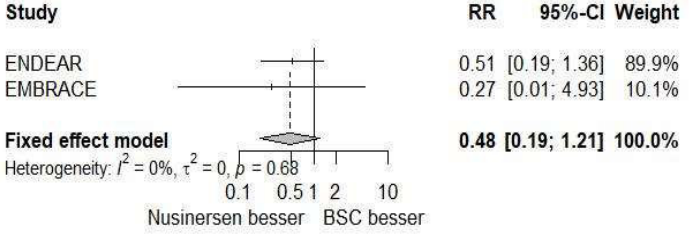
Forest Plot for Severe AEs 5 pct SOC Cardiac disorders (ARR)



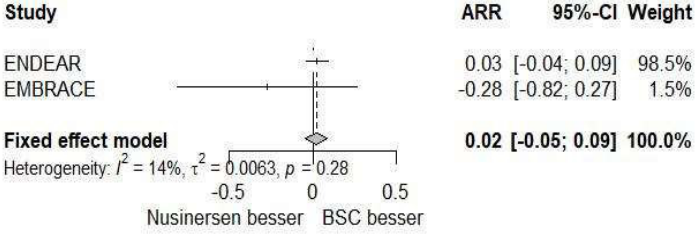
Forest Plot for Severe AEs 5 pct SOC Cardiac disorders (OR)



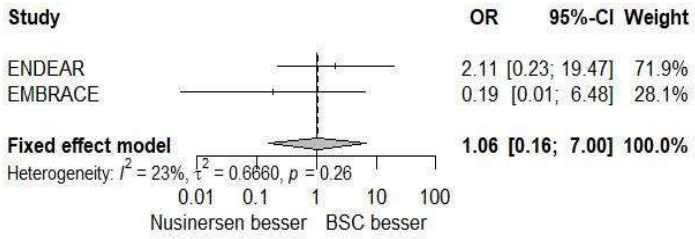
Forest Plot for Severe AEs 5 pct SOC Cardiac disorders (RR)



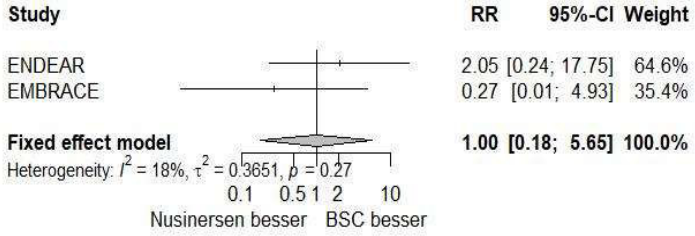
Forest Plot for Severe AEs 5 pct SOC General disorders and administration site conditions (ARR)



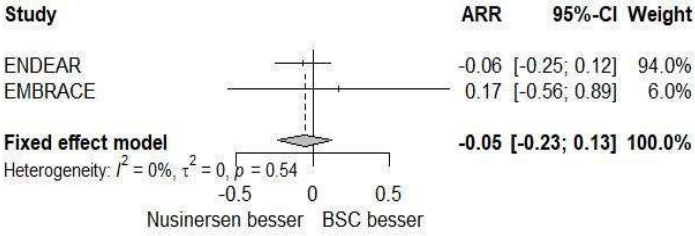
Forest Plot for Severe AEs 5 pct SOC General disorders and administration site conditions (OR)



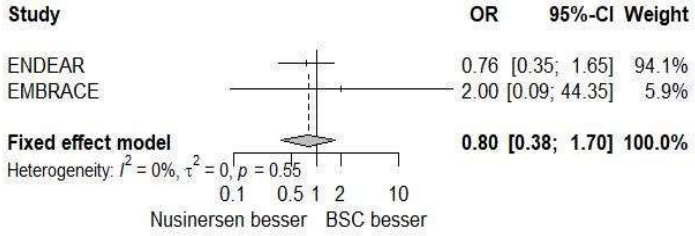
Forest Plot for Severe AEs 5 pct SOC General disorders and administration site conditions (RR)



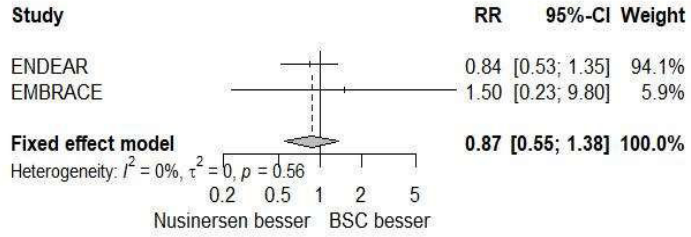
Forest Plot for Severe AEs 5 pct SOC Infections and infestations (ARR)



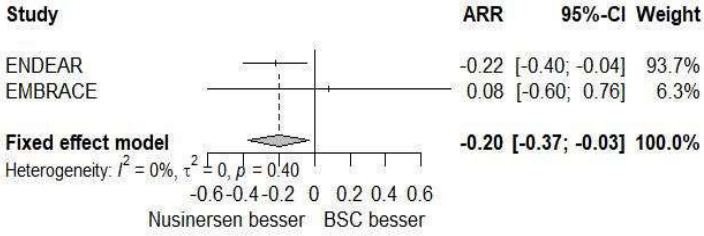
Forest Plot for Severe AEs 5 pct SOC Infections and infestations (OR)



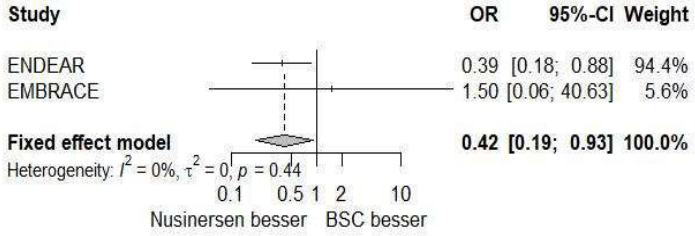
Forest Plot for Severe AEs 5 pct SOC Infections and infestations (RR)



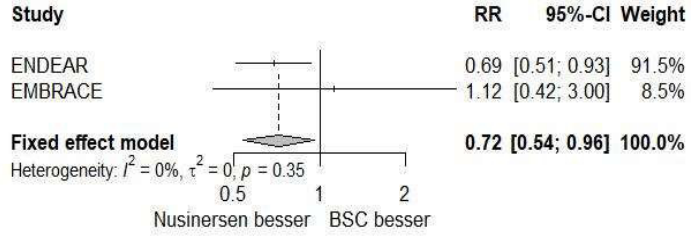
Forest Plot for Severe AEs 5 pct SOC Respiratory, thoracic and mediastinal disorders (ARR)



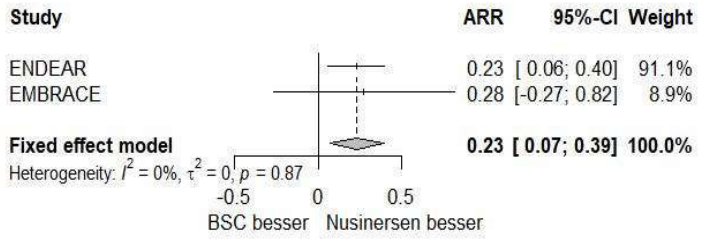
Forest Plot for Severe AEs 5 pct SOC Respiratory, thoracic and mediastinal disorders (OR)



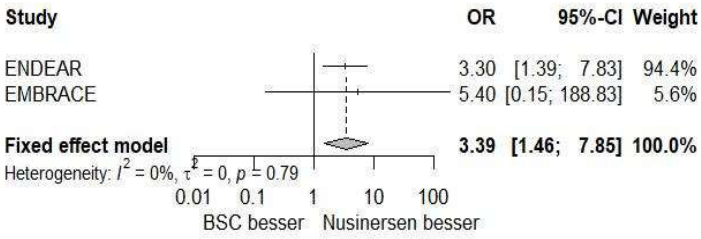
Forest Plot for Severe AEs 5 pct SOC Respiratory, thoracic and mediastinal disorders (RR)



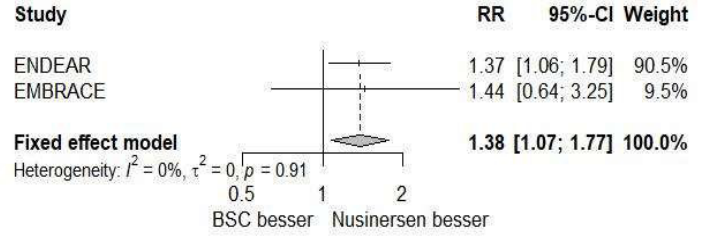
Forest Plot for Survival Rate (ARR)



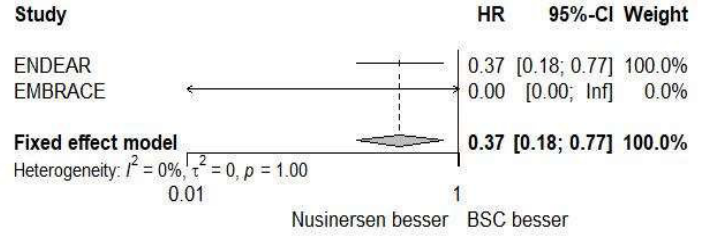
Forest Plot for Survival Rate (OR)



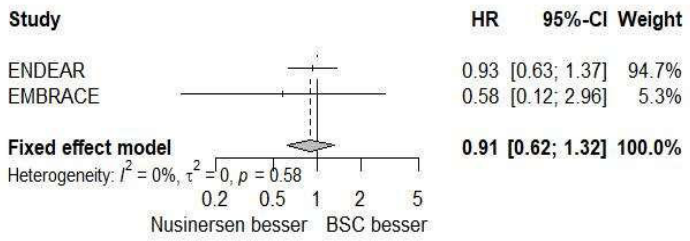
Forest Plot for Survival Rate (RR)



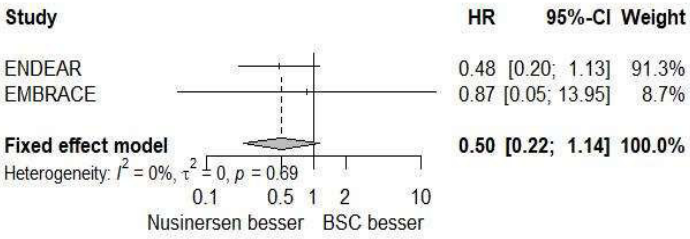
Forest Plot for Time to adverse events leading to discontinuation of therapy (HR)



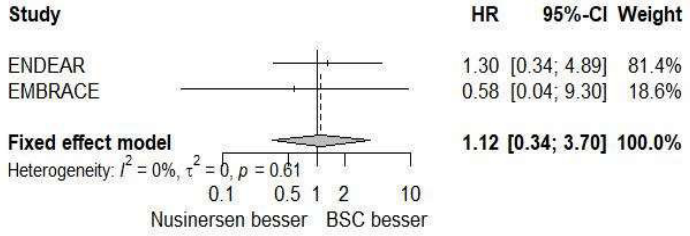
Forest Plot for Time to adverse events (HR)



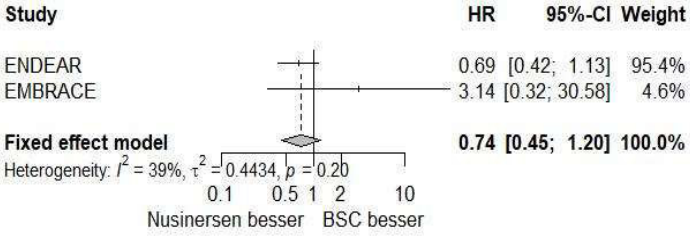
Forest Plot for Time to any AEs 10 pct PT Acute respiratory failure (HR)



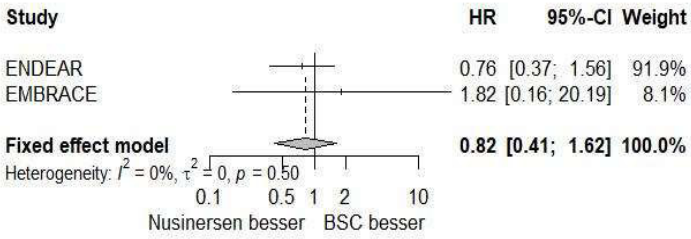
Forest Plot for Time to any AEs 10 pct PT Bronchiolitis (HR)



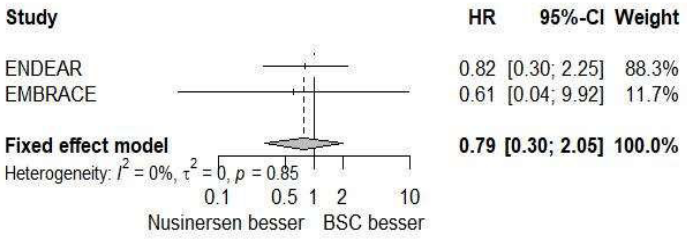
Forest Plot for Time to any AEs 10 pct PT Pyrexia (HR)



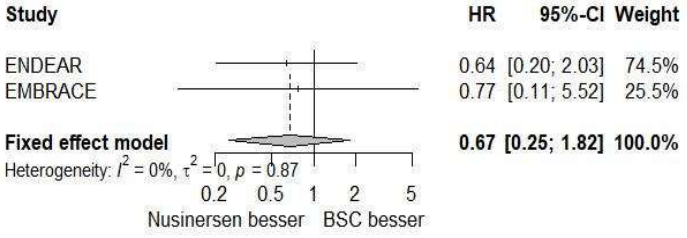
Forest Plot for Time to any AEs 10 pct PT Respiratory distress (HR)



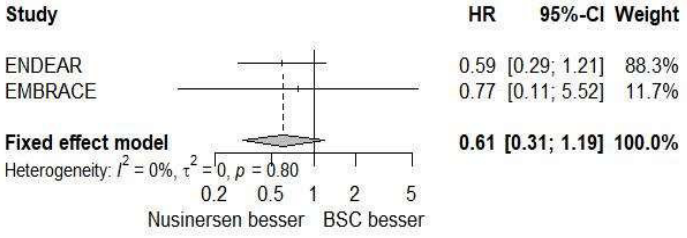
Forest Plot for Time to any AEs 10 pct PT Rhinovirus infection (HR)



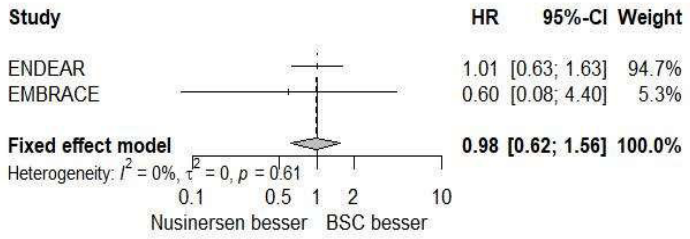
Forest Plot for Time to any AEs 10 pct PT Tachycardia (HR)



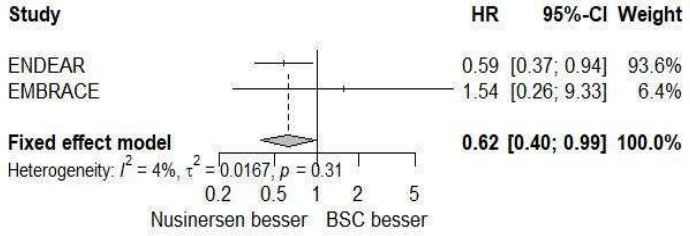
Forest Plot for Time to any AEs 10 pct SOC Cardiac disorders (HR)



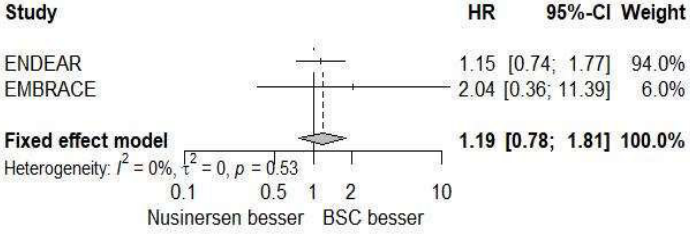
Forest Plot for Time to any AEs 10 pct SOC Gastrointestinal disorders (HR)



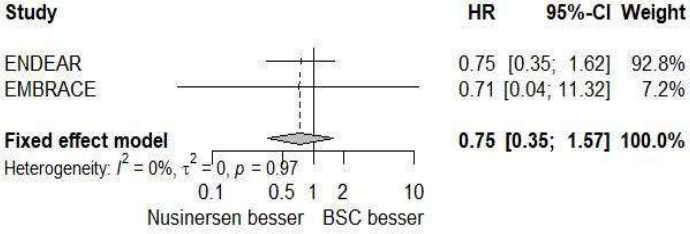
Forest Plot for Time to any AEs 10 pct SOC General disorders and administration site conditions (HR)



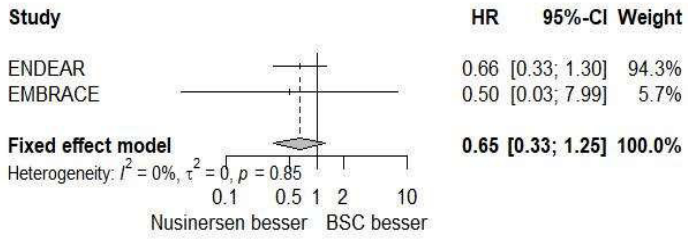
Forest Plot for Time to any AEs 10 pct SOC Infections and infestations (HR)



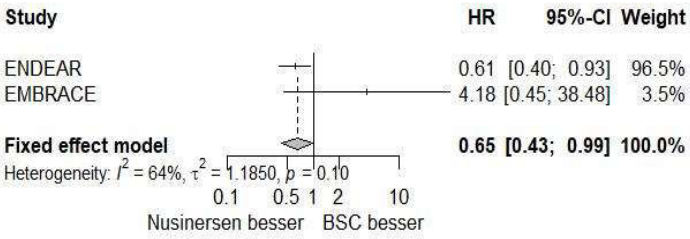
Forest Plot for Time to any AEs 10 pct SOC Injury, poisoning and procedural complications (HR)



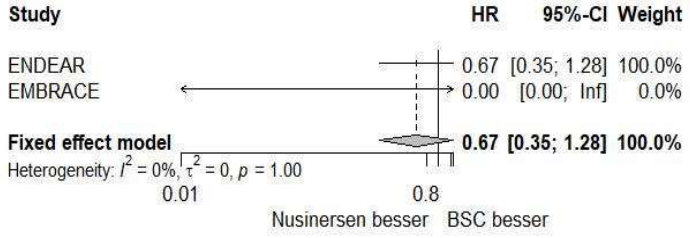
Forest Plot for Time to any AEs 10 pct SOC Investigations (HR)



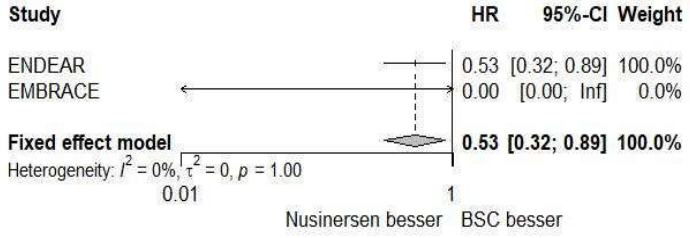
Forest Plot for Time to any AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders (HR)



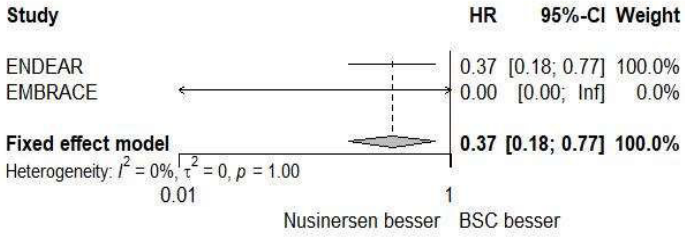
Forest Plot for Time to any AEs 10 pct SOC Skin and subcutaneous tissue disorders (HR)



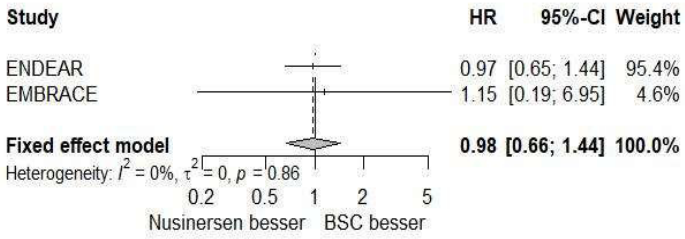
Forest Plot for Time to death or permanent ventilation (HR)



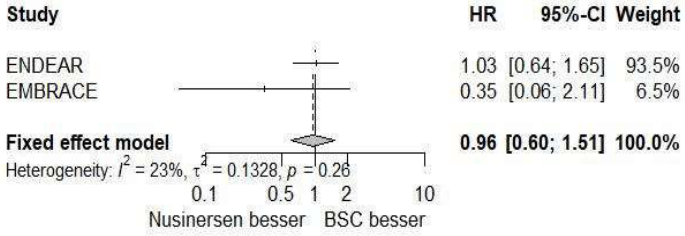
Forest Plot for Time to death (HR)



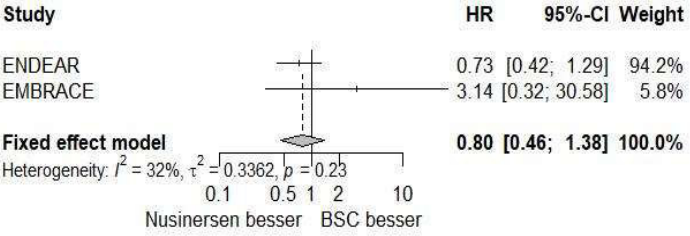
Forest Plot for Time to hospitalization (HR)



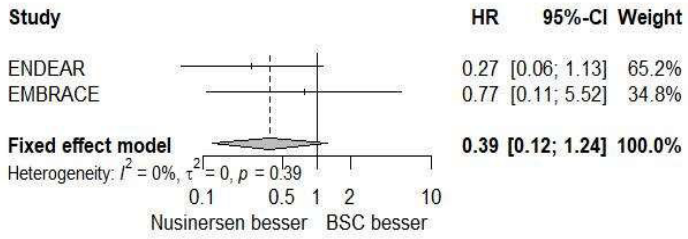
Forest Plot for Time to mild adverse events (HR)



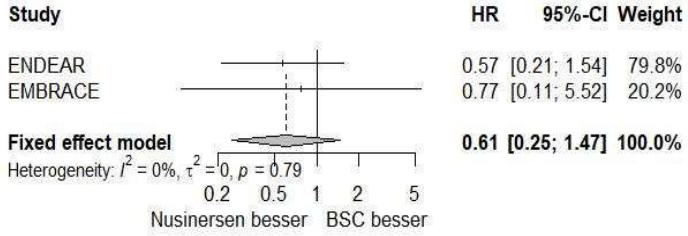
Forest Plot for Time to mild AEs 10 pct PT Pyrexia (HR)



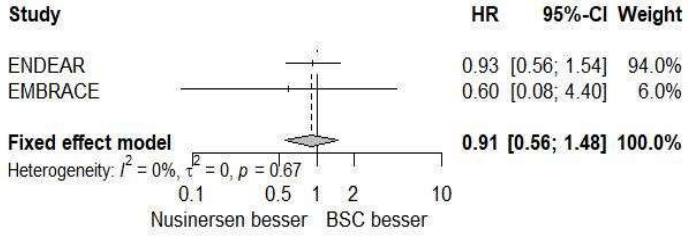
Forest Plot for Time to mild AEs 10 pct PT Tachycardia (HR)



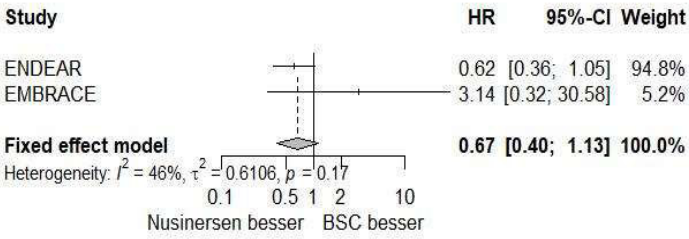
Forest Plot for Time to mild AEs 10 pct SOC Cardiac disorders (HR)



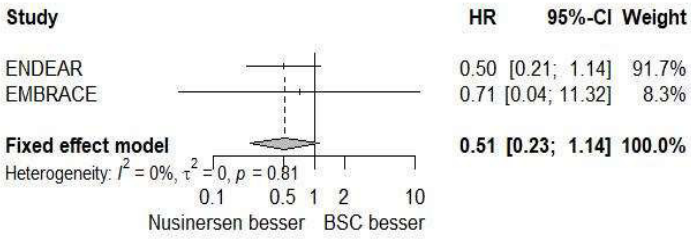
Forest Plot for Time to mild AEs 10 pct SOC Gastrointestinal disorders (HR)



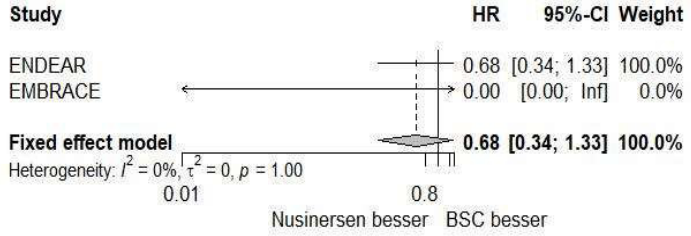
Forest Plot for Time to mild AEs 10 pct SOC General disorders and administration site conditions (HR)



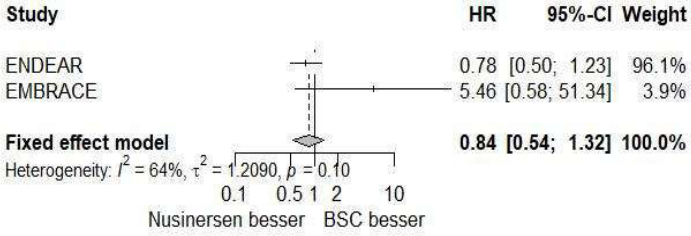
Forest Plot for Time to mild AEs 10 pct SOC Injury, poisoning and procedural complications (HR)



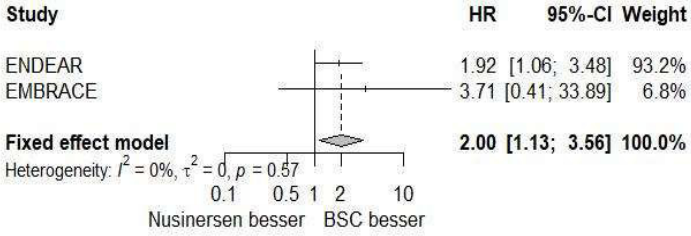
Forest Plot for Time to mild AEs 10 pct SOC Skin and subcutaneous tissue disorders (HR)



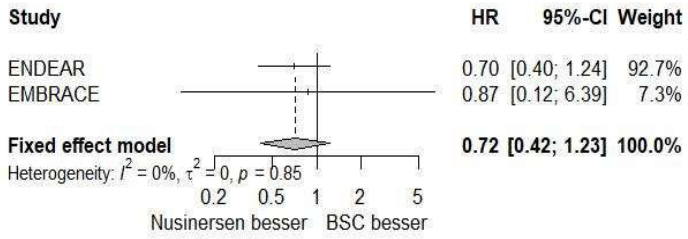
Forest Plot for Time to moderate adverse events (HR)



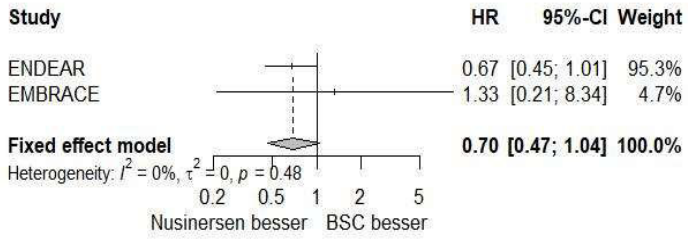
Forest Plot for Time to moderate AEs 10 pct SOC Infections and infestations (HR)



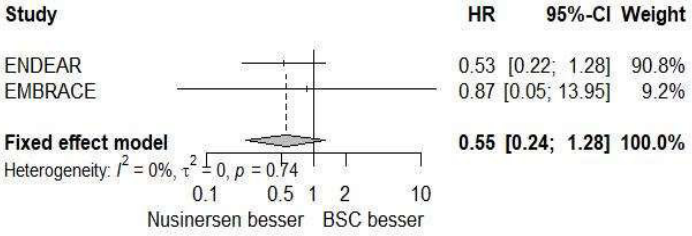
Forest Plot for Time to moderate AEs 10 pct SOC Respiratory, thoracic and mediastinal disorders (HR)



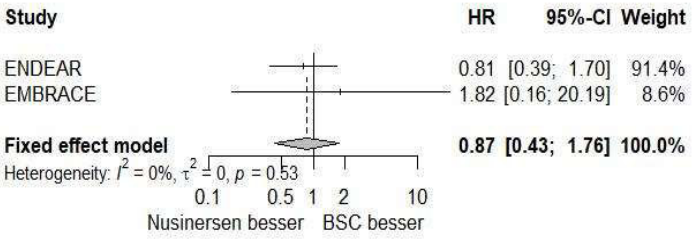
Forest Plot for Time to moderate and severe adverse events (HR)



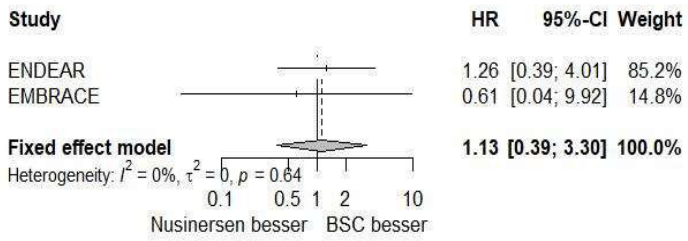
Forest Plot for Time to moderate or severe AEs 10 pct PT Acute respiratory failure (HR)



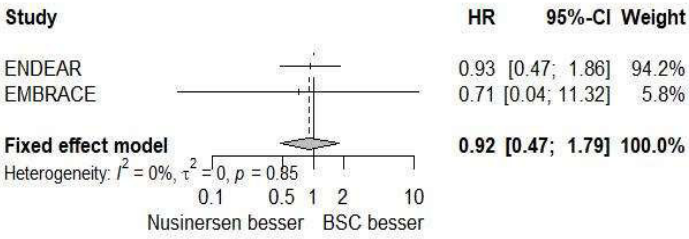
Forest Plot for Time to moderate or severe AEs 10 pct PT Respiratory distress (HR)



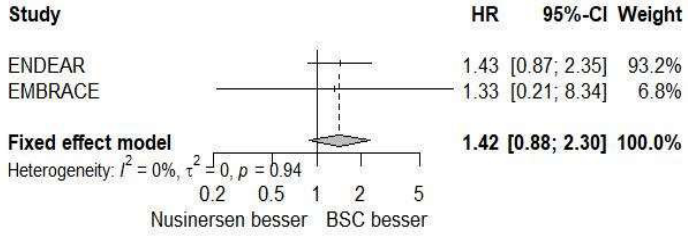
Forest Plot for Time to moderate or severe AEs 10 pct PT
Rhinovirus infection (HR)



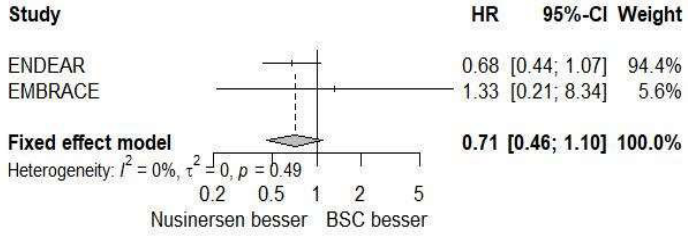
Forest Plot for Time to moderate or severe AEs 10 pct SOC
General disorders and administration site conditions (HR)



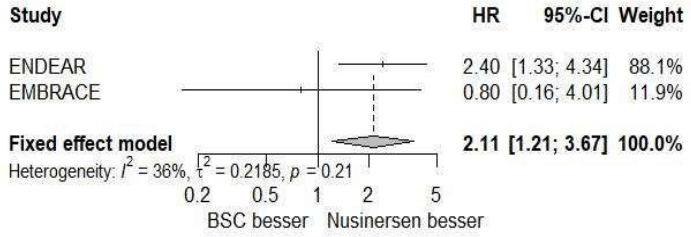
Forest Plot for Time to moderate or severe AEs 10 pct SOC
Infections and infestations (HR)



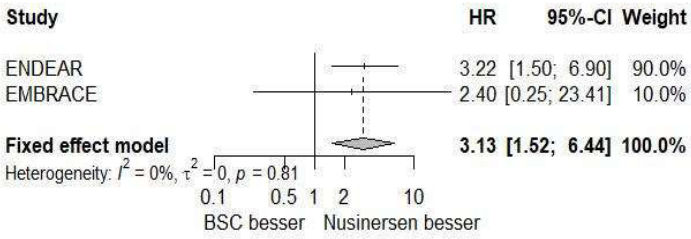
Forest Plot for Time to moderate or severe AEs 10 pct SOC
Respiratory, thoracic and mediastinal disorders (HR)



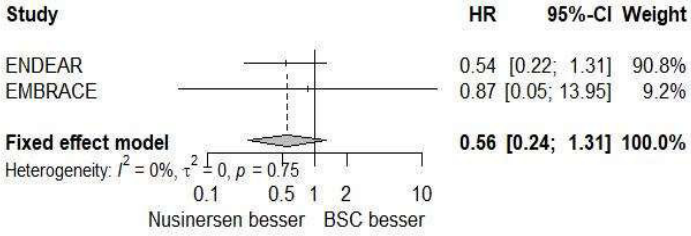
Forest Plot for Time to motor milestone responders (HINE section 2) TOTSCORE (HR)



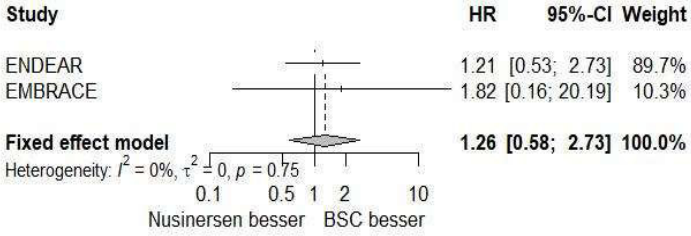
Forest Plot for Time to motor milestone responders (HINE section 2) (HR)



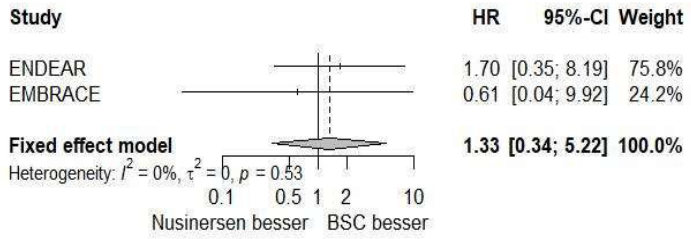
Forest Plot for Time to SAEs 5 pct PT Acute respiratory failure (HR)



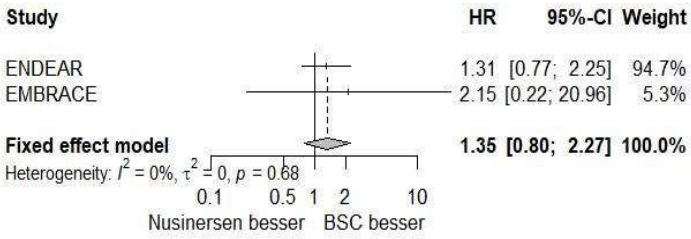
Forest Plot for Time to SAEs 5 pct PT Respiratory distress (HR)



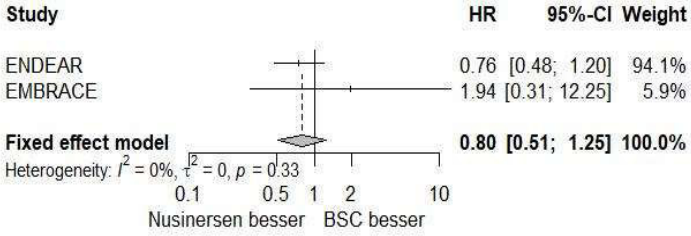
Forest Plot for Time to SAEs 5 pct PT Rhinovirus infection (HR)



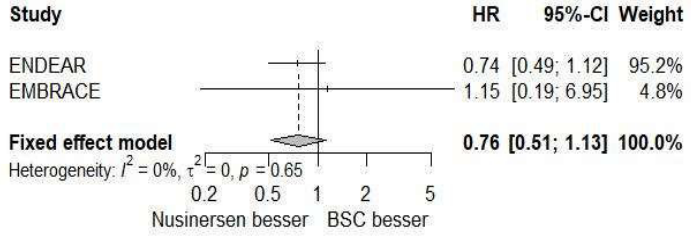
Forest Plot for Time to SAEs 5 pct SOC Infections and infestations (HR)



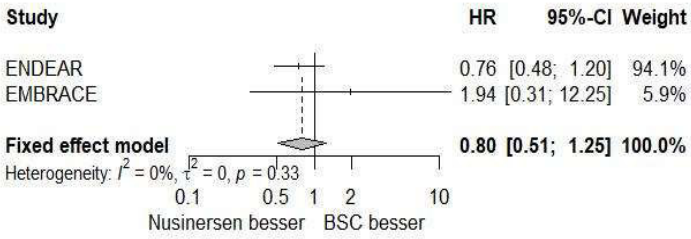
Forest Plot for Time to SAEs 5 pct SOC Respiratory, thoracic and mediastinal disorders (HR)



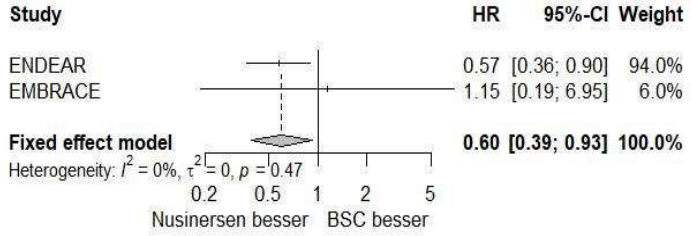
Forest Plot for Time to serious adverse events (HR)



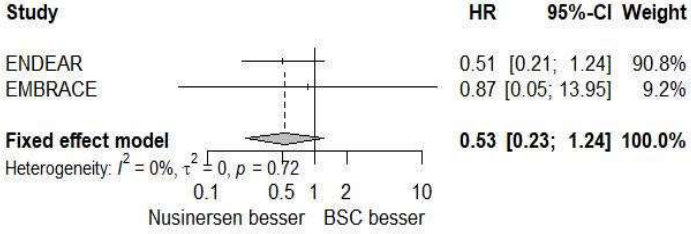
Forest Plot for Time to serious respiratory events (HR)



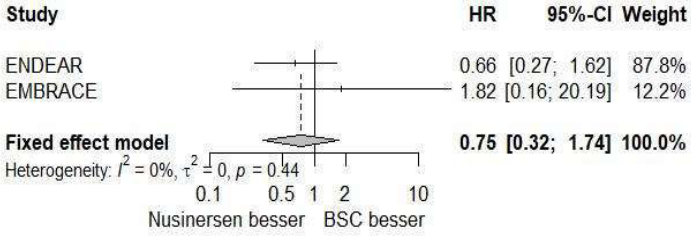
Forest Plot for Time to severe adverse events (HR)



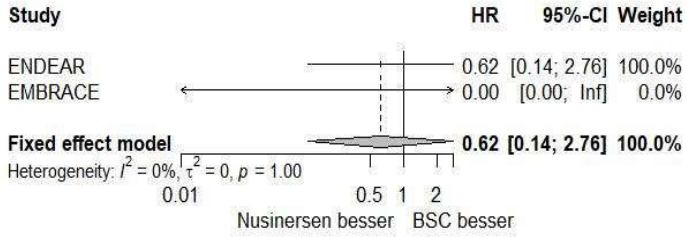
Forest Plot for Time to severe AEs 5 pct PT Acute respiratory failure (HR)



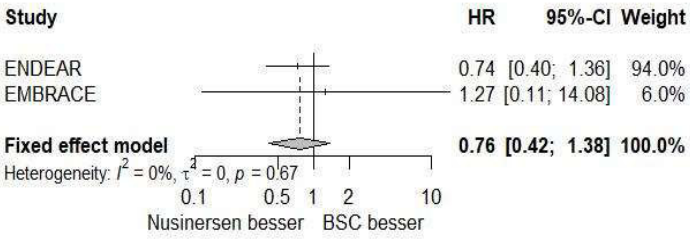
Forest Plot for Time to severe AEs 5 pct PT Respiratory distress (HR)



Forest Plot for Time to severe AEs 5 pct PT Rhinovirus infection (HR)



Forest Plot for Time to severe AEs 5 pct SOC Infections and infestations (HR)



Forest Plot for Time to severe AEs 5 pct SOC Respiratory, thoracic and mediastinal disorders (HR)

